.....

(Original Signature of Member)

____TH
CONGRESS
____ SESSION

# H. R. _____

To enact certain laws relating to food and drugs as title 21, United States Code, ''Food and Drugs''.

---

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on the Judiciary

---

# A BILL

To enact certain laws relating to food and drugs as title 21, United States Code, ''Food and Drugs''.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. TABLE OF CONTENTS.**

The table of contents for this Act is as follows:

Sec. 1. Table of contents.
Sec. 2. Purpose; restatement does not change meaning or effect of existing law.
Sec. 3. Enactment of title 21, United States Code.
Sec. 4. Conforming amendments.
Sec. 5. Transitional and savings provisions.
Sec. 6. Repeals.

**SEC. 2. PURPOSE; RESTATEMENT DOES NOT CHANGE MEANING OR EFFECT OF EXISTING LAW.**

(a) PURPOSE.—The purpose of this Act is to enact a restatement of existing law relating to food and drugs as a positive law title of the United States Code.

(b) RESTATEMENT DOES NOT CHANGE MEANING OR EFFECT OF EXISTING LAW.—

(1) IN GENERAL.—The restatement of existing law enacted by this Act does not change the meaning or effect of the existing law. The restatement consolidates various provisions that were enacted separately over a period of many years, reorganizing them, conforming style and terminology, modernizing obsolete language, and correcting drafting errors. These changes serve to remove ambiguities, contradictions, and other imperfections, but they do not change the meaning or effect of the existing law or impair the precedential value of earlier judicial decisions or other interpretations.

(2) RULE OF CONSTRUCTION.—

(A) IN GENERAL.—Notwithstanding the plain meaning rule or other rules of statutory construction, a change in wording made in the restatement of existing law enacted by this Act serves to clarify the existing law as indicated in

paragraph (1), but not to change the meaning or effect of the existing law.

(B) REVISION NOTES.—Subparagraph (A) applies whether or not a change in wording is explained by a revision note appearing in a congressional report accompanying this Act. If such a revision note does appear, a court shall consider the revision note in interpreting the change.

**SEC. 3. ENACTMENT OF TITLE 21, UNITED STATES CODE.**

Title 21, United States Code, ''Food and Drugs'', is enacted as follows:

# TITLE 21—FOOD AND DRUGS

**Subtitle I—Federal Food, Drug, and Cosmetic Provisions**

**Division A—General Provisions**

| Chap. | | Sec. |
|---|---|---|
| 101. | Definitions Applicable to Subtitle | 10101 |
| 103. | Food and Drug Administration | 10301 |

**Division B—Procedure and Prohibited Acts and Penalties**

| | | |
|---|---|---|
| 105. | Procedure and Prohibited Acts and Penalties | 10501 |

**Division C—Food**

| | | |
|---|---|---|
| 111. | General Provisions | 11101 |
| 113. | Misbranded Food | 11301 |

**Division D—Drugs and Devices**

| | | |
|---|---|---|
| 131. | Drugs and Devices Generally | 13101 |
| 133. | Misbranded Drugs and Devices | 13301 |
| 135. | New Drugs | 13501 |
| 137. | New Animal Drugs | 13701 |
| 139. | Drugs for Rare Diseases or Conditions | 13901 |
| 141. | Electronic Product Radiation Control | 14101 |
| 143. | General Provisions Relating to Drugs and Devices | 14301 |
| 145. | New Animal Drugs for Minor Use and Minor Species | 14501 |
| 147. | Medical Gases | 14701 |
| 149. | Pharmaceutical Distribution Supply Chain | 14901 |
| 151. | Nonprescription Sunscreen and Other Active Ingredients | 15101 |

**Division E—Cosmetics**

| | | |
|---|---|---|
| 171. | Cosmetics | 17101 |

**Division F—General Authorities**

175. General Administrative Provisions ..... 17501
177. Colors ..... 17701
179. Fees ..... 17901
181. Information and Education ..... 18101
183. Environmental Impact Review ..... 18301
185. National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics. 18501
187. Safety Reports ..... 18701
189. Serious Adverse Event Reports ..... 18901
191. Reagan-Udall Foundation for the Food and Drug Administration. 19101

**Division G—Imports and Exports**

201. Imports and Exports ..... 20101

**Division H—Tobacco Products**

211. Tobacco Products ..... 21101

**Subtitle II—Supplemental Food and Drug Administration Provisions**

251. General Provisions ..... 25101
253. Organization and Administration ..... 25301
255 Through 289. ..... Reserved
291. Guidance Documents ..... 29101
293 Through 299. ..... Reserved

**Subtitle III—Food**

301. Adulterated or Misbranded Foods ..... 30101
303. Meat Inspection ..... 30301
305. Supplemental Federal Meat Inspection Provisions ..... 30501
307. Filled Milk ..... 30701
309. Importation of Milk and Cream ..... 30901
311. Oleomargarine ..... 31101
313. Poultry and Poultry Products Inspection ..... 31301
315. Supplemental Poultry and Poultry Products Inspection Provisions. 31501
317. Egg Products Inspection ..... 31701
319. Pesticide Monitoring Improvement ..... 31901
321. Food Allergen Labeling and Consumer Protection ..... 32101
323. Food Safety ..... 32301
325. Food Safety Modernization ..... 32501
327 Through 397. ..... Reserved
399. Miscellaneous ..... 39901

**Subtitle IV—Pharmacology, Drugs, and Devices**

401. Practice of Pharmacy and Sale of Poisons in Consular Districts in China. 40101
403. Improvements on Regulation of Drugs ..... 40301
405. Biomaterials Access Assurance ..... 40501
407. Federal Trade Commission Review of Agreements Relating to Generic Drugs and Brand Name Drugs. 40701
409. Substance Use Disorder Prevention ..... 40901
411. Coronavirus Aid, Relief, and Economic Security ..... 41101
413. Accelerating Access to Critical Therapies for ALS ..... 41301
415. Medical Marijuana and Cannabidiol Research Expansion ..... 41501
417 Through 493. ..... Reserved
495. Miscellaneous ..... 49501

**Subtitle V—Comprehensive Drug Abuse Prevention and Control**

**Division A—Controlled Substances**

501. General Provisions ..... 50101
503. Authority To Control; Standards and Schedules ..... 50301
505. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances. 50501
507. Offenses and Penalties ..... 50701
509. Administrative and Enforcement Provisions ..... 50901
511. Miscellaneous ..... 51101

**Division B—Controlled Substances Import and Export**

517. Importation and Exportation ..... 51701

**Subtitle VI—Drug Control and Enforcement**

601. Smuggling of Controlled Substances ..... 60101
603. Drug Abuse Prevention, Treatment, and Rehabilitation ..... 60301
605. Drug Free Communities ..... 60501
607. Other Coalition Grants ..... 60701
609. Office of National Drug Control Policy ..... 60901
611. Foreign Narcotics Kingpin Designation ..... 61101
613. Date-Rape Drug Prohibition ..... 61301
615. United States Anti-Doping Agency ..... 61501
617. National Methamphetamine Information Clearinghouse ..... 61701
619. Sanctions With Respect to Foreign Traffickers of Illicit Synthetic Opioids. 61901
621. International Sports Doping ..... 62101
623. Fentanyl Eradication and Narcotics Deterrence ..... 62301
625 Through 697. ..... Reserved
699. Miscellaneous Drug Control and Enforcement Provisions ..... 69901

**Subtitle VII—Cosmetics**

701. Modernization of Cosmetics Regulation ..... 70101

**Subtitle VIII—Tobacco**

801. Family Smoking Prevention and Tobacco Control ..... 80101
803 Through 897. ..... Reserved
899. Miscellaneous ..... 89901

# Subtitle I—Federal Food, Drug, and Cosmetic Provisions

# Division A—General Provisions

# Chapter 101—Definitions Applicable to Subtitle

Sec.
10101. Subtitle definitions.
10102. Nonfat dry milk.
10103. Market names for catfish and ginseng.
10104. FDA and FDA website.

**§ 10101. Subtitle definitions**

(a) GENERAL DEFINITIONS.—In this subtitle:

(1) ABBREVIATED DRUG APPLICATION.—The term ''abbreviated drug application'' means an application submitted under section 13511 of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(A) in the case of section 10506 of this title, includes a supplement to the approved application for a different or additional use of the drug but does not include a supplement to the approved application for other than a different or additional use of the drug; and

(B) in the case of sections 10507 and 10508 of this title, includes any supplement to the approved application.

(2) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Environmental Protection Agency.

(3) ANIMAL FEED.—

(A) APPLICABILITY.—This paragraph applies only to—

(i) paragraph (33);

(ii) chapter 137 of this title; and

(iii) the provisions of this subtitle referring to paragraph (33) or chapter 137 of this title.

(B) IN GENERAL.—The term ''animal feed'' means an article that is intended for use—

(i) for food for animals other than humans; and

(ii) as a substantial source of nutrients in the diet of any such animal.

(C) NOT LIMITED.—The term ''animal feed'' is not limited to a mixture intended to be the sole ration of the animal.

(4) ANTIBIOTIC DRUG.—

(A) IN GENERAL.—The term ''antibiotic drug'' means a drug composed wholly or partly of—

(i) any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin;

(ii) any other drug intended for human use containing any quantity of a chemical substance (including a chemically-synthesized equivalent of a chemical substance)—

(I) that is produced by a microorganism; and

(II) that has the capacity to inhibit or destroy microorganisms in dilute solution; or

(iii) a derivative of any drug under clause (i) or (ii).

(B) EXCEPTION.—The term ''antibiotic drug'' does not include a drug for use in animals other than humans.

(5) BUTTER.—The term ''butter'' means the food product—

(A) that is usually known as butter;

(B) that is made exclusively from milk, cream, or both, with or without common salt, and with or without additional coloring matter; and

(C) that contains not less than 80 percent of milk fat (by weight), all tolerances having been allowed for.

(6) COLOR.—The term ''color'' includes black, white, and intermediate grays.

(7) COLOR ADDITIVE.—

(A) IN GENERAL.—The term ''color additive'' means a material that—

(i) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; and

(ii) when added or applied to a food, drug, or cosmetic, or to the human body or any part of the human body, is capable (alone or through reaction with other substance) of imparting color to the food, drug, or cosmetic, or to the human body or the part of the human body.

(B) EXCLUSION.—The term ''color additive'' does not include any material that the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose other than coloring.

(C) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other

natural physiological processes of produce of the soil, by which growth or processes the color of the produce is affected, whether before or after harvest.

(8) COMMISSIONER.—The term ''Commissioner'' means the Commissioner of Food and Drugs.

(9) COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUG.—

(A) IN GENERAL.—The term ''compounded positron emission tomography drug'' means a drug that—

(i) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(ii)(I) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in clause (i); and

(II) is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control.

(B) INCLUSIONS.—The term ''compounded positron emission tomography drug'' includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of a drug under subparagraph (A).

(10) COSMETIC.—

(A) IN GENERAL.—The term ''cosmetic'' means—

(i) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part of the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance; and

(ii) articles intended for use as a component of any article under clause (i).

(B) EXCLUSION.—The term ''cosmetic'' does not include soap.

(11) COUNTERFEIT DEVICE.—The term ''counterfeit device'' means a device or the container, packaging, or labeling of the device—

(A) that, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness of the trademark, trade name, or other identifying mark or imprint, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed the device; and

(B) that, by the unauthorized bearing described in subparagraph (A), falsely purports or is represented to be the product of, or to have been packed or distributed by, the other device manufacturer, processor, packer, or distributor.

(12) COUNTERFEIT DRUG.—The term ''counterfeit drug'' means a drug or the container or labeling of the drug—

(A) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness of the trademark, trade name, or other identifying mark, imprint, or device, of a drug manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed the drug; and

(B) that, by the unauthorized bearing described in subparagraph (A), falsely purports or is represented to be the product of, or to have been packed or distributed by, the other drug manufacturer, processor, packer, or distributor.

(13) CRITICAL FOOD.—The term ''critical food'' means a food that is—

(A) an infant formula; or

(B) a medical food, as defined in section 49502(a)(1) of this title.

(14) CRITICAL REPROCESSED SINGLE-USE DEVICE.—The term ''critical reprocessed single-use device'' means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(15) DEPARTMENT.—The term ''Department'' means the Department of Health and Human Services.

(16) DEVICE.—

(A) IN GENERAL.—The term ''device'' (except when used in subsection (c)(1) and sections 10501(9), 11306, 13303, and 17112(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, in-

cluding any component, part, or accessory, that—

(i) is—

(I) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to those publications;

(II) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or

(III) intended to affect the structure or any function of the body of humans or other animals;

(ii) does not achieve its primary intended purposes through chemical action within or on the body of humans or other animals; and

(iii) is not dependent on being metabolized for the achievement of its primary intended purposes.

(B) EXCLUSIONS.—The term ''device'' does not include software functions excluded pursuant to section 13152(o) of this title.

(17) DIETARY SUPPLEMENT.—

(A) IN GENERAL.—The term ''dietary supplement''—

(i) means a product (other than tobacco) intended to supplement the diet that bears or contains 1 or more of the dietary ingredients listed in this clause, which dietary ingredients consist of—

(I) a vitamin;

(II) a mineral;

(III) an herb or other botanical;

(IV) an amino acid;

(V) a dietary substance for use by humans to supplement the diet by increasing the total dietary intake; or

(VI) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (I), (II), (III, (IV), or (V);

(ii) means a product that—

(I)(aa) is intended for ingestion in a form described in section 11113(a)(1)(D)(i) of this title; or

(bb) complies with section 11113(a)(1)(D)(ii) of this title;

(II) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(III) is labeled as a dietary supplement; and

(iii) does—

(I) include an article that is approved as a new drug under chapter 135 of this title or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to the approval or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for the dietary supplement, is unlawful under section 11102(f) of this title; and

(II) not include an article—

(aa) that is—

(AA) approved as a new drug under chapter 135 of this title or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(BB) authorized for investigation as a new drug or biologic for which substantial clinical investigations have been instituted and for which the existence of the investigations has been made public; and

(bb) that was not, before the approval, licensing, or authorization under item (aa), marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this subtitle.

(B) DEEMED TO BE A FOOD.—Except for purposes of paragraphs (12) and (18) and section 11119 of this title, a dietary supplement shall be deemed to be a food within the meaning of this subtitle.

(18) DRUG.—

(A) IN GENERAL.—The term ''drug'' means—

(i) an article recognized in the official United States Pharmacopeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of those publications;

(ii) an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

(iii) an article (other than food) intended to affect the structure or any function of the body of humans or other animals; and

(iv) an article intended for use as a component of any article specified in clause (i), (ii), or (iii).

(B) ARTICLES WITH CLAIMS ON LABEL OR LABELING.—A food or dietary supplement for which a claim, subject to subsections (a)(1)(B) and (c) of section 11317 of this title or subsections (a)(1)(B) and (e)(4) of section 11317 of this title, is made in accordance with the requirements of section 11317 of this title is not a drug solely because the label or the labeling contains such a claim.

(C) ARTICLES WITH CERTAIN TRUTHFUL STATEMENTS ON LABEL OR LABELING.—A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 11317(f) of this title is not a drug under subparagraph (A)(iii) solely because the label or the labeling contains such a statement.

(19) FOOD.—The term ''food'' means—

(A) articles used for food or drink for humans or other animals;

(B) chewing gum; or

(C) articles used for components of any article under subparagraph (A) or (B).

(20) FOOD ADDITIVE.—

(A) IN GENERAL.—The term ''food additive'' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if the substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

(B) INCLUSIONS.—The term ''food additive'' includes—

(i) any substance described in subparagraph (A) intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and

(ii) any source of radiation intended for any use described in clause (i).

(C) EXCLUSIONS.—The term ''food additive'' does not include—

(i) a pesticide chemical residue in or on a raw agricultural commodity or processed food;

(ii) a pesticide chemical;

(iii) a color additive;

(iv) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this subtitle, chapter 303 of this title, or chapter 313 of this title;

(v) a new animal drug; or

(vi) an ingredient described in paragraph (17) in, or intended for use in, a dietary supplement.

(21) IMMEDIATE CONTAINER.—The term ''immediate container'' does not include package liners.

(22) INFANT FORMULA.—The term ''infant formula'' means a food that purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(23) INFORMAL HEARING.—The term ''informal hearing'' means a hearing that is not subject to sec-

tion 554, 556, or 557 of title 5 and that provides for the following:

(A) PRESIDING OFFICER.—The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary that is the subject of the hearing and who are not directly responsible to an officer or employee of the Department that has participated in any such action.

(B) ATTORNEY REPRESENTATION.—Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(C) NOTICE.—Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary that is the subject of the hearing and a general summary of the information that will be presented by the Secretary at the hearing in support of the action.

(D) RIGHTS OF PARTIES.—At the hearing, the parties to the hearing shall have the right—

(i) to hear a full and complete statement of the action of the Secretary that is the subject of the hearing and the information and reasons supporting the action;

(ii) to conduct reasonable questioning; and

(iii) to present any oral or written information relevant to the action.

(E) WRITTEN REPORT BY PRESIDING OFFICER.—The presiding officer in the hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(F) TRANSCRIPTION.—The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at the party's expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(24) INTERSTATE COMMERCE.—The term ''interstate commerce'' means—

(A) commerce between any State or territory of the United States and any place outside of the State or territory of the United States; or

(B) commerce within the District of Columbia or within any other territory of the United States not organized with a legislative body.

(25) KNOW.—The term ''know'' means, with respect to a person that knows information, the person—

(A) has actual knowledge of the information; or

(B) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(26) KNOWINGLY.—The term ''knowingly'' means, with respect to a person's knowing of information, the person—

(A) has actual knowledge of the information; or

(B) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(27) LABEL.—

(A) IN GENERAL.—The term ''label'' means a display of written, printed, or graphic matter on the immediate container of any article.

(B) COMPLIANCE.—A requirement made by or under the authority of this subtitle that any word, statement, or other information appear on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if there is any outside container or wrapper, of the retail package of the article, or is easily legible through the outside container or wrapper.

(28) LABELING.—The term ''labeling'' means all labels and other written, printed, or graphic matter—

(A) on any article or any of its containers or wrappers; or

(B) accompanying the article.

(29) MAJOR FOOD ALLERGEN.—The term ''major food allergen'' means—

(A) milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or

walnuts), wheat, peanuts, soybeans, or sesame; or

(B) a food ingredient that contains protein derived from a food specified in subparagraph (A), except—

(i) any highly refined oil derived from a food specified in subparagraph (A) and any ingredient derived from the highly refined oil; or

(ii) a food ingredient that is exempt under subsection (e) or (f) of section 11323 of this title.

(30) MAJOR SPECIES.—The term ''major species'' means cattle, horses, swine, chickens, turkeys, dogs, or cats, except that the Secretary may add species to this definition by regulation.

(31) MINOR SPECIES.—The term ''minor species'' means animals other than humans that are not major species.

(32) MINOR USE.—The term ''minor use'' means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(33) NEW ANIMAL DRUG.—

(A) IN GENERAL.—The term ''new animal drug'' means any drug intended for use for animals other than humans the composition of which is such that—

(i) the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of the drug; or

(ii) the drug, as a result of investigations to determine its safety and effectiveness for use under the conditions prescribed, recommended, or suggested in the labeling of the drug, has become generally recognized as described in clause (i) but has not, other than in the investigations, been used to a material extent or for a material time under the conditions.

(B) EXCEPTION.—A drug that is not generally recognized as safe and effective as described under subparagraph (A)(i) shall not be deemed to be a new animal drug if at any time

prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906 (ch. 3915, 34 Stat. 768), and if at that time, its labeling contained the same representations concerning the conditions of its use.

(C) INCLUSIONS.—The term ''new animal drug'' includes any drug intended for use in animal feed (but not including the animal feed).

(D) DRUGS INTENDED FOR MINOR USE OR USE IN A MINOR SPECIES.—Any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of clauses (i) and (ii) of subparagraph (A) have not been met (or that the exception under subparagraph (B) to the criterion in subparagraph (A)(i) has been met) is a new animal drug.

(34) NEW DRUG.—

(A) IN GENERAL.—The term ''new drug'' means—

(i) any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that the drug is not

generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of the drug; or

(ii) any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under the conditions prescribed, recommended, or suggested in the labeling of the drug, has become generally recognized as described in clause (i), but has not, other than in the investigations, been used to a material extent or for a material time under the conditions.

(B) EXCEPTION.—A drug under subparagraph (A)(i) that is not generally recognized as described in subparagraph (A)(i) shall not be deemed to be a ''new drug'' if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906 (ch. 3915, 34

Stat. 768), and if at that time, its labeling contained the same representations concerning the conditions of its use.

(35) OFFICIAL COMPENDIUM.—The term ''official compendium'' means the official United States Pharmacopeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of those publications.

(36) PACKAGE.—The term ''package'' includes wrapped meat enclosed in paper or other material as prepared by the manufacturers of the wrapped meat for sale.

(37) PERSON.—The term ''person'' includes an individual, partnership, corporation, and association.

(38) PESTICIDE CHEMICAL.—

(A) IN GENERAL.—Except as provided in subparagraph (C), the term ''pesticide chemical'' means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), including all active and inert ingredients of the pesticide.

(B) PESTICIDE.—Notwithstanding any other provision of law, the term ''pesticide'' within the meaning under subparagraph (A) in-

cludes ethylene oxide and propylene oxide if the substances are applied on food.

(C) USE IN FOOD.—In the case of the use, with respect to food, of a substance described in subparagraph (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of subparagraph (A):

(i) EXCLUSION.—

(I) IN GENERAL.—The term ''pesticide chemical'' does not include the substance if the substance is applied for the use on food, or the substance is included for the use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes.

(II) SUBSTANCES NOT EXCLUDED.—The substance is not excluded under subclause (I) from the definition if the substance is ethylene oxide or propylene oxide, and is applied for the use on food described in subclause (I).

(III) USE IN RAW AGRICULTURAL COMMODITY.—The substance is not excluded under subclause (I) from the definition if the substance is applied for the use on a raw agricultural commodity, or the substance is included for the use in water that comes into contact with the agricultural commodity, as follows:

(aa) The substance is applied in the field.

(bb) The substance is applied at a treatment facility in which raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing the commodities in that manner).

(cc) The substance is applied during the transportation of the agricultural commodity be-

tween the field and a treatment facility described in item (bb).

(ii) EXCLUSION RELATING TO USE AS FOOD CONTACT SUBSTANCE.—

(I) IN GENERAL.—The term ''pesticide chemical'' does not include the substance if the substance is a food contact substance as defined in section 11111(a) of this title, and any of the following circumstances exist:

(aa) The substance is included for the use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object.

(bb) The substance is included for the use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface.

(cc) The substance is included for the use in or is applied

for the use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging).

(II) SEMIPERMANENT OR PERMANENT FOOD CONTACT SURFACE.—The food contact substance is not excluded under this clause from the definition under subparagraph (A) if—

(aa) the substance is applied for the use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or

(bb) the substance is included for the use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

(D) EFFECT ON FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.—With respect to the definition of the term ''pesticide'' that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), subparagraph (C) does not exclude any substance from the definition.

(E) EXCEPTION BY REGULATION.—Notwithstanding this paragraph, the Administrator may by regulation except a substance from the definition of ''pesticide chemical'' if—

(i) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(ii) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under 1 or more provisions of this subtitle other than sections 11102(a)(2)(B) and 11110 of this title.

(39) PESTICIDE CHEMICAL RESIDUE.—

(A) IN GENERAL.—The term ''pesticide chemical residue'' means a residue in or on raw agricultural commodity or processed food of—

(i) a pesticide chemical; or

(ii) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(B) EXCEPTION BY REGULATION.—Notwithstanding this paragraph, the Administrator may by regulation except a substance from the definition of ''pesticide chemical residue'' if—

(i) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(ii) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under 1 or more provisions of

this subtitle other than sections 11102(a)(2)(B) and 11110 of this title.

(40) PRIORITY SUPPLEMENT.—The term ''priority supplement'' means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2298).

(41) PROCESSED FOOD.—The term ''processed food'' means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(42) RAW AGRICULTURAL COMMODITY.—The term ''raw agricultural commodity'' means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(43) SACCHARIN.—The term ''saccharin'' includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(44) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(45) SEMI-CRITICAL REPROCESSED SINGLE-USE DEVICE.—The term ''semi-critical reprocessed single-use device'' means a reprocessed single-use de-

vice that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(46) SINGLE-USE DEVICE.—

(A) IN GENERAL.—The term ''single-use device'' means a device that is intended—

(i) for 1 use; or

(ii) for use on a single patient during a single procedure.

(B) REPROCESSED.—

(i) IN GENERAL.—The term ''reprocessed'', with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(ii) DESCRIPTIONS USED BY MANUFACTURERS.—A single-use device that meets the definition under clause (i) shall be considered a reprocessed device without

regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term ''recycled'' rather than the term ''reprocessed''.

(C) ORIGINAL DEVICE.—The term ''original device'' means a new, unused single-use device.

(47) STATE.—The term ''State'', except as used in section 17502(a)(1) of this title, means any State or territory of the United States, the District of Columbia, or Puerto Rico.

(48) TERRITORY OF THE UNITED STATES.—The term ''territory of the United States'' means any territory (including a possession) of the United States, including the District of Columbia, and excluding Puerto Rico.

(49) TOBACCO PRODUCT.—

(A) IN GENERAL.—The term ''tobacco product'' means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing

a component, part, or accessory of a tobacco product).

(B) ARTICLES THAT ARE NOT TOBACCO PRODUCTS.—

(i) DRUGS, DEVICES, AND COMBINATION PRODUCTS.—The term ''tobacco product'' does not mean an article that is a drug under paragraph (18), a device under paragraph (16), or a combination product described in section 13104 of this title.

(ii) APPLICABILITY OF PROVISIONS.—The articles described in clause (i) shall be subject to division D.

(iii) FOOD.—The term ''tobacco product'' does not mean an article that is a food under paragraph (19), if the article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

(C) MARKETING OF TOBACCO PRODUCTS.—A tobacco product shall not be marketed in combination with any other article or product regulated under this subtitle (including a drug, biologic, food, cosmetic, medical device, or dietary supplement).

(b) SPECIFIC DEFINITIONS.—

(1) DRUG PRODUCT.—For purposes of sections 10506 and 10507 of this title, the term ''drug product'' means a drug subject to regulation under chapter 135 or 137 of this title, section 20102 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) HIGH MANAGERIAL AGENT.—For purposes of section 10506 of this title, the term ''high managerial agent''—

(A) means—

(i) an officer or director of a corporation or an association having duties such that the conduct of the officer or director may fairly be assumed to represent the policy of the corporation or association;

(ii) a partner of a partnership having duties such that the conduct of the partner may fairly be assumed to represent the policy of the partnership; or

(iii) any employee or other agent of a corporation, association, or partnership having duties such that the conduct of the employee or agent may fairly be assumed

to represent the policy of the corporation, association, or partnership; and

(B) includes individuals having management responsibility for—

(i) submissions to the FDA regarding the development or approval of any drug product;

(ii) production, quality assurance, or quality control of any drug product; or

(iii) research and development of any drug product.

(3) SAFE.—The term ''safe'', as used in subsection (a)(20), in sections 11111, 14502, and 17701 of this title, and in chapter 137 of this title, has reference to the health of humans or animals.

(c) PROVISIONS RELATING TO MISBRANDING AND LABELING.—

(1) MISLEADING LABELING OR ADVERTISING.—If an article is alleged to be misbranded because the labeling or advertising is misleading, in determining whether the labeling or advertising is misleading, there shall be taken into account (among other things)—

(A) the representations made or suggested by—

(i) statement, word, design, or device; or

(ii) any combination of statement, word, design, or device; and

(B) the extent to which the labeling or advertising fails to reveal facts—

(i) material in the light of the representations; or

(ii) material with respect to consequences that may result from the use of the article (to which the labeling or advertising relates)—

(I) under the conditions of use prescribed in the labeling or advertising of the article; or

(II) under such conditions of use as are customary or usual.

(2) REPRESENTATION OF A DRUG AS ANTISEPTIC.—The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

**§ 10102. Nonfat dry milk**

(a) MILK.—In this section, the term ''milk'' means sweet milk of cows.

(b) NONFAT DRY MILK.—For the purposes of this subtitle:

(1) NONFAT DRY MILK.—Nonfat dry milk—

(A) is the product resulting from the removal of fat and water from milk;

(B) contains the lactose, milk proteins, and milk minerals in the same relative proportions as in the fresh milk from which made; and

(C) contains not over 5 percent by weight of moisture.

(2) FAT CONTENT.—The fat content of nonfat dry milk is not over 1½ percent by weight unless otherwise indicated.

**§ 10103. Market names for catfish and ginseng**

(a) CATFISH LABELING.—Notwithstanding any other provision of law, for purposes of this subtitle—

(1) the term ''catfish'' may only be considered to be a common or usual name (or part of a common or usual name) for fish classified within the family Ictaluridae; and

(2) only labeling or advertising for fish classified within the family Ictaluridae may include the term ''catfish''.

(b) GINSENG LABELING.—Notwithstanding any other provision of law, for purposes of this subtitle—

(1) the term ''ginseng'' may only be considered to be a common or usual name (or part of a common or usual name) for any herb or herbal ingredient derived from a plant classified within the genus Panax; and

(2) only labeling or advertising for herbs or herbal ingredients classified within the genus Panax may include the term ''ginseng''.

**§ 10104. FDA and FDA website**

In this subtitle:

(1) FDA.—The term ''FDA'' means the Food and Drug Administration established in section 10301 of this title.

(2) FDA WEBSITE.—The term ''FDA website'' means the internet website of the FDA.

# Chapter 103—Food and Drug Administration

**Subchapter I—Establishment**
Sec.
10301. Food and Drug Administration.
10302. Office of the Chief Scientist.
10303. Office of Women's Health.
10304. FDA Intercenter Institutes.
10305. Scientific review groups.
**Subchapter II—Administrative Provisions**
10321. Exemption of meats and meat food products.
10322. Loan repayment program.
10323. Practice of medicine.
10324. Contracts for expert review.
10325. Notices to States regarding imported food.

10326. Grants to enhance food safety.
10327. Improving the training of State, local, territorial, and tribal food safety officials.
10328. Employee protections.

# Subchapter I—Establishment

## § 10301. Food and Drug Administration

(a) ESTABLISHMENT.—There is established in the Department the Food and Drug Administration.

(b) MISSION.—The FDA shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to the products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

(c) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that fosters collaboration between the FDA, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

(d) COMMISSIONER.—

(1) APPOINTMENT.—There shall be in the FDA a Commissioner of Food and Drugs who shall be ap-

pointed by the President by and with the advice and consent of the Senate.

(2) GENERAL POWERS.—The Secretary, through the Commissioner, shall be responsible for executing this subtitle and for—

(A) providing overall direction to the FDA and establishing and implementing general policies respecting the management and operation of programs and activities of the FDA;

(B) coordinating and overseeing the operation of all administrative entities within the FDA;

(C) research relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out this subtitle;

(D) conducting educational and public information programs relating to the responsibilities of the FDA; and

(E) performing such other functions as the Secretary may prescribe.

(e) TECHNICAL AND SCIENTIFIC REVIEW GROUPS.—The Secretary, through the Commissioner, may, without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of

title 5 relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the FDA, including functions under this subtitle, and appoint and pay the members of the groups, except that officers and employees of the Federal Government shall not receive additional compensation for service as members of the groups.

(f) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

(1) IN GENERAL.—The Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this subtitle. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with the persons.

(2) OBJECTIVES OF AGENCY PLAN.—The plan required by paragraph (1) shall establish objectives and mechanisms to achieve the objectives, including objectives related to—

(A) maximizing the availability and clarity of information about the process for review of applications and submissions (including peti-

tions, notifications, and any other similar forms of request) made under this subtitle;

(B) maximizing the availability and clarity of information for consumers and patients concerning new products;

(C) implementing inspection and postmarket monitoring provisions of this subtitle;

(D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

(E) establishing mechanisms for meeting the time periods specified in this subtitle for the review of all applications and submissions described in subparagraph (A); and

(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

(g) ANNUAL REPORT.—The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that—

(1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f);

(2) compares the performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

(3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.

(h) ANNUAL REPORT REGARDING FOOD.—Not later than February 1 of each year, the Secretary shall submit to Congress a report, including efforts to coordinate and cooperate with other Federal agencies with responsibilities for food inspections, regarding—

(1) information about food facilities including—

(A) the appropriations used to inspect facilities registered pursuant to section 11117 of this title in the previous fiscal year;

(B) the average cost of a non-high-risk food facility inspection and the average cost of a high-risk food facility inspection, if a difference exists between the costs, in the previous fiscal year;

(C) the number of domestic facilities and the number of foreign facilities registered pur-

suant to section 11117 of this title that the Secretary inspected in the previous fiscal year;

(D) the number of domestic facilities and the number of foreign facilities registered pursuant to section 11117 of this title that were scheduled for inspection in the previous fiscal year and that the Secretary did not inspect in that year;

(E) the number of high-risk facilities identified pursuant to section 11123 of this title that the Secretary inspected in the previous fiscal year; and

(F) the number of high-risk facilities identified pursuant to section 11123 of this title that were scheduled for inspection in the previous fiscal year and that the Secretary did not inspect in that year;

(2) information about food imports including—

(A) the number of lines of food imported into the United States that the Secretary physically inspected or sampled in the previous fiscal year;

(B) the number of lines of food imported into the United States that the Secretary did

not physically inspect or sample in the previous fiscal year; and

(C) the average cost of physically inspecting or sampling a line of food subject to this subtitle that is imported or offered for import into the United States; and

(3) information on the foreign offices of the FDA, including—

(A) the number of foreign offices established; and

(B) the number of personnel permanently stationed in each foreign office.

(i) PUBLIC AVAILABILITY OF ANNUAL FOOD REPORTS.—The Secretary shall make the reports required under subsection (h) available to the public on the FDA website.

**§ 10302. Office of the Chief Scientist**

(a) DEFINITION OF OFFICE.—In this section, the term ''Office'' means the Office of the Chief Scientist established under subsection (b).

(b) ESTABLISHMENT.—The Secretary shall establish within the Office of the Commissioner an office to be known as the Office of the Chief Scientist. The Secretary shall appoint a Chief Scientist to lead the Office.

(c) DUTIES OF THE OFFICE.—The Office shall—

(1) oversee, coordinate, and ensure quality and regulatory focus of the intramural research programs of the FDA;

(2) track and, to the extent necessary, coordinate intramural research awards made by each center of the FDA or science-based office within the Office of the Commissioner, and ensure that there is no duplication of research efforts supported by the Reagan-Udall Foundation for the Food and Drug Administration;

(3) develop and advocate for a budget to support intramural research;

(4) develop a peer review process by which intramural research can be evaluated;

(5) identify and solicit intramural research proposals from across the FDA through an advisory board composed of employees of the FDA, which advisory board shall include—

(A) representatives of each of the centers and the science-based offices within the Office of the Commissioner; and

(B) experts on trial design, epidemiology, demographics, pharmacovigilance, basic science, and public health; and

(6) develop postmarket safety performance measures that are as measurable and rigorous as the ones already developed for premarket review.

**§ 10303. Office of Women's Health**

(a) DEFINITION OF OFFICE.—In this section, the term ''Office'' means the Office of Women's Health established under subsection (b).

(b) ESTABLISHMENT.—There is established within the Office of the Commissioner an office to be known as the Office of Women's Health. The Commissioner shall appoint a Director who shall be the head of the Office.

(c) PURPOSE.—The Director of the Office shall—

(1) report to the Commissioner on current FDA levels of activity regarding women's participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

(2) establish short-range and long-range goals and objectives within the FDA for issues of particular concern to women's health within the jurisdiction of the FDA, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in FDA protocols and policies;

(3) provide information to women and health care providers on those areas in which differences between men and women exist;

(4) consult, with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals, on FDA policy with regard to women;

(5) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex in accordance with needs that are identified; and

(6) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4) of the Public Health Service Act (42 U.S.C. 237a(b)(4))).

**§ 10304. FDA Intercenter Institutes**

(a) DEFINITIONS.—In this section:

(1) CENTERS.—The term ''Centers'' means the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

(2) INSTITUTE.—The term ''Institute'' means an Intercenter Institute established under subsection (b).

(b) IN GENERAL.—The Secretary shall establish 1 or more Intercenter Institutes within the FDA for a major disease area or areas. With respect to a major disease area of focus of an Institute, the Institute shall develop and implement processes for coordination of activities, as applicable to the major disease area, among the Centers. The activities may include—

(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

(2) streamlining, where appropriate, the review of medical products to diagnose, cure, mitigate, treat, or prevent the specific diseases relevant to the major disease area of focus of the Institute, applying relevant standards under chapter 135 of this title, sections 13136(k), 13140(h)(2), and 13142 of this title, and section 351 of the Public Health Service Act (42 U.S.C. 262), and other applicable authorities;

(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department regarding the major disease area of focus of the Institute.

(c) PUBLIC PROCESS.—The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

(d) TERMINATION OF INSTITUTES.—The Secretary may terminate any Institute established pursuant to this section if the Secretary determines that the Institute is no longer benefitting the public health. Not less than 60 days prior to the termination of the Institute, the Secretary shall provide public notice, including the rationale for the termination.

**§ 10305. Scientific review groups**

(a) IN GENERAL.—Without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5 relating to classification and General Schedule pay rates, the Commissioner may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the FDA (including functions prescribed under this subtitle); and

(2) appoint and pay the members of the groups, except that officers and employees of the Federal Government shall not receive additional compensation for service as members of the groups.

(b) DELEGATION OF APPOINTMENT AND OVERSIGHT AUTHORITY.—The Secretary may delegate the appointment and oversight authority granted under this section to a director of a center or successor entity within the FDA.

# Subchapter II—Administrative Provisions

**§ 10321. Exemption of meats and meat food products**

(a) LAW DETERMINATIVE OF EXEMPTION.—Meats and meat food products shall be exempt from the provisions of this subtitle to the extent of the application or

the extension to meats and meat food products of chapter 303 of this title.

(b) EFFECT OF SUBTITLE.—Nothing in this subtitle shall be construed as affecting, modifying, repealing, or superseding—

(1) the provisions of section 351 of the Public Health Service Act (42 U.S.C. 262) (relating to viruses, serums, toxins, and analogous products applicable to humans);

(2) the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of March 4, 1913 (ch. 145, 37 Stat. 832);

(3) chapter 307 of this title; or

(4) chapter 309 of this title.

**§ 10322. Loan repayment program**

(a) IN GENERAL.—

(1) AUTHORITY FOR PROGRAM.—Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which the health professionals agree to conduct research, as employees of the FDA, in consideration of the Federal Government agreeing to repay, for each year of the service, not more than $20,000 of the principal and in-

terest of the educational loans of the health professionals.

(2) LIMITATION.—The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless the professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the FDA for purposes of paragraph (1) for a period of not less than 3 years.

(b) APPLICABILITY OF CERTAIN PROVISIONS.—With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III of the Public Health Service Act (42 U.S.C. 254l et seq.), the provisions of that subpart shall, except as inconsistent with subsection (a), apply to the program established in subsection (a) in the same manner and to the same extent as the provisions apply to the National Health Service Corps Loan Repayment Program.

**§ 10323. Practice of medicine**

(a) IN GENERAL.—Nothing in this subtitle shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or

disease within a legitimate health care practitioner-patient relationship.

(b) EFFECT OF SECTION.—

(1) LIMITATION ON AUTHORITY OF SECRETARY.—This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations.

(2) PROHIBITION ON PROMOTION OF UNAPPROVED USES.—This section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

**§ 10324. Contracts for expert review**

(a) IN GENERAL.—

(1) AUTHORITY TO ENTER CONTRACT.—

(A) IN GENERAL.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a

petition, notification, and any other similar form of request)—

(i) made under this subtitle for the approval or classification of an article; or

(ii) made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product.

(B) CONFIDENTIALITY OF INFORMATION.—Any contract under subparagraph (A) shall be subject to the requirements of section 17508 of this title relating to the confidentiality of information.

(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—

(A) TIMELINESS.—The Secretary may use the authority granted in paragraph (1) if the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using the authority would reduce the quality, or unduly increase the cost, of the review.

(B) QUALITY.—The Secretary may use the authority granted under paragraph (1) if the

Secretary determines that use of a contract under paragraph (1) will improve the quality of the review of an application or submission described in paragraph (1), unless using the authority would unduly increase the cost of the review.

(C) INCREASED SCIENTIFIC OR TECHNICAL EXPERTISE RELATING TO REVIEW OF NEW TECHNOLOGIES.—Improvement in timeliness or quality under this paragraph may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

(b) REVIEW OF EXPERT REVIEW.—

(1) IN GENERAL.—Subject to paragraph (2), the official of the FDA responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

(2) LIMITATION.—A final decision by the Secretary on any application or submission reviewed under this section shall be made within the applicable prescribed time period for review of the matter

as set forth in this subtitle or in the Public Health Service Act (42 U.S.C. 201 et seq.).

**§ 10325. Notices to States regarding imported food**

(a) IN GENERAL.—

(1) PROVIDING NOTICE TO STATES.—If the Secretary has credible evidence or information indicating that a shipment of imported food or portion of the food presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding the threat to the States in which the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located, to the extent that the Secretary has knowledge of which States are involved as described in this paragraph.

(2) REQUEST TO TAKE ACTION.—In providing notice to a State, the Secretary shall request the State to take such action as the State considers appropriate, if any, to protect the public health regarding the food involved.

(b) RULE OF CONSTRUCTION.—This section may not be construed as limiting the authority of the Secretary with respect to food under any other provision of this subtitle.

**§ 10326. Grants to enhance food safety**

(a) DEFINITION OF ELIGIBLE ENTITY.—In this section, the term ''eligible entity'' means an entity—

(1) that is—

(A) a State;

(B) a locality;

(C) a territory of the United States;

(D) an Indian tribe (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e))); or

(E) a nonprofit food safety training entity that collaborates with 1 or more institutions of higher education; and

(2) that submits an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

(b) IN GENERAL.—The Secretary may make grants to eligible entities to—

(1) undertake examinations, inspections, and investigations, and related food safety activities under section 17502 of this title;

(2) train, to the standards of the Secretary, for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and importation, including as such ex-

amination, inspection, and investigation relate to retail food establishments;

(3) build the food safety capacity of the laboratories of the eligible entity, including the detection of zoonotic diseases;

(4) build the infrastructure and capacity of the food safety programs of the eligible entity to meet the standards as outlined in the grant application; and

(5) take appropriate action to protect the public health in response to—

(A) a notification under section 10325 of this title, including planning and otherwise preparing to take the action; or

(B) a recall of food under this subtitle.

(c) APPLICATION CONTENTS.—Each application submitted under subsection (a) shall include—

(1) an assurance that the eligible entity has developed plans to engage in the types of activities described in subsection (b);

(2) a description of the types of activities to be funded by the grant;

(3) an itemization of how grant funds received under this section will be expended;

(4) a description of how grant activities will be monitored; and

(5) an agreement by the eligible entity to report information required by the Secretary to conduct evaluations under this section.

(d) LIMITATIONS.—The funds provided under subsection (b) shall be available to an eligible entity that receives a grant under this section only to the extent the entity funds the food safety programs of the entity independently of any grant under this section in each year of the grant at a level equal to the level of the funding in the previous year, increased by the Consumer Price Index. The non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) ADDITIONAL AUTHORITY.—The Secretary may—

(1) award a grant under this section in each subsequent fiscal year without reapplication for a period of not more than 3 years, provided the requirements of subsection (d) are met for the previous fiscal year; and

(2) award a grant under this section in a fiscal year for which the requirement of subsection (d) has not been met only if the requirement was not met

because the funding was diverted for response to 1 or more natural disasters or in other extenuating circumstances that the Secretary may determine appropriate.

(f) DURATION OF AWARDS.—The Secretary may award grants to an individual grant recipient under this section for periods of not more than 3 years. In the event the Secretary conducts a program evaluation, funding in the second year or third year of the grant, if applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

(g) PROGRESS AND EVALUATION.—

(1) IN GENERAL.—

(A) MEASUREMENT.—The Secretary shall measure the status and success of each grant program authorized under chapter 325 of this title and under the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) (and any amendment made by the Act), including the grant program under this section.

(B) INFORMATION REQUIRED FROM RECIPIENT.—A recipient of a grant described in subparagraph (A) shall, at the end of each grant year, provide the Secretary with information on how grant funds were spent and the

status of the efforts by the recipient to enhance food safety.

(C) PERFORMANCE OF RECIPIENT.—To the extent practicable, the Secretary shall take the performance of a grant recipient under subparagraph (B) into account when determining whether to continue funding for the recipient.

(2) NO DUPLICATION.—In carrying out paragraph (1), the Secretary shall not duplicate the efforts of the Secretary under other provisions of this subtitle, chapter 325 of this title, or the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) that require measurement and review of the activities of grant recipients under this subtitle, chapter 325 of this title, or the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885).

(h) SUPPLEMENT NOT SUPPLANT.—Grant funds received under this section shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this section.

**§ 10327. Improving the training of State, local, territorial, and tribal food safety officials**

(a) TRAINING.—The Secretary shall set standards and administer training and education programs for the employees of State, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by this subtitle, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 17502 and 17504 of this title;

(3) training to achieve advanced product or process specialization in the inspections;

(4) training that addresses best practices;

(5) training in administrative process and procedure and integrity issues;

(6) training in appropriate sampling and laboratory analysis methodology; and

(7) training in building enforcement actions following inspections, examinations, testing, and investigations.

(b) PARTNERSHIPS WITH STATE AND LOCAL OFFICIALS.—

(1) IN GENERAL.—The Secretary, pursuant to a contract or memorandum of understanding between the Secretary and the head of a State, local,

territorial, or tribal department or agency, is authorized and encouraged to conduct examinations, testing, and investigations for the purposes of determining compliance with the food safety provisions of this subtitle through the officers and employees of the State, local, territorial, or tribal department or agency.

(2) CONTENT.—

(A) ADEQUATE TRAINING.—A contract or memorandum described under paragraph (1) shall include provisions to ensure adequate training of the officers and employees to conduct the examinations, testing, and investigations.

(B) REIMBURSEMENT.—The contract or memorandum shall contain provisions regarding reimbursement. The reimbursement provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations, testing, or investigations performed pursuant to this section by the officers or employees of the State, territorial, or tribal department or agency.

(3) EFFECT.—Nothing in this subsection shall be construed to limit the authority of the Secretary under section 17502 of this title.

(c) EXTENSION SERVICE.—The Secretary shall ensure coordination with the extension activities of the National Institute of Food and Agriculture of the Department of Agriculture in advising producers and small processors transitioning into new practices required as a result of the enactment of the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) and assisting regulated industry with compliance with the Act.

(d) NATIONAL FOOD SAFETY TRAINING, EDUCATION, EXTENSION, OUTREACH, AND TECHNICAL ASSISTANCE PROGRAM.—

(1) IN GENERAL.—In order to improve food safety and reduce the incidence of foodborne illness, the Secretary shall enter into 1 or more memoranda of understanding, or enter into other cooperative agreements, with the Secretary of Agriculture to establish a competitive grant program within the National Institute for Food and Agriculture to provide food safety training, education, extension, outreach, and technical assistance to—

(A) owners and operators of farms;

(B) small food processors; and

(C) small fruit and vegetable merchant wholesalers.

(2) IMPLEMENTATION.—The competitive grant program established under paragraph (1) shall be carried out in accordance with section 405 of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7625).

**§ 10328. Employee protections**

(a) IN GENERAL.—An entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food shall not discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee's initiative or in the ordinary course of the employee's duties (or any person acting pursuant to a request of the employee)—

(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of, any provision of this subtitle or any order, rule, regulation, standard, or ban under this subtitle;

(2) testified or is about to testify in a proceeding concerning the violation;

(3) assisted or participated or is about to assist or participate in a proceeding concerning the violation; or

(4) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or the person) reasonably believed to be in violation of any provision of this subtitle, or any order, rule, regulation, standard, or ban under this subtitle.

(b) PROCESS.—

(1) IN GENERAL.—

(A) FILING OF COMPLAINT.—An individual who believes that the individual has been discharged or otherwise discriminated against by any person in violation of subsection (a) may, not later than 180 days after the date on which the violation occurs, file (or have any person file on the individual's behalf) a complaint with the Secretary of Labor alleging the discharge or discrimination and identifying the person responsible for the act.

(B) NOTIFICATION.—On receipt of a complaint under subparagraph (A), the Secretary of

Labor shall notify, in writing, the person named in the complaint of the filing of the complaint, of the allegations contained in the complaint, of the substance of evidence supporting the complaint, and of the opportunities that will be afforded to the person under paragraph (2).

(2) INVESTIGATION.—

(A) IN GENERAL.—Not later than 60 days after the date of receipt of a complaint filed under paragraph (1) and after affording the complainant and the person named in the complaint an opportunity to submit to the Secretary of Labor a written response to the complaint and an opportunity to meet with a representative of the Secretary of Labor to present statements from witnesses, the Secretary of Labor shall initiate an investigation and determine whether there is reasonable cause to believe that the complaint has merit and notify, in writing, the complainant and the person alleged to have committed a violation of subsection (a) of the findings of the Secretary of Labor.

(B) REASONABLE CAUSE FOUND; PRELIMINARY ORDER.—

(i) REASONABLE CAUSE THAT VIOLATION OCCURRED.—If the Secretary of Labor concludes that there is reasonable cause to believe that a violation of subsection (a) has occurred, the Secretary of Labor shall accompany the findings of the Secretary of Labor with a preliminary order providing the relief prescribed by paragraph (3)(B).

(ii) OBJECTIONS; REQUEST FOR HEARING.—Not later than 30 days after the date of notification of findings under this paragraph, the person alleged to have committed the violation or the complainant may file objections to the findings or preliminary order, or both, and request a hearing on the record. A hearing under this clause shall be conducted expeditiously. If a hearing is not requested within the 30-day period, the preliminary order shall be deemed a final order that is not subject to judicial review.

(iii) FILING OF OBJECTIONS NOT TO OPERATE TO STAY REINSTATEMENT REMEDY.—The filing of objections under clause

(ii) shall not operate to stay any reinstatement remedy contained in the preliminary order.

(C) DISMISSAL OF COMPLAINT.—

(i) STANDARD FOR COMPLAINANT.—The Secretary of Labor shall dismiss a complaint filed under this subsection and shall not conduct an investigation otherwise required under subparagraph (A) unless the complainant makes a prima facie showing that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

(ii) STANDARD FOR EMPLOYER.—Notwithstanding a finding by the Secretary of Labor that the complainant has made the showing required under clause (i), no investigation otherwise required under subparagraph (A) shall be conducted if the employer demonstrates, by clear and convincing evidence, that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

(iii) VIOLATION STANDARD.—The Secretary of Labor may determine that a violation of subsection (a) has occurred only if the complainant demonstrates that any behavior described in paragraphs (1) through (4) of subsection (a) was a contributing factor in the unfavorable personnel action alleged in the complaint.

(iv) RELIEF STANDARD.—Relief may not be ordered under subparagraph (A) if the employer demonstrates by clear and convincing evidence that the employer would have taken the same unfavorable personnel action in the absence of that behavior.

(3) FINAL ORDER.—

(A) IN GENERAL.—Not later than 120 days after the date of conclusion of any hearing under paragraph (2), the Secretary of Labor shall issue a final order providing the relief prescribed by this paragraph or denying the complaint. At any time before issuance of a final order, a proceeding under this subsection may be terminated on the basis of a settlement agreement entered into by the Secretary of

Labor, the complainant, and the person alleged to have committed the violation.

(B) CONTENT OF ORDER.—If, in response to a complaint filed under paragraph (1), the Secretary of Labor determines that a violation of subsection (a) has occurred, the Secretary of Labor shall order the person that committed the violation—

(i) to take affirmative action to abate the violation;

(ii) to reinstate the complainant to the complainant's former position together with compensation (including back pay) and restore the terms, conditions, and privileges associated with the complainant's employment; and

(iii) to provide compensatory damages to the complainant.

(C) PENALTY.—If an order described in subparagraph (B) is issued under this paragraph, the Secretary of Labor, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys' and expert witness

fees) reasonably incurred, as determined by the Secretary of Labor, by the complainant for, or in connection with, the bringing of the complaint on which the order was issued.

(D) BAD FAITH CLAIM.—If the Secretary of Labor finds that a complaint under paragraph (1) is frivolous or has been brought in bad faith, the Secretary may award to the prevailing employer a reasonable attorneys' fee, not exceeding $1,000, to be paid by the complainant.

(4) ACTION IN COURT.—

(A) IN GENERAL.—If the Secretary of Labor has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination, the complainant may bring an action at law or equity for de novo review in the appropriate district court of the United States with jurisdiction, which shall have jurisdiction over such an action without regard to the amount in controversy, and which action shall, at the request of either party to the action, be tried by the court with a jury. The proceedings

shall be governed by the same legal burdens of proof specified in paragraph (2)(C).

(B) RELIEF.—The court shall have jurisdiction to grant all relief necessary to make the employee whole, including injunctive relief and compensatory damages, including—

(i) reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimination;

(ii) the amount of back pay, with interest; and

(iii) compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorneys' fees.

(5) APPEALS.—

(A) IN GENERAL.—

(i) COURT.—Unless the complainant brings an action under paragraph (4), any person adversely affected or aggrieved by a final order issued under paragraph (3) may obtain review of the order in the United States Court of Appeals for the cir-

cuit in which the violation, with respect to which the order was issued, allegedly occurred or the circuit in which the complainant resided on the date of the violation.

(ii) FILING DEADLINE.—The petition for review shall be filed not later than 60 days after the date of the issuance of the final order of the Secretary of Labor.

(iii) PROCEDURE.—Review under this paragraph shall conform to chapter 7 of title 5.

(iv) EFFECT OF COMMENCEMENT OF PROCEEDING.—The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the order.

(B) NO JUDICIAL REVIEW.—An order of the Secretary of Labor with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

(6) FAILURE TO COMPLY WITH ORDER.—If any person has failed to comply with an order issued under paragraph (3), the Secretary of Labor may

file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce the order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory damages.

(7) CIVIL ACTION TO REQUIRE COMPLIANCE.—

(A) IN GENERAL.—A person on whose behalf an order was issued under paragraph (3) may commence a civil action against the person to whom the order was issued to require compliance with the order. The appropriate United States district court shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce the order.

(B) AWARD.—The court, in issuing any final order under this paragraph, may award costs of litigation (including reasonable attorneys' fees and expert witness fees) to any party whenever the court determines that the award is appropriate.

(c) EFFECT OF SECTION.—

(1) SAFEGUARDS PROVIDED BY OTHER LAWS.—Nothing in this section preempts or diminishes any other safeguards against discrimination, demotion, discharge, suspension, threats, harassment, reprimand, retaliation, or any other manner of discrimination provided by Federal or State law.

(2) RIGHTS OF EMPLOYEES.—Nothing in this section shall be construed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement. The rights and remedies in this section may not be waived by any agreement, policy, form, or condition of employment.

(d) ENFORCEMENT.—Any nondiscretionary duty imposed by this section shall be enforceable in a mandamus proceeding brought under section 1361 of title 28.

(e) LIMITATION.—Subsection (a) shall not apply with respect to an employee of an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food, which employee, acting without direction from the entity (or the entity's agent), deliberately causes a violation of any requirement relating to any violation or alleged violation of any order, rule, regulation, standard, or ban under this subtitle.

# Division B—Procedure and Prohibited Acts and Penalties

# Chapter 105—Procedure and Prohibited Acts and Penalties

Sec.
10501. Prohibitions.
10502. Injunction proceedings.
10503. Penalties.
10504. Seizure.
10505. Hearing before report of criminal violation.
10506. Debarment, temporary denial of approval, and suspension.
10507. Civil penalties.
10508. Authority to withdraw approval of abbreviated drug applications.
10509. Report of minor violations.
10510. Proceedings in name of United States or a State.
10511. Extraterritorial jurisdiction.

## § 10501. Prohibitions

The following acts and the causing of the acts are prohibited:

(1) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(2) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(3) The receipt in interstate commerce, and the delivery or proffered delivery for pay or otherwise, of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(4) The introduction or delivery for introduction into interstate commerce of any article in violation of section 11106, 11117, 14306, or 17123 of this title or chapter 135 of this title.

(5)(A) The refusal to permit access to or copying of any record as required by section 11114, 11116, 11118, 11119(j), 13110, 14306, 17121, 17503, 17504(a), 18901, or 18902 of this title.

(B)(i) The failure to establish or maintain any record, or make any report, required under section 11114, 11116(b), 11118, 11119, 13110, 13142(f), 13151, 13510, 13512, 13702(d)(3), 13711, 13713, 13714, 14306, 14503(i), 17121, 17127, 18901, 18902, 21110, or 21121 of this title; or

(ii) the refusal to permit access to or verification or copying of any required record described in clause (i).

(C) The violation of any recordkeeping requirement under section 32533 of this title (except when the violation is committed by a farm).

(6) The refusal to permit entry or inspection as authorized by section 17504 of this title.

(7) The manufacture within any territory of the United States of any food, drug, device, tobacco

product, or cosmetic that is adulterated or misbranded.

(8) The giving of—

(A) a guaranty or undertaking referred to in section 10503(c)(2) of this title, which guaranty or undertaking is false, except by a person that relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of, another person residing in the United States from whom the former received in good faith the food, drug, device, tobacco product, or cosmetic; or

(B) a guaranty or undertaking referred to in section 10503(c)(3) of this title, which guaranty or undertaking is false.

(9)(A) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under section 11106 or 17701 of this title.

(B) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade

name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing on any drug or container or labeling of the drug or container so as to render the drug a counterfeit drug.

(C) The doing of any act that causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(10)(A) The using by any person to the person's own advantage, or revealing (other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this subtitle) any information—

(i) acquired under section 11106, 11111, 11114, 11116, 13136, 13140, 13141, 13142, 13146, 13149, 13151, 13152, 17504, 17508, 17701, 21105, 21106, 21107, 21108, 21109, 21110, or 21121(b) of this title or chapter 135, 137, or 145 of this title; and

(ii) concerns any method or process which, as a trade secret, is entitled to protection.

(B) The violating of section 11110(j)(2) of this title or any regulation issued under that section.

(C) This paragraph does not authorize the withholding of information from—

(i) the Senate or House of Representatives; or

(ii) to the extent of matter within its jurisdiction—

(I) any committee of Congress or any subcommittee of the committee; or

(II) any joint committee of Congress or any subcommittee of the joint committee.

(11) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if the act—

(A) is done while the article is held for sale (whether or not the first sale) after shipment in interstate commerce; and

(B) results in the article being adulterated or misbranded.

(12) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsection (d) or (e) of section 11109 of this title.

(13) The using, in labeling, advertising or other sales promotion, of any reference to any report or

analysis furnished in compliance with section 17504 of this title.

(14)(A) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor of the prescription drug to maintain for transmittal, or to transmit, to any practitioner (licensed by applicable State law to administer the prescription drug) who makes a written request for information as to the prescription drug, true and correct copies of—

(i) all printed matter that is required to be included in any package in which that prescription drug is distributed or sold; or

(ii) such other printed matter as is approved by the Secretary.

(B) Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this subtitle.

(15) The failure—

(A) to register in accordance with section 13136 or 21106 of this title;

(B) to provide any information required by section 13136(j), 13136(k), 21106(i), or 21106(j) of this title; or

(C) to provide a notice required by section 13136(j)(2) or 21106(i)(3) of this title.

(16)(A) The failure or refusal—

(i) to comply with any requirement prescribed under section 13149, 13152(g), 21104(b), 21108, 21109, or 21116 of this title;

(ii) to furnish any notification or other material or information required by or under section 13151, 13152(g), 21105, 21110, or 21121 of this title; or

(iii) to comply with a requirement under section 13154 or 21114 of this title.

(B) With respect to any device or tobacco product, the submission of any report that is required by or under this subtitle that is false or misleading in any material respect.

(C)(i) The failure to comply with any requirement under section 13158(c)(2) of this title (relating to ensuring device cybersecurity).

(ii) Nothing in clause (i) shall be construed to affect the Secretary's authority related to ensuring that there is a reasonable assurance of the safety

and effectiveness of devices, which may include ensuring that there is a reasonable assurance of the cybersecurity of certain cyber devices, including for devices approved or cleared prior to December 29, 2022.

(17)(A) The movement of a device, drug, or tobacco product in violation of an order under section 10504(g) of this title.

(B) The removal or alteration of any mark or label required by the order described in subparagraph (A) to identify the device, drug, or tobacco product as detained.

(18) The failure—

(A) to provide the notice required by subsection (c) or (e) of section 11114 of this title;

(B) to make the reports required by section 11114(f)(1)(B) of this title;

(C) to retain the records required by section 11114(b)(4) of this title; or

(D) to meet the requirements prescribed under section 11114(f)(3) of this title.

(19)(A) The importation of a drug in violation of section 20101(d)(1) of this title.

(B) The sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade

a drug or drug sample in violation of section 13103(b) of this title.

(C) The sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade a coupon, or the counterfeiting of a coupon in violation of section 13103(b)(2) of this title.

(D) The distribution of a drug sample in violation of section 13103(c) of this title or the failure to otherwise comply with the requirements of section 13103(c) of this title.

(E) The distribution of drugs in violation of section 13103(d) of this title or the failure to otherwise comply with the requirements of section 13103(d) of this title.

(F) The failure to comply with the requirements under section 14902 of this title or the failure to comply with the requirements under section 14904 of this title, as applicable.

(20) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary under, section 13702(d)(1), 13702(d)(4), or 13702(e) of this title.

(21) The introduction or delivery for introduction into interstate commerce of a dietary supple-

ment that is unsafe under section 11115 of this title.

(22)(A) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 20101(d)(3) of this title.

(B) The failure to submit a certificate of analysis as required under section 20101(d)(3) of this title.

(C) The failure to maintain records or to submit records or reports as required by section 20101(d)(3) of this title.

(D) The release into interstate commerce of any article or portion of the article imported into the United States under section 20101(d)(3) of this title or any finished product made from the article or portion, except for export in accordance with section 20101(e) or 20102 of this title, or with section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)).

(E) The failure to export as described in subparagraph (D) or to destroy an article, portion, or finished product described in subparagraph (D).

(23)(A) The falsification of a declaration of conformity submitted under section 13141(c) of this title.

(B) The failure or refusal to provide data or information requested by the Secretary under section 13141(c)(3) of this title.

(24) In the case of a drug, device, or food—

(A) the submission of a report or recommendation by a person accredited under section 13155 of this title that is false or misleading in any material respect;

(B) the disclosure by a person accredited under section 13155 of this title of confidential commercial information or any trade secret without the express written consent of the person that submitted the information or secret to the accredited person; or

(C) the receipt by a person accredited under section 13155 of this title of a bribe in any form or the doing of any corrupt act by the person associated with a responsibility delegated to the person under this subtitle.

(25)(A) The importation of a prescription drug in violation of section 20104 of this title.

(B) The falsification of any record required to be maintained or provided to the Secretary under section 20104 of this title.

(C) Any other violation of regulations under section 20104 of this title.

(26)(A) The transfer of an article of food in violation of an order under section 10504(h) of this title.

(B) The removal or alteration of any mark or label required by the order under subparagraph (A) to identify the article as detained.

(27) The importing or offering for import into the United States of an article of food or a drug by, with the assistance of, or at the direction of, a person debarred from the activity under section 10506(b)(3) of this title.

(28) The failure to register in accordance with section 11117 of this title.

(29) The importing or offering for import into the United States of an article of food in violation of the requirements under section 20101(m) of this title.

(30) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request

of the Secretary to submit to the Secretary a statement under section 20101(o) of this title.

(31)(A) The knowing failure to comply with paragraph (7)(E) of section 17504(g) of this title.

(B) The knowing inclusion by a person accredited under paragraph (2) of section 17504(g) of this title of false information in an inspection report under paragraph (7)(A) of section 17504(g) of this title.

(C) The knowing failure of a person described in subparagraph (B) to include material facts in an inspection report described in subparagraph (B).

(32) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 11118 of this title.

(33)(A) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 17101, 18901, or 18902 of this title).

(B) The falsification of a serious adverse event report (as defined under section 18901 or 18902 of this title or required under section 17121(a) of this title) submitted to the Secretary.

(34)(A) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. 282(j)(5)(B)), or knowingly submitting a false certification under that section.

(B) The failure to submit clinical trial information required under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(C) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act (42 U.S.C. 282(j)) that is false or misleading in any particular under paragraph (5)(D) of that subsection.

(35) The dissemination of a television advertisement without complying with section 13108 of this title.

(36) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under chapter 135 of this title, a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of the investigations has been made public, unless—

(A) the drug or the biological product was marketed in food before any approval of the drug under chapter 135 of this title, before licensure of the biological product under section 351 of the Public Health Service Act (42 U.S.C. 262), and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(B) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of the drug or the biological product in the food;

(C)(i) the use of the drug or the biological product in the food—

(I) is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans; and

(II) is in conformity with—

(aa) a regulation issued under section 11111 of this title prescribing conditions of safe use in food;

(bb) a regulation listing or affirming conditions under which the use of the drug

or the biological product in food is generally recognized as safe;

(cc) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier; or

(dd) a food contact substance notification that is effective under section 11111(i) of this title; or

(ii) the drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

(D) the drug is a new animal drug whose use is not unsafe under chapter 137 of this title.

(37) The failure to submit a report or provide a notification required under section 11119(d) of this title.

(38) The falsification of a report or notification required under section 11119(d) of this title.

(39) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 10503(f) of this title.

(40) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 21112 of this title.

(41)(A) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device on any tobacco product or container or labeling of the tobacco product or container so as to render the tobacco product a counterfeit tobacco product.

(B) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing on any tobacco product or container or labeling of the tobacco product or container so as to render the tobacco product a counterfeit tobacco product.

(C) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(42) The charitable distribution of tobacco products.

(43) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of its knowledge of tobacco products used in illicit trade.

(44) Making—

(A) any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that conveys, or misleads or would mislead consumers into believing, that—

(i) the product is approved by the FDA;

(ii) the FDA considers the product to be safe for use by consumers;

(iii) the product is endorsed by the FDA for use by consumers; or

(iv) the product is safe or less harmful by virtue of—

(I) its regulation or inspection by the FDA; or

(II) its compliance with regulatory requirements set by the FDA; or

(B) any statement or representation described in subparagraph (A) rendering the product misbranded under section 21104 of this title.

(45) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of the facility is not in compliance with section 11120 of this title.

(46) The failure to comply with the requirements under section 11121 of this title.

(47) The failure to comply with section 11122 of this title.

(48) The refusal or failure to follow an order under section 11125 of this title.

(49) The knowing and willful failure to comply with the notification requirement under section 11119(h) of this title.

(50) The importation or offering for importation of a food if the importer (as defined in section

20105 of this title) does not have in place a foreign supplier verification program in compliance with section 20105 of this title.

(51) The failure to register in accordance with section 20101(s) of this title.

(52) The failure to notify the Secretary in violation of section 14315 of this title.

(53)(A) The resale of a compounded drug that is labeled ''not for resale'' in accordance with section 13107 of this title.

(B) With respect to a drug to be compounded pursuant to section 13106 or 13107 of this title, the intentional falsification of a prescription, as applicable.

(C) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (c) of section 13107 of this title.

(54)(A) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally added plastic microbeads.

(B) In this paragraph:

(i) PLASTIC MICROBEAD.—The term ''plastic microbead'' means any solid plastic particle that is less than 5 millimeters in size and is intended to be

used to exfoliate or cleanse the human body or any part of the human body.

(ii) RINSE-OFF COSMETIC.—The term ''rinse-off cosmetic'' includes toothpaste.

(55) The failure to comply with any order issued under section 14320 of this title.

(56)(A) The forging, counterfeiting, or simulating of, or the false represention of, or the using without proper authority of, any mark, stamp, tag, label, or other identification on any device or container, packaging, or labeling of the device so as to render the device a counterfeit device.

(B) The making, selling, or disposing of, or the keeping in possession, control, or custody of, or the concealing of, any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark or imprint of another or any likeness of any of the foregoing on any device or container, packaging, or labeling of the device so as to render the device a counterfeit device.

(C) The doing of any act that causes a device to be a counterfeit device, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit device.

(57) The failure of a sponsor of a product approved under accelerated approval pursuant to section 13119(d) of this title—

(A) to conduct with due diligence any post-approval study required under section 13119(d) of this title with respect to the product; or

(B) to submit timely reports with respect to the product in accordance with section 13121(a)(2) of this title.

(58) The failure to register or submit listing information in accordance with section 17123 of this title.

(59) The refusal or failure to follow an order under section 17127 of this title.

**§ 10502. Injunction proceedings**

(a) JURISDICTION OF COURTS.—The district courts of the United States and the United States courts of the territories of the United States shall have jurisdiction, for cause shown, to issue an injunction or restraining order for a violation of section 10501 of this title, except paragraphs (8), (9), and (10) of that section.

(b) VIOLATION OF INJUNCTION.—In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this subtitle, trial

shall be by the court, or, on demand of the accused, by a jury.

**§ 10503. Penalties**

(a) VIOLATION OF SECTION 10501 OF THIS TITLE.—

(1) IN GENERAL.—Any person that violates a provision of section 10501 of this title shall be imprisoned for not more than 1 year, fined under title 18, or both.

(2) SUBSEQUENT VIOLATION; INTENT TO DEFRAUD OR MISLEAD.—Notwithstanding paragraph (1), a person shall be imprisoned for not more than 3 years, fined under title 18, or both, if the person—

(A) commits a violation under paragraph (1) after a conviction of the person under this section has become final; or

(B) commits a violation under paragraph (1) with the intent to defraud or mislead.

(b) PRESCRIPTION DRUG MARKETING VIOLATIONS.—

(1) VIOLATIONS OF SECTION 10501(19) OF THIS TITLE.—Notwithstanding subsection (a), any person shall be imprisoned for not more than 10 years,

fined not more than $250,000, or both, if the person violates section 10501(19) of this title by—

(A) knowingly importing a drug in violation of section 20101(d)(1) of this title;

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 13103(b)(1) of this title;

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 13103(b)(2) of this title; or

(D) knowingly distributing drugs in violation of section 13103(d)(2) of this title.

(2) CIVIL PENALTIES FOR VIOLATIONS RELATING TO A CONVICTION OF A REPRESENTATIVE.—

(A) IN GENERAL.—Any manufacturer or distributor that distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 10501(19) of this title because of a viola-

tion of section 13103(b)(1) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 13103(a) of this title or the offer to sell, purchase, or trade a drug sample subject to section 13103(a) of this title shall, on conviction of the representative for the violation, be subject to a civil penalty of—

(i) not more than $50,000 for each of the first 2 such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period; and

(ii) not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

(B) MULTIPLE CONVICTIONS OUT OF SAME OR RELATED EVENTS OR TRANSACTIONS.—For the purposes of this paragraph, multiple convictions of 1 or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as 1 violation.

(3) CIVIL PENALTY FOR FAILURE TO MAKE A REPORT.—Any manufacturer or distributor that violates section 10501(19) of this title because of a failure to make a report required by section 13103(c)(4)(E) of this title shall be subject to a civil penalty of not more than $100,000.

(4) DEFENSES RELATING TO PARAGRAPH (2).—

(A) PROVIDING INFORMATION AS DEFENSE.—If a manufacturer or distributor or any representative of the manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 10501(19) of this title because of a sale, purchase, or trade or offer to sell, purchase, or trade a drug sample in violation of section 13103(b)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of the representative shall not be considered as a violation for purposes of paragraph (2).

(B) INVESTIGATION AS DEFENSE.—For purposes of paragraph (2), the conviction of a

representative of a manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug as described in paragraph (2) shall not be considered as a conviction in an action brought under paragraph (2) against the manufacturer or distributor relating to the conviction of the representative, if it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against the representative for the violation that resulted in the conviction, an investigation of events or transactions that would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, the representative for the purchase, sale, or trade or offer to purchase, sell, or trade; or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and secu-

rity system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected the violation.

(5) REWARD FOR PROVIDING INFORMATION LEADING TO CONVICTION.—If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 10501(19) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 13103(b)(1) of this title, the person shall be entitled to ½ of the criminal fine imposed and collected for the violation but not more than $125,000.

(6) VIOLATIONS OF SECTION 20104(e) OF THIS TITLE.—Notwithstanding subsection (a), any person that is a manufacturer or importer of a prescription drug under section 20104(b) of this title and knowingly fails to comply with a requirement of section 20104(e) of this title that is applicable to the manufacturer or importer, respectively, shall be imprisoned for not more than 10 years, fined not more than $250,000, or both.

(7) ADULTERATION OF A DRUG.—Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(2)(A), (b), (c), or (d) of section 13101 of this title and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years, fined not more than $1,000,000, or both.

(8) COUNTERFEITING.—Notwithstanding subsection (a), any person that violates section 10501(9)(C) of this title by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug, or that violates section 10501(56)(C) of this title by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit device, shall be imprisoned for not more than 10 years or fined under title 18, or both.

(c) EXCEPTIONS IN CERTAIN CASES OF GOOD FAITH.—A person shall not be subject to the penalties of subsection (a)(1)—

(1) for having received in interstate commerce any article and delivered the article or proffered delivery of the article, if the delivery or proffer was made in good faith, unless the person refuses to fur-

nish on request of an officer or employee designated by the Secretary—

(A) the name and address of the source from whom the person purchased or received the article; and

(B) copies of all documents, if any, pertaining to the delivery of the article to the person;

(2) for having violated paragraph (1) or (4) of section 10501 of this title, if the person establishes a guaranty or undertaking—

(A) signed by, and containing the name and address of, the source residing in the United States from whom the person received in good faith the article; and

(B) to the effect—

(i) in case of an alleged violation of section 10501(1) of this title, that the article is not adulterated or misbranded, within the meaning of this subtitle designating this subtitle; or

(ii) in case of an alleged violation of section 10501(4) of this title, that the article is not an article that may not, under the provisions of section 11106 of this title

or chapter 135 of this title, be introduced into interstate commerce;

(3) for having violated section 10501(1) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this subtitle, if the person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that the color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this subtitle;

(4) for having violated paragraph (2), (3) or (11) of section 10501 of this title by failure to comply with section 13305 of this title with respect to an article received in interstate commerce to which neither section 13102 nor 13103(a)(1) of this title is applicable, if—

(A) the delivery or proffered delivery was made in good faith; and

(B) the labeling at the time of delivery or proffered delivery contained the same directions for use and warning statements as were con-

tained in the labeling at the time of the receipt of the article;

(5)(A) for having violated section 10501(9)(B) of this title, if the person—

(i) acted in good faith; and

(ii) had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug; or

(B) for having violated section 10501(9)(C) of this title, if the person doing the act or causing it to be done—

(i) acted in good faith; and

(ii) had no reason to believe that the drug was a counterfeit drug; or

(6) for having violated—

(A) section 10501(56)(B) of this title if the person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a device being a counterfeit device; or

(B) section 10501(56)(C) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the device was a counterfeit device.

(d) EXCEPTIONS INVOLVING MISBRANDED FOOD.—A person shall not be subject to the penalties of subsection (a)(1) for a violation of section 10501 of this title involving misbranded food if the violation exists solely because the food is misbranded under section 11301(2) of this title because of its advertising.

(e) PROHIBITED DISTRIBUTION OF HUMAN GROWTH HORMONE.—

(1) DEFINITION OF HUMAN GROWTH HORMONE.—In this subsection, the term ''human growth hormone'' means somatrem, somatropin, or an analogue of somatrem or somatropin.

(2) DISTRIBUTION OR POSSESSION.—Except as provided in paragraph (3), a person that knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where the use has been authorized by the Secretary under chapter 135 of this title and pursuant to the order of a physician, shall be imprisoned for not more than 5 years, fined under title 18, or both.

(3) OFFENSES INVOLVING MINORS.—A person that commits any offense set forth in paragraph (2) shall be imprisoned not more than 10 years, fined

under title 18, or both if the offense involves an individual under 18 years of age.

(4) EFFECT OF DIVISION A OF SUBTITLE V; FORFEITURES.—Any conviction for a violation of paragraphs (2) and (3) shall be considered a felony violation of division A of subtitle V of this title for the purposes of forfeiture under section 50713 of this title.

(5) INVESTIGATION AUTHORITY OF THE DEA.—The Drug Enforcement Administration may investigate offenses punishable by this subsection.

(f) CIVIL PENALTIES.—

(1) DEVICES.—

(A) IN GENERAL.—

(i) AMOUNT.—Except as provided in subparagraph (B), any person that violates a requirement of this subtitle that relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(ii) PERSONS ACCREDITED TO CONDUCT INSPECTIONS.—For purposes of

clause (i), a person accredited under paragraph (2) of section 17504(g) of this title shall be considered to have violated a requirement of this subtitle that relates to devices if the person—

(I) is substantially not in compliance with the standards of accreditation under that section; or

(II) poses a threat to public health or fails to act in a manner that is consistent with the purposes of that section.

(B) INAPPLICABILITY.—Subparagraph (A) shall not apply—

(i) to any person that violates the requirements of section 13151(a) or 13152(f) of this title unless the violation constitutes—

(I) a significant or knowing departure from the requirements; or

(II) a risk to public health;

(ii) to any person that commits a minor violation of section 13151(d) or 13151(f) of this title (only with respect to correction reports) if the person dem-

onstrates substantial compliance with the section; or

(iii) to violations of section 13101(a)(2)(B)(i) of this title that involve 1 or more devices that are not defective.

(2) ADULTERATED OR MISBRANDED FOOD.—

(A) IN GENERAL.—Any person that introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 11102(a)(2)(B) of this title or any person that does not comply with a recall order under section 11125 of this title shall be subject to a civil penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for the introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) EFFECT OF PARAGRAPH.—

(i) INAPPLICABILITY.—This paragraph shall not apply to any person that grew the article of food that is adulterated.

(ii) USE OF OTHER AUTHORITIES PRECLUDED.—

(I) CRIMINAL AUHTORITIES.—If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction the person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated.

(II) SEIZURE OR INJUNCTION AUTHORITIES.—If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 10504 of this title or the injunction authorities of section 10502 of this title with respect to the article of food that is adulterated.

(C) HEARING PROCEDURES.—

(i) IN GENERAL.—In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a pre-

siding officer has under section 11110(h)(2)(B) of this title.

(ii) INAPPLICABILITY OF PARAGRAPH (5)(A)(iii).—Paragraph (5)(A)(iii) shall not apply to any investigation under this paragraph.

(3) CLINICAL TRIAL CERTIFICATION OR INFORMATION SUBMISSIONS.—

(A) IN GENERAL.—Any person that violates section 10501(34) of this title shall be subject to a civil penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

(B) ADDITIONAL PENALTY FOR VIOLATION NOT CORRECTED.—If a violation of section 10501(34) of this title is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(5)(C)(ii)), the person shall, in addition to any civil penalty under subparagraph (A), be subject to a civil penalty of not more than $10,000 for each day of the violation after the period until the violation is corrected.

(4) DRUGS.—

(A) IN GENERAL.—

(i) DEFINITION OF RESPONSIBLE PERSON.—In this subparagraph, the term ''responsible person'' has the meaning given the term in section 13111 of this title.

(ii) PENALTY.—Any responsible person that violates a requirement of section 13111, 13515, or 13516 of this title shall be subject to a civil penalty of—

(I) not more than $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil penalty of $250,000 for the first 30-day period (or any portion of that 30-day period) that the responsible person continues to be in violation, and the amount shall double for every 30-day period after the first 30-day period that the viola-

tion continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(B) EFFORTS TOWARD CORRECTION TO BE CONSIDERED.—In determining the amount of a civil penalty under subparagraph (A)(ii)(II), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 13111, 13515, or 13516 of this title for which the responsible person is subject to the civil penalty.

(5) PROCEDURE FOR ASSESSMENT OF CIVIL PENALTY OR IMPOSITION OF NO-TOBACCO-SALE ORDER.—

(A) IN GENERAL.—

(i) ORDER BY SECRETARY; HEARING.—A civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order may be imposed, by the Secretary by an order made on the record after opportunity for a hearing pro-

vided in accordance with this subparagraph and section 554 of title 5.

(ii) NOTICE.—Before issuing an order under clause (i), the Secretary shall—

(I) give written notice to the person to be assessed a civil penalty under the order, or on whom a no-tobacco-sale order is to be imposed, of the Secretary's proposal to issue the order; and

(II) provide the person an opportunity for a hearing on the order.

(iii) SUBPOENAS.—In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) FACTORS TO CONSIDER.—

(i) IN GENERAL.—In determining the amount of a civil penalty, or the period to be covered by a no-tobacco-sale order, the Secretary shall take into account—

(I) with respect to the violation, the nature, circumstances, extent, and gravity; and

(II) with respect to the violator—

(aa) the ability to pay;

(bb) the effect on ability to continue to do business;

(cc) any history of prior such violations;

(dd) the degree of culpability; and

(ee) such other matters as justice may require.

(ii) REQUIRED PROVISIONS FOR PERMANENT NO-TOBACCO-SALE ORDERS.—A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.

(C) COMPROMISE, MODIFICATION, AND REMISSION OF CIVIL PENALTY.—

(i) IN GENERAL.—The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), (3), (4), or (9).

(ii) DEDUCTION FROM AMOUNTS OWED.—The amount of the civil penalty, when finally determined, or the amount agreed on in compromise, may be deducted from any sums the United States owes to the person charged.

(D) COMPROMISE, MODIFICATION, AND REMISSION OF NO-TOBACCO-SALE ORDER.—The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) PETITION FOR JUDICIAL REVIEW.—

(A) IN GENERAL.—Any person that requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty or the imposition of a no-tobacco-sale order and that is aggrieved by an order assessing a civil penalty or the imposition of a no-tobacco-sale order may file a petition for judicial review of the order with the United States

Court of Appeals for the District of Columbia Circuit or for any other circuit in which the person resides or transacts business.

(B) FILING PERIOD.—A petition under subparagraph (A) may be filed only within the 60-day period beginning on the date the order making the assessment was issued, or on which the no-tobacco-sale order was imposed, as the case may be.

(7) FAILURE TO PAY CIVIL PENALTY.—

(A) IN GENERAL.—The Attorney General shall recover an amount described in subparagraph (B) in an action brought against a person in any appropriate district court of the United States if the person fails to pay an assessment of a civil penalty—

(i) after the order making the assessment becomes final, and if the person does not file a petition for judicial review of the order in accordance with paragraph (6); or

(ii) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary.

(B) AMOUNT TO BE RECOVERED.—The amount referred to in subparagraph (A) is the

amount assessed, plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of the final judgment, as the case may be.

(C) VALIDITY, AMOUNT, AND APPROPRIATENESS OF CIVIL PENALTY.—In an action described in subparagraph (A), the validity, amount, and appropriateness of the civil penalty shall not be subject to review.

(8) NO-TOBACCO-SALE ORDERS.—

(A) IN GENERAL.—If the Secretary finds that a person has committed repeated violations of section 21107(d)(5) of this title or of restrictions promulgated under section 21107(d) of this title at a particular retail outlet, the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet.

(B) IMPOSITION WITH CIVIL PENALTY.—A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1).

(C) HEARING.—Prior to the entry of a no-tobacco-sale order under this paragraph, a person shall be entitled to a hearing pursuant to

the procedures established through regulations of the FDA for assessing civil penalties, including at a retailer's request a hearing—

(i) by telephone;

(ii) at the nearest regional or field office of the FDA; or

(iii) at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

(9) CIVIL PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

(A) IN GENERAL.—Subject to subparagraph (B), any person that violates a requirement of this subtitle that relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(B) ENHANCED PENALTIES.—

(i) ADULTERATED TOBACCO PRODUCTS; INFORMATION SUBMISSION; ORDERS TO CEASE DISTRIBUTION AND RECALL; MODIFIED RISK TOBACCO PRODUCTS IN

INTERSTATE COMMERCE.—Any person that intentionally violates a requirement of paragraph (5) or (6) of section 21103 or section 21105, 21109(c), or 21112(b) of this title shall be subject to a civil penalty of—

(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to the person, $250,000 for the first 30-day period (or any portion of that 30-day period) that the person continues to be in violation, and the amount shall double for every 30-day period after the first 30-day period that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(ii) POSTMARKET SURVEILLANCE AND STUDIES.—Any person that violates a re-

quirement of section 21112(g)(2)(C)(ii) or 21112(i)(1) of this title, shall be subject to a civil penalty of—

(I) not to exceed $250,000 per violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to the person, $250,000 for the first 30-day period (or any portion of that 30-day period) that the person continues to be in violation, and the amount shall double for every 30-day period after the first 30-day period that the violation continues, not to exceed $1,000,000 for any 30-day period, and not to exceed $10,000,000 for all such violations adjudicated in a single proceeding.

(iii) EFFORTS TOWARD CORRECTION TO BE CONSIDERED.—In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is

making efforts toward correcting the violation of the requirements of the section for which the person is subject to the civil penalty.

(g) VIOLATIONS REGARDING DIRECT-TO-CONSUMER ADVERTISING.—

(1) IN GENERAL.—

(A) PENALTIES.—With respect to a person that is a holder of an approved application under chapter 135 of this title for a drug subject to section 13103(a) of this title or under section 351 of the Public Health Service Act (42 U.S.C. 262), any such person that disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period.

(B) INAPPLICABILITY OF OTHER CIVIL PENALTIES.—No other civil penalties in this subtitle (including the civil penalty in sub-

section (f)(4)) shall apply to a violation regarding direct-to-consumer advertising.

(C) REPEATED ACTS.—For purposes of this paragraph—

(i) repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for the advertisements shall be considered 1 violation; and

(ii) on and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered 1 violation.

(D) ADVERTISEMENTS IN MAGAZINES AND OTHER PUBLICATIONS.—With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) PROCEDURE FOR ASSESSMENT OF CIVIL PENALTY.—

(A) IN GENERAL.—A civil penalty under paragraph (1) shall be assessed by the Sec-

retary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5.

(B) SUBPOENAS.—If on receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to the hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

(3) FACTORS FOR THE DETERMINATION OF CIVIL PENALTY AMOUNT.—The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including—

(A) whether the person submitted the advertisement for review if required under section 13108 of this title;

(B) whether, after submission of the advertisement as described in subparagraph (A), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period;

(C) whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination;

(D) whether the person ceased distribution of the advertisement on receipt of the written notice referred to in paragraph (2) for the advertisement;

(E) whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination;

(F) whether the violations were material;

(G) whether the person that created the advertisement or caused the advertisement to be created acted in good faith;

(H) whether the person that created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this subsection within the previous 1-year period;

(I) the scope and extent of any voluntary, subsequent remedial action by the person; and

(J) such other matters, as justice may require.

(4) COMMENTS FROM SECRETARY.—

(A) NO CIVIL PENALTY ON INCORPORATION OF COMMENTS INTO ADVERTISEMENT.—Subject to subparagraph (B), a person shall not be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate the advertisement after incorporating each comment received from the Secretary.

(B) RETRACTION OR MODIFICATION OF COMMENTS.—The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary—

(i) provides written notice to the person of the new views of the Secretary on the advertisement; and

(ii) provides a reasonable time for modification or correction of the advertise-

ment prior to seeking any civil penalty under paragraph (1).

(5) COMPROMISE, MODIFICATION, REMISSION.—

(A) IN GENERAL.—The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty that may be assessed under paragraph (1).

(B) DEDUCTION FROM AMOUNTS OWED.—The amount of the civil penalty described in subparagraph (A), when finally determined, or the amount charged upon in compromise, may be deducted from any sums the United States owes to the person charged.

(6) PETITION FOR JUDICIAL REVIEW.—

(A) IN GENERAL.—Any person that requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and that is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of the order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which the person resides or transacts business.

(B) FILING PERIOD.—A petition under subparagraph (A) may be filed only within the

60-day period beginning on the date the order making the assessments was issued.

(7) FAILURE TO PAY CIVIL PENALTY.—

(A) IN GENERAL.—The Attorney General shall recover an amount described in subparagraph (B) in an action brought against a person in any appropriate district court of the United States if the person fails to pay an assessment of a civil penalty under paragraph (1)—

(i) after the order making the assessment becomes final, and if the person does not file a petition for judicial review of the order in accordance with paragraph (6); or

(ii) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary.

(B) AMOUNT TO BE RECOVERED.—The amount referred to in subparagraph (A) is the amount assessed, plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of the final judgment, as the case may be.

(C) VALIDITY, AMOUNT, AND APPROPRIATENESS OF CIVIL PENALTY.—In an action described in subparagraph (A), the validity, amount, and appropriateness of the penalty shall not be subject to review.

**§ 10504. Seizure**

(a) PROCEEDINGS FOR CONDEMNATION.—

(1) IN GENERAL.—

(A) ARTICLES IN INTERSTATE COMMERCE.—Any article of food, drug, or cosmetic shall be subject to an action for condemnation proceeding, while the article is in interstate commerce or at any time after being in interstate commerce, and condemned in any district court of the United States or United States court of a territory of the United States within the jurisdiction of which the article is found—

(i) if the article is adulterated or misbranded—

(I) when introduced into or while in interstate commerce; or

(II) while held for sale (whether or not the first sale) after shipment in interstate commerce; or

(ii) if the article may not, under the provisions of section 10501(36) or 11106 of this title, or chapter 135 of this title, be introduced into interstate commerce.

(B) ONE PROCEEDING AT A TIME.—

(i) IN GENERAL.—

(I) PENDING PROCEEDINGS.—An action for condemnation proceeding shall not be instituted under this subtitle for an alleged misbranding if there is pending in any court an action for condemnation proceeding under this subtitle based on the same alleged misbranding.

(II) MULTIPLE PROCEEDINGS NOT TO BE INSTITUTED.—Not more than 1 condemnation proceeding described in subclause (I) shall be instituted if no such proceeding is pending.

(ii) EXCEPTIONS.—The limitations under clause (i) shall not apply—

(I) if the misbranding has been the basis of a prior judgment in favor of the United States in a criminal, in-

junction, or action for condemnation proceeding under this subtitle; or

(II) if the Secretary has probable cause to believe from facts found, without hearing, by the Secretary or any officer or employee of the Department—

(aa) that the misbranded article is dangerous to health; or

(bb) that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.

(C) REMOVAL PROCEEDING.—

(i) IN GENERAL.—In any case in which the number of condemnation proceedings is limited as provided in subparagraph (B), the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed on by stipulation between the parties.

(ii) FAILURE OF PARTIES TO AGREE TO DISTRICT.—If the parties fail to agree to a district by stipulation within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and the court (after giving the United States attorney for the district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) ARTICLES LIABLE TO BE PROCEEDED AGAINST AT ANY TIME.—The following shall be subject to condemnation proceedings at any time and condemned in any district court of the United States or United States court of a territory of the United States within the jurisdiction of which they are found:

(A) Any drug that is a counterfeit drug.

(B) Any container of a counterfeit drug.

(C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs.

(D) Any adulterated or misbranded device.

(E) Any adulterated or misbranded tobacco product.

(F) Any device that is a counterfeit device.

(G) Any container, packaging, or labeling of a counterfeit device.

(H) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit device.

(3) LIMITATION.—

(A) IN GENERAL.—Except as provided in subparagraph (B), an action for condemnation proceeding shall not be instituted under paragraph (1) or (2) against any food that—

(i) is misbranded under section 11301(2) of this title because of its advertising; and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) EXCEPTIONS TO LIMITATION.—An action for condemnation proceeding may be insti-

tuted under paragraph (1) or (2) against a food described in subparagraph (A) if—

(i) with respect to the food's advertising—

(I) the advertising that resulted in the food being misbranded under section 11301(2) of this title was disseminated in the establishment in which the food is being held for sale to the ultimate consumer;

(II) the advertising was disseminated by, or under the direction of, the owner or operator of the establishment; or

(III) all or part of the cost of the advertising was paid by the owner or operator; and

(ii) the owner or operator of the establishment used the advertising in the establishment to promote the sale of the food.

(b) CONFORMATION TO PROCEDURE IN ADMIRALTY AND CONSOLIDATION OF PROCEEDINGS.—

(1) CONFORMANCE TO PROCEDURE IN ADMIRALTY.—The article, equipment, or other thing pro-

ceeded against shall be liable to seizure by process pursuant to the action for condemnation proceeding, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty, except that, on demand of either party, any issue of fact joined in the case shall be tried by jury.

(2) CONSOLIDATION OF MULTIPLE PROCEEDINGS FOR TRIAL.—If actions for condemnation proceedings under this section are pending in 2 or more jurisdictions, and the actions involve the same claimant and the same issues of adulteration or misbranding, the pending actions, on application of the claimant seasonably made to the court of one of the jurisdictions, shall be consolidated for trial by order of the court, and tried in—

(A) any district selected by the claimant where one of the actions is pending; or

(B) a district agreed on by stipulation between the parties.

(3) APPLICATION FOR CONSOLIDATION.—

(A) IN GENERAL.—If no order for consolidation is made under paragraph (2) within a reasonable time, the claimant may apply to the court of one of the jurisdictions and the court

(after giving the United States attorney for the district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried.

(B) CASE WITH FIXED TRIAL DATE.—An order of consolidation under subparagraph (A) shall not apply so as to require the removal of any case the date for trial of which has been fixed.

(C) NOTICE TO OTHER COURTS.—The court granting the order of consolidation under subparagraph (A) shall give prompt notification of the order to the other courts having jurisdiction of the cases covered by the consolidation.

(c) AVAILABILITY OF SAMPLES OF SEIZED GOODS PRIOR TO TRIAL.—The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, or the party's attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks

or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) DISPOSITION OF GOODS AFTER DECREE OF CONDEMNATION.—

(1) IN GENERAL.—

(A) DISPOSITION BY DESTRUCTION OR SALE.—Any food, drug, device, tobacco product, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct.

(B) SALE.—If the article is sold, the proceeds of the sale (less the legal costs and charges) shall be paid into the Treasury. The article shall not be sold under the decree contrary to the provisions of this subtitle or the laws of the jurisdiction in which the article is sold.

(C) RELEASE OF ARTICLE UNDER BOND.—After entry of the decree and on the payment of the costs of the proceedings and the execution of a good and sufficient bond conditioned that the article shall not be sold or disposed of contrary to the provisions of this subtitle or the laws of any State or territory of the United

States in which the article is sold, the court may by order direct that the article be delivered to the owner of the article to be destroyed or brought into compliance with the provisions of this subtitle, under the supervision of an officer or employee designated by the Secretary, and the expenses of the supervision shall be paid by the person obtaining release of the article under bond.

(D) EXPORTATION IN LIEU OF DESTRUCTION.—

(i) IN GENERAL.—If the article was imported into the United States, the court may permit the article to be delivered to the owner for exportation in lieu of destruction—

(I) if the person seeking its release establishes—

(aa) that the adulteration, misbranding, or violation did not occur after the article was imported; and

(bb) that the person had no cause for believing that the article was adulterated, misbranded,

or in violation before it was released from customs custody; and

(II) on a showing by the owner that all of the conditions of section 20101(e) of this title can and will be met.

(ii) LIMITATION.—Clause (i) shall not apply if condemnation is based on violation of—

(I) paragraph (1), (2), or (6) of section 11102(a) of this title;

(II) section 13101(a)(2)(C) of this title;

(III) section 13309 of this title; or

(IV) subsection (b) or (e) of section 17111 of this title.

(iii) EXPORTATION MADE TO ORIGINAL FOREIGN SUPPLIER.—If the exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 20101(e)(1) of this title and clause (ii) shall not be applicable.

(iv) BOND CONDITION.—In all cases of exportation, the bond shall be condi-

tioned that the article shall not be sold or disposed of until the applicable conditions of section 20101(e) of this title have been met.

(v) REQUIREMENT TO ESTABLISH THAT ARTICLE WAS INTENDED FOR EXPORT.—Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.

(vi) REQUIREMENT TO DISPOSE BY DESTRUCTION.—Any article condemned by reason of its being an article that may not, under section 11106 of this title or chapter 135 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

(2) APPLICABILITY OF PARAGRAPH (1) TO ADDITIONAL ARTICLES.—The provisions of paragraph (1) shall, to the extent considered appropriate by the court, apply to any equipment or other thing that is not otherwise within the scope of the paragraph and that is referred to in subsection (a)(2).

(3) REMISSION OR MITIGATION OF FORFEITURE.—If in any proceeding under this section involving subsection (a)(2), the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of the claimant's interest, for remission or mitigation of the forfeiture if the claimant proves to the satisfaction of the court—

(A) that the claimant has not committed or caused to be committed any prohibited act referred to in subsection (a)(2) and has no interest in any drug referred to in subsection (a)(2);

(B) that the claimant has an interest in the equipment or other thing as owner or lienor or otherwise, acquired by the claimant in good faith; and

(C) that the claimant at no time had any knowledge or reason to believe that the equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) COSTS.—If a decree of condemnation is entered against the article, court costs and fees, and storage and

other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) REMOVAL OF CASE FOR TRIAL.—In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) the clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that the court may exercise jurisdiction; and

(2) the court to which the case was removed shall have the powers and be subject to the duties, for purposes of the case, that the court from which removal was made would have had, or to which the court would have been subject, if the case had not been removed.

(g) ADMINISTRATIVE DETENTION OF DEVICES, DRUGS, AND TOBACCO PRODUCTS.—

(1) IN GENERAL.—

(A) DETENTION AUTHORITY; PERIOD OF DETENTION.—If during an inspection conducted under section 17504 of this title of a facility or a vehicle, a device, drug, or tobacco product that the officer or employee making the inspection has reason to believe is adulterated

or misbranded is found in the facility or vehicle, the officer or employee may order the device, drug, or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period that may not exceed 20 days, unless the Secretary determines that a period of detention greater than 20 days is required to institute an action under subsection (a) or section 10502 of this title, in which case the Secretary may authorize a detention period of not to exceed 30 days.

(B) APPROVAL OF DETENTION ORDER.—Regulations of the Secretary prescribed under this paragraph shall require that before a device, drug, or tobacco product may be ordered detained under this paragraph, the Secretary or an officer or employee designated by the Secretary approve the order.

(C) LABELING OR MARKING DURING DETENTION PERIOD.—A detention order under this paragraph may require the labeling or marking of a device, drug, or tobacco product during the period of its detention for the purpose of identifying the device, drug, or tobacco product as detained.

(D) APPEAL OF DETENTION ORDER.—

(i) IN GENERAL.—Any person that would be entitled to claim a device, drug, or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of the device, drug, or tobacco product under this paragraph.

(ii) CONFIRMATION OR REVOCATION OF DETENTION.—Within 5 days of the date an appeal of a detention is filed with the Secretary, the Secretary shall, after affording opportunity for an informal hearing, by order confirm or revoke the detention.

(2) MOVEMENT OF DETAINED ARTICLE PROHIBITED.—

(A) IN GENERAL.—Except as authorized by subparagraph (B), a device, drug, or tobacco product subject to a detention order issued under paragraph (1) shall not be moved by any person from the place at which it is ordered detained until the earlier of—

(i) release of the device, drug, or tobacco product by the Secretary; or

(ii) the expiration of the detention period applicable to the order.

(B) AUTHORIZED MOVEMENT OF DETAINED ARTICLE.—A device or drug subject to a detention order under paragraph (1) may be moved—

(i) in accordance with regulations prescribed by the Secretary; and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device or drug for the purpose of completing the work required to put it in that form.

(h) ADMINISTRATIVE DETENTION OF FOODS.—

(1) DETENTION AUTHORITY.—

(A) IN GENERAL.—An officer or qualified employee of the FDA may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this subtitle conducted by the officer or qualified employee, if the officer or qualified employee has reason to believe that the article is adulterated or misbranded.

(B) SECRETARY'S APPROVAL.—An article of food may be ordered detained under subparagraph (A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be designated unless the official is the director of the district under this subtitle in which the article involved is located, or is an official senior to the director.

(2) PERIOD OF DETENTION.—An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 10502 of this title. The Secretary shall by regulation provide for procedures for instituting the action on an expedited basis with respect to perishable foods.

(3) SECURITY OF DETAINED ARTICLE.—

(A) IN GENERAL.—An order under paragraph (1) with respect to an article of food may require that the article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate.

(B) TRANSFER OF ARTICLE.—An article subject to such an order shall not be trans-

ferred by any person from the place at which the article is ordered detained, or from the place to which the article is removed, as the case may be, until the earlier of—

(i) release of the article by the Secretary; or

(ii) expiration of the detention period applicable under the order.

(C) EFFECT OF PROVISIONS ON DELIVERY OF ARTICLE.—This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 20101(b) of this title does not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) APPEAL OF DETENTION ORDER.—

(A) IN GENERAL.—

(i) PERSONS THAT MAY APPEAL.—With respect to an article of food ordered detained under paragraph (1), any person that would be entitled to be a claimant for the article if the article were seized under subsection (a) may appeal the order to the Secretary.

(ii) CONFIRMATION OR TERMINATION OF DETENTION.—Within 5 days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and the confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5.

(iii) ORDER DEEMED TERMINATED.—If, during the 5-day period, the Secretary fails to provide an opportunity for an informal hearing, or to confirm or terminate the order, the order is deemed to be terminated.

(B) EFFECT OF INSTITUTING COURT ACTION.—The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) or section 10502 of this title regarding the article of food involved.

(i) PROCEDURES FOR PROMULGATING REGULATIONS.—

(1) IN GENERAL.—In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the regulation's effective date.

(2) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (1).

**§ 10505. Hearing before report of criminal violation**

Before any violation of this subtitle is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present the person's views, orally or in writing, with regard to the contemplated proceeding.

**§ 10506. Debarment, temporary denial of approval, and suspension**

(a) MANDATORY DEBARMENT.—

(1) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—If the Secretary finds that a person other than an individual has been convicted, after

May 13, 1992, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar the person from submitting, or assisting in the submission of, any such application.

(2) INDIVIDUALS.—

(A) IN GENERAL.—The Secretary shall debar an individual as described in subparagraph (B) if the Secretary finds that the individual has been convicted of a felony under Federal law for conduct—

(i) relating to the development or approval, including the process for development or approval, of any drug product; or

(ii) otherwise relating to the regulation of any drug product under this subtitle.

(B) DEBARMENT.—The Secretary shall debar an individual whom the Secretary finds has been convicted as described in subparagraph (A) from providing services in any capacity to a person that has an approved or pending drug product application.

(b) PERMISSIVE DEBARMENT.—

(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2) or (3), debar—

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application;

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application;

(C) a person from importing an article of food or offering an article of food for import into the United States; or

(D) a person from importing or offering for import into the United States a drug.

(2) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; DRUG APPLICATIONS.—The following persons are subject to debarment under subparagraph (A) or (B) of paragraph (1):

(A) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—Any person other than an individual that the Secretary finds has been convicted (if the Secretary finds that the type of conduct that served as the basis for the convic-

tion undermines the process for the regulation of drugs)—

(i) for conduct that—

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before May 13, 1992), a misdemeanor under Federal law, or a felony under State law; or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1).

(B) INDIVIDUALS.—

(i) Any individual whom the Secretary finds has been convicted (if the Secretary finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs) of—

(I) a misdemeanor under Federal law or a felony under State law for

conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this subtitle; or

(II) a conspiracy to commit, or aiding or abetting, the criminal offense or a felony described in subsection (a)(2).

(ii) Any individual whom the Secretary finds has been convicted (if the Secretary finds, on the basis of the conviction of the individual and other information, that the individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that the individual may violate requirements under this subtitle relating to drug products) of—

(I) a felony—

(aa) that is not described in subsection (a)(2) or clause (i); and

(bb) that involves bribery, payment of illegal gratuities,

fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense; or

(II) a conspiracy to commit, or aiding or abetting, a felony described in subclause (I).

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of the participation and other information, that the individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that the individual may violate requirements under this subtitle relating to drug products.

(iv) Any high managerial agent whom the Secretary finds—

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which the other individual took actions for which a felony conviction was obtained (if the Secretary finds that the type of conduct that served as the basis for the other individual's conviction undermines the process for the regulation of drugs) and that resulted in the debarment under subsection (a)(2), or clause (i), of the other individual;

(II) had actual knowledge of the actions described in subclause (I) of the other individual, took action to avoid the actual knowledge, or failed to take action for the purpose of avoiding the actual knowledge;

(III) knew that the actions described in subclause (I) were violative of law; and

(IV) did not report the actions, or did not cause the actions to be reported, to an officer, employee, or

agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after the agent first knew of the actions.

(3) PERSONS SUBJECT TO PERMISSIVE DEBARMENT; FOOD OR DRUG IMPORTATION.—

(A) DEFINITION OF PATTERN OF IMPORTING OR OFFERING FOR IMPORT.—For purposes of subparagraph (B)(iv), the term ''pattern of importing or offering for import'' means importing or offering for import a drug described in subclause (I) or (II) of subparagraph (B)(iv) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.

(B) IN GENERAL.—A person is subject to debarment under paragraph (1)(C) if—

(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any food;

(ii) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals;

(iii) the person has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance (as defined in section 50101 of this title); or

(iv) the person has engaged in a pattern of importing or offering for import—

(I) controlled substances that are prohibited from importation under section 401(m) of the Tariff Act of 1930 (19 U.S.C. 1401(m)); or

(II) adulterated or misbranded drugs that are—

(aa) not designated in an authorized electronic data interchange system as a product that is regulated by the Secretary; or

(bb) knowingly or intentionally falsely designated in an authorized electronic data inter-

change system as a product that is regulated by the Secretary.

(4) STAY OF CERTAIN ORDERS.—An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

(c) DEBARMENT PERIOD AND CONSIDERATIONS.—

(1) EFFECT OF DEBARMENT.—The Secretary—

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) during the period the person is debarred;

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B), debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from the individual; and

(C) shall, if the Secretary makes the finding described in subparagraph (F) or (G) of section 10507(a)(1) of this title, assess a civil

penalty in accordance with section 10507 of this title.

(2) DEBARMENT PERIODS.—

(A) IN GENERAL.—

(i) LENGTH.—The Secretary shall debar a person under subsection (a) or (b) for the following periods:

(I) The period of debarment of a person (other than an individual) under subsection (a)(1) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) occurs within 10 years after the person has been debarred under subsection (a)(1), the period of debarment shall be permanent.

(II) The debarment of an individual under subsection (a)(2) shall be permanent.

(III) The period of debarment of any person under paragraph (2) or (3) of subsection (b) shall not be more than 5 years.

(ii) MULTIPLE OFFENSES.—The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

(B) NOTIFICATION.—On a conviction for an offense described in subsection (a) or (b) or on execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Secretary that the person acquiesces to debarment and the person's debarment shall commence on the notification.

(3) CONSIDERATIONS.—In determining the appropriateness and the period of a debarment of a person under subsection (b) and any period of debarment beyond the minimum specified in paragraph (2)(A)(i)(I), the Secretary shall consider, as applicable—

(A) the nature and seriousness of any offense involved;

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the

offense, including whether inadequate institutional controls contributed to the offense;

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health;

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future;

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements; and

(F) prior convictions under this subtitle or under other Acts involving matters within the jurisdiction of the FDA.

(d) TERMINATION OF DEBARMENT.—

(1) APPLICATION.—Any person that is debarred under subsection (a) (other than a person permanently debarred) or any person that is debarred under subsection (b) may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(2) DEADLINE.—The Secretary shall grant or deny any application respecting a debarment that is submitted under paragraph (1) within 180 days of the date the application is submitted.

(3) ACTION BY THE SECRETARY.—

(A) CORPORATIONS.—

(i) CONVICTION REVERSAL.—If the conviction that served as the basis for the debarment of a person under subsection (a)(1) or paragraph (2)(A) or (3) of subsection (b) is reversed, the Secretary shall withdraw the order of debarment.

(ii) APPLICATION.—On application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that—

(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future; and

(II) in applicable cases, sufficient audits, conducted by the FDA or by independent experts acceptable to the FDA, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

(iii) EFFECTIVE DATE OF TERMINATION.—In the case of persons debarred under subsection (a)(1), the termination shall take effect no earlier than the expiration of 1 year from the date of the debarment.

(B) INDIVIDUALS.—

(i) CONVICTION REVERSAL.—If the conviction that served as the basis for the debarment of an individual under subsection (a)(2) or clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) or subsection (b)(3) is reversed, the Secretary shall withdraw the order of debarment.

(ii) APPLICATION.—On application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) or subsection (b)(3) if the termination serves the interests of justice and adequately protects the integrity of the drug approval process or the food importation process, as the case may be.

(4) SPECIAL TERMINATION.—

(A) APPLICATION.—Any person that is debarred under subsection (a)(1) (other than a person permanently debarred under subsection (c)(2)(A)(i)(I)) or any individual who is debarred under subsection (a)(2) may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this subpara-

graph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(B) CORPORATIONS.—On an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that—

(i) the person making the application under subparagraph (A) has demonstrated that the felony conviction that was the basis for the person's debarment involved the commission of an offense that was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment;

(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offense have been removed from employment involving the development or approval of any drug subject to chapter 135 of this title;

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities; and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

(C) INDIVIDUALS.—On an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that the individual has provided substantial assistance in the investigations or prosecutions of offenses that are described in subsection (a) or (b) or that relate to any matter under the jurisdiction of the FDA.

(D) SECRETARIAL ACTION.—The action referred to in subparagraphs (B) and (C) is any of the following that best serves the interest of

justice and protects the integrity of the drug approval process:

(i) In the case of a person other than an individual—

(I) terminating the debarment immediately; or

(II) limiting the period of debarment to less than 1 year.

(ii) In the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year.

(e) PUBLICATION AND LIST OF DEBARRED PERSONS.—The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b), the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of the persons, of the effective dates and minimum periods of the debarments, and of the termination of debarments.

(f) TEMPORARY DENIAL OF APPROVAL.—

(1) IN GENERAL.—The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (4), refuse by order, for the period prescribed by paragraph (3), to

approve any abbreviated drug application submitted by any person—

(A) if the person is under an active Federal criminal investigation in connection with an action described in subparagraph (B);

(B) if the Secretary finds that the person—

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, the actions; or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department, or has con-

spired to commit, or aided or abetted, the actions; and

(C) if a significant question has been raised regarding—

(i) the integrity of the approval process with respect to the abbreviated drug application; or

(ii) the reliability of data in or concerning the person's abbreviated drug application.

(2) MODIFICATION; TERMINATION.—An order under paragraph (1) may be modified or terminated at any time.

(3) APPLICABLE PERIOD.—

(A) IN GENERAL.—Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate the denial—

(i) if the investigation with respect to which the finding was made does not result

in a criminal charge against the person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered; or

(ii) if the Secretary determines that the finding was in error.

(B) EXTENSION.—If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in paragraph (1)(B), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate the extension if the charges have been dismissed, if a judgment of acquittal has been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

(4) INFORMAL HEARING.—Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide the person with an opportunity for an informal hearing, to be held within the 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which the hearing is held, the

Secretary shall notify the person given the hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. The notification shall be final agency action.

(g) SUSPENSION AUTHORITY.—

(1) IN GENERAL.—

(A) CONDITIONS.—The Secretary shall issue an order described in subparagraph (B) if—

(i) the Secretary finds—

(I) that a person has engaged in conduct described in subsection (f)(1)(B) in connection with 2 or more drugs under abbreviated drug applications; or

(II) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of 1 or more drugs approved under an abbreviated drug application during a 2-year period, and—

(aa) the violations may undermine the safety and efficacy of the drugs; and

(bb) the causes of the violations have not been corrected within a reasonable period of time following notice of the violations by the Secretary; and

(ii) the person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in clause (i).

(B) ORDER.—If the conditions under subparagraph (A) are met, the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to the conduct described in subparagraph (A)(i) or suspending the distribution of all drugs approved under abbreviated drug applications of the person if the Secretary finds that the conduct may have affected the development or approval of a significant number of drugs that the Secretary is unable to identify.

(C) EXCLUSION OF DRUG FROM SUSPENSION.—The Secretary shall exclude a drug from

the order under subparagraph (B) if the Secretary determines that the conduct was not likely to have influenced the safety or efficacy of the drug.

(2) PUBLIC HEALTH WAIVER.—

(A) IN GENERAL.—The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)(I)) with respect to any drug if the Secretary finds that the waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available.

(B) ACTION ON PETITION; DEADLINE.—The Secretary shall act on any petition seeking action under this paragraph within 180 days of the date the petition is submitted to the Secretary.

(h) TERMINATION OF SUSPENSION.—

(1) IN GENERAL.—The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) if the person with respect to whom the order was issued demonstrates in a petition to the Secretary—

(A)(i) on the basis of an audit by the FDA or by experts acceptable to the FDA, or on the basis of other information, that the development, approval, manufacturing, and distribution of the drug is in substantial compliance with the applicable requirements of this subtitle; and

(ii) changes in ownership, management, or operations—

(I) fully remedy the patterns or practices with respect to which the order was issued; and

(II) provide reasonable assurances that the actions will not occur in the future; or

(B) the initial determination was in error.

(2) ACTION ON PETITION; DEADLINE; CONCURRENT CONSIDERATION.—The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding.

(3) INFORMATION SUBMITTED NOT AN AMENDMENT OR SUPPLEMENT.—Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

(i) PROCEDURE.—The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) with respect to any person unless the Secretary has issued an order for the action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(j) JUDICIAL REVIEW.—

(1) IN GENERAL.—Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) may obtain a review of the decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in the court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(2) EXCEPTION.—Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) may obtain a review of the

decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by filing in the court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

(k) CERTIFICATION.—Any application for approval of a drug product shall include—

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b), in connection with the application; and

(2) if the application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) that occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of the application.

(l) APPLICABILITY.—

(1) CONVICTION.—For purposes of this section, a person is considered to have been convicted of a criminal offense—

(A) if a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending;

(B) if a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court; or

(C) if the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement or program in which judgment of conviction has been withheld.

(2) EFFECTIVE DATES.—Subsection (a), subparagraph (A) of subsection (b)(2), clauses (i) and (ii) of subsection (b)(2)(B), and subsection (b)(3)(A) shall not apply to a conviction that occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b). Clauses (iii) and (iv) of subsection (b)(2)(B), subsection (b)(3)(B), and subsections (f) and (g) shall not apply to an act or action that occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g). Subsection (b)(2)(B)(iv) shall not apply to an action that occurred before June 1, 1992. Sub-

section (k) shall not apply to applications submitted to the Secretary before June 1, 1992.

(m) DEVICES; MANDATORY DEBARMENT REGARDING THIRD-PARTY INSPECTIONS AND REVIEWS.—

(1) IN GENERAL.—If the Secretary finds that a person has been convicted of a felony under section 10501(31) of this title, the Secretary shall debar the person from being accredited under section 13155(b) or 17504(g)(2) of this title and from carrying out activities under an agreement described in section 20103(b) of this title.

(2) DEBARMENT PERIOD.—The Secretary shall debar a person under paragraph (1) for the following periods:

(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under paragraph (1) occurs within 10 years after the person has been debarred under paragraph (1), the period of debarment shall be permanent.

(B) The debarment of an individual shall be permanent.

(3) TERMINATION OF DEBARMENT; JUDICIAL REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),

(e), (i), (j), and (l)(1) apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as the subsections apply with respect to a person that is debarred under subsection (a)(1), or an individual who is debarred under subsection (a)(2), respectively.

**§ 10507. Civil penalties**

(a) IN GENERAL.—

(1) PERSONS LIABLE.—A person shall be liable under paragraph (2) if the Secretary finds that the person—

(A) knowingly made or caused to be made, to any officer, employee, or agent of the Department, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application;

(B) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department in connection with an abbreviated drug application;

(C) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document

or other material evidence that was the property of or in the possession of the Department for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application;

(D) knowingly failed to disclose, to an officer or employee of the Department, a material fact that the person had an obligation to disclose relating to any drug subject to an abbreviated drug application;

(E) knowingly obstructed an investigation of the Department into any drug subject to an abbreviated drug application;

(F) is a person that has an approved or pending drug product application and has knowingly—

(i) employed or retained as a consultant or contractor a person that was debarred under section 10506 of this title; or

(ii) otherwise used in any capacity the services of a person that was debarred under section 10506 of this title; or

(G) is an individual debarred under section 10506 of this title and, during the period of de-

barment, provided services in any capacity to a person that had an approved or pending drug product application.

(2) AMOUNTS.—A person described under paragraph (1) shall be liable to the United States for a civil penalty for each violation under paragraph (1) in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

(b) PROCEDURE.—

(1) IN GENERAL.—

(A) ACTION BY THE SECRETARY.—A civil penalty under subsection (a) shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) ACTION BY THE ATTORNEY GENERAL.—In lieu of a proceeding under subparagraph (A), the Attorney General may, on request of the Secretary, institute a civil action to recover a civil penalty in the amount and for any of the acts set forth in subsection (a). Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated by the Attorney General under this subtitle.

(2) AMOUNT.—In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

(3) LIMITATION ON ACTIONS.—An action shall not be initiated under this section more than 6 years after the date on which facts material to the act described in subsection (a) are known or reasonably should have been known by the Secretary but not more than 10 years after the date the act took place.

(c) JUDICIAL REVIEW.—Any person that is the subject of an adverse decision under subsection (b)(1)(A) may obtain a review of the decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in the court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(d) RECOVERY OF PENALTIES.—

(1) IN GENERAL.—The Attorney General may recover any civil penalty (plus interest at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) in an action brought in the name of the United States.

(2) DEDUCTION FROM AMOUNTS OWED.—The amount of the penalty may be deducted, when the penalty has become final, from any sums then or later owed by the United States to the person against whom the penalty has been assessed.

(3) VALIDITY, AMOUNT, APPROPRIATENESS.—In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

(e) INFORMANTS.—

(1) IN GENERAL.—The Secretary may award to any individual (other than an officer or employee of the Federal Government or an individual who materially participated in any conduct described in subsection (a)) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed $250,000 or ½ of the penalty imposed and collected, whichever is less.

(2) REVIEWABILITY.—The decision of the Secretary on the award shall not be reviewable.

**§ 10508. Authority to withdraw approval of abbreviated drug applications**

(a) IN GENERAL.—The Secretary—

(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement; and

(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to

introduce, the adulterated or misbranded drug into commerce.

(b) PROCEDURE.—The Secretary may not take any action under subsection (a) with respect to any person unless the Secretary has issued an order for the action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(c) APPLICABILITY.—Subsection (a) shall apply with respect to offenses or acts regardless of when the offenses or acts occurred.

(d) JUDICIAL REVIEW.—Any person that is the subject of an adverse decision under subsection (a) may obtain a review of the decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in the court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

**§ 10509. Report of minor violations**

Nothing in this subtitle shall be construed as requiring the Secretary to report for prosecution, or for the institution of civil action or injunction proceedings, minor violations of this subtitle if the Secretary believes that the public interest will be adequately served by a suitable written notice or warning.

**§ 10510. Proceedings in name of United States or a State**

(a) UNITED STATES.—

(1) IN GENERAL.—Except as provided in subsection (b), all proceedings for the enforcement, or to restrain violations, of this subtitle shall be by and in the name of the United States.

(2) SUBPOENAS.—Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b) STATES.—

(1) IN GENERAL.—A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 11101, 11302, 11303, 11304, 11305, 11306, 11307, 11308, 11309, 11310, 11312, 11316, or 11317 of this title if the food that is the subject of the proceedings is located in the State.

(2) COMMENCEMENT.—A proceeding shall not be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring the proceeding;

(B) before 90 days after the State has given notice to the Secretary of the intent if the Secretary has, within the 30 days, commenced an informal or formal enforcement action pertaining to the food that would be the subject of the proceeding; or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to the food, has settled the proceeding, or has settled the informal or formal enforcement action pertaining to the food.

(3) INTERVENTION.—In any court proceeding described in paragraph (2)(C), a State may intervene as a matter of right.

**§ 10511. Extraterritorial jurisdiction**

There is extraterritorial jurisdiction over any violation of this subtitle relating to any article regulated under this subtitle if the article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

# Division C—Food

# Chapter 111—General Provisions

Sec.
11101. Definitions and standards for food.
11102. Adulterated food.
11103. National uniform nutrition labeling.
11104. Dietary supplement labeling exemptions.
11105. Disclosure relating to radiation.
11106. Emergency permit relating to contaminated food.
11107. Regulations making labeling exemptions.
11108. Added poisonous or deleterious substances deemed unsafe; tolerances.
11109. Intrastate sales of colored oleomargarine.
11110. Tolerances and exemptions for pesticide chemical residues.
11111. Food additives.
11112. Bottled drinking water.
11113. Vitamins and minerals.
11114. Infant formulas.
11115. New dietary ingredients.
11116. Maintenance and inspection of records.
11117. Registration of food facilities.
11118. Sanitary transportation practices.
11119. Reportable food registry.
11120. Hazard analysis and risk-based preventive controls.
11121. Standards for produce safety.
11122. Protection against intentional adulteration.
11123. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry.
11124. Laboratory accreditation for analyses of foods.
11125. Mandatory recall authority.
11126. Requirements for critical food.

## § 11101. Definitions and standards for food

(a) IN GENERAL.—The Secretary shall promulgate regulations fixing and establishing for any food, under its common or usual name, to the extent practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container if, in the judgment of the Secretary, promulgating the regulations will promote honesty and fair dealing in the interest of consumers.

(b) FRESH AND DRIED FRUITS; BUTTER.—

(1) IN GENERAL.—Except as provided in paragraph (2)(A), a definition and standard of identity or a standard of quality shall not be established for fresh or dried fruits, fresh or dried vegetables, or butter.

(2) AVOCADOES, CANTALOUPES, CITRUS FRUITS, AND MELONS.—

(A) IN GENERAL.—Definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons.

(B) MATURITY AND EFFECTS OF FREEZING ONLY.—Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

(c) FACTORS TO CONSIDER IN REGULATING STANDARD OF FILL OF CONTAINER.—In prescribing any standard of fill of container, the Secretary shall consider—

(1) the natural shrinkage in storage and in transit of fresh natural food; and

(2) the need for the necessary packing and protective material.

(d) FACTOR TO CONSIDER IN REGULATING STANDARD OF QUALITY FOR CANNED FRUITS AND VEGETA-

BLES.—In prescribing any standard of quality for any canned fruit or canned vegetable, the Secretary shall consider and allow for the differing characteristics of the several varieties of the fruit or vegetable.

(e) OPTIONAL INGREDIENTS.—In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients that shall be named on the label.

**§ 11102. Adulterated food**

(a) POISONOUS, INSANITARY, OR UNSAFE SUBSTANCES, INGREDIENTS, OR CONDITIONS.—A food shall be deemed to be adulterated—

(1) if it bears or contains any poisonous or deleterious substance that may render it injurious to health, but if the substance is not an added substance, the food shall not be considered adulterated under this paragraph if the quantity of the substance in the food does not ordinarily render the food injurious to health;

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food,

a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 11108 of this title;

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 11110(b) of this title; or

(C) if it is or if it bears or contains—

(i) any food additive that is unsafe within the meaning of section 11111 of this title; or

(ii) a new animal drug (or conversion product of a new animal drug) that is unsafe within the meaning of chapter 137 of this title;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby—

(A) it may have become contaminated with filth; or

(B) it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of a diseased animal or of an animal that has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 11111 of this title.

(b) ABSENCE, SUBSTITUTION, OR ADDITION OF CONSTITUENTS.—A food shall be deemed to be adulterated—

(1) if any valuable constituent has been in whole or in part omitted or abstracted from the food;

(2) if any substance has been substituted wholly or in part for the food;

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added to the food or mixed or packed with the food so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) COLOR ADDITIVES.—A food shall be deemed to be adulterated if it is, or if it bears or contains, a color additive that is unsafe within the meaning of section 17701(a) of this title.

(d) CONFECTIONERY CONTAINING ALCOHOL OR NONNUTRITIVE SUBSTANCE.—

(1) EMBEDDED NONNUTRITIVE OBJECT.—

(A) IN GENERAL.—A food shall be deemed to be adulterated if—

(i) it is confectionery; and

(ii) a nonnutritive object is partially or completely embedded in the food.

(B) INAPPLICABILITY.—This paragraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, the object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health.

(2) ALCOHOL.—

(A) IN GENERAL.—A food shall be deemed to be adulterated if—

(i) it is confectionery; and

(ii) it bears or contains any alcohol other than alcohol not in excess of ½ of 1 percent by volume derived solely from the use of flavoring extracts.

(B) INAPPLICABILITY.—This paragraph shall not apply to confectionery that is intro-

duced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of the confectionery is permitted under the laws of the State in which the confectionery is intended to be offered for sale.

(3) BEARING OR CONTAINING NONNUTRITIVE SUBSTANCE.—

(A) IN GENERAL.—A food shall be deemed to be adulterated if—

(i) it is confectionery; and

(ii) it bears or contains any nonnutritive substance.

(B) INAPPLICABILITY.—This paragraph shall not apply to a safe nonnutritive substance that is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of the confectionery if the use of the substance does not—

(i) promote deception of the consumer; or

(ii) otherwise result in adulteration or misbranding in violation of any provision of this subtitle.

(C) ISSUANCE OF REGULATIONS TO AVOID OR RESOLVE UNCERTAINTY AS TO APPLICABILITY.—The Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this paragraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) OLEOMARGARINE.—A food shall be deemed to be adulterated if it is oleomargarine, margarine, or butter and—

(1) any of the raw material used in the oleomargarine, margarine, or butter consisted in whole or in part of any filthy, putrid, or decomposed substance; or

(2) the oleomargarine, margarine, or butter is otherwise unfit for food.

(f) DIETARY SUPPLEMENT OR DIETARY INGREDIENT; SAFETY.—

(1) IN GENERAL.—A food shall be deemed to be adulterated if it is a dietary supplement or contains a dietary ingredient that—

(A) presents a significant or unreasonable risk of illness or injury—

(i) under conditions of use recommended or suggested in labeling; or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make the declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under subsection (a)(1) under the conditions of use recommended or suggested in the labeling of the dietary supplement.

(2) BURDEN OF PROOF; STANDARD OF REVIEW.—In any proceeding under paragraph (1), the United States shall bear the burden of proof on each element to show that a dietary supplement is adul-

terated. The court shall decide any issue under paragraph (1) on a de novo basis.

(3) NOTICE AND OPPORTUNITY TO PRESENT VIEWS.—Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) for a civil proceeding, the person against whom the proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before the notice, with regard to the proceeding.

(g) DIETARY SUPPLEMENT; MANUFACTURING PRACTICES.—

(1) IN GENERAL.—A food shall be deemed to be adulterated if it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under paragraph (2).

(2) REGULATIONS.—

(A) IN GENEAL.—The Secretary may by regulation prescribe good manufacturing practices for dietary supplements.

(B) MODEL.—The regulations shall be modeled after current good manufacturing

practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology.

(C) NOTICE AND COMMENT.—A standard of current good manufacturing practice shall not be imposed unless the standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) REOFFER OF FOOD PREVIOUSLY DENIED ADMISSION.—A food shall be deemed to be adulterated if it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 20101(a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this subtitle, as determined by the Secretary.

(i) NONCOMPLIANCE WITH SANITARY TRANSPORTATION PRACTICES.—A food shall be deemed to be adulterated if it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food

under conditions that are not in compliance with regulations promulgated under section 11118 of this title.

**§ 11103. National uniform nutrition labeling**

(a) IN GENERAL.—Except as provided in subsection (c), a State or political subdivision of a State shall not directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food that is the subject of a standard of identity established under section 11101 of this title that is not identical to the standard of identity or that is not identical to the requirement of section 11307 of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 11101 and 11307 of this title;

(2) any requirement for the labeling of food of the type required by section 11303, 11305, 11310(a)(2), 11323, or 11324 of this title that is not identical to the requirement of the section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 11303 of this title and that is applicable to maple syrup;

(3) any requirement for the labeling of food of the type required by section 11302, 11304, 11306, 11308, 11309, 11310(a)(1), or 11312 of this title that is not identical to the requirement of the section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 11308(1) of this title and that is applicable to maple syrup;

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 11316 of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and that offers for sale substantially the same menu items unless the restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 11316(g)(10) of this title; or

(5) any requirement respecting any claim of the type described in section 11317(a) of this title made in the label or labeling of food that is not identical

to the requirement of section 11317 of this title, except a requirement respecting a claim made in the label or labeling of food that is exempt under section 11317(e)(2) of this title.

(b) APPLICATION OF SUBSECTION (a)(3).—Subsection (a)(3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535, 104 Stat. 2363).

(c) EXEMPTION BY PETITION.—On petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law;

(2) would not unduly burden interstate commerce; and

(3) is designed to address a particular need for information, which need is not met by the requirements of the provisions referred to in subsection (a).

**§ 11104. Dietary supplement labeling exemptions**

(a) IN GENERAL.—A publication (including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publi-

cation) that is reprinted in its entirety shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers if it—

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other publications on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

(b) APPLICATION.—Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in the sale of books or other publications as a part of the business of the retailer or wholesaler.

(c) BURDEN OF PROOF.—In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that a publication is false or misleading.

**§ 11105. Disclosure relating to radiation**

(a) DEFINITION OF RADIATION DISCLOSURE STATEMENT.—In this section, the term ''radiation disclosure statement'' means a written statement that discloses that a food has been intentionally subject to radiation.

(b) CONSTRUCTION OF CERTAIN PROVISIONS.—Sections 10101(c)(1), 11301, and 11111 of this title shall not be construed to require, on the label or labeling of a food, a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 11310(a)(2) of this title.

**§ 11106. Emergency permit relating to contaminated food**

(a) REGULATIONS FOR THE ISSUANCE OF PERMITS.—

(1) IN GENERAL.—The Secretary shall prescribe regulations providing for the issuance of permits described in this subsection if the Secretary finds, after investigation, that—

(A) the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing, in any locality, of articles of food within the class, be injurious to health; and

(B) the injurious nature cannot be adequately determined after the articles have entered interstate commerce.

(2) PERMITTEES.—The permits under paragraph (1) shall be issued to manufacturers, processors, or packers of the class of food described in paragraph (1) in the locality.

(3) CONDITIONS.—Conditions governing the manufacture, processing, or packing of the class of food under paragraph (1) shall be attached to the permits under paragraph (1) for such temporary period of time as may be necessary to protect the public health.

(4) PROHIBITION ON INTRODUCTION OR DELIVERY FOR INTRODUCTION INTO INTERSTATE COMMERCE.—After the effective date of the regulations under paragraph (1), and during the temporary period described in paragraph (3), a person shall not introduce or deliver for introduction into interstate commerce any article of food within the class described in paragraph (1) manufactured, processed, or packed by any manufacturer, processor, or packer of the class of food described in paragraph (1) in the locality unless the manufacturer, processor, or pack-

er holds a permit issued by the Secretary as provided by the regulations.

(b) SUSPENSION AND REINSTATEMENT OF PERMITS.—

(1) SUSPENSION.—The Secretary may suspend immediately upon notice any permit issued under this section if the Secretary finds that any of the conditions of the permit has been violated.

(2) REINSTATEMENT.—

(A) APPLICATION.—The holder of a permit suspended under paragraph (1) shall be privileged at any time to apply for the reinstatement of the permit.

(B) COMPLIANCE AND REINSTATEMENT.—The Secretary shall, immediately after prompt hearing and an inspection of the manufacturing, processing, or packing establishment, reinstate the permit if the Secretary finds that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) INSPECTION OF PERMIT-HOLDING ESTABLISHMENTS.—

(1) ACCESS TO ESTABLISHMENTS.—Any officer or employee designated by the Secretary shall have

access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with.

(2) DENIAL OF ACCESS AS GROUND FOR SUSPENSION OF PERMIT.—Denial of access for the inspection shall be ground for suspension of the permit until access is freely given by the operator.

**§ 11107. Regulations making labeling exemptions**

(a) IN GENERAL.—The Secretary shall promulgate regulations exempting from any labeling requirement of this subtitle—

(1) small open containers of fresh fruits and fresh vegetables; and

(2) food that is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that the food is not adulterated or misbranded under this subtitle on removal from the processing, labeling, or repacking establishment.

(b) INAPPLICABILITY.—This section does not apply to the labeling requirements of sections 11316 and 11317 of this title.

**§ 11108. Added poisonous or deleterious substances deemed unsafe; tolerances**

(a) IN GENERAL.—Any poisonous or deleterious substance added to any food shall be deemed to be unsafe for purposes of the application of section 11102(a)(2)(A) of this title.

(b) EXCEPTIONS.—A poisonous or deleterious substance added to any food shall not be deemed to be unsafe under subsection (a) if the substance—

(1) is required in the production of the food; or

(2) cannot be avoided by good manufacturing practice.

(c) LIMITING QUANTITIES BY REGULATION.—If a substance is required or cannot be avoided under subsection (b), the Secretary or the Administrator, as applicable pursuant to section 2(a)(4) of Reorganization Plan No. 3 of 1970 (42 U.S.C. 4321 note), shall prescribe regulations limiting the quantity in or on the food to such extent as the Secretary or Administrator finds necessary for the protection of public health.

(d) EXCEEDING LIMITS.—Any quantity exceeding the limits prescribed by regulation under subsection (c) shall also be deemed to be unsafe for purposes of the application of section 11102(a)(2)(A) of this title.

(e) EFFECT OF REGULATION ON CERTAIN FOOD DEEMED ADULTERATED.—While a regulation under sub-

section (c) is in effect limiting the quantity of a substance in the case of any food, the food shall not, by reason of bearing or containing any added amount of the substance, be considered to be adulterated within the meaning of section 11102(a)(1) of this title.

(f) TOLERANCE.—In determining the quantity of an added poisonous or deleterious substance to be tolerated in or on different articles of food, the Secretary or the Administrator, as applicable pursuant to section 2(a)(4) of Reorganization Plan No. 3 of 1970 (42 U.S.C. 4321 note), shall take into account the extent to which the use of the substance is required or cannot be avoided in the production of each of those articles, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

**§ 11109. Intrastate sales of colored oleomargarine**

(a) MARGARINE; OLEOMARGARINE.—

(1) MARGARINE; INCLUSIONS.—In this section, the term ''margarine'' includes—

(A) all substances, mixtures, and compounds known as margarine; and

(B) all substances, mixtures, and compounds that have a consistency similar to butter and that contain any edible oil or fat other than

milk fat if made in imitation or semblance of butter.

(2) OLEOMARGARINE; INCLUSIONS.—In this section, the term ''oleomargarine'' includes—

(A) all substances, mixtures, and compounds known as oleomargarine; and

(B) all substances, mixtures, and compounds that have a consistency similar to butter and that contain any edible oil or fat other than milk fat if made in imitation or semblance of butter.

(b) COLOR CONTENT OF OLEOMARGARINE.—For the purpose of this section, colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than $1^{6}/_{10}$ degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent.

(c) SUBJECT TO SUBTITLE AS IF INTRODUCED IN INTERSTATE COMMERCE.—Colored oleomargarine or colored margarine that is sold in the same State or territory of the United States in which it is produced shall be subject in the same manner and to the same extent to this subtitle as if it had been introduced in interstate commerce.

(d) LABELING AND PACKAGING REQUIREMENTS.—

(1) IN GENERAL.—A person shall not sell, or offer for sale, colored oleomargarine or colored margarine unless—

(A) the colored oleomargarine or colored margarine is packaged;

(B) the net weight of the contents of the package sold in a retail establishment is 1 pound or less;

(C) the label of the package shows—

(i) the word ''oleomargarine'' or ''margarine'' in type or lettering at least as large as any other type or lettering on the label; and

(ii) a full and accurate statement of all the ingredients contained in the oleomargarine or margarine; and

(D) each part of the contents of the package is contained in a wrapper that bears the word ''oleomargarine'' or ''margarine'' in type or lettering not smaller than 20-point type.

(2) EFFECT OF SUBSECTION.—The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this subtitle.

(e) SALES IN PUBLIC EATING PLACES.—

(1) PROMINENT DISPLAY.—A person shall not possess, in a form ready for serving, colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served—

(A) is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by an ordinary individual being served in the eating place; or

(B) is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items.

(2) MANNER OF SERVING.—A person shall not serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made for the colored oleomargarine or colored margarine, unless—

(A) each separate serving bears or is accompanied by labeling identifying the serving as oleomargarine or margarine; or

(B) each separate serving is triangular in shape.

(f) EXEMPTION FROM LABELING REQUIREMENTS.—Colored oleomargarine or colored margarine, when served with meals at a public eating place, shall, at the time of the service, be exempt from the labeling requirements of chapter 113 of this title (except sections 11301 and 11306 of this title) if it complies with the requirements of subsection (d).

**§ 11110. Tolerances and exemptions for pesticide chemical residues**

(a) DEFINITIONS.—In this section:

(1) FOOD.—The term ''food'', when used as a noun without modification, means a raw agricultural commodity or processed food.

(2) MODIFY.—The term ''modify'', with respect to a tolerance, does not mean to expand the tolerance to cover additional foods.

(3) SAFE.—The term ''safe'', with respect to a tolerance for a pesticide chemical residue or to an exemption from the requirement for a tolerance, means that there is, as determined by the Administrator, a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(b) REQUIREMENT FOR TOLERANCE OR EXEMPTION.—

(1) IN GENERAL.—Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 11102(a)(2)(B) of this title unless—

(A) a tolerance for the pesticide chemical residue in or on the food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement for a tolerance is in effect under this section for the pesticide chemical residue.

(2) PROCESSED FOOD.—Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 11102(a)(2)(B) of this title despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if—

(i) the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section;

(ii) the pesticide chemical residue in or on the raw agricultural commodity is removed to the extent possible in good manufacturing practice; and

(iii) the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 11102(a)(2)(B) of this title.

(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation

product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, the pesticide chemical residue present in or on the food shall not be considered to be unsafe within the meaning of section 11102(a)(2)(B) of this title despite the lack of a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue in or on the food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for pesticide chemical residues of the precursor substance in or on the food, and the combined level of pesticide chemical residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the pesticide chemical residue consisted only of the precursor sub-

stance rather than the degradation product; or

(ii) an exemption from the requirement for a tolerance is in effect under this section for pesticide chemical residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for pesticide chemical residues of the precursor substance does not state that it applies only to particular-named substances and does not state that it does not apply to pesticide chemical residues of the degradation product.

(4) EFFECT OF TOLERANCE OR EXEMPTION.—While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not, by reason of bearing or containing any amount of the pesticide chemical residue, be considered to be adulterated within the meaning of section 11102(a)(1) of this title.

(c) AUTHORITY AND STANDARD FOR TOLERANCE.—

(1) AUTHORITY.—The Administrator may issue regulations establishing, modifying, or revoking a

tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (e); or

(B) on the Administrator's own initiative under subsection (f).

(2) STANDARD.—

(A) ESTABLISHMENT; MODIFICATION; REVOCATION.—

(i) IN GENERAL.—

(I) ESTABLISHMENT.—The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe.

(II) MODIFICATION; REVOCATION.—The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

(i) DEFINITION OF ELIGIBLE PESTICIDE CHEMICAL RESIDUE.—In this subparagraph, the term ''eligible pesticide chemical residue'' means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the pesticide chemical residue at which the pesticide chemical residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a ''nonthreshold effect'');

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the pesticide chemical residue will not cause the harm (referred to in this section as a

''threshold effect''), the Administrator determines that the level of aggregate exposure is safe.

(ii) DETERMINATION OF TOLERANCE.—Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) CONDITIONS REGARDING USE.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the pesticide chemical residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the pesticide chemical residue.

(II) Use of the pesticide chemical that produces the pesticide chemical residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the pesticide chemical residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for the nonthreshold effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the pesticide chemical residue is not greater than twice the lifetime risk

that would be allowed under subparagraph (A) for the nonthreshold effect.

(v) REVIEW.—

(I) IN GENERAL.—Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator considers appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that—

(aa) a condition described in subclause (I) or (II) of clause (iii) continues to exist with respect to the tolerance; and

(bb) the yearly and lifetime risks from aggregate exposure to the pesticide chemical residue continue to comply with the limits specified in clause (iv).

(II) NO DEMONSTRATION THAT CONDITIONS WERE MET.—If the Administrator determines that the dem-

onstration under subclause (I) is not made by the date described in subclause (I), the Administrator shall, not later than 180 days after the date of the determination, issue a regulation under subsection (f)(1) to modify or revoke the tolerance.

(vi) INFANTS AND CHILDREN.—Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) EXPOSURE OF INFANTS AND CHILDREN.—

(i) IN GENERAL.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(I) shall assess the risk of the pesticide chemical residue based on—

(aa) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing the

pesticide chemical residue among infants and children in comparison to the general population;

(bb) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(cc) available information concerning the cumulative effects, on infants and children, of the pesticide chemical residues and other substances that have a common mechanism of toxicity; and

(II) shall—

(aa) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure

to the pesticide chemical residue; and

(bb) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

(ii) SURVEYS.—The Secretary and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children.

(iii) DEVELOPMENT AND IMPLEMENTATION OF SURVEY PROCEDURES.—

(I) IN GENERAL.—The Secretary of Agriculture, in consultation with the Administrator and the Secretary, shall coordinate the development and implementation of survey procedures to ensure that adequate data on food consumption patterns of infants and children are collected.

(II) INCLUSIONS.—To the extent practicable, the procedures referred to in subclause (I) shall include the collection of data on food consumption

patterns of a statistically valid sample of infants and children.

(III) RESIDUE DATA COLLECTION.—The Secretary of Agriculture shall ensure that the residue data collection activities conducted by the Department of Agriculture, in cooperation with the Environmental Protection Agency and the Department, provide for the improved data collection of pesticide residues, including guidelines for the use of comparable analytical and standardized reporting methods, and the increased sampling of foods most likely consumed by infants and children.

(iv) THRESHOLD EFFECTS.—

(I) ADDITIONAL MARGIN OF SAFETY.—In the case of threshold effects, for purposes of clause (i)(II)(aa), an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential

pre-natal and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children.

(II) USE OF A DIFFERENT MARGIN OF SAFETY.—Notwithstanding the requirement for an additional margin of safety under subclause (I), the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, the margin will be safe for infants and children.

(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chem-

ical or pesticide chemical residue in the studies;

(iii) available information concerning the relationship of the results of the studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of the pesticide chemical residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data.

(E) DATA AND INFORMATION REGARDING ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

(i) AUTHORITY.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the FDA.

(ii) REQUIREMENT.—

(I) IN GENERAL.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall, pursuant to paragraphs (1) through (3) of subsection (g), require that data be provided 5 years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator considers appropriate, demonstrating that the residue levels are not above the levels relied on by the Administrator.

(II) MODIFICATION OR REVOCATION OF TOLERANCE IF DATA REQUIREMENT IS NOT MET.—If data described in subclause (I) are not provided, or if the data do not demonstrate that the residue levels are not above the levels relied on by the Administrator under subclause (I), the Administrator shall, not later than 180 days after the date on which the data are required to be provided, issue

a regulation under subsection (f)(1), or an order under subsection (g)(4), as appropriate, to modify or revoke the tolerance.

(F) PERCENT OF FOOD ACTUALLY TREATED.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percentage of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from crop that is treated with the pesticide chemical is likely to contain the pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in the area

is not dietarily exposed to pesticide chemical residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) DETECTION AND MEASUREMENT.—

(A) IN GENERAL.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) DETECTION LIMIT.—A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) INTERNATIONAL STANDARDS.—

(A) DETERMINATION WHETHER CODEX ALIMENTARIUS COMMISSION ESTABLISHED

MAXIMUM RESIDUE LEVEL.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission.

(B) DEPARTING FROM CODEX LEVEL.—If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(d) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

(1) AUTHORITY.—The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (e); or

(B) on the Administrator's initiative under subsection (f).

(2) STANDARD.—

(A) IN GENERAL.—

(i) ESTABLISHMENT OR LEAVING IN EFFECT.—The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe.

(ii) MODIFICATION; REVOCATION.—The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(B) FACTORS.—In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (c)(2).

(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on food; or

(B) that there is no need for a method described in subparagraph (A), and states the reasons for the determination in issuing the regulation establishing or modifying the exemption.

(e) PETITION FOR TOLERANCE OR EXEMPTION.—

(1) PETITIONS AND PETITIONERS.—Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on a food.

(2) PETITION CONTENTS.—

(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)(I) an informative summary of the petition and of the data, information, and

arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that the summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the pesticide chemical residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue

that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing methods used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (c)(2)(C);

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for the pesticide chemical residue;

(xii) practical methods for removing any amount of the pesticide chemical residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

(B) CITING TO AVAILABLE INFORMATION OR DATA.—If information or data required by subparagraph (A) is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it.

(C) SAMPLES.—The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(D) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition—

(i) to modify or revoke a tolerance; or

(ii) to modify or revoke an exemption from the requirement for a tolerance.

(3) NOTICE.—

(A) IN GENERAL.—A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after the determination.

(B) ANALYTICAL METHODS.—The notice—

(i) shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed; or

(ii) shall set forth the petitioner's statement of why an analytical method described in clause (i) is not needed.

(C) SUMMARY.—The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) ACTIONS BY THE ADMINISTRATOR.—

(A) IN GENERAL.—The Administrator shall, after giving due consideration to a peti-

tion filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement for a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (f), and after the proposed regulation is issued, issue a final regulation under subsection (f); or

(iii) issue an order denying the petition.

(B) PRIORITIES.—The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (c)(2)(B), the Administrator shall complete action on the petition under this paragraph within 1 year.

(ii) REQUIRED DETERMINATIONS.—

(I) IN GENERAL.—If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (c)(2)(B)(iii) continues to

exist with respect to a tolerance that is left in effect or modified under subsection (c)(2)(B).

(II) CONDITION NO LONGER EXISTS.—If, under subclause (I), the Administrator determines that a condition described in subclause (I) or (II) of subsection (c)(2)(B)(iii) does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination is made, issue a regulation under subsection (f)(1) to modify or revoke the tolerance.

(f) ACTION ON ADMINISTRATOR'S OWN INITIATIVE.—

(1) IN GENERAL.—The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (m)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (m)(3), or revoking an exemp-

tion of a pesticide chemical residue from the requirement for a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) NOTICE AND COMMENT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation.

(B) SHORTER COMMENT PERIOD.—A period for comment shorter than the period described in subparagraph (A) may be provided if the Administrator, for good cause—

(i) finds that the shorter comment period would be in the public interest; and

(ii) states the reasons for the finding under clause (i) in the notice of proposed rulemaking under subparagraph (A).

(g) SPECIAL DATA REQUIREMENTS.—

(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption

that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with the tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(2)(B));

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act (15 U.S.C. 2603); or

(C) publish in the Federal Register, after providing notice and an opportunity for comment for a period of not less than 60 days, an order—

(i) requiring the submission to the Administrator by any interested person of a notice identifying the person that will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained

under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(2)(B)) or section 4 of the Toxic Substances Control Act (15 U.S.C. 2603);

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) shall be made.

(2) REVISION OF ORDER TO CORRECT AN ERROR.—The Administrator may, under paragraph (1)(C), revise an order to correct an error.

(3) DATA OR INFORMATION RELATING TO CERTAIN EFFECTS OF PESTICIDE CHEMICAL.—The Administrator may, under paragraph (1), require data or information pertaining to whether the pesticide chemical may have an effect in humans that is simi-

lar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(4) NONCOMPLIANCE.—

(A) IN GENERAL.—If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in the notice, rule, or order, the Administrator may, by order published in the Federal Register, modify or revoke the tolerance or exemption in question.

(B) MATERIAL ISSUE IN REVIEW.—In any review under subsection (h)(2) of an order to modify or revoke a tolerance or exemption under clause (A), the only material issue shall be whether a submission required under paragraphs (1) through (3) was not made by the time specified.

(h) EFFECTIVE DATE; OBJECTIONS; HEARINGS; ADMINISTRATIVE REVIEW.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—A regulation or order issued under subsection (e)(4), (f)(1), or (g)(4)

shall take effect on publication unless the regulation or order specifies otherwise.

(B) EFFECT OF OBJECTIONS.—The Administrator may stay the effectiveness of the regulation or order if, after issuance of the regulation or order, objections are filed with respect to the regulation or order pursuant to paragraph (2).

(2) FURTHER PROCEEDINGS.—

(A) OBJECTIONS.—

(i) IN GENERAL.—Within 60 days after a regulation or order is issued under subsection (e)(4), (f)(1)(A), (f)(1)(B), (g)(4), (o)(2), or (o)(4)(C), any person may file objections to the regulation or order with the Administrator, specifying with particularity the provisions of the regulation or order considered objectionable and stating reasonable grounds for considering the provisions objectionable.

(ii) REGULATION OR ORDER ISSUED BY PETITION; SERVICE OF OBJECTIONS.—If the regulation or order was issued in response to a petition under subsection (e)(1), a copy of each objection filed by a

person other than the petitioner shall be served by the Administrator on the petitioner.

(B) HEARING.—

(i) REQUEST.—An objection may include a request for a public evidentiary hearing on the objection.

(ii) DETERMINATION THAT HEARING IS NECESSARY TO RECEIVE EVIDENCE.—The Administrator shall, on the initiative of the Administrator or on the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that the public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections.

(iii) AUTHORIZATION OF DISCOVERY; SUBPOENA TO COMPEL TESTIMONY OR PRODUCTION OF DOCUMENTS.—The presiding officer in the public hearing may authorize a party to obtain discovery from other persons and may, on a showing of good cause made by a party, issue a sub-

poena to compel testimony or production of documents from any person.

(iv) PROTECTION OF WITNESS AND DOCUMENTS; FEDERAL RULES OF CIVIL PROCEDURE.—The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness.

(v) ENFORCEMENT OF SUBPOENA.—On contest, a subpoena under clause (iii) may be enforced by a Federal district court.

(C) FINAL DECISION.—

(i) IN GENERAL.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order—

(I) stating the action taken on each objection under this paragraph; and

(II) setting forth any revision to the regulation or prior order that the Administrator has found to be warranted.

(ii) ORDER AND REVISIONS TO BE BASED ON SUBSTANTIAL EVIDENCE AND TO SET FORTH FINDINGS OF FACTS AND CONCLUSIONS OF LAW.—If a hearing was held under subparagraph (B), an order issued under clause (i) and any revision to the regulation or prior order—

(I) shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at the hearing; and

(II) shall set forth in detail the findings of facts and the conclusions of law or policy on which the order or regulation is based.

(i) JUDICIAL REVIEW.—

(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection (f)(1)(C), any order issued under subsection (g)(1)(C) or (h)(2)(C), or any regulation that is the subject of an order issued under subsection

(g)(1)(C) or (h)(2)(C), any person that will be adversely affected by the order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit in which the person resides or in which the person's principal place of business is located, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of the order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) RECORD AND JURISDICTION.—

(A) TRANSMITTALS BETWEEN COURT AND ADMINISTRATOR.—A copy of the petition under paragraph (1) shall be immediately transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and on the transmittal, the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28.

(B) EXCLUSIVE JURISDICTION.—On the filing of a petition under paragraph (1), the court shall have exclusive jurisdiction to affirm

or set aside, in whole or in part, the order or regulation that is petitioned to be set aside.

(C) FINDINGS OF FACT SUSTAINED IF SUPPORTED BY SUBSTANTIAL EVIDENCE.—In the case of orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) ADDITIONAL EVIDENCE.—

(A) IN GENERAL.—If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the Administrator in the manner and on the terms and conditions the court considers proper.

(B) MODIFICATION OF PRIOR FINDINGS OF FACTS.—The Administrator may modify prior findings of facts by reason of the additional evi-

dence taken under this paragraph and may modify the order or regulation accordingly.

(C) COURT FILING.—The Administrator shall file with the court any modified finding, order, or regulation under subparagraph (B).

(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation, or any order and any regulation that is the subject of the order, shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28.

(5) EFFECT OF COMMENCEMENT OF PROCEEDINGS.—The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(6) REVIEWABILITY OF REVIEWS UNDER THIS SUBSECTION.—Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(j) CONFIDENTIALITY AND USE OF DATA.—

(1) GENERAL RULE.—Data and information submitted to the Administrator under this section or

section 11111 of this title in support of a tolerance or an exemption from the requirement for a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a, 136h).

(2) EXCEPTIONS.—

(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) Federal employees authorized by the Administrator to examine the data and information in the carrying out of their official duties under this subtitle or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine the data and information in the carrying out of contracts under this subtitle

or other Federal statutes intended to protect the public health.

(B) CONGRESS.—This subsection does not authorize the withholding of data or information from—

(i) the Senate or the House of Representatives; or

(ii) to the extent of matter within its jurisdiction—

(I) any committee or subcommittee of the committee of Congress; or

(II) any joint committee or subcommittee of the joint committee of Congress.

(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may—

(A) publish the informative summary required by subsection (e)(2)(A)(i)(I); and

(B) in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(k) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

(1) REGULATIONS UNDER SECTION 11108 OF THIS TITLE.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 17501(e) of this title, under the authority of section 11108 of this title on the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (e) and (f).

(2) REGULATIONS UNDER SECTION 11111 OF THIS TITLE.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which the pesticide chemicals could be safely used, and that were issued under section 11111 of this title on or before August 3, 1996, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (e) or (f).

(3) REGULATIONS UNDER THIS SECTION.—Regulations that established tolerances or exemptions under this section that were issued on or before Au-

gust 3, 1996, shall remain in effect unless modified or revoked under subsection (e) or (f).

(4) CERTAIN SUBSTANCES.—With respect to a substance that is not included in the definition of the term ''pesticide chemical'' under section 10101(a)(38) of this title but was included in the definition on the day before October 30, 1998, the following applies as of October 30, 1998:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before October 30, 1998, and was on that day deemed in the paragraph to have been issued under this section, shall be considered to have been issued under section 11111 of this title.

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on the day before October 30, 1998, and was issued under this section (including any such regulation issued before August 3, 1996) is deemed to have been issued under section 11111 of this title.

(l) EXEMPTIONS BASED ON STATUS AS OF AUGUST 3, 1996.—

(1) IN GENERAL.—With respect to a particular pesticidal use of a substance that is a pesticide chemical and any resulting pesticide chemical residue in or on a particular food, the pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of August 3, 1996, if, on the day before August 3, 1996, the substance was—

(A) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of section 408(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(a)) or section 201(s) of the Act as in effect on the day before August 3, 1996; or

(B) regarded by the Secretary as a substance described by section 10101(a)(20)(C)(iv) of this title.

(2) NOTICE.—The Administrator shall by regulation indicate which substances are described by this subsection.

(3) MODIFICATION; REVOCATION.—Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (d).

(m) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

(1) COORDINATION WITH FIFRA.—To the extent practicable, in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate the issuance with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—

(A) IN GENERAL.—The Administrator shall revoke any tolerance or exemption that allows the presence of a pesticide chemical, or any pesticide chemical residue that results from its use, in or on a food, if the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), due in whole or in part to dietary risks to humans posed by residues of the pesticide chemical on the food—

(i) cancels the registration of each pesticide that—

(I) contains the pesticide chemical; and

(II) is labeled for use on the food; or

(ii) requires that the registration of each pesticide described in clause (i) be modified to prohibit its use in connection with the production, storage, or transportation of the food.

(B) APPLICABILITY OF SUBSECTION (f).—Subsection (f) shall apply to actions taken under this paragraph.

(C) EFFECTIVE DATE OF REVOCATIONS.—A revocation under this paragraph shall become effective not later than 180 days after the later of—

(i) the date by which each such cancellation of a registration has become effective; or

(ii) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation.

(3) SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS.—

(A) SUSPENSION.—

(i) IN GENERAL.—The Administrator shall suspend any tolerance or exemption that allows the presence of a pesticide chemical, or any pesticide chemical residue that results from its use, in or on a food, if the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), due in whole or in part to dietary risks to humans posed by residues of the pesticide chemical on the food, suspends the use of each registered pesticide that—

(I) contains the pesticide chemical; and

(II) is labeled for use on the food.

(ii) APPLICABILITY OF SUBSECTION (f).—Subsection (f) shall apply to actions taken under this paragraph.

(iii) EFFECTIVE DATE OF SUSPENSIONS.—A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) EFFECT OF SUSPENSION.—

(i) DURATION OF EFFECTIVITY.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

(ii) TOLERANCE OR EXEMPTION NOT CONSIDERED IN EFFECT.—While a suspension of a tolerance or exemption is effective, the tolerance or exemption shall not be considered to be in effect.

(iii) TERMINATION OF SUSPENSION OF USE OF PESTICIDE.—If the suspension of use of the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) is terminated, leaving the registration of the pesticide for that use in effect under the Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—

(A) IN GENERAL.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to August 3, 1996, under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment so that it will be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue.

(B) FACTORS.—In establishing a tolerance under subparagraph (A), the Administrator shall take into account—

(i) the factors set forth in subsection (c)(2); and

(ii) the unavoidability of the residue.

(C) APPLICABILITY OF SUBSECTION (f).—Subsection (f) shall apply to the establishment of a tolerance under subparagraph (A).

(D) REVIEW.—The Administrator shall review any tolerance established under subparagraph (A) periodically and modify it as nec-

essary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—

(A) IN GENERAL.—Notwithstanding any other provision of this subtitle, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of the pesticide chemical residue in or on the food if it is shown to the satisfaction of the Secretary that—

(i) the pesticide chemical residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.); and

(ii) the pesticide chemical residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this subtitle.

(B) INAPPLICABILITY.—Subparagraph (A) does not apply in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (e) or (f) if the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—

(A) IN GENERAL.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue.

(B) EXPIRATION DATE.—A tolerance or exemption from a tolerance established under subparagraph (A) shall have an expiration date.

(C) NOTICE OR PERIOD FOR COMMENT NOT REQUIRED.—The Administrator may establish a tolerance or exemption under subpara-

graph (A) without providing notice or a period for comment on the tolerance or exemption.

(D) REGULATIONS GOVERNING ESTABLISHMENT OF TOLERANCES AND EXEMPTIONS.—

(i) IN GENERAL.—The Administrator shall promulgate regulations governing the establishment of tolerances and exemptions under this paragraph.

(ii) EFFECT OF OTHER LAWS.—The regulations under clause (i) shall be consistent with the safety standard under subsections (c)(2) and (d)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p).

(n) FEES.—

(1) AMOUNT.—

(A) IN GENERAL.—The Administrator shall, by regulation, require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section.

(B) PERFORMANCE OF FUNCTIONS CONDITIONED ON PAYMENT OF FEES.—Under the regulations in subparagraph (A), the performance of the Administrator's services or other functions under this section may be conditioned on the payment of the fees required under subparagraph (A).

(C) SERVICES AND OTHER FUNCTIONS.—The services and other functions referred to in subparagraph (B) include—

(i) the acceptance for filing of a petition submitted under subsection (e);

(ii) the establishment, modification, leaving in effect, or revocation of a tolerance or the establishment, modification, leaving in effect, or revocation of an exemption from the requirement for a tolerance under this section;

(iii) the acceptance for filing of objections under subsection (h); and

(iv) the certification and filing in court of a transcript of the proceedings and the record under subsection (i).

(D) WAIVER; REFUND OF FEES.—The regulations under subparagraph (A) may provide

for waiver or refund of fees, in whole or in part, if in the judgment of the Administrator, the waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) DEPOSIT.—

(A) IN GENERAL.—All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(k)).

(B) AVAILABILITY.—Fees described in subparagraph (A) shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3) PROHIBITION.—During the period beginning on December 29, 2022, and ending on September 30, 2027, the Administrator shall not collect any tolerance fees under paragraph (1).

(o) NATIONAL UNIFORMITY OF TOLERANCES.—

(1) DEFINITIONS.—In this subsection:

(A) QUALIFYING FEDERAL DETERMINATION.—The term ''qualifying Federal determination'' means a tolerance or exemption from

the requirement for a tolerance for a qualifying pesticide chemical residue that—

(i) is issued under this section after August 3, 1996, and determined by the Administrator to meet the standard under subsection (c)(2)(A) (in the case of a tolerance) or (d)(2) (in the case of an exemption); or

(ii)(I) pursuant to subsection (k), is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (l) as exempt from the requirement for a tolerance; and

(II) is determined by the Administrator to meet the standard under subsection (c)(2)(A) (in the case of a tolerance) or (d)(2) (in the case of an exemption).

(B) QUALIFYING PESTICIDE CHEMICAL RESIDUE.—The term ''qualifying pesticide chemical residue'' means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(i) is first approved for that use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(5)) on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act on April 25, 1985; or

(ii) is approved for that use in a reregistration eligibility determination issued under section 4(g) of that Act (7 U.S.C. 136a–1(g)) on or after August 3, 1996.

(2) PROCEDURE FOR DETERMINATION UNDER PARAGRAPH (1)(A)(ii)(II).—

(A) IN GENERAL.—The Administrator may make the determination described in paragraph (1)(A)(ii)(II)—

(i) only by issuing a rule in accordance with the procedure set forth in subsection (e) or (f); and

(ii) only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule.

(B) REVIEWABILITY.—A rule under subparagraph (A) shall be reviewable in accordance with subsections (h) and (i).

(3) STATE AUTHORITY.—

(A) IN GENERAL.—Except as provided in paragraphs (4), (5), and (7), a State or political subdivision shall not establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of the pesticide chemical residue in or on the food, unless the State regulatory limit is identical to the qualifying Federal determination.

(B) DEEMED TO ESTABLISH OR ENFORCE A REGULATORY LIMIT.—A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if the regulatory limit purports to prohibit or penalize the production, processing, shipping, or other handling of a food because the food contains a pesticide chemical residue (in excess of a prescribed limit).

(4) PETITION PROCEDURE.—

(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in the State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to the qualifying pesticide chemical residue.

(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A)—

(i) shall satisfy any requirement prescribed, by rule, by the Administrator; and

(ii) shall be supported by—

(I) scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues;

(II) data on the consumption within the State of food bearing the pesticide chemical residue; and

(III) data on exposure of humans within the State to the pesticide chemical residue.

(C) AUTHORIZATION.—The Administrator may, by order, grant the authorization described in subparagraph (A) if the Adminis-

trator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be in violation of Federal law.

(D) TREATMENT.—

(i) IN GENERAL.—In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (e) to modify or revoke a tolerance or an exemption.

(ii) EFFECT OF TREATMENT.—If the Administrator determines to treat a petition under this paragraph as a petition under subsection (e), the Administrator shall act on the petition pursuant to subsection (e).

(E) REVIEW.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (h) and (i).

(5) URGENT PETITION PROCEDURE.—

(A) IN GENERAL.—Any State petition to the Administrator pursuant to paragraph (4) that demonstrates that consumption of a food containing the pesticide chemical residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition.

(B) TEMPORARY REGULATORY LIMIT.—

(i) IN GENERAL.—If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food.

(ii) VALIDATION; TERMINATION.—The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(6) RESIDUES FROM LAWFUL APPLICATION.—A State or political subdivision shall not enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the

time of the application of the pesticide that resulted in the pesticide chemical residue, the sale of the food with the pesticide chemical residue level was lawful under this section and under the law of the State, unless the State demonstrates that consumption of the food containing the pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within the State.

(7) NONPREEMPTION RELATING TO WARNING OR STATEMENT.—Nothing in this subtitle preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on the food.

(p) CONSUMER RIGHT TO KNOW.—

(1) IN GENERAL.—The Administrator shall annually, in consultation with the Secretary of Agriculture and the Secretary, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(A) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(B) A listing of actions taken under subsection (c)(2)(B) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subsection (c)(2)(A), and the food on which the pesticide chemicals producing the pesticide chemical residues are used.

(C) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under subparagraph (B).

(2) PROVIDING OF ADDITIONAL INFORMATION.—Nothing in this subsection shall prevent retail grocers from providing additional information.

(q) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

(1) DEVELOPMENT.—The Administrator shall, in consultation with the Secretary, develop a screening program, using appropriate validated test systems and other scientifically relevant information, to

determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) IMPLEMENTATION.—After obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w(d)) or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration Authorization Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

(3) SUBSTANCES.—In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substan-

tial population may be exposed to the substance.

(4) EXEMPTION.—Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5) COLLECTION OF INFORMATION.—

(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person that manufactures or imports a substance for which testing is required under this subsection, to—

(i) conduct testing in accordance with the screening program described in paragraph (1); and

(ii) submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

(B) PROCEDURES.—To the extent practicable, the Administrator shall—

(i) minimize duplicative testing of the same substance for the same endocrine effect;

(ii) develop, as appropriate, procedures for fair and equitable sharing of test costs; and

(iii) develop, as necessary, procedures for handling of confidential business information.

(C) FAILURE OF REGISTRANTS TO SUBMIT INFORMATION.—

(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A), the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant.

(ii) WHEN SUSPENSION BECOMES FINAL.—Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice

of intent to suspend, unless during that period—

(I) a person adversely affected by the notice requests a hearing; or

(II) the Administrator determines that the registrant has complied fully with this paragraph.

(iii) HEARING.—

(I) IN GENERAL.—If a person requests a hearing under clause (ii), the hearing shall be conducted in accordance with section 554 of title 5.

(II) MATTER FOR RESOLUTION.—The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A).

(III) DECISION AS FINAL AGENCY ACTION.—A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iv) TERMINATION OF SUSPENSIONS.—The Administrator shall terminate a suspension under this subparagraph

issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) that fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) in the case of a violation referred to in that section. The penalties and sanctions shall be assessed and imposed in the same manner as provided in that section.

(6) AGENCY ACTION.—In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this subtitle, as is necessary to ensure the protection of public health.

(r) TEMPORARY TOLERANCE OR EXEMPTION RELATING TO EXPERIMENTAL PERMIT FOR PESTICIDE CHEMICAL.—

(1) IN GENERAL.—The Administrator may, on the request of any person that has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) or on the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit.

(2) APPLICABILITY OF OTHER PROVISIONS.—Subsections (c)(2), (d)(2), (e), and (f) shall apply to actions taken under this subsection.

(s) REGULATION OF SULFURYL FLUORIDE.—Notwithstanding any other provision of law, the Administrator shall exclude nonpesticidal sources of fluoride from any aggregate exposure assessment required under this section when assessing tolerances associated with residues from the pesticide.

(t) EFFECT OF SECTION.—Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act (15 U.S.C. 2601 et seq.) or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

**§ 11111. Food additives**

(a) DEFINITION OF FOOD CONTACT SUBSTANCE.—In this section, the term ''food contact substance'' means

any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if that use is not intended to have any technical effect in the food.

(b) UNSAFE FOOD ADDITIVES; EXCEPTIONS.—

(1) IN GENERAL.—A food additive shall, with respect to any particular use or intended use of the food additive, be deemed to be unsafe for the purposes of the application of section 11102(a)(2)(C) of this title, unless—

(A) the food additive and its use or intended use conform to the terms of an exemption that is in effect pursuant to subsection (k);

(B) there is in effect, and the food additive and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which the food additive may be safely used; or

(C) in the case of a food additive that is a food contact substance, there is—

(i) in effect, and the food contact substance and the use of the food contact substance are in conformity with, a regulation issued under this section prescribing the

conditions under which the food additive may be safely used; or

(ii) a notification submitted under subsection (i) that is effective.

(2) ADULTERATED FOOD; EXCEPTION.—While such a regulation relating to a food additive, or such a notification under subsection (i)(1) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (j), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 11102(a)(1) of this title.

(c) PETITION FOR REGULATION PRESCRIBING CONDITIONS OF SAFE USE.—

(1) IN GENERAL.—Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which the food additive may be safely used.

(2) CONTENTS.—A petition under paragraph (1) shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning the food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of the food additive, including all directions, recommendations, and suggestions proposed for the use of the food additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect the food additive is intended to produce, and the quantity of the food additive required to produce the effect;

(D) a description of practicable methods for determining the quantity of the food additive in or on food, and any substance formed in or on food, because of the use of the food additive; and

(E) full reports of investigations made with respect to the safety for use of the food additive, including full information as to the methods and controls used in conducting the investigations.

(3) DESCRIPTION OF METHODS, FACILITIES, AND CONTROLS RELATING TO PRODUCTION.—On request of the Secretary, the petitioner shall furnish

(or, if the petitioner is not the manufacturer of the food additive, the petitioner shall have the manufacturer of the food additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of the food additive.

(4) SAMPLES.—On request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components of the food additive, and of the food in or on which the food additive is proposed to be used.

(5) NOTICE.—Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within 30 days after filing.

(d) APPROVAL OR DENIAL OF PETITION.—

(1) IN GENERAL.—The Secretary—

(A) shall—

(i) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to 1 or more proposed uses of the food additive involved, the conditions under which the food additive may be safely used (including specifications as to the particular food or classes of food in or on

which the food additive may be used, the maximum quantity that may be used or permitted to remain in or on the food, the manner in which the food additive may be added to or used in or on the food, and any directions or other labeling or packaging requirements for the food additive that the Secretary considers necessary to ensure the safety of the use); and

(ii) notify the petitioner of the order and the reasons for the action; or

(B) shall—

(i) by order deny the petition; and

(ii) notify the petitioner of the order and of the reasons for the action.

(2) DATE BY WHICH ORDER SHALL BE ISSUED.—The order required by subparagraph (A) or (B) of paragraph (1) shall be issued within 90 days after the date of filing of the petition, except that the Secretary may (prior to the 90th day), by written notice to the petitioner, extend the 90-day period to such time (not more than 180 days after the date of filing of the petition) as the Secretary considers necessary to enable the Secretary to study and investigate the petition.

(3) ISSUANCE OF REGULATION PRECLUDED.—A regulation proposed to be issued under this subsection shall not be issued if either subparagraph (A) or (B) applies:

(A) SAFETY.—A fair evaluation of the data before the Secretary fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe. No food additive shall be deemed to be safe if it is found to induce cancer when ingested by humans or animals, or if it is found, after tests that are appropriate for the evaluation of the safety of food additives, to induce cancer in humans or animals. The preceding sentence shall not apply with respect to the use of a substance as an ingredient of feed for animals that are raised for food production, if the Secretary finds—

(i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, the food additive will not adversely affect the animals for which the feed is intended; and

(ii) that no residue of the food additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (g) and (h)) in any edible portion of the animal after slaughter or in any food yielded by or derived from the living animal.

(B) CONSUMER DECEPTION.—A fair evaluation of the data before the Secretary shows that the proposed use of the food additive would promote deception of the consumer in violation of this subtitle or would otherwise result in adulteration or in misbranding of food within the meaning of this subtitle.

(4) TOLERANCE LIMITATION REQUIRED.—If, in the judgment of the Secretary, based on a fair evaluation of the data before the Secretary, a tolerance limitation is required in order to ensure that the proposed use of a food additive will be safe, the Secretary—

(A) shall not fix the tolerance limitation at a level higher than the Secretary finds to be reasonably required to accomplish the physical

or other technical effect for which the food additive is intended; and

(B) shall not establish a regulation for the proposed use if the Secretary finds, on a fair evaluation of the data before the Secretary, that the data do not establish that the use would accomplish the intended physical or other technical effect.

(5) SAFETY FACTORS.—In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the food additive and of any substance formed in or on food because of the use of the food additive;

(B) the cumulative effect of the food additive in the diet of humans or animals, taking into account any chemically or pharmacologically related substance in the diet; and

(C) safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives, are generally recognized as appropriate for the use of animal experimentation data.

(e) REGULATION ISSUED ON SECRETARY'S INITIATIVE.—

(1) PROPOSAL OF ISSUANCE.—The Secretary may at any time, on the Secretary's own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which the food additive may be safely used, and the reasons for the conditions.

(2) ESTABLISHMENT.—After the 30th day following publication of a proposal under paragraph (1), the Secretary may by order establish a regulation based on the proposal.

(f) PUBLICATION AND EFFECTIVE DATE OF ORDERS.—Any order, including any regulation established by the order, issued under subsection (d) or (e), shall be published and shall be effective on publication, but the Secretary may stay the effectiveness if, after issuance of the order, a hearing is sought with respect to the order pursuant to subsection (g).

(g) OBJECTIONS AND PUBLIC HEARING; BASIS AND CONTENTS OF ORDER; STATEMENT.—

(1) OBJECTIONS.—

(A) IN GENERAL.—Within 30 days after publication of an order made pursuant to subsection (d) or (e), any person adversely affected

by the order may file objections to the order with the Secretary, specifying with particularity the provisions of the order considered objectionable, stating reasonable grounds for the objections, and requesting a public hearing on the objections.

(B) HEARING.—The Secretary shall, after due notice, as promptly as possible, hold the public hearing for the purpose of receiving evidence relevant and material to the issues raised by the objections. As soon as practicable after completion of the hearing, the Secretary shall by order act on the objections and make the order public.

(2) BASIS AND CONTENTS OF ORDER.—The order under paragraph (1)(B) shall be based on a fair evaluation of the entire record at the hearing, and shall include a statement setting forth in detail the findings and conclusions on which the order is based.

(3) EFFECTIVE DATE OF ORDER.—The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the 90th day after its publication, unless the Secretary finds that emergency con-

ditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order the Secretary's findings as to the conditions.

(h) JUDICIAL REVIEW.—

(1) PETITION.—In a case of actual controversy as to the validity of any order issued under subsection (g), including any order under subsection (g) with respect to amendment or repeal of a regulation issued under this section, any person that will be adversely affected by the order may obtain judicial review by filing in the United States Court of Appeals for the circuit in which the person resides or in which the person's principal place of business is located, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after the entry of the order, a petition praying that the order be set aside in whole or in part.

(2) RECORD AND JURISDICTION.—

(A) TRANSMITTALS BETWEEN COURT AND SECRETARY.—A copy of the petition shall be immediately transmitted by the clerk of the court to the Secretary, or any officer designated by the Secretary for that purpose, and on the transmittal, the Secretary shall file in the court the record of the proceedings on which the Sec-

retary based the Secretary's order, as provided in section 2112 of title 28.

(B) JURISDICTION.—On the filing of the petition, the court shall have jurisdiction, which on the filing of the record with the court shall be exclusive, to affirm or set aside the order complained of in whole or in part.

(C) AUTHORITY TO MODIFY ORDER.—Until the filing of the record, the Secretary may modify or set aside the Secretary's order.

(D) FINDINGS OF FACTS TO BE SUSTAINED IF BASED ON FAIR EVALUATION OF RECORD.—The findings of the Secretary with respect to questions of fact shall be sustained if based on a fair evaluation of the entire record at the hearing.

(3) ORDER NOT TO BE SUSTAINED ON NONCOMPLIANCE OF SECRETARY.—The court, on the judicial review, shall not sustain the order of the Secretary if the Secretary failed to comply with any requirement imposed on the Secretary by subsection (g)(2).

(4) ADDITIONAL EVIDENCE.—

(A) IN GENERAL.—If application is made to the court for leave to adduce additional evi-

dence, the court may order the additional evidence to be taken before the Secretary and to be adduced on the hearing in such manner and on such terms and conditions as to the court may seem proper, if the evidence is material and there were reasonable grounds for failure to adduce the evidence in the prior proceedings before the Secretary.

(B) MODIFICATION OF FINDINGS OF FACTS AND ORDER.—The Secretary—

(i) may modify the Secretary's findings as to the facts and order by reason of the additional evidence taken under this paragraph; and

(ii) shall file with the court the modified findings and order.

(5) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States on certiorari or certification as provided in section 1254 of title 28.

(6) EFFECT OF COMMENCEMENT OF PROCEEDINGS.—The commencement of proceedings under this section shall not, unless specifically or-

dered by the court to the contrary, operate as a stay of an order.

(i) NOTIFICATION RELATING TO FOOD CONTACT SUBSTANCE.—

(1) NOTIFICATION OF SECRETARY.—

(A) IN GENERAL.—Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of the food contact substance is safe under the standard described in subsection (d)(3)(A).

(B) CONTENTS.—The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

(2) EFFECTIVE DATE.—

(A) DEFINITION OF FOOD CONTACT SUBSTANCE.—In this paragraph, the term ''food

contact substance'' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

(B) IN GENERAL.—A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary—

(i) makes a determination within the 120-day period that, based on the data and information before the Secretary, the use of the food contact substance has not been shown to be safe under the standard described in subsection (d)(3)(A); and

(ii) informs the manufacturer or supplier of the determination.

(C) FINAL AGENCY ACTION.—A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

(3) USE OF PETITION INSTEAD OF NOTIFICATION.—

(A) IN GENERAL.—The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except—

(i) where the Secretary determines that submission and review of a petition under subsection (c) is necessary to provide adequate assurance of safety; or

(ii) where the Secretary and any manufacturer or supplier agree that the manufacturer or supplier may submit a petition under subsection (c).

(B) REGULATIONS.—The Secretary—

(i) may promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (c); and

(ii) shall consider criteria such as the probable consumption of the food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (c).

(4) CONFIDENTIALITY OF INFORMATION.—The Secretary shall keep confidential any information

provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of the 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

(5) CONDITIONS RELATING TO APPROPRIATIONS.—

(A) IN GENERAL.—

(i) The notification program established under this subsection shall not operate in any fiscal year unless—

(I) an appropriation equal to or exceeding the applicable amount under clause (ii) is made for the fiscal year for carrying out the notification program in the fiscal year; and

(II) the Secretary certifies that the amount appropriated for the fiscal year for the Center for Food Safety and Applied Nutrition of the FDA (exclusive of the appropriation referred to in subclause (I)) equals or exceeds the amount appropriated for the Center for fiscal year 1997, ex-

cluding any amount appropriated for new programs.

(ii) APPLICABLE AMOUNT.—The applicable amount under this clause is $3,000,000, or the amount specified in the budget request of the President for the fiscal year involved for carrying out the notification program under this subsection, whichever is less.

(B) REPORT.—Not later than February 1 of each fiscal year, the Secretary shall submit to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report that provides an estimate of the Secretary of the costs of carrying out the notification program established under this subsection for the next fiscal year.

(j) AMENDMENT OR REPEAL OF REGULATIONS.—The Secretary shall by regulation prescribe the procedure by which regulations under subsections (a) through (i) may be amended or repealed, and the procedure shall conform to the procedure provided in this section for the pro-

mulgation of the regulations. The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (i) to no longer be effective.

(k) EXEMPTIONS FOR INVESTIGATIONAL USE.—Without regard to subsections (c) through (j), the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing the food additive, intended solely for investigational use by qualified experts when in the Secretary's opinion the exemption is consistent with the public health.

(l) FOOD ADDITIVES INTENDED FOR USE IN ANIMAL FOOD.—

(1) REVIEW OF REPORTS OF INVESTIGATIONS IN FOREIGN COUNTRIES.—In taking action on a petition under subsection (d) for, or for recognition of, a food additive intended for use in animal food, the Secretary shall review reports of investigations conducted in foreign countries, provided by the petitioner.

(2) INFORMATION TO BE POSTED ON FDA WEBSITE.—Not later than 12 months after August 14, 2018, the Secretary shall post on the FDA website—

(A) the number of petitions for food additives intended for use in animal food filed under subsection (c) that are pending;

(B) how long each the petition submitted under subsection (c) has been pending, including the petitions the Secretary has extended under subsection (d)(2); and

(C) the number of study protocols that have been pending review for over 50 days, and the number that have received an extension.

(3) REQUIRED CONTENTS OF PETITION.—In the case of a food additive petition intended for use in animal food, the Secretary shall provide information to the petitioner on the required contents of the petition. If the Secretary requires additional studies beyond what the petitioner proposed, the Secretary shall provide the scientific rationale for the requirement.

(4) GUIDANCE ON PRE-PETITION CONSULTATION PROCESS.—

(A) IN GENERAL.—Not later than 18 months after August 14, 2018, the Secretary shall publish draft guidance relating to the voluntary pre-petition consultation process for food additives intended for use in animal food.

(B) CONTENTS.—The guidance under subparagraph (A) shall include—

(i) the recommended format to submit to the FDA existing data, including any applicable foreign data, for assessment prior to submission of a food additive petition for animal food under subsection (c);

(ii) the manner and the number of days by which the FDA intends to review and respond to the existing data, including with respect to providing a scientific rationale for any additional data request;

(iii) circumstances under which the submission of study protocols is recommended prior to submission of a food additive petition under such subsection (c);

(iv) the manner in which the Secretary intends to inform the person submitting a study protocol for a food additive if the review of the study protocol will take longer than 50 days; and

(v) best practices for communication between the FDA and industry on the development of pre-petition submissions of

study protocols and existing data for food additives.

(C) FINAL GUIDANCE.—The guidance under subparagraph (A) shall be finalized, withdrawn, or reissued not later than 1 year after the close of the comment period on the draft guidance.

**§ 11112. Bottled drinking water**

(a) ACTIONS REQUIRED OF SECRETARY RELATING TO NATIONAL PRIMARY DRINKING WATER REGULATIONS.—Except as provided in subsection (b), whenever the Administrator prescribes an interim or revised national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the Secretary—

(1) shall consult with the Administrator; and

(2) within 180 days after the promulgation of the interim or revised national primary drinking water regulation—

(A) promulgate amendments to regulations under this subtitle applicable to bottled drinking water; or

(B) publish in the Federal Register the reasons of the Secretary for not making the amendments.

(b) STANDARD OF QUALITY REGULATION.—

(1) PROMULGATION.—

(A) IN GENERAL.—Not later than 180 days before the effective date of a national primary drinking water regulation promulgated by the Administrator for a contaminant under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the Secretary—

(i) shall promulgate a standard of quality regulation under this subsection for that contaminant in bottled water; or

(ii) make a finding that the standard of quality regulation under clause (i) is not necessary to protect the public health because the contaminant is contained in water in public water systems (as defined under section 1401(4) of the Safe Drinking Water Act (42 U.S.C. 300f(4))) but not in water used for bottled drinking water.

(B) EFFECTIVE DATE.—

(i) IN GENERAL.—The effective date for a standard of quality regulation promulgated under subparagraph (A) shall be the same as the effective date for the na-

tional primary drinking water regulation, except for any standard of quality of regulation promulgated by the Secretary before August 6, 1996, for which (as of August 6, 1996) an effective date had not been established.

(ii) MONITORING REQUIREMENTS FOR CONTAMINANTS REGULATED BEFORE AUGUST 6, 1996.—In the case of a standard of quality regulation to which the exception under clause (i) applies, the Secretary shall promulgate monitoring requirements for the contaminants covered by the regulation not later than 2 years after August 6, 1996.

(2) MONITORING REQUIREMENTS.—A standard of quality regulation issued by the Secretary under this subsection shall include any monitoring requirements that the Secretary determines appropriate for bottled water.

(3) REQUIRED PROVISIONS.—A standard of quality regulation issued by the Secretary under this subsection shall require the following:

(A) MAXIMUM CONTAMINANT LEVEL NOT LESS STRINGENT.—In the case of contaminants

for which a maximum contaminant level is established in a national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the standard of quality regulation shall establish a maximum contaminant level for the contaminant in bottled water that is no less stringent than the maximum contaminant level provided in the national primary drinking water regulation.

(B) REQUIREMENTS NO LESS PROTECTIVE OF PUBLIC HEALTH.—In the case of contaminants for which a treatment technique is established in a national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1), the standard of quality regulation shall require that bottled water be subject to requirements no less protective of the public health than those applicable to water provided by public water systems using the treatment technique required by the national primary drinking water regulation.

(4) NO STANDARD OF QUALITY REGULATION PROMULGATED.—

(A) IN GENERAL.—If the Secretary does not promulgate a standard of quality regulation under this subsection within the period described in paragraph (1), the national primary drinking water regulation referred to in paragraph (1) shall be deemed, as of the date on which the Secretary is required to establish a regulation under paragraph (1), as the standard of quality regulation applicable under this subsection to bottled water.

(B) PUBLICATION.—

(i) DEFINITION OF SUBSTITUTE REGULATION.—In this subparagraph, the term ''substitute regulation'' means a national primary drinking water regulation that, pursuant to subparagraph (A), is deemed to be a standard of quality regulation.

(ii) IN GENERAL.—In the case of a substitute regulation, the Secretary shall, not later than the applicable date referred to in subparagraph (A), publish in the Federal Register a notice—

(I) specifying the contents of the substitute regulation, including monitoring requirements; and

(II) providing that, for purposes of this paragraph—

(aa) the effective date for the substitute regulation is the same as the effective date for the national primary drinking water regulation for purposes of the Safe Drinking Water Act (42 U.S.C. 300f et seq.); or

(bb) if the exception under paragraph (1)(B) applies to the substitute regulation, the effective date for the regulation is not later than 2 years and 180 days after August 6, 1996.

**§ 11113. Vitamins and minerals**

(a) DEFINITION OF FOOD TO WHICH THIS SECTION APPLIES.—

(1) IN GENERAL.—In this section, the term ''food to which this section applies'' means a food—

(A) for humans;

(B) for special dietary use;

(C) that is or contains any natural or synthetic vitamin or mineral; and

(D) that—

(i) is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form; or

(ii) if not intended for ingestion in a form described in clause (i)—

(I) is not represented as conventional food; and

(II) is not represented for use as a sole item of a meal or of the diet.

(2) INTENDED FOR INGESTION IN LIQUID FORM.—For purposes of paragraph (1)(D)(i), a food shall be considered intended for ingestion in liquid form only if—

(A) it is formulated in a fluid carrier; and

(B) it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) SPECIAL DIETARY USE.—For purposes of paragraph (1) and of section 11311 of this title to the extent that section 11311 of this title is applicable to food to which this section applies, the term ''special dietary use'' means a particular use for which a food purports or is represented to be used, including—

(A) supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including—

(i) the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, being underweight, being overweight; and

(ii) the need to control the intake of sodium;

(B) supplying a vitamin, mineral, or other ingredient for use by a human to supplement that human's diet by increasing the total dietary intake; and

(C) supplying a special dietary need by reason of being a food for use as the sole item of the diet.

(b) REGULATING POTENCY AND CONTENT.—Except as provided in subsection (c)—

(1) the Secretary may not establish, under chapter 113 of this title or section 10101(c)(1) or 11101 of this title, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(2) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination of

any natural or synthetic vitamin or mineral) as a drug solely because it exceeds the level of potency that the Secretary determines is nutritionally rational or useful; and

(3) the Secretary may not limit, under chapter 113 of this title or section 10101(c)(1) or 11101 of this title, within a food to which this section applies, the combination or number of any synthetic or natural—

(A) vitamin;

(B) mineral; or

(C) other ingredient of food.

(c) INAPPLICABILITY RELATING TO INDIVIDUALS WITH DISEASES OR DISORDERS, CHILDREN, AND PREGNANT OR LACTATING WOMEN.—

(1) DEFINITION OF CHILDREN.—In this subsection, the term ''children'' means individuals who are under the age of 12 years.

(2) IN GENERAL.—Subsection (b) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food that is represented for use by—

(A) individuals in the treatment or management of specific diseases or disorders;

(B) children; or

(C) pregnant or lactating women.

(d) LABELING AND ADVERTISING REQUIREMENTS FOR FOODS.—

(1) MISBRANDING PROVISIONS.—A food to which this section applies shall not be considered under chapter 113 of this title to be misbranded solely because—

(A) its label bears, in accordance with section 11310(a)(2) of this title, all the ingredients in the food; or

(B) its advertising contains references to ingredients in the food that are not vitamins or minerals.

(2) LISTING OF INGREDIENTS ON LABELING.—

(A) IN GENERAL.—The labeling for any food to which this section applies may not list the food's ingredients that are not dietary supplement ingredients described in section 10101(a)(17) of this title—

(i) except as a part of a list of all the ingredients of the food; and

(ii) unless the ingredients are listed in accordance with applicable regulations under chapter 113 of this title.

(B) EXEMPTIONS.—To the extent that compliance with subparagraph (A)(i) is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(e) AMENDMENT OF INCONSISTENT REGULATIONS BY SECRETARY.—

(1) IN GENERAL.—The Secretary shall amend any regulation promulgated under this subtitle that is inconsistent with this section.

(2) SECTION 553 OF TITLE 5.—Any amendment to a regulation under paragraph (1) shall be promulgated in accordance with section 553 of title 5.

**§ 11114. Infant formulas**

(a) ADULTERATION.—An infant formula, including an infant formula powder, shall be deemed to be adulterated if—

(1) the infant formula does not provide nutrients as required by subsection (i);

(2) the infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1); or

(3) the processing of the infant formula is not in compliance with the good manufacturing practices

and the quality control procedures prescribed by the Secretary under subsection (b)(2).

(b) REQUIREMENTS FOR QUALITY FACTORS, GOOD MANUFACTURING PRACTICES, AND RETENTION OF RECORDS.—

(1) QUALITY FACTORS.—The Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i).

(2) GOOD MANUFACTURING PRACTICES.—

(A) IN GENERAL.—The Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to ensure that an infant formula—

(i) provides nutrients in accordance with this subsection and subsection (i); and

(ii) is manufactured in a manner designed to prevent adulteration of the infant formula.

(B) REQUIREMENTS FOR REGULATIONS ON GOOD MANUFACTURING PRACTICES AND QUALITY CONTROL PROCEDURES.—

(i) IN GENERAL.—The good manufacturing practices and quality control procedures prescribed by the Secretary under subparagraph (A) shall include requirements for—

(I) the testing, by the manufacturer of an infant formula (or an agent of the manufacturer), of each batch of infant formula for each nutrient required by subsection (i) before the distribution of the batch, which testing shall be in accordance with paragraph (3);

(II) regularly scheduled testing, by the manufacturer of an infant formula or an agent of the manufacturer, of samples of infant formulas during the shelf life of the formulas to ensure that the formulas are in compliance with this section;

(III) in-process controls including, where necessary, testing required

by good manufacturing practices designed to prevent adulteration of each batch of infant formula; and

(IV) the conduct by the manufacturer of an infant formula or an agent of the manufacturer of regularly scheduled audits to determine that the manufacturer has complied with the regulations prescribed under subparagraph (A).

(ii) AUDIT REQUIREMENTS.—In prescribing requirements for audits under clause (i)(IV), the Secretary shall provide that the audits be conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula.

(3) TESTING REQUIREMENTS.—

(A) DEFINITION OF FINAL PRODUCT STAGE.—In this paragraph, the term ''final product stage'' means the point in the manufacturing process, before distribution of an infant formula, at which an infant formula is homogenous and is not subject to further degradation.

(B) VITAMINS.—At the final product stage, each batch of infant formula shall be tested for vitamin A, vitamin B1, vitamin C, and vitamin E to ensure that the infant formula is in compliance with the requirements of this subsection and subsection (i) relating to the vitamins.

(C) PREMIX NUTRIENTS.—Each nutrient premix used in the manufacture of an infant formula shall be tested for each relied on nutrient required by subsection (i) that is contained in the premix to ensure that the premix is in compliance with its specifications or certifications by a premix supplier.

(D) NUTRIENTS NOT TESTED IN SUBPARAGRAPHS (B) AND (C).—

(i) IN GENERAL.—During the manufacturing process or at the final product stage and before distribution of an infant formula, an infant formula shall be tested for all nutrients required to be included in the formula by subsection (i) for which testing has not been conducted pursuant to subparagraph (B) or (C).

(ii) PURPOSE OF TESTING.—Testing under this subparagraph shall be conducted to—

(I) ensure that each batch of the infant formula is in compliance with the requirements of subsection (i) relating to the nutrients; and

(II) confirm that nutrients contained in any nutrient premix used in the infant formula are present in each batch of the infant formula in the proper concentration.

(E) NEWLY ADDED NUTRIENTS.—If the Secretary adds a nutrient to the list of nutrients in the table in subsection (i), the Secretary shall by regulation require that the manufacturer of an infant formula test each batch of the formula for the new nutrient in accordance with subparagraph (B), (C), or (D).

(4) RETENTION OF RECORDS.—

(A) ESTABLISHMENT OF REQUIREMENTS.—The Secretary shall by regulation establish requirements respecting the retention of records.

(B) REQUIRED PROVISIONS.—The requirements under subparagraph (A) shall provide for—

(i) the retention of all records necessary to demonstrate compliance with the good manufacturing practices and quality control procedures prescribed by the Secretary under paragraph (2), including records containing the results of all testing required under paragraph (2)(B);

(ii) the retention of all certifications or guarantees of analysis by premix suppliers;

(iii) the retention by a premix supplier of all records necessary to confirm the accuracy of all premix certifications and guarantees of analysis;

(iv) the retention of—

(I) all records pertaining to the microbiological quality and purity of raw materials used in infant formula powder and in finished infant formula; and

(II) all records pertaining to food packaging materials that show that

the materials do not cause an infant formula to be adulterated within the meaning of section 11102(a)(2)(C) of this title;

(v) the retention of all records of the results of regularly scheduled audits conducted pursuant to the requirements prescribed by the Secretary under paragraph (2)(B)(i)(IV); and

(vi) the retention of all complaints and the maintenance of files with respect to, and the review of, complaints concerning infant formulas that may reveal the possible existence of a hazard to health.

(C) DURATION OF RETENTION.—Records required under this paragraph with respect to an infant formula shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

(D) AVAILABILITY FOR REVIEW.—Except as provided in subparagraph (E), the records shall be made available to the Secretary for review and duplication on request of the Secretary.

(E) WRITTEN ASSURANCES RELATING TO AUDITS.—A manufacturer need only provide written assurances to the Secretary that the regularly scheduled audits required by paragraph (2)(B)(i)(IV) are being conducted by the manufacturer, and need not make available to the Secretary the actual written reports of the audits.

(c) REGISTRATION OF PERSONS DISTRIBUTING NEW INFANT FORMULA.—

(1) DEFINITION OF NEW INFANT FORMULA.—

(A) IN GENERAL.—In this subsection, the term ''new infant formula'' includes—

(i) an infant formula manufactured by a person that has not previously manufactured infant formula; and

(ii) an infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by the manufacturer.

(B) MAJOR CHANGE.—In this paragraph, the term ''major change'' has the meaning given the term in section 106.30(c)(2) of title

21, Code of Federal Regulations, as in effect on August 1, 1986, and guidelines issued under that section.

(2) IN GENERAL.—A person shall not introduce or deliver for introduction into interstate commerce any new infant formula unless—

(A) the person has, before introducing the new infant formula, or delivering the new infant formula for introduction, into interstate commerce, registered with the Secretary the name of the person, the place of business of the person, and all establishments at which the person intends to manufacture the new infant formula; and

(B) the person has, at least 90 days before marketing the new infant formula, made the submission to the Secretary required by subsection (d)(1).

(d) SUBMISSION OF INFORMATION ABOUT NEW INFANT FORMULA REQUIRED.—

(1) IN GENERAL.—A person shall, with respect to any infant formula subject to subsection (c), make a submission to the Secretary that includes—

(A) the quantitative formulation of the infant formula;

(B) a description of any reformulation of the formula or change in processing of the infant formula;

(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b)(1) and (i), as demonstrated by the testing required under subsection (b)(3); and

(D) assurances that the processing of the infant formula complies with subsection (b)(2).

(2) WRITTEN VERIFICATION OF TEST RESULTS AND RECORDS DEMONSTRATING COMPLIANCE.—After the first production of an infant formula subject to subsection (c), and before the introduction into interstate commerce of the formula, the manufacturer of the formula shall submit to the Secretary, in such form as may be prescribed by the Secretary, a written verification that summarizes test results and records demonstrating that the formula complies with the requirements of paragraph(1), paragraph (2)(A), subclauses (I) and (III) of paragraph (2)(B)(i), and subparagraphs (B) and (D) of paragraph (3) of subsection (b) and subsection (i).

(3) SUBMISSION BASED ON CHANGE IN FORMULA.—If the manufacturer of an infant formula for commercial or charitable distribution for human consumption determines that a change in the formulation of the formula or a change in the processing of the formula may affect whether the formula is adulterated under subsection (a), the manufacturer shall, before the first processing of the formula, make the submission to the Secretary required by paragraph (1).

(4) RESPONSE.—The Secretary shall provide a response to a submission under this subsection not later than 45 days after receiving the submission.

(e) ADDITIONAL NOTICE REQUIREMENTS FOR MANUFACTURER.—

(1) DEFINITION OF KNOWLEDGE.—In this subsection, the term ''knowledge'', as applied to a manufacturer, means—

(A) the actual knowledge that the manufacturer had; or

(B) the knowledge that a reasonable person would have had under like circumstances or that would have been obtained on the exercise of due care.

(2) NOTIFICATION.—

(A) IN GENERAL.—If the manufacturer of an infant formula has knowledge that reasonably supports the conclusion described in subparagraph (B), the manufacturer shall promptly notify the Secretary of that knowledge.

(B) CONCLUSION.—The conclusion described in this subparagraph is the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer—

(i) may not provide the nutrients required by subsection (i); or

(ii) may be otherwise adulterated or misbranded.

(3) RECALL.—If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of the infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

(f) PROCEDURES APPLICABLE TO RECALLS BY MANUFACTURER; REGULATORY OVERSIGHT.—

(1) REVIEW BY SECRETARY; REPORT BY MANUFACTURER.—If a manufacturer begins a recall of an infant formula, the manufacturer shall carry out the recall in accordance with such requirements as the Secretary shall prescribe under paragraph (2) and—

(A) the Secretary shall, not later than the 15th day after the beginning of the recall and at least once every 15 days after that day until the recall is terminated, review the actions taken under the recall to determine whether the recall meets the requirements prescribed under paragraph (2); and

(B) the manufacturer shall, not later than the 14th day after the beginning of the recall and at least once every 14 days after that day until the recall is terminated, report to the Secretary the actions taken to implement the recall.

(2) REGULATIONS.—The Secretary shall by regulation prescribe the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risks to human health presented by the formula subject to the recall.

(3) NOTICE TO PUBLIC.—The Secretary shall by regulation require each manufacturer of an infant

formula that begins a recall of the formula because of a risk to human health to request each retail establishment at which the formula is sold or available for sale to post at the point of purchase of the formula a notice of the recall at the establishment for the time that the Secretary determines necessary to inform the public of the recall.

(g) RECORDKEEPING REQUIREMENTS FOR MANUFACTURER; REGULATORY OVERSIGHT AND ENFORCEMENT.—

(1) REQUIREMENT.—

(A) IN GENERAL.—Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by the manufacturer as may be necessary to effect and monitor recalls of the formula.

(B) DURATION OF RETENTION OF RECORDS.—The records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

(2) REGULATIONS DUE TO NONCOMPLIANCE.—

(A) IN GENERAL.—To the extent that the Secretary determines that records are not being

made or maintained in accordance with paragraph (1), the Secretary may by regulation prescribe—

(i) the records required to be made under paragraph (1); and

(ii) the requirements respecting the retention of the records under paragraph (1).

(B) EFFECTIVE DATE OF REGULATIONS.—The regulations under subparagraph (A) shall take effect on such date as the Secretary prescribes but not sooner than the 180th day after the date the regulations are prescribed.

(C) APPLICABILITY OF REGULATIONS.—The regulations under subparagraph (A) shall apply only with respect to distributions of infant formulas made after the effective date under subparagraph (B).

(h) EXEMPTIONS; REGULATORY OVERSIGHT.—

(1) REQUIREMENT FOR EXEMPTION.—

(A) IN GENERAL.—Any infant formula that is represented and labeled for use by an infant described in subparagraph (B) is exempt from the requirements of subsections (a), (b), and (c).

(B) INFANT.—An infant described in this paragraph is an infant—

(i) who has an inborn error of metabolism or a low birth weight; or

(ii) who otherwise has an unusual medical or dietary problem.

(C) EFFECT OF EXEMPTION.—The manufacturer of an infant formula exempt under this paragraph shall, in the case of the exempt formula, be required to provide the notice required by subsection (e)(2) only with respect to adulteration or misbranding described in subsection (e)(2)(B)(ii) and to comply with the regulations prescribed by the Secretary under paragraph (2).

(2) REGULATIONS.—

(A) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a), (b), and (c).

(B) WITHDRAWAL OF EXEMPTION.—An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if the formula is not in compliance with applica-

ble terms and conditions prescribed under this paragraph.

(i) NUTRIENT REQUIREMENTS.—

(1) IN GENERAL.—An infant formula shall contain nutrients in accordance with the table set out in this subsection, which shall be reviewed by the Secretary every 4 years as appropriate. In reviewing the table, the Secretary shall consider any new scientific data or information related to infant formula nutrients, including international infant formula standards. The Secretary may revise the list of nutrients and the required level for any nutrient required by the table.

(2) REVISION.—The Secretary may by regulation—

(A) revise the list of nutrients in the table in this subsection; and

(B) revise the required level for any nutrient required by the table.

(3) TABLE.—The table under this subsection is the following table:

NUTRIENTS

| Nutrient | Minimum[a] | Maximum[a] |
|---|---|---|
| Protein (gm) | 1.8[b] | 4.5. |
| Fat: | | |
| gm | 3.3 | 6.0. |
| percent cal | 30.0 | 54.0. |
| Essential fatty acids (linoleate): | | |
| percent cal | 2.7 | |
| mg | 300.0 | |
| Vitamins: | | |
| A (IU) | 250.0 (75 µg)[c] | 750.0 (225 µg).[c] |
| D (IU) | 40.0 | 100.0. |

NUTRIENTS—Continued

| Nutrient | Minimum[a] | Maximum[a] |
|---|---|---|
| K (µg) | 4.0 | |
| E (IU) | 0.7 (with 0.7 IU/gm linoleic acid) | |
| C (ascorbic acid) (mg) | 8.0 | |
| $B_1$ (thiamine) (µg) | 40.0 | |
| $B_2$ (riboflavin) (µg) | 60.0 | |
| $B_6$ (pyridoxine) (µg) | 35.0 (with 15 µg/gm of protein in formula) | |
| $B_{12}$ (µg) | 0.15 | |
| Niacin (µg) | 250.0 | |
| Folic acid (µg) | 4.0 | |
| Pantothenic acid (µg) | 300.0 | |
| Biotin (µg) | 1.5[d] | |
| Choline (mg) | 7.0[d] | |
| Inositol (mg) | 4.0[d] | |
| Minerals: | | |
| Calcium (mg) | 50.0[e] | |
| Phosphorus (mg) | 25.0[e] | |
| Magnesium (mg) | 6.0 | |
| Iron (mg) | 0.15 | |
| Iodine (µg) | 5.0 | |
| Zinc (mg) | 0.5 | |
| Copper (µg) | 60.0 | |
| Manganese (µg) | 5.0 | |
| Sodium (mg) | 20.0 | 60.0. |
| Potassium (mg) | 80.0 | 200.0. |
| Chloride (mg) | 55.0 | 150.0 |

[a]Stated per 100 kilocalories.

[b]The source of protein shall be at least nutritionally equivalent to casein.

[c]Retinol equivalents.

[d]Required to be included in this amount only in formulas which are not milk-based.

[e]Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.

(j) PREMARKET SUBMISSIONS TO ADDRESS SHORTAGES.—

(1) IN GENERAL.—The Secretary shall waive the 90-day premarket submission requirement under subsection (c) and apply a 30-day premarket submission requirement for any person that intends to introduce or deliver for introduction into interstate commerce any new infant formula.

(2) EFFECTIVE PERIOD.—The waiver authority under this subsection shall remain in effect—

(A) for 90 days beginning on the date that the Secretary distributes information under sec-

tion 11126(a)(3) of this title with respect to a shortage of infant formula; or

(B) such longer period as the Secretary determines appropriate, to prevent or mitigate a shortage of infant formula.

(k) CONGRESSIONAL NOTIFICATION OF RECALL.—

(1) IN GENERAL.—Not later than 24 hours after the initiation of a recall of infant formula as described in subsection (e), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a notification of the recall.

(2) CONTENTS.—A notification under paragraph (1) shall include the following:

(A) If the recall is required by the FDA, a summary of the information supporting a determination that the adulterated or misbranded infant formula presents a risk to human health.

(B) If the recall is voluntarily initiated by the manufacturer, a summary of the information provided to the FDA by the manufacturer regarding infant formula that has left the control of the manufacturer that may be adulterated or misbranded.

(C) Specification of when the FDA was first made aware of the instance or circumstances surrounding the recall.

(D) An initial estimate of the disruption in domestic production that may result from the recall.

(l) ANNUAL REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than March 30 of each year, the Secretary shall submit a report to Congress containing, with respect to the preceding calendar year, the following information:

(A) The number of submissions received by the Secretary under subsection (d).

(B) The number of the submissions described in subparagraph (A) that included any new ingredients that were not included in any infant formula already on the market.

(C) The number of inspections conducted by the FDA or any agent of the FDA to evaluate compliance with the requirements for infant formulas under subsection (b).

(D) The time between any inspection referred to in subparagraph (C) and any necessary reinspection to evaluate compliance with

the requirements for infant formulas under subsection (b).

(E) A breakdown of the information described in subparagraphs (A) through (D) between foreign and domestic manufacturers and facilities.

(2) CONFIDENTIALITY.—The Secretary shall ensure that the reports under paragraph (1) do not include any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(m) WAIVER OF REQUIREMENTS FOR IMPORTATION OF SPECIALTY INFANT FORMULA.—

(1) DEFINITION OF SPECIALTY INFANT FORMULA.—In this subsection, the term ''specialty infant formula'' means infant formula described in subsection (h)(1).

(2) IN GENERAL.—The Secretary may, during a shortage of specialty infant formula as determined by the Secretary, waive any requirement under this subtitle applicable to facilitate the importation of specialty infant formula. The waiver may be applicable to—

(A) the importation of specialty infant formula from any country that is determined by

the Secretary to be implementing and enforcing requirements for infant formula that provide a similar assurance of safety and nutritional adequacy as the requirements of this subtitle; or

(B) the distribution and sale of the imported specialty infant formula.

(3) RULE OF CONSTRUCTION.—Nothing in paragraph (2) shall be construed to limit the authority of the Secretary to require a recall of, or otherwise impose restrictions and requirements under this subtitle with respect to, specialty infant formula that is subject to a waiver under paragraph (2).

**§ 11115. New dietary ingredients**

(a) DEFINITION OF NEW DIETARY INGREDIENT.—In this section, the term ''new dietary ingredient'' means a dietary ingredient that was not marketed in the United States before October 15, 1994, and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.

(b) REQUIREMENTS FOR NOT BEING DEEMED ADULTERATED.—

(1) IN GENERAL.—A dietary supplement that contains a new dietary ingredient shall be deemed adulterated under section 11102(f) of this title unless it meets one of the following requirements:

(A) CONTAINS ONLY CERTAIN DIETARY INGREDIENTS.—The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(B) EXISTENCE OF EVIDENCE OF SAFETY.—There is a history of use or other evidence of safety establishing that the dietary ingredient—

(i) when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe; and

(ii) at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing the dietary ingredient will reasonably be expected to be safe.

(2) CONFIDENTIALITY FOR 90 DAYS.—The Secretary shall keep confidential any information provided under paragraph (1)(B) for 90 days following receipt of the information.

(3) PUBLIC DISPLAY FOLLOWING CONFIDENTIALITY.—After the expiration of the 90 days under paragraph (2), the Secretary shall place the information described in paragraph (2) on public display, except matters in the information that are trade secrets or otherwise confidential, commercial information.

(c) PETITION FOR ORDER RELATING TO SAFETY.—

(1) FILING.—Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe.

(2) DECISION PERIOD.—The Secretary shall make a decision on the petition within 180 days of the date the petition is filed with the Secretary.

(3) DECISION AS FINAL AGENCY ACTION.—For purposes of chapter 7 of title 5, the decision of the Secretary shall be considered final agency action.

(d) NOTIFICATION RELATING TO ANABOLIC STEROID.—

(1) DEFINITIONS.—In this subsection:

(A) ANABOLIC STEROID.—The term ''anabolic steroid'' has the meaning given the term in section 50101 of this title.

(B) ANALOGUE OF AN ANABOLIC STEROID.—The term ''analogue of an anabolic steroid'' means a substance whose chemical structure is substantially similar to the chemical structure of an anabolic steroid.

(2) IN GENERAL.—If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to establish that a dietary supplement containing the article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid, the Secretary shall notify the Drug Enforcement Administration of the determination.

(3) INCLUSIONS.—The notification by the Secretary shall include, at a minimum—

(A) the name of the dietary supplement or article;

(B) the name of the person or persons that marketed the product or made the submission

of information regarding the article to the Secretary under this section; and

(C) any contact information for the person or persons that the Secretary has.

(e) GUIDANCE.—Not later than 180 days after January 4, 2011, the Secretary shall publish guidance that clarifies—

(1) when a dietary supplement ingredient is a new dietary ingredient;

(2) when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in subsection (b)(1)(B);

(3) the evidence needed to document the safety of new dietary ingredients; and

(4) appropriate methods for establishing the identity of a new dietary ingredient.

**§ 11116. Maintenance and inspection of records**

(a) RECORDS INSPECTION.—

(1) ADULTERATED FOOD.—If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or

animals, each person (excluding farms and restaurants) that manufactures, processes, packs, distributes, receives, holds, or imports the article shall, at the request of an officer or employee designated by the Secretary, permit the officer or employee, on presentation of appropriate credentials and a written notice to the person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to the article (and to have access to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner) that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

(2) USE OF OR EXPOSURE TO FOOD OF CONCERN.—If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) that manufactures, processes, packs, distributes, receives,

holds, or imports the article shall, at the request of an officer or employee designated by the Secretary, permit the officer or employee, on presentation of appropriate credentials and a written notice to the person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to the article (and to have access to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner) that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.

(3) APPLICABILITY.—The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of the article maintained by or on behalf of the person in any format (including paper and electronic formats) and at any location.

(b) REGULATIONS CONCERNING RECORDKEEPING.—

(1) AUTHORITY TO ESTABLISH RECORDKEEPING REQUIREMENTS BY REGULATION.—The Secretary, in consultation and coordination, as ap-

propriate, with other Federal agencies with responsibilities for regulating food safety, may by regulation establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) that manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, to address credible threats of serious adverse health consequences or death to humans or animals.

(2) SIZE OF BUSINESS AS A FACTOR.—The Secretary shall take into account the size of a business in promulgating regulations under this subsection.

(c) PROTECTION OF SENSITIVE INFORMATION.—The Secretary shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.

(d) LIMITATIONS.—This section shall not be construed—

(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this subtitle;

(2) to authorize the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to chapters 303, 313, and 317 of this title;

(3) to have any legal effect on section 552 of title 5 or section 1905 of title 18; or

(4) to extend to recipes for food, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

**§ 11117. Registration of food facilities**

(a) DEFINITIONS.—

(1) DOMESTIC FACILITY.—The term ''domestic facility'' means a facility located in any State or territory of the United States.

(2) FACILITY.—

(A) INCLUSIONS.—The term ''facility'' includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food.

(B) EXCLUSIONS.—The term ''facility'' does not include—

(i) farms;

(ii) restaurants or other retail food establishments;

(iii) nonprofit food establishments in which food is prepared for or served directly to the consumer; or

(iv) fishing vessels (except vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

(3) FOREIGN FACILITY.—

(A) DEFINITION.—The term ''foreign facility'' means a facility that manufactures, processes, packs, or holds food, but only if food from the facility is exported to the United States without further processing or packaging outside the United States.

(B) FURTHER PROCESSING OR PACKAGING.—A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any simi-

lar activity of a de minimis nature was carried out with respect to the food.

(b) REGISTRATION.—

(1) REQUIREMENT TO REGISTER.—

(A) IN GENERAL.—The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary.

(B) DOMESTIC AND FOREIGN FACILITIES.—To be registered—

(i) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and

(ii) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

(2) SUBMISSIONS.—

(A) IN GENERAL.—An entity (referred to in this section as the ''registrant'') shall submit

a registration under paragraph (1) to the Secretary containing—

(i) information necessary to notify the Secretary of—

(I) the name and address of each facility at which the registrant conducts business; and

(II) all trade names under which the registrant conducts business;

(ii) the e-mail address for the contact person of the facility or, in the case of a foreign facility, the United States agent for the facility; and

(iii) when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations, or any other food categories as determined appropriate by the Secretary, including by guidance) of any food manufactured, processed, packed, or held at the facility.

(B) ASSURANCE.—The registration shall contain an assurance that the Secretary will be

permitted to inspect the facility at the times and in the manner permitted by this subtitle.

(C) NOTIFICATIONS RELATING TO CHANGES TO INFORMATION.—The registrant shall notify the Secretary in a timely manner of changes to the information submitted under this paragraph.

(3) BIENNIAL REGISTRATION RENEWAL.—

(A) IN GENERAL.—During the period beginning on October 1 and ending on December 31 of each even-numbered year, a registrant that has submitted a registration under paragraph (1) shall submit to the Secretary a renewal registration containing the information described in paragraph (2).

(B) ABBREVIATED PROCESS.—The Secretary shall provide for an abbreviated registration renewal process for any registrant that has not had any changes to the information since the registrant submitted the preceding registration or registration renewal for the facility involved.

(4) NOTIFICATION OF RECEIPT; ASSIGNMENT OF REGISTRATION NUMBER.—On receipt of a completed registration described in paragraph (1), the

Secretary shall notify the registrant of the receipt of the registration and assign a registration number to each registered facility.

(5) LIST.—

(A) COMPILATION AND MAINTENANCE.—The Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section.

(B) DISCLOSURE UNDER SECTION 552 OF TITLE 5.—

(i) LIST AND REGISTRATION DOCUMENTS.—The list and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5.

(ii) INFORMATION DERIVED RELATING TO SPECIFIC REGISTERED PERSON.—Information derived from the list or registration documents shall not be subject to disclosure under section 552 of title 5 to the extent that it discloses the identity or location of a specific registered person.

(c) SUSPENSION OF REGISTRATION.—

(1) IN GENERAL.—If the Secretary determines that food manufactured, processed, packed, received,

or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the Secretary may by order suspend the registration of a facility—

(A) that created, caused, or was otherwise responsible for the reasonable probability; or

(B) that—

(i) knew of, or had reason to know of, the reasonable probability; and

(ii) packed, received, or held the food.

(2) HEARING ON SUSPENSION.—The Secretary shall provide the registrant subject to an order under paragraph (1) with an opportunity for an informal hearing, to be held as soon as possible but not later than 2 business days after the issuance of the order or such other time period, as agreed on by the Secretary and the registrant, on—

(A) the actions required for reinstatement of registration; and

(B) why the registration that is subject to suspension should be reinstated.

(3) REINSTATEMENT.—The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds

do not exist to continue the suspension of the registration.

(4) POST-HEARING CORRECTIVE ACTION PLAN; VACATING OF ORDER.—

(A) CORRECTIVE ACTION PLAN.—

(i) SUBMISSION.—If, after providing opportunity for an informal hearing under paragraph (2), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary.

(ii) REVIEW.—The Secretary shall review the corrective action plan not later than 14 days after submission under clause (i) or such other time period as determined by the Secretary.

(B) VACATING OR MODIFICATION OF ORDER.—On a determination by the Secretary that adequate grounds do not exist to continue the suspension actions required by the order, or that the actions should be modified, the Secretary shall promptly vacate the order and rein-

state the registration of the facility subject to the order or modify the order, as appropriate.

(5) EFFECT OF SUSPENSION.—If the registration of a facility is suspended under this subsection, a person shall not—

(A) import or export food into the United States from the facility;

(B) offer to import or export food into the United States from the facility; or

(C) otherwise introduce food from the facility into interstate or intrastate commerce in the United States.

(6) REGULATIONS.—

(A) IN GENERAL.—The Secretary shall promulgate regulations to implement this subsection. The Secretary may promulgate the regulations on an interim final basis.

(B) AUTHORITY TO REQUIRE SUBMISSION OF REGISTRATION IN ELECTRONIC FORMAT.—The Secretary may require that registration under this section be submitted in electronic format.

(C) SMALL ENTITY COMPLIANCE POLICY GUIDE.—The Secretary shall issue a small entity compliance policy guide setting forth in plain

language the requirements of the regulations under this paragraph to assist small entities in complying with registration requirements and other activities required under this paragraph.

(7) NO DELEGATION.—The authority conferred by this subsection to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process for a facility to be registered, except with respect to the reinstatement of a registration that is suspended under subsection (c).

**§ 11118. Sanitary transportation practices**

(a) DEFINITIONS.—In this section:

(1) BULK VEHICLE.—The term ''bulk vehicle'' includes a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, and hopper bin, and any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

(2) TRANSPORTATION.—The term ''transportation'' means any movement in commerce by motor vehicle or rail vehicle.

(b) REGULATIONS.—The Secretary shall by regulation require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.

(c) CONTENTS.—The regulations under subsection (b) shall—

(1) prescribe such practices as the Secretary determines to be appropriate relating to—

(A) sanitation;

(B) packaging, isolation, and other protective measures;

(C) limitations on the use of vehicles;

(D) information to be disclosed—

(i) to a carrier by a person arranging for the transport of food; and

(ii) to a manufacturer or other person that—

(I) arranges for the transportation of food by a carrier; or

(II) furnishes a tank vehicle or bulk vehicle for the transportation of food; and

(E) recordkeeping; and

(2) include—

(A) a list of nonfood products that the Secretary determines may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle; and

(B) a list of nonfood products that the Secretary determines may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), render adulterated food that is simultaneously or subsequently transported in the same vehicle.

(d) WAIVERS.—

(1) IN GENERAL.—The Secretary may waive any requirement under this section, with respect to any class of persons, vehicles, food, or nonfood products, if the Secretary determines that the waiver—

(A) will not result in the transportation of food under conditions that would be unsafe for human or animal health; and

(B) will not be contrary to the public interest.

(2) PUBLICATION.—The Secretary shall publish in the Federal Register any waiver and the reasons for the waiver.

(e) PREEMPTION.—

(1) IN GENERAL.—A requirement of a State or political subdivision of a State that concerns the transportation of food is preempted if—

(A) complying with a requirement of the State or political subdivision and a requirement of this section, or a regulation prescribed under this section, is not possible; or

(B) the requirement of the State or political subdivision as applied or enforced is an obstacle to accomplishing and carrying out this section or a regulation prescribed under this section.

(2) APPLICABILITY.—This subsection applies to transportation that occurs on or after the effective date of the regulations promulgated under subsection (b).

(f) ASSISTANCE OF OTHER AGENCIES.—The Secretary of Transportation, the Secretary of Agriculture, the Administrator, and the heads of other Federal agencies, as appropriate, shall provide assistance on request, to the

extent resources are available, to the Secretary for the purposes of carrying out this section.

**§ 11119. Reportable food registry**

(a) DEFINITIONS.—In this section:

(1) REPORTABLE FOOD.—The term ''reportable food'' means an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, the article of food will cause serious adverse health consequences or death to humans or animals.

(2) RESPONSIBLE PARTY.—The term ''responsible party'', with respect to an article of food, means a person that submits the registration under section 11117(b) of this title for a food facility that is required to register under section 11117(b) of this title, at which the article of food is manufactured, processed, packed, or held.

(b) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish within the FDA a Reportable Food Registry to which instances of reportable food may be submitted by the FDA after receipt of reports under subsection (d), via an electronic portal, from—

(A) Federal, State, and local public health officials; or

(B) responsible parties.

(2) REVIEW BY SECRETARY.—The Secretary shall promptly review and assess the information submitted under paragraph (1) for the purposes of—

(A) identifying reportable food;

(B) submitting entries to the Reportable Food Registry;

(C) acting under subsection (c); and

(D) exercising other existing food safety authorities under this subtitle to protect the public health.

(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

(1) IN GENERAL.—The Secretary shall issue, or cause to be issued, an alert or a notification with respect to a reportable food using information from the Reportable Food Registry as the Secretary considers necessary to protect the public health.

(2) EFFECT.—Paragraph (1) shall not affect the authority of the Secretary to issue an alert or a notification under any other provision of this subtitle.

(d) REPORTING AND NOTIFICATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), as soon as practicable, but not later than

24 hours after a responsible party determines that an article of food is a reportable food, the responsible party shall—

(A) submit a report to the FDA through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) (except the elements described in paragraphs (8), (9), and (10) of subsection (e)); and

(B) investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

(2) NO REPORT REQUIRED.—A responsible party is not required to submit a report under paragraph (1) if—

(A) the adulteration originated with the responsible party;

(B) the responsible party detected the adulteration prior to any transfer to another person of the article of food; and

(C) the responsible party—

(i) corrected the adulteration; or

(ii) destroyed or caused the destruction of the article of food.

(3) REPORTS BY PUBLIC HEALTH OFFICIALS.—A Federal, State, or local public health official may submit a report about a reportable food to the FDA through the electronic portal established under subsection (b) that includes the data elements described in subsection (e) that the official is able to provide.

(4) REPORT NUMBER.—The Secretary shall ensure that, on submission of a report under paragraph (1) or (3), a unique number is issued through the electronic portal established under subsection (b) to the person submitting the report, by which number the Secretary is able to—

(A) link reports about the reportable food submitted and amended under this subsection; and

(B) identify the supply chain for the reportable food.

(5) REVIEW.—The Secretary shall promptly review a report submitted under paragraph (1) or (3).

(6) RESPONSE TO REPORT SUBMITTED BY A RESPONSIBLE PARTY.—After consultation with the responsible party that submitted a report under paragraph (1), the Secretary may require the responsible party to do, as soon as practicable, but not

later than a time specified by the Secretary, 1 or more of the following:

(A) Amend the report submitted by the responsible party under paragraph (1) to include the data element described in subsection (e)(9).

(B) Provide a notification—

(i) to the immediate previous source of the article of food, if the Secretary considers necessary;

(ii) to the immediate subsequent recipient of the article of food, if the Secretary considers necessary; and

(iii) that includes—

(I) the data elements described in subsection (e) that the Secretary considers necessary;

(II) the actions described under paragraph (7) that the recipient of the notification shall perform, as required by the Secretary; and

(III) any other information that the Secretary may require.

(7) SUBSEQUENT REPORTS AND NOTIFICATIONS.—Except as provided in paragraph (8), the Secretary may require a responsible party to do, as

soon as practicable, but not later than a time specified by the Secretary, after the responsible party receives a notification under subparagraph (C) or paragraph (6)(B), 1 or more of the following:

(A) Submit a report to the FDA through the electronic portal established under subsection (b) that includes those data elements described in subsection (e) and other information that the Secretary considers necessary.

(B) Investigate the cause of the adulteration if the adulteration of the article of food may have originated with the responsible party.

(C) Provide a notification—

(i) to the immediate previous source of the article of food, if the Secretary considers necessary;

(ii) to the immediate subsequent recipient of the article of food, if the Secretary considers necessary; and

(iii) that includes—

(I) the data elements described in subsection (e) that the Secretary considers necessary;

(II) the actions described under this paragraph that the recipient of

the notification shall perform, as required by the Secretary; and

(III) any other information that the Secretary may require.

(8) AMENDED REPORT.—If a responsible party receives a notification under paragraph (6)(B) or (7)(C) with respect to an article of food after the responsible party has submitted a report to the FDA under paragraph (1) with respect to the article of food—

(A) the responsible party is not required to submit an additional report or make a notification under paragraph (7); and

(B) the responsible party shall amend the report submitted by the responsible party under paragraph (1) to include the data elements described in subsection (e)(9), and, with respect to both the notification and the report, subsection (e)(11).

(e) DATA ELEMENTS.—The data elements described in this subsection are the following:

(1) The registration numbers of the responsible party under section 11117(b)(4) of this title.

(2) The date on which an article of food was determined to be a reportable food.

(3) A description of the article of food, including the quantity or amount.

(4) The extent and nature of the adulteration.

(5) If the adulteration of the article of food may have originated with the responsible party, the results of the investigation required under paragraph (1)(B) or (7)(B) of subsection (d), as applicable and when known.

(6) The disposition of the article of food, when known.

(7) Product information typically found on packaging including product codes, use-by dates, and names of manufacturers, packers, or distributors sufficient to identify the article of food.

(8) Contact information for the responsible party.

(9) The contact information for parties directly linked in the supply chain and notified under paragraph (6)(B) or (7)(C) of subsection (d), as applicable.

(10) The information required by the Secretary to be included in a notification provided by the responsible party involved under paragraph (6)(B) or (7)(C) of subsection (d) or required in a report under subsection (d)(7)(A).

(11) The unique number described in subsection (d)(4).

(f) CRITICAL INFORMATION.—Except with respect to fruits and vegetables that are raw agricultural commodities, not more than 18 months after January 4, 2011, the Secretary may require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food, which shall include—

(1) a description of the article of food as provided in subsection (e)(3);

(2) as provided in subsection (e)(7), affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient for the consumer to identify the article of food;

(3) contact information for the responsible party as provided in subsection (e)(8); and

(4) any other information the Secretary determines is necessary to enable a consumer to accurately identify whether the consumer is in possession of the reportable food.

(g) GROCERY STORE NOTIFICATION.—

(1) ACTION BY SECRETARY.—The Secretary shall—

(A) prepare the critical information described under subsection (f) for a reportable food as a standardized 1-page summary; and

(B) publish the 1-page summary on the FDA website in a format that can be easily printed by a grocery store for purposes of consumer notification.

(2) ACTION BY GROCERY STORE.—A notification described under paragraph (1)(B) printed by a grocery store shall include the date and time the summary was posted on the FDA website.

(h) CONSUMER NOTIFICATION.—

(1) IN GENERAL.—If a grocery store sold a reportable food that is the subject of the posting and the establishment is part of a chain of establishments with 15 or more physical locations, the establishment shall, not later than 24 hours after a 1-page summary described in subsection (g) is published, prominently display the summary or the information from the summary via at least one of the methods identified under paragraph (2) and maintain the display for 14 days.

(2) LIST OF CONSPICUOUS LOCATIONS.—

(A) IN GENERAL.—Not more than 1 year after January 4, 2011, the Secretary shall de-

velop and publish a list of acceptable conspicuous locations and manners, from which grocery stores shall select at least 1, for providing the notification required in paragraph (1).

(B) CONTENTS.—The list under subparagraph (A) shall include—

(i) posting the notification at or near the register;

(ii) providing the location of the reportable food;

(iii) providing targeted recall information given to customers on purchase of a food; and

(iv) other such prominent and conspicuous locations and manners utilized by grocery stores as of January 4, 2011, to provide notice of the recalls to consumers as considered appropriate by the Secretary.

(i) COORDINATION OF FEDERAL, STATE, AND LOCAL EFFORTS.—

(1) DEPARTMENT OF AGRICULTURE.—In implementing this section, the Secretary shall—

(A) share information and coordinate regulatory efforts with the Department of Agriculture; and

(B) if the Secretary receives a report submitted about a food within the jurisdiction of the Department of Agriculture, promptly provide the report to the Department of Agriculture.

(2) STATES AND LOCALITIES.—In implementing this section, the Secretary shall work with State and local public health officials to share information and coordinate regulatory efforts, to—

(A) help to ensure coverage of the safety of the food supply chain, including those food establishments regulated by the States and localities that are not required to register under section 11117 of this title; and

(B) reduce duplicative regulatory efforts.

(j) MAINTENANCE AND INSPECTION OF RECORDS.—

(1) MAINTENTANCE.—The responsible party shall maintain records related to each report received, notification made, and report submitted to the FDA under this section for 2 years.

(2) INSPECTION.—A responsible party shall, at the request of the Secretary, permit inspection of the

records maintained under paragraph (1) as provided for in section 11116 of this title.

(k) REQUEST FOR INFORMATION.—Except as provided by section 11117(b)(5) of this title, section 552 of title 5 shall apply to any request for information regarding a record in the Reportable Food Registry.

(l) SAFETY REPORT.—A report or notification under subsection (d) shall be considered to be a safety report under section 18701 of this title and may be accompanied by a statement, which shall be part of any report released for public disclosure, that denies that the report or the notification constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness.

(m) ADMISSION.—A report or notification under this section shall not be considered an admission that the article of food involved is adulterated or caused or contributed to a death, serious injury, or serious illness.

(n) HOMELAND SECURITY NOTIFICATION.—

(1) IN GENERAL.—If, after receiving a report under subsection (d), the Secretary believes the food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security.

(2) AVAILABILITY OF INFORMATION FROM REPORTABLE FOOD REGISTRY.—The Secretary shall make relevant information from the Reportable Food Registry available to the Secretary of Homeland Security.

(o) GUIDANCE.—The Secretary shall issue a guidance to industry about submitting reports to the electronic portal established under this section and providing notifications to other persons in the supply chain of an article of food under this section.

**§ 11120. Hazard analysis and risk-based preventive controls**

(a) DEFINITIONS.—In this section:

(1) CRITICAL CONTROL POINT.—The term ''critical control point'' means a point, step, or procedure in a food process at which control—

(A) can be applied; and

(B) is essential to prevent or eliminate a food safety hazard or reduce the hazard to an acceptable level.

(2) FACILITY.—The term ''facility'' means a domestic facility or a foreign facility that is required to register under section 11117 of this title.

(3) PREVENTIVE CONTROLS.—

(A) IN GENERAL.—The term ''preventive controls'' means those risk-based, reasonably appropriate procedures, practices, and processes—

(i) that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (c); and

(ii) that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the hazard analysis.

(B) INCLUSIONS.—The procedures, practices, and processes under subparagraph (A) may include—

(i) sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment;

(ii) supervisor, manager, and employee hygiene training;

(iii) an environmental monitoring program to verify the effectiveness of pathogen controls in processes in which a food

is exposed to a potential contaminant in the environment;

(iv) a food allergen control program;

(v) a recall plan;

(vi) current good manufacturing practices under part 110 of title 21, Code of Federal Regulations (or any successor regulations); or

(vii) supplier verification activities that relate to the safety of food.

(b) IN GENERAL.—The owner, operator, or agent in charge of a facility shall, in accordance with this section—

(1) evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility;

(2) identify and implement preventive controls to significantly minimize or prevent the occurrence of the hazards and provide assurances that the food is not adulterated under section 11102 of this title or misbranded under section 11323 of this title;

(3) monitor the performance of the preventive controls implemented under paragraph (2); and

(4) maintain records of the monitoring under paragraph (3) as a matter of routine practice.

(c) HAZARD ANALYSIS.—The owner, operator, or agent in charge of a facility shall—

(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and

(B) hazards that occur naturally, or may be unintentionally introduced;

(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and

(3) develop a written analysis of the hazards.

(d) PREVENTIVE CONTROLS.—The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

(1) hazards identified in the hazard analysis conducted under subsection (c)(1) will be significantly minimized or prevented;

(2) any hazards identified in the hazard analysis conducted under subsection (c)(2) will be significantly minimized or prevented and addressed,

consistent with section 11122 of this title, as applicable; and

(3) the food manufactured, processed, packed, or held by the facility will not be adulterated under section 11102 of this title or misbranded under section 11323 of this title.

(e) MONITORING OF EFFECTIVENESS.—The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (d) to provide assurances that the outcomes described in subsection (d) shall be achieved.

(f) CORRECTIVE ACTIONS.—The owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under subsection (d) are not properly implemented or are found to be ineffective—

(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;

(2) all affected food is evaluated for safety; and

(3) all affected food is prevented from entering into commerce if the owner, operator, or agent in charge of the facility cannot ensure that the affected food is not adulterated under section 11102 of this title or misbranded under section 11323 of this title.

(g) VERIFICATION.—The owner, operator, or agent in charge of a facility shall verify that—

(1) the preventive controls implemented under subsection (d) are adequate to control the hazards identified under subsection (c);

(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (e);

(3) the owner, operator, or agent is making appropriate decisions about corrective actions taken under subsection (f);

(4) the preventive controls implemented under subsection (d) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and

(5) there is documented, periodic reanalysis of the plan under subsection (j) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats.

(h) RECORDKEEPING.—The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting—

(1) the monitoring of the preventive controls implemented under subsection (d);

(2) instances of nonconformance material to food safety;

(3) the results of testing and other appropriate means of verification under subsection (g)(4);

(4) instances when corrective actions were implemented; and

(5) the efficacy of preventive controls and corrective actions.

(i) WRITTEN PLAN AND DOCUMENTATION.—

(1) IN GENERAL.—The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with this section, including analyzing the hazards under subsection (c) and identifying the preventive controls adopted under subsection (d) to address those hazards.

(2) AVAILABILITY.—The written plan under paragraph (1), together with the documentation described in subsection (h), shall be made promptly available to an authorized representative of the Secretary on oral or written request.

(j) REQUIREMENT TO REANALYZE.—

(1) FREQUENCY.—The owner, operator, or agent in charge of a facility shall conduct a reanalysis under subsection (c) whenever a significant change is made in the activities conducted at a facility operated by the owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier.

(2) CONDITIONS BEFORE CHANGE IN ACTIVITIES IS OPERATIVE.—The reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities under paragraph (1) at the facility is operative.

(3) DOCUMENTATION.—The owner, operator, or agent shall—

(A) revise the written plan required under subsection (i) if a significant change under this subsection is made; or

(B) document the basis for the conclusion that no additional or revised preventive controls are needed.

(4) REANALYSIS BASED ON NEW HAZARDS AND DEVELOPMENTS.—The Secretary may require a rea-

nalysis under this section to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

(k) EXEMPTION FOR SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES SUBJECT TO HACCP.—

(1) IN GENERAL.—This section shall not apply to a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, one of the following standards and regulations with respect to the facility:

(A) The Seafood Hazard Analysis Critical Control Points Program of the FDA.

(B) The Juice Hazard Analysis Critical Control Points Program of the FDA.

(C) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the FDA (or any successor standards).

(2) APPLICABILITY.—The exemption under paragraph (1)(C) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers under

part 113 of title 21, Code of Federal Regulations (or any successor regulations).

(l) EXCEPTION FOR ACTIVITIES OF FACILITIES SUBJECT TO SECTION 11121 OF THIS TITLE.—This section shall not apply to activities of a facility that are subject to section 11121 of this title.

(m) MODIFIED REQUIREMENTS FOR QUALIFIED FACILITIES.—

(1) DEFINITIONS.—In this subsection:

(A) AFFILIATE.—The term ''affiliate'' means any facility that controls, is controlled by, or is under common control with another facility.

(B) QUALIFIED END-USER.—

(i) IN GENERAL.—The term ''qualified end-user'', with respect to a food, means—

(I) the consumer of the food; or

(II) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 11117 of this title) that—

(aa) is located—

(AA) in the same State as the qualified facility that

sold the food to the restaurant or establishment; or

(BB) not more than 275 miles from the facility; and

(bb) is purchasing the food for sale directly to consumers at the restaurant or retail food establishment.

(ii) CONSUMER.—For the purposes of clause (i), the term ''consumer'' does not include a business.

(C) SUBSIDIARY.—The term ''subsidiary'' means any company that is owned or controlled directly or indirectly by another company.

(2) QUALIFIED FACILITIES.—

(A) IN GENERAL.—A facility is a qualified facility for purposes of this subsection if the facility meets the conditions under subparagraph (B) or (C).

(B) VERY SMALL BUSINESS.—A facility is a qualified facility under this subparagraph—

(i) if the facility, including any subsidiary or affiliate of the facility, is, collectively, a very small business (as defined in

the regulations promulgated under subsection (o)); and

(ii) in a case in which the facility is a subsidiary or affiliate of an entity, if the subsidiaries or affiliates, are, collectively, a very small business (as defined in the regulations promulgated under subsection (o)).

(C) LIMITED ANNUAL MONETARY VALUE OF SALES.—

(i) IN GENERAL.—A facility is a qualified facility under this subparagraph if clause (ii) applies—

(I) to the facility, including any subsidiary or affiliate of the facility, collectively; and

(II) to the subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate.

(ii) AVERAGE ANNUAL MONETARY VALUE.—This clause applies if—

(I) during the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed,

packed, or held at the facility (or the collective average annual monetary value of the food at any subsidiary or affiliate, as described in clause (i)) that is sold directly to qualified end-users during the period exceeded the average annual monetary value of the food manufactured, processed, packed, or held at the facility (or the collective average annual monetary value of the food at any subsidiary or affiliate, as described in clause (i)) sold by the facility (or collectively by any such subsidiary or affiliate) to all other purchasers during the period; and

(II) the average annual monetary value of all food sold by the facility (or the collective average annual monetary value of the food sold by any subsidiary or affiliate, as described in clause (i)) during the period was less than $500,000, adjusted for inflation.

(3) EXEMPTION.—A qualified facility—

(A) shall not be subject to the requirements under subsections (b) through (j) and

subsection (o) in an applicable calendar year; and

(B) shall submit to the Secretary—

(i)(I) documentation that demonstrates that the owner, operator, or agent in charge of the facility—

(aa) has identified potential hazards associated with the food being produced;

(bb) is implementing preventive controls to address the hazards; and

(cc) is monitoring the preventive controls to ensure that the controls are effective; or

(II) documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law; and

(ii) documentation, as specified by the Secretary in a guidance document, that the

facility is a qualified facility under subparagraph (B) or (C) of paragraph (2).

(4) WITHDRAWAL OF EXEMPTION.—In the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under this subsection, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at the facility, the Secretary may withdraw the exemption provided to the facility under this subsection.

(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.

(6) NONPREEMPTION.—

(A) IN GENERAL.—This subsection does not preempt any State, local, county, or other non-Federal law regarding the safe production of food.

(B) EFFECT OF COMPLIANCE.—Compliance with this subsection shall not relieve any

person from liability at common law or under State statutory law.

(7) NOTIFICATION TO CONSUMERS.—

(A) IN GENERAL.—A qualified facility that is exempt from the requirements under subsections (b) through (j) and subsection (o) and does not prepare documentation under paragraph (3)(B)(i)(I) shall—

(i) with respect to a food for which a food packaging label is required by the Secretary under any other provision of this subtitle, include prominently and conspicuously on the label the name and business address of the facility where the food was manufactured or processed; or

(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provision of this subtitle, prominently and conspicuously display, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of internet sales, in an electronic notice, the name and business address of the

facility where the food was manufactured or processed.

(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this subtitle.

(n) AUTHORITY WITH RESPECT TO CERTAIN FACILITIES.—The Secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in—

(1) the production of food for animals other than humans;

(2) the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing; or

(3) the storage of packaged foods that are not exposed to the environment.

(o) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall promulgate regulations—

(A) to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation

of the preventive controls under this section; and

(B) to define, for purposes of this section, the terms ''small business'' and ''very small business'', taking into consideration the study described in section 418(l)(5)(A) of the Federal Food, Drug, and Cosmetic Act (ch. 675), as added by section 103(a) of the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3894).

(2) FACTORS TO CONSIDER IN DEFINING TERMS.—In defining the terms under paragraph (1)(B), the Secretary shall include consideration of harvestable acres, income, the number of employees, and the volume of food harvested.

(3) COORDINATION.—In promulgating the regulations under paragraph (1)(A), with regard to hazards that may be intentionally introduced, including by acts of terrorism, the Secretary shall coordinate with the Secretary of Homeland Security, as appropriate.

(4) CONTENT.—The regulations promulgated under paragraph (1)(A) shall—

(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, in-

cluding small businesses such as a small food processing facility co-located on a farm;

(B) comply with chapter 35 of title 44 (commonly known as the ''Paperwork Reduction Act''), with special attention to minimizing the burden (as defined in section 3502(2) of title 44) on the facility, and collection of information (as defined in section 3502(3) of title 44), associated with the regulations;

(C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and

(D) not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventive controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party.

(5) GUIDANCE DOCUMENT.—The Secretary shall issue a guidance document related to the regulations promulgated under paragraph (1)(A) with respect to the hazard analysis and preventive controls.

(6) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to provide the Sec-

retary with the authority to prescribe specific technologies, practices, or critical controls for an individual facility.

(p) EFFECT OF SECTION.—

(1) LIMITATION RELATING TO ENFORCEMENT OF PROGRAMS AND STANDARDS.—Nothing in this section and section 10501(45) of this title limits the authority of the Secretary under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce Hazard Analysis Critical Control Points programs and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

(2) INAPPLICABILITY TO FACILITIES THAT MANUFACTURE, PROCESS, PACK, OR HOLD DIETARY SUPPLEMENTS.—Nothing in this section and section 10501(45) of this title shall apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement that is in compliance with the requirements of sections 11102(g)(2) and 18902 of this title.

**§ 11121. Standards for produce safety**

(a) PROPOSED RULEMAKING.—

(1) IN GENERAL.—

(A) RULEMAKING.—Not later than 1 year after January 4, 2011, the Secretary, in coordination with the Secretary of Agriculture and representatives of State departments of agriculture (including with regard to the national organic program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.)), and in consultation with the Secretary of Homeland Security, shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that the standards minimize the risk of serious adverse health consequences or death.

(B) DETERMINATION BY SECRETARY.—With respect to small businesses and very small businesses (as the terms are defined in the regulation promulgated under subparagraph (A)) that produce and harvest those types of fruits and vegetables that are raw agricultural commodities that the Secretary has determined are low risk and do not present a risk of serious ad-

verse health consequences or death, the Secretary may determine not to include production and harvesting of the fruits and vegetables in the rulemaking, or may modify the applicable requirements of regulations promulgated pursuant to this section.

(2) PUBLIC INPUT.—During the comment period on the notice of proposed rulemaking under paragraph (1), the Secretary shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

(3) CONTENT.—The proposed rulemaking under paragraph (1) shall—

(A) provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of the commodities;

(B) include, with respect to growing, harvesting, sorting, packing, and storage operations, science-based minimum standards re-

lated to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water;

(C) consider hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism;

(D) take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies;

(E) in the case of production that is certified organic, not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.), while providing the same level of public health protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under chapter 325 of this title; and

(F) define, for purposes of this section, the terms ''small business'' and ''very small business''.

(4) PRIORITIZATION.—The Secretary shall prioritize the implementation of the regulations under this section for specific fruits and vegetables that are raw agricultural commodities based on known risks that may include a history and severity of foodborne illness outbreaks.

(b) FINAL REGULATION.—

(1) IN GENERAL.—Not later than 1 year after the close of the comment period for the proposed rulemaking under subsection (a), the Secretary shall adopt a final regulation to provide for minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, which standards shall be based on known safety risks, which may include a history of foodborne illness outbreaks.

(2) FINAL REGULATION.—The final regulation shall—

(A) provide for coordination of education and enforcement activities by State and local officials, as designated by the Governors of the

respective States or the appropriate elected State official as recognized by State statute; and

(B) include a description of the variance process under subsection (c) and the types of permissible variances the Secretary may grant.

(3) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding paragraph (1)—

(A) the regulations promulgated under this section shall apply to a small business (as defined in the regulation promulgated under subsection (a)(1)) after the date that is 1 year after the effective date of the final regulation under paragraph (1); and

(B) the regulations promulgated under this section shall apply to a very small business (as defined in the regulation promulgated under subsection (a)(1)) after the date that is 2 years after the effective date of the final regulation under paragraph (1).

(c) CRITERIA.—

(1) IN GENERAL.—The regulations adopted under subsection (b) shall—

(A) set forth those procedures, processes, and practices that the Secretary determines to

minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary—

(i) to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that—

(I) occur naturally; and

(II) may be unintentionally introduced or may be intentionally introduced, including by acts of terrorism, into fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities; and

(ii) to provide reasonable assurances that the produce is not adulterated under section 11102 of this title;

(B) provide sufficient flexibility to be practicable for all sizes and types of businesses, including small businesses such as a small food processing facility co-located on a farm;

(C) comply with chapter 35 of title 44 (commonly known as the ''Paperwork Reduction

Act''), with special attention to minimizing the burden (as defined in section 3502(2) of title 44) on the business, and collection of information (as defined in section 3502(3) of title 44), associated with the regulations;

(D) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods;

(E) not require a business to hire a consultant or other third party to identify, implement, or certify compliance with the procedures, processes, and practices described in subparagraph (A), except in the case of negotiated enforcement resolutions that may require such a consultant or third party; and

(F) permit States and foreign countries from which food is imported into the United States to request from the Secretary variances from the requirements of the regulations, subject to paragraph (2), where the State or foreign country determines—

(i) that the variance is necessary in light of local growing conditions; and

(ii) that the procedures, processes, and practices to be followed under the variance are reasonably likely—

(I) to ensure that the produce is not adulterated under section 11102 of this title; and

(II) to provide the same level of public health protection as the requirements of the regulations adopted under subsection (b).

(2) VARIANCES.—

(A) REQUESTS FOR VARIANCES.—

(i) IN GENERAL.—A State or foreign country from which food is imported into the United States may, in writing, request a variance from the Secretary.

(ii) CONTENTS.—A request under clause (i) shall describe the variance requested and present information demonstrating—

(I) that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under section 11102 of this title; and

(II) that the variance provides the same level of public health protection as the requirements of the regulations adopted under subsection (b).

(iii) REVIEW.—The Secretary shall review requests for variance in a reasonable timeframe.

(B) APPROVAL OF VARIANCES.—The Secretary may approve a variance in whole or in part, as appropriate, and may specify the scope of applicability of a variance to other similarly situated persons.

(C) DENIAL OF VARIANCES.—

(i) IN GENERAL.—The Secretary may deny a variance request if the Secretary determines that the variance is not reasonably likely—

(I) to ensure that the food is not adulterated under section 11102 of this title; and

(II) to provide the same level of public health protection as the requirements of the regulation adopted under subsection (b).

(ii) NOTIFICATION.—The Secretary shall notify the person requesting the variance of the reasons for the denial.

(D) MODIFICATION OR REVOCATION OF A VARIANCE.—The Secretary, after notice and an opportunity for a hearing, may modify or revoke a variance if the Secretary determines that the variance is not reasonably likely—

(i) to ensure that the food is not adulterated under section 11102 of this title; and

(ii) to provide the same level of public health protection as the requirements of the regulations adopted under subsection (b).

(d) ENFORCEMENT.—The Secretary may coordinate with the Secretary of Agriculture and, as appropriate, shall contract and coordinate with the agency or department designated by the Governor of each State to perform activities to ensure compliance with this section.

(e) GUIDANCE.—

(1) IN GENERAL.—Not later than 1 year after January 4, 2011, the Secretary shall publish, after consultation with the Secretary of Agriculture, representatives of State departments of agriculture,

farmer representatives, and various types of entities engaged in the production and harvesting or importing of fruits and vegetables that are raw agricultural commodities, including small businesses, updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce under this section.

(2) PUBLIC MEETINGS.—The Secretary shall conduct not fewer than 3 public meetings in diverse geographical areas of the United States as part of an effort to conduct education and outreach regarding the guidance described in paragraph (1)—

(A) for persons in different regions that are involved in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including persons that sell directly to consumers and farmer representatives; and

(B) for importers of fruits and vegetables that are raw agricultural commodities.

(3) PAPERWORK REDUCTION.—The Secretary shall ensure that any updated guidance under this section will—

(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, in-

cluding small businesses such as a small food processing facility co-located on a farm; and

(B) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods.

(f) EXEMPTION FOR DIRECT FARM MARKETING.—

(1) DEFINITION OF QUALIFIED END-USER.—

(A) IN GENERAL.—In this subsection, the term ''qualified end-user'', with respect to a food, means—

(i) the consumer of the food; or

(ii) a restaurant or retail food establishment (as those terms are defined by the Secretary for purposes of section 11117 of this title) that is located—

(I) in the same State as the farm that produced the food; or

(II) not more than 275 miles from the farm.

(B) CONSUMER.—For purposes of subparagraph (A), the term ''consumer'' does not include a business.

(2) IN GENERAL.—A farm shall be exempt from the requirements under this section in a calendar year if—

(A) during the previous 3-year period, the average annual monetary value of the food sold by the farm directly to qualified end-users during the period exceeded the average annual monetary value of the food sold by the farm to all other buyers during the period; and

(B) the average annual monetary value of all food sold during the period was less than $500,000, adjusted for inflation.

(3) NOTIFICATION TO CONSUMERS.—

(A) IN GENERAL.—A farm that is exempt from the requirements under this section shall—

(i) with respect to a food for which a food packaging label is required by the Secretary under any other provision of this subtitle, include prominently and conspicuously on the label the name and business address of the farm where the produce was grown; or

(ii) with respect to a food for which a food packaging label is not required by the Secretary under any other provision of this subtitle, prominently and conspicuously display, at the point of purchase, on a

label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of internet sales, in an electronic notice, the name and business address of the farm where the produce was grown.

(B) NO ADDITIONAL LABEL.—Subparagraph (A) does not provide authority to the Secretary to require a label that is in addition to any label required under any other provision of this subtitle.

(4) WITHDRAWAL; RULE OF CONSTRUCTION.—

(A) IN GENERAL.—The Secretary may withdraw the exemption provided to a farm under this subsection—

(i) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the farm subject to an exemption under this subsection; or

(ii) if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm that are material

to the safety of the food produced or harvested at the farm.

(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to expand or limit the inspection authority of the Secretary.

(5) NONPREEMPTION.—

(A) IN GENERAL.—Nothing in this subsection preempts State, local, county, or other non-Federal law regarding the safe production, harvesting, holding, transportation, and sale of fresh fruits and vegetables.

(B) LIABILITY UNDER COMMON LAW OR STATE STATUTORY LAW.—Compliance with this subsection shall not relieve any person from liability at common law or under State statutory law.

(6) LIMITATION OF EFFECT.—Nothing in this subsection shall prevent the Secretary from exercising any authority granted in the other sections of this subtitle.

(g) SMALL ENTITY COMPLIANCE POLICY GUIDE.—Not later than 180 days after the issuance of regulations under this section, the Secretary shall issue a small entity compliance policy guide setting forth in plain language the requirements of this section to assist small entities in com-

plying with standards for safe production and harvesting and other activities required under this section.

(h) INAPPLICABILITY RELATING TO PERSONAL CONSUMPTION.—This section shall not apply to produce that is produced by an individual for personal consumption.

(i) EXCEPTION FOR ACTIVITIES OF CERTAIN FACILITIES.—This section shall not apply to activities of a facility that are subject to section 11120 of this title.

(j) EFFECT OF SECTION.—Nothing in this section and section 10501(46) of this title limits the authority of the Secretary under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) to revise, issue, or enforce product and category-specific regulations, such as the Seafood Hazard Analysis Critical Control Points Program, the Juice Hazard Analysis Critical Control Points Program, and the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards.

**§ 11122. Protection against intentional adulteration**

(a) DEFINITION OF FARM.—In this section, the term ''farm'' has the meaning given the term in section 1.227 of title 21, Code of Federal Regulations (or any successor regulation).

(b) DETERMINATIONS.—

(1) IN GENERAL.—The Secretary shall—

(A) conduct a vulnerability assessment of the food system, including by consideration of the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessments;

(B) consider the best available understanding of uncertainties, risks, costs, and benefits associated with guarding against intentional adulteration of food at vulnerable points; and

(C) determine the types of science-based mitigation strategies or measures that are necessary to protect against the intentional adulteration of food.

(2) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form in which determinations made under paragraph (1) are made publicly available.

(c) REGULATIONS.—

(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Homeland Security and in consultation with the Secretary of Agriculture, shall

promulgate regulations to protect against the intentional adulteration of food subject to this subtitle.

(2) CONTENTS.—The regulations promulgated under paragraph (1) shall—

(A) specify how a person shall assess whether the person is required to implement mitigation strategies or measures intended to protect against the intentional adulteration of food; and

(B) specify appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points, as appropriate.

(d) GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Agriculture, shall issue guidance documents related to protection against intentional adulteration of food, including mitigation strategies or measures to guard against intentional adulteration of food as required under this section.

(2) CONTENT.—The guidance documents issued under paragraph (1) shall—

(A) include a model assessment for a person to use under subsection (c)(2)(A);

(B) include examples of mitigation strategies or measures described in subsection (c)(2)(B); and

(C) specify situations in which the examples of mitigation strategies or measures described in subsection (c)(2)(B) are appropriate.

(3) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary, in consultation with the Secretary of Homeland Security, may determine the time, manner, and form in which the guidance documents issued under paragraph (1) are made public, including by releasing the documents to targeted audiences.

(e) PERIODIC REVIEW.—The Secretary shall periodically review and, as appropriate, update the regulations under subsection (c) and the guidance documents under subsection (d).

(f) APPLICABILITY.—

(1) IN GENERAL.—Regulations promulgated under subsection (c) shall apply only to food for which there is a high risk of intentional contamination, as determined by the Secretary, in consultation with the Secretary of Homeland Security, under subsection (b), which intentional contamination could

cause serious adverse health consequences or death to humans or animals.

(2) INCLUSIONS.—The food to which the regulations under subsection (c) apply as described in paragraph (1) shall include food—

(A) for which the Secretary has identified clear vulnerabilities (including short shelf-life or susceptibility to intentional contamination at critical control points); and

(B) in bulk or batch form, prior to being packaged for the final consumer.

(g) INAPPLICABILITY.—This section shall not apply to farms, except for those that produce milk.

**§ 11123. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry**

(a) DEFINITION OF FACILITY.—In this section, the term ''facility'' means a domestic facility or a foreign facility that is required to register under section 11117 of this title.

(b) IDENTIFICATION AND INSPECTION OF FACILITIES.—

(1) IDENTIFICATION.—The Secretary shall identify high-risk facilities and shall allocate resources to inspect facilities according to the known

safety risks of the facilities, which shall be based on—

(A) the known safety risks of the food manufactured, processed, packed, or held at the facility;

(B) the compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards;

(C) the rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls;

(D) whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 20101(h)(1) of this title;

(E) whether the food or the facility that manufactured, processed, packed, or held the food has received a certification as described in section 20101(q) or 20106 of this title, as appropriate; and

(F) any other criteria considered necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(2) INSPECTIONS.—

(A) IN GENERAL.—Beginning on January 4, 2011, the Secretary shall increase the frequency of inspection of all facilities.

(B) DOMESTIC HIGH-RISK FACILITIES.—The Secretary shall increase the frequency of inspection of domestic facilities identified under paragraph (1) as high-risk facilities so that each of those facilities is inspected—

(i) not less often than once in the 5-year period following January 4, 2011; and

(ii) not less often than once every 3 years thereafter.

(C) DOMESTIC NON-HIGH-RISK FACILITIES.—The Secretary shall ensure that each domestic facility that is not identified under paragraph (1) as a high-risk facility is inspected—

(i) not less often than once in the 7-year period following January 4, 2011; and

(ii) not less often than once every 5 years thereafter.

(D) FOREIGN FACILITIES.—

(i) YEAR 1.—In the 1-year period following January 4, 2011, the Secretary shall inspect not fewer than 600 foreign facilities.

(ii) SUBSEQUENT YEARS.—In each of the 5 years following the 1-year period described in clause (i), the Secretary shall inspect not fewer than twice the number of foreign facilities inspected by the Secretary during the previous year.

(E) RELIANCE ON FEDERAL, STATE, OR LOCAL INSPECTIONS.—In meeting the inspection requirements under this subsection for domestic facilities, the Secretary may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memorandum of understanding, or other obligation.

(c) IDENTIFICATION AND INSPECTION AT PORTS OF ENTRY.—The Secretary, in consultation with the Secretary of Homeland Security, shall allocate resources to inspect any article of food imported into the United States according to the known safety risks of the article of food, which shall be based on—

(1) the known safety risks of the food imported;

(2) the known safety risks of the countries or regions of origin and countries through which the article of food is transported;

(3) the compliance history of the importer, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards;

(4) the rigor and effectiveness of the activities conducted by the importer of the article of food to satisfy the requirements of the foreign supplier verification program under section 20105 of this title;

(5) whether the food importer participates in the voluntary qualified importer program under section 20106 of this title;

(6) whether the food meets the criteria for priority under section 20101(h)(1) of this title;

(7) whether the food or the facility that manufactured, processed, packed, or held the food received a certification as described in section 20101(q) or 20106 of this title; and

(8) any other criteria considered necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(d) INTERAGENCY AGREEMENTS WITH RESPECT TO SEAFOOD.—

(1) IN GENERAL.—The Secretary, the Secretary of Commerce, the Secretary of Homeland Security,

the Chairman of the Federal Trade Commission, and the heads of other appropriate agencies may enter into such agreements as may be necessary or appropriate to improve seafood safety.

(2) SCOPE OF AGREEMENTS.—The agreements under paragraph (1) may include—

(A) cooperative arrangements for examining and testing seafood imports that leverage the resources, capabilities, and authorities of each party to the agreement;

(B) coordination of inspections of foreign facilities to increase the percentage of imported seafood and seafood facilities inspected;

(C) standardization of data on seafood names, inspection records, and laboratory testing to improve interagency coordination;

(D) coordination to detect and investigate violations under applicable Federal law;

(E) a process, including the use or modification of existing processes, by which officers and employees of the National Oceanic and Atmospheric Administration may be designated by the Secretary to carry out seafood examinations and investigations under section 11323, 11324, or 20101 of this title;

(F) the sharing of information concerning observed non-compliance with United States food requirements domestically and in foreign nations and new regulatory decisions and policies that may affect the safety of food imported into the United States;

(G) conducting joint training on subjects that affect and strengthen seafood inspection effectiveness by Federal authorities; and

(H) outreach on Federal efforts to enhance seafood safety and compliance with Federal food safety requirements.

(e) COORDINATION.—The Secretary shall improve coordination and cooperation with the Secretary of Agriculture and the Secretary of Homeland Security to target food inspection resources.

(f) ADVISORY COMMITTEE CONSULTATION.—In allocating inspection resources as described in this section, the Secretary may, as appropriate, consult with any relevant advisory committee within the Department.

**§ 11124. Laboratory accreditation for analyses of foods**

(a) RECOGNITION OF LABORATORY ACCREDITATION.—

(1) IN GENERAL.—The Secretary shall—

(A) establish a program for the testing of food by accredited laboratories;

(B) establish a publicly available registry of accreditation bodies recognized by the Secretary and laboratories accredited by a recognized accreditation body, including the name of, contact information for, and other information considered appropriate by the Secretary about the bodies and laboratories; and

(C) require, as a condition of recognition or accreditation, as appropriate, that recognized accreditation bodies and accredited laboratories report to the Secretary any changes that would affect the recognition of the accreditation body or the accreditation of the laboratory.

(2) PROGRAM REQUIREMENTS.—The program established under paragraph (1)(A) shall provide for the recognition of laboratory accreditation bodies that meet criteria established by the Secretary for accreditation of laboratories, including independent private laboratories and laboratories run and operated by a Federal agency (including the Department of Commerce), State, or locality with a demonstrated capability to conduct 1 or more sampling and analytical testing methodologies for food.

(3) INCREASING THE NUMBER OF QUALIFIED LABORATORIES.—The Secretary shall work with the laboratory accreditation bodies recognized under paragraph (1), as appropriate, to increase the number of qualified laboratories that are eligible to perform testing under subsection (b) beyond the number so qualified on January 4, 2011.

(4) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary, in coordination with the Secretary of Homeland Security, may determine the time, manner, and form in which the registry established under paragraph (1)(B) is made publicly available.

(5) FOREIGN LABORATORIES.—Accreditation bodies recognized by the Secretary under paragraph (1) may accredit laboratories that operate outside the United States, so long as the laboratories meet the accreditation standards applicable to domestic laboratories accredited under this section.

(6) MODEL LABORATORY STANDARDS.—

(A) DEVELOPMENT.—The Secretary shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical

testing methodology and included in the registry provided for under paragraph (1).

(B) EXISTING STANDARDS.—In developing the model standards, the Secretary shall consult existing standards for guidance.

(C) CONTENTS.—The model standards shall include—

(i) methods to ensure that—

(I) appropriate sampling, analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are certified as true and accurate;

(II) internal quality systems are established and maintained;

(III) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited; and

(IV) individuals who conduct the sampling and analyses are qualified by training and experience to do so; and

(ii) any other criteria determined appropriate by the Secretary.

(7) REVIEW OF RECOGNITION; REVOCATION OF RECOGNITION.—To ensure compliance with the requirements of this section, the Secretary—

(A) shall periodically, but not less than once every 5 years, reevaluate accreditation bodies recognized under paragraph (1) and may accompany auditors from an accreditation body to assess whether the accreditation body meets the criteria for recognition; and

(B) shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section, specifying, as appropriate, any terms and conditions necessary for laboratories accredited by the body to continue to perform testing as described in this section.

(b) TESTING PROCEDURES.—

(1) IN GENERAL.—Food testing shall be conducted by Federal laboratories or non-Federal laboratories that have been accredited for the appropriate sampling or analytical testing methodology or methodologies by a recognized accreditation body on the registry established by the Secretary under sub-

section (a)(1)(B) whenever the testing is conducted—

(A) by or on behalf of an owner or consignee—

(i) in response to a specific testing requirement under this subtitle or implementing regulations, when applied to address an identified or suspected food safety problem; and

(ii) as required by the Secretary, as the Secretary considers appropriate, to address an identified or suspected food safety problem; or

(B) on behalf of an owner or consignee—

(i) in support of admission of an article of food under section 20101(a) of this title; and

(ii) under an Import Alert that requires successful consecutive tests.

(2) RESULTS OF TESTING.—

(A) SUBMISSION.—The results of any testing under paragraph (1) shall be sent directly to the FDA.

(B) EXEMPTION FROM SUBMISSION.—The Secretary may by regulation exempt test results

from the submission requirement under subparagraph (A) if the Secretary determines that the results do not contribute to the protection of public health.

(C) ELECTRONIC SUBMISSION.—Test results required to be submitted may be submitted to the FDA through electronic means.

(3) EXCEPTION.—The Secretary may waive requirements under this subsection if—

(A) a new methodology or methodologies have been developed and validated but a laboratory has not yet been accredited to perform the methodology or methodologies; and

(B) the use of the methodology or methodologies is necessary to prevent, control, or mitigate a food emergency or foodborne illness outbreak.

(c) REVIEW BY SECRETARY.—If food sampling and testing performed by a laboratory run and operated by a State or locality that is accredited by a recognized accreditation body on the registry established by the Secretary under subsection (a) result in a State recalling a food, the Secretary shall review the sampling and testing results for the purpose of determining the need for a national recall or other compliance and enforcement activities.

(d) NO LIMIT ON SECRETARIAL AUTHORITY.—Nothing in this section shall be construed to limit the ability of the Secretary to review and act on information from food testing, including determining the sufficiency of the information and testing.

**§ 11125. Mandatory recall authority**

(a) VOLUNTARY PROCEDURES.—If the Secretary determines, based on information gathered through the reportable food registry under section 11119 of this title or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 11102 of this title or misbranded under section 11323 of this title and the use of or exposure to the article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 11119 of this title) with an opportunity to cease distribution and recall the article.

(b) PREHEARING ORDER TO CEASE DISTRIBUTION AND GIVE NOTICE.—

(1) IN GENERAL.—If the responsible party refuses to or does not voluntarily cease distribution or recall the article within the time and in the manner that the Secretary may prescribe, the Secretary by

order may require, as the Secretary considers necessary, the responsible party to—

(A) immediately cease distribution of the article; and

(B) as applicable, immediately notify, to immediately cease distribution of the article, all persons—

(i) manufacturing, processing, packing, transporting, distributing, receiving, holding, or importing and selling the article; and

(ii) to which the article was distributed, transported, or sold.

(2) REQUIRED ADDITIONAL INFORMATION.—

(A) IN GENERAL.—If an article of food covered by a recall order issued under paragraph (1)(B) has been distributed to a warehouse-based third-party logistics provider without providing the provider sufficient information to know or reasonably determine the precise identity of the article of food covered by a recall order that is in its possession, the notice provided by the responsible party subject to the order issued under paragraph (1)(B) shall include such information as is necessary for the

warehouse-based third-party logistics provider to identify the food.

(B) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) to exempt a warehouse-based third-party logistics provider from the requirements of this subtitle, including the requirements in this section and section 11116 of this title; or

(ii) to exempt a warehouse-based third-party logistics provider from being the subject of a mandatory recall order.

(3) DETERMINATION TO LIMIT AREAS AFFECTED.—If the Secretary requires a responsible party to cease distribution under paragraph (1)(A) of an article of food identified in subsection (a), the Secretary may limit the size of the geographic area and the markets affected by the cessation if the limitation would not compromise the public health.

(c) HEARING ON ORDER.—The Secretary shall provide the responsible party subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible, but not later than 2 days after the issuance of the order, on the actions required

by the order and on the reasons that the article that is the subject of the order should not be recalled.

(d) POST-HEARING RECALL ORDER AND MODIFICATION OF ORDER.—

(1) AMENDMENT OF ORDER.—If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that removal of the article from commerce is necessary, the Secretary shall, as appropriate—

(A) amend the order to require recall of the article or other appropriate action;

(B) specify a timetable in which the recall shall occur;

(C) require periodic reports to the Secretary describing the progress of the recall; and

(D) provide notice to consumers to whom the article was, or may have been, distributed.

(2) VACATING OF ORDER.—If, after the hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, or that the actions should be modified, the Secretary shall vacate the order or modify the order.

(e) RULE REGARDING ALCOHOLIC BEVERAGES.—The Secretary shall not initiate a mandatory recall or take any other action under this section with respect to any

alcohol beverage until the Secretary has provided the Alcohol and Tobacco Tax and Trade Bureau with a reasonable opportunity to cease distribution and recall the article under the Alcohol and Tobacco Tax and Trade Bureau authority.

(f) COOPERATION AND CONSULTATION.—The Secretary shall work with State and local public health officials in carrying out this section, as appropriate.

(g) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Secretary shall—

(1) ensure that a press release is published regarding the recall, as well as alerts and public notices, as appropriate, to provide notification—

(A) of the recall to consumers and retailers to whom the article was, or may have been, distributed; and

(B) that includes, at a minimum—

(i) the name of the article of food subject to the recall;

(ii) a description of the risk associated with the article; and

(iii) to the extent practicable, information for consumers about similar articles of food that are not affected by the recall;

(2)(A) consult the policies of the Department of Agriculture regarding providing to the public a list of retail consignees receiving products involved in a Class I recall; and

(B) consider providing such a list to the public, as determined appropriate by the Secretary; and

(3) publish on the FDA website an image of the article (if available) that is the subject of the press release described in paragraph (1).

(h) NO DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

(i) COORDINATED COMMUNICATION.—

(1) IN GENERAL.—To assist in carrying out the requirements of this subsection, the Secretary shall establish an incident command operation or a similar operation within the Department that will operate not later than 24 hours after the initiation of a mandatory recall or the recall of an article of food for which the use of, or exposure to, the article will cause serious adverse health consequences or death to humans or animals.

(2) REQUIREMENTS.—To reduce the potential for miscommunication during recalls or regarding in-

vestigations of a foodborne illness outbreak associated with a food that is subject to a recall, each incident command operation or similar operation under paragraph (1) shall use regular staff and resources of the Department to—

(A) ensure timely and coordinated communication within the Department, including enhanced communication and coordination between different agencies and organizations within the Department;

(B) ensure timely and coordinated communication from the Department, including public statements, throughout the duration of the investigation and related foodborne illness outbreak;

(C) identify a single point of contact within the Department for public inquiries regarding any actions by the Secretary related to a recall;

(D) coordinate with Federal, State, local, and tribal authorities, as appropriate, that have responsibilities related to the recall of a food or a foodborne illness outbreak associated with a food that is subject to the recall, including notification of the Secretary of Agriculture and the Secretary of Education in the event the recalled

food is a commodity intended for use in a child nutrition program (as identified in section 25(b) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1769f(b))); and

(E) conclude operations at such time as the Secretary determines appropriate.

(3) MULTIPLE RECALLS.—The Secretary may establish multiple or concurrent incident command operations or similar operations in the event of multiple recalls or foodborne illness outbreaks necessitating the action by the Department.

(j) EFFECT.—Nothing in this section shall affect the authority of the Secretary—

(1) to request or participate in a voluntary recall; or

(2) to issue an order to cease distribution or to recall under any other provision of this subtitle or under the Public Health Service Act (42 U.S.C. 201 et seq.).

(k) SEARCH ENGINE.—The Secretary shall include in the FDA website a search engine that—

(1) is consumer-friendly, as determined by the Secretary; and

(2) provides a means by which an individual may locate relevant information regarding each arti-

cle of food subject to a recall under this section and the status of the recall (such as whether a recall is ongoing or has been completed).

(l) ANNUAL REPORT TO CONGRESS.—

(1) IN GENERAL.—The Secretary shall annually submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the use of—

(A) recall authority under this section; and

(B) any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.

(2) CONTENT.—The report under paragraph (1) shall include, with respect to the report year—

(A) the identity of each article of food that was the subject of—

(i) a public health advisory described in paragraph (1);

(ii) an opportunity to cease distribution and recall under subsection (a); or

(iii) a mandatory recall order under subsection (b);

(B) the number of responsible parties, as defined in section 11119 of this title, formally given the opportunity to cease distribution of an article of food and recall the article, as described in subsection (a);

(C) the number of responsible parties described in subparagraph (B) that did not cease distribution of or recall an article of food after given the opportunity to cease distribution or recall under subsection (a);

(D) the number of recall orders issued under subsection (b); and

(E) a description of any instance in which there was no testing that confirmed adulteration of an article of food that was the subject of a recall under subsection (b) or a public health advisory described in paragraph (1).

**§ 11126. Requirements for critical food**

(a) NOTIFICATION OF MEANINGFUL DISRUPTION FOR CRITICAL FOOD.—

(1) MEANINGFUL DISRUPTION.—In this subsection, the term ''meaningful disruption''—

(A) means a change in production that is reasonably likely to lead to a significant reduction in the supply of a critical food by a manu-

facturer that affects the ability of the manufacturer to meet expected demand for its product; and

(B) does not include interruptions in manufacturing due to matters such as routine maintenance, changes or discontinuance of flavors, colors, or other insignificant formulation characteristics, or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

(2) IN GENERAL.—A manufacturer of a critical food shall notify the Secretary of a permanent discontinuance in the manufacture or an interruption of the manufacture of the food that is likely to lead to a meaningful disruption in the supply of the food in the United States, and the reasons for the discontinuance or interruption, as soon as practicable, but not later than 5 business days after the discontinuance or the interruption.

(3) DISTRIBUTION OF INFORMATION.—Not later than 5 calendar days after receiving a notification under paragraph (2), if the Secretary has determined that the discontinuance or interruption has resulted, or is likely to result, in a shortage of the critical food, the Secretary shall distribute, to the

Secretary of Agriculture and to the maximum extent practicable to the appropriate entities, as determined by the Secretary through such means as the Secretary determines appropriate, information on the shortage.

(4) CONFIDENTIALITY.—Nothing in this subsection authorizes the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(b) RISK MANAGEMENT PLANS.—Each manufacturer of a critical food shall develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of the food, as applicable, for each establishment in which the food is manufactured. A risk management plan under this subsection—

(1) may identify and evaluate risks to the supply of more than 1 critical food, or critical food category, manufactured at the same establishment;

(2) may identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means; and

(3) shall be subject to inspection and copying by the Secretary pursuant to an inspection under section 17504 of this title.

(c) FAILURE TO MEET REQUIREMENTS.—

(1) IN GENERAL.—If a person fails to submit information required under, and in accordance with, subsection (a)—

(A) the Secretary shall issue a letter to the person informing the person of the failure; and

(B) not later than 45 calendar days after the issuance of a letter under subparagraph (A), subject to paragraph (2), the Secretary shall make available to the public on the FDA website, with appropriate redactions made to protect the information described in subsection (a)(4)—

(i) the letter issued under subparagraph (A); and

(ii) at the request of the person, any response to the letter that the person submitted to the Secretary.

(2) EXCEPTION.—If the Secretary determines that the letter under paragraph (1) was issued in error or, after review of the response, the person had a reasonable basis for not submitting a notification

as required under subsection (a), the requirements of paragraph (1)(B) shall not apply.

# Chapter 113—Misbranded Food

Sec.
11301. False or misleading label.
11302. Offer for sale under another name.
11303. Imitation of another food.
11304. Misleading container.
11305. Package form.
11306. Prominence of information on label.
11307. Representation as to definition and standard of identity.
11308. Representation as to standards of quality and fill of container.
11309. Representation as to pasteurization.
11310. Label to bear common or usual name.
11311. Representation for special dietary use.
11312. Artificial flavoring, artificial coloring, or chemical preservatives.
11313. Pesticide chemicals on raw agricultural commodities.
11314. Color additives.
11315. Packaging or labeling of drugs in violation of regulations.
11316. Nutrition information.
11317. Nutrition levels and health-related claims.
11318. Dietary supplements; general.
11319. Dietary supplements; serious adverse event.
11320. Catfish.
11321. Ginseng.
11322. Failure to label; health threat.
11323. Major food allergen labeling requirements.
11324. Nonmajor food allergen labeling requirements.

## § 11301. False or misleading label

A food shall be deemed to be misbranded if—

(1) its labeling is false or misleading in any particular; or

(2) in the case of a food to which section 11113 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 11113(d)(2) of this title.

**§ 11302. Offer for sale under another name**

A food shall be deemed to be misbranded if it is offered for sale under the name of another food.

**§ 11303. Imitation of another food**

A food shall be deemed to be misbranded if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and, immediately after that word, the name of the food imitated.

**§ 11304. Misleading container**

A food shall be deemed to be misbranded if its container is made, formed, or filled so as to be misleading.

**§ 11305. Package form**

A food shall be deemed to be misbranded if in package form unless it bears a label containing—

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under this paragraph, reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

**§ 11306. Prominence of information on label**

A food shall be deemed to be misbranded if any word, statement, or other information required by or under au-

thority of this subtitle to appear on the label or labeling is not prominently placed on the label or labeling with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

**§ 11307. Representation as to definition and standard of identity**

(a) IN GENERAL.—A food shall be deemed to be misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 11101 of this title, unless—

(1) it conforms to the definition and standard; and

(2) its label bears—

(A) the name of the food specified in the definition and standard; and

(B) to the extent that the regulations may require, the common names of optional ingredients (other than spices, flavoring, and coloring) present in the food.

(b) ARTIFICIAL COLORING IN BUTTER, CHEESE, OR ICE CREAM.—The provisions of this section with respect

to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

**§ 11308. Representation as to standards of quality and fill of container**

A food shall be deemed to be misbranded if it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 11101 of this title, and its quality falls below the standard, unless its label bears, in such manner and form as the regulations specify, a statement that it falls below the standard; or

(2) a food for which a standard of fill of container has been prescribed by regulations as provided by section 11101 of this title, and it falls below the standard of fill of container applicable to the food, unless its label bears, in such manner and form as the regulations specify, a statement that it falls below the standard.

**§ 11309. Representation as to pasteurization**

(a) IN GENERAL.—A food shall be deemed to be misbranded if it purports to be or is represented as a food that is pasteurized unless—

(1) the food has been subjected to a safe process or treatment that is prescribed as pasteurization

for the food in a regulation promulgated under this subtitle; or

(2)(A) the food has been subjected to a safe process or treatment that—

(i) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(ii) is at least as protective of the public health as a process or treatment described in paragraph (1);

(iii) is effective for a period that is at least as long as the shelf life of the food when stored under normal and moderate abuse conditions; and

(iv) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(B) at least 120 days have passed after the date of receipt of the notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of clauses (i) through (iii) of subparagraph (A).

(b) DETERMINATION NOT TO MEET REQUIREMENTS AS FINAL AGENCY ACTION.—For purposes of this section, a determination by the Secretary that a process or treatment has not been shown to meet the requirements of clauses (i) through (iii) of subsection (a)(2)(A) shall constitute final agency action under those clauses.

**§ 11310. Label to bear common or usual name**

(a) IN GENERAL.—A food shall be deemed to be misbranded unless its label bears—

(1) the common or usual name of the food, if any; and

(2) in case it is fabricated from 2 or more ingredients, the common or usual name of each ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of the fruit or vegetable juice contained in the food.

(b) SPICES, FLAVORINGS, AND COLORS.—Spices, flavorings, and colors not required to be certified under section 17701(c) of this title, unless sold as spices, flavorings, or those colors, may be designated as spices, flavorings, and colorings without naming each.

(c) EXEMPTIONS BY REGULATIONS.—To the extent that compliance with the requirements of subsection (a)(2)

is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(d) ARTIFICIAL COLORING IN BUTTER, CHEESE, OR ICE CREAM.—The provisions of this section with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

**§ 11311. Representation for special dietary use**

A food shall be deemed to be misbranded if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary to fully inform purchasers as to its value for the uses.

**§ 11312. Artificial flavoring, artificial coloring, or chemical preservatives**

(a) IN GENERAL.—A food shall be deemed to be misbranded if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this section is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(b) ARTIFICIAL COLORING; BUTTER, CHEESE, OR ICE CREAM.—The provisions of this section with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

(c) CHEMICAL PRESERVATIVES; PESTICIDE CHEMICALS.—

(1) IN GENERAL.—The provisions of this section with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity that is the produce of the soil.

(2) EFFECT.—Nothing in paragraph (1) shall affect any requirement of the laws of any State or territory of the United States.

**§ 11313. Pesticide chemicals on raw agricultural commodities**

(a) IN GENERAL.—A food shall be deemed to be misbranded if it is a raw agricultural commodity that is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of the commodity bears labeling that declares the presence of the chemical in or on the commodity and the common or usual name and the function of the chemical.

(b) EXCEPTION.—A declaration under subsection (a) shall not be required while the commodity, having been

removed from the shipping container, is being held or displayed for sale at retail out of the container in accordance with the custom of the trade.

(c) EFFECT.—Nothing in this section shall affect any requirement of the laws of any State or territory of the United States.

**§ 11314. Color additives**

A food shall be deemed to be misbranded if it is a color additive, unless its packaging and labeling are in conformity with the packaging and labeling requirements, applicable to the color additive, as may be contained in regulations issued under section 17701 of this title.

**§ 11315. Packaging or labeling of drugs in violation of regulations**

A food shall be deemed to be misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1472, 1473).

**§ 11316. Nutrition information**

(a) IN GENERAL.—

(1) LABEL AND LABELING REQUIREMENTS.—Except as provided in subsections (c), (d), (e), (f), and (g), a food shall be deemed to be misbranded if it is a food intended for human consumption and is

offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food; or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food;

(B) the number of servings or other units of measure per container;

(C) the total number (in each serving size or other unit of measure of the food) of calories—

(i) derived from any source; and

(ii) derived from the total fat;

(D) the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure; and

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this subtitle before October 1,

1990, if the Secretary determines that the information will assist consumers in maintaining healthy dietary practices.

(2) HIGHLIGHTING OF CERTAIN INFORMATION.—The Secretary may by regulation require any information required to be placed on the label or labeling by this subsection or subsection (b)(1) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that the highlighting will assist consumers in maintaining healthy dietary practices.

(b) INCLUSION OF NUTRIENT BY REGULATION.—

(1) IN GENERAL.—If the Secretary determines that a nutrient other than a nutrient required by subparagraph (C), (D), or (E) of subsection (a)(1) should be included in the label or labeling of food subject to subsection (a) for purposes of providing information regarding the nutritional value of the food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to the additional nutrient be included in the label or labeling of the food.

(2) REMOVAL OF REQUIRED INFORMATION BY REGULATION.—If the Secretary determines that the

information relating to a nutrient required by paragraph (1) or by subparagraph (C), (D), or (E) of subsection (a)(1) to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to the nutrient from the requirement.

(c) FOOD IN BULK CONTAINERS.—For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subsections (a) and (b) be displayed at the location in the retail establishment at which the food is offered for sale.

(d) RAW AGRICULTURAL COMMODITIES; RAW FISH.—

(1) DEFINITION OF FISH.—In this subsection, the term ''fish'' includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(2) ISSUANCE OF VOLUNTARY GUIDELINES OR MANDATORY REGULATIONS.—The Secretary shall provide for furnishing the nutrition information required by subsections (a) and (b) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines as provided by para-

graph (3) or by issuing regulations that are mandatory as provided by paragraph (5).

(3) ISSUANCE OF GUIDELINES.—

(A) PROCEDURE.—

(i) IN GENERAL.—On the expiration of 12 months after November 8, 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subsections (a) and (b). The guidelines shall take into account the actions taken by food retailers during the 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. The guidelines shall apply only—

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year; and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

(ii) DETERMINATION BY REGULATION; REGIONAL APPLICABILITY.—The vegetables, fruits, and raw fish to which the guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply the guidelines regionally.

(B) FINAL REGULATION ON SUBSTANTIAL COMPLIANCE.—

(i) ISSUANCE.—On the expiration of 12 months after November 8, 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subparagraph (A).

(ii) NO SUBSTANTIAL COMPLIANCE.—The regulation shall provide that there is no substantial compliance if a significant number of retailers have failed to comply with the guidelines.

(iii) CONSIDERATION OF SIZE OF RETAILERS AND PORTION OF MARKET.—The

size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(4) REPORT.—

(A) IN GENERAL.—

(i) ISSUANCE.—On the expiration of 30 months after November 8, 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under paragraph (2).

(ii) INCLUSION OF SUBSTANTIAL COMPLIANCE.—The report shall include a determination of whether there is substantial compliance with the guidelines.

(B) RECURRENCE.—If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subparagraph (A) every 2 years.

(5) MANDATORY PROVISION OF NUTRITION INFORMATION.—

(A) REGULATIONS.—

(i) PROPOSED REGULATIONS.—If the Secretary determines that there is no substantial compliance with the guidelines issued under paragraph (2), the Secretary shall, at the time the determination is made, issue proposed regulations requiring that any person that offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subsections (a) and (b).

(ii) FINAL REGULATIONS.—The Secretary shall issue final regulations imposing the requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their issuance.

(B) REQUIRING NUTRITION INFORMATION FOR LARGER NUMBER OF FREQUENTLY CONSUMED PRODUCTS.—

(i) IN GENERAL.—Regulations issued under subparagraph (A) may require that

the nutrition information required by subsections (a) and (b) be provided for more than the 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of the products are frequently consumed.

(ii) SINGLE LOCATION.—Regulations issued under subparagraph (A) shall permit the information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale.

(iii) EXPRESSED AS AVERAGE OR RANGE PER SERVING.—Regulations issued under subparagraph (A) may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish.

(iv) AVAILABILITY OF REQUIRED INFORMATION TO PERSONS THAT OFFER FOOD TO CONSUMERS.—The Secretary shall develop and make available to the persons that offer the varieties of food described in clause (i) to consumers the in-

formation required by subsections (a) and (b).

(C) AREA; FORMAT; SUPPLEMENTATION.—

(i) AREA.—Regulations issued under subparagraph (A) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale.

(ii) FORMAT.—The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information.

(iii) SUPPLEMENTATION.—The regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media that the Secretary approves.

(6) NO PROSECUTION FOR MINOR VIOLATIONS.—A person that offers raw agricultural commodities or raw fish to consumers shall not be prosecuted for minor violations of this subsection if there

has been substantial compliance with the requirements of this section.

(e) DIETARY SUPPLEMENT PRODUCT.—A dietary supplement product (including a food to which section 11113 of this title applies) shall comply with the requirements of subsections (a) and (b) in a manner that is appropriate for the product and that is specified in regulations of the Secretary which shall provide that—

(1) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(2) the listing of dietary ingredients shall include the quantity of each of the dietary ingredients (or the quantity of a proprietary blend of the dietary ingredients) per serving;

(3) the listing of dietary ingredients may include the source of a dietary ingredient; and

(4) the nutrition information shall immediately precede the ingredient information required under

paragraph (1), except that no ingredient identified pursuant to paragraph (1) shall be required to be identified a second time.

(f) INAPPLICABILITY.—

(1) IN GENERAL.—Subsections (a), (b), (c), and (d) shall not apply to food—

(A) except as provided in subsection (g)(3)(C), that is—

(i) served in restaurants or other establishments in which food is served for immediate human consumption; or

(ii) sold for sale or use in those establishments;

(B) except as provided in subsection (g)(3)(C), that is—

(i) processed and prepared primarily in a retail establishment;

(ii) ready for human consumption;

(iii) of the type described in subparagraph (A); and

(iv) offered for sale to consumers but not for immediate human consumption in the establishment and is not offered for sale outside the establishment;

(C) that is an infant formula subject to section 11114 of this title;

(D) that is a medical food as defined in section 49502(a) of this title; or

(E) that is described in section 11107(a)(2) of this title.

(2) PACKAGING TOO SMALL.—Subsections (a) and (b) shall not apply to the label of a food if—

(A) the Secretary determines by regulations that compliance with the subsections is impracticable because the package of the food is too small to comply with the requirements of the subsections; and

(B) the label of the food does not contain any nutrition information.

(3) INSIGNIFICANT AMOUNT OF NUTRIENTS.—

(A) FOOD CONTAINING ALL THE NUTRIENTS THAT REQUIRE LISTING.—If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subsections (a) and (b) to be listed in the label or labeling of food, the requirements of the subsections shall not apply to the food if the label, labeling, or advertising of the food does not

make any claim with respect to the nutritional value of the food.

(B) FOOD CONTAINING MORE THAN HALF OF THE NUTRIENTS THAT REQUIRE LISTING.—If a food contains insignificant amounts, as determined by the Secretary, of more than ½ the nutrients required by subsections (a) and (b) to be in the label or labeling of the food, the Secretary shall require the amounts of the nutrients to be stated in a simplified form prescribed by the Secretary.

(4) SALES BELOW A CERTAIN AMOUNT.—If a person offers food for sale and has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers that is not more than $50,000, the requirements of subsections (a), (b), (c), and (d) shall not apply with respect to food sold by the person to consumers unless the label or labeling of food offered by the person provides nutrition information or makes a nutrition claim.

(5) LOW NUMBER OF UNITS SOLD.—

(A) DEFINITIONS.—In this paragraph:

(i) FOOD PRODUCT.—The term ''food product'' means food in any sized package that is manufactured by a single manufacturer or that bears the same brand name, that bears the same statement of identity, and that has similar preparation methods.

(ii) PERSON.—The term ''person'' in the case of a corporation includes all domestic and foreign affiliates of the corporation.

(iii) UNIT.—The term ''unit'' means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers.

(B) IN GENERAL.—During the 12-month period for which an exemption from subsections (a) and (b) is claimed pursuant to this subparagraph, the requirements of the subsections shall not apply to any food product if—

(i) the labeling for the product does not provide nutrition information or make a claim subject to section 11317 of this title;

(ii) the person that claims for the product an exemption from the subsections

employed fewer than an average of 100 full-time equivalent employees;

(iii) the person provided the notice described in subparagraph (C); and

(iv) in the case of a food product that was sold in the 12-month period preceding the period for which an exemption was claimed, fewer than 100,000 units of the product were sold in the United States during the preceding period, or in the case of a food product that was not sold in the 12-month period preceding the period for which the exemption is claimed, fewer than 100,000 units of the product are reasonably anticipated to be sold in the United States during the period for which the exemption is claimed.

(C) NOTICE.—The notice referred to in subparagraph (B)—

(i) shall be given to the Secretary prior to the beginning of the period during which the exemption under subparagraph (B) is to be in effect;

(ii) shall state that the person claiming the exemption for a food product has

complied with the applicable requirements of subparagraph (B); and

(iii) shall—

(I) state the average number of full-time equivalent employees the person employed during the 12 months preceding the date the person claims the exemption;

(II) state the approximate number of units the person claiming the exemption sold in the United States;

(III) if the exemption is claimed for a food product that was sold in the 12-month period preceding the period for which the exemption was claimed, state the approximate number of units of the product that were sold in the United States during the preceding period, and, if the exemption is claimed for a food product that was not sold in the preceding period, state the number of units of the product that the person reasonably anticipates will be sold in the United States

during the period for which the exemption was claimed; and

(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subparagraph if the Secretary has questioned the validity of the information.

(D) EXEMPTION FROM FILING NOTICE.—If a person is not an importer, has fewer than 10 full-time equivalent employees, and sells fewer than 10,000 units of any food product in any year, the person is not required to file a notice for the product under subparagraph (C) for the year.

(E) EXTENSION.—In the case of a person that claimed an exemption under subparagraph (B), if, during the period of the exemption, the number of full-time equivalent employees of the person exceeds the number in subparagraph (B) or if the number of food products sold in the United States exceeds the number in subparagraph (B), the exemption shall extend to the expiration of 18 months after the date the num-

ber of full-time equivalent employees or food products sold exceeded the applicable number.

(F) LOWERING REQUIRED NUMBERS BY REGULATION.—For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subparagraph (B) if the Secretary determines that the cost of compliance with the lower requirement will not place an undue burden on persons subject to the lower requirement.

(6) FOOD SOLD BY FOOD DISTRIBUTORS.—Subsections (a), (b), (c), and (d) shall not apply to food that is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(g) RESTAURANTS, RETAIL FOOD ESTABLISHMENTS, AND VENDING MACHINES.—

(1) DEFINITIONS.—In this subsection:

(A) MENU.—The term ''menu'' means the primary writing of the restaurant or other simi-

lar retail food establishment from which a consumer makes an order selection.

(B) MENU BOARD.—The term ''menu board'' means the primary writing, on a board, of the restaurant or other similar retail food establishment from which a consumer makes an order selection.

(2) GENERAL REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.—Except for food described in paragraph (8), in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items, the restaurant or similar retail food establishment shall disclose the information described in paragraphs (3) and (4).

(3) INFORMATION REQUIRED TO BE DISCLOSED BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—Except as provided in paragraph (8), the restaurant or similar retail food establishment shall disclose in a clear and conspicuous manner—

(A)(i) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(ii) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu board, designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu;

(B)(i) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu board, including a drive-through menu board, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(ii) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently

on the menu board, designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided on the menu board;

(C) in a written form, available on the premises of the restaurant or similar retail establishment and to the consumer on request, the nutrition information required under subparagraphs (C) and (D) of subsection (a)(1); and

(D) on the menu or menu board, a prominent, clear, and conspicuous statement regarding the availability of the information described in subparagraph (C).

(4) SELF-SERVICE FOOD AND FOOD ON DISPLAY.—Except as provided in paragraph (8), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, a restaurant or similar retail food establishment shall place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

(5) REASONABLE BASIS.—For the purposes of this subsection, a restaurant or similar retail food

establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations, or any successor regulation, or in a related guidance of the FDA.

(6) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but that are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children's combination meals, through means determined by the Secretary, including ranges, averages, or other methods.

(7) ADDITIONAL INFORMATION.—If the Secretary determines that a nutrient, other than a nutrient required under paragraph (3)(C), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of the nutrient in the written form required under paragraph (3)(C).

(8) INAPPLICABILITY TO CERTAIN FOOD.—

(A) IN GENERAL.—Paragraphs (2) through (7) do not apply to—

(i) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use);

(ii) daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or

(iii) such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

(B) WRITTEN FORMS.—Subsection (f)(3) shall apply to any regulations promulgated under paragraphs (3)(C) and (7).

(9) VENDING MACHINES.—

(A) IN GENERAL.—In the case of an article of food sold from a vending machine described in subparagraph (B), the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous

statement disclosing the number of calories contained in the article.

(B) VENDING MACHINE.—A vending machine described in this subparagraph is a vending machine that—

(i) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and

(ii) is operated by a person that is engaged in the business of owning or operating 20 or more vending machines.

(10) VOLUNTARY PROVISION OF NUTRITION INFORMATION.—

(A) IN GENERAL.—An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this subsection may elect to be subject to the requirements of this subsection, by registering biannually the name and address of the restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation.

(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to authorize the Secretary to require an application, review, or licensing process for any entity to register with the Secretary, as described in subparagraph (A).

(11) REGULATIONS.—

(A) PROPOSED REGULATION.—The Secretary shall promulgate proposed regulations to carry out this subsection.

(B) CONTENTS.—In promulgating regulations, the Secretary shall—

(i) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines; and

(ii) specify the format and manner of the nutrient content disclosure requirements under this paragraph.

(C) REPORTING.—The Secretary shall submit to the Committee on Health, Education,

Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a quarterly report that describes the Secretary's progress toward promulgating final regulations under this subsection.

(12) CONSTRUCTION; INAPPLICABILITY; PREEMPTION.—Nothing in this subsection shall be construed—

(A) to preempt any provision of State or local law, unless the provision—

(i) establishes or continues into effect nutrient content disclosures of the type required under this subsection; and

(ii) is expressly preempted under section 11103(a)(4) of this title;

(B) to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food; or

(C) except as provided in paragraph (10), to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in paragraph (2).

(h) LABELING EXEMPTION FOR SINGLE-INGREDIENT FOODS AND PRODUCTS.—The food labeling requirements under this section shall not require that the nutrition facts label of any single-ingredient sugar, honey, agave, or syrup, including maple syrup, that is packaged and offered for sale as a single-ingredient food bear the declaration ''Includes X g Added Sugars.''.

**§ 11317. Nutrition levels and health-related claims**

(a) IN GENERAL.—

(1) CLAIMS THAT DEEM FOOD TO BE MISBRANDED.—Except as provided in paragraphs (1) through (3) of subsection (e), a food shall be deemed to be misbranded if it is a food intended for human consumption that is offered for sale and for which a claim is made in the label or labeling of the food that expressly or by implication—

(A) characterizes the level of any nutrient that is of the type required by subsection (a) or (b) of section 11316 of this title to be in the label or labeling of the food unless the claim is made in accordance with subsection (b) of this section; or

(B) characterizes the relationship of any nutrient that is of the type required by subsection (a) or (b) of section 11316 of this title

to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subsection (c) or (e)(4).

(2) LIMITATION OF APPLICABILITY.—A statement of the type required by section 11316 of this title that appears as part of the nutrition information required or permitted by that section is not a claim that is subject to this section and a claim subject to paragraph (1)(A) is not subject to paragraph (1)(B).

(b) REQUIREMENTS FOR NUTRITIONAL CLAIMS UNDER SUBSECTION (a)(1)(A).—

(1) IN GENERAL.—Except as provided in subparagraphs (B) and (C) of subsection (d)(1) and paragraphs (1) through (3) of subsection (e), a claim described in subsection (a)(1)(A)—

(A) may be made only if the characterization of the level made in the claim uses terms that are defined in regulations of the Secretary;

(B) may not state the absence of a nutrient unless—

(i) the nutrient is usually present in the food or in another food that substitutes

for the food as defined by the Secretary by regulation; or

(ii) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food;

(C) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount that increases to individuals in the general population the risk of disease or a health-related condition that is diet-related unless—

(i) the Secretary—

(I) finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in another food that substitutes for the food and that has a significant market share; or

(II) by regulation permits a statement regarding the absence of

cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food; and

(ii) the label or labeling of the food discloses the level of the fat or saturated fat in immediate proximity to the claim and with appropriate prominence, which shall be no less than ½ the size of the claim with respect to the level of cholesterol;

(D) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to the claim and with appropriate prominence, which shall be no less than ½ the size of the claim with respect to the level of saturated fat;

(E) may not state that a food is high in dietary fiber unless the food is low in total fat

as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to the statement and with appropriate prominence, which shall be no less than ½ the size of the claim with respect to the level of dietary fiber; and

(F) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(2) INCREASED RISK OF DISEASE OR HEALTH-RELATED CONDITION.—

(A) STATEMENT.—If a claim described in subsection (a)(1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet-related, the label or labeling of the food shall contain, prominently and in immediate proximity to the claim, the following statement: ''See nutrition information for _____ content.''

(B) BLANK SPACE.—The blank shall identify the nutrient associated with the increased disease or health-related condition risk.

(C) DETERMINATION.—In making the determination described in subparagraph (A), the Secretary shall take into account the significance of the food in the total daily diet.

(3) CERTAIN CLAIMS UNDER SUBSECTION (a)(1)(A) CONTAINED IN BRAND NAMES.—

(A) IN GENERAL.—Paragraph (1) does not apply to a claim described in subsection (a)(1)(A) and contained in the label or labeling of a food if the claim is contained in the brand name of the food and the brand name was in use on the food before October 25, 1989, unless the brand name contains a term defined by the Secretary under paragraph (1)(A).

(B) CLAIM SUBJECT TO MISBRANDING PROVISIONS RELATING TO FALSE OR MISLEADING LABELING.—A claim under subparagraph (A) is subject to section 11301 of this title.

(4) CERTAIN CLAIMS UNDER SUBSECTION (a)(1)(A) CONTAINED IN SOFTDRINK BRAND NAMES.—

(A) IN GENERAL.—This subsection does not apply to a claim described in subsection (a)(1)(A) that uses the term ''diet'' and is contained in the label or labeling of a soft drink if—

(i) the claim is contained in the brand name of the soft drink;

(ii) the brand name was in use on the soft drink before October 25, 1989; and

(iii) the use of the term ''diet'' was in conformity with section 105.66 of title 21, Code of Federal Regulations.

(B) CLAIM SUBJECT TO MISBRANDING PROVISIONS RELATING TO FALSE OR MISLEADING LABELING.—A claim under subparagraph (A) is subject to section 11301 of this title.

(5) CLAIMS DESCRIBING PERCENTAGE OF VITAMINS AND MINERALS.—Subparagraphs (A) through (E) of paragraph (1) do not apply to a statement in the label or labeling of food that describes the percentage of vitamins and minerals in the food in relation to the amount of the vitamins and minerals recommended for daily consumption by the Secretary.

(6) CLAIM IN DIETARY SUPPLEMENT LABELING CHARACTERIZING PERCENTAGE LEVEL OF DIETARY INGREDIENT.—Paragraph (1)(A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(7) CLAIM FOR A NUTRIENT FOR WHICH NO REGULATION HAS BEEN PROMULGATED.—

(A) IN GENERAL.—A claim of the type described in subsection (a)(1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under paragraph (1)(A), shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of

Sciences or any of its subdivisions has published an authoritative statement—

(I) that is currently in effect; and

(II) that identifies the nutrient level to which the claim refers;

(ii) a person, at least 120 days (during which the Secretary may notify any person that is making a claim as authorized by paragraph (3) that the person has not submitted all the information required by the paragraph) before the first introduction into interstate commerce of the food with a label containing the claim, has submitted to the Secretary—

(I) a notice of the claim, which shall include—

(aa) the exact words used in the claim; and

(bb) a concise description of the basis on which the person relied for determining that the requirements of clause (i) have been satisfied;

(II) a copy of the statement referred to in clause (i) on which the person relied in making the claim; and

(III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with paragraphs (1) and (2), and are otherwise in compliance with sections 10101(c)(1) and 11301 of this title; and

(iv) the claim is stated in a manner—

(I) so that the claim is an accurate representation of the authoritative statement referred to in clause (i); and

(II) so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of the information in the context of a total daily diet.

(B) AUTHORITATIVE STATEMENT.—

(i) IN GENERAL.—For purposes of this paragraph, a statement shall be regarded as an authoritative statement of a scientific body described in subparagraph (A)(i) only if the statement is published by the scientific body.

(ii) STATEMENT OF EMPLOYEE.—An authoritative statement of a scientific body described in subparagraph (A)(i) shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(C) SUBMISSION PERIOD.—A claim submitted under the requirements of this paragraph may be made until—

(i) such time as the Secretary issues a regulation—

(I) prohibiting or modifying the claim and the regulation has become effective; or

(II) finding that the requirements of this paragraph have not been met, including finding that the petitioner had not submitted all the

information required by this paragraph; or

(ii) a district court of the United States in an enforcement proceeding under chapter 105 of this title has determined that the requirements of this paragraph have not been met.

(c) REQUIREMENTS FOR NUTRITIONAL CLAIMS UNDER SUBSECTION (a)(1)(B).—

(1) IN GENERAL.—Except as provided in subsection (e), a claim described in subsection (a)(1)(B) may be made only—

(A) if the claim meets the requirements of the regulations of the Secretary promulgated under paragraph (2); and

(B) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition which is diet-related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in

maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subsection (b)(2).

(2) REGULATIONS.—

(A) IN GENERAL.—The Secretary shall promulgate regulations authorizing claims of the type described in subsection (a)(1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate the claims, that the claims to be authorized are supported by the evidence.

(B) CONTENTS.—A regulation described in subparagraph (A) shall describe—

(i) the relationship between a nutrient of the type required in the label or labeling of food by subsection (a) or (b) of section 11316 of this title and a disease or health-related condition; and

(ii) the significance of each such nutrient in affecting the disease or health-related condition.

(C) MANNER OF STATEMENT.—A regulation described in subparagraph (A) shall require the claim to be stated in a manner—

(i) so that the claim is an accurate representation of the matters set out in subparagraph (B); and

(ii) so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of the information in the context of a total daily diet.

(3) CLAIM UNDER SUBSECTION (a)(1)(B) NOT AUTHORIZED BY REGULATION.—

(A) IN GENERAL.—Notwithstanding the provisions of paragraphs (1)(A) and (2), a claim of the type described in subsection (a)(1)(B) that is not authorized by the Secretary in a regulation promulgated in accordance with paragraph (2) shall be authorized and may be made with respect to a food if—

(i) a scientific body of the United States Government with official responsi-

bility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement—

(I) that is currently in effect; and

(II) that is about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(ii) a person, at least 120 days (during which the Secretary may notify any person that is making a claim as authorized by this paragraph that the person has not submitted all the information required by this paragraph) before the first introduction into interstate commerce of the food with a label containing the claim, has submitted to the Secretary—

(I) a notice of the claim, which shall include—

(aa) the exact words used in the claim; and

(bb) a concise description of the basis on which the person relied for determining that the requirements of clause (i) have been satisfied;

(II) a copy of the statement referred to in clause (i) on which the person relied in making the claim; and

(III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with paragraph (1)(B) and are otherwise in compliance with sections 10101(c)(1) and 11301 of this title; and

(iv) the claim is stated in a manner—

(I) so that the claim is an accurate representation of the authoritative statement referred to in clause (i); and

(II) so that the claim enables the public to comprehend the information

provided in the claim and to understand the relative significance of the information in the context of a total daily diet.

(B) AUTHORITATIVE STATEMENT.—

(i) IN GENERAL.—For purposes of this paragraph, a statement shall be regarded as an authoritative statement of a scientific body described in subparagraph (A)(i) only if the statement is published by the scientific body.

(ii) STATEMENT OF EMPLOYEE.—An authoritative statement of a scientific body described in subparagraph (A)(i) shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(4) SUBMISSION PERIOD.—A claim submitted under the requirements of paragraph (3) may be made until—

(A) such time as the Secretary issues a regulation under the standard in paragraph (2)(A)—

(i) prohibiting or modifying the claim and the regulation has become effective; or

(ii) finding that the requirements of paragraph (3) have not been met, including finding that the petitioner has not submitted all the information required by the paragraph; or

(B) a district court of the United States in an enforcement proceeding under chapter 105 of this title has determined that the requirements of paragraph (3) have not been met.

(d) PETITIONS.—

(1) REGULATIONS.—

(A) IN GENERAL.—

(i) SUBMISSION.—Any person may petition the Secretary to issue a regulation under subsection (b)(1)(A) or (c)(2) relating to a claim described in subparagraph (A) or (B) of subsection (a)(1).

(ii) FINAL DECISION.—Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary.

(iii) NO ACTION AFTER PETITION IS RECEIVED.—If the Secretary does not act

within the 100 days under clause (ii), the petition shall be deemed to be denied unless an extension is mutually agreed on by the Secretary and the petitioner.

(iv) DENIAL; PETITION NOT TO BE MADE PUBLIC.—If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public.

(v) FURTHER AGENCY ACTIONS AFTER SECRETARY FILES PETITION.—If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of the decision.

(vi) NO FURTHER AGENCY ACTION AFTER SECRETARY FILES PETITION.—If the Secretary does not act within the 90 days under clause (v), the petition shall be deemed to be denied unless an extension is mutually agreed on by the Secretary and the petitioner.

(vii) RULEMAKING PERIOD.—If the Secretary issues a proposed regulation, the

rulemaking shall be completed within 540 days of the date the petition is received by the Secretary.

(viii) SUBMISSION TO CONGRESS OF REASONS IF REGULATIONS NOT PRESCRIBED.—If the Secretary does not issue a regulation within the 540 days under clause (vii), the Secretary shall provide the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate the reasons action on the regulation did not occur within the 540 days.

(B) USE OF TERMS CONSISTENT WITH DEFINED TERMS.—

(i) IN GENERAL.—Any person may petition the Secretary for permission to use in a claim described in subsection (a)(1)(A) terms that are consistent with the terms defined by the Secretary under subsection (b)(1)(A).

(ii) FINAL DECISION.—Within 90 days of the submission of a petition under clause (i), the Secretary shall issue a final

decision denying the petition or granting the permission.

(C) IMPLIED CLAIMS IN BRAND NAMES.—

(i) IN GENERAL.—Any person may petition the Secretary for permission to use an implied claim described in subsection (a)(1)(A) in a brand name.

(ii) PUBLICATION OF NOTICE; GRANT OF PETITION.—After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that the claim is not misleading and is consistent with terms defined by the Secretary under subsection (b)(1)(A).

(iii) DECISION PERIOD.—The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within the 100 days.

(2) INCLUSION OF REASONS.—A petition under paragraph (1)(A) respecting a claim described in subparagraph (A) or (B) of subsection (a)(1) shall

include an explanation of the reasons why the claim meets the requirements of this section and a summary of the scientific data that supports the reasons.

(3) CONSIDERATION OF REPORT FROM SCIENTIFIC BODY.—If a petition for a regulation under subsection (c)(2) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider the report and shall justify any decision rejecting the conclusions of the report.

(e) INAPPLICABILITY TO SPECIFIC FOODS.—

(1) INFANT FORMULAS AND MEDICAL FOODS.—This section does not apply to infant formulas subject to section 11114(h) of this title and medical foods as defined in section 49502(a) of this title.

(2) FOODS SERVED IN RESTAURANTS OR OTHER ESTABLISHMENTS.—Subparagraphs (C) through (E) of subsection (b)(1) and subsection (b)(2) do not apply to food—

(A) that is served in restaurants or other establishments in which food is served for immediate human consumption; or

(B) that is sold for sale or use in those establishments.

(3) FOOD FOR WHICH CLAIM IS REQUIRED BY A STANDARD OF IDENTITY.—A subsection (a)(1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 11101 of this title shall not be subject to subsection (b)(1)(A) or (b)(2).

(4) DIETARY SUPPLEMENTS.—A subsection (a)(1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subsection (c) but shall be subject to a procedure and standard, respecting the validity of the claim, established by regulation of the Secretary.

(f) CLAIMS UNDER SUBSECTION (a)(1)(B) FOR DIETARY SUPPLEMENTS.—

(1) IN GENERAL.—For purposes of subsection (a)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and—

(i) discloses the prevalence of the disease in the United States;

(ii) describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans;

(iii) characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function; or

(iv) describes general well-being from consumption of a nutrient or dietary ingredient;

(B) the manufacturer of the dietary supplement has substantiation that the statement is truthful and not misleading; and

(C) the statement contains, prominently displayed and in boldface type, the following: ''This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.''.

(2) UNAUTHORIZED CLAIMS.—A statement under this subsection may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

(3) NOTIFICATION BY MANUFACTURER.—If the manufacturer of a dietary supplement proposes to make a statement described in paragraph (1) in the labeling of the dietary supplement, the manufacturer shall notify the Secretary not later than 30 days

after the first marketing of the dietary supplement with the statement that such a statement is being made.

(g) PROPOSED REGULATIONS AUTHORIZED TO BE EFFECTIVE ON PUBLICATION.—

(1) IN GENERAL.—The Secretary may make proposed regulations issued under this section effective on publication pending consideration of public comment and publication of a final regulation if the Secretary determines that the action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

(i) enable consumers to develop and maintain healthy dietary practices;

(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this section.

(2) FINAL AGENCY ACTION.—The proposed regulations under paragraph (1) shall be deemed final agency action for purposes of judicial review.

**§ 11318. Dietary supplements; general**

(a) IN GENERAL.—A food shall be deemed to be misbranded if—

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the dietary supplement fails to list—

(i) the name of each ingredient of the dietary supplement that is described in section 10101(a)(17) of this title; and

(ii)(I) the quantity of each such ingredient; or

(II) with respect to a proprietary blend of the ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term ''dietary supplement'', which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section 10101(a)(17)(A)(i)(III) of this title, and the label or labeling of the supplement fails

to identify any part of the plant from which the ingredient is derived;

(D) the supplement—

(i) is covered by the specifications of an official compendium;

(ii) is represented as conforming to the specifications of an official compendium; and

(iii) fails to conform as described in clause (ii); or

(E) the supplement—

(i) is not covered by the specifications of an official compendium; and

(ii)(I) fails to have the identity and strength that the supplement is represented to have; or

(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

(b) DIRECTIONS FOR OR CONDITIONS OF USE; WARNINGS.—A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions for or conditions of use or warnings.

**§ 11319. Dietary supplements; serious adverse event**

A food shall be deemed to be misbranded if it is a dietary supplement that is marketed in the United States, unless the label of the dietary supplement includes a domestic address or domestic phone number through which the responsible person (as described in section 18902 of this title) may receive a report of a serious adverse event with the dietary supplement.

**§ 11320. Catfish**

A food shall be deemed to be misbranded if it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.

**§ 11321. Ginseng**

A food shall be deemed to be misbranded if it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus Panax.

**§ 11322. Failure to label; health threat**

(a) IN GENERAL.—A food shall be deemed to be misbranded if—

(1) it fails to bear a label required by the Secretary under section 20101(n)(1) of this title (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) on or after notifying the owner or consignee involved that the label is required under section 20101 of this title, the Secretary informs the owner or consignee that the food presents such a threat.

(b) EFFECT OF SECTION.—With respect to articles of food that are imported or offered for import into the United States, nothing in this section limits the authority of the Secretary or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law.

**§ 11323. Major food allergen labeling requirements**

(a) IN GENERAL.—

(1) DEFINITION OF NAME OF THE FOOD SOURCE FROM WHICH THE MAJOR FOOD ALLERGEN IS DERIVED.—

(A) IN GENERAL.—In this subsection, the term ''name of the food source from which the major food allergen is derived'' means the name described in section 10101(a)(29)(A) of this title, except as provided in subparagraph (B).

(B) TREE NUTS; FISH; CRUSTACEAN SHELLFISH.—In the case of a tree nut, fish, or

crustacean shellfish, the term ''name of the food source from which the major food allergen is derived'' means the name of the specific type of nut or species of fish or crustacean shellfish.

(2) IN GENERAL.—A food shall be deemed to be misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless—

(A) the word ''Contains'', followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under sections 11307 and 11310 of this title; or

(B) the common or usual name of the major food allergen in the list of ingredients required under sections 11307 and 11310 of this title is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source from which the major food allergen is derived is not required when—

(i) the common or usual name of the ingredient uses the name of the food

source from which the major food allergen is derived; or

(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source from which the major food allergen is derived that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under clause (i) or (ii) of section 10101(a)(29)(B) of this title.

(b) INFORMATION MAY APPEAR IN LABELING IN LIEU OF APPEARING ON LABEL.—

(1) IN GENERAL.—The information required under this section may appear in labeling in lieu of appearing on the label only if the Secretary finds that such other labeling is sufficient to protect the public health.

(2) FINDING EFFECTIVE ON PUBLICATION.—A finding by the Secretary under this subsection (including any change in an earlier finding under this subsection) is effective on publication in the Federal Register as a notice.

(c) FLAVORING; COLORING; INCIDENTAL ADDITIVE.—Notwithstanding section 11307, 11310, or 11312 of this title, or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this section.

(d) MODIFICATION OR ELIMINATION OF REQUIREMENTS.—The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of subsection (a)(2), or eliminate the requirement of subparagraph (A) or the requirements of subparagraph (B) of subsection (a)(2), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) of subsection (a)(2) is necessary to protect the public health.

(e) PETITION TO EXEMPT CERTAIN FOOD INGREDIENTS.—

(1) IN GENERAL.—Any person may petition the Secretary to exempt a food ingredient described in section 10101(a)(29)(B) of this title from the allergen labeling requirements of this section.

(2) DECISION PERIOD.—The Secretary shall approve or deny the petition within 180 days of receipt of the petition or the petition shall be deemed de-

nied, unless an extension of time is mutually agreed on by the Secretary and the petitioner.

(3) BURDEN.—The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

(4) FINAL AGENCY ACTION.—A determination regarding a petition under this subsection shall constitute final agency action.

(5) PUBLIC SITE.—The Secretary shall promptly post to a public site all petitions received under this subsection within 14 days of receipt and the Secretary shall promptly post the Secretary's response to each.

(f) EXEMPTION BY NOTIFICATION.—

(1) IN GENERAL.—A person need not file a petition under subsection (e) to exempt a food ingredient described in section 10101(a)(29)(B) of this title from the allergen labeling requirements of this section, if the person files with the Secretary a notification containing—

(A) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

(B) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 11111 of this title.

(2) INTRODUCTION OF FOOD INGREDIENT INTO INTERSTATE COMMERCE.—The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this subsection, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

(3) PUBLIC SITE.—The Secretary shall promptly post to a public site all notifications received under this paragraph within 14 days of receipt and

promptly post any objections to the notifications by the Secretary.

### § 11324. Nonmajor food allergen labeling requirements

Notwithstanding section 11307, 11310, or 11312 of this title, or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.

# Division D—Drugs and Devices

# Chapter 131—Drugs and Devices Generally

Sec.

13101. Adulterated drugs and devices.
13102. Exemption from labeling and packaging requirements for drugs and devices to be processed, labeled, or repacked elsewhere.
13103. Prescription drugs.
13104. Combination products.
13105. Regulation of certain products as drugs.
13106. Pharmacy compounding.
13107. Outsourcing facilities.
13108. Prereview of television advertisements.
13109. Process to update labeling for certain generic drugs.
13110. Veterinary feed directive drugs.
13111. Risk evaluation and mitigation strategies.
13112. Pediatric studies of drugs.
13113. Research into pediatric uses for drugs and biological products.
13114. Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers.
13115. Pharmaceutical security.
13116. Extension of exclusivity period for new qualified infectious disease products.
13117. Utilizing real-world evidence.
13118. Regulation of certain nonprescription drugs that are marketed without an approved drug application.
13119. Expedited approval of drugs for serious or life-threatening diseases or conditions.
13120. Manufacturing changes.

13121. Reports of postmarketing studies.
13122. Discontinuance or interruption in the production of life-saving drugs.
13123. Annual reporting on drug shortages.
13124. Coordination relating to drug shortages.
13125. Drug shortage list.
13126. Hospital repackaging of drugs in shortage.
13127. Standards for regenerative medicine and regenerative advanced therapies.
13128. Competitive generic therapies.
13129. Prompt reports of marketing status.
13130. Discontinuance or interruption in the production of medical devices.
13131. Platform technologies.
13132. Advanced manufacturing technologies designation program.
13133. Qualification of drug development tools.
13134. Authority to designate official names.
13135. Inapplicability of division to cosmetics.
13136. Registration of producers of drugs or devices.
13137. Clinical trial guidance for antibiotic drugs.
13138. Susceptibility test interpretive criteria for microorganisms.
13139. Priority zoonotic animal drugs.
13140. Classification of devices intended for human use.
13141. Performance standards.
13142. Premarket approval.
13143. Pediatric uses of devices.
13144. Breakthrough devices.
13145. Predetermined change control plans for devices.
13146. Banned devices.
13147. Judicial review.
13148. Agency documentation and review of significant decisions regarding devices.
13149. Notification and other remedies.
13150. Program to improve the device recall system.
13151. Records and reports on devices.
13152. General provisions respecting control of devices intended for human use.
13153. State and local requirements respecting devices.
13154. Postmarket surveillance.
13155. Accredited persons.
13156. Priority review to encourage treatments for tropical diseases.
13157. Priority review for qualified infectious disease products.
13158. Ensuring cybersecurity of devices.

## § 13101. Adulterated drugs and devices

(a) POISONOUS, INSANITARY, OR UNSAFE SUBSTANCES OR CONDITIONS.—

(1) DEFINITION OF CURRENT GOOD MANUFACTURING PRACTICE.—For purposes of paragraph (2)(B)(ii), the term ''current good manufacturing practice'' includes the implementation of oversight

and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

(2) IN GENERAL.—A drug or device shall be deemed to be adulterated—

(A) if it consists in whole or in part of any filthy, putrid, or decomposed substance;

(B) if—

(i) it has been prepared, packed, or held under insanitary conditions whereby—

(I) it may have been contaminated with filth; or

(II) it may have been rendered injurious to health;

(ii) it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to ensure that the drug—

(I) meets the requirements of this subtitle as to safety; and

(II) has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or

(iii) it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopeia to ensure that the drug—

(I) meets the requirements of this subtitle as to safety; and

(II) has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess;

(C) if its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(D) if—

(i) it bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of section 17701(a) of this title; or

(ii) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 17701(a) of this title;

(E) if it is a new animal drug that is unsafe within the meaning of chapter 137 of this title; or

(F) if it is an animal feed bearing or containing a new animal drug, and the animal feed is unsafe within the meaning of chapter 137 of this title.

(b) STRENGTH, QUALITY, OR PURITY DIFFERING FROM OFFICIAL COMPENDIUM.—

(1) IN GENERAL.—A drug shall be deemed to be adulterated if it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium.

(2) DETERMINATION OF STRENGTH, QUALITY, OR PURITY.—

(A) IN GENERAL.—The determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium.

(B) TESTS OR METHODS OF ASSAY NOT PRESCRIBED OR INSUFFICIENT.—If tests or methods of assay have not been prescribed in the compendium, or if the tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of the determination, the Secretary shall bring that fact to the attention of the appropriate body charged with the revision of the compendium.

(C) PRESCRIBING TESTS OR METHODS OF ASSAY BY SECRETARY.—If the body charged with the revision of the compendium fails within a reasonable time to prescribe tests or methods of assay that, in the judgment of the Secretary, are sufficient for purposes of this subsection, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which the determina-

tion as to strength, quality, or purity shall be made.

(D) EXCEPTION.—No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity set forth for the drug in the compendium, if its difference in strength, quality, or purity from the standard is plainly stated on its label.

(E) REQUIREMENTS FOR DRUGS RECOGNIZED BY COMPENDIA.—If a drug is recognized in both the United States Pharmacopeia and the Homoeopathic Pharmacopoeia of the United States, the drug shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homoeopathic drug, in which case the drug shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopeia.

(c) MISREPRESENTATION OF STRENGTH IF DRUG IS UNRECOGNIZED IN COMPENDIUM.—A drug or device shall be deemed to be adulterated if it is not subject to the provisions of subsection (b) and its strength differs from, or

its purity or quality falls below, that which it purports or is represented to possess.

(d) MIXTURE WITH OR SUBSTITUTION OF ANOTHER SUBSTANCE.—A drug shall be deemed to be adulterated if any substance has been—

(1) mixed or packed with the drug so as to reduce its quality or strength; or

(2) substituted wholly or in part for the drug.

(e) DEVICES NOT IN CONFORMITY WITH PERFORMANCE STANDARDS.—A device shall be deemed to be adulterated—

(1) if it is, or purports to be or is represented as, a device that is subject to a performance standard established under section 13141 of this title unless the device is in all respects in conformity with the standard; or

(2) if it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 13141(c) of this title unless the device is in all respects in conformity with the standard.

(f) CERTAIN CLASS III DEVICES.—

(1) IN GENERAL.—A device shall be deemed to be adulterated if it is a class III device—

(A)(i) that—

(I) is required by an order issued under section 13142(b) of this title to have an approval under section 13142 of this title of an application for premarket approval; and

(II) is not exempt from section 13142 of this title under section 13152(g) of this title; and

(ii) for which—

(I) an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the 90-day period beginning on the date of the issuance of the order; or

(II) an application for premarket approval was filed and approval of the application has been denied, suspended, or withdrawn, or a notice of completion of a product development protocol was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B) that—

(i) was classified under section 13140(h) of this title into class III, which—

(I) under section 13142(a) of this title is required to have in effect an approved application for premarket approval; and

(II) is not exempt from section 13142 of this title under section 13152(g) of this title; and

(ii) has an application that has been suspended or is otherwise not in effect; or

(C) that was classified under section 13152(l) of this title into class III, which—

(i) under that section is required to have in effect an approved application under section 13142 of this title; and

(ii) has an application that has been suspended or is otherwise not in effect.

(2) INAPPLICABILITY DURING SPECIFIED PERIOD.—

(A) DEVICE INTENDED SOLELY FOR INVESTIGATIONAL USE.—In the case of a device classified under section 13140(h) of this title into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to the device during the period ending on the 90th day after the date of the

promulgation of the regulations prescribing the procedures and conditions required by section 13152(g)(2) of this title.

(B) DEVICE SUBJECT TO ORDER.—In the case of a device subject to an order issued under section 13142(b) of this title, paragraph (1) shall not apply with respect to the device during the period ending on the later of—

(i) the last day of the 30th calendar month beginning after the month in which the classification of the device in class III became effective under section 13140 of this title; or

(ii) the 90th day after the date of the issuance of the order.

(C) DEVICE SUBJECT TO REGULATION PRIOR TO JULY 9, 2012.—In the case of a device with respect to which a regulation was promulgated under section 13142(b) of this title prior to July 9, 2012, a reference in this subsection to an order issued under section 13142(b) of this title shall be deemed to include the regulation.

(g) BANNED DEVICES.—A device shall be deemed to be adulterated if it is a banned device.

(h) MANUFACTURE, PACKING, STORAGE, OR INSTALLATION OF DEVICE NOT IN CONFORMITY WITH APPLICABLE REQUIREMENTS OR CONDITIONS.—A device shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 13152(f)(1) of this title or an applicable condition prescribed by an order under section 13152(f)(2) of this title.

(i) FAILURE TO COMPLY WITH REQUIREMENTS UNDER WHICH DEVICE WAS EXEMPTED FOR INVESTIGATIONAL USE.—A device shall be deemed to be adulterated if—

(1) it is a device for which an exemption has been granted under section 13152(g) of this title for investigational use; and

(2) the person that was granted the exemption or any investigator who uses the device under the exemption fails to comply with a requirement prescribed by or under the section.

(j) DELAYED, DENIED, OR LIMITED INSPECTION; REFUSAL TO PERMIT ENTRY OR INSPECTION.—

(1) IN GENERAL.—A drug or device shall be deemed to be adulterated if it has been manufactured, processed, packed, or held in any factory,

warehouse, or establishment and the owner, operator, or agent of the factory, warehouse, or establishment—

(A) delays, denies, or limits an inspection; or

(B) refuses to permit entry or inspection.

(2) GUIDANCE.—The Secretary shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of this subsection.

**§ 13102. Exemption from labeling and packaging requirements for drugs and devices to be processed, labeled, or repacked elsewhere**

The Secretary shall promulgate regulations exempting from any labeling or packaging requirement of this subtitle drugs and devices that are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that the drugs and devices are not adulterated or misbranded under this subtitle upon removal from the processing, labeling, or repacking establishment.

**§ 13103. Prescription drugs**

(a) PRESCRIPTION REQUIRED FOR CERTAIN DRUGS.—

(1) IN GENERAL.—

(A) TYPES OF DRUGS.—A drug intended for human use shall be dispensed only on the conditions under subparagraph (B) if the drug—

(i) because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug; or

(ii) is limited by an approved application under chapter 135 of this title to use under the professional supervision of a practitioner licensed by law to administer the drug.

(B) CONDITIONS.—A drug described in subparagraph (A) shall be dispensed only—

(i) on a written prescription of a practitioner licensed by law to administer the drug;

(ii) on an oral prescription of the practitioner that is reduced promptly to writing and filed by the pharmacist; or

(iii) by refilling any such written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order that is reduced promptly to writing and filed by the pharmacist.

(C) MISBRANDED DRUG.—The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act that results in the drug being misbranded while held for sale.

(2) EXEMPTION FROM MISBRANDING PROVISIONS.—

(A) IN GENERAL.—Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer the drug shall be exempt from the requirements of chapter 133 of this title, except sections 13301, 13308(2), and 13308(3) of this title and the packaging requirements of sections 13306, 13307, and 13313 of this title, if the drug bears a label containing—

(i) the name and address of the dispenser;

(ii) the serial number and date of the prescription or of its filling;

(iii) the name of the prescriber, and, if stated in the prescription, the name of the patient; and

(iv) the directions for use and cautionary statements, if any, contained in the prescription.

(B) INAPPLICABILITY.—This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1).

(3) EXEMPTION FROM REQUIRED PRESCRIPTION.—The Secretary may by regulation exempt drugs subject to chapter 135 of this title from the requirements of paragraph (1) if the requirements are not necessary for the protection of the public health.

(4) PRESCRIPTION SYMBOL.—

(A) DRUGS THAT REQUIRE PRESCRIBING.—A drug that is subject to paragraph

(1) shall be deemed to be misbranded if, at any time prior to dispensing, the label of the drug fails to bear, at a minimum, the symbol ''Rx only''.

(B) DRUGS THAT DO NOT REQUIRE PRESCRIBING.—A drug to which paragraph (1) does not apply shall be deemed to be misbranded if, at any time prior to dispensing, the label of the drug bears the symbol described in subparagraph (A).

(b) SALES RESTRICTIONS.—

(1) DRUG SAMPLES.—

(A) DEFINITION OF DRUG SAMPLE.—In this paragraph, the term ''drug sample'' means a unit of a drug, subject to subsection (a), that—

(i) is not intended to be sold; and

(ii) is intended to promote the sale of the drug.

(B) IN GENERAL.—A person shall not sell, purchase, or trade or offer to sell, purchase, or trade any drug sample.

(C) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to

criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) COUPONS.—

(A) DEFINITION OF COUPON.—In this paragraph, the term ''coupon'' means a form that may be redeemed, at no cost or at a reduced cost, for a drug that is prescribed in accordance with subsection (a).

(B) IN GENERAL.—A person shall not sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon.

(3) DRUGS PURCHASED BY HOSPITAL OR OTHER HEALTH CARE ENTITY.—

(A) DEFINITIONS.—In this paragraph:

(i) EMERGENCY MEDICAL REASONS.—The term ''emergency medical reasons'' includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(ii) ENTITY.—The term ''entity'' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(B) IN GENERAL.—A person shall not sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) that is subject to subsection (a); and

(ii) that—

(I) was purchased by a public or private hospital or other health care entity; or

(II) was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)).

(C) INAPPLICABILITY.—Subparagraph (B) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from

other hospitals or health care entities that are members of the organization;

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (B)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (a).

(c) DISTRIBUTION OF DRUG SAMPLES.—

(1) DEFINITIONS.—In this subsection:

(A) AUTHORIZED DISTRIBUTORS OF RECORD.—The term ''authorized distributors of

record'' means those distributors with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products.

(B) DISTRIBUTE.—The term ''distribute'' does not include the providing of a drug sample to a patient by a—

(i) practitioner licensed to prescribe the drug;

(ii) health care professional acting at the direction and under the supervision of such a practitioner; or

(iii) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received the sample pursuant to paragraph (3) or (4).

(C) DRUG SAMPLE.—The term ''drug sample'' has the meaning given the term in subsection (b).

(D) WHOLESALE DISTRIBUTION.—The term ''wholesale distribution'' has the meaning given the term in subsection (d).

(2) IN GENERAL.—Except as provided in paragraphs (3) and (4), a person shall not distribute any drug sample.

(3) CONDITIONS FOR DISTRIBUTION BY MAIL OR COMMON CARRIER.—

(A) IN GENERAL.—

(i) AUTHORIZED RECIPIENTS.—The manufacturer or authorized distributor of record of a drug subject to subsection (a) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe the drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities.

(ii) MANNER.—Any distribution of drug samples under clause (i) may be made only—

(I) in response to a written request for drug samples made on a form that meets the requirements of subparagraph (B); and

(II) under a system that requires the recipient of the drug sample to execute a written receipt for the drug

sample on its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) WRITTEN REQUESTS.—A written request for a drug sample required by subparagraph (A)(ii)(I) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request;

(ii) the identity of the drug sample requested and the quantity requested;

(iii) the name of the manufacturer of the drug sample requested; and

(iv) the date of the request.

(C) MAINTENANCE OF RECORD.—

(i) IN GENERAL.—Each drug manufacturer or authorized distributor of record that makes distributions by mail or common carrier under this paragraph shall—

(I) maintain, for a period of 3 years—

(aa) the request forms submitted for the distributions; and

(bb) the receipts submitted for the distributions; and

(II) maintain a record of distributions of drug samples that identifies the drugs distributed and the recipients of the distributions.

(ii) AVAILABILITY TO FEDERAL AND STATE OFFICIALS.—Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(4) CONDITIONS FOR DISTRIBUTION OTHER THAN BY MAIL OR COMMON CARRIER.—

(A) IN GENERAL.—

(i) CONDITIONS.—The manufacturer or authorized distributor of record of a drug subject to subsection (a) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with clause (ii) and carries out the activities described in subparagraphs (B) through (F).

(ii) AUTHORIZED RECIPIENTS.—

(I) IN GENERAL.—Drug samples may be distributed only—

(aa) to practitioners licensed to prescribe the drugs if they make a written request for the drug samples; or

(bb) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

(II) WRITTEN REQUESTS.—A written request for drug samples under subclause (I) shall be made on a form that contains—

(aa) the practitioner's name, address, and professional designation;

(bb) the identity of the drug sample requested;

(cc) the quantity of drug samples requested;

(dd) the name of the manufacturer or authorized distributor of record of the drug sample;

(ee) the date of the request; and

(ff) the signature of the practitioner making the request.

(B) STORAGE CONDITIONS.—Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will ensure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) RECORDKEEPING.—

(i) INVENTORY.—Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record.

(ii) LIST OF REPRESENTATIVES.—Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug sam-

ples and of the sites where drug samples are stored.

(iii) MAINTENANCE OF RECORDS.—Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of—

(I) all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record;

(II) all inventories maintained under this subparagraph;

(III) all thefts or significant losses of drug samples; and

(IV) all requests made under subparagraph (A) for drug samples.

(iv) AVAILABILITY.—Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) NOTIFICATION OF LOSS OR THEFT.—Drug manufacturers or authorized distributors of record shall notify the Secretary of any sig-

nificant loss of drug samples and any known theft of drug samples.

(E) REPORTING OF CONVICTION OF REPRESENTATIVE.—Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (b)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) CONTACT INFORMATION.—Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(d) WHOLESALE DISTRIBUTION.—

(1) DEFINITIONS.—In this subsection:

(A) AFFILIATE.—The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(i) 1 business entity controls, or has the power to control, the other business entity; or

(ii) a third party controls, or has the power to control, both of the business entities.

(B) WHOLESALE DISTRIBUTION.—

(i) IN GENERAL.—The term ''wholesale distribution'' means the distribution of a drug subject to subsection (a) to a person other than a consumer or patient, or receipt of a drug subject to subsection (a) by a person other than the consumer or patient.

(ii) EXCLUSIONS.—The term ''wholesale distribution'' does not include—

(I) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(II) the distribution of a drug or an offer to distribute a drug among hospitals or other health care entities that are under common control;

(III) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public

Health Service Act (42 U.S.C. 247d), except that, for purposes of this subparagraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(IV) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (a)(1);

(V) the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use;

(VI) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(VII) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by the dispenser, hospital, or other health care entity;

(VIII) the distribution of a drug by the manufacturer of the drug;

(IX) the receipt or transfer of a drug by an authorized third-party logistics provider provided that the third-party logistics provider does not take ownership of the drug;

(X) the transportation, by a common carrier, of a drug, provided that the common carrier does not take ownership of the drug;

(XI) the distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 14902(e) of this title;

(XII) salable drug returns when conducted by a dispenser;

(XIII) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subclause as a ''medical convenience kit'') if—

(aa) the medical convenience kit is assembled in an establishment that is registered with the FDA as a device manufacturer in accordance with section 13136(b)(2) of this title;

(bb) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in division A of subtitle V of this title;

(cc) in the case of a medical convenience kit that includes a product, the person that manufactures the kit—

(AA) purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(BB) does not alter the primary container or label of

the product as purchased from the manufacturer or wholesale distributor; and

(dd) in the case of a medical convenience kit that includes a product, the product is—

(AA) an intravenous solution intended for the replenishment of fluids and electrolytes;

(BB) a product intended to maintain the equilibrium of water and minerals in the body;

(CC) a product intended for irrigation or reconstitution;

(DD) an anesthetic;

(EE) an anticoagulant;

(FF) a vasopressor; or

(GG) a sympathomimetic;

(XIV) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment

of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(XV) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(XVI) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for those purposes or for injection;

(XVII) the distribution of medical gas, as defined in section 14701 of this title;

(XVIII) the facilitation of the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(XIX) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health

care entity, to a repackager described in section 14901(16)(B) of this title and registered under section 13136 of this title for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(2) REQUIRED LICENSURE.—Subject to section 14903 of this title:

(A) IN GENERAL.—A person shall not engage in wholesale distribution of a drug subject to subsection (a)(1) in any State unless the person—

(i) is—

(I) licensed by the State from which the drug is distributed; or

(II) if the State from which the drug is distributed has not established a licensure requirement, licensed by the Secretary; and

(ii) if the drug is distributed interstate, is licensed by the State into which

the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

(B) STANDARDS.—Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 14903 of this title.

(3) REPORTING AND DATABASE.—

(A) REPORTING.—Any person that owns or operates an establishment that engages in wholesale distribution shall—

(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

(I) each State by which the person is licensed and the appropriate identification number of each such license; and

(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

(B) DATABASE.—The Secretary shall establish a database of authorized wholesale distributors. The database shall—

(i) identify each authorized wholesale distributor by name, contact information, and each State where the wholesale distributor is appropriately licensed to engage in wholesale distribution;

(ii) be available to the public on the FDA website; and

(iii) be regularly updated on a schedule determined by the Secretary.

(C) COORDINATION.—The Secretary shall establish a format and procedure for appropriate State officials to access the information

provided pursuant to subparagraph (A) in a prompt and secure manner.

(D) CONFIDENTIALITY.—Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(4) LICENSING BY SECRETARY.—

(A) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection (a), the Secretary—

(i) shall license a person engaged in wholesale distribution located in the State; and

(ii) may collect a reasonable fee in the amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section.

(B) ADJUSTMENT OF FEES.—The Secretary shall adjust fee rates as needed on an

annual basis to generate only the amount of revenue needed to perform this service.

(C) LIMITATION ON COLLECTION AND AVAILABILITY.—Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.

(D) AVAILABLE UNTIL EXPENDED.—Fees authorized under this paragraph are authorized to remain available until expended.

(E) TRANSFER OF SUMS TO ACCOUNT WITHOUT FISCAL YEAR LIMITATION.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation.

(F) STATE LICENSING FEES.—Nothing in this subtitle shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of the distributors.

(5) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1)(B), (2), (3), and (4), each entity that meets the definition of a third-party logistics provider under section 14901(22) of this

title shall obtain a license as a third-party logistics provider as described in section 14904(a) of this title and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

(e) VETERINARY PRESCRIPTION DRUGS.—

(1) PRESCRIPTION REQUIRED FOR CERTAIN DRUGS INTENDED FOR ANIMALS.—

(A) IN GENERAL.—

(i) TYPES OF DRUGS.—A drug intended for use by animals other than humans (other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug) shall be dispensed only on the condition under clause (ii) if it is a drug that—

(I) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian; or

(II) is limited by an approved application under section 13703 of this title, a conditionally approved application under section 14502 of this title, or an index listing under section 14503 of this title to use under the professional supervision of a licensed veterinarian.

(ii) CONDITION.—A drug described in clause (i) shall be dispensed only by or on the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) ORDER.—For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law;

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person; and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) MISBRANDED DRUG.—The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act that results in the drug being misbranded while held for sale.

(2) EXEMPTION FROM MISBRANDING PROVISIONS.—

(A) IN GENERAL.—Any drug when dispensed in accordance with paragraph (1)—

(i) shall be exempt from the requirements of chapter 133 of this title, except sections 13301, 13306, 13307, 13308(2), 13308(3), and 13313 of this title; and

(ii) shall be exempt from the packaging requirements of section 13306, 13307, and 13313 of this title, if—

(I) when dispensed by a licensed veterinarian, the drug bears a label containing—

(aa) the name and address of the practitioner; and

(bb) any directions for use and cautionary statements specified by the practitioner; or

(II) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing—

(aa) the name and address of the dispenser;

(bb) the serial number and date of the order or of its filling;

(cc) the name of the licensed veterinarian; and

(dd) the directions for use and cautionary statements, if any, contained in the order.

(B) INAPPLICABILITY.—Subparagraph (A) shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) EXEMPTION FROM REQUIRED ORDER.—The Secretary may by regulation exempt drugs for animals other than humans subject to chapter 137 of this title or section 14502 or 14503 of this title from the requirements of paragraph (1) if the requirements are not necessary for the protection of the public health.

(4) CAUTIONARY STATEMENT.—

(A) DRUGS THAT REQUIRE AN ORDER FROM VETERINARIAN.—A drug that is subject to paragraph (1) shall be deemed to be misbranded if, at any time prior to dispensing, its label fails to bear the statement ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''.

(B) DRUGS THAT DO NOT REQUIRE AN ORDER FROM VETERINARIAN.—A drug to which paragraph (1) does not apply shall be deemed to be misbranded if, at any time prior to dispensing, its label bears the statement specified in subparagraph (A).

**§ 13104. Combination products**

(a) DEFINITIONS.—In this section:

(1) AGENCY CENTER.—The term ''agency center'' means a center or alternative organizational component of the FDA.

(2) BIOLOGICAL PRODUCT.—The term ''biological product'' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(3) MARKET CLEARANCE.—The term ''market clearance'' includes—

(A) approval of an application under chapter 135 of this title or section 13142 or 13152(g) of this title;

(B) a finding of substantial equivalence under this chapter;

(C) approval of a biologics license application under section 351(a) of the Public Health Service Act (42 U.S.C. 262); and

(D) de novo classification under section 13140(c)(1) of this title.

(4) PREMARKET REVIEW; REVIEW.—The terms ''premarket review'' and ''review'' include all activities of the FDA conducted prior to approval or clearance of an application, notification, or request for classification submitted under chapter 135 of this title, section 13136(k), 13140(h)(2), 13142, or 13152 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262), including with respect to investigational use of the product.

(5) PRIMARY MODE OF ACTION.—The term ''primary mode of action'' means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

(b) PRIMARY AGENCY CENTER.—The Secretary shall, in accordance with this section, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

(c) PREMARKET REVIEW.—The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

(d) DETERMINATION OF PRIMARY MODE OF ACTION.—

(1) IN GENERAL.—The Secretary shall determine the primary mode of action of the combination product.

(2) AGENCY CENTER WITH JURISDICTION BASED ON DETERMINATION.—If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

(B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

(C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(3) COMBINATION PRODUCT THAT HAS CHEMICAL ACTION ON HUMAN BODY.—In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action in or on the human body.

(e) DISAGREEMENT BY SPONSOR.—

(1) REQUEST FOR SUBSTANTIVE RATIONALE; PROPOSAL OF STUDIES.—If a sponsor of a combination product disagrees with the determination under subsection (d)—

(A) the sponsor may request, and the Secretary shall provide to the sponsor, a substantive rationale that references scientific evidence provided by the sponsor and any other scientific evidence relied on by the Secretary to support the determination; and

(B) the sponsor of the combination product may propose 1 or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of the product.

(2) COLLABORATION AND AGREEMENT ON DESIGN OF STUDIES.—If the sponsor proposes any study described in paragraph (1)(B), the Secretary and the sponsor of the combination product shall collaborate and seek to reach agreement, within a reasonable time of the proposal, not to exceed 90 calendar days, on the design of the studies.

(3) CONSIDERATION OF DATA FROM STUDIES.—If an agreement is reached under paragraph (2) and the sponsor conducts 1 or more of the studies under paragraph (1)(B), the Secretary shall consider the data resulting from the studies when reevaluating the determination of the primary mode of action of the combination product, and until the reevaluation occurs and the Secretary issues a new determination, the determination of the Secretary under subsection (d) shall remain in effect.

(f) MEETING REQUESTED BY SPONSOR.—

(1) IN GENERAL.—To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on the combination product.

(2) IF MAKING A DETERMINATION IS NECESSARY.—If the Secretary concludes that a determination of the primary mode of action pursuant to

subsection (d) is necessary, the sponsor may request the meeting only after the Secretary makes the determination.

(3) IF SPONSOR SUBMITS A WRITTEN MEETING REQUEST.—If the sponsor submits a written meeting request, the Secretary shall, not later than 75 calendar days after receiving the request, meet with the sponsor of the combination product.

(4) ISSUES FOR DISCUSSION.—A meeting under this subsection may—

(A) address the standards and requirements for market approval or clearance of the combination product;

(B) address other issues relevant to the combination product, such as requirements related to postmarket modification of the combination product and good manufacturing practices applicable to the combination product; and

(C) identify elements under subparagraphs (A) and (B) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding the elements, at the time a request for the meeting is made.

(5) AGREEMENT REQUIRED TO BE IN WRITING AND PART OF RECORD.—Any agreement under this subsection shall be in writing and made part of the administrative record by the Secretary.

(6) EFFECTIVE PERIOD OF AGREEMENT.—Any agreement under this subsection shall remain in effect, except—

(A) on the written agreement of the Secretary and the sponsor or applicant; or

(B) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior than the director, in consultation with consulting centers and the Office, as appropriate, that—

(i) an issue essential to determining whether the standard for market clearance or other applicable standard under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) applicable to the combination product has been identified since the agreement was reached; or

(ii) deviating from the agreement is otherwise justifiable based on scientific evidence, for public health reasons.

(g) PREMARKET REVIEW.—

(1) DEFINITION OF APPROVED DRUG.—In this subsection, the term ''approved drug'' means an active ingredient—

(A) that was in an application previously approved under section 13504 of this title, which application is relied on by the applicant submitting the application or request described in paragraph (4);

(B) for which full reports of investigations that have been made to show whether the drug is safe for use and whether the drug is effective in use were not conducted by or for the applicant submitting the application or request described in paragraph (4); and

(C) for which the applicant submitting the application or request described in paragraph (4) has not obtained a right of reference or use from the person by or for whom the investigations described in subparagraph (B) were conducted.

(2) IN GENERAL.—For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (3), the Secretary may require that the sponsor of the combination product submit to the

Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.), including any incremental risks and benefits posed by the combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or substantial equivalence for the approved constituent part relied on by the applicant in accordance with paragraphs (1), (4), (5), and (6).

(3) APPROVED CONSTITUENT PART.—For purposes of paragraph (2), an approved constituent part is—

(A) a drug constituent part of a combination product being reviewed in a single application or request under section 13136(k), 13140(h)(2), or 13142 of this title (submitted in accordance with paragraphs (1), (4), (5), and (6)), that is an approved drug, provided the application or request complies with paragraphs (1), (4), (5), and (6);

(B) a device constituent part approved under section 13142 of this title that is referenced by the sponsor and that is available for

use by the Secretary under section 13152(h)(4) of this title; or

(C) any constituent part that was previously approved, cleared, or classified under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 18901(a)(2) of this title.

(4) APPLICATION REQUIREMENTS.—If an application is submitted under section 13136(k) or 13142 of this title or a request is submitted under section 13140(h)(2) of this title, consistent with any determination made under subsection (d), for a combination product containing as a constituent part an approved drug—

(A) the application or request shall include the certification or statement described in section 13503(b) of this title; and

(B) the applicant or requester shall provide notice as described in section 13503(c) of this title.

(5) APPLICABLE PROVISIONS.—The following provisions shall apply with respect to an application or request described in paragraph (4) to the same

extent and in the same manner as if the application or request were an application described in section 13503(b) of this title that referenced the approved drug:

(A) Paragraphs (1), (2), (3), and (4) of section 13504(c) of this title.

(B) Subparagraphs (A), (B) and (C) of section 13504(c)(5) of this title.

(C) Subsections (b) and (c) of section 13112 of this title.

(D) Section 13116(b) of this title.

(E) Section 13903(a) of this title.

(6) PATENT INFRINGEMENT IMPLICATIONS.—Notwithstanding any other provision of this section, an application or request for classification for a combination product described in paragraph (4) shall be considered an application submitted under section 13503(b) of this title for purposes of section 271(e)(2)(A) of title 35.

(h) SEPARATE APPLICATIONS FOR CONSTITUENT PARTS.—Nothing in this section shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.

(i) USE OF AGENCY RESOURCES.—Nothing in this section shall prevent the Secretary from using any agency resources of the FDA necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(j) OFFICE RELATING TO COMBINATION PRODUCTS.—

(1) DEFINITION OF OFFICE.—In this subsection, the term ''Office'' means the office established under paragraph (2).

(2) ESTABLISHMENT.—The Secretary shall establish in the Office of the Commissioner of Food and Drugs an office to ensure—

(A) the prompt assignment of combination products to agency centers;

(B) the timely and effective premarket review of the combination products; and

(C) consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(3) CONSULTATION.—The Office shall, in determining whether a product is to be designated a combination product, consult with the component in the

Office of the Commissioner of Food and Drugs that is responsible for the determinations.

(4) EXPERTISE.—The Office shall have appropriate scientific and medical expertise.

(5) HEAD.—The Office shall be headed by a director.

(6) DUTIES RELATING TO PREMARKET REVIEW.—

(A) ASSIGNMENT OF AGENCY CENTER.—In carrying out this section, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with subsections (b), (c), (d), and (e) for the premarket review of the combination product.

(B) ENSURING TIMELY AND EFFECTIVE REVIEW.—

(i) IN GENERAL.—In carrying out this section, the Office shall help to ensure timely and effective premarket review that involves more than 1 agency center by—

(I) coordinating the reviews;

(II) overseeing the timeliness of the reviews; and

(III) overseeing the alignment of feedback regarding the reviews.

(ii) TIMELINESS AND ALIGNMENT.—To ensure the timeliness and alignment of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness and alignment of the premarket review.

(C) COMMUNICATIONS.—

(i) DESIGNATED PERSONS AS POINTS OF CONTACT FOR SPONSORS.—The Office shall ensure that, with respect to a combination product, a designated person (or persons) in the primary agency center is the primary point (or points) of contact for the sponsor of the combination product.

(ii) CONSULTING CENTER.—The Office shall also coordinate communications to and from any consulting center involved in the premarket review, if requested by the primary agency center or any such consulting center.

(iii) COMMUNICATION FROM PRIMARY AGENCY CENTER AS COMMUNICATION FROM SECRETARY.—Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

(D) MANAGEMENT OF PREMARKET REVIEWS.—The Office shall, with respect to the premarket review of a combination product—

(i) ensure that any meeting between the Secretary and the sponsor of the combination product is attended by each agency center involved in the review, as appropriate;

(ii) ensure that each consulting agency center has completed its premarket review and provided the results of the review to the primary agency center in a timely manner; and

(iii) ensure that each consulting center follows the guidance described in sub-

section (k) and advises, as appropriate, on other relevant regulations, guidances, and policies.

(7) SPONSOR ACTIONS.—In seeking agency action with respect to a combination product, the sponsor of the combination product—

(A) shall identify the product as a combination product; and

(B) may request in writing the participation of representatives of the Office in meetings related to the combination product, or to have the Office otherwise engage on the regulatory matters concerning the combination product.

(8) ENSURING CONSISTENCY AND APPROPRIATENESS OF POSTMARKET REGULATION.—In carrying out this section, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(9) DISPUTES.—

(A) TIMELINESS OF PREMARKET REVIEW.—Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.

(B) SUBSTANCE OF PREMARKET REVIEW.—During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for the agency center. The Commissioner shall consult with the Director of the Office in resolving the substantive dispute.

(10) REVIEW OF AGREEMENT, GUIDANCE, OR PRACTICE.—

(A) IN GENERAL.—The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this section.

(B) CONSULTATION WITH STAKEHOLDERS AND DIRECTORS OF AGENCY CENTERS.—In carrying out the review under subparagraph (A), the Secretary shall consult with stakeholders and the directors of the agency centers.

(C) DETERMINATION AND PUBLICATION BY SECRETARY.—After the consultation under subparagraph (B), the Secretary shall—

(i) determine whether to continue in effect, modify, revise, or eliminate the agreement, guidance, or practice; and

(ii) publish in the Federal Register a notice of the availability of the modified or revised agreement, guidance or practice.

(D) EFFECT OF SUBSECTION.—Nothing in this subsection shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(11) EFFECT ON REGULATORY AUTHORITY OF AGENCY CENTER.—Nothing in this subsection shall be construed to limit the regulatory authority of any agency center.

(k) GUIDANCE RELATING TO PRESUBMISSION INTERACTIONS.—Not later than 4 years after December 13, 2016, the Secretary shall issue a final guidance that describes—

(1) the structured process for managing pre-submission interactions with sponsors developing combination products;

(2) the best practices for ensuring that the feedback in the presubmission interactions represents the Agency's best advice based on the information provided during the presubmission interactions; and

(3) the information that is required to be submitted with a meeting request under subsection (f), how the meetings relate to other types of meetings in the FDA, and the form and content of any agreement reached through a meeting under subsection (f).

(l) REPORT.—

(1) IN GENERAL.—The Secretary shall annually report to the appropriate committees of Congress on the activities and impact of the Office.

(2) INCLUSIONS.—The report shall include provisions—

(A) describing the numbers and types of combination products under review and the timeliness in days of the assignments, reviews, and dispute resolutions;

(B) identifying the number of premarket reviews of the products that involved a consulting agency center;

(C) describing improvements in the consistency of postmarket regulation of combination products; and

(D) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product's sponsor.

**§ 13105. Regulation of certain products as drugs**

(a) DEFINITIONS.—In this section:

(1) CONTRAST AGENT.—The term ''contrast agent'' means an article that is intended for use in conjunction with a medical imaging device, and—

(A) is a diagnostic radiopharmaceutical, as defined in sections 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

(B) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.

(2) RADIOACTIVE DRUG.—The term ''radioactive drug'' has the meaning given the term in section 310.3(n) of title 21, Code of Federal Regula-

tions (or any successor regulations), except that the term does not include—

(A) an implant or article similar to an implant;

(B) an article that applies radiation from outside of the body; or

(C) the radiation source of an article described in subparagraph (A) or (B).

(3) OTC MONOGRAPH DRUG .—The term ''OTC monograph drug'' has the meaning given the term in section 17976 of this title.

(b) DEEMED TO BE A DRUG.—Any contrast agent, radioactive drug, or OTC monograph drug shall be deemed to be a drug under section 10101(a)(18) of this title and not a device under section 10101(a)(16) of this title.

(c) CONSTRUCTION.—Unless another provision of this subtitle otherwise indicates a different classification, nothing in this section shall be construed as allowing for the classification of a product as a drug (as defined in section 10101(a)(18) of this title) if the product—

(1) is not described in subsection (b); and

(2) meets the definition of a device under section 10101(a)(16) of this title.

(d) FEE WAIVER.—The Secretary shall waive the application fee under sections 17907 and 17952 of this title for applications for drugs that are—

(1) on September 30, 2022, legally marketed as devices; and

(2) deemed drugs pursuant to subsection (b).

**§ 13106. Pharmacy compounding**

(a) DEFINITION OF COMPOUNDING.—In this section, the term ''compounding'' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(b) IN GENERAL.—Chapter 135 of this title and sections 13101(a)(2)(B)(ii) and 13305(a)(1) of this title shall not apply to a drug product—

(1) if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient;

(2) if the drug product meets the requirements of this section; and

(3) if the compounding—

(A) on the prescription order for the individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs, is by a licensed pharmacist in a State-licensed pharmacy or a Federal facility or a licensed physician; or

(B)(i) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for the individual patient; and

(ii) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(I) the licensed pharmacist or licensed physician; and

(II)(aa) the individual patient for whom the prescription order will be provided; or

(bb) the physician or other licensed practitioner who will write the prescription order.

(c) COMPOUNDED DRUG.—

(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product may be compounded

under subsection (b) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances (as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21, Code of Federal Regulations)—

(i) that—

(I) comply with the standards of—

(aa) an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists; and

(bb) the United States Pharmacopeia chapter on pharmacy compounding;

(II) if a monograph under subclause (I)(aa) does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if a monograph under subclause (I)(aa) does not exist and the drug substance is not a component of a drug approved by the Secretary, ap-

pear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);

(ii) that are manufactured by an establishment that is registered under section 13136 of this title (including a foreign establishment that is registered under section 13136(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because the drug products or components of the drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug product that is essentially a copy of a commercially available drug product.

(2) ESSENTIALLY A COPY OF A COMMERCIALLY AVAILABLE DRUG PRODUCT.—In paragraph (1)(D), the term ''essentially a copy of a commercially available drug product'' does not include a drug product in which there is a change, made for an identified individual patient, that produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) DRUG PRODUCT.—A drug product may be compounded under subsection (b) only if—

(A) the drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) the drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary, which memorandum—

(I) addresses the distribution of inordinate amounts of compounded drug products interstate; and

(II) provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside the State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by the pharmacy or physician.

(4) STANDARD MEMORANDUM OF UNDERSTANDING.—The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of under-

standing for use by the States in complying with paragraph (3)(B)(i).

(d) REGULATIONS.—

(1) IN GENERAL.—

(A) ISSUANCE.—The Secretary shall issue regulations to implement this section.

(B) ADVISORY COMMITTEE CONSULTATION RELATING TO CERTAIN REGULATIONS.—Before issuing regulations to implement subparagraph (A)(i)(III) or (C) of paragraph (1) of subsection (c) or paragraph (3)(A) of subsection (c), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of the regulations before consultation is necessary to protect the public health.

(C) ADVISORY COMMITTEE MEMBERS.—The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) LIMITING COMPOUNDING.—

(A) IN GENERAL.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (c)(1)(A)(i)(III) for which a monograph does not exist or that are not components of drug products approved by the Secretary.

(B) CRITERIA REQUIRED.—The Secretary shall include in the regulation under subparagraph (A) the criteria for the substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(e) INAPPLICABILITY.—This section shall not apply to—

(1) compounded positron emission tomography drugs as defined in section 10101(a)(9) of this title; or

(2) radiopharmaceuticals.

**§ 13107. Outsourcing facilities**

(a) DEFINITIONS.—In this section:

(1) APPROVED DRUG.—The term ''approved drug'' means a drug that is approved under chapter

135 of this title and does not appear on the list described in subsection (b)(4).

(2) COMPOUNDING.—The term ''compounding'' includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

(3) ESSENTIALLY A COPY OF AN APPROVED DRUG.—The term ''essentially a copy of an approved drug'' means—

(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 13103(a) of this title and not subject to approval in an application submitted under chapter 135 of this title, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 13125 of this title at the time of compounding, distribution, and dispensing; or

(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 13103(a) of this title and not subject to approval in an application submitted under chapter 135 of this title, unless there is a change that produces for an individual patient

a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

(4) OUTSOURCING FACILITY.—

(A) IN GENERAL.—The term ''outsourcing facility'' means a facility at 1 geographic location or address that—

(i) is engaged in the compounding of sterile drugs;

(ii) has elected to register as an outsourcing facility; and

(iii) complies with all of the requirements of this section.

(B) LICENSED PHARMACY.—An outsourcing facility is not required to be a licensed pharmacy.

(C) OBTAINING PRESCRIPTIONS FOR INDIVIDUAL PATIENTS.—An outsourcing facility may or may not obtain prescriptions for identified individual patients.

(5) STERILE DRUG.—The term ''sterile drug'' means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

(b) IN GENERAL.—Chapter 135 of this title and sections 13305(a)(1) and 14902 of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility if each of the following conditions is met:

(1) REGISTRATION AND REPORTING.—The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (c).

(2) BULK DRUG SUBSTANCES.—The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

(A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for the proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from the bulk drug substance appears on the drug shortage list in effect under section 13125 of this title at the time of compounding, distribution, and dispensing;

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(C) the bulk drug substances are each manufactured by an establishment that is registered under section 13136 of this title (including a foreign establishment that is registered under section 13136(i) of this title); and

(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

(3) INGREDIENTS OTHER THAN BULK DRUG SUBSTANCES.—If any ingredient (other than a bulk drug substance) is used in compounding the drug, the ingredient complies with the standards of the ap-

plicable United States Pharmacopeia or National Formulary monograph, if the monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, if any.

(4) DRUGS WITHDRAWN OR REMOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The drug does not appear on a list, published by the Secretary, of drugs that have been withdrawn or removed from the market because the drugs or components of the drugs have been found to be unsafe or not effective.

(5) ESSENTIALLY A COPY OF AN APPROVED DRUG.—The drug is not essentially a copy of an approved drug.

(6) DRUGS PRESENTING DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING.—The drug—

(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (d), of drugs or categories of drugs that present demonstrable difficulties for compounding, which difficulties are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of

drugs, taking into account the risks and benefits to patients; or

(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

(7) ELEMENTS TO ENSURE SAFE USE.—In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to ensure safe use pursuant to section 13111 of this title, or from a bulk drug substance that is a component of such a drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that the outsourcing facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

(8) PROHIBITION ON WHOLESALING.—

(A) IN GENERAL.—The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded the drug.

(B) WHEN ADMINISTRATION OF DRUG NOT PROHIBITED.—This paragraph does not pro-

hibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 13103(a)(1) of this title.

(9) FEES.—The drug is compounded in an outsourcing facility that has paid all fees owed by the outsourcing facility pursuant to section 17972 of this title.

(10) LABELING OF DRUGS.—

(A) LABEL.—The label of the drug includes—

(i) the statement ''This is a compounded drug.'' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug—

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement ''Not for resale'', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement ''Office Use Only''; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) CONTAINER.—The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

(i) the information described under subparagraph (A)(iii)(X), if there is no space on the label for the information;

(ii) to facilitate adverse event reporting, the information ''www.fda.gov/medwatch and 1–800–FDA–1088'', or any successor internet website or phone number; and

(iii) directions for use, including, as appropriate, dosage and administration.

(C) ADDITIONAL INFORMATION.—The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

(11) OUTSOURCING FACILITY REQUIREMENT.—The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

(c) REGISTRATION OF OUTSOURCING FACILITIES AND REPORTING OF DRUGS.—

(1) REGISTRATION OF OUTSOURCING FACILITIES.—

(A) ANNUAL REGISTRATION.—On electing and in order to become an outsourcing facility,

and during the period beginning on October 1 and ending on December 31 of each year after becoming an outsourcing facility, a facility—

(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 13136 of this title), and a point of contact email address; and

(ii) shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 13125 of this title during the subsequent calendar year.

(B) AVAILABILITY OF REGISTRATION FOR INSPECTION; LIST.—

(i) REGISTRATIONS.—The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

(ii) LIST.—The Secretary shall make available on the public FDA website a list of the names of each facility registered under this subsection as an outsourcing fa-

cility, the State in which each of those outsourcing facilities is located, whether the outsourcing facility compounds from bulk drug substances, and whether the compounding from bulk drug substances is for sterile or nonsterile drugs.

(2) DRUG REPORTING BY OUTSOURCING FACILITIES.—

(A) IN GENERAL.—On initially registering as an outsourcing facility, once during the month of June of each year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

(i) identifying the drugs compounded by the outsourcing facility during the previous 6-month period; and

(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of the active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and

route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

(B) FORM.—Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

(C) CONFIDENTIALITY.—Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that the exemption would be inconsistent with the protection of the public health.

(3) ELECTRONIC REGISTRATION AND REPORTING.—Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of the electronic submission requirement because use of electronic means is not reasonable for the person requesting waiver.

(4) RISK-BASED INSPECTION FREQUENCY.—

(A) IN GENERAL.—Outsourcing facilities—

(i) shall be subject to inspection pursuant to section 17504 of this title; and

(ii) shall not be eligible for the exemption under section 17504(a)(2)(A) of this title.

(B) RISK-BASED SCHEDULE.—The Secretary, acting through 1 or more officers or employees designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

(C) RISK FACTORS.—In establishing the risk-based schedule, the Secretary shall inspect an outsourcing facility according to the known safety risks of the outsourcing facility, which safety risks shall be based on the following factors:

(i) The compliance history of the outsourcing facility.

(ii) The record, history, and nature of recalls linked to the outsourcing facility.

(iii) The inherent risk of the drugs compounded at the outsourcing facility.

(iv) The inspection frequency and history of the outsourcing facility, including

whether the outsourcing facility has been inspected pursuant to section 17504 of this title within the last 4 years.

(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to compound a drug that appears on the list in effect under section 13125 of this title.

(vi) Any other criteria considered necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) ADVERSE EVENT REPORTING.—An outsourcing facility shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulation).

(d) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall implement the list described in subsection (b)(6) through regulations.

(2) ADVISORY COMMITTEE ON COMPOUNDING.—

(A) IN GENERAL.—Before issuing regulations to implement subsection (b)(6), the Secretary shall convene and consult an advisory committee on compounding.

(B) MEMBERS.—The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

(3) INTERIM LIST.—

(A) IN GENERAL.—Before the effective date of the regulations finalized to implement subsection (b)(6), the Secretary may designate drugs, categories of drugs, or conditions as described in the subsection by—

(i) publishing a notice of the substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for the designation, in the Federal Register;

(ii) providing a period of not less than 60 calendar days for comment on the notice; and

(iii) publishing a notice in the Federal Register designating the drugs, categories of drugs, or conditions.

(B) SUNSET OF NOTICE.—Any notice provided under subparagraph (A) shall not be effective after the earlier of—

(i) the date that is 5 years after November 27, 2013; or

(ii) the effective date of the final regulations issued to implement subsection (b)(6).

(4) UPDATES.—

(A) IN GENERAL.—The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (b)(6) regularly, but not less than once every 4 years.

(B) EFFECT OF SUBPARAGRAPH (A).—Nothing in subparagraph (A) prohibits submissions to the Secretary, before or during any 4-

year period described in subparagraph (A), requesting updates to the lists.

(e) OBLIGATION TO PAY FEES.—Payment of the fee under section 17972 of this title, as described in subsection (b)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay the State fees.

**§ 13108. Prereview of television advertisements**

(a) IN GENERAL.—The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

(b) REVIEW.—In conducting a review of a television advertisement under this section, the Secretary may make recommendations with respect to information included in the label of the drug—

(1) on changes that are—

(A) necessary to protect the consumer good and well-being; or

(B) consistent with prescribing information for the product under review; and

(2) if appropriate and if information exists, on statements for inclusion in the advertisement to ad-

dress the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities.

(c) ELDERLY POPULATIONS, CHILDREN, RACIALLY AND ETHNICALLY DIVERSE COMMUNITIES.—In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

(d) NO AUTHORITY TO REQUIRE CHANGES.—Except as provided by subsection (e), this section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

(e) SPECIFIC DISCLOSURES.—

(1) SERIOUS RISK; SAFETY PROTOCOL.—In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of the disclosure in the advertisement.

(2) DATE OF APPROVAL.—In conducting a review of a television advertisement under this section, the Secretary may require the advertisement to in-

clude, for a period not to exceed 2 years from the date of the approval of the drug under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), a specific disclosure of the date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.

(f) RULE OF CONSTRUCTION.—Nothing in this section may be construed as having any effect on requirements under section 13311 of this title or the authority of the Secretary under section 314.550, 314.640, 601.45, or 601.94 of title 21, Code of Federal Regulations (or successor regulations).

**§ 13109. Process to update labeling for certain generic drugs**

(a) DEFINITIONS.—In this section:

(1) COVERED DRUG.—The term ''covered drug'' means a drug approved under section 13504 of this title—

(A) for which there are no unexpired patents included in the list under section 13511(h) of this title and no unexpired period of exclusivity;

(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

(C) for which—

(i)(I) there is new scientific evidence available pertaining to new or existing conditions of use that is not reflected in the approved labeling;

(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or

(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and

(ii) updating the approved labeling would benefit the public health.

(2) PERIOD OF EXCLUSIVITY.—The term ''period of exclusivity'', with respect to a drug approved under section 13504 of this title, means any period of exclusivity under subparagraph (A), (B), or (C) of section 13504(c)(5) of this title, subparagraph (A), (B), or (C) of section 13511(f)(6) of this title, or section 13112, 13116, or 13903 of this title.

(3) GENERIC VERSION.—The term ''generic version'' means a drug approved under section

13511 of this title whose reference listed drug is a covered drug.

(4) RELEVANT ACCEPTED USE.—The term ''relevant accepted use'' means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under chapter 135 of this title.

(5) SELECTED DRUG.—The term ''selected drug'' means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

(b) IDENTIFICATION OF COVERED DRUGS.—The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist in identifying covered drugs, the Secretary may do 1 or both of the following:

(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning the drugs.

(2) Seek public input concerning the drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of the drugs or whether new scientific evidence is available regarding the conditions of use for the drugs, by—

(A) holding 1 or more public meetings;

(B) opening a public docket for the submission of public comments; or

(C) other means, as the Secretary determines appropriate.

(c) SELECTION OF DRUGS FOR UPDATING.—If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under chapter 135 of this title for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the covered drug, the Secretary may initiate the process under subsection (d).

(d) INITIATION OF THE PROCESS OF UPDATING.—If the Secretary determines that labeling changes are appropriate for a selected drug pursuant to subsection (c), the Secretary shall provide notice to the holders of approved applications for a generic version of the drug that—

(1) summarizes the findings supporting the determination of the Secretary that the available scientific evidence meets the standards under chapter 135 of this title for adding or modifying information or providing supplemental information to the labeling of the covered drug pursuant to subsection (c);

(2) provides a clear statement regarding the additional, modified, or supplemental information for the labeling, according to the determination by the Secretary (including, as applicable, modifications to add the relevant accepted use to the labeling of the drug as an additional indication for the drug); and

(3) states whether the statement under paragraph (2) applies to the selected drug as a class of covered drugs or only to a specific drug product.

(e) RESPONSE TO NOTIFICATION.—Within 30 days of receipt of notification provided by the Secretary pursuant to subsection (d), the holder of an approved application for a generic version of the selected drug shall—

(1) agree to change the approved labeling to reflect the additional, modified, or supplemental information the Secretary has determined to be appropriate; or

(2) notify the Secretary that the holder of the approved application does not believe that the requested labeling changes are warranted and submit a statement detailing the reasons why the changes are not warranted.

(f) REVIEW OF APPLICATION HOLDER'S RESPONSE.—

(1) IN GENERAL.—On receipt of the application holder's response, the Secretary shall promptly review each statement received under subsection (e)(2) and determine which labeling changes pursuant to the Secretary's notice under subsection (d) are appropriate, if any. If the Secretary disagrees with the reasons why the labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect available scientific evidence, and if so, the content of the labeling changes.

(2) CHANGES TO LABELING.—After considering all responses from the holder of an approved application under paragraph (1) or (2) of subsection (e), and any discussion under paragraph (1), the Secretary may order the holder to make the labeling changes the Secretary determines are appropriate. The holder of an approved application shall—

(A) update its paper labeling for the drug at the next printing of that labeling;

(B) update any electronic labeling for the drug within 30 days of the order; and

(C) submit the revised labeling through the form, ''Supplement—Changes Being Effected''.

(g) VIOLATION.—If the holder of an approved application for the generic version of the selected drug does not comply with the requirements of subsection (f)(2), the generic version of the selected drug shall be deemed to be misbranded under chapter 133 of this title.

(h) LIMITATIONS; GENERIC DRUGS.—

(1) IN GENERAL.—With respect to any labeling change required under this section, the generic version shall be deemed to have the same conditions of use and the same labeling as its reference listed drug for purposes of subparagraphs (A) and (E) of section 13511(c)(1) of this title. Any labeling change so required shall not have any legal effect for the applicant that is different than the legal effect that would have resulted if a supplemental application had been submitted and approved to conform the labeling of the generic version to a change in the labeling of the reference drug.

(2) SUPPLEMENTAL APPLICATIONS.—Changes to labeling made in accordance with this section shall not be eligible for an exclusivity period under this subtitle.

(3) SELECTION OF DRUGS.—The Secretary shall not identify a drug as a covered drug or select a drug label for updating under subsection (b) or (c)

solely based on the availability of new safety information. On identification of a drug as a covered drug under subsection (b), the Secretary may then consider the availability of new safety information (as defined in section 13111(a) of this title) in determining whether the drug is a selected drug and in determining what labeling changes are appropriate.

(i) RULES OF CONSTRUCTION.—

(1) APPROVAL STANDARDS.—This section shall not be construed as altering the applicability of the standards for approval of an application under chapter 135 of this title. No order shall be issued under this subsection unless the scientific evidence supporting the changed labeling meets the standards for approval applicable to any change to labeling under chapter 135 of this title.

(2) REMOVAL OF INFORMATION.—Nothing in this section shall be construed to give the Secretary additional authority to remove approved indications for drugs, other than the authority described in this section.

(3) SECRETARY AUTHORITY.—Nothing in this section shall be construed to limit the authority of

the Secretary to require labeling changes under section 13515 of this title.

(4) MAINTENANCE OF LABELING.—Nothing in this section shall be construed to affect the responsibility of the holder of an approved application under section 13511 of this title to maintain its labeling in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 314.97 of title 21, Code of Federal Regulations (or any successor regulations).

(j) REPORTS.—Not later than 4 years after December 27, 2020, and every 4 years thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that—

(1) describes the actions of the Secretary under this section, including—

(A) the number of covered drugs and description of the types of drugs the Secretary has selected for labeling changes and the rationale for the recommended changes; and

(B) the number of times the Secretary entered into discussions concerning a disagreement with an application holder and a summary

of the decision regarding a labeling change, if any; and

(2) includes any recommendations of the Secretary for modifying the program under this section.

**§ 13110. Veterinary feed directive drugs**

(a) LAWFUL VETERINARY FEED DIRECTIVE REQUIREMENT.—

(1) VETERINARY FEED DIRECTIVE DRUG.—

(A) IN GENERAL.—A veterinary feed directive drug is a drug that—

(i) is intended for use in or on animal feed; and

(ii) is limited by—

(I) an approved application filed pursuant to section 13703 of this title;

(II) a conditionally approved application filed pursuant to section 14502 of this title; or

(III) an index listing pursuant to section 14503 of this title to use under the professional supervision of a licensed veterinarian.

(B) DIRECTIVE REQUIRED FOR ADMINISTERING DRUG.—Any animal feed bearing or

containing a veterinary feed directive drug shall be fed to animals only by or on a lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice.

(C) EXEMPTION FROM CERTAIN LABELING REQUIREMENTS.—When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 13305 of this title.

(2) VETERINARY FEED DIRECTIVE REQUIREMENTS.—A veterinary feed directive is lawful if it—

(A) contains such information as the Secretary may by general regulation or by order require; and

(B) is in compliance with the conditions and indications for use of the drug set forth in—

(i) the notice published pursuant to section 13710 of this title; or

(ii) the index listing pursuant to section 14503(e) of this title.

(3) DISTRIBUTION REQUIREMENTS.—

(A) MAINTENANCE OF RECORDS.—

(i) VETERINARY FEED DIRECTIVE.—Any person involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing the feed to another person for further distribution.

(ii) WRITTEN ACKNOWLEDGMENT.—The person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move the feed to an animal production facility without a veterinary feed directive or ship the feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier.

(B) AVAILABILITY OF RECORDS.—Every person required under subparagraph (A) to maintain records, and every person in charge or

custody of the records, shall, on request of an officer or employee designated by the Secretary, permit the officer or employee at all reasonable times to have access to and copy and verify the records.

(C) NOTIFICATION OF NAME AND ADDRESS.—

(i) IN GENERAL.—Any person that distributes animal feed bearing or containing a veterinary feed directive drug shall, on first engaging in the distribution, notify the Secretary of that person's name and place of business.

(ii) FAILURE TO NOTIFY RESULTS IN MISBRANDING.—The failure to provide the notification shall be deemed to be an act that results in the drug being misbranded.

(b) LABELING AND ADVERTISING.—A veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if—

(1) their labeling fails to bear such cautionary statement and such other information as the Secretary may by general regulation or by order prescribe; or

(2) their advertising—

(A) fails to conform to—

(i) the conditions and indications for use published pursuant to section 13710 of this title; or

(ii) the index listing pursuant to section 14503(e) of this title; or

(B) fails to contain the general cautionary statement prescribed by the Secretary.

(c) NONPRESCRIPTION STATUS.—Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law.

**§ 13111. Risk evaluation and mitigation strategies**

(a) DEFINITIONS.—In this section:

(1) ADVERSE DRUG EXPERIENCE.—The term ''adverse drug experience'' means any adverse event associated with the use of a drug in humans, whether or not considered drug-related, including—

(A) an adverse event occurring in the course of the use of the drug in professional practice;

(B) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

(C) an adverse event occurring from abuse of the drug;

(D) an adverse event occurring from withdrawal of the drug; and

(E) any failure of expected pharmacological action of the drug, which may include reduced effectiveness under the conditions of use prescribed in the labeling of the drug, but which may not include reduced effectiveness that is in accordance with the labeling.

(2) COVERED APPLICATION.—The term ''covered application'' means an application referred to in section 13516(a)(1) of this title.

(3) NEW SAFETY INFORMATION.—

(A) IN GENERAL.—The term ''new safety information'', with respect to a drug, means—

(i) information described in subparagraph (B) derived from a clinical trial, an adverse event report, a postapproval study (including a study under section 13515(c) of this title), or peer-reviewed biomedical literature;

(ii) data described in subparagraph (B) derived from the postmarket risk iden-

tification and analysis system under section 13512 of this title; or

(iii) other scientific data described in subparagraph (B) considered appropriate by the Secretary.

(B) INFORMATION; DATA.—Information and data described in this subparagraph are information and data about—

(i) a serious risk or an unexpected serious risk associated with use of the drug that the Secretary has become aware of (that may be based on a new analysis of existing information)—

(I) since the drug was approved;

(II) since the risk evaluation and mitigation strategy was required; or

(III) since the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

(ii) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the last assessment of such strategy.

(4) RESPONSIBLE PERSON.—The term ''responsible person'' means the person submitting a covered

application or the holder of the approved covered application.

(5) SEPARATE REMS.—The term ''different, comparable aspect of the elements to ensure safe use'' means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 13511 of this title that uses different methods or operational means than the strategy required under subsection (b) for—

(A) the applicable listed drug, but achieves the same level of safety as the strategy for the listed drug; or

(B) another application under section 13511 of this title with the same listed drug, but achieves the same level of safety as the strategy for the listed drug.

(6) SERIOUS ADVERSE DRUG EXPERIENCE.—The term ''serious adverse drug experience'' is an adverse drug experience that—

(A) results in—

(i) death;

(ii) an adverse drug experience that places the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug

experience that might have caused death had it occurred in a more severe form);

(iii) inpatient hospitalization or prolongation of existing hospitalization;

(iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

(v) a congenital anomaly or birth defect; or

(B) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(7) SERIOUS RISK.—The term ''serious risk'' means a risk of a serious adverse drug experience.

(8) SIGNAL OF A SERIOUS RISK.—The term ''signal of a serious risk'' means information related to a serious adverse drug experience associated with use of a drug and derived from—

(A) a clinical trial;

(B) adverse event reports;

(C) a postapproval study, including a study under section 13515(c) of this title;

(D) peer-reviewed biomedical literature;

(E) data derived from the postmarket risk identification and analysis system under section 13512(d) of this title; or

(F) other scientific data considered appropriate by the Secretary.

(9) UNEXPECTED SERIOUS RISK.—The term ''unexpected serious risk'' means a serious adverse drug experience that is not listed in the labeling of a drug, or that may be symptomatically and pathophysiologically related to an adverse drug experience identified in the labeling, but differs from the adverse drug experience because of greater severity, specificity, or prevalence.

(b) SUBMISSION OF PROPOSED STRATEGY.—

(1) INITIAL APPROVAL.—

(A) IN GENERAL.—If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person that submits the application of the determination, the person shall submit to the Secretary as part of the ap-

plication a proposed risk evaluation and mitigation strategy.

(B) FACTORS.—In making a determination under subparagraph (A), the Secretary shall consider the following factors:

(i) The estimated size of the population likely to use the drug involved.

(ii) The seriousness of the disease or condition that is to be treated with the drug.

(iii) The expected benefit of the drug with respect to the disease or condition.

(iv) The expected or actual duration of treatment with the drug.

(v) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of the events in the population likely to use the drug.

(vi) Whether the drug is a new molecular entity.

(2) POSTAPPROVAL REQUIREMENT.—

(A) IN GENERAL.—If the Secretary has approved a covered application (including an application approved before the effective date of

this section) and did not when approving the application require a risk evaluation and mitigation strategy under paragraph (1), the Secretary, in consultation with the offices described in paragraph (1), may subsequently require such a strategy for the drug involved (including when acting on a supplemental application seeking approval of a new indication for use of the drug) if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

(B) SUBMISSION OF PROPOSED STRATEGY.—Not later than 120 days after the Secretary notifies the holder of an approved covered application that the Secretary has made a determination under subparagraph (A) with respect to the drug involved, or within such other reasonable time as the Secretary requires to protect the public health, the holder shall submit to the Secretary a proposed risk evaluation and mitigation strategy.

(3) ABBREVIATED NEW DRUG APPLICATIONS.—The applicability of this section to an application

under section 13511 of this title is subject to subsection (i).

(4) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(c) CONTENTS.—A proposed risk evaluation and mitigation strategy under subsection (b) shall—

(1) include the timetable required under subsection (d); and

(2) to the extent required by the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, include additional elements described in subsections (e) and (f).

(d) MINIMAL STRATEGY.—For purposes of subsection (c)(1), the risk evaluation and mitigation strategy for a drug shall require a timetable for submission of assessments of the strategy that—

(1) includes an assessment by the date that is 18 months after the strategy is initially approved;

(2) includes an assessment by the date that is 3 years after the strategy is initially approved;

(3) includes an assessment in the seventh year after the strategy is so approved; and

(4) subject to paragraphs (1), (2), and (3)—

(A) is at a frequency specified in the strategy;

(B) is increased or reduced in frequency as necessary as provided for in subsection (g)(4)(A); and

(C) is eliminated after the 3-year period described in paragraph (2) if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed.

(e) ADDITIONAL POTENTIAL ELEMENTS OF STRATEGY.—

(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), may under subsection (c)(2) require that the risk evaluation and mitigation strategy for a drug include 1 or more of the additional elements described in this subsection if the Secretary makes the determination required with respect to each element involved.

(2) MEDICATION GUIDE; PATIENT PACKAGE INSERT.—The risk evaluation and mitigation strategy

for a drug may require that, as applicable, the responsible person develop for distribution to each patient when the drug is dispensed—

(A) a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations); and

(B) a patient package insert, if the Secretary determines that the insert may help mitigate a serious risk of the drug.

(3) COMMUNICATION PLAN.—The risk evaluation and mitigation strategy for a drug may require that the responsible person conduct a communication plan to health care providers, if, with respect to the drug, the Secretary determines that the plan may support implementation of an element of the strategy (including under this paragraph). The plan may include—

(A) sending letters to health care providers;

(B) disseminating information about the elements of the risk evaluation and mitigation strategy to encourage implementation by health care providers of components that apply to the health care providers, or to explain certain safe-

ty protocols (such as medical monitoring by periodic laboratory tests);

(C) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to ensure safe use; or

(D) disseminating information to health care providers about drug formulations or properties, including information about the limitations or patient care implications of the formulations or properties, and how the formulations or properties may be related to serious adverse drug events associated with use of the drug.

(4) PACKAGING AND DISPOSAL.—The Secretary may require a risk evaluation mitigation strategy for a drug for which there is a serious risk of an adverse drug experience described in subparagraph (B) or (C) of subsection (a)(1), taking into consideration the factors described in subparagraphs (C) and (D) of subsection (f)(2) and in consultation with other relevant Federal agencies with authorities over drug disposal packaging, which may include requiring that—

(A) the drug be made available for dispensing to certain patients in unit dose pack-

aging, packaging that provides a set duration, or another packaging system that the Secretary determines may mitigate the serious risk; or

(B) the drug be dispensed to certain patients with a safe disposal packaging or safe disposal system if the Secretary determines that the safe disposal packaging or system may mitigate the serious risk and is sufficiently available.

(f) PROVIDING SAFE ACCESS FOR PATIENTS TO DRUGS WITH KNOWN SERIOUS RISKS THAT WOULD OTHERWISE BE UNAVAILABLE.—

(1) ALLOWING SAFE ACCESS TO DRUGS WITH KNOWN SERIOUS RISKS.—The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to ensure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

(A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, the elements are required as part of the strategy to mitigate a

specific serious risk listed in the labeling of the drug; and

(B) for a drug initially approved without elements to ensure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate the serious risk.

(2) ENSURING ACCESS AND MINIMIZING BURDEN.—The elements to ensure safe use under paragraph (1) shall—

(A) be commensurate with the specific serious risk listed in the labeling of the drug;

(B) within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how the elements will mitigate the observed safety risk;

(C) considering the risk, not be unduly burdensome on patient access to the drug, considering in particular—

(i) patients with serious or life-threatening diseases or conditions;

(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

(iii) patients with functional limitations; and

(D) to the extent practicable, so as to minimize the burden on the health care delivery system—

(i) conform with elements to ensure safe use for other drugs with similar, serious risks; and

(ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

(3) ELEMENTS TO ENSURE SAFE USE.—

(A) IN GENERAL.—The elements to ensure safe use under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate the risk, may require that—

(i) health care providers who prescribe the drug have particular training or experience, or are specially certified;

(ii) pharmacies, practitioners, or health care settings that dispense the drug are specially certified;

(iii) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(iv) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

(v) each patient using the drug be subject to certain monitoring; or

(vi) each patient using the drug be enrolled in a registry.

(B) TRAINING AND CERTIFICATION OF HEALTH CARE PROVIDERS; FRONTIER AREAS.—The opportunity to obtain the training or certification referred to in subparagraph (A)(i) with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an online course or via mail) as approved by the Secretary at reasonable cost to the provider.

(C) CERTIFICATION OF PHARMACIES, PRACTITIONERS, OR HEALTH CARE SETTINGS; FRONTIER AREAS.—The opportunity to obtain the certification referred to in subparagraph

(A)(ii) shall be available to any willing provider from a frontier area.

(4) IMPLEMENTATION SYSTEM.—The elements to ensure safe use under paragraph (1) that are described in clauses (ii), (iii), and (iv) of paragraph (3)(A) may include a system through which the applicant is able to take reasonable steps to—

(A) monitor and evaluate implementation of the elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing the elements; and

(B) work to improve implementation of the elements by the persons.

(5) EVALUATION OF ELEMENTS TO ENSURE SAFE USE.—The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) or other advisory committee of the FDA, shall—

(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to ensure safe use under this subsection for 1 or more drugs may be standardized—

(i) so as not to be unduly burdensome on patient access to the drug; and

(ii) to the extent practicable, to minimize the burden on the health care delivery system;

(B) periodically evaluate, for 1 or more drugs, the elements to ensure safe use of the drug to assess whether the elements—

(i) ensure safe use of the drug;

(ii) are not unduly burdensome on patient access to the drug; and

(iii) to the extent practicable, minimize the burden on the health care delivery system; and

(C) considering the input and evaluations—

(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

(ii) modify elements under this subsection for 1 or more drugs as appropriate.

(6) ADDITIONAL MECHANISMS TO ENSURE ACCESS.—

(A) IN GENERAL.—The mechanisms under section 14301 of this title to provide for ex-

panded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to ensure safe use under this subsection.

(B) REGULATIONS.—The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 14301 of this title.

(7) LIMITATION.—A holder of an approved covered application shall not use any element to ensure safe use required by the Secretary under this subsection to block or delay approval of an application under section 13503(b) or 13511 of this title or to prevent application of the element under subsection (i)(1)(A)(ii) to a drug that is the subject of an abbreviated new drug application.

(g) ASSESSMENT AND MODIFICATION OF APPROVED STRATEGY.—

(1) VOLUNTARY ASSESSMENTS.—After the approval of a risk evaluation and mitigation strategy under subsection (b), the responsible person involved may, subject to paragraph (2), submit to the Sec-

retary an assessment of the approved strategy for the drug involved at any time.

(2) REQUIRED ASSESSMENTS.—A responsible person shall submit an assessment of the approved risk evaluation and mitigation strategy for a drug—

(A) when submitting a supplemental application for a new indication for use under section 13503 of this title or under section 351 of the Public Health Service Act (42 U.S.C. 262), unless the drug is not subject to section 13103(a) of this title and the risk evaluation and mitigation strategy for the drug includes only the timetable under subsection (d);

(B) when required by the strategy, as provided for in the timetable under subsection (d); and

(C) within a time period to be determined by the Secretary, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that an assessment is needed to evaluate whether the approved strategy should be modified to—

(i) ensure the benefits of the drug outweigh the risks of the drug; or

(ii) minimize the burden on the health care delivery system of complying with the strategy.

(3) REQUIREMENTS FOR ASSESSMENTS.—An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include, with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more of the goals or elements should be modified.

(4) MODIFICATION.—

(A) ON INITIATIVE OF RESPONSIBLE PERSON.—After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. The proposal may propose the addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support the proposed addition, modification, or removal of any goal or element of the strategy.

(B) ON INITIATIVE OF SECRETARY.—After the approval of a risk evaluation and mitigation

strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

(i) ensure the benefits of the drug outweigh the risks of the drug;

(ii) minimize the burden on the health care delivery system of complying with the strategy; or

(iii) accommodate different, comparable aspects of the elements to ensure safe use for a drug that is the subject of an application under section 13511 of this title, and the applicable listed drug.

(h) REVIEW OF PROPOSED STRATEGIES AND ASSESSMENTS AND MODIFICATIONS OF APPROVED STRATEGIES.—

(1) IN GENERAL.—The Secretary, in consultation with the offices described in subsection (c)(2), shall promptly review each proposed risk evaluation

and mitigation strategy for a drug submitted under subsection (b) and each assessment of and proposed modification to an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g), and, if necessary, promptly initiate discussions with the responsible person about the proposed strategy, assessment, or modification.

(2) ACTION.—

(A) IN GENERAL.—

(i) TIMEFRAME.—Unless the dispute resolution process described under paragraph (3) or (4) applies, and, except as provided in clause (ii) or (iii) below, the Secretary, in consultation with the offices described in subsection (c)(2), shall review and act on the proposed risk evaluation and mitigation strategy for a drug or any proposed modification to any required strategy within 180 days of receipt of the proposed strategy or modification.

(ii) MINOR MODIFICATIONS.—

(I) IN GENERAL.—The Secretary shall review and act on a proposed minor modification, as defined by the

Secretary in guidance, within 60 days of receipt of the modification.

(II) GUIDANCE.—The Secretary shall issue guidance that, for purposes of this subparagraph, describes the types of modifications to approved risk evaluation and mitigation strategies that shall be considered to be minor modifications of the strategies.

(iii) MODIFICATION DUE TO SAFETY LABELING CHANGES.—Not later than 60 days after the Secretary receives a proposed modification to an approved risk evaluation and mitigation strategy to conform the strategy to approved safety labeling changes, including safety labeling changes initiated by the responsible person in accordance with FDA regulatory requirements, or to a safety labeling change that the Secretary has directed the holder of the application to make pursuant to section 13515(d) of this title, the Secretary shall review and act on the proposed modification to the approved strategy.

(iv) GUIDANCE.—The Secretary shall establish, through guidance, that responsible persons may implement certain modifications to an approved risk evaluation and mitigation strategy following notification to the Secretary.

(B) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under subparagraph (A).

(C) PUBLIC AVAILABILITY.—On acting on a proposed risk evaluation and mitigation strategy or proposed modification to a risk evaluation and mitigation strategy under subparagraph (A), the Secretary shall make publicly available an action letter describing the actions taken by the Secretary under subparagraph (A).

(3) DISPUTE RESOLUTION AT INITIAL APPROVAL.—If a proposed risk evaluation and mitigation strategy is submitted under subsection (b)(1) in an application for initial approval of a drug and there is a dispute about the strategy, the responsible person shall use the major dispute resolution proce-

dures as set forth in the letters described in section 101(c) of the Prescription Drug User Fee Amendments of 2007 (Public Law 110–85, title I, 121 Stat. 825).

(4) DISPUTE RESOLUTION IN ALL OTHER CASES.—

(A) REQUEST FOR REVIEW.—

(i) IN GENERAL.—The responsible person may, after the sponsor is required to make a submission under subsection (b)(2) or (g), request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board under subsection (j), except that the determination of the Secretary to require a risk evaluation and mitigation strategy is not subject to review under this paragraph. This clause does not prohibit review under this paragraph of the particular elements of such a strategy.

(ii) SCHEDULING.—On receipt of a request under clause (i), the Secretary shall schedule the dispute involved for review under subparagraph (B) and, not later than 5 business days after scheduling the

dispute for review, shall publish by posting on the Internet or otherwise a notice that the dispute will be reviewed by the Drug Safety Oversight Board.

(B) SCHEDULING REVIEW.—If a responsible person requests review under subparagraph (A), the Secretary—

(i) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

(ii) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application).

(C) AGREEMENT AFTER DISCUSSION OR ADMINISTRATIVE APPEALS.—

(i) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—

(I) IN GENERAL.—A request for review under subparagraph (A) shall not preclude further discussions to reach agreement on the risk evaluation and mitigation strategy, and shall

not preclude the use of administrative appeals within the FDA to reach agreement on the strategy, including appeals as described in the letters described in section 101(c) of the Prescription Drug User Fee Amendments of 2007 (Public Law 110–85, title I, 121 Stat. 825) for procedural or scientific matters involving the review of human drug applications and supplemental applications that cannot be resolved at the divisional level.

(II) WITHDRAWAL OF REQUEST OR TERMINATION OF ADMINISTRATIVE APPEALS.—At the time a review has been scheduled under subparagraph (B) and notice of the review has been posted, the responsible person shall either withdraw the request under subparagraph (A) or terminate the use of the administrative appeals.

(ii) AGREEMENT TERMINATES DISPUTE RESOLUTION.—At any time before a decision and order is issued under subparagraph (G), the Secretary (in consulta-

tion with the offices described in subsection (c)(2)) and the responsible person may reach an agreement on the risk evaluation and mitigation strategy through further discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

(D) MEETING OF THE BOARD.—At a meeting of the Drug Safety Oversight Board described in subparagraph (B), the Board shall—

(i) hear from both parties via written or oral presentation; and

(ii) review the dispute.

(E) RECORD OF PROCEEDINGS.—The Secretary shall ensure that the proceedings of any such meeting are recorded, transcribed, and made public within 90 days of the meeting. The Secretary shall redact the transcript to protect any trade secrets and other information that is exempted from disclosure under section 552 or 552a of title 5.

(F) RECOMMENDATION OF THE BOARD.—Not later than 5 days after any such meeting, the Drug Safety Oversight Board shall provide a written recommendation on resolving the dispute to the Secretary. Not later than 5 days after the Board provides the written recommendation to the Secretary, the Secretary shall make the recommendation available to the public.

(G) ACTION BY THE SECRETARY.—

(i) ACTION LETTER.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

(I) the action deadline for the action letter on the application; or

(II) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

(ii) ORDER.—With respect to an assessment of an approved risk evaluation and mitigation strategy under subsection (g)(1) or under subparagraph (B) or (C) of subsection (g)(2), the Secretary shall

issue an order, which shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

(H) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under subparagraph (G).

(I) EFFECT ON ACTION DEADLINE.—With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall be considered to have met the action deadline for the action letter on the application if the responsible person requests the dispute resolution process described in this paragraph and if the Secretary complies with the timing requirements of scheduling review by the Drug Safety Oversight Board, provides a written recommendation, and issues an action letter under subparagraphs (B), (F), and (G), respectively.

(J) DISQUALIFICATION.—An individual who is an employee of the FDA and who reviews a drug or who participated in an administrative appeal under subparagraph (C)(i) with

respect to the drug shall not serve on the Drug Safety Oversight Board at a meeting under subparagraph (D) to review a dispute about the risk evaluation and mitigation strategy for the drug.

(K) ADDITIONAL EXPERTISE.—The Drug Safety Oversight Board may add members with relevant expertise from the FDA, including the Office of Pediatric Therapeutics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under subparagraph (D).

(5) USE OF ADVISORY COMMITTEES.—The Secretary may convene a meeting of 1 or more advisory committees of the FDA to—

(A) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of the drug or drugs is required to be submitted under subparagraph (B) or (C) of subsection (g)(2);

(B) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

(C) review a dispute under paragraph (3) or (4).

(6) PROCESS FOR ADDRESSING DRUG CLASS EFFECTS.—

(A) IN GENERAL.—When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary, in consultation with the offices described in subsection (c)(2), may defer assessments of the approved risk evaluation and mitigation strategies for the drugs until the Secretary has convened 1 or more public meetings to consider possible responses to the concern.

(B) NOTICE.—If the Secretary defers an assessment under subparagraph (A), the Secretary shall—

(i) give notice of the deferral to the holder of the approved covered application not later than 5 days after the deferral;

(ii) publish the deferral in the Federal Register; and

(iii) give notice to the public of any public meetings to be convened under subparagraph (A), including a description of the deferral.

(C) PUBLIC MEETINGS.—The public meetings may include—

(i) 1 or more meetings of the responsible person for the drugs;

(ii) 1 or more meetings of 1 or more advisory committees of the FDA, as provided for under paragraph (5); or

(iii) 1 or more workshops of scientific experts and other stakeholders.

(D) ACTION.—After considering the discussions from any meetings under subparagraph (A), the Secretary may—

(i) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

(ii) seek public comment about the action; and

(iii) after seeking public comment, issue an order addressing the regulatory action.

(7) INTERNATIONAL COORDINATION.—

(A) IN GENERAL.—The Secretary, in consultation with the offices described in sub-

section (c)(2), may coordinate the timetable for submission of assessments under subsection (d), or a study or clinical trial under section 13515(c) of this title, with efforts to identify and assess the serious risks of the drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary considers comparable to the drug approval and risk management processes of the United States.

(B) NOTICE.—If the Secretary takes action to coordinate the timetable, the Secretary shall give notice to the responsible person.

(8) EFFECT.—Use of the processes described in paragraphs (6) and (7) shall not be the sole source of delay of action on an application or a supplement to an application for a drug.

(i) ABBREVIATED NEW DRUG APPLICATIONS.—

(1) ELEMENTS OF STRATEGY.—

(A) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under section 13511 of this title is subject to only the following elements of the risk evaluation and mitigation strategy required under subsection (b) for the applicable listed drug:

(i) A Medication Guide or patient package insert, if required under subsection (e) for the applicable listed drug.

(ii) A packaging or disposal requirement, if required under subsection (e)(4) for the applicable listed drug.

(iii) Elements to ensure safe use, if required under subsection (f) for the listed drug, which, subject to subparagraph (B), for a drug that is the subject of an application under section 13511 of this title, may use—

(I) a single, shared system with the listed drug under subsection (f); or

(II) a different, comparable aspect of the elements to ensure safe use under subsection (f).

(B) AUTHORITY TO REQUIRE SINGLE, SHARED SYSTEM.—The Secretary may require a drug that is the subject of an application under section 13511 of this title and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to

ensure safe use could satisfy the requirements of subsection (f).

(2) ACTION BY SECRETARY.—For an applicable listed drug for which a drug is approved under section 13511 of this title, the Secretary—

(A) shall undertake any communication plan to health care providers required under subsection (e)(3) for the applicable listed drug;

(B) shall permit packaging systems and safe disposal packaging or safe disposal systems that are different from those required for the applicable listed drug under subsection (e)(4); and

(C) shall inform the responsible person for the drug that is approved under section 13511 of this title if the risk evaluation and mitigation strategy for the applicable listed drug is modified.

(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(A)(iii)(II), a different, comparable aspect of the elements to ensure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 13511 of this title, the Secretary may require that the different, comparable aspect of the

elements to ensure safe use can be used with respect to any other drug that is the subject of an application under section 13503 or 13511 of this title that references the same listed drug.

(j) DRUG SAFETY OVERSIGHT BOARD.—

(1) IN GENERAL.—There is established a Drug Safety Oversight Board.

(2) COMPOSITION; MEETINGS.—The Drug Safety Oversight Board shall—

(A) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

(B) include representatives from offices throughout the FDA, including the offices responsible for postapproval safety of drugs;

(C) include at least 1 representative each from the National Institutes of Health and the Department (other than the FDA);

(D) include such representatives as the Secretary shall designate from other appropriate agencies that wish to provide representatives; and

(E) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.

(k) WAIVER IN PUBLIC HEALTH EMERGENCIES.—The Secretary may waive any requirement of this section with respect to a qualified countermeasure (as defined in section 319F–1(a)(2) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2))) to which a requirement under this section has been applied, if the Secretary determines that the waiver is required to mitigate the effects of, or reduce the severity of, the circumstances under which—

(1) a determination described in subparagraph (A), (B), or (C) of section 14306(c)(1) of this title has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(2) the identification of a material threat described in section 14306(c)(1)(D) of this title has been made pursuant to section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

(l) PROVISION OF SAMPLES NOT A VIOLATION OF STRATEGY.—The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 49519(a) of this title) shall not be considered a violation of the requirements of any risk evalua-

tion and mitigation strategy that may be in place under this section for the drug.

**§ 13112. Pediatric studies of drugs**

(a) DEFINITION OF PEDIATRIC STUDIES.—In this section, the term ''pediatric studies'' means at least 1 clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups (including neonates in appropriate cases) in which a drug is anticipated to be used, and, at the discretion of the Secretary, may include preclinical studies.

(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

(1) IN GENERAL.—

(A) CONDITIONS.—Except as provided in paragraph (2), each period described in subparagraph (B) is extended as provided in subparagraph (B) if, prior to approval of an application that is submitted under section 13503(a) of this title—

(i) the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population;

(ii) the Secretary makes a written request for pediatric studies (which shall in-

clude a timeframe for completing the pediatric studies);

(iii) the applicant agrees to the request;

(iv) the pediatric studies are completed using appropriate formulations for each age group for which the pediatric study is requested within any such timeframe; and

(v) the reports of the pediatric studies are submitted and accepted in accordance with subsection (d)(4).

(B) EXTENDED PERIODS.—With regard to the drug concerned under subparagraph (A)—

(i)(I)(aa) the period referred to in section 13504(c)(5)(A) of this title, and in section 13511(f)(6)(A) of this title, is deemed to be 5 years and 6 months rather than 5 years, and the references in sections 13504(c)(5)(A) and 13511(f)(6)(A) of this title to 4 years, to 48 months, and to 7½ years are deemed to be 4½ years, 54 months, and 8 years, respectively; or

(bb) the period referred to in subparagraphs (B) and (C) of section 13504(c)(5)

of this title, and in subparagraphs (B) and (C) of section 13511(f)(6) of this title, is deemed to be 3 years and 6 months rather than 3 years; and

(II) if the drug is designated under section 13902 of this title for a rare disease or condition, the period referred to in section 13903(a) of this title is deemed to be 7 years and 6 months rather than 7 years; and

(ii)(I) if the drug is the subject of a listed patent described in subparagraph (C), the period during which an application may not be approved under section 13504(c) of this title or section 13511(f)(2) of this title shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

(II) if the drug is the subject of a listed patent for which a certification has been submitted under section 13503(b)(1)(D) or 13511(c)(1)(G)(iv) of this title, and in the patent infringement litigation resulting from the certification the court determines

that the patent is valid and would be infringed, the period during which an application may not be approved under section 13504(c) or 13511(f)(2) of this title shall be extended by a period of 6 months after the date the patent expires (including any patent extensions).

(C) LISTED PATENT.—A listed patent is described in this subparagraph if it is—

(i) a listed patent for which a certification has been submitted under section 13503(b)(1)(B) or 13511(c)(1)(G)(ii) of this title and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(ii) a listed patent for which a certification has been submitted under section 13503(b)(1)(C) or 13511(c)(1)(G)(iii) of this title.

(2) EXCEPTION.—The Secretary shall not extend the period referred to in clause (i) or (ii) of paragraph (1)(B) if the determination made under subsection (d)(4) is made later than 9 months prior to the expiration of the period.

(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—

(1) IN GENERAL.—

(A) CONDITIONS.—Except as provided in paragraph (2), each period described in subparagraph (B) is extended as provided in subparagraph (B) if—

(i) the Secretary determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population;

(ii) the Secretary makes a written request to the holder of an approved application under section 13503(a) of this title for pediatric studies (which shall include a timeframe for completing the pediatric studies);

(iii) the holder agrees to the request;

(iv) the pediatric studies are completed using appropriate formulations for each age group for which the pediatric study is requested within any such timeframe; and

(v) the reports of the pediatric studies are submitted and accepted in accordance with subsection (d)(4).

(B) EXTENDED PERIODS.—With regard to the drug concerned under subparagraph (A)—

(i)(I)(aa) the period referred to in section 13504(c)(5)(A) of this title, and in section 13511(f)(6)(A) of this title, is deemed to be 5 years and 6 months rather than 5 years, and the references in sections 13504(c)(5)(A) and 13511(f)(6)(A) of this title to 4 years, to 48 months, and to 7½ years are deemed to be 4½ years, 54 months, and 8 years, respectively; or

(bb) the period referred to in subparagraphs (B) and (C) of section 13504(c)(5) of this title, and in subparagraphs (B) and (C) of section 13511(f)(6) of this title, is deemed to be 3 years and 6 months rather than 3 years; and

(II) if the drug is designated under section 13902 of this title for a rare disease or condition, the period referred to in section 13903(a) of this title is deemed to

be 7 years and 6 months rather than 7 years; and

(ii)(I) if the drug is the subject of a listed patent described in subparagraph (C), the period during which an application may not be approved under section 13504(c) of this title or section 13511(f)(2)(B) of this title shall be extended by a period of 6 months after the date the patent expires (including any patent extensions); or

(II) if the drug is the subject of a listed patent for which a certification has been submitted under section 13503(b)(1)(D) or 13511(c)(1)(G)(iv) of this title, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 13504(c) or 13511(f)(2) of this title shall be extended by a period of 6 months after the date the patent expires (including any patent extensions).

(C) LISTED PATENT.—A listed patent is described in this subparagraph if it is—

(i) a listed patent for which a certification has been submitted under section 13503(b)(1)(B) or 13511(c)(1)(G)(ii) of this title and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

(ii) a listed patent for which a certification has been submitted under section 13503(b)(1)(C) or 13511(c)(1)(G)(iii) of this title.

(2) EXCEPTION.—The Secretary shall not extend the period referred to in clause (i) or (ii) of paragraph (1)(B) if the determination made under subsection (d)(4) is made later than 9 months prior to the expiration of the period.

(d) CONDUCT OF PEDIATRIC STUDIES.—

(1) REQUEST TO CONDUCT PEDIATRIC STUDIES.—

(A) AUTHORITY.—

(i) IN GENERAL.—The Secretary may, after consultation with the sponsor of an application for an investigational new drug

under section 13510 of this title, the sponsor of an application for a new drug under section 13503(a) of this title, or the holder of an approved application for a drug under section 13503(a) of this title, issue to the sponsor or holder a written request to conduct pediatric studies for the drug.

(ii) REPRESENTATION OF CHILDREN OF ETHNIC AND RACIAL MINORITIES.—In issuing the request, the Secretary shall take into account adequate representation of children of ethnic and racial minorities.

(iii) REQUEST TO BE IN WRITING; TIMEFRAME; PROPOSAL RELATING TO PEDIATRIC LABELING.—The request to conduct pediatric studies shall be in writing and shall include a timeframe for the pediatric studies and a request to the sponsor or holder to propose pediatric labeling resulting from the pediatric studies.

(iv) PEDIATRIC STUDIES IN NEONATES.—If a request under this subparagraph does not request pediatric studies in neonates, the request shall include a state-

ment describing the rationale for not requesting pediatric studies in neonates.

(B) SINGLE WRITTEN REQUEST.—A single written request—

(i) may relate to more than 1 use of a drug; and

(ii) may include uses that are both approved and unapproved.

(2) WRITTEN REQUEST FOR PEDIATRIC STUDIES.—

(A) REQUEST AND RESPONSE.—

(i) IN GENERAL.—If the Secretary makes a written request for pediatric studies (including neonates, as appropriate) under subsection (b) or (c), the applicant or holder, not later than 180 days after receiving the written request, shall respond to the Secretary as to the intention of the applicant or holder to act on the request by—

(I) indicating when the pediatric studies will be initiated, if the applicant or holder agrees to the request; or

(II) indicating that the applicant or holder does not agree to the request and stating the reasons for declining the request.

(ii) DISAGREEMENT WITH REQUEST.—If the applicant or holder does not agree to the request on the grounds that it is not possible to develop the appropriate pediatric formulation, the applicant or holder shall submit to the Secretary the reasons the pediatric formulation cannot be developed.

(B) ADVERSE EVENT REPORTS.—An applicant or holder that agrees to the request for the pediatric studies shall provide the Secretary, at the same time as the submission of the reports of the pediatric studies, with all postmarket adverse event reports—

(i) regarding the drug that is the subject of the pediatric studies; and

(ii) that are available prior to submission of the reports of the pediatric studies.

(3) ACTION ON SUBMISSIONS.—The Secretary shall review and act on a submission by a sponsor or holder of a proposed pediatric study request or a

proposed amendment to a written request for pediatric studies within 120 calendar days of the submission.

(4) MEETING THE PEDIATRIC STUDIES REQUIREMENT.—

(A) ACCEPTANCE OR REJECTION OF REPORTS.—Not later than 180 days after the submission of the reports of the pediatric studies, the Secretary shall accept or reject the reports and notify the sponsor or holder of the acceptance or rejection.

(B) DETERMINATION BY SECRETARY.—The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 180-day period, whether the pediatric studies—

(i) fairly respond to the written request;

(ii) have been conducted in accordance with commonly accepted scientific principles and protocols; and

(iii) have been reported in accordance with the requirements of the Secretary for filing.

(5) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends—

(A) section 10501(10) of this title;

(B) section 552 of title 5; or

(C) section 1905 of title 18.

(6) CONSULTATION.—With respect to a drug that is a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a)), a security countermeasure (as defined in section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b)), or a qualified pandemic or epidemic product (as defined in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d)), the Secretary shall solicit input from the Assistant Secretary for Preparedness and Response regarding the need for and, from the Director of the Biomedical Advanced Research and Development Authority regarding the conduct of, pediatric studies under this section.

(e) NOTICE OF DETERMINATIONS ON PEDIATRIC STUDIES REQUIREMENT.—

(1) PUBLICATION.—

(A) IN GENERAL.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met

and that submissions and approvals under section 13503(b) or 13511 for a drug will be subject to the provisions of this section.

(B) DATE.—The notice shall be published not later than 30 days after the date of the Secretary's determination regarding market exclusivity and shall include a copy of the written request made under subsection (b) or (c).

(2) IDENTIFICATION OF CERTAIN DRUGS.—

(A) IN GENERAL.—The Secretary shall publish a notice identifying any drug for which a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for the drug is not introduced onto the market within 1 year after the date that the Secretary publishes the notice described in paragraph (1).

(B) DATE.—The notice identifying the drug shall be published not later than 30 days after the date of the expiration of the 1-year period.

(f) INTERNAL REVIEW OF WRITTEN REQUESTS AND PEDIATRIC STUDIES.—

(1) INTERNAL REVIEW.—The Secretary shall utilize the internal committee established under section 13114 of this title to review all written requests issued in accordance with paragraph (2).

(2) REVIEW OF WRITTEN REQUESTS.—The committee referred to in paragraph (1) shall review all written requests issued pursuant to this section prior to being issued.

(3) REVIEW OF PEDIATRIC STUDIES.—The committee referred to in paragraph (1) may review pediatric studies conducted pursuant to this section to make a recommendation to the Secretary whether to accept or reject the reports under subsection (d)(4).

(4) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of the committee and need not convene all members of the committee.

(5) DOCUMENTATION OF COMMITTEE ACTION.—For each drug, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (2) or (3), which members of the committee participated in the activity.

(6) TRACKING PEDIATRIC STUDIES AND LABELING CHANGES.—The Secretary, in consultation with

the committee referred to in paragraph (1), shall track and make available to the public, in an easily accessible manner, including through posting on the FDA website—

(A) the number of pediatric studies conducted under this section and under section 409I of the Public Health Service Act (42 U.S.C. 284m);

(B) the specific drugs and drug uses, including labeled and off-labeled indications, studied under the sections;

(C) the types of pediatric studies conducted under the sections, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

(D) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons the formulations were not developed;

(E) the labeling changes made as a result of pediatric studies conducted under the sections;

(F) an annual summary of labeling changes made as a result of pediatric studies

conducted under the sections for distribution pursuant to subsection (k)(2); and

(G) information regarding reports submitted on or after September 27, 2007.

(7) INFORMING INTERNAL COMMITTEE.—The Secretary shall provide to the committee referred to in paragraph (1) any response issued to an applicant or holder with respect to a proposed pediatric study request.

(g) LIMITATIONS.—Notwithstanding subsection (c)(2), a drug to which the 6-month period under subsection (b) or (c) has already been applied—

(1) may receive an additional 6-month period under subsection (c)(1)(B)(i)(I)(bb) for a supplemental application if all other requirements under this section are satisfied, except that the drug may not receive any additional such period under subsection (c)(1)(B)(ii); and

(2) may not receive any additional such period under subsection (c)(1)(B)(i)(II).

(h) RELATIONSHIP TO PEDIATRIC RESEARCH REQUIREMENTS.—Exclusivity under this section shall be granted only for the completion of a pediatric study or pediatric studies that are the subject of a written request and for which reports are submitted and accepted in ac-

cordance with subsection (d)(4). Written requests under this section may consist of a pediatric study or pediatric studies required under section 13113 of this title.

(i) LABELING CHANGES.—

(1) PRIORITY STATUS FOR PEDIATRIC APPLICATIONS AND SUPPLEMENTS.—Any application or supplement to an application under chapter 135 of this title proposing a labeling change as a result of any pediatric study conducted pursuant to this section—

(A) shall be considered to be a priority application or supplement; and

(B) shall be subject to the performance goals established by the Commissioner for priority drugs.

(2) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that the sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application, not later than 180 days after the date of submission of the application—

(i) the Commissioner shall request that the sponsor of the application make

any labeling change that the Commissioner determines to be appropriate; and

(ii) if the sponsor of the application does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

(i) review the pediatric study reports; and

(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application to make any labeling change that the Commissioner determines to be appropriate.

(D) MISBRANDING.—If the sponsor of the application, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application to be misbranded.

(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this subtitle when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(j) OTHER LABELING CHANGES.—If the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug that is the subject of the pediatric study is safe and effective, including whether the pediatric study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of the product to include information about the results of the pediatric study and a statement of the Secretary's determination.

(k) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) IN GENERAL.—Not later than 210 days after the date of submission of a report on a pediatric study under this section, the Secretary shall make available to the public the medical, statistical, and clinical pharmacology reviews of pediatric studies conducted under subsection (b) or (c).

(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—The Secretary shall include as a requirement of a written request that the sponsors of the pediatric studies that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(F) distribute, at least annually (or more frequently if the Secretary determines that it would be beneficial to the public health), that information to physicians and other health care providers.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends—

(A) section 10501(10) of this title;

(B) section 552 of title 5; or

(C) section 1905 of title 18.

(l) ADVERSE EVENT REPORTING.—

(1) REPORTING IN FIRST 18-MONTH PERIOD.—

(A) REFERRAL TO OFFICE OF PEDIATRIC THERAPEUTICS.—During the 18-month period beginning on the date a labeling change is approved pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for the drug (regardless of when the report was received) are referred to the Office of Pediatric Therapeutics.

(B) REVIEW BY PEDIATRIC ADVISORY COMMITTEE.—In considering the reports, the Director of the Office of Pediatric Therapeutics shall provide for the review of the reports by the Pediatric Advisory Committee, including obtaining any recommendations of the Committee regarding whether the Secretary should take action under this subtitle in response to the reports.

(2) REPORTING IN SUBSEQUENT PERIODS.—

(A) REFERRAL TO OFFICE OF PEDIATRIC THERAPEUTICS.—Following the 18-month period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section.

(B) REVIEW BY PEDIATRIC ADVISORY COMMITTEE.—In considering the reports, the Director of the Office of Pediatric Therapeutics may provide for the review of the reports by the Pediatric Advisory Committee, including obtaining any recommendation of the Committee regarding whether the Secretary should take action in response to the reports.

(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if the review is necessary to ensure safe use of a drug in a pediatric population.

(4) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of the adverse event reports by the Secretary.

(m) CLARIFICATION OF INTERACTION OF MARKET EXCLUSIVITY UNDER THIS SECTION AND MARKET EXCLUSIVITY AWARDED TO AN APPLICANT FOR APPROVAL OF A DRUG UNDER SECTION 13511 OF THIS TITLE.—If a 180-day period under section 13511(f)(2)(D) of this title overlaps with a 6-month exclusivity period under this section, so that the applicant for approval of a drug under

section 13511 of this title entitled to the 180-day period under that section loses a portion of the 180-day period to which the applicant is entitled for the drug, the 180-day period shall be extended from—

(1) the date on which the 180-day period would have expired by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire after the 6-month exclusivity period; or

(2) the date on which the 6-month exclusivity period expires by the number of days of the overlap, if the 180-day period would, but for the application of this subsection, expire during the 6-month exclusivity period.

(n) REFERRAL IF PEDIATRIC STUDIES NOT SUBMITTED.—

(1) IN GENERAL.—If pediatric studies of a drug have not been submitted by the date specified in the written request issued or if the applicant or holder does not agree to the request under subsection (d) and if the Secretary, through the committee established under section 13114 of this title, determines that there is a continuing need for information relating to the use of the drug in the pediatric population

(including neonates, as appropriate), the Secretary shall carry out the following:

(A) For a drug for which a listed patent has not expired, or for which a period of exclusivity eligible for extension under subsection (b)(1) or (c)(1), or under paragraph (2) or (3) of section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)), has not ended, the Secretary shall make a determination regarding whether an assessment shall be required to be submitted under section 13113(b) of this title.

(B) For a drug that has no unexpired listed patents and for which no unexpired periods of exclusivity eligible for extension under subsection (b)(1) or (c)(1), or under paragraph (2) or (3) of section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)), apply, the Secretary shall refer the drug for inclusion on the list established under section 409I of the Public Health Service Act (42 U.S.C. 284m) for the conduct of pediatric studies.

(C) For a drug that is a qualified countermeasure (as defined in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a)), a security countermeasure (as defined in

section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b)), or a qualified pandemic or epidemic product (as defined in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d)), in addition to any action with respect to the drug under subparagraph (A) or (B), the Secretary shall notify the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority of all pediatric studies in the written request issued by the Commissioner.

(2) PUBLIC NOTICE.—The Secretary shall give the public notice of a decision under paragraph (1)(A) not to require an assessment under section 13113 of this title and the basis for the decision.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends—

(A) section 10501(10) of this title;

(B) section 552 of title 5; or

(C) section 1905 of title 18.

(o) PROMPT APPROVAL OF DRUGS WHEN PEDIATRIC INFORMATION IS ADDED TO LABELING.—

(1) IN GENERAL.—A drug for which an application has been submitted or approved under section

13503(b) or 13511 of this title shall not be considered ineligible for approval under chapter 135 of this title or misbranded under chapter 133 of this title on the basis that the labeling of the drug omits a pediatric indication or any other aspect of labeling pertaining to pediatric use when the omitted indication or other aspect is protected by patent, or by exclusivity under subparagraph (B) or (C) of section 13511(f)(6) of this title, subparagraph (B) or (C) of section 13504(c)(5) of this title, or section 13903(a) of this title, or by an extension of the exclusivity under this section or section 13116 of this title.

(2) LABELING.—Notwithstanding subparagraphs (B) and (C) of section 13511(f)(6) of this title, subparagraphs (B) and (C) of section 13504(c)(5) of this title, or section 13903 of this title, the Secretary may require that the labeling of a drug approved pursuant to an application submitted under section 13503(b) or 13511 of this title that omits a pediatric indication or other aspect of labeling as described in paragraph (1) include—

(A) a statement that, because of marketing exclusivity for a manufacturer—

(i) the drug is not labeled for pediatric use; or

(ii) in the case of a drug for which there is an additional pediatric use not referred to in paragraph (1), the drug is not labeled for the pediatric use under paragraph (1); and

(B) a statement of any appropriate pediatric contraindications, warnings, precautions, or other information that the Secretary considers necessary to ensure safe use.

(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND EXTENSIONS.—This subsection does not affect—

(A) the availability or scope of exclusivity under—

(i) this section;

(ii) chapter 135 of this title for pediatric formulations; or

(iii) section 13903 of this title;

(B) the availability or scope of an extension to any such exclusivity, including an extension under this section or section 13116 of this title;

(C) the question of the eligibility for approval under chapter 135 of this title of any application described in section 13503(b) or

13511 of this title that omits any other aspect of labeling protected by exclusivity under—

(i) subparagraph (B) or (C) of section 13511(f)(6) of this title;

(ii) subparagraph (B) or (C) of section 13504(c)(5) of this title; or

(iii) section 13903(a) of this title; or

(D) except as expressly provided in paragraphs (1) and (2), the operation of chapter 135 of this title or section 13903 of this title.

**§ 13113. Research into pediatric uses for drugs and biological products**

(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—

(A) SUBMISSION OF ASSESSMENTS.—

(i) IN GENERAL.—Except with respect to an application for which subparagraph (B) applies, a person that submits an application (or supplement to an application) described in clause (ii) shall submit with the application the assessments described in paragraph (2).

(ii) APPLICATION.—An application (or supplement to an application) is described

in this clause if it is an application (or supplement to an application) for a drug—

(I) under chapter 135 of this title for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

(II) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration.

(B) CERTAIN MOLECULARLY TARGETED CANCER INDICATIONS.—A person that submits, on or after the date that is 3 years after August 18, 2017, an original application for a new active ingredient under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), shall submit with the application reports on the investigation described in paragraph (3) if the drug or biological product that is the subject of the application is—

(i) intended for the treatment of an adult cancer; and

(ii) directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

(2) ASSESSMENTS.—

(A) IN GENERAL.—The assessments referred to in paragraph (1)(A) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pe-

diatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.

(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262).

(3) MOLECULARLY TARGETED PEDIATRIC CANCER INVESTIGATION.—

(A) IN GENERAL.—With respect to a drug or biological product described in paragraph (1)(B), the investigation described in this paragraph is a molecularly targeted pediatric cancer investigation, which shall be designed to yield

clinically meaningful pediatric study data, gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

(B) EXTRAPOLATION OF DATA.—Paragraph (2)(B) shall apply to investigations described in this paragraph to the same extent and in the same manner as paragraph (2)(B) applies with respect to the assessments required under paragraph (1)(A).

(C) DEFERRALS AND WAIVERS.—Deferrals and waivers under paragraphs (4) and (5) shall apply to investigations described in this paragraph to the same extent and in the same manner as the deferrals and waivers apply with respect to the assessments under paragraph (2)(B).

(4) DEFERRAL.—

(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1)(A) or reports on the investigation required under paragraph (1)(B) until a specified date after

approval of the drug or issuance of the license for a biological product if—

(i) the Secretary finds that—

(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

(III) there is another appropriate reason for deferral; and

(ii) the applicant submits to the Secretary—

(I) certification of the grounds for deferring the assessments or reports on the investigation;

(II) a pediatric study plan as described in subsection (e);

(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

(IV) a timeline for the completion of the studies.

(B) DEFERRAL EXTENSION.—

(i) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral approved under subparagraph (A) for submission of some or all assessments required under paragraph (1)(A) or reports on the investigation required under paragraph (1)(B) if—

(I) the Secretary determines that the conditions described in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

(II) the applicant submits a new timeline under subparagraph (A)(ii)(IV) and any significant updates to the information required under subparagraph (A)(ii).

(ii) TIMING AND INFORMATION.—

(I) SUBMISSION OF DEFERRAL EXTENSION REQUEST.—If the deferral extension under this subparagraph is requested by the applicant, the applicant shall submit the deferral extension request containing the informa-

tion described in this subparagraph not less than 90 days prior to the date that the deferral would expire.

(II) RESPONSE BY SECRETARY.—The Secretary shall respond to the request not later than 45 days after the receipt of the letter.

(III) EXTENDED DATE.—If the Secretary grants such an extension, the specified date shall be the extended date.

(IV) NON-COMPLIANCE LETTER NOT TO BE ISSUED.—The sponsor of the required assessment under paragraph (1)(A) or reports on the investigation under paragraph (1)(B) shall not be issued a letter described in subsection (d) unless the specified or extended date of submission for the required studies has passed or if the request for an extension is pending.

(V) PUBLIC UPDATE OF STATUS OF STUDIES.—Nothing in this clause shall prevent the Secretary from updating the status of a study or studies

publicly if components of the study or studies are late or delayed.

(C) ANNUAL REVIEW.—

(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary—

(I) information detailing the progress made in conducting pediatric studies;

(II) if no progress has been made in conducting the studies, evidence and documentation that the studies will be conducted with due diligence and at the earliest possible time;

(III) projected completion date for pediatric studies; and

(IV) the reason or reasons why a deferral or deferral extension continues to be necessary.

(ii) PUBLIC AVAILABILITY.—Not later than 90 days after the submission to the Secretary of the information submitted through the annual review under clause (i), the Secretary shall make available to the

public in an easily accessible manner, including through the FDA website—

(I) the information;

(II) the name of the applicant for the product subject to the assessment or investigation;

(III) the date on which the product was approved; and

(IV) the date of each deferral or deferral extension under this paragraph for the product.

(5) WAIVERS.—

(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments or reports on the investigation for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments or reports on the investigation for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—

(i) SCOPE OF PARTIAL WAIVER.—If a partial waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

(ii) REQUIRED DOCUMENTATION.—An applicant seeking a partial waiver under clause (i) shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the FDA website.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—The Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under chapter 135 of this title or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to sub-

mit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—

(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.

(2) WAIVERS.—

(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii)(I) the drug or biological product—

(aa) does not represent a meaningful therapeutic benefit over existing

therapies for pediatric patients in that age group; and

(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—

(i) SCOPE OF WAIVER.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

(ii) REQUIRED DOCUMENTATION.—An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission

shall promptly be made available to the public in an easily accessible manner, including through posting on the FDA website.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends—

(A) section 10501(10) of this title;

(B) section 552 of title 5; or

(C) section 1905 of title 18.

(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of subparagraphs (A)(iii)(I) and (B)(iii)(I) of subsection (a)(5) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—

(1) if approved, the drug or biological product could represent an improvement in the treatment,

diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

(d) SUBMISSION OF ASSESSMENTS AND REPORTS ON THE INVESTIGATION.—If a person fails to submit a required assessment described in subsection (a)(2) or report on the investigation described in subsection (a)(3), fails to meet the applicable requirements in subsection (a)(4), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b), the following shall apply:

(1) NON-COMPLIANCE LETTER.—

(A) IN GENERAL.—The Secretary shall issue a non-compliance letter to the person informing the person of the failure to submit or meet the requirements of the applicable subsection.

(B) DEADLINE FOR RESPONSE.—The letter shall require the person to respond in writing within 45 calendar days of issuance of the letter

(C) DEFERRAL EXTENSION MAY BE INCLUDED IN RESPONSE.—The response may include the person's request for a deferral extension if applicable.

(D) PUBLIC AVAILAIBILITY.—The letter and the person's written response to the letter shall be made publicly available on the FDA website 60 calendar days after issuance, with redactions for any trade secrets and confidential commercial information.

(E) INAPPLICABILITY RELATING TO LETTER ISSUED IN ERROR.—If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply.

(F) PEDIATRIC ADVISORY COMMITTEE.—The Secretary shall inform the Pediatric Advisory Committee of letters issued under this paragraph and responses to the letters.

(2) MISBRANDED DRUG OR BIOLOGICAL PRODUCT.—The drug or biological product that is the subject of an assessment described in subsection (a)(2) or the investigation described in subsection (a)(3), applicable requirements in subsection (a)(4), or request for approval of a pediatric formulation described in subsection (a) or (b), may be considered

misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 10503 of this title), but the failure shall not be the basis for a proceeding—

(A) to withdraw approval for a drug under section 13506 of this title; or

(B) to revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

(e) PEDIATRIC STUDY PLANS.—

(1) IN GENERAL.—An applicant subject to subsection (a) shall submit to the Secretary an initial pediatric study plan.

(2) TIMING; CONTENT; MEETINGS.—

(A) TIMING.—

(i) IN GENERAL.—An applicant shall submit the initial pediatric study plan under paragraph (1)—

(I) before the date on which the applicant submits the assessments under subsection (a)(2) or reports on the investigation described in subsection (a)(3); and

(II) not later than—

(aa) 60 calendar days after the date of the end-of-Phase 2 meeting (as the term is used in section 312.47 of title 21, Code of Federal Regulations, or successor regulations); or

(bb) such other time as may be agreed on between the Secretary and the applicant.

(ii) EFFECT OF SECTION.—Nothing in this section shall preclude the Secretary from accepting the submission of an initial pediatric study plan earlier than the date otherwise applicable under this subparagraph.

(B) CONTENT OF INITIAL PEDIATRIC STUDY PLAN.—The initial pediatric study plan shall include—

(i) an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable, study objectives and design, age groups, relevant endpoints, and statistical approach);

(ii) any request for a deferral, partial waiver, or waiver under this section, if ap-

plicable, along with any supporting information; and

(iii) other information specified in the regulations promulgated under paragraph (7).

(C) MEETINGS.—The Secretary—

(i) shall meet with the applicant—

(I) if requested by the applicant with respect to a drug or biological product that is intended to treat a serious or life-threatening disease or condition, to discuss preparation of the initial pediatric study plan, not later than the end-of-Phase 1 meeting (as the term is used in section 312.82(b) of title 21, Code of Federal Regulations, or successor regulations) or within 30 calendar days of receipt of the request, whichever is later;

(II) to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of the plan under subparagraph (A); and

(III) to discuss the bases for the deferral under subsection (a)(4) or a full or partial waiver under subsection (a)(5);

(ii) may determine that a written response to the initial pediatric study plan is sufficient to communicate comments on the initial pediatric study plan, and that no meeting under clause (i)(II) is necessary; and

(iii) if the Secretary determines that no meeting under clause (i)(II) is necessary, shall notify the applicant of the determination and provide written comments of the Secretary as soon as practicable, but not later than 90 calendar days after the receipt of the initial pediatric study plan.

(3) AGREED INITIAL PEDIATRIC STUDY PLAN.—Not later than 90 calendar days following the meeting under paragraph (2)(C)(i)(II) or the receipt of a written response from the Secretary under paragraph (2)(C)(iii), the applicant shall document agreement on the initial pediatric study plan in a submission to the Secretary marked ''Agreed Initial Pediatric Study Plan'', and the Secretary shall con-

firm the agreement to the applicant in writing not later than 30 calendar days of receipt of the agreed initial pediatric study plan.

(4) DEFERRAL AND WAIVER.—If the agreed initial pediatric study plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under paragraph (3) shall include a recommendation from the Secretary as to whether the request meets the standards under paragraph (4) or (5) of subsection (a).

(5) AMENDMENTS TO THE AGREED INITIAL PEDIATRIC STUDY PLAN.—

(A) TIMING.—At the initiative of the Secretary or the applicant, the agreed initial pediatric study plan may be amended at any time.

(B) APPLICABILITY OF CERTAIN REQUIREMENTS.—The requirements of paragraph (2)(C) shall apply to any such proposed amendment in the same manner and to the same extent as the requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) shall apply to any agreement resulting from the proposed amendment in the same manner and to the same ex-

tent as the requirements apply to an agreed initial pediatric study plan.

(6) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 13114 of this title on the review of the initial pediatric study plan, the agreed initial pediatric study plan, and any significant amendments to the plans.

(7) REQUIRED RULEMAKING.—Not later than 1 year after July 9, 2012, the Secretary shall promulgate proposed regulations and issue guidance to implement the provisions of this subsection.

(f) REVIEW OF PEDIATRIC STUDY PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.—

(1) REVIEW.—The Secretary shall utilize the internal committee established under section 13114 of this title to provide consultation to reviewing divisions on—

(A) initial pediatric study plans, agreed initial pediatric study plans, and any significant amendments to the plans;

(B) assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section; and

(C) all deferral, deferral extension, and waiver requests granted pursuant to this section.

(2) ACTIVITY BY COMMITTEE.—The internal committee referred to in paragraph (1) may operate using appropriate members of the internal committee and need not convene all members of the internal committee.

(3) DOCUMENTATION OF INTERNAL COMMITTEE ACTION.—For each drug or biological product, the internal committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee participated in the activity.

(4) REVIEW OF PEDIATRIC STUDY PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.—

(A) TIMING OF CONSULTATIONS.—Consultation on initial pediatric study plans, agreed initial pediatric study plans, and assessments by the internal committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section.

(B) REVIEW.—The internal committee shall review all requests for deferrals, deferral extensions, and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.

(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—Not later than 1 year after September 27, 2007, the internal committee referred to in paragraph (1) shall conduct a retrospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since December 3, 2003. The review shall include an analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on the review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.

(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The Secretary, in consultation with the internal committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the FDA website—

(A) the number of assessments conducted under this section;

(B) the specific drugs and biological products and their uses assessed under this section;

(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

(D) aggregated on an annual basis—

(i) the total number of deferrals and deferral extensions requested and granted under this section and, if granted, the reasons for each such deferral or deferral extension;

(ii) the timeline for completion of the assessments;

(iii) the number of assessments completed and pending; and

(iv) the number of postmarket noncompliance letters issued pursuant to subsection (d), and the recipients of the letters;

(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers;

(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;

(G) the labeling changes made as a result of assessments conducted under this section;

(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);

(I) an annual summary of information submitted pursuant to subsection (a)(4)(C); and

(J) the number of times the internal committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed,

the reasons why such a recommendation was not followed.

(g) LABELING CHANGES.—

(1) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review—

(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

(ii) if the sponsor does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

(i) review the pediatric study reports; and

(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.

(D) MISBRANDING.—If the sponsor of the application or supplement, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded.

(E) NO EFFECT ON AUTHORITY.—

(i) ENFORCEMENT ACTION.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this subtitle when a drug lacks appropriate pediatric labeling.

(ii) PRECLUSION; DELAY; STAY OF ACTION.—Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in clause (i)) shall preclude, delay, or serve as the basis to stay the other course of action.

(2) OTHER LABELING CHANGES.—If the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of the assessment is safe and effective in pediatric populations or subpopulations, including whether the assessment results are inconclusive, the Secretary shall order the labeling of the product to include information about the results of the assessment and a statement of the Secretary's determination.

(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) IN GENERAL.—Not later than 210 days after the date of submission of an application (or

supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of the pediatric assessments, and shall post the assessments on the FDA website.

(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—The Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) distribute the information to physicians and other health care providers.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend—

(A) section 10501(10) of this title;

(B) section 552 of title 5; or

(C) section 1905 of title 18.

(i) ADVERSE EVENT REPORTING.—

(1) REPORTING IN FIRST 18-MONTH PERIOD.—

(A) IN GENERAL.—During the 18-month period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for the drug (regardless of when the adverse event report was received) are referred to the Office of Pediatric Therapeutics.

(B) REVIEW BY PEDIATRIC ADVISORY COMMITTEE.—In considering the adverse event reports, the Director of the Office of Pediatric Therapeutics shall provide for the review of the adverse event reports by the Pediatric Advisory Committee, including obtaining any recommendations of the Pediatric Advisory Committee regarding whether the Secretary should take action under this subtitle in response to the adverse event reports.

(2) REPORTING IN SUBSEQUENT PERIODS.—

(A) IN GENERAL.—Following the 18-month period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric ad-

verse event reports for a drug for which a pediatric study was conducted under this section.

(B) REVIEW BY PEDIATRIC ADVISORY COMMITTEE.—In considering the pediatric adverse event reports, the Director of the Office of Pediatric Therapeutics may provide for the review of the pediatric adverse event reports by the Pediatric Advisory Committee, including obtaining any recommendation of the Pediatric Advisory Committee regarding whether the Secretary should take action in response to the pediatric adverse event reports.

(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if the review is necessary to ensure safe use of a drug in a pediatric population.

(4) EFFECT OF SUBSECTION.—The requirements of this subsection shall supplement, not supplant, other review of the adverse event reports by the Secretary.

(j) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pedi-

atric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

(k) RELATION TO ORPHAN DRUGS.—

(1) IN GENERAL.—Unless the Secretary requires otherwise by regulation and except as provided in paragraph (2), this section does not apply to any drug or biological product for an indication for which orphan designation has been granted under section 13902 of this title.

(2) APPLICABILITY DESPITE ORPHAN DESIGNATION OF CERTAIN INDICATIONS.—This section shall apply with respect to a drug or biological product for which an indication has been granted orphan designation under section 13902 of this title if the investigation described in subsection (a)(3) applies to the drug or biological product as described in subsection (a)(1)(B).

(l) NEW ACTIVE INGREDIENT.—

(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act (42 U.S.C. 262), and that the Secretary has not determined to meet

the standards described in subsection (k)(4) of that section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act (42 U.S.C. 262) shall not be considered to have a new active ingredient under this section.

(m) LIST OF PRIMARY MOLECULAR TARGETS.—

(1) IN GENERAL.—The Secretary shall update regularly, and shall publish on the FDA website—

(A) a list of molecular targets considered, on the basis of data the Secretary determines to be adequate, to be substantially relevant to the growth and progression of a pediatric cancer, and that may trigger the requirements under this section; and

(B) a list of molecular targets of new cancer drugs and biological products in development for which pediatric cancer study requirements under this section will be automatically waived.

(2) CONSULTATION.—In establishing the lists described in paragraph (1), the Secretary shall consult the National Cancer Institute, members of the internal committee under section 13114 of this title, and the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee, and shall take into account comments from the meeting under section 504(c) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1041).

(3) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) to require the inclusion of a molecular target on the list published under the paragraph as a condition for triggering the requirements under subsection (a)(1)(B) with respect to a drug or biological product directed at the molecular target; or

(B) to authorize the disclosure of confidential commercial information, as prohibited under section 10501(10) of this title or section 1905 of title 18.

**§ 13114. Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers**

(a) ESTABLISHMENT.—The Secretary shall establish an internal committee within the FDA to carry out the activities as described in sections 13112(f) and 13113(f) of this title.

(b) MEMBERS.—The internal committee shall include—

(1) employees of the FDA, with expertise in—

(A) pediatrics (including representation from the Office of Pediatric Therapeutics);

(B) biopharmacology;

(C) statistics;

(D) chemistry;

(E) legal issues;

(F) pediatric ethics;

(G) neonatology; and

(H) the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry or pediatric rare diseases; and

(2) other individuals designated by the Secretary.

**§ 13115. Pharmaceutical security**

(a) DEFINITION OF PRESCRIPTION DRUG.—In this section, the term ''prescription drug'' means a drug subject to section 13103(a)(1) of this title.

(b) IN GENERAL.—The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

(c) STANDARDS DEVELOPMENT.—

(1) IN GENERAL.—The Secretary shall, in consultation with the agencies specified in paragraph (4), manufacturers, distributors, pharmacies, and other supply chain stakeholders, prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs.

(2) STANDARDIZED NUMERAL IDENTIFIER.—The Secretary shall develop a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet

level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

(3) PROMISING TECHNOLOGIES.—The standards developed under this subsection shall address promising technologies, which may include—

(A) radio frequency identification technology;

(B) nanotechnology;

(C) encryption technologies; and

(D) other track-and-trace or authentication technologies.

(4) INTERAGENCY COLLABORATION.—In carrying out this subsection, the Secretary shall consult with Federal health and security agencies, including—

(A) the Department of Justice;

(B) the Department of Homeland Security;

(C) the Department of Commerce; and

(D) other appropriate Federal and State agencies.

(d) INSPECTION AND ENFORCEMENT.—

(1) IN GENERAL.—The Secretary shall expand and enhance the resources and facilities of agency components of the FDA involved with regulatory

and criminal enforcement of this subtitle to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs including biological products and active pharmaceutical ingredients from domestic and foreign sources.

(2) ACTIVITIES.—The Secretary shall undertake enhanced and joint enforcement activities with other Federal and State agencies, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain.

**§ 13116. Extension of exclusivity period for new qualified infectious disease products**

(a) DEFINITIONS.—In this section:

(1) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term ''qualified infectious disease product'' means a drug (including a biological product), including an antibacterial or antifungal drug, for human use that—

(A) acts on bacteria or fungi or on substances produced by bacteria or fungi; and

(B) is intended to treat a serious or life-threatening infection, including such an infection caused by—

(i) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

(ii) qualifying pathogens listed by the Secretary under subsection (g).

(2) QUALIFYING PATHOGEN.—The term ''qualifying pathogen'' means a pathogen identified and listed by the Secretary under subsection (g) that has the potential to pose a serious threat to public health, such as—

(A) resistant gram-positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

(B) multi-drug resistant gram-negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

(C) multi-drug resistant tuberculosis; and

(D) Clostridium difficile.

(b) EXTENSION.—If the Secretary approves an application pursuant to chapter 135 of this title for a drug that has been designated as a qualified infectious disease product under subsection (e), the 4-year and 5-year periods described in sections 13504(c)(5)(A) and 13511(f)(6)(A) of this title, the 3-year periods described

in subparagraphs (B) and (C) of section 13504(c)(5) of this title and subparagraphs (B) and (C) of section 13511(f)(6) of this title, or the 7-year period described in section 13903 of this title, as applicable, shall be extended by 5 years.

(c) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (b) of a period shall be in addition to any extension of the period under section 13112 of this title with respect to the drug.

(d) LIMITATIONS.—Subsection (b) does not apply to the approval of—

(1) a supplement to an application under section 13503 of this title for any qualified infectious disease product for which an extension described in subsection (b) is in effect or has expired;

(2) a subsequent application filed with respect to a product approved under chapter 135 of this title for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength;

(3) a product that does not meet the definition of a qualified infectious disease product under subsection (a)(1) based on its approved uses; or

(4) an application pursuant to section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(e) DESIGNATION.—

(1) IN GENERAL.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for the drug. The Secretary shall, not later than 60 days after the submission of the request, determine whether the drug is a qualified infectious disease product.

(2) LIMITATION.—Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (g)(3).

(3) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for the designation contained an untrue statement of material fact.

(f) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall promulgate regulations implementing this section, including

developing the list of qualifying pathogens described in subsection (g).

(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the effective date of the regulation.

(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (e) prior to the promulgation of the regulations.

(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary shall designate drugs as qualified infectious disease products under subsection (e) prior to the promulgation of regulations under this subsection, if the drugs meet the definition of a quali-

fied infectious disease product described in subsection (a)(1).

(g) LIST OF QUALIFYING PATHOGENS.—

(1) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing the list.

(2) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under this section, the Secretary shall—

(A) consider—

(i) the impact on the public health due to drug-resistant organisms in humans;

(ii) the rate of growth of drug-resistant organisms in humans;

(iii) the increase in resistance rates in humans; and

(iv) the morbidity and mortality in humans; and

(B) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the FDA, medical professionals, and the clinical research community.

(3) REVIEW.—Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under paragraph (1) and shall by regulation revise the list as necessary, in accordance with subsection (f).

**§ 13117. Utilizing real-world evidence**

(a) DEFINITION OF REAL-WORLD EVIDENCE.—In this section, the term ''real-world evidence'' means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials.

(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to evaluate the potential use of real-world evidence—

(1) to help to support the approval of a new indication for a drug approved under section 13504 of this title; and

(2) to help to support or satisfy postapproval study requirements.

(c) PROGRAM FRAMEWORK.—

(1) IN GENERAL.—Not later than 2 years after December 13, 2016, the Secretary shall establish a draft framework for implementation of the program under this section.

(2) CONTENTS OF FRAMEWORK.—The framework shall include information describing—

(A) the sources of real-world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

(B) the gaps in data collection activities;

(C) the standards and methodologies for collection and analysis of real-world evidence; and

(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

(3) CONSULTATION.—

(A) IN GENERAL.—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties.

(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

(i) a public-private partnership with the entities described in subparagraph (A) in which the Secretary may participate;

(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

(iii) public workshops with the entities described in subparagraph (A).

(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than 3 years after December 13, 2016, and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real-world evidence.

(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

(1) utilize the program established under subsection (b), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

(A) the circumstances under which sponsors of drugs and the Secretary may rely on real-world evidence for the purposes described in paragraphs (1) and (2) of subsection (b); and

(B) the appropriate standards and methodologies for collection and analysis of real-world evidence submitted for those purposes;

(2) not later than 5 years after December 13, 2016, issue draft guidance for industry as described in paragraph (1); and

(3) not later than 18 months after the close of the public comment period for the draft guidance described in paragraph (2), issue revised draft guidance or final guidance.

(f) RULE OF CONSTRUCTION.—

(1) OTHER PURPOSES FOR USING REAL-WORLD EVIDENCE.—Subject to paragraph (2), nothing in this section prohibits the Secretary from using real-world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.

(2) STANDARDS OF EVIDENCE AND SECRETARY'S AUTHORITY.—This section shall not be construed to alter—

(A) the standards of evidence under—

(i) section 13504 or 13505 of this title, including the substantial evidence standard in section 13505 of this title; or

(ii) section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); or

(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.

**§ 13118. Regulation of certain nonprescription drugs that are marketed without an approved drug application**

(a) DEFINITIONS.—In this section:

(1) NONPRESCRIPTION DRUG.—The term ''nonprescription drug'' refers to a drug not subject to the requirements of section 13103(a)(1) of this title.

(2) REQUESTOR.—The term ''requestor'' refers to any person or group of persons marketing, manufacturing, processing, or developing a drug.

(3) SPONSOR.—The term ''sponsor'' refers to any person marketing, manufacturing, or processing a drug that—

(A) is listed pursuant to section 13136(j) of this title; and

(B) is or will be subject to an administrative order of the FDA under this section.

(b) NONPRESCRIPTION DRUGS MARKETED WITHOUT AN APPROVED APPLICATION.—Nonprescription drugs

marketed without an approved drug application under chapter 135 of this title, as of March 27, 2020, shall be treated in accordance with this subsection as follows:

(1) DRUGS SUBJECT TO A FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH.—A drug is deemed to be generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title, not a new drug under section 10101(a)(34) of this title, and not subject to section 13103(a)(1) of this title, if—

(A) the drug is—

(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and conditions or requirements under subsections (c), (d), and (l); and

(ii) except as permitted by an order issued under subsection (c) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (d), in a dosage form that, immediately prior to March 27, 2020, has been

used to a material extent and for a material time under section 10101(a)(34)(A)(ii) of this title; or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with the proposed requirements for nonprescription use of the tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (c), (d), and (l); and

(iii) except as permitted by an order issued under subsection (c) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (d), in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a mate-

rial time under section 10101(a)(34)(A)(ii) of this title.

(2) TREATMENT OF SUNSCREEN DRUGS.—With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations.

(3) CATEGORY III DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE NOTICE OF PROPOSED RULEMAKING.—A drug that is not described in paragraph (1), (2), or (4) is not required to be the subject of an application approved under chapter 135 of this title, and is not subject to section 13103(a)(1) of this title, if—

(A) the drug is—

(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final

monograph that is the most recently applicable proposal or determination for the drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with—

(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

(II) the proposed requirements for drugs classified in the tentative final monograph in category I in the most recently proposed rule establishing requirements related to the tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

(III) the general requirements for nonprescription drugs and conditions or requirements under subsection (c) or (l); and

(iii) in a dosage form that, immediately prior to March 27, 2020, had been used to a material extent and for a mate-

rial time under section 10101(a)(34)(A)(ii) of this title; or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for the drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with the requirements for nonprescription use of the proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (c) or (l); and

(iii) in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 10101(a)(34)(A)(ii) of this title.

(4) CATEGORY II DRUGS DEEMED NEW DRUGS.—A drug that is classified in category II for

safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 10101(a)(34) of this title, misbranded under section 13328 of this title, and subject to the requirement for an approved new drug application under chapter 135 of this title beginning on the day that is 180 calendar days after March 27, 2020, unless, before that day, the Secretary determines that it is in the interest of public health to extend the period during which the drug may be marketed without such an approved new drug application.

(5) DRUGS NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE DEEMED NEW DRUGS.—A drug that the Secretary has determined not to be generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title under a final determination issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 10101(a)(34) of this title, misbranded under section 13328 of this title, and sub-

ject to the requirement for an approved new drug application under chapter 135 of this title.

(6) OTHER DRUGS DEEMED NEW DRUGS.—Except as provided in subsection (n), a drug is deemed to be a new drug under section 10101(a)(34) of this title and misbranded under section 13328 of this title if the drug—

(A) is not subject to section 13103(a)(1) of this title; and

(B) is not described in paragraph (1), (2), (3), (4), or (5), or subsection (c)(1)(B).

(c) ADMINISTRATIVE ORDERS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary may, on the initiative of the Secretary or at the request of 1 or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs, is determined to be—

(i) not subject to section 13103(a)(1) of this title; and

(ii) generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title.

(B) EFFECT.—A drug or combination of drugs shall be deemed to not require approval under chapter 135 of this title if the drug or combination of drugs—

(i) is determined by the Secretary to meet the conditions specified in clauses (i) and (ii) of subparagraph (A);

(ii) is marketed in conformity with an administrative order under this subsection;

(iii) meets the general requirements for nonprescription drugs; and

(iv) meets the requirements under subsections (d) and (l).

(C) STANDARD.—The Secretary shall find that a drug is not generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title if—

(i) the evidence shows that the drug is not generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title; or

(ii) the evidence is inadequate to show that the drug is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title.

(2) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

(A) IN GENERAL.—In issuing an administrative order under paragraph (1) on the initiative of the Secretary, the Secretary shall—

(i) make reasonable efforts to notify informally, not later than 2 business days before the issuance of the proposed order, the sponsors of drugs who have a listing in effect under section 13136(j) of this title for the drugs or combination of drugs that will be subject to the administrative order;

(ii) after any such reasonable efforts of notification—

(I) issue a proposed administrative order by publishing it on the FDA website and include in the order the reasons for the issuance of the order; and

(II) publish a notice of availability of the proposed order in the Federal Register;

(iii) except as provided in subparagraph (B), provide for a public comment

period with respect to the proposed order of not less than 45 calendar days; and

(iv) if, after completion of the proceedings specified in clauses (i) through (iii), the Secretary determines that it is appropriate to issue a final administrative order—

(I) issue the final administrative order, together with a detailed statement of reasons, which order shall not take effect until the time for requesting judicial review under paragraph (3)(D)(ii) has expired;

(II) publish a notice of the final administrative order in the Federal Register;

(III) afford requestors of drugs that will be subject to the order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which initially must be requested within 45 calendar days of the issuance of the order, and, for subsequent levels of appeal, within 30

calendar days of the prior decision; and

(IV) except with respect to drugs described in paragraph (3)(B), on completion of the formal dispute resolution procedure, inform the persons that sought the dispute resolution of their right to request a hearing.

(B) EXCEPTIONS.—When issuing an administrative order under paragraph (1) on the Secretary's initiative proposing to determine that a drug described in subsection (b)(3) is not generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title, the Secretary shall follow the procedures in subparagraph (A), except that—

(i) the proposed order shall include notice of—

(I) the general categories of data the Secretary has determined necessary to establish that the drug is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title; and

(II) the format for submissions by interested persons;

(ii) the Secretary shall provide for a public comment period of no less than 180 calendar days with respect to the proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interest of public health; and

(iii) any person that submits data in the comment period shall include a certification that the person has submitted all evidence created, obtained, or received by that person that is both within the categories of data identified in the proposed order and relevant to a determination as to whether the drug is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title.

(3) HEARINGS; JUDICIAL REVIEW.—

(A) IN GENERAL.—

(i) PERSON THAT MAY REQUEST HEARING.—Only a person that participated in each stage of formal dispute resolution under paragraph (2)(A)(iv)(III) of an administrative order with respect to a

drug may request a hearing concerning a final administrative order issued under the paragraph with respect to the drug.

(ii) TIMING OF REQUEST.—A person seeking a hearing shall submit a request for a hearing, which shall be based solely on information in the administrative record, to the Secretary not later than 30 calendar days after receiving notice of the final decision of the formal dispute resolution procedure.

(B) NO HEARING REQUIRED WITH RESPECT TO ORDERS RELATING TO CERTAIN DRUGS.—

(i) DEFINITIONS.—In this subparagraph:

(I) HUMAN DATA STUDIES.—The term ''human data studies'' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies.

(II) NON-HUMAN DATA.—The term ''non-human data'' means data from testing other than with human

subjects that provides information concerning safety or effectiveness.

(ii) IN GENERAL.—The Secretary shall not be required to provide notice and an opportunity for a hearing pursuant to paragraph (2)(A)(iv) if the final administrative order involved relates to a drug—

(I) that is described in subsection (b)(3)(A); and

(II) with respect to which no human or non-human data studies relevant to the safety or effectiveness of the drug have been submitted to the administrative record since the issuance of the most recent tentative final monograph relating to the drug.

(C) HEARING PROCEDURES.—

(i) DENIAL OF REQUEST FOR HEARING.—If the Secretary determines that information submitted in a request for a hearing under subparagraph (A) with respect to a final administrative order issued under paragraph (2)(A)(iv) does not identify the existence of a genuine and substantial question of material fact, the Sec-

retary may deny the request. In making such a determination, the Secretary may consider only information and data that are based on relevant and reliable scientific principles and methodologies.

(ii) SINGLE HEARING FOR MULTIPLE RELATED REQUESTS.—If more than 1 request for a hearing is submitted with respect to the same administrative order under subparagraph (A), the Secretary may direct that a single hearing be conducted in which all persons whose hearing requests were granted may participate.

(iii) PRESIDING OFFICER.—The presiding officer of a hearing requested under subparagraph (A) shall—

(I) be designated by the Secretary;

(II) not be an employee of the Center for Drug Evaluation and Research; and

(III) not have been previously involved in the development of the administrative order involved or pro-

ceedings relating to that administrative order.

(iv) RIGHTS OF PARTIES TO HEARING.—The parties to a hearing requested under subparagraph (A) shall have the right to present testimony, including testimony of expert witnesses, and to cross-examine witnesses presented by other parties. Where appropriate, the presiding officer may require that cross-examination by parties representing substantially the same interests be consolidated to promote efficiency and avoid duplication.

(v) FINAL DECISION.—

(I) IN GENERAL.—At the conclusion of a hearing requested under subparagraph (A), the presiding officer of the hearing shall issue a decision containing findings of fact and conclusions of law. The decision of the presiding officer shall be final.

(II) EFFECTIVE DATE OF FINAL DECISION.—The final decision may not take effect until the period under subparagraph (D)(ii) for submitting a

request for judicial review of the decision expires.

(D) JUDICIAL REVIEW OF FINAL ADMINISTRATIVE ORDER.—

(i) IN GENERAL.—The procedures described in section 13509 of this title shall apply with respect to judicial review of final administrative orders issued under this subsection in the same manner and to the same extent as that section applies to an order described in that section except that the judicial review shall be taken by filing in an appropriate district court of the United States in lieu of the appellate courts specified in the section.

(ii) PERIOD TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph and seeking judicial review of a final administrative order issued under this subsection shall file the request for judicial review not later than 60 calendar days after the latest of—

(I) the date on which notice of the order is published;

(II) the date on which a hearing with respect to the order is denied under subparagraph (B) or (C)(i);

(III) the date on which a final decision is made following a hearing under subparagraph (C)(v); or

(IV) if no hearing is requested, the date on which the time for requesting a hearing expires.

(4) EXPEDITED PROCEDURE WITH RESPECT TO ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

(A) IMMINENT HAZARD TO THE PUBLIC HEALTH.—

(i) IN GENERAL.—In the case of a determination by the Secretary that a drug, class of drugs, or combination of drugs subject to this section poses an imminent hazard to the public health, the Secretary, after first making reasonable efforts to notify, not later than 48 hours before issuance of the order under this subparagraph, sponsors who have a listing in effect under section 13136(j) of this title for the drug or combination of drugs—

(I) may issue an interim final administrative order for the drug, class of drugs, or combination of drugs under paragraph (1), together with a detailed statement of the reasons for the order;

(II) shall publish in the Federal Register a notice of availability of the interim final order; and

(III) shall provide for a public comment period of at least 45 calendar days with respect to the interim final order.

(ii) NONDELEGATION.—The Secretary may not delegate the authority to issue an interim final administrative order under this subparagraph.

(B) SAFETY LABELING CHANGES.—

(i) IN GENERAL.—In the case of a determination by the Secretary that a change in the labeling of a drug, class of drugs, or combination of drugs subject to this section is reasonably expected to mitigate a significant or unreasonable risk of a seri-

ous adverse event associated with use of the drug, the Secretary may—

(I) make reasonable efforts to notify informally, not later than 48 hours before the issuance of the interim final order, the sponsors of drugs who have a listing in effect under section 13136(j) of this title for the drug or combination of drugs;

(II) after reasonable efforts of notification, issue an interim final administrative order in accordance with paragraph (1) to require the change, together with a detailed statement of the reasons for the order;

(III) publish in the Federal Register a notice of availability of the order; and

(IV) provide for a public comment period of at least 45 calendar days with respect to the interim final order.

(ii) CONTENT OF ORDER.—An interim final order issued under this subparagraph with respect to the labeling of a drug may

provide for new warnings and other information required for safe use of the drug.

(C) EFFECTIVE DATE.—An order under subparagraph (A) or (B) shall take effect on a date specified by the Secretary.

(D) FINAL ORDER.—After the completion of the proceedings in subparagraph (A) or (B), the Secretary shall—

(i) issue a final order in accordance with paragraph (1);

(ii) publish a notice of availability of the final administrative order in the Federal Register; and

(iii) afford sponsors of the drugs that will be subject to the final administrative order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which must initially be within 45 calendar days of the issuance of the order, and for subsequent levels of appeal, within 30 calendar days of the prior decision.

(E) HEARINGS.—

(i) SPONSOR THAT MAY REQUEST HEARING.—A sponsor of a drug subject to

a final order issued under subparagraph (D) and that participated in each stage of formal dispute resolution under clause (iii) of the subparagraph may request a hearing on the order.

(ii) PROVISIONS APPLICABLE TO HEARING.—The provisions of subparagraphs (A), (B), and (C) of paragraph (3), other than paragraph (3)(C)(v)(II), shall apply with respect to a hearing on the order in the same manner and to the same extent as the provisions apply with respect to a hearing on an administrative order issued under paragraph (2)(A)(iv).

(F) TIMING.—

(i) FINAL ORDER AND HEARING.—The Secretary shall—

(I) not later than 6 months after the date on which the comment period closes under subparagraph (A) or (B), issue a final order in accordance with paragraph (1); and

(II) not later than 12 months after the date on which the final order

is issued, complete any hearing under subparagraph (E).

(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

(G) JUDICIAL REVIEW.—A final order issued pursuant to subparagraph (F) shall be subject to judicial review in accordance with paragraph (3)(D).

(5) ADMINISTRATIVE ORDER INITIATED AT THE REQUEST OF A REQUESTOR.—

(A) IN GENERAL.—

(i) DETERMINATION RELATING TO COMPLETENESS AND FORMATTING OF REQUEST.—In issuing an administrative order under paragraph (1) at the request of a requestor with respect to certain drugs, classes of drugs, or combinations of drugs, the Secretary shall, after receiving a request under this subparagraph, deter-

mine whether the request is sufficiently complete and formatted to permit a substantive review.

(ii) REQUEST SUFFICIENTLY COMPLETE AND FORMATTED TO PERMIT SUBSTANTIVE REVIEW.—If the Secretary determines that the request is sufficiently complete and formatted to permit a substantive review, the Secretary shall—

(I) file the request; and

(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (2) and (3).

(iii) REQUEST DOES NOT MEET FILING REQUIREMENTS OR IS NOT SUFFICIENTLY COMPLETE AND FORMATTED TO PERMIT SUBSTANTIVE REVIEW.—Except as provided in paragraph (6), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete and formatted to permit a substantive review, the requestor may demand that the request be filed over protest, and the Secretary shall initiate pro-

ceedings to review the request in accordance with paragraph (2)(A).

(B) REQUEST TO INITIATE PROCEEDINGS.—

(i) IN GENERAL.—A requestor seeking an administrative order under paragraph (1) with respect to certain drugs, classes of drugs, or combinations of drugs shall submit to the Secretary a request to initiate proceedings for the order in the form and manner as specified by the Secretary. The requestor may submit a request under this subparagraph for the issuance of an administrative order—

(I) determining whether a drug is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title, exempt from section 13103(a)(1) of this title, and not required to be the subject of an approved application under chapter 135 of this title; or

(II) determining whether a change to a condition of use of a drug is generally recognized as safe and ef-

fective under section 10101(a)(34)(A)(i) of this title, exempt from section 13103(a)(1) of this title, and not required to be the subject of an approved application under chapter 135 of this title, if, absent such a changed condition of use, the drug is—

(aa) generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title in accordance with paragraph (1) or (2) of subsection (b), or with an order under this subsection; or

(bb) subject to subsection (b)(3), but only if the requestor initiates the request in conjunction with a request for the Secretary to determine whether the drug is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title, which is filed by the Secretary under subparagraph (A)(ii).

(ii) EXCEPTION.—The Secretary is not required to complete review of a request for a change described in clause (i)(II) if the Secretary determines that there is an inadequate basis to find that the drug is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title under paragraph (1) and issues a final order announcing that determination.

(iii) WITHDRAWAL.—The requestor may withdraw a request under this paragraph, according to the procedures set forth pursuant to subsection (e)(2)(B). Notwithstanding any other provision of this section, if the request is withdrawn, the Secretary may cease proceedings under this subparagraph.

(C) EXCLUSIVITY.—

(i) DEFINITION OF NEW HUMAN DATA STUDIES.—In this subparagraph, the term ''new human data studies'' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics stud-

ies, or bioavailability studies, the results of which—

(I) have not been relied on by the Secretary to support—

(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iv) is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title; or

(bb) approval of a drug that was approved under chapter 135 of this title; and

(II) do not duplicate the results of another study that was relied on by the Secretary to support—

(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title; or

(bb) approval of a drug that was approved under chapter 135 of this title.

(ii) IN GENERAL.—A final administrative order issued in response to a request under this section shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of the requestor with respect to the subject of the order), for a period of 18 months following the effective date of the final order and beginning on the date the requestor may lawfully market the drugs pursuant to the order, to market drugs—

(I) incorporating changes described in clause (iii); and

(II) subject to the limitations under clause (v).

(iii) CHANGES DESCRIBED.—A change described in this clause is a change subject to an order specified in clause (ii), which—

(I) provides for a drug to contain an active ingredient (including any ester or salt of the active ingredient)

not previously incorporated in a drug described in clause (iv); or

(II) provides for a change in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive right of reference) were essential to the issuance of the order.

(iv) DRUGS DESCRIBED.—The drugs described in this clause are drugs—

(I) specified in paragraph (1), (2), or (3) of subsection (b);

(II) subject to a final order issued under this section;

(III) subject to a final sunscreen order (as defined in section 15101(2)(A) of this title); or

(IV) described in subsection (n)(1), other than drugs subject to an active enforcement action under chapter 105 of this title.

(v) LIMITATIONS ON EXCLUSIVITY.—

(I) IN GENERAL.—Only one 18-month period under this subpara-

graph shall be granted, under each order described in clause (ii), with respect to changes (to the drug subject to the order) that are either—

(aa) changes described in clause (iii)(I), relating to active ingredients; or

(bb) changes described in clause (iii)(II), relating to conditions of use.

(II) NO EXCLUSIVITY ALLOWED.—No exclusivity shall apply to changes to a drug that are—

(aa) the subject of a Tier 2 OTC monograph order request (as defined in section 17976 of this title);

(bb) safety-related changes, as defined by the Secretary, or any other changes the Secretary considers necessary to ensure safe use; or

(cc) changes related to methods of testing safety or efficacy.

(vi) NOTIFICATION OF DRUG NOT AVAILABLE FOR SALE.—A requestor that is granted exclusivity with respect to a drug under this subparagraph shall notify the Secretary in writing within 1 year of the issuance of the final administrative order if the drug that is the subject of the order will not be available for sale within 1 year of the date of issuance of the order. The requestor shall include with the notice the—

(I) identity of the drug by established name and by proprietary name, if any;

(II) strength of the drug;

(III) date on which the drug will be available for sale, if known; and

(IV) reason for not marketing the drug after issuance of the order.

(6) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS CONDITION FOR FILING A GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE REQUEST.—

(A) IN GENERAL.—In response to a request under this section that a drug described

in subparagraph (B) be generally recognized as safe and effective, the Secretary—

(i) may file the request, if the request includes information specified under subparagraph (C) with respect to safe nonprescription marketing and use of the drug; or

(ii) if the request fails to include information specified under subparagraph (C), shall refuse to file the request and require that nonprescription marketing of the drug be pursuant to a new drug application as described in subparagraph (D).

(B) DRUG DESCRIBED.—A drug described in this subparagraph is a nonprescription drug that contains an active ingredient not previously incorporated in a drug—

(i) specified in paragraph (1), (2), or (3) of subsection (b);

(ii) subject to a final order under this section; or

(iii) subject to a final sunscreen order (as defined in section 15101(2)(A) of this title).

(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MARKETING AND USE.—Information specified in this subparagraph, with respect to a request described in subparagraph (A)(i), is—

(i) information sufficient for a prima facie demonstration that the drug subject to the request has a verifiable history of being marketed and safely used by consumers in the United States as a nonprescription drug under comparable conditions of use;

(ii) if the drug has not been previously marketed in the United States as a nonprescription drug, information sufficient for a prima facie demonstration that the drug was marketed and safely used under comparable conditions of marketing and use in a country listed in section 20102(c)(1)(A) of this title or designated by the Secretary in accordance with section 20102(c)(1)(B) of this title—

(I) for such period as needed to provide reasonable assurances con-

cerning the safe nonprescription use of the drug; and

(II) during that time was subject to sufficient monitoring by a regulatory body considered acceptable by the Secretary for those monitoring purposes, including for adverse events associated with nonprescription use of the drug; or

(iii) if the Secretary determines that information described in clause (i) or (ii) is not needed to provide a prima facie demonstration that the drug can be safely marketed and used as a nonprescription drug, such other information the Secretary determines is sufficient for those purposes.

(D) MARKETING PURSUANT TO NEW DRUG APPLICATION.—In the case of a request described in subparagraph (A)(ii), the drug subject to the request may be resubmitted for filing only if—

(i) the drug is marketed as a nonprescription drug, under conditions of use comparable to the conditions specified in the request, for such period as the Sec-

retary determines appropriate (not to exceed 5 consecutive years) pursuant to an application approved under chapter 135 of this title; and

(ii) during that period, 1,000,000 retail packages of the drug, or an equivalent quantity as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary finds appropriate.

(E) RULE OF APPLICATION.—Except in the case of a request involving a drug described in section 15101(9) of this title, as in effect on January 1, 2017, if the Secretary refuses to file a request under this paragraph, the requestor may not file the request over protest under paragraph (5)(A)(iii).

(7) PACKAGING.—

(A) CERTAIN ORDERS MAY INCLUDE PACKAGING REQUIREMENTS.—An administrative order issued under paragraph (2), (4)(A), or (5) may include requirements for the packaging of a drug to encourage use in accordance with labeling.

(B) REQUIREMENTS.—The requirements may include unit dose packaging, requirements for products intended for use by pediatric populations, requirements to reduce risk of harm from unsupervised ingestion, and other appropriate requirements.

(C) CERTAIN STANDARDS AND TESTING PROCEDURES NOT AUTHORIZED.—This paragraph does not authorize the FDA to require standards or testing procedures as described in part 1700 of title 16, Code of Federal Regulations.

(8) FINAL AND TENTATIVE FINAL MONOGRAPHS FOR CATEGORY I DRUGS DEEMED FINAL ADMINISTRATIVE ORDERS.—

(A) IN GENERAL.—A final monograph or tentative final monograph described in subparagraph (B) shall be deemed to be a final administrative order under this subsection and may be amended, revoked, or otherwise modified in accordance with the procedures of this subsection.

(B) MONOGRAPHS DESCRIBED.—For purposes of subparagraph (A), a final monograph

or tentative final monograph is described in this subparagraph if it—

(i) establishes conditions of use for a drug described in paragraph (1) or (2) of subsection (b); and

(ii) represents the most recently promulgated version of the conditions, including as modified, in whole or in part, by any proposed or final rule.

(C) DEEMED ORDERS INCLUDE HARMONIZING TECHNICAL AMENDMENTS.—The deemed establishment of a final administrative order under subparagraph (A) shall be construed to include any technical amendments to the order as the Secretary determines necessary to ensure that the order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of this chapter (and regulations thereunder) and any other orders issued under this section.

(d) PROCEDURE FOR MINOR CHANGES.—

(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in paragraph (1) or (2) of subsection (b) or the subject of an order issued under subsection (c) may be made by a re-

questor without the issuance of an order under subsection (c) if—

(A) the requestor maintains such information as is necessary to demonstrate that the change—

(i) will not affect the safety or effectiveness of the drug; and

(ii) will not materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product; and

(B) the change is in conformity with the requirements of an applicable administrative order issued by the Secretary under paragraph (3).

(2) ADDITIONAL INFORMATION.—

(A) ACCESS TO RECORDS.—A sponsor shall submit records requested by the Secretary relating to such a minor change under section 17504(a)(4) of this title, within 15 business days of receiving such a request, or such longer period as the Secretary may provide.

(B) INSUFFICIENT INFORMATION.—If the Secretary determines that the information contained in the records is not sufficient to dem-

onstrate that the change does not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the active ingredient, the Secretary—

(i) may so inform the sponsor of the drug in writing; and

(ii) if the Secretary so informs the sponsor, shall provide the sponsor of the drug with a reasonable opportunity to provide additional information.

(C) FAILURE TO SUBMIT SUFFICIENT INFORMATION.—The drug as modified is a new drug under section 10101(a)(34) of this title and shall be deemed to be misbranded under section 13328 of this title if the sponsor fails to provide the additional information within a time prescribed by the Secretary, or if the Secretary determines that the additional information does not demonstrate that the change does not—

(i) affect the safety or effectiveness of the drug; or

(ii) materially affect the extent of absorption or other exposure to the active in-

gredient in comparison to a suitable reference product.

(3) DETERMINING WHETHER A CHANGE WILL AFFECT SAFETY OR EFFECTIVENESS.—

(A) IN GENERAL.—The Secretary shall issue 1 or more administrative orders specifying requirements for determining whether a minor change made by a sponsor pursuant to this subsection will affect the safety or effectiveness of a drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product, together with guidance for applying those orders to specific dosage forms.

(B) STANDARD PRACTICES.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drugs, and may take into account the special needs of populations, including children.

(e) CONFIDENTIALITY OF INFORMATION SUBMITTED TO THE SECRETARY.—

(1) IN GENERAL.—Subject to paragraph (2), any information, including reports of testing con-

ducted on the drug or drugs involved, that is submitted by a requestor in connection with proceedings on an order under this section (including any minor change under subsection (d)) and is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18 shall not be disclosed to the public unless the requestor consents to that disclosure.

(2) PUBLIC AVAILABILITY.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall—

(i) make any information submitted by a requestor in support of a request under subsection (c)(5)(A) available to the public not later than the date on which the proposed order is issued; and

(ii) make any information submitted by any other person with respect to an order requested (or initiated by the Secretary) under subsection (c) available to the public on the submission.

(B) LIMITATIONS ON PUBLIC AVAILABILITY.—Information described in subparagraph (A) shall not be made public if—

(i) the information pertains to pharmaceutical quality information, unless the information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title;

(ii) the information is submitted in a requestor-initiated request, but the requestor withdraws the request, in accordance with withdrawal procedures established by the Secretary, before the Secretary issues the proposed order;

(iii) the Secretary requests and obtains the information under subsection (d) and the information is not submitted in relation to an order under subsection (c); or

(iv) the information is of the type contained in raw datasets.

(f) UPDATES TO DRUG LISTING INFORMATION.—A sponsor that makes a change to a drug subject to this section shall submit updated drug listing information for the drug in accordance with section 13136(j) of this title within 30 calendar days of the date when the drug is first commercially marketed, except that a sponsor that was the order requestor with respect to an order subject to sub-

section (c)(5)(C) (or a licensee, assignee, or successor in interest of the requestor) shall submit updated drug listing information on or before the date when the drug is first commercially marketed.

(g) APPROVALS UNDER CHAPTER 135 OF THIS TITLE.—

(1) CONSTRUCTION RELATING TO APPLICATIONS.—The provisions of this section shall not be construed to preclude a person from seeking or maintaining the approval of an application for a drug under sections 13503(a), 13503(b), and 13511 of this title.

(2) EFFECT OF CERTAIN DETERMINATIONS UNDER THIS SECTION.—A determination under this section that a drug is not subject to section 13103(a)(1) of this title, is generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title, and is not a new drug under section 10101(a)(34) of this title shall constitute a finding that the drug is safe and effective that may be relied on for purposes of an application under section 13503(b) of this title, so that the applicant shall be required to submit for purposes of the application only information needed to support any modification

of the drug that is not covered by the determination under this section.

(h) PUBLIC AVAILABILITY OF ADMINISTRATIVE ORDERS.—The Secretary shall establish, maintain, update (as determined necessary by the Secretary but no less frequently than annually), and make publicly available, with respect to orders issued under this section—

(1) a repository of each final order and interim final order in effect, including the complete text of the order; and

(2) a listing of all orders proposed and under development under subsection (c)(2), including—

(A) a brief description of each such order; and

(B) the Secretary's expectations, if resources permit, for issuance of proposed orders over a 3-year period.

(i) DEVELOPMENT ADVICE TO SPONSORS OR REQUESTORS.—The Secretary shall establish procedures under which sponsors or requestors may meet with appropriate officials of the FDA to obtain advice on the studies and other information necessary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

(j) PARTICIPATION OF MULTIPLE SPONSORS OR REQUESTORS.—The Secretary shall establish procedures to facilitate efficient participation by multiple sponsors or requestors in proceedings under this section, including provision for joint meetings with multiple sponsors or requestors or with organizations nominated by sponsors or requestors to represent their interests in a proceeding.

(k) ELECTRONIC FORMAT.—All submissions under this section shall be in electronic format.

(l) EFFECT ON EXISTING REGULATIONS GOVERNING NONPRESCRIPTION DRUGS.—

(1) REGULATIONS OF GENERAL APPLICABILITY TO NONPRESCRIPTION DRUGS.—Except as provided in this subsection, nothing in this section supersedes regulations establishing general requirements for nonprescription drugs, including regulations of general applicability contained in parts 201, 250, and 330 of title 21, Code of Federal Regulations, or any successor regulations. The Secretary shall establish or modify the regulations by means of rulemaking in accordance with section 553 of title 5.

(2) REGULATIONS ESTABLISHING REQUIREMENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

(A) CERTAIN PROVISIONS DEEMED TO BE FINAL ORDER.—The provisions of section

310.545 of title 21, Code of Federal Regulations, as in effect on the day before March 27, 2020, shall be deemed to be a final order under subsection (c).

(B) CERTAIN PROVISIONS DEEMED TO BE FINAL ORDERS ONLY AS THEY APPLY TO SPECIFIC DRUGS.—Regulations in effect on the day before March 27, 2020, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including the requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (c), only as they apply to drugs—

(i) subject to paragraph (1), (2), (3), or (4) of subsection (b); or

(ii) otherwise subject to an order under this section.

(3) WITHDRAWAL OF REGULATIONS.—

(A) IN GENERAL.—The Secretary shall withdraw regulations establishing final monographs and the procedures governing the over-the-counter drug review under part 330 and other relevant parts of title 21, Code of Federal Regulations (as in effect on the day before

March 27, 2020), or make technical changes to the regulations to ensure conformity with appropriate terminology and cross references.

(B) NO PUBLIC NOTICE AND COMMENT; EFFECTIVE ON PUBLICATION.—Notwithstanding subchapter II of chapter 5 of title 5, any withdrawal or technical changes under subparagraph (A) shall be made without public notice and comment and shall be effective on publication through notice in the Federal Register (or on such date as specified in the notice).

(m) GUIDANCE.—The Secretary shall issue guidance that specifies—

(1) the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to this section;

(2) the format and content of data submissions to the Secretary under this section;

(3) the format of electronic submissions to the Secretary under this section;

(4) consolidated proceedings for appeal and the procedures for the consolidated proceedings where appropriate; and

(5) for minor changes in drugs, recommendations on how to comply with the requirements in orders issued under subsection (d)(3).

(n) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—This section shall not affect the treatment or status of a nonprescription drug—

(A) that is marketed without an application approved under chapter 135 of this title as of March 27, 2020;

(B) that is not subject to an order issued under this section; and

(C) to which paragraph (1), (2), (3), (4), or (5) of subsection (b) do not apply.

(2) TREATMENT OF PRODUCTS PREVIOUSLY FOUND TO BE SUBJECT TO TIME AND EXTENT REQUIREMENTS.—

(A) IN GENERAL.—Notwithstanding subsection (b), a drug described in subparagraph (B) may be lawfully marketed, without an application approved under chapter 135 of this title, only pursuant to an order issued under this section.

(B) DRUG DESCRIBED.—A drug described in this subparagraph is a drug that, prior to March 27, 2020, the Secretary determined in a

proposed or final rule to be ineligible for review under the OTC drug review (as the phrase ''OTC drug review'' was used in section 330.14 of title 21, Code of Federal Regulations, as in effect on the day before March 27, 2020).

(3) PRESERVATION OF AUTHORITY.—

(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude or limit the applicability of any provision of this subtitle other than this section.

(B) ISSUANCE OF ORDER FINDING DRUG TO BE NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE.—Nothing in subsection (b) shall be construed to prohibit the Secretary from issuing an order under this section finding a drug to be not generally recognized as safe and effective under section 10101(a)(34)(A)(i) of this title, as the Secretary determines appropriate.

(o) INAPPLICABILITY TO DRUGS EXEMPTED FOR INVESTIGATIONAL USE.—A drug is not subject to this section if an exemption for investigational use under section 13510 of this title is in effect for the drug.

(p) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44 shall not apply to collections of information made under this section.

(q) INAPPLICABILITY OF NOTICE AND COMMENT RULEMAKING AND OTHER REQUIREMENTS.—The requirements of subsection (c) shall apply with respect to orders issued under this section instead of the requirements of subchapter II of chapter 5 of title 5.

**§ 13119. Expedited approval of drugs for serious or life-threatening diseases or conditions**

(a) DEFINITIONS.—In this section:

(1) ACCELERATED APPROVAL.—The term ''accelerated approval'' means the approval described in subsection (d)(1)(A).

(2) BREAKTHROUGH THERAPY.—The term ''breakthrough therapy'' means a drug intended to treat, alone or in combination with 1 or more other drugs, a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

(3) FAST-TRACK PRODUCT.—The term ''fast-track product'' means a drug that is intended,

whether alone or in combination with 1 or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition, or if the Secretary designates the drug as a qualified infectious disease product under section 13116(e) of this title.

(4) REGENERATIVE MEDICINE THERAPY.—The term ''regenerative medicine therapy'' includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and part 1271 of title 21, Code of Federal Regulations.

(b) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of the drug if the drug is a breakthrough therapy.

(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at

any time after, the submission of an application for the investigation of the drug under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)).

(3) DESIGNATION.—

(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria in subsection (a)(2). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of the drug.

(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

(i) holding meetings with the sponsor and the review team throughout the development of the drug;

(ii) providing timely advice to, and interactive communication with, the spon-

sor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

(c) DESIGNATION OF A DRUG AS A FAST TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the

development and expedite the review of the drug if the drug is a fast-track product.

(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)).

(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria in subsection (a)(3). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast-track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of the fast-track product.

(d) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST-TRACK PRODUCT.—

(1) IN GENERAL.—

(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast-track product, under section 13504 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) on a determination that the product has an effect, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments, on—

(i) a surrogate endpoint that is reasonably likely to predict clinical benefit; or

(ii) a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence devel-

oped using biomarkers, for example, or other scientific methods or tools.

(2) LIMITATION.—

(A) IN GENERAL.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

(i) That the sponsor conduct an appropriate postapproval study or studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(ii) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for the period after approval as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(B) STUDIES NOT REQUIRED.—If the Secretary does not require that the sponsor of a product approved under accelerated approval conduct a postapproval study under this paragraph, the Secretary shall publish on the FDA

website the rationale for why the study is not appropriate or necessary.

(C) POSTAPPROVAL STUDY CONDITIONS.—Not later than the date of approval of a product under accelerated approval, the Secretary shall specify the conditions for a postapproval study or studies required to be conducted under this paragraph with respect to the product, which may include enrollment targets, the study protocol, and milestones, including the target date of study completion.

(D) STUDIES BEGUN BEFORE APPROVAL.—The Secretary may require, as appropriate, a study or studies to be underway prior to approval, or within a specified time period after the date of approval, of the applicable product.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—

(A) IN GENERAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures described in subparagraph (B) if—

(i) the sponsor fails to conduct any required postapproval study of the product with due diligence, including with respect

to conditions specified by the Secretary under paragraph (2)(C);

(ii) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe the effect or benefit;

(iii) other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; or

(iv) the sponsor disseminates false or misleading promotional materials with respect to the product.

(B) EXPEDITED PROCEDURES.—Expedited procedures described in this subparagraph shall consist of, prior to the withdrawal of accelerated approval—

(i) providing the sponsor with—

(I) due notice;

(II) an explanation for the proposed withdrawal;

(III) an opportunity for a meeting with the Commissioner or the Commissioner's designee; and

(IV) an opportunity for written appeal to—

(aa) the Commissioner; or

(bb) a designee of the Commissioner who has not participated in the proposed withdrawal of approval (other than a meeting pursuant to subclause (III)) and is not a subordinate of an individual (other than the Commissioner) who participated in the proposed withdrawal;

(ii) providing an opportunity for public comment on the proposal to withdraw approval;

(iii) the publication of a summary of the public comments received, and the Secretary's response to the comments, on the FDA website; and

(iv) convening and consulting an advisory committee on issues related to the proposed withdrawal, if requested by the sponsor and if no such advisory committee has previously advised the Secretary on those issues with respect to the withdrawal

of the product prior to the sponsor's request.

(e) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST-TRACK PRODUCT.—

(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence the review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 17907 of this title.

(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 17907 of this title to expedite the drug development process and the review of human drug applications) shall not apply to

an application submitted under paragraph (1) until the date on which the application is complete.

(f) CONSTRUCTION.—

(1) PURPOSE.—The amendments made by the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 193) and the 21st Century Cures Act (Public Law 114–255, 130 Stat. 1033) to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

(2) EFFECT OF PROVISIONS.—

(A) EFFECT OF SECTION ON STANDARDS OF EVIDENCE.—Nothing in this section shall be construed to alter the standards of evidence under—

(i) section 13504 or 13505 of this title, including the substantial evidence standard in section 13505 of this title; or

(ii) section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(B) APPLICABILITY OF PROVISIONS AND STANDARDS OF EVIDENCE.—The sections and

standards of evidence referred to in subparagraph (A) apply to the review and approval of products under this section, including whether a product is safe and effective.

(C) EFFECT OF SECTION ON RELIANCE OF SECRETARY ON CERTAIN EVIDENCE.—Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (d)(1)(B).

(g) AWARENESS EFFORTS.—The Secretary shall—

(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to breakthrough therapies, accelerated approval, and fast-track products; and

(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or

life-threatening conditions for which significant unmet medical needs exist.

(h) REGENERATIVE ADVANCED THERAPY.—

(1) IN GENERAL.—The Secretary, at the request of the sponsor of a drug, shall facilitate an efficient development program for, and expedite review of, the drug if the drug qualifies as a regenerative advanced therapy under the criteria described in paragraph (2).

(2) CRITERIA.—A drug is eligible for designation as a regenerative advanced therapy under this subsection if—

(A) the drug is a regenerative medicine therapy;

(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition.

(3) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, submission of an

application for the investigation of the drug under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)).

(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (3), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (2). If the Secretary determines that the drug meets the criteria, the Secretary shall designate the drug as a regenerative advanced therapy and shall take such actions as are appropriate under paragraph (1). If the Secretary determines that a drug does not meet the criteria for the designation, the Secretary shall include with the determination a written description of the rationale for the determination.

(5) ACTIONS.—The sponsor of a regenerative advanced therapy shall be eligible for the actions to expedite development and review of the therapy under subsection (b)(3)(B), including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (d).

(6) ACCESS TO EXPEDITED APPROVAL PATHWAYS.—An application for a regenerative advanced therapy under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) may be—

(A) eligible for priority review, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 (Public Law 112–144, title I, 126 Stat. 996); and

(B) eligible for accelerated approval under subsection (d), as agreed on pursuant to subsection (b)(3)(B), through, as appropriate—

(i) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or

(ii) reliance on data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

(7) POSTAPPROVAL REQUIREMENTS.—The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the

postapproval requirements under subsection (d) may, as appropriate, fulfill such requirements, as the Secretary may require, through—

(A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records;

(B) the collection of larger confirmatory data sets, as agreed on pursuant to subsection (b)(3)(B); or

(C) postapproval monitoring of all patients treated with the therapy prior to approval of the therapy.

(8) REPORT TO CONGRESS.—Before March 1 of each calendar year, the Secretary shall, with respect to the previous calendar year, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on—

(A) the number and type of applications for approval of regenerative advanced therapies filed, approved or licensed as applicable, withdrawn, or denied; and

(B) how many of the applications or therapies, as applicable, were granted accelerated approval or priority review.

(i) LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—

(1) IN GENERAL.—The Secretary may approve an antibacterial or antifungal drug, alone or in combination with 1 or more other drugs, as a limited population drug pursuant to this subsection only if—

(A) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs;

(B) the standards for approval under sections 13504 and 13505 of this title, or the standards for licensure under section 351 of the Public Health Service Act (2 U.S.C. 262), as applicable, are met; and

(C) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.

(2) BENEFIT-RISK CONSIDERATION.—The Secretary's determination of safety and effectiveness of an antibacterial or antifungal drug shall reflect the

benefit-risk profile of the drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in the limited population. The drug may be approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

(3) ADDITIONAL REQUIREMENTS.—A drug approved under this subsection shall be subject to the following requirements, in addition to any other applicable requirements of this subtitle:

(A) LABELING.—To indicate that the safety and effectiveness of a drug approved under this subsection has been demonstrated only with respect to a limited population—

(i) all labeling and advertising of an antibacterial or antifungal drug approved under this subsection shall contain the statement ''Limited Population'' in a prominent manner and adjacent to, and not more prominent than—

(I) the proprietary name of the drug, if any; or

(II) if there is no proprietary name, the established name of the drug, if any, as defined in section 13304(a)(1) of this title, or, in the case of a drug that is a biological product, the proper name, as defined by regulation; and

(ii) the prescribing information for the drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: ''This drug is indicated for use in a limited and specific population of patients.''.

(B) PROMOTIONAL MATERIAL.—The sponsor of an antibacterial or antifungal drug subject to this subsection shall submit to the Secretary copies of all promotional materials related to the drug at least 30 calendar days prior to dissemination of the materials.

(4) OTHER PROGRAMS.—A sponsor of a drug that seeks approval of a drug under this subsection may also seek designation or approval, as applicable, of the drug under other applicable sections or sub-

sections of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.).

(5) GUIDANCE.—Not later than 18 months after December 13, 2016, the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. The Secretary shall publish final guidance within 18 months of the close of the public comment period on the draft guidance. The Secretary may approve antibacterial and antifungal drugs under this subsection prior to issuing guidance under this paragraph.

(6) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a drug for which the sponsor seeks approval under this subsection to enable the sponsor to plan a development program to obtain the necessary data for the approval, and to conduct any additional studies that would be required to gain approval of the drug for use in a broader population.

(7) TERMINATION OF LIMITATIONS.—If, after approval of a drug under this subsection, the Secretary approves a broader indication for the drug under section 13503 of this title or section 351(a)

of the Public Health Service Act (42 U.S.C. 262(a)), the Secretary may remove any postmarketing conditions, including requirements with respect to labeling and review of promotional materials under paragraph (3), applicable to the approval of the drug under this subsection.

(8) RULES OF CONSTRUCTION.—

(A) AUTHORITY OF SECRETARY AND STANDARDS OF EVIDENCE.—Nothing in this subsection shall be construed to alter—

(i) the authority of the Secretary to approve drugs pursuant to this subtitle or section 351 of the Public Health Service Act (42 U.S.C. 262), including—

(I) the standards of evidence and applicable conditions for approval under this subtitle or that Act; and

(II) the standards of approval of a drug under this subtitle or that Act; or

(ii) the authority of the Secretary to monitor drugs pursuant to this subtitle or that Act.

(B) PRESCRIBING AUTHORITY OF HEALTH CARE PROFESSIONALS AND PRACTICE OF

HEALTH CARE.—Nothing in this subsection shall be construed—

(i) to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under this subsection by health care professionals; or

(ii) to limit the practice of health care.

(9) REPORTING AND ACCOUNTABILITY.—

(A) BIENNIAL REPORTING.—The Secretary shall report to Congress not less often than once every 2 years on the number of requests for approval, and the number of approvals, of an antibacterial or antifungal drug under this subsection.

(B) GAO REPORT.—

(i) IN GENERAL.—Not later than December 2021, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the coordination of activities required under section 319E of the Public Health Service Act (42 U.S.C. 247d–5).

(ii) INCLUSIONS.— The report shall include a review of the activities, and the extent to which the use of the pathway established under this subsection has streamlined premarket approval for antibacterial or antifungal drugs for limited populations, if the pathway has functioned as intended, if the pathway has helped provide for safe and effective treatment for patients, if the premarket approval would be appropriate for other categories of drugs, and if the authorities under this subsection have affected antibacterial or antifungal resistance.

**§ 13120. Manufacturing changes**

(a) IN GENERAL.—With respect to a drug for which there is in effect an approved application under chapter 135 or 137 of this title or a license under section 351 of the Public Health Service Act (42 U.S.C. 262), a change from the manufacturing process approved pursuant to the application or license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this section as a ''holder'') has

validated the effects of the change in accordance with subsection (b); and

(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

(b) VALIDATION OF EFFECTS OF CHANGES.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

(c) MAJOR MANUFACTURING CHANGES.—

(1) REQUIREMENT TO SUBMIT SUPPLEMENTAL APPLICATION.—

(A) IN GENERAL.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Sec-

retary a supplemental application for the change and the Secretary approves the application.

(B) CONTENTS.—The supplemental application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(2) CHANGES QUALIFYING AS MAJOR CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. Such a change includes a change that—

(A) is made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

(B) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

(C) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

(d) OTHER MANUFACTURING CHANGES.—

(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute the drugs without submitting a supplemental application for the changes.

(B) The Secretary may in accordance with paragraph (3) require that, prior to the distribution of the drugs, holders submit to the Secretary supplemental applications for the changes.

(C) The Secretary may establish categories of the changes and designate categories to

which subparagraph (A) applies and categories to which subparagraph (B) applies.

(2) CHANGES NOT REQUIRING SUPPLEMENTAL APPLICATION.—

(A) SUBMISSION OF REPORT.—

(i) IN GENERAL.—A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which report shall—

(I) contain such information as the Secretary determines to be appropriate; and

(II) include the information developed under subsection (b) by the holder in validating the effects of the change.

(ii) DATE OF SUBMISSION.—The report shall be submitted by such date as the Secretary may specify.

(B) AUTHORITY REGARDING ANNUAL REPORTS.—In the case of a holder that during a single year makes more than 1 manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph

(A) authorize the holder to comply with the subparagraph by submitting a single report for the year that provides the information required in the subparagraph for all the changes made by the holder during the year.

(3) CHANGES REQUIRING SUPPLEMENTAL APPLICATION.—

(A) SUBMISSION OF SUPPLEMENTAL APPLICATION.—The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

(B) AUTHORITY FOR DISTRIBUTION.—In the case of a manufacturing change to which paragraph (1)(B) applies:

(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under paragraph (1)(B), unless the Secretary notifies the holder within the 30-day period that prior

approval of the application is required before distribution may be commenced.

(ii) The Secretary may designate a category of the changes for the purpose of providing that, in the case of a change that is in the category, the holder involved may commence distribution of the drug involved on the receipt by the Secretary of a supplemental application for the change.

(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.

**§ 13121. Reports of postmarketing studies**

(a) SUBMISSION.—

(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of the drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall

be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

(2) ACCELERATED APPROVAL.—Notwithstanding paragraph (1), a sponsor of a drug approved pursuant to accelerated approval shall submit to the Secretary a report of the progress of any study required under section 13119(d) of this title, including progress toward enrollment targets, milestones, and other information as required by the Secretary, not later than 180 days after the approval of the drug and not less frequently than every 180 days thereafter, until the study is completed or terminated. The Secretary shall promptly publish on the FDA website, in an easily searchable format, the information reported under this paragraph.

(3) AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to November 21, 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report de-

scribed in subsection (a) shall be considered to be public information to the extent that the information is necessary—

(1) to identify the sponsor; and

(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides information on the status of the postmarketing studies—

(1) that sponsors have entered into agreements to conduct; and

(2) for which reports have been submitted under subsection (a)(1).

(d) DISCLOSURE.—If a sponsor fails to complete an agreed upon study required by this section by its original or otherwise negotiated deadline, the Secretary shall publish a statement on the FDA website stating that the study was not completed and, if the reasons for the failure to complete the study were not satisfactory to the Secretary, a statement that the reasons were not satisfactory to the Secretary.

(e) NOTIFICATION.—

(1) IN GENERAL.—With respect to studies of the type required under section 13119(d)(2)(A) of this title or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of those sections was in effect on September 30, 2002, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of those sections of the type for a drug or biological product (including such a study conducted after the effective date) notify practitioners who prescribe the drug or biological product of the failure to complete the study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete the study.

(2) EFFECT OF SUBSECTION.—Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 13119(d)(2)(A) of this title or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as in effect as described in paragraph (1), or as prohibiting the Secretary from modifying sections 314.510 and 601.41 of title 21, Code of Fed-

eral Regulations, to provide for studies in addition to those of the type described in paragraph (1).

**§ 13122. Discontinuance or interruption in the production of life-saving drugs**

(a) DEFINITIONS.—In this section:

(1) DRUG.—The term ''drug''—

(A) means a drug (as defined in section 10101(a)(18) of this title) that is intended for human use and that is subject to section 13103(a)(1) of this title; and

(B) does not include biological products (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)), unless otherwise provided by the Secretary in the regulations promulgated under subsection (i).

(2) DRUG SHORTAGE.—The term ''drug shortage'', with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

(3) MEANINGFUL DISRUPTION.—The term ''meaningful disruption''—

(A) means a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is

more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product; and

(B) does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

(b) NOTIFICATION.—

(1) IN GENERAL.—A manufacturer of a drug shall notify the Secretary, in accordance with subsection (c), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the supply of that drug in the United States, or a permanent discontinuance in the manufacture of an active pharmaceutical ingredient or an interruption in the manufacture of the active pharmaceutical ingredient of the drug that is likely to lead to a meaningful disruption in the supply of the active pharmaceutical ingredient of the drug, and the reasons for the discontinuance or interruption, if the drug—

(A) is—

(i) life-supporting;

(ii) life-sustaining; or

(iii) intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

(B) is not a radiopharmaceutical drug product or any other product as designated by the Secretary.

(2) REQUIRED DISCLOSURES.—Notification under this subsection shall include disclosure of—

(A)(i) reasons for the discontinuation or interruption; and

(ii) if applicable, an active pharmaceutical ingredient that is a reason for, or risk factor in, the discontinuation or interruption, the source of the active pharmaceutical ingredient, and any alternative sources for the active pharmaceutical ingredient known by the manufacturer;

(B) whether any associated device used for preparation or administration included in the

drug is a reason for, or a risk factor in, the discontinuation or interruption;

(C) the expected duration of the interruption; and

(D) such other information as the Secretary may require.

(c) TIMING.—A notice required under subsection (b) shall be submitted to the Secretary—

(1) at least 6 months prior to the date of the discontinuance or interruption; or

(2) if compliance with paragraph (1) is not possible, as soon as practicable.

(d) DISTRIBUTION OF INFORMATION.—To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary considers appropriate, information on the discontinuance or interruption of the manufacture of the drugs described in subsection (b) to appropriate organizations, including physician, health provider, and patient organizations, as described in section 13125 of this title.

(e) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(f) COORDINATION WITH ATTORNEY GENERAL.—

(1) IN GENERAL.—Not later than 30 days after the receipt of a notification described in subsection (b), the Secretary shall—

(A) determine whether the notification pertains to a controlled substance subject to a production quota under section 50506 of this title; and

(B) if necessary, as determined by the Secretary—

(i) notify the Attorney General that the Secretary has received such a notification; and

(ii) request that the Attorney General increase the aggregate and individual production quotas under section 50506 of this title applicable to the controlled substance and any ingredient in the controlled substance to a level the Secretary considers necessary to address a drug shortage of a controlled substance based on the best available market data.

(2) LEVEL REQUESTED NOT NECESSARY TO ADDRESS DRUG SHORTAGE.—If the Attorney General determines that the level requested under paragraph

(1)(B)(ii) is not necessary to address a drug shortage of a controlled substance, the Attorney General shall provide to the Secretary a written response detailing the basis for the Attorney General's determination.

(3) AVAILABILITY OF WRITTEN RESPONSE.—The Secretary shall make the written response provided under paragraph (2) available to the public on the FDA website.

(g) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit information required under subsection (b) in accordance with subsection (c)—

(1) the Secretary shall issue a letter to the person informing the person of the failure;

(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person that receives the letter shall submit to the Secretary a written response to the letter setting forth the basis for noncompliance and providing information required under subsection (b); and

(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make the letter and any response to the letter under paragraph (2) available to the public on the FDA website, with appropriate redactions made

to protect information described in subsection (e), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of the response, the person had a reasonable basis for not notifying as required under subsection (b), the requirements of this paragraph shall not apply.

(h) EXPEDITED INSPECTIONS AND REVIEWS.—If, based on notifications described in subsection (b) or any other relevant information, the Secretary concludes that there is, or is likely to be, a drug shortage of a drug described in subsection (b), the Secretary shall, as appropriate—

(1) prioritize and expedite the review of a supplement to a new drug application submitted under section 13503 of this title, an abbreviated new drug application submitted under section 13511 of this title, or a supplement to such an application submitted under section 13511 of this title, that could help mitigate or prevent the drug shortage; or

(2) prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent the drug shortage.

(i) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall adopt a final regulation implementing this section.

(2) CONTENTS.—The regulation shall define, for purposes of this section, the terms ''life-supporting'', ''life-sustaining'', and ''intended for use in the prevention or treatment of a debilitating disease or condition''.

(3) INCLUSION OF BIOLOGICAL PRODUCTS.—

(A) IN GENERAL.—The Secretary may by regulation apply this section to biological products (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)), including plasma products derived from human plasma protein and their recombinant analogs, if the Secretary determines the inclusion would benefit the public health. The regulation shall take into account any supply reporting programs and shall aim to reduce duplicative notification.

(B) RULE FOR VACCINES.—If the Secretary applies this section to vaccines pursuant to subparagraph (A), the Secretary shall—

(i) consider whether the notification requirement under subsection (b) may be satisfied by submitting a notification to the Centers for Disease Control and Preven-

tion under the vaccine shortage notification program of the Centers; and

(ii) explain the determination made by the Secretary under clause (i) in the regulation.

(4) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the regulation's effective date.

(5) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this section, the Secretary shall only promulgate regulations as described in paragraph (4).

(j) RISK MANAGEMENT PLANS.—

(1) IN GENERAL.—Each manufacturer of a drug described in subsection (b) or of any active pharmaceutical ingredient or any associated medical device used for preparation or administration included in the drug shall develop, maintain, and im-

plement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of the drug, as applicable, for each establishment in which the drug or active pharmaceutical ingredient of the drug is manufactured.

(2) INSPECTION OF RISK MANAGEMENT PLAN.—A risk management plan under this section shall be subject to inspection and copying by the Secretary pursuant to an inspection or a request under section 17504(a)(4) of this title.

(k) EFFECT OF SUBMISSION OF NOTIFICATION.—The submission of a notification to the Secretary for purposes of complying with the requirement in subsection (b) shall not be construed—

(1) as an admission that any product that is the subject of the notification violates any provision of this subtitle; or

(2) as evidence of an intention to promote or market the product for an indication or use for which the product has not been approved by the Secretary.

**§ 13123. Annual reporting on drug shortages**

(a) DEFINITION OF DRUG SHORTAGE.—In this section, the term ''drug shortage'' has the meaning given the term in section 13122 of this title.

(b) ANNUAL REPORTS TO CONGRESS.—Not later than March 31 of each calendar year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report, with respect to the preceding calendar year, on drug shortages, which report—

(1) specifies the number of manufacturers that submitted a notification to the Secretary under section 13122(b) of this title during the calendar year;

(2) describes the communication between the field investigators of the FDA and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the FDA's procedures for enabling and ensuring the communication;

(3) describes the coordination and alignment activities undertaken pursuant to section 13124(f) of this title;

(4) provides the number of reports that were required under section 17504(b)(2) of this title to be sent to the appropriate offices of the FDA with expertise regarding drug shortages, and the number of the reports that were sent;

(5)(A) lists the major actions taken by the Secretary to prevent or mitigate the drug shortages described in paragraph (9); and

(B) in the list under subparagraph (A), includes—

(i) the number of applications and supplements for which the Secretary expedited review under section 13122(h)(1) of this title during the calendar year; and

(ii) the number of establishment inspections or reinspections that the Secretary expedited under section 13122(h)(2) of this title during the calendar year;

(6) describes the coordination between the FDA and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(7) identifies the number of and describes the instances in which the FDA exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(8) lists the names of manufacturers that were issued letters under section 13122(g) of this title; and

(9) specifies the number of drug shortages occurring during the calendar year, as identified by the Secretary.

(c) TREND ANALYSIS.—The Secretary may retain a third party to conduct a study, if the Secretary believes that the study would help clarify the causes, trends, or solutions related to drug shortages.

**§ 13124. Coordination relating to drug shortages**

(a) COMMUNICATION.—The Secretary shall ensure that, prior to any enforcement action or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described under section 13122(b) of this title, there is communication with the appropriate office of the FDA with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug.

(b) ACTION.—If the Secretary determines, after the communication described in subsection (a), that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of a drug described under section 13122(b) of this title, then the Secretary shall evaluate the risks associated with the impact of the shortage on patients and those risks associated with the violation involved before taking the action or issuing the letter,

unless there is imminent risk of serious adverse health consequences or death to humans.

(c) REPORTING BY OTHER ENTITIES.—The Secretary shall identify or establish a mechanism by which health care providers and other third-party organizations may report to the Secretary evidence of a drug shortage.

(d) REVIEW AND CONSTRUCTION.—No determination, finding, action, or omission of the Secretary under this section shall—

(1) be subject to judicial review; or

(2) be construed to establish a defense to an enforcement action by the Secretary.

(e) TEMPORARY SUNSET.—Subsections (a), (b), and (d) shall not be in effect during the period beginning 5 years after July 9, 2012, and ending on December 29, 2022. Subsections (b), (c), and (e) shall be in effect beginning on December 29, 2022.

(f) COORDINATION.—The Secretary shall ensure timely and effective internal coordination and alignment among the field investigators of the FDA and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding—

(1) the reviews of reports shared pursuant to section 17504(b)(2) of this title; and

(2) any feedback or corrective or preventive actions in response to the reports.

**§ 13125. Drug shortage list**

(a) ESTABLISHMENT.—The Secretary shall maintain an up-to-date list of drugs that are determined by the Secretary to be in shortage in the United States.

(b) CONTENTS.—For each drug on the list described in subsection (a), the Secretary shall include the following information:

(1) The name of the drug in shortage, including the National Drug Code number for the drug.

(2) The name of each manufacturer of the drug.

(3) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

(A) Requirements related to complying with good manufacturing practices.

(B) Regulatory delay.

(C) Shortage of an active ingredient.

(D) Shortage of an inactive ingredient component.

(E) Discontinuance of the manufacture of the drug.

(F) Delay in shipping of the drug.

(G) Demand increase for the drug.

(4) The estimated duration of the shortage as determined by the Secretary.

(c) PUBLIC AVAILABILITY.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary shall make the information in the list publicly available.

(2) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18 or section 552(b)(4) of title 5.

(3) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available under paragraph (1) or section 13122(d) of this title if the Secretary determines that disclosure of the information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of drug products to patients).

(d) INTERAGENCY NOTIFICATION.—Not later than 180 days after March 27, 2020, and every 90 days thereafter, the Secretary shall transmit a report regarding the drugs of the current drug shortage list under this section to the Administrator of the Centers for Medicare & Medicaid Services.

**§ 13126. Hospital repackaging of drugs in shortage**

(a) DEFINITIONS.—In this section:

(1) DRUG.—The term ''drug'' excludes any controlled substance (as the term is defined in section 50101 of this title).

(2) HEALTH SYSTEM.—The term ''health system'' means a collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients.

(3) REPACKAGE.—The term ''repackage'', with respect to a drug, means to divide the volume of a drug into smaller amounts in order to—

(A) extend the supply of a drug in response to the placement of the drug on a drug shortage list under section 13125 of this title; and

(B) facilitate access to the drug by hospitals within the same health system.

(b) EXCLUSION FROM REGISTRATION.—Notwithstanding any other provision of this subtitle, a hospital shall not be considered an establishment for which registration is required under section 13136 of this title solely because it repackages a drug and transfers it to another hospital within the same health system in accordance with the conditions in subsection (c)—

(1) during any period in which the drug is listed on the drug shortage list under section 13125 of this title; or

(2) during the 60-day period following any period described in paragraph (1).

(c) CONDITIONS.—Subsection (b) shall only apply to a hospital, with respect to the repackaging of a drug for transfer to another hospital within the same health system, if the following conditions are met:

(1) DRUG FOR INTRASYSTEM USE ONLY.—In no case may a drug that has been repackaged in accordance with this section be sold or otherwise distributed by the health system or a hospital within the system to an entity or individual that is not a hospital within the health system.

(2) COMPLIANCE WITH STATE RULES.—Repackaging of a drug under this section shall be done in compliance with applicable State requirements of each State in which the drug is repackaged and received.

(d) TERMINATION.—This section shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the FDA regarding hospital pharmacies repackaging and safely transferring re-

packaged drugs to other hospitals within the same health system during a drug shortage.

**§ 13127. Standards for regenerative medicine and regenerative advanced therapies**

(a) DEFINITIONS.—In this section:

(1) REGENERATIVE ADVANCED THERAPY.—The term ''regenerative advanced therapy'' has the meaning given the term in section 13119(h) of this title.

(2) REGENERATIVE MEDICINE THERAPY.—The term ''regenerative medicine therapy'' has the meaning given the term in section 13119(a)(4) of this title.

(b) IN GENERAL.—Not later than 2 years after December 13, 2016, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and re-

generative advanced therapies, including with respect to the manufacturing processes and controls of the products.

(c) ACTIVITIES.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall continue to—

(A) identify opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

(C) work with stakeholders, such as those described in subsection (b), as appropriate, in the development of the standards.

(2) REGULATIONS AND GUIDANCE.—Not later than 1 year after the development of standards as described in subsection (b), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

**§ 13128. Competitive generic therapies**

(a) DEFINITIONS.—In this section:

(1) GENERIC DRUG.—The term ''generic drug'' means a drug that is approved pursuant to section 13511 of this title.

(2) INADEQUATE GENERIC COMPETITION.—The term ''inadequate generic competition'' means, with respect to a drug, there is not more than 1 approved drug on the list of drugs described in section 13511(h)(1) of this title (not including drugs on the discontinued section of the list) that is—

(A) the reference listed drug; or

(B) a generic drug with the same reference listed drug as the drug for which designation as a competitive generic therapy is sought.

(3) REFERENCE LISTED DRUG.—The term ''reference listed drug'' means the listed drug (as the term is used in section 13511 of this title) for the drug involved.

(b) IN GENERAL.—The Secretary may, at the request of an applicant of a drug that is designated as a competitive generic therapy pursuant to subsection (c), expedite the development and review of an abbreviated new drug application under section 13511 of this title for the drug.

(c) DESIGNATION PROCESS.—

(1) REQUEST.—The applicant may request the Secretary to designate the drug as a competitive generic therapy.

(2) TIMING.—A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 13511 of this title.

(3) CRITERIA.—A drug is eligible for designation as a competitive generic therapy under this section if the Secretary determines that there is inadequate generic competition.

(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary may—

(A) determine whether the drug that is the subject of the request meets the criteria described in paragraph (3); and

(B) if the Secretary finds that the drug meets the criteria, designate the drug as a competitive generic therapy.

(d) ACTIONS.—In expediting the development and review of an application under subsection (b), the Secretary may, as requested by the applicant, take actions, including—

(1) holding meetings with the applicant and the review team throughout the development of the drug prior to submission of the application for the drug under section 13511 of this title;

(2) providing timely advice to, and interactive communication with, the applicant regarding the development of the drug to ensure that the development program to gather the data necessary for approval is as efficient as practicable;

(3) involving senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of the application, including with respect to drug-device combination products and other complex products; and

(4) assigning a cross-disciplinary project lead—

(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

(B) to serve as a scientific liaison between the review team and the applicant.

(e) REPORTING REQUIREMENT.—Not later than 1 year after the date of the approval of an application under section 13511 of this title with respect to a drug for which the development and review is expedited under this section, the sponsor of the drug shall report to the Secretary

on whether the drug has been marketed in interstate commerce since the date of the approval.

**§ 13129. Prompt reports of marketing status**

(a) NOTIFICATION OF WITHDRAWAL.—The holder of an application approved under section 13504 or 13511 of this title or subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)) shall notify the Secretary in writing 180 days prior to withdrawing the approved drug from sale, or if 180 days is not practicable, as soon as practicable but not later than the date of withdrawal. The holder shall include with the notice the—

(1) National Drug Code;

(2) identity of the drug by established name (or, in the case of a biological product, the proper name) and by proprietary name, if any;

(3) new drug application number, abbreviated application number, or biologics license application number;

(4) strength of the drug;

(5) date on which the drug is expected to no longer be available for sale; and

(6) reason for withdrawal of the drug.

(b) NOTIFICATION THAT DRUG IS NOT AVAILABLE FOR SALE AFTER APPROVAL.—The holder of an applica-

tion approved under section 13504 or 13511 of this title or subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)) shall notify the Secretary in writing within 180 calendar days of the date of approval of the drug if the drug will not be available for sale within 180 calendar days of the date of approval. The holder shall include with the notice the—

(1) identity of the drug by established name (or, in the case of a biological product, the proper name) and by proprietary name, if any;

(2) new drug application number, abbreviated application number, or biologics license application number;

(3) strength of the drug;

(4) date on which the drug will be available for sale, if known; and

(5) reason for not marketing the drug after approval.

(c) ADDITIONAL ONE-TIME REPORT.—Within 180 days of December 29, 2022, all holders of applications approved under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)) shall review the information in the list published under section 351(k)(9)(A) of the Public Health Service Act (42 U.S.C.

262(k)(9)(A)) and shall submit a written notice to the Secretary—

(1) stating that all of the application holder's biological products in the list published under section 351(k)(9)(A) of the Public Health Service Act (42 U.S.C. 262(k)(9)(A)) that are not listed as discontinued are available for sale; or

(2) including the information required pursuant to subsection (a) or (b), as applicable, for each of the application holder's biological products that is in the list published under section 351(k)(9)(A) of the Public Health Service Act (42 U.S.C. 262(k)(9)(A)) and not listed as discontinued, but has been discontinued from sale or never has been available for sale.

(d) FAILURE TO MEET REQUIREMENTS.—If a holder of an approved application fails to submit the information required under subsection (a), (b), or (c), the Secretary may—

(1) move the application holder's drugs from the active section of the list published under section 13511(h)(1) of this title to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with section 13511(h)(3) of this title drugs that the Secretary determines

have been withdrawn from sale for reasons of safety or effectiveness; and

(2) identify the application holder's biological products as discontinued in the list published under section 351(k)(9)(A) of the Public Health Service Act (42 U.S.C. 262(k)(9)(A)), except that the Secretary shall remove from the list in accordance with section 351(k)(9)(B) of that Act (42 U.S.C. 262(k)(9)(B)) biological products for which the license has been revoked or suspended for reasons of safety, purity, or potency.

(e) UPDATES.—The Secretary shall update the list published under section 13511(h)(1) of this title based on the information provided under subsections (a), (b), and (c) by moving drugs that are not available for sale from the active section to the discontinued section of the list, except that drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness shall be removed from the list in accordance with section 13511(h)(3) of this title. The Secretary shall update the list published under section 351(k)(9)(A) of the Public Health Service Act (42 U.S.C. 262(k)(9)(A)) based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that biological products for which

the license has been revoked or suspended for safety, purity, or potency reasons shall be removed from the list in accordance with section 351(k)(9)(B) of the Public Health Service Act (42 U.S.C. 262(k)(9)(B)). The Secretary shall make monthly updates to the lists referred to in the preceding sentences based on the information provided pursuant to subsections (a) and (b), and shall update the lists based on the information provided under subsection (c) as soon as practicable.

(f) LIMITATION ON USE OF NOTICES.—Any notice submitted under this section shall not be made public by the Secretary and shall be used solely for the purpose of the updates described in subsection (e).

**§ 13130. Discontinuance or interruption in the production of medical devices**

(a) DEFINITIONS.—In this section:

(1) MEANINGFUL DISRUPTION.—

(A) IN GENERAL.—The term ''meaningful disruption'' means a change in production that is reasonably likely to lead to a reduction in the supply of a device by a manufacturer that—

(i) is more than negligible; and

(ii) affects the ability of the manufacturer to fill orders or meet expected demand for its product.

(B) EXCLUSIONS.—The term ''meaningful disruption'' does not include—

(i) interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time, not to exceed 6 months;

(ii) interruptions in manufacturing of components or raw materials so long as the interruptions do not result in a shortage of the device and the manufacturer expects to resume operations in a reasonable period of time; or

(iii) interruptions in manufacturing that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform more than 1 procedure or diagnostic test.

(2) SHORTAGE.—The term ''shortage'', with respect to a device, means a period of time when the demand or projected demand for the device within the United States exceeds the supply of the device.

(b) IN GENERAL.—

(1) NOTIFICATION.—A manufacturer of a device described in paragraph (2) shall, during, or in advance of, a public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d), notify the Secretary, in accordance with subsection (c), of—

(A) a permanent discontinuance in the manufacture of the device (except for discontinuances as a result of an approved modification of the device) or an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in the supply of that device in the United States; and

(B) the reasons for the discontinuance or interruption.

(2) DEVICE.—A device described in this paragraph is a device—

(A) that is critical to public health during a public health emergency, including devices that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or

(B) for which the Secretary determines that information on potential meaningful supply

disruptions of the device is needed during, or in advance of, a public health emergency.

(c) TIMING.—A notice required under subsection (b) shall be submitted to the Secretary—

(1) at least 6 months prior to the date of the discontinuance or interruption; or

(2) if compliance with paragraph (1) is not possible, as soon as practicable.

(d) DISTRIBUTION.—

(1) PUBLIC AVAILABILITY.—To the maximum extent practicable, subject to paragraph (2), the Secretary shall distribute, through such means as the Secretary determines appropriate, information on the discontinuance or interruption of the manufacture of devices reported under subsection (b) to appropriate organizations (including physician, health provider, and patient organizations) and supply chain partners, as appropriate and applicable, as described in subsection (h).

(2) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available pursuant to this section if the Secretary determines that disclosure of the information would adversely affect the public health, such as by increasing the possibility of—

(A) unnecessary overpurchase of product or component parts; or

(B) other disruption of the availability of medical products to patients.

(e) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(f) FAILURE TO MEET REQUIREMENTS.—If a person fails to submit information required under subsection (b) in accordance with subsection (c)—

(1) the Secretary shall issue a letter to the person informing the person of the failure;

(2) not later than 30 calendar days after the issuance of a letter under paragraph (1), the person that receives the letter shall submit to the Secretary a written response to the letter setting forth the basis for noncompliance and providing information required under subsection (b); and

(3) not later than 45 calendar days after the issuance of a letter under paragraph (1), the Secretary shall make the letter and any response to the letter under paragraph (2) available to the public on the FDA website, with appropriate redactions made

to protect information described in subsection (e), except that, if the Secretary determines that the letter under paragraph (1) was issued in error or, after review of the response, the person had a reasonable basis for not notifying as required under subsection (b), the requirements of this paragraph shall not apply.

(g) EXPEDITED INSPECTIONS AND REVIEWS.—If, based on notifications described in subsection (b) or (i) or any other relevant information, the Secretary concludes that there is, or is likely to be, a shortage of a device, the Secretary shall, as appropriate—

(1) prioritize and expedite the review of a submission under section 13140(h)(2), 13142, or 13152(m) of this title or review of a notification under section 13136(k) of this title for a device that could help mitigate or prevent the shortage; or

(2) prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent the shortage.

(h) DEVICE SHORTAGE LIST.—

(1) ESTABLISHMENT.—The Secretary shall establish and maintain an up-to-date list of devices that are determined by the Secretary to be in shortage in the United States.

(2) CONTENTS.—For each device included on the list under paragraph (1), the Secretary shall include the following information:

(A) The category or name of the device in shortage.

(B) The name of each manufacturer of the device.

(C) The reason for the shortage, as determined by the Secretary, selecting from the following categories:

(i) Requirements related to complying with good manufacturing practices.

(ii) Regulatory delay.

(iii) Shortage or discontinuance of a component or part.

(iv) Discontinuance of the manufacture of the device.

(v) Delay in shipping of the device.

(vi) Delay in sterilization of the device.

(vii) Demand increase for the device.

(viii) Facility closure.

(D) The estimated duration of the shortage as determined by the Secretary.

(3) PUBLIC AVAILABILITY.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C), the Secretary shall make the information in the list under paragraph (1) publicly available.

(B) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this subsection shall be construed to alter or amend section 1905 of title 18 or section 552(b)(4) of title 5.

(C) PUBLIC HEALTH EXCEPTION.—The Secretary may elect not to make information collected under this subsection publicly available if the Secretary determines that disclosure of the information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the device to patients).

(i) ADDITIONAL NOTIFICATIONS.—The Secretary may receive voluntary notifications from a manufacturer of a device that is life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery, or any other device the Secretary determines to be critical to the public health, pertaining to a permanent discontinuance in the manufacture of the device (except for any discontinuance as a result of an approved modification of the device) or an interruption of the manufacture of

the device that is likely to lead to a meaningful disruption in the supply of that device in the United States, and the reasons for the discontinuance or interruption.

(j) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the authority of the Secretary on March 27, 2020, to expedite the review of devices under section 13142 of this title, section 13144 of this title relating to the priority review program for devices, and section 14306 of this title relating to the emergency use authorization authorities.

**§ 13131. Platform technologies**

(a) DEFINITIONS.—In this section:

(1) DESIGNATED PLATFORM TECHNOLOGY.—The term ''designated platform technology'' means a platform technology that is designated as a platform technology under subsection (e).

(2) PLATFORM TECHNOLOGY.—The term ''platform technology'' means a well-understood and reproducible technology, which may include a nucleic acid sequence, molecular structure, mechanism of action, delivery method, vector, or a combination of any of those technologies that the Secretary determines to be appropriate, that the sponsor demonstrates—

(A) is incorporated in or utilized by a drug or biological product and is essential to the structure or function of the drug or biological product;

(B) can be adapted for, incorporated into, or utilized by more than 1 drug or biological product sharing common structural elements; and

(C) facilitates the manufacture or development of more than 1 drug or biological product through a standardized production or manufacturing process or processes.

(b) IN GENERAL.—The Secretary shall establish a program for the designation of platform technologies that meet the criteria described in subsection (c).

(c) CRITERIA.—A platform technology incorporated within or utilized by a drug or biological product is eligible for designation as a designated platform technology under this section if—

(1) the platform technology is incorporated in, or utilized by, a drug approved under chapter 135 of this title or a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262);

(2) preliminary evidence submitted by the sponsor of the approved or licensed drug described in paragraph (1), or a sponsor that has been granted a right of reference to data submitted in the application for the drug, demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than 1 drug without an adverse effect on quality, manufacturing, or safety; and

(3) data or information submitted by the applicable sponsor under paragraph (2) indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process.

(d) REQUEST FOR DESIGNATION.—A person may request the Secretary to designate a platform technology as a designated platform technology concurrently with, or at any time after, submission under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)) for the investigation of a drug that incorporates or utilizes the platform technology that is the subject of the request.

(e) DESIGNATION.—

(1) IN GENERAL.—Not later than 90 calendar days after the receipt of a request under subsection

(d), the Secretary shall determine whether the platform technology that is the subject of the request meets the criteria described in subsection (c).

(2) DESIGNATION.—If the Secretary determines that the platform technology meets the criteria described in subsection (c), the Secretary shall designate the platform technology as a designated platform technology and may expedite the development and review of any subsequent application submitted under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a drug that uses or incorporates the platform technology pursuant to subsection (f), as appropriate.

(3) DETERMINATION NOT TO DESIGNATE.—If the Secretary determines that the platform technology does not meet the criteria under subsection (c), the Secretary shall include with the determination not to designate the technology a written description of the rationale for the determination.

(4) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation made under paragraph (2), if the Secretary determines that the designated platform technology no longer meets the criteria described in subsection (c). The Secretary shall

communicate the determination to revoke a designation to the requesting sponsor in writing, including a description of the rationale for the determination.

(5) APPLICABILITY.—Nothing in this section shall prevent a product that uses or incorporates a designated platform technology from being eligible for expedited approval pathways if it is otherwise eligible under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.).

(f) ACTIONS.—The Secretary may take actions to expedite the development and review of an application for a drug that incorporates or utilizes a designated platform technology, including—

(1) engaging in early interactions with the sponsor to discuss the use of the designated platform technology and what is known about the technology, including data previously submitted that is relevant to establishing, as applicable, safety or efficacy under section 13503 of this title or safety, purity, or potency under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug that proposes to use the designated platform technology to ensure that the devel-

opment program designed to gather data necessary for approval or licensure is as efficient as practicable, which may include holding meetings with the sponsor and the review team throughout the development of the drug; and

(3) considering inspectional findings, including prior findings, related to the manufacture of a drug that incorporates or utilizes the designated platform technology.

(g) LEVERAGING DATA FROM DESIGNATED PLATFORM TECHNOLOGIES.—The Secretary shall, consistent with applicable standards for approval, authorization, or licensure under this subtitle and section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), allow the sponsor of an application under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) or a request for emergency use authorization under section 14306 of this title, in order to support approval, licensure, or authorization, to reference or rely on data and information in an application or request for a drug or biological product that incorporates or utilizes the same platform technology designated under subsection (e), if—

(1) the data and information were submitted by the same sponsor, pursuant to the application for

the drug with respect to which designation of the designated platform technology under subsection (e) was granted; or

(2) the sponsor relying on the data and information received a right of reference to the data and information from the sponsor described in paragraph (1).

(h) CHANGES TO A DESIGNATED PLATFORM TECHNOLOGY.—A sponsor of more than 1 application approved under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for drugs that incorporate or utilize a designated platform technology may submit a single supplemental application for proposed changes to the designated platform technology that may be applicable to more than 1 of those drugs that incorporate or utilize the same designated platform technology. The supplemental application may cross-reference data and information submitted in other applications and may include 1 or more comparability protocols regarding how the proposed changes to the platform technology would be made for each applicable drug or biological product.

(i) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

(1) alter the authority of the Secretary to approve drugs pursuant to chapter 135 of this title or license biological products pursuant to section 351 of the Public Health Service Act (42 U.S.C. 262), including standards of evidence and applicable conditions for approval or licensure under the chapter or the Act; or

(2) confer any new rights with respect to the permissibility of a sponsor of an application for a drug product or biological product referencing information contained in another application submitted by the holder of an approved application under section 13504 of this title or of a license under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

**§ 13132. Advanced manufacturing technologies designation program**

(a) IN GENERAL.—Not later than 1 year after December 29, 2022, the Secretary shall initiate a program under which persons may request designation of an advanced manufacturing technology as described in subsection (b).

(b) DESIGNATION PROCESS.—The Secretary shall establish a process for the designation under this section of methods of manufacturing drugs, including biological

products, and active pharmaceutical ingredients of those drugs, as advanced manufacturing technologies. A method of manufacturing, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology if the method or combination of methods incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process for a drug while maintaining equivalent, or providing superior, drug quality, including by—

(1) reducing development time for a drug using the designated manufacturing method; or

(2) increasing or maintaining the supply of—

(A) a drug that is life-supporting, life-sustaining, or of critical importance to providing health care; or

(B) a drug that is on the drug shortage list under section 13125 of this title.

(c) EVALUATION AND DESIGNATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

(1) SUBMISSION.—A person that requests designation of a method of manufacturing as an advanced manufacturing technology under this section shall submit to the Secretary data or information demonstrating that the method of manufacturing

meets the criteria described in subsection (b) in a particular context of use. The Secretary may facilitate the development and review of the data or information by—

(A) providing timely advice to, and interactive communication with, the person regarding the development of the method of manufacturing; and

(B) involving senior managers and experienced staff of the FDA, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing, as applicable.

(2) EVALUATION AND DESIGNATION.—Not later than 180 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether to designate the method of manufacturing as an advanced manufacturing technology, in a particular context of use, based on the data and information submitted under paragraph (1) and the criteria described in subsection (b).

(d) REVIEW OF ADVANCED MANUFACTURING TECHNOLOGIES.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology, the Secretary shall—

(1) expedite the development and review of an application submitted under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), including supplemental applications, for drugs that are manufactured using a designated advanced manufacturing technology; and

(2) allow the holder of an advanced technology designation, or a person authorized by the advanced manufacturing technology designation holder, in an application submitted under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), including a supplemental application, to reference or rely on data and information about the designated advanced manufacturing technology for use in manufacturing drugs in the same context of use for which the designation was granted.

(e) IMPLEMENTATION AND EVALUATION OF ADVANCED MANUFACTURING TECHNOLOGIES PROGRAM.—

(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting, to be held not later than 180 days after December 29, 2022, to discuss, and obtain input and recommendations from relevant stakeholders regarding—

(A) the goals and scope of the program under this section, and the framework, procedures, and requirements suitable for the program; and

(B) ways in which the FDA will support the use of advanced manufacturing technologies and other innovative manufacturing approaches for drugs.

(2) PROGRAM GUIDANCE.—

(A) IN GENERAL.—The Secretary shall—

(i) not later than 180 days after the public meeting under paragraph (1), issue draft guidance regarding the goals and implementation of the program under this section; and

(ii) not later than 2 years after December 29, 2022, issue final guidance regarding the implementation of the program.

(B) CONTENT.—The guidance described in subparagraph (A) shall address—

(i) the process by which a person may request a designation under subsection (b);

(ii) the data and information that a person requesting the designation is re-

quired to submit under subsection (c), and how the Secretary intends to evaluate the submissions;

(iii) the process to expedite the development and review of applications under subsection (d); and

(iv) the criteria described in subsection (b) for eligibility for designation.

(3) REPORT.—Not later than 3 years after December 29, 2022, and annually thereafter, the Secretary shall publish on the FDA website and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing a description and evaluation of the program being conducted under this section, including the types of innovative manufacturing approaches supported under the program. The report shall include the following:

(A) The number of persons that have requested designations and that have been granted designations.

(B) The number of methods of manufacturing that have been the subject of designation

requests and that have been granted designations.

(C) The average number of calendar days for completion of evaluations under subsection (c)(2).

(D) An analysis of the factors in data submissions that result in determinations to designate and not to designate after evaluation under subsection (c)(2).

(E) The number of applications received under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), including supplemental applications, that have included an advanced manufacturing technology designated under this section, and the number of the applications approved.

(f) SUNSET.—The Secretary—

(1) may not consider any requests for designation submitted under subsection (c) after October 1, 2032; and

(2) may continue all activities under this section with respect to advanced manufacturing technologies that were designated pursuant to subsection (b) prior to that date, if the Secretary determines

that the activities are in the interest of the public health.

**§ 13133. Qualification of drug development tools**

(a) DEFINITIONS.—In this section:

(1) BIOMARKER.—The term ''biomarker''—

(A) means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and

(B) includes a surrogate endpoint.

(2) BIOMEDICAL RESEARCH CONSORTIA.—The term ''biomedical research consortia'' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a))), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

(3) CLINICAL OUTCOME ASSESSMENT.—The term ''clinical outcome assessment''—

(A) means a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

(B) includes a patient-reported outcome.

(4) CONTEXT OF USE.—The term ''context of use'' means, with respect to a drug development tool, the circumstances under which the drug development tool is to be used in drug development and regulatory review.

(5) DRUG DEVELOPMENT TOOL.—The term ''drug development tool'' includes—

(A) a biomarker;

(B) a clinical outcome assessment; and

(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

(6) PATIENT-REPORTED OUTCOME.—The term ''patient-reported outcome'' means a measurement based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

(7) QUALIFICATION.—The term ''qualification'' means a determination by the Secretary that a drug development tool and its proposed context of use can be relied on to have a specific interpretation and application in drug development and regulatory review under this subtitle.

(8) REQUESTOR.—The term ''requestor'' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

(9) SURROGATE ENDPOINT.—The term ''surrogate endpoint'' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 13119(d) of this title.

(b) PROCESS FOR QUALIFICATION.—

(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

(A)(i) a requestor initiates the process by submitting a letter of intent to the Secretary; and

(ii) the Secretary accepts or declines to accept the letter of intent;

(B)(i) if the Secretary accepts the letter of intent, a requestor submits a qualification plan to the Secretary; and

(ii) the Secretary accepts or declines to accept the qualification plan; and

(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

(ii) the Secretary determines whether to accept the qualification package for review; and

(iii) if the Secretary accepts the qualification package for review, the Secretary conducts the review in accordance with this section.

(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

(A) IN GENERAL.—Subparagraphs (B), (C), and (D) shall apply with respect to the

treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as ''qualification submissions'').

(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—

(i) SCIENTIFIC MERIT AS A FACTOR.—The Secretary shall determine whether to accept a qualification submission based on factors that may include the scientific merit of the qualification submission.

(ii) NOT A FINAL DETERMINATION.—A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and the availability or lack of alternative treatments for the disease or condition; and

(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of the drug development tool and its proposed context of use as a public health priority.

(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of the consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (3).

(c) EFFECT OF QUALIFICATION.—

(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (b)(4) for a proposed context of use specified by the requestor may be used by any person in that context of use for the purposes described in paragraph (2).

(2) USE OF A DRUG DEVELOPMENT TOOL.—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 13119(d) of this title) under chapter 135 of

this title or section 351 of the Public Health Service Act (42 U.S.C. 262); or

(B) supporting the investigational use of a drug or biological product under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)).

(3) RESCISSION OR MODIFICATION.—

(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. The determination may be based on new information that calls into question the basis for the qualification.

(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall, on request, be granted a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

(d) TRANSPARENCY.—

(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the FDA website the following:

(A) Information with respect to each qualification submission under the qualification process under subsection (b), including—

(i) the stage of the review process applicable to the submission;

(ii) the date of the most recent change in stage status;

(iii) whether external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

(iv) submissions from requestors under the qualification process under subsection (b), including any data and evidence contained in the submissions, and any updates to the submissions.

(B) The Secretary's formal written determinations in response to the qualification submissions.

(C) Any rescissions or modifications under subsection (c)(3) of a determination to qualify a drug development tool.

(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (b).

(E) A comprehensive list of—

(i) all drug development tools qualified under subsection (b); and

(ii) all surrogate endpoints that were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 13119(d) of this title) under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18.

(3) APPLICABILITY.—

(A) IN GENERAL.—Nothing in this section shall be construed as authorizing or directing the Secretary to disclose—

(i) any information contained in an application submitted under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5 or section 1905 of title 18; or

(ii) in the case of a drug development tool that may be used to support the development of a qualified countermeasure, security countermeasure, or qualified pandemic or epidemic product, as defined in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act (42 U.S.C. 247d–6a, 247d–6b, 247d–6d), any information that the Secretary determines has a significant potential to affect national security.

(B) PUBLIC ACKNOWLEDGMENT.—In the case that the Secretary, pursuant to subparagraph (A)(ii), does not make information publicly available, the Secretary shall provide on

the FDA website an acknowledgment of the information that has not been disclosed, pursuant to subparagraph (A)(ii).

(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to alter the standards of evidence under section 13504 or 13505 of this title, including the substantial evidence standard in section 13505 of this title, or under section 351 of the Public Health Service Act (42 U.S.C. 262) (as applicable); or

(2) to limit the authority of the Secretary to approve or license products under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.), as applicable (as in effect before December 13, 2016).

**§ 13134. Authority to designate official names**

(a) IN GENERAL.—

(1) DETERMINATION THAT DESIGNATION IS NECESSARY OR DESIRABLE.—The Secretary may designate an official name for any drug or device if the Secretary determines that the action is necessary or desirable in the interest of usefulness and simplicity.

(2) ONLY OFFICIAL NAME TO BE USED.—An official name designated under this section for any

drug or device shall be the only official name of that drug or device used in any official compendium published after the name has been prescribed or for any other purpose of this subtitle.

(3) OFFICIAL NAME NOT TO INFRINGE VALID TRADEMARK.—The Secretary shall not establish an official name so as to infringe a valid trademark.

(b) REVIEW OF NAMES IN OFFICIAL COMPENDIA.—

(1) DRUGS.—At such times as the Secretary may consider necessary, the Secretary shall review the official names by which drugs are identified in the official United States Pharmacopeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements to those compendia, to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(2) DEVICES.—At such times as the Secretary may consider necessary, the Secretary shall review the official names by which devices are identified in any official compendium (and all supplements to the compendium) to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(c) USEFULNESS OF NAME.—

(1) DETERMINATIONS OF COMPLEXITY, USEFULNESS, MULTIPLICITY, OR LACK OF NAME.—The Secretary shall make the transmittal described in paragraph (2) if the Secretary determines after any review under subsection (b) that—

(A) any official name reviewed under subsection (b) is unduly complex or is not useful for any other reason;

(B) 2 or more official names have been applied to—

(i) a single drug or device;

(ii) 2 or more drugs that are identical in chemical structure and pharmacological action and that are substantially identical in strength, quality, and purity; or

(iii) 2 or more devices that are substantially equivalent in design and purpose; or

(C) no official name has been applied to a medically useful drug or device.

(2) TRANSMITTAL.—If the Secretary makes a determination under paragraph (1), the Secretary shall transmit in writing to the compiler of each official compendium in which the drug or drugs or device are identified and recognized the Secretary's re-

quest for the recommendation of a single official name for the drug or drugs or device that will have usefulness and simplicity.

(3) NO SINGLE OFFICIAL NAME RECOMMENDED.—If a single official name has not been recommended within 180 days after the request, or if the Secretary determines that any name recommended is not useful for any reason, the Secretary shall designate a single official name for the drug or drugs or device.

(4) USEFUL NAME RECOMMENDED.—If the Secretary determines that the name recommended is useful, the Secretary shall designate that name as the official name of the drug or drugs or device.

(5) NOTICE.—The designation shall be made as a regulation on public notice and in accordance with the procedure set forth in section 553 of title 5.

(d) REVISED OFFICIAL NAMES; COMPILATION, PUBLICATION, AND PUBLIC DISTRIBUTION.—After each review under this section, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall compile, publish, and publicly distribute a list that—

(1) shall list all revised official names of drugs or devices designated under this section; and

(2) shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

(e) REQUEST BY COMPILER OF OFFICIAL COMPENDIUM FOR DESIGNATION OF NAME.—On a request in writing by any compiler of an official compendium that the Secretary exercise the authority granted to the Secretary under subsection (a), the Secretary shall, on public notice and in accordance with the procedure set forth in section 553 of title 5, designate the official name of the drug or device for which the request is made.

**§ 13135. Inapplicability of division to cosmetics**

This division, as amended by the Drug Amendments of 1962 (Public Law 87–781, 76 Stat. 780), shall not apply to any cosmetic unless the cosmetic is also a drug or device or component of a drug or device.

**§ 13136. Registration of producers of drugs or devices**

(a) DEFINITIONS.—In this section:

(1) MANUFACTURE, PREPARATION, PROPAGATION, COMPOUNDING, OR PROCESSING.—The term ''manufacture, preparation, propagation, compounding, or processing'' shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device

from the original place of manufacture to the person that makes final delivery or sale to the ultimate consumer or user.

(2) NAME.—The term ''name'' shall include, in the case of a partnership, the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) ANNUAL REGISTRATION.—

(1) DRUG PRODUCERS.—During the period beginning on October 1 and ending on December 31 of each year, each person that owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary—

(A) the name of the person;

(B) places of business of the person;

(C) all such establishments;

(D) the unique facility identifier of each such establishment; and

(E) a point of contact e-mail address.

(2) DEVICE PRODUCERS.—During the period beginning on October 1 and ending on December 31 of each year, each person that owns or operates any

establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary—

(A) the name of the person;

(B) places of business of the person; and

(C) all such establishments.

(3) UNIQUE FACILITY IDENTIFIER.—

(A) SPECIFICATION BY SECRETARY.—The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1).

(B) DATE ON WHICH REQUIREMENT TO INCLUDE IS APPLICABLE.—The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under subparagraph (A).

(c) NEW PRODUCERS.—Each person, on first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment that the person owns or operates in any State, shall immediately register with the Secretary—

(1) with respect to drugs, the information described under subsection (b)(1); and

(2) with respect to devices, the information described under subsection (b)(2).

(d) ADDITIONAL ESTABLISHMENTS.—Each person registered in accordance with subsections (b) and (c) shall immediately register with the Secretary any additional establishment that the person owns or operates in any State and in which the person begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) REGISTRATION NUMBERS AND OTHER IDENTIFICATION NUMBERS.—

(1) REGISTRATION NUMBER.—The Secretary may assign a registration number to any person or any establishment registered in accordance with this section.

(2) LISTING NUMBER FOR DRUGS.—The Secretary may assign a listing number to each drug or class of drugs listed under subsection (j).

(3) CONFORMITY WITH NATIONAL DRUG CODE.—Any number assigned pursuant to paragraph (2) shall be the same as that assigned pursuant to the National Drug Code.

(4) UNIFORM SYSTEM FOR THE IDENTIFICATION OF DEVICES.—The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require persons that are required to list the devices pursuant to subsection (j) to list the devices in accordance with the system.

(f) AVAILABILITY OF REGISTRATIONS FOR INSPECTION.—

(1) IN GENERAL.—The Secretary shall make available for inspection, to any person requesting such an inspection, any registration filed pursuant to this section, except as provided in paragraph (2).

(2) EXCEPTION.—Any list submitted pursuant to paragraph (4) of subsection (j) and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from the inspection under paragraph (1) unless the Secretary finds that the exemption would be inconsistent with protection of the public health.

(g) EXCLUSIONS FROM APPLICATION OF SECTION.—

(1) DEFINITION OF WHOLESALE DISTRIBUTOR.—In this subsection, the term ''wholesale distributor'' means any person (other than the manufacturer or the initial importer) that distributes a

device from the original place of manufacture to the person that makes the final delivery or sale of the device to the ultimate consumer or user.

(2) IN GENERAL.—Subsections (a) through (f) shall not apply to—

(A) pharmacies—

(i) that maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and that are regularly engaged in dispensing prescription drugs or devices, on prescriptions of practitioners licensed to administer the drugs or devices to patients under the care of the practitioners in the course of their professional practice; and

(ii) that do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners who—

(i) are licensed by law to prescribe or administer drugs or devices; and

(ii) manufacture, prepare, propagate, compound, or process drugs or devices

solely for use in the course of their professional practice;

(C) persons that manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(D) any distributor that—

(i) acts as a wholesale distributor of devices; and

(ii) does not manufacture, repackage, process, or relabel a device; or

(E) such other classes of persons as the Secretary may by regulation exempt from the application of this section on a finding that registration by the classes of persons in accordance with this section is not necessary for the protection of the public health.

(h) INSPECTIONS.—

(1) IN GENERAL.—Each establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 17504 of this title.

(2) RISK-BASED SCHEDULE FOR DEVICES.—

(A) IN GENERAL.—The Secretary, acting through 1 or more officers or employees des-

ignated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices (referred to in this subsection as ''device establishments'') in accordance with a risk-based schedule established by the Secretary.

(B) FACTORS AND CONSIDERATIONS.—In establishing the risk-based schedule under subparagraph (A), the Secretary shall—

(i) apply, to the extent applicable for device establishments, the factors identified in paragraph (4); and

(ii) consider the participation of the device establishment, as applicable, in international device audit programs in which the United States participates or the United States recognizes for purposes of inspecting device establishments.

(3) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary, acting through 1 or more officers or employees designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs in

accordance with a risk-based schedule established by the Secretary.

(4) RISK FACTORS.—In establishing a risk-based schedule under paragraph (2) or (3), the Secretary shall inspect establishments according to the known safety risks of the establishments, which shall be based on the following factors:

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug or device manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 17504 of this title within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 20109 of this title.

(F) The compliance history of establishments in the country or region in which the establishment is located, which establishments are

subject to regulation under this subtitle, including the history of violations related to products exported from the country or region, which products are subject to the regulation.

(G) Any other criteria considered necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by the establishment are drugs described in section 13103(a) of this title.

(6) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Not later than May 1 of each year, the Secretary shall make available on the FDA website a report regarding—

(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous fiscal year;

(ii) the number of the registered establishments described in clause (i) in each region of interest;

(iii) the number of the domestic establishments described in clause (i) and the number of the foreign establishments described in clause (i), including the number of establishments in each region of interest, that the Secretary inspected in the previous fiscal year;

(iv) the number of inspections to support actions by the Secretary on applications under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), including the number of inspections to support actions by the Secretary on supplemental applications, including changes to manufacturing processes, the Secretary conducted in the previous fiscal year;

(v) the number of routine surveillance inspections the Secretary conducted in the previous fiscal year, including in each region of interest;

(vi) the number of for-cause inspections the Secretary conducted in the previous fiscal year, not including inspections described in clause (iv), including in each region of interest; and

(vii) the number of inspections the Secretary has recognized pursuant to an agreement entered into pursuant to section 20109 of this title, or otherwise recognized, for each of the types of inspections described in clauses (v) and (vi), including for inspections of establishments in each region of interest;

(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug or a finished drug product, the number of each such type of establishment;

(C) the percentage of the budget of the FDA used to fund the inspections described under subparagraph (A); and

(D) the status of the efforts of the FDA to expand its recognition of inspections conducted or recognized by foreign regulatory authorities under section 20109 of this title, including any obstacles to expanding the use of the recognition.

(7) REGION OF INTEREST.—For purposes of paragraph (6)(A), the term ''region of interest'' means a foreign geographic region or country, including the People's Republic of China, India, the

European Union, the United Kingdom, and any other country or geographic region, as the Secretary determines appropriate.

(i) REGISTRATION OF FOREIGN ESTABLISHMENTS.—

(1) IN GENERAL.—Each person that owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

(A) on first engaging in any such activity, immediately submit a registration to the Secretary that includes—

(i) with respect to drugs—

(I) the name and place of business of the person;

(II) all establishments owned or operated by the person;

(III) the unique facility identifier of each of the establishments;

(IV) a point of contact e-mail address;

(V) the name of the United States agent of each of the establishments;

(VI) the name of each importer of the drug in the United States, which importer is known to the establishment; and

(VII) the name of each person that imports or offers for import the drug to the United States for purposes of importation; and

(ii) with respect to devices—

(I) the name and place of business of the establishment;

(II) the name of the United States agent for the establishment;

(III) the name of each importer of the device in the United States, which importer is known to the establishment; and

(IV) the name of each person that imports or offers for import the device to the United States for purposes of importation; and

(B) after the initial registration under subparagraph (A), register with the Secretary, during the period beginning on October 1 and ending on December 31 of each year, each establishment subject to the requirements of subparagraph (A).

(2) ADDITIONAL INFORMATION.—The establishment shall also provide the information required by subsection (j).

(3) COOPERATIVE AGREEMENTS.—The Secretary may enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 20101(a) of this title.

(4) UNIQUE FACILITY IDENTIFIER.—

(A) SPECIFICATION BY SECRETARY.—The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs.

(B) DATE ON WHICH REQUIREMENT TO INCLUDE IS APPLICABLE.—The requirement to include a unique facility identifier in a registration under paragraph (1) with respect to drugs shall not apply until the date that the identifier system is specified by the Secretary under subparagraph (A).

(5) APPLICABILITY OF REQUIREMENTS REGARDLESS OF FURTHER MANUFACTURE, PREPARATION, PROPAGATION, COMPOUNDING, OR PROCESSING AT A SEPARATE ESTABLISHMENT OUTSIDE THE UNITED STATES.—The requirements of paragraphs (1) and (2) shall apply regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

(j) OTHER SUBMISSIONS.—

(1) FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED, PREPARED, PROPAGATED, COMPOUNDED, OR PROCESSED BY REGISTRANTS.—Each person that registers with the Secretary under subsection (b), (c), (d), or (i) shall, at the time of registration under any of those subsections, file with

the Secretary a list of all drugs and a list of all devices (including a brief statement of the basis for believing that each device included in the list is a device rather than a drug), with each drug and device in each list listed by its established name (as defined in section 13304 of this title) and by any proprietary name, that are being manufactured, prepared, propagated, compounded, or processed by the person for commercial distribution and that the person has not included in any list of drugs or devices filed by the person with the Secretary under this paragraph or paragraph (2) before the time of registration. The list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug that is contained in the applicable list and subject to chapter 135 or 137 of this title, or a device that is intended for human use contained in the applicable list with respect to which a performance standard has been established under section 13141 of this title or that is subject to section 13142 of this title, a reference to the authority for the marketing of the drug or device and a copy of all labeling for the drug or device;

(B) in the case of any other drug or device contained in an applicable list—

(i) which drug is subject to section 13103(a)(1) of this title, or which device is a restricted device, a copy of all labeling for the drug or device, a representative sampling of advertisements for the drug or device, and, on request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device; or

(ii) which drug is not subject to section 13103(a)(1) of this title or which device is not a restricted device, the label and package insert for the drug or device and a representative sampling of any other labeling for the drug or device;

(C) in the case of any drug contained in an applicable list that is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product, the Secretary may require the submission of a quantitative listing of all ingredients if the Secretary finds that the

submission is necessary to carry out the purposes of this subtitle;

(D) if the registrant filing a list has determined that a particular drug product or device contained in the list is not subject to chapter 135 or 137 of this title, or the particular device contained in the list is not subject to a performance standard established under section 13141 of this title or to section 13142 of this title or is not a restricted device, a brief statement of the basis on which the registrant made the determination if the Secretary requests a statement with respect to that particular drug product or device; and

(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the production of the excipient, the unique facility identifier of each of those establishments, and a point of contact e-mail address for each of the excipient manufacturers.

(2) REPORTS.—

(A) IN GENERAL.—Each person that registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:

(i) A list of each drug or device introduced by the registrant for commercial distribution that has not been included in any list previously filed by the registrant with the Secretary under this clause or paragraph (1).

(ii) If, since the date the registrant last made a report under this paragraph (or if the registrant has not made a report under this paragraph since February 1, 1973), the registrant has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by the registrant under clause (i) or paragraph (1)—

(I) notice of the discontinuance;

(II) the date of the discontinuance; and

(III) the identity (by established name (as defined in section 13304 of this title) and by any proprietary name) of the drug or device.

(iii) If, since the date the registrant reported pursuant to clause (ii) a notice of discontinuance, the registrant has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which the notice of discontinuance was reported, unless the registrant has previously reported the resumption to the Secretary pursuant to this clause—

(I) notice of the resumption;

(II) the date of the resumption;

(III) the identity of the drug or device (each by established name (as defined in section 13304 of this title) and by any proprietary name); and

(IV) the other information required by paragraph (1).

(iv) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(B) LIST FORMAT; ACCOMPANYING INFORMATION.—A list under subparagraph (A)(i) shall list a drug or device by its established name (as defined in section 13304 of this title) and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(3) REPORTS RELATING TO AMOUNT OF DRUG MANUFACTURED, PREPARED, PROPAGATED, COMPOUNDED, OR PROCESSED.—

(A) IN GENERAL.—

(i) ANNUAL REPORTING REQUIREMENT.—Each person that registers with the Secretary under this section with regard to a drug shall report annually to the Secretary on the amount of each drug listed under paragraph (1) that was manufactured, prepared, propagated, compounded, or processed by the person for commercial distribution.

(ii) ELECTRONIC FORMAT.—The information may be required to be submitted

in an electronic format as determined by the Secretary.

(iii) PUBLIC HEALTH EMERGENCY.—The Secretary may require that information required to be reported under this paragraph be submitted at the time a public health emergency is declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d).

(B) BIOLOGICAL PRODUCTS.—By order of the Secretary, certain biological products or categories of biological products regulated under section 351 of the Public Health Service Act (42 U.S.C. 262) may be exempt from some or all of the reporting requirements under subparagraph (A), if the Secretary determines that applying the reporting requirements to the biological products or categories of biological products is not necessary to protect the public health.

(4) ADDITIONAL INFORMATION.—

(A) IN GENERAL.—The Secretary may require each registrant under this section to submit a list of each drug product that—

(i) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution; and

(ii) contains a particular ingredient.

(B) FINDING REQUIRED.—The Secretary may not require the submission of a list under subparagraph (A) unless the Secretary has made a finding that the submission of the list is necessary to carry out this subtitle.

(5) UNIQUE FACILITY IDENTIFIER SYSTEMS.—

(A) REQUIRED USE.—The Secretary shall require persons subject to this subsection to use, for purposes of this subsection, the unique facility identifier systems specified under subsections (b)(3) and (i)(4) with respect to drugs.

(B) DATE ON WHICH REQUIREMENT TO USE IS APPLICABLE.—The requirement under subparagraph (A) shall not apply until the date that the identifier system under subsection (b)(3) or (i)(4), as applicable, is specified by the Secretary.

(k) REPORT PRECEDING INTRODUCTION OF DEVICES INTO INTERSTATE COMMERCE.—

(1) IN GENERAL.—Each person that is required to register under this section and that proposes to

begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least 90 days before making the introduction or delivery, report to the Secretary or person that is accredited under section 13155(a) of this title (in such form and manner as the Secretary shall by regulation prescribe)—

(A) the class in which the device is classified under section 13140 of this title or if the person determines that the device is not classified under that section, a statement of that determination and the basis for the person's determination that the device is or is not classified under that section; and

(B) action taken by the person to comply with requirements under section 13141 or 13142 of this title that are applicable to the device.

(2) CERTIFICATION REQUIRED TO ACCOMPANY CLINICAL TRIAL DATA FOR APPLICABLE DEVICE.—A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act (42 U.S.C. 282(j)(1)))

shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. 282(j)(5)(B)). The certification shall not be considered an element of the notification.

(l) EXEMPTION FROM REPORTING REQUIREMENTS.—

(1) IN GENERAL.—A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified in class I under section 13140 of this title, or with respect to a change that is consistent with a predetermined change control plan cleared under section 13145 of this title. The exemption established in the preceding sentence does not apply to any class I device that is intended for a use that is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

(2) IDENTIFICATION OF CLASS I DEVICES THAT NO LONGER REQUIRE A REPORT.—

(A) IN GENERAL.—Not later than 120 calendar days after December 13, 2016, and at

least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness.

(B) EXEMPTION.—On publication under subparagraph (A)—

(i) each type of class I device identified under subparagraph (A) shall be exempt from the requirement for a report under subsection (k); and

(ii) the classification regulation applicable to each such type of device shall be deemed amended to incorporate the exemption.

(m) EXEMPTION OF CLASS II DEVICES FROM REPORTING REQUIREMENTS.—

(1) PUBLICATION OF LIST.—The Secretary shall—

(A) not later than 90 days after December 13, 2016, and at least once every 5 years thereafter, as the Secretary determines appropriate—

(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

(ii) provide, for a period of not less than 60 calendar days, for public comment beginning on the date of the publication of the notice; and

(B) not later than 210 calendar days after December 13, 2016, have published in the Federal Register a list representing the Secretary's original final determination with respect to the devices contained in the list published under subparagraph (A).

(2) EXEMPTION BY SECRETARY'S INITIATIVE OR BY PETITION.—

(A) IN GENERAL.—Beginning on the date that is 1 calendar day after the date of publication of the final list under paragraph (1)(B), the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), on the Secretary's own initiative or a petition of an interested person, if the Sec-

retary determines that the report is not necessary to ensure the safety and effectiveness of the device.

(B) NOTICE AND COMMENT.—The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment.

(C) PUBLICATION OR FINAL DETERMINATION.—Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice.

(D) FAILURE OF SECRETARY TO RESPOND TO PETITION.—If the Secretary fails to respond to a petition under this paragraph within 180 days of receiving it, the petition shall be deemed to be granted.

(3) EFFECT OF LISTING.—On the publication of the final list under paragraph (1)(B)—

(A) each type of class II device on the list shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate the exemption.

(n) REVIEW OF REPORT.—

(1) IN GENERAL.—The Secretary shall review the report required in subsection (k) and make a determination under section 13140(h)(1) of this title not later than 90 days after receiving the report.

(2) GUIDANCE.—

(A) WITHDRAWAL OF 2011 GUIDANCE.—

(i) IN GENERAL.—The Secretary shall withdraw the FDA draft guidance entitled ''Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device'', dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review or any compliance or enforcement decisions or actions.

(ii) RECEIPT OF REPORT REQUIRED BEFORE ISSUANCE OF GUIDANCE OR REGULATION.—The Secretary shall not issue—

(I) any draft guidance or proposed regulation that addresses when

to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in section 510(n)(2)(A) of the Federal Food, Drug, and Cosmetic Act, as added by section 604(2) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1052); and

(II) any final guidance or regulation on that topic for 1 year after date of receipt of the report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(B) USE OF 1997 GUIDANCE AND ISSUANCE OF SUBSEQUENT GUIDANCE.—The FDA guidance entitled ''Deciding When to Submit a

510(k) for a Change to an Existing Device'', dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (A), and the Secretary shall interpret the guidance in a manner that is consistent with the manner in which the Secretary has interpreted the guidance since 1997.

(o) REPROCESSED SINGLE-USE DEVICES.—

(1) DEVICES FOR WHICH REPORTS MUST INCLUDE VALIDATION DATA TO ENSURE SUBSTANTIAL EQUIVALENCE.—With respect to reprocessed single-use devices for which reports are required under subsection (k), the following applies:

(A) IDENTIFICATION.—

(i) IN GENERAL.—The Secretary shall identify the devices or types of devices for which reports under subsection (k) must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially

equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

(ii) LIST.—The Secretary shall publish in the Federal Register a list of the types identified under clause (i), and shall revise the list as appropriate.

(iii) REQUIREMENT TO INCLUDE VALIDATION DATA.—Reports under subsection (k) for devices or types of devices within a type included on the list are, on publication of the list, required to include the validation data.

(B) REPORTS SUBMITTED BEFORE PUBLICATION OF LIST.—

(i) IN GENERAL.—In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision of the list, and was for a device or type of device included on the list, the person that submitted the report under subsection (k) shall submit validation data as described in subparagraph (A)

to the Secretary not later than 9 months after the publication of the list.

(ii) NO ACTION ON GROUNDS THAT VALIDATION DATA HAVE NOT BEEN SUBMITTED.—During the 9-month period, the Secretary may not take any action under this subtitle against the device solely on the basis that the validation data for the device have not been submitted to the Secretary.

(iii) ACTIONS BY SECRETARY AFTER SUBMISSION OF VALIDATION DATA.—After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 13312 of this title or adulterated under section 13101(f)(1)(B) of this title, or take action against the device under section 10501(15) of this title for failure to provide any information required by subsection (k) until—

(I) the review is terminated by withdrawal of the submission of the report under subsection (k);

(II) the Secretary finds the data to be acceptable and issues a letter; or

(III) the Secretary determines that the device is not substantially equivalent to a predicate device.

(iv) MARKETING OF DEVICE NOT LEGAL.—On a determination that a device is not substantially equivalent to a predicate device, or if the submission is withdrawn, the device can no longer be legally marketed.

(C) REQUIREMENT TO INCLUDE VALIDATION DATA IN ADVANCE OF REVISION OF LIST.—In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under subsection (k), the Secretary may, in advance of revising the list under subparagraph (A) to include the type, require that the report include the validation data specified in subparagraph (A).

(D) APPLICABILITY OF SECTION 13312 OF THIS TITLE.—Section 13312 of this title applies with respect to the failure of a report under

subsection (k) to include validation data required under subparagraph (A).

(2) CRITICAL OR SEMI-CRITICAL REPROCESSED SINGLE-USE DEVICES FOR WHICH EXEMPTIONS SHOULD BE TERMINATED.—With respect to critical or semi-critical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k), the following applies:

(A) IDENTIFICATION.—

(i) IN GENERAL.—The Secretary shall identify the devices or types of devices for which the exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices.

(ii) LIST.—The Secretary shall publish in the Federal Register a list of the devices or types of devices identified under clause (i), and shall revise the list as appropriate.

(iii) TERMINATION OF EXEMPTION.—The exemption for each device or type included on the list is terminated on the publication of the list.

(iv) VALIDATION DATA REQUIRED.—For each report under subsection (k) submitted pursuant to this subparagraph, the Secretary shall require the validation data described in paragraph (1)(A).

(B) SUBMISSION OF REPORT.—

(i) DEADLINE.—For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device.

(ii) NO ACTION ON GROUNDS THAT REPORT HAS NOT BEEN SUBMITTED.—During the 15-month period, the Secretary may not take any action under this subtitle against the device solely on the basis that the report has not been submitted to the Secretary.

(iii) ACTIONS BY SECRETARY AFTER SUBMISSION OF REPORT.—After the submission of the report to the Secretary, the Secretary may not determine that the de-

vice is misbranded under section 13312 of this title or adulterated under section 13101(f)(1)(B) of this title, or take action against the device under section 10501(15) of this title for failure to provide any information required by subsection (k) until—

(I) the review is terminated by withdrawal of the submission;

(II) the Secretary determines by order that the device is substantially equivalent to a predicate device; or

(III) the Secretary determines by order that the device is not substantially equivalent to a predicate device.

(iv) MARKETING OF DEVICE NOT LEGAL.—On a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

(C) APPLICABILITY OF SECTION 13312 OF THIS TITLE.—Section 13312 of this title applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the

report to include validation data required in subparagraph (A).

(D) TERMINATION NOT TO APPLY TO ORIGINAL DEVICE.—The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semi-critical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

(p) ELECTRONIC REGISTRATION AND LISTING.—

(1) IN GENERAL.—Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of the requirement because use of electronic means is not reasonable for the person requesting the waiver.

(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

(A) enables personnel of the FDA to search the database by any field of information submitted in a registration described under paragraph (1), or combination of the fields; and

(B) uses the unique facility identifier system to link with other relevant databases within the FDA, including the database for submission of information under section 20101(r) of this title.

(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant FDA databases in order to identify and inform risk-based inspections under subsection (h).

(q) REUSABLE MEDICAL DEVICES.—

(1) IN GENERAL.—The Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

(A) instructions for use, which have been validated in a manner specified by the Secretary, regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based; and

(B) validation data, the types of which shall be specified by the Secretary, regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

(2) REVISION OF LIST.—The Secretary shall revise the list under paragraph (1), as the Secretary determines appropriate, with notice in the Federal Register.

(3) CONTENT OF REPORTS.—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on the list, shall include the instructions for use and validation data.

**§ 13137. Clinical trial guidance for antibiotic drugs**

(a) IN GENERAL.—The Secretary shall issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. The guidance shall indicate the appropriate models and valid surrogate markers.

(b) REVIEW.—The Secretary shall review and update the guidance described under subsection (a) to reflect de-

velopments in scientific and medical information and technology.

**§ 13138. Susceptibility test interpretive criteria for microorganisms**

(a) PURPOSE.—The purpose of this section is to clarify the Secretary's authority to—

(1) efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health, due to, among other things, the constant evolution of microorganisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies;

(2) provide for public notice of the availability of recognized interpretive criteria and interpretive criteria standards; and

(3) clear under section 13136(k) of this title, classify under section 13140(h)(2) of this title, or approve under section 13142 of this title, antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of

particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.

(b) DEFINITIONS.—In this section:

(1) ANTIMICROBIAL DRUG.—

(A) IN GENERAL.—The term ''antimicrobial drug'' means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

(ii) may include a qualified infectious disease product designated under section 13116(e) of this title; and

(iii) is subject to section 13103(a)(1) of this title.

(B) INCLUSIONS.—If provided by the Secretary through regulations, the term ''antimicrobial drug'' may include—

(i) drugs other than systemic antibacterial and antifungal drugs; and

(ii) biological products (as the term is defined in section 351 of the Public Health Service Act (42 U.S.C. 262)) to the extent the products exhibit antimicrobial activity.

(2) ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICE.—The term ''antimicrobial susceptibility testing device'' means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

(3) INTERPRETIVE CRITERIA STANDARD.—The term ''interpretive criteria standard'' means a compilation of susceptibility test interpretive criteria developed by a standard development organization that meets the criteria set forth in subsection (d)(2)(A)(i).

(4) INTERPRETIVE CRITERIA WEBSITE.—The term ''Interpretive Criteria Website'' means the website established in subsection (d)(1).

(5) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term ''qualified infectious disease product'' means a qualified infectious disease product designated under section 13116(e) of this title.

(6) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA.—The term ''susceptibility test interpretive criteria'' means—

(A) 1 or more specific numerical values that characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

(B) related categorizations of the susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

(c) IDENTIFICATION OF CRITERIA.—

(1) IN GENERAL.—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

(A) if the criteria are available on the date of approval of the drug under chapter 135 of this title or licensure of the drug under section 351 of the Public Health Service Act (42 U.S.C. 262) (as applicable), on the approval or licensure; or

(B) if the criteria are unavailable on the date described in subparagraph (A), on the date on which the criteria are available for the drug.

(2) BASES FOR INITIAL IDENTIFICATION.—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (1), based on the Secretary's review of, to the extent available and relevant—

(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

(B) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which the drug is used; and

(C) such other evidence and information as the Secretary considers appropriate.

(d) SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.—

(1) IN GENERAL.—The Secretary shall establish, and maintain after the establishment, on the FDA website, the Interpretative Criteria Website, which contains a list of any appropriate new or updated susceptibility test interpretive criteria standards and interpretive criteria in accordance with paragraph (2).

(2) LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS AND INTERPRETIVE CRITERIA.—

(A) IN GENERAL.—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

(i) established by a nationally or internationally recognized standard development organization that—

(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that the input is considered in decisionmaking; and

(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

(ii) recognized in whole, or in part, by the Secretary under subsection (e).

(B) OTHER LIST.—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect

to legally marketed antimicrobial drugs, where—

(i) the Secretary does not recognize, in whole or in part, an interpretive criteria standard described under subparagraph (A) otherwise applicable to such a drug;

(ii) the Secretary withdraws under subsection (e)(1)(A) recognition of a standard, in whole or in part, otherwise applicable to such a drug;

(iii) the Secretary approves an application under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, with respect to marketing of such a drug for which there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (e); or

(iv) because the characteristics of such a drug differ from other drugs with the same active ingredient, the interpretive criteria with respect to the drug—

(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph

(A) or interpretive criteria otherwise listed under this subparagraph; and

(II) are determined by the Secretary to be appropriate for the drug.

(C) REQUIRED STATEMENTS.—The Interpretive Criteria Website shall include statements conveying—

(i) that the Website provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to a certain drug (or drugs);

(ii) that—

(I) the safety and efficacy of the drugs in treating clinical infections due to the bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the susceptibility information described in clause (i) to be included on the Website; and

(II) the clinical significance of the susceptibility information in those instances is unknown;

(iii) that the approved product labeling for specific drugs provides the uses for which the Secretary has approved the product; and

(iv) any other information that the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria included on the Website.

(3) INAPPLICABILITY OF MISBRANDING PROVISION.—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of chapter 133 of this title.

(4) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5.

(e) RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA.—

(1) EVALUATION AND PUBLICATION.—

(A) IN GENERAL.—At least every 6 months, the Secretary shall—

(i) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (d)(2)(A)(i); and

(ii) publish on the public FDA website a notice—

(I) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

(II) recognizing the new or updated standards;

(III) recognizing 1 or more parts of the new or updated interpretive criteria specified in the standard and declining to recognize the remainder of the standard; and

(IV) making any necessary updates to the lists under subsection (d)(2).

(B) ON APPROVAL OF A DRUG.—On the approval of an initial or supplemental application for an antimicrobial drug under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, where the approval is based on susceptibility test interpretive criteria that differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to this subsection, or for which there are no relevant interpretive criteria standards recognized, or interpretive criteria otherwise listed, by the Secretary pursuant to this subsection, the Secretary shall update the lists under subparagraphs (A) and (B) of subsection (d)(2) to include the susceptibility test interpretive criteria on which the approval was based.

(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

(A) the Secretary's determination that such a standard is not applicable to a particular drug because the characteristics of the drug dif-

fer from other drugs with the same active ingredient;

(B) information provided by interested third parties, including public comment on the annual compilation of notices published under paragraph (3);

(C) any bases used to identify susceptibility test interpretive criteria under subsection (c)(1); and

(D) such other information or factors as the Secretary determines appropriate.

(3) ANNUAL COMPILATION OF NOTICES.—

(A) IN GENERAL.—Each year, the Secretary shall compile the notices published under paragraph (1)(A) and publish the compilation in the Federal Register and provide for public comment.

(B) REVIEW OF COMMENTS AND UPDATE OF STANDARDS.—If the Secretary receives comments, the Secretary shall review the comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards or criteria—

(i) recognized by the Secretary under this subsection; or

(ii) otherwise listed on the Interpretive Criteria Website under subsection (d)(2).

(4) RELATION TO SECTION 13141(c) OF THIS TITLE.—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (d)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 13141(c)(1) of this title.

(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria that differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to subsection (d)(2).

(f) ANTIMICROBIAL DRUG LABELING.—

(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—

(A) IN GENERAL.—With respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce

for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, for the drug, not later than 1 year after establishment of the Interpretive Criteria Website described in subsection (d)(1), shall remove susceptibility test interpretive criteria, if any, and related information from the approved drug labeling and replace it with a reference to the Interpretive Criteria Website.

(B) LABELING CHANGES.—The labeling changes required by this section shall be considered a minor change under section 314.70 of title 21, Code of Federal Regulations, or any successor regulations, that may be implemented through documentation in the next applicable annual report.

(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs approved on or after the date of the establishment of the Interpretive Criteria Website described in subsection (d)(1), the labeling for the drug shall include, in lieu of sus-

ceptibility test interpretive criteria and related information, a reference to the Website.

(g) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

(1) IN GENERAL.—Notwithstanding chapters 133 and 135 of this title and sections 13101, 13136, 13140, and 13142 of this title, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this division) with respect to an antimicrobial susceptibility testing device described in subsection (b)(2), the Secretary may authorize the marketing of the antimicrobial susceptibility testing device for a use described in subsection (b)(2).

(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

(A) USED TO MAKE A DETERMINATION OF SUSCEPTIBILITY.—The antimicrobial susceptibility testing device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

(i) included in a standard recognized by the Secretary under subsection (e); or

(ii) otherwise listed on the Interpretive Criteria Website under subsection (d)(2).

(B) LABELING INCLUDES CERTAIN STATEMENTS.—The labeling of the antimicrobial susceptibility testing device includes statements conveying—

(i) that the antimicrobial susceptibility testing device provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to antimicrobial drugs;

(ii) that—

(I) the safety and efficacy of the drugs in treating clinical infections due to the bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the antimicrobial susceptibility testing device to report the susceptibility of the bacteria, fungi, or other microorganisms, as applicable, to the drugs; and

(II) the clinical significance of the susceptibility information in those instances is unknown;

(iii) that the approved labeling for drugs tested using the antimicrobial susceptibility testing device provides the uses for which the Secretary has approved the drugs; and

(iv) any other information the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria described in subparagraph (A).

(C) DEVICE MEETS OTHER REQUIREMENTS.—The antimicrobial susceptibility testing device meets all other requirements to be cleared under section 13136(k) of this title, classified under section 13140(h)(2) of this title, or approved under section 13142 of this title.

(h) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to alter the standards of evidence under—

(A) section 13504 or 13505 of this title, including the substantial evidence standard under section 13505 of this title; or

(B) section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) with respect to clearing devices under section 13136(k) of this title, classifying devices under section 13140(h)(2) of this title, or approving devices under section 13142 of this title—

(A) to apply with respect to any drug, device, or biological product, in any context other than an antimicrobial drug and an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the susceptibility of certain bacteria, fungi, or other microorganisms, as applicable, to the drug to reflect patient morbidity and mortality in accordance with this section; or

(B) unless specifically stated, to have any effect on authorities provided under other sections of this subtitle, including any regulations issued under those sections.

(i) APPLICABILITY OF CHAPTER 35 OF TITLE 44.—Chapter 35 of title 44 shall not apply to the collection

of information from interested parties regarding updating the lists established under subsection (d) and posted on the Interpretive Criteria Website established under subsection (d).

**§ 13139. Priority zoonotic animal drugs**

(a) IN GENERAL.—The Secretary shall, at the request of the sponsor intending to submit an application for approval of a new animal drug under section 13703(a) of this title or an application for conditional approval of a new animal drug under section 14502 of this title, expedite the development and review of the new animal drug if preliminary clinical evidence indicates that the new animal drug, alone or in combination with 1 or more other animal drugs, has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.

(b) REQUEST FOR DESIGNATION.—

(1) IN GENERAL.—The sponsor of a new animal drug may request the Secretary to designate a new animal drug described in subsection (a) as a priority zoonotic animal drug.

(2) TIMING OF REQUEST.—A request for the designation may be made concurrently with, or at

any time after, the opening of an investigational new animal drug file under section 13711 of this title or the filing of an application under section 13703(a) or 14502 of this title.

(c) DESIGNATION.—

(1) IN GENERAL.—

(A) DETERMINATION BY SECRETARY.—Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the new animal drug that is the subject of the request meets the criteria described in subsection (a).

(B) EFFECT OF DETERMINATION THAT NEW ANIMAL DRUG MEETS CRITERIA.—If the Secretary determines that the new animal drug meets the criteria, the Secretary shall designate the new animal drug as a priority zoonotic animal drug and shall take such actions as are appropriate to expedite the development and review of the application for approval or conditional approval of the new animal drug.

(2) ACTIONS.—The actions to expedite the development and review of an application under paragraph (1) may include, as appropriate—

(A) taking steps to ensure that the design of clinical trials is as efficient as practicable, when scientifically appropriate, such as by utilizing novel trial designs or drug development tools (including biomarkers) that may reduce the number of animals needed for studies;

(B) providing timely advice to, and interactive communication with, the sponsor (which may include meetings with the sponsor and review team) regarding the development of the new animal drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

(C) involving senior managers and review staff with experience in zoonotic or vector-borne disease to facilitate collaborative, cross-disciplinary review, including, as appropriate, across agency centers; and

(D) implementing additional administrative or process enhancements, as necessary, to facilitate an efficient review and development program.

**§ 13140. Classification of devices intended for human use**

(a) REFERENCES TO CERTAIN TERMS IN PARTICULAR SECTIONS.—For purposes of this section and sections 13101, 13136, 13141, 13142, 13146, 13151, and 13152 of this title—

(1) a reference to ''general controls'' is a reference to the controls authorized by or under chapter 133 of this title and sections 13101, 13136, 13146, 13149, 13151, and 13152 of this title;

(2) a reference to ''class I'', ''class II'', or ''class III'' is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (c)(1); and

(3) a reference to a ''panel under section 13140 of this title'' is a reference to a panel established or authorized to be used under this section.

(b) SUBSTANTIAL EQUIVALENCE.—

(1) DETERMINATION OF SUBSTANTIAL EQUIVALENCE.—

(A) IN GENERAL.—For purposes of determinations of substantial equivalence under subsection (h) and section 13152(l) of this title, a device is substantially equivalent to a predicate device if the device has the same intended use

as the predicate device and the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device; or

(ii)(I) has different technological characteristics and the information submitted showing that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if considered necessary by the Secretary or a person accredited under section 13155 of this title, that demonstrates that the device is as safe and effective as a legally marketed device; and

(II) does not raise different questions of safety and effectiveness than the predicate device.

(B) DIFFERENT TECHNOLOGICAL CHARACTERISTICS.—For purposes of subparagraph (A), the term ''different technological characteristics'' means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) RELIANCE ON POSTMARKET CONTROLS.—To facilitate reviews of reports submitted to the Secretary under section 13136(k) of this title, the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (h)(1).

(D) INFORMATION DEMONSTRATING SUBSTANTIAL EQUIVALENCE OF DEVICES WITH DIFFERING TECHNOLOGICAL CHARACTERISTICS.—

(i) DEFINITION OF NECESSARY.—For purposes of clause (ii), the term ''necessary'' means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

(ii) IN GENERAL.—Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall request only information that is necessary to making substantial equivalence determinations. In making the request, the Secretary shall consider

the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(iii) EFFECT OF SUBPARAGRAPH ON SUBSTANTIAL EQUIVALENCE STANDARD.—Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

(E) PROPOSED LABELING.—

(i) IN GENERAL.—

(I) DETERMINATION OF INTENDED USE.—Any determination by the Secretary of the intended use of a device shall be based on the proposed labeling submitted in a report for the device under section 13136(k) of this title.

(II) STATEMENT IN LABELING THAT MAY BE REQUIRED.—When determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subpara-

graph referred to as the ''Director'') may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person that submitted the report, the Director determines and states in writing—

(aa) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(bb) that the use could cause harm.

(ii) REQUIREMENTS RELATING TO DETERMINATION OF SUBSTANTIAL EQUIVALENCE.—A determination of substantial equivalence under clause (i) shall—

(I) be provided to the person that submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for the device conforms to the limitations specified in subclause (II).

(iii) NONDELEGATION.—The responsibilities of the Director under this subparagraph may not be delegated.

(F) GUIDANCE RELATING TO DETERMINATION THAT SPECIFIC INTENDED USE IS NOT INCLUDED IN GENERAL USE.—The Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of the device for purposes of a determination of substantial equivalence under subsection (h) or section 13152(l) of this title.

(2) PREDICATE DEVICE; REMOVED FROM MARKET, MISBRANDED, OR ADULTERATED.—A device may not be found to be substantially equivalent to a predicate device that has been removed from the

market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3) SUMMARY OF INFORMATION ON SAFETY AND EFFECTIVENESS.—

(A) IN GENERAL.—As part of a submission under section 13136(k) of this title respecting a device, the person required to file a premarket notification under that section shall provide an adequate summary of any information respecting safety and effectiveness or state that the information will be made available on request by any person.

(B) CONTENTS; DATE ON WHICH SUMMARY IS TO BE MADE PUBLICLY AVAILABLE.—Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that the device is substantially equivalent to another device.

(c) CLASSES OF DEVICES.—

(1) IN GENERAL.—There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) DEVICES FOR WHICH THERE ARE SUFFICIENT CONTROLS.—A device for which the controls authorized by or under chapter 133 of this title or section 13101, 13136, 13146, 13149, 13151, or 13152 of this title, or any combination of those provisions, are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) DEVICES FOR WHICH THERE IS INSUFFICIENT INFORMATION RELATING TO CONTROLS.—

(I) IN GENERAL.—A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide the assurance, but because it is a device described in subclause (II), is to be regulated by the controls referred to in clause (i).

(II) DEVICE.—A device is described in this subclause if it—

(aa) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health; and

(bb) does not present a potential unreasonable risk of illness or injury.

(B) CLASS II, SPECIAL CONTROLS.—

(i) IN GENERAL.—A device that cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide the assurance, including—

(I) the promulgation of performance standards;

(II) postmarket surveillance;

(III) patient registries;

(IV) development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 13136(k) of this title);

(V) recommendations; and

(VI) other appropriate actions as the Secretary considers necessary to provide the assurance.

(ii) DEVICES FOR USE IN SUPPORTING OR SUSTAINING HUMAN LIFE.—For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how the controls provide the assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device that—

(i) because it—

(I) cannot be classified as a class I device because insufficient informa-

tion exists to determine that the application of general controls is sufficient to provide reasonable assurance of the safety and effectiveness of the device; and

(II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness; and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health; or

(II) presents a potential unreasonable risk of illness or injury;

is to be subject, in accordance with section 13142 of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

(2) INSUFFICIENT INFORMATION TO ESTABLISH PERFORMANCE STANDARD.—If there is not suffi-

cient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain the information.

(3) SAFETY AND EFFECTIVENESS OF A DEVICE.—For purposes of this section and sections 13141 and 13142 of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended;

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device; and

(C) by weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from the use.

(4) EFFECTIVENESS OF A DEVICE.—

(A) DETERMINATION ON THE BASIS OF WELL-CONTROLLED INVESTIGATIONS.—Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 13141 and 13142 of this title, to be determined, in accordance with regulations promulgated by the Secretary, on the

basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) DETERMINATION ON THE BASIS OF VALID SCIENTIFIC EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)), then, for purposes of this section and sections 13141 and 13142 of this title, the Secretary may authorize the effectiveness of a device to be determined on the basis of the valid scientific evidence if—

(i) the evidence is sufficient to determine the effectiveness of the device; and

(ii) from the evidence, it can fairly and responsibly be concluded by qualified experts that the device will have the effect

it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(C) RELIANCE ON POSTMARKET CONTROLS.—In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 13142 of this title has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

(D) PROCEDURE.—

(i) MEETING RELATING TO VALID SCIENTIFIC EVIDENCE.—

(I) IN GENERAL.—The Secretary, on the written request of any person intending to submit an application under section 13142 of this title, shall meet with the person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to

demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by the person.

(II) WRITTEN REQUEST.—The written request shall include—

(aa) a detailed description of the device;

(bb) a detailed description of the proposed conditions of use of the device;

(cc) a proposed plan for determining whether there is a reasonable assurance of effectiveness; and

(dd) if available, information regarding the expected performance from the device.

(III) SECRETARY TO SPECIFY TYPE OF VALID SCIENTIFIC EVIDENCE.—Within 30 days after the meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective

under the conditions of use proposed by the person.

(ii) CLINICAL DATA SPECIFIED.—

(I) DEFINITION OF NECESSARY.—In subclause (II), the term ''necessary'' means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

(II) IN GENERAL.—Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that the data are necessary to establish device effectiveness.

(III) LEAST BURDENSOME MEANS OF EVALUATION.—The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating

device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.

(iv) DETERMINATION AS BINDING.—The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding on the Secretary, unless the determination by the Secretary could be contrary to the public health.

(d) CLASSIFICATION PANELS.—

(1) IN GENERAL.—

(A) PURPOSE OF CLASSIFICATION.—The Secretary shall classify devices (other than devices classified by subsection (h)) into the classes established by subsection (c) for purposes of—

(i) determining which devices intended for human use should be subject to the requirements of general controls, perform-

ance standards, or premarket approval; and

(ii) providing notice to the manufacturers and importers of the devices to enable them to prepare for the application of the requirements to devices manufactured or imported by them.

(B) ESTABLISHMENT OF PANELS.—For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before May 28, 1976, or both.

(C) INAPPLICABILITY OF SECTION 1013 OF TITLE 5.—Section 1013 of title 5 shall not apply to the duration of a panel established under this paragraph.

(2) PANEL MEMBERS.—

(A) APPOINTMENT.—The Secretary shall appoint to each panel established under paragraph (1) individuals who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the de-

velopment, manufacture, or utilization of, the devices.

(B) EXPERTISE.—The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in fields such as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

(C) NOMINATIONS FROM ORGANIZATIONS.—Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels.

(D) FEDERAL EMPLOYEES.—An individual who is in the regular full-time employ of the United States and engaged in the administration of this subtitle shall not be a member of any panel.

(E) CHAIRPERSON.—The Secretary shall designate one of the members of each panel to serve as chairperson of the panel.

(3) COMPENSATION AND TRAVEL EXPENSES RELATING TO MEETINGS AND CONFERENCES.—

(A) IN GENERAL.—Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the maximum rate payable under section 5376 of title 5, for each day so engaged, including travel time.

(B) SERVICE AWAY FROM HOME OR REGULAR PLACE OF BUSINESS.—While a panel member is serving as described in subparagraph (A) away from the panel member's home or regular place of business, the panel member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, for individuals in the Government service employed intermittently.

(4) PERSONNEL.—The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(5) PANEL MEETINGS; ADEQUATE EXPERTISE.—

(A) SCHEDULE OF MEETINGS.—Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(B) ADEQUATE EXPERTISE WITHIN PANELS.—When a device is specifically the subject of review by a classification panel, the Secretary shall—

(i) ensure that adequate expertise is represented on the classification panel to assess—

(I) the disease or condition that the device is intended to cure, treat, mitigate, prevent, or diagnose; and

(II) the technology of the device; and

(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

(C) ADEQUATE EXPERTISE REPRESENTED.—In subparagraph (B)(i), adequate expertise is represented on the classification panel if the membership of the classification panel includes—

(i) 2 or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

(ii) at least 1 voting member who is knowledgeable about the technology of the device.

(D) ANNUAL OPPORTUNITY TO PROVIDE RECOMMENDATIONS.—The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical devices that may be specifically the subject of a review by a classification panel to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.

(6) PANEL REVIEW PROCEDURE.—

(A) RIGHTS OF PERSON WHOSE DEVICE IS SUBJECT OF REVIEW.—Any person whose device is specifically the subject of review by a classification panel shall have—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 13142 of this title by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel, including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address the specific issues in the time provided.

(B) PANEL MEETINGS.—

(i) CONDUCT OF MEETING.—Any meeting of a classification panel with respect to the review of a device shall—

(I) provide adequate time for initial presentations by the person whose device is specifically the subject of the review and by the Secretary; and

(II) encourage free and open participation by all interested persons.

(ii) QUESTIONS FOLLOWING INITIAL PRESENTATION.—Following the initial presentations described in clause (i), the panel may—

(I) pose questions to a designated representative described in subparagraph (A)(iii); and

(II) consider the responses to the questions in the panel's review of the device.

(7) DUTIES OF SECRETARY AFTER PANEL REVIEW.—After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary—

(A) shall review the conclusions and recommendations;

(B) shall make a final decision on the matter in accordance with section 13142(d)(2) of this title; and

(C) shall—

(i) notify the affected persons of the decision in writing; and

(ii) if the decision differs from the conclusions and recommendations of the panel, include in the notification under clause (i) the reasons for the difference.

(8) REQUIREMENTS UNDER CHAPTER 10 OF TITLE 5.—A classification panel under this subsection shall not be subject to the annual chartering and annual reporting requirements of chapter 10 of title 5.

(e) CLASSIFICATION PANEL ORGANIZATION AND OPERATION.—

(1) IN GENERAL.—

(A) BY FIELDS OF CLINICAL MEDICINE AND FUNDAMENTAL SCIENCES.—The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental

sciences in which devices intended for human use are used.

(B) REFERRAL.—The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (d) for its review and for its recommendation respecting the classification of the device.

(C) PROCEDURE TO BE PRESCRIBED BY REGULATION.—The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations.

(D) OPPORTUNITY FOR INTERESTED PERSONS TO MAKE SUBMISSIONS.—In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2) RECOMMENDATIONS.—

(A) SUBMISSION TO SECRETARY.—

(i) IN GENERAL.—On completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit

to the Secretary its recommendation for the classification of the device.

(ii) CONTENTS OF RECOMMENDATION.—Any recommendation under clause (i) shall—

(I) contain—

(aa) a summary of the reasons for the recommendation;

(bb) a summary of the data on which the recommendation is based; and

(cc) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made; and

(II) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 13141 or 13142 of this title to a device recommended to be classified in class II or class III.

(B) RECOMMENDATION RELATING TO EXEMPTIONS.—A recommendation of a panel for

the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 13136, 13151, or 13152(f) of this title.

(C) DEVICE TO BE RECOMMENDED FOR CLASSIFICATION IN CLASS III.—

(i) IN GENERAL.—A panel shall recommend to the Secretary that a device be classified in class III, unless the panel determines that classification of the device in class III is not necessary to provide reasonable assurance of its safety and effectiveness, if the device (which has been referred to the panel under paragraph (1))—

(I) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life; and

(II)(aa) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(bb) is within a type of device that was introduced or delivered as

described in item (aa) before the date under item (aa) and is substantially equivalent to another device within that type.

(ii) CLASS III RECOMMENDATION NOT MADE; REASONS.—If a panel does not recommend that a device described in clause (i) be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in class III.

(f) REGULATIONS CLASSIFYING DEVICES.—

(1) IN GENERAL.—

(A) PUBLICATION AND PROPOSED REGULATION.—On receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying the device and shall provide interested persons an opportunity to submit comments on the recommendation and the proposed regulation.

(B) FINAL REGULATION.—After reviewing the comments, the Secretary shall, subject to paragraph (2), by regulation classify the device.

(2) REGULATION REQUIREMENTS FOR SPECIFIC DEVICES.—

(A) CLASS I DEVICES; INAPPLICABILITY OF CERTAIN PROVISIONS.—A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 13136, 13151, or 13152(f) of this title shall not apply to the device. A regulation that makes a requirement of section 13136, 13151, or 13152(f) of this title inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making the requirement inapplicable.

(B) DEVICES TO BE CLASSIFIED AS CLASS III DEVICES.—

(i) IN GENERAL.—A device described in subsection (e)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in class III is not necessary to provide reasonable assurance of its safety and effectiveness.

(ii) CLASS III CLASSIFICATION NOT MADE; REASONS.—A proposed regulation under paragraph (1) classifying the device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying the device in class III and an identification of the risks to health (if any) presented by the device.

(3) PRIORITIES FOR CERTAIN DEVICES.—In the case of devices classified in class II and devices classified under this subsection in class III and described in section 13142(b)(1) of this title, the Secretary may establish priorities that, in the Secretary's discretion, shall be used in applying sections 13141 and 13142 of this title, as appropriate, to the devices.

(g) CLASSIFICATION CHANGES.—

(1) AUTHORITY.—

(A) IN GENERAL.—

(i) ADMINISTRATIVE ORDER FOLLOWING PROCEDURAL REQUIREMENTS.—Based on new information respecting a device, the Secretary may, on the initiative of

the Secretary or on petition of an interested person, change the classification of the device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 13141 or 13142 of this title with respect to the device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (d), and consideration of comments to a public docket, notwithstanding subchapter II of chapter 5 of title 5.

(ii) CONTENTS OF PROPOSED RECLASSIFICATION ORDER.—

(I) IN GENERAL.—The proposed reclassification order published in the Federal Register shall set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including—

(aa) the public health benefit of the use of the device, and

the nature and, if known, incidence of the risk of the device;

(bb) in the case of a reclassification from class II to class III, why general controls pursuant to subsection (c)(1)(A) and special controls pursuant to subsection (c)(1)(B) together are not sufficient to provide a reasonable assurance of safety and effectiveness for the device; and

(cc) in the case of reclassification from class III to class II, why general controls pursuant to subsection (c)(1)(A) and special controls pursuant to subsection (c)(1)(B) together are sufficient to provide a reasonable assurance of safety and effectiveness for the device.

(II) ORDER CHANGING CLASSIFICATION FROM CLASS III TO CLASS II.—An order under this subsection changing the classification of a device from class III to class II may provide

that the classification shall not take effect until the effective date of a performance standard established under section 13141 of this title for the device.

(B) DELEGATION.—Authority to issue an administrative order under this paragraph shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) RECLASSIFIYING CLASS III DEVICES.—By an order issued under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device; or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(h) INITIAL CLASSIFICATION AND RECLASSIFICATION OF CERTAIN DEVICES.—

(1) INITIAL CLASSIFICATION AS CLASS III.—

(A) IN GENERAL.—Any device intended for human use that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(i) the device—

(I) is within a type of device—

(aa) that was introduced or delivered for introduction into interstate commerce for commercial distribution before that date and that is to be classified pursuant to subsection (d); or

(bb) that was not so introduced or delivered before that date and has been classified in class I or II; and

(II) is substantially equivalent to another device within that type;

(ii) the Secretary in response to a petition submitted under paragraph (3) has classified the device in class I or II; or

(iii) the device is classified pursuant to a request submitted under paragraph (2).

(B) DATE UNTIL WHICH CLASS III CLASSIFICATION IS EFFECTIVE.—A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2) CLASSIFICATION BY REQUEST.—

(A) SUBMISSION BY PERSON MAKING A CLASSIFICATION REQUEST.—

(i) REQUEST AFTER NOTICE FROM SECRETARY OF CLASS III CLASSIFICATION.—Any person that submits a report under section 13136(k) of this title for a type of device that has not been previously classified under this subtitle, and that is classified in class III under paragraph (1), may request, after receiving written notice of the classification, the Secretary to classify the device.

(ii) REQUEST IN LIEU OF REPORT AND REQUEST UNDER CLAUSE (i).—In lieu of submitting a report under section

13136(k) of this title and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device on which to base a determination of substantial equivalence under subsection (b), a person may submit a request under this clause for the Secretary to classify the device.

(iii) DEADLINE FOR SECRETARY TO MAKE THE CLASSIFICATION.—On receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (c)(1) within 120 days.

(iv) AUTHORITY TO DECLINE CLASSIFICATION REQUEST.—Notwithstanding clause (iii), the Secretary may decline to undertake a classification request submitted under clause (ii)—

(I) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1); or

(II) if the Secretary determines—

(aa) that the device submitted is not of low to moderate risk; or

(bb) that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

(v) RECOMMENDATION FROM PERSON SUBMITTING THE REQUEST.—

(I) IN GENERAL.—The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (c)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of

how the special controls provide the assurance.

(II) DESCRIPTION OF DEVICE AND REASONS FOR RECOMMENDATION.—Any request under subclause (I) shall describe the device and provide detailed information and reasons for the recommended classification.

(B) ACTIONS BY SECRETARY; EFFECT OF CLASSIFICATION.—

(i) CLASSIFICATION.—

(I) IN GENERAL.—The Secretary shall by written order classify the device that is the subject of a request under subparagraph (A).

(II) INITIAL CLASSIFICATION.—The classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) DEVICE THAT REMAINS IN CLASS III.—A device that remains in class III

under this subparagraph shall be deemed to be adulterated within the meaning of section 13101(f)(1)(B) of this title until approved under section 13142 of this title or exempted from the approval under section 13152(g) of this title.

(C) PUBLICATION OF CLASSIFICATION.—Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing the classification.

(3) CLASSIFICATION ON SECRETARY'S INITIATIVE; PETITION BY MANUFACTURER OR IMPORTER.—

(A) AUTHORITY.—

(i) IN GENERAL.—The Secretary may initiate the reclassification of a device classified in class III under paragraph (1) or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as the Secretary shall prescribe) for the issuance of an order classifying the device in class I or class II.

(ii) NOTIFICATION OF DEFICIENCIES.—Within 30 days of the filing of a petition under clause (i), the Secretary shall notify the petitioner of any deficiencies in the petition that prevent the Secretary from making a decision on the petition.

(B) REFERRAL TO AND CONSIDERATION BY PANEL.—

(i) REFERRAL.—

(I) IN GENERAL.—On determining that a petition does not contain any deficiency that prevents the Secretary from making a decision on the petition, the Secretary may, for good cause shown, refer the petition to an appropriate panel established or authorized to be used under subsection (d).

(II) RECOMMENDATION.—A panel to which a petition under subclause (I) has been referred shall, not later than 90 days after the referral of the petition, make a recommenda-

tion to the Secretary respecting approval or denial of the petition.

(III) CONTENTS OF RECOMMENDATION.—Any recommendation under subclause (II) shall contain—

(aa) a summary of the reasons for the recommendation;

(bb) a summary of the data on which the recommendation is based; and

(cc) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

(IV) DEVICE TO BE IMPLANTED IN HUMAN BODY OR FOR USE IN SUPPORTING OR SUSTAINING HUMAN LIFE.—In the case of a petition for a device that is intended to be implanted in the human body or that is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied

unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that the petition be approved, it shall in its recommendation to the Secretary set forth its reasons for the recommendation.

(ii) APPLICABILITY OF CERTAIN PROVISIONS.—The requirements of paragraphs (1) and (2) of subsection (e) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 13136, 13151, and 13152(f) of this title) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C) ACTIONS BY SECRETARY AFTER RECEIPT OF RECOMMENDATION.—

(i) DENIAL OF APPROVAL; ORDER.—

(I) IN GENERAL.—Within 90 days from the date the Secretary receives the recommendation of a panel

respecting a petition (but not later than 210 days after the filing of the petition), the Secretary shall by order deny or approve the petition.

(II) ORDER ON APPROVAL.—If the Secretary approves the petition, the Secretary shall order the classification of the device in class I or class II in accordance with the criteria prescribed by subsection (c)(1)(A) or (c)(1)(B).

(III) DEVICE TO BE IMPLANTED IN HUMAN BODY OR FOR USE IN SUPPORTING OR SUSTAINING HUMAN LIFE.—In the case of a petition for a device that is intended to be implanted in the human body or that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order ap-

proving the petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which the order applies.

(ii) APPLICABILITY OF CERTAIN PROVISIONS.—The requirements of paragraphs (1) and (2)(A) of subsection (f) (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 13136, 13151, and 13152(f) of this title) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(4) CERTIFICATION BY MANUFACTURERS OF DEVICES SUBJECT TO PREMARKET REPORT AND SUBSTANTIALLY EQUIVALENT TO CERTAIN OTHER DEVICES.—

(A) IN GENERAL.—A manufacturer shall make the certification described in subparagraph (B) if the manufacturer reports to the Secretary under section 13136(k) of this title

that a device is substantially equivalent to another device—

(i) that the Secretary has classified as a class III device under subsection (d);

(ii) that was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(iii) for which no final regulation requiring premarket approval has been promulgated under section 13142(b) of this title (as in effect prior to July 9, 2012).

(B) CONTENT OF CERTIFICATION.—If a manufacturer reports to the Secretary as described in subparagraph (A), the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting the other device and has included in the report under section 13136(k) of this title a summary of and a citation to all adverse safety and effectiveness data respecting the other device and respecting the device for which the section 13136(k) report is being made and that has not been submitted to

the Secretary under section 13151 of this title. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

(5) DETERMINATION OF INITIAL CLASSIFICATION NOT TO BE WITHHELD.—The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this subtitle unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 13152(f) of this title (other than a finding that there is a substantial likelihood that the failure to comply with the regulations will potentially present a serious risk to human health).

(6) ACCESSORIES.—

(A) CLASSIFICATION BY WRITTEN ORDER.—Subject to the succeeding subparagraphs of this paragraph, the Secretary shall, by written order, classify an accessory under this section based on the risks of the accessory when used as intended and the level of regu-

latory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which the accessory is intended to be used.

(B) CLASSIFICATION APPLICABLE UNTIL RECLASSIFIED.—

(i) IN GENERAL.—The classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, shall continue to apply unless and until the accessory is reclassified by the Secretary, notwithstanding the classification of any other device with which the accessory is intended to be used.

(ii) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preclude the Secretary's authority to initiate the classification of an accessory through regulation or written order, as appropriate.

(C) CLASSIFICATION OF ACCESSORIES INTENDED TO BE USED WITH DEVICE.—

(i) INCLUSION OF REQUEST FOR CLASSIFICATION OF ACCESSORY IN APPLI-

CATION OR REPORT RELATING TO THE DEVICE.—In the case of a device intended to be used with an accessory, where the accessory has been included in an application for premarket approval of the device under section 13142 of this title or a report under section 13136(k) of this title for clearance of the device and the Secretary has not classified the accessory distinctly from another device in accordance with subparagraph (A), the person filing the application or report (as applicable) at the time the application or report is filed—

(I) may include a written request for the proper classification of the accessory pursuant to subparagraph (A);

(II) shall include in any such request such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (c); and

(III) shall, if the request under subclause (I) is requesting classifica-

tion of the accessory in class II, include in the application an initial draft proposal for special controls, if special controls would be required pursuant to subsection (c)(1)(B).

(ii) GRANT OR DENIAL OF REQUEST.—The Secretary's response under section 13142(d) or 13136(n) of this title (as applicable) to an application or report described in clause (i) shall also contain the Secretary's granting or denial of the request for classification of the accessory involved.

(iii) SECRETARY'S EVALUATION OF ACCESSORY CONSTITUTES ORDER ESTABLISHING CLASSIFICATION.—The Secretary's evaluation of an accessory under clause (i) shall constitute an order establishing a new classification for the accessory for the specified intended use or uses of the accessory and for any accessory with the same intended use or uses as the accessory.

(D) ACCESSORIES PREVIOUSLY GRANTED MARKETING AUTHORIZATION.—For accessories

that have been granted marketing authorization as part of a submission for another device with which the accessory involved is intended to be used, through an application for the other device under section 13142(c) of this title, a report under section 13136(k) of this title, or a request for classification under paragraph (2), the following shall apply:

(i) CLASS I LIST.—

(I) PROPOSED LIST.—Not later than the date that is 1 year after August 18, 2017, and at least once every 5 years thereafter, and as the Secretary otherwise determines appropriate, pursuant to this paragraph, the Secretary shall publish in the Federal Register a notice proposing a list of the accessories that the Secretary determines may be suitable for a distinct classification in class I and the proposed regulations for the classifications.

(II) CONSIDERATION OF RECOMMENDATIONS FROM SPONSORS AND STAKEHOLDERS.—In developing the

list, the Secretary shall consider recommendations from sponsors of device submissions and other stakeholders for accessories to be included on the list.

(III) PUBLIC COMMENT.—Each notice shall provide for a period of not less than 60 calendar days for public comment.

(IV) FINAL ACTION.—Within 180 days after the end of the comment period, the Secretary shall publish in the Federal Register a final action classifying the suitable accessories in class I.

(ii) CLASSIFICATION BY REQUEST.—

(I) IN GENERAL.—A manufacturer or importer of an accessory that has been granted the marketing authorization—

(aa) may submit to the Secretary a written request for the appropriate classification of the accessory based on the risks and appropriate level of regulatory

controls as described in subparagraph (A); and

(bb) shall, if the request is requesting classification of the accessory in class II, include in the submission an initial draft proposal for special controls, if special controls would be required pursuant to subsection (c)(1)(B).

(II) REQUEST TO INCLUDE NECESSARY INFORMATION FOR EVALUATION BY SECRETARY.—A request under subclause (I) shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (c).

(III) OPPORTUNITY TO MEET WITH FDA PERSONNEL.—The Secretary shall provide an opportunity for a manufacturer or importer to meet with appropriate personnel of the FDA to discuss the appropriate classification of the accessory prior to sub-

mitting a written request under this clause for classification of the accessory.

(iii) RESPONSE BY SECRETARY.—

(I) IN GENERAL.—The Secretary shall respond to a request made under clause (ii) not later than 85 calendar days after receiving the request by issuing a written order classifying the accessory or denying the request.

(II) JUSTIFICATION REQUIRED IF SECRETARY DISAGREES.—If the Secretary does not agree with the recommendation for classification submitted by the manufacturer or importer, the response shall include a detailed description and justification for the determination.

(III) PUBLICATION ANNOUNCING RESPONSE.—Within 30 calendar days after granting such a request, the Secretary shall publish a notice in the Federal Register announcing the response.

(E) EFFECT OF PARAGRAPH ON USE OF CLASSIFICATION PROCESS ON NEW TYPE OF ACCESSORY.—Nothing in this paragraph may be construed as precluding a manufacturer of an accessory of a new type from using the classification process described in paragraph (2) to obtain classification of the accessory in accordance with the criteria and requirements set forth in that paragraph.

(i) INFORMATION.—Within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this subtitle, the Secretary shall provide the person a written statement of the classification (if any) of the device and the requirements of this subtitle applicable to the device.

(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

(1) IN GENERAL.—The Secretary shall—

(A) ensure that each employee of the FDA who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under

subsections (b)(1)(D) and (c)(4)(D) and section 13142(c)(5) of this title; and

(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

(2) AUDIT.—Not later than 18 months after December 13, 2016, the ombudsman for any organizational unit of the FDA responsible for the premarket review of devices—

(A) shall conduct an audit of the training described in paragraph (1)(A), including the effectiveness of the training in implementing the least burdensome requirements;

(B) shall include in the audit interviews of individuals who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decision-making;

(C) shall include in the audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome re-

quirements, including under paragraph (1)(B) and section 13148(a)(3) of this title, and may provide feedback on the effectiveness of the tools in the implementation of the least burdensome requirements;

(D) shall summarize the findings of the audit in a final audit report; and

(E) within 30 calendar days of completion of the final audit report, shall make the final audit report available—

(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

(ii) on the FDA website.

(k) DUAL SUBMISSION FOR CERTAIN DEVICES.—For a device authorized for emergency use under section 14306 of this title for which, in accordance with section 14306(n) of this title, the Secretary has deemed a laboratory examination or procedure associated with the device to be in the category of examinations and procedures described in section 353(d)(3) of the Public Health Service Act (42 U.S.C. 263a(d)(3)), the sponsor of the device

may, when submitting a request for classification under subsection (h)(2), submit a single submission containing—

(1) the information needed for the request; and

(2) sufficient information to enable the Secretary to determine whether the laboratory examination or procedure satisfies the criteria to be categorized under section 353(d)(3) of the Public Health Service Act (42 U.S.C. 263a(d)(3)).

**§ 13141. Performance standards**

(a) REASONABLE ASSURANCE OF SAFE AND EFFECTIVE PERFORMANCE.—

(1) REQUIRED INCLUSION OF PERFORMANCE STANDARDS FOR CLASS II DEVICES.—The special controls required by section 13140(c)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under subsection (b) if the device has been reclassified as a class II device under an administrative order under section 13140(g) of this title (or a regulation promulgated under that section prior to July 9, 2012) but the order (or regulation)

provides that the reclassification is not to take effect until the effective date of the standard for the device.

(2) REQUIRED PROVISIONS IN A PERFORMANCE STANDARD.—A performance standard established under subsection (b) for a device—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to those power systems;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to ensure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an indi-

vidual basis) by the Secretary or by another person at the direction of the Secretary;

(iii) provisions for the measurement of the performance characteristics of the device;

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required; and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 13152(e) of this title; and

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) PERIODIC EVALUATION.—The Secretary shall provide for periodic evaluation of performance

standards established under subsection (b) to determine if the standards should be changed to reflect new medical, scientific, or other technological data.

(4) COOPERATION.—In carrying out the Secretary's duties under this subsection and subsection (b), the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed individuals representative of scientific, professional, industry, or consumer organizations, which individuals, in the Secretary's judgment, can make a significant contribution.

(b) ESTABLISHMENT, AMENDMENT, AND REVOCATION OF A STANDARD.—

(1) PUBLICATION OF PROPOSED RULEMAKING.—

(A) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) REQUIREMENTS FOR ESTABLISHMENT OR AMENDMENT.—A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device;

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate;

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 13140(g) of this title based on new information relevant to the classification; and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) REQUIRED FINDING FOR REVOCATION.—A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) COMMENT PERIOD.—The Secretary shall provide for a comment period of not less than 60 days.

(2) REQUESTS FOR A CHANGE IN CLASSIFICATION.—If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 13140 of this title, either deny the request or give notice of an intent to initiate the change under section 13140(g) of this title.

(3) FINAL REGULATION; ESTABLISHING A STANDARD OR TERMINATING DEVELOPMENT OF A STANDARD.—

(A) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of the comments and any report from an advisory committee under paragraph (5), the Secretary shall—

(i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1); or

(ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for the termination.

(B) RECLASSIFICATION OF DEVICE FOR WHICH NOTICE OF TERMINATION OF PROCEEDING IS PUBLISHED.—If a notice of termination is published, the Secretary shall (unless the notice is issued because the device is a banned device under section 13146 of this title) initiate a proceeding under section 13140(g) of

this title to reclassify the device subject to the proceeding terminated by the notice.

(C) EFFECTIVE DATE OF STANDARD.—

(i) IN GENERAL.—A regulation establishing a performance standard shall set forth the date or dates on which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless—

(I) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety; or

(II) the standard has been established for a device that, effective on the effective date of the standard, has been reclassified from class III to class II.

(ii) CONSIDERATION OF DOMESTIC AND INTERNATIONAL TRADE.—The date or dates under clause (i) shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4) AMENDMENT OR REVOCATION OF PERFORMANCE STANDARD.—

(A) IN GENERAL.—The Secretary, on the Secretary's own initiative or on petition of an interested person, may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(C), amend or revoke a performance standard.

(B) EFFECTIVE DATE OF PROPOSED AMENDMENT ON DATE OF PUBLICATION.—The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on the amendment if the Secretary determines that making it so effective is in the public interest.

(C) LIMITATION ON PROHIBITION OF INTRODUCTION OR DELIVERY FOR INTRODUCTION INTO INTERSTATE COMMERCE.—A proposed amendment of a performance standard made effective as described in subparagraph (B) may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device

that conforms to the standard without the change or changes provided by the proposed amendment.

(5) REFERRAL TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—

(i) AUTHORITY.—

(I) IN GENERAL.—The Secretary—

(aa) may, on the Secretary's own initiative, refer a proposed regulation as described in subclause (II) for the establishment, amendment, or revocation of a performance standard; or

(bb) shall, on the request of an interested person, which request demonstrates good cause for referral and which request is made before the expiration of the period for submission of comments on the proposed regulation, refer the proposed regulation as described in subclause (II).

(II) REFERRAL.—The referral of a proposed regulation under item (aa) or (bb) of subclause (I) shall be made to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation that requires the exercise of scientific judgment.

(ii) PROVISION OF DATA AND INFORMATION BY SECRETARY TO ADVISORY COMMITTEE.—If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which the proposed regulation is based.

(iii) RECOMMENDATION.—The advisory committee shall, within 60 days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting the regulation, to-

gether with all underlying data and information and a statement of the reason or basis for the recommendation.

(iv) PUBLIC AVAILABILITY OF RECOMMENDATION.—A copy of the report and recommendation shall be made public by the Secretary.

(B) ESTABLISHMENT OF ADVISORY COMMITTEES.—

(i) IN GENERAL.—The Secretary shall establish advisory committees (which may not be panels under section 13140 of this title) to receive referrals under subparagraph (A).

(ii) QUALIFICATION OF MEMBERS; LIMITATION ON FEDERAL EMPLOYEES.—The Secretary shall appoint as members of any advisory committee under clause (i) individuals who are qualified in the subject matter to be referred to the advisory committee and who are of appropriately diversified professional background, except that the Secretary may not appoint to the advisory committee any individual who is in the regular full-time employ of the United

States and engaged in the administration of this subtitle.

(iii) REPRESENTATION OF CONSUMER AND INDUSTRY INTERESTS.—Each advisory committee established under this subparagraph shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

(iv) COMPENSATION AND TRAVEL EXPENSES RELATING TO CONFERENCES AND MEETINGS.—

(I) IN GENERAL.—Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the maximum rate payable under section 5376 of title 5, for each day (including travel time) they are so engaged.

(II) SERVICE AWAY FROM HOME OR REGULAR PLACE OF BUSINESS.—While serving as described in subclause (I) away from the member's home or regular place of business, each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for individuals in the Government service employed intermittently.

(v) CHAIRPERSON.—The Secretary shall designate one of the members of each advisory committee to serve as chairperson of the advisory committee.

(vi) PERSONNEL; PROCEDURES.—The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such advisory committee in acting on referrals made under subparagraph (A).

(c) RECOGNITION OF STANDARD.—

(1) IN GENERAL.—

(A) PUBLICATION.—In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register (or, with respect to a susceptibility test interpretive criteria standard under section 13138 of this title, by posting on the Interpretive Criteria Website in accordance with that section), recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this subtitle to which the standard is applicable.

(B) DECLARATION OF CONFORMITY.—If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with the standard. A person may elect to use data, or information other than data, required by a standard recog-

nized under subparagraph (A) to meet any requirement regarding devices under this subtitle.

(C) REQUEST FOR RECOGNITION.—

(i) IN GENERAL.—Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard development organization.

(ii) ACTIONS BY SECRETARY.—Not later than 60 calendar days after the Secretary receives a request under clause (i), the Secretary shall—

(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

(II) issue to the person that submitted the request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for the determination.

(iii) PUBLIC AVAILABILITY OF RESPONSE.—The Secretary shall make a re-

sponse issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

(iv) NECESSARY ACTIONS FOR IMPLEMENTATION.—The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

(D) PUBLIC AVAILABILITY OF RATIONALE FOR RECOGNITION.—The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding the recognition.

(2) WITHDRAWAL OF RECOGNITION.—The Secretary may withdraw the recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this subtitle.

(3) ACCEPTANCE OF DECLARATION OF CONFORMITY.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

(i) that the data or information submitted to support the declaration of conformity does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

(B) AUTHORITY OF SECRETARY TO REQUEST DATA OR INFORMATION.—The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

(C) MAINTENANCE OF DATA AND INFORMATION.—A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity

of the device to the standard for a period of 2 years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.

(4) TRAINING.—The Secretary shall provide to all employees of the FDA who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this subtitle, including standards relevant to an employee's area of device review.

(d) ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—

(1) IN GENERAL.—The Secretary shall establish a program under which—

(A) testing laboratories meeting criteria specified in guidance by the Secretary may be accredited, by accreditation bodies meeting criteria specified in guidance by the Secretary, to conduct testing to support the assessment of the conformity of a device to certain standards recognized under this section; and

(B) subject to paragraph (2), results from tests conducted to support the assessment of conformity of devices as described in subparagraph (A) conducted by testing laboratories accredited pursuant to this subsection shall be accepted by the Secretary for purposes of demonstrating the conformity unless the Secretary finds that certain results of those tests should not be so accepted.

(2) SECRETARIAL REVIEW OF ACCREDITED LABORATORY RESULTS.—The Secretary may—

(A) review the results of tests conducted by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of the results or of the processes of accredited bodies or testing laboratories;

(B) following the review, take additional measures under this subtitle, as the Secretary determines appropriate, such as—

(i) suspension or withdrawal of accreditation of a testing laboratory or of recognition of an accreditation body under paragraph (1)(A); or

(ii) requesting additional information with respect to a device; and

(C) if the Secretary becomes aware of information materially bearing on the safety or effectiveness of a device for which an assessment of conformity was supported by testing conducted by a testing laboratory accredited under this subsection, take such additional measures under this subtitle, as the Secretary determines appropriate, such as—

(i) suspension or withdrawal of accreditation of a testing laboratory or of recognition of an accreditation body under paragraph (1)(A); or

(ii) requesting additional information with regard to the device.

(3) REPORT.—The Secretary shall make available on the FDA website an annual report on the progress of the program under this subsection.

**§ 13142. Premarket approval**

(a) REQUIRED PREMARKET APPROVAL FOR CLASS III DEVICES.—

(1) IN GENERAL.—A class III device described in paragraph (2) is required to have, unless exempt under section 13152(g) of this title, an approval under this section of an application for premarket approval or, as applicable, an approval under sub-

section (c)(2) of a report seeking premarket approval.

(2) CLASS III DEVICE.—A class III device is described in this paragraph if the device is—

(A) subject to an order issued under subsection (b) (or a regulation promulgated under that subsection prior to July 9, 2012); or

(B) a class III device because of section 13140(h) of this title.

(b) ORDER TO REQUIRE PREMARKET APPROVAL.—

(1) AUTHORITY.—

(A) IN GENERAL.—In the case of a class III device described in subparagraph (B), the Secretary shall, by administrative order, following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 13140(d) of this title, and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, require that the device have an approval under this section of an application for premarket approval.

(B) CLASS III DEVICE.—A class III device is described in this subparagraph if it—

(i) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(ii) is—

(I) of a type introduced or delivered as described in clause (i); and

(II) is substantially equivalent to another device within that type.

(C) NONDELEGATION.—Authority to issue an administrative order under subparagraph (A) shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) CONTENTS OF PROPOSED ORDER.—A proposed order required under paragraph (1) shall contain—

(A) the proposed order;

(B) proposed findings with respect to—

(i) the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval; and

(ii) the benefit to the public from use of the device;

(C) opportunity for the submission of comments on the proposed order and the proposed findings; and

(D) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(3) ISSUANCE OF ORDER; TERMINATION OF PROCEEDING FOR THE ISSUANCE OF ORDER.—

(A) IN GENERAL.—After the expiration of the period for comment on a proposed order and proposed findings published under paragraph (2), consideration of comments submitted on the proposed order and findings, and a meeting of a device classification panel described in section 13140(d) of this title, the Secretary shall—

(i) issue an administrative order under paragraph (1) and publish in the Federal Register findings on the matters referred to in paragraph (2)(B); or

(ii) publish a notice terminating the proceeding for the issuance of the adminis-

trative order together with the reasons for the termination.

(B) RECLASSIFICATION ON TERMINATION OF PROCEEDING.—If a notice of termination is published, the Secretary shall (unless the notice is issued because the device is a banned device under section 13146 of this title) initiate a proceeding under section 13140(g) of this title to reclassify the device subject to the proceeding terminated by the notice.

(c) APPLICATION FOR PREMARKET APPROVAL.—

(1) IN GENERAL.—Any person may file with the Secretary an application for premarket approval for a class III device. The application for the device shall contain—

(A) full reports of all information, published or known to, or that should reasonably be known to, the applicant, concerning investigations that have been made to show whether or not the device is safe and effective;

(B) a full statement of the components, ingredients, and properties, and of the principle or principles of operation, of the device;

(C) a full description of the methods used in, and the facilities and controls used for, the

manufacture, processing, and, when relevant, packing and installation, of the device;

(D) an identifying reference to any performance standard under section 13141 of this title that would be applicable to any aspect of the device if it were a class II device, and either adequate information to show that the aspect of the device fully meets the performance standard or adequate information to justify any deviation from the standard;

(E) such samples of the device and of components of the device as the Secretary may reasonably require, except that where the submission of the samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more of the devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for the device;

(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. 282(j)(5)(B)) (which shall not be considered an element of the application); and

(H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 13140 of this title, may require.

(2) REPORT SEEKING PREMARKET APPROVAL FOR A CLASS III DEVICE THAT IS A REPROCESSED, SINGLE-USE DEVICE.—

(A) IN GENERAL.—Any person may file with the Secretary a report seeking premarket approval for a class III device referred to in subsection (a) that is a reprocessed single-use device. The report shall contain—

(i) the device name, including both the trade or proprietary name and the common or usual name;

(ii) the establishment registration number of the owner or operator submitting the report;

(iii) actions taken to comply with performance standards under section 13141 of this title;

(iv) proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use;

(v) full reports of all information, published or known to, or that should be reasonably known to, the applicant, concerning investigations that have been made to show whether or not the device is safe or effective;

(vi) a description of the device's components, ingredients, and properties;

(vii) a full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device;

(viii) such samples of the device that the Secretary may reasonably require;

(ix) a financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations;

(x) a statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report;

(xi) any additional data and information, including information of the type required in paragraph (1) for an application under paragraph (1), that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device; and

(xii) validation data described in section 13136(o)(1)(A) of this title that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting the report.

(B) APPLICABILITY OF CERTAIN PROVISIONS.—In the case of a class III device referred to in subsection (a) that is a reprocessed single-use device—

(i) subparagraph (A) applies in lieu of paragraph (1);

(ii) subject to clause (i), the provisions of this section apply to a report under subparagraph (A) to the same extent and in

the same manner as the provisions apply to an application under paragraph (1);

(iii) each reference in other sections of this subtitle to an application under this section, other than such a reference in section 17916 or 17917 of this title, shall be considered to be a reference to a report under subparagraph (A); and

(iv) each reference in other sections of this subtitle to a device for which an application under this section has been approved, or has been denied, suspended, or withdrawn, other than such a reference in section 17916 or 17917 of this title, shall be considered to be a reference to a device for which a report under subparagraph (A) has been approved, or has been denied, suspended, or withdrawn, respectively.

(3) REFERRAL OF APPLICATION TO CLASSIFICATION PANEL.—

(A) IN GENERAL.—

(i) AUTHORITY.—On receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(I) may, on the Secretary's own initiative, refer the application as described in clause (ii); or

(II) shall, on the request of an applicant, unless the Secretary finds that the information in the application that would be reviewed by a panel substantially duplicates information that has previously been reviewed by a panel appointed under section 13140 of this title, refer the application as described in clause (ii).

(ii) REFERRAL.—The referral of an application under subclause (I) or (II) of clause (i) shall be made to the appropriate panel under section 13140 of this title for study and for submission (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

(B) INVOLVEMENT OF PEDIATRIC EXPERTS.—If appropriate, the Secretary shall ensure that the panel under subparagraph (A) in-

cludes, or consults with, 1 or more pediatric experts.

(4) REVIEW OF APPLICATION PRIOR TO SUBMISSION.—

(A) IN GENERAL.—Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that this requirement does not apply, and the Secretary may accept and review the portion, during any period in which, under section 17917(g) of this title, the Secretary does not have the authority to collect fees under section 17917(a) of this title.

(B) FURTHER REVIEW ON RECEIPT OF APPLICATION.—Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless a significant issue of safety or effectiveness provides the Secretary reason to review the accepted portion.

(C) DEFICIENCIES IN SUBMISSION.—If the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in the portion and identify the information that is required to correct the deficiencies, unless the applicant is no longer pursuing the application.

(5) REQUEST FOR ADDITIONAL INFORMATION; LEAST BURDENSOME APPROACH.—

(A) IN GENERAL.—

(i) DEFINITION OF NECESSARY.—In clause (ii), the term ''necessary'' means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

(ii) CONSIDERATION OF LEAST BURDENSOME APPROACH.—In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a

reasonable assurance of device safety and effectiveness.

(B) POSTMARKET INFORMATION.—For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

(C) EFFECT OF PARAGRAPH ON STANDARDS FOR PREMARKET APPROVAL.—Nothing in this paragraph alters the standards for premarket approval of a device.

(d) ACTION ON APPLICATION FOR PREMARKET APPROVAL.—

(1) APPROVAL OR DENIAL OF APPROVAL OF APPLICATION.—

(A) AUTHORITY.—

(i) IN GENERAL.—As promptly as possible, but not later than 180 days after the receipt of an application under subsection (c) (except as provided in section 13152(l)(3)(D)(ii) of this title or unless, in accordance with subparagraph (B)(i), an additional period is agreed on by the Secretary and the applicant), the Secretary,

after considering the report and recommendation submitted under subsection (c)(2), shall—

(I) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in paragraph (2) applies; or

(II) deny approval of the application if the Secretary finds (and sets forth the basis for the finding as part of or accompanying the denial) that 1 or more grounds for denial specified in paragraph (2) apply.

(ii) RELIANCE ON CONDITIONS OF USE IN PROPOSED LABELING.—

(I) IN GENERAL.—In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the pro-

posed labeling is neither false nor misleading.

(II) DETERMINATION WHETHER LABELING IS FALSE OR MISLEADING.—In determining whether or not the labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

(B) CONDUCT OF ACTIONS BY SECRETARY.—

(i) EXTENSIONS.—The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application submitted for a device subject to an order issued under subsection (b) unless the Secretary finds that the continued availability of the device is necessary for the public health.

(ii) RESTRICTED SALE CONDITION.—An order approving an application for a device may require as a condition to the approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a de-

vice may be restricted under a regulation under section 13152(e) of this title.

(iii) DATA AND INFORMATION TO BE ACCEPTED AND REVIEWED.—The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 13152(g) of this title to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)), and the modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

(II) the data or information relates to a device approved under this section, is available for use under this subtitle, and is relevant to the design and intended use of the device for which the application is pending.

(2) DENIAL OF APPROVAL OF APPLICATIONS.—

(A) IN GENERAL.—The Secretary shall deny approval of an application for a device if, on the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to the device, the Secretary finds that—

(i) there is a lack of a showing of reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling of the device;

(ii) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling of the device;

(iii) the methods used in, or the facilities or controls used for, the manufacture,

processing, packing, or installation of the device do not conform to the requirements of section 13152(f) of this title;

(iv) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(v) the device is not shown to conform in all respects to a performance standard in effect under section 13141 of this title, compliance with which is a condition to approval of the application, and there is a lack of adequate information to justify the deviation from the standard.

(B) STATEMENT TO ACCOMPANY DENIAL.—Any denial of an application shall, to the extent that the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place the application in approvable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(3) MEETING ON REQUEST BY APPLICANT AFTER RECEIPT OF APPLICATION.—

(A) REQUEST.—

(i) IN GENERAL.—The Secretary shall, on the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

(ii) DESCRIPTION OF DEFICIENCIES.—The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

(iii) NOTIFICATION OF ADDITIONAL DEFICIENCIES.—The Secretary shall notify the applicant promptly of—

(I) any additional deficiency identified in the application, which deficiency was not described as a deficiency in the written description provided by the Secretary under clause (ii); or

(II) any additional information required to achieve completion of the review and final action on the application, which information was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) SCHEDULE OF MEETING BY MUTUAL CONSENT.—The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

(4) REVIEW OF DENIALS AND APPROVALS.—An applicant whose application has been denied approval may, by petition filed on or before the 30th day after the date on which the applicant receives notice of the denial, obtain review of the denial in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

(5) CHANGE TO A DEVICE.—

(A) SUPPLEMENTAL APPLICATION OR WRITTEN NOTICE REQUIRED.—

(i) IN GENERAL.—Unless the change is consistent with a predetermined change control plan approved under section 13145 of this title, a supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless the change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 13152(f) of this title.

(ii) DATE ON WHICH DEVICE WITH MANUFACTURING CHANGE MAY BE DISTRIBUTED.—

(I) IN GENERAL.—The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days

after the date on which the Secretary receives the notice, unless the Secretary, within the 30-day period, notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of the change.

(II) NOTIFICATION THAT SUPPLEMENTAL APPLICATION IS REQUIRED.—If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement.

(III) ADJUSTMENTS TO REVIEW PERIOD.—The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

(B) APPROVAL OF SUPPLEMENT.—

(i) IN GENERAL.—Subject to clause (ii), in reviewing a supplement to an ap-

proved application, which supplement is for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve the supplement if—

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

(ii) ADDITIONAL CLINICAL DATA.—The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

(e) WITHDRAWAL AND TEMPORARY SUSPENSION OF APPROVAL OF APPLICATION.—

(1) WITHDRAWAL.—The Secretary shall, on obtaining, where appropriate, advice on scientific matters from a panel or panels under section 13140 of this title, and after due notice and opportunity for informal hearing provided to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

(A) that the device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling of the device;

(B) on the basis of new information before the Secretary with respect to the device, evaluated together with the evidence available to the Secretary when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling of the device;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 13151(a) of this title;

(ii) has refused to permit access to, or copying or verification of, the records as required by section 17504 of this title; or

(iii) has not complied with the requirements of section 13136 of this title;

(E) on the basis of new information before the Secretary with respect to the device, evaluated together with the evidence before the Secretary when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of the device do not conform with the requirements of section 13152(f) of this title and were not brought into conformity with the requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(F) on the basis of new information before the Secretary, evaluated together with the evi-

dence before the Secretary when the application was approved, that the labeling of the device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of that fact; or

(G) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, that the device is not shown to conform in all respects to a performance standard that is in effect under section 13141 of this title, compliance with which was a condition to approval of the application, and that there is a lack of adequate information to justify the deviation from the standard.

(2) REVIEW OF WITHDRAWAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the 30th day after the date on which the holder receives notice of the withdrawal, obtain review of the withdrawal in accordance with either paragraph (1) or (2) of subsection (g).

(3) TEMPORARY SUSPENSION OF APPROVAL.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall, by order, temporarily suspend the approval of the application approved under this section. If the Secretary issues the order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw the application.

(f) PRODUCT DEVELOPMENT PROTOCOL.—

(1) COMPLETION OF TESTING IN ACCORDANCE WITH PRODUCT DEVELOPMENT PROTOCOL DEEMED AS APPROVAL OF CLASS III DEVICE.—In the case of a class III device that is required to have an approval of an application submitted under subsection (c), the device shall be considered as having the approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) SUBMISSION OF PROPOSED PRODUCT DEVELOPMENT PROTOCOL.—

(A) IN GENERAL.—Any person may submit to the Secretary a proposed product development protocol with respect to a device. The protocol shall be accompanied by data supporting the protocol.

(B) REFERRAL TO CLASSIFICATION PANEL.—If, within 30 days of the receipt of the protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, the Secretary—

(i) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 13140 of this title for its recommendation respecting approval of the protocol; or

(ii) shall so refer the protocol on the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data that would be reviewed by the panel substantially duplicate a product development protocol and accompanying data that have previously been reviewed by such a panel.

(3) REQUIREMENTS FOR APPROVAL OF PROPOSED PRODUCT DEVELOPMENT PROTOCOL.—A proposed product development protocol for a device may be approved only if—

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c); and

(B) the Secretary determines that the proposed protocol provides—

(i) a description of the device and the changes that may be made in the device;

(ii) a description of the preclinical trials (if any) of the device and a specification of—

(I) the results from the preclinical trials to be required before the commencement of clinical trials of the device; and

(II) any permissible variations in preclinical trials and the results from the preclinical trials;

(iii) a description of the clinical trials (if any) of the device and a specification of—

(I) the results from the clinical trials to be required before the filing of a notice of completion of the requirements of the protocol; and

(II) any permissible variations in the clinical trials and the results from the clinical trials;

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture, processing, and, when relevant, packing and installation of the device;

(v) an identifying reference to any performance standard under section 13141 of this title to be applicable to any aspect of the device;

(vi) if appropriate, specimens of the labeling proposed to be used for the device;

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the ap-

propriate panel or panels under section 13140 of this title, may require; and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol, which records are adequate to show compliance with the protocol.

(4) APPROVAL OR DENIAL OF APPROVAL OF PROPOSED PRODUCT DEVELOPMENT PROTOCOL.—

(A) DATE BY WHICH SECRETARY IS TO APPROVE OR DENY PROPOSED PRODUCT DEVELOPMENT PROTOCOL.—The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within 120 days of its receipt unless an additional period is agreed on by the Secretary and the person that submitted the protocol.

(B) FINAL AGENCY ACTION.—Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5.

(5) COMPLETION OF PROTOCOL.—At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the

person for whom the protocol was approved may submit a notice of completion—

(A) stating—

(i) the person's determination that the requirements of the protocol have been fulfilled and that, to the best of the person's knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective; and

(ii) the data and other information on which the determination was made; and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

(6) FINAL ORDERS RELATING TO COMPLETION OF PROTOCOL.—

(A) REVOCATION OF APPROVED PROTOCOL.—The Secretary may, after providing the person that has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of the protocol, issue a final order to revoke the protocol if the Secretary finds that—

(i) the person has failed substantially to comply with the requirements of the protocol;

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified; or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) DECLARATION THAT PROTOCOL IS COMPLETED OR NOT COMPLETED.—

(i) IN GENERAL.—After the receipt of a notice of completion of an approved protocol, the Secretary shall, within the 90-day period beginning on the date the notice is received, by order, either declare the protocol completed or declare it not completed.

(ii) OPPORTUNITY FOR INFORMAL HEARING RELATING TO DECLARATIONS THAT PROTOCOL IS NOT COMPLETED.—An order declaring a protocol not completed

may take effect only after the Secretary has provided the person that has the protocol opportunity for an informal hearing on the order.

(iii) FINDINGS REQUIRED TO ISSUE ORDER OF DECLARATION THAT PROTOCOL IS NOT COMPLETED.—An order declaring a protocol not completed may be issued only if the Secretary finds that—

(I) the person has failed substantially to comply with the requirements of the protocol;

(II) the results of the trials obtained under the protocol differ substantially from the results required by the protocol; or

(III) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling of the device.

(C) FINAL ORDER TO BE IN WRITING AND TO CONTAIN REASONS.—A final order issued under subparagraph (A) or (B) shall be in writ-

ing and shall contain the reasons to support the conclusions of the final order.

(7) REVOCATION OF APPROVAL OF DEVICE PROVIDED BY NOTICE OF COMPLETION.—At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing provided to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion that has become effective as provided in paragraph (6)(B) if the Secretary finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) apply. Each reference in the subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of the protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) REVIEW OF ORDER REVOKING PROTOCOL, DECLARING PROTOCOL NOT COMPLETED, OR REVOKING APPROVAL OF DEVICE.—A person that has an approved protocol subject to an order issued under paragraph (6)(A) revoking the protocol, a person

that has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the 30th day after the date on which the person receives notice of the order, obtain review of the order in accordance with either paragraph (1) or (2) of subsection (g).

(g) REVIEW.—

(1) HEARING ON PETITION FOR REVIEW.—

(A) ORDERS PETITIONED FOR REVIEW.—The Secretary shall hold a hearing as described in subparagraph (B) on petition for review of—

(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application; or

(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device.

(B) REQUIRED HEARING.—On petition for review of any order described in subparagraph (A), the Secretary shall, unless the Secretary finds the petition to be without good cause or unless a petition for review of the order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5, on the order.

(C) PANEL MEMBER DESIGNATED TO TESTIFY AT HEARING.—The panel or panels that considered the application, protocol, or device subject to the order shall designate a member to appear and testify at any hearing under subparagraph (B) on request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any hearing under subparagraph (B).

(D) ISSUANCE OF ORDER AFTER HEARING.—On completion of the hearing and after considering the record established in the hearing, the Secretary shall issue an order affirming the order subject to the hearing or reversing the order and, as appropriate, approving or denying

approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2) REFERRAL ON PETITION FOR REVIEW.—

(A) IN GENERAL.—

(i) ORDERS SUBJECT TO REFERRAL.—The Secretary shall make the referral under clause (ii) on petition for review of—

(I) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application; or

(II) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device.

(ii) REQUIRED REFERRAL.—On petition for review of any order under clause (i), the Secretary shall refer the application or protocol subject to the order and

the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order.

(iii) REPORT AND RECOMMENDATION.—The advisory committee shall, after independent study of the data and information furnished to the advisory committee by the Secretary and other data and information before the advisory committee, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation.

(iv) AVAILABILITY OF REPORT TO PETITIONER.—A copy of the report under clause (iii) shall be promptly supplied by the Secretary to any person that petitioned for the referral to the advisory committee.

(B) ADVISORY COMMITTEES.—

(i) ESTABLISHMENT.—The Secretary shall establish advisory committees (which may not be panels under section 13140 of

this title) to receive referrals under subparagraph (A).

(ii) QUALIFICATION OF MEMBERS; LIMITATION ON FEDERAL EMPLOYEES.—The Secretary shall appoint as members of any advisory committee under clause (i) individuals who are qualified in the subject matter to be referred to the advisory committee and who are of appropriately diversified professional backgrounds, except that the Secretary may not appoint to the advisory committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this subtitle.

(iii) COMPENSATION AND TRAVEL EXPENSES RELATING TO CONFERENCES AND MEETINGS.—

(I) IN GENERAL.—Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of the advisory committee or otherwise serving at the request of the Secretary, shall be entitled to re-

ceive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent for the maximum rate payable under section 5376 of title 5 for each day (including travel time) they are so engaged.

(II) SERVICE AWAY FROM HOME OR REGULAR PLACE OF BUSINESS.—While serving as described in subclause (I) away from the member's home or regular place of business, each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for individuals in the Government service employed intermittently.

(iv) CHAIRPERSON.—The Secretary shall designate the chairperson of an advisory committee from its members.

(v) PERSONNEL; PROCEDURES.—The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the proce-

dures to be followed by each advisory committee in acting on referrals made under subparagraph (A).

(C) PUBLIC AVAILABILITY OF REPORT AND RECOMMENDATION; AFFIRMING OR REVERSING ORDER REFERRED TO ADVISORY COMMITTEE.—The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall, by order, stating the reasons for the order, either affirm the order referred to the advisory committee or reverse the order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

(h) SERVICE OF ORDERS.—Orders of the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(i) REVISION.—

(1) ORDER RELATING TO DEVICES INTRODUCED OR DELIVERED FOR INTRODUCTION INTO INTERSTATE COMMERCE BEFORE MAY 28, 1976.—

(A) IN GENERAL.—Before December 1, 1995, the Secretary shall, by order, require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting the devices, including adverse safety or effectiveness information that has not been submitted under section 13151 of this title.

(B) AUTHORITY TO REQUIRE SUBMISSION OF SAFETY AND EFFECTIVENESS DATA.—The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if the data are available to the manufacturer.

(2) ADMINISTRATIVE ORDER REVISING CLASSIFICATION.—

(A) ISSUANCE FOR EACH DEVICE.—After the issuance of an order under paragraph (1) but before the date that is 2 years after July 9, 2012, the Secretary shall issue an administrative order described in subparagraph (B) following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 13140(d) of this title, and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, for each device—

(i) that the Secretary classified as a class III device; and

(ii) for which no administrative order was issued under subsection (b) (or no regulation was promulgated under subsection (b) prior to July 9, 2012).

(B) ADMINISTRATIVE ORDER.—An administrative order described in this subparagraph is an administrative order revising the classification of the device referred to in subparagraph (A) so that the device is classified in class I or class II, unless the administrative order issued

under this paragraph requires the device to remain in class III.

(C) APPLICATION OF CRITERIA IN DETERMINING WHETHER TO REVISE CLASSIFICATION.—In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 13140(c) of this title.

(3) SCHEDULE OF ISSUANCE OF ADMINISTRATIVE ORDER FOR DEVICES REQUIRED TO REMAIN IN CLASS III.—The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the order requiring a device to remain in class III, establish a schedule for the issuance of an administrative order under subsection (b) for each device that is subject to the order requiring the device to remain in class III.

**§ 13143. Pediatric uses of devices**

(a) DEFINITION OF PEDIATRIC SUBPOPULATION.—In this section, the term ''pediatric subpopulation'' has the meaning given the term in section 13152(m)(6)(A)(iii) of this title.

(b) NEW DEVICES.—

(1) IN GENERAL.—A person that submits to the Secretary an application under section 13152(m) of this title, or an application (or supplement to an application) or a product development protocol under section 13142 of this title, shall include in the application or protocol the information described in paragraph (2).

(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(B) the number of affected pediatric patients.

(3) ANNUAL REPORT.—

(A) IN GENERAL.—The Secretary shall annually submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

(i) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

(ii) any information, based on a review of data available to the Secretary, regarding devices used in pediatric patients but not labeled for that use for which the Secretary determines that approved pediatric labeling could confer a benefit to pediatric patients;

(iii) the number of pediatric devices that receive a humanitarian use exemption under section 13152(m) of this title;

(iv) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

(v) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 17917(a)(2)(B)(v) of this title;

(vi) the review time for each device described in clauses (i), (iii), (iv), and (v);

(vii) the number of devices for which the Secretary relied on data with respect to adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients; and

(viii) the number of devices for which the Secretary relied on data from 1 pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.

(B) DISAGGREGATION OF NUMBER OF DEVICES BY PEDIATRIC SUBPOPULATION.—For the items described in this paragraph, the report shall disaggregate the number of devices by pediatric subpopulation.

(c) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR CONDITION OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used

to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from 1 subpopulation can be extrapolated to another subpopulation.

**§ 13144. Breakthrough devices**

(a) PURPOSE.—The purpose of this section is to encourage the Secretary, and to provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the FDA's review of, devices that represent breakthrough technologies.

(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

(2)(A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients.

(c) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate a device described in subsection (b) for expedited development and priority review under this section. The request for designation may be made at any time prior to the submission of an application under section 13142(c) of this title, a notification under section 13136(k) of this title, or a petition for classification under section 13140(h)(2) of this title.

(d) DESIGNATION PROCESS.—

(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Sec-

retary shall designate the device for expedited development and priority review.

(2) REVIEW.—Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the FDA.

(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

(A) was designated under this section; or

(B) was given priority review under section 13142(d)(5) of this title, as in effect prior to December 13, 2016.

(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (d), the Secretary shall—

(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (c) for the device;

(C) adopt an efficient process for timely dispute resolution;

(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend the external experts;

(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the spon-

sor) for applications submitted under section 13142(c) of this title; and

(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 13152(g) of this title.

(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

(A) coordinate with the sponsor regarding early agreement on a data development plan;

(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to ap-

plication for approval under section 13142(c) of this title; and

(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

(i) changes to the protocols agreed to in writing by the sponsor and the Secretary; or

(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of the device exists, provided that the decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

(f) PRIORITY REVIEW GUIDANCE.—

(1) CONTENT.—Not later than 1 year after December 13, 2016, the Secretary shall issue guidance on the implementation of this section. The guidance shall—

(A) set forth the process by which a person may seek a designation under subsection (d);

(B) provide a template for requests under subsection (c);

(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for the personnel to ensure effective and efficient review.

(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a draft version of that guidance.

(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

(1) the criteria and standards for evaluating an application pursuant to section 13142(c) of this title, a report and request for classification under section 13140(h)(2) of this title, or a report under section 13136(k) of this title, including the recognition of valid scientific evidence as described in sec-

tion 13140(c)(4)(B) of this title and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

(2) the authority of the Secretary with respect to clinical holds under section 13152(g)(8)(A) of this title;

(3) the authority of the Secretary to act on an application pursuant to section 13142(d) of this title before completion of an establishment inspection, as the Secretary determines appropriate; or

(4) the authority of the Secretary with respect to postmarket surveillance under sections 13151(g) and 13154 of this title.

**§ 13145. Predetermined change control plans for devices**

(a) APPROVED DEVICES.—

(1) IN GENERAL.—Notwithstanding section 13142(d)(5)(A) of this title, a supplemental application shall not be required for a change to a device approved under section 13142 of this title, if the change is consistent with a predetermined change control plan that is approved pursuant to paragraph (2).

(2) PREDETERMINED CHANGE CONTROL PLAN.—The Secretary may approve a predetermined change control plan submitted in an application, including a supplemental application, under section 13142 of this title that describes planned changes that may be made to the device (and that would otherwise require a supplemental application under section 13142 of this title), if the device remains safe and effective without any change.

(3) SCOPE.—The Secretary may require that a change control plan include labeling required for safe and effective use of the device as the device changes pursuant to the plan, notification requirements if the device does not function as intended pursuant to the plan, and performance requirements for changes made under the plan.

(b) CLEARED DEVICES.—

(1) IN GENERAL.—Notwithstanding section 13136(k) of this title, a premarket notification shall not be required for a change to a device cleared under section 13136(k) of this title, if the change is consistent with an established predetermined change control plan granted pursuant to paragraph (2).

(2) PREDETERMINED CHANGE CONTROL PLAN.—The Secretary may clear a predetermined

change control plan submitted in a notification submitted under section 13136(k) of this title that describes planned changes that may be made to the device (and that would otherwise require a new notification), if—

(A) the device remains safe and effective without any of those planned changes; and

(B) the device would remain substantially equivalent to the predicate.

(3) SCOPE.—The Secretary may require that a change control plan include labeling required for safe and effective use of the device as the device changes pursuant to the plan, notification requirements if the device does not function as intended pursuant to the plan, and performance requirements for changes made under the plan.

(c) PREDICATE DEVICES.—In making a determination of substantial equivalence pursuant to section 13140(b) of this title, the Secretary shall not compare a device to changed versions of a device implemented in accordance with an established predetermined change control plan as a predicate device. Only the version of the device cleared or approved, prior to changes made under the predetermined change control plan, may be used by a sponsor as a predicate device.

**§ 13146. Banned devices**

(a) IN GENERAL.—

(1) FINDINGS BY SECRETARY.—The Secretary may act as described in paragraph (2) whenever the Secretary finds, on the basis of all available data and information, that—

(A) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury for 1 or more intended uses; and

(B) in the case of substantial deception or an unreasonable and substantial risk of illness or injury that the Secretary determined could be corrected or eliminated by labeling or a change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce the risk, and the period within which the labeling or change in labeling was to be done, the labeling or change in labeling was not done within the period.

(2) ACTION BY SECRETARY.—

(A) IN GENERAL.—Whenever the Secretary makes the findings described in paragraph (1),

the Secretary may initiate a proceeding to promulgate a regulation to make the device a banned device or to make the intended use or uses a banned intended use or uses.

(B) NOT A LEGALLY MARKETED DEVICE.—A device that is banned for 1 or more intended uses is not a legally marketed device under section 10323 of this title when intended for those uses.

(b) SPECIAL EFFECTIVE DATE.—

(1) IN GENERAL.—The Secretary may declare a proposed regulation under subsection (a) to be effective on its publication in the Federal Register and until the effective date of any final action taken respecting the regulation if—

(A) the Secretary determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device that is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals; and

(B) before the date of the publication of the regulation, the Secretary notifies the manufacturer of the device that the regulation is to

be made effective as described in this paragraph.

(2) CONDITIONS.—If the Secretary makes a proposed regulation effective as described in paragraph (1), the Secretary shall, as expeditiously as possible, give interested persons prompt notice of the Secretary's action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and affirm, modify, or revoke the proposed regulation.

**§ 13147. Judicial review**

(a) DEFINITION OF RECORD.—In this section, the term ''record'' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to the regulation or order, proceedings of any panel or advisory committee with respect to the regulation or order, any hearing held with respect to the regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to the regulation or order, as being relevant to the regulation or order.

(b) PETITION.—

(1) IN GENERAL.—

(A) TIMEFRAME.—A person described in subparagraph (B) may file a petition as described in subparagraph (B) not later than 30 days after—

(i) the promulgation of a regulation under section 13140 of this title classifying a device in class I, an administrative order changing the classification of a device to class I, or an order under section 13140(h)(2) of this title reclassifying a device or denying a petition for reclassification of a device;

(ii) the promulgation of a regulation under section 13141 of this title establishing, amending, or revoking a performance standard for a device;

(iii) the issuance of an order under section 13141(b)(2) of this title denying a request for reclassification of a device;

(iv) the issuance of an order under section 13142(b)(3) of this title requiring a device to have an approval of a premarket application or an order pursuant to paragraph (1) or (2)(C) of section 13142(g) of this title;

(v) the promulgation of a regulation under section 13146 of this title (other than a proposed regulation made effective under subsection (b) of that section on the regulation's publication) making a device a banned device;

(vi) the issuance of an order under section 13152(f)(2) of this title;

(vii) an order under section 13152(g)(4) of this title disapproving an application for an exemption of a device for investigational use or an order under section 13152(g)(5) of this title withdrawing such an exemption for a device;

(viii) an order pursuant to section 13140(b) of this title; or

(ix) a regulation under section 13142(i)(2) or 13152(l)(4)(B) of this title.

(B) FILING.—Any person adversely affected by a regulation or order described in subparagraph (A) may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides or in which the person's principal

place of business is located for judicial review of the regulation or order.

(2) TRANSMISSION BY CLERK.—A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose.

(3) FILING OF RECORD.—The Secretary shall file in the court the record of the proceedings on which the Secretary based the Secretary's regulation or order as provided in section 2112 of title 28.

(c) ADDITIONAL DATA, VIEWS, AND ARGUMENTS.—

(1) IN GENERAL.—If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that the additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce the data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions.

(2) MODIFICATION OF FINDINGS; MAKING NEW FINDINGS.—The Secretary may modify the Sec-

retary's findings, or make new findings by reason of the additional data, views, or arguments taken under paragraph (1) and shall file with the court the modified or new findings, and the Secretary's recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of the additional data, views, or arguments.

(d) STANDARD FOR REVIEW.—On the filing of the petition under subsection (b) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5. A regulation described in clause (ii) or (v) of subsection (b)(1)(A) or an order issued after the review provided by section 13142(g) of this title shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

(e) FINALITY OF JUDGMENTS.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States on certiorari or certification, as provided in section 1254 of title 28.

(f) REMEDIES.—The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

(g) STATEMENT OF REASONS.—To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 13140, 13141, 13142, 13146, 13149, 13151, 13152, or 13153 of this title, each of those regulations or orders shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

**§ 13148. Agency documentation and review of significant decisions regarding devices**

(a) DOCUMENTATION OF RATIONALE FOR SIGNIFICANT DECISIONS.—

(1) IN GENERAL.—The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 13136(k) of this title, a petition for classification under section 13140(h) of this title, an application under section 13142 of this title, or an application for an exemption under section 13152(g) of this title, including documentation of significant con-

troversies or differences of opinion and the resolution of the controversies or differences of opinion.

(2) PROVISION OF DOCUMENTATION.—On request, the Secretary shall furnish the substantive summary to the person that is seeking to submit, or that has submitted, the report or application.

(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with subsections (b)(1)(D) and (c)(4)(D) of section 13140 of this title and section 13142(c)(5) of this title, as applicable.

(b) REVIEW OF SIGNIFICANT DECISIONS.—

(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—Any person may request a supervisory review of the significant decision described in subsection (a)(1). The review may be conducted at the next supervisory level or higher above the individual who made the significant decision.

(2) SUBMISSION OF REQUEST.—A person requesting a supervisory review under paragraph (1) shall submit the request to the Secretary not later than 30 days after the decision and shall indicate in

the request whether the person seeks an in-person meeting or a teleconference review.

(3) TIMEFRAME.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after the request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person that requests an in-person meeting or teleconference, 30 days after the meeting or teleconference.

(B) EXCEPTION.—Subparagraph (A) shall not apply in cases that are referred to experts outside of the FDA.

**§ 13149. Notification and other remedies**

(a) NOTIFICATION.—

(1) IN GENERAL.—The Secretary may issue such order as may be necessary to ensure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use a device and to any

other person (including manufacturers, importers, distributors, retailers, and device users) that should properly receive the notification in order to eliminate the risk described in subparagraph (A), if the Secretary determines that—

(A) the device, which is intended for human use, and which is introduced or delivered for introduction into interstate commerce for commercial distribution, presents an unreasonable risk of substantial harm to the public health; and

(B) notification under this subsection is necessary to eliminate the unreasonable risk of substantial harm and no more practicable means is available under this subtitle (other than this section) to eliminate the risk.

(2) INDIVIDUALS AT RISK.—An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to the individuals would present a greater danger to the health of the individuals than no such notification.

(3) HEALTH PROFESSIONALS.—If the Secretary makes a determination under paragraph (2) with respect to individuals described in paragraph (2), the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action that may be taken by or on behalf of the individuals to eliminate or reduce the risk.

(4) CONSULTATION WITH PERSONS TO GIVE NOTICE.—Before issuing an order under this subsection, the Secretary shall consult with the persons that are to give notice under the order.

(b) REPAIR, REPLACEMENT, OR REFUND.—

(1) PLAN.—

(A) ORDER TO SUBMIT A PLAN.—

(i) IN GENERAL.—The Secretary may order the manufacturer, importer, or any distributor of a device, or any combination of those persons, to submit to the Secretary, within a reasonable time, a plan for taking 1 or more of the actions described in paragraph (2) if, after affording oppor-

tunity for an informal hearing, the Secretary determines that—

(I) the device, which is intended for human use and which is introduced or delivered for introduction into interstate commerce for commercial distribution, presents an unreasonable risk of substantial harm to the public health;

(II) there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture;

(III) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device; and

(IV) the notification authorized by subsection (a) would not by itself

be sufficient to eliminate the unreasonable risk and action described in paragraph (2) is necessary to eliminate the risk.

(ii) SPECIFICATION OF RESPONSIBILITIES IN ORDERS DIRECTED TO MORE THAN 1 PERSON.—An order issued under clause (i) that is directed to more than 1 person shall specify which person may decide which action shall be taken under the plan and the person specified shall be the person that the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears the responsibility or the Secretary determines that the protection of the public health requires that the decision be made by a person (including a device user or health professional) other than the person the Secretary determines bears the responsibility.

(B) APPROVAL OR DISAPPROVAL OF PLAN.—

(i) IN GENERAL.—The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless the Secretary determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which the action or actions are to be taken under the plan will not ensure that the unreasonable risk with respect to which the order was issued will be eliminated.

(ii) DISAPPROVAL.—

(I) REVISED PLAN.—If the Secretary disapproves a plan, the Secretary shall order a revised plan to be submitted to the Secretary within a reasonable time.

(II) REVISED PLAN UNSATISFACTORY OR NOT SUBMITTED.—If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary

within the prescribed time, the Secretary shall—

(aa) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed; or

(bb) after affording an opportunity for an informal hearing, by order, prescribe a plan to be carried out by a person that is a manufacturer, importer, distributor, or retailer of the device with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

(2) ACTIONS AUTHORIZED UNDER PLAN.—The actions that may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

(A) To repair the device so that the device does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

(B) To replace the device with a like or equivalent device that is in conformity with all applicable requirements of this subtitle.

(C) To refund the purchase price of the device (less a reasonable allowance for use if the device has been in the possession of the device user for 1 year or more at the time of notification ordered under subsection (a) or at the time the device user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1), whichever first occurs).

(3) AVAILING OF REMEDIES.—No charge shall be made to any person (other than a manufacturer, importer, distributor, or retailer) for availing itself or one's self of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a manufacturer, importer, distributor, or retailer) that is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by the person in availing itself or one's self of the remedy.

(c) REIMBURSEMENT.—An order issued under subsection (b) with respect to a device may require any person

that is a manufacturer, importer, distributor, or retailer of the device to reimburse any other person that is a manufacturer, importer, distributor, or retailer of the device for that other person's expenses actually incurred in connection with carrying out the order if the Secretary determines that the reimbursement is required for the protection of the public health. The requirement to reimburse shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making the reimbursement is a party.

(d) EFFECT ON OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in the action of any remedy provided to the plaintiff under the order shall be taken into account.

(e) RECALL AUTHORITY.—

(1) ORDER TO CEASE DISTRIBUTION.—

(A) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers,

importers, distributors, or retailers of the device)—

(i) to immediately cease distribution of the device; and

(ii) to immediately notify health professionals and device user facilities of the order and to instruct the health professionals and device user facilities to cease use of the device.

(B) HEARING.—The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of the device.

(C) INADEQUATE GROUNDS; VACATING OF AN ORDER.—If, after providing an opportunity for a hearing under subparagraph (B), the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2) AMENDING AN ORDER TO INCLUDE RECALL.—

(A) IN GENERAL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subclauses (I) and (II) of subparagraph (B)(i), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) CONTENTS OF AMENDED ORDER.—An amended order under subparagraph (A)—

(i) shall—

(I) not include recall of a device from individuals; and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling the device from the device user facilities presents a greater health risk than the health risk of not recalling the device from use; and

(ii) shall provide for notice to individuals subject to the risks associated with the use of the device.

(C) NOTICE TO INDIVIDUALS.—In providing the notice required by subparagraph (B)(ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of the individuals cannot be identified, the Secretary shall notify the individuals pursuant to section 17505(b) of this title.

(3) RECALL AS ADDITIONAL REMEDY.—The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

**§ 13150. Program to improve the device recall system**

(a) DEFINITION OF RECALL.—In this section, the term ''recall'' means—

(1) the removal from the market of a device pursuant to an order of the Secretary under subsection (b) or (e) of section 13149 of this title; or

(2) the correction or removal from the market of a device at the initiative of the manufacturer or importer of the device that is required to be reported to the Secretary under section 13151(f) of this title.

(b) IN GENERAL.—The Secretary shall—

(1) establish a program to routinely and systematically assess information relating to device recalls and use the information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices;

(2) clarify procedures for conducting device recall audit checks to improve the ability of investigators to perform those checks in a consistent manner;

(3) develop detailed criteria for assessing whether a person performing a device recall has performed an effective correction or action plan for the recall; and

(4) document the basis for each termination by the FDA of a device recall.

(c) ASSESSMENT CONTENT.—The program established under subsection (b)(1) shall, at a minimum, identify—

(1) trends in the number and types of device recalls;

(2) devices that are most frequently the subject of a recall; and

(3) underlying causes of device recalls.

**§ 13151. Records and reports on devices**

(a) IN GENERAL.—

(1) REGULATIONS.—Each person that is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to ensure that the device is not adulterated or misbranded and to otherwise ensure its safety and effectiveness. Regulations prescribed under this paragraph—

(A) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(i) may have caused or contributed to a death or serious injury; or

(ii) has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, which report under this clause—

(I) shall be submitted in accordance with part 803 of title 21, Code

of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under the regulations pursuant to section 803.19 of title 21, Code of Federal Regulations (or successor regulations), if the device involved is—

(aa) a class III device;

(bb) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

(cc) a type of device that the Secretary has, by notice published in the Federal Register or letter to the person that is the manufacturer or importer of the device, indicated should be subject to part 803 of title 21, Code of Federal Regulations (or successor regulations), in order to protect the public health;

(II) shall, if the device is not subject to subclause (I), be submitted in

accordance with criteria established by the Secretary for reports made pursuant to this subclause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

(III) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations);

(B) shall define the term ''serious injury'' to mean an injury that—

(i) is life threatening;

(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

(iii) necessitates medical or surgical intervention to preclude permanent impair-

ment of a body function or permanent damage to a body structure;

(C) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(D) shall not impose requirements unduly burdensome to a device manufacturer or importer taking into account the manufacturer's or importer's cost of complying with the requirements and the need for the protection of the public health and the implementation of this subtitle;

(E) that prescribe the procedure for making requests for reports or information shall require that each request made under the regulations for submission of a report or information to the Secretary state the reason or purpose for the request and identify to the fullest extent practicable the report or information;

(F) that require submission of a report or information to the Secretary shall state the reason or purpose for the submission of the report or information and identify to the fullest extent practicable the report or information;

(G) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this subtitle; and

(H) may not require a manufacturer or importer of a class I device—

(i) to maintain for the class I device records respecting information not in the possession of the manufacturer or importer; or

(ii) to submit for the class I device to the Secretary any report or information, unless the report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded, which report or information—

(I) is not in the possession of the manufacturer or importer; or

(II) is submitted on a periodic basis.

(2) CONSIDERATION OF PROFESSIONAL ETHICS.—In prescribing regulations under paragraph (1), the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients.

(3) CONTINUED PROTECTION OF PATIENT IDENTITY.—The prohibitions of paragraph (1)(G) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when the individual ceases to be a patient.

(4) AVAILABILITY OF DISTRIBUTOR RECORDS ON SECRETARY'S REQUEST.—The Secretary shall by regulation require distributors to keep records and make the records available to the Secretary upon request.

(5) APPLICABILITY OF CERTAIN PROVISIONS TO DISTRIBUTORS.—Subparagraphs (D) and (H) of paragraph (1) apply to distributors to the same extent and in the same manner as the subparagraphs apply to manufacturers and importers.

(b) USER REPORTS.—

(1) DEFINITIONS.—In this subsection:

(A) DEVICE USER FACILITY.—

(i) IN GENERAL.—The term ''device user facility'' means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility that is not a physician's office.

(ii) INCLUSION.—The Secretary may by regulation include in the term an outpatient diagnostic facility that is not a physician's office.

(B) SERIOUS ILLNESS.—The term ''serious illness'' means illness that—

(i) is life threatening;

(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(C) SERIOUS INJURY.—The term ''serious injury'' means injury that—

(i) is life threatening;

(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(2) IN GENERAL.—

(A) DEATH.—Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the device user facility, the device user facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of the information.

(B) SERIOUS ILLNESS OR SERIOUS INJURY; SIGNIFICANT ADVERSE DEVICE EXPERIENCE.—A device user facility shall, as soon as practicable but not later than 10 working days after becoming aware of information or experience described in clause (i) or (ii), respectively, report the information or experience to the

manufacturer of a device or to the Secretary if the identity of the manufacturer is not known, whenever the device user facility receives or otherwise becomes aware of—

(i) information that reasonably suggests that the device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the device user facility; or

(ii) any other significant adverse device experience as determined by the Secretary by regulation to be necessary to be reported.

(C) SUMMARY OF REPORTS.—

(i) SUBMISSION.—Each device user facility shall submit to the Secretary on an annual basis a summary of the reports made under subparagraphs (A) and (B). The summary shall be submitted on January 1 of each year.

(ii) FORMAT AND CONTENTS.—The summary shall be in such form and contain such information from the reports as the Secretary may require and shall include—

(I) sufficient information to identify the device user facility that made the reports for which the summary is submitted;

(II) in the case of any product that was the subject of a report, the product name, serial number, and model number;

(III) the name and the address of the manufacturer of the device; and

(IV) a brief description of the event reported to the manufacturer.

(D) IMPUTED KNOWLEDGE.—For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that device user facility when medical personnel who are employed by or otherwise formally affiliated with the device user facility receive or otherwise become aware of information with respect to that device in the course of their duties.

(3) NONDISCLOSURE OF IDENTITY OF REPORTING DEVICE USER FACILITY.—

(A) IN GENERAL.—The Secretary may not disclose the identity of a device user facility that makes a report under paragraph (2) except in connection with—

(i) an action brought to enforce section 10501(16) of this title; or

(ii) a communication to a manufacturer of a device that is the subject of a report under paragraph (2).

(B) EFFECT OF PARAGRAPH ON SECRETARY DISCLOSURE TO AGENCIES AND CONGRESS.—This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (2) or any information in the report to employees of the Department, to the Department of Justice, or to the authorized committees and subcommittees of Congress.

(4) ADMISSIBILITY OF REPORTS IN PRIVATE ACTIONS.—A report made under paragraph (2) by a device user facility, an individual who is employed by or otherwise formally affiliated with a device user facility, or a physician who is not required to make such a report shall not be admissible into evidence or otherwise used in any civil action involving private

parties unless the device user facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(5) EFFECT OF USER REPORTS ON MANUFACTURER REPORTS.—A report made under paragraph (2) does not affect any obligation of a manufacturer that receives the report to file a report as required under subsection (a).

(6) PROGRAM THAT LIMITS USER REPORTING TO A SUBSET OF DEVICE USER FACILITIES.—With respect to device user facilities:

(A) IN GENERAL.—The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (2) through (5) to a subset of device user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

(B) PERIOD OF PLANNING.—During the period of planning the program under subparagraph (A), paragraphs (2) through (5) continue to apply.

(C) TRANSITION.—During the period in which the Secretary is providing for a transition to the full implementation of the program,

paragraphs (2) through (5) apply except to the extent that the Secretary determines otherwise.

(D) FULL IMPLEMENTATION.—On and after the date on which the program is fully implemented, paragraphs (2) through (5) do not apply to a device user facility unless the device user facility is included in the subset referred to in subparagraph (A).

(c) PERSONS EXEMPT.—Subsection (a) shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of the practitioner's professional practice;

(2) any person that manufactures or imports devices intended for use in humans solely for the person's use in research or teaching and not for sale (including any person that uses a device under an exemption granted under section 13152(g) of this title); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) on a finding that compliance with the requirements of

subsection (a) by the class with respect to a device is not necessary to—

(A) ensure that a device is not adulterated or misbranded; or

(B) otherwise to ensure its safety and effectiveness.

(d) DEVICE TRACKING.—

(1) IN GENERAL.—The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) that is—

(i) intended to be implanted in the human body for more than 1 year; or

(ii) a life sustaining or life supporting device used outside a device user facility.

(2) REFUSAL BY PATIENT TO RELEASE PERSONAL INFORMATION.—Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.

(e) UNIQUE DEVICE IDENTIFICATION SYSTEM.—The Secretary shall issue regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

(f) REPORTS OF REMOVALS AND CORRECTIONS.—

(1) IN GENERAL.—

(A) PROMPT REPORTING.—Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by the manufacturer or importer if the removal or correction was undertaken—

(i) to reduce a risk to health posed by the device; or

(ii) to remedy a violation of this subtitle caused by the device, which violation may present a risk to health.

(B) KEEPING RECORDS.—A manufacturer or importer of a device that undertakes a cor-

rection or removal of a device that is not required to be reported under this paragraph shall keep a record of the correction or removal.

(2) LIMITATION ON REQUIREMENT TO SUBMIT REPORT UNDER PARAGRAPH (1).—A report of the corrective action or removal of a device shall not be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

(3) ROUTINE SERVICING NOT INCLUDED.—For purposes of paragraphs (1) and (2), the terms ''correction'' and ''removal'' do not include routine servicing.

(g) INCLUSION OF DEVICES IN THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(1) IN GENERAL.—

(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under subparagraphs (A), (B), (C), and (E) of section 13512(c)(3) of this title in order to expand the postmarket risk identification and analysis system established under section 13512(c)(3) of this title to include and apply to devices.

(B) EXCEPTION.—Section 13512(c)(3)(A)(ii) of this title shall not apply to devices.

(C) CLARIFICATION.—With respect to devices, the private sector health-related electronic data provided under section 13512(c)(3)(A)(iii)(II) of this title may include medical device utilization data, health insurance claims data, and procedure and device registries.

(2) DATA.—In expanding the system as described in paragraph (1)(A), the Secretary shall use relevant data with respect to devices cleared under section 13136(k) of this title or approved under section 13142 of this title, including claims data, patient survey data, and any other data considered appropriate by the Secretary.

(3) STAKEHOLDER INPUT.—To help ensure effective implementation of the system as described in paragraph (1) with respect to devices, the Secretary shall engage outside stakeholders in the development of the system, and gather information from outside stakeholders regarding the content of an effective sentinel program, through a public hearing, advisory

committee meeting, maintenance of a public docket, or other similar public measure.

(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44 shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification, mitigation, and analysis for devices.

(h) POSTMARKET PILOT.—

(1) IN GENERAL.—

(A) PROJECTS.—In order to provide timely and reliable information on the safety and effectiveness of devices approved under section 13142 of this title, cleared under section 13136(k) of this title, or classified under section 13140(h)(2) of this title, including responses to adverse events and malfunctions, and to advance the objectives of part 803 of title 21, Code of Federal Regulations (or successor regulations), and to advance the objectives of, and to evaluate innovative new methods of compliance with, this section and section 13154 of this title, the Secretary shall, within 1 year of August 18, 2017, initiate 1 or more pilot projects for voluntary participation by a

manufacturer or manufacturers of a device or device type, or continue existing projects, in accordance with paragraph (3), that—

(i) are designed to efficiently generate reliable and timely safety and active surveillance data for use by the Secretary or manufacturers of the devices that are involved in the pilot project;

(ii) inform the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for devices included or not included in the project;

(iii) may be designed and conducted in coordination with a comprehensive system for evaluating medical device technology that operates under a governing board with appropriate representation of stakeholders, including patient groups and device manufacturers;

(iv) use electronic health data including claims data, patient survey data, or any other data, as the Secretary determines appropriate; and

(v) prioritize devices and device types that meet 1 or more of the criteria under subparagraph (B).

(B) CRITERIA.—The criteria under this subparagraph are the following:

(i) Devices and device types for which the collection and analysis of real-world evidence regarding a device's safety and effectiveness is likely to advance public health.

(ii) Devices and device types that are widely used.

(iii) Devices and device types, the failure of which has significant health consequences.

(iv) Devices and device types for which the Secretary—

(I) has received public recommendations in accordance with paragraph (2)(B); and

(II) has determined to meet 1 or more of the criteria under clause (i), (ii), or (iii) and is appropriate for such a pilot project.

(2) PARTICIPATION.—The Secretary shall establish the conditions and processes—

(A) under which a manufacturer of a device may voluntarily participate in a pilot project described in paragraph (1); and

(B) for facilitating public recommendations for devices to be prioritized under such a pilot project, including requirements for the data necessary to support the recommendations.

(3) CONTINUATION OF ONGOING PROJECTS.—The Secretary may continue or expand projects, with respect to providing timely and reliable information on the safety and effectiveness of devices approved under section 13142 of this title, cleared under section 13136(k) of this title, or classified under section 13140(h)(2) of this title, that were being carried out as of August 18, 2017. The Secretary shall, beginning on that date, take such steps as may be necessary—

(A) to ensure the projects meet the requirements of clauses (i) through (v) of paragraph (1)(A); and

(B) to increase the voluntary participation in the projects of manufacturers of devices and

facilitate public recommendations for any devices prioritized under the projects.

(4) IMPLEMENTATION.—

(A) CONTRACTING AUTHORITY.—The Secretary may carry out a pilot project meeting the criteria specified in clauses (i) through (v) of paragraph (1)(A) or a project continued or expanded under paragraph (3) by entering into contracts, cooperative agreements, grants, or other appropriate agreements with public or private entities that have a significant presence in the United States and meet the following conditions:

(i) AGREEMENT RELATING TO SECURITY MEASURES TO MAINTAIN CONFIDENTIALITY AND PRIVACY OF DATA.—If such an entity is a component of another organization, the entity and the organization have established an agreement under which appropriate security measures are implemented to maintain the confidentiality and privacy of the data described in paragraph (1)(A)(iv) and the agreement ensures that the entity will not make an unauthorized disclosure of the data to the other compo-

nents of the organization in breach of requirements with respect to confidentiality and privacy of the data established under the security measures.

(ii) COMPLIANCE REQUIREMENTS IN CASE OF TERMINATION OR NONRENEWAL OF AGREEMENT.—In the case of the termination or nonrenewal of the contract, cooperative agreement, grant, or other appropriate agreement, the entity or entities involved shall comply with each of the following:

(I) The entity or entities shall continue to comply with the requirements with respect to confidentiality and privacy referred to in clause (i) with respect to all data disclosed to the entity under the agreement.

(II) The entity or entities shall return any data disclosed to the entity pursuant to this subsection and to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(iii) QUALIFICATIONS.—The entity or entities shall have 1 or more qualifications with respect to—

(I) research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary access to de-identified data consistent with the requirements of this subsection;

(II) an information technology infrastructure to support electronic data and operational standards to provide security for the data, as appropriate;

(III) experience with, and expertise on, the development of research on, and surveillance of, device safety and effectiveness using electronic health data; or

(IV) such other expertise that the Secretary determines necessary to carry out such a project.

(B) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review any contract, cooperative agreement, grant, or other appropriate agreement entered into under this paragraph with an entity meeting the conditions specified in subparagraph (A) in the event of a merger or acquisition of the entity in order to ensure that the requirements specified in this subsection will continue to be met.

(5) COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—The participation of a manufacturer in pilot projects under this subsection or a project continued or expanded under paragraph (3) shall not affect the eligibility of the manufacturer to participate in any quarterly reporting program with respect to devices carried out under this section or section 13154 of this title. The Secretary may determine that, for a specified time period to be determined by the Secretary, a manufacturer's participation in a pilot project under this subsection or a project continued or expanded under paragraph (3) may meet the applicable requirements of this section or section 13154 of this title, if—

(A) the project has demonstrated success in capturing relevant adverse event information; and

(B) the Secretary has established procedures for making adverse event and safety information collected from the project public, to the extent possible.

(6) PRIVACY REQUIREMENTS.—With respect to the disclosure of any health information collected through a project conducted under this subsection—

(A) individually identifiable health information so collected shall not be disclosed when presenting any information from the project; and

(B) the disclosure shall be made in compliance with regulations issued pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and sections 552 and 552a of title 5.

(7) LIMITATIONS.—A pilot project under this subsection, or in coordination with the comprehensive system described in paragraph (1)(A)(iii), shall not allow for an entity participating in the project, other than the Secretary, to make determinations of

safety or effectiveness, or substantial equivalence, for purposes of this subtitle.

(8) OTHER PROJECTS REQUIRED TO COMPLY.—Paragraphs (1)(A)(ii), clauses (i) and (ii) of paragraph (4)(A), and paragraph (5) through (7) shall apply with respect to any pilot project undertaken in coordination with the comprehensive system described in paragraph (1)(A)(iii) that relates to the use of real-world evidence for devices in the same manner and to the same extent as the paragraphs apply with respect to pilot projects conducted under this subsection.

(9) REPORT TO CONGRESS.—Not later than 18 months after August 18, 2017, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing a description of the pilot projects being conducted under this subsection and projects continued or expanded pursuant to paragraph (3), including for each project—

(A) how the project is being implemented in accordance with paragraph (4), including how the project is being implemented through a

contract, cooperative agreement, grant, or other appropriate agreement, if applicable;

(B) the number of manufacturers that have agreed to participate in the project;

(C) the data sources used to conduct the project;

(D) the devices or device categories involved in the project;

(E) the number of patients involved in the project; and

(F) the findings of the project in relation to device safety, including adverse events, malfunctions, and other safety information.

(10) SUNSET.—The Secretary may not carry out a pilot project initiated by the Secretary under this subsection after October 1, 2022.

**§ 13152. General provisions respecting control of devices intended for human use**

(a) IN GENERAL.—Any requirement authorized by or under chapter 133 of this title or section 13101, 13136, or 13151 of this title applicable to a device intended for human use shall apply to the device until the applicability of the requirement to the device has been changed by action taken under section 13140, 13141, or 13142 of this title or under subsection (g), and any requirement estab-

lished by or under chapter 133 of this title or section 13101, 13136, or 13151 of this title that is inconsistent with a requirement imposed on the device under section 13141 or 13142 of this title or under subsection (g) shall not apply to the device.

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 13141 and 13142 of this title shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 13141 of this title or requirement under section 13142 of this title;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E) is intended—

(i) to meet the special needs of the physician or dentist (or other specially qualified person designated as described in subparagraph (A)) in the course of the professional practice of the physician or dentist (or other specially qualified person designated as described in subparagraph (A)); or

(ii) for use by an individual patient named in the order of the physician or dentist (or other specially qualified person designated as described in subparagraph (A));

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material com-

positions, and manufacturing processes as commercially distributed devices.

(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

(A) the device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on the device would be impractical;

(B) production of the device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that the replication otherwise complies with this section; and

(C) the manufacturer of the device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of the device.

(3) GUIDANCE.—The Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

(c) TRADE SECRETS.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under section 13140, 13141, 13142, 13146, 13149, 13151, or 17504 of this title or under subsection (f) or (g) that is exempt from disclosure pursuant to sec-

tion 552(a) of title 5 by reason of section 552(b)(4) of title 5 shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 13141 of this title for a device reclassified from class III to class II, except—

(1) in accordance with subsection (h); and

(2) that the information may be disclosed to other officers or employees concerned with carrying out this subtitle or when relevant in any proceeding under this subtitle (other than section 13140 or 13141 of this title).

(d) NOTICES AND FINDINGS.—Each notice of proposed rulemaking under section 13140, 13141, 13142, 13146, 13149, or 13151 of this title, or under this section, any other notice that is published in the Federal Register with respect to any other action taken under any of those sections and that states the reasons for the action, and each publication of findings required to be made in connection with rulemaking under any of those sections shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings are based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause for the extension.

(e) RESTRICTED DEVICES.—

(1) AUTHORITY TO RESTRICT DEVICES.—

(A) IN GENERAL.—If, because of a device's potentiality for harmful effect or the collateral measures necessary to the use of the device, the Secretary determines that there cannot otherwise be reasonable assurance of the safety and effectiveness of the device, the Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(i) only on the written or oral authorization of a practitioner licensed by law to administer or use the device; or

(ii) on such other conditions as the Secretary may prescribe in the regulation.

(B) LIMITATIONS ON RESTRICTIONS.—A condition prescribed under subparagraph (A)(ii) shall not—

(i) restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device; or

(ii) exclude a person from using a device solely because the person—

(I) does not have the training or experience to make the person eligible for certification by a certifying board recognized by the American Board of Medical Specialties; or

(II) has not been certified by a certifying board described in subclause (I).

(C) RESTRICTED DEVICE.—A device subject to a regulation under this subsection is a restricted device.

(2) LABEL.—The label of a restricted device shall bear such appropriate statements of the re-

strictions required by a regulation under paragraph (1) as the Secretary may in the regulation prescribe.

(f) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

(1) REGULATIONS.—

(A) IN GENERAL.—The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in the regulations, to ensure that the device will be safe and effective and otherwise in compliance with this subtitle.

(B) PROCEDURE.—

(i) IN GENERAL.—Before the Secretary may promulgate any regulation under subparagraph (A), the Secretary shall—

(I) afford the advisory committee established under paragraph (3) an

opportunity to submit recommendations to the Secretary with respect to the regulation proposed to be promulgated;

(II) afford opportunity for an oral hearing; and

(III) ensure that the regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

(ii) REASONABLE TIME FOR RECOMMENDATIONS FROM ADVISORY COMMITTEE.—The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2) PETITION FOR EXEMPTION OR VARIANCE.—

(A) IN GENERAL.—Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from the requirement. The petition shall be submitted to the

Secretary in such form and manner as the Secretary shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to ensure that the device will be safe and effective and otherwise in compliance with this subtitle;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Secretary shall prescribe.

(B) REFERRAL TO ADVISORY COMMITTEE.—

(i) IN GENERAL.—The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A).

(ii) DATE ON WHICH ADVISORY COMMITTEE IS TO REPORT ITS RECOMMENDATION.—The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to the advisory committee within 60 days of the date of the petition's referral.

(iii) DENIAL OR APPROVAL OF PETITION.—The Secretary shall, by order, deny or approve a petition submitted under subparagraph (A) within 60 days after the later of—

(I) the date the petition was submitted to the Secretary; or

(II) if the petition was referred to an advisory committee, the expiration of the 60-day period beginning on the date the petition was referred to the advisory committee.

(C) APPROVAL.—

(i) IN GENERAL.—The Secretary may approve—

(I) a petition for an exemption for a device from a requirement if the Secretary determines that compliance

with the requirement is not required to ensure that the device will be safe and effective and otherwise in compliance with this subtitle; and

(II) a petition for a variance for a device from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to ensure that the device will be safe and effective and otherwise in compliance with this subtitle.

(ii) ORDER APPROVING PETITION FOR A VARIANCE.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to ensure that

the device will be safe and effective and otherwise in compliance with this subtitle.

(D) HEARING AFTER ORDER TO DENY OR APPROVE PETITION.—After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on the order.

(3) ADVISORY COMMITTEE.—

(A) ESTABLISHMENT.—The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to the Secretary with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2).

(B) MEMBERS.—The advisory committee shall be composed of 9 members—

(i) 3 of which shall be appointed from individuals who are officers or employees of any State or local government or of the Federal Government; and

(ii)(I) 2 of whom shall be appointed from individuals who are representative of interests of the device manufacturing industry;

(II) 2 of whom shall be appointed from individuals who are representative of the interests of physicians and other health professionals; and

(III) 2 of whom shall be representative of the interests of the general public.

(C) COMPENSATION AND TRAVEL EXPENSES RELATING TO MEETINGS AND CONFERENCES.—

(i) IN GENERAL.—Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the maximum rate payable under section 5376 of title 5, for each day (including travel time) they are so engaged.

(ii) SERVICE AWAY FROM HOME OR REGULAR PLACE OF BUSINESS.—While serving as described in clause (i) away from the member's home or regular place

of business, each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for individuals in the Government service employed intermittently.

(D) CHAIRPERSON.—The Secretary shall designate one of the members of the advisory committee to serve as its chairperson.

(E) PERSONNEL.—The Secretary shall furnish the advisory committee with clerical and other assistance.

(F) INAPPLICABILITY OF SECTION 1013 OF TITLE 5.—Section 1013 of title 5 shall not apply with respect to the duration of the advisory committee established under this paragraph.

(g) EXEMPTION FOR DEVICES FOR INVESTIGATIONAL USE.—

(1) PURPOSE.—The purpose of this subsection is to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2) PRESCRIPTION OF REGULATIONS.—

(A) REGULATIONS.—The Secretary shall by regulation prescribe procedures and conditions under which devices intended for human use may on application be granted an exemption from the requirements of chapter 133 of this title or section 13136, 13141, 13142, 13146, 13151, or 17701 of this title or subsection (e) or (f) or from any combination of those requirements to permit the investigational use of the devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of the devices.

(B) REQUIREMENTS.—The conditions prescribed pursuant to subparagraph (A) shall include—

(i) a requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify;

(ii) a requirement that the person applying for an exemption for a device ensure the establishment and maintenance of such records, and the making of such reports to

the Secretary of safety or effectiveness data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable the Secretary to ensure compliance with the conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device; and

(iii) such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) VARIATIONS; FACTORS.—Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on—

(i) the scope and duration of clinical testing to be conducted under the exemption;

(ii) the number of human subjects that are to be involved in the testing;

(iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accord-

ance with a clinical testing plan required under paragraph (3)(A)(i); and

(iv) whether the clinical testing of the device is for the purpose of developing data to obtain approval for the commercial distribution of the device.

(3) RESPONSIBILITIES OF APPLICANTS FOR EXEMPTION.—

(A) IN GENERAL.—Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption—

(i)(I) submit, for review for adequacy to justify the commencement of the testing, a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(aa) to the institutional review committee established in accordance with regulations of the Secretary to supervise clinical testing of devices in

the facilities where the proposed clinical testing is to be conducted; or

(bb) to the Secretary, if—

(AA) an institutional review committee under item (aa) does not exist; or

(BB) the Secretary finds that the process of review by the institutional review committee is inadequate (whether or not the plan for the testing has been approved by the institutional review committee); and

(II) if the plan and report are not submitted to the Secretary under subclause (I)(bb), submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(ii) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by an institutional review committee of any clinical testing plan submitted to it in accordance with clause (i);

(iii) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of the investigators that any testing of the device involving human subjects will be under the investigator's supervision and in accordance with clause (iv) and submit the agreements to the Secretary; and

(iv) ensure that informed consent will be obtained from each human subject (or a representative of the human subject) of proposed clinical testing involving the device, except where, subject to such conditions as the Secretary may prescribe—

(I) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

(II) the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life-threatening situation involving the human

subject of the testing which necessitates the use of the device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain the consent from the human subject's representative.

(B) DETERMINATION TO BE CONCURRED IN BY LICENSED PHYSICIAN.—The determination required by subparagraph (A)(iv)(II) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which the determination is made, unless immediate use of the device is required to save the life of the human subject of the testing and there is not sufficient time to obtain the concurrence.

(4) APPROVAL OR DISAPPROVAL.—

(A) IN GENERAL.—An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 13146 of this title) shall be deemed approved on the 30th day after the submission of the application to the Secretary

unless, on or before that day, the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) CONDITIONS FOR DISAPPROVAL.—The Secretary may disapprove an application only if the Secretary finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). A notification of disapproval under subparagraph (A) shall—

(i) contain—

(I) the order of disapproval; and

(II) a complete statement of the reasons for the Secretary's disapproval of the application; and

(ii) afford the applicant opportunity for an informal hearing on the disapproval order.

(C) DETERMINATIONS FOR WHICH APPLICATION SHALL NOT BE DISAPPROVED.—Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines that—

(i) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

(ii) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

(iii) an additional or different investigation may be necessary to support clearance or approval of the device.

(5) WITHDRAWAL OF EXEMPTION.—

(A) IN GENERAL.—The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for the exemption are not met.

(B) HEARING.—An order for withdrawal under subparagraph (A) may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption

with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(6) CHANGES IN DEVICE OR CLINICAL PROTOCOLS.—

(A) IN GENERAL.—The Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to an application for an exemption, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) the validity of data or information resulting from the completion of an approved protocol, or the rela-

tionship of likely patient risk to benefit relied on to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A)(i); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) REQUIRED PROVISIONS.—Regulations under subparagraph (A) shall provide that a change or modification described in subparagraph (A) may be made if—

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary), that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

(7) CLASS III DEVICES AND IMPLANTABLE DEVICES.—

(A) OPPORTUNITY TO SUBMIT INVESTIGATIONAL PLAN FOR REVIEW PRIOR TO SUBMITTING APPLICATION.—

(i) IN GENERAL.—In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol).

(ii) REQUEST FOR MEETING TO REACH AGREEMENT ON INVESTIGATIONAL PLAN.—If the applicant submits a written request for a meeting with the Secretary regarding the review under clause (i), the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol).

(iii) CONTENT OF WRITTEN REQUEST.—The written request under clause (ii) shall include—

(I) a detailed description of the device;

(II) a detailed description of the proposed conditions of use of the device;

(III) a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness; and

(IV) if available, information regarding the expected performance from the device.

(B) AGREEMENT.—Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. The agreement shall not be changed, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(C) DECISION.—A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.

(8) CLINICAL HOLDS.—

(A) IN GENERAL.—At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a ''clinical hold'') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary that

served as the basis for the clinical hold, and confirm the determination in writing.

(B) DETERMINATION.—For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

(i) the device involved represents an unreasonable risk to the safety of the individuals who are the subjects of the clinical investigation, taking into account—

(I) the qualifications of the clinical investigators;

(II) information about the device;

(III) the design of the clinical investigation;

(IV) the condition for which the device is to be investigated; and

(V) the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

(C) REQUEST TO REMOVE CLINICAL HOLD.—Any written request to the Secretary from the sponsor of an investigation that a clin-

ical hold be removed shall receive a decision, in writing and specifying the reasons for the decision, within 30 days after receipt of the request. The request shall include sufficient information to support the removal of the clinical hold.

(9) DIVERSITY ACTION PLAN.—

(A) SUBMISSION.—

(i) DEVICE FOR WHICH AN APPLICATION FOR AN INVESTIGATIONAL DEVICE EXEMPTION IS REQUIRED.—The sponsor of a device for which submission of an application for an investigational device exemption is required shall submit to the Secretary in the application a diversity action plan for clinical studies of the device, in the form and manner specified in guidance issued by the Secretary.

(ii) DEVICE FOR WHICH AN APPLICATION FOR AN INVESTIGATIONAL DEVICE EXEMPTION IS NOT REQUIRED.—The sponsor of a device for which submission of an application for an investigational device exemption is not required, except for a device being studied as described in section 812.2(c) of title 21, Code of Federal Regu-

lations, or successor regulations, shall develop a diversity action plan for any clinical study with respect to the device. The diversity action plan shall be submitted to the Secretary in any premarket notification under section 13136(k) of this title, request for classification under section 13140(h)(2) of this title, or application for premarket approval under section 13142 of this title for the device.

(B) CONTENT.—A diversity action plan under clause (i) or (ii) of subparagraph (A) shall include—

(i) the sponsor's goals for enrollment in the clinical study;

(ii) the sponsor's rationale for the goals; and

(iii) an explanation of how the sponsor intends to meet the goals.

(C) WAIVER.—

(i) AUTHORITY.—On the initiative of the Secretary or at the request of a sponsor, the Secretary may waive any requirement in subparagraph (A) or (B) if the Secretary determines that a waiver is nec-

essary based on what is known or can be determined about the prevalence or incidence of the disease or condition for which the device is under investigation (including in terms of the patient population that may use the device), if conducting a clinical investigation in accordance with a diversity action plan would otherwise be impracticable, or if the waiver is necessary to protect public health during a public health emergency.

(ii) WRITTEN RESPONSE REQUIRED.—The Secretary shall issue a written response granting or denying a request from a sponsor for a waiver within 60 days of receiving the request.

(D) INAPPLICABILITY.—A diversity action plan shall not be required for a submission described in section 14301 of this title.

(h) RELEASE OF INFORMATION RESPECTING SAFETY AND EFFECTIVENESS.—

(1) INFORMATION SUBMITTED TO SECRETARY.—

(A) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations

under which a detailed summary of information respecting the safety and effectiveness of a device shall be made available to the public on issuance of the order described in clause (i), (ii), or (iii), as applicable, which information was submitted to the Secretary and which was the basis for—

(i) an order under section 13142(d)(1)(A) of this title approving an application for premarket approval for the device or denying approval of such an application or an order under section 13142(e) of this title withdrawing approval of such an application for the device;

(ii) an order under section 13142(f)(6)(A) of this title revoking an approved protocol for the device, an order under section 13142(f)(6)(B) of this title declaring a protocol for the device completed or not completed, or an order under section 13142(f)(7) of this title revoking the approval of the device; or

(iii) an order approving an application under subsection (g) for an exemption for the device from section 13146 of this title

or an order disapproving, or withdrawing approval of, an application for an exemption under subsection (g) for the device.

(B) ADVERSE EFFECTS ON HEALTH.—Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) INFORMATION SUBMITTED TO ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary shall promulgate regulations under which each advisory committee established under section 13142(g)(2)(B) of this title shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device, which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 13142(g)(2)(A) of this title.

(B) AVAILABILITY OF INFORMATION RELATING TO RECOMMENDATION; ADVERSE EFFECTS ON HEALTH.—A summary of information on which a recommendation described in subparagraph (A) is based shall be made avail-

able pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to the order.

(3) LIMITATIONS ON USE OF INFORMATION.—Except as provided in paragraph (4), any information respecting a device that is made available pursuant to paragraph (1) or (2)—

(A) may not be used to establish the safety or effectiveness of another device for purposes of this subtitle by any person other than the person that submitted the information that was made available; and

(B) shall be made available subject to subsection (c).

(4) USE OF INFORMATION BY SECRETARY.—

(A) IN GENERAL.—Subject to subparagraph (C), any information contained in an application for premarket approval filed with the Secretary pursuant to section 13142(c) of this title (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but exclud-

ing descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

(i) approving another device;

(ii) determining whether a product development protocol has been completed under section 13142 of this title for another device;

(iii) establishing a performance standard or special control under this subtitle; or

(iv) classifying or reclassifying another device under section 13140 of this title and subsection (l)(2).

(B) EVIDENTIARY BASIS.—The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A)(i) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

(C) COMBINATION PRODUCT CONTAINING AN APPROVED DRUG.—Information contained in

an application for premarket approval filed with the Secretary pursuant to section 13142(c) of this title shall not be used to approve or clear any application submitted under section 13136(k) or 13142 of this title or to classify a product under section 13140(h)(2) of this title for a combination product containing as a constituent part an approved drug (as defined in section 13104(g)(1) of this title) unless—

(i) the application includes the certification or statement referenced in section 13104(g)(4) of this title;

(ii) the applicant provides notice as described in section 13104(g)(4) of this title; and

(iii) the Secretary's approval of the application is subject to the provisions in section 13104(g)(5) of this title.

(i) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—Each panel under section 13140 of this title and each advisory committee established under section 13141(b)(5)(B) or 13142(g) of this title or under subsection (f) shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pur-

suant to this subsection information that under subsection (c) is to be considered confidential.

(j) TRACEABILITY.—Except as provided in section 13151(d) of this title, a regulation under this subtitle shall not impose on a type or class of device requirements for the traceability of the type or class of device unless the requirements are necessary to ensure the protection of the public health.

(k) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to subsections (a) and (b) of section 3324 of title 31 and section 6101 of title 41.

(l) TRANSITIONAL PROVISIONS FOR DEVICES CONSIDERED AS NEW DRUGS.—

(1) CLASS III.—

(A) IN GENERAL.—A device described in subparagraph (B) is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified the device in class I or II.

(B) DEVICE.—A device described in this subparagraph is a device intended for human use—

(i) for which on May 28, 1976 (in this subsection, referred to as the ''enactment date'') an approval of an application submitted under section 13503 of this title was in effect;

(ii) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on that date under section 13504 or 13505 of this title;

(iii) for which on the enactment date an exemption under section 13510 of this title was in effect;

(iv) which is within a type of device described in clause (i), (ii), or (iii) and is substantially equivalent to another device within that type;

(v) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to chapter 135 of this tile; or

(vi) with respect to which on the enactment date an action is pending in a

United States court under section 10502, 10503, or 10504 of this title for an alleged violation of a provision of section 10501 of this title that enforces a requirement of chapter 135 of this title or for an alleged violation of section 13502 of this title.

(2) RECLASSIFICATION.—

(A) INITIATION.—The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as the Secretary shall prescribe) for the issuance of an order classifying the device in class I or class II.

(B) NOTIFICATION RELATING TO DEFICIENCIES.—Within 30 days of the filing of the petition, the Secretary shall notify the petitioner of any deficiencies in the petition that prevent the Secretary from making a decision on the petition.

(C) ORDER.—Except as provided in paragraph (3)(D)(ii), within 180 days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appro-

priate panel under section 13140 of this title, by order deny the petition or order the classification, in accordance with the criteria prescribed by subparagraph (A) or (B) of section 13140(c)(1) of this title, of the device in class I or class II.

(3) PREMARKET APPROVAL.—

(A) DEVICE DESCRIBED IN PARAGRAPH (1)(B)(i).—In the case of a device that is described in paragraph (1)(B)(i) and that is in class III—

(i) the device shall on the enactment date be considered a device with an approved application under section 13142 of this title; and

(ii) the requirements applicable to the device before the enactment date under chapter 135 of this title shall continue to apply to the device until changed by the Secretary as authorized by this subtitle.

(B) DEVICE DESCRIBED IN PARAGRAPH (1)(B)(ii).—In the case of a device that is described in paragraph (1)(B)(ii) and that is in class III, an application for the device shall be considered as having been filed under section

13142 of this title on the enactment date. The period in which the Secretary shall act on the application in accordance with section 13142(d)(1) of this title shall be 180 days from the enactment date (or such greater period as the Secretary and the applicant may agree on after the Secretary has made the finding required by section 13142(d)(1)(B)(i) of this title) less the number of days in the period beginning on the date an application for the device was filed under chapter 135 of this title and ending on the enactment date. After the expiration of the period, the device is required, unless exempt under subsection (g), to have in effect an approved application under section 13142 of this title.

(C) DEVICE DESCRIBED IN PARAGRAPH (1)(B)(iii).—A device that is described in paragraph (1)(B)(iii) and that is in class III shall be considered a new drug until the expiration of the 90-day period beginning on the date of the promulgation of regulations under subsection (g). After the expiration of the period, the device is required, unless exempt under subsection

(g), to have in effect an approved application under section 13142 of this title.

(D) DEVICE DESCRIBED IN CLAUSE (iv), (v), OR (vi) OF PARAGRAPH (1)(B).—

(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), a device that is described in clause (iv), (v), or (vi) of paragraph (1)(B) and that is in class III is required, unless exempt under subsection (g), to have, on and after 60 days after the enactment date, in effect an approved application under section 13142 of this title.

(ii) PETITION FOR RECLASSIFICATION OR APPLICATION FOR PREMARKET APPROVAL FILED.—

(I) ACTION BY SECRETARY.—

(aa) IN GENERAL.—The Secretary shall act on a petition or application in accordance with paragraph (2) or section 13142 of this title if, within the 60-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required

under section 13142(d)(1)(B) of this title, and the petitioner or applicant may agree on)—

(AA) the petition is filed under paragraph (2) for a device described in clause (iv), (v), or (vi) of paragraph (1)(B); or

(BB) the application for premarket approval is filed under section 13142 of this title for such a device.

(bb) TIMEFRAME.—The period within which the Secretary must act on the petition or application under item (aa) shall be within the 120-day period beginning on the date the petition or application is filed.

(II) EFFECT OF FILING OF PETITION OR APPLICATION ON REQUIREMENT TO HAVE AN APPROVED APPLICATION.—If a petition or application described in subclause (I) is filed within the 60-day (or greater) period,

clause (i) shall not apply to the device before the expiration of the 120-day period, or if the petition is denied or the application is denied approval, before the date of the denial, whichever occurs first.

(iii) DEVICE DESCRIBED IN PARAGRAPH (1)(B)(V).—

(I) IN GENERAL.—In the case of a device that is described in paragraph (1)(B)(v), that the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to chapter 135 of this title, and that is in class III—

(aa) the device shall, after 18 months after the enactment date, have in effect an approved application under section 13142 of this title unless exempt under subsection (g); and

(bb) the Secretary may, during the period beginning 180 days after the enactment date

and ending 18 months after that date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of the device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) to investigational use of devices granted an exemption under the subsection.

(II) REASONABLE AVAILABILITY TO PHYSICIANS.—If the requirements under subsection (g) are made applicable to the investigational use of a device described in subclause (I), the requirements shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(4) REQUIRED SUBMISSION BY MANUFACTURERS OF DEVICES SUBJECT TO RECLASSIFICATION.—

(A) ORDER.—Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information that has not been submitted under section 13151 of this title. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if the data are available to the manufacturer.

(B) REGULATION.—

(i) IN GENERAL.—Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device that is classified in class III under paragraph (1) revising the classification of the device so that the device is classified in class I or class II, un-

less the regulation requires the device to remain in class III.

(ii) DETERMINATION RELATING TO RECLASSIFICATION.—In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 13140(c) of this title.

(iii) PROPOSED REGULATION.—Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on the regulation.

(iv) EFFECTIVE DATE.—A regulation under this subparagraph requiring a device to remain in class III or revising its classification shall not take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) EXTENSION.—The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

(m) HUMANITARIAN DEVICE EXEMPTION.—

(1) PURPOSE.—To the extent consistent with the protection of the public health and safety and with ethical standards, the purpose of this subsection is to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect not more than 8,000 individuals in the United States.

(2) EXEMPTION FROM EFFECTIVENESS REQUIREMENT.—

(A) IN GENERAL.—The Secretary may grant a request for an exemption from the effectiveness requirements of sections 13141 and 13142 of this title for a device for which the Secretary finds that—

(i) the device is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States;

(ii) the device would not be available to a person with a disease or condition referred to in clause (i) unless the Secretary grants the exemption and there is no comparable device, other than under this exemption, available to treat or diagnose the disease or condition; and

(iii) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

(B) SUBMISSION OF APPLICATION; APPROVAL OR DENIAL.—The request shall be in the form of an application submitted to the Secretary and the application shall include the certification required under section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. 282(j)(5)(B)) (which shall not be considered an element of the application). Not later than 75 days after the date of the receipt of the applica-

tion, the Secretary shall issue an order approving or denying the application.

(C) GUIDANCE RELATING TO PROBABLE BENEFIT.—The Secretary, acting through the Commissioner, shall publish a draft guidance that defines the criteria for establishing ''probable benefit'' as that term is used in subparagraph (A)(iii).

(3) PROHIBITION RELATING TO SALE PRICE.—Except as provided in paragraph (6), a person granted an exemption under paragraph (2) with respect to a device shall not sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) LIMITATIONS ON USE.—

(A) IN GENERAL.—Devices granted an exemption under paragraph (2) may be used only—

(i) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and

(ii) if, before the use of a device, an institutional review committee or an appropriate local committee approves the use in

the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A)(i), unless a physician determines in an emergency situation that approval from an institutional review committee or an appropriate local committee cannot be obtained in time to prevent serious harm or death to a patient.

(B) NOTIFICATION RELATING TO EMERGENCY USE.—In a case described in subparagraph (A)(ii) in which a physician uses a device without an approval from an institutional review committee or an appropriate local committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee or an appropriate local committee of the use. The notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

(5) DEMONSTRATION OF CONTINUED COMPLIANCE.—

(A) IN GENERAL.—The Secretary may require a person granted an exemption under

paragraph (2) to demonstrate continued compliance with the requirements of this subsection—

(i) if the Secretary believes the demonstration to be necessary to protect the public health;

(ii) if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met; or

(iii) if the Secretary has reason to believe that the criteria for the exemption are no longer met.

(B) SUSPENSION OR WITHDRAWAL OF EXEMPTION.—If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 13141 and 13142 of this title for a humanitarian device only after providing notice and an opportunity for an informal hearing.

(6) INAPPLICABILITY OF PROHIBITION ON SALE PRICE.—

(A) DEFINITIONS.—In this paragraph:

(i) ANNUAL DISTRIBUTION NUMBER.—The term ''annual distribution number'' means the number of the devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States.

(ii) PEDIATRIC PATIENTS.—The term ''pediatric patients'' means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

(iii) PEDIATRIC SUBPOPULATION.—The term ''pediatric subpopulation'' means one of the following populations:

(I) Neonates.

(II) Infants.

(III) Children.

(IV) Adolescents.

(B) CONDITIONS.—Except as provided in subparagraph (E), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

(i) The device with respect to which the exemption is granted—

(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and the device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for the patients is impossible, highly impracticable, or unsafe.

(ii) During any calendar year, the number of the devices distributed during that year under each exemption granted under this subsection does not exceed the annual distribution number for the device. The Secretary shall determine the annual distribution number when the Secretary grants the exemption.

(iii) The person immediately notifies the Secretary if the number of the devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

(iv) The request for the exemption is submitted on or before October 1, 2027.

(C) INSPECTION OF RECORDS.—The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

(D) PETITION TO MODIFY ANNUAL DISTRIBUTION NUMBER.—A person may petition the Secretary to modify the annual distribution number determined by the Secretary under subparagraph (B)(ii) with respect to a device if additional information arises, and the Secretary may modify the annual distribution number.

(E) EFFECT OF EXCEEDING ANNUAL DISTRIBUTION NUMBER ON PROHIBITION RELATING TO SALE PRICE.—If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (C), that the

number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (B)(iii), and modified under subparagraph (D), if applicable, the prohibition in paragraph (3) shall apply with respect to the person for the device for any sales of the device after the notification or determination.

(7) REFERRAL OF ADVERSE EVENT REPORT.—The Secretary shall refer to the Office of Pediatric Therapeutics any report of an adverse event regarding a device described in paragraph (6)(B)(i)(I) for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(B) that the Secretary receives. In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of the Committee regarding whether the Secretary should take action under this subtitle in response to the report.

(8) REVIEW OF ALL DEVICES TO ENSURE APPROPRIATENESS OF EXEMPTION.—The Secretary,

acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6)(B)(i)(I) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.

(n) REGULATION OF CONTACT LENSES AS DEVICES.—

(1) IN GENERAL.—All contact lenses shall be deemed to be devices under section 10101(a)(16) of this title.

(2) EFFECT OF PARAGRAPH (1).—Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 10101(a)(16) of this title or a drug as defined by section 10101(a)(18) of this title.

(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

(1) LIMITATION ON DEFINITION OF DEVICE.—The term ''device'', as defined in section 10101(a)(16) of this title, shall not include a software function that is intended—

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that the records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) the records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of the professionals;

(ii) the records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)); and

(iii) the function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to the data and results, general information about the findings, and general background information about the laboratory test or other device, unless the function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

(iii) enabling the health care professional to independently review the basis for the recommendations that the software presents so that it is not the intent that the health care professional rely primarily on any of the recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

(2) PRODUCT WITH MULTIPLE FUNCTIONS.—

(A) IN GENERAL.—

(i) FUNCTIONS.—Clause (ii) applies if a product has multiple functions that contains—

(I) at least 1 software function that meets the criteria under paragraph (1) or that otherwise does not

meet the definition of device under section 10101(a)(16) of this title; and

(II) at least 1 function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 10101(a)(16) of this title.

(ii) NO REGULATION.—The Secretary shall not regulate the software function of the product described in subparagraph (A)(i)(I) as a device.

(B) EXCEPTION RELATING TO SAFETY AND EFFECTIVENESS OF DEVICE FUNCTION.—Notwithstanding subparagraph (A), when assessing the safety and effectiveness of the device function or functions of the product described in subparagraph (A)(i)(II), the Secretary may assess the impact that the software function or functions described in subparagraph(A)(i)(I) have on the device function or functions.

(3) EXCEPTIONS TO PARAGRAPH (1).—

(A) IN GENERAL.—Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1)

shall not be excluded from the definition of device under section 10101(a)(16) of this title if—

(i) the Secretary makes a finding that use of the software function would be reasonably likely to have serious adverse health consequences; and

(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

(B) APPLICABILITY.—Subparagraph (A) shall apply only if the Secretary—

(i) publishes a notification and proposed order in the Federal Register;

(ii) includes in the notification the Secretary's finding, including the rationale and identification of the evidence on which the finding was based, as described in subparagraph (A)(i); and

(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing the proposed order.

(C) FACTORS.—In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in paragraph (1)(E).

(4) EFFECT OF SUBSECTION.—Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

(A) exercise enforcement discretion as to any device subject to regulation under this subtitle;

(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

(C) regulate software as a device under this subtitle if the software meets the criteria under section 13140(c)(1)(C) of this title.

(p) DIAGNOSTIC IMAGING DEVICES INTENDED FOR USE WITH CONTRAST AGENTS.—

(1) DEFINITIONS.—In this subsection:

(A) APPLICABLE MEDICAL IMAGING DEVICE.—The term ''applicable medical imaging device'' means a device intended to be used in conjunction with a contrast agent (or class of contrast agents) for an imaging use that is not described in the approved labeling of the contrast agent (or the approved labeling of any contrast agent in the same class as the contrast agent).

(B) CONTRAST AGENT.—The term ''contrast agent'' means a drug that is approved under chapter 135 of this title or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), is intended for use in conjunc-

tion with an applicable medical imaging device, and—

(i) is a diagnostic radiopharmaceutical, as defined in sections 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.

(2) IN GENERAL.—The Secretary may, subject to this subsection, approve an application (or a supplement to such an application) submitted under section 13142 of this title with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification is submitted under section 13136(k) of this title, may make a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 13140(h)(2) of this title for an applicable medical imaging device, if the application, notification, or request involves the use of a contrast agent that is not—

(A) in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve the application, make the substantial equivalence determination, or grant the request if the Secretary determines that the differences in concentration, rate of administration, or route of administration exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

(B) in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve the application, make the substantial equivalence determination, or grant the request if the Secretary determines that the differences in region, organ, or system of the body exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

(C) in a patient population that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve the application, make the substan-

tial equivalence determination, or grant the request if the Secretary determines the differences in patient population exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device; or

(D) in an imaging modality that is different from those described in the approved labeling of the contrast agent.

(3) PREMARKET REVIEW.—The agency center charged with premarket review of devices shall have primary jurisdiction with respect to the review of an application, notification, or request described in paragraph (2). In conducting the review, the agency center may—

(A) consult with the agency center charged with the premarket review of drugs or biological products; and

(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application submitted under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), so long as the sponsor of the contrast agent has provided to the sponsor of the applicable medical imag-

ing device that is the subject of the review a right of reference and the application is submitted in accordance with this subsection.

(4) APPLICABLE REQUIREMENTS.—An application submitted under section 13142 of this title, a notification submitted under section 13136(k) of this title, or a request submitted under section 13140(h)(2) of this title, as described in paragraph (2), with respect to an applicable medical imaging device, shall be subject to the requirements of the respective section. The application, notification, or request shall be subject only to the requirements of this subtitle applicable to devices.

(q) REGULATION OF OVER-THE-COUNTER HEARING AIDS.—

(1) DEFINITION.—

(A) IN GENERAL.—In this subsection, the term ''over-the-counter hearing aid'' means a device that—

(i) uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations, or any successor regulation) or wireless air conduction hearing aids (as defined in sec-

tion 874.3305 of title 21, Code of Federal Regulations, or any successor regulation);

(ii) is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment;

(iii) through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

(iv) may—

(I) use wireless technology; or

(II) include tests for self-assessment of hearing loss; and

(v) is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(B) EXCLUSION.—The term ''over-the-counter hearing aid'' does not include a personal sound amplification product intended to amplify sound for non-hearing impaired consumers in situations including hunting and birdwatching.

(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 49516(a) of this title and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).

**§ 13153. State and local requirements respecting devices**

(a) IN GENERAL.—Except as provided in subsection (b), a State or political subdivision of a State shall not establish or continue in effect with respect to a device intended for human use any requirement—

(1) that is different from, or in addition to, any requirement applicable under this subtitle to the device; or

(2) that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this subtitle.

(b) EXEMPTION REQUIREMENTS.—On application of a State or a political subdivision of a State, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in the regula-

tion, a requirement of the State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this subtitle that would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions; and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this subtitle.

**§ 13154. Postmarket surveillance**

(a) POSTMARKET SURVEILLANCE.—

(1) IN GENERAL.—

(A) CONDUCT.—The Secretary may by order, at the time of approval or clearance of a device or at any time after the approval or clearance, require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

(i) the failure of which would be reasonably likely to have serious adverse health consequences;

(ii) that is expected to have significant use in pediatric populations; or

(iii) that is intended to be—

(I) implanted in the human body for more than 1 year; or

(II) a life-sustaining or life-supporting device used outside a device user facility.

(B) CONDITION.—The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

(2) RULE OF CONSTRUCTION.—Paragraph (1) shall have no effect on authorities otherwise provided under this subtitle or regulations issued under this subtitle.

(b) SURVEILLANCE APPROVAL.—

(1) IN GENERAL.—

(A) SUBMISSION OF PLAN.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct the surveillance, submit, for the ap-

proval of the Secretary, a plan for the required surveillance.

(B) DETERMINATIONS OF THE SECRETARY.—The Secretary, within 60 days of the receipt of the plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health.

(C) COMMENCEMENT OF SURVEILLANCE.—The manufacturer shall commence surveillance under this section not later than 15 months after the day on which the Secretary issues an order under this section.

(D) ORDER OF SECRETARY RELATING TO LENGTH OF SURVEILLANCE.—

(i) IN GENERAL.—Except as provided in paragraph (2), the Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months.

(ii) LONGER PERIOD TO BE MUTUALLY AGREED ON BETWEEN SECRETARY

AND MANUFACTURER.—Except as provided in paragraph (2), any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 14304 of this title.

(2) LONGER SURVEILLANCE FOR PEDIATRIC DEVICES.—The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if the period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.

(c) DISPUTE RESOLUTION.—

(1) REQUEST FOR REVIEW.—A manufacturer may request review under section 14304 of this title of any order or condition requiring postmarket surveillance under this section.

(2) NONCOMPLIANCE DURING PENDENCY OF REVIEW.—During the pendency of the review, the device subject to such a postmarket surveillance order or condition shall not, because of noncompliance with the order or condition, be deemed in violation of section 10501(16)(A)(iii) of this title, adulterated under section 13101(f)(1) of this title, misbranded under section 13317(3) of this title, or in violation of, as applicable, section 13136(k) or 13142 of this title, unless considered necessary to protect the public health.

**§ 13155. Accredited persons**

(a) IN GENERAL.—

(1) REVIEW AND CLASSIFICATION OF DEVICES.—The Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 13136(k) of this title and making recommendations to the Secretary regarding the initial classification of devices under section 13140(h)(1) of this title.

(2) REQUIREMENTS REGARDING REVIEW.—

(A) IN GENERAL.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Sec-

retary in writing of the reasons for the recommendation.

(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

(C) SPECIAL RULE.—The Secretary may change the initial classification under section 13140(h)(1) of this title that is recommended under paragraph (1) by an accredited person, and in that case shall provide to the person, and the person that submitted the report under section 13136(k) of this title for the device, a statement explaining in detail the reasons for the change.

(3) CERTAIN DEVICES.—

(A) IN GENERAL.—An accredited person may not be used to perform a review of—

(i) a class III device;

(ii) a device classified under section 13140(h)(2) of this title or designated under section 13144(d) of this title;

(iii) a device that is intended to be permanently implantable, life sustaining, or life supporting, unless otherwise determined by the Secretary in accordance with subparagraph (B)(i)(II) and listed as eligible for review under subparagraph (B)(iii); or

(iv) a device that is of a type, or subset of a type, listed as not eligible for review under subparagraph (B)(iii).

(B) DESIGNATION FOR REVIEW.—The Secretary shall—

(i) issue draft guidance on the factors the Secretary will use in determining whether a class I or class II device type, or subset of the device types, is eligible for review by an accredited person, including—

(I) the risk of the device type, or subset of the device type; and

(II) whether the device type, or subset of the device type, is permanently implantable, life sustaining, or life supporting, and whether there is a detailed public health justification for

permitting the review by an accredited person of the device type or subset;

(ii) not later than 24 months after the date on which the Secretary issues the draft guidance, finalize the guidance; and

(iii) beginning on the date the guidance is finalized, designate and post on the FDA website an updated list of class I and class II device types, or subsets of the device types, and the Secretary's determination with respect to whether each of those device types, or each of those subsets, is eligible or not eligible for review by an accredited person under this section based on the factors described in clause (i).

(C) INTERIM RULE.—Until the date on which the updated list is designated and posted in accordance with subparagraph (B)(iii), the list in effect on August 18, 2017, shall be in effect.

(b) ACCREDITATION.—

(1) PROGRAMS.—The Secretary shall provide for the accreditation through programs administered by the FDA, other government agencies, or by other qualified nongovernment organizations.

(2) ACCREDITATION.—

(A) IN GENERAL.—

(i) CRITERIA.—The Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to any person that requests to perform the duties specified in subsection (a).

(ii) RESPONSE TO REQUEST FOR ACCREDITATION.—The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request.

(iii) SPECIFICATION OF ACTIVITIES.—The accreditation of a person shall specify the particular activities under subsection (a) for which the person is accredited.

(B) SUSPENSION OR WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when the person is substantially not in compliance with the requirements of this section, poses a threat to public health, or fails to act in a manner that is consistent with the purposes of this section.

(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

(i) make onsite visits on a periodic basis to each accredited person to audit the performance of the person; and

(ii) take such additional measures as the Secretary determines to be appropriate.

(D) PERIODIC REACCREDITATION.—

(i) PERIOD.—Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

(ii) RESPONSE TO REACCREDITATION REQUEST.—On the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny the request not later than 60 days after receipt of the request.

(iii) CRITERIA.—The Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section.

The reaccreditation of persons under this section shall specify the particular activities under subsection (a), and the devices, for which the persons are reaccredited.

(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

(A) The person may not be an employee of the Federal Government.

(B) The person shall be an independent organization that is not owned or controlled by a manufacturer, supplier, or vendor of devices and that has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

(C) The person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) The person shall not engage in the design, manufacture, promotion, or sale of devices.

(E) The operations of the person shall be in accordance with generally accepted professional and ethical business practices.

(F) The person shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to this section—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as proprietary information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person that has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements

under this clause relating to financial conflicts of interest.

(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide, for each person that chooses to use an accredited person to receive a report under section 13136(k) of this title, a panel of at least 2 or more accredited persons from which the regulated person may select 1 for a specific regulatory function.

(5) COMPENSATION OF ACCREDITED PERSONS.—Compensation for an accredited person shall be determined by agreement between the accredited person and the person that engages the services of the accredited person, and shall be paid by the person that engages the services.

(c) DURATION.—The authority provided by this section terminates on October 1, 2027.

**§ 13156. Priority review to encourage treatments for tropical diseases**

(a) DEFINITIONS.—In this section:

(1) PRIORITY REVIEW.—The term ''priority review'', with respect to a human drug application as defined in section 17906(a) of this title, means review and action by the Secretary on the human drug application not later than 6 months after receipt by

the Secretary of the human drug application, as described in the Manual of Policies and Procedures of the FDA and goals identified in the letters described in section 101(c) of the Prescription Drug User Fee Amendments of 2007 (Public Law 110–85, title I, 121 Stat. 825).

(2) PRIORITY REVIEW VOUCHER.—The term ''priority review voucher'' means a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of the voucher to priority review of a single human drug application submitted under section 13503(a) of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) after the date of approval of the tropical disease product application.

(3) TROPICAL DISEASE.—The term ''tropical disease'' means any of the following:

(A) Tuberculosis.

(B) Malaria.

(C) Blinding trachoma.

(D) Buruli Ulcer.

(E) Cholera.

(F) Dengue/dengue haemorrhagic fever.

(G) Dracunculiasis (guinea-worm disease).

(H) Fascioliasis.

(I) Human African trypanosomiasis.

(J) Leishmaniasis.

(K) Leprosy.

(L) Lymphatic filariasis.

(M) Onchocerciasis.

(N) Schistosomiasis.

(O) Soil transmitted helmithiasis.

(P) Yaws.

(Q) Filovirus Diseases.

(R) Zika Virus Disease.

(S) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by order of the Secretary.

(4) TROPICAL DISEASE PRODUCT APPLICATION.—The term ''tropical disease product application'' means an application that—

(A) is a human drug application as defined in section 17906(a) of this title—

(i) for prevention or treatment of a tropical disease;

(ii) that the Secretary considers eligible for priority review;

(iii) that contains reports of 1 or more new clinical investigations (other than bioavailability studies) that are essential to the approval of the application and conducted or sponsored by the sponsor of the application; and

(iv) that contains an attestation from the sponsor of the application that the reports were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007;

(B) is approved after September 27, 2007, by the Secretary for use in the prevention, detection, or treatment of a tropical disease; and

(C) is for—

(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other ap-

plication under section 13503(a) of this title; or

(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) PRIORITY REVIEW VOUCHER.—

(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product application on approval by the Secretary of the tropical disease product application.

(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to the voucher to a sponsor of a human drug for which an application under section 13503(a) of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) will be submitted after the date of the approval of the tropical disease product application. There is no limit on the number of times a priority review voucher may be transferred before the voucher is used.

(3) LIMITATION.—A sponsor of a tropical disease product may not receive a priority review

voucher under this section if the tropical disease product application was submitted to the Secretary prior to September 27, 2007.

(4) NOTIFICATION.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the human drug application. The notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(c) PRIORITY REVIEW USER FEE.—

(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). The fee shall be in addition to any fee required to be submitted by the sponsor under chapter 179 of this title.

(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and shall be based on the average cost incurred by the agency in the review of a

human drug application subject to priority review in the previous fiscal year.

(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year, for that fiscal year, the amount of the priority review user fee.

(4) PAYMENT.—

(A) IN GENERAL.—The priority review user fee required by this subsection shall be due on the submission of a human drug application under section 13503(a) of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) for which the priority review voucher is used.

(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying the fees.

(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not

grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the FDA; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

**§ 13157. Priority review for qualified infectious disease products**

(a) IN GENERAL.—If the Secretary designates a drug under section 13116(e) of this title as a qualified infectious disease product, the Secretary shall give priority review to the first application submitted for approval for that drug under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness.

(b) CONSTRUCTION.—Nothing in this section prohibits the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 13503 of this title that other-

wise meets the criteria for the Secretary to grant priority review.

**§ 13158. Ensuring cybersecurity of devices**

(a) DEFINITION OF CYBER DEVICE.—In this section, the term ''cyber device'' means a device that—

(1) includes software validated, installed, or authorized by the sponsor as a device or in a device;

(2) has the ability to connect to the internet; and

(3) contains any technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats.

(b) IN GENERAL.—A person that submits an application or submission under section 13136(k), 13140, or 13152(m) of this title or under subsection (c) or (f) of section 13142 of this title for a device that meets the definition of a cyber device under this section shall include such information as the Secretary may require to ensure that the cyber device meets the cybersecurity requirements under subsection (c).

(c) CYBERSECURITY REQUIREMENTS.—The sponsor of an application or submission described in subsection (b) shall—

(1) submit to the Secretary a plan to monitor, identify, and address, as appropriate, in a reasonable

time, postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures;

(2) design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and make available postmarket updates and patches to the device and related systems to address—

(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and

(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks;

(3) provide to the Secretary a software bill of materials, including commercial, open-source, and off-the-shelf software components; and

(4) comply with such other requirements as the Secretary may require through regulation to demonstrate reasonable assurance that the device and related systems are cybersecure.

(d) EXEMPTION.—

(1) IN GENERAL.—The Secretary may identify devices, or categories or types of devices, that are exempt from meeting the cybersecurity requirements

established by this section and regulations promulgated pursuant to this section.

(2) PUBLICATION.—The Secretary shall publish in the Federal Register, and update, as appropriate, a list of the devices, or categories or types of devices, identified by the Secretary under paragraph (1).

(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the Secretary's authority related to ensuring that there is a reasonable assurance of the safety and effectiveness of devices, which may include ensuring that there is a reasonable assurance of the cybersecurity of certain cyber devices, including for devices approved or cleared prior to December 29, 2022.

# Chapter 133—Misbranded Drugs and Devices

Sec.
13301. False or misleading label.
13302. Package form.
13303. Prominence of information on label.
13304. Designation of drugs or devices by established names.
13305. Directions for use and warnings on label.
13306. Representations as recognized drug.
13307. Deteriorative drugs.
13308. Misleading container; imitation; offered for sale under another name.
13309. Health-endangering when used as prescribed.
13310. Color additives.
13311. Prescription drug advertisements.
13312. Drugs or devices from nonregistered establishments.
13313. Packaging or labeling of drugs in violation of regulations.
13314. Restricted devices using false or misleading advertising or used in violation of regulations.
13315. Restricted device advertisements.
13316. Devices subject to performance standards not bearing requisite labeling.
13317. Devices for which there has been a failure or refusal to give required notification or to furnish required material or information.
13318. Identification of manufacturer.
13319. Reprocessed single-use devices.

13320. New animal drugs.
13321. Nonprescription drugs.
13322. Drugs subject to approved risk evaluation and mitigation strategy.
13323. Postmarket studies and clinical trials; new safety information in labeling.
13324. Unpaid fees; failure to submit identifying information.
13325. False or misleading advertisement or promotion of compounded drug.
13326. Failure to bear product identifier.
13327. Improper labeling of antimicrobial drugs.
13328. Nonprescription drug subject to regulation.
13329. Drugs manufactured, prepared, propagated, compounded, or processed in facilities for which fees have not been paid.
13330. Product information prior to approval.

**§ 13301. False or misleading label**

(a) DEFINITION OF HEALTH CARE ECONOMIC INFORMATION.—

(1) IN GENERAL.—In this section, the term ''health care economic information'' means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug or device. The analysis may be comparative to the use of another drug or device, to another health care intervention, or to no intervention.

(2) EXCLUSION.—The term ''health care economic information'' does not include any analysis that relates only to an indication that is not approved under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or

under section 351 of the Public Health Service Act (42 U.S.C. 262) for the drug or device.

(b) IN GENERAL.—A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular.

(c) EXCEPTION FOR CERTAIN HEALTH CARE ECONOMIC INFORMATION.—Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement, shall not be considered to be false or misleading under this section if the health care economic information—

(1) relates to an indication approved under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or under section 351 of the Public Health Service Act (42 U.S.C. 262) for the drug or device;

(2) is based on competent and reliable scientific evidence; and

(3) includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug or de-

vice under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or under section 351 of the Public Health Service Act (42 U.S.C. 262).

(d) INAPPLICABILITY OF REQUIREMENTS.—The requirements set forth in chapter 135 of this title or in section 13136(k), 13140(h)(2), or 13142 of this title or in section 351 of the Public Health Service Act (42 U.S.C. 262) shall not apply to health care economic information provided to a payor, committee, or entity in accordance with this section.

(e) AVAILABILITY OF INFORMATION TO SECRETARY.—Information that is relevant to the substantiation of the health care economic information presented pursuant to this section shall be made available to the Secretary upon request.

**§ 13302. Package form**

(a) IN GENERAL.—A drug or device shall be deemed to be misbranded if in package form unless it bears a label containing—

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(b) REASONABLE VARIATIONS; EXEMPTIONS.—Under subsection (a)(2), reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

**§ 13303. Prominence of information on label**

A drug or device shall be deemed to be misbranded if any word, statement, or other information required by or under authority of this subtitle to appear on the label or labeling is not prominently placed on the label or labeling with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

**§ 13304. Designation of drugs or devices by established names**

(a) DRUGS.—

(1) DEFINITION OF ESTABLISHED NAME.—

(A) IN GENERAL.—In this subsection, the term ''established name'', with respect to a drug or ingredient of a drug, means—

(i) the applicable official name designated pursuant to section 13134 of this title; or

(ii) if there is no such name and the drug, or the ingredient, is an article recognized in an official compendium, then the official title of the drug or ingredient in the compendium; or

(iii) if neither clause (i) nor (ii) applies, then the common or usual name, if any, of the drug or of the ingredient.

(B) ARTICLE RECOGNIZED IN BOTH COMPENDIA.—If subparagraph (A)(ii) applies to an article recognized in the United States Pharmacopeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply.

(2) IN GENERAL.—A drug shall be deemed to be misbranded, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(A) the established name of the drug, if there is such a name;

(B) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained in the drug, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subparagraph, shall not apply to nonprescription drugs not intended for human use; and

(C) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in

regulation promulgated by the Secretary, except that—

(i) nothing in this subparagraph shall be deemed to require that any trade secret be divulged; and

(ii)(I) the requirements of this subparagraph with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics; and

(II) this subparagraph shall not apply to nonprescription drugs not intended for human use.

(3) PRINTING AND TYPE SIZE REQUIREMENTS RELATING TO PRESCRIPTION DRUGS.—For any prescription drug, the established name of the drug or ingredient, as the case may be, on the label (and on any labeling on which a name for the drug or ingredient is used) shall be printed prominently and in type at least half as large as that used on the label for any proprietary name or designation for the drug or ingredient.

(4) EXCEPTIONS ESTABLISHED BY REGULATION.—To the extent that compliance with the requirements of subparagraph (B) or (C) of paragraph (2) or paragraph (3) is impracticable, exemptions

shall be established by regulations promulgated by the Secretary.

(b) DEVICES.—

(1) DEFINITION OF ESTABLISHED NAME.—In this subsection, the term ''established name'', with respect to a device, means—

(A) the applicable official name of the device designated pursuant to section 13134 of this title;

(B) if there is no such name and the device is an article recognized in an official compendium, then the official title of the device in the compendium; or

(C) if neither subparagraph (A) nor subparagraph (B) applies, then any common or usual name of the device.

(2) IN GENERAL.—A device shall be deemed to be misbranded if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type at least half as large as that used on the label for any proprietary name or designation for the device.

(3) EXCEPTIONS ESTABLISHED BY REGULATION.—To the extent compliance with the require-

ments of paragraph (2) is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

**§ 13305. Directions for use and warnings on label**

(a) IN GENERAL.—A drug or device shall be deemed to be misbranded unless its labeling bears—

(1) adequate directions for use; and

(2) in such manner and form as are necessary for the protection of users, adequate warnings—

(A) against use in those pathological conditions or by children where its use may be dangerous to health; or

(B) against unsafe dosage or methods or duration of administration or application.

(b) EXEMPTIONS BY REGULATIONS.—If any requirement of subsection (a)(1), as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting the drug or device from the requirement.

(c) DEVICES FOR WHICH REQUIRED LABELING MAY BE MADE AVAILABLE BY ELECTRONIC MEANS.—Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood es-

tablishments may be made available solely by electronic means, provided that—

(1) the labeling complies with all applicable requirements of law; and

(2) the manufacturer—

(A) affords the users the opportunity to request the labeling in paper form; and

(B) after the request, promptly provides the requested information without additional cost.

**§ 13306. Representations as recognized drug**

(a) IN GENERAL.—A drug shall be deemed to be misbranded if it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed in the compendium.

(b) MODIFICATION OF METHOD OF PACKING.—The method of packing for a drug described in subsection (a) may be modified with the consent of the Secretary.

(c) DRUGS RECOGNIZED IN BOTH COMPENDIA.—

(1) IN GENERAL.—If a drug is recognized in both the United States Pharmacopeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as

a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not those of the United States Pharmacopoeia.

(2) INCONSISTENT REQUIREMENTS WITH RESPECT TO DESIGNATED NAME.—In the event of inconsistency between the requirements of this section and those of section 13304 of this title as to the name by which the drug or its ingredients shall be designated, the requirements of section 13304 of this title shall prevail.

**§ 13307. Deteriorative drugs**

(a) IN GENERAL.—A drug shall be deemed to be misbranded if it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health.

(b) REQUIREMENTS TO BE FIRST PRESCRIBED BY BODY CHARGED WITH REVISION OF COMPENDIUM.—The Secretary shall not establish any regulation under subsection (a) for any drug recognized in an official compendium until—

(1) the Secretary informs the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements; and

(2) the body fails within a reasonable time to prescribe the requirements.

**§ 13308. Misleading container; imitation; offered for sale under another name**

A drug shall be deemed to be misbranded—

(1) if its container is made, formed, or filled so as to be misleading;

(2) if it is an imitation of another drug; or

(3) if it is offered for sale under the name of another drug.

**§ 13309. Health-endangering when used as prescribed**

A drug or device shall be deemed to be misbranded if it is dangerous to health when used in the dosage or manner, or with the frequency or duration, prescribed, recommended, or suggested in the labeling of the drug or device.

**§ 13310. Color additives**

A drug or device shall be deemed to be misbranded if it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to the color additive, as may be

contained in regulations issued under section 17701 of this title.

**§ 13311. Prescription drug advertisements**

(a) IN GENERAL.—A drug shall be deemed to be misbranded if it is a prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor of the prescription drug includes—

(1) in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug, a true statement of—

(A) the established name as defined in section 13304 of this title, printed prominently and in type at least half as large as that used for any trade or brand name of the drug;

(B) the formula showing quantitatively each ingredient of the drug to the extent required for labels under section 13304 of this title; and

(C) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations that shall be issued by the Secretary in accordance with section 17501(a) of this title; and

(2) in the case of published direct-to-consumer advertisements, the following statement printed in conspicuous text: ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.''.

(b) PRIOR APPROVAL OF CONTENT.—Except in extraordinary circumstances, a regulation issued under this section shall not require prior approval by the Secretary of the content of any advertisement.

(c) INAPPLICABILITY OF CERTAIN PROVISIONS OF THE FEDERAL TRADE COMMISSION ACT.—An advertisement of a prescription drug, published after the effective date of regulations issued under this section applicable to advertisements of prescription drugs, shall not with respect to the matters specified in this section or covered by the regulations, be subject to sections 12 through 17 of the Federal Trade Commission Act (15 U.S.C. 52 through 57).

(d) INAPPLICABILITY TO LABELING.—This section shall not be applicable to any printed matter that the Secretary determines to be labeling as defined in section 10101(a) of this title.

(e) EFFECT OF CONVENTION ON PSYCHOTROPIC SUBSTANCES.—Nothing in the Convention on Psycho-

tropic Substances, done at Vienna, Austria February 21, 1971 (32 UST 543; TIAS 9725), shall be construed to prevent drug price communications to consumers.

(f) SPECIAL REQUIREMENT FOR TELEVISION OR RADIO ADVERTISEMENTS.—

(1) IN GENERAL.—In the case of an advertisement for a drug subject to section 13103(a)(1) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(2) REGULATIONS.—Not later than 30 months after September 27, 2007, the Secretary shall by regulation establish standards for determining whether a major statement relating to side effects and contraindications of a drug, described in paragraph (1), is presented in the manner required under the paragraph.

**§ 13312. Drugs or devices from nonregistered establishments**

A drug or device shall be deemed to be misbranded—

(1) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not registered under section 13136 of this title;

(2) if it is a drug and was imported or offered for import by a commercial importer of drugs not registered under section 20101(s) of this title;

(3) if it was not included in a list required by section 13136(j) of this title;

(4) if a notice or other information respecting it was not provided as required by subsection (j) or (k) of section 13136 of this title; or

(5) if it is a device and it does not bear such symbols from the uniform system for identification of devices prescribed under section 13136(e) of this title as the Secretary by regulation requires.

**§ 13313. Packaging or labeling of drugs in violation of regulations**

A drug shall be deemed to be misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1472, 1473).

**§ 13314. Restricted devices using false or misleading advertising or used in violation of regulations**

A device shall be deemed to be misbranded in the case of any restricted device distributed or offered for sale in any State, if—

(1) its advertising is false or misleading in any particular; or

(2) it is sold, distributed, or used in violation of regulations prescribed under section 13152(e) of this title.

**§ 13315. Restricted device advertisements**

(a) IN GENERAL.—A device shall be deemed to be misbranded in the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor of the restricted device includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device—

(1)(A) true statement of the device's established name as defined in section 13304 of this title, printed prominently and in type at least half as large as that used for any trade or brand name of the device; and

(B) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications; and

(2) in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that the action is necessary to protect the public health, a full description of the components of the device or the formula showing quantitatively each ingredient of the device to the extent required in regulations that shall be issued by the Secretary after an opportunity for a hearing.

(b) PRIOR APPROVAL OF CONTENT.—Except in extraordinary circumstances, a regulation issued under this section shall not require prior approval by the Secretary of the content of any advertisement.

(c) INAPPLICABILITY OF THE FEDERAL TRADE COMMISSION ACT.—An advertisement of a restricted device, published after May 28, 1976, shall not, with respect to the matters specified in this section or covered by regulations issued under this section, be subject to sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55).

(d) INAPPLICABILITY TO LABELING.—This section shall not be applicable to any printed matter that the Sec-

retary determines to be labeling as defined in section 10101(a) of this title.

**§ 13316. Devices subject to performance standards not bearing requisite labeling**

A device shall be deemed to be misbranded if it is subject to a performance standard established under section 13141 of this title, unless it bears such labeling as may be prescribed in the performance standard.

**§ 13317. Devices for which there has been a failure or refusal to give required notification or to furnish required material or information**

A device shall be deemed to be misbranded if there was a failure or refusal—

(1) to comply with any requirement prescribed under section 13149 of this title respecting the device;

(2) to furnish any material or information required by or under section 13151 of this title respecting the device; or

(3) to comply with a requirement under section 13154 of this title respecting the device.

**§ 13318. Identification of manufacturer**

(a) IN GENERAL.—Subject to subsection (b), a device shall be deemed to be misbranded if it is a reprocessed

single-use device, unless it, or an attachment to the device, prominently and conspicuously bears—

(1) the name of the manufacturer of the reprocessed device;

(2) a generally recognized abbreviation of the name; or

(3) a unique and generally recognized symbol identifying the manufacturer.

(b) DETACHABLE LABEL IN LIEU OF NAME, ABBREVIATION, OR SYMBOL.—If the original device or an attachment to the device does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of the name, or a unique and generally recognized symbol identifying the manufacturer, a reprocessed device may satisfy the requirements of subsection (a) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

(c) GUIDANCE.—The Secretary shall issue guidance to identify circumstances in which the name of the manufacturer of the original device, a generally recognized abbreviation of the name of the manufacturer, or a unique and generally recognized symbol identifying the manufac-

turer, is not ''prominent and conspicuous'' as used in this section.

**§ 13319. Reprocessed single-use devices**

(a) IN GENERAL.—A device shall be deemed to be misbranded if it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement ''Reprocessed device for single use. Reprocessed by _____.''.

(b) SPACE.—In subsection (a), the name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

**§ 13320. New animal drugs**

(a) IN GENERAL.—A drug shall be deemed to be misbranded if it is a new animal drug—

(1) that is conditionally approved under section 14502 of this title and its labeling does not conform with the approved application or section 14502(g) of this title, or that is not conditionally approved under section 14502 of this title and its label bears the statement set forth in section 14502(g)(1)(A) of this title;

(2) that is indexed under section 14503 of this title and its labeling does not conform with the index listing under subsection (e) or (h) of section 14503 of this title, or that has not been indexed under sec-

tion 14503 of this title and its label bears the statement set forth in section 14503(h) of this title; or

(3) for which an application has been approved under chapter 137 of this title and the labeling of the drug does not include the application number in the format ''Approved by FDA under (A)NADA # xxx–xxx'', except that this paragraph shall not apply to representative labeling required under section 514.1(b)(3)(v)(b) of title 21, Code of Federal Regulations, or any successor regulation, for animal feed bearing or containing a new animal drug.

(b) EFFECTIVE DATE.—Subsection (a)(3) shall apply beginning on September 30, 2023.

**§ 13321. Nonprescription drugs**

A drug shall be deemed to be misbranded if it is a nonprescription drug (as defined in section 18901 of this title) that is marketed in the United States, unless the label of the drug includes a domestic address or domestic phone number through which the responsible person (as described in section 18901 of this title) may receive a report of a serious adverse event (as defined in section 18901 of this title) with the drug.

**§ 13322. Drugs subject to approved risk evaluation and mitigation strategy**

A drug shall be deemed to be misbranded if it is subject to an approved risk evaluation and mitigation strategy pursuant to section 13516 of this title and the responsible person (as the term is used in section 13111 of this title) fails to comply with a requirement of the strategy provided for under subsection (d), (e), or (f) of section 13111 of this title.

**§ 13323. Postmarket studies and clinical trials; new safety information in labeling**

A drug shall be deemed to be misbranded if the responsible person (as the term is used in section 13515 of this title) is in violation of a requirement established under subsection (c) or subsection (d) of section 13515 of this title with respect to the drug.

**§ 13324. Unpaid fees; failure to submit identifying information**

A drug shall be deemed to be misbranded if—

(1) it is a drug or an active pharmaceutical ingredient; and

(2)(A) it was manufactured, prepared, propagated, compounded, or processed in a facility—

(i) for which fees have not been paid as required by section 17952(a)(4) of this title; or

(ii) for which identifying information required by section 17952(f) of this title has not been submitted; or

(B) it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in a facility described in subparagraph (A).

**§ 13325. False or misleading advertisement or promotion of compounded drug**

A drug shall be deemed to be misbranded if it is a compounded drug and its advertising or promotion is false or misleading in any particular.

**§ 13326. Failure to bear product identifier**

A drug shall be deemed to be misbranded if it fails to bear the product identifier as required by section 14902 of this title.

**§ 13327. Improper labeling of antimicrobial drugs**

A drug shall be deemed to be misbranded if it is an antimicrobial drug, as defined in section 13138(b) of this title, and its labeling fails to conform with the requirements under section 13138(f) of this title.

**§ 13328. Nonprescription drug subject to regulation**

A drug shall be deemed to be misbranded if it is a nonprescription drug that is subject to section 13118 of this title, is not the subject of an application approved

under chapter 135 of this title, and does not comply with the requirements under section 13118 of this title.

**§ 13329. Drugs manufactured, prepared, propagated, compounded, or processed in facilities for which fees have not been paid**

A drug shall be deemed to be misbranded if it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 17977 of this title.

**§ 13330. Product information prior to approval**

(a) DEFINITION OF PRODUCT INFORMATION.—In this section, the term ''product information'' includes—

(1) information describing the drug or device (such as drug class, device description, and features);

(2) information about the indication or indications being investigated;

(3) the anticipated timeline for a possible approval, clearance, marketing authorization, or licensure pursuant to chapter 135 of this title or section 13136(k), 13140, or 13142 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262);

(4) drug or device pricing information;

(5) patient utilization projections;

(6) product-related programs or services; and

(7) factual presentations of results from studies that do not characterize or make conclusions regarding safety or efficacy.

(b) IN GENERAL.—A drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use in accordance with section 13305 of this title, except that (in addition to drugs or devices that conform with exemptions pursuant to section 13305 of this title) no drug or device shall be deemed to be misbranded under section 13305 of this title through the provision of truthful and not misleading product information to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement if the product information relates to an investigational drug or device or investigational use of a drug or device that is approved, cleared, granted marketing authorization, or licensed under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) (as applicable), provided—

(1) the product information includes—

(A) a clear statement that the investigational drug or device or investigational use of a drug or device has not been approved, cleared, granted marketing authorization, or licensed under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) (as applicable) and that the safety and effectiveness of the drug or device for that use has not been established;

(B) information related to the stage of development of the drug or device involved, such as—

(i) the status of any study or studies in which the investigational drug or device or investigational use is being investigated;

(ii) how the study or studies relate to the overall plan for the development of the drug or device; and

(iii) whether an application, premarket notification, or request for classification for the investigational drug or device or investigational use has been submitted to the Secretary or when such a submission is planned;

(C) in the case of information that includes factual presentations of results from studies, which shall not be selectively presented, a description of—

(i) all material aspects of study design, methodology, and results; and

(ii) all material limitations related to the study design, methodology, and results;

(D) where applicable, a prominent statement disclosing the indication or indications for which the Secretary has approved, granted marketing authorization for, cleared, or licensed the product pursuant to chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), and a copy of the most current required labeling; and

(E) updated information, if previously communicated information becomes materially outdated as a result of significant changes or as a result of new information regarding the product or its review status; and

(2) the product information does not include—

(A) information that represents that an unapproved product—

(i) has been approved, cleared, granted marketing authorization, or licensed under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) (as applicable); or

(ii) has otherwise been determined to be safe or effective for the purpose or purposes for which the drug or device is being studied; or

(B) information that represents—

(i) that an unapproved use of a drug or device that has been approved, cleared, granted marketing authorization, or licensed under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) (as applicable) is so approved, cleared, granted marketing authorization, or licensed; or

(ii) that the product is safe or effective for the use or uses for which the drug or device is being studied.

# Chapter 135—New Drugs

Sec.
13501. Definitions.
13502. Necessity of effective approval of application.
13503. Filing application; contents.
13504. Period for approval of application.
13505. Grounds for refusing to approve application; approval.
13506. Withdrawal of and suspension of approval.
13507. Revocation of order refusing, withdrawing, or suspending approval of application.
13508. Service of orders.
13509. Appeal from order.
13510. Drugs for investigational use.
13511. Abbreviated new drug applications.
13512. Records and reports.
13513. Public disclosure of safety and effectiveness data and action package.
13514. Scientific advisory panels.
13515. Postmarket studies and clinical trials; labeling changes.
13516. Risk evaluation and mitigation strategy.
13517. Petitions and civil actions regarding approval of certain applications.
13518. Postmarket drug safety information for patients and providers.
13519. Referral to advisory committee.
13520. Database for authorized generic drugs.
13521. Certain drugs containing single enantiomers.
13522. Antibiotic drugs submitted before November 21, 1997.
13523. Deadline for determination on certain petitions.
13524. Date of approval in the case of recommended controls under division A of subtitle V of this title.
13525. Contrast agents intended for use with applicable medical imaging devices.
13526. Diversity action plan for clinical studies.

## § 13501. Definitions

In this chapter:

(1) DATE OF APPROVAL.—With respect to an application described in section 13524 of this title, the term ''date of approval'' means the later of—

(A) the date an application under section 13503 of this title is approved under section 13504 of this title; or

(B) the date of issuance of the interim final rule controlling the drug.

(2) NONCLINICAL TEST.—The term ''nonclinical test'' means a test conducted in vitro, in silico, or in chemico, or a nonhuman in vivo test, that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. The test may include the following:

(A) Cell-based assays.

(B) Organ chips and microphysiological systems.

(C) Computer modeling.

(D) Other nonhuman or human biology-based test methods, such as bioprinting.

(E) Animal tests.

(3) PATENT.—The term ''patent'' means a patent issued by the United States Patent and Trademark Office.

**§ 13502. Necessity of effective approval of application**

A person shall not introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to section 13503 or 13511 of this title is effective with respect to the drug.

**§ 13503. Filing application; contents**

(a) IN GENERAL.—

(1) PERSON THAT MAY FILE; REQUIRED SUBMISSIONS.—Any person may file with the Secretary

an application with respect to any drug subject to the provisions of section 13502 of this title. The person shall submit to the Secretary as part of the application—

(A) full reports of investigations that have been made to show whether the drug is safe for use and whether the drug is effective in use;

(B) a full list of the articles used as components of the drug;

(C) a full statement of the composition of the drug;

(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;

(E) such samples of the drug and of the articles used as components of the drug as the Secretary may require;

(F) specimens of the labeling proposed to be used for the drug;

(G) any assessments required under section 13113 of this title; and

(H) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a

person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

(i) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(ii) claims a method of using the drug for which approval is sought or has been granted in the application.

(2) PATENT ISSUANCE SUBSEQUENT TO FILING OF APPLICATION.—If an application is filed under this section for a drug, and a patent of the type described in paragraph (1)(H) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.

(b) ADDITIONAL REQUIREMENTS FOR CERTAIN APPLICATIONS.—An application submitted under subsection (a) for a drug for which the investigations described in subsection (a)(1)(A) (which investigations were relied on by the applicant for approval of the application) were not conducted by or for the applicant and for which drug the applicant has not obtained a right of reference or use from

the person by or for whom the investigations were conducted shall also include—

(1) a certification, in the opinion of the applicant and to the best of the applicant's knowledge, with respect to each patent that claims the drug for which the investigations were conducted or that claims a use for the drug for which the applicant is seeking approval under this section and for which information is required to be filed under subsection (a) or section 13504 of this title—

(A) that the patent information has not been filed;

(B) that the patent has expired;

(C) of the date on which the patent will expire; or

(D) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(2) if, with respect to the drug for which investigations described in subsection (a)(1)(A) were conducted, information was filed under subsection (a) or section 13504 of this title for a method of use patent that does not claim a use for which the applicant is seeking approval under this section, a statement

that the method of use patent does not claim that use.

(c) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(1) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subsection (b)(1)(D) shall include in the application a statement that the applicant will give notice as required by this subsection.

(2) TIMING OF NOTICE.—An applicant that makes a certification described in subsection (b)(1)(D) shall give notice as required under this subsection—

(A) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(B) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application

or in an amendment or supplement to the application.

(3) RECIPIENTS OF NOTICE.—An applicant required under this subsection to give notice shall give notice to—

(A) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(B) the holder of the approved application under this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(4) CONTENTS OF NOTICE.—A notice required under this subsection shall—

(A) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this section for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(B) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(d) AMENDMENT OR SUPPLEMENTATION OF AN APPLICATION FOR A DRUG TO SEEK APPROVAL FOR A DIFFERENT DRUG.—

(1) IN GENERAL.—An applicant may not amend or supplement an application referred to in subsection (b) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(2) DIFFERENT STRENGTH.—With respect to the drug for which such an application is submitted, nothing in this section or section 13504(c) of this title prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(e) GUIDANCE FOR INDIVIDUALS WHO REVIEW APPLICATIONS; AGREEMENT ON DESIGN AND SIZE OF CLINICAL TRIALS OR STUDIES.—

(1) GUIDANCE.—The Secretary shall issue guidance for the individuals who review applications submitted under subsection (a) or under section 351

of the Public Health Service Act (42 U.S.C. 262), which guidance shall—

(A) relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards; and

(B) apply equally to all individuals who review the applications.

(2) AGREEMENT.—

(A) REVIEWING DIVISION.—In this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this section or section 351 of the Public Health Service Act (42 U.S.C. 262) (including all scientific and medical matters, chemistry, manufacturing, and controls).

(B) MEETING TO REACH AGREEMENT.—

(i) IN GENERAL.—The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this section or section 351 of the Public Health Service Act (42 U.S.C. 262) if the sponsor or applicant makes a reasonable written request for a meeting for the pur-

pose of reaching agreement on the design and size—

(I)(aa) of clinical trials intended to form the primary basis of an effectiveness claim; or

(bb) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials that, in combination, are intended to form the primary basis of an effectiveness claim; or

(II) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), of any necessary clinical study or studies.

(ii) PROVISION OF INFORMATION.—The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials.

(iii) MINUTES.—Minutes of any meeting under clause (i) shall be prepared by

the Secretary and made available to the sponsor or applicant upon request.

(C) AGREEMENT REQUIRED TO BE IN WRITING; CONDITIONS ON WHICH AGREEMENT MAY BE CHANGED.—

(i) AGREEMENT REQUIRED TO BE IN WRITING.—Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary.

(ii) CONDITIONS ON WHICH AGREEMENT MAY BE CHANGED.—The agreement shall not be changed after the testing begins, except—

(I) with the written agreement of the sponsor or applicant; or

(II) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or

effectiveness of the drug has been identified after the testing has begun.

(D) REQUIREMENTS FOR DECISION.—A decision under subparagraph (C)(ii)(II) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) DECISION OF REVIEWING DIVISION AS BINDING; MODIFICATION BY FIELD OR COMPLIANCE DIVISION PERSONNEL.—The written decisions of the reviewing division shall be binding on, and may not directly or indirectly be changed by, the field or compliance division personnel unless the field or compliance division personnel demonstrate to the reviewing division why the decision should be modified.

(F) DELAY OF ACTION BY REVIEWING DIVISION.—An action by the reviewing division shall not be delayed because of the unavailability of information from or action by field personnel unless the reviewing division deter-

mines that a delay is necessary to ensure the marketing of a safe and effective drug.

(f) CERTIFICATION UNDER SECTION 402(j)(5)(B) OF THE PUBLIC HEALTH SERVICE ACT REQUIRED.—An application submitted under this section shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. 282(j)(5)(B)). The certification shall not be considered an element of the application.

**§ 13504. Period for approval of application**

(a) IN GENERAL.—

(1) APPROVAL; NOTICE OF OPPORTUNITY FOR HEARING.—Within 180 days after the filing of an application under section 13503 of this title, or such additional period as may be agreed on by the Secretary and the applicant, the Secretary shall—

(A) approve the application if the Secretary then finds that none of the grounds for denying approval specified in section 13505 of this title applies; or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under section 13505 of this title on the question whether the application is approvable.

(2) ELECTION TO ACCEPT HEARING; COMMENCEMENT OF HEARING.—If the applicant elects to accept the opportunity for hearing by written request within 30 days after the notice, the hearing shall commence not more than 90 days after the expiration of the 30 days unless the Secretary and the applicant otherwise agree.

(3) HEARING ON EXPEDITED BASIS; ISSUANCE OF ORDER.—The hearing shall be conducted on an expedited basis and the Secretary's order thereon shall be issued within 90 days after the date fixed by the Secretary for filing final briefs.

(b) SUBMISSION OF PATENT INFORMATION AFTER APPROVAL OF APPLICATION.—

(1) IN GENERAL.—Not later than 30 days after the date of approval of an application submitted under section 13503 of this title, the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in section 13503(a)(1)(H) of this title, except that a patent that is identified as claiming a method of using the drug shall be filed only if the patent claims a method of use approved in the application.

(2) PATENT ISSUED AFTER DATE OF APPROVAL OF APPLICATION.—If a patent described in section 13503(a)(1)(H) of this title is issued after the date of approval of an application submitted under section 13503 of this title, the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using the drug shall be filed only if approval for the use has been granted in the application.

(3) TRANSITIONAL AND OTHER PROVISIONS.—If the patent information described in section 13503 of this title could not be filed with the submission of an application under section 13503 of this title because the application was filed before the patent information was required under section 13503 of this title or a patent was issued after the application was approved under section 13503 of this title, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent described in section 13503(a)(1)(H) of this title. If the holder of an approved application could not file patent information under section 13503 of this title because it was not required at the

time the application was approved, the holder shall file the information under this section not later than 30 days after September 24, 1984, and if the holder of an approved application could not file patent information under section 13503 of this title because no patent of the type for which information is required to be submitted in section 13503(a)(1)(H) of this title had been issued when an application was filed or approved, the holder shall file the information under this section not later than 30 days after the date the patent involved is issued.

(4) PUBLICATION.—On the submission of patent information under this section, the Secretary shall publish the patent information.

(5) PATENT INFORMATION NOT TO BE SUBMITTED.—Patent information that is not the type of patent information required by section 13503(a)(1)(H) of this title shall not be submitted under this subsection.

(c) EFFECTIVE DATES OF APPROVAL.—The approval of an application filed under section 13503 of this title that contains a certification required by subsection (b) of that section shall be made effective on the last applicable date determined by applying the following to each certification made under section 13503(b)(1) of this title:

(1) CERTIFICATION UNDER SUBPARAGRAPH (A) OR (B) OF SECTION 13503(b)(1) OF THIS TITLE.—If the applicant made only a certification described in subparagraph (A) or (B) of section 13503(b)(1) of this title or in both such subparagraphs, the approval may be made effective immediately.

(2) CERTIFICATION UNDER SUBPARAGRAPH (C) OF SECTION 13503(b)(1) OF THIS TITLE.—If the applicant made a certification described in subparagraph (C) of section 13503(b)(1) of this title, the approval may be made effective on the date certified under subparagraph (C) of section 13503(b)(1) of this title.

(3) CERTIFICATION UNDER SUBPARAGRAPH (D) OF SECTION 13503(b)(1) OF THIS TITLE.—

(A) IN GENERAL.—If the applicant made a certification described in subparagraph (D) of section 13503(b)(1) of this title, the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in section 13503(c) of this title is received, an action is brought for infringement of the patent—

(i) that is the subject of the certification; and

(ii) for which information was submitted to the Secretary under subsection (b) or section 13503(a) of this title before the date on which the application (excluding an amendment or supplement to the application) was submitted.

(B) PATENT INFRINGEMENT ACTION BROUGHT.—If an action described in subparagraph (A) is brought before the expiration of the 45 days, the approval may be made effective on the expiration of the 30-month period beginning on the date of the receipt of the notice provided under section 13503(c) of this title or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of the period, the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of the period, the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that

is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(iii) if before the expiration of the period, the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that the patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of the period, the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that the patent

has been infringed, the approval shall be made effective as provided in clause (ii).

(C) COOPERATION TO EXPEDITE PATENT INFRINGEMENT ACTION.—In an action described in subparagraph (A), each of the parties shall reasonably cooperate in expediting the action.

(4) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(A) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(i) IN GENERAL.—An action shall not be brought under section 2201 of title 28 by an applicant referred to in section 13503(b) of this title for a declaratory judgment with respect to a patent that is the subject of the certification referred to in paragraph (3) unless—

(I) the 45-day period referred to in paragraph (3) has expired;

(II) neither the owner of the patent nor the holder of the approved application under section 13503 of this title for the drug that is claimed by the patent or a use of which is

claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of the period; and

(III) in any case in which the notice provided under section 13503(c) of this title relates to noninfringement, the notice was accompanied by a document described in clause (iii).

(ii) FILING OF CIVIL ACTION.—

(I) IN GENERAL.—If the conditions described in subclauses (I), (II), and as applicable, (III) of clause (i) have been met, the applicant referred to in clause (i) may, in accordance with section 2201 of title 28, bring a civil action under that section against the owner or holder referred to in the clause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the

applicant seeks approval, except that the civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in clause (i)(III) is applicable.

(II) JURISDICTION.—A civil action referred to in this clause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iii) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—

(I) IN GENERAL.—For purposes of clause (i)(III), the document described in this clause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in section 13503(b) of this title for the purpose of determining whether an action referred to in paragraph (3) should be brought.

(II) RESTRICTIONS TO PROTECT TRADE SECRETS AND BUSINESS INFORMATION.—The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information.

(III) REQUEST FOR ACCESS AS ACCEPTANCE OF OFFER OF CONFIDENTIAL ACCESS; ENFORCEABLE CONTRACT.—A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of

confidential access shall be considered terms of an enforceable contract.

(IV) LIMITATION ON PURPOSE AND DISCLOSURE.—Any person provided an offer of confidential access—

(aa) shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under section 13503(b)(1)(D) of this title and for no other purpose; and

(bb) may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access.

(V) REDACTION OF APPLICATION.—The application subject to the offer may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(B) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(i) IN GENERAL.—If an owner of the patent or the holder of the approved application under section 13503 of this title for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under section 13503 of this title or this section on the ground that the patent does not claim—

(I) the drug for which the application was approved; or

(II) an approved method of using the drug.

(ii) NO INDEPENDENT CAUSE OF ACTION.—Clause (i) does not authorize the assertion of a claim described in clause (i) in any civil action or proceeding other than a counterclaim described in clause (i).

(C) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under subparagraph (A) or a counterclaim under subparagraph (B).

(5) LIMITATIONS ON CERTAIN SUBMISSIONS AND APPROVALS.—

(A) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED APPLICATION.—If an application submitted under section 13503 of this title for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 13503 of this title, is approved (referred to in this subparagraph as ''approved application'') after September 24, 1984, no application that refers (referred to in this subparagraph as ''referring application'') to the drug for which the approved application was submitted and for which the investigations described in section 13503(a)(1)(A) of this title and relied on by the applicant for approval of the referring application were not conducted by or for the applicant and for which the applicant

has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under section 13503 of this title before the expiration of 5 years from the date of the approval of the approved application, except that the referring application may be submitted under section 13503 of this title after the expiration of 4 years from the date of the approval of the approved application if the referring application contains a certification of patent invalidity or noninfringement described in section 13503(b)(1)(D) of this title. The approval of the referring application shall be made effective in accordance with this subsection except that, if an action for patent infringement is commenced during the 1-year period beginning 48 months after the date of the approval of the approved application, the 30-month period referred to in paragraph (3) shall be extended by such amount of time (if any) that is required for 7½ years to have elapsed from the date of approval of the approved application.

(B) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY AP-

PROVED APPLICATION; ACTIVE MOIETY PREVIOUSLY APPROVED.—If an application submitted under section 13503 of this title for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under section 13503 of this title, is approved (referred to in this subparagraph as ''approved application'') after September 24, 1984, and if the approved application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the approved application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under section 13503 of this title (referred to in this subparagraph as ''submitted application'') for the conditions of approval of the drug in the approved application effective before the expiration of 3 years from the date of the approval of the approved application if the investigations described in section 13503(a)(1)(A) of this title and relied on by the applicant for approval of

the submitted application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(C) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED SUPPLEMENT.—If a supplement to an application approved under section 13503 of this title is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under section 13503 of this title for a change approved in the supplement effective before the expiration of 3 years from the date of the approval of the supplement under section 13503 of this title if the investigations described in section 13503(a)(1)(A) of this title and relied on by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained

a right of reference or use from the person by or for whom the investigations were conducted.

(D) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED APPLICATION OR SUPPLEMENT DURING SPECIFIED PERIOD.—If an application (or supplement to an application) submitted under section 13503 of this title for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under section 13503 of this title, was approved (referred to in this subparagraph as ''approved application or supplement'') during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this section (referred to in this subparagraph as ''submitted application'') and for which the investigations described in section 13503(a)(1)(A) of this title and relied on by the applicant for approval of the submitted application were not conducted by or for the applicant and for which the applicant has not obtained a right of ref-

erence or use from the person by or for whom the investigations were conducted and which refers to the drug for which the approved application or supplement was submitted effective before the expiration of 2 years from September 24, 1984.

(d) DRUGS MANUFACTURED IN PILOT OR OTHER SMALL FACILITY.—A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(e) QUALIFIED DATA SUMMARIES AS SUPPORT FOR SUPPLEMENTAL APPLICATION.—

(1) DEFINITIONS.—In this subsection:

(A) QUALIFIED DATA SUMMARY.—The term ''qualified data summary'' means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(B) QUALIFIED INDICATION.—The term ''qualified indication'' means an indication for a drug that the Secretary determines to be appro-

priate for summary level review under this subsection.

(2) IN GENERAL.—The Secretary may rely on qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under section 13503 of this title, if the supplemental application complies with paragraph (3).

(3) ELIGIBILITY FOR REVIEW.—A supplemental application is eligible for review as described in paragraph (2) only if—

(A) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(B) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(4) PUBLICATION.—The Secretary shall post on the FDA website and update annually—

(A) the number of applications reviewed solely under paragraph (2) or section 351(a)(2)(E) of the Public Health Service Act (42 U.S.C. 262(a)(2)(E));

(B) the average time for completion of review under paragraph (2) or section

351(a)(2)(E) of the Public Health Service Act (42 U.S.C. 262(a)(2)(E));

(C) the average time for review of supplemental applications where the Secretary did not use review flexibility under paragraph (2) or section 351(a)(2)(E) of the Public Health Service Act (42 U.S.C. 262(a)(2)(E)); and

(D) the number of applications reviewed under paragraph (2) or section 351(a)(2)(E) of the Public Health Service Act (42 U.S.C. 262(a)(2)(E)) for which the Secretary made use of full data sets in addition to the qualified data summary.

**§ 13505. Grounds for refusing to approve application; approval**

(a) DEFINITION OF SUBSTANTIAL EVIDENCE.—In this section:

(1) IN GENERAL.—The term ''substantial evidence'' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by the experts that the drug will have the effect it purports or is rep-

resented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling of the drug.

(2) SUFFICIENCY OF DATA AND CONFIRMATORY EVIDENCE.—If the Secretary determines, based on relevant science, that data from 1 adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after the investigation) are sufficient to establish effectiveness, the Secretary may consider the data and evidence to constitute substantial evidence for purposes of paragraph (1).

(b) ORDER REFUSING TO APPROVE APPLICATION.—The Secretary shall issue an order refusing to approve an application under section 13503 of this title if the Secretary finds, after due notice to the applicant in accordance with section 13504 of this title and after giving the applicant an opportunity for a hearing, in accordance with that section, that—

(1) the investigations, reports of which are required to be submitted to the Secretary pursuant to section 13503 of this title, do not include adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the

conditions prescribed, recommended, or suggested in the proposed labeling of the drug;

(2) the results of the tests show that the drug is unsafe for use under the conditions described in paragraph (1) or do not show that the drug is safe for use under the conditions;

(3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to preserve its identity, strength, quality, and purity;

(4) on the basis of the information submitted to the Secretary as part of the application, or on the basis of any other information before the Secretary with respect to the drug, the Secretary has insufficient information to determine whether the drug is safe for use under the conditions described in paragraph (1);

(5) evaluated on the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to the drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling of the drug;

(6) the application failed to contain the patent information prescribed by section 13503 of this title; or

(7) based on a fair evaluation of all material facts, the labeling is false or misleading in any particular.

(c) ORDER OF APPROVAL.—If, after notice and opportunity for hearing under subsection (b), the Secretary finds that paragraphs (1) through (7) of subsection (b) do not apply, the Secretary shall issue an order approving the application.

(d) STRUCTURED RISK-BENEFIT ASSESSMENT FRAMEWORK.—

(1) IN GENERAL.—The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate—

(A) the balanced consideration of benefits and risks;

(B) a consistent and systematic approach to the discussion and regulatory decision-making; and

(C) the communication of the benefits and risks of new drugs.

(2) EFFECT OF PARAGRAPH (1).—Nothing in paragraph (1) shall alter the criteria for evaluating an application for marketing approval of a drug.

**§ 13506. Withdrawal of and suspension of approval**

(a) DEFINITION OF SUBSTANTIAL EVIDENCE.—In this section:

(1) IN GENERAL.—The term ''substantial evidence'' has the meaning given the term in section 13505(a)(1) of this title.

(2) SUFFICIENCY OF DATA AND CONFIRMATORY EVIDENCE.—Section 13505(a)(2) of this title applies for purposes of paragraph (1).

(b) REQUIRED WITHDRAWAL OF APPROVAL OF APPLICATION.—The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this chapter if the Secretary finds—

(1) that clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the conditions of use on the basis of which the application was approved;

(2) that new evidence of clinical experience, not contained in the application or not available to the Secretary until after the application was approved, or tests by new methods, or tests by methods not

considered reasonably applicable when the application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that the drug is not shown to be safe for use under the conditions of use on the basis of which the application was approved;

(3) on the basis of new information before the Secretary with respect to the drug, evaluated together with the evidence available to the Secretary when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the drug;

(4) that the patent information prescribed by section 13504 of this title was not filed within 30 days after the receipt of written notice from the Secretary specifying the failure to file the information; or

(5) that the application contains any untrue statement of a material fact.

(c) SUSPENSION OF APPROVAL ON FINDING OF IMMINENT HAZARD TO HEALTH.—

(1) IN GENERAL.—If the Secretary (or in the Secretary's absence, the officer acting as Secretary)

finds that there is an imminent hazard to the public health, the Secretary may suspend the approval of the application immediately, and give the applicant prompt notice of the Secretary's action and afford the applicant the opportunity for an expedited hearing under this section.

(2) NONDELEGATION.—The authority conferred by paragraph (1) to suspend the approval of an application shall not be delegated.

(d) AUTHORIZED WITHDRAWAL OF APPROVAL OF APPLICATION.—The Secretary may, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under section 13503 or 13511 of this title with respect to any drug under this chapter if the Secretary finds—

(1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain the records or to make required reports, in accordance with a regulation or order under section 13512 of this title or to comply with the notice requirements of section 13136(j)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, the records as required by section 13512(b) of this title;

(2) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(3) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(e) ORDER TO STATE FINDINGS.—Any order under this section shall state the findings on which it is based.

**§ 13507. Revocation of order refusing, withdrawing, or suspending approval of application**

If the Secretary finds that the facts so require, the Secretary shall revoke any previous order under section 13505 or 13506 of this title refusing, withdrawing, or sus-

pending approval of an application and shall approve the application or reinstate the approval, as may be appropriate.

**§ 13508. Service of orders**

Orders of the Secretary issued under this chapter shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at the applicant's or respondent's last-known address in the records of the Secretary.

**§ 13509. Appeal from order**

(a) IN GENERAL.—An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this chapter.

(b) PROCEDURE.—

(1) DEADLINE; CONTENT OF PETITION.—An appeal under subsection (a) shall be taken by filing in the United States court of appeals for the circuit in which the applicant resides or in which the applicant's principal place of business is located, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after the entry of

the order, a written petition praying that the order of the Secretary be set aside.

(2) TRANSMISSION OF COPY OF PETITION TO SECRETARY; FILING OF RECORD IN COURT.—A copy of the petition shall be immediately transmitted by the clerk of the court to the Secretary, or any officer designated by the Secretary for that purpose, and on the transmission, the Secretary shall certify and file in the court the record on which the order complained of was entered, as provided in section 2112 of title 28.

(3) EXCLUSIVE JURISDICTION.—On the filing of the petition, the court shall have exclusive jurisdiction to affirm or set aside the order, except that until the filing of the record the Secretary may modify or set aside the Secretary's order.

(4) OBJECTION TO THE ORDER.—An objection to the order of the Secretary shall not be considered by the court unless the objection shall have been urged before the Secretary or unless there were reasonable grounds for failure to do so.

(5) FINDING OF FACTS BY SECRETARY AS CONCLUSIVE.—The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(6) ADDUCING OF ADDITIONAL EVIDENCE.—

(A) IN GENERAL.—If any person applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for failure to adduce the evidence in the proceeding before the Secretary, the court may order the additional evidence to be taken before the Secretary and to be adduced on the hearing in such manner and on such terms and conditions as to the court may seem proper.

(B) MODIFICATION OF FINDINGS.—The Secretary may modify the Secretary's findings as to the facts by reason of the additional evidence taken under subparagraph (A), and the Secretary shall file with the court—

(i) the modified findings, which, if supported by substantial evidence, shall be conclusive; and

(ii) the Secretary's recommendation, if any, for the setting aside of the original order.

(7) JUDGMENT OF COURT AS FINAL.—The judgment of the court affirming or setting aside the

original order of the Secretary shall be final, subject to review by the Supreme Court of the United States on certiorari or certification as provided in section 1254 of title 28.

(8) COMMENCEMENT OF APPEAL NOT TO OPERATE AS STAY OF SECRETARY'S ORDER.—The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

**§ 13510. Drugs for investigational use**

(a) EXEMPTION.—

(1) IN GENERAL.—The Secretary shall promulgate regulations for exempting from the operation of sections 13502 through 13509 of this title drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs.

(2) CONTENT.—In the regulations, the Secretary may provide for, among other conditions relating to the protection of public health, conditioning the exemption on—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of the drug, of non-

clinical tests of the drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining, from each of the investigators, a signed agreement—

(i) that patients to whom the drug is administered will be under the investigator's personal supervision, or under the supervision of investigators responsible to the investigator; and

(ii) that the investigator will not supply the drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of the drug, of data (including analytical reports by investigators) obtained as the result of the investigational use of the drug, as the Secretary finds will enable the Secretary to evaluate the safety and effectiveness of the drug in the event of the filing of an

application pursuant to section 13503 of this title; and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(b) REQUIRED SUBMISSION OF INFORMATION.—Subject to subsection (c), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing information about the drug and the clinical investigation, including—

(1) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(2) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from nonclinical tests or human studies.

(c) CLINICAL HOLD.—

(1) IN GENERAL.—

(A) AUTHORITY.—At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this subsection as a ''clinical hold'') if the Secretary makes a determination described in paragraph (2).

(B) BASIS; WRITTEN CONFIRMATION OF DETERMINATION.—The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary that served as the basis for the clinical hold, and confirm the determination in writing.

(2) DETERMINATION.—For purposes of paragraph (1), a determination described in this paragraph with respect to a clinical hold is that—

(A) the drug involved represents an unreasonable risk to the safety of the individuals who are the subjects of the clinical investigation, taking into account—

(i) the qualifications of the clinical investigators;

(ii) information about the drug;

(iii) the design of the clinical investigation;

(iv) the condition for which the drug is to be investigated; and

(v) the health status of the subjects involved; or

(B) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(3) REQUEST TO REMOVE CLINICAL HOLD.—Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons for the decision, within 30 days after receipt of the request. The request shall include sufficient information to support the removal of the clinical hold.

(d) INFORMING AND OBTAINING CONSENT FROM HUMAN SUBJECTS.—

(1) IN GENERAL.—Regulations under subsection (a) shall provide that the exemption shall be conditioned on the manufacturer, or the sponsor of the investigation, requiring that experts using the drugs for investigational purposes certify to the manufacturer or sponsor that the experts will inform

any human beings to whom the drugs, or any controls used in connection with the drugs, are being administered, or their representatives, that the drugs are being used for investigational purposes and will obtain the consent of the human beings or their representatives, except where—

(A) it is not feasible;

(B) it is contrary to the best interests of the human beings; or

(C) the proposed clinical testing—

(i) poses no more than minimal risk to the human beings; and

(ii) includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of the human beings.

(2) INCLUSION OF STATEMENT IN CONSENT DOCUMENTS.—The Secretary shall require in the regulations under subsection (a) the inclusion, in the informed consent documents and process, a statement that clinical trial information for the clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(e) DIRECT SUBMISSION OF REPORTS BY INVESTIGATORS NOT REQUIRED.—Nothing in this section shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

**§ 13511. Abbreviated new drug applications**

(a) DEFINITIONS.—In this section:

(1) BIOAVAILABILITY.—

(A) IN GENERAL.—The term ''bioavailability'' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) DRUG NOT INTENDED TO BE ABSORBED INTO THE BLOODSTREAM.—For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(C) EFFECT OF PARAGRAPH.—This paragraph does not alter the standards for approval of drugs under this section.

(2) BIOEQUIVALENT.—

(A) IN GENERAL.—A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug—

(I) is intentional;

(II) is reflected in its proposed labeling;

(III) is not essential to the attainment of effective body drug concentrations on chronic use; and

(IV) is considered medically insignificant for the drug.

(B) DRUG NOT INTENDED TO BE ABSORBED INTO THE BLOODSTREAM.—

(i) IN GENERAL.—For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(ii) EFFECT OF SUBPARAGRAPH.—This subparagraph does not alter the standards for approval of drugs under this section.

(3) LISTED DRUG.—The term ''listed drug'' means a drug listed under subsection (h).

(b) AUTHORITY.—Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(c) CONTENTS.—

(1) IN GENERAL.—An abbreviated application for a new drug shall contain—

(A) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a listed drug;

(B)(i) if the listed drug referred to in subparagraph (A) has only 1 active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(ii) if the listed drug referred to in subparagraph (A) has more than 1 active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug; or

(iii) if the listed drug referred to in subparagraph (A) has more than 1 active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under paragraph (4)—

(I) information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug;

(II) information to show that the different active ingredient is an active ingredient of a listed drug or of a drug that does not meet the requirements of section 10101(a)(34) of this title; and

(III) such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(C)(i) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in subparagraph (A); or

(ii) if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under paragraph (4), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(D) information to show that the new drug is bioequivalent to the listed drug referred to in subparagraph (A), except that if the application

is filed pursuant to the approval of a petition filed under paragraph (4), information to show that—

(i) the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in subparagraph (A); and

(ii) the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in subparagraph (A);

(E) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in subparagraph (A) except for changes required because of differences approved under a petition filed under paragraph (4) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(F) the items specified in subparagraphs (B) through (F) of section 13503(a)(1) of this title;

(G) a certification, in the opinion of the applicant and to the best of the applicant's

knowledge, with respect to each patent that claims the listed drug referred to in subparagraph (A) or that claims a use for the listed drug for which the applicant is seeking approval under this section and for which information is required to be filed under section 13503 or 13504 of this title—

(i) that the patent information has not been filed;

(ii) that the patent has expired;

(iii) of the date on which the patent will expire; or

(iv) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(H) if with respect to the listed drug referred to in subparagraph (A) information was filed under section 13503 or 13504 of this title for a method of use patent that does not claim a use for which the applicant is seeking approval under this section, a statement that the method of use patent does not claim such a use.

(2) ADDITIONAL INFORMATION NOT REQUIRED.—The Secretary may not require that an

abbreviated application contain information in addition to that required by subparagraphs (A) through (H) of paragraph (1).

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (1)(G)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (1)(G)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certifi-

cation contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under section 13503 of this title for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this section for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug

before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4) SUBMISSION OF PETITION TO FILE ABBREVIATED APPLICATION.—

(A) IN GENERAL.—If a person wants to submit an abbreviated application for a new drug that has a different active ingredient or that the route of administration, dosage form, or strength of which differs from that of a listed drug, the person shall submit to the Secretary a petition seeking permission to file the application.

(B) DEADLINE FOR SECRETARY TO APPROVE OR DISAPPROVE A PETITION.—The Secretary shall approve or disapprove a petition submitted under this paragraph within 90 days of the date the petition is submitted.

(C) APPROVAL.—The Secretary shall approve the petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness

of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength that differs from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(5) AMENDMENT OR SUPPLEMENTATION.—

(A) IN GENERAL.—An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(B) DIFFERENT STRENGTH.—With respect to the drug for which an application is submitted, nothing in this section prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(C) GUIDANCE.—The Secretary shall issue guidance defining the term ''listed drug'' for purposes of this paragraph.

(d) GUIDANCE FOR REVIEW OF APPLICATIONS; DESIGN AND SIZE OF BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES.—

(1) GUIDANCE.—The Secretary shall issue guidance for the individuals who review applications submitted under subsection (b), which guidance shall—

(A) relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards; and

(B) apply equally to all individuals who review the applications.

(2) DESIGN AND SIZE OF BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES.—

(A) REVIEWING DIVISION.—In this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this section (including scientific matters, chemistry, manufacturing, and controls).

(B) MEETING TO REACH AGREEMENT.—

(i) IN GENERAL.—The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under

this section if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of the application.

(ii) PROVISION OF INFORMATION.—The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the bioavailability and bioequivalence studies.

(iii) MINUTES.—Minutes of the meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) AGREEMENT REQUIRED TO BE IN WRITING; CONDITIONS ON WHICH AGREEMENT MAY BE CHANGED.—

(i) AGREEMENT REQUIRED TO BE IN WRITING.—Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and

made part of the administrative record by the Secretary.

(ii) CONDITIONS ON WHICH AGREEMENT MAY BE CHANGED.—The agreement shall not be changed after the testing begins, except—

(I) with the written agreement of the sponsor or applicant; or

(II) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) REQUIREMENTS FOR DECISION.—A decision under subparagraph (C)(ii)(II) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) DECISION OF REVIEWING DIVISION AS BINDING; MODIFICATION BY FIELD OR COMPLI-

ANCE DIVISION PERSONNEL.—The written decisions of the reviewing division shall be binding on, and may not directly or indirectly be changed by, the field or compliance office personnel unless the field or compliance office personnel demonstrate to the reviewing division why the decision should be modified.

(F) DELAY OF ACTION BY REVIEWING DIVISION.—An action by the reviewing division shall not be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to ensure the marketing of a safe and effective drug.

(e) GROUNDS FOR DISAPPROVAL.—Subject to subsection (f), the Secretary shall approve an application for a drug unless the Secretary finds that—

(1) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity;

(2) information submitted with the application is insufficient to show that each of the proposed conditions of use has been previously approved for the listed drug referred to in the application;

(3) if the listed drug—

(A) has only 1 active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(B) has more than 1 active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug; or

(C) has more than 1 active ingredient and if the application is for a drug that has an active ingredient different from the listed drug—

(i) information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug; or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug that does not meet the requirements of section 10101(a)(34) of this title; or

(ii) no petition to file an application for the drug with the different ingredient was approved under subsection (c)(4);

(4) if the application is for a drug the route of administration, dosage form, or strength of which—

(A) is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug; or

(B) is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under subsection (c)(4);

(5) if the application was filed pursuant to the approval of a petition under subsection (c)(4), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength that is not the same;

(6)(A) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application; or

(B) if the application was filed pursuant to a petition approved under subsection (c)(4), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in subsection (c)(1)(A) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in the subsection;

(7) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required—

(A) because of differences approved under a petition filed under subsection (c)(4); or

(B) because the drug and the listed drug are produced or distributed by different manufacturers;

(8) information submitted in the application or any other information available to the Secretary shows that—

(A) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug; or

(B) the composition of the drug is unsafe under the conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(9)(A) the approval under section 13504 of this title of the listed drug referred to in the application under this section has been withdrawn for grounds described in section 13506(b) of this title or suspended for grounds described in section 13506(c) of this title;

(B) the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under section 13504 of this title for grounds described in section 13506(b) of this title;

(C) the approval under this section of the listed drug referred to in the application under this section

has been withdrawn or suspended under subsection (g); or

(D) the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(10) the application does not meet any other requirement of subsection (c)(1); or

(11) the application contains an untrue statement of material fact.

(f) APPROVAL.—

(1) IN GENERAL.—Within 180 days of the initial receipt of an application under subsection (c) or within such additional period as may be agreed on by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(2) EFFECTIVE DATES OF APPROVAL.—The approval of an application submitted under subsection (c) shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (c)(1)(G):

(A) CERTIFICATION UNDER CLAUSE (i) OR (ii) OF SUBSECTION (c)(1)(G).—If the applicant only made a certification described in clause (i) or (ii) of subsection (c)(1)(G) or in both

clauses, the approval may be made effective immediately.

(B) CERTIFICATION UNDER CLAUSE OF SUBSECTION (c)(1)(G)(iii).—If the applicant made a certification described in subsection (c)(1)(G)(iii), the approval may be made effective on the date certified under subsection (c)(1)(G)(iii).

(C) CERTIFICATION UNDER SUBSECTION (c)(1)(G)(iv).—

(i) IN GENERAL.—If the applicant made a certification described in subsection (c)(1)(G)(iv), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (c)(3) is received, an action is brought for infringement of the patent—

(I) that is the subject of the certification; and

(II) for which information was submitted to the Secretary under section 13503(a) or 13504(b) of this title before the date on which the application (excluding an amendment or sup-

plement to the application), which the Secretary later determines to be a substantially complete application (as defined in subparagraph (D)(ii)(II), was submitted.

(ii) PATENT INFRINGEMENT ACTION BROUGHT.—If an action under clause (i) is brought before the expiration of the 45 days, the approval shall be made effective on the expiration of the 30-month period beginning on the date of the receipt of the notice provided under subsection (c)(3)(A) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of the period, the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of the period, the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of the period, the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that the patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of the period, the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that the patent has been infringed, the approval shall be made effective as provided in subclause (II).

(iii) COOPERATION TO EXPEDITE PATENT INFRINGEMENT ACTION.—In an action described in clause (i), each of the parties shall reasonably cooperate in expediting the action.

(D) 180-DAY EXCLUSIVITY PERIOD.—

(i) SUBSECTION-WIDE DEFINITIONS.—In this subsection:

(I) 180-DAY EXCLUSIVITY PERIOD.—The term ''180-day exclusivity period'' means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant

could become effective under this subparagraph.

(II) TENTATIVE APPROVAL.—

(aa) IN GENERAL.—The term ''tentative approval'' means notification to an applicant by the Secretary that an application under this section meets the requirements of subsection (c)(1), but cannot receive effective approval because—

(AA) the application does not meet the requirements of this paragraph;

(BB) there is a period of exclusivity for the listed drug under paragraph (6) or section 13112 of this title; or

(CC) there is a 7-year period of exclusivity for the listed drug under section 13903 of this title.

(bb) LIMITATION.—A drug that is granted tentative approval

by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(ii) SUBPARAGRAPH-WIDE DEFINITIONS.—

(I) FIRST APPLICANT.—In this subparagraph, the term ''first applicant'' means an applicant that, on the first day on which a substantially complete application containing a certification described in subsection (c)(1)(G)(iv) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in subsection (c)(1)(G)(iv) for the drug.

(II) SUBSTANTIALLY COMPLETE APPLICATION.—In subclause (I), the term ''substantially complete application'' means an application under this section that on its face is sufficiently

complete to permit a substantive review and contains all the information required by subsection (c)(1).

(iii) EFFECTIVENESS OF APPLICATION.—Subject to paragraph (4), if the application contains a certification described in subsection (c)(1)(G)(iv) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(E) 180-DAY EXCLUSIVITY PERIOD FOR COMPETITIVE GENERIC THERAPIES.—

(i) DEFINITIONS.—In this subparagraph and paragraph (4)(D):

(I) COMPETITIVE GENERIC THERAPY.—The term ''competitive generic therapy'' means a drug—

(aa) that is designated as a competitive generic therapy

under section 13128 of this title; and

(bb) for which there are no unexpired patents or exclusivities on the list of products described in subsection (h)(1) at the time of submission.

(II) FIRST APPROVED APPLICANT.—The term ''first approved applicant'' means any applicant that has submitted an application that—

(aa) is for a competitive generic therapy that is approved on the first day on which any application for the competitive generic therapy is approved;

(bb) is not eligible for a 180-day exclusivity period under subparagraph (D) for the drug that is the subject of the application for the competitive generic therapy; and

(cc) is not for a drug for which all drug versions have forfeited eligibility for a 180-day ex-

clusivity period under subparagraph (D) pursuant to paragraph (4).

(ii) EFFECTIVENESS OF APPLICATION.—Subject to paragraph (4)(D), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(iii) LIMITATION.—The exclusivity period under clause (ii) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under clause (ii).

(3) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(A) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(i) IN GENERAL.—An action shall not be brought under section 2201 of title 28 by an applicant under subsection (c) for a declaratory judgment with respect to a patent that is the subject of the certification referred to in paragraph (2)(C) unless—

(I) the 45-day period referred to in paragraph (2)(C) has expired;

(II) neither the owner of the patent nor the holder of the approved application under section 13503 of this title for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of the period; and

(III) in any case in which the notice provided under subsection (c)(3) relates to noninfringement, the notice was accompanied by a document described in clause (iii).

(ii) FILING OF CIVIL ACTION.—

(I) IN GENERAL.—If the conditions described in subclauses (I), (II), and as applicable, (III) of clause (i) have been met, the applicant referred to in the clause may, in accordance with section 2201 of title 28, bring a civil action under that section against the owner or holder referred to in the clause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that the civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in clause (i)(III) is applicable.

(II) JURISDICTION.—A civil action referred to in this clause shall be brought in the judicial district where the defendant has its principal place

of business or a regular and established place of business.

(iii) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—

(I) IN GENERAL.—For purposes of clause (i)(III), the document described in this clause is a document providing an offer of confidential access to the application that is in the custody of the applicant under subsection (c) for the purpose of determining whether an action referred to in paragraph (2)(C) should be brought.

(II) RESTRICTIONS TO PROTECT TRADE SECRETS AND BUSINESS INFORMATION.—The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and

other confidential business information.

(III) REQUEST FOR ACCESS AS ACCEPTANCE OF OFFER OF CONFIDENTIAL ACCESS; ENFORCEABLE CONTRACT.—A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract.

(IV) LIMITATION ON PURPOSE AND DISCLOSURE.—Any person provided an offer of confidential access—

(aa) shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification

under subsection (c)(1)(G)(iv) and for no other purpose; and

(bb) may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access.

(V) REDACTION.—The application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(B) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(i) IN GENERAL.—If an owner of the patent or the holder of the approved application under section 13503 of this title for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder

under section 13503 or 13504 of this title on the ground that the patent does not claim—

(I) the drug for which the application was approved; or

(II) an approved method of using the drug.

(ii) NO INDEPENDENT CAUSE OF ACTION.—Clause (i) does not authorize the assertion of a claim described in clause (i) in any civil action or proceeding other than a counterclaim described in clause (i).

(C) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under subparagraph (A) or a counterclaim under subparagraph (B).

(4) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(A) DEFINITIONS.—In this paragraph:

(i) FIRST APPLICANT.—The term ''first applicant'' has the meaning given the term in paragraph (2)(D)(ii)(I).

(ii) FORFEITURE EVENT.—The term ''forfeiture event'', with respect to an ap-

plication under this section, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under paragraph (2)(C); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certifi-

cation qualifying the first applicant for the 180-day exclusivity period under paragraph (2)(D), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a

final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under section 13503 or 13504 of this title is withdrawn by the holder of the application approved under section 13503 of this title.

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under subsection (e).

(III) AMENDMENT OR WITHDRAWAL OF CERTIFICATION FOR ALL PATENTS.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a cer-

tification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this section for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under subsection (c)(1)(G)(iv), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal

Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(B) FORFEITURE.—The 180-day exclusivity period described in paragraph (2)(D) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(C) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under subparagraph (B)—

(i) approval of any application containing a certification described in subsection (c)(1)(G)(iv) shall be made effective in accordance with paragraph (2)(C); and

(ii) no applicant shall be eligible for a 180-day exclusivity period.

(D) SPECIAL FORFEITURE RULE FOR COMPETITIVE GENERIC THERAPY.—The 180-day exclusivity period described in paragraph (2)(E) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(5) HEARING ON DISAPPROVAL.—

(A) NOTICE.—If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether the application is approvable.

(B) ELECTION TO ACCEPT OPPORTUNITY FOR HEARING; COMMENCEMENT OF HEARING.—If the applicant elects to accept the opportunity for hearing by written request within 30 days after the notice, the hearing shall commence not more than 90 days after the expiration of the 30 days unless the Secretary and the applicant otherwise agree.

(C) EXPEDITED BASIS; ISSUANCE OF ORDER.—The hearing shall be conducted on an expedited basis and the Secretary's order on the hearing shall be issued within 90 days after the date fixed by the Secretary for filing final briefs.

(6) LIMITATIONS ON CERTAIN SUBMISSIONS AND APPROVALS.—

(A) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED APPLICATION.—If an application submitted under section 13503 of this title for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 13503 of this title, is ap-

proved (referred to in this subparagraph as ''approved application'') after September 24, 1984, no application may be submitted under this section which refers (referred to in this subparagraph as ''referring application'') to the drug for which the approved application was submitted before the expiration of 5 years from the date of the approval of the approved application, except that the referring application may be submitted under this section after the expiration of 4 years from the date of the approval of the approved application if the referring application contains a certification of patent invalidity or noninfringement described in subsection (c)(1)(G)(iv). The approval of the referring application shall be made effective in accordance with paragraph (2) except that, if an action for patent infringement is commenced during the 1-year period beginning 48 months after the date of the approval of the approved application, the 30-month period referred to in paragraph (2)(C) shall be extended by such amount of time (if any) which is required for 7½ years to have elapsed from the date of approval of the approved application.

(B) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED APPLICATION; ACTIVE MOIETY PREVIOUSLY APPROVED.—If an application submitted under section 13503 of this title for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under section 13503 of this title, is approved (referred to in this subparagraph as ''approved application'') after September 24, 1984, and if the approved application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the approved application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this section for the conditions of approval of the drug in the approved application effective before the expiration of 3 years from the date of the approval of the approved application for the drug.

(C) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY AP-

PROVED SUPPLEMENT.—If a supplement to an application approved under section 13503 of this title is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this section for a change approved in the supplement effective before the expiration of 3 years from the date of the approval of the supplement under section 13503 of this title.

(D) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED APPLICATION OR SUPPLEMENT DURING SPECIFIED PERIOD.—If an application (or supplement to an application) submitted under section 13503 of this title for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under section 13503 of this title, was approved (referred to in this subparagraph as ''approved

application'') during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this section which refers to the drug for which the approved application was submitted or which refers to a change approved in a supplement to the approved application effective before the expiration of 2 years from September 24, 1984.

(g) WITHDRAWN OR SUSPENDED APPROVAL OF DRUGS REFERRED TO IN APPROVED APPLICATION.—If a drug approved under this section refers to, in its approved application, a drug the approval of which was withdrawn for grounds described in section 13506(b) of this title or suspended for grounds described in section 13506(c) of this title or was withdrawn or suspended under this subsection or that, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this section shall be withdrawn or suspended—

(1) for the same period as the withdrawal under section 13506(b) of this title or suspension under section 13506(c) of this title or the withdrawal or suspension under this subsection; or

(2) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(h) LIST OF APPROVED DRUGS.—

(1) PUBLICATION.—

(A) IN GENERAL.—The Secretary shall publish and make available to the public—

(i) a list in alphabetical order of the official and proprietary name of each drug that has been approved for safety and effectiveness under section 13504 of this title before September 24, 1984;

(ii) the date of approval if the drug is approved after 1981 and the number of the application that was approved; and

(iii) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this section which will refer to the drug published.

(B) REVISIONS.—Every 30 days after the publication of the first list under subparagraph (A), the Secretary shall revise the list to include

each drug that has been approved for safety and effectiveness under section 13504 of this title or approved under this section during the 30-day period.

(C) PATENT INFORMATION.—When patent information submitted under section 13504 of this title respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under subparagraph (B), include the patent information for the drug.

(D) EXCLUSIVITY PERIOD.—For each drug included on the list under subparagraph (A), the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which the period has not yet expired, under—

(i) subparagraph (A), (B), or (C) of section 13504(c)(5) of this title;

(ii) subparagraph (D) or (E) of subsection (f)(2);

(iii) subparagraph (A), (B), or (C) of subsection (f)(6);

(iv) section 13112 of this title;

(v) section 13116 of this title;

(vi) section 13903(a) of this title; or

(vii) section 13521 of this title.

(E) THERAPEUTIC EQUIVALENCE EVALUATIONS.—

(i) REQUIREMENTS RELATING TO REQUESTS FOR EVALUATION.—With respect to an application submitted pursuant to section 13503(b) of this title for a drug that is subject to section 13103(a) of this title for which the sole difference from a listed drug relied on in the application is a difference in inactive ingredients not permitted under clause (iii) or (iv) of section 314.94(a)(9) of title 21, Code of Federal Regulations, or any successor regulations, the Secretary shall make an evaluation with respect to whether the drug is a therapeutic equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations, or any successor regulations) to another approved drug product in the prescription drug product section of the list under this subsection as follows:

(I) IN GENERAL.—With respect to such an application submitted after

December 29, 2022, the evaluation shall be made with respect to a listed drug relied on in the application pursuant to section 13503(b) of this title that is a pharmaceutical equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations, or any successor regulations) to the drug in the application pursuant to section 13503(b) of this title at the time of approval of the application or not later than 180 days after the date of the approval, if the request for such an evaluation is made in the original application (or in a resubmission to a complete response letter), and all necessary data and information are submitted in the original application (or in a resubmission in response to a complete response letter) for the therapeutic equivalence evaluation, including information to demonstrate bioequivalence, in a form and manner prescribed by the Secretary.

(II) TRANSITIONAL PROVISIONS.—With respect to such an application approved prior to or on December 29, 2022, the evaluation shall be made not later than 180 days after receipt of a request for a therapeutic equivalence evaluation submitted as part of a supplement to the application. With respect to an application that was submitted prior to December 29, 2022, but not approved as of December 29, 2022, the evaluation shall be made not later than 180 days after the date of approval of the application, if a request for the evaluation is submitted as an amendment to the application, and if—

(aa) the request for a therapeutic equivalence evaluation is being sought with respect to a listed drug relied on in the application, and the relied-on listed drug is in the prescription drug product section of the list under this subsection and is a pharma-

ceutical equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations, or any successor regulations) to the drug for which a therapeutic equivalence evaluation is sought; and

(bb) the amendment or supplement, as applicable, containing the request, or the relevant application, includes all necessary data and information for the therapeutic equivalence evaluation, including information to demonstrate bioequivalence, in a form and manner prescribed by the Secretary.

(ii) INFORMATION TO INCLUDE IN REVISIONS TO LIST.—When the Secretary makes an evaluation under clause (i), the Secretary shall, in revisions made to the list pursuant to subparagraph (B), include that information for the drug.

(2) PUBLICATION DATE.—A drug approved for safety and effectiveness under section 13504 of this title or approved under this section shall, for pur-

poses of this section, be considered to have been published under paragraph (1) on the date of its approval or September 24, 1984, whichever is later.

(3) WITHDRAWN OR SUSPENDED APPROVAL OF DRUGS; EXCLUSION OR REMOVAL FROM LIST.—

(A) IN GENERAL.—If the approval of a drug was withdrawn for grounds described in section 13506(b) of this title or suspended for grounds described in section 13506(c) of this title or was withdrawn or suspended under subsection (g) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, the drug may not be published in the list under paragraph (1) or, if the withdrawal or suspension occurred after its publication in the list, it shall be immediately removed from the list—

(i) for the same period as the withdrawal under section 13506(b) of this title or suspension under section 13506(c) of this title or the withdrawal or suspension under subsection (g); or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period

ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(B) NOTICE OF REMOVAL.—A notice of the removal shall be published in the Federal Register.

(4) CANCELLATION OR INVALIDATION OF PATENT.—In the case of a listed drug for which the list under paragraph (1)(A) includes a patent for the drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under section 13504 of this title determines that a patent for the drug, or any patent information for the drug, no longer meets the listing requirements under this chapter—

(A) the holder of the approved application shall notify the Secretary, in writing, within 14 days of the decision of the cancellation or invalidation and request that the patent or patent information, as applicable, be amended or with-

drawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court;

(B) the holder of the approved application shall include in any notification under subparagraph (A) information related to the patent cancellation or invalidation decision and submit the information, including a copy of the decision, to the Secretary; and

(C) the Secretary shall, in response to a notification under subparagraph (A), amend or remove patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information before the expiration of any 180-day exclusivity period under subsection (f)(2)(D) that relies on a certification described in subsection (c)(1)(G).

(i) MAINTENANCE OF RECORDS BY SECRETARY.—

(1) IN GENERAL.—The Secretary shall, with respect to each application submitted under this section, maintain a record of—

(A) the name of the applicant;

(B) the name of the drug covered by the application;

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of the assignment; and

(D) the name of each person to whom the bioequivalence review for the application was assigned and the date of the assignment.

(2) AVAILABILITY TO THE PUBLIC.—The information the Secretary is required to maintain under this subsection with respect to an application submitted under this section shall be made available to the public after the approval of the application.

(j) VARIATION IN LABELING.—

(1) IN GENERAL.—If the proposed labeling of a drug that is the subject of an application under this section differs from the listed drug due to a labeling revision described under subparagraph (A), the drug that is the subject of the application shall, notwithstanding any other provision of this subtitle, be eligible for approval and shall not be considered misbranded under chapter 133 of this title if—

(A) a revision to the labeling of the listed drug has been approved by the Secretary within 90 days of when the application is otherwise eligible for approval under this section;

(B) the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application not later than 60 days after approval under this section of the application;

(C) the labeling revision described under subparagraph (A) does not include a change to the ''Warnings'' section of the labeling; and

(D) the application otherwise meets the applicable requirements for approval under this section.

(2) EFFECT OF ADVERSE IMPACT OF LABELING PRIOR TO REVISION.—If, after a labeling revision described in paragraph (1)(A), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in paragraph (1)(A)) adversely impacts the safe use of the drug, an application under this section shall not be eligible for approval with the labeling.

(k) PRIORITY REVIEW FOR CERTAIN DRUGS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an

original abbreviated new drug application submitted for review under this section that is for a drug—

(A) for which there are not more than 3 approved drug products listed under subsection (h) and for which there are no blocking patents and exclusivities; or

(B) that has been included on the list under section 13125 of this title.

(2) REQUIRED INFORMATION.—

(A) IN GENERAL.—To qualify for priority review under this subsection, not later than 60 days prior to the submission of an application described in paragraph (1) or that the Secretary may prioritize pursuant to paragraph (4), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determina-

tion regarding whether an inspection of a facility is necessary.

(B) INCLUSIONS.—The information described in subparagraph (A) shall include the relevant (as determined by the Secretary) sections of the application, which shall be unchanged relative to the date of the submission of the application, except to the extent that a change is made to the information to exclude a facility that was not used to generate data to meet any application requirements for the submission and that is not the only facility intended to conduct 1 or more unit operations in commercial production.

(C) INFORMATION PROVIDED NOT CONSIDERED SUBMISSION OF APPLICATION.—Information provided by an applicant under this paragraph shall not be considered the submission of an application under this section.

(3) EXPEDITED INSPECTION.—The Secretary may expedite an inspection or reinspection under section 17504 of this title of an establishment that proposes to manufacture a drug described in paragraph (1).

(4) EFFECT OF SUBSECTION.—Nothing in this subsection shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

(l) PUBLICATION OF LIST OF DRUGS.—The Secretary shall publish on the FDA website, and update at least once every 6 months, a list of all drugs approved under section 13504 of this title for which all patents and periods of exclusivity under this subtitle have expired and for which no application has been approved under this section.

(m) REVIEW STATUS UPDATES.—On the request of an applicant regarding 1 or more specified pending applications under this section, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.

**§ 13512. Records and reports**

(a) RECORDS AND REPORTS RELATING TO GROUNDS FOR WITHDRAWAL OR SUSPENSION OF APPROVAL REQUIRED BY REGULATION OR ORDER.—

(1) IN GENERAL.—In the case of any drug for which an approval of an application filed under section 13503 or 13511 of this title is in effect, the applicant shall establish and maintain such records,

and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by the applicant with respect to the drug, as the Secretary may by general regulation, or by order with respect to the application, prescribe on the basis of a finding that the records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking section 13506 of this title.

(2) REQUIREMENTS FOR REGULATIONS AND ORDERS.—Regulations and orders issued under this section and under section 13510 of this title—

(A) shall have due regard for the professional ethics of the medical profession and the interests of patients; and

(B) shall provide, where the Secretary considers it to be appropriate, for the examination, upon request, by the persons to whom the regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(b) ACCESS TO RECORDS.—Every person required under this chapter to maintain records, and every person in charge or custody of the records, shall, on request of

an officer or employee designated by the Secretary, permit the officer or employee at all reasonable times to have access to and copy and verify the records.

(c) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(1) DEFINITION OF DATA.—In this subsection, the term ''data'' refers to information with respect to a drug approved under this chapter or under section 351 of the Public Health Service Act (42 U.S.C. 262), including—

(A) claims data;

(B) patient survey data;

(C) standardized analytic files that allow for the pooling and analysis of data from disparate data environments; and

(D) any other data considered appropriate by the Secretary.

(2) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, in collaboration with public, academic, and private entities—

(A) develop methods to obtain access to disparate data sources including the data sources specified in paragraph (3);

(B) develop validated methods for the establishment of a postmarket risk identification

and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

(i) at least 25,000,000 patients by July 1, 2010; and

(ii) at least 100,000,000 patients by July 1, 2012; and

(C) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under paragraph (3), including recommendations on the development of effective research methods for the study of drug safety questions.

(3) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(A) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under paragraph (2), establish and maintain procedures—

(i) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note), and in a manner that does not disclose individually identifiable health information in violation of subsection (d)(2);

(ii) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 13111(a) of this title) submitted to the Secretary under subsection (a), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(iii) to provide for active adverse event surveillance using the following data sources, as available:

(I) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(II) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(III) other data as the Secretary considers necessary to create a robust system to identify adverse events and potential drug safety signals;

(iv) to identify certain trends and patterns with respect to data accessed by the system;

(v) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(vi) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(B) TIMELINESS OF REPORTING.—The procedures established under subparagraph (A) shall ensure that the data are accessed, ana-

lyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(C) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this section not later than 1 year after the development of the risk identification and analysis methods under paragraph (2), as required under subparagraph (A), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(D) COMPLEMENTARY APPROACHES.—To the extent the active postmarket risk identification and analysis system under this section is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze the data and information, including—

(i) approaches that are complementary with respect to assessing the safety of

use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(ii) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(E) AUTHORITY FOR ENTERING INTO CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this paragraph.

(d) ADVANCED ANALYSIS OF DRUG SAFETY DATA.—

(1) PURPOSE.—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act (42 U.S.C. 299b–1), to provide for advanced analysis of drug safety data described in subsection (c)(3) and other information that is publicly available or is provided by the Secretary, in order to—

(A) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(B) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(C) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(2) PRIVACY.—The analysis under paragraph (1) shall not disclose individually identifiable health information when presenting the drug safety signals and trends or when responding to inquiries regarding the drug safety signals and trends.

(3) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the FDA on—

(A) priority drug safety questions; and

(B) mechanisms for answering the questions, including through—

(i) active risk identification under subsection (c); and

(ii) when the risk identification is not sufficient, postapproval studies and clinical trials under section 13515(c) of this title.

(4) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(A) IN GENERAL.—The Secretary shall establish and implement procedures under which the Secretary may routinely contract with 1 or more qualified entities to—

(i) classify, analyze, or aggregate data described in subsection (c)(3) and information that is publicly available or is provided by the Secretary;

(ii) allow for prompt investigation of priority drug safety questions, including—

(I) unresolved safety questions for drugs or classes of drugs; and

(II) for a newly-approved drug—

(aa) safety signals from clinical trials used to approve the drug and other preapproval trials;

(bb) rare, serious drug side effects; and

(cc) the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such

as older people, people with comorbidities, pregnant women, or children);

(iii) perform advanced research and analysis on identified drug safety risks;

(iv) focus postapproval studies and clinical trials under section 13515(c) of this title more effectively on cases for which reports under subsection (a) and other safety signal detection are not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(v) carry out other activities as the Secretary considers necessary to carry out the purposes of this paragraph.

(B) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in subparagraph (A) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(5) USE OF ANALYSES.—The Secretary shall provide the analyses described in this subsection, in-

cluding the methods and results of the analyses, about a drug to the sponsor or sponsors of the drug.

(6) QUALIFIED ENTITIES.—

(A) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(B) QUALIFICATION.—The Secretary shall enter into a contract with an entity under subparagraph (A) only if the Secretary determines that the entity has a significant presence in the United States and has 1 or more of the following qualifications:

(i) RESEARCH, STATISTICAL, EPIDEMIOLOGIC, OR CLINICAL CAPABILITY AND EXPERTISE.—The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this section.

(ii) INFORMATION TECHNOLOGY INFRASTRUCTURE.—An information technology infrastructure in place to support

electronic data and operational standards to provide security for the data.

(iii) EXPERIENCE AND EXPERTISE ON DEVELOPMENT OF DRUG SAFETY AND EFFECTIVENESS RESEARCH.—Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(iv) UNDERSTANDING OF DRUG DEVELOPMENT OR RISK/BENEFIT BALANCING.—An understanding of drug development or risk/benefit balancing in a clinical setting.

(v) OTHER EXPERTISE.—Other expertise that the Secretary considers necessary to fulfill the activities under this subsection.

(7) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under paragraph (6)(A) shall contain the following requirements:

(A) ENSURING PRIVACY.—

(i) IN GENERAL.—The qualified entity shall ensure that the entity will not use data under this section in a manner that—

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note);

(II) violates section 552 or 552a of title 5 with regard to the privacy of individually identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph prohibits lawful disclosure for other purposes.

(B) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

(i) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of the data; and

(ii) the entity shall not make an unauthorized disclosure of the data to the other components of the organization in breach of the confidentiality and privacy requirement.

(C) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this paragraph is terminated or not renewed, the following requirements shall apply:

(i) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this subsection with respect to all data disclosed to the entity.

(ii) DISPOSITION OF DATA.—The entity shall return any data disclosed to the entity under this section to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(8) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 132 of title 41) to enter into contracts under paragraph (7).

(9) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this subsection in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subsection will continue to be met.

(10) COMMUNICATION AND COORDINATION.—In carrying out this subsection, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate activities with private entities, professional associations, or other entities that may have sources of drug safety data.

(e) REPORTING TO CONGRESS AND ONLINE PUBLICATION RELATING TO SAFETY.—The Secretary shall—

(1) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System website of any new safety information or potential signal of a serious risk identified by the Adverse Event Reporting System within the last quarter;

(2) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be

eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for the commitments; and

(3) make available on the FDA website—

(A) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

(B) criteria for public posting of adverse event signals.

(f) EFFECT OF PROVISIONS ON LAWFUL DISCLOSURE OF INFORMATION.—Nothing in subsections (c) and (d), or in section 905 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 121 Stat. 944), shall be construed to prohibit the lawful disclosure or use of data or information by an entity other than as described in paragraph (2) or (7) of subsection (d).

**§ 13513. Public disclosure of safety and effectiveness data and action package**

(a) WHEN SAFETY AND EFFECTIVENESS DATA SHALL BE MADE AVAILABLE.—Safety and effectiveness data and information that has been submitted in an application under section 13503 of this title for a drug and

that has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved;

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted;

(3) if approval of the application under section 13504 of this title is withdrawn and all legal appeals have been exhausted;

(4) if the Secretary has determined that the drug is not a new drug; or

(5) on the effective date of the approval of the first application under section 13511 of this title that refers to the drug or on the date on which the approval of an application under section 13511 of this title that refers to the drug could be made effective if such an application had been submitted.

(b) ACTION PACKAGE FOR APPROVAL.—

(1) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under section 13503 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) on the FDA website—

(A) not later than 30 days after the date of approval of the application—

(i) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this chapter; or

(ii) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act (42 U.S.C. 262); and

(B) not later than 30 days after the third request for the action package for approval received under section 552 of title 5 for any other drug or biological product.

(2) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding paragraph (1), the Secretary shall publish, on the FDA website, the materials described in paragraph (3)(D) not later than 48 hours after the date of approval of the drug, except where the materials require redaction by the Secretary.

(3) CONTENTS.—An action package for approval of an application under paragraph (1) shall be dated and shall include the following:

(A) Documents generated by the FDA related to review of the application.

(B) Documents pertaining to the format and content of the application generated during drug development.

(C) Labeling submitted by the applicant.

(D) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(E) The Division Director and Office Director's decision document, which includes—

(i) a brief statement of concurrence with the summary review;

(ii) a separate review or addendum to the review if disagreeing with the summary review; and

(iii) a separate review or addendum to the review to add further analysis.

(F) Identification by name of each officer or employee of the FDA who—

(i) participated in the decision to approve the application; and

(ii) consents to have his or her name included in the package.

(4) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(5) CONFIDENTIAL INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5.

**§ 13514. Scientific advisory panels**

(a) PURPOSE OF ESTABLISHMENT OR USE OF PANELS.—For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under this chapter or section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall establish panels of experts, use panels of experts established before November 21, 1997, or both.

(b) MEMBERS.—

(1) IN GENERAL.—The Secretary shall make appointments to each panel established under subsection (a) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of the drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C)(i) a representative of consumer interests; and

(ii) a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) 2 or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

(2) OPPORTUNITY FOR ORGANIZATIONS TO NOMINATE INDIVIDUALS FOR MEMBERSHIP.—Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels.

(3) LIMITATION RELATING TO FEDERAL EMPLOYMENT.—An individual who is in the regular full-time employ of the Federal Government and engaged in the administration of this subtitle shall not be a voting member of any panel.

(4) CHAIRPERSON.—The Secretary shall designate one of the members of each panel to serve as chairperson of the panel.

(c) EDUCATION AND TRAINING OF MEMBERS.—The Secretary shall, as appropriate, provide education and training to each new panel member before the member participates in a panel's activities, including education regarding requirements under this subtitle and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(d) COMPENSATION.—

(1) IN GENERAL.—Panel members (other than officers or employees of the Federal Government), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be enti-

tled to receive compensation for each day of attendance or engagement, including travel time, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule.

(2) TRAVEL EXPENSES.—While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5 for individuals in the Government service employed intermittently.

(e) MEETINGS.—

(1) IN GENERAL.—The Secretary shall ensure that any scientific advisory panel meets regularly and at appropriate intervals so that any matter to be reviewed by the panel can be presented to the panel not more than 60 days after the matter is ready for the review.

(2) ELECTRONIC COMMUNICATIONS.—A meeting of a panel under paragraph (1) may be held using electronic communication to convene the meetings.

(f) REVIEW OF PANEL RECOMMENDATIONS; FINAL DECISION.—

(1) IN GENERAL.—Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the FDA official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no final decision has been reached.

(2) DOCUMENTATION.—Each final decision under paragraph (1) shall be documented, including the rationale for the decision.

**§ 13515. Postmarket studies and clinical trials; labeling changes**

(a) DEFINITIONS.—In this section:

(1) COVERED APPLICATION.—The term ''covered application'' means—

(A) an application under section 13503 of this title for a drug that is subject to section 13103(a) of this title; and

(B) an application under section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) NEW SAFETY INFORMATION.—The term ''new safety information'' has the meaning given the term in section 13111(a) of this title.

(3) RESPONSIBLE PERSON.—The term ''responsible person'' means a person that—

(A) has submitted to the Secretary a covered application that is pending; or

(B) is the holder of an approved covered application.

(4) SERIOUS RISK.—The term ''serious risk'' has the meaning given the term in section 13111(a) of this title.

(5) SIGNAL OF A SERIOUS RISK.—The term ''signal of a serious risk'' has the meaning given the term in section 13111(a) of this title.

(b) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under subsection (c) or (d) with respect to the drug.

(c) STUDIES AND CLINICAL TRIALS.—

(1) IN GENERAL.—For any or all of the purposes specified in paragraph (2), the Secretary may, subject to paragraph (4), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data considered appropriate by the Secretary, including

information regarding chemically-related or pharmacologically-related drugs.

(2) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this paragraph with respect to a postapproval study or postapproval clinical trial are the following:

(A) To assess a known serious risk related to the use of the drug involved.

(B) To assess signals of serious risk related to the use of the drug.

(C) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(3) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish the requirement only if the Secretary becomes aware of new safety information.

(4) DETERMINATION BY SECRETARY.—

(A) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this subsection, unless

the Secretary makes a determination that the reports under section 13512(a) of this title and the active postmarket risk identification and analysis system as available under section 13512(c) of this title will not be sufficient to meet the purposes set forth in paragraph (2).

(B) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this subsection, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in paragraph (2).

(5) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

(A) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this subsection to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Prescription

Drug User Fee Amendments of 2007 (Public Law 110–85, title I, 121 Stat. 825).

(B) TIMETABLE; PERIODIC REPORTS.—

(i) SUBMISSION OF TIMETABLE.—For each study or clinical trial required to be conducted under this subsection, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial.

(ii) PERIODIC REPORTING OF STATUS.—

(I) STUDIES.—With respect to each study required to be conducted under this subsection or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of the study including whether any difficulties in completing the study have been encountered.

(II) CLINICAL TRIALS.—With respect to each clinical trial required to be conducted under this subsection or

otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of the clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(iii) NONCOMPLIANCE OR VIOLATION; DEMONSTRATION OF GOOD CAUSE.—

(I) IN GENERAL.—If the responsible person fails to comply with the timetable or violates any other requirement of this paragraph, the responsible person shall be considered in violation of this section, unless the responsible person demonstrates good

cause for the noncompliance or other violation.

(II) DETERMINATION OF GOOD CAUSE.—The Secretary shall determine what constitutes good cause under subclause (I).

(6) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this subsection using dispute resolution procedures established by the Secretary in regulation and guidance.

(d) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

(1) NEW SAFETY OR NEW EFFECTIVENESS INFORMATION.—If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 13503 of this title is not currently marketed, the holder of an approved application under section 13511 of this title.

(2) RESPONSE TO NOTIFICATION.—Following notification pursuant to paragraph (1), the respon-

sible person or the holder of the approved application under section 13511 of this title shall within 30 days—

(A) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions, or new effectiveness information; or

(B) notify the Secretary that the responsible person or the holder of the approved application under section 13511 of this title does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(3) REVIEW.—

(A) IN GENERAL.—On receipt of a supplement under paragraph (2)(A), the Secretary shall promptly review and act on the supplement.

(B) DISAGREEMENT BY SECRETARY; DISCUSSIONS.—If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall

initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety or new effectiveness information, and if so, the contents of the labeling changes.

(4) DISCUSSIONS.—The discussions described in paragraph (3)(B) shall not extend for more than 30 days after the response to the notification under paragraph (2), unless the Secretary determines an extension of the discussion period is warranted.

(5) ORDER.—

(A) ISSUANCE.—Within 15 days of the conclusion of the discussions under paragraph (4), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 13511 of this title to make such a labeling change as the Secretary considers appropriate to address the new safety or new effectiveness information.

(B) SUBMISSION OF SUPPLEMENT CONTAINING LABELING CHANGE.—Within 15 days of the order under subparagraph (A), the responsible person or the holder of the approved application under section 13511 of this title

shall submit a supplement containing the labeling change.

(6) DISPUTE RESOLUTION.—Within 5 days of receiving an order under paragraph (5), the responsible person or the holder of the approved application under section 13511 of this title may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(7) VIOLATIONS.—

(A) REQUIRED SUPPLEMENT UNDER PARAGRAPH (5) NOT SUBMITTED.—If the responsible person or the holder of the approved application under section 13511 of this title has not submitted a supplement within 15 days of the date of the order under paragraph (5), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this section.

(B) REQUIRED SUPPLEMENT AT CONCLUSION OF DISPUTE RESOLUTION NOT SUBMITTED.—If, at the conclusion of any dispute resolution procedures, the Secretary determines that a supplement must be submitted and the supplement is not submitted within 15 days of the date of that determination, the responsible

person or holder shall be in violation of this section.

(8) PUBLIC HEALTH THREAT.—Notwithstanding paragraphs (1) through (6), if the Secretary concludes that a labeling change under this subsection is necessary to protect the public health, the Secretary may accelerate the timelines in the paragraphs.

(9) RULE OF CONSTRUCTION.—This subsection shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 13511 of this title to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(e) NON-DELEGATION.—Determinations by the Secretary under this section for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

**§ 13516. Risk evaluation and mitigation strategy**

(a) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

(1)(A) the application for the drug is approved under section 13503 or 13511 of this title and is subject to section 13103(a) of this title; or

(B) the application for the drug is approved under section 351 of the Public Health Service Act (42 U.S.C. 262); and

(2) a risk evaluation and mitigation strategy is required under section 13111 of this title with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 13111 of this title, including requirements regarding assessments of approved strategies.

(b) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 13119 of this title of this title or subpart H of part 314 or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of subsection (a).

**§ 13517. Petitions and civil actions regarding approval of certain applications**

(a) DEFINITIONS.—In this section:

(1) APPLICATION.—The term ''application'' means an application submitted under section

13503(b) or 13511 of this title or section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(2) PETITION.—Except in subsection (b)(1)(A)(i), the term ''petition'' means a request described in subsection (b)(1)(A)(i).

(b) IN GENERAL.—

(1) DETERMINATION.—

(A) IN GENERAL.—The Secretary shall not delay approval of a pending application because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, on reviewing the petition, that a delay is necessary to protect the public health.

(B) SEPARATE AND APART FROM REVIEW OF APPLICATION.—Consideration of the petition shall be separate and apart from review and approval of any application.

(2) NOTIFICATION.—If the Secretary determines under paragraph (1) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making the determination, the following information:

(A) Notification of the fact that a determination under paragraph (1) has been made.

(B) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(C) A brief summary of the specific substantive issues raised in the petition that form the basis of the determination.

(3) FORMAT.—The information described in paragraph (2) shall be conveyed via, at the discretion of the Secretary, either—

(A) a document; or

(B) a meeting with the applicant involved.

(4) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under paragraph (3) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in the application.

(5) DENIAL BASED ON INTENT TO DELAY.—

(A) IN GENERAL.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on the determination.

(B) GUIDANCE.—The Secretary may issue guidance to describe the factors that will be used to determine under this paragraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(6) FINAL AGENCY ACTION.—

(A) DEADLINE.—The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted.

(B) NO EXTENSION.—The Secretary shall not extend the period under subparagraph (A) for any reason, including—

(i) any determination made under paragraph (1);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(7) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under section 13511(f)(4)(A)(ii)(IV) of this title and approval of the application was delayed because of a petition, the 30-month period under that section is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of the beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(8) CERTIFICATION.—

(A) IN GENERAL.—The Secretary shall not consider a petition for review unless the party submitting the petition does so in written form and the subject document is signed and contains the following certification: ''I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition in-

cludes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____ . If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ . I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.''.

(B) DATE; PERSONS AND ORGANIZATIONS.—The date on which the information first became known to the party shall be inserted in the first blank space and the names of the persons or organizations from whom the payments are received or expected to be re-

ceived shall be inserted in the second blank space.

(9) VERIFICATION.—

(A) IN GENERAL.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting the information or comments does so in written form and the subject document is signed and contains the following verification: ''I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____ . If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.''.

(B) DATE; PERSONS AND ORGANIZATIONS.—The date on which the information first became known to the party shall be inserted in the first blank space and the names of the persons or organizations from whom the payments are received or expected to be received shall be inserted in the second blank space.

(c) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(1) FINAL AGENCY ACTION WITHIN 150 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(A) during the 150-day period referred to in subsection (b)(6), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(B) the 150-day period expires without the Secretary having made a final decision described in subparagraph (A).

(2) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of paragraph (1), the court

shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(3) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under subsection (b) was submitted, the administrative record regarding any issue raised by the petition shall include—

(A) the petition filed under subsection (b) and any supplements to and comments on the petition;

(B) the Secretary's response to the petition, if issued; and

(C) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in the petition, as long as the information was considered by the agency no later than the date of final agency action as defined under paragraph (1), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(d) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to Congress a report that specifies—

(1) the number of applications that were approved during the preceding 12-month period;

(2) the number of applications described in paragraph (1) whose effective dates were delayed by petitions referred to in subsection (b) during the 12-month period;

(3) the number of days by which the applications described in paragraph (2) were delayed; and

(4) the number of petitions referred to in subsection (b) that were submitted during the 12-month period.

(e) INAPPLICABILITY OF PROVISIONS OF THIS SECTION.—

(1) IN GENERAL.—This section does not apply to—

(A) a petition that relates solely to the timing of the approval of an application pursuant to section 13511(f)(2)(D) of this title; or

(B) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(2) SUBSECTION (c).—Subsection (c) does not apply to a petition addressing issues concerning an

application submitted pursuant to section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

**§ 13518. Postmarket drug safety information for patients and providers**

(a) ESTABLISHMENT.—The Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an internet website that—

(1) provides links to drug safety information listed in subsection (b) for prescription drugs that are approved under this chapter or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); and

(2) improves communication of drug safety information to patients and providers.

(b) INTERNET WEBSITE.—The Secretary shall carry out subsection (a) by—

(1) developing and maintaining an accessible, consolidated internet website with easily searchable drug safety information, including the information found on United States Government internet websites, such as the United States National Library of Medicine's Daily Med and Medline Plus websites,

in addition to other such websites maintained by the Secretary;

(2) ensuring that the information provided on the internet website is comprehensive and includes, when available and appropriate—

(A) patient labeling and patient packaging inserts;

(B) a link to a list of each drug, whether approved under this chapter or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(C) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act (42 U.S.C. 282(i), (j));

(D) the most recent safety information and alerts issued by the FDA for drugs approved by the Secretary under this chapter, such as product recalls, warning letters, and import alerts;

(E) publicly available information about implemented RiskMAPs and risk evaluation and

mitigation strategies under section 13515 of this title;

(F) guidance documents and regulations related to drug safety; and

(G) other material determined appropriate by the Secretary;

(3) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under section 13512(c) of this title to provide information of known and serious side-effects for drugs approved under this chapter or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262);

(4) preparing and making publicly available on the internet website established under subsection (a) best practices for drug safety surveillance activities for drugs approved under this chapter or section 351 of the Public Health Service Act (42 U.S.C. 262);

(5) enabling patients, providers, and drug sponsors to submit adverse event reports through the internet website;

(6) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(7) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the internet website.

(c) POSTING OF DRUG LABELING.—The Secretary shall post on the internet website developed and maintained under subsection (a) the approved professional labeling and any required patient labeling of a drug approved under this chapter or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(d) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this section.

(e) REVIEW.—The Advisory Committee on Risk Communication established under section 14314 of this title—

(1) shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the internet website developed and maintained under subsection (a) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers; and

(2) shall recommend ways for the FDA to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

**§ 13519. Referral to advisory committee**

The Secretary shall—

(1) refer a drug or biological product to an advisory committee of the FDA for review at a meeting of the advisory committee prior to the approval of the drug or biological product if it is—

(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this chapter; or

(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to an advisory committee of the FDA prior to the approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biologi-

cal product to an advisory committee prior to approval.

**§ 13520. Database for authorized generic drugs**

(a) DEFINITION OF AUTHORIZED GENERIC DRUG.—In this section, the term ''authorized generic drug'' means a listed drug (as that term is used in section 13511 of this title) that—

(1) has been approved under section 13504 of this title; and

(2) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark than the listed drug.

(b) IN GENERAL.—

(1) PUBLICATION.—The Commissioner shall—

(A) publish a complete list, on the FDA website, of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(B) update the list quarterly to include each authorized generic drug included in an an-

nual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(2) NOTIFICATION.—When the Commissioner first publishes the information described in paragraph (1), the Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, that the information has been published and that the information will be updated quarterly.

(c) INCLUSION.—The Commissioner shall include in the list described in subsection (b) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

**§ 13521. Certain drugs containing single enantiomers**

(a) DEFINITION OF THERAPEUTIC CATEGORY.—

(1) IN GENERAL.—In this section, the term ''therapeutic category'' means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)(C)(ii)) and as in effect on September 27, 2007.

(2) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in paragraph (1) and may amend the list by regulation.

(b) IN GENERAL.—For purposes of sections 13504(c)(5)(A) and 13511(f)(6)(A) of this title, if an application is submitted under section 13503 of this title for a non-racemic drug containing as an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) a single enantiomer that is contained in a racemic drug approved in another application under section 13503 of this title, the applicant may, in the application for the non-racemic drug, elect to have the single enantiomer not be considered the same active moiety as that contained in the approved racemic drug, if—

(1)(A) the single enantiomer has not been previously approved except in the approved racemic drug; and

(B) the application submitted under section 13503 of this title for the non-racemic drug—

(i) includes full reports of new clinical investigations (other than bioavailability studies)—

(I) necessary for the approval of the application under sections 13504 and 13505 of this title; and

(II) conducted or sponsored by the applicant; and

(ii) does not rely on any clinical investigations (other than bioavailability studies) that are part of an application submitted under section 13503 of this title for approval of the approved racemic drug; and

(2) the application submitted under section 13503 of this title for the non-racemic drug is not submitted for approval of a condition of use—

(A) in a therapeutic category in which the approved racemic drug has been approved; or

(B) for which any other enantiomer of the racemic drug has been approved.

(c) LIMITATION.—

(1) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in subsection (b) and with respect to which the applicant has made the election provided for by subsection (b), the Secretary shall not approve the non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(2) LABELING.—If applicable, the labeling of a non-racemic drug described in subsection (b) and

with respect to which the applicant has made the election provided for by subsection (b) shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(d) AVAILABILITY.—The election referred to in subsection (b) may be made only in an application that is submitted to the Secretary after September 27, 2007, and before October 1, 2027.

**§ 13522. Antibiotic drugs submitted before November 21, 1997**

(a) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

(1) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2296) or any other provision of law, a sponsor of a drug that is the subject of an application described in paragraph (2)(A) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under subparagraphs (B) and (C) of section 13504(c)(5) of this title and subparagraphs (B) and (C) of section 13511(f)(6) of this title, subject to the requirements of those subparagraphs, as applicable.

(2) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(A) APPLICATION.—An application described in this subparagraph is an application for marketing submitted under this chapter after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in subparagraph (B).

(B) ANTIBIOTIC DRUG.—An antibiotic drug described in this subparagraph is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) (as in effect before November 21, 1997).

(b) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

(1) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2296) or any other provision of law, a sponsor of a drug that is the subject of an application described in paragraph (2)(A) may elect to be eligible for, with respect to the drug—

(A)(i) the 3-year exclusivity period referred to under subparagraphs (B) and (C) of section 13504(c)(5) of this title and subparagraphs (B) and (C) of section 13511(f)(6) of this title, subject to the requirements of those subparagraphs, as applicable; and

(ii) the 5-year exclusivity period referred to under subparagraph (A) of section 13504(c)(5) of this title and subparagraph (A) of section 13511(f)(6) of this title, subject to the requirements of those subparagraphs, as applicable; or

(B) a patent term extension under section 156 of title 35, subject to the requirements of that section.

(2) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(A) APPLICATION.—An application described in this subparagraph is an application for marketing submitted under this section after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in subparagraph (B).

(B) ANTIBIOTIC DRUG.—An antibiotic drug described in this subparagraph is an antibiotic drug that was the subject of 1 or more

applications received by the Secretary under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) (as in effect before November 21, 1997), none of which was approved by the Secretary under that section.

(c) LIMITATIONS.—

(1) EXCLUSIVITIES AND EXTENSIONS.—Subsections (a)(1) and (b)(1) shall not be construed to entitle a drug that is the subject of an approved application described in subsection (a)(2)(A) or (b)(2)(A), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in subsection (a)(1) or (b)(1).

(2) CONDITIONS OF USE.—Subsections (a)(1) and (b)(1)(A)(i) do not apply to any condition of use for which the drug referred to in subsection (a)(2)(A) or (b)(2)(A), as applicable, was approved before October 8, 2008.

(d) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2296), or any other provision of law, and subject to the limitations in subsections (a), (b), and (c), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public

Law 98–417, 98 Stat. 1585) shall apply to any drug subject to subsection (a) or any drug with respect to which an election is made under subsection (b)(1).

**§ 13523. Deadline for determination on certain petitions**

The Secretary shall issue a final, substantive determination on a petition submitted pursuant to section 314.161(b) of title 21, Code of Federal Regulations (or any successor regulations), not later than 270 days after the date the petition is submitted.

**§ 13524. Date of approval in the case of recommended controls under division A of subtitle V of this title**

In the case of an application under 13503 of this title with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under division A of subtitle V of this title, approval of the application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 50301(j) of this title.

**§ 13525. Contrast agents intended for use with applicable medical imaging devices**

(a) DEFINITIONS.—In this subsection:

(1) APPLICABLE MEDICAL IMAGING DEVICE.—The term ''applicable medical imaging device'' has the meaning given the term in section 13152(p) of this title.

(2) CONTRAST AGENT.—The term ''contrast agent'' has the meaning given the term in section 13152(p) of this title.

(3) NEW USE.—The term ''new use'' means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 13152(p) of this title, but that is not described in the approved labeling of the contrast agent.

(b) IN GENERAL.—The sponsor of a contrast agent for which an application has been approved under this chapter may submit a supplement to the application seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 13152(p)(2) of this title.

(c) REVIEW OF SUPPLEMENT.—In reviewing a supplement submitted under this section, the agency center charged with the premarket review of drugs may—

(1) consult with the center charged with the premarket review of devices; and

(2) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 13136(k), 13140(h)(2), or 13142 of this title so long as the sponsor of the applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

**§ 13526. Diversity action plan for clinical studies**

(a) IN GENERAL.—With respect to a clinical investigation of a new drug that is a phase 3 study, as defined in section 312.21(c) of title 21, Code of Federal Regulations, or successor regulations, or, as appropriate, another pivotal study of a new drug (other than bioavailability or bioequivalence studies), the sponsor of the drug shall submit to the Secretary a diversity action plan.

(b) CONTENT.—The diversity action plan shall include—

(1) the sponsor's goals for enrollment in the clinical study;

(2) the sponsor's rationale for the goals; and

(3) an explanation of how the sponsor intends to meet the goals.

(c) SUBMISSION REQUIREMENTS.—

(1) IN GENERAL.—The sponsor shall submit to the Secretary the diversity action plan, in the form

and manner specified by the Secretary in guidance, as soon as practicable but not later than the date on which the sponsor submits the protocol to the Secretary for the phase 3 study or other pivotal study of the drug.

(2) MODIFICATIONS.—The sponsor may submit modifications to the diversity action plan. The modifications shall be in the form and manner specified by the Secretary in guidance.

(d) WAIVER.—

(1) AUTHORITY.—On the initiative of the Secretary or at the request of a sponsor, the Secretary may waive any requirement in subsection (a), (b), or (c) if the Secretary determines that a waiver is necessary based on what is known or what can be determined about the prevalence or incidence of the disease or condition for which the new drug is under investigation (including in terms of the patient population that may use the drug), if conducting a clinical investigation in accordance with a diversity action plan would otherwise be impracticable, or if the waiver is necessary to protect public health during a public health emergency.

(2) WRITTEN RESPONSE REQUIRED.—The Secretary shall issue a written response granting or de-

nying a request from a sponsor for a waiver within 60 days of receiving the request.

(e) INAPPLICABILITY.—A diversity action plan shall not be required for a submission described in section 14301 of this title.

# Chapter 137—New Animal Drugs

Sec.
13701. Definitions.
13702. Unsafe new animal drugs and animal feed.
13703. Application procedures.
13704. Approval of applications.
13705. Grounds for refusing application.
13706. Withdrawal and suspension of approval.
13707. Revocation of order refusing, withdrawing, or suspending approval of application.
13708. Service of orders.
13709. Appeals from orders.
13710. Publication of approval in Federal Register.
13711. Exemption for drugs for investigational use.
13712. Food containing approved new animal drug considered unadulterated.
13713. Records and reports.
13714. Feed mill licenses.
13715. Abbreviated applications for new animal drugs.
13716. Safety and effectiveness data.
13717. Date of approval in the case of recommended controls under the CSA.

## § 13701. Definitions

In this chapter:

(1) DATE OF APPROVAL.—With respect to an application described in section 13717 of this title, the term ''date of approval'' means the later of—

(A) the date an application under section 13703 of this title is approved under section 13704 of this title; or

(B) the date of issuance of the interim final rule controlling the drug.

(2) PATENT.—The term ''patent'' means a patent issued by the United States Patent and Trademark Office.

(3) SUBSTANTIAL EVIDENCE.—

(A) IN GENERAL.—The term ''substantial evidence'' means evidence consisting of 1 or more adequate and well-controlled investigations described in subparagraph (B) such as—

(i) a study in a target species;

(ii) a study in laboratory animals;

(iii) any field investigation that may be required under this chapter and that meets the requirements of section 13703(c) of this title if a presubmission conference is requested by the applicant;

(iv) a bioequivalence study; or

(v) an in vitro study.

(B) INVESTIGATIONS.—The investigations described in this subparagraph are investigations by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by the experts that the drug will have the effect it purports or is represented to have under the condi-

tions of use prescribed, recommended, or suggested in the labeling or proposed labeling of the drug.

**§ 13702. Unsafe new animal drugs and animal feed**

(a) NEW ANIMAL DRUGS.—

(1) IN GENERAL.—A new animal drug shall, with respect to any particular use or intended use of the drug, be deemed unsafe for purposes of sections 13101(a)(2)(E) and 11102(a)(2)(C)(ii) of this title unless—

(A) there is in effect an approval of an application filed pursuant to section 13703 of this title with respect to the use or intended use of the drug, and the drug, its labeling, and the use conform to the approved application;

(B) there is in effect a conditional approval of an application filed pursuant to section 14502 of this title with respect to the use or intended use of the drug, and the drug, its labeling, and the use conform to the conditionally approved application;

(C) there is in effect an index listing pursuant to section 14503 of this title with respect to the use or intended use of the drug in a

minor species, and the drug, its labeling, and the use conform to the index listing; or

(D) there is in effect an authorization pursuant to section 14306 of this title with respect to the use or intended use of the drug, and the drug, its labeling, and the use conform to all conditions of the authorization.

(2) REMOVAL FROM ESTABLISHMENT.—A new animal drug shall also be deemed unsafe for the purposes described in paragraph (1) in the event of removal from the establishment of a manufacturer, packer, or distributor of the drug for use in the manufacture of animal feed in any State unless, at the time of the removal, the manufacturer, packer, or distributor has an unrevoked written statement from the consignee of the drug, or notice from the Secretary, to the effect that, with respect to the use of the drug in animal feed, the consignee—

(A) holds a license issued under section 13714 of this title and has in its possession current approved labeling for the drug in animal feed; or

(B) will, if the consignee is not a user of the drug, ship the drug only to a holder of a license issued under section 13714 of this title.

(b) ANIMAL FEED.—An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of the animal feed, be deemed unsafe for purposes of section 13101(a)(2)(F) of this title unless—

(1) there is in effect—

(A) an approval of an application filed pursuant to section 13703 of this title with respect to the drug, as used in the animal feed, and the animal feed and its labeling, distribution, holding, and use conform to the approved application;

(B) a conditional approval of an application filed pursuant to section 14502 of this title with respect to the drug, as used in the animal feed, and the animal feed and its labeling, distribution, holding, and use conform to the conditionally approved application; or

(C) an index listing pursuant to section 14503 of this title with respect to the drug, as used in the animal feed, and the animal feed and its labeling, distribution, holding, and use conform to the index listing; and

(2) the animal feed is manufactured at a site for which there is in effect a license issued pursuant

to section 13714(a) of this title to manufacture the animal feed.

(c) EXEMPTION RELATING TO INVESTIGATIONAL USE.—A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of subparagraph (E) or (F) of section 13101(a)(2) of this title if the article is for investigational use and conforms to the terms of an exemption in effect with respect to the new animal drug or the animal feed under section 13711 of this title.

(d) CONDITIONS OF USE.—

(1) NOT DEEMED UNSAFE; EXEMPTION FROM CERTAIN LABELING REQUIREMENTS.—

(A) IN GENERAL.—Except as provided in paragraph (2), if an approval of an application filed under section 13703 of this title is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of subsection (a) and shall be exempt from the requirements of section 13305 of this title with respect to a different use or intended use of the drug, other than a use in or on animal feed, if the use or intended use—

(i) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(ii) is in compliance with regulations promulgated by the Secretary that establish the conditions for the different use or intended use.

(B) LIMITATIONS BY REGULATION.—The regulations promulgated by the Secretary under subparagraph (A)(ii) may prohibit particular uses of an animal drug and shall not permit the different use of an animal drug if the labeling of another animal drug that contains the same active ingredient and that is in the same dosage form and concentration provides for the different use.

(2) RISK TO PUBLIC HEALTH; ACTIONS BY SECRETARY.—

(A) IN GENERAL.—If the Secretary finds that there is a reasonable probability that a use of an animal drug authorized under paragraph (1) may present a risk to the public health, the Secretary may—

(i) establish a safe level for a residue of an animal drug when it is used for the different use authorized by paragraph (1); and

(ii) require the development of a practical, analytical method for the detection of residues of the drug above the safe level established under clause (i).

(B) USE EXCEEDING SAFE LEVEL.—The use of an animal drug that results in residues exceeding a safe level established under subparagraph (A)(i) shall be considered an unsafe use of the drug under subsection (a).

(C) SAFE LEVELS BY REGULATION OR ORDER.—Safe levels may be established under subparagraph (A)(i) either by regulation or order.

(3) ACCESS TO RECORDS OF VETERINARIANS BY REGULATION.—The Secretary may by general regulation provide access to the records of veterinarians to ascertain any use or intended use authorized under paragraph (1) that the Secretary has determined may present a risk to the public health.

(4) PROHIBITION OF USE.—If the Secretary finds, after affording an opportunity for public com-

ment, that a use of an animal drug authorized under paragraph (1) presents a risk to the public health or that an analytical method required under paragraph (2) has not been developed and submitted to the Secretary, the Secretary may, by order, prohibit that use.

(e) NEW DRUG APPROVAL IN EFFECT.—If the approval of an application filed under chapter 135 of this title is in effect, the drug under the application shall not be deemed unsafe for purposes of subsection (a) and shall be exempt from the requirements of section 13305 of this title with respect to a use or intended use of the drug in animals if the use or intended use—

(1) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(2) is in compliance with regulations promulgated by the Secretary that establish the conditions for the use or intended use of the drug in animals.

(f) ESTABLISHMENT OF TOLERANCES.—

(1) DEFINITION OF RELEVANT INTERNATIONAL ORGANIZATION.—In this subsection, the term ''relevant international organization'' means the Codex

Alimentarius Commission or other international organization considered appropriate by the Secretary.

(2) IN GENERAL.—For purposes of section 11102(a)(2)(C)(ii) of this title, a use or intended use of a new animal drug shall not be deemed unsafe under this chapter if—

(A) the Secretary establishes a tolerance for the drug; and

(B) any edible portion of any animal imported into the United States does not contain residues exceeding the tolerance.

(3) RELIANCE ON DATA BASED ON FOOD SAFETY CRITERIA.—In establishing the tolerance under paragraph (2), the Secretary shall rely on data sufficient to demonstrate that a proposed tolerance is safe based on similar food safety criteria used by the Secretary to establish tolerances for applications for new animal drugs filed under section 13703(a) of this title.

(4) RELIANCE ON DATA SUBMITTED BY DRUG MANUFACTURER.—The Secretary may consider and rely on data submitted by the drug manufacturer, including data submitted to appropriate regulatory authorities in any country where the new animal drug is lawfully used or data available from a rel-

evant international organization, to the extent the data are not inconsistent with the criteria used by the Secretary to establish a tolerance for applications for new animal drugs filed under section 13703(a) of this title.

(5) REVOCATION OF TOLERANCE.—The Secretary may, under procedures specified by regulation, revoke a tolerance established under this subsection if—

(A) information demonstrates that the use of the new animal drug under actual use conditions results in food being imported into the United States with residues exceeding the tolerance; or

(B) scientific evidence shows the tolerance to be unsafe.

**§ 13703. Application procedures**

(a) NEW ANIMAL DRUG APPLICATIONS.—

(1) FILING.—Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug.

(2) CONTENTS.—A person filing an application under paragraph (1) shall submit to the Secretary as part of the application—

(A) full reports of investigations that have been made to show whether or not the drug is safe and effective for use;

(B) a full list of the articles used as components of the drug;

(C) a full statement of the composition of the drug;

(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug;

(E) such samples of the drug and of the articles used as components of the drug, of any animal feed for use in or on which the drug is intended, and of the edible portions or products (before or after slaughter) of animals to which the drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require;

(F) specimens of the labeling proposed to be used for the drug, or in case the drug is intended for use in animal feed, proposed labeling appropriate for the use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant;

(G) a description of practicable methods for determining the quantity, if any, of the drug in or on food, and any substance formed in or on food, because of its use; and

(H) the proposed tolerance or withdrawal period or other use restrictions for the drug if any tolerance or withdrawal period or other use restrictions are required in order to ensure that the proposed use of the drug will be safe.

(3) PATENT INFORMATION.—The applicant shall file with the application the patent number and the expiration date of any patent—

(A) that—

(i) claims the new animal drug for which the applicant filed the application; or

(ii) claims a method of using the drug; and

(B) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

(4) AMENDMENT OF APPLICATION TO INCLUDE PATENT INFORMATION.—If an application is filed under this section for a drug and a patent that claims the drug or a method of using the drug is

issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by paragraph (3).

(5) PUBLICATION OF PATENT INFORMATION.—On approval of the application, the Secretary shall publish information submitted under paragraph (3) and (4), as applicable.

(b) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—

(1) FILING.—Any person may file with the Secretary an abbreviated application for the approval of a new animal drug.

(2) CONTENTS.—An abbreviated application shall contain the information required by section 13715 of this title.

(3) LIMITATION.—Notwithstanding this subsection, the Secretary may not approve an abbreviated application submitted under this subsection for a new animal drug that is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques.

(c) AGREEMENT WITH SECRETARY RELATING TO SUBMISSION AND INVESTIGATIONAL REQUIREMENTS.—

(1) CONFERENCES.—Any person intending to file an application under subsection (a) or section 14502 of this title or a request for an investigational exemption under section 13711 of this title shall be entitled to 1 or more conferences prior to the submission to reach an agreement acceptable to the Secretary establishing a submission or an investigational requirement, which may include a requirement for a field investigation.

(2) DECISION AS BINDING.—A decision establishing a submission or an investigational requirement shall bind the Secretary and the applicant or requestor unless—

(A) the Secretary and the applicant or requestor mutually agree to modify the requirement; or

(B) the Secretary, by written order, determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference.

(3) SCIENTIFIC JUSTIFICATION FOR REQUIRING MORE THAN 1 FIELD INVESTIGATION.—Not later than 25 calendar days after each conference described in paragraph (1), the Secretary shall provide

a written order setting forth a scientific justification specific to the animal drug and intended uses under consideration if the agreement referred to in paragraph (1) requires more than 1 field investigation as being essential to provide substantial evidence of effectiveness for the intended uses of the drug.

(4) EFFECT OF SUBSECTION.—Nothing in this subsection shall be construed as compelling the Secretary to require a field investigation.

(d) ELECTRONIC SUBMISSION.—All applications or submissions pursuant to this section shall be submitted by electronic means in such format as the Secretary may require.

**§ 13704. Approval of applications**

(a) NEW ANIMAL DRUG APPLICATIONS.—

(1) IN GENERAL.—Within 180 days after the filing of an application pursuant to section 13703(a) of this title, or such additional period as may be agreed on by the Secretary and the applicant, the Secretary shall—

(A) issue an order approving the application if the Secretary finds that none of the grounds for denying approval specified in section 13705 of this title applies; or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under section 13705 of this title on the question of whether the application is approvable.

(2) HEARINGS.—

(A) COMMENCEMENT.—If the applicant elects to accept the opportunity for a hearing by written request within 30 days after the notice under paragraph (1)(B), the hearing shall commence not more than 90 days after the expiration of the 30 days unless the Secretary and the applicant otherwise agree.

(B) HEARING ON EXPEDITED BASIS; ISSUANCE OF ORDER.—The hearing shall be conducted on an expedited basis and the Secretary's order on the hearing shall be issued within 90 days after the date fixed by the Secretary for filing final briefs.

(b) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—

(1) DEFINITION OF BIOEQUIVALENCE.—

(A) IN GENERAL.—In this subsection, the term ''bioequivalence'' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a new animal

drug and becomes available at the site of drug action.

(B) CONDITIONS OF BIOEQUIVALENCE.—A new animal drug shall be considered to be bioequivalent to the approved new animal drug referred to in its application under section 13715 of this title if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses;

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the approved new animal drug referred to in the application when administered at the same dose of the active ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the approved new animal drug in the rate of absorption of the drug—

(I) is intentional;

(II) is reflected in its proposed labeling;

(III) is not essential to the attainment of effective drug concentrations in use; and

(IV) is considered scientifically insignificant for the drug in attaining the intended purposes of its use and preserving human food safety; or

(iii) in any case in which the Secretary determines that the measurement of the rate and extent of absorption or excretion of the new animal drug in biological fluids is inappropriate or impractical, an appropriate acute pharmacological effects test or other test of the new animal drug and, when considered scientifically necessary, of the approved new animal drug referred to in the application in the species to be tested or in an appropriate animal model does not show a significant difference between the new animal drug and the approved new animal drug when ad-

ministered at the same dose under similar experimental conditions.

(C) BIOEQUIVALENCY INFORMATION; STUDIES.—

(i) BIOEQUIVALENCY INFORMATION REQUIRED FOR 1 SPECIES UNLESS OTHERWISE CONSIDERED APPROPRIATE BY SECRETARY.—If the approved new animal drug referred to in the application for a new animal drug under section 13715 of this title is approved for use in more than 1 animal species, the bioequivalency information described in clauses (i), (ii), and (iii) of subparagraph (B) shall be obtained for 1 species, or if the Secretary considers appropriate based on scientific principles, shall be obtained for more than 1 species.

(ii) DOSAGE IN DETERMINING BIOEQUIVALENCY.—The Secretary may prescribe the dose to be used in determining bioequivalency under clauses (i), (ii), and (iii) of subparagraph (B).

(iii) ENSURING CONSISTENCY WITH ESTABLISHED TOLERANCES.—To ensure that the residues of the new animal drug

will be consistent with the established tolerances for the approved new animal drug referred to in the application under section 13703(b) of this title on the expiration of the withdrawal period contained in the application for the new animal drug, the Secretary shall require bioequivalency data or residue depletion studies of the new animal drug or such other data or studies as the Secretary considers appropriate based on scientific principles.

(iv) ASSAY METHODOLOGY NOT MORE RIGOROUS.—If the Secretary requires 1 or more residue studies under clause (iii), the Secretary may not require that the assay methodology used to determine the withdrawal period of the new animal drug be more rigorous than the methodology used to determine the withdrawal period for the approved new animal drug referred to in the application.

(v) STUDIES TO BE CONDUCTED FOR 1 SPECIES UNLESS OTHERWISE CONSIDERED APPROPRIATE BY SECRETARY.—If the studies are required and if the ap-

proved new animal drug, referred to in the application for the new animal drug for which the studies are required, is approved for use in more than 1 animal species, the studies shall be conducted for 1 species, or if the Secretary considers appropriate based on scientific principles, shall be conducted for more than 1 species.

(2) APPROVAL.—Subject to paragraph (4), the Secretary shall approve an abbreviated application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity;

(B) the conditions of use prescribed, recommended, or suggested in the proposed labeling are not reasonably certain to be followed in practice or, except as provided in paragraph (3), information submitted with the application is insufficient to show that each of the proposed conditions of use or similar limitations (whether in the labeling or published pursuant to section 13710 of this title) have been previously ap-

proved for the approved new animal drug referred to in the application;

(C) information submitted with the application is insufficient to show that the active ingredients are the same as those of the approved new animal drug referred to in the application;

(D)(i) if the application is for a drug the active ingredients, route of administration, dosage form, strength, or use of which with other animal drugs in animal feed is the same as the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed of the approved new animal drug referred to in the application, information submitted in the application is insufficient to show that the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed is the same as that of the approved new animal drug; or

(ii) if the application is for a drug the active ingredients, route of administration, dosage form, strength, or use of which with other animal drugs in animal feed is different from that of the approved new animal drug referred to in

the application, no petition to file an application for the drug with the different active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed was approved under section 13715(d) of this title;

(E) if the application was filed pursuant to the approval of a petition under section 13715(d) of this title, the application did not contain the information required by the Secretary respecting the active ingredients, route of administration, dosage form, strength, or use with other animal drugs in animal feed that is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the approved new animal drug referred to in the application, or if the application is filed under a petition approved pursuant to section 13715(d) of this title, information submitted in the application is insufficient to show that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug

and that the new animal drug can be expected to have the same therapeutic effect as the approved new animal drug when used in accordance with the labeling;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the approved new animal drug referred to in the application except for changes required—

(i) because of differences approved under a petition filed under section 13715(d) of this title;

(ii) because of a different withdrawal period; or

(iii) because the drug and the approved new animal drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that—

(i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug;

(ii) the composition of the drug is unsafe under the conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included; or

(iii) in the case of a drug for food producing animals, the inactive ingredients of the drug or its composition may be unsafe with respect to human food safety;

(I)(i) the approval under section 13703(a) of this title of the approved new animal drug referred to in the application filed under section 13703(b) of this title has been withdrawn or suspended for grounds described in subsection (a) or (b) of section 13706 of this title;

(ii) the Secretary has published a notice of a hearing to withdraw approval of the approved new animal drug for those grounds;

(iii) the approval under this subsection of the new animal drug for which the application under section 13703(b) of this title was filed has been withdrawn or suspended under paragraph (8) for those grounds; or

(iv) the Secretary has determined that the approved new animal drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of section 13715 of this title; or

(K) the application contains an untrue statement of material fact.

(3) DIFFERENT WITHDRAWAL PERIODS FOR BIOEQUIVALENT NEW ANIMAL DRUGS.—If the Secretary finds that a new animal drug for which an application is submitted under section 13703(b) of this title is bioequivalent to the approved new animal drug referred to in the application and that residues of the new animal drug are consistent with the tolerances established for the approved new animal drug but at a withdrawal period that is different than the withdrawal period approved for the approved new animal drug, the Secretary may establish, on the basis of information submitted, that different withdrawal period as the withdrawal period for the new animal drug for purposes of the approval of the application for the drug.

(4) APPROVAL; TIMING.—Within 180 days of the initial receipt of an application under section

13703(b) of this title or within such additional period as may be agreed on by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(5) EFFECTIVE DATE OF APPROVAL.—The approval of an application filed under section 13703(b) of this title shall be made effective on the last applicable date determined under the following:

(A) CERTIFICATION UNDER CLAUSE (i) OR (ii) OF SECTION 13715(b)(1)(H) OF THIS TITLE.—If the applicant made only a certification described in clause (i) or (ii) of section 13715(b)(1)(H) of this title or in both of the clauses, the approval may be made effective immediately.

(B) CERTIFICATION UNDER CLAUSE (iii) OF SECTION 13715(b)(1)(H) OF THIS TITLE.—If the applicant made a certification described in clause (iii) of section 13715(b)(1)(H) of this title, the approval may be made effective on the date certified under that clause.

(C) CERTIFICATION UNDER CLAUSE (iv) OF SECTION 13715 (b)(1)(H) OF THIS TITLE.—

(i) IN GENERAL.—If the applicant made a certification described in clause

(iv) of section 13715(b)(1)(H) of this title, the approval shall be made effective immediately unless an action is brought for infringement of a patent that is the subject of the certification before the expiration of 45 days from the date the notice provided under section 13715(c)(1)(A) of this title is received.

(ii) PATENT INFRINGEMENT ACTION BROUGHT.—If an action for patent infringement is brought as described in clause (i) before the expiration of the 45 days, the approval shall be made effective on the expiration of the 30-month period beginning on the date of the receipt of the notice provided under section 13715(c)(1) of this title or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that if before the expiration of that period—

(I) the court decides that the patent is invalid or not infringed, the

approval shall be made effective on the date of the court decision;

(II) the court decides that the patent has been infringed, the approval shall be made effective on the date that the court orders under section 271(e)(4)(A) of title 35; or

(III) the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that the patent is invalid or not infringed, the approval shall be made effective on the date of the court decision.

(iii) COOPERATION OF PARTIES TO EXPEDITE ACTION.—In an action for patent infringement described in clause (i), each of the parties shall reasonably cooperate in expediting the action.

(iv) ACTION FOR DECLARATORY JUDGMENT WITH RESPECT TO PATENT.—

(I) IN GENERAL.—Until the expiration of 45 days from the date the notice made under section 13715(c)(2) of this title is received, an action shall not be brought under section 2201 of title 28 for a declaratory judgment with respect to the patent.

(II) JURISDICTION.—Any action brought under section 2201 of title 28 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(D) CERTIFICATION UNDER CLAUSE (iv) OF SECTION 13715(b)(1)(H) OF THIS TITLE; PREVIOUS APPLICATION FILED WITH SUCH A CERTIFICATION.—If the application contains a certification described in clause (iv) of section 13715(b)(1)(H) of this title and is for a drug for which a previous application has been filed under this section containing such a certification, the application shall be made effective not earlier than 180 days after the date that is the earlier of—

(i) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application; or

(ii) the date of a decision of a court in an action described in subparagraph (C)(ii)(III) holding the patent that is the subject of the certification to be invalid or not infringed.

(6) DISAPPROVAL OF APPLICATION; HEARING.—

(A) OPPORTUNITY FOR A HEARING.—If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether the application is approvable.

(B) COMMENCEMENT OF HEARING.—If the applicant elects to accept the opportunity for hearing by written request within 30 days after the notice, the hearing shall commence not more than 90 days after the expiration of the 30 days unless the Secretary and the applicant otherwise agree.

(C) HEARING ON EXPEDITED BASIS; ISSUANCE OF ORDER.—The hearing shall be conducted on an expedited basis and the Secretary's order on the hearing shall be issued within 90 days after the date fixed by the Secretary for filing final briefs.

(7) LIMITATIONS ON CERTAIN SUBMISSIONS AND APPROVALS.—

(A) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED APPLICATION.—

(i) IN GENERAL.—If an application submitted under section 13703(a) of this title for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 13703(a) of this title, is approved (referred to in this subparagraph as ''approved application'') after November 16, 1988, no application may be submitted under section 13703(b) of this title (referred to in this subparagraph as ''abbreviated application'') that refers to the drug

for which the approved application was submitted before the expiration of 5 years from the date of the approval of the approved application, except that an abbreviated application may be submitted under section 13703(b) of this title after the expiration of 4 years from the date of the approval of the approved application if it contains a certification of patent invalidity or noninfringement described in section 13715(b)(1)(H)(iv) of this title.

(ii) EFFECTIVE DATE OF APPROVAL; EXCEPTION RELATING TO PATENT INFRINGEMENT ACTION.—The approval of an abbreviated application under clause (i) shall be made effective in accordance with paragraph (5) except that, if an action for patent infringement is commenced during the 1-year period beginning 48 months after the date of the approval of the approved application, the 30-month period referred to in paragraph (5)(C) shall be extended by the amount of time (if any) that is required for 7½ years to have elapsed

from the date of approval of the approved application.

(B) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED APPLICATION; ACTIVE MOIETY PREVIOUSLY APPROVED.—If an application submitted under section 13703(a) of this title for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under section 13703(a) of this title, is approved (referred to in this subparagraph as ''approved application'') after November 16, 1988, and if the approved application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species) required for the approval of the approved application and conducted or sponsored by the applicant, the Secretary may not make the approval of an

application submitted under section 13703(b) of this title for the conditions of approval of the drug in the approved application effective before the expiration of 3 years from the date of the approval of the approved application for the drug.

(C) LIMITATION FOR APPLICATIONS FOR A DRUG FOR WHICH THERE IS A PREVIOUSLY APPROVED SUPPLEMENT.—If a supplement to an application approved under section 13703(a) of this title is approved after November 16, 1988, and the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species) required for the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under section 13703(b) of this title for a change approved in the supplement effective be-

fore the expiration of 3 years from the date of the approval of the supplement.

(D) WAIVER OF SUBPARAGRAPH (A).—An applicant under section 13703(a) of this title that comes within the provisions of subparagraph (A) as a result of an application that seeks approval for a use solely in non-food-producing animals, may elect, within 10 days of receiving the approval, to waive subparagraph (A), in which event the limitation on approval of applications submitted under section 13703(b) of this title set forth in subparagraph (B) shall be applicable to the application under section 13703(a) of this title.

(E) LIMITATION FOR ABBREVIATED APPLICATIONS FOR NEW CONDITIONS OF APPROVAL OF A DRUG THAT INCLUDES AN ACTIVE MOIETY THAT HAS BEEN THE SUBJECT OF A WAIVER UNDER SUBPARAGRAPH (D).—If an application (including any supplement to a new animal drug application) submitted under section 13703(a) of this title for a new animal drug for a food-producing-animal use, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regu-

lations (or any successor regulations)) that has been the subject of a waiver under subparagraph (D), is approved after November 16, 1988, and if the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or human food safety studies (other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species) required for the new approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application (including any supplement to such application) submitted under section 13703(b) of this title for the new conditions of approval of the drug in the section 13703(a) application effective before the expiration of 5 years from the date of approval of the application under section 13703(a) of this title for the drug. The provisions of this subsection shall apply only to the first approval for a food-producing-animal use for the same applicant after the waiver under subparagraph (D).

(8) WITHDRAWN OR SUSPENDED APPROVAL OF DRUGS REFERRED TO IN APPROVED ABBREVIATED

NEW ANIMAL DRUG APPLICATION.—If an approved application submitted under section 13703(b) of this title for a new animal drug refers to a drug the approval of which was withdrawn or suspended for grounds described in subsection (a), (b), or (c) of section 13706 of this title or was withdrawn or suspended under this paragraph or that, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under section 13706 of this title or this paragraph; or

(B) if the approved new animal drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(c) SUBMISSION OF PATENT INFORMATION AFTER APPROVAL OF APPLICATION.—

(1) IN GENERAL.—If the patent information described in section 13703(a) of this title could not be filed with the submission of an application under

section 13703(a) of this title because a patent was issued after the application was approved under that section, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent—

(A) that claims—

(i) the new animal drug for which the application was filed; or

(ii) a method of using the drug; and

(B) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

(2) DEADLINE FOR FILING.—If the holder of an approved application could not file patent information under section 13703(a) of this title because no patent had been issued when an application was filed or approved, the holder shall file the information under this section not later than 30 days after the date the patent involved is issued.

(3) PUBLICATION.—On the submission of patent information under this section, the Secretary shall publish it.

(d) DRUGS MANUFACTURED IN PILOT OR OTHER SMALL FACILITY.—A drug manufactured in a pilot or

other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

**§ 13705. Grounds for refusing application**

(a) ORDER REFUSING TO APPROVE APPLICATION.—

(1) IN GENERAL.—The Secretary shall issue an order refusing to approve an application under section 13703(a) of this title if the Secretary finds, after due notice to the applicant in accordance with section 13704 of this title and giving the applicant an opportunity for a hearing, in accordance with section 13704 of this title, that—

(A) the investigations, reports of which are required to be submitted to the Secretary pursuant to section 13703(a) of this title, do not include adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling of the drug;

(B) the results of the tests show that the drug is unsafe for use under the conditions or

do not show that the drug is safe for use under the conditions;

(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to preserve its identity, strength, quality, and purity;

(D) on the basis of the information submitted to the Secretary as part of the application, or on the basis of any other information before the Secretary with respect to the drug, the Secretary has insufficient information to determine whether the drug is safe for use under the conditions;

(E) evaluated on the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to the drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling of the drug;

(F) on the basis of information submitted to the Secretary as part of the application or

any other information before the Secretary with respect to the drug, any use prescribed, recommended, or suggested in labeling proposed for the drug will result in a residue of the drug in excess of a tolerance found by the Secretary to be safe for the drug;

(G) the application failed to contain the patent information prescribed by section 13703(a) of this title;

(H) based on a fair evaluation of all material facts, the labeling is false or misleading in any particular; or

(I) the drug induces cancer when ingested by humans or animals or, after tests that are appropriate for the evaluation of the safety of the drug, induces cancer in humans or animals, except that this subparagraph shall not apply with respect to the drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice—

(i) the drug will not adversely affect the animals for which it is intended; and

(ii) no residue of the drug will be found (by methods of examination pre-

scribed or approved by the Secretary by regulations, which regulations shall not be subject to this section and sections 13704 and 13709 of this title) in any edible portion of the animals after slaughter or in any food yielded by or derived from the living animals.

(2) ISSUANCE OF ORDER APPROVING APPLICATION.—If, after the notice and opportunity for hearings under paragraph (1), the Secretary finds that subparagraphs (A) through (I) of paragraph (1) do not apply, the Secretary shall issue an order approving the application.

(b) FACTORS FOR DETERMINING SAFETY.—In determining whether the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling of the drug, the Secretary shall consider, among other relevant factors—

(1) the probable consumption of the drug and of any substance formed in or on food because of the use of the drug;

(2) the cumulative effect on humans or animals of the drug, taking into account any chemically or pharmacologically related substance;

(3) safety factors that in the opinion of experts, qualified by scientific training and experience to evaluate the safety of the drugs, are appropriate for the use of animal experimentation data; and

(4) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice.

(c) FINDINGS TO BE STATED IN ORDER REFUSING TO APPROVE APPLICATION.—Any order issued under this section refusing to approve an application shall state the findings on which it is based.

(d) DRUGS CONTAINING 1 OR MORE ACTIVE INGREDIENTS; DRUGS USED IN COMBINATION WITH OTHER DRUGS.—In a case in which an animal drug contains more than 1 active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with 1 or more other animal drugs, and the active ingredients or drugs intended for use in the combination have previously been separately approved pursuant to an application submitted under section 13703(a) of this title for particular uses and conditions of use for which they are intended for use in the combination—

(1) the Secretary shall not issue an order under subparagraph (A), (B), or (D) of subsection (a)(1) refusing to approve the application for the combina-

tion on human food safety grounds unless the Secretary finds that the application fails to establish that—

(A) none of the active ingredients or drugs intended for use in the combination, respectively, at the longest withdrawal time of any of the active ingredients or drugs in the combination, respectively, exceeds its established tolerance; or

(B) none of the active ingredients or drugs in the combination interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively;

(2) the Secretary shall not issue an order under subparagraph (A), (B), or (D) of subsection (a)(1) refusing to approve the application for the combination on target animal safety grounds unless the Secretary finds that—

(A) there is—

(i) a substantiated scientific issue, specific to 1 or more of the active ingredients or animal drugs in the combination, that cannot adequately be evaluated based on information contained in the application for the combination (including any inves-

tigations, studies, or tests for which the applicant has a right of reference or use from the person by or for whom the investigations, studies, or tests were conducted); or

(ii) a scientific issue raised by target animal observations contained in studies submitted to the Secretary as part of the application; and

(B) based on the Secretary's evaluation of the information contained in the application with respect to the issues identified in clauses (i) and (ii) of subparagraph (A), subparagraph (A), (B), or (D) of subsection (a)(1) applies;

(3) except in the case of a combination that contains a nontopical antibacterial ingredient or animal drug, the Secretary shall not issue an order under subsection (a)(1)(E) refusing to approve an application for a combination animal drug intended for use other than in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

(A) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or

animal drug in the combination makes a contribution to labeled effectiveness;

(B) each active ingredient or animal drug intended for at least 1 use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population; or

(C) where, based on scientific information, the Secretary has reason to believe the active ingredients or animal drugs may be physically incompatible or have disparate dosing regimens, the active ingredients or animal drugs are physically compatible or do not have disparate dosing regimens; and

(4) the Secretary shall not issue an order under subsection (a)(1)(E) refusing to approve an application for a combination animal drug intended for use in animal feed or drinking water unless the Secretary finds that the application fails to demonstrate that—

(A) there is substantial evidence that any active ingredient or animal drug intended only for the same use as another active ingredient or

animal drug in the combination makes a contribution to the labeled effectiveness;

(B) each of the active ingredients or animal drugs intended for at least 1 use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population;

(C) where a combination contains more than 1 nontopical antibacterial ingredient or animal drug, there is substantial evidence that each of the nontopical antibacterial ingredients or animal drugs makes a contribution to the labeled effectiveness, except that for purposes of this subparagraph, the term ''antibacterial ingredient'' or ''animal drug'' does not include the ionophore or arsenical classes of animal drugs; or

(D) where, based on scientific information, the Secretary has reason to believe the active ingredients or animal drugs intended for use in drinking water may be physically incompatible, the active ingredients or animal drugs intended for use in drinking water are physically compatible.

(e) ADDITION OF INTENDED USE FOR MINOR USE OR MINOR SPECIES.—

(1) REEVALUATION OF RELEVANT INFORMATION ONLY IN APPROVED APPLICATION.—In reviewing an application that proposes a change to add an intended use for a minor use or a minor species to an approved new animal drug application, the Secretary shall reevaluate only the relevant information in the approved application to determine whether the application for the minor use or minor species can be approved.

(2) EFFECT OF APPROVAL.—A decision to approve the application for the minor use or minor species is not, implicitly or explicitly, a reaffirmation of the approval of the original application.

**§ 13706. Withdrawal and suspension of approval**

(a) REQUIRED WITHDRAWAL OF APPROVAL OF APPLICATION.—The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to section 13703(a) of this title with respect to any new animal drug if the Secretary finds—

(1) that experience or scientific data show that the drug is unsafe for use under the conditions of use on the basis of which the application was ap-

proved or the condition of use authorized under section 13702(d)(1) of this title;

(2) that new evidence not contained in the application or not available to the Secretary until after the application was approved, or tests by new methods, or tests by methods not considered reasonably applicable when the application was approved, evaluated together with the evidence available to the Secretary when the application was approved, show—

(A) that the drug is not shown to be safe for use under the conditions of use on the basis of which the application was approved; or

(B) that section 13705(a)(1)(I) of this title applies to the drug;

(3) on the basis of new information before the Secretary with respect to the drug, evaluated together with the evidence available to the Secretary when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the drug;

(4) that the patent information prescribed by section 13704(c) of this title was not filed within 30

days after the receipt of written notice from the Secretary specifying the failure to file the information;

(5) that the application contains any untrue statement of a material fact; or

(6) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless the applicant has supplemented the application by filing with the Secretary adequate information respecting all the changes and unless there is in effect an approval of the supplemental application, which approved supplemental application shall be treated in the same manner as the original application.

(b) SUSPENSION OF APPROVAL ON FINDING OF IMMINENT HAZARD TO HEALTH.—

(1) IN GENERAL.—If the Secretary (or in the Secretary's absence, the officer acting as Secretary) finds that there is an imminent hazard to the health of humans or of the animals for which the drug is intended, the Secretary may suspend the approval of the application immediately, and give the applicant prompt notice of the Secretary's action and afford the applicant the opportunity for an expedited hearing under this section.

(2) NONDELEGATION.—The authority conferred by paragraph (1) to suspend the approval of an application shall not be delegated.

(c) AUTHORIZED WITHDRAWAL OF APPROVAL OF APPLICATION.—The Secretary may, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this chapter if the Secretary finds—

(1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain the records or to make required reports in accordance with a regulation or order under section 13713 of this title, or the applicant has refused to permit access to, or copying or verification of, the records as required by section 13713(b) of this title;

(2) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to ensure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable

time after receipt of written notice from the Secretary specifying the matter complained of; or

(3) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(d) ORDER TO STATE FINDINGS.—Any order under this section shall state the findings on which it is based.

**§ 13707. Revocation of order refusing, withdrawing, or suspending approval of application**

If the Secretary finds that the facts so require, the Secretary shall revoke any previous order under section 13705, 13706, or 13714 of this title, or subsection (d), (e), or (f) of section 14502 of this title, refusing, withdrawing, or suspending approval of an application and shall approve the application or reinstate the approval, as may be appropriate.

**§ 13708. Service of orders**

Orders of the Secretary issued under this chapter, or section 14502 of this title (other than orders issuing, amending, or repealing regulations), shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at the applicant's or respondent's last known address in the records of the Secretary.

**§ 13709. Appeals from orders**

(a) IN GENERAL.—An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application filed under section 13703 or 13714 of this title.

(b) PROVISIONS TO GOVERN APPEALS.—The provisions of section 13509 of this title shall govern the appeal.

**§ 13710. Publication of approval in Federal Register**

(a) APPROVAL OF NEW ANIMAL DRUG APPLICATION.—When a new animal drug application filed pursuant to section 13703 or 14502 of this title is approved, the Secretary shall by notice, which on publication shall be effective as a regulation, publish in the Federal Register—

(1) the name and address of the applicant;

(2) the conditions and indications of use of the new animal drug covered by the application, including—

(A) any tolerance and withdrawal period or other use restrictions; and

(B) if the new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements and any requirement that an animal feed bearing or containing the new animal drug be limited to use under the professional supervision of a licensed veterinarian) applicable to any animal feed for use in which the drug is approved; and

(3) such other information, on the basis of which the application was approved, as the Secretary considers necessary to ensure the safe and effective use of the drug.

(b) WITHDRAWAL OF APPROVAL OF NEW ANIMAL DRUG APPLICATION.—On withdrawal of approval of the new animal drug application or on its suspension or on failure to renew a conditional approval under section 14502 of this title, the Secretary shall immediately revoke or suspend, as the case may be, the regulation published pursuant to this section to the extent that it is based on the approval of the application.

**§ 13711. Exemption for drugs for investigational use**

(a) IN GENERAL.—To the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of this chapter new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs.

(b) AUTHORIZED CONTENT.—The regulations promulgated under subsection (a) may, in the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning the exemption on the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of the article, of data (including analytical reports by investigators) obtained as a result of the investigational use of the article, as the Secretary finds will enable the Secretary to evaluate the safety and effectiveness of the article in the event of the filing of an application pursuant to this chapter.

(c) REQUIRED CONTENT.—The regulations promulgated under subsection (a), among other things, shall set forth the conditions (if any) on which animals treated with the articles, and any products of the animals (before or after slaughter), may be marketed for food use.

**§ 13712. Food containing approved new animal drug considered unadulterated**

While approval of an application for a new animal drug is effective, a food shall not, by reason of bearing or containing the drug or any substance formed in or on the food because of its use in accordance with the application (including the conditions and indications of use prescribed pursuant to section 13710 of this title), be considered adulterated within the meaning of section 11102(a)(1) of this title.

**§ 13713. Records and reports**

(a) REQUIREMENT TO MAINTAIN RECORDS AND MAKE REPORTS BY REGULATION.—

(1) IN GENERAL.—In the case of any new animal drug for which an approval of an application filed pursuant to section 13703 or 14502 of this title is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under section 13702(d)(1) of this title, and other data or information, received or otherwise obtained by the applicant with respect to the drug, or with respect to animal feeds bearing or containing the drug, as the Secretary may by general regulation, or by order with respect to the application, prescribe on the basis of

a finding that the records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking section 13706 or 13714(d) of this title.

(2) EXAMINATION BY PERSONS.—The regulation or order shall provide, where the Secretary considers it to be appropriate, for the examination, upon request, by the persons to whom the regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(b) ACCESS TO RECORDS BY OFFICERS AND EMPLOYEES DESIGNATED BY SECRETARY.—Each person required under this section to maintain records, and each person in charge or custody of the records, shall, on request of an officer or employee designated by the Secretary, permit the officer or employee at all reasonable times to have access to and copy and verify the records.

(c) REPORTING REQUIREMENTS RELATING TO ANTIMICROBIAL ACTIVE INGREDIENTS.—

(1) IN GENERAL.—In the case of each new animal drug described in subsection (a) that contains an antimicrobial active ingredient, the sponsor of the drug shall submit an annual report to the Secretary on the amount of each antimicrobial active ingre-

dient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product.

(2) CONTENTS OF REPORT.—

(A) RELATING TO AMOUNT OF EACH ANTIMICROBIAL ACTIVE INGREDIENT.—Each report under this subsection shall specify the amount of each antimicrobial active ingredient—

(i) by container size, strength, and dosage form;

(ii) by quantities distributed domestically and quantities exported; and

(iii) by dosage form, including, for each dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.

(B) RELATING TO SUBMISSION AND FORMAT.—Each report under this subsection shall—

(i) be submitted not later than March 31 each year;

(ii) cover the period of the preceding calendar year; and

(iii) include separate information for each month of the preceding calendar year.

(3) SHARING OF INFORMATION WITH ANTIMICROBIAL RESISTANCE TASK FORCE.—The Secretary may share information reported under this subsection with the Antimicrobial Resistance Task Force established under section 319E of the Public Health Service Act (42 U.S.C. 247d–5).

(4) SUMMARIES.—The Secretary shall make summaries of the information reported under this subsection publicly available, except that—

(A) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

(B) the data shall be reported in a manner consistent with protecting both national security and confidential business information.

**§ 13714. Feed mill licenses**

(a) APPLICATION.—

(1) FILING.—Any person may file with the Secretary an application for a license to manufacture animal feeds bearing or containing new animal drugs.

(2) CONTENTS.—A person filing under paragraph (1) shall submit to the Secretary as part of the application—

(A) a full statement of the business name and address of the specific facility at which the manufacturing is to take place and the facility's registration number;

(B) the name and signature of the responsible individual or individuals for that facility;

(C) a certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled—

(i) in accordance with the applicable regulations published pursuant to section 13710 of this title; or

(ii) for indexed new animal drugs, in accordance with—

(I) the index listing published pursuant to section 14503(e)(2) of this title; and

(II) the labeling requirements set forth in section 14503(h) of this title; and

(D) a certification that the methods used in, and the facilities and controls used for,

manufacturing, processing, packaging, and holding the animal feeds are in conformity with current good manufacturing practice as described in section 13101(a)(2)(B)(ii) of this title.

(b) APPROVAL; HEARING.—

(1) IN GENERAL.—Within 90 days after the filing of an application pursuant to subsection (a), or such additional period as may be agreed on by the Secretary and the applicant, the Secretary shall—

(A) issue an order approving the application if the Secretary then finds that none of the grounds for denying approval specified in subsection (c) applies; or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (c) on the question whether the application is approvable.

(2) HEARING PROCEDURE.—The procedure governing such a hearing shall be the procedure set forth in section 13704(a)(2) of this title.

(c) REFUSAL TO APPROVE APPLICATION.—

(1) GROUNDS.—The Secretary shall issue an order refusing to approve an application under subsection (a) if the Secretary, after due notice to the

applicant in accordance with subsection (b) and giving the applicant an opportunity for a hearing in accordance with subsection (b), finds, on the basis of information submitted to the Secretary as part of the application, on the basis of a preapproval inspection, or on the basis of any other information before the Secretary—

(A) that the application is incomplete, false, or misleading in any particular;

(B) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug in the animal feed; or

(C) that the facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published pursuant to section 13710 of this title or an index listing pursuant to section 14503(e) of this title.

(2) APPROVAL ON INAPPLICABILITY OF GROUNDS.—If, after the notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (C) of paragraph (1) do not apply, the Secretary shall issue an order approving the application.

(3) LIMITATION ON APPROVALS.—An order under this section approving an application for a license to manufacture animal feeds bearing or containing new animal drugs shall permit a facility to manufacture only those animal feeds bearing or containing new animal drugs for which—

(A) there are in effect regulations pursuant to section 13710 of this title relating to the use of the drugs in or on the animal feed; or

(B) there is an index listing pursuant to section 14503(e) of this title relating to the use of the drugs in or on the animal feed.

(d) REVOCATION OF LICENSE.—

(1) REQUIRED REVOCATION.—The Secretary shall, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feeds bearing or containing new animal drugs under this section if the Secretary finds—

(A) that the application for the license contains any untrue statement of a material fact; or

(B) that the applicant has made changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing with the Secretary adequate information respecting all the changes and unless there is in effect an approval of the supplemental application.

(2) SUSPENSION OF APPROVAL ON FINDING OF IMMINENT HAZARD TO HEALTH.—

(A) IN GENERAL.—If the Secretary (or in the Secretary's absence, the officer acting as the Secretary) finds that there is an imminent hazard to the health of humans or of the animals for which the animal feed is intended, the Secretary may suspend the license immediately, and give the applicant prompt notice of the action and afford the applicant the opportunity for an expedited hearing under this section.

(B) NONDELEGATION.—The authority conferred by subparagraph (A) shall not be delegated.

(3) AUTHORIZED REVOCATION.—The Secretary may, after due notice and opportunity for hearing to the applicant, revoke a license to manufacture animal feed under this section if the Secretary finds—

(A) that the applicant—

(i) has failed to establish a system for maintaining required records;

(ii) has repeatedly or deliberately failed to maintain the records or to make required reports in accordance with a regulation or order under subsection (e)(1) or section 13110(a)(3)(A) of this title; or

(iii) has refused to permit access to, or copying or verification of, the records as required by subsection (e)(2) or section 13110(a)(3)(B) of this title;

(B) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of the

animal feed are inadequate to ensure and preserve the identity, strength, quality, and purity of the new animal drug in the animal feed, and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of;

(C) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(D) that on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the license was issued, the facility has manufactured, processed, packed, or held animal feed bearing or containing a new animal drug adulterated under section 13101(a)(2)(F) of this title and the facility did not discontinue the manufacture, processing, packing, or holding of the animal feed within a reasonable time after receipt

of written notice from the Secretary specifying the matter complained of.

(4) INTENTION TO DISCONTINUE MANUFACTURE.—The Secretary may revoke a license to manufacture animal feeds under this section if an applicant gives notice to the Secretary of intention to discontinue the manufacture of all animal feed covered under this section and waives an opportunity for a hearing on the matter.

(5) ORDER TO STATE FINDINGS.—Any order under this subsection shall state the findings on which it is based.

(e) ISSUANCE OF LICENSE AND MAINTENANCE OF RECORDS.—When a license to manufacture animal feeds bearing or containing new animal drugs has been issued—

(1) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under section 13703 of this title, as the Secretary may by general regulation, or by order with respect to the application, prescribe on the basis of a finding that the records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is

or may be ground for invoking section 13706 of this title or subsection (d); and

(2) each person required under this section to maintain records, and each person in charge or custody of the records, shall, on request of an officer or employee designated by the Secretary, permit the officer or employee at all reasonable times to have access to and copy and verify the records.

(f) EXEMPTION BY REGULATION.—To the extent consistent with the public health, the Secretary may promulgate regulations for exempting from the operation of this section facilities that manufacture, process, pack, or hold animal feeds bearing or containing new animal drugs.

**§ 13715. Abbreviated applications for new animal drugs**

(a) DEFINITION OF APPROVED NEW ANIMAL DRUG.—In this section, the term ''approved new animal drug'' means a new animal drug listed under subsection (e).

(b) APPLICATION.—

(1) CONTENTS.—An abbreviated application for a new animal drug shall contain—

(A)(i) except as provided in clause (ii), information to show that the conditions of use or similar limitations (whether in the labeling or

published pursuant to section 13710 of this title) prescribed, recommended, or suggested in the labeling proposed for the new animal drug have been previously approved for an approved new animal drug; and

(ii) information to show that the withdrawal period at which residues of the new animal drug will be consistent with the tolerances established for the approved new animal drug is the same as the withdrawal period previously established for the approved new animal drug or, if the withdrawal period is proposed to be different, information showing that the residues of the new animal drug at the proposed different withdrawal period will be consistent with the tolerances established for the approved new animal drug;

(B)(i) information to show that the active ingredients of the new animal drug are the same as those of the approved new animal drug; and

(ii) if the approved new animal drug has more than 1 active ingredient, and if 1 of the active ingredients of the new animal drug is different from 1 of the active ingredients of the

approved new animal drug and the application is filed pursuant to the approval of a petition filed under subsection (d)—

(I) information to show that the other active ingredients of the new animal drug are the same as the active ingredients of the approved new animal drug;

(II) information to show that the different active ingredient is an active ingredient of either another approved new animal drug or an animal drug that does not meet the requirements of section 10101(a)(33) of this title; and

(III) such other information respecting the different active ingredients as the Secretary may require;

(C)(i) if the approved new animal drug is permitted to be used with 1 or more animal drugs in animal feed, information to show that the proposed uses of the new animal drug with other animal drugs in animal feed are the same as the uses of the approved new animal drug; and

(ii) if the approved new animal drug is permitted to be used with 1 or more other animal drugs in animal feed, and 1 of the other animal

drugs proposed for use with the new animal drug in animal feed is different from 1 of the other animal drugs permitted to be used in animal feed with the approved new animal drug, and the application is filed pursuant to the approval of a petition filed under subsection (d)—

(I) information to show that the different animal drug proposed for use with the approved new animal drug in animal feed is an approved new animal drug permitted to be used in animal feed or does not meet the requirements of section 10101(a)(33) of this title when used with another animal drug in animal feed;

(II) information to show that other animal drugs proposed for use with the new animal drug in animal feed are the same as the other animal drugs permitted to be used with the approved new animal drug; and

(III) such other information respecting the different animal drug or combination with respect to which the petition was filed as the Secretary may require;

(D)(i) information to show that the route of administration, the dosage form, and the

strength of the new animal drug are the same as those of the approved new animal drug; or

(ii) if the route of administration, the dosage form, or the strength of the new animal drug is different and the application is filed pursuant to the approval of a petition filed under subsection (d), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(E) information to show that the new animal drug is bioequivalent to the approved new animal drug, except that if the application is filed pursuant to the approval of a petition filed under subsection (d) for the purposes described in subparagraph (B) or (C), information to show—

(i) that the active ingredients of the new animal drug are of the same pharmacological or therapeutic class as the pharmacological or therapeutic class of the approved new animal drug; and

(ii) that the new animal drug can be expected to have the same therapeutic ef-

fect as the approved new animal drug when used in accordance with the labeling;

(F) information to show that the labeling proposed for the new animal drug is the same as the labeling approved for the approved new animal drug except for changes required—

(i) because of differences approved under a petition filed under subsection (d);

(ii) because of a different withdrawal period; or

(iii) because the new animal drug and the approved new animal drug are produced or distributed by different manufacturers;

(G) the items specified in subparagraphs (B) through (F) of section 13703(a)(2) of this title;

(H) a certification, in the opinion of the applicant and to the best of the applicant's knowledge, with respect to each patent that claims the approved new animal drug or that claims a use for the approved new animal drug for which the applicant is seeking approval under this section and for which information is

required to be filed under section 13703(a) or 13704(c) of this title—

(i) that the patent information has not been filed;

(ii) that the patent has expired;

(iii) of the date on which the patent will expire; or

(iv) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new animal drug for which the application is filed; and

(I) if, with respect to the approved new animal drug, information was filed under section 13703(a) or 13704(c) of this title for a method of use patent that does not claim a use for which the applicant is seeking approval of an application under section 13704(b) of this title, a statement that the method of use patent does not claim such a use.

(2) NO OTHER REQUIRED INFORMATION.—The Secretary may not require that an abbreviated application contain information in addition to that required by subparagraphs (A) through (I) of paragraph (1).

(c) STATEMENT RELATING TO NOTICE OF INVALIDITY OR NON-INFRINGEMENT CERTIFICATION.—

(1) IN GENERAL.—An applicant that makes a certification described in subsection (b)(1)(H)(iv) shall include in the application a statement that the applicant will give the notice required by paragraph (2) to—

(A) each owner of the patent that is the subject of the certification or the representative of the owner designated to receive the notice; and

(B) the holder of the approved application under section 13704(a) of this title for the drug that is claimed by the patent or a use of which is claimed by the patent or the representative of the holder designated to receive the notice.

(2) NOTICE.—

(A) IN GENERAL.—The notice referred to in paragraph (1) shall state that an application, which contains data from bioequivalence studies, has been filed under this section for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug

before the expiration of the patent referred to in the certification.

(B) BASIS FOR INVALIDITY OR NON-INFRINGEMENT OPINION.—The notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(3) APPLICATIONS AMENDED TO INCLUDE INVALIDITY OR NON-INFRINGEMENT CERTIFICATION.—If an application is amended to include a certification described in subsection (b)(1)(H)(iv), the notice required by paragraph (2) shall be given when the amended application is filed.

(d) PETITION TO FILE CERTAIN ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—

(1) SUBMISSION.—A person shall submit a petition to the Secretary seeking permission to file an abbreviated new animal drug application if the person wants to submit the application for a new animal drug—

(A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug; or

(B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug.

(2) APPROVAL.—The Secretary shall approve a petition for a new animal drug unless the Secretary finds that—

(A) investigations must be conducted to show the safety and effectiveness, in animals to be treated with the drug, of—

(i) the active ingredients; or

(ii) the route of administration, dosage form, strength, or use with other animal drugs in animal feed that differ from the approved new animal drug; or

(B) investigations must be conducted to show the safety for human consumption of any residues in food resulting from—

(i) the proposed active ingredients;

(ii) the route of administration, dosage form, strength, or use with other animal drugs in animal feed for the new animal drug that is different from the active ingredients; or

(iii) the route of administration, dosage form, strength, or use with other ani-

mal drugs in animal feed of the approved new animal drug.

(3) DECISION TIMEFRAME.—The Secretary shall approve or disapprove a petition submitted under this subsection within 90 days of the date the petition is submitted.

(e) LIST OF NEW ANIMAL DRUGS APPROVED FOR SAFETY AND EFFECTIVENESS.—

(1) IN GENERAL.—

(A) PUBLICATION.—The Secretary shall publish and make available to the public a list in alphabetical order of the official and proprietary name of each new animal drug that was approved for safety and effectiveness before November 16, 1988.

(B) UPDATES.—Every 30 days, the Secretary shall revise the list to include each new animal drug that has been approved for safety and effectiveness under section 13704 of this title during the 30-day period.

(C) PATENT INFORMATION.—When patent information submitted under section 13703(a) or 13704(c) of this title respecting a new animal drug included on the list is to be published by the Secretary, the Secretary shall, in revi-

sions made under subparagraph (B), include the information for the drug.

(2) DATE OF PUBLICATION.—A new animal drug approved for safety and effectiveness before November 16, 1988, or approved for safety and effectiveness under section 13704 of this title shall, for purposes of this section, be considered to have been published under paragraph (1) on the date of its approval or November 16, 1988, whichever is later.

(3) NON-PUBLICATION IN LIST; REMOVAL FROM LIST.—

(A) IN GENERAL.—If the approval of a new animal drug was withdrawn or suspended under section 13704(b)(8) of this title or for grounds described in section 13706 of this title or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, the new animal drug may not be published in the list under paragraph (1) or, if the withdrawal or suspension occurred after its publication in the list, it shall be immediately removed from the list—

(i) for the same period as the withdrawal or suspension under section 13704(b)(8) or 13706 of this title; or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(B) NOTICE OF REMOVAL.—A notice of the removal shall be published in the Federal Register.

(f) APPLICATIONS DEEMED FILED AS ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—An application shall be deemed to be an application filed under section 13703(b) of this title if the application contains the information required by subparagraphs (A), (G), and (H) of section 13703(a)(2) of this title and the information—

(1) is relied on by the applicant for the approval of the application; and

(2) is not information derived either from investigations, studies, or tests conducted by or for the applicant or for which the applicant had obtained a right of reference or use from the person by or for

whom the investigations, studies, or tests were conducted.

**§ 13716. Safety and effectiveness data**

(a) AVAILABILITY TO THE PUBLIC.—Safety and effectiveness data and information that have been submitted in an application filed under section 13703(a) or 14502(b) of this title for a drug and that have not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved;

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted;

(3) if approval of the application under section 13704 of this title is withdrawn and all legal appeals have been exhausted;

(4) if the Secretary has determined that the drug is not a new drug; or

(5) on the effective date of the approval of the first application filed under section 13703(b) of this title that refers to the drug or on the date on which the approval of an application filed under section

13703(b) of this title that refers to the drug could be made effective if the application had been filed.

(b) NON-DISCLOSURE STATEMENT.—Any request for data and information pursuant to subsection (a) shall include a verified statement by the person making the request that any data or information received under subsection (a) shall not be disclosed by the person to any other person—

(1) for the purpose of, or as part of a plan, scheme, or device for, obtaining the right to make, use, or market, or making, using, or marketing, outside the United States, the drug identified in the application filed under section 13703(a) or 14502(b) of this title; and

(2) without obtaining from any person to whom the data and information are disclosed an identical verified statement, a copy of which is to be provided by the person to the Secretary, that meets the requirements of this subsection.

**§ 13717. Date of approval in the case of recommended controls under the CSA**

In the case of an application under section 13703 of this title with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and rec-

ommend controls under division A of subtitle V of this title, approval of the application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 50301(j) of this title.

# Chapter 139—Drugs for Rare Diseases or Conditions

Sec.
13901. Recommendations for investigations of drugs for rare diseases or conditions.
13902. Designation of drugs for rare diseases or conditions.
13903. Protection for drugs for rare diseases or conditions.
13904. Open protocols for investigations of drugs for rare diseases or conditions.
13905. Priority review to encourage treatments for rare pediatric diseases.
13906. Targeted drugs for rare diseases.

## § 13901. Recommendations for investigations of drugs for rare diseases or conditions

(a) REQUEST BY SPONSOR.—

(1) IN GENERAL.—The sponsor of a drug for a disease or condition that is rare in the States may request the Secretary to provide written recommendations for the non-clinical and clinical investigations that must be conducted with the drug before—

(A) it may be approved for the disease or condition under chapter 135 of this title; or

(B) if the drug is a biological product, it may be licensed for the disease or condition under section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) PROVISION OF WRITTEN RECOMMENDATION BY SECRETARY.—If the Secretary has reason to believe that a drug for which a request is made under this section is a drug for a disease or condition that is rare in the States, the Secretary shall provide the person making the request written recommendations for the non-clinical and clinical investigations that the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval of the drug for the disease or condition under chapter 135 of this title or licensing of the drug for the disease or condition under section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) REGULATIONS.—The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

**§ 13902. Designation of drugs for rare diseases or conditions**

(a) REQUEST BY SPONSOR; PPRECONDITIONS.—

(1) DEFINITION OF RARE DISEASE OR CONDITION.—

(A) IN GENERAL.—In this subsection, the term ''rare disease or condition'' means any disease or condition that—

(i) affects less than 200,000 persons in the United States; or

(ii) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for the disease or condition will be recovered from sales in the United States of the drug.

(B) BASIS.—Determinations under subparagraph (A) with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

(2) REQUEST FOR DESIGNATION.—

(A) IN GENERAL.—The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition.

(B) TIMING.—A request for designation of a drug shall be made before the submission of an application under section 13503 of this title for the drug, or the submission of an application for licensing of the drug under section 351

of the Public Health Service Act (42 U.S.C. 262).

(C) DESIGNATION.—

(i) IN GENERAL.—The Secretary shall designate a drug as a drug for a rare disease or condition if the Secretary finds that the drug, for which a request is submitted under this subsection, is being or will be investigated for the rare disease or condition; and

(I) if an application for the drug is approved under chapter 135 of this title, the approval would be for use for the disease or condition; or

(II) if a license for the drug is issued under section 351 of the Public Health Service Act (42 U.S.C. 262), the license would be for use for the disease or condition.

(ii) CONSENT TO NOTICE REQUIRED.—A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (c) respecting the designation of the drug.

(b) NOTIFICATION OF DISCONTINUANCE OF DRUG OR APPLICATION AS CONDITION.—A designation of a drug under subsection (a) shall be subject to the condition that—

(1) if an application was approved for the drug under section 13503 of this title or a license was issued for the drug under section 351 of the Public Health Service Act (42 U.S.C. 262), the manufacturer of the drug will notify the Secretary of any discontinuance of the production of the drug at least 1 year before discontinuance; and

(2) if an application has not been approved for the drug under section 13503 of this title or a license has not been issued for the drug under section 351 of the Public Health Service Act (42 U.S.C. 262) and if preclinical investigations or investigations under section 13510 of this title are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 13503 of this title or approval of a license under section 351 of the Public Health Service Act (42 U.S.C. 262).

(c) NOTICE TO PUBLIC.—Notice respecting the designation of a drug under subsection (a) shall be made available to the public.

(d) REGULATIONS.—The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

**§ 13903. Protection for drugs for rare diseases or conditions**

(a) EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSE.—

(1) IN GENERAL.—Except as provided in subsection (b), if the Secretary approves an application filed pursuant to chapter 135 of this title or issues a license under section 351 of the Public Health Service Act (42 U.S.C. 262) for a drug designated under section 13902 of this title for a rare disease or condition, the Secretary may not approve another application under chapter 135 of this title or issue another license under section 351 of the Public Health Service Act (42 U.S.C. 262) for the same drug for the same disease or condition for a person that is not the holder of the approved application or of the license until the expiration of 7 years from the date of the approval of the approved application or the issuance of the license.

(2) INAPPLICABILITY OF CERTAIN PROVISION.—Section 13504(a)(1)(B) of this title does not apply to the refusal to approve an application under paragraph (1).

(b) EXCEPTIONS.—During the 7-year period described in subsection (a) for an approved application under chapter 135 of this title or a license under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary may approve an application or issue a license for a drug that is otherwise the same, as determined by the Secretary, as the already approved drug for the same rare disease or condition if—

(1) the Secretary finds, after providing the holder of exclusive approval or licensure notice and opportunity for the submission of views, that during the 7-year period, the holder of the exclusive approval or licensure cannot ensure the availability of sufficient quantities of the drug to meet the needs of individuals with the disease or condition for which the drug was designated; or

(2) the holder provides the Secretary in writing the consent of the holder for the approval of other applications or the issuance of other licenses before the expiration of the 7-year period.

(c) CONDITION OF CLINICAL SUPERIORITY.—

(1) DEFINITION OF CLINICALLY SUPERIOR.—In this subsection, the term ''clinically superior'', with respect to a drug, means that the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy or greater safety, or by providing a major contribution to patient care.

(2) IN GENERAL.—If a sponsor of a drug that is designated under section 13902 of this title and that is otherwise the same, as determined by the Secretary, as an already approved or licensed drug is seeking exclusive approval or exclusive licensure described in subsection (a) for the same rare disease or condition as the already approved drug, the Secretary shall require the sponsor, as a condition of the exclusive approval or licensure, to demonstrate that the drug is clinically superior to any already approved or licensed drug that is the same drug.

(3) APPLICABILITY.—This subsection applies to any drug designated under section 13902 of this title for which an application was approved under chapter 135 of this title or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) after August 18, 2017, regardless of the date

on which the drug was designated under section 13902 of this title.

(d) REGULATIONS.—The Secretary may promulgate regulations for the implementation of subsection (c). Beginning on August 18, 2017, until such time as the Secretary promulgates regulations in accordance with this subsection, the Secretary may apply any definitions set forth in regulations that were promulgated prior to that date, to the extent the definitions are not inconsistent with the terms of this section.

(e) DEMONSTRATION OF CLINICAL SUPERIORITY STANDARD.—To assist sponsors in demonstrating clinical superiority as described in subsection (c), the Secretary—

(1) on the designation of any drug under section 13902 of this title, shall notify the sponsor of the drug in writing of the basis for the designation, including, as applicable, any plausible hypothesis offered by the sponsor and relied on by the Secretary that the drug is clinically superior to a previously approved drug; and

(2) on granting exclusive approval or licensure under subsection (a) on the basis of a demonstration of clinical superiority as described in subsection (c), shall publish a summary of the clinical superiority findings.

**§ 13904. Open protocols for investigations of drugs for rare diseases or conditions**

If a drug is designated under section 13902 of this title as a drug for a rare disease or condition and if notice of a claimed exemption under section 13510 of this title or regulations issued under section 13510 of this title is filed for the drug, the Secretary shall encourage the sponsor of the drug to design protocols for clinical investigations of the drug that may be conducted under the exemption to permit the addition to the investigations of individuals with the disease or condition who need the drug to treat the disease or condition and who cannot be satisfactorily treated by available alternative drugs.

**§ 13905. Priority review to encourage treatments for rare pediatric diseases**

(a) DEFINITIONS.—In this section:

(1) PRIORITY REVIEW.—The term ''priority review'', with respect to a human drug application as defined in section 17906(a) of this title, means review and action by the Secretary on the human drug application not later than 6 months after receipt by the Secretary of the human drug application, as described in the Manual of Policies and Procedures of the FDA and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee

Amendments of 2012 (Public Law 112–144, title I, 126 Stat. 996).

(2) PRIORITY REVIEW VOUCHER.—The term ''priority review voucher'' means a voucher issued by the Secretary to the sponsor of a rare pediatric disease product application that entitles the holder of the voucher to priority review of a single human drug application submitted under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) after the date of approval of the rare pediatric disease product application.

(3) RARE PEDIATRIC DISEASE.—The term ''rare pediatric disease'' means a disease that is—

(A) a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and

(B) a rare disease or condition, within the meaning of section 13902 of this title.

(4) RARE PEDIATRIC DISEASE PRODUCT APPLICATION.—The term ''rare pediatric disease product

application'' means a human drug application, as defined in section 17906(a) of this title, that—

(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

(B)(i) is for such a drug—

(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (a) or (b) of section 13503 of this title or section 13511 of this title; and

(II) that is the subject of an application submitted under section 13503(a) of this title; or

(ii) is for such a biological product—

(I) that contains no active ingredient that has been previously approved in any other application under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)); and

(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(C) the Secretary considers eligible for priority review;

(D) relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population;

(E) does not seek approval for an adult indication in the original rare pediatric disease product application; and

(F) is approved after September 30, 2016.

(b) PRIORITY REVIEW VOUCHER.—

(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a rare pediatric disease product application on approval by the Secretary of the rare pediatric disease product application.

(2) TRANSFERABILITY.—

(A) IN GENERAL.—The sponsor of a rare pediatric disease product application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to the voucher. There is no limit on the

number of times a priority review voucher may be transferred before the voucher is used.

(B) NOTIFICATION OF TRANSFER.—Each person to whom a voucher is transferred shall notify the Secretary of the change in ownership of the voucher not later than 30 days after the transfer.

(3) LIMITATION.—A sponsor of a rare pediatric disease product application may not receive a priority review voucher under this section if the rare pediatric disease product application was submitted to the Secretary prior to the date that is 90 days after July 9, 2012.

(4) NOTIFICATION.—

(A) SPONSOR OF A RARE PEDIATRIC DISEASE PRODUCT.—

(i) IN GENERAL.—Beginning on the date that is 90 days after September 30, 2016, the sponsor of a rare pediatric disease product application that intends to request a priority review voucher under this section shall notify the Secretary of the intent on submission of the rare pediatric disease product application that is the

basis of the request for a priority review voucher.

(ii) APPLICATIONS SUBMITTED BUT NOT YET APPROVED.—The sponsor of a rare pediatric disease product application that was submitted and that has not been approved as of September 30, 2016, shall be considered eligible for a priority review voucher, if—

(I) the sponsor has submitted the rare pediatric disease product application—

(aa) on or after the date that is 90 days after July 9, 2012; and

(bb) on or before September 30, 2016; and

(II) the application otherwise meets the criteria for a priority review voucher under this section.

(B) SPONSOR OF A DRUG APPLICATION USING A PRIORITY REVIEW VOUCHER.—

(i) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to

submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the human drug application. The notification shall be a legally binding commitment to pay the user fee to be assessed in accordance with this section.

(ii) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of the sponsor to use the voucher for the human drug application under clause (i) may transfer the voucher after the notification is provided, if the sponsor has not yet submitted the human drug application described in the notification.

(5) TERMINATION OF AUTHORITY.—The Secretary may not award any priority review vouchers under paragraph (1) after December 20, 2024, unless the rare pediatric disease product application—

(A) is for a drug that, not later than December 20, 2024, is designated under sub-

section (d) as a drug for a rare pediatric disease; and

(B) is, not later than September 30, 2026, approved under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(c) PRIORITY REVIEW USER FEE.—

(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). The fee shall be in addition to any fee required to be submitted by the sponsor under chapter 179 of this title.

(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary, based on the difference between—

(A) the average cost incurred by the FDA in the review of a human drug application subject to priority review in the previous fiscal year; and

(B) the average cost incurred by the FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year, the amount of the priority review user fee for that fiscal year.

(4) PAYMENT.—

(A) IN GENERAL.—The priority review user fee required by this subsection shall be due on the notification by a sponsor of the intent of the sponsor to use the voucher, as specified in subsection (b)(4)(B). All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.

(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying the fees.

(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the FDA; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriations Acts.

(d) DESIGNATION PROCESS.—

(1) IN GENERAL.—On the request of the manufacturer or the sponsor of a new drug, the Secretary may designate—

(A) the new drug as a drug for a rare pediatric disease; and

(B) the application for the new drug as a rare pediatric disease product application.

(2) REQUEST FOR DESIGNATION.—The request for a designation under paragraph (1) shall be made at the same time a request for designation of orphan disease status under section 13902 of this title or fast-track designation under section 13119 of this title is made. Requesting designation under this subsection is not a prerequisite to receiving a priority review voucher under this section.

(3) DETERMINATION BY SECRETARY.—Not later than 60 days after a request is submitted under paragraph (1), the Secretary shall determine whether—

(A) the disease or condition that is the subject of the request is a rare pediatric disease; and

(B) the application for the new drug is a rare pediatric disease product application.

(e) MARKETING OF RARE PEDIATRIC DISEASE PRODUCTS.—

(1) REVOCATION.—The Secretary may revoke any priority review voucher awarded under subsection (b) if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within the 365-day period beginning on the date of the approval of the drug under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) POSTAPPROVAL PRODUCTION REPORT.—The sponsor of an approved rare pediatric disease product shall submit a report to the Secretary not later than 5 years after the approval of the applicable rare pediatric disease product application. The report shall provide the following information, with

respect to each of the first 4 years after approval of the product:

(A) The estimated population in the United States suffering from the rare pediatric disease.

(B) The estimated demand in the United States for the rare pediatric disease product.

(C) The actual amount of the rare pediatric disease product distributed in the United States.

(f) NOTICE AND REPORT.—

(1) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the FDA website not later than 30 days after the occurrence of each of the following:

(A) The Secretary issues a priority review voucher under this section.

(B) The Secretary approves a drug pursuant to an application submitted under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for which the sponsor of the application used a priority review voucher under this section.

(2) NOTIFICATION.—If, after the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, a sponsor of an application submitted under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a drug uses a priority review voucher under this section for the application, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a document—

(A) notifying the Committees of the use of the voucher; and

(B) identifying the drug for which the priority review voucher is used.

(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor that seeks a priority review voucher under this section from participating in any other incentive program, including under this subtitle, except that a sponsor of a rare pediatric disease product application shall not receive more than 1 priority review voucher issued under any section of this subtitle with respect to the drug for which the application is made.

(h) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) that encourage the development of drugs for tropical diseases and rare pediatric diseases.

(i) GAO STUDY AND REPORT.—

(1) STUDY.—

(A) IN GENERAL.—Beginning on the date that the Secretary awards the third rare pediatric disease priority voucher under this section, the Comptroller General shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under this section in the development of human drug products that treat or prevent the diseases.

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

(i) The indications for which each rare disease product for which a priority review voucher was awarded was approved under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262).

(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval of such a rare disease product.

(iii) The value of the priority review voucher if transferred.

(iv) Identification of each drug for which a priority review voucher was used.

(v) The length of the period of time between the date on which a priority review voucher was awarded and the date on which it was used.

(2) REPORT.—Not later than 1 year after the date under paragraph (1)(A), the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report containing the results of the study under paragraph (1).

**§ 13906. Targeted drugs for rare diseases**

(a) PURPOSES.—The purposes of this section, through the approach provided for in subsection (c), are—

(1) to facilitate the development, review, and approval of genetically targeted drugs and variant

protein targeted drugs to address an unmet medical need in 1 or more patient subgroups, including subgroups of patients with different mutations of a gene, with respect to rare diseases or conditions that are serious or life-threatening; and

(2) to maximize the use of scientific tools or methods, including surrogate endpoints and other biomarkers, for those purposes.

(b) DEFINITIONS.—In this section:

(1) GENETICALLY TARGETED DRUG.—The term ''genetically targeted drug'' means a drug that—

(A) is the subject of an application under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for the treatment of a rare disease or condition (as the term is defined in section 13902 of this title) that is serious or life-threatening;

(B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and

(C) incorporates or utilizes a genetically targeted technology.

(2) GENETICALLY TARGETED TECHNOLOGY.—The term ''genetically targeted technology'' means a technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat 1 or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene.

(3) VARIANT PROTEIN TARGETED DRUG.—The term ''variant protein targeted drug'' means a drug that—

(A) is the subject of an application under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for the treatment of a rare disease or condition (as the term is defined in section 13902 of this title) that is serious or life-threatening;

(B) modulates the function of a product of a mutated gene where the mutation is responsible in whole or in part for a given disease or condition; and

(C) is intended to treat 1 or more patient subgroups, including subgroups of patients with

different mutations of a gene, with the same disease or condition.

(c) LEVERAGING OF DATA FROM PREVIOUSLY APPROVED DRUG APPLICATION OR APPLICATIONS.—

(1) IN GENERAL.—The Secretary may, consistent with applicable standards for approval under this subtitle or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), allow the sponsor of an application under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for a genetically targeted drug or a variant protein targeted drug to rely on data and information described in paragraph (2), which data and information were—

(A) previously developed by the same sponsor (or another sponsor that has provided the sponsor with a contractual right of reference to the data and information); and

(B) submitted by a sponsor described in subparagraph (A) in support of 1 or more previously approved applications that were submitted under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(2) DATA AND INFORMATION.—Data and information described in this paragraph are data and information for a drug that incorporates or utilizes the same or similar genetically targeted technology as the drug or drugs that are the subject of an application or applications described in paragraph (1)(B) or for a variant protein targeted drug that is the same or incorporates or utilizes the same variant protein targeted drug as the drug or drugs that are the subject of an application or applications described in paragraph (1)(B).

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to alter the authority of the Secretary to approve drugs pursuant to this subtitle or section 351 of the Public Health Service Act (42 U.S.C. 262) (as authorized prior to December 13, 2016), including the standards of evidence, and applicable conditions, for approval under the applicable subtitle or Act; or

(2) to confer any new rights, beyond those authorized under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) prior to December 13, 2016, with respect to the permissibility of a sponsor referencing information contained in an-

other application submitted under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

# Chapter 141—Electronic Product Radiation Control

Sec.
14101. Definitions.
14102. Program of control.
14103. Studies by Secretary.
14104. Performance standards for electronic products.
14105. Notification of defects in and repair or replacement of electronic products.
14106. Imports.
14107. Inspection, records, and reports.
14108. Prohibited acts.
14109. Enforcement.
14110. Federal-State cooperation.
14111. Preemption.

## § 14101. Definitions

In this chapter:

(1) COMMERCE.—The term ''commerce'' means—

(A) commerce between any place in any State and any place outside the State; and

(B) commerce wholly within the District of Columbia.

(2) ELECTRONIC PRODUCT.—The term ''electronic product'' means—

(A) any manufactured or assembled product that, when in operation—

(i) contains or acts as part of an electronic circuit; and

(ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation; or

(B) any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in subparagraph (A) and that when in operation emits (or in the absence of effective shielding or other controls would emit) electronic product radiation.

(3) ELECTRONIC PRODUCT RADIATION.—The term ''electronic product radiation'' means—

(A) any ionizing or non-ionizing electromagnetic or particulate radiation; or

(B) any sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in the electronic product.

(4) MANUFACTURER.—The term ''manufacturer'' means any person engaged in the business of manufacturing, assembling, or importing of electronic products.

(5) STATE.—The term ''State'' includes the District of Columbia, Puerto Rico, Guam, American

Samoa, the Virgin Islands, and the Northern Mariana Islands.

**§ 14102. Program of control**

(a) ESTABLISHMENT.—The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of the program, the Secretary shall—

(1) pursuant to section 14104 of this title, develop and administer performance standards for electronic products;

(2) plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of, and the exposure of people to, unnecessary electronic product radiation;

(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation;

(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, and other appropriate Federal agencies (including the agency to which was transferred the functions of the Atomic Energy Commission relating to this paragraph) on—

(A) techniques, equipment, and programs for testing and evaluating electronic product radiation; and

(B) the development of performance standards pursuant to section 14104 of this title to control the radiation emissions.

(b) AUTHORITIES OF SECRETARY.—In carrying out subsection (a), the Secretary may—

(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation; and

(B) make such recommendations relating to the hazards and control as the Secretary considers appropriate;

(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a);

(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324 of title 31 and section 6101 of title 41; and

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of the electronic products.

(c) RECORDKEEPING.—

(1) IN GENERAL.—Each recipient of assistance under this chapter pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including—

(A) records that fully disclose—

(i) the amount and disposition by the recipient of the proceeds of the assistance;

(ii) the total cost of the project or undertaking in connection with which the assistance is given or used; and

(iii) the amount of the portion of the cost of the project or undertaking supplied by other sources; and

(B) such other records as will facilitate an effective audit.

(2) ACCESS TO RECORDS.—The Secretary and the Comptroller General, or any of their authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under this chapter under other than competitive bidding procedures.

**§ 14103. Studies by Secretary**

(a) REPORT TO CONGRESS.—The Secretary shall conduct the following studies and shall make a report or reports of the results of the studies to Congress from time to time as the Secretary may find necessary, with such recommendations for legislation as the Secretary may consider appropriate:

(1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include—

(A) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.);

(B) any gaps and inconsistencies in present controls;

(C) the need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading the electronic products to meet the standards for new electronic products or separate standards for used electronic products;

(D) measures to ensure consistent and effective control of the aforementioned health hazards;

(E) measures to strengthen radiological health programs of State governments; and

(F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation.

(2) A study to determine the necessity for the development of standards for the use of nonmedical

electronic products for commercial and industrial purposes.

(3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation that may be emitted from electronic products manufactured or imported prior to the effective date of any applicable standard established pursuant to this chapter.

(b) PARTICIPATION OF OTHER FEDERAL AGENCIES.—In carrying out the studies under subsection (a), the Secretary shall invite the participation of other Federal agencies having related responsibilities and interests, State governments (particularly those States that regulate radioactive materials under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021)), and interested professional, labor, and industrial organizations. On request from congressional committees interested in the studies, the Secretary shall keep the congressional committees currently informed as to the progress of the studies and shall permit the congressional committees to send observers to meetings of the study groups.

(c) ORGANIZATION OF STUDIES AND PARTICIPATION.—The Secretary shall organize the studies and the participation of the invited participants as the Secretary considers best. Any dissent from the findings and rec-

ommendations of the Secretary shall be included in the report if the inclusion is requested by the dissenter.

**§ 14104. Performance standards for electronic products**

(a) PRESCRIPTION OF REGULATIONS.—

(1) IN GENERAL.—

(A) PRESCRIPTION ON DETERMINATION OF NECESSITY FOR PROTECTION OF PUBLIC HEALTH AND SAFETY.—The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from the electronic products if the Secretary determines that the standards are necessary for the protection of the public health and safety.

(B) CONTENTS.—The standards may—

(i) include provisions for the testing of the electronic products and the measurement of their electronic product radiation emissions;

(ii) require the attachment of warning signs and labels; and

(iii) require the provision of instructions for the installation, operation, and use of the electronic products.

(C) TIMING.—The standards may be prescribed from time to time whenever the determinations under subparagraph (A) are made.

(D) DEVELOPMENT OF STANDARDS; CONSULTATIONS; FACTORS TO CONSIDER.—In the development of the standards, the Secretary shall consult with Federal and State agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations that would be affected by the standards, and shall give consideration to—

(i) the latest available scientific and medical data in the field of electronic product radiation;

(ii) the standards currently recommended by—

(I) other Federal agencies having responsibilities relating to the control and measurement of electronic product radiation; and

(II) public or private groups having an expertise in the field of electronic product radiation;

(iii) the reasonableness and technical feasibility of the standards as applied to a particular electronic product;

(iv) the adaptability of the standards to the need for uniformity and reliability of testing and measuring procedures and equipment; and

(v) in the case of a component, or accessory described in section 14101(2)(B) of this title, the performance of the article in the manufactured or assembled product for which it is designed.

(2) DIFFERENT AND INDIVIDUAL PERFORMANCE STANDARDS.—The Secretary may prescribe different and individual performance standards, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses.

(3) ELECTRONIC PRODUCTS FOR EXPORT.—The performance standards prescribed under this section shall not apply to any electronic product that is intended solely for export if—

(A) the electronic product and the outside of any shipping container used in the export of the electronic product are labeled or tagged to

show that the electronic product is intended for export; and

(B) the electronic product meets all the applicable requirements of the country to which the electronic product is intended for export.

(4) AMENDMENT; REVOCATION.—The Secretary may by regulation amend or revoke any performance standard prescribed under this section.

(5) EXEMPTION FOR ELECTRONIC PRODUCTS FOR USE BY FEDERAL AGENCIES.—The Secretary may exempt from the provisions of this section any electronic product intended for use by any Federal agency, provided that the Federal agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that the electronic product is of a type used solely or predominantly by Federal agencies.

(b) ADMINISTRATIVE PROCEDURE.—The provisions of subchapter II of chapter 5 of title 5 (relating to the administrative procedure for rulemaking), and of chapter 7 of title 5 (relating to judicial review), shall apply with respect to any regulation prescribing, amending, or revoking any standard prescribed under this section.

(c) PUBLICATION IN FEDERAL REGISTER.—Each regulation prescribing, amending, or revoking a standard

shall specify the date on which it shall take effect which, in the case of any regulation prescribing or amending any standard, may not be sooner than 1 year or not later than 2 years after the date on which the regulation is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest and publishes in the Federal Register the Secretary's reason for the finding, in which case the earlier or later date shall apply.

(d) JUDICIAL REVIEW.—

(1) FILING OF PETITION.—

(A) IN GENERAL.—In a case of actual controversy as to the validity of any regulation issued under this section prescribing, amending, or revoking a performance standard, any person that will be adversely affected by the regulation when it is effective may, at any time prior to the 60th day after the regulation is issued, file a petition with the United States court of appeals for the circuit in which the person resides or in which the person's principal place of business is located, for a judicial review of the regulation.

(B) TRANSMISSION TO SECRETARY.—A copy of the petition shall be immediately trans-

mitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose.

(C) FILING OF RECORD OF PROCEEDINGS.—On the transmission under subparagraph (B), the Secretary shall file in the court the record of the proceedings on which the Secretary based the regulation, as provided in section 2112 of title 28.

(2) ADDITIONAL EVIDENCE.—

(A) IN GENERAL.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Secretary, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the Secretary, and to be adduced on the hearing, in such manner and on such terms and conditions as to the court may seem proper.

(B) MODIFICATION OF FINDINGS OR MAKING OF NEW FINDINGS.—The Secretary may modify the Secretary's findings, or make new

findings, by reason of the additional evidence taken before the Secretary under subparagraph (A), and the Secretary shall file the modified or new findings, and the Secretary's recommendations, if any, for the modification or setting aside of the Secretary's original regulation, with the return of the additional evidence.

(3) JURISDICTION.—On the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to review the regulation in accordance with chapter 7 of title 5 and to grant appropriate relief as provided in chapter 7 of title 5.

(4) FINALITY; REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any such regulation of the Secretary shall be final, subject to review by the Supreme Court of the United States on certiorari or certification as provided in section 1254 of title 28.

(5) EFFECT OF CHANGE IN THE OFFICE OF SECRETARY.—Any action instituted under this subsection shall survive, notwithstanding any change in the individual occupying the Office of the Secretary or any vacancy in the Office.

(6) REMEDIES NOT IN SUBSTITUTION FOR OTHER REMEDIES.—The remedies provided for in

this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(e) AVAILABILITY OF RECORD.—

(1) IN GENERAL.—The Secretary shall furnish a certified copy of the transcript of the record and administrative proceedings under this section to any interested party at the request and payment of the interested party.

(2) ADMISSIBILITY.—The certified copy under paragraph (1) shall be admissible in any criminal, exclusion of imports, or other proceeding arising under or in respect of this chapter, regardless of whether proceedings with respect to the regulation have previously been initiated or become final under this section.

(f) TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE.—

(1) DEFINITION OF COMMITTEE.—In this subsection, the term ''Committee'' means the Technical Electronic Product Radiation Safety Standards Committee established under paragraph (2).

(2) ESTABLISHMENT.—The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee that the Secretary shall

consult before prescribing any standard under this section.

(3) APPOINTMENT AND COMPOSITION.—The Committee shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety, and shall be composed of 15 members, each of whom shall be technically qualified by training and experience in 1 or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(A) Five members shall be selected from governmental agencies, including State and Federal Governments.

(B) Five members shall be selected from the affected industries after consultation with industry representatives.

(C) Five members shall be selected from the general public, of which at least 1 shall be a representative of organized labor.

(4) AUTHORITY TO PROPOSE STANDARDS.—The Committee may propose electronic product radiation safety standards to the Secretary for the Secretary's consideration.

(5) RECORDS OF PROCEEDINGS.—All proceedings of the Committee shall be recorded and the record of each of those proceedings shall be available for public inspection.

(6) PAYMENTS NOT TO RENDER COMMITTEE MEMBERS FEDERAL EMPLOYEES.—Payments to members of the Committee who are not officers or employees of the United States pursuant to section 208(c) of the Public Health Service Act (42 U.S.C. 210(c)) shall not render members of the Committee officers or employees of the United States for any purpose.

(g) REVIEW AND EVALUATION.—The Secretary shall review and evaluate on a continuing basis testing programs carried out by industry to ensure the adequacy of safeguards against hazardous electronic product radiation and to ensure that electronic products comply with standards prescribed under this section.

(h) ELECTRONIC PRODUCT CERTIFICATION.—

(1) IN GENERAL.—Each manufacturer of an electronic product to which is applicable a standard in effect under this section shall furnish to the distributor or dealer at the time of delivery of the electronic product, in the form of a label or tag permanently affixed to the electronic product or in such

manner as approved by the Secretary, the certification that the electronic product conforms to all applicable standards under this section.

(2) TEST.—The certification under paragraph (1) shall be based on a test, in accordance with the standard in effect described in paragraph (1), of the individual article to which the certification is attached or on a testing program that is in accord with good manufacturing practice and that has not been disapproved by the Secretary (in such manner as the Secretary shall prescribe by regulation) on the grounds that the testing program does not ensure the adequacy of safeguards against hazardous electronic product radiation or that the testing program does not ensure that electronic products comply with the standards prescribed under this section.

**§ 14105. Notification of defects in and repair or replacement of electronic products**

(a) NOTIFICATION.—

(1) IN GENERAL.—Each manufacturer of electronic products that discovers that an electronic product produced, assembled, or imported by the manufacturer has a defect that relates to the safety of use of the electronic product by reason of the emission of electronic product radiation, or that an

electronic product produced, assembled, or imported by the manufacturer on or after the effective date of an applicable standard prescribed pursuant to section 14104 of this title fails to comply with the standard, shall immediately notify the Secretary of the defect or failure to comply if the electronic product has left the place of manufacture and shall (except as authorized by paragraph (2)) with reasonable promptness furnish notification of the defect or failure to the persons (which persons are known to the manufacturer) specified in subsection (b).

(2) EXEMPTION.—

(A) APPLICATION.—If, in the opinion of the manufacturer described in paragraph (1), the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the manufacturer may, at the time of giving notice to the Secretary of the defect or failure to comply, apply to the Secretary for an exemption from the requirement of notice to the persons specified in subsection (b).

(B) OPPORTUNITY TO PRESENT VIEWS; BURDEN OF PROOF.—If the exemption application states reasonable grounds for the exemp-

tion, the Secretary shall afford the manufacturer an opportunity to present the manufacturer's views and evidence in support of the application, the burden of proof being on the manufacturer.

(C) GRANTING OF EXEMPTION.—If, after the presentation afforded under subparagraph (B), the Secretary is satisfied that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall exempt the manufacturer from the requirement of notice to the persons specified in subsection (b) and from the requirements of repair or replacement imposed by subsection (f).

(b) METHOD OF NOTIFICATION.—The notification (other than to the Secretary) required by subsection (a)(1) shall be accomplished—

(1) by certified mail to the first purchaser of the electronic product for purposes other than resale, and to any subsequent transferee of the electronic product; and

(2) by certified mail or other more expeditious means to the dealers or distributors of the manufacturer to whom the electronic product was delivered.

(c) REQUISITE ELEMENTS OF NOTIFICATION.—The notifications required by subsection (a)(1) shall contain a clear description of the defect or failure to comply with an applicable standard, an evaluation of the hazard reasonably related to the defect or failure to comply, and a statement of the measures to be taken to repair the defect. In the case of a notification to a person referred to in subsection (b), the notification shall also advise the person of the person's rights under subsection (f).

(d) COPIES TO SECRETARY OF COMMUNICATIONS BY MANUFACTURERS REGARDING DEFECTS.—

(1) IN GENERAL.—Each manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of the manufacturer or to purchasers (or subsequent transferees) of electronic products of the manufacturer regarding the defect or failure to comply.

(2) DISCLOSURE TO PUBLIC.—The Secretary shall disclose to the public such information contained in the notice or other information obtained under section 14107 of this title as the Secretary considers will assist in carrying out the purposes of this chapter, but the Secretary shall not disclose any information that contains or relates to a trade secret

or other matter referred to in section 1905 of title 18 unless the Secretary determines that it is necessary to carry out the purposes of this chapter.

(e) NOTICE FROM SECRETARY TO MANUFACTURER OF DEFECTS OR FAILURE TO COMPLY WITH STANDARDS.—

(1) IN GENERAL.—The Secretary shall immediately notify the manufacturer of an electronic product of the defect or failure to comply described in subparagraph (A) or (B) if through testing, inspection, investigation, or research carried out pursuant to this chapter, examination of reports submitted pursuant to section 14107 of this title, or otherwise, the Secretary determines that the electronic product—

(A) does not comply with an applicable standard prescribed pursuant to section 14104 of this title; or

(B) contains a defect that relates to the safety of use of the electronic product by reason of the emission of electronic product radiation.

(2) FINDINGS.—The notice under paragraph (1) shall contain the findings of the Secretary and shall include all information on which the findings are based.

(3) OPPORTUNITY TO PRESENT VIEWS.—The Secretary shall afford the manufacturer an opportunity to present the manufacturer's views and evidence in support of the views, to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the electronic product by reason of the emission of the radiation hazard.

(4) DETERMINATION OF NONCOMPLIANCE OR DEFECT AFTER OPPORTUNITY TO PRESENT VIEWS.—If, after the presentation by the manufacturer as described in paragraph (3), the Secretary determines that the electronic product does not comply with an applicable standard prescribed pursuant to section 14104 of this title, or that it contains a defect that relates to the safety of use of the electronic product by reason of the emission of electronic product radiation, the Secretary shall direct the manufacturer to furnish the notification specified in subsection (c) to the persons specified in paragraphs (1) and (2) of subsection (b) (which persons are known to the manufacturer), unless the manufacturer has applied for an exemption from the requirement of the notification on the ground specified in subsection (a)(2) and the Secretary is satis-

fied that the noncompliance or defect does not create a significant risk of injury, including genetic injury, to any person.

(f) CORRECTION OF DEFECTS.—

(1) IN GENERAL.—If any electronic product is found under subsection (a) or (e) to fail to comply with an applicable standard prescribed under this chapter or to have a defect that relates to the safety of use of the electronic product, and the notification specified in subsection (c) is required to be furnished on account of the failure or defect, the manufacturer of the electronic product shall—

(A) without charge, bring the electronic product into conformity with the standard or remedy the defect and provide reimbursement for any expenses for transportation of the electronic product incurred in connection with having the electronic product brought into conformity or having the defect remedied;

(B) replace the electronic product with a like or equivalent electronic product—

(i) that complies with each applicable standard prescribed under this chapter; and

(ii) that has no defect relating to the safety of its use; or

(C) make a refund of the cost of the electronic product.

(2) EFFECT OF REGULATIONS.—The manufacturer shall take the action required by this subsection in such manner, and with respect to such persons, as the Secretary by regulations shall prescribe.

(g) EFFECTIVE DATE.—This section shall not apply to any electronic product that was manufactured before October 18, 1968.

**§ 14106. Imports**

(a) REFUSAL OF ADMISSION TO NONCOMPLYING ELECTRONIC PRODUCTS.—

(1) IN GENERAL.—Any electronic product offered for importation into the United States shall be refused admission into the United States if it is an electronic product—

(A) that fails to comply with an applicable standard prescribed under this chapter; or

(B) to which is not affixed a certification in the form of a label or tag in conformity with section 14104(h) of this title.

(2) REQUEST FOR SAMPLES BEING IMPORTED.—The Secretary of the Treasury shall deliver to the Secretary, on the latter's request, samples of electronic products that are being imported or offered for import into the United States, giving to the owner or consignee notice of the delivery, which owner or consignee may have a hearing before the Secretary.

(3) EFFECT OF NONCOMPLIANCE.—If it appears from an examination of the samples or otherwise that any electronic product fails to comply with applicable standards prescribed pursuant to section 14104 of this title, then, unless subsection (b) applies and is complied with—

(A) the electronic product shall be refused admission; and

(B) the Secretary of the Treasury shall cause the destruction of the electronic product unless the article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days after the date of notice of refusal of admission or within such additional time as may be permitted by the regulations.

(b) BOND.—

(1) AUTHORITY TO DEFER FINAL DETERMINATION AS TO ADMISSION.—If it appears to the Secretary that any electronic product refused admission pursuant to subsection (a) can be brought into compliance with applicable standards prescribed pursuant to section 14104 of this title, final determination as to admission of the electronic product may be deferred on filing of timely written application by the owner or consignee and the execution by the owner or consignee of a good and sufficient bond providing for the payment of the liquidated damages in the event of default as the Secretary may by regulation prescribe.

(2) PERMISSION.—If the application is filed and the bond is executed, the Secretary may, in accordance with rules prescribed by the Secretary, permit the applicant to perform the operations with respect to the electronic product as may be specified in the notice of permission.

(c) LIABILITY OF OWNER OR CONSIGNEE FOR EXPENSES CONNECTED WITH REFUSAL OF ADMISSION.—All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) and the supervision of operations provided for

in subsection (b), and all expenses in connection with the storage, cartage, or labor with respect to any electronic product refused admission pursuant to subsection (a), shall be paid by the owner or consignee, and, in the event of default, shall constitute a lien against any future importations made by the owner or consignee.

(d) DESIGNATION OF AGENT FOR PURPOSES OF SERVICE.—

(1) IN GENERAL.—Each manufacturer offering an electronic product for importation into the United States shall designate in writing an agent on whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer, and to file the designation with the Secretary.

(2) DESIGNATION CHANGE.—A designation under paragraph (1) may from time to time be changed in writing, filed with the Secretary.

(3) SERVICE.—

(A) IN GENERAL.—Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made on the manufacturer by service on the designated agent at the agent's office or usual place of res-

idence, the effect of which is as if service was made personally on the manufacturer.

(B) DESIGNATION NOT MADE.—If designation of an agent under this subsection is not made, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this chapter or any standards prescribed pursuant to this chapter may be made by posting the process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by the Secretary by regulation.

**§ 14107. Inspection, records, and reports**

(a) INSPECTION OF PREMISES.—

(1) IN GENERAL.—If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held may not be adequate or reliable, officers or employees designated by the Secretary, on presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, may—

(A) enter, at reasonable times, any area in the factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 14104(h) of this title are carried out; and

(B) inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within the area that are related to electronic product radiation safety.

(2) PROMPTNESS OF INSPECTIONS.—Each inspection under paragraph (1) shall be commenced and completed with reasonable promptness.

(3) GOOD CAUSE.—In addition to other grounds on which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case in which the manufacturer has introduced into commerce any electronic product that does not comply with an applicable standard prescribed under this chapter and with respect to which no exemption from the notification requirements has been granted by the Secretary under subsection (a)(2) or (e) of section 14105 of this title.

(b) RECORDKEEPING.—Each manufacturer of electronic products—

(1) shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable the Secretary to determine whether the manufacturer has acted or is acting in compliance with this chapter and standards prescribed pursuant to this chapter; and

(2) shall, on request of an officer or employee designated by the Secretary, permit the officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether the manufacturer has acted or is acting in compliance with standards prescribed pursuant to this chapter.

(c) DISCLOSURE OF TECHNICAL DATA.—Each manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out this chapter. The Secretary may require the manufacturer to give such notification of the performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product as the Secretary determines necessary to carry out the purposes of this chapter after consulting with the affected industry.

(d) PUBLIC NATURE OF REPORTS.—

(1) IN GENERAL.—Accident and investigation reports made under this chapter by any officer, employee, or agent of the Secretary shall be available for use in any civil, criminal, or other judicial proceeding arising out of the accident.

(2) TESTIMONY.—Any officer, employee, or agent under paragraph (1) may be required to testify in the proceedings as to the facts developed in the investigations.

(3) PUBLIC AVAILABILITY.—Any report under paragraph (1) shall be made available to the public in a manner that need not identify individuals. All reports on research projects, demonstration projects, and other related activities shall be public information.

(e) TRADE SECRETS.—

(1) IN GENERAL.—The Secretary or the Secretary's representative shall not disclose any information reported to or otherwise obtained by the Secretary or the representative, pursuant to subsection (a) or (b), that concerns any information that contains or relates to a trade secret or other matter referred to in section 1905 of title 18, except that the information may be disclosed—

(A) to other officers or employees of the Department and of other agencies concerned with carrying out this chapter; or

(B) when relevant in any proceeding under this chapter.

(2) EFFECT OF SECTION ON WITHHOLDING INFORMATION FROM CONGRESS.—Nothing in this section authorizes the withholding of information by the Secretary, or by any officers or employees under the Secretary's control, from the authorized committees of Congress.

(f) INFORMATION REQUIRED TO IDENTIFY AND LOCATE FIRST PURCHASERS OF ELECTRONIC PRODUCTS.—

(1) IN GENERAL.—The Secretary may by regulation—

(A) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this chapter and the retail prices of which is not less than $50, to furnish manufacturers of the electronic products such information as may be necessary to identify and locate, for purposes of section 14105 of this title, the first purchasers of the electronic products for purposes other than resale; and

(B) require manufacturers to preserve the information.

(2) CONTENTS.—Any regulation establishing a requirement pursuant to paragraph (1)(A) shall—

(A) authorize the dealers and distributors to elect, in lieu of immediately furnishing the information to the manufacturer, to hold and preserve the information until advised by the manufacturer or Secretary that the information is needed by the manufacturer for purposes of section 14105 of this title; and

(B) provide that the dealer or distributor shall, on making the election, give prompt notice of the election (together with information identifying the notifier and the electronic product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need for the required information for the purposes of section 14105 of this title, immediately furnish the manufacturer with the required information.

(3) DISCONTINUATION BY DEALER OR DISTRIBUTOR.—If a dealer or distributor discontinues the dealing in or distribution of electronic products, the dealer or distributor shall turn the information

over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of electronic products for purposes other than resale shall treat the information as confidential and may use the information only if necessary for the purpose of notifying persons pursuant to section 14105(a) of this title.

**§ 14108. Prohibited acts**

(a) IN GENERAL.—It shall be unlawful—

(1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product that does not comply with an applicable standard prescribed pursuant to section 14104 of this title;

(2) for any person—

(A) to fail to furnish any notification or other material or information required by section 14105 or 14107 of this title; or

(B) to fail to comply with the requirements of section 14105(f) of this title;

(3) for any person to fail or to refuse—

(A) to establish or maintain records required by this chapter;

(B) to permit access by the Secretary or any of the Secretary's authorized representatives—

(i) to the records; or

(ii) to the copying of the records; or

(C) to permit entry or inspection, as required by section 14107 of this title;

(4) for any person to fail or to refuse—

(A) to make any report required pursuant to section 14107(b) of this title; or

(B) to furnish or preserve any information required pursuant to section 14107(f) of this title; or

(5) for any person—

(A) to fail to issue a certification as required by section 14104(h) of this title; or

(B) to issue a certification required by section 14104(h) of this title—

(i) if the certification is not based on a test or testing program meeting the requirements of section 14104(h) of this title; or

(ii) if the issuer, in the exercise of due care, would have reason to know that the

certification is false or misleading in a material respect.

(b) EXEMPTION.—The Secretary may exempt any electronic product, or class of an electronic product, from all or part of subsection (a), on such conditions as the Secretary may find necessary—

(1) to protect the public health or welfare;

(2) for the purpose of research, investigations, studies, demonstrations, or training; or

(3) for reasons of national security.

**§ 14109. Enforcement**

(a) JURISDICTION OF COURTS.—The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of section 14108 of this title and to restrain dealers and distributors of electronic products from selling or otherwise disposing of electronic products that do not conform to an applicable standard prescribed pursuant to section 14104 of this title except when the electronic products are disposed of by returning them to the distributor or manufacturer from whom they were obtained. The district courts of the United States shall also have jurisdiction in accordance with section 1355 of title 28 to enforce the provisions of subsection (b).

(b) CIVIL PENALTIES.—

(1) MAXIMUM AMOUNT.—

(A) IN GENERAL.—Any person that violates section 14108 of this title shall be subject to a civil penalty of not more than $1,000.

(B) SEPARATE VIOLATIONS.—For purposes of this subsection, any violation described in subparagraph (A) shall, with respect to each electronic product involved or with respect to each act or omission made unlawful by section 14108 of this title, constitute a separate violation, except that the maximum civil penalty imposed on any person under this subsection for any related series of violations shall not exceed $300,000.

(2) REMISSION OR MITIGATION.—Any civil penalty under paragraph (1) may on application be remitted or mitigated by the Secretary.

(3) FACTORS TO CONSIDER.—In determining the amount of the civil penalty, or whether the civil penalty should be remitted or mitigated and in what amount, the appropriateness of the civil penalty to the size of the business of the person charged and the gravity of the violation shall be considered.

(4) OFFSETTING OF AMOUNT OWED.—The amount of the civil penalty, when finally determined,

may be deducted from any amounts owed by the United States to the person charged.

(c) VENUE; PROCESS.—Actions under subsections (a) and (b) may be brought in the district court of the United States for the district in which any act or omission or transaction constituting the violation occurred, or in the court for the district in which the defendant is found or transacts business, and process in those cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

(d) EFFECT OF CHAPTER.—Nothing in this chapter shall be construed as requiring the Secretary to report, for the institution of proceedings, minor violations of this chapter whenever the Secretary believes that the public interest will be adequately served by a suitable written notice or warning.

(e) COMPLIANCE WITH REGULATIONS.—Except as provided in section 14111(a) of this title, compliance with this chapter or any regulations issued under this chapter shall not relieve any person from liability at common law or under statutory law.

(f) ADDITIONAL REMEDIES.—The remedies provided for in this chapter shall be in addition to and not in substitution for any other remedies provided by law.

**§ 14110. Federal-State cooperation**

The Secretary—

(1) may accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this chapter that the Secretary may request and that the State and local authorities may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of the assistance; and

(2) may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any authority described in paragraph (1) as an officer of the Department.

**§ 14111. Preemption**

(a) IN GENERAL.—If a standard prescribed pursuant to section 14104 of this title with respect to an aspect of performance of an electronic product is in effect, a State or political subdivision of a State shall not have any authority to establish, or to continue in effect, any standard that is applicable to the same aspect of performance of the electronic product and that is not identical to the Federal standard.

(b) EFFECT OF CHAPTER.—Nothing in this chapter shall be construed to prevent the Federal Government or

the government of any State or political subdivision of any State from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if the requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.

# Chapter 143—General Provisions Relating to Drugs and Devices

Sec.
14301. Expanded access to unapproved therapies and diagnostics.
14302. Expanded access policy required for investigational drugs.
14303. Investigational drugs for use by eligible patients.
14304. Dispute resolution.
14305. Classification of products.
14306. Authorization for medical products for use in emergencies.
14307. Emergency use of medical products.
14308. Products held for emergency use.
14309. Countermeasure development, review, and technical assistance.
14310. Priority review to encourage treatments for agents that present national security threats.
14311. Medical countermeasure master files.
14312. Critical Path Public-Private Partnerships.
14313. Emerging technology program.
14314. Risk communication.
14315. Notification.
14316. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.
14317. Optimizing global clinical trials.
14318. Use of clinical investigation data from outside the United States.
14319. Patient participation in medical product discussion.
14320. Notification, nondistribution, and recall of controlled substances.

## § 14301. Expanded access to unapproved therapies and diagnostics

(a) DEFINITIONS.—In this section:

(1) INVESTIGATIONAL DEVICE.—The term ''investigational device'' has the meaning given the term in regulations prescribed by the Secretary.

(2) INVESTIGATIONAL DRUG.—The term ''investigational drug'' has the meaning given the term in regulations prescribed by the Secretary.

(3) TREATMENT INVESTIGATIONAL DEVICE EXEMPTION.—The term ''treatment investigational device exemption'' has the meaning given the term in regulations prescribed by the Secretary.

(4) TREATMENT INVESTIGATIONAL NEW DRUG APPLICATION.—The term ''treatment investigational new drug application'' has the meaning given the term in regulations prescribed by the Secretary.

(b) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(c) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any individual, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to the physician an investigational drug

or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

(1) the licensed physician determines that the individual has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the individual from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;

(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with section 13510 or 13152(g) of this title, including any regulations promulgated under section 13510 or 13152(g) of this title, describing the use of the in-

vestigational drug or investigational device in a single patient or a small group of patients.

(d) TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS AND TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS.—

(1) IN GENERAL.—On submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an ''expanded access protocol''), the Secretary shall permit the investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

(A) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

(B) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition

in the population of patients to which the investigational drug or investigational device is intended to be administered;

(C)(i) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in subparagraph (A) under an investigational drug application in effect under section 13510 of this title or investigational device exemption in effect under section 13152(g) of this title; or

(ii) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

(D) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in subparagraph (A) with due diligence;

(E) in the case of an investigational drug or investigational device described in subparagraph (C)(i), the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 13510 or 13152(g) of this title;

(F) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in subparagraph (A); and

(G) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

(2) APPLICABILITY OF CERTAIN PROVISIONS.—An expanded access protocol submitted under this subsection shall be subject to section 13510 or 13152(g) of this title, including regulations promulgated under section 13510 or 13152(g) of this title.

(3) AUTHORITY TO INFORM PUBLIC OF AVAILABILITY.—

(A) IN GENERAL.—The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or inves-

tigational device under expanded access protocols submitted under this subsection.

(B) CONTENT OF INFORMATION.—The information provided by the Secretary, in accordance with subparagraph (A), shall be the same type of information that is required by section 402(i)(3) of the Public Health Service Act (42 U.S.C. 282(i)(3)).

(e) TERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

**§ 14302. Expanded access policy required for investigational drugs**

(a) IN GENERAL.—The manufacturer or distributor of 1 or more investigational drugs for the diagnosis, monitoring, or treatment of 1 or more serious diseases or conditions shall make available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 14301(c) of this title for provision of such a drug.

(b) PUBLIC AVAILABILITY OF EXPANDED ACCESS POLICY.—The policies under subsection (a) shall be made

public and readily available, such as by posting the policies on a publicly available internet website.

(c) GENERAL APPLICABILITY.—The policies under subsection (a) may be generally applicable to all investigational drugs of the manufacturer or distributor.

(d) CONTENT OF POLICY.—A policy described in subsection (a) shall include—

(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

(2) procedures for making the requests;

(3) the general criteria the manufacturer or distributor will use—

(A) to evaluate the requests for individual patients; and

(B) for responses to the requests;

(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of the requests; and

(5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for the drug that is required under section 402(j)(2)(A)(ii)(II)(gg) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)(II)(gg)).

(e) NO GUARANTEE OF ACCESS.—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

(f) REVISED POLICY.—Nothing in this section prevents a manufacturer or distributor from revising a policy required under this section at any time.

(g) APPLICATION.—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the earlier of—

(1) the first initiation of a phase 2 or phase 3 study (as the terms are defined in subsections (b) and (c) of section 312.21 of title 21, Code of Federal Regulations (or any successor regulations)) with respect to the investigational drug; or

(2) as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy under subsection (b), (c), or (h), respectively, of section 13119 of this title.

**§ 14303. Investigational drugs for use by eligible patients**

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE INVESTIGATIONAL DRUG.—The term ''eligible investigational drug'' means an inves-

tigational drug (as the term is used in section 14301 of this title)—

(A) for which a Phase 1 clinical trial has been completed;

(B) that has not been approved or licensed for any use under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262);

(C)(i) for which an application has been filed under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); or

(ii) that is under investigation in a clinical trial that—

(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262); and

(II) is the subject of an active investigational new drug application under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)), as applicable; and

(D) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 13510 of this title.

(2) ELIGIBLE PATIENT.—The term ''eligible patient'' means a patient—

(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

(i) is in good standing with the physician's licensing organization or board; and

(ii) will not be compensated directly by the manufacturer for the certification; and

(C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided the consent.

(3) PHASE 1 TRIAL.—The term ''phase 1 trial'' means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

(b) EXEMPTIONS.—

(1) IN GENERAL.—Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from the provisions listed under paragraph (2) provided that the sponsor of the eligible investigational drug or any person that manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient, an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.

(2) PROVISIONS.—The provisions under this paragraph are—

(A) sections 13103(a)(4), 13305, 13502, and 13510 of this title;

(B) section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); and

(C) parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations).

(c) USE OF CLINICAL OUTCOMES.—

(1) IN GENERAL.—Notwithstanding any other provision of this subtitle, the Public Health Service Act (42 U.S.C. 201 et seq.), or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of the drug under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) unless—

(A) the Secretary makes a determination, in accordance with paragraph (2), that use of the clinical outcome is critical to determining the safety of the eligible investigational drug; or

(B) the sponsor requests use of the outcomes.

(2) LIMITATION.—

(A) NOTICE.—If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of the determination to the sponsor, including a public health justification for the determination, and

the notice shall be made part of the administrative record.

(B) DELEGATION OF DETERMINATION.—The determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

(d) REPORTING.—

(1) IN GENERAL.—

(A) SUBMISSION OF ANNUAL SUMMARY.—The manufacturer or sponsor of an eligible investigational drug shall submit to the Secretary an annual summary of any use of the drug under this section.

(B) CONTENTS.—The summary shall include the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events.

(C) REGULATION.—The Secretary—

(i) shall specify by regulation the deadline of submission of the annual summary; and

(ii) may amend section 312.33 of title 21, Code of Federal Regulations (or any

successor regulations) to require the submission of the annual summary in conjunction with the annual report for an applicable investigational new drug application for the drug.

(2) POSTING OF INFORMATION.—The Secretary shall post an annual summary report of the use of this section on the FDA website, including the number of drugs for which clinical outcomes associated with the use of an eligible investigational drug pursuant to this section was—

(A) used in accordance with subsection (c)(1)(A);

(B) used in accordance with subsection (c)(1)(B); and

(C) not used in the review of an application under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262).

(e) NO LIABILITY.—

(1) ALLEGED ACTS OR OMISSIONS.—With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to this section and in compli-

ance with this section, no liability in a cause of action shall lie against—

(A) a sponsor or manufacturer; or

(B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

(2) DETERMINATION NOT TO PROVIDE DRUG.—No liability shall lie against a sponsor, manufacturer, prescriber, dispenser, or other individual entity for its determination not to provide access to an eligible investigational drug under this section.

(3) LIMITATION.—Except as set forth in paragraphs (1) and (2), nothing in this section shall be construed to modify or otherwise affect the right of any person to bring a private action under any State or Federal product liability, tort, consumer protection, or warranty law.

**§ 14304. Dispute resolution**

(a) IN GENERAL.—If, regarding an obligation concerning drugs or devices under this subtitle or section 351 of the Public Health Service Act (42 U.S.C. 262), there is a scientific controversy between the Secretary and a per-

son that is a sponsor, applicant, or manufacturer and no specific provision of this subtitle involved, including a regulation promulgated under this subtitle, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which the sponsor, applicant, or manufacturer may request a review of the controversy, including a review by an appropriate scientific advisory panel described in section 13514 of this title or an advisory committee described in section 13142(g)(2)(B) of this title.

(b) TIMELINESS OF REVIEW.—Any review under subsection (a) shall take place in a timely manner.

**§ 14305. Classification of products**

(a) REQUEST.—

(1) IN GENERAL.—A person that submits an application or submission (including a petition, notification, and any other similar form of request) under this subtitle for a product, may submit a request to the Secretary—

(A) respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 13104 of this title; or

(B) respecting the component of the FDA that will regulate the product.

(2) RECOMMENDATION.—In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

(b) STATEMENT.—

(1) IN GENERAL.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary—

(A) shall determine—

(i) the classification of the product under subsection (a); or

(ii) the component of the FDA that will regulate the product; and

(B) shall provide to the person a written statement that identifies the classification or the component, and the reasons for the determination.

(2) MODIFICATION.—The Secretary may not modify the statement except with the written consent of the person, or for public health reasons based on scientific evidence.

(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a

final determination by the Secretary of the classification of the product, or the component of the FDA that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

**§ 14306. Authorization for medical products for use in emergencies**

(a) DEFINITIONS.—In this section:

(1) BIOLOGICAL PRODUCT.—The term ''biological product'' has the meaning given the term in section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) EMERGENCY USE.—The term ''emergency use'' means use in an actual or potential emergency.

(3) PRODUCT.—The term ''product'' means a drug, device, or biological product.

(4) UNAPPROVED PRODUCT.—The term ''unapproved product'' means a product that is not approved, licensed, or cleared for commercial distribution as described in subsection (b)(2)(A) or that is not conditionally approved as described in subsection (b)(2)(A).

(5) UNAPPROVED USE OF AN APPROVED PRODUCT.—The term ''unapproved use of an approved

product'' means a use that is not an approved, licensed, or cleared use of a product as described in subsection (b)(2)(B) or that is not a conditionally approved use of a product as described in subsection (b)(2)(B), which product is approved, licensed, or cleared as described in subsection (b)(2)(B) or conditionally approved as described in subsection (b)(2)(B).

(b) IN GENERAL.—

(1) EMERGENCY USES.—Notwithstanding any provision of this subtitle and section 351 of the Public Health Service Act (42 U.S.C. 262), and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (c), of a drug, device, or biological product intended for emergency use.

(2) APPROVAL STATUS OF PRODUCT.—An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under chapter 135 or 137 of this title, section 13136(k) or 13142 of this title, or section 351 of the Public Health

Service Act (42 U.S.C. 262) or conditionally approved under section 14502 of this title; or

(B) is approved, licensed, or cleared under chapter 135 or 137 of this title, section 13136(k) or 13142 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262), or conditionally approved under section 14502 of this title, but which use is not under chapter 135 or 137 of this title, section 13136(k) or 13142 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262) an approved, licensed, or cleared use of the product or which use is not a conditionally approved use of the product under section 14502 of this title.

(3) RELATION TO OTHER USES.—An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) referred to in paragraph (2)(A).

(c) DECLARATION OF EMERGENCY OR THREAT JUSTIFYING EMERGENCY AUTHORIZED USE.—

(1) IN GENERAL.—The Secretary may make a declaration that the circumstances exist justifying

the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or the provisions classified to title 50, of attack with—

(i) a biological, chemical, radiological, or nuclear agent or agents; or

(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to af-

fect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to the agent or agents; or

(D) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of United States citizens living abroad.

(2) TERMINATION OF DECLARATION.—

(A) IN GENERAL.—A declaration under this subsection shall terminate on the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) a change in the approval status of the product such that the circumstances

described in subsection (b)(2) have ceased to exist.

(B) DISPOSITION OF PRODUCT.—If an authorization under this section with respect to an unapproved product ceases to be effective as a result of a termination under subparagraph (A), the Secretary shall consult with the manufacturer of the product with respect to the appropriate disposition of the product.

(3) ADVANCE NOTICE OF TERMINATION.—The Secretary shall provide advance notice that a declaration under this subsection will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of the product, including the return of the product (except such quantities of product as are necessary to provide for continued use consistent with subsection (g)(2)) to the manufacturer (in the case of a manufacturer that chooses to have the product returned); and

(B) in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information

under subsection (f)(2)(B)(ii), as the case may be, that was provided with respect to the emergency use involved.

(4) PUBLICATION.—The Secretary shall promptly publish in the Federal Register each declaration, determination, and advance notice of termination under this subsection.

(5) EXPLANATION BY SECRETARY.—If an authorization under this section with respect to an unapproved product or an unapproved use of an approved product has been in effect for more than 1 year, the Secretary shall provide in writing to the sponsor of the product an explanation of the scientific, regulatory, or other obstacles to approval, licensure, or clearance of the product or use, including specific actions to be taken by the Secretary and the sponsor to overcome the obstacles.

(6) MILITARY EMERGENCIES.—In the case of a determination described in paragraph (1)(B), the Secretary shall determine, within 45 calendar days of the determination, whether to make a declaration under paragraph (1), and, if appropriate, shall promptly make such a declaration.

(d) CRITERIA FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this sec-

tion with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (c)(1)), the Secretary concludes—

(1) that an agent referred to in a declaration under subsection (c) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in diagnosing, treating, or preventing—

(i) the disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this subtitle, or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), for diagnosing, treating, or preventing such a dis-

ease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat the disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (c)(1)(D), if applicable;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition;

(4) in the case of a determination described in subsection (c)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and

(5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

(e) SCOPE OF AUTHORIZATION.—An authorization of a product under this section shall state—

(1) each disease or condition that the product may be used to diagnose, prevent, or treat within the scope of the authorization;

(2) the Secretary's conclusions, made under subsection (d)(2)(B), that the known and potential benefits of the product, when used to diagnose, pre-

vent, or treat the disease or condition, outweigh the known and potential risks of the product; and

(3) the Secretary's conclusions, made under subsection (d), concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating the diseases or conditions, including, to the extent practicable given the circumstances of the emergency, an assessment of the available scientific evidence.

(f) CONDITIONS OF AUTHORIZATION.—

(1) UNAPPROVED PRODUCT.—

(A) REQUIRED CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (c)(1), shall, for a person that carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) CONDITIONS TO ENSURE INFORMED HEALTH CARE PROFESSIONALS.—Appropriate conditions designed to ensure

that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which the benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) CONDITIONS TO ENSURE INFORMED INDIVIDUALS.—Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of

the extent to which the benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) CONDITIONS FOR MONITORING AND REPORTING OF ADVERSE EVENTS.—Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.

(iv) CONDITIONS RELATING TO RECORDKEEPING AND REPORTING BY MANUFACTURERS.—For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) AUTHORITY FOR ADDITIONAL CONDITIONS.—With respect to the emergency use of an unapproved product, the Secretary may, for a person that carries out any activity for which

the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) CONDITIONS RELATING TO DISTRIBUTION.—Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) CONDITIONS RELATING TO ADMINISTRATION.—Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to the emergency use.

(iii) CONDITIONS RELATING TO COLLECTION AND ANALYSIS OF SAFETY AND EFFECTIVENESS INFORMATION.—Appropriate conditions with respect to collection and analysis of information concerning the

safety and effectiveness of the product with respect to the use of the product during the period when the authorization is in effect and a reasonable time following the period.

(iv) CONDITIONS RELATING TO RECORDKEEPING AND REPORTING BY PERSONS OTHER THAN MANUFACTURERS.—For persons other than manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(2) UNAPPROVED USE.—With respect to the emergency use of a product that is an unapproved use of an approved product:

(A) CONDITIONS DESCRIBED IN PARAGRAPH (1)(A).—For a person that carries out any activity for which the authorization is issued, the Secretary shall, to the extent practicable given the applicable circumstances described in subsection (c)(1), establish conditions described in clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described

in clauses (iii) and (iv) of paragraph (1)(A) or in paragraph (1)(B).

(B) CONDITIONS RELATING TO LABELING.—

(i) ALTERING OR OBSCURING BY DISTRIBUTORS.—If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make the change, the authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer, except as provided in section 14307 of this title with respect to authorized changes to the product expiration date.

(ii) INFORMATION IN ADDITION TO LABELING.—In the circumstances described in clause (i), for a person that does not manufacture the product and that chooses to act under this clause, an authorization under this section regarding the emergency use shall, to the extent practicable given the circumstances of the

emergency, authorize the person to provide appropriate information with respect to the product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). While the authorization under this section is effective, the additional information shall not be considered labeling for purposes of chapter 133 of this title.

(C) RESTRICTION ON DISTRIBUTION OR ADMINISTRATION.—In establishing conditions under this paragraph with respect to the distribution and administration of the product for the unapproved use, the Secretary shall not impose conditions that would restrict distribution or administration of the product when distributed or administered for the approved use.

(3) WAIVER OR LIMITATION OF GOOD MANUFACTURING PRACTICE.—With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the applicable circumstances described in subsection (c)(1)—

(A) requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this subtitle, including the requirements established under section 13101 or 13152(f)(1) of this title, and including relevant conditions prescribed with respect to the product by an order under section 13152(f)(2) of this title;

(B) requirements established under section 13103(a), 13103(e), or 13110 of this title; and

(C) requirements established under section 13152(e) of this title.

(4) ADVERTISING.—The Secretary may establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), including, as appropriate—

(A) with respect to drugs and biological products, requirements applicable to prescription drugs pursuant to section 13311 of this title; or

(B) with respect to devices, requirements applicable to restricted devices pursuant to section 13315 of this title.

(g) DURATION OF AUTHORIZATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the termination of the declaration under subsection (c) or a revocation under subsection (h).

(2) CONTINUED USE AFTER END OF EFFECTIVE PERIOD.—Notwithstanding the termination of the declaration under subsection (c) or a revocation under subsection (h), an authorization shall continue to be effective to provide for continued use of an unapproved product with respect to a patient to whom, or an animal to which, it was administered during the period described by paragraph (1), to the extent found necessary by the patient's attending physician or by the veterinarian caring for the animal, as applicable.

(h) REVIEW AND REVOCATION OF AUTHORIZATION.—

(1) REVIEW.—The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section. As part of the

review, the Secretary shall regularly review the progress made with respect to the approval, licensure, or clearance of, or the conditional approval under section 14502 of this title of—

(A) an unapproved product for which an authorization was issued under this section; or

(B) an unapproved use of an approved product for which an authorization was issued under this section.

(2) REVISION AND REVOCATION.—The Secretary may revise or revoke an authorization under this section if—

(A) the circumstances described under subsection (c)(1) no longer exist;

(B) the criteria under subsection (d) for issuance of the authorization are no longer met; or

(C) other circumstances make the revision or revocation appropriate to protect the public health or safety.

(i) PUBLICATION; CONFIDENTIAL INFORMATION.—

(1) PUBLICATION.—

(A) FEDERAL REGISTER.—The Secretary shall promptly publish on the FDA website and in the Federal Register a notice of each author-

ization, and each termination or revocation of an authorization, under this section, and an explanation of the reasons for the authorization, termination, or revocation (which may include a summary of data or information that has been submitted to the Secretary in an application, request, or submission under this section, section 13136(k), 13140(h)(2), 13142, 13503, 13510, 13511, 13703, 13711, 13715, 14502, or 14503 of this title, subsection (g) or (m) of section 13152 of this title, or subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)), even if the summary may reveal the existence of the application, request, or submission or the data contained in the application, request, or submission).

(B) REVISIONS TO AUTHORIZATIONS TO BE AVAILABLE ONLINE.—The Secretary shall make any revisions to an authorization under this section available on the FDA website, which may include a summary of the data and information supporting the revisions.

(2) CONFIDENTIAL INFORMATION.—Nothing in this section alters or amends section 1905 of title 18 or section 552(b)(4) of title 5. Information made

publicly available by the Secretary in accordance with paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18.

(j) ACTIONS COMMITTED TO AGENCY DISCRETION.—Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

(k) RULES OF CONSTRUCTION.—The following applies with respect to this section:

(1) Nothing in this section impairs the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution.

(2) Nothing in this section impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law.

(3) Nothing in this section (including any exercise of authority by a manufacturer under subsection (f)(2)) impairs the authority of the United States to use or manage quantities of a product that are owned or controlled by the United States (including quantities in the stockpile maintained under section

319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b)).

(4) Nothing in this section shall be construed as authorizing a delay in the review or other consideration by the Secretary of any application or submission pending before the FDA for a product for which an authorization under this section is issued.

(l) RELATION TO OTHER PROVISIONS.—If a product is the subject of an authorization under this section, the use of the product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section 13510, 13711, or 13152(g) of this title, or any other provision of this subtitle or section 351 of the Public Health Service Act (42 U.S.C. 262).

(m) OPTION TO CARRY OUT AUTHORIZED ACTIVITIES.—

(1) IN GENERAL.—Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out the activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall report to the Secretary within a reasonable period of

time after the issuance by the Secretary of the authorization if the manufacturer does not intend to carry out any activity under the authorization.

(2) PERSONS ON WHICH SECTION HAS LEGAL EFFECT.—This section has legal effect only on a person that carries out an activity for which an authorization under this section is issued.

(3) EFFECT OF SUBSECTION.—This section does not modify or affect activities carried out pursuant to other provisions of this subtitle or section 351 of the Public Health Service Act (42 U.S.C. 262).

(4) AUTHORITY OF SECRETARY TO IMPOSE CONDITIONS.—Nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons that carry out any activity pursuant to an authorization under this section.

(n) CATEGORIZATION OF LABORATORY TESTS ASSOCIATED WITH DEVICES SUBJECT TO AUTHORIZATION.—

(1) IN GENERAL.—In issuing an authorization under this section with respect to a device, the Secretary may, subject to the provisions of this section, determine that a laboratory examination or procedure associated with the device shall be deemed, for purposes of section 353 of the Public Health Service

Act (42 U.S.C. 263a), to be in a particular category of examinations and procedures (including the category described by subsection (d)(3) of that section) if, based on the totality of scientific evidence available to the Secretary—

(A) the categorization would be beneficial to protecting the public health; and

(B) the known and potential benefits of the categorization under the circumstances of the authorization outweigh the known and potential risks of the categorization.

(2) CONDITIONS OF DETERMINATION.—The Secretary may establish appropriate conditions on the performance of the examination or procedure pursuant to the determination.

(3) EFFECTIVE PERIOD.—A determination under this subsection shall be effective for purposes of section 353 of the Public Health Service Act (42 U.S.C. 263a) notwithstanding any other provision of that section during the effective period of the relevant declaration under subsection (c).

**§ 14307. Emergency use of medical products**

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE PRODUCT.—The term ''eligible product'' means a product that—

(A) is approved or cleared under this division, conditionally approved under section 14502 of this title, or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262);

(B) is intended for use to prevent, diagnose, or treat—

(i) a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents; or

(ii) a serious or life-threatening disease or condition caused by a product described in clause (i); and

(C) is intended for use during the circumstances under which—

(i) a determination described in subparagraph (A), (B), or (C) of section 14306(c)(1) of this title has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(ii) the identification of a material threat described in section 14306(c)(1)(D) of this title has been made pursuant to

section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

(2) PRODUCT.—The term ''product'' means a drug, device, or biological product.

(b) EXPIRATION DATING.—

(1) DEFINITION OF EXPIRATION DATE.—In this subsection, the term ''expiration date'' means the date established through appropriate stability testing required by the regulations issued by the Secretary to ensure that the product meets applicable standards of identity, strength, quality, and purity at the time of use.

(2) IN GENERAL.—The Secretary may extend the expiration date and authorize the introduction or delivery for introduction into interstate commerce of an eligible product after the expiration date provided by the manufacturer if—

(A) the expiration date extension is intended to support the ability of the United States to protect—

(i) the public health; or

(ii) military preparedness and effectiveness; and

(B) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary.

(3) REQUIREMENTS AND CONDITIONS.—Any extension of an expiration date under paragraph (2) shall, as part of the extension, identify—

(A) each specific lot, batch, or other unit of the product for which extended expiration is authorized;

(B) the duration of the extension; and

(C) any other requirements or conditions as the Secretary may consider appropriate for the protection of the public health, which may include requirements for, or conditions on, product sampling, storage, packaging or repackaging, transport, labeling, notice to product recipients, recordkeeping, periodic testing or retesting, or product disposition.

(4) EFFECT.—Notwithstanding any other provision of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.), an eligible product shall not be considered an unapproved product (as defined in section 14306(a)(4) of this title) and shall not be deemed adulterated or misbranded under this subtitle because, with respect to the product, the Sec-

retary has, under paragraph (2), extended the expiration date and authorized the introduction or delivery for introduction into interstate commerce of the product after the expiration date provided by the manufacturer.

(c) DEVIATIONS FROM CURRENT GOOD MANUFACTURING PRACTICE.—

(1) IN GENERAL.—The Secretary may authorize, if the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) warrant the authorization, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this subtitle, including requirements under section 13101 or 13152(f)(1) of this title or applicable conditions prescribed with respect to the eligible product by an order under section 13152(f)(2) of this title.

(2) EFFECT.—Notwithstanding any other provision of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.), an eligible product shall not be considered an unapproved product (as defined in section 14306(a)(4) of this title) and shall not be

deemed adulterated or misbranded under this subtitle because, with respect to the product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

(d) EMERGENCY DISPENSING.—The requirements of sections 13103(a), 13103(e), 13110, and 13152(e) of this title shall not apply to an eligible product, and the product shall not be considered an unapproved product (as defined in section 14306(a)(4) of this title) and shall not be deemed adulterated or misbranded under this subtitle because it is dispensed without an individual prescription, if—

(1) the product is dispensed during the circumstances described in subsection (a)(1)(C); and

(2) the dispensing without an individual prescription occurs—

(A) as permitted under the law of the State in which the product is dispensed; or

(B) in accordance with an order issued by the Secretary, for the purposes and duration of the circumstances described in subsection (a)(1)(C).

(e) EMERGENCY USE INSTRUCTIONS.—

(1) IN GENERAL.—The Secretary, acting through an appropriate official within the Depart-

ment, may create and issue emergency use instructions to inform health care providers or individuals to whom an eligible product is to be administered concerning the product's approved, licensed, or cleared conditions of use.

(2) EFFECT.—Notwithstanding any other provisions of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.), a product shall not be considered an unapproved product and shall not be deemed adulterated or misbranded under this subtitle because of the issuance of emergency use instructions under paragraph (1) with respect to the product or the introduction or delivery for introduction of the product into interstate commerce accompanied by the instructions—

(A) during an emergency response to an actual emergency that is the basis for a determination described in subsection (a)(1)(C); or

(B) by a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of the government entity, in preparation for an emergency response.

**§ 14308. Products held for emergency use**

It is not a violation of any section of this subtitle or of the Public Health Service Act (42 U.S.C. 201 et seq.) for a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of such a government entity, to introduce into interstate commerce a product (as defined in section 14306(a) of this title) intended for emergency use, if that product—

(1) is intended to be held and not used; and

(2) is held and not used, unless and until that product—

(A) is approved, cleared, or licensed under chapter 135 or 137 of this title, section 13136(k) or 13142 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262) or conditionally approved under section 14502 of this title;

(B) is authorized for investigational use under chapter 135 or 137 of this title, section 13152 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262); or

(C) is authorized for use under section 14306 or 14307 of this title.

**§ 14309. Countermeasure development, review, and technical assistance**

(a) DEFINITIONS.—In this section:

(1) COUNTERMEASURE.—The term ''countermeasure'' means a qualified countermeasure, a security countermeasure, and a qualified pandemic or epidemic product.

(2) QUALIFIED COUNTERMEASURE.—The term ''qualified countermeasure'' has the meaning given the term in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a).

(3) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term ''qualified pandemic or epidemic product'' means a product that meets the definition given the term in section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) and—

(A) that has been identified by the Department or the Department of Defense as receiving funding directly related to addressing chemical, biological, radiological, or nuclear threats, including pandemic influenza; or

(B) that is included under this paragraph pursuant to a determination by the Secretary.

(4) SECURITY COUNTERMEASURE.—The term ''security countermeasure'' has the meaning given the term in section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

(b) GENERAL DUTIES.—In order to accelerate the development, stockpiling, approval, licensure, and clearance of qualified countermeasures, security countermeasures, and qualified pandemic or epidemic products, the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, shall—

(1) ensure the appropriate involvement of FDA personnel in interagency activities related to countermeasure advanced research and development, consistent with sections 319F, 319F–1, 319F–2, 319F–3, 319L, and 2811 of the Public Health Service Act (42 U.S.C. 247d–6, 247d–6a, 247d–6b, 247d–6d, 247d–7e, 300hh–10);

(2) ensure the appropriate involvement and consultation of FDA personnel in any flexible manufacturing activities carried out under section 319L of the Public Health Service Act (42 U.S.C. 247d–7e), including with respect to meeting regulatory requirements under this subtitle;

(3) promote countermeasure expertise within the FDA by—

(A) ensuring that FDA personnel involved in reviewing countermeasures for approval, licensure, or clearance are informed by the Assistant Secretary for Preparedness and Re-

sponse on the material threat assessment conducted under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) for the agent or agents for which the countermeasure under review is intended;

(B) training FDA personnel regarding review of countermeasures for approval, licensure, or clearance;

(C) holding public meetings at least twice annually to encourage the exchange of scientific ideas; and

(D) establishing protocols to ensure that countermeasure reviewers have sufficient training or experience with countermeasures;

(4) maintain teams, composed of FDA personnel with expertise on countermeasures, including specific countermeasures, populations with special clinical needs (including populations of children and pregnant women that may use countermeasures, as applicable and appropriate), classes or groups of countermeasures, or other countermeasure-related technologies and capabilities, which teams shall—

(A) consult with countermeasure experts, including countermeasure sponsors and applicants, to identify and help resolve scientific

issues related to the approval, licensure, or clearance of countermeasures, through workshops or public meetings; and

(B) improve and advance the science relating to the development of new tools, standards, and approaches to assessing and evaluating countermeasures—

(i) in order to inform the process for countermeasure approval, clearance, and licensure; and

(ii) with respect to the development of countermeasures for populations with special clinical needs, including populations of children and pregnant women, in order to meet the needs of the populations, as necessary and appropriate; and

(5) establish within the FDA a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to any manufacturer of qualified countermeasures, security countermeasures, or vaccines, at the request of the manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may

occur in the United States in the supply of the vaccines or countermeasures and that the provision of the assistance would be beneficial in helping alleviate or avert the shortage.

(c) FINAL GUIDANCE ON DEVELOPMENT OF ANIMAL MODELS.—The Secretary shall provide final guidance to industry regarding the development of animal models to support approval, clearance, or licensure of countermeasures referred to in subsection (a) when human efficacy studies are not ethical or feasible.

(d) DEVELOPMENT AND ANIMAL MODELING PROCEDURES.—

(1) AVAILABILITY OF ANIMAL MODEL MEETINGS.—To facilitate the timely development of animal models and support the development, stockpiling, licensure, approval, and clearance of countermeasures, the Secretary shall establish a procedure by which a sponsor or applicant that is developing a countermeasure for which human efficacy studies are not ethical or practicable, and that has an approved investigational new drug application or investigational device exemption, may request and receive—

(A) a meeting to discuss proposed animal model development activities; and

(B) a meeting prior to initiating pivotal animal studies.

(2) PEDIATRIC MODELS.—To facilitate the development and selection of animal models that could translate to pediatric studies, any meeting conducted under paragraph (1) shall include discussion of animal models for pediatric populations, as appropriate.

(e) REVIEW AND APPROVAL OF COUNTERMEASURES.—

(1) MATERIAL THREAT.—When evaluating an application or submission for approval, licensure, or clearance of a countermeasure, the Secretary shall take into account the material threat posed by the chemical, biological, radiological, or nuclear agent or agents identified under section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) for which the countermeasure under review is intended.

(2) REVIEW EXPERTISE.—When practicable and appropriate, teams of FDA personnel reviewing applications or submissions described under paragraph (1) shall include a reviewer with sufficient training or experience with countermeasures pursuant to the protocols established under subsection (b)(3)(D).

(f) REGULATORY MANAGEMENT PLAN.—

(1) DEFINITION OF ELIGIBLE COUNTERMEASURE.—In this subsection, the term ''eligible countermeasure'' means—

(A) a security countermeasure with respect to which the Secretary has entered into a procurement contract under section 319F–2(c) of the Public Health Service Act (42 U.S.C. 247d–6b(c)); or

(B) a countermeasure with respect to which the Biomedical Advanced Research and Development Authority has provided funding under section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) for advanced research and development.

(2) REGULATORY MANAGEMENT PLAN PROCESS.—The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority, shall establish a formal process for obtaining scientific feedback and interactions regarding the development and regulatory review of eligible countermeasures by facilitating the development of written regulatory management plans in accordance with this subsection.

(3) PUBLICATION.—The Secretary shall make available on the FDA website information regarding regulatory management plans, including—

(A) the process by which an applicant may submit a request for a regulatory management plan;

(B) the timeframe by which the Secretary is required to respond to the request under subparagraph (A);

(C) the information required for the submission of the request under subparagraph (A);

(D) a description of the types of development milestones and performance targets that could be discussed and included in the regulatory management plans; and

(E) contact information for beginning the regulatory management plan process.

(4) SUBMISSION OF REQUEST AND PROPOSED PLAN BY SPONSOR OR APPLICANT.—

(A) IN GENERAL.—A sponsor or applicant of an eligible countermeasure may initiate the process described under paragraph (2) on submission of a written request to the Secretary. The request shall include a proposed regulatory management plan.

(B) TIMING OF SUBMISSION.—A sponsor or applicant may submit a written request under subparagraph (A) after the eligible countermeasure has an investigational new drug or investigational device exemption in effect.

(C) RESPONSE BY SECRETARY.—The Secretary shall direct the FDA, on submission of a written request by a sponsor or applicant under subparagraph (A), to work with the sponsor or applicant to agree on a regulatory management plan within a reasonable time not to exceed 90 days. If the Secretary determines that no plan can be agreed on, the Secretary shall provide to the sponsor or applicant, in writing, the scientific or regulatory rationale why an agreement cannot be reached.

(5) PLAN.—The content of a regulatory management plan agreed to by the Secretary and a sponsor or applicant shall include—

(A) an agreement between the Secretary and the sponsor or applicant regarding developmental milestones that will trigger responses by the Secretary as described in subparagraph (B);

(B) performance targets and goals for timely and appropriate responses by the Sec-

retary to the triggers described under subparagraph (A), including meetings between the Secretary and the sponsor or applicant, written feedback, decisions by the Secretary, and other activities carried out as part of the development and review process; and

(C) an agreement on how the plan shall be modified, if needed.

(6) MILESTONES AND PERFORMANCE TARGETS.—The developmental milestones described in paragraph (5)(A) and the performance targets and goals described in paragraph (5)(B) shall include—

(A) feedback from the Secretary regarding the data required to support the approval, clearance, or licensure of the eligible countermeasure involved;

(B) feedback from the Secretary regarding the data necessary to inform any authorization under section 14306 of this title;

(C) feedback from the Secretary regarding the data necessary to support the positioning and delivery of the eligible countermeasure, including to the Strategic National Stockpile;

(D) feedback from the Secretary regarding the data necessary to support the submission of

protocols for review under section 13503(e)(2)(B) of this title;

(E) feedback from the Secretary regarding any gaps in scientific knowledge that will need resolution prior to approval, licensure, or clearance of the eligible countermeasure and plans for conducting the necessary scientific research;

(F) identification of the population for which the countermeasure sponsor or applicant seeks approval, licensure, or clearance and the population for which desired labeling would not be appropriate, if known; and

(G) as necessary and appropriate, and to the extent practicable, a plan for demonstrating safety and effectiveness in pediatric populations, and for developing pediatric dosing, formulation, and administration with respect to the eligible countermeasure, provided that the plan would not delay authorization under section 14306 of this title, approval, licensure, or clearance for adults.

(7) PRIORITIZATION.—

(A) PLANS FOR SECURITY COUNTERMEASURES.—The Secretary shall establish regulatory management plans for all security coun-

termeasures for which a request is submitted under paragraph (4)(A).

(B) PLANS FOR OTHER ELIGIBLE COUNTERMEASURES.—The Secretary shall determine whether resources are available to establish regulatory management plans for eligible countermeasures that are not security countermeasures. If resources are available to establish regulatory management plans for eligible countermeasures that are not security countermeasures, and if resources are not available to establish regulatory management plans for all eligible countermeasures for which requests have been submitted, the Director of the Biomedical Advanced Research and Development Authority, in consultation with the Commissioner, shall prioritize which eligible countermeasures may receive regulatory management plans.

(g) ANNUAL REPORT.—The Secretary shall annually make publicly available on the FDA website a report that details the countermeasure development and review activities of the FDA, including—

(1) with respect to the development of new tools, standards, and approaches to assess and evaluate countermeasures—

(A) the identification of the priorities of the FDA and the progress made on those priorities; and

(B) the identification of scientific gaps that impede the development, approval, licensure, or clearance of countermeasures for populations with special clinical needs, including for populations of children and pregnant women, and the progress made on resolving these challenges;

(2) with respect to countermeasures for which a regulatory management plan has been agreed on under subsection (f), the extent to which the performance targets and goals set forth in subsection (f)(5)(B) and the regulatory management plan have been met, including, for each of those countermeasures—

(A) whether the regulatory management plan was completed within the required timeframe, and the length of time taken to complete the plan;

(B) whether the Secretary adhered to the timely and appropriate response times set forth in the plan; and

(C) explanations for any failure to meet the performance targets and goals;

(3) the number of regulatory teams established pursuant to subsection (b)(4), the number of products, classes of products, or technologies assigned to each of those regulatory teams, and the number of, type of, and any progress made as a result of consultations carried out under subsection (b)(4)(A);

(4) an estimate of resources obligated to countermeasure development and regulatory assessment, including—

(A) Center-specific objectives and accomplishments; and

(B) the number of full-time equivalent employees of the FDA who directly support the review of countermeasures;

(5) the number of countermeasure applications and submissions submitted, the number of countermeasures approved, licensed, or cleared, the status of remaining submitted applications and submissions, and the number of each type of authorization issued pursuant to section 14306 of this title;

(6) the number of written requests for a regulatory management plan submitted under subsection (f)(4)(A), the number of regulatory management plans developed, and the number of the plans developed for security countermeasures; and

(7) the number, type, and frequency of meetings between the FDA and—

(A) sponsors of a countermeasure; or

(B) another agency engaged in development or management of portfolios for the countermeasures, including the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the appropriate agencies of the Department of Defense.

(h) ACCELERATING COUNTERMEASURE DEVELOPMENT AND REVIEW DURING AN EMERGENCY.—

(1) ACCELERATION OF COUNTERMEASURE DEVELOPMENT AND REVIEW.—The Secretary may, at the request of the sponsor of a countermeasure, during a domestic, military, or public health emergency or material threat described in section 14307(a)(1)(C) of this title, expedite the development and review of countermeasures that are in-

tended to address the domestic, military, or public health emergency or material threat for approval, licensure, clearance, or authorization under this title or section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) ACTIONS.—The actions to expedite the development and review of a countermeasure under paragraph (1) may include the following:

(A) Expedited review of submissions made by sponsors of countermeasures to the FDA, including rolling submissions of countermeasure applications and other submissions.

(B) Expedited and increased engagement with sponsors regarding countermeasure development and manufacturing, including—

(i) holding meetings with the sponsor and the review team and providing timely advice to, and interactive communication with, the sponsor regarding the development of the countermeasure to ensure that the development program to gather the nonclinical and clinical data necessary for approval, licensure, clearance, or authorization is as efficient as practicable;

(ii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iii) assigning a cross-disciplinary project lead for the review team to facilitate;

(iv) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment; and

(v) streamlining the review of approved, licensed, cleared, or authorized countermeasures to treat or prevent new or emerging threats, including the review of any changes to the countermeasures.

(C) Expedited issuance of guidance documents and publication of other regulatory information regarding countermeasure development and manufacturing.

(D) Other steps to expedite the development and review of a countermeasure application submitted for approval, licensure, clear-

ance, or authorization, as the Secretary determines appropriate.

(3) LIMITATION OF EFFECT.—Nothing in this subsection shall be construed to require the Secretary to grant, or take any other action related to, a request of a sponsor to expedite the development and review of a countermeasure for approval, licensure, clearance, or authorization under paragraph (1).

(i) THIRD PARTY EVALUATION OF TESTS USED DURING AN EMERGENCY.—

(1) IN GENERAL.—For purposes of conducting evaluations regarding whether an in vitro diagnostic product (as defined in section 809.3 of title 21, Code of Federal Regulations, or any successor regulations) for which a request for emergency use authorization is submitted under section 14306 of this title meets the criteria for issuance of the authorization, the Secretary may, as appropriate, consult with persons with appropriate expertise with respect to the evaluations or enter into cooperative agreements or contracts with those persons under which those persons conduct the evaluations and make recommendations, including, as appropriate, evaluations and rec-

ommendations regarding the scope of authorization and conditions of authorization.

(2) REQUIREMENTS REGARDING EVALUATIONS AND RECOMMENDATIONS.—

(A) IN GENERAL.—In evaluating and making recommendations to the Secretary regarding the validity, accuracy, and reliability of in vitro diagnostic products, as described in paragraph (1), a person shall consider and document whether the relevant criteria under section 14306(d)(2) of this title for issuance of authorization under that section are met with respect to the in vitro diagnostic product.

(B) WRITTEN RECOMMENDATIONS.—Recommendations made by a person under this subsection shall be submitted to the Secretary in writing, and shall include the reasons for the recommendation and other information that may be requested by the Secretary.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the Secretary to consult with, or enter into cooperative agreements or contracts with, persons as described in paragraph (1) for purposes of authorizing an in vitro diagnostic product or otherwise affecting the

emergency use authorization authorities under this section or section 14306 of this title.

**§ 14310. Priority review to encourage treatments for agents that present national security threats**

(a) DEFINITIONS.—In this section:

(1) HUMAN DRUG APPLICATION.—The term ''human drug application'' has the meaning given the term in section 17906(a) of this title.

(2) MATERIAL THREAT MEDICAL COUNTERMEASURE APPLICATION.—The term ''material threat medical countermeasure application'' means an application that—

(A) is a human drug application for a drug intended for use—

(i) to prevent or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(2)(A)(ii)); or

(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and

may be caused by administering a drug or biological product against the agent; and

(B) the Secretary determines is eligible for priority review;

(C) is approved after December 13, 2016; and

(D) is for—

(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 13503(a) of this title; or

(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act (42 U.S.C. 262).

(3) PRIORITY REVIEW.—The term ''priority review'', with respect to a human drug application, means review and action by the Secretary on the human drug application not later than 6 months after receipt by the Secretary of the human drug application, as described in the Manual of Policies and

Procedures in the FDA and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 (Public Law 112–144, title I, 126 Stat. 996).

(4) PRIORITY REVIEW VOUCHER.—The term ''priority review voucher'' means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of the voucher to priority review of a single human drug application submitted under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) after the date of approval of the material threat medical countermeasure application.

(b) PRIORITY REVIEW VOUCHER.—

(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application on approval by the Secretary of the material threat medical countermeasure application.

(2) TRANSFERABILITY.—The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to the voucher to a sponsor of a human drug

for which an application under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before the voucher is used.

(3) NOTIFICATION.—

(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary, not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher, of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. The notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of the sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after the notification is provided, if the

sponsor has not yet submitted the human drug application described in the notification.

(c) PRIORITY REVIEW USER FEE.—

(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). The fee shall be in addition to any fee required to be submitted by the sponsor under division F.

(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year, for that fiscal year, the amount of the priority review user fee.

(4) PAYMENT.—

(A) IN GENERAL.—The priority review user fee required by this subsection shall be due on the submission of a human drug application under section 13503(a) of this title or section

351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for which the priority review voucher is used.

(B) INCOMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying the fees.

(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the FDA; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary

shall publish a notice in the Federal Register and on the FDA website not later than 30 calendar days after the occurrence of each of the following:

(1) The Secretary issues a priority review voucher under this section.

(2) The Secretary approves a drug pursuant to an application submitted under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) for which the sponsor of the application used a priority review voucher issued under this section.

(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this subtitle, except that a sponsor of a material threat medical countermeasure application shall not receive more than 1 priority review voucher issued under any section of this subtitle with respect to the drug.

(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) that encourage the development of medical countermeasures.

(g) SUNSET.—The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.

**§ 14311. Medical countermeasure master files**

(a) DEFINITIONS.—In this section:

(1) MASTER FILE HOLDER.—The term ''master file holder'' means a person that submits data and information to the Secretary with the intent to reference or authorize another person to reference the data or information to support a medical countermeasure submission, as described in subsection (b).

(2) MEDICAL COUNTERMEASURE SUBMISSION.—The term ''medical countermeasure submission'' means an investigational new drug application under section 13510 of this title, a new drug application under section 13503 of this title, or an abbreviated new drug application under section 13511 of this title, a biological product license application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) or a biosimilar biological product license application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), a new animal drug application under section 13703(a) of this title or abbreviated new animal drug application under section 13703(b) of this title, an applica-

tion for conditional approval of a new animal drug under section 14502 of this title, an investigational device application under section 13152(g) of this title, an application with respect to a device under section 13142(c) of this title, a request for classification of a device under section 13140(h)(2) of this title, a notification with respect to a device under section 13136(k) of this title, or a request for an emergency use authorization under section 14306 of this title to support—

(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

(3) QUALIFIED COUNTERMEASURE.—The term ''qualified countermeasure'' has the meaning given the term in section 319F–1 of the Public Health Service Act (42 U.S.C. 247d–6a).

(4) QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT.—The term ''qualified pandemic or epidemic product'' has the meaning given the term in section

319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d).

(5) SECURITY COUNTERMEASURE.—The term ''security countermeasure'' has the meaning given the term in section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b).

(b) APPLICABILITY OF REFERENCE.—

(1) IN GENERAL.—A person may submit data and information in a master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, the data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to the person authorized to reference the master file. The data and information shall be available for reference by the master file holder or by a person authorized by the master file holder, in accordance with applicable privacy and confidentiality protocols and regulations.

(2) REFERENCE OF CERTAIN MASTER FILES.—In the case that data or information within a medical countermeasure master file is used only to support the conditional approval of an application filed

under section 14502 of this title, the master file may be relied on to support the effectiveness of a product that is the subject of a subsequent medical countermeasure submission only if the application is supplemented by additional data or information to support review and approval in a manner consistent with the standards applicable to the review and approval for the countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

(c) MEDICAL COUNTERMEASURE MASTER FILE CONTENT.—

(1) IN GENERAL.—A master file under this section may include data or information to support—

(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of 1 or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

(2) REQUIRED UPDATES.—The Secretary may require, as appropriate, that the master file holder ensure that the contents of the master file are up-

dated during the time the master file is referenced for a medical countermeasure submission.

(d) SPONSOR REFERENCE.—

(1) IN GENERAL.—Each incorporation of data or information within a medical countermeasure master file shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of the information within the master file without necessitating resubmission of the data or information. Master files shall be submitted in an electronic format in accordance with sections 13703(d), 14502(b)(4), and 18102 of this title, as applicable, and as specified in applicable guidance.

(2) REFERENCE BY A MASTER FILE HOLDER.—A master file holder that is the sponsor of a medical countermeasure submission shall notify the Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

(3) REFERENCE BY AN AUTHORIZED PERSON.—A person submitting an application for review may, where the Secretary determines appropriate, incorporate by reference all or part of the contents of a medical countermeasure master file, if the mas-

ter file holder authorizes the incorporation in writing.

(e) ACKNOWLEDGMENT OF AND RELIANCE ON A MASTER FILE BY THE SECRETARY.—

(1) IN GENERAL.—The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied on specified data or information within a master file and the purposes for which the data or information was incorporated by reference if the Secretary has reviewed and relied on the specified data or information to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely on the data and information within the medical countermeasure master file for which the written notification was provided in additional applications, as applicable and appropriate and on the request of the master file holder so notified in writing or by an authorized person of the holder.

(2) CERTAIN APPLICATIONS.—If the Secretary has reviewed and relied on specified data or information within a medical countermeasure master file to

support the conditional approval of an application under section 14502 of this title to subsequently support the approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product, the Secretary shall provide a brief written description to the master file holder regarding the elements of the application fulfilled by the data or information within the master file and how the data or information contained in the application meets the standards of evidence under section 13504 or 13505 of this title, section 13701(3) of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262) (as applicable), which written description shall not include any trade secret or confidential commercial information.

(f) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to—

(1) limit the authority of the Secretary to approve, license, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to, as applicable, this subtitle or section 351 of the Public Health Service Act (42 U.S.C. 262) (as the subtitle or Act, as applicable, is in effect on June 23, 2019), including the standards of evidence,

and applicable conditions, for approval under the subtitle or Act, as applicable;

(2) alter the standards of evidence with respect to approval, licensure, or clearance, as applicable, of drugs, biological products, or devices under this subtitle or section 351 of the Public Health Service Act (42 U.S.C. 262), including, as applicable, the substantial evidence standards under sections 13505 and 13701(3) of this title and section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); or

(3) alter the authority of the Secretary under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) to determine the types of data or information previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under section 13136(k), 13140(h)(2), 13142(c), 13152(g), 13503, 13510, 13511, 13703(a), 13703(b), 13711, 14306, or 14502 of this title, or subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262), including a supplement or amendment to any such submission, and the requirements associated with the reference.

**§ 14312. Critical Path Public-Private Partnerships**

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term ''eligible entity'' means an entity—

(A) that is—

(i) an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)) or a consortium of those institutions; or

(ii) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and exempt from tax under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a));

(B) that has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative of the FDA; and

(C) that demonstrates to the Secretary's satisfaction that the entity is capable of—

(i) developing and critically evaluating tools, methods, and processes—

(I) to increase efficiency, predictability, and productivity of medical product development; and

(II) to more accurately identify the benefits and risks of new and existing medical products;

(ii) establishing partnerships, consortia, and collaborations with—

(I) health care practitioners and other providers of health care goods or services;

(II) pharmacists;

(III) pharmacy benefit managers and purchasers;

(IV) health maintenance organizations and other managed health care organizations;

(V) health care insurers;

(VI) government agencies;

(VII) patients and consumers;

(VIII) manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and

(IX) academic scientists; and

(iii) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(2) MEDICAL PRODUCT.—The term ''medical product'' includes a drug, a biological product as defined in section 351 of the Public Health Service Act (42 U.S.C. 262), a device, and any combination of those products.

(b) ESTABLISHMENT.—The Secretary, acting through the Commissioner, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with 1 or more eligible entities to implement the Critical Path Initiative of the FDA by developing innovative, collaborative projects in research, education, and outreach for the purpose of—

(1) fostering medical product innovation;

(2) enabling the acceleration of medical product development, manufacturing, and translational therapeutics; and

(3) enhancing medical product safety.

(c) FUNDING.—The Secretary may not enter into a collaborative agreement under subsection (b) unless the eligible entity involved provides an assurance that the entity

will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the FDA unless the entity provides assurances in its agreement with the FDA that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(d) ANNUAL REPORT.—The Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall annually submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) reviewing the operations and activities of the Partnerships in the previous year; and

(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $6,000,000 for each of fiscal years 2023 through 2027.

**§ 14313. Emerging technology program**

(a) PROGRAM ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a program to support the adoption of, and improve

the development of, innovative approaches to drug design and manufacturing.

(2) ACTIONS.—In carrying out the program under paragraph (1), the Secretary may—

(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative drug product design and manufacturing;

(B) solicit information regarding, and conduct or support research on, innovative approaches to drug product design and manufacturing;

(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

(D) convene working groups to support drug product design and manufacturing research and development;

(E) support education and training for regulatory staff and scientists related to innovative approaches to drug product design and manufacturing;

(F) advance regulatory science related to the development and review of innovative ap-

proaches to drug product design and manufacturing;

(G) convene or participate in working groups to support the harmonization of international regulatory requirements related to innovative approaches to drug product design and manufacturing; and

(H) award grants or contracts to carry out or support the program under paragraph (1).

(3) GRANTS AND CONTRACTS.—To seek a grant or contract under this section, an entity shall submit an application—

(A) in such form and manner as the Secretary may require; and

(B) containing such information as the Secretary may require, including a description of—

(i) how the entity will conduct the activities to be supported through the grant or contract; and

(ii) how the activities will further research and development related to, or adoption of, innovative approaches to drug product design and manufacturing.

(b) GUIDANCE.—The Secretary shall—

(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to drug product design and manufacturing; and

(2) include in the guidance descriptions of—

(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to drug product design and manufacturing, including updates and improvements to the technologies after product approval; and

(B) data that can be used to demonstrate the identity, safety, purity, and potency of drugs manufactured using the technologies.

(c) REPORT TO CONGRESS.—Not later than 4 years after December 29, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

(1) an annual accounting of the allocation of funds made available to carry out this section;

(2) a description of how FDA staff were utilized to carry out this section and, as applicable, any challenges or limitations related to staffing;

(3) the number of public meetings held or participated in by the FDA pursuant to this section, including meetings convened as part of a working group described in subparagraph (D) or (G) of subsection (a)(2), and the topics of each meeting; and

(4) the number of drug products approved or licensed, after December 29, 2022, using an innovative approach to drug product design and manufacturing.

**§ 14314. Risk communication**

(a) DEFINITION OF COMMITTEE.—In this section, the term ''Committee'' means the Advisory Committee on Risk Communication established under subsection (b).

(b) ADVISORY COMMITTEE ON RISK COMMUNICATION.—

(1) IN GENERAL.—The Secretary shall establish the Advisory Committee on Risk Communication.

(2) DUTIES OF COMMITTEE.—The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the FDA.

(3) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in

subsection (c), and representatives of patient, consumer, and health professional organizations.

(4) PERMANENCE OF COMMITTEE.—Section 1013 of title 5 shall not apply to the Committee.

(c) PARTNERSHIPS FOR RISK COMMUNICATION.—

(1) IN GENERAL.—The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multifaceted systems for communication to health care providers about emerging postmarket drug risks.

(2) PARTNERSHIPS.—The systems developed under paragraph (1) shall—

(A) account for the diversity among physicians in terms of practice, willingness to adopt technology, and medical specialty; and

(B) include the use of existing communication channels, including electronic communications, in place at the FDA.

**§ 14315. Notification**

(a) DEFINITION OF REGULATED PERSON.—In this section, the term ''regulated person'' means—

(1) a person that is required to register under section 13136 or 20101(s) of this title;

(2) a wholesale distributor of a drug product; or

(3) any other person that distributes drugs, except a person that distributes drugs exclusively for retail sale.

(b) NOTIFICATION TO SECRETARY.—With respect to a drug, the Secretary may require notification to the Secretary by a regulated person if the regulated person knows—

(1) that the use of the drug in the United States may result in serious injury or death;

(2) of a significant loss or known theft of the drug intended for use in the United States; or

(3) that—

(A) the drug has been or is being counterfeited; and

(B)(i) the counterfeit product is in commerce in the United States or could be reasonably expected to be introduced into commerce in the United States; or

(ii) the drug has been or is being imported into the United States or may reasonably be expected to be offered for import into the United States.

(c) MANNER OF NOTIFICATION.—Notification under this section shall be made in such manner and by such

means as the Secretary may specify by regulation or guidance.

(d) EFFECT OF SECTION.—Nothing in this section shall be construed as limiting any other authority of the Secretary to require notifications related to a drug under any other provision of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.).

**§ 14316. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments**

(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the FDA of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 (Public Law 112–144, title I, 126 Stat. 996), the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for

consultations with stakeholders on the topics described in subsection (b).

(2) CONSULTATION WITH EXTERNAL EXPERTS.—

(A) IN GENERAL.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (b). The Secretary may, when appropriate to address a specific regulatory question, consult the external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), if the consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and the necessary expertise can be provided by the external experts.

(B) EXTERNAL EXPERTS.—For purposes of subparagraph (A), external experts are individuals who possess scientific or medical train-

ing that the Secretary lacks with respect to 1 or more rare diseases.

(b) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

(1) rare diseases;

(2) the severity of rare diseases;

(3) the unmet medical need associated with rare diseases;

(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

(5) an assessment of the benefits and risks of therapies to treat rare diseases;

(6) the general design of clinical trials for rare disease populations and subpopulations;

(7) the demographics and the clinical description of patient populations; and

(8) the science of small population studies.

(c) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special Government employees, as defined under section 202 of title 18.

(d) PROTECTION OF CONFIDENTIAL INFORMATION AND TRADE SECRETS.—

(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter the protections of-

fered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5 as the provisions would be applied to consultation with individuals and organizations prior to July 9, 2012.

(2) CONSENT REQUIRED FOR DISCLOSURE.—The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special Government employee (as defined under section 202 of title 18) or the disclosure is otherwise authorized by law.

(e) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to July 9, 2012.

(f) EFFECT OF SECTION.—

(1) NO RIGHT TO CONSULTATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder.

(2) NO ALTERING OF GOALS.—Nothing in this section shall be construed to alter agreed on goals

and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 (Public Law 112–144, title I, 126 Stat. 996).

(3) NO CHANGE TO NUMBER OF REVIEW CYCLES.—Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

(g) NO DELAY IN PRODUCT REVIEW.—

(1) IN GENERAL.—Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 13510 of this title, a new drug application under section 13503 of this title, or a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262), the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or appropriate Division Director), as appropriate, shall determine that—

(A) the consultation will—

(i) facilitate the Secretary's ability to complete the Secretary's review; and

(ii) address outstanding deficiencies in the application; or

(B) the sponsor authorized the consultation.

(2) LIMITATION.—The requirements of this subsection shall apply only in instances where the consultation is undertaken solely under the authority of this section. The requirements of this subsection shall not apply to any consultation initiated under any other authority.

**§ 14317. Optimizing global clinical trials**

(a) DEFINITION OF MEDICAL PRODUCT.—In this section, the term ''medical product'' means—

(1) a drug;

(2) a device; or

(3) a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))).

(b) IN GENERAL.—The Secretary shall—

(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically driven clinical trial standards with respect to medical products around the world; and

(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers

seeking simultaneous global development of new medical products in order to—

(A) enhance medical product development;

(B) facilitate the use of foreign data; and

(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or nonclinical studies.

(c) SAVINGS CLAUSE.—Nothing in this section alters the criteria for evaluating the safety or effectiveness of a medical product under this subtitle or under the Public Health Service Act (42 U.S.C. 201 et seq.).

**§ 14318. Use of clinical investigation data from outside the United States**

(a) IN GENERAL.—In determining whether to approve, license, or clear a drug, biological product, or device pursuant to an application submitted under this division, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that the data are adequate under applicable standards to support approval, licensure, or clearance of the drug, biological product, or device in the United States.

(b) NOTICE TO SPONSOR.—If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the

European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug, biological product, or device pursuant to an application submitted under this division, the Secretary shall provide written notice to the sponsor of the application of the finding and include the rationale for the finding.

**§ 14319. Patient participation in medical product discussion**

(a) DEFINITIONS.—In this section:

(1) FINANCIAL INTEREST.—The term ''financial interest'' means a financial interest under section 208(a) of title 18.

(2) PATIENT EXPERIENCE DATA.—The term ''patient experience data'' includes data that—

(A) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

(B) are intended to provide information about patients' experiences with a disease or condition, including—

(i) the impact (including physical and psychosocial impacts) of the disease or

condition, or a related therapy or clinical investigation, on patients' lives; and

(ii) patient preferences with respect to treatment of the disease or condition.

(b) PATIENT ENGAGEMENT IN DRUGS AND DEVICES.—

(1) IN GENERAL.—The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

(A) fostering participation of a patient representative who may serve as a special Government employee (as defined under section 202 of title 18) in appropriate agency meetings with medical product sponsors and investigators; and

(B) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

(2) PROTECTION OF PROPRIETARY INFORMATION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, or policies governing disclosure of confidential commercial or trade secret information and any other infor-

mation exempt from disclosure pursuant to section 552(b) of title 5 as the laws, regulations, or policies would apply to consultation with individuals and organizations prior to July 9, 2012.

(3) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to July 9, 2012.

(4) EFFECT OF SECTION.—

(A) NO RIGHT TO CONSULTATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder.

(B) NO ALTERING OF GOALS AND PROCEDURES.—Nothing in this section shall be construed to alter agreed on goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012 (Public Law 112–144, title I, 126 Stat. 996).

(C) NO CHANGE TO NUMBER OF REVIEW CYCLES.—Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

(c) STATEMENT OF PATIENT EXPERIENCE.—

(1) IN GENERAL.—Following the approval of an application that was submitted under section 13503 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) at least 180 days after December 13, 2016, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of the application.

(2) DATA AND INFORMATION.—The data and information referred to in paragraph (1) are—

(A) patient experience data;

(B) information on patient-focused drug development tools; and

(C) other relevant information, as determined by the Secretary.

(d) INAPPLICABILITY OF CHAPTER 35 OF TITLE 44.—Chapter 35 of title 44 shall not apply to the collection of information to which a response is voluntary, which collection is initiated by the Secretary under this section.

**§ 14320. Notification, nondistribution, and recall of controlled substances**

(a) ORDER TO CEASE DISTRIBUTION AND RECALL.—

(1) IN GENERAL.—If the Secretary determines there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death, the Secretary may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists that distribute the controlled substance to immediately cease distribution of the controlled substance.

(2) HEARING.—An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on—

(A) whether adequate evidence exists to justify an amendment to the order; and

(B) what actions are required by the amended order pursuant to paragraph (3).

(3) ORDER RESOLUTION.—After an order is issued according to the process under paragraphs (1) and (2), the Secretary shall, except as provided in paragraph (4)—

(A) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

(B) continue the order ceasing distribution of the controlled substance until a date specified in the order; or

(C) amend the order to require a recall of the controlled substance, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding the recall.

(4) RISK ASSESSMENT.—If the Secretary determines that the risk of recalling a controlled substance presents a greater health risk than the health risk of not recalling the controlled substance from use, an amended order under subparagraph (B) or (C) of paragraph (3) shall not include either a recall order for, or an order to cease distribution of, the controlled substance, as applicable.

(5) ACTION FOLLOWING ORDER.—Any person that is subject to an order pursuant to subparagraph (B) or (C) of paragraph (3) shall immediately cease distribution of or recall, as applicable, the controlled

substance and provide notification as required by the order.

(b) NOTICE TO PERSONS AFFECTED.—

(1) IN GENERAL.—If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to subsection (a)(1) or an amended order pursuant to subparagraph (B) or (C) of subsection (a)(3) to provide either a notice of a recall order for, or an order to cease distribution of, the controlled substance, as applicable, under this section to appropriate persons, including persons that manufacture, distribute, import, or offer for sale the product that is the subject of an order and to the public.

(2) ASSISTANCE OF HEALTH PROFESSIONALS.—In providing the notice under paragraph (1), the Secretary may use the assistance of health professionals who prescribed or dispensed the controlled substances.

(c) NONDELEGATION.—

(1) IN GENERAL.—An order described in subsection (a)(3) shall be ordered by the Secretary or an official designated by the Secretary.

(2) DESIGNATED OFFICIAL.—An official may not be designated under paragraph (1) unless the of-

ficial is the Director of the Center for Drug Evaluation and Research or an official senior to the Director.

(d) SAVINGS CLAUSE.—Nothing in this section shall be construed as limiting—

(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, any drug under any other provision of this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.); or

(2) the ability of the Secretary to request any person to perform a voluntary activity related to any drug subject to this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.).

# Chapter 145—New Animal Drugs for Minor Use and Minor Species

Sec.
14501. Definition of transgenic animal.
14502. Conditional approval of new animal drugs for minor use and minor species and certain new animal drugs.
14503. Index of legally marketed unapproved new animal drugs for minor species.
14504. Designated new animal drugs for minor use or minor species.

## § 14501. Definition of transgenic animal

In this chapter, the term ''transgenic animal'' means an animal whose genome contains a nucleotide sequence that has been intentionally modified in vitro, and the progeny of such an animal. The term ''transgenic animal'' does not include an animal of which the nucleotide sequence

of the genome has been modified solely by selective breeding.

**§ 14502. Conditional approval of new animal drugs for minor use and minor species and certain new animal drugs**

(a) DEFINITION OF DATE OF APPROVAL.—In this section, with respect to an application described in subsection (e)(3), the term ''date of approval'' means the later of—

(1) the date an application under subsection (b) is conditionally approved under subsection (c); or

(2) the date of issuance of the interim final rule controlling the drug.

(b) APPLICATION.—

(1) IN GENERAL.—

(A) FILING OF APPLICATION.—Except as provided in paragraph (3), any person may file with the Secretary an application for conditional approval of—

(i) a new animal drug intended for a minor use or a minor species; or

(ii) a new animal drug not intended for a minor use or minor species—

(I) that is intended to treat a serious or life-threatening disease or

condition or addresses an unmet animal or human health need; and

(II) for which the Secretary determines that a demonstration of effectiveness would require a complex or particularly difficult study or studies.

(B) ISSUANCE OF GUIDANCE OR REGULATIONS.—The Secretary shall issue guidance or regulations further clarifying the criteria specified in subparagraph (A)(ii).

(C) COMPLIANCE WITH OTHER PROVISIONS OF LAW.—An application under this paragraph shall comply in all respects with—

(i) chapter 137 of this title, except sections 13702(d), 13703(b), 13704(a), 13704(b), 13704(c), 13705(a), 13706, 13709, and 13715 of this title unless otherwise stated in this section; and

(ii) any additional provisions of this section.

(D) APPLICABILITY OF SAFETY STANDARDS.—New animal drugs for which conditional approval is sought under this section are subject to the same safety standards that would be applied to new animal drugs under section

13705 of this title (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).

(2) SUBMISSION REQUIREMENTS.—The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

(A) all information necessary to meet the requirements of section 13703(a) of this title except section 13703(a)(2)(A) of this title;

(B) full reports of investigations that have been made to show—

(i) whether or not the drug is safe under section 13705 of this title (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance); and

(ii) that there is a reasonable expectation of effectiveness for use;

(C) data for establishing a conditional dose;

(D) projections of expected need and the justification for that expectation based on the best information available;

(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 13705(a)(1)(E) of this title within 5 years.

(3) FILING OF APPLICATION NOT AUTHORIZED.—

(A) IN GENERAL.—A person may not file an application under paragraph (1) if—

(i) the application seeks conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal;

(ii) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (c); or

(iii) the person obtained the application, or data or other information con-

tained in the application, directly or indirectly from the person that filed for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (c).

(B) NEW ANIMAL DRUG CONTAINING ANTIMICROBIAL ACTIVE INGREDIENT.—A person may not file an application under paragraph (1)(A)(ii) if the application seeks conditional approval of a new animal drug that contains an antimicrobial active ingredient.

(4) ELECTRONIC SUBMISSION.—Beginning on October 1, 2018, all applications or submissions pursuant to this subsection shall be submitted by electronic means in such format as the Secretary may require.

(c) ORDER OF APPROVAL OR HEARING.—Within 180 days after the filing of an application pursuant to subsection (b), or such additional period as may be agreed on by the Secretary and the applicant, the Secretary shall—

(1) issue an order, effective for 1 year, conditionally approving the application if the Secretary

finds that none of the grounds for denying conditional approval, specified in subsection (d), applies and publish a Federal Register notice of the conditional approval; or

(2) give the applicant notice of an opportunity for an informal hearing on the question whether the application can be conditionally approved.

(d) ORDER OF APPROVAL OR REFUSAL AFTER HEARING.—

(1) GROUNDS FOR REFUSAL.—The Secretary shall issue an order refusing to conditionally approve an application under subsection (b) if the Secretary finds, after giving the applicant notice and an opportunity for an informal hearing, that—

(A) any of subparagraphs (A) through (D) or (F) through (I) of section 13705(a)(1) of this title is applicable;

(B) the information submitted to the Secretary as part of the application, and any other information before the Secretary with respect to the drug, is insufficient to show that there is a reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, rec-

ommended, or suggested in the proposed labeling of the drug; or

(C) another person has received approval under chapter 137 of this title for the same drug in the same dosage form for the same intended use, and that person is able to ensure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended.

(2) APPROVAL.—If, after the notice and opportunity for an informal hearing, the Secretary finds that subparagraphs (A) through (C) of paragraph (1) do not apply, the Secretary shall issue an order conditionally approving the application effective for 1 year and publish a Federal Register notice of the conditional approval.

(3) ORDER TO STATE FINDINGS.—Any order issued under this subsection refusing to conditionally approve an application shall state the findings on which the refusal is based.

(e) EFFECTIVE PERIOD.—

(1) IN GENERAL.—

(A) LENGTH; RENEWAL.—A conditional approval under this section is effective for a 1-year period and is, after that period, renewable

by the Secretary annually for up to 4 additional 1-year terms.

(B) MAXIMUM PERIOD.—A conditional approval shall be in effect for no more than 5 years from the date of approval under subsection (c)(1) or (d) unless extended as provided for in subsection (i).

(C) PROCEDURE FOR RENEWALS.—The following shall also apply:

(i) SUBMISSION OF REQUEST.—No later than 90 days from the end of the 1-year period for which the original or renewed conditional approval is effective, the applicant may submit a request to renew a conditional approval for an additional 1-year term.

(ii) CONDITIONS.—A conditional approval shall be deemed renewed at the end of the 1-year period, or at the end of a 90-day extension that the Secretary may grant by letter in order to complete review of the renewal request, unless the Secretary determines before the expiration of the 1-year period or the 90-day extension that—

(I) the applicant failed to submit a timely renewal request;

(II) the request fails to contain sufficient information to show that—

(aa) the applicant is making sufficient progress toward meeting approval requirements under section 13705(a)(1)(E) of this title, and is likely to be able to fulfill those requirements and obtain an approval under chapter 137 of this title before the expiration of the 5-year maximum term of the conditional approval;

(bb) the quantity of the drug that has been distributed is consistent with the conditionally approved intended use and conditions of use, unless there is adequate explanation that ensures that the drug is used only for its intended purpose; or

(cc) the same drug in the same dosage form for the same intended use has not received ap-

proval under chapter 137 of this title, or if the drug has been approved, the holder of the approved application is unable to ensure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended; or

(III) any of paragraphs (1), (2), (4), (5), or (6) of section 13706(a) of this title is applicable.

(2) ORDER REFUSING TO RENEW.—

(A) IN GENERAL.—If the Secretary determines before the end of the 1-year period or the 90-day extension, if granted, that a conditional approval should not be renewed, the Secretary shall issue an order refusing to renew the conditional approval, and the conditional approval shall be deemed withdrawn and no longer in effect.

(B) REINSTATEMENT.—The Secretary shall, after the issuance under subparagraph (A), provide an opportunity for an informal hearing to the applicant on the issue whether the conditional approval shall be reinstated.

(3) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER DIVISION A OF SUBTITLE V OF THIS TITLE.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under division A of subtitle V of this title, conditional approval of the application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 50301(j) of this title.

(f) WITHDRAWAL OF CONDITIONAL APPROVAL.—

(1) APPROVAL OF SAME DRUG.—The Secretary shall issue an order withdrawing conditional approval of an application filed pursuant to subsection (b) if the Secretary finds that another person has received approval under chapter 137 of this title for the same drug in the same dosage form for the same intended use and that person is able to ensure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended.

(2) OTHER BASES FOR REQUIRED WITHDRAWAL.—The Secretary shall, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of

an application filed pursuant to subsection (b) if the Secretary finds that—

(A) any of paragraphs (1), (2), (4), (5), or (6) of section 13706(a) of this title is applicable; or

(B) on the basis of new information before the Secretary with respect to the drug, evaluated together with the evidence available to the Secretary when the application was conditionally approved, there is no reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the drug.

(3) AUTHORIZED WITHDRAWAL.—The Secretary may, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of an application filed pursuant to subsection (b) if the Secretary finds that any of the provisions of section 13706(c) of this title are applicable.

(g) LABELING.—

(1) CONTENT.—The label and labeling of a new animal drug with a conditional approval under this section shall for the conditionally approved use—

(A) bear the statement, ''conditionally approved by FDA pending a full demonstration of effectiveness under application number''; and

(B) contain such other information as prescribed by the Secretary.

(2) INCLUSION OF INTENDED USE SUBJECT TO CONDITIONAL APPROVAL IN SAME PRODUCT LABEL WITH APPROVED USE.—The Secretary shall, through regulation or guidance, determine under what conditions an intended use that is the subject of a conditional approval under this section may be included in the same product label with any intended use approved under chapter 137 of this title.

(h) AMENDMENT OF APPLICATION.—A conditionally approved new animal drug application may not be amended or supplemented to add indications for use.

(i) ORDER OF APPROVAL AFTER CONDITIONAL APPROVAL PERIOD TERMINATION.—

(1) SUBMISSION OF INFORMATION SUPPORTING NEW ANIMAL DRUG APPLICATION.—One hundred eighty days prior to the termination date established under subsection (e), an applicant shall have submitted all the information necessary to support a complete new animal drug application in accordance with section 13703(a) of this title or the conditional

approval issued under this section is no longer in effect.

(2) ACTIONS BY SECRETARY.—Following review of the information submitted as described in paragraph (1), the Secretary shall—

(A) issue an order approving the application under section 13704 of this title if the Secretary finds that none of the grounds for denying approval specified in section 13705(a) of this title applies; or

(B) give the applicant an opportunity for a hearing before the Secretary under section 13705 of this title on the question whether the application can be approved.

(3) MODIFICATION OF PRODUCT LABELING AND ADMINISTRATIVE RECORDS ON APPROVAL.—On issuance of an order approving the application, product labeling and administrative records of approval shall be modified accordingly.

(4) EFFECT OF SECRETARY NOT GRANTING NEW ANIMAL DRUG APPLICATION APPROVAL; EXTENSION.—If the Secretary has not issued an order under section 13704 of this title approving the application prior to the termination date established under subsection (e), the conditional approval issued

under this section is no longer in effect unless the Secretary grants an extension of an additional 180-day period so that the Secretary can complete review of the application. The decision to grant an extension is committed to the discretion of the Secretary and not subject to judicial review.

(j) JUDICIAL REVIEW.—The decision of the Secretary under subsection (d), (e), or (f) refusing or withdrawing conditional approval of an application shall constitute final agency action subject to judicial review.

(k) SUNSET RELATING TO CERTAIN NEW ANIMAL DRUGS.—

(1) IN GENERAL.—The Secretary's authority to grant conditional approval of new animal drugs not intended for a minor use or minor species pursuant to subsection (b)(1)(A)(ii) terminates on October 1, 2028.

(2) ACCEPTANCE OF NEW APPLICATIONS FOR CONDITIONAL APPROVAL; CONTINUANCE OF ACTIVITIES UNDER THIS SECTION.—The Secretary—

(A) may not accept any new applications for conditional approval pursuant to subsection (b)(1)(A)(ii) on or after October 1, 2028; and

(B) may continue all activities under this section with respect to drugs that were condi-

tionally approved pursuant to subsection (b)(1)(A)(ii) prior to October 1, 2028.

(3) ACCEPTANCE OF APPLICATIONS FOR APPROVAL OF NEW ANIMAL DRUGS.—The Secretary may, until October 1, 2032, accept applications for approval under chapter 137 of this title of drugs conditionally approved pursuant to subsection (b)(1)(A)(ii).

**§ 14503. Index of legally marketed unapproved new animal drugs for minor species**

(a) ESTABLISHMENT AND CONTENT.—

(1) IN GENERAL.—The Secretary shall establish an index limited to—

(A) new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; and

(B) new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 13705 of this title (including, for an anti-

microbial new animal drug, with respect to antimicrobial resistance).

(2) TRANSGENIC ANIMALS.—The index shall not include a new animal drug that is contained in or a product of a transgenic animal.

(b) CONFERENCES.—Any person intending to file a request under this section shall be entitled to 1 or more conferences to discuss the requirements for indexing a new animal drug.

(c) REQUEST FOR DETERMINATION OF ELIGIBILITY FOR INCLUSION IN INDEX.—

(1) SUBMISSION.—Any person may submit a request to the Secretary for a determination whether a new animal drug may be eligible for inclusion in the index. The request shall include—

(A) information regarding the need for the new animal drug, the species for which the new animal drug is intended, the proposed intended use and conditions of use, and anticipated annual distribution;

(B) information to support the conclusion that the proposed use meets the conditions of subparagraph (A) or (B) of subsection (a)(1);

(C) information regarding the components and composition of the new animal drug;

(D) a description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the new animal drug;

(E) an environmental assessment that meets the requirements of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), and as defined in part 25 of title 21, Code of Federal Regulations, as it appeared on August 2, 2004, and amended after that date, or information to support a categorical exclusion from the requirement to prepare an environmental assessment;

(F) information sufficient to support the conclusion that the proposed use of the new animal drug is safe under section 13705 of this title with respect to individuals exposed to the new animal drug through its manufacture or use; and

(G) such other information as the Secretary may consider necessary to make the eligibility determination.

(2) GRANT OF REQUEST.—Within 90 days after the submission of a request for a determination of eligibility for indexing based on subsection (a)(1)(A),

or 180 days for a request submitted based on subsection (a)(1)(B), the Secretary shall grant or deny the request, and notify the person that requested the determination of the Secretary's decision. The Secretary shall grant the request if the Secretary finds that—

(A) the same drug in the same dosage form for the same intended use is not approved or conditionally approved;

(B) the proposed use of the drug meets the conditions of subparagraph (A) or (B) of subsection (a)(1), as appropriate;

(C) the person requesting the determination has established appropriate specifications for the manufacture and control of the new animal drug and has demonstrated an understanding of the requirements of current good manufacturing practices;

(D) the new animal drug will not significantly affect the human environment; and

(E) the new animal drug is safe with respect to individuals exposed to the new animal drug through its manufacture or use.

(3) DENIAL OF REQUEST.—If the Secretary denies the request, the Secretary shall, after the de-

nial, provide due notice and an opportunity for an informal conference. A decision of the Secretary to deny an eligibility request following an informal conference shall constitute final agency action subject to judicial review.

(d) REQUEST FOR ADDITION TO INDEX.—

(1) QUALIFIED EXPERT PANEL.—

(A) IN GENERAL.—In this section, a qualified expert panel is a panel that—

(i) is composed of experts qualified by scientific training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration;

(ii) operates external to the FDA; and

(iii) is not subject to chapter 10 of title 5.

(B) CRITERIA FOR SELECTION.—The Secretary shall define the criteria for selection of a qualified expert panel and the procedures for the operation of the panel by regulation.

(2) IN GENERAL.—With respect to a new animal drug for which the Secretary has made a determination of eligibility under subsection (c), the person that made a request under subsection (c) may

ask that the Secretary add the new animal drug to the index established under subsection (a). The request for addition to the index shall include—

(A) a copy of the Secretary's determination of eligibility issued under subsection (c);

(B) a written report that meets the requirements in paragraph (3);

(C) a proposed index entry;

(D) facsimile labeling;

(E) anticipated annual distribution of the new animal drug;

(F) a written commitment to manufacture the new animal drug and animal feeds bearing or containing the new animal drug according to current good manufacturing practices;

(G) a written commitment to label, distribute, and promote the new animal drug only in accordance with the index entry;

(H) on specific request of the Secretary, information submitted to the qualified expert panel described in paragraph (1); and

(I) any additional requirements that the Secretary may prescribe by general regulation or specific order.

(3) REPORT.—The report required in paragraph (2) shall—

(A) be authored by a qualified expert panel;

(B) include an evaluation of all available target animal safety and effectiveness information, including anecdotal information;

(C) state the qualified expert panel's opinion regarding whether the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm being caused by the absence of an approved or conditionally approved new animal drug for the minor species in question;

(D) include information from which labeling can be written; and

(E) include a recommendation regarding whether the new animal drug should be limited to use under the professional supervision of a licensed veterinarian.

(4) GRANT OR DENIAL OF REQUEST.—

(A) IN GENERAL.—Within 180 days after the receipt of a request for listing a new animal

drug in the index, the Secretary shall grant or deny the request.

(B) CONDITIONS FOR REQUEST TO BE GRANTED.—The Secretary shall grant the request if the request for indexing continues to meet the eligibility criteria in subsection (a) and the Secretary finds, on the basis of the report of the qualified expert panel and other information available to the Secretary, that the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally approved new animal drug for the minor species in question.

(C) DENIAL OF REQUEST.—If the Secretary denies the request, the Secretary shall, after the denial, provide due notice and the opportunity for an informal conference. The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

(e) INDEX CONTENTS; PUBLICATION.—

(1) CONTENTS.—The index established under subsection (a) shall, for each listed drug, include—

(A) the name and address of the person that holds the index listing;

(B) the name of the drug and the intended use and conditions of use for which it is being indexed;

(C) product labeling; and

(D) conditions and any limitations that the Secretary considers necessary regarding use of the drug.

(2) PUBLICATION; REVISION.—The Secretary shall publish the index, and revise it periodically.

(3) PROCESS FOR REPORTING CHANGES.—The Secretary may establish by regulation a process for reporting changes in the conditions of manufacturing or labeling of indexed products.

(f) REMOVAL FROM INDEX; SUSPENDED LISTING.—

(1) REMOVAL.—

(A) IN GENERAL.—The Secretary shall remove a new animal drug from the index if the Secretary finds, after due notice to the person that requested the index listing and an opportunity for an informal conference, that—

(i) the qualified expert panel failed to meet the requirements as set forth by the Secretary by regulation;

(ii) on the basis of new information before the Secretary, evaluated together with the evidence available to the Secretary when the new animal drug was listed in the index, the benefits of using the new animal drug for the indexed use do not outweigh its risks to the target animal;

(iii) the conditions of subsection (c)(2) are no longer satisfied;

(iv) the manufacture of the new animal drug is not in accordance with current good manufacturing practices;

(v) the labeling, distribution, or promotion of the new animal drug is not in accordance with the index entry;

(vi) the conditions and limitations of use associated with the index listing have not been followed; or

(vii) the request for indexing contains any untrue statement of material fact.

(B) DECISION FOLLOWING INFORMAL CONFERENCE AS FINAL AGENCY ACTION.—The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

(2) SUSPENSION.—

(A) IN GENERAL.—If the Secretary finds that there is a reasonable probability that the use of the drug would present a risk to the health of humans or other animals, the Secretary may—

(i) suspend the listing of the drug immediately;

(ii) give the person listed in the index prompt notice of the Secretary's action; and

(iii) afford that person the opportunity for an informal conference.

(B) DECISION FOLLOWING INFORMAL CONFERENCE AS FINAL AGENCY ACTION.—The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

(g) REGULATIONS CONCERNING EXEMPTIONS FOR INVESTIGATIONAL USE.—

(1) IN GENERAL.—For purposes of indexing new animal drugs under this section, to the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of chapter 137 of this title minor species new

animal drugs and animal feeds bearing or containing new animal drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of minor species animal drugs.

(2) AUTHORIZED CONDITIONS FOR EXEMPTIONS.—In the regulations under paragraph (1), the Secretary may provide for, among other conditions relating to the protection of the public health, conditioning the exemption on the establishment and maintenance of the records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of the article, of data (including analytical reports by investigators) obtained as a result of the investigational use of the article, as the Secretary finds will enable the Secretary to evaluate the safety and effectiveness of the article in the event of the filing of a request for an index listing pursuant to this section.

(h) LABELING CONTENTS.—The labeling of a new animal drug that is the subject of an index listing shall state, prominently and conspicuously—

(1) the statement ''LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Con-

ditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF #'', followed by the applicable minor species index file number and a period, and followed by the statement ''Extra-label use is prohibited.'';

(2) except in the case of new animal drugs indexed for use in an early life stage of a food-producing animal, the statement ''This product is not to be used in animals intended for use as food for humans or food-producing animals.''; and

(3) such other information as may be prescribed by the Secretary in the index listing.

(i) RECORDS AND REPORTS.—

(1) REQUIREMENTS BY REGULATION OR ORDER.—

(A) IN GENERAL.—In the case of any new animal drug for which an index listing pursuant to subsection (a) is in effect, the person that has an index listing shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, and other data or information, received or otherwise obtained by the person with respect to the drug, or with respect to animal feeds bearing or con-

taining the drug, as the Secretary may by general regulation, or by order with respect to the listing, prescribe on the basis of a finding that the records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (f).

(B) EXAMINATION BY PERSONS OF INFORMATION RECEIVED BY SECRETARY.—The regulation or order under subparagraph (A) shall provide, if the Secretary considers the provision to be appropriate, for the examination, upon request, by the persons to whom the regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) ACCESS TO RECORDS.—Each person required under this subsection to maintain records, and each person in charge or custody of the records, shall, on request of an officer or employee designated by the Secretary, permit the officer or employee at all reasonable times to have access to and copy and verify the records.

(j) PUBLIC DISCLOSURE OF SAFETY AND EFFECTIVENESS DATA.—

(1) IN GENERAL.—Safety and effectiveness data and information that has been submitted in support of a request for a new animal drug to be indexed under this section and that has not been previously disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the drug indexed in accordance with the request;

(B) if the Secretary has determined that the drug cannot be indexed and all legal appeals have been exhausted;

(C) if the indexing of the drug is terminated and all legal appeals have been exhausted; or

(D) if the Secretary has determined that the drug is not a new animal drug.

(2) VERIFIED STATEMENT.—Any request for data and information pursuant to paragraph (1) shall include a verified statement by the person making the request that any data or information received under paragraph (1) shall not be disclosed by the person to any other person—

(A) for the purpose of, or as part of a plan, scheme, or device for, obtaining the right to make, use, or market, or making, using, or marketing, outside the United States, the drug identified in the request for indexing; and

(B) without obtaining from any person to whom the data and information are disclosed an identical verified statement, a copy of which is to be provided by the person to the Secretary, that meets the requirements of this paragraph.

(k) DATE OF DETERMINATION IN THE CASE OF RECOMMENDED CONTROLS UNDER DIVISION A OF SUBTITLE V OF THIS TITLE.—In the case of a request under subsection (d) to add a drug to the index under subsection (a) with respect to a drug for which the Secretary provides notice to the person filing the request that the Secretary intends to issue a scientific and medical evaluation and recommend controls under division A of subtitle V of this title, a determination to grant the request to add the drug to the index shall not take effect until the interim final rule controlling the drug is issued in accordance with section 50301(j) of this title.

**§ 14504. Designated new animal drugs for minor use or minor species**

(a) DESIGNATION.—

(1) REQUEST.—

(A) IN GENERAL.—The manufacturer or the sponsor of a new animal drug for a minor use or use in a minor species may request that the Secretary declare that drug a ''designated new animal drug''.

(B) TIMING.—A request for designation of a new animal drug shall be made before the submission of an application under section 13703 or 14502 of this title for the new animal drug.

(2) CRITERIA.—The Secretary may declare a new animal drug a ''designated new animal drug'' if—

(A) it is intended for a minor use or use in a minor species; and

(B) the same drug in the same dosage form for the same intended use is not approved under chapter 137 or section 14502 of this title or designated under this section at the time the request is made.

(3) TERMINATION OF DESIGNATION.—With respect to a termination of a designation, the following shall apply:

(A) DISCONTINUATION OF PURSUIT OF APPROVAL.—The sponsor of a new animal drug shall notify the Secretary of any decision to discontinue active pursuit of approval under chapter 137 or section 14502 of this title of an application for a designated new animal drug. The Secretary shall terminate the designation on the notification.

(B) LACK OF DUE DILIGENCE.—The Secretary may terminate designation if the Secretary independently determines that the sponsor is not actively pursuing approval under chapter 137 or section 14502 of this title with due diligence.

(C) DISCONTINUANCE OF MANUFACTURE.—The sponsor of an approved designated new animal drug shall notify the Secretary of any discontinuance of the manufacture of the new animal drug at least 1 year before discontinuance. The Secretary shall terminate the designation on the notification.

(D) EXPIRATION OF EXCLUSIVITY PERIOD.—The designation shall terminate on the expiration of any applicable exclusivity period under subsection (c).

(4) NOTICE TO PUBLIC.—Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

(b) GRANTS AND CONTRACTS FOR DEVELOPMENT OF DESIGNATED NEW ANIMAL DRUGS.—

(1) DEFINITIONS.—In this subsection:

(A) MANUFACTURING EXPENSES.—The term ''manufacturing expenses'' means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug that occur after the new animal drug is designated under this section and before the date on which an application with respect to the new animal drug is submitted under chapter 137 or section 14502 of this title.

(B) QUALIFIED SAFETY AND EFFECTIVENESS TESTING.—The term ''qualified safety and effectiveness testing'' means testing—

(i) that occurs after the date the new animal drug is designated under this section and before the date on which an application with respect to the drug is submitted under chapter 137 of this title; and

(ii) that is carried out under an investigational exemption under section 13711 of this title.

(2) IN GENERAL.—The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

(c) EXCLUSIVITY FOR DESIGNATED NEW ANIMAL DRUGS.—

(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for the new animal drug with the same intended use as the designated new animal drug for another applicant before the expiration of 7 years from the date of approval or conditional approval of the application.

(2) EXCEPTIONS.—If an application filed pursuant to chapter 137 or section 14502 of this title is approved for a designated new animal drug, the Secretary may, during the 7-year exclusivity period

beginning on the date of the application approval or conditional approval, approve or conditionally approve another application under chapter 137 or section 14502 of this title for the drug for the minor use or minor species for another applicant if—

(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot ensure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

(B) the holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of the exclusivity period.

(3) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER DIVISION A OF SUBTITLE V OF THIS TITLE.—For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to issue a scientific and medical evaluation and recommend controls under division A of subtitle V of this title, the drug shall not be considered approved

or conditionally approved until the date that the interim final rule controlling the drug is issued in accordance with section 50301(j) of this title.

# Chapter 147—Medical Gases

Sec.
14701. Definitions.
14702. Regulation of medical gases.
14703. Inapplicability of drug fees to designated medical gases.
14704. Rules of construction.

## § 14701. Definitions

In this chapter:

(1) DESIGNATED MEDICAL GAS.—The term ''designated medical gas'' means—

(A) oxygen that meets the standards set forth in an official compendium;

(B) nitrogen that meets the standards set forth in an official compendium;

(C) nitrous oxide that meets the standards set forth in an official compendium;

(D) carbon dioxide that meets the standards set forth in an official compendium;

(E) helium that meets the standards set forth in an official compendium;

(F) carbon monoxide that meets the standards set forth in an official compendium;

(G) medical air that meets the standards set forth in an official compendium; or

(H) any other medical gas considered appropriate by the Secretary, after taking into account any investigational new drug application or investigational new animal drug application for the same medical gas submitted in accordance with regulations applicable to the applications in title 21 of the Code of Federal Regulations, unless any period of exclusivity for a new drug under section 13504(c)(5)(A) or 13511(f)(6)(A) of this title, the extension of any such period under section 13112 of this title, or any period of exclusivity for a new animal drug under section 13704(b)(7) of this title, applicable to the medical gas, has not expired.

(2) MEDICAL GAS.—The term ''medical gas'' means a drug that—

(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

(B) is administered as a gas.

**§ 14702. Regulation of medical gases**

(a) CERTIFICATION OF DESIGNATED MEDICAL GASES.—

(1) SUBMISSION.—Any person that seeks to initially introduce or deliver for introduction a des-

ignated medical gas into interstate commerce may file with the Secretary a request for certification of a medical gas as a designated medical gas. The request shall contain—

(A) a description of the medical gas;

(B) the name and address of the sponsor;

(C) the name and address of the facility or facilities where the medical gas is or will be manufactured; and

(D) any other information considered appropriate by the Secretary to determine whether the medical gas is a designated medical gas.

(2) GRANT OF CERTIFICATION.—The certification requested under paragraph (1) is deemed to be granted unless, within 60 days of the filing of the request, the Secretary finds that—

(A) the medical gas subject to the certification is not a designated medical gas;

(B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas; or

(C) denying the request is necessary to protect the public health.

(3) EFFECT OF CERTIFICATION.—

(A) IN GENERAL.—

(i) APPROVED USES.—A designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or other designated medical gases for which a certification or certifications have been granted, to have in effect an approved application under chapter 135 or 137 of this title, subject to all applicable post-approval requirements, for the following indications for use:

(I) In the case of oxygen, the treatment or prevention of hypoxemia or hypoxia.

(II) In the case of nitrogen, use in hypoxic challenge testing.

(III) In the case of nitrous oxide, analgesia.

(IV) In the case of carbon dioxide, use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

(V) In the case of helium, the treatment of upper airway obstruction or increased airway resistance.

(VI) In the case of medical air, to reduce the risk of hyperoxia.

(VII) In the case of carbon monoxide, use in lung diffusion testing.

(VIII) Any other indication for use for a designated medical gas or combination of designated medical gases considered appropriate by the Secretary, unless any period of exclusivity for a new drug under subparagraph (B) or (C) of section 13504(c)(5) of this title, subparagraph (B) or (C) of section 13511(f)(6) of this title, or section 13903 of this title, or the extension of any such period under section 13112 of this title, applicable to the indication for use for the gas or combination of gases has not expired.

(ii) LABELING.—The requirements of sections 13103(a)(4) and 13305 of this title are deemed to have been met for a

designated medical gas if the labeling on the final use container for the medical gas bears—

(I) the information required by section 13103(a)(4) of this title;

(II) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and

(III) appropriate directions and warnings concerning storage and handling.

(B) INAPPLICABILITY OF EXCLUSIVITY PROVISIONS.—

(i) NO EXCLUSIVITY FOR A CERTIFIED MEDICAL GAS.—No designated medical gas deemed under subparagraph (A)(i) to have in effect an approved application is eligible for any period of exclusivity for a new drug under section 13504, 13511, or 13903 of this title, or the extension of any such period under section 13112 of this title, on the basis of the deemed approval.

(ii) EFFECT ON CERTIFICATION.—No period of exclusivity under section 13504,

13511, or 13903 of this title, or the extension of any such period under section 13112 of this title, with respect to an application for a drug product, shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in subparagraph (A)(i)(VIII) and section 14701(1)(H) of this title.

(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

(A) WITHDRAWAL OR SUSPENSION OF APPROVAL.—Nothing in this chapter limits the Secretary's authority to withdraw or suspend approval of a drug product, including a designated medical gas deemed under this section to have in effect an approved application under chapter 135 or 137 of this title.

(B) REVOCATION OF CERTIFICATION.—The Secretary may revoke the grant of a certification under paragraph (2) if the Secretary determines that the request for certification contains any material omission or falsification.

(b) PRESCRIPTION REQUIREMENT.—

(1) IN GENERAL.—A designated medical gas shall be subject to the requirements of section 13103(a)(1) of this title unless—

(A) the Secretary exercises the authority provided in section 13103(a)(3) of this title to remove the medical gas from the requirements of section 13103(a)(1) of this title;

(B) the gas is approved for use without a prescription pursuant to an application under chapter 135 or 137 of this title; or

(C) the use in question is authorized pursuant to another provision of this subtitle relating to use of medical products in emergencies.

(2) OXYGEN.—

(A) NO PRESCRIPTION REQUIRED FOR CERTAIN USES.—Notwithstanding paragraph (1), oxygen may be provided without a prescription—

(i) for use in the event of depressurization or other environmental oxygen deficiency; or

(ii) for oxygen deficiency or for use in emergency resuscitation, when administered by properly trained personnel.

(B) LABELING.—For oxygen provided pursuant to subparagraph (A), the requirements of section 13103(a)(4) of this title shall be deemed to have been met if its labeling bears a warning that the oxygen can be used for emergency use only and for all other medical applications a prescription is required.

**§ 14703. Inapplicability of drug fees to designated medical gases**

A designated medical gas, alone or in combination with another designated gas or other designated medical gases (as medically appropriate), deemed under section 14702 of this title to have in effect an approved application shall not be assessed fees under section 17907(a) or 17927(a) of this title on the basis of the deemed approval.

**§ 14704. Rules of construction**

Nothing in this chapter applies with respect to—

(1) a drug that is approved prior to May 1, 2012, pursuant to an application submitted under chapter 135 or 137 of this title;

(2) any gas listed in subparagraphs (A) through (G) of section 14701(1) of this title, or any combination of any such gases, for an indication that—

(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 14702(a)(3)(A)(i) of this title; and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under chapter 135 or 137 of this title; or

(3) any designated medical gas added pursuant to subparagraph (H) of section 14701(1) of this title for an indication that—

(A) is not included in, or is different from, those originally added pursuant to sections 14701(1)(H) and 14702(a)(3)(A)(i)(VIII) of this title; and

(B) is approved on or after May 1, 2012, pursuant to an application submitted under chapter 135 or 137 of this title.

# Chapter 149—Pharmaceutical Distribution Supply Chain

Sec.
14901. Definitions.
14902. Requirements.
14903. National standards for prescription drug wholesale distributors.
14904. National standards for third-party logistics providers.
14905. Uniform national policy.

## § 14901. Definitions

In this chapter:

(1) AFFILIATE.—The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) 1 business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has the power to control, both of the business entities.

(2) AUTHORIZED.—The term ''authorized'' means—

(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 13136 of this title;

(B) in the case of a wholesale distributor, having a valid license under State law or section 14903 of this title, in accordance with section 14902(a)(6) of this title, and complying with the licensure reporting requirements under section 13103(d) of this title;

(C) in the case of a third-party logistics provider, having a valid license under State law or section 14904(a)(1) of this title, in accordance with section 14902(a)(7) of this title, and complying with the licensure reporting requirements under section 14904(b) of this title; and

(D) in the case of a dispenser, having a valid license under State law.

(3) DISPENSER.—

(A) IN GENERAL.—The term ''dispenser'' means a retail pharmacy, a hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of the entities under common ownership and control that do not act as a wholesale distributor.

(B) EXCLUSION.—The term ''dispenser'' does not include a person that dispenses only products to be used in animals in accordance with section 13702(e) of this title.

(4) DISPOSITION.—The term ''disposition'', with respect to a product within the possession or control of an entity, means the removal of the product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination

or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

(5) DISTRIBUTION.—

(A) IN GENERAL.—The term ''distribution'' means the sale, purchase, trade, delivery, handling, storage, or receipt of a product.

(B) EXCLUSION.—The term ''distribution'' does not include the dispensing of a product pursuant to a prescription executed in accordance with section 13103(a)(1) of this title or the dispensing of a product approved under section 13703 of this title.

(6) EXCLUSIVE DISTRIBUTOR.—The term ''exclusive distributor'' means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

(7) HOMOGENEOUS CASE.—The term ''homogeneous case'' means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

(8) ILLEGITIMATE PRODUCT.—The term ''illegitimate product'' means a product for which credible evidence shows that the product—

(A) is counterfeit, diverted, or stolen;

(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is the subject of a fraudulent transaction; or

(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

(9) LICENSED.—The term ''licensed'' means—

(A) in the case of a wholesale distributor, having a valid license in accordance with section 13103(d) or 14902(a)(6) of this title, as applicable;

(B) in the case of a third-party logistics provider, having a valid license in accordance with section 14902(a)(7) or 14904(a) of this title, as applicable; or

(C) in the case of a dispenser, having a valid license under State law.

(10) MANUFACTURER.—The term ''manufacturer'', with respect to a product, means—

(A) a person that holds an application approved under chapter 135 of this title or a li-

cense issued under section 351 of the Public Health Service Act (42 U.S.C. 262) for the product, or if the product is not the subject of an approved application or license, the person that manufactured the product;

(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or

(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

(11) PACKAGE.—

(A) IN GENERAL.—The term ''package'' means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of the product.

(B) INDIVIDUAL SALEABLE UNIT.—For purposes of this paragraph, an ''individual saleable unit'' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufac-

turer or repackager for individual sale to a dispenser.

(12) PRESCRIPTION DRUG.—The term ''prescription drug'' means a drug for human use subject to section 13103(a)(1) of this title.

(13) PRODUCT.—

(A) IN GENERAL.—The term ''product'' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).

(B) EXCLUSION.—For purposes of section 14902 of this title, the term ''product'' does not include—

(i) blood or blood components intended for transfusion;

(ii) radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with the Nuclear Regulatory Commission under section 274

of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

(iii) imaging drugs;

(iv) an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B);

(v) any medical gas (as defined in section 14701 of this title);

(vi) homeopathic drugs marketed in accordance with applicable guidance under this subtitle; or

(vii) a drug compounded in compliance with section 13106 or 13107 of this title.

(14) PRODUCT IDENTIFIER.—The term ''product identifier'' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

(15) QUARANTINE.—The term ''quarantine'' means the storage or identification of a product, to prevent distribution or transfer of the product, in a

physically separate area clearly identified for that use or through other procedures.

(16) REPACKAGER.—The term ''repackager'' means a person that owns or operates an establishment that repacks and relabels a product or package for—

(A) further sale; or

(B) distribution without a further transaction.

(17) RETURN.—The term ''return'' means providing product to the authorized immediate trading partner from which the product was purchased or received, or to a returns processor for handling of the product.

(18) RETURNS PROCESSOR.—The term ''returns processor'' means a person that owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

(19) SPECIFIC PATIENT NEED.—

(A) IN GENERAL.—The term ''specific patient need'' refers to the need for the transfer

of a product from 1 pharmacy to another to fill a prescription for an identified patient.

(B) EXCLUSION.—The term ''specific patient need'' does not include the need for the transfer of a product from 1 pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

(20) STANDARDIZED NUMERICAL IDENTIFIER.—The term ''standardized numerical identifier'' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

(21) SUSPECT PRODUCT.—The term ''suspect product'' means a product for which there is reason to believe that the product—

(A) is potentially counterfeit, diverted, or stolen;

(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is potentially the subject of a fraudulent transaction; or

(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(22) THIRD-PARTY LOGISTICS PROVIDER.—The term ''third-party logistics provider'' means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, or has no responsibility to direct the sale or disposition of the product.

(23) TRADING PARTNER.—The term ''trading partner'' means—

(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale

distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(24) TRANSACTION.—

(A) IN GENERAL.—The term ''transaction'' means the transfer of product between persons in which a change of ownership occurs.

(B) EXCLUSIONS.—The term ''transaction'' does not include—

(i) intracompany distribution of any product between members of an affiliate or within a manufacturer;

(ii) the distribution of a product among hospitals or other health care entities that are under common control;

(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d), except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 13103(a)(1) of this title;

(v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 13103(c) of this title;

(vi) the distribution of blood or blood components intended for transfusion;

(vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C.501(c)(3)) to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any

records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

(x) the dispensing of a product approved under section 13704 of this title;

(xi) the transfer of products to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with the Nuclear Regulatory Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

(xii) a combination product that is not subject to approval under chapter 135 of this title or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and that is—

(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or oth-

erwise combined or mixed and produced as a single entity;

(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

(III) 2 or more finished medical devices plus 1 or more drug or biological products that are packaged together in what is referred to as a ''medical convenience kit'' as described in clause (xiii);

(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a ''medical convenience kit'') if—

(I) the medical convenience kit is assembled in an establishment that is registered with the FDA as a device manufacturer in accordance with section 13136(b)(2) of this title;

(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in division A of subtitle V of this title;

(III) in the case of a medical convenience kit that includes a product, the person that manufactures the medical convenience kit—

(aa) purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(IV) in the case of a medical convenience kit that includes a product, the product is—

(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

(bb) a product intended to maintain the equilibrium of water and minerals in the body;

(cc) a product intended for irrigation or reconstitution;

(dd) an anesthetic;

(ee) an anticoagulant;

(ff) a vasopressor; or

(gg) a sympathomimetic;

(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(xvi) the distribution of a product that is intended for irrigation, or sterile water,

whether intended for those purposes or for injection;

(xvii) the distribution of a medical gas (as defined in section 14701 of this title); or

(xviii) the distribution or sale of any licensed product under section 351 of the Public Health Service Act (42 U.S.C. 262) that meets the definition of a device under section 10101(a)(16) of this title.

(25) TRANSACTION HISTORY.—The term ''transaction history'' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(26) TRANSACTION INFORMATION.—The term ''transaction information'' means—

(A) the proprietary or established name or names of the product;

(B) the strength and dosage form of the product;

(C) the National Drug Code number of the product;

(D) the container size;

(E) the number of containers;

(F) the lot number of the product;

(G) the date of the transaction;

(H) the date of the shipment, if more than 24 hours after the date of the transaction;

(I) the business name and address of the person from whom ownership is being transferred; and

(J) the business name and address of the person to whom ownership is being transferred.

(27) TRANSACTION STATEMENT.—The term ''transaction statement'' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—

(A) is authorized as required under this chapter;

(B) received the product from a person that is authorized as required under this chapter;

(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 14902 of this title;

(D) did not knowingly ship a suspect product or illegitimate product;

(E) had systems and processes in place to comply with verification requirements under section 14902 of this title;

(F) did not knowingly provide false transaction information; and

(G) did not knowingly alter the transaction history.

(28) VERIFICATION.—The term ''verification'' means the determination of whether the product identifier affixed to, or imprinted on, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 14902 of this title.

(29) WHOLESALE DISTRIBUTOR.—The term ''wholesale distributor'' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 13103(d)(1)(B) of this title).

**§ 14902. Requirements**

(a) IN GENERAL.—

(1) COMPLIANCE.—

(A) IN GENERAL.—Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in this section with respect to the role of the manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving product.

(B) CERTAIN ENTITIES.—If an entity meets the definition of more than 1 of the entities listed in subparagraph (A), the entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.

(2) INITIAL STANDARDS.—

(A) GUIDANCE.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for compliance with this subsection and subsections (b), (c), (d), and (e).

(B) STANDARDIZED DOCUMENTATION.—In establishing the standards under subparagraph (A), the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data.

(C) EFFECT OF OTHER STANDARDS.—The standards established under this paragraph shall take into consideration the standards established under section 13115 of this title and shall comply with a form and format developed by a widely recognized international standards development organization.

(3) WAIVERS, EXCEPTIONS, AND EXEMPTIONS.—

(A) IN GENERAL.—The Secretary shall, by guidance—

(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set

forth in this section, which the Secretary may grant—

(I) if the Secretary determines that the requirements would result in an undue economic hardship; or

(II) for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d);

(ii) establish a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

(iii) establish a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of this section.

(B) CONTENT.—The guidance issued under subparagraph (A) shall include a process for the biennial review and renewal of the waivers, exceptions, and exemptions, as applicable.

(C) PROCESS.—In issuing the guidance under this paragraph, the Secretary shall provide an effective date that is not later than 180 days prior to the date on which manufacturers are required to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce consistent with this section.

(4) SELF-EXECUTING REQUIREMENTS.—Except where otherwise specified, the requirements of this section may be enforced without further regulations or guidance from the Secretary.

(5) GRANDFATHERING PRODUCT.—

(A) PRODUCT IDENTIFIER.—The Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the require-

ments of this section shall be exempted from the requirements of this section.

(B) TRACING.—For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015—

(i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii);

(ii) transaction history required under this section shall begin with the owner of the product on that date; and

(iii) the owners of the product on that date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

(6) WHOLESALE DISTRIBUTOR LICENSES.—Notwithstanding section 14901(9)(A) of this title, until the effective date of the wholesale distributor licensing regulations under section 14903 of this title, the term ''licensed'' or ''authorized'', as it relates to a wholesale distributor with respect to pre-

scription drugs, shall mean a wholesale distributor with a valid license under State law.

(7) THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the effective date of the third-party logistics provider licensing regulations under section 14904 of this title, a third-party logistics provider shall be considered ''licensed'' under section 14901(9)(B) of this title unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice of the finding.

(8) LABEL CHANGES.—Changes made to package labels solely to incorporate the product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of title 21, Code of Federal Regulations (or any successor regulation).

(9) PRODUCT IDENTIFIERS.—With respect to any requirement relating to product identifiers under this chapter—

(A) unless the Secretary allows, through guidance, the use of other technologies for data instead of or in addition to the technologies described in clauses (i) and (ii), the applicable data—

(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted on, a package; and

(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted on, a homogeneous case; and

(B) verification of the product identifier may occur by using human-readable or machine-readable methods.

(b) MANUFACTURER REQUIREMENTS.—

(1) PRODUCT TRACING.—

(A) IN GENERAL.—A manufacturer shall—

(i) prior to, or at the time of, each transaction in which the manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in a paper or electronic format; and

(ii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain the information, history, and statement for

not less than 6 years after the date of the transaction.

(B) REQUESTS FOR INFORMATION.—On a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

(C) ELECTRONIC FORMAT.—

(i) IN GENERAL.—Except as provided under clause (ii), a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format.

(ii) EXCEPTION.—A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under subpara-

graph (A)(i) in a paper format to a licensed health care practitioner authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.

(2) PRODUCT IDENTIFIER.—

(A) IN GENERAL.—A manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. The manufacturer shall maintain the product identifier information for the product for not less than 6 years after the date of the transaction.

(B) EXCEPTION.—A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

(3) AUTHORIZED TRADING PARTNERS.—The trading partners of a manufacturer may be only authorized trading partners.

(4) VERIFICATION.—A manufacturer shall have systems in place to enable the manufacturer to comply with the following requirements:

(A) SUSPECT PRODUCT.—

(i) IN GENERAL.—On making a determination that a product in the possession or control of the manufacturer is a suspect product, or on receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a manufacturer is a suspect product, a manufacturer shall—

(I) quarantine the product within the possession or control of the manufacturer from product intended for distribution until the product is cleared or dispositioned; and

(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the posses-

sion of the manufacturer and otherwise investigating to determine whether the product is an illegitimate product, and verifying the product at the package level, including the standardized numerical identifier.

(ii) CLEARED PRODUCT.—If the manufacturer makes the determination that a suspect product is not an illegitimate product, the manufacturer shall promptly notify the Secretary, if applicable, of the determination and the product may be further distributed.

(iii) RECORDS.—A manufacturer shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRODUCT.—

(i) IN GENERAL.—On determining that a product in the possession or control of a manufacturer is an illegitimate product, the manufacturer shall, in a manner consistent with the systems and processes of the manufacturer—

(I) quarantine the product within the possession or control of the manufacturer from product intended for distribution until the product is dispositioned;

(II) disposition the illegitimate product within the possession or control of the manufacturer;

(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the manufacturer; and

(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) on request by the Secretary (or other appropriate Federal or State official), as necessary and appropriate.

(ii) NOTIFICATION.—

(I) ILLEGITIMATE PRODUCT.—On determining that a product in the possession or control of the manufac-

turer is an illegitimate product, the manufacturer shall notify the Secretary, and all immediate trading partners that the manufacturer has reason to believe may have received the illegitimate product, of the determination not later than 24 hours after making the determination.

(II) HIGH RISK OF ILLEGITIMACY.—

(aa) HIGH RISK.—In this subclause, the term ''high risk'' may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h).

(bb) IN GENERAL.—A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in

the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that the product is an illegitimate product.

(iii) RESPONDING TO A NOTIFICATION.—On the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a manufacturer shall identify all illegitimate product subject to the notification that is in the possession or control of the manufacturer, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

(iv) TERMINATING A NOTIFICATION.—On making a determination, in consultation with the Secretary, that a notification is no longer necessary, a manufacturer

shall promptly notify immediate trading partners that the manufacturer notified pursuant to clause (ii) that the notification has been terminated.

(v) RECORDS.—A manufacturer shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

(C) REQUESTS FOR VERIFICATION.—

(i) NOTIFICATION.—On receiving a request for verification from an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product that the authorized repackager, wholesale distributor, or dispenser believes to be manufactured by the manufacturer, a manufacturer shall, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the authorized repackager, wholesale distributor, or dispenser making the request whether the product identifier, including the standardized numerical identifier, that

is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer.

(ii) PRODUCT IDENTIFIER DOES NOT CORRESPOND TO PRODUCT IDENTIFIER AFFIXED OR IMPRINTED BY MANUFACTURER.—If a manufacturer responding to a request for verification identifies a product identifier that does not correspond to that affixed or imprinted by the manufacturer, the manufacturer shall treat the product as suspect product and conduct an investigation as described in subparagraph (A).

(iii) SUSPICION THAT PRODUCT IS ILLEGITIMATE PRODUCT.—If the manufacturer has reason to believe the product is an illegitimate product, the manufacturer shall advise the person making the request of the belief at the time the manufacturer responds to the request for verification.

(D) ELECTRONIC DATABASE.—

(i) IN GENERAL.—A manufacturer may satisfy the requirements of this paragraph by developing a secure electronic

database or utilizing a secure electronic database developed or operated by another entity.

(ii) REQUIREMENTS AND PROCESSES; ACCESS.—The owner of the database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate.

(iii) REQUESTS FOR VERIFICATION BY MEANS OTHER THAN SECURE ELECTRONIC DATABASE.—The development and operation of an electronic database under this subparagraph shall not relieve a manufacturer of the requirement under this paragraph to respond to a request for verification submitted by means other than a secure electronic database.

(E) SALEABLE RETURNED PRODUCT.—Except as provided pursuant to subsection (a)(5), on receipt of a returned product that the manufacturer intends to further distribute, before further distributing the product, the manufacturer shall verify the product identifier, includ-

ing the standardized numerical identifier, for each sealed homogeneous case of the product or, if the product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

(F) NONSALEABLE RETURNED PRODUCT.—A manufacturer may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information described in paragraph (1)(A)(i).

(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

(1) PRODUCT TRACING.—

(A) IN GENERAL.—The following requirements shall apply to wholesale distributors:

(i) PROVISION OF INFORMATION BY PREVIOUS OWNER TO WHOLESALE DISTRIBUTOR.—A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a

transaction statement for the product, as applicable under this subparagraph.

(ii) PROVISION OF INFORMATION BY WHOLESALE DISTRIBUTOR TO SUBSEQUENT PURCHASER; DIRECT PURCHASE.—

(I) IN GENERAL.—

(aa) LIST OF INFORMATION.—If the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser—

(AA) a transaction statement, which shall state that the wholesale distributor, or a member of the affiliate of the wholesale dis-

tributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased the product directly from the manufacturer; and

(BB) subject to subclause (II), the transaction history and transaction information.

(bb) FORMAT.—The wholesale distributor shall provide the transaction history, transaction information, and transaction statement under item (aa)—

(AA) if provided to a dispenser, on a single document in a paper or electronic format; and

(BB) if provided to a wholesale distributor, through any combination of self-generated paper, elec-

tronic data, or manufacturer-provided information on the product package.

(II) INFORMATION NOT REQUIRED.—For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 14901(26) of this title).

(iii) PROVISION OF INFORMATION BY WHOLESALE DISTRIBUTOR TO SUBSEQUENT PURCHASER; INDIRECT PURCHASE.—If the wholesale distributor did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, as described in clause (ii), then prior to, or at the time of, each transaction or subsequent transaction, the wholesale distributor

shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the guidance document issued under subsection (a)(2).

(iv) TRANSACTION HISTORY RELATING TO DIRECT PURCHASERS.—For the purposes of clause (iii), the transaction history supplied shall begin only with the wholesale distributor described in clause (ii)(I), but the wholesale distributor described in clause (iii) shall inform the subsequent purchaser that the wholesale distributor received a direct purchase statement from a wholesale distributor described in clause (ii)(I).

(v) MAINTENANCE OF INFORMATION; CONFIDENTIALITY.—A wholesale distributor shall—

(I) capture the transaction information (including lot level information) consistent with the requirements of this section, transaction history, and transaction statement for each

transaction described in clauses (i), (ii), and (iii) and maintain the information, history, and statement for not less than 6 years after the date of the transaction; and

(II) maintain the confidentiality of the transaction information (including any lot level information consistent with the requirements of this section), transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and, as applicable, pursuant to an agreement under subparagraph (D).

(B) RETURNS.—

(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A)(i), the following shall apply:

(I) REQUIREMENTS.—Until the date that is 6 years after November 27, 2013 (except as provided pursuant

to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and, notwithstanding subparagraph (A)(ii), may distribute the returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of the product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this subsection.

(II) ENHANCED REQUIREMENTS.—Beginning 6 years after November 27, 2013 (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all trans-

actions after that date, the transaction history, as applicable, of the product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain the dates.

(ii) NONSALEABLE RETURNS.—A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, or to a person acting on behalf of the manufacturer, repackager, or wholesale distributor from whom the product was purchased, including a returns processor, without providing the information required under subparagraph (A)(i).

(C) REQUESTS FOR INFORMATION.—On a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect

product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

(D) TRADING PARTNER AGREEMENTS.—

(i) IN GENERAL.—A wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between the wholesale distributor and the subsequent purchaser.

(ii) EFFECT OF SUBPARAGRAPH.—Nothing in this subparagraph shall be construed to limit the applicability of subparagraphs (A) through (C).

(2) PRODUCT IDENTIFIER.—A wholesale distributor may engage in transactions involving a product only if the product is encoded with a prod-

uct identifier (except as provided pursuant to subsection (a)(5)).

(3) AUTHORIZED TRADING PARTNERS.—The trading partners of a wholesale distributor may be only authorized trading partners.

(4) VERIFICATION.—A wholesale distributor shall have systems in place to enable the wholesale distributor to comply with the following requirements:

(A) SUSPECT PRODUCT.—

(i) IN GENERAL.—On making a determination that a product in the possession or control of a wholesale distributor is a suspect product, or on receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a wholesale distributor is a suspect product, a wholesale distributor shall—

(I) quarantine the product within the possession or control of the wholesale distributor from product intended for distribution until the product is cleared or dispositioned; and

(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the wholesale distributor and otherwise investigating to determine whether the product is an illegitimate product, and, except as provided pursuant to subsection (a)(5), verifying the product at the package level, including the standardized numerical identifier.

(ii) CLEARED PRODUCT.—If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the Secretary, if applicable, of the determination and the product may be further distributed.

(iii) RECORDS.—A wholesale distributor shall keep records of the investigation of a suspect product for not less than

6 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRODUCT.—

(i) IN GENERAL.—On determining, in coordination with the manufacturer, that a product in the possession or control of a wholesale distributor is an illegitimate product, the wholesale distributor shall, in a manner that is consistent with the systems and processes of the wholesale distributor—

(I) quarantine the product within the possession or control of the wholesale distributor from product intended for distribution until the product is dispositioned;

(II) disposition the illegitimate product within the possession or control of the wholesale distributor;

(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the wholesale distributor; and

(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) on request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

(ii) NOTIFICATION.—On determining that a product in the possession or control of the wholesale distributor is an illegitimate product, the wholesale distributor shall notify the Secretary, and all immediate trading partners that the wholesale distributor has reason to believe may have received the illegitimate product, of the determination not later than 24 hours after making the determination.

(iii) RESPONDING TO A NOTIFICATION.—On the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a wholesale distributor shall identify all illegit-

imate product subject to the notification that is in the possession or control of the wholesale distributor, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

(iv) TERMINATING A NOTIFICATION.—On making a determination, in consultation with the Secretary, that a notification is no longer necessary, a wholesale distributor shall promptly notify immediate trading partners that the wholesale distributor notified pursuant to clause (ii) that the notification has been terminated.

(v) RECORDS.—A wholesale distributor shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

(C) ELECTRONIC DATABASE.—

(i) IN GENERAL.—A wholesale distributor may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure elec-

tronic database developed or operated by another entity.

(ii) REQUIREMENTS AND PROCESSES; ACCESS.—The owner of the database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate.

(iii) REQUESTS FOR VERIFICATION BY MEANS OTHER THAN SECURE ELECTRONIC DATABASE.—The development and operation of an electronic database under this subparagraph shall not relieve a wholesale distributor of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

(D) VERIFICATION OF SALEABLE RETURNED PRODUCT.—On receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing the product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier, for each

sealed homogeneous case of the product or, if the product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

(d) DISPENSER REQUIREMENTS.—

(1) PRODUCT TRACING.—

(A) IN GENERAL.—A dispenser—

(i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;

(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns), shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

(iii) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain the information, history, and statements for not less than 6 years after the transaction.

(B) AGREEMENTS WITH THIRD PARTIES.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

(C) RETURNS.—

(i) SALEABLE RETURNS.—A dispenser may return product to the trading partner from which the dispenser obtained the

product without providing the information required under subparagraph (A).

(ii) NONSALEABLE RETURNS.—A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom the product was purchased, to a returns processor, or to a person acting on behalf of the manufacturer, repackager, wholesale distributor from whom the product was purchased, or returns processor without providing the information required under subparagraph (A).

(D) REQUESTS FOR INFORMATION.—

(i) IN GENERAL.—On a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction statement, and trans-

action history that the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless the information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser.

(ii) FORMAT.—The dispenser may respond to the request by providing the applicable information in either paper or electronic format.

(iii) TEMPORARY LIMITATION ON CERTAIN REQUIREMENTS.—Until the date that is 4 years after November 27, 2013, the Secretary or other appropriate Federal or State official shall grant a dispenser additional time, as necessary, only with respect to a request to provide lot level information described in subparagraph (F) of section 14901(26) of this title that was provided to the dispenser in paper format, shall limit the request time period to the 6

months preceding the request or other relevant date, and, in the event of a recall, may request information only if the recall involves a serious adverse health consequence or death to humans.

(2) PRODUCT IDENTIFIER.—A dispenser may engage in transactions involving a product only if the product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

(3) AUTHORIZED TRADING PARTNERS.—The trading partners of a dispenser may be only authorized trading partners.

(4) VERIFICATION.—A dispenser shall have systems in place to enable the dispenser to comply with the following requirements:

(A) SUSPECT PRODUCT.—

(i) IN GENERAL.—On making a determination that a product in the possession or control of the dispenser is a suspect product, or on receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a dispenser is a suspect product, a dispenser shall—

(I) quarantine the product within the possession or control of the dispenser from product intended for distribution until the product is cleared or dispositioned; and

(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.

(ii) INVESTIGATION.—An investigation conducted under clause (i)(II) shall include—

(I) verifying whether the lot number of a suspect product corresponds with the lot number for the product;

(II) verifying that the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of the suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for the product;

(III) validating any applicable transaction history and transaction information in the possession of the dispenser; and

(IV) otherwise investigating to determine whether the product is an illegitimate product.

(iii) CLEARED PRODUCT.—If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the Secretary, if applicable, of the determination and the product may be further distributed or dispensed.

(iv) RECORDS.—A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRODUCT.—

(i) IN GENERAL.—On determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall—

(I) disposition the illegitimate product within the possession or control of the dispenser;

(II) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the dispenser; and

(III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) on request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

(ii) NOTIFICATION.—On determining that a product in the possession or control of the dispenser is an illegitimate product, the dispenser shall notify the Secretary, and all immediate trading partners that the dispenser has reason to believe may have received the illegitimate product, of

the determination not later than 24 hours after making the determination.

(iii) RESPONDING TO A NOTIFICATION.—On the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a dispenser shall identify all illegitimate product subject to the notification that is in the possession or control of the dispenser, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

(iv) TERMINATING A NOTIFICATION.—On making a determination, in consultation with the Secretary, that a notification is no longer necessary, a dispenser shall promptly notify immediate trading partners that the dispenser notified pursuant to clause (ii) that the notification has been terminated.

(v) RECORDS.—A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

(C) ELECTRONIC DATABASE.—A dispenser may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity.

(5) EXCEPTION.—Notwithstanding any other provision of law, the requirements under paragraphs (1) and (4) shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of the practitioners who dispense or administer product in the usual course of professional practice.

(e) REPACKAGER REQUIREMENTS.—

(1) PRODUCT TRACING.—

(A) IN GENERAL.—A repackager described in section 14901(16)(A) of this title shall—

(i) not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement for the product;

(ii) prior to, or at the time of, each transaction in which the repackager trans-

fers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product; and

(iii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction described in clauses (i) and (ii) and maintain the information, history, and statement for not less than 6 years after the transaction.

(B) RETURNS.—

(i) NONSALEABLE PRODUCT.—A repackager described in section 14901(16)(A) of this title may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom the product was purchased, or to a person acting on behalf of the manufacturer, repackager, or wholesale distributor from whom the product was purchased, including a returns processor, without providing the information required under subparagraph (A)(ii).

(ii) SALEABLE OR NONSALEABLE PRODUCT.—A repackager described in section 14901(16)(B) of this title may return a saleable or nonsaleable product to the manufacturer, repackager, or wholesale distributor from whom the product was received without providing the information required under subparagraph (A)(ii) on behalf of the hospital or other health care entity that took ownership of the product pursuant to the terms and conditions of any agreement between the repackager and the entity that owns the product.

(C) REQUESTS FOR INFORMATION.—On a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager described in section 14901(16)(A) of this title shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, provide the applicable transaction information, transaction history, and transaction statement for the product.

(2) PRODUCT IDENTIFIER.—

(A) IN GENERAL.—A repackager described in section 14901(16)(A) of this title—

(i) shall affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce;

(ii) shall maintain the product identifier information for the product for not less than 6 years after the date of the transaction;

(iii) may engage in transactions involving a product only if the product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)); and

(iv) shall maintain records for not less than 6 years to allow the repackager to associate the product identifier the repackager affixes or imprints with the product identifier assigned by the original manufacturer of the product.

(B) EXCEPTION.—A package that is required to have a standardized numerical identi-

fier is not required to have a unique device identifier.

(3) AUTHORIZED TRADING PARTNERS.—The trading partners of a repackager described in section 14901(16) of this title may be only authorized trading partners.

(4) VERIFICATION.—A repackager described in section 14901(16)(A) of this title shall have systems in place to enable the repackager to comply with the following requirements:

(A) SUSPECT PRODUCT.—

(i) IN GENERAL.—On making a determination that a product in the possession or control of the repackager is a suspect product, or on receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a repackager is a suspect product, a repackager shall—

(I) quarantine the product within the possession or control of the repackager from product intended for distribution until the product is cleared or dispositioned; and

(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include—

(aa) validating any applicable transaction history and transaction information in the possession of the repackager and otherwise investigating to determine whether the product is an illegitimate product; and

(bb) except as provided pursuant to subsection (a)(5), verifying the product at the package level, including the standardized numerical identifier.

(ii) CLEARED PRODUCT.—If the repackager makes the determination that a suspect product is not an illegitimate product, the repackager shall promptly notify the Secretary, if applicable, of the determination and the product may be further distributed.

(iii) RECORDS.—A repackager shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

(B) ILLEGITIMATE PRODUCT.—

(i) IN GENERAL.—On determining, in coordination with the manufacturer, that a product in the possession or control of a repackager is an illegitimate product, the repackager shall, in a manner that is consistent with the systems and processes of the repackager—

(I) quarantine the product within the possession or control of the repackager from product intended for distribution until the product is dispositioned;

(II) disposition the illegitimate product within the possession or control of the repackager;

(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the repackager; and

(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) on request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

(ii) NOTIFICATION.—On determining that a product in the possession or control of the repackager is an illegitimate product, the repackager shall notify the Secretary, and all immediate trading partners that the repackager has reason to believe may have received the illegitimate product, of the determination not later than 24 hours after making the determination.

(iii) RESPONDING TO A NOTIFICATION.—On the receipt of a notification from the Secretary or a trading partner, a repackager shall identify all illegitimate product subject to the notification that is in the possession or control of the repackager, including any product that is subse-

quently received, and shall perform the activities described in subparagraph (A).

(iv) TERMINATING A NOTIFICATION.—On making a determination, in consultation with the Secretary, that a notification is no longer necessary, a repackager shall promptly notify immediate trading partners that the repackager notified pursuant to clause (ii) that the notification has been terminated.

(v) RECORDS.—A repackager shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

(C) REQUESTS FOR VERIFICATION.—

(i) NOTIFICATION.—On receiving a request for verification from an authorized manufacturer, wholesale distributor, or dispenser that is in possession or control of a product the manufacturer, wholesale distributor, or dispenser believes to be repackaged by the repackager, a repackager shall, not later than 24 hours after receiving the verification request or in other such reasonable time as determined by the Sec-

retary, based on the circumstances of the request, notify the authorized manufacturer, wholesale distributor, or dispenser making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the repackager.

(ii) PRODUCT IDENTIFIER DOES NOT CORRESPOND TO PRODUCT IDENTIFIER AFFIXED OR IMPRINTED BY REPACKAGER.—If a repackager responding to a verification request identifies a product identifier that does not correspond to that affixed or imprinted by the repackager, the repackager shall treat the product as suspect product and conduct an investigation as described in subparagraph (A).

(iii) SUSPICION THAT PRODUCT IS ILLEGITIMATE PRODUCT.—If the repackager has reason to believe the product is an illegitimate product, the repackager shall advise the person making the request of that belief at the time the repackager responds to the verification request.

(D) ELECTRONIC DATABASE.—

(i) IN GENERAL.—A repackager may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity.

(ii) REQUIREMENTS AND PROCESSES; ACCESS.—The owner of the database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate.

(iii) REQUESTS FOR VERIFICATION BY MEANS OTHER THAN SECURE ELECTRONIC DATABASE.—The development and operation of an electronic database under this subparagraph shall not relieve a repackager of the requirement under subparagraph (C) to respond to a verification request submitted by means other than a secure electronic database.

(E) VERIFICATION OF SALEABLE RETURNED PRODUCT.—On receipt of a returned product that the repackager intends to further

distribute, before further distributing the product, the repackager shall verify the product identifier for each sealed homogeneous case of the product or, if the product is not in a sealed homogeneous case, verify the product identifier on each package.

(f) DROP SHIPMENTS.—

(1) IN GENERAL.—A wholesale distributor that does not physically handle or store product shall be exempt from this section except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B), provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for the wholesale distributor includes on the transaction information and transaction history to the dispenser the contact information of the wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

(2) CLARIFICATION.—For purposes of this subsection, providing administrative services, including processing of orders and payments, shall not by itself, be construed as being involved in the handling, distribution, or storage of a product.

(g) ENHANCED DRUG DISTRIBUTION SECURITY.—

(1) IN GENERAL.—On the date that is 10 years after November 27, 2013, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

(A) EXCHANGE OF TRANSACTION INFORMATION AND TRANSACTION STATEMENTS.—The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of the guidance issued in accordance with paragraph (5) of subsection (h).

(B) INCLUSION OF PRODUCT IDENTIFIER IN TRANSACTION INFORMATION.—The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

(C) SYSTEMS AND PROCESSES FOR VERIFICATION OF PRODUCT AT PACKAGE LEVEL.—Systems and processes for verification

of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of the guidances issued in accordance with paragraph (5) of subsection (h), which may include the use of aggregation and inference as necessary.

(D) SYSTEMS AND PROCESSES FOR RESPONDING ON REQUEST.—The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product on a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

(E) SYSTEMS AND PROCESSES FOR PROMPT FACILITATION OF GATHERING INFORMATION.—The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction informa-

tion for each transaction going back to the manufacturer, as applicable, shall be required—

(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

(F) ACCEPTANCE OF SALEABLE RETURNS.—Each person accepting a saleable return shall have systems and processes in place to allow acceptance of the product and may accept saleable returns only if the person can associate the saleable return product with the transaction information and transaction statement associated with that product.

(2) COMPLIANCE.—

(A) INFORMATION MAINTENANCE AGREEMENT.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information and statements required to be maintained under this section. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

(B) ALTERNATIVE METHODS.—The Secretary, taking into consideration the assessment conducted under paragraph (3), shall provide for alternative methods of compliance with any of the requirements set forth in paragraph (1), including—

(i) establishing timelines for compliance by small businesses (including small business dispensers with 25 or fewer full-time employees) with the requirements, in order to ensure that the requirements do not impose undue economic hardship for small businesses, including small business dispensers for whom the criteria set forth

in the assessment under paragraph (3) are not met, if the Secretary determines that the requirements under paragraph (1) would result in undue economic hardship; and

(ii) establishing a process by which a dispenser may request a waiver from any of the requirements set forth in paragraph (1) if the Secretary determines that the requirements would result in an undue economic hardship, which shall include a process for the biennial review and renewal of the waiver.

(3) ASSESSMENT.—

(A) IN GENERAL.—Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (h), the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. The assessment

shall be completed not later than 8½ years after November 27, 2013.

(B) CONDITION.—As a condition of the award of the contract under subparagraph (A), the private, independent consulting firm shall agree to consult with dispensers with 25 or fewer full-time employees when conducting the assessment under the subparagraph.

(C) CONTENT.—The assessment under subparagraph (A) shall assess whether—

(i) the necessary software and hardware is readily accessible to the dispensers;

(ii) the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for the dispensers; and

(iii) the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors, for the dispensers.

(D) PUBLICATION.—The Secretary shall—

(i) publish the statement of work for the assessment under subparagraph (A) for public comment prior to beginning the assessment;

(ii) publish the final assessment for public comment not later than 30 calendar days after receiving the assessment; and

(iii) hold a public meeting not later than 180 calendar days after receiving the final assessment at which public stakeholders may present their views on the assessment.

(4) PROCEDURE.—Notwithstanding section 553 of title 5, the Secretary, in promulgating any regulation pursuant to this section, shall—

(A) provide appropriate flexibility by—

(i) not requiring the adoption of specific business systems for the maintenance and transmission of data;

(ii) prescribing alternative methods of compliance for any of the requirements set forth in paragraph (1) or set forth in regulations implementing the requirements, including—

(I) timelines for small businesses to comply with the requirements set forth in the regulations in order to ensure that the requirements do not impose undue economic hardship for

small businesses (including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) are not met), if the Secretary determines that the requirements would result in undue economic hardship; and

(II) the establishment of a process by which a dispenser may request a waiver from any of the requirements set forth in the regulations if the Secretary determines that the requirements would result in an undue economic hardship; and

(iii) taking into consideration—

(I) the results of pilot projects, including pilot projects pursuant to this section and private sector pilot projects, including those involving the use of aggregation and inference;

(II) the public meetings held and related guidance documents issued under this section;

(III) the public health benefits of any additional regulations in compari-

son to the cost of compliance with the requirements, including on entities of varying sizes and capabilities;

(IV) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector, including both large and small businesses; and

(V) the assessment pursuant to paragraph (3) with respect to small business dispensers, including related public comment and the public meeting, and requirements under this section;

(B) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

(C) provide a period of not less than 60 days for comments on the proposed regulation; and

(D) publish in the Federal Register the final regulation not less than 2 years prior to the effective date of the regulation.

(h) GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—For the purposes of facilitating the successful and efficient adoption of se-

cure, interoperable product tracing at the package level in order to enhance drug distribution security and further protect the public health, the Secretary shall issue the guidance documents as provided for in this subsection.

(2) SUSPECT PRODUCT AND ILLEGITIMATE PRODUCT.—

(A) IN GENERAL.—The Secretary shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. The guidance document shall—

(i) identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain;

(ii) provide a recommendation on how trading partners may identify the product and make a determination on whether the product is a suspect product as soon as practicable; and

(iii) set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Sec-

retary regarding illegitimate product pursuant to subsections (b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B).

(B) REVISED GUIDANCE.—If the Secretary revises the guidance issued under subparagraph (A), the Secretary shall follow the procedure set forth in paragraph (5).

(3) UNIT LEVEL TRACING.—

(A) IN GENERAL.—In order to enhance drug distribution security at the package level, not later than 18 months after conducting a public meeting on the system attributes necessary to enable secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary, the Secretary shall issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable secure tracing at the package level as required under the requirements established under subsection (g). The guidance document shall—

(i) define the circumstances under which the sectors within the pharmaceutical distribution supply chain may, in

the most efficient manner practicable, infer the contents of a case, pallet, tote, or other aggregate of individual packages or containers of product, from a product identifier associated with the case, pallet, tote, or other aggregate, without opening each case, pallet, tote, or other aggregate or otherwise individually scanning each package;

(ii) identify methods and processes to enhance secure tracing of product at the package level, such as secure processes to facilitate the use of inference, enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, including the standardized numerical identifier, or package security features; and

(iii) ensure the protection of confidential commercial information and trade secrets.

(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising the

guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

(4) STANDARDS FOR INTEROPERABLE DATA EXCHANGE.—

(A) IN GENERAL.—In order to enhance secure tracing of a product at the package level, the Secretary, not later than 18 months after conducting a public meeting on the interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain, shall update the guidance issued pursuant to subsection (a)(2), as necessary and appropriate, and finalize the guidance document so that the guidance document—

(i) identifies and makes recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization;

(ii) takes into consideration standards established pursuant to subsection (a)(2) and section 13115 of this title;

(iii) facilitates the creation of a uniform process or methodology for product tracing; and

(iv) ensures the protection of confidential commercial information and trade secrets.

(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising the guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

(5) PROCEDURE.—In issuing or revising any guidance issued pursuant to this subsection or subsection (g), except the initial guidance issued under paragraph (2)(A), the Secretary shall—

(A) publish a notice in the Federal Register for a period not less than 30 days announcing that the draft or revised draft guidance is available;

(B) post the draft guidance document on the FDA website and make the draft guidance document available in hard copy;

(C) provide an opportunity for comment and review and take into consideration any comments received;

(D) revise the draft guidance, as appropriate;

(E) publish a notice in the Federal Register for a period not less than 30 days announcing that the final guidance or final revised guidance is available;

(F) post the final guidance document on the FDA website and make the final guidance document available in hard copy; and

(G) provide for an effective date of not earlier than 1 year after the guidance becomes final.

(i) PUBLIC MEETINGS.—

(1) IN GENERAL.—The Secretary shall hold not less than 5 public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide for comment. The Secretary may hold the first public meeting not earlier than 1 year after November 27, 2013. In carrying out the public meetings described in this paragraph, the Secretary shall—

(A) prioritize topics necessary to inform the issuance of the guidance described in paragraphs (3) and (4) of subsection (h); and

(B) take all measures reasonable and practicable to ensure the protection of confidential commercial information and trade secrets.

(2) CONTENT.—Each of the following topics shall be addressed in at least 1 of the public meetings described in paragraph (1):

(A) An assessment of the steps taken under subsections (b) through (e) to build capacity for a unit-level system, including the impact of the requirements of the subsections on—

(i) the ability of the health care system collectively to maintain patient access to medicines;

(ii) the scalability of the requirements, including as it relates to product lines; and

(iii) the capability of different sectors and subsectors, including both large and small businesses, to affix and utilize the product identifier.

(B) The system attributes necessary to support the requirements set forth under sub-

section (g), including the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among sectors within the pharmaceutical distribution supply chain.

(C) Best practices in each of the different sectors within the pharmaceutical distribution supply chain to implement the requirements of this section.

(D) The costs and benefits of the implementation of this section, including the impact on each pharmaceutical distribution supply chain sector and on public health.

(E) Whether electronic tracing requirements, including tracing of product at the package level, are feasible, cost effective, and needed to protect the public health.

(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary.

(G) The technical capabilities and legal authorities, if any, needed to establish an inter-

operable, electronic system that provides for tracing of product at the package level.

(H) The impact that the additional requirements would have on patient safety, the drug supply, cost and regulatory burden, and timely patient access to prescription drugs.

(I) Other topics, as determined appropriate by the Secretary.

(j) PILOT PROJECTS.—

(1) IN GENERAL.—The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. The projects shall build on efforts, in existence as of November 27, 2013, to enhance the safety and security of the pharmaceutical distribution supply chain, take into consideration any pilot projects conducted prior to November 27, 2013, including any pilot projects that use aggregation and inference, and inform the draft and final guidance under paragraphs (3) and (4) of subsection (h).

(2) CONTENT.—

(A) IN GENERAL.—The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the pharmaceutical distribution supply chain and that the pilot projects, when taken as a whole, include participants representative of every sector, including both large and small businesses.

(B) PROJECT DESIGN.—The pilot projects under paragraph (1) shall be designed to—

(i) utilize the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;

(ii) improve the technical capabilities of each sector and subsector to comply with systems and processes needed to utilize the product identifiers to enhance tracing of a product;

(iii) identify system attributes that are necessary to implement the requirements established under this section; and

(iv) complete other activities as determined by the Secretary.

(k) SUNSET.—The following requirements shall have no force or effect beginning on the date that is 10 years after November 27, 2013:

(1) The provision and receipt of transaction history under this section.

(2) The requirements set forth for returns under subsections (b)(4)(E), (c)(1)(B)(i), (d)(1)(C)(i), and (e)(4)(E).

(3) The requirements set forth under subparagraphs (A)(v)(II) and (D) of subsection (c)(1), as applied to lot level information only.

(l) RULE OF CONSTRUCTION.—The requirements set forth in subsections (g)(4), (i), and (j) shall not be construed as a condition, prohibition, or precedent for precluding or delaying the provisions becoming effective pursuant to subsection (g).

(m) REQUESTS FOR INFORMATION.—On the date that is 10 years after November 27, 2013, the timeline for responses to requests for information from the Secretary, or other appropriate Federal or State official, as applicable, under subsections (b)(1)(B), (c)(1)(C), and (e)(1)(C) shall be not later than 24 hours after receiving the request from the Secretary or other appropriate Federal or State official, as applicable, or in such other rea-

sonable time as determined by the Secretary based on the circumstances of the request.

**§ 14903. National standards for prescription drug wholesale distributors**

(a) IN GENERAL.—The Secretary shall, not later than 2 years after November 27, 2013, establish by regulation standards for the licensing of persons under section 13103(d)(2) of this title, including the revocation, reissuance, and renewal of a license under the section.

(b) CONTENT.—For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under subsection (a) shall apply to all State and Federal licenses described under section 13103(d)(2) of this title and shall include standards for the following:

(1) The storage and handling of prescription drugs, including facility requirements.

(2) The establishment and maintenance of records of the distributions of the drugs described in paragraph (1).

(3) The furnishing of a bond or other equivalent means of security, as follows:

(A)(i) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated whole-

sale distributor shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the State.

(ii) For purposes of clause (i), the State or other applicable authority may accept a surety bond in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less.

(B) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State shall be waived.

(4) Mandatory background checks and fingerprinting of facility managers or designated representatives.

(5) The establishment and implementation of qualifications for key personnel.

(6) The mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable timeframe from the initial application of the facility and to be conducted by the licensing authority or by the State, consistent with subsection (c).

(7) In accordance with subsection (d), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.

(c) INSPECTIONS.—To satisfy the inspection requirement under subsection (b)(6), the Federal or State licensing authority may—

(1) conduct the inspection; or

(2) accept an inspection by—

(A) the State in which the facility is located; or

(B) a third-party accreditation or inspection service approved by the Secretary or the State licensing the wholesale distributor.

(d) PROHIBITED PERSONS.—The standards established under subsection (a) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of paragraph (9) or (11) of section 10501 of this title, or any felony violation of section 1365 of title 18 relating to product tampering; or

(2) has engaged in a pattern of violating the requirements of this section, or State requirements for

licensure, that presents a threat of serious adverse health consequences or death to humans.

(e) PROCEDURE.—The Secretary, in promulgating any regulation pursuant to this section, shall, notwithstanding section 553 of title 5—

(1) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

(2) provide a period of not less than 60 days for comments on the proposed regulation; and

(3) provide that the final regulation take effect on the date that is 2 years after the date the final regulation is published.

**§ 14904. National standards for third-party logistics providers**

(a) REQUIREMENTS.—A third-party logistics provider in any State shall not conduct activities in any State unless each facility of the third-party logistics provider—

(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (d); or

(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the

Secretary, in accordance with the regulations promulgated under subsection (d); and

(2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if the State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

(b) REPORTING.—A facility of a third-party logistics provider shall report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

(1) the State by which the facility is licensed and the appropriate identification number of the license; and

(2) the name and address of the facility and all trade names under which the facility conducts business.

(c) COSTS.—

(1) LICENSING BY SECRETARY; AUTHORIZED FEES OF SECRETARY.—

(A) IN GENERAL.—If a State does not establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider located in the

State and may collect a reasonable fee in the amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section.

(B) ANNUAL ADJUSTMENT OF FEE RATES.—The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform the service described in subparagraph (A).

(C) AVAILABILITY.—Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. The fees are authorized to remain available until expended. Such amounts as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation.

(2) STATE LICENSING FEES.—

(A) STATE-ESTABLISHED PROGRAM.—Nothing in this subtitle shall prohibit a State that has established a program to license a

third-party logistics provider from collecting fees from a third-party logistics provider for the license.

(B) NO STATE-ESTABLISHED PROGRAM.—A State that does not establish a program to license a third-party logistics provider in accordance with this section shall be prohibited from collecting a State licensing fee from a third-party logistics provider.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 2 years after November 27, 2013, the Secretary shall issue regulations regarding the standards for licensing under subsection (a), including the revocation and reissuance of the license, to third-party logistics providers under this section.

(2) CONTENT.—The regulations under paragraph (1) shall—

(A) establish a process by which a third-party accreditation program approved by the Secretary shall, on request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section;

(B) establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of a third-party accreditation program;

(C) require that the entity complies with storage practices, as determined by the Secretary for the facility, including—

(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;

(ii) maintaining adequate security; and

(iii) having written policies and procedures to—

(I) address receipt, security, storage, inventory, shipment, and distribution of a product;

(II) identify, record, and report confirmed losses or thefts in the United States;

(III) correct errors and inaccuracies in inventories;

(IV) provide support for manufacturer recalls;

(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(VI) ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;

(VII) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

(VIII) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

(D) provide for periodic inspection by the licensing authority, as determined by the Sec-

retary, of the facility warehouse space to ensure compliance with this section;

(E) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of paragraph (9) or (11) of section 10501 of this title or any violation of section 1365 of title 18, relating to product tampering;

(F) provide for mandatory background checks of a facility manager or a designated representative of the manager;

(G) require a third-party logistics provider to provide the applicable licensing authority, on a request by the authority, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at the facility; and

(H) include procedures under which any third-party logistics provider license—

(i) expires on the date that is 3 years after issuance of the license; and

(ii) may be renewed for additional 3-year periods.

(3) PROCEDURE.—In promulgating the regulations under this subsection, the Secretary shall, notwithstanding section 553 of title 5—

(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) provide that the final regulation takes effect on the expiration of 1 year after the date that the final regulation is issued.

(e) VALIDITY.—A license issued under this section shall remain valid as long as the third-party logistics provider remains licensed consistent with this section. If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider receiving accreditation, pursuant to subsection (d)(2)(A).

**§ 14905. Uniform national policy**

(a) PRODUCT TRACING AND OTHER REQUIREMENTS.—A State or political subdivision of a State shall not establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of dis-

tribution history, transaction history, transaction information, or transaction statement of a product as the product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to the systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system)—

(1) that are inconsistent with, more stringent than, or in addition to, any requirements applicable under this chapter or section 13103(d) of this title (or regulations issued under this chapter or section 13103(d) of this title); or

(2) that are inconsistent with—

(A) any waiver, exception, or exemption pursuant to section 14901 or 14902 of this title; or

(B) any restrictions specified in section 14902 of this title.

(b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER STANDARDS.—

(1) IN GENERAL.—A State or political subdivision of a State shall not establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are incon-

sistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 13103(d) of this title, in the case of a wholesale distributor, or section 14904 of this title, in the case of a third-party logistics provider.

(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—A State shall not regulate third-party logistics providers as wholesale distributors.

(3) ADMINISTRATION FEES.—Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale drug distributor and third-party logistics provider licensure requirements under sections 13103(d), 14903, and 14904 of this title.

(4) ENFORCEMENT, SUSPENSION, AND REVOCATION.—Notwithstanding paragraph (1), a State—

(A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with this chapter or section 13103(d) of this title;

(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of the State;

(C) on conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties; and

(D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 14902 of this title.

(c) EXCEPTION.—Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if the requirements are not related to product tracing as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under this chapter or section 13103(d) of this title (or regulations issued under this chapter or section 13103(d) of this title).

# Chapter 151—Nonprescription Sunscreen and Other Active Ingredients

Sec.
15101. Definitions.
15102. Submission of requests.
15103. Eligibility determinations; data submission; filing.
15104. GRASE determination.
15105. Guidance; other provisions.
15106. Effect of sections.
15107. Non-sunscreen time and extent applications.
15108. Report.
15109. Sunset.

**§ 15101. Definitions**

In this chapter:

(1) ADVISORY COMMITTEE.—The term ''Advisory Committee'' means the Nonprescription Drug Advisory Committee of the FDA or any successor to the Advisory Committee.

(2) FINAL SUNSCREEN ORDER.—The term ''final sunscreen order'' means an order published by the Secretary in the Federal Register containing information stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

(A) is GRASE and is not misbranded if marketed in accordance with the order; or

(B) is not GRASE and is misbranded.

(3) GRASE.—The term ''GRASE'' means generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of a drug as described in section 10101(a)(34) of this title.

(4) GRASE DETERMINATION.—The term ''GRASE determination'' means, with respect to a nonprescription active ingredient or a combination of nonprescription active ingredients, a determination

of whether the ingredient or combination of ingredients is GRASE.

(5) NONPRESCRIPTION.—The term ''nonprescription'' means not subject to section 13103(a)(1) of this title.

(6) PENDING REQUEST.—The term ''pending request'' means each request with respect to a nonprescription sunscreen active ingredient submitted under section 330.14 of title 21, Code of Federal Regulations, as in effect on November 26, 2014, for consideration for inclusion in the over-the-counter drug monograph system—

(A) that was determined to be eligible for the review by publication of a notice of eligibility in the Federal Register prior to November 26, 2014; and

(B) for which safety and effectiveness data have been submitted to the Secretary prior to November 26, 2014.

(7) PROPOSED SUNSCREEN ORDER.—The term ''proposed sunscreen order'' means an order containing a tentative determination published by the Secretary in the Federal Register containing information proposing that a nonprescription sunscreen

active ingredient or combination of nonprescription sunscreen active ingredients—

(A) is GRASE and is not misbranded if marketed in accordance with the order;

(B) is not GRASE and is misbranded; or

(C) is not GRASE and is misbranded because the data are insufficient to classify the ingredient or combination of ingredients as GRASE and not misbranded and additional information is necessary to allow the Secretary to determine otherwise.

(8) SPONSOR.—The term ''sponsor'' means the person that submitted—

(A) a request under section 15102 of this title;

(B) a pending request; or

(C) any other application subject to this chapter.

(9) SUNSCREEN.—The term ''sunscreen'' means a drug containing 1 or more sunscreen active ingredients.

(10) SUNSCREEN ACTIVE INGREDIENT.—The term ''sunscreen active ingredient'' means an active ingredient that is intended for application to the

skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation.

**§ 15102. Submission of requests**

Any person may submit a request to the Secretary for a determination of whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling of the ingredient or combination of ingredients (including dosage form, dosage strength, and route of administration) is GRASE and should be included in part 352 of title 21, Code of Federal Regulations, or any successor regulations, concerning nonprescription sunscreen.

**§ 15103. Eligibility determinations; data submission; filing**

(a) ELIGIBILITY DETERMINATIONS.—

(1) IN GENERAL.—Not later than 60 calendar days after the date of receipt of a request under section 15102 of this title, the Secretary shall—

(A) determine, in accordance with paragraph (2), whether the request is eligible for further review under subsection (b) and section 15104 of this title;

(B) notify the sponsor of the determination of the Secretary; and

(C) make the determination publicly available in accordance with paragraph (3) and subsection (b)(1).

(2) CRITERIA FOR ELIGIBILITY.—

(A) IN GENERAL.—To be eligible for review under subsection (b) and section 15104 of this title, a request shall be for a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under specified conditions to be prescribed, recommended, or suggested in the labeling of the ingredient or combination of ingredients, that—

(i) is not included in part 352 of title 21, Code of Federal Regulations, or any successor regulations, concerning nonprescription sunscreen; and

(ii) has been used to a material extent and for a material time under the conditions, as described in section 10101(a)(34)(A)(ii) of this title.

(B) ESTABLISHMENT OF TIME AND EXTENT.—A sponsor shall include in a request

under section 15102 of this title the information required under section 330.14 of title 21, Code of Federal Regulations, or any successor regulations, to meet the standard described in subparagraph (A)(ii).

(3) PUBLIC AVAILABILITY.—

(A) REDACTIONS FOR CONFIDENTIAL INFORMATION.—If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined under paragraph (1)(A) to be eligible for further review, the Secretary shall make the request publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, section 1905 of title 18, or section 10501(10) of this title.

(B) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—At the time that a request is made under section 15102 of this title, the sponsor of the request shall identify any information that the sponsor considers to be confidential information described in subparagraph (A).

(C) CONFIDENTIALITY DURING ELIGIBILITY REVIEW.—The information contained in

a request under section 15102 of this title shall remain confidential during the Secretary's consideration under this section of whether the request is eligible for further review consistent with section 330.14 of title 21, Code of Federal Regulations, or any successor regulations.

(b) DATA SUBMISSION AND FILING OF REQUESTS.—

(1) IN GENERAL.—In the case of a request under section 15102 of this title that is determined to be eligible under subsection (a) for further review under this section and section 15104 of this title, the Secretary shall, in notifying the public under subsection (a)(1)(C) of the eligibility determination, post the eligibility determination on the FDA website, invite the sponsor of the request and any other interested party to submit comments, and provide a period of not less than 45 calendar days for comments in support of or otherwise relating to a GRASE determination, including published and unpublished data and other information related to the safety and efficacy of the request.

(2) FILING DETERMINATION.—Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, the Secretary shall determine whether the

data and other information submitted by the sponsor under this section are sufficiently complete, including being formatted in a manner that enables the Secretary to determine the completeness of the data and information, to enable the Secretary to conduct a substantive review under section 15104 of this title with respect to the request. Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, if the Secretary determines—

(A) that the data and other information are sufficiently complete, the Secretary shall—

(i) issue a written notification, to the sponsor, of the determination to file the request, and make the notification publicly available; and

(ii) file the request made under section 15102 of this title; or

(B) that the data and other information are not sufficiently complete, the Secretary shall issue a written notification to the sponsor of the determination to refuse to file the request, which shall include the reasons for the refusal, including why the data and other infor-

mation are not sufficiently complete, and make the notification publicly available.

(3) REFUSAL TO FILE A REQUEST.—

(A) REQUEST FOR MEETINGS; SUBMISSION OF ADDITIONAL DATA OR OTHER INFORMATION.—If the Secretary refuses to file a request made under section 15102 of this title, the sponsor may—

(i) within 30 calendar days of receipt of written notification of the refusal, request, in writing, a meeting with the Secretary regarding the filing determination; and

(ii) submit additional data or other information.

(B) MEETINGS.—

(i) IN GENERAL.—If a sponsor seeks a meeting under subparagraph (A)(i), the Secretary shall convene the meeting within 30 calendar days of the request for the meeting.

(ii) ACTIONS AFTER MEETING.—Following any meeting held under clause (i)—

(I) the Secretary may file the request within 60 calendar days;

(II) the sponsor may submit additional data or other information; or

(III) if the sponsor elects, within 120 calendar days, to have the Secretary file the request (with or without amendments to correct any purported deficiencies to the request)—

(aa) the Secretary shall file the request over protest, not later than 30 calendar days after the sponsor makes the election;

(bb) at the time of filing, the Secretary shall provide written notification of the filing to the sponsor; and

(cc) the Secretary shall make the notification publicly available.

(iii) REQUESTS FILED OVER PROTEST.—The Secretary shall not require the sponsor to resubmit a copy of the request for purposes of filing a request filed over protest, as described in clause (ii)(III).

(C) SUBMISSIONS OF ADDITIONAL DATA OR OTHER INFORMATION.—Within 60 calendar

days of any submission of additional data or other information under subparagraph (A)(ii) or (B)(ii)(II), the Secretary shall reconsider the previous determination made under paragraph (2) with respect to the applicable request and make a new determination in accordance with paragraph (2).

(4) PUBLIC AVAILABILITY.—

(A) REDACTIONS FOR CONFIDENTIAL INFORMATION.—After the period of confidentiality described in subsection (a)(3)(C), the Secretary shall make data and other information submitted in connection with a request under section 15102 of this title publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, section 1905 of title 18, or section 10501(10) of this title.

(B) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—A person submitting information under this section shall identify at the time of the submission the portions of the information that the person considers to be confidential information described in subparagraph (A).

**§ 15104. GRASE determination**

(a) REVIEW OF NEW REQUEST.—

(1) PROPOSED SUNSCREEN ORDER.—In the case of a request under section 15102 of this title, not later than 300 calendar days after the date on which the request is filed under subsection (b)(2)(A) or (b)(3)(B)(ii)(III) of section 15103 of this title, the Secretary—

(A) may convene a meeting of the Advisory Committee to review the request; and

(B) shall complete the review of the request and issue a proposed sunscreen order with respect to the request.

(2) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—

(A) NOTIFICATION AND REQUEST FOR REVIEW.—If the Secretary does not issue a proposed sunscreen order under paragraph (1)(B) within the 300-day period, the sponsor of the request may notify the Office of the Commissioner of the request and request review by the Office of the Commissioner.

(B) ISSUANCE.—If the sponsor notifies the Office of the Commissioner under subparagraph (A), the Commissioner shall, not later than 60 calendar days after the date of notification

under this paragraph, issue a proposed sunscreen order with respect to the request.

(3) PUBLIC COMMENT PERIOD.—A proposed sunscreen order issued under paragraph (1)(B) or (2) with respect to a request shall provide for a period of 45 calendar days for public comment.

(4) MEETING.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection and described in subparagraph (B) or (C) of section 15101(7) of this title, not later than 30 calendar days after the Secretary issues the order. The Secretary shall convene a meeting with the sponsor not later than 45 calendar days after the request for a meeting.

(5) FINAL SUNSCREEN ORDER.—With respect to a proposed sunscreen order under paragraph (1)(B) or (2)—

(A) the Secretary shall issue a final sunscreen order—

(i) in the case of a proposed sunscreen order described in subparagraph (A) or (B) of section 15101(7) of this title, not later than 90 calendar days after the end of the public comment period under paragraph (3); or

(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 15101(7) of this title, not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to the proposed sunscreen order; or

(B) if the Secretary does not issue the final sunscreen order within the 90-calendar day period or 210-calendar-day period, as applicable, the sponsor of the request may notify the Office of the Commissioner of the request and request review by the Office of the Commissioner.

(6) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (5)(B) not later than 60 calendar days after the date of notification under paragraph (5)(B).

(b) REVIEW OF PENDING REQUESTS.—

(1) IN GENERAL.—The Secretary shall carry out the review of a pending request in accordance with this subsection.

(2) INAPPLICABILITY OF CERTAIN PROVISIONS.—Sections 15102 and 15103 of this title shall not apply with respect to any pending request.

(3) FEEDBACK LETTERS AS PROPOSED SUNSCREEN ORDER.—Notwithstanding the requirements of section 15101(7) of this title, a letter issued pursuant to section 330.14(g) of title 21, Code of Federal Regulations, before November 26, 2014, with respect to a pending request, shall be deemed to be a proposed sunscreen order and displayed on the FDA website. Notification of the availability of the letter shall be published in the Federal Register not later than 45 calendar days after November 26, 2014.

(4) PROPOSED SUNSCREEN ORDER.—In the case of a pending request for which the Secretary has not issued a letter pursuant to section 330.14(g) of title 21, Code of Federal Regulations, before November 26, 2014, the Secretary shall complete review of the request and, not later than 90 calendar days after November 26, 2014, issue a proposed sunscreen order with respect to the request.

(5) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—If the Secretary does not issue a proposed sunscreen order under paragraph (4), or the Sec-

retary does not publish a notification of the availability of a letter under paragraph (3), as applicable, the sponsor of the request may notify the Office of the Commissioner of the request and request review by the Office of the Commissioner. The Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed order with respect to the request.

(6) PUBLIC COMMENT PERIOD.—A proposed sunscreen order issued under paragraph (4) or (5), or a notification of the availability of a letter under paragraph (3), with respect to a pending request shall provide for a period of 45 calendar days for public comment.

(7) MEETING.—

(A) IN GENERAL.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection, including a letter deemed to be a proposed sunscreen order under paragraph (3), not later than 30 calendar days after the Secretary issues the order or the date on which the feedback letter is deemed to be a proposed sunscreen order, as applicable. The Secretary shall convene a meeting with the sponsor not later

than 45 calendar days after the date of the request for a meeting.

(B) CONFIDENTIAL MEETINGS.—

(i) REQUEST BY SPONSOR.—A sponsor may request 1 or more confidential meetings with respect to a proposed sunscreen order, including a letter deemed to be a proposed sunscreen order under paragraph (3), to discuss matters relating to data requirements to support a general recognition of safety and effectiveness involving confidential information and public information related to the proposed sunscreen order, as appropriate.

(ii) TIMING.—The Secretary shall convene a confidential meeting with the sponsor in a reasonable time period.

(iii) REQUEST FOR MORE THAN 1 MEETING.—If a sponsor requests more than 1 confidential meeting for the same proposed sunscreen order, the Secretary may refuse to grant an additional confidential meeting request—

(I) if the Secretary determines that the additional confidential meet-

ing is not reasonably necessary for the sponsor to advance its proposed sunscreen order; or

(II) if the request for a confidential meeting fails to include sufficient information on which to base a substantive discussion.

(iv) PUBLICATION OF POST-MEETING SUMMARY.—The Secretary shall publish a post-meeting summary of each confidential meeting under this subparagraph that does not disclose confidential commercial information or trade secrets.

(v) OTHER LAWS.—This subparagraph does not authorize the disclosure of confidential commercial information or trade secrets subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(8) ADVISORY COMMITTEE MEETING.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5), an Advisory Committee meeting may be convened for the purpose of reviewing and providing recommendations regarding the pending request.

(9) FINAL SUNSCREEN ORDER.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5)—

(A) the Secretary shall issue a final sunscreen order with respect to the request—

(i) in the case of a proposed sunscreen order described in subparagraph (A) or (B) of section 15101(7) of this title, not later than 90 calendar days after the end of the public comment period under paragraph (6); or

(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 15101(7) of this title—

(I) if the Advisory Committee is not convened under paragraph (8), not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to the proposed sunscreen order, which shall include a rationale for not convening the Advisory Committee; or

(II) if the Advisory Committee is convened under paragraph (8), not

later than 270 calendar days after the date on which the sponsor submits the additional information; or

(B) if the Secretary does not issue the final sunscreen order within the 90-calendar day period, 210-calendar day period, or 270-calendar-day period, as applicable, the sponsor of the request may notify the Office of the Commissioner about the request and request review by the Office of the Commissioner.

(10) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (9)(B) not later than 60 calendar days after the date of notification under paragraph (9)(B).

(c) ADVISORY COMMITTEE.—The Secretary shall not be required to—

(1) convene the Advisory Committee—

(A) more than once with respect to any request under section 15102 of this title or any pending request; or

(B) more than twice in any calendar year with respect to the review under this section; or

(2) submit more than a total of 3 requests under section 15102 of this title or pending requests to the Advisory Committee per meeting.

(d) NO DELEGATION.—Any responsibility vested in the Commissioner by paragraph (2) or (6) of subsection (a) or paragraph (5) or (10) of subsection (b) shall not be delegated.

(e) EFFECT OF FINAL SUNSCREEN ORDER.—

(1) IN GENERAL.—

(A) SUNSCREEN ACTIVE INGREDIENTS DETERMINED TO BE GRASE.—On issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded, a sunscreen containing the ingredient or combination of ingredients shall be permitted to be introduced or delivered into interstate commerce for use under the conditions described in the final sunscreen order, in accordance with all requirements applicable to drugs not subject to section 13103(a)(1) of this title, for so long as the final sunscreen order remains in effect.

(B) SUNSCREEN ACTIVE INGREDIENTS DETERMINED NOT TO BE GRASE.—On issuance of

a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded, a sunscreen containing the ingredient or combination of ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions described in the final sunscreen order, unless an application is approved pursuant to chapter 135 of this title with respect to a sunscreen containing the ingredient or combination of ingredients, or unless conditions are later established under which the ingredient or combination of ingredients is later determined to be GRASE and not misbranded under the over-the-counter drug monograph system.

(2) AMENDMENTS TO FINAL SUNSCREEN ORDERS.—

(A) AMENDMENTS AT INITIATIVE OF SECRETARY.—In the event that information relevant to a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients becomes available to the Secretary after issuance of a final sunscreen

order, the Secretary may amend the final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

(B) PETITION TO AMEND FINAL ORDER.—Any interested person may petition the Secretary to amend a final sunscreen order under section 10.30 of title 21, Code of Federal Regulations (or any successor regulations). If the Secretary grants any petition under that section, the Secretary shall initiate the process for amending a final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

(C) APPLICABILITY OF FINAL ORDERS.—Once the Secretary issues a new proposed sunscreen order to amend a final sunscreen order under subparagraph (A) or (B), the final sunscreen order shall remain in effect and paragraph (3) shall not apply to the final sunscreen order until the Secretary has issued a new final sunscreen order or has determined not to amend the final sunscreen order.

(3) RELATIONSHIP TO ORDERS UNDER SECTION 13118 OF THIS TITLE.—A final sunscreen order shall be deemed to be a final order under section 13118 of this title.

(f) EXCLUSIVITY.—

(1) IN GENERAL.—A final sunscreen order shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of the requestor with respect to the subject of the request and listed under paragraph (5)), for a period of 18 months, to market a sunscreen ingredient under this section incorporating changes described in paragraph (2) subject to the limitations under paragraph (4), beginning on the date the requestor (or any licensees, assignees, or successors in interest of the requestor with respect to the subject of the request and listed under paragraph (5)) may lawfully market the sunscreen ingredient pursuant to the order.

(2) CHANGES DESCRIBED.—A change described in this paragraph is a change subject to an order specified in paragraph (1) that permits a sunscreen to contain an active sunscreen ingredient not previously incorporated in a marketed sunscreen listed in paragraph (3).

(3) MARKETED SUNSCREEN.—The marketed sunscreen ingredients described in this paragraph are sunscreen ingredients—

(A) marketed in accordance with a final monograph for sunscreen drug products set forth at part 352 of title 21, Code of Federal Regulations (as published at 64 Fed. Reg. 27687 (May 21, 1999)); or

(B) marketed in accordance with a final order issued under this section.

(4) LIMITATIONS ON EXCLUSIVITY.—Only one 18-month period may be granted per ingredient under paragraph (1).

(5) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—Requestors shall submit to the Secretary, at the time when a drug subject to the request is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or successors in interest under paragraph (1).

**§ 15105. Guidance; other provisions**

(a) GUIDANCE.—

(1) IN GENERAL.—

(A) DRAFT GUIDANCE.—The Secretary shall issue final guidance on the implementation

of, and compliance with, the requirements with respect to sunscreen under this chapter, including guidance on—

(i) the format and content of information submitted by a sponsor in support of a request under section 15102 of this title or a pending request;

(ii) the data required to meet the safety and efficacy standard for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

(iii) the process by which a request under section 15102 of this title or a pending request is withdrawn; and

(iv) the process by which the Secretary will carry out section 15104(c) of this title, including with respect to how the Secretary will address the total number of requests received under section 15102 of this title and pending requests.

(B) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44 shall not

apply to collections of information made for purposes of guidance under this subsection.

(2) SUBMISSIONS PENDING ISSUANCE OF FINAL GUIDANCE.—Irrespective of whether final guidance under paragraph (1) has been issued—

(A) persons may make submissions under this chapter; and

(B) the Secretary shall review and act on the submissions in accordance with this chapter.

(b) RULES OF CONSTRUCTION.—

(1) CURRENTLY MARKETED SUNSCREENS.—Nothing in this chapter shall be construed to affect the marketing of sunscreens that are marketed in interstate commerce on or before November 26, 2014, except as otherwise provided in this chapter.

(2) ENSURING SAFETY AND EFFECTIVENESS.—Nothing in this chapter shall be construed to alter the authority of the Secretary with respect to prohibiting the marketing of a sunscreen that is not safe and effective or is misbranded, or with respect to imposing restrictions on the marketing of a sunscreen to ensure safety and effectiveness, except as otherwise provided in this chapter, including section 15104(e) of this title.

(3) OTHER DRUGS.—Except as otherwise provided in section 15107 of this title, nothing in this chapter shall be construed to affect the authority of the Secretary under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) with respect to a drug other than a nonprescription sunscreen.

(4) EFFECT ON DRUGS OTHERWISE APPROVED.—Nothing in this chapter affects the marketing of a drug approved under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262).

(c) TIMELINES.—The timelines for the processes and procedures under paragraphs (1), (2), (5), and (6) of section 15104(a) of this title shall not apply to any requests submitted to the Secretary under section 15102 of this title after the date that is 6 years after November 26, 2014.

**§ 15106. Effect of sections**

Nothing in sections 15101, 15102, 15103, 15104, and 15105 of this title shall be construed to—

(1) limit the right of a sponsor to request that the Secretary convene an advisory committee; or

(2) limit the authority of the Secretary to meet with a sponsor.

**§ 15107. Non-sunscreen time and extent applications**

(a) PENDING TIME AND EXTENT APPLICATIONS.—

(1) IN GENERAL.—

(A) REQUEST FOR FRAMEWORK FOR REVIEW.—If, prior to November 26, 2014, an application was submitted pursuant to section 330.14 of title 21, Code of Federal Regulations, for a GRASE determination for a drug other than a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients and the drug was found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations, the sponsor of the application may request that the Secretary provide a framework under paragraph (2) for the review of the application.

(B) REQUEST REQUIREMENTS.—A request for a framework for review of an application made under subparagraph (A) shall be made within 180 calendar days of November 26, 2014, and shall include the preference of the sponsor as to whether the application is reviewed by the Secretary in accordance with—

(i) the processes and procedures set forth for pending requests under section 15104(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section;

(ii) the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations, or any successor regulations;

(iii) an initial filing determination under the processes and procedures described in section 15103(b) of this title and the processes and procedures set forth for pending requests under section 15104(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section; or

(iv) an initial filing determination under the processes and procedures described in section 15103(b) of this title and the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations, or any successor regulations.

(C) NO REQUEST.—If a sponsor described in subparagraph (A) does not make the request within 180 calendar days of November 26, 2014, the application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when the regulations are finalized under subsection (b).

(2) FRAMEWORK.—Not later than 1 year after November 26, 2014, the Secretary shall provide, in writing, a framework to each sponsor that submitted a request under paragraph (1). The framework shall set forth the various timelines, in calendar days, with respect to the processes and procedures for review under clauses (i), (ii), (iii), and (iv) of paragraph (1)(B) and—

(A) the timelines shall account for the considerations under paragraph (5); and

(B) the timelines for the various processes and procedures shall not be shorter than the timelines set forth for pending requests under sections 15103(b) and 15104(b) of this title, as applicable.

(3) GOVERNING PROCESSES AND PROCEDURES FOR REVIEW.—

(A) ELECTION.—

(i) IN GENERAL.—Not later than 60 calendar days after the Secretary provides a framework to a sponsor under paragraph (2), the sponsor may provide an election to the Secretary regarding the processes and procedures for review under clause (i), (ii), (iii), or (iv) of paragraph (1)(B).

(ii) REVIEW.—If the sponsor makes the election, the Secretary shall review the application that is the subject of the election pursuant to the processes and procedures elected by the sponsor and the applicable timelines in calendar days set forth under the framework, which the Secretary shall confirm in writing to the sponsor not later than the date on which the Secretary provides a report under paragraph (4).

(iii) ELECTION NOT MADE.—If the sponsor does not make the election, the application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when the regulations are finalized under subsection (b).

(B) DIFFERENT PROCESSES AND PROCEDURES.—At any time during review of an appli-

cation, the Secretary may review the application under different processes and procedures under clause (i), (ii), (iii), or (iv) of paragraph (1)(B) than the processes and procedures the sponsor elected in accordance with subparagraph (A), so long as the Secretary proposes, in writing, the change and the sponsor agrees, in writing, to the change.

(C) INCLUSION OF INGREDIENTS IN MONOGRAPHS.—If the sponsor elects to use the processes and procedures for review in accordance with clause (i) or (iii) of paragraph (1)(B), the Secretary may incorporate any resulting final order into a regulation addressing the conditions under which other drugs in the same therapeutic category are GRASE and not misbranded, including through direct final rulemaking, and the incorporated final order shall cease to be effective on the effective date of the final regulation that addresses the drug.

(4) LETTER REGARDING PENDING APPLICATIONS.—Not later than 18 months after November 26, 2014, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and

Commerce of the House of Representatives, in writing, regarding all pending applications subject to paragraph (1). In the letter, the Secretary shall provide a report on the review of the applications, including the timelines, in calendar days, for the review and GRASE determination for each application. The timelines shall account for the considerations under paragraph (5).

(5) TIMELINES.—The timelines in calendar days established by the Secretary pursuant to this subsection—

(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

(B) shall—

(i) reflect the public health priorities of the FDA, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

(ii) take into consideration the resources available to the Secretary for carrying out the priorities and the processes and procedures described in paragraphs (1)(B) and (2); and

(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

(b) NEW TIME AND EXTENT APPLICATIONS.—

(1) IN GENERAL.—The Secretary shall issue final regulations establishing timelines for the review of applications for GRASE determinations for drugs other than nonprescription sunscreen active ingredients or combinations of nonprescription sunscreen active ingredients that are submitted to the Secretary after November 26, 2014, under section 330.14 of title 21, Code of Federal Regulations, or any successor regulations, and that are found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations, or any successor regulations, or that are subject to this subsection pursuant to paragraph (1) or (3) of subsection (a), as applicable, providing—

(A) timely and efficient completion of evaluations of applications under section 330.14 of title 21, Code of Federal Regulations, or any successor regulations, for drugs other than sunscreens; and

(B) timely and efficient completion of the review of the safety and effectiveness submissions pursuant to the applications, including establishing—

(i) reasonable timelines, in calendar days, for the applicable proposed and final regulations for applications of various content, complexity, and format, and timelines for internal procedures related to the processes; and

(ii) measurable metrics for tracking the extent to which the timelines set forth in the regulations are met.

(2) TIMELINES.—The timelines in calendar days established in the regulations under paragraph (1)—

(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

(B) shall—

(i) reflect the public health priorities of the FDA, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

(ii) take into consideration the resources available to the Secretary for carrying out the priorities and the processes and procedures described in paragraph (1); and

(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

(3) PROCEDURE.—In promulgating regulations under this subsection, the Secretary shall issue a notice of proposed rulemaking that includes a copy of the proposed regulation, provide a period of not less than 60 calendar days for comments on the proposed regulation, and publish the final regulation not less than 30 calendar days before the effective date of the regulation.

(4) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraphs (1), (2), and (3).

**§ 15108. Report**

(a) IN GENERAL.—

(1) IN GENERAL.—Not later than 18 months after November 26, 2014, and on the dates that are 2 and 4 years thereafter, the Secretary shall issue

a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives describing actions taken under this chapter.

(2) CONTENTS.—The reports under this subsection shall include—

(A) a review of the progress made in issuing GRASE determinations for pending requests, including the number of pending requests—

(i) reviewed and the decision times for each request, measured from the date of the original request for an eligibility determination submitted by the sponsor;

(ii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

(iii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE

and is misbranded and the reasons for the determinations; and

(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

(B) a review of the progress made in issuing GRASE determinations for requests not included in the reporting under subparagraph (A), including the number of the requests—

(i) reviewed and the decision times for each request;

(ii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is GRASE and is not misbranded;

(iii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is not GRASE and is misbranded

and the reasons for the determinations; and

(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

(C) an annual accounting (including information from years prior to November 26, 2014, if the information is available) of the total number of requests submitted, pending, or completed under this chapter, including whether the requests were the subject of an advisory committee convened by the Secretary;

(D) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to requests under this chapter;

(E) a review of the progress made in meeting the deadlines with respect to processing requests under this chapter; and

(F) to the extent the Secretary determines appropriate, recommendations for process im-

provements in the handling of requests under this chapter, including the advisory committee review process.

(b) METHOD.—The Secretary shall publish the reports under subsection (a) in the manner the Secretary determines to be the most effective for efficiently disseminating the report, including publication of the report on the FDA website.

### § 15109. Sunset

This chapter shall cease to be effective at the end of fiscal year 2022.

# Division E—Cosmetics

# Chapter 171—Cosmetics

**Subchapter I—General Provisions**
Sec.
17101. Definitions.
**Subchapter II—Adulterated and Misbranded Cosmetics**
17111. Adulterated cosmetics.
17112. Misbranded cosmetics.
17113. Regulations making exemptions.
**Subchapter III—General Safety Regulations**
17121. Adverse events.
17122. Good manufacturing practice.
17123. Registration and product listing.
17124. Safety substantiation.
17125. Labeling.
17126. Records.
17127. Mandatory recall authority.
17128. Small businesses.
17129. Exemption for certain products and facilities.
17130. Preemption.

## Subchapter I—General Provisions

### § 17101. Definitions

In this chapter:

(1) ADVERSE EVENT.—The term ''adverse event'' means any health-related event associated with the use of a cosmetic product that is adverse.

(2) COSMETIC PRODUCT.—The term ''cosmetic product'' means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

(3) FACILITY.—

(A) IN GENERAL.—The term ''facility'' includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

(B) EXCLUSIONS.—The term ''facility'' does not include any of the following:

(i) Beauty shops and salons, unless the establishment manufactures or processes cosmetic products at that location.

(ii) Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b) of the Internal Revenue Act of 1986 (26 U.S.C. 3508(b))), retail distribution facilities, and pharmacies, unless the establishment manufactures or processes cosmetic products

that are not sold directly to consumers at that location.

(iii) Hospitals, physicians' offices, and health care clinics.

(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.

(v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.

(vi) Trade shows and other venues where cosmetic product samples are provided free of charge.

(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing, and not offered for retail sale.

(viii) An establishment that solely performs 1 or more of the following with respect to cosmetic products:

(I) Labeling.

(II) Relabeling.

(III) Packaging.

(IV) Repackaging.

(V) Holding.

(VI) Distributing.

(C) CLARIFICATION.—For the purposes of subparagraph (B)(viii), the terms ''packaging'' and ''repackaging'' do not include filling a product container with a cosmetic product.

(4) RESPONSIBLE PERSON.—The term ''responsible person'' means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the cosmetic product in accordance with section 17125(a) of this title or section 4(a) of the Fair Packaging and Labeling Act (15 U.S.C. 1453(a)).

(5) SERIOUS ADVERSE EVENT.—The term ''serious adverse event'' means an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity;

(v) a congenital anomaly or birth defect;

(vi) an infection; or

(vii) significant disfigurement (including serious and persistent rashes, second-degree or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

# Subchapter II—Adulterated and Misbranded Cosmetics

### § 17111. Adulterated cosmetics

(a) DEFINITION OF HAIR DYE.—In this section, the term ''hair dye'' does not include eyelash dyes or eyebrow dyes.

(b) POISONOUS OR DELETERIOUS SUBSTANCE.—

(1) IN GENERAL.—A cosmetic shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling of the cosmetic, or under such conditions of use as are customary or usual.

(2) INAPPLICABILITY.—This subsection shall not apply to coal-tar hair dye—

(A) the label of which bears the statement, conspicuously displayed on the label, ''Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.''; and

(B) the labeling of which bears adequate directions for the preliminary testing referred to in the statement under subparagraph (A).

(c) FILTHY, PUTRID, OR DECOMPOSED SUBSTANCE.—A cosmetic shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance.

(d) INSANITARY CONDITIONS.—A cosmetic shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions—

(1) in which it may have become contaminated with filth; or

(2) in which it may have been rendered injurious to health.

(e) CONTAINER COMPOSED OF POISONOUS OR DELETERIOUS SUBSTANCE.—A cosmetic shall be deemed to be adulterated if its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

(f) COLOR ADDITIVE.—A cosmetic shall be deemed to be adulterated if it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of section 17701(a) of this title.

(g) DOES NOT MEET GOOD MANUFACTURING PRACTICE REQUIREMENTS.—A cosmetic shall be deemed to be adulterated if it has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of section 17122 of this title.

(h) NO ADEQUATE SUBSTANTIATION OF SAFETY.—A cosmetic shall be deemed to be adulterated if it is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for safety, as defined in section 17124(a) of this title.

**§ 17112. Misbranded cosmetics**

(a) FALSE OR MISLEADING LABEL.—A cosmetic shall be deemed to be misbranded if its labeling is false or misleading in any particular.

(b) LABEL CONTENT.—

(1) IN GENERAL.—A cosmetic shall be deemed to be misbranded if in package form unless it bears a label containing—

(A) the name and place of business of the manufacturer, packer, or distributor;

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and

(C) the information required under section 17125 of this title.

(2) STATEMENT VARIATIONS.—With respect to paragraph (1)(B), reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) PROMINENT PLACEMENT OF INFORMATION ON LABEL OR LABELING.—A cosmetic shall be deemed to be misbranded if any word, statement, or other information required under this subtitle to appear on the label or labeling is not prominently placed on the label or labeling with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) MISLEADING CONTAINER.—A cosmetic shall be deemed to be misbranded if its container is made, formed, or filled in a manner that is misleading.

(e) COLOR ADDITIVES.—

(1) IN GENERAL.—A cosmetic shall be deemed to be misbranded if it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to the color additive, as may be contained in regulations issued under section 17701 of this title.

(2) INAPPLICABILITY TO HAIR DYES.—This subsection shall not apply to packages of color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in section 17111(a) of this title).

(f) PACKAGING OR LABELING IN VIOLATION OF CERTAIN PROVISIONS.—A cosmetic shall be deemed to be misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1472, 1473).

**§ 17113. Regulations making exemptions**

The Secretary shall promulgate regulations exempting from any labeling requirement of this subtitle cosmetics that are, in accordance with the practice of the

trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that the cosmetics are not adulterated or misbranded under this subtitle upon removal from the processing, labeling, or repacking establishment.

# Subchapter III—General Safety Regulations

### § 17121. Adverse events

(a) SERIOUS ADVERSE EVENT REPORTING REQUIREMENTS.—The responsible person shall submit to the Secretary any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by the person.

(b) SUBMISSION OF REPORTS.—

(1) SERIOUS ADVERSE EVENT REPORT.—The responsible person shall submit to the Secretary a serious adverse event report accompanied by a copy of the label on or within the retail packaging of the cosmetic product no later than 15 business days after the report is received by the responsible person.

(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new

and material medical information, related to a serious adverse event report submitted to the Secretary in accordance with paragraph (1), that is received by the responsible person within 1 year of the initial report to the Secretary, no later than 15 business days after the information is received by the responsible person.

(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to enable responsible persons to submit a single report that includes duplicate reports of, or new medical information related to, a serious adverse event.

(c) EXEMPTIONS.—The Secretary may establish by regulation an exemption to any of the requirements of this section if the Secretary determines that the exemption would have no significant adverse effect on public health.

(d) CONTACT INFORMATION.—The responsible person shall receive reports of adverse events through the domestic address, domestic telephone number, or electronic contact information included on the label in accordance with section 17125(a) of this title.

(e) MAINTENANCE AND INSPECTION OF ADVERSE EVENT RECORDS.—

(1) MAINTENANCE.—

(A) IN GENERAL.—The responsible person shall maintain records related to each report of an adverse event associated with the use, in the United States, of a cosmetic product manufactured or distributed by the person received by the person, for a period of 6 years, except as provided in subparagraph (B).

(B) EXCEPTION.—A responsible person that is considered a small business for the purposes of section 17128 of this title and that does not engage in the manufacturing or processing of the cosmetic products described in section 17128(b) of this title shall maintain the records described in subparagraph (A) for a period of 3 years.

(2) INSPECTION.—

(A) AUTHORIZED INDIVIDUAL.—In this paragraph, the term ''authorized individual'' means an officer or employee of the Department who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been designated by the Secretary to have access to the records required under this section.

(B) IN GENERAL.—The responsible person shall permit an authorized individual to have access to records required to be maintained under this section during an inspection pursuant to section 17504 of this title.

(f) FRAGRANCE AND FLAVOR INGREDIENTS.—

(1) IN GENERAL.—If the Secretary has reasonable grounds to believe that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event required to be reported under this section, the Secretary may request in writing a list of the ingredients or categories of ingredients in the specific fragrances or flavors in the cosmetic product, from the responsible person.

(2) SUBMISSION PERIOD.—The responsible person shall ensure that the requested information is submitted to the Secretary within 30 days of the request.

(3) EXEMPTION FROM PUBLIC INFORMATION DISCLOSURE.—In response to a request under section 552 of title 5, information submitted to the Secretary under this subsection shall be withheld under section 552(b)(3) of title 5.

(g) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (b)(2), or an adverse event report, or any new information, voluntarily submitted to the Secretary, shall be considered to be—

(1) a safety report under section 18701 of this title and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5 and a medical or similar file the disclosure of which would constitute a violation of section 552 of title 5, and shall not be publicly disclosed unless all personally identifiable information is redacted.

(h) EFFECT OF SECTION.—

(1) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory of the United States, or political subdivision of

a State or territory of the United States, under a memorandum of understanding between the Secretary and the State, territory of the United States, or political subdivision.

(2) PERSONALLY IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory of the United States, or political subdivision of a State or territory of the United States, shall not—

(A) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(B) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting the information to the Secretary.

(3) USE OF REPORTS.—Nothing in this section shall permit a State, territory of the United States, or political subdivision of a State or territory of the United States to use any safety report received from the Secretary in a manner inconsistent with this section.

(4) RULE OF CONSTRUCTION.—The submission of any report in compliance with this section shall not be construed as an admission that the cosmetic product involved caused or contributed to the relevant adverse event.

**§ 17122. Good manufacturing practice**

(a) ESTABLISHMENT BY REGULATION.—

(1) IN GENERAL.—The Secretary shall by regulation establish good manufacturing practices for facilities that are consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 17111 of this title.

(2) PROTECTION OF PUBLIC HEALTH.—Any regulation described in paragraph (1) shall be intended to protect the public health and ensure that cosmetic products are not adulterated.

(3) INSPECTION OF RECORDS.—The regulations described in paragraph (1) may allow for the Secretary to inspect records necessary to demonstrate compliance with good manufacturing practices prescribed by the Secretary under this subsection during an inspection conducted under section 17504 of this title.

(b) CONSIDERATIONS.—

(1) IN GENERAL.—In establishing regulations for good manufacturing practices under this section, the Secretary shall—

(A) take into account—

(i) the size and scope of the businesses engaged in the manufacture of cosmetics; and

(ii) the risks to public health posed by the cosmetics; and

(B) provide sufficient flexibility to be practicable for all sizes and types of facilities to which the regulations will apply.

(2) SMALLER BUSINESSES.—The regulations for good manufacturing practices under this section—

(A) shall include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that the regulations do not impose undue economic hardship for smaller businesses; and

(B) may include longer compliance times for smaller businesses.

(3) CONSULTATION WITH EXPERTS.—Before issuing regulations to implement subsection (a), the Secretary shall consult with cosmetics manufactur-

ers, including smaller businesses, consumer organizations, and other experts selected by the Secretary.

(c) TIMEFRAME.—The Secretary shall publish a notice of proposed rulemaking not later than 2 years after December 29, 2022, and shall publish final regulations under this section not later than 3 years after December 29, 2022.

**§ 17123. Registration and product listing**

(a) SUBMISSION OF REGISTRATION.—

(1) INITIAL REGISTRATION.—

(A) EXISTING FACILITIES.—Every person that, on December 29, 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States shall register each facility with the Secretary not later than 1 year after December 29, 2022.

(B) NEW FACILITIES.—Every person that owns or operates a facility that first engages, after December 29, 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, shall register with the Secretary the facility within 60 days of first engaging in the activity or 60 days after the dead-

line for registration under subparagraph (A), whichever is later.

(2) BIENNIAL RENEWAL OF REGISTRATION.—A person required to register a facility under paragraph (1) shall renew the registrations with the Secretary biennially.

(3) CONTRACT MANUFACTURERS.—If a facility manufactures or processes cosmetic products on behalf of a responsible person, the Secretary shall require only a single registration for the facility even if the facility is manufacturing or processing its own cosmetic products or cosmetic products on behalf of more than 1 responsible person. The single registration may be submitted to the Secretary by the facility or any responsible person whose products are manufactured or processed at the facility.

(4) UPDATES TO CONTENT.—A person that is required to register under subsection (a)(1) shall notify the Secretary within 60 days of any changes to information required under subsection (b)(2).

(5) ABBREVIATED RENEWAL REGISTRATIONS.—The Secretary shall provide for an abbreviated registration renewal process for any person that owns or operates a facility that has not been required to submit updates under paragraph (4) for a registered

facility since submission of the most recent registration of the facility under paragraph (1) or (2).

(b) FORMAT; CONTENTS OF REGISTRATION.—

(1) IN GENERAL.—Registration information under this section may be submitted at such time and in such manner as the Secretary may prescribe.

(2) CONTENTS.—The registration under subsection (a) shall contain—

(A) the facility's name, physical address, email address, and telephone number;

(B) with respect to any foreign facility, the contact for the United States agent of the facility, and, if available, the electronic contact information;

(C) the facility registration number, if any, previously assigned by the Secretary under subsection (d);

(D) all brand names under which cosmetic products manufactured or processed in the facility are sold; and

(E) the product category or categories and responsible person for each cosmetic product manufactured or processed at the facility.

(c) COSMETIC PRODUCT LISTING.—

(1) IN GENERAL.—For each cosmetic product, the responsible person shall submit to the Secretary a cosmetic product listing, or ensure that the submission is made, at such time and in such manner as the Secretary may prescribe.

(2) COSMETIC PRODUCT LISTING.—The responsible person of a cosmetic product that is marketed on December 29, 2022, shall submit to the Secretary a cosmetic product listing not later than 1 year after December 29, 2022, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing the product in interstate commerce. Any updates to the listing shall be made annually, consistent with paragraphs (4) and (5).

(3) ABBREVIATED RENEWAL.—The Secretary shall provide for an abbreviated process for the renewal of any cosmetic product listing under this subsection with respect to which there has been no change since the responsible person submitted the previous listing.

(4) CONTENTS OF LISTING.—

(A) IN GENERAL.—Each cosmetic product listing under this subsection shall include—

(i) the facility registration number of each facility where the cosmetic product is manufactured or processed;

(ii) the name and contact number of the responsible person and the name for the cosmetic product, as the name appears on the label;

(iii) the applicable cosmetic category or categories for the cosmetic product;

(iv) a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations, or any successor regulations, or by the common or usual name of the ingredient; and

(v) the product listing number, if any, previously assigned by the Secretary under subsection (d).

(B) FLEXIBLE LISTINGS.—A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with re-

spect to colors, fragrances or flavors, or quantity of contents.

(5) UPDATES TO CONTENT.—A responsible person that is required to submit a cosmetic product listing shall submit any updates to the cosmetic product listing annually.

(6) SUBMISSION.—A responsible person may submit product listing information as part of a facility registration or separately.

(d) FACILITY REGISTRATION AND PRODUCT LISTING NUMBERS.—At the time of the initial registration of any facility under subsection (a)(1) or initial listing of any cosmetic product under subsection (c)(1), the Secretary shall assign a facility registration number to the facility and a product listing number to each cosmetic product. The Secretary shall not make the product listing number publicly available.

(e) CONFIDENTIALITY.—In response to a request under section 552 of title 5, information described in subsection (b)(2)(D) or (c)(4)(A)(i) that is derived from a registration or listing under this section shall be withheld under section 552(b)(3) of title 5.

(f) SUSPENSIONS.—

(1) SUSPENSION OF REGISTRATION OF A FACILITY.—The Secretary may suspend the registration of a facility if—

(A) the Secretary determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans; and

(B) the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure—

(i) that cannot be isolated to a product or products; or

(ii) that is sufficiently pervasive to raise concerns about other products manufactured in the facility.

(2) NOTICE OF SUSPENSION.—Before suspending a facility registration under this section, the Secretary shall provide—

(A) notice to the facility registrant of the cosmetic product or other responsible person, as appropriate, of the intent to suspend the facility registration, which notice shall specify the basis

of the determination by the Secretary that the facility registration should be suspended; and

(B) an opportunity, within 5 business days of the notice provided under subparagraph (A), for the responsible person to provide a plan for addressing the reasons for possible suspension of the facility registration.

(3) HEARING ON SUSPENSION.—

(A) IN GENERAL.—The Secretary shall provide the registrant subject to an order under paragraph (1) or (2) with an opportunity for an informal hearing, to be held as soon as possible but not later than 5 business days after the issuance of the order, or such other time period agreed on by the Secretary and the registrant, on the actions required for reinstatement of registration and why the registration that is subject to the suspension should be reinstated.

(B) REINSTATEMENT.—The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

(4) POST-HEARING CORRECTIVE ACTION PLAN.—

(A) IN GENERAL.—If, after providing opportunity for an informal hearing under paragraph (3), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary.

(B) REVIEW OF CORRECTIVE ACTION PLAN.—The Secretary shall review the corrective action plan not later than 14 business days after the submission of the corrective action plan or such other time period as determined by the Secretary, in consultation with the registrant.

(5) VACATING OF ORDER; REINSTATEMENT.—On a determination by the Secretary that adequate grounds do not exist to continue the suspension actions, the Secretary shall promptly vacate the suspension and reinstate the registration of the facility.

(6) EFFECT OF SUSPENSION.—If the registration of the facility is suspended under this section, no person shall introduce or deliver for introduction into commerce in the United States cosmetic products from the facility.

(7) NO DELEGATION.—The authority conferred by this section to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.

**§ 17124. Safety substantiation**

(a) DEFINITIONS.—In this section:

(1) ADEQUATE SUBSTANTIATION OF SAFETY.—The term ''adequate substantiation of safety'' means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

(2) SAFE.—

(A) IN GENERAL.—The term ''safe'' means that the cosmetic product, including any ingredient of the cosmetic product, is not injurious to users under the conditions of use prescribed in the labeling of the cosmetic product, or under such conditions of use as are customary or usual.

(B) NOT INJURIOUS TO USERS.—The Secretary shall not consider a cosmetic ingredient

or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users.

(C) CUMULATIVE OR OTHER RELEVANT EXPOSURE TO COSMETIC PRODUCT.—In determining for purposes of this section whether a cosmetic product is safe, the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient of the cosmetic product.

(b) SUBSTANTIATION OF SAFETY.—A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of the cosmetic product.

(c) COAL-TAR HAIR DYE.—Subsection (b) shall not apply to coal-tar hair dye that otherwise complies with the requirements of section 17111(b) of this title. A responsible person for a coal-tar hair dye shall maintain records related to the safety of the product.

**§ 17125. Labeling**

(a) IN GENERAL.—Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may in-

clude a website, through which the responsible person can receive adverse event reports with respect to the cosmetic product.

(b) FRAGRANCE ALLERGENS.—

(1) IDENTIFICATION ON LABEL.—The responsible person shall identify on the label of a cosmetic product each fragrance allergen included in the cosmetic product.

(2) DETERMINED BY REGULATION.—The Secretary shall determine, by regulation, substances that are fragrance allergens for purposes of this subsection.

(3) RULEMAKING.—The Secretary—

(A) shall issue a notice of proposed rulemaking promulgating the regulation implementing this subsection not later than 18 months after December 29, 2022; and

(B) not later than 180 days after the date on which the public comment period on the proposed rulemaking closes, shall issue a final rulemaking.

(4) CONSIDERATIONS; CONTENT.—In promulgating regulations implementing this subsection, the Secretary shall consider international, State, and local requirements for allergen disclosure, including

the substance and format of requirements in the European Union, and may establish threshold levels of amounts of substances subject to disclosure pursuant to the regulations.

(c) COSMETIC PRODUCTS FOR PROFESSIONAL USE.—

(1) DEFINITION OF PROFESSIONAL.—In this subsection, the term ''professional'' means an individual who is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics.

(2) PROFESSIONAL USE LABELING.—A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that—

(A) contains a clear and prominent statement that the product shall be administered or used only by professionals; and

(B) is in conformity with the requirements of the Secretary for cosmetics labeling under this subtitle and section 4(a) of the Fair Packaging and Labeling Act (15 U.S.C. 1453(a)).

**§ 17126. Records**

(a) ACCESS BY SECRETARY.—

(1) IN GENERAL.—If the Secretary has a reasonable belief that a cosmetic product, including an ingredient in the cosmetic product, and any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to the product presents a threat of serious adverse health consequences or death to humans, each responsible person and facility shall, at the request of an officer or employee designated by the Secretary, permit the officer or employee, on presentation of appropriate credentials and a written notice to the person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to the cosmetic product, and to any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, which records are needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans.

(2) INAPPLICABILITY TO CERTAIN DATA.—This subsection shall not be construed to extend to recipes or formulas for cosmetics, financial data, pric-

ing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this subtitle), research data (other than safety substantiation data for cosmetic products and their ingredients), or sales data (other than shipment data regarding sales).

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit the authority of the Secretary to inspect records or require establishment and maintenance of records under any other provision of this subtitle, including section 17121 or 17122 of this title.

**§ 17127. Mandatory recall authority**

(a) IN GENERAL.—

(1) IN GENERAL.—If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 17111 of this title or misbranded under section 17112 of this title and the use of or exposure to the cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall the cosmetic.

(2) REFUSAL TO CEASE DISTRIBUTION OR TO RECALL.—If the responsible person refuses to or does not voluntarily cease distribution or recall the

cosmetic within the time and manner prescribed by the Secretary (if prescribed), the Secretary may, by order, require, as the Secretary determines necessary, the person to immediately cease distribution of the cosmetic.

(b) HEARING.—The Secretary shall provide the responsible person that is subject to an order under subsection (a) with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify the order.

(c) ORDER RESOLUTION.—After an order is issued according to the process under subsections (a) and (b), the Secretary shall, except as provided in subsection (d)—

(1) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

(2) continue the order ceasing distribution of the cosmetic until a date specified in the order; or

(3) amend the order to require a recall of the cosmetic, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding the recall.

(d) ACTION FOLLOWING ORDER.—Any person that is subject to an order pursuant to paragraph (2) or (3) of subsection (c) shall immediately cease distribution of or recall, as applicable, the cosmetic and provide notification as required by the order.

(e) NOTICE TO PERSONS AFFECTED.—If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to subsection (a) or an amended order pursuant to paragraph (2) or (3) of subsection (c) to provide either a notice of a recall order for, or an order to cease distribution of, the cosmetic, as applicable, under this section to—

(1) appropriate persons, including persons that manufacture, distribute, import, or offer for sale the cosmetic that is the subject of an order; and

(2) the public.

(f) PUBLIC NOTIFICATION.—In conducting a recall under this section, the Secretary shall—

(1) ensure that a press release is published regarding the recall, and that alerts and public notices are issued, as appropriate, in order to provide notification—

(A) of the recall to consumers and retailers to whom the cosmetic was, or may have been, distributed; and

(B) that includes, at a minimum—

(i) the name of the cosmetic subject to the recall;

(ii) a description of the risk associated with the cosmetic; and

(iii) to the extent practicable, information for consumers about similar cosmetics that are not affected by the recall; and

(2) ensure publication, as appropriate, on the FDA website, of an image of the cosmetic that is the subject of the press release described in paragraph (1), if available.

(g) NO DELEGATION.—The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

(h) EFFECT.—Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this chapter.

**§ 17128. Small businesses**

(a) IN GENERAL.—Responsible persons, and owners and operators of facilities, whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted

for inflation, and that do not engage in the manufacturing or processing of the cosmetic products described in subsection (b), shall be considered small businesses and not subject to the requirements of section 17122 or 17123 of this title.

(b) REQUIREMENTS APPLICABLE TO ALL MANUFACTURERS AND PROCESSORS OF COSMETICS.—The exemptions under subsection (a) shall not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products:

(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

(2) Cosmetic products that are injected.

(3) Cosmetic products that are intended for internal use.

(4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of the conditions of use that are customary or usual.

**§ 17129. Exemption for certain products and facilities**

(a) IN GENERAL.—Notwithstanding any other provision of law, except as provided in subsection (b), a cosmetic product or facility that is also subject to the require-

ments of division D shall be exempt from the requirements of sections 17121, 17122, 17123, 17124, 17125(a), 17126, and 17127 of this title.

(b) EXCEPTION.—A facility described in subsection (a) that also manufactures or processes cosmetic products that are not subject to the requirements of division D shall not be exempt from the requirements of sections 17121, 17122, 17123, 17124, 17125(a), 17126, and 17127 of this title, with respect to the cosmetic products.

**§ 17130. Preemption**

(a) IN GENERAL.—No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under this chapter with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

(b) LIMITATION.—Nothing in the amendments to this subtitle made by the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 136 Stat. 5847) shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection (a). Notwithstanding subsection (a), nothing

in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 136 Stat. 5847) for the reporting to the State of an ingredient in a cosmetic product.

(c) SAVINGS.—Nothing in the amendments to this subtitle made by the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 136 Stat. 5847), nor any standard, rule, requirement, regulation, or adverse event report shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any State, whether statutory or based in common law.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to amend, expand, or limit the provisions under section 18502 of this title.

# Division F—General Authorities

## Chapter 175—General Administrative Provisions

Sec.
17501. Regulations and hearings.
17502. Examinations and investigations.
17503. Records.
17504. Inspection.
17505. Publicity.
17506. Examination of seafood on request of packer.

17507. Advertising of foods.
17508. Confidential information.
17509. Existence of jurisdiction.
17510. Consolidated administrative and laboratory facility.
17511. Automation of FDA.
17512. Conflicts of interest.
17513. Policy on the review and clearance of scientific articles published by FDA employees.
17514. Hiring authority for scientific, technical, and professional personnel.
17515. Strategic Workforce Plan and report.
17516. Reporting requirements for biosimilar biological products.

### § 17501. Regulations and hearings

(a) AUTHORITY TO PROMULGATE REGULATIONS.—The authority to promulgate regulations for the efficient enforcement of this subtitle, except as otherwise provided in this section, is vested in the Secretary.

(b) REGULATIONS FOR IMPORTS AND EXPORTS.—The Secretary of the Treasury and the Secretary shall jointly prescribe regulations for the efficient enforcement of section 20101 of this title, except as otherwise provided in that section. The regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary shall determine.

(c) CONDUCT OF HEARINGS.—Hearings authorized or required by this subtitle shall be conducted by the Secretary or such officer or employee as the Secretary may designate for that purpose.

(d) EFFECTIVENESS OF DEFINITIONS AND STANDARDS OF IDENTITY.—The definitions and standards of identity promulgated in accordance with this subtitle shall be effective for the purposes of the enforcement of this

subtitle, notwithstanding the definitions and standards as may be contained in other laws of the United States and regulations promulgated under those laws.

(e) PROCEDURE FOR ESTABLISHMENT.—

(1) PROPOSAL.—

(A) IN GENERAL.—Any action for the issuance, amendment, or repeal of any regulation under section 11106(a), 11108, 11311, 13101(b), or 13307 of this title, and any action for the amendment or repeal of any definition and standard of identity under section 11101 of this title for any dairy product (including products regulated under parts 131, 133, and 135 of title 21, Code of Federal Regulations) shall be initiated by a proposal made—

(i) by the Secretary on the Secretary's own initiative; or

(ii) by petition of any interested person, showing reasonable grounds for the petition, filed with the Secretary.

(B) PUBLICATION.—The Secretary shall publish the proposal under subparagraph (A) and shall afford all interested persons an opportunity to present their views on the proposal, orally or in writing.

(C) ORDER.—

(i) IN GENERAL.—As soon as practicable after the presentation of views under subparagraph (B), the Secretary shall by order act on the proposal and shall make the order public.

(ii) EFFECTIVE DATE.—Except as provided in paragraph (2), the order shall become effective at such time as may be specified in the order, but not prior to the day following the last day on which objections may be filed under paragraph (2).

(2) OBJECTIONS.—

(A) FILING.—On or before the 30th day after the date on which an order entered under paragraph (1) is made public, any person that will be adversely affected by the order if placed in effect may file objections to the order with the Secretary, specifying with particularity the provisions of the order considered objectionable, stating the grounds for the objections, and requesting a public hearing on the objections.

(B) EFFECT OF OBJECTIONS.—

(i) IN GENERAL.—Until final action on the objections is taken by the Secretary

under paragraph (3), the filing of the objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made.

(ii) PUBLICATION.—As soon as practicable after the time for filing objections has expired, the Secretary shall publish a notice in the Federal Register specifying those parts of the order that have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) HEARING.—

(A) IN GENERAL.—As soon as practicable after the request for a public hearing under paragraph (2)(A), the Secretary, after due notice, shall hold the public hearing for the purpose of receiving evidence relevant and material to the issues raised by the objections.

(B) PERSONS TO BE HEARD.—At the hearing, any interested person may be heard in person or by representative.

(C) ORDER.—

(i) IN GENERAL.—As soon as practicable after completion of the hearing, the

Secretary shall by order act on the objections and make the order public.

(ii) SUBSTANTIAL EVIDENCE.—The order shall be based only on substantial evidence of record at the hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based.

(iii) EFFECTIVE DATE.—The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the 90th day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order the Secretary's findings as to the conditions.

(f) REVIEW OF ORDER.—

(1) PETITION.—

(A) FILING.—In a case of actual controversy as to the validity of any order under subsection (e), any person that will be adversely affected by the order if placed in effect may, at any time prior to the 90th day after the order

is issued, file a petition with the United States court of appeals for the circuit in which the person resides or in which the person's principal place of business is located, for a judicial review of the order.

(B) TRANSMISSION TO SECRETARY.—A copy of the petition shall be immediately transmitted by the clerk of the court to the Secretary or other officer designated by the Secretary for that purpose.

(C) FILING OF RECORD OF PROCEEDINGS.—The Secretary, on the transmission, shall file in the court the record of the proceedings on which the Secretary based the order, as provided in section 2112 of title 28.

(2) ADDITIONAL EVIDENCE.—

(A) IN GENERAL.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Secretary, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the

Secretary, and to be adduced on the hearing, in such manner and on such terms and conditions as to the court may seem proper.

(B) FINDINGS; RECOMMENDATION.—The Secretary may modify the Secretary's findings as to the facts, or make new findings, by reason of the additional evidence taken under subparagraph (A), and the Secretary shall file the modified or new findings, and the Secretary's recommendation, if any, for the modification or setting aside of the Secretary's original order, with the return of the additional evidence.

(3) DECISION OF THE COURT.—

(A) IN GENERAL.—On the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently.

(B) ORDER BY THE COURT.—If the Secretary, in the Secretary's order, refuses to issue, amend, or repeal a regulation and the order is not in accordance with law, the court shall, by its judgment, order the Secretary to take action, with respect to the regulation, in accordance with law.

(C) CONCLUSIVENESS OF SECRETARY'S FINDINGS.—The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) FINALITY OF COURT JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States on certiorari or certification as provided in section 1254 of title 28.

(5) CHANGE IN THE INDIVIDUAL HOLDING OFFICE; VACANCY.—Any action instituted under this subsection shall survive notwithstanding any change in the individual occupying the Office of Secretary or any vacancy in the Office.

(6) REMEDIES UNDER THIS SUBSECTION IN ADDITION TO OTHER REMEDIES.—The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) COPIES OF RECORDS OF HEARINGS.—

(1) FURNISHMENT.—The Secretary shall furnish a certified copy of the transcript of the record and proceedings under subsection (e) to any inter-

ested party at the request and payment of the interested party.

(2) ADMISSIBILITY.—The certified copy under paragraph (1) shall be admissible in any criminal, action for condemnation, exclusion of imports, or other proceeding arising under or in respect to this subtitle, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

(h) GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—

(A) DEVELOPMENT; PUBLIC AVAILABILITY; VIEWS OF THE SECRETARY.—The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of the documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. The documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the FDA.

(B) USE BY EMPLOYEES.—Although guidance documents shall not be binding on the

Secretary, the Secretary shall ensure that employees of the FDA do not deviate from the guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of the documents.

(C) GUIDANCE DOCUMENTS SETTING FORTH INTERPRETATION OR COMPLEX OR CONTROVERSIAL ISSUES.—

(i) IN GENERAL.—For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of the guidance documents, unless the Secretary determines that prior public participation is not feasible or appropriate. In cases in which prior public participation is not feasible or appropriate, the Secretary shall provide for public comment on implementation and take the comment into account.

(ii) NOTICE TO INDUSTRY AS GUIDANCE DOCUMENT FOR DEVICES.—With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulation or policy or sets forth changes in interpretation or policy, the notice shall be treated as a guidance document for purposes of this subparagraph.

(D) GUIDANCE DOCUMENTS SETTING FORTH EXISTING PRACTICES AND MINOR CHANGES IN POLICY.—For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment on implementation.

(2) UNIFORMITY; REVIEW AND REVISION.—In developing guidance documents, the Secretary shall ensure uniform nomenclature for the documents and uniform internal procedures for approval of the documents. The Secretary shall ensure that guidance documents and revisions of the documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review

all guidance documents and, where appropriate, revise the documents.

(3) PUBLICATION.—The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

(4) APPEALS AND COMPLAINTS RELATING TO DEVELOPMENT AND USE OF GUIDANCE DOCUMENTS.—The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the FDA is not developing and using guidance documents in accordance with this subsection.

(5) POLICIES AND PROCEDURES FOR THE DEVELOPMENT, ISSUANCE, AND USE OF GUIDANCE DOCUMENTS.—Not later than July 1, 2000, the Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961 (Feb. 27, 1997), shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the FDA for the development, issuance, and use of guidance documents.

**§ 17502. Examinations and investigations**

(a) AUTHORITY TO CONDUCT.—

(1) DEFINITION OF UNITED STATES.—In this subsection, the term ''United States'' means the States and the District of Columbia.

(2) IN GENERAL.—

(A) INDVIDUALS AUTHORIZED.—The Secretary may conduct examinations and investigations for the purposes of this subtitle through officers and employees of the Department or through any health, food, or drug officer or employee of any State, territory of the United States, or political subdivision of a State or territory of the United States, commissioned by the Secretary as an officer of the Department.

(B) TOBACCO PRODUCTS.—

(i) IN GENERAL.—For a tobacco product, to the extent feasible, the Secretary shall contract with a State in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this subtitle.

(ii) EXCEPTION RELATING TO INDIAN COUNTRY.—The Secretary shall not enter into any contract under clause (i) with the

government of any State to exercise enforcement authority under this subtitle on Indian country without the express written consent of the Indian tribe involved.

(3) MEMORANDUM OF UNDERSTANDING.—

(A) AUTHORITY.—

(i) IN GENERAL.—In addition to the authority established in paragraph (2), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal agency, may conduct examinations and investigations for the purposes of this subtitle through the officers and employees of the other Federal agency, subject to subparagraph (B).

(ii) TRAINING.—The memorandum of understanding under clause (i) shall include provisions to ensure adequate training of the officers and employees to conduct the examinations and investigations.

(iii) REIMBURSEMENT.—The memorandum of understanding shall contain provisions regarding reimbursement. The reimbursement provisions may, at the sole

discretion of the head of the other Federal agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other Federal agency.

(B) EFFECTIVE IN FACILITIES OR LOCATIONS JOINTLY REGULATED.—A memorandum of understanding under subparagraph (A) between the Secretary and another Federal agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and the other Federal agency.

(C) REPORT.—For any fiscal year in which the Secretary and the head of another Federal agency carries out 1 or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of the other Federal agency shall, with respect to their respective agencies, submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for the year—

(i) the number of officers or employees that carried out 1 or more programs, projects, or activities under the memorandum;

(ii) the number of additional articles that were inspected or examined as a result of the memorandum; and

(iii) the number of additional examinations or investigations that were carried out pursuant to the memorandum.

(4) FOOD PACKED IN PUERTO RICO OR TERRITORY OF THE UNITED STATES.—In the case of food packed in Puerto Rico or a territory of the United States, the Secretary shall attempt to inspect the food at the first point of entry within the United States when, in the Secretary's opinion and with due regard to the enforcement of all the provisions of this subtitle, the facilities at the Secretary's disposal will permit of the inspection.

(b) AVAILABILITY TO OWNER OF PART OF ANALYSIS SAMPLES.—

(1) IN GENERAL.—If a sample of a food, drug, or cosmetic is collected for analysis under this subtitle, the Secretary shall, upon request, provide a part of the official sample for examination or anal-

ysis by any person named on the label of the article, the owner of the article, or the person's or owner's attorney or agent.

(2) EXCEPTION.—The Secretary may, by regulations, make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as the Secretary finds necessary for the proper administration of this subtitle.

(c) RECORDS OF OTHER AGENCIES.—For purposes of enforcement of this subtitle, records of any agency or independent establishment in the Executive Branch of the Government shall be open to inspection by any official of the Department authorized by the Secretary to make the inspection.

(d) INFORMATION ON PATENTS FOR DRUGS.—

(1) IN GENERAL.—The Secretary shall, on request from the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application.

(2) RESEARCH.—The Secretary may, on receipt of any request under paragraph (1), conduct or

cause to be conducted, such research as may be required.

(e) AUTHORITIES OF ENFORCEMENT PERSONNEL.—

(1) IN GENERAL.—Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this subtitle relating to counterfeit drugs may, when authorized by the Secretary—

(A) carry firearms;

(B) execute and serve search warrants and arrest warrants;

(C) execute seizure by process issued pursuant to an action under section 10504 of this title;

(D) make arrests without warrant for offenses under this subtitle with respect to the drugs if the offense is committed in the officer's or employee's presence or, in the case of a felony, if the officer or employee has probable cause to believe that the person arrested has committed, or is committing, the offense; and

(E) make, prior to the institution of an action for condemnation proceeding under section 10504(a)(2) of this title, seizures of drugs or containers or of equipment, punches, dies,

plates, stones, labeling, or other things, if they are, or the officer or employee has reasonable grounds to believe that they are, subject to seizure and condemnation under section 10504(a)(2) of this title.

(2) SEIZURE.—In the event of seizure pursuant to paragraph (1)(E), an action for condemnation proceeding under section 10504(a)(2) of this title shall be instituted promptly and the property seized shall be placed under the jurisdiction of the court.

**§ 17503. Records**

(a) IN GENERAL.—

(1) REQUIRED ACCESS.—For the purpose of enforcing this subtitle, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, tobacco products, or cosmetics in interstate commerce or holding the articles received in interstate commerce, shall, on the request of an officer or employee designated by the Secretary, permit the officer or employee, at reasonable times, to have access to and to copy all records showing—

(A) the movement in interstate commerce of any food, drug, device, tobacco product, or cosmetic, or the holding of the food, drug, de-

vice, tobacco product, or cosmetic during or after the movement; and

(B) the quantity, shipper, and consignee of the food, drug, device, tobacco product, or cosmetic.

(2) PROHIBITION.—It shall be unlawful for any carrier or person under paragraph (1) to fail to permit access to and copying of any record requested as described in paragraph (1) when the request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, tobacco product, or cosmetic to which the request relates.

(3) EVIDENCE.—Evidence obtained under this section, or any evidence that is directly or indirectly derived from the evidence obtained under this section, shall not be used in a criminal prosecution of the person from whom obtained.

(4) INAPPLICABILITY OF OTHER PROVISIONS TO CARRIERS IN THE USUAL COURSE OF BUSINESS.—Carriers shall not be subject to the other provisions of this subtitle by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, tobacco products, or cosmetics in the usual course of business as carriers, except as provided in subsection (b).

(b) FOOD TRANSPORTATION RECORDS.—A shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 11118 of this title shall, on request of an officer or employee designated by the Secretary, permit the officer or employee, at reasonable times, to have access to and to copy all records that the Secretary requires to be kept under section 11118(c)(1)(E) of this title.

**§ 17504. Inspection**

(a) IN GENERAL.—

(1) AUTHORITY TO ENTER; SCOPE; NOTICE; PROMPTNESS.—

(A) AUTHORITY TO ENTER.—For purposes of enforcement of this subtitle, officers or employees designated by the Secretary, on presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, may—

(i) enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after the introduction, or enter any vehicle being used to trans-

port or hold the food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and

(ii) inspect, at reasonable times and within reasonable limits and in a reasonable manner, the factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling in the factory, warehouse, establishment, or vehicle.

(B) SCOPE OF INSPECTION RELATING TO FOODS.—In the case of any person (excluding farms and restaurants) that manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 11116 of this title, if the standard for records inspection under paragraph (1) or (2) of section 11116(a) of this title applies, subject to the limitations established in section 11116(d) of this title.

(C) SCOPE OF INSPECTION RELATING TO COSMETICS.—In the case of a facility (as defined in section 17101 of this title) that manufactures or processes cosmetic products, the in-

spection shall extend to all records and other information described in sections 17121, 17122, and 17126 of this title, when the standard for records inspection under the section applies.

(D) SCOPE OF INSPECTION RELATING TO DRUGS, DEVICES, AND TOBACCO PRODUCTS.—In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, devices, or tobacco products are manufactured, processed, packed, or held, the inspection shall extend to all things in the factory, warehouse, establishment, or consulting laboratory (including records, files, papers, processes, controls, and facilities)—

(i) bearing on whether prescription drugs, nonprescription drugs intended for human use, devices, or tobacco products that are adulterated or misbranded within the meaning of this subtitle, or that may not be manufactured, introduced into interstate commerce, sold, or offered for sale by reason of any provision of this subtitle, have been or are being manufactured,

processed, packed, transported, or held in any such place; or

(ii) otherwise bearing on violation of this subtitle.

(E) SCOPE LIMITATION.—An inspection authorized by subparagraph (D) or by paragraph (3) shall not extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this subtitle), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 13151, 13152(g), 13510, or 13512 of this title or chapter 211 of this title and data relating to other drugs, devices, or tobacco products that in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 13511 of this title).

(F) NOTICE.—A separate notice shall be given for each inspection under this paragraph, but a notice shall not be required for each entry

made during the period covered by the inspection.

(G) PROMPTNESS.—Each inspection under this paragraph shall be commenced and completed with reasonable promptness.

(2) INAPPLICABILITY OF PARAGRAPH (1)(D).—Paragraph (1)(D) shall not apply to—

(A) pharmacies—

(i) that—

(I) maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine; and

(II) are regularly engaged in dispensing prescription drugs or devices, on prescriptions of practitioners licensed to administer the drugs or devices to patients under the care of the practitioners in the course of their professional practice; and

(ii) that do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular

course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners—

(i) licensed by law to prescribe or administer drugs or prescribe or use devices; and

(ii) who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices, solely for use in the course of their professional practice;

(C) persons who manufacture, prepare, propagate, compound, or process drugs or manufacture or process devices, solely for use in research, teaching, or chemical analysis and not for sale; or

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section on a finding that inspection as applied to the classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) INSPECTIONS RELATING TO REQUIREMENTS FOR INFANT FORMULAS.—An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 11114

of this title applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 11114 of this title; or

(B) required to be maintained under section 11114 of this title.

(4) ADVANCED PROVISION OF RECORDS OR INFORMATION BY PERSONS THAT OWN DRUG OR DEVICE ESTABLISHMENTS.—

(A) IN GENERAL.—Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device, or a site or facility that is subject to inspection under paragraph (5)(C), shall, on the request of the Secretary, be provided to the Secretary by the person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the

expense of the person. The Secretary's request shall include a sufficient description of the records or other information requested and a rationale for requesting the records or other information in advance of, or in lieu of, an inspection.

(B) CONFIRMATION OF RECEIPT.—On receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of receipt.

(C) SATISFACTION OF CERTAIN REQUIREMENTS.—The Secretary may rely on any records or other information that the Secretary may inspect under this section to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to resolve deficiencies identified during the inspections, if applicable and appropriate.

(D) EFFECT OF PARAGRAPH.—Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this subtitle in order to ensure compliance with this subtitle.

(5) INSPECTIONS RELATING TO ACCURACY AND RELIABILITY OF STUDIES AND RECORDS AND COMPLIANCE WITH REQUIREMENTS.—

(A) IN GENERAL.—The Secretary may, to ensure the accuracy and reliability of studies and records or other information described in subparagraph (B) and to assess compliance with applicable requirements under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.), enter sites and facilities specified in subparagraph (C) in order to inspect the records or other information.

(B) SCOPE OF INSPECTION.—An inspection under this paragraph shall extend to all records and other information related to the studies and submissions described in subparagraph (E), including records and information related to the conduct, results, and analyses of, and the protection of human and animal trial participants participating in, the studies.

(C) SITES AND FACILITIES.—

(i) IN GENERAL.—The sites and facilities subject to inspection by the Secretary under this paragraph are those owned or operated by a person described in clause

(ii) and which are (or were) utilized by the person in connection with—

(I) developing an application or other submission to the Secretary under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) related to marketing authorization for a product described in paragraph (1);

(II) preparing, conducting, or analyzing the results of a study described in subparagraph (E); or

(III) holding any records or other information described in subparagraph (B).

(ii) PERSON.—A person described in this clause is—

(I) the sponsor of an application or submission specified in subparagraph (E);

(II) a person engaged in any activity described in clause (i) on behalf of a sponsor described in subclause (I), through a contract, grant, or

other business arrangement with the sponsor;

(III) an institutional review board, or other individual or entity, engaged by contract, grant, or other business arrangement with a non-sponsor in preparing, collecting, or analyzing records or other information described in subparagraph (B); or

(IV) any person not otherwise described in this clause that conducts, or has conducted, a study described in subparagraph (E) yielding records or other information described in subparagraph (B).

(D) ACCESS BY SECRETARY.—

(i) IN GENERAL.—Subject to clause (ii), an entity that owns or operates any site or facility subject to inspection under this paragraph shall provide the Secretary with access to records and other information described in subparagraph (B) that is held by or under the control of the entity, including—

(I) permitting the Secretary to record or copy the information for purposes of this paragraph;

(II) providing the Secretary with access to any electronic information system utilized by the entity to hold, process, analyze, or transfer any records or other information described in subparagraph (B); and

(III) permitting the Secretary to inspect the facilities, equipment, written procedures, processes, and conditions through which records or other information described in subparagraph (B) is or was generated, held, processed, analyzed, or transferred.

(ii) EFFECT ON CONFIDENTIAL INFORMATION.—Nothing in clause (i) shall negate, supersede, or otherwise affect the applicability of provisions, under this subtitle or under any Act, preventing or limiting the disclosure of confidential commercial information or other information considered proprietary or trade secret.

(iii) CONDUCT OF INSPECTION.—An inspection under this paragraph shall be conducted at reasonable times and within reasonable limits and in a reasonable manner.

(E) STUDIES AND SUBMISSIONS.—The studies and submissions described in this subparagraph are each of the following:

(i) Clinical and nonclinical studies submitted to the Secretary in support of, or otherwise related to, applications and other submissions to the Secretary under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) for marketing authorization of a product described in paragraph (1).

(ii) Postmarket safety activities conducted under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.).

(iii) Any other clinical investigation of—

(I) a drug subject to chapter 135 or 137 of this title or section 351 of

the Public Health Service Act (42 U.S.C. 262); or

(II) a device subject to section 13152(g) of this title.

(iv) Any other submissions made under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.) with respect to which the Secretary determines an inspection under this paragraph is warranted in the interest of public health.

(F) CONSTRUCTION.—This paragraph clarifies the authority of the Secretary to conduct inspections of the type described in this paragraph and shall not be construed as a basis for inferring that, prior to December 29, 2022, the Secretary lacked the authority to conduct the inspections, including under this subtitle or the Public Health Service Act (42 U.S.C. 201 et seq.).

(b) WRITTEN REPORT TO OWNER.—

(1) IN GENERAL.—

(A) CONTENT.—On completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or em-

ployee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by the officer or employee that, in the judgment of the officer or employee, indicate that any food, drug, device, tobacco product, or cosmetic in the establishment—

(i) consists in whole or in part of any filthy, putrid, or decomposed substance; or

(ii) has been prepared, packed, or held under insanitary conditions in which it may have become contaminated with filth, or in which it may have been rendered injurious to health.

(B) COPY TO SECRETARY.—A copy of the report under subparagraph (A) shall be sent promptly to the Secretary.

(2) DRUGS FOR WHICH NOTIFICATION OF DISCONTINUANCE OR INTERRUPTION HAS BEEN SUBMITTED; DRUGS ON SHORTAGE LIST.—

(A) IN GENERAL.—In carrying out this subsection with respect to any establishment manufacturing a drug described in subparagraph (B), a copy of the report shall be sent

promptly to the appropriate offices of the FDA with expertise regarding drug shortages.

(B) DRUG DESCRIBED.—A drug described in this subparagraph is a drug approved under section 13504 or 13511 of this title—

(i) for which a notification has been submitted in accordance with section 13122 of this title;

(ii) that is, or has been in the last 5 years, listed on the drug shortage list under section 13125 of this title; or

(iii) that is described in section 13511(k)(1) of this title.

(c) RECEIPT FOR SAMPLES TAKEN.—If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, on completion of the inspection and prior to leaving the premises, the officer or employee shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) ANALYSIS OF SAMPLES FURNISHED TO OWNER.—If, in the course of any such inspection of a factory or other establishment in which food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an anal-

ysis is made of the sample for the purpose of ascertaining whether the food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of the analysis shall be furnished promptly to the owner, operator, or agent in charge.

(e) ACCESSIBILITY OF RECORDS.—Each person required under section 13151 or 13152(g) of this title to maintain records and each person that is in charge or custody of the records shall, on request of an officer or employee designated by the Secretary, permit the officer or employee at all reasonable times to have access to, and to copy and verify, the records.

(f) RECORDKEEPING.—

(1) DEFINITION OF ACCREDITED PERSON.—In this subsection, the term ''accredited person'' means a person that—

(A) is accredited under subsection (g); or

(B) is accredited under section 13155 of this title.

(2) IN GENERAL.—

(A) RESPONSIBILITY OF ACCREDITED PERSON.—An accredited person shall maintain records documenting—

(i) the training qualifications of the accredited person and the employees of the accredited person;

(ii) the procedures used by the accredited person for handling confidential information;

(iii) the compensation arrangements made by the accredited person; and

(iv) the procedures used by the accredited person to identify and avoid conflicts of interest.

(B) ACCESS.—On the request of an officer or employee designated by the Secretary, the accredited person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify the records.

(3) PRODUCTION OF COPIES.—Within 15 days after the receipt of a written request from the Secretary to an accredited person for copies of records described in paragraph (2), the accredited person shall produce the copies of the records at the place designated by the Secretary.

(g) INSPECTIONS BY ACCREDITED PERSONS.—

(1) ACCREDITATION.—

(A) IN GENERAL.—The Secretary shall, subject to this subsection, accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 13136(h) of this title or are inspections of the establishments required to register under section 13136(i) of this title.

(B) SELECTION OF ACCREDITED PERSON BY ELIGIBLE ESTABLISHMENT.—The owner or operator of an establishment described in subparagraph (A) that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct the inspections.

(2) REQUESTS FOR ACCREDITATION.—

(A) PUBLICATION OF CRITERIA.—The Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons that request to perform the duties specified in paragraph (1).

(B) ACTIONS BY SECRETARY ON RECEIPT OF REQUEST.—The Secretary shall inform a person requesting accreditation, within 60 days

after the receipt of the request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation.

(C) AUTHORITIES TO BE STATED IN ACCREDITATION.—

(i) IN GENERAL.—Any resulting accreditation shall state that the person is accredited to conduct inspections at device establishments identified in paragraph (1).

(ii) PARTICULAR ACTIVITIES.—The accreditation of the person shall specify the particular activities under this subsection for which the person is accredited.

(3) REQUIREMENTS.—An accredited person shall, at a minimum, meet the following requirements:

(A) NOT A FEDERAL EMPLOYEE.—The person may not be an employee of the Federal Government.

(B) INDEPENDENT ORGANIZATION.—The person shall be an independent organization that is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this subtitle and that has no organiza-

tional, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(C) LEGALLY CONSTITUTED ENTITY PERMITTED TO CONDUCT ACTIVITIES UNDER THE ACCREDITATION.—The person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) NOT ENGAGED IN ACTIVITIES RELATING TO REGULATED ARTICLES.—The person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this subtitle.

(E) OPERATIONS IN ACCORDANCE WITH PROFESSIONAL AND ETHICAL BUSINESS PRACTICES; OTHER REQUIREMENTS AGREED TO IN WRITING.—The operations of the person shall be in accordance with generally accepted professional and ethical business practices, and the person shall agree in writing that, at a minimum, the person will—

(i) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with

this subtitle, and recommendations made during an inspection or at an inspection's closing meeting;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except the information may be made available to the Secretary;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person that has a financial conflict of interest regarding any product regulated under this subtitle, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this

clause relating to financial conflicts of interest.

(F) NOTIFICATION RELATING TO CERTIFICATE OF CONFORMANCE WITH THE QUALITY SYSTEMS STANDARD.—The person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of a certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that the person inspects under this subsection not later than 30 days after the withdrawal, suspension, restriction, or expiration.

(G) AUDITS.—The person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).

(4) LIST OF ACCREDITED PERSONS.—

(A) PUBLICATION.—The Secretary shall publish on the FDA website a list of persons that are accredited under paragraph (2).

(B) IDENTITY OF ACCREDITED PERSONS AND ACTIVITIES FOR WHICH ACCREDITED AS PUBLIC INFORMATION.—The list under subparagraph (A) shall be updated to ensure that the identity of each accredited person, and the

particular activities for which the person is accredited, is known to the public. The updating of the list shall be no later than 1 month after the accreditation of a person under this subsection or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

(5) CONTINUED COMPLIANCE WITH REQUIREMENTS OF ACCREDITATION.—

(A) AUDIT; ADDITIONAL MEASURES.—To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall—

(i) audit the performance of the persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of a device establishment and the performance of accredited persons; and

(ii) take such additional measures as the Secretary determines to be appropriate.

(B) WITHDRAWAL OF ACCREDITATION.—

(i) IN GENERAL.—The Secretary may withdraw accreditation of any person ac-

credited under paragraph (2), after providing notice and an opportunity for an informal hearing, if—

(I) the person—

(aa) is substantially not in compliance with the standards of accreditation;

(bb) poses a threat to public health; or

(cc) fails to act in a manner that is consistent with the purposes of this subsection; or

(II) the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection.

(ii) SUSPENSION.—The Secretary may suspend the accreditation of the person during the pendency of the process under clause (i).

(6) ELIGIBILITY FOR INSPECTION OF DEVICE ESTABLISHMENT.—

(A) CONDITIONS.—Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

(i) CLASSIFICATION OF RESULTS OF INSPECTION.—The Secretary classified the results of the most recent inspection of the device establishment as ''no action indicated'' or ''voluntary action indicated''.

(ii) SUBMISSION OF NOTICE.—With respect to inspections of the device establishment to be conducted by an accredited person, the owner or operator of the device establishment submits to the Secretary a notice that—

(I) provides the date of the last inspection of the device establishment by the Secretary and the classification of that inspection;

(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the device establishment;

(III) identifies the particular accredited person the owner or operator intends to select to conduct the inspections; and

(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the device establishment—

(aa) at least 1 of the devices is marketed in the United States; and

(bb) at least 1 of the devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

(B) CLEARANCE TO PARTICIPATE.—

(i) IN GENERAL.—Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the device establishment unless the Secretary, not later than 30 days after receiving the notice, issues a response that—

(I) denies clearance to participate as provided under subparagraph (C); or

(II) makes a request under clause (ii).

(ii) REQUEST FOR INFORMATION BY SECRETARY.—

(I) IN GENERAL.—The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the device establishment, or from the particular accredited person identified in the notice—

(aa) compliance data for the device establishment in accordance with clause (iii)(I); or

(bb) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in the notice in accordance with clause (iii)(II).

(II) RESPONSE BY OWNER OR OPERATOR OR ACCREDITED PERSON.—The owner or operator of the device establishment, or the accredited person, as the case may be, shall respond to a request under subclause (I) not later than 60 days after receiving the request.

(iii) COMPLIANCE DATA.—

(I) CONTENT.—

(aa) QUALITY CONTROLS SUFFICIENT FOR ENSURING COMPLIANCE WITH GOOD MANUFACTURING PRACTICE.—The compliance data to be submitted by the owner or operator of a device es-

tablishment in response to a request under clause (ii)(I)(aa) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 13101(h) of this title and with other applicable provisions of this subtitle.

(bb) REPORTS OF INSPECTIONAL FINDINGS.—The compliance data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the device establishment by persons other than the owner or operator of the device establishment, together with all other compliance data the Secretary considers necessary.

(cc) CORRECTION OF COMPLIANCE PROBLEMS.—Data under item (bb) shall demonstrate to the Secretary whether the device establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in the inspections.

(II) INFORMATION NOT REQUIRED NOT TO BE REQUESTED.—A request to an accredited person under clause (ii)(I)(bb) may not seek any information that is not required to be maintained by the person in records under subsection (f)(2).

(iv) DEEMED TO HAVE CLEARANCE TO PARTICIPATE UNLESS CLEARANCE IS DENIED.—A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the informa-

tion requested under clause (ii), issues a response that denies clearance to participate as provided under subparagraph (C).

(C) DENIAL OF CLEARANCE; REJECTION OF SELECTION OF ACCREDITED PERSON.—

(i) EVIDENCE THAT CERTIFICATION IS UNTRUE.—The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing the evidence.

(ii) FAILURE TO DEMONSTRATE CONSISTENT COMPLIANCE.—The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the device establishment a statement of the reasons for the determination.

(iii) REJECTION OF THE SELECTION OF ACCREDITED PERSON.—

(I) REASONS TO BE PROVIDED BY SECRETARY.—The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the device establishment a statement of the reasons for the rejection. Reasons for the rejection may include—

(aa) that the device establishment or the accredited person, as the case may be, has failed to fully respond to the request; or

(bb) that the Secretary has concerns regarding the relationship between the device establishment and the accredited person.

(II) ADDITIONAL SELECTIONS.—

(aa) IN GENERAL.—If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional se-

lection of an accredited person by submitting to the Secretary a notice that identifies the additional selection.

(bb) APPLICABILITY OF PROVISIONS.—Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under item (aa) in the same manner and to the same extent as the provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

(iv) REVIEW OF REASONS OR EVIDENCE.—In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing the evidence, as the case may be, of the Secretary under the clause if, during the 30-day pe-

riod beginning on the date on which the owner or operator of the device establishment receives the statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.

(7) INSPECTION REPORTS.—

(A) IN GENERAL.—

(i) OBSERVATIONS; CONDUCT OF INSPECTION.—A person accredited under paragraph (2) to conduct inspections shall record in writing the inspection observations of the person and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, the accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards.

(ii) CLASSIFICATION OF INSPECTION.—Any official classification of the inspection shall be determined by the Secretary.

(B) CONTENT.—At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected device establishment, the dates of the inspection, and the scope of the inspection, and shall describe in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this subtitle, and describe any recommendations during the inspection or at the inspection's closing meeting.

(C) RECIPIENTS; DATE OF SUBMISSION.—An inspection report under subparagraph (A) shall be sent to the Secretary and to the designated representative of the inspected device establishment at the same time, but not later than 3 weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection observa-

tions previously provided to the designated representative of the device establishment.

(D) CRIMINAL VIOLATION.—Any statement or representation made by an employee or agent of a device establishment to a person accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18.

(E) NOTIFICATION OF CONDITION THAT COULD CAUSE UNREASONABLE RISK TO PUBLIC HEALTH.—If at any time during an inspection by an accredited person, the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the device establishment subject to inspection and the condition.

(F) VOLUNTARY REPORTS.—For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an es-

tablishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year period.

(8) COMPENSATION.—Compensation for an accredited person shall be determined by agreement between the accredited person and the person that engages the services of the accredited person, and shall be paid by the person that engages the services.

(9) EFFECT OF SUBSECTION ON INSPECTIONS BY SECRETARY.—Nothing in this subsection affects the authority of the Secretary to inspect any device establishment pursuant to this subtitle.

(10) LIMITATION OF INSPECTIONS RELATING TO AMOUNTS OBLIGATED.—

(A) DEFINITIONS.—In this paragraph:

(i) BASE AMOUNT.—The term ''base amount'' means the inspection budget determined under subparagraph (C) for fiscal year 2002.

(ii) ADJUSTED BASE AMOUNT.—

(I) FISCAL YEAR 2003.—The term ''adjusted base amount'', in the

case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(II) FISCAL YEAR 2004 AND SUBSEQUENT FISCAL YEARS.—The term ''adjusted base amount'', with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted base amount applicable to the preceding year increased by 5 percent.

(B) IN GENERAL.—For fiscal year 2005 and each subsequent fiscal year, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

(i) of the amounts appropriated for salaries and expenses of the FDA for the preceding fiscal year (referred to in this subparagraph as the ''first prior fiscal year''), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to the first prior fiscal year; and

(ii) of the amounts appropriated for salaries and expenses of the FDA for the fiscal year preceding the first prior fiscal year (referred to in this subparagraph as the ''second prior fiscal year''), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to the second prior fiscal year.

(C) DETERMINATION OF AMOUNTS OBLIGATED.—

(i) IN GENERAL.—Subject to clause (ii), the Comptroller General shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the FDA with respect to devices (referred to in this subparagraph as the ''compliance budget''), and of that amount, the amount that was obligated by the Secretary for inspections of device establishments (referred to in this subparagraph as the ''inspection budget'').

(ii) AMOUNTS OBLIGATED FOR INSPECTIONS CONDUCTED AS PART OF THE PROCESS OF REVIEWING PREMARKET AP-

PROVAL APPLICATIONS.—For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 13142 of this title.

(iii) COMPLETION OF DETERMINATIONS; REPORT.—Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and to Congress a report describing the findings made through the determinations.

(11) TERMINATION.—The authority provided by this subsection terminates on October 1, 2027.

(12) REPORT.—No later than 4 years after October 26, 2002, the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 13136(h) of this title and of device establishments required to register under section 13136(i) of this title;

(B) the number of persons that sought accreditation under this subsection, as well as the number of persons that were accredited under this subsection;

(C) the reasons why persons that sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this subtitle, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is being presented to the Secretary, and whether that infor-

mation is of a quality consistent with information obtained by the Secretary pursuant to inspections conducted by Federal employees;

(F) whether this subsection is advancing efforts to allow device establishments to rely on third-party inspections for purposes of compliance with the laws of foreign governments; and

(G) whether Congress should continue, modify, or terminate the program under this subsection.

(13) INCLUSION OF INFORMATION IN REQUIRED ANNUAL REPORT.—The Secretary shall include in the annual report required under section 10301(g) of this title the names of all accredited persons and the particular activities under this subsection for which each person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(14) LEGAL EFFECT ON CERTAIN AGREEMENTS.—Notwithstanding any provision of this subsection, this subsection does not have any legal effect on any agreement described in section 20103(b) of this title between the Secretary and a foreign country.

(15) RECOGNITION OF CERTAIN AUDITING ORGANIZATIONS.—

(A) IN GENERAL.—Notwithstanding any other provision of this subsection, the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization for purposes of conducting inspections of—

(i) establishments that manufacture, prepare, propagate, compound, or process devices (other than types of devices licensed under section 351 of the Public Health Service Act (42 U.S.C. 262)), as required under section 13136(h) of this title; or

(ii) establishments required to register pursuant to section 13136(i) of this title.

(B) EFFECT OF PARAGRAPH ON AUTHORITY OF SECRETARY.—Nothing in this paragraph affects—

(i) the authority of the Secretary to inspect any device establishment pursuant to this subtitle; or

(ii) the authority of the Secretary to determine the official classification of an inspection.

(h) UNIFORM PROCESSES AND STANDARDS.—

(1) IN GENERAL.—In the case of inspections other than for-cause inspections, the Secretary shall review processes and standards applicable to inspections of domestic and foreign device establishments in effect as of August 18, 2017, and update the processes and standards through the adoption of uniform processes and standards applicable to the inspections. The uniform processes and standards shall provide for—

(A) exceptions to the processes and standards, as appropriate;

(B) announcing the inspection of the device establishment within a reasonable time before the inspection occurs, including by providing to the owner, operator, or agent in charge of the establishment a notification regarding the type and nature of the inspection;

(C) a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or employees carrying out the inspection under subsection

(a)(1) and the owner, operator, or agent in charge of the device establishment concerning appropriate working hours during the inspection, and, to the extent feasible, advance notice of some records that will be requested; and

(D) regular communications during the inspection with the owner, operator, or agent in charge of the device establishment regarding inspection status, which may be recorded by either party with advance notice and mutual consent.

(2) FEEDBACK.—

(A) PROVISION OF FEEDBACK BY SECRETARY.—The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to the request not later than 45 days after the Secretary receives the request.

(B) REQUEST FROM OWNER, OPERATOR, OR AGENT.—A request described in this subparagraph is a request for feedback—

(i) that is made by the owner, operator, or agent in charge of the establishment in a timely manner; and

(ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by the device establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

(3) EFFECT OF SUBSECTION.—Nothing in this subsection affects the authority of the Secretary to conduct inspections otherwise permitted under this subtitle in order to ensure compliance with this subtitle.

**§ 17505. Publicity**

(a) REPORTS.—The Secretary shall publish from time to time reports summarizing all judgments, decrees, and court orders that have been rendered under this subtitle, including the nature of the charge and the disposition of all of those judgments, decrees, and court orders.

(b) INFORMATION REGARDING CERTAIN GOODS.—The Secretary may disseminate information regarding food, drugs, devices, tobacco products, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer.

(c) EFFECT OF SECTION.—Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

**§ 17506. Examination of seafood on request of packer**

(a) DESIGNATION OF INSPECTORS; EXAMINATION AND INSPECTION OF SEAFOOD.—The Secretary, on application of any packer of any seafood for shipment or sale subject to this subtitle, may designate inspectors to examine and inspect the seafood and the production, packing, and labeling of the seafood.

(b) COMPLIANCE MARKED.—If, on the examination and inspection under subsection (a), compliance is found with this subtitle and regulations promulgated under this subtitle, the applicant shall be authorized or required to mark the seafood as provided by regulation to show the compliance.

(c) FEES.—Services under this section shall be rendered only on payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service.

(d) AVAILABILITY OF FEES FOR EXPENDITURES.—Receipts from the fees shall be deposited in the Treasury and shall be available to the Secretary for expenditures

incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors if necessary to supplement the number of inspectors for whose salaries Congress has appropriated.

(e) REGULATIONS RELATING TO SANITARY AND OTHER CONDITIONS.—The Secretary may promulgate regulations governing the sanitary and other conditions under which the service provided under this section shall be granted and maintained, and for otherwise carrying out the purposes of this section.

(f) CRIMINAL PENALTIES.—Any person that forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by this section or regulations under this section, shall be imprisoned for not more than 1 year, fined under title 18 but not less than $1,000, or both.

**§ 17507. Advertising of foods**

(a) NOTIFICATION OF FEDERAL TRADE COMMISSION.—

(1) IN GENERAL.—Except as provided in subsection (c), before the Secretary may initiate any action under chapter 105 of this title with respect to any food or advertising of food, the Secretary shall, in accordance with paragraph (2), notify in writing

the Federal Trade Commission of the action the Secretary proposes to take respecting the food or advertising—

(A) if, in the case of food, the Secretary determines that the food is misbranded under section 11301(2) of this title because of its advertising; or

(B) if, in the case of advertising of food, the Secretary determines that the advertising causes the food to be misbranded under section 11301(2) of this title.

(2) CONTENTS.—The notice required by paragraph (1) shall—

(A) contain—

(i) a description of the action the Secretary proposes to take and of the advertising that the Secretary has determined causes a food to be misbranded; and

(ii) a statement of the reasons for the Secretary's determination that the advertising has caused the food to be misbranded; and

(B) be accompanied by the records, documents, and other written materials that the Secretary determines supports the Secretary's

determination that the food is misbranded because of the advertising.

(b) ACTION BY FEDERAL TRADE COMMISSION PRECLUDING ACTION BY SECRETARY.—

(1) IN GENERAL.—If the Secretary notifies the Federal Trade Commission under subsection (a) of action proposed to be taken under chapter 105 of this title with respect to a food or food advertising, the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice if the Federal Trade Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of the Secretary's notice, that—

(A) the Federal Trade Commission has initiated under the Federal Trade Commission Act (15 U.S.C. 41 et seq.) an investigation of the advertising to determine if the advertising is prohibited by the Act or any order or rule under the Act;

(B) the Federal Trade Commission has commenced (or intends to commence) a civil action under section 5, 13, or 19 of the Federal Trade Commission Act (15 U.S.C. 45, 53, 57b) with respect to the advertising or the Attorney

General has commenced (or intends to commence) a civil action under section 5 of the Act (15 U.S.C. 45) with respect to the advertising;

(C) the Federal Trade Commission has issued and served (or intends to issue and serve) a complaint under section 5(b) of the Act (15 U.S.C. 45(b)) respecting the advertising; or

(D) pursuant to section 16(b) of the Act (15 U.S.C. 56(b)), the Federal Trade Commission has made a certification to the Attorney General respecting the advertising.

(2) EXCEPTION.—The Secretary may, after the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice under subsection (a) of the Secretary to the Commission, initiate the action described in the notice under subsection (a) if, before the expiration of the 60-day period—

(A) the Commission or the Attorney General does not commence a civil action described in paragraph (1)(B) respecting the advertising described in the Secretary's notice;

(B) the Commission does not issue and serve a complaint described in paragraph (1)(C) respecting the advertising; or

(C) the Commission does not (as described in paragraph (1)(D)) make a certification to the Attorney General respecting the advertising, or, if the Commission does make the certification to the Attorney General respecting the advertising, the Attorney General, before the expiration of the period, does not cause appropriate criminal proceedings to be brought against the advertising.

(3) NOTIFICATION TO SECRETARY.—The Federal Trade Commission shall promptly notify the Secretary of the commencement by the Commission of such a civil action, the issuance and service by the Commission of such a complaint, or the causing by the Attorney General of such criminal proceedings to be brought against the advertising.

(c) SECRETARY'S DETERMINATION OF IMMINENT HAZARD TO HEALTH AS SUSPENDING APPLICABILITY OF PROVISIONS.—The requirements of subsections (a) and (b) do not apply with respect to action under chapter 105 of this title with respect to any food or food advertising

if the Secretary determines that the action is required to eliminate an imminent hazard to health.

(d) COORDINATION OF ACTION BY SECRETARY WITH FEDERAL TRADE COMMISSION.—For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under chapter 105 of this title because of advertising that the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act (15 U.S.C. 41 et seq.) with respect to the advertising.

**§ 17508. Confidential information**

(a) CONTRACTORS.—

(1) PROVISION BY SECRETARY OF INFORMATION EXEMPT FROM DISCLOSURE.—The Secretary may provide any information that is exempt from disclosure under section 552(a) of title 5 by reason of section 552(b)(4) of that title to a person other than an officer or employee of the Department if the Secretary determines that the person requires the information in connection with an activity that is undertaken under contract with the Secretary, which relates to the administration of this subtitle, and with respect to which the Secretary (or an officer or

employee of the Department) is not prohibited from using the information.

(2) SECURITY PRECAUTIONS AS CONDITION.—The Secretary shall require as a condition to the provision of information under this section that the person receiving the information take the security precautions respecting the information as the Secretary may by regulation prescribe.

(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENTS.—

(1) IN GENERAL.—The Secretary shall not be required to disclose under section 552 of title 5, or any other provision of law, any information relating to drugs obtained from a foreign government agency, if—

(A) the information concerns the inspection of a facility, is part of an investigation, alerts the United States to the potential need for an investigation, or concerns a drug that has a reasonable probability of causing serious adverse health consequences or death to humans or animals;

(B) the information is provided or made available to the United States Government vol-

untarily on the condition that it not be released to the public; and

(C) the information is covered by, and subject to, a written agreement between the Secretary and the foreign government.

(2) TIME LIMITATIONS.—

(A) IN GENERAL.—The written agreement described in paragraph (1)(C) shall specify the time period for which paragraph (1) shall apply to the voluntarily disclosed information.

(B) APPLICABILITY OF OTHER LEGAL PROTECTIONS.—Paragraph (1) shall not apply with respect to the information after the date specified in the agreement, but all other applicable legal protections, including the provisions of section 552 of title 5 and section 319L(e)(1) of the Public Health Service Act (42 U.S.C. 247d–7e(e)(1)), as applicable, shall continue to apply to the information.

(C) NO DATE SPECIFIED IN AGREEEMENT.—If no date is specified in the written agreement, paragraph (1) shall not apply with respect to the information for a period of more than 36 months.

(3) DISCLOSURES NOT AFFECTED.—Nothing in this section authorizes any official to withhold, or to authorize the withholding of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States.

(4) RELATION TO OTHER LAW.—For purposes of section 552 of title 5, this subsection shall be considered a statute described in section 552(b)(3)(B) of title 5.

(c) AUTHORITY TO ENTER INTO MEMORANDA OF UNDERSTANDING FOR PURPOSES OF INFORMATION EXCHANGE.—The Secretary may enter into written agreements to provide information referenced in section 10501(10) of this title to foreign governments subject to the following criteria:

(1) CERTIFICATION.—The Secretary may enter into a written agreement to provide information under this subsection to a foreign government only if the Secretary has certified the government as having the authority and demonstrated ability to protect trade secret information from disclosure. Responsibility for this certification shall not be delegated to any officer or employee other than the Commissioner.

(2) WRITTEN AGREEMENT.—The written agreement to provide information to the foreign government under this subsection shall include a commitment by the foreign government to protect information exchanged under this subsection from disclosure unless and until the sponsor gives written permission for disclosure or the Secretary makes a declaration of a public health emergency pursuant to section 319 of the Public Health Service Act (42 U.S.C. 247d) that is relevant to the information.

(3) INFORMATION EXCHANGE.—The Secretary may provide to a foreign government that has been certified under paragraph (1) and that has executed a written agreement under paragraph (2) information referenced in section 10501(10) of this title in only the following circumstances:

(A) Information concerning the inspection of a facility may be provided to a foreign government if—

(i) the Secretary reasonably believes, or the written agreement described in paragraph (2) establishes, that the government has authority to otherwise obtain the information; and

(ii) the written agreement executed under paragraph (2) limits the recipient's use of the information to the recipient's civil regulatory purposes.

(B) Information not described in subparagraph (A) may be provided as part of an investigation, or to alert the foreign government to the potential need for an investigation, if the Secretary has reasonable grounds to believe that a drug has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

(4) EFFECT OF SUBSECTION.—Nothing in this subsection affects the ability of the Secretary to enter into any written agreement authorized by other provisions of law to share confidential information.

**§ 17509. Existence of jurisdiction**

In any action to enforce the requirements of this subtitle respecting a device, tobacco product, food, drug, or cosmetic, the connection with interstate commerce required for jurisdiction in the action shall be deemed to exist.

**§ 17510. Consolidated administrative and laboratory facility**

(a) AUTHORITY.—The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated FDA administrative and laboratory facility.

(b) AWARDING OF CONTRACT.—

(1) SOLICITATION.—The Secretary shall solicit contract proposals under subsection (a) from interested parties.

(2) REVIEW OF PROPOSALS; CONSIDERATIONS.—In awarding contracts under subsection (a), the Secretary shall review the proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements.

(3) NET COST SAVINGS REQUIRED.—A contract under this subsection shall not be entered into unless the contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

(c) DONATIONS.—In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the FDA gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

**§ 17511. Automation of FDA**

The Secretary, acting through the Commissioner, shall automate appropriate activities of the FDA to ensure timely review of activities regulated under this subtitle.

**§ 17512. Conflicts of interest**

(a) DEFINITIONS.—In this section:

(1) ADVISORY COMMITTEE.—The term ''advisory committee'' means an advisory committee under chapter 10 of title 5 that provides advice or recommendations to the Secretary regarding activities of the FDA.

(2) FINANCIAL INTEREST.—The term ''financial interest'' means a financial interest under section 208(a) of title 18.

(b) RECRUITMENT FOR ADVISORY COMMITTEES.—

(1) IN GENERAL.—The Secretary shall—

(A) develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and

medical societies, and patient and consumer groups;

(B) seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities;

(C) at least every 180 days, request referrals for potential members of advisory committees from a variety of stakeholders, including—

(i) product developers, patient groups, and disease advocacy organizations; and

(ii) relevant—

(I) professional societies;

(II) medical societies;

(III) academic organizations; and

(IV) governmental organizations; and

(D) in carrying out subparagraphs (A) and (B), take into account the levels of activity (including the numbers of annual meetings) and the numbers of vacancies of the advisory committees.

(2) RECRUITMENT ACTIVITIES.—The recruitment activities under paragraph (1) may include—

(A) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

(B) making widely available, including by using existing electronic communications channels, the contact information for the FDA point of contact regarding advisory committee nominations; and

(C) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person that the FDA can contact regarding the nomination of individuals to serve on advisory committees.

(3) EXPERTISE.—In carrying out this subsection, the Secretary shall seek to ensure that the Secretary has access to the most current expert advice.

(c) DISCLOSURE OF DETERMINATIONS AND CERTIFICATIONS.—Notwithstanding section 13109(a)(2) of title 5, the following shall apply:

(1) FIFTEEN OR MORE DAYS IN ADVANCE.—As soon as practicable, but (except as provided in para-

graph (2)) not later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18 or a written certification as referred to in section 208(b)(3) of title 18 applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 or 552a of title 5) on the FDA website—

(A) the type, nature, and magnitude of the financial interests of the advisory committee member to which the determination or certification applies; and

(B) the reasons of the Secretary for the determination or certification, including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter before the advisory committee.

(2) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18 or a written certification as referred to in section 208(b)(3) of title 18 applies, the Secretary shall dis-

close (other than information exempted from disclosure under section 552 or 552a of title 5) on the FDA website, the information described in subparagraphs (A) and (B) of paragraph (1) as soon as practicable after the Secretary makes the determination or certification, but not later than the date of the meeting.

(d) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c) (other than information exempted from disclosure under section 552 or 552a of title 5).

(e) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives, a report that describes, with respect to the fiscal year that ended on September 30 of the previous year—

(A) the number of individuals nominated for participation at meetings for each advisory committee, the number of individuals so nomi-

nated, and willing to serve, the number of vacancies on each advisory committee, and the number of individuals contacted for service as members on each advisory committee meeting for each advisory committee who did not participate because of the potential for the participation to constitute a disqualifying financial interest under section 208 of title 18;

(B) the number of individuals contacted for service as members for each advisory committee meeting for each advisory committee who did not participate because of reasons other than the potential for the participation to constitute a disqualifying financial interest under section 208 of title 18;

(C) the number of members attending meetings for each advisory committee; and

(D) the aggregate number of disclosures required under subsection (d) and the percentage of individuals to whom the disclosures did not apply who served on the advisory committee.

(2) PUBLIC AVAILABILITY.—Not later than 30 days after submitting any report under paragraph (1) to the congressional committees specified in

paragraph (1), the Secretary shall make each such report available to the public.

(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall—

(1) review guidance of the FDA with respect to advisory committees regarding disclosure of conflicts of interest and the application of section 208 of title 18; and

(2) update the guidance as necessary to ensure that the FDA receives appropriate access to needed scientific expertise, with due consideration of the requirements of section 208 of title 18.

(g) GUIDANCE ON REPORTED DISCLOSED FINANCIAL INTEREST OR INVOLVEMENT.—The Secretary shall issue guidance that describes how the Secretary reviews the financial interests and involvement of advisory committee members that are disclosed under subsection (c) but that the Secretary determines not to meet the definition of a disqualifying interest under section 208 of title 18 for the purposes of participating in a particular matter.

**§ 17513. Policy on the review and clearance of scientific articles published by FDA employees**

(a) DEFINITION OF ARTICLE.—In this section, the term ''article'' means a paper, poster, abstract, book, book chapter, or other published writing.

(b) POLICIES.—The Secretary, through the Commissioner, shall establish and make publicly available clear written policies to implement this section and govern the timely submission, review, clearance, and disclaimer requirements for articles.

(c) TIMING OF SUBMISSION FOR REVIEW.—If an officer or employee, including a Staff Fellow or a contractor who performs staff work, of the FDA is directed by the policies established under subsection (b) to submit an article to the supervisor of the officer or employee, or to some other official of the FDA, for review and clearance before the officer or employee may seek to publish or present the article at a conference, the officer or employee shall submit the article for the review and clearance not less than 30 days before submitting the article for publication or presentation.

(d) TIMING FOR REVIEW AND CLEARANCE.—The supervisor or other reviewing official shall review the article and provide written clearance, or written clearance on the condition of specified changes being made, to the officer

or employee not later than 30 days after the officer or employee submitted the article for review.

(e) NON-TIMELY REVIEW.—If, 31 days after the submission under subsection (c), the supervisor or other reviewing official has not cleared or has not reviewed the article and provided written clearance, the officer or employee may consider the article not to have been cleared and may submit the article for publication or presentation with an appropriate disclaimer as specified in the policies established under subsection (b).

(f) EFFECT.—Nothing in this section shall be construed as affecting any restrictions on the publication or presentation provided by other provisions of law.

**§ 17514. Hiring authority for scientific, technical, and professional personnel**

(a) IN GENERAL.—The Secretary may, notwithstanding title 5 governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions, including cross-cutting operational positions, that support the development, review, and regulation of medical products and the regulation of food and cosmetics. The positions shall be within the competitive service.

(b) COMPENSATION.—

(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, and consistent with the requirements of paragraph (2), the Commissioner may determine and set—

(A) the annual rate of pay of any individual appointed under subsection (a); and

(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before December 13, 2016.

(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3.

(3) PUBLIC AVAILABILITY.—The annual rate of pay provided to an individual in accordance with this section shall be publicly available information.

(c) REPORT ON WORKFORCE PLANNING.—

(1) IN GENERAL.—Not later than 18 months after December 29, 2022, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Sen-

ate and the Committee on Energy and Commerce of the House of Representatives that includes—

(A) an updated analysis of the workforce needs at the FDA and the Secretary's strategic plan for addressing the needs, including through use of the authority under this section;

(B) an analysis of how the Secretary has used the authorities provided under this section, and a plan for how the Secretary will use the authority under this section, and other applicable hiring authorities, for employees of the FDA; and

(C) an updated recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

(i) recruitment through nongovernmental recruitment or placement agencies;

(ii) recruitment through academic institutions;

(iii) recruitment or hiring bonuses, if applicable;

(iv) recruitment using targeted direct hiring authorities; and

(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

(2) RECOMMENDATIONS.—The report under paragraph (1) may include the recommendations of the Commissioner that would help the FDA to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.

**§ 17515. Strategic Workforce Plan and report**

(a) IN GENERAL.—Not later than September 30, 2023, and at least every 4 years thereafter, the Secretary shall develop, begin implementation of, and submit to the appropriate committees of Congress and post on the FDA website, a coordinated strategy and report to provide direction for the activities and programs of the Secretary to recruit, hire, train, develop, and retain the workforce needed to fulfill the public health mission of the FDA, including to facilitate collaboration across centers, to keep pace with new biomedical, technological, and scientific advancements, and to support the development, review, and regulation of medical products. Each report shall be known as the ''Food and Drug Administration Strategic Workforce Plan''.

(b) USE OF THE FOOD AND DRUG ADMINISTRATION STRATEGIC WORKFORCE PLANS.—Each center within the FDA shall develop and update, as appropriate, a strategic plan that will be informed by the Food and Drug Administration Strategic Workforce Plans developed under subsection (a).

(c) CONTENTS OF THE FOOD AND DRUG ADMINISTRATION STRATEGIC WORKFORCE PLAN.—Each Food and Drug Administration Strategic Workforce Plan under subsection (a) shall—

(1) include agency-wide human capital strategic goals and priorities for recruiting, hiring, training, developing, and retaining a qualified workforce for the FDA;

(2) establish specific actions the Secretary will take to achieve the strategic goals and priorities and address the workforce needs of the FDA in the forthcoming fiscal years;

(3) identify challenges and risks the Secretary will face in meeting its strategic goals and priorities, and the actions the Secretary will take to overcome those challenges and mitigate those risks;

(4) establish performance measures, benchmarks, or other elements that the Secretary will use to measure and evaluate progress in achieving the

strategic goals and priorities and the effectiveness of the strategic goals and priorities; and

(5) define functions, capabilities, and gaps in the FDA workforce and identify strategies to recruit, hire, train, develop, and retain the workforce.

(d) CONSIDERATIONS.—In developing each Food and Drug Administration Strategic Workforce Plan under subsection (a), the Secretary shall consider—

(1) the number of employees (including senior leadership and non-senior leadership employees) eligible for retirement, the expertise of those employees, and the employing center of those employees;

(2) the vacancy and turnover rates for employees with different types of expertise and from different centers, including any changes or trends related to the rates;

(3) the results of the Federal Employee Viewpoint Survey for employees of the FDA, including any changes or trends related to the results;

(4) rates of pay for different types of positions, including rates for different types of expertise within the same field (such as differences in pay between different medical specialists), and how the rates of pay impact the ability of the Secretary to achieve the

strategic goals and priorities described in subsection (c);

(5) the statutory hiring authorities used to hire FDA employees, and the time to hire across different hiring authorities; and

(6) any other timely and relevant information, as the Secretary determines appropriate.

(e) EVALUATION OF PROGRESS.—Each Food and Drug Administration Strategic Workforce Plan issued pursuant to subsection (a), with the exception of the first Food and Drug Administration Strategic Workforce Plan, shall include an evaluation of—

(1) the progress the Secretary has made, based on the performance measures, benchmarks, and other elements that measure successful recruitment, hiring, training, development, and retention activities; and

(2) whether actions taken in response to the previous Food and Drug Administration Strategic Workforce Plan improved the capacity of the FDA to achieve the strategic goals and priorities described in subsection (c)(1).

(f) ADDITIONAL CONSIDERATIONS.—The Food and Drug Administration Strategic Workforce Plan issued in fiscal year 2023 shall address the effect of the COVID–

19 pandemic on hiring, retention, and other workforce challenges for the FDA, including protecting the workforce during public health emergencies.

**§ 17516. Reporting requirements for biosimilar biological products**

(a) IN GENERAL.—Not later than 120 days after the end of each fiscal year for which fees are collected under subchapter VIII of chapter 179 of this title, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning—

(1) the number of applications for approval filed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(2) the percentage of applications described in paragraph (1) that were approved by the Secretary.

(b) ADDITIONAL INFORMATION.—As part of the performance report described in subsection (a), the Secretary shall include an explanation of how the FDA is managing the biological product review program to ensure that the user fees collected under subchapter II of chapter 179 of this title are not used to review an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

# Chapter 177—Colors

See.
17701. Listing and certification of color additives for foods, drugs, devices, and cosmetics.

## § 17701. Listing and certification of color additives for foods, drugs, devices, and cosmetics

(a) UNSAFE COLOR ADDITIVES.—

(1) IN GENERAL.—A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food, drugs, devices, or cosmetics, be deemed unsafe for the purposes of the application of section 11102(c), 13101(a)(2)(D), or 17111(f) of this title, as the case may be, unless—

(A)(i) there is in effect, and the color additive and the use are in conformity with, a regulation issued under subsection (b) listing the color additive for the use, including any provision of the regulation prescribing the conditions under which the color additive may be safely used; and

(ii) the color additive—

(I) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for the use; or

(II) has, with respect to the use, been exempted by the Secretary from the requirement of certification; or

(B) the color additive and the use of the color additive conform to the terms of an exemption that is in effect pursuant to subsection (f).

(2) EFFECT OF REGULATIONS ON WHETHER ARTICLE IS ADULTERATED.—While there are in effect regulations under subsections (b) and (c) relating to a color additive or an exemption pursuant to subsection (f) with respect to the color additive, an article shall not, by reason of bearing or containing the color additive in all respects in accordance with the regulations or the exemption, be considered adulterated—

(A) within the meaning of section 11102(a)(1) of this title if the article is a food; or

(B) within the meaning of section 17111(b) of this title if the article is a cosmetic other than a hair dye (as defined in section 17111(a) of this title).

(3) DIRECT CONTACT WITH BODY REQUIRED.—A color additive for use in or on a device shall be

subject to this section only if the color additive comes in direct contact with the body of a human or other animal for a significant period of time.

(4) DESIGNATION OF COLOR ADDITIVES IN OR ON DEVICES.—The Secretary may by regulation designate the uses of color additives in or on devices that are subject to this section.

(b) LISTING OF COLORS; ADVISORY COMMITTEES.—

(1) DEFINITION OF TOLERANCE LIMITATION.—In this subsection, the term ''tolerance limitation'' means a specification as to the maximum quantity or quantities of a color additive that may be used or permitted to remain in or on an article in or on which the color additive is used.

(2) IN GENERAL.—The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs or devices, and color additives for use in or on cosmetics, if and to the extent that the color additives are suitable and safe for any such use when employed in accordance with the regulations.

(3) LISTING FOR GENERAL USE.—

(A) IN GENERAL.—The regulations under paragraph (2) may list any color additive for use generally in or on food, or in or on drugs

or devices, or in or on cosmetics, if the Secretary finds that the color additive is suitable and may safely be employed for the general use.

(B) LIMITED USES.—If the data before the Secretary do not establish that the color additive satisfies the requirements for listing the color additive on the applicable list pursuant to subparagraph (A), or if the proposal is for listing the color additive for a more limited use or uses, the regulations may list the color additive only for any more limited use or uses for which it is suitable and may safely be employed.

(4) CONDITIONS OF SAFE USE.—The regulations shall, to the extent considered necessary by the Secretary to ensure the safety of the use for which a particular color additive is listed, prescribe the conditions under which the color additive may be safely employed for the use, including—

(A) tolerance limitations;

(B) specifications as to the manner in which the color additive may be added to or used in or on an article; and

(C) directions or other labeling or packaging requirements for the color additive.

(5) SAFE USE.—

(A) DATA SHOWING SAFE USE REQUIRED.—The Secretary shall not list a color additive under this section for a proposed use unless the data before the Secretary establish that the use, under the conditions of use specified in the regulations, is safe.

(B) COLOR ADDITIVES EXEMPT AS FOOD ADDITIVES.—A color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring the color additive exempt from the term ''food additive'' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 10101(a)(20) of this title.

(6) FACTORS FOR DETERMINING SAFE USE.—

(A) IN GENERAL.—In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the color additive and of any substance formed in or

on food, drugs or devices, or cosmetics because of the use of the color additive;

(ii) the cumulative effect, if any, of the color additive in the diet of humans or animals, taking into account the same or any chemically or pharmacologically related substance or substances in the diet;

(iii) safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the color additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of—

(I) the pure dye and all intermediates and other impurities contained in the color additive;

(II) the color additive in or on any article of food, drug or device, or cosmetic; and

(III) any substance formed in or on the article because of the use of the color additive.

(B) CANCER-INDUCING ADDITIVES.—

(i) IN GENERAL.—A color additive—

(I) shall be deemed unsafe, and shall not be listed, for any use that will or may result in ingestion of all or part of the color additive, if—

(aa) the color additive is found by the Secretary to induce cancer when ingested by a human or animal; or

(bb) the color additive is found by the Secretary, after tests that are appropriate for the evaluation of the safety of color additives for use in food, to induce cancer in humans or animals; and

(II) shall be deemed unsafe, and shall not be listed, for any use that will not result in ingestion of any part of the color additive, if, after tests that are appropriate for the evaluation

of the safety of color additives for the use, or after other relevant exposure of a human or animal to the color additive, it is found by the Secretary to induce cancer in humans or animals.

(ii) EXCEPTION.—Clause (i)(I) shall not apply with respect to the use of a color additive as an ingredient of feed for animals that are raised for food production, if the Secretary finds—

(I) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, the color additive will not adversely affect the animals for which the feed is intended; and

(II) that no residue of the color additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d))—

(aa) in any edible portion of the animals after slaughter; or

(bb) in any food yielded by or derived from any such living animal.

(C) REFERRAL TO ADVISORY COMMITTEE FOR REPORT AND RECOMMENDATIONS.—

(i) IN GENERAL.—

(I) REQUEST FOR REFERRAL.—In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on the Secretary's own initiative or by a proposal contained in a petition, the petitioner, or any other person that will be adversely affected by the proposal or by the Secretary's order issued in accordance with paragraph (1) of section 17501(e) of this title if placed in effect, may request, within the time specified in subclause (IV), that the petition or order on the petition, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under

subparagraph (B) that is involved in the proposal or order and that requires the exercise of scientific judgment.

(II) APPOINTMENT AND REFERRAL.—On a request under subclause (I), or if the Secretary within the time specified in subclause (IV) considers such a referral necessary, the Secretary—

(aa) shall immediately appoint an advisory committee under subparagraph (D); and

(bb) shall refer to the advisory committee, together with all the data before the Secretary, the matter arising under subparagraph (B) for study of the matter and for a report and recommendations on the matter.

(III) CONSULTATION WITH ADVISORY COMMITTEE.—A person that has filed a petition or that has requested the referral of a matter to an advisory committee pursuant to this subpara-

graph, as well as representatives of the Department, shall have the right to consult with the advisory committee in connection with the matter referred to the advisory committee.

(IV) TIME.—The request for referral under this subparagraph, or the Secretary's referral on the Secretary's own initiative, may be made at any time before, or within 30 days after, publication of an order of the Secretary acting on the petition or proposal.

(ii) REPORT AND RECOMMENDATIONS.—

(I) CERTIFICATION.—Within 60 days after the date of the referral, or within an additional 30 days if the advisory committee considers the additional time necessary, the advisory committee shall, after independent study of the data furnished to the advisory committee by the Secretary and other data before the advisory committee, certify to the Secretary—

(aa) a report and recommendations; and

(bb) all underlying data and a statement of the reasons or basis for the recommendations.

(II) COPY TO BE SUPPLIED BY SECRETARY.—A copy of the items described in items (aa) and (bb) of subclause (I) shall be promptly supplied by the Secretary to any person that has filed a petition, or that has requested the referral to the advisory committee.

(III) ACTION BY SECRETARY.—Within 30 days after the certification, and after giving due consideration to all data then before the Secretary, including the report, recommendations, underlying data, and statement, and to any prior order issued by the Secretary in connection with the matter, the Secretary shall by order confirm or modify any order previously issued or, if no such prior order has been

issued, shall by order act on the petition or other proposal.

(iii) REMOVAL OF CANCER-INDUCING COLOR ADDITIVE FROM LISTING.—

(I) CONDITIONS.—Subclause (II) applies if—

(aa) by reason of subparagraph (B), the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

(bb) a request has been made for referral of the proposal to an advisory committee.

(II) SECRETARIAL ACTION.—If items (aa) and (bb) of subclause (I) are met, the Secretary may not act by order on the proposal described in subclause (I)(aa) until the advisory committee has made a report and recommendations to the Secretary under clause (ii) and the Secretary has considered the recommendations, unless the Secretary finds that emergency

conditions exist necessitating the issuance of an order notwithstanding this clause.

(D) ADVISORY COMMITTEE.—

(i) COMPOSITION.—

(I) IN GENERAL.—The advisory committee referred to in subparagraph (C) shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the advisory committee, and of adequately diversified professional background.

(II) INABILITY OR REFUSAL OF NATIONAL ACADEMY OF SCIENCES TO ACT.—In the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the advisory committee.

(ii) SIZE.—The Secretary shall determine the size of the advisory committee.

(iii) COMPENSATION AND TRAVEL EXPENSES RELATING TO MEETINGS AND CONFERENCES.—

(I) IN GENERAL.—A member of any advisory committee established under this subtitle, while attending conferences or meetings of the member's advisory committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary but at rates not exceeding the daily equivalent, at the time of service, of the maximum rate payable under section 5376 of title 5, including travel time.

(II) SERVICE AWAY FROM HOME OR REGULAR PLACE OF BUSINESS.—While away from the member's home or regular place of business, the member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for individuals in the Government service employed intermittently.

(iv) EFFECT OF OTHER LAWS RELATING TO APPOINTMENT AND COMPENSATION.—The member shall not be subject to

any other law regarding the appointment and compensation of employees of the United States.

(v) CLERICAL AND OTHER ASSISTANCE.—The Secretary shall furnish the advisory committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the advisory committee.

(7) PROPOSED USE TO PROMOTE DECEPTION OR TO RESULT IN MISBRANDING OR ADULTERATION.—The Secretary shall not list a color additive under this subsection for a proposed use if the data before the Secretary show that the proposed use would promote deception of the consumer in violation of this subtitle or would otherwise result in misbranding or adulteration within the meaning of this subtitle.

(8) TOLERANCE LIMITATIONS.—If, in the judgment of the Secretary, a tolerance limitation is required in order to ensure that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the color additive for the use if the Secretary finds that the data before the Secretary do not establish that the color ad-

ditive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix the tolerance limitation at a level higher than the Secretary finds to be reasonably required to accomplish the intended physical or other technical effect.

(9) FACTORS FOR DETERMINING WHICH USES A COLOR ADDITIVE IS TO BE LISTED.—If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before the Secretary fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed for the color additive and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses the color additive (or the related color additives) shall be or remain listed, or how the aggregate allowable safe tolerance for the color additive or color additives shall be allocated by the Secretary among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety)—

(A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of the related color additives) in or on the articles, and the relative dependence of the industries concerned on the uses;

(B) the relative aggregate amounts of the color additive that the Secretary estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and

(C) the availability, if any, of other color additives suitable and safe for 1 or more of the uses proposed.

(c) CERTIFICATION OF COLORS.—

(1) IN GENERAL.—The Secretary shall, by regulation, provide—

(A) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for the color additives established by regulations under subsection (b) and this subsection; and

(B) for exemption from the requirement of certification in the case of any such color addi-

tive, or any listing or use of the color additive, for which the Secretary finds the requirement not to be necessary in the interest of the protection of the public health.

(2) COLOR ADDITIVES EXEMPT AS FOOD ADDITIVES.—With respect to any use in or on food for which a listed color additive is deemed to be safe by reason of subsection (b)(5)(B), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

(d) PROCEDURE FOR ISSUANCE, AMENDMENT, OR REPEAL OF REGULATIONS.—

(1) IN GENERAL.—The provisions of subsections (e), (f), and (g) of section 17501 of this title shall, subject to the provisions of subsection (b)(5)(C), apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) (including judicial review of the Secretary's action in the proceedings) and the admissibility of transcripts of the record of the proceedings in other proceedings, except that—

(A) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general

terms by the Secretary within 30 days after the filing, and the Secretary's order (required by section 17501(e)(1) of this title) acting on the proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within 90 days after the date of the filing, except that the Secretary may (prior to the 90th day), by written notice to the petitioner, extend the 90-day period to such time (not more than 180 days after the date of filing of the petition) as the Secretary considers necessary to enable the Secretary to study and investigate the petition;

(B) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subsection (b)(5)(D) shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 556(d) of title 5;

(C) the Secretary's order after public hearing (acting on objections filed to an order made prior to hearing) shall be subject to the requirements of section 11111(g)(3)(B) of this title; and

(D) the scope of judicial review of the order shall be in accordance with paragraphs (2)(D) and (3) of section 11111(h) of this title.

(2) HEARING.—The advisory committee shall designate a member to appear and testify at any hearing described in paragraph (1)(B) with respect to the report and recommendations of the advisory committee on request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at the hearing.

(e) FEES.—The admitting to listing and certification of color additives, in accordance with regulations prescribed under this subtitle, shall be performed only on payment of such fees, which shall be specified in the regulations, as may be necessary to provide, maintain, and equip an adequate service for the purposes.

(f) EXEMPTIONS.—The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use of the color additive, and any article of food, drug or device, or cosmetic bearing or containing the color additive, intended solely for inves-

tigational use by qualified experts if, in the Secretary's opinion, the exemption is consistent with the public health.

# Chapter 179—Fees

**Subchapter I—Freedom of Information Fees**
Sec.
17901. Recovery and retention of fees for freedom of information requests.
**Subchapter II—Fees Relating to Drugs**
17906. Definitions.
17907. Authority to assess and use drug fees.
17908. Reauthorization; reporting requirements.
**Subchapter III—Fees Relating to Devices**
17916. Definitions.
17917. Authority to assess and use device fees.
17918. Reauthorization; reporting requirements.
**Subchapter IV—Fees Relating to Animal Drugs**
17926. Definitions.
17927. Authority to assess and use animal drug fees.
17928. Reauthorization; reporting requirements.
**Subchapter V—Fees Relating to Generic New Animal Drugs**
17936. Definitions.
17937. Authority to assess and use generic new animal drug fees.
17938. Reauthorization; reporting requirements.
**Subchapter VI—Fees Relating to Food**
17946. Definitions.
17947. Authority to collect and use fees.
**Subchapter VII—Fees Relating to Generic Drugs**
17951. Definitions.
17952. Authority to assess and use human generic drug fees.
17953. Reauthorization; reporting requirements.
**Subchapter VIII—Fees Relating to Biosimilar Biological Products**
17961. Definitions.
17962. Authority to assess and use biosimilar biological product fees.
17963. Reauthorization; reporting requirements.
**Subchapter IX—Fees Relating to Outsourcing Facilities**
17971. Definitions.
17972. Authority to assess and use outsourcing facility fees.
**Subchapter X—Fees Relating to Over-the-Counter Drugs**
17976. Definitions.
17977. Authority to assess and use OTC monograph fees.
17978. Reauthorization; reporting requirements.

# Subchapter I—Freedom of Information Fees

### § 17901. Recovery and retention of fees for freedom of information requests

(a) IN GENERAL.—The Secretary, acting through the Commissioner, may—

(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, to recover all reasonable costs incurred in processing requests made under section 552 of title 5 for records obtained or created under this subtitle or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

(2) retain all fees charged for the requests; and

(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

(b) USE OF FEES.—

(1) NOT FOR OTHER PURPOSE.—The Secretary and the Commissioner shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1).

(2) NOT FOR REDUCTION OF OTHER FUNDS.—The fees shall not be used to reduce the amount of

funds made to carry out other provisions of this subtitle.

(c) WAIVER OF FEES.—Nothing in this section supersedes the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5.

# Subchapter II—Fees Relating to Drugs

### § 17906. Definitions

(a) DEFINITIONS.—In this subchapter:

(1) ACTIVE.—The term ''active'', with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.

(2) ADJUSTMENT FACTOR.—The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by the Index for October 1996.

(3) AFFILIATE.—The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) 1 business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(4) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS.—The term ''costs of resources allocated for the process for the review of human drug applications'' means the expenses, in connection with the process for the review of human drug applications, for—

(A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to the officers, employees, and committees and to contracts with the contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collection of fees under section 17907 of this title and accounting for resources allo-

cated for the review of human drug applications and supplements.

(5) FINAL DOSAGE FORM.—The term ''final dosage form'' means, with respect to a prescription drug product, a finished dosage form that is approved for administration to a patient without substantial further manufacturing (such as capsules, tablets, or lyophilized products before reconstitution).

(6) HUMAN DRUG APPLICATION.—

(A) IN GENERAL.—The term ''human drug application'' means an application for—

(i) approval of a new drug submitted under section 13503 of this title; or

(ii) licensure of a biological product under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(B) EXCLUSIONS.—The term ''human drug application'' does not include—

(i) a supplement to an application under subparagraph (A);

(ii) an application with respect to whole blood or a blood component for transfusion;

(iii) an application with respect to a bovine blood product for topical application licensed before September 1, 1992;

(iv) an application with respect to an allergenic extract product licensed before October 1, 2022;

(v) an application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022;

(vi) an application with respect to an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262);

(vii) an application with respect to a large volume parenteral drug product approved before September 1, 1992;

(viii) an application for a licensure of a biological product for further manufacturing use only; or

(ix) an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially.

(C) INCLUSIONS.—The term ''human drug application'' includes an application for licensure, as described in subparagraph (A)(ii), of a large volume biological product intended for single dose injection for intravenous use or infusion.

(7) PERSON.—The term ''person'' includes an affiliate of the person.

(8) PRESCRIPTION DRUG ESTABLISHMENT.—

(A) IN GENERAL.—The term ''prescription drug establishment'' means a foreign or domestic place of business—

(i) which is at 1 general physical location consisting of 1 or more buildings, all of which are within 5 miles of each other; and

(ii) at which 1 or more prescription drug products are manufactured in final dosage form.

(B) MANUFACTURED.—In this paragraph, the term ''manufactured'' does not include packaging.

(9) PRESCRIPTION DRUG PRODUCT.—

(A) IN GENERAL.—The term ''prescription drug product'' means a specific strength or potency of a drug in final dosage form—

(i) for which a human drug application has been approved;

(ii) that may be dispensed only under prescription pursuant to section 13103(a) of this title; and

(iii) that is—

(I) on the list of products described in section 13511(h)(1) of this title (not including the discontinued section of the list); or

(II) on a list, created and maintained by the Secretary, of products approved under human drug applications under section 351 of the Public Health Service Act (42 U.S.C. 262) (not including the discontinued section of the list).

(B) EXCLUSIONS.—The term ''prescription drug product'' does not include—

(i) whole blood or a blood component for transfusion;

(ii) a bovine blood product for topical application licensed before September 1, 1992;

(iii) an allergenic extract product licensed before October 1, 2022;

(iv) a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022;

(v) an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262);

(vi) a biological product that is licensed for further manufacturing use only; or

(vii) a drug that is not distributed commercially and is the subject of an ap-

plication or supplement submitted by a State or Federal Government entity.

(C) INCLUSIONS.—The term ''prescription drug product'' includes a large volume biological product intended for single dose injection for intravenous use or infusion.

(D) REQUEST TO PLACE PRODUCT IN DISCONTINUED SECTION OF SPECIFIED LISTS.—

(i) IN GENERAL.—If a written request to place a product in the discontinued section of either of the lists referenced in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, withdrawn from sale, then for purposes of assessing the prescription drug program fee under section 17907(a)(2) of this title, the Secretary shall consider the product to have been included in the discontinued section on the later of—

(I) the date the request was received; or

(II) if the product will be withdrawn from sale on a future date, the

future date when the product is withdrawn from sale.

(ii) PRODUCT CONSIDERED WITHDRAWN FROM SALE.—For purposes of this subparagraph, a product is considered withdrawn from sale once the applicant ceases its own distribution of the product, whether or not the applicant orders recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply does not render a product withdrawn from sale.

(10) PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS.—The term ''process for the review of human drug applications'' means the following activities of the Secretary with respect to the review of human drug applications and supplements:

(A) The activities necessary for the review of human drug applications and supplements.

(B) The issuance of action letters that approve human drug applications or that set forth in detail the specific deficiencies in the applications and, where appropriate, the actions necessary to place the applications in condition for approval.

(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary's review of pending human drug applications and supplements.

(D) Activities necessary for the review of applications for licensure of establishments subject to section 351 of the Public Health Service Act (42 U.S.C. 262) and for the release of lots of biologics under the section.

(E) Monitoring of research conducted in connection with the review of human drug applications.

(F) Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety

problems, including access to external databases.

(iv) Implementing and enforcing section 13515 of this title and section 13516 of this title.

(v) Carrying out section 13512(e) of this title.

(11) SKIN-TEST DIAGNOSTIC PRODUCT.—

(A) IN GENERAL.—The term ''skin-test diagnostic product'' means a product—

(i) for prick, scratch, intradermal, or subcutaneous administration;

(ii) expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;

(iii) not intended to be a preventive or therapeutic intervention; and

(iv) intended to detect an immediate-type or delayed-type skin hypersensitivity reaction to aid in the diagnosis of—

(I) an allergy to an antimicrobial agent;

(II) an allergy that is not to an antimicrobial agent, if the diagnostic

product was authorized for marketing prior to October 1, 2022; or

(III) an infection with fungal or mycobacterial pathogens.

(B) INCLUSIONS.—The term ''skin-test diagnostic product'' includes positive and negative controls required to interpret the results of a product described in subparagraph (A).

(12) SUPPLEMENT.—The term ''supplement'' means a request to the Secretary to approve a change in a human drug application that has been approved.

(b) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17907. Authority to assess and use drug fees**

(a) TYPES OF FEES.—The Secretary shall assess and collect fees in accordance with this section as follows:

(1) HUMAN DRUG APPLICATION FEE.—

(A) IN GENERAL.—Each person that submits a human drug application shall be subject to a fee as follows:

(i) A fee established under subsection (c)(6) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with

respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(6) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval. The fee shall be half of the amount of the fee established under clause (i).

(B) PAYMENT.—The fee required by subparagraph (A) shall be due on submission of the application.

(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION.—If a human drug application (which was submitted by a person that paid the fee for the application) was accepted for filing and was not approved or was withdrawn prior to approval (without a waiver), the submission of a human drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE

FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application that is refused for filing or withdrawn without a waiver before filing.

(E) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A human drug application that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

(F) EXCEPTION FOR DESIGNATED ORPHAN DRUG.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 13902 of this title shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition.

(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—

(i) IN GENERAL.—If an application is withdrawn after the application was filed,

the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application after the application was filed.

(ii) SOLE DISCRETION.—The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph.

(iii) REVIEWABILITY.—A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(H) EXCEPTION FOR SKIN-TEST DIAGNOSTIC PRODUCTS.—A human drug application for a skin-test diagnostic product shall not be subject to a fee under subparagraph (A).

(2) PRESCRIPTION DRUG PROGRAM FEE.—

(A) IN GENERAL.—

(i) ANNUAL PAYMENT.—

(I) PERSON NAMED AS APPLICANT TO PAY FEE.—Except as provided in subparagraphs (B) and (C), each person that is named as the applicant in a human drug application, and that, after September 1, 1992,

had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for each prescription drug product that is identified in such a human drug application approved as of October 1 of the fiscal year.

(II) DATE DUE.—The fee under clause (i) shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section.

(III) PAYMENT TO BE ONCE PER PRODUCT PER FISCAL YEAR.—The fee shall be paid only once for each product for a fiscal year in which the fee is payable.

(ii) SPECIAL RULE FOR PREVIOUSLY DISCONTINUED DRUG PRODUCTS.—If a drug product that is identified in a human

drug application approved as of October 1 of a fiscal year is not a prescription drug product as of that date because the drug product is in the discontinued section of a list referenced in section 17906(a)(9)(A)(iii) of this title, and on any subsequent day during the fiscal year the drug product is a prescription drug product, then except as provided in subparagraphs (B) and (C), each person that is named as the applicant in a human drug application with respect to the drug product, and that, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for the prescription drug product. The fee shall be due on the last business day of the fiscal year and shall be paid only once for each prescription drug product described in this clause for a fiscal year in which the fee is payable.

(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—A prescription drug

program fee shall not be assessed for a prescription drug product under subparagraph (A) if the prescription drug product is—

(i) a large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not including powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 13511(h) of this title;

(ii) pharmaceutically equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulation)) to another product on the list of products compiled under section 13511(h) of this title (not including the discontinued section of the list); or

(iii) a skin-test diagnostic product.

(C) LIMITATION.—A person that is named as the applicant in an approved human drug application shall not be assessed more than 5 prescription drug program fees for a fiscal year for prescription drug products identified in the approved human drug application.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under subsection (a) that is equal to the sum of—

(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the strategic hiring and retention adjustment for the fiscal year (as determined under subsection (c)(2));

(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

(F) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(5)); and

(G) an additional dollar amount, for each fiscal year, of—

(i) $25,097,671 for fiscal year 2024;

(ii) $14,154,169 for fiscal year 2025;

(iii) $4,864,860 for fiscal year 2026; and

(iv) $1,314,620 for fiscal year 2027.

(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

(A) 20 percent shall be derived from human drug application fees under subsection (a)(1); and

(B) 80 percent shall be derived from prescription drug program fees under subsection (a)(2).

(3) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

(A) for fiscal year 2023, $1,151,522,958; and

(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, not including any adjustments made under paragraph (4) or (5) of subsection (c).

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—

(A) IN GENERAL.—For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

(i) the annual base revenue for the fiscal year under subsection (b)(1)(A); and

(ii) the inflation adjustment percentage under subparagraph (B).

(B) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—

(i) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to

the positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications for the first 3 years of the preceding 4 fiscal years; and

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications for the first 3 years of the preceding 4 fiscal years.

(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee rev-

enue and fees by $4,000,000 for each of fiscal years 2024 through 2027.

(3) CAPACITY PLANNING ADJUSTMENT.—

(A) IN GENERAL.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted in accordance with paragraphs (1) and (2), the annual base revenue shall be adjusted further for the fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for the process for the review of human drug applications.

(B) METHODOLOGY.—

(i) IN GENERAL.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled ''Prescription Drug User Fee Rates for Fiscal Year 2021'' published in the Federal Register on August 3, 2020 (85 Fed. Reg. 46651).

(ii) WORKLOAD CATEGORIES; INCLUSIONS.—The workload categories used in applying the methodology in forecasting

shall include only the activities described in that notice and, as feasible, additional activities that are directly related to the direct review of applications and supplements, including—

(I) additional formal meeting types;

(II) the direct review of post-marketing commitments and requirements;

(III) the direct review of risk evaluation and mitigation strategies; and

(IV) the direct review of annual reports for approved prescription drug products.

(iii) WORKLOAD CATEGORIES; EXCLUSIONS.—Subject to the exceptions in clause (ii), the Secretary shall not include any non-core review activities (including those activities that the Secretary referenced for potential future use in the notice described in clause (i), but did not utilize in setting fees for fiscal year 2021) as workload cat-

egories in applying the methodology in forecasting.

(C) LIMITATION.—An adjustment under this paragraph shall not result in fee revenue for a fiscal year that is less than the sum of the amounts under subparagraphs (A), (B), and (C) of subsection (b)(1).

(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish, in the Federal Register notice under paragraph (6), the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

(4) OPERATING RESERVE ADJUSTMENT.—

(A) INCREASE.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if the increase is necessary to provide for operating reserves of carryover user fees for the process for the review of human drug applications for each fiscal year in at least the following amounts:

(i) For fiscal year 2024, at least 9 weeks of operating reserves.

(ii) For fiscal year 2025 and subsequent fiscal years, at least 10 weeks of operating reserves.

(B) DECREASE.—If the Secretary has carryover balances for the process in excess of 14 weeks of the operating reserves, the Secretary shall decrease the fee revenue and fees to provide for not more than 14 weeks of the operating reserves.

(C) NOTICE OF RATIONALE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (6) establishing fee revenue and fees for the fiscal year involved.

(5) ADDITIONAL DIRECT COST ADJUSTMENT.—

(A) INCREASE.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), (3), and (4), further increase the fee revenue and fees, for each of fiscal years 2024 through 2027, by the amount set forth in clauses (i) through (iv) of subparagraph (B), as applicable, multiplied by the Consumer Price Index for urban consumers (Washington-Arling-

ton-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by the Index for 2021.

(B) APPLICABLE AMOUNTS.—The amounts referred to in subparagraph (A)(ii) are the following:

(i) For fiscal year 2024, $60,967,993.

(ii) For fiscal year 2025, $35,799,314.

(iii) For fiscal year 2026, $35,799,314.

(iv) For fiscal year 2027, $35,799,314.

(6) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year—

(A) establish, for each fiscal year, human drug application fees and prescription drug program fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(B) publish the fee revenue and fees in the Federal Register.

(7) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of human drug applications.

(d) FEE WAIVER OR REDUCTION.—

(1) IN GENERAL.—The Secretary shall grant to a person that is named as the applicant in a human drug application a waiver from or a reduction of 1 or more fees assessed to that person under subsection (a) if the Secretary finds that—

(A) the waiver or reduction is necessary to protect the public health;

(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to the person or other circumstances; or

(C) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

(2) CONSIDERATIONS.—In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) RULES RELATING TO SMALL BUSINESSES.—

(A) DEFINITION OF SMALL BUSINESS.—In paragraph (1)(C), the term ''small business'' means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce.

(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(C) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted the waiver, the small business or its affiliate shall pay application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

(e) EFFECT OF FAILURE TO PAY FEES.—A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Sec-

retary until all such fees owed by the person have been paid.

(f) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the FDA for the fiscal year (excluding the amount of fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the FDA for fiscal year 1997 (excluding the amount of fees appropriated for the fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in the fiscal year the Secretary may assess the fees, the Secretary may assess and collect the fees, without any modification in the rate, for human drug applications and prescription drug program fees at any time in the fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(3) LIMITATION.—The authorities under section 17906(a)(4)(C) of this title shall include only expenditures for leasing and necessary scientific equipment.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for the fiscal year; and

(ii) shall be available, for each fiscal year, to defray the costs of resources allocated for the process for the review of human drug applications (including the costs for an additional number of full-time equivalent positions in the Department to be engaged in the process for the review of human drug applications), only if the sum of the amounts allocated by the Secretary for the costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with the process for the review of human drug applications, is no less

than the amount allocated for the costs, excluding the costs paid from fees collected under this section, for fiscal year 1997, multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated as described in subparagraph (A)(ii)—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which the costs fell below the level specified in the subparagraph; and

(II) are not more than 5 percent below the level specified in the subparagraph.

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for the

fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c).

(h) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver or reduction under subsection (d), an exemption under subsection (k), or the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall—

(1) not later than 180 days after the fee is due, submit to the Secretary a written request justifying the waiver, reduction, exemption, or return; and

(2) include in the request any legal authorities under which the request is made.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department, for officers, employees, and advisory committees not engaged in the process for the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees engaged in the process for the review of human drug applications.

(k) ORPHAN DRUGS.—

(1) EXEMPTION.—A drug designated under section 13902 of this title for a rare disease or condition and approved under chapter 135 of this title or under section 351 of the Public Health Service Act (42 U.S.C. 262) shall be exempt from prescription drug program fees under this section, if the drug—

(A) meets the public health requirements contained in this subtitle as the requirements are applied to requests for waivers for prescription drug program fees; and

(B) is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue as determined under paragraph (2).

(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that the applicant's gross annual revenues did not exceed $50,000,000 for the last calendar year ending prior to the fiscal year for which the exemption is requested. The certification shall be supported by—

(A) tax returns submitted to the Internal Revenue Service; or

(B) as necessary, other appropriate financial information.

(l) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17908. Reauthorization; reporting requirements**

(a) PERFORMANCE REPORT.—

(1) CONTENT.—

(A) IN GENERAL.—Not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Com-

mittee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning—

(i) the progress of the FDA in achieving the goals identified in the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140) during the fiscal year and the future plans of the FDA for meeting the goals, including the status of the independent assessment described in the letters; and

(ii) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

(I) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

(II) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

(III) the number of standard efficacy supplements filed per fiscal year for each review division;

(IV) the number of priority efficacy supplements filed per fiscal year for each review division;

(V) the number of applications filed for review under accelerated approval per fiscal year for each review division;

(VI) the number of applications filed for review as fast track products per fiscal year for each review division;

(VII) the number of applications filed for orphan-designated products per fiscal year for each review division;

(VIII) the number of breakthrough designations for a fiscal year for each review division; and

(IX) the number of investigational new drug applications submitted per fiscal year, including for each review division.

(B) CONSTRUCTION.—Nothing in subparagraph (A)(ii) shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 10501(10) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5.

(2) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(3) REAL TIME REPORTING.—

(A) IN GENERAL.—Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subchapter, the Secretary shall post the data described in subparagraph (B) on the FDA website for the quarter and on a cumulative basis for the fiscal year, and may remove

duplicative data from the annual performance report under this subsection.

(B) DATA.—The Secretary shall post the following data in accordance with subparagraph (A):

(i) The number and titles of draft and final guidance on topics related to the process for the review of human drug applications, and whether the guidance documents were issued as required by statute or pursuant to a commitment under the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140).

(ii) The number and titles of public meetings held on topics related to the process for the review of human drug applications, and whether the meetings were required by statute or pursuant to a commitment under the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140).

(iii) The number of new drug applications and biological licensing applications approved.

(iv) The number of new drug applications and biological licensing applications filed.

(v) For fiscal years 2023 and 2024, of the meeting requests from sponsors for which the Secretary has determined that a face-to-face meeting is appropriate, the number of face-to-face meetings requested by sponsors to be conducted in person (in such manner as the Secretary shall prescribe on the FDA website), and the number of those in-person meetings granted by the Secretary, with both numbers disaggregated by the relevant agency center.

(4) RATIONALE FOR PDUFA PROGRAM CHANGES.—The Secretary shall include in the annual report under paragraph (1)—

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed on in the letters described in section 1001(b) of the Prescription Drug User Fee

Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140) and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 17907 of this title, and the number of full-time equivalents funded by budget authority at the FDA by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs of resources allocated for the process for the review of human drug applications, including identifying—

(i) drivers of the changes; and

(ii) changes in the average total cost per full-time equivalent in the prescription drug review program;

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time

reporting is required and the number of employees for whom time reporting is not required; and

(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of human drug application.

(5) ANALYSIS.—For each fiscal year, the Secretary shall include in the report under paragraph (1) an analysis of the following:

(A) The difference between the aggregate number of human drug applications filed and the aggregate number of approvals, accounting for—

(i) the applications filed during 1 fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(ii) the aggregate number of applications for each fiscal year that did not meet the goals identified in the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140).

(B) Relevant data to determine whether the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have met performance enhancement goals identified in the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140) for the applicable fiscal year.

(C) The most common causes and trends of external or other circumstances affecting the ability of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, Office of Regulatory Affairs, and the FDA to meet the review time and performance enhancement goals identified in the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140).

(b) FISCAL REPORT.—Not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report

on the implementation of the authority for the fees during the fiscal year and the use, by the FDA, of the fees collected for the fiscal year.

(c) CORRECTIVE ACTION REPORT.—For each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate. The report shall include the following information, as applicable:

(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(5), that each of the goals identified in the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140) for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the human drug application review process.

(2) GOALS MISSED.—For any of the goals identified in the letters described in section 1001(b) of

the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140) for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(A) a detailed justification for the determination and a description, as applicable, of the types of circumstances and trends under which human drug applications that missed the review goal time were approved during the first cycle review, or application review goals were missed; and

(B) with respect to performance enhancement goals that were not achieved, a description of efforts the FDA has put in place for the fiscal year in which the report is submitted to improve the ability of the agency to meet each such goal for the fiscal year.

(d) ENHANCED COMMUNICATION.—

(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of human drugs shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on En-

ergy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and requested, representatives from the FDA shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. The hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter.

(e) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the FDA website.

(f) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2027, and for the reauthorization of this subchapter for the fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this subchapter, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subchapter; and

(D) publish the comments on the FDA website.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subchapter as expressed under paragraph (2).

(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this subchapter to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(5) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in the paragraph;

(B) publish the recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on the recommendations;

(D) hold a meeting at which the public may present its views on the recommendations; and

(E) after consideration of the public views and comments, revise the recommendations as necessary.

(6) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2027, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under the paragraph, and any changes made to the recommendations in response to the views and comments.

(7) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the public FDA website, minutes of all negotiation meetings conducted under this subsection between the FDA and the regulated industry, not later than 30 days after each such negotiation meeting.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize, in sufficient detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(g) REPEAL OF SECTION.—This section is repealed on January 31, 2028.

# Subchapter III—Fees Relating to Devices

### § 17916. Definitions

(a) IN GENERAL.—In this subchapter:

(1) ADJUSTMENT FACTOR .—The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by the Index for October 2021.

(2) AFFILIATE.—The term ''affiliate'' means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly—

(A) 1 business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(3) ANNUAL FEE.—The term ''annual fee'', for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.

(4) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.—The term ''costs of resources allocated for the process for the review of device applications'' means the expenses, in connection with the process for the review of device applications, for—

(A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to the officers, employees, and committees and to contracts with the contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific

equipment, and other necessary materials and supplies; and

(D) collection of fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, submissions, and de novo classification requests.

(5) DE NOVO CLASSIFICATION REQUEST.—The term ''de novo classification request'' means a request made under section 13140(h)(2)(A) of this title with respect to the classification of a device.

(6) ESTABLISHMENT SUBJECT TO A REGISTRATION FEE.—The term ''establishment subject to a registration fee'' means an establishment that is registered (or is required to register) with the Secretary under section 13136 of this title because the establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.

(7) PERSON.—The term ''person'' includes an affiliate of the person.

(8) PREMARKET APPLICATION.—

(A) IN GENERAL.—The term ''premarket application'' means—

(i) an application for approval of a device submitted under section 13142(c) of

this title or section 351 of the Public Health Service Act (42 U.S.C. 262); or

(ii) a product development protocol described in section 13142(f) of this title.

(B) EXCLUSIONS.—The term ''premarket application'' does not include a supplement, a premarket report, or a premarket notification submission.

(9) PREMARKET NOTIFICATION SUBMISSION.—The term ''premarket notification submission'' means a report submitted under section 13136(k) of this title.

(10) PREMARKET REPORT.—The term ''premarket report'' means a report submitted under section 13142(c)(2) of this title.

(11) PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS.—The term ''process for the review of device applications'' means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, premarket notification submissions, and de novo classification requests:

(A) The activities necessary for the review of premarket applications, premarket reports,

supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or that set forth in detail the specific deficiencies in the applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of the applications, reports, supplements, submissions, and de novo classification requests.

(E) Review of device applications subject to section 351 of the Public Health Service Act (42 U.S.C. 262) for an investigational new drug application under section 13510 of this title or for an investigational device exemption under section 13152(g) of this title and activities conducted in anticipation of the submission of the

applications under section 13510 or 13152(g) of this title.

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, premarket notification submissions, and de novo classification requests.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 13141 of this title in connection with the review of the applications, reports, supplements, submissions, or requests and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of the applications, reports, supplements, submissions, or requests.

(I) Any activity undertaken under section 13140 or 13142(i) of this title in connection with the initial classification or reclassification of a device or under section 13142(b) of this title in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 13142 of this title or a premarket application under section 351 of the Public Health Service Act (42 U.S.C. 262).

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, premarket notification submissions, or de novo classification requests.

(12) REQUEST FOR CLASSIFICATION INFORMATION.—The term ''request for classification information'' means a request made under section 13140(i) of this title for information respecting the class in which a device has been classified or the requirements applicable to a device.

(13) SUPPLEMENT.—

(A) IN GENERAL.—The term ''supplement'', with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

(i) an application or report has been approved under section 13142(d) of this title, or an application has been approved under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(ii) a notice of completion has become effective under section 13142(f) of this title.

(B) PANEL-TRACK SUPPLEMENT.—The term ''panel-track supplement'' means a supplement to an approved premarket application or premarket report under section 13142 of this title that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) ONE-HUNDRED-EIGHTY-DAY SUPPLEMENT.—The term ''180-day supplement'' means a supplement to an approved premarket application or premarket report under section 13142 of this title that is not a panel-track supplement and requests a significant change in

components, materials, design, specification, software, color additives, or labeling.

(D) REAL-TIME SUPPLEMENT.—The term ''real-time supplement'' means a supplement to an approved premarket application or premarket report under section 13142 of this title that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) EFFICACY SUPPLEMENT.—The term ''efficacy supplement'' means a supplement to an approved premarket application under section 351 of the Public Health Service Act (42 U.S.C. 262) that requires substantive clinical data.

(14) THIRTY-DAY NOTICE.—The term ''30-day notice'' means a notice under section 13142(d)(5) of this title that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

(b) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17917. Authority to assess and use device fees**

(a) TYPES OF FEES.—

(1) IN GENERAL.—The Secretary shall assess and collect fees in accordance with this section.

(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (d) and (e), each person that submits any of the following shall be subject to a fee established under subsection (c) for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel-track supplement, a fee equal to 80 percent of the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 15 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7 percent of the fee that applies under clause (i).

(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).

(vii) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(viii) For a premarket notification submission, a fee equal to 4.5 percent of the fee that applies under clause (i).

(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).

(xi) For a de novo classification request, a fee equal to 30 percent of the fee that applies under clause (i).

(B) EXCEPTIONS.—

(i) HUMANITARIAN DEVICE EXEMPTION.—An application under section 13152(m) of this title is not subject to any fee under subparagraph (A).

(ii) FURTHER MANUFACTURING USE.—A fee shall not be required under subparagraph (A) for the submission of a premarket application under section 351 of the Public Health Service Act (42 U.S.C. 262) for a product licensed for further manufacturing use only.

(iii) STATE OR FEDERAL GOVERNMENT SPONSORS.—A fee shall not be required under subparagraph (A) for a premarket application, premarket report, supplement, premarket notification submission, or de novo classification request submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

(iv) PREMARKET NOTIFICATIONS BY THIRD PARTIES.—A fee shall not be required under subparagraph (A) for a premarket notification submission reviewed by

an accredited person pursuant to section 13155 of this title.

(v) PEDIATRIC CONDITIONS OF USE.—

(I) IN GENERAL.—A fee shall not be required under subparagraph (A) for a premarket application, premarket report, premarket notification submission, or de novo classification request if the proposed conditions of use for the device involved are solely for a pediatric population. A fee shall not be required under subparagraph (A) for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

(II) SUBSEQUENT PROPOSAL OF ADULT CONDITIONS OF USE.—In the case of a person that submits a premarket application or premarket report for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to the application that proposes conditions of use

for any adult population is subject to the fee that applies under subparagraph (A) for a premarket application.

(C) PAYMENT.—The fee required by subparagraph (A) shall be due on submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, periodic reporting concerning a class III device, or de novo classification request. Applicants submitting portions of applications pursuant to section 13142(c)(4) of this title shall pay the fees on submission of the first portion of the applications.

(D) REFUNDS.—

(i) APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

(ii) APPLICATION WITHDRAWN BEFORE FILING DECISION.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any applica-

tion, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

(iii) APPLICATION WITHDRAWN BEFORE FIRST ACTION.—After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of the refund, if any, shall be based on the level of effort already expended on the review of the application, report, or supplement.

(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 13142(c)(4) of this title that is withdrawn before a second portion is submitted and before a first action on the first portion.

(v) LATER WITHDRAWN MODULAR APPLICATIONS.—If an application submitted under section 13142(c)(4) of this title is

withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

(vi) SOLE DISCRETION TO REFUND.—The Secretary shall have the sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.

(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 13136 of this title.

(B) EXCEPTION.—

(i) IN GENERAL.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal

governmental entity or an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.)), unless a device manufactured by the establishment is to be distributed commercially.

(ii) SMALL BUSINESSES FEE WAIVER.—

(I) DEFINITION OF SMALL BUSINESS.—In this clause, the term ''small business'' means an entity that reported $1,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including the returns of all of its affiliates.

(II) WAIVER.—The Secretary may grant a waiver of the fee required under subparagraph (A) for the annual registration (excluding the initial registration) of an establishment for a year, beginning on October 1, 2024, if the Secretary finds that the establishment is a small business and that paying the fee for the year represents

a financial hardship to the establishment as determined by the Secretary.

(III) FIRMS SUBMITTING TAX RETURNS TO THE INTERNAL REVENUE SERVICE.—

(aa) IN GENERAL.—The establishment shall support its claim that it meets the definition under subclause (I) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of the returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subclause (I).

(bb) CERTIFICATION; TRUE AND ACCURATE COPY.—The establishment, and each of the affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service.

(cc) NO AFFILIATES.—If no tax forms are submitted for any affiliate, the establishment shall certify that the establishment has no affiliates.

(IV) FIRMS NOT SUBMITTING TAX RETURNS TO THE INTERNAL REVENUE SERVICE.—

(aa) IN GENERAL.—In the case of an establishment that has not previously submitted a Federal income tax return, the establishment and each of its affiliates shall demonstrate that it meets the definition under subclause (I) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the establishment or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, if extant, of the country in which the es-

tablishment or, if applicable, affiliate is headquartered.

(bb) CERTIFICATION FROM TAXING AUTHORITY.—The certification from the taxing authority shall bear the official seal of the taxing authority and shall provide the establishment's or affiliate's gross receipts or sales for the most recent year in both the local currency of the country and in United States dollars, the exchange rate used in converting the local currency to dollars, and the dates during which these receipts or sales were collected.

(cc) STATEMENT RELATING TO AFFILIATES.—The establishment shall submit a statement signed by the head of the establishment's firm or by its chief financial officer that the establishment has submitted certifications for all of its affiliates, or that the establishment has no affiliates.

(V) REQUEST FOR WAIVER.—An establishment seeking a fee waiver for a year under this clause shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subparagraph (C). The decision of the Secretary regarding whether an entity may receive the waiver for the year is not reviewable.

(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, on the later of—

(i) the initial or annual registration (as applicable) of the establishment under section 13136 of this title; or

(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for the year under this section.

(b) FEE AMOUNTS.—

(1) IN GENERAL.—Subject to subsections (c), (d), (e), and (h), for each of fiscal years 2023 through 2027, fees under subsection (a) shall be derived from the base fee amounts specified in para-

graph (2), to generate the total revenue amounts specified in paragraph (3).

(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

| Fee Type | Fiscal Year 2023 | Fiscal Year 2024 | Fiscal Year 2025 | Fiscal Year 2026 | Fiscal Year 2027 |
|---|---|---|---|---|---|
| Premarket Application | $425,000 | $435,000 | $445,000 | $455,000 | $470,000 |
| Establishment Registration | $6,250 | $6,875 | $7,100 | $7,575 | $8,465 |

(3) TOTAL REVENUE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

(A) $312,606,000 for fiscal year 2023.

(B) $335,750,000 for fiscal year 2024.

(C) $350,746,400 for fiscal year 2025.

(D) $366,486,300 for fiscal year 2026.

(E) $418,343,000 for fiscal year 2027.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish the fees, and the rationale for any adjustments to the fees, in the Federal Register.

(2) INFLATION ADJUSTMENTS.—

(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—The Secretary shall adjust the total revenue amount specified in subsection (b)(3) for the fiscal year by multiplying the amount by the applicable inflation adjustment under subparagraph (B) for the year.

(B) APPLICABLE INFLATION ADJUSTMENT.—The applicable inflation adjustment is the product of—

(i) the base inflation adjustment under subparagraph (C) for the fiscal year; and

(ii) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding the fiscal year, beginning with fiscal year 2022.

(C) BASE INFLATION ADJUSTMENT.—

(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of 1 plus—

(I) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid

with respect to the positions for the first 3 years of the preceding 4 fiscal years, multiplied by 0.60; and

(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.40.

(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

(I) is less than 1, the adjustment shall be deemed to be equal to 1; or

(II) is greater than 1.04, the adjustment shall be deemed to be equal to 1.04.

(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2023 through 2027, the Secretary shall—

(i) adjust the base fee amounts specified in subsection (b)(2) for the fiscal year by multiplying the amounts by the applicable inflation adjustment under subparagraph (B) for the year; and

(ii) if the Secretary determines necessary, increase (in addition to the adjustment under clause (i)) the base fee amounts, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).

(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years 2023 through 2027, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in the subsection shall be increased, as the Secretary estimates is necessary in order for total fee collections for the fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).

(4) PERFORMANCE IMPROVEMENT ADJUSTMENT.—

(A) GOALS DEFINED.—For purposes of this paragraph, the terms ''Presubmission Written Feedback goal'', ''De Novo Decision goal'', ''510(k) decision goal'', ''510(k) Shared Outcome Total Time to Decision goal'', ''PMA decision goal'', and ''PMA Shared Outcome Total Time to Decision goal'' refer to the goals identified by the same names in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147).

(B) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2) and (3), the base establishment registration fee amounts for the fiscal year shall be increased to reflect changes in the resource needs of the Secretary due to improved review performance goals for the process for the review of device applications identified in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147), as the Secretary determines necessary to achieve an increase in total fee collections for

the fiscal year equal to the following amounts, as applicable:

(i) For fiscal year 2025, the product of—

(I) the amount determined under subparagraph (C)(i)(I); and

(II) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year.

(ii) For fiscal year 2026, the product of—

(I) the sum of the amounts determined under clauses (i)(II), (ii)(I), and (iii)(I) of subparagraph (C); and

(II) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year.

(iii) For fiscal year 2027, the product of—

(I) the sum of the amounts determined under clauses (i)(III), (ii)(II), and (iii)(II) of subparagraph (C); and

(II) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year.

(C) AMOUNTS.—

(i) PRESUBMISSION AMOUNT.—For purposes of subparagraph (B), with respect to the Presubmission Written Feedback goal, the amounts determined under this subparagraph are as follows:

(I) For fiscal year 2025, $15,396,600 if the goal for fiscal year 2023 is met.

(II) For fiscal year 2026:

(aa) $15,396,600 if the goal for fiscal year 2023 is met and the goal for fiscal year 2024 is not met.

(bb) $36,792,200 if the goal for fiscal year 2024 is met.

(III) For fiscal year 2027:

(aa) $15,396,600 if the goal for fiscal year 2023 is met and the goal for each of fiscal years 2024 and 2025 is not met.

(bb) $36,792,200 if the goal for fiscal year 2024 is met and the goal for fiscal year 2025 is not met.

(cc) $40,572,600 if the goal for fiscal year 2025 is met.

(ii) DE NOVO CLASSIFICATION REQUEST AMOUNT.—For purposes of subparagraph (B), with respect to the De Novo Decision goal, the amounts determined under this subparagraph are as follows:

(I) For fiscal year 2026, $6,323,500 if the goal for fiscal year 2023 is met.

(II) For fiscal year 2027:

(aa) $6,323,500 if the goal for fiscal year 2023 is met and the goal for fiscal year 2024 is not met.

(bb) $11,765,400 if the goal for fiscal year 2024 is met.

(iii) PREMARKET NOTIFICATION AND PREMARKET APPROVAL AMOUNT.—For purposes of subparagraph (B), with re-

spect to the 510(k) decision goal, 510(k) Shared Outcome Total Time to Decision goal, PMA decision goal, and PMA Shared Outcome Total Time to Decision goal, the amounts determined under this subparagraph are as follows:

(I) For fiscal year 2026, $1,020,000 if the 4 goals for fiscal year 2023 are met.

(II) For fiscal year 2027:

(aa) $1,020,000 if the 4 goals for fiscal year 2023 are met and 1 or more of the 4 goals for fiscal year 2024 are not met.

(bb) $3,906,000 if the 4 goals for fiscal year 2024 are met.

(D) PERFORMANCE CALCULATION.—For purposes of this paragraph, performance of the following goals shall be determined as specified in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147) and based on data available, as follows:

(i) The performance of the Pre-submission Written Feedback goal shall be based on data available as of—

(I) for fiscal year 2023, March 31, 2024;

(II) for fiscal year 2024, March 31, 2025; and

(III) for fiscal year 2025, March 31, 2026.

(ii) The performance of the De Novo Decision goal, 510(k) decision goal, 510(k) Shared Outcome Total Time to Decision goal, PMA decision goal, and PMA Shared Outcome Total Time to Decision goal shall be based on data available as of—

(I) for fiscal year 2023, March 31, 2025; and

(II) for fiscal year 2024, March 31, 2026.

(5) HIRING ADJUSTMENT.—

(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2), (3), and (4), if applicable, if the number of hires to support the process for the review of device applications falls

below the thresholds specified in subparagraph (B) for the applicable fiscal years, the base establishment registration fee amounts shall be decreased as the Secretary determines necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount under subparagraph (C).

(B) THRESHOLDS.—The thresholds specified in this subparagraph are as follows:

(i) For fiscal year 2025, the threshold is 123 hires for fiscal year 2023.

(ii) For fiscal year 2026, the threshold is 38 hires for fiscal year 2024.

(iii) For fiscal year 2027, the threshold is—

(I) 22 hires for fiscal year 2025 if the base establishment registration fees are not increased by the amount determined under paragraph (4)(B)(i); or

(II) 75 hires for fiscal year 2025 if the base establishment registration fees are increased by the amount determined under paragraph (4)(B)(i).

(C) HIRING ADJUSTMENT AMOUNT.—The hiring adjustment amount for fiscal year 2025 and each subsequent fiscal year is the product of—

(i) the number of hires by which the hiring goal specified in subparagraph (D) for the fiscal year before the prior fiscal year was not met;

(ii) $72,877; and

(iii) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year for which the hiring goal was not met.

(D) HIRING GOALS.—The hiring goals for each of fiscal years 2023 through 2025 are as follows:

(i) For fiscal year 2023, 144 hires.

(ii) For fiscal year 2024, 42 hires.

(iii) For fiscal year 2025:

(I) 24 hires if the base establishment registration fees are not increased by the amount determined under paragraph (4)(B)(i).

(II) 83 hires if the base establishment registration fees are in-

creased by the amount determined under paragraph (4)(B)(i).

(E) NUMBER OF HIRES.—For purposes of this paragraph, the number of hires for a fiscal year shall be determined by the Secretary as set forth in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147).

(6) OPERATING RESERVE ADJUSTMENT.—

(A) IN GENERAL.—For each of fiscal years 2023 through 2027, after the adjustments under paragraphs (2), (3), (4), and (5), if applicable, if the Secretary has operating reserves of carryover user fees for the process for the review of device applications in excess of the designated amount in subparagraph (B), the Secretary shall decrease the base establishment registration fee amounts to provide for not more than the designated amount of operating reserves.

(B) DESIGNATED AMOUNT.—Subject to subparagraph (C), for each fiscal year, the designated amount in this subparagraph is equal to the sum of—

(i) 13 weeks of operating reserves of carryover user fees; and

(ii) 1 month of operating reserves maintained pursuant to paragraph (8).

(C) EXCLUDED AMOUNT.—For the period of fiscal years 2023 through 2026, a total amount equal to $118,000,000 shall not be considered part of the designated amount under subparagraph (B) and shall not be subject to the decrease under subparagraph (A).

(7) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of device applications.

(8) SUPPLEMENT.—

(A) IN GENERAL.—The Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in the fiscal year referred to in paragraph (7), so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of the next fiscal year.

(B) NOTICE TO CONGRESS.—Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—

(1) IN GENERAL.—

(A) DEFINITION OF SMALL BUSINESS.—In this paragraph, the term ''small business'' means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including the returns of all of its affiliates.

(B) FEE WAIVER.—The Secretary shall grant a waiver of the fee required under subsection (a) for 1 premarket application, or 1 premarket report, if the Secretary finds that the applicant involved is a small business submitting its first premarket application to the

Secretary, or its first premarket report, respectively, for review.

(C) FEE REDUCTION.—In addition, if the Secretary finds that, for subsequent premarket applications, premarket reports, and supplements, the applicant involved is a small business, the fees specified in clauses (i) through (vii), (ix), (x), and (xi) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—In this paragraph, the term ''small business'' means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including the returns of all of its affiliates.

(B) EVIDENCE OF QUALIFICATION.—

(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate.

(ii) FIRMS SUBMITTING TAX RETURNS TO THE INTERNAL REVENUE SERVICE.—

(I) IN GENERAL.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of the returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A).

(II) CERTIFICATION OF INFORMATION.—The applicant, and each of the affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE INTERNAL REVENUE SERVICE.—

(I) IN GENERAL.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, if extant, of the country in which the applicant or, if applicable, affiliate is headquartered.

(II) CERTIFICATION REQUIREMENTS.—The certification from the taxing authority shall bear the official seal of the taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of the country and in United States dollars, the exchange rate used in con-

verting the local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) REDUCED FEES.—If the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

(i) 25 percent of the fee established under the subsection for a premarket application, a premarket report, a supplement, periodic reporting concerning a class III device, or a de novo classification request; and

(ii) 50 percent of the fee established under the subsection for a 30-day notice or a request for classification information.

(D) REQUEST FOR FEE WAIVER OR REDUCTION.—

(i) SUBMISSION DEADLINE.—An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a).

(ii) REVIEWABILITY OF DECISION.—The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) DEFINITION OF SMALL BUSINESS.—In this subsection, the term ''small business'' means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including the returns of all of its affiliates.

(2) IN GENERAL.—If the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(viii) may be paid at a reduced rate in accordance with paragraph (3)(B).

(3) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) EVIDENCE OF QUALIFICATION.—

(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

(ii) FIRMS SUBMITTING TAX RETURNS TO THE INTERNAL REVENUE SERVICE.—

(I) IN GENERAL.—The applicant shall support its claim that it meets the definition under paragraph (1) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of the returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in paragraph (1).

(II) CERTIFICATION OF INFORMATION.—The applicant, and each of the affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall

certify that the applicant has no affiliates.

(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE INTERNAL REVENUE SERVICE.—

(I) IN GENERAL.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under paragraph (1) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, if extant, of the country in which the applicant or, if applicable, affiliate is headquartered.

(II) CERTIFICATION REQUIREMENTS.—The certification from the taxing authority shall bear the official seal of the taxing authority and shall

provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of the country and in United States dollars, the exchange rate used in converting the local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(B) REDUCED FEES.—If the Secretary finds that the applicant involved meets the definition under paragraph (1), the fee for a premarket notification submission may be paid at 25 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).

(C) REQUEST FOR REDUCTION.—

(i) SUBMISSION DEADLINE.—An applicant seeking a fee reduction under this subsection shall submit supporting infor-

mation to the Secretary at least 60 days before the fee is required pursuant to subsection (a).

(ii) REVIEWABILITY OF DECISION.—The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

(f) EFFECT OF FAILURE TO PAY FEES.—

(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, periodic reporting concerning a class III device, or de novo classification request submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all the fees owed by the person have been paid.

(2) NO REGISTRATION.—Registration information submitted under section 13136 of this title by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is

complete, the establishment is deemed to have failed to register in accordance with section 13136 of this title.

(g) CONDITIONS.—

(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the FDA, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $398,566,000 multiplied by the adjustment factor applicable to the fiscal year; or

(B) fees were not assessed under subsection (a) for the previous fiscal year.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in the fiscal year the Secretary may assess the fees, the Secretary may assess and collect the

fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, de novo classification requests, and establishment registrations at any time in the fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(3) LIMITATION.—The authorities under section 17916(a)(4)(C) of this title shall include only leasing and necessary scientific equipment.

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts.

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to be appropriated to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA

salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for the fiscal year; and

(ii) shall be available, for each fiscal year, to defray the costs of resources allocated for the process for the review of device applications (including the costs for an additional number of full-time equivalent positions in the Department to be engaged in the process for the review of device applications), only if the sum of the amounts allocated by the Secretary for the costs, excluding costs paid from fees collected

under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture and other necessary materials and supplies in connection with the process for the review of device applications, is no less than the amount allocated for the costs, excluding the costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

(B) COMPLIANCE.—

(i) IN GENERAL.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated as described in subparagraph (A)(ii)—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased

by the amount in excess of 3 percent by which the costs fell below the level specified in the subparagraph; and

(bb) are not more than 5 percent below the level specified in subparagraph (A)(ii).

(ii) MORE THAN 5 PERCENT.—To the extent the costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for the fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—

(A) IN GENERAL.—For each of fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the revenue amount determined under subparagraph (B), less the amount of reductions determined under subparagraph (C).

(B) REVENUE AMOUNT.—For purposes of this paragraph, the revenue amount for each fiscal year is the sum of—

(i) the total revenue amount under subsection (b)(3) for the fiscal year, as adjusted under paragraphs (2) and (3) of subsection (c); and

(ii) the performance improvement adjustment amount for the fiscal year under subsection (c)(4), if applicable.

(C) AMOUNT OF REDUCTIONS.—For purposes of this paragraph, the amount of reductions for each fiscal year is the sum of—

(i) the hiring adjustment amount for the fiscal year under subsection (c)(5), if applicable; and

(ii) the operating reserve adjustment amount for the fiscal year under subsection (c)(6), if applicable.

(i) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(j) WRITTEN REQUESTS FOR REFUNDS.—To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the Secretary a written request for the refund not later than 180 days after the fee is due.

(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department, for officers, employees, and advisory committees not engaged in the process for the review of device applications, be reduced to offset the number of officers, employees, and advisory committees engaged in the process for the review of device applications.

(l) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17918. Reauthorization; reporting requirements**

(a) REPORTS.—

(1) PERFORMANCE REPORT.—

(A) IN GENERAL.—

(i) GENERAL REQUIREMENTS.—For each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Represent-

atives annual reports concerning the progress of the FDA in achieving the goals identified in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147) during the fiscal year and the future plans of the FDA for meeting the goals.

(ii) ADDITIONAL INFORMATION.—

(I) IN GENERAL.—The annual report under this subparagraph shall include the progress of the Center for Devices and Radiological Health in achieving the goals, and future plans for meeting the goals, including—

(aa) the number of premarket applications filed under section 13142 of this title per fiscal year for each review division;

(bb) the number of reports submitted under section 13136(k) of this title per fiscal year for each review division;

(cc) the number of expedited development and priority review

designations under section 13144 of this title per fiscal year;

(dd) the number of investigational device exemption applications submitted under section 13152(g) of this title per fiscal year, including for each review division; and

(ee) the number of expedited development and priority review requests and designations under section 13144 of this title per fiscal year, including for each review division.

(II) CONSTRUCTION.—Nothing in this clause shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 10501(10) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5.

(iii) REAL TIME REPORTING.—

(I) IN GENERAL.—Not later than 30 calendar days after the end of the

second quarter of fiscal year 2023, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the FDA website for the quarter and on a cumulative basis for the fiscal year, and may remove duplicative data from the annual report under this subparagraph.

(II) DATA.—The Secretary shall post the following data in accordance with subclause (I):

(aa) The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether the guidance documents were issued as required by statute or pursuant to the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147).

(bb) The number and titles of public meetings held on topics related to the process for the review of devices, and if the meetings were required by statute or pursuant to a commitment under the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147).

(iv) RATIONALE FOR MDUFA PROGRAM CHANGES.—The Secretary shall include in the annual report under clause (i)—

(I) data, analysis, and discussion of the changes in the number of individuals hired as agreed on in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147) and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to

section 17917 of this title, and the number of full time equivalents funded by budget authority at the FDA by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs of resources allocated for the process for the review of device applications, including identifying—

(aa) drivers of the changes; and

(bb) changes in the average total cost per full-time equivalent in the medical device review program;

(III) for each of the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Af-

fairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required; and

(IV) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of medical device application types.

(v) ANALYSIS.—For each fiscal year, the Secretary shall include in the report under clause (i) an analysis of the following:

(I) The difference between the aggregate number of premarket applications filed under section 13142 of this title and aggregate reports submitted under section 13136(k) of this title and the aggregate number of major deficiency letters, non-approvable letters, and denials for the applications issued by the agency, accounting for—

(aa) the number of applications filed and reports submitted during 1 fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147) for the applicable fiscal year.

(II) Relevant data to determine whether the Center for Devices and Radiological Health has met performance enhancement goals identified by the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136

Stat. 2147) for the applicable fiscal year.

(III) The most common causes and trends for external or other circumstances affecting the ability of the Center for Devices and Radiological Health, the Office of Regulatory Affairs, or the FDA to meet review time and performance enhancement goals identified by the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147).

(B) PUBLICATION.—With regard to information to be reported by the FDA to industry on a quarterly and annual basis pursuant to the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147), the Secretary shall make the information publicly available on the FDA website not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which the information applies.

This information shall include the status of the independent assessment identified in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147).

(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) CORRECTIVE ACTION REPORT.—For each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate. The report shall include the following information, as applicable:

(A) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under paragraph (1)(A)(v), that each of the

goals identified by the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147) for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the medical device application review process.

(B) GOALS MISSED.—For each of the goals identified by the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147) for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(i) a justification for the determination;

(ii) a description of the types of circumstances, in the aggregate, under which applications or reports submitted under section 13142 of this title or notifications submitted under section 13136(k) of this title missed the review goal times but were

approved during the first cycle review, as applicable;

(iii) a summary and any trends with regard to the circumstances for which a review goal was missed; and

(iv) the performance enhancement goals that were not achieved during the previous fiscal year and a description of efforts the FDA has put in place for the fiscal year in which the report is submitted to improve the ability of the agency to meet each of those goals for the fiscal year.

(3) ENHANCED COMMUNICATION.—

(A) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of devices shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

(B) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and

requested, representatives from the FDA shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. The hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter.

(4) FISCAL REPORT.—For fiscal years 2023 through 2027, not later than 120 days after the end of each fiscal year during which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for the fees during the fiscal year and the use, by the FDA, of the fees collected during the fiscal year for which the report is made.

(5) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the FDA website.

(b) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2027, and for the reauthorization of this subchapter for the fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this subchapter, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthoriza-

tion, including specific suggestions for changes to the goals referred to in subsection (a)(1);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subchapter; and

(D) publish the comments on the FDA website.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subchapter as expressed under paragraph (2).

(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this subchapter to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(5) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in paragraph (1);

(B) publish the recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on the recommendations;

(D) hold a meeting at which the public may present its views on the recommendations; and

(E) after consideration of the public views and comments, revise the recommendations as necessary.

(6) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2027, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under paragraph (4), and any changes made to the recommendations in response to the views and comments.

(7) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the public FDA website, minutes of all negotiation meetings conducted under this subsection between the FDA and the regulated industry, not later than 30 days after each such negotiation meeting.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize, in sufficient detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(c) REPEAL OF SECTION.—This section is repealed on January 31, 2028.

# Subchapter IV—Fees Relating to Animal Drugs

### § 17926. Definitions

(a) IN GENERAL.—For purposes of this subchapter:

(1) ADJUSTMENT FACTOR.—The term ''adjustment factor'' applicable to a fiscal year refers to the formula set forth in section 17906(a)(2) of this title with the base or comparator month being October 2002.

(2) AFFILIATE.—The term ''affiliate'' has the meaning given the term in section 17906(a) of this title.

(3) ANIMAL DRUG APPLICATION.—

(A) IN GENERAL.—The term ''animal drug application'' means—

(i) an application for approval of any new animal drug submitted under section 13703(a) of this title; or

(ii) an application for conditional approval of a new animal drug submitted under section 14502 of this title.

(B) EXCLUSION.—The term ''animal drug application'' does not include a new animal drug application submitted under section 13703(b) of this title or a supplemental animal drug application.

(4) ANIMAL DRUG ESTABLISHMENT.—The term ''animal drug establishment'' means a foreign or domestic place of business that is at 1 general physical location consisting of 1 or more buildings all of which are within 5 miles of each other, at which 1 or more animal drug products are manufactured in final dosage form.

(5) ANIMAL DRUG PRODUCT.—The term ''animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an animal drug application or a supplemental animal drug application has been approved.

(6) ANIMAL DRUG SPONSOR.—The term ''animal drug sponsor'' means an applicant named in an animal drug application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person that has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

(7) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS.—The term ''costs of resources allocated for the process for the review of animal drug applications'' means the expenses, in connection with the process for the review of animal drug applications, for—

(A) officers and employees of the FDA, contractors of the FDA, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to the officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

(B) management of information and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collection of fees under section 17927 of this title and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(8) FINAL DOSAGE FORM.—

(A) IN GENERAL.—The term ''final dosage form'' means, with respect to an animal drug

product, a finished dosage form that is approved for administration to an animal without substantial further manufacturing.

(B) INCLUSION.—The term ''final dosage form'' includes animal drug products intended for mixing in animal feeds.

(9) INVESTIGATIONAL ANIMAL DRUG SUBMISSION.—The term ''investigational animal drug submission'' means—

(A) the filing of a claim for an investigational exemption under section 13711 of this title for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application; or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

(10) PERSON.—The term ''person'' includes an affiliate of the person.

(11) PROCESS FOR THE REVIEW OF ANIMAL DRUG APPLICATIONS.—The term ''process for the review of animal drug applications'' means the following activities of the Secretary with respect to the

review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(B) The issuance of action letters that approve animal drug applications or supplemental animal drug applications or that set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place the applications, supplements or submissions in condition for approval.

(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applica-

tions, and investigational animal drug submissions.

(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not after the application has been approved.

(I) The activities necessary for implementation of the United States and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the United States and United Kingdom Mutual Recognition Agreement Sectoral Annex for Pharmaceutical Good Manufacturing Practices, and other mutual recognition agreements, with respect to animal drug products subject to review, including implementation

activities prior to and following product approval.

(12) SUPPLEMENTAL ANIMAL DRUG APPLICATION.—The term ''supplemental animal drug application'' means—

(A) a request to the Secretary to approve a change in an animal drug application that has been approved; or

(B) a request to the Secretary to approve a change to an application approved under section 13704(b) of this title for which data with respect to safety or effectiveness are required.

(b) REPEAL OF SECTION.—This section is repealed on October 1, 2028.

**§ 17927. Authority to assess and use animal drug fees**

(a) TYPES OF FEES.—The Secretary shall assess and collect fees in accordance with this section as follows:

(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (c) for an animal drug application, except an

animal drug application subject to the criteria set forth in section 13705(d) of this title.

(ii) A fee established in subsection (c), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

(I) a supplemental animal drug application for which safety or effectiveness data are required;

(II) an animal drug application subject to the criteria set forth in section 13705(d) of this title; and

(III) an application for conditional approval under section 14502 of this title of a new animal drug for which an animal drug application submitted under section 13703(a) of this title has been previously approved under section 13705(a) of this title for another intended use.

(B) PAYMENT.—The fee required by subparagraph (A) shall be due on submission of the animal drug application or supplemental animal drug application.

(C) EXCEPTIONS FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—

(i) IN GENERAL.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for the application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(ii) PREVIOUSLY SUBMITTED APPLICATION FOR CONDITIONAL APPROVAL.—In the case of an animal drug application submitted by a person under section 13703(a) of this title, where the person (or the person's licensor, assignor, or predecessor-in-interest) previously submitted an application for conditional approval under section 14502 of this title for the same product and paid the applicable fee under subparagraph (A), the application under section

13703(a) of this title shall not be subject to a fee under subparagraph (A) if submitted within the timeframe specified in section 14502(i) of this title.

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application that is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—

(i) IN GENERAL.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed.

(ii) SOLE DISCRETION.—The Secretary shall have the sole discretion to refund the fee under this paragraph.

(iii) REVIEWABILITY.—A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) ANIMAL DRUG PRODUCT FEE.—

(A) IN GENERAL.—

(i) PERSON.—A person described in this clause is a person—

(I) that is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product that has been submitted for listing under section 13136 of this title; and

(II) that, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application.

(ii) REQUIREMENT TO PAY ANNUAL FEE.—Each person described in clause (i) shall pay for each such animal drug product the annual fee established in subsection (c).

(B) PAYMENT; FEE DUE DATE.—The fee under subparagraph (A) shall be payable for

the fiscal year in which the animal drug product is first submitted for listing under section 13136 of this title, or is submitted for relisting under section 13136 of this title if the animal drug product has been withdrawn from listing and relisted. After the fee is paid for that fiscal year, the fee shall be due each subsequent fiscal year that the product remains listed, on the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—The fee under subparagraph (A) shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

(3) ANIMAL DRUG ESTABLISHMENT FEE.—

(A) IN GENERAL.—

(i) PERSON.—A person described in this clause is a person—

(I) that owns or operates, directly or through an affiliate, an animal drug establishment;

(II) that is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product that has been submitted for listing under section 13136 of this title; and

(III) that, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application.

(ii) REQUIREMENT TO PAY ANNUAL FEE.—Each person described in clause (i) shall be assessed an annual establishment fee as established in subsection (c) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application.

(B) PAYMENT; FEE DUE DATE.—The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under

paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee under this paragraph for a fiscal year shall be due on the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—An establishment shall be assessed only 1 fee per fiscal year under this section.

(4) ANIMAL DRUG SPONSOR FEE.—

(A) IN GENERAL.—A person shall be assessed an annual sponsor fee as established under subsection (c) if the person—

(i) meets the definition of an animal drug sponsor within a fiscal year; and

(ii) after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal

drug application, or an investigational animal drug submission.

(B) PAYMENT; FEE DUE DATE.—The fee under this paragraph for a fiscal year shall be due on the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—Each animal drug sponsor shall pay only 1 fee each fiscal year under this paragraph.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g), for each of fiscal years 2024 through 2028, the fees required under subsection (a) shall be established to generate a total revenue amount of $33,500,000.

(2) TYPES OF FEES.—Of the total revenue amount established for a fiscal year under paragraph (1)—

(A) 20 percent shall be derived from fees under subsection (a)(1);

(B) 27 percent shall be derived from fees under subsection (a)(2);

(C) 26 percent shall be derived from fees under subsection (a)(3); and

(D) 27 percent shall be derived from fees under subsection (a)(4).

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) ANNUAL FEE SETTING.—Not later than 60 days before the start of each fiscal year beginning after September 30, 2023, the Secretary shall—

(A) establish for that fiscal year animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(B) publish the fee revenue amounts and fees in the Federal Register.

(2) INFLATION ADJUSTMENT.—

(A) IN GENERAL.—For fiscal year 2025 and subsequent fiscal years, the revenue amounts established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by

multiplying the revenue amounts by an amount equal to the sum of—

(i) 1;

(ii) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to the positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total FDA costs for the first 3 years of the preceding 4 fiscal years for which data are available; and

(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total FDA costs for the first 3 years of

the preceding 4 fiscal years for which data are available.

(B) COMPOUNDED BASIS.—The adjustment made each fiscal year after fiscal year 2025 under this paragraph shall be applied on a compounded basis to the revenue amount calculated under this paragraph for the most recent previous fiscal year.

(3) WORKLOAD ADJUSTMENTS.—

(A) IN GENERAL.—For fiscal year 2025 and subsequent fiscal years, after the fee revenue amounts established under subsection (b) are adjusted for inflation in accordance with paragraph (2), the fee revenue amounts shall be further adjusted for the fiscal year to reflect changes in the workload of the Secretary for the process for the review of animal drug applications, subject to subparagraph (B). With respect to the adjustment—

(i) the adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are

required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary;

(ii) the adjustment shall be made for each fiscal year that the adjustment determined by the Secretary is greater than 3 percent, except for the first fiscal year that the adjustment is greater than 3 percent; and

(iii) the Secretary shall publish, in the Federal Register notice under paragraph (1), the amount of the adjustment and the supporting methodologies.

(B) RULE OF APPLICATION.—The workload adjustments under this paragraph shall not result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established under subsection (b), as adjusted for inflation under paragraph (2).

(4) OPERATING RESERVE ADJUSTMENT.—

(A) IN GENERAL.—For fiscal year 2025 and each subsequent fiscal year, after the fee revenue amount established under subsection

(b) is adjusted in accordance with paragraphs (2) and (3), the Secretary shall—

(i) increase the fee revenue amount for the fiscal year, if necessary to provide an operating reserve of not less than 12 weeks; or

(ii) if the Secretary has an operating reserve in excess of the number of weeks specified in subparagraph (C) for that fiscal year, the Secretary shall decrease the fee revenue amount to provide not more than the number of weeks specified in subparagraph (C) for that fiscal year.

(B) CARRYOVER USER FEES.—For purposes of this paragraph, the operating reserve of carryover user fees for the process for the review of animal drug applications does not include carryover user fees that have not been appropriated.

(C) NUMBER OF WEEKS OF OPERATING RESERVES.—The number of weeks of operating reserves specified in this subparagraph is—

(i) 22 weeks for fiscal year 2025;

(ii) 20 weeks for fiscal year 2026;

(iii) 18 weeks for fiscal year 2027; and

(iv) 16 weeks for fiscal year 2028.

(D) PUBLICATION.—If an adjustment to the operating reserve is made under this paragraph, the Secretary shall publish, in the Federal Register notice under paragraph (1), the rationale for the amount of the adjustment and the supporting methodologies.

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of animal drug applications.

(d) FEE WAIVER OR REDUCTION; EXEMPTIONS FROM FEES.—

(1) DEFINITION OF SMALL BUSINESS.—In this subsection, the term ''small business'' means an entity that has fewer than 500 employees, including employees of affiliates.

(2) WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) if the Secretary finds that—

(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to the person or other circumstances;

(B) the fees to be paid by the person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for the person;

(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds; or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation));

(D) the animal drug application or supplemental animal drug application is intended sole-

ly to provide for a minor use or minor species indication; or

(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

(3) USE OF STANDARD COSTS.—In making the finding in paragraph (2)(B), the Secretary may use standard costs.

(4) RULES FOR SMALL BUSINESSES.—

(A) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (2)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted the waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

(B) CERTIFICATION.—The Secretary shall require any person that applies for a waiver under paragraph (2)(E) to certify their quali-

fication for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making the certifications.

(5) EXEMPTION FROM FEES.—Fees under paragraphs (2), (3), and (4) of subsection (a) shall not apply with respect to any person that is the named applicant or sponsor of an animal drug application, supplemental animal drug application, or investigational animal drug submission if the application or submission involves the intentional genomic alteration of an animal that is intended to produce a drug, device, or biological product subject to fees under section 17907, 17917, 17952, or 17962 of this title.

(e) EFFECT OF FAILURE TO PAY FEES.—

(1) ANIMAL DRUG APPLICATION; SUPPLEMENTAL ANIMAL DRUG APPLICATION.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by the person have been paid.

(2) INVESTIGATIONAL ANIMAL DRUG SUBMISSION.—An investigational animal drug submission under section 17926(9)(B) of this title that is sub-

mitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by the person have been paid.

(3) DISCONTINUANCE OF REVIEW.—The Secretary may discontinue review of any animal drug application, supplemental animal drug application, or investigational animal drug submission from a person if the person has not submitted for payment all fees owed under this section by 30 days after the date on which they are due.

(f) ASSESSMENT OF FEES.—

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year unless appropriations for salaries and expenses of the FDA for the fiscal year (excluding the amount of fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the FDA for fiscal year 2003 (excluding the amount of fees appropriated for the fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a

later date in the fiscal year the Secretary may assess the fees, the Secretary may assess and collect the fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments, and animal drug products at any time in the fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to be appropriated to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salary and expenses with fiscal

year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for the fiscal year; and

(ii) shall be available to defray increases in the costs of resources allocated for the process for the review of animal drug applications (including increases in the costs for an additional number of full-time equivalent positions in the Department to be engaged in the process for the review of animal drug applications) to the extent that those costs exceed the costs (excluding costs paid from fees collected under this section) for fiscal year 2003 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which the costs fell below the level specified in subparagraph (A)(ii); and

(II) are not more than 5 percent below the level specified in subparagraph (A)(ii).

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for the fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2024 through 2028, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount established under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c).

(4) EXCESS COLLECTIONS.—If the sum total of fees collected under this section for a fiscal year exceeds the amount of fees authorized to be appropriated for the fiscal year under paragraph (3), the excess collections shall be credited to the appropriations account of the FDA as provided in paragraph (1).

(h) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for

the waiver, reduction, or refund not later than 180 days after the fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department, for officers, employees, and advisory committees not engaged in the process for the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees engaged in the process for the review of animal drug applications.

(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications; and

(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.

(l) REPEAL OF SECTION.—This section is repealed on October 1, 2028.

**§ 17928. Reauthorization; reporting requirements**

(a) PERFORMANCE REPORT.—Beginning with fiscal year 2024, not later than 120 days after the end of each

fiscal year during which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the FDA in achieving the goals identified in the letters described in section 2301(b) of the Animal Drug User Fee Amendments of 2023 (Public Law 118–15, div. B, title III, subtitle A, chapter 1, 137 Stat. 86) toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during the fiscal year, the future plans of the FDA for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the FDA to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

(b) FISCAL REPORT.—Beginning with fiscal year 2024, not later than 120 days after the end of each fiscal year during which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the

House of Representatives a report on the implementation of the authority for the fees during the fiscal year and the use, by the FDA, of the fees collected during the fiscal year for which the report is made.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the FDA website.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of animal drug applications for the first 5 fiscal years after fiscal year 2028, and for the reauthorization of this subchapter for the fiscal years, the Secretary shall consult with—

(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

(B) the Committee on Energy and Commerce of the House of Representatives;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this subchapter, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subchapter; and

(D) publish the comments on the FDA website.

(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subchapter as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in the paragraph;

(B) publish the recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on the recommendations;

(D) hold a meeting at which the public may present its views on the recommendations; and

(E) after consideration of the public views and comments, revise the recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2028, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under the paragraph, and any changes made to the recommendations in response to the views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the FDA website, minutes of all negotiation meetings conducted under this subsection between the FDA and the regulated industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(e) REPEAL OF SECTION.—This section is repealed on January 31, 2029.

# Subchapter V—Fees Relating to Generic New Animal Drugs

## § 17936. Definitions

(a) IN GENERAL.—In this subchapter:

(1) ABBREVIATED APPLICATION.—

(A) IN GENERAL.—The term ''abbreviated application'' means an abbreviated application for the approval of any generic new animal drug submitted under section 13703(b) of this title.

(B) EXCLUSION.—The term ''abbreviated application'' does not include a supplemental abbreviated application.

(2) ADJUSTMENT FACTOR.—The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by—

(A) for purposes of section 17937(f)(1) of this title, the Index for October 2002; and

(B) for purposes of section 17937(g)(2)(A)(ii) of this title, the Index for October 2007.

(3) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS.—The term ''costs of resources allocated for the process for the review of abbreviated applications'' means the expenses, in connection with the process for the review of abbreviated applications, for—

(A) officers and employees of the FDA, contractors of the FDA, advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submis-

sions, and costs related to the officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collection of fees under section 17937 of this title and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(4) FINAL DOSAGE FORM.—

(A) IN GENERAL.—The term ''final dosage form'' means, with respect to a generic new animal drug product, a finished dosage form that is approved for administration to an animal without substantial further manufacturing.

(B) INCLUSION.—The term ''final dosage form'' includes generic new animal drug products intended for mixing in animal feeds.

(5) GENERIC NEW ANIMAL DRUG.—The term ''generic new animal drug'' means a new animal drug that is the subject of an abbreviated application.

(6) GENERIC NEW ANIMAL DRUG PRODUCT.—The term ''generic new animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application or a supplemental abbreviated application has been approved.

(7) GENERIC NEW ANIMAL DRUG SPONSOR.—The term ''generic new animal drug sponsor'' means either an applicant named in an abbreviated application that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary, or a person that has submitted an investigational submission that has not been termi-

nated or otherwise rendered inactive by the Secretary.

(8) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG MEETING REQUEST.—The term ''generic investigational new animal drug meeting request'' means a request submitted by a generic new animal drug sponsor to meet with the Secretary to discuss an investigational submission for a generic new animal drug.

(9) INVESTIGATIONAL SUBMISSION.—The term ''investigational submission'' means—

(A) the filing of a claim for an investigational exemption under section 13711 of this title for a generic new animal drug intended to be the subject of an abbreviated application or a supplemental abbreviated application; or

(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of a generic new animal drug in the event of the filing of an abbreviated application or supplemental abbreviated application for the drug.

(10) PERSON.—The term ''person'' includes an affiliate of the person (as the term is defined in section 17906(a) of this title).

(11) PROCESS FOR THE REVIEW OF ABBREVIATED APPLICATIONS.—The term ''process for the review of abbreviated applications'' means the following activities of the Secretary with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

(A) The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(B) The issuance of action letters that approve abbreviated applications or supplemental abbreviated applications or that set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place the abbreviated applications, supplemental abbreviated applications, or investigational submissions in condition for approval.

(C) The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental ab-

breviated applications, and investigational submissions.

(D) Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(E) The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

(F) Development of standards for products subject to review.

(G) Meetings between the agency and the generic new animal drug sponsor.

(H) Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after the application has been approved.

(I) The activities necessary for exploration and implementation of the United States and European Union Mutual Recognition Agreement for Pharmaceutical Good Manufacturing Practice Inspections, and the United States and United Kingdom Mutual Recognition Agreement Sectoral Annex for Pharmaceutical Good

Manufacturing Practices, and other mutual recognition agreements, with respect to generic new animal drug products subject to review, including implementation activities prior to and following product approval.

(12) REQUEST TO ESTABLISH A GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—The term ″request to establish a generic investigational new animal drug file″ means the submission to the Secretary of a request to establish a generic investigational new animal drug file to contain investigational submissions for a generic new animal drug.

(13) SUPPLEMENTAL ABBREVIATED APPLICATION.—The term ''supplemental abbreviated application'' means a request to the Secretary to approve a change in an approved abbreviated application.

(b) REPEAL OF SECTION.—This section is repealed on October 1, 2028.

**§ 17937. Authority to assess and use generic new animal drug fees**

(a) TYPES OF FEES.—The Secretary shall assess and collect fees in accordance with this section as follows:

(1) ABBREVIATED APPLICATION FEE.—

(A) IN GENERAL.—Each person that submits an abbreviated application shall be subject

to a fee as established in subsection (c) for such an application.

(B) PAYMENT.—The fee required by subparagraph (A) shall be due on submission of the abbreviated application.

(C) EXCEPTIONS.—

(i) PREVIOUSLY FILED APPLICATION.—If an abbreviated application was submitted by a person that paid the fee for the abbreviated application, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an abbreviated application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(ii) CERTAIN ABBREVIATED APPLICATIONS INVOLVING COMBINATION ANIMAL DRUGS.—An abbreviated application subject to the criteria in section 13705(d) of this title shall be subject to a fee equal to 50 percent of the amount of the abbreviated application fee established in subsection (c).

(D) REFUND OF FEE IF ABBREVIATED APPLICATION IS REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any abbreviated application that is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—

(i) IN GENERAL.—If an abbreviated application is withdrawn after the abbreviated application was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the abbreviated application after the abbreviated application was filed.

(ii) SOLE DISCRETION.—The Secretary shall have the sole discretion to refund the fee under this subparagraph.

(iii) REVIEWABILITY.—A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

(2) GENERIC NEW ANIMAL DRUG PRODUCT FEE.—

(A) IN GENERAL.—A person shall pay the annual fee established in subsection (c) for each generic new animal drug product for which an abbreviated application or supplemental abbreviated application has been submitted for listing under section 13136 of this title if the person—

(i) is named as the applicant in the abbreviated application or supplemental abbreviated application for the generic new animal drug product; and

(ii) after September 1, 2008, had pending before the Secretary an abbreviated application or supplemental abbreviated application.

(B) PAYMENT; FEE DUE DATE.—The fee under subparagraph (A) shall be payable for the fiscal year in which the generic new animal drug product is first submitted for listing under section 13136 of this title, or is submitted for relisting under section 13136 of this title if the generic new animal drug product has been withdrawn from listing and relisted. After the fee is paid for that fiscal year, the fee shall be due each subsequent fiscal year that the product remains listed, on the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—The fee under subparagraph (A) shall be paid only once for each generic new animal drug product for a fiscal year in which the fee is payable.

(3) GENERIC NEW ANIMAL DRUG SPONSOR FEE.—

(A) IN GENERAL.—A person shall be assessed an annual generic new animal drug sponsor fee as established under subsection (c) if the person—

(i) meets the definition of a generic new animal drug sponsor within a fiscal year; and

(ii) after September 1, 2008, had pending before the Secretary an abbreviated application, a supplemental abbreviated application, or an investigational submission.

(B) PAYMENT; FEE DUE DATE.—The fee under subparagraph (A) shall be due each fiscal year on the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section; or

(ii) January 31 of each year.

(C) AMOUNT OF FEE.—Each generic new animal drug sponsor shall pay the fee under subparagraph (A) only once per year, as follows:

(i) One hundred percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 6 approved abbreviated applications.

(ii) Seventy-five percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

(iii) Fifty percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c) for an applicant with 1 or fewer approved abbreviated applications.

(4) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE FEE.—

(A) IN GENERAL.—

(i) NEW FILE REQUEST.—Each person that submits a request to establish a generic investigational new animal drug file on or after October 1, 2023, shall be assessed a fee as established under subsection (c).

(ii) NEW SUBMISSION TO ESTABLISHED FILE.—Each person that makes a submission to a generic investigational new animal drug file on or after October 1, 2023, where the file was established prior to October 1, 2023, shall be assessed a fee for the first submission on or after October 1, 2023, as established under subsection (c).

(B) PAYMENT.—

(i) NEW FILE REQUEST.—The fee required by subparagraph (A)(i) shall be due on submission of the request to establish the generic investigational new animal drug file.

(ii) NEW SUBMISSION TO ESTABLISHED FILE.—The fee required by subparagraph (A)(ii) shall be due on the first submission to the generic investigational new animal drug file.

(C) EXCEPTIONS.—

(i) TERMINATING AN EXISTING GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—If a person makes a submission to the generic investigational new animal drug file to terminate that file, the person shall not be subject to a fee under subparagraph (A)(ii) for that submission.

(ii) TRANSFERRING AN EXISTING GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—If a person makes a submission to the generic investigational new animal drug file to transfer that file to a different generic new animal drug sponsor, the person shall not be subject to a fee

under subparagraph (A)(ii) for that submission.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g), for each of fiscal years 2024 through 2028, the fees required under subsection (a) shall be established to generate a total revenue amount of $25,000,000.

(2) TYPES OF FEES.—Of the total revenue amount established for a fiscal year under paragraph (1)—

(A) 20 percent shall be derived from fees under subsection (a)(1) and fees under subsection (a)(4);

(B) 40 percent shall be derived from fees under subsection (a)(2); and

(C) 40 percent shall be derived from fees under subsection (a)(3).

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) ANNUAL FEE SETTING.—The Secretary shall establish, not later than 60 days before the start of each fiscal year, for that fiscal year—

(A) abbreviated application fees that are based on the revenue amounts established under subsection (b), the adjustments provided

under this subsection, and the amount of fees anticipated to be collected under subsection (a)(4) during that fiscal year;

(B) generic new animal drug sponsor fees, and generic new animal drug product fees, based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(C) a generic investigational new animal drug file fee of $50,000 for each request or submission described in subsection (a)(4)(A).

(2) INFLATION ADJUSTMENT.—

(A) IN GENERAL.—For fiscal year 2025 and subsequent fiscal years, the revenue amounts established under subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by multiplying the revenue amounts by an amount equal to the sum of—

(i) 1;

(ii) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to the positions for the first 3 of the pre-

ceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total FDA costs for the first 3 of the preceding 4 fiscal years for which data are available; and

(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total FDA costs for the first 3 of the preceding 4 fiscal years for which data are available.

(B) COMPOUNDED BASIS.—The adjustment made each fiscal year after fiscal year 2025 under this paragraph shall be applied on a compounded basis to the revenue amount calculated under this paragraph for the most recent previous fiscal year.

(3) WORKLOAD ADJUSTMENTS.—

(A) IN GENERAL.—For fiscal year 2025 and subsequent fiscal years, after the fee revenue amounts established under subsection (b) are adjusted for inflation in accordance with paragraph (2), the fee revenue amounts shall be further adjusted for each such fiscal year to reflect changes in the workload of the Secretary for the process for the review of abbreviated applications, subject to subparagraphs (B) and (C). With respect to the adjustment—

(i) this adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of abbreviated applications, manufacturing supplemental abbreviated applications, investigational generic new animal drug study submissions, investigational generic new animal drug protocol submissions, requests to establish a generic investigational new animal drug file, and generic investigational new animal drug meeting requests submitted to the Secretary;

(ii) if the workload adjustment calculated by the Secretary under clause (i) exceeds 25 percent, the Secretary shall use 25 percent for the adjustment; and

(iii) the Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

(B) REDUCTION OF WORKLOAD-BASED INCREASE BY AMOUNT OF CERTAIN EXCESS COLLECTIONS.—For each of fiscal years 2026 through 2028, if application of the workload adjustment under subparagraph (A) increases the fee revenue amounts otherwise established for the fiscal year under subsection (b), as adjusted for inflation under paragraph (2), the fee revenue increase shall be reduced by the amount of any excess collections, as described in subsection (g)(4), for the second preceding fiscal year, up to the amount of the fee revenue increase.

(C) RULE OF APPLICATION.—The workload adjustments under this paragraph shall not result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal

year established under subsection (b), as adjusted for inflation under paragraph (2).

(4) FINAL YEAR ADJUSTMENT.—

(A) IN GENERAL.—For fiscal year 2028, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of abbreviated applications for the first 3 months of fiscal year 2029.

(B) ADJUSTMENT NOT AUTHORIZED.—If the FDA has carryover balances for the process for the review of abbreviated applications in excess of 3 months of the operating reserves, an adjustment under this paragraph shall not be made.

(C) RATIONALE.—If an adjustment under this paragraph is necessary, the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2028.

(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year,

may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of abbreviated applications.

(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from, or a reduction of, 1 or more fees assessed under subsection (a) where the Secretary finds that the generic new animal drug is intended solely to provide for a minor use or minor species indication.

(e) EFFECT OF FAILURE TO PAY FEES.—

(1) ABBREVIATED APPLICATIONS.—An abbreviated application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by the person have been paid.

(2) INVESTIGATIONAL SUBMISSIONS.—An investigational submission that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by the person have been paid.

(3) GENERIC INVESTIGATIONAL NEW ANIMAL DRUG FILE.—A request to establish a generic investigational new animal drug file that is submitted by a person subject to fees under subsection (a) shall

be considered incomplete and shall not be accepted for action by the Secretary until all fees owed by the person have been paid.

(4) DISCONTINUANCE OF REVIEW.—The Secretary may discontinue review of any abbreviated application, supplemental abbreviated application, or investigational submission from a person if the person has not submitted for payment all fees owed under this section by 30 days after the date on which they are due.

(f) ASSESSMENT OF FEES.—

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year unless appropriations for salaries and expenses of the FDA for the fiscal year (excluding the amount of fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the FDA for fiscal year 2003 (excluding the amount of fees appropriated for the fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in the fiscal year the Secretary may assess

the fees, the Secretary may assess and collect the fees, without any modification in the rate, for abbreviated applications, generic new animal drug products, generic new animal drug sponsors, and generic investigational new animal drug files at any time in the fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to be appropriated to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salary and expenses with fiscal year limitation. The sums transferred shall be

available solely for the process for the review of abbreviated applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for the fiscal year; and

(ii) shall be available to defray increases in the costs of resources allocated for the process for the review of abbreviated applications (including increases in the costs for an additional number of full-time equivalent positions in the Department to be engaged in the process for the review of abbreviated applications) to the extent that those costs exceed the costs (excluding costs paid from fees collected under this section) for fiscal year 2008 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of sub-

paragraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of abbreviated applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which the costs fell below the level specified in subparagraph (A)(ii); and

(II) are not more than 5 percent below the level specified in subparagraph (A)(ii).

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for the fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2024 through 2028, there is

authorized to be appropriated for fees under this section an amount equal to the total revenue amount established under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c).

(4) EXCESS COLLECTIONS.—If the sum total of fees collected under this section for a fiscal year exceeds the amount of fees authorized to be appropriated for the fiscal year under paragraph (3), the excess collections shall be credited to the appropriations account of the FDA as provided in paragraph (1).

(5) RECOVERY OF COLLECTION SHORTFALLS.—The amount of fees otherwise authorized to be collected under this section shall be increased—

(A) for fiscal year 2026, by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2024 falls below the amount of fees authorized for fiscal year 2024 under paragraph (3);

(B) for fiscal year 2027, by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2025 falls below the amount of fees authorized for fiscal year 2025 under paragraph (3); and

(C) for fiscal year 2028, by the amount, if any, by which the amount collected under this section and appropriated for fiscal years 2026 and 2027 (including estimated collections for fiscal year 2027) falls below the amount of fees authorized for those fiscal years under paragraph (3).

(h) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for the waiver, reduction, or refund not later than 180 days after the fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department, for officers, employees, and advisory committees not engaged in the process for the review of abbreviated applications, be reduced to offset the

number of officers, employees, and advisory committees engaged in the process for the review of abbreviated applications.

(k) REPEAL OF SECTION.—This section is repealed on October 1, 2028.

**§ 17938. Reauthorization; reporting requirements**

(a) PERFORMANCE REPORTS.—Beginning with fiscal year 2024, not later than 120 days after the end of each fiscal year during which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the FDA in achieving the goals identified in the letters described in section 2311(b) of the Animal Generic Drug User Fee Amendments of 2023 (Public Law 118–15, div. B, title III, subtitle A, chapter 2, 137 Stat. 90) toward expediting the generic new animal drug development process and the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions during the fiscal year.

(b) FISCAL REPORT.—Beginning with fiscal year 2024, not later than 120 days after the end of each fiscal year during which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee

on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for the fees during the fiscal year and the use, by the FDA, of the fees collected during the fiscal year for which the report is made.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the FDA website.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of abbreviated applications for the first 5 fiscal years after fiscal year 2028, and for the reauthorization of this subchapter for the fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) veterinary professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this subchapter, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subchapter; and

(D) publish the comments on the FDA website.

(3) PERIODIC CONSULTATION.—Not less frequently than once every 4 months during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subchapter as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in paragraph (1);

(B) publish the recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on the recommendations;

(D) hold a meeting at which the public may present its views on the recommendations; and

(E) after consideration of the public views and comments, revise the recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2028, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under paragraph (4), and any changes made to the recommendations in response to the views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the FDA website, minutes of all negotiation meetings conducted under this subsection between the FDA and the regulated industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(e) REPEAL OF SECTION.—This section is repealed on January 31, 2029.

# Subchapter VI—Fees Relating to Food

### § 17946. Definitions

In this subchapter:

(1) REINSPECTION.—The term ''reinspection'' means—

(A) with respect to domestic facilities (as defined in section 11117(a) of this title), 1 or more inspections conducted under section 17504 of this title subsequent to an inspection

conducted under section 17504 of this title that identified noncompliance materially related to a food safety requirement of this subtitle, specifically to determine whether compliance has been achieved to the Secretary's satisfaction; and

(B) with respect to importers, 1 or more examinations conducted under section 20101 of this title subsequent to an examination conducted under section 20101 of this title that identified noncompliance materially related to a food safety requirement of this subtitle, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

(2) REINSPECTION-RELATED COSTS.—The term ''reinspection-related costs'' means all expenses, including administrative expenses, incurred in connection with—

(A) arranging, conducting, and evaluating the results of reinspections; and

(B) assessing and collecting reinspection fees under this subchapter.

(3) RESPONSIBLE PARTY.—The term ''responsible party'' has the meaning given the term in section 11119(a)(2) of this title.

**§ 17947. Authority to collect and use fees**

(a) IN GENERAL.—For each fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

(1) the responsible party for each domestic facility (as defined in section 11117(a) of this title) and the United States agent for each foreign facility subject to a reinspection in the fiscal year, to cover reinspection-related costs for the year;

(2) the responsible party for a domestic facility (as defined in section 11117(a) of this title) and an importer that does not comply with a recall order under section 11125 of this title or under section 11114(f) of this title in the fiscal year, to cover food recall activities associated with the order performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for the year;

(3) each importer participating in the voluntary qualified importer program under section 20106 of this title in the year, to cover the administrative costs of the program for the year; and

(4) each importer subject to a reinspection in the fiscal year, to cover reinspection-related costs for the year.

(b) ESTABLISHMENT OF FEES.—

(1) IN GENERAL.—Subject to subsections (c) and (d), the Secretary shall establish the fees to be collected under this section for each fiscal year, based on the methodology described under paragraph (2), and shall publish the fees in a Federal Register notice not later than 60 days before the start of each fiscal year.

(2) FEE METHODOLOGY.—

(A) FEES.—Fee amounts established for collection—

(i) under subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the reinspection-related activities (including by type or level of reinspection activity, as the Secretary determines applicable) described in subsection (a)(1) for the year;

(ii) under subsection (a)(2) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in subsection (a)(2) for the year;

(iii) under subsection (a)(3) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the

activities described in subsection (a)(3) for the year; and

(iv) under subsection (a)(4) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in subsection (a)(4) for the year.

(B) OTHER CONSIDERATIONS.—

(i) VOLUNTARY QUALIFIED IMPORTER PROGRAM.—In establishing the fee amounts under subparagraph (A)(iii) for a fiscal year, the Secretary shall provide for the number of importers that have submitted to the Secretary a notice under section 20106(d) of this title informing the Secretary of the intent of the importer to participate in the program under section 20106 of this title in the fiscal year.

(ii) CREDITING OF FEES.—In establishing the fee amounts under subparagraph (A) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of fees needed to carry out the activities, and con-

sider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

(iii) PUBLISHED GUIDELINES RELATING TO BURDEN ON SMALL BUSINESS.—

(I) IN GENERAL.—The Secretary shall publish in the Federal Register a proposed set of guidelines in consideration of the burden of fee amounts on small business.

(II) CONSIDERATION INCLUSIONS.—The consideration may include reduced fee amounts for small businesses.

(III) PUBLIC COMMENT.—The Secretary shall provide for a period of public comment on the guidelines.

(IV) ADJUSTMENT OF FEE SCHEDULE.—The Secretary shall adjust the fee schedule for small businesses subject to the fees only through notice and comment rulemaking.

(3) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to clauses (i), (ii), (iii), and (iv) of paragraph (2)(A) available to pay

solely for the costs referred to in clauses (i), (ii), (iii), and (iv) of paragraph (2)(A), respectively.

(c) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year unless the amount of the total appropriations for food safety activities at the FDA for the fiscal year (excluding the amount of fees appropriated for the fiscal year) is equal to or greater than the amount of appropriations for food safety activities at the FDA for fiscal year 2009 (excluding the amount of fees appropriated for the fiscal year), multiplied by the adjustment factor under paragraph (3).

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) for a portion of a fiscal year because paragraph (1) applies and if at a later date in the fiscal year, paragraph (1) ceases to apply, the Secretary may assess and collect the fees under subsection (a), without any modification to the rate of the fees, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(3) ADJUSTMENT FACTOR.—

(A) IN GENERAL.—The adjustment factor described in paragraph (1) shall be the total

percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year, but the adjustment factor shall not be negative.

(B) COMPOUNDED BASIS.—The adjustment under subparagraph (A) made each fiscal year shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2009.

(4) LIMITATION ON AMOUNT OF CERTAIN FEES.—

(A) IN GENERAL.—Notwithstanding any other provision of this section and subject to subparagraph (B), the Secretary may not collect fees in a fiscal year such that the amount collected—

(i) under subsection (a)(2) exceeds $20,000,000; and

(ii) under paragraphs (1) and (4) of subsection (a) exceeds $25,000,000 combined.

(B) EXCEPTION.—If a domestic facility (as defined in section 11117(a) of this title) or an

importer becomes subject to a fee described in paragraph (1), (2), or (4) of subsection (a) after the maximum amount of fees has been collected by the Secretary under subparagraph (A), the Secretary may collect a fee from the facility or importer.

(d) CREDITING AND AVAILABILITY OF FEES.—

(1) AVAILABILITY FOR OBLIGATION.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in appropriations Acts.

(2) AVAILABLE UNTIL EXPENDED.—The fees are authorized to remain available until expended.

(3) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the operating expenses of the FDA employees and contractors performing activities associated with fees under subsection (a).

(e) COLLECTION OF FEES.—

(1) IN GENERAL.—The Secretary shall specify in the Federal Register notice described in sub-

section (b)(1) the time and manner in which fees assessed under this section shall be collected.

(2) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under this section within 30 days after it is due, the fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31.

(f) ANNUAL REPORT TO CONGRESS.—Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report to include a description of fees assessed and collected for each such year and a summary description of the entities paying the fees and the types of business in which the entities engage.

(g) AUTHORIZATION OF APPROPRIATIONS.—For each fiscal year, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under the other provisions of this section.

# Subchapter VII—Fees Relating to Generic Drugs

## § 17951. Definitions

(a) IN GENERAL.—In this subchapter:

(1) ABBREVIATED NEW DRUG APPLICATION.—

(A) IN GENERAL.—The term ''abbreviated new drug application'' means an application submitted under section 13511 of this title, an abbreviated application submitted under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) (as in effect on November 20, 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417, 98 Stat. 1585).

(B) EXCLUSIONS.—The term ''abbreviated new drug application'' does not include an application—

(i) for a positron emission tomography drug; or

(ii) submitted by a State or Federal governmental entity for a drug that is not distributed commercially.

(2) ACTIVE PHARMACEUTICAL INGREDIENT.—The term ''active pharmaceutical ingredient'' means—

(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

(i) to be used as a component of a drug; and

(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).

(3) ADJUSTMENT FACTOR.—The term ''adjustment factor'' means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by the Index for October 2011.

(4) AFFILIATE.—The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) 1 business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(5) CONTRACT MANUFACTURING ORGANIZATION FACILITY.—The term ''contract manufacturing organization facility'' means a manufacturing facility of a finished dosage form of a drug approved pursuant to an abbreviated new drug application, if the manufacturing facility is not identified in an approved abbreviated new drug application held by the owner of the facility or an affiliate of the owner or facility.

(6) FACILITY.—

(A) IN GENERAL.—The term ''facility'' means a business or other entity—

(i) under 1 management, either direct or indirect; and

(ii) at 1 geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form.

(B) EXCLUSION.—The term ''facility'' does not include a business or other entity whose only manufacturing or processing activities are 1 or more of the following: repackaging, relabeling, or testing.

(C) GEOGRAPHIC LOCATION.—For purposes of subparagraph (A), separate buildings within close proximity are considered to be at 1 geographic location or address if the activities in them are—

(i) closely related to the same business enterprise;

(ii) under the supervision of the same local management; and

(iii) capable of being inspected by the FDA during a single inspection.

(D) MULTIPLE MANAGEMENT.—If a business or other entity otherwise meets the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, 1 per management entity, for purposes of this paragraph.

(7) FINISHED DOSAGE FORM .—The term ''finished dosage form'' means—

(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

(8) GENERIC DRUG SUBMISSION.—The term ''generic drug submission'' means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

(9) HUMAN GENERIC DRUG ACTIVITIES.—The term ''human generic drug activities'' means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in the submissions.

(B) The issuance of—

(i) approval letters that approve abbreviated new drug applications or supplements to the applications; or

(ii) complete response letters that set forth in detail the specific deficiencies in abbreviated new drug applications and, if appropriate, the actions necessary to place the applications in condition for approval.

(C) The issuance of letters related to Type II active pharmaceutical drug master files that—

(i) set forth in detail the specific deficiencies in the submissions, and if appropriate, the actions necessary to resolve those deficiencies; or

(ii) document that no deficiencies need to be addressed.

(D) Inspections related to generic drugs.

(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

(F) Postmarket safety activities with respect to drugs approved under abbreviated new

drug applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external databases.

(iv) Implementing and enforcing section 13515 of this title and section 13516 of this title to the extent that those activities relate to abbreviated new drug applications.

(v) Carrying out section 13512(e) of this title.

(G) Regulatory science activities related to generic drugs.

(10) POSITRON EMISSION TOMOGRAPHY DRUG.—The term ''positron emission tomography drug'' has the meaning given the term ''compounded positron emission tomography drug'' in section

10101(a)(9) of this title, except that subparagraph (A)(ii) of that section does not apply.

(11) PRIOR APPROVAL SUPPLEMENT.—The term ''prior approval supplement'' means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

(12) RESOURCES ALLOCATED FOR HUMAN GENERIC DRUG ACTIVITIES.—The term ''resources allocated for human generic drug activities'' means the expenses for—

(A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to the officers and employees and to contracts with the contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collection of fees under section 17952 of this title and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

(13) TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—The term ''Type II active pharmaceutical ingredient drug master file'' means a submission of information to the Secretary by a person that intends to authorize the FDA to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

(b) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17952. Authority to assess and use human generic drug fees**

(a) TYPES OF FEES.—Beginning in fiscal year 2023, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each 1-time backlog fee shall be calculated by dividing $50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

(C) NOTICE.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due not later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

(2) DRUG MASTER FILE FEE.—

(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee if that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

(C) NOTICE.—Not later than 60 days before the start of each of fiscal years 2023 through 2027, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for the fiscal year.

(D) AVAILABILITY FOR REFERENCE.—

(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file shall be deemed available for reference by the Secretary.

(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

(iii) LIST.—The Secretary shall make publicly available on the FDA website a list of the drug master file numbers that

correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

(E) FEE DUE DATE.—

(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due on the earlier of—

(I) the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file; or

(II) the date on which the drug master file holder requests the initial completeness assessment.

(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

(I) 30 calendar days after publication of the notice provided for in subparagraph (C); or

(II) 30 calendar days after the date of enactment of an appropria-

tions Act providing for the collection and obligation of fees for the year under this section.

(3) ABBREVIATED NEW DRUG APPLICATION FILING FEE.—

(A) IN GENERAL.—Each applicant that submits an abbreviated new drug application shall be subject to a fee for each such submission in the amount established under subsection (d).

(B) NOTICE.—Not later than 60 days before the start of each of fiscal years 2023 through 2027, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for the fiscal year.

(C) FEE DUE DATE.—The fees required by subparagraphs (A) and (F) shall be due not later than the date of submission of the abbreviated new drug application or prior approval supplement for which the fee applies.

(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED, IS WITHDRAWN PRIOR TO BEING RECEIVED, OR IS NO LONGER RECEIVED.—

(i) ABBREVIATED NEW DRUG APPLICATIONS NOT CONSIDERED TO HAVE BEEN RECEIVED OR WITHDRAWN PRIOR TO BEING RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 13511(f)(1) of this title for a cause other than failure to pay fees, or that has been withdrawn prior to being received within the meaning of section 13511(f)(1) of this title.

(ii) ABBREVIATED NEW DRUG APPLICATIONS NO LONGER RECEIVED.—The Secretary shall refund 100 percent of the fee paid under subparagraph (A) for any abbreviated new drug application if the Secretary initially receives the abbreviated new drug application under section 13511(f)(1) of this title and subsequently determines that an exclusivity period for a listed drug should have prevented the Secretary from receiving the abbreviated new drug application, such that the abbreviated

new drug application is no longer received within the meaning of section 13511(f)(1) of this title.

(E) FEE FOR AN ABBREVIATED NEW DRUG APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED OR HAS BEEN WITHDRAWN.—An abbreviated new drug application that was submitted and that the Secretary considers not to have been received, or that has been withdrawn, shall, on resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2017, shall pay a fee, in the amount determined under subsection (d)(2), in addition to the fee required under subparagraph (A), if—

(i) the submission contains information concerning the manufacture of an ac-

tive pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to the information.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Facilities identified in at least 1 generic drug submission that is approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

(i) GENERIC DRUG FACILITY.—Each person that owns a facility that is identified in at least 1 generic drug submission that is approved to produce 1 or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns

a facility that is identified in at least 1 generic drug submission in which the facility is approved to produce 1 or more active pharmaceutical ingredients or in a Type II active pharmaceutical ingredient drug master file referenced in at least 1 such generic drug submission, shall be assessed an annual fee for each such facility.

(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified in at least 1 generic drug submission that is approved to produce both 1 or more finished dosage forms subject to clause (i) and 1 or more active pharmaceutical ingredients subject to clause (ii) shall be subject only to the fee attributable to the manufacture of the finished dosage forms for that facility.

(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

(C) NOTICE.—Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of

the fees under subparagraph (A) for the fiscal year.

(D) FEE DUE DATE.—For each of fiscal years 2023 through 2027, the fees under subparagraph (A) for the fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for the year under this section for the year.

(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

(A) IN GENERAL.—A generic drug applicant program fee shall be assessed annually as described in subsection (b)(2)(E).

(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

(C) NOTICE.—Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for the fiscal year.

(D) FEE DUE DATE.—For each of fiscal years 2023 through 2027, the fees under subparagraph (A) for the fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such fiscal year; or

(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section for the fiscal year.

(6) DATE OF SUBMISSION.—For purposes of this subtitle, a generic drug submission or Type II active pharmaceutical ingredient drug master file is deemed to be ''submitted'' to the FDA—

(A) if it is submitted via an electronic gateway of the FDA, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the FDA office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the FDA.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—

(A) FISCAL YEAR 2023.—For fiscal year 2023, fees under subsection (a) shall be established to generate a total estimated revenue amount under subsection (a) of $582,500,000.

(B) FISCAL YEARS 2024 THROUGH 2027.—

(i) IN GENERAL.—For each of the fiscal years 2024 through 2027, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under the subsection that is equal to the base revenue amount for the fiscal year under clause (ii), as adjusted pursuant to subsection (c).

(ii) BASE REVENUE AMOUNT.—The base revenue amount for a fiscal year referred to in clause (i) is equal to the total revenue amount established under this paragraph for the previous fiscal year, not including any adjustments made for the

previous fiscal year under subsection (c)(3).

(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in paragraph (1) for a fiscal year, the fees shall be derived from the fees under paragraphs (2) through (5) of subsection (a) as follows:

(A) Five percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

(B) Thirty-three percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications).

(C) Twenty percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a contract manufacturing organization facility shall be equal to 24 percent of the fee for a facility that is not a contract manufacturing organization facility. The amount of the fee for a facility located outside the United States and territories of the United States shall be $15,000 higher than the amount of the fee for a facility located in the United States and territories of the United States.

(D) Six percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and territories of the United States shall be $15,000 higher than the amount of the fee for a facility located in the United States, including territories of the United States.

(E)(i) Thirty-six percent shall be derived from fees under subsection (a)(5) (relating to generic drug applicant program fees). For purposes of this subparagraph, if a person has affiliates, a single program fee shall be assessed with respect to that person, including its affiliates, and may be paid by that person or any one of its affiliates. The Secretary shall determine the fees as follows:

(I) If a person (including its affiliates) owns at least 1 but not more than 5 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a small business generic drug applicant program fee equal to $^1/_{10}$ of

the large size operation generic drug applicant program fee.

(II) If a person (including its affiliates) owns at least 6 but not more than 19 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium-size operation generic drug applicant program fee equal to ⅖ of the large-size operation generic drug applicant program fee.

(III) If a person (including its affiliates) owns 20 or more approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a large-size operation generic drug applicant program fee.

(ii) For purposes of this subparagraph, an abbreviated new drug application shall be deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of the abbreviated new drug application by April 1 of the previous fiscal year.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—For fiscal year 2024 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, to equal the base revenue amount for the fiscal year (as specified in subsection (b)(1)(B)(ii)) multiplied by an amount equal to the sum of—

(A) 1;

(B) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to the positions for the first 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other

than personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years.

(2) CAPACITY PLANNING ADJUSTMENT.—

(A) IN GENERAL.—Beginning with fiscal year 2024, the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

(B) CAPACITY PLANNING METHODOLOGY.—The Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

(i) be derived from the methodology and recommendations made in the report titled ''Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations'' announced in the Federal Register on August 3, 2020 (85 Fed. Reg. 46658); and

(ii) incorporate approaches and attributes determined appropriate by the Secretary, including approaches and attributes made in the report described in clause (i), except that in incorporating the approaches and attributes, the workload categories used in forecasting resources shall only be the workload categories specified in section VIII.B.2.e. of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155).

(C) LIMITATIONS.—

(i) IN GENERAL.—An adjustment under this paragraph shall not result in fee revenue for a fiscal year that is less than the sum of the amounts under subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

(ii) ADDITIONAL LIMITATION.—An adjustment under this paragraph shall not exceed 3 percent of the sum described in

clause (i) for the fiscal year, except that the limitation shall be 4 percent if—

(I) for purposes of a fiscal year 2024 adjustment, the Secretary determines that during the period from April 1, 2021, through March 31, 2023—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,000; or

(bb) 35 percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155));

(II) for purposes of a fiscal year 2025 adjustment, the Secretary determines that during the period from

April 1, 2022, through March 31, 2024—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) 35 percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155));

(III) for purposes of a fiscal year 2026 adjustment, the Secretary determines that during the period from April 1, 2023, through March 31, 2025—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) 35 percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155)); and

(IV) for purposes of a fiscal year 2027 adjustment, the Secretary determines that during the period from April 1, 2024, through March 31, 2026—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) 35 percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 3001(b) of

the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155)).

(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish, in the Federal Register notice referred to in subsection (a), the fee revenue and fees resulting from the adjustment and the methodology under this paragraph.

(3) OPERATING RESERVE ADJUSTMENT.—

(A) IN GENERAL.—For fiscal year 2024 and each subsequent fiscal year, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section for the fiscal year if the increase is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B) with respect to that fiscal year.

(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

(i) 8 weeks for fiscal year 2024;

(ii) 9 weeks for fiscal year 2025; and

(iii) 10 weeks for each of fiscal years 2026 and 2027.

(C) DECREASE.—If the Secretary has carryover balances for human generic drug activities in excess of 12 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in subparagraph (A) to provide for not more than 12 weeks of the operating reserves.

(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under subsection (a) publishing the fee revenue and fees for the fiscal year involved.

(d) ANNUAL FEE SETTING.—

(1) FISCAL YEARS 2023 THROUGH 2027.—Not later than 60 days before the first day of each of fiscal years 2023 through 2027, the Secretary shall establish the fees described in paragraphs (2) through (5) of subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

(2) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fee under paragraph (1), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

(A) the sum of—

(i) the total number of the active pharmaceutical ingredients in the submission; and

(ii) for each such ingredient that is manufactured at more than 1 such facility, the total number of the additional facilities; and

(B) the amount equal to the drug master file fee established in subsection (a)(2) for the submission.

(e) LIMITATIONS.—

(1) IN GENERAL.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for the fiscal year for the resources allocated for human generic drug activities.

(2) LEASING AND NECESSARY EQUIPMENT.—Beginning on October 1, 2023, the authorities under section 17951(a)(12)(C) of this title shall include only leasing and necessary scientific equipment.

(f) IDENTIFICATION OF FACILITIES.—

(1) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (3) shall submit to the Secretary the information required under this subsection each year. The information shall, for each fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous fiscal year.

(2) INFORMATION REQUIRED TO BE SUBMITTED.—At a minimum, the submission required by paragraph (1) shall include for each such facility—

(A) identification of a facility identified in an approved or pending generic drug submission;

(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

(C) whether or not the facility is located within the United States and territories of the United States;

(D) whether the facility manufactures positron emission tomography drugs solely or in addition to other drugs;

(E) whether the facility manufactures drugs that are not generic drugs; and

(F) whether the facility is a contract manufacturing organization facility.

(3) CERTAIN SITES AND ORGANIZATIONS.—

(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

(i) a site in which a bioanalytical study is conducted;

(ii) a clinical research organization;

(iii) a contract analytical testing site; or

(iv) a contract repackager site.

(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 17504(a)(1) of this title shall extend to all such sites and organizations.

(g) EFFECT OF FAILURE TO PAY FEES.—

(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on a publicly available arrears list, such that no new abbreviated new drug applications or supplement submitted from that person, or any affiliate of that person, will be received within the meaning of section 13511(f)(1) of this title until the outstanding fee is paid.

(2) DRUG MASTER FILE FEE.—

(A) IN GENERAL.—Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of subsection (a)(2) (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

(B) AVAILABLE FOR REFERENCE.—

(i) IN GENERAL.—Any generic drug submission submitted that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 13511(f)(1) of this title unless the condition specified in clause (ii) is met.

(ii) CONDITION.—The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the

owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

(C) NOTIFICATION.—

(i) IN GENERAL.—If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

(ii) NOT RECEIVED.—If the fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 13511(f)(1) of this title.

(3) ABBREVIATED NEW DRUG APPLICATION FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of subsection (a)(3) shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 13511(f)(1) of this title until the outstanding fee is paid.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of subsection (a)(4) shall result in the following:

(i) ARREARS LIST.—The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted from the person that is responsible for paying the fee, or any affiliate of that person, will be received within the

meaning of section 13511(f)(1) of this title.

(ii) SUBMISSION NOT TO BE RECEIVED.—Any new generic drug submission submitted that references such a facility shall not be received within the meaning of section 13511(f)(1) of this title if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

(iii) MISBRANDED.—All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 13324 of this title.

(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

(C) APPLICATION NOT TO BE RECEIVED ON NONPAYMENT.—

(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

(ii) NOT TO BE RECEIVED.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 13511(f)(1) of this title.

(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

(A) IN GENERAL.—A person that fails to pay a fee as required under subsection (a)(5) by the date that is 20 calendar days after the due

date, as specified in subparagraph (D) of subsection (a)(5), shall be subject to the following:

(i) The Secretary shall place the person on a publicly available arrears list.

(ii) Any abbreviated new drug application submitted by the generic drug applicant or an affiliate of the applicant shall not be received, within the meaning of section 13511(f)(1) of this title.

(iii) All drugs marketed pursuant to any abbreviated new drug application held by the applicant or an affiliate of the applicant shall be deemed misbranded under section 13324 of this title.

(B) APPLICATION OF PENALTIES.—The penalties under subparagraph (A) shall apply until the fee required under subsection (a)(5) is paid.

(h) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year, unless appropriations for salaries and expenses of the FDA for the fiscal year (excluding the amount of fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for the salaries

and expenses of the FDA for fiscal year 2009 (excluding the amount of fees appropriated for the fiscal year) multiplied by the adjustment factor (as defined in section 17951 of this title) applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in the fiscal year the Secretary may assess the fees, the Secretary may assess and collect the fees, without any modification in the rate, at any time in the fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(i) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2).

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation. The sums transferred shall be available solely for human generic drug activities.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for the fiscal year; and

(ii) shall be available, for each fiscal year, to defray the costs of human generic drug activities (including the costs for an additional number of full-time equivalent positions in the Department to be engaged in those activities), only if the sum of the amounts allocated by the Secretary for the costs, excluding costs paid from fees col-

lected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with human generic drug activities, is no less than $97,000,000 multiplied by the adjustment factor defined in section 17951(a)(3) of this title applicable to the fiscal year involved.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated as described in subclause (I) or (II) of subparagraph (A)(ii), as applicable, are not more than 10 percent below the level specified in subparagraph (A)(ii).

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for the fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2).

(j) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees engaged in the activities.

(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities

that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of the drugs are required to be identified pursuant to subsection (f).

(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying the return within 180 calendar days after the fee was paid.

(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—

(1) IN GENERAL.—An abbreviated new drug application that is not considered to be received within the meaning of section 13511(f)(1) of this title because of failure to pay an applicable fee under this section within the time period specified in subsection (g) shall be deemed not to have been ''substantially complete'' on the date of its submission within the meaning of section 13511(f)(2)(D)(ii)(II) of this title.

(2) EFFECT OF RECEIVING FEE.—An abbreviated new drug application that is not substantially complete on the date of its submission solely because

of failure to pay an applicable fee under paragraph (1) shall be deemed substantially complete and received within the meaning of section 13511(f)(1) of this title as of the date the applicable fee is received.

(o) INFORMATION ON ABBREVIATED NEW DRUG APPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILIATES.—

(1) IN GENERAL.—By April 1 of each year, each person that owns an abbreviated new drug application, or a designated affiliate of the person, shall submit, on behalf of the person and the affiliates of the person, to the Secretary a list of—

(A) all approved abbreviated new drug applications owned by the person; and

(B) if any affiliate of the person also owns an abbreviated new drug application, all affiliates that own any such abbreviated new drug application and all approved abbreviated new drug applications owned by any such affiliate.

(2) FORMAT AND METHOD.—The Secretary shall specify in guidance the format and method for submission of lists under this subsection.

(p) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17953. Reauthorization; reporting requirements**

(a) PERFORMANCE REPORT.—

(1) GENERAL REQUIREMENTS.—Not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the FDA in achieving the goals identified in the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155) during the fiscal year and the future plans of the FDA for meeting the goals.

(2) REAL TIME REPORTING.—

(A) IN GENERAL.—Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subchapter, the Secretary shall post the data described in subparagraph (B) on the FDA website, and may remove duplicative data from the annual report under this subsection.

(B) DATA.—The Secretary shall post the following data in accordance with subparagraph (A):

(i) The number and titles of draft and final guidance on topics related to human generic drug activities and whether the guidance documents were issued as required by statute or pursuant to a commitment under the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155).

(ii) The number and titles of public meetings held on topics related to human generic drug activities and whether the meetings were required by statute or pursuant to a commitment under the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155).

(3) RATIONALE FOR GDUFA PROGRAM CHANGES.—The Secretary shall include in the annual report under paragraph (1)—

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed on in the letters described in section 3001(b) of the Generic Drug User Fee Amend-

ments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155) and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 17952 of this title, and the number of full-time equivalents funded by budget authority at the FDA by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including—

(i) identifying drivers of the changes; and

(ii) changes in the total average cost per full-time equivalent in the generic drug review program;

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of em-

ployees for whom time reporting is not required; and

(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of abbreviated new drug application.

(4) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

(A) The difference between the aggregate number of abbreviated new drug applications filed and the aggregate number of approvals or aggregate number of complete response letters issued by the agency, accounting for—

(i) the applications filed during 1 fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(ii) the aggregate number of applications for each fiscal year that did not meet the goals identified by the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155) for the applicable fiscal year.

(B) Relevant data to determine whether the FDA has met the performance enhancement goals identified by the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155) for the applicable fiscal year.

(C) The most common causes and trends for external or other circumstances that affected the ability of the Secretary to meet review time and performance enhancement goals identified by the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155).

(b) FISCAL REPORT.—Not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for the fees during the fiscal year and the use, by the FDA, of the fees collected for the fiscal year.

(c) CORRECTIVE ACTION REPORT.—For each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate. The report shall include the following information, as applicable:

(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(4), that each of the goals identified by the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155) for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the abbreviated new drug application review process.

(2) GOALS MISSED.—For each of the goals identified by the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155) for the applicable fiscal year that the Sec-

retary determines to not have been met, the corrective action report shall include—

(A) a detailed justification for the determination and a description, as applicable, of the types of circumstances and trends under which abbreviated new drug applications missed the review goal times but were approved during the first cycle review, or review goals were missed; and

(B) with respect to performance enhancement goals that were not achieved, a detailed description of efforts the FDA has put in place for the fiscal year in which the report is submitted to improve the ability of the agency to meet each such goal for the fiscal year.

(d) ENHANCED COMMUNICATION.—

(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of human drugs shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and requested, representatives from the FDA shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. The hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter.

(e) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the FDA website.

(f) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year 2027, and for the reauthorization of this subchapter for the fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the generic drug industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this subchapter, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subchapter; and

(D) publish the comments on the FDA website.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subchapter as expressed under paragraph (2).

(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this subchapter to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(5) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in paragraph (1);

(B) publish the recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on the recommendations;

(D) hold a meeting at which the public may present its views on the recommendations; and

(E) after consideration of the public views and comments, revise the recommendations as necessary.

(6) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2027, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under paragraph (4), and any changes made to the recommendations in response to the views and comments.

(7) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the FDA website, minutes of all negotiation meetings conducted under this subsection between the FDA and the generic drug industry, not later than 30 days after each such negotiation meeting.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize, in sufficient detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(g) REPEAL OF SECTION.—This section is repealed on January 31, 2028.

# Subchapter VIII—Fees Relating to Biosimilar Biological Products

### § 17961. Definitions

(a) IN GENERAL.—In this subchapter:

(1) ADJUSTMENT FACTOR.—The term ''adjustment factor'' applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items) for September of the preceding fiscal year divided by the Index for September 2011.

(2) AFFILIATE.—The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) 1 business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(3) BIOSIMILAR BIOLOGICAL PRODUCT.—The term ''biosimilar biological product'' means a specific strength of a biological product in final dosage form for which a biosimilar biological product application has been approved.

(4) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the term ''biosimilar biological product application'' means an application for licensure of a biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(B) EXCLUSIONS.—The term ''biosimilar biological product application'' does not include—

(i) a supplement to such an application;

(ii) an application filed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that cites as the reference product a bovine blood product for topical application licensed before Sep-

tember 1, 1992, or a large volume parenteral drug product approved before that date;

(iii) an application filed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) with respect to—

(I) whole blood or a blood component for transfusion;

(II) an in vitro diagnostic biological product; or

(III) a biological product for further manufacturing use only; or

(iv) an application for licensure under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

(5) BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETING.—The term ''biosimilar biological product development meeting'' means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study

intended to support a biosimilar biological product application.

(6) BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM.—The term ''biosimilar biological product development program'' means the program under this subchapter for expediting the process for the review of submissions in connection with biosimilar biological product development.

(7) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT.—

(A) IN GENERAL.—The term ''biosimilar biological product establishment'' means a foreign or domestic place of business—

(i) that is at 1 general physical location consisting of 1 or more buildings, all of which are within 5 miles of each other; and

(ii) at which 1 or more biosimilar biological products are manufactured in final dosage form.

(B) EXCLUSION.—For purposes of subparagraph (A)(ii), the term ''manufactured'' does not include packaging.

(8) BIOSIMILAR INITIAL ADVISORY MEETING.—

(A) IN GENERAL.—The term ''biosimilar initial advisory meeting'' means a meeting, if requested, that is limited to—

(i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) may be feasible for a particular product; and

(ii) if licensure may be feasible as described in clause (i), general advice on the expected content of the development program.

(B) EXCLUSION.—The term ''biosimilar initial advisory meeting'' does not include any meeting that involves substantive review of summary data or full study reports.

(9) COSTS OF RESOURCES ALLOCATED FOR THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—The term ''costs of resources allocated for the process for the review of biosimilar biological product applications'' means the expenses, in connection with the process for the review of biosimilar biological product applications, for—

(A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to the officers, employees, and committees and to contracts with the contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collection of fees under section 17962 of this title and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(10) FINAL DOSAGE FORM.—The term ''final dosage form'' means, with respect to a biosimilar biological product, a finished dosage form that is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

(11) FINANCIAL HOLD.—The term ''financial hold''—

(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 17962(a)(1) of this title; and

(B) does not mean that any of the bases for a ''clinical hold'' under section 13510(c) of this title have been determined by the Secretary to exist concerning the investigation.

(12) PERSON.—The term ''person'' includes an affiliate of the person.

(13) PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—The term ''process for the review of biosimilar biological product applications'' means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters that approve biosimilar biological product applications or that set forth in detail the specific deficiencies in the applications, and if appropriate, the actions necessary to place the applications in condition for approval.

(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external databases.

(iv) Implementing and enforcing section 13515 of this title and section 13516 of this title.

(v) Carrying out section 13512(e) of this title.

(14) SUPPLEMENT.—The term ''supplement'' means a request to the Secretary to approve a change in a biosimilar biological product application that has been approved, including a supplement requesting that the Secretary determine that the bio-

similar biological product meets the standards for interchangeability described in section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(b) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17962. Authority to assess and use biosimilar biological product fees**

(a) TYPES OF FEES.—The Secretary shall assess and collect fees in accordance with this section as follows:

(1) BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM FEES.—

(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay, for the product named in the meeting request or the investigational new drug application, the initial biosimilar biological product development fee established under subsection (c)(5).

(ii) MEETING REQUEST.—The meeting request described in this clause is a re-

quest for a biosimilar biological product development meeting for a product.

(iii) CLINICAL PROTOCOL FOR INVESTIGATIONAL NEW DRUG PROTOCOL.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with section 13510 of this title and any regulations promulgated under section 13510 of this title (referred to in this section as ''investigational new drug application'') describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of—

(I) not later than 7 days after the Secretary grants a request for a biosimilar biological product development meeting; or

(II) the date of submission of an investigational new drug application describing an investigation that the

Secretary determines is intended to support a biosimilar biological product application.

(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for the product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (c)(5) for the biosimilar biological product development program (referred to in this section as ''annual biosimilar biological product development fee''), except that, in the case that the product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of the person, and written notice of the transfer is provided to the Secretary, the licensee, assignee, or successor shall pay the annual

biosimilar biological product development fee.

(ii) DUE DATE.—The annual biosimilar biological product development fee for each fiscal year is due on the later of—

(I) the first business day on or after October 1 of that fiscal year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section.

(iii) EXCEPTION.—The annual biosimilar biological product development fee for each fiscal year is due on the date specified in clause (ii), unless the person has—

(I) submitted a marketing application for the biological product that was accepted for filing;

(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C); or

(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).

(iv) REFUND.—

(I) IN GENERAL.—If a person submits a marketing application for a biosimilar biological product before October 1 of a fiscal year and the application is subsequently accepted for filing, the person may request a refund equal to the annual biosimilar biological product development fee paid by the person for the product for the fiscal year.

(II) REQUIREMENTS.—To qualify for consideration for a refund under this clause, a person shall submit to the Secretary a written request for the refund not later than 180 days after the marketing application is accepted for filing.

(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development

program for a product, effective October 1 of a fiscal year, by, not later than August 1 of the preceding fiscal year—

(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

(ii) if an investigational new drug application concerning the product has been submitted, withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

(D) REACTIVATION FEE.—

(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C), or that has been administratively removed from the program for a product under subparagraph (E)(v), shall, if the person seeks to resume participation in the program, pay

all annual biosimilar biological product development fees previously assessed for the product and still owed and a fee (referred to in this section as ''reactivation fee'') by the earlier of the following:

(I) Not later than 7 days after the Secretary grants a request by the person for a biosimilar biological product development meeting for the product (after the date on which the participation was discontinued or the date of administrative removal, as applicable).

(II) On the date of submission (after the date on which the participation was discontinued or the date of administrative removal, as applicable) by the person of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a

product shall pay for the product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B), except that, in the case that the product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of the person, and written notice of the transfer is provided to the Secretary, the licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.

(E) EFFECT OF FAILURE TO PAY FEES.—

(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 13510(b) of this title if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) FINANCIAL HOLD.—Notwithstanding section 13510(b) of this title, except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigation is intended to sup-

port a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all of those fees owed by the person have been paid.

(v) ADMINISTRATIVE REMOVAL FROM THE BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM.—If a person has

failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of 2 consecutive fiscal years, the Secretary may administratively remove the person from the biosimilar biological product development program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to the person of the intended administrative removal.

(F) LIMITS REGARDING FEES.—

(i) REFUNDS.—Except as provided in subparagraph (B)(iv), the Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).

(ii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological

product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—

(A) IN GENERAL.—Each person that submits a biosimilar biological product application shall be subject to the following fees:

(i) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval. The fee shall be equal to half of the amount of the fee described in clause (i).

(B) RULE OF APPLICABILITY; TREATMENT OF CERTAIN PREVIOUSLY PAID FEES.—Any

person that paid a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after that date, shall—

(i) be subject to any biosimilar biological product application fees that may be assessed at the time when the biosimilar biological product application is submitted; and

(ii) be entitled to no reduction of the application fees based on the amount of fees paid for that product before October 1, 2017, under subparagraph (A), (B), or (D) of paragraph (1).

(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due on submission of the application for which the fee applies.

(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION.—If a biosimilar biological product application was submitted by a person that paid the fee for the application, was accepted for filing, and was not approved or was withdrawn prior to approval (without a waiver), the

submission of a biosimilar biological product application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application that is refused for filing or withdrawn without a waiver before filing.

(F) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A biosimilar biological product application that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (d).

(3) BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.—

(A) IN GENERAL.—Each person that is named as the applicant in a biosimilar biologi-

cal product application shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for each biosimilar biological product that—

(i) is identified in the biosimilar biological product application approved as of October 1 of the fiscal year;

(ii) may be dispensed only under prescription pursuant to section 13103(a) of this title; and

(iii) as of October 1 of the fiscal year, does not appear on a list, developed and maintained by the Secretary, of discontinued biosimilar biological products.

(B) DUE DATE.—The biosimilar biological product program fee for a fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such fiscal year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for the fiscal year under this section.

(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product program fee

shall be paid only once for each product for each fiscal year.

(D) LIMITATION.—A person that is named as the applicant in a biosimilar biological product application shall not be assessed more than 5 biosimilar biological product program fees for a fiscal year for biosimilar biological products identified in the biosimilar biological product application.

(E) MOVEMENT TO DISCONTINUED LIST.—

(i) DATE OF INCLUSION.—If a written request to place a product on the list referenced in subparagraph (A) of discontinued biosimilar biological products is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, withdrawn from sale, then for purposes of assessing the biosimilar biological product program fee, the Secretary shall consider the product to have been included on the list on the later of—

(I) the date the request was received; or

(II) if the product will be withdrawn from sale on a future date, the future date when the product is withdrawn from sale.

(ii) TREATMENT AS WITHDRAWN FROM SALE.—For purposes of clause (i), a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

(iii) SPECIAL RULE FOR PRODUCTS REMOVED FROM DISCONTINUED LIST.—If a biosimilar biological product that is identified in a biosimilar biological product application approved as of October 1 of a fiscal year appears, as of October 1 of that fiscal year, on the list referenced in subparagraph (A) of discontinued biosimilar biological products, and on any subsequent day during that fiscal year the biosimilar biological product does not appear on the

list, except as provided in subparagraph (D), each person that is named as the applicant in a biosimilar biological product application with respect to the product shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for the biosimilar biological product. Notwithstanding subparagraph (B), the fee shall be due on the last business day of the fiscal year and shall be paid only once for each such product for each fiscal year.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, fees under subsection (a) shall, except as provided in subsection (c), be established to generate a total revenue amount equal to the sum of—

(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the strategic hiring and retention adjustment (as determined under subsection (c)(2));

(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

(F) for fiscal year 2023 an additional amount of $4,428,886; and

(G) for fiscal year 2024 an additional amount of $320,569.

(2) ALLOCATION OF REVENUE AMOUNT AMONG FEES.—

(A) ALLOCATION.—The Secretary shall determine the percentage of the total revenue amount for a fiscal year to be derived from, respectively—

(i) initial and annual biosimilar biological product development fees and reactivation fees under subsection (a)(1);

(ii) biosimilar biological product application fees under subsection (a)(2); and

(iii) biosimilar biological product program fees under subsection (a)(3).

(B) BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEES.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.

(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to twice the amount of the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.

(3) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

(A) for fiscal year 2023, $43,376,922; and

(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, excluding any adjustments to the revenue amount under subsection (c)(4).

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—

(A) IN GENERAL.—For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

(i) the annual base revenue for the fiscal year under subsection (b)(1)(A); and

(ii) the inflation adjustment percentage under subparagraph (B).

(B) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—

(i) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to the positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 fiscal years; and

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 fiscal years.

(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall increase the fee revenue and fees by $150,000.

(3) CAPACITY PLANNING ADJUSTMENT.—

(A) IN GENERAL.—For each fiscal year, the Secretary shall, in addition to the adjustments under paragraphs (1) and (2), adjust the fee revenue and fees under this section for a fiscal year to reflect changes in the resource ca-

pacity needs of the Secretary for the process for the review of biosimilar biological product applications.

(B) METHODOLOGY.—

(i) IN GENERAL.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled ''Biosimilar User Fee Rates for Fiscal Year 2021'' published in the Federal Register on August 4, 2020 (85 Fed. Reg. 47220).

(ii) WORKLOAD CATEGORIES.—The workload categories used in applying the methodology in forecasting shall include only the activities described in the notice described in clause (i) and, as feasible, additional activities that are directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strate-

gies, and the direct review of annual reports for approved biosimilar biological products.

(iii) EXCLUSIONS TO WORKLOAD CATEGORIES.—Subject to the exceptions in clause (ii), the Secretary shall not include as workload categories in applying the methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in the notice described in clause (i) but did not utilize in setting fees for fiscal year 2021.

(C) LIMITATIONS.—An adjustment under this paragraph shall not result in fee revenue for a fiscal year that is less than the sum of the amounts under subparagraphs (A), (B), and (C) of subsection (b)(1).

(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish, in the Federal Register notice under paragraph (5), the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

(4) OPERATING RESERVE ADJUSTMENT.—

(A) INCREASE.—For each fiscal year, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), increase the fee revenue and fees if the increase is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

(B) DECREASE.—

(i) FISCAL YEAR 2024.—For fiscal year 2024, if the Secretary has carryover balances for the process for the review of biosimilar biological product applications in excess of 27 weeks of the operating reserves, the Secretary shall decrease the fee revenue and fees to provide for not more than 27 weeks of the operating reserves.

(ii) FISCAL YEAR 2025 AND SUBSEQUENT FISCAL YEARS.—For fiscal year 2025 and subsequent fiscal years, if the Secretary has carryover balances for the process for the review of biosimilar biological product applications in excess of 21 weeks of the operating reserves, the Secretary shall decrease the fee revenue and

fees to provide for not more than 21 weeks of the operating reserves.

(C) FEDERAL REGISTER NOTICE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5)(B) establishing fee revenue and fees for the fiscal year involved.

(5) ANNUAL FEE SETTING.—For each fiscal year, the Secretary shall, not later than 60 days before the start of that fiscal year—

(A) establish initial and annual biosimilar biological product development fees and reactivation fees under subsection (a)(1), biosimilar biological product application fees under subsection (a)(2), and biosimilar biological product program fees under subsection (a)(3), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(B) publish the fee revenue and fees in the Federal Register.

(6) LIMIT.—The total amount of fees assessed for a fiscal year under this section may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of biosimilar biological product applications.

(d) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—

(1) DEFINITION OF SMALL BUSINESS.—In this subsection, the term ''small business'' means an entity that—

(A) has fewer than 500 employees, including employees of affiliates; and

(B) does not have a drug product that has been—

(i) approved under a human drug application (as defined in section 17906(a) of this title) or a biosimilar biological product application; and

(ii) introduced or delivered for introduction into interstate commerce.

(2) WAIVER OF APPLICATION FEE.—

(A) IN GENERAL.—The Secretary shall grant to a person that is named in a biosimilar biological product application a waiver from the application fee assessed to that person under

subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review.

(B) SUBSEQUENT APPLICATIONS.—After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

(3) CONSIDERATIONS.—In determining whether to grant a waiver of a fee under paragraph (2), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(e) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all those fees owed by the person have been paid.

(f) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for the fiscal year.

(B) USE OF FEES AND LIMITATIONS.—

(i) IN GENERAL.—The fees authorized by this section shall be available, for each fiscal year, to defray the costs of resources allocated for the process for the review of biosimilar biological product applications (including the costs for an additional number of full-time equivalent positions in the Department to be engaged in the process for the review of biosimilar biological product applications), only if the sum of the amounts allocated by the Secretary for the costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, and other necessary materials and supplies in connection with the process for the review of biosimilar biological product applications, is no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

(ii) LEASING AND NECESSARY EQUIPMENT.—The authorities under section

17961(a)(9)(C) of this title shall include only leasing and necessary scientific equipment.

(C) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (B)(i) in any fiscal year if the costs allocated as described in subparagraph (B)(i) are not more than 15 percent below the level specified in subparagraph (B)(i).

(D) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for the fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for the fiscal year under this section.

(g) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, the fee shall be treated as a claim of the United States

Government subject to subchapter II of chapter 37 of title 31.

(h) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—

(1) IN GENERAL.—To qualify for consideration for a waiver under subsection (d), or for the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying the waiver or return and, except as otherwise specified in this section, the written request shall be submitted to the Secretary not later than 180 days after the fee is due.

(2) INCLUSION OF LEGAL AUTHORITIES.—A request submitted under paragraph (1) shall include any legal authorities under which the request is made.

(i) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department, for officers, employees, and advisory committees not engaged in the process for the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees engaged in the process for the review of biosimilar biological product applications.

(j) REPEAL OF SECTION.—This section is repealed on October 1, 2027.

**§ 17963. Reauthorization; reporting requirements**

(a) PERFORMANCE REPORT.—

(1) GENERAL REQUIREMENTS.—Not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the FDA in achieving the goals identified in the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160) during the fiscal year and the future plans of the FDA for meeting the goals.

(2) ADDITIONAL INFORMATION.—The report under this subsection shall include the progress of the FDA in achieving the goals, and future plans for meeting the goals, including—

(A) information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort;

(B) the number of original biosimilar biological product applications filed per fiscal year and the number of approvals issued by the agency for the applications; and

(C) the number of resubmitted original biosimilar biological product applications filed per fiscal year and the number of approval letters issued by the agency for the applications.

(3) REAL TIME REPORTING.—

(A) IN GENERAL.—Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this subchapter, the Secretary shall post the data described in subparagraph (B) for the quarter and on a cumulative basis for the fiscal year on the FDA website, and may remove duplicative data from the annual report under this subsection.

(B) DATA.—The Secretary shall post the following data in accordance with subparagraph (A):

(i) The number and titles of draft and final guidance on topics related to the process for the review of biosimilar biological product applications, and whether the

guidance documents were required by statute or pursuant to a commitment under the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160).

(ii) The number and titles of public meetings held on topics related to the process for the review of biosimilar biological product applications, and whether the meetings were required by statute or pursuant to a commitment under the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160).

(4) RATIONALE FOR BSUFA PROGRAM CHANGES.—The Secretary shall include in the annual report under paragraph (1)—

(A) data, analysis, and discussion of the changes in the number of individuals hired as agreed on in the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160) and the number of re-

maining vacancies, the number of full-time equivalents funded by fees collected pursuant to section 17962 of this title, and the number of full-time equivalents funded by budget authority at the FDA by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs of resources allocated for the process for the review of biosimilar biological product applications, including identifying—

(i) drivers of the changes; and

(ii) changes in the average total cost per full-time equivalent in the biosimilar biological product review program;

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of em-

ployees for whom time reporting is not required; and

(D) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of biosimilar biological product application.

(5) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

(A) The difference between the aggregate number of biosimilar biological product applications and supplements filed and the aggregate number of approvals issued by the agency, accounting for—

(i) the applications filed during 1 fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(ii) the aggregate number of applications for each fiscal year that did not meet the goals identified by the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160) for the applicable fiscal year.

(B) Relevant data to determine whether the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have met the performance enhancement goals identified by the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160) for the applicable fiscal year.

(C) The most common causes and trends for external or other circumstances affecting the ability of the Secretary to meet review time and performance enhancement goals identified by the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160).

(b) FISCAL REPORT.—Not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for the fees during

the fiscal year and the use, by the FDA, of the fees collected for the fiscal year.

(c) CORRECTIVE ACTION REPORT.—For each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate. The report shall include the following information, as applicable:

(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(5), that each of the goals identified by the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160) for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the biosimilar biological product application review process.

(2) GOALS MISSED.—For each of the goals identified by the letters described in section 4001(b) of the Biosimilar User Fee Amendments of 2022

(Public Law 117–180, div. F, title IV, 136 Stat. 2160) for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(A) a justification for the determination and a description of the types of circumstances and trends, as applicable, under which biosimilar biological product applications missed the review goal times but were approved during the first cycle review, or review goals were missed; and

(B) with respect to performance enhancement goals that were not achieved, a description of efforts the FDA has put in place for the fiscal year in which the report is submitted to improve the ability of the agency to meet each such goal for the fiscal year.

(d) ENHANCED COMMUNICATION.—

(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of human drugs shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives

to report on the contents described in the reports under this section.

(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and requested, representatives from the FDA shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. The hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this subchapter.

(e) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the FDA website.

(f) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year 2027, and for the reauthorization of this subchapter for the fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this subchapter, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization;

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subchapter; and

(D) publish the comments on the FDA website.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subchapter as expressed under paragraph (2).

(4) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of this subchapter to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(5) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in paragraph (1);

(B) publish the recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on the recommendations;

(D) hold a meeting at which the public may present its views on the recommendations; and

(E) after consideration of the public views and comments, revise the recommendations as necessary.

(6) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2027, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under paragraph (2), and any changes made to the recommendations in response to the views and comments.

(7) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the public FDA website, minutes of all negotiation meetings conducted under this subsection between the FDA and the regulated industry, not later than 30 days after each negotiation meeting.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize, in

sufficient detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(g) REPEAL OF SECTION.—This section is repealed on January 31, 2028.

# Subchapter IX—Fees Relating to Outsourcing Facilities

### § 17971. Definitions

In this subchapter:

(1) AFFILIATE.—The term ''affiliate'' has the meaning given the term in section 17906(a) of this title.

(2) GROSS ANNUAL SALES.—The term ''gross annual sales'' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.

(3) OUTSOURCING FACILITY.—The term ''outsourcing facility'' has the meaning given the term in section 13107(a) of this title.

(4) REINSPECTION.—The term ''reinspection'' means, with respect to an outsourcing facility, 1 or more inspections conducted under section 17504 of this title subsequent to an inspection conducted

under that section that identified noncompliance materially related to an applicable requirement of this subtitle, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

**§ 17972. Authority to assess and use outsourcing facility fees**

(a) ESTABLISHMENT AND REINSPECTION FEES.—

(1) IN GENERAL.—For each fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

(A) an annual establishment fee from each outsourcing facility; and

(B) a reinspection fee from each outsourcing facility subject to a reinspection in the fiscal year.

(2) MULTIPLE REINSPECTIONS.—An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

(b) ESTABLISHMENT AND REINSPECTION FEE SETTING.—The Secretary shall—

(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and

(2) publish the fee amounts in a Federal Register notice not later than 60 calendar days before the start of each fiscal year.

(c) AMOUNT OF ESTABLISHMENT FEE AND REINSPECTION FEE.—

(1) IN GENERAL.—For each outsourcing facility in a fiscal year—

(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of—

(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); and

(ii) the small business adjustment factor described in paragraph (3); and

(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).

(2) INFLATION ADJUSTMENT FACTOR.—

(A) IN GENERAL.—For each fiscal year, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice,

published in the Federal Register, for a fiscal year by the amount equal to the sum of—

(i) 1;

(ii) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to the positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average full-time equivalent position of the FDA for the first 3 years of the preceding 4 fiscal years; and

(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the FDA

for the first 3 years of the preceding 4 fiscal years.

(B) COMPOUNDED BASIS.—The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

(3) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

(A) the number of small businesses that will pay a reduced establishment fee for the fiscal year; and

(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

(4) EXCEPTION FOR SMALL BUSINESSES.—

(A) IN GENERAL.—In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending

April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to ⅓ of the amount calculated under paragraph (1)(A)(i) for the fiscal year.

(B) APPLICATION.—To qualify for the exception under this paragraph, a small business shall submit to the Secretary an application for the exception, in the form of a written request and in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. The application shall be submitted to the Secretary not later than April 30 of the immediately preceding fiscal year.

(5) CREDITING OF FEES.—In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall—

(A) provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small

business adjustment factor for the previous fiscal year; and

(B) consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

(d) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to subparagraphs (A) and (B) of subsection (a)(1) available solely to pay for the costs of oversight of outsourcing facilities.

(e) NOT TO SUPPLANT OTHER FUNDS.—Funds received by the Secretary pursuant to this section shall be used to supplement and not to supplant any other Federal funds available to carry out the activities described in this section.

(f) CREDITING AND AVAILABILITY OF FEES.—

(1) AVAILABILITY FOR OBLIGATION.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.

(2) AVAILABLE UNTIL EXPENDED.—The fees are authorized to remain available until expended.

(3) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for sala-

ries and expenses with fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the costs of oversight of outsourcing facilities.

(g) COLLECTION OF FEES.—

(1) ESTABLISHMENT FEE.—An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 13107(c) of this title for the fiscal year.

(2) REINSPECTION FEE.—The Secretary shall specify in the Federal Register notice described in subsection (b)(2) the manner in which reinspection fees assessed under this section shall be collected and the timeline for payment of the fees. A reinspection fee under this section shall be collected after the Secretary has conducted a reinspection of the outsourcing facility involved.

(3) EFFECT OF FAILURE TO PAY FEES.—

(A) REGISTRATION.—An outsourcing facility shall not be considered registered under section 13107(c) of this title in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for the fiscal year.

(B) MISBRANDING.—All drugs manufactured, prepared, propagated, compounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under chapter 133 of this title until the fees owed for the outsourcing facility under this section have been paid.

(4) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under this section within 30 calendar days after it is due, the fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31.

(h) ANNUAL REPORT TO CONGRESS.—Not later than 120 calendar days after each fiscal year in which fees are assessed and collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report to include a description of fees assessed and collected for the year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to sup-

port inspecting outsourcing facilities, and the number of inspections and reinspections of the facilities performed each year.

(i) AUTHORIZATION OF APPROPRIATIONS.—For each fiscal year, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for the fiscal year under this section.

# Subchapter X—Fees Relating to Over-the-Counter Drugs

### § 17976. Definitions

In this subchapter:

(1) AFFILIATE.—The term ''affiliate'' means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) 1 business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(2) CONTRACT MANUFACTURING ORGANIZATION FACILITY.—The term ''contract manufacturing organization facility'' means an OTC monograph drug facility where neither the owner of the manufacturing facility nor any affiliate of the owner or facility sells the OTC monograph drug produced at the

facility directly to wholesalers, retailers, or consumers in the United States.

(3) COSTS OF RESOURCES ALLOCATED FOR OTC MONOGRAPH DRUG ACTIVITIES.—The term ''costs of resources allocated for OTC monograph drug activities'' means the expenses, in connection with OTC monograph drug activities, for—

(A) officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to the officers, employees, and committees and costs related to contracts with the contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collection of fees under section 17977 of this title and accounting for resources allocated for OTC monograph drug activities.

(4) FDA ESTABLISHMENT IDENTIFIER.—The term ''FDA establishment identifier'' means the

unique number automatically generated by the FDA's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

(5) OTC MONOGRAPH DRUG.—The term ''OTC monograph drug'' means a nonprescription drug without an approved new drug application that is governed by the provisions of section 13118 of this title.

(6) OTC MONOGRAPH DRUG ACTIVITIES.—The term ''OTC monograph drug activities'' means activities of the Secretary associated with OTC monograph drugs and inspection of facilities associated with the OTC monograph drugs, including the following activities:

(A) The activities necessary for review and evaluation of OTC monographs and OTC monograph order requests, including—

(i) orders proposing or finalizing applicable conditions of use for OTC monograph drugs;

(ii) orders affecting status regarding general recognition of safety and effectiveness of an OTC monograph ingredient or

combination of ingredients under specified conditions of use;

(iii) all OTC monograph drug development and review activities, including intra-agency collaboration;

(iv) regulation and policy development activities related to OTC monograph drugs;

(v) development of product standards for products subject to review and evaluation;

(vi) meetings referred to in section 13118(j) of this title;

(vii) review of labeling prior to issuance of orders related to OTC monograph drugs or conditions of use; and

(viii) regulatory science activities related to OTC monograph drugs.

(B) Inspections related to OTC monograph drugs.

(C) Monitoring of clinical and other research conducted in connection with OTC monograph drugs.

(D) Safety activities with respect to OTC monograph drugs, including—

(i) collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports;

(ii) developing and using improved adverse event data-collection systems, including information technology systems; and

(iii) developing and using improved analytical tools to assess potential safety risks, including access to external databases.

(E) Other activities necessary for implementation of section 13118 of this title.

(7) OTC MONOGRAPH DRUG FACILITY.—

(A) IN GENERAL.—The term ''OTC monograph drug facility'' means a foreign or domestic business or other entity that—

(i) is—

(I) under 1 management, either direct or indirect; and

(II) at 1 geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;

(ii) includes a finished dosage form manufacturer facility in a contractual rela-

tionship with the sponsor of 1 or more OTC monograph drugs to manufacture or process the drugs; and

(iii) does not include a business or other entity whose only manufacturing or processing activities are 1 or more of the following: production of clinical research supplies, testing, or placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging.

(B) SEPARATE BUILDINGS OR LOCATIONS.—For purposes of subparagraph (A)(i)(II), separate buildings or locations within close proximity are considered to be at 1 geographic location or address if the activities conducted in the buildings or locations are—

(i) closely related to the same business enterprise;

(ii) under the supervision of the same local management; and

(iii) under a single FDA establishment identifier and capable of being inspected by the FDA during a single inspection.

(C) MULTIPLE MANAGEMENT.—If a business or other entity would meet criteria specified in subparagraph (A), but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, 1 per management entity, for purposes of this paragraph.

(8) OTC MONOGRAPH DRUG MEETING.—The term ''OTC monograph drug meeting'' means any meeting regarding the content of a proposed OTC monograph order request.

(9) OTC MONOGRAPH ORDER REQUEST.—The term ''OTC monograph order request'' means a request for an order submitted under section 13118(c)(5) of this title.

(10) PERSON.—The term ''person'' includes an affiliate of a person.

(11) REQUESTOR.—The term ''requestor'' has the meaning given the term in section 13118 of this title.

(12) SPONSOR.—The term ''sponsor'' has the meaning given the term in section 13118 of this title.

(13) TIER 1 OTC MONOGRAPH ORDER REQUEST.—The term ''Tier 1 OTC monograph order request'' means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request.

(14) TIER 2 OTC MONOGRAPH ORDER REQUEST.—

(A) IN GENERAL.—The term ''Tier 2 OTC monograph order request'' means, subject to subparagraph (B), an OTC monograph order request for—

(i) the reordering of existing information in the drug facts label of an OTC monograph drug;

(ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

(iii) modification to the directions for use section of the drug facts label of an

OTC monograph drug, if the modification conforms to changes made pursuant to section 13118(d)(3)(A) of this title;

(iv) the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;

(v) a change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or

(vi) addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

(B) DETERMINATION BY SECRETARY.—The Secretary may, based on program implementation experience or other factors found appropriate by the Secretary, characterize any OTC monograph order request as a Tier 2 OTC monograph order request (including recharacterizing a request from Tier 1 to Tier 2) and publish the determination in a proposed order issued pursuant to section 13118 of this title.

**§ 17977. Authority to assess and use OTC monograph fees**

(a) TYPES OF FEES.—The Secretary shall assess and collect fees in accordance with this section as follows:

(1) FACILITY FEE.—

(A) IN GENERAL.—Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility as determined under subsection (c).

(B) EXCEPTIONS.—

(i) FACILITIES THAT CEASE ACTIVITIES.—A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility—

(I) has ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year; and

(II) has updated its registration to reflect the change under the requirements for drug establishment registration set forth in section 13136 of this title.

(ii) CONTRACT MANUFACTURING ORGANIZATIONS.—The amount of the fee for a contract manufacturing organization facility shall be equal to $^2/_3$ of the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

(C) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (c).

(D) DUE DATE.—The facility fees required under subparagraph (A) shall be due on the later of—

(i) the first business day of June of that year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for that year.

(2) OTC MONOGRAPH ORDER REQUEST FEE.—

(A) IN GENERAL.—Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of the fee shall be—

(i) for a Tier 1 OTC monograph order request, $500,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)); and

(ii) for a Tier 2 OTC monograph order request, $100,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)).

(B) DUE DATE.—The OTC monograph order request fees required under subparagraph (A) shall be due on the date of submission of the OTC monograph order request.

(C) EXCEPTION FOR CERTAIN SAFETY CHANGES.—A person that is named as the requestor in an OTC monograph order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the OTC monograph order request seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen—

(i) a contraindication, warning, or precaution;

(ii) a statement about risk associated with misuse or abuse; or

(iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.

(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 OTC MONOGRAPH ORDER REQUEST.—If the Secretary determines that an OTC monograph request initially characterized as Tier 1 shall be recharacterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

(E) REFUND OF FEE IF ORDER REQUEST REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any order request that is refused for filing or was withdrawn before being accepted or refused for filing.

(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An OTC monograph order

request that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest.

(G) REFUND OF FEE IF ORDER REQUEST WITHDRAWN.—

(i) IN GENERAL.—If an order request is withdrawn after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed.

(ii) DISCRETION OF THE SECRETARY.—The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph.

(iii) REVIEWABILITY.—A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

(3) REFUNDS.—

(A) IN GENERAL.—Other than refunds provided pursuant to any of subparagraphs (D) through (G) of paragraph (2), the Secretary

shall not refund any fee paid under paragraph (1) except as provided in subparagraph (B).

(B) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under paragraph (1) or (2), a person shall submit to the Secretary a written request justifying the return within 180 calendar days after the fee was paid.

(4) NOTICE.—Within the timeframe specified in subsection (c), the Secretary shall publish in the Federal Register the amount of the fees under paragraph (1) for the fiscal year.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—For each of the fiscal years 2022 through 2025, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

(A) the annual base revenue for the fiscal year (as determined under paragraph (2));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if

applicable (as determined under subsection (c)(2));

(D) additional direct cost adjustments (as determined under subsection (c)(3)); and

(E) additional dollar amounts for each fiscal year as follows:

(i) $7,000,000 for fiscal year 2022.

(ii) $6,000,000 for fiscal year 2023.

(iii) $7,000,000 for fiscal year 2024.

(iv) $3,000,000 for fiscal year 2025.

(2) ANNUAL BASE REVENUE.—For purposes of paragraphs (1)(A), the dollar amount of the annual base revenue for a fiscal year shall be, for fiscal years 2022 through 2025, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made under subsection (c)(2) or (c)(3).

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—

(A) IN GENERAL.—For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

(i) the annual base revenue for that fiscal year under subsection (b)(1); and

(ii) the inflation adjustment percentage under subparagraph (C).

(B) OTC MONOGRAPH ORDER REQUEST FEES.—For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for each fiscal year shall be equal to the product of—

(i) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

(ii) the inflation adjustment percentage under subparagraph (C).

(C) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to, for each of fiscal years 2024 and 2025, the sum of—

(i) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to the positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and

benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years; and

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years.

(2) OPERATING RESERVE ADJUSTMENT.—

(A) IN GENERAL.—For each fiscal year, for purposes of subsection (b)(1)(C), the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for OTC monograph drug activities for not more than the number of weeks specified in subparagraph (B).

(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

(i) 10 weeks for fiscal year 2024; and

(ii) 10 weeks for fiscal year 2025.

(C) DECREASE.—If the Secretary has carryover balances for OTC monograph drug activities in excess of 10 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in the subparagraph to provide for not more than 10 weeks of the operating reserves.

(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (4) establishing fee revenue and fees for the fiscal year involved.

(3) ADDITIONAL DIRECT COST ADJUSTMENT.—The Secretary shall, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees for purposes of subsection (b)(1)(D) by an amount equal to—

(A) $7,000,000 for fiscal year 2022;

(B) $4,000,000 for fiscal year 2023;

(C) $3,000,000 for fiscal year 2024; and

(D) $3,000,000 for fiscal year 2025.

(4) ANNUAL FEE SETTING.—The Secretary shall, for each fiscal year, not later than the second Monday in March that precedes the fiscal year—

(A) establish for the fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

(i) OTC monograph drug facility fees under subsection (a)(1); and

(ii) OTC monograph order request fees under subsection (a)(2); and

(B) publish the fee revenue amounts, facility fees, and OTC monograph order request fees in the Federal Register.

(d) IDENTIFICATION OF FACILITIES.—Each person that owns an OTC monograph drug facility shall submit to the Secretary the information required under this subsection each year. The information shall, for each fiscal year—

(1) be submitted as part of the requirements for drug establishment registration set forth in section 13136 of this title; and

(2) include for each facility, at a minimum, identification of the facility's business operation as that of an OTC monograph drug facility.

(e) EFFECT OF FAILURE TO PAY FEES.—

(1) OTC MONOGRAPH DRUG FACILITY FEE.—

(A) IN GENERAL.—Failure to pay the fee under subsection (a)(1) within 20 calendar days of the due date as specified in subparagraph (D) of that subsection shall result in the following:

(i) The Secretary shall place the facility on a publicly available arrears list.

(ii) All OTC monograph drugs manufactured in the facility or containing an ingredient manufactured in the facility shall be deemed misbranded under section 13329 of this title.

(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(1) is paid.

(2) ORDER REQUESTS.—An OTC monograph order request submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary

until all fees owed by the person under this section have been paid.

(3) MEETINGS.—A person subject to fees under this section shall be considered ineligible for OTC monograph drug meetings until all such fees owed by the person have been paid.

(f) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation. The sums transferred shall be available solely for OTC monograph drug activities.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—Subject to subparagraph (C), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for the fiscal year.

(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available to defray increases in the costs of the resources allocated for OTC monograph drug activities (including increases in the costs for an additional number of full-time equivalent positions in the Department to be engaged in the activities) only if the Secretary allocates for that purpose an amount for the fiscal year (excluding amounts from fees collected under this section) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

(C) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs funded by appropriations and allocated for OTC monograph drug activities are not more than 15

percent below the level specified in the subparagraph.

(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for the fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2021 through 2025, there is authorized to be appropriated for fees under this section an amount equal to the total amount of fees assessed for the fiscal year under this section.

(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

(h) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department, for officers, employers, and advisory committees not engaged in OTC monograph drug activities, be reduced to offset the number of officers, em-

ployees, and advisory committees engaged in OTC monograph drug activities.

**§ 17978. Reauthorization; reporting requirements**

(a) PERFORMANCE REPORT.—Not later than 120 calendar days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the FDA in achieving the goals identified in the letters described in section 3861 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136, div. A, title III, 134 Stat. 458) during the fiscal year and the future plans of the FDA for meeting the goals.

(b) FISCAL REPORT.—Not later than 120 calendar days after the end of each fiscal year for which fees are collected under this subchapter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for the fees during the fiscal year and the use, by the FDA, of the fees collected for the fiscal year.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the FDA website.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC monograph drug activities for the first 5 fiscal years after fiscal year 2025, and for the reauthorization of this subchapter for the fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in the paragraph;

(B) publish the recommendations in the Federal Register;

(C) provide for a period of 30 calendar days for the public to provide written comments on the recommendations;

(D) hold a meeting at which the public may present its views on the recommendations; and

(E) after consideration of the public views and comments, revise the recommendations as necessary.

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2025, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received under the paragraph, and any changes made to the recommendations in response to the views and comments.

# Chapter 181—Information and Education

Sec.
18101. Information system.
18102. Electronic format for submissions.
18103. Education.

**§ 18101. Information system**

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the FDA requesting agency action.

**§ 18102. Electronic format for submissions**

(a) DRUGS AND BIOLOGICS.—

(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under section 13503, 13510, or 13511 of this title or subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262(a), (k)) shall be submitted in such electronic format as specified by the Secretary in the guidance.

(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by paragraph (1); and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) EXCEPTION.—This subsection shall not apply to submissions described in section 14301 of this title.

(b) DEVICES.—

(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, presubmissions and submissions for devices under section 13136(k), 13140(h)(2)(A), 13142(c), 13142(d), 13142(f), 13152(g), 13152(m), or 14306 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262), and any supplements to the presubmissions or submissions, shall include an electronic copy of the presubmissions or submissions.

(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

(A) provide standards for the electronic copy required under paragraph (1); and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) PRESUBMISSIONS AND SUBMISSIONS SOLELY IN ELECTRONIC FORMAT.—

(A) IN GENERAL.—Beginning on such date as the Secretary specifies in the final guidance

issued under subparagraph (C), presubmissions and submissions for devices described in paragraph (1) (and any appeals of action taken by the Secretary with respect to the presubmissions or submissions) shall be submitted solely in such electronic format as specified by the Secretary in the guidance.

(B) DRAFT GUIDANCE.—The Secretary shall, not later than October 1, 2019, issue draft guidance providing for—

(i) any further standards for the submission by electronic format required under subparagraph (A);

(ii) a timetable for the establishment by the Secretary of the further standards; and

(iii) criteria for waivers of and exemptions from the requirements of this subsection.

(C) FINAL GUIDANCE.—The Secretary shall, not later than 1 year after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance.

**§ 18103. Education**

(a) IN GENERAL.—The Secretary shall conduct training and education programs for the employees of the FDA relating to the regulatory responsibilities and policies established by this subtitle, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 17504 of this title;

(3) training to achieve product specialization in the inspections; and

(4) training in administrative process and procedure and integrity issues.

(b) INTRAMURAL FELLOWSHIPS AND OTHER TRAINING PROGRAMS.—

(1) IN GENERAL.—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians.

(2) VOLUNTARY SERVICES.—Any fellowships and training programs under this section or under section 19102(d)(2)(A)(ix) of this title may include provision by the scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. The scientists and

physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department.

# Chapter 183—Environmental Impact Review

Sec.
18301. Environmental impact.

### § 18301. Environmental impact

Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this subtitle shall be deemed to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).

# Chapter 185—National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics

Sec.
18501. National uniformity for nonprescription drugs.
18502. Preemption for labeling or packaging of cosmetics.

**§ 18501. National uniformity for nonprescription drugs**

(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), a State or political subdivision of a State shall not establish or continue in effect any requirement—

(1) that relates to the regulation of a drug that is not subject to the requirements of subsection (a)(1) or (e)(1)(A) of section 13103 of this title; and

(2) that is not identical with or that is in addition to a requirement under this subtitle, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) EXEMPTION.—

(1) IN GENERAL.—On application of a State or political subdivision of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in the regulation, a State or political subdivision requirement that—

(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

(C) would not unduly burden interstate commerce.

(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

(c) SCOPE.—

(1) IN GENERAL.—This section shall not apply to—

(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

(B) any State or political subdivision requirement that a drug be dispensed only on the prescription of a practitioner licensed by law to administer the drug.

(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or

any other form of public communication relating to a warning of any kind for a drug.

(d) EXCEPTIONS.—

(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under chapter 135 of this title or section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) (as in effect on November 20, 1997) or a final order under section 13118 of this title by the Secretary establishing conditions under which the drug is generally recognized as safe and effective, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is not identical with or is in addition to—

(A) a regulation or order in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made after November 20, 1997.

(2) STATE INITIATIVES.—This section shall not apply to a State requirement adopted by a State

public initiative or referendum enacted prior to September 1, 1997.

(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision of a State from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this subtitle.

**§ 18502. Preemption for labeling or packaging of cosmetics**

(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), a State or political subdivision of a State shall not establish or continue in effect any requirement for labeling or packaging of a cosmetic that is not identical with or that is in addition to a requirement specifically applicable to a particular cosmetic or class of cosmetics under this subtitle, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) EXEMPTION.—On application of a State or political subdivision of a State, the Secretary may by regulation, after notice and opportunity for written and oral

presentation of views, exempt from subsection (a), under such conditions as may be prescribed in the regulation, a State or political subdivision requirement for labeling or packaging that—

(1) protects an important public interest that would otherwise be unprotected;

(2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

(3) would not unduly burden interstate commerce.

(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of the cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this subtitle for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

# Chapter 187—Safety Reports

See.
18701. Safety reports as admission.

## § 18701. Safety reports as admission

(a) PRODUCT; INCLUSIONS.—In this section, the term ''product'' includes a product that is a food, drug, device, dietary supplement, or cosmetic.

(b) CONSTRUCTION OF SUBMISSION.—With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product under this subtitle (and any release by the Secretary of that report or information), the report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved—

(1) malfunctioned;

(2) caused or contributed to an adverse experience; or

(3) otherwise caused or contributed to a death, serious injury, or serious illness.

(c) NON-ADMISSION; DENIAL.—An entity under subsection (b) need not admit, and may deny, that the report

or information submitted by the entity constitutes an admission that the product involved—

(1) malfunctioned;

(2) caused or contributed to an adverse experience; or

(3) caused or contributed to a death, serious injury, or serious illness.

# Chapter 189—Serious Adverse Event Reports

Sec.
18901. Serious adverse event reporting for nonprescription drugs.
18902. Serious adverse event reporting for dietary supplements.

## § 18901. Serious adverse event reporting for nonprescription drugs

(a) DEFINITIONS.—In this section:

(1) ADVERSE EVENT.—

(A) IN GENERAL.—The term ''adverse event'' means any health-related event associated with the use of a nonprescription drug that is adverse.

(B) INCLUSIONS.—The term ''adverse event'' includes—

(i) an event occurring from an overdose of the drug, whether accidental or intentional;

(ii) an event occurring from abuse of the drug;

(iii) an event occurring from withdrawal from the drug; and

(iv) any failure of expected pharmacological action of the drug.

(2) NONPRESCRIPTION DRUG.—The term ''nonprescription drug'' means a drug that is—

(A) not subject to section 13103(a) of this title; and

(B) not subject to approval in an application submitted under chapter 135 of this title.

(3) SERIOUS ADVERSE EVENT.—The term ''serious adverse event'' is an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity; or

(v) a congenital anomaly or birth defect; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(4) SERIOUS ADVERSE EVENT REPORT.—The term ''serious adverse event report'' means a report that is required to be submitted to the Secretary under subsection (b).

(b) REPORTING REQUIREMENT.—

(1) IN GENERAL.—The manufacturer, packer, or distributor whose name (pursuant to section 13302(a)(1) of this title) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the ''responsible person'') shall submit to the Secretary any report received of a serious adverse event associated with the nonprescription drug when used in the United States, accompanied by a copy of the label on or within the retail package of the nonprescription drug.

(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the nonprescription drug to submit the required reports for the drugs to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with the drug that are reported to the retailer through

the address or telephone number described in section 13321 of this title.

(c) SUBMISSION OF REPORTS.—

(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report not later than 15 business days after the report is received through the address or phone number described in section 13321 of this title.

(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, not later than 15 business days after the new information is received by the responsible person.

(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the

Secretary determines that the exemption would have no adverse effect on public health.

(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for nonprescription drugs, and may be accompanied by additional information.

(e) MAINTENANCE AND INSPECTION OF RECORDS.—

(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

(2) RECORDS INSPECTION.—

(A) DEFINITION OF AUTHORIZED INDIVIDUAL.—In this paragraph, the term ''authorized individual'' means an officer or employee of the Department who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been designated by the Secretary to have access to the records required under this section.

(B) IN GENERAL.—The responsible person shall permit an authorized individual, during an inspection pursuant to section 17504 of this

title, to have access to records required to be maintained under this section.

(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

(1) a safety report under section 18701 of this title, and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5 and a medical or similar file the disclosure of which would constitute a violation of section 552 of title 5, and shall not be publicly disclosed unless all personally identifiable information is redacted.

(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the nonprescription drug involved caused or contributed to the adverse event.

(h) PREEMPTION.—

(1) IN GENERAL.—A State or local government shall not establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for nonprescription drugs, that is not identical to or that is in addition to this section.

(2) EFFECT OF SECTION.—

(A) IN GENERAL.—Nothing in this section affects the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory of the United States, or political subdivision of a State or territory of the United States, under a memorandum of understanding between the Secretary and the State, territory of the United States, or political subdivision.

(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory of the United States, or political subdivision of a State or territory of the United States shall not—

(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting the information to the Secretary.

(C) USE OF SAFETY REPORTS.—Nothing in this section permits a State, territory of the United States, or political subdivision of a State or territory of the United States to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 18701 of this title.

(i) CONSISTENCY WITH INTERNATIONAL HARMONIZATION EFFORTS.—The Secretary may modify requirements under this section and the amendments made by section 2 of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462, 120 Stat. 3469) in accordance with section 553 of title 5 to maintain consistency with international harmonization efforts over time.

**§ 18902. Serious adverse event reporting for dietary supplements**

(a) DEFINITIONS.—In this section:

(1) ADVERSE EVENT.—The term ''adverse event'' means any health-related event associated with the use of a dietary supplement that is adverse.

(2) SERIOUS ADVERSE EVENT.—The term ''serious adverse event'' is an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity; or

(v) a congenital anomaly or birth defect; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(3) SERIOUS ADVERSE EVENT REPORT.—The term ''serious adverse event report'' means a report that is required to be submitted to the Secretary under subsection (b).

(b) REPORTING REQUIREMENT.—

(1) IN GENERAL.—The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 11305(1) of this title) appears

on the label of a dietary supplement marketed in the United States (referred to in this section as the ''responsible person'') shall submit to the Secretary any report received of a serious adverse event associated with the dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of the dietary supplement.

(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for the dietary supplement to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with the dietary supplement that are reported to the retailer through the address or telephone number described in section 11319 of this title.

(c) SUBMISSION OF REPORTS.—

(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report not later than 15 business days after the report is received through the address or phone number described in section 11319 of this title.

(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, not later than 15 business days after the new information is received by the responsible person.

(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that the exemption would have no adverse effect on public health.

(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

(e) MAINTENANCE AND INSPECTION OF RECORDS.—

(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

(2) RECORDS INSPECTION.—

(A) DEFINITION OF AUTHORIZED INDIVIDUAL.—In this paragraph, the term ''authorized individual'' means an officer or employee of the Department, who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been designated by the Secretary to have access to the records required under this section.

(B) IN GENERAL.—The responsible person shall permit an authorized individual to have access to records required to be maintained under this section during an inspection pursuant to section 17504 of this title.

(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

(1) a safety report under section 18701 of this title, and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5 and a medical or similar file the disclosure of which would constitute a violation of section 552 of title 5, and shall not be publicly disclosed unless all personally identifiable information is redacted.

(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.

(h) PREEMPTION.—

(1) IN GENERAL.—A State or local government shall not establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is not identical to or that is in addition to this section.

(2) EFFECT OF SECTION.—

(A) IN GENERAL.—Nothing in this section affects the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory of the United States, or political subdivision of a State or territory of the United States, under a memorandum of understanding between the Secretary and the State, territory of the United States, or political subdivision.

(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory of the United States, or political subdivision of a State or territory of the United States, shall not—

(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting the information to the Secretary.

(C) USE OF SAFETY REPORTS.—Nothing in this section permits a State, territory of the United States, or political subdivision of a State or territory of the United States, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 18701 of this title.

# Chapter 191—Reagan-Udall Foundation for the Food and Drug Administration

Sec.
19101. Definitions.
19102. Establishment and functions of the Foundation.
19103. Location of Foundation.
19104. Activities of the FDA.

## § 19101. Definitions

In this chapter:

(1) BOARD.—The term ''Board'' means the Board of Directors established under section 19102(d)(1)(A) of this title.

(2) FOUNDATION.—The term ''Foundation'' means the Reagan-Udall Foundation for the Food and Drug Administration established in section 19102(a)(1) of this title.

## § 19102. Establishment and functions of the Foundation

(a) ESTABLISHMENT.—

(1) IN GENERAL.—A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration shall be established in accordance with this section.

(2) HEAD.—The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (f).

(3) NOT A FEDERAL AGENCY.—The Foundation shall not be an agency or instrumentality of the United States Government.

(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

(c) DUTIES OF THE FOUNDATION.—The Foundation shall—

(1) taking into consideration the Critical Path reports and priorities published by the FDA, identify unmet needs in—

(A) the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of devices (including diagnostics, biologics, and drugs); and

(B) the safety of food, food ingredients, and cosmetics, including the incorporation of more sensitive and predictive tools and devices to measure safety;

(2) establish goals and priorities to meet the unmet needs identified in paragraph (1);

(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with the programs, and minimize Foundation duplication of existing efforts;

(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the FDA, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) (and exempt from tax under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a))), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of the material, reagents, and techniques for use by the FDA, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

(7) ensure that—

(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation; and

(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other like instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial

applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

(8) provide objective clinical and scientific information to the FDA and, upon request, to other Federal agencies to assist in agency determinations of how to ensure that regulatory policy accommodates scientific advances and meets the agency's public health mission;

(9) conduct annual assessments of the unmet needs identified in paragraph (1); and

(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

(d) BOARD OF DIRECTORS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Foundation shall have a Board of Directors, which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) EX OFFICIO MEMBERS.—The ex officio members of the Board, who shall be nonvoting members of the Board, shall be the following individuals or their designees:

(i) The Commissioner.

(ii) The Director of the National Institutes of Health.

(C) APPOINTED MEMBERS.—

(i) IN GENERAL.—The initial members of the Board appointed by the ex officio members described in subsection (d)(1)(B) (as in effect on the day before the enactment of this title) shall consist of 14 individuals, of which 9 shall be from a list of candidates to be provided by the National Academy of Sciences and 5 shall be from lists of candidates provided by patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations. Of the appointed members—

(I) 4 shall be representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;

(II) 3 shall be representatives of academic research organizations;

(III) 2 shall be representatives of patient or consumer advocacy organizations;

(IV) 1 shall be a representative of health care providers; and

(V) 4 shall be at-large members with expertise or experience relevant to the purpose of the Foundation.

(ii) ADDITIONAL MEMBERS.—

(I) AMENDMENT TO BYLAWS.—The Board, through an amendment to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in the amendment) greater than 14.

(II) APPOINTMENT; LIMITATIONS.—Any Board positions that are established by any amendment under subclause (I) shall be appointed (by majority vote) by the individuals who, as of the date of the amendment, are voting members of the Board and individuals appointed under this subclause may represent any of the cat-

egories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by the amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.

(iii) REQUIREMENTS.—

(I) EXPERTISE.—The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure that the Board membership includes individuals with expertise in areas, including the sciences, of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

(II) FEDERAL EMPLOYEES.—

(aa) EMPLOYEE OF THE FEDERAL GOVERNMENT.—In this

subclause, the term ''employee of the Federal Government'' does not include a special Government employee, as that term is defined in section 202(a) of title 18.

(bb) IN GENERAL.—No employee of the Federal Government shall be appointed as a member of the Board under this subparagraph or under paragraph (3)(B).

(D) CHAIR.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as the Chair of the Board.

(2) DUTIES OF THE BOARD.—The Board shall—

(A) establish bylaws for the Foundation that—

(i) are published in the Federal Register and available for public comment;

(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including appropriate limits on the ability of donors to designate, by stipulation or restriction, the use or recipient of donated funds;

(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18;

(v) establish licensing, distribution, and publication policies that—

(I) support the widest and least restrictive use by the public of information and inventions developed by the Foundation or with Foundation funds to carry out the duties described in paragraphs (6) and (7) of subsection (c); and

(II) may include charging cost-based fees for published material produced by the Foundation;

(vi) specify principles for the review of proposals and awarding of grants and contracts that include peer review and that are consistent with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board;

(vii) specify a cap on administrative expenses for recipients of a grant, contract, or cooperative agreement from the Foundation;

(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the FDA;

(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the FDA, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostics, manufacturing techniques, and potential barriers to trans-

lating basic research into clinical and regulatory practice;

(x) specify a process for annual Board review of the operations of the Foundation; and

(xi) establish specific duties of the Executive Director;

(B) prioritize and provide overall direction to the activities of the Foundation;

(C) evaluate the performance of the Executive Director; and

(D) carry out any other necessary activities regarding the functioning of the Foundation.

(3) TERMS AND VACANCIES.—

(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

(i) the terms of offices for the members of the Board appointed under paragraph (1)(C)(i) shall be on a staggered basis (as established by the staggered expi-

ration of terms under this clause as in effect on the day before the enactment of this title); and

(ii) the terms of office for the individuals initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing the positions, are members of the Board.

(B) VACANCY.—Any vacancy in the membership of the Board—

(i) shall not affect the power of the remaining members to execute the duties of the Board; and

(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the re-

mainder of the term of the predecessor of the individual.

(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) COMPENSATION.—

(A) IN GENERAL.—Members of the Board may not receive compensation for service on the Board.

(B) OTHER EXPENSES.—Members of the Board may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(e) NONPROFIT STATUS.—In carrying out subsection (b), the Board shall establish such policies and bylaws under subsection (d), and the Executive Director shall carry out such activities under subsection (f), as may be necessary to ensure that the Foundation maintains status as an organization that—

(1) is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)); and

(2) is, under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)), exempt from taxation.

(f) EXECUTIVE DIRECTOR.—

(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board.

(g) ADMINISTRATIVE POWERS.—In carrying out this chapter, the Board, acting through the Executive Director, may—

(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

(3) prescribe the manner in which—

(A) real or personal property of the Foundation is acquired, held, and transferred;

(B) general operations of the Foundation are to be conducted; and

(C) the privileges granted to the Board by law are exercised and enjoyed;

(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of the department or agency in carrying out this section;

(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (h);

(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation;

(8) modify, or consent to the modification of, any contract or agreement to which it is a party or in which it has an interest under this chapter;

(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this chapter.

(h) ACCEPTANCE OF FUNDS FROM OTHER SOURCES.—The Executive Director may solicit and accept on behalf of the Foundation any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

(i) SERVICE OF FEDERAL EMPLOYEES.—Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as the employees do not direct or control Foundation activities.

(j) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

(1) DETAIL FROM FEDERAL AGENCIES.—

(A) IN GENERAL.—Federal employees may be detailed from Federal agencies to the Foundation at any time, with or without reimbursement to those agencies, and the detail shall be

without interruption or loss of civil service status or privilege.

(B) STATUTORY, REGULATORY, ETHICAL, AND PROCEDURAL STANDARDS.—Each employee detailed under subparagraph (A) shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which the employee is detailed and those of the Foundation.

(2) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

(A) FOUNDATION.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

(B) FDA.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. The services shall be considered to be an undertaking of an activity under contract with the Secretary as described in section 17508 of this title.

(k) ANNUAL REPORTS.—

(1) REPORTS TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of un-

derstanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of the grant, contract, fellowship, memorandum of understanding, or cooperative agreement, which report describes the activities carried out under the grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

(2) REPORT TO CONGRESS AND THE COMMISSIONER.—The Executive Director shall submit to Congress and the Commissioner an annual report that—

(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out the activities; and

(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the FDA.

(l) SEPARATION OF FUNDS.—The Executive Director shall ensure that the funds received from the Treasury are managed as individual programmatic funds under subsection (h), according to best accounting practices.

(m) FUNDING.—From amounts appropriated to the FDA for each fiscal year, the Commissioner shall transfer not less than $1,250,000 and not more than $5,000,000, to the Foundation to carry out subsections (a), (b), and (d) through (l).

**§ 19103. Location of Foundation**

The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

**§ 19104. Activities of the FDA**

(a) ASSESSMENT BY COMMISSIONER OF REPORT FROM FOUNDATION.—The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 19102(k)(2) of this title.

(b) REPORT TO CONGRESS.—The Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 19102(k)(2) of this title and by other recipients of grants, contracts, memoranda of understanding, or cooperative agreements into regulatory and product review activities of the FDA.

(c) EFFECT OF CHAPTER ON GRANTS, CONTRACTS, MEMORANDA OF UNDERSTANDING, AND COOPERATIVE AGREEMENT.—The provisions of this chapter and section 14312 of this title do not affect any grant, contract, memorandum of understanding, or cooperative agreement between the FDA and any other entity entered into before, on, or after September 27, 2007.

# Division G—Imports and Exports

# Chapter 201—Imports and Exports

Sec.
20101. Imports and exports.
20102. Exports of certain unapproved products.
20103. Office of International Relations.
20104. Importation of prescription drugs.
20105. Foreign supplier verification program.
20106. Voluntary qualified importer program.
20107. Inspection of foreign food facilities.
20108. Accreditation of third-party auditors.
20109. Recognition of foreign government inspections.

## § 20101. Imports and exports

(a) IN GENERAL.—

(1) DELIVERY OF SAMPLES ON REQUEST BY SECRETARY.—The Secretary of the Treasury shall deliver to the Secretary, on the Secretary's request, samples of food, drugs, devices, tobacco products, and cosmetics that are being imported or offered for import into the United States, giving notice of the delivery to the owner or consignee, who may appear before the Secretary and have the right to introduce testimony.

(2) LIST OF ESTABLISHMENTS; SAMPLES FROM UNREGISTERED FOREIGN ESTABLISHMENTS.—The Secretary—

(A) shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to section 13136(i) of this title or section 21106(h) of this title; and

(B) shall request that if any drugs, devices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not registered pursuant to the provisions referred to in subparagraph (A) are imported or offered for import into the United States, samples of the drugs, devices, or tobacco products be delivered to the Secretary, with notice of the delivery to the owner or consignee, who may appear before the Secretary and have the right to introduce testimony.

(3) ARTICLES TO BE REFUSED ADMISSION.—

(A) IN GENERAL.—Any article described in clauses (i) through (v) shall be refused admission, except as provided in subsection (b), if it appears from the examination of the samples or otherwise that—

(i)(I) the article has been manufactured, processed, or packed under insanitary conditions; or

(II) in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 13152(f) of this title;

(ii) the article is forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii)(I) the article—

(aa) is adulterated, misbranded, or in violation of chapter 135 of this title or prohibited from introduction or delivery for introduction into interstate commerce under section 10501(36) of this title; or

(bb) is a controlled substance subject to an order under section 14320 of this title; or

(II) the importer (as defined in section 20105 of this title) is in violation of section 20105 of this title;

(iv) the recordkeeping requirements under section 32533 of this title (other than the requirements under subsection (f) of that section) have not been complied with regarding the article; or

(v) the article is being imported or offered for import in violation of section 10501(27) of this title.

(B) COUNTERFEIT DRUGS AND COUNTERFEIT DEVICES.—If it appears from the examination of the samples or otherwise that the article is a counterfeit drug or counterfeit device, the article shall be refused admission.

(C) CERTIFICATION OF COMPLIANCE WITH SUBTITLE.—With respect to an article of food, if importation of the food is subject to, but not compliant with, the requirement under subsection (q) that the food be accompanied by a certification or other assurance that the food meets applicable requirements of this subtitle, the article shall be refused admission.

(D) SERIOUS ADVERSE EVENT REPORTING.—If the article is subject to a requirement under section 17121, 18901, or 18902 of this title and if the Secretary has credible evidence or information indicating that the responsible person (as defined in section 17101, 18901, or 18902 of this title) has not complied with a requirement of section 17121, 18901, or 18902 of this title with respect to the article, or has not allowed access to records described in section 17121, 18901, or 18902 of this title, the article shall be refused admission, except as provided in subsection (b).

(E) EFFECT OF CERTAIN PROVISIONS ON ADMISSION OF NARCOTIC DRUGS.—Neither clause (ii) nor clause (v) of subparagraph (A) shall be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under division B of subtitle V of this title.

(4) DESTRUCTION OF ARTICLES REFUSED ADMISSION.—

(A) IN GENERAL.—The Secretary of the Treasury shall cause the destruction of any article refused admission under this subsection

unless the article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of the refusal or within such additional time as may be permitted pursuant to the regulations.

(B) DESTRUCTION WITHOUT OPPORTUNITY FOR EXPORT.—Notwithstanding subparagraph (A), the Secretary may destroy, without the opportunity for export, any drug or device refused admission under this section, if the drug or device—

(i) is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1))); and

(ii) was not brought into compliance as described under subsection (b).

(5) NOTICE AND OPPORTUNITY TO APPEAR AND INTRODUCE TESTIMONY.—

(A) ISSUANCE OF REGULATIONS.—The Secretary shall issue regulations providing for notice and an opportunity to appear before the Secretary and introduce testimony, as described

in paragraph (1), on destruction of a drug or device under paragraph (4).

(B) DUE PROCESS.—The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device.

(C) STORAGE AND DISPOSITION.—If the Secretary provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c).

(D) COMBINED PROCESS.—The process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in paragraph (1), as long as appropriate notice is provided to the owner or consignee.

(b) DISPOSITION OF REFUSED ARTICLES.—

(1) BOND.—Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize

delivery of the article to the owner or consignee on the execution by the owner or consignee of a good and sufficient bond providing for such payment of the liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(2) CONDITION AND AUTHORIZATIONS RELATING TO BOND.—

(A) CONDITION.—Subparagraph (B) applies if it appears to the Secretary that—

(i) an article included within the provisions of subsection (a)(3)(A)(iii) can, by relabeling or other action, be brought into compliance with this subtitle or rendered other than a food, drug, device, or cosmetic; or

(ii) with respect to an article described in subsection (a)(3)(D), the responsible person (as defined in section 17101, 18901, or 18902 of this title) can take action that would ensure that the responsible person is in compliance with section 17121, 18901, or 18902 of this title, as the case may be.

(B) DEFERMENT OF DETERMINATION ON ADMISSION OF ARTICLE; OTHER AUTHORIZATIONS.—If the condition under subparagraph (A) applies—

(i) final determination as to admission of the article may be deferred; and

(ii) on filing of timely written application by the owner or consignee and the execution by the owner or consignee of a bond as provided in paragraph (1), the Secretary may, in accordance with regulations, authorize the applicant, or, with respect to subparagraph (A)(ii), the responsible person, to perform the relabeling or other action specified in the authorization (including destruction or export of rejected articles or portions of the articles, as may be specified in the Secretary's authorization).

(C) SUPERVISION OF ACTIONS.—All relabeling or other action pursuant to the authorization under subparagraph (B)(ii) shall, in accordance with regulations, be under the supervision of an officer or employee of the Department designated by the Secretary, or an officer

or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) CHARGES CONCERNING REFUSED ARTICLES.—All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) and the supervision of the relabeling or other action authorized under subsection (b), the amount of the expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a), shall be paid by the owner or consignee and, in default of the payment, shall constitute a lien against any future importations made by the owner or consignee.

(d) REIMPORTATION.—

(1) IN GENERAL.—

(A) DRUGS MANUFACTURED IN A STATE.—Except as provided in paragraph (2) and section 20104 of this title, a drug subject to section 13103(a) of this title or composed wholly or partly of insulin that is manufactured in a State and exported shall not be imported into the United States unless the drug is imported by the manufacturer of the drug.

(B) DRUGS MANUFACTURED OUTSIDE THE UNITED STATES.—Except as authorized by the Secretary in the case of a drug that appears on the drug shortage list under section 13125 of this title or in the case of importation pursuant to section 20104 of this title, a drug that is subject to section 13103(a)(1) of this title shall not be imported into the United States for commercial use if the drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States.

(2) EMERGENCY MEDICAL CARE.—The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

(3) CONDITIONS FOR REIMPORTATION.—

(A) IN GENERAL.—Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of a device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, in-

cluding a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

(i) The importer of the article of a drug or device or importer of the article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

(I) The statement provides that the article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e), section 20102 of this title, or section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)).

(II) The statement identifies the manufacturer of the article and each

processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to the importer of the article.

(III) The statement is accompanied by such certificates of analysis as are necessary to identify the article, unless the article is a device or is an article described in paragraph (4).

(ii) At the time of initial importation and before the delivery of the article to the importer or the initial owner or consignee, the owner or consignee executes a good and sufficient bond providing for the payment of the liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(iii) The article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

(iv) The initial owner or consignee maintains records on the use or destruction of the article or portions of the article, as the case may be, and submits to the Secretary any such records requested by the Secretary.

(v) On request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of the article or portions of the article, and the manner in which the owner or consignee complied with the requirements of this subparagraph.

(B) EXCEPTION.—Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under subparagraph (A) if the Secretary determines that there is credible evidence or information indicating that the article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary

supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e), section 20102 of this title, or section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)).

(C) EFFECT OF SECTION.—This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under the authority of subparagraph (A) meet each of the conditions established in subparagraph (A) for importation.

(4) COMPLIANCE WITH CERTAIN PROVISIONS OF THE PUBLIC HEALTH SERVICE ACT.—

(A) BLOOD, BLOOD COMPONENTS, SOURCE PLASMA, AND SOURCE LEUKOCYTES.—The importation into the United States of blood, blood components, source plasma, or source leukocytes or of a component, accessory, or part of the blood, blood components, source plasma, or source leukocytes is not permitted pursuant to paragraph (3) unless the importation complies with section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) or the Secretary permits the importation under appropriate cir-

cumstances and conditions, as determined by the Secretary.

(B) TISSUE.—The importation of tissue or a component or part of tissue is not permitted pursuant to paragraph (3) unless the importation complies with section 361 of the Public Health Service Act (42 U.S.C. 264).

(e) EXPORTS.—

(1) IN GENERAL.—A food, drug, device, tobacco product or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this subtitle, and a tobacco product intended for export shall not be deemed to be in violation of section 21107(e), 21108, 21112, or 21121(a) of this title, if it—

(A) accords to the specifications of the foreign purchaser;

(B) is not in conflict with the laws of the country to which it is intended for export;

(C) is labeled on the outside of the shipping package that it is intended for export; and

(D) is not sold or offered for sale in domestic commerce.

(2) DEVICES TO WHICH PARAGRAPH (1) IS INAPPLICABLE.—

(A) DEVICES.—A device under this subparagraph is a device—

(i) that does not comply with an applicable requirement of section 13141 or 13142 of this title;

(ii) that, under section 13152(g) of this title, is exempt from section 13141 or 13142 of this title; or

(iii) that is a banned device under section 13146 of this title.

(B) INAPPLICABILITY OF PARAGRAPH (1).—Paragraph (1) does not apply to any device under subparagraph (A) unless, in addition to the requirements of paragraph (1)—

(i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export; or

(ii) the device is eligible for export under section 20102 of this title.

(3) NEW ANIMAL DRUGS.—A new animal drug that requires approval under chapter 137 of this title shall not be exported pursuant to paragraph (1) if the drug has been banned in the United States.

(4) CERTIFICATION.—

(A) IN GENERAL.—

(i) REQUEST.—Any person that exports a food, drug, animal drug, or device may request that the Secretary—

(I) certify in writing that the exported food, drug, animal drug, or device meets the requirements of paragraph (1) or section 20102 of this title; or

(II) certify in writing that the food, drug, animal drug, or device being exported meets the applicable requirements of this subtitle on a showing that the food, drug, animal drug, or device meets the applicable requirements of this subtitle.

(ii) ISSUANCE.—The Secretary shall issue the certification under clause (i) within 20 days of the receipt of a request for the certification.

(B) FEE.—

(i) IN GENERAL.—If the Secretary issues a written export certification within the 20 days prescribed by subparagraph

(A), a fee not to exceed $175 may be charged for the certification.

(ii) ACCOUNT; AVAILABILITY.—Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the FDA and shall be available in accordance with appropriations Acts until expended without fiscal year limitation.

(iii) AMOUNT.—Fees under this subparagraph shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for the fiscal year and shall be collected and available only for the costs of the FDA.

(iv) LIMITATIONS RELATING TO FEES IN CONNECTION WITH WRITTEN EXPORT CERTIFICATIONS FOR FOOD.—

(I) AVAILABLE ONLY FOR COSTS OF ISSUANCE OF CERTIFICATIONS.—Fees under this subparagraph in connection with written export certifications for food shall be collected and available solely for the costs of the

FDA associated with issuing the certifications.

(II) FISCAL YEAR COSTS ONLY.—Fees under this subparagraph in connection with written export certifications for food may not be retained in an amount that exceeds the costs for the respective fiscal year.

(C) BASIS AND FORM.—For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.

(D) DENIAL OF REQUEST FOR CERTIFICATION.—

(i) IN GENERAL.—

(I) DENIAL TO BE IN WRITING.—If the Secretary denies a request for certification under subparagraph (A)(i)(II) with respect to a device manufactured in an establishment (foreign or domestic) registered under section 13136 of this title, the Secretary shall—

(aa) provide in writing to the person seeking the certification the basis for the denial; and

(bb) specifically identify the finding on which the denial is based.

(II) SUBSTANTIVE SUMMARY OF SPECIFIC GROUNDS.—If the denial of a request as described in subclause (I) is based on grounds other than an injunction proceeding pursuant to section 10502 of this title, a seizure action pursuant to section 10504 of this title, or a recall designated Class I or Class II pursuant to part 7 of title 21, Code of Federal Regulations, and is based on the facility being out of compliance with part 820 of title 21, Code of Federal Regulations, the Secretary shall provide a substantive summary of the specific grounds for noncompliance identified by the Secretary.

(III) ESTABLISHMENTS THAT RECEIVED A REPORT UNDER SECTION 17504(b).—With respect to a device manufactured in an establishment that has received a report under section 17504(b) of this title, the Secretary shall not deny a request for certification as described in subclause (I) with respect to a device based solely on the issuance of that report if the owner, operator, or agent in charge of the establishment has agreed to a plan of correction in response to the report.

(ii) PROCESS FOR REQUESTING REVIEW OF DENIAL.—

(I) IN GENERAL.—The Secretary shall provide a process for a person that is denied a certification as described in clause (i)(I) to request a review that conforms to the standards of section 13148(b) of this title.

(II) REQUEST FOR REVIEW AFTER CORRECTIVE ACTIONS.—Notwithstanding any previous review con-

ducted pursuant to subclause (I), a person that has been denied a certification as described in clause (i)(I) may at any time request a review in order to present new information relating to actions taken by the person to address the reasons identified by the Secretary for the denial of certification, including evidence that corrective actions are being or have been implemented to address grounds for noncompliance identified by the Secretary.

(III) GUIDANCE.—The Secretary shall issue final guidance providing for a process to carry out this subparagraph.

(E) CERTIFICATES TO FOREIGN GOVERNMENTS.—

(i) APPLICABILITY TO CERTAIN DEVICES.—This paragraph applies to requests for certification under this subparagraph of a device manufactured by a device establishment located outside of the United States that is registered under section

13136 of this title, if the device is listed pursuant to section 13136(j) of this title, the device has been cleared, approved, or is not required to submit a premarket report pursuant to subsection (l) or (m) of section 13136 of this title, and the device is imported or offered for import into the United States.

(ii) ISSUANCE OF CERTIFICATION.—The Secretary shall issue the certification as described in clause (iii) if the device or devices for which certification is requested under this subparagraph meet the applicable requirements of this subtitle.

(iii) CERTIFICATION REQUIREMENTS.—

(I) FEE.—A certification for a device described in clause (i) shall be subject to the fee described in subparagraph (B).

(II) SAME MATERIAL INFORMATION AS CERTIFICATES TO FOREIGN GOVERNMENT.—Notwithstanding subparagraph (C), a certification for a device described in clause (i) shall ad-

dress and include the same material information as a ''Certificate to Foreign Government'' and shall have a document title including the words ''Certificate to Foreign Government''.

(iv) REQUIREMENTS AND PROCEDURES.—The requirements and procedures of subparagraph (D) shall apply to a denial of a certification under this subparagraph.

(f) LABELING OF EXPORTED DRUGS.—

(1) AUTHORITY TO COMPLY WITH FOREIGN COUNTRY REQUIREMENTS.—If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 20102 of this title) being exported in accordance with subsection (e) is being exported to a country that has different or additional labeling requirements or conditions for use and the country requires the drug to be labeled in accordance with those requirements or uses, the drug may be labeled in accordance with the requirements and conditions for use in the country to which the drug is being exported if it also is labeled in accordance with the requirements of this subtitle.

(2) LABELING TO STATE UNAPPROVED CONDITIONS OF USE.—

(A) IN GENERAL.—If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this subtitle, the labeling shall state that the conditions for use have not been approved under this subtitle.

(B) EXEMPTION.—A drug exported under section 20102 of this title is exempt from this section.

(g) WARNING NOTICE OF IMPORTATION IN VIOLATION OF SUBTITLE.—

(1) DEFINITION OF WARNING NOTICE.—In this subsection, the term ''warning notice'', with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this subtitle.

(2) CONDITIONS FOR WARNING INDIVIDUALS NOT IN THE BUSINESS OF IMPORTATION.—With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the

business of such an importation, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of subsection (a) because the drug is or appears to be adulterated, misbranded, or in violation of chapter 135 of this title;

(ii) importation is in violation of subsection (a) because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of subsection (d)(1); or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying the determination by the Secretary, including a brief application to the principal facts

involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(h) PROTECTION AGAINST ADULTERATION OF FOOD.—

(1) INCREASE IN THE NUMBER OF INSPECTIONS.—The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) IMPROVEMENTS TO INFORMATION MANAGEMENT SYSTEMS.—The Secretary shall give high priority to making necessary improvements to the information management systems of the FDA that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this subtitle.

(3) IMPROVING LINKAGES WITH REGULATORY AGENCIES, STATES, AND INDIAN TRIBES.—The Sec-

retary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall, with respect to the safety, improve linkages with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e))).

(i) TESTING FOR RAPID DETECTION OF ADULTERATION OF FOOD.—

(1) RESEARCH ON THE DEVELOPMENT OF TESTS AND SAMPLING METHODOLOGIES.—For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) PRIORITIZING TESTS FOR INSPECTIONS AT PORTS OF ENTRY.—In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that

are suitable for inspections of food at ports of entry into the United States.

(3) COORDINATION.—In providing for research under paragraph (1), the Secretary shall, as appropriate, coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) REPORT.—The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).

(j) TEMPORARY HOLDS AT PORTS OF ENTRY.—

(1) IN GENERAL.—If an officer or qualified employee of the FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and the officer or qualified employee is unable to inspect, examine, or investigate the article upon the article being offered for import at a port of entry into the United States,

the officer or qualified employee shall request the Secretary of the Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

(2) REMOVING OR TRANSFERRING OF ARTICLE.—

(A) REMOVING ARTICLE TO SECURE FACILITY.—The Secretary shall request the Secretary of the Treasury to remove an article held under paragraph (1) to a secure facility, as appropriate.

(B) TRANSFER OF ARTICLE.—During the period of time that the article is held under paragraph (1) (including after removal under subparagraph (A)), the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(C) EFFECT OF SUBSECTION (b).—Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is held under paragraph (1)

(including after removal under subparagraph (A)).

(3) REQUEST FOR HOLD BY OFFICER OR QUALIFIED EMPLOYEE OF THE FDA.—

(A) IN GENERAL.—An officer or qualified employee of the FDA may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request.

(B) DESIGNATION OF OFFICIAL.—An official may not be designated under subparagraph (A) unless the official is the director of the district under this subtitle in which the article involved is located, or is an official senior to the director.

(4) NOTIFICATION OF STATE OF PORT OF ENTRY.—With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that the article is being held under this subsection.

(k) IMPORTATION BY DEBARRED PERSONS.—

(1) TEMPORARY HOLD AT PORT OF ENTRY.—

(A) IN GENERAL.—If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person that has been debarred under section 10506(b)(3) of this title, the article shall be held at the port of entry for the article, and may not be delivered to the person.

(B) EFFECT OF SUBSECTION (b).—Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is held under this subsection.

(C) REMOVAL TO SECURE FACILITY.—The article shall be removed to a secure facility, as appropriate.

(D) TRANSFER OF ARTICLE.—During the period of time that the article is held under this paragraph (including after removal under subparagraph (C)), the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(2) DELIVERY TO PERSON NOT DEBARRED.—An article of food held under paragraph (1) may be

delivered to a person that is not a debarred person under section 10506(b)(3) of this title if the person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this subtitle, as determined by the Secretary.

(l) FAILURE TO REGISTER.—

(1) TEMPORARY HOLD AT PORT OF ENTRY.—If an article of food is being imported or offered for import into the United States, and the article is from a foreign facility for which a registration has not been submitted to the Secretary under section 11117 of this title (or for which a registration has been suspended under section 11117 of this title), the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is registered under section 11117 of this title.

(2) EFFECT OF SUBSECTION (b).—Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is held under this subsection.

(3) REMOVAL TO SECURE FACILITY.—The article shall be removed to a secure facility, as appropriate.

(4) TRANSFER OF ARTICLE.—During the period of time that the article is held under this subsection (including after removal under paragraph (3)), the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(m) PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.—

(1) REQUIRED SUBMISSION.—

(A) IN GENERAL.—In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling the article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of—

(i) the article;

(ii) the manufacturer and shipper of the article;

(iii) if known within the specified period of time that notice is required to be provided, the grower of the article;

(iv) the country from which the article originates;

(v) the country from which the article is shipped;

(vi) any country to which the article has been refused entry; and

(vii) the anticipated port of entry for the article.

(B) REFUSED ADMISSION.—An article of food imported or offered for import without submission of the notice in accordance with the requirements under this paragraph shall be refused admission into the United States.

(C) EFFECT OF SECTION.—Nothing in this section may be construed as a limitation on the port of entry for an article of food.

(2) PROCEDURES.—

(A) PERIOD OF TIME FOR PROVISION OF NOTICE.—

(i) IN GENERAL.—Regulations under paragraph (1) shall require that a notice under paragraph (1) be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for

import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to the notification, but may not exceed 5 days.

(ii) FACTORS TO CONSIDER IN DETERMINING PERIOD OF TIME.—In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of the period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration.

(iii) EFFECT OF CLAUSE (ii).—Nothing in clause (ii) may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

(B) TEMPORARY HOLD AT PORT OF ENTRY.—

(i) IN GENERAL.—

(I) NOTICE NOT PROVIDED IN ADVANCE.—If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the notice is submitted to the Secretary and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1).

(II) EFFECT OF SUBSECTION (b).—Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is held under this clause.

(III) REMOVAL TO SECURE FACILITY.—The article shall be removed to a secure facility, as appropriate.

(IV) TRANSFER OF ARTICLE.—During the period of time that the article is held under this clause (including after removal under subclause (III)), the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(ii) ARTICLE PRESENTING THREAT OF SERIOUS ADVERSE HEALTH CONSEQUENCES OR DEATH.—In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that the article presents a threat of serious adverse health consequences or death to humans or animals.

(3) EFFECT OF SUBSECTION.—

(A) AUTHORITY OF SECRETARY TO OBTAIN INFORMATION.—This subsection may not be construed as limiting the authority of the Sec-

retary to obtain information under any other provision of this subtitle.

(B) FOOD WITHIN EXCLUSIVE JURISDICTION OF SECRETARY OF AGRICULTURE.—This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to chapters 303, 313, and 317 of this title.

(n) LABELING OF FOOD REFUSED ADMISSION.—

(1) IN GENERAL.—If a food has been refused admission under subsection (a), other than a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: ''UNITED STATES: REFUSED ENTRY''.

(2) EXPENSES.—All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of the payment, shall constitute a lien against future importations made by the owner or consignee.

(3) DURATION OF REQUIREMENT.—A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this subtitle.

(4) EFFECT OF SUBSECTION.—With respect to articles of food that are imported or offered for import into the United States, nothing in this subsection shall be construed to limit the authority of the Secretary or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law.

(o) REGISTRATION STATEMENT.—

(1) REFUSED ADMISSION.—If an article that is a device is being imported or offered for import into the United States, and the importer, owner, or consignee of the article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 13136(i) of this title of each establishment that with respect to the article is required under section 13136(i) of this title to register with the Secretary, the article may be refused admission.

(2) TEMPORARY HOLD AT PORT OF ENTRY.—If the article is refused admission for failure to submit the statement described in paragraph (1), the article

shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the statement is submitted to the Secretary.

(3) EFFECT OF SUBSECTION (b).—Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is held under this subsection.

(4) REMOVAL TO SECURE FACILITY.—The article shall be removed to a secure facility, as appropriate.

(5) TRANSFER OF ARTICLE.—During the period of time that the article is held under this subsection (including after removal under paragraph (4)), the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(p) REPORT.—

(1) IN GENERAL.—The Secretary shall annually submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding—

(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established under this subtitle;

(B) the public health implications of the exports, including any evidence of a negative public health impact; and

(C) recommendations or assessments of policy alternatives available to Congress and the Executive Branch to reduce any negative public health impact caused by the exports.

(2) INFORMATION DISCLOSURE REQUIREMENTS.—The Secretary may establish appropriate information disclosure requirements to carry out this subsection.

(q) CERTIFICATIONS CONCERNING IMPORTED FOODS.—

(1) REQUIREMENT.—

(A) IN GENERAL.—The Secretary may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines

appropriate, that the article of food complies with applicable requirements of this subtitle.

(B) FORM.—The certification or assurances may be provided—

(i) in the form of shipment-specific certificates;

(ii) in the form of a listing of certified facilities that manufacture, process, pack, or hold the food; or

(iii) in such other form as the Secretary may specify.

(2) FACTORS TO BE CONSIDERED IN REQUIRING CERTIFICATION.—The Secretary shall base the determination that an article of food is required to have a certification described in paragraph (1) on the risk of the food, including—

(A) known safety risks associated with the food;

(B) known food safety risks associated with the country, territory, or region of origin of the food;

(C) a finding by the Secretary, supported by scientific, risk-based evidence, that—

(i) the food safety programs, systems, and standards in the country, territory, or

region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this subtitle; and

(ii) the certification would assist the Secretary in determining whether to refuse or admit the article of food under subsection (a); and

(D) information submitted to the Secretary in accordance with the process established in paragraph (7).

(3) CERTIFYING ENTITIES.—For purposes of paragraph (1), entities that shall provide the certification or assurances described in paragraph (1) are—

(A) an agency or a representative of the government of the country from which the article of food at issue originated, as designated by the Secretary; or

(B) such other persons or entities accredited pursuant to section 20108 of this title to provide the certification or assurance.

(4) RENEWAL AND REFUSAL OF CERTIFICATIONS.—The Secretary may—

(A) require that any certification or other assurance provided by an entity specified in paragraph (3) be renewed by the entity at such times as the Secretary determines appropriate; and

(B) refuse to accept any certification or assurance if the Secretary determines that the certification or assurance is not valid or reliable.

(5) ELECTRONIC SUBMISSION.—The Secretary shall provide for the electronic submission of certifications under this subsection.

(6) FALSE STATEMENTS.—Any statement or representation made by an entity described in paragraph (3) to the Secretary shall be subject to section 1001 of title 18.

(7) ASSESSMENT OF FOOD SAFETY PROGRAMS, SYSTEMS, AND STANDARDS.—If the Secretary determines that the food safety programs, systems, and standards in a foreign region, country, or territory are inadequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United

States in accordance with the requirements of this subtitle, the Secretary shall, to the extent practicable, identify the inadequacies and establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to the food safety program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this subtitle.

(8) EFFECT OF SUBSECTION.—Nothing in this subsection and subsection (a)(3)(C) limits the authority of the Secretary to conduct inspections of imported food or to take such other steps as the Secretary considers appropriate to determine the admissibility of imported food.

(r) STANDARDS FOR ADMISSION OF IMPORTED DRUGS.—

(1) ELECTRONIC SUBMISSION OF INFORMATION DEMONSTRATING COMPLIANCE.—The Secretary may require, pursuant to the regulations promulgated under paragraph (4)(A), as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electroni-

cally submit information demonstrating that the drug complies with applicable requirements of this subtitle.

(2) INFORMATION INCLUSIONS.—The information described under paragraph (1) may include—

(A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;

(B) facility information, such as proof of registration and the unique facility identifier;

(C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and

(D) any other information considered necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

(3) DOCUMENTATION.—Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

(A) through representation by a foreign government, if an inspection is conducted by a foreign government using standards and practices as determined appropriate by the Secretary;

(B) through representation by a foreign government or an agency of a foreign government recognized under section 20109 of this title; or

(C) other appropriate documentation or evidence as described by the Secretary.

(4) REGULATIONS.—

(A) IN GENERAL.—

(i) PROMULGATION.—The Secretary shall promulgate final regulations implementing this subsection.

(ii) REGULATION REQUIREMENTS.—The regulation requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under section 13510 of this title.

(B) PROMULGATION CONSIDERATIONS; EXPEDITED CLEARANCE; RULEMAKING PROCEDURES.—In promulgating the regulations under subparagraph (A), the Secretary—

(i) may, as appropriate, take into account differences among importers and types of imports, and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections; and

(ii) shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(C) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).

(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

(1) REGISTRATION.—The Secretary shall require a commercial importer of drugs—

(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

(B) subject to paragraph (4), to submit, at the time of registration, a unique identifier for the principal place of business for which the importer is required to register under this subsection.

(2) REGULATIONS.—

(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the requirements of this subtitle and the Public Health Service Act (42 U.S.C. 201 et seq.).

(B) PROCEDURE.—In promulgating a regulation under subparagraph (A), the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

(iii) publish the final regulation not less than 30 days before the regulation's effective date.

(C) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this subsection, the Secretary shall promulgate regulations only as described in subparagraph (B).

(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary, provide a reasonable period of time for an importer of a drug to comply with good im-

porter practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.

(3) DISCONTINUANCE OF REGISTRATION.—The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

(4) UNIQUE FACILITY IDENTIFIER.—

(A) IN GENERAL.—The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1).

(B) DATE OF APPLICABILITY.—The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under subparagraph (A).

(5) EXEMPTIONS.—The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection.

(t) SINGLE SOURCE PATTERN OF IMPORTED ILLEGAL DRUGS.—If the Secretary determines that a person

subject to debarment as a result of engaging in a pattern of importing or offering for import controlled substances or drugs as described in section 10506(b)(3)(B)(iv) of this title, and the pattern is identified by the Secretary as offering for import from the same manufacturer, distributor, or importer the controlled substances or drugs, the Secretary may by order determine all drugs being offered for import from the person as adulterated or misbranded, unless the person can provide evidence otherwise.

(u) ILLICIT ARTICLES CONTAINING ACTIVE PHARMACEUTICAL INGREDIENTS.—

(1) IN GENERAL.—For purposes of this section, an article that is being imported or offered for import into the United States may be treated by the Secretary as a drug if the article—

(A) is not—

(i) accompanied by an electronic import entry for the article submitted using an authorized electronic data interchange system; and

(ii) designated in the system as an article regulated by the Secretary (which may include regulation as a drug, a device, a dietary supplement, or other product that is regulated under this subtitle); and

(B) is an ingredient that presents significant public health concern and is, or contains—

(i) an active ingredient in a drug—

(I) that is approved under chapter 135 of this title or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(II) for which—

(aa) an investigational use exemption has been authorized under section 13510 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); and

(bb) a substantial clinical investigation has been instituted, and the investigation has been made public; or

(ii) a substance that has a chemical structure that is substantially similar to the chemical structure of an active ingredient in a drug or biological product described in subclause (I) or (II) of clause (i).

(2) EFFECT.—This subsection shall not be construed to bear on any determination of whether an article is a drug within the meaning of section 10101(a)(18) of this title, other than for the purposes described in paragraph (1).

**§ 20102. Exports of certain unapproved products**

(a) DEFINITIONS.—In this section:

(1) DRUG.—The term ''drug'' includes—

(A) drugs for human use; and

(B) biologicals under section 351 of the Public Health Service Act (42 U.S.C. 262) or the Act of March 4, 1913 (ch. 145, 37 Stat. 832) (commonly known as the Virus-Serum Toxin Act).

(2) SECRETARY.—The term ''Secretary'' means, in the case of a biological product that is required to be licensed under the Act of March 4, 1913 (ch. 145, 37 Stat. 832) (commonly known as the Virus-Serum Toxin Act), the Secretary of Agriculture.

(b) DRUGS OR DEVICES INTENDED FOR HUMAN OR ANIMAL USE THAT REQUIRE APPROVAL OR LICENSING.—

(1) EXPORT AUTHORIZATION.—A drug or device under paragraph (2) is adulterated, misbranded,

and in violation of the provisions referred to in paragraph (2) unless the export of the drug or device is, except as provided in subsection (g), authorized under subsection (c), (d), (e), or (f) or section 20101(e)(2) of this title.

(2) DRUG OR DEVICE.—A drug or device under this paragraph is a drug or device—

(A) that, in the case of a drug—

(i) requires—

(I) approval by the Secretary under chapter 135 of this title before the drug may be introduced or delivered for introduction into interstate commerce; or

(II) licensing by the Secretary under section 351 of the Public Health Service Act (42 U.S.C. 262) or by the Secretary of Agriculture under the Act of March 4, 1913 (ch. 145, 37 Stat. 832) before it may be introduced or delivered for introduction into interstate commerce;

(ii) does not have the approval or license described in clause (i); and

(iii) is not exempt from the provisions referred to in clause (i); and

(B) that, in the case of a device—

(i) does not comply with an applicable requirement under section 13141 or 13142 of this title;

(ii) under section 13152(g) of this title, is exempt from either section referred to in clause (i); or

(iii) is a banned device under section 13146 of this title.

(3) NOTIFICATION OF DISAPPROVAL.—If a drug or device described in paragraph (2) may be exported under subsection (c) and if an application for the drug or device under chapter 135 of this title, section 13142 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262) was disapproved, the Secretary shall notify the appropriate public health official of the country to which the drug will be exported of the disapproval.

(c) LIST OF ELIGIBLE COUNTRIES FOR EXPORT; CRITERIA FOR ADDITION TO LIST; DIRECT EXPORT; PETITION FOR EXEMPTION.—

(1) LIST OF COUNTRIES.—

(A) IN GENERAL.—A drug or device described in subsection (b) may be exported to any country if the drug or device complies with the laws of that country and has valid marketing authorization by the appropriate authority—

(i) in Australia, Canada, Israel, Japan, New Zealand, Switzerland, or South Africa; or

(ii) in the European Union or a country in the European Economic Area (the countries in the European Union and the European Free Trade Association) if the drug or device is marketed in that country or the drug or device is authorized for general marketing in the European Economic Area.

(B) DESIGNATION OF ADDITIONAL COUNTRIES.—

(i) IN GENERAL.—The Secretary may designate an additional country to be included in the list of countries described in clauses (i) and (ii) of subparagraph (A) if all of the following requirements are met in the country:

(I) Statutory or regulatory requirements that require the review of drugs and devices for safety and effectiveness by an entity of the government of the country and that authorize the approval of only those drugs and devices that have been determined to be safe and effective by experts employed by or acting on behalf of the entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and devices.

(II) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for—

(aa) the manufacture, processing, and packing of drugs in

the country are adequate to preserve their identity, quality, purity, and strength; and

(bb) the manufacture, preproduction design validation, packing, storage, and installation of a device are adequate to ensure that the device will be safe and effective.

(III) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and devices and procedures to withdraw approval and remove drugs and devices found not to be safe or effective.

(IV) Statutory or regulatory requirements that the labeling and promotion of drugs and devices must be in accordance with the approval of the drug or device.

(V) The valid marketing authorization system in the country is equivalent to the systems in the countries described in clauses (i) and (ii) of subparagraph (A).

(ii) NONDELEGATION.—The Secretary shall not delegate the authority granted under this subparagraph.

(C) REQUEST FOR DESIGNATION.—

(i) SUBMISSION OF DOCUMENTATION IN SUPPORT OF DESIGNATION.—An appropriate country official, manufacturer, or exporter may request the Secretary to take action under subparagraph (B) to designate an additional country or countries to be added to the list of countries described in clauses (i) and (ii) of subparagraph (A) by submitting documentation to the Secretary in support of the designation.

(ii) LETTER FROM COUNTRY INDICATING DESIRE TO BE DESIGNATED.—Any person other than a country requesting the designation shall include, along with the request, a letter from the country indicating the desire of the country to be designated.

(2) EXPORTATION OF DRUG TO UNLISTED COUNTRY.—A drug described in subsection (b) may

be directly exported to a country that is not listed in clause (i) or (ii) of paragraph (1)(A) if—

(A) the drug complies with the laws of that country and has valid marketing authorization by the responsible authority in that country; and

(B) the Secretary determines that all of the following requirements are met in that country:

(i) Statutory or regulatory requirements that require the review of drugs for safety and effectiveness by an entity of the government of the country and that authorize the approval of only those drugs that have been determined to be safe and effective by experts employed by or acting on behalf of the entity and qualified by scientific training and experience to evaluate the safety and effectiveness of drugs on the basis of adequate and well-controlled investigations, including clinical investigations, conducted by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs.

(ii) Statutory or regulatory requirements that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of drugs in the country are adequate to preserve their identity, quality, purity, and strength.

(iii) Statutory or regulatory requirements for the reporting of adverse reactions to drugs and procedures to withdraw approval and remove drugs found not to be safe or effective.

(iv) Statutory or regulatory requirements that the labeling and promotion of drugs must be in accordance with the approval of the drug.

(3) PETITION TO EXPORT DRUG NOT MEETING APPROVAL REQUIREMENTS TO UNLISTED COUNTRY.—

(A) IN GENERAL.—The exporter of a drug described in subsection (b) that would not meet the conditions for approval under this subtitle or conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A) may petition the Secretary for authorization to export the drug to a country that is not de-

scribed in clause (i) or (ii) of paragraph (1)(A) or that is not described in paragraph (2).

(B) PERMISSION TO EXPORT.—The Secretary shall permit the export under subparagraph (A) if—

(i) the person exporting the drug—

(I) certifies that the drug would not meet the conditions for approval under this subtitle or the conditions for approval of a country described in clause (i) or (ii) of paragraph (1)(A); and

(II) provides the Secretary with credible scientific evidence, acceptable to the Secretary, that the drug would be safe and effective under the conditions of use in the country to which it is being exported; and

(ii) the appropriate health authority in the country to which the drug is being exported—

(I) requests approval of the export of the drug to the country;

(II) certifies that the health authority understands that the drug is

not approved under this subtitle or in a country described in clause (i) or (ii) of paragraph (1)(A); and

(III) concurs that the scientific evidence provided pursuant to clause (i) is credible scientific evidence that the drug would be reasonably safe and effective in the country.

(C) SECRETARIAL ACTION.—The Secretary shall take action on a request for export of a drug under this paragraph within 60 days of receiving the request.

(d) INVESTIGATIONAL USE EXEMPTION.—A drug or device intended for investigational use in any country described in clause (i) or (ii) of subsection (c)(1)(A) may be exported in accordance with the laws of that country and shall be exempt from regulation under section 13510 or 13152(g) of this title.

(e) ANTICIPATION OF MARKET AUTHORIZATION.—A drug or device intended for formulation, filling, packaging, labeling, or further processing in anticipation of market authorization in any country described in clause (i) or (ii) of subsection (c)(1)(A) may be exported for use in accordance with the laws of that country.

(f) DIAGNOSIS, PREVENTION, OR TREATMENT OF TROPICAL DISEASE.—

(1) IN GENERAL.—A drug or device that is used in the diagnosis, prevention, or treatment of a tropical disease or another disease not of significant prevalence in the United States and that does not otherwise qualify for export under this section shall, on approval of an application, be permitted to be exported if the Secretary finds that—

(A) the drug or device will not expose patients in the country to an unreasonable risk of illness or injury; and

(B) the probable benefit to health from the use of the drug or device (under conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling of the drug or device) outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available drug or device treatment.

(2) REPORTING REQUIREMENT.—The holder of an approved application for the export of a drug or device under this subsection shall report to the Secretary—

(A) the receipt of any credible information indicating that the drug or device is being or may have been exported from a country for which the Secretary made a finding under paragraph (1) to a country for which the Secretary cannot make such a finding; and

(B) the receipt of any information indicating adverse reactions to the drug.

(3) WITHDRAWAL OF APPROVED APPLICATION; PROHIBITION OF EXPORT.—

(A) WITHDRAWAL OF APPROVED APPLICATION.—The Secretary may, after providing the holder of an approved application under paragraph (1) an opportunity for an informal hearing, withdraw the approved application if the Secretary determines that—

(i) the drug or device for which the application is approved under paragraph (1) does not continue to meet the requirements of paragraph (1); or

(ii) the holder of the approved application under paragraph (1) has not made the report required by paragraph (2).

(B) PROHIBITION OF EXPORT.—If the Secretary determines that the holder of an ap-

proved application under paragraph (1) or an importer is exporting a drug or device from the United States to an importer and the importer is exporting the drug or device to a country for which the Secretary cannot make a finding under paragraph (1) and the export presents an imminent hazard, the Secretary shall—

(i) immediately prohibit the export of the drug or device to the importer;

(ii) provide the person exporting the drug or device from the United States prompt notice of the prohibition; and

(iii) afford the person an opportunity for an expedited hearing.

(g) PROHIBITION OF EXPORT OF DRUG OR DEVICE.—

(1) IN GENERAL.—A drug or device may not be exported under this section—

(A) if the drug or device is not manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements or does not meet international standards as certified by an international standards organization recognized by the Secretary;

(B) if the drug or device is adulterated under subparagraph (A), (B)(i), or (C) of subsection (a)(2) of section 13101 of this title or under subsection (c) or (d) of section 13101 of this title;

(C) if the requirements of subparagraphs (A) through (D) of section 20101(e)(1) of this title have not been met;

(D)(i) if the drug or device is the subject of a notice by the Secretary or the Secretary of Agriculture of a determination that the probability of reimportation of the exported drug or device would present an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the drug or device; or

(ii) if the drug or device presents an imminent hazard to the public health of the country to which the drug or device would be exported;

(E) if the labeling of the drug or device is not—

(i) in accordance with the requirements and conditions for use in—

(I) the country in which the drug or device received valid marketing authorization under subsection (c); and

(II) the country to which the drug or device would be exported; and

(ii) in the language and units of measurement of the country to which the drug or device would be exported or in the language designated by the country; or

(F) if the drug or device is not promoted in accordance with the labeling requirements set forth in subparagraph (E).

(2) CONSULTATION.—In making a finding under subparagraph (D)(ii), (E), or (F) of paragraph (1), the Secretary shall consult with the appropriate public health official in the affected country.

(h) NOTIFICATION OF SECRETARY.—

(1) LISTED COUNTRIES.—The exporter of a drug or device exported under subsection (c)(1) shall provide a simple notification to the Secretary identifying the drug or device when the exporter first begins to export the drug or device to any country listed in clause (i) or (ii) of subsection (c)(1)(A).

(2) UNLISTED COUNTRIES.—The exporter of a drug or device shall provide a simple notification to the Secretary identifying the drug or device and the country to which the drug or device is being exported when an exporter first begins to export a drug or device to a country that is not listed in clause (i) or (ii) of subsection (c)(1)(A) .

(3) RECORDS.—Any exporter of a drug or device shall maintain records of all drugs or devices exported and the countries to which they were exported.

(i) EXPORTATION OF INSULIN AND ANTIBIOTIC DRUGS.—Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 20101(e)(1) of this title.

**§ 20103. Office of International Relations**

(a) ESTABLISHMENT.—There is established in the Department an Office of International Relations.

(b) AGREEMENTS WITH FOREIGN COUNTRIES.—In carrying out the functions of the Office under subsection (a), the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and the countries consistent with the re-

quirements of this subtitle. In the agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 13152(f) of this title; and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

(c) AUTHORITIES OF THE SECRETARY.—

(1) REDUCING BURDEN OF REGULATION AND HARMONIZATION OF REQUIREMENTS.—The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that the harmonization continues consumer protections consistent with the purposes of this subtitle.

(2) ACCEPTANCE OF MUTUAL RECOGNITION AGREEMENTS.—The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food addi-

tives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

(3) PARTICIPATION IN MEETINGS.—

(A) IN GENERAL.—The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

(B) AUTHORITIES RELATING TO MEETINGS.—In carrying out subparagraph (A), the Secretary may participate in appropriate fora, including the International Medical Device Regulators Forum, and may—

(i) provide guidance to the fora on strategies, policies, directions, membership, and other activities of a forum as appropriate;

(ii) to the extent appropriate, solicit, review, and consider comments from industry, academia, health care professionals, and patient groups regarding the activities of the fora; and

(iii) to the extent appropriate, inform the public of the Secretary's activities within the fora, and share with the public any documentation relating to a forum's strategies, policies, and other activities.

(4) ARRANGEMENTS.—With respect to devices, the Secretary may, when appropriate, enter into arrangements with nations regarding methods and approaches to harmonizing regulatory requirements for activities, including inspections and common international labeling symbols.

(5) APPLICABILITY OF CERTAIN PROVISIONS.—Paragraphs (1) and (4) shall not apply with respect to products defined in section 10101(a)(17) of this title.

**§ 20104. Importation of prescription drugs**

(a) DEFINITIONS.—In this section:

(1) IMPORTER.—The term ''importer'' means a pharmacist or wholesaler.

(2) PHARMACIST.—The term ''pharmacist'' means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

(3) PRESCRIPTION DRUG.—The term ''prescription drug'' means a drug subject to section 13103(a) of this title, except—

(A) a controlled substance (as defined in section 50101 of this title);

(B) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

(C) an infused drug (including a peritoneal dialysis solution);

(D) an intravenously injected drug;

(E) a drug that is inhaled during surgery; or

(F) a drug that is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 20101(d)(1) of this title shall continue to apply.

(4) QUALIFYING LABORATORY.—The term ''qualifying laboratory'' means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

(5) WHOLESALER.—

(A) IN GENERAL.—The term ''wholesaler'' means a person licensed as a wholesaler or dis-

tributor of prescription drugs in the United States under section 13103(d)(2)(A) of this title.

(B) EXCLUSION.—The term ''wholesaler'' does not include a person authorized to import drugs under section 20101(d)(1) of this title.

(b) REGULATIONS.—The Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

(c) LIMITATION.—The regulations under subsection (b) shall—

(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with—

(A) chapter 135 of this title (including with respect to being safe and effective for the intended use of the prescription drug);

(B) chapter 133 of this title and section 13101 of this title; and

(C) other applicable requirements of this subtitle;

(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

(d) INFORMATION AND RECORDS.—

(1) IN GENERAL.—The regulations under subsection (b) shall require an importer of a prescription drug under subsection (b) to submit to the Secretary the following information and documentation:

(A) The name and quantity of the active ingredient of the prescription drug.

(B) A description of the dosage form of the prescription drug.

(C) The date on which the prescription drug is shipped.

(D) The quantity of the prescription drug that is shipped.

(E) The point of origin and destination of the prescription drug.

(F) The price paid by the importer for the prescription drug.

(G) Documentation from the foreign seller specifying—

(i) the original source of the prescription drug; and

(ii) the quantity of each lot of the prescription drug originally received by the seller from that source.

(H) The lot or control number assigned to the prescription drug by the manufacturer of the prescription drug.

(I) The name, address, telephone number, and professional license number (if any) of the importer.

(J)(i) In the case of a prescription drug that is shipped directly from the first foreign recipient of the prescription drug from the manufacturer:

(I) Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

(II) Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating

that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient.

(III)(aa) In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

(bb) In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

(ii) In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

(K) Certification from the importer or manufacturer of the prescription drug that the prescription drug—

(i) is approved for marketing in the United States and is not adulterated or misbranded; and

(ii) meets all labeling requirements under this subtitle.

(L) Laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards.

(M) Documentation demonstrating that the testing required by subparagraphs (J) and (L) was conducted at a qualifying laboratory.

(N) Any other information that the Secretary determines is necessary to ensure the protection of the public health.

(2) MAINTENANCE BY THE SECRETARY.—The Secretary shall maintain information and documentation submitted under paragraph (1) for such period of time as the Secretary determines to be necessary.

(e) TESTING.—The regulations under subsection (b)—

(1) shall require—

(A) that testing described in subparagraphs (J) and (L) of subsection (d)(1) be conducted by the importer or by the manufacturer of the prescription drug at a qualified laboratory; and

(B) if the tests are conducted by the importer—

(i) that information needed to authenticate the prescription drug being tested, and to confirm that the labeling of the prescription drug complies with labeling requirements under this subtitle, be supplied by the manufacturer of the prescription drug to the pharmacist or wholesaler; and

(ii) that the information supplied under clause (i) be kept in strict confidence and used only for purposes of testing or otherwise complying with this subtitle; and

(2) may include such additional provisions as the Secretary determines to be appropriate to provide for the protection of trade secrets and commercial or financial information that is privileged or confidential.

(f) REGISTRATION OF FOREIGN SELLERS.—Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

(g) SUSPENSION OF IMPORTATION.—The Secretary shall require that importations of a specific prescription drug or importations by a specific importer under subsection (b) be immediately suspended on discovery of a pattern of importation of that specific prescription drug or by that specific importer of drugs that are counterfeit or in violation of any requirement under this section, until an investigation is completed and the Secretary determines that the public is adequately protected from counterfeit and violative prescription drugs being imported under subsection (b).

(h) APPROVED LABELING.—The manufacturer of a prescription drug shall provide an importer written authorization for the importer to use, at no cost, the approved labeling for the prescription drug.

(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 20101(d)(1) of this title continues to apply to a prescription drug that

is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVIDUALS.—

(1) DECLARATIONS.—Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

(B) exercise discretion to permit individuals to make importations in circumstances in which—

(i) the importation is clearly for personal use; and

(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

(2) WAIVER AUTHORITY.—

(A) IN GENERAL.—The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of im-

portation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

(3) DRUGS IMPORTED FROM CANADA.—In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

(B) is accompanied by a copy of a valid prescription;

(C) is imported from Canada, from a seller registered with the Secretary;

(D) is a prescription drug approved by the Secretary under division D;

(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 13136 of this title; and

(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

(k) EFFECT OF SECTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs, other than with respect to section 20101(d)(1) of this title as provided in this section.

(l) CERTIFICATION REQUIRED FOR SECTION TO BE EFFECTIVE.—

(1) COMMENCEMENT OF PROGRAM.—This section shall become effective only if the Secretary certifies to Congress that the implementation of this section will—

(A) pose no additional risk to the public's health and safety; and

(B) result in a significant reduction in the cost of covered products to the American consumer.

(2) TERMINATION OF PROGRAM.—

(A) IN GENERAL.—If, after the date that is 1 year after the effective date of the regulations under subsection (b) and before the date that is 18 months after the effective date, the Secretary submits to Congress a certification that, in the opinion of the Secretary, based on substantial evidence obtained after the effective date, the benefits of implementation of this section do not outweigh any detriment of implementation of this section, this section shall cease to be effective as of the date that is 30 days after the date on which the Secretary submits the certification.

(B) PROCEDURE.—The Secretary shall not submit a certification under subparagraph (A) unless, after a hearing on the record under sections 556 and 557 of title 5, the Secretary—

(i)(I) determines that it is more likely than not that implementation of this section would result in an increase in the risk to the public health and safety;

(II) identifies specifically, in qualitative and quantitative terms, the nature of the increased risk;

(III) identifies specifically the causes of the increased risk; and

(IV)(aa) considers whether any measures can be taken to avoid, reduce, or mitigate the increased risk; and

(bb) if the Secretary determines that any measures described in item (aa) would require additional statutory authority, submits to Congress a report describing the legislation that would be required;

(ii) identifies specifically, in qualitative and quantitative terms, the benefits that would result from implementation of this section (including the benefit of reductions in the cost of covered products to consumers in the United States, allowing consumers to procure needed medication that consumers might not otherwise be able to procure without foregoing other necessities of life); and

(iii)(I) compares in specific terms the detriment identified under clause (i) with the benefits identified under clause (ii); and

(II) determines that the benefits do not outweigh the detriment.

**§ 20105. Foreign supplier verification program**

(a) DEFINITION OF IMPORTER.—In this section, the term ''importer'' means, with respect to an article of food—

(1) the United States owner or consignee of the article of food at the time of entry of the article into the United States; or

(2) in a case in which there is no United States owner or consignee as described in paragraph (1), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of the article into the United States.

(b) VERIFICATION REQUIREMENT.—Except as provided under subsections (f) and (g), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of an importer is—

(1) produced in compliance with the requirements of section 11120 or 11121 of this title, as appropriate; and

(2) not adulterated under section 11102 of this title or misbranded under section 11323 of this title.

(c) GUIDANCE.—The Secretary shall issue guidance to assist importers in developing foreign supplier verification programs.

(d) REGULATIONS.—

(1) IN GENERAL.—The Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (b).

(2) REQUIREMENTS.—The regulations promulgated under paragraph (1)—

(A) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food in compliance with—

(i) processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under section 11120 of this title or section 11121 of this title (taking into consideration variances granted under section 11121 of this title), as appropriate; and

(ii) sections 11102 and 11323 of this title; and

(B) shall include such other requirements as the Secretary considers necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

(3) CONSIDERATIONS.—In promulgating regulations under this subsection, the Secretary shall, as appropriate, take into account differences among importers and types of imported foods, including based on the level of risk posed by the imported food.

(4) ACTIVITIES.—Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

(e) RECORD MAINTENANCE AND ACCESS.—Records of an importer related to a foreign supplier verification program shall be maintained for a period of not less than 2 years and shall be made available promptly to an authorized representative of the Secretary on request.

(f) EXEMPTION OF SEAFOOD, JUICE, AND LOW-ACID CANNED FOOD FACILITIES IN COMPLIANCE WITH CERTAIN STANDARDS AND REGULATIONS.—

(1) IN GENERAL.—This section shall not apply to a facility if the owner, operator, or agent in charge of the facility is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to the facility:

(A) The Seafood Hazard Analysis Critical Control Points Program of the FDA.

(B) The Juice Hazard Analysis Critical Control Points Program of the FDA.

(C) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the FDA (or any successor standards).

(2) APPLICABILITY.—The exemption under paragraph (1)(C) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers under part 113 of title 21, Code of Federal Regulations (or any successor regulations).

(g) ADDITIONAL EXEMPTIONS.—The Secretary, by notice published in the Federal Register, shall establish

an exemption from the requirements of this section for articles of food imported in small quantities for research and evaluation purposes or for personal consumption, provided that the foods are not intended for retail sale and are not sold or distributed to the public.

(h) PUBLICATION OF LIST OF PARTICIPANTS.—The Secretary shall publish and maintain on the FDA website a current list that includes the name of, location of, and other information considered necessary by the Secretary about, importers participating under this section.

**§ 20106. Voluntary qualified importer program**

(a) DEFINITION OF IMPORTER.—In this section, the term ''importer'' means the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.

(b) IN GENERAL.—The Secretary shall—

(1) in consultation with the Secretary of Homeland Security—

(A) establish a program to provide for the expedited review and importation of food offered for importation by importers that have voluntarily agreed to participate in the program; and

(B) consistent with section 20108 of this title, establish a process for the issuance of a

facility certification to accompany food offered for importation by importers that have voluntarily agreed to participate in the program; and

(2) issue a guidance document related to participation in, revocation of the participation in, reinstatement in, and compliance with, the program.

(c) VOLUNTARY PARTICIPATION.—An importer may request the Secretary to provide for the expedited review and importation of designated foods in accordance with the program established by the Secretary under subsection (b).

(d) NOTICE OF INTENT TO PARTICIPATE.—An importer that intends to participate in the program under this section in a fiscal year shall submit a notice and application to the Secretary of the intent at the time and in a manner established by the Secretary.

(e) ELIGIBILITY.—Eligibility shall be limited to an importer offering food for importation from a facility that has a certification described in subsection (b). In reviewing the applications and making determinations on the applications, the Secretary shall consider the risk of the food to be imported based on factors, such as the following:

(1) The known safety risks of the food to be imported.

(2) The compliance history of foreign suppliers used by the importer, as appropriate.

(3) The capability of the regulatory system of the country of export to ensure compliance with United States food safety standards for a designated food.

(4) The compliance of the importer with the requirements of section 20105 of this title.

(5) The recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer.

(6) The potential risk for intentional adulteration of the food.

(7) Any other factor that the Secretary determines appropriate.

(f) REVIEW AND REVOCATION.—Any importer qualified by the Secretary in accordance with the eligibility criteria set forth in this section shall be reevaluated not less often than once every 3 years and the Secretary shall promptly revoke the qualified importer status of any importer found not to be in compliance with the criteria.

(g) FALSE STATEMENTS.—Any statement or representation made by an importer to the Secretary shall be subject to section 1001 of title 18.

**§ 20107. Inspection of foreign food facilities**

(a) INSPECTION.—The Secretary—

(1) may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 11117 of this title; and

(2) shall direct resources to inspections of foreign facilities, suppliers, and food types, especially the facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

(b) EFFECT OF INABILITY TO INSPECT.—

(1) REFUSED ADMISSION.—Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals designated by the Secretary, upon request, to inspect the factory, warehouse, or other establishment.

(2) TIME PERIOD FOR PERMITTING ENTRY.—For purposes of this subsection, an owner, operator, or agent in charge shall be considered to have re-

fused an inspection under paragraph (1) if the owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after the request is submitted, or after such other time period, as agreed on by the Secretary and the foreign factory, warehouse, or other establishment.

**§ 20108. Accreditation of third-party auditors**

(a) DEFINITIONS.—In this section:

(1) ACCREDITATION BODY.—The term ''accreditation body'' means an authority that performs accreditation of third-party auditors.

(2) ACCREDITED THIRD-PARTY AUDITOR.—

(A) IN GENERAL.—The term ''accredited third-party auditor'' means a third-party auditor accredited by an accreditation body to conduct audits of eligible entities to certify that the eligible entities meet the applicable requirements of this section.

(B) INDIVIDUAL.—An accredited third-party auditor may be an individual who conducts food safety audits to certify that eligible entities meet the applicable requirements of this section.

(3) AUDIT AGENT.—The term ''audit agent'' means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor.

(4) CONSULTATIVE AUDIT.—The term ''consultative audit'' means an audit of an eligible entity—

(A) to determine whether the entity is in compliance with this subtitle and with applicable industry standards and practices; and

(B) the results of which are for internal purposes only.

(5) ELIGIBLE ENTITY.—The term ''eligible entity'' means a foreign entity, including a foreign facility registered under section 11117 of this title, in the food import supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of the accredited third-party auditor.

(6) REGULATORY AUDIT.—The term ''regulatory audit'' means an audit of an eligible entity—

(A) to determine whether the entity is in compliance with this subtitle; and

(B) the results of which determine—

(i) whether an article of food manufactured, processed, packed, or held by the entity is eligible to receive a food certification under section 20101(q) of this title; or

(ii) whether a facility is eligible to receive a facility certification under section 20106(b) of this title for purposes of participating in the program under section 20106 of this title.

(7) THIRD-PARTY AUDITOR.—

(A) IN GENERAL.—The term ''third-party auditor'' means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, as the Secretary determines appropriate in accordance with the model standards described in subsection (b)(2), that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable requirements of this section.

(B) SINGLE INDIVIDUAL.—A third-party auditor may be an individual.

(C) AUDIT AGENTS.—A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits.

(b) ACCREDITATION SYSTEM.—

(1) ACCREDITATION BODIES.—

(A) RECOGNITION OF ACCREDITATION BODIES.—

(i) IN GENERAL.—The Secretary shall establish a system for the recognition of accreditation bodies that accredit third-party auditors to certify that eligible entities meet the applicable requirements of this section.

(ii) DIRECT ACCREDITATION.—If, by the date that is 2 years after the date of establishment of the system described in clause (i), the Secretary has not identified and recognized an accreditation body to meet the requirements of this section, the Secretary may directly accredit third-party auditors.

(B) NOTIFICATION.—Each accreditation body recognized by the Secretary shall submit to the Secretary a list of all accredited third-

party auditors accredited by the body and the audit agents of the auditors.

(C) REVOCATION OF RECOGNITION AS AN ACCREDITATION BODY.—The Secretary shall promptly revoke the recognition of any accreditation body found not to be in compliance with the requirements of this section.

(D) REINSTATEMENT.—The Secretary shall establish procedures to reinstate recognition of an accreditation body if the Secretary determines, based on evidence presented by the accreditation body, that revocation was inappropriate or that the body meets the requirements for recognition under this section.

(2) MODEL ACCREDITATION STANDARDS.—

(A) IN GENERAL.—The Secretary shall develop model standards, including requirements for regulatory audit reports, and each recognized accreditation body shall ensure that third-party auditors and audit agents of the auditors meet the standards in order to qualify the third-party auditors as accredited third-party auditors under this section.

(B) STANDARDS TO LOOK TO IN DEVELOPING MODEL STANDARDS.—In developing the

model standards, the Secretary shall look to standards in place on January 4, 2011, for guidance, to avoid unnecessary duplication of efforts and costs.

(c) THIRD-PARTY AUDITORS.—

(1) REQUIREMENTS FOR ACCREDITATION AS A THIRD-PARTY AUDITOR.—

(A) FOREIGN GOVERNMENTS.—Prior to accrediting a foreign government or an agency of a foreign government as an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of food safety programs, systems, and standards of the government or agency of the government as the Secretary considers necessary, including requirements under the model standards developed under subsection (b)(2), to determine that the foreign government or agency of the foreign government is capable of adequately ensuring that eligible entities or foods certified by the government or agency meet the requirements of this subtitle with respect to food manufactured, processed,

packed, or held for import into the United States.

(B) FOREIGN COOPERATIVES AND OTHER THIRD PARTIES.—Prior to accrediting a foreign cooperative that aggregates the products of growers or processors, or any other third party, to be an accredited third-party auditor, the accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) shall perform such reviews and audits of the training and qualifications of audit agents used by that cooperative or party and conduct such reviews of internal systems and such other investigation of the cooperative or party as the Secretary considers necessary, including requirements under the model standards developed under subsection (b)(2), to determine that each eligible entity certified by the cooperative or party has systems and standards in use to ensure that the entity or food meets the requirements of this subtitle.

(2) REQUIREMENT TO ISSUE CERTIFICATION OF ELIGIBLE ENTITIES OR FOODS.—

(A) IN GENERAL.—

(i) ISSUANCE BY THIRD-PARTY AUDITOR.—An accreditation body (or, in the case of direct accreditation under subsection (b)(1)(A)(ii), the Secretary) may not accredit a third-party auditor unless the third-party auditor agrees to issue a written and, as appropriate, electronic food certification, described in section 20101(q) of this title, or facility certification under section 20106(b) of this title, as appropriate, to accompany each food shipment for import into the United States from an eligible entity, subject to requirements set forth by the Secretary.

(ii) INCLUSION WITH OTHER DOCUMENTATION.—The written or electronic certification under clause (i) may be included with other documentation regarding the food shipment.

(iii) CONSIDERATIONS RELATING TO TARGETING INSPECTION RESOURCES.—The Secretary shall consider certifications under section 20101(q) of this title and participation in the voluntary qualified importer program described in section 20106

of this title when targeting inspection resources under section 11123 of this title.

(B) PURPOSE OF CERTIFICATION.—The Secretary shall use certification provided by accredited third-party auditors to—

(i) determine, in conjunction with any other assurances the Secretary may require under section 20101(q) of this title, whether a food satisfies the requirements of the section; and

(ii) determine whether a facility is eligible to be a facility from which food may be offered for import under the voluntary qualified importer program under section 20106 of this title.

(C) REQUIREMENTS FOR ISSUING CERTIFICATION.—

(i) IN GENERAL.—An accredited third-party auditor shall issue a food certification under section 20101(q) of this title or a facility certification described under section 20106(b) of this title only after conducting a regulatory audit and other activities that may be necessary to

establish compliance with the requirements of the sections.

(ii) PROVISION OF CERTIFICATION.—Only an accredited third-party auditor or the Secretary may provide a facility certification under section 20106(b) of this title. Only those parties described in section 20101(q)(3) of this title or the Secretary may provide a food certification under section 20101(q) of this title.

(3) AUDIT REPORT SUBMISSION REQUIREMENTS.—

(A) REQUIREMENTS IN GENERAL.—As a condition of accreditation, not later than 45 days after conducting an audit, an accredited third-party auditor or audit agent of the auditor shall prepare, and, in the case of a regulatory audit, submit, the audit report for each audit conducted, in a form and manner designated by the Secretary, which shall include—

(i) the identity of the persons at the audited eligible entity responsible for compliance with food safety requirements;

(ii) the dates of the audit;

(iii) the scope of the audit; and

(iv) any other information required by the Secretary that relates to or may influence an assessment of compliance with this subtitle.

(B) RECORDS.—Following any accreditation of a third-party auditor, the Secretary may, at any time, require the accredited third-party auditor to submit to the Secretary an on-site audit report and such other reports or documents required as part of the audit process, for any eligible entity certified by the third-party auditor or audit agent of the auditor. The report may include documentation that the eligible entity is in compliance with any applicable registration requirements.

(C) LIMITATION.—The requirement under subparagraph (B) shall not include any report or other documents resulting from a consultative audit by the accredited third-party auditor, except that the Secretary may access the results of a consultative audit in accordance with section 11116 of this title.

(4) REQUIREMENTS OF ACCREDITED THIRD-PARTY AUDITORS AND AUDIT AGENTS OF THE AUDITORS.—

(A) RISKS TO PUBLIC HEALTH.—If, at any time during an audit, an accredited third-party auditor or audit agent of the auditor discovers a condition that could cause or contribute to a serious risk to the public health, the auditor shall immediately notify the Secretary of—

(i) the identification of the eligible entity subject to the audit; and

(ii) the condition.

(B) TYPES OF AUDITS.—An accredited third-party auditor or audit agent of the auditor may perform consultative audits and regulatory audits of eligible entities.

(C) LIMITATIONS.—

(i) IN GENERAL.—An accredited third-party auditor may not perform a regulatory audit of an eligible entity if the agent has performed a consultative audit or a regulatory audit of the eligible entity during the previous 13-month period.

(ii) WAIVER.—The Secretary may waive the application of clause (i) if the Secretary determines that there is insufficient access to accredited third-party auditors in a country or region.

(5) CONFLICTS OF INTEREST.—

(A) THIRD-PARTY AUDITORS.—An accredited third-party auditor shall—

(i) not be owned, managed, or controlled by any person that owns or operates an eligible entity to be certified by the auditor;

(ii) in carrying out audits of eligible entities under this section, have procedures to ensure against the use of any officer or employee of the auditor that has a financial conflict of interest regarding an eligible entity to be certified by the auditor; and

(iii) annually make available to the Secretary disclosures of the extent to which the auditor and the officers and employees of the auditor have maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

(B) AUDIT AGENTS.—An audit agent shall—

(i) not own or operate an eligible entity to be audited by the agent;

(ii) in carrying out audits of eligible entities under this section, have procedures to ensure that the agent does not have a financial conflict of interest regarding an eligible entity to be audited by the agent; and

(iii) annually make available to the Secretary disclosures of the extent to which the agent has maintained compliance with clauses (i) and (ii) relating to financial conflicts of interest.

(C) REGULATIONS.—The Secretary shall promulgate regulations to implement this section and to ensure that there are protections against conflicts of interest between an accredited third-party auditor and the eligible entity to be certified by the auditor or audited by the audit agent. The regulations shall include—

(i) requiring that audits performed under this section be unannounced;

(ii) a structure to decrease the potential for conflicts of interest, including timing and public disclosure, for fees paid by eligible entities to accredited third-party auditors; and

(iii) appropriate limits on financial affiliations between an accredited third-party auditor or audit agents of the auditor and any person that owns or operates an eligible entity to be certified by the auditor, as described in subparagraphs (A) and (B).

(6) WITHDRAWAL OF ACCREDITATION.—

(A) IN GENERAL.—The Secretary shall withdraw accreditation from an accredited third-party auditor—

(i) if food certified under section 20101(q) of this title or from a facility certified under section 20106(b) of this title by the third-party auditor is linked to an outbreak of foodborne illness that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

(ii) following an evaluation and finding by the Secretary that the third-party auditor no longer meets the requirements for accreditation; or

(iii) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary

to ensure continued compliance with the requirements under this section.

(B) ADDITIONAL BASIS FOR WITHDRAWAL OF ACCREDITATION.—The Secretary may withdraw accreditation from an accredited third-party auditor in the case that the third-party auditor is accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked, if the Secretary determines that there is good cause for the withdrawal.

(C) EXCEPTION.—The Secretary may waive the application of subparagraph (A)(i) if the Secretary—

(i) conducts an investigation of the material facts related to the outbreak of human or animal illness; and

(ii) reviews the steps or actions taken by the third-party auditor to justify the certification and determines that the accredited third-party auditor satisfied the requirements under section 20101(q) of this title of certifying the food, or the requirements under section 20106(b) of this title of certifying the entity.

(7) REACCREDITATION.—The Secretary shall establish procedures to reinstate the accreditation of a third-party auditor for which accreditation has been withdrawn under paragraph (6)—

(A) if the Secretary determines, based on evidence presented, that the third-party auditor satisfies the requirements of this section and adequate grounds for revocation no longer exist; and

(B) in the case of a third-party auditor accredited by an accreditation body for which recognition as an accreditation body under subsection (b)(1)(C) is revoked—

(i) if the third-party auditor becomes accredited not later than 1 year after revocation of accreditation under paragraph (6)(A), through direct accreditation under subsection (b)(1)(A)(ii) or by an accreditation body in good standing; or

(ii) under such conditions as the Secretary may require for a third-party auditor under paragraph (6)(B).

(8) NEUTRALIZING COSTS.—

(A) REIMBURSEMENT PROGRAM.—The Secretary shall establish by regulation a reim-

bursement (user fee) program, similar to the method described in section 203(h) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1622(h)), by which the Secretary assesses fees and requires accredited third-party auditors and audit agents to reimburse the FDA for the work performed to establish and administer the accreditation system under this section.

(B) REVENUE-NEUTRAL; NO GENERATION OF SURPLUS REVENUE.—The Secretary—

(i) shall make operating the reimbursement program under this paragraph revenue-neutral; and

(ii) shall not generate surplus revenue from such a reimbursement mechanism.

(C) AVAILABILITY.—Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. The fees are authorized to remain available until expended.

(d) RECERTIFICATION OF ELIGIBLE ENTITIES.—An eligible entity shall apply for annual recertification by an accredited third-party auditor if the entity—

(1) intends to participate in the voluntary qualified importer program under section 20106 of this title; or

(2) is required to provide to the Secretary a certification under section 20101(q) of this title for any food from the entity.

(e) FALSE STATEMENTS.—A statement or representation shall be subject to section 1001 of title 18 if the statement or representation is made—

(1) by an employee or agent of an eligible entity to an accredited third-party auditor or audit agent; or

(2) by an accredited third-party auditor to the Secretary.

(f) MONITORING.—To ensure compliance with this section, the Secretary shall—

(1) periodically, or at least once every 4 years, reevaluate the accreditation bodies described in subsection (b)(1);

(2) periodically, or at least once every 4 years, evaluate the performance of each accredited third-party auditor, through the review of regulatory audit reports by the auditors, the compliance history, as available, of eligible entities certified by the auditors,

and any other measures considered necessary by the Secretary;

(3) at any time, conduct an onsite audit of any eligible entity certified by an accredited third-party auditor, with or without the auditor present; and

(4) take any other measures considered necessary by the Secretary.

(g) PUBLICLY AVAILABLE REGISTRY.—The Secretary shall establish a publicly available registry of accreditation bodies and of accredited third-party auditors, including the name of, contact information for, and other information considered necessary by the Secretary about the bodies and auditors.

(h) EFFECTS OF SECTION.—

(1) CERTAIN INSPECTIONS.—The audits performed under this section shall not be considered inspections under section 17504 of this title.

(2) INSPECTION AUTHORITY.—Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this subtitle.

**§ 20109. Recognition of foreign government inspections**

(a) INSPECTION.—The Secretary—

(1) may enter into arrangements and agreements with a foreign government or an agency of a

foreign government to recognize the inspection of foreign establishments registered under section 13136(i) of this title in order to facilitate preapproval or risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 13136(h) of this title;

(2) may enter into arrangements and agreements under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conducting inspections that meet the applicable requirements of this subtitle; and

(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary considers necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this subtitle.

(b) RESULTS OF INSPECTION.—The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used—

(1) as evidence of compliance with section 13101(a)(2)(B)(ii) or 20101(r) of this title; and

(2) for any other purposes as determined appropriate by the Secretary.

(c) PERIODIC REVIEW.—

(1) IN GENERAL.—Beginning not later than 1 year after December 29, 2022, the Secretary shall periodically assess whether additional arrangements and agreements with a foreign government or an agency of a foreign government, as allowed under this section, are appropriate.

(2) REPORTS TO CONGRESS.—Beginning not later than 4 years after December 29, 2022, and every 4 years thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the findings and conclusions of each review conducted under paragraph (1).

# Division H—Tobacco Products

# Chapter 211—Tobacco Products

Sec.
21101. Definitions.
21102. FDA authority over tobacco products.
21103. Adulterated tobacco products.
21104. Misbranded tobacco products.
21105. Submission of health information to the Secretary.
21106. Annual registration.
21107. General provisions respecting control of tobacco products.
21108. Tobacco product standards.
21109. Notification and other remedies.
21110. Records and reports on tobacco products.
21111. Application for review of certain tobacco products.
21112. Modified risk tobacco products.

21113. Judicial review.
21114. Equal treatment of retail outlets.
21115. Jurisdiction of and coordination with the Federal Trade Commission.
21116. Regulation requirement.
21117. Preservation of State and local authority.
21118. Tobacco Products Scientific Advisory Committee.
21119. Drug products used to treat tobacco dependence.
21120. User fees.
21121. Labeling, recordkeeping, records inspection.

**§ 21101. Definitions**

In this chapter:

(1) ADDITIVE.—

(A) IN GENERAL.—The term ''additive'' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding).

(B) EXCLUSIONS.—The term ''additive'' does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

(2) BRAND.—The term ''brand'' means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trade-

mark, brand name, identifiable pattern of colors, or any combination of those attributes.

(3) CIGARETTE.—

(A) IN GENERAL.—The term ''cigarette'' means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term ''cigarette'' in section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)).

(B) INCLUSION.—The term ''cigarette'' includes tobacco, in any form, that is functional in the product, that, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(4) CIGARETTE TOBACCO.—

(A) IN GENERAL.—The term ''cigarette tobacco'' means any product that consists of loose tobacco that is intended for use by consumers in a cigarette.

(B) APPLICABILITY OF CHAPTER TO CIGARETTE TOBACCO.—Unless otherwise stated, the

requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

(5) COMMERCE.—The term ''commerce'' has the meaning given the term in section 3(2) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(2)).

(6) COUNTERFEIT TOBACCO PRODUCT.—The term ''counterfeit tobacco product'' means a tobacco product (or the container or labeling of a tobacco product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness of the trademark, trade name, or other identifying mark, imprint, or device, of a tobacco product listed in a registration under section 21106(i)(1) of this title.

(7) DISTRIBUTOR.—

(A) IN GENERAL.—The term ''distributor'', with respect to a tobacco product, means any person that furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person that sells or distributes the product to individuals for personal consumption.

(B) EXCLUSION.—Common carriers are not considered distributors for purposes of this chapter.

(8) ILLICIT TRADE.—The term ''illicit trade'' means any practice or conduct prohibited by law that relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products, including any practice or conduct intended to facilitate the activity.

(9) INDIAN COUNTRY.—The term ''Indian country'' has the meaning given the term in section 1151 of title 18.

(10) INDIAN TRIBE.—The term ''Indian tribe'' has the meaning given the term in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e)).

(11) LITTLE CIGAR.—The term ''little cigar'' means a product that—

(A) is a tobacco product; and

(B) meets the definition of the term ''little cigar'' in section 3(7) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(7)).

(12) NICOTINE.—

(A) IN GENERAL.—The term ''nicotine'' means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2].

(B) INCLUSIONS.—The term ''nicotine'' includes any salt or complex of nicotine.

(13) PACKAGE.—The term ''package'' means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

(14) RETAILER.—The term ''retailer'' means any person, government, or entity that sells tobacco products to individuals for personal consumption, or that operates a facility in which self-service displays of tobacco products are permitted.

(15) ROLL-YOUR-OWN TOBACCO.—The term ''roll-your-own tobacco'' means any tobacco product that, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

(16) SMALL TOBACCO PRODUCT MANUFACTURER.—

(A) IN GENERAL.—The term ''small tobacco product manufacturer'' means a tobacco product manufacturer that employs fewer than 350 employees.

(B) NUMBER OF EMPLOYEES.—For purposes of determining the number of employees of a manufacturer under subparagraph (A), the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with the manufacturer.

(17) SMOKE CONSTITUENT.—The term ''smoke constituent'' means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

(18) SMOKELESS TOBACCO.—The term ''smokeless tobacco'' means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

(19) TOBACCO PRODUCT MANUFACTURER.—The term ''tobacco product manufacturer'' means

any person, including any repacker or relabeler, that—

(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(B) imports a finished tobacco product for sale or distribution in the United States.

(20) TOBACCO WAREHOUSE.—

(A) INCLUSIONS.—Subject to subparagraphs (B) and (C), the term ''tobacco warehouse'' includes any person—

(i) that—

(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

(ii) that performs no other actions with respect to tobacco leaf; and

(iii) that provides to any manufacturer to whom the person sells tobacco all information related to the person's actions

described in clause (i) that is necessary for compliance with this subtitle.

(B) EXCLUSIONS.—The term ''tobacco warehouse'' excludes any person that—

(i) reconstitutes tobacco leaf;

(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

(C) APPLICABILITY.—The definition of the term ''tobacco warehouse'' in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this chapter of the actions described in subparagraph (A) is appropriate for the protection of the public health.

(21) UNITED STATES.—The term ''United States'' means the States of the United States and the District of Columbia, Puerto Rico, Guam, American Samoa, the Virgin Islands, the Northern Mariana Islands, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, and any other trust territory or possession of the United States.

**§ 21102. FDA authority over tobacco products**

(a) IN GENERAL.—Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 21112 of this title, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of division D.

(b) APPLICABILITY.—This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation considers to be subject to this chapter. This chapter shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco.

(c) SCOPE.—

(1) IN GENERAL.—Nothing in this chapter (or any policy issued or regulation promulgated under this chapter), section 80101 or 80102 of this title, section 101(a) or 103 of the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1783, 1833), or title II or title III of the Act (Public Law 111–31, 123 Stat. 1842, 1850) shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this subtitle that

are not tobacco products under division D or any other division.

(2) LIMITATION OF AUTHORITY.—

(A) TOBACCO LEAF.—

(i) INAPPLICABILITY OF CHAPTER.—This chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives.

(ii) AUTHORITY OF FDA EMPLOYEES.—An employee of the FDA shall not have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of the producer.

(B) EXCEPTION.—

(i) IN GENERAL.—Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer.

(ii) INAPPLICABILITY OF EXCEPTION.—The exception in this subparagraph shall not apply to a producer of tobacco leaf—

(I) that grows tobacco under a contract with a tobacco product manufacturer; and

(II) that is not otherwise engaged in the manufacturing process.

(C) RULE OF CONSTRUCTION.—Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer of tobacco leaf, other than activities by a manufacturer affecting production.

(d) RULEMAKING PROCEDURES.—

(1) APPLICABILITY OF CHAPTER 5 OF TITLE 5.—Each rulemaking under this chapter shall be in accordance with chapter 5 of title 5.

(2) EFFECT OF SUBSECTION.—This subsection shall not be construed to affect the rulemaking provisions of section 80101(a) of this title.

(e) CENTER FOR TOBACCO PRODUCTS.—The Secretary shall establish within the FDA the Center for To-

bacco Products, which shall report to the Commissioner in the same manner as the other agency centers within the FDA. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT MANUFACTURERS.—The Secretary shall establish within the FDA an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this subtitle.

(g) CONSULTATION PRIOR TO RULEMAKING.—Prior to promulgating rules under this chapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

**§ 21103. Adulterated tobacco products**

A tobacco product shall be deemed to be adulterated if—

(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the tobacco product injurious to health;

(2) it has been prepared, packed, or held under insanitary conditions by which it may have been con-

taminated with filth, or by which it may have been rendered injurious to health;

(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to the manufacturer or importer pursuant to section 21120 of this title by the date specified in section 21120 of this title or by the 30th day after final agency action on a resolution of any dispute as to the amount of the fee;

(5) it is, or purports to be or is represented as, a tobacco product that is subject to a tobacco product standard established under section 21108 of this title unless the tobacco product is in all respects in conformity with the standard;

(6) it is—

(A) required by section 21111(b) of this title to have premarket review and does not have an order in effect under section 21111(d)(1)(A)(i) of this title; or

(B) in violation of an order under section 21111(d)(1)(A) of this title;

(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 21107(e)(1) of this title or an applicable condition prescribed by an order under section 21107(e)(2) of this title; or

(8) it is in violation of section 21112 of this title.

**§ 21104. Misbranded tobacco products**

(a) IN GENERAL.—

(1) CONDITIONS.—A tobacco product shall be deemed to be misbranded—

(A) if its labeling is false or misleading in any particular;

(B) if in package form unless it bears a label containing—

(i) the name and place of business of the tobacco product manufacturer, packer, or distributor;

(ii) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(iii) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the

percentage that is foreign grown tobacco; and

(iv) the statement required under section 21121(a) of this title;

(C) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed on the label or labeling with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(D) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

(E) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to the regulations;

(F) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not registered under subsection (b), (c), (d), or (h) of section 21106 of this title, if it was not included in a list required by section 21106(i) of this title, if a notice or other information respecting it was not provided as required by subsection (i) or (j) of section 21106 of this title, or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 21106(e) of this title as the Secretary by regulation requires;

(G) if, in the case of any tobacco product distributed or offered for sale in any State—

(i) its advertising is false or misleading in any particular; or

(ii) it is sold or distributed in violation of section 21107(d)(5) of this title or of regulations prescribed under section 21107(d) of this title;

(H) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor of the tobacco product includes in all advertise-

ments and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

(i) a true statement of the tobacco product's established name as described in subparagraph (D), printed prominently; and

(ii) a brief statement of—

(I) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

(II) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that the action is appropriate to protect the public health, a full description of the components of the tobacco product or the formula showing quantitatively each ingredient of the tobacco product to the extent required in regulations that shall be issued by the Secretary after an opportunity for a hearing;

(I) if it is a tobacco product subject to a tobacco product standard established under section 21108 of this title, unless it bears such labeling as may be prescribed in the tobacco product standard; or

(J) if there was a failure or refusal—

(i) to comply with any requirement prescribed under section 21105 or 21109 of this title; or

(ii) to furnish any material or information required under section 21110 of this title.

(2) EXCEPTION RELATING TO LABELS.—Under paragraph (1)(B)(ii), reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(b) PRIOR APPROVAL OF LABEL STATEMENTS.—

(1) IN GENERAL.—The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that the statements do not violate the misbranding provisions of subsection (a) and that the statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31,

123 Stat. 1776), including the amendments made by that Act, and chapter 701 of this title.

(2) NO PRIOR APPROVAL FOR CONTENT OF ADVERTISEMENTS.—A regulation issued under this subsection shall not require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 21112 of this title.

(3) FEDERAL TRADE COMMISSION ACT.—An advertisement of a tobacco product published after June 22, 2009, shall not, with respect to the language of label statements as prescribed under section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) or the regulations issued under those sections, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55).

**§ 21105. Submission of health information to the Secretary**

(a) REQUIREMENT.—

(1) IN GENERAL.—Each tobacco product manufacturer or importer, or agents of the manufacturer

or importer, shall submit to the Secretary the following information:

(A) A listing of all ingredients, including tobacco, substances, compounds, and additives that were, as of not later than 6 months after June 22, 2009, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.

(B) A description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(e)).

(C) A listing of all constituents, including smoke constituents as applicable, identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand.

(D) All documents developed after June 22, 2009, that relate to health, toxicological, be-

havioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

(2) COMPLIANCE WITH REGULATIONS IN REPORTING CERTAIN INFORMATION.—The manufacturer, importer, or agent shall comply with regulations promulgated under section 21116 of this title in reporting information under paragraph (1)(C), as applicable.

(b) DATA SUBMISSION.—

(1) IN GENERAL.—At the request of the Secretary, each tobacco product manufacturer or importer of tobacco products, or agents of the manufacturer or importer, shall submit the following:

(A) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents of the manufacturer) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives.

(B) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents of the manufacturer) that relate to the issue of whether a reduction in risk to health from tobacco products can occur on the employment of technology available or known to the manufacturer.

(C) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of the practices used by tobacco manufacturers and distributors.

(2) IMPORTERS.—An importer of a tobacco product not manufactured in the United States shall supply the information required of a tobacco product manufacturer under this subsection.

(c) TIME FOR SUBMISSION.—

(1) IN GENERAL.—At least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on June 22, 2009, the manufacturer of the product shall provide the information required under subsection (a).

(2) DISCLOSURE OF ADDITIVE.—If at any time a tobacco product manufacturer adds to its tobacco products a new tobacco additive or increases the quantity of an existing tobacco additive, the manufacturer shall, except as provided in paragraph (3), at least 90 days prior to the action, advise the Secretary of the action in writing.

(3) DISCLOSURE OF OTHER ACTIONS.—If at any time a tobacco product manufacturer eliminates or decreases an existing additive, or adds or increases an additive that has by regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use, the manufacturer shall, within 60 days of the action, advise the Secretary of the action in writing.

(d) DATA LIST.—

(1) IN GENERAL.—The Secretary shall annually publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list established under subsection (e).

(2) CONSUMER RESEARCH.—The Secretary shall conduct periodic consumer research to ensure that the list published under paragraph (1) is not

misleading to lay persons. Not later than 5 years after June 22, 2009, the Secretary shall submit to the appropriate committees of Congress a report on the results of the research, together with recommendations on whether the publication should be continued or modified.

(e) DATA COLLECTION.—The Secretary shall establish, and periodically revise as appropriate, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand. The Secretary shall publish a public notice requesting the submission by interested persons of scientific and other information concerning the harmful and potentially harmful constituents in tobacco products and tobacco smoke.

**§ 21106. Annual registration**

(a) DEFINITIONS.—In this section:

(1) MANUFACTURE, PREPARATION, COMPOUNDING, OR PROCESSING.—The term ''manufacture, preparation, compounding, or processing'' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufac-

ture to the person that makes final delivery or sale to the ultimate consumer or user.

(2) NAME.—The term ''name'' shall include, in the case of a partnership, the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) REGISTRATION BY OWNERS AND OPERATORS.—On or before December 31 of each year, each person that owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product shall register with the Secretary the name, places of business, and all such establishments of that person.

(c) REGISTRATION BY NEW OWNERS AND OPERATORS.—Each person, on first engaging in the manufacture, preparation, compounding, or processing of a tobacco product in any establishment owned or operated in any State by that person, shall immediately register with the Secretary the name, place of business, and establishment of that person.

(d) REGISTRATION OF ADDED ESTABLISHMENTS.—Each person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment that the person owns or operates in

any State and in which the person begins the manufacture, preparation, compounding, or processing of a tobacco product.

(e) UNIFORM PRODUCT IDENTIFICATION SYSTEM.—The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons that are required to list the tobacco products under subsection (i) shall list the tobacco products in accordance with the system.

(f) PUBLIC ACCESS TO REGISTRATION INFORMATION.—The Secretary shall make available for inspection, to any person requesting the inspection, any registration filed under this section.

(g) BIENNIAL INSPECTION OF REGISTERED ESTABLISHMENTS.—Each establishment registered with the Secretary under this section shall be subject to inspection under section 17504 of this title or subsection (h), and each such establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product shall be so inspected by 1 or more officers or employees designated by the Secretary at least once in the 2-year period beginning with the date of registration of the establishment under this section and at least once in every successive 2-year period.

(h) REGISTRATION BY FOREIGN ESTABLISHMENTS.—

(1) IN GENERAL.—Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product shall register under this section under regulations promulgated by the Secretary.

(2) CONTENT OF REGULATIONS.—The regulations under paragraph (1) shall require the establishment to provide the information required by subsection (i) and shall include provisions for registration of the establishment on condition that adequate and effective means are available, by arrangement with the government of the foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in the establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 20101(a) of this title.

(i) REGISTRATION INFORMATION.—

(1) PRODUCT LIST.—Each person that registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such

subsection, file with the Secretary a list of all tobacco products that are being manufactured, prepared, compounded, or processed by that person for commercial distribution and that have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before the time of registration. The list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a tobacco product contained in the applicable list with respect to which a tobacco product standard has been established under section 21108 of this title or that is subject to section 21111 of this title, a reference to the authority for the marketing of the tobacco product and a copy of all labeling for the tobacco product;

(B) in the case of any other tobacco product contained in an applicable list, a copy of all consumer information and other labeling for the tobacco product, a representative sampling of advertisements for the tobacco product, and, on request made by the Secretary for good cause,

a copy of all advertisements for a particular tobacco product; and

(C) if the registrant filing a list has determined that a tobacco product contained in the list is not subject to a tobacco product standard established under section 21108 of this title, a brief statement of the basis on which the registrant made the determination if the Secretary requests such a statement with respect to that particular tobacco product.

(2) CONSULTATION WITH RESPECT TO FORMS.—The Secretary shall consult with the Secretary of the Treasury in developing the forms to be used for registration under this section to minimize the burden on those persons required to register with both the Secretary and the Tax and Trade Bureau of the Department of the Treasury.

(3) BIANNUAL REPORT OF ANY CHANGE IN PRODUCT LIST.—

(A) IN GENERAL.—Each person that registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

(i) A list of each tobacco product introduced by the registrant for commercial distribution that has not been included in any list previously filed by that person with the Secretary under this clause or paragraph (1).

(ii) If, since the date the registrant last made a report under this paragraph, the registrant has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under clause (i) or paragraph (1), notice of the discontinuance, the date of the discontinuance, and the identity of its established name.

(iii) If, since the date the registrant reported under clause (ii) a notice of discontinuance, the registrant has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which the notice of discontinuance was reported, notice of the resumption, the date of the resumption, the identity of the

tobacco product by established name, and other information required by paragraph (1), unless the registrant has previously reported the resumption to the Secretary under this clause.

(iv) Any material change in any information previously submitted under this paragraph or paragraph (1).

(B) LIST REQUIREMENT.—A list under subparagraph (A)(i) shall list a tobacco product by its established name and shall be accompanied by the other information required by paragraph (1).

(j) REPORT PRECEDING INTRODUCTION OF CERTAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO INTERSTATE COMMERCE.—

(1) DEFINITION OF SUBSTANTIALLY EQUIVALENT.—

(A) IN GENERAL.—In this subsection, the term ''substantially equivalent'' means, with respect to the tobacco product being compared to the predicate tobacco product, a tobacco product that the Secretary by order has found—

(i) to have the same characteristics as the predicate tobacco product; or

(ii) to have different characteristics and the information submitted contains information, including clinical data if considered necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under section 21111 of this title because the product does not raise different questions of public health.

(B) CHARACTERISTICS.—In subparagraph (A), the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) LIMITATION.—A tobacco product shall not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(2) IN GENERAL.—Each person that is required to register under this section and that proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15,

2007, shall, at least 90 days prior to making the introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

(A) the basis for the person's determination that—

(i) the tobacco product is substantially equivalent, within the meaning of paragraph (1), to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to paragraph (1), is substantially equivalent and that is in compliance with the requirements of this subtitle; or

(ii) the tobacco product is modified within the meaning of paragraph (4), the modifications are to a product that is commercially marketed and in compliance with the requirements of this subtitle, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (4); and

(B) action taken by the person to comply with the requirements under section 21108 of this title that are applicable to the tobacco product.

(3) APPLICATION TO CERTAIN PRODUCTS.—A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009, shall be submitted to the Secretary not later than 21 months after June 22, 2009.

(4) EXEMPTIONS.—

(A) IN GENERAL.—The Secretary may exempt, from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of paragraph (1), tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

(i) the modification would be a minor modification of a tobacco product that can be sold under this subtitle;

(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

(iii) an exemption is otherwise appropriate.

(B) REGULATIONS.—The Secretary shall issue regulations to implement this paragraph.

**§ 21107. General provisions respecting control of tobacco products**

(a) IN GENERAL.—Any requirement established by or under section 21103, 21104, 21106, or 21110 of this title applicable to a tobacco product shall apply to the tobacco product until the applicability of the requirement to the tobacco product has been changed by action taken under subsection (d) or under section 21108, 21111, or 21112 of this title, and any requirement under section 21103, 21104, 21106, or 21110 of this title that is inconsistent with a requirement imposed on the tobacco product under subsection (d) or under section 21108, 21111, or 21112 of this title shall not apply to the tobacco product.

(b) INFORMATION ON PUBLIC ACCESS AND COMMENT.—Each notice of proposed rulemaking or other notification under section 21108, 21109, 21110, 21111, or

21112 of this title or under this section, any other notice that is published in the Federal Register with respect to any other action taken under any of those sections and that states the reasons for the action, and each publication of findings required to be made in connection with rulemaking under any of those sections shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings are based; and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least 60 days but may not exceed 90 days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause for the extension.

(c) LIMITED CONFIDENTIALITY OF INFORMATION.—Any information reported to or otherwise obtained by the Secretary or the Secretary's representative under subsection (e) or (f), or under section 17504, 21104, 21105, 21108, 21109, 21110, 21111, or 21112 of this title, that is exempt from disclosure under subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of section 552 of title 5 shall be considered confidential and shall

not be disclosed, except that the information may be disclosed—

(1) to other officers or employees concerned with carrying out this chapter; or

(2) if disclosure is relevant in any proceeding under this chapter.

(d) RESTRICTIONS.—

(1) IN GENERAL.—

(A) SALE AND DISTRIBUTION; INCLUSIONS.—The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that the regulation would be appropriate for the protection of the public health.

(B) ADVERTISING AND PROMOTION.—The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to the full extent permitted by the First Amendment to the Constitution.

(C) DETERMINATION OF APPROPRIATENESS.—The finding as to whether a regulation under this paragraph would be appropriate for

the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(i) the increased or decreased likelihood that existing users of tobacco products will stop using the tobacco products; and

(ii) the increased or decreased likelihood that those who do not use tobacco products will start using the tobacco products.

(D) LIMITATION.—A regulation under this paragraph shall not require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

(2) LABEL STATEMENTS.—The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in the regulation prescribe.

(3) LIMITATIONS.—

(A) IN GENERAL.—A restriction under paragraph (1) shall not—

(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

(ii) establish a minimum age of sale of tobacco products to any person older than 21 years of age.

(B) MATCHBOOKS.—

(i) IN GENERAL.—For purposes of any regulations issued by the Secretary, matchbooks of conventional size containing not more than 20 paper matches, and that are customarily given away for free with the purchase of tobacco products, shall be considered as adult-written publications that shall be permitted to contain advertising.

(ii) TREATMENT.—Notwithstanding clause (i), if the Secretary finds that the treatment of matchbooks is not appropriate for the protection of the public health, the Secretary may determine by regulation that matchbooks shall not be considered adult-written publications.

(4) REMOTE SALES.—

(A) IN GENERAL.—The Secretary shall—

(i) within 18 months after June 22, 2009, promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer to prevent the sale and distribution of tobacco products to individuals who have not attained the minimum age established by applicable law for the purchase of tobacco products, including requirements for age verification; and

(ii) within 2 years after June 22, 2009, issue regulations to address the promotion and marketing of tobacco products that are sold or distributed through means other than a direct, face-to-face exchange between a retailer and a consumer in order to protect individuals who have not attained the minimum age established by applicable law for the purchase of tobacco products.

(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph limits the authority of the Sec-

retary to take additional actions under this subsection.

(5) MINIMUM AGE OF SALE.—It shall be unlawful for any retailer to sell a tobacco product to any individual younger than 21 years of age.

(e) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—

(1) METHODS, FACILITIES, AND CONTROLS TO CONFORM.—

(A) IN GENERAL.—

(i) IN GENERAL.—In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in the regulations to ensure that

the public health is protected and that the tobacco product is in compliance with this chapter.

(ii) TESTING FOR PESTICIDE CHEMICAL RESIDUES.—The regulations under clause (i) may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for the chemical residues has been established.

(B) REQUIREMENTS.—The Secretary shall—

(i) before promulgating any regulation under subparagraph (A), afford the Tobacco Products Scientific Advisory Committee an opportunity to submit recommendations with respect to the regulation proposed to be promulgated;

(ii) before promulgating any regulation under subparagraph (A), afford opportunity for an oral hearing;

(iii) provide the Tobacco Products Scientific Advisory Committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A);

(iv) in establishing the effective date of a regulation promulgated under this subsection—

(I) take into account the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, and the state of their existing manufacturing facilities; and

(II) provide for a reasonable period of time for the manufacturers to conform to good manufacturing practices; and

(v) not require any small tobacco product manufacturer to comply with a regulation under subparagraph (A) for at least 4 years following the effective date established by the Secretary for the regulation.

(2) EXEMPTIONS; VARIANCES.—

(A) PETITION.—Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or

temporary exemption or variance from the requirement. The petition shall be submitted to the Secretary in such form and manner as the Secretary shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to ensure that the tobacco product will be in compliance with this chapter;

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement; and

(iii) contain such other information as the Secretary shall prescribe.

(B) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—

(i) IN GENERAL.—The Secretary may refer to the Tobacco Products Scientific

Advisory Committee any petition submitted under subparagraph (A).

(ii) RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall report its recommendations to the Secretary with respect to a petition referred to it within 60 days after the date of the petition's referral.

(C) DENIAL OR APPROVAL OF PETITION.—The Secretary shall by order deny or approve the petition within 60 days after the later of—

(i) the date the petition was submitted to the Secretary under subparagraph (A); or

(ii) the day after the petition was referred to the Tobacco Products Scientific Advisory Committee.

(D) APPROVAL.—The Secretary may approve—

(i) a petition for an exemption for a tobacco product from a requirement if the Secretary determines that compliance with the requirement is not required to ensure that the tobacco product will be in compliance with this chapter; and

(ii) a petition for a variance for a tobacco product from a requirement if the Secretary determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, and storage of the tobacco product in lieu of the methods, facilities, and controls prescribed by the requirement are sufficient to ensure that the tobacco product will be in compliance with this chapter.

(E) CONDITIONS.—An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, and storage of the tobacco product to be granted the variance under the petition as may be necessary to ensure that the tobacco product will be in compliance with this chapter.

(F) DENIAL OR APPROVAL OF PETITION; HEARING.—After the issuance of an order under subparagraph (C) respecting a petition, the petitioner shall have an opportunity for an informal hearing on the order.

(f) RESEARCH AND DEVELOPMENT.—The Secretary may enter into contracts for research, testing, and demonstrations respecting tobacco products and may obtain tobacco products for research, testing, and demonstration purposes.

**§ 21108. Tobacco product standards**

(a) IN GENERAL.—

(1) SPECIAL RULES.—

(A) SPECIAL RULE FOR CIGARETTES.—

(i) IN GENERAL.—A cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.

(ii) EFFECT OF SUBPARAGRAPH ON AUTHORITY OF SECRETARY.—Nothing in this subparagraph shall be construed to limit the Secretary's authority to take ac-

tion under this subtitle applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

(B) ADDITIONAL SPECIAL RULE.—A tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

(2) REVISION OF TOBACCO PRODUCT STANDARDS.—The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

(3) ADDITIONAL TOBACCO PRODUCT STANDARDS.—

(A) IN GENERAL.—The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) DETERMINATIONS.—

(i) CONSIDERATIONS.—In making a finding described in subparagraph (A), the

Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using tobacco products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using tobacco products.

(ii) ADDITIONAL CONSIDERATIONS.—In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may

be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide, for the Secretary's consideration, scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(4) CONTENT OF TOBACCO PRODUCT STANDARDS.—A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, if appropriate—

(i) for nicotine yields of the product;

(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B);

(B) shall, if appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives,

constituents, including smoke constituents, and properties of the tobacco product;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 21107(d) of this title;

(C) shall, if appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

(5) TESTING.—The Secretary may provide for testing under paragraph (4)(B) by any person.

(6) PERIODIC REEVALUATION OF TOBACCO PRODUCT STANDARDS.—The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether the standards should be changed to reflect new medical, scientific, or other technological data.

(7) INVOLVEMENT OF OTHER AGENCIES; INFORMED PERSONS.—In carrying out duties under this section, the Secretary shall endeavor to—

(A) use personnel, facilities, and other technical support available in other Federal agencies;

(B) consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons represent-

ative of scientific, professional, industry, agricultural, or consumer organizations that in the Secretary's judgment can make a significant contribution.

(b) CONSIDERATIONS BY SECRETARY.—

(1) TECHNICAL ACHIEVABILITY.—The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with the standard, including with regard to any differences related to the technical achievability of compliance with the standard for products in the same class containing nicotine not made or derived from tobacco and products containing nicotine made or derived from tobacco.

(2) OTHER CONSIDERATIONS.—The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter and the significance of the demand.

(c) PROPOSED STANDARDS.—

(1) IN GENERAL.—The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

(2) REQUIREMENTS OF NOTICE.—A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

(A) set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

(B) invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

(C) invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

(D) invite the Secretary of Agriculture to provide any information or analysis that the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

(3) FINDING.—A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

(4) COMMENT.—The Secretary shall provide for a comment period of not less than 60 days.

(d) PROMULGATION.—

(1) IN GENERAL.—After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for the termination.

(2) EFFECTIVE DATE.—

(A) IN GENERAL.—A regulation establishing a tobacco product standard shall set forth the date or dates on which the standard shall take effect, but any such regulation shall not take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

(B) MINIMIZING LOSS TO TRADE.—The date or dates under subparagraph (A) shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade.

(C) FACTORS.—In establishing the effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard.

(D) SUBSTANTIAL CHANGES TO FARMING METHODS.—If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

(3) LIMITATION ON POWER GRANTED TO THE FDA.—

(A) IN GENERAL.—The prohibition under subparagraph (B) applies because of the importance of a decision of the Secretary to issue a regulation—

(i) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(ii) requiring the reduction of nicotine yields of a tobacco product to zero.

(B) PROHIBITION.—The Secretary is prohibited from taking actions described in subparagraph (A) under this subtitle.

(4) AMENDMENT; REVOCATION.—

(A) AUTHORITY.—The Secretary, on the Secretary's own initiative or on petition of an interested person, may by regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

(B) EFFECTIVE DATE.—The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on the amendment if the Secretary determines that making it effective as described in this subparagraph is in the public interest.

(5) REFERRAL TO THE TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and

recommendation with respect to any matter involved in the proposed regulation that requires the exercise of scientific judgment.

(B) INITIATION OF REFERRAL.—The Secretary may make a referral under this paragraph—

(i) on the Secretary's own initiative; or

(ii) on the request of an interested person that demonstrates good cause for the referral, which request is made before the expiration of the period for submission of comments on the proposed regulation.

(C) PROVISION OF DATA.—If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which the proposed regulation is based.

(D) REPORT AND RECOMMENDATION.—The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and

other data and information before it, submit to the Secretary a report and recommendation respecting the regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

(E) PUBLIC AVAILABILITY.—The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

**§ 21109. Notification and other remedies**

(a) NOTIFICATION.—

(1) In general—The Secretary may issue an order described in paragraph (2) if the Secretary determines that—

(A) a tobacco product that is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health; and

(B) notification under this subsection is necessary to eliminate the unreasonable risk of the harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate the risk.

(2) ORDER.—If the Secretary makes the determination described in paragraph (1), the Secretary may issue such order as may be necessary to ensure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all persons that should properly receive the notification in order to eliminate the risk.

(3) MEANS OF NOTIFICATION.—The Secretary may order notification under this subsection by any appropriate means, including public service announcements.

(4) CONSULTATION.—Before issuing an order under this subsection, the Secretary shall consult with the persons that are to give notice under the order.

(b) NO EXEMPTION FROM OTHER LIABILITY.—

(1) IN GENERAL.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law.

(2) DAMAGES; VALUE TO PLAINTIFF OF REMEDY UNDER ORDER TO BE CONSIDERED.—In awarding damages for economic loss in an action brought for the enforcement of any liability described in paragraph (1), the value to the plaintiff in the action

of any remedy provided under the order shall be taken into account.

(c) RECALL AUTHORITY.—

(1) IN GENERAL.—

(A) CEASING DISTRIBUTION.—If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect, not ordinarily contained in tobacco products on the market, that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of the tobacco product.

(B) HEARING.—The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of the tobacco product.

(C) INADEQUATE GROUNDS.—If, after providing an opportunity for a hearing under subparagraph (B), the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2) AMENDMENT OF ORDER TO REQUIRE RECALL.—

(A) IN GENERAL.—

(i) DETERMINATION THAT ORDER SHOULD INCLUDE RECALL.—If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the tobacco product with respect to which the order was issued, the Secretary shall, except as provided in subparagraph (B), amend the order to require a recall.

(ii) TIMETABLE.—The Secretary shall specify a timetable in which the tobacco product recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) NOTICE.—

(i) IN GENERAL.—An amended order under subparagraph (A)—

(I) shall not include recall of a tobacco product from individuals; and

(II) shall provide for notice to persons subject to the risks associated with the use of the tobacco product.

(ii) ASSISTANCE OF RETAILERS.—In providing the notice required by clause (i)(II), the Secretary may use the assistance of retailers and other persons that distributed the tobacco product.

(iii) PERSONS SUBJECT TO RISKS NOT IDENTIFIED.—If a significant number of the persons under clause (i)(II) cannot be identified, the Secretary shall notify the persons under section 17505(b) of this title.

(3) REMEDY NOT EXCLUSIVE.—The remedy provided by this subsection shall be in addition to remedies provided by subsection (a).

**§ 21110. Records and reports on tobacco products**

(a) IN GENERAL.—

(1) REQUIREMENT.—Each person that is a tobacco product manufacturer or importer of a tobacco

product shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to ensure that the tobacco product is not adulterated or misbranded and to otherwise protect public health.

(2) REGULATIONS.—Regulations prescribed under paragraph (1)—

(A) may require a tobacco product manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed tobacco products may have caused or contributed to a serious unexpected adverse experience associated with the use of the tobacco product or any significant increase in the frequency of a serious, expected adverse product experience;

(B) shall require reporting of other significant adverse tobacco product experiences as determined by the Secretary to be necessary to be reported;

(C) shall not impose requirements unduly burdensome to a tobacco product manufacturer or importer, taking into account—

(i) the cost of complying with the requirements;

(ii) the need for the protection of the public health; and

(iii) the implementation of this chapter;

(D) when prescribing the procedure for making requests for reports or information, shall require that each request made under the regulations for submission of a report or information to the Secretary state the reason or purpose for the request and identify to the fullest extent practicable the report or information;

(E) when requiring submission of a report or information to the Secretary, shall state the reason or purpose for the submission of the report or information and identify to the fullest extent practicable the report or information; and

(F) may not require that the identity of any patient or user be disclosed in records, reports, or information required under this subsection unless required—

(i) for the medical welfare of an individual;

(ii) when determining risks to public health of a tobacco product; or

(iii) when verifying a record, report, or information submitted under this chapter.

(3) PROFESSIONAL ETHICS OF THE MEDICAL PROFESSION.—In prescribing regulations under this subsection, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients.

(4) CONFIDENTIALITY OF IDENTITY OF PATIENT TO CONTINUE TO BE APPLICABLE.—The prohibitions of paragraph (2)(F) continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when the individual ceases to be a patient.

(b) REPORTS OF REMOVALS AND CORRECTIONS.—

(1) IN GENERAL.—

(A) REPORT TO SECRETARY.—Except as provided in paragraph (2), the Secretary shall by regulation require a tobacco product manufacturer or importer of a tobacco product to report promptly to the Secretary any corrective action taken or removal from the market of a

tobacco product undertaken by the manufacturer or importer if the removal or correction was undertaken—

(i) to reduce a risk to health posed by the tobacco product; or

(ii) to remedy a violation of this chapter caused by the tobacco product that may present a risk to health.

(B) RECORD OF CORRECTION OR REMOVAL.—A tobacco product manufacturer or importer of a tobacco product that undertakes a corrective action or removal from the market of a tobacco product that is not required to be reported under this subsection shall keep a record of the correction or removal.

(2) EXCEPTION.—A report of the corrective action or removal of a tobacco product shall not be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

**§ 21111. Application for review of certain tobacco products**

(a) DEFINITIONS.—In this section:

(1) NEW TOBACCO PRODUCT.—The term ''new tobacco product'' means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product in which the modified tobacco product was commercially marketed in the United States after February 15, 2007.

(2) SUBSTANTIALLY EQUIVALENT.—

(A) IN GENERAL.—The term ''substantially equivalent'' means, with respect to the tobacco product being compared to the predicate tobacco product, a tobacco product that the Secretary by order has found—

(i) to have the same characteristics as the predicate tobacco product; or

(ii) to have different characteristics and the information submitted contains information, including clinical data if considered necessary by the Secretary, that demonstrates that it is not appropriate to reg-

ulate the product under this section because the product does not raise different questions of public health.

(B) CHARACTERISTICS.—In subparagraph (A), the term ''characteristics'' means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) LIMITATION.—A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(b) EFFECT OF SUBMISSION OF PREMARKET REPORT RELATING TO SUBSTANTIALLY EQUIVALENT PRODUCT.—

(1) PREMARKET REVIEW REQUIRED.—

(A) NEW PRODUCTS.—An order under subsection (d)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 21106(j) of this title and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this subtitle; or

(ii) the tobacco product is exempt from the requirements of section 21106(j) of this title pursuant to a regulation issued under section 21106(j)(4) of this title.

(B) APPLICATION TO CERTAIN PRODUCTS.—

(i) IN GENERAL.—Except as provided in clause (ii), subparagraph (A) shall not apply to a tobacco product—

(I) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(II) for which a report was submitted under section 21106(j) of this title within the 21-month period.

(ii) EXCEPTION.—Subparagraph (A) shall apply to a tobacco product described in clause (i) if the Secretary issues an order that the tobacco product is not substantially equivalent.

(2) HEALTH INFORMATION.—

(A) SUMMARY.—As part of a submission under section 21106(j) of this title respecting a tobacco product, the person required to file a premarket notification under that section shall provide an adequate summary of any health information related to the tobacco product or state that the information will be made available on request by any person.

(B) REQUIRED INFORMATION.—Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that the tobacco product is

substantially equivalent to another tobacco product.

(c) APPLICATION.—

(1) CONTENTS.—An application under this section shall contain—

(A) full reports of all information, published or known to, or that should reasonably be known to, the applicant, concerning investigations that have been made to show the health risks of the tobacco product and whether the tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of the tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, the tobacco product;

(D) an identifying reference to any tobacco product standard under section 21108 of this title that would be applicable to any aspect of the tobacco product, and—

(i) adequate information to show that the aspect of the tobacco product fully meets the tobacco product standard; or

(ii) adequate information to justify any deviation from the standard;

(E) such samples of the tobacco product and of components of the tobacco product as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for the tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) REFERRAL TO TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—On receipt of an application meeting the requirements set forth in paragraph (1), the Secretary may, on the Secretary's own initiative or on the request of an applicant, refer the application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(d) ACTION ON APPLICATION.—

(1) DEADLINE.—

(A) IN GENERAL.—As promptly as possible, but not later than 180 days after the receipt of an application under subsection (c), the Secretary, after considering the report and recommendation submitted under subsection (c)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for the finding as part of or accompanying the denial) that 1 or more grounds for denial specified in paragraph (2) apply.

(B) RESTRICTIONS ON SALE AND DISTRIBUTION.—An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution

of a tobacco product may be restricted under a regulation under section 21107(d) of this title.

(2) DENIAL OF APPLICATION.—The Secretary shall deny an application submitted under subsection (c) if, on the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to the tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting the tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the tobacco product do not conform to the requirements of section 21107(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) the tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 21108 of this title, and there is a lack of adequate information to justify the deviation from the standard.

(3) DENIAL INFORMATION.—Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove the application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) BASIS FOR FINDING.—For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using the tobacco products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using the tobacco products.

(5) BASIS FOR ACTION.—

(A) INVESTIGATIONS.—For purposes of paragraph (2)(A), whether permitting a tobacco

product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) OTHER EVIDENCE.—If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) that is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of the evidence.

(e) WITHDRAWAL AND TEMPORARY SUSPENSION.—

(1) IN GENERAL.—The Secretary shall, on obtaining, if appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (d)(1)(A)(i), issue an order withdrawing the order that was issued under subsection (d)(1)(A)(i) if the Secretary finds—

(A) that the continued marketing of the tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 21110 of this title;

(ii) has refused to permit access to, or copying or verification of, the records as required by section 17504 of this title; or

(iii) has not complied with the requirements of section 21106 of this title;

(D) on the basis of new information before the Secretary with respect to the tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of the to-

bacco product do not conform with the requirements of section 21107(e) of this title and were not brought into conformity with the requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of the tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of the fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the order was issued, that the tobacco product is not shown to conform in all respects to a tobacco product standard that is in effect under section 21108 of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate

information to justify the deviation from the standard.

(2) APPEAL.—The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (d)(1)(A)(i) may, by petition filed on or before the 30th day after the date on which the holder receives notice of the withdrawal, obtain review of the withdrawal in accordance with section 21113 of this title.

(3) TEMPORARY SUSPENSION.—If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw the application.

(f) SERVICE OF ORDER.—An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(g) RECORDS.—

(1) IN GENERAL.—In the case of any tobacco product for which an order issued pursuant to subsection (d)(1)(A)(i) for an application filed under subsection (c) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to the application, prescribe on the basis of a finding that the records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending the order.

(2) ACCESS TO RECORDS.—Each person required under this section to maintain records, and each person in charge of custody of the records, shall, on request of an officer or employee designated by the Secretary, permit the officer or em-

ployee at all reasonable times to have access to and copy and verify the records.

(h) INVESTIGATIONAL TOBACCO PRODUCT EXEMPTION FOR INVESTIGATIONAL USE.—The Secretary may exempt tobacco products intended for investigational use from the provisions of this chapter under such conditions as the Secretary may by regulation prescribe.

**§ 21112. Modified risk tobacco products**

(a) DEFINITIONS.—In this section:

(1) MODIFIED RISK TOBACCO PRODUCT.—The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) SOLD OR DISTRIBUTED FOR USE TO REDUCE HARM OR THE RISK OF TOBACCO-RELATED DISEASE ASSOCIATED WITH COMMERCIALLY MARKETED TOBACCO PRODUCTS.—

(A) IN GENERAL.—With respect to a tobacco product, the term ''sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products'' means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than 1 or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors ''light'', ''mild'', or ''low'' or similar descriptors; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after June 22, 2009, respecting the tobacco product, which action would be reasonably

expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than 1 or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

(B) LIMITATION.—A tobacco product shall not be considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products, except as described in subparagraph (A).

(C) SMOKELESS TOBACCO PRODUCT.—A smokeless tobacco product shall not be considered to be sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products solely because its label, labeling, or advertising uses the following phrases to describe the product and its use: ''smokeless tobacco'', ''smokeless tobacco product'', ''not consumed by smoking'', ''does not produce smoke'', ''smokefree'', ''smoke-free'', ''without smoke'', ''no smoke'', or ''not smoke''.

(b) IN GENERAL.—A person shall not introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to the modified risk tobacco product.

(c) TOBACCO DEPENDENCE PRODUCTS.—A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the FDA and is subject to the requirements of division D.

(d) FILING.—Any person may file with the Secretary an application for a modified risk tobacco product. The application shall include—

(1) a description of the proposed product and any proposed advertising and labeling;

(2) the conditions for using the product;

(3) the formulation of the product;

(4) sample product labels and labeling;

(5) all documents (including underlying scientific information) relating to research findings conducted, supported, or possessed by the tobacco product manufacturer relating to the effect of the product on tobacco-related diseases and health-related conditions, including information both favor-

able and unfavorable to the ability of the product to reduce risk or exposure and relating to human health;

(6) data and information on how consumers actually use the tobacco product; and

(7) such other information as the Secretary may require.

(e) PUBLIC AVAILABILITY.—The Secretary shall make the application described in subsection (d) publicly available (except matters in the application that are trade secrets or otherwise confidential commercial information) and shall request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application.

(f) TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee any application submitted under this section.

(2) RECOMMENDATIONS.—Not later than 60 days after the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its recommendations on the application to the Secretary.

(g) MARKETING.—

(1) MODIFIED RISK TOBACCO PRODUCTS.—Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a modified risk tobacco product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that the modified risk tobacco product, as it is actually used by consumers, will—

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) benefit the health of the population as a whole taking into account both users of tobacco products and individuals who do not currently use tobacco products.

(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

(A) IN GENERAL.—The Secretary may issue an order that a tobacco product may be introduced or delivered for introduction into interstate commerce, pursuant to an application under this section, with respect to a tobacco product that may not be commercially marketed under paragraph (1) if the Secretary makes the findings required under this paragraph and de-

termines that the applicant has demonstrated that—

(i) the order would be appropriate to promote the public health;

(ii) any aspect of the label, labeling, and advertising for the tobacco product that would cause the tobacco product to be a modified risk tobacco product under subsection (a) is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;

(iii) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth in paragraph (1); and

(iv) the scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual

tobacco users is reasonably likely in subsequent studies.

(B) ADDITIONAL FINDINGS REQUIRED.—To issue an order under subparagraph (A), the Secretary shall also find that the applicant has demonstrated that—

(i) the magnitude of the overall reductions in exposure to the substance or substances that are the subject of the application is substantial, the substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;

(ii) the tobacco product as actually used by consumers will not expose the consumers to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless the increases are minimal and the reasonably likely overall impact of use of the tobacco product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

(iii) testing of actual consumer perception shows that, as the applicant proposes to label and market the tobacco product, consumers will not be misled into believing that the tobacco product—

(I) is or has been demonstrated to be less harmful; or

(II) presents or has been demonstrated to present less of a risk of disease than 1 or more other commercially marketed tobacco products; and

(iv) issuance of an order with respect to the application is expected to benefit the health of the population as a whole taking into account both users of tobacco products and individuals who do not currently use tobacco products.

(C) CONDITIONS OF MARKETING.—

(i) IN GENERAL.—Applications subject to an order under this paragraph shall be limited to a term of not more than 5 years, but may be renewed on a finding by the Secretary that the requirements of this paragraph continue to be satisfied based on the filing of a new application.

(ii) AGREEMENTS BY APPLICANT.—An order under this paragraph shall be conditioned on the applicant's agreement to conduct postmarket surveillance and studies and to submit to the Secretary the results of the surveillance and studies to determine the impact of the order on consumer perception, behavior, and health and to enable the Secretary to review the accuracy of the determinations on which the order was based in accordance with a protocol approved by the Secretary.

(iii) ANNUAL SUBMISSION.—The results of the postmarket surveillance and studies described in clause (ii) shall be submitted annually.

(3) BASIS.—The determinations under paragraphs (1) and (2) shall be based on—

(A) the scientific evidence submitted by the applicant; and

(B) scientific evidence and other information that is made available to the Secretary.

(4) BENEFIT TO HEALTH OF INDIVIDUALS AND OF POPULATION AS A WHOLE.—In making the de-

terminations under paragraphs (1) and (2), the Secretary shall take into account—

(A) the relative health risks to individuals of the tobacco product that is the subject of the application;

(B) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using the products will switch to the tobacco product that is the subject of the application;

(C) the increased or decreased likelihood that individuals who do not use tobacco products will start using the tobacco product that is the subject of the application;

(D) the risks and benefits to individuals from the use of the tobacco product that is the subject of the application as compared to the use of products for smoking cessation approved under division D to treat nicotine dependence; and

(E) comments, data, and information submitted by interested persons.

(h) ADDITIONAL CONDITIONS FOR MARKETING.—

(1) ADVERTISING OR LABELING TO ENABLE PUBLIC TO COMPREHEND INFORMATION CON-

CERNING MODIFIED RISK.—The Secretary shall require, for the marketing of a tobacco product under this section, that any advertising or labeling concerning modified risk tobacco products enable the public to comprehend the information concerning modified risk and to understand the relative significance of the information in the context of total health and in relation to all of the diseases and health-related conditions associated with the use of tobacco products.

(2) COMPARATIVE CLAIMS.—

(A) IN GENERAL.—The Secretary may require, for the marketing of a tobacco product under this subsection, that a claim comparing a tobacco product to 1 or more other commercially marketed tobacco products compare the tobacco product to a commercially marketed tobacco product that is representative of that type of tobacco product on the market (for example, the average value of the top 3 brands of an established regular tobacco product).

(B) QUANTITATIVE COMPARISONS.—The Secretary may also require, for purposes of subparagraph (A), that the percent (or fraction) of change and identity of the reference tobacco

product and a quantitative comparison of the amount of the substance claimed to be reduced be stated in immediate proximity to the most prominent claim.

(3) LABEL DISCLOSURE.—

(A) IN GENERAL.—The Secretary may require the disclosure on the label of other substances in the tobacco product, or substances that may be produced by the consumption of that tobacco product, that may affect a disease or health-related condition or may increase the risk of other diseases or health-related conditions associated with the use of tobacco products.

(B) CONDITIONS OF USE.—If the conditions of use of the tobacco product may affect the risk of the tobacco product to human health, the Secretary may require the labeling of conditions of use.

(4) TIME.—An order issued under subsection (g)(1) shall be effective for a specified period of time.

(5) ADVERTISING.—The Secretary may require, with respect to a tobacco product for which an applicant obtained an order under subsection (g)(1), that

the product comply with requirements relating to advertising and promotion of the tobacco product.

(i) POSTMARKET SURVEILLANCE AND STUDIES.—

(1) IN GENERAL.—

(A) REQUIREMENT.—The Secretary shall require, with respect to a tobacco product for which an applicant obtained an order under subsection (g)(1), that the applicant conduct postmarket surveillance and studies for the tobacco product to determine the impact of the order issuance on consumer perception, behavior, and health, to enable the Secretary to review the accuracy of the determinations on which the order was based, and to provide information that the Secretary determines is otherwise necessary regarding the use or health risks involving the tobacco product.

(B) ANNUAL SUBMISSION OF RESULTS.—The results of postmarket surveillance and studies shall be submitted to the Secretary on an annual basis.

(2) SURVEILLANCE PROTOCOL.—

(A) SUBMISSION.—Each applicant required to conduct a surveillance of a tobacco product under paragraph (1) shall, within 30 days after

receiving notice that the applicant is required to conduct the surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance.

(B) QUALIFICATIONS AND EXPERIENCE OF PRINCIPAL INVESTIGATOR.—The Secretary, within 60 days of the receipt of the protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct the surveillance and if the protocol will result in collection of the data or other information designated by the Secretary as necessary to protect the public health.

(j) WITHDRAWAL OF AUTHORIZATION.—The Secretary, after an opportunity for an informal hearing, shall withdraw an order under subsection (g) if the Secretary determines that—

(1) the applicant, based on new information, can no longer make the demonstrations required under subsection (g), or the Secretary can no longer make the determinations required under subsection (g);

(2) the application failed to include material information or included any untrue statement of material fact;

(3) any explicit or implicit representation that the tobacco product reduces risk or exposure is no longer valid, including if—

(A) a tobacco product standard is established pursuant to section 21108 of this title;

(B) an action is taken that affects the risks presented by other commercially marketed tobacco products that were compared to the tobacco product that is the subject of the application; or

(C) any postmarket surveillance or studies reveal that the order is no longer consistent with the protection of the public health;

(4) the applicant failed to conduct or submit the postmarket surveillance and studies required under subsection (g)(2)(C)(ii) or subsection (i); or

(5) the applicant failed to meet a condition imposed under subsection (h).

(k) DIVISION C OR D.—A tobacco product for which the Secretary has issued an order pursuant to subsection (g) shall not be subject to division C or D.

(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

(1) SCIENTIFIC EVIDENCE; CONTENTS.—The Secretary shall issue regulations or guidance (or any combination of regulations and guidance) on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. The regulations or guidance shall—

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for tobacco products described in subsection (g)(1) or is reasonably likely for tobacco products described in subsection (g)(2);

(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;

(C) establish minimum standards for postmarket studies that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate;

(D) establish minimum standards for required postmarket surveillance, including ongoing assessments of consumer perception;

(E) require that data from the required studies and surveillance be made available to the Secretary prior to the decision on renewal of a modified risk tobacco product; and

(F) establish a reasonable timetable for the Secretary to review an application under this section.

(2) CONSULTATION.—The regulations or guidance issued under paragraph (1) shall be developed in consultation with the National Academy of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of the studies and surveillance.

(3) REVISION.—The regulations or guidance under paragraph (1) shall be revised on a regular basis as new scientific information becomes available.

(4) NEW TOBACCO PRODUCTS.—The Secretary shall issue a regulation or guidance that permits the filing of a single application for any tobacco product that is a new tobacco product under section 21111

of this title and that the applicant seeks to commercially market under this section.

(m) DISTRIBUTORS.—Except as provided in this section, a distributor shall not take any action with respect to a tobacco product that would reasonably be expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than 1 or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

**§ 21113. Judicial review**

(a) DEFINITION OF RECORD.—In this section, the term ''record'' means—

(1) all notices and other matter published in the Federal Register with respect to a regulation or order reviewed;

(2) all information submitted to the Secretary with respect to the regulation or order;

(3) proceedings of any panel or advisory committee with respect to the regulation or order;

(4) any hearing held with respect to the regulation or order; and

(5) any other information identified by the Secretary, in the administrative proceeding held with re-

spect to the regulation or order, as being relevant to the regulation or order.

(b) RIGHT TO REVIEW.—

(1) IN GENERAL.—

(A) TIMING.—Any person described in subparagraph (B) may file a petition for judicial review as described in subparagraph (B) not later than 30 days after—

(i) the promulgation of a regulation under section 21108 of this title establishing, amending, or revoking a tobacco product standard; or

(ii) a denial of an application under section 21111(d) of this title.

(B) FILING.—Any person adversely affected by a regulation under subparagraph (A)(i) or a denial under subparagraph (A)(ii) may file a petition for judicial review of the regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides or in which the person's principal place of business is located.

(2) REQUIREMENTS.—

(A) COPY OF PETITION.—A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

(B) RECORD OF PROCEEDINGS.—On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which the petition was filed—

(i) the record of the proceedings on which the regulation or denial order was based; and

(ii) a statement of the reasons for the issuance of the regulation or denial order.

(c) STANDARD OF REVIEW.—On the filing of the petition under subsection (b) for judicial review of a regulation or denial order, the court shall have jurisdiction to review the regulation or denial order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided for in chapter 7 of title 5. A regulation or denial described in subsection (b) shall be reviewed in accordance with section 706(2)(A) of title 5.

(d) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or denial order shall be final, subject to review

by the Supreme Court on certiorari or certification, as provided in section 1254 of title 28.

(e) OTHER REMEDIES.—The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(f) REASONS FOR ISSUANCE.—To facilitate judicial review, a regulation or order issued under section 21107, 21108, 21109, 21110, 21111, or 21117 of this title shall contain a statement of the reasons for the issuance of the regulation or order in the record of the proceedings held in connection with its issuance.

**§ 21114. Equal treatment of retail outlets**

The Secretary shall issue regulations to require that retail establishments for which the predominant business is the sale of tobacco products comply with any advertising restrictions applicable to retail establishments accessible to individuals under the age of 18.

**§ 21115. Jurisdiction of and coordination with the Federal Trade Commission**

(a) JURISDICTION.—

(1) IN GENERAL.—Except as expressly provided in this chapter, nothing in this chapter shall be construed as limiting or diminishing the authority of the Federal Trade Commission to enforce the laws

under its jurisdiction with respect to the advertising, sale, or distribution of tobacco products.

(2) ENFORCEMENT.—Any advertising that violates this chapter or a provision of the regulations referred to in section 80101 of this title is an unfair or deceptive act or practice under section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)) and shall be considered a violation of a rule promulgated under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a).

(b) COORDINATION.—With respect to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402)—

(1) the Chairman of the Federal Trade Commission shall coordinate with the Secretary concerning the enforcement of the Acts as the enforcement relates to unfair or deceptive acts or practices in the advertising of cigarettes or smokeless tobacco; and

(2) the Secretary shall consult with the Chairman of the Federal Trade Commission in revising the label statements and requirements under the sections.

**§ 21116. Regulation requirement**

(a) PROMULGATION.—Not later than 36 months after June 22, 2009, the Secretary shall promulgate regulations under this subtitle that meet the requirements of subsection (b).

(b) CONTENTS OF REGULATIONS.—The regulations promulgated under subsection (a)—

(1) shall require testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, by brand and subbrand that the Secretary determines should be tested to protect the public health, provided that, for purposes of the testing requirements of this paragraph, tobacco products manufactured and sold by a single tobacco product manufacturer that are identical in all respects except the labels, packaging design, logo, trade dress, trademark, brand name, or any combination thereof, shall be considered as a single brand; and

(2) may require that tobacco product manufacturers, packagers, or importers make disclosures relating to the results of the testing of tar and nicotine through labels or advertising or other appropriate means, and make disclosures regarding the results of the testing of other constituents, including smoke constituents, ingredients, or additives, that

the Secretary determines should be disclosed to the public to protect the public health and will not mislead consumers about the risk of tobacco-related disease.

(c) AUTHORITY.—The Secretary shall have the authority under this chapter to conduct or to require the testing, reporting, or disclosure of tobacco product constituents, including smoke constituents.

(d) SMALL TOBACCO PRODUCT MANUFACTURERS.—

(1) FIRST COMPLIANCE DATE.—The initial regulations promulgated under subsection (a) shall not impose requirements on small tobacco product manufacturers before the later of—

(A) the end of the 2-year period following the final promulgation of the regulations; or

(B) the initial date set by the Secretary for compliance with the regulations by manufacturers that are not small tobacco product manufacturers.

(2) TESTING AND REPORTING INITIAL COMPLIANCE PERIOD.—

(A) FOUR-YEAR PERIOD.—

(i) IN GENERAL.—The initial regulations promulgated under subsection (a) shall give each small tobacco product man-

ufacturer a 4-year period over which to conduct testing and reporting for all of its tobacco products.

(ii) TIMELINE.—Subject to paragraph (1), the end of the first year of the 4-year period shall coincide with the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers or the end of the 2-year period following the final promulgation of the regulations, as described in paragraph (1)(A).

(iii) REQUIREMENTS.—A small tobacco product manufacturer shall be required—

(I) to conduct the testing and reporting for 25 percent of its tobacco products during each year of the 4-year period; and

(II) to conduct the testing and reporting for its largest-selling tobacco products (as determined by the Secretary) before its other tobacco products, or in such other order of

priority as determined by the Secretary.

(B) CASE-BY-CASE DELAY.—

(i) UNDUE HARDSHIP.—Notwithstanding subparagraph (A), the Secretary may, on a case-by-case basis, delay the date by which an individual small tobacco product manufacturer must conduct testing and reporting for its tobacco products under this section based on a showing of undue hardship to the manufacturer.

(ii) LIMITATION.—Notwithstanding clause (i), the Secretary shall not extend the deadline for a small tobacco product manufacturer to conduct testing and reporting for all of its tobacco products beyond a total of 5 years after the initial date of compliance under this section set by the Secretary with respect to manufacturers that are not small tobacco product manufacturers.

(3) SUBSEQUENT AND ADDITIONAL TESTING AND REPORTING.—The regulations promulgated under subsection (a) shall provide that, with respect to any subsequent or additional testing and report-

ing of tobacco products required under this section, the testing and reporting by a small tobacco product manufacturer shall be conducted in accordance with the timeframes described in paragraph (2)(A), except that, in the case of a new product, or if there has been a modification described in section 21111(a)(1)(B) of this title of any product of a small tobacco product manufacturer since the last testing and reporting required under this section, the Secretary shall require that any subsequent or additional testing and reporting be conducted in accordance with the same timeframe applicable to manufacturers that are not small tobacco product manufacturers.

(4) JOINT LABORATORY TESTING SERVICES.—The Secretary shall allow any 2 or more small tobacco product manufacturers to join together to purchase laboratory testing services required by this section on a group basis in order to ensure that the manufacturers receive access to, and fair pricing of, the testing services.

(e) EXTENSIONS FOR LIMITED LABORATORY CAPACITY.—

(1) IN GENERAL.—The regulations promulgated under subsection (a) shall provide that a small to-

bacco product manufacturer shall not be considered to be in violation of this section before the deadline applicable under paragraphs (3) and (4), if—

(A) the tobacco products of the manufacturer are in compliance with all other requirements of this chapter; and

(B) the conditions described in paragraph (2) are met.

(2) CONDITIONS.—Notwithstanding the requirements of this section, the Secretary may delay the date by which a small tobacco product manufacturer must be in compliance with the testing and reporting required by this section until such time as the testing is reported if, not later than 90 days before the deadline for reporting in accordance with this section, a small tobacco product manufacturer provides evidence to the Secretary demonstrating that—

(A) the manufacturer has submitted the required tobacco products for testing to a laboratory and has done so sufficiently in advance of the deadline to create a reasonable expectation of completion by the deadline;

(B) the tobacco products currently are awaiting testing by the laboratory; and

(C) neither the laboratory nor any other laboratory is able to complete testing by the deadline at customary, nonexpedited testing fees.

(3) EXTENSION.—

(A) REVIEW AND VERIFICATION OF EVIDENCE.—The Secretary, taking into account the laboratory testing capacity that is available to tobacco product manufacturers, shall review and verify the evidence submitted by a small tobacco product manufacturer in accordance with paragraph (2).

(B) NOTIFICATION.—If the Secretary finds that the conditions described in paragraph (2) are met, the Secretary shall notify the small tobacco product manufacturer that the manufacturer shall not be considered to be in violation of the testing and reporting requirements of this section until the testing is reported or until 1 year after the reporting deadline has passed, whichever occurs sooner. If, however, the Secretary has not made a finding before the reporting deadline, the manufacturer shall not be considered to be in violation of the requirements until the Secretary finds that the conditions de-

scribed in paragraph (2) have not been met, or until 1 year after the reporting deadline, whichever occurs sooner.

(4) ADDITIONAL EXTENSION.—In addition to the time that may be provided under paragraph (3), the Secretary may provide further extensions of time, in increments of no more than 1 year, for required testing and reporting to occur if the Secretary determines, based on evidence properly and timely submitted by a small tobacco product manufacturer in accordance with paragraph (2), that a lack of available laboratory capacity prevents the manufacturer from completing the required testing during the period described in paragraph (3).

(f) RULE OF CONSTRUCTION.—Nothing in subsection (d) or (e) shall be construed to authorize the extension of any deadline, or to otherwise affect any timeframe, under any provision of this subtitle (other than this section), chapter 701 of this title, or the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776).

**§ 21117. Preservation of State and local authority**

(a) IN GENERAL.—

(1) PRESERVATION.—

(A) IN GENERAL.—Except as provided in paragraph (2)(A), nothing in this chapter, or rules promulgated under this chapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure—

(i) relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age;

(ii) relating to information reporting to the State; or

(iii) relating to fire safety standards for tobacco products.

(B) TAXATION OF TOBACCO PRODUCTS.—A provision of this chapter shall not limit or otherwise affect any State, tribal, or local taxation of tobacco products.

(2) PREEMPTION OF CERTAIN STATE AND LOCAL REQUIREMENTS.—

(A) IN GENERAL.—A State or political subdivision of a State shall not establish or continue in effect with respect to a tobacco product any requirement that is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

(B) EXCEPTION.—

(i) IN GENERAL.—Subparagraph (A) does not apply to requirements—

(I) relating to—

(aa) the sale, distribution, possession, or information reporting to the State of tobacco products by individuals of any age; or

(bb) exposure to, access to, the advertising and promotion of, or use of tobacco products by individuals of any age; or

(II) relating to fire safety standards for tobacco products.

(ii) INFORMATION DISCLOSED TO STATE.—Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5 shall be treated as a trade secret and confidential information by the State.

(b) RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY.—No provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

**§ 21118. Tobacco Products Scientific Advisory Committee**

(a) DEFINITION OF ADVISORY COMMITTEE.—In this section, the term ''Advisory Committee'' means the Tobacco Products Scientific Advisory Committee established under subsection (b).

(b) ESTABLISHMENT.—The Secretary shall establish a 12-member advisory committee, to be known as the Tobacco Products Scientific Advisory Committee.

(c) MEMBERSHIP.—

(1) IN GENERAL.—

(A) MEMBERS.—The Secretary shall appoint as members of the Tobacco Products Scientific Advisory Committee individuals who are technically qualified by training and experience in medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products, and who are of appropriately diversified professional backgrounds. The Advisory Committee shall be composed of—

(i) 7 individuals who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty;

(ii) 1 individual who is an officer or employee of a State or local government or of the Federal Government;

(iii) 1 individual as a representative of the general public;

(iv) 1 individual as a representative of the interests of the tobacco manufacturing industry;

(v) 1 individual as a representative of the interests of the small business tobacco manufacturing industry, which position may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Advisory Committee; and

(vi) 1 individual as a representative of the interests of the tobacco growers.

(B) NONVOTING MEMBERS.—The members of the Advisory Committee appointed under clauses (iv), (v), and (vi) of subparagraph (A) shall serve as consultants to those described in clauses (i) through (iii) of subparagraph (A) and shall be nonvoting representatives.

(C) CONFLICTS OF INTEREST.—A member of the committee, other than a member appointed pursuant to clauses (iv), (v), and (vi) of subparagraph (A), shall not, during the member's tenure on the Advisory Committee or for the 18-month period prior to becoming a member, receive any salary, grants, or other payments or support from any business that manu-

factures, distributes, markets, or sells cigarettes or other tobacco products.

(2) LIMITATION.—The Secretary may not appoint to the Advisory Committee any individual who is in the regular full-time employ of the FDA or any agency responsible for the enforcement of this subtitle. The Secretary may appoint Federal officials as ex officio members.

(3) CHAIRPERSON.—The Secretary shall designate 1 of the members appointed under clauses (i), (ii), and (iii) of paragraph (1)(A) to serve as chairperson.

(d) DUTIES.—The Advisory Committee shall provide to the Secretary, as provided in this chapter, advice, information, and recommendations—

(1) on the effects of the alteration of the nicotine yields from tobacco products;

(2) on whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and

(3) on the Advisory Committee's review of other safety, dependence, or health issues relating to tobacco products as requested by the Secretary.

(e) COMPENSATION; SUPPORT; CHAPTER 10 OF TITLE 5.—

(1) COMPENSATION AND TRAVEL.—

(A) IN GENERAL.—A member of the Advisory Committee who is not an officer or employee of the United States, while attending conferences or meetings of the Advisory Committee or otherwise engaged in the Advisory Committee's business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which may not exceed the daily equivalent of the rate in effect under the Senior Executive Schedule under section 5382 of title 5, for each day (including travel time) that the member is engaged in the Advisory Committee's business.

(B) TRAVEL.—While serving under subparagraph (A) away from the member's home or regular place of business, each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for individuals in the Government service employed intermittently.

(2) ADMINISTRATIVE SUPPORT.—The Secretary shall furnish the Advisory Committee clerical and other assistance.

(3) INAPPLICABILITY OF CHAPTER 10 OF TITLE 5.—Section 1013 of title 5 does not apply to the Advisory Committee.

(f) PROCEEDINGS OF ADVISORY PANELS AND COMMITTEES.—The Advisory Committee shall make and maintain a transcript of any proceeding of the Advisory Committee. The Advisory Committee shall delete from any transcript made under this subsection information that is exempt from disclosure under section 552(b) of title 5.

**§ 21119. Drug products used to treat tobacco dependence**

The Secretary shall—

(1) at the request of the applicant, consider designating products for smoking cessation, including nicotine replacement products, as fast track research and approval products within the meaning of section 13119 of this title;

(2) consider approving the extended use of nicotine replacement products (such as nicotine patches, nicotine gum, and nicotine lozenges) for the treatment of tobacco dependence; and

(3) review and consider the evidence for additional indications for nicotine replacement products, such as for craving relief or relapse prevention.

**§ 21120. User fees**

(a) ESTABLISHMENT OF QUARTERLY FEE.—The Secretary shall, in accordance with this section, assess user fees on, and collect the fees from, each manufacturer and importer of tobacco products subject to this chapter. The fees shall be assessed and collected with respect to each quarter of each fiscal year, and the total amount assessed and collected for a fiscal year shall be the amount specified in subsection (b)(1) for the fiscal year, subject to subsection (c).

(b) ASSESSMENT OF USER FEE.—

(1) AMOUNT OF ASSESSMENT.—The total amount of user fees authorized to be assessed and collected under subsection (a) for each fiscal year is $712,000,000.

(2) ALLOCATIONS OF ASSESSMENT BY CLASS OF TOBACCO PRODUCTS.—

(A) IN GENERAL.—The total user fees assessed and collected under subsection (a) each fiscal year with respect to each class of tobacco products shall be an amount that is equal to the applicable percentage of each class for the fiscal year multiplied by the amount specified in paragraph (1) for the fiscal year.

(B) APPLICABLE PERCENTAGE.—

(i) IN GENERAL.—For purposes of subparagraph (A), the applicable percentage for a fiscal year for each of the following classes of tobacco products shall be determined in accordance with clause (ii):

(I) Cigarettes.

(II) Cigars, including small cigars and cigars other than small cigars.

(III) Snuff.

(IV) Chewing tobacco.

(V) Pipe tobacco.

(VI) Roll-your-own tobacco.

(ii) ALLOCATIONS.—The applicable percentage of each class of tobacco product described in clause (i) for a fiscal year shall be the percentage determined under section 625(c) of the Fair and Equitable Tobacco Reform Act of 2004 (7 U.S.C. 518d(c)) for each class of tobacco product for the fiscal year.

(iii) REQUIREMENT OF REGULATIONS.—Notwithstanding clause (ii), user fees shall not be assessed on a class of tobacco products unless the class of tobacco

products is listed in section 21102(b) of this title or is deemed by the Secretary in a regulation under section 21102(b) of this title to be subject to this chapter.

(iv) REALLOCATIONS.—In the case of a class of tobacco products that is not listed in section 21102(b) of this title or deemed by the Secretary in a regulation under section 21102(b) of this title to be subject to this chapter, the amount of user fees that would otherwise be assessed to the class of tobacco products shall be reallocated to the classes of tobacco products that are subject to this chapter in the same manner and based on the same relative percentages otherwise determined under clause (ii).

(3) DETERMINATION OF USER FEE BY COMPANY.—

(A) IN GENERAL.—The total user fee to be paid by each manufacturer or importer of a particular class of tobacco products shall be determined for each quarter by multiplying—

(i) the manufacturer's or importer's percentage share as determined under paragraph (4); and

(ii) the portion of the user fee amount for the current quarter to be assessed on all manufacturers and importers of the class of tobacco products as determined under paragraph (2).

(B) NO FEE IN EXCESS OF PERCENTAGE SHARE.—A manufacturer or importer of tobacco products shall not be required to pay a user fee in excess of the percentage share of the manufacturer or importer.

(4) ALLOCATION OF ASSESSMENT WITHIN EACH CLASS OF TOBACCO PRODUCTS.—The percentage share of each manufacturer or importer of a particular class of tobacco products of the total user fee to be paid by all manufacturers or importers of that class of tobacco products shall be the percentage determined for purposes of allocations under subsections (e) through (h) of section 625 of the Fair and Equitable Tobacco Reform Act of 2004 (7 U.S.C. 518d(e) through (h)).

(5) ALLOCATION FOR CIGARS.—Notwithstanding paragraph (4), if a user fee assessment is

imposed on cigars, the percentage share of each manufacturer or importer of cigars shall be based on the excise taxes paid by the manufacturer or importer during the prior fiscal year.

(6) TIMING OF ASSESSMENT.—The Secretary shall notify each manufacturer and importer of tobacco products subject to this section of the amount of the quarterly assessment imposed on the manufacturer or importer under this subsection for each quarter of each fiscal year. The notifications shall occur not later than 30 days prior to the end of the quarter for which the assessment is made, and payments of all assessments shall be made by the last day of the quarter involved.

(7) MEMORANDUM OF UNDERSTANDING.—

(A) IN GENERAL.—The Secretary shall request the appropriate Federal agency to enter into a memorandum of understanding that provides for the regular and timely transfer from the head of the Federal agency to the Secretary of the information described in paragraphs (2)(B)(ii) and (4) and all necessary information regarding all tobacco product manufacturers and importers required to pay user fees. The Secretary shall maintain all disclosure restric-

tions established by the head of the Federal agency regarding the information provided under the memorandum of understanding.

(B) ASSURANCES.—For each fiscal year, the Secretary shall ensure that the FDA is able to determine the applicable percentages described in paragraph (2) and the percentage shares described in paragraph (4). The Secretary may carry out this subparagraph by entering into a contract with the head of the Federal agency referred to in subparagraph (A) to continue to provide the necessary information.

(c) CREDITING AND AVAILABILITY OF FEES.—

(1) DEFINITION OF TOBACCO REGULATION ACTIVITIES.—In this subsection, the term ''tobacco regulation activities'' means the activities of the FDA related to the regulation of tobacco products under this chapter, chapter 701 of this title, and the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776).

(2) IN GENERAL.—

(A) AVAILABILITY FOR OBLIGATION.—Fees authorized under subsection (a) shall be collected and available for obligation only to the

extent and in the amount provided in advance in appropriations Acts.

(B) AVAILABLE UNTIL EXPENDED.—The fees are authorized to remain available until expended.

(C) TRANSFERS.—Such sums as may be necessary may be transferred from the FDA salaries and expenses appropriation account without fiscal year limitation to the appropriation account for salaries and expenses with fiscal year limitation.

(3) AVAILABILITY.—

(A) IN GENERAL.—Fees appropriated under paragraph (4) are available only for the purpose of paying the costs of tobacco regulation activities.

(B) PROHIBITION AGAINST USE OF OTHER FUNDS.—Fees collected under subsection (a) are the only funds authorized to be made available for tobacco regulation activities.

(4) AUTHORIZATION OF APPROPRIATIONS.—For each fiscal year, there is authorized to be appropriated for fees under this section an amount equal to the amount specified in subsection (b)(1) for the fiscal year.

(d) COLLECTION OF UNPAID FEES.—In any case in which the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, the fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

**§ 21121. Labeling, recordkeeping, records inspection**

(a) ORIGIN LABELING.—

(1) REQUIREMENT.—Beginning 1 year after June 22, 2009, the label, packaging, and shipping containers of tobacco products other than cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement ''sale only allowed in the United States''. Beginning 15 months after the issuance of the regulations required by section 4(d) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(d)), as amended by section 201 of the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1842), the label, packaging, and shipping containers of cigarettes for introduction or delivery for introduction into interstate commerce in the United States shall bear the statement ''Sale only allowed in the United States''.

(2) EFFECTIVE DATE.—The effective date specified in paragraph (1) shall be with respect to the date of manufacture, provided that, in any case, beginning 30 days after the effective date, a manufacturer shall not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with paragraph (1).

(b) REGULATIONS CONCERNING RECORDKEEPING FOR TRACKING AND TRACING.—

(1) IN GENERAL.—The Secretary shall promulgate regulations regarding the establishment and maintenance of records by any person that manufactures, processes, transports, distributes, receives, packages, holds, exports, or imports tobacco products.

(2) INSPECTION.—In promulgating the regulations described in paragraph (1), the Secretary shall consider which records are needed for inspection to monitor the movement of tobacco products from the point of manufacture through distribution to retail outlets to assist in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

(3) CODES.—The Secretary may require codes on the labels of tobacco products or other designs or devices for the purpose of tracking or tracing the tobacco products through the distribution system.

(4) SIZE OF BUSINESS.—The Secretary shall take into account the size of a business in promulgating regulations under this section.

(5) RECORDKEEPING BY RETAILERS.—The Secretary shall not require any retailer to maintain records relating to individual purchasers of tobacco products for personal consumption.

(c) RECORDS INSPECTION.—

(1) IN GENERAL.—If the Secretary has a reasonable belief that a tobacco product is part of an illicit trade or smuggling or is a counterfeit product, each person that manufactures, processes, transports, distributes, receives, holds, packages, exports, or imports tobacco products shall, at the request of an officer or employee designated by the Secretary, permit the officer or employee, at reasonable times and within reasonable limits and in a reasonable manner, on the presentation of appropriate credentials and a written notice to the person, to have access to and copy all records (including financial records) relating to the article that are needed to as-

sist the Secretary in investigating potential illicit trade, smuggling, or counterfeiting of tobacco products.

(2) INDIAN COUNTRY.—The Secretary shall not authorize an officer or employee of the government of any State to exercise authority under paragraph (1) on Indian country without the express written consent of the Indian tribe involved.

(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

(1) DEFINITION OF KNOWLEDGE.—In this subsection, the term ''knowledge'' as applied to a manufacturer or distributor means—

(A) the actual knowledge that the manufacturer or distributor had; or

(B) the knowledge that a reasonable person would have had under like circumstances or that would have been obtained on the exercise of due care.

(2) NOTIFICATION.—The manufacturer or distributor of a tobacco product shall promptly notify the Attorney General and the Secretary of the Treasury that the manufacturer or distributor has knowledge that reasonably supports the conclusion that a tobacco product manufactured or distributed

by the manufacturer or distributor that has left the control of the person may be or has been—

(A) imported, exported, distributed, or offered for sale in interstate commerce by a person without paying duties or taxes required by law; or

(B) imported, exported, distributed, or diverted for possible illicit marketing.

(e) CONSULTATION.—In carrying out this section, the Secretary shall consult with the Attorney General of the United States and the Secretary of the Treasury, as appropriate.

# Subtitle II—Supplemental Food and Drug Administration Provisions

## Chapter 251—General Provisions

Sec.
25101. Subtitle definitions.

### § 25101. Subtitle definitions

In this subtitle:

(1) DEPARTMENT.—The term ''Department'' means the Department of Health and Human Services.

(2) FDA.—The term ''FDA'' means the Food and Drug Administration established in section 10301 of this title.

(3) FDA WEBSITE.—The term ''FDA website'' means the internet website of the FDA.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

# Chapter 253—Organization and Administration

Sec.
25301. Office of Pediatric Therapeutics.
25302. Office of Minor Use and Minor Species Animal Drug Development.
25303. Nanotechnology.
25304. FDA Working Capital Fund.
25305. Accelerated approval council.
25306. Improving FDA guidance and communication.
25307. Food and Drug Administration Strategic Information Technology Plan.
25308. Office of Critical Foods; infant supply.
25309. International harmonization relating to modernizing clinical trials.

## § 25301. Office of Pediatric Therapeutics

(a) ESTABLISHMENT.—The Secretary shall establish an Office of Pediatric Therapeutics within the FDA.

(b) DUTIES.—The Office of Pediatric Therapeutics shall be responsible for coordination and facilitation of all activities of the FDA that may have any effect on a pediatric population or the practice of pediatrics or may in any other way involve pediatric issues, including increasing pediatric access to medical devices.

(c) STAFF.—The staff of the Office of Pediatric Therapeutics—

(1) shall coordinate with employees of the Department who exercise responsibilities relating to pediatric therapeutics; and

(2) shall include—

(A) 1 or more additional individuals with expertise concerning ethical issues presented by the conduct of clinical research in the pediatric population;

(B) subject to subsection (d), 1 or more additional individuals with necessary expertise in a pediatric subpopulation that is, as determined through consideration of the reports and recommendations issued by the National Academy of Medicine and the Comptroller General, less likely to be studied as a part of a written request issued under section 13112 of this title or an assessment under section 13113 of this title;

(C) 1 or more additional individuals with expertise in pediatric epidemiology; and

(D) 1 or more additional individuals with expertise in pediatrics as may be necessary to perform the activities described in subsection (b).

(d) NEONATOLOGY EXPERTISE.—At least 1 of the individuals described in subsection (c)(2)(B) shall have expertise in neonatology.

**§ 25302. Office of Minor Use and Minor Species Animal Drug Development**

(a) ESTABLISHMENT.—The Secretary shall establish within the Center for Veterinary Medicine (of the FDA), an Office of Minor Use and Minor Species Animal Drug Development that reports directly to the Director of the Center for Veterinary Medicine.

(b) RESPONSIBILITIES.—The Office established in subsection (a) shall be responsible for overseeing the development and legal marketing of new animal drugs for minor uses and minor species.

**§ 25303. Nanotechnology**

(a) IN GENERAL.—The Secretary shall intensify and expand activities related to enhancing scientific knowledge regarding nanomaterials included or intended for inclusion in products regulated under subtitle I of this title or other statutes administered by the FDA, to address issues relevant to the regulation of those products, including the potential toxicology of the nanomaterials, the potential benefit of new therapies derived from nanotechnology, the effects of the nanomaterials on biological systems, and the interaction of the nanomaterials with biological systems.

(b) ACTIVITIES.—In conducting activities related to nanotechnology, the Secretary may—

(1) assess scientific literature and data on general nanomaterials interactions with biological sys-

tems and on specific nanomaterials of concern to the FDA;

(2) in cooperation with other Federal agencies, develop and organize information using databases and models that will facilitate the identification of generalized principles and characteristics regarding the behavior of classes of nanomaterials with biological systems;

(3) promote FDA programs and participate in collaborative efforts, to further the understanding of the science of novel properties of nanomaterials that might contribute to toxicity;

(4) promote and participate in collaborative efforts to further the understanding of measurement and detection methods for nanomaterials;

(5) collect, synthesize, interpret, and disseminate scientific information and data related to the interactions of nanomaterials with biological systems;

(6) build scientific expertise on nanomaterials within the FDA, including field and laboratory expertise, for monitoring the production and presence of nanomaterials in domestic and imported products regulated under the Food and Drug Administration

Safety and Innovation Act (Public Law 112–144, 126 Stat. 993);

(7) ensure ongoing training, as well as dissemination of new information within the centers of the FDA, and more broadly across the FDA, to ensure timely, informed consideration of the most current science pertaining to nanomaterials;

(8) encourage the FDA to participate in international and national consensus standards activities pertaining to nanomaterials; and

(9) carry out other activities that the Secretary determines are necessary and consistent with the purposes described in paragraphs (1) through (8).

**§ 25304. FDA Working Capital Fund**

(a) DEFINITION OF FUND.—In this section, the term ''Fund'' means the Working Capital Fund established under subsection (b).

(b) IN GENERAL.—

(1) ESTABLISHMENT.—There is established in the Treasury of the United States a Working Capital Fund to be administered by the FDA, without fiscal year limitation, for the payment of salaries, travel, and other expenses necessary to the maintenance and operation of—

(A) a supply service for the purchase, storage, handling, issuance, packing, or shipping of stationery, supplies, materials, equipment, and blank forms, for which stocks may be maintained to meet, in whole or in part, the needs of the FDA and requisitions of other Government offices; and

(B) such other services as the Commissioner of Food and Drugs, subject to review by the Secretary, determines may be performed more advantageously as central services.

(2) REIMBURSEMENT.—The Fund shall be reimbursed from applicable discretionary resources, notwithstanding any otherwise applicable purpose limitations, available when services are performed or stock furnished, or in advance, on a basis of rates which shall include estimated or actual charges for personal services, materials, equipment, information technology, and other expenses.

(3) CHARGES FOR EQUIPMENT AND INFORMATION TECHNOLOGY.—Charges for equipment and information technology shall include costs associated with maintenance, repair, and depreciation (including improvement and replacement).

(c) EMERGENCY FUNDS EXCLUDED.—No amounts may be transferred pursuant to this section that are designated by the Congress as an emergency requirement pursuant to a concurrent resolution on the budget or the Balanced Budget and Emergency Deficit Control Act of 1985 (2 U.S.C. 900 et seq.).

**§ 25305. Accelerated approval council**

(a) IN GENERAL.—Not later than 1 year after December 29, 2022, the Secretary shall establish an intra-agency coordinating council (referred to in this subsection as the ''Council'') within the FDA to ensure the consistent and appropriate use of accelerated approval across the FDA, pursuant to section 13119(d) of this title.

(b) MEMBERSHIP.—The members of the Council shall consist of the following senior officials, or a designee of the official, from the FDA and relevant Centers:

(1) The Director of the Center for Drug Evaluation and Research.

(2) The Director of the Center for Biologics Evaluation and Research.

(3) The Director of the Oncology Center of Excellence.

(4) The Director of the Office of New Drugs.

(5) The Director of the Office of Orphan Products Development.

(6) The Director of the Office of Tissues and Advanced Therapies.

(7) The Director of the Office of Medical Policy.

(8) At least 3 directors of review divisions or offices overseeing products approved under accelerated approval, including at least 1 director in the Office of Neuroscience.

(c) DUTIES OF THE COUNCIL.—

(1) MEETINGS.—The Council shall convene not fewer than 3 times per calendar year to discuss issues related to accelerated approval, including any relevant cross-disciplinary approaches related to product review with respect to accelerated approval.

(2) POLICY DEVELOPMENT.—The Council shall directly engage with product review teams to support the consistent and appropriate use of accelerated approval across the FDA. That engagement may include—

(A) developing guidance for FDA staff and best practices for, and across, product review teams, including with respect to communication between sponsors and the FDA and the review of products under accelerated approval;

(B) providing training for product review teams; and

(C) advising review divisions on best practices with respect to product-specific development, review, and withdrawal of products under accelerated approval.

(d) PUBLICATION OF A REPORT.—Not later than 1 year after December 29, 2022, and annually thereafter, the Council shall publish on the public FDA website a report on the activities of the Council.

**§ 25306. Improving FDA guidance and communication**

(a) FDA REPORT AND IMPLEMENTATION OF GOOD GUIDANCE PRACTICES.—The Secretary shall develop, and publish on the FDA website—

(1) a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents, within centers, across the FDA, and across other applicable agencies; and

(2) a plan for implementation of the best practices described in paragraph (1), including across other applicable agencies, that shall address—

(A) streamlining development and review of guidance documents within centers and across the FDA;

(B) streamlining processes for regulatory submissions to the FDA, including through the revision or issuance of guidance documents; and

(C) implementing innovative guidance development processes and practices and transitioning or updating guidance issued during the COVID–19 public health emergency, as appropriate.

(b) REPORT AND IMPLEMENTATION OF FDA BEST PRACTICES FOR COMMUNICATING WITH EXTERNAL STAKEHOLDERS.—The Secretary, acting through the Commissioner of Food and Drugs, shall develop and publish on the FDA website a report on the practices of the FDA to broadly communicate with external stakeholders, other than through guidance documents, that shall include—

(1) a review of the types and methods of public communication that the FDA uses to communicate and interact with medical product sponsors and other external stakeholders;

(2) the identification of best practices for the efficient development, issuance, and use of those communications; and

(3) a plan for implementation of best practices for communication with external stakeholders, that shall address—

(A) advancing the use of innovative forms of communication, including novel document types and formats, to provide increased regulatory clarity to product sponsors and other stakeholders, and advancing methods of communicating and interacting with medical product sponsors and other external stakeholders, including the use of tools such as product submission templates, webinars, and frequently asked questions communications;

(B) streamlining processes for regulatory submissions; and

(C) implementing innovative communication development processes and transitioning or updating communication practices used during the COVID–19 public health emergency, as appropriate.

(c) CONSULTATION.—In developing and publishing the report and implementation plan under this section, the Secretary shall consult with stakeholders, including researchers, academic organizations, pharmaceutical, biotechnology, and medical device developers, clinical re-

search organizations, clinical laboratories, health care providers, patient groups, and other appropriate stakeholders.

(d) MANNER OF ISSUANCE.—For purposes of carrying out this section, the Secretary may update an existing report or plan, and may combine the reports and implementation plans described in subsections (a) and (b) into 1 or more documents.

(e) TIMING.—The Secretary shall—

(1) not later than 1 year after December 29, 2022, publish a draft of the reports and plans required under this section; and

(2) not later than 180 days after publication of the draft reports and plans under paragraph (1)—

(A) publish a final report and plan; and

(B) begin implementation of the best practices pursuant to the final plan.

**§ 25307. Food and Drug Administration Strategic Information Technology Plan**

(a) IN GENERAL.—

(1) DEVELOPMENT AND SUBMISSION.—Not later than September 30, 2023, and at least every 4 years thereafter, the Secretary shall develop and submit to the appropriate committees of Congress and post on the FDA website, a coordinated infor-

mation technology strategic plan to modernize the information technology systems of the FDA.

(2) NAME OF REPORT.—Each report shall be known as the ''Food and Drug Administration Strategic Information Technology Plan'' (referred to in this section as ''Plan'').

(3) INCLUSION.—The first report may include the Data and Technology Modernization Strategy, as set forth in the letters described in section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 21 U.S.C. 379g note).

(b) CONTENT OF STRATEGIC PLAN.—The Plan shall include—

(1) agency-wide strategic goals and priorities for modernizing the information technology systems of the FDA to maximize the efficiency and effectiveness of the systems for enabling the FDA to fulfill its public health mission;

(2) specific activities and strategies for achieving the goals and priorities identified under paragraph (1), and specific milestones, metrics, and performance measures for assessing progress against those strategic goals and priorities;

(3) specific activities and strategies for improving and streamlining internal coordination and communication within the FDA, including for activities and communications related to signals of potential public health concerns;

(4) challenges and risks the FDA will face in meeting its strategic goals and priorities, and the activities the FDA will undertake to overcome those challenges and mitigate those risks;

(5) the ways in which the FDA will use the Plan to guide and coordinate the projects and activities of the FDA across its offices and centers; and

(6) a skills inventory, needs assessment, gap analysis, and initiatives to address skills gaps as part of a strategic approach to information technology human capital planning.

(c) EVALUATION OF PROGRESS.—Each Plan issued pursuant to this section, with the exception of the first Plan, shall include an evaluation of—

(1) the progress the Secretary has made, based on the metrics, benchmarks, and other milestones that measure successful development and implementation of information technology systems; and

(2) whether actions taken in response to the previous Plan improved the capacity of the FDA to

achieve the strategic goals and priorities set forth in previous Plans.

**§ 25308. Office of Critical Foods; infant supply**

(a) DEFINITION OF INFANT FORMULA.—In this section, the term ''infant formula'' has the meaning given the term in section 10101(a) of this title.

(b) OFFICE OF CRITICAL FOODS.—

(1) IN GENERAL.—The Secretary shall establish within the Center for Food Safety and Applied Nutrition an office to be known as the Office of Critical Foods. The Secretary shall appoint a Director to lead the Office.

(2) DUTIES.—The Office of Critical Foods shall be responsible for oversight, coordination, and facilitation of activities related to critical foods, as defined in section 10101(a) of this title.

(c) INFANT FORMULA FLEXIBILITIES.—The Secretary shall publish a list, on the website of the Department, providing information on how to identify appropriate substitutes for infant formula products in shortage that are relied on by infants and other individuals with inborn errors of metabolism or other serious health conditions.

(d) INTERNATIONAL HARMONIZATION OF INFANT FORMULA REQUIREMENTS.—The Secretary—

(1) shall participate in meetings with representatives from other countries to discuss methods and approaches to harmonizing regulatory requirements for infant formula, including with respect to inspections, labeling, and nutritional requirements; and

(2) may enter into arrangements or agreements regarding the regulatory requirements with other countries, as appropriate, including arrangements or agreements with a foreign government or agency of a foreign government to recognize the inspection of foreign establishments that manufacture infant formula for export to the United States.

(e) GUIDANCE RELATING TO INFORMATION TO INCLUDE IN PREMARKET SUBMISSIONS FOR NEW INFANT FORMULA.—Not later than 1 year after December 29, 2022, the Secretary shall issue guidance regarding information sponsors may consider including in submissions required under section 11114(d) of this title, including considerations for meeting each of the requirements of paragraphs (1), (2), and (3) of section 11114(d) of this title.

(f) COORDINATION WITH MANUFACTURER.—

(1) IN GENERAL.—

(A) COMMUNICATION FOLLOWING INSPECTION.—On completing an inspection of an infant formula manufacturing facility impacted

by a recall, the Secretary, acting through the Commissioner of Food and Drugs, shall provide the manufacturer involved a list of any actions necessary to—

(i) address deficiencies contributing to the potential adulteration or misbranding of product at the facility; and

(ii) safely restart production at the facility.

(B) RESPONSE TO MANUFACTURER.—Not later than 7 days after receiving a written communication from a manufacturer of infant formula containing corrective actions to address manufacturing deficiencies identified during an inspection of a facility engaged in the manufacturing of an infant formula impacted by a recall, the Secretary, acting through the Commissioner of Food and Drugs, shall provide a substantive response to the communication concerning the sufficiency of the proposed corrective actions.

(2) INSPECTIONS AND REINSPECTIONS.—

(A) TIMELY COMMUNICATION.—The Secretary shall ensure timely communication with a manufacturer of infant formula following an in-

spection of a facility engaged in the manufacturing of infant formula for consumption in the United States.

(B) TIMELY REINSPECTION.—If a reinspection of a manufacturer of an infant formula is required to ensure that the manufacturer completed any remediation actions or addressed any deficiencies, the Secretary shall reinspect the facility in a timely manner.

(C) PRIORITIZING OR EXPEDITING INSPECTION OR REINSPECTION.—The Secretary shall prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent a shortage of an infant formula.

(3) ANNUAL INSPECTIONS.—

(A) IN GENERAL.—Not later than 6 months after December 29, 2022, and not less than once per calendar year thereafter, the Secretary shall—

(i) conduct inspections, including unannounced inspections, of the facilities (including foreign facilities) of each manufacturer of an infant formula required to be registered under section 11114(c)(2)(A) of

this title, in accordance with a risk-based approach; and

(ii) ensure timely and effective internal coordination and alignment between the Office of Regulatory Affairs and the Center for Food Safety and Applied Nutrition.

(B) RELIANCE ON INSPECTIONS CONDUCTED BY FOREIGN REGULATORY AUTHORITIES AND STATE AGENCIES.—In meeting the inspection requirements under this subsection, the Secretary may rely on inspections conducted by foreign regulatory authorities, under arrangements or agreements, and conducted by State agencies under contract, memoranda of understanding, or any other obligation.

(g) NATIONAL STRATEGY ON INFANT FORMULA.—

(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Agriculture and other heads of relevant departments and agencies, shall develop and issue, not later than 90 days after December 29, 2022, a national strategy on infant formula to increase the resiliency of the infant formula supply chain, protect against future contamination and other potential causes of supply disruptions and

shortages, and ensure parents and caregivers have access to infant formula and information they need.

(2) IMMEDIATE NATIONAL STRATEGY.—The national strategy under paragraph (1) shall include efforts—

(A) to increase the resiliency of the infant formula supply chain in the short-term by—

(i) assessing causes of any supply disruption or shortage of infant formula in existence as of December 29, 2022, and potential causes of future supply disruptions and shortages;

(ii) assessing and addressing immediate infant formula needs associated with the shortage; and

(iii) developing a plan to increase infant formula supply, including through increased competition; and

(B) to ensure the development and updating of education and communication materials for parents and caregivers that cover—

(i) where and how to find infant formula;

(ii) comparable infant formulas on the market;

(iii) what to do if a specialty infant formula is unavailable;

(iv) safe practices for handling infant formula; and

(v) other topics, as appropriate.

(3) LONG-TERM STRATEGY.—Not later than 90 days after the submission of the report described in section 3401(f)(2) of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5839), the Secretary shall update the national strategy under paragraph (1) to include efforts to improve preparedness against infant formula shortages in the long-term by—

(A) outlining methods to improve information-sharing between the Federal Government and State and local governments, and other entities as appropriate, regarding shortages;

(B) recommending measures for protecting the integrity of the infant formula supply and preventing contamination;

(C) outlining methods to incentivize new infant formula manufacturers to increase supply and mitigate future shortages; and

(D) recommending other necessary authorities to gain insight into the supply chain

and risk for shortages, and to incentivize new infant formula manufacturers.

### § 25309. International harmonization relating to modernizing clinical trials

The Secretary shall, as appropriate, work with foreign regulators pursuant to memoranda of understanding or other arrangements governing the exchange of information to facilitate international harmonization of the regulation and use of decentralized clinical trials, digital technology in clinical trials, and seamless, concurrent, and other adaptive or innovative clinical trial designs.

## Chapter —Reserved

## Chapter 291—Guidance Documents

Sec.

29101. Guidance relating to serious adverse reporting for nonprescription drugs.
29102. Guidance relating to serious adverse reporting for dietary supplements.
29103. Guidance on pathogen-focused antibacterial drug development.
29104. Guidance document regarding product promotion using the internet.
29105. Guidance on abuse-deterrent products.
29106. Guidance relating to novel clinical trial designs.
29107. Guidance relating to neonatal studies.
29108. Guidance relating to inspections.
29109. Guidance relating to use of elements of investigations in the development of new animal drugs.
29110. Guidance relating to consultations with persons with expertise on evaluations on whether an in vitro diagnostic product meets the criteria for issuance of emergency use authorization.
29111. Guidance relating to platform technologies.
29112. Guidance relating to extending expiration dates for certain drugs.
29113. Guidance relating to discontinuance or interruption in the production of medical devices.
29114. Guidance relating to best practices and strategies for development of efficacy endpoints for rare diseases.
29115. Guidance relating to early-stage development meetings, novel clinical trial designs for postapproval studies, expedited procedures, and surrogate or intermediate clinical endpoints for accelerated approvals.
29116. Guidance relating to approval or licensure of antifungal therapies designed to treat Valley Fever.

29117. Guidance on device cybersecurity.
29118. Guidance relating to diversity action plans for clinical studies.
29119. Guidance relating to decentralized clinical studies.
29120. Guidance relating to clarifying the use of digital health technologies in clinical trials.
29121. Guidance relating to seamless and concurrent clinical trials.
29122. Guidance relating to provision of records or other information in advance of inspection of certain establishments, sites, or facilities.
29123. Guidance relating to processes and practices applicable to inspections of certain sites and facilities.
29124. Guidance relating to facilitating the use of real world evidence.

**§ 29101. Guidance relating to serious adverse reporting for nonprescription drugs**

The Secretary shall issue guidance on the minimum data elements that should be included in a serious adverse event report described in section 18901 of this title.

**§ 29102. Guidance relating to serious adverse reporting for dietary supplements**

The Secretary shall issue guidance on the minimum data elements that should be included in a serious adverse event report described in section 18902 of this title.

**§ 29103. Guidance on pathogen-focused antibacterial drug development**

(a) DRAFT GUIDANCE.—To facilitate the development of antibacterial drugs for serious or life-threatening bacterial infections, particularly in areas of unmet need, the Secretary shall publish draft guidance that—

(1) specifies how preclinical and clinical data can be utilized to inform an efficient and streamlined pathogen-focused antibacterial drug develop-

ment program that meets the approval standards of the FDA; and

(2) provides advice on approaches for the development of antibacterial drugs that target a more limited spectrum of pathogens.

(b) FINAL GUIDANCE.—After notice and opportunity for public comment on the draft guidance under subsection (a), the Secretary shall publish final guidance consistent with this section.

**§ 29104. Guidance document regarding product promotion using the internet**

The Secretary shall issue guidance that describes FDA policy regarding the promotion, using the internet (including social media), of medical products that are regulated by the FDA.

**§ 29105. Guidance on abuse-deterrent products**

The Secretary shall issue guidance on the development of abuse-deterrent drug products.

**§ 29106. Guidance relating to novel clinical trial designs**

(a) PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs under chap-

ter 135 of this title and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) GUIDANCE ADDRESSING USE OF NOVEL CLINICAL TRIAL DESIGNS.—

(1) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall update or issue guidance addressing the use of complex adaptive and other novel trial design in the development and regulatory review and approval or licensure for drugs and biological products.

(2) CONTENTS.—The guidance under paragraph (1) shall address—

(A) the use of complex adaptive and other novel trial designs, including how the clinical trials proposed or submitted help to satisfy the substantial evidence standard under section 13505 of this title;

(B) how sponsors may obtain feedback from the Secretary on technical issues related to modeling and simulations prior to—

(i) completion of the modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) the types of quantitative and qualitative information that should be submitted for review; and

(D) recommended analysis methodologies.

(3) PUBLIC MEETING.—Prior to updating or issuing the guidance required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patient advocacy organizations, consumer groups, and disease research foundations, through a public meeting to be held not later than 18 months after the December 13, 2016.

(4) TIMING.—The Secretary shall update or issue a draft version of the guidance required by paragraph (1) not later than 18 months after the date of the public meeting required by paragraph (3) and finalize the guidance not later than 1 year after the date on which the public comment period for the draft guidance closes.

**§ 29107. Guidance relating to neonatal studies**

The Secretary shall issue draft guidance on clinical pharmacology considerations for neonatal studies for drugs and biological products.

**§ 29108. Guidance relating to inspections**

(a) DRAFT GUIDANCE.—Not later than 18 months after August 18, 2017, the Secretary, acting through the Commissioner of Food and Drugs, shall issue draft guidance that—

(1) specifies—

(A) how the FDA will implement the processes and standards described in paragraph (1) of section 17504(h) of this title; and

(B) the requirements described in paragraph (2) of section 17504(h) of this title;

(2) provides for standardized methods for communications described in the paragraphs;

(3) establishes, with respect to inspections of both domestic and foreign device establishments (as referred to in section 13136(h)(2) of this title), a standard timeframe for the inspections—

(A) that occurs over consecutive days; and

(B) to which each investigator conducting such an inspection shall adhere unless the investigator identifies to the establishment involved a reason that more time is needed to conduct the inspection; and

(4) identifies practices for investigators and device establishments to facilitate the continuity of inspections of the establishments.

(b) FINAL GUIDANCE.—Not later than 1 year after providing notice and opportunity for public comment on the draft guidance issued under subsection (a), the Secretary shall issue final guidance to implement section 17504(h) of this title.

**§ 29109. Guidance relating to use of elements of investigations in the development of new animal drugs**

(a) DEFINITION OF ELEMENTS OF INVESTIGATIONS.—In this section, the term ''elements of investigations'' means—

(1) complex adaptive and other novel investigation designs;

(2) data from foreign countries;

(3) real-world evidence (including ongoing surveillance activities, observational studies, and registry data);

(4) biomarkers; and

(5) surrogate endpoints.

(b) IN GENERAL.—For purposes of assisting sponsors in incorporating elements of investigations into proposed clinical investigation protocols and applications for new animal drugs under chapter 137 of this title and section 14502 of this title, the Secretary shall issue guidance

addressing the use of elements of investigations in the development and regulatory review of the new animal drugs.

(c) CONTENTS.—The guidance under subsection (b) shall address—

(1) how—

(A) the Secretary will evaluate the elements of investigations proposed or submitted pursuant to section 13703(a)(2)(A) of this title; or

(B) to meet the commitment under section 14502(b)(2)(F) of this title; and

(2) how sponsors of the applications may obtain feedback from the Secretary on technical issues related to the investigations prior to the submission of an application to the Secretary.

(d) MEETING.—Prior to issuing the guidance under subsection (b), the Secretary shall consult with stakeholders, including representatives of regulated industry, consumer groups, academia, veterinarians, and food producers, through a public meeting to be held not later than 1 year after August 14, 2018.

(e) TIMING.—The Secretary shall issue a draft guidance under subsection (b) not later than 1 year after the date of the public meeting under subsection (d), and shall finalize the guidance not later than 1 year after the date

on which the public comment period on the draft guidance ends.

**§ 29110. Guidance relating to consultations with persons with expertise on evaluations on whether an in vitro diagnostic product meets the criteria for issuance of emergency use authorization**

Not later than 1 year after December 29, 2022, the Secretary shall issue draft guidance on consultations with persons under section 14309(i) of this title, including considerations concerning conflicts of interest, compensation arrangements, and information sharing. Not later than 1 year after the end of the public comment period on the draft guidance, the Secretary shall issue a revised draft guidance or final guidance.

**§ 29111. Guidance relating to platform technologies**

(a) ISSUANCE OF DRAFT GUIDANCE.—Not later than 1 year after December 29, 2022, the Secretary shall issue draft guidance on the implementation of section 13131 of this title.

(b) CONTENT INCLUSIONS.—The guidance shall include—

(1) examples of drugs that can be manufactured using platform technologies, including drugs that contain or consist of vectors and nucleic acids;

(2) information about the Secretary's review of platform technologies;

(3) information regarding submitting for designation;

(4) considerations for persons submitting a request for designation that have been granted a right of reference;

(5) the implementation of the designated platform technology designation program;

(6) efficiencies that may be achieved in the development and review of products that incorporate or utilize designated platform technologies; and

(7) recommendations and requirements for making and reporting manufacturing changes to a designated platform technology in accordance with sections 13120 and 13131(h) of this title, as applicable.

**§ 29112. Guidance relating to extending expiration dates for certain drugs**

Not later than 1 year after December 29, 2022, the Secretary shall issue draft guidance, or revise existing guidance, to address recommendations for sponsors of applications submitted under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) regarding—

(1) the submission of stability testing data in the applications, including considerations for data requirements that could be streamlined or reduced to facilitate faster review of longer proposed expiration dates;

(2) establishing in the labeling of drugs the longest feasible expiration date scientifically supported by the data, taking into consideration how extended expiration dates may—

(A) help prevent or mitigate drug shortages; and

(B) affect product quality; and

(3) the use of innovative approaches for drug and combination product stability modeling to support initial product expiration dates and expiration date extensions.

**§ 29113. Guidance relating to discontinuance or interruption in the production of medical devices**

(a) GUIDANCE ON VOLUNTARY NOTIFICATIONS OF DISCONTINUANCE OR INTERRUPTION OF DEVICE MANUFACTURE.—

(1) ISSUANCE OF DRAFT GUIDANCE.—Not later than 1 year after December 29, 2022, the Secretary

shall issue draft guidance to facilitate voluntary notifications under section 13130(i) of this title.

(2) CONTENT INCLUSIONS.—The guidance shall include—

(A) a description of circumstances in which a voluntary notification under section 13130(i) of this title may be appropriate;

(B) recommended timeframes for the notification;

(C) the process for receiving the notification; and

(D) actions the Secretary may take to mitigate or prevent a shortage resulting from a discontinuance or interruption in the manufacture of a device for which the notification is received.

(3) ISSUANCE OF FINAL GUIDANCE.—The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

(b) GUIDANCE ON DEVICE SHORTAGE NOTIFICATION REQUIREMENT.—

(1) ISSUANCE OR REVISION OF DRAFT GUIDANCE.—Not later than 1 year after December 29, 2022, the Secretary shall issue or revise draft guid-

ance regarding requirements under section 13130 of this title.

(2) CONTENT INCLUSION.—The guidance shall include a list of each device product code for which a manufacturer of the device is required to notify the Secretary in accordance with section 13130 of this title.

**§ 29114. Guidance relating to best practices and strategies for development of efficacy endpoints for rare diseases**

Not later than September 30, 2027, the Secretary shall issue guidance describing best practices and strategies for development of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.

**§ 29115. Guidance relating to early-stage development meetings, novel clinical trial designs for postapproval studies, expedited procedures, and surrogate or intermediate clinical endpoints for accelerated approvals**

(a) IN GENERAL.—The Secretary shall issue guidance describing—

(1) how sponsor questions related to the identification of novel surrogate or intermediate clinical

endpoints may be addressed in early-stage development meetings with the FDA;

(2) the use of novel clinical trial designs that may be used to conduct appropriate postapproval studies as may be required under section 13119(d)(2)(A) of this title;

(3) the expedited procedures described in section 13119(d)(3)(B) of this title; and

(4) considerations related to the use of surrogate or intermediate clinical endpoints that may support the accelerated approval of an application under section 13119(d)(1)(A) of this title, including considerations in evaluating the evidence related to any such endpoints.

(b) FINAL GUIDANCE.—The Secretary shall issue—

(1) draft guidance under subsection (a) not later than 18 months after December 29, 2022; and

(2) final guidance not later than 1 year after the close of the public comment period on the draft guidance.

**§ 29116. Guidance relating to approval or licensure of antifungal therapies designed to treat Valley Fever**

(a) DRAFT GUIDANCE.—Not later than 3 years after December 29, 2022, the Secretary, acting through the

Commissioner of Food and Drugs, shall issue draft guidance for industry for the purposes of assisting entities seeking approval under chapter 135 of this title or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of antifungal therapies designed to treat coccidioidomycosis (commonly known as Valley Fever).

(b) FINAL GUIDANCE.—Not later than 18 months after the close of the public comment period on the draft guidance issued pursuant to subsection (a), the Secretary, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance.

(c) WORKSHOP.—To assist entities developing preventive vaccines for fungal infections and coccidioidomycosis, the Secretary shall hold a public workshop.

**§ 29117. Guidance on device cybersecurity**

(a) DEFINITION OF DEVICE.—In this section, the term ''device'' has the meaning given the term in section 10101(a) of this title.

(b) GUIDANCE UPDATE.—Not later than 2 years after December 29, 2022, and periodically thereafter as appropriate, the Secretary, in consultation with the Director of the Cybersecurity and Infrastructure Security Agency, shall review and, as appropriate and after soliciting and receiving feedback from device manufacturers, health care providers, third-party-device servicers, patient advo-

cates, and other appropriate stakeholders, update the guidance entitled ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices'' (or a successor document).

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the Secretary's authority related to ensuring that there is a reasonable assurance of the safety and effectiveness of devices, which may include ensuring that there is a reasonable assurance of the cybersecurity of certain cyber devices, including for devices approved or cleared prior to December 29, 2022.

**§ 29118. Guidance relating to diversity action plans for clinical studies**

(a) IN GENERAL.—The Secretary shall update or issue guidance relating to—

(1) the format and content of the diversity action plans required by sections 13526 and 13152(g)(9) of this title pertaining to the sponsor's goals for clinical study enrollment, disaggregated by age group, sex, and racial and ethnic demographic characteristics of clinically relevant study populations, and may include characteristics such as geographic location and socioeconomic status, including with respect to—

(A) the rationale for the sponsor's enrollment goals, which may include—

(i) the estimated prevalence or incidence in the United States of the disease or condition for which the drug or device is being investigated in the relevant clinical trial, if the estimated prevalence or incidence is known or can be determined based on available data;

(ii) what is known about the disease or condition for which the drug or device is being investigated;

(iii) any relevant pharmacokinetic or pharmacogenomic data;

(iv) what is known about the patient population for the disease or condition, including, to the extent data is available—

(I) demographic information, which may include age group, sex, race, geographic location, socioeconomic status, and ethnicity;

(II) non-demographic factors, including co-morbidities affecting the patient population; and

(III) potential barriers to enrolling diverse participants, such as patient population size, geographic location, and socioeconomic status; and

(v) any other data or information relevant to selecting appropriate enrollment goals, disaggregated by demographic subgroup, such as the inclusion of pregnant and lactating women; and

(B) an explanation for how the sponsor intends to meet the goals, including demographic-specific outreach and enrollment strategies, study-site selection, clinical study inclusion and exclusion practices, and any diversity training for study personnel;

(2) submission of any modifications to the diversity action plan;

(3) considerations for the public posting by a sponsor of key information from the diversity action plan that would be useful to patients and providers on the sponsor's website, as appropriate;

(4) criteria that the Secretary will consider in assessing whether to grant a sponsor's request to waive the requirement to submit a diversity action

plan under section 13526(d) or 13152(g)(9)(C) of this title; and

(5) how sponsors may include in regular reports otherwise required by the Secretary—

(A) the sponsor's progress in meeting the goals referred to in paragraph (1)(A); and

(B) any updates needed to be made to a diversity action plan referred to in paragraph (1) to help meet goals referred to in paragraph (1)(A); and

(C) if the sponsor does not expect to meet goals referred to in paragraph (1)(A), the sponsor's reasons for why the sponsor does not expect to meet the goals.

(b) ISSUANCE.—The Secretary shall—

(1) not later than 12 months after December 29, 2022, issue new draft guidance or update existing draft guidance described in subsection (a); and

(2) not later than 9 months after closing the comment period on the draft guidance, finalize the guidance.

**§ 29119. Guidance relating to decentralized clinical studies**

(a) DEFINITION OF DECENTRALIZED CLINICAL STUDY.—In this section, the term ''decentralized clinical

study'' means a clinical study in which some or all of the study-related activities occur at a location separate from the investigator's location.

(b) IN GENERAL.—The Secretary shall—

(1) not later than 1 year after December 29, 2022, issue or revise draft guidance that includes recommendations to clarify and advance the use of decentralized clinical studies to support the development of drugs and devices, including recommendations for how to advance the use of flexible and novel clinical trial designs and to help improve trial participant engagement, recruitment, enrollment, and retention of a meaningfully diverse clinical population, including with respect to race, ethnicity, age, sex, and geographic location, when appropriate; and

(2) not later than 1 year after closing the comment period on the draft guidance, finalize the guidance.

(c) CONTENT.—The guidance under subsection (b) shall address the following:

(1) Recommendations related to digital health technology or other assessment options, such as telehealth, local laboratories, local health care providers, or other options for remote data collection, that could support decentralized clinical studies, including

guidance on considerations for selecting technological platforms and mediums, data collection and use, data integrity and security, and communication to study participants through digital technology.

(2) Recommendations for subject recruitment, retention, and engagement, including considerations for sponsors to minimize or reduce burdens for clinical study participants through the use of digital health technology, telehealth, local health care providers and laboratories, health care provider home visits, direct-to-participant engagement, electronic informed consent, or other means, as appropriate.

(3) Recommendations with respect to the evaluation of data collected within a decentralized clinical study setting.

(4) Recommendations for methods of remote data collection, including clinical trial participant experience data, through the use of digital health technologies, telemedicine, local laboratories, local health care providers, or other options for data collection.

(5) Considerations for sponsors to minimize or reduce burdens for clinical trial participants associated with participating in a clinical trial, such as the use of digital technologies, telemedicine, local laboratories, local health care providers, or other data col-

lection or assessment options, health care provider home visits, direct-to-participant shipping of investigational drugs and devices, and electronic informed consent, as appropriate.

(6) Recommendations regarding conducting decentralized clinical trials to facilitate and encourage meaningful diversity among clinical trial participants, including with respect to race, ethnicity, age, sex, and geographic location, as appropriate.

(7) Recommendations for strategies and methods for recruiting, retaining, and engaging with clinical trial participants, including communication regarding the role of clinical trial participants and community partners to facilitate clinical trial recruitment and engagement, including with respect to diverse and underrepresented populations, as appropriate.

(8) Considerations for review and oversight by sponsors and institutional review boards, including remote trial oversight.

(9) Recommendations for decentralized clinical trial protocol designs and processes for evaluating the proposed clinical trial designs.

(10) Recommendations related to digital health technology and other remote assessment tools that

may support decentralized clinical trials, including guidance on appropriate technological platforms and tools, data collection and use, data integrity, and communication to clinical trial participants through the technology.

(11) A description of the manner in which the Secretary will assess or evaluate data collected within a decentralized clinical trial to support the development of the drug or device, if the manner is different from that used for a nondecentralized trial.

(12) Considerations for sponsors to validate digital technologies and establish appropriate clinical endpoints for use in decentralized trials.

(13) Considerations for privacy and security of personally identifiable information of trial participants.

(14) Considerations for conducting clinical trials using centralized approaches in conjunction with decentralized approaches.

**§ 29120. Guidance relating to clarifying the use of digital health technologies in clinical trials**

(a) IN GENERAL.—Not later than 1 year after December 29, 2022, the Secretary shall issue or revise draft guidance regarding the appropriate use of digital health

technologies in clinical trials to help improve recruitment for, retention in, participation in, and data collection during, clinical trials, and provide for novel clinical trial designs utilizing the technology for purposes of supporting the development of, and review of applications for, drugs and devices. Not later than 18 months after the end of the public comment period on the draft guidance, the Secretary shall issue a revised draft guidance or final guidance.

(b) CONTENT.—The guidance described in subsection (a) shall include—

(1) recommendations for data collection methodologies by which sponsors may incorporate the use of digital health technologies in clinical trials to collect data remotely from trial participants;

(2) considerations for privacy and security protections for data collected during a clinical trial, including—

(A) recommendations for the protection of trial participant data that are collected or used in research using digital health technologies;

(B) compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191, 42 U.S.C. 1320d–2

note), subpart B of part 50 of title 21, Code of Federal Regulations, subpart C of part 56 of title 21, Code of Federal Regulations, the Federal policy for the protection of human subjects under subpart A of part 46 of title 45, Code of Federal Regulations (commonly known as the ''Common Rule''), and part 2 of title 42, Code of Federal Regulations (or any successor regulations); and

(C) recommendations for the protection of clinical trial participant data against cybersecurity threats, as applicable;

(3) considerations on data collection methods to help increase recruitment of clinical trial participants and the level of participation of the participants, reduce burden on clinical trial participants, and optimize data quality;

(4) recommendations for the use of electronic methods to obtain informed consent from clinical trial participants, taking into consideration applicable Federal law, including subpart B of part 50 of title 21, Code of Federal Regulations, or successor regulations, and, as appropriate, State law;

(5) best practices for communication between sponsors and the Secretary on the development of data collection methods;

(6) the appropriate format to submit the data to the Secretary;

(7) a description of the manner in which the Secretary may assess or evaluate data collected through digital health technologies to support the development of the drug or device;

(8) recommendations regarding the data and information needed to demonstrate that a digital health technology is fit-for-purpose for a clinical trial, and a description of how the Secretary will evaluate the data and information; and

(9) recommendations for increasing access to, and the use of, digital health technologies in clinical trials to facilitate the inclusion of diverse and underrepresented populations, as appropriate, including considerations for access to, and the use of, digital health technologies in clinical trials by people with disabilities and pediatric populations.

**§ 29121. Guidance relating to seamless and concurrent clinical trials**

(a) IN GENERAL.—Not later than 1 year after December 29, 2022, the Secretary shall issue or revise draft

guidance on the use of seamless, concurrent, and other innovative clinical trial designs to support the expedited development and review of applications for drugs, as appropriate. Not later than 18 months after the public comment period on the draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(b) CONTENT.—The guidance described in subsection (a) shall include—

(1) recommendations on the use of expansion cohorts and other seamless clinical trial designs to assess different aspects of product candidates in 1 continuous trial, including how the clinical trial designs can be used as part of meeting the substantial evidence standard under section 13505 of this title;

(2) recommendations on the use of clinical trial designs that involve the concurrent conduct of different or multiple clinical trial phases, and the concurrent conduct of preclinical testing, to expedite the development of new drugs and facilitate the timely collection of data;

(3) recommendations for how to streamline trial logistics and facilitate the efficient collection and analysis of clinical trial data, including any planned interim analyses and how the analyses could be used

to streamline the product development and review processes;

(4) considerations to assist sponsors in ensuring the rights, safety, and welfare of clinical trial participants, maintaining compliance with good clinical practice regulations, minimizing risks to clinical trial data integrity, and ensuring the reliability of clinical trial results;

(5) recommendations for communication between sponsors and the FDA on the development of seamless, concurrent, or other adaptive clinical trial designs, including review of, and feedback on, clinical trial protocols; and

(6) a description of the manner in which the Secretary will assess or evaluate data collected through seamless, concurrent, or other adaptive clinical trial designs to support the development of drugs.

**§ 29122. Guidance relating to provision of records or other information in advance of inspection of certain establishments, sites, or facilities**

(a) IN GENERAL.—The Secretary shall issue or update guidance describing—

(1) circumstances in which the Secretary intends to issue requests for records or other information in advance of, or in lieu of, an inspection under section 17504(a)(4) of this title;

(2) processes for responding to the requests electronically or in physical form; and

(3) factors the Secretary intends to consider in evaluating whether the records and other information are provided within a reasonable timeframe, within reasonable limits, and in a reasonable manner, accounting for resource and other limitations that may exist, including for small businesses.

(b) TIMING.—The Secretary shall—

(1) not later than 1 year after December 29, 2022, issue draft guidance under subsection (a); and

(2) not later than 1 year after the close of the comment period for the draft guidance, issue final guidance under subsection (a).

**§ 29123. Guidance relating to processes and practices applicable to inspections of certain sites and facilities**

(a) IN GENERAL.—The Secretary shall issue guidance describing the processes and practices applicable to inspections of sites and facilities described in section 17504(a)(5)(C)(i) of this title, including with respect to

the types of records and information required to be provided, best practices for communication between the FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct, to the extent not specified in existing publicly available FDA guides and manuals for the inspections.

(b) TIMING.—The Secretary shall—

(1) not later than 18 months after December 29, 2022, issue draft guidance under subsection (a); and

(2) not later than 1 year after the close of the public comment period for the draft guidance, issue final guidance under subsection (a).

**§ 29124. Guidance relating to facilitating the use of real world evidence**

(a) IN GENERAL.—Not later than 1 year after December 29, 2022, the Secretary shall issue or revise existing guidance on considerations for the use of real world data and real world evidence to support regulatory decision-making, as follows:

(1) DRUGS.—

(A) IN GENERAL.—With respect to drugs, the guidance shall address the use of the data and evidence to support the approval of a drug

application under chapter 135 of this title or a biological product application under section 351 of the Public Health Service Act (42 U.S.C. 262), and to support an investigational use exemption submission under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)).

(B) CONSIDERATIONS TO INCLUDE IN GUIDANCE.—The guidance shall include considerations for the inclusion, in the applications and submissions described in subparagraph (A), of real world data and real world evidence obtained as a result of the use of drugs authorized for emergency use under section 14306 of this title, and considerations for standards and methodologies for collection and analysis of real world evidence included in those applications and submissions, as appropriate.

(2) DEVICES.—

(A) IN GENERAL.—With respect to devices, the guidance shall address the use of the data and evidence to support the approval, clearance, or classification of a device pursuant to an application or submission submitted under section 13136(k), 13140(h)(2), or 13142 of this title,

to support an investigational use exemption submission under section 13152(g) of this title, and to support a determination by the Secretary for purposes of section 353 of the Public Health Service Act (42 U.S.C. 263a) (including the category described under subsection (d)(3) of that section).

(B) CONSIDERATIONS TO INCLUDE IN GUIDANCE.—The guidance shall include considerations for the inclusion, in the applications and submissions described in subparagraph (A), of real world data and real world evidence obtained as a result of the use of devices authorized for emergency use under section 14306 of this title, including considerations related to a determination under section 353(d)(3) of the Public Health Service Act (42 U.S.C. 263a(d)(3)), and considerations for standards and methodologies for collection and analysis of real world evidence included in those applications, submissions, or determinations, as appropriate.

(b) INFORMATION DISCLOSURE.—Nothing in this section and in section 3629(b) of the Food and Drug Omnibus Reform Act of 2022 (Pub. L. 117–328, div. FF,

title III, 136 Stat. 5892) shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 1905 of title 18, or subject to withholding under subsection (b)(4) of section 552 of title 5.

# Chapter —Reserved

# Subtitle III—Food

# Chapter 301—Adulterated or Misbranded Foods

Sec.
30101. Suspension of importation of adulterated articles.
30102. Oleomargarine, butterine, or imitation butter or cheese.
30103. Introduction into, or sale in, State, territory of the United States, or District of Columbia of dairy or food products falsely labeled or branded.
30104. Criminal penalties.

## § 30101. Suspension of importation of adulterated articles

(a) PROCLAMATION BY PRESIDENT.—If the President is satisfied that there is good reason to believe that any importation is being made, or is about to be made, into the United States, from any foreign country, of any article used for human food or drink that is adulterated to an extent dangerous to the health or welfare of the people of the United States, or any of the people of the United States, the President may issue a proclamation suspending the importation of the articles from the country for such period of time as the President may consider necessary to prevent the importation.

(b) UNLAWFUL ACT.—It shall be unlawful to import articles into the United States in violation of a proclamation issued under subsection (a) during the period the proclamation is in effect.

**§ 30102. Oleomargarine, butterine, or imitation butter or cheese**

Any article known as oleomargarine, butterine, imitation, process, renovated, or adulterated butter, or imitation cheese, or any substance in the semblance of butter or cheese that is not the usual product of the dairy and not made exclusively of pure and unadulterated milk or cream, transported into any State, territory of the United States, or the District of Columbia, and remaining in the State, territory of the United States, or the District of Columbia, respectively, for use, consumption, sale, or storage in the State, territory of the United States, or the District of Columbia, respectively, shall, on the arrival within the limits of the State, territory of the United States, or the District of Columbia, respectively, be subject to the operation and effect of the laws of the State, territory of the United States, or the District of Columbia, respectively, enacted in the exercise of its police powers to the same extent and in the same manner as though the article or substance had been produced in the State, territory of the United States, or the District of Columbia, re-

spectively, and shall not be exempt from those laws by reason of being introduced in the State, territory of the United States, or the District of Columbia, respectively, in original packages or otherwise.

**§ 30103. Introduction into, or sale in, State, territory of the United States, or District of Columbia of dairy or food products falsely labeled or branded**

A person shall not—

(1) introduce into any State, territory of the United States, or the District of Columbia from any other State, territory of the United States, or the District of Columbia, or sell in the District of Columbia or in any territory of the United States, any dairy or food products that are falsely labeled or branded as to the State or territory of the United States in which they are made, produced, or grown; or

(2) cause an action described in paragraph (1) to be done by another.

**§ 30104. Criminal penalties**

(a) IN GENERAL.—Any person that violates section 30103 of this title or causes another to violate section 30103 of this title shall be fined under title 18 but not less than $500.

(b) JURISDICTION.—The district court of the United States for the district in which the violation under subsection (a) is committed shall have jurisdiction for the prosecution of the violation.

# Chapter 303—Meat Inspection

**Subchapter I—Inspection Requirements; Adulteration and Misbranding**

Sec.
30301. Definitions.
30302. Congressional statement of findings.
30303. Examination of animals prior to slaughter; use of humane methods.
30304. Post mortem examination of carcasses.
30305. Examination of carcasses brought into slaughtering or packing establishments.
30306. Inspection and labeling of meat food products.
30307. Labeling, marking, and container requirements.
30308. Sanitary inspection and regulation of slaughtering and packing establishments.
30309. Examination of animals and food products of the animals slaughtered and prepared during nighttime.
30310. Prohibited acts.
30311. Devices, marks, labels, and certificates; simulations.
30312. Notification.
30313. Plans and reassessments.
30314. Inspection of carcasses, meat of which is intended for export.
30315. Certificates of condition from inspectors of meat for export.
30316. Clearance prohibited to vessel carrying meat for export without inspector's certificate.
30317. Delivery of inspectors' certificates.
30318. Marking, labeling, or other identification of articles relating to the kinds of animals from which derived; separate preparations.
30319. Imports.
30320. Appointment of inspectors.
30321. Bribery of or gifts to inspectors or other officers and acceptance of gifts.
30322. Exemptions from inspection requirements.
30323. Storage and handling regulations.
30324. Inapplicability of certain requirements to catfish.

**Subchapter II—Meat Processors and Related Industries**

30341. Prohibition of subchapter I inspection of articles not intended for use as human food.
30342. Recordkeeping requirements.
30343. Registration of business, name of person, and trade names.
30344. Regulation of transactions, transportation, or importation of animals to prevent use as human food.
30345. Federal provisions applicable to State or territorial business transactions.

**Subchapter III—Federal and State Cooperation**

30356. Federal and State cooperation.

**Subchapter IV—Other Provisions**

30361. Refusal or withdrawal of inspection services based on certain convictions.
30362. Administrative detention.
30363. Seizure and condemnation.
30364. Federal court jurisdiction.
30365. Assaulting, resisting, or impeding certain persons; murder.
30366. Minor violations.
30367. Other Federal laws applicable to administration and enforcement of chapter.
30368. Prohibition of additional or different requirements.
30369. Applicability of subtitle I.
30370. Safe Meat and Poultry Inspection Panel.

**Subchapter V—Inspections by Federal and State Agencies**

30381. Interstate shipment of meat inspected by Federal and State agencies for certain small establishments.

# Subchapter I—Inspection Requirements; Adulteration and Misbranding

## § 30301. Definitions

In this chapter, except as otherwise specified:

(1) ADULTERATED.—

(A) In general—The term ''adulterated'' shall apply to any carcass, part of a carcass, meat, or meat food product under 1 or more of the following circumstances:

(i) It bears or contains any poisonous or deleterious substance that may render it injurious to health, but in case the substance is not an added substance, the article shall not be considered adulterated under this clause if the quantity of the substance in or on the article does not ordinarily render it injurious to health.

(ii)(I) It bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is a pesticide chemical in or on a raw agricultural commodity, a food additive, or a color additive) that may, in the judgment of the Secretary, make the article unfit for human food.

(II) It is, in whole or in part, a raw agricultural commodity and the commodity bears or contains a pesticide chemical that is unsafe within the meaning of section 11110 of this title.

(III) It bears or contains any food additive that is unsafe within the meaning of section 11111 of this title.

(IV) It bears or contains any color additive that is unsafe within the meaning of section 17701 of this title.

(iii) It consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.

(iv) It has been prepared, packed, or held under insanitary conditions by which it may have become contaminated with filth, or by which it may have been rendered injurious to health.

(v) It is, in whole or in part, the product of an animal that has died otherwise than by slaughter.

(vi) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

(vii) It has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 11111 of this title.

(viii)(I) Any valuable constituent of the article has been, in whole or in part, omitted or abstracted from the article.

(II) Any substance has been substituted, wholly or in part, for the article.

(III) Damage or inferiority of the article has been concealed in any manner.

(IV) Any substance has been added to the article or mixed or packed with the article so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(ix) It is margarine containing animal fat and any of the raw material used in the margarine consisted in whole or in part of any filthy, putrid, or decomposed substance.

(B) PESTICIDE CHEMICAL, FOOD ADDITIVE, COLOR ADDITIVE PROHIBITED BY REGULATION.—An article that is not adulterated under subclause (II), (III), or (IV) of subparagraph (A)(ii) shall be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on the article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter.

(2) AMENABLE SPECIES.—The term ''amenable species'' means—

(A) those species subject to the provisions of this chapter on November 9, 2005;

(B) all fish of the order Siluriformes; and

(C) any additional species of livestock that the Secretary considers appropriate.

(3) ANIMAL FOOD MANUFACTURER.—The term ''animal food manufacturer'' means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines.

(4) CAPABLE OF USE AS HUMAN FOOD.—The term ''capable of use as human food'' shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.

(5) COLOR ADDITIVE.—The term ''color additive'' has the meaning given the term in subtitle I of this title.

(6) COMMERCE.—The term ''commerce'' means commerce—

(A) between any State, any territory of the United States, or the District of Columbia, and any place outside of the State, the territory of

the United States, or the District of Columbia; or

(B) within—

(i) any territory of the United States not organized with a legislative body; or

(ii) the District of Columbia.

(7) FIRM.—The term ''firm'' means any partnership, association, or other unincorporated business organization.

(8) FOOD ADDITIVE.—The term ''food additive'' has the meaning given the term in subtitle I of this title.

(9) LABEL.—The term ''label'' means a display of written, printed, or graphic matter on the immediate container (not including package liners) of any article.

(10) LABELING.—The term ''labeling'' means all labels and other written, printed, or graphic matter—

(A) on any article or any of its containers or wrappers; or

(B) accompanying the article.

(11) MEAT BROKER.—The term ''meat broker'' means any person, firm, or corporation engaged in the business of buying or selling carcasses, parts of

carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines on commission, or otherwise negotiating purchases or sales of the articles other than for the meat broker's own account or as an employee of another person, firm, or corporation.

(12) MEAT FOOD PRODUCT.—

(A) IN GENERAL.—The term ''meat food product'' means any product capable of use as human food that is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, except products—

(i) that contain meat or other portions of the carcasses only in a relatively small proportion or that historically have not been considered by consumers as products of the meat food industry; and

(ii) that are exempted from definition as a meat food product by the Secretary under such conditions as the Secretary may prescribe to ensure that the meat or other portions of the carcasses contained in the product are not adulterated and that the products are not represented as meat food products.

(B) EQUINES.—The term ''meat food product'' as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(13) MISBRANDED.—

(A) IN GENERAL.—The term ''misbranded'' shall apply to any carcass, part of a carcass, meat, or meat food product under 1 or more of the following circumstances:

(i) Its labeling is false or misleading in any particular.

(ii) It is offered for sale under the name of another food.

(iii) It is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately after that word, the name of the food imitated.

(iv) Its container is made, formed, or filled so as to be misleading.

(v) It is in a package or other container, unless it bears a label showing—

(I) the name and place of business of the manufacturer, packer, or distributor; and

(II) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(vi) Any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed on the label or other labeling with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(vii) It purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 30307 of this title unless—

(I) it conforms to the definition and standard; and

(II) its label bears the name of the food specified in the definition and standard and, to the extent that may be required by the regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in the food;

(viii) It purports to be or is represented as a food for which a standard of fill of container has been prescribed by regulations of the Secretary under section 30307 of this title, and it falls below the standard of fill of container applicable to the food, unless its label bears, in such manner and form as the regulations specify, a statement that it falls below the standard.

(ix) It is not subject to the provisions of clause (vii), unless its label bears—

(I) the common or usual name of the food, if any; and

(II) in case it is fabricated from 2 or more ingredients, the common or usual name of each ingredient, except that spices, flavorings, and colorings

may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each.

(x) It purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for those uses.

(xi) It bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact.

(xii) It fails to bear, directly on the article or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in the regulations to ensure that it will not have false or mis-

leading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(B) REASONABLE VARIATIONS; SMALL PACKAGES.—Under subparagraph (A)(v)(II), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary.

(C) COMPLIANCE WITH CERTAIN LABELING REQUIREMENTS IMPRACTICABLE OR RESULTS IN DECEPTION OR UNFAIR COMPETITION.—To the extent that compliance with the requirements of subparagraph (A)(ix)(II) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(D) ARTIFICIAL FLAVORINGS, ARTIFICIAL COLORINGS, AND CHEMICAL PRESERVATIVES.—To the extent that compliance with the requirements of subparagraph (A)(xi) is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(14) OFFICIAL CERTIFICATE.—The term ''official certificate'' means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(15) OFFICIAL DEVICE.—The term ''official device'' means any device prescribed or authorized by the Secretary for use in applying any official mark.

(16) OFFICIAL INSPECTION LEGEND.—The term ''official inspection legend'' means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this chapter.

(17) OFFICIAL MARK.—The term ''official mark'' means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this chapter.

(18) PESTICIDE CHEMICAL.—The term ''pesticide chemical'' has the meaning given the term in subtitle I of this title.

(19) PREPARED.—The term ''prepared'' means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(20) RAW AGRICULTURAL COMMODITY .—The term ''raw agricultural commodity'' has the meaning given the term in subtitle I of this title.

(21) RENDERER.—The term ''renderer'' means any person, firm, or corporation engaged in the business of rendering carcasses, or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines, except rendering conducted under inspection or exemption under this subchapter.

(22) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture or the Secretary's delegate.

(23) STATE.—The term ''State'' means any State of the United States or Puerto Rico.

(24) TERRITORY OF THE UNITED STATES.—The term ''territory of the United States'' means Guam, the Virgin Islands, American Samoa, or any other territory (including a possession) of the United States.

(25) UNITED STATES.—The term ''United States'' means the States, the District of Columbia, and the territories of the United States.

**§ 30302. Congressional statement of findings**

(a) IN GENERAL.—Congress finds the following:

(1) Meat and meat food products are an important source of the Nation's total supply of food.

(2) Meat and meat food products are consumed throughout the Nation and the major portion of meat and meat food products moves in interstate or foreign commerce.

(3) It is essential in the public interest that the health and welfare of consumers be protected by ensuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.

(4) Unwholesome, adulterated, or misbranded meat or meat food products—

(A) impair the effective regulation of meat and meat food products in interstate or foreign commerce;

(B) are injurious to the public welfare;

(C) destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products; and

(D) result in—

(i) sundry losses to livestock producers and processors of meat and meat food products; and

(ii) injury to consumers.

(5) The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally.

(b) ARTICLES AND ANIMALS IN INTERSTATE AND FOREIGN COMMERCE.—Because of the findings in subsection (a), Congress finds—

(1) that all articles and animals that are regulated under this chapter are either in interstate or foreign commerce or substantially affect interstate or foreign commerce; and

(2) that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate—

(A) to prevent and eliminate burdens on interstate and foreign commerce;

(B) to effectively regulate interstate and foreign commerce; and

(C) to protect the health and welfare of consumers.

**§ 30303. Examination of animals prior to slaughter; use of humane methods**

(a) EXAMINATION OF ANIMALS BEFORE SLAUGHTERING.—

(1) IN GENERAL.—For the purpose of preventing the use in commerce of meat and meat food products that are adulterated, the Secretary shall examine and inspect, through inspectors appointed for that purpose, all amenable species before they are allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment in which they are to be slaughtered and in which the meat and meat food products of the amenable species are to be used in commerce.

(2) ANIMALS WITH DISEASE TO BE SLAUGHTERED AND EXAMINED SEPARATELY.—All amenable species found on the inspection under paragraph (1) to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and if slaughtered separately, the carcasses of the cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

(b) HUMANE METHODS OF SLAUGHTER.—

(1) IN GENERAL.—For the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall examine and inspect, through inspectors appointed for that purpose, the method by which amenable species are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter.

(2) REFUSAL TO INSPECT.—The Secretary may refuse to provide inspection to a new slaughtering establishment or may temporarily suspend inspection at a slaughtering establishment if the Secretary finds that any cattle, sheep, swine, goats, horses, mules, or other equines have been slaughtered or handled in connection with slaughter at the establishment by any method not in accordance with Public Law 85–765 (7 U.S.C. 1901 et seq.) until the establishment furnishes assurances satisfactory to the Secretary that all slaughtering and handling in connection with slaughter of livestock shall be in accordance with a method in accordance with Public Law 85–765 (7 U.S.C. 1901 et seq.).

**§ 30304. Post mortem examination of carcasses**

(a) IN GENERAL.—For the purpose of preventing the use in commerce of meat and meat food products that are

adulterated, the Secretary shall conduct, through inspectors appointed for that purpose, a post mortem examination and inspection of the carcasses and parts of the carcasses of all amenable species to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, territory of the United States, or the District of Columbia as articles of commerce that are capable of use as human food.

(b) INSPECTED AND PASSED.—The carcasses and parts of the carcasses of all the animals under subsection (a) found to be not adulterated shall be marked, stamped, tagged, or labeled as ''Inspected and passed''.

(c) INSPECTED AND CONDEMNED.—

(1) IN GENERAL.—The inspectors shall label, mark, stamp, or tag as ''Inspected and condemned'' all carcasses and parts of the carcasses of animals under subsection (a) found to be adulterated.

(2) DESTRUCTION.—All carcasses and parts of carcasses inspected and condemned under paragraph (1) shall be destroyed for food purposes by the establishment described in subsection (a) in the presence of an inspector.

(3) REMOVAL OF INSPECTORS.—The Secretary may remove inspectors from any establishment described in subsection (a) that fails to destroy as de-

scribed in paragraph (2) any condemned carcass or part of a carcass.

(d) REINSPECTION.—

(1) IN GENERAL.—Inspectors, after the first inspection under this section, shall, when they consider it necessary, reinspect the carcasses or parts of the carcasses to determine whether, since the first inspection, the carcasses or parts have become adulterated.

(2) DESTRUCTION.—If any carcass or any part of a carcass shall, on examination and inspection subsequent to the first examination and inspection, be found to be adulterated, it shall be destroyed for food purposes by the establishment described in subsection (a) in the presence of an inspector.

(3) REMOVAL OF INSPECTORS.—The Secretary may remove inspectors from any establishment that fails to destroy as described in paragraph (2) any condemned carcass or part of a carcass.

**§ 30305. Examination of carcasses brought into slaughtering or packing establishments**

(a) CARCASSES AND PARTS.—Sections 30301 through 30304 of this title shall apply to all carcasses or parts of carcasses of amenable species or the meat or meat products of amenable species that may be brought into

any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and the examination and inspection shall be had before the carcasses or parts of the carcasses shall be allowed to enter into any department in which the carcasses or the parts are to be treated and prepared for meat food products.

(b) MEAT FOOD PRODUCTS.—Sections 30301 through 30304 of this title shall also apply to all such products, that, after having been issued from any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, shall be returned to the same or to any similar establishment in which the inspection is maintained.

(c) LIMITATION OF ENTRY.—The Secretary may limit the entry of carcasses, parts of carcasses, meat and meat food products, and other materials into any establishment at which inspection under this subchapter is maintained, under such conditions as the Secretary may prescribe, to ensure that allowing the entry of the articles into the inspected establishments will be consistent with the purposes of this chapter.

**§ 30306. Inspection and labeling of meat food products**

(a) IN GENERAL.—

(1) EXAMINATION AND INSPECTION.—For the purpose of preventing the use in commerce of meat and meat food products that are adulterated, the Secretary shall examine and inspect, through inspectors appointed for that purpose, all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment.

(2) ACCESS.—For the purposes of any examination and inspection under paragraph (1), inspectors shall have access at all times, by day or night, whether the establishment is being operated or not, to every part of the establishment.

(3) INSPECTED AND PASSED.—The inspectors shall mark, stamp, tag, or label as ''Inspected and passed'' all meat food products examined and inspected under paragraph (1) that are found to be not adulterated.

(4) INSPECTED AND CONDEMNED.—

(A) IN GENERAL.—The inspectors shall label, mark, stamp, or tag as ''Inspected and condemned'' all meat food products examined and inspected under paragraph (1) that are found to be adulterated.

(B) DESTRUCTION.—All condemned meat food products under subparagraph (A) shall be destroyed for food purposes by the establishment described in paragraph (1) in the presence of an inspector.

(C) REMOVAL OF INSPECTORS.—The Secretary may remove inspectors from any establishment that fails to destroy as described in subparagraph (B) the condemned meat food products.

(5) PRESERVATIVES.—

(A) IN GENERAL.—Subject to the rules and regulations of the Secretary, the provisions of this section with regard to preservatives shall not apply to meat food products for export to any foreign country and that are prepared or packed according to the specifications or directions of the foreign purchaser, if no substance is used in the preparation or packing of the meat food products in conflict with the laws of the foreign country to which the meat food products are to be exported.

(B) DOMESTIC USE.—If the meat food products under subparagraph (A) are to be sold or offered for sale for domestic use or consump-

tion, subparagraph (A) shall not exempt the meat food products from the operation of all the other provisions of this chapter.

(b) CERTAIN FISH.—In the case of an examination and inspection under subsection (a) of a meat food product derived from any fish described in section 30301(2)(B) of this title, the Secretary shall take into account the conditions under which the fish is raised and transported to a processing establishment.

**§ 30307. Labeling, marking, and container requirements**

(a) LABELING RECEPTACLES OR COVERINGS OF MEAT OR MEAT FOOD PRODUCTS INSPECTED AND PASSED.—

(1) IN GENERAL.—If any meat or meat food product prepared for commerce that has been inspected as provided in sections 30303 through 30306 of this title and marked ''Inspected and passed'' is placed or packed in any can, pot, tin, canvas, or other receptacle or covering in any establishment in which inspection under the provisions of this chapter is maintained, the person, firm, or corporation preparing the product shall attach a label to the can, pot, tin, canvas, or other receptacle or covering, under the supervision of an inspector,

which label shall state that the contents of the receptacle or covering have been ''inspected and passed'' under the provisions of this chapter.

(2) INSPECTION AND EXAMINATION COMPLETED ONLY AFTER ENCLOSURE.—An inspection and examination of any meat or meat food product deposited or enclosed in any can, tin, pot, canvas, or other receptacle or covering in any establishment in which inspection under the provisions of this chapter is maintained shall not be deemed to be complete until the meat or meat food product has been sealed or enclosed in the can, tin, pot, canvas, or other receptacle or covering under the supervision of an inspector.

(b) INFORMATION ON ARTICLES OR CONTAINERS.—All carcasses, parts of carcasses, meat, and meat food products inspected at any establishment under the authority of this subchapter and found to be not adulterated, shall, at the time they leave the establishment, bear, in distinctly legible form, directly on the carcasses, parts, meat, and meat food products or on their containers, as the Secretary may require, the information required under section 30301(13) of this title.

(c) TYPE STYLES AND SIZES IN LABELING; DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION; STANDARDS OF FILL OF CONTAINER.—

(1) IN GENERAL.—The Secretary, if the Secretary determines the action is necessary for the protection of the public, may prescribe—

(A) the styles and sizes of type to be used with respect to—

(i) material required to be incorporated in labeling to avoid false or misleading labeling in marketing; and

(ii) labeling any articles or animals subject to this subchapter or subchapter II; and

(B) definitions and standards of identity or composition for articles subject to this subchapter and standards of fill of container for the articles not inconsistent with any such standards established under subtitle I of this title.

(2) CONSULTATION WITH SECRETARY OF HEALTH AND HUMAN SERVICES.—There shall be consultation between the Secretary and the Secretary of Health and Human Services prior to the issuance of the standards under this subchapter or

subtitle I of this title relating to articles subject to this chapter to avoid inconsistency in the standards and possible impairment of the coordinated effective administration of this chapter and subtitle I of this title.

(3) CONSULTATION WITH ADVISORY COMMITTEE.—There shall be consultation between the Secretary and an appropriate advisory committee provided for in section 30356 of this title, prior to the issuance of the standards under this chapter, to avoid, insofar as feasible, inconsistency between Federal and State standards.

(d) SALES OF ARTICLES UNDER FALSE OR MISLEADING NAME.—An article subject to this subchapter shall not be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling that is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers that are not false or misleading and that are approved by the Secretary are permitted.

(e) WITHHOLDING OF USE.—

(1) IN GENERAL.—If the Secretary has reason to believe that any marking or labeling or the size or form of any container in use or proposed for use

with respect to any article subject to this subchapter is false or misleading in any particular, the Secretary may direct that the use be withheld unless the marking, labeling, or container is modified in such manner as the Secretary may prescribe so that it will not be false or misleading.

(2) HEARING.—If the person, firm, or corporation using or proposing to use the marking, labeling or container does not accept the determination of withholding of the Secretary under paragraph (1), the person, firm, or corporation may request a hearing, but the use of the marking, labeling, or container shall be withheld, if the Secretary directs the withholding, pending hearing and final determination by the Secretary.

(3) APPEALS.—

(A) IN GENERAL.—A determination of withholding under this subsection by the Secretary shall be conclusive unless, within 30 days after receipt of notice of the final determination, the person, firm, or corporation adversely affected by the final determination appeals to the United States court of appeals for the circuit in which the person, firm, or corporation has its principal place of business or to the

United States Court of Appeals for the District of Columbia Circuit.

(B) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of section 204 of the Packers and Stockyards Act, 1921 (7 U.S.C. 194) shall be applicable to appeals taken under this section.

(f) LAMB AND MUTTON.—The Secretary, consistent with United States international obligations, shall establish standards for the labeling of sheep carcasses, parts of sheep carcasses, sheepmeat, and sheepmeat food products.

**§ 30308. Sanitary inspection and regulation of slaughtering and packing establishments**

(a) IN GENERAL.—The Secretary shall—

(1) inspect, through experts in sanitation or other competent inspectors, all slaughtering, meat canning, salting, packing, rendering, or similar establishments in which amenable species are slaughtered and in which the meat and meat food products of the amenable species are prepared for commerce as may be necessary to inform the Secretary concerning the sanitary conditions of the establishments; and

(2) prescribe the rules and regulations of sanitation under which the establishments shall be maintained.

(b) ADULTERATED MEAT AND MEAT FOOD PRODUCTS.—If the sanitary conditions of any establishment under subsection (a) are such that the meat or meat food products are rendered adulterated, the Secretary shall refuse to allow the meat or meat food products to be labeled, marked, stamped, or tagged as ''inspected and passed''.

**§ 30309. Examination of animals and food products of the animals slaughtered and prepared during nighttime**

The Secretary shall examine and inspect all amenable species, and the food products of the amenable species, slaughtered and prepared in the establishments described in section 30308 of this title for the purposes of commerce, which examination and inspection are to be made—

(1) during the nighttime; or

(2) if the slaughtering of the amenable species or the preparation of the food products is conducted during the nighttime, during the daytime.

**§ 30310. Prohibited acts**

A person, firm, or corporation shall not, with respect to any cattle, sheep, swine, goats, horses, mules, or other

equines, or any carcasses, parts of carcasses, meat, or meat food products of any such animals—

(1) slaughter any such animals or prepare any such articles that are capable of use as human food at any establishment preparing any such articles for commerce, except in compliance with the requirements of this chapter;

(2) slaughter or handle in connection with slaughter any such animals in any manner not in accordance with Public Law 85–765 (7 U.S.C. 1901 et seq.);

(3) sell, transport, offer for sale or transportation, or receive for transportation, in commerce—

(A) any such articles that—

(i) are capable of use as human food; and

(ii) are adulterated or misbranded at the time of the sale, transportation, offer for sale or transportation, or receipt for transportation; or

(B) any articles required to be inspected under this subchapter unless they have been inspected under this subchapter and passed;

(4) do, with respect to any such articles that are capable of use as human food, any act while they

are being transported in commerce or held for sale after the transportation, which is intended to cause or has the effect of causing the articles to be adulterated or misbranded.

**§ 30311. Devices, marks, labels, and certificates; simulations**

(a) DEVICES TO BE MADE UNDER AUTHORIZATION OF SECRETARY.—A brand manufacturer, printer, or other person, firm, or corporation shall not cast, print, lithograph, or otherwise make any device containing any official mark or simulation of an official mark, or any label bearing any such mark or simulation, or any form of official certificate or simulation of an official certificate, except as authorized by the Secretary.

(b) OTHER MISCONDUCT.—A person, firm, or corporation shall not—

(1) forge any official device, mark, or certificate;

(2) without authorization from the Secretary, use any official device, mark, or certificate, or simulation of an official device, mark, or certificate, or alter, detach, deface, or destroy any official device, mark, or certificate;

(3) contrary to the regulations prescribed by the Secretary, detach, deface, or destroy, or fail to use, any official device, mark, or certificate;

(4) knowingly possess, without promptly notifying the Secretary or the Secretary's representative—

(A) any official device or any counterfeit, simulated, forged, or improperly altered official certificate;

(B) any device or label bearing any counterfeit, simulated, forged, or improperly altered official mark; or

(C) any carcass of any animal, or part or product of the carcass, bearing any counterfeit, simulated, forged, or improperly altered official mark;

(5) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary; or

(6) knowingly represent that any article has been inspected and passed, or exempted, under this chapter if, in fact, it has, respectively, not been inspected and passed, or exempted.

**§ 30312. Notification**

Any establishment subject to inspection under this chapter that believes, or has reason to believe, that an adulterated or misbranded meat or meat food product received by or originating from the establishment has entered into commerce shall promptly notify the Secretary with regard to the type, amount, origin, and destination of the meat or meat food product.

**§ 30313. Plans and reassessments**

The Secretary shall require that each establishment subject to inspection under this chapter shall, at a minimum—

(1) prepare and maintain current procedures for the recall of all meat or meat food products produced and shipped by the establishment;

(2) document each reassessment of the process control plans of the establishment; and

(3) upon request, make the procedures and reassessed process control plans available to inspectors appointed by the Secretary for review and copying.

**§ 30314. Inspection of carcasses, meat of which is intended for export**

The Secretary shall carefully inspect the carcasses and parts of the carcasses of all amenable species, the meat of which, fresh, salted, canned, corned, packed, cured, or otherwise prepared, is intended and offered for

export to any foreign country, at such times and places and in such manner as the Secretary may consider proper.

**§ 30315. Certificates of condition from inspectors of meat for export**

For the purpose of section 30314 of this title, the Secretary may appoint inspectors who shall be authorized to give an official certificate stating the condition in which the cattle, sheep, swine, goats, horses, mules, or other equines, and the meat of those animals, are found.

**§ 30316. Clearance prohibited to vessel carrying meat for export without inspector's certificate**

A clearance shall not be given to any vessel having on board any fresh, salted, canned, corned, or packed beef, mutton, pork, goat, or equine meat for export to and sale in a foreign country from any port in the United States, until the owner or shipper of the meat obtains from an inspector appointed under the provisions of this chapter a certificate that the amenable species were sound and healthy at the time of inspection, and that their meat is sound and wholesome, unless the Secretary waives the requirements of the certificate for the country to which the amenable species or meats are to be exported.

**§ 30317. Delivery of inspectors' certificates**

(a) AUTHORITY TO GIVE OFFICIAL CERTIFICATES.—The inspectors provided for under this subchapter shall

be authorized to give official certificates of the condition of the carcasses and products of amenable species.

(b) COPIES TO BE DELIVERED.—One copy of each certificate granted under this chapter shall be filed in the Department of Agriculture, another copy shall be delivered to the owner or shipper, and if the amenable species, or their carcasses and products, are sent abroad, a third copy shall be delivered to the chief officer of the vessel on which the shipment is made.

**§ 30318. Marking, labeling, or other identification of articles relating to the kinds of animals from which derived; separate preparations**

(a) IN GENERAL.—A person, firm, or corporation shall not sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any carcasses of species designated by regulations in effect on November 9, 2005, or parts of the carcasses, or the meat or meat food products of the carcasses, unless they are plainly and conspicuously marked or labeled or otherwise identified as required by regulations prescribed by the Secretary to show the kinds of animals from which they were derived.

(b) PREPARATION IN SEPARATE ESTABLISHMENTS.—If required by the Secretary, with respect to establishments at which inspection is maintained under this

subchapter, the animals and their carcasses, parts of the carcasses, meat, and meat food products shall be prepared in establishments separate from those in which other amenable species are slaughtered or their carcasses, parts of carcasses, meat, or meat food products are prepared.

**§ 30319. Imports**

(a) REQUIREMENTS FOR IMPORTATION.—

(1) IN GENERAL.—Carcasses, parts of carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines that are capable of use as human food shall not be imported into the United States—

(A) if the articles are adulterated or misbranded; and

(B) unless they comply with all the inspection and building construction standards, and all other provisions of this chapter and regulations issued under this chapter applicable to the articles in commerce within the United States.

(2) HUMAN METHODS OF SLAUGHTER.—Carcasses, parts of carcasses, meat, or meat food products described in paragraph (1) shall not be imported into the United States unless the livestock from which they were produced was slaughtered and

handled in connection with slaughter in accordance with Public Law 85–765 (7 U.S.C. 1901 et seq.).

(3) TREATMENT AS DOMESTIC ARTICLES.—All imported articles under this subsection shall, on entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter and subtitle I of this title.

(4) MARKING AND LABELING AS REQUIRED BY REGULATIONS.—All imported articles under this subsection shall be marked and labeled as required by the regulations for imported articles.

(5) EFFECT OF SECTION ON PURCHASE BY INDIVIDUAL FOR CONSUMPTION.—Nothing in this section applies to any individual who purchases meat or meat products outside the United States for the individual's own consumption except that the total amount of the meat or meat products shall not exceed 50 pounds.

(b) TERMS AND CONDITIONS FOR DESTRUCTION.—The Secretary may prescribe the terms and conditions for the destruction of all articles described in subsection (a) that are imported contrary to this section, unless—

(1) they are exported by the consignee within the time fixed for exportation by the Secretary; or

(2) in the case of articles that are not in compliance with the chapter solely because of misbranding, the articles are brought into compliance with the chapter under supervision of authorized representatives of the Secretary.

(c) PAYMENT OF STORAGE, CARTAGE, AND LABOR CHARGES.—All charges for storage, cartage, and labor with respect to any article that is imported contrary to this section shall be paid by the owner or consignee, and in default of the payment, shall constitute a lien against the article and any other article thereafter imported under this chapter by or for the owner or consignee.

(d) PROHIBITION.—The knowing importation of any article contrary to this section is prohibited.

(e) INSPECTION AND OTHER STANDARDS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, all carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, offered for importation into the United States shall be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States.

(2) ENTRY NOT PERMITTED.—Any imported meat articles described in paragraph (1) that do not meet the standards shall not be permitted entry in to the United States.

(3) ENFORCEMENT.—The Secretary shall enforce this subsection through—

(A) the imposition of random inspections for the species verification and for residues; and

(B) random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country in accordance with methods approved by the Secretary.

(4) CERTIFICATION RELATING TO COMPLIANCE WITH UNITED STATES STANDARDS.—

(A) IN GENERAL.—Each foreign country from which the meat articles under this subsection are offered for importation into the United States shall obtain a certification issued by the Secretary stating that the country maintains a program using reliable analytical methods to ensure compliance with the United States standards for residues in the meat articles.

(B) ENTRY NOT PERMITTED.—A meat article under this subsection shall not be permitted entry into the United States from a country for which the Secretary has not issued a certification under subparagraph (A).

(C) PERIODIC REVIEW; REVOCATION.—The Secretary shall periodically review the certifications and shall revoke any certification if the Secretary determines that the country involved is not maintaining a program that uses reliable analytical methods to ensure compliance with United States standards for residues in the meat articles.

(D) INSPECTION OF INDIVIDUAL ESTABLISHMENTS.—The consideration of any application for a certification under this subsection and the review of any such certification, by the Secretary, shall include the inspection of individual establishments to ensure that the inspection program of the foreign country involved is meeting the United States standards.

(f) ADMINISTRATION OF ANIMAL DRUGS OR ANTIBIOTICS.—The Secretary may prescribe terms and conditions under which amenable species that have been administered an animal drug or antibiotic banned for use in the

United States may be imported for slaughter and human consumption. A person shall not enter amenable species into the United States in violation of any order issued under this subsection by the Secretary.

(g) RECIPROCAL MEAT INSPECTION REQUIREMENT.—

(1) DEFINITIONS.—In this subsection:

(A) MEAT ARTICLES.—The term ''meat articles'' means carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, that are capable of use as human food.

(B) STANDARDS.—The term ''standards'' means inspection, building construction, sanitary, quality, species verification, residue, and other standards that are applicable to meat articles.

(2) STANDARDS OF FOREIGN COUNTRIES NOT RELATED TO PUBLIC HEALTH.—On request of the Committee on Agriculture or the Committee on Ways and Means of the House of Representatives or the Committee on Agriculture, Nutrition, and Forestry or the Committee on Finance of the Senate, or at the initiative of the Secretary, the Secretary shall, as soon as practicable, determine whether a par-

ticular foreign country applies standards for the importation of meat articles from the United States that are not related to public health concerns about end-product quality that can be substantiated by reliable analytical methods.

(3) CONSULTATION; RECOMMENDATION TO PRESIDENT.—If the Secretary determines that a foreign country applies standards described in paragraph (2)—

(A) the Secretary shall consult with the United States Trade Representative; and

(B) within 30 days after the determination of the Secretary under paragraph (2), the Secretary and the United States Trade Representative shall recommend to the President whether action should be taken under paragraph (4).

(4) PROHIBITION OF IMPORTATION BY PRESIDENT.—Within 30 days after receiving a recommendation for action under paragraph (3), the President shall, if and for such time as the President considers appropriate, prohibit imports into the United States of any meat articles produced in the foreign country unless it is determined that the meat articles produced in that country meet the standards

applicable to meat articles in commerce within the United States.

(5) RELATIONSHIP TO OTHER ACTIONS.—The action authorized under paragraph (4) may be used instead of, or in addition to, any other action taken under any other law.

**§ 30320. Appointment of inspectors**

(a) IN GENERAL.—The Secretary shall appoint from time to time inspectors to examine and inspect—

(1) all amenable species, the inspection of which is provided for under this subchapter;

(2) all carcasses and parts of carcasses of the species described in paragraph (1);

(3) all meats and meat food products of the carcasses described in paragraph (2); and

(4) the sanitary conditions of all establishments in which the meat and meat food products described in paragraph (3) are prepared.

(b) REFUSAL TO STAMP, MARK, TAG, OR LABEL.—The inspectors under subsection (a) shall refuse to stamp, mark, tag, or label any carcass or any part of the carcass, or meat food product from the carcass, prepared in any establishment described in subsection (a), until the article is inspected and found to be not adulterated.

(c) OTHER DUTIES.—The inspectors under subsection (a) shall perform such other duties as are provided by this chapter and by the rules and regulations to be prescribed by the Secretary.

(d) RULES AND REGULATIONS.—The Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter.

(e) RULES AND REGULATIONS RELATING TO INSPECTIONS AND EXAMINATIONS.—All inspections and examinations made under this chapter shall be made according to this chapter and made in such manner as described in the rules and regulations prescribed by the Secretary not inconsistent with provisions of this chapter.

**§ 30321. Bribery of or gifts to inspectors or other officers and acceptance of gifts**

(a) PERSON THAT GIVES BRIBERY.—Any person, firm, or corporation, or any agent or employee of any person, firm, or corporation, that shall give, pay, or offer, directly or indirectly, to any inspector, deputy inspector, chief inspector, or any other officer or employee of the United States authorized to perform any of the duties prescribed by this chapter or by the rules and regulations of the Secretary any money or other thing of value, with intent to influence the inspector, deputy inspector, chief in-

spector, or other officer or employee of the United States in the discharge of any duty provided for in this chapter, shall be, on conviction, imprisoned not less than 1 year nor more than 3 years and fined under title 18 but not less than $5,000.

(b) OFFICER OR EMPLOYEE THAT ACCEPTS BRIBERY.—Any inspector, deputy inspector, chief inspector, or other officer or employee of the United States authorized to perform any of the duties prescribed by this chapter who accepts any money, gift, or other thing of value from any person, firm, or corporation, or officers, agents, or employees of the person, firm, or corporation, given with intent to influence the officer or employee's official action, or that receives or accepts from any person, firm, or corporation engaged in commerce any gift, money, or other thing of value, given with any purpose or intent, shall be, on conviction, summarily discharged from office and shall be imprisoned not less than 1 year nor more than 3 years and fined under title 18 but not less than $1,000.

**§ 30322. Exemptions from inspection requirements**

(a) PERSONAL SLAUGHTERING AND CUSTOM SLAUGHTERING.—

(1) IN GENERAL.—The provisions of this subchapter requiring inspection of the slaughter of animals and the preparation of the carcasses, parts of

carcasses, meat, and meat food products at establishments conducting the operations for commerce shall not apply—

(A) to the slaughtering by any individual of animals of the individual's own raising, and the preparation by the individual and transportation in commerce of the carcasses, parts of the carcasses, meat, and meat food products of the animals exclusively for use by the individual and members of the individual's household and the individual's nonpaying guests and employees;

(B) to the custom slaughter, by any person, firm, or corporation, of cattle, sheep, swine or goats delivered by the owner of the cattle, sheep, swine or goats for the slaughter, and the preparation by the slaughterer and transportation in commerce of the carcasses, parts of the carcasses, meat, and meat food products of the animals, exclusively for use, in the household of the owner, by the owner and members of the owner's household and the owner's nonpaying guests and employees; or

(C) to the custom preparation, by any person, firm, or corporation, of carcasses, parts of

the carcasses, meat, or meat food products, derived—

(i) from the slaughter by any individual of cattle, sheep, swine, or goats of the individual's own raising; or

(ii) from game animals, delivered by the owner of the cattle, sheep, swine, or goats for the custom preparation, and transportation in commerce of the custom prepared articles, exclusively for use in the household of the owner, by the owner and members of the owner's household and the owner's nonpaying guests and employees.

(2) EXEMPTION FOR CUSTOM OPERATIONS AT ESTABLISHMENTS.—In cases in which a person, firm, or corporation engages in custom operations described in paragraph (1) at an establishment at which inspection under this subchapter is maintained, the Secretary may exempt from the inspection at the establishment any animals slaughtered or any meat or meat food products otherwise prepared on the custom basis.

(3) EXEMPTION ONLY ON COMPLIANCE WITH REGULATIONS.—Custom operations at any establishment shall be exempt from inspection requirements

as provided by this section only if the establishment complies with regulations that the Secretary may promulgate to ensure—

(A) that any carcasses, parts of carcasses, meat, or meat food products wherever handled on a custom basis, or any containers or packages containing the articles, are separated at all times from carcasses, parts of carcasses, meat, or meat food products prepared for sale, and that all such articles prepared on a custom basis, or any containers or packages containing the articles, are plainly marked ''Not for Sale'' immediately after being prepared and kept so identified until delivered to the owner; and

(B) that the establishment conducting the custom operation is maintained and operated in a sanitary manner.

(b) TERRITORIAL EXEMPTION.—

(1) IN GENERAL.—The Secretary may, under such sanitary conditions as the Secretary may by regulations prescribe, exempt from the inspection requirements of this subchapter the slaughter of animals, and the preparation of carcasses, parts of the carcasses, meat, and meat food products, by any person, firm, or corporation in any territory of the

United States not organized with a legislative body solely for distribution within the territory of the United States if the Secretary determines—

(A) that it is impracticable to provide the inspection within the limits of funds appropriated for administration of this chapter; and

(B) that the exemption will otherwise facilitate enforcement of this chapter.

(2) REFUSAL, WITHDRAWAL, OR MODIFICATION OF EXEMPTION.—The Secretary may refuse, withdraw, or modify any exemption under this subsection in the discretion of the Secretary if the Secretary determines that the action is necessary to effectuate the purposes of this chapter.

(c) PIZZAS CONTAINING MEAT FOOD PRODUCTS.—

(1) IN GENERAL.—Under such terms and conditions as the Secretary shall prescribe through rules and regulations issued under section 30323 of this title that may be necessary to ensure food safety and protect public health such as special handling procedures, the Secretary shall exempt pizzas containing a meat food product from the inspection requirements of this chapter if—

(A) the meat food product components of the pizzas have been prepared, inspected, and

passed in a cured or cooked form as ready-to-eat in compliance with the requirements of this chapter; and

(B) the pizzas are to be served in public or private nonprofit institutions.

(2) WITHDRAWAL OR MODIFICATION OF EXEMPTION.—The Secretary may withdraw or modify any exemption under this subsection if the Secretary determines that the action is necessary to ensure food safety and to protect public health.

(3) REINSTATEMENT; FURTHER MODIFICATION.—The Secretary may reinstate or further modify any exemption withdrawn or modified under this subsection.

(d) APPLICABLE ADULTERATION AND MISBRANDING PROVISIONS.—The adulteration and misbranding provisions of this subchapter, other than the requirement of the inspection legend, shall apply to articles that are exempted from inspection or not required to be inspected under this section.

**§ 30323. Storage and handling regulations**

(a) IN GENERAL.—The Secretary may by regulations prescribe conditions under which carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of

use as human food, shall be stored or otherwise handled by any person, firm, or corporation engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, the articles, if the Secretary considers the action necessary to ensure that the articles will not be adulterated or misbranded when delivered to the consumer.

(b) VIOLATION.—Violation of a regulation under subsection (a) is prohibited.

(c) REGULATION BY STATE OR TERRITORY OF THE UNITED STATES.—The regulations under subsection (a) shall not apply to the storage or handling of the articles at any retail store or other establishment in any State or organized territory of the United States that would be subject to this section only because of purchases in commerce, if the storage and handling of the articles at the establishment is regulated under the laws of the State or territory of the United States in which the establishment is located, in a manner which the Secretary, after consultation with the appropriate advisory committee provided for in section 30356 of this title, determines is adequate to effectuate the purposes of this section.

### § 30324. Inapplicability of certain requirements to catfish

Notwithstanding any other provision of this chapter, the requirements of sections 30303, 30304, 30305, 30310(2), and 30322 of this title shall not apply to any fish described in section 30301(2)(B) of this title.

## Subchapter II—Meat Processors and Related Industries

### § 30341. Prohibition of subchapter I inspection of articles not intended for use as human food

(a) IN GENERAL.—Inspection shall not be provided under subchapter I at any establishment for the slaughter of cattle, sheep, swine, goats, horses, mules, or other equines, or the preparation of any carcasses or parts or products of the animals, that are not intended for use as human food, but the articles shall, prior to their offer for sale or transportation in commerce, unless naturally inedible by humans, be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food.

(b) PROHIBITION OF PURCHASE, SALE, OR TRANSPORT.—A person, firm, or corporation shall not buy, sell, transport, or offer for sale or transportation, or receive for transportation, in commerce, or import, any carcasses, parts of carcasses, meat, or meat food products of any animals listed under subsection (a), that are not intended

for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary or are naturally inedible by humans.

**§ 30342. Recordkeeping requirements**

(a) IN GENERAL.—

(1) CLASSES OF PERSONS, FIRMS, AND CORPORATIONS.—The following classes of persons, firms, and corporations shall keep such records as will fully and correctly disclose all transactions involved in their businesses:

(A) Any persons, firms, or corporations that engage, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food.

(B) Any persons, firms, or corporations that engage in the business of buying or selling (as meat brokers, wholesalers or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any animals under subparagraph (A).

(C) Any persons, firms, or corporations that engage in business, in or for commerce, as renderers, or engage in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

(2) ACCESS.—All persons, firms, and corporations subject to the requirements under paragraph (1) shall, at all reasonable times on notice by an authorized representative of the Secretary, afford the representative access to their places of business and opportunity to examine the facilities, inventory, and records of inventory, to copy all the records, and to take reasonable samples of their inventory on payment of the fair market value for the samples.

(b) PERIOD OF MAINTENANCE.—Any record required to be maintained by this section shall be maintained for such period of time as the Secretary may by regulations prescribe.

**§ 30343. Registration of business, name of person, and trade names**

Unless, when required by regulations of the Secretary, a person, firm, or corporation has registered with the Secretary the person's, firm's, or corporation's name, and the address of each place of business at which, and all trade names under which, the person, firm, or corporation conducts business described in paragraph (1), (2), (3), or (4), the person, firm, or corporation shall not—

(1) engage in business, in or for commerce, as a meat broker, renderer, or animal food manufacturer;

(2) engage in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any cattle, sheep, swine, goats, horses, mules, or other equines, whether intended for human food or other purposes;

(3) engage in business as a public warehouseman storing any articles described in paragraph (2) in or for commerce; or

(4) engage in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased animals of the specified kinds under paragraph (2), or parts of the carcasses of any such animals that died otherwise than by slaughter.

**§ 30344. Regulation of transactions, transportation, or importation of animals to prevent use as human food**

A person, firm, or corporation engaged in the business of buying, selling, or transporting in commerce, or importing, dead, dying, disabled, or diseased animals, or any parts of the carcasses of any animals that died otherwise than by slaughter, shall not buy, sell, transport, offer for sale or transportation, or receive for transportation, in commerce, or import, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter, unless the transaction, transportation, or importation is made in accordance with such regulations as the Secretary may prescribe to ensure that the animals, or the unwholesome parts or products of the animals, will be prevented from being used for human food purposes.

**§ 30345. Federal provisions applicable to State or territorial business transactions**

(a) IN GENERAL.—The authority conferred on the Secretary by section 30342, 30343, or 30344 of this title with respect to persons, firms, and corporations engaged in the specified kinds of business in or for commerce may be exercised with respect to persons, firms, or corporations engaged, in any State or organized territory of the United

States, in those kinds of business but not in or for commerce, if the Secretary determines, after consultation with an appropriate advisory committee provided for in section 30356 of this title, that the State or territory of the United States does not have at least equal authority under its laws or the authority is not exercised in a manner to effectuate the purposes of this chapter, including the State or territory of the United States providing for the Secretary or the Secretary's representative being afforded access to the places of business and the facilities, inventories, and records of the inventories, and the taking of reasonable samples, if the Secretary determines necessary in carrying out the Secretary's responsibilities under this chapter.

(b) TREATMENT OF PERSONS AS IF ENGAGED IN COMMERCE.—In a case described in paragraph (1), the provisions of section 30342, 30343, or 30344 of this title, respectively, shall apply to the persons, firms, and corporations to the same extent and in the same manner as if they were engaged in the business in or for commerce and the transactions involved were in commerce.

# Subchapter III—Federal and State Cooperation

### § 30356. Federal and State cooperation

(a) DEFINITION OF STATE.—In this section, the term ''State'' means any State (including Puerto Rico) or organized territory of the United States.

(b) IN GENERAL.—

(1) POLICY.—It is the policy of Congress to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist in efforts by State and other government agencies to accomplish this objective.

(2) AUTHORITIES.—In furtherance of the policy under paragraph (1), the following shall apply:

(A) DEVELOPMENT AND ADMINISTRATION OF STATE MEAT INSPECTION PROGRAM EQUAL TO SUBCHAPTER I ANTE AND POST MORTEM INSPECTION, REINSPECTION, AND SANITATION REQUIREMENTS.—The Secretary may, if the Secretary determines that it would effectuate the purposes of this chapter, cooperate with the appropriate State agency in developing and administering a State meat inspection program in any State that has enacted a State meat inspection law that imposes mandatory ante mortem

and post mortem inspection, reinspection, and sanitation requirements that are at least equal to those under subchapter I, with respect to all or certain classes of persons engaged in the State in slaughtering cattle, sheep, swine, goats, or equines, or preparing the carcasses, parts of the carcasses, meat, or meat food products, of any such animals for use as human food solely for distribution within the State.

(B) DEVELOPMENT AND ADMINISTRATION OF STATE PROGRAM WITH AUTHORITIES EQUAL TO SUBCHAPTER II AUTHORITIES; COOPERATION WITH FEDERAL AGENCIES.—The Secretary may, if the Secretary determines that it would effectuate the purposes of this chapter—

(i) cooperate with appropriate State agencies in developing and administering State programs under State laws containing authorities at least equal to those provided in subchapter II; and

(ii) cooperate with other agencies of the United States in carrying out any provisions of this chapter.

(C) SCOPE OF COOPERATION.—

(i) IN GENERAL.—Cooperation with State agencies under this section may include furnishing to the appropriate State agency—

(I) advisory assistance in planning and otherwise developing an adequate State program under the State law; and

(II) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other aid for administration of such a program.

(ii) AMOUNT OF FEDERAL CONTRIBUTION.—The amount to be contributed to any State by the Secretary under this section from Federal funds for any year shall not exceed 50 percent of the estimated total cost of the cooperative program.

(iii) ALLOCATION.—The Federal funds shall be allocated among the States desiring to cooperate on an equitable basis.

(iv) CONDITION; ADEQUATE ADMINISTRATION.—The cooperation and payment

shall be contingent at all times on the administration of the State program in a manner that the Secretary, in consultation with the appropriate advisory committee appointed under subparagraph (D), considers adequate to effectuate the purposes of this section.

(D) ADVISORY COMMITTEES.—The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with the Secretary concerning State and Federal programs with respect to meat inspection and other matters within the scope of this chapter, including evaluating State programs for purposes of this chapter and obtaining better coordination and more uniformity among the State programs and between the Federal and State programs and adequate protection of consumers.

(c) SINGLE STATE AGENCY.—

(1) IN GENERAL.—The appropriate State agency with which the Secretary may cooperate under this chapter shall be a single agency in the State that is primarily responsible for the coordination of

the State programs having objectives similar to those under this chapter.

(2) TREATMENT OF SUBORDINATE GOVERNMENTAL UNIT.—If the State program includes performance of certain functions by a municipality or other subordinate governmental unit, the unit shall be deemed to be a part of the State agency for purposes of this section.

(d) STATE MEAT INSPECTION REQUIREMENTS.—

(1) DESIGNATED STATES.—

(A) NOTIFICATION.—If the Secretary has reason to believe, by 30 days prior to the expiration of 2 years after December 15, 1967, that a State has failed to develop or is not enforcing, with respect to all establishments within its jurisdiction (except those that would be exempted from Federal inspection under paragraph (2)) at which cattle, sheep, swine, goats, or equines are slaughtered, or their carcasses, or parts or products of the carcasses, are prepared for use as human food, solely for distribution within the State, and the products of the establishments, requirements at least equal to those imposed under subchapters I and IV, the Sec-

retary shall promptly notify the Governor of the State of this fact.

(B) PROVISIONS APPLICABLE TO DESIGNATED STATES.—If the Secretary determines, after consultation with the Governor of the State, or representative selected by the Governor, that the requirements have not been developed and activated, the Secretary shall promptly, after the expiration of the 2-year period, designate the State as one in which the provisions of subchapters I and IV shall apply to operations and transactions wholly within the State.

(C) AUTHORIZED DELAY.—If the Secretary has reason to believe that the State will activate the requirements within 1 additional year, the Secretary may delay the designation for that period, and not designate the State, if the Secretary determines at the end of the year that the State then has the requirements in effective operation.

(D) PUBLICATION OF DESIGNATION.—The Secretary shall publish any designation under this paragraph in the Federal Register and, on the expiration of 30 days after the publication,

the provisions of subchapters I and IV shall apply to operations and transactions and to persons, firms, and corporations engaged in operations and transactions in the State to the same extent and in the same manner as if the operations and transactions were conducted in or for commerce.

(E) REVOCATION OF DESIGNATION.—On request of the Governor, the Secretary shall revoke a designation under this paragraph if the Secretary determines that the State has developed and will enforce requirements at least equal to those imposed under subchapter I and subchapter IV.

(F) ADULTERATED MEAT AND MEAT FOOD PRODUCTS BEING DISTRIBUTED WITHIN A STATE.—

(i) NOTIFICATION OF GOVERNOR BY SECRETARY.—Notwithstanding any other provision of this section, if the Secretary determines that any establishment within a State is producing adulterated meat or meat food products for distribution within the State that would clearly endanger the public health, the Secretary shall notify the

Governor of the State and the appropriate advisory committee provided by section 30356 of this title of the fact for effective action under State or local law.

(ii) NO STATE ACTION TAKEN.—If the State does not take action to prevent the endangering of the public health within a reasonable time after the notice, as determined by the Secretary, in light of the risk to public health, the Secretary may immediately designate the establishment described in clause (i) as subject to the provisions of subchapters I and IV, and on the designation, the establishment and operator of the establishment shall be subject to those provisions as though engaged in commerce until such time as the Secretary determines that the State has developed and will enforce requirements at least equal to those imposed under subchapters I and IV.

(2) RETAIL ESTABLISHMENTS AND RESTAURANTS.—

(A) IN GENERAL.—The provisions of this chapter requiring inspection of the slaughter of

animals and the preparation of carcasses, parts of carcasses, meat, and meat food products shall not apply to operations of types traditionally and usually conducted at retail stores and restaurants, if conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of the articles to consumers at the establishments if the establishments are subject to the inspection provisions only under this subsection.

(B) OPERATIONS AT A RESTAURANT CENTRAL KITCHEN.—

(i) IN GENERAL.—For the purposes of this paragraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that are ready to eat when they leave the facility and are served in meals or as entrees only to customers at restaurants owned or operated by the same person, firm, or corporation owning or operating the facility.

(ii) APPLICABILITY OF PROVISION.—The facility described in clause (i) shall be

subject to the provisions of section 30342 of this title.

(iii) INSPECTIONS.—The facility described in clause (i) may be subject to the inspection requirements under subchapter I for as long as the Secretary considers necessary, if the Secretary determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated.

(3) TERMINATION; REDESIGNATION.—

(A) TERMINATION OF DESIGNATION.—If the Secretary determines that any State designated under this subsection has developed and will enforce State meat inspection requirements at least equal to those imposed under subchapters I and IV, with respect to the operations and transactions within the State that are regulated under paragraph (1), the Secretary shall terminate the designation of the State under this subsection.

(B) REDESIGNATION.—The termination under subparagraph (A) shall not preclude the

subsequent redesignation of the State at any time on 30 days' notice to the Governor and publication in the Federal Register in accordance with this subsection, and any State may be designated on the notice and publication at any time after the period specified in this subsection whether the State has previously been designated, on the Secretary determining that it is not effectively enforcing requirements at least equal to those imposed under subchapters I and IV.

(4) ANNUAL REVIEW AND REPORT.—The Secretary shall periodically, but at least annually, review the requirements, including the enforcement of the requirements, of the States not designated under this subsection, with respect to the slaughter, and the preparation, storage, handling, and distribution of carcasses, parts of carcasses, meat, and meat food products, of the animals, and inspection of the operations.

# Subchapter IV—Other Provisions

## § 30361. Refusal or withdrawal of inspection services based on certain convictions

(a) REFUSAL OR WITHDRAWAL.—

(1) IN GENERAL.—The Secretary may (for such period, or indefinitely, as the Secretary considers necessary to effectuate the purposes of this chapter) refuse to provide, or withdraw, inspection services under subchapter I with respect to any establishment if the Secretary determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, the service, that the applicant or recipient is unfit to engage in any business requiring inspection under subchapter I because the applicant or recipient, or anyone responsibly connected with the applicant or recipient, has been convicted, in any Federal or State court, based on the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or on fraud in connection with transactions in food, of—

(A) any felony; or

(B) more than 1 violation of any law, other than a felony.

(2) RESPONSIBLY CONNECTED.—For the purpose of this section an individual shall be deemed to be responsibly connected with the business if the individual was a partner, officer, director, holder, or owner of 10 percent or more of its voting stock, or an employee in a managerial or executive capacity.

(b) FINALITY AND CONCLUSIVENESS OF DETERMINATION.—

(1) IN GENERAL.—The determination and order of the Secretary with respect to the determination under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files an application for judicial review within 30 days after the effective date of the order in the appropriate court as provided in section 30364 of this title.

(2) JUDICIAL REVIEW; BASIS.—Judicial review of any order under paragraph (1) shall be on the record on which the determination and order are based.

(c) EFFECT OF SECTION.—This section does not affect other provisions of this chapter for withdrawal of inspection services under subchapter I from establishments failing to maintain sanitary conditions or to destroy condemned carcasses, parts, meat, or meat food products.

**§ 30362. Administrative detention**

(a) IN GENERAL.—If any carcass, part of a carcass, meat, or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines, or any product exempted from the definition of a meat food product, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or

equine is found by any authorized representative of the Secretary on any premises in which it is held for purposes of, or during or after distribution in, commerce or otherwise subject to subchapter I or II, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of subchapter I or of any other Federal law or the laws of any State or territory of the United States, or the District of Columbia, or that the article or animal has been, or is intended to be, distributed in violation of any such provisions, it may be detained by the representative for a period not to exceed 20 days, pending action under section 30363 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over the article or animal.

(b) REMOVAL OF ARTICLE.—The article or animal detained under subsection (a) shall not be moved by any person, firm, or corporation from the place at which it is located while detained under subsection (a), until released by the representative.

(c) OFFICIAL MARKS.—All official marks may be required by the representative to be removed from the article or animal before it is released unless it appears to the sat-

isfaction of the Secretary that the article or animal is eligible to retain the marks.

**§ 30363. Seizure and condemnation**

(a) PROCEEDINGS.—

(1) IN GENERAL.—

(A) SEIZURE AND CONDEMNATION.—Any article described in subparagraph (B) shall be liable to be proceeded against and seized and condemned, at any time, on a filing of an action in any United States district court or other proper court as provided in section 30364 of this title within the jurisdiction of which the article or animal is found.

(B) ARTICLES; ANIMALS.—An article described in this subparagraph is any carcass, part of a carcass, meat, or meat food product of cattle, sheep, swine, goats, horses, mules, or other equines, or any dead, dying, disabled, or diseased cattle, sheep, swine, goat, or equine, that is being transported in commerce or otherwise subject to subchapter I or II, or is held for sale in the United States after the transportation, and that—

(i) is or has been prepared, sold, transported, or otherwise distributed or of-

fered or received for distribution in violation of this chapter;

(ii) is capable of use as human food and is adulterated or misbranded; or

(iii) in any other way, is in violation of this chapter.

(2) DISPOSITION.—

(A) IN GENERAL.—If the article or animal is condemned, it shall, after entry of the decree—

(i) be distributed in accordance with paragraph (5); or

(ii) be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the article or animal shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold.

(B) BOND.—On the execution and delivery of a good and sufficient bond conditioned that the article or animal shall not be sold or otherwise disposed of contrary to the provisions of

this chapter, or the laws of the jurisdiction in which disposition is made, the court may direct that the article or animal be delivered to the owner of the article or animal subject to such supervision by authorized representatives of the Secretary as is necessary to ensure compliance with the applicable laws.

(3) COURT COSTS; STORAGE AND OTHER EXPENSES.—If a decree of condemnation is entered against the article or animal and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article or animal.

(4) ADMIRALTY PROCEEDINGS; UNITED STATES AS NAMED PARTY.—Proceedings under this section shall conform, as nearly as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be brought by and in the name of the United States.

(5) DISTRIBUTION.—

(A) IN GENERAL.—An article that is condemned under paragraph (1) may as the court may direct, after entry of the decree, be distrib-

uted without charge to nonprofit, private entities or to Federal, State, or local government entities engaged in the distribution of food without charge to individuals, if the article—

(i) has been inspected under this chapter and found to be wholesome and not to be adulterated within the meaning of clauses (i) through (vii) and (ix) of section 30301(1)(A) of this title and a determination is made at the time of the entry of the decree that the article is wholesome and not adulterated; and

(ii) is plainly marked ''Not for Sale'' on the article or its container.

(B) LEGAL RESPONSIBILITY OF THE UNITED STATES.—The United States may not be held legally responsible for any article that is distributed under subparagraph (A) to a nonprofit, private entity or to a Federal, State, or local government entity, if the article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of clauses (i) through (vii) and (ix) of section 30301(1)(A) of this title and a determina-

tion was made at the time of the entry of the decree that the article was wholesome and not adulterated; and

(ii) was plainly marked ''Not for Sale'' on the article or its container.

(C) LEGAL RESPONSIBILITY OF PERSON FROM WHOM ARTICLE WAS SEIZED AND CONDEMNED.—The person from whom the article was seized and condemned may not be held legally responsible for the article, if the article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of clauses (i) through (vii) and (ix) of section 30301(1)(A) of this title and a determination was made at the time of the entry of the decree that the article was wholesome and not adulterated; and

(ii) was plainly marked ''Not for Sale'' on the article or its container.

(b) CONDEMNATION OR SEIZURE UNDER OTHER PROVISIONS UNAFFECTED.—The provisions of this section shall not derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

**§ 30364. Federal court jurisdiction**

The United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and the United States courts of the other territories of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other kinds of cases arising under this chapter, except as provided in section 30307(e) of this title.

**§ 30365. Assaulting, resisting, or impeding certain persons; murder**

(a) IN GENERAL.—Any individual who forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any individual while engaged in or on account of the performance of the latter's official duties under this chapter shall be imprisoned not more than 3 years, fined under title 18, or both.

(b) USE OF DEADLY OR DANGEROUS WEAPON.—Any individual who, in the commission of acts described in subsection (a), uses a deadly or dangerous weapon, shall be imprisoned not more than 10 years, fined under title 18, or both.

(c) MURDER.—Any individual who kills any individual while engaged in or on account of the performance of the latter's official duties under this chapter shall be

punished as provided under sections 1111 and 1114 of title 18.

**§ 30366. Minor violations**

(a) IN GENERAL.—Any person, firm, or corporation that violates any provision of this chapter for which no other criminal penalty is provided by this chapter shall, on conviction, be imprisoned not more than 1 year, fined under title 18, or both.

(b) INTENT TO DEFRAUD.—If a violation under subsection (a) involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except as defined in section 30301(1)(A)(viii) of this title), the person, firm, or corporation shall be imprisoned not more than 3 years, fined under title 18, or both.

(c) GOOD FAITH.—A person, firm, or corporation shall not be subject to penalties under this section for receiving for transportation any article or animal in violation of this chapter if the receipt was made in good faith, unless the person, firm, or corporation refuses to furnish on request of a representative of the Secretary—

(1) the name and address of the individual from whom the person, firm, or corporation received the article or animal; and

(2) copies of all documents, if any, pertaining to the delivery of the article or animal to the person, firm, or corporation.

(d) EFFECT OF CHAPTER ON REPORTING OF MINOR VIOLATIONS.—Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution or for the institution of civil action or injunction proceedings minor violations of this chapter if the Secretary believes that the public interest will be adequately served by a suitable written notice of warning.

**§ 30367. Other Federal laws applicable to administration and enforcement of chapter**

(a) IN GENERAL.—For the efficient administration and enforcement of this chapter, the provisions (including penalties) of sections 6, 8, 9, and 10 of the Federal Trade Commission Act (15 U.S.C. 46, 48, 49, 50) (except subsections (c) through (h) of section 6 of the Act (15 U.S.C. 46)), are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person, firm, or corporation with respect to whom the authority is exercised.

(b) PROSECUTION OF INQUIRY.—The Secretary, or such agents as the Secretary may designate, may prosecute any inquiry necessary to the Secretary's duties under this chapter in any part of the United States.

(c) AUHTORITY OF THE COURTS.—The powers conferred by sections 9 and 10 of the Federal Trade Commission Act (15 U.S.C. 49, 50) on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 30364 of this title.

**§ 30368. Prohibition of additional or different requirements**

(a) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT REQUIREMENTS RELATING TO PREMISES, FACILITIES, AND OPERATIONS; AUTHORITY TO IMPOSE RECORDKEEPING REQUIREMENTS.—Requirements within the scope of this chapter with respect to premises, facilities, and operations of any establishment at which inspection is provided under subchapter I that are in addition to, or different than, those made under this chapter may not be imposed by any State, territory of the United States, or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 30342 of this title, if consistent with section 30342 of this title, with respect to the establishment.

(b) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT STANDARDS AND LABELING REQUIREMENTS.—Marking, labeling, packaging, or ingredient requirements

in addition to, or different than, those made under this chapter may not be imposed by any State, territory of the United States, or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I, but any State, territory of the United States, or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles that are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles that are not at such an establishment, after their entry into the United States.

(c) EFFECT OF CHAPTER.—This chapter does not preclude any State, territory of the United States, or the District of Columbia from making requirements or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

**§ 30369. Applicability of subtitle I**

(a) EFFECT ON AUTHORITIES UNDER SUBTITLE I.—Notwithstanding any other provisions of law, including section 10321(a) of this title, the provisions of this chapter

shall not derogate from any authority conferred by subtitle I of this title prior to December 15, 1967.

(b) APPLICABILITY OF DETAINER AUTHORITY TO REPRESENTATIVE OF SECRETARY OF HEALTH AND HUMAN SERVICES.—The detainer authority conferred by section 30362 of this title shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of subtitle I of this title with respect to any carcass, part of a carcass, meat, or meat food product of cattle, sheep, swine, goats, or equines that is outside any premises at which inspection is being maintained under this chapter, and for those purposes, the first reference to the Secretary in section 30362 of this title shall be deemed to refer to the Secretary of Health and Human Services.

**§ 30370. Safe Meat and Poultry Inspection Panel**

(a) DEFINITION OF PANEL.—In this section, the term ''Panel'' means the Safe Meat and Poultry Inspection Panel established in subsection (b).

(b) ESTABLISHMENT.—There is established in the Department of Agriculture a permanent advisory panel to be known as the ''Safe Meat and Poultry Inspection Panel''.

(c) DUTIES.—

(1) REVIEW AND EVALUATION.—The Panel shall review and evaluate, as the Panel considers necessary, the adequacy, necessity, safety, cost effectiveness, and scientific merit of—

(A) inspection procedures of, and work rules and worker relations involving Federal employees employed in, plants inspected under this chapter;

(B) informal petitions or proposals for changes in inspection procedures, processes, and techniques of plants inspected under this chapter;

(C) formal changes in meat inspection regulations promulgated under this chapter, whether in notice, proposed, or final form; and

(D) such other matters as may be referred to the Panel by the Secretary regarding the quality or effectiveness of a safe and cost-effective meat inspection system under this chapter.

(2) REPORTS.—

(A) IN GENERAL.—The Panel shall submit to the Secretary a report on the results of each review and evaluation carried out under paragraph (1), including such recommendations as the Panel considers appropriate.

(B) REPORTS ON FORMAL CHANGES.—In the case of a report concerning a formal change in meat inspection regulations, the report shall be made within the time limits prescribed for formal comments on the changes.

(C) PUBLICATION IN FEDERAL REGISTER.—Each report of the Panel to the Secretary shall be published in the Federal Register.

(d) SECRETARIAL RESPONSE.—Not later than 90 days after the publication of a Panel report under subsection (c)(2)(C), the Secretary shall publish in the Federal Register any response required of the Secretary to the report.

(e) COMPOSITION OF PANEL.—The Panel shall be composed of 7 members, not fewer than 5 of whom shall be from the food science, meat science, or poultry science profession, appointed to staggered terms not to exceed 3 years by the Secretary from nominations received from the National Institutes of Health and the Federation of American Societies of Food Animal Science and based on the professional qualifications of the nominees.

(f) NOMINATIONS.—

(1) INITIAL PANEL.—In constituting the initial panel, the Secretary shall solicit 6 nominees from

the National Institutes of Health and 6 nominees from the Federation of American Societies of Food Animal Science for membership on the Panel.

(2) VACANCIES.—Any subsequent vacancy on the Panel shall be filled by the Secretary after soliciting 2 nominees from the National Institutes of Health and 2 nominees from the Federation of American Societies of Food Animal Science.

(3) REQUIREMENTS FOR NOMINEES.—

(A) IN GENERAL.—Each nominee provided under paragraph (1) or (2) shall have a background in public health issues and a scientific expertise in food, meat, or poultry science or in veterinary science.

(B) SUBMISSION OF INFORMATION.—The Secretary may require nominees to submit such information as the Secretary considers necessary prior to completing the selection process.

(4) ADDITIONAL NOMINEES.—If any list of nominees provided under paragraph (1) or (2) is unsatisfactory to the Secretary, the Secretary may request the nominating entities to submit an additional list of nominees.

(g) TRAVEL EXPENSES.—While away from the home or regular place of business of a member of the Panel in

the performance of services for the Panel, the member shall be allowed travel expenses, including per diem in lieu of subsistence, at the same rate as an individual employed intermittently in the Government service would be allowed under section 5703 of title 5.

(h) CONFLICTS OF INTEREST.—The Secretary shall promulgate regulations regarding conflicts of interest with respect to the members of the Panel.

(i) EXEMPTION.—Chapter 10 of title 5 and title XVIII of the Food and Agriculture Act of 1977 (7 U.S.C. 2281 et seq.) shall not apply to the Panel.

(j) FUNDING.—From funds available to the Secretary to carry out this chapter and chapter 313 of this title, the Secretary shall allocate such sums as may be necessary to carry out this section.

# Subchapter V—Inspections by Federal and State Agencies

## §30381. Interstate shipment of meat inspected by Federal and State agencies for certain small establishments

(a) DEFINITIONS.—In this section:

(1) APPROPRIATE STATE AGENCY.—The term ''appropriate State agency'' means a State agency described in section 30356(c) of this title.

(2) DESIGNATED PERSONNEL.—The term ''designated personnel'' means inspection personnel of a State agency that have undergone all necessary inspection training and certification to assist the Secretary in the administration and enforcement of this chapter, including rules and regulations issued under this chapter.

(3) ELIGIBLE ESTABLISHMENT.—The term ''eligible establishment'' means an establishment that is in compliance with—

(A) the State inspection program of the State in which the establishment is located; and

(B) this chapter, including rules and regulations issued under this chapter.

(4) MEAT ITEM.—The term ''meat item'' means—

(A) a portion of meat; or

(B) a meat food product.

(5) SELECTED ESTABLISHMENT.—The term ''selected establishment'' means an eligible establishment that is selected by the Secretary, in coordination with the appropriate State agency of the State in which the eligible establishment is located, under subsection (b) to ship carcasses, portions of carcasses, and meat items in interstate commerce.

(b) AUTHORITY OF SECRETARY TO ALLOW SHIPMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary, in coordination with the appropriate State agency of the State in which an establishment is located, may select the establishment to ship carcasses, portions of carcasses, and meat items in interstate commerce, and place on each carcass, portion of a carcass, and meat item shipped in interstate commerce a Federal mark, stamp, tag, or label of inspection, if—

(A) the carcass, portion of carcass, or meat item qualifies for the mark, stamp, tag, or label of inspection under the requirements of this chapter;

(B) the establishment is an eligible establishment; and

(C) inspection services for the establishment are provided by designated personnel.

(2) PROHIBITED ESTABLISHMENTS.—In carrying out paragraph (1), the Secretary, in coordination with an appropriate State agency, shall not select an establishment that—

(A) on average, employs more than 25 employees (including supervisory and non-

supervisory employees), as defined by the Secretary;

(B) as of June 18, 2008, ships in interstate commerce carcasses, portions of carcasses, or meat items that are inspected by the Secretary in accordance with this chapter;

(C)(i) is a Federal establishment;

(ii) was a Federal establishment that was reorganized on a later date under the same name or a different name or person by the person, firm, or corporation that controlled the establishment as of June 18, 2008; or

(iii) was a State establishment as of June 18, 2008, that—

(I) as of June 18, 2008, employed more than 25 employees; and

(II) was reorganized on a later date by the person, firm, or corporation that controlled the establishment as of June 18, 2008;

(D) is in violation of this chapter;

(E) is located in a State that does not have a State inspection program; or

(F) is the subject of a transition carried out in accordance with a procedure developed by the Secretary under paragraph (3)(A).

(3) ESTABLISHMENTS THAT EMPLOY MORE THAN 25 EMPLOYEES.—

(A) DEVELOPMENT OF PROCEDURE.—The Secretary may develop a procedure to transition to a Federal establishment any establishment under this section that, on average, consistently employs more than 25 employees.

(B) ELIGIBILITY OF CERTAIN ESTABLISHMENTS.—

(i) IN GENERAL.—A State establishment that employs more than 25 employees but less than 35 employees as of June 18, 2008, may be selected as a selected establishment under this subsection.

(ii) PROCEDURES.—A State establishment shall be subject to the procedures established under subparagraph (A).

(c) REIMBURSEMENT OF STATE COSTS.—The Secretary shall reimburse a State for costs related to the inspection of selected establishments in the State in accordance with Federal requirements in an amount of not less than 60 percent of eligible State costs.

(d) COORDINATION BETWEEN FEDERAL AND STATE AGENCIES.—

(1) IN GENERAL.—The Secretary shall designate an employee of the Federal Government as State coordinator for each appropriate State agency—

(A) to provide oversight and enforcement of this subchapter; and

(B) to oversee the training and inspection activities of designated personnel of the State agency.

(2) SUPERVISION.—A State coordinator shall be under the direct supervision of the Secretary.

(3) DUTIES OF STATE COORDINATOR.—

(A) IN GENERAL.—A State coordinator shall visit selected establishments with a frequency that is appropriate to ensure that selected establishments are operating in a manner that is consistent with this chapter (including regulations and policies under this chapter).

(B) QUARTERLY REPORTS.—A State coordinator shall, on a quarterly basis, submit to the Secretary a report that describes the status of each selected establishment that is under the jurisdiction of the State coordinator with respect to the level of compliance of each selected

establishment with the requirements of this chapter.

(C) IMMEDIATE NOTIFICATION REQUIREMENT.—If a State coordinator determines that any selected establishment that is under the jurisdiction of the State coordinator is in violation of any requirement of this chapter, the State coordinator shall—

(i) immediately notify the Secretary of the violation; and

(ii) deselect the selected establishment or suspend inspection at the selected establishment.

(4) PERFORMANCE EVALUATIONS.—Performance evaluations of State coordinators designated under this subsection shall be conducted by the Secretary as part of the Federal agency management control system.

(e) AUDITS.—Not later than 2 years after the effective date described in subsection (j), and not less often than every 3 years thereafter, the Inspector General of the Department of Agriculture shall conduct an audit of each activity taken by the Secretary under this section for the period covered by the audit to determine compliance with this section.

(f) TECHNICAL ASSISTANCE DIVISION.—

(1) ESTABLISHMENT.—The Secretary shall establish in the Food Safety and Inspection Service of the Department of Agriculture a technical assistance division to coordinate the initiatives of any other appropriate agency of the Department of Agriculture to provide—

(A) outreach, education, and training to very small or certain small establishments (as defined by the Secretary); and

(B) grants to appropriate State agencies to provide outreach, technical assistance, education, and training to very small or certain small establishments (as defined by the Secretary).

(2) PERSONNEL.—The technical assistance division shall be comprised of individuals that, as determined by the Secretary—

(A) are of a quantity sufficient to carry out the duties of the technical assistance division; and

(B) possess appropriate qualifications and expertise relating to the duties of the technical assistance division.

(g) TRANSITION GRANTS.—The Secretary may provide grants to appropriate State agencies to assist the appropriate State agencies in helping establishments covered by subchapter III to transition to selected establishments.

(h) VIOLATIONS.—Any selected establishment that the Secretary determines to be in violation of any requirement of this chapter shall be transitioned to a Federal establishment in accordance with a procedure developed by the Secretary under subsection (b)(3)(A).

(i) EFFECT.—Nothing in this section limits the jurisdiction of the Secretary with respect to the regulation of meat and meat products under this chapter.

(j) EFFECTIVE DATE.—

(1) IN GENERAL.—This section takes effect on the date on which the Secretary, after providing a period of public comment (including through the conduct of public meetings or hearings), promulgates final regulations to carry out this section.

(2) REQUIREMENT.—The Secretary shall promulgate final regulations in accordance with paragraph (1).

# Chapter 305—Supplemental Federal Meat Inspection Provisions

Sec.
30501. Inspection extended to reindeer.
30502. Purchase of tags, labels, stamps, and certificates.
30503. Inspection costs.
30504. Protection of religious freedom and ritual slaughter.

30505. Pasteurization of meat and poultry.
30506. Expansion of Food Safety Inspection Service activities.
30507. Grants for improvements to meat and poultry facilities to allow for interstate shipment.

**§ 30501. Inspection extended to reindeer**

The provisions of the meat inspection law may be extended to the inspection of reindeer.

**§ 30502. Purchase of tags, labels, stamps, and certificates**

The Secretary may expend appropriations for meat inspection for the purchase of printed tags, labels, stamps, and certificates without regard to existing laws applicable to public printing.

**§ 30503. Inspection costs**

(a) DEFINITION OF HOLIDAY.—The term ''holiday'', for the purposes of assessment or reimbursement of the cost of inspection performed under chapter 303 of this title, means the legal public holidays specified by Congress in section 6103(a) of title 5.

(b) OVERTIME AND HOLIDAY WORK COSTS.—The cost of inspection rendered under the requirements of laws relating to Federal inspection of meat and meat food products shall be borne by the United States except the cost of overtime and holiday pay paid pursuant to section 10703 of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 2219a).

**§ 30504. Protection of religious freedom and ritual slaughter**

(a) DEFINITION OF RITUAL SLAUGHTER.—In this section, the term ''ritual slaughter'' means slaughter in accordance with section 2(b) of Public Law 85–765 (7 U.S.C. 1902(b)).

(b) IN GENERAL.—Nothing in the Humane Methods of Slaughter Act of 1978 (Public Law 95–445, 92 Stat. 1069) shall be construed to prohibit, abridge, or in any way hinder the religious freedom of any person or group.

(c) EXEMPTION.—Notwithstanding any provision of the Humane Methods of Slaughter Act of 1978 (Public Law 95–445, 92 Stat. 1069), in order to protect freedom of religion, ritual slaughter and the handling or other preparation of livestock for ritual slaughter are exempted from the terms of that Act.

**§ 30505. Pasteurization of meat and poultry**

The Secretary shall conduct an education program regarding the availability and safety of processes and treatments that eliminate or substantially reduce the level of pathogens on meat, meat food products, poultry, and poultry products.

**§ 30506. Expansion of Food Safety Inspection Service activities**

The Secretary may utilize existing authorities to give high priority to enhancing and expanding the capacity of

the Food Safety Inspection Service to conduct activities to—

(1) enhance the ability of the Service to inspect and ensure the safety and wholesomeness of meat and poultry products;

(2) improve the capacity of the Service to inspect international meat and meat products, poultry and poultry products, and egg products at points of origin and at ports of entry;

(3) strengthen the ability of the Service to collaborate with relevant agencies within the Department of Agriculture and with other entities in the Federal Government, the States, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e))) through the sharing of information and technology; and

(4) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

**§ 30507. Grants for improvements to meat and poultry facilities to allow for interstate shipment**

(a) IN GENERAL.—The Secretary shall make grants to meat and poultry slaughter and processing facilities described in subsection (b) (including the facilities operating

under State inspection or the facilities that are exempt from Federal inspection) to assist the facilities with respect to costs incurred in making improvements to the facilities and carrying out other planning activities necessary—

(1) to obtain a Federal grant of inspection under chapter 303 or 313 of this title, as applicable; or

(2) to operate as a State-inspected facility that is compliant with—

(A) chapter 303 of this title under the cooperative interstate shipment program established under section 30381 of this title; or

(B) chapter 313 of this title under the cooperative interstate shipment program established under section 31325 of this title.

(b) ELIGIBLE FACILITIES.—To be eligible for a grant under this section, a meat or poultry slaughter or processing facility shall be—

(1) in operation as of the date on which the facility submits to the Secretary an application for the grant; and

(2) seeking—

(A) to obtain a Federal grant of inspection described in subsection (a)(1); or

(B) to be eligible for inspection under a cooperative interstate shipment program described in subparagraph (A) or (B), as applicable, of subsection (a)(2), in a State that participates in that program.

(c) ELIGIBLE ACTIVITIES.—A facility that receives a grant under this section may use the grant amount for—

(1) the modernization or expansion of existing facilities;

(2) the modernization of equipment;

(3) compliance with packaging and labeling requirements under applicable law;

(4) compliance with safety requirements under applicable law;

(5) the development of processes to ensure food safety; and

(6) such other purposes as the Secretary determines to be appropriate.

(d) GRANT REQUIREMENTS.—

(1) AMOUNT.—The amount of a grant under this section shall not exceed $200,000.

(2) CONDITION.—As a condition of receiving a grant under this section, a grant recipient shall agree that the grant recipient shall make a payment (or payments) to the Secretary in an amount equal

to the amount of the grant if the recipient, within 36 months of receiving the grant—

(A) as applicable—

(i) is not subject to inspection under chapter 303 or 313 of this title, as applicable; or

(ii) is not eligible for inspection under a cooperative interstate shipment program described in subparagraph (A) or (B), as applicable, of subsection (a)(2); or

(B) is not making a good faith effort to be subject to the inspection or to be eligible under such a cooperative interstate shipment program, as applicable.

(3) MATCHING FUNDS.—The Secretary shall require a recipient of a grant under this section to provide matching non-Federal funds in an amount equal to the amount of the grant.

(e) REPORTS.—

(1) REPORTS ON GRANTS MADE.—Beginning not later than 1 year after the date on which the first grant is awarded under this section, and continuing annually thereafter through the year that is 10 years after the date on which the final grant is awarded under this section, the Secretary shall sub-

mit to the Committee on Agriculture and the Committee on Appropriations of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry and the Committee on Appropriations of the Senate a report on grants made under this section, including—

(A) any facilities that used a grant awarded under this section to carry out eligible activities described in subsection (c) during the year covered by the report; and

(B) the operational status of facilities that were awarded grants under this section.

(2) REPORT ON THE COOPERATIVE INTERSTATE SHIPMENT PROGRAM.—The Secretary shall submit to the Committee on Agriculture and the Committee on Appropriations of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry and the Committee on Appropriations of the Senate a report describing any recommendations, developed in consultation with all States, for possible improvements to the cooperative interstate shipment programs under sections 30381 and 31325 of this title.

(f) FUNDING.—Of the funds of the Treasury not otherwise appropriated, there is appropriated to carry out

this section $60,000,000 for the period of fiscal years 2021 through 2023, to remain available until expended.

# Chapter 307—Filled Milk

Sec.
30701. Definitions.
30702. Manufacture, shipment, or delivery for shipment in interstate or foreign commerce prohibited.
30703. Criminal penalties.
30704. Regulations for enforcement.

## § 30701. Definitions

In this chapter:

(1) FILLED MILK.—

(A) IN GENERAL.—The term ''filled milk'' means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated.

(B) EXCLUSIONS.—The term ''filled milk'' does not include any distinctive proprietary food compound not readily mistaken in taste for milk or cream or for evaporated, condensed, or powdered milk, or cream, if the compound—

(i) is prepared and designed for feeding infants and young children and customarily used on the order of a physician;

(ii) is packed in individual cans containing not more than 16½ ounces and bearing a label in bold type that the content is to be used only for feeding infants and young children; and

(iii) is shipped in interstate or foreign commerce exclusively to physicians, wholesale and retail druggists, orphan asylums, child-welfare associations, hospitals, and similar institutions and generally disposed of by those entities.

(2) INTERSTATE COMMERCE.—The term ''interstate or foreign commerce'' means commerce—

(A) between any State, territory (including a possession) of the United States, or the District of Columbia, and any place outside the State, territory of the United States, or the District of Columbia;

(B) between points within the same State or territory (including a possession) of the United States, or within the District of Columbia, but through any place outside of the State,

territory of the United States, or the District of Columbia; or

(C) within any territory (including a possession) of the United States or within the District of Columbia.

(3) PERSON.—The term ''person'' includes an individual, partnership, corporation, or association.

**§ 30702. Manufacture, shipment, or delivery for shipment in interstate or foreign commerce prohibited**

(a) ADULTERATION; FRAUD.—Filled milk is declared to be an adulterated article of food, injurious to the public health, and its sale is declared to constitute a fraud on the public.

(b) UNLAWFUL ACTS.—It shall be unlawful for any person to manufacture filled milk within any territory (including a possession) of the United States, or within the District of Columbia, or to ship or deliver filled milk for shipment in interstate or foreign commerce.

**§ 30703. Criminal penalties**

(a) IN GENERAL.—Any person violating any provision of this chapter shall, on conviction, be imprisoned not more than 1 year, fined under title 18, or both.

(b) ACTS OF AGENTS DEEMED ACTS OF PRINCIPALS.—When construing and enforcing the provisions of

this chapter, the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association, within the scope of the person's employment or office, shall be deemed the act, omission, or failure, of the individual, partnership, corporation, or association, as well as of the person.

### § 30704. Regulations for enforcement

The Secretary of Health and Human Services shall make and enforce the regulations as may, in the Secretary's judgment, be necessary to carry out this chapter.

# Chapter 309—Importation of Milk and Cream

Sec.
30901. Definitions.
30902. Prohibition of importation without permit.
30903. Milk or cream unfit for importation.
30904. Compliance; permits.
30905. Unlawful receiving of imported milk or cream.
30906. Criminal penalties.
30907. Authorization of appropriations.
30908. Repeal of inconsistent laws.
30909. Nonpreemption.

### § 30901. Definitions

In this chapter:

(1) PERSON.—The term ''person'' means an individual, partnership, association, or corporation.

(2) UNITED STATES.—The term ''United States'' means the 50 States and the District of Columbia.

**§ 30902. Prohibition of importation without permit**

The importation into the United States of milk and cream is prohibited unless the person by whom the milk or cream is shipped or transported into the United States holds a valid permit from the Secretary of Health and Human Services.

**§ 30903. Milk or cream unfit for importation**

Milk or cream is unfit for importation if—

(1) all cows producing the milk or cream are not healthy and a physical examination of all the cows has not been made within 1 year previous to the milk being offered for importation;

(2) the milk or cream, if raw, is not produced from cows that have passed a tuberculin test applied by an authorized official veterinarian of the United States, or of the country in which the milk or cream is produced, within 1 year previous to the time of the importation, showing that the cows are free from tuberculosis;

(3) the sanitary conditions of the dairy farm or plant in which the milk or cream is produced or handled do not score at least 50 points out of 100 points according to the methods for scoring as provided by the score cards used by the Secretary of Health and Human Services at the time the dairy farms or plants are scored;

(4)(A) in the case of raw milk, the number of bacteria per cubic centimeter exceeds 300,000;

(B) in the case of raw cream, the number of bacteria per cubic centimeter exceeds 750,000;

(C) in the case of pasteurized milk, the number of bacteria per cubic centimeter exceeds 100,000; or

(D) in the case of pasteurized cream, the number of bacteria per cubic centimeter exceeds 500,000; or

(5) the temperature of milk or cream at the time of importation exceeds 50 degrees Fahrenheit.

**§ 30904. Compliance; permits**

(a) IN GENERAL.—

(1) INSPECTIONS.—The Secretary of Health and Human Services shall cause such inspections to be made as are necessary to ensure that milk and cream are produced and handled so as to comply with the provisions of section 30903 of this title.

(2) PERMITS.—In all cases in which the Secretary of Health and Human Services finds that milk or cream is produced and handled so as not to be unfit for importation under paragraphs (1), (2), and (3) of section 30903 of this title, the Secretary of Health and Human Services shall issue to persons

applying for importation permits to ship milk or cream into the United States.

(3) AUTHORITY TO ACCEPT STATEMENT IN LIEU OF INSPECTION.—In lieu of inspections under this subsection, the Secretary of Health and Human Services may accept a certified statement signed by an accredited official of an authorized department of any foreign government or of any State of the United States or any municipality of the foreign government or the State that the provisions in paragraphs (1), (2), and (3) of section 30903 of this title have been complied with.

(4) FORM OF CERTIFIED STATEMENTS; REGULATIONS.—The certified statement under paragraph (3) of the accredited official of an authorized department of any foreign government shall be in the form prescribed by the Secretary of Health and Human Services, who shall prescribe the form and the rules and regulations regulating the issuance of permits to import milk or cream into the United States.

(b) WAIVER OF CERTAIN REQUIREMENTS.—

(1) PARAGRAPH (4) OF SECTION 30903.—

(A) IN GENERAL.—The Secretary of Health and Human Services may, in the discretion of the Secretary of Health and Human

Services, waive the requirement of paragraph (4) of section 30903 of this title when issuing permits to operators of condenseries in which milk or cream is used if sterilization of the milk or cream is a necessary process.

(B) LIMITATION.—Notwithstanding subparagraph (A), milk or cream shall not be imported if the bacterial count of the milk or cream exceeds 1,200,000 per cubic centimeter.

(C) DISTANCE REQUIREMENT.—Notwithstanding subparagraph (A), paragraph (4) of section 30903 of this title shall not be waived unless the farm producing the milk to be imported is within a radius of 15 miles of the condensery in which it is to be processed.

(D) REVOCATION OF PERMIT; CRIMINAL PENALTIES.—If milk or cream imported under a waiver authorized under this paragraph is sold, used, or disposed of in its raw state or otherwise than as condensed milk by any person, the permit shall be revoked and the importer shall be subject to fine, imprisonment, or other penalty prescribed by this chapter.

(2) PARAGRAPHS (2) AND (5) OF SECTION 30903.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall waive the requirements of paragraphs (2) and (5) of section 30903 of this title with regard to milk when issuing permits to operators of, or to producers for delivery to, creameries and condensing plants in the United States within 20 miles of the point of production of the milk, and which creameries and condensing plants import no raw milk except for pasteurization or condensing.

(B) REVOCATION OF PERMIT; CRIMINAL PENALTIES.—If milk imported under a waiver authorized under this paragraph is sold, used, or disposed of in its raw state, or otherwise than as pasteurized, condensed, or evaporated milk by any person, the permit shall be revoked and the importer shall be subject to fine, imprisonment, or other penalty prescribed by this chapter.

(c) REGULATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall make and enforce such regulations as may, in the judgment of the Secretary of

Health and Human Services, be necessary to carry out this chapter—

(A) for the handling of milk and cream; and

(B) for the inspection of milk, cream, cows, barns, and other facilities used in—

(i) the production and handling of milk or cream; and

(ii) the handling, keeping, transporting, and importing of milk or cream.

(2) INSPECTIONS; TEMPORARY PERMITS.—Unless and until the Secretary of Health and Human Services provides for inspections to ascertain that paragraphs (1), (2), and (3) of section 30903 of this title have been complied with, the Secretary of Health and Human Services shall issue temporary permits to any applicants for the temporary permits to ship or transport milk or cream into the United States.

(d) SUSPENSION OR REVOCATION OF PERMITS.—The Secretary of Health and Human Services may suspend or revoke any permit for the shipment of milk or cream into the United States if the Secretary of Health and Human Services finds that—

(1) the holder of the permit failed to comply with or violated this chapter or any of the regulations made under this chapter; or

(2) the milk or cream brought or shipped by the holder of the permit into the United States is not produced and handled in conformity with, or that the quality of the milk or cream does not conform to, all of the provisions of section 30903 of this title.

**§ 30905. Unlawful receiving of imported milk or cream**

It shall be unlawful for any person in the United States to receive milk or cream imported into the United States unless the importation is in accordance with this chapter.

**§ 30906. Criminal penalties**

Any person that knowingly violates this chapter shall, in addition to all other penalties prescribed by law, be imprisoned for not more than 1 year, fined under title 18 but not less than $50, or both.

**§ 30907. Authorization of appropriations**

There is authorized to be appropriated, out of amounts in the Treasury not otherwise appropriated, the sum of $50,000 annually, to enable the Secretary of Health and Human Services to carry out the provisions of this chapter.

**§ 30908. Repeal of inconsistent laws**

Any laws or parts of laws inconsistent with this chapter are repealed.

**§ 30909. Nonpreemption**

Nothing in this chapter is intended or shall be construed to affect the powers of any State, or any political subdivision of a State, to regulate the shipment of milk or cream into, or the handling, sale, or other disposition of milk or cream in, the State or political subdivision after the milk or cream has been lawfully imported under the provisions of this chapter.

# Chapter 311—Oleomargarine

Sec.
31101. Congressional declaration of policy regarding oleomargarine sales.
31102. Contravention of State laws.

**§ 31101. Congressional declaration of policy regarding oleomargarine sales**

(a) IN GENERAL.—Congress finds and declares that the sale, or the serving in public eating places, of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of subtitle I of this title—

(1) depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded; and

(2) constitutes a burden on interstate commerce in the articles.

(b) EXISTENCE OF BURDEN IRRESPECTIVE OF SOURCE.—The burden on interstate commerce exists, irrespective of whether the oleomargarine or margarine originates from an interstate source or from the State in which it is sold.

**§ 31102. Contravention of State laws**

Nothing in section 31101 of this title and the Act of March 16, 1950 (ch. 61, 64 Stat. 20) shall be construed as authorizing the possession, sale, or serving of colored oleomargarine or colored margarine in any State or territory of the United States in contravention of the laws of the State or territory of the United States.

# Chapter 313—Poultry and Poultry Products Inspection

Sec.
31301. Definitions.
31302. Congressional declaration of policy.
31303. Federal and State cooperation in development and administration of State poultry product inspection programs.
31304. Inspection in official establishments.
31305. Operation of premises, facilities, and equipment.
31306. Labeling and container standards.
31307. Prohibited acts.
31308. Compliance by all establishments.
31309. Miscellaneous activities subject to regulation.
31310. Offenses and punishment.
31311. Reporting of violations.
31312. Rules and regulations.
31313. Exemptions.
31314. Limitations on entry of poultry products and other materials into official establishments.
31315. Imports.
31316. Refusal or withdrawal of inspection services based on certain convictions.
31317. Administrative detention.

31318. Seizure and condemnation.
31319. Federal court jurisdiction.
31320. Other Federal laws applicable for administration and enforcement of chapter.
31321. State or local regulations.
31322. Applicability of subtitle I.
31323. Inspection and administration costs.
31324. Safe Meat and Poultry Inspection Panel.
31325. Interstate shipment of poultry inspected by Federal and State agencies for certain small establishments.

**§ 31301. Definitions**

In this chapter:

(1) ADULTERATED.—

(A) IN GENERAL.—The term ''adulterated'' shall apply to any poultry product under 1 or more of the following circumstances:

(i) It bears or contains any poisonous or deleterious substance that may render it injurious to health. In case the substance is not an added substance, the article shall not be considered adulterated under this clause if the quantity of the substance in or on the article does not ordinarily render it injurious to health.

(ii)(I) It bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or added deleterious substance (other than one that is a pesticide chemical in or on a raw agricultural commodity, a

food additive, or a color additive) that may, in the judgment of the Secretary, make the article unfit for human food.

(II) It is, in whole or in part, a raw agricultural commodity and the commodity bears or contains a pesticide chemical that is unsafe within the meaning of section 11110 of this title.

(III) It bears or contains any food additive that is unsafe within the meaning of section 11111 of this title.

(IV) It bears or contains any color additive that is unsafe within the meaning of section 17701 of this title.

(iii) It consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.

(iv) It has been prepared, packed, or held under insanitary conditions by which it may have become contaminated with filth, or by which it may have been rendered injurious to health.

(v) It is, in whole or in part, the product of any poultry that has died otherwise than by slaughter.

(vi) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

(vii) It has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 11111 of this title.

(viii)(I) Any valuable constituent of the article has been in whole or in part omitted or abstracted from the article.

(II) Any substance has been substituted, wholly or in part, for the article

(III) Damage or inferiority of the article has been concealed in any manner.

(IV) Any substance has been added to the article or mixed or packed with the article so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(B) PESTICIDE CHEMICAL, FOOD ADDITIVE, COLOR ADDITIVE PROHIBITED BY REGULATION.—An article that is not otherwise deemed adulterated under subclause (II), (III), or (IV) of subparagraph (A)(ii) shall be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on the article is prohibited by regulations of the Secretary in official establishments.

(2) ANIMAL FOOD MANUFACTURER.—The term ''animal food manufacturer'' means any person engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of poultry.

(3) CAPABLE OF USE AS HUMAN FOOD.—The term ''capable of use as human food'' shall apply to any carcass, or part or product of a carcass, of any poultry, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.

(4) COLOR ADDITIVE.—The term ''color additive'' has the meaning given the term in section 10101 of this title.

(5) COMMERCE.—The term ''commerce'' means commerce—

(A) between any State, any territory of the United States, or the District of Columbia, and any place outside the State or territory of the United States, or the District of Columbia; or

(B) within any territory of the United States not organized with a legislative body, or the District of Columbia.

(6) CONTAINER.—The term ''container'' includes any box, can, tin, cloth, plastic, or other receptacle, wrapper, or cover.

(7) FOOD ADDITIVE.—The term ''food additive'' has the meaning given the term in section 10101 of this title.

(8) IMMEDIATE CONTAINER.—The term ''immediate container'' includes—

(A) any consumer package; and

(B) any other container in which poultry products, not consumer packaged, are packed.

(9) INSPECTION SERVICE.—The term ''inspection service'' means the official Government service within the Department of Agriculture designated by the Secretary as having the responsibility for carrying out the provisions of this chapter.

(10) INSPECTOR.—The term ''inspector'' means—

(A) an employee or official of the Federal Government authorized by the Secretary to inspect poultry and poultry products under the authority of this chapter; or

(B) any employee or official of the government of any State, territory of the United States, or the District of Columbia authorized by the Secretary to inspect poultry and poultry products under this chapter, under an agreement entered into between the Secretary and the appropriate State or other agency.

(11) LABEL.—The term ''label'' means a display of written, printed, or graphic matter on any article or the immediate container (not including packaged liners) of any article.

(12) LABELING.—The term ''labeling'' means all labels and other written, printed, or graphic matter—

(A) on any article or any of its containers or wrappers; or

(B) accompanying the article.

(13) MISBRANDED.—

(A) IN GENERAL.—The term ''misbranded'' shall apply to any poultry product under 1 or more of the following circumstances:

(i) Its labeling is false or misleading in any particular.

(ii) It is offered for sale under the name of another food.

(iii) It is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately after that word, the name of the food imitated.

(iv) Its container is made, formed, or filled so as to be misleading.

(v) Unless it bears a label showing—

(I) the name and the place of business of the manufacturer, packer, or distributor; and

(II) an accurate statement of the quantity of the product in terms of weight, measure, or numerical count.

(vi) Any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed on

the label or labeling with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(vii) It purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 31306 of this title unless—

(I) it conforms to the definition and standard; and

(II) its label bears the name of the food specified in the definition and standard and, to the extent that may be required by the regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in the food.

(viii) It purports to be or is represented as a food for which a standard or standards of fill of container have been

prescribed by regulations of the Secretary under section 31306 of this title, and it falls below the standard of fill of container applicable to the food, unless its label bears, in such manner and form as the regulations specify, a statement that it falls below the standard.

(ix) It is not subject to the provisions of clause (vii), unless its label bears—

(I) the common or usual name of the food, if any; and

(II) in case it is fabricated from 2 or more ingredients, the common or usual name of each ingredient, except that spices, flavorings, and colorings may, if authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each.

(x) It purports to be or is represented for special dietary uses unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations

prescribes as, necessary in order fully to inform purchasers as to its value for those uses.

(xi) It bears or contains any artificial flavoring, artificial coloring, or chemical preservative unless it bears labeling stating that fact.

(xii) It fails to bear on its containers, and in the case of nonconsumer packaged carcasses (if the Secretary requires), directly on the nonconsumer packaged carcasses, as the Secretary may by regulations prescribe, the official inspection legend and official establishment number of the establishment where the article was processed, and, unrestricted by any of the foregoing, such other information as the Secretary may require in the regulations to ensure that the article will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

(B) SMALL PACKAGES AND ARTICLES NOT IN PACKAGES AND CONTAINERS.—Under sub-

paragraph (A)(v)(II), reasonable variations may be permitted, and exemptions as to small packages or articles not in packages or other containers may be established, by regulations prescribed by the Secretary.

(C) COMPLIANCE WITH CERTAIN LABELING REQUIREMENTS IMPRACTICABLE OR RESULTS IN DECEPTION OR UNFAIR COMPETITION.—To the extent that compliance with the requirements of subparagraph (A)(ix)(II) is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(D) ARTIFICIAL FLAVORINGS, ARTIFICIAL COLORINGS, AND CHEMICAL PRESERVATIVES.—To the extent that compliance with the requirements of subparagraph (A)(xi) is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(14) OFFICIAL CERTIFICATE.—The term ''official certificate'' means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(15) OFFICIAL DEVICE.—The term ''official device'' means any device prescribed or authorized by the Secretary for use in applying any official mark.

(16) OFFICIAL ESTABLISHMENT.—The term ''official establishment'' means any establishment as determined by the Secretary at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained under the authority of this chapter.

(17) OFFICIAL INSPECTION LEGEND.—The term ''official inspection legend'' means any symbol prescribed by regulations of the Secretary showing that an article was inspected for wholesomeness in accordance with this chapter.

(18) OFFICIAL MARK.—The term ''official mark'' means the official inspection legend or any other symbol prescribed by regulation of the Secretary to identify the status of any article or poultry under this chapter.

(19) PACKAGE.—The term package'' includes any box, can, tin, cloth, plastic, or other receptacle, wrapper, or cover.

(20) PERSON.—The term ''person'' means any individual, partnership, corporation, association, or other business unit.

(21) PESTICIDE CHEMICAL.—The term ''pesticide chemical'' has the meaning given the term in section 10101 of this title.

(22) POULTRY.—The term ''poultry'' means any domesticated bird, whether live or dead.

(23) POULTRY PRODUCT.—

(A) IN GENERAL.—The term ''poultry product'' means—

(i) any poultry carcass, or part of a poultry carcass; or

(ii) any product that is made wholly or in part from any poultry carcass or part of a poultry carcass.

(B) EXCLUSIONS.—The term ''poultry product'' does not include a product—

(i) that contains poultry ingredients only in a relatively small proportion or historically has not been considered by consumers as a product of the poultry food industry; and

(ii) that is exempted by the Secretary from definition as a poultry product under such conditions as the Secretary may prescribe to ensure that the poultry ingredients in the product are not adulterated and

that the product is not represented as a poultry product.

(24) POULTRY PRODUCTS BROKER.—The term ''poultry products broker'' means any person engaged in the business of buying or selling poultry products on commission, or otherwise negotiating purchases or sales of the articles other than for the person's own account or as an employee of another person.

(25) PROCESSED.—The term ''processed'' means slaughtered, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed.

(26) RAW AGRICULTURAL COMMODITY.—The term ''raw agricultural commodity'' has the meaning given the term in section 10101 of this title.

(27) RENDERER.—The term ''renderer'' means any person engaged in the business of rendering carcasses, or parts or products of the carcasses, of poultry, except rendering conducted under inspection or exemption under this chapter.

(28) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture or a delegate of the Secretary of Agriculture.

(29) SHIPPING CONTAINER.—The term ''shipping container'' means any container used or intended for use in packaging the product packed in an immediate container.

(30) STATE.—Except as otherwise provided in this chapter, the term ''State'' means any State of the United States or Puerto Rico.

(31) TERRITORY OF THE UNITED STATES.—The term ''territory of the United States'' means Guam, American Samoa, the Virgin Islands, or any other territory (including a possession) of the United States.

(32) UNITED STATES.—The term ''United States'' means the States, the District of Columbia, and the territories of the United States.

**§ 31302. Congressional declaration of policy**

(a) POLICY.—It is the policy of Congress to provide for the inspection of poultry and poultry products and otherwise regulate the processing and distribution of the articles as prescribed in this chapter to prevent the movement or sale in interstate or foreign commerce of, or the burdening of interstate or foreign commerce by, poultry products that are adulterated or misbranded.

(b) INTENT.—It is the intent of Congress that when poultry and poultry products are condemned because of

disease, the reason for condemnation in those instances shall be supported by scientific fact, information, or criteria, and the condemnation under this chapter shall be achieved through uniform inspection standards and uniform applications of the standards.

**§ 31303. Federal and State cooperation in development and administration of State poultry product inspection programs**

(a) DEFINITION OF STATE.—In this section, the term ''State'' means any State, Puerto Rico, or organized territory of the United States.

(b) AUTHORITIES OF THE SECRETARY TO COOPERATE.—It is the policy of Congress to protect the consuming public from poultry products that are adulterated or misbranded and to assist in efforts by State and other government agencies to accomplish this objective. In furtherance of this policy, the following are authorized:

(1) DEVELOPMENT AND ADMINISTRATION OF A STATE POULTRY PRODUCT INSPECTION PROGRAM.—The Secretary may, if the Secretary determines that it would effectuate the purposes of this chapter, cooperate with the appropriate State agency in developing and administering a State poultry product inspection program in any State that has enacted a mandatory State poultry product inspection law that

imposes ante mortem and post mortem inspection, reinspection, and sanitation requirements that are at least equal to those under this chapter, with respect to all or certain classes of persons engaged in the State in slaughtering poultry or processing poultry products for use as human food solely for distribution within the State.

(2) COOPERATION WITH STATE AND FEDERAL AGENCIES.—

(A) IN GENERAL.—The Secretary may, if the Secretary determines that it would effectuate the purposes of this chapter—

(i) cooperate with appropriate State agencies in developing and administering State programs under State laws containing authorities at least equal to those provided in section 31309 of this title; and

(ii) cooperate with other agencies of the United States in carrying out any provisions of this chapter.

(B) EXAMINATIONS, INVESTIGATIONS, AND INSPECTIONS.—In carrying out the provisions of this chapter, the Secretary may conduct such examinations, investigations, and inspections as the Secretary determines practicable through

any officer or employee of any State, territory of the United States, or the District of Columbia commissioned by the Secretary for that purpose.

(3) ASSISTANCE PROVIDED IN COOPERATION WITH STATE AGENCIES.—

(A) IN GENERAL.—Cooperation with State agencies under this section may include furnishing to the appropriate State agency—

(i) advisory assistance in planning and otherwise developing an adequate State program under the State law; and

(ii) technical and laboratory assistance and training (including necessary curricular and instructional materials and equipment), and financial and other aid for administration of such a program.

(B) FEDERAL CONTRIBUTION AMOUNT.—

(i) IN GENERAL.—The amount to be contributed to any State by the Secretary under this section from Federal funds for any year shall not exceed 50 percent of the estimated total cost of the cooperative program.

(ii) EQUITABLE ALLOCATION.—The Federal funds under clause (i) shall be allocated among the States desiring to cooperate on an equitable basis.

(C) CONDITION RELATING TO ADEQUACY OF ADMINISTRATION.—The cooperation and payment under this paragraph shall be contingent at all times on the administration of the State program in a manner which the Secretary, in consultation with the appropriate advisory committee appointed under paragraph (4), considers adequate to effectuate the purposes of this section.

(4) APPOINTMENT OF ADVISORY COMMITTEES.—The Secretary may appoint advisory committees consisting of such representatives of appropriate State agencies as the Secretary and the State agencies may designate to consult with the Secretary concerning State and Federal programs with respect to poultry product inspection and other matters within the scope of this chapter, including evaluating State programs for purposes of this chapter, and obtaining better coordination and more uniformity among the State programs and between the Federal

and State programs and adequate protection of consumers.

(c) APPROPRIATE STATE AGENCY.—

(1) IN GENERAL.—The appropriate State agency with which the Secretary may cooperate under this chapter shall be a single agency in the State that is primarily responsible for the coordination of the State programs having objectives similar to those under this chapter.

(2) PERFORMANCE BY SUBORDINATE GOVERNMENTAL UNIT OF STATE.—If a State program described in paragraph (1) includes performance of certain functions by a municipality or other subordinate governmental unit, the unit shall be deemed to be a part of the State agency for purposes of this section.

(d) INTRASTATE ACTIVITIES.—

(1) DESIGNATED STATES.—

(A) NOTIFICATION.—If the Secretary has reason to believe that a State has failed to develop, or is not enforcing, with respect to all establishments within its jurisdiction (except those that would be exempted from Federal inspection under paragraph (2)) at which poultry are slaughtered, or poultry products are proc-

essed for use as human food, solely for distribution within the State, and the products of the establishments, requirements at least equal to those imposed under sections 31301, 31302, 31304, 31305, 31306, 31307, 31308, 31310, 31311, 31312, 31313, 31314, 31315, 31316, 31317, 31318, 31319, and 31320 of this title, the Secretary shall promptly notify the Governor of the State of this fact.

(B) SECTIONS OF THIS CHAPTER APPLICABLE TO DESIGNATED STATES.—If the Secretary determines, after consultation with the Governor of the State, or representative selected by the Governor, that the requirements have not been developed and activated, the Secretary shall promptly designate the State as one in which the provisions of the sections referred to in subparagraph (A) shall apply to operations and transactions wholly within the State.

(C) PUBLICATION OF DESIGNATION.—The Secretary shall publish any designation under this paragraph in the Federal Register and, on the expiration of 30 days after the publication, the provisions of the sections referred to in subparagraph (A) shall apply to operations and

transactions and to persons engaged in the operations and transactions in the State to the same extent and in the same manner as if the operations and transactions were conducted in or for commerce.

(D) ADULTERATED POULTRY PRODUCTS BEING DISTRIBUTED WITHIN A STATE.—

(i) NOTIFICATION OF GOVERNOR BY SECRETARY.—Notwithstanding any other provision of this section, if the Secretary determines that any establishment within a State is producing adulterated poultry products for distribution in the State that would clearly endanger the public health, the Secretary shall notify the Governor of the State and the appropriate advisory committee provided for by subsection (b)(4) of the fact for effective action under State or local law.

(ii) NO STATE ACTION TAKEN.—If the State does not take action to prevent the endangering of the public health described in clause (i) within a reasonable time after the notice, as determined by the Secretary, in light of the risk to public health, the

Secretary may immediately designate the establishment described in clause (i) as subject to the provisions of the sections referred to in subparagraph (A), and on the designation, the establishment and operator of the establishment shall be subject to the provisions as though engaged in commerce until such time as the Secretary determines that the State has developed and will enforce requirements at least equal to those imposed under the sections.

(2) RETAIL ESTABLISHMENTS AND RESTAURANTS.—

(A) IN GENERAL.—The provisions of this chapter requiring inspection of the slaughter of poultry and the processing of poultry products shall not apply to operations of types traditionally and usually conducted at retail stores and restaurants, if conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of the articles to consumers at the establishments if the establishments are subject to the inspection provisions only under this subsection.

(B) OPERATIONS AT A RESTAURANT CENTRAL KITCHEN.—

(i) IN GENERAL.—For the purposes of this paragraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares poultry products that are ready to eat when they leave the facility and are served in meals or as entrees only to customers at restaurants owned or operated by the same person owning or operating the facility.

(ii) APPLICABILITY OF PROVISION.—The facility described in clause (i) shall be subject to the provisions of section 31309(b) of this title.

(iii) INSPECTIONS.—The facility described in clause (i) may be subject to the inspection requirements of this chapter for as long as the Secretary considers necessary, if the Secretary determines that the sanitary conditions or practices of the facility or the processing procedures or meth-

ods at the facility are such that any of its poultry products are rendered adulterated.

(3) TERMINATION; REDESIGNATION.—

(A) TERMINATION OF DESIGNATION.—If the Secretary determines that any State designated under this subsection has developed and will enforce State poultry products inspection requirements at least equal to those imposed under the sections referred to in paragraph (1)(A), with respect to the operations and transactions within the State that are regulated under paragraph (1), the Secretary shall terminate the designation of the State under this subsection.

(B) REDESIGNATION.—The termination under subparagraph (A) shall not preclude the subsequent redesignation of the State at any time on 30 days' notice to the Governor and publication in the Federal Register in accordance with this subsection, and any State may be designated on the notice and publication, at any time after the period specified in this subsection whether the State has previously been designated, on the Secretary determining that it is not effectively enforcing requirements at least

equal to those imposed under the sections referred to in paragraph (1)(A).

(4) ANNUAL REVIEW AND REPORT.—The Secretary shall periodically, but at least annually, review the requirements, including the enforcement of the requirements, of the States not designated under this subsection, with respect to the slaughter, and the processing, storage, handling, and distribution of poultry products, and inspection of the operations.

**§ 31304. Inspection in official establishments**

(a) ANTE MORTEM INSPECTION.—For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any poultry product that is capable of use as human food and is adulterated, the Secretary shall conduct (if and to the extent considered by the Secretary necessary), through inspectors, ante mortem inspection of poultry in each official establishment processing poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

(b) POST MORTEM INSPECTION.—The Secretary, whenever processing operations are being conducted, shall conduct—

(1) through inspectors, post mortem inspection of the carcass of each bird processed; and

(2) at any time, as the Secretary considers necessary, such quarantine, segregation, and reinspection of poultry and poultry products capable of use as human food in each official establishment processing the poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

(c) CONDEMNATION.—

(1) IN GENERAL.—All poultry carcasses and parts of the carcasses and other poultry products found to be adulterated shall be condemned and shall, if no appeal is taken from the determination of condemnation, be destroyed for human food purposes under the supervision of an inspector.

(2) REPROCESSING.—Carcasses, parts, and products, which may by reprocessing be made not adulterated, need not be condemned and destroyed as described in paragraph (1) if so reprocessed under the supervision of an inspector and, after the reprocessing, found to be not adulterated.

(3) APPEALS.—

(A) IN GENERAL.—If an appeal is taken from the determination of condemnation, the carcasses, parts, or products shall be appropriately marked and segregated pending com-

pletion of an appeal inspection, which appeal shall be at the cost of the appellant if the Secretary determines that the appeal is frivolous.

(B) DETERMINATION OF CONDEMNATION SUSTAINED.—If the determination of condemnation is sustained, the carcasses, parts, and products shall be destroyed for human food purposes under the supervision of an inspector.

**§ 31305. Operation of premises, facilities, and equipment**

(a) SANITARY PRACTICES.—Each official establishment slaughtering poultry or processing poultry products for commerce or otherwise subject to inspection under this chapter shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purpose of preventing the entry into or flow or movement in commerce, or a burdensome effect on commerce, of poultry products that are adulterated.

(b) REFUSAL OF INSPECTION.—The Secretary shall refuse to render inspection to any establishment whose premises, facilities, or equipment, or the operation thereof, fail to meet the requirements of this section.

**§ 31306. Labeling and container standards**

(a) REQUIREMENTS FOR SHIPPING CONTAINERS AND IMMEDIATE CONTAINERS.—

(1) IN GENERAL.—All poultry products inspected at any official establishment under this chapter and found to be not adulterated, shall, at the time they leave the establishment, bear, in distinctly legible form, on their shipping containers and immediate containers as the Secretary may require, the information required under section 31301(13) of this title.

(2) NONCONSUMER PACKAGED CARCASSES.—In addition to paragraph (1), the Secretary, if the Secretary determines that the action is practicable and necessary for the protection of the public, may require nonconsumer packaged carcasses at the time they leave the establishment to bear directly on the nonconsumer packaged carcasses in distinctly legible form any information required under section 31301(13) of this title.

(b) LABELING REQUIREMENTS.—

(1) IN GENERAL.—The Secretary, if the Secretary determines that the action is necessary for the protection of the public, may prescribe—

(A) the styles and sizes of type to be used with respect to material required to be incor-

porated in labeling to avoid false or misleading labeling in marking and labeling any articles or poultry subject to this chapter; and

(B) definitions and standards of identity or composition for articles subject to this chapter and standards of fill of container for the articles not inconsistent with any such standards established under subtitle I of this title.

(2) CONSULTATIONS.—

(A) SECRETARY OF HEALTH AND HUMAN SERVICES.—The Secretary and the Secretary of Health and Human Services shall consult prior to the issuance of the standards under this chapter or subtitle I of this title relating to articles subject to this chapter to avoid inconsistency in the standards and possible impairment of the coordinated effective administration of this chapter and subtitle I of this title.

(B) ADVISORY COMMITTEES.—The Secretary and an appropriate advisory committee provided for in section 31303 of this title shall consult, prior to the issuance of the standards under this chapter, to avoid, to the extent feasible, inconsistency between Federal and State standards.

(c) FALSE OR MISLEADING MARKING OR LABELING; MISLEADING FORM OR SIZE OF CONTAINER; USE OF TRADE NAMES.—An article subject to this chapter shall not be sold or offered for sale by any person in commerce, under any name or other marking or labeling that is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers that are not false or misleading and that are approved by the Secretary are permitted.

(d) WITHHOLDING USE OF FALSE OR MISLEADING MARK, LABELING, OR CONTAINER SIZE OR FORM.—

(1) IN GENERAL.—If the Secretary has reason to believe that any marking, labeling, or size or form of any container in use or proposed for use with respect to any article subject to this chapter is false or misleading in any particular, the Secretary may direct that the use be withheld unless the marking, labeling, or container is modified in such manner as the Secretary may prescribe so that it will not be false or misleading.

(2) HEARING REQUEST.—If the person using or proposing to use the marking, labeling, or container does not accept the determination of the Secretary, the person may request a hearing, but the use of the

marking, labeling, or container shall, if the Secretary directs, be withheld pending hearing and final determination by the Secretary.

(3) APPEALS.—

(A) IN GENERAL.—Any final determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of the final determination, the person adversely affected by the final determination appeals to the United States Court of Appeals for the circuit in which the person has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(B) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of section 204 of the Packers and Stockyards Act, 1921 (7 U.S.C. 194) shall be applicable to appeals taken under this section.

**§ 31307. Prohibited acts**

(a) IN GENERAL.—A person shall not—

(1) slaughter any poultry or process any poultry products that are capable of use as human food at any establishment processing any poultry or poultry products for commerce, except in compliance with the requirements of this chapter;

(2) sell, transport, offer for sale or transportation, or receive for transportation, in commerce—

(A) any poultry products that are capable of use as human food and are adulterated or misbranded at the time of the sale, transportation, offer for sale or transportation, or receipt for transportation; or

(B) any poultry products required to be inspected under this chapter unless they have been inspected and passed;

(3) do, with respect to any poultry products that are capable of use as human food, any act while they are being transported in commerce or held for sale after the transportation, which act is intended to cause or has the effect of causing the products to be adulterated or misbranded;

(4) sell, transport, offer for sale or transportation, or receive for transportation, in commerce or from an official establishment, any slaughtered poultry from which the blood, feathers, feet, head, or viscera have not been removed in accordance with regulations promulgated by the Secretary, except as may be authorized by regulations of the Secretary; or

(5) use to the person's own advantage, or reveal other than to the authorized representatives of the Federal Government or any State or other government in their official capacity, or as ordered by a court in any judicial proceedings, any information acquired under the authority of this chapter concerning any matter that is entitled to protection as a trade secret.

(b) MAKING OF DEVICES CONTAINING MARKS AND CERTIFICATES.—A brand manufacturer, printer, or other person shall not cast, print, lithograph, or otherwise make any device containing any official mark or simulation of an official mark, any label bearing any such mark or simulation, or any form of official certificate or simulation of an official certificate, except as authorized by the Secretary.

(c) FORGED OR COUNTERFEIT MARKS AND CERTIFICATES.—A person shall not —

(1) forge any official device, mark, or certificate;

(2) without authorization from the Secretary, use any official device, mark, or certificate, or simulation of an official device, mark, or certificate, or alter, detach, deface, or destroy any official device, mark, or certificate;

(3) contrary to the regulations prescribed by the Secretary, detach, deface, or destroy, or fail to use, any official device, mark, or certificate;

(4) knowingly possess, without promptly notifying the Secretary or the Secretary's representative—

(A) any official device or any counterfeit, simulated, forged, or improperly altered official certificate;

(B) any device or label bearing any counterfeit, simulated, forged, or improperly altered official mark; or

(C) any carcass of any poultry, or part or product of the carcass, bearing any counterfeit, simulated, forged, or improperly altered official mark;

(5) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary; or

(6) knowingly represent that any article has been inspected and passed, or exempted, under this chapter if, in fact, it has not been, respectively, so inspected and passed, or exempted.

**§ 31308. Compliance by all establishments**

(a) IN GENERAL.—An establishment processing poultry or poultry products for commerce otherwise subject to this chapter shall not process any poultry or poultry products except in compliance with this chapter.

(b) NOTIFICATION.—Any establishment subject to inspection under this chapter that believes, or has reason to believe, that an adulterated or misbranded poultry or poultry product received by or originating from the establishment has entered into commerce shall promptly notify the Secretary with regard to the type, amount, origin, and destination of the poultry or poultry product.

(c) PLANS AND REASSESSMENTS.—The Secretary shall require that each establishment subject to inspection under this chapter shall, at a minimum—

(1) prepare and maintain current procedures for the recall of all poultry or poultry products produced and shipped by the establishment;

(2) document each reassessment of the process control plans of the establishment; and

(3) on request, make the procedures and reassessed process control plans available to inspectors appointed by the Secretary for review and copying.

**§ 31309. Miscellaneous activities subject to regulation**

(a) ARTICLES NOT INTENDED FOR USE AS HUMAN FOOD.—

(1) INSPECTION.—Inspection shall not be provided under this chapter at any establishment for the slaughter of poultry or the processing of any carcasses or parts or products of poultry, which are not intended for use as human food, but the articles shall, prior to their offer for sale or transportation in commerce, unless naturally inedible by humans, be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food.

(2) SALE, PURCHASE, OR TRANSPORT.—A person shall not buy, sell, transport, or offer for sale or transportation, or receive for transportation, in commerce, or import, any poultry carcasses or parts or products of the carcasses that are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary or are naturally inedible by humans.

(b) RECORDKEEPING REQUIREMENTS; ACCESS TO PLACES OF BUSINESS.—

(1) REQUIREMENTS.—The classes of persons under paragraph (2)—

(A) shall, for such period of time as the Secretary may by regulations prescribe, not to exceed 2 years unless otherwise directed by the

Secretary for good cause shown, keep such records as are properly necessary for the effective enforcement of this chapter in order to ensure against adulterated or misbranded poultry products for the American consumer; and

(B) shall, at all reasonable times, on notice by an authorized representative of the Secretary, afford the representative access to their places of business and opportunity to examine the facilities, inventory, and records of inventory, to copy all the records, and to take reasonable samples of their inventory on payment of the fair market value for the samples.

(2) CLASSES OF PERSONS.—The classes of persons under this paragraph are the following:

(A) Any person that engages in the business of slaughtering any poultry or processing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food.

(B) Any person that engages in the business of buying or selling (as poultry products brokers, wholesalers or otherwise), or transporting, in commerce, storing in or for com-

merce, or importing any carcasses, or parts or products of carcasses, of any poultry.

(C) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting, in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.

(c) REGISTRATION OF BUSINESS.—Unless when required by regulations of the Secretary, a person has registered with the Secretary the person's name, and the address of each place of business at which, and all trade names under which, the person conducts the business, the person shall not—

(1) engage in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer;

(2) engage in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any poultry, whether intended for human food or other purposes;

(3) engage in business as a public warehouseman storing any articles described in paragraph (2) in or for commerce; or

(4) engage in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter.

(d) REGULATION OF TRANSACTIONS, TRANSPORTATION, OR IMPORTATION.—A person engaged in the business of buying, selling, or transporting in commerce, or importing, dead, dying, disabled, or diseased poultry, or any parts of the carcasses of any poultry that died otherwise than by slaughter, shall not buy, sell, transport, offer for sale or transportation, or receive for transportation, in commerce, or import, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, unless the transaction, transportation, or importation is made in accordance with such regulations as the Secretary may prescribe to ensure that the poultry, or the unwholesome parts or products of the poultry, will be prevented from being used for human food.

(e) FEDERAL PROVISIONS APPLICABLE TO STATE OR TERRITORIAL BUSINESS TRANSACTIONS OF A LOCAL NATURE AND NOT SUBJECT TO LOCAL AUTHORITY.—

(1) IN GENERAL.—The authority conferred on the Secretary by subsection (b), (c), or (d) with re-

spect to persons engaged in the specified kinds of business in or for commerce may be exercised with respect to persons engaged, in any State or organized territory of the United States, in those kinds of business but not in or for commerce, if the Secretary determines, after consultation with an appropriate advisory committee provided for in section 31303 of this title, that the State or territory of the United States does not have at least equal authority under its laws or the authority is not exercised in a manner to effectuate the purposes of this chapter, including the State or territory of the United States providing for the Secretary or the Secretary's representative being afforded access to the places of business and the facilities, inventories, and records of inventories, and the taking of reasonable samples, if the Secretary determines necessary in carrying out the Secretary's responsibilities under this chapter.

(2) TREATMENT OF BUSINESS AS IN OR FOR COMMERCE.—In a case described in paragraph (1), the provisions of subsection (b), (c), or (d), respectively, shall apply to the persons described in paragraph (1) to the same extent and in the same manner as if they were engaged in the business in or for

commerce and the transactions involved were in commerce.

**§ 31310. Offenses and punishment**

(a) PENALTIES.—

(1) IN GENERAL.—Any person that violates the provisions of section 31307, 31308, 31309, 31312, or 31315 of this title shall be imprisoned not more than 1 year, fined under title 18, or both.

(2) INTENT TO DEFRAUD.—If the violation described in paragraph (1) involves intent to defraud, or any distribution or attempted distribution of an article that is adulterated (except as defined in section 31301(1)(A)(viii) of this title), the person shall be imprisoned not more than 3 years, fined under title 18, or both.

(3) SCOPE OF LIABILITY.—In construing or enforcing the provisions of the sections referred to in paragraph (1), the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association within the scope of the person's employment or office shall be deemed the act, omission, or failure of the individual, partnership, corporation, or association, as well as of the person.

(b) PERSONS IMPEDING ENFORCEMENT.—

(1) IN GENERAL.—Any person that forcibly assaults, resists, opposes, impedes, intimidates, or interferes with any individual while engaged in or on account of the performance of the individual's official duties under this chapter shall be imprisoned not more than 3 years, fined under title 18, or both.

(2) USE OF DEADLY OR DANGEROUS WEAPON.—Any person that, in the commission of any act under paragraph (1), uses a deadly or dangerous weapon, shall be imprisoned not more than 10 years, fined under title 18, or both.

(3) MURDER.—A person that kills an individual while engaged in or on account of the performance of the individual's official duties under this chapter shall be punished as provided under sections 1111 and 1114 of title 18.

(c) LIABILITY OF CARRIER.—A carrier shall not be subject to the penalties of this chapter, other than the penalties for violation of section 31309 of this title, by reason of the carrier's receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of poultry or poultry products, owned by another person unless—

(1) the carrier has knowledge, or is in possession, of facts that would cause a reasonable person to believe that the poultry or poultry products—

(A) were not inspected or marked in accordance with this chapter; or

(B) were otherwise not eligible for transportation under this chapter; or

(2) the carrier refuses to furnish on request of a representative of the Secretary—

(A) the name and address of the person from whom the carrier received the poultry or poultry products; and

(B) copies of all documents, if any, pertaining to the delivery of the poultry or poultry products to the carrier.

**§ 31311. Reporting of violations**

(a) NOTICE AND OPPORTUNITY TO PRESENT VIEWS.—Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given reasonable notice of the alleged violation and opportunity to present the person's views orally or in writing with regard to the contemplated proceeding.

(b) EFFECT ON ISSUANCE OF WRITTEN NOTICE OR WARNING.—Nothing in this chapter shall be construed as requiring the Secretary to report for criminal prosecution violations of this chapter if the Secretary believes that the

public interest will be adequately served and compliance with the chapter obtained by a suitable written notice or warning.

**§ 31312. Rules and regulations**

(a) STORAGE AND HANDLING OF POULTRY PRODUCTS.—The Secretary may by regulations prescribe conditions under which poultry products capable of use as human food shall be stored or otherwise handled by any person engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, the articles, if the Secretary considers the action necessary to ensure that the articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited.

(b) OTHER NECESSARY RULES AND REGULATIONS.—The Secretary shall promulgate such other rules and regulations as are necessary to carry out this chapter.

(c) ORAL PRESENTATION OF VIEWS.—In applying the provisions of section 553(c) of title 5 to proposed rulemaking under this chapter, an opportunity for the oral presentation of views shall be accorded all interested persons.

**§ 31313. Exemptions**

(a) PERSONS EXEMPTED.—The Secretary shall, by regulation and under such conditions relating to sanitary

standards, practices, and procedures as the Secretary may prescribe, exempt from specific provisions of this chapter—

(1) retail dealers with respect to poultry products sold directly to consumers in individual retail stores, if the only processing operation performed by the retail dealers is the cutting up of poultry products on the premises in which the sales to consumers are made; and

(2) persons slaughtering, processing, or otherwise handling poultry or poultry products that have been or are to be processed as required by recognized religious dietary laws, to the extent that the Secretary determines necessary to avoid conflict with the requirements while still effectuating the purposes of this chapter.

(b) TERRITORIAL EXEMPTION.—The Secretary may, under such sanitary conditions as the Secretary may by regulations prescribe, exempt from the inspection requirements of this chapter the slaughter of poultry, and the processing of poultry products, by any person in any territory of the United States not organized with a legislative body, solely for distribution within the territory of the United States, if the Secretary determines that it is impracticable to provide the inspection within the limits of

funds appropriated for administration of this chapter and that the exemption will aid in the effective administration of this chapter.

(c) PERSONAL SLAUGHTERING; CUSTOM SLAUGHTERING.—

(1) IN GENERAL.—

(A) PERSONS EXEMPTED.—The Secretary shall, by regulation and under such conditions, including sanitary standards, practices, and procedures, as the Secretary may prescribe, exempt from specific provisions of this chapter—

(i) the slaughtering by any person of poultry of the person's own raising, and the processing by the person and transportation in commerce of the poultry products exclusively for use by the person and members of the person's household and the person's nonpaying guests and employees;

(ii) the custom slaughter by any person of poultry delivered by the owner of the poultry for the slaughter, and the processing by the slaughterer and transportation in commerce of the poultry products exclusively for use, in the household of the owner, by the owner and members of the

owner's household and the owner's non-paying guests and employees, except that the custom slaughterer shall not engage in the business of buying or selling any poultry products capable of use as human food;

(iii) the slaughtering of poultry and processing of poultry products in any State, territory of the United States, or the District of Columbia by any poultry producer on the poultry producer's own premises with respect to sound and healthy poultry raised on the poultry producer's premises and the distribution, by any person, of the poultry products derived from those operations, which distribution is solely within the jurisdiction of the State, territory of the United States, or the District of Columbia, if, in lieu of other labeling requirements, the poultry products are identified with the name and address of the poultry producer, and if they are not otherwise misbranded, and are sound, clean, and fit for human food when distributed; and

(iv) the slaughtering of sound and healthy poultry or the processing of poultry products of the poultry in any State, territory of the United States, or the District of Columbia by any poultry producer or other person for distribution by the poultry producer or other person, which distribution is solely within the jurisdiction of the State, territory of the United States, or the District of Columbia, and which distribution is made directly to household consumers, restaurants, hotels, and boarding houses, for use in their own dining rooms, or in the preparation of meals for sales direct to consumers, if, in lieu of other labeling requirements, the poultry products are identified with the name and address of the processor, and if they are not otherwise misbranded and are sound, clean, and fit for human food when distributed by the processor.

(B) INAPPLICABILITY OF CERTAIN EXEMPTIONS.—The exemptions provided for in clauses (iii) and (iv) of subparagraph (A) shall not apply if the poultry producer or other person

engages in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in those clauses.

(2) SMALL ENTERPRISES.—In addition to the specific exemptions provided under this subsection, the Secretary shall, if the Secretary determines that the protection of consumers from adulterated or misbranded poultry products will not be impaired by the action, provide by regulation, consistent with paragraph (3), for the exemption of the operation and products of small enterprises (including poultry producers), not exempted under paragraph (1), that are engaged in any State, territory of the United States, or the District of Columbia in slaughtering or cutting up poultry for distribution as carcasses or parts of carcasses solely for distribution within the jurisdiction of the State, territory of the United States, or the District of Columbia, from such provisions of this chapter as the Secretary considers appropriate, while still protecting the public from adulterated or misbranded products, under such conditions, including sanitary requirements, as the Secretary shall prescribe to effectuate the purposes of this chapter.

(3) INAPPLICABILITY OF CERTAIN EXEMPTIONS.—

(A) IN GENERAL.—An exemption under clause (iii) or (iv) of paragraph (1)(A), or paragraph (2), shall not apply to any poultry producer or other person that, in the current calendar year—

(i) slaughters or processes the products of more than 20,000 poultry; or

(ii) slaughters or processes the products of poultry at a facility used for slaughtering or processing of the products of poultry by any other poultry producer or person.

(B) EXEMPTION ON DETERMINATION BY SECRETARY.—Notwithstanding subparagraph (A)(ii), the Secretary may grant the exemption to any poultry producer or other person if the Secretary determines, on application of the poultry producer or other person, that granting the exemption will not impair effectuating the purposes of this chapter.

(4) INAPPLICABILITY OF CHAPTER.—The provisions of this chapter shall not apply to poultry pro-

ducers with respect to poultry of their own raising on their own farms if—

(A) the producers slaughter not more than 1,000 poultry during the calendar year for which this exemption is being determined;

(B) the poultry producers do not engage in buying or selling poultry products other than those produced from poultry raised on their own farms; and

(C) none of the poultry moves in commerce (as defined in section 31301 of this title).

(d) PIZZAS CONTAINING POULTRY PRODUCTS.—

(1) IN GENERAL.—Under such terms and conditions as the Secretary shall prescribe through rules and regulations issued under this section, which terms and conditions may be necessary to ensure food safety and protect public health, such as special handling procedures, the Secretary shall exempt pizzas containing a poultry product from the inspection requirements of this chapter if—

(A) the poultry product components of the pizzas have been prepared, inspected, and passed in a cured or cooked form as ready-to-eat in compliance with the requirements of this chapter; and

(B) the pizzas are to be served in public or private nonprofit institutions.

(2) WITHDRAWAL OR MODIFICATION OF EXEMPTION; REINSTATEMENT.—The Secretary may withdraw or modify any exemption under this subsection if the Secretary determines that the action is necessary to ensure food safety and to protect public health. The Secretary may reinstate or further modify any exemption withdrawn or modified under this subsection.

(e) APPLICABILITY OF ADULTERATION AND MISBRANDING PROVISIONS TO ARTICLES EXEMPTED FROM INSPECTION.—The adulteration and misbranding provisions of this chapter, other than the requirement of the inspection legend, shall apply to articles that are exempted from inspection under this section, except as otherwise specified under subsections (a) and (d).

(f) SUSPENSION OR TERMINATION OF EXEMPTION.—The Secretary may by order suspend or terminate any exemption under this section with respect to any person if the Secretary finds that the action will aid in effectuating the purposes of this chapter.

**§ 31314. Limitations on entry of poultry products and other materials into official establishments**

The Secretary may limit the entry of poultry products and other materials into any official establishment, under such conditions as the Secretary may prescribe to ensure that allowing the entry of the articles into the inspected establishments will be consistent with the purposes of this chapter.

**§ 31315. Imports**

(a) COMPLIANCE WITH STANDARDS AND REGULATIONS; STATUS AFTER IMPORTATION.—

(1) IN GENERAL.—Any slaughtered poultry, or parts or products of slaughtered poultry, of any kind shall not be imported into the United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient that renders them unhealthful, unwholesome, adulterated, or unfit for human food and unless they also comply with the rules and regulations made by the Secretary to ensure that imported poultry or poultry products comply with the standards provided for in this chapter.

(2) TREATMENT AS DOMESTIC SLAUGHTERED POULTRY.—All imported, slaughtered poultry, or parts or products of imported, slaughtered poultry,

shall, after entry into the United States in compliance with the rules and regulations described in paragraph (1), be deemed and treated as domestic, slaughtered poultry, or parts or products of domestic, slaughtered poultry, within the meaning and subject to the provisions of this chapter and subtitle I of this title and Acts amendatory of, supplemental to, or in substitution for this chapter or subtitle I of this title.

(b) RULES AND REGULATIONS; DESTRUCTION AND EXPORTATION OF REFUSED IMPORTS.—The Secretary may make rules and regulations to carry out this section, and in the rules and regulations, the Secretary may prescribe the terms and conditions for the destruction of all slaughtered poultry, or parts or products of slaughtered poultry, offered for entry and refused admission into the United States unless the slaughtered poultry, or parts or products of slaughtered poultry, are exported by the consignee within the time fixed for the exportation in the rules and regulations.

(c) STORAGE, CARTAGE, AND LABOR CHARGES FOR IMPORTS REFUSED ADMISSION.—All charges for storage, cartage, and labor with respect to any product that is refused admission pursuant to this section shall be paid by the owner or consignee, and in default of the payment

shall constitute a lien against any other products subsequently imported by or for the owner or consignee.

(d) EQUIVALENT STANDARDS.—

(1) DEFINITION OF SANITARY PROTECTION.—In this subsection, the term ''sanitary protection'' means protection to safeguard public health.

(2) IN GENERAL.—Notwithstanding any other provision of law, all poultry, or parts or products of poultry, capable of use as human food offered for importation into the United States shall—

(A) be subject to inspection, sanitary, quality, species verification, and residue standards that achieve a level of sanitary protection equivalent to that achieved under United States standards; and

(B) have been processed in facilities and under conditions that achieve a level of sanitary protection equivalent to that achieved under United States standards.

(3) EQUIVALENCE.—

(A) IN GENERAL.—The Secretary may treat as equivalent to a United States standard a standard of an exporting country described in paragraph (2) if the exporting country provides the Secretary with scientific evidence or other

information, in accordance with risk assessment methodologies determined appropriate by the Secretary, to demonstrate that the standard of the exporting country achieves the level of sanitary protection achieved under the United States standard.

(B) DETERMINATION OF NONEQUIVALENCE.—The Secretary may—

(i) determine, on a scientific basis, that the standard of the exporting country does not achieve the level of protection that the Secretary considers appropriate; and

(ii) provide the basis for the determination in writing to the exporting country on request.

(4) IMPORTED ARTICLES THAT DO NOT MEET STANDARDS.—Any imported poultry article under this subsection that does not meet the standards that achieve the level of sanitary protection equivalent to that achieved under United States standards shall not be permitted entry into the United States.

(5) ENFORCEMENT.—The Secretary shall enforce this subsection through—

(A) random inspections for the species verification and for residues; and

(B) random sampling and testing of internal organs and fat of carcasses for residues at the point of slaughter by the exporting country, in accordance with methods approved by the Secretary.

**§ 31316. Refusal or withdrawal of inspection services based on certain convictions**

(a) REFUSAL OR WITHDRAWAL.—

(1) IN GENERAL.—The Secretary may (for such period, or indefinitely, as the Secretary considers necessary to effectuate the purposes of this chapter) refuse to provide, or withdraw, inspection service under this chapter with respect to any establishment if the Secretary determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, the service, that the applicant or recipient is unfit to engage in any business requiring inspection under this chapter because the applicant or recipient or anyone responsibly connected with the applicant or recipient, has been convicted, in any Federal or State court, within the previous 10 years of—

(A) any felony or more than 1 misdemeanor under any law based on the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food or

fraud in connection with transactions in food; or

(B) any felony, involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health.

(2) RESPONSIBLY CONNECTED.—For the purpose of this subsection, a person shall be deemed to be responsibly connected with the business if the person was a partner, officer, director, holder, or owner of 10 percent or more of its voting stock, or employee in a managerial or executive capacity.

(b) HEARING TO DETERMINE VALIDITY OF WITHDRAWAL OR REFUSAL OF INSPECTION SERVICES.—On the withdrawal of inspection service from any official establishment for failure to destroy condemned poultry products as required under section 31304 of this title, or other failure of an official establishment to comply with the requirements as to premises, facilities, or equipment, or the operation of the premises, facilities, or equipment, as provided in section 31305 of this title, or the refusal of inspection service to any applicant for inspection service because of failure to comply with any requirements under section 31305 of this title, the applicant for, or recipient

of, the service shall, on request, be afforded opportunity for a hearing with respect to the merits or validity of the action, but the withdrawal or refusal shall continue in effect unless otherwise ordered by the Secretary.

(c) FINALITY AND CONCLUSIVENESS OF DETERMINATION.—

(1) IN GENERAL.—The determination and order of the Secretary when made after opportunity for hearing, with respect to withdrawal or refusal of inspection service under this chapter, shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within 30 days after the effective date of the order in the United States Court of Appeals as provided in section 31306 of this title.

(2) BASIS.—Judicial review of any order under paragraph (1) shall be based on the record on which the determination and order are based.

(3) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of section 204 of the Packers and Stockyards Act, 1921 (7 U.S.C. 194) shall be applicable to appeals taken under this section.

**§ 31317. Administrative detention**

(a) IN GENERAL.—If any poultry product, any product exempted from the definition of a poultry product, or

any dead, dying, disabled, or diseased poultry is found by any authorized representative of the Secretary on any premises in which it is held for purposes of, or during or after distribution in, commerce or otherwise subject to this chapter, and there is reason to believe that any such article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected, in violation of the provisions of this chapter or of any other Federal law or the laws of any State, territory of the United States, or the District of Columbia, or that it has been or is intended to be, distributed in violation of any such provisions, the article—

(1) may be detained by the representative for a period not to exceed 20 days, pending action under section 31318 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over the article or poultry; and

(2) shall not be moved by any person, from the place at which it is located when detained under paragraph (1), until released by the representative.

(b) MARKS.—All official marks may be required by the representative to be removed from the article or poultry before it is released unless it appears to the satisfaction of the Secretary that the article or poultry is eligible to retain the marks.

**§ 31318. Seizure and condemnation**

(a) PROCEEDINGS.—

(1) IN GENERAL.—

(A) SEIZURE AND CONDEMNATION.—Any poultry product or any dead, dying, disabled, or diseased poultry described in subparagraph (B) shall be liable to be proceeded against and seized and condemned, at any time, on a filing of an action in any United States district court or other proper court as provided in section 31319 of this title within the jurisdiction of which the article or poultry is found.

(B) POULTRY PRODUCT OR DEAD, DYING, DISABLED, OR DISEASED POULTRY.—Poultry products or dead, dying, disabled, or diseased poultry under this subparagraph are those that are being transported in commerce or otherwise subject to this chapter, or are held for sale in the United States after the transportation, and that—

(i) are or have been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of this chapter;

(ii) are capable of use as human food and are adulterated or misbranded; or

(iii) in any other way are in violation of this chapter.

(2) EFFECT OF CONDEMNATION.—

(A) IN GENERAL.—If the article or poultry is condemned, it shall, after entry of the decree—

(i) be distributed in accordance with paragraph (5); or

(ii) be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury, but the article or poultry shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold.

(B) BOND.—On the execution and delivery of a good and sufficient bond conditioned that the article or poultry shall not be sold or otherwise disposed of contrary to the provisions of this chapter, or the laws of the jurisdiction in which disposal is made, the court may direct that the article or poultry be delivered to the owner of the article subject to such supervision by authorized representatives of the Secretary

as is necessary to ensure compliance with the applicable laws.

(3) COSTS AND EXPENSES.—When a decree of condemnation is entered against the article or poultry and it is released under bond, or destroyed, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article or poultry.

(4) ADMIRALTY PROCEEDINGS; UNITED STATES AS NAMED PARTY.—The procedure for actions under this section shall conform, as nearly as may be, to the procedure in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such actions shall be brought by and in the name of the United States.

(5) DISTRIBUTION.—

(A) IN GENERAL.—An article that is condemned under paragraph (1) may as the court may direct, after entry of the decree, be distributed without charge to nonprofit, private entities or to Federal, State, or local government entities engaged in the distribution of food without charge to individuals, if the article—

(i) is capable of use as a human food;

(ii) has been inspected under this chapter and found to be wholesome and not to be adulterated within the meaning of clauses (i) through (vii) of section 31301(1)(A) of this title and a determination is made at the time of the entry of the decree that the article is wholesome and not so adulterated; and

(iii) is plainly marked ''Not for Sale'' on the article or its container.

(B) LEGAL RESPONSIBILITY OF THE UNITED STATES.—The United States may not be held legally responsible for any article that is distributed under subparagraph (A) to a nonprofit, private entity, or to a Federal, State, or local government entity, if the article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of clauses (i) through (vii) of section 31301(1)(A) of this title and a determination was made at the time of the entry of the decree that the article was wholesome and not so adulterated; and

(ii) was plainly marked ''Not for Sale'' on the article or its container.

(C) LEGAL RESPONSIBILITY OF PERSON FROM WHOM ARTICLE WAS SEIZED AND CONDEMNED.—The person from whom the article was seized and condemned may not be held legally responsible for the article, if the article—

(i) was found after inspection under this chapter to be wholesome and not adulterated within the meaning of clauses (i) through (vii) of section 31301(1)(A) of this title and a determination was made at the time of entry of the decree that the article was wholesome and not so adulterated; and

(ii) was plainly marked ''Not for Sale'' on the article or its container.

(b) CONDEMNATION OR SEIZURE UNDER OTHER PROVISIONS UNAFFECTED.—The provisions of this section shall not derogate from authority for condemnation or seizure conferred by other provisions of this chapter, or other laws.

**§ 31319. Federal court jurisdiction**

(a) IN GENERAL.—The United States district courts, the District Court of Guam, the District Court of the Virgin Islands, the highest court of American Samoa, and

the United States courts of the other territories of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other kinds of cases arising under this chapter, except as provided in section 31306(d) or 31316 of this title.

(b) UNITED STATES AS NAMED PARTY.—All proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States.

(c) SUBPOENAS.—Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

**§ 31320. Other Federal laws applicable for administration and enforcement of chapter**

(a) IN GENERAL.—For the efficient administration and enforcement of this chapter, the provisions (including penalties) of sections 6, 8, 9, and 10 of the Federal Trade Commission Act (15 U.S.C. 46, 48, 49, 50), except paragraphs (c) through (h) of section 6 of the Act (15 U.S.C. 46), are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person with respect to whom the authority is exercised.

(b) PROSECUTION OF INQUIRY.—The Secretary, in person or by such agents as the Secretary may designate, may prosecute any inquiry necessary to the Secretary's duties under this chapter in any part of the United States.

(c) AUTHORITY OF THE COURTS.—The powers conferred by sections 9 and 10 of the Federal Trade Commission Act (15 U.S.C. 49, 50) on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 31319 of this title.

**§ 31321. State or local regulations**

(a) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT REQUIREMENTS RELATING TO PREMISES, FACILITIES, AND OPERATIONS; AUTHORITY TO IMPOSE RECORDKEEPING REQUIREMENTS.—Requirements within the scope of this chapter with respect to premises, facilities, and operations of any official establishment that are in addition to, or different than those made under this chapter may not be imposed by any State, territory of the United States, or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 31309(b) of this title, if consistent with that provision, with respect to any such establishment.

(b) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT MARKING, LABELING, PACKAGING, OR INGREDIENT REQUIREMENTS.—

(1) IN GENERAL.—Marking, labeling, packaging, or ingredient requirements (or storage or handling requirements found by the Secretary to unduly interfere with the free flow of poultry products in commerce) in addition to, or different than, those made under this chapter may not be imposed by any State, territory of the United States, or the District of Columbia with respect to articles prepared at any official establishment in accordance with the requirements under this chapter.

(2) CONCURRENT JURISDICTION.—Any State, territory of the United States, or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under this chapter for the purpose of preventing the distribution for human food purposes of any such articles that are adulterated or misbranded and are outside of an official establishment. In the case of imported articles that are not at an official establishment, concurrent jurisdiction maybe be exercised after their entry into the United States.

(c) EFFECT OF CHAPTER.—This chapter shall not preclude any State, territory of the United States, or the District of Columbia from making requirements or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

**§ 31322. Applicability of subtitle I**

(a) EXEMPTION FROM APPLICABILITY.—Poultry and poultry products shall be exempt from the provisions of subtitle I of this title to the extent of the application or extension to the poultry or poultry products of the provisions of this chapter, except that the provisions of this chapter shall not derogate from any authority conferred by subtitle I of this title prior to August 18, 1968.

(b) APPLICABILITY OF DETAINER AUTHORITY TO REPRESENTATIVE OF SECRETARY OF HEALTH AND HUMAN SERVICES.—The detainer authority conferred by section 31317 of this title shall apply to any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of subtitle I of this title with respect to any poultry carcass, or part or product of a poultry carcass, that is outside any official establishment, and for those purposes, the first reference to the Secretary in section 31317 of this title shall be deemed to refer to the Secretary of Health and Human Services.

**§ 31323. Inspection and administration costs**

(a) DEFINITION OF HOLIDAY.—The term ''holiday'', for the purposes of assessment or reimbursement of the cost of inspection performed under this chapter, means the legal public holidays specified by Congress in section 6103(a) of title 5.

(b) OVERTIME AND HOLIDAY WORK COSTS.—The cost of inspection rendered under the requirements of this chapter shall be borne by the United States, except the cost of overtime and holiday pay paid pursuant to section 10703 of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 2219a).

**§ 31324. Safe Meat and Poultry Inspection Panel**

(a) REVIEW AND EVALUATION.—The advisory panel known as the Safe Meat and Poultry Inspection Panel established by section 30370 of this title shall review and evaluate, as the Panel considers necessary, the adequacy, necessity, safety, cost-effectiveness, and scientific merit of—

(1) inspection procedures of, and work rules and worker relations involving Federal employees employed in, plants inspected under this chapter;

(2) informal petitions or proposals for changes in inspection procedures, processes, and techniques of plants inspected under this chapter;

(3) formal changes in poultry inspection regulations promulgated under this chapter, whether in notice, proposed, or final form; and

(4) such other matters as may be referred to the Panel by the Secretary regarding the quality or effectiveness of a safe and cost-effective poultry inspection system under this chapter.

(b) REPORTS.—

(1) IN GENERAL.—The Safe Meat and Poultry Inspection Panel shall submit to the Secretary a report on the results of each review and evaluation carried out under subsection (a), including such recommendations as the Panel considers appropriate.

(2) REPORTS ON FORMAL CHANGES.—In the case of a report concerning a formal change in poultry inspection regulations, the report shall be made within the time limits prescribed for formal comments on the changes.

**§ 31325. Interstate shipment of poultry inspected by Federal and State agencies for certain small establishments**

(a) DEFINITIONS.—In this section:

(1) APPROPRIATE STATE AGENCY.—The term ''appropriate State agency'' means a State agency described in section 31303(b)(1) of this title.

(2) DESIGNATED PERSONNEL.—The term ''designated personnel'' means inspection personnel of a State agency who have undergone all necessary inspection training and certification to assist the Secretary in the administration and enforcement of this chapter, including rules and regulations issued under this chapter.

(3) ELIGIBLE ESTABLISHMENT.—The term ''eligible establishment'' means an establishment that is in compliance with—

(A) the State inspection program of the State in which the establishment is located; and

(B) this chapter, including rules and regulations issued under this chapter.

(4) POULTRY ITEM.—The term ''poultry item'' means—

(A) a portion of poultry; or

(B) a poultry product.

(5) SELECTED ESTABLISHMENT.—The term ''selected establishment'' means an eligible establishment that is selected by the Secretary, in coordination with the appropriate State agency of the State in which the eligible establishment is located, under subsection (b) to ship poultry items in interstate commerce.

(b) AUTHORITY OF SECRETARY TO ALLOW SHIPMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary, in coordination with the appropriate State agency of the State in which an establishment is located, may select the establishment to ship poultry items in interstate commerce, and place on each poultry item shipped in interstate commerce a Federal mark, stamp, tag, or label of inspection, if—

(A) the poultry item qualifies for the Federal mark, stamp, tag, or label of inspection under the requirements of this chapter;

(B) the establishment is an eligible establishment; and

(C) inspection services for the establishment are provided by designated personnel.

(2) PROHIBITED ESTABLISHMENTS.—In carrying out paragraph (1), the Secretary, in coordination with an appropriate State agency, shall not select an establishment that—

(A) on average, employs more than 25 employees (including supervisory and non-supervisory employees), as defined by the Secretary;

(B) as of June 18, 2008, ships in interstate commerce carcasses, portions of carcasses, or poultry items that are inspected by the Secretary in accordance with this chapter;

(C)(i) is a Federal establishment;

(ii) was a Federal establishment as of June 18, 2008, and was reorganized on a later date under the same name or a different name or person by the person, firm, or corporation that controlled the establishment as of June 18, 2008; or

(iii) was a State establishment as of June 18, 2008, that—

(I) as of June 18, 2008, employed more than 25 employees; and

(II) was reorganized on a later date by the person, firm, or corporation that controlled the establishment as of June 18, 2008;

(D) is in violation of this chapter;

(E) is located in a State that does not have a State inspection program; or

(F) is the subject of a transition carried out in accordance with a procedure developed by the Secretary under paragraph (3)(A).

(3) ESTABLISHMENTS THAT EMPLOY MORE THAN 25 EMPLOYEES.—

(A) DEVELOPMENT OF PROCEDURE.—The Secretary may develop a procedure to transition to a Federal establishment any establishment under this section that, on average, consistently employs more than 25 employees.

(B) ELIGIBILITY OF CERTAIN ESTABLISHMENTS.—

(i) IN GENERAL.—A State establishment that employs more than 25 employees but fewer than 35 employees as of June 18, 2008, may be selected as a selected establishment under this subsection.

(ii) PROCEDURES.—A State establishment shall be subject to the procedures established under subparagraph (A) beginning on the date that is 3 years after the effective date described in subsection (i).

(c) REIMBURSEMENT OF STATE COSTS.—The Secretary shall reimburse a State for costs related to the inspection of selected establishments in the State in accordance with Federal requirements in an amount of not less than 60 percent of eligible State costs.

(d) COORDINATION BETWEEN FEDERAL AND STATE AGENCIES.—

(1) IN GENERAL.—The Secretary shall designate an employee of the Federal Government as State coordinator for each appropriate State agency—

(A) to provide oversight and enforcement of this section; and

(B) to oversee the training and inspection activities of designated personnel of the State agency.

(2) SUPERVISION.—A State coordinator shall be under the direct supervision of the Secretary.

(3) DUTIES OF STATE COORDINATOR.—

(A) IN GENERAL.—A State coordinator shall visit selected establishments with a frequency that is appropriate to ensure that selected establishments are operating in a manner that is consistent with this chapter (including regulations and policies under this chapter).

(B) QUARTERLY REPORTS.—A State coordinator shall, on a quarterly basis, submit to the Secretary a report that describes the status of each selected establishment that is under the jurisdiction of the State coordinator with re-

spect to the level of compliance of each selected establishment with the requirements of this chapter.

(C) IMMEDIATE NOTIFICATION REQUIREMENT.—If a State coordinator determines that any selected establishment that is under the jurisdiction of the State coordinator is in violation of any requirement of this chapter, the State coordinator shall—

(i) immediately notify the Secretary of the violation; and

(ii) deselect the selected establishment or suspend inspection at the selected establishment.

(4) PERFORMANCE EVALUATIONS.—Performance evaluations of State coordinators designated under this subsection shall be conducted by the Secretary as part of the Federal agency management control system.

(e) AUDITS.—Not later than 2 years after the effective date described in subsection (i), and not less often than every 3 years thereafter, the Inspector General of the Department of Agriculture shall conduct an audit of each activity taken by the Secretary under this section for the

period covered by the audit to determine compliance with this section.

(f) TRANSITION GRANTS.—The Secretary may provide grants to appropriate State agencies to assist the appropriate State agencies in helping establishments covered by this chapter to transition to selected establishments.

(g) VIOLATIONS.—Any selected establishment that the Secretary determines to be in violation of any requirement of this chapter shall be transitioned to a Federal establishment in accordance with a procedure developed by the Secretary under subsection (b)(3)(A).

(h) EFFECT.—Nothing in this section limits the jurisdiction of the Secretary with respect to the regulation of poultry and poultry products under this chapter.

(i) EFFECTIVE DATE.—

(1) IN GENERAL.—This section takes effect on the date on which the Secretary, after providing a period of public comment (including through the conduct of public meetings or hearings), promulgates final regulations to carry out this section.

(2) REQUIREMENT.—The Secretary shall promulgate final regulations in accordance with paragraph (1).

# Chapter 315—Supplemental Poultry and Poultry Products Inspection Provisions

Sec.
31501. Applicability of chapter requirements to birds of the order Ratitae.

### § 31501. Applicability of chapter requirements to birds of the order Ratitae

Establishments in the United States that slaughter or process birds of the order Ratitae, such as ostriches, emus and rheas, and squab, for distribution in commerce as human food shall be subject to the ante mortem and post mortem inspection, reinspection, and sanitation requirements of chapter 313 of this title rather than the voluntary poultry inspection program of the Department of Agriculture under section 203 of the Agricultural Marketing Act of 1946 (7 U.S.C. 1622).

# Chapter 317—Egg Products Inspection

Sec.
31701. Definitions.
31702. Congressional statement of findings.
31703. Congressional declaration of policy.
31704. Inspection of egg products.
31705. Sanitary operating practices in official plants.
31706. Pasteurization and labeling of egg products at official plants.
31707. Prohibited acts.
31708. Cooperation with appropriate State and other governmental agencies.
31709. Eggs and egg products not intended for use as human food.
31710. Recordkeeping requirements.
31711. Enforcement provisions.
31712. Procedures prior to reporting to attorney general for institution of criminal proceeding.
31713. Rules and regulations.
31714. Exemption of certain activities.

31715. Limitation on entry of eggs and egg products and other materials into official plants.
31716. Imports.
31717. Refusal or withdrawal of inspection services.
31718. Detention of articles.
31719. Seizure and condemnation proceedings.
31720. Jurisdiction of district courts.
31721. Other Federal laws applicable for administration and enforcement of chapter.
31722. State or local regulation.
31723. Inspection and administration costs.
31724. Annual report to congressional committees.

**§ 31701. Definitions**

In this chapter:

(1) ADULTERATED.—

(A) IN GENERAL.—The term ''adulterated'' applies to any egg or egg product under 1 or more of the following circumstances:

(i) It bears or contains any poisonous or deleterious substance that may render it injurious to health. In case the substance is not an added substance, the article shall not be considered adulterated under this clause if the quantity of the substance in or on the article does not ordinarily render it injurious to health.

(ii)(I) It bears or contains any added poisonous or added deleterious substance (other than one that is a pesticide chemical in or on a raw agricultural commodity, a food additive, or a color additive) that

may, in the judgment of the Secretary, make the article unfit for human food.

(II) It is, in whole or in part, a raw agricultural commodity and the commodity bears or contains a pesticide chemical that is unsafe within the meaning of section 11110 of this title.

(III) It bears or contains any food additive that is unsafe within the meaning of section 11111 of this title.

(IV) It bears or contains any color additive that is unsafe within the meaning of section 17701 of this title.

(iii) It consists in whole or in part of any filthy, putrid, or decomposed substance, or it is otherwise unfit for human food.

(iv) It has been prepared, packaged, or held under insanitary conditions by which it may have become contaminated with filth, or by which it may have been rendered injurious to health.

(v) It is an egg that has been subjected to incubation or the product of any egg that has been subjected to incubation.

(vi) Its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

(vii) It has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 11111 of this title.

(viii)(I) Any valuable constituent of the article has been in whole or in part omitted or abstracted from the article.

(II) Any substance has been substituted, wholly or in part, for the article.

(III) Damage or inferiority of the article has been concealed in any manner.

(IV) Any substance has been added to the article or mixed or packed with the article so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(B) PESTICIDE CHEMICAL, FOOD ADDITIVE, COLOR ADDITIVE PROHIBITED BY REGULATION.—An article that is not otherwise

deemed adulterated under subclause (II), (III), or (IV) of subparagraph (A)(ii) shall be deemed adulterated if use of the pesticide chemical, food additive, or color additive, in or on the article, is prohibited by regulations of the Secretary in official plants.

(2) CAPABLE OF USE AS HUMAN FOOD.—The term ''capable of use as human food'' shall apply to any egg or egg product, unless it is denatured, or otherwise identified, as required by regulations prescribed by the Secretary to deter its use as human food.

(3) COLOR ADDITIVE.—The term ''color additive'' has the meaning given the term in section 10101 of this title.

(4) COMMERCE.—The term ''commerce'' means interstate, foreign, or intrastate commerce.

(5) CONTAINER.—The term ''container'' includes any box, can, tin, plastic, or other receptacle, wrapper, or cover.

(6) EGG.—

(A) IN GENERAL.—The term ''egg'' means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

(B) CHECK.—The term ''check'' means an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(C) CLEAN AND SOUND SHELL EGG.—The term ''clean and sound shell egg'' means any egg whose shell is free of adhering dirt or foreign material and is not cracked or broken.

(D) DIRTY EGG.—The term ''dirty egg'' means an egg that has a shell that is unbroken and has adhering dirt or foreign material.

(E) INCUBATOR REJECT.—The term ''incubator reject'' means an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(F) INEDIBLE.—The term ''inedible'' means eggs of the following descriptions: black rots, yellow rots, white rots, mixed rots (addled eggs), sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(G) LEAKER.—The term ''leaker'' means an egg that has a crack or break in the shell

and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(H) LOSS.—The term ''loss'' means an egg that is unfit for human food—

(i) because it is—

(I) smashed or broken so that its contents are leaking;

(II) overheated, frozen, or contaminated; or

(III) an incubator reject; or

(ii) because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

(I) RESTRICTED EGG.—The term ''restricted egg'' means any check, dirty egg, incubator reject, inedible, leaker, or loss.

(7) EGG HANDLER.—The term ''egg handler'' means any person that engages in any business in commerce that involves buying or selling any eggs (as a poultry producer or otherwise), processing any egg products, or otherwise using any eggs in the preparation of human food.

(8) EGG PRODUCT.—The term ''egg product'' means any dried, frozen, or liquid eggs, with or

without added ingredients, except products that contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and that may be exempted by the Secretary under such conditions as the Secretary may prescribe to ensure that the egg ingredients are not adulterated and the products are not represented as egg products.

(9) FAIR PACKAGING AND LABELING ACT.—The term ''Fair Packaging and Labeling Act'' means the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.) and Acts amendatory of or supplementary to the Fair Packaging and Labeling Act.

(10) FOOD ADDITIVE.—The term ''food additive'' has the meaning given the term in section 10101 of this title.

(11) IMMEDIATE CONTAINER.—The term ''immediate container'' means—

(A) any consumer package; or

(B) any other container in which egg products, not consumer packaged, are packed.

(12) INSPECTION.—The term ''inspection'' means the application of such inspection methods

and techniques as are considered necessary by the responsible Secretary to carry out this chapter.

(13) INSPECTOR.—The term ''inspector'' means—

(A) any employee or official of the Federal Government authorized to inspect eggs or egg products under the authority of this chapter; or

(B) any employee or official of the government of any State or local jurisdiction authorized by the Secretary to inspect eggs or egg products under the authority of this chapter, under an agreement entered into between the Secretary and the appropriate State or other agency.

(14) MISBRANDED.—The term ''misbranded'' shall apply to egg products that are not labeled and packaged in accordance with the requirements prescribed by regulations of the Secretary under section 31706 of this title.

(15) OFFICIAL CERTIFICATE.—The term ''official certificate'' means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(16) OFFICIAL DEVICE.—The term ''official device'' means any device prescribed or authorized by the Secretary for use in applying any official mark.

(17) OFFICIAL INSPECTION LEGEND.—The term ''official inspection legend'' means any symbol prescribed by regulations of the Secretary showing that egg products were inspected in accordance with this chapter.

(18) OFFICIAL MARK.—The term ''official mark'' means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article under this chapter.

(19) OFFICIAL PLANT.—The term ''official plant'' means any plant, as determined by the Secretary, at which inspection of the processing of egg products is maintained by the Department of Agriculture under the authority of this chapter.

(20) OFFICIAL STANDARDS.—The term ''official standards'' means the standards of quality, grades, and weight classes for eggs, in effect on the effective date of this chapter, or as amended under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.).

(21) PACKAGE.—The term ''package'' includes any box, can, tin, plastic, or other receptacle, wrapper, or cover.

(22) PASTEURIZE.—The term ''pasteurize'' means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable micro-organisms by such processes as may be prescribed by regulations of the Secretary.

(23) PERSON.—The term ''person'' means any individual, partnership, corporation, association, or other business unit.

(24) PESTICIDE CHEMICAL.—The term ''pesticide chemical,'' has the meaning given the term in section 10101 of this title.

(25) PLANT.—The term ''plant'' means any place of business in which egg products are processed.

(26) PROCESSING.—The term ''processing'' means manufacturing egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing, drying, or packaging egg products.

(27) RAW AGRICULTURAL COMMODITY.—The term ''raw agricultural commodity'' has the meaning given the term in section 10101 of this title.

(28) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture or the Secretary's delegate.

(29) SHIPPING CONTAINER.—The term ''shipping container'' means any container used in packaging a product packed in an immediate container.

(30) STATE.—The term ''State'' means any State, the District of Columbia, Puerto Rico, and the Virgin Islands.

(31) UNITED STATES.—The term ''United States'' means the States.

**§ 31702. Congressional statement of findings**

(a) IN GENERAL.—Congress finds the following:

(1) Eggs and egg products are an important source of the Nation's total supply of food, and are used in food in various forms.

(2) Eggs and egg products are consumed throughout the Nation and the major portion of eggs and egg products moves in interstate or foreign commerce.

(3) It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed in this chapter for ensuring that eggs and egg products distributed to them and used in products consumed by them are

wholesome, otherwise not adulterated, and properly labeled and packaged.

(4) Lack of effective regulation for the handling or disposition of unwholesome, otherwise adulterated, or improperly labeled or packaged egg products and certain qualities of eggs—

(A) is injurious to the public welfare;

(B) destroys markets for wholesome, not adulterated, and properly labeled and packaged eggs and egg products; and

(C) results in—

(i) sundry losses to producers and processors; and

(ii) injury to consumers.

(5) Unwholesome, otherwise adulterated, or improperly labeled or packaged products can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged products, to the detriment of consumers and the public generally.

(b) EGG PRODUCTS AND QUALITIES OF EGGS IN INTERSTATE AND FOREIGN COMMERCE.—Because of the findings in subsection (a), Congress finds—

(1) that all egg products and the qualities of eggs that are regulated under this chapter are either

in interstate or foreign commerce or substantially affect interstate or foreign commerce; and

(2) that regulation by the Secretary and the Secretary of Health and Human Services, and cooperation by the States and other jurisdictions, as contemplated by this chapter, are appropriate—

(A) to prevent and eliminate burdens on interstate and foreign commerce;

(B) to effectively regulate interstate and foreign commerce; and

(C) to protect the health and welfare of consumers.

**§ 31703. Congressional declaration of policy**

It is the policy of Congress to provide for the inspection of certain egg products, restrictions on the disposition of certain qualities of eggs, and uniformity of standards for eggs, and otherwise regulate the processing and distribution of eggs and egg products as prescribed in this chapter to prevent the movement or sale for human food of eggs and egg products that are adulterated or misbranded or otherwise in violation of this chapter.

**§ 31704. Inspection of egg products**

(a) PROCESSING OPERATIONS AND ESTABLISHMENTS.—

(1) IN GENERAL.—For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any egg product that is capable of use as human food and is misbranded or adulterated, the Secretary shall, whenever processing operations are being conducted, continuously inspect, in accordance with the regulations promulgated under this chapter, the processing of egg products, in each plant processing egg products for commerce, unless exempted under section 31714 of this title.

(2) FOOD MANUFACTURING ESTABLISHMENTS, INSTITUTIONS, AND RESTAURANTS.—Without restricting the application of paragraph (1) to other kinds of establishments within its provisions, any food manufacturing establishment, institution, or restaurant that uses any eggs that do not meet the requirements of section 31714(a)(1) of this title in the preparation of any articles for human food shall be deemed to be a plant processing egg products, with respect to the operations.

(b) AUTHORITY OF SECRETARY TO RETAIN, SEGREGATE, AND REINSPECT.—The Secretary, at any time, shall retain, segregate, and reinspect, as the Secretary

considers necessary, eggs and egg products capable of use as human food in each official plant.

(c) CONDEMNATION.—

(1) IN GENERAL.—Eggs and egg products found to be adulterated at official plants shall be condemned and, if no appeal is taken from the determination of condemnation, the articles shall be destroyed for human food purposes under the supervision of an inspector.

(2) ARTICLES THAT MAY BE REPROCESSED.—Articles that may, by reprocessing, be made not adulterated need not be condemned and destroyed if reprocessed under the supervision of an inspector and, after the reprocessing, found not to be adulterated.

(3) APPEALS.—

(A) IN GENERAL.—If an appeal is taken from a determination of condemnation under paragraph (1), the eggs or egg products shall be appropriately marked and segregated pending completion of an appeal inspection, which appeal shall be at the cost of the appellant if the Secretary determines that the appeal is frivolous.

(B) DETERMINATION OF CONDEMNATION SUSTAINED.—If the determination of condemnation is sustained, the eggs or egg products shall be destroyed for human food purposes under the supervision of an inspector.

(d) INSPECTIONS OF BUSINESS PREMISES, FACILITIES, INVENTORY, OPERATIONS, AND RECORDS.—

(1) INSPECTIONS BY SECRETARY.—The Secretary shall cause such other inspections to be made of the business premises, facilities, inventory, operations, and records of egg handlers, and the records and inventory of other persons required to keep records under section 31710 of this title, as the Secretary considers appropriate (and in the case of shell egg packers, packing eggs for the ultimate consumer, at least once each calendar quarter) to ensure that only eggs fit for human food are used for that purpose, and otherwise to ensure compliance by egg handlers and other persons with the requirements of section 31707 of this title.

(2) INSPECTIONS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—The Secretary of Health and Human Services shall inspect as described in paragraph (1), as the Secretary of Health and Human Services considers appropriate, to ensure

compliance with the requirements at food manufacturing establishments, institutions, and restaurants, other than plants processing egg products.

(3) ACCESS.—Representatives of the Secretary and the Secretary of Health and Human Services shall be afforded access to all places of business described in this subsection for purposes of making the inspections provided for in this chapter.

(e) REFRIGERATION AND LABELING REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraphs (2), (3), and (4), the Secretary shall make such inspections as the Secretary considers appropriate of a facility of an egg handler (including a transport vehicle) to determine if shell eggs destined for the ultimate consumer—

(A) are being held under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit after packing; and

(B) contain labeling that indicates that refrigeration is required.

(2) SHELL EGG PACKERS.—In the case of a shell egg packer packing eggs for the ultimate consumer, the Secretary shall make an inspection in ac-

cordance with paragraph (1) at least once each calendar quarter.

(3) INSPECTIONS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—The Secretary of Health and Human Services shall cause such inspections to be made as the Secretary considers appropriate to ensure compliance with the requirements of paragraph (1) at food manufacturing establishments, institutions, and restaurants, other than plants packing eggs.

(4) CERTAIN EGG HANDLERS NOT SUBJECT TO INSPECTION.—The Secretary shall not make an inspection as provided in paragraph (1) on any egg handler with a flock of not more than 3,000 layers.

(5) ACCESS.—Any representative of the Secretary or the Secretary of Health and Human Services shall be afforded access to a place of business referred to in this subsection, including a transport vehicle, for purposes of making an inspection required under this subsection.

**§ 31705. Sanitary operating practices in official plants**

(a) PREMISES, FACILITIES, AND EQUIPMENT.—Each official plant shall be operated in accordance with such sanitary practices and shall have such premises, facilities,

and equipment as are required by regulations promulgated by the Secretary to carry out this chapter, including requirements for segregation and disposition of restricted eggs.

(b) REFUSAL BY SECRETARY TO INSPECT NONCONFORMING PLANTS.—The Secretary shall refuse to render inspection to any plant whose premises, facilities, or equipment, or the operation of the plant, fail to meet the requirements of this section.

**§ 31706. Pasteurization and labeling of egg products at official plants**

(a) PASTEURIZATION; CONTENTS OF LABEL.—Egg products inspected at any official plant under the authority of this chapter and found not to be adulterated—

(1) shall be pasteurized before they leave the official plant, except as otherwise permitted by regulations of the Secretary; and

(2) shall, at the time they leave the official plant, bear in distinctly legible form on their shipping containers or immediate containers, or both, if required by regulations of the Secretary—

(A) the official inspection legend and official plant number of the plant in which the products were processed; and

(B) such other information as the Secretary may require by regulations to describe the products adequately and to ensure that they will not have false or misleading labeling.

(b) FALSE OR MISLEADING LABELING OR CONTAINER; UNAPPROVED CONTAINERS.—

(1) IN GENERAL.—A labeling or container shall not be used for egg products at official plants if the labeling or container is false or misleading or has not been approved as required by the regulations of the Secretary.

(2) WITHHOLDING OF USE OF LABELING OR CONTAINER.—If the Secretary has reason to believe that any labeling or the size or form of any container in use or proposed for use with respect to egg products at any official plant is false or misleading in any particular, the Secretary may direct that the use be withheld unless the labeling or container is modified in such manner as the Secretary may prescribe so that it will not be false or misleading.

(3) REQUEST FOR HEARING.—If the person using or proposing to use the labeling or container does not accept the determination of the Secretary under paragraph (1), the person may request a hearing, but the use of the labeling or container

shall, if the Secretary directs, be withheld pending hearing and final determination by the Secretary.

(4) CONCLUSIVENESS OF FINAL DETERMINATION; APPEALS.—

(A) IN GENERAL.—Any final determination by the Secretary under paragraph (3) shall be conclusive unless, within 30 days after receipt of notice of the final determination, the person adversely affected by the final determination appeals to the United States court of appeals for the circuit in which the person has the person's principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(B) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of section 204 of the Packers and Stockyards Act, 1921 (7 U.S.C. 194) shall be applicable to appeals taken under this section.

**§ 31707. Prohibited acts**

(a) RESTRICTED EGGS.—

(1) PERSONS.—A person shall not buy, sell, or transport, offer to buy or sell, or offer or receive for transportation, in any business in commerce, any restricted eggs, capable of use as human food, except

as authorized by regulations of the Secretary under such conditions as the Secretary may prescribe to ensure that only eggs fit for human food are used for human food.

(2) EGG HANDLERS.—An egg handler shall not possess with intent to use, or use, any restricted eggs in the preparation of human food for commerce except that the restricted eggs may be possessed and used if authorized by regulations of the Secretary under such conditions as the Secretary may prescribe to ensure that only eggs fit for human food are used for human food.

(b) COMPLIANCE WITH CHAPTER.—

(1) IN GENERAL.—A person shall not process any egg products for commerce at any plant except in compliance with this chapter.

(2) PERSONS.—A person shall not buy, sell, or transport, offer to buy or sell, or offer or receive for transportation, in commerce any egg products required to be inspected under this chapter unless the egg products have been inspected under this chapter and are labeled and packaged in accordance with section 31706 of this title.

(3) OPERATORS OF OFFICIAL PLANTS; SANITATION PRACTICES.—An operator of any official plant

shall not fail to comply with section 31705(a) of this title or the regulations under the section.

(4) OPERATORS OF OFFICIAL PLANTS; ADULTERATED OR MISBRANDED EGG PRODUCTS.—An operator of any official plant shall not allow any egg products to be moved from the plant if the egg products are adulterated or misbranded and capable of use as human food.

(c) EGG HANDLERS; POSSESSION OF EGGS UNDER CERTAIN CONDITIONS.—An egg handler shall not possess any eggs after the eggs have been packed into a container that is destined for the ultimate consumer unless the eggs are stored and transported under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit, as prescribed by rules and regulations promulgated by the Secretary.

(d) VIOLATION OF CERTAIN PROVISIONS.—A person shall not violate any provision of section 31709, 31710, or 31716 of this title.

(e) MARKS AND CERTIFICATES; MISREPRESENTATIONS; ACCESS.—A person shall not—

(1) manufacture, cast, print, lithograph, or otherwise make any device containing any official mark or simulation of the official mark, any label bearing any such mark or simulation, or any form of official

certificate or simulation of the official certificate, except as authorized by the Secretary;

(2) forge or alter any official device, mark, or certificate;

(3) without authorization from the Secretary—

(A) use any official device, mark, or certificate, or simulation of the official device, mark, or certificate, or detach, deface, or destroy any official device or mark; or

(B) use any labeling or container ordered to be withheld from use under section 31706 of this title after final judicial affirmance of the order or expiration of the time for appeal if no appeal is taken under that section;

(4) contrary to the regulations prescribed by the Secretary, detach, deface, or destroy, or fail to use, any official device, mark, or certificate;

(5) knowingly possess, without promptly notifying the Secretary or the Secretary's representative—

(A) any official device or any counterfeit, simulated, forged, or improperly altered official certificate;

(B) any device or label bearing any counterfeit, simulated, forged, or improperly altered official mark; or

(C) any eggs or egg products bearing any counterfeit, simulated, forged, or improperly altered official mark;

(6) knowingly make any false statement in any shipper's certificate or other nonofficial or official certificate provided for in the regulations prescribed by the Secretary;

(7) knowingly represent that any article has been inspected or exempted, under this chapter, when in fact, the article has, respectively, not been inspected or exempted; or

(8) refuse access, at any reasonable time, to any representative of the Secretary or the Secretary of Health and Human Services, to any plant or other place of business subject to inspection under this chapter.

(f) FEDERAL OFFICIALS AND EMPLOYEES.—An individual, while an official or employee of the Federal Government or any State or local governmental agency, or after holding the office or the employment, shall not use to the individual's own advantage, or reveal other than to the authorized representatives of the Federal Government

or any State or other government in their official capacity, or as ordered by a court in a judicial proceeding, any information acquired under this chapter concerning any matter that is entitled to protection as a trade secret.

**§ 31708. Cooperation with appropriate State and other governmental agencies**

(a) IN GENERAL.—The Secretary shall, if the Secretary determines that it would effectuate the purposes of this chapter, cooperate with appropriate State and other governmental agencies, in carrying out this chapter.

(b) EXAMINATIONS, INVESTIGATIONS, AND INSPECTIONS.—In carrying out this chapter, the Secretary may conduct such examinations, investigations, and inspections as the Secretary determines practicable through any officer or employee of any such agency commissioned by the Secretary for the purpose of carrying out this chapter.

(c) REIMBURSEMENT.—The Secretary shall reimburse the States and other agencies for the costs incurred by the States and agencies in the cooperative programs.

**§ 31709. Eggs and egg products not intended for use as human food**

(a) INSPECTIONS; DENATURING OR OTHERWISE IDENTIFYING.—Inspection shall not be provided under this chapter at any plant for the processing of any egg products that are not intended for use as human food,

but the articles, prior to their offer for sale or transportation in commerce, shall be denatured or otherwise identified as prescribed by regulations of the Secretary to deter their use for human food.

(b) PROHIBITION ON SALES AND TRANSPORT.—A person shall not buy, sell, or transport, offer to buy or sell, or offer or receive for transportation, in commerce, any restricted eggs or egg products that are not intended for use as human food unless they are denatured or otherwise identified as required by the regulations of the Secretary.

**§ 31710. Recordkeeping requirements**

For the purpose of enforcing the provisions of this chapter and the regulations promulgated under this chapter, all persons engaged in the business of transporting, shipping, or receiving any eggs or egg products in commerce or holding the articles received in commerce, and all egg handlers—

(1) shall maintain such records showing, for such time and in such form and manner, as the Secretary or the Secretary of Health and Human Services may prescribe, to the extent that they are concerned therewith, the receipt, delivery, sale, movement, and disposition of all eggs and egg products handled by the persons and egg handlers; and

(2) shall, on the request of an authorized representative of the Secretary or the Secretary of Health and Human Services, permit the representative at reasonable times to have access to and to copy all the records.

**§ 31711. Enforcement provisions**

(a) PENALTIES FOR PROHIBITED ACTS.—

(1) IN GENERAL.—Any person that commits any offense prohibited by section 31707 of this title shall be imprisoned for not more than 1 year, fined not more than $5,000, or both.

(2) INTENT TO DEFRAUD; KNOWN ADULTERATION.—If a violation under paragraph (1) involves intent to defraud, or any distribution or attempted distribution of any article that is known to be adulterated (except as defined in section 31701(1)(A)(viii) of this title), the person shall be imprisoned for not more than 3 years, fined not more than $10,000, or both.

(b) PERSONS PREVENTING ENFORCEMENT.—

(1) IN GENERAL.—Any person that forcibly assaults, resists, opposes, impedes, intimidates, or interferes with an individual while engaged in or on account of the performance of the individual's offi-

cial duties under this chapter shall be imprisoned not more than 3 years, fined under title 18, or both.

(2) USE OF DEADLY OR DANGEROUS WEAPON.—Any person that, in the commission of any act under paragraph (1), uses a deadly or dangerous weapon, shall be imprisoned not more than 10 years, fined under title 18, or both.

(3) MURDER.—Any person that kills an individual while engaged in or on account of the performance of the individual's official duties under this chapter shall be punished as provided under sections 1111 and 1112 of title 18.

(c) CIVIL PENALTY.—

(1) IN GENERAL.—

(A) AMOUNT; SEPARATE OFFENSE.—Except as otherwise provided in this subsection, any person that violates any provision of this chapter or any regulation issued under this chapter, other than a violation for which a criminal penalty has been imposed under this chapter, may be assessed a civil penalty by the Secretary of not more than $5,000 for each violation. Each violation to which this subparagraph applies shall be considered a separate offense.

(B) HEARING.—A civil penalty shall not be assessed against any person under this subsection unless the person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5.

(C) WRITTEN ORDER; REVIEW.—The amount of the civil penalty imposed under this subsection—

(i) shall be assessed by the Secretary, by written order, taking into account the gravity of the violation, degree of culpability, and history of prior offenses; and

(ii) may be reviewed only as provided in paragraph (2).

(2) FINALITY AND CONCLUSIVENESS OF ORDER; JUDICIAL REVIEW.—

(A) IN GENERAL.—The determination and order of the Secretary under this subsection shall be final and conclusive unless the person against whom a violation is found under paragraph (1) files an application for judicial review within 30 days after service of the order in the United States court of appeals for the circuit in which the person has the person's principal

place of business or in the United States Court of Appeals for the District of Columbia Circuit.

(B) BASIS OF JUDICIAL REVIEW.—Judicial review of any order under subparagraph (A) shall be based on the record on which the determination and order are based.

(C) ADDITIONAL EVIDENCE.—If the court determines that additional evidence needs to be taken, the court shall order the hearing to be reopened for the purpose of taking additional evidence in such manner and on such terms and conditions as the court considers proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, on the basis of the additional evidence so taken.

(3) FAILURE TO PAY.—

(A) REFERRAL TO ATTORNEY GENERAL.—If any person fails to pay an assessment of a civil penalty after the civil penalty has become a final and unappealable order, or after the appropriate court of appeals has entered a final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General.

(B) INSTITUTION OF CIVIL ACTION.—The Attorney General shall institute a civil action to recover the amount assessed in an appropriate district court of the United States.

(C) VALIDITY AND APPROPRIATENESS OF ORDER NOT SUBJECT TO REVIEW.—In the collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.

(4) TREASURY.—All civil penalties collected under this subsection shall be paid into the Treasury.

(5) COMPROMISING, MODIFYING, REMITTING CIVIL PENALTY.—The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty assessed under this subsection.

(6) APPLICABILITY.—Paragraph (1) shall not apply to an official plant.

(d) SCOPE OF LIABILITY FOR VIOLATIONS.—In construing or enforcing the provisions of section 31707 of this title, the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association within the scope of the person's employment or office shall in every case be deemed the act, omission,

or failure of the individual, partnership, corporation, or association, as well as of the person.

(e) PENALTIES APPLICABLE TO CARRIERS OR WAREHOUSEMEN.—A carrier or warehouseman shall not be subject to the penalties of this chapter, other than the penalties for violation of section 31710 of this title or subsection (c), by reason of the carrier's or the warehouseman's receipt, carriage, holding, or delivery, in the usual course of business, as a carrier or warehouseman of eggs or egg products owned by another person unless—

(1) the carrier or warehouseman has knowledge, or is in possession, of facts that would cause a reasonable person to believe that the eggs or egg products were not eligible for transportation under, or were otherwise in violation of, this chapter; or

(2) the carrier or warehouseman refuses to furnish on request of a representative of the Secretary—

(A) the name and address of the person from whom the carrier or warehouseman received the eggs or egg products; and

(B) copies of all documents, if any, pertaining to the delivery of the eggs or egg products to, or by, the carrier or warehouseman.

**§ 31712. Procedures prior to reporting to attorney general for institution of criminal proceeding**

(a) NOTICE AND OPPORTUNITY TO PRESENT VIEWS.—Before the Secretary or Secretary of Health and Human Services reports any violation of this chapter to any United States attorney for institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given reasonable notice of the alleged violation and opportunity to present the person's views orally or in writing with regard to the contemplated proceeding.

(b) EFFECT ON ISSUANCE OF WRITTEN NOTICE OR WARNING.—Nothing in this chapter shall be construed as requiring the Secretary or Secretary of Health and Human Services to report for criminal prosecution violations of this chapter if the Secretary or Secretary of Health and Human Services believes that the public interest will be adequately served and compliance with this chapter obtained by a suitable written notice of warning or an action to assess civil penalties.

**§ 31713. Rules and regulations**

The Secretary shall promulgate such rules and regulations as the Secretary considers necessary to carry out this chapter, and shall be responsible for the administra-

tion and enforcement of this chapter except as otherwise provided in section 31704(d) of this title.

**§ 31714. Exemption of certain activities**

(a) REGULATION FOR EXEMPTIONS.—The Secretary may, by regulation and under such conditions and procedures as the Secretary may prescribe, exempt from specific provisions of this chapter—

(1) the sale, transportation, possession, or use of eggs that contain no more restricted eggs than are allowed by the tolerance in the official standards of United States consumer grades for shell eggs;

(2) the processing of egg products at any plant in which the facilities and operating procedures meet such sanitary standards as may be prescribed by the Secretary, and in which the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards of United States consumer grades for shell eggs, and the egg products processed at the plant;

(3) the sale of eggs by any poultry producer from the poultry producer's own flocks directly to a household consumer exclusively for use by the consumer and members of the consumer's household and the consumer's nonpaying guests and employees,

and the transportation, possession, and use of the eggs in accordance with this subsection;

(4) the processing of egg products by any poultry producer from eggs of the poultry producer's own flocks' production for sale of the products directly to a household consumer exclusively for use by the consumer and members of the consumer's household and the consumer's nonpaying guests and employees, and the egg products processed when handled in accordance with this subsection;

(5) the sale of eggs by any shell egg packer on the shell egg packer's own premises directly to household consumers for use by the consumer and members of the consumer's household and the consumer's nonpaying guests and employees, and the transportation, possession, and use of the eggs in accordance with this subsection;

(6) for such period of time (not to exceed 2 years) during the initiation of operations under this chapter as the Secretary determines is impracticable to provide inspection, the processing of egg products at any class of plants and the egg products processed at the plants; and

(7) the sale of eggs by any egg producer with an annual egg production from a flock of 3,000 or fewer hens.

(b) SUSPENSION OR TERMINATION OF CERTAIN EXEMPTIONS.—The Secretary may immediately suspend or terminate any exemption under paragraph (2) or (6) of subsection (a) at any time with respect to any person, if the conditions of exemption prescribed by this section or the regulations of the Secretary are not being met.

(c) MODIFICATION OR REVOCATION OF EXEMPTIONS.—The Secretary may modify or revoke any regulation granting exemption under this chapter if the Secretary considers the action appropriate to effectuate the purposes of this chapter.

**§ 31715. Limitation on entry of eggs and egg products and other materials into official plants**

The Secretary may limit the entry of eggs and egg products and other materials into official plants under such conditions as the Secretary may prescribe to ensure that allowing the entry of the articles into the plants will be consistent with the purposes of this chapter.

**§ 31716. Imports**

(a) AUTHORIZATION FOR IMPORTATION OF RESTRICTED EGGS.—

(1) RESTRICTED EGGS.—Restricted eggs capable of use as human food shall not be imported into the United States except as authorized by regulations of the Secretary.

(2) EGG PRODUCTS.—Egg products capable of use as human food shall not be imported into the United States unless they were processed under an approved continuous inspection system of the government of the foreign country of origin or subdivision of the foreign country and are labeled and packaged in accordance with, and otherwise comply with the standards of, this chapter and regulations issued under this chapter applicable to the articles within the United States.

(3) CERTIFICATION FOR EGGS RELATING TO TEMPERATURE.—Eggs packed into a container that is destined for the ultimate consumer shall not be imported into the United States unless the eggs are accompanied by a certification that the eggs have at all times after packaging been stored and transported under refrigeration at an ambient temperature of no greater than 45 degrees Fahrenheit, as required by sections 31704(e) and 31707(c) of this title.

(4) TREATMENT AS DOMESTIC ARTICLES.—

(A) IN GENERAL.—All imported articles under this subsection shall, on entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter.

(B) REQUIRED LABELING.—The articles described in paragraph (1) shall be labeled as required by the regulations for imported articles.

(C) EFFECT OF SECTION.—Nothing in this section applies to eggs or egg products purchased outside the United States by any individual for consumption by the individual and members of the individual's household and the individual's nonpaying guests and employees.

(b) TERMS AND CONDITIONS FOR DESTRUCTION.—The Secretary may prescribe the terms and conditions for the destruction of all articles described in subsection (a) that are imported contrary to this section, unless—

(1) they are exported by the consignee within the time fixed for the exportation by the Secretary; or

(2) in the case of articles that are not in compliance solely because of misbranding, the articles are brought into compliance with this chapter under

supervision of authorized representatives of the Secretary.

(c) PAYMENT OF STORAGE, CARTAGE, AND LABOR CHARGES BY OWNER OR CONSIGNEE.—All charges for storage, cartage, and labor with respect to any article that is imported contrary to this section shall be paid by the owner or consignee, and in default of the payment shall constitute a lien against the article and any other article thereafter imported under this chapter by or for the owner or consignee.

(d) PROHIBITION.—The importation of any article contrary to this section is prohibited.

**§ 31717. Refusal or withdrawal of inspection services**

(a) IN GENERAL.—The Secretary (for such period, or indefinitely, as the Secretary considers necessary to effectuate the purposes of this chapter) may refuse to provide or may withdraw inspection service under this chapter with respect to any plant if the Secretary determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, the service, that the applicant or recipient is unfit to engage in any business requiring inspection under this chapter because the applicant or recipient or anyone responsibly connected with the applicant or recipient has been convicted in any Federal or State court, within the previous 10 years, of—

(1) any felony or more than 1 misdemeanor under any law based on—

(A) the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food; or

(B) fraud in connection with transactions in food; or

(2) any felony involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health.

(b) RESPONSIBLY CONNECTED.—For the purpose of this section, a person shall be deemed to be responsibly connected with the business if the person is a partner, officer, director, holder, or owner of 10 percent or more of its voting stock, or employee in a managerial or executive capacity.

(c) FINALITY AND CONCLUSIVENESS OF ORDER; JUDICIAL REVIEW.—

(1) IN GENERAL.—The determination and order of the Secretary with respect to the refusal or withdrawal under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within 30 days after the effective date of the order

in the United States court of appeals for the circuit in which the applicant or recipient has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit.

(2) BASIS.—Judicial review of any order under this section shall be on the record on which the determination and order are based.

(3) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of section 204 of the Packers and Stockyards Act, 1921 (7 U.S.C. 194) shall be applicable to appeals taken under this section.

(d) EFFECT OF SECTION.—This section shall not affect other provisions of this chapter for refusal of inspection services.

**§ 31718. Detention of articles**

(a) IN GENERAL.—If any eggs or egg products subject to this chapter are found, by any authorized representative of the Secretary, on any premises, and there is reason to believe that they are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of this chapter or that they are in any other way in violation of this chapter, or if any restricted eggs capable of use as human food are found, by any authorized representative of the Secretary, in the possession of any person not authorized

to acquire the eggs under the regulations of the Secretary, the articles may be detained by the representative for a reasonable period but not to exceed 20 days, pending action under section 31719 of this title or notification of any Federal, State, or other governmental authorities having jurisdiction over the articles.

(b) REMOVAL.—The articles detained under subsection (a) shall not be moved by any person from the place at which they are located while the articles are detained until released by the representative.

(c) MARKS.—All official marks may be required by the representative to be removed from the articles before they are released unless it appears to the satisfaction of the Secretary that the articles are eligible to retain the marks.

(d) APPLICABILITY OF DETAINER AUTHORITY TO REPRESENTATIVE OF SECRETARY OF HEALTH AND HUMAN SERVICES.—The detainer authority conferred on representatives of the Secretary by this section shall also apply to any authorized representative of the Secretary of Health and Human Services for the purposes of section 31704(d) of this title, with respect to any eggs or egg products that are outside any plant processing egg products.

**§ 31719. Seizure and condemnation proceedings**

(a) IN GENERAL.—The following articles shall be liable to be proceeded against and seized and condemned, at any time, on a complaint in any United States district court or other proper court as provided in section 31720 of this title within the jurisdiction of which the articles are found:

(1) Any eggs or egg products that are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation, in violation of this chapter, or in any other way are in violation of this chapter.

(2) Any restricted eggs, capable of use as human food, in the possession of any person not authorized to acquire the eggs under the regulations of the Secretary.

(b) DISPOSITION OF ARTICLES.—

(1) IN GENERAL.—If the articles under subsection (a) are condemned, they shall, after entry of the decree, be disposed of by destruction or sale as the court may direct.

(2) PROCEEDS.—The proceeds, if the articles are sold under paragraph (1), less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury.

(3) LIMITATION ON DISPOSITION BY SALE.—The articles under paragraph (1) shall not be sold contrary to this chapter, subtitle I of this title, the Fair Packaging and Labeling Act, or the laws of the jurisdiction in which they are sold.

(c) BOND.—On the execution and delivery of a good and sufficient bond conditioned that the articles shall not be sold or otherwise disposed of contrary to this chapter, subtitle I of this title, the Fair Packaging and Labeling Act, or the laws of the jurisdiction in which disposition is made, the court may direct that they be delivered to the owner of the articles subject to such supervision by authorized representatives of the Secretary as is necessary to ensure compliance with the applicable laws.

(d) COURT COSTS; STORAGE AND OTHER EXPENSES.—If a decree of condemnation is entered against the articles and the articles are released under bond, or destroyed, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the articles.

(e) APPLICABILITY OF ADMIRALTY AND MARITIME RULES.—Proceedings under this section shall conform, as nearly as may be, to the supplemental rules for certain admiralty and maritime claims, except that either party may demand trial by jury of any issue of fact joined in

any case, and all such proceedings shall be brought by and in the name of the United States.

(f) CONDEMNATION OR SEIZURE UNDER OTHER PROVISIONS UNAFFECTED.—This section does not derogate from authority for condemnation or seizure conferred by other provisions of this chapter or by other laws.

**§ 31720. Jurisdiction of district courts**

(a) IN GENERAL.—The United States district courts and the District Court of the Virgin Islands are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this chapter, and shall have jurisdiction in all other cases arising under this chapter, except as provided in section 31717 of this title.

(b) UNITED STATES AS NAMED PARTY.—All proceedings for the enforcement or to restrain violations of this chapter shall be by and in the name of the United States.

(c) SUBPOENAS.—Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

**§ 31721. Other Federal laws applicable for administration and enforcement of chapter**

(a) IN GENERAL.—For the efficient administration and enforcement of this chapter, the provisions (including

penalties) of sections 6, 8, 9, and 10 of the Federal Trade Commission Act (15 U.S.C. 46, 48, 49, 50), except subsections (c) through (h) of section 6 of the Act (15 U.S.C. 46(c) through (h)), are made applicable to the jurisdiction, powers, and duties of the Secretary in administering and enforcing the provisions of this chapter and to any person with respect to whom the authority is exercised.

(b) PROSECUTION OF INQUIRY.—The Secretary, or such agents as the Secretary may designate, may prosecute any inquiry necessary to the Secretary's duties under this chapter in any part of the United States.

(c) AUTHORITY OF THE COURTS.—The powers conferred by sections 9 and 10 of the Federal Trade Commission Act (15 U.S.C. 49, 50) on the district courts of the United States may be exercised for the purposes of this chapter by any court designated in section 31720 of this title.

**§ 31722. State or local regulation**

(a) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT REQUIREMENTS RELATING TO PREMISES, FACILITIES, AND OPERATIONS; AUTHORITY TO IMPOSE RECORDKEEPING REQUIREMENTS.—Requirements within the scope of this chapter with respect to premises, facilities, and operations of any official plant that are in addition to or different than those made under this chapter may

not be imposed by any State or local jurisdiction except that any State or local jurisdiction may impose record-keeping and other requirements within the scope of section 31710 of this title, if consistent with section 31710 of this title, with respect to any official plant.

(b) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT STANDARDS AND LABELING REQUIREMENTS.—

(1) IN GENERAL.—For eggs that have moved or are moving in interstate or foreign commerce—

(A) a State or local jurisdiction shall not require the use of standards of quality, condition, weight, quantity, or grade that are in addition to or different from the official Federal standards;

(B) with respect to egg handlers specified in paragraphs (1) and (2) of section 31704(e) of this title, a State or local jurisdiction shall not impose temperature requirements pertaining to eggs packaged for the ultimate consumer that are in addition to, or different from, Federal requirements; and

(C) a State or local jurisdiction other than those in noncontiguous areas of the United States shall not require labeling to show the

State or other geographical area of production or origin.

(2) NAME, ADDRESS, AND LICENSE NUMBER ON CONTAINER.—Paragraph (1) shall not preclude a State from requiring that the name, address, and license number of the person processing or packaging eggs be shown on each container.

(c) PROHIBITION AGAINST ADDITIONAL OR DIFFERENT LABELING, PACKAGING, OR INGREDIENT REQUIREMENTS.—With respect to egg products processed at any official plant in accordance with the requirements under this chapter, subtitle I of this title, and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), labeling, packaging, or ingredient requirements, in addition to or different than those made under this chapter, subtitle I of this title, and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), may not be imposed by any State or local jurisdiction.

(d) JURISDICTION CONFERRED TO PREVENT DISTRIBUTION OF ARTICLES IN VIOLATION OF LAWS.—Notwithstanding this section, any State or local jurisdiction may exercise jurisdiction with respect to eggs and egg products to prevent the distribution for human food purposes of eggs and egg products that are outside of an official plant and are in violation of this chapter, subtitle I

of this title, and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.) or any State or local law consistent with this chapter, subtitle I of this title, and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.)

(e) EFFECT OF CHAPTER ON STATE LAW.—Except as provided in this section, the provisions of this chapter shall not invalidate any law or other provisions of any State or other jurisdiction in the absence of a conflict with this chapter.

(f) EFFECT OF CHAPTER ON FEDERAL LAWS AND ON AUTHORITY OF SECRETARY OF HEALTH AND HUMAN SERVICES.—This chapter does not affect the applicability of subtitle I of this title, the Fair Packaging and Labeling Act, or other Federal laws to eggs, egg products, or other food products or diminish any authority conferred on the Secretary of Health and Human Services or other Federal officials by such other laws, except that the Secretary shall have exclusive jurisdiction to regulate official plants processing egg products and operations of the official plants as to all matters within the scope of this chapter.

**§ 31723. Inspection and administration costs**

(a) DEFINITION OF HOLIDAY.—The term ''holiday'', for the purposes of assessment or reimbursement of the cost of inspection performed under this chapter, means the

legal public holidays specified by Congress in section 6103(a) of title 5.

(b) OVERTIME AND HOLIDAY WORK COSTS.—

(1) IN GENERAL.—The cost of inspection rendered under the requirements of this chapter, and other costs of administration of this chapter, shall be borne by the United States, except that the cost of overtime and holiday work performed in official plants subject to the provisions of this chapter at such rates as the Secretary may determine shall be borne by the official plants.

(2) AVAILABILITY OF AMOUNTS.—Amounts received by the Secretary from official plants under this section shall be available without fiscal year limitation to carry out this chapter.

**§ 31724. Annual report to congressional committees**

Not later than March 1 of each year, the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a comprehensive and detailed written report with respect to—

(1)(A) the processing, storage, handling, and distribution of eggs and egg products subject to this chapter;

(B) the inspection of establishments operated in connection with the process, storage, and handling described in subparagraph (A);

(C) the effectiveness of the operation of the inspection, including the effectiveness of the operations of State egg inspection programs; and

(D) recommendations for legislation to improve the program; and

(2) the administration of section 31716 of this title during the immediately preceding calendar year, including—

(A) a certification by the Secretary that foreign plants exporting eggs or egg products to the United States have complied with this chapter and regulations issued under this chapter;

(B) the names and locations of plants authorized or permitted to export eggs or egg products to the United States;

(C) the number of inspectors employed by the Department of Agriculture in the calendar year concerned who were assigned to inspect plants referred to in subparagraph (B) and the frequency with which each of those plants was inspected by the inspectors;

(D)(i) the number of inspectors that were licensed by each country from which any imports were received and that were assigned, during the calendar year concerned, to inspect the imports and the facilities in which the imports were handled; and

(ii) the frequency and effectiveness of the inspections under clause (i);

(E) the total volume of eggs and egg products that was imported into the United States during the calendar year concerned from each country, including a separate itemization of the volume of each major category of the imports from each country during the year, and a detailed report of rejections of plants and products because of failure to meet appropriate standards prescribed by this chapter; and

(F) recommendations for legislation to improve the program.

# Chapter 319—Pesticide Monitoring Improvement

Sec.
31901. Pesticide monitoring and enforcement information.
31902. Foreign pesticide information.
31903. Pesticide analytical methods.

**§ 31901. Pesticide monitoring and enforcement information**

(a) DATA MANAGEMENT SYSTEMS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall place in effect computerized data management systems for the Food and Drug Administration under which the Food and Drug Administration will—

(A) record, summarize, and evaluate the results of its program for monitoring food products for pesticide residues;

(B) identify gaps in its pesticide monitoring program in the monitoring of—

(i) pesticides;

(ii) food products; and

(iii) food from specific countries and from domestic sources;

(C) detect trends in the presence of pesticide residues in food products and identify public health problems emerging from the occurrence of pesticide residues in food products;

(D) focus its testing resources for monitoring pesticide residues in food on detecting those residues that pose a public health concern;

(E) prepare summaries of the information listed in subsection (b); and

(F) provide information to assist the Environmental Protection Agency in carrying out its responsibilities under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and subtitle I of this title.

(2) MAKING OF SUMMARY.—As soon as practicable, the Secretary of Health and Human Services shall develop a means to enable the computerized data management systems placed into effect under paragraph (1) to make the summary described in subsection (c).

(3) RELATIONSHIP WITH OTHER LAWS.—

(A) SUBTITLE I.—Paragraph (1) does not limit the authority of the Food and Drug Administration to—

(i) use the computerized data management systems placed in effect under paragraph (1) to facilitate the regulation of any substance or product covered under the requirements of subtitle I of this title; or

(ii) develop additional data management systems to facilitate the regulation described in clause (i).

(B) COMPLIANCE WITH REGULATIONS ON COMPUTER SYSTEM DESIGN AND PROCUREMENT.—In placing into effect the computerized data management systems under paragraph (1) and in carrying out paragraph (2), the Secretary of Health and Human Services shall comply with applicable regulations governing computer system design and procurement.

(b) INFORMATION.—The Food and Drug Administration shall use the computerized data management systems placed into effect under subsection (a)(1) to prepare a summary of—

(1) information on—

(A) the types of imported and domestically produced food products analyzed for compliance with the requirements of subtitle I of this title regarding the presence of pesticide residues;

(B) the number of samples of each such food product analyzed for the compliance by country of origin;

(C) the pesticide residues that may be detected using the testing methods employed;

(D) the pesticide residues in the food detected and the levels detected;

(E) the compliance status of each sample of the food tested and the violation rate for each country-product combination; and

(F) the action taken with respect to each sample of the food found to be in violation of subtitle I of this title and its ultimate disposition; and

(2) information on—

(A) the country of origin of each imported food product referred to in paragraph (1)(A); and

(B) the United States district of entry for each such imported food product.

(c) VOLUME DATA.—

(1) SUMMARY.—The Food and Drug Administration shall use the computerized data management systems placed into effect under subsection (a)(1) to summarize the volume of each type of food product subject to the requirements of subtitle I of this title that is imported into the United States and that has an entry value that exceeds an amount established by the Secretary of Health and Human Services.

(2) SORTING OF SUMMARY.—The summary shall be made by country of origin and district of entry.

(3) DATABASE FROM OTHER FEDERAL AGENCIES.—Information with respect to volumes of food products to be included in the summary shall, to the extent feasible, be obtained from databases of other Federal agencies.

(d) COMPILATION.—

(1) INFORMATION.—The Secretary of Health and Human Services shall annually compile a summary of the information described in subsection (b) with respect to the previous year.

(2) VOLUME DATA.—When the Food and Drug Administration is able to make summaries under subsection (c), the Secretary of Health and Human Services shall include in the compilation under paragraph (1) a compilation of the information described in subsection (c).

(3) AVAILABILITY.—Compilations under this subsection shall be made available to Federal and State agencies and other interested persons.

**§ 31902. Foreign pesticide information**

(a) COOPERATIVE AGREEMENTS.—The Secretary of Health and Human Services shall enter into cooperative agreements with the governments of the countries that are the major sources of food imports into the United States subject to pesticide residue monitoring by the Food and

Drug Administration for the purpose of improving the ability of the Food and Drug Administration to ensure compliance with the pesticide tolerance requirements of subtitle I of this title with regard to imported food.

(b) INFORMATION ACTIVITIES.—

(1) IN GENERAL.—The cooperative agreements entered into under subsection (a) with governments of foreign countries shall specify the action to be taken by the parties to the agreements to accomplish the purpose described in subsection (a), including the means by which the governments of the foreign countries will provide to the Secretary of Health and Human Services current information identifying each of the pesticides used in the production, transportation, and storage of food products imported from production regions of the countries into the United States.

(2) NO AGREEMENT; INSUFFICIENT INFORMATION TO ENSURE EFFECTIVE PROGRAM.—In the case of a foreign country with which the Secretary of Health and Human Services is unable to enter into an agreement under subsection (a) or for which the information provided under paragraph (1) is insufficient to ensure an effective pesticide monitoring program, the Secretary of Health and Human Serv-

ices shall, to the extent practicable, obtain the information described in paragraph (1) with respect to the country from other Federal or international agencies or private sources.

(3) ENSURING APPROPRIATE FDA OFFICES RECEIVE INFORMATION.—The Secretary of Health and Human Services shall ensure that appropriate offices of the Food and Drug Administration that are engaged in the monitoring of imported food for pesticide residues receive the information obtained under paragraph (1) or (2).

(4) AVAILABILITY OF INFORMATION TO STATE AGENCIES.—The Secretary of Health and Human Services shall make available any information obtained under paragraph (1) or (2) to State agencies engaged in the monitoring of imported food for pesticide residues other than information obtained from private sources the disclosure of which to the agencies is restricted.

(c) COORDINATION WITH OTHER AGENCIES.—The Secretary of Health and Human Services shall—

(1) notify in writing the Department of Agriculture, the Environmental Protection Agency, and the Department of State at the initiation of negotia-

tions with a foreign country to develop a cooperative agreement under subsection (a); and

(2) coordinate the activities of the Department of Health and Human Services with the activities of the agencies referred to in paragraph (1), as appropriate, during the course of the negotiations.

**§ 31903. Pesticide analytical methods**

The Secretary of Health and Human Services shall, in consultation with the Administrator of the Environmental Protection Agency—

(1) develop a detailed long-range plan and timetable for research that is necessary for the development of and validation of—

(A) new and improved analytical methods capable of detecting at 1 time the presence of multiple pesticide residues in food; and

(B) rapid pesticide analytical methods; and

(2) conduct a review to determine whether the use of rapid pesticide analytical methods by the Secretary of Health and Human Services would enable the Secretary of Health and Human Services to improve the cost-effectiveness of monitoring and enforcement activities under subtitle I of this title, including increasing the number of pesticide residues that can be detected and the number of tests for

pesticide residues that can be conducted in a cost-effective manner.

# Chapter 321—Food Allergen Labeling and Consumer Protection

Sec.
32101. Inspections relating to food allergens.
32102. Gluten-free labeling.
32103. Improvement and publication of data on food-related allergic responses.

## § 32101. Inspections relating to food allergens

The Secretary of Health and Human Services shall conduct inspections, consistent with section 17504 of this title, of facilities in which foods are manufactured, processed, packed, or held—

(1) to ensure that the entities operating the facilities comply with practices to reduce or eliminate cross-contact of a food with residues of major food allergens that are not intentional ingredients of the food; and

(2) to ensure that major food allergens are properly labeled on foods.

## § 32102. Gluten-free labeling

The Secretary of Health and Human Services shall issue a final rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods.

### § 32103. Improvement and publication of data on food-related allergic responses

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, shall improve (including by educating physicians and other health care providers) the collection of, and publish as it becomes available, national data on—

(1) the prevalence of food allergies;

(2) the incidence of clinically significant or serious adverse events related to food allergies; and

(3) the use of different modes of treatment for and prevention of allergic responses to foods.

# Chapter 323—Food Safety

Sec.
32301. Ensuring the safety of pet food.
32302. Ensuring efficient and effective communications during a recall.
32303. State and Federal cooperation.
32304. Enhanced aquaculture and seafood inspection.
32305. Consultation regarding genetically engineered seafood products.
32306. Annual report to Congress.
32307. Publication of annual reports.
32308. Rule of construction.

### § 32301. Ensuring the safety of pet food

(a) PROCESSING AND INGREDIENT STANDARDS.—The Secretary of Health and Human Services (referred to in this chapter as the ''Secretary''), in consultation with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary

medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) processing standards for pet food; and

(2) updated standards for the labeling of pet food that include nutritional and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—The Secretary shall establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing the system, the Secretary shall—

(1) consider using surveillance and monitoring mechanisms similar to, or in coordination with, those used to monitor human or animal health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet of the Centers for Disease Control and Prevention, the Food Emergency Response Network of the Food and Drug Administration and the Department of Agriculture, and the National Animal Health Laboratory Network of the Department of Agriculture;

(2) consult with relevant professional associations and private sector veterinary hospitals;

(3) work with the National Companion Animal Surveillance Program, the Health Alert Network, or other notification networks as appropriate to inform veterinarians and relevant stakeholders during any recall of pet food; and

(4) use such information and conduct such other activities as the Secretary considers appropriate.

**§ 32302. Ensuring efficient and effective communications during a recall**

The Secretary shall, during an ongoing recall of human or pet food regulated by the Secretary—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication, including electronic forms of information dissemination, to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled human and pet foods on the internet website of the Food and Drug Administration in a single location, which shall include a searchable database of recalled human foods and a searchable database of recalled

pet foods, that is easily accessed and understood by the public.

**§ 32303. State and Federal cooperation**

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of food, including fresh and processed produce, so that State food safety programs and activities conducted by the Secretary function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing a food safety program described in subsection (a)—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

**§ 32304. Enhanced aquaculture and seafood inspection**

(a) HEIGHTENED INSPECTIONS.—The Secretary may enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(b) PARTNERSHIPS WITH STATES.—On the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs to Federal standards regarding the importation of aquaculture and seafood.

**§ 32305. Consultation regarding genetically engineered seafood products**

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine

Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

**§ 32306. Annual report to Congress**

The Secretary shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on the products; and

(3) aggregated data on the findings of the inspections, including data related to violations of subtitle I of this title, and enforcement actions used to follow up on the findings and violations.

**§ 32307. Publication of annual reports**

(a) IN GENERAL.—The Commissioner of Food and Drugs shall annually submit to Congress and publish on the internet website of the Food and Drug Administration a report concerning the results of the Food and Drug Administration's pesticide residue monitoring program, which report includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the United States (including details on the plans for the additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested com-

modity that were sampled, including recommendations on—

(A) whether sampling—

(i) is statistically significant; and

(ii) provides confidence intervals or other related statistical information; and

(B) whether the number of samples should be increased and the details of any plans to provide for the increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent the smuggling.

(b) COMPLETION DATE.—Annual reports under subsection (a) shall be completed by June 1 of each year for the data collected for the year that was 2 years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a), which data relates to testing carried out by the Food Safety and Inspection Service and the Agricultural Mar-

keting Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

**§ 32308. Rule of construction**

(a) DIETARY SUPPLEMENTS.—Nothing in this chapter (or an amendment made by title X of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 121 Stat. 962)) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417, 108 Stat. 4325); or

(2) the adverse event reporting system for dietary supplements under section 18902 of this title.

(b) JURISDICTION OF SECRETARIES.—Nothing in this chapter (or an amendment made by title X of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 121 Stat. 962)) shall be construed to alter the jurisdiction between the Secretary of Agriculture and the Secretary, under applicable statutes and regulations.

# Chapter 325—Food Safety Modernization

**Subchapter I—General Provisions**

Sec.

32501. Definition of foodborne illness outbreak.

**Subchapter II—Improving Capacity To Prevent Food Safety Problems**

32511. Performance standards.

32512. National Agriculture and Food Defense Strategy.

32513. Food and Agriculture Coordinating Councils.
32514. Building domestic capacity.
32515. Food allergy and anaphylaxis management.
32516. Alcohol-related facilities.

**Subchapter III—Improving Capacity To Detect and Respond to Food Safety Problems**

32531. Food emergency response network.
32532. Integrated consortium of laboratory networks.
32533. Enhancing tracking and tracing of food and recordkeeping.
32534. Surveillance.
32535. Decontamination and disposal standards and plans.

**Subchapter IV—Improving the Safety of Imported Food**

32551. Inspection by the Secretary of Commerce.
32552. Foreign offices of the Food and Drug Administration.
32553. Smuggled food.

**Subchapter V—Miscellaneous Provisions**

32561. Effect of food safety modernization provisions on jurisdiction and authorities.
32562. Effect of food safety modernization provisions on compliance with international agreements.

# Subchapter I—General Provisions

## § 32501. Definition of foodborne illness outbreak

In this chapter, the term ''foodborne illness outbreak'' means the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a certain food.

# Subchapter II—Improving Capacity To Prevent Food Safety Problems

## § 32511. Performance standards

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this chapter as the ''Secretary'') shall, in coordination with the Secretary of Agriculture, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological stud-

ies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants.

(b) GUIDANCE DOCUMENTS AND REGULATIONS.—Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 11102 of this title or to prevent the spread of communicable disease by food under section 361 of the Public Health Service Act (42 U.S.C. 264), the Secretary shall issue contaminant-specific and science-based guidance documents (including guidance documents regarding action levels) or regulations. The guidance documents (including guidance documents regarding action levels) or regulations—

(1) shall apply to products or product classes;

(2) shall, where appropriate, differentiate between food for human consumption and food intended for consumption by animals other than humans; and

(3) shall not be written to be facility-specific.

(c) NO DUPLICATION OF EFFORTS.—The Secretary shall coordinate with the Secretary of Agriculture to avoid issuing duplicative guidance on the same contaminants.

(d) REVIEW.—The Secretary shall periodically review and revise, as appropriate, the guidance documents (including guidance documents regarding action levels) or regulations issued under this section.

**§ 32512. National Agriculture and Food Defense Strategy**

(a) DEVELOPMENT AND SUBMISSION OF STRATEGY.—

(1) IN GENERAL.—The Secretary and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall prepare and submit to the relevant committees of Congress, and make publicly available on the internet websites of the Department of Health and Human Services and the Department of Agriculture, the National Agriculture and Food Defense Strategy (referred to in this section as the ''Strategy'').

(2) IMPLEMENTATION PLAN.—The Strategy shall include an implementation plan for use by the Secretaries described under paragraph (1) in carrying out the Strategy.

(3) RESEARCH.—The Strategy shall include a coordinated research agenda for use by the Secretaries described under paragraph (1) in conducting research to support the goals and activities described in paragraphs (1) and (2) of subsection (b).

(4) REVISIONS.—Not later than 4 years after the date on which the Strategy is submitted to the relevant committees of Congress under paragraph (1), and not less frequently than every 4 years thereafter, the Secretary and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, shall revise and submit to the relevant committees of Congress the Strategy.

(5) CONSISTENCY WITH EXISTING PLANS.—The Strategy described in paragraph (1) shall be consistent with—

(A) the National Incident Management System;

(B) the National Response Framework;

(C) the National Infrastructure Protection Plan;

(D) the National Preparedness Goals; and

(E) other relevant national strategies.

(b) COMPONENTS.—

(1) IN GENERAL.—The Strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security—

(A) to achieve each goal described in paragraph (2); and

(B) to evaluate the progress made by Federal, State, local, and tribal governments towards the achievement of each goal described in paragraph (2).

(2) GOALS.—The Strategy shall include a description of the process to be used by the Department of Health and Human Services, the Department of Agriculture, and the Department of Homeland Security to achieve the following goals:

(A) PREPAREDNESS GOAL.—Enhance the preparedness of the agriculture and food system by—

(i) conducting vulnerability assessments of the agriculture and food system;

(ii) mitigating vulnerabilities of the system;

(iii) improving communication and training relating to the system;

(iv) developing and conducting exercises to test decontamination and disposal plans;

(v) developing modeling tools to improve event consequence assessment and decision support; and

(vi) preparing risk communication tools and enhancing public awareness through outreach.

(B) DETECTION GOAL.—Improve agriculture and food system detection capabilities by—

(i) identifying contamination in food products at the earliest possible time; and

(ii) conducting surveillance to prevent the spread of diseases.

(C) EMERGENCY RESPONSE GOAL.—Ensure an efficient response to agriculture and food emergencies by—

(i) immediately investigating animal disease outbreaks and suspected food contamination;

(ii) preventing additional human illnesses;

(iii) organizing, training, and equipping animal, plant, and food emergency response teams of—

(I) the Federal Government; and

(II) State, local, and tribal governments;

(iv) designing, developing, and evaluating training and exercises carried out under agriculture and food defense plans; and

(v) ensuring consistent and organized risk communication to the public by—

(I) the Federal Government;

(II) State, local, and tribal governments; and

(III) the private sector.

(D) RECOVERY GOAL.—Secure agriculture and food production after an agriculture or food emergency by—

(i) working with the private sector to develop business recovery plans to rapidly resume agriculture, food production, and international trade;

(ii) conducting exercises of the plans described in subparagraph (C) with the goal of long-term recovery results;

(iii) rapidly removing, and effectively disposing of—

(I) contaminated agriculture and food products; and

(II) infected plants and animals; and

(iv) decontaminating and restoring areas affected by an agriculture or food emergency.

(3) EVALUATION.—The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall—

(A) develop metrics to measure progress for the evaluation process described in paragraph (1)(B); and

(B) report on the progress measured in subparagraph (A) as part of the Strategy.

(c) LIMITED DISTRIBUTION.—In the interest of national security, the Secretary and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, may determine the manner and format in which the Strategy is made publicly available on the internet

websites of the Department of Health and Human Services, the Department of Homeland Security, and the Department of Agriculture, as described in subsection (a)(1).

**§ 32513. Food and Agriculture Coordinating Councils**

The Secretary of Homeland Security, in coordination with the Secretary and the Secretary of Agriculture, shall, within 180 days of January 4, 2011, and annually thereafter, submit to the relevant committees of Congress, and make publicly available on the internet website of the Department of Homeland Security, a report on the activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council, including the progress of the Councils on—

(1) facilitating partnerships between public and private entities to help coordinate and enhance the protection of the agriculture and food system of the United States;

(2) providing for the regular and timely interchange of information between each Council, which information relates to the security of the agriculture and food system (including intelligence information);

(3) identifying best practices and methods for improving the coordination among Federal, State, local, and private sector preparedness and response plans for agriculture and food defense; and

(4) recommending methods by which to protect the economy and the public health of the United States from the effects of—

(A) animal or plant disease outbreaks;

(B) food contamination; and

(C) natural disasters affecting agriculture and food.

**§ 32514. Building domestic capacity**

(a) IN GENERAL.—

(1) INITIAL REPORT.—The Secretary, in coordination with the Secretary of Agriculture and the Secretary of Homeland Security, shall, not later than 2 years after January 4, 2011, submit to Congress a comprehensive report that identifies programs and practices that are intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities. The report shall include a description of the following:

(A) Analysis of the need for further regulations or guidance to industry.

(B) Outreach to food industry sectors, including through the Food and Agriculture Coordinating Councils referred to in section 32513

of this title, to identify potential sources of emerging threats to the safety and security of the food supply and preventive strategies to address those threats.

(C) Systems to ensure the prompt distribution to the food industry of information and technical assistance concerning preventive strategies.

(D) Communication systems to ensure that information about specific threats to the safety and security of the food supply are rapidly and effectively disseminated.

(E) Surveillance systems and laboratory networks to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards, including how the systems and networks are integrated.

(F) Outreach, education, and training provided to States and local governments to build State and local food safety and food defense capabilities, including progress in implementing strategies developed under sections 32512 and 32534 of this title.

(G) The estimated resources needed to effectively implement the programs and practices

identified in the report developed in this section over a 5-year period.

(H) The impact of requirements under this chapter and under amendments made by the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) on certified organic farms and facilities (as defined in section 11117 of this title).

(I) Specific efforts taken pursuant to the agreements authorized under section 11123(d) of this title, together with, as necessary, a description of any additional authorities necessary to improve seafood safety.

(2) BIENNIAL REPORTS.—On a biennial basis following the submission of the report under paragraph (1), the Secretary shall submit to Congress a report that—

(A) reviews previous food safety programs and practices;

(B) outlines the success of those programs and practices;

(C) identifies future programs and practices; and

(D) includes information related to any matter described in subparagraphs (A) through (H) of paragraph (1), as necessary.

(b) RISK-BASED ACTIVITIES.—The report developed under subsection (a)(1) shall describe methods that seek to ensure that resources available to the Secretary for food safety-related activities are directed at those actions most likely to reduce risks from food, including the use of preventive strategies and allocation of inspection resources. The Secretary shall promptly undertake those risk-based actions that are identified during the development of the report as likely to contribute to the safety and security of the food supply.

(c) CAPABILITY FOR LABORATORY ANALYSES; RESEARCH.—The report developed under subsection (a)(1) shall provide a description of methods to increase capacity to undertake analyses of food samples promptly after collection, to identify new and rapid analytical techniques, including commercially-available techniques that can be employed at ports of entry and by Food Emergency Response Network laboratories, and to provide for well-equipped and staffed laboratory facilities and progress toward laboratory accreditation under section 11124 of this title.

(d) INFORMATION TECHNOLOGY.—The report developed under subsection (a)(1) shall include a description of such information technology systems as may be needed to identify risks and receive data from multiple sources, including foreign governments, State, local, and tribal governments, other Federal agencies, the food industry, laboratories, laboratory networks, and consumers. The information technology systems that the Secretary describes shall also provide for the integration of the facility registration system under section 11117 of this title and the prior notice system under section 20101(m) of this title with other information technology systems that are used by the Federal Government for the processing of food offered for import into the United States.

(e) AUTOMATED RISK ASSESSMENT.—The report developed under subsection (a)(1) shall include a description of progress toward developing and improving an automated risk assessment system for food safety surveillance and allocation of resources.

(f) TRACEBACK AND SURVEILLANCE REPORT.—The Secretary shall include in the report developed under subsection (a)(1) an analysis of the FDA's performance in foodborne illness outbreaks during the 5-year period preceding January 4, 2011, involving fruits and vegetables that are raw agricultural commodities (as defined in sec-

tion 10101(a) of this title) and recommendations for enhanced surveillance, outbreak response, and traceability. The findings and recommendations shall address communication and coordination with the public, industry, and State and local governments, as such communication and coordination relates to outbreak identification and traceback.

(g) BIENNIAL FOOD SAFETY AND FOOD DEFENSE RESEARCH PLAN.—The Secretary, the Secretary of Agriculture, and the Secretary of Homeland Security shall, on a biennial basis, submit to Congress a joint food safety and food defense research plan which may include studying the long-term health effects of foodborne illness. The biennial plan shall include a list and description of projects conducted during the previous 2-year period and the plan for projects to be conducted during the subsequent 2-year period.

(h) EFFECTIVENESS OF PROGRAMS ADMINISTERED BY THE DEPARTMENT.—

(1) IN GENERAL.—To determine whether existing Federal programs administered by the Department of Health and Human Services are effective in achieving the stated goals of the programs, the Secretary shall—

(A) conduct an annual evaluation of each program of the Department of Health and Human Services to determine the effectiveness of each program in achieving legislated intent, purposes, and objectives; and

(B) submit to Congress a report concerning the evaluation.

(2) CONTENT.—The report described under paragraph (1)(B) shall—

(A) include conclusions concerning the reasons that the existing programs have proven successful or not successful and what factors contributed to the conclusions;

(B) include recommendations for consolidation and elimination to reduce duplication and inefficiencies in the programs at the Department of Health and Human Services as identified during the evaluation conducted under this subsection; and

(C) be made publicly available in a publication entitled ''Guide to the U.S. Department of Health and Human Services Programs''.

(i) UNIQUE IDENTIFICATION NUMBERS.—

(1) IN GENERAL.—Not later than 1 year after January 4, 2011, the Secretary, acting through the

Commissioner of Food and Drugs, shall conduct a study regarding the need for, and challenges associated with, development and implementation of a program that requires a unique identification number for each food facility registered with the Secretary and, as appropriate, each broker that imports food into the United States. The study shall include an evaluation of the costs associated with development and implementation of such a system, and make recommendations about what new authorities, if any, would be necessary to develop and implement such a system.

(2) REPORT.—Not later than 15 months after January 4, 2011, the Secretary shall submit to Congress a report that describes the findings of the study conducted under paragraph (1) and that includes any recommendations determined appropriate by the Secretary.

**§ 32515. Food allergy and anaphylaxis management**

(a) DEFINITIONS.—In this section:

(1) EARLY CHILDHOOD EDUCATION PROGRAM.—The term ''early childhood education program'' means—

(A) a Head Start program or an Early Head Start program carried out under the Head Start Act (42 U.S.C. 9831 et seq.);

(B) a State-licensed or State-regulated child care program or school; or

(C) a State prekindergarten program that serves children from birth through kindergarten.

(2) ELEMENTARY SCHOOL.—The term ''elementary school'' has the meaning given the term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(3) LOCAL EDUCATION AGENCY.—The term ''local educational agency'' has the meaning given the term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(4) PARENT.—The term ''parent'' has the meaning given the term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(5) SCHOOL.—The term ''school'' includes public—

(A) kindergartens;

(B) elementary schools; and

(C) secondary schools.

(6) SECONDARY SCHOOL.—The term ''secondary school'' has the meaning given the term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(b) ESTABLISHMENT OF VOLUNTARY FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT GUIDELINES.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Education, shall—

(i) develop guidelines to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and early childhood education programs; and

(ii) make the guidelines available to local educational agencies, schools, early childhood education programs, and other interested entities and individuals to be implemented on a voluntary basis only.

(B) APPLICABILITY OF FERPA.—Each plan described in subparagraph (A) that is developed for an individual shall be considered an education record for the purpose of section 444 of

the General Education Provisions Act (20 U.S.C. 1232g).

(2) CONTENTS.—The voluntary guidelines developed by the Secretary under paragraph (1) shall address each of the following and may be updated as the Secretary determines necessary:

(A) Parental obligation to provide the school or early childhood education program, prior to the start of every school year, with—

(i) documentation from their child's physician or nurse—

(I) supporting a diagnosis of food allergy, and any risk of anaphylaxis, if applicable;

(II) identifying any food to which the child is allergic;

(III) describing, if appropriate, any prior history of anaphylaxis;

(IV) listing any medication prescribed for the child for the treatment of anaphylaxis;

(V) detailing emergency treatment procedures in the event of a reaction;

(VI) listing the signs and symptoms of a reaction; and

(VII) assessing the child's readiness for self-administration of prescription medication; and

(ii) a list of substitute meals that may be offered to the child by school or early childhood education program food service personnel.

(B) The creation and maintenance of an individual plan for food allergy management, in consultation with the parent, tailored to the needs of each child with a documented risk for anaphylaxis, including any procedures for the self-administration of medication by the child in instances where—

(i) the child is capable of self-administering medication; and

(ii) the self-administration is not prohibited by State law.

(C) Communication strategies between individual schools or early childhood education programs and providers of emergency medical services, including appropriate instructions for emergency medical response.

(D) Strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms and common school or early childhood education program areas such as cafeterias.

(E) The dissemination of general information on life-threatening food allergies to school or early childhood education program staff, parents, and children.

(F) Food allergy management training of school or early childhood education program personnel who regularly come into contact with children with life-threatening food allergies.

(G) The authorization and training of school or early childhood education program personnel to administer epinephrine when the nurse is not immediately available.

(H) The timely accessibility of epinephrine by school or early childhood education program personnel when the nurse is not immediately available.

(I) The creation of a plan contained in each individual plan for food allergy management that addresses the appropriate response to an incident of anaphylaxis of a child while the child is engaged in extracurricular programs of

a school or early childhood education program, such as non-academic outings and field trips, before-school and after-school programs or before-early child education and after-early child education programs, and school-sponsored or early childhood education program-sponsored programs held on weekends.

(J) Maintenance of information for each administration of epinephrine to a child at risk for anaphylaxis and prompt notification to parents.

(K) Other elements the Secretary determines necessary for the management of food allergies and anaphylaxis in schools and early childhood education programs.

(3) RELATION TO STATE LAW.—Nothing in this section or the guidelines developed by the Secretary under paragraph (1) shall be construed to preempt State law, including any State law regarding whether students at risk for anaphylaxis may self-administer medication.

(c) SCHOOL-BASED FOOD ALLERGY MANAGEMENT GRANTS.—

(1) IN GENERAL.—The Secretary may award grants to local educational agencies to assist the

agencies with implementing voluntary food allergy and anaphylaxis management guidelines described in subsection (b).

(2) APPLICATION.—

(A) IN GENERAL.—To be eligible to receive a grant under this subsection, a local educational agency shall submit an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

(B) CONTENTS.—Each application submitted under subparagraph (A) shall include—

(i) an assurance that the local educational agency has developed plans in accordance with the food allergy and anaphylaxis management guidelines described in subsection (b);

(ii) a description of the activities to be funded by the grant in carrying out the food allergy and anaphylaxis management guidelines, including—

(I) how the guidelines will be carried out at individual schools served by the local educational agency;

(II) how the local educational agency will inform parents and students of the guidelines in place;

(III) how school nurses, teachers, administrators, and other school-based staff will be made aware of, and given training on, when applicable, the guidelines in place; and

(IV) any other activities that the Secretary determines appropriate;

(iii) an itemization of how grant funds received under this subsection will be expended;

(iv) a description of how adoption of the guidelines and implementation of grant activities will be monitored; and

(v) an agreement by the local educational agency to report information required by the Secretary to conduct evaluations under this subsection.

(3) USE OF FUNDS.—Each local educational agency that receives a grant under this subsection may use the grant funds for the following:

(A) Purchase of materials and supplies, including limited medical supplies such as epi-

nephrine and disposable wet wipes, to support carrying out the food allergy and anaphylaxis management guidelines described in subsection (b).

(B) In partnership with local health departments, school nurse, teacher, and personnel training for food allergy management.

(C) Programs that educate students as to the presence of, and policies and procedures in place related to, food allergies and anaphylactic shock.

(D) Outreach to parents.

(E) Any other activities consistent with the guidelines described in subsection (b).

(4) DURATION OF AWARDS.—The Secretary may award grants under this subsection for a period of not more than 2 years. In the event the Secretary conducts a program evaluation under this subsection, funding in the second year of the grant, where applicable, shall be contingent on a successful program evaluation by the Secretary after the first year.

(5) LIMITATION ON GRANT FUNDING.—The Secretary may not provide grant funding to a local educational agency under this subsection after the

local educational agency has received 2 years of grant funding under this subsection.

(6) MAXIMUM AMOUNT OF ANNUAL AWARDS.—A grant awarded under this subsection may not be made in an amount that is more than $50,000 annually.

(7) PRIORITY.—In awarding grants under this subsection, the Secretary shall give priority to local educational agencies with the highest percentages of children who are counted under section 1124(c) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 6333(c)).

(8) MATCHING FUNDS.—

(A) IN GENERAL.—The Secretary may not award a grant under this subsection unless the local educational agency agrees that, with respect to the costs to be incurred by the local educational agency in carrying out the grant activities, the local educational agency shall make available (directly or through donations from public or private entities) non-Federal funds toward the costs in an amount equal to not less than 25 percent of the amount of the grant.

(B) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal funds

required under subparagraph (A) may be cash or in-kind, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of the non-Federal funds.

(9) ADMINISTRATIVE FUNDS.—A local educational agency that receives a grant under this subsection may use not more than 2 percent of the grant amount for administrative costs related to carrying out this subsection.

(10) PROGRESS AND EVALUATIONS.—At the completion of the grant period referred to in paragraph (4), a local educational agency shall provide the Secretary with information on how grant funds were spent and the status of implementation of the food allergy and anaphylaxis management guidelines described in subsection (b).

(11) SUPPLEMENT NOT SUPPLANT.—Grant funds received under this subsection shall be used to supplement, and not supplant, non-Federal funds and any other Federal funds available to carry out the activities described in this subsection.

(d) VOLUNTARY NATURE OF GUIDELINES.—

(1) IN GENERAL.—The food allergy and anaphylaxis management guidelines developed by the Secretary under subsection (b) are voluntary. Nothing in this section or the guidelines developed by the Secretary under subsection (b) shall be construed to require a local educational agency to implement the guidelines.

(2) EXCEPTION.—Notwithstanding paragraph (1), the Secretary may enforce an agreement by a local educational agency to implement food allergy and anaphylaxis management guidelines as a condition of the receipt of a grant under subsection (c).

**§ 32516. Alcohol-related facilities**

(a) IN GENERAL.—Except as provided by sections 32561 and 32562 of this title, and except as provided by sections 102, 206, 207, 302, 304, and 402 of the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) and amendments made by those sections of that Act, nothing in this chapter or amendments made by the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) shall be construed to apply to a facility that—

(1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C.

5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and

(2) under section 11117 of this title is required to register as a facility because the facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of the facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages.

(b) LIMITED RECEIPT AND DISTRIBUTION OF NON-ALCOHOL FOOD.—Subsection (a) shall not apply to a facility engaged in the receipt and distribution of any non-alcohol food, except that subsection (a) shall apply to a facility described in subsection (a) that receives and distributes non-alcohol food, provided the food is received and distributed—

(1) in a prepackaged form that prevents any direct human contact with the food; and

(2) in amounts that constitute not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(c) RULE OF CONSTRUCTION.—Except as provided in subsections (a) and (b), this section shall not be construed to exempt any food, other than alcoholic beverages, as de-

fined in section 203 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of this chapter or the amendments made by the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885).

# Subchapter III—Improving Capacity To Detect and Respond to Food Safety Problems

### § 32531. Food emergency response network

The Secretary, in coordination with the Secretary of Agriculture, the Secretary of Homeland Security, and State, local, and tribal governments shall, not later than 180 days after January 4, 2011, biennially submit to the relevant committees of Congress, and make publicly available on the internet website of the Department of Health and Human Services, a report on the progress in implementing a national food emergency response laboratory network that—

(1) provides ongoing surveillance, rapid detection, and surge capacity for large-scale food-related emergencies, including intentional adulteration of the food supply;

(2) coordinates the food laboratory capacities of State, local, and tribal food laboratories, including the adoption of novel surveillance and identification

technologies and the sharing of data between Federal agencies and State laboratories to develop national situational awareness;

(3) provides accessible, timely, accurate, and consistent food laboratory services throughout the United States;

(4) develops and implements a methods repository for use by Federal, State, and local officials;

(5) responds to food-related emergencies; and

(6) is integrated with relevant laboratory networks administered by other Federal agencies.

**§ 32532. Integrated consortium of laboratory networks**

(a) IN GENERAL.—The Secretary of Homeland Security, in coordination with the Secretary, the Secretary of Agriculture, the Secretary of Commerce, and the Administrator of the Environmental Protection Agency, shall maintain an agreement through which relevant laboratory network members, as determined by the Secretary of Homeland Security, shall—

(1) agree on common laboratory methods to reduce the time required—

(A) to detect and respond to foodborne illness outbreaks; and

(B) to facilitate the sharing of knowledge and information relating to animal health, agriculture, and human health;

(2) identify means by which laboratory network members could work cooperatively—

(A) to optimize national laboratory preparedness; and

(B) to provide surge capacity during emergencies; and

(3) engage in ongoing dialogue and build relationships that will support a more effective and integrated response during emergencies.

(b) REPORTING REQUIREMENT.—The Secretary of Homeland Security shall, on a biennial basis, submit to the relevant committees of Congress, and make publicly available on the internet website of the Department of Homeland Security, a report on the progress of the integrated consortium of laboratory networks, as established under subsection (a), in carrying out this section.

**§ 32533. Enhancing tracking and tracing of food and recordkeeping**

(a) PILOT PROJECTS.—

(1) IN GENERAL.—Not later than 270 days after January 4, 2011, the Secretary, taking into account recommendations from the Secretary of Agri-

culture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 11102 of this title or misbranded under section 11323 of this title.

(2) CONTENT.—The Secretary shall conduct 1 or more pilot projects under paragraph (1) in coordination with the processed food sector and 1 or more pilot projects under paragraph (1) in coordination with processors or distributors of fruits and vegetables that are raw agricultural commodities. The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the food supply and include at least 3 different types of foods that have been the subject of significant outbreaks during the 5-year period preceding January 4, 2011, and are selected to—

(A) develop and demonstrate methods for rapid and effective tracking and tracing of

foods in a manner that is practicable for facilities of varying sizes, including small businesses;

(B) develop and demonstrate appropriate technologies, including technologies existing on January 4, 2011, that enhance the tracking and tracing of food; and

(C) inform the promulgation of regulations under subsection (d).

(3) REPORT.—Not later than 18 months after January 4, 2011, the Secretary shall report to Congress on the findings of the pilot projects under this subsection together with recommendations for improving the tracking and tracing of food.

(b) ADDITIONAL DATA GATHERING.—

(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Agriculture and multiple representatives of State departments of health and agriculture, shall assess—

(A) the costs and benefits associated with the adoption and use of several product tracing technologies, including technologies used in the pilot projects under subsection (a);

(B) the feasibility of the technologies for different sectors of the food industry, including small businesses; and

(C) whether the technologies are compatible with the requirements of this subsection.

(2) REQUIREMENTS.—To the extent practicable, in carrying out paragraph (1), the Secretary shall—

(A) evaluate domestic and international product tracing practices in commercial use;

(B) consider international efforts, including an assessment of whether product tracing requirements developed under this section are compatible with global tracing systems, as appropriate; and

(C) consult with a diverse and broad range of experts and stakeholders, including representatives of the food industry, agricultural producers, and nongovernmental organizations that represent the interests of consumers.

(c) PRODUCT TRACING SYSTEM.—The Secretary, in consultation with the Secretary of Agriculture, shall, as appropriate, establish within the Food and Drug Administration a product tracing system to receive information that improves the capacity of the Secretary to effectively and rapidly track and trace food that is in the United States or offered for import into the United States. Prior to the establishment of the product tracing system, the

Secretary shall examine the results of applicable pilot projects and shall ensure that the activities of the system are adequately supported by the results of the pilot projects.

(d) ADDITIONAL RECORDKEEPING REQUIREMENTS FOR HIGH-RISK FOODS.—

(1) IN GENERAL.—

(A) NOTICE OF PROPOSED RULEMAKING.—To rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 11102 of this title or misbranded under section 11323 of this title, not later than 2 years after January 4, 2011, the Secretary shall publish a notice of proposed rulemaking to establish recordkeeping requirements, in addition to the requirements under section 11116 of this title and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations), for facilities that manufacture, process, pack, or hold foods that the Secretary

designates under paragraph (2) as high-risk foods.

(B) EFFECTIVE DATE OF ADDITIONAL REQUIREMENTS.—The Secretary shall set an appropriate effective date for the additional recordkeeping requirements for foods designated as high risk that takes into account the length of time necessary to comply with the requirements.

(C) REQUIREMENTS.—The requirements shall—

(i) relate only to information that is reasonably available and appropriate;

(ii) be science-based;

(iii) not prescribe specific technologies for the maintenance of records;

(iv) ensure that the public health benefits of imposing additional recordkeeping requirements outweigh the cost of compliance with the requirements;

(v) be scale-appropriate and practicable for facilities of varying sizes and capabilities with respect to costs and recordkeeping burdens, and not require the creation and maintenance of duplicate records

where the information is contained in other company records kept in the normal course of business;

(vi) minimize the number of different recordkeeping requirements for facilities that handle more than 1 type of food;

(vii) to the extent practicable, not require a facility to change business systems to comply with the requirements;

(viii) allow any person subject to this subsection to maintain records required under this subsection at a central or reasonably accessible location provided that the records can be made available to the Secretary not later than 24 hours after the Secretary requests the records;

(ix) include a process by which the Secretary may issue a waiver of the requirements under this subsection if the Secretary determines that the requirements would result in an economic hardship for an individual facility or a type of facility;

(x) be commensurate with the known safety risks of the designated food;

(xi) take into account international trade obligations;

(xii) not require—

(I) a full pedigree, or a record of the complete previous distribution history of the food from the point of origin of the food;

(II) records of recipients of a food beyond the immediate subsequent recipient of the food; or

(III) product tracking to the case level by persons subject to the requirements; and

(xiii) include a process by which the Secretary may remove a high-risk food designation developed under paragraph (2) for a food or type of food.

(2) DESIGNATION OF HIGH-RISK FOODS.—

(A) IN GENERAL.—Not later than 1 year after January 4, 2011, and after that date, as the Secretary determines necessary, the Secretary shall designate high-risk foods for which the additional recordkeeping requirements described in paragraph (1) are appropriate and

necessary to protect the public health. Each designation shall be based on—

(i) the known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to the food, taking into consideration foodborne illness data collected by the Centers for Disease Control and Prevention;

(ii) the likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce the food;

(iii) the point in the manufacturing process of the food where contamination is most likely to occur;

(iv) the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;

(v) the likelihood that consuming a particular food will result in a foodborne

illness due to contamination of the food; and

(vi) the likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

(B) LIST OF HIGH-RISK FOODS.—

(i) IN GENERAL.—At the time the Secretary promulgates the final rules under paragraph (1), the Secretary shall publish the list of the foods designated under subparagraph (A) as high-risk foods on the internet website of the Food and Drug Administration.

(ii) UPDATES.—The Secretary may update the list to designate new high-risk foods and to remove foods that are no longer deemed to be high-risk foods, provided that each update to the list is consistent with the requirements of this subsection and notice of the update is published in the Federal Register.

(3) PROTECTION OF SENSITIVE INFORMATION.—In promulgating regulations under this subsection, the Secretary shall take appropriate meas-

ures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section, including—

(A) periodic risk assessment and planning to prevent unauthorized release; and

(B) controls to—

(i) prevent unauthorized reproduction of trade secret or confidential information;

(ii) prevent unauthorized access to trade secret or confidential information; and

(iii) maintain records with respect to access by any person to trade secret or confidential information maintained by the agency.

(4) PUBLIC INPUT.—During the comment period in the notice of proposed rulemaking under paragraph (1), the Secretary shall conduct not fewer than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.

(5) RETENTION OF RECORDS.—Except as otherwise provided in this subsection, the Secretary may require that a facility retain records under this sub-

section for not more than 2 years, taking into consideration the risk of spoilage, loss of value, or loss of palatability of the applicable food when determining the appropriate timeframes.

(6) LIMITATIONS.—

(A) FARM-TO-SCHOOL PROGRAMS.—In establishing requirements under this subsection, the Secretary shall, in consultation with the Secretary of Agriculture, consider the impact of requirements on farm-to-school or farm-to-institution programs of the Department of Agriculture and other farm-to-school and farm-to-institution programs outside the Department of Agriculture, and shall modify the requirements under this subsection, as appropriate, with respect to the programs so that the requirements do not place undue burdens on farm-to-school or farm-to-institution programs.

(B) IDENTITY-PRESERVED LABELS WITH RESPECT TO FARM SALES OF FOOD THAT IS PRODUCED AND PACKAGED ON A FARM.—The requirements under this subsection shall not apply to a food that is produced and packaged on a farm if—

(i) the packaging of the food maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and

(ii) the labeling of the food includes the name, complete address (street address, town, State, country, and zip or other postal code), and business phone number of the farm, unless the Secretary waives the requirement to include a business phone number of the farm, as appropriate, to accommodate a religious belief of the individual in charge of the farm.

(C) FISHING VESSELS.—The requirements under this subsection with respect to a food that is produced through the use of a fishing vessel (as defined in section 3(18) of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18))) shall be limited to the requirements under subparagraph (F) until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel.

(D) COMMINGLED RAW AGRICULTURAL COMMODITIES.—

(i) DEFINITIONS.—In this subparagraph:

(I) COMMINGLED RAW AGRICULTURAL COMMODITY.—

(aa) IN GENERAL.—The term ''commingled raw agricultural commodity'' means any commodity that is combined or mixed after harvesting, but before processing.

(bb) EXCLUSIONS.—The term ''commingled raw agricultural commodity'' does not include types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that standards promulgated under section 11121 of this title would minimize the risk of serious adverse health consequences or death.

(II) PROCESSING.—The term ''processing'' means operations that alter the general state of the com-

modity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

(ii) LIMITATION ON EXTENT OF TRACING.—Recordkeeping requirements under this subsection with regard to any commingled raw agricultural commodity shall be limited to the requirements under subparagraph (F).

(E) EXEMPTION OF OTHER FOODS.—The Secretary may, by notice in the Federal Register, modify the requirements under this subsection with respect to, or exempt a food or a type of facility from, the requirements of this subsection (other than the requirements under subparagraph (F), if applicable) if the Secretary determines that product tracing requirements for the food (such as bulk or commingled ingredients that are intended to be processed to destroy pathogens) or type of facility are not necessary to protect the public health.

(F) RECORDKEEPING REGARDING PREVIOUS SOURCES AND SUBSEQUENT RECIPIENTS.—In the case of a person or food to which

a limitation or exemption under subparagraph (C), (D), or (E) applies, if the person, or a person that manufactures, processes, packs, or holds the food, is required to register with the Secretary under section 11117 of this title with respect to the manufacturing, processing, packing, or holding of the applicable food, the Secretary shall require the person to maintain records that identify the immediate previous source of the food and the immediate subsequent recipient of the food.

(G) GROCERY STORES.—With respect to a sale of a food described in subparagraph (H) to a grocery store, the Secretary shall not require the grocery store to maintain records under this subsection other than records documenting the farm that was the source of the food. The Secretary shall not require that the records be kept for more than 180 days.

(H) FARM SALES TO CONSUMERS.—The Secretary shall not require a farm to maintain any distribution records under this subsection with respect to a sale of a food described in subparagraph (I) (including a sale of a food that is produced and packaged on the farm), if

the sale is made by the farm directly to a consumer.

(I) SALE OF A FOOD.—A sale of a food described in this subparagraph is a sale of a food in which—

(i) the food is produced on a farm; and

(ii) the sale is made by the owner, operator, or agent in charge of the farm directly to a consumer or grocery store.

(7) NO IMPACT ON NON-HIGH-RISK FOODS.—

(A) IN GENERAL.—The recordkeeping requirements established under paragraph (1) shall have no effect on foods that are not designated by the Secretary under paragraph (2) as high-risk foods.

(B) APPLICABLE RECORDKEEPING REQUIREMENTS.—Foods described in subparagraph (A) shall be subject solely to the recordkeeping requirements under section 11116 of this title and subpart J of part 1 of title 21, Code of Federal Regulations (or any successor regulations).

(e) EVALUATION AND RECOMMENDATIONS.—

(1) REPORT.—Not later than 1 year after the effective date of the final rule promulgated under subsection (d)(1), the Comptroller General shall submit to Congress a report, taking into consideration the costs of compliance and other regulatory burdens on small businesses and Federal, State, and local food safety practices and requirements, that evaluates the public health benefits and risks, if any, of limiting—

(A) the product tracing requirements under subsection (d) to foods identified under paragraph (2) of subsection (d), including whether the requirements provide adequate assurance of traceability in the event of intentional adulteration, including by acts of terrorism; and

(B) the participation of restaurants in the recordkeeping requirements.

(2) DETERMINATION AND RECOMMENDATIONS.—In conducting the evaluation and report under paragraph (1), if the Comptroller General determines that the limitations described in paragraph (1) do not adequately protect the public health, the Comptroller General shall submit to Congress recommendations, if appropriate, regarding record-

keeping requirements for restaurants and additional foods, in order to protect the public health.

(f) FARMS.—

(1) REQUEST FOR INFORMATION.—Notwithstanding subsection (d), during an active investigation of a foodborne illness outbreak, or if the Secretary determines it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak, the Secretary, in consultation and coordination with State and local agencies responsible for food safety, as appropriate, may request that the owner, operator, or agent of a farm identify potential immediate recipients, other than consumers, of an article of the food that is the subject of the investigation if the Secretary reasonably believes the article of food—

(A) is adulterated under section 11102 of this title;

(B) presents a threat of serious adverse health consequences or death to humans or animals; and

(C) was adulterated as described in subparagraph (A) on a particular farm (as defined in section 1.227 of title 21, Code of Federal Regulations (or any successor regulation)).

(2) MANNER OF REQUEST.—In making a request under paragraph (1), the Secretary, in consultation and coordination with State and local agencies responsible for food safety, as appropriate, shall issue a written notice to the owner, operator, or agent of the farm to which the article of food has been traced. The individual providing the notice shall present to the owner, operator, or agent appropriate credentials and shall deliver the notice at reasonable times and within reasonable limits and in a reasonable manner.

(3) DELIVERY OF INFORMATION REQUESTED.—The owner, operator, or agent of a farm shall deliver the information requested under paragraph (1) in a prompt and reasonable manner. The information may consist of records kept in the normal course of business, and may be in electronic or non-electronic format.

(4) LIMITATION.—A request made under paragraph (1) shall not include a request for information relating to the finances, pricing of commodities produced, personnel, research, sales (other than information relating to shipping), or other disclosures that may reveal trade secrets or confidential information from the farm to which the article of food

has been traced, other than information necessary to identify potential immediate recipients of the food. Section 10501(10) of this title and section 552 of title 5 shall apply with respect to any confidential commercial information that is disclosed to the Food and Drug Administration in the course of responding to a request under paragraph (1).

(5) RECORDS.—Except with respect to identifying potential immediate recipients in response to a request under this subsection, nothing in this subsection requires the establishment or maintenance by farms of new records.

(g) NO LIMITATION ON COMMINGLING OF FOOD.—Nothing in this section shall be construed to authorize the Secretary to impose any limitation on the commingling of food.

(h) SMALL ENTITY COMPLIANCE GUIDE.—Not later than 180 days after promulgation of a final rule under subsection (d), the Secretary shall issue a small entity compliance guide setting forth in plain language the requirements of the regulations under subsection (d) to assist small entities, including farms and small businesses, in complying with the recordkeeping requirements under subsection (d).

(i) FLEXIBILITY FOR SMALL BUSINESSES.—Notwithstanding any other provision of law, the regulations promulgated under subsection (d) shall apply—

(1) to small businesses (as defined by the Secretary in section 11120 of this title) beginning on the date that is 1 year after the effective date of the final regulations promulgated under subsection (d); and

(2) to very small businesses (as defined by the Secretary in section 11120 of this title) beginning on the date that is 2 years after the effective date of the final regulations promulgated under subsection (d).

**§ 32534. Surveillance**

(a) FOODBORNE ILLNESS SURVEILLANCE SYSTEMS.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enhance foodborne illness surveillance systems to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses by—

(A) coordinating Federal, State, and local foodborne illness surveillance systems, including complaint systems, and increasing participation

in national networks of public health and food regulatory agencies and laboratories;

(B) facilitating sharing of surveillance information on a more timely basis among governmental agencies, including the Food and Drug Administration, the Department of Agriculture, the Department of Homeland Security, and State and local agencies, and with the public;

(C) developing improved epidemiological tools for obtaining quality exposure data and microbiological methods for classifying cases;

(D) augmenting the systems to improve attribution of a foodborne illness outbreak to a specific food;

(E) expanding capacity of the systems, including working toward automatic electronic searches, for implementation of identification practices, including fingerprinting strategies, for foodborne infectious agents, to identify new or rarely documented causes of foodborne illness and submit standardized information to a centralized database;

(F) allowing timely public access to aggregated, de-identified surveillance data;

(G) at least annually, publishing current reports on findings from the systems;

(H) establishing a flexible mechanism for rapidly initiating scientific research by academic institutions;

(I) integrating foodborne illness surveillance systems and data with other biosurveillance and public health situational awareness capabilities at the Federal, State, and local levels, including by sharing foodborne illness surveillance data with the National Biosurveillance Integration Center; and

(J) performing other activities as determined appropriate by the Secretary.

(2) WORKING GROUP.—The Secretary shall support and maintain a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food and food testing industries, consumer organizations, and academia. The working group shall provide the Secretary, through at least annual meetings of the working group and an annual public report, advice and recommendations on an ongoing and regular basis regarding the improvement of foodborne illness

surveillance and implementation of this section, including advice and recommendations on—

(A) the priority needs of regulatory agencies, the food industry, and consumers for information and analysis on foodborne illness and its causes;

(B) opportunities to improve the effectiveness of initiatives at the Federal, State, and local levels, including coordination and integration of activities among Federal agencies, and between the Federal, State, and local levels of government;

(C) improvement in the timeliness and depth of access by regulatory and health agencies, the food industry, academic researchers, and consumers to foodborne illness aggregated, de-identified surveillance data collected by government agencies at all levels, including data compiled by the Centers for Disease Control and Prevention;

(D) key barriers at Federal, State, and local levels to improving foodborne illness surveillance and the utility of the surveillance for preventing foodborne illness;

(E) the capabilities needed for establishing automatic electronic searches of surveillance data; and

(F) specific actions to reduce barriers to improvement, implement the working group's recommendations, and achieve the purposes of this section, with measurable objectives and timelines, and identification of resource and staffing needs.

(b) IMPROVING FOOD SAFETY AND DEFENSE CAPACITY AT THE STATE AND LOCAL LEVEL.—

(1) IN GENERAL.—The Secretary shall develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies to achieve the following goals:

(A) Improve foodborne illness outbreak response and containment.

(B) Accelerate foodborne illness surveillance and outbreak investigation, including—

(i) rapid shipment of clinical isolates from clinical laboratories to appropriate State laboratories; and

(ii) conducting more standardized illness outbreak interviews.

(C) Strengthen the capacity of State and local agencies to carry out inspections and enforce safety standards.

(D) Improve the effectiveness of Federal, State, and local partnerships to coordinate food safety and defense resources and reduce the incidence of foodborne illness.

(E) Share information on a timely basis among public health and food regulatory agencies, with the food industry, with health care providers, and with the public.

(F) Strengthen the capacity of State and local agencies to achieve the goals described in section 32512 of this title.

(2) REVIEW.—In developing the strategies required by paragraph (1), the Secretary shall, not later than 1 year after January 4, 2011, complete a review of State and local capacities, and needs for enhancement, which may include a survey with respect to—

(A) staffing levels and expertise available to perform food safety and defense functions;

(B) laboratory capacity to support surveillance, outbreak response, inspection, and enforcement activities;

(C) information systems to support data management and sharing of food safety and defense information among State and local agencies and with counterparts at the Federal level; and

(D) other State and local activities and needs as determined appropriate by the Secretary.

**§ 32535. Decontamination and disposal standards and plans**

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred to in this section as the ''Administrator''), in coordination with the Secretary, Secretary of Homeland Security, and Secretary of Agriculture, shall provide support for, and technical assistance to, State, local, and tribal governments in preparing for, assessing, decontaminating, and recovering from an agriculture or food emergency.

(b) DEVELOPMENT OF STANDARDS.—In carrying out subsection (a), the Administrator, in coordination with the Secretary, Secretary of Homeland Security, Secretary of Agriculture, and State, local, and tribal governments, shall develop and disseminate specific standards and protocols to undertake clean-up, clearance, and recovery activities

following the decontamination and disposal of specific threat agents and foreign animal diseases.

(c) DEVELOPMENT OF MODEL PLANS.—In carrying out subsection (a), the Administrator, the Secretary, and the Secretary of Agriculture shall jointly develop and disseminate model plans for—

(1) the decontamination of individuals, equipment, and facilities following an intentional contamination of agriculture or food; and

(2) the disposal of large quantities of animals, plants, or food products that have been infected or contaminated by specific threat agents and foreign animal diseases.

(d) EXERCISES.—In carrying out subsection (a), the Administrator, in coordination with the entities described in subsection (b), shall conduct exercises at least annually to evaluate and identify weaknesses in the decontamination and disposal model plans described in subsection (c). The exercises shall be carried out, to the maximum extent practicable, as part of the national exercise program under section 648(b)(1) of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. 748(b)(1)).

(e) MODIFICATIONS.—Based on the exercises described in subsection (d), the Administrator, in coordination with the entities described in subsection (b), shall re-

view and modify as necessary the plans described in subsection (c) not less frequently than biennially.

(f) PRIORITIZATION.—The Administrator, in coordination with the entities described in subsection (b), shall develop standards and plans under subsections (b) and (c) in an identified order of priority that takes into account—

(1) highest-risk biological, chemical, and radiological threat agents;

(2) agents that could cause the greatest economic devastation to the agriculture and food system; and

(3) agents that are most difficult to clean or remediate.

# Subchapter IV—Improving the Safety of Imported Food

### § 32551. Inspection by the Secretary of Commerce

(a) IN GENERAL.—The Secretary of Commerce, in coordination with the Secretary, may send 1 or more inspectors to a country or facility of an exporter from which seafood imported into the United States originates. The inspectors shall assess practices and processes used in connection with the farming, cultivation, harvesting, preparation for market, or transportation of the seafood and may provide technical assistance related to the activities.

(b) INSPECTION REPORT.—

(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Commerce, shall—

(A) prepare an inspection report for each inspection conducted under subsection (a);

(B) provide the report to the country or exporter that is the subject of the report; and

(C) provide a 30-day period during which the country or exporter may provide a rebuttal or other comments on the findings of the report to the Secretary.

(2) DISTRIBUTION AND USE OF REPORT.—The Secretary shall consider the inspection reports described in paragraph (1) in distributing inspection resources under section 11123 of this title.

**§ 32552. Foreign offices of the Food and Drug Administration**

(a) IN GENERAL.—The Secretary shall establish offices of the Food and Drug Administration in foreign countries selected by the Secretary to provide assistance to the appropriate governmental entities of the countries with respect to measures to provide for the safety of articles of food and other products regulated by the Food and Drug Administration exported by the country to the United States, including by directly conducting risk-based

inspections of the articles and supporting the inspections by the governmental entity.

(b) CONSULTATION.—In establishing the foreign offices described in subsection (a), the Secretary shall consult with the Secretary of State, the Secretary of Homeland Security, and the United States Trade Representative.

**§ 32553. Smuggled food**

(a) DEFINITION OF SMUGGLED FOOD.—In this subsection, the term ''smuggled food'' means any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.

(b) IN GENERAL.—The Secretary shall, in coordination with the Secretary of Homeland Security, develop and implement a strategy to better identify smuggled food and prevent entry of the food into the United States.

(c) NOTIFICATION TO HOMELAND SECURITY.—Not later than 10 days after the Secretary identifies a smuggled food that the Secretary believes would cause serious adverse health consequences or death to humans or animals, the Secretary shall provide to the Secretary of Homeland Security a notification under section 11119(n) of this title describing the smuggled food and, if available, the names of the individuals or entities that attempted to import the food into the United States.

(d) PUBLIC NOTIFICATION.—The Secretary shall promptly issue a press release describing a smuggled food and shall use other emergency communication or recall networks, as appropriate, to warn consumers and vendors about the potential threat described in this subsection if the Secretary—

(1) identifies the smuggled food;

(2) reasonably believes exposure to the food would cause serious adverse health consequences or death to humans or animals; and

(3) reasonably believes that the food has entered domestic commerce and is likely to be consumed.

(e) EFFECT OF SECTION.—Nothing in this section affects the authority of the Secretary to issue public notifications under other circumstances.

# Subchapter V—Miscellaneous Provisions

### § 32561. Effect of food safety modernization provisions on jurisdiction and authorities

Nothing in this chapter or an amendment made by the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) shall be construed—

(1) to alter the jurisdiction between the Secretary of Agriculture and the Secretary, under appli-

cable statutes, regulations, or agreements regarding voluntary inspection of non-amenable species under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.);

(2) to alter the jurisdiction between the Alcohol and Tobacco Tax and Trade Bureau and the Secretary, under applicable statutes and regulations;

(3) to limit the authority of the Secretary under—

(A) subtitle I of this title (as the Federal Food, Drug, and Cosmetic Act was in effect on January 3, 2011); or

(B) the Public Health Service Act (42 U.S.C. 201 et seq.) as in effect on January 3, 2011;

(4) to alter or limit the authority of the Secretary of Agriculture under the laws administered by the Secretary of Agriculture, including—

(A) chapter 303 of this title;

(B) chapter 313 of this title;

(C) chapter 317 of this title;

(D) the United States Grain Standards Act (7 U.S.C. 71 et seq.);

(E) the Packers and Stockyards Act, 1921 (7 U.S.C. 181 et seq.);

(F) the United States Warehouse Act (7 U.S.C. 241 et seq.);

(G) the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.); and

(H) the Agricultural Adjustment Act (7 U.S.C. 601 et seq.), reenacted with the amendments made by the Agricultural Marketing Agreement Act of 1937 (ch. 296, 50 Stat. 246); or

(5) to alter, impede, or affect the authority of the Secretary of Homeland Security under the Homeland Security Act of 2002 (6 U.S.C. 101 et seq.) or any other statute, including any authority related to securing the borders of the United States, managing ports of entry, or agricultural import and entry inspection activities.

**§ 32562. Effect of food safety modernization provisions on compliance with international agreements**

Nothing in this chapter or an amendment made by the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885) shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party.

# Chapter —Reserved

# Chapter 399—Miscellaneous

Sec.
39901. Consumer education.
39902. Food safety and security strategy.
39903. Regulation of export of shrimp to the United States.

## § 39901. Consumer education

The Secretary of Health and Human Services shall carry out activities that educate consumers about—

(1) the availability of nutrition information in the label or labeling of food; and

(2) the importance of that information in maintaining healthy dietary practices.

## § 39902. Food safety and security strategy

The President's Council on Food Safety (as established by Executive Order No. 13100) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. The strategy shall address threat assessments, technologies and procedures for securing food processing and manufacturing facilities and modes of transportation, response and notification procedures, and risk communications to the public.

**§ 39903. Regulation of export of shrimp to the United States**

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (''Commissioner''), shall develop and, if the Secretary determines it feasible, implement a number of options for regulating the export of shrimp to the United States from other countries, including the 3 largest exporting countries by volume to the United States over the last 3 calendar years, such as sampling of products prior to export to the United States, increasing foreign inspections of export facilities, increased seafood importer inspections, foreign surveillance inspections at overseas manufacturing sites, enhanced import screening, higher rates of examination and sampling, use of third-party audits, and formal seafood arrangements with foreign competent authorities.

(b) PRIORITY CONSIDERATIONS.—The Commissioner shall especially give priority consideration to the following with the funds appropriated:

(1) That appropriate controls are applied to shrimp feed and production ponds, processing plants, and facilities throughout the chain of distribution to determine compliance with seafood safety requirements.

(2) Dedicate its inspectional effort to determine compliance with seafood arrangements, once established, from any dedicated funds.

(3) Provide an annual report to the Committee before the end of fiscal years 2021, 2022, and 2023 with the reporting requirement goal being to provide the Committee information related to FDA's oversight of the safety of shrimp products imported into the United States.

# Subtitle IV—Pharmacology, Drugs, and Devices

# Chapter 401—Practice of Pharmacy and Sale of Poisons in Consular Districts in China

Sec.
40101. General provisions.
40102. Unlawful acts.
40103. Practitioners and other businesses.
40104. Application for license; qualifications.
40105. Issuance of license.
40106. Display of license in pharmacy.
40107. Revocation of license.
40108. Unlawful sales.
40109. Inapplicability of section 40108.
40110. Poisons.
40111. Pharmacist; unauthorized use of title.
40112. Prescription records.
40113. Criminal penalties; enforcement.
40114. Fraudulent representations to evade or defeat restrictions.

## § 40101. General provisions

(a) DEFINITION OF CONSUL.—In this chapter, the term ''consul'' means the consular officer in charge of the district concerned.

(b) POISON LABELING.—For the purpose of this chapter, a box, bottle, or other package shall not be regarded as having been labeled ''Poison'' unless the word ''Poison'' appears conspicuously on the box, bottle, or package, printed in plain, uncondensed gothic letters in red ink.

**§ 40102. Unlawful acts**

(a) UNLAWFUL MANAGEMENT OR COMPOUNDING IN CONSULAR DISTRICTS OF THE UNITED STATES IN CHINA.—Except as provided in this chapter, it is unlawful in the consular districts of the United States in China for any individual whose permanent allegiance is due to the United States, which individual is not licensed as a pharmacist within the meaning of this chapter—

(1) to conduct or manage any pharmacy, drug or chemical store, apothecary shop, or other place of business—

(A) for the retailing, compounding, or dispensing of any drugs, chemicals, or poisons; or

(B) for the compounding of physicians' prescriptions;

(2) to keep exposed for sale at retail, any drugs, chemicals, or poisons;

(3) to compound, dispense, or sell, at retail, any drug, chemical, poison, or pharmaceutical prepara-

tion on the prescription of a physician, or otherwise; or

(4) to compound physicians' prescriptions, except as an aid to and under the proper supervision of a pharmacist licensed under this chapter.

(b) UNLAWFUL COMPOUNDING, DISPENSING, OR SELLING.—It is unlawful for any individual, firm, or corporation owing permanent allegiance to the United States, which individual, firm, or corporation owns (partly or wholly) or manages a pharmacy, drug store, or other place of business, to cause or permit any individual other than a licensed pharmacist to compound, dispense, or sell at retail any drug, medicine, or poison, except as an aid to and under the proper supervision of a licensed pharmacist.

(c) EMPLOYMENT OF CHINESE SUBJECTS.—

(1) DEFINITION OF PHARMACY EMPLOYER.—In this subsection, the term ''pharmacy employer'' means an individual, firm, or corporation whose permanent allegiance is due to the United States and that owns (partly or wholly) or manages a pharmacy, drug store, or other place of business.

(2) ALLOWABLE EMPLOYMENT.—If necessary, a pharmacy employer may employ Chinese subjects to compound, dispense, or sell at retail any drug, medicine, or poison, if the character, ability, and attain-

ment of at least 21 years of age of the Chinese subjects are certified by at least—

(A) 2 recognized and reputable practitioners of medicine; or

(B) 2 pharmacists licensed under this chapter whose permanent allegiance is due to the United States.

**§ 40103. Practitioners and other businesses**

Nothing in section 40102 of this title shall be construed—

(1) to interfere with any recognized and reputable practitioner of medicine, dentistry, or veterinary surgery in the compounding of the practitioner's own prescriptions, or to prevent the practitioner from supplying to the practitioner's patients such medicines as the practitioner may consider proper, except as provided in this chapter;

(2) to interfere with the exclusively wholesale business of any individual, firm, or corporation whose permanent allegiance is due to the United States, which individual, firm, or corporation is dealing and licensed as a pharmacist or has in the individual's, firm's, or corporation's employ at least 1 individual that is licensed as a pharmacist, except as provided in this chapter; or

(3) to interfere with the sale, by any individual, firm, or corporation whose permanent allegiance is due to the United States (other than pharmacists), of poisonous substances sold exclusively for use in the arts, or as insecticides, if the substances are sold in unbroken packages bearing labels having plainly printed on them—

(A) the name of the contents;

(B) the word ''Poison'';

(C) if practicable, the name of at least 1 suitable antidote; and

(D) the name and address of the vendor.

**§ 40104. Application for license; qualifications**

(a) APPLICATION.—Each individual whose permanent allegiance is due to the United States desiring to practice as a pharmacist in the consular districts in China—

(1) shall file with the consul an application, verified under oath, setting forth—

(A) the name and age of the applicant;

(B) the place or places at which the applicant pursued, and the time spent in, the study of pharmacy;

(C) the experience that the applicant has had in compounding physicians' prescriptions

under the direction of a licensed pharmacist; and

(D) the name and location of the school or college of pharmacy, if any, of which the applicant is a graduate; and

(2) shall submit evidence sufficient to show to the satisfaction of the consul that the applicant is of good moral character and not addicted to the use of alcoholic liquors or narcotic drugs so as to render the applicant unfit to practice pharmacy.

(b) QUALIFICATIONS.—Applicants under this section—

(1) shall be not less than 21 years of age; and

(2)(A) shall have had at least 4 years of experience in the practice of pharmacy; or

(B) shall have served 3 years under the instruction of a regularly licensed pharmacist.

(c) GRADUATES OF SCHOOL OR COLLEGE OF PHARMACY.—Any applicant who has graduated from a school or college of pharmacy recognized by the proper board of a State, territory (including a possession) of the United States, or the District of Columbia as in good standing shall be entitled to practice on presentation of the applicant's diploma.

**§ 40105. Issuance of license**

If the applicant for a license as a pharmacist has complied with the requirements of section 40104 of this title, the consul shall issue to the applicant a license that entitles the applicant to practice pharmacy in the consular districts of the United States in China, subject to the provisions of this chapter.

**§ 40106. Display of license in pharmacy**

Each license to practice pharmacy shall be conspicuously displayed by the individual to whom the license has been issued in the pharmacy, drug store, or place of business, if any, of which the individual is the owner or part owner or manager.

**§ 40107. Revocation of license**

(a) IN GENERAL.—The license of any individual, whose permanent allegiance is due to the United States, to practice pharmacy in the consular districts of the United States in China may be revoked by the consul—

(1) if the individual is found—

(A) to have obtained the license by fraud, to be addicted to the use of any narcotic or stimulant, or to be suffering from physical or mental disease, in such manner and to such extent as to render it expedient that in the interests of the public, the individual's license be canceled; or

(B) to be of an immoral character; or

(2) if the individual is convicted in any court of competent jurisdiction of any offense involving moral turpitude.

(b) INVESTIGATION AND JUDGMENT BY CONSUL.—The consul—

(1) shall investigate any case in which the consul discovers, or it appears to the consul's satisfaction, that any license issued under this chapter is revocable; and

(2) shall, after full hearing, if in the consul's judgment the facts warrant revocation, revoke the license.

**§ 40108. Unlawful sales**

(a) IN GENERAL.—Except as provided under subsection (b), it shall be unlawful for any individual, firm, or corporation whose permanent allegiance is due to the United States, either personally or by an agent or as the agent of any other individual or of any firm or corporation, to sell, furnish, or give away—

(1) any cocaine, salts of cocaine, or preparation containing cocaine or salts of cocaine;

(2) any morphine or preparation containing morphine or salts of morphine;

(3) any opium or preparation containing opium; or

(4) any chloral hydrate or preparation containing chloral hydrate.

(b) EXCEPTION.—Selling, furnishing, or giving away an article as described in subsection (a) is not unlawful if done on the original written order or prescription of a recognized and reputable practitioner of medicine, dentistry, or veterinary medicine, which order or prescription shall be dated and shall contain the name of the individual for whom prescribed, or, if ordered by a practitioner of veterinary medicine, shall state the kind of animal for which ordered and shall be signed by the individual giving the order or prescription.

(c) RECORDKEEPING.—The individual, firm, or corporation that compounds or dispenses the article ordered or prescribed under subsection (b) shall, for a period of 3 years, retain on file the order or prescription under subsection (b).

(d) SUBSEQUENT COMPOUNDING OR DISPENSING.—The article ordered or prescribed shall not be compounded or dispensed after the first time except on the written order of the original prescriber.

**§ 40109. Inapplicability of section 40108**

(a) IN GENERAL.—Section 40108 of this title shall not apply—

(1) to preparations containing—

(A) not more than 2 grains of opium;

(B) not more than ¼ grain of morphine;

(C) not more than ¼ grain of cocaine; or

(D) not more than 2 grains of chloral hydrate in the fluid ounce, or, of a solid preparation, in 1 avoirdupois ounce;

(2) to preparations sold in good faith for diarrhea and cholera, each bottle or package of which is accompanied by specific directions for use and caution against habitual use;

(3) to liniments or ointments sold in good faith as liniments or ointments, respectively, when plainly labeled ''for external use only''; or

(4) to powder of ipecac and opium, commonly known as Dover's powder, when sold in quantities not exceeding 20 grains.

(b) EFFECT OF PROVISIONS ON GIVING HABITUAL USERS SPECIFIED SUBSTANCES.—

(1) IN GENERAL.—This section and section 40108 of this title shall not be construed to permit the selling, furnishing, giving away, or prescribing for the use of any habitual users of the same—

(A) any cocaine, salts of cocaine, or preparation containing cocaine or salts of cocaine;

(B) morphine or salts of morphine, or preparations containing morphine or salts of morphine;

(C) any opium or preparation containing opium; or

(D) any chloral hydrate or preparation containing chloral hydrate.

(2) INAPPLICABILITY.—Paragraph (1) shall not be construed to prevent any recognized or reputable practitioner of medicine whose permanent allegiance is due to the United States from furnishing in good faith for the use of any habitual user of narcotic drugs who is under the practitioner's professional care such substances as the practitioner may consider necessary for the treatment of the habitual user, if the prescriptions are not given or the substances are not furnished for the purpose of evading the provisions of this section or section 40108 of this title.

(c) EFFECT ON WHOLESALE.—This section and section 40108 of this title shall not apply to sales at wholesale between jobbers, manufacturers, and retail druggists, hospitals, and scientific or public institutions.

**§ 40110. Poisons**

(a) UNLAWFUL ACTS.—

(1) IN GENERAL.—It shall be unlawful for any individual, firm, or corporation whose permanent allegiance is due to the United States to sell or deliver to any other individual any substance described in paragraph (2), or any poisonous compound, combination, or preparation of a substance described in paragraph (2)—

(A) except as provided in this section; and

(B) if the applicant is less than 18 years of age, except on the written order of an individual known or believed to be an adult.

(2) SUBSTANCES.—The substances referred to in paragraph (1) are the following:

(A) The compounds of and salts of antimony, arsenic, barium, chromium, copper, gold, lead, mercury, silver, and zinc.

(B) The caustic hydrates of sodium and potassium.

(C) Solution or water of ammonia, methyl alcohol, paregoric, the concentrated mineral acids, oxalic and hydrocyanic acids and their salts, yellow phosphorus, Paris green, and carbolic acid.

(D) The essential oils of almonds, pennyroyal, tansy, rue, and savin.

(E) Croton oil, creosote, chloroform, cantharides, or aconite, belladonna, bitter almonds, colchicum, cotton root, cocculus indicus, conium, cannabis indica, digitalis, ergot, hyoscyamus, ignatia, lobelia, nux vomica, physostigma, phytolacca, strophanthus, stramonium, and veratrum viride.

(F) Any of the poisonous alkaloids or alkaloidal salts derived from the substances listed in subparagraphs (A) through (E), or any other poisonous alkaloids or their salts, or any other virulent poison.

(b) AUTHORIZED SALE AND DELIVERY.—Prior to sale or delivery of a substance described in subsection (a)—

(1) it shall first be learned, by due inquiry, that—

(A) the individual to whom delivery is about to be made is aware of the poisonous character of the substance; and

(B) the substance is desired for a lawful purpose; and

(2) the box, bottle, or other package shall be plainly labeled with the name of the substance, the word ''Poison'', the name of at least 1 suitable antidote, if practicable, and the name and address of the individual, firm, or corporation dispensing the substance.

(c) RECORDKEEPING.—

(1) IN GENERAL.—Before delivery of a substance described in subsection (a), except solution or water of ammonia and sulphate of copper, there shall be recorded in a book—

(A) the name of the article;

(B) the quantity delivered;

(C) the purpose for which the article is to be used;

(D) the date of delivery;

(E) the name and address of the individual for whom the article is procured; and

(F) the name of the individual personally dispensing the article.

(2) MAINTENANCE.—The owner of the book under paragraph (1) shall preserve the book for at least 3 years after the date of the last entry in the book.

(d) ARTICLES DISPENSED ON ORDER OF INDIVIDUALS BELIEVED TO BE PRACTITIONERS.—Subsections (a) through (c) shall not apply to articles dispensed on the order of individuals believed by the dispenser to be recognized and reputable practitioners of medicine, dentistry, or veterinary surgery.

(e) LABELING AT THE REQUEST OF PHYSICIAN.—If a physician writes on the physician's prescription a request that an article be marked or labeled ''Poison'', the pharmacist shall, in the case of liquids, place the liquid in a colored glass, roughened bottle, of the kind commonly known in trade as a ''poison bottle'', and, in the case of dry substances, the pharmacist shall place a poison label on the container.

(f) SALES AT WHOLESALE TO LICENSED PHARMACISTS.—The record of sale and delivery described in subsection (c) shall not be required of manufacturers and wholesalers that sell a substance described in subsection (a) at wholesale to licensed pharmacists, but the box, bottle, or other package containing the substance, when sold at wholesale, shall be properly labeled with the name of the substance, the word ''Poison'', and the name and address of the manufacturer or wholesaler.

(g) LABELING AND RECORDKEEPING FOR CERTAIN SUBSTANCES.—It is not necessary, in sales either at

wholesale or at retail, to place a poison label on, or to record the delivery of—

(1) the sulphide of antimony, or the oxide or carbonate of zinc, or of colors ground in oil and intended for use as paints, or calomel;

(2) preparations containing any of the substances named in this section, if a single box, bottle, or other package, or if the bulk of ½ fluid ounce or the weight of ½ avoirdupois ounce, does not contain more than an adult medicinal dose of the substance;

(3) liniments or ointments sold in good faith as liniments or ointments, respectively, if plainly labeled ''For external use only''; or

(4) preparations put up and sold in the form of pills, tablets, or lozenges, containing any of the substances enumerated in this section and intended for internal use, if the dose recommended does not contain more than ¼ of an adult medicinal dose of the substance.

**§ 40111. Pharmacist; unauthorized use of title**

It shall be unlawful for any individual whose permanent allegiance is due to the United States, which individual is not legally licensed as a pharmacist, to take, use, or exhibit the title of pharmacist, or licensed or registered

pharmacist, or the title of druggist or apothecary, or any other title or description of like import.

**§ 40112. Prescription records**

(a) IN GENERAL.—Each individual, firm, or corporation whose permanent allegiance is due to the United States, which individual, firm, or corporation owns, partly owns, or manages a drug store or pharmacy, shall keep in the individual's, firm's, or corporation's place of business a suitable book or file, in which shall be preserved for a period of not less than 3 years the original of every prescription compounded or dispensed at the drug store or pharmacy, or a copy of the prescription, except if the preservation of the original is required by section 40108 or 40109 of this title.

(b) PROVISION UPON REQUEST.—On request, the owner, part owner, or manager of the drug store or pharmacy under subsection (a) shall furnish to the prescribing physician, or to the individual for whom the prescription was compounded or dispensed, a true and correct copy of the prescription.

(c) INSPECTIONS.—Any prescription required by section 40108 or 40109 of this title, and any prescription for, or register of sales of, substances mentioned in those sections shall at all times be open to inspection by author-

ized consular officers in the consular districts of the United States in China.

(d) NAME OF DRUG AND DIRECTIONS ON CONTAINERS.—An individual, firm, or corporation whose permanent allegiance is due to the United States shall not, in a consular district, compound or dispense any drug or deliver the drug to any other individual without marking on the container of the drug the name of the drug or drugs contained in the container and directions for using the drug.

**§ 40113. Criminal penalties; enforcement**

(a) CRIMINAL PENALTIES.—

(1) IN GENERAL.—Any individual, firm, or corporation, whose permanent allegiance is due to the United States, that violates this chapter shall be imprisoned for not less than 1 month and not more than 60 days, fined under title 18 but not less than $50, or both.

(2) SEPARATE AND DISTINCT OFFENSE.—If the offense is continuing in its character, each week or part of a week during which the offense continues shall constitute a separate and distinct offense.

(b) ENFORCEMENT.—Consular and judicial officers of the United States in China shall enforce the provisions of this chapter.

### § 40114. Fraudulent representations to evade or defeat restrictions

An individual, firm, or corporation whose permanent allegiance is due to the United States seeking to procure in the consular districts of the United States in China any substance the sale of which is regulated by this chapter shall not make any fraudulent representations so as to evade or defeat the restrictions imposed in this chapter.

# Chapter 403—Improvements on Regulation of Drugs

Sec.
40301. Data requirements for drugs and biologics.
40302. Approval procedures and current good manufacturing requirements for positron emission tomography drugs.
40303. Approval of radiopharmaceuticals.
40304. Minimizing differences in the review and approval of biologics license applications and new drug applications.
40305. Regulations for over-the-counter sunscreen products.

### § 40301. Data requirements for drugs and biologics

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 13503 of this title and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies.

(b) CONTENTS.—The guidance under subsection (a) shall describe the kinds of studies for which abbreviated

reports are appropriate and the appropriate abbreviated report formats.

**§ 40302. Approval procedures and current good manufacturing requirements for positron emission tomography drugs**

(a) DEFINITION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUG.—In this section, the term ''compounded positron emission tomography drug'' has the meaning given the term in section 10101 of this title.

(b) PROCEDURES AND REQUIREMENTS.—

(1) IN GENERAL.—In order to take account of the special characteristics of positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after November 21, 1997, the Secretary shall establish—

(A) appropriate procedures for the approval of positron emission tomography drugs pursuant to chapter 135 of this title; and

(B) appropriate current good manufacturing practice requirements for positron emission tomography drugs.

(2) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by paragraph (1), the Secretary of Health

and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use positron emission tomography drugs.

(c) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary of Health and Human Services shall not require the submission of new drug applications under section 13503 of this title or abbreviated new drug applications under section 13511 of this title for compounded positron emission tomography drugs that are not adulterated drugs described in section 13101(a)(2)(B)(iii) of this title for a period of 4 years after November 21, 1997, or for 2 years after the date on which the Secretary establishes procedures and requirements under subsection (b), whichever is longer.

(2) EXCEPTION FOR VOLUNTARY SUBMISSIONS.—Nothing in this chapter or in the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2296) shall prohibit the voluntary submission of applications described in paragraph (1) or the review of the applications by the Secretary.

(3) PROVISIONS NOT TO EXEMPT POSITRON EMISSION TOMOGRAPHY DRUGS FROM SECTION 13510.—Nothing in this chapter or in the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2296) shall constitute an exemption for a positron emission tomography drug from the requirements of regulations issued under section 13510 of this title.

**§ 40303. Approval of radiopharmaceuticals**

(a) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any article described in paragraph (1).

(b) REGULATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue regulations governing the approval of radiopharmaceuticals.

(2) CONTENTS.—The regulations shall provide that the determination of the safety and effectiveness of a radiopharmaceutical under chapter 135 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include—

(A) consideration of the proposed use of the radiopharmaceutical in the practice of medicine;

(B) the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical); and

(C) the estimated absorbed radiation dose of the radiopharmaceutical.

(c) SPECIAL RULE.—In the case of a radiopharmaceutical, the indications for which the radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, 1 or more disease states.

### § 40304. Minimizing differences in the review and approval of biologics license applications and new drug applications

The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applications under section 13503(a) of this title.

### § 40305. Regulations for over-the-counter sunscreen products

The Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

# Chapter 405—Biomaterials Access Assurance

Sec.
40501. Definitions.
40502. General requirements; applicability; preemption.
40503. Liability of biomaterials suppliers.

40504. Procedures for dismissal of civil actions against biomaterials suppliers.
40505. Subsequent impleader of dismissed biomaterials supplier.

**§ 40501. Definitions**

In this chapter:

(1) BIOMATERIALS SUPPLIER.—

(A) IN GENERAL.—The term ''biomaterials supplier'' means an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant.

(B) INCLUSIONS.—The term ''biomaterials supplier'' includes any person that—

(i) has submitted master files to the Secretary for purposes of premarket approval of a medical device; or

(ii) licenses a biomaterials supplier to produce component parts or raw materials.

(2) CLAIMANT.—

(A) IN GENERAL.—The term ''claimant'' means any person that brings a civil action, or on whose behalf a civil action is brought, arising from harm allegedly caused directly or indirectly by an implant, including a person other than the individual—

(i)(I) into whose body the implant is placed, or

(II) with whose blood or tissue the implant is in contact; and

(ii) who claims to have suffered harm as a result of the implant.

(B) ACTION BROUGHT ON BEHALF OF AN ESTATE.—With respect to an action brought on behalf of or through the estate of a deceased individual into whose body the implant was placed or with whose blood or tissue the implant was in contact, the term ''claimant'' includes the decedent that is the subject of the action.

(C) ACTION BROUGHT ON BEHALF OF A MINOR OR INCOMPETENT.—With respect to an action brought on behalf of or through a minor or incompetent, the term ''claimant'' includes the parent or guardian of the minor or incompetent.

(D) EXCLUSIONS.—The term ''claimant'' does not include—

(i) a provider of professional health care services in any case in which—

(I) the sale or use of an implant is incidental to the services; and

(II) the essence of the professional health care services provided is

the furnishing of judgment, skill, or services;

(ii) a person acting in the capacity of a manufacturer, seller, or biomaterials supplier; or

(iii) a person alleging harm caused by either the silicone gel or the silicone envelope utilized in a breast implant containing silicone gel, except that—

(I) neither the exclusion provided by this clause nor any other provision of this chapter may be construed as a finding that silicone gel (or any other form of silicone) may or may not cause harm; and

(II) the existence of the exclusion under this clause may not—

(aa) be disclosed to a jury in any civil action or other proceeding; and

(bb) except as necessary to establish the applicability of this chapter, otherwise be presented in any civil action or other proceeding.

(3) COMPONENT PART.—

(A) IN GENERAL.—The term ''component part'' means a manufactured piece of an implant.

(B) CERTAIN COMPONENTS.—The term ''component part'' includes a manufactured piece of an implant that—

(i) has significant non-implant applications; and

(ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant.

(4) HARM.—

(A) IN GENERAL.—The term ''harm'' means—

(i) any injury to or damage suffered by an individual;

(ii) any illness, disease, or death of that individual resulting from that injury or damage; and

(iii) any loss to that individual or any other individual resulting from that injury or damage.

(B) EXCLUSION.—The term ''harm'' does not include any commercial loss or loss of or damage to an implant.

(5) IMPLANT.—The term ''implant'' means—

(A) a medical device that is intended by the manufacturer of the device—

(i) to be placed into a surgically or naturally formed or existing cavity of the body for a period of at least 30 days; or

(ii) to remain in contact with bodily fluids or internal human tissue through a surgically produced opening for a period of less than 30 days; and

(B) suture materials used in implant procedures.

(6) MANUFACTURER.—The term ''manufacturer'' means any person that, with respect to an implant—

(A) is engaged in the manufacture, preparation, propagation, compounding, or processing (as defined in section 13136(a) of this title) of the implant; and

(B) is required—

(i) to register with the Secretary pursuant to section 13136 of this title and the regulations issued under that section; and

(ii) to include the implant on a list of devices filed with the Secretary pursuant to section 13136(j) of this title and the regulations issued under that section.

(7) MEDICAL DEVICE.—The term ''medical device'' means a device, as defined in section 10101(a) of this title, and includes any device component of any combination product as that term is used in section 13104 of this title.

(8) RAW MATERIAL.—The term ''raw material'' means a substance or product that—

(A) has a generic use; and

(B) may be used in an application other than an implant.

(9) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(10) SELLER.—

(A) IN GENERAL.—The term ''seller'' means a person that, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce.

(B) EXCLUSIONS.—The term ''seller'' does not include—

(i) a seller or lessor of real property;

(ii) a provider of professional health care services in any case in which—

(I) the sale or use of the implant is incidental to the services; and

(II) the essence of the professional health care services provided is the furnishing of judgment, skill, or services; or

(iii) any person that acts in only a financial capacity with respect to the sale of an implant.

**§ 40502. General requirements; applicability; preemption**

(a) GENERAL REQUIREMENTS.—

(1) IN GENERAL.—In any civil action covered by this chapter, a biomaterials supplier may—

(A) raise any exclusion from liability set forth in section 40503 of this title; and

(B) make a motion for dismissal or for summary judgment as set forth in section 40504 of this title.

(2) PROCEDURES.—Notwithstanding any other provision of law, a Federal or State court in which an action covered by this chapter is pending shall, in connection with a motion under section 40504 or 40505 of this title, use the procedures set forth in this chapter.

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (2), this chapter applies to any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant.

(2) EXCLUSION.—A civil action brought by a purchaser of a medical device, purchased for use in providing professional health care services, for loss or damage to an implant or for commercial loss to the purchaser—

(A) shall not be considered an action that is subject to this chapter; and

(B) shall be governed by applicable commercial or contract law.

(c) SCOPE OF PREEMPTION.—

(1) IN GENERAL.—This chapter supersedes any State law regarding recovery for harm caused by an

implant and any rule of procedure applicable to a civil action to recover damages for the harm only to the extent that this chapter establishes a rule of law applicable to the recovery of the damages.

(2) APPLICABILITY OF OTHER LAWS.—Any issue that arises under this chapter and that is not governed by a rule of law applicable to the recovery of damages described in paragraph (1) shall be governed by applicable Federal or State law.

(d) EFFECT OF CHAPTER.—Nothing in this chapter may be construed—

(1) to affect any defense available to a defendant under any other provisions of Federal or State law in an action alleging harm caused by an implant; or

(2) to create a cause of action or Federal court jurisdiction pursuant to section 1331 or 1337 of title 28 that otherwise would not exist under applicable Federal or State law.

**§ 40503. Liability of biomaterials suppliers**

(a) IN GENERAL.—Except as provided in section 40505 of this title, a biomaterials supplier shall not be liable for harm to a claimant caused by an implant unless the supplier is liable—

(1) as a manufacturer of the implant, as provided in subsection (b);

(2) as a seller of the implant, as provided in subsection (c); or

(3) for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in subsection (d).

(b) LIABILITY AS MANUFACTURER.—

(1) IN GENERAL.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the biomaterials supplier is the manufacturer of the implant.

(2) GROUNDS FOR LIABILITY.—The biomaterials supplier may be considered the manufacturer of the implant that allegedly caused harm to a claimant only if the biomaterials supplier—

(A)(i) registered or was required to register with the Secretary pursuant to section 13136 of this title and the regulations issued under that section; and

(ii) included or was required to include the implant on a list of devices filed with the Sec-

retary pursuant to section 13136(j) of this title and the regulations issued under that section;

(B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier, with respect to the implant that allegedly caused harm to the claimant, was required to—

(i) register with the Secretary under section 13136 of this title, and the regulations issued under that section, but failed to do so; or

(ii) include the implant on a list of devices filed with the Secretary pursuant to section 13136(j) of this title and the regulations issued under that section, but failed to do so; or

(C) is related by common ownership or control to a person meeting all the requirements described in subparagraph (A) or (B), if the court deciding a motion to dismiss in accordance with section 40504(c)(3)(B)(i) of this title finds, on the basis of affidavits submitted in accordance with section 40504 of this title, that it is necessary to impose liability on the biomaterials supplier as a manufacturer because

the related manufacturer meeting the requirements of subparagraph (A) or (B) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(3) ADMINISTRATIVE PROCEDURES.—

(A) IN GENERAL.—The Secretary may issue a declaration described in paragraph (2)(B) on the motion of the Secretary or on petition by any person, after providing—

(i) notice to the affected persons; and

(ii) an opportunity for an informal hearing.

(B) DOCKETING AND FINAL DECISION.—Immediately on receipt of a petition filed pursuant to this paragraph, the Secretary shall docket the petition. Not later than 120 days after the petition is filed, the Secretary shall issue a final decision on the petition.

(C) APPLICABILITY OF STATUTE OF LIMITATIONS.—Any applicable statute of limitations shall toll during the period from the time a claimant files a petition with the Secretary under this paragraph until—

(i) the Secretary issues a final decision on the petition; or

(ii) the petition is withdrawn.

(D) STAY PENDING PETITION FOR DECLARATION.—If a claimant has filed a petition for a declaration with respect to a defendant, and the Secretary has not issued a final decision on the petition, the court shall stay all proceedings with respect to that defendant until such time as the Secretary issues a final decision on the petition.

(c) LIABILITY AS SELLER.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable as a seller for harm to a claimant caused by an implant only if—

(1) the biomaterials supplier—

(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or

(B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or

(2) the biomaterials supplier is related by common ownership or control to a person meeting all the

requirements described in paragraph (1), if a court deciding a motion to dismiss in accordance with section 40504(c)(3)(B)(ii) of this title finds, on the basis of affidavits submitted in accordance with section 40504 of this title, that it is necessary to impose liability on the biomaterials supplier as a seller because the related seller meeting the requirements of paragraph (1) lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail.

(d) LIABILITY FOR FAILURE TO MEET APPLICABLE CONTRACTUAL REQUIREMENTS OR SPECIFICATIONS.—A biomaterials supplier may, to the extent required and permitted by any other applicable law, be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence, that—

(1) the biomaterials supplier supplied raw materials or component parts for use in the implant that—

(A) did not constitute the product described in the contract between the biomaterials supplier and the person that contracted for the supplying of the product; or

(B) failed to meet any specifications that were—

(i) accepted, pursuant to applicable law, by the biomaterials supplier;

(ii) published by the biomaterials supplier;

(iii) provided by the biomaterials supplier to the person that contracted for the product;

(iv) contained in a master file that was submitted by the biomaterials supplier to the Secretary and that is currently maintained by the biomaterials supplier for purposes of premarket approval of medical devices; or

(v) included in the submissions for purposes of premarket approval or review by the Secretary under section 13136, 13140, 13142, or 13152 of this title, which specifications received clearance from the Secretary if the specifications were accepted, pursuant to applicable law, by the biomaterials supplier; and

(2) the failure to meet applicable contractual requirements or specifications was an actual and proximate cause of the harm to the claimant.

**§ 40504. Procedures for dismissal of civil actions against biomaterials suppliers**

(a) MOTION TO DISMISS.—A defendant may, at any time during which a motion to dismiss may be filed under applicable law, move to dismiss an action against it on the grounds that the defendant is a biomaterials supplier and 1 or more of the following apply:

(1) The defendant is not liable as a manufacturer, as provided in section 40503(b) of this title.

(2) The defendant is not liable as a seller, as provided in section 40503(c) of this title.

(3) The defendant is not liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in section 40503(d) of this title.

(4) The claimant did not name the manufacturer as a party to the action, as provided in subsection (b).

(b) MANUFACTURER OF IMPLANT SHALL BE NAMED A PARTY.—In any civil action covered by this chapter, the claimant shall be required to name the manufacturer of the implant as a party to the action, unless—

(1) the manufacturer is subject to service of process solely in a jurisdiction in which the biomate-

rials supplier is not domiciled or subject to a service of process; or

(2) a claim against the manufacturer is barred by applicable law or rule of practice.

(c) PROCEEDING ON MOTION TO DISMISS.—The following rules shall apply to any proceeding on a motion to dismiss filed by a defendant under this section:

(1) EFFECT OF MOTION TO DISMISS ON DISCOVERY.—

(A) IN GENERAL.—Except as provided in subparagraph (B), if a defendant files a motion to dismiss under subsection (a), no discovery shall be permitted in connection with the action that is the subject of the motion, other than discovery necessary to determine a motion to dismiss for lack of jurisdiction, until such time as the court rules on the motion to dismiss.

(B) DISCOVERY.—If a defendant files a motion to dismiss under subsection (a)(3) on the grounds that it did not furnish raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, the court may permit discovery limited to issues that are directly relevant to—

(i) the pending motion to dismiss; or

(ii) the jurisdiction of the court.

(2) AFFIDAVITS.—

(A) DEFENDANT.—A defendant may submit affidavits supporting the grounds for dismissal contained in its motion to dismiss under subsection (a). If the motion is made under subsection (a)(1), the defendant may submit an affidavit demonstrating that the defendant has not included the implant on a list, if any, filed with the Secretary pursuant to section 13136(j) of this title.

(B) CLAIMANT.—In response to a motion to dismiss, the claimant may submit affidavits demonstrating that—

(i) the Secretary has, with respect to the defendant and the implant that allegedly caused harm to the claimant, issued a declaration pursuant to section 40503(b)(2)(B) of this title; or

(ii) the defendant is a seller of the implant that is liable under section 40503(c) of this title.

(3) BASIS OF RULING ON MOTION TO DISMISS.—The court shall rule on a motion to dismiss

filed under subsection (a) solely on the basis of the pleadings and affidavits of the parties made pursuant to this subsection. The court shall grant a motion to dismiss filed under subsection (a)—

(A) unless the claimant submits a valid affidavit that demonstrates that the defendant is not a biomaterials supplier;

(B) unless the court determines, to the extent raised in the pleadings and affidavits, that 1 or more of the following apply:

(i) the defendant may be liable as a manufacturer, as provided in section 40503(b) of this title;

(ii) the defendant may be liable as a seller, as provided in section 40503(c) of this title; or

(iii) the defendant may be liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications, as provided in section 40503(d) of this title; or

(C) if the claimant did not name the manufacturer as a party to the action, as provided in subsection (b).

(4) TREATMENT OF MOTION AS MOTION FOR SUMMARY JUDGMENT.—The court may treat a motion to dismiss as a motion for summary judgment subject to subsection (d) to determine whether the pleadings and affidavits, in connection with the action, raise genuine issues of material fact concerning whether the defendant furnished raw materials or component parts of the implant that failed to meet applicable contractual requirements or specifications as provided in section 40503(d) of this title.

(d) SUMMARY JUDGMENT.—

(1) IN GENERAL.—

(A) BASIS FOR ENTRY OF JUDGMENT.—If a biomaterials supplier's motion to dismiss is to be treated as a motion for summary judgment under subsection (c)(4) or if a biomaterials supplier moves for summary judgment, the biomaterials supplier shall be entitled to entry of judgment without trial if the court finds there is no genuine issue of material fact for each applicable element set forth in paragraphs (1) and (2) of section 40503(d) of this title.

(B) ISSUES OF MATERIAL FACT.—With respect to a finding made under subparagraph (A), the court shall consider a genuine issue of

material fact to exist only if the evidence submitted by the claimant would be sufficient to allow a reasonable jury to reach a verdict for the claimant if the jury found the evidence to be credible.

(2) DISCOVERY MADE PRIOR TO A RULING ON A MOTION FOR SUMMARY JUDGMENT.—If, under applicable rules, the court permits discovery prior to a ruling on a motion for summary judgment governed by section 40503(d) of this title, the discovery shall be limited solely to establishing whether a genuine issue of material fact exists as to the applicable elements set forth in paragraphs (1) and (2) of section 40503(d) of this title.

(3) DISCOVERY WITH RESPECT TO A BIOMATERIALS SUPPLIER.—A biomaterials supplier shall be subject to discovery in connection with a motion seeking dismissal or summary judgment on the basis of the inapplicability of section 40503(d) of this title or the failure to establish the applicable elements of section 40503(d) of this title solely to the extent permitted by the applicable Federal or State rules for discovery against nonparties.

(e) DISMISSAL WITH PREJUDICE.—An order granting a motion to dismiss or for summary judgment pursu-

ant to this section shall be entered with prejudice, except to the extent that the moving defendant may be rejoined to the action as provided in section 40505 of this title.

(f) MANUFACTURER CONDUCT OF LITIGATION.—The manufacturer of an implant that is the subject of an action covered under this chapter shall be permitted to conduct litigation on any motion for summary judgment or dismissal filed by a biomaterials supplier who is a defendant under this section on behalf of the supplier if the manufacturer and any other defendant in the action enter into a valid and applicable contractual agreement under which the manufacturer agrees to bear the cost of the litigation or to conduct the litigation.

**§ 40505. Subsequent impleader of dismissed biomaterials supplier**

(a) IMPLEADING OF DISMISSED DEFENDANT.—A court, on motion by a manufacturer or a claimant within 90 days after entry of a final judgment in an action by the claimant against a manufacturer, and notwithstanding any otherwise applicable statute of limitations, may implead a biomaterials supplier who has been dismissed from the action pursuant to this chapter if—

(1) the manufacturer has made an assertion, in a motion or other pleading filed with the court, in an opening or closing statement at trial, or as part

of a claim for contribution or indemnification, and the court finds based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the manufacturer's liability for damages should be reduced in whole or in part because of the negligence or intentionally tortious conduct; or

(2) the claimant has moved to implead the supplier and the court finds, based on the court's independent review of the evidence contained in the record of the action, that under applicable law—

(A) the negligence or intentionally tortious conduct of the dismissed supplier was an actual and proximate cause of the harm to the claimant; and

(B) the claimant is unlikely to be able to recover the full amount of its damages from the remaining defendants.

(b) STANDARD OF LIABILITY.—Notwithstanding any preliminary finding under subsection (a), a biomaterials

supplier who has been impleaded into an action covered by this chapter, as provided for in this section—

(1) may, prior to entry of judgment on the claim against it, supplement the record of the proceeding that was developed prior to the grant of the motion for impleader under subsection (a); and

(2) may be found liable to a manufacturer or a claimant only to the extent required and permitted by any applicable State or Federal law other than this chapter.

(c) DISCOVERY.—Nothing in this section shall give a claimant or any other party the right to obtain discovery from a biomaterials supplier at any time prior to grant of a motion for impleader beyond that allowed under section 40504 of this title.

# Chapter 407—Federal Trade Commission Review of Agreements Relating to Generic Drugs and Brand Name Drugs

Sec.
40701. Definitions.
40702. Notification of agreements.
40703. Filing deadline.
40704. Disclosure exemption.
40705. Enforcement.
40706. Rulemaking.
40707. Effect of chapter.

## § 40701. Definitions

In this chapter:

(1) ANDA.—The term ''ANDA'' means an abbreviated drug application, as defined under section 10101(a) of this title.

(2) ASSISTANT ATTORNEY GENERAL.—The term ''Assistant Attorney General'' means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BIOSIMILAR BIOLOGICAL PRODUCT.—The term ''biosimilar biological product'' means a biological product for which a biosimilar biological product application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved.

(4) BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.—The term ''biosimilar biological product applicant'' means a person that has filed or received approval for a biosimilar biological product application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(5) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—The term ''biosimilar biological product application'' means an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) for licensure of a biological product as biosimilar to, or interchangeable with, a reference product.

(6) BRAND NAME DRUG.—The term ''brand name drug'' means a drug for which an application is approved under section 13504 of this title, including an application referred to in section 13503(b) of this title, or a biological product for which an application is approved under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(7) BRAND NAME DRUG COMPANY.—The term ''brand name drug company'' means the party that holds the approved application referred to in paragraph (6) for a brand name drug that is a listed drug in an ANDA or a reference product in a biosimilar biological product application, or a party that is the owner of a patent for which information is submitted for the drug under section 13503 or 13504 of this title or the owner, or exclusive licensee, of a patent included in a list provided under section 351(l)(3) of the Public Health Service Act (42 U.S.C. 262(l)(3)).

(8) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(9) GENERIC DRUG.—The term ''generic drug'' means a drug for which an application under section 13511 of this title is approved.

(10) GENERIC DRUG APPLICANT.—The term ''generic drug applicant'' means a person that has filed or received approval for an ANDA under section 13511 of this title.

(11) LISTED DRUG.—The term ''listed drug'' means a brand name drug that is listed under section 13511(h) of this title.

(12) REFERENCE PRODUCT.—The term ''reference product'' has the meaning given the term in section 351(i) of the Public Health Service Act (21 U.S.C. 262(i)).

**§ 40702. Notification of agreements**

(a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

(1) REQUIREMENT.—

(A) IN GENERAL.—A generic drug applicant that has submitted an ANDA containing a certification under section 13511(c)(1)(G)(iv) of this title or a biosimilar biological product applicant that has submitted a biosimilar biological product application and a brand name drug company that enter into an agreement described in paragraph (2) shall each file the agreement in accordance with subsection (c).

(B) DATE OF FILING.—The agreement shall be filed prior to the date of the first commercial marketing of the generic drug that is the subject of the ANDA or the biosimilar biological product that is the subject of the biosimilar biological product application, as applicable.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph between a generic drug applicant or a biosimilar biological product applicant and a brand name drug company is an agreement regarding—

(A) the manufacture, marketing, or sale of the brand name drug that is the listed drug in the ANDA or the reference product in the biosimilar biological product application involved;

(B) the manufacture, marketing, or sale of the generic drug for which the ANDA was submitted or of the biosimilar biological product for which the biosimilar biological product application was submitted; or

(C) as applicable—

(i) the 180-day period referred to in section 13511(f)(2)(D) of this title as it

applies to the ANDA or to any other ANDA based on the same listed drug; or

(ii) any of the time periods referred to in section 351(k)(6) of the Public Health Service Act (42 U.S.C. 262(k)(6)) as the period applies to the biosimilar biological product application or to any other biosimilar biological product application based on the same reference product.

(b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLICANT OR BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT.—

(1) REQUIREMENT.—

(A) GENERIC DRUGS.—A generic drug applicant that has submitted an ANDA containing a certification under section 13511(c)(1)(G)(iv) of this title with respect to a listed drug and another generic drug applicant that has submitted an ANDA containing such a certification for the same listed drug, where the generic drug applicants enter into an agreement described in paragraph (2), shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of

the generic drugs for which the ANDAs were submitted.

(B) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biosimilar biological product applicant that has submitted a biosimilar biological product application that references a reference product and another biosimilar biological product applicant that has submitted a biosimilar biological product application that references the same reference product, where the biosimilar biological product applicants enter into an agreement described in paragraph (2), shall each file the agreement in accordance with subsection (c). The agreement shall be filed prior to the date of the first commercial marketing of either of the biosimilar biological products for which the biosimilar biological product applications were submitted.

(2) SUBJECT MATTER OF AGREEMENT.—An agreement described in this paragraph is, as applicable—

(A) an agreement between 2 or more generic drug applicants regarding the 180-day period referred to in section 13511(f)(2)(D) of

this title as it applies to the ANDAs with which the agreement is concerned;

(B) an agreement between 2 or more biosimilar biological product applicants regarding a time period referred to in section 351(k)(6) of the Public Health Service Act (42 U.S.C. 262(k)(6)) as it applies to the biosimilar biological product; or

(C) an agreement between 2 or more biosimilar biological product applicants regarding the manufacture, marketing, or sale of a biosimilar biological product.

(c) FILING.—

(1) AGREEMENT.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of the agreement, except that the parties are not required to file an agreement that solely concerns—

(A) purchase orders for raw material supplies;

(B) equipment and facility contracts;

(C) employment or consulting contracts; or

(D) packaging and labeling contracts.

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and the Commission the text of any agreements between the parties that are not described in those subsections and are contingent on, provide a contingent condition for, were entered into within 30 days of, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection.

(3) AGREEMENTS NOT REDUCED TO TEXT.—In the event that any agreement required in subsection (a) or (b) to be filed in accordance with this subsection has not been reduced to text, each of the parties involved shall file written descriptions of the agreement that are sufficient to disclose all the terms and conditions of the agreement.

**§ 40703. Filing deadline**

Any filing required under section 40702 of this title shall be filed with the Assistant Attorney General and the Commission not later than 10 business days after the date the agreements are executed.

**§ 40704. Disclosure exemption**

(a) IN GENERAL.—Except as may be relevant to any administrative or judicial action or proceeding, any information or documentary material filed with the Assistant Attorney General or the Commission pursuant to this chapter—

(1) shall be exempt from disclosure under section 552 of title 5; and

(2) shall not be made public.

(b) EFFECT OF SECTION.—Nothing in this section is intended to prevent disclosure to either body of Congress or to any authorized committee or subcommittee of Congress.

**§ 40705. Enforcement**

(a) CIVIL PENALTY.—

(1) IN GENERAL.—Any brand name drug company, generic drug applicant, or biosimilar biological product applicant that fails to comply with any provision of this chapter shall be liable for a civil penalty of not more than $11,000, for each day during which the entity is in violation of this chapter.

(2) AUTHORIZED PLAINTIFFS.—The civil penalty under paragraph (1) may be recovered in a civil action brought by the United States, or brought by the Commission in accordance with the procedures

established in section 16(a)(1) of the Federal Trade Commission Act (15 U.S.C. 56(a)(1)).

(b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand name drug company, generic drug applicant, or biosimilar biological product applicant fails to comply with any provision of this chapter, the United States district court may order compliance, and may grant such other equitable relief as the court in its discretion determines necessary or appropriate, on application of the Assistant Attorney General or the Commission.

**§ 40706. Rulemaking**

The Commission, with the concurrence of the Assistant Attorney General and by rule in accordance with section 553 of title 5, consistent with the purposes of this chapter—

(1) may define the terms used in this chapter;

(2) may exempt classes of persons or agreements from the requirements of this chapter; and

(3) may prescribe such other rules as may be necessary and appropriate to carry out the purposes of this chapter.

**§ 40707. Effect of chapter**

Any action taken by the Assistant Attorney General or the Commission, or any failure of the Assistant Attorney General or the Commission to take action, under this

chapter shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant or a biosimilar biological product applicant, any agreement between generic drug applicants, or any agreement between biosimilar biological product applicants, under any other provision of law, nor shall any filing under this chapter constitute or create a presumption of any violation of any competition laws.

# Chapter 409—Substance Use Disorder Prevention

Sec.
40901. Clarifying FDA regulation of non-addictive pain products.
40902. Evidence-based opioid analgesic prescribing guidelines and report.
40903. Strengthening FDA and CBP Coordination and capacity.
40904. FDA and U.S. Customs and Border Protection cooperation.
40905. Access to increased drug disposal.

## § 40901. Clarifying FDA regulation of non-addictive pain products

(a) DEFINITIONS.—In this section:

(1) MEDICAL PRODUCT.—The term ''medical product'' means—

(A) a drug (as defined in section 10101(a) of this title);

(B) a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))); or

(C) a device (as defined in section 10101(a) of this title).

(2) OPIOID-SPARING.—The term ''opioid-sparing'' means reducing, replacing, or avoiding the use of opioids or other controlled substances intended to treat acute or chronic pain.

(b) PUBLIC MEETINGS.—Not later than 1 year after October 24, 2018, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall hold not less than 1 public meeting to address the challenges and barriers of developing non-addictive medical products intended to treat acute or chronic pain or addiction, which may include—

(1) the manner by which the Secretary may incorporate the risks of misuse and abuse of a controlled substance (as defined in section 50101 of this title) into the risk benefit assessments under section 13136(k) or 13142(c) of this title, or sections 13505 and 13506 of this title, as applicable;

(2) the application of novel clinical trial designs (consistent with section 29106 of this title), use of real-world evidence (consistent with section 13117 of this title), and use of patient experience data (consistent with section 14319 of this title) for the devel-

opment of non-addictive medical products intended to treat pain or addiction;

(3) the evidentiary standards and the development of opioid-sparing data for inclusion in the labeling of medical products intended to treat acute or chronic pain; and

(4) the application of eligibility criteria under sections 13119 and 13144 of this title for non-addictive medical products intended to treat pain or addiction.

(c) GUIDANCE.—Not less than 1 year after the public meetings are conducted under subsection (b), the Secretary shall issue 1 or more final guidance documents, or update existing guidance documents, to help address challenges to developing non-addictive medical products to treat pain or addiction. The guidance documents shall include information regarding—

(1) how the Food and Drug Administration may apply sections 13119 and 13144 of this title to non-addictive medical products intended to treat pain or addiction, including the circumstances under which the Secretary—

(A) may apply the eligibility criteria under sections 13119 and 13144 of this title to non-

addictive medical products intended to treat pain or addiction;

(B) considers the risk of addiction of controlled substances approved to treat pain when establishing unmet medical need; and

(C) considers pain, pain control, or pain management in assessing whether a disease or condition is a serious or life-threatening disease or condition;

(2) the methods by which sponsors may evaluate acute and chronic pain, endpoints for non-addictive medical products intended to treat pain, the manner in which endpoints and evaluations of efficacy will be applied across and within review divisions, taking into consideration the etiology of the underlying disease, and the manner in which sponsors may use surrogate endpoints, intermediate endpoints, and real-world evidence;

(3) the manner in which the Food and Drug Administration will assess evidence to support the inclusion of opioid-sparing data in the labeling of non-addictive medical products intended to treat acute or chronic pain, including—

(A) alternative data collection methodologies, including the use of novel clinical trial de-

signs (consistent with section 29106 of this title) and real-world evidence (consistent with section 13117 of this title), including patient registries and patient reported outcomes, as appropriate, to support product labeling;

(B) ethical considerations of exposing subjects to controlled substances in clinical trials to develop opioid-sparing data and considerations on data collection methods that reduce harm, which may include the reduction of opioid use as a clinical benefit;

(C) endpoints, including primary, secondary, and surrogate endpoints, to evaluate the reduction of opioid use;

(D) best practices for communication between sponsors and the agency on the development of data collection methods, including the initiation of data collection; and

(E) the appropriate format in which to submit the data results to the Secretary; and

(4) the circumstances under which the Food and Drug Administration considers misuse and abuse of a controlled substance (as defined in section 50101 of this title) in making the risk benefit assessment under paragraphs (2) and (4) of section

13505(b) of this title and in finding that a drug is unsafe under paragraph (1) or (2) of section 13506(b) of this title.

**§ 40902. Evidence-based opioid analgesic prescribing guidelines and report**

(a) GUIDELINES.—The Commissioner of Food and Drugs shall develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain only for the relevant therapeutic areas where the guidelines do not exist.

(b) PUBLIC INPUT.—In developing the guidelines under subsection (a), the Commissioner of Food and Drugs shall—

(1) consult with stakeholders, which may include conducting a public meeting of medical professional societies (including any State-based societies), health care providers, State medical boards, medical specialties (including pain medicine specialty) societies, patient groups, pharmacists, academic or medical research entities, and other entities with experience in health care, as appropriate;

(2) collaborate with the Director of the Centers for Disease Control and Prevention, as applicable and appropriate, and other Federal agencies with relevant expertise as appropriate; and

(3) provide for a notice and comment period consistent with section 17501(h) of this title for the submission of comments by the public.

(c) REPORT.—Not later than 1 year after October 24, 2018, or, if earlier, at the time the guidelines under subsection (a) are finalized, the Commissioner of Food and Drugs shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and post on the public website of the Food and Drug Administration, a report on how the Food and Drug Administration will utilize the guidelines under subsection (a) to protect the public health and a description of the public health need with respect to each such indication-specific treatment guideline.

(d) UPDATES.—The Commissioner of Food and Drugs shall periodically—

(1) update the guidelines under subsection (a), informed by public input described in subsection (b); and

(2) submit to the committees specified in subsection (c) and post on the public website of the Food and Drug Administration an updated report under the subsection.

(e) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS.—The Commissioner of Food and Drugs shall ensure that opioid analgesic prescribing guidelines and other recommendations developed under this section are accompanied by a clear statement that the guidelines or recommendations, as applicable—

(1) are intended to help inform clinical decision-making by prescribers and patients; and

(2) are not intended to be used for the purposes of restricting, limiting, delaying, or denying coverage for, or access to, a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

**§ 40903. Strengthening FDA and CBP Coordination and capacity**

(a) IN GENERAL.—

(1) COORDINATION.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall coordinate with the Secretary of Homeland Security to carry out activities related to customs and border protection and in response to illegal controlled substances and drug imports, including at sites of import (such as international mail facilities), which activities will provide

improvements to the facilities, technologies, and inspection capacity.

(2) MEMORANDUM OF UNDERSTANDING.—The Secretary and the Secretary of Homeland Security may carry out the activities under paragraph (1) through a memorandum of understanding between the Food and Drug Administration and U.S. Customs and Border Protection.

(b) FDA IMPORT FACILITIES AND INSPECTION CAPACITY.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall, in collaboration with the Secretary of Homeland Security and the Postmaster General, provide that import facilities in which the Food and Drug Administration operates or carries out activities related to drug imports within the international mail facilities include—

(A) facility upgrades and improved capacity in order to increase and improve inspection and detection capabilities, which may include, as the Secretary determines appropriate—

(i) improvements to facilities, such as upgrades or renovations, and support for the maintenance of existing import facili-

ties and sites to improve coordination between Federal agencies;

(ii) improvements in equipment and information technology enhancement to identify unapproved, counterfeit, or other unlawful controlled substances for destruction;

(iii) the construction of, or upgrades to, laboratory capacity for purposes of detection and testing of imported goods;

(iv) upgrades to the security of import facilities; and

(v) innovative technology and equipment to facilitate improved and near-real-time information sharing between the Food and Drug Administration, the Department of Homeland Security, and the United States Postal Service; and

(B) innovative technology, including controlled substance detection and testing equipment and other applicable technology, in order to collaborate with U.S. Customs and Border Protection to share near-real-time information, including information about test results, as appropriate.

(2) INNOVATIVE TECHNOLOGY.—Any technology used in accordance with paragraph (1)(B) shall be interoperable with technology used by other relevant Federal agencies, including U.S. Customs and Border Protection, as the Secretary determines appropriate and practicable.

(c) REPORT.—Not later than 6 months after October 24, 2018, the Secretary, in consultation with the Secretary of Homeland Security and the Postmaster General, shall report to the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate on the implementation of this section, including a summary of progress made toward near-real-time information sharing and the interoperability of the technologies.

**§ 40904. FDA and U.S. Customs and Border Protection cooperation**

(a) IN GENERAL.—

(1) LIST OF CONTROLLED SUBSTANCES.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs and in consultation with U.S. Customs and Border Pro-

tection, shall develop and periodically update a mutually agreed on list of the controlled substances that the Secretary will refer to U.S. Customs and Border Protection, unless the Secretary and U.S. Customs and Border Protection agree otherwise, when the controlled substances are offered for import via international mail and appear to violate division A or B of subtitle V of this title, subtitle I of this title, or any other applicable law.

(2) TRANSFER OF CONTROLLED SUBSTANCES.—The Secretary shall transfer controlled substances on the list to U.S. Customs and Border Protection. If the Secretary identifies additional packages that appear to be the same as the package containing a controlled substance, the additional packages may also be transferred to U.S. Customs and Border Protection. U.S. Customs and Border Protection shall receive the packages consistent with the requirements of division A of subtitle V of this title.

(b) REPORT.—Not later than 9 months after October 24, 2018, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Secretary of Homeland Security, shall report to the Committee on Energy and Commerce of the House of Representatives

and the Committee on Health, Education, Labor, and Pensions of the Senate on the implementation of this section.

**§ 40905. Access to increased drug disposal**

(a) DEFINITIONS.—In this section:

(1) ATTORNEY GENERAL.—The term ''Attorney General'' means the Attorney General, acting through the Assistant Attorney General for the Office of Justice Programs.

(2) AUTHORIZED COLLECTOR.—The term ''authorized collector'' means a narcotic treatment program, a hospital or clinic with an on-site pharmacy, a retail pharmacy, or a reverse distributor, that is authorized as a collector under section 1317.40 of title 21, Code of Federal Regulations (or any successor regulation).

(3) COVERED GRANT.—The term ''covered grant'' means a grant awarded under subsection (b).

(4) ELIGIBLE COLLECTOR.—The term ''eligible collector'' means a person that is eligible to be an authorized collector.

(b) AUTHORITY TO MAKE GRANTS.—The Attorney General shall award grants to States to enable the States to increase the participation of eligible collectors as authorized collectors.

(c) APPLICATION.—A State desiring a covered grant shall submit to the Attorney General an application that, at a minimum—

(1) identifies the single State agency that oversees pharmaceutical care and will be responsible for complying with the requirements of the grant;

(2) details a plan to increase participation rates of eligible collectors as authorized collectors; and

(3) describes how the State will select eligible collectors to be served under the grant.

(d) USE OF GRANT FUNDS.—A State that receives a covered grant, and any subrecipient of the grant, may use the grant amounts only for the costs of installation, maintenance, training, purchasing, and disposal of controlled substances associated with the participation of eligible collectors as authorized collectors.

(e) ELIGIBILITY FOR GRANT.—The Attorney General shall award a covered grant to 5 States, not less than 3 of which shall be States in the lowest quartile of States based on the participation rate of eligible collectors as authorized collectors, as determined by the Attorney General.

(f) DURATION OF GRANTS.—The Attorney General shall determine the period of years for which a covered grant is made to a State.

(g) ACCOUNTABILITY AND OVERSIGHT.—A State that receives a covered grant shall submit to the Attorney General a report, at such time and in such manner as the Attorney General may reasonably require, that—

(1) lists the ultimate recipients of the grant amounts;

(2) describes the activities undertaken by the State using the grant amounts; and

(3) contains performance measures relating to the effectiveness of the grant, including changes in the participation rate of eligible collectors as authorized collectors.

(h) DURATION OF PROGRAM.—The Attorney General may award covered grants for each of the first 5 fiscal years beginning after October 24, 2018.

# Chapter 411—Coronavirus Aid, Relief, and Economic Security

Sec.
41101. Drugs excluded from the over-the-counter drug review.
41102. Confidentiality.

## § 41101. Drugs excluded from the over-the-counter drug review

(a) IN GENERAL.—Nothing in subtitle F of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136, div. A, title III, 134 Stat. 435) (or the amendments made by the subtitle) shall apply to any nonprescription drug (as defined in section 13118(a) of this

title) that was excluded by the Food and Drug Administration from the Over-the-Counter Drug Review in accordance with the paragraph numbered 25 on page 9466 of volume 37 of the Federal Register, published on May 11, 1972.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude or limit the applicability of any provision of subtitle I of this title (other than those provisions in subtitle I that were added or amended by subtitle F of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136, div. A, title III, 134 Stat. 435)).

**§ 41102. Confidentiality**

Nothing in the amendments made by section 3112 of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136, div. A, title III, 134 Stat. 362) shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

# Chapter 413—Accelerating Access to Critical Therapies for ALS

Sec.
41301. Grants for research on therapies for ALS.
41302. HHS public-private partnership for rare neurodegenerative diseases.
41303. ALS and other rare neurodegenerative disease action plan.
41304. FDA rare neurodegenerative disease grant program.

**§ 41301. Grants for research on therapies for ALS**

(a) DEFINITIONS.—In this section:

(1) PARTICIPATING CLINICAL TRIAL.—The term ''participating clinical trial'' means a phase 3 clinical trial conducted pursuant to an exemption under section 13510 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) to investigate a drug intended to prevent, diagnose, mitigate, treat, or cure amyotrophic lateral sclerosis.

(2) PARTICIPATING CLINICAL TRIAL SITE.—The term ''participating clinical trial site'' means a health care facility, or network of facilities, at which patients participating in a participating clinical trial receive an investigational drug through the trial.

(3) PARTICIPATING ENTITY.—The term ''participating entity'' means a participating clinical trial site sponsored by a small business concern (as defined in section 3(a) of the Small Business Act (15 U.S.C. 632(a))) that is the sponsor of a drug that is the subject of an investigational new drug application under section 13510 of this title to prevent, diagnose, mitigate, treat, or cure amyotrophic lateral sclerosis.

(b) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall award grants to participating entities for

purposes of scientific research utilizing data from expanded access to investigational drugs for individuals who are not otherwise eligible for clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis. In the case of a participating entity seeking such a grant, an expanded access request must be submitted, and allowed to proceed by the Secretary, under section 14301 of this title and part 312 of title 21, Code of Federal Regulations (or any successor regulations), before the application for the grant is submitted.

(c) APPLICATION.—

(1) IN GENERAL.—A participating entity seeking a grant under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary shall specify.

(2) USE OF DATA.—An application submitted under paragraph (1) shall include a description of how data generated through an expanded access request under section 14301 of this title with respect to the investigational drug involved will be used to support research or development related to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.

(3) NONINTERFERENCE WITH CLINICAL TRIALS.—An application submitted under paragraph (1) shall include a description of how the proposed expanded access program will be designed so as not to interfere with patient enrollment in ongoing clinical trials for investigational therapies for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.

(d) SELECTION.—Consistent with sections 406 and 492 of the Public Health Service Act (42 U.S.C. 284a, 289a), the Secretary shall, in determining whether to award a grant under this section, confirm that—

(1) the grant will be used to support a scientific research objective relating to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis (as described in subsection (b));

(2) the grant shall not have the effect of diminishing eligibility for, or impeding enrollment of, ongoing clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis by determining that individuals who receive expanded access to investigational drugs through the grant are not eligible for enrollment in—

(A) ongoing clinical trials that are registered on ClinicalTrials.gov (or successor

website), with respect to a drug for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis; or

(B) clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis for which an exemption under section 13510 of this title has been granted by the Food and Drug Administration and that are expected to begin enrollment within 1 year; and

(3) the resulting project funded by the grant will allow for equitable access to investigational drugs by minority and underserved populations.

(e) USE OF FUNDS.—A participating entity shall use funds received through the grant—

(1) to pay the manufacturer or sponsor for the direct costs of the investigational drug, as authorized under section 312.8(d) of title 21, Code of Federal Regulations (or successor regulations), to prevent, diagnose, mitigate, treat, or cure amyotrophic lateral sclerosis that is the subject of an expanded access request described in subsection (b), if the costs are justified as part of peer review of the grant;

(2) for the entity's direct costs incurred in providing the drug consistent with the research mission of the grant; or

(3) for the direct and indirect costs of the entity in conducting research with respect to the drug.

(f) SUNSET.—The Secretary may not award grants under this section on or after September 30, 2026.

**§ 41302. HHS public-private partnership for rare neurodegenerative diseases**

(a) DEFINITIONS.—

(1) ELIGIBLE ENTITY.—The term ''eligible entity'' means an entity that—

(A) is—

(i) an institution of higher education (as the term is defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)) or a consortium of those institutions; or

(ii) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and exempt from tax under section 501(a) of that Code;

(B) has experienced personnel with clinical and other technical expertise in the field of bio-

medical sciences and demonstrated connection to the patient population;

(C) demonstrates to the Secretary's satisfaction that the entity is capable of identifying and establishing collaborations between public and private entities and individuals with expertise in neurodegenerative diseases, including patients, to facilitate—

(i) development and critical evaluation of tools, methods, and processes—

(I) to characterize neurodegenerative diseases and their natural history;

(II) to identify molecular targets for neurodegenerative diseases; and

(III) to increase efficiency, predictability, and productivity of clinical development of therapies, including advancement of rational therapeutic development and establishment of clinical trial networks; and

(ii) securing funding for the Partnership (as defined in this subsection) from Federal and non-Federal governmental

sources, foundations, and private individuals; and

(D) provides an assurance that the entity will not accept funding for a Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Secretary that the results of the project will not be influenced by any source of funding.

(2) PARTNERSHIP.—The term ''Partnership'' means the Public-Private Partnership for Neurodegenerative Diseases established under subsection (b).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) ESTABLISHMENT.—The Secretary shall implement a Public-Private Partnership for Neurodegenerative Diseases between the National Institutes of Health, the Food and Drug Administration, and 1 or more eligible entities through cooperative agreements, contracts, or other appropriate mechanisms with the eligible entities, for the purpose of advancing the understanding of neurodegenerative diseases and fostering the development

of treatments for amyotrophic lateral sclerosis and other rare neurodegenerative diseases. The Partnership shall—

(1) establish partnerships and consortia with other public and private entities and individuals with expertise in amyotrophic lateral sclerosis and other rare neurodegenerative diseases for the purposes described in this subsection;

(2) focus on advancing regulatory science and scientific research that will support and accelerate the development and review of drugs for patients with amyotrophic lateral sclerosis and other rare neurodegenerative diseases; and

(3) foster the development of effective drugs that improve the lives of people that suffer from amyotrophic lateral sclerosis and other rare neurodegenerative diseases.

(c) GIFTS.—

(1) IN GENERAL.—The Partnership may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of basic research and research associated with phase 3 clinical trials conducted with respect to investigational drugs that are the subjects of expanded access requests under section 14301 of this title.

(2) USE.—In addition to any amounts appropriated for purposes of carrying out this section, the Partnership may use, without further appropriation, any funds derived from a gift, grant, or other donation accepted pursuant to paragraph (1).

**§ 41303. ALS and other rare neurodegenerative disease action plan**

(a) IN GENERAL.—Not later than 6 months after December 23, 2021, the Commissioner of Food and Drugs shall publish on the website of the Food and Drug Administration an action plan describing actions the Food and Drug Administration intends to take during the 5-year period following publication of the plan with respect to program enhancements, policy development, regulatory science initiatives, and other appropriate initiatives to—

(1) foster the development of safe and effective drugs that improve or extend, or both, the lives of people living with amyotrophic lateral sclerosis and other rare neurodegenerative diseases; and

(2) facilitate access to investigational drugs for amyotrophic lateral sclerosis and other rare neurodegenerative diseases.

(b) CONTENTS.—The initial action plan published under subsection (a) shall—

(1) identify appropriate representation from within the Food and Drug Administration to be responsible for implementation of the action plan;

(2) include elements to facilitate—

(A) interactions and collaboration between the Food and Drug Administration, including the review centers of the Food and Drug Administration, and stakeholders including patients, sponsors, and the external biomedical research community;

(B) consideration of cross-cutting clinical and regulatory policy issues, including consistency of regulatory advice and decisionmaking;

(C) identification of key regulatory science and policy issues critical to advancing development of safe and effective drugs; and

(D) enhancement of collaboration and engagement of the relevant centers and offices of the Food and Drug Administration with other operating divisions within the Department of Health and Human Services, the Partnership, and the broader neurodegenerative disease community; and

(3) be subject to revision, as determined appropriate by the Secretary of Health and Human Services.

**§ 41304. FDA rare neurodegenerative disease grant program**

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall award grants and contracts to public and private entities to cover the costs of research on, and development of interventions intended to prevent, diagnose, mitigate, treat, or cure, amyotrophic lateral sclerosis and other rare neurodegenerative diseases in adults and children, including costs incurred with respect to the development and critical evaluation of tools, methods, and processes—

(1) to characterize such neurodegenerative diseases and their natural history;

(2) to identify molecular targets for such neurodegenerative diseases; and

(3) to increase efficiency and productivity of clinical development of therapies, including through—

(A) the use of master protocols and adaptive and addon clinical trial designs; and

(B) efforts to establish new or leverage existing clinical trial networks.

# Chapter 415—Medical Marijuana and Cannabidiol Research Expansion

**Subchapter I—General Provisions**
Sec.
41501. Definitions.
**Subchapter II—Registrations for Marijuana Research**
41511. Adequate and uninterrupted supply.
41512. Security requirements.
41513. Prohibition against reinstating interdisciplinary review process for non-NIH-funded researchers.
**Subchapter III—Development of Food and Drug Administration-Approved Drugs Using Cannabidiol and Marijuana**
41521. Medical research on cannabidiol.
41522. Registration for the commercial production and distribution of FDA-approved drugs.
**Subchapter IV—Doctor-Patient Relationship**
41531. Discussing harms and benefits of marijuana and marijuana derivatives as a treatment.
**Subchapter V—Federal Research**
41541. Federal research.

# Subchapter I—General Provisions

## § 41501. Definitions

In this Act:

(1) APPROPRIATELY REGISTERED.—The term ''appropriately registered'' means, with respect to an individual or entity, that the individual or entity is registered under division A of subtitle V of this title to engage in the type of activity that is carried out by the individual or entity with respect to a controlled substance on the schedule that is applicable to cannabidiol or marijuana, as applicable.

(2) CANNABIDIOL .—The term ''cannabidiol'' means—

(A) the substance, cannabidiol, as derived from marijuana that has a delta-9-tetrahydrocannabinol level that is greater than 0.3 percent; and

(B) the synthetic equivalent of the substance described in subparagraph (A).

(3) CONTROLLED SUBSTANCE.—The term ''controlled substance'' has the meaning given the term in section 50101 of this title.

(4) COVERED INSTITUTION OF HIGHER EDUCATION.—The term ''covered institution of higher education'' means an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001))—

(A) that—

(i) has highest or higher research activity, as defined by the Carnegie Classification of Institutions of Higher Education; or

(ii) is an accredited medical school or an accredited school of osteopathic medicine; and

(B) that is appropriately registered under division A of subtitle V of this title.

(5) DISPENSE.—The term ''dispense'' has the meaning given the term in section 50101 of this title.

(6) DISTRIBUTE.—The term ''distribute'' has the meaning given the term in section 50101 of this title.

(7) DRUG.—The term ''drug'' has the meaning given the term in section 10101(a)(18) of this title.

(8) MANUFACTURE.—The term ''manufacture'' has the meaning given the term in section 50101 of this title.

(9) MARIJUANA.—The term ''marijuana'' has the meaning given the term in section 50101 of this title.

(10) MEDICAL RESEARCH FOR DRUG DEVELOPMENT.—The term ''medical research for drug development'' means medical research that is—

(A) a preclinical study or clinical investigation conducted in accordance with section 13510 of this title or otherwise permitted by the Department of Health and Human Services to determine the potential medical benefits of marijuana or cannabidiol as a drug; and

(B) conducted by a covered institution of higher education, practitioner, or manufacturer

that is appropriately registered under division A of subtitle V of this title.

(11) PRACTITIONER.—The term ''practitioner'' has the meaning given the term in section 50101 of this title.

(12) STATE.—The term ''State'' means a State, the District of Columbia, and any territory of the United States.

# Subchapter II—Registrations for Marijuana Research

### § 41511. Adequate and uninterrupted supply

(a) IN GENERAL.—On an annual basis, the Attorney General, in consultation with the Secretary of Health and Human Services, shall assess whether there is an adequate and uninterrupted supply of marijuana, including of specific strains, for research purposes.

(b) REPORT TO CONGRESS.—If the Attorney General, in consultation with the Secretary of Health and Human Services, determines there is an inadequate or interrupted supply of marijuana, including of specific strains for research purposes, the Attorney General shall report to Congress within 60 days of the determination on at least—

(1) the factors contributing to the inadequate or interrupted supply of marijuana;

(2) expected impacts of the inadequate or interrupted supply on ongoing research protocols; and

(3) specific steps the Attorney General will take to restore an adequate and uninterrupted supply of marijuana, including of specific strains, for research purposes.

**§ 41512. Security requirements**

(a) IN GENERAL.—An individual or entity engaged in researching marijuana or its components shall store it in a securely locked, substantially constructed cabinet.

(b) REQUIREMENTS FOR OTHER MEASURES.—Any other security measures required by the Attorney General to safeguard against diversion shall be consistent with those required for practitioners conducting research on other controlled substances in schedules I and II in section 50302(c) of this title that have a similar risk of diversion and abuse.

**§ 41513. Prohibition against reinstating interdisciplinary review process for non-NIH-funded researchers**

The Secretary of Health and Human Services may not—

(1) reinstate the Public Health Service interdisciplinary review process described in the guidance entitled ''Guidance on Procedures for the Provision

of Marijuana for Medical Research'' (issued on May 21, 1999); or

(2) require another review of scientific protocols that is applicable only to research on marijuana or its components.

# Subchapter III—Development of Food and Drug Administration-Approved Drugs Using Cannabidiol and Marijuana

### § 41521. Medical research on cannabidiol

Notwithstanding any provision of division A of subtitle V of this title, chapter 81 of title 41, or any other Federal law, an appropriately registered covered institution of higher education, practitioner, or manufacturer may manufacture, distribute, dispense, or possess marijuana or cannabidiol if the marijuana or cannabidiol is manufactured, distributed, dispensed, or possessed, respectively, for purposes of medical research for drug development or subsequent commercial production in accordance with section 41522 of this title.

### § 41522. Registration for the commercial production and distribution of FDA-approved drugs

The Attorney General shall register an applicant to manufacture or distribute cannabidiol or marijuana for the purpose of commercial production of a drug containing

or derived from marijuana that is approved by the Secretary of Health and Human Services under chapter 135 of this title, in accordance with the applicable requirements under subsection (b) or (c) of section 50503 of this title.

# Subchapter IV—Doctor-Patient Relationship

### § 41531. Discussing harms and benefits of marijuana and marijuana derivatives as a treatment

It shall not be a violation of division A of subtitle V of this title for a State-licensed physician to discuss—

(1) the currently known potential harms and benefits of marijuana derivatives, including cannabidiol, as a treatment with the legal guardian of the patient of the physician if the patient is a child; or

(2) the currently known potential harms and benefits of marijuana and marijuana derivatives, including cannabidiol, as a treatment with the patient or the legal guardian of the patient of the physician if the patient is a legal adult.

# Subchapter V—Federal Research

### § 41541. Federal research

(a) IN GENERAL.—Not later than 1 year after December 2, 2022, the Secretary of Health and Human Serv-

ices, in coordination with the Director of the National Institutes of Health and the heads of other relevant Federal agencies, shall submit to the Caucus on International Narcotics Control, the Committee on the Judiciary, and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and the Committee on the Judiciary of the House of Representatives a report on—

(1) the potential therapeutic effects of cannabidiol or marijuana on serious medical conditions, including intractable epilepsy;

(2) the potential effects of marijuana, including—

(A) the effect of increasing delta-9-tetrahydrocannabinol levels on the human body and developing adolescent brains; and

(B) the effect of various delta-9-tetrahydrocannabinol levels on cognitive abilities, such as those that are required to operate motor vehicles or other heavy equipment; and

(3) the barriers associated with researching marijuana or cannabidiol in States that have legalized the use of those substances, which shall include—

(A) recommendations as to how the barriers might be overcome, including whether public-private partnerships or Federal-State research partnerships may or should be implemented to provide researchers with access to additional strains of marijuana and cannabidiol; and

(B) recommendations as to what safeguards must be in place to verify—

(i) that the levels of tetrahydrocannabinol, cannabidiol, or other cannabinoids contained in products obtained from the States are accurate; and

(ii) that the products do not contain harmful or toxic components.

(b) ACTIVITIES.—To the extent practicable, the Secretary of Health and Human Services, either directly or through awarding grants, contacts, or cooperative agreements, shall expand and coordinate the activities of the National Institutes of Health and other relevant Federal agencies to better determine the effects of cannabidiol and marijuana, as outlined in the report submitted under paragraphs (1) and (2) of subsection (a).

# Chapter —Reserved

# Chapter 495—Miscellaneous

Sec.
49501. Revision of United States Pharmacopeia; development of analysis and mechanical and physical tests.
49502. Grants and contracts for development of drugs for rare diseases and conditions.
49503. Adverse-event reporting.
49504. Accelerated approval of priority countermeasures.
49505. Effect of provisions on drugs used by licensed veterinarians.
49506. Reports relating to pediatric uses of drugs.
49507. Report on reclassification of devices.
49508. Clinical trials.
49509. Communication plan relating to benefits and risks of medical products particularly on underrepresented populations.
49510. Enhanced communication.
49511. Recommendations regarding education programs for prescribers of opioids.
49512. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing.
49513. Variations from current good manufacturing practices relating to combination products and manufacturing processes.
49514. Report relating to software functions.
49515. Predictable review timelines of vaccines by the Advisory Committee on Immunization Practices.
49516. Regulations relating to over-the-counter hearing aids.
49517. Annual report on inspections.
49518. Expedited development and review of medical products for emergency uses.
49519. Actions for delays of generic drugs and biosimilar biological products.
49520. Resources regarding cybersecurity of devices.
49521. Third party data transparency.
49522. Annual summary report on progress to increase diversity in clinical studies.

## § 49501. Revision of United States Pharmacopeia; development of analysis and mechanical and physical tests

The Secretary of Health and Human Services, in carrying out subtitle I of this title, may cooperate with associations and scientific societies in the revision of the United States Pharmacopeia and in the development of methods of analysis and mechanical and physical tests

necessary to carry out the work of the Food and Drug Administration.

**§ 49502. Grants and contracts for development of drugs for rare diseases and conditions**

(a) DEFINITIONS.—In this section:

(1) MEDICAL FOOD.—The term ''medical food'' means a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

(2) QUALIFIED TESTING.—The term ''qualified testing'' means—

(A) human clinical testing—

(i) that is carried out under an exemption for a drug for a rare disease or condition under section 13510 of this title (or regulations issued under section 13510 of this title); and

(ii) that occurs before the date on which an application with respect to the drug is submitted under section 13503 of

this title or under section 351 of the Public Health Service Act (42 U.S.C. 262);

(B) preclinical testing involving a drug for a rare disease or condition that occurs after the date the drug is designated under section 13902 of this title and before the date on which an application with respect to the drug is submitted under section 13503 of this title or under section 351 of the Public Health Service Act (42 U.S.C. 262); and

(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

(i) develop or validate a drug development tool related to a rare disease or condition; or

(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.

(3) RARE DISEASE OR CONDITION.—

(A) IN GENERAL.—The term ''rare disease or condition'' means—

(i) in the case of a drug, any disease or condition that—

(I) affects fewer than 200,000 persons in the United States; or

(II) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for the disease or condition will be recovered from sales in the United States of the drug;

(ii) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for the disease or condition will be developed without assistance under subsection (b); and

(iii) in the case of a medical food, any disease or condition that occurs so infrequently in the United States that there is

no reasonable expectation that a medical food for the disease or condition will be developed without assistance under subsection (b).

(B) BASIS FOR DETERMINATIONS.—Determinations under subparagraph (A) with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 13902 of this title is made.

(b) AUTHORITY OF SECRETARY.—The Secretary of Health and Human Services may make grants to and enter into contracts with public and private entities and individuals to assist in—

(1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses;

(2) defraying the costs of developing medical devices for rare diseases or conditions;

(3) defraying the costs of developing medical foods for rare diseases or conditions; and

(4) developing regulatory science pertaining to the chemistry, manufacturing, and controls of individualized medical products to treat individuals with rare diseases or conditions.

(c) AUTHORIZATION OF APPROPRIATIONS.—For grants and contracts under subsection (b), there is authorized to be appropriated $30,000,000 for each of fiscal years 2023 through 2027.

**§ 49503. Adverse-event reporting**

(a) TOLL-FREE NUMBER IN LABELING.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall promulgate a final rule requiring that the labeling of each drug for which an application is approved under chapter 135 of this title (regardless of the date on which approved) include the toll-free number maintained by the Secretary for the purpose of receiving reports of adverse events regarding drugs and a statement that the number is to be used for reporting purposes only, not to receive medical advice.

(2) REGULATION REQUIREMENTS.—

(A) BROADEST CONSUMER AUDIENCE.—The rule shall provide for the implementation of the labeling requirement in a manner that the Secretary considers to be most likely to reach the broadest consumer audience.

(B) MINIMIZING COST ON PHARMACY PROFESSION.—In promulgating the rule, the Sec-

retary shall seek to minimize the cost of the rule on the pharmacy profession.

(b) DRUGS WITH PEDIATRIC MARKET EXCLUSIVITY.—

(1) REFERRAL TO OFFICE OF PEDIATRIC THERAPEUTICS.—

(A) IN GENERAL.—During the 1 year beginning on the date on which a drug receives a period of market exclusivity under section 13112 of this title, any report of an adverse event regarding the drug that the Secretary receives shall be referred to the Office of Pediatric Therapeutics.

(B) REVIEW BY PEDIATRIC ADVISORY COMMITTEE.—In considering the report, the Director of the Office of Pediatric Therapeutics shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of the Pediatric Advisory Committee regarding whether the Secretary should take action under subtitle I of this title in response to the report.

(2) RULE OF CONSTRUCTION.—Paragraph (1) may not be construed as restricting the authority of the Secretary to continue carrying out the activities

described in the paragraph regarding a drug after the 1-year period described in the paragraph regarding the drug has expired.

**§ 49504. Accelerated approval of priority countermeasures**

(a) DEFINITIONS.—In this section:

(1) PRIORITY COUNTERMEASURE.—The term ''priority countermeasure'' has the meaning given the term in section 319F(e)(4) of the Public Health Service Act (42 U.S.C. 247d–6(e)(4)).

(2) PRIORITY DRUG OR BIOLOGICAL PRODUCT.—The term ''priority drug or biological product'' means a drug or biological product that is the subject of a drug or biologics application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2298).

(b) DESIGNATION AS A FAST-TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary of Health and Human Services may designate a priority countermeasure as a fast-track product pursuant to section 13119 of this title.

(2) TIMING.—The designation under paragraph (1) may be made prior to the submission of—

(A) a request for designation by the sponsor or applicant; or

(B) an application for the investigation of the drug under section 13510 of this title or section 351(a)(3) of the Public Health Service Act (42 U.S.C. 262(a)(3)).

(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall be construed to prohibit a sponsor or applicant from declining the designation.

(c) USE OF ANIMAL TRIALS.—A drug for which approval is sought under section 13503 of this title or section 351 of the Public Health Service Act (42 U.S.C. 262) on the basis of evidence of effectiveness that is derived from animal studies pursuant to section 123 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188, 116 Stat. 613) may be designated as a fast track product for purposes of this section.

(d) PRIORITY REVIEW OF DRUGS AND BIOLOGICAL PRODUCTS.—A priority countermeasure that is a drug or biological product shall be considered a priority drug or biological product for purposes of performance goals for priority drugs or biological products agreed to by the Commissioner of Food and Drugs.

**§ 49505. Effect of provisions on drugs used by licensed veterinarians**

Subtitle A of title IX of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 121 Stat. 922), and the amendments made by the subtitle, shall have no effect on the use of drugs approved under chapter 135 of this title by, or on the lawful written or oral order of, a licensed veterinarian within the context of a veterinarian-client-patient relationship, as provided for under section 13702(e) of this title.

**§ 49506. Reports relating to pediatric uses of drugs**

(a) IN GENERAL.—Not later than 4 years after July 9, 2012, and every 5 years thereafter, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the internet website of the Food and Drug Administration, a report on the implementation of sections 13112 and 13113 of this title.

(b) CONTENTS.—Each report under subsection (a) shall include—

(1) an assessment of the effectiveness of sections 13112 and 13113 of this title in improving information about pediatric uses for approved drugs

and biological products, including the number and type of labeling changes made since July 9, 2012, and the importance of the uses in the improvement of the health of children;

(2) the number of required studies under section 13113 of this title that have not met the initial deadline provided under section 13113 of this title, including—

(A) the number of deferrals and deferral extensions granted and the reasons the extensions were granted;

(B) the number of waivers and partial waivers granted; and

(C) the number of letters issued under section 13113(d) of this title;

(3) an assessment of the timeliness and effectiveness of pediatric study planning since July 9, 2012, including the number of initial pediatric study plans not submitted in accordance with the requirements of section 13113(e) of this title and any resulting rulemaking;

(4) the number of written requests issued, accepted, and declined under section 13112 of this title since July 9, 2012, and a listing of any impor-

tant gaps in pediatric information as a result of the declined requests;

(5) a description and current status of referrals made under section 13112(n) of this title;

(6) an assessment of the effectiveness of studying biological products in pediatric populations under sections 13112 and 13113 of this title and section 409I of the Public Health Service Act (42 U.S.C. 284m);

(7)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonatal population (including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe); and

(B) the results of those efforts;

(8)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs under sections 13112 and 13113 of this title and under section 409I of the Public Health Service Act (42 U.S.C. 284m); and

(B) any recommendations for modifications to the programs that would lead to new and better

therapies for children with cancer, including a detailed rationale for each recommendation;

(9) any recommendations for modification to the programs that would improve pediatric drug research and increase pediatric labeling of drugs and biological products;

(10) an assessment of the successes of and limitations to studying drugs for rare diseases under sections 13112 and 13113 of this title;

(11) an assessment of the impact of the amendments to section 13113 of this title made by the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1044) on pediatric research and labeling of drugs and biological products and pediatric labeling of molecularly targeted drugs and biological products for the treatment of cancer;

(12) an assessment of the efforts of the Secretary to implement the plan developed under section 505(c) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1046) regarding earlier submission of pediatric studies under sections 13112 and 13113 of this title and section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)), including—

(A) the average length of time after the approval of an application under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) before studies conducted pursuant to section 13112 or 13113 of this title or section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) are completed, submitted, and incorporated into labeling;

(B) the average length of time after the receipt of a proposed pediatric study request before the Secretary responds to the request;

(C) the average length of time after the submission of a proposed pediatric study request before the Secretary issues a written request for the studies;

(D) the number of written requests issued for each investigational new drug or biological product prior to the submission of an application under section 13503(a) of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)); and

(E) the average number, and range of numbers, of amendments to written requests issued, and the time the Secretary requires to

review and act on proposed amendments to written requests;

(13) a list of sponsors of applications or holders of approved applications who received exclusivity under section 13112 of this title or section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) after receiving a letter issued under section 13113(d)(1) of this title for any drug or biological product before the studies referred to in the letter were completed and submitted;

(14) a list of assessments and investigations required under section 13113 of this title;

(15) the number of requests under section 13112 of this title for molecular targeted cancer drugs (as defined by section 13113(a)(1)(B) of this title), approved prior to 3 years after August 18, 2017, which requests have been issued by the Food and Drug Administration, and the number of the requests that have been completed; and

(16) the Secretary's assessment of the overall impact of the amendments made by section 504 of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1039) on the conduct and effectiveness of pediatric cancer research and the orphan

drug program, as well any subsequent recommendations.

(c) STAKEHOLDER COMMENT.—At least 180 days prior to the submission of each report under subsection (a), the Secretary shall consult with representatives of patient groups (including pediatric patient groups), consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products.

**§ 49507. Report on reclassification of devices**

The Secretary of Health and Human Services shall annually post on the internet website of the Food and Drug Administration—

(1) the number and type of class I and class II devices reclassified as class II or class III in the previous calendar year under section 13140(g)(1) of this title;

(2) the number and type of class II and class III devices reclassified as class I or class II in the previous calendar year under section 13140(g)(1) of this title; and

(3) the number and type of devices reclassified in the previous calendar year under section 13142 of this title.

**§ 49508. Clinical trials**

(a) DEFINITION OF QUALIFIED INFECTIOUS DISEASE PRODUCT.—In this section, the term ''qualified infectious disease product'' has the meaning given the term in section 13116(a)(1) of this title.

(b) REVIEW AND REVISION OF GUIDANCE DOCUMENTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall review and, as appropriate, revise not fewer than 3 guidance documents per year, which shall include—

(A) reviewing the guidance documents of the Food and Drug Administration for the conduct of clinical trials with respect to antibacterial and antifungal drugs; and

(B) as appropriate, revising the guidance documents to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of antibacterial and

antifungal drugs under division D of subtitle I of this title.

(2) ISSUES FOR REVIEW.—At a minimum, the review under paragraph (1) shall address the appropriate animal models of infection, in vitro techniques, valid microbiological surrogate markers, the use of noninferiority versus superiority trials, trial enrollment, data requirements, and appropriate delta values for noninferiority trials.

(3) RULE OF CONSTRUCTION.—Except to the extent to which the Secretary makes revisions under paragraph (1)(B), nothing in this section shall be construed to repeal or otherwise affect the guidance documents of the Food and Drug Administration.

(c) RECOMMENDATIONS FOR INVESTIGATIONS.—

(1) REQUEST.—The sponsor of a drug intended to be designated as a qualified infectious disease product may request that the Secretary provide written recommendations for nonclinical and clinical investigations that the Secretary believes may be necessary to be conducted with the drug before the drug may be approved under chapter 135 of this title for use in treating, detecting, preventing, or identifying a qualifying pathogen, as defined in section 13116 of this title.

(2) RECOMMENDATIONS.—If the Secretary has reason to believe that a drug for which a request is made under this subsection is a qualified infectious disease product, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations that the Secretary believes, on the basis of information available to the Secretary at the time of the request, would be necessary for approval under chapter 135 of this title of the drug for the use described in paragraph (1).

**§ 49509. Communication plan relating to benefits and risks of medical products particularly on underrepresented populations**

(a) COMMUNICATION PLAN.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall review and modify, as necessary, the Food and Drug Administration's communication plan to inform and educate health care providers and patients on the benefits and risks of medical products, with particular focus on underrepresented subpopulations, including racial subgroups.

(b) CONTENT.—The communication plan described under subsection (a)—

(1) shall take into account—

(A) the goals and principles set forth in the Strategic Action Plan to Reduce Racial and Ethnic Health Disparities issued by the Department of Health and Human Services;

(B) the nature of the medical product; and

(C) health and disease information available from other agencies within the Department of Health and Human Services, as well as any new means of communicating health and safety benefits and risks related to medical products;

(2) taking into account the nature of the medical product, shall address the best strategy for communicating safety alerts, labeled indications for the medical products, changes to the label or labeling of medical products (including black-box warnings, health advisories, and health and safety benefits and risks), particular actions to be taken by health care professionals and patients, any information identifying particular subpopulations, and any other relevant information as determined appropriate to enhance communication, including varied means of electronic communication; and

(3) shall include a process for implementation of any improvements or other modifications determined to be necessary.

(c) POSTING OF COMMUNICATION PLAN ON THE OFFICE OF MINORITY HEALTH WEBSITE.—The Secretary, acting through the Commissioner of Food and Drugs, shall publicly post the communication plan on the internet website of the Office of Minority Health of the Food and Drug Administration, and provide links to any other appropriate internet website, and seek public comment on the communication plan.

**§ 49510. Enhanced communication**

(a) SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—In a manner specified by the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), the Secretary shall receive submissions from State boards of pharmacy—

(1) describing actions taken against compounding pharmacies, as described in subsection (b); or

(2) expressing concerns that a compounding pharmacy may be acting contrary to section 13106 of this title.

(b) CONTENT OF SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—An action referred to in sub-

section (a)(1) is, with respect to a pharmacy that compounds drugs, any of the following:

(1) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for a violation of a State's pharmacy regulation pertaining to compounding.

(2) The suspension or revocation of a State-issued pharmacy license or registration for a violation of a State's pharmacy regulation pertaining to compounding.

(3) The recall of a compounded drug due to concerns relating to the quality or purity of the drug.

(c) CONSULTATION.—The Secretary shall implement subsection (a) in consultation with the National Association of Boards of Pharmacy.

(d) NOTIFYING STATE BOARDS OF PHARMACY.—The Secretary shall immediately notify State boards of pharmacy when—

(1) the Secretary receives a submission under subsection (a)(1); or

(2) the Secretary makes a determination that a pharmacy is acting contrary to section 13106 of this title.

**§ 49511. Recommendations regarding education programs for prescribers of opioids**

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, as part of the Food and Drug Administration's evaluation of the Extended-Release/Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy, and in consultation with relevant stakeholders, shall develop recommendations regarding education programs for prescribers of opioids pursuant to this chapter, including recommendations on—

(1) which prescribers should participate in those programs; and

(2) how often participation in those programs is necessary.

**§ 49512. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing**

(a) DEFINITIONS.—In this section:

(1) ADVANCED AND CONTINUOUS PHARMACEUTICAL MANUFACTURING.—The term ''advanced and continuous pharmaceutical manufacturing'' refers to a method, or a combination of methods, of pharmaceutical manufacturing, which method or combination—

(A) incorporates a novel technology, or uses an established technique or technology in

a new or innovative way, that enhances drug quality or improves the manufacturing process for a drug, including processes that may apply to advanced therapies and the production of biological products, such as cell and gene therapies; or

(B) continuously feeds input materials into and transforms those input materials within the process, and continuously removes the output materials from the system, utilizing an integrated manufacturing process that consists of a series of 2 or more simultaneous unit operations.

(2) BIOLOGICAL PRODUCT.—The term ''biological product'' has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(3) DRUG.—The term ''drug'' has the meaning given the term in section 10101(a)(18) of this title.

(4) FDA.—The term ''FDA'' means the Food and Drug Administration.

(5) INSTITUTION OF HIGHER EDUCATION.—The term ''institution of higher education'' has the meaning given the term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(b) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs—

(1) may, to support the advancement, development, and implementation of advanced and continuous pharmaceutical manufacturing—

(A) solicit requests for designation as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing (in this section referred to as a ''National Center of Excellence'');

(B) beginning not later than 1 year after December 29, 2022, designate as National Centers of Excellence institutions of higher education or consortia of institutions of higher education that—

(i) request the designation; and

(ii) meet the eligibility criteria specified in subsection (d); and

(C) award grants to those institutions or consortia of institutions; and

(2) shall designate under paragraph (1) not more than 5 institutions of higher education or consortia of institutions of higher education.

(c) REQUEST FOR DESIGNATION.—A request for designation under subsection (b) shall be made to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(d) ELIGIBILITY CRITERIA FOR DESIGNATION.—To be eligible to receive a designation under this section, an institution of higher education or consortium of institutions of higher education shall include in its request for designation a description of the institution's or consortium's—

(1) physical capacity and technical capabilities to conduct advanced research on, and to develop and implement, advanced and continuous pharmaceutical manufacturing;

(2) collaboration or partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities;

(3) proven capacity to design, develop, implement, and demonstrate new, highly effective technologies for use in advanced and continuous pharmaceutical manufacturing;

(4) proven ability to facilitate training of a qualified workforce for advanced research on, and development and implementation of, advanced and continuous pharmaceutical manufacturing; and

(5)(A) experience in participating in and leading advanced and continuous pharmaceutical manufacturing technology partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities, to—

(i) support the implementation of advanced or continuous pharmaceutical manufacturing for companies manufacturing or seeking to manufacture in the United States;

(ii) support Federal agencies with technical assistance and workforce training, which may include regulatory and quality metric guidance as applicable, and hands-on training, for advanced and continuous pharmaceutical manufacturing;

(iii) organize and conduct advanced research and development activities, with respect to advanced or continuous pharmaceutical man-

ufacturing, needed to develop new and more effective technology, and to develop and support technological leadership;

(iv) develop best practices for designing, developing, and implementing advanced and continuous pharmaceutical manufacturing processes; and

(v) identify and assess workforce needs for advanced and continuous pharmaceutical manufacturing, and address those workforce needs, which may include the development and implementing of training programs; or

(B) a plan, to be implemented within 2 years, to establish partnerships described in subparagraph (A).

(e) TERMINATION OF DESIGNATION.—The Secretary may terminate the designation of any National Center of Excellence designated under this section if the Secretary determines that the National Center of Excellence no longer meets the criteria specified in subsection (d). Not later than 90 days before the effective date of the termination, the Secretary shall provide written notice to the National Center of Excellence, including the rationale for the termination.

(f) CONDITIONS FOR DESIGNATION.—As a condition of designation as a National Center of Excellence under this section, the Secretary shall require that an institution of higher education or consortium of institutions of higher education enter into an agreement with the Secretary under which the institution or consortium agrees—

(1) to collaborate directly with the FDA to publish the reports required by subsection (h);

(2) to share data with the FDA regarding best practices and research generated through the funding under subsection (g);

(3) to develop, along with industry partners (which may include large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, and contract research organizations or contract manufacturers that carry out drug development and manufacturing activities) and another institution or consortium designated under this section, if any, a strategic plan for developing an advanced and continuous pharmaceutical manufacturing workforce;

(4) to develop, along with industry partners and other institutions or consortia designated under this section, a strategic plan for strengthening existing, and developing new, partnerships with other institu-

tions of higher education or consortia of institutions of higher education, or nonprofit organizations; and

(5) to provide an annual report to the FDA regarding the designee's activities under this section, including a description of how the designee continues to meet and make progress on the criteria specified in subsection (d).

(g) FUNDING.—

(1) IN GENERAL.—The Secretary shall award funding, through grants, contracts, or cooperative agreements, to the entities designated as National Centers of Excellence under this section for the purposes of supporting the advanced research on, and development and implementation of, advanced and continuous pharmaceutical manufacturing, and recommending improvements to advanced and continuous pharmaceutical manufacturing, including—

(A) expanding capacity for advanced research on, and development of, advanced and continuous pharmaceutical manufacturing; and

(B) implementing advanced research capacity and capabilities in advanced and continuous pharmaceutical manufacturing suitable for accelerating the development of drug products needed to respond to public health threats, miti-

gate or prevent drug shortages, address drug quality issues and supply chain disruptions, and other circumstances with respect to which the Secretary may determine the rapid development of new products or new manufacturing processes may be appropriate.

(2) CONSISTENCY WITH FDA MISSION.—As a condition on receipt of funding under this subsection, a National Center of Excellence shall consider any input from the Secretary regarding the use of funding related to—

(A) best practices to increase, and provide for the advancement of, advanced and continuous pharmaceutical manufacturing through the National Center of Excellence; and

(B) the extent to which activities conducted by the National Center of Excellence are consistent with the mission of the FDA.

(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as precluding a National Center for Excellence designated under this section from receiving funds under any other provision of the 21st Century Cures Act (Public Law 114–255, 130 Stat. 1033) or any other Federal law.

(h) ANNUAL REVIEW AND REPORTS.—

(1) ANNUAL REPORT TO CONGRESS.—Beginning not later than 1 year after the date on which the first designation is made under subsection (b), and annually thereafter, the Secretary shall—

(A) submit to Congress a report describing the activities, partnerships and collaborations, Federal policy recommendations, previous and continuing funding, and findings of, and any other applicable information from, the National Centers of Excellence designated under this section;

(B) include in the report an accounting of the Federal administrative expenses described in subsection (i)(2) over the reporting period; and

(C) make the report available to the public in an easily accessible electronic format on the website of the FDA.

(2) CENTER OF EXCELLENCE REPORT.—An entity receiving a grant under this section shall, not later than 1 year after receiving the grant, and annually thereafter for the duration of the grant period, submit to the Secretary a summary of programs and activities funded under the grant.

(3) PERIODIC REVIEW.—The Secretary shall periodically review the National Centers of Excellence designated under this section to ensure that the National Centers of Excellence continue to meet the criteria for designation under this section.

(4) ADDITIONAL REPORT TO CONGRESS.—Not later than 1 year after the date on which the first designation is made under subsection (b), the Secretary, in consultation with the National Centers of Excellence designated under this section, shall submit a report to the Congress on the role of the FDA in supporting advanced and continuous pharmaceutical manufacturing, including—

(A) a national framework of principles related to the implementation of advanced and continuous pharmaceutical manufacturing;

(B) a plan for the development of Federal regulations and guidance to support and facilitate the incorporation of advanced or continuous manufacturing into the development of pharmaceuticals;

(C) a plan for development of Federal regulations or guidance related to the review of advanced and continuous pharmaceutical manufacturing, including how those manufacturing

practices may be incorporated into the review of medical product applications; and

(D) a summary of relevant feedback related to improving advanced and continuous pharmaceutical manufacturing solicited from the public, which may include other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, and contract manufacturers, and other relevant entities.

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $100,000,000 for fiscal years 2026 and 2027.

(2) FEDERAL ADMINISTRATIVE EXPENSES.—Of the amounts made available to carry out this section for a fiscal year, the Secretary shall not use more than 8 percent for Federal administrative expenses, including training, technical assistance, reporting, and evaluation.

**§ 49513. Variations from current good manufacturing practices relating to combination products and manufacturing processes**

(a) IN GENERAL.—Not later than 18 months after December 13, 2016, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall identify types of combination products and manufacturing processes with respect to which the Secretary proposes that good manufacturing practices may be adopted—

(1) that vary from the requirements set forth in section 4.4 of title 21, Code of Federal Regulations (or any successor regulations); or

(2) that the Secretary proposes can satisfy the requirements in section 4.4 of title 21, Code of Federal Regulations, through alternative or streamlined mechanisms.

(b) PUBLICATION OF PROPOSED LIST.—The Secretary shall identify the types, variations from the requirements, and the mechanisms, in a proposed list published in the Federal Register.

(c) PUBLICATION OF FINAL LIST.—After a public comment period regarding the appropriate good manufacturing practices for the types, the Secretary shall publish a final list in the Federal Register, notwithstanding section 553 of title 5.

(d) RISK-BASED EVALUATION.—The Secretary shall evaluate the types, variations, and mechanisms using a risk-based approach.

(e) REVIEW OF FINAL LIST.—The Secretary shall periodically review the final list.

**§ 49514. Report relating to software functions**

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after December 13, 2016, and every 2 years thereafter, that—

(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;

(2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 13152(o)(1) of this title; and

(3) summarizes findings regarding the impact of the software functions on patient safety, including best practices to promote safety, education, and competency related to the functions.

**§ 49515. Predictable review timelines of vaccines by the Advisory Committee on Immunization Practices**

(a) DEFINITION OF ADVISORY COMMITTEE.—In this section, the term ''Advisory Committee'' means the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

(b) CONSIDERATION OF NEW VACCINES.—On the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

(c) ADDITIONAL INFORMATION.—If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee shall provide an update on the status of the Advisory Committee's review.

(d) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—

(1) are designated as a breakthrough therapy under section 13119 of this title and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) could be used in a public health emergency.

**§ 49516. Regulations relating to over-the-counter hearing aids**

(a) REGULATIONS TO ESTABLISH CATEGORY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue final regulations to establish a category of over-the-counter hearing aids (as defined in section 13152(q) of this title).

(2) REQUIREMENTS.—In promulgating the regulations under paragraph (1), the Secretary shall—

(A) include requirements that provide reasonable assurances of the safety and effectiveness of over-the-counter hearing aids;

(B) include requirements that establish or adopt output limits appropriate for over-the-counter hearing aids;

(C) include requirements for appropriate labeling of over-the-counter hearing aids, including—

(i) requirements that the labeling include a conspicuous statement that the device is only intended for adults age 18 and older;

(ii) information on how consumers may report adverse events;

(iii) information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss; and

(iv) advisements to consult promptly with a licensed health care practitioner; and

(D) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(3) PREMARKET NOTIFICATION.—The Secretary shall make findings under section 13136(m) of this title to determine whether over-the-counter hearing aids (as defined in section 13152(q) of this title) require a report under section 13136(k) of this title to provide reasonable assurance of safety and effectiveness.

(4) EFFECT ON STATE LAW.—A State or local government shall not establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids (as defined in section 13152(q) of this title) through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids.

(5) NO EFFECT ON PRIVATE REMEDIES.—Nothing in this section shall be construed to modify or otherwise affect the ability of any person to exercise

a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(b) GUIDANCE.—The final guidance of the Department of Health and Human Services entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device in section 10101 of this title and which products meet the definition of a personal sound amplification product, as set forth in the guidance.

**§ 49517. Annual report on inspections**

Not later than 120 days after the end of each fiscal year, the Secretary of Health and Human Services shall post on the website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under section 13504 or 13511 of this title or approval of a device under section 13142 of this title that were conducted during the previous fiscal year. The information shall include the following:

(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, including—

(A) the median time for drugs described in section 13511(k)(1)(A) of this title;

(B) the median time for drugs for which a notification has been submitted in accordance with section 13122(b) of this title during the previous fiscal year; and

(C) the median time for drugs on the drug shortage list in effect under section 13125 of this title at the time of the request.

(2) The median time from the issuance of a report pursuant to section 17504(b) of this title to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated, including the median time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting related to conditions observed by the Secretary during an inspection, to the time at which the Secretary concludes that corrective actions to resolve the conditions have been taken.

(4) The number of facilities that failed to implement adequate corrective or preventive actions

following a report issued pursuant to section 17504(b) of this title, resulting in a withhold recommendation for an application under review, including the number of the facilities manufacturing each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

**§ 49518. Expedited development and review of medical products for emergency uses**

(a) DEFINITION OF MEDICAL PRODUCT.—In this section, the term ''medical product'' means a drug (as defined in section 10101 of this title), a device (as defined in section 10101 of this title), or a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)).

(b) IN GENERAL.—The Secretary of Defense may request that the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, take actions to expedite the development of a medical product, review of investigational new drug applications under section 13510 of this title, review of investigational device exemptions under section 13152(g) of this title, and review of applications for approval and clearance of medical products under chapter 135 of this title, sections 13136(k) and 13142 of this title, and section 351 of the Public Health Service Act (42 U.S.C. 262), including applications for li-

censing of vaccines or blood as biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), or applications for review of regenerative medicine advanced therapy products under section 13119(h) of this title, if there is a military emergency, or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of the application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate the life-threatening risk.

(c) ACTIONS.—On a request by the Secretary of Defense under subsection (b), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall take action to expedite the development and review of an applicable application or notification with respect to a medical product described in subsection (b), which may include, as appropriate—

(1) holding meetings with the sponsor and the review team throughout the development of the medical product;

(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the medical product to ensure that the development program to gather the nonclinical and

clinical data necessary for approval or clearance is as efficient as practicable;

(3) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(4) assigning a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor;

(5) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment;

(6) applying any applicable Food and Drug Administration program intended to expedite the development and review of a medical product; and

(7) in appropriate circumstances, permitting expanded access to the medical product during the investigational phase, in accordance with applicable requirements of the Food and Drug Administration.

(d) ENHANCED COLLABORATION AND COMMUNICATION.—Unless the Secretary of Defense determines that any meetings described in this subsection are not nec-

essary, in order to facilitate enhanced collaboration and communication with respect to the most current priorities of the Department of Defense—

(1) the Food and Drug Administration shall meet with the Department of Defense and any other appropriate development partners, such as the Biomedical Advanced Research and Development Authority, on a semi-annual basis for the purposes of conducting a full review of the relevant products in the Department of Defense portfolio; and

(2) the Director of the Center for Biologics Evaluation and Research shall meet quarterly with the Department of Defense to discuss the development status of regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to the Department of Defense (which may include freeze dried plasma products and platelet alternatives).

**§ 49519. Actions for delays of generic drugs and biosimilar biological products**

(a) DEFINITIONS.—In this section:

(1) COMMERCIALLY REASONABLE, MARKET-BASED TERMS.—The term ''commercially reasonable, market-based terms'' means—

(A) a nondiscriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product.

(2) COVERED PRODUCT.—

(A) IN GENERAL.—The term ''covered product'' means—

(i) any drug approved under section 13504 or 13511 of this title or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) any product, including any device, that is marketed or intended for use with

such a drug or biological product, when reasonably necessary—

(I) to support approval of an application under chapter 135 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable; or

(II) otherwise to meet the requirements for approval under chapter 135 of this title, or section 351 of the Public Health Service Act (42 U.S.C. 262).

(B) EXCLUSION.—The term ''covered product'' does not include any drug or biological product that appears on the drug shortage list in effect under section 13125 of this title, unless—

(i) the drug or biological product has been on the drug shortage list in effect under section 13125 of this title continuously for more than 6 months; or

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage.

(3) DEVICE.—The term ''device'' has the meaning given the term in section 10101 of this title.

(4) ELIGIBLE PRODUCT DEVELOPER.—The term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under section 13503(b) or 13511 of this title or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

(5) LICENSE HOLDER.—The term ''license holder'' means the holder of an application approved under section 13504 or 13511 of this title or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product.

(6) REMS.—The term ''REMS'' means a risk evaluation and mitigation strategy under section 13111 of this title.

(7) REMS WITH ETASU.—The term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 13111(f) of this title.

(8) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(9) SINGLE, SHARED SYSTEM OF ELEMENTS TO ENSURE SAFE USE.—The term ''single, shared system of elements to ensure safe use'' means a single, shared system of elements to ensure safe use under section 13111(f) of this title.

(10) SUFFICIENT QUANTITIES.—The term ''sufficient quantities'' means an amount of a covered product that the eligible product developer determines allows the eligible product developer to—

(A) conduct testing to support an application under—

(i) section 13503(b) or 13511 of this title; or

(ii) section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined

to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the eligible product developer has not obtained sufficient quan-

tities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has submitted a written request to purchase sufficient quantities of the covered product to the license holder, and the request—

(I) was sent to a named corporate officer of the license holder;

(II) was made by certified or registered mail with return receipt requested;

(III) specified—

(aa) an individual as the point of contact for the license holder to direct communications related to the sale of the covered product to the eligible product developer; and

(bb) a means for electronic and written communications with that individual; and

(IV) specified an address to which the covered product was to be

shipped on reaching an agreement to transfer the covered product; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that the protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms;

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to the individual specified pursuant to paragraph (2)(A)(iii)(III), by a means of communication (electronic, written, or both) specified pursuant to that paragraph, to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept the offer by the date that is 7 days after the date on which the eligible product developer received the offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept the offer by the date that is 10 days after the date on which the eligible product developer received the offer from the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide eligible product developers with suffi-

cient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the

date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of the award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards

to ensure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that the section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

(e) RULE OF CONSTRUCTION.—Nothing in this section, section 13111 of this title, or the amendments made by subsections (d) and (f) of section 610 of division N of the Further Consolidated Appropriations Act, 2020 (Public Law 116–94, 133 Stat. 3135, 3136) shall be construed as—

(1) prohibiting a license holder from providing an eligible product developer access to a covered

product in the absence of an authorization under this section; or

(2) in any way negating the applicability of a REMS with ETASU, as otherwise required under such section 13111 of this title, with respect to the covered product.

**§ 49520. Resources regarding cybersecurity of devices**

(a) DEFINITION OF DEVICE.—In this section, the term ''device'' has the meaning given the term in section 10101(a) of this title.

(b) UPDATING PUBLIC INFORMATION.—Not later than 180 days after December 29, 2022, and not less than annually thereafter, the Secretary of Health and Human Services shall update public information provided by the Food and Drug Administration, including on the website of the Food and Drug Administration, with information regarding improving cybersecurity of devices, which information shall include information on—

(1) identifying and addressing cyber vulnerabilities for health care providers, health systems, and device manufacturers; and

(2) how the entities under paragraph (1) may access support through the Cybersecurity and Infrastructure Security Agency and other Federal entities, including the Department of Health and

Human Services, to improve the cybersecurity of devices.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the Secretary's authority related to ensuring that there is a reasonable assurance of the safety and effectiveness of devices, which may include ensuring that there is a reasonable assurance of the cybersecurity of certain cyber devices, including for devices approved or cleared prior to December 29, 2022.

**§ 49521. Third party data transparency**

(a) IN GENERAL.—To the extent the Secretary of Health and Human Services (''Secretary'') relies on any data, analysis, or other information or findings provided by entities that has been funded in whole or in part by, or otherwise performed under contract with, the Food and Drug Administration, in regulatory decision-making with respect to devices, the Secretary shall—

(1) request access to the datasets, inputs, clinical or other assumptions, methods, analytical code, results, and other components underlying or comprising the analysis, conclusions, or other findings on which the Secretary seeks to rely; and

(2) in the event that information described in paragraph (1) is used to support regulatory decision-making, and as otherwise appropriate, to the extent

practicable, provide the manufacturer or manufacturers subject to the decision a summary of the information, subject to protection of confidential commercial information or trade secret information or personally identifiable information.

(b) REPORT.—Not later than September 30, 2023, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and publish on the website of the Food and Drug Administration, a report on the number of postmarket device signals communications issued by the Secretary, the sources of data for the signals, and how the signals were revised or resolved.

(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the delay of any regulatory decision-making or other action of the Food and Drug Administration.

**§ 49522. Annual summary report on progress to increase diversity in clinical studies**

(a) IN GENERAL.—Beginning not later than 2 years after December 29, 2022, and each year thereafter, the Secretary of Health and Human Services shall submit to Congress, and publish on the public website of the Food and Drug Administration, a report that—

(1) summarizes, in aggregate, the diversity action plans received pursuant to section 13526 or 13152(g)(9) of this title; and

(2) contains information, in the aggregate, on—

(A) for drugs, biological products, and devices approved, licensed, cleared, or classified under chapter 135 of this title or section 13136(k), 13140(h)(2), or 13142 of this title, or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), whether the clinical studies conducted with respect to the applications met the demographic subgroup enrollment goals from the diversity action plan submitted for the applications; and

(B) the reasons provided, if any, for why enrollment goals from submitted diversity action plans were not met.

(b) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

# Subtitle V—Comprehensive Drug Abuse Prevention and Control

# Division A—Controlled Substances

# Chapter 501—General Provisions

Sec.
50101. Definitions.
50102. Congressional findings and declarations.

## § 50101. Definitions

In this division:

(1) ADDICT.—The term ''addict'' means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to the individual's addiction.

(2) ADMINISTER.—The term ''administer'' refers to the direct application, whether the application is by injection, inhalation, ingestion, or any other means, of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in the practitioner's presence, by the practitioner's authorized agent); or

(B) the patient or research subject at the direction and in the presence of the practitioner.

(3) AGENT.—

(A) IN GENERAL.—The term ''agent'', when referring to an agent of a manufacturer, distributor, or dispenser, means an authorized person that acts on behalf of or at the direction of the manufacturer, distributor, or dispenser.

(B) EXCLUSION.—The term ''agent'' does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) ANABOLIC STEROID.—

(A) IN GENERAL.—The term ''anabolic steroid'' means any drug or hormonal substance chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone).

(B) INCLUSIONS.—The term ''anabolic steroid'' includes—

(i) androstanediol—

(I) 3β,17β-dihydroxy-5α-androstane; and

(II) 3α,17β-dihydroxy-5α-androstane;

(ii) androstanedione (5α-androstan-3,17-dione);

(iii) androstenediol—

(I) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);

(II) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);

(III) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene); and

(IV) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);

(iv) androstenedione—

(I) 1-androstenedione ([5α]-androst-1-en-3,17-dione);

(II) 4-androstenedione (androst-4-en-3,17-dione); and

(III) 5-androstenedione (androst-5-en-3,17-dione);

(v) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(vi) boldenone (17β-hydroxyandrost-1,4,-diene-3-one);

(vii) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(viii) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one);

(ix) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one);

(x) Δ1-dihydrotestosterone (a.k.a. ''1-testosterone'') (17β-hydroxy-5α-androst-1-en-3-one);

(xi) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);

(xii) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one);

(xiii) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);

(xiv) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one);

(xv) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one);

(xvi) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan);

(xvii) 13β-ethyl-17β-hydroxygon-4-en-3-one;

(xviii) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);

(xix) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);

(xx) mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one);

(xxi) mesterolone (1α-methyl-17β-hydroxy-[5α]-androstan-3-one);

(xxii) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);

(xxiii) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene);

(xxiv) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);

(xxv) 17α-methyl-3β, 17β-dihydroxy-5α-androstane;

(xxvi) 17α-methyl-3α,17β-dihydroxy-5α-androstane;

(xxvii) 17α-methyl-3β,17β-dihydroxyandrost-4-ene;

(xxviii) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);

(xxix) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);

(xxx) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9-11-trien-3-one);

(xxxi) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);

(xxxii) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);

(xxxiii) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. ''17-α-methyl-1-testosterone'');

(xxxiv) nandrolone (17β-hydroxyestr-4-en-3-one);

(xxxv) norandrostenediol—

(I) 19-nor-4-androstenediol (3β, 17β-dihydroxyestr-4-ene);

(II) 19-nor-4-androstenediol (3α, 17β-dihydroxyestr-4-ene);

(III) 19-nor-5-androstenediol (3β, 17β-dihydroxyestr-5-ene); and

(IV) 19-nor-5-androstenediol (3α, 17β-dihydroxyestr-5-ene);

(xxxvi) norandrostenedione—

(I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and

(II) 19-nor-5-androstenedione (estr-5-en-3,17-dione;

(xxxvii) norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);

(xxxviii) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);

(xxxix) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);

(xl) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);

(xli) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one);

(xlii) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);

(xliii) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one);

(xliv) stanozolol (17α-methyl-17β-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole);

(xlv) stenbolone (17β-hydroxy-2-methyl-[5α]-androst-1-en-3-one);

(xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);

(xlvii) testosterone (17β-hydroxyandrost-4-en-3-one);

(xlviii) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one);

(xlix) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one);

(l) 5α-Androstan-3,6,17-trione;

(li) 6-bromo-androstan-3,17-dione;

(lii) 6-bromo-androsta-1,4-diene-3,17-dione;

(liii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;

(liv) 4-chloro-17α-methyl-androst-4-ene-3β,17β-diol;

(lv) 4-chloro-17α-methyl-17β-hydroxy-androst-4-en-3-one;

(lvi) 4-chloro-17α-methyl-17β-hydroxy-androst-4-ene-3,11-dione;

(lvii) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;

(lviii) 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one;

(lix) 2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one;

(lx) 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol;

(lxi) [3,2-c]-furazan-5α-androstan-17β-ol;

(lxii) 3β-hydroxy-estra-4,9,11-trien-17-one;

(lxiii) 17α-methyl-androst-2-ene-3,17β-diol;

(lxiv) 17α-methyl-androsta-1,4-diene-3,17β-diol;

(lxv) Estra-4,9,11-triene-3,17-dione;

(lxvi) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;

(lxvii) 6α-Methyl-androst-4-ene-3,17-dione;

(lxviii) 17α-Methyl-androstan-3-hydroxyimine-17β-ol;

(lxix) 17α-Methyl-5α-androstan-17β-ol;

(lxx) 17β-Hydroxy-androstano[2,3-d]isoxazole;

(lxxi) 17β-Hydroxy-androstano[3,2-c]isoxazole;

(lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5α-androstan-17β-ol;

(lxxiii) [3,2-c]pyrazole-androst-4-en-17β-ol;

(lxxiv) [3,2-c]pyrazole-5α-androstan-17β-ol; and

(lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

(C) SCHEDULED BY ATTORNEY GENERAL.—The substances excluded under subparagraph (B) may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 50301 of this title.

(D) EXCLUSIONS.—

(i) IN GENERAL.—Except as provided in clause (ii), the term ''anabolic steroid'' does not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the Secretary for the administration.

(ii) PRESCRIBING, DISPENSING, OR DISTRIBUTING FOR HUMAN USE.—If any person prescribes, dispenses, or distributes

the steroid described in clause (i) for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraphs (A) through (C).

(E) DRUG OR SUBSTANCE NOT LISTED BUT DERIVED FROM LISTED ANABOLIC STEROID.—

(i) IN GENERAL.—Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (B) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (B) shall be considered to be an anabolic steroid for purposes of this division if—

(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—

(aa) promotes muscle growth; or

(bb) otherwise causes a pharmacological effect similar to that of testosterone; or

(II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) NOT CONSIDERED DRUG OR HORMONAL SUBSTANCE.—A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it—

(I) is—

(aa) an herb or other botanical;

(bb) a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(cc) a combination of 2 or more substances described in item (aa) or (bb);

(II) is a dietary ingredient for purposes of subtitle I of this title; and

(III) is not anabolic or androgenic.

(iii) BURDEN.—In accordance with section 50915(a) of this title, any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to the exemption or exception.

(5) AT RETAIL.—The term ''at retail'', with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

(6) BROKER.—The term ''broker'' means a person that assists in arranging an international transaction in a listed chemical by—

(A) negotiating contracts;

(B) serving as an agent or intermediary; or

(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(7) CHEMICAL MIXTURE.—

(A) IN GENERAL.—The term ''chemical mixture'' means a combination of 2 or more

chemical substances, at least 1 of which is not a list I chemical or a list II chemical.

(B) EXCLUSIONS.—The term ''chemical mixture'' does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(8) CONTROL.—The term ''control'' means to add a drug or other substance, or immediate precursor, to a schedule under chapter 503 of this title, whether by transfer from another schedule or otherwise.

(9) CONTROLLED SUBSTANCE.—

(A) IN GENERAL.—The term ''controlled substance'' means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V under chapter 503 of this title.

(B) EXCLUSION.—The term ''controlled substance'' does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.).

(10) CONTROLLED SUBSTANCE ANALOGUE.—

(A) IN GENERAL.—Except as provided in subparagraph (C), the term ''controlled substance analogue'' means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) that has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, that the person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) DESIGNATION AS LISTED CHEMICAL.—The designation of gamma butyrolactone or any

other chemical as a listed chemical pursuant to paragraph (30) or (31) does not preclude a finding pursuant to subparagraph (A) that the chemical is a controlled substance analogue.

(C) EXCLUSIONS.—The term ''controlled substance analogue'' does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person, any substance, if an exemption is in effect for investigational use, for that person, under chapter 135 of this title to the extent conduct with respect to the substance is pursuant to the exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(11) CONVENTION ON PSYCHOTROPIC SUBSTANCES.—The term ''Convention on Psychotropic Substances'' means the Convention on Psychotropic Substances, done at Vienna, Austria February 21, 1971 (32 UST 543; TIAS 9725).

(12) COUNTERFEIT SUBSTANCE.—The term ''counterfeit substance'' means a controlled substance that, or the container or labeling of which, without authorization—

(A) bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness of the trademark, trade name, or other identifying mark, imprint, number, or device, of a manufacturer, distributor, or dispenser other than the person or persons that in fact manufactured, distributed, or dispensed the substance; and

(B) falsely purports or is represented to be the product of, or to have been distributed by, the other manufacturer, distributor, or dispenser.

(13) DELIVER, DISTRIBUTE, OR DISPENSE BY MEANS OF THE INTERNET.—The term ''deliver, distribute, or dispense by means of the internet'' refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the internet.

(14) DELIVERY.—The term ''delivery'' means the actual, constructive, or attempted transfer of a

controlled substance or a listed chemical, whether or not there exists an agency relationship.

(15) DEPRESSANT OR STIMULANT SUBSTANCE.—The term ''depressant or stimulant substance'' means—

(A) a drug that contains any quantity of barbituric acid or any of the salts of barbituric acid;

(B) a drug that contains any quantity of—

(i) amphetamine or any of its optical isomers;

(ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or

(iii) any substance that the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system;

(C) lysergic acid diethylamide; or

(D) any drug that contains any quantity of a substance that the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on

the central nervous system or its hallucinogenic effect.

(16) DETOXIFICATION TREATMENT.—The term ''detoxification treatment'' means the dispensing, for a period not in excess of 180 days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within the period.

(17) DISPENSE.—

(A) IN GENERAL.—The term ''dispense'' means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for the delivery.

(B) DISPENSER.—The term ''dispenser'' means a practitioner that delivers a controlled substance to an ultimate user or research subject as described in subparagraph (A).

(18) DISTRIBUTE.—

(A) IN GENERAL.—The term ''distribute'' means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.

(B) DISTRIBUTOR.—The term ''distributor'' means a person that delivers a controlled substance or a listed chemical as described in subparagraph (A).

(19) DRUG.—The term ''drug'' has the meaning given the term in section 10101(a) of this title.

(20) DRUG ENFORCEMENT ADMINISTRATION.—The term ''Drug Enforcement Administration'' means the Drug Enforcement Administration in the Department of Justice.

(21) FELONY.—The term ''felony'' means any Federal or State offense classified by applicable Federal or State law as a felony.

(22) FELONY DRUG OFFENSE.—The term ''felony drug offense'' means an offense that is punishable by imprisonment for more than 1 year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.

(23) FENTANYL-RELATED SUBSTANCE.—The term ''fentanyl-related substance'' has the meaning given the term in section 50302(c)(1)(E)(i) of this title.

(24) FILLING NEW PRESCRIPTIONS FOR CONTROLLED SUBSTANCES IN SCHEDULE III, IV, OR V.—The term ''filling new prescriptions for controlled substances in schedule III, IV, or V'' means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if—

(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 50509 of this title (in this paragraph referred to as the ''original prescription'');

(B) the pharmacy contacts the practitioner that issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

(25) HOMEPAGE.—The term ''homepage'' means the opening or main page or screen of the website of an online pharmacy that is viewable on the internet.

(26) IMMEDIATE PRECURSOR.—The term ''immediate precursor'' means a substance—

(A) that the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) that is an immediate chemical intermediary used or likely to be used in the manufacture of the controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of the controlled substance.

(27) INTERNATIONAL TRANSACTION.—The term ''international transaction'' means a transaction involving the shipment of a listed chemical across an international border (other than a United

States border) in which a broker or trader located in the United States participates.

(28) INTERNET.—The term ''internet'' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, that comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to the protocol, to communicate information of all kinds by wire or radio.

(29) ISOMER.—

(A) IN GENERAL.—The term ''isomer'' means the optical isomer, except as used in schedule I(C) and schedule II(A)(iv).

(B) CERTAIN SCHEDULES.—In schedule I(C), the term ''isomer'' means any optical, positional, or geometric isomer. In schedule II(A)(iv), the term ''isomer'' means any optical or geometric isomer.

(30) LIST I CHEMICAL.—

(A) IN GENERAL.—The term ''list I chemical'' means a chemical specified by regulation of the Attorney General as a chemical that—

(i) is used in manufacturing a controlled substance in violation of this division; and

(ii) is important to the manufacture of the controlled substances.

(B) INCLUSIONS.—The term ''list I chemical'' includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or on petition to the Attorney General by any person) the following:

(i) Anthranilic acid, its esters, and its salts.

(ii) Benzyl cyanide.

(iii) Ephedrine, its salts, optical isomers, and salts of optical isomers.

(iv) Ergonovine and its salts.

(v) Ergotamine and its salts.

(vi) N-Acetylanthranilic acid, its esters, and its salts.

(vii) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(viii) Phenylacetic acid, its esters, and its salts.

(ix) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(x) Piperidine and its salts.

(xi) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(xii) 3,4-Methylenedioxyphenyl-2-propanone.

(xiii) Methylamine.

(xiv) Ethylamine.

(xv) Propionic anhydride.

(xvi) Isosafrole.

(xvii) Safrole.

(xviii) Piperonal.

(xix) N-Methylephedrine.

(xx) N-methylpseudoephedrine.

(xxi) Hydriodic acid.

(xxii) Benzaldehyde.

(xxiii) Nitroethane.

(xxiv) Gamma butyrolactone.

(xxv) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in clauses (xiii) through (xxi).

(31) LIST II CHEMICAL.—

(A) IN GENERAL.—The term ''list II chemical'' means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this division.

(B) INCLUSIONS.—The term ''list II chemical'' includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or on petition to the Attorney General by any person) the following chemicals:

(i) Acetic anhydride.

(ii) Acetone.

(iii) Benzyl chloride.

(iv) Ethyl ether.

(v) Potassium permanganate.

(vi) 2-Butanone (or Methyl Ethyl Ketone).

(vii) Toluene.

(viii) Iodine.

(ix) Hydrochloric gas.

(32) LISTED CHEMICAL.—The term ''listed chemical'' means any list I chemical or any list II chemical.

(33) MAINTENANCE TREATMENT.—The term ''maintenance treatment'' means the dispensing, for a period in excess of 21 days, of a narcotic drug in the treatment of an individual for dependence on heroin or other morphine-like drugs.

(34) MANUFACTURE.—

(A) IN GENERAL.—The term ''manufacture'' means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

(B) INCLUSIONS.—The term ''manufacture'' includes any packaging or repackaging of a substance under subparagraph (A) or labeling or relabeling of its container.

(C) EXCLUSIONS.—The term ''manufacture'' does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to the practitioner's administration or dis-

pensing of the drug or substance in the course of the practitioner's professional practice.

(D) MANUFACTURER.—The term ''manufacturer'' means a person that manufactures a drug or other substance.

(35) MARIHUANA.—

(A) IN GENERAL.—Subject to subparagraph (B), the terms ''marihuana'' and ''marijuana'' mean—

(i) all parts of the plant Cannabis sativa L., whether growing or not;

(ii) the seeds of the plant Cannabis sativa L.;

(iii) the resin extracted from any part of the plant Cannabis sativa L.; and

(iv) every compound, manufacture, salt, derivative, mixture, or preparation of the plant Cannabis sativa L., its seeds or resin.

(B) EXCLUSIONS.—The terms ''marihuana'' and ''marijuana'' do not include—

(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639o); or

(ii) the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted from the mature stalks), fiber, oil, or cake, or the sterilized seed of the plant that is incapable of germination.

(36) MOBILE RETAIL VENDOR.—The term ''mobile retail vendor'' means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from 1 location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(37) NARCOTIC DRUG.—

(A) IN GENERAL.—The term ''narcotic drug'' means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently

by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(i) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation.

(ii) Poppy straw and concentrate of poppy straw.

(iii) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(iv) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(v) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(vi) Any compound, mixture, or preparation that contains any quantity of any of the substances referred to in clauses (i) through (v).

(B) EXCLUSIONS.—The term ''narcotic drug'' does not include the isoquinoline alkaloids of opium.

(38) ONLINE PHARMACY.—

(A) IN GENERAL.—The term ''online pharmacy'' means a person, entity, or internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the internet.

(B) EXCLUSIONS.—The term ''online pharmacy'' does not include—

(i) manufacturers or distributors registered under subsection (b), (c), (f), or (g) of section 50503 of this title that do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners that are registered under section 50503(h) of this title and whose activities are authorized by that registration;

(iii) any hospital or other medical facility that is operated by a Federal agency (including the Armed Forces), provided the

hospital or other facility is registered under section 50503(h) of this title;

(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent the facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.);

(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided the agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of the agent or employee, with the hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent the individuals are furnishing services pursuant to the contracts or compacts described in clause (iv);

(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(vii) a person, entity, or internet site that is not in the United States and does

not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the internet to any person in the United States;

(viii) a pharmacy registered under section 50503(h) of this title whose dispensing of controlled substances via the internet consists solely of—

(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (45); or

(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (24); or

(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an ''online pharmacy''.

(39) OPIATE; OPIOID.—The term ''opiate'' or ''opioid'' means any drug or other substance having an addiction-forming or addiction-sustaining liability

similar to morphine or being capable of conversion into a drug having the addiction-forming or addiction-sustaining liability.

(40) OPIUM POPPY.—The term ''opium poppy'' means the plant of the species Papaver somniferum L., except the seed of the plant.

(41) POPPY STRAW.—The term ''poppy straw'' means all parts, except the seeds, of the opium poppy, after mowing.

(42) PRACTICE OF TELEMEDICINE.—The term ''practice of telemedicine'' means the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) that is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), which practice—

(A) is being conducted—

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 50503(h) of this title; and

(ii) by a practitioner—

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 50503(h) of this title in the State in which the patient is located, unless the practitioner—

(aa) is exempted from the registration in all States under section 50502(d) of this title; or

(bb) is—

(AA) an employee or contractor of the Department of Veterans Affairs that is acting in the scope of the employment or contract; and

(BB) registered under section 50503(h) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Af-

fairs registered under section 50503(h) of this title;

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner—

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under section 50503(h) of this title in the State in which the patient is located, unless the practitioner—

(I) is exempted from the registration in all States under section 50502(d) of this title; or

(II) is—

(aa) an employee or contractor of the Department of Veterans Affairs that is acting in the scope of the employment or contract; and

(bb) registered under section 50503(h) of this title in any State or is using the registration of a hospital or clinic operated by

the Department of Veterans Affairs registered under section 50503(h) of this title;

(C) is being conducted by a practitioner—

(i) that is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.);

(ii) that is acting within the scope of the employment, contract, or compact described in clause (i); and

(iii) that is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 50512(g)(2) of this title;

(D)(i) is being conducted during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

(ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney

General, designates, provided that the designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5;

(E) is being conducted by a practitioner that has obtained from the Attorney General a special registration under section 50512(h) of this title;

(F) is being conducted—

(i) in a medical emergency situation—

(I) that prevents the patient from being in the physical presence of a practitioner registered under section 50503(h) of this title that is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

(II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 50503(h) of this title;

(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) by a practitioner who—

(I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(II) is registered under section 50503(h) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered

under section 50503(h) of this title; and

(III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or

(G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(43) PRACTITIONER.—The term ''practitioner'' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the person practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(44) PRODUCTION.—The term ''production'' includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(45) REFILLING PRESCRIPTIONS FOR CONTROLLED SUBSTANCES IN SCHEDULE III, IV, OR V.—

(A) IN GENERAL.—The term ''refilling prescriptions for controlled substances in schedule III, IV, or V'' means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 50509 of this title, as appropriate.

(B) EXCLUSIONS.—The term ''refilling prescriptions for controlled substances in schedule III, IV, or V'' does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(46) REGULAR CUSTOMER.—The term ''regular customer'' means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(47) REGULAR IMPORTER.—The term ''regular importer'' means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(48) REGULATED PERSON.—The term ''regulated person'' means a person that manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or that acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(49) REGULATED SELLER.—

(A) IN GENERAL.—The term ''regulated seller'' means a retail distributor (including a pharmacy or a mobile retail vendor).

(B) EXCLUSIONS.—The term ''regulated seller'' does not include an employee or agent of a distributor described in subparagraph (A).

(50) REGULATED TRANSACTION.—

(A) IN GENERAL.—The term ''regulated transaction'' means—

(i) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of,

a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical; and

(ii) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(B) EXCLUSIONS.—The term ''regulated transaction'' does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of

the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 50511 of this title;

(iii) any category of transaction, or any category of transaction for a specific listed chemical or chemicals, specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this division or division B;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under subtitle I of this title, subject to clause (v), unless—

(I) the Attorney General has determined under section 50304 of this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General;

(v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under section 50511(b)(3) of this title; or

(vi) any transaction in a chemical mixture that the Attorney General has by regulation designated as exempt from the application of this division or division B based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered.

(51) RETAIL DISTRIBUTOR.—

(A) IN GENERAL.—The term ''retail distributor'' means a grocery store, general merchandise store, drug store, or other entity or

person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) ENTITIES.—For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

(52) SCHEDULED LISTED CHEMICAL PRODUCT.—

(A) IN GENERAL.—The term ''scheduled listed chemical product'' means, subject to subparagraph (C), a product that—

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under subtitle I of this title as a nonprescription drug.

(B) INCLUSIONS.—Each reference in subparagraph (A)(i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of the chemical.

(C) EXCLUSIONS.—The term ''scheduled listed chemical product'' does not include a product described in subparagraph (A) if the product contains a chemical specified in subparagraph (A) that the Attorney General has under section 50301(a) of this title added to any of the schedules under section 50302(c) of this title. In the absence of any such scheduling by the Attorney General, a chemical specified in subparagraph (A) may not be considered to be a controlled substance.

(53) SECRETARY.—The term ''Secretary'', unless the context otherwise indicates, means the Secretary of Health and Human Services.

(54) SERIOUS BODILY INJURY.—The term ''serious bodily injury'' means bodily injury that involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(55) SERIOUS DRUG FELONY.—The term ''serious drug felony'' means an offense described in section 924(e)(2) of title 18 for which—

(A) the offender served a term of imprisonment of more than 12 months; and

(B) the offender's release from any term of imprisonment was within 15 years of the commencement of the instant offense.

(56) SERIOUS VIOLENT FELONY.—The term ''serious violent felony'' means—

(A) an offense described in section 3559(c)(2) of title 18 for which the offender

served a term of imprisonment of more than 12 months; and

(B) any offense that would be a felony violation of section 113 of title 18, if the offense were committed in the special maritime and territorial jurisdiction of the United States, for which the offender served a term of imprisonment of more than 12 months.

(57) SINGLE CONVENTION ON NARCOTIC DRUGS.—The term ''Single Convention on Narcotic Drugs'' means the Single Convention on Narcotic Drugs, 1961, done at New York, New York March 30, 1961 (18 UST 1407; TIAS 6298).

(58) STATE.—The term ''State'' means a State, the District of Columbia, and any commonwealth or territory (including a possession) of the United States.

(59) SUSPICIOUS ORDER.—The term ''suspicious order'' includes—

(A) an order of a controlled substance of unusual size;

(B) an order of a controlled substance deviating substantially from a normal pattern; and

(C) orders of controlled substances of unusual frequency.

(60) TRADER.—The term ''trader'' has the meaning given the term ''broker'' in paragraph (6).

(61) ULTIMATE USER.—The term ''ultimate user'' means an individual who has lawfully obtained, and who possesses, a controlled substance for the individual's own use or for the use of a member of the individual's household or for an animal owned by the individual or by a member of the individual's household.

(62) UNITED STATES.—The term ''United States'', when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

**§ 50102. Congressional findings and declarations**

Congress makes the following findings and declarations:

(1) Many of the drugs included within this division have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detri-

mental effect on the health and general welfare of the American people.

(3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic that are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect on interstate commerce because—

(A) after manufacture, many controlled substances are transported in interstate commerce;

(B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution; and

(C) controlled substances possessed commonly flow through interstate commerce immediately prior to the possession.

(4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in those controlled substances.

(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed

interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of the traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

# Chapter 503—Authority To Control; Standards and Schedules

Sec.
50301. Authority and criteria for classification of substances.
50302. Schedules of controlled substances.
50303. Treatment of controlled substance analogues.
50304. Removal of exemption of certain drugs.

## § 50301. Authority and criteria for classification of substances

(a) RULES AND REGULATIONS OF ATTORNEY GENERAL.—

(1) IN GENERAL.—The Attorney General shall apply the provisions of this division to the controlled substances listed in the schedules established by sec-

tion 50302 of this title and to any other drug or other substance added to the schedules under this division. Except as provided in subsections (d) and (e), the Attorney General may by rule—

(A) add to such a schedule or transfer between the schedules any drug or other substance if the Attorney General—

(i) finds that the drug or other substance has a potential for abuse; and

(ii) makes with respect to the drug or other substance the findings prescribed by subsection (b) of section 50302 of this title for the schedule in which the drug is to be placed; or

(B) remove any drug or other substance from the schedules if the Attorney General finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

(2) HEARING.—Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of title 5.

(3) INITIATION OF PROCEEDINGS.—Proceedings for the issuance, amendment, or repeal of the rules may be initiated by the Attorney General—

(A) on the Attorney General's own motion;

(B) at the request of the Secretary; or

(C) on the petition of any interested party.

(b) EVALUATION OF DRUGS AND OTHER SUBSTANCES.—

(1) REQUEST FOR SCIENTIFIC AND MEDICAL EVALUATION AND FOR RECOMMENDATIONS FROM SECRETARY.—The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and the Secretary's recommendations, as to whether the drug or other substance should be controlled or removed as a controlled substance.

(2) FACTORS TO BE CONSIDERED BY SECRETARY.—In making the evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical con-

siderations involved in paragraphs (1), (4), and (5) of subsection (c).

(3) RECOMMENDATIONS WITH RESPECT TO SCHEDULE.—The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which the drug or other substance should be listed.

(4) FORMAT; DEADLINE.—The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time.

(5) BINDING NATURE OF RECOMMENDATIONS.—The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to the scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.

(6) SUBSTANTIAL EVIDENCE OF POTENTIAL FOR ABUSE.—If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, they Attorney General

shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) FACTORS DETERMINATIVE OF CONTROL OR REMOVAL FROM SCHEDULES.—In making any finding under subsection (a) or under section 50302(b) of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this division.

(d) INTERNATIONAL TREATIES, CONVENTIONS, AND PROTOCOLS REQUIRING CONTROL.—

(1) CONTROL REQUIRED BY OBLIGATIONS.—If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling the drug under the schedule that the Attorney General considers most appropriate to carry out the obligations, without regard to—

(A) the findings required by subsection (a) or section 50302(b) of this title; and

(B) the procedures prescribed by subsections (a) and (b).

(2) RESPONSIBILITIES OF THE SECRETARY.—

(A) NOTIFICATION FROM SECRETARY-GENERAL OF UNITED NATIONS RELATING TO INFORMATION TRANSMITTED BY OR TO WORLD HEALTH ORGANIZATION.—If the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, that may justify adding a drug or other substance to one of the schedules of the Convention on Psychotropic Substances, transferring a drug or sub-

stance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary who shall publish it in the Federal Register and provide opportunity to interested persons to submit to the Secretary comments respecting the scientific and medical evaluations that the Secretary is to prepare respecting the drug or substance. The Secretary shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) INFORMATION RELATING TO COMMISSION ON NARCOTIC DRUGS OF THE UNITED NATIONS.—If the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention on Psychotropic Substances, transfer a drug or substance from

one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice, to the Secretary, of the information and the Secretary shall publish a summary of the information in the Federal Register and provide opportunity to interested persons to submit to the Secretary comments respecting the recommendation that the Secretary is to furnish, pursuant to this subparagraph, respecting the proposal. The Secretary shall evaluate the proposal and furnish a recommendation to the Secretary of State, which recommendation shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) NOTIFICATION OF SCHEDULING DECISION.—If the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a ''schedule notice'') that existing legal controls applicable under this division to a drug or substance and the controls required by subtitle I of this title do not

meet the requirements of the schedule of the Convention on Psychotropic Substances in which the drug or substance has been placed, the Secretary, after consultation with the Attorney General, shall first determine whether existing legal controls under this division applicable to the drug or substance and the controls required by subtitle I of this title meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If the requirements are met by the existing controls but the Secretary nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that the Attorney General initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b), to apply the more stringent controls.

(B) If the requirements are not met by the existing controls and the Secretary concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that the Attorney General initiate proceedings for sched-

uling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b).

(C) If the requirements are not met by the existing controls and the Secretary does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall—

(i) if the Secretary determines that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that the Attorney General initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b), to apply the additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention on Psychotropic Substances, pursuant to paragraph 7 of article 2 of the Convention on Psychotropic Substances, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as

prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention on Psychotropic Substances, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention on Psychotropic Substances to initiate proceedings to remove the drug or substance from the schedules under the Convention on Psychotropic Substances or to transfer the drug or substance to a schedule under the Convention on Psychotropic Substances different from the one specified in the schedule notice.

(4) ACTIONS BY ATTORNEY GENERAL.—

(A) TEMPORARY ORDER.—

(i) IN GENERAL.—If the Attorney General determines, after consultation with the Secretary, that proceedings initiated under recommendations made under subparagraph (B) or (C)(i) of paragraph (3)

will not be completed within the time period required by paragraph 7 of article 2 of the Convention on Psychotropic Substances, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this clause, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances.

(ii) EXCEPTING DRUG OR SUBSTANCE FROM APPLICATION OF CERTAIN PROVISIONS.—As a part of the order, the Attorney General shall, after consultation with the Secretary, except the drug or substance from the application of any provision of chapter 505 of this title that the Attorney General finds is not required to carry out the United States obligations

under paragraph 7 of article 2 of the Convention on Psychotropic Substances.

(iii) NOTICE OF QUALIFIED ACCEPTANCE.—In the case of proceedings initiated under paragraph (3)(B), the Attorney General, concurrently with the issuance of the order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention on Psychotropic Substances.

(iv) EXPIRATION.—A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) shall expire on the effective date of the application to the drug or substance of the controls resulting from the proceedings.

(B) ORDER CONTROLLING THE DRUG OR SUBSTANCE UNDER SCHEDULE IV OR V.—

(i) IN GENERAL.—After a notice of qualified acceptance of a scheduling decision with respect to a drug or other sub-

stance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under paragraph (3)(C)(iv) with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this clause, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice.

(ii) EXCEPTING DRUG OR SUBSTANCE FROM APPLICATION OF CERTAIN PROVI-

SIONS.—As a part of the order, the Attorney General shall, after consultation with the Secretary, except the drug or substance from the application of any provision of chapter 505 of this title that the Attorney General finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances.

(iii) EXPIRATION ON RECEIPT OF REVIEW DECISION.—

(I) REVIEW.—Expiration under subclause (II) shall apply if, as a result of a review under paragraph 8 of article 2 of the Convention on Psychotropic Substances of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)—

(aa) the scheduling decision is reversed; and

(bb) the drug or substance subject to the scheduling decision is not required to be controlled

under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances.

(II) EXPIRATION.—An order issued under this subparagraph with respect to the drug or substance under subclause (I)(bb) shall expire on receipt by the United States of the decision to reverse under subclause (I)(aa).

(iv) EXPIRATION ON RECEIPT OF NOTICE OF ACTION.—If, as a result of action taken pursuant to action initiated under a request transmitted under paragraph (3)(C)(iv), the drug or substance with respect to which the action was taken is not required to be controlled under schedule IV or V, the order issued under this subparagraph with respect to the drug or substance shall expire on receipt by the United States of a notice of the action taken with respect to the drug or sub-

stance under the Convention on Psychotropic Substances.

(C) EFFECT OF FINDINGS AND PROCEDURES TO ORDERS.—An order issued under subparagraph (A) or (B) may be issued without regard to—

(i) the findings required by subsection (a) or section 50302(b) of this title; and

(ii) the procedures prescribed by subsection (a) or (b).

(5) EFFECT OF CERTAIN PROVISIONS ON REQUESTS FOR REVIEW OF SCHEDULING DECISIONS UNDER CONVENTION.—Nothing in the amendments made by the Psychotropic Substances Act of 1978 (Public Law 95–633, 92 Stat. 3768) or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention on Psychotropic Substances, for review of scheduling decisions under the Convention on Psychotropic Substances, based on new or additional information.

(e) IMMEDIATE PRECURSORS.—The Attorney General may, without regard to the findings required by sub-

section (a) or section 50302(b) of this title and without regard to the procedures prescribed by subsections (a) and (b), place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) ABUSE POTENTIAL.—If, at the time a new drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that the drug has an abuse potential, the information shall be forwarded by the Secretary to the Attorney General.

(g) EXCLUSION OF NON-NARCOTIC SUBSTANCES SOLD OVER THE COUNTER WITHOUT A PRESCRIPTION.—

(1) IN GENERAL.—The Attorney General shall by regulation exclude any non-narcotic drug that contains a controlled substance from the application of this division and division B if the drug may, under subtitle I of this title, be lawfully sold over the counter without a prescription.

(2) DEXTROMETHORPHAN.—Dextromethorphan shall not be deemed to be included in any schedule

by reason of enactment of this division unless controlled pursuant to subsections (a) through (f).

(3) COMPOUND, MIXTURE, OR PREPARATION CONTAINING A CONTROLLED SUBSTANCE.—The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this division if the Attorney General finds that the compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a non-narcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains 1 or more other active ingredients that are not listed in any schedule and that are included in a schedule in the combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation that contains any controlled substance, that is not for administration to a human being or animal, and that is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged, it does not present any significant potential for abuse.

(C) On the recommendation of the Secretary, a compound, mixture, or preparation that contains any anabolic steroid, that is intended for administration to a human being or an animal, and that, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h) TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY.—

(1) IN GENERAL.—

(A) AUTHORITY.—If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, the Attorney General may, by order and without regard to the requirements of subsection (b) relating to the Secretary, schedule the substance in schedule I if the substance is not listed in any other schedule in section 50302 of this title or if no exemption or approval is in effect for the substance under chapter 135 of this title.

(B) ORDER.—An order under subparagraph (A) may not be issued before the expiration of 30 days from—

(i) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue the order and the grounds on which the order is to be issued; and

(ii) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) EXPIRATION.—The scheduling of a substance under this subsection shall expire at the end of 2 years from the date of the issuance of the order scheduling the substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1)(A) with respect to the substance, extend the temporary scheduling for up to 1 year.

(3) REQUIRED CONSIDERATIONS RELATING TO FINDING OF IMMINENT HAZARD.—When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5),

and (6) of subsection (c), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) NOTICE TO AND RESPONSE BY SECRETARY.—The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) ORDER TO BE VACATED ON SUBSEQUENT RULEMAKING.—An order issued under paragraph (1) with respect to a substance shall be vacated on the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) with respect to the substance.

(6) JUDICIAL REVIEW.—An order issued under paragraph (1) is not subject to judicial review.

(i) TEMPORARY AND PERMANENT SCHEDULING OF RECENTLY EMERGED ANABOLIC STEROIDS.—

(1) IN GENERAL.—The Attorney General may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Attorney General finds that—

(A) the drug or other substance satisfies the criteria for being considered an anabolic steroid under section 50101(4) of this title but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(B) adding the drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(2) EFFECTIVE DATE OF ORDER; PUBLICATION; GROUNDS; EXPIRATION.—

(A) IN GENERAL.—An order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue the order and the grounds on which the order is to be issued.

(B) EXPIRATION.—The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.

(3) NOTICE TO AND RESPONSE BY SECRETARY.—The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(4) ORDER TO BE VACATED ON SUBSEQUENT RULEMAKING.—A temporary scheduling order issued under paragraph (1) shall be vacated on the issuance of a permanent scheduling order under paragraph (6).

(5) JUDICIAL REVIEW.—An order issued under paragraph (1) is not subject to judicial review.

(6) PERMANENT ORDER.—The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if the drug or other substance satisfies the criteria for being considered an anabolic steroid under section 50101(4) of this title. The rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).

(j) INTERIM FINAL RULE; DATE OF ISSUANCE; PROCEDURE FOR FINAL RULE.—

(1) ISSUANCE.—With respect to a drug referred to in subsection (f), if the Secretary recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with the subsections and section 50302(b) of this title using the procedures described in paragraph (3).

(2) DATE.—The date described in this paragraph shall be the later of—

(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary in accordance with subsection (b); or

(B) the date on which the Attorney General receives notification from the Secretary that the Secretary has approved an application under section 13504, chapter 137, or section 14502 of this title or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or indexed a drug under section 14503 of this

title, with respect to the drug described in paragraph (1).

(3) PROCEDURE.—A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause for the regulation. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of the proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) and section 50302(b) of this title.

**§ 50302. Schedules of controlled substances**

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There are established 5 schedules of controlled substances, to be known as schedules I, II, III, IV, and V.

(2) SUBSTANCES.—The schedules shall initially consist of the substances listed in this section.

(3) ANNUAL UPDATE AND PUBLICATION.—The schedules established by this section shall be updated and republished on an annual basis.

(b) PLACEMENT ON SCHEDULES.—Except where control is required by United States obligations under an

international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for the schedule are made with respect to the drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) INITIAL SCHEDULES OF CONTROLLED SUBSTANCES.—Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 50301 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

(1) SCHEDULE I.—

(A) OPIATES.—Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(i) Acetylmethadol.

(ii) Allylprodine.

(iii) Alphacetylmethadol.

(iv) Alphameprodine.

(v) Alphamethadol.

(vi) Benzethidine.

(vii) Betacetylmethadol.

(viii) Betameprodine.

(ix) Betamethadol.

(x) Betaprodine.

(xi) Clonitazene.

(xii) Dextromoramide.

(xiii) Dextrorphan.

(xiv) Diampromide.

(xv) Diethylthiambutene.

(xvi) Dimenoxadol.

(xvii) Dimepheptanol.

(xviii) Dimethylthiambutene.

(xix) Dioxaphetyl butyrate.

(xx) Dipipanone.

(xxi) Ethylmethylthiambutene.

(xxii) Etonitazene.

(xxiii) Etoxeridine.

(xxiv) Furethidine.

(xxv) Hydroxypethidine.

(xxvi) Ketobemidone.

(xxvii) Levomoramide.

(xxviii) Levophenacylmorphan.

(xxix) Morpheridine.

(xxx) Noracymethadol.

(xxxi) Norlevorphanol.

(xxxii) Normethadone.

(xxxiii) Norpipanone.

(xxxiv) Phenadoxone.

(xxxv) Phenampromide.

(xxxvi) Phenomorphan.

(xxxvii) Phenoperidine.

(xxxviii) Piritramide.

(xxxix) Proheptazine.

(xl) Properidine.

(xli) Racemoramide.

(xlii) Trimeperidine.

(B) OPIUM DERIVATIVES.—Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(i) Acetorphine.

(ii) Acetyldihydrocodeine.

(iii) Benzylmorphine.

(iv) Codeine methylbromide.

(v) Codeine-N-Oxide.

(vi) Cyprenorphine.

(vii) Desomorphine.

(viii) Dihydromorphine.

(ix) Etorphine.

(x) Heroin.

(xi) Hydromorphinol.

(xii) Methyldesorphine.

(xiii) Methylhydromorphine.

(xiv) Morphine methylbromide.

(xv) Morphine methylsulfonate.

(xvi) Morphine-N-Oxide.

(xvii) Myrophine.

(xviii) Nicocodeine.

(xix) Nicomorphine.

(xx) Normorphine.

(xxi) Pholcodine.

(xxii) Thebacon.

(C) HALLUCINOGENIC SUBSTANCES.—Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following hallucinogenic substances, or

that contains any of their salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

(i) 3,4-methylenedioxy amphetamine.

(ii) 5-methoxy-3,4-methylenedioxy amphetamine.

(iii) 3,4,5-trimethoxy amphetamine.

(iv) Bufotenine.

(v) Diethyltryptamine.

(vi) Dimethyltryptamine.

(vii) 4-methyl-2,5-dimethoxyamphetamine.

(viii) Ibogaine.

(ix) Lysergic acid diethylamide.

(x) Marihuana.

(xi) Mescaline.

(xii) Peyote.

(xiii) N-ethyl-3-piperidyl benzilate.

(xiv) N-methyl-3-piperidyl benzilate.

(xv) Psilocybin.

(xvi) Psilocyn.

(xvii) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricul-

tural Marketing Act of 1946 (7 U.S.C. 1639o)).

(xviii) 4-methylmethcathinone (Mephedrone).

(xix) 3,4-methylenedioxypyrovalerone (MDPV).

(xx) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).

(xxi) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).

(xxii) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).

(xxiii) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).

(xxiv) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2).

(xxv) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4).

(xxvi) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).

(xxvii) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N).

(xxviii) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).

(D) CANNABIMIMETIC AGENTS.—

(i) DEFINITION OF CANNABIMIMETIC AGENTS.—In clause (ii):

(I) IN GENERAL.—The term ''cannabimimetic agents'' means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(aa) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(bb) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(cc) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(dd) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(ee) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(II) INCLUSIONS.—The term ''cannabimimetic agents'' includes—

(aa) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497);

(bb) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog);

(cc) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678);

(dd) 1-butyl-3-(1-naphthoyl)indole (JWH–073);

(ee) 1-hexyl-3-(1-naphthoyl)indole (JWH–019);

(ff) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200);

(gg) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250);

(hh) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081);

(ii) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122);

(jj) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398);

(kk) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

(ll) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

(mm) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4);

(nn) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8); and

(oo) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).

(ii) IN GENERAL.—Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of cannabimimetic agents, or that contains their salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation.

(E) FENTANYL-RELATED SUBSTANCE.—

(i) DEFINITION OF FENTANYL-RELATED SUBSTANCE.—

(I) IN GENERAL.—In clause (ii), except as provided in subclause (II), the term ''fentanyl-related substance'' means any substance that is structurally related to fentanyl by one or more of the following modifications:

(aa) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle.

(bb) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups.

(cc) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups.

(dd) By replacement of the aniline ring with any aromatic monocycle whether or not further

substituted in or on the aromatic monocycle.

(ee) By replacement of the N-propionyl group with another acyl group.

(II) NOT TREATED AS FENTANYL-RELATED SUBSTANCE.—A substance that satisfies the definition of the term ''fentanyl-related substance'' in subclause (I) shall nonetheless not be treated as a fentanyl-related substance subject to this schedule if the substance is—

(aa) controlled by action of the Attorney General under section 50301 of this title; or

(bb) otherwise expressly listed in a schedule other than this schedule.

(III) AUTHORITY TO PUBLISH LIST IN THE FEDERAL REGISTER.—

(aa) IN GENERAL.—The Attorney General may by order publish in the Federal Register a list of substances that satisfy the

definition of the term ''fentanyl-related substance'' in subclause (I).

(bb) ABSENCE OF SUBSTANCE FROM LIST.—The absence of a substance from a list published under item (aa) does not negate the control status of the substance under this schedule if the substance satisfies the definition of the term ''fentanyl-related substance'' in subclause (I).

(ii) IN GENERAL.—Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of a fentanyl-related substance, or that contains the salts, isomers, and salts of isomers of a fentanyl-related substance whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation.

(2) SCHEDULE II.—

(A) IN GENERAL.—Unless specifically excepted or unless listed in another schedule, any

of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(i) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(ii) Any salt, compound, derivative, or preparation of the salt, compound, or derivative that is chemically equivalent or identical with any of the substances referred to in clause (i), except that these substances shall not include the isoquinoline alkaloids of opium.

(iii) Opium poppy and poppy straw.

(iv)(I) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation that contains any quantity of any of the substances referred to in this clause.

(B) OPIATES.—Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation:

(i) Alphaprodine.

(ii) Anileridine.

(iii) Bezitramide.

(iv) Dihydrocodeine.

(v) Diphenoxylate.

(vi) Fentanyl.

(vii) Isomethadone.

(viii) Levomethorphan.

(ix) Levorphanol.

(x) Metazocine.

(xi) Methadone.

(xii) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.

(xiii) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(xiv) Pethidine.

(xv) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(xvi) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(xvii) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(xviii) Phenazocine.

(xix) Piminodine.

(xx) Racemethorphan.

(xxi) Racemorphan.

(C) LIQUID CONTAINING METHAMPHETAMINE.—Unless specifically excepted or unless listed in another schedule, any injectable liquid that contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(3) SCHEDULE III.—

(A) SUBSTANCES WITH STIMULANT EFFECT.—Unless specifically excepted or unless listed in another schedule, any material, com-

pound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system:

(i) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(ii) Phenmetrazine and its salts.

(iii) Any substance (except an injectable liquid) that contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(iv) Methylphenidate.

(B) SUBSTANCES WITH DEPRESSANT EFFECT.—Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system:

(i) Any substance that contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(ii) Chorhexadol.

(iii) Glutethimide.

(iv) Lysergic acid.

(v) Lysergic acid amide.

(vi) Methyprylon.

(vii) Phencyclidine.

(viii) Sulfondiethylmethane.

(ix) Sulfonethylmethane.

(x) Sulfonmethane.

(C) NALORPHINE.—Nalorphine.

(D) NARCOTIC DRUGS.—Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts of the following narcotic drugs:

(i) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(ii) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with 1 or more active, non-narcotic ingredients in recognized therapeutic amounts.

(iii) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(iv) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(v) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(vi) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(vii) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with 1 or more active, nonnar-

cotic ingredients in recognized therapeutic amounts.

(viii) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(E) ANABOLIC STEROIDS.—Anabolic steroids.

(4) SCHEDULE IV.—

(A) Barbital.

(B) Chloral betaine.

(C) Chloral hydrate.

(D) Ethchlorvynol.

(E) Ethinamate.

(F) Methohexital.

(G) Meprobamate.

(H) Methylphenobarbital.

(I) Paraldehyde.

(J) Petrichloral.

(K) Phenobarbital.

(5) SCHEDULE V.—Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include 1 or more nonnarcotic active medicinal ingredients in suf-

ficient proportion to confer on the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(A) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(B) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(C) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(D) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(E) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

**§ 50303. Treatment of controlled substance analogues**

(a) IN GENERAL.—A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law, as a controlled substance in schedule I.

(b) DETERMINATION.—In determining whether a controlled substance analogue was intended for human

consumption under subsection (a), the following factors may be considered, along with any other relevant factors:

(1) The marketing, advertising, and labeling of the substance.

(2) The known efficacy or usefulness of the substance for the marketed, advertised, or labeled purpose.

(3) The difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold.

(4) The diversion of the substance from legitimate channels and the clandestine importation, manufacture, or distribution of the substance.

(5) Whether the defendant knew or should have known that the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means.

(6) Any controlled substance analogue that is manufactured, formulated, sold, distributed, or marketed with the intent to avoid the provisions of existing drug laws.

(c) LIMITATION.—For purposes of this section, evidence that a substance was not marketed, advertised, or labeled for human consumption, by itself, shall not be suf-

ficient to establish that the substance was not intended for human consumption.

**§ 50304. Removal of exemption of certain drugs**

(a) REMOVAL OF EXEMPTION.—The Attorney General shall by regulation remove from exemption under section 50101(50)(B)(iv) of this title a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

(b) FACTORS TO BE CONSIDERED.—In removing a drug or group of drugs from exemption under subsection (a), the Attorney General shall consider, with respect to a drug or group of drugs that is proposed to be removed from exemption—

(1) the scope, duration, and significance of the diversion;

(2) whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and

(3) whether the listed chemical can be readily recovered from the drug or group of drugs.

(c) SPECIFICITY OF DESIGNATION.—The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) to

the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) REINSTATEMENT OF EXEMPTION WITH RESPECT TO PARTICULAR DRUG PRODUCTS.—

(1) REINSTATEMENT.—On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a), the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

(2) FACTORS TO BE CONSIDERED.—In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider—

(A) the package sizes and manner of packaging of the drug product;

(B) the manner of distribution and advertising of the drug product;

(C) evidence of diversion of the drug product;

(D) any actions taken by the manufacturer to prevent diversion of the drug product; and

(E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) as applied to the drug product.

(3) STATUS PENDING APPLICATION FOR REINSTATEMENT.—A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—

(A) the Attorney General has evidence that, applying the factors described in subsection (b) to the drug product, the drug product is being diverted; and

(B) the Attorney General so notifies the applicant.

(4) AMENDMENT AND MODIFICATION.—A regulation reinstating an exemption under paragraph (1) may be modified or revoked with respect to a particular drug product on a finding that—

(A) applying the factors described in subsection (b) to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

# Chapter 505—Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

Sec.
50501. Rules and regulations.
50502. Persons required to register.
50503. Registration requirements.
50504. Denial, revocation, or suspension of registration.
50505. Labeling and packaging.
50506. Production quotas for controlled substances.
50507. Records and reports of registrants.
50508. Order forms.
50509. Prescriptions.
50510. Delivery of a controlled substance by a pharmacy to an administering practitioner.
50511. Regulation of listed chemicals and certain machines.
50512. Additional requirements relating to online pharmacies and telemedicine.
50513. Suspicious orders.

## § 50501. Rules and regulations

The Attorney General may promulgate rules and regulations and charge reasonable fees relating to the registration and control of the manufacture, distribution, and

dispensing of controlled substances and to listed chemicals.

**§ 50502. Persons required to register**

(a) PERIOD OF REGISTRATION.—

(1) MANUFACTURERS AND DISTRIBUTORS.—Each person that manufactures or distributes any controlled substance or list I chemical, or that proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by the Attorney General.

(2) DISPENSERS.—Each person that dispenses, or that proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by the Attorney General. The Attorney General shall, by regulation, determine the period of the registration. A registration under this paragraph shall not be issued for less than 1 year or for more than 3 years.

(3) MODIFICATION, TRANSFER, AND TERMINATION OF REGISTRATION TO MANUFACTURE, DISTRIBUTE, OR DISPENSE CONTROLLED SUBSTANCES.—

(A) IN GENERAL.—Except as provided in subparagraph (C), the registration of any registrant under this division to manufacture, distribute, or dispense controlled substances or list I chemicals terminates when the registrant—

(i) dies;

(ii) ceases legal existence;

(iii) discontinues business or professional practice; or

(iv) surrenders the registration.

(B) NOTIFICATION REQUIREMENT FOR CERTAIN REGISTRANTS.—In the case of such a registrant who ceases legal existence or discontinues business or professional practice, the registrant shall promptly notify the Attorney General in writing of that fact.

(C) ASSIGNMENT OF REGISTRATION OR OTHER AUTHORITY.—A registration under this division to manufacture, distribute, or dispense controlled substances or list I chemicals, and any authority conferred by the registration, may not be assigned or otherwise transferred except on such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a reg-

istration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to the registration until the Attorney General receives the written consent.

(D) DISCONTINUATION OF BUSINESS OR PROFESSIONAL PRACTICE.—In the case of a registrant under this division to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring the business or professional practice to another entity), the registrant shall return to the Attorney General for cancellation—

(i) the registrant's certificate of registration;

(ii) any unexecuted order forms in the registrant's possession; and

(iii) any other documentation that the Attorney General may require.

(b) AUTHORIZED ACTIVITIES.—A person registered by the Attorney General under this division to manufac-

ture, distribute, or dispense controlled substances or list I chemicals may possess, manufacture, distribute, or dispense the substances or chemicals (including any such activity in the conduct of research) to the extent authorized by the person's registration and in conformity with the other provisions of this division.

(c) EXCEPTIONS.—The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this division:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if the agent or employee is acting in the usual course of the agent's or employee's business or employment.

(2) A common or contract carrier or warehouseman, or an employee of the carrier or warehouseman, whose possession of the controlled substance or list I chemical is in the usual course of the carrier's, warehouseman's, or employee's business or employment.

(3) An ultimate user who possesses the substance for a purpose specified in section 50101(61) of this title.

(4) An agent or employee of a research institution that is conducting research with a controlled substance if—

(A) the agent or employee is acting within the scope of the professional practice of the agent or employee;

(B) another agent or employee of the institution is registered to conduct research with a controlled substance in the same schedule;

(C) the researcher who is registered as described in subparagraph (B)—

(i) informs the Attorney General of the name, position title, and employing institution of the agent or employee who is not separately registered;

(ii) authorizes that agent or employee to perform research under the registration of the registered researcher; and

(iii) affirms that any act taken by that agent or employee involving a controlled substance shall be attributable to the registered researcher, as if the researcher had directly committed the act, for purposes of any proceeding under section 50504(a) of this title to suspend or re-

voke the registration of the registered researcher; and

(D) the Attorney General does not, within 30 days of receiving the information, authorization, and affirmation described in subparagraph (C), refuse, for a reason listed in section 50504(a) of this title, to allow the agent or employee to possess the substance without a separate registration.

(d) WAIVER.—The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if the Attorney General finds it consistent with the public health and safety.

(e) SEPARATE REGISTRATION.—

(1) IN GENERAL.—A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) VETERINARIANS.—Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at

a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State in which the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(3) MOBILE MEDICATION UNITS.—Notwithstanding paragraph (1), a registrant that is dispensing, pursuant to section 50503(i) of this title, narcotic drugs to individuals for maintenance treatment or detoxification treatment shall not be required to have a separate registration to incorporate 1 or more mobile medication units into the registrant's practice to dispense the narcotics at locations other than the registrant's principal place of business or professional practice described in paragraph (1), so long as the registrant meets such standards for operation of a mobile medication unit as the Attorney General may establish.

(4) SINGLE REGISTRATION FOR RELATED RESEARCH SITES.—

(A) IN GENERAL.—Notwithstanding paragraph (1), a person registered to conduct research with a controlled substance under sec-

tion 50503(h) of this title may conduct the research under a single registration if—

(i) the research occurs exclusively on sites all of which are—

(I) within the same city or county; and

(II) under the control of the same institution, organization, or agency; and

(ii) before commencing the research, the researcher notifies the Attorney General of each site where—

(I) the research will be conducted; or

(II) the controlled substance will be stored or administered.

(B) NOTIFICATION.—A site described in subparagraph (A) shall be included in a registration described in that subparagraph only if the researcher has notified the Attorney General of the site—

(i) in the application for the registration; or

(ii) before the research is conducted, or before the controlled substance is stored or administered, at the site.

(C) REGULATIONS.—The Attorney General may, in consultation with the Secretary, issue regulations addressing, with respect to research sites described in subparagraph (A)—

(i) the manner in which controlled substances may be delivered to the research sites;

(ii) the storage and security of controlled substances at the research sites;

(iii) the maintenance of records for the research sites; and

(iv) any other matters necessary to ensure effective controls against diversion at the research sites.

(f) INSPECTION.—

(1) IN GENERAL.—The Attorney General may inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by the Attorney General.

(2) SECOND CONTROLLED SUBSTANCE.—

(A) If a person is registered to conduct research with a controlled substance and applies

for a registration, or for a modification of a registration, to conduct research with a second controlled substance that is in the same schedule as the first controlled substance, or is in a schedule with a higher numerical designation than the schedule of the first controlled substance, a new inspection by the Attorney General of the registered location is not required.

(B) EFFECT OF SUBPARAGRAPH (A).—Nothing in subparagraph (A) shall prohibit the Attorney General from conducting an inspection that the Attorney General determines necessary to ensure that a registrant maintains effective controls against diversion.

(g) DELIVERY OF CONTROLLED SUBSTANCES BY ULTIMATE USERS FOR DISPOSAL.—

(1) IN GENERAL.—An ultimate user who has lawfully obtained a controlled substance in accordance with this division may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this division to engage in the disposal; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) CONSIDERATIONS AND REQUIREMENTS RELATING TO REGULATIONS.—In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. The regulations may not require any entity to establish or operate a delivery or disposal program.

(3) LONG-TERM CARE FACILITIES.—The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at the long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) DEATH OF USER.—If an individual dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose

of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(5) DISPOSAL OF CONTROLLED SUBSTANCES OF A HOSPICE PATIENT BY EMPLOYEES OF A QUALIFIED HOSPICE PROGRAM.—

(A) DEFINITIONS.—In this paragraph:

(i) EMPLOYEE OF A QUALIFIED HOSPICE PROGRAM.—The term ''employee of a qualified hospice program'' means a physician, physician assistant, nurse, or other individual who—

(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

(bb) is acting within the scope of the employment in accordance with applicable State law; and

(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible

manner so as to discourage abuse, misuse, or diversion.

(ii) HOSPICE CARE.—The term ''hospice care'' has the meaning given the term in section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

(iii) HOSPICE PROGRAM.—The term ''hospice program'' has the meaning given the term in section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

(iv) QUALIFIED HOSPICE PROGRAM.—The term ''qualified hospice program'' means a hospice program that—

(I) has written policies and procedures for assisting in the disposal of the controlled substances of an individual receiving hospice care after the individual's death;

(II) at the time when the controlled substances are first ordered—

(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

(bb) discusses the policies and procedures with the patient or patient representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

(III) at the time following the disposal of the controlled substances—

(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

(bb) the time, date, and manner in which that disposal occurred.

(B) IN GENERAL.—In the case of an individual receiving hospice care, an employee of a

qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the individual receiving hospice care, for the purpose of disposal of the controlled substance so long as the disposal occurs onsite in accordance with all applicable Federal, State, tribal, and local law and—

(i) the disposal occurs after the death of the individual receiving hospice care;

(ii) the controlled substance is expired; or

(iii)(I) the employee is—

(aa) the physician of the individual receiving hospice care; and

(bb) registered under section 50503(h) of this title; and

(II) the individual no longer requires the controlled substance because the plan of care of the individual has been modified.

(C) GUIDANCE.—The Attorney General may issue guidance to hospice programs to assist the hospice programs in satisfying the requirements under this paragraph.

(D) RULE OF CONSTRUCTION RELATING TO STATE AND LOCAL LAW.—Nothing in this paragraph shall be construed to prevent a State or local government from imposing additional controls or restrictions relating to the regulation of the disposal of controlled substances in hospice care or hospice programs.

(h) CONTINUATION OF RESEARCH ON SUBSTANCES NEWLY ADDED TO SCHEDULE I.—If a person is conducting research on a substance when the substance is added to schedule I, and the person is already registered to conduct research with a controlled substance in schedule I—

(1) not later than 90 days after the scheduling of the newly scheduled substance, the person shall submit a completed application for registration or modification of the existing registration, to conduct research on the substance, in accordance with regulations issued by the Attorney General for purposes of this paragraph;

(2) the person may, notwithstanding subsections (a) and (b), continue to conduct the research on the substance until—

(A) the person withdraws the application described in paragraph (1); or

(B) the Attorney General serves on the person an order to show cause proposing the denial of the application under section 50504(c) of this title;

(3) if the Attorney General serves an order to show cause as described in paragraph (2)(B) and the person requests a hearing, the hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time if requested by the person; and

(4) if the person sends a copy of the application described in paragraph (1) to a manufacturer or distributor of the substance, receipt of the copy by the manufacturer or distributor shall constitute sufficient evidence that the person is authorized to receive the substance.

(i) TREATMENT OF CERTAIN MANUFACTURING ACTIVITIES AS COINCIDENT TO RESEARCH.—

(1) IN GENERAL.—Except as provided in paragraph (3), a person that is registered to perform research on a controlled substance may perform manufacturing activities with small quantities of that substance, including activities described in paragraph

(2), without being required to obtain a manufacturing registration, if—

(A) the activities are performed for the purpose of the research; and

(B) the activities and the quantities of the substance involved in the activities are stated in—

(i) a notification submitted to the Attorney General under section 50503(n) of this title;

(ii) a research protocol filed with an application for registration approval under section 50503(h) of this title; or

(iii) a notification to the Attorney General that includes—

(I) the name of the registrant; and

(II) an attestation that the research to be conducted with the small quantities of manufactured substance is consistent with the scope of the research that is the basis for the registration.

(2) ACTIVITIES INCLUDED.—Activities permitted under paragraph (1) include—

(A) processing the substance to create extracts, tinctures, oils, solutions, derivatives, or other forms of the substance consistent with—

(i) the information provided as part of a notification submitted to the Attorney General under section 50503(n) of this title; or

(ii) a research protocol filed with an application for registration approval under section 50503(h) of this title; and

(B) dosage form development studies performed for the purpose of requesting an investigational new drug exemption under section 13510 of this title.

(3) EXCEPTION REGARDING MARIHUANA.—The authority under paragraph (1) to manufacture substances does not include the authority to grow marihuana.

**§ 50503. Registration requirements**

(a) DEFINITIONS.—In this section:

(1) AUTHORIZING MEDICAL PROFESSIONAL.—The term ''authorizing medical professional'' means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(A) who is registered under this division;

(B) who is acting within the scope of the registration; and

(C) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(2) DESIGNATED LOCATION.—The term ''designated location'' means a location designated by an emergency medical services agency under subsection (l)(5).

(3) EMERGENCY MEDICAL SERVICES.—The term ''emergency medical services'' means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(4) EMERGENCY MEDICAL SERVICES AGENCY.—The term ''emergency medical services agency'' means an organization providing emergency medical services, including such an organization that—

(A) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(B) provides emergency medical services by ground, air, or otherwise; and

(C) is authorized by the State in which the organization is providing the services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(5) EMERGENCY MEDICAL SERVICES PROFESSIONAL.—The term ''emergency medical services professional'' means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(6) EMERGENCY MEDICAL SERVICES VEHICLE.—The term ''emergency medical services vehicle'' means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(7) FACTORS AS MAY BE RELEVANT TO AND CONSISTENT WITH THE PUBLIC HEALTH AND SAFE-

TY.—The term ''factors as may be relevant to and consistent with the public health and safety'' means factors that are relevant to and consistent with the findings contained in section 50102 of this title.

(8) HOSPITAL-BASED.—The term ''hospital-based'' means, with respect to an agency, owned or operated by a hospital.

(9) MEDICAL DIRECTOR.—The term ''medical director'' means a physician who is registered under subsection (h) and who provides medical oversight for an emergency medical services agency.

(10) MEDICAL OVERSIGHT.—The term ''medical oversight'' means supervision of the provision of medical care by an emergency medical services agency.

(11) REGISTERED EMERGENCY MEDICAL SERVICES AGENCY.—The term ''registered emergency medical services agency'' means—

(A) an emergency medical services agency that is registered pursuant to subsection (l); or

(B) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (h).

(12) REGISTERED LOCATION.—The term ''registered location'' means a location that appears on

the certificate of registration issued to an emergency medical services agency under subsection (h) or (l), which shall be where the agency receives controlled substances from distributors.

(13) SPECIFIC STATE AUTHORITY.—The term ''specific State authority'' means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of the agency or authority within the State that may be adopted by medical directors.

(14) STANDING ORDER.—The term ''standing order'' means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(15) VERBAL ORDER.—The term ''verbal order'' means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency

medical services outside the physical presence of the medical director or authorizing medical professional.

(b) MANUFACTURERS OF CONTROLLED SUBSTANCES IN SCHEDULE I OR II.—The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if the Attorney General determines that the registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded from the particular controlled substances into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of the controlled substances to a number of establishments that can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.

(2) Compliance with applicable State and local law.

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances.

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of the substances.

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective controls against diversion.

(6) Such other factors as may be relevant to and consistent with the public health and safety.

(c) DISTRIBUTORS OF CONTROLLED SUBSTANCES IN SCHEDULE I OR II.—The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless the Attorney General determines that the issuance of the registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.

(2) Compliance with applicable State and local law.

(3) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of the substances.

(4) Past experience in the distribution of controlled substances.

(5) Such other factors as may be relevant to and consistent with the public health and safety.

(d) MANUFACTURERS OF MARIJUANA FOR RESEARCH PURPOSES.—

(1) APPLICATION TO MANUFACTURE.—

(A) IN GENERAL.—As it relates to applications to manufacture marijuana for research purposes, when the Attorney General places a notice in the Federal Register to increase the number of entities registered under this division to manufacture marijuana to supply appropriately registered researchers in the United States, the Attorney General shall, not later than 60 days after the date on which the Attorney General receives a completed application—

(i) approve the application; or

(ii) request supplemental information.

(B) APPLICATION DEEMED COMPLETE.—For purposes of subparagraph (A), an application shall be deemed complete when the appli-

cant has submitted documentation showing each of the following:

(i) The requirements designated in the notice in the Federal Register are satisfied.

(ii) The requirements under this division are satisfied.

(iii) The applicant will limit the transfer and sale of any marijuana manufactured under this subsection—

(I) to researchers who are registered under this division to conduct research with controlled substances in schedule I; and

(II) for purposes of use in preclinical research or in a clinical investigation pursuant to an investigational new drug exemption under section 13510 of this title.

(iv) The applicant will transfer or sell any marijuana manufactured under this subsection only with prior, written consent for the transfer or sale by the Attorney General.

(v) The applicant has completed the application and review process under subsection (b) for the bulk manufacture of controlled substances in schedule I.

(vi) The applicant has established and begun operation of a process for storage and handling of controlled substances in schedule I, including for inventory control and monitoring security in accordance with section 41512 of this title.

(vii) The applicant is licensed, by each State in which the applicant will conduct operations under this subsection, to manufacture marijuana, if that State requires such a license.

(C) ACTION ON APPLICATION AFTER RECEIPT OF SUPPLEMENTAL INFORMATION.—Not later than 30 days after the date on which the Attorney General receives supplemental information requested under subparagraph (A)(ii) with respect to an application, the Attorney General shall approve or deny the application.

(2) DENIAL; WRITTEN EXPLANATION.—If an application described in this subsection is denied, the

Attorney General shall provide a written explanation of the basis of denial to the applicant.

(e) LIMITS OF AUTHORIZED ACTIVITIES.—Registration granted under subsections (b) and (c) shall not entitle a registrant to—

(1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration; or

(2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 50506 of this title.

(f) MANUFACTURERS OF CONTROLLED SUBSTANCES IN SCHEDULE III, IV, OR V.—The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless the Attorney General determines that the issuance of the registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded from the particular controlled substances into other than legitimate medical, scientific, or industrial channels.

(2) Compliance with applicable State and local law.

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances.

(4) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of the substances.

(5) Past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion.

(6) Such other factors as may be relevant to and consistent with the public health and safety.

(g) DISTRIBUTORS OF CONTROLLED SUBSTANCES IN SCHEDULE III, IV, OR V.—The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless the Attorney General determines that the issuance of the registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.

(2) Compliance with applicable State and local law.

(3) Prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of the substances.

(4) Past experience in the distribution of controlled substances.

(5) Such other factors as may be relevant to and consistent with the public health and safety.

(h) RESEARCH BY PRACTITIONERS.—

(1) REGISTRATION.—

(A) IN GENERAL.—The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which the applicant practices.

(B) DENIAL OF APPLICATION OR MODIFICATION; FACTORS.—The Attorney General

may deny an application for the registration or the modification of registration if the Attorney General determines that the issuance of the registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(i) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(ii) The applicant's experience in dispensing, or conducting research with respect to, controlled substances.

(iii) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(iv) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(v) Such other conduct that may threaten the public health and safety.

(C) SEPARATE REGISTRATION.—Separate registration under this chapter for practitioners engaging in research with controlled substances

in schedule II, III, IV, or V, that are already registered under this chapter in another capacity, shall not be required.

(2) CONDUCTING RESEARCH WITH SCHEDULE I.—

(A) REFERRAL TO SECRETARY.—Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of the controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 50504(a) of this title.

(B) MARIJUANA.—

(i) IN GENERAL.—The Attorney General shall register a practitioner to conduct research with marijuana (including any derivative, extract, preparation, and compound of marijuana) if—

(I) the applicant's research protocol has been reviewed and allowed—

(aa) by the Secretary under section 13510 of this title;

(bb) by the National Institutes of Health or another Federal agency that funds scientific research; or

(cc) pursuant to sections 1301.18 and 1301.32 of title 21, Code of Federal Regulations (or any successor regulations); and

(II) the applicant has demonstrated to the Attorney General that there are effective procedures in place to adequately safeguard against diversion of the marijuana for legitimate medical or scientific use pursuant to section 41512 of this title, including demonstrating that the secu-

rity measures are adequate for storing the quantity of marijuana the applicant would be authorized to possess.

(ii) DENIAL OF APPLICATION.—The Attorney General may deny an application for registration under this subparagraph only if the Attorney General determines that the issuance of the registration would be inconsistent with the public interest. In determining the public interest, the Attorney General shall consider the factors listed in—

(I) clauses (ii) through (v) of paragraph (1)(B); and

(II) clause (i) of paragraph (1)(B), if the applicable State requires practitioners conducting research to register with a board or authority described in that clause (i).

(iii) APPROVAL OF APPLICATION OR REQUEST FOR SUPPLEMENTAL INFORMATION.—

(I) IN GENERAL.—Not later than 60 days after the date on which the Attorney General receives a complete

application for registration under this subparagraph, the Attorney General shall—

(aa) approve the application; or

(bb) request supplemental information.

(II) DEEMED COMPLETE.—For purposes of subclause (I), an application shall be deemed complete when the applicant has submitted documentation showing that the requirements under clause (i) are satisfied.

(iv) PERIOD TO APPROVE OR DENY APPLICATION AFTER RECEIPT OF SUPPLEMENTAL INFORMATION.—Not later than 30 days after the date on which the Attorney General receives supplemental information as described in clause (iii)(I)(bb) in connection with an application described in this subparagraph, the Attorney General shall approve or deny the application.

(v) DENIAL; WRITTEN EXPLANATION.—If an application described in this subparagraph is denied, the Attorney

General shall provide a written explanation of the basis of denial to the applicant.

(vi) DRUG ENFORCEMENT ADMINISTRATION.—

(I) NOTIFICATION OR REVIEW NOT REQUIRED; NO CHANGES TO MARIJUANA OR CANNABIDIOL.—If the Attorney General grants an application for registration under clause (i), the registrant may amend or supplement the research protocol without notification to, or review by, the Drug Enforcement Administration if the registrant does not change—

(aa) the quantity or type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound of marijuana or cannabidiol);

(bb) the source of the marijuana or cannabidiol; or

(cc) the conditions under which the marijuana or cannabidiol is stored, tracked, or administered.

(II) NOTIFICATION REQUIRED; CHANGES TO MARIJUANA OR CANNABIDIOL.—

(aa) IN GENERAL.—If a registrant under clause (i) seeks to change the type of marijuana or cannabidiol (including any derivative, extract, preparation, and compound of marijuana or cannabidiol), the source of the marijuana or cannabidiol, or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered, the registrant shall notify the Attorney General via registered mail, or an electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(bb) NO OBJECTION FROM ATTORNEY GENERAL.—A registrant may proceed with an amended or supplemental re-

search protocol described in item (aa) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (aa).

(cc) NEED FOR ADDITIONAL SECURITY MEASURES AS BASIS FOR OBJECTION.—The Attorney General may object to an amended or supplemental research protocol under this subclause only if additional security measures are needed to safeguard against diversion or abuse.

(dd) ADDRESSING ADDITIONAL SECURITY MEASURES; NOTIFICATION.—If a registrant under clause (i) seeks to address additional security measures identified by the Attorney General under item (cc), the registrant shall notify the Attorney General via registered mail, or an

electronic means permitted by the Attorney General, not later than 30 days before implementing an amended or supplemental research protocol.

(ee) NO OBJECTION FROM ATTORNEY GENERAL.—A registrant may proceed with an amended or supplemental research protocol described in item (dd) if the Attorney General does not explicitly object during the 30-day period beginning on the date on which the Attorney General receives the notice under item (dd).

(III) NOTIFICATION REQUIRED; CHANGES IN QUANTITY OF MARIJUANA OR CANNABIDIOL WITHOUT IMPACTING CERTAIN FACTORS.—

(aa) IN GENERAL.—If a registrant under clause (i) seeks to change the quantity of marijuana needed for research and the change in quantity does not im-

pact the factors described in item (bb) or (cc) of subclause (I), the registrant shall notify the Attorney General via registered mail or using an electronic means permitted by the Attorney General.

(bb) CONTENT OF NOTIFICATION.—A notification under item (aa) shall include—

(AA) the Drug Enforcement Administration registration number of the registrant;

(BB) the quantity of marijuana or cannabidiol already obtained;

(CC) the quantity of additional marijuana or cannabidiol needed to complete the research; and

(DD) an attestation that the change in quantity does not impact the source of the marijuana or cannabidiol or the conditions

under which the marijuana or cannabidiol is stored, tracked, or administered.

(cc) The Attorney General shall ensure that—

(AA) any registered mail return receipt with respect to a notification under item (aa) is submitted for delivery to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General; and

(BB) notice of receipt of a notification using an electronic means permitted under item (aa) is provided to the registrant providing the notification not later than 3 days after receipt of the notification by the Attorney General.

(dd) WHEN TO PROCEED WITH RESEARCH AFTER SUBMISSION OF NOTIFICATION.—

(AA) IN GENERAL.—On and after the date described in subitem (BB), a registrant that submits a notification in accordance with item (aa) may proceed with the research as if the change in quantity has been approved on that date, unless the Attorney General notifies the registrant of an objection described in item (ee).

(BB) DATE.—The date described in this subitem is the date on which a registrant submitting a notification under item (aa) receives the registered mail return receipt with respect to the notification or the date on which the registrant receives

notice that the notification using an electronic means permitted under item (aa) was received by the Attorney General, as the case may be.

(ee) NOTIFICATION DEEMED APPROVED; OBJECTION BY ATTORNEY GENERAL.—A notification submitted under item (aa) shall be deemed to be approved unless the Attorney General, not later than 10 days after receiving the notification, explicitly objects based on a finding that the change in quantity—

(AA) does impact the source of the marijuana or cannabidiol or the conditions under which the marijuana or cannabidiol is stored, tracked, or administered; or

(BB) necessitates that the registrant implement additional security measures to

safeguard against diversion or abuse.

(IV) EFFECT OF CLAUSE.—Nothing in this clause shall limit the authority of the Secretary over requirements related to research protocols, including changes in—

(aa) the method of administration of marijuana or cannabidiol;

(bb) the dosing of marijuana or cannabidiol; and

(cc) the number of individuals or patients involved in research.

(3) EFFECT OF CONVENTION ON PSYCHOTROPIC SUBSTANCES.—Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions on, research involving drugs or other substances scheduled under the convention, which research is conducted in conformity with this subsection and other applicable provisions of this division.

(i) PRACTITIONERS DISPENSING NARCOTIC DRUGS FOR NARCOTIC TREATMENT.—Practitioners that dispense

narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

(1) if the applicant is a practitioner that is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(2) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting—

(A) the security of stocks of narcotic drugs for the treatment; and

(B) the maintenance of records (in accordance with section 50507 of this title) on the drugs; and

(3) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs

which may be provided for unsupervised use by individuals in the treatment.

(j) APPLICANTS FOR DISTRIBUTION OF LIST I CHEMICALS.—The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 50101(50)(B) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(k) REGISTRATION TO MANUFACTURE CERTAIN CONTROLLED SUBSTANCES FOR USE ONLY IN A CLINICAL TRIAL.—

(1) MANUFACTURERS OF CONTROLLED SUBSTANCES UNDER SCHEDULE III, IV, OR V.—For purposes of registration to manufacture a controlled substance under subsection (f) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause on the applicant in accordance with section 50504(c) of this title, not later than 180 days after the date on which the application is accepted for filing.

(2) MANUFACTURERS OF CONTROLLED SUBSTANCES UNDER SCHEDULE I OR II.—For purposes of registration to manufacture a controlled substance under subsection (b) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to the notice ends, the Attorney General shall register the applicant, or serve an order to show cause on the applicant in accordance with section 50504(c) of this title, unless the Attorney Gen-

eral has granted a hearing on the application under section 51708(i) of this title.

(l) EMERGENCY MEDICAL SERVICES THAT ADMINISTER CONTROLLED SUBSTANCES.—

(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct the activity under the laws of each State in which the agency practices; and

(B) may deny an application for the registration if the Attorney General determines that the issuance of the registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (h).

(2) OPTION FOR SINGLE REGISTRATION.—In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow the agency the option of a single registra-

tion in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) HOSPITAL-BASED AGENCY.—If a hospital-based emergency medical services agency is registered under subsection (h), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) ADMINISTRATION OUTSIDE PHYSICAL PRESENCE OF MEDICAL DIRECTOR OR AUTHORIZING MEDICAL PROFESSIONAL.—Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by 1 or more medical directors of

the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) DELIVERY.—A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for the delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) STORAGE.—A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) DELIVERY NOT TREATED AS DISTRIBUTION.—The delivery of controlled substances by a registered emergency medical services agency pursu-

ant to this subsection shall not be treated as distribution for purposes of section 50508 of this title.

(8) RESTOCKING OF EMERGENCY MEDICAL SERVICES VEHICLES AT A HOSPITAL.—Notwithstanding subsection (a)(11), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 50508 of this title, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of the receipt in accordance with paragraph (9).

(B) The hospital maintains a record of the delivery to the agency in accordance with section 50507 of this title.

(C) If the vehicle is primarily situated at a designated location, the location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) MAINTENANCE OF RECORDS.—

(A) IN GENERAL.—A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 50507 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to section 50507(c)(1)(A)(ii) of this title.

(B) REQUIREMENTS.—The records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) OTHER REQUIREMENTS.—A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances

using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) REGULATIONS.—The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under paragraph (5); and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6),

the manner in which the substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of the substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) RULE OF CONSTRUCTION.—Nothing in this subsection and subsection (a) shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this division to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(m) REQUIRED TRAINING FOR PRESCRIBERS.—

(1) DEFINITIONS.—In this subsection:

(A) FIRST APPLICABLE REGISTRATION.—The term ''first applicable registration'' means the first registration or renewal of registration by a qualified practitioner under this section that occurs on or after the date that is 180 days after December 29, 2022.

(B) QUALIFIED PRACTITIONER.—The term ''qualified practitioner'' means a practitioner that—

(i) is licensed under State law to prescribe controlled substances; and

(ii) is not solely a veterinarian.

(2) TRAINING REQUIRED.—As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

(A) If the practitioner is a physician (as defined under section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), the practitioner meets 1 or more of the following conditions:

(i) The physician holds a board certification in addiction psychiatry or addic-

tion medicine from the American Board of Medical Specialties.

(ii) The physician holds a board certification from the American Board of Addiction Medicine.

(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid or other substance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the

American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the Commission for Continuing Education Provider Recognition (CCEPR);

(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME or the CCEPR;

(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

(IV) any organization approved by the Assistant Secretary for Mental Health and Substance Use, the ACCME, or the CCEPR.

(v) The physician graduated in good standing from an accredited school of allopathic medicine, osteopathic medicine,

dental surgery, or dental medicine in the United States during the 5-year period immediately preceding the date on which the physician first registers or renews under this section and has successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency or dental surgery or dental medicine curriculum that included not fewer than 8 hours of training on—

(I) treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder; or

(II) the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders.

(B) If the practitioner is not a physician (as defined under section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)), the practitioner—

(i) is legally authorized by the State to dispense controlled substances under schedule II, III, IV, or V;

(ii) is dispensing the controlled substances described in clause (i) within the State in accordance with all applicable State laws; and

(iii) meets 1 or more of the following conditions:

(I) The practitioner has completed not fewer than 8 hours of training with respect to the treatment and management of patients with opioid or other substance use disorders (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Asso-

ciation, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Associates, or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use or the Accreditation Council for Continuing Medical Education.

(II) The practitioner has graduated in good standing from an accredited physician assistant school or accredited school of advanced practice nursing in the United States during the 5-year period immediately preceding the date on which the practitioner first registers or renews under this section and has successfully completed a comprehensive physician assistant or advanced practice nursing curriculum that included not fewer than 8 hours of training on treating

and managing patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder.

(3) ONE-TIME TRAINING.—

(A) IN GENERAL.—The Attorney General shall not require any qualified practitioner to complete the training described in clauses (iv) and (v) of paragraph (2)(A) or clauses (i) and (ii) of paragraph (2)(B) more than once.

(B) NOTIFICATION.—Not later than 90 days after December 29, 2022, the Attorney General shall provide to qualified practitioners a single written, electronic notification of the training described in clauses (iv) and (v) of paragraph (2)(A) or clauses (i) and (ii) of paragraph (2)(B).

(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

(A) to preclude the use, by a qualified practitioner, of training received pursuant to this subsection to satisfy registration require-

ments of a State or for some other lawful purpose; or

(B) to preempt any additional requirements by a State related to the dispensing of controlled substances under schedule II, III, IV, or V.

(n) SPECIAL PROVISIONS FOR PRACTITIONERS CONDUCTING CERTAIN RESEARCH WITH SCHEDULE I CONTROLLED SUBSTANCES.—

(1) IN GENERAL.—Notwithstanding subsection (h), a practitioner may conduct research described in paragraph (2) with one or more schedule I substances in accordance with subparagraph (A) or (B) of paragraph (3).

(2) RESEARCH SUBJECT TO EXPEDITED PROCEDURES.—Research described in this paragraph is research that—

(A) is with respect to a drug that is the subject of an investigational use exemption under section 13510 of this title; or

(B) is—

(i) conducted by the Department of Health and Human Services, the Department of Defense, or the Department of Veterans Affairs; or

(ii) funded partly or entirely by a grant, contract, cooperative agreement, or other transaction from the Department of Health and Human Services, the Department of Defense, or the Department of Veterans Affairs.

(3) EXPEDITED PROCEDURES.—

(A) RESEARCHER WITH A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—

(i) IN GENERAL.—If a practitioner is registered to conduct research with a controlled substance in schedule I or II, the practitioner may conduct research under this subsection on and after the date that is 30 days after the date on which the practitioner sends a notice to the Attorney General containing the following information, with respect to each substance with which the practitioner will conduct the research:

(I) The chemical name of the substance.

(II) The quantity of the substance to be used in the research.

(III) A demonstration that the research is in the category described in paragraph (2), which demonstration may be satisfied—

(aa) in the case of a grant, contract, cooperative agreement, or other transaction, or intramural research project, by identifying the sponsoring agency and supplying the number of the grant, contract, cooperative agreement, other transaction, or project; or

(bb) in the case of an application under section 13510 of this title, by supplying the application number and the sponsor of record on the application.

(IV) A demonstration that the researcher is authorized to conduct research with respect to the substance under the laws of the State in which the research will take place.

(ii) VERIFICATION OF INFORMATION BY HHS OR VA.—On request from the At-

torney General, the Secretary of Health and Human Services, the Secretary of Defense, or the Secretary of Veterans Affairs, as appropriate, shall verify information submitted by an applicant under clause (i)(III).

(B) RESEARCHER WITHOUT A CURRENT SCHEDULE I OR II RESEARCH REGISTRATION.—

(i) IN GENERAL.—If a practitioner is not registered to conduct research with a controlled substance in schedule I or II, the practitioner may send a notice to the Attorney General containing the information listed in subparagraph (A)(i), with respect to each substance with which the practitioner will conduct the research.

(ii) ATTORNEY GENERAL ACTION.—The Attorney General shall—

(I) treat the notice received under clause (i) as a sufficient application for a research registration; and

(II) not later than 45 days of receiving the notice that contains all information required under subparagraph (A)(i)—

(aa) register the applicant; or

(bb) serve an order to show cause upon the applicant in accordance with section 50504(c) of this title.

(4) ELECTRONIC SUBMISSIONS.—The Attorney General shall provide a means to permit a practitioner to submit a notification under paragraph (3) electronically.

(5) LIMITATION ON AMOUNTS.—A practitioner conducting research with a schedule I substance under this subsection may only possess the amounts of schedule I substance identified in—

(A) the notification to the Attorney General under paragraph (3); or

(B) a supplemental notification that the practitioner may send if the practitioner needs additional amounts for the research, which supplemental notification shall include—

(i) the name of the practitioner;

(ii) the additional quantity needed of the substance; and

(iii) an attestation that the research to be conducted with the substance is con-

sistent with the scope of the research that was the subject of the notification under paragraph (3).

(6) IMPORTATION AND EXPORTATION REQUIREMENTS NOT AFFECTED.—Nothing in this subsection alters the requirements of division B, regarding the importation and exportation of controlled substances.

(7) INSPECTOR GENERAL REPORT.—Not later than 1 year after July 16, 2025, the Inspector General of the Department of Justice shall complete a study, and submit to Congress a report on the study, about research described in paragraph (2) with fentanyl.

(o) TRANSPARENCY REGARDING SPECIAL PROCEDURES.—

(1) IN GENERAL.—If the Attorney General determines, with respect to a controlled substance, that an application by a practitioner to conduct research with the substance should be considered under a process, or subject to criteria, different from the process or criteria applicable to applications to conduct research with other controlled substances in the same schedule, the Attorney General shall make

public, including by posting on the website of the Drug Enforcement Administration—

(A) the identities of all substances for which the determinations have been made;

(B) the process and criteria that shall be applied to applications to conduct research with those substances; and

(C) how the process and criteria described in subparagraph (B) differ from the process and criteria applicable to applications to conduct research with other controlled substances in the same schedule.

(2) TIMING OF POSTING.—The Attorney General shall make the information described in paragraph (1) public on making a determination described in that paragraph, regardless of whether a practitioner has submitted an application described in paragraph (1) at that time.

**§ 50504. Denial, revocation, or suspension of registration**

(a) GROUNDS.—

(1) CONTROLLED SUBSTANCE OR A LIST I CHEMICAL.—A registration pursuant to section 50503 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may

be suspended or revoked by the Attorney General on a finding that the registrant—

(A) has materially falsified any application filed pursuant to or required by this division or division B;

(B) has been convicted of a felony under this division or division B or any other law of the United States, or of any State, relating to any substance defined in this division as a controlled substance or a list I chemical;

(C) has had the registrant's State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of the registrant's registration recommended by competent State authority;

(D) has committed such acts as would render the registrant's registration under section 50503 of this title inconsistent with the public interest as determined under that section; or

(E) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act (42 U.S.C. 1320a–7(a)).

(2) NARCOTIC DRUG FOR MAINTENANCE TREATMENT OR DETOXIFICATION TREATMENT.—A registration pursuant to section 50503(i) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General on a finding that the registrant has failed to comply with any standard referred to in section 50503(i) of this title.

(b) LIMITS OF REVOCATION OR SUSPENSION.—The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

(c) SERVICE OF SHOW CAUSE ORDER; PROCEEDINGS.—

(1) IN GENERAL.—Before taking action pursuant to this section, or pursuant to a denial of registration under section 50503 of this title, the Attorney General shall serve on the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) ORDER REQUIREMENTS.—An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) REVIEW OF CORRECTIVE ACTION PLAN; DETERMINATION BY ATTORNEY GENERAL.—On review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to the plan.

(4) PROCEEDINGS.—Proceedings to deny, revoke, or suspend shall be conducted pursuant to this

section in accordance with subchapter II of chapter 5 of title 5. The proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this division or any other law of the United States.

(5) APPLICABILITY TO IMMEDIATE SUSPENSION ORDERS.—The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

(d) SUSPENSION OF REGISTRATION IN CASES OF IMMINENT DANGER.—

(1) DEFINITION OF IMMINENT DANGER TO THE PUBLIC HEALTH OR SAFETY.—In this subsection, the phrase ''imminent danger to the public health or safety'' means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this division or division B, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

(2) IN GENERAL.—

(A) AUTHORITY.—The Attorney General may, in the Attorney General's discretion, sus-

pend any registration simultaneously with the institution of proceedings under this section, in cases in which the Attorney General finds that there is an imminent danger to the public health or safety.

(B) FAILURE TO COMPLY WITH STANDARD.—A failure to comply with a standard referred to in section 50503(i) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under that section.

(C) EFFECTIVE PERIOD.—A suspension under this subsection shall continue in effect until the conclusion of the proceedings, including judicial review of the suspension, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(e) SUSPENSION AND REVOCATION OF QUOTAS.—The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 50506 of this title.

(f) DISPOSITION OF CONTROLLED SUBSTANCES OR LIST I CHEMICALS.—

(1) UNDER SEAL.—In the event the Attorney General suspends or revokes a registration granted

under section 50503 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to the registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal.

(2) DISPOSITION; SALE.—No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court may at any time order the sale, on application for the sale, of perishable controlled substances or list I chemicals.

(3) PROCEEDS.—Any order under paragraph (2) shall require the deposit of the proceeds of the sale with the court.

(4) FORFEITURE AND DISPOSITION ON REVOCATION ORDER BECOMING FINAL.—On a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States, and the Attorney General shall dispose of the controlled substances or list I chemicals in accordance with section 50911(e) of this title. All right, title, and interest in the controlled substances or list I chemicals

shall vest in the United States on a revocation order becoming final.

(g) SEIZURE OR PLACEMENT UNDER SEAL OF CONTROLLED SUBSTANCES OR LIST I CHEMICALS.—

(1) IN GENERAL.—The Attorney General may, in the Attorney General's discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by the registrant's registration.

(2) PERSON FOR WHOM ITEMS ARE TO BE HELD.—The controlled substances or list I chemicals shall be held for the benefit of the registrant, or the registrant's successor in interest.

(3) NOTIFICATION OF PROCEDURES FOR RETURN OF SEIZED ITEMS.—The Attorney General shall notify a registrant, or the registrant's successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned.

(4) DATE ON WHICH ITEMS MAY BE DISPOSED.—The Attorney General may not dispose of

any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of 180 days from the date the substance or chemical was seized or placed under seal.

(h) DEBARMENT OF CERTAIN REGISTRANTS.—The Attorney General may issue an order to prohibit, conditionally or unconditionally, and permanently or for such period as the Attorney General may determine, any person from being registered under this division to manufacture, distribute, or dispense a controlled substance or a list I chemical, if the Attorney General finds that—

(1) the person meets or has met any of the conditions for suspension or revocation of registration under subsection (a); and

(2) the person has a history of prior suspensions or revocations of registration.

**§ 50505. Labeling and packaging**

(a) SYMBOL.—It shall be unlawful to distribute a controlled substance in a commercial container unless the container, when and as required by regulations of the Attorney General, bears a label (as defined in section 10101(a) of this title) containing an identifying symbol for the substance in accordance with the regulations. A different symbol shall be required for each schedule of controlled substances.

(b) UNLAWFUL DISTRIBUTION WITHOUT IDENTIFYING SYMBOL.—It shall be unlawful for the manufacturer of any controlled substance to distribute the substance unless the labeling (as defined in section 10101(a) of this title) of the substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

(c) WARNING ON LABEL.—The Secretary shall prescribe regulations under section 13103(a) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

(d) CONTAINERS TO BE SECURELY SEALED.—It shall be unlawful to distribute a controlled substance in schedule I or II, or a narcotic drug in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper of the controlled substance or the narcotic drug is securely sealed as required by regulations of the Attorney General.

(e) FALSE LABELING OF ANABOLIC STEROIDS.—

(1) IN GNEERAL.—It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing

an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

(2) EXEMPTION.—

(A) IN GENERAL.—A product described in subparagraph (B) is exempt from the IUPAC nomenclature requirement of this subsection if the product is labeled in the manner required under subtitle I of this title.

(B) PRODUCT.—A product is described in this subparagraph if the product—

(i) is the subject of an approved application as described in section 13503 or 13511 of this title; or

(ii) is exempt from the provisions of chapter 135 of this title relating to new drugs because—

(I) it is intended solely for investigational use as described in section 13510 of this title; and

(II) the product is being used exclusively for purposes of a clinical trial

that is the subject of an effective investigational new drug application.

**§ 50506. Production quotas for controlled substances**

(a) ESTABLISHMENT OF TOTAL ANNUAL NEEDS.—

(1) IN GENERAL.—The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Except as provided in paragraph (2), production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(2) AGGREGATE OR INDIVIDUAL PRODUCTION QUOTA OR PROCUREMENT QUOTA IN TERMS OF PHARMACEUTICAL DOSAGE FORMS.—The Attorney General may, if the Attorney General determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, establish an

aggregate or individual production quota under this subsection, or a procurement quota established by the Attorney General by regulation, in terms of pharmaceutical dosage forms prepared from or containing the controlled substance.

(b) INDIVIDUAL MANUFACTURING QUOTAS; REVISED QUOTAS.—

(1) LIMITATION OR REDUCTION.—The Attorney General shall limit or reduce individual manufacturing quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a).

(2) REVISION.—The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas.

(3) SUBTRACTION.—If any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of the registrant's revised quota, the amount of the excess shall be subtracted from the registrant's quota for the following year.

(c) MANUFACTURING QUOTAS FOR REGISTERED MANUFACTURERS.—

(1) IN GENERAL.—On or before December 1 of each year, on application for a manufacturing quota by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine that the manufacturer seeks to produce.

(2) APPLICABILITY OF PROVISIONS.—The quota shall be subject to the provisions of subsections (a) and (b).

(3) DETERMINATIONS AND CONSIDERATIONS BY ATTORNEY GENERAL.—In fixing the quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year, and, in making the Attorney General's determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and sta-

bility problems, emergencies such as strikes and fires, and other factors.

(d) QUOTAS FOR REGISTRANTS WHO HAVE NOT MANUFACTURED A BASIC CLASS OF CONTROLLED SUBSTANCE DURING 1 OR MORE PRECEDING YEARS.—

(1) IN GENERAL.—The Attorney General shall, on application and subject to the provisions of subsections (a) and (b), fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance or ephedrine, pseudoephedrine, or phenylpropanolamine during 1 or more preceding calendar years.

(2) CONSIDERATIONS BY ATTORNEY GENERAL.—In fixing the quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year, and, in making the Attorney General's determination of the requirements, the Attorney General shall consider such factors specified in subsection (c) as may be relevant.

(e) QUOTA INCREASES.—

(1) APPLICATION.—At any time during the year, any registrant who has applied for or received a manufacturing quota for a basic class of controlled

substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine may apply for an increase in that quota to meet the registrant's estimated disposal, inventory, and other requirements during the remainder of that year.

(2) CONSIDERATION OF OCCURRENCES SINCE INITIAL QUOTA APPLICATION.—In passing on the application, the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year.

(3) CONSIDERATION OF AGGREGATE AMOUNT.—In passing on the application, the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) exceeds the aggregate of the quotas of all registrants under this section.

(f) INCIDENTAL PRODUCTION EXCEPTION.—

(1) IN GENERAL.—Notwithstanding any other provisions of this division, a registration or quota shall not be required for the manufacture of the quantities of controlled substances in schedules I and II or ephedrine, pseudoephedrine, or phenylpropanolamine, which quantities incidentally and

necessarily result from the manufacturing process used for the manufacture of a controlled substance or of ephedrine, pseudoephedrine, or phenylpropanolamine with respect to which its manufacturer is registered under this division.

(2) RESTRICTIONS.—The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of the incidentally produced substances or chemicals under paragraph (1).

(g) REFERENCE TO EPHEDRINE, PSEUDOEPHEDRINE, OR PHENYLPROPANOLAMINE.—Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of the chemical.

(h) QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.—

(1) IN GENERAL.—

(A) ACTIONS BY ATTORNEY GENERAL.—Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

(i) complete review of the request; and

(ii)(I) as necessary to address a shortage of a controlled substance, increase the

aggregate and individual production quotas under this section applicable to the controlled substance and any ingredient in the controlled substance to the level requested; or

(II) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, provide a written response detailing the basis for the Attorney General's determination.

(B) AVAILABILITY OF RESPONSE ON FDA WEBSITE.—The Secretary shall make the written response provided under subparagraph (A)(ii)(II) available to the public on the internet website of the Food and Drug Administration.

(2) REQUEST.—A request is described in this paragraph if—

(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 13125 of this title;

(B) the request is submitted by the manufacturer of the controlled substance; and

(C) the controlled substance is in schedule II.

(i) COVERED CONTROLLED SUBSTANCES.—

(1) DEFINITION OF COVERED CONTROLLED SUBSTANCE.—In this subsection, the term ''covered controlled substance'' means fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone.

(2) ESTIMATION OF AMOUNT OF DIVERSION.—

(A) IN GENERAL.—In establishing any quota under this section, or any procurement quota established by the Attorney General by regulation, for a covered controlled substance, the Attorney General shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

(B) CONSIDERATIONS.—In estimating diversion under this paragraph, the Attorney General—

(i) shall consider information the Attorney General, in consultation with the Secretary, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(ii) may take into consideration whatever other sources of information the Attorney General determines reliable.

(C) QUOTA REDUCTIONS.—After estimating the amount of diversion of a covered controlled substance, the Attorney General shall make appropriate quota reductions, as determined by the Attorney General, from the quota the Attorney General would have otherwise established had the diversion not been considered.

(3) INCREASED AGGREGATE PRODUCTION QUOTA.—

(A) IN GENERAL.—For any year for which the approved aggregate production quota for a covered controlled substance is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Attorney General, in consultation with the Secretary, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

(B) ANNUAL REPORT.—Not later than 1 year after October 24, 2018, and every year thereafter, the Attorney General shall submit to the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions, and the Committee on Appropriations of the Senate and the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives the following information with regard to each covered controlled substance:

(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance.

(ii) An anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.

(4) REPORT.—Not later than 1 year after October 24, 2018, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufac-

turing quotas under this section for covered controlled substances, will—

(A) take into consideration changes in the accepted medical use of the covered controlled substances; and

(B) work with the Secretary on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.

(j) ATTORNEY GENERAL REPORT ON DRUG SHORTAGES.—The Attorney General shall annually submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on the Judiciary of the Senate a report on drug shortages that—

(1) identifies the number of requests received under subsection (h), the average review time for the requests, the number of requests granted and denied under subsection (h), and, for each of the requests denied under subsection (h), the basis for the denial;

(2) describes the coordination between the Drug Enforcement Administration and Food and Drug Administration on efforts to prevent or alleviate drug shortages; and

(3) identifies drugs containing a controlled substance subject to this section when such a drug is determined by the Secretary to be in shortage.

**§ 50507. Records and reports of registrants**

(a) INVENTORY.—Except as provided in subsection (c)—

(1) each registrant shall, as soon as the registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every 2 years, make a complete and accurate record of all stocks of the controlled substances on hand, except that the regulations prescribed under this section shall permit each such biennial inventory to be prepared on the registrant's regular general physical inventory date (if any) that is nearest to and does not vary by more than 6 months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to that date was not a controlled substance, each registrant under this division manufacturing, distributing, or dispensing the substance shall make a complete and accurate record of all stocks of the substance on hand; and

(3) each registrant under this division manufacturing, distributing, or dispensing a controlled substance shall maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, received, sold, delivered, or otherwise disposed of by the registrant, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) AVAILABILITY OF RECORDS.—Each inventory or other record required under this section—

(1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General;

(2) shall—

(A) be maintained separately from all other records of the registrant; or

(B) in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant; and

(3) shall be kept and be available, for at least 2 years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) INAPPLICABILITY.—

(1) IN GENERAL.—Subsections (a) and (b) shall not apply—

(A)(i) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless the substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(ii) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges the practitioner's patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless the substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(B)(i) to the use of controlled substances, at establishments registered under this division that keep records with respect to the substances, in research conducted in conformity

with an exemption granted under section 13510 or 13711 of this title;

(ii) to the use of controlled substances, at establishments registered under this division that keep records with respect to the substances, in preclinical research or in teaching; or

(C) to the extent of any exemption granted to any person, with respect to all or part of the provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of the provisions (or part of the provisions) to the person is not necessary for carrying out the purposes of this division.

(2) EFFECT OF COVENTION.—Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of subparagraphs (A)(ii), (B), and (C) of paragraph (1).

(d) PERIODIC REPORTS TO ATTORNEY GENERAL.—

(1) MANUFACTURERS AND DISRIBUTORS.—Each manufacturer registered under section 50503 of this title shall, at such time and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery,

or other disposal by the manufacturer of any controlled substance, and each distributor shall make the reports with respect to narcotic controlled substances, identifying by the registration number assigned under this division the person or establishment (unless exempt from registration under section 50502(d) of this title) to whom the sale, delivery, or other disposal was made.

(2) PHARMACY.—

(A) IN GENERAL.—Each pharmacy with a modified registration under section 50503(h) of this title that authorizes the dispensing of controlled substances by means of the internet shall report to the Attorney General the controlled substances it dispenses, in the amount specified, and in such time and manner as the Attorney General by regulation shall require, except that the Attorney General, under this paragraph, may not require any pharmacy to report any information other than the total quantity of each controlled substance that the pharmacy has dispensed each month.

(B) REPORTING NOT REQUIRED UNLESS THRESHOLD IS MET.—For purposes of this paragraph, no reporting shall be required unless

the pharmacy has met 1 of the following thresholds in the month for which the reporting is required:

(i) 100 or more prescriptions dispensed.

(ii) 5,000 or more dosage units of all controlled substances combined.

(e) REPORTING AND RECORDKEEPING REQUIREMENTS OF DRUG CONVENTIONS.—In addition to the reporting and recordkeeping requirements under any other provision of this division, each manufacturer registered under section 50503 of this title shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this division on manufacturers subject to the requirements of this subsection.

(f) AVAILABILITY OF INFORMATION RELATING TO DISTRIBUTOR REGISTRANTS AND OPIOIDS DISTRIBUTED.—

(1) IN GENERAL.—The Attorney General shall, not less frequently than quarterly, make the following information available to manufacturer and distributor registrants through the Automated Reports and Consolidated Orders System, or any subsequent automated system developed by the Drug Enforcement Administration to monitor selected controlled substances:

(A) The total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant.

(B) The total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant described in subparagraph (A).

(2) TIMING OF AVAILABILITY.—The information required to be made available under paragraph (1) shall be made available not later than the 30th

day of the first month following the quarter to which the information relates.

(3) DUTY TO REVIEW INFORMATION.—

(A) IN GENERAL.—All registered manufacturers and distributors shall be responsible for reviewing the information made available by the Attorney General under this subsection.

(B) AVAILABILITY OF INFORMATION TO BE TAKEN INTO ACCOUNT IN DETERMINING WHETHER TO INITIATE PROCEEDINGS.—In determining whether to initiate proceedings under this division against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or otherwise comply with the requirements of this division or the regulations issued under this division, the Attorney General may take into account that the information made available under this subsection was available to the registrant.

(g) INVESTIGATIONAL USES OF DRUGS; PROCEDURES.—Regulations under sections 13136(j) and 13510 of this title, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary

to ensure the security and accountability of controlled substances used in research to which the regulations apply.

(h) CHANGE OF ADDRESS.—Each registrant under this division shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

(i) REPORTING REQUIREMENTS FOR GHB.—In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under chapter 135 of this title, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

(1) Each person that is registered as a manufacturer of bulk or dosage form, or as a packager, repackager, labeler, relabeler, or distributor, shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.

(2) All annual inventory reports shall be filed not later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close

of business December 31, indicating whether materials reported are in storage or in process of manufacturing.

(3) Each person that is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions, both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.

(4) All reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.

(5) Each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of the registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe the controlled substance, the

patient's name and address, the name of the patient's insurance provider, and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. The information shall be available for inspection and copying by the Attorney General.

(6) Section 50511(b)(3) of this title applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as that section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of section 50511(b)(3) of this title.

(j) REPORTS TO BE IN ELECTRONIC FORMAT.—All of the reports required under this section shall be provided in an electronic format.

**§ 50508. Order forms**

(a) UNLAWFUL DISTRIBUTION OF CONTROLLED SUBSTANCES.—It shall be unlawful for any person to distribute a controlled substance in schedule I or II to another except in pursuance of a written order of the person to whom the substance is distributed, made on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by the Attorney General pursuant to this section.

(b) INAPPLICABILITY OF PROVISIONS.—Subsection (a) shall not apply to—

(1) the exportation of the substances from the United States in conformity with division B;

(2) the delivery of such a substance to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business, but if the carriage or storage is in connection with the distribution by the owner of the substance to a third person, this paragraph shall not relieve the distributor from compliance with subsection (a); or

(3) the delivery of such a substance for the purpose of disposal by an ultimate user, long-term care facility, or other person acting in accordance with section 50502(g) of this title.

(c) PRESERVATION AND AVAILABILITY.—

(1) PERSON DISTRIBUTING SUBSTANCE.—Each person that in pursuance of an order required under subsection (a) distributes a controlled substance shall preserve the order for a period of 2 years, and shall make the order available for inspection and copying by Federal officers and employees authorized for that purpose by the Attorney General, and

by officers or employees of States or their political subdivisions who are charged with the enforcement of State or local laws regulating the production, or regulating the distribution or dispensing, of controlled substances and who are authorized under the laws to inspect the orders.

(2) PERSON GIVING ORDER.—Each person that gives an order required under subsection (a) shall, at or before the time of giving the order, make or cause to be made a duplicate of the order on a form to be issued by the Attorney General in blank in accordance with subsection (d) and regulations prescribed by the Attorney General pursuant to this section, and shall, if the order is accepted, preserve the duplicate for a period of 2 years and make it available for inspection and copying by the officers and employees described in paragraph (1).

(d) ISSUANCE.—

(1) IN GENERAL.—The Attorney General shall issue forms pursuant to subsections (a) and (c)(2) only to persons validly registered under section 50503 of this title (or exempted from registration under section 50502(d) of this title). If any such form is issued to a person, the Attorney General shall, before delivery of the form, insert in the form

the name of the person, and it shall be unlawful for any other person—

(A) to use the form for the purpose of obtaining controlled substances; or

(B) to furnish the form to any person with intent to procure the distribution of the substances.

(2) FEES.—The Attorney General may charge reasonable fees for the issuance of the forms in such amounts as the Attorney General may prescribe for the purpose of covering the cost to the United States of issuing the forms, and other necessary activities in connection with the issuance.

(e) UNLAWFUL ACTS.—It shall be unlawful for any person to obtain, by means of order forms issued under this section, controlled substances for any purpose other than their use, distribution, dispensing, or administration in the conduct of a lawful business in the substances or in the course of the person's professional practice or research.

**§ 50509. Prescriptions**

(a) SCHEDULE II SUBSTANCES.—Except if dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, a controlled substance in schedule II, which is a prescription drug as determined under subtitle I of

this title, shall not be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, the drug may be dispensed on oral prescription in accordance with section 13103(a) of this title. Prescriptions shall be retained in conformity with the requirements of section 50507 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) SCHEDULES III AND IV SUBSTANCES.—Except if dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, a controlled substance in schedule III or IV, which is a prescription drug as determined under subtitle I of this title, shall not be dispensed without a written or oral prescription in conformity with section 13103(a) of this title. The prescriptions may not be filled or refilled more than 6 months after the date of the filling or refilling, or be refilled more than 5 times after the date of the prescription unless renewed by the practitioner.

(c) SCHEDULE V SUBSTANCES.—A controlled substance in schedule V, which is a drug, shall not be distributed or dispensed other than for a medical purpose.

(d) NON-PRESCRIPTION DRUGS WITH ABUSE POTENTIAL.—If it appears to the Attorney General that a

drug not considered to be a prescription drug under subtitle I of this title should be considered a prescription drug under the subtitle because of its abuse potential, the Attorney General shall so advise the Secretary and furnish to the Secretary all available data relevant to the advice.

(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—

(1) DEFINITIONS.—In this subsection:

(A) COVERING PRACTITIONER.—The term ''covering practitioner'' means, with respect to a patient, a practitioner that conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner that—

(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(ii) is temporarily unavailable to conduct the evaluation of the patient.

(B) IN-PERSON MEDICAL EVALUATION.—

(i) IN GENERAL.—The term ''in-person medical evaluation'' means a medical evaluation that is conducted with the pa-

tient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) EFFECT OF CLAUSE (i).—Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) VALID PRESCRIPTION.—The term ''valid prescription'' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

(i) a practitioner that has conducted at least 1 in-person medical evaluation of the patient; or

(ii) a covering practitioner.

(2) IN GENERAL.—No controlled substance that is a prescription drug as determined under subtitle I of this title may be delivered, distributed, or dispensed by means of the internet without a valid prescription.

(3) INAPPLICABILITY.—Nothing in this subsection applies to—

(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.

(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

(1) PARTIAL FILLS.—A prescription for a controlled substance in schedule II may be partially filled if—

(A) it is not prohibited by State law;

(B) the prescription is written and filled in accordance with this division, regulations prescribed by the Attorney General, and State law;

(C) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

(D) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(2) REMAINING PORTIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

(i) may be filled; and

(ii) shall be filled not later than 30 days after the date on which the prescription is written.

(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II—

(i) may be filled; and

(ii) shall be filled not later than 72 hours after the prescription is issued.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V to be partially filled.

(g) PROGRAMS AND MATERIALS FOR TRAINING ON CERTAIN CIRCUMSTANCES UNDER WHICH A PHARMACIST MAY DECLINE TO FILL A PRESCRIPTION.—

(1) IN GENERAL.—The Secretary, in consultation with the Administrator of the Drug Enforcement Administration, Commissioner of Food and Drugs, Director of the Centers for Disease Control and Prevention, and Assistant Secretary for Mental Health and Substance Use, shall develop and disseminate not later than 1 year after December 29, 2022, and update periodically thereafter, as appropriate, materials for pharmacists, health care providers, and patients on—

(A) circumstances under which a pharmacist may, consistent with this section and regulations under this section, including section 1306.04 of title 21, Code of Federal Regulations, decline to fill a prescription for a controlled substance because the pharmacist suspects the prescription is fraudulent, forged, or of doubtful, questionable, or suspicious origin; and

(B) other Federal requirements pertaining to declining to fill a prescription under the circumstances described in subparagraph (A), including the partial fill of prescriptions for certain controlled substances.

(2) MATERIALS INCLUDED.—In developing materials under paragraph (1), the Secretary shall include information for—

(A) pharmacists on how to verify the identity of the patient;

(B) pharmacists on how to decline to fill a prescription and actions to take after declining to fill a prescription; and

(C) other health care practitioners and the public on a pharmacist's ability to decline to fill prescriptions in certain circumstances and a description of those circumstances (as described in the materials developed under paragraph (1)(A)).

(3) STAKEHOLDER INPUT.—In developing the programs and materials required under paragraph (1), the Secretary shall seek input from relevant national, State, and local associations, boards of pharmacy, medical societies, licensing boards, health care practitioners, and patients, including individuals with chronic pain.

(4) MATERIALS FOR TRAINING ON VERIFICATION OF IDENTITY.—Not later than 1 year after December 29, 2022, the Secretary, after seek-

ing stakeholder input in accordance with paragraph (3), shall—

(A) update the materials developed under paragraph (1) to include information for pharmacists on how to verify the identity of the patient; and

(B) disseminate, as appropriate, the updated materials.

**§ 50510. Delivery of a controlled substance by a pharmacy to an administering practitioner**

(a) IN GENERAL.—Notwithstanding section 50101(17) of this title, a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this division and the regulations issued by the Attorney General under this division, for the purpose of administering the controlled substance by the practitioner, if—

(1) the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner's certificate of registration issued under this division;

(2) the controlled substance is a narcotic drug in schedule III, IV, or V to be administered for the purpose of maintenance or detoxification treatment

and is to be administered by injection or implantation;

(3) the pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which the activities take place;

(4) the prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

(5) except as provided in subsection (b), the controlled substance is to be administered only to the patient named on the prescription not later than 45 days after the date of receipt of the controlled substance by the practitioner; and

(6) notwithstanding any exceptions under section 50507 of this title, the prescribing practitioner, and the practitioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations of the Attorney General.

(b) MODIFICATION OF NUMBER OF DAYS BEFORE WHICH CONTROLLED SUBSTANCE SHALL BE ADMINISTERED.—The Attorney General, in coordination with the Secretary, may modify the number of days described in subsection (a)(5). Any modification under this subsection shall be for a period of not less than 7 days.

**§ 50511. Regulation of listed chemicals and certain machines**

(a) RECORD OF REGULATED TRANSACTIONS.—

(1) IN GENERAL.—Each regulated person that engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction for 2 years after the date of the transaction.

(2) CONTENTS; ACCESS.—A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. The record shall be available for inspection and copying by the Attorney General.

(3) DUTIES OF PARTIES RELATING TO PROOF OF IDENTITY.—It is the duty of each regulated per-

son that engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

(b) REPORTS TO ATTORNEY GENERAL.—

(1) CERTAIN IRREGULARITIES.—

(A) CONTENTS.—Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation—

(i) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this division;

(ii) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(iii) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(iv) any regulated transaction in a tableting machine or an encapsulating machine.

(B) WHEN TO REPORT.—Each report under subparagraph (A)(i) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved.

(C) TRANSACTIONS WITH PERSONS IDENTIFIED BY ATTORNEY GENERAL.—A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (A)(ii) unless the transaction is approved by the Attorney General.

(D) GUIDANCE DOCUMENTS.—The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under clauses (i) and (iii) of subparagraph (A).

(2) LISTED CHEMICALS.—

(A) IN GENERAL.—A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person.

(B) INAPPLICABILITY.—The requirement of subparagraph (A) shall not apply to the manufacture of a drug product that is exempted under section 50101(50)(B)(iv) of this title.

(3) MAIL ORDER REPORTING.—

(A) DEFINITIONS.—In this paragraph:

(i) DRUG PRODUCT.—The term ''drug product'' means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under subtitle I of this title for distribution in the United States.

(ii) VALID PRESCRIPTION.—The term ''valid prescription'' means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual

course of the practitioner's professional practice.

(B) IN GENERAL.—

(i) SUBMISSION OF REPORT.—Each regulated person described in clause (ii) shall, on a monthly basis, submit a report of each transaction described in clause (ii) conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

(ii) REGULATED PERSON.—A regulated person described in this clause is a regulated person that engages in a transaction with a nonregulated person or that engages in an export transaction that—

(I) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and

(II) uses or attempts to use the Postal Service or any private or commercial carrier.

(C) DATA.—The data required for the reports under subparagraph (B) shall include—

(i) the name of the purchaser;

(ii) the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and

(iii) the address to which the ephedrine, pseudoephedrine, or phenylpropanolamine was sent.

(D) TRANSACTIONS NOT SUBJECT TO REPORTING REQUIREMENT.—Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, shall not be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products if the packages contain not more than 2 solid dosage units or the equivalent of 2 dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than 1 package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that may not include

face-to-face transactions to the extent that the distributions are consistent with the activities authorized for a retail distributor as specified in section 50101(51) of this title, except that this clause does not apply to sales of scheduled listed chemical products at retail.

(iii) Distributions of drug products to a resident of a long-term care facility (as that term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long-term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports that have been reported to the Attorney General pursuant to section 51704 or 51719 of this title or that are subject to a waiver granted under section 51719(f)(2) of this title.

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or

drug products) or of a group of listed chemicals (including specific formulations or drug products) that the Attorney General has excluded by regulation from the reporting requirement on the basis that the reporting is not necessary for the enforcement of this division or division B.

(E) REVOCATION.—The Attorney General may revoke any or all of the exemptions listed in subparagraph (D) for an individual regulated person if the Attorney General finds that drug products distributed by the regulated person are being used in violation of this division or division B. The regulated person shall be notified of the revocation, which will be effective on receipt by the person of the notice, as provided in section 51719(c)(1) of this title, and shall have the right to an expedited hearing as provided in section 51719(c)(2) of this title.

(c) CONFIDENTIALITY OF INFORMATION OBTAINED BY ATTORNEY GENERAL.—

(1) IN GENERAL.—Except as provided in paragraph (2), any information obtained by the Attorney General under this section that is exempt from disclosure under section 552(a) of title 5, by reason of

section 552(b)(4) of title 5, is confidential and may not be disclosed to any person.

(2) DISCLOSURE.—Information referred to in paragraph (1) may be disclosed only—

(A) to an officer or employee of the United States engaged in carrying out this division, division B, or the customs laws;

(B) if relevant in any investigation or proceeding for the enforcement of this division, division B, or the customs laws;

(C) if necessary to comply with an obligation of the United States under a treaty or other international agreement; or

(D) to a State or local official or employee in conjunction with the enforcement of controlled substances laws or chemical control laws.

(3) ACTIONS BY ATTORNEY GENERAL TO PREVENT OR LIMIT DISCLOSURE.—The Attorney General shall—

(A) take such action as may be necessary to prevent unauthorized disclosure of information by any person to whom the information is disclosed under paragraph (2); and

(B) issue guidelines that limit, to the maximum extent feasible, the disclosure of propri-

etary business information, including the names or identities of United States exporters of listed chemicals, to any person to whom the information is disclosed under paragraph (2).

(4) CIVIL ACTION.—Any person that is aggrieved by a disclosure of information in violation of this section may bring a civil action against the violator for appropriate relief.

(5) CIVIL ACTION AGAINST PERSONNEL OF THE DEA.—Notwithstanding paragraph (4), a civil action may not be brought under the paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

(d) SCHEDULED LISTED CHEMICALS; RESTRICTIONS ON SALES QUANTITY; REQUIREMENTS REGARDING NON-LIQUID FORMS.—With respect to ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product—

(1) the quantity of the base sold at retail in the product by a regulated seller, or a distributor required to submit reports by subsection (b)(3), may not, for any purchaser, exceed a daily amount of 3.6 grams, without regard to the number of transactions; and

(2) the seller or distributor may not sell the product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or if the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches.

(e) SCHEDULED LISTED CHEMICALS; BEHIND-THE-COUNTER ACCESS; LOGBOOK REQUIREMENT; TRAINING OF SALES PERSONNEL; PRIVACY PROTECTIONS.—

(1) REQUIREMENTS REGARDING RETAIL TRANSACTIONS.—

(A) IN GENERAL.—Each regulated seller shall ensure that, subject to subparagraph (F), sales by the seller of a scheduled listed chemical product at retail are made in accordance with the following:

(i) BEHIND-THE COUNTER PLACEMENT.—In offering the product for sale, the seller places the product such that customers do not have direct access to the product before the sale is made (in this paragraph referred to as ''behind-the-counter'' placement). For purposes of this paragraph, a behind-the-counter placement

of a product includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility involved to which customers do have direct access.

(ii) DELIVERY BY SELLER.—The seller delivers the product directly into the custody of the purchaser.

(iii) LOGBOOK.—The seller maintains, in accordance with criteria issued by the Attorney General, a written or electronic list of the sales that identifies the products by name, the quantity sold, the names and addresses of purchasers, and the dates and times of the sales (which list is referred to in this subsection as the ''logbook''), except that the requirement does not apply to any purchase by an individual of a single sales package if that package contains not more than 60 milligrams of pseudoephedrine.

(iv) REQUIREMENTS RELATING TO TAKING OF INFORMATION AND SIGNATURE DURING SALE.—In the case of a sale to which the requirement of clause (iii) applies, the seller does not sell such a prod-

uct unless the sale is made in accordance with the following:

(I) The prospective purchaser—

(aa) presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (as in effect on or after March 9, 2006); and

(bb) signs the written logbook and enters in the logbook the prospective purchaser's name and address and the date and time of the sale, or for transactions involving an electronic logbook, the purchaser provides a signature by—

(AA) signing a device presented by the seller that

captures signatures in an electronic format;

(BB) signing a bound paper book; or

(CC) signing a printed document that includes, for the purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale.

(II) In the case of subclause (I)(bb)(AA), the device shall display the notice described in clause (v). Any device used shall preserve each signature in a manner that clearly links that signature to the other electronically captured logbook information relating to the prospective purchaser providing that signature.

(III) In the case of subclause (I)(bb)(BB), the bound paper book shall include, for the purchaser—

(aa) a printed sticker affixed to the bound paper book at the time of sale, which printed sticker displays—

(AA) the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale; or

(BB) a unique identifier which can be linked to the information listed in subitem (AA) in electronic form; or

(bb) a unique identifier that can be linked to the information under item (aa) and that is written into the book by the seller at the time of sale.

(IV) In the case of subclause (III), the purchaser shall sign adjacent to the printed sticker or written unique identifier related to that sale. The bound paper book shall display the notice described in clause (v).

(V) In the case of subclause (I)(bb)(CC), the document shall be printed by the seller at the time of the sale. The document shall contain a clearly identified signature line for a purchaser to sign. The printed document shall display the notice described in clause (v). Each signed document shall be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(VI) The seller enters in the logbook the name of the product and the quantity sold. The information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(VII) The logbook maintained by the seller includes the prospective purchaser's name, address, and the date and time of the sale, as follows:

(aa) If the purchaser enters the information, the seller must

determine that the name entered in the logbook corresponds to the name provided on the identification and that the date and time entered are correct.

(bb) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(cc) The information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(v) NOTICE RELATING TO FALSE STATEMENTS OR MISREPRESENTATIONS.—The written or electronic logbook includes, in accordance with criteria of the Attorney General, a notice to purchasers that entering false statements or misrepresentations in the logbook, or supplying false information or identification that results in the entry of false statements or misrepresentations, may subject the purchasers to criminal penalties under section 1001 of title

18, which notice specifies the maximum fine and term of imprisonment under the section.

(vi) PERIOD OF MAINTENANCE OF LOGBOOK.—Regardless of whether the logbook entry is written or electronic, the seller maintains each entry in the logbook for not fewer than 2 years after the date on which the entry is made.

(vii) SELF-CERTIFICATION BY SELLERS.—In the case of individuals who are responsible for delivering the products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the seller has submitted to the Attorney General a self-certification that all such individuals have, in accordance with criteria under subparagraph (B)(ii), undergone training provided by the seller to ensure that the individuals understand the requirements that apply under this subsection and subsection (d).

(viii) MAINTENANCE OF CERTIFICATION AND RECORDS.—The seller maintains a copy of the certification and

records demonstrating that individuals referred to in clause (vii) have undergone the training.

(ix) MOBILE RETAIL VENDORS.—If the seller is a mobile retail vendor—

(I) the seller complies with clause (i) by placing the product in a locked cabinet; and

(II) the seller does not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in the products per customer during a 30-day period.

(B) ADDITIONAL PROVISIONS REGARDING CERTIFICATIONS AND TRAINING.—

(i) IN GENERAL.—A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii). The certification is not effective for purposes of the preceding sentence unless, in addition to provisions regarding the training of individuals referred to in the subparagraph, the certification includes a

statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements.

(ii) ISSUANCE OF CRITERIA; SELF-CERTIFICATION.—The Attorney General shall by regulation establish criteria for certifications under this paragraph. The criteria shall—

(I) provide that the certifications are self-certifications provided through the program under clause (iii);

(II) provide that a separate certification is required for each place of business at which a regulated seller sells scheduled listed chemical products at retail; and

(III) include criteria for training under subparagraph (A)(vii).

(iii) PROGRAM FOR REGULATED SELLERS.—The Attorney General shall establish a program regarding the certifications and training in accordance with the following:

(I) The program shall be carried out through an internet site of the

Department of Justice and such other means as the Attorney General determines to be appropriate.

(II) The program shall inform regulated sellers that section 1001 of title 18 applies to the certifications.

(III) The program shall make available to the sellers an explanation of the criteria under clause (ii).

(IV) The program shall be designed to permit the submission of the certifications through the internet site.

(V) The program shall be designed to automatically provide the explanation referred to in subclause (III), and an acknowledgement that the Department of Justice has received a certification, without requiring direct interactions of regulated sellers with staff of the Department of Justice (other than the provision of technical assistance, as appropriate).

(iv) AVAILABILITY OF CERTIFICATION TO STATE AND LOCAL OFFICIALS.—

Promptly after receiving a certification under subparagraph (A)(vii), the Attorney General shall make available a copy of the certification to the appropriate State and local officials.

(v) PUBLICATION OF LIST OF SELF-CERTIFIED PERSONS.—The Attorney General shall develop and make available a list of all persons who are currently self-certified in accordance with this section. This list shall be made publicly available on the website of the Drug Enforcement Administration in an electronically downloadable format.

(C) PRIVACY PROTECTIONS.—In order to protect the privacy of individuals who purchase scheduled listed chemical products, the Attorney General shall by regulation establish restrictions on disclosure of information in logbooks under subparagraph (A)(iii). The regulations shall—

(i) provide for the disclosure of the information as appropriate to the Attorney General and to State and local law enforcement agencies; and

(ii) prohibit accessing, using, or sharing information in the logbooks for any purpose other than to ensure compliance with this division or to facilitate a product recall to protect public health and safety.

(D) FALSE STATEMENTS OR MISREPRESENTATIONS BY PURCHASERS.—For purposes of section 1001 of title 18, entering information in the logbook under subparagraph (A)(iii) shall be considered a matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States.

(E) GOOD FAITH PROTECTION.—A regulated seller who in good faith releases information in a logbook under subparagraph (A)(iii) to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

(F) INAPPLICABILITY OF REQUIREMENTS TO CERTAIN SALES.—Subparagraph (A) does not apply to the sale at retail of a scheduled listed chemical product if a report on the sales

transaction is required to be submitted to the Attorney General under subsection (b)(3).

(G) CERTAIN MEASURES REGARDING THEFT AND DIVERSION.—A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants for employment whether they have been convicted of any crime involving or related to the products or controlled substances.

(2) MAIL-ORDER REPORTING; VERIFICATION OF IDENTITY OF PURCHASER; 30-DAY RESTRICTION ON QUANTITIES FOR INDIVIDUAL PURCHASERS.—Each regulated person that makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General is subject to the following:

(A) The person shall, prior to shipping the product, confirm the identity of the purchaser in accordance with procedures established by the Attorney General. The Attorney General shall by regulation establish the procedures.

(B) The person may not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in the products per customer during a 30-day period.

(C) Each regulated person that makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) to submit a report of the sales transaction to the Attorney General may not sell any scheduled listed chemical product at retail unless the regulated person has submitted to the Attorney General a self-certification including a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) and agrees to comply with the requirements. The Attorney General shall by regulation establish criteria for certifications of mail-order distributors that are consistent with the criteria established for the certifications of regulated sellers under paragraph (1)(B).

(3) EXEMPTIONS FOR CERTAIN PRODUCTS.—On the application of a manufacturer of a scheduled listed chemical product, the Attorney General may by regulation provide that the product is exempt

from paragraphs (1) and (2) and from subsection (d) if the Attorney General determines that the product cannot be used in the illicit manufacture of methamphetamine.

**§ 50512. Additional requirements relating to online pharmacies and telemedicine**

(a) IN GENERAL.—An online pharmacy shall display in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances and shall at all times display on the homepage of its internet site a declaration of compliance in accordance with this section.

(b) LICENSURE.—Each online pharmacy shall comply with the requirements of State law concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers, distributes, or dispenses or offers to deliver, distribute, or dispense controlled substances by means of the internet, pursuant to applicable licensure requirements, as determined by each such State.

(c) INTERNET PHARMACY SITE DISCLOSURE INFORMATION.—Each online pharmacy shall post in a visible and clear manner on the homepage of each internet site it operates, or on a page directly linked to the homepage in which the hyperlink is also visible and clear on the

homepage, the following information for each pharmacy that delivers, distributes, or dispenses controlled substances pursuant to orders made on, through, or on behalf of, that website:

(1) The name and address of the pharmacy as it appears on the pharmacy's Drug Enforcement Administration certificate of registration.

(2) The pharmacy's telephone number and email address.

(3) The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted.

(4) A list of the States in which the pharmacy is licensed to dispense controlled substances.

(5) A certification that the pharmacy is registered under this chapter to deliver, distribute, or dispense, by means of the internet, controlled substances.

(6) The name, address, telephone number, professional degree, and States of licensure of any practitioner that has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator

of the website, or any employee or agent of the owner or operator.

(7) The following statement, unless revised by the Attorney General by regulation: ''This online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation or medical evaluation via telemedicine in accordance with applicable requirements of section 309.''.

(d) NOTIFICATION.—

(1) IN GENERAL.—Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing, the online pharmacy shall notify the Attorney General, in such form and manner as the Attorney General shall determine, and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances.

(2) CONTENTS.—The notification required under paragraph (1) shall include—

(A) the information required to be posted on the online pharmacy's internet site under subsection (c) and shall notify the Attorney

General and the applicable State boards of pharmacy, under penalty of perjury, that the information disclosed on its internet site under subsection (c) is true and accurate;

(B) the online pharmacy's internet site address and a certification that the online pharmacy shall notify the Attorney General of any change in the address at least 30 days in advance; and

(C) the Drug Enforcement Administration registration numbers of any pharmacies and practitioners referred to in subsection (c), as applicable.

(e) DECLARATION OF COMPLIANCE.—On and after the date on which it makes the notification under subsection (d), each online pharmacy shall display on the homepage of its internet site, in such form as the Attorney General shall by regulation require, a declaration that it has made the notification to the Attorney General.

(f) REPORTS.—Any statement, declaration, notification, or disclosure required under this section shall be considered a report required to be kept under this chapter.

(g) NOTICE AND DESIGNATIONS CONCERNING INDIAN TRIBES.—

(1) IN GENERAL.—For purposes of sections 50101(38) and 50912(c)(6)(B) of this title, the Secretary shall notify the Attorney General, at such times and in such manner as the Secretary and the Attorney General determine appropriate, of the Indian tribes or tribal organizations with which the Secretary has contracted or compacted under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.) for the tribes or tribal organizations to provide pharmacy services.

(2) DESIGNATIONS.—

(A) IN GENERAL.—The Secretary may designate a practitioner described in subparagraph (B) as an Internet Eligible Controlled Substances Provider. The designations shall be made only in cases in which the Secretary has found that there is a legitimate need for the practitioner to be so designated because the population served by the practitioner is in a sufficiently remote location that access to medical services is limited.

(B) PRACTITIONERS.—A practitioner described in this subparagraph is a practitioner that is an employee or contractor of the Indian Health Service, or is working for an Indian

tribe or tribal organization under its contract or compact under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.) with the Indian Health Service.

(h) SPECIAL REGISTRATION FOR TELEMEDICINE.—

(1) IN GENERAL.—The Attorney General may issue to a practitioner a special registration to engage in the practice of telemedicine for purposes of section 50101(42)(E) of this title if the practitioner, on application for the special registration—

(A) demonstrates a legitimate need for the special registration; and

(B) is registered under section 50503(h) of this title in the State in which the patient will be located when receiving the telemedicine treatment, unless the practitioner—

(i) is exempted from the registration in all States under section 50502(d) of this title; or

(ii) is an employee or contractor of the Department of Veterans Affairs that is acting in the scope of the employment or contract and is registered under section 50503(h) of this title in any State or is utilizing the registration of a hospital or

clinic operated by the Department of Veterans Affairs registered under section 50503(h) of this title.

(2) REGULATIONS.—Not later than 1 year after October 24, 2018, in consultation with the Secretary, the Attorney General shall promulgate final regulations specifying—

(A) the limited circumstances in which a special registration under this subsection may be issued; and

(B) the procedure for obtaining a special registration under this subsection.

(3) DENIALS.—Proceedings to deny an application for registration under this subsection shall be conducted in accordance with section 50504(c) of this title.

(i) REPORTING OF TELEMEDICINE BY VETERANS HEALTH ADMINISTRATION DURING MEDICAL EMERGENCY SITUATIONS.—

(1) IN GENERAL.—Any practitioner issuing a prescription for a controlled substance under the authorization to conduct telemedicine during a medical emergency situation described in section 50101(42)(F) of this title shall report to the Secretary of Veterans Affairs the authorization of that

emergency prescription, in accordance with such requirements as the Secretary of Veterans Affairs shall, by regulation, establish.

(2) TO ATTORNEY GENERAL.—Not later than 30 days after the date that a prescription described in paragraph (1) is issued, the Secretary of Veterans Affairs shall report to the Attorney General the authorization of that emergency prescription.

(j) CLARIFICATION CONCERNING PRESCRIPTION TRANSFERS.—Any transfer between pharmacies of information relating to a prescription for a controlled substance shall meet the applicable requirements under regulations promulgated by the Attorney General under this division.

**§ 50513. Suspicious orders**

(a) REPORTING.—Each registrant shall—

(1) design and operate a system to identify suspicious orders for the registrant;

(2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

(3) on discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforce-

ment Administration for the area in which the registrant is located or conducts business.

(b) SUSPICIOUS ORDER DATABASE.—

(1) IN GENERAL.—The Attorney General shall establish a centralized database for collecting reports of suspicious orders.

(2) SATISFACTION OF REPORTING REQUIREMENTS.—If a registrant reports a suspicious order to the centralized database established under paragraph (1), the registrant shall be considered to have complied with the requirement under subsection (a)(3) to notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

(c) SHARING INFORMATION WITH STATES.—

(1) IN GENERAL.—The Attorney General shall prepare and make available information regarding suspicious orders in a State, including information in the database established under subsection (b)(1), to the point of contact for purposes of administrative, civil, and criminal oversight relating to the diversion of controlled substances for the State, as

designated by the Governor or chief executive officer of the State.

(2) TIMING.—The Attorney General shall provide information in accordance with paragraph (1) within a reasonable period of time after obtaining the information.

(3) COORDINATION.—In establishing the process for the provision of information under this subsection, the Attorney General shall coordinate with States to ensure that the Attorney General has access to information, as permitted under State law, possessed by the States relating to prescriptions for controlled substances that will assist in enforcing Federal law.

# Chapter 507—Offenses and Penalties

Sec.
50701. Prohibited acts A.
50702. Prohibited acts B.
50703. Prohibited acts C.
50704. Penalties for simple possession.
50705. Civil penalty for possession of small amounts of certain controlled substances.
50706. Attempt and conspiracy.
50707. Additional penalties.
50708. Continuing criminal enterprise.
50709. Transportation safety offenses.
50710. Information for sentencing.
50711. Proceedings to establish prior convictions.
50712. Application of treaties and other international agreements.
50713. Criminal forfeitures.
50714. Investment of illicit drug profits.
50715. Alternative fine.
50716. Maintaining drug-involved premises.
50717. Creating substantial risk of harm to human life while illegally manufacturing controlled substance.

50718. Distribution to individuals under age 21.
50719. Distribution or manufacturing in or near schools and colleges and other facilities.
50720. Consecutive sentence for manufacturing or distributing methamphetamine on premises where children are present or reside.
50721. Employment or use of persons under 18 years of age in drug operations.
50722. Denial of Federal benefits to drug traffickers and possessors.
50723. Drug paraphernalia.
50724. Stealing or transporting anhydrous ammonia.

**§ 50701. Prohibited acts A**

(a) UNLAWFUL ACTS.—Except as authorized by this division, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or

(2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

(b) PENALTIES.—Except as otherwise provided in section 50709, 50718, 50719, or 50721 of this title, any person that violates subsection (a) shall be sentenced as follows:

(1) CERTAIN SPECIFIC SUBSTANCES.—

(A) SPECIFIED SUBSTANCES.—

(i) QUANTITIES.—A person shall be sentenced as described in clause (ii) in the case of the person's violation of subsection (a) involving—

(I) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(II) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(aa) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(bb) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(cc) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(dd) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in items (aa) through (cc);

(III) 280 grams or more of a mixture or substance described in subclause (II) that contains cocaine base;

(IV) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(V) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(VI) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or a fentanyl-related substance;

(VII) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(VIII) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

(ii) PERSON.—

(I) IN GENERAL.—A person that violates subsection (a) as described in clause (i) shall be sentenced to a term of imprisonment which may be not less than 10 years or more than life and if death or serious bodily injury results from the use of the substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both.

(II) PRIOR CONVICTION.—If any person commits such a violation after

a prior conviction for a serious drug felony or serious violent felony has become final, the person shall be sentenced to a term of imprisonment of not less than 15 years and not more than life imprisonment and if death or serious bodily injury results from the use of the substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $20,000,000 if the defendant is an individual or $75,000,000 if the defendant is other than an individual, or both.

(III) TWO OR MORE PRIOR CONVICTIONS.—If any person commits a violation of this subparagraph or of section 50709, 50718, 50719, or 50721 of this title after 2 or more prior convictions for a serious drug felony or serious violent felony have become final, the person shall be sentenced to a term of imprisonment of

not less than 25 years and fined in accordance with subclause (II).

(iii) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any sentence under this subparagraph shall, in the absence of a prior conviction described in clause (ii), impose a term of supervised release of at least 5 years in addition to the term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to the term of imprisonment.

(iv) PROBATION; SUSPENSION OF SENTENCE.—Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph.

(v) PAROLE.—No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed in the sentence.

(B) SPECIFIED SUBSTANCES.—

(i) QUANTITIES.—A person shall be sentenced as described in clause (ii) in the

case of the person's violation of subsection (a) involving—

(I) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(II) 500 grams or more of a mixture or substance containing a detectable amount of—

(aa) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(bb) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(cc) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(dd) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in items (aa) through (cc);

(III) 28 grams or more of a mixture or substance described in subclause (II) that contains cocaine base;

(IV) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(V) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(VI) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or a fentanyl-related substance;

(VII) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100

or more marihuana plants regardless of weight; or

(VIII) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

(ii) PERSON.—

(I) IN GENERAL.—A person that violates subsection (a) as described in clause (i) shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of the substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $5,000,000 if the defendant is an individual or $25,000,000 if the defendant is other than an individual, or both.

(II) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, the person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of the substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both.

(iii) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any sentence imposed under this subparagraph shall, in the absence of a prior conviction described in clause (ii), include a term of supervised release of at least 4 years in addition to the term of imprisonment and

shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to the term of imprisonment.

(iv) PROBATION; SUSPENSION OF SENTENCE.—Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph.

(v) PAROLE.—No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed in the sentence.

(C) CONTROLLED SUBSTANCE IN SCHEDULE I OR II; GAMMA HYDROXYBUTYRIC ACID; FLUNITRAZEPAM.—

(i) IN GENERAL.—In the case of a person's violation of subsection (a) involving a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 61302(2) of this title), or 1 gram of flunitrazepam, except as provided in subparagraphs (A), (B), and (D), the person shall be sentenced

to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of the substance shall be sentenced to a term of imprisonment of not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both.

(ii) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a felony drug offense has become final, the person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of the substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both.

(iii) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of a prior conviction described in clause (ii), impose a term of supervised release of at least 3 years in addition to the term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to the term of imprisonment.

(iv) PROBATION; SUSPENSION OF SENTENCE; PAROLE.—Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) MARIHUANA; HASHISH.—

(i) IN GENERAL.—In the case of a person's violation of subsection (a) involving less than 50 kilograms of marihuana,

except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or 1 kilogram of hashish oil, the person shall, except as provided in paragraphs (4) and (5), be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both.

(ii) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a felony drug offense has become final, the person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both.

(iii) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any

sentence imposing a term of imprisonment under this subparagraph shall, in the absence of a prior conviction described in clause (ii), impose a term of supervised release of at least 2 years in addition to the term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to the term of imprisonment.

(E) CONTROLLED SUBSTANCE IN SCHEDULE III.—

(i) IN GENERAL.—Except as provided in subparagraphs (C) and (D), in the case of a person's violation of subsection (a) involving any controlled substance in schedule III, the person shall be sentenced to a term of imprisonment of not more than 10 years and if death or serious bodily injury results from the use of the substance shall be sentenced to a term of imprisonment of not more than 15 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual

or $2,500,000 if the defendant is other than an individual, or both.

(ii) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a felony drug offense has become final, the person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of the substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both.

(iii) SUPERVISED RELEASE.—Any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of a prior conviction described in clause (ii), impose a term of supervised release of at least 2 years in addition to the term of imprisonment and shall, if there was such a prior conviction, impose a term

of supervised release of at least 4 years in addition to the term of imprisonment.

(2) CONTROLLED SUBSTANCE IN SCHEDULE IV.—

(A) IN GENERAL.—In the case of a person's violation of subsection (a) involving a controlled substance in schedule IV, the person shall be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $250,000 if the defendant is an individual or $1,000,000 if the defendant is other than an individual, or both.

(B) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a felony drug offense has become final, the person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $500,000 if the defendant is an individual or $2,000,000 if the defendant is other than an individual, or both.

(C) SUPERVISED RELEASE.—Any sentence imposing a term of imprisonment under this

paragraph shall, in the absence of a prior conviction described in subparagraph (B), impose a term of supervised release of at least 1 year in addition to the term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 2 years in addition to the term of imprisonment.

(3) CONTROLLED SUBSTANCE IN SCHEDULE V.—

(A) IN GENERAL.—In the case of a person's violation of subsection (a) involving a controlled substance in schedule V, the person shall be sentenced to a term of imprisonment of not more than 1 year, a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $100,000 if the defendant is an individual or $250,000 if the defendant is other than an individual, or both.

(B) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a felony drug offense has become final, the person shall be sentenced to a term of imprisonment of not more than 4 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or

$200,000 if the defendant is an individual or $500,000 if the defendant is other than an individual, or both.

(C) SUPERVISED RELEASE.—Any sentence imposing a term of imprisonment under this paragraph may, if there was a prior conviction, impose a term of supervised release of not more than 1 year, in addition to the term of imprisonment.

(4) SMALL AMOUNT OF MARIHUANA FOR NO REMUNERATION.—Notwithstanding paragraph (1)(D), any person that violates subsection (a) by distributing a small amount of marihuana for no remuneration shall be treated as provided in section 50704 of this title and section 3607 of title 18.

(5) CULTIVATING OR MANUFACTURING A CONTROLLED SUBSTANCE ON FEDERAL PROPERTY.—

(A) IN GENERAL.—Any person that violates subsection (a) by cultivating or manufacturing a controlled substance on Federal property shall be imprisoned as provided in this subsection, shall be fined as provided in subparagraph (B), or both.

(B) FINE.—A fine provided in this subparagraph is any amount not to exceed—

(i) the amount authorized in accordance with this section;

(ii) the amount authorized in accordance with the provisions of title 18;

(iii) $500,000 if the defendant is an individual; or

(iv) $1,000,000 if the defendant is other than an individual.

(6) KNOWING OR INTENTIONAL USE OF A POISON, CHEMICAL, OR OTHER HAZARDOUS SUBSTANCE ON FEDERAL LAND.—

(A) IN GENERAL.—Any person that violates subsection (a), or attempts to do so, and is described in subparagraph (B) shall be fined in accordance with title 18, imprisoned not more than 5 years, or both.

(B) PERSON.—A person is described in this subparagraph if the person knowingly or intentionally uses a poison, chemical, or other hazardous substance on Federal land, and, by the use—

(i) creates a serious hazard to humans, wildlife, or domestic animals;

(ii) degrades or harms the environment or natural resources; or

(iii) pollutes an aquifer, spring, stream, river, or body of water.

(7) DISTRIBUTION.—

(A) DEFINITION.—In this paragraph, the term ''without that individual's knowledge'' means that the individual is unaware that a substance with the ability to alter that individual's ability to appraise conduct or to decline participation in or communicate unwillingness to participate in conduct is administered to the individual.

(B) IN GENERAL.—Whoever, with intent to commit a crime of violence, as defined in section 16 of title 18 (including rape), against an individual, violates subsection (a) by distributing a controlled substance or controlled substance analogue to that individual without that individual's knowledge, shall be imprisoned not more than 20 years and fined in accordance with title 18.

(c) OFFENSES INVOLVING LISTED CHEMICALS.—

(1) PENALTIES.—Any person described in paragraph (2) shall be fined in accordance with title 18 or imprisoned not more than 20 years in the case of a violation of subparagraph (A) or (B) of paragraph

(2) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of subparagraph (A) or (B) of paragraph (2) involving a list I chemical, or both.

(2) PERSON.—A person is described in this paragraph if the person knowingly or intentionally—

(A) possesses a listed chemical with intent to manufacture a controlled substance except as authorized by this division;

(B) possesses or distributes a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by this division; or

(C) with the intent of causing the evasion of the recordkeeping or reporting requirements of section 50511 of this title, or the regulations issued under section 50511 of this title, receives or distributes a reportable amount of any listed chemical in units small enough so that the making of records or filing of reports under section 50511 of this title is not required.

(d) BOOBYTRAPS ON FEDERAL PROPERTY.—

(1) DEFINITION OF BOOBYTRAP.—In this subsection:

(A) IN GENERAL.—The term ''boobytrap'' means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of any unsuspecting person making contact with the device.

(B) INCLUSIONS.—The term ''boobytrap'' includes guns, ammunition, or explosive devices attached to trip wires or other triggering mechanisms, sharpened stakes, and lines or wires with hooks attached.

(2) IN GENERAL.—Any person that assembles, maintains, places, or causes to be placed a boobytrap on Federal property where a controlled substance is being manufactured, distributed, or dispensed shall be sentenced to a term of imprisonment for not more than 10 years, fined under title 18, or both.

(3) PRIOR CONVICTIONS.—If any person commits such a violation after 1 or more prior convictions for an offense punishable under this subsection, the person shall be sentenced to a term of imprisonment of not more than 20 years, fined under title 18, or both.

(e) WRONGFUL DISTRIBUTION OR POSSESSION OF LISTED CHEMICALS.—

(1) DISTRIBUTION.—Whoever knowingly distributes a listed chemical in violation of this division (other than in violation of a recordkeeping or reporting requirement of section 50511 of this title) shall, except to the extent that subparagraph (L), (M), or (N) of section 50702(a)(1) of this title applies, be fined under title 18, imprisoned not more than 5 years, or both.

(2) POSSESSION.—Whoever possesses any listed chemical, with knowledge that the recordkeeping or reporting requirements of section 50511 of this title have not been adhered to, if, after the knowledge is acquired, the person does not take immediate steps to remedy the violation shall be fined under title 18, imprisoned not more than 1 year, or both.

(f) INTERNET SALES OF DATE RAPE DRUGS.—

(1) DEFINITIONS.—In this subsection:

(A) AUTHORIZED PURCHASER.—The term ''authorized purchaser'' means any of the following persons, provided the person has acquired the controlled substance in accordance with this division and division B:

(i) An individual with a valid prescription that is issued for a legitimate medical purpose in the usual course of professional

practice that is based on a qualifying medical relationship by a practitioner registered by the Attorney General. A ''qualifying medical relationship'' means a medical relationship that exists when the practitioner has conducted at least 1 medical evaluation with the authorized purchaser in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals. The preceding sentence shall not be construed to imply that 1 medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(ii) Any practitioner or other registrant that is otherwise authorized by the practitioner's or other registrant's registration to dispense, procure, purchase, manufacture, transfer, distribute, import, or export the substance under this division or division B.

(iii) A person or entity providing documentation that establishes the name, ad-

dress, and business of the person or entity and that provides a legitimate purpose for using any date rape drug for which a prescription is not required.

(B) DATE RAPE DRUG.—

(i) IN GENERAL.—The term ''date rape drug'' means—

(I) gamma hydroxybutyric acid (GHB) or any controlled substance analogue of GHB, including gamma butyrolactone (GBL) or 1,4–butanediol;

(II) ketamine;

(III) flunitrazepam; or

(IV) any substance that the Attorney General designates, pursuant to the rulemaking procedures prescribed by section 553 of title 5, to be used in committing rape or sexual assault.

(ii) REMOVAL BY RULEMAKING.—The Attorney General may remove any substance from the list of date rape drugs pursuant to the rulemaking authority described in clause (i)(IV).

(2) IN GENERAL.—

(A) PENALTIES.—A person described in subparagraph (B) shall be fined under this division, imprisoned not more than 20 years, or both.

(B) PERSON.—A person described in this subparagraph is a person that knowingly uses the internet to distribute a date rape drug to another person, knowing or with reasonable cause to believe that—

(i) the drug would be used in the commission of criminal sexual conduct; or

(ii) the other person is not an authorized purchaser.

(3) REGULATIONS RELATING TO RECORDKEEPING AND REPORTING.—The Attorney General may promulgate regulations for recordkeeping and reporting by persons handling 1,4–butanediol in order to implement and enforce the provisions of this section. Any record or report required by the regulations shall be considered a record or report required under this division or division B.

(g) OFFENSES INVOLVING DISPENSING OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.—

(1) IN GENERAL.—It shall be unlawful for any person to knowingly or intentionally—

(A) deliver, distribute, or dispense a controlled substance by means of the internet, except as authorized by this division; or

(B) aid or abet (as the terms are used in section 2 of title 18) any activity described in subparagraph (A) that is not authorized by this division.

(2) EXAMPLES.—Examples of activities that violate paragraph (1) include knowingly or intentionally—

(A) delivering, distributing, or dispensing a controlled substance by means of the internet by an online pharmacy that is not validly registered with a modification authorizing the activity as required by section 50503(h) of this title (unless exempt from the registration);

(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the internet in violation of section 50509(e) of this title;

(C) serving as an agent, intermediary, or other entity that causes the internet to be used to bring together a buyer and seller to engage

in the dispensing of a controlled substance in a manner not authorized by section 50503(h) or 50509(e) of this title;

(D) offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and

(E) making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under subsection (d) or (e), respectively, of section 50512 of this title.

(3) INAPPLICABILITY.—

(A) IN GENERAL.—This subsection does not apply to—

(i) the delivery, distribution, or dispensation of controlled substances by nonpractitioners to the extent authorized by their registration under this division;

(ii) the placement on the internet of material that merely advocates the use of a controlled substance or includes pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance; or

(iii) except as provided in subparagraph (B), any activity that is limited to—

(I) the provision of a telecommunications service, or of an Internet access service or Internet information location tool (as those terms are defined in section 231 of the Communications Act of 1934 (47 U.S.C. 231)); or

(II) the transmission, storage, retrieval, hosting, formatting, or translation (or any combination of those activities) of a communication, without selection or alteration of the content of the communication, except that deletion of a particular communication or material made by another person in a manner consistent with section 230(c) of the Communications Act of 1934 (47 U.S.C. 230(c)) shall not constitute the selection or alteration of the content of the communication.

(B) EXCEPTIONS.—The exceptions under subclauses (I) and (II) of subparagraph (A)(iii)

shall not apply to a person acting in concert with a person that violates paragraph (1).

(4) KNOWING OR INTENTIONAL VIOLATION.—Any person that knowingly or intentionally violates this subsection shall be sentenced in accordance with subsection (b).

(h) TEN-YEAR INJUNCTION AS ADDITIONAL PENALTY.—In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, manufacture, exportation, or importation of a listed chemical may be enjoined from engaging in any transaction involving a listed chemical for not more than 10 years.

**§ 50702. Prohibited acts B**

(a) UNLAWFUL ACTS.—

(1) IN GENERAL.—It shall be unlawful for any person—

(A) that is subject to the requirements of chapter 505 of this title to distribute or dispense a controlled substance in violation of section 50509 of this title;

(B) that is a registrant to distribute or dispense a controlled substance not authorized by the person's registration to another registrant or other authorized person or to manufacture a

controlled substance not authorized by the person's registration;

(C) that is a registrant to distribute a controlled substance in violation of section 50505 of this title;

(D) to remove, alter, or obliterate a symbol or label required by section 50505 of this title;

(E) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this division or division B;

(F) to refuse any entry into any premises or inspection authorized by this division or division B;

(G) to remove, break, injure, or deface a seal placed on controlled substances pursuant to section 50504(f) or 50911 of this title or to remove or dispose of substances so placed under seal;

(H) to use, to the person's own advantage, or to reveal, other than to authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this division or division B, any information ac-

quired in the course of an inspection authorized by this division concerning any method or process which as a trade secret is entitled to protection, or to use, to the person's own advantage, or to reveal (other than as authorized by section 50511 of this title) any information that is confidential under section 50511 of this title;

(I) that is a regulated person to engage in a regulated transaction without obtaining the identification required by section 50511(a)(3) of this title;

(J) negligently to fail to keep a record or make a report under section 50511 of this title or negligently to fail to self-certify as required under section 50511 of this title;

(K) to distribute a laboratory supply to a person that uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, in violation of this division or division B, with reckless disregard for the illegal uses to which that laboratory supply will be put;

(L) that is a regulated seller, or a distributor required to submit reports under section 50511(b)(3) of this title—

(i) to sell at retail a scheduled listed chemical product in violation of section 50511(d)(1) of this title, knowing at the time of the transaction involved (independent of consulting the logbook under section 50511(e)(1)(A)(iii) of this title) that the transaction is a violation; or

(ii) to knowingly or recklessly sell at retail such a product in violation of section 50511(d)(2) of this title;

(M) that is a regulated seller to knowingly or recklessly sell at retail a scheduled listed chemical product in violation of section 50511(e) of this title;

(N) that is a regulated seller or an employee or agent of the seller to disclose, in violation of regulations under section 50511(e)(1)(C) of this title, information in logbooks under section 50511(e)(1)(A)(iii) of this title, or to refuse to provide such a logbook to Federal, State, or local law enforcement authorities;

(O) to distribute a scheduled listed chemical product to a regulated seller, or to a regulated person referred to in section

50511(b)(3)(B) of this title, unless the regulated seller or regulated person is, at the time of the distribution, currently registered with the Drug Enforcement Administration, or on the list of persons referred to under section 50511(e)(1)(B)(v) of this title;

(P) to violate section 50505(e) of this title; or

(Q) in the case of a registered manufacturer or distributor of opioids, to fail to review the most recent information, directly related to the customers of the manufacturer or distributor, made available by the Attorney General in accordance with section 50507(f) of this title.

(2) PROVISIONS THAT APPLY TO CERTAIN SUBPARAGRAPHS IN PARAGRAPH (1).—

(A) LABORATORY SUPPLY.—In paragraph (1)(K), the term ''laboratory supply'' means a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals.

(B) REBUTTABLE PRESUMPTION.—For purposes of paragraph (1)(K), there is a rebuttable presumption of reckless disregard at trial if the Attorney General notifies a firm in writing that a laboratory supply sold by the firm, or any other person or firm, has been used by a customer of the notified firm, or distributed further by that customer, for the unlawful production of controlled substances or listed chemicals a firm distributes and 2 weeks or more after the notification the notified firm distributes a laboratory supply to the customer.

(C) ACCESS TO LIST OF PERSONS.—For purposes of paragraph (1)(O), if the distributor is temporarily unable to access the list of persons referred to under section 50511(e)(1)(B)(v) of this title, the distributor may rely on a written, faxed, or electronic copy of a certificate of self-certification submitted by the regulated seller or regulated person, provided the distributor confirms within 7 business days of the distribution that the regulated seller or regulated person is on the list referred to under section 50511(e)(1)(B)(v) of this title.

(b) MANUFACTURE.—It shall be unlawful for any person that is a registrant to manufacture a controlled substance in schedule I or II, or ephedrine, pseudoephedrine, or phenylpropanolamine or any of the salts, optical isomers, or salts of optical isomers of the chemical, that is—

(1) not expressly authorized by the person's registration and by a quota assigned to the person pursuant to section 50506 of this title; or

(2) in excess of a quota assigned to the person pursuant to section 50506 of this title.

(c) CRIMINAL PENALTIES.—

(1) IN GENERAL.—If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, the person shall, except as otherwise provided in paragraph (2) or (3), be sentenced to imprisonment of not more than 1 year, a fine under title 18, or both.

(2) PRIOR CONVICTIONS.—If a violation referred to in paragraph (1) was committed after 1 or more prior convictions of the offender for an offense punishable under this subsection, or for a crime under any other provision of this division or division

B or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, the person shall be sentenced to a term of imprisonment of not more than 2 years, a fine under title 18, or both.

(3) LIMITATION ON CERTAIN CRIMINAL FINES.—In the case of a violation described in paragraph (1) that was a violation of subparagraph (E), (J), or (Q) of subsection (a)(1) committed by a registered manufacturer or distributor of opioids that relates to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 50507(f) of this title, the criminal fine under title 18 shall not exceed $500,000.

(d) CIVIL PENALTIES.—

(1) IN GENERAL.—

(A) VIOLATIONS OF THIS SECTION.—Except as provided in subparagraph (B), (C), or (D) and paragraph (2), any person that violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United

States (or, where there is no district court of the United States in the case of any territory (including a possession) of the United States, then the court in the territory of the United States having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of title 28 to enforce this paragraph.

(B) VIOLATIONS OF SUBPARAGRAPHS (E), (J), AND (Q) OF SUBSECTION (a)(1).—

(i) IN GENERAL.—Except as provided in clause (ii), in the case of a violation of subparagraph (E), (J), or (Q) of subsection (a)(1), the civil penalty shall not exceed $10,000.

(ii) VIOLATION COMMITTED BY REGISTERED MANUFACTURER OR DISTRIBUTOR OF OPIOIDS.—In the case of a violation described in clause (i) committed by a registered manufacturer or distributor of opioids and related to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent

information made available by the Attorney General in accordance with section 50507(f) of this title, the penalty shall not exceed $100,000.

(C) VIOLATIONS OF SUBSECTION (a)(1)(P).—In the case of a violation of subsection (a)(1)(P) by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (D)), the civil penalty shall not exceed $500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of subsection (a)(1)(P).

(D) SPECIFIC VIOLATIONS OF SUBSECTION (a)(1)(P).—

(i) DEFINITION OF AT THE RETAIL LEVEL.—In this subparagraph, the term ''at the retail level'' refers to products sold, or held for sale, directly to the consumer for personal use.

(ii) IN GENERAL.—In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation

of subsection (a)(1)(P) at the retail level, the civil penalty shall not exceed $1000 per violation. Each package, container or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of subsection (a)(1)(P) shall be considered a separate violation.

(2) ADDITIONAL PENALTIES FOR BUSINESSES.—In addition to the penalties set forth elsewhere in this division or division B, any business that violates subsection (a)(1)(K) shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil penalty of not more than $250,000 or double the last previously imposed penalty, whichever is greater.

(3) RELATIONSHIP TO CRIMINAL OFFENSES.—Except under the conditions specified in subsection (c), a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph

(1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

(4) PROHIBITION OF SALE BY ORDER DUE TO CERTAIN VIOLATIONS.—

(A) IN GENERAL.—If a regulated seller, or a distributor required to submit reports under section 50511(b)(3) of this title, violates subsection (a)(1)(L), or if a regulated seller violates subsection (a)(1)(M), the Attorney General may by order prohibit the seller or distributor (as the case may be) from selling any scheduled listed chemical product. Any sale of such a product in violation of such an order is subject to the same penalties that apply under subsection (c)(2).

(B) PROCEDURES.—An order under subparagraph (A) may be imposed only through the same procedures that apply under section 50504(c) of this title for an order to show cause.

**§ 50703. Prohibited acts C**

(a) UNLAWFUL ACTS.—It shall be unlawful for any person knowingly or intentionally—

(1) to distribute, if the person is a registrant, a controlled substance classified in schedule I or II,

in the course of the person's legitimate business, except pursuant to an order or an order form as required by section 50508 of this title;

(2) to use in the course of the manufacture, distribution, or dispensing of a controlled substance, or to use for the purpose of acquiring or obtaining a controlled substance, a registration number that is fictitious, revoked, suspended, expired, or issued to another person;

(3) to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4)(A) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this division or division B; or

(B) to present false or fraudulent identification where the person is receiving or purchasing a listed chemical and the person is required to present identification under section 50511(a) of this title;

(5) to make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another

or any likeness of any of the foregoing on any drug or container or labeling of the drug or container so as to render the drug a counterfeit substance;

(6) to possess any 3-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material that may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this division or division B;

(7) to manufacture, distribute, export, or import any 3-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material that may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance or listed chemical in violation of this division or division B or, in the case of an exportation, in violation of this division or division B or of the laws of the country to which it is exported;

(8) to create a chemical mixture for the purpose of evading a requirement of section 50511 of this

title or to receive a chemical mixture created for that purpose; or

(9) to distribute, import, or export a list I chemical without the registration required by this division or division B.

(b) COMMUNICATION FACILITY.—

(1) DEFINITION OF COMMUNICATION FACILITY.—In this subsection, the term ''communication facility'' means any and all public and private instrumentalities used or useful in the transmission of writing, signs, signals, pictures, or sounds of all kinds and includes mail, telephone, wire, radio, and all other means of communication.

(2) IN GENERAL.—It shall be unlawful for any person knowingly or intentionally to use any communication facility in committing or in causing or facilitating the commission of any act or acts constituting a felony under any provision of this division or division B.

(3) SEPARATE OFFENSE.—Each separate use of a communication facility shall be a separate offense under this subsection.

(c) ADVERTISEMENT.—

(1) DEFINITION OF ADVERTISEMENT.—In this subsection:

(A) INCLUSIONS.—The term ''advertisement'' includes, in addition to its ordinary meaning, such advertisements as those for a catalog of schedule I controlled substances and any similar written advertisement that has the purpose of seeking or offering illegally to receive, buy, or distribute a schedule I controlled substance.

(B) EXCLUSIONS.—The term ''advertisement'' does not include material that merely advocates the use of a similar material, that advocates a position or practice, and that does not attempt to propose or facilitate an actual transaction in a schedule I controlled substance.

(2) WRITTEN ADVERTISEMENTS.—It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a schedule I controlled substance.

(3) INTERNET ADVERTISEMENTS.—

(A) IN GENERAL.—It shall be unlawful for any person to knowingly or intentionally use the internet, or cause the internet to be used, to advertise the sale of, or to offer to sell, distribute,

or dispense, a controlled substance where the sale, distribution, or dispensing is not authorized by this division or division B.

(B) EXAMPLES.—Examples of activities that violate subparagraph (A) include knowingly or intentionally causing the placement on the internet of an advertisement that refers to or directs prospective buyers to internet sellers of controlled substances who are not registered with a modification under section 50503(h) of this title.

(C) INAPPLICABILITY.—Subparagraph (A) does not apply to material that—

(i) merely advertises the distribution of controlled substances by nonpractitioners to the extent authorized by their registration under this division; or

(ii) merely advocates the use of a controlled substance or includes pricing information without attempting to facilitate an actual transaction involving a controlled substance.

(d) CRIMINAL PENALTIES.—

(1) IN GENERAL.—

(A) PENALTIES.—Except as provided in paragraph (2), any person that violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine under title 18, or both.

(B) PRIOR CONVICTIONS.—If any person commits such a violation after 1 or more prior convictions of the person for violation of this section, or for a felony under any other provision of this division or division B or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, the person shall be sentenced to a term of imprisonment of not more than 8 years, a fine under title 18, or both.

(2) MANUFACTURE OF METHAMPHETAMINE.—

(A) IN GENERAL.—Any person that, with the intent to manufacture or to facilitate the manufacture of methamphetamine, violates paragraph (6) or (7) of subsection (a), shall be sentenced to a term of imprisonment of not more than 10 years, a fine under title 18, or both.

(B) PRIOR CONVICTIONS.—

(i) IN GENERAL.—A person shall be sentenced to a term of imprisonment of not more than 20 years, a fine under title 18, or both if the person commits a violation under subparagraph (A) after 1 or more prior convictions of that person, which prior conviction or convictions are described in clause (ii), has become final.

(ii) PRIOR CONVICTIONS.—A prior conviction is described in this clause if the prior conviction is—

(I) for a violation of paragraph (6) or (7) of subsection (a);

(II) for a felony under any other provision of this division or division B; or

(III) under any other law of the United States or any State relating to controlled substances or listed chemicals.

(e) ADDITIONAL PENALTIES.—In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, manufacture, exportation, or importation of a listed chemical may be enjoined from engaging in any trans-

action involving a listed chemical for not more than 10 years.

(f) INJUNCTIONS.—

(1) IN GENERAL.—In addition to any penalty provided in this section, the Attorney General may commence a civil action for appropriate declaratory or injunctive relief relating to violations of this section or section 50702 or 50716 of this title.

(2) JURISDICTION.—Any action under this subsection may be brought in the district court of the United States for the district in which the defendant is located or resides or is doing business.

(3) ORDERS AND JUDGMENTS TO RESTRAIN VIOLATIONS.—Any order or judgment issued by the court pursuant to this subsection shall be tailored to restrain violations of this section or section 50702 of this title.

(4) PROCEDURE.—The court shall proceed as soon as practicable to the hearing and determination of such an action. An action under this subsection is governed by the Federal Rules of Civil Procedure (28 U.S.C. App.) except that, if an indictment has been returned against the respondent, discovery is governed by the Federal Rules of Criminal Procedure (18 U.S.C. App.).

**§ 50704. Penalties for simple possession**

(a) DEFINITION OF DRUG, NARCOTIC, OR CHEMICAL OFFENSE.—In this section, the term ''drug, narcotic, or chemical offense'' means any offense that proscribes the possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell, or transfer any substance the possession of which is prohibited under this division.

(b) UNLAWFUL ACTS; PENALTIES.—

(1) POSSESSION OF CONTROLLED SUBSTANCE.—It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless the substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of the practitioner's professional practice, or except as otherwise authorized by this division or division B.

(2) POSSESSION OF LIST I CHEMICAL.—It shall be unlawful for any person knowingly or intentionally to possess any list I chemical obtained pursuant to or under authority of a registration issued to that person under section 50503 or 51708 of this title if that registration has been revoked or suspended, if that registration has expired, or if the

person has ceased to do business in the manner contemplated by the person's registration.

(3) PURCHASE AT RETAIL.—It shall be unlawful for any person to knowingly or intentionally purchase at retail during a 30-day period more than 9 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product, except that, of the 9 grams, not more than 7.5 grams may be imported by means of shipping through any private or commercial carrier or the Postal Service.

(4) PENALTIES.—Any person that violates this subsection may be sentenced to a term of imprisonment of not more than 1 year, shall be fined a minimum of $1,000, or both.

(5) PRIOR CONVICTION.—If the person under paragraph (4) commits the offense after a prior conviction under this division or division B, or a prior conviction for any drug, narcotic, or chemical offense chargeable under the law of any State, has become final, the person shall be sentenced to a term of imprisonment for not less than 15 days but not more than 2 years, and shall be fined a minimum of $2,500.

(6) 2 OR MORE PRIOR CONVICTIONS.—If the person under paragraph (4) commits the offense after 2 or more prior convictions under this division or division B, or 2 or more prior convictions for any drug, narcotic, or chemical offense chargeable under the law of any State, or a combination of 2 or more such offenses have become final, the person shall be sentenced to a term of imprisonment for not less than 90 days but not more than 3 years, and shall be fined a minimum of $5,000.

(7) POSSESSION OF FLUNITRAZEPAM.—Notwithstanding any penalty provided in this subsection, any person convicted under this subsection for the possession of flunitrazepam shall be imprisoned for not more than 3 years, shall be fined as otherwise provided in this section, or both.

(8) SUSPENSION OR DEFERMENT.—The imposition or execution of a minimum sentence required to be imposed under this subsection shall not be suspended or deferred.

(9) COSTS OF INVESTIGATION AND PROSECUTION.—On conviction, a person that violates this subsection shall be fined the reasonable costs of the investigation and prosecution of the offense, including the costs of prosecution of an offense as defined

in sections 1918 and 1920 of title 28, except that this paragraph shall not apply and a fine under this section need not be imposed if the court determines under title 18 that the defendant lacks the ability to pay.

**§ 50705. Civil penalty for possession of small amounts of certain controlled substances**

(a) IN GENERAL.—Any individual who knowingly possesses a controlled substance that is listed in section 50701(b)(1)(A) of this title in violation of section 50704 of this title in an amount that, as specified by regulation of the Attorney General, is a personal use amount shall be liable to the United States for a civil penalty in an amount not to exceed $10,000 for each such violation.

(b) INCOME AND NET ASSETS.—The income and net assets of an individual shall not be relevant to the determination whether to assess a civil penalty under this section or to prosecute the individual criminally. However, in determining the amount of a penalty under this section, the income and net assets of an individual shall be considered.

(c) PRIOR CONVICTION.—A civil penalty may not be assessed under this section if the individual previously was convicted of a Federal or State offense relating to a controlled substance.

(d) LIMITATION ON NUMBER OF ASSESSMENTS.—A civil penalty may not be assessed on an individual under this section on more than 2 separate occasions.

(e) ASSESSMENT.—

(1) IN GENERAL.—A civil penalty under this section may be assessed by the Attorney General only by an order made on the record after opportunity for a hearing in accordance with section 554 of title 5.

(2) NOTICE.—The Attorney General shall provide written notice to the individual who is the subject of the proposed order informing the individual of the opportunity to receive such a hearing with respect to the proposed order.

(3) REQUEST.—The hearing may be held only if the individual makes a request for the hearing before the expiration of the 30-day period beginning on the date the notice is issued.

(f) COMPROMISE.—The Attorney General may compromise, modify, or remit, with or without conditions, any civil penalty imposed under this section.

(g) JUDICIAL REVIEW.—

(1) IN GENERAL.—If the Attorney General issues an order pursuant to subsection (e) after a hearing described in subsection (e), the individual

who is the subject of the order may, before the expiration of the 30-day period beginning on the date the order is issued, bring a civil action in the appropriate district court of the United States.

(2) STANDARD OF REVIEW; RIGHTS.—In an action described in paragraph (1), the law and the facts of the violation and the assessment of the civil penalty shall be determined de novo, and shall include the right of a trial by jury, the right to counsel, and the right to confront witnesses. The facts of the violation shall be proved beyond a reasonable doubt.

(h) CIVIL ACTION.—

(1) COMMENCEMENT BY ATTORNEY GENERAL.—If an individual does not request a hearing pursuant to subsection (e) and the Attorney General issues an order pursuant to subsection (e), or if an individual does not under subsection (g) seek judicial review of such an order, the Attorney General may commence a civil action in any appropriate district court of the United States for the purpose of recovering the amount assessed and an amount representing interest at a rate computed in accordance with section 1961 of title 28.

(2) INTEREST.—The interest shall accrue from the expiration of the 30-day period described in subsection (g).

(3) JUDICIAL REVIEW.—In an action under this subsection, the decision of the Attorney General to issue the order, and the amount of the penalty assessed by the Attorney General, shall not be subject to review.

(i) LIMITATION.—The Attorney General may not under this section commence proceeding against an individual after the expiration of the 5-year period beginning on the date on which the individual allegedly violated subsection (a).

(j) EXPUNGEMENT PROCEDURES.—

(1) IN GENERAL.—The Attorney General shall dismiss the proceedings under this section against an individual on application of the individual at any time after the expiration of 3 years if—

(A) the individual has not previously been assessed a civil penalty under this section;

(B) the individual has paid the assessment;

(C) the individual has complied with any conditions imposed by the Attorney General;

(D) the individual has not been convicted of a Federal or State offense relating to a controlled substance; and

(E) the individual agrees to submit to a drug test, and the test shows the individual to be drug free.

(2) RETENTION OF RECORD.—A nonpublic record of a disposition under this subsection shall be retained by the Department of Justice solely for the purpose of determining in any subsequent proceeding whether the person qualified for a civil penalty or expungement under this section.

(3) FAILURE TO ACKNOWLEDGE PROCEEDING NOT GROUNDS FOR PERJURY.—If a record is expunged under this subsection, an individual concerning whom such an expungement has been made shall not be held, after the expungement, under any provision of law to be guilty of perjury, false swearing, or making a false statement by reason of the individual's failure to recite or acknowledge a proceeding under this section or the results of the proceeding in response to an inquiry made of the individual for any purpose.

**§ 50706. Attempt and conspiracy**

Any person that attempts or conspires to commit any offense defined in this division shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

**§ 50707. Additional penalties**

Any penalty imposed for violation of this division shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

**§ 50708. Continuing criminal enterprise**

(a) PENALTIES; FORFEITURES.—

(1) DEFINITION OF CONTINUING CRIMINAL ENTERPRISE.—In this subsection, a person is engaged in a continuing criminal enterprise if—

(A) the person violates any provision of this division or division B the punishment for which is a felony; and

(B) the violation is a part of a continuing series of violations of this division or division B—

(i) that are undertaken by the person in concert with 5 or more other persons with respect to whom the person occupies a position of organizer, a supervisory position, or any other position of management; and

(ii) from which the person obtains substantial income or resources.

(2) IN GENERAL.—Any person that engages in a continuing criminal enterprise shall be sentenced—

(A) to a term of imprisonment which may not be less than 20 years and which may be up to life imprisonment;

(B) to a fine not to exceed the greater of that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual; and

(C) to the forfeiture prescribed in section 50713 of this title.

(3) PRIOR CONVICTIONS.—If any person engages in an activity under paragraph (2) after 1 or more prior convictions of the person under this section have become final, the person shall be sentenced—

(A) to a term of imprisonment which may not be less than 30 years and which may be up to life imprisonment;

(B) to a fine not to exceed the greater of twice the amount authorized in accordance with the provisions of title 18 or $4,000,000 if the

defendant is an individual or $10,000,000 if the defendant is other than an individual; and

(C) to the forfeiture prescribed in section 50713 of this title.

(b) LIFE IMPRISONMENT FOR ENGAGING IN CONTINUING CRIMINAL ENTERPRISE.—Any person that engages in a continuing criminal enterprise shall be imprisoned for life and fined in accordance with subsection (a), if—

(1) the person is the principal administrator, organizer, or leader of the enterprise or is 1 of several such principal administrators, organizers, or leaders; and

(2)(A) the violation referred to in subsection (a)(1)(A) involved at least 300 times the quantity of a substance described in section 50701(b)(1)(B) of this title; or

(B) the enterprise, or any other enterprise in which the defendant was the principal or 1 of several principal administrators, organizers, or leaders, received $10 million dollars in gross receipts during any 12-month period of its existence for the manufacture, importation, or distribution of a substance described in section 50701(b)(1)(B) of this title.

(c) SUSPENSION OF SENTENCE AND PROBATION PROHIBITED.—In the case of any sentence imposed under this section, imposition or execution of the sentence shall not be suspended, probation shall not be granted, and the Act of July 15, 1932 (ch. 492, D.C. Code §§24–403 through 24–407), shall not apply.

(d) DEATH PENALTY.—

(1) DEFINITION OF LAW ENFORCEMENT OFFICER.—In this subsection, the term ''law enforcement officer'' means a public servant authorized by law or by a Government agency or Congress to conduct or engage in the prevention, investigation, prosecution, or adjudication of an offense, and includes those engaged in corrections, probation, or parole functions.

(2) IN GENERAL.—In addition to the other penalties set forth in this section—

(A) any person engaging in or working in furtherance of a continuing criminal enterprise, or any person engaging in an offense punishable under section 50701(b)(1)(A) or 51710(b)(1) of this title which person intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of an individual (and the counseling, commanding, inducing, procuring, or causing results in the kill-

ing), shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death; and

(B) any person, during the commission of, in furtherance of, or while attempting to avoid apprehension, prosecution, or service of a prison sentence for, a felony violation of this division or division B which person intentionally kills or counsels, commands, induces, procures, or causes the intentional killing of any Federal, State, or local law enforcement officer engaged in, or on account of, the performance of the officer's official duties (and the counseling, commanding, inducing, procuring, or causing results in the killing), shall be sentenced to any term of imprisonment, which shall not be less than 20 years, and which may be up to life imprisonment, or may be sentenced to death.

(e) SPECIAL PROVISION FOR METHAMPHETAMINE.—For the purposes of subsection (b), in the case of a continuing criminal enterprise involving methamphetamine or its salts, isomers, or salts of isomers, subsection (b)(2)(A) shall be applied by substituting ''200'' for ''300'', and sub-

section (b)(2)(B) shall be applied by substituting ''$5,000,000'' for ''$10 million dollars''.

**§ 50709. Transportation safety offenses**

(a) DEFINITIONS.—In this section:

(1) SAFETY REST AREA.—The term ''safety rest area'' means a roadside facility with parking facilities for the rest or other needs of motorists.

(2) TRUCK STOP.—The term ''truck stop'' means a facility (including any parking lot appurtenant to the facility) that—

(A) has the capacity to provide fuel or service, or both, to any commercial motor vehicle (as defined in section 31301 of title 49), operating in commerce (as defined in that section); and

(B) is located within 2,500 feet of the National System of Interstate and Defense Highways or the Federal-Aid Primary System.

(b) FIRST OFFENSE.—A person that violates section 50701(a)(1) or 50716 of this title by distributing or possessing with intent to distribute a controlled substance in or on, or within 1,000 feet of, a truck stop or safety rest area is (except as provided in subsection (c)) subject to—

(1) twice the maximum punishment authorized by section 50701(b) of this title; and

(2) twice any term of supervised release authorized by section 50701(b) of this title for a first offense.

(c) SUBSEQUENT OFFENSE.—A person that violates section 50701(a)(1) or 50716 of this title by distributing or possessing with intent to distribute a controlled substance in or on, or within 1,000 feet of, a truck stop or a safety rest area after a prior conviction or convictions under subsection (b) have become final is subject to—

(1) 3 times the maximum punishment authorized by section 50701(b) of this title; and

(2) 3 times any term of supervised release authorized by section 50701(b) of this title for a first offense.

**§ 50710. Information for sentencing**

Except as otherwise provided in this division, no limitation shall be placed on the information concerning the background, character, and conduct of a person convicted of an offense which a court of the United States may receive and consider for the purpose of imposing an appropriate sentence under this division or division B.

**§ 50711. Proceedings to establish prior convictions**

(a) INFORMATION FILED BY UNITED STATES ATTORNEY.—

(1) REQUIRED FILING.—

(A) IN GENERAL.—A person that stands convicted of an offense under this chapter shall not be sentenced to increased punishment by reason of 1 or more prior convictions, unless before trial, or before entry of a plea of guilty, the United States attorney files an information with the court (and serves a copy of the information on the person or counsel for the person) stating in writing the previous convictions to be relied on.

(B) FACTS NOT OBTAINED BY TRIAL OR ENTRY OF GUILTY PLEA.—On a showing by the United States attorney that facts regarding prior convictions could not with due diligence be obtained prior to trial or before entry of a plea of guilty, the court may postpone the trial or the taking of the plea of guilty for a reasonable period for the purpose of obtaining the facts.

(C) CLERICAL MISTAKES.—Clerical mistakes in the information may be amended at any time prior to the pronouncement of sentence.

(2) LIMITATION.—An information may not be filed under this section if the increased punishment that may be imposed is imprisonment for a term in

excess of 3 years unless the person waived or was afforded prosecution by indictment for the offense for which the increased punishment may be imposed.

(b) AFFIRMATION OR DENIAL OF PREVIOUS CONVICTION.—If the United States attorney files an information under this section, the court shall after conviction but before pronouncement of sentence inquire of the person with respect to whom the information was filed whether the person affirms or denies that the person has been previously convicted as alleged in the information, and shall inform the person that any challenge to a prior conviction that is not made before sentence is imposed may not be raised to attack the sentence.

(c) DENIAL; WRITTEN RESPONSE; HEARING.—

(1) DENIAL.—

(A) FILING OF RESPONSE.—If the person denies any allegation of the information of prior conviction, or claims that any conviction alleged is invalid, the person shall file a written response to the information. A copy of the response shall be served on the United States attorney.

(B) HEARING.—The court shall hold a hearing to determine any issues raised by the

response which would except the person from increased punishment.

(C) FAILURE TO INCLUDE COMPLETE CRIMINAL RECORD DOES NOT INVALIDATE NOTICE.—The failure of the United States attorney to include in the information the complete criminal record of the person or any facts in addition to the convictions to be relied on shall not constitute grounds for invalidating the notice given in the information required by subsection (a)(1).

(D) COURT HEARING.—The hearing shall be before the court without a jury and either party may introduce evidence.

(E) BURDEN OF PROOF.—Except as otherwise provided in paragraph (2), the United States attorney shall have the burden of proof beyond a reasonable doubt on any issue of fact.

(F) FINDINGS OF FACT AND CONCLUSIONS OF LAW BY THE COURT.—At the request of either party, the court shall enter findings of fact and conclusions of law.

(2) CONSTITUTIONAL VIOLATION.—

(A) CLAIM.—A person claiming that a conviction alleged in the information was obtained

in violation of the Constitution of the United States shall set forth the person's claim, and the factual basis for the claim, with particularity in the person's response to the information.

(B) BURDEN OF PROOF.—The person shall have the burden of proof by a preponderance of the evidence on any issue of fact raised by the response.

(3) CHALLENGE TO PRIOR CONVICTION.—Any challenge to a prior conviction, not raised by response to the information before an increased sentence is imposed in reliance on the prior conviction, shall be waived unless good cause is shown for failure to make a timely challenge.

(d) IMPOSITION OF SENTENCE.—

(1) IN GENERAL.—If the person files no response to the information, or if the court determines, after hearing, that the person is subject to increased punishment by reason of prior convictions, the court shall proceed to impose sentence on the person as provided by this chapter.

(2) POSTPONING SENTENCE TO ALLOW FOR APPEAL.—If the court determines that the person has not been convicted as alleged in the information,

that a conviction alleged in the information is invalid, or that the person is otherwise not subject to an increased sentence as a matter of law, the court shall, at the request of the United States attorney, postpone sentence to allow an appeal from that determination. If no such request is made, the court shall impose sentence as provided by this chapter. The person may appeal from an order postponing sentence as if sentence had been pronounced and a final judgment of conviction entered.

(e) STATUTE OF LIMITATIONS.—A person that stands convicted of an offense under this chapter shall not challenge the validity of any prior conviction alleged under this section that occurred more than 5 years before the date of the information alleging the prior conviction.

**§ 50712. Application of treaties and other international agreements**

Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit the provision of treatment, education, or rehabilitation as alternatives to conviction or criminal penalty for offenses involving any drug or other substance subject to control under any such treaty or agreement.

**§ 50713. Criminal forfeitures**

(a) PROPERTY.—Property subject to criminal forfeiture under this section includes—

(1) real property, including things growing on, affixed to, and found in land; and

(2) tangible and intangible personal property, including rights, privileges, interests, claims, and securities.

(b) PROPERTY SUBJECT TO CRIMINAL FORFEITURE.—

(1) IN GENERAL.—Any person convicted of a violation of this division or division B punishable by imprisonment for more than 1 year shall forfeit to the United States, irrespective of any provision of State law—

(A) any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of the violation;

(B) any of the person's property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, the violation; and

(C) in the case of a person convicted of engaging in a continuing criminal enterprise in violation of section 50708 of this title, in addition to any property described in subparagraph

(A) or (B), any of the person's interest in, claims against, and property or contractual rights affording a source of control over, the continuing criminal enterprise.

(2) ORDER.—The court, in imposing sentence on the person, shall order, in addition to any other sentence imposed pursuant to this division or division B, that the person forfeit to the United States all property described in this subsection.

(3) DEFENDANT DERIVING PROFITS FROM OFFENSE.—In lieu of a fine otherwise authorized by this chapter, a defendant who derives profits or other proceeds from an offense may be fined not more than twice the gross profits or other proceeds.

(c) THIRD PARTY TRANSFERS.—All right, title, and interest in property described in subsection (b) vests in the United States on the commission of the act giving rise to forfeiture under this section. Any such property that is subsequently transferred to a person other than the defendant may be the subject of a special verdict of forfeiture, and after the special verdict, shall be ordered forfeited to the United States, unless the transferee establishes in a hearing pursuant to subsection (n) that the transferee is a bona fide purchaser for value of the property who at the time of purchase was reasonably without

cause to believe that the property was subject to forfeiture under this section.

(d) REBUTTABLE PRESUMPTION.—There is a rebuttable presumption at trial that any property of a person convicted of a felony under this division or division B is subject to forfeiture under this section if the United States establishes by a preponderance of the evidence that—

(1) the property was acquired by the person during the period of the violation of this division or division B or within a reasonable time after the period; and

(2) there was no likely source for the property other than the violation of this division or division B.

(e) PROTECTIVE ORDERS.—

(1) IN GENERAL.—

(A) ACTION BY COURT TO PRESERVE AVAILABILITY OF PROPERTY FOR FORFEITURE.—On application of the United States, the court may enter a restraining order or injunction, require the execution of a satisfactory performance bond, or take any other action to preserve the availability of property described in subsection (b) for forfeiture under this section—

(i) on the filing of an indictment or information charging a violation of this division or division B for which criminal forfeiture may be ordered under this section and alleging that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section; or

(ii) prior to the filing of such an indictment or information, if, after notice to persons appearing to have an interest in the property and opportunity for a hearing, the court determines that—

(I) there is a substantial probability that the United States will prevail on the issue of forfeiture and that failure to enter the order will result in the property being destroyed, removed from the jurisdiction of the court, or otherwise made unavailable for forfeiture; and

(II) the need to preserve the availability of the property through the entry of the requested order outweighs the hardship on any party

against whom the order is to be entered.

(B) EFFECTIVE DATE OF ORDER UNDER SUBPARAGRAPH (A)(ii).—An order entered pursuant to subparagraph (A)(ii) shall be effective for not more than 90 days, unless extended by the court for good cause shown or unless an indictment or information described in subparagraph (A)(i) has been filed.

(2) TEMPORARY RESTRAINING ORDER.—

(A) CONDITIONS.—A temporary restraining order under this subsection may be entered on application of the United States without notice or opportunity for a hearing when an information or indictment has not yet been filed with respect to the property, if the United States demonstrates—

(i) that there is probable cause to believe that the property with respect to which the order is sought would, in the event of conviction, be subject to forfeiture under this section; and

(ii) that provision of notice will jeopardize the availability of the property for forfeiture.

(B) EXPIRATION.—A temporary restraining order under this paragraph shall expire not more than 14 days after the date on which it is entered, unless extended for good cause shown or unless the party against whom it is entered consents to an extension for a longer period.

(C) HEARING.—A hearing requested concerning a temporary restraining order entered under this paragraph shall be held at the earliest possible time and prior to the expiration of the temporary restraining order.

(3) EVIDENCE INADMISSIBLE UNDER FEDERAL RULES OF EVIDENCE.—The court may receive and consider, at a hearing held pursuant to this subsection, evidence and information that would be inadmissible under the Federal Rules of Evidence (28 U.S.C. App.).

(4) ORDER TO REPATRIATE AND DEPOSIT.—

(A) IN GENERAL.—Pursuant to its authority to enter a pretrial restraining order under this section, the court may order a defendant to repatriate any property that may be seized and forfeited, and to deposit that property pending trial in the registry of the court, or with the

United States Marshals Service or the Secretary of the Treasury, in an interest-bearing account, if appropriate.

(B) FAILURE TO COMPLY.—Failure to comply with an order under this subsection, or an order to repatriate property under subsection (p), shall be punishable as a civil or criminal contempt of court, and may also result in an enhancement of the sentence of the defendant under the obstruction of justice provision of the Federal Sentencing Guidelines.

(f) WARRANT OF SEIZURE.—The United States may request the issuance of a warrant authorizing the seizure of property subject to forfeiture under this section in the same manner as provided for a search warrant. If the court determines that there is probable cause to believe that the property to be seized would, in the event of conviction, be subject to forfeiture and that an order under subsection (e) may not be sufficient to ensure the availability of the property for forfeiture, the court shall issue a warrant authorizing the seizure of the property.

(g) EXECUTION.—

(1) ORDER.—On entry of an order of forfeiture under this section, the court shall authorize the Attorney General to seize all property ordered forfeited

on such terms and conditions as the court considers proper.

(2) ACTIONS TO PROTECT INTEREST OF THE UNITED STATES.—Following entry of an order declaring the property forfeited, the court may, on application of the United States, enter appropriate restraining orders or injunctions, require the execution of satisfactory performance bonds, appoint receivers, conservators, appraisers, accountants, or trustees, or take any other action to protect the interest of the United States in the property ordered forfeited.

(3) INCOME DERIVED FROM PROPERTY TO OFFSET EXPENSES.—Any income accruing to or derived from property ordered forfeited under this section may be used to offset ordinary and necessary expenses to the property that are required by law, or that are necessary to protect the interests of the United States or third parties.

(h) DISPOSITION OF PROPERTY.—

(1) IN GENERAL.—Following the seizure of property ordered forfeited under this section, the Attorney General shall direct the disposition of the property by sale or any other commercially feasible means, making due provision for the rights of any innocent persons.

(2) PROPERTY RIGHT OR INTEREST NOT TO REVERT TO DEFENDANT.—Any property right or interest not exercisable by, or transferable for value to, the United States shall expire and shall not revert to the defendant, nor shall the defendant or any person acting in concert with the defendant or on the defendant's behalf be eligible to purchase forfeited property at any sale held by the United States.

(3) INTEREST OF OTHER PERSON.—On application of a person, other than the defendant or a person acting in concert with the defendant or on the defendant's behalf, the court may restrain or stay the sale or disposition of the property pending the conclusion of any appeal of the criminal case giving rise to the forfeiture, if the applicant demonstrates that proceeding with the sale or disposition of the property will result in irreparable injury, harm, or loss to the applicant.

(i) AUTHORITY OF THE ATTORNEY GENERAL.—With respect to property ordered forfeited under this section, the Attorney General may—

(1) grant petitions for mitigation or remission of forfeiture, restore forfeited property to victims of a violation of this division, or take any other action to protect the rights of innocent persons which ac-

tion is in the interest of justice and is not inconsistent with the provisions of this section;

(2) compromise claims arising under this section;

(3) award compensation to persons providing information resulting in a forfeiture under this section;

(4) direct the disposition by the United States, in accordance with the provisions of section 50911(e) of this title, of all property ordered forfeited under this section by public sale or any other commercially feasible means, making due provision for the rights of innocent persons; and

(5) take appropriate measures necessary to safeguard and maintain property ordered forfeited under this section pending its disposition.

(j) APPLICABILITY OF CIVIL FORFEITURE PROVISIONS.—Except to the extent that they are inconsistent with the provisions of this section, the provisions of section 50911(d) of this title shall apply to a criminal forfeiture under this section.

(k) BAR ON INTERVENTION.—Except as provided in subsection (n), a party claiming an interest in property subject to forfeiture under this section shall not—

(1) intervene in a trial or appeal of a criminal case involving the forfeiture of the property under this section; or

(2) commence an action at law or equity against the United States concerning the validity of the party's alleged interest in the property subsequent to the filing of an indictment or information alleging that the property is subject to forfeiture under this section.

(l) JURISDICTION TO ENTER ORDERS.—The district courts of the United States shall have jurisdiction to enter orders as provided in this section without regard to the location of any property that may be subject to forfeiture under this section or that has been ordered forfeited under this section.

(m) DEPOSITIONS.—To facilitate the identification and location of property declared forfeited and to facilitate the disposition of petitions for remission or mitigation of forfeiture, after the entry of an order declaring property forfeited to the United States, the court may, on application of the United States, order that the testimony of any witness relating to the property forfeited be taken by deposition and that any designated book, paper, document, record, recording, or other material not privileged be produced at the same time and place, in the same manner

as provided for the taking of depositions under Rule 15 of the Federal Rules of Criminal Procedure (18 U.S.C. App.).

(n) THIRD PARTY INTERESTS.—

(1) PUBLICATION OF ORDER; WRITTEN NOTICE.—Following the entry of an order of forfeiture under this section, the United States shall publish notice of the order and of its intent to dispose of the property in such manner as the Attorney General may direct. The United States may also, to the extent practicable, provide direct written notice to any person known to have alleged an interest in the property that is the subject of the order of forfeiture as a substitute for published notice as to those persons so notified.

(2) PETITION FOR HEARING.—Any person, other than the defendant, asserting a legal interest in property that has been ordered forfeited to the United States pursuant to this section may, within 30 days of the final publication of notice or the person's receipt of notice under paragraph (1), whichever is earlier, petition the court for a hearing to adjudicate the validity of the person's alleged interest in the property. The hearing shall be held before the court alone, without a jury.

(3) CONTENTS OF PETITION.—The petition shall be signed by the petitioner under penalty of perjury and shall set forth the nature and extent of the petitioner's right, title, or interest in the property, the time and circumstances of the petitioner's acquisition of the right, title, or interest in the property, any additional facts supporting the petitioner's claim, and the relief sought.

(4) DATE ON WHICH HEARING IS TO BE HELD; CONSOLIDATION.—The hearing on the petition shall, to the extent practicable and consistent with the interests of justice, be held within 30 days of the filing of the petition. The court may consolidate the hearing on the petition with a hearing on any other petition filed by a person other than the defendant under this subsection.

(5) HEARING PROCEDURES.—At the hearing, the petitioner may testify and present evidence and witnesses on the petitioner's own behalf, and cross-examine witnesses who appear at the hearing. The United States may present evidence and witnesses in rebuttal and in defense of its claim to the property and cross-examine witnesses who appear at the hearing. In addition to testimony and evidence presented at the hearing, the court shall consider the relevant

portions of the record of the criminal case that resulted in the order of forfeiture.

(6) AMENDMENT OF ORDER OF FORFEITURE.—The court shall amend the order of forfeiture in accordance with its determination under this paragraph if, after the hearing, the court determines that the petitioner has established by a preponderance of the evidence that—

(A) the petitioner has a legal right, title, or interest in the property, and the right, title, or interest renders the order of forfeiture invalid in whole or in part because the right, title, or interest was vested in the petitioner rather than the defendant or was superior to any right, title, or interest of the defendant at the time of the commission of the acts that gave rise to the forfeiture of the property under this section; or

(B) the petitioner is a bona fide purchaser for value of the right, title, or interest in the property and was at the time of purchase reasonably without cause to believe that the property was subject to forfeiture under this section.

(7) CLEAR TITLE TO PROPERTY.—Following the court's disposition of all petitions filed under this subsection, or if no such petitions are filed fol-

lowing the expiration of the period provided in paragraph (2) for the filing of the petitions, the United States shall have clear title to property that is the subject of the order of forfeiture and may warrant good title to any subsequent purchaser or transferee.

(o) CONSTRUCTION.—The provisions of this section shall be liberally construed to effectuate its remedial purposes.

(p) FORFEITURE OF SUBSTITUTE PROPERTY.—

(1) IN GENERAL.—Paragraph (2) shall apply, if any property described in subsection (b), as a result of any act or omission of the defendant—

(A) cannot be located upon the exercise of due diligence;

(B) has been transferred or sold to, or deposited with, a third party;

(C) has been placed beyond the jurisdiction of the court;

(D) has been substantially diminished in value; or

(E) has been commingled with other property which cannot be divided without difficulty.

(2) SUBSTITUTE PROPERTY.—In any case described in any of subparagraphs (A) through (E) of paragraph (1), the court shall order the forfeiture of

any other property of the defendant, up to the value of any property described in subparagraphs (A) through (E) of paragraph (1), as applicable.

(3) RETURN OF PROPERTY TO JURISDICTION.—In the case of property described in paragraph (1)(C), the court may, in addition to any other action authorized by this subsection, order the defendant to return the property to the jurisdiction of the court so that the property may be seized and forfeited.

(q) RESTITUTION FOR CLEANUP OF CLANDESTINE LABORATORY SITES.—The court, when sentencing a defendant convicted of an offense under this division or division B involving the manufacture, the possession, or the possession with intent to distribute, of amphetamine or methamphetamine, shall—

(1) order restitution as provided in sections 3612 and 3664 of title 18;

(2) order the defendant to reimburse the United States, the State or local government concerned, or both the United States and the State or local government concerned for the costs incurred by the United States or the State or local government concerned, as the case may be, for the cleanup associated with the manufacture of amphetamine or meth-

amphetamine by the defendant, or on premises or in property that the defendant owns, resides, or does business in; and

(3) order restitution to any person injured as a result of the offense as provided in section 3663A of title 18.

**§ 50714. Investment of illicit drug profits**

(a) DEFINITION OF ENTERPRISE.—In this section, the term ''enterprise'' includes any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.

(b) PROHIBITION.—

(1) IN GENERAL.—It shall be unlawful for any person that has received any income derived, directly or indirectly, from a violation of this division or division B punishable by imprisonment for more than 1 year in which the person has participated as a principal within the meaning of section 2 of title 18, to use or invest, directly or indirectly, any part of the income, or the proceeds of the income, in acquisition of any interest in, or the establishment or operation of, any enterprise that is engaged in, or the activities of which affect, interstate or foreign commerce.

(2) PURCHASE OF SECURITIES NOT UNLAWFUL IF CERTAIN CONDITIONS MET.—A purchase of securities on the open market for purposes of investment, and without the intention of controlling or participating in the control of the issuer, or of assisting another to do so, shall not be unlawful under this section if the securities of the issuer held by the purchaser, the members of the purchaser's immediate family, and the purchaser's or the members' accomplices in any violation of this division or division B after the purchase do not amount in the aggregate to 1 percent of the outstanding securities of any 1 class, and do not confer, either in law or in fact, the power to elect 1 or more directors of the issuer.

(c) PENALTY.—Whoever violates this section shall be fined under title 18 or imprisoned not more than 10 years, or both.

(d) CONSTRUCTION.—The provisions of this section shall be liberally construed to effectuate its remedial purposes.

**§ 50715. Alternative fine**

In lieu of a fine otherwise authorized by this chapter, a defendant that derives profits or other proceeds from

an offense may be fined not more than twice the gross profits or other proceeds.

**§ 50716. Maintaining drug-involved premises**

(a) UNLAWFUL ACTS.—Except as authorized by this division, it shall be unlawful to—

(1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance; or

(2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.

(b) CRIMINAL PENALTIES.—Any person that violates subsection (a) shall be sentenced to a term of imprisonment of not more than 20 years, a fine of not more than $500,000 or an alternative amount provided under title 18, or both, or, if the violator is a person other than an individual, a fine of $2,000,000 or an alternative amount provided under title 18.

(c) VIOLATION AS OFFENSE AGAINST PROPERTY.—A violation of subsection (a) shall be considered an offense against property for purposes of section 3663A(c)(1)(A)(ii) of title 18.

(d) CIVIL PENALTIES.—

(1) IN GENERAL.—Any person that violates subsection (a) shall be subject to a civil penalty of not more than the greater of—

(A) $250,000; or

(B) 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person.

(2) MORE THAN 1 DEFENDANT.—If a civil penalty is calculated under paragraph (1)(B), and there is more than 1 defendant, the court may apportion the penalty between multiple violators, but each violator shall be jointly and severally liable for the civil penalty under this subsection.

(e) DECLARATORY AND INJUNCTIVE REMEDIES.—Any person that violates subsection (a) shall be subject to declaratory and injunctive remedies as set forth in section 50703(f) of this title.

**§ 50717. Creating substantial risk of harm to human life while illegally manufacturing controlled substance**

Whoever, while manufacturing a controlled substance in violation of this division, or attempting to do so, or transporting or causing to be transported materials, including chemicals, to do so, creates a substantial risk of harm to human life shall be fined in accordance with title 18, imprisoned not more than 10 years, or both.

**§ 50718. Distribution to individuals under age 21**

(a) FIRST OFFENSE.—

(1) IN GENERAL.—Except as provided in section 50719 of this title, any individual at least 18 years of age, or any other person other than an individual, that violates section 50701(a)(1) of this title by distributing a controlled substance to an individual under 21 years of age is (except as provided in subsection (b)) subject to—

(A) twice the maximum punishment authorized by section 50701(b) of this title for a first offense involving the same controlled substance and schedule; and

(B) at least twice any term of supervised release authorized by section 50701(b) of this title for a first offense involving the same controlled substance and schedule.

(2) MINIMUM TERM OF IMPRISONMENT.—Except to the extent a greater minimum sentence is otherwise provided by section 50701(b) of this title, a term of imprisonment under this subsection shall be not less than 1 year. The mandatory minimum sentencing provisions of this subsection shall not apply to offenses involving 5 grams or less of marihuana.

(b) SECOND OFFENSE.—

(1) IN GENERAL.—Except as provided in section 50719 of this title, any individual at least 18 years of age, or any other person other than an individual, that violates section 50701(a)(1) of this title by distributing a controlled substance to an individual under 21 years of age after a prior conviction under subsection (a) (or under section 303(b)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by section 3 of Public Law 90–639 (82 Stat. 1362) and as in effect prior to May 1, 1971) has become final, is subject to—

(A) 3 times the maximum punishment authorized by section 50701(b) of this title for a second or subsequent offense involving the same controlled substance and schedule; and

(B) at least 3 times any term of supervised release authorized by section 50701(b) of this title for a second or subsequent offense involving the same controlled substance and schedule.

(2) MINIMUM TERM OF IMPRISONMENT.—Except to the extent a greater minimum sentence is otherwise provided by section 50701(b) of this title, a term of imprisonment under this subsection shall be not less than 1 year.

(3) THIRD AND SUBSEQUENT CONVICTIONS.—Penalties for third and subsequent convictions shall be governed by section 50701(b)(1)(A) of this title.

**§ 50719. Distribution or manufacturing in or near schools and colleges and other facilities**

(a) DEFINITIONS.—In this section:

(1) PLAYGROUND.—The term ''playground'' means any outdoor facility (including any parking lot appurtenant to the outdoor facility) intended for recreation, open to the public, and with any portion of the facility containing 3 or more separate apparatuses intended for the recreation of children, including sliding boards, swingsets, and teeterboards.

(2) YOUTH CENTER.—The term ''youth center'' means any recreational facility or gymnasium (in-

cluding any parking lot appurtenant to the recreational facility or gymnasium), intended primarily for use by individuals under 18 years of age, which regularly provides athletic, civic, or cultural activities.

(3) VIDEO ARCADE FACILITY.—The term ''video arcade facility'' means any facility, legally accessible to individuals under 18 years of age, intended primarily for the use of pinball and video machines for amusement containing a minimum of 10 pinball or video machines.

(4) SWIMMING POOL.—The term ''swimming pool'' includes any parking lot appurtenant to the swimming pool.

(b) PENALTY.—

(1) IN GENERAL.—Any person that violates section 50701(a)(1) of this title or section 50716 of this title by distributing, possessing with intent to distribute, or manufacturing a controlled substance in or on, or within 1,000 feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private

youth center, public swimming pool, or video arcade facility, is (except as provided in subsection (c)) subject to—

(A) twice the maximum punishment authorized by section 50701(b) of this title; and

(B) at least twice any term of supervised release authorized by section 50701(b) of this title for a first offense.

(2) FINES.—A fine up to twice that authorized by section 50701(b) of this title may be imposed in addition to any term of imprisonment authorized by this subsection.

(3) MINIMUM TERM OF IMPRISONMENT.—Except to the extent a greater minimum sentence is otherwise provided by section 50701(b) of this title, a person shall be sentenced under this subsection to a term of imprisonment of not less than 1 year.

(4) OFFENSES INVOLVING 5 GRAMS OR LESS OF MARIHUANA.—The mandatory minimum sentencing provisions of this subsection shall not apply to offenses involving 5 grams or less of marihuana.

(c) SECOND OFFENDERS.—

(1) IN GENERAL.—Any person that violates section 50701(a)(1) of this title or section 50716 of this title by distributing, possessing with intent to

distribute, or manufacturing a controlled substance in or on, or within 1,000 feet of, the real property comprising a public or private elementary, vocational, or secondary school or a public or private college, junior college, or university, or a playground, or housing facility owned by a public housing authority, or within 100 feet of a public or private youth center, public swimming pool, or video arcade facility, after a prior conviction under subsection (b) has become final, is punishable—

(A) by the greater of—

(i) a term of imprisonment of not less than 3 years and not more than life imprisonment; or

(ii) 3 times the maximum punishment authorized by section 50701(b) of this title for a first offense; and

(B) at least 3 times any term of supervised release authorized by section 50701(b) of this title for a first offense.

(2) FINES.—A fine up to 3 times that authorized by section 50701(b) of this title may be imposed in addition to any term of imprisonment authorized by this subsection.

(3) MINIMUM TERM OF IMPRISONMENT.—Except to the extent a greater minimum sentence is otherwise provided by section 50701(b) of this title, a person shall be sentenced under this subsection to a term of imprisonment of not less than 3 years.

(4) THIRD AND SUBSEQUENT CONVICTIONS.—Penalties for third and subsequent convictions shall be governed by section 50701(b)(1)(A) of this title.

(d) EMPLOYING CHILDREN TO DISTRIBUTE DRUGS NEAR SCHOOLS OR PLAYGROUNDS.—

(1) IN GENERAL.—Notwithstanding any other law, any person described in paragraph (2) is subject to a term of imprisonment, a fine, or both, up to triple those authorized by section 50701 of this title.

(2) PERSON.—A person is described in this paragraph if the person is an individual at least 18 years of age, or any other person other than an individual, that knowingly and intentionally—

(A) employs, hires, uses, persuades, induces, entices, or coerces an individual under 18 years of age to violate this section; or

(B) employs, hires, uses, persuades, induces, entices, or coerces an individual under 18 years of age to assist in avoiding detection

or apprehension for any offense under this section by any Federal, State, or local law enforcement official.

(e) SUSPENSION OF SENTENCE; PROBATION; PAROLE.—In the case of any mandatory minimum sentence imposed under this section, imposition or execution of the sentence shall not be suspended and probation shall not be granted. An individual convicted under this section shall not be eligible for parole until the individual has served the mandatory minimum term of imprisonment as provided by this section.

**§ 50720. Consecutive sentence for manufacturing or distributing methamphetamine on premises where children are present or reside**

A person that violates section 50701(a)(1) of this title by manufacturing or distributing, or possessing with intent to manufacture or distribute, methamphetamine or its salts, isomers, or salts of isomers on premises in which an individual who is under the age of 18 years is present or resides, shall, in addition to any other sentence imposed, be imprisoned for a period of any term of years but not more than 20 years, fined, or both.

**§ 50721. Employment or use of persons under 18 years of age in drug operations**

(a) UNLAWFUL ACTS.—It shall be unlawful for any individual at least 18 years of age, or any other person other than an individual, to knowingly and intentionally—

(1) employ, hire, use, persuade, induce, entice, or coerce an individual under 18 years of age to violate any provision of this division or division B;

(2) employ, hire, use, persuade, induce, entice, or coerce an individual under 18 years of age to assist in avoiding detection or apprehension for any offense of this division or division B by any Federal, State, or local law enforcement official; or

(3) receive a controlled substance from an individual under 18 years of age, other than an immediate family member, in violation of this division or division B.

(b) PENALTY FOR FIRST OFFENSE.—Any individual at least 18 years of age, or any other person other than an individual, that violates subsection (a) is subject to twice the maximum punishment otherwise authorized and at least twice any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise provided, a term of imprisonment under this subsection shall not be less than 1 year.

(c) PENALTY FOR SUBSEQUENT OFFENSES.—Any individual at least 18 years of age, or any other person other than an individual, that violates subsection (a), after a prior conviction under subsection (a) has become final, is subject to 3 times the maximum punishment otherwise authorized and at least 3 times any term of supervised release otherwise authorized for a first offense. Except to the extent a greater minimum sentence is otherwise provided, a term of imprisonment under this subsection shall not be less than 1 year. Penalties for third and subsequent convictions shall be governed by section 50701(b)(1)(A) of this title.

(d) PENALTY FOR PROVIDING OR DISTRIBUTING CONTROLLED SUBSTANCE TO UNDERAGE INDIVIDUAL.—

(1) IN GENERAL.—Any person described in paragraph (2) shall be subject to a term of imprisonment for not more than 5 years or a fine under title 18, or both, in addition to any other punishment authorized by this section.

(2) PERSON.—A person described in this paragraph is an individual at least 18 years of age, or any other person other than an individual, that violates paragraph (1) or (2) of subsection (a)—

(A) by knowingly providing or distributing a controlled substance or a controlled substance

analogue to any individual under 18 years of age; or

(B) if the individual employed, hired, or used is 14 years of age or younger.

(e) SUSPENSION OF SENTENCE; PROBATION; PAROLE.—In any case of any sentence imposed under this section, imposition or execution of the sentence shall not be suspended and probation shall not be granted. An individual convicted under this section of an offense for which a mandatory minimum term of imprisonment is applicable shall not be eligible for parole until the individual has served the mandatory term of imprisonment as enhanced by this section.

(f) DISTRIBUTION OF CONTROLLED SUBSTANCE TO PREGNANT INDIVIDUAL.—Except as authorized by this division, it shall be unlawful for any person to knowingly or intentionally provide or distribute any controlled substance to a pregnant individual in violation of any provision of this division. Any person that violates this subsection shall be subject to the provisions of subsections (b), (c), and (e).

**§ 50722. Denial of Federal benefits to drug traffickers and possessors**

(a) DEFINITIONS.—In this section:

(1) FEDERAL BENEFIT.—The term ''Federal benefit''—

(A) means the issuance of any grant, contract, loan, professional license, or commercial license provided by an agency of the United States or by appropriated funds of the United States; and

(B) does not include any retirement, welfare, social security, health, disability, veterans benefit, public housing, or other similar benefit, or any other benefit for which payments or services are required for eligibility.

(2) VETERANS BENEFIT.—The term ''veterans benefit'' means all benefits provided to veterans, their families, or survivors by virtue of the service of a veteran in the Armed Forces of the United States.

(b) DRUG TRAFFICKERS.—

(1) IN GENERAL.—Any individual who is convicted of any Federal or State offense consisting of the distribution of controlled substances shall—

(A) at the discretion of the court, on the first conviction for such an offense, be ineligible for any or all Federal benefits for up to 5 years after the conviction;

(B) at the discretion of the court, on a second conviction for such an offense, be ineligible for any or all Federal benefits for up to 10 years after the conviction; and

(C) on a third or subsequent conviction for such an offense, be permanently ineligible for all Federal benefits.

(2) EXCLUDED BENEFITS.—The benefits that are denied under this subsection shall not include benefits relating to long-term drug treatment programs for addiction for any individual who, if there is a reasonable body of evidence to substantiate the declaration, declares oneself to be an addict and submits oneself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary.

(c) DRUG POSSESSORS.—

(1) IN GENERAL.—

(A) PENALTIES.—Any individual who is convicted of any Federal or State offense involving the possession of a controlled substance shall—

(i) on the first conviction for such an offense and at the discretion of the court—

(I) be ineligible for any or all Federal benefits for up to 1 year;

(II) be required to successfully complete an approved drug treatment program that includes periodic testing to ensure that the individual remains drug free;

(III) be required to perform appropriate community service; or

(IV) be subject to any combination of subclause (I), (II), or (III); and

(ii) on a second or subsequent conviction for such an offense, be ineligible for all Federal benefits for up to 5 years after the conviction as determined by the court.

(B) COURT DISCRETION AND IMPOSITION OF PENALTIES.—The court shall continue to have the discretion in subparagraph (A)(i). In imposing penalties and conditions under subparagraph (A)(i), the court may require that the completion of the conditions imposed by subclause (II) or (III) of subparagraph (A)(i) be a requirement for the reinstatement of benefits under subparagraph (A)(i)(I).

(2) WAIVER.—The penalties and conditions that may be imposed under this subsection shall be waived in the case of an individual who, if there is a reasonable body of evidence to substantiate the declaration, declares oneself to be an addict and submits oneself to a long-term treatment program for addiction, or is deemed to be rehabilitated pursuant to rules established by the Secretary.

(d) SUSPENSION OF PERIOD OF INELIGIBILITY.—The period of ineligibility referred to in subsections (b) and (c) shall be suspended if the individual—

(1) completes a supervised drug rehabilitation program after becoming ineligible under this section;

(2) has otherwise been rehabilitated; or

(3) has made a good faith effort to gain admission to a supervised drug rehabilitation program, but is unable to do so because of inaccessibility or unavailability of such a program, or the inability of the individual to pay for such a program.

(e) INAPPLICABILITY OF THIS SECTION TO GOVERNMENT WITNESSES.—The penalties provided by this section shall not apply to any individual who cooperates or testifies with the Government in the prosecution of a Federal or State offense or who is in a Government witness protection program.

(f) INDIANS AND INDIAN TRIBES.—Nothing in this section shall be construed to affect the obligation of the United States to any Indian or Indian tribe arising out of any treaty, statute, executive order, or the trust responsibility of the United States owing to the Indian or Indian tribe. Nothing in this subsection shall exempt any individual Indian from the sanctions provided for in this section, provided that no individual Indian shall be denied any benefit under Federal Indian programs comparable to those described in subsection (a)(1)(B) or (a)(2).

**§ 50723. Drug paraphernalia**

(a) DEFINITION OF DRUG PARAPHERNALIA.—

(1) IN GENERAL.—The term ''drug paraphernalia'' means any equipment, product, or material of any kind that is primarily intended or designed for use in manufacturing, compounding, converting, concealing, producing, processing, preparing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance, possession of which is unlawful under this division.

(2) INCLUSIONS.—The term ''drug paraphernalia'' includes items primarily intended or designed for use in ingesting, inhaling, or otherwise introducing marihuana, cocaine, hashish, hashish oil,

PCP, methamphetamine, or amphetamines into the human body, such as—

(A) metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;

(B) water pipes;

(C) carburetion tubes and devices;

(D) smoking and carburetion masks;

(E) roach clips (meaning objects used to hold burning material, such as a marihuana cigarette, that has become too small or too short to be held in the hand);

(F) miniature spoons with level capacities of $^{1}/_{10}$ cubic centimeter or less;

(G) chamber pipes;

(H) carburetor pipes;

(I) electric pipes;

(J) air-driven pipes;

(K) chillums;

(L) bongs;

(M) ice pipes or chillers;

(N) wired cigarette papers; or

(O) cocaine freebase kits.

(b) IN GENERAL.—It is unlawful for any person—

(1) to sell or offer for sale drug paraphernalia;

(2) to use the mails or any other facility of interstate commerce to transport drug paraphernalia; or

(3) to import or export drug paraphernalia.

(c) CRIMINAL PENALTIES.—Any person convicted of an offense under subsection (b) shall be imprisoned for not more than 3 years and fined under title 18.

(d) SEIZURE AND FORFEITURE.—Any drug paraphernalia involved in any violation of subsection (b) shall be subject to seizure and forfeiture on the conviction of a person for the violation. The drug paraphernalia shall be delivered to the Administrator of General Services, who may order the drug paraphernalia destroyed or may authorize its use for law enforcement or educational purposes by Federal, State, or local authorities.

(e) FACTORS CONSIDERED IN DETERMINATION OF WHAT CONSTITUTES DRUG PARAPHERNALIA.—In determining whether an item constitutes drug paraphernalia, in addition to all other logically relevant factors, the following may be considered:

(1) Instructions, oral or written, provided with the item concerning its use.

(2) Descriptive materials accompanying the item that explain or depict its use.

(3) National and local advertising concerning its use.

(4) The manner in which the item is displayed for sale.

(5) Whether the owner, or anyone in control of the item, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products.

(6) Direct or circumstantial evidence of the ratio of sales of the item to the total sales of the business enterprise.

(7) The existence and scope of legitimate uses of the item in the community.

(8) Expert testimony concerning its use.

(f) EXEMPTIONS.—This section shall not apply to—

(1) any person authorized by local, State, or Federal law to manufacture, possess, or distribute the items; or

(2) any item that, in the normal lawful course of business, is imported, exported, transported, or sold through the mail or by any other means, and traditionally intended for use with tobacco products, including any pipe, paper, or accessory.

**§ 50724. Stealing or transporting anhydrous ammonia**

(a) UNLAWFUL ACTS.—It is unlawful for any person, knowing, intending, or having reasonable cause to believe that any anhydrous ammonia will be used to manufacture a controlled substance in violation of this chapter—

(1) to steal the anhydrous ammonia; or

(2) to transport the anhydrous ammonia, if stolen, across State lines.

(b) PENALTIES.—Any person that violates subsection (a) shall be imprisoned, fined, or both, in accordance with section 50703(d) of this title as if the violation were a violation of a provision of section 50703 of this title.

# Chapter 509—Administrative and Enforcement Provisions

Sec.
50901. Attorney General.
50902. Education and research programs of Attorney General.
50903. Cooperative arrangements.
50904. Advisory committees.
50905. Administrative hearings.
50906. Subpoenas.
50907. Judicial review.
50908. Powers of enforcement personnel.
50909. Search warrants.
50910. Administrative inspections and warrants.
50911. Forfeitures.
50912. Injunctions.
50913. Notice and opportunity to present views.
50914. Immunity and privilege.
50915. Burden of proof; liabilities.
50916. Payments and advances.
50917. Coordination and consolidation of post-seizure administration.
50918. Production control of controlled substances.
50919. Review of Federal sales of chemicals usable to manufacture controlled substances.

**§ 50901. Attorney General**

(a) DELEGATION OF FUNCTIONS.—The Attorney General may delegate any of the Attorney General's functions under this division to any officer or employee of the Department of Justice.

(b) RULES AND REGULATIONS.—The Attorney General may promulgate and enforce any rules, regulations, and procedures that the Attorney General may consider necessary and appropriate for the efficient execution of the Attorney General's functions under this division.

(c) ACCEPTANCE OF DEVISES, BEQUESTS, GIFTS, AND DONATIONS.—The Attorney General may accept in the name of the Department of Justice any form of devise, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. The Attorney General may take all appropriate steps to secure possession of the property and may sell, assign, transfer, or convey any the property other than moneys.

**§ 50902. Education and research programs of Attorney General**

(a) AUTHORIZATION.—The Attorney General may carry out educational and research programs directly related to enforcement of the laws under the Attorney General's jurisdiction concerning drugs or other substances

that are or may be subject to control under this division. The programs may include—

(1) educational and training programs on drug abuse and controlled substances law enforcement for local, State, tribal, and Federal personnel;

(2) studies or special projects designed to compare the deterrent effects of various enforcement strategies on drug use and abuse;

(3) studies or special projects designed to assess and detect accurately the presence in the human body of drugs or other substances that are or may be subject to control under this division, including the development of rapid field identification methods that would enable agents to detect microquantities of the drugs or other substances;

(4) studies or special projects designed to evaluate the nature and sources of the supply of illegal drugs throughout the country;

(5) studies or special projects to develop more effective methods to prevent diversion of controlled substances into illegal channels; and

(6) studies or special projects to develop information necessary to carry out the Attorney General's functions under section 50301 of this title.

(b) CONTRACTS.—The Attorney General may enter into contracts for the educational and research activities without performance bonds and without regard to section 6101 of title 41.

(c) IDENTIFICATION OF RESEARCH POPULATIONS; AUTHORIZATION TO WITHHOLD.—The Attorney General may authorize persons engaged in research to withhold the names and other identifying characteristics of persons who are the subjects of the research. Persons that obtain this authorization may not be compelled in any Federal, State, tribal, or local civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which the authorization was obtained.

(d) EFFECT OF TREATIES AND OTHER INTERNATIONAL AGREEMENTS ON CONFIDENTIALITY.—Nothing in the Single Convention on Narcotic Drugs, the Convention on Psychotropic Substances, or other treaties or international agreements shall be construed to limit, modify, or prevent the protection of the confidentiality of patient records or of the names and other identifying characteristics of research subjects as provided by any Federal, State, or local law or regulation.

(e) USE OF CONTROLLED SUBSTANCES IN RESEARCH.—The Attorney General, on the Attorney General's own motion or at the request of the Secretary, may

authorize the possession, distribution, and dispensing of controlled substances by persons engaged in research. Persons that obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, and dispensing of controlled substances to the extent authorized by the Attorney General.

(f) PROGRAM TO CURTAIL DIVERSION OF PRECURSOR AND ESSENTIAL CHEMICALS.—The Attorney General shall maintain an active program, both domestic and international, to curtail the diversion of precursor chemicals and essential chemicals used in the illicit manufacture of controlled substances.

**§ 50903. Cooperative arrangements**

(a) COOPERATION OF ATTORNEY GENERAL WITH LOCAL, STATE, TRIBAL, AND FEDERAL AGENCIES.—The Attorney General shall cooperate with local, State, tribal, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To carry out this subsection, the Attorney General may—

(1) arrange for the exchange of information between governmental officials concerning the use and abuse of controlled substances;

(2) cooperate in the institution and prosecution of cases in the courts of the United States and before the licensing boards and courts of the States;

(3) conduct training programs on controlled substance law enforcement for local, State, tribal, and Federal personnel;

(4) maintain in the Department of Justice a unit that will accept, catalog, file, and otherwise utilize all information and statistics, including records of controlled substance abusers and other controlled substance law offenders, that may be received from Federal, State, tribal, and local agencies, and make the information available for Federal, State, tribal, and local law enforcement purposes;

(5) conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted;

(6) assist State, tribal, and local governments in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels by—

(A) making periodic assessments of the capabilities of State, tribal, and local governments to adequately control the diversion of controlled substances;

(B) providing advice and counsel to State, tribal, and local governments on the methods by which the governments may strengthen their controls against diversion; and

(C) establishing cooperative investigative efforts to control diversion; and

(7) notwithstanding any other provision of law, enter into contractual agreements with State, tribal, and local law enforcement agencies to provide for cooperative enforcement and regulatory activities under this division and division B.

(b) REQUESTS BY ATTORNEY GENERAL FOR ASSISTANCE FROM FEDERAL AGENCIES OR INSTRUMENTALITIES.—When requested by the Attorney General, an agency or instrumentality of the Federal Government shall furnish assistance, including technical advice, to the Attorney General for carrying out the functions of the Attorney General under this division, except that the agency or instrumentality shall not be required to furnish the name of, or other identifying information about, a patient or research subject whose identity it has undertaken to keep confidential.

(c) AVAILABILITY OF STANDARDIZED REPORT RELATING TO DISTRIBUTION PATTERNS FOR SCHEDULE II

CONTROLLED SUBSTANCES THAT HAVE THE HIGHEST ABUSE.—

(1) IN GENERAL.—The Attorney General shall, once every 6 months, prepare and make available to regulatory, licensing, attorneys general, and law enforcement agencies of States a standardized report—

(A) that contains descriptive and analytic information on the actual distribution patterns, as gathered through the Automated Reports and Consolidated Orders System, or any subsequent automated system, pursuant to section 50507 of this title; and

(B) that includes detailed amounts, outliers, and trends of distributor and pharmacy registrants, in the States, for the controlled substances contained in schedule II, that, in the discretion of the Attorney General, are determined to have the highest abuse.

(2) COURT ACTIONS.—If the Attorney General publishes the report described in paragraph (1) once every 6 months as required under paragraph (1), nothing in this subsection shall be construed to create a cause of action in any court to challenge the sufficiency of the information or to compel the At-

torney General to produce any documents or reports referred to in this subsection.

(d) GRANTS BY ATTORNEY GENERAL.—

(1) IN GENERAL.—The Attorney General may make grants, in accordance with paragraphs (2), (3), and (4), to State, tribal, and local governments to assist in meeting the costs of—

(A) collecting and analyzing data on the diversion of controlled substances;

(B) conducting investigations and prosecutions of the diversions;

(C) improving regulatory controls and other authorities to control the diversions;

(D) programs to prevent the diversions;

(E) preventing and detecting forged prescriptions; and

(F) training law enforcement and regulatory personnel to improve the control of the diversions.

(2) APPLICATION REQUIRED.—A grant shall not be made under paragraph (1) unless an application for the grant is submitted to the Attorney General in such form and manner as the Attorney General may prescribe.

(3) COST-SHARING.—A grant under this subsection—

(A) shall not exceed 80 percent of the costs for which the grant is made; and

(B) shall not be made unless the recipient of the grant provides assurances satisfactory to the Attorney General that the recipient will obligate funds to meet the remaining 20 percent of the costs.

(4) REVIEW OF ACTIVITIES.—The Attorney General shall review the activities carried out with grants under paragraph (1) and shall report annually to Congress on the activities.

**§ 50904. Advisory committees**

(a) IN GENERAL.—The Attorney General may from time to time appoint committees to advise the Attorney General with respect to preventing and controlling the abuse of controlled substances.

(b) COMPENSATION.—Members of the committees may be entitled to receive compensation at the rate of $100 for each day (including travel time) during which they are engaged in the actual performance of duties.

(c) TRAVEL EXPENSES.—While traveling on official business in the performance of duties for the committees, members of the committees shall be allowed expenses of

travel, including per diem instead of subsistence, in accordance with subchapter I of chapter 57 of title 5.

**§ 50905. Administrative hearings**

(a) POWER OF ATTORNEY GENERAL.—In carrying out the functions of the Attorney General under this division, the Attorney General may hold hearings, sign and issue subpoenas, administer oaths, examine witnesses, and receive evidence at any place in the United States.

(b) PROCEDURES APPLICABLE.—Except as otherwise provided in this division, notice shall be given and hearings shall be conducted under appropriate procedures of subchapter II of chapter 5 of title 5.

**§ 50906. Subpoenas**

(a) AUTHORIZATION OF USE BY ATTORNEY GENERAL.—

(1) IN GENERAL.—In any investigation relating to the functions of the Attorney General under this division with respect to controlled substances, listed chemicals, tableting machines, or encapsulating machines, the Attorney General may subpoena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things that constitute or contain evidence) that

the Attorney General finds relevant or material to the investigation.

(2) JURISDICTION; LIMITATION.—The attendance of witnesses and the production of records may be required from any place in any State, territory of the United States, or any other place subject to the jurisdiction of the United States at any designated place of hearing, except that a witness shall not be required to appear at any hearing more than 500 miles distant from the place in which the witness was served with a subpoena.

(3) PAYMENT OF WITNESSES.—Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(b) SERVICE.—

(1) DESIGNATED PERSON TO SERVE.—A subpoena issued under this section may be served by any person designated in the subpoena to serve it.

(2) NATURAL PERSONS.—Service on a natural person may be made by personal delivery of the subpoena to the natural person.

(3) OTHER ENTITIES.—Service may be made on a domestic or foreign corporation or on a partnership or other unincorporated association that is sub-

ject to suit under a common name, by delivering the subpoena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process.

(4) AFFIDAVIT.—The affidavit of the person serving the subpoena entered on a true copy of the subpoena by the person serving it shall be proof of service.

(c) ENFORCEMENT.—

(1) CONTUMACY.—In the case of contumacy by or refusal to obey a subpoena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which the subpoenaed person carries on business or may be found, to compel compliance with the subpoena.

(2) COURT ORDER.—The court may issue an order requiring the subpoenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation.

(3) CONTEMPT.—Any failure to obey the order of the court may be punished by the court as a contempt of court. All process in any such case may be

served in any judicial district in which the person may be found.

**§ 50907. Judicial review**

(a) IN GENERAL.—All final determinations, findings, and conclusions of the Attorney General under this division shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which the person's principal place of business is located on petition filed with the court and delivered to the Attorney General within 30 days after notice of the decision.

(b) SUBSTANTIAL EVIDENCE.—Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

**§ 50908. Powers of enforcement personnel**

(a) IN GENERAL.—Any officer or employee of the Drug Enforcement Administration or any State, tribal, or local law enforcement officer designated by the Attorney General may—

(1) carry firearms;

(2) execute and serve search warrants, arrest warrants, administrative inspection warrants, sub-

poenas, and summonses issued under the authority of the United States;

(3) make arrests without warrant—

(A) for any offense against the United States committed in the officer's or employee's presence; or

(B) for any felony, cognizable under the laws of the United States, if the officer or employee has probable cause to believe that the person to be arrested has committed or is committing a felony;

(4) make seizures of property pursuant to the provisions of this division; and

(5) perform such other law enforcement duties as the Attorney General may designate.

(b) TREATMENT OF STATE AND LOCAL LAW ENFORCEMENT OFFICERS.—State and local law enforcement officers performing functions under this section shall not be deemed Federal employees and shall not be subject to provisions of law relating to Federal employees, except that the officers shall be subject to section 3374(c) of title 5.

**§ 50909. Search warrants**

A search warrant relating to offenses involving controlled substances may be served at any time of the day

or night if the judge or United States magistrate judge issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant and for its service at that time.

**§ 50910. Administrative inspections and warrants**

(a) DEFINITIONS.—In this section:

(1) CONTROLLED PREMISES.—The term ''controlled premises'' means—

(A) places in which original or other records or documents required under this division are kept or required to be kept; and

(B) places, including factories, warehouses, and other establishments, and conveyances, in which persons registered under section 50503 of this title (or exempt from registration under section 50502(d) of this title or by regulation of the Attorney General) or regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances or listed chemicals or in which records relating to those activities are maintained.

(2) PROBABLE CAUSE.—The term ''probable cause'' means a valid public interest in the effective enforcement of this division or regulations under this

division sufficient to justify administrative inspections of the area, premises, building, or conveyance, or contents of the premises, building, or conveyance, in the circumstances specified in the application for the warrant.

(b) GRANT OF AUTHORITY; SCOPE OF INSPECTIONS.—

(1) IN GENERAL.—For the purpose of inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under this division and otherwise facilitating the carrying out of the functions of the Attorney General under this division, the Attorney General may, in accordance with this section, enter controlled premises and conduct administrative inspections of the controlled premises, and of the things specified in this section, relevant to those functions.

(2) INSPECTORS.—

(A) DESIGNATION.—The entries and inspections under paragraph (1) shall be carried out through officers or employees (referred to in this subsection as ''inspectors'') designated by the Attorney General.

(B) CREDENTIALS; NOTICE OF INSPECTION AUTHORITY.—Any inspector under subparagraph (A) shall have the right to enter the controlled premises and conduct the inspection at reasonable times, on stating the inspector's purpose and presenting to the owner, operator, or agent in charge of the premises—

(i) appropriate credentials; and

(ii) a written notice of the inspector's inspection authority (which notice in the case of an inspection requiring, or in fact supported by, an administrative inspection warrant shall consist of the warrant).

(3) AUTHORITIES.—Except as may otherwise be indicated in an applicable inspection warrant, the inspector shall have the right—

(A) to inspect and copy records, reports, and other documents required to be kept or made under this division;

(B) to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs, listed chemicals, and other substances or materials, containers, and labeling found in the containers, and, except as provided

in paragraph (4), all other things in the controlled premises (including records, files, papers, processes, controls, and facilities) appropriate for verification of the records, reports, and documents referred to in subparagraph (A) or otherwise bearing on the provisions of this division; and

(C) to inventory any stock of any controlled substance or listed chemical in the controlled substance and obtain samples of any such substance or chemical.

(4) LIMITATION OF INSPECTION.—Except when the owner, operator, or agent in charge of the controlled premises consents in writing, an inspection authorized by this section shall not extend to—

(A) financial data;

(B) sales data other than shipment data; or

(C) pricing data.

(c) SITUATIONS NOT REQUIRING WARRANTS.—A warrant under this section shall not be required for the inspection of books and records pursuant to an administrative subpoena issued in accordance with section 50906 of this title, nor for entries and administrative inspections (including seizures of property)—

(1) with the consent of the owner, operator, or agent in charge of the controlled premises;

(2) in situations presenting imminent danger to health or safety;

(3) in situations involving inspection of conveyances, in which situation there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(4) in any other exceptional or emergency circumstance in which time or opportunity to apply for a warrant is lacking; or

(5) in any other situations in which a warrant is not constitutionally required.

(d) ADMINISTRATIVE INSPECTION WARRANTS.—Issuance and execution of administrative inspection warrants shall be as follows:

(1) IN GENERAL.—Any judge of the United States or of a State court of record, or any United States magistrate judge, may, within the judge's or magistrate judge's territorial jurisdiction, and on proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this division or regulations under this division, and seizures of property appropriate to the inspections.

(2) REQUIREMENTS FOR ISSUANCE.—

(A) IN GENERAL.—A warrant shall issue only on an affidavit of an officer or employee having knowledge of the facts alleged, sworn to before the judge or magistrate judge and establishing the grounds for issuing the warrant.

(B) SATISFACTION OF GROUNDS; IDENTIFICATION OF AREAS, PURPOSE, AND TYPE OF PROPERTY.—If the judge or magistrate judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist, the judge or magistrate judge shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected, if any.

(C) IDENTIFICATION OF ITEMS TO BE SEIZED.—The warrant shall identify the items or types of property to be seized, if any.

(D) OTHER CONTENTS.—The warrant shall be directed to a person authorized under subsection (b)(2) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support of the issuance. It

shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and, if appropriate, shall direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate judge to whom it shall be returned.

(3) MANNER OF EXECUTION.—

(A) PERIOD FOR EXECUTION.—A warrant issued pursuant to this section shall be executed and returned within 10 days of its date unless, on a showing by the United States of a need for additional time, the judge or magistrate judge allows additional time in the warrant.

(B) SEIZURE.—If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken.

(C) INVENTORY OF PROPERTY SEIZED.—The return of the warrant shall be made promptly and shall be accompanied by a written

inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least 1 credible person other than the person making the inventory, and shall be verified by the person executing the warrant. The judge or magistrate judge, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and the applicant for the warrant.

(4) ATTACHMENT TO WARRANT; FILING BY JUDGE OR MAGISTRATE.—The judge or magistrate judge who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection with the warrant and shall file them with the clerk of the district court of the United States for the judicial district in which the inspection was made.

**§ 50911. Forfeitures**

(a) SUBJECT PROPERTY.—The following shall be subject to forfeiture to the United States and no property right shall exist in them:

(1) All controlled substances that have been manufactured, distributed, dispensed, or acquired in violation of this division.

(2) All raw materials, products, and equipment of any kind that are used, or intended for use, in manufacturing, compounding, processing, delivering, importing, or exporting any controlled substance or listed chemical in violation of this division.

(3) All property that is used, or intended for use, as a container for property described in paragraph (1), (2), or (9).

(4) All conveyances, including aircraft, vehicles, or vessels, that are used, or are intended for use, to transport or in any manner to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1), (2), or (9).

(5) All books, records, and research, including formulas, microfilm, tapes, and data that are used, or intended for use, in violation of this division.

(6) All moneys, negotiable instruments, securities, or other things of value furnished or intended to be furnished by any person in exchange for a controlled substance or listed chemical in violation of this division, all proceeds traceable to such an exchange, and all moneys, negotiable instruments, and

securities used or intended to be used to facilitate any violation of this division.

(7) All real property, including any right, title, and interest (including any leasehold interest) in the whole of any lot or tract of land and any appurtenances or improvements, that is used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, a violation of this division punishable by more than 1 year's imprisonment.

(8) All controlled substances that have been possessed in violation of this division.

(9) All listed chemicals, all drug manufacturing equipment, all tableting machines, all encapsulating machines, and all gelatin capsules, that have been imported, exported, manufactured, possessed, distributed, dispensed, acquired, or intended to be distributed, dispensed, acquired, imported, or exported, in violation of this division or division B.

(10) Any drug paraphernalia (as defined in section 50723 of this title).

(11) Any firearm (as defined in section 921 of title 18) used or intended to be used to facilitate the transportation, sale, receipt, possession, or concealment of property described in paragraph (1) or (2) and any proceeds traceable to the property.

(b) SEIZURE PROCEDURES.—Any property subject to forfeiture to the United States under this section may be seized by the Attorney General in the manner set forth in section 981(b) of title 18.

(c) CUSTODY OF ATTORNEY GENERAL.—Property taken or detained under this section shall not be repleviable, but shall be deemed to be in the custody of the Attorney General, subject only to the orders and decrees of the court or the official having jurisdiction of the property. If property is seized under this division, the Attorney General may—

(1) place the property under seal;

(2) remove the property to a place designated by the Attorney General; or

(3) require that the General Services Administration take custody of the property and remove it, if practicable, to an appropriate location for disposition in accordance with law.

(d) OTHER LAWS AND PROCEEDINGS APPLICABLE.—

(1) IN GENERAL.—The provisions set forth in paragraph (2) shall apply to seizures and forfeitures incurred, or alleged to have been incurred, under any of the provisions of this division, to the extent

applicable and not inconsistent with the provisions of this section.

(2) PROVISIONS.—The provisions set forth in this paragraph are the provisions of law relating to—

(A) the seizure, summary and judicial forfeiture, and condemnation of property for violation of the customs laws;

(B) the disposition of the property or the proceeds from the sale of the property;

(C) the remission or mitigation of the forfeitures; and

(D) the compromise of claims.

(3) DUTIES.—Such duties as are imposed on the customs officer or any other person with respect to the seizure and forfeiture of property under the customs laws shall be performed with respect to seizures and forfeitures of property under this division by the officers, agents, or other persons as may be authorized or designated for that purpose by the Attorney General, except to the extent that the duties arise from seizures and forfeitures effected by any customs officer.

(e) DISPOSITION OF FORFEITED PROPERTY.—

(1) IN GENERAL.—If property is civilly or criminally forfeited under this division, the Attorney General may—

(A) retain the property for official use or, in the manner provided with respect to transfers under section 616 of the Tariff Act of 1930 (19 U.S.C. 1616a), transfer the property to any Federal agency or to any State or local law enforcement agency that participated directly in the seizure or forfeiture of the property;

(B) except as provided in paragraph (4), sell, by public sale or any other commercially feasible means, any forfeited property that is not required to be destroyed by law and that is not harmful to the public;

(C) require that the General Services Administration take custody of the property and dispose of it in accordance with law;

(D) forward it to the Drug Enforcement Administration for disposition (including delivery for medical or scientific use to any Federal or State agency under regulations of the Attorney General); or

(E) transfer the forfeited personal property or the proceeds of the sale of any forfeited personal or real property to any foreign country that participated directly or indirectly in the seizure or forfeiture of the property, if the transfer—

(i) has been agreed to by the Secretary of State;

(ii) is authorized in an international agreement between the United States and the foreign country; and

(iii) is made to a country that, if applicable, has been certified under section 490(b) of The Foreign Assistance Act of 1961 (22 U.S.C. 2291j(b)).

(2) PROCEEDS FROM SALE.—

(A) IN GENERAL.—

(i) USE.—The proceeds from any sale under paragraph (1)(B) and any moneys forfeited under this division shall be used to pay—

(I) all property expenses of the proceedings for forfeiture and sale including expenses of seizure, mainte-

nance of custody, advertising, and court costs; and

(II) awards of up to $100,000 to any individual who provides original information that leads to the arrest and conviction of a person that kills or kidnaps a Federal drug law enforcement agent.

(ii) AWARD TO BE PAID AT DISCRETION OF ATTORNEY GENERAL.—Any award paid for information concerning the killing or kidnapping of a Federal drug law enforcement agent, as provided in clause (i)(II), shall be paid at the discretion of the Attorney General.

(B) BALANCE TO BE DEPOSITED.—The Attorney General shall forward to the Secretary of the Treasury for deposit in accordance with section 524(c) of title 28, any amounts of the moneys and proceeds remaining after payment of the expenses provided in subparagraph (A), except that, with respect to forfeitures conducted by the Postal Service, the Postal Service shall deposit in the Postal Service Fund, under

section 2003(b)(7) of title 39, the moneys and proceeds.

(3) PROPERTY TRANSFERRED TO STATE OR LOCAL LAW ENFORCEMENT AGENCY.—The Attorney General shall ensure that any property transferred to a State or local law enforcement agency under paragraph (1)(A)—

(A) has a value that bears a reasonable relationship to the degree of direct participation of the State or local agency in the law enforcement effort resulting in the forfeiture, taking into account the total value of all property forfeited and the total law enforcement effort with respect to the violation of law on which the forfeiture is based; and

(B) will serve to encourage further cooperation between the recipient State or local agency and Federal law enforcement agencies.

(4) USE AS PUBLIC RECREATIONAL OR HISTORIC AREA BY STATES.—

(A) REQUEST.—With respect to real property described in subparagraph (B), if the chief executive officer of the State involved submits to the Attorney General a request for purposes of subparagraph (B), the authority established

in subparagraph (B) is in lieu of the authority established in paragraph (1)(B).

(B) CONDITIONS FOR TRANSFER.—In the case of property described in paragraph (1)(B) that is civilly or criminally forfeited under this division, if the property is real property that is appropriate for use as a public area reserved for recreational or historic purposes or for the preservation of natural conditions, the Attorney General, on the request of the chief executive officer of the State in which the property is located, may transfer title to the property to the State, either without charge or for a nominal charge, through a legal instrument providing that—

(i) the use will be the principal use of the property; and

(ii) title to the property reverts to the United States in the event that the property is used otherwise.

(f) FORFEITURE AND DESTRUCTION OF SCHEDULE I AND II SUBSTANCES.—

(1) FORFEITURE.—

(A) CONTRABAND ITEMS.—The following shall be deemed contraband and seized and summarily forfeited to the United States:

(i) All controlled substances in schedule I or II that are possessed, transferred, sold, or offered for sale in violation of the provisions of this division.

(ii) All dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2).

(iii) Any equipment or container subject to forfeiture under paragraph (2) or (3) of subsection (a) that cannot be separated safely from the raw materials or products.

(B) UNKNOWN OWNERS.—All substances in schedule I or II that are seized or come into the possession of the United States, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the United States.

(2) DESTRUCTION.—The Attorney General may direct the destruction of—

(A) all controlled substances in schedule I or II seized for violation of this division;

(B) all dangerous, toxic, or hazardous raw materials or products subject to forfeiture under subsection (a)(2); and

(C) any equipment or container subject to forfeiture under paragraph (2) or (3) of subsection (a) that cannot be separated safely from the raw materials or products under such circumstances as the Attorney General may consider necessary.

(g) PLANTS.—

(1) FORFEITURE.—All species of plants from which controlled substances in schedules I and II may be derived that have been planted or cultivated in violation of this division, or of which the owners or cultivators are unknown, or that are wild growths, may be seized and summarily forfeited to the United States.

(2) REGISTRATION.—The failure, upon demand by the Attorney General or an authorized agent of the Attorney General, of the person in occupancy or in control of land or premises on which the species of plants are growing or being stored, to produce an appropriate registration, or proof that the person is the holder of an appropriate registration, shall constitute authority for the seizure and forfeiture.

(3) ENTRY BY ATTORNEY GENERAL.—The Attorney General, or an authorized agent of the Attorney General, shall have authority to enter on any land, or into any dwelling pursuant to a search warrant, to cut, harvest, carry off, or destroy the plants.

(h) VESTING OF TITLE IN UNITED STATES.—All right, title, and interest in property described in subsection (a) shall vest in the United States on commission of the act giving rise to forfeiture under this section.

(i) STAY OF CIVIL FORFEITURE PROCEEDINGS.—The provisions of section 981(g) of title 18 regarding the stay of a civil forfeiture proceeding shall apply to forfeitures under this section.

(j) VENUE.—In addition to the venue provided for in section 1395 of title 28 or any other provision of law, in the case of property of a defendant charged with a violation that is the basis for forfeiture of the property under this section, a proceeding for forfeiture under this section may be brought in the judicial district in which the defendant owning the property is found or in the judicial district in which the criminal prosecution is brought.

(k) AGREEMENT BETWEEN ATTORNEY GENERAL AND POSTAL SERVICE FOR PERFORMANCE OF FUNCTIONS.—The functions of the Attorney General under this section shall be carried out by the Postal Service pursuant

to such agreement as may be entered into between the Attorney General and the Postal Service.

**§ 50912. Injunctions**

(a) JURISDICTION.—The district courts of the United States and all courts exercising general jurisdiction in the territories (including possessions) of the United States shall have jurisdiction in proceedings in accordance with the Federal Rules of Civil Procedure (28 U.S.C. App.) to enjoin violations of this division.

(b) JURY TRIAL.—In case of an alleged violation of an injunction or restraining order issued under this section, trial shall, on demand of the accused, be by a jury in accordance with the Federal Rules of Civil Procedure (28 U.S.C. App.).

(c) STATE CAUSE OF ACTION PERTAINING TO ONLINE PHARMACIES.—

(1) IN GENERAL.—In any case in which a State has reason to believe that an interest of the residents of that State has been or is being threatened or adversely affected by the action of a person, entity, or internet site that violates the provisions of section 50503(h), 50509(e), or 50512 of this title, the State may bring a civil action on behalf of the residents in a district court of the United States with appropriate jurisdiction—

(A) to enjoin the conduct that violates this section;

(B) to enforce compliance with this section;

(C) to obtain damages, restitution, or other compensation, including civil penalties under section 50702(b) of this title; and

(D) to obtain such other legal or equitable relief as the court may find appropriate.

(2) SERVICE; INTERVENTION.—

(A) SERVICE.—Prior to filing a complaint under paragraph (1), the State shall serve a copy of the complaint on the Attorney General and on the United States Attorney for the judicial district in which the complaint is to be filed. In any case in which the prior service is not feasible, the State shall serve the complaint on the Attorney General and the appropriate United States Attorney on the same day that the State's complaint is filed in Federal district court of the United States. The proceedings shall be independent of, and not in lieu of, criminal prosecutions or any other proceedings under this division or any other laws of the United States.

(B) INTERVENTION.—On receiving notice respecting a civil action pursuant to this section, the United States shall have the right to intervene in the action and, on intervening under this subparagraph, to be heard on all matters arising in the action, and to file petitions for appeal.

(C) FEDERAL RULES OF CIVIL PROCEDURE.—Service of a State's complaint on the United States as required in this paragraph shall be made in accordance with the requirements of rule 4(i)(1) of the Federal Rules of Civil Procedure (28 U.S.C. App.).

(3) POWERS CONFERRED BY STATE LAW.—For purposes of bringing any civil action under paragraph (1), nothing in this division prevents an attorney general of a State from exercising the powers conferred on the attorney general of a State by the laws of the State to conduct investigations or to administer oaths or affirmations or to compel the attendance of witnesses of or the production of documentary or other evidence.

(4) VENUE.—Any civil action brought under paragraph (1) in a district court of the United States may be brought in the district in which the

defendant is found, is an inhabitant, or transacts business or in which venue is proper under section 1391 of title 28. Process in the action may be served in any district in which the defendant is an inhabitant or in which the defendant may be found.

(5) NO PRIVATE RIGHT OF ACTION.—No private right of action is created under this subsection.

(6) LIMITATION.—A civil action shall not be brought under paragraph (1) against—

(A) the United States;

(B) an Indian tribe or tribal organization, to the extent the tribe or tribal organization is lawfully carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.); or

(C) any employee of the United States or the Indian tribe or tribal organization, provided the employee is acting in the usual course of business or employment, and within the scope of the official duties of the employee relating to the business or employment.

**§ 50913. Notice and opportunity to present views**

Before any violation of this division is reported by the Administrator of the Drug Enforcement Administra-

tion to any United States attorney for institution of a criminal proceeding, the Administrator may require that the person against whom the proceeding is contemplated is given appropriate notice and an opportunity to present the person's views, either orally or in writing, with regard to the contemplated proceeding.

**§ 50914. Immunity and privilege**

(a) REFUSAL TO TESTIFY.—

(1) IN GENERAL.—If a witness refuses, on the basis of the privilege of the witness against self-incrimination, to testify or provide other information in a proceeding before a court or grand jury of the United States, involving a violation of this division, and the person presiding over the proceeding communicates to the witness an order issued under this section, the witness may not refuse to comply with the order on the basis of the privilege of the witness against self-incrimination.

(2) CRIMINAL CASE AGAINST WITNESS.—Testimony or other information compelled under the order issued under subsection (b) and information obtained by the exploitation of the testimony or other information shall not be used against the witness in any criminal case, including any criminal case brought in a court of a State, except a prosecu-

tion for perjury, giving a false statement, or otherwise failing to comply with the order.

(b) ORDER OF UNITED STATES DISTRICT COURT.—In the case of any individual who has been or may be called to testify or provide other information at any proceeding before a court or grand jury of the United States, the United States district court for the judicial district in which the proceeding is or may be held shall issue, on the request of the United States attorney for the district, an order requiring the individual to give any testimony or provide any other information that the individual refuses to give or provide on the basis of the individual's privilege against self-incrimination.

(c) REQUEST BY UNITED STATES ATTORNEY.—A United States attorney may, with the approval of the Attorney General or the Deputy Attorney General, the Associate Attorney General, or any Assistant Attorney General designated by the Attorney General, request an order under subsection (b) when in the judgment of the United States attorney—

(1) the testimony or other information from the individual may be necessary to the public interest; and

(2) the individual has refused or is likely to refuse to testify or provide other information on the

basis of the privilege of the individual against self-incrimination.

**§ 50915. Burden of proof; liabilities**

(a) EXEMPTIONS AND EXCEPTIONS; PRESUMPTION IN SIMPLE POSSESSION OFFENSES.—

(1) IN GENERAL.—It shall not be necessary for the United States to negative any exemption or exception set forth in this division in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this division, and the burden of going forward with the evidence with respect to the exemption or exception shall be on the person claiming its benefit.

(2) LABEL AS EVIDENCE.—In the case of a person charged under section 50704(b) of this title with the possession of a controlled substance, any label identifying the substance for purposes of section 13103(a)(2) of this title shall be admissible in evidence and shall be prima facie evidence that the substance was obtained pursuant to a valid prescription from a practitioner while acting in the course of the practitioner's professional practice.

(b) REGISTRATION AND ORDER FORMS.—In the absence of proof that a person is the authorized holder of an appropriate registration or order form issued under

this division, the person shall be presumed not to be the holder of the registration or form, and the burden of going forward with the evidence with respect to the registration or form shall be on the person.

(c) USE OF VEHICLES, VESSELS, AND AIRCRAFT.—The burden of going forward with the evidence to establish that a vehicle, vessel, or aircraft used in connection with controlled substances in schedule I was used in accordance with the provisions of this division shall be on the persons engaged in the use.

(d) IMMUNITY OF FEDERAL, STATE, LOCAL AND OTHER OFFICIALS.—Except as provided in sections 2234 and 2235 of title 18, civil or criminal liability shall not be imposed by virtue of this division on any authorized Federal officer lawfully engaged in the enforcement of this division, or on any authorized officer of any State, territory (including any possession) of the United States, political subdivision of the State or territory (including any possession) of the United States, or the District of Columbia, who is lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

**§ 50916. Payments and advances**

(a) PAYMENT TO INFORMERS.—The Attorney General may pay any person, from funds appropriated for the

Drug Enforcement Administration, for information concerning a violation of this division, such sums as the Attorney General may consider appropriate, without reference to any moieties or rewards to which the person may otherwise be entitled by law.

(b) REIMBURSEMENT FOR PURCHASE OF CONTROLLED SUBSTANCES.—Moneys expended from appropriations of the Drug Enforcement Administration for purchase of controlled substances and subsequently recovered shall be reimbursed to the current appropriation for the Administration.

(c) ADVANCE OF FUNDS FOR ENFORCEMENT PURPOSES.—The Attorney General may direct the advance of funds by the Department of the Treasury in connection with the enforcement of this division.

(d) DRUG POLLUTION FUND.—

(1) ESTABLISHMENT.—There is established in the Treasury a trust fund to be known as the ''Drug Pollution Fund'' (referred to in this subsection as the ''Fund''), consisting of amounts appropriated or credited to the Fund under section 50701(b)(6) of this title.

(2) AMOUNTS APPROPRIATED.—There are appropriated to the Fund amounts equivalent to the fines imposed under section 50701(b)(6) of this title.

(3) AVAILABILITY.—Amounts in the Fund shall be available, as provided in appropriations Acts, for the purpose of making payments in accordance with paragraph (4) for the cleanup of certain pollution resulting from the actions referred to in section 50701(b)(6) of this title.

(4) PAYMENTS.—

(A) IN GENERAL.—The Secretary of the Treasury, after consultation with the Attorney General, shall make payments under paragraph (3), in such amounts as the Secretary of the Treasury determines appropriate, to the heads of executive agencies or departments that meet the requirements of subparagraph (B).

(B) APPLICATION BY AGENCIES.—In order to receive a payment under paragraph (3), the head of an executive agency or department shall submit an application in such form and containing such information as the Secretary of the Treasury shall by regulation require. The application shall contain a description of the fine imposed under section 50701(b)(6) of this title, the circumstances surrounding the imposition of the fine, and the type and severity of pollution

that resulted from the actions to which the fine applies.

(5) TREATMENT FOR PURPOSES OF THE INTERNAL REVENUE CODE.—For purposes of subchapter B of chapter 98 of the Internal Revenue Code of 1986 (26 U.S.C. 9601 et seq.), the Fund established under this subsection shall be treated in the same manner as a trust fund established under subchapter A of that chapter (26 U.S.C. 9501 et seq.).

**§ 50917. Coordination and consolidation of post-seizure administration**

The Attorney General and the Secretary of the Treasury shall take such action as may be necessary to develop and maintain a joint plan to coordinate and consolidate post-seizure administration of property seized under this division, division B, or provisions of the customs laws relating to controlled substances.

**§ 50918. Production control of controlled substances**

(a) DEFINITIONS.—In this section:

(1) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture.

(2) STATE.—The term ''State'' means each of the 50 States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, or the Northern Mariana Islands.

(b) PERSONS INELIGIBLE FOR FEDERAL AGRICULTURAL PROGRAM BENEFITS.—Notwithstanding any other provision of law, any person that is convicted under Federal or State law of planting, cultivation, growing, producing, harvesting, or storing a controlled substance in any crop year shall be ineligible for—

(1) as to any commodity produced during that crop year, and the 4 succeeding crop years, by the person—

(A) any price support or payment made available under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.), the Commodity Credit Corporation Charter Act (15 U.S.C. 714 et seq.), or any other Act;

(B) a farm storage facility loan made under section 4(h) of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b(h));

(C) crop insurance under the Federal Crop Insurance Act (7 U.S.C. 1501 et seq.);

(D) a disaster payment made under the Agricultural Act of 1949 (7 U.S.C. 1421 et seq.); or

(E) a loan made, insured, or guaranteed under the Consolidated Farm and Rural Development Act (7 U.S.C. 1921 et seq.) or any

other provision of law administered by the Farmers Home Administration; or

(2) a payment made under section 4 or 5 of the Commodity Credit Corporation Charter Act (15 U.S.C. 714b, 714c) for the storage of an agricultural commodity that is—

(A) produced during that crop year, or any of the 4 succeeding crop years, by the person; and

(B) acquired by the Commodity Credit Corporation.

(c) REGULATIONS.—The Secretary shall issue such regulations as the Secretary determines are necessary to carry out this section, including regulations that—

(1) define the term ''person'';

(2) govern the determination of persons that shall be ineligible for program benefits under this section; and

(3) protect the interests of tenants and sharecroppers.

**§ 50919. Review of Federal sales of chemicals usable to manufacture controlled substances**

A Federal agency may not sell from the stocks of the agency any chemical that, as determined by the Administrator of the Drug Enforcement Administration, could be

used in the manufacture of a controlled substance unless the Administrator certifies in writing to the head of the agency that there is no reasonable cause to believe that the sale of the chemical would result in the illegal manufacture of a controlled substance.

# Chapter 511—Miscellaneous

Sec.
51101. Effect of provisions.
51102. Preemption.
51103. Payment of tort claims.

## § 51101. Effect of provisions

(a) EFFECT ON SUBTITLE I OF THIS TITLE.—Nothing in this division, division B, and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236), except sections 51102 and 51103 of this title and part G of title II of the Act (Public Law 91–513, 84 Stat. 1281) and, to the extent of any inconsistency, sections 50507(e) and 50509 of this title, shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of subtitle I of this title.

(b) EFFECT OF CERTAIN PROVISIONS ON ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES.—Nothing in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Public Law 110–425, 122 Stat. 4820) or the amendments made by the Act shall

be construed as authorizing, prohibiting, or limiting the use of electronic prescriptions for controlled substances.

(c) EFFECT OF CERTAIN PROVISIONS ON SECTION 51102 OF THIS TITLE.—Section 711 of the Combat Methamphetamine Epidemic Act of 2005 (Public Law 109–177, 120 Stat. 256) and the amendments made by that section may not be construed as having any legal effect on section 51102 of this title as applied to the regulation of scheduled listed chemical products.

**§ 51102. Preemption**

No provision of this division shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter that would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this division and that State law so that the two cannot consistently stand together.

**§ 51103. Payment of tort claims**

Notwithstanding section 2680(k) of title 28, the Attorney General, in carrying out the functions of the Department of Justice under this division, may pay tort claims in the manner authorized by section 2672 of title 28, if the claims arise in a foreign country in connection

with the operations of the Drug Enforcement Administration abroad.

# Division B—Controlled Substances Import and Export

# Chapter 517—Importation and Exportation

Sec.
51701. Definitions.
51702. Importation of controlled substances.
51703. Exportation of controlled substances.
51704. Transshipment and in-transit shipment of controlled substances.
51705. Possession on board vessels.
51706. Exemption authority.
51707. Persons required to register.
51708. Registration requirements.
51709. Possession, manufacture, or distribution of controlled substance.
51710. Prohibited acts A.
51711. Foreign terrorist organizations and terrorist persons and groups.
51712. Prohibited acts B.
51713. Second or subsequent offenses.
51714. Attempt and conspiracy.
51715. Additional penalties.
51716. Applicability of chapter 509 of this title.
51717. Authority of Secretary of the Treasury.
51718. Criminal forfeitures.
51719. Notification, suspension of shipment, and penalties with respect to importation and exportation of listed chemicals.

## § 51701. Definitions

(a) IN GENERAL.—In this division:

(1) CUSTOMS TERRITORY OF THE UNITED STATES.—The term ''customs territory of the United States'' has the meaning given the term by general note 2 of the Harmonized Tariff Schedule of the United States.

(2) IMPORT.—The term ''import'' means, with respect to any article, any bringing in or introduc-

tion of the article into any area (whether the bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

(b) APPLICABILITY OF DEFINED TERMS IN SECTION 50101.—Each term defined in section 50101 of this title shall have the same meaning for purposes of this division as the term has for purposes of division A.

**§ 51702. Importation of controlled substances**

(a) CONTROLLED SUBSTANCES IN SCHEDULE I OR II AND NARCOTIC DRUGS IN SCHEDULE III, IV, OR V.—

(1) IN GENERAL.—It shall be unlawful to import into the customs territory of the United States from any place outside of the customs territory of the United States (but within the United States), or to import into the United States from any place outside of the United States, any controlled substance in schedule I or II of division A, any narcotic drug in schedule III, IV, or V of division A, or ephedrine, pseudoephedrine, or phenylpropanolamine, except as described in paragraph (2).

(2) EXCEPTION.—Notwithstanding paragraph (1), the following may be imported as described in paragraph (1) under such regulations as the Attorney General shall prescribe:

(A) Such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves, and of ephedrine, pseudoephedrine, and phenylpropanolamine, as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes.

(B) Such amounts of any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States—

(i) during an emergency in which domestic supplies of the substance or drug are found by the Attorney General to be inadequate;

(ii) in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 50503 of this title; or

(iii) in any case in which the Attorney General finds that the controlled substance

is in limited quantities exclusively for scientific, analytical, or research uses.

(3) CRUDE OPIUM.—No crude opium may be imported under this subsection for the purpose of manufacturing heroin or smoking opium.

(b) NONNARCOTIC CONTROLLED SUBSTANCES IN SCHEDULE III, IV, OR V.—It shall be unlawful to import into the customs territory of the United States from any place outside of the customs territory of the United States (but within the United States), or to import into the United States from any place outside of the United States, any nonnarcotic controlled substance in schedule III, IV, or V, unless the nonnarcotic controlled substance—

(1) is imported for medical, scientific, or other legitimate uses; and

(2) is imported pursuant to such notification, or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such import permit, notification, or declaration, as the Attorney General may by regulation prescribe, except that if a nonnarcotic controlled substance in schedule IV or V is also listed in schedule I or II of the Convention on Psychotropic Substances, it shall be imported pursuant to the import permit requirements, pre-

scribed by regulation of the Attorney General, as are required by the Convention.

(c) COCA LEAVES.—In addition to the amount of coca leaves authorized to be imported into the United States under subsection (a), the Attorney General may permit the importation of additional amounts of coca leaves. All cocaine and ecgonine (and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made) contained in the additional amounts of coca leaves imported under this subsection shall be destroyed under the supervision of an authorized representative of the Attorney General.

(d) APPLICATION FOR INCREASED IMPORTATION OF EPHEDRINE, PSEUDOEPHEDRINE, OR PHENYLPROPANOLAMINE.—

(1) IN GENERAL.—With respect to a registrant under section 51708 of this title that may, under subsection (a)(2)(A), import ephedrine, pseudoephedrine, or phenylpropanolamine, the registrant may apply, at any time during the year, for an increase in the amount of the chemical that the registrant may import, and the Attorney General may approve the application if the Attorney General determines that the approval is necessary to provide

for medical, scientific, or other legitimate purposes regarding the chemical.

(2) PROCEDURES.—With respect to the application under paragraph (1), the following shall apply:

(A) APPROVAL OR DENIAL.—Not later than 60 days after receiving the application, the Attorney General shall approve or deny the application.

(B) EFFECTIVE PERIOD OF APPROVAL.—In approving the application, the Attorney General shall specify the period of time for which the approval is in effect, or shall provide that the approval is effective until the registrant involved is notified in writing by the Attorney General that the approval is terminated.

(C) DEEMED APPROVED.—If the Attorney General does not approve or deny the application before the expiration of the 60-day period under subparagraph (A), the application is deemed to be approved, and the approval remains in effect until the Attorney General notifies the registrant in writing that the approval is terminated.

(e) REFERENCE TO EPHEDRINE, PSEUDOEPHEDRINE, OR PHENYLPROPANOLAMINE.—

Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of the chemical.

**§ 51703. Exportation of controlled substances**

(a) NARCOTIC DRUGS IN SCHEDULE I, II, III, OR IV.—It shall be unlawful to export from the United States any narcotic drug in schedule I, II, III, or IV unless—

(1) it is exported to a country that is a party to—

(A) the International Opium Convention of 1912 for the Suppression of the Abuses of Opium, Morphine, Cocaine, and Derivative Drugs, or to the International Opium Convention, signed at Geneva February 19, 1925;

(B) the Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, concluded at Geneva July 13, 1931, as amended by the protocol signed at Lake Success on December 11, 1946, and the protocol bringing under international control drugs outside the scope of the convention of July 13, 1931, for limiting the manufacture and regulating the distribution of narcotic drugs (as amended by the protocol signed at

Lake Success on December 11, 1946), signed at Paris November 19, 1948; or

(C) the Single Convention on Narcotic Drugs;

(2) the country has instituted and maintains, in conformity with the conventions to which it is a party, a system for the control of imports of narcotic drugs that the Attorney General considers adequate;

(3) the narcotic drug is consigned to a holder of such permits or licenses as may be required under the laws of the country of import, and a permit or license to import the drug has been issued by the country of import;

(4) substantial evidence is furnished to the Attorney General by the exporter that—

(A) the narcotic drug is to be applied exclusively to medical or scientific uses within the country of import; and

(B) there is an actual need for the narcotic drug for medical or scientific uses within the country; and

(5) a permit to export the narcotic drug in each instance has been issued by the Attorney General.

(b) EXCEPTION FOR EXPORTATION FOR SPECIAL SCIENTIFIC PURPOSES.—Notwithstanding subsection (a),

the Attorney General may authorize any narcotic drug (including crude opium and coca leaves) in schedule I, II, III, or IV to be exported from the United States to a country that is a party to any of the international instruments mentioned in subsection (a) if the particular drug is to be applied to a special scientific purpose in the country of destination and the authorities of the country will permit the importation of the particular drug for that purpose.

(c) NONNARCOTIC CONTROLLED SUBSTANCES IN SCHEDULE I OR II.—It shall be unlawful to export from the United States any nonnarcotic controlled substance in schedule I or II unless—

(1) it is exported to a country that has instituted and maintains a system that the Attorney General considers adequate for the control of imports of the substances;

(2) the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country of import;

(3) substantial evidence is furnished to the Attorney General that—

(A) the controlled substance is to be applied exclusively to medical, scientific, or other

legitimate uses within the country to which exported;

(B) it will not be exported from the country; and

(C) there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and

(4) a permit to export the controlled substance in each instance has been issued by the Attorney General.

(d) EXCEPTION FOR EXPORTATION FOR SPECIAL SCIENTIFIC PURPOSES.—Notwithstanding subsection (c), the Attorney General may authorize any nonnarcotic controlled substance in schedule I or II to be exported from the United States if the particular substance is to be applied to a special scientific purpose in the country of destination and the authorities of the country will permit the importation of the particular drug for that purpose.

(e) NONNARCOTIC CONTROLLED SUBSTANCES IN SCHEDULE III OR IV; CONTROLLED SUBSTANCES IN SCHEDULE V.—It shall be unlawful to export from the United States to any other country any nonnarcotic controlled substance in schedule III or IV or any controlled substances in schedule V unless—

(1) there is furnished (before export) to the Attorney General documentary proof that importation is not contrary to the laws or regulations of the country of destination for consumption for medical, scientific, or other legitimate purposes;

(2) it is exported pursuant to such notification or declaration, or in the case of any nonnarcotic controlled substance in schedule III, such export permit, notification, or declaration as the Attorney General may by regulation prescribe; and

(3) in the case of a nonnarcotic controlled substance in schedule IV or V that is also listed in schedule I or II of the Convention on Psychotropic Substances, it is exported pursuant to such export permit requirements, prescribed by regulation of the Attorney General, as are required by the Convention.

(f) EXCEPTION FOR EXPORTATION FOR SUBSEQUENT EXPORT.—Notwithstanding subsections (a)(4) and (c)(3), the Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met:

(1) Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the ''first country'') and the country to which the controlled substance is exported from the first country (referred to in this subsection as the ''second country'') are parties to the Single Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

(2) The first country and the second country have each instituted and maintain, in conformity with the Conventions, a system of controls of imports of controlled substances that the Attorney General considers adequate.

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of the country, and a permit or license to import the controlled substance has been issued by the country.

(4) With respect to the second country, substantial evidence is furnished to the Attorney General by the person that will export the controlled substance from the United States that—

(A) the controlled substance is to be consigned to a holder of such permits or licenses

as may be required under the laws of the country, and a permit or license to import the controlled substance is to be issued by the country; and

(B) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

(5)(A) The controlled substance will not be exported from the second country, except that the controlled substance may be exported from a second country that is a member of the European Economic Area to another country that is a member of the European Economic Area, provided that the first country is also a member of the European Economic Area.

(B) Subsequent to any reexportation described in subparagraph (A), a controlled substance may continue to be exported from any country that is a member of the European Economic Area to any other such country, if—

(i) the conditions applicable with respect to the first country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country from which the controlled substance is exported pursuant to this paragraph; and

(ii) the conditions applicable with respect to the second country under paragraphs (1), (2), (3), (4), (6), and (7) are met by each subsequent country to which the controlled substance is exported pursuant to this paragraph.

(6)(A) Within 30 days after the controlled substance is exported from the first country to the second country, the person that exported the controlled substance from the United States delivers to the Attorney General documentation certifying that the export from the first country has occurred.

(B) In the case of reexportation among members of the European Economic Area, within 30 days after each reexportation, the person that exported the controlled substance from the United States delivers to the Attorney General—

(i) documentation certifying that the reexportation has occurred; and

(ii) information concerning the consignee, country, and product.

(7) A permit to export the controlled substance from the United States has been issued by the Attorney General.

(g) LIMITATION.—Subject to paragraphs (5) and (6) of subsection (f) in the case of any controlled substance

in schedule I or II or any narcotic drug in schedule III or IV, the Attorney General shall not promulgate nor enforce any regulation, subregulatory guidance, or enforcement policy that impedes reexportation of any controlled substance among European Economic Area countries, including by promulgating or enforcing any requirement that—

(1) reexportation from the first country to the second country or reexportation from the second country to another country occur within a specified period of time; or

(2) information concerning the consignee, country, and product be provided prior to exportation of the controlled substance from the United States or prior to each reexportation among members of the European Economic Area.

**§ 51704. Transshipment and in-transit shipment of controlled substances**

(a) CONTROLLED SUBSTANCES IN SCHEDULE I.—

(1) IN GENERAL.—Notwithstanding sections 51702, 51703, and 51707 of this title, if the conditions in paragraph (2) are met, a controlled substance in schedule I may—

(A) be imported into the United States for transshipment to another country; or

(B) be transferred or transshipped from 1 vessel, vehicle, or aircraft to another vessel, vehicle, or aircraft within the United States for immediate exportation.

(2) CONDITIONS.—The importation, transfer, or transshipment under paragraph (1) may be made only if the controlled substance under paragraph (1) is imported, transferred, or transshipped—

(A) for scientific, medical, or other legitimate purposes in the country of destination; and

(B) with the prior written approval of the Attorney General (which shall be granted or denied within 21 days of the request).

(b) CONTROLLED SUBSTANCES IN SCHEDULE II, III, OR IV.—A controlled substance in schedule II, III, or IV may be imported, transferred, or transshipped as described in subsection (a) only if advance notice is given to the Attorney General in accordance with regulations of the Attorney General.

**§ 51705. Possession on board vessels**

It shall be unlawful for any person to bring or possess on board any vessel or aircraft, or on board any vehicle of a carrier, arriving in or departing from the United States or the customs territory of the United States, a

controlled substance in schedule I or II or a narcotic drug in schedule III or IV, unless the substance or drug is a part of the cargo entered in the manifest or part of the official supplies of the vessel, aircraft, or vehicle.

**§ 51706. Exemption authority**

(a) INDIVIDUAL POSSESSING CONTROLLED SUBSTANCE.—

(1) IN GENERAL.—Subject to paragraph (2), the Attorney General may by regulation exempt from subsections (a) and (b) of section 51702 of this title and from sections 51703, 51704, and 51705 of this title any individual who has a controlled substance (except a substance in schedule I) in the individual's possession for the individual's personal medical use, or for administration to an animal accompanying the individual, if the individual lawfully obtained the substance and the individual makes such declaration (or gives such other notification) as the Attorney General may by regulation require.

(2) NO VALID PRESCRIPTION.—

(A) IN GENERAL.—Notwithstanding any exemption under paragraph (1), a United States resident who enters the United States through an international land border with a controlled substance (except a substance in

schedule I) for which the individual does not possess a valid prescription issued by a practitioner in accordance with applicable Federal and State law (or documentation that verifies the issuance of such a prescription to that individual) may not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.

(B) MINIMUM FEDERAL REQUIREMENT.—Subparagraph (A) is a minimum Federal requirement and shall not be construed to limit a State from imposing any additional requirement.

(C) EFFECT OF SUBPARAGRAPH (A).—Subparagraph (A) shall not be construed to affect the jurisdiction of the Secretary under subtitle I of this title.

(b) COMPOUND, MIXTURE, OR PREPARATION.—The Attorney General may by regulation except any compound, mixture, or preparation containing any depressant or stimulant substance listed in subparagraph (A) or (B) of section 50302(c)(3) of this title (which relates to schedule III), in section 50302(c)(4) of this title (which relates to schedule IV), or in section 50302(c)(5) of this title (which

relates to schedule V) from the application of all or any part of this division if—

(1) the compound, mixture, or preparation contains 1 or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system; and

(2) the ingredients are included in the compound, mixture, or preparation in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances that do have a depressant or stimulant effect on the central nervous system.

**§ 51707. Persons required to register**

(a) COVERAGE.—Unless there is in effect with respect to a person a registration issued by the Attorney General under section 51708 of this title, or unless the person is exempt from registration under subsection (b), the person shall not—

(1) import into the customs territory of the United States from any place outside of the customs territory of the United States (but within the United States), or import into the United States from any place outside of the United States, any controlled substance or list I chemical; or

(2) export from the United States any controlled substance or list I chemical.

(b) EXEMPTIONS.—

(1) PERSONS.—The following persons shall not be required to register under this section and may lawfully possess a controlled substance or list I chemical:

(A) An agent or an employee of any importer or exporter registered under section 51708 of this title if the agent or employee is acting in the usual course of the agent's or employee's business or employment.

(B) A common or contract carrier or warehouseman, or an employee of the carrier or warehouseman, whose possession of any controlled substance or list I chemical is in the usual course of the carrier's, warehouseman's, or employee's business or employment.

(C) An ultimate user who possesses the substance for a purpose specified in section 50101(61) of this title and in conformity with an exemption granted under section 51706(a) of this title.

(2) WAIVER.—The Attorney General may, by regulation, waive the requirement for registration of

certain importers and exporters if the Attorney General finds it consistent with the public health and safety, and may authorize any such importer or exporter to possess controlled substances or list I chemicals for purposes of importation and exportation.

**§ 51708. Registration requirements**

(a) APPLICANTS TO IMPORT OR EXPORT CONTROLLED SUBSTANCES IN SCHEDULE I OR II.—

(1) IN GENERAL.—The Attorney General shall register an applicant to import or export a controlled substance in schedule I or II if the Attorney General determines that the registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

(2) FACTORS.—In determining the public interest under subparagraph (A), the factors enumerated in paragraphs (1) through (6) of section 50503(b) of this title shall be considered.

(b) ACTIVITY LIMITED TO SPECIFIED SUBSTANCES.—Registration granted under this section shall not entitle a registrant to import or export controlled substances other than specified in the registration.

(c) OTHER APPLICANTS.—

(1) APPLICANTS TO IMPORT CONTROLLED SUBSTANCES IN SCHEDULE III, IV, OR V OR TO EXPORT CONTROLLED SUBSTANCES IN SCHEDULE III OR IV.—

(A) IN GENERAL.—The Attorney General shall register an applicant to import a controlled substance in schedule III, IV, or V or to export a controlled substance in schedule III or IV, unless the Attorney General determines that the issuance of the registration is inconsistent with the public interest.

(B) FACTORS.—In determining the public interest under subparagraph (A), the factors enumerated in paragraphs (1) through (6) of section 50503(f) of this title shall be considered.

(2) APPLICANTS TO IMPORT OR EXPORT LIST I CHEMICALS.—

(A) IN GENERAL.—The Attorney General shall register an applicant to import or export a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the import or export of a drug product that

is exempted under section 50101(50)(B)(iv) of this title.

(B) FACTORS.—In determining the public interest under subparagraph (A), the Attorney General shall consider the factors specified in section 50503(j) of this title.

(d) DENIAL OF APPLICATION.—

(1) DENIAL OF SUBSECTION (a) APPLICATION.—The Attorney General may deny an application for registration under subsection (a) if the Attorney General is unable to determine that the registration is consistent with the public interest (as described in subsection (a)) and with the United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971.

(2) DENIAL OF SUBSECTION (c) APPLICATION; REVOCATION OR SUSPENSION OF SUBSECTIONS (a) AND (c) REGISTRATIONS.—The Attorney General may deny an application for registration under subsection (c), or revoke or suspend a registration under subsection (a) or (c), if the Attorney General determines that the registration is inconsistent with the public interest (as described in subsection (a) or (c)) or with the United States obligations under

international treaties, conventions, or protocols in effect on May 1, 1971.

(3) LIMITATION OF REVOCATION OR SUSPENSION.—The Attorney General may limit the revocation or suspension of a registration to the particular controlled substance, or substances, or list I chemical or chemicals, with respect to which grounds for revocation or suspension exist.

(4) ORDER TO SHOW CAUSE; PROCEEDINGS TO DENY, REVOKE, OR SUSPEND.—

(A) ORDER TO SHOW CAUSE.—Before taking action pursuant to this subsection, the Attorney General shall serve on the applicant or registrant an order to show cause as to why the registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis of the order and shall call on the applicant or registrant to appear before the Attorney General, or the designee of the Attorney General, at a time and place stated in the order, but not less than 30 days after the date of receipt of the order.

(B) PROCEEDINGS TO DENY, REVOKE, OR SUSPEND.—Proceedings to deny, revoke, or suspend shall be conducted pursuant to this sub-

section in accordance with subchapter II of chapter 5 of title 5. The proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this division or any other law of the United States.

(5) SUSPENSION OF REGISTRATION AND INSTITUTION OF PROCEEDINGS.—The Attorney General may, in the discretion of the Attorney General, suspend any registration simultaneously with the institution of proceedings under this subsection, in cases in which the Attorney General finds that there is an imminent danger to the public health and safety. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review of the proceedings, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(6) SEIZURE AND FORFEITURE.—

(A) IN GENERAL.—In the event that the Attorney General suspends or revokes a registration granted under this section, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to the registration at the time of suspension or the effective date of the revocation order, as the case

may be, may, in the discretion of the Attorney General, be seized or placed under seal.

(B) DISPOSITION.—A disposition shall not be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded, except that a court, on application for sale, may at any time order the sale of perishable controlled substances or list I chemicals. The order shall require the deposit of the proceeds of the sale with the court.

(C) FORFEITURE.—On a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of the sale under subparagraph (B) that have been deposited with the court) shall be forfeited to the United States, and the Attorney General shall dispose of the controlled substances or list I chemicals in accordance with section 50911(e) of this title.

(e) REGISTRATION PERIOD.—No registration shall be issued under this division for a period in excess of 1 year. Unless the regulations of the Attorney General otherwise provide, sections 50502(f), 50505, 50507, and 50511 of this title shall apply to persons registered under this sec-

tion to the same extent the sections apply to persons registered under section 50503 of this title.

(f) RULES AND REGULATIONS.—The Attorney General may promulgate rules and regulations and charge reasonable fees relating to the registration and control of importers and exporters of controlled substances or listed chemicals.

(g) SCOPE OF AUTHORIZED ACTIVITY.—Persons registered by the Attorney General under this section to import or export controlled substances or list I chemicals may import or export (and for the purpose of the importing or exporting, may possess) the substances or chemicals to the extent authorized by their registration and in conformity with the other provisions of this division and division A.

(h) SEPARATE REGISTRATIONS FOR EACH PRINCIPAL PLACE OF BUSINESS.—A separate registration shall be required at each principal place of business in which the applicant imports or exports controlled substances or list I chemicals.

(i) HEARING FOR BULK MANUFACTURERS.—Except in emergency situations as described in section 51702(a)(2)(B)(i) of this title, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in schedule I or II, and prior to issuing

a regulation under section 51702(a) of this title authorizing the importation of the substance, the Attorney General shall give manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

**§ 51709. Possession, manufacture, or distribution of controlled substance**

(a) MANUFACTURE OR DISTRIBUTION FOR PURPOSE OF UNLAWFUL IMPORTATION.—It shall be unlawful for any person to manufacture or distribute a controlled substance in schedule I or II or flunitrazepam or a listed chemical intending, knowing, or having reasonable cause to believe that the substance or chemical will be unlawfully imported into the United States or into waters within a distance of 12 miles of the coast of the United States.

(b) MANUFACTURE OR DISTRIBUTION OF LISTED CHEMICAL FOR PURPOSE OF MANUFACTURE OR UNLAWFUL IMPORTATION OF CONTROLLED SUBSTANCE.—It shall be unlawful for any person to manufacture or distribute a listed chemical—

(1) intending or knowing that the listed chemical will be used to manufacture a controlled substance; and

(2) intending, knowing, or having reasonable cause to believe that the controlled substance will be unlawfully imported into the United States.

(c) POSSESSION, MANUFACTURE, OR DISTRIBUTION BY PERSON ON BOARD AIRCRAFT.—It shall be unlawful for any United States citizen on board any aircraft, or any person on board an aircraft owned by a United States citizen or registered in the United States, to—

(1) manufacture or distribute a controlled substance or listed chemical; or

(2) possess a controlled substance or listed chemical with intent to distribute.

(d) ACTS COMMITTED OUTSIDE TERRITORIAL JURISDICTION OF UNITED STATES.—This section is intended to reach acts of manufacture or distribution committed outside the territorial jurisdiction of the United States.

**§ 51710. Prohibited acts A**

(a) UNLAWFUL ACTS.—A person shall be punished as provided in subsection (b) if the person—

(1) contrary to section 50505, 51702, 51703, or 51707 of this title, knowingly or intentionally imports or exports a controlled substance;

(2) contrary to section 51705 of this title, knowingly or intentionally brings or possesses on

board a vessel, aircraft, or vehicle a controlled substance; or

(3) contrary to section 51709 of this title, manufactures, possesses with intent to distribute, or distributes a controlled substance.

(b) PENALTIES.—

(1) SPECIFIED SUBSTANCES.—

(A) QUANTITIES.—A person shall be sentenced as described in subparagraph (B) in the case of the person's violation of subsection (a) involving—

(i) 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation that contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 280 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-

piperidinyl] propanamide or a fentanyl-related substance;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(viii) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

(B) PENALTIES.—A person committing a violation described in subparagraph (A) shall be sentenced to a term of imprisonment of not less than 10 years and not more than life and if death or serious bodily injury results from the use of the substance shall be sentenced to a term of imprisonment of not less than 20 years and not more than life, fined not to exceed the greater of that authorized in accordance with the provisions of title 18 or $10,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both.

(C) PRIOR CONVICTION; DEATH OR SERIOUS BODILY INJURY.—If any person commits

such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, the person shall be sentenced to a term of imprisonment of not less than 15 years and not more than life imprisonment and if death or serious bodily injury results from the use of the substance shall be sentenced to life imprisonment, fined not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $20,000,000 if the defendant is an individual or $75,000,000 if the defendant is other than an individual, or both.

(D) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any sentence under this paragraph shall, in the absence a prior conviction described in subparagraph (C), impose a term of supervised release of at least 5 years in addition to the term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to the term of imprisonment.

(E) PROBATION; SUSPENSION OF SENTENCE.—Notwithstanding any other provision of law, the court shall not place on probation or

suspend the sentence of any person sentenced under this paragraph.

(F) PAROLE.—A person sentenced under this paragraph shall not be eligible for parole during the term of imprisonment imposed in the sentence.

(2) SPECIFIED SUBSTANCES IN LESSER QUANTITIES.—

(A) QUANTITIES.—A person shall be sentenced as described in subparagraph (B) in the case of the person's violation of subsection (a) involving—

(i) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) 500 grams or more of a mixture or substance containing a detectable amount of—

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts or isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation that contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 28 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing

a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or a fentanyl-related substance;

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana; or

(viii) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers.

(B) PENALTIES.—A person committing a violation described in subparagraph (A) shall be sentenced to a term of imprisonment of not less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of the substance shall be sentenced to a term of imprisonment of not less than 20 years and not more than life, fined not to exceed the greater of that authorized in accordance with the provisions of title 18 or $5,000,000 if the defendant is an individual or

$25,000,000 if the defendant is other than an individual, or both.

(C) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a serious drug felony or serious violent felony has become final, the person shall be sentenced to a term of imprisonment of not less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of the substance shall be sentenced to life imprisonment, fined not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $8,000,000 if the defendant is an individual or $50,000,000 if the defendant is other than an individual, or both.

(D) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any sentence imposed under this paragraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to the term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to the term of imprisonment.

(E) PROBATION; SUSPENSION OF SENTENCE.—Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this paragraph.

(F) PAROLE.—A person sentenced under this paragraph shall not be eligible for parole during the term of imprisonment imposed in the sentence.

(3) CONTROLLED SUBSTANCE IN SCHEDULE I OR II; GAMMA HYDROXYBUTYRIC ACID; FLUNITRAZEPAM.—

(A) IN GENERAL.—In the case of a violation under subsection (a) involving a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 61302(2) of this title), or flunitrazepam, the person committing the violation shall, except as provided in paragraphs (1), (2), and (4), be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of the substance shall be sentenced to a term of imprisonment of not less than 20 years and not more than life,

fined not to exceed the greater of that authorized in accordance with the provisions of title 18 or $1,000,000 if the defendant is an individual or $5,000,000 if the defendant is other than an individual, or both.

(B) PRIOR CONVICTION.—If any person commits such a violation after a prior conviction for a felony drug offense has become final, the person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of the substance shall be sentenced to life imprisonment, fined not to exceed the greater of twice that authorized in accordance with the provisions of title 18 or $2,000,000 if the defendant is an individual or $10,000,000 if the defendant is other than an individual, or both.

(C) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any sentence imposing a term of imprisonment under this paragraph shall, in the absence of a prior conviction under subparagraph (B), impose a term of supervised release of at least 3 years in addition to the term of imprisonment and shall, if there was such a prior conviction, impose a

term of supervised release of at least 6 years in addition to the term of imprisonment.

(D) PROBATION; SUSPENSION OF SENTENCE.—Notwithstanding subparagraph (C), and notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this paragraph which provide for a mandatory term of imprisonment if death or serious bodily injury results.

(4) MARIHUANA; HASHISH.—In the case of a violation under subsection (a) with respect to less than 50 kilograms of marihuana, except in the case of 100 or more marihuana plants regardless of weight, less than 10 kilograms of hashish, or less than 1 kilogram of hashish oil, the person committing the violation shall be sentenced in accordance with section 50701(b)(1)(D) of this title.

(5) CONTROLLED SUBSTANCE IN SCHEDULE III.—In the case of a violation of subsection (a) involving a controlled substance in schedule III, the person shall be sentenced in accordance with section 50701(b)(1) of this title.

(6) CONTROLLED SUBSTANCE IN SCHEDULE IV.—In the case of a violation of subsection (a) in-

volving a controlled substance in schedule IV, the person shall be sentenced in accordance with section 50701(b)(2) of this title.

(7) CONTROLLED SUBSTANCE IN SCHEDULE V.—In the case of a violation of subsection (a) involving a controlled substance in schedule V, the person shall be sentenced in accordance with section 50701(b)(3) of this title.

(c) PENALTY FOR IMPORTATION OR EXPORTATION.—A person shall be fined in accordance with title 18, imprisoned not more than 20 years in the case of a violation of paragraph (1) or (3) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (3) involving a list I chemical, or both, if the person knowingly or intentionally—

(1) imports or exports a listed chemical with intent to manufacture a controlled substance in violation of this division or division A;

(2) exports a listed chemical in violation of the laws of the country to which the chemical is exported or serves as a broker or trader for an international transaction involving a listed chemical, if the transaction is in violation of the laws of the country to which the chemical is exported;

(3) imports or exports a listed chemical knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of this division or division A;

(4) exports a listed chemical, or serves as a broker or trader for an international transaction involving a listed chemical, knowing, or having reasonable cause to believe, that the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported;

(5) imports or exports a listed chemical, with the intent to evade the reporting or recordkeeping requirements of section 51719 of this title applicable to the importation or exportation by falsely representing to the Attorney General that the importation or exportation qualifies for a waiver of the 15-day notification requirement granted pursuant to paragraph (2) or (3) of section 51719(f) of this title by misrepresenting the actual country of final destination of the listed chemical or the actual listed chemical being imported or exported;

(6) imports a listed chemical in violation of section 51702 of this title, imports or exports such a chemical in violation of section 51707 or 51719 of

this title, or transfers such a chemical in violation of section 51719(d) of this title; or

(7) manufactures, possesses with intent to distribute, or distributes a listed chemical in violation of section 51709 of this title.

**§ 51711. Foreign terrorist organizations and terrorist persons and groups**

(a) DEFINITION OF ANYTHING OF PECUNIARY VALUE.—In this section, the term ''anything of pecuniary value'' has the meaning given the term in section 1958(b)(1) of title 18.

(b) PROHIBITED ACTS.—

(1) IN GENERAL.—Whoever engages in conduct that would be punishable under section 50701(a) of this title if committed within the jurisdiction of the United States, or attempts or conspires to do so, knowing or intending to provide, directly or indirectly, anything of pecuniary value to any person or organization that has engaged or engages in terrorist activity (as defined in section 212(a)(3)(B) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(3)(B))) or terrorism (as defined in section 140(d)(2) of the Foreign Relations Authorization Act, Fiscal Years 1988 and 1989 (22 U.S.C. 2656f(d)(2))), shall be sentenced to a term of im-

prisonment of not less than twice the minimum punishment under section 50701(b)(1) of this title, and not more than life, fined in accordance with the provisions of title 18, or both.

(2) SUPERVISED RELEASE.—Notwithstanding section 3583 of title 18, any sentence imposed under this subsection shall include a term of supervised release of at least 5 years in addition to the term of imprisonment.

(c) JURISDICTION.—There is jurisdiction over an offense under this section if—

(1) the prohibited drug activity or the terrorist offense is in violation of the criminal laws of the United States;

(2) the offense, the prohibited drug activity, or the terrorist offense occurs in or affects interstate or foreign commerce;

(3) an offender provides anything of pecuniary value for a terrorist offense that causes or is designed to cause death or serious bodily injury to a national of the United States while that national is outside the United States, or substantial damage to the property of a legal entity organized under the laws of the United States (including any of its States, districts, commonwealths, territories, or pos-

sessions) while that property is outside of the United States;

(4) the offense or the prohibited drug activity occurs in whole or in part outside of the United States (including on the high seas), and a perpetrator of the offense or the prohibited drug activity is a national of the United States or a legal entity organized under the laws of the United States (including any of its States, districts, commonwealths, territories, or possessions); or

(5) after the conduct required for the offense occurs, an offender is brought into or found in the United States, even if the conduct required for the offense occurs outside the United States.

(d) PROOF REQUIREMENTS.—To violate subsection (b), a person must have knowledge that the person or organization has engaged or engages in terrorist activity (as defined in section 212(a)(3)(B) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(3)(B))) or terrorism (as defined in section 140(d)(2) of the Foreign Relations Authorization Act, Fiscal Years 1988 and 1989 (22 U.S.C. 2656f(d)(2))).

**§ 51712. Prohibited acts B**

Any person that violates section 51704 of this title or fails to notify the Attorney General of an importation

or exportation under section 51719 of this title shall be subject to the following penalties:

(1) CIVIL PENALTIES.—Except as provided in paragraph (2), any such person shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. Paragraphs (1) and (3) of section 50702(d) of this title shall apply to any civil penalty assessed under this paragraph.

(2) CRIMINAL PENALTIES.—If such a violation is prosecuted by an information or indictment that alleges that the violation was committed knowingly or intentionally and the trier of fact specifically finds that the violation was so committed, the person shall be sentenced to imprisonment for not more than 1 year, fined under title 18, or both.

**§ 51713. Second or subsequent offenses**

(a) TERM OF IMPRISONMENT AND FINE.—

(1) IN GENERAL.—Any person convicted of any offense under this division is, if the offense is a second or subsequent offense, punishable by a term of imprisonment twice that otherwise authorized, by twice the fine otherwise authorized, or by both.

(2) CERTAIN OFFENSES.—If the conviction is for an offense punishable under section 51710(b) of this title, and if it is the offender's second or subse-

quent offense, the court shall impose, in addition to any term of imprisonment and fine, twice the term of supervised release otherwise authorized.

(b) DETERMINATION OF STATUS.—For purposes of this section, a person shall be considered convicted of a second or subsequent offense if, prior to the commission of the offense, 1 or more prior convictions of the person for a felony drug offense have become final.

(c) PROCEDURES APPLICABLE.—Section 50711 of this title shall apply with respect to any proceeding to sentence a person under this section.

**§ 51714. Attempt and conspiracy**

Any person that attempts or conspires to commit any offense defined in this division shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

**§ 51715. Additional penalties**

Any penalty imposed for violation of this division shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

**§ 51716. Applicability of chapter 509 of this title**

(a) IN GENERAL.—Chapter 509 of this title shall apply with respect to functions of the Attorney General (and of officers and employees of the Drug Enforcement Administration) under this division, to administrative and

judicial proceedings under this division, and to violations of this division, to the same extent that the chapter applies to functions of the Attorney General (and the officers and employees) under division A, to the proceedings under division A, and to violations of division A.

(b) REFERENCES.—For purposes of the application of this section to section 50910 or 50911 of this title, any reference in section 50910 or 50911 of this title to ''this division'' shall be deemed to be a reference to this division, any reference to section 50503 of this title shall be deemed to be a reference to section 51708 of this title, and any reference to section 50502(d) of this title shall be deemed to be a reference to section 51707(b)(2) of this title.

**§ 51717. Authority of Secretary of the Treasury**

Nothing in this division and division A shall derogate from the authority of the Secretary of the Treasury under the customs and related laws.

**§ 51718. Criminal forfeitures**

Section 50713 of this title, relating to criminal forfeitures, shall apply in every respect to a violation of this division punishable by imprisonment for more than 1 year.

**§ 51719. Notification, suspension of shipment, and penalties with respect to importation and exportation of listed chemicals**

(a) NOTIFICATION PRIOR TO TRANSACTION.—Each regulated person that imports or exports a listed chemical shall notify the Attorney General of the importation or exportation not later than 15 days before the transaction is to take place.

(b) REGULAR CUSTOMERS OR IMPORTERS.—

(1) INAPPLICABILITY OF REQUIREMENT.—

(A) IN GENERAL.—The Attorney General shall provide by regulation for circumstances in which the requirement of subsection (a) does not apply to a transaction between a regulated person and a regular customer or to a transaction that is an importation by a regular importer.

(B) WHEN NOTIFICATION IS REQUIRED.—At the time of any importation or exportation constituting a transaction referred to in subparagraph (A), the regulated person shall notify the Attorney General of the transaction.

(2) QUALIFICATION AS REGULAR CUSTOMER OR REGULAR IMPORTER.—The regulations under this subsection shall provide that the initial notification under subsection (a) with respect to a customer of

a regulated person or to an importer shall, on the expiration of the 15-day period, qualify the customer as a regular customer or the importer as a regular importer, unless the Attorney General otherwise notifies the regulated person in writing.

(c) SUSPENSION OF IMPORTATION OR EXPORTATION; DISQUALIFICATION OF REGULAR CUSTOMERS OR IMPORTERS.—

(1) IN GENERAL.—

(A) ORDER.—The Attorney General may order the suspension of any importation or exportation of a listed chemical (other than a regulated transaction to which the requirement of subsection (a) does not apply by reason of subsection (b)) or may disqualify any regular customer or regular importer on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred).

(B) EFFECT OF WRITTEN NOTICE OF ORDER.—From and after the time when the Attorney General provides written notice of the

order (including a statement of the legal and factual basis for the order) to the regulated person, the regulated person may not carry out the transaction.

(2) HEARING.—On written request to the Attorney General, a regulated person to whom an order applies under paragraph (1) is entitled to an agency hearing on the record in accordance with subchapter II of chapter 5 of title 5. The hearing shall be held on an expedited basis and not later than 45 days after the request is made, except that the hearing may be held at a later time, if requested by the regulated person.

(d) INFORMATION REQUIRED IN NOTICE.—

(1) DEFINITIONS.—In this subsection:

(A) EXPORTER.—The term ''exporter'' means a regulated person that exports a listed chemical.

(B) IMPORTER.—The term ''importer'' means a regulated person that imports a listed chemical.

(C) TRANSFER.—The term ''transfer'', with respect to a listed chemical, includes the sale of the chemical.

(D) TRANSFEREE.—The term ''transferee'' means a person to whom an importer or exporter transfers a listed chemical.

(2) IN GENERAL.—

(A) NAME OF TRANSFEREE; QUANTITY.—Information provided in a notice under subsection (a) or (b) shall include the name of the person to whom the importer or exporter involved intends to transfer the listed chemical involved, and the quantity of the chemical to be transferred.

(B) DATE OF TRANSFER.—In the case of a notice under subsection (b) submitted by a regular importer, if the transferee identified in the notice is not a regular customer, the importer may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the notice is submitted to the Attorney General.

(C) UPDATE FOR CHANGE OF CIRCUMSTANCES.—

(i) IN GENERAL.—After a notice under subsection (a) or (b) is submitted to the Attorney General, if circumstances change and the importer or exporter will

not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the importer or exporter shall update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to the Attorney General, except that the 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer.

(ii) SUBSEQUENT UPDATES.—Clause (i) applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as clause (i) applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under subsection (a) or (b).

(D) EXPIRATION OF 15-DAY PERIOD.—In the case of a transfer of a listed chemical that is subject to a 15-day restriction under subparagraph (B) or (C), the transferee involved shall, on the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Attorney General otherwise notifies the importer or exporter involved in writing.

(3) SUSPENSION; DISQUALIFICATION.—With respect to a transfer of a listed chemical with which a notice or update referred to in paragraph (2) is concerned:

(A) IN GENERAL.—The Attorney General, in accordance with the same procedures as apply under subsection (c)(2)—

(i) may order the suspension of the transfer of the listed chemical by the importer or exporter involved, except for a transfer to a regular customer, on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk

chemicals to be transferred), subject to the Attorney General ordering the suspension before the expiration of the 15-day period referred to in paragraph (2) with respect to the importation or exportation (in any case in which such a period applies); and

(ii) may, for purposes of clause (i) and paragraph (2), disqualify a regular customer on the ground described in clause (i).

(B) EFFECT OF WRITTEN NOTICE OF ORDER.—From and after the time when the Attorney General provides written notice of the order under subparagraph (A) (including a statement of the legal and factual basis for the order) to the importer or exporter, the importer or exporter may not carry out the transfer.

(e) BROKER OR TRADER FOR INTERNATIONAL TRANSACTION IN LISTED CHEMICAL.—A person located in the United States that is a broker or trader for an international transaction in a listed chemical that is a regulated transaction solely because of that person's involvement as a broker or trader shall, with respect to that transaction, be subject to all of the notification, reporting,

recordkeeping, and other requirements placed on exporters of listed chemicals by this division and division A.

(f) APPLICABILITY OF NOTIFICATION REQUIREMENT TO EXPORTS OF LISTED CHEMICAL.—

(1) COUNTRY-WIDE.—The Attorney General may by regulation require that the 15-day notification requirement of subsection (a) apply to all exports of a listed chemical to a specified country, regardless of the status of certain customers in the country as regular customers, if the Attorney General finds that the notification is necessary to support effective chemical diversion control programs or is required by treaty or other international agreement to which the United States is a party.

(2) WAIVER FOR EXPORTS.—The Attorney General may by regulation waive the 15-day notification requirement for exports of a listed chemical to a specified country if the Attorney General determines that the notification is not required for effective chemical diversion control. If the notification requirement is waived, exporters of the listed chemical shall be required to submit to the Attorney General reports of individual exportations or periodic reports of the exportation of the listed chemical, at such

time or times and containing such information as the Attorney General shall establish by regulation.

(3) WAIVER FOR IMPORTS.—The Attorney General may by regulation waive the 15-day notification requirement for the importation of a listed chemical if the Attorney General determines that the notification is not necessary for effective chemical diversion control. If the notification requirement is waived, importers of the listed chemical shall be required to submit to the Attorney General reports of individual importations or periodic reports of the importation of the listed chemical, at such time or times and containing such information as the Attorney General shall establish by regulation.

(g) RETURN DECLARATION.—

(1) IN GENERAL.—Within 30 days after a transaction covered by this section is completed, the importer or exporter shall send the Attorney General a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and such other information as the Attorney General may specify in regulations.

(2) IMPORTERS.—For importers, a single return declaration may include the particulars of both

the importation and distribution. If the importer has not distributed all chemicals imported by the end of the initial 30-day period, the importer shall file supplemental return declarations no later than 30 days from the date of any further distribution, until the distribution or other disposition of all chemicals imported pursuant to the import notification or any update is accounted for.

(h) IMPORTATION AND DISTRIBUTION OF EPHEDRINE, PSEUDOEPHEDRINE, OR PHENYLPROPANOLAMINE.—

(1) IN GENERAL.—With respect to a regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine (referred to in this section as an ''importer''), a notice of importation under subsection (a) or (b) shall include all information known to the importer on the chain of distribution of the chemical from the manufacturer to the importer.

(2) FOREIGN-CHAIN DISTRIBUTORS.—For the purpose of preventing or responding to the diversion of ephedrine, pseudoephedrine, or phenylpropanolamine for use in the illicit production of methamphetamine, the Attorney General may, in the case of any person that is a manufacturer or distributor of the chemical in the chain of distribution referred to in

paragraph (1) (which person is referred to in this subsection as a ''foreign-chain distributor''), request that the foreign-chain distributor provide to the Attorney General information known to the foreign-chain distributor on the distribution of the chemical, including sales.

(3) REFUSAL TO COOPERATE BY FOREIGN-CHAIN DISTRIBUTOR.—

(A) IN GENERAL.—If the Attorney General determines that a foreign-chain distributor is refusing to cooperate with the Attorney General in obtaining the information referred to in paragraph (2), the Attorney General may, in accordance with procedures that apply under subsection (c), issue an order prohibiting the importation of ephedrine, pseudoephedrine, or phenylpropanolamine in any case in which the foreign-chain distributor is part of the chain of distribution for the chemical.

(B) PUBLICATION OF ORDER.—Not later than 60 days prior to issuing the order, the Attorney General shall publish in the Federal Register a notice of intent to issue the order.

(C) RESTRICTION NOT APPLICABLE DURING 60-DAY PERIOD.—During the 60-day pe-

riod, imports of the chemical with respect to the foreign-chain distributor may not be restricted under this paragraph.

(i) EXCEPTION FOR IODINE.—

(1) IN GENERAL.—Iodine shall not be subject to the requirements for listed chemicals provided in this section.

(2) EFFECT OF EXCEPTION.—The exception made by paragraph (1) shall not limit the authority of the Attorney General to impose the requirements for listed chemicals provided in this section.

# Subtitle VI—Drug Control and Enforcement

# Chapter 601—Smuggling of Controlled Substances

Sec.
60101. Smuggling of controlled substances; investigations.
60102. Service of subpoena.
60103. Contempt proceedings.

## § 60101. Smuggling of controlled substances; investigations

(a) IN GENERAL.—For the purpose of any investigation that, in the opinion of the Secretary of the Treasury, is necessary and proper to the enforcement of section 545 of title 18 with respect to any controlled substance, the Secretary of the Treasury may administer oaths and affirmations, subpoena witnesses, compel their attendance,

take evidence, and require the production of records (including books, papers, documents, and tangible things that constitute or contain evidence) relevant or material to the investigation.

(b) JURISDICTION; LIMITATION.—The attendance of witnesses and the production of records may be required from any place within the customs territory of the United States, except that a witness shall not be required to appear at any hearing distant more than 100 miles from the place where the witness was served with a subpoena.

(c) PAYMENTS TO WITNESSES.—Witnesses summoned by the Secretary shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

(d) OATHS AND AFFIRMATIONS.—Oaths and affirmations may be made at any place subject to the jurisdiction of the United States.

**§ 60102. Service of subpoena**

(a) IN GENERAL.—A subpoena of the Secretary of the Treasury may be served by any person designated in the subpoena to serve it.

(b) NATURAL PERSONS.—Service on a natural person may be made by personal delivery of the subpoena to the natural person.

(c) OTHER ENTITIES.—Service may be made on a domestic or foreign corporation or on a partnership or other unincorporated association that is subject to suit under a common name, by delivering the subpoena to an officer, a managing or general agent, or any other agent authorized by appointment or by law to receive service of process.

(d) AFFIDAVIT.—The affidavit of the person serving the subpoena entered on a true copy of the subpoena by the person serving it shall be proof of service.

**§ 60103. Contempt proceedings**

(a) CONTUMACY.—In case of contumacy by, or refusal to obey a subpoena issued to, any person, the Secretary of the Treasury may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, carries on business, or may be found, to compel compliance with the subpoena of the Secretary of the Treasury.

(b) COURT ORDER.—The court may issue an order requiring the subpoenaed person to appear before the Secretary of the Treasury to produce records, if so ordered, or to give testimony relating to the matter under investigation.

(c) CONTEMPT.—Any failure to obey the order of the court may be punished by the court as a contempt of

court. All process in any such case may be served in the judicial district in which the subpoenaed person is an inhabitant or in which the person may be found.

# Chapter 603—Drug Abuse Prevention, Treatment, and Rehabilitation

Sec.
60301. Congressional declaration of national policy.
60302. Notice relating to the control of dangerous drugs.
60303. Drug abuse prevention function appropriations.
60304. Special project grants and contracts.
60305. Records and audit.
60306. Contract authority.

## § 60301. Congressional declaration of national policy

(a) GENERAL POLICY AND PURPOSE; GOALS.—Congress declares that it is the policy of the United States and the purpose of this chapter—

(1) to focus the comprehensive resources of the Federal Government and bring them to bear on drug abuse with the objective of significantly reducing the incidence, as well as the social and personal costs, of drug abuse in the United States; and

(2) to develop and ensure the implementation of a comprehensive, coordinated long-term Federal strategy to combat drug abuse.

(b) SPECIFIC POLICY AND PURPOSE.—To reach the goals in subsection (a), Congress further declares that it is the policy of the United States and the purpose of this chapter to meet the problems of drug abuse through—

(1) comprehensive Federal, State, and local planning for, and effective use of, Federal assistance to States and to community-based programs to meet the urgent needs of special populations, in coordination with all other governmental and nongovernmental sources of assistance;

(2) the development and support of community-based prevention programs;

(3) the development and encouragement of effective occupational prevention and treatment programs within the Government and in cooperation with the private sector; and

(4) increased Federal commitment to research into the behavioral and biomedical etiology of, the treatment of, and the mental and physical health and social and economic consequences of, drug abuse.

**§ 60302. Notice relating to the control of dangerous drugs**

(a) IN GENERAL.—The Attorney General shall, prior to initiating any proceeding under section 50301(a) of this title, give the President timely notice of the determination described in this section, whenever the Attorney General determines that there is evidence that—

(1) a drug or other substance, which is not a controlled substance (as defined in section 50101 of this title), has a potential for abuse; or

(2) a controlled substance should be transferred or removed from a schedule under section 50302 of this title.

(b) INFORMATION FORWARDED TO ATTORNEY GENERAL.—Information forwarded to the Attorney General pursuant to section 50301(f) of this title shall also be forwarded by the Secretary of Health and Human Services to the President.

**§ 60303. Drug abuse prevention function appropriations**

Any request for appropriations by a Federal agency shall specify—

(1) on a line item basis, that part of the appropriations that the Federal agency is requesting to carry out its drug abuse prevention functions; and

(2) the authorization of the appropriations requested to carry out each of its drug abuse prevention functions.

**§ 60304. Special project grants and contracts**

(a) SCOPE OF PROGRAMS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the

''Secretary''), acting through the National Institute on Drug Abuse, may make grants to and enter into contracts with individuals and public and private nonprofit entities—

(A) to provide training seminars, educational programs, and technical assistance for the development, demonstration, and evaluation of drug abuse prevention, treatment, and rehabilitation programs; and

(B) to conduct demonstration and evaluation projects, with a high priority on prevention and early intervention projects and on identifying new and more effective drug abuse prevention, treatment, and rehabilitation programs.

(2) PRIORITY.—

(A) IN GENERAL.—In the implementation of the Secretary's authority under this section, the Secretary shall accord a high priority to applications for grants or contracts for primary prevention programs.

(B) PRIMARY PREVENTION PROGRAMS.—For purposes of subparagraph (A), primary prevention programs include programs designed to discourage persons from beginning drug abuse.

(3) FUNDING NOT LIMITED TO OPIATE ABUSE.—To the extent that appropriations authorized under this section are used to fund treatment services, the Secretary shall not limit the funding to treatment for opiate abuse, but shall also provide support for treatment for non-opiate drug abuse including polydrug abuse.

(4) FUNDING FOR ALCOHOL ABUSE.—Nothing shall prevent the use of funds provided under this section for programs and projects aimed at the prevention, treatment, and rehabilitation of alcohol abuse and alcoholism as well as drug abuse.

(b) COORDINATION OF APPLICATIONS FOR PROGRAMS IN A STATE.—

(1) IN GENERAL.—In carrying out this section, the Secretary shall require coordination of all applications for programs in a State and shall not give precedence to public agencies over private agencies, institutions, and organizations, or to State agencies over local agencies.

(2) EVALUATION BY STATE AGENCY.—

(A) SUBMISSION FOR REVIEW TO STATE AGENCY.—Each applicant within a State, on filing the applicant's application with the Secretary for a grant or contract under this sec-

tion, shall submit a copy of its application for review by the State agency (if any) responsible for the administration of drug abuse prevention activities.

(B) REVIEW PERIOD.—The State agency shall be given not more than 30 days from the date of receipt of the application to submit to the Secretary, in writing, an evaluation of the project set forth in the application.

(C) REQUIRED EVALUATION COMMENTS.—The evaluation shall include comments on the relationship of the project to other projects pending and approved and to any State comprehensive plan for treatment and prevention of drug abuse.

(D) COPY OF EVALUATION TO BE FURNISHED TO APPLICANT.—The State shall furnish the applicant a copy of the evaluation.

(E) WAIVER.—A State, if it desires, may, in writing, waive its rights under this paragraph.

(3) CRITERIA FOR APPROVAL.—Approval of any application for a grant or contract under this section by the Secretary, including the earmarking of financial assistance for a program or project, may be

granted only if the application substantially meets a set of criteria that—

(A) provide that the activities and services for which assistance under this section is sought will be substantially administered by or under the supervision of the applicant;

(B) provide for such methods of administration as are necessary for the proper and efficient operation of the programs or projects; and

(C) provide for such fiscal control and fund accounting procedures as may be necessary to ensure proper disbursement of and accounting for Federal funds paid to the applicant.

(4) PROPOSED PERFORMANCE STANDARDS OR RESEARCH PROTOCOL.—Each applicant within a State, on filing the applicant's application with the Secretary for a grant or contract to provide treatment or rehabilitation services shall provide a proposed performance standard or standards, to measure, or research protocol to determine, the effectiveness of the treatment or rehabilitation program or project.

(c) PROGRAMS AND PROJECTS AIMED AT UNDERSERVED GROUPS.—The Secretary shall encourage the

submission of and give special consideration to applications under this section to programs and projects aimed at underserved populations such as racial and ethnic minorities, Native Americans (including Native Hawaiians and Native American Pacific Islanders), youth, the elderly, women, disabled individuals, and families of drug abusers.

(d) PAYMENTS.—Payment under grants or contracts under this section may be made in advance or by way of reimbursement and in such installments as the Secretary may determine.

(e) PREVENTION AND TREATMENT SERVICES.—Projects and programs for which grants and contracts are made or entered into under this section shall, in the case of prevention and treatment services, seek to—

(1) be responsive to special requirements of disabled individuals in receiving the services;

(2) whenever possible, be community-based, ensure care of good quality in general community care facilities and under health insurance plans, and be integrated with, and provide for the active participation of, a wide range of public and nongovernmental agencies, organizations, institutions, and individuals;

(3) where a substantial number of the individuals in the population served by the project or program are of limited English-speaking ability—

(A) utilize the services of outreach workers fluent in the language spoken by a predominant number of the individuals and develop a plan and make arrangements responsive to the needs of the population for providing services to the extent practicable in the language and cultural context most appropriate to the individuals; and

(B) identify an individual who is fluent both in that language and English and whose responsibilities shall include providing guidance to the individuals of limited English-speaking ability and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences; and

(4) if appropriate, utilize existing community resources (including community mental health centers).

(f) AUTHORIZATION BY CHIEF EXECUTIVE OFFICER OF STATE REQUIRED.—

(1) IN GENERAL.—A grant shall not be made under this section to a State or to any entity within the government of a State unless the grant application has been authorized by the chief executive officer of the State.

(2) MAXIMUM AMOUNT AND DURATION OF GRANTS.—A grant or contract shall not be made under this section for a period in excess of 5 years.

(3) AMOUNT LIMITATION PER FISCAL YEAR.—The amount of any grant or contract under this section may not exceed 100 percent of the cost of carrying out the grant or contract in the first fiscal year for which the grant or contract is made under this section, 80 percent of the cost in the second fiscal year for which the grant or contract is made under this section, 70 percent of the cost in the third fiscal year for which the grant or contract is made under this section, and 60 percent of the cost in each of the fourth and fifth fiscal years for which the grant or contract is made under this section.

**§ 60305. Records and audit**

(a) ASSISTANCE RECORDS; CONTENTS.—Each recipient of assistance under section 60304 of this title pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep—

(1) such records as the Secretary of Health and Human Services shall prescribe, including records that fully disclose—

(A) the amount and disposition by the recipient of the proceeds of the grant or contract;

(B) the total cost of the project or undertaking in connection with which the grant or contract is given or used; and

(C) the amount of that portion of the cost of the project or undertaking supplied by other sources; and

(2) such other records as will facilitate an effective audit.

(b) ACCESS TO PERTINENT INFORMATION FOR AUDIT AND EXAMINATION.—The Secretary of Health and Human Services and Comptroller General, or any of their authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts.

**§ 60306. Contract authority**

The authority of the Secretary of Health and Human Services to enter into contracts under section 60304 of this title shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

# Chapter 605—Drug Free Communities

**Subchapter I—General Provisions**

Sec.
60501. Definitions.
60502. Purposes.
60503. Authorization of appropriations.

**Subchapter II—Drug-Free Communities Support Program**

60511. Establishment of drug-free communities support program.
60512. Program authorization.
60513. Information collection and dissemination with respect to grant recipients.
60514. Technical assistance and training.
60515. Supplemental grants for coalition mentoring activities.

# Subchapter I—General Provisions

## § 60501. Definitions

In this chapter:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator appointed by the Director under section 60511(c) of this title.

(2) COMMUNITY.—The term ''community'' has the meaning given the term by the Administrator.

(3) DIRECTOR.—The term ''Director'' means the Director of National Drug Control Policy.

(4) ELIGIBLE COALITION.—The term ''eligible coalition'' means a coalition that meets the applicable criteria under section 60512(a) of this title.

(5) GRANT RECIPIENT.—The term ''grant recipient'' means the recipient of a grant award under section 60512 of this title.

(6) NONPROFIT ORGANIZATION.—The term ''nonprofit organization'' means an organization described under section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) that is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

(7) PROGRAM.—The term ''Program'' means the program established under section 60511(a) of this title.

(8) SUBSTANCE USE AND MISUSE.—The term ''substance use and misuse'' means—

(A) the illegal use or misuse of drugs, including substances for which a listing is in effect under any of schedules I through V under section 50302 of this title;

(B) the misuse of inhalants or over-the-counter drugs; or

(C) the use of alcohol, tobacco, or other related product as the use is prohibited by State or local law.

(9) YOUTH.—The term ''youth'' has the meaning given the term by the Administrator.

**§ 60502. Purposes**

The purposes of this chapter are—

(1) to reduce substance use and misuse among youth in communities throughout the United States, and over time, to reduce substance use and misuse among adults;

(2) to strengthen collaboration among communities, the Federal Government, and State, local, and tribal governments;

(3) to enhance intergovernmental cooperation and coordination on the issue of substance use and misuse among youth;

(4) to serve as a catalyst for increased citizen participation and greater collaboration among all sectors and organizations of a community that first demonstrates a long-term commitment to reducing substance use and misuse among youth;

(5) to rechannel resources from the fiscal year 1998 Federal drug control budget to provide technical assistance, guidance, and financial support to communities that demonstrate a long-term commitment in reducing substance use and misuse among youth;

(6) to disseminate to communities timely information regarding the state-of-the-art practices and initiatives that have proven to be effective in reducing substance use and misuse among youth;

(7) to enhance, not supplant, local community initiatives for reducing substance use and misuse among youth; and

(8) to encourage the creation of and support for community anti-drug coalitions throughout the United States.

**§ 60503. Authorization of appropriations**

(a) IN GENERAL.—There is authorized to be appropriated to the Office of National Drug Control Policy to carry out this chapter $99,000,000 for each of fiscal years 2018 through 2023.

(b) ADMINISTRATIVE COSTS.—Not more than 8 percent of the funds appropriated to carry out this chapter may be used by the Office of National Drug Control Policy to pay administrative costs associated with the responsibilities of the Office under this chapter.

# Subchapter II—Drug-Free Communities Support Program

**§ 60511. Establishment of drug-free communities support program**

(a) ESTABLISHMENT.—The Director shall establish a program to support communities in the development and implementation of comprehensive, long-term plans and programs to prevent and treat substance use and misuse among youth.

(b) PROGRAM.—In carrying out the Program, the Director shall—

(1) make and track grants to grant recipients;

(2) provide for technical assistance and training, data collection, and dissemination of information on state-of-the-art practices that the Director

determines to be effective in reducing substance use and misuse; and

(3) provide for the general administration of the Program.

(c) ADMINISTRATION.—The Director shall appoint an Administrator to carry out the Program.

(d) CONTRACTING.—The Director may employ any necessary staff and may enter into contracts or agreements with national drug control agencies, including interagency agreements to delegate authority for the execution of grants and for such other activities necessary to carry out this chapter.

**§ 60512. Program authorization**

(a) GRANT ELIGIBILITY.—To be eligible to receive an initial grant or a renewal grant under this subchapter, a coalition shall meet each of the following criteria:

(1) APPLICATION.—The coalition shall submit an application to the Administrator in accordance with section 60513(a)(2) of this title.

(2) MAJOR SECTOR INVOLVEMENT.—

(A) IN GENERAL.—The coalition shall consist of 1 or more representatives of each of the following categories:

(i) Youth.

(ii) Parents.

(iii) Businesses.

(iv) The media.

(v) Schools.

(vi) Organizations serving youth.

(vii) Law enforcement.

(viii) Religious or fraternal organizations.

(ix) Civic and volunteer groups.

(x) Health care professionals.

(xi) State, local, or tribal governmental agencies with expertise in the field of substance use and misuse (including, if applicable, the State authority with primary authority for substance use and misuse).

(xii) Other organizations involved in reducing substance use and misuse.

(B) ELECTED OFFICIALS.—If feasible, in addition to representatives from the categories listed in subparagraph (A), the coalition shall have an elected official (or a representative of an elected official) from—

(i) the Federal Government; and

(ii) the government of the appropriate State and political subdivision of the State

or the governing body or an Indian tribe (as that term is defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e))).

(C) REPRESENTATION.—An individual who is a member of the coalition may serve on the coalition as a representative of not more than 1 category listed under subparagraph (A).

(3) COMMITMENT.—The coalition shall demonstrate, to the satisfaction of the Administrator—

(A) that the representatives of the coalition have worked together on substance use and misuse reduction initiatives, that, at a minimum, includes initiatives that target drugs referenced in section 60501(8)(A) of this title, for a period of not less than 6 months, acting through entities such as task forces, subcommittees, or community boards; and

(B) substantial participation from volunteer leaders in the community involved (especially in cooperation with individuals involved with youth such as parents, teachers, coaches, youth workers, and members of the clergy).

(4) MISSION AND STRATEGIES.—The coalition shall, with respect to the community involved—

(A) have as its principal mission the reduction of substance use and misuse, which, at a minimum, includes the use and abuse of drugs referenced in section 60501(8)(A) of this title, in a comprehensive and long-term manner, with a primary focus on youth in the community;

(B) describe and document the nature and extent of the substance use and misuse problem, which, at a minimum, includes the use and abuse of drugs referenced in section 60501(8)(A) of this title, in the community;

(C)(i) provide a description of substance use and misuse prevention and treatment programs and activities, which, at a minimum, includes programs and activities relating to the use and abuse of drugs referenced in section 60501(8)(A) of this title, in existence at the time of the grant application; and

(ii) identify substance use and misuse programs and service gaps, which, at a minimum, includes programs and gaps relating to the use and abuse of drugs referenced in section 60501(8)(A) of this title, in the community;

(D) develop a strategic plan to reduce substance use and misuse among youth, which, at a minimum, includes the use and abuse of drugs referenced in section 60501(8)(A) of this title, in a comprehensive and long-term fashion; and

(E) work to develop a consensus regarding the priorities of the community to combat substance use and misuse among youth, which, at a minimum, includes the use and abuse of drugs referenced in section 60501(8)(A) of this title.

(5) SUSTAINABILITY.—The coalition shall demonstrate that the coalition is an ongoing concern by demonstrating that the coalition—

(A) is—

(i)(I) a nonprofit organization; or

(II) an entity that the Administrator determines to be appropriate; or

(ii) part of, or is associated with, an established legal entity;

(B) receives financial support (including, in the discretion of the Administrator, in-kind contributions) from non-Federal sources; and

(C) has a strategy to solicit substantial financial support from non-Federal sources to ensure that the coalition and the programs operated by the coalition are self-sustaining.

(6) ACCOUNTABILITY.—The coalition shall—

(A) establish a system to measure and report outcomes—

(i) consistent with common indicators and evaluation protocols established by the Administrator; and

(ii) approved by the Administrator;

(B) conduct—

(i) for an initial grant under this subchapter, an initial benchmark survey of drug use among youth (or use local surveys or performance measures available or accessible in the community at the time of the grant application); and

(ii) biennial surveys (or incorporate local surveys in existence at the time of the evaluation) to measure the progress and effectiveness of the coalition; and

(C) provide assurances that the entity conducting an evaluation under this paragraph, or

from which the coalition receives information, has experience—

(i) in gathering data related to substance use and misuse among youth; or

(ii) in evaluating the effectiveness of community anti-drug coalitions.

(7) ADDITIONAL CRITERIA.—The Director shall not impose any eligibility criteria on new applicants or renewal grantees not provided in this chapter.

(b) GRANT AMOUNTS.—

(1) IN GENERAL.—

(A) GRANTS.—

(i) IN GENERAL.—Subject to clause (iv), for a fiscal year, the Administrator may grant to an eligible coalition under this paragraph, an amount not to exceed the amount of non-Federal funds raised by the coalition, including in-kind contributions, for that fiscal year.

(ii) SUSPENSION OF GRANTS.—If the grant recipient fails to continue to meet the criteria specified in subsection (a), the Administrator may suspend the grant, after providing written notice to the grant recipient and an opportunity to appeal.

(iii) RENEWAL GRANTS.—Subject to clause (iv), the Administrator may award a renewal grant to a grant recipient under this subparagraph for each fiscal year following the fiscal year for which an initial grant is awarded, in an amount not to exceed the amount of non-Federal funds raised by the coalition, including in-kind contributions, for that fiscal year, during the 4-year period following the period of the initial grant.

(iv) LIMITATION.—The amount of a grant award under this subparagraph may not exceed $125,000 for a fiscal year.

(B) COALITION AWARDS.—

(i) IN GENERAL.—Except as provided in clause (ii), the Administrator may, with respect to a community, make a grant to 1 eligible coalition that represents that community.

(ii) EXCEPTION.—The Administrator may make a grant to more than 1 eligible coalition that represents a community if—

(I) the eligible coalitions demonstrate that the coalitions are collaborating with one another; and

(II) each of the coalitions has independently met the requirements set forth in subsection (a).

(2) RURAL COALITION GRANTS.—

(A) IN GENERAL.—

(i) AUTHORITY; WAIVER.—In addition to awarding grants under paragraph (1), to stimulate the development of coalitions in sparsely populated and rural areas, the Administrator may award a grant in accordance with this section to a coalition that represents a county with a population that does not exceed 30,000 individuals. In awarding a grant under this paragraph, the Administrator may waive any requirement under subsection (a) if the Administrator considers that waiver to be appropriate.

(ii) MATCHING REQUIREMENT.—Subject to subparagraph (C), for a fiscal year, the Administrator may grant to an eligible coalition under this paragraph, an amount

not to exceed the amount of non-Federal funds raised by the coalition, including in-kind contributions, for that fiscal year.

(iii) SUSPENSION OF GRANTS.—If the grant recipient fails to continue to meet any criteria specified in subsection (a) that has not been waived by the Administrator pursuant to clause (i), the Administrator may suspend the grant, after providing written notice to the grant recipient and an opportunity to appeal.

(B) RENEWAL GRANTS.—The Administrator may award a renewal grant to an eligible coalition that is a grant recipient under this paragraph for each fiscal year following the fiscal year for which an initial grant is awarded, in an amount not to exceed the amount of non-Federal funds raised by the coalition, including in-kind contributions, during the 4-year period following the period of the initial grant.

(C) LIMITATIONS.—

(i) AMOUNT.—The amount of a grant award under this paragraph shall not exceed $125,000 for a fiscal year.

(ii) AWARDS.—With respect to a county referred to in subparagraph (A), the Administrator may award a grant under this section to not more than 1 eligible coalition that represents the county.

(3) ADDITIONAL GRANTS.—

(A) IN GENERAL.—Subject to subparagraph (F), the Administrator may award an additional grant under this paragraph to an eligible coalition awarded a grant under paragraph (1) or (2) for any first fiscal year after the end of the 4-year period following the period of the initial grant under paragraph (1) or (2), as the case may be.

(B) SCOPE OF GRANTS.—A coalition awarded a grant under paragraph (1) or (2), including a renewal grant under the paragraph, may not be awarded another grant under the paragraph, and is eligible for an additional grant under this section only under this paragraph.

(C) NO PRIORITY FOR APPLICATIONS.—The Administrator may not afford a higher priority in the award of an additional grant under this paragraph than the Administrator would

afford the applicant for the grant if the applicant were submitting an application for an initial grant under paragraph (1) or (2) rather than an application for a grant under this paragraph.

(D) RENEWAL GRANTS.—Subject to subparagraph (F), the Administrator may award a renewal grant to a grant recipient under this paragraph for each fiscal year of the 4-fiscal-year period following the first fiscal year for which the initial additional grant is awarded in an amount not to exceed the following:

(i) For the first and second fiscal years of the 4-fiscal-year period, the amount of the non-Federal funds, including in-kind contributions, raised by the coalition for the applicable fiscal year is not less than 125 percent of the amount awarded.

(ii) For the third and fourth fiscal years of the 4-fiscal-year period, the amount of the non-Federal funds, including in-kind contributions, raised by the coalition for the applicable fiscal year is not

less than 150 percent of the amount awarded.

(E) SUSPENSION.—If a grant recipient under this paragraph fails to continue to meet the criteria specified in subsection (a), the Administrator may suspend the grant, after providing written notice to the grant recipient and an opportunity to appeal.

(F) LIMITATION.—The amount of a grant award under this paragraph may not exceed $125,000 for a fiscal year.

(4) PROCESS FOR SUSPENSION.—A grantee shall not be suspended or terminated under paragraph (1)(A)(ii), (2)(A)(iii), or (3)(E) unless that grantee is afforded a fair, timely, and independent appeal prior to the suspension or termination.

(c) TREATMENT OF FUNDS FOR COALITIONS REPRESENTING CERTAIN ORGANIZATIONS.—Funds appropriated for the substance use and misuse activities of a coalition that includes a representative of the Bureau of Indian Affairs, the Indian Health Service, or a tribal government agency with expertise in the field of substance use and misuse may be counted as non-Federal funds raised by the coalition for purposes of this section.

(d) PRIORITY IN AWARDING GRANTS.—In awarding grants under subsection (b)(1)(A)(i), priority shall be given to a coalition serving economically disadvantaged areas.

**§ 60513. Information collection and dissemination with respect to grant recipients**

(a) COALITION INFORMATION.—

(1) GENERAL AUDITING AUTHORITY.—For the purpose of audit and examination, the Administrator—

(A) shall have access to any books, documents, papers, and records that are pertinent to any grant or grant renewal request under this chapter; and

(B) may periodically request information from a grant recipient to ensure that the grant recipient meets the applicable criteria under section 60512(a) of this title.

(2) APPLICATION PROCESS.—The Administrator shall issue a request for proposal regarding, with respect to the grants awarded under section 60512 of this title, the application process, grant renewal, and suspension or withholding of renewal grants. Each application under this paragraph shall

be in writing and shall be subject to review by the Administrator.

(3) REPORTING.—The Administrator shall, to the maximum extent practicable and in a manner consistent with applicable law, minimize reporting requirements by a grant recipient and expedite any application for a renewal grant made under this subchapter.

(b) DATA COLLECTION AND DISSEMINATION.—

(1) IN GENERAL.—The Administrator may collect data from—

(A) national substance use and misuse organizations that work with eligible coalitions, community anti-drug coalitions, Federal agencies, or State or local governments and the governing bodies of Indian tribes; and

(B) any other entity or organization that carries out activities that relate to the purposes of the Program.

(2) ACTIVITIES OF ADMINISTRATOR.—The Administrator may—

(A) evaluate the utility of specific initiatives relating to the purposes of the Program;

(B) conduct an evaluation of the Program; and

(C) disseminate information described in this subsection to—

(i) eligible coalitions and other substance use and misuse organizations; and

(ii) the general public.

(3) CONSULTATION.—The Administrator shall carry out activities under this subsection in consultation with the National Community Antidrug Coalition Institute.

(4) LIMITATION ON USE OF CERTAIN FUNDS FOR EVALUATION OF PROGRAM.—Amounts for activities under paragraph (2)(B) may not be derived from amounts under section 60503(a) of this title except for amounts that are available under section 60503(b) of this title for administrative costs.

**§ 60514. Technical assistance and training**

(a) IN GENERAL.—

(1) TECHNICAL ASSISTANCE AND AGREEMENTS.—With respect to any grant recipient or other organization, the Administrator may—

(A) offer technical assistance and training; and

(B) enter into contracts and cooperative agreements.

(2) COORDINATION OF PROGRAMS.—The Administrator may facilitate the coordination of programs between a grant recipient and other organizations and entities.

(b) TRAINING.—The Administrator may provide training to any representative designated by a grant recipient in—

(1) coalition building;

(2) task force development;

(3) mediation and facilitation, direct service, assessment and evaluation; or

(4) any other activity related to the purposes of the Program.

**§ 60515. Supplemental grants for coalition mentoring activities**

(a) AUTHORITY TO MAKE GRANTS.—As part of the Program, the Director may award an initial grant under this subsection, and renewal grants under subsection (f), to any coalition awarded a grant under section 60512 of this title that meets the criteria specified in subsection (d) in order to fund coalition mentoring activities by the coalition in support of the Program.

(b) TREATMENT WITH OTHER GRANTS.—

(1) SUPPLEMENT.—A grant awarded to a coalition under this section is in addition to any grant

awarded to the coalition under section 60512 of this title.

(2) REQUIREMENT FOR BASIC GRANT.—A coalition may not be awarded a grant under this section for a fiscal year unless the coalition was awarded a grant or renewal grant under section 60512(b) of this title for that fiscal year.

(c) APPLICATION.—A coalition seeking a grant under this section shall submit to the Administrator an application for the grant in such form and manner as the Administrator may require.

(d) CRITERIA.—A coalition meets the criteria specified in this subsection if the coalition—

(1) has been in existence for at least 5 years;

(2) has achieved, by or through its own efforts, measurable results in the prevention and treatment of substance use and misuse among youth;

(3) has staff or members willing to serve as mentors for persons seeking to start or expand the activities of other coalitions in the prevention and treatment of substance use and misuse;

(4) has demonstrable support from some members of the community in which the coalition mentoring activities to be supported by the grant under this section are to be carried out; and

(5) submits to the Administrator a detailed plan for the coalition mentoring activities to be supported by the grant under this section.

(e) USE OF GRANT FUNDS.—A coalition awarded a grant under this section shall use the grant amount for mentoring activities to support and encourage the development of new, self-supporting community coalitions that are focused on the prevention and treatment of substance use and misuse in the new coalitions' communities. The mentoring coalition shall encourage the development in accordance with the plan submitted by the mentoring coalition under subsection (d)(5).

(f) RENEWAL GRANTS.—The Administrator may make a renewal grant to any coalition awarded a grant under subsection (a), or a previous renewal grant under this subsection, if the coalition, at the time of application for the renewal grant—

(1) continues to meet the criteria specified in subsection (d); and

(2) has made demonstrable progress in the development of 1 or more new, self-supporting community coalitions that are focused on the prevention and treatment of substance use and misuse.

(g) GRANT AMOUNTS.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the total amount of grants awarded to a coalition under this section for a fiscal year may not exceed the amount of non-Federal funds raised by the coalition, including in-kind contributions, for that fiscal year. Funds appropriated for the substance use and misuse activities of a coalition that includes a representative of the Bureau of Indian Affairs, the Indian Health Service, or a tribal government agency with expertise in the field of substance use and misuse may be counted as non-Federal funds raised by the coalition.

(2) INITIAL GRANTS.—The amount of the initial grant awarded to a coalition under subsection (a) may not exceed $75,000.

(3) RENEWAL GRANTS.—The total amount of renewal grants awarded to a coalition under subsection (f) for any fiscal year may not exceed $75,000.

(h) FISCAL YEAR LIMITATION ON AMOUNT AVAILABLE FOR GRANTS.—The total amount available for grants under this section, including renewal grants under subsection (f), in any fiscal year may not exceed the amount equal to 5 percent of the amount authorized to

be appropriated by section 60503(a) of this title for that fiscal year.

(i) PRIORITY IN AWARDING INITIAL GRANTS.—In awarding initial grants under this section, priority shall be given to a coalition that expressly proposes to provide mentorship to a coalition or aspiring coalition serving economically disadvantaged areas.

# Chapter 607—Other Coalition Grants

Sec.
60701. National Community Antidrug Coalition Institute.
60702. Prohibition against duplication of effort.
60703. Community-based coalition enhancement grants to address local drug crises.

## § 60701. National Community Antidrug Coalition Institute

(a) IN GENERAL.—The Director of National Drug Control Policy shall make a competitive grant to provide for the continuation of the National Community Antidrug Coalition Institute.

(b) ELIGIBLE ORGANIZATIONS.—An organization eligible for the grant under subsection (a) is any national nonprofit organization that represents, provides technical assistance and training to, and has special expertise and broad, national-level experience in community antidrug coalitions under chapter 605 of this title.

(c) USE OF GRANT AMOUNT.—The organization that receives the grant under subsection (a) shall continue a National Community Antidrug Coalition Institute to—

(1) provide education, training, and technical assistance for coalition leaders and community teams, with emphasis on the development of coalitions serving economically disadvantaged areas;

(2) develop and disseminate evaluation tools, mechanisms, and measures to better assess and document coalition performance measures and outcomes; and

(3) bridge the gap between research and practice by translating knowledge from research into practical information.

(d) ADMINISTRATION OF GRANT.—

(1) DURATION.—With respect to a grant made under subsection (a) in fiscal year 2020, the term of the grant shall be 4 years.

(2) DISBURSEMENT.—To the extent amounts are provided in appropriation Acts for the grant, the Director of National Drug Control Policy shall disburse the amount of the grant made under subsection (a) on an annual basis.

**§ 60702. Prohibition against duplication of effort**

The Director of National Drug Control Policy shall ensure that the same or similar activities are not carried out, through the use of funds for administrative costs provided under subchapter II of chapter 605 of this title or funds provided under section 60701 of this title, by more than 1 recipient of the funds.

**§ 60703. Community-based coalition enhancement grants to address local drug crises**

(a) DEFINITIONS.—In this section:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Substance Abuse and Mental Health Services Administration.

(2) DIRECTOR.—The term ''Director'' means the Director of National Drug Control Policy.

(3) ELIGIBLE ENTITY.—The term ''eligible entity'' means an organization that—

(A) on or before the date of submitting an application for a grant under this section, receives or has received a grant under chapter 605 of this title; and

(B) has documented, using local data, rates of abuse of opioids or methamphetamines at levels that are—

(i) significantly higher than the national average as determined by the Sec-

retary (including appropriate consideration of the results of the Monitoring the Future Survey published by the National Institute on Drug Abuse and the National Survey on Drug Use and Health published by the Substance Abuse and Mental Health Services Administration); or

(ii) higher than the national average, as determined by the Secretary (including appropriate consideration of the results of the surveys described in clause (i)), over a sustained period of time.

(4) EMERGING DRUG ABUSE ISSUE.—The term ''emerging drug abuse issue'' means a substance use disorder within an area involving—

(A) a sudden increase in demand for particular drug abuse treatment services relative to previous demand; and

(B) a lack of resources in the area to address the emerging problem.

(5) LOCAL DRUG CRISIS.—The term ''local drug crisis'' means, with respect to the area served by an eligible entity—

(A) a sudden increase in the abuse of opioids or methamphetamines, as documented by local data;

(B) the abuse of prescription medications, specifically opioids or methamphetamines, that is significantly higher than the national average, over a sustained period of time, as documented by local data; or

(C) a sudden increase in opioid-related deaths, as documented by local data.

(6) OPIOID.—The term ''opioid'' means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having the addiction-forming or addiction-sustaining liability.

(b) PROGRAM AUTHORIZED.—The Director, in coordination with the Administrator, may make grants to eligible entities to implement comprehensive community-wide strategies that address local drug crises and emerging drug abuse issues within the area served by the eligible entity.

(c) APPLICATION.—

(1) IN GENERAL.—An eligible entity seeking a grant under this section shall submit an application to the Director at such time, in such manner, and

accompanied by such information as the Director may require.

(2) CRITERIA.—As part of an application for a grant under this section, the Director shall require an eligible entity to submit a detailed, comprehensive, multisector plan for addressing the local drug crisis or emerging drug abuse issue within the area served by the eligible entity.

(d) USE OF FUNDS.—An eligible entity shall use a grant received under this section—

(1) for programs designed to implement comprehensive community-wide prevention strategies to address the local drug crisis in the area served by the eligible entity, in accordance with the plan submitted under subsection (c)(2);

(2) to obtain specialized training and technical assistance from the organization funded under section 60701 of this title; and

(3) for programs designed to implement comprehensive community-wide strategies to address emerging drug abuse issues in the community.

(e) SUPPLEMENT NOT SUPPLANT.—An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal

and non-Federal sources for the activities described in this section, and not to supplant those funds.

(f) EVALUATION.—A grant under this section shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on the recipient of a grant under the chapter 605 of this title. Evaluation requirements to which a grant under this section is subject may also include an evaluation of the effectiveness at reducing abuse of opioids or methamphetamines.

(g) LIMITATION ON ADMINISTRATIVE EXPENSES.—Not more than 8 percent of the amounts made available to carry out this section for a fiscal year may be used to pay for administrative expenses.

(h) DELEGATION AUTHORITY.—The Director may enter into an interagency agreement with the Administrator to delegate authority for the execution of grants and for such other activities as may be necessary to carry out this section.

(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2017 through 2021.

# Chapter 609—Office of National Drug Control Policy

Sec.
60901. Definitions.
60902. Office of National Drug Control Policy.
60903. Appointment and duties of Director and Deputy Directors.
60904. Coordination with National Drug Control Program agencies in demand reduction, supply reduction, and State and local affairs.
60905. Development, submission, implementation, and assessment of National Drug Control Strategy.
60906. High Intensity Drug Trafficking Areas Program.
60907. Emerging Threats Committee, Emerging Threat Response Plans, and media campaign.
60908. United States Interdiction Coordinator and Interdiction Committee.
60909. Requirement for disclosure of Federal sponsorship of all Federal advertising or other communication materials.
60910. Authorization of appropriations.
60911. Awards for demonstration programs by local partnerships to coerce abstinence in chronic hard-drug users under community supervision through the use of drug testing and sanctions.

## § 60901. Definitions

In this chapter:

(1) AGENCY.—The term ''agency'' has the meaning given the term ''executive agency'' in section 102 of title 31.

(2) APPROPRIATE CONGRESSIONAL COMMITTEES.—

(A) IN GENERAL.—The term ''appropriate congressional committees'' means—

(i) the Committee on the Judiciary, the Committee on Appropriations, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(ii) the Committee on Oversight and Government Reform, the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives.

(B) SUBMISSION TO CONGRESS.—Any submission to Congress shall mean submission to the appropriate congressional committees.

(3) DEMAND REDUCTION.—The term ''demand reduction'' means any activity conducted by a National Drug Control Program agency, other than an enforcement activity, that is intended to reduce or prevent the use of drugs or support, expand, or provide treatment and recovery efforts, including—

(A) education about the dangers of illicit drug use;

(B) services, programs, or strategies to prevent substance use disorder, including evidence-based education campaigns, community-based prevention programs, collection and disposal of unused prescription drugs, and services to at-risk populations to prevent or delay initial use of an illicit drug;

(C) substance use disorder treatment;

(D) support for long-term recovery from substance use disorders;

(E) drug-free workplace programs;

(F) drug testing, including the testing of employees;

(G) interventions for illicit drug use and dependence;

(H) expanding availability of access to health care services for the treatment of substance use disorders;

(I) international drug control coordination and cooperation with respect to activities described in this paragraph;

(J) pre-arrest and post-arrest criminal justice interventions such as diversion programs, drug courts, and the provision of evidence-based treatment to individuals with substance use disorders who are arrested or under some form of criminal justice supervision, including medication-assisted treatment;

(K) other coordinated and joint initiatives among Federal, State, local, and Tribal agencies to promote comprehensive drug control strategies designed to reduce the demand for, and the availability of, illegal drugs;

(L) international illicit drug use education, prevention, treatment, recovery, research, and rehabilitation activities, and interventions for illicit drug use and dependence; and

(M) research related to illicit drug use and any of the activities described in this paragraph.

(4) DIRECTOR.—The term ''Director'' means the Director of National Drug Control Policy.

(5) DRUG.—The term ''drug'' has the meaning given the term ''controlled substance'' in section 50101 of this title.

(6) DRUG CONTROL.—The term ''drug control'' means any activity conducted by a National Drug Control Program agency involving supply reduction or demand reduction.

(7) EMERGING DRUG THREAT.—The term ''emerging drug threat'' means the occurrence of a new and growing trend in the use of an illicit drug or class of drugs, including rapid expansion in the supply of or demand for the drug or class of drugs.

(8) ILLICIT DRUG USE; ILLICIT DRUGS; ILLEGAL DRUGS.—The terms ''illicit drug use'', ''illicit drugs'', and ''illegal drugs'' include the illegal or illicit use of prescription drugs.

(9) LAW ENFORCEMENT; DRUG LAW ENFORCEMENT.—The term ''law enforcement'' or ''drug law enforcement'' means all efforts by a Federal, State, local, or Tribal government agency to enforce the drug laws of the United States or any State, including investigation, arrest, prosecution, and incarceration or other punishments or penalties.

(10) NATIONAL DRUG CONTROL PROGRAM.—The term ''National Drug Control Program'' means programs, policies, and activities undertaken by National Drug Control Program agencies pursuant to the responsibilities of the National Drug Control Program agencies under the National Drug Control Strategy, including any activities involving supply reduction, demand reduction, or State, local, and Tribal affairs.

(11) NATIONAL DRUG CONTROL PROGRAM AGENCY.—

(A) IN GENERAL.—The term ''National Drug Control Program agency'' means any agency (or bureau, office, independent agency, board, division, commission, subdivision, unit, or other component of the agency) that is responsible for implementing any aspect of the National Drug Control Strategy, including any

agency that receives Federal funds to implement any aspect of the National Drug Control Strategy.

(B) EXCLUSION.—The term ''National Drug Control Program agency'' does not include any agency that receives funds for drug control activity solely under the National Intelligence Program or the Joint Military Intelligence Program.

(12) NATIONAL DRUG CONTROL STRATEGY.—The term ''National Drug Control Strategy'' or ''Strategy'' means the strategy developed and submitted to Congress under section 60905 of this title, including any report, plan, or strategy required to be incorporated into or issued concurrently with the strategy.

(13) NONPROFIT ORGANIZATION.—The term ''nonprofit organization'' means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and exempt from tax under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

(14) OFFICE.—The term ''Office'' means the Office of National Drug Control Policy established under section 60902(a) of this title.

(15) STATE, LOCAL, AND TRIBAL AFFAIRS.—The term ''State, local, and Tribal affairs'' means domestic activities conducted by a National Drug Control Program agency that are intended to reduce the availability and use of illegal drugs, including—

(A) coordination and enhancement of Federal, State, local, and Tribal law enforcement drug control efforts;

(B) coordination and enhancement of efforts among National Drug Control Program agencies and State, local, and Tribal demand reduction and supply reduction agencies;

(C) coordination and enhancement of Federal, State, local, and Tribal law enforcement initiatives to gather, analyze, and disseminate information and law enforcement intelligence relating to drug control among domestic law enforcement agencies; and

(D) other coordinated and joint initiatives among Federal, State, local, and Tribal agencies to promote comprehensive drug control strategies designed to reduce the demand for, and the availability of, illegal drugs.

(16) SUBSTANCE USE DISORDER TREATMENT.—The term ''substance use disorder treat-

ment'' means an evidence-based, professionally directed, deliberate, and planned regimen including evaluation, observation, medical monitoring, and rehabilitative services and interventions such as pharmacotherapy, behavioral therapy, and individual and group counseling, on an inpatient or outpatient basis, to help patients with substance use disorder reach recovery.

(17) SUPPLY REDUCTION.—The term ''supply reduction'' means any activity or program conducted by a National Drug Control Program agency that is intended to reduce the availability or use of illegal drugs in the United States or abroad, including—

(A) law enforcement outside the United States;

(B) domestic law enforcement;

(C) source country programs, including economic development programs primarily intended to reduce the production or trafficking of illicit drugs;

(D) activities to control international trafficking in, and availability of, illegal drugs, including—

(i) accurate assessment and monitoring of international drug production and interdiction programs and policies; and

(ii) coordination and promotion of compliance with international treaties relating to the production, transportation, or interdiction of illegal drugs;

(E) activities to conduct and promote international law enforcement programs and policies to reduce the supply of drugs;

(F) activities to facilitate and enhance the sharing of domestic and foreign intelligence information among National Drug Control Program agencies, relating to the production and trafficking of drugs in the United States and in foreign countries;

(G) activities to prevent the diversion of drugs for their illicit use; and

(H) research related to any of the activities described in this paragraph.

**§ 60902. Office of National Drug Control Policy**

(a) ESTABLISHMENT OF OFFICE.—There is established in the Executive Office of the President an Office of National Drug Control Policy, which shall—

(1) lead the national drug control effort, including coordinating with the National Drug Control Program agencies;

(2) coordinate and oversee the implementation of the national drug control policy, including the National Drug Control Strategy;

(3) assess and certify the adequacy of National Drug Control Programs and the budget for those programs;

(4) evaluate the effectiveness of national drug control policy efforts, including the National Drug Control Program agencies' programs, by developing and applying specific goals and performance measurements and monitoring the agencies' program-level spending;

(5) identify and respond to emerging drug threats related to illicit drug use;

(6) administer the Drug-Free Communities Program, the High Intensity Drug Trafficking Areas Program, and other grant programs directly authorized to be administered by the Office in furtherance of the National Drug Control Strategy; and

(7) facilitate broad-scale information sharing and data standardization among Federal, State, and

local entities to support the national drug control efforts.

(b) ACCESS BY CONGRESS.—The location of the Office in the Executive Office of the President shall not be construed as affecting access by Congress, or any committee of the House of Representatives or the Senate, to any—

(1) information, document, or study in the possession of, or conducted by or at the direction of, the Director; or

(2) personnel of the Office.

(c) OFFICE OF NATIONAL DRUG CONTROL POLICY GIFT FUND.—

(1) ESTABLISHMENT.—There is established in the Treasury a fund (''Fund'') for the receipt of gifts, both real and personal, for the purpose of aiding or facilitating the work of the Office under section 60903(c) of this title.

(2) CONTRIBUTIONS.—The Office may accept, hold, and administer contributions to the Fund.

(3) USE OF AMOUNTS DEPOSITED.—Amounts deposited in the Fund are authorized to be appropriated, to remain available until expended for authorized purposes at the discretion of the Director.

(4) ETHICS GUIDELINES.—The Director shall establish written guidelines setting forth the criteria to be used in determining whether a gift or donation should be declined under this subsection because the acceptance of the gift or donation would—

(A) reflect unfavorably on the ability of the Director or the Office, or any employee of the Office, to carry out responsibilities or official duties under this chapter in a fair and objective manner; or

(B) compromise the integrity or the appearance of integrity of programs or services provided under this chapter or of any official involved in those programs or services.

(5) REGISTRY OF GIFTS.—The Director shall maintain a list of—

(A) the source and amount of each gift or donation accepted by the Office; and

(B) the source and amount of each gift or donation accepted by a contractor to be used in its performance of a contract for the Office.

(6) REPORT TO CONGRESS.—The Director shall include in the annual assessment under section 60905(g) of this title a copy of the registry maintained under paragraph (5).

(d) AUTHORITIES RELATING TO GIFTS.—The Office may accept, hold, administer, and utilize gifts, both real and personal, public and private, without fiscal year limitation, for the purpose of aiding or facilitating the work of the Office.

**§ 60903. Appointment and duties of Director and Deputy Directors**

(a) APPOINTMENT.—

(1) IN GENERAL.—

(A) DIRECTOR.—

(i) IN GENERAL.—There shall be at the head of the Office a Director who shall hold the same rank and status as the head of an executive department listed in section 101 of title 5.

(ii) APPOINTMENT.—The Director shall be appointed by the President, by and with the advice and consent of the Senate, and shall serve at the pleasure of the President.

(B) DEPUTY DIRECTOR OF NATIONAL DRUG CONTROL POLICY.—There shall be a Deputy Director of National Drug Control Policy (referred to in this subsection as the ''Deputy Director'') who shall report directly to the Di-

rector, and who shall be appointed by the President, and shall serve at the pleasure of the President.

(C) COORDINATORS.—The following coordinators shall be appointed by the Director:

(i) United States Performance Budget Coordinator, as described in subsection (c)(5).

(ii) United States Interdiction Coordinator, as described in section 60908 of this title.

(iii) United States Emerging and Continuing Threats Coordinator, as described in section 60907 of this title.

(iv) United States State, Local, and Tribal Affairs Coordinator, to carry out the activities described in subsection (j).

(v) United States Demand Reduction Coordinator, as described in subparagraph (D).

(D) DEMAND REDUCTION COORDINATOR.—The Director shall designate or appoint a United States Demand Reduction Coordinator to be responsible for the activities described in section 60901(3) of this title. For

purposes of carrying out the previous sentence, the Director shall designate or appoint an appointee in the Senior Executive Service or an appointee in a position at level 15 of the General Schedule (or equivalent).

(2) DUTIES OF DEPUTY DIRECTOR OF NATIONAL DRUG CONTROL POLICY.—The Deputy Director of National Drug Control Policy shall—

(A) carry out the duties and powers prescribed by the Director; and

(B) serve as the Director in the absence of the Director or during any period in which the office of the Director is vacant.

(3) ACTING DIRECTOR.—If the Director dies, resigns, or is otherwise unable to perform the functions and duties of the office, the Deputy Director shall perform the functions and duties of the Director temporarily in an acting capacity pursuant to subchapter III of chapter 33 of title 5.

(4) PROHIBITION.—An individual shall not serve as Director or Deputy Director while serving in any other position in the Federal Government.

(5) PROHIBITION ON POLITICAL CAMPAIGNING.—Any officer or employee of the Office who is appointed to that position by the President,

by and with the advice and consent of the Senate, may not participate in Federal election campaign activities, except that the officer or employee is not prohibited by this paragraph from making contributions to individual candidates.

(6) PROHIBITION ON THE USE OF FUNDS FOR BALLOT INITIATIVES.—Funds authorized under this chapter shall not be obligated for the purpose of expressly advocating the passage or defeat of a State or local ballot initiative.

(b) RESPONSIBILITIES OF THE DIRECTOR.—The Director—

(1) shall assist the President in the establishment of policies, goals, objectives, and priorities for the National Drug Control Program;

(2) shall promulgate the National Drug Control Strategy under section 60905(a) of this title and submit each report under section 60905(g)(1) of this title in accordance with section 60905 of this title;

(3) shall coordinate and oversee the implementation by the National Drug Control Program agencies of the policies, goals, objectives, and priorities established under paragraph (1) and the fulfillment of the responsibilities of the National Drug Control Program agencies under the National Drug Control

Strategy and make recommendations to National Drug Control Program agency heads with respect to implementation of Federal counter-drug programs;

(4) shall make such recommendations to the President as the Director determines are appropriate regarding changes in the organization, management, and budgets of National Drug Control Program agencies, and changes in the allocation of personnel to and within those National Drug Control Program agencies, to implement the policies, goals, priorities, and objectives established under paragraph (1) and the National Drug Control Strategy;

(5) shall consult with and assist State and local governments with respect to the formulation and implementation of National Drug Control Policy and their relations with the National Drug Control Program agencies;

(6) shall appear before duly constituted committees and subcommittees of the House of Representatives and of the Senate to represent the drug policies of the Executive Branch;

(7) shall notify any National Drug Control Program agency if its policies are not in compliance with the responsibilities of the National Drug Control Program agency under the National Drug Con-

trol Strategy, transmit a copy of each notification to the President and the appropriate congressional committees, and maintain a copy of each notification;

(8) shall provide, by July 1 of each year, budget recommendations, including requests for specific initiatives that are consistent with the priorities of the President under the National Drug Control Strategy, to the heads of departments and agencies with responsibilities under the National Drug Control Program, which recommendations shall—

(A) apply to the next budget year scheduled for formulation under chapter 11 of title 31, and each of the 4 subsequent fiscal years; and

(B) address funding priorities developed in the National Drug Control Strategy;

(9) may serve as the representative of the President in appearing before Congress on all issues relating to the National Drug Control Program;

(10) shall, in any matter affecting national security interests, work in conjunction with the Assistant to the President for National Security Affairs;

(11) may serve as spokesperson of the Administration of the President on drug issues;

(12) shall ensure that no Federal funds appropriated to the Office of National Drug Control Policy shall be expended for any study or contract relating to the legalization (for a medical use or any other use) of a substance listed in schedule I of section 50302 of this title and take such actions as necessary to oppose any attempt to legalize the use of a substance (in any form) that—

(A) is listed in schedule I of section 50302 of this title; and

(B) has not been approved for use for medical purposes by the Food and Drug Administration;

(13) shall submit to the appropriate congressional committees on an annual basis, not later than 60 days after the date of the last day of the applicable period, a summary of—

(A) each of the evaluations received by the Director under section 60905(g)(2) of this title; and

(B) the progress of each National Drug Control Program agency toward the drug control program goals of the National Drug Control Program agency using the performance

measures for the National Drug Control Program agency developed under this chapter;

(14) shall ensure that drug prevention and drug treatment research and information is effectively disseminated by National Drug Control Program agencies to State and local governments and nongovernmental entities involved in demand reduction by—

(A) encouraging formal consultation between any National Drug Control Program agency that conducts or sponsors research, and any National Drug Control Program agency that disseminates information in developing research and information product development agendas;

(B) encouraging the National Drug Control Program agencies (as appropriate) to develop and implement dissemination plans that specifically target State and local governments and nongovernmental entities involved in demand reduction; and

(C) supporting the substance abuse information clearinghouse administered by the Administrator of the Substance Abuse and Mental Health Services Administration and established

in section 501(d)(16) of the Public Health Service Act (42 U.S.C. 290aa(d)(16)) by—

(i) encouraging all National Drug Control Program agencies to provide all appropriate and relevant information; and

(ii) supporting the dissemination of information to all interested entities;

(15) shall coordinate with the private sector to promote private research and development of medications to treat addiction;

(16) shall monitor and evaluate the allocation of resources among Federal law enforcement agencies in response to significant local and regional drug trafficking and production threats;

(17) shall submit an annual report to Congress detailing how the Office of National Drug Control Policy has consulted with and assisted State, local, and Tribal governments with respect to the formulation and implementation of the National Drug Control Strategy and other relevant issues; and

(18) in order to formulate the national drug control policies, goals, objectives, and priorities—

(A) shall consult with and assist—

(i) State and local governments;

(ii) National Drug Control Program agencies;

(iii) each committee, working group, council, or other entity established under this chapter, as appropriate;

(iv) the public;

(v) appropriate congressional committees; and

(vi) any other person in the discretion of the Director; and

(B) may—

(i) establish advisory councils;

(ii) acquire data from agencies; and

(iii) request data from any other entity.

(c) NATIONAL DRUG CONTROL PROGRAM BUDGET.—

(1) RESPONSIBILITIES OF NATIONAL DRUG CONTROL PROGRAM AGENCIES.—

(A) IN GENERAL.—For each fiscal year, the head of each department, agency, or program of the Federal Government with responsibilities under the National Drug Control Program Strategy shall transmit to the Director a copy of the proposed drug control budget re-

quest of the department, agency, or program at the same time as that budget request is submitted to the head's superior (and before submission to the Office of Management and Budget) in the preparation of the budget of the President submitted to Congress under section 1105(a) of title 31.

(B) SUBMISSION OF DRUG CONTROL BUDGET REQUESTS.—The head of each National Drug Control Program agency shall ensure timely development and submission to the Director of each proposed drug control budget request transmitted pursuant to this paragraph, in such format as may be designated by the Director with the concurrence of the Director of the Office of Management and Budget.

(C) CONTENT OF DRUG CONTROL BUDGET REQUESTS.—A drug control budget request submitted by a department, agency, or program under this paragraph shall include all requests for funds for any drug control activity undertaken by that department, agency, or program, including demand reduction, supply reduction, and State, local, and Tribal affairs (including any drug law enforcement activities). If an ac-

tivity has both drug control and nondrug control purposes or applications, the department, agency, or program shall estimate by a documented calculation the total funds requested for that activity that would be used for drug control, and shall set forth in its request the basis and method for making the estimate.

(2) NATIONAL DRUG CONTROL PROGRAM BUDGET PROPOSAL.—For each fiscal year, following the transmission of proposed drug control budget requests to the Director under paragraph (1), the Director shall, in consultation with the head of each National Drug Control Program agency and the head of each major national organization that represents law enforcement officers, agencies, or associations—

(A) develop a consolidated National Drug Control Program budget proposal designed to implement the National Drug Control Strategy and to inform Congress and the public about the total amount proposed to be spent on all supply reduction, demand reduction, and State, local, and Tribal affairs (including any drug law enforcement), and other drug control activities by the Federal Government, which shall con-

form to the content requirements set forth in paragraph (1)(C) and include—

(i) the funding level for each National Drug Control Program agency; and

(ii) alternative funding structures that could improve progress on achieving the goals of the National Drug Control Strategy; and

(B) submit the consolidated budget proposal to the President and Congress.

(3) REVIEW AND CERTIFICATION OF BUDGET REQUESTS AND BUDGET SUBMISSIONS OF NATIONAL DRUG CONTROL PROGRAM AGENCIES.—

(A) IN GENERAL.—The Director shall review each drug control budget request submitted to the Director under paragraph (1).

(B) REVIEW OF BUDGET REQUESTS.—

(i) INADEQUATE REQUESTS.—If the Director concludes that a budget request submitted under paragraph (1) is inadequate, in whole or in part, to implement the objectives of the National Drug Control Strategy with respect to the department, agency, or program at issue for the year for which the request is submitted,

the Director shall submit to the head of the applicable National Drug Control Program agency a written description of funding levels and specific initiatives that would, in the determination of the Director, make the request adequate to implement those objectives.

(ii) ADEQUATE REQUESTS.—If the Director concludes that a budget request submitted under paragraph (1) is adequate to implement the objectives of the National Drug Control Strategy with respect to the department, agency, or program at issue for the year for which the request is submitted, the Director shall submit to the head of the applicable National Drug Control Program agency a written statement confirming the adequacy of the request.

(iii) RECORD.—The Director shall maintain a record of each description submitted under clause (i) and each statement submitted under clause (ii).

(C) SPECIFIC REQUESTS.—The Director shall not confirm the adequacy of any budget request that requests a level of funding that will

not enable achievement of the goals of the National Drug Control Strategy, including any budget request that—

(i) requests funding for Federal law enforcement activities that do not adequately compensate for transfers of drug enforcement resources and personnel to law enforcement and investigation activities;

(ii) requests funding for law enforcement activities on the borders of the United States that do not adequately direct resources to drug interdiction and enforcement;

(iii) requests funding for substance use disorder prevention and treatment activities that do not provide adequate results and accountability measures; and

(iv) requests funding for drug treatment activities that do not adequately support and enhance Federal drug treatment programs and capacity.

(D) AGENCY RESPONSE.—

(i) IN GENERAL.—The head of a National Drug Control Program agency that

receives a description under subparagraph (B)(i) shall include the funding levels and initiatives described by the Director in the budget submission for that National Drug Control Program agency to the Office of Management and Budget.

(ii) IMPACT STATEMENT.—The head of a National Drug Control Program agency that has altered its budget submission under this subparagraph shall include as an appendix to the budget submission for that National Drug Control Program agency to the Office of Management and Budget an impact statement that summarizes—

(I) the changes made to the budget under this subparagraph; and

(II) the impact of those changes on the ability of that National Drug Control Program agency to perform its other responsibilities, including any impact on specific missions or programs of the National Drug Control Program agency.

(iii) CONGRESSIONAL NOTIFICATION.—The head of a National Drug Con-

trol Program agency shall submit a copy of any impact statement under clause (ii) to the Senate and the House of Representatives and the appropriate congressional committees, at the time the budget for that National Drug Control Program agency is submitted to Congress under section 1105(a) of title 31.

(E) CERTIFICATION OF BUDGET SUBMISSIONS.—

(i) IN GENERAL.—At the time a National Drug Control Program agency submits its budget request to the Office of Management and Budget, the head of the National Drug Control Program agency shall submit a copy of the budget request to the Director.

(ii) CERTIFICATION.—The Director shall—

(I) review each budget submission submitted under clause (i);

(II) based on the review under subclause (I), make a determination as to whether the budget submission of a National Drug Control Program

agency includes the funding levels and initiatives described in subparagraph (B); and

(III) submit to the appropriate congressional committees—

(aa) a written statement that—

(AA) certifies that the budget submission includes sufficient funding; or

(BB) decertifies the budget submission as not including sufficient funding;

(bb) a copy of the description made under subparagraph (B); and

(cc) the budget recommendations made under subsection (b)(8).

(4) REPROGRAMMING AND TRANSFER REQUESTS.—

(A) IN GENERAL.—A National Drug Control Program agency shall not submit to Congress a reprogramming or transfer request with respect to any amount of appropriated funds in

an amount exceeding $5,000,000 or 10 percent of a specific program or account that is included in the National Drug Control Program budget unless the request has been approved by the Director. If the Director has not responded to a request for reprogramming subject to this subparagraph within 30 days after receiving notice of the request having been made, the request shall be deemed approved by the Director under this subparagraph and forwarded to Congress.

(B) APPEAL.—The head of any National Drug Control Program agency may appeal to the President any disapproval by the Director of a reprogramming or transfer request under this paragraph.

(5) PERFORMANCE BUDGET COORDINATOR.—

(A) DESIGNATION.—The Director shall designate or appoint a United States Performance Budget Coordinator to—

(i) ensure that the Director has sufficient information necessary to analyze the performance of each National Drug Control Program agency, the impact Federal funding has had on the goals in the Strat-

egy, and the likely contributions to the goals of the Strategy based on funding levels of each National Drug Control Program agency, to make an independent assessment of the budget request of each National Drug Control Program agency under this subsection;

(ii) advise the Director on agency budgets, performance measures and targets, and additional data and research needed to make informed policy decisions under this section and section 60905 of this title; and

(iii) perform other duties as may be determined by the Director with respect to measuring or assessing performance or agency budgets.

(B) DETERMINATION OF POSITION.—For purposes of carrying out subparagraph (A), the Director shall designate or appoint an appointee in the Senior Executive Service or an appointee in a position at level 15 of the General Schedule (or equivalent).

(6) BUDGET ESTIMATE OR REQUEST; SUBMISSION TO CONGRESS.—Whenever the Director sub-

mits any budget estimate or request to the President or the Office of Management and Budget, the Director shall concurrently transmit to the appropriate congressional committees a detailed statement of the budgetary needs of the Office to execute its mission based on the good faith assessment of the Director.

(d) POWERS OF THE DIRECTOR.—In carrying out subsection (b), the Director may—

(1) select, appoint, employ, and fix compensation of such officers and employees of the Office as may be necessary to carry out the functions of the Office under this chapter;

(2) subject to subsection (e)(3), request the head of a department, agency, or program of the Federal Government to place department, agency, or program personnel who are engaged in drug control activities on temporary detail to another department, agency, or program in order to implement the National Drug Control Strategy, and the head of the department, agency, or program shall comply with the request;

(3) use for administrative purposes, on a reimbursable basis, the available services, equipment, personnel, and facilities of Federal, State, and local agencies;

(4) procure the services of experts and consultants in accordance with section 3109 of title 5, relating to appointments in the Federal Service, at rates of compensation for individuals not to exceed the daily equivalent of the rate of pay payable under level IV of the Executive Schedule under section 5311 of title 5;

(5) accept and use gifts and donations of property from Federal, State, and local government agencies, and from the private sector, as authorized in section 60902(c) of this title;

(6) use the mails in the same manner as any other department or agency of the Executive Branch;

(7) monitor implementation of the National Drug Control Program, including—

(A) conducting program and performance audits and evaluations; and

(B) requesting assistance from the Inspector General of the relevant agency in the audits and evaluations;

(8) transfer funds made available to a National Drug Control Program agency for National Drug Control Strategy programs and activities to another account within the National Drug Control Program

agency or to another National Drug Control Program agency for National Drug Control Strategy programs and activities, except that—

(A) the authority under this paragraph may be limited in an annual appropriations Act or other provision of Federal law;

(B) the Director may exercise the authority under this paragraph only with the concurrence of the head of each affected agency;

(C) in the case of an interagency transfer, the total amount of transfers under this paragraph may not exceed 3 percent of the total amount of funds made available for National Drug Control Strategy programs and activities to the agency from which those funds are to be transferred;

(D) funds transferred to an agency under this paragraph may be used only to increase the funding for programs or activities authorized by law;

(E) the Director shall—

(i) submit to the appropriate congressional committees and any other applicable committees of jurisdiction, a reprogramming or transfer request in advance of any

transfer under this paragraph in accordance with the regulations of the affected agency; and

(ii) annually submit to the appropriate congressional committees a report describing the effect of all transfers of funds made pursuant to this paragraph or subsection (c)(4) during the 12-month period preceding the date on which the report is submitted; and

(F) funds may only be used for—

(i) expansion of demand reduction activities;

(ii) interdiction of illicit drugs on the high seas, in United States territorial waters, and at United States ports of entry by officers and employees of National Drug Control Program agencies and domestic and foreign law enforcement officers;

(iii) accurate assessment and monitoring of international drug production and interdiction programs and policies;

(iv) activities to facilitate and enhance the sharing, among National Drug Control

Program agencies, of domestic and foreign intelligence information related to the production and trafficking of drugs in the United States and foreign countries; and

(v) research related to any of these activities;

(9) issue to the head of a National Drug Control Program agency a fund control notice described in subsection (f) to ensure compliance with the National Drug Control Program Strategy and notify the appropriate congressional committees of any fund control notice issued in accordance with subsection (f)(5); and

(10) participate in the drug certification process pursuant to section 490 of the Foreign Assistance Act of 1961 (22 U.S.C. 2291j) and section 706 of the Foreign Relations Authorization Act, Fiscal Year 2003 (22 U.S.C. 2291j–1).

(e) PERSONNEL DETAILED TO OFFICE.—

(1) EVALUATIONS.—Notwithstanding any provision of chapter 43 of title 5, the Director shall perform the evaluation of the performance of any employee detailed to the Office for purposes of the applicable performance appraisal system established under the chapter for any rating period, or part of

the rating period, that the employee is detailed to the Office.

(2) COMPENSATION.—

(A) BONUS PAYMENTS.—Subject to the availability of appropriations, the Director may provide periodic bonus payments to any employee detailed to the Office.

(B) RESTRICTIONS.—An amount paid under this paragraph to an employee for any period—

(i) shall not be greater than 20 percent of the basic pay paid or payable to the employee for the period; and

(ii) shall be in addition to the basic pay of the employee.

(C) AGGREGATE AMOUNT.—The aggregate amount paid during any fiscal year to an employee detailed to the Office as basic pay, awards, bonuses, and other compensation shall not exceed the annual rate payable at the end of the fiscal year for positions at level III of the Executive Schedule.

(3) MAXIMUM NUMBER OF DETAILEES.—The maximum number of personnel who may be detailed to another department or agency (including the Of-

fice) under subsection (d)(2) during any fiscal year is—

(A) for the Department of Defense, 50; and

(B) for any other department or agency, 10.

(f) FUND CONTROL NOTICES.—

(1) IN GENERAL.—A fund control notice may direct that all or part of an amount appropriated to the National Drug Control Program agency account be obligated by—

(A) months, fiscal year quarters, or other time periods; and

(B) activities, functions, projects, or object classes.

(2) UNAUTHORIZED OBLIGATION OR EXPENDITURE PROHIBITED.—An officer or employee of a National Drug Control Program agency shall not make or authorize an expenditure or obligation contrary to a fund control notice issued by the Director.

(3) DISCIPLINARY ACTION FOR VIOLATION.—In the case of a violation of paragraph (2) by an officer or employee of a National Drug Control Program agency, the head of the National Drug Control Program agency, on the request of and in consultation

with the Director, may subject the officer or employee to appropriate administrative discipline, including, when circumstances warrant, suspension from duty without pay or removal from office.

(4) CONGRESSIONAL NOTICE.—A copy of each fund control notice shall be transmitted to the appropriate congressional committees.

(5) RESTRICTIONS.—The Director shall not issue a fund control notice to direct that all or part of an amount appropriated to the National Drug Control Program agency account be obligated, modified, or altered in any manner contrary, in whole or in part, to a specific appropriation or statute.

(g) INAPPLICABILITY TO CERTAIN PROGRAMS.—The provisions of this section shall not apply to the National Intelligence Program, the Joint Military Intelligence Program, and Tactical and Related Activities, unless the program or an element of the program is designated as a National Drug Control Program—

(1) by the President; or

(2) jointly by—

(A) in the case of the National Intelligence Program, the Director and the Director of National Intelligence; or

(B) in the case of the Joint Military Intelligence Program and Tactical and Related Activities, the Director, the Director of National Intelligence, and the Secretary of Defense.

(h) CONSTRUCTION.—Nothing in this chapter shall be construed as derogating the authorities and responsibilities of the Director of National Intelligence or the Director of the Central Intelligence Agency contained in the National Security Act of 1947 (50 U.S.C. 3001 et seq.), the Central Intelligence Agency Act of 1949 (50 U.S.C. 3501 et seq.), or any other law.

(i) MODEL ACTS PROGRAM.—

(1) IN GENERAL.—The Director shall provide for or shall enter into an agreement with a nonprofit organization to—

(A) advise States on establishing laws and policies to address illicit drug use issues; and

(B) revise model State drug laws and draft supplementary model State laws to take into consideration changes in illicit drug use issues in the State involved.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $1,250,000 for each of fiscal years 2018 through 2023.

(j) STATE, LOCAL, AND TRIBAL AFFAIRS COORDINATOR.—The Director shall designate or appoint a United States State, Local, and Tribal Affairs Coordinator to perform the duties of the Office outlined in this section and section 60905 of this title and such other duties as may be determined by the Director with respect to coordination of drug control efforts between agencies and State, local, and Tribal governments. For purposes of carrying out the previous sentence, the Director shall designate or appoint an appointee in the Senior Executive Service or an appointee in a position at level 15 of the General Schedule (or equivalent).

(k) HARM REDUCTION PROGRAMS.—When developing the national drug control policy, any policy of the Director, including policies relating to syringe exchange programs for intravenous drug users, shall be based on the best available medical and scientific evidence regarding the effectiveness of the policy in promoting individual health and preventing the spread of infectious disease and the impact of the policy on drug addiction and use. In making any policy relating to harm reduction programs, the Director shall consult with the National Institutes of Health and the National Academy of Sciences.

**§ 60904. Coordination with National Drug Control Program agencies in demand reduction, supply reduction, and State and local affairs**

(a) ACCESS TO INFORMATION.—

(1) IN GENERAL.—On the request of the Director, the head of any National Drug Control Program agency shall cooperate with and provide to the Director any statistics, studies, reports, and other information prepared or collected by the National Drug Control Program agency concerning the responsibilities of the National Drug Control Program agency under the National Drug Control Strategy that relate to—

(A) drug control; or

(B) the manner in which amounts made available to that National Drug Control Program agency for drug control are being used by that National Drug Control Program agency.

(2) PROTECTION OF INTELLIGENCE INFORMATION.—

(A) IN GENERAL.—The authorities conferred on the Office and the Director by this chapter shall be exercised in a manner consistent with provisions of the National Security Act of 1947 (50 U.S.C. 3001 et seq.). The Di-

rector of National Intelligence shall prescribe such regulations as may be necessary to protect information provided pursuant to this chapter regarding intelligence sources and methods.

(B) DUTY OF OTHER DIRECTORS TO RENDER ASSISTANCE.—The Director of National Intelligence and the Director of the Central Intelligence Agency shall, to the maximum extent practicable in accordance with subparagraph (A), render full assistance and support to the Office and the Director.

(3) REQUIRED REPORTS.—

(A) SECRETARY OF AGRICULTURE AND SECRETARY OF THE INTERIOR.—Not later than July 1 of each year, the Secretary of Agriculture and the Secretary of the Interior shall jointly submit to the Director and the appropriate congressional committees an assessment of the quantity of illegal drug cultivation and manufacturing in the United States on land owned or under the jurisdiction of the Federal Government for the preceding year.

(B) SECRETARY OF HOMELAND SECURITY.—Not later than July 1 of each year, the Secretary of Homeland Security shall submit to

the Director and the appropriate congressional committees information for the preceding year regarding—

(i) the number and type of seizures of drugs by each component of the Department of Homeland Security seizing drugs, as well as statistical information on the geographic areas of the seizures; and

(ii) the number of air and maritime patrol hours primarily dedicated to drug supply reduction missions undertaken by each component of the Department of Homeland Security.

(C) SECRETARY OF DEFENSE.—The Secretary of Defense shall, by July 1 of each year, submit to the Director and the appropriate congressional committees information for the preceding year regarding the number of air and maritime patrol hours primarily dedicated to drug supply reduction missions undertaken by each component of the Department of Defense.

(D) ATTORNEY GENERAL.—The Attorney General shall, by July 1 of each year, submit to the Director and the appropriate congressional

committees information for the preceding year regarding the number and type of—

(i) arrests for drug violations;

(ii) prosecutions for drug violations by United States Attorneys; and

(iii) seizures of drugs by each component of the Department of Justice seizing drugs, as well as statistical information on the geographic areas of the seizures.

(b) CERTIFICATION OF POLICY CHANGES TO DIRECTOR.—

(1) IN GENERAL.—Subject to paragraph (2), the head of a National Drug Control Program agency shall, unless exigent circumstances require otherwise, notify the Director in writing regarding any proposed change in policies relating to the activities of that National Drug Control Program agency under the National Drug Control Program prior to implementation of the change. The Director shall promptly review the proposed change and certify to the head of that National Drug Control Program agency in writing whether the change is consistent with the National Drug Control Strategy.

(2) EXCEPTION.—If prior notice of a proposed change under paragraph (1) is not practicable—

(A) the head of the National Drug Control Program agency shall notify the Director of the proposed change as soon as practicable; and

(B) on the notification, the Director shall review the change and certify to the head of that National Drug Control Program agency in writing whether the change is consistent with the National Drug Control Strategy.

(c) GENERAL SERVICES ADMINISTRATION.—The Administrator of General Services shall provide to the Director, on a reimbursable basis, such administrative support services as the Director may request.

(d) ACCOUNTING OF FUNDS EXPENDED.—

(1) IN GENERAL.—Not later than February 1 of each year, in accordance with guidance issued by the Director, the head of each National Drug Control Program agency shall submit to the Director a detailed accounting of all funds expended by the National Drug Control Program agency for National Drug Control Program activities during the previous fiscal year and shall ensure that the detailed accounting is authenticated for the previous fiscal year by the Inspector General for the National Drug Control Program agency prior to the submission to the Director as frequently as determined by the Inspec-

tor General but not less frequently than every 3 years.

(2) SUBMISSION TO CONGRESS.—The Director shall submit to Congress not later than April 1 of each year the information submitted to the Director under paragraph (1).

(e) DRUG COURT TRAINING AND TECHNICAL ASSISTANCE PROGRAM.—

(1) GRANTS AUTHORIZED.—The Director may make a grant to a nonprofit organization for the purpose of providing training and technical assistance to drug courts.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $2,000,000 for each of fiscal years 2018 through 2023.

(f) TRACKING SYSTEM FOR FEDERALLY FUNDED GRANT PROGRAMS.—

(1) ESTABLISHMENT.—The Director, or the head of an agency designated by the Director, in coordination with the Secretary of Health and Human Services, shall track federally funded grant programs to—

(A) ensure that the public has electronic access to information identifying—

(i) all drug control grants and pertinent identifying information for each grant; and

(ii) any available performance metrics, evaluations, or other information indicating the effectiveness of the programs;

(B) facilitate efforts to identify duplication, overlap, or gaps in funding to provide increased accountability of federally funded grants for substance use disorder treatment, prevention, and enforcement; and

(C) identify barriers that may impede applicants in the grant application process.

(2) NATIONAL DRUG CONTROL PROGRAM AGENCIES.—The head of each National Drug Control Program agency shall—

(A) provide to the Director a complete list of all drug control program grant programs and any other relevant information for inclusion in the system developed under paragraph (1); and

(B) annually update the list.

(3) UPDATING EXISTING SYSTEMS.—The Director may meet the requirements of this subsection by utilizing, updating, or improving existing Federal in-

formation systems to ensure that they meet the requirements of this subsection.

(4) REPORT.—Not later than 3 years after October 24, 2018, the Comptroller General shall submit to Congress a report examining implementation of this subsection.

**§ 60905. Development, submission, implementation, and assessment of National Drug Control Strategy**

(a) IN GENERAL.—

(1) STATEMENT OF DRUG POLICY PRIORITIES.—The Director shall release a statement of drug control policy priorities in the calendar year of a Presidential inauguration following the inauguration, but not later than April 1.

(2) NATIONAL DRUG CONTROL STRATEGY SUBMITTED BY THE PRESIDENT.—Not later than the first Monday in February following the year in which the term of the President commences, and every 2 years thereafter, the President (through the Director) shall submit to Congress a National Drug Control Strategy.

(b) DEVELOPMENT OF THE NATIONAL DRUG CONTROL STRATEGY.—

(1) PROMULGATION.—The Director shall promulgate the National Drug Control Strategy, which shall set forth a comprehensive plan to reduce illicit drug use and the consequences of illicit drug use in the United States by limiting the availability of and reducing the demand for illegal drugs and promoting prevention, early intervention, treatment, and recovery support for individuals with substance use disorders.

(2) STATE AND LOCAL COMMITMENT.—The Director shall seek the support and commitment of State, local, and Tribal officials in the formulation and implementation of the National Drug Control Strategy.

(3) STRATEGY BASED ON EVIDENCE.—The Director shall ensure that the National Drug Control Strategy is based on the best available evidence regarding the policies that are most effective in reducing the demand for and supply of illegal drugs.

(4) PROCESS FOR DEVELOPMENT AND SUBMISSION OF NATIONAL DRUG CONTROL STRATEGY.—In developing and effectively implementing the National Drug Control Strategy, the Director—

(A) shall consult with—

(i) the heads of the National Drug Control Program agencies;

(ii) each Coordinator listed in section 60903 of this title;

(iii) the Interdiction Committee and the Emerging Threats Committee;

(iv) the appropriate congressional committees and any other committee of jurisdiction;

(v) State, local, and Tribal officials;

(vi) private citizens and organizations, including community and faith-based organizations, with experience and expertise in demand reduction;

(vii) private citizens and organizations with experience and expertise in supply reduction; and

(viii) appropriate representatives of foreign governments; and

(B) in satisfying the requirements of subparagraph (A), shall ensure, to the maximum extent possible, that State, local, and Tribal officials and relevant private organizations commit to support and take steps to achieve the

goals and objectives of the National Drug Control Strategy.

(c) CONTENTS OF THE NATIONAL DRUG CONTROL STRATEGY.—

(1) IN GENERAL.—The National Drug Control Strategy submitted under subsection (a)(2) shall include the following:

(A) A mission statement detailing the major functions of the National Drug Control Program.

(B) Comprehensive, research-based, long-range, and quantifiable goals for reducing illicit drug use, and the consequences of illicit drug use in the United States.

(C) Annual quantifiable and measurable objectives and specific targets to accomplish long-term quantifiable goals that the Director determines may be achieved during each year beginning on the date on which the National Drug Control Strategy is submitted.

(D) A 5-year projection for the National Drug Control Program and budget priorities.

(E) A review of international, State, local, and private sector drug control activities to ensure that the United States pursues coordinated

and effective drug control at all levels of government.

(F) A description of how each goal established under subparagraph (B) will be achieved, including for each goal—

(i) a list of each relevant National Drug Control Program agency and the related programs, activities, and available assets of each of those National Drug Control Program agencies and the role of each of those programs, activities, and assets in achieving the goal;

(ii) a list of relevant stakeholders and the role of each of those stakeholders in achieving the goal;

(iii) an estimate of Federal funding and other resources needed to achieve the goal;

(iv) a list of each existing or new coordinating mechanism needed to achieve the goal; and

(v) a description of the Office's role in facilitating the achievement of the goal.

(G) For each year covered by the Strategy, a performance evaluation plan for each goal es-

tablished under subparagraph (B) for each National Drug Control Program agency, including—

(i) specific performance measures for each National Drug Control Program agency;

(ii) annual and, to the extent practicable, quarterly objectives and targets for each performance measure; and

(iii) an estimate of Federal funding and other resources needed to achieve each performance objective and target.

(H) A list identifying existing data sources or a description of data collection needed to evaluate performance, including a description of how the Director will obtain the data.

(I) A list of any anticipated challenges to achieving the National Drug Control Strategy goals and planned actions to address the challenges.

(J) A description of how each goal established under subparagraph (B) was determined, including—

(i) a description of each required consultation and a description of how the consultation was incorporated; and

(ii) data, research, or other information used to inform the determination to establish the goal.

(K) A description of the current prevalence of illicit drug use in the United States, including both the availability of illicit drugs and the prevalence of substance use disorders.

(L) Such other statistical data and information as the Director considers appropriate to demonstrate and assess trends relating to illicit drug use, the effects and consequences of illicit drug use (including the effects on children), supply reduction, demand reduction, drug-related law enforcement, and the implementation of the National Drug Control Strategy.

(M) A systematic plan for increasing data collection to enable real time surveillance of drug control threats, developing analysis and monitoring capabilities, and identifying and addressing policy questions related to the National Drug Control Strategy and National Drug Control Program, which shall include—

(i) a list of policy-relevant questions for which the Director and each National Drug Control Program agency intends to develop evidence to support the National Drug Control Program and the National Drug Control Strategy;

(ii) a list of data the Director and each National Drug Control Program agency intends to collect, use, or acquire to facilitate the use of evidence in drug control policymaking and monitoring;

(iii) a list of methods and analytical approaches that may be used to develop evidence to support the National Drug Control Program and the National Drug Control Strategy and related policy;

(iv) a list of any challenges to developing evidence to support policymaking, including any barriers to accessing, collecting, or using relevant data;

(v) a description of the steps the Director and the head of each National Drug Control Program agency will take to effectuate the plan; and

(vi) any other relevant information as determined by the Director.

(N) A plan to expand treatment of substance use disorders, which shall—

(i) identify unmet needs for treatment for substance use disorders and a strategy for closing the gap between available and needed treatment;

(ii) describe the specific roles and responsibilities of the relevant National Drug Control Program agencies for implementing the plan;

(iii) identify the specific resources required to enable the relevant National Drug Control Program agencies to implement that strategy; and

(iv) identify the resources, including private sources, required to eliminate the unmet need for evidence-based substance use disorder treatment.

(2) CONSULTATION.—In developing the plan required under paragraph (1)(M), the Director shall consult with the following:

(A) The public.

(B) Any evaluation or analysis units and personnel of the Office.

(C) Office officials responsible for implementing privacy policy.

(D) Office officials responsible for data governance.

(E) The appropriate congressional committees.

(F) Any other individual or entity as determined by the Director.

(3) ADDITIONAL STRATEGIES.—

(A) IN GENERAL.—The Director shall include in the National Drug Control Strategy the additional strategies described under this paragraph and shall comply with the following:

(i) Provide a copy of the additional strategies to the appropriate congressional committees and to the Committee on Armed Services and the Committee on Homeland Security of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs and the Committee on Armed Services of the Senate.

(ii) Issue the additional strategies in consultation with the head of each relevant National Drug Control Program agency, any relevant official of a State, local, or Tribal government, and the government of any other relevant country.

(iii) Not change any existing agency authority or construe any strategy described under this paragraph to amend or modify any law governing interagency relationship but may include recommendations about changes to the authority or law.

(iv) Present separately from the rest of any strategy described under this paragraph any information that is classified under criteria established by an executive order, or the public disclosure of which, as determined by the Director or the head of any relevant National Drug Control Program agency, would be detrimental to the law enforcement or national security activities of any Federal, State, local, or Tribal agency.

(B) REQUIREMENT FOR SOUTHWEST BORDER COUNTERNARCOTICS STRATEGY.—

(i) PURPOSES.—The Southwest Border Counternarcotics Strategy shall—

(I) set forth the Federal Government's strategy for preventing the illegal trafficking of drugs across the international border between the United States and Mexico, including through ports of entry and between ports of entry on that border;

(II) state the specific roles and responsibilities of the relevant National Drug Control Program agencies for implementing that strategy; and

(III) identify the specific resources required to enable the relevant National Drug Control Program agencies to implement that strategy.

(ii) SPECIFIC CONTENT RELATED TO DRUG TUNNELS BETWEEN THE UNITED STATES AND MEXICO.—The Southwest Border Counternarcotics Strategy shall include—

(I) a strategy to end the construction and use of tunnels and subterranean passages that cross the

international border between the United States and Mexico for the purpose of illegal trafficking of drugs across the border; and

(II) recommendations for criminal penalties for persons that construct or use such a tunnel or subterranean passage for that purpose.

(C) REQUIREMENT FOR NORTHERN BORDER COUNTERNARCOTICS STRATEGY.—

(i) PURPOSES.—The Northern Border Counternarcotics Strategy shall—

(I) set forth the strategy of the Federal Government for preventing the illegal trafficking of drugs across the international border between the United States and Canada, including through ports of entry and between ports of entry on the border;

(II) state the specific roles and responsibilities of each relevant National Drug Control Program agency for implementing the strategy;

(III) identify the specific resources required to enable the relevant

National Drug Control Program agencies to implement the strategy;

(IV) be designed to promote, and not hinder, legitimate trade and travel; and

(V) reflect the unique nature of small communities along the international border between the United States and Canada, ongoing cooperation and coordination with Canadian law enforcement authorities, and variations in the volumes of vehicles and pedestrians crossing through ports of entry along the international border between the United States and Canada.

(ii) SPECIFIC CONTENT RELATED TO CROSS-BORDER INDIAN RESERVATIONS.—The Northern Border Counternarcotics Strategy shall include—

(I) a strategy to end the illegal trafficking of drugs to or through Indian reservations on or near the international border between the United States and Canada; and

(II) recommendations for additional assistance, if any, needed by Tribal law enforcement agencies relating to the strategy, including an evaluation of Federal technical and financial assistance, infrastructure capacity building, and interoperability deficiencies.

(4) CLASSIFIED INFORMATION.—Any contents of the National Drug Control Strategy that involve information properly classified under criteria established by an executive order shall be presented to Congress separately from the rest of the National Drug Control Strategy.

(5) SELECTION OF DATA AND INFORMATION.—In selecting data and information for inclusion in the National Drug Control Strategy, the Director shall ensure—

(A) the inclusion of data and information that will permit analysis of current trends against previously compiled data and information where the Director believes the analysis enhances long-term assessment of the National Drug Control Strategy; and

(B) the inclusion of data and information to permit a standardized and uniform assessment of the effectiveness of drug treatment programs in the United States.

(d) SUBMISSION OF REVISED NATIONAL DRUG CONTROL STRATEGY.—The President may submit to Congress a revised National Drug Control Strategy that meets the requirements of this section—

(1) at any time, on a determination of the President, in consultation with the Director, that the National Drug Control Strategy in effect is not sufficiently effective; or

(2) if a new President or Director takes office.

(e) FAILURE OF DIRECTOR TO SUBMIT NATIONAL DRUG CONTROL STRATEGY.—If the Director does not submit a National Drug Control Strategy to Congress in accordance with subsection (a)(2), not later than 5 days after the first Monday in February following the year in which the term of the President commences, the Director shall send a notification to the appropriate congressional committees—

(1) explaining why the Strategy was not submitted; and

(2) specifying the date by which the Strategy will be submitted.

(f) DRUG CONTROL DATA DASHBOARD.—

(1) IN GENERAL.—The Director shall collect and disseminate, as appropriate, such information as the Director determines is appropriate, but not less than the information described in this subsection. The data shall be publicly available in a machine-readable format on the online portal of the Office, and to the extent practicable on the Drug Control Data Dashboard.

(2) ESTABLISHMENT.—The Director shall publish to the online portal of the Office in a machine-readable, sortable, and searchable format, or to the extent practicable, establish and maintain a data dashboard on the online portal of the Office to be known as the ''Drug Control Data Dashboard''. To the extent practicable, when establishing the Drug Control Data Dashboard, the Director shall ensure that the user interface of the dashboard is constructed with modern design standards. To the extent practicable, the data made available on the dashboard shall be publicly available in a machine-readable format and searchable by year, agency, drug, and location.

(3) DATA.—The data included in the Drug Control Data Dashboard shall be updated quarterly

to the extent practicable, but not less frequently than annually, and shall include, at a minimum, the following:

(A) For each substance identified by the Director as having a significant impact on the prevalence of illicit drug use—

(i) data sufficient to show the quantities of the substance available in the United States, including—

(I) the total amount seized and disrupted in the calendar year and each of the previous 3 calendar years, including to the extent practicable the amount seized by State, local, and Tribal governments;

(II) the known and estimated flows into the United States from all sources in the calendar year and each of the previous 3 calendar years;

(III) the total amount of known flows that could not be interdicted or disrupted in the calendar year and each of the previous 3 calendar years;

(IV) the known and estimated levels of domestic production in the

calendar year and each of the previous 3 calendar years, including the levels of domestic production if the drug is a prescription drug, as determined under subtitle I of this title, for which a listing is in effect under section 50302 of this title;

(V) the average street price for the calendar year and the highest known street price during the preceding 10-year period; and

(VI) to the extent practicable, related prosecutions by State, local, and Tribal governments; and

(ii) data sufficient to show the frequency of use of the substance, including—

(I) use of the substance in the workplace and productivity lost by the use;

(II) use of the substance by arrestees, probationers, and parolees;

(III) crime and criminal activity related to the substance; and

(IV) to the extent practicable, related prosecutions by State, local, and Tribal governments.

(B) For the calendar year and each of the previous 3 years, data sufficient to show, disaggregated by State and, to the extent feasible, by region within a State, county, or city, the following:

(i) The number of fatal and non-fatal overdoses caused by each drug identified under subparagraph (A)(i).

(ii) The prevalence of substance use disorders.

(iii) The number of individuals who have received substance use disorder treatment, including medication assisted treatment, for a substance use disorder, including treatment provided through publicly financed health care programs.

(iv) The extent of the unmet need for substance use disorder treatment, including the unmet need for medication-assisted treatment.

(C) Data sufficient to show the extent of prescription drug diversion, trafficking, and

misuse in the calendar year and each of the previous 3 calendar years.

(D) Any quantifiable measures the Director determines to be appropriate to detail progress toward the achievement of the goals of the National Drug Control Strategy.

(g) DEVELOPMENT OF AN ANNUAL NATIONAL DRUG CONTROL ASSESSMENT.—

(1) TIMING.—Not later than the first Monday in February of each year, the Director shall submit to the President, Congress, and the appropriate congressional committees, a report assessing the progress of each National Drug Control Program agency toward achieving each goal, objective, and target contained in the National Drug Control Strategy applicable to the prior fiscal year.

(2) PROCESS FOR DEVELOPMENT OF THE ANNUAL ASSESSMENT.—Not later than November 1 of each year, the head of each National Drug Control Program agency shall submit, in accordance with guidance issued by the Director, to the Director an evaluation of progress by the National Drug Control Program agency with respect to the National Drug Control Strategy goals using the performance measures for the National Drug Control Program agency

developed under this chapter, including progress with respect to—

(A) success in achieving the goals of the National Drug Control Strategy;

(B) success in reducing domestic and foreign sources of illegal drugs;

(C) success in expanding access to and increasing the effectiveness of substance use disorder treatment;

(D) success in protecting the borders of the United States (and in particular the Southwestern border of the United States) from penetration by illegal narcotics;

(E) success in reducing crime associated with drug use in the United States;

(F) success in reducing the negative health and social consequences of drug use in the United States;

(G) implementation of evidence-based substance use disorder treatment and prevention programs in the United States and improvements in the adequacy and effectiveness of the programs; and

(H) success in increasing the prevention of illicit drug use.

(3) CONTENTS OF THE ANNUAL ASSESSMENT.—The Director shall include in the annual assessment required under paragraph (1)—

(A) a summary of each evaluation received by the Director under paragraph (2);

(B) a summary of the progress of each National Drug Control Program agency toward the National Drug Control Strategy goals of the National Drug Control Program agency using the performance measures for the National Drug Control Program agency developed under this chapter; and

(C) an assessment of the effectiveness of each National Drug Control Program agency and National Drug Control Program in achieving the National Drug Control Strategy for the previous year, including a specific evaluation of whether the applicable goals, measures, objectives, and targets for the previous year were met.

(4) BASIS.—The assessments required under this subsection shall be based on the performance measurement system described in subsection (h).

(h) PERFORMANCE MEASUREMENT SYSTEM.—Not later than February 1 of each year, the Director shall sub-

mit to Congress, as part of the National Drug Control Strategy, a description of a national drug control performance measurement system, that—

(1) develops 2-year and 5-year performance measures and targets for each National Drug Control Strategy goal and objective established for reducing drug use, availability, and the consequences of drug use;

(2) describes the sources of information and data that will be used for each performance measure incorporated into the performance measurement system;

(3) identifies major programs and activities of the National Drug Control Program agencies that support the goals and annual objectives of the National Drug Control Strategy;

(4) evaluates the contribution of demand reduction and supply reduction implemented by each National Drug Control Program agency in support of the National Drug Control Strategy;

(5) monitors consistency between the drug-related goals and objectives of the National Drug Control Program agencies and ensures that each agency's goals and budgets support and are fully consistent with the National Drug Control Strategy;

(6) coordinates the development and implementation of national drug control data collection and reporting systems to support policy formulation and performance measurement, including an assessment of—

(A) the quality of current drug use measurement instruments and techniques to measure supply reduction and demand reduction;

(B) the adequacy of the coverage of existing national drug use measurement instruments and techniques to measure the illicit drug user population, and groups that are at risk for illicit drug use;

(C) the adequacy of the coverage of existing national treatment outcome monitoring systems to measure the effectiveness of drug abuse treatment in reducing illicit drug use and criminal behavior during and after the completion of substance abuse treatment; and

(D) the actions the Director shall take to correct any deficiencies and limitations identified pursuant to subparagraphs (A) and (B); and

(7) develops performance measures and targets for the National Drug Control Strategy for supple-

mental strategies (the Southwest Border, Northern Border, and Caribbean Border Counternarcotics Strategies) to effectively evaluate region-specific goals, and to the extent the performance measurement system does not adequately measure the effectiveness of the supplemental strategies, as determined by the Director, those strategies may evaluate interdiction efforts at and between ports of entry, interdiction technology, intelligence sharing, diplomacy, and other appropriate metrics, specific to each supplemental strategies region, as determined by the Director.

(i) MODIFICATIONS.—A description of any modifications made during the preceding year to the national drug performance measurement system described in subsection (h) shall be included in each report submitted under subsection (g).

**§ 60906. High Intensity Drug Trafficking Areas Program**

(a) DEFINITIONS.—In this section:

(1) HIDTA.—The term ''HIDTA'' means high intensity drug trafficking area.

(2) PROGRAM.—The term ''Program'' means the High Intensity Drug Trafficking Areas Program established under subsection (b).

(b) ESTABLISHMENT.—

(1) IN GENERAL.—There is established in the Office a program to be known as the High Intensity Drug Trafficking Areas Program.

(2) PURPOSE.—The purpose of the Program is to reduce drug trafficking and drug production in the United States by—

(A) facilitating cooperation among Federal, State, local, and tribal law enforcement agencies to share information and implement coordinated enforcement activities;

(B) enhancing law enforcement intelligence sharing among Federal, State, local, and tribal law enforcement agencies;

(C) providing reliable law enforcement intelligence to law enforcement agencies needed to design effective enforcement strategies and operations; and

(D) supporting coordinated law enforcement strategies that maximize use of available resources to reduce the supply of illegal drugs in designated areas and in the United States as a whole.

(c) DESIGNATION.—

(1) IN GENERAL.—The Director, in consultation with the Attorney General, the Secretary of the Treasury, the Secretary of Homeland Security, heads of the National Drug Control Program agencies, and the Governor of each applicable State, may designate any specified area of the United States as a HIDTA.

(2) ACTIVITIES.—After making a designation under paragraph (1) and to provide Federal assistance to the area so designated, the Director may—

(A) obligate such sums as are appropriated for the Program;

(B) direct the temporary reassignment of Federal personnel to the area, subject to the approval of the head of the department or agency that employs the personnel;

(C) take any other action authorized under section 60903 of this title to provide increased Federal assistance to those areas; and

(D) coordinate activities under this section (specifically administrative, recordkeeping, and funds management activities) with State, local, and tribal officials.

(d) PETITIONS FOR DESIGNATION.—The Director shall establish regulations under which a coalition of inter-

ested law enforcement agencies from an area may petition for designation as a HIDTA. The regulations shall provide for a regular review by the Director of the petition, including a recommendation regarding the merit of the petition to the Director by a panel of qualified, independent experts.

(e) FACTORS FOR CONSIDERATION.—In considering whether to designate an area under this section as a HIDTA, the Director shall consider, in addition to such other criteria as the Director considers to be appropriate, the extent to which—

(1) the area is a significant center of illegal drug production, manufacturing, importation, or distribution;

(2) State, local, and tribal law enforcement agencies have committed resources to respond to the drug trafficking problem in the area, thereby indicating a determination to respond aggressively to the problem;

(3) drug-related activities in the area are having a significant harmful impact in the area, and in other areas of the country; and

(4) a significant increase in allocation of Federal resources is necessary to respond adequately to drug-related activities in the area.

(f) ORGANIZATION OF HIDTAS.—

(1) EXECUTIVE BOARD AND OFFICERS.—To be eligible for funds appropriated under this section, each HIDTA shall be governed by an Executive Board. The Executive Board shall designate a chairman, vice chairman, and any other officers to the Executive Board that it determines are necessary.

(2) RESPONSIBILITIES.—The Executive Board of a HIDTA shall be responsible for—

(A) providing direction and oversight in establishing and achieving the goals of the HIDTA;

(B) managing the funds of the HIDTA;

(C) reviewing and approving all funding proposals consistent with the overall objective of the HIDTA; and

(D) reviewing and approving all reports to the Director on the activities of the HIDTA.

(3) BOARD REPRESENTATION.—None of the funds appropriated under this section may be expended for any HIDTA, or for a partnership or region of a HIDTA, if the Executive Board for the HIDTA, region, or partnership, does not apportion an equal number of votes between representatives of participating Federal agencies and representatives of

participating State, local, and tribal agencies. Where it is impractical for an equal number of representatives of Federal agencies and State, local, and tribal agencies to attend a meeting of an Executive Board in person, the Executive Board may use a system of proxy votes or weighted votes to achieve the voting balance required by this paragraph.

(4) NO AGENCY RELATIONSHIP.—The eligibility requirements of this section are intended to ensure the responsible use of Federal funds. Nothing in this section is intended to create an agency relationship between individual HIDTAs and the Federal Government.

(g) USE OF FUNDS.—The Director shall ensure that not more than a total of 5 percent of Federal funds appropriated for the Program are expended for substance use disorder treatment programs and drug prevention programs.

(h) COUNTERTERRORISM ACTIVITIES.—

(1) ASSISTANCE AUTHORIZED.—The Director may authorize use of resources available for the Program to assist Federal, State, local, and tribal law enforcement agencies in investigations and activities related to terrorism and prevention of terrorism, especially but not exclusively with respect to the inves-

tigations and activities that are also related to drug trafficking.

(2) LIMITATION.—The Director shall ensure—

(A) that assistance provided under paragraph (1) remains incidental to the purpose of the Program to reduce drug availability and carry out drug-related law enforcement activities; and

(B) that significant resources of the Program are not redirected to activities exclusively related to terrorism, except on a temporary basis under extraordinary circumstances, as determined by the Director.

(i) ROLE OF DRUG ENFORCEMENT ADMINISTRATION.—The Director, in consultation with the Attorney General, shall ensure that a representative of the Drug Enforcement Administration is included in the Intelligence Support Center for each HIDTA.

(j) ANNUAL HIDTA PROGRAM BUDGET SUBMISSIONS.—As part of the documentation that supports the President's annual budget request for the Office, the Director shall submit to Congress a budget justification that includes—

(1) the amount proposed for each HIDTA, conditional on a review by the Office of the request sub-

mitted by the HIDTA and the performance of the HIDTA, with supporting narrative descriptions and rationale for each request;

(2) a detailed justification that explains—

(A) the reasons for the proposed funding level (including how the funding level was determined based on a current assessment of the drug trafficking threat in each HIDTA);

(B) how the funding will ensure that the goals and objectives of each such area will be achieved; and

(C) how the funding supports the National Drug Control Strategy; and

(3) the amount of HIDTA funds used to investigate and prosecute organizations and individuals trafficking in methamphetamine in the prior calendar year, and a description of how those funds were used.

(k) EMERGING THREAT RESPONSE FUND.—

(1) IN GENERAL.—Subject to the availability of appropriations, the Director may expend up to 10 percent of the amounts appropriated under this section on a discretionary basis, to respond to any emerging drug trafficking threat in an existing HIDTA, or to establish a new HIDTA or expand an

existing HIDTA, in accordance with the criteria established under paragraph (2).

(2) CONSIDERATION OF IMPACT.—In allocating funds under this subsection, the Director shall consider—

(A) the impact of activities funded on reducing overall drug traffic in the United States, or minimizing the probability that an emerging drug trafficking threat will spread to other areas of the United States; and

(B) such other criteria as the Director considers appropriate.

(l) EVALUATION OF HIDTA PROGRAM AS PART OF NATIONAL DRUG CONTROL STRATEGY.—For each designated HIDTA, the Director shall submit, as part of the annual National Drug Control Strategy report, a report that—

(1) describes—

(A) the specific purposes for the HIDTA; and

(B) the specific long-term and short-term goals and objectives for the HIDTA; and

(2) includes an evaluation of the performance of the HIDTA in accomplishing the specific long-term and short-term goals and objectives identified under

section 707(k)(1)(B) of the Office of National Drug Control Policy Reauthorization Act of 1988, as amended by section 301 of the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469, 120 Stat. 3522).

(m) ASSESSMENT OF DRUG ENFORCEMENT TASK FORCES IN HIDTAS.—As part of each annual National Drug Control Strategy report, the Director shall submit to Congress a report—

(1) assessing the number and operation of all federally funded drug enforcement task forces within each HIDTA; and

(2) describing—

(A) each Federal, State, local, and tribal drug enforcement task force operating in the HIDTA;

(B) how the task forces coordinate with each other, with any HIDTA task force, and with investigations receiving funds from the Organized Crime and Drug Enforcement Task Force;

(C) what steps, if any, each task force takes to share information regarding drug trafficking and drug production with other federally

funded drug enforcement task forces in the HIDTA;

(D) the role of the HIDTA in coordinating the sharing of the information among task forces;

(E) the nature and extent of cooperation by each Federal, State, local, and tribal participant in ensuring that the information is shared among law enforcement agencies and with the HIDTA;

(F) the nature and extent to which information sharing and enforcement activities are coordinated with joint terrorism task forces in the HIDTA; and

(G) any recommendations for measures needed to ensure that task force resources are utilized efficiently and effectively to reduce the availability of illegal drugs in the HIDTAs.

(n) ASSESSMENT OF LAW ENFORCEMENT INTELLIGENCE SHARING IN THE PROGRAM.—As part of each annual National Drug Control Strategy report, the Director, in consultation with the Director of National Intelligence, shall submit to Congress a report evaluating—

(1) existing and planned law enforcement intelligence systems supported by each HIDTA, or uti-

lized by task forces receiving any funding under the Program, including the extent to which the systems ensure access and availability of law enforcement intelligence to Federal, State, local, and tribal law enforcement agencies within the HIDTA and outside of it;

(2) the extent to which Federal, State, local, and tribal law enforcement agencies participating in each HIDTA are sharing law enforcement intelligence information to assess current drug trafficking threats and design appropriate enforcement strategies; and

(3) the measures needed to improve effective sharing of information and law enforcement intelligence regarding drug trafficking and drug production among Federal, State, local, and tribal law enforcement participating in a HIDTA, and between the agencies and similar agencies outside the HIDTA.

(o) COORDINATION OF LAW ENFORCEMENT INTELLIGENCE SHARING WITH ORGANIZED CRIME DRUG ENFORCEMENT TASK FORCE PROGRAM.—The Director, in consultation with the Attorney General, shall ensure that any drug enforcement intelligence obtained by the Intelligence Support Center for each HIDTA is shared, on a

timely basis, with the drug intelligence fusion center operated by the Organized Crime Drug Enforcement Task Force of the Department of Justice.

(p) USE OF FUNDS TO COMBAT METHAMPHETAMINE TRAFFICKING.—

(1) REQUIREMENT.—As part of the documentation that supports the President's annual budget request for the Office, the Director shall submit to Congress a report describing the use of HIDTA funds to investigate and prosecute organizations and individuals trafficking in methamphetamine in the prior calendar year.

(2) CONTENTS.—The report shall include—

(A) the number of methamphetamine manufacturing facilities discovered through HIDTA-funded initiatives in the previous fiscal year;

(B) the amounts of methamphetamine or listed chemicals (as that term is defined in section 50101 of this title) seized by HIDTA-funded initiatives in the area during the previous year; and

(C) law enforcement intelligence and predictive data from the Drug Enforcement Administration showing patterns and trends in

abuse, trafficking, and transportation in methamphetamine and listed chemicals.

(3) CERTIFICATION.—Before the Director awards any funds to a HIDTA, the Director shall certify that the law enforcement entities participating in that HIDTA are providing laboratory seizure data to the national clandestine laboratory database at the El Paso Intelligence Center.

(q) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office to carry out this section $280,000,000 for fiscal year 2023.

(r) SPECIFIC PURPOSES.—

(1) IN GENERAL.—The Director shall ensure that, of the amounts appropriated for a fiscal year for the Program, at least $7,000,000 is used in HIDTAs with severe neighborhood safety and illegal drug distribution problems.

(2) REQUIRED USES.—The funds used under paragraph (1) shall be used to ensure the safety of neighborhoods and the protection of communities, including the prevention of the intimidation of witnesses of illegal drug distribution and related activities and the establishment of, or support for, programs that provide protection or assistance to witnesses in court proceedings.

(3) BEST PRACTICE MODELS.—The Director shall work with HIDTAs to develop and maintain best practice models to assist State, local, and tribal governments in addressing witness safety, relocation, financial and housing assistance, or any other services related to witness protection or assistance in cases of illegal drug distribution and related activities. The Director shall ensure dissemination of the best practice models to each HIDTA.

(s) DRUG OVERDOSE RESPONSE STRATEGY IMPLEMENTATION.—The Director may use funds appropriated to carry out this section to implement a drug overdose response strategy in HIDTAs on a nationwide basis by—

(1) coordinating multi-disciplinary efforts to prevent, reduce, and respond to drug overdoses, including the uniform reporting of fatal and non-fatal overdoses to public health and safety officials;

(2) increasing data sharing among public safety and public health officials concerning drug-related abuse trends, including new psychoactive substances, and related crime; and

(3) enabling collaborative deployment of prevention, intervention, and enforcement resources to address substance use addiction and narcotics trafficking.

(t) SUPPLEMENTAL GRANTS.—The Director is authorized to use not more than $10,000,000 of the amounts otherwise appropriated to carry out this section to provide supplemental competitive grants to HIDTAs that have experienced high seizures of fentanyl and new psychoactive substances for the purposes of—

(1) purchasing portable equipment to test for fentanyl and other substances;

(2) training law enforcement officers and other first responders on best practices for handling fentanyl and other substances; and

(3) purchasing protective equipment, including overdose reversal drugs.

**§ 60907. Emerging Threats Committee, Emerging Threat Response Plans, and media campaign**

(a) EMERGING AND CONTINUING THREATS COORDINATOR.—The Director shall designate or appoint a United States Emerging and Continuing Threats Coordinator to perform the duties of that position described in this section and such other duties as may be determined by the Director. For purposes of carrying out the previous sentence, the Director shall designate or appoint an appointee in the Senior Executive Service or an appointee in a position at level 15 of the General Schedule (or equivalent).

(b) EMERGING THREATS COMMITTEE.—

(1) IN GENERAL.—The Emerging Threats Committee shall—

(A) monitor evolving and emerging drug threats in the United States;

(B) identify and discuss evolving and emerging drug trends in the United States using the criteria required to be established under paragraph (6);

(C) assist in the formulation and oversee implementation of any Emerging Threat Response Plan described in subsection (d);

(D) provide such other advice to the Emerging and Continuing Threats Coordinator and Director concerning strategy and policies for emerging drug threats and trends as the Emerging Threats Committee determines to be appropriate; and

(E) disseminate, and facilitate the sharing with Federal, State, local, and Tribal officials and other entities (as determined by the Director) of, pertinent information and data relating to—

(i) recent trends in drug supply and demand;

(ii) fatal and nonfatal overdoses;

(iii) demand for and availability of evidence-based substance use disorder treatment, including the extent of the unmet treatment need, and treatment admission trends;

(iv) recent trends in drug interdiction, supply, and demand from State, local, and Tribal law enforcement agencies; and

(v) other subject matter as determined necessary by the Director.

(2) CHAIRPERSON.—The Director shall designate one of the members of the Emerging Threats Committee to serve as Chairperson.

(3) MEMBERS.—The Director shall appoint other members of the Committee, which shall include—

(A) representatives from National Drug Control Program agencies or other agencies;

(B) representatives from State, local, and Tribal governments; and

(C) representatives from other entities as designated by the Director.

(4) MEETINGS.—The members of the Emerging Threats Committee shall meet, in person and not

through any delegate or representative, not less frequently than once per calendar year, before June 1. At the call of the Director or the Chairperson, the Emerging Threats Committee may hold additional meetings as the members may choose.

(5) CONTRACT, AGREEMENT, AND OTHER AUTHORITY.—The Director may award contracts, enter into interagency agreements, manage individual projects, and conduct other activities in support of the identification of emerging drug threats and in support of the development, implementation, and assessment of any Emerging Threat Response Plan.

(6) CRITERIA TO IDENTIFY EMERGING DRUG THREATS.—The Emerging Threats Committee shall develop and recommend to the Director criteria to be used to identify an emerging drug threat or the termination of an emerging drug threat designation based on information gathered by the Emerging Threats Committee, statistical data, and other evidence.

(c) DESIGNATION.—

(1) IN GENERAL.—The Director, in consultation with the Emerging and Continuing Threats Coordinator, the Emerging Threats Committee, and the head of each National Drug Control Program

agency, may designate an emerging drug threat in the United States.

(2) STANDARDS FOR DESIGNATION.—The Director, in consultation with the Emerging and Continuing Threats Coordinator, shall promulgate and make publicly available standards by which a designation under paragraph (1) and the termination of the designation may be made. In developing the standards, the Director shall consider the recommendations of the Emerging Threats Committee and other criteria the Director considers to be appropriate.

(3) PUBLIC STATEMENT REQUIRED.—The Director shall publish a public written statement on the portal of the Office explaining the designation of an emerging drug threat or the termination of the designation and shall notify the appropriate congressional committees of the availability of the statement when a designation or termination of the designation has been made.

(d) EMERGING THREAT RESPONSE PLAN.—

(1) PUBLIC AVAILABILITY OF PLAN.—Not later than 90 days after making a designation under subsection (c), the Director shall publish and make publicly available an Emerging Threat Response Plan

and notify the President and the appropriate congressional committees of the Emerging Threat Response Plan's availability.

(2) TIMING.—Concurrently with the annual submissions under section 60905(g) of this title, the Director shall update the Emerging Threat Response Plan and report on implementation of the Emerging Threat Response Plan, until the Director issues the public statement required under subsection (c)(3) to terminate the emerging drug threat designation.

(3) CONTENTS OF AN EMERGING THREAT RESPONSE PLAN.—The Director shall include in the Emerging Threat Response Plan required under this subsection—

(A) a comprehensive strategic assessment of the emerging drug threat, including the current availability of, demand for, and effectiveness of evidence-based prevention, treatment, and enforcement programs and efforts to respond to the emerging drug threat;

(B) comprehensive, research-based, short-term and long-term, and quantifiable goals for addressing the emerging drug threat, including for reducing the supply of the drug designated

as the emerging drug threat and for expanding the availability and effectiveness of evidence-based substance use disorder treatment and prevention programs to reduce the demand for the emerging drug threat;

(C) performance measures pertaining to the Emerging Threat Response Plan's goals, including quantifiable and measurable objectives and specific targets;

(D) the level of funding needed to implement the Emerging Threat Response Plan, including whether funding is available to be reprogrammed or transferred to support implementation of the Emerging Threat Response Plan or whether additional appropriations are necessary to implement the Emerging Threat Response Plan;

(E) an implementation strategy for the media campaign under subsection (f), including goals as described under subparagraph (B) and performance measures, objectives, and targets, as described under subparagraph (C); and

(F) any other information necessary to inform the public of the status, progress, or response to an emerging drug threat.

(4) IMPLEMENTATION.—

(A) IN GENERAL.—Not later than 120 days after the date on which a designation is made under subsection (c), the Director, in consultation with the President, the appropriate congressional committees, and the head of each National Drug Control Program agency, shall issue guidance on implementation of the Emerging Threat Response Plan described in this subsection to the National Drug Control Program agencies and any other relevant agency determined to be necessary by the Director.

(B) EMERGING AND CONTINUING THREATS COORDINATOR'S RESPONSIBILITIES.—The Emerging and Continuing Threats Coordinator shall—

(i) direct the implementation of the plan among the agencies identified in the Emerging Threat Response Plan, State, local, and Tribal governments, and other relevant entities;

(ii) facilitate information-sharing between agencies identified in the Emerging Threat Response Plan, State, local, and

Tribal governments, and other relevant entities; and

(iii) monitor implementation of the Emerging Threat Response Plan by coordinating the development and implementation of collection and reporting systems to support performance measurement and adherence to the Emerging Threat Response Plan by agencies identified in the Emerging Threat Response Plan, where appropriate.

(C) REPORTING.—Not later than 180 days after the date on which a designation is made under subsection (c) and in accordance with subparagraph (A), the head of each agency identified in the Emerging Threat Response Plan shall submit to the Emerging and Continuing Threats Coordinator a report on implementation of the Emerging Threat Response Plan.

(e) EVALUATION OF MEDIA CAMPAIGN.—On designation of an emerging drug threat, the Director shall evaluate whether a media campaign would be appropriate to address that threat.

(f) NATIONAL ANTI-DRUG MEDIA CAMPAIGN.—

(1) IN GENERAL.—The Director shall, to the extent feasible and appropriate, conduct a national anti-drug media campaign (referred to in this subsection as the ''national media campaign'') in accordance with this subsection for the purposes of—

(A) preventing substance abuse among people in the United States;

(B) educating the public about the dangers and negative consequences of substance use and abuse, including patient and family education about the characteristics and hazards of substance abuse and methods to safeguard against substance use, to include the safe disposal of prescription medications;

(C) supporting evidence-based prevention programs targeting the attitudes, perception, and beliefs of persons concerning substance use and intentions to initiate or continue the use;

(D) encouraging individuals affected by substance use disorders to seek treatment and providing the individuals with information on—

(i) how to recognize addiction issues;

(ii) what forms of evidence-based treatment options are available; and

(iii) how to access the treatment;

(E) combating the stigma of addiction and substance use disorders, including the stigma of treating the disorders with medication-assisted treatment therapies; and

(F) informing the public about the dangers of any drug identified by the Director as an emerging drug threat as appropriate.

(2) USE OF FUNDS.—

(A) IN GENERAL.—Amounts made available to carry out this subsection for the national media campaign may be used only for the following:

(i) The purchase of media time and space, including the strategic planning for, tracking, and accounting of, any such purchase.

(ii) Creative and talent costs, consistent with subparagraph (B)(i).

(iii) Advertising production costs, which may include television, radio, internet, social media, and other commercial marketing venues.

(iv) Testing and evaluation of advertising.

(v) Evaluation of the effectiveness of the national media campaign.

(vi) Costs of contracts to carry out activities authorized by this subsection.

(vii) Partnerships with professional and civic groups, community-based organizations, including faith-based organizations, and government organizations related to the national media campaign.

(viii) Entertainment industry outreach, interactive outreach, media projects and activities, public information, news media outreach, and corporate sponsorship and participation.

(ix) Operational and management expenses.

(B) SPECIFIC REQUIREMENTS.—

(i) CREATIVE SERVICES.—In using amounts for creative and talent costs under subparagraph (A)(ii), the Director shall use creative services donated at no cost to the Government wherever feasible and may procure creative services only for advertising—

(I) responding to high-priority or emergent campaign needs that cannot timely be obtained at no cost; or

(II) intended to reach a minority, ethnic, or other special audience that cannot reasonably be obtained at no cost.

(ii) TESTING AND EVALUATION OF ADVERTISING.—In using amounts for testing and evaluation of advertising under subparagraph (A)(iv), the Director shall test all advertisements prior to use in the national media campaign to ensure that the advertisements are effective with the target audience and meet industry-accepted standards. The Director may waive this requirement for advertisements using no more than 10 percent of the purchase of advertising time purchased under this subsection in a fiscal year and no more than 10 percent of the advertising space purchased under this subsection in a fiscal year, if the advertisements respond to emergent and time-sensitive campaign needs or the advertisements will not be

widely utilized in the national media campaign.

(iii) CONSULTATION.—For the planning of the campaign under paragraph (1), the Director may consult with—

(I) the head of any appropriate National Drug Control Program agency;

(II) experts on the designated drug;

(III) State, local, and Tribal government officials and relevant agencies;

(IV) communications professionals;

(V) the public; and

(VI) appropriate congressional committees.

(iv) EVALUATION OF EFFECTIVENESS OF NATIONAL MEDIA CAMPAIGN.—In using amounts for the evaluation of the effectiveness of the national media campaign under subparagraph (A)(v), the Director shall—

(I) designate an independent entity to evaluate by April 20 of each

year the effectiveness of the national media campaign based on data from—

(aa) the Monitoring the Future Study published by the Department of Health and Human Services;

(bb) the National Survey on Drug Use and Health; and

(cc) other relevant studies or publications, as determined by the Director, including tracking and evaluation data collected according to marketing and advertising industry standards; and

(II) ensure that the effectiveness of the national media campaign is evaluated in a manner that enables consideration of whether the national media campaign has contributed to changes in attitude or behaviors among the target audience with respect to substance use and such other measures of evaluation as the Director determines are appropriate.

(3) ADVERTISING.—In carrying out this subsection, the Director shall ensure that sufficient funds are allocated to meet the stated goals of the national media campaign.

(4) RESPONSIBILITIES AND FUNCTIONS UNDER THE PROGRAM.—

(A) IN GENERAL.—The Director shall determine the overall purposes and strategy of the national media campaign.

(B) DIRECTOR.—

(i) IN GENERAL.—The Director shall approve—

(I) the strategy of the national media campaign;

(II) all advertising and promotional material used in the national media campaign; and

(III) the plan for the purchase of advertising time and space for the national media campaign.

(ii) IMPLEMENTATION.—The Director shall be responsible for implementing a focused national media campaign to meet the purposes set forth in paragraph (1) and shall ensure that—

(I) information disseminated through the campaign is accurate and scientifically valid; and

(II) the campaign is designed using strategies demonstrated to be the most effective at achieving the goals and requirements of paragraph (1), which may include—

(aa) a media campaign, as described in paragraph (2);

(bb) local-specific, regional-specific, or population-specific messaging;

(cc) the development of websites to publicize and disseminate information;

(dd) conducting outreach and providing educational resources for parents;

(ee) collaborating with law enforcement agencies; and

(ff) providing support for school-based public health education classes to improve teen

knowledge about the effects of substance use.

(5) PROHIBITIONS.—None of the amounts made available under paragraph (2) may be obligated or expended for any of the following:

(A) To supplant current anti-drug community-based coalitions.

(B) To supplant pro bono public service time donated by national and local broadcasting networks for other public service campaigns.

(C) For partisan political purposes, or to express advocacy in support of or to defeat any clearly identified candidate, clearly identified ballot initiative, or clearly identified legislative or regulatory proposal.

(D) To fund advertising that features any elected officials, individuals seeking elected office, cabinet level officials, or other Federal officials employed pursuant to Schedule C under subpart C of part 213 of title 5, Code of Federal Regulations.

(E) To fund advertising that does not contain a primary message intended to reduce or prevent substance use.

(F) To fund advertising containing a primary message intended to promote support for the national media campaign or private sector contributions to the national media campaign.

(6) MATCHING REQUIREMENT.—

(A) IN GENERAL.—Amounts made available under paragraph (2) for media time and space shall be matched by an equal amount of non-Federal funds for the national media campaign, or be matched with in-kind contributions of the same value.

(B) NO-COST MATCH ADVERTISING DIRECT RELATIONSHIP REQUIREMENT.—The Director shall ensure that not less than 85 percent of no-cost match advertising directly relates to substance abuse prevention consistent with the specific purposes of the national media campaign.

(C) NO-COST MATCH ADVERTISING NOT DIRECTLY RELATED.—The Director shall ensure that no-cost match advertising that does not directly relate to substance abuse prevention consistent with the purposes of the national media campaign includes a clear anti-drug message.

The anti-drug message is not required to be the primary message of the match advertising.

(7) FINANCIAL AND PERFORMANCE ACCOUNTABILITY.—The Director shall cause to be performed—

(A) audits and reviews of costs of the national media campaign pursuant to section 4706 of title 41; and

(B) an audit to determine whether the costs of the national media campaign are allowable under chapter 43 of title 41.

(8) REPORT TO CONGRESS.—The Director shall submit on an annual basis a report to Congress that describes—

(A) the strategy of the national media campaign and whether specific objectives of the national media campaign were accomplished;

(B) steps taken to ensure that the national media campaign operates in an effective and efficient manner consistent with the overall strategy and focus of the national media campaign;

(C) plans to purchase advertising time and space;

(D) policies and practices implemented to ensure that Federal funds are used responsibly

to purchase advertising time and space and eliminate the potential for waste, fraud, and abuse;

(E) all contracts entered into with a corporation, partnership, or individual working on behalf of the national media campaign;

(F) the results of any financial audit of the national media campaign;

(G) a description of any evidence used to develop the national media campaign;

(H) specific policies and steps implemented to ensure compliance with this section;

(I) a detailed accounting of the amount of funds obligated during the previous fiscal year for carrying out the national media campaign, including each recipient of funds, the purpose of each expenditure, the amount of each expenditure, any available outcome information, and any other information necessary to provide a complete accounting of the funds expended; and

(J) a review and evaluation of the effectiveness of the national media campaign strategy for the past year.

(9) REQUIRED NOTICE FOR COMMUNICATION FROM THE OFFICE.—Any communication, including an advertisement, paid for or otherwise disseminated by the Office directly or through a contract awarded by the Office shall include a prominent notice informing the audience that the communication was paid for by the Office.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office to carry out this section $25,000,000 for fiscal year 2023.

**§ 60908. United States Interdiction Coordinator and Interdiction Committee**

(a) UNITED STATES INTERDICTION COORDINATOR.—

(1) IN GENERAL.—The Director shall designate or appoint an appointee in the Senior Executive Service or an appointee in a position at level 15 of the General Schedule (or equivalent) as the United States Interdiction Coordinator to perform the duties of that position described in paragraph (2) and such other duties as may be determined by the Director with respect to coordination of efforts to interdict illicit drugs from entering the United States.

(2) RESPONSIBILITIES.—The United States Interdiction Coordinator shall be responsible to the Director for—

(A) coordinating the interdiction activities of the National Drug Control Program Agencies to ensure consistency with the National Drug Control Strategy;

(B) on behalf of the Director, developing and issuing, on or before September 1 of each year and in accordance with paragraph (4), a National Interdiction Command and Control Plan to ensure the coordination and consistency described in subparagraph (A);

(C) assessing the sufficiency of assets committed to illicit drug interdiction by the relevant National Drug Control Program Agencies; and

(D) advising the Director on the efforts of each National Drug Control Program Agency to implement the National Interdiction Command and Control Plan.

(3) STAFF.—The Director shall assign such permanent staff of the Office as the Director considers appropriate to assist the United States Interdiction Coordinator to carry out the responsibilities described in paragraph (2), and may request that

appropriate National Drug Control Program Agencies detail or assign staff to assist in carrying out the responsibilities.

(4) NATIONAL INTERDICTION COMMAND AND CONTROL PLAN.—

(A) PURPOSES.—The National Interdiction Command and Control Plan shall—

(i) set forth the Government's strategy for drug interdiction;

(ii) state the specific roles and responsibilities of the relevant National Drug Control Program Agencies for implementing that strategy; and

(iii) identify the specific resources required to enable the relevant National Drug Control Program Agencies to implement that strategy.

(B) CONSULTATION WITH OTHER AGENCIES.—Before submission of the National Drug Control Strategy or annual assessment required under section 60905 of this title, as applicable, the United States Interdiction Coordinator shall issue the National Interdiction Command and Control Plan in consultation with the other

members of the Interdiction Committee described in subsection (b).

(C) REPORT TO CONGRESS.—On or before September 1 of each year, the Director, acting through the United States Interdiction Coordinator, shall provide to the appropriate congressional committees, to the Committee on Armed Services and the Committee on Homeland Security of the House of Representatives, and to the Committee on Homeland Security and Governmental Affairs and the Committee on Armed Services of the Senate a report that—

(i) includes—

(I) a copy of that year's National Interdiction Command and Control Plan, including information about how each National Drug Control Program Agency conducting drug interdiction activities is engaging with relevant international partners;

(II) information for the previous 10 years regarding the number and type of seizures of drugs by each National Drug Control Program Agency conducting drug interdiction activities

and statistical information on the geographic areas of the seizures; and

(III) information for the previous 10 years regarding the number of air and maritime patrol hours undertaken by each National Drug Control Program Agency conducting drug interdiction activities and statistical information on the geographic areas in which the patrol hours took place; and

(ii) may include recommendations for changes to existing agency authorities or laws governing interagency relationships.

(D) CLASSIFIED ANNEX.—Each report required to be submitted under subparagraph (C) shall be in unclassified form, but may include a classified annex.

(b) INTERDICTION COMMITTEE.—

(1) IN GENERAL.—The Interdiction Committee shall meet to—

(A) discuss and resolve issues related to the coordination, oversight, and integration of international, border, and domestic drug interdiction efforts in support of the National Drug Control Strategy;

(B) review the annual National Interdiction Command and Control Plan, and provide advice to the Director and the United States Interdiction Coordinator concerning that Plan and how to strengthen international partnerships to better achieve the goals of that Plan; and

(C) provide such other advice to the Director concerning drug interdiction strategy and policies as the Interdiction Committee determines is appropriate.

(2) CHAIRPERSON.—The Director shall designate one of the members of the Interdiction Committee to serve as Chairperson.

(3) MEETINGS.—The members of the Interdiction Committee shall meet, in person and not through any delegate or representative, at least once per calendar year, before June 1. At the call of the Director or the Chairperson, the Interdiction Committee may hold additional meetings, which shall be attended by the members in person, or through such delegates or representatives as the members may choose.

(4) REPORT.—Not later than September 30 of each year, the Chairperson of the Interdiction Com-

mittee shall submit to the Director and to the appropriate congressional committees a report describing the results of the meetings and any significant findings of the Interdiction Committee during the previous 12 months. The report required under this paragraph shall be in unclassified form, but may include a classified annex.

(c) INTERNATIONAL COORDINATION.—The Director may facilitate international drug control coordination efforts.

**§ 60909. Requirement for disclosure of Federal sponsorship of all Federal advertising or other communication materials**

(a) DEFINITION OF ADVERTISEMENT OR OTHER COMMUNICATION.—In this section, the term ''advertisement or other communication'' includes—

(1) an advertisement disseminated in any form, including by print or any electronic means; and

(2) a communication by an individual in any form, including by speech, print, or any electronic means.

(b) REQUIREMENT.—Each advertisement or other communication paid for by the Office, either directly or through a contract awarded by the Office, shall include a prominent notice informing the target audience that the

advertisement or other communication is paid for by the Office.

**§ 60910. Authorization of appropriations**

There are authorized to be appropriated to carry out this chapter except activities otherwise specified, to remain available until expended, $18,400,000 for fiscal year 2023.

**§ 60911. Awards for demonstration programs by local partnerships to coerce abstinence in chronic hard-drug users under community supervision through the use of drug testing and sanctions**

(a) DEFINITION OF ELIGIBLE PARTNERSHIP.—In this section, the term ''eligible partnership'' means a working group whose application to the Director—

(1) identifies the roles played, and certifies the involvement of, 2 or more agencies or organizations, which may include—

(A) State, local, or tribal agencies (such as those carrying out police, probation, prosecution, courts, corrections, parole, or treatment functions);

(B) Federal agencies (such as the Drug Enforcement Agency, the Bureau of Alcohol, Tobacco, Firearms, and Explosives, and United States Attorney offices); and

(C) community-based organizations;

(2) includes a qualified researcher;

(3) includes a plan for using judicial or other criminal justice authority to administer drug tests to individuals described in subsection (b) at least twice a week, and to swiftly and certainly impose a known set of graduated sanctions for non-compliance with community-release provisions relating to drug abstinence (whether imposed as a pre-trial, probation, or parole condition or otherwise);

(4) includes a strategy for responding to a range of substance use and abuse problems and a range of criminal histories;

(5) includes a plan for integrating data infrastructure among the agencies and organizations included in the eligible partnership to enable seamless, real-time tracking of individuals described in subsection (b); and

(6) includes a plan to monitor and measure the progress toward reducing the percentage of the population of individuals described in subsection (b) who, on being summoned for a drug test, either fail to show up or test positive for drugs.

(b) AWARDS REQUIRED.—The Director shall make competitive awards to fund demonstration programs by el-

igible partnerships for the purpose of reducing the use of illicit drugs by chronic hard-drug users living in the community while under the supervision of the criminal justice system.

(c) USE OF AWARD AMOUNTS.—Award amounts received under this section shall be used—

(1) to support the efforts of the agencies, organizations, and researchers included in the eligible partnership;

(2) to develop and field a drug testing and graduated sanctions program for chronic hard-drug users living in the community under criminal justice supervision; and

(3) to assist individuals described in subsection (b) by strengthening rehabilitation efforts through such means as job training, drug treatment, or other services.

# Chapter 611—Foreign Narcotics Kingpin Designation

Sec.
61101. Definitions.
61102. Policy.
61103. Purpose.
61104. Public identification of significant foreign narcotics traffickers and required reports.
61105. Blocking assets and prohibiting transactions.
61106. Authorities.
61107. Penalties.

## § 61101. Definitions

In this chapter:

(1) CONTROLLED SUBSTANCE.—The term ''controlled substance'' has the meaning given the term in section 50101 of this title.

(2) ENTITY.—The term ''entity'' means a partnership, joint venture, association, corporation, organization, network, group, or subgroup, or any form of business collaboration.

(3) FOREIGN PERSON.—The term ''foreign person'' means any citizen or national of a foreign state or any entity not organized under the laws of the United States, but does not include a foreign state.

(4) LISTED CHEMICAL.—The term ''listed chemical'' has the meaning given the term in section 50101 of this title.

(5) NARCOTIC DRUG.—The term ''narcotic drug'' has the meaning given the term in section 50101 of this title.

(6) NARCOTICS TRAFFICKING.—The term ''narcotics trafficking'' means any illicit activity to cultivate, produce, manufacture, distribute, sell, finance, or transport narcotic drugs, controlled substances, or listed chemicals, or otherwise endeavor or attempt to do so, or to assist, abet, conspire, or collude with others to do so.

(7) PERSON.—The term ''person'' means an individual or entity.

(8) SIGNIFICANT FOREIGN NARCOTICS TRAFFICKER.—The term ''significant foreign narcotics trafficker'' means any foreign person that plays a significant role in international narcotics trafficking, that the President has determined to be appropriate for sanctions pursuant to this chapter, and that the President has publicly identified in the report required under subsection (b) or (h)(1) of section 61104 of this title.

(9) UNITED STATES PERSON.—The term ''United States person'' means any United States citizen or national, permanent resident alien, entity organized under the laws of the United States (including its foreign branches), or person within the United States.

**§ 61102. Policy**

It is the policy of the United States to apply economic and other financial sanctions to significant foreign narcotics traffickers and their organizations worldwide to protect the national security, foreign policy, and economy of the United States from the threat of the activities of international narcotics traffickers and their organizations.

**§ 61103. Purpose**

The purpose of this chapter is to provide authority for the identification of, and application of sanctions on a worldwide basis to, significant foreign narcotics traffickers, their organizations, and the foreign persons that provide support to those significant foreign narcotics traffickers and their organizations, whose activities threaten the national security, foreign policy, and economy of the United States.

**§ 61104. Public identification of significant foreign narcotics traffickers and required reports**

(a) PROVISION OF INFORMATION TO THE PRESIDENT.—The Secretary of the Treasury, the Attorney General, the Secretary of Defense, the Secretary of State, and the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)) shall consult among themselves and provide the appropriate and necessary information to enable the President to submit the report under subsection (b). This information shall also be provided to the Director of National Drug Control Policy.

(b) PUBLIC IDENTIFICATION AND SANCTIONING OF SIGNIFICANT FOREIGN NARCOTICS TRAFFICKERS.—

(1) IN GENERAL.—

(A) SUBMISSION.—Not later than June 1 of each year, the President shall submit a report described in subparagraph (B) to the following committees:

(i) Permanent Select Committee on Intelligence of the House of Representatives.

(ii) The Committees on the Judiciary, Foreign Relations, Armed Services, and Ways and Means of the House of Representatives.

(iii) the Select Committee on Intelligence of the Senate.

(iv) The Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate.

(B) REPORT.—A report described in this subparagraph is a report—

(i) identifying publicly the foreign persons that the President determines are appropriate for sanctions pursuant to this chapter; and

(ii) detailing publicly the President's intent to impose sanctions on those signifi-

cant foreign narcotics traffickers pursuant to this chapter.

(2) EXCLUSION OF PERSONS ON WHICH SANCTIONS ARE ALREADY IN EFFECT.—The report required in this subsection shall not include information on persons on which United States sanctions imposed under this chapter, or otherwise on account of narcotics trafficking, are already in effect.

(c) UNCLASSIFIED REPORT REQUIRED.—The report required by subsection (b) shall be submitted in unclassified form and made available to the public.

(d) CLASSIFIED REPORT.—

(1) IN GENERAL.—Not later than July 1 of each year, the President shall provide the Permanent Select Committee on Intelligence of the House of Representatives and the Select Committee on Intelligence of the Senate with a report in classified form describing in detail the status of the sanctions imposed under this chapter, including the personnel and resources directed towards the imposition of the sanctions during the preceding fiscal year, and providing background information with respect to newly-identified significant foreign narcotics traffickers and their activities.

(2) ACTIONS BY PRESIDENT.—The classified report shall describe actions the President intends to undertake or has undertaken with respect to the significant foreign narcotics traffickers.

(3) ADDITIONAL OBLIGATION.—The report required under this subsection is in addition to the President's obligations to keep the intelligence committees of Congress fully and currently informed pursuant to the provisions of the National Security Act of 1947 (50 U.S.C. 3001 et seq.).

(e) EXCLUSION OF CERTAIN INFORMATION.—

(1) INTELLIGENCE.—Notwithstanding any other provision of this section, the reports described in subsections (b) and (d) shall not disclose the identity of any person, if the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)) determines that the disclosure could compromise an intelligence operation, activity, source, or method of the United States.

(2) LAW ENFORCEMENT.—Notwithstanding any other provision of this section, the reports described in subsections (b) and (d) shall not disclose the name of any person if the Attorney General, in co-

ordination as appropriate with the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, and the Secretary of the Treasury, determines that the disclosure could reasonably be expected to—

(A) compromise the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution that furnished information on a confidential basis;

(B) jeopardize the integrity or success of an ongoing criminal investigation or prosecution;

(C) endanger the life or physical safety of any person; or

(D) cause substantial harm to physical property.

(f) NOTIFICATION REQUIRED.—

(1) NOTIFICATION OF COMMITTEES ON DETERMINATION.—Whenever the Attorney General, or the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)), makes a determination under subsection (e), the At-

torney General, or the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)), shall notify the Permanent Select Committee on Intelligence of the House of Representatives and the Select Committee on Intelligence of the Senate, and explain the reasons for the determination.

(2) ANNUAL SUBMISSION.—The notification required under this subsection shall be submitted to the Permanent Select Committee on Intelligence of the House of Representatives and the Select Committee on Intelligence of the Senate on an annual basis.

(g) DETERMINATIONS NOT TO APPLY SANCTIONS.—

(1) IN GENERAL.—The President may waive the application to a significant foreign narcotics trafficker of any sanction authorized by this chapter if the President determines that the application of sanctions under this chapter would significantly harm the national security of the United States.

(2) NOTIFICATION OF COMMITTEES.—When the President determines not to apply sanctions that are authorized by this chapter to any significant foreign

narcotics trafficker, the President shall notify, not later than 21 days after making the determination—

(A) the Permanent Select Committee on Intelligence of the House of Representatives,

(B) the Committees on the Judiciary, Foreign Relations, Armed Services, and Ways and Means of the House of Representatives;

(C) the Select Committee on Intelligence of the Senate; and

(D) the Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate.

(h) CHANGES IN DETERMINATIONS TO IMPOSE SANCTIONS.—

(1) ADDITIONAL DETERMINATIONS.—

(A) IN GENERAL.—If, at any time after the report required under subsection (b), the President finds that a foreign person is a significant foreign narcotics trafficker and the foreign person has not been publicly identified in a report required under subsection (b), the President shall submit an additional public report containing the information described in subsection (b) with respect to the foreign person to—

(i) the Permanent Select Committee on Intelligence of the House of Representatives;

(ii) the Committees on the Judiciary, Foreign Relations, Armed Services, and Ways and Means of the House of Representatives;

(iii) the Select Committee on Intelligence of the Senate; and

(iv) the Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate.

(B) TREATMENT.—The President may apply sanctions authorized under this chapter to the significant foreign narcotics trafficker identified in the report submitted under subparagraph (A) as if the trafficker were originally included in the report submitted pursuant to subsection (b).

(C) NOTIFICATION OF SECRETARY OF THE TREASURY.—The President shall notify the Secretary of the Treasury of any determination made under this paragraph.

(2) REVOCATION OF DETERMINATION.—

(A) ISSUANCE OF PUBLIC NOTICE.—Whenever the President finds that a foreign person that has been publicly identified as a significant foreign narcotics trafficker in the report required under subsection (b) or this subsection no longer engages in those activities for which sanctions under this chapter may be applied, the President shall issue public notice of the finding.

(B) NOTIFICATION OF COMMITTEES.—Not later than the date of the public notice issued pursuant to subparagraph (A), the President shall notify, in writing and in classified or unclassified form, the following committees of actions taken under this paragraph and a description of the basis for the actions:

(i) The Permanent Select Committee on Intelligence of the House of Representatives.

(ii) The Committees on the Judiciary, Foreign Relations, Armed Services, and Ways and Means of the House of Representatives.

(iii) The Select Committee on Intelligence of the Senate.

(iv) The Committees on the Judiciary, Foreign Relations, Armed Services, and Finance of the Senate.

(i) PROTECTION OF CLASSIFIED INFORMATION IN FEDERAL COURT CHALLENGES RELATING TO DESIGNATIONS.—In any judicial review of a determination made under this section, if the determination was based on classified information (as defined in section 1(a) of the Classified Information Procedures Act (18 U.S.C. App.)), the information may be submitted to the reviewing court ex parte and in camera. This subsection does not confer or imply any right to judicial review.

**§ 61105. Blocking assets and prohibiting transactions**

(a) APPLICABILITY OF SANCTIONS.—A significant foreign narcotics trafficker publicly identified in the report required under subsection (b) or (h)(1) of section 61104 of this title and foreign persons designated by the Secretary of the Treasury pursuant to subsection (b) shall be subject to any and all sanctions as authorized by this chapter. The application of sanctions on any foreign person pursuant to subsection (b) or (h)(1) of section 61104 of this title or subsection (b) shall remain in effect until revoked pursuant to section 61104(h)(2) of this title or subsection (e)(1)(A) or waived pursuant to section 61104(g)(1) of this title.

(b) BLOCKING OF ASSETS.—Except to the extent provided in regulations, orders, instructions, licenses, or directives issued pursuant to this chapter, and notwithstanding any contract entered into or any license or permit granted prior to the date on which the President submits the report required under subsection (b) or (h)(1) of section 61104 of this title, there are blocked as of the date of the submission, and any date after the date of the submission, all property and interests in property within the United States, or within the possession or control of any United States person, that are owned or controlled by—

(1) any significant foreign narcotics trafficker publicly identified by the President in the report required under subsection (b) or (h)(1) of section 61104 of this title;

(2) any foreign person that the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)), the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, designates as materially assisting in,

providing financial or technological support for or to, or providing goods or services in support of the international narcotics trafficking activities of a significant foreign narcotics trafficker so identified in the report required under subsection (b) or (h)(1) of section 61104 of this title, or foreign persons designated by the Secretary of the Treasury pursuant to this subsection;

(3) any foreign person that the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)), the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, designates as owned, controlled, or directed by, or acting for or on behalf of, a significant foreign narcotics trafficker so identified in the report required under subsection (b) or (h)(1) of section 61104 of this title, or foreign persons designated by the Secretary of the Treasury pursuant to this subsection; and

(4) any foreign person that the Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)), the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, designates as playing a significant role in international narcotics trafficking.

(c) PROHIBITED TRANSACTIONS.—Except to the extent provided in regulations, orders, instructions, licenses, or directives issued pursuant to this chapter, and notwithstanding any contract entered into or any license or permit granted prior to the date on which the President submits the report required under subsection (b) or (h)(1) of section 61104 of this title, the following transactions are prohibited:

(1) Any transaction or dealing by a United States person, or within the United States, in property or interests in property of any significant foreign narcotics trafficker so identified in the report required pursuant to subsection (b) or (h)(1) of section 61104 of this title, and foreign persons des-

ignated by the Secretary of the Treasury pursuant to subsection (b).

(2) Any transaction or dealing by a United States person, or within the United States, that evades or avoids, or has the effect of evading or avoiding, and any endeavor, attempt, or conspiracy to violate, any of the prohibitions contained in this chapter.

(d) LAW ENFORCEMENT AND INTELLIGENCE ACTIVITIES NOT AFFECTED.—Nothing in this chapter prohibits or otherwise limits the authorized law enforcement or intelligence activities of the United States, or the law enforcement activities of any State or subdivision of a State.

(e) IMPLEMENTATION.—

(1) IN GENERAL.—The Secretary of the Treasury, in consultation with the Attorney General, the Director of the Central Intelligence Agency or the Director of National Intelligence (as appropriate under section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note)), the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, and the Secretary of State, may take such actions as may be necessary to carry out this chapter, including—

(A) making those designations authorized by paragraphs (2), (3), and (4) of subsection (b) and revocation of those designations;

(B) promulgating rules and regulations permitted under this chapter; and

(C) employing all powers conferred on the Secretary of the Treasury under this chapter.

(2) FEDERAL AGENCIES.—Each agency of the United States shall take all appropriate measures within its authority to carry out the provisions of this chapter.

(3) AVAILABILITY OF RECORDS AND INFORMATION.— Section 552(a)(3) of title 5 shall not apply to any record or information obtained or created in the implementation of this chapter.

**§ 61106. Authorities**

(a) IN GENERAL.—To carry out the purposes of this chapter, the Secretary of the Treasury may, under such regulations as the Secretary of the Treasury may prescribe, by means of instructions, licenses, or otherwise—

(1) investigate, regulate, or prohibit—

(A) any transactions in foreign exchange, currency, or securities, which transactions are by any person subject to the jurisdiction of the United States, or which transactions are with

respect to any property subject to the jurisdiction of the United States; and

(B) transfers of credit or payments between, by, through, or to any banking institution, to the extent that the transfers or payments involve any interests of any foreign country or a national of a foreign country, which transfers or payments are by any person subject to the jurisdiction of the United States, or which transfers or payments are with respect to any property subject to the jurisdiction of the United States; and

(2) investigate, block during the pendency of an investigation, regulate, direct and compel, nullify, void, prevent, or prohibit any acquisition, holding, withholding, use, transfer, withdrawal, transportation, placement into foreign or domestic commerce of, or dealing in, or exercising any right, power, or privilege with respect to, or transaction involving, any property in which any foreign country or a national of a foreign country has any interest, which acquisition, holding, withholding, use, transfer, withdrawal, transportation, placement, dealing, exercising, or transaction is by any person, or is with re-

spect to any property, subject to the jurisdiction of the United States.

(b) RECORDKEEPING.—Pursuant to subsection (a), the Secretary of the Treasury may require recordkeeping, reporting, and production of documents to carry out the purposes of this chapter.

(c) DEFENSES.—

(1) COMPLIANCE.—Full and actual compliance with any regulation, order, license, instruction, or direction issued under this chapter shall be a defense in any proceeding alleging a violation of any of the provisions of this chapter.

(2) GOOD FAITH.—A person shall not be held liable in any court for or with respect to anything done or omitted in good faith in connection with the administration of, or pursuant to, and in reliance on this chapter, or any regulation, instruction, or direction issued under this chapter.

(d) RULEMAKING.—The Secretary of the Treasury may issue such other regulations or orders, including regulations prescribing recordkeeping, reporting, and production of documents, definitions, licenses, instructions, or directions, as may be necessary for the exercise of the authorities granted by this chapter.

**§ 61107. Penalties**

(a) CRIMINAL PENALTIES.—

(1) IN GENERAL.—A person that willfully violates the provisions of this chapter, or any license, rule, or regulation issued pursuant to this chapter, or willfully neglects or refuses to comply with any order of the President issued under this chapter shall be—

(A) imprisoned for not more than 10 years;

(B) fined in the amount provided in title 18 or, in the case of an entity, fined not more than $10,000,000; or

(C) both.

(2) OFFICER, DIRECTOR, OR AGENT.—Any officer, director, or agent of any entity who knowingly participates in a violation of the provisions of this chapter shall be imprisoned for not more than 30 years, fined not more than $5,000,000, or both.

(b) CIVIL PENALTIES.—The Secretary of the Treasury may impose a civil penalty not to exceed $1,000,000 on any person that violates any license, order, rule, or regulation issued in compliance with the provisions of this chapter.

(c) JUDICIAL REVIEW OF CIVIL PENALTY.—Any penalty imposed under subsection (b) shall be subject to judi-

cial review only to the extent provided in section 702 of title 5.

# Chapter 613—Date-Rape Drug Prohibition

Sec.
61301. Definition of GHB.
61302. Emergency scheduling of GHB.
61303. Investigations and prosecutions relating to violations that result in or contribute to rape and other crimes.
61304. Annual report on date-rape drugs; national awareness campaign.

## § 61301. Definition of GHB

In this chapter, the term ''GHB'' means gamma hydroxybutyric acid.

## § 61302. Emergency scheduling of GHB

Congress finds that the abuse of illicit GHB is an imminent hazard to the public safety. Accordingly, the Attorney General, notwithstanding sections 50301(a), 50301(b), 50301(c), and 50302 of this title, shall issue a final order that schedules GHB (together with its salts, isomers, and salts of isomers) in the same schedule under section 50302(c) of this title as would apply to a scheduling of a substance by the Attorney General under section 50301(h)(1) of this title (relating to imminent hazards to the public safety), except as follows:

(1) DRUGS FOR INVESTIGATIONAL USE.—

(A) IN GENERAL.—For purposes of any requirements that relate to the physical security of registered manufacturers and registered dis-

tributors, the final order shall treat GHB, when the drug is manufactured, distributed, or possessed in accordance with an exemption under section 13510 of this title (whether the exemption involved is authorized before, on, or after February, 18, 2000), as being in the same schedule as that recommended by the Secretary of Health and Human Services for the drug when the drug is the subject of an authorized investigational new drug application (relating to section 13510 of this title).

(B) RECOMMENDATION.—The recommendation referred to in subparagraph (A) is contained in the first paragraph of the letter transmitted on May 19, 1999, by the Secretary of Health and Human Services (acting through the Assistant Secretary for Health) to the Attorney General (acting through the Deputy Administrator of the Drug Enforcement Administration), which letter was in response to the letter transmitted by the Attorney General (acting through the Deputy Administrator of the Drug Enforcement Administration) on September 16, 1997.

(C) PUBLICATION.—In publishing the final order in the Federal Register, the Attorney General shall publish a copy of the letter that was transmitted by the Secretary of Health and Human Services.

(2) DRUG PRODUCT WITH AN APPROVED NEW DRUG APPLICATION.—

(A) IN GENERAL.—In the case of GHB that is contained in a drug product for which an application is approved under chapter 135 of this title (whether the application involved is approved before, on, or after February 18, 2000), the final order shall schedule the drug in the same schedule as that recommended by the Secretary of Health and Human Services for authorized formulations of the drug.

(B) RECOMMENDATION.—The recommendation referred to in subparagraph (A) is contained in the last sentence of the fourth paragraph of the letter (transmitted on May 19, 1999) referred to in paragraph (1).

**§ 61303. Investigations and prosecutions relating to violations that result in or contribute to rape and other crimes**

(a) IN GENERAL.—The Attorney General, in consultation with the Administrator of the Drug Enforcement Administration and the Director of the Federal Bureau of Investigation, shall—

(1) develop—

(A) model protocols for the collection of toxicology specimens and the taking of victim statements in connection with investigations into and prosecutions related to possible violations of division A of subtitle V of this title or other Federal or State laws that result in or contribute to rape, other crimes of violence, or other crimes involving abuse of GHB, other controlled substances, or ''designer drugs''; and

(B) model training materials for law enforcement personnel involved in the investigations; and

(2) make the protocols and training materials available to Federal, State, and local personnel responsible for the investigations.

(b) GRANT.—The Attorney General shall make a grant, in such amount and to such public or private person or entity as the Attorney General considers appropriate,

for the development of forensic field tests to assist law enforcement officials in detecting the presence of GHB and related substances.

**§ 61304. Annual report on date-rape drugs; national awareness campaign**

(a) DEFINITION OF DATE-RAPE DRUGS.—In this section, the term ''date-rape drugs'' means GHB and its salts, isomers, and salts of isomers and such other drugs or substances as the Secretary of Health and Human Services (referred to in this section as ''Secretary''), after consultation with the Attorney General, determines to be appropriate.

(b) ANNUAL REPORT.—The Secretary shall annually submit to Congress reports, each of which provides an estimate of the number of incidents of the abuse of date-rape drugs that occurred during the most recent 1-year period for which data are available.

(c) NATIONAL AWARENESS CAMPAIGN.—

(1) DEVELOPMENT OF PLAN; RECOMMENDATIONS OF ADVISORY COMMITTEE.—

(A) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall develop a plan for carrying out a national campaign to educate individuals described in subparagraph (B) on the following:

(i) The dangers of date-rape drugs.

(ii) The applicability of division A of subtitle V of this title to date-rape drugs, including penalties under the division.

(iii) Recognizing the symptoms that indicate that an individual may be a victim of date-rape drugs, including symptoms with respect to sexual assault.

(iv) Appropriately responding when an individual has the symptoms described in clause (iii).

(B) INTENDED POPULATION.—The individuals referred to in subparagraph (A) are young adults, youths, law enforcement personnel, educators, school nurses, counselors of rape victims, and emergency room personnel in hospitals.

(C) ADVISORY COMMITTEE.—Not later than 180 days after February 18, 2000, the Secretary shall establish an advisory committee to make recommendations to the Secretary regarding the plan under subparagraph (A). The advisory committee shall be composed of individuals who collectively possess expertise on the

effects of date-rape drugs and on detecting and controlling the drugs.

(2) IMPLEMENTATION OF PLAN.—Not later than 180 days after the date on which the advisory committee under paragraph (1) is established, the Secretary, in consultation with the Attorney General, shall commence carrying out the national campaign under the paragraph in accordance with the plan developed under the paragraph. The campaign may be carried out directly by the Secretary and through grants and contracts.

# Chapter 615—United States Anti-Doping Agency

Sec.
61501. Definitions.
61502. Designation of United States Anti-Doping Agency.
61503. Records, audit, and report.
61504. Authorization of appropriations.

## § 61501. Definitions

In this chapter:

(1) AMATEUR ATHLETE.—The term ''amateur athlete'' has the meaning given the term in section 220501(b)(1) of title 36.

(2) AMATEUR ATHLETIC COMPETITION.—The term ''amateur athletic competition'' has the meaning given the term in section 220501(b)(2) of title 36.

(3) UNITED STATES OLYMPIC AND PARALYMPIC COMMITTEE.—The term ''United States Olympic and Paralympic Committee'' means the organization established by the Ted Stevens Olympic and Amateur Sports Act (36 U.S.C. 220501 et seq.).

**§ 61502. Designation of United States Anti-Doping Agency**

(a) IN GENERAL.—The United States Anti-Doping Agency—

(1) shall—

(A) serve as the independent anti-doping organization for the amateur athletic competitions recognized by the United States Olympic and Paralympic Committee;

(B) be responsible for certifying in advance any testing conducted by international organizations under the World Anti-Doping Code for international amateur athletes and athletic competitions occurring within the jurisdiction of the United States; and

(C) be recognized worldwide as the independent national anti-doping organization for the United States;

(2) shall ensure that athletes participating in amateur athletic activities recognized by the United

States Olympic and Paralympic Committee are prevented from using performance-enhancing drugs or prohibited performance-enhancing methods adopted by the Agency;

(3) shall implement anti-doping education, research, testing, and adjudication programs to prevent United States amateur athletes participating in any activity recognized by the United States Olympic and Paralympic Committee from using performance-enhancing drugs or prohibited performance-enhancing methods adopted by the Agency;

(4) shall serve as the United States representative responsible for coordination with other anti-doping organizations coordinating amateur athletic competitions recognized by the United States Olympic and Paralympic Committee to ensure the integrity of athletic competition, the health of the athletes, and the prevention of use by United States amateur athletes of performance-enhancing drugs or prohibited performance-enhancing methods adopted by the Agency; and

(5) shall promote a positive youth sport experience by using a portion of the funding of the United States Anti-Doping Agency to provide educational materials on sportsmanship, character building, and

healthy performance for the athletes, parents, and coaches who participate in youth sports.

(b) DUE PROCESS IN ARBITRATION PROCEEDINGS.—Any action taken by the United States Anti-Doping Agency to enforce a policy, procedure, or requirement of the United States Anti-Doping Agency against a person with respect to a violation of Federal law, including an investigation, a disciplinary action, a sanction, or any other administrative action, shall be carried out in a manner that provides due process protection to the person.

**§ 61503. Records, audit, and report**

(a) RECORDS.—The United States Anti-Doping Agency shall keep correct and complete records of account.

(b) REPORT.—The United States Anti-Doping Agency shall submit an annual report to Congress that includes—

(1) an audit conducted and submitted in accordance with section 10101 of title 36; and

(2) a description of the activities of the agency.

**§ 61504. Authorization of appropriations**

There are authorized to be appropriated to the United States Anti-Doping Agency—

(1) for fiscal year 2025, $16,900,000;

(2) for fiscal year 2026, $17,700,000;

(3) for fiscal year 2027, $18,500,000;

(4) for fiscal year 2028, $19,800,000;

(5) for fiscal year 2029, $22,100,000;

(6) for fiscal year 2030, $24,900,000; and

(7) for fiscal year 2031, $23,700,000.

# Chapter 617—National Methamphetamine Information Clearinghouse

Sec.
61701. Definitions.
61702. Establishment of clearinghouse and advisory council.
61703. NMIC requirements and review.

## § 61701. Definitions

In this chapter:

(1) COUNCIL.—The term ''Council'' means the National Methamphetamine Advisory Council established under section 61702(b)(1) of this title.

(2) DRUG-ENDANGERED CHILDREN.—The term ''drug-endangered children'' means children whose physical, mental, or emotional health are at risk because of the production, use, or other effects of methamphetamine production or use by another person.

(3) NATIONAL METHAMPHETAMINE INFORMATION CLEARINGHOUSE.—

(A) IN GENERAL.—The term ''National Methamphetamine Information Clearinghouse''

means the information clearinghouse established under section 61702(a) of this title.

(B) NMIC.—The term ''NMIC'' means the National Methamphetamine Information Clearinghouse.

(4) QUALIFIED ENTITY.—The term ''qualified entity'' means a State, local, or tribal government, school board, or public health, law enforcement, nonprofit, community anti-drug coalition, or other nongovernmental organization providing services related to methamphetamines.

**§ 61702. Establishment of clearinghouse and advisory council**

(a) CLEARINGHOUSE.—There is established, under the supervision of the Attorney General, an information clearinghouse to be known as the National Methamphetamine Information Clearinghouse.

(b) ADVISORY COUNCIL.—

(1) IN GENERAL.—There is established an advisory council to be known as the National Methamphetamine Advisory Council.

(2) MEMBERSHIP.—The Council shall consist of 10 members appointed by the Attorney General—

(A) not fewer than 3 of whom shall be representatives of law enforcement agencies;

(B) not fewer than 4 of whom shall be representatives of nongovernmental and nonprofit organizations providing services or training and implementing programs or strategies related to methamphetamines; and

(C) 1 of whom shall be a representative of the Department of Health and Human Services.

(3) PERIOD OF APPOINTMENT; VACANCIES.—Members shall be appointed for 3 years. Any vacancy in the Council shall not affect its powers, and shall be filled in the same manner as the original appointment.

(4) PERSONNEL MATTERS.—

(A) TRAVEL EXPENSES.—The members of the Council shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, while away from their homes or regular places of business in the performance of services for the Council.

(B) NO COMPENSATION.—The members of the Council shall not receive compensation for the performance of the duties of a member of the Council.

**§ 61703. NMIC requirements and review**

(a) IN GENERAL.—The NMIC shall promote sharing information regarding successful law enforcement, treatment, environmental, prevention, social services, and other programs related to the production, use, or effects of methamphetamine and grants available for the programs.

(b) COMPONENTS.—

(1) IN GENERAL.—The NMIC shall include—

(A) a toll-free number; and

(B) a website that provides a searchable database, which website—

(i) provides information on the short-term and long-term effects of methamphetamine use;

(ii) provides information regarding methamphetamine treatment and prevention programs and strategies and programs for drug-endangered children, including descriptions of successful programs and strategies and contact information for the programs and strategies;

(iii) provides information regarding grants for methamphetamine-related programs, including contact information and links to websites;

(iv) allows a qualified entity to submit items to be posted on the website regarding successful public or private programs or other useful information related to the production, use, or effects of methamphetamine;

(v) includes a restricted section that may only be accessed by a law enforcement organization and that contains successful strategies, training techniques, and other information that the Council determines helpful to law enforcement agency efforts to identify or combat the production, use, or effects of methamphetamine;

(vi) allows public access to all information not in a restricted section; and

(vii) contains any additional information the Council determines may be useful in identifying or combating the production, use, or effects of methamphetamine.

(2) FUNDS.—Thirty days after the website in paragraph (1)(B) is operational, no funds shall be expended to continue the website methresources.gov.

(c) REVIEW OF POSTED INFORMATION.—

(1) IN GENERAL.—Not later than 30 days after the date of submission of an item by a qualified entity for posting on the website described in subsection (b)(1)(B), the Council shall review the item—

(A) to evaluate and determine whether the item, as submitted or as modified, meets the requirements for posting; and

(B) to determine, in consultation with the Attorney General, whether the item should be posted in a restricted section of the website.

(2) DETERMINATION.—Not later than 45 days after the date of submission of the item, the Council shall—

(A) post the item on the website described in subsection (b)(1)(B); or

(B) notify the qualified entity that submitted the item regarding the reason the item shall not be posted and modifications, if any, that the qualified entity may make to allow the item to be posted.

# Chapter 619—Sanctions With Respect to Foreign Traffickers of Illicit Synthetic Opioids

**Subchapter I—General Provisions**

Sec.
61901. Definitions.

**Subchapter II—Sanctions With Respect to Foreign Opioid Traffickers**

61911. Identification of foreign opioid traffickers.
61912. Imposition of sanctions.
61913. Description of sanctions.
61914. Designation of transactions of sanctioned persons as of primary money laundering concern.
61915. Waivers.
61916. Procedures for judicial review of classified information.
61917. Briefings on implementation.

**Subchapter III—Other Matters**

61931. Director of National Intelligence program on use of intelligence resources in efforts to sanction foreign opioid traffickers.
61932. Authorization of appropriations.
61933. Regulatory authority.
61934. Termination.
61935. Exception relating to importation of goods.

# Subchapter I—General Provisions

## § 61901. Definitions

In this chapter:

(1) ALIEN.—The term ''alien'' has the meaning given the term in section 101 of the Immigration and Nationality Act (8 U.S.C. 1101).

(2) APPROPRIATE CONGRESSIONAL COMMITTEES AND LEADERSHIP.—The term ''appropriate congressional committees and leadership'' means—

(A) the Committee on Appropriations, the Committee on Armed Services, the Committee on Banking, Housing, and Urban Affairs, the Committee on Foreign Relations, the Committee on Homeland Security and Governmental Affairs, the Committee on the Judiciary, the Select Committee on Intelligence, and the

majority leader and the minority leader of the Senate; and

(B) the Committee on Appropriations, the Committee on Armed Services, the Committee on Financial Services, the Committee on Foreign Affairs, the Committee on Homeland Security, the Committee on the Judiciary, the Committee on Oversight and Reform, the Permanent Select Committee on Intelligence, and the Speaker and the minority leader of the House of Representatives.

(3) CONTROLLED SUBSTANCE.—The term ''controlled substance'' has the meaning given the term in section 50101 of this title.

(4) ENTITY.—The term ''entity'' means a partnership, joint venture, association, corporation, organization, network, group, or subgroup, or any form of business collaboration.

(5) FOREIGN OPIOID TRAFFICKER.—The term ''foreign opioid trafficker'' means any foreign person that the President determines plays a significant role in opioid trafficking.

(6) FOREIGN PERSON.—

(A) IN GENERAL.—The term ''foreign person'' means—

(i) any citizen or national of a foreign country; or

(ii) any entity not organized under the laws of the United States or a jurisdiction within the United States.

(B) EXCLUSION.—The term ''foreign person'' does not include the government of a foreign country.

(7) KNOWINGLY.—The term ''knowingly'', with respect to conduct, a circumstance, or a result, means that a person has actual knowledge, or should have known, of the conduct, the circumstance, or the result.

(8) LISTED CHEMICAL.—The term ''listed chemical'' has the meaning given the term in section 50101 of this title.

(9) NARCOTIC DRUG.—The term ''narcotic drug'' has the meaning given the term in section 50101 of this title.

(10) NATIONAL.—The term ''national'' has the meaning given the term in section 101 of the Immigration and Nationality Act (8 U.S.C. 1101).

(11) NATIONAL OF THE UNITED STATES.—The term ''national of the United States'' has the mean-

ing given the term in section 101 of the Immigration and Nationality Act (8 U.S.C. 1101).

(12) OPIOID.—The term ''opioid'' has the meaning given the term in section 50101 of this title.

(13) OPIOID TRAFFICKING.—The term ''opioid trafficking'' means any illicit activity—

(A) to produce, manufacture, distribute, sell, or knowingly finance or transport—

(i) synthetic opioids, including controlled substances that are synthetic opioids and listed chemicals that are synthetic opioids; or

(ii) active pharmaceutical ingredients or chemicals that are used in the production of controlled substances that are synthetic opioids;

(B) to attempt to carry out an activity described in subparagraph (A); or

(C) to assist, abet, conspire, or collude with other persons to carry out an activity described in subparagraph (A).

(14) PERSON.—The term ''person'' means an individual or entity.

(15) UNITED STATES PERSON.—The term ''United States person'' means—

(A) any citizen or national of the United States;

(B) any alien lawfully admitted for permanent residence in the United States;

(C) any entity organized under the laws of the United States or any jurisdiction within the United States (including a foreign branch of the entity); or

(D) any person located in the United States.

# Subchapter II—Sanctions With Respect to Foreign Opioid Traffickers

## §61911. Identification of foreign opioid traffickers

(a) PUBLIC REPORT.—

(1) IN GENERAL.—The President shall submit to the appropriate congressional committees and leadership, in accordance with subsection (c), a report—

(A) identifying the foreign persons that the President determines are foreign opioid traffickers;

(B) detailing progress the President has made in implementing this subchapter; and

(C) providing an update on cooperative efforts with the governments of Mexico, the People's Republic of China, and other countries of concern with respect to combating foreign opioid traffickers.

(2) IDENTIFICATION OF ADDITIONAL PERSONS.—If, at any time after submitting a report required by paragraph (1) and before the submission of the next such report, the President determines that a foreign person not identified in the report is a foreign opioid trafficker, the President shall submit to the appropriate congressional committees and leadership an additional report containing the information required by paragraph (1) with respect to the foreign person.

(3) EXCLUSION.—The President shall not be required to include in a report under paragraph (1) or (2) any persons with respect to which the United States has imposed, before the date of the report, sanctions under this subchapter or any other provision of law with respect to opioid trafficking.

(4) FORM OF REPORT.—

(A) IN GENERAL.—Each report required by paragraph (1) or (2) shall be submitted in unclassified form but may include a classified annex.

(B) AVAILABILITY TO PUBLIC.—The unclassified portion of a report required by paragraph (1) or (2) shall be made available to the public.

(b) CLASSIFIED REPORT.—

(1) IN GENERAL.—The President shall submit to the appropriate congressional committees and leadership, in accordance with subsection (c), a report, in classified form—

(A) describing in detail the status of sanctions imposed under this subchapter, including the personnel and resources directed toward the imposition of the sanctions during the preceding fiscal year;

(B) providing background information with respect to persons newly identified as foreign opioid traffickers and their illicit activities;

(C) describing actions the President intends to undertake or has undertaken to implement this subchapter; and

(D) providing a strategy for identifying additional foreign opioid traffickers.

(2) EFFECT ON OTHER REPORTING REQUIREMENTS.—The report required by paragraph (1) is in addition to, and does not delimit or restrict, the obligations of the President to keep Congress fully and currently informed pursuant to the provisions of the National Security Act of 1947 (50 U.S.C. 3001 et seq.).

(c) SUBMISSION OF REPORTS.—Not later than 180 days after December 20, 2019, and annually thereafter until December 20, 2024, the President shall submit the reports required by subsections (a) and (b) to the appropriate congressional committees and leadership.

(d) EXCLUSION OF CERTAIN INFORMATION.—

(1) INTELLIGENCE.—Notwithstanding any other provision of this section, a report required by subsection (a) or (b) shall not disclose the identity of any person if the Director of National Intelligence determines that the disclosure could compromise an intelligence operation, activity, source, or method of the United States.

(2) LAW ENFORCEMENT.—Notwithstanding any other provision of this section, a report required by subsection (a) or (b) shall not disclose the identity

of any person if the Attorney General, in coordination, as appropriate, with the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of the Treasury, the Secretary of State, and the head of any other appropriate Federal law enforcement agency, determines that the disclosure could reasonably be expected—

(A) to compromise the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution that furnished information on a confidential basis;

(B) to jeopardize the integrity or success of an ongoing criminal investigation or prosecution;

(C) to endanger the life or physical safety of any individual; or

(D) to cause substantial harm to physical property.

(3) NOTIFICATION REQUIRED.—If the Director of National Intelligence makes a determination under paragraph (1) or the Attorney General makes a determination under paragraph (2), the Director of National Intelligence or the Attorney General, as

the case may be, shall notify the appropriate congressional committees and leadership of the determination and the reasons for the determination.

(4) RULE OF CONSTRUCTION.—Nothing in this section may be construed to authorize or compel the disclosure of information determined by the President to be law enforcement information, classified information, national security information, or other information the disclosure of which is prohibited by any other provision of law.

(e) PROVISION OF INFORMATION REQUIRED FOR REPORTS.—The Secretary of the Treasury, the Attorney General, the Secretary of Defense, the Secretary of State, the Secretary of Homeland Security, and the Director of National Intelligence shall consult among themselves and provide to the President and the Director of National Drug Control Policy the appropriate and necessary information to enable the President to submit the reports required by subsection (a).

**§ 61912. Imposition of sanctions**

The President shall impose 5 or more of the sanctions described in section 61913 of this title with respect to each foreign person that is an entity, and 4 or more of the sanctions with respect to each foreign person that is an individual, that—

(1) is identified as a foreign opioid trafficker in a report submitted under section 61911(a) of this title; or

(2) the President determines is—

(A) owned, controlled, or directed by such a foreign opioid trafficker;

(B) knowingly supplying or sourcing precursors for such a foreign opioid trafficker; or

(C) knowingly acting for or on behalf of such a foreign opioid trafficker.

**§ 61913. Description of sanctions**

(a) IN GENERAL.—The sanctions that may be imposed with respect to a foreign person under section 61912 of this title are the following:

(1) LOANS FROM UNITED STATES FINANCIAL INSTITUTIONS.—The United States Government may prohibit any United States financial institution from making loans or providing credits to the foreign person.

(2) PROHIBITIONS ON FOREIGN FINANCIAL INSTITUTIONS.—

(A) IN GENERAL.—The following prohibitions may be imposed with respect to a foreign person that is a financial institution:

(i) PROHIBITION ON DESIGNATION AS PRIMARY DEALER.—Neither the Board of Governors of the Federal Reserve System nor the Federal Reserve Bank of New York may designate, or permit the continuation of any prior designation of, the financial institution as a primary dealer in United States Government debt instruments.

(ii) PROHIBITION ON SERVICE AS A REPOSITORY OF GOVERNMENT FUNDS.—The financial institution may not serve as an agent of the United States Government or serve as a repository for United States Government funds.

(B) AGGREGATION OF SANCTIONS.—The imposition of either sanction under clause (i) or (ii) of subparagraph (A) shall be treated as 1 sanction for purposes of section 61912 of this title, and the imposition of both sanctions shall be treated as 2 sanctions for purposes of that section.

(3) PROCUREMENT BAN.—The United States Government may not procure, or enter into any con-

tract for the procurement of, any goods or services from the foreign person.

(4) FOREIGN EXCHANGE.—The President may, pursuant to such regulations as the President may prescribe, prohibit any transactions in foreign exchange that are subject to the jurisdiction of the United States and in which the foreign person has any interest.

(5) BANKING TRANSACTIONS.—The President may, pursuant to such regulations as the President may prescribe, prohibit any transfers of credit or payments between financial institutions or by, through, or to any financial institution, to the extent that the transfers or payments are subject to the jurisdiction of the United States and involve any interest of the foreign person.

(6) PROPERTY TRANSACTIONS.—The President may, pursuant to such regulations as the President may prescribe, prohibit any person from—

(A) acquiring, holding, withholding, using, transferring, withdrawing, or transporting any property—

(i) that is subject to the jurisdiction of the United States; and

(ii) with respect to which the foreign person has any interest;

(B) dealing in or exercising any right, power, or privilege with respect to the property; or

(C) conducting any transaction involving the property.

(7) BAN ON INVESTMENT IN EQUITY OR DEBT OF SANCTIONED PERSON.—The President may, pursuant to such regulations or guidelines as the President may prescribe, prohibit any United States person from investing in or purchasing significant amounts of equity or debt instruments of the foreign person.

(8) EXCLUSION OF CORPORATE OFFICERS.—The President may direct the Secretary of State to deny a visa to, and the Secretary of Homeland Security to exclude from the United States, any alien that the President determines is a corporate officer or principal of, or a shareholder with a controlling interest in, the foreign person.

(9) SANCTIONS ON PRINCIPAL EXECUTIVE OFFICERS.—The President may impose on a principal executive officer of the foreign person, or on an individual performing similar functions and with similar

authorities as the officer, any of the sanctions described in paragraphs (1) through (8) that are applicable.

(b) PENALTIES.—A person that violates, attempts to violate, conspires to violate, or causes a violation of any regulation, license, or order issued to carry out subsection (a) shall be subject to the penalties set forth in subsections (b) and (c) of section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705(b), (c)) to the same extent as a person that commits an unlawful act described in subsection (a) of that section.

(c) EXCEPTIONS.—

(1) INTELLIGENCE AND LAW ENFORCEMENT ACTIVITIES.—Sanctions under this section shall not apply with respect to—

(A) any activity subject to the reporting requirements under title V of the National Security Act of 1947 (50 U.S.C. 3091 et seq.); or

(B) any authorized intelligence or law enforcement activities of the United States.

(2) COMPLIANCE WITH INTERNATIONAL OBLIGATIONS.—Sanctions under subsection (a)(8) shall not apply to an alien if admitting the alien into the United States is necessary to permit the United States to comply with—

(A) the Agreement regarding the Headquarters of the United Nations, signed at Lake Success June 26, 1947, and entered into force November 21, 1947, between the United Nations and the United States (TIAS 1676);

(B) the Convention on Consular Relations, done at Vienna April 24, 1963, and entered into force March 19, 1967 (21 UST 77; TIAS 6820); or

(C) other applicable international obligations.

(d) IMPLEMENTATION.—The President may exercise all authorities provided under sections 203 and 205 of the International Emergency Economic Powers Act (50 U.S.C. 1702 and 1704) to carry out this section.

**§ 61914. Designation of transactions of sanctioned persons as of primary money laundering concern**

(a) IN GENERAL.—If the Secretary of the Treasury determines that reasonable grounds exist for concluding that one or more financial institutions operating outside of the United States, one or more classes of transactions within, or involving, a jurisdiction outside of the United States, or one or more types of accounts within, or involving, a jurisdiction outside of the United States, is of pri-

mary money laundering concern in connection with illicit opioid trafficking, the Secretary of the Treasury may, by order, regulation, or otherwise as permitted by law—

(1) require domestic financial institutions and domestic financial agencies to take one or more of the special measures provided for in section 9714(a)(1) of the Combating Russian Money Laundering Act (Public Law 116–283, div. H, title XCVII, subtitle B, 31 U.S.C. 5318A note); or

(2) prohibit, or impose conditions on, certain transmittals of funds (to be defined by the Secretary of the Treasury) by any domestic financial institution or domestic financial agency, if the transmittal of funds involves any such institution, class of transaction, or type of accounts.

(b) CLASSIFIED INFORMATION.—In any judicial review of a finding of the existence of a primary money laundering concern, or of the requirement for one or more special measures with respect to a primary money laundering concern made under this section, if the designation, imposition, or both were based on classified information (as defined in section 1(a) of the Classified Information Procedures Act (18 U.S.C. App.)), the information may be submitted by the Secretary of the Treasury to the reviewing court ex parte and in camera. This subsection does

not confer or imply any right to judicial review of any finding made or any requirement imposed under this section.

(c) AVAILABILITY OF INFORMATION.—The exemptions from, and prohibitions on, search and disclosure referred to in section 9714(c) of the Combating Russian Money Laundering Act (Public Law 116–283, div. H, title XCVII, subtitle B, 31 U.S.C. 5318A note) shall apply to any report or record of report filed pursuant to a requirement imposed under subsection (a). For purposes of section 552 of title 5, this subsection shall be considered a statute described in subsection (b)(3)(B) of that section.

(d) PENALTIES.—The penalties referred to in section 9714(d) of the Combating Russian Money Laundering Act (Public Law 116–283, div. H, title XCVII, subtitle B, 31 U.S.C. 5318A note) shall apply to violations of any order, regulation, special measure, or other requirement imposed under subsection (a), in the same manner and to the same extent as described in that section 9714(d).

(e) INJUNCTIONS.—The Secretary of the Treasury may bring a civil action to enjoin a violation of any order, regulation, special measure, or other requirement imposed under subsection (a) in the same manner and to the same extent as described in section 9714(e) of the Combating Russian Money Laundering Act (Public Law 116–283, div. H, title XCVII, subtitle B, 31 U.S.C. 5318A note).

**§ 61915. Waivers**

(a) WAIVER FOR STATE-OWNED ENTITIES IN COUNTRIES THAT COOPERATE IN MULTILATERAL ANTI-TRAFFICKING EFFORTS.—

(1) IN GENERAL.—The President may waive for a period of not more than 12 months the application of sanctions under this subchapter with respect to an entity that is owned or controlled, directly or indirectly, by a foreign government or any political subdivision, agency, or instrumentality of a foreign government, if, not less than 15 days before the waiver is to take effect, the President certifies to the appropriate congressional committees and leadership that the foreign government is closely cooperating with the United States in efforts to prevent opioid trafficking.

(2) CERTIFICATION.—

(A) IN GENERAL.—The President may certify under paragraph (1) that a foreign government is closely cooperating with the United States in efforts to prevent opioid trafficking if that government is—

(i) implementing domestic laws to schedule all fentanyl analogues as controlled substances; and

(ii) doing 2 or more of the activities listed under subparagraph (B).

(B) ACTIVITIES.—The activities listed under this subparagraph are the following:

(i) Implementing substantial improvements in regulations involving the chemical and pharmaceutical production and export of illicit opioids.

(ii) Implementing substantial improvements in judicial regulations to combat transnational criminal organizations that traffic opioids.

(iii) Increasing efforts to prosecute foreign opioid traffickers.

(iv) Increasing intelligence sharing and law enforcement cooperation with the United States with respect to opioid trafficking.

(3) SUBSEQUENT RENEWAL OF WAIVER.—The President may renew a waiver under paragraph (1) for subsequent periods of not more than 12 months each if, not less than 15 days before the renewal is to take effect, the Secretary of State certifies to the appropriate congressional committees and leadership that the government of the country to which the

waiver applies has effectively implemented and is effectively enforcing the measures that formed the basis for the certification under paragraph (2).

(b) WAIVERS FOR NATIONAL SECURITY AND ACCESS TO PRESCRIPTION MEDICATIONS.—

(1) IN GENERAL.—The President may waive the application of sanctions under this subchapter if the President determines that the application of the sanctions would harm—

(A) the national security interests of the United States; or

(B) subject to paragraph (2), the access of United States persons to prescription medications.

(2) MONITORING.—The President shall establish a monitoring program to verify that a person that receives a waiver under paragraph (1)(B) is not trafficking illicit opioids.

(3) NOTIFICATION.—Not later than 15 days after making a determination under paragraph (1), the President shall notify the appropriate congressional committees and leadership of the determination and the reasons for the determination.

(c) HUMANITARIAN WAIVER.—The President may waive, for renewable periods of 180 days, the application

of the sanctions under this subchapter if the President certifies to the appropriate congressional committees and leadership that the waiver is necessary for the provision of humanitarian assistance.

**§ 61916. Procedures for judicial review of classified information**

(a) IN GENERAL.—If a finding under this subchapter, or a prohibition, condition, or penalty imposed as a result of the finding, is based on classified information (as defined in section 1(a) of the Classified Information Procedures Act (18 U.S.C. App.)) and a court reviews the finding or the imposition of the prohibition, condition, or penalty, the President may submit the information to the court ex parte and in camera.

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to confer or imply any right to judicial review of any finding under this subchapter, or any prohibition, condition, or penalty imposed as a result of the finding; or

(2) to limit or restrict any other practice, procedure, right, remedy, or safeguard that—

(A) relates to the protection of classified information; and

(B) is available to the United States in connection with any type of administrative hearing, litigation, or other proceeding.

**§ 61917. Briefings on implementation**

Not later than 90 days after December 20, 2019, and every 180 days thereafter until the December 20, 2024, the President, acting through the Secretary of State and the Director of National Intelligence, in coordination with the Secretary of the Treasury, shall provide to the appropriate congressional committees and leadership a comprehensive briefing on efforts to implement this subchapter.

# Subchapter III—Other Matters

**§ 61931. Director of National Intelligence program on use of intelligence resources in efforts to sanction foreign opioid traffickers**

(a) DEFINITION OF INTELLIGENCE COMMUNITY.—In this section, the term ''intelligence community'' has the meaning given the term in section 3(4) of the National Security Act of 1947 (50 U.S.C. 3003(4)).

(b) PROGRAM REQUIRED.—

(1) IN GENERAL.—The Director of National Intelligence shall, in consultation with the Director of National Drug Control Policy, carry out a program to allocate and enhance the use of resources of the

intelligence community, including intelligence collection and analysis, to assist the Secretary of the Treasury, the Secretary of State, and the Administrator of the Drug Enforcement Administration in efforts to identify and impose sanctions with respect to foreign opioid traffickers under subchapter II.

(2) FOCUS ON ILLICIT FINANCE.—To the extent practicable, efforts described in paragraph (1) shall—

(A) take into account specific illicit finance risks related to narcotics trafficking; and

(B) be developed in consultation with the Undersecretary of the Treasury for Terrorism and Financial Crimes, appropriate officials of the Office of Intelligence and Analysis of the Department of the Treasury, the Director of the Financial Crimes Enforcement Network, and appropriate Federal law enforcement agencies.

(c) REVIEW OF COUNTERNARCOTICS EFFORTS OF THE INTELLIGENCE COMMUNITY.—The Director of National Intelligence shall, in coordination with the Director of National Drug Control Policy, carry out a comprehensive review of the current intelligence collection priorities of the intelligence community for counternarcotics pur-

poses in order to identify whether the priorities are appropriate and sufficient in light of the number of lives lost in the United States each year due to use of illegal drugs.

(d) REPORTS AND BRIEFINGS.—

(1) REPORTS AND BRIEFINGS ON PROGRAM.—

(A) ANNUAL REPORTS.—Not later than 90 days after December 20, 2019, and annually thereafter, the Director of National Intelligence and the Director of National Drug Control Policy shall jointly submit to the appropriate congressional committees and leadership a report on the status and accomplishments of the program required by subsection (b) during the year ending on the date of the report.

(B) SEMIANNUAL BRIEFINGS.—On a semiannual basis, the Director of National Intelligence and the Director of National Drug Control Policy shall jointly brief the appropriate congressional committees and leadership on the status and accomplishments of the program required by subsection (b).

(2) REPORT ON REVIEW.—Not later than 120 days after December 20, 2019, the Director of National Intelligence, in consultation with the Director of National Drug Control Policy and other relevant

agencies, shall submit to the appropriate congressional committees and leadership—

(A) a comprehensive description of the results of the review required by subsection (c); and

(B) an assessment of whether—

(i) the priorities described in that subsection are appropriate and sufficient in light of the number of lives lost in the United States each year due to use of illegal drugs; and

(ii) any changes to the priorities are necessary.

**§ 61932. Authorization of appropriations**

(a) DEFINITION OF APPROPRIATE COMMITTEES OF CONGRESS.—In this section, the term ''appropriate committees of Congress'' means—

(1) the Committee on Armed Services, the Committee on Banking, Housing, and Urban Affairs, the Committee on Foreign Relations, the Select Committee on Intelligence, the Committee on the Judiciary, and the Committee on Appropriations of the Senate; and

(2) the Committee on Armed Services, the Committee on Financial Services, the Committee on

Foreign Affairs, the Permanent Select Committee on Intelligence, the Committee on Oversight and Reform, and the Committee on Appropriations of the House of Representatives.

(b) DEPARTMENT OF THE TREASURY.—There are authorized to be appropriated to the Secretary of the Treasury such sums as may be necessary for fiscal year 2020 to carry out operations and activities of the Department of the Treasury solely for purposes of carrying out this chapter and the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2261).

(c) SUPPLEMENT NOT SUPPLANT.—Amounts authorized to be appropriated by subsection (b) shall supplement and not supplant other amounts available to carry out operations and activities described in the subsection.

(d) NOTIFICATION REQUIREMENT.—Amounts authorized to be appropriated by subsection (b) may not be obligated until 15 days after the date on which the President notifies the appropriate committees of Congress of the President's intention to obligate the funds.

**§ 61933. Regulatory authority**

Not later than 90 days after December 20, 2019, the President shall issue such regulations as are necessary to carry out this chapter and the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2261), in-

cluding guidance with respect to the activities that are included under the definition of ''opioid trafficking'' under section 61901 of this title.

**§ 61934. Termination**

The provisions of this chapter and the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2261), and any sanctions imposed pursuant to this chapter, shall terminate on December 20, 2026.

**§ 61935. Exception relating to importation of goods**

(a) DEFINITION OF GOOD.—In this section, the term ''good'' means any article, natural or manmade substance, material, supply, or manufactured product, including inspection and test equipment, and excluding technical data.

(b) IN GENERAL.—The authorities and requirements to impose sanctions under this chapter shall not include the authority or a requirement to impose sanctions on the importation of goods.

# Chapter 621—International Sports Doping

Sec.
62101. Definitions.
62102. Major international doping fraud conspiracies.
62103. Criminal penalties and statute of limitations.
62104. Coordination and sharing of information with USADA.

**§ 62101. Definitions**

In this chapter:

(1) ANTI-DOPING ORGANIZATION.—The term ''anti-doping organization'' has the meaning given the term in Article 2 of the Convention.

(2) ATHLETE.—The term ''athlete'' has the meaning given the term in Article 2 of the Convention.

(3) CODE.—The term ''Code'' means the World Anti-Doping Code most recently adopted by WADA on March 5, 2003.

(4) CONVENTION.—The term ''Convention'' means the United Nations Educational, Scientific, and Cultural Organization International Convention Against Doping in Sport, done at Paris October 19, 2005 (TIAS 08-1001.2), and ratified by the United States in 2008.

(5) MAJOR INTERNATIONAL SPORTS COMPETITION.—The term ''major international sports competition''—

(A) means a competition—

(i) in which 1 or more United States athletes and 3 or more athletes from other countries participate;

(ii) that is governed by the anti-doping rules and principles of the Code; and

(iii) in which—

(I) the competition organizer or sanctioning body receives sponsorship or other financial support from an organization doing business in the United States; or

(II) the competition organizer or sanctioning body receives compensation for the right to broadcast the competition in the United States; and

(B) includes a competition that is a single event or a competition that consists of a series of events held at different times which, when combined, qualify an athlete or team for an award or other recognition.

(6) PERSON.—The term ''person'' means any individual, partnership, corporation, association, or other entity.

(7) PROHIBITED METHOD.—The term ''prohibited method'' has the meaning given the term in Article 2 of the Convention.

(8) PROHIBITED SUBSTANCE.—The term ''prohibited substance'' has the meaning given the term in Article 2 of the Convention.

(9) SCHEME IN COMMERCE.—The term ''scheme in commerce'' means any scheme effectuated in whole or in part through the use in interstate or foreign commerce of any facility for transportation or communication.

(10) USADA.—The term ''USADA'' means the United States Anti-Doping Agency.

(11) WADA.—The term ''WADA'' means the World Anti-Doping Agency.

**§ 62102. Major international doping fraud conspiracies**

(a) IN GENERAL.—It shall be unlawful for any person, other than an athlete, to knowingly carry into effect, attempt to carry into effect, or conspire with any other person to carry into effect a scheme in commerce to influence by use of a prohibited substance or prohibited method any major international sports competition.

(b) EXTRATERRITORIAL JURISDICTION.—There is extraterritorial Federal jurisdiction over an offense under this section.

**§ 62103. Criminal penalties and statute of limitations**

(a) IN GENERAL.—

(1) CRIMINAL PENALTY.—A person that violates section 62102 of this title shall be sentenced to a term of imprisonment for not more than 10 years,

fined $250,000 if the person is an individual or $1,000,000 if the defendant is other than an individual, or both.

(2) FORFEITURE.—Any property, real or personal, tangible or intangible, may be seized and criminally forfeited to the United States if that property—

(A) is used or intended to be used, in any manner, to commit or facilitate a violation of section 62102 of this title; or

(B) constitutes or is traceable to the proceeds taken, obtained, or retained in connection with or as a result of a violation of section 62102 of this title.

(b) LIMITATION ON PROSECUTION.—

(1) IN GENERAL.—A person shall not be prosecuted, tried, or punished for violation of section 62102 of this title unless the indictment is returned or the information is filed within 10 years after the date on which the offense was completed.

(2) TOLLING.—On application in the United States, filed before a return of an indictment, indicating that evidence of an offense under this chapter is in a foreign country, the district court before which a grand jury is impaneled to investigate the

offense shall suspend the running of the statute of limitations under this section for the offense if the court finds by a preponderance of the evidence that an official request has been made for the evidence and that it reasonably appears, or reasonably appeared at the time the request was made, that the evidence is, or was, in the foreign country.

### § 62104. Coordination and sharing of information with USADA

Except as otherwise prohibited by law and except in cases in which the integrity of a criminal investigation would be affected, in furtherance of the obligation of the United States under Article 7 of the Convention, the Department of Justice, the Department of Homeland Security, and the Food and Drug Administration shall coordinate with USADA with regard to any investigation related to a potential violation of section 62102 of this title, including sharing with USADA all information in the possession of the Department of Justice, the Department of Homeland Security, or the Food and Drug Administration which may be relevant to any such potential violation.

# Chapter 623—Fentanyl Eradication and Narcotics Deterrence

**Subchapter I—General Provisions**

Sec.
62301. Definitions.

**Subchapter II—Sanctions in Response to National Emergency Relating to Fentanyl Trafficking**

62311. Policy.

62312. Use of national emergency authorities; reporting.

62313. Imposition of sanctions with respect to fentanyl trafficking by transnational criminal organizations.

62314. Penalties; waivers; exceptions.

62315. Treatment of forfeited property of transnational criminal organizations.

**Subchapter III— Anti-Money Laundering Reports**

62331. Treatment of transnational criminal organizations in suspicious transactions reports of the financial crimes enforcement network.

**Subchapter IV—Exception Relating to Importation of Goods**

62341. Exception relating to importation of goods.

# Subchapter I—General Provisions

## § 62301. Definitions

In this chapter:

(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ''appropriate congressional committees'' means—

(A) the Committee on Banking, Housing, and Urban Affairs of the Senate;

(B) the Committee on Foreign Relations of the Senate;

(C) the Committee on Financial Services of the House of Representatives; and

(D) the Committee on Foreign Affairs of the House of Representatives.

(2) FOREIGN PERSON.—

(A) IN GENERAL.—The term ''foreign person'' means—

(i) any citizen or national of a foreign country; or

(ii) any entity not organized under the laws of the United States or a jurisdiction within the United States.

(B) EXCLUSION.—The term ''foreign person'' does not include the government of a foreign country.

(3) KNOWINGLY.—The term ''knowingly'', with respect to conduct, a circumstance, or a result, means that a person has actual knowledge, or should have known, of the conduct, the circumstance, or the result.

(4) TRAFFICKING.—The term ''trafficking'', with respect to fentanyl, fentanyl precursors, or other related opioids, has the meaning given the term ''opioid trafficking'' in section 61901 of this title.

(5) TRANSNATIONAL CRIMINAL ORGANIZATION.—The term ''transnational criminal organization'' includes—

(A) any organization designated as a significant transnational criminal organization under part 590 of title 31, Code of Federal Regulations;

(B) any of the organizations known as—

(i) the Sinaloa Cartel;

(ii) the Jalisco New Generation Cartel;

(iii) the Gulf Cartel;

(iv) the Los Zetas Cartel;

(v) the Juarez Cartel;

(vi) the Tijuana Cartel;

(vii) the Beltran-Leyva Cartel; or

(viii) La Familia Michoacana; or

(C) any successor organization to an organization described in subparagraph (B) or as otherwise determined by the President.

(6) UNITED STATES PERSON.—The term ''United States person'' means—

(A) a United States citizen or an alien lawfully admitted for permanent residence to the United States;

(B) an entity organized under the laws of the United States or of any jurisdiction within the United States, including a foreign branch of the entity; or

(C) any person in the United States.

# Subchapter II—Sanctions in Response to National Emergency Relating to Fentanyl Trafficking

## § 62311. Policy

It shall be the policy of the United States to apply economic and other financial sanctions to those who engage in the international trafficking of fentanyl, fentanyl precursors, or other related opioids to protect the national security, foreign policy, and economy of the United States.

## § 62312. Use of national emergency authorities; reporting

(a) IN GENERAL.—The President may exercise all authorities provided under sections 203 and 205 of the International Emergency Economic Powers Act (50 U.S.C. 1702 and 1704) to carry out this subchapter.

(b) REPORT REQUIRED.—

(1) IN GENERAL.—The President shall annually submit to the appropriate congressional committees a report on actions taken by the Executive Branch pursuant to this subchapter and any national emergency declared with respect to the trafficking of fentanyl and trade in other illicit drugs, including—

(A) the issuance of any new or revised regulations, policies, or guidance;

(B) the imposition of sanctions;

(C) the collection of relevant information from outside parties;

(D) the issuance or closure of general licenses, specific licenses, and statements of licensing policy by the Office of Foreign Assets Control;

(E) a description of any pending enforcement cases; and

(F) the implementation of mitigation procedures.

(2) FORM OF REPORT.—Each report required under paragraph (1) shall be submitted in unclassified form, but may include the matters required under subparagraphs (C), (D), (E), and (F) of that paragraph in a classified annex.

**§ 62313. Imposition of sanctions with respect to fentanyl trafficking by transnational criminal organizations**

(a) IN GENERAL.—The President shall impose the sanctions described in subsection (b) with respect to any foreign person the President determines—

(1) is knowingly involved in the significant trafficking of fentanyl, fentanyl precursors, or other related opioids, including the significant trafficking by a transnational criminal organization; or

(2) otherwise is knowingly involved in significant activities of a transnational criminal organization relating to the trafficking of fentanyl, fentanyl precursors, or other related opioids.

(b) SANCTIONS.—The President, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.), may block and prohibit all transactions in property and interests in property of a foreign person described in subsection (a) if the property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person.

(c) REPORT REQUIRED.—The President shall annually submit to the appropriate congressional committees a report on actions taken by the Executive Branch with respect to the foreign persons identified under subsection (a).

**§ 62314. Penalties; waivers; exceptions**

(a) PENALTIES.—Any person that violates, attempts to violate, conspires to violate, or causes a violation of this subchapter or any regulation, license, or order issued to carry out this subchapter shall be subject to the penalties set forth in subsections (b) and (c) of section 206 of the International Emergency Economic Powers Act (50 U.S.C. 1705(b), (c)) to the same extent as a person that

commits an unlawful act described in section 206(a) of that Act.

(b) NATIONAL SECURITY WAIVER.—The President may waive the application of sanctions under this subchapter with respect to a foreign person if the President determines that the waiver is in the national security interest of the United States.

(c) EXCEPTIONS.—

(1) INTELLIGENCE ACTIVITIES.—This subchapter shall not apply with respect to activities subject to the reporting requirements under title V of the National Security Act of 1947 (50 U.S.C. 3091 et seq.) or any authorized intelligence activities of the United States.

(2) COMPLIANCE WITH INTERNATIONAL OBLIGATIONS AND LAW ENFORCEMENT ACTIVITIES.—Sanctions under this subchapter shall not apply with respect to an alien if admitting or paroling the alien into the United States is necessary—

(A) to permit the United States to comply with the Agreement regarding the Headquarters of the United Nations, signed at Lake Success on June 26, 1947 (TIAS 1676; 61 Stat. 3416), or other applicable international obligations of the United States; or

(B) to carry out or assist law enforcement activity of the United States.

(3) HUMANITARIAN EXEMPTION.—The President may not impose sanctions under this subchapter with respect to any person for conducting or facilitating a transaction for the sale of agricultural commodities, food, medicine, or medical devices or for the provision of humanitarian assistance.

**§ 62315. Treatment of forfeited property of transnational criminal organizations**

(a) TRANSFER OF FORFEITED PROPERTY TO FORFEITURE FUNDS.—

(1) COVERED FORFEITED PROPERTY DEFINED.—In this subsection, the term ''covered forfeited property'' means property—

(A) forfeited to the United States under chapter 46 or section 1963 of title 18; and

(B) that belonged to or was possessed by an individual affiliated with or connected to a transnational criminal organization subject to sanctions under—

(i) this subchapter;

(ii) chapter 619 of this title; or

(iii) Executive Order 14059 (50 U.S.C. 1701 note; 86 Federal Register 71549 (December 17, 2021)).

(2) IN GENERAL.—Any covered forfeited property shall be deposited into the Department of the Treasury Forfeiture Fund established under section 9705 of title 31 or the Department of Justice Assets Forfeiture Fund established under section 524(c) of title 28.

(3) REPORT REQUIRED.—Not later than 180 days after April 24, 2024, and every 180 days thereafter, the President shall submit to the appropriate congressional committees a report on any deposits made under paragraph (2) during the 180-day period preceding submission of the report.

(b) BLOCKED ASSETS UNDER TERRORISM RISK INSURANCE ACT OF 2002.—Nothing in this subchapter may be construed to affect the treatment of blocked assets of a terrorist party described in section 201(a) of the Terrorism Risk Insurance Act of 2002 (28 U.S.C. 1610 note).

# Subchapter III—Anti-Money Laundering Reports

## § 62331. Treatment of transnational criminal organizations in suspicious transactions reports of the financial crimes enforcement network

(a) FILING INSTRUCTIONS.—Not later than 180 days after April 24, 2024, the Director of the Financial Crimes Enforcement Network shall issue guidance or instructions to United States financial institutions for filing reports on suspicious transactions required under section 1010.320 of title 31, Code of Federal Regulations, related to suspected fentanyl trafficking by transnational criminal organizations.

(b) PRIORITIZATION OF REPORTS RELATING TO FENTANYL TRAFFICKING OR TRANSNATIONAL CRIMINAL ORGANIZATIONS.—The Director shall prioritize research into reports described in subsection (a) that indicate a connection to trafficking of fentanyl or related synthetic opioids or financing of suspected transnational criminal organizations.

## Subchapter IV—Exception Relating to Importation of Goods

### § 62341. Exception relating to importation of goods

(a) DEFINITION OF GOOD.—In this section, the term ''good'' means any article, natural or manmade substance, material, supply or manufactured product, including inspection and test equipment, and excluding technical data.

(b) IN GENERAL.—The authority or a requirement to block and prohibit all transactions in all property and interests in property under this chapter shall not include the authority or a requirement to impose sanctions on the importation of goods.

## Chapter —Reserved

## Chapter 699—Miscellaneous Drug Control and Enforcement Provisions

Sec.

69901. Placement of Pipradrol and SPA in schedule IV to carry out obligation under Convention on Psychotropic Substances.
69902. Interagency coordination.
69903. Regulations for expedited administrative forfeiture procedures.
69904. Constructive seizure procedures.
69905. Exemption of certain substances from production regulations.
69906. Diversion Control Fee Account.
69907. Denial of assistance and benefits for certain drug-related convictions.
69908. Sanctioning for testing positive for controlled substances.
69909. Support for international efforts to control methamphetamine and precursors.
69910. Public-private education program.
69911. Educational program for police departments.
69912. Annual report on development and deployment of narcotics detection technologies.
69913. Authorization of use of environmentally approved herbicides to eliminate illicit narcotics crops.
69914. Combating amphetamine and methamphetamine manufacturing and trafficking.

69915. Antidrug messages on Federal Government internet websites.
69916. Coordination with United States Trade Representative.
69917. Smuggling methamphetamine or methamphetamine precursor chemicals into the United States while using facilitated entry programs.
69918. Semiannual reports to Congress.
69919. Grants to reduce production of methamphetamines from anhydrous ammonia.
69920. Identification and publication of list of products containing anabolic steroids.
69921. Prescription drug take back expansion.
69922. GAO Audit.
69923. Dispensation of narcotic drugs for the purpose of relieving acute withdrawal symptoms from opioid use disorder.
69924. Methamphetamine as an emerging drug threat.
69925. Information sharing.
69926. Eliminating requirement relating to opioid treatment programs.

### § 69901. Placement of Pipradrol and SPA in schedule IV to carry out obligation under Convention on Psychotropic Substances

For the purpose of carrying out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances, done at Vienna, Austria February 21, 1971 (32 UST 543; TIAS 9725), with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections 50301 and 50302 of this title, place the drugs in schedule IV of section 50302(c) of this title.

### § 69902. Interagency coordination

The Secretary of Education, the Secretary of Health and Human Services, and the Secretary of Labor shall each designate an officer or employee of the Department of Education, the Department of Health and Human Services, and the Department of Labor, respectively, to

coordinate interagency drug abuse prevention activities to prevent duplication of effort.

**§ 69903. Regulations for expedited administrative forfeiture procedures**

(a) PERSONAL USE QUANTITIES OF A CONTROLLED SUBSTANCE.—In this section, the term ''personal use quantities of a controlled substance'' shall not include sweepings or other evidence of non-personal use amounts.

(b) IN GENERAL.—The Attorney General and the Secretary of the Treasury shall prescribe regulations for expedited administrative procedures for seizures under paragraphs (4), (6), and (7) of section 50911(a) of this title, section 596 of the Tariff Act of 1930 (19 U.S.C. 1595a(a)), and section 80303 of title 49 for violations involving the possession of personal use quantities of a controlled substance.

(c) SPECIFICATIONS.—

(1) IN GENERAL.—The regulations prescribed pursuant to subsection (b) shall—

(A) minimize the adverse impact caused by prolonged detention; and

(B) provide for a final administrative determination of the case within 21 days of seizure, or provide a procedure by which the de-

fendant can obtain release of the property pending a final determination of the case.

(2) CONDITIONS FOR RETURN.—The regulations shall provide that the appropriate agency official rendering a final determination shall immediately return the property if—

(A) the owner or interested party did not know of or consent to the violation;

(B) the owner establishes a valid, good faith interest in the seized property as owner or otherwise; and

(C)(i) the owner establishes that the owner at no time had any knowledge or reason to believe that the property in which the owner claims an interest was being or would be used in a violation of the law; and

(ii) in a case in which the owner at any time had, or should have had, knowledge or reason to believe that the property in which the owner claims an interest was being or would be used in a violation of the law, the owner did what reasonably could be expected to prevent the violation.

(3) ACTING IN A NORMAL AND CUSTOMARY MANNER TO ASCERTAIN PROPERTY USE.—An owner

shall not have the seized property returned under this subsection if the owner had not acted in a normal and customary manner to ascertain how the property would be used.

(d) NOTICE.—At the time of seizure or on issuance of a summons to appear under subsection (e), the officer making the seizure shall furnish to any person in possession of the conveyance a written notice specifying the procedures under this section. At the earliest practicable opportunity after determining ownership of the seized conveyance, the head of the agency that seizes the conveyance shall furnish a written notice to the owner and other interested parties (including lienholders) of the legal and factual basis of the seizure.

(e) SUMMONS IN LIEU OF SEIZURE OF COMMERCIAL FISHING INDUSTRY VESSELS.—

(1) IN GENERAL.—The Attorney General, the Secretary of the Treasury, and the Secretary of Transportation shall prescribe joint regulations providing for issuance of a summons to appear in lieu of seizure of a commercial fishing industry vessel as defined in paragraph (12), (13), or (14) of section 2101 of title 46 for violations involving the possession of personal use quantities of a controlled substance.

(2) APPLICABILITY.—The regulations under paragraph (1) shall apply when the violation is committed on a commercial fishing industry vessel that is proceeding to or from a fishing area or intermediate port of call, or is actively engaged in fishing operations.

(3) EFFECT OF SECTION.—The authority provided under this section shall not affect existing authority to arrest an individual for drug-related offenses or to release that individual into the custody of the vessel's master.

(4) PROCEDURES.—On answering a summons to appear, the procedures set forth in subsections (b), (c), and (d) shall apply.

(5) EFFECT ON JURISDICTION.—The jurisdiction of the district court for any forfeiture incurred shall not be affected by the use of a summons under this section.

**§ 69904. Constructive seizure procedures**

The Secretary of Transportation and the Secretary of the Treasury, in order to avoid the devastating economic effects on innocent owners of seizures of their vessels, shall develop a procedure for constructive seizure of vessels of the United States that are—

(1) engaged in commercial service as defined in section 2101 of title 46; and

(2) suspected of being used for committing violations of law involving personal use quantities of controlled substances.

**§ 69905. Exemption of certain substances from production regulations**

(a) DRUGS FOR TREATMENT OF RARE DISEASES.—The Attorney General may exempt a drug listed in section 50101(4) of this title from any production regulations otherwise issued under division A of subtitle V of this title as may be necessary to ensure adequate supplies of the drug for medical purposes if the Attorney General finds that the drug is—

(1) approved by the Food and Drug Administration as an accepted treatment for a rare disease or condition, as defined in section 13902 of this title; and

(2) does not have a significant potential for abuse.

(b) DATE OF ISSUANCE OF REGULATIONS.—The Attorney General shall issue regulations implementing this section.

**§ 69906. Diversion Control Fee Account**

(a) DEFINITIONS.—In this section:

(1) CONTROLLED SUBSTANCE AND CHEMICAL DIVERSION CONTROL ACTIVITIES.—The term ''controlled substance and chemical diversion control activities'' means those activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals.

(2) DIVERSION CONTROL PROGRAM.—The term ''diversion control program'' means the controlled substance and chemical diversion control activities of the Drug Enforcement Administration.

(b) IN GENERAL.—There is established in the general fund of the Treasury a separate account which shall be known as the Diversion Control Fee Account. For each fiscal year, the following shall apply:

(1) AMOUNTS TO BE DEPOSITED.—There shall be deposited as offsetting receipts into that account all fees collected by the Drug Enforcement Administration, in excess of $15,000,000, for the operation of its diversion control program.

(2) AVAILABILITY; REIMBURSEMENTS.—Amounts deposited into the Diversion Control Fee Account shall remain available until expended and shall be refunded out of that account by the Secretary of the Treasury, at least on a quarterly basis,

to reimburse the Drug Enforcement Administration for expenses incurred in the operation of the diversion control program. The reimbursements shall be made without distinguishing between expenses related to controlled substance activities and expenses related to chemical activities.

(3) FEE SETTING.—Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of the diversion control program.

(4) ESTIMATES IN BUDGET REQUEST TO BE FOLLOWED.—The amount required to be refunded from the Diversion Control Fee Account for each fiscal year shall be refunded in accordance with estimates made in the budget request of the Attorney General for those fiscal years. Any proposed changes in the amounts designated in the budget requests shall be made only after notification to the Committees on Appropriations of the House of Representatives and the Senate 15 days in advance.

**§ 69907. Denial of assistance and benefits for certain drug-related convictions**

(a) DEFINITION OF STATE.—In this section, the term ''State'' has the meaning given the term—

(1) in section 419(5) of the Social Security Act (42 U.S.C. 619(5)), when referring to assistance provided under a State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 et seq.); and

(2) in section 3 of the Food and Nutrition Act of 2008 (7 U.S.C. 2012), when referring to the supplemental nutrition assistance program (as defined in that section) or any State program carried out under that Act (7 U.S.C. 2011 et seq.).

(b) IN GENERAL.—An individual convicted (under Federal or State law) of any offense that is classified as a felony by the law of the jurisdiction involved and that has as an element the possession, use, or distribution of a controlled substance (as defined in section 50101 of this title) shall not be eligible for—

(1) assistance under any State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 et seq.); or

(2) benefits under the supplemental nutrition assistance program (as defined in section 3 of the Food and Nutrition Act of 2008 (7 U.S.C. 2012)) or any State program carried out under that Act (7 U.S.C. 2011 et seq.).

(c) EFFECTS ON ASSISTANCE AND BENEFITS FOR OTHERS.—

(1) PROGRAM OF TEMPORARY ASSISTANCE FOR NEEDY FAMILIES.—The amount of assistance otherwise required to be provided under a State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 et seq.) to the family members of an individual to whom subsection (b) applies shall be reduced by the amount that would have otherwise been made available to the individual under that part.

(2) BENEFITS UNDER THE FOOD AND NUTRITION ACT OF 2008.—The amount of benefits otherwise required to be provided to a household under the supplemental nutrition assistance program (as defined in section 3 of the Food and Nutrition Act of 2008 (7 U.S.C. 2012)), or any State program carried out under that Act (7 U.S.C. 2011 et seq.), shall be determined by considering the individual to whom subsection (b) applies not to be a member of the household, except that the income and resources of the individual shall be considered to be income and resources of the household.

(d) ENFORCEMENT.—A State that has not exercised its authority under subsection (e)(1)(A) shall require each

individual applying for assistance or benefits referred to in subsection (b), during the application process, to state, in writing, whether the individual, or any member of the household of the individual, has been convicted of a crime described in subsection (b).

(e) LIMITATIONS.—

(1) STATE ELECTIONS.—

(A) OPT OUT.—A State may, by specific reference in a law enacted after August 22, 1996, exempt any or all individuals domiciled in the State from the application of subsection (b).

(B) LIMIT PERIOD OF PROHIBITION.—A State may, by law enacted after August 22, 1996, limit the period for which subsection (b) shall apply to any or all individuals domiciled in the State.

(2) INAPPLICABILITY TO CONVICTIONS OCCURRING ON OR BEFORE AUGUST 22, 1996.—Subsection (b) shall not apply to a conviction if the conviction is for conduct occurring on or before August 22, 1996.

(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to deny the following Federal benefits:

(1) Emergency medical services under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(2) Short-term, noncash, in-kind emergency disaster relief.

(3)(A) Public health assistance for immunizations.

(B) Public health assistance for testing and treatment of communicable diseases if the Secretary of Health and Human Services determines that it is necessary to prevent the spread of the disease.

(4) Prenatal care.

(5) Job training programs.

(6) Drug treatment programs.

**§ 69908. Sanctioning for testing positive for controlled substances**

Notwithstanding any other provision of law, States shall not be prohibited by the Federal Government from testing welfare recipients for use of controlled substances nor from sanctioning welfare recipients who test positive for use of controlled substances.

**§ 69909. Support for international efforts to control methamphetamine and precursors**

The Attorney General, in consultation with the Secretary of State, shall coordinate international drug enforcement efforts to decrease the movement of meth-

amphetamine and methamphetamine precursors into the United States.

**§ 69910. Public-private education program**

(a) ADVISORY PANEL.—The Attorney General shall establish an advisory panel consisting of an appropriate number of representatives from Federal, State, tribal, and local law enforcement and regulatory agencies with experience in investigating and prosecuting illegal transactions of precursor chemicals. The Attorney General shall convene the panel as often as necessary to develop and coordinate educational programs for wholesale and retail distributors of precursor chemicals and supplies.

(b) CONTINUATION OF EFFORTS.—The Attorney General shall continue—

(1) to maintain an active program of seminars and training to educate wholesale and retail distributors of precursor chemicals and supplies regarding the identification of suspicious transactions and their responsibility to report the transactions; and

(2) to provide assistance to State, tribal, and local law enforcement and regulatory agencies to facilitate the establishment and maintenance of educational programs for distributors of precursor chemicals and supplies.

**§ 69911. Educational program for police departments**

The Attorney General may—

(1) create educational materials regarding the use of controlled substances (as defined in section 50101 of this title) in the furtherance of rapes and sexual assaults; and

(2) disseminate those materials to police departments throughout the United States.

**§ 69912. Annual report on development and deployment of narcotics detection technologies**

(a) REPORT REQUIREMENT.—Not later than December 1 of each year, the Director of National Drug Control Policy shall submit to Congress and the President a report on the development and deployment of narcotics detection technologies by Federal agencies. Each report shall be prepared in consultation with the Secretary of Defense, the Secretary of State, the Secretary of Homeland Security, and the Secretary of the Treasury.

(b) MATTERS TO BE INCLUDED.—Each report under subsection (a) shall include—

(1) a description of each project implemented by a Federal agency relating to the development or deployment of narcotics detection technology;

(2) the agency responsible for each project described in paragraph (1);

(3) the amount of funds obligated or expended to carry out each project described in paragraph (1) during the fiscal year in which the report is submitted or during any fiscal year preceding the fiscal year in which the report is submitted;

(4) the amount of funds estimated to be obligated or expended for each project described in paragraph (1) during any fiscal year after the fiscal year in which the report is submitted to Congress; and

(5) a detailed timeline for implementation of each project described in paragraph (1).

**§ 69913. Authorization of use of environmentally approved herbicides to eliminate illicit narcotics crops**

The Secretary of State, the Attorney General, the Secretary of Agriculture, the Secretary of Defense, the Director of National Drug Control Policy, and the Administrator of the Environmental Protection Agency may support the development and use of environmentally approved herbicides to eliminate illicit narcotics crops, including coca, cannabis, and opium poppy, both in the United States and in foreign countries.

**§ 69914. Combating amphetamine and methamphetamine manufacturing and trafficking**

(a) ACTIVITIES.—To combat the illegal manufacturing and trafficking in amphetamine and methamphetamine, the Administrator (referred to in this section as ''Administrator'') of the Drug Enforcement Administration (referred to in this section as ''Administration'') may—

(1) assist State and local law enforcement in small and mid-sized communities in all phases of investigations related to the manufacturing and trafficking, including assistance with foreign-language interpretation;

(2) staff additional regional enforcement and mobile enforcement teams related to the manufacturing and trafficking;

(3) establish additional resident offices and posts of duty to assist State and local law enforcement in rural areas in combating the manufacturing and trafficking;

(4) provide the Special Operations Division of the Administration with additional agents and staff to collect, evaluate, interpret, and disseminate critical intelligence targeting the command and control operations of major amphetamine and methamphetamine manufacturing and trafficking organizations;

(5) enhance the investigative and related functions of the Chemical Control Program of the Administration to implement more fully the provisions of the Comprehensive Methamphetamine Control Act of 1996 (Public Law 104–237, 110 Stat. 3099);

(6) design an effective means of requiring an accurate accounting of the import and export of list I chemicals, and coordinate investigations relating to the diversion of the chemicals;

(7) develop a computer infrastructure sufficient to receive, process, analyze, and redistribute time-sensitive enforcement information from suspicious order reporting to field offices of the Administration and other law enforcement and regulatory agencies, including the continuing development of the Suspicious Order Reporting and Tracking System (SORTS) and the Chemical Transaction Database (CTRANS) of the Administration;

(8) establish an education, training, and communication process in order to alert the industry to current trends and emerging patterns in the illegal manufacturing of amphetamine and methamphetamine; and

(9) carry out such other activities as the Administrator considers appropriate.

(b) ADDITIONAL POSITIONS AND PERSONNEL.—

(1) IN GENERAL.—In carrying out activities under subsection (a), the Administrator may establish in the Administration not more than 50 full-time positions, including not more than 31 special-agent positions, and may appoint personnel to the positions.

(2) PARTICULAR POSITIONS.—In carrying out activities under paragraphs (5) through (8) of subsection (a), the Administrator may establish in the Administration not more than 15 full-time positions, including not more than 10 diversion investigator positions, and may appoint personnel to the positions. Positions established under this paragraph are in addition to positions established under paragraph (1).

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the Administration for each fiscal year $9,500,000 for purposes of carrying out the activities authorized by subsection (a) and employing personnel in positions established under subsection (b), of which $3,000,000 shall be available for activities under paragraphs (5) through (8) of subsection (a) and for employing personnel in positions established under subsection (b)(2).

**§ 69915. Antidrug messages on Federal Government internet websites**

(a) IN GENERAL.—The head of each agency and establishment of the Federal Government shall, in consultation with the Director of National Drug Control Policy, place antidrug messages on appropriate internet websites controlled by the agency or establishment, which messages shall, where appropriate, contain an electronic hyperlink to the internet website, if any, of the Office of National Drug Control Policy.

(b) NATIONAL AERONAUTICS AND SPACE ADMINISTRATION.—The Administrator of the National Aeronautics and Space Administration, in consultation with the Director of National Drug Control Policy, shall place antidrug messages on internet sites controlled by the National Aeronautics and Space Administration.

**§ 69916. Coordination with United States Trade Representative**

In implementing sections 713 through 717 and section 721 of the Combat Methamphetamine Epidemic Act of 2005 (Public Law 109–177, title VII, 120 Stat. 264, 267), the Attorney General shall consult with the United States Trade Representative to ensure implementation complies with all applicable international treaties and obligations of the United States.

**§ 69917. Smuggling methamphetamine or methamphetamine precursor chemicals into the United States while using facilitated entry programs**

(a) ENHANCED PRISON SENTENCE.—The sentence of imprisonment imposed on a person convicted of an offense under division A or B of subtitle V of this title, involving methamphetamine or any listed chemical that is defined in section 50101 of this title, shall, if the offense is committed under the circumstance described in subsection (b), be increased by a consecutive term of imprisonment of not more than 15 years.

(b) CIRCUMSTANCES.—For purposes of subsection (a), the circumstance described in this subsection is that the offense described in subsection (a) was committed by a person that—

(1) was enrolled in, or that was acting on behalf of any person or entity enrolled in, any dedicated commuter lane, alternative or accelerated inspection system, or other facilitated entry program administered or approved by the Federal Government for use in entering the United States; and

(2) committed the offense while entering the United States, using the lane, system, or program.

(c) PERMANENT INELIGIBILITY.—Any person whose term of imprisonment is increased under subsection (a)

shall be permanently and irrevocably barred from being eligible for or using any lane, system, or program described in subsection (b)(1).

**§ 69918. Semiannual reports to Congress**

(a) IN GENERAL.—The Attorney General shall, on a semiannual basis, submit to the congressional committees and organizations specified in subsection (b) reports that describe—

(1) the allocation of the resources of the Drug Enforcement Administration and the Federal Bureau of Investigation for the investigation and prosecution of alleged violations of division A of subtitle V of this title involving methamphetamine; and

(2) the measures being taken to give priority in the allocation of the resources to the violations involving—

(A) persons alleged to have imported into the United States substantial quantities of methamphetamine or scheduled listed chemical products;

(B) persons alleged to have manufactured methamphetamine; and

(C) circumstances in which the violations have endangered children.

(b) CONGRESSIONAL COMMITTEES.—The congressional committees and organizations referred to in subsection (a) are—

(1) in the House of Representatives, the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Oversight and Government Reform; and

(2) in the Senate, the Committee on the Judiciary, the Committee on Commerce, Science, and Transportation, and the Caucus on International Narcotics Control.

**§ 69919. Grants to reduce production of methamphetamines from anhydrous ammonia**

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term ''eligible entity'' means—

(A) a producer of agricultural commodities;

(B) a cooperative association, a majority of the members of which produce or process agricultural commodities; or

(C) a person in the trade or business of—

(i) selling an agricultural product (including an agricultural chemical) at retail, predominantly to farmers and ranchers; or

(ii) aerial and ground application of an agricultural chemical.

(2) NURSE TANK.—The term ''nurse tank'' shall be considered to be a cargo tank (within the meaning of section 173.315(m) of title 49, Code of Federal Regulations, as in effect on June 18, 2008).

(b) GRANT AUTHORITY.—The Secretary of Agriculture may make a grant to an eligible entity to enable the eligible entity to obtain and add to an anhydrous ammonia fertilizer nurse tank a physical lock or a substance to reduce the amount of methamphetamine that can be produced from any anhydrous ammonia removed from the nurse tank.

(c) GRANT AMOUNT.—The amount of a grant made under this section to an eligible entity shall be the product obtained by multiplying—

(1) an amount not less than $40 and not more than $60, as determined by the Secretary; and

(2) the number of fertilizer nurse tanks of the eligible entity.

**§ 69920. Identification and publication of list of products containing anabolic steroids**

(a) IN GENERAL.—The Attorney General may, in the Attorney General's discretion, collect data and analyze products to determine whether they contain anabolic steroids and are properly labeled in accordance with section 50505(e) of this title. The Attorney General may publish in the Federal Register or on the website of the Drug Enforcement Administration a list of products that the Attorney General has determined, based on substantial evidence—

(1) contain an anabolic steroid; and

(2) are not labeled in accordance with section 50505(e) of this title.

(b) ABSENCE FROM LIST.—The absence of a product from the list referred to in subsection (a) shall not constitute evidence that the product does not contain an anabolic steroid.

**§ 69921. Prescription drug take back expansion**

(a) DEFINITION OF COVERED ENTITY.—In this section, the term ''covered entity'' means—

(1) a State, local, or tribal law enforcement agency;

(2) a manufacturer, distributor, or reverse distributor of prescription medications;

(3) a retail pharmacy;

(4) a registered narcotic treatment program;

(5) a hospital or clinic with an onsite pharmacy;

(6) an eligible long-term care facility; or

(7) any other entity authorized by the Drug Enforcement Administration to dispose of prescription medications.

(b) PROGRAM AUTHORIZED.—The Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of National Drug Control Policy, shall coordinate with covered entities in expanding or making available disposal sites for unwanted prescription medications.

**§ 69922. GAO Audit**

Not later than 4 years after October 24, 2018, and every 4 years thereafter, the Comptroller General of the United States shall—

(1) conduct an audit relating to the programs and operations of—

(A) the Office of National Drug Control Policy; and

(B) certain programs within the Office of National Drug Control Policy, including—

(i) the High Intensity Drug Trafficking Areas Program;

(ii) the Drug-Free Communities Program; and

(iii) the campaign under section 60907(f) of this title; and

(2) submit to the Director of National Drug Control Policy and to the Committee on the Judiciary, the Committee on Appropriations, and the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on Oversight and Government Reform, the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives a report containing an evaluation of and recommendations on the—

(A) policies and activities of the programs and operations subject to the audit;

(B) economy, efficiency, and effectiveness in the administration of the reviewed programs and operations; and

(C) policy or management changes needed to prevent and detect fraud and abuse in the programs and operations.

**§ 69923. Dispensation of narcotic drugs for the purpose of relieving acute withdrawal symptoms from opioid use disorder**

Not later than 180 days after December 11, 2020, the Attorney General shall revise section 1306.07(b) of title 21, Code of Federal Regulations, so that practitioners, in accordance with applicable State, Federal, or local laws relating to controlled substances, are allowed to dispense not more than a 3-day supply of narcotic drugs to 1 person or for 1 person's use at 1 time for the purpose of initiating maintenance treatment or detoxification treatment (or both).

**§ 69924. Methamphetamine as an emerging drug threat**

(a) IN GENERAL.—Congress declares methamphetamine an emerging drug threat, as defined in section 60901 of this title, in the United States.

(b) REQUIRED EMERGING THREAT RESPONSE PLAN.—Not later than 90 days after March 14, 2022, the Director of National Drug Control Policy shall establish and implement an Emerging Threat Response Plan that is specific to methamphetamine in accordance with section 60907(d) of this title.

**§ 69925. Information sharing**

Except as otherwise prohibited by law and except in cases in which the integrity of a criminal investigation

would be affected, pursuant to the obligation of the United States under Article 7 of the International Convention Against Doping in Sport, done at Paris October 19, 2005 (TIAS 08-1001.2), and ratified by the United States in 2008, the Attorney General, the Secretary of Homeland Security, and the Commissioner of Food and Drugs shall provide to the United States Anti-Doping Agency any relevant information relating to the prevention of the use of performance-enhancing drugs or the prohibition of performance-enhancing methods.

### § 69926. Eliminating requirement relating to opioid treatment programs

Not later than 18 months after December 29, 2022, the Secretary of Health and Human Services shall revise section 8.12(e)(1) of title 42, Code of Federal Regulations, or successor regulations, to eliminate the requirement that an opioid treatment program only admit an individual for treatment under the program if the individual has been addicted to opioids for at least 1 year before being so admitted for treatment.

# Subtitle VII—Cosmetics

# Chapter 701—Modernization of Cosmetics Regulation

Sec.
70101. Confidentiality.
70102. Talc-containing cosmetics.

**§ 70101. Confidentiality**

(a) IN GENERAL.—The Secretary of Health and Human Services shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential commercial information that is obtained by the Secretary of Health and Human Services pursuant to the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 136 Stat. 5847), including the amendments made by that Act.

(b) CLARIFICATION.—Nothing in the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 136 Stat. 5847), including the amendments made by that Act, shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 10501(10) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5.

**§ 70102. Talc-containing cosmetics**

The Secretary of Health and Human Services—

(1) not later than 1 year December 29, 2022, shall promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products; and

(2) not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue the final regulations.

# Subtitle VIII—Tobacco

# Chapter 801—Family Smoking Prevention and Tobacco Control

Sec.
80101. Final rule.
80102. Guidance relating to civil penalties for violations relating to sale of tobacco products.
80103. Enforcement action plan for advertising and promotion restrictions.
80104. Studies of progress and effectiveness.
80105. Effect of chapter and other related provisions.

## § 80101. Final rule

(a) CIGARETTES AND SMOKELESS TOBACCO.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall publish in the Federal Register a final rule regarding cigarettes and smokeless tobacco, which final rule—

(A) is deemed to be issued under chapter 211 of this title; and

(B) shall be deemed to be in compliance with all applicable provisions of chapter 5 of title 5 and all other provisions of law relating to rulemaking procedures.

(2) CONTENTS OF RULE.—Except as provided in this subsection, the final rule published under paragraph (1) shall be identical in its provisions to

part 897 of the regulations promulgated by the Secretary in the issue of the Federal Register dated August 28, 1996 (61 Fed. Reg. 44615 through 44618). The rule shall—

(A) provide for the designation of jurisdictional authority that is in accordance with this subsection in accordance with this chapter and the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776) and the amendments made by that Act;

(B) strike Subpart C—Labels and section 897.32(c);

(C) strike paragraphs (a), (b), and (i) of section 897.3 and insert definitions of the terms ''cigarette'', ''cigarette tobacco'', and ''smokeless tobacco'' as defined in section 21101 of this title;

(D) insert ''or roll-your-own paper'' in section 897.34(a) after ''other than cigarettes or smokeless tobacco'';

(E) include such modifications to section 897.30(b), if any, that the Secretary determines are appropriate in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in

Lorillard Tobacco Co. v. Reilly (533 U.S. 525 (2001));

(F) become effective on June 22, 2010; and

(G) amend paragraph (d) of section 897.16 to read as follows:

''(d)(1) Except as provided in subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

''(2)(A) Subparagraph (1) does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

''(B) This subparagraph does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

''(C) For purposes of this paragraph, the term 'qualified adult-only facility' means a facility or restricted area that—

''(i) requires each person present to provide to a law enforcement officer (whether on or off duty) or to a secu-

rity guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

''(ii) does not sell, serve, or distribute alcohol;

''(iii) is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

''(iv) is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this subparagraph;

''(v) is enclosed by a barrier that—

''(I) is constructed of, or covered with, an opaque material (except for entrances and exits);

''(II) extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

''(III) prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

''(vi) does not display on its exterior—

''(I) any tobacco product advertising;

''(II) a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

''(III) any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate section 897.34(c).

''(D) Distribution of samples of smokeless tobacco under this subparagraph permitted to be taken out of the qualified adult-only facility shall be limited to 1 package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed 8 individual portions and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the above amounts are limited to one such package per adult consumer per day.

''(3) Notwithstanding subparagraph (2), no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco—

''(A) to a sports team or entertainment group; or

''(B) at any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by this subparagraph.

''(4) The Secretary shall implement a program to ensure compliance with this paragraph and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

''(5) Nothing in this paragraph shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.''.

(3) AMENDMENTS TO RULE.—Prior to making amendments to the rule published under paragraph (1), the Secretary shall promulgate a proposed rule in accordance with chapter 5 of title 5.

(4) RULE OF CONSTRUCTION.—Except as provided in paragraph (3) nothing in this section shall be construed to limit the authority of the Secretary to amend, in accordance with chapter 5 of title 5, the regulation promulgated pursuant to this section, including the provisions of the regulation relating to distribution of free samples.

(5) ENFORCEMENT OF RETAIL SALE PROVISIONS.—The Secretary shall ensure that the provisions of this chapter, the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776), the amendments made by that Act, and the implementing regulations (including the provisions, amendments, and regulations relating to the retail sale of tobacco products) are enforced with respect to the United States and Indian tribes.

(6) QUALIFIED ADULT-ONLY FACILITY.—A qualified adult-only facility (as the term is defined in section 1140.16(d) of title 21, Code of Federal Regulations) that is also a retailer and that commits a violation as a retailer shall not be subject to the limitations in section 80102 of this title and shall be subject to penalties applicable to a qualified adult-only facility.

(7) CONGRESSIONAL REVIEW PROVISIONS.—Section 801 of title 5 shall not apply to the final rule published under paragraph (1).

(b) LIMITATION ON ADVISORY OPINIONS.—As of June 22, 2009, the following documents issued by the Food and Drug Administration shall not constitute advisory opinions under section 10.85(d)(1) of title 21, Code of Federal Regulations, except as they apply to tobacco

products, and shall not be cited by the Secretary of Health and Human Services or the Food and Drug Administration as binding precedent:

(1) The preamble to the proposed rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products To Protect Children and Adolescents'' (60 Fed. Reg. 41314 through 41372 (Aug. 11, 1995)).

(2) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco Products Is A Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act'' (60 Fed. Reg. 41453 through 41787 (Aug. 11, 1995)).

(3) The preamble to the final rule in the document titled ''Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents'' (61 Fed. Reg. 44396 through 44615 (Aug. 28, 1996)).

(4) The document titled ''Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional

Determination'' (61 Fed. Reg. 44619 through 45318 (Aug. 28, 1996)).

**§ 80102. Guidance relating to civil penalties for violations relating to sale of tobacco products**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall issue guidance—

(1) defining the term ''repeated violation'', as used in section 10503(f)(8) of this title, as including at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation and providing for civil penalties in accordance with subsection (b);

(2) providing for timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a follow-up compliance check, the notice to be sent to the location specified on the retailer's registration or to the retailer's registered agent if the retailer has provided the agent information to the Food and Drug Administration prior to the violation;

(3) providing for a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money

penalties, including at a retailer's request a hearing by telephone or at the nearest regional or field office of the Food and Drug Administration, and providing for an expedited procedure for the administrative appeal of an alleged violation;

(4) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;

(5) establishing that civil money penalties for multiple violations shall increase from 1 violation to the next violation pursuant to subsection (b) within the time periods provided for in the subsection;

(6) providing that good faith reliance on the presentation of a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products if the retailer has taken effective steps to prevent the violations, including—

(A) adopting and enforcing a written policy against sales to minors;

(B) informing its employees of all applicable laws;

(C) establishing disciplinary sanctions for employee noncompliance; and

(D) requiring its employees to verify age by way of photographic identification or electronic scanning device; and

(7) providing for the Secretary, in determining whether to impose a no-tobacco-sale order and in determining whether to compromise, modify, or terminate such an order, to consider whether the retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including the steps listed in paragraph (6).

(b) PENALTIES FOR VIOLATIONS.—

(1) TRAINING PROGRAM.—For purposes of paragraph (2), the term ''approved training program'' means a training program that complies with standards developed by the Food and Drug Administration for the program.

(2) IN GENERAL.—The amount of the civil penalty to be applied for violations of section 21107(d)(5) of this title or of restrictions promulgated under section 21107(d) of this title, as described in subsection (a), shall be as follows:

(A) With respect to a retailer with an approved training program, the amount of the civil penalty shall not exceed—

(i) in the case of the first violation, $0.00 together with the issuance of a warning letter to the retailer;

(ii) in the case of a second violation within a 12-month period, $250;

(iii) in the case of a third violation within a 24-month period, $500;

(iv) in the case of a fourth violation within a 24-month period, $2,000;

(v) in the case of a fifth violation within a 36-month period, $5,000; and

(vi) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(B) With respect to a retailer that does not have an approved training program, the amount of the civil penalty shall not exceed—

(i) in the case of the first violation, $250;

(ii) in the case of a second violation within a 12-month period, $500;

(iii) in the case of a third violation within a 24-month period, $1,000;

(iv) in the case of a fourth violation within a 24-month period, $2,000;

(v) in the case of a fifth violation within a 36-month period, $5,000; and

(vi) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

(3) CONSIDERATION OF STATE PENALTIES.—The Secretary shall coordinate with the States in enforcing the provisions of this chapter and the Family Smoking Prevention and Tobacco Act (Public Law 111–31, div. A, 123 Stat. 1776) and, for purposes of mitigating a civil penalty to be applied for a violation by a retailer of section 21107(d)(5) of this title or of any restriction promulgated under section 21107(d) of this title, shall consider the amount of any penalties paid by the retailer to a State for the same violation.

**§ 80103. Enforcement action plan for advertising and promotion restrictions**

(a) ACTION PLAN.—

(1) DEVELOPMENT.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop and publish an action plan to enforce restrictions adopted pursuant to section 21107 of this title, or pursuant to section 80101(a) of this title, on promotion and advertising of menthol and other cigarettes to youth.

(2) CONSULTATION.—The action plan required by paragraph (1) shall be developed in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities.

(3) PRIORITY.—The action plan required by paragraph (1) shall include provisions designed to ensure enforcement of the restrictions described in paragraph (1) in minority communities.

(b) STATE AND LOCAL ACTIVITIES.—

(1) INFORMATION ON AUTHORITY.—The Secretary shall inform State, local, and tribal governments of the authority provided to those governments under section 5(c) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334(c)) or preserved by those governments under section 21117 of this title.

(2) COMMUNITY ASSISTANCE.—At the request of communities seeking assistance to prevent underage tobacco use, the Secretary shall provide the assistance, including assistance with strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors.

**§ 80104. Studies of progress and effectiveness**

(a) FDA REPORT.—Not later than 3 years after June 22, 2009, and not less than every 2 years thereafter, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning—

(1) the progress of the Food and Drug Administration in implementing this chapter and the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776), including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;

(2) impediments identified by the Food and Drug Administration to progress in implementing this chapter and the Family Smoking Prevention

and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776) and to meeting statutory timeframes;

(3) data on the number of new product applications received under section 21111 of this title and modified risk tobacco product applications received under section 21112 of this title, and the number of applications acted on under each category; and

(4) data on the number of full-time equivalents engaged in implementing this chapter and the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776).

(b) GAO REPORT.—The Comptroller General shall conduct a study of, and submit to the Committees described in subsection (a) a report concerning—

(1) the adequacy of the authority and resources provided to the Secretary for this chapter and the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776) to carry out its goals and purposes; and

(2) any recommendations for strengthening that authority to more effectively protect the public health with respect to the manufacture, marketing, and distribution of tobacco products.

(c) PUBLIC AVAILABILITY.—The Secretary and the Comptroller General, respectively, shall make the reports

required under subsections (a) and (b) available to the public, including by posting the reports on the respective internet websites of the Food and Drug Administration and the Government Accountability Office.

**§ 80105. Effect of chapter and other related provisions**

(a) IN GENERAL.—Nothing in this chapter or the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776) (or an amendment made by the Act) shall be construed to—

(1) establish a precedent with regard to any other industry, situation, circumstance, or legal action; or

(2) affect any action pending in Federal, State, or tribal court, or any agreement, consent decree, or contract of any kind.

(b) AGRICULTURAL ACTIVITIES.—The provisions of this chapter or the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776) (or an amendment made by the Act) that authorize the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') to take certain actions with regard to tobacco and tobacco products shall not be construed to affect any authority of the Secretary of Agri-

culture under existing law regarding the growing, cultivation, or curing of raw tobacco.

(c) REVENUE ACTIVITIES.—The provisions of this chapter or the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776) (or an amendment made by the Act) that authorize the Secretary to take certain actions with regard to tobacco products shall not be construed to affect any authority of the Secretary of the Treasury under chapter 52 of the Internal Revenue Code of 1986 (26 U.S.C. 5701 et seq.).

# Chapter —Reserved

# Chapter 899—Miscellaneous

Sec.
89901. Reporting on tobacco regulation activities.

## § 89901. Reporting on tobacco regulation activities

(a) IN GENERAL.—For each fiscal year for which fees are collected under section 21120 of this title, the Secretary of Health and Human Services shall, not later than 180 days after the end of the fiscal year, prepare and submit to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, an annual report that contains the information required under subsection (b).

(b) REQUIRED INFORMATION.—Each report submitted under subsection (a) shall contain the following information for the previous fiscal year:

(1) Total annual user fee collections.

(2) Total amount of fees obligated.

(3) The amount of unobligated carryover balance from fees collected.

(4) The amount obligated by the Center for Tobacco Products for each of the following activities:

(A) Compliance and enforcement.

(B) Public education campaigns.

(C) Scientific research and research infrastructure.

(D) Communications.

(E) Leadership, management oversight, and administrative services.

(F) Related overhead activities.

(5) The numbers of applications, categorized by class of tobacco product and review pathway under sections 21106, 21111, and 21112 of this title, that were—

(A) submitted;

(B) pending;

(C) accepted;

(D) refused to file;

(E) withdrawn;

(F) denied;

(G) authorized for marketing under an order;

(H) issued a deficiency letter or environmental information request letter; or

(I) referred to the Tobacco Products Scientific Advisory Committee.

(6) The number and titles of draft and final guidance documents and proposed and final regulations issued on topics related to the process for the review of tobacco product applications, whether the regulations and guidance documents were issued as required by statute or by other legal or regulatory requirements, and whether the issuance met the deadlines set forth by the applicable statute or other requirements.

(7) The number and titles of public meetings related to the review of tobacco product applications by the Center for Tobacco Products or other offices or centers within the Food and Drug Administration.

(8) The number of pre-submission meetings relating to applications under section 21111 of this title, including the number of meeting requests re-

ceived, the number of meetings held, and the median amount of time between when the meeting requests were made and when the meeting requests were granted or denied.

(9) The number of full-time equivalent employees funded pursuant to fees collected under section 21120 of this title, including identification of the centers and offices within the Food and Drug Administration in which the positions are located.

(10) The number of inspections and investigations conducted at domestic and foreign establishments required to register under section 21106 of this title.

(11) The total number of compliance and enforcement actions issued or taken with respect to tobacco products, including warning letters, civil money penalties, no-tobacco-sale orders, and other enforcement actions (including seizures, injunctions, and criminal prosecution).

(c) PUBLIC AVAILABILITY.—The Secretary of Health and Human Services shall make the reports required under this section available to the public on the website of the Food and Drug Administration.

(d) LIMITATIONS.—Reporting under this section shall include best estimates for any reporting category for which

the Food and Drug Administration does not have precise calculations. Those best estimates shall be accompanied with an explanatory statement for why the Food and Drug Administration does not have access to, or cannot calculate, the exact figure and a date by which the Food and Drug Administration will update its internal accounting procedures to allow for reporting with precise calculations. If a category is successfully reported by the Food and Drug Administration with regard to another type of user fee but is provided a best estimate by the Center for Tobacco Products, the explanatory statement shall include information regarding how the Food and Drug Administration will align systems and apply learning across the agency to allow for accurate reporting.

**SEC. 4. CONFORMING AMENDMENTS.**

(1) TITLE 5.—

(A) Section 3113(2) of title 5, United States Code, is amended by striking ''section 1010(a) of the Controlled Substances Import and Export Act (21 U.S.C. 960(a))'' and inserting ''section 51710(a) of title 21''.

(B) Section 8105(a)(1)(B) of the Fighting Opioid Abuse in Transportation Act (Public Law 115–271, 5 U.S.C. 7301 note) is amended by striking ''section 202 of the Controlled Sub-

stances Act (21 U.S.C. 812)'' and inserting ''section 50302 of title 21, United States Code,''.

(2) TITLE 6.—Section 843(b)(1)(A) of the Homeland Security Act of 2002 (6 U.S.C. 413(b)(1)(A)) is amended by striking ''section 702(7) of the Office of National Drug Control Policy Reauthorization Act of 1998 (as last in effect)'' and inserting ''section 60901(11) of title 21, United States Code''.

(3) TITLE 7.—

(A) FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.—

(i) Section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136) is amended as follows:

(I) Subsection (u) is amended—

(aa) by striking ''section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w))'' and inserting ''section 10101(a)(33) of title 21, United States Code'';

(bb) by striking ''section 201(x) of such Act (21 U.S.C.

321(x))'' and inserting ''section 10101(a)(3) of such title''; and

(cc) by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(II) Subsection (bb) is amended by striking ''section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)'' and inserting ''section 11110 of title 21, United States Code''.

(III) Subsection (mm)(1)(B) is amended by striking ''a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or a food additive regulation under section 409 of such Act'' and inserting ''a tolerance under section 11110 of title 21, United States Code, or a food additive regulation under section 11111 of such title''.

(ii) Section 4(g)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a–1(g)(2)) is amended—

(I) in subparagraph (A)(i)—

(aa) by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''; and

(bb) by striking ''section 408(q)(1)(C) of that Act (21 U.S.C. 346a(q)(1)(C))'' and inserting ''section 408(q)(1)(C) of the Federal Food, Drug, and Cosmetic Act (ch. 675), as amended by section 405 of the Food Quality Protection Act of 1996 (Public Law 104–170, title IV, 110 Stat. 1534)''.

(II) in subparagraph (E)—

(aa) in clause (i), by striking ''section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)'' and inserting

''section 11110 of title 21, United States Code'';

(bb) in clause (ii), by striking ''requirements of that Act'' and inserting ''requirements of subtitle I of title 21, United States Code''; and

(cc) in clause (v), by striking ''section 408 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 11110 of title 21, United States Code,''.

(iii) Section 24(c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136v(c)(3)) is amended—

(I) by striking ''under the Federal Food, Drug, and Cosmetic Act'' and inserting ''under subtitle I of title 21, United States Code,''; and

(II) by striking ''inconsistent with the Federal Food, Drug, and Cosmetic Act'' and inserting ''inconsistent with subtitle I of title 21, United States Code''.

(iv) Section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–8) is amended—

(I) in subsection (b)(2)(B)(ii), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''; and

(II) in subsection (f)(4)(B)(iv)(II), by striking ''section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a)'' and inserting ''section 11110 of title 21, United States Code''.

(B) FOOD, AGRICULTURE, CONSERVATION, AND TRADE ACT OF 1990.—

(i) Section 1327(a) of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138f(a)) is amended by striking ''this subtitle, the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.)'' and inserting ''this subtitle or chapter 303 or 313 of title 21, United States Code,''.

(ii) Section 1330 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 138i) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(C) PUBLIC LAW 86–341.—Section 201(a) of Public Law 86–341 (7 U.S.C. 1431c(a)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(D) PUBLIC LAW 106–387.—Section 1(a) [title VII, §729(2)] of Public Law 106–387 is amended (7 U.S.C. 1622 note) is amended by striking ''the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)'' and inserting ''chapter 303, 313, or 317 of title 21, United States Code''.

(E) AGRICULTURAL MARKETING ACT OF 1946.—

(i) Section 291(2) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639(2))

is amended by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(ii) Section 292(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639a(c)) is amended—

(I) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code'';

(II) in paragraph (2) (matter before subparagraph (A)), by striking ''the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)'' and inserting ''chapter 303, 313, or 317 of title 21, United States Code,'';

(III) in paragraph (2)(A), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et

seq.)'' and inserting ''subtitle I of title 21, United States Code''; and

(IV) in paragraph (2)(B)(ii), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(iii) Section 294(b)(1) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639c(b)(1)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(iv) Section 295(a) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639i(a)) is amended by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(v) Section 297D(c) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639r(c)) is amended—

(I) in paragraph (1), by striking ''the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''; and

(II) in paragraph (3)(A)(i), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(F) FOOD AND NUTRITION ACT OF 2008.—

(i) Section 6(b)(1)(B) of the Food and Nutrition Act of 2008 (7 U.S.C. 2015(b)(1)(B)) is amended—

(I) in clause (ii)(II), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''; and

(II) in clause (iii)(II), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(ii) Section 12(b)(3)(C) of the Food and Nutrition Act of 2008 (7 U.S.C. 2021(b)(3)(C)) is amended by striking

''section 802 of title 21, United States Code'' and inserting ''section 50101 of title 21, United States Code''.

(G) FARM SECURITY AND RURAL INVESTMENT ACT OF 2002.—Section 10703(a)(1) of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 2219a(a)(1)) is amended by striking ''the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.)'' and inserting ''chapter 303 or 313 of title 21, United States Code,''.

(H) COMPETITIVE, SPECIAL, AND FACILITIES RESEARCH GRANT ACT.—Subsection (e)(1)(B) of the Competitive, Special, and Facilities Research Grant Act (7 U.S.C. 3157(e)(1)(B)) is amended by striking ''sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a, 348)'' and inserting ''sections 11110 and 11111 of title 21, United States Code''.

(I) NATIONAL NUTRITION MONITORING AND RELATED RESEARCH ACT OF 1990.—Section 301(c)(3) of the National Nutrition Monitoring and Related Research Act of 1990 (7

U.S.C. 5341(c)(3)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(J) PUBLIC LAW 101–624.—Section 1672(f)(3)(F) of Public Law 101–624 (7 U.S.C. 5925(f)(3)(F)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(K) ORGANIC FOODS PRODUCTION ACT OF 1990.—Section 2120(c)(6) of the Organic Foods Production Act of 1990 (7 U.S.C. 6519(c)(6)) is amended—

(i) in subparagraph (A)—

(I) in clause (i), by striking ''the Federal Meat Inspection Act (21 U.S.C. 601 et seq.)'' and inserting ''chapter 303 of title 21, United States Code'';

(II) in clause (ii), by striking ''the Poultry Products Inspection Act (21 U.S.C. 451 et seq.)'' and inserting ''chapter 313 of title 21, United States Code''; and

(III) in clause (iii), by striking ''the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)'' and inserting ''chapter 317 of title 21, United States Code''; and

(ii) in subparagraph (B), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(L) AGRICULTURAL RESEARCH, EXTENSION, AND EDUCATION REFORM ACT OF 1998.—

(i) Section 405(a) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7625(a)) is amended by striking ''section 1011(d) of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 10327(d) of title 21, United States Code,''.

(ii) Section 604(b)(2)(A) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7642(b)(2)(A)) is amended by striking ''section 512(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

360b(a));'' and inserting ''section 13702 of title 21, United States Code;''.

(iii) Section 614(b)(3) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7653(b)(3)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(M) AGRICULTURAL BIOTERRORISM PROTECTION ACT OF 2002.—Section 212(g)(1)(C) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(g)(1)(C)) is amended—

(i) in clause (i), by striking ''or registered under any of the Acts specified in clause (ii),'' and inserting ''or registered under any of the provisions specified in clause (ii),''; and

(ii) in clause (ii)—

(I) in the matter before subclause (I), by striking ''the Acts specified in this clause are the following:'' and inserting ''the provisions specified in this clause are the following:''; and

(II) in subclause (I), by striking ''The Federal Food, Drug, and Cosmetic Act.'' and inserting ''Subtitle I of title 21, United States Code.''

(4) TITLE 8.—

(A) Section 101(a)(43)(B) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(43)(B)) is amended by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''.

(B) Section 212(a)(2) of the Immigration and Nationality Act (8 U.S.C. 1182(a)(2)) is amended—

(i) in subparagraph (A)(i)(II), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''; and

(ii) in subparagraph (C)(i), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(C) Section 237(a)(2)(B)(i) of the Immigration and Nationality Act (8 U.S.C. 1227(a)(2)(B)(i)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(5) TITLE 10.—

(A) Section 1602(e) of the National Defense Authorization Act for Fiscal Year 2004 (Public Law 108–136, 10 U.S.C. 113 note) is amended—

(i) in paragraph (1)(A)—

(I) by striking ''section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)'' and inserting ''section 13502 of title 21, United States Code,''; and

(II) by striking ''section 515 or cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e and 360)'' and inserting ''section 13142 or cleared under section 13136(k) of title 21, United States Code,''.

(ii) in paragraph (2) (matter before subparagraph (A))—

(I) by striking ''section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))'' and inserting ''section 10101(a)(18) of title 21, United States Code''; and

(II) by striking ''section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))'' and inserting ''section 10101(a)(16) of title 21, United States Code''.

(B) Section 274(b)(4)(A)(i) of title 10, United States Code, is amended by striking ''The Controlled Substances Act (21 U.S.C. 801 et seq.) or the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.).'' and inserting ''Division A or B of subtitle V of title 21.''.

(C) Section 912a(b)(3) of title 10, United States Code, is amended by striking ''section 202 of the Controlled Substances Act (21 U.S.C. 812)'' and inserting ''section 50302 of title 21''.

(D) Section 1074g of title 10, United States Code, is amended—

(i) in subsection (h), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21'';

(ii) in subsection (i)(3), by striking ''section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b))'' and inserting ''section 13103(a) of title 21''; and

(iii) in subsection (i)(4), by striking ''section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b))'' and inserting ''section 13103(a) of title 21''.

(E) Section 705(f) of the John Warner National Defense Authorization Act for Fiscal Year 2007 (Public Law 109–364, 10 U.S.C. 1074g note) is amended—

(i) in paragraph (3), by striking ''section 503(b) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13103(a) of title 21, United States Code''; and

(ii) in paragraph (4), by striking ''section 503(b) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13103(a) of title 21, United States Code''.

(F) Section 1107 of title 10, United States Code is amended—

(i) in subsection (f)—

(I) in paragraph (1), by striking ''section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4))'' and inserting ''section 13510(d) of title 21'';

(II) in paragraph (2), by striking ''section 505(i) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13510 of title 21'';

(III) in paragraph (4)(A), by striking ''section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i))'' and inserting ''section 13510 of title 21''; and

(IV) in paragraph (4)(B), by striking ''section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 355(i)(4))'' and inserting ''section 13510(d) of title 21''; and

(ii) in subsection (g)—

(I) in paragraph (1), by striking ''section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i))'' and inserting ''section 13510 of title 21''; and

(II) in paragraph (2), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)'' and inserting ''chapter 135 of title 21''.

(G) Section 731(a)(3) (matter before subparagraph (A)) of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (Public Law 105–261, 10 U.S.C. 1107 note) is amended by striking ''paragraph (4) of section 505(i) of the Federal Food, Drug, and Cosmetic Act (or under any antecedent provision of law or regulations) that has been granted under that section (or antecedent provision of law or regulations)'' and inserting ''subsection (d) of section 13510 of title 21, United States Code, or under any antecedent provision

of law or regulations, that has been granted under that section, or antecedent provision of law or regulations,''.

(H) Section 1107a of title 10, United States Code, is amended—

(i) in subsection (a)—

(I) in paragraph (1)—

(aa) by striking ''section 564 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14306 of title 21'';

(bb) by striking ''section 564(e)(1)(A)(ii)(III) of such Act'' and inserting ''section 14306(f)(1)(A)(ii)(III) of such title''; and

(cc) by striking ''paragraph (1)(A) or (2)(A) of such section 564(e),'' and inserting ''paragraph (1)(A) or (2)(A) of such section 14306(f),''; and

(II) in paragraph (2), by striking ''section 564 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14306 of title 21'';

(ii) in subsection (b)—

(I) by striking ''section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14306(f)(1)(A)(ii)(III) of title 21'';

(II) by striking ''section 564(e)(1)(A)(ii)(I) or (II) of such Act'' and inserting ''section 14306(f)(1)(A)(ii)(I) or (II) of such title''; and

(III) by striking ''paragraph (1)(A) or (2)(A) of such section 564(e)'' and inserting ''paragraph (1)(A) or (2)(A) of such section 14306(f); and

(iii) in subsection (c)—

(I) by striking ''section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14306(b)(1) of title 21''; and

(II) by striking ''section 564(b)(1)(B) of such Act'' and inserting ''section 14306(c)(1)(B) of such title''.

(6) TITLE 12.—Section 1120(b)(1)(A) of the Right to Financial Privacy Act of 1978 (12 U.S.C. 3420(b)(1)(A)) is amended by striking ''the Controlled Substance Act, the Controlled Substances Import and Export Act,'' and inserting ''division A or B of subtitle V of title 21, United States Code,''.

(7) TITLE 15.—

(A) FEDERAL TRADE COMMISSION ACT.—

(i) Section 14(a) of the Federal Trade Commission Act (15 U.S.C. 54(a)) is amended by striking ''the Meat Inspection Act approved March 4, 1907, as amended,'' and inserting ''chapter 303 of title 21, United States Code,''.

(ii) Section 15(f) (matter before paragraph (1)) of the Federal Trade Commission Act (15 U.S.C. 55(f) (matter before paragraph (1)) is amended by striking ''and section 407 of the Federal Food, Drug, and Cosmetic Act, as amended'' in the matter before paragraph (1).

(B) TEXTILE FIBER PRODUCTS IDENTIFICATION ACT.—Section 12(a)(8) of the Textile Fiber Products Identification Act (15 U.S.C. 70j(a)(8)) is amended by striking ''the Federal

Food, Drug and Cosmetic Act of 1938, as amended'' and inserting ''subtitle I of title 21, United States Code''.

(C) INTERNATIONAL ANTI-BRIBERY AND FAIR COMPETITION ACT OF 1998.—Section 5(e)(1) of the International Anti-Bribery and Fair Competition Act of 1998 (Public Law 105–366, 15 U.S.C. 78dd–1 note) is amended by striking ''section 514 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 884)'' and inserting ''section 50914 of title 21, United States Code''.

(D) SMALL BUSINESS ACT.—Section 27(a)(2)(D)(ii) of the Small Business Act (15 U.S.C. 654(a)(2)(D)(ii)) is amended by striking ''chapter 2 of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1521 et seq.)'' and inserting ''chapter 605 of title 21, United States Code''.

(E) FEDERAL HAZARDOUS SUBSTANCES ACT.—

(i) Section 19 of the Federal Hazardous Substances Act (Public Law 86–613, 15 U.S.C. 401 note) is amended by striking ''the Federal Food, Drug, and

Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(ii) Section 2(f)(2) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f)(2)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(iii) Section 18(a) of the Federal Hazardous Substances Act (Public Law 86–613, 15 U.S.C. 1261 note) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(iv) Section 3(e)(1) of the Federal Hazardous Substances Act (15 U.S.C. 1262(e)(1)) is amended—

(I) by striking ''subsection (e) of section 701 of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''subsection (e) of section 17501 of title 21, United States Code,''; and

(II) by striking ''subsections (f) and (g) of such section 701'' and in-

serting ''subsections (f) and (g) of such section 17501''.

(v) Section 4(f) of the Federal Hazardous Substances Act (15 U.S.C. 1263(f)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(vi) Section 23(b)(1) of the Federal Hazardous Substances Act (15 U.S.C. 1277(b)(1)) is amended by striking ''the Federal Food, Drug, and Cosmetics Act'' and inserting ''subtitle I of title 21, United States Code''.

(F) FEDERAL CIGARETTE LABELING AND ADVERTISING ACT.—

(i) Section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) is amended—

(I) in subsection (b)(4), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code'';

(II) in subsection (d) (as added by section 202(b) of the Family

Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1845)), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''; and

(III) in subsection (e)(3), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(ii) Section 5(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1334(a)) is amended by striking ''section 903(a)(2) or section 920(a) of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 21104(a)(1)(B) or 21121(a) of title 21, United States Code,''.

(G) FAIR PACKAGING AND LABELING ACT.—

(i) Section 13 of the Fair Packaging and Labeling Act (Public Law 89–755, 15 U.S.C. 1451 note) is amended by striking ''the Federal Food, Drug, and Cosmetic

Act'' and inserting ''subtitle I of title 21, United States Code''.

(ii) Section 5 of the Fair Packaging and Labeling Act (15 U.S.C. 1454) is amended—

(I) in subsection (a), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''; and

(II) in subsection (c)(3), by striking ''section 201(f) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(19) of title 21, United States Code''.

(iii) Section 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1455) is amended—

(I) in subsection (a), by striking ''subsections (e), (f), and (g) of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e), (f), and (g)'' and inserting ''subsections (e), (f), and (g) of section

17501 of title 21, United States Code''; and

(II) in subsection (b), by striking ''subsections (e), (f), and (g) of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e), (f), and (g))'' and inserting ''subsections (e), (f), and (g) of section 17501 of title 21, United States Code,''.

(iv) Section 7 of the Fair Packaging and Labeling Act (15 U.S.C. 1456) is amended—

(I) in subsection (a)—

(aa) by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code'';

(bb) by striking ''chapter III of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 105 of title 21, United States Code''; and

(cc) by striking ''section 303 of that Act (21 U.S.C. 333)'' and inserting ''section 10503 of title 21, United States Code,''; and

(II) in subsection (c), by striking ''section 801(a) and (b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)'' and inserting ''subsections (a) and (b) of section 20101 of title 21, United States Code''.

(v) Section 10(a) of the Fair Packaging and Labeling Act (15 U.S.C. 1459(a)) is amended—

(I) in the matter before paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''; and

(II) in paragraph (3), by striking ''section 503(b)(1) or 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1) and 356)'' and inserting ''section 13103(a)(1) of title 21, United States Code''.

(vi) Section 11(b) of the Fair Packaging and Labeling Act (15 U.S.C. 1460(b)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(H) POISON PREVENTION PACKAGING ACT OF 1970.—

(i) Section 2(2)(B) of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471(2)(B)) is amended by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(ii) Section 5(a) of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1474(a)) is amended—

(I) by striking ''subsection (e) of section 701 of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''subsection (e) of section 17501 of title 21, United States Code,''; and

(II) by striking ''subsections (f) and (g) of such section 701'' and in-

serting ''subsections (f) and (g) of such section 17501''.

(I) CHILD NICOTINE POISONING PREVENTION ACT OF 2015.—Section 2(b)(1)(A) of the Child Nicotine Poisoning Prevention Act of 2015 (15 U.S.C. 1472a(b)(1)(A)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code,''.

(J) CONSUMER PRODUCT SAFETY ACT.—

(i) Section 3(a)(5) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(5)) is amended—

(I) in subparagraph (H), by striking ''drugs, devices, or cosmetics (as such terms are defined in sections 201(g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act)'' and inserting ''cosmetics, devices, or drugs (as such terms are defined in paragraphs (10), (16), and (18) of section 10101(a) of title 21, United States Code)''; and

(II) in subparagraph (I)—

(aa) by striking ''section 201(f) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(19) of title 21, United States Code'';

(bb) by striking ''sections 4 (e) and (f) of the Poultry Products Inspection Act'' and inserting ''paragraphs (22) and (23) of section 31301 of title 21, United States Code'';

(cc) by striking ''section 1(j) of the Federal Meat Inspection Act'' and inserting ''section 30301(12) of title 21, United States Code''; and

(dd) by striking ''section 4 of the Egg Products Inspection Act'' and inserting ''section 31701 of title 21, United States Code''.

(ii) Section 30(a) of the Consumer Product Safety Act (15 U.S.C. 2079(a)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (15 U.S.C. 301 et

seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(iii) Section 31(a) of the Consumer Product Safety Act (15 U.S.C. 2080(a)) is amended—

(I) by striking ''sections 355 (1) and (2) of the Public Health Service Act'' and inserting ''paragraphs (2) and (3) of section 14101 of title 21, United States Code''; and

(II) by striking ''subpart 3 of part F of title III of the Public Health Service Act'' and inserting ''chapter 141 of title 21, United States Code''.

(K) ANTI-DRUG ABUSE ACT OF 1988.—Section 2404(b) of the Anti-Drug Abuse Act of 1988 (15 U.S.C. 2057a(b)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(L) CRIME CONTROL ACT OF 1990.—Section 3202(b) of the Crime Control Act of 1990 (15 U.S.C. 2057b(b)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act''

and inserting ''subtitle I of title 21, United States Code''.

(M) TOXIC SUBSTANCES CONTROL ACT.—Section 3(2)(B) of the Toxic Substances Control Act (15 U.S.C. 2602(2)(B)) is amended—

(i) in clause (vi), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101 of title 21, United States Code''; and

(ii) in the matter after clause (vi)—

(I) by striking ''sections 4(e) and (f) of the Poultry Products Inspection Act'' and inserting ''paragraphs (22) and (23) of section 31301 of title 21, United States Code'';

(II) by striking ''section 1(j) of the Federal Meat Inspection Act'' and inserting ''section 30301(12) of title 21, United States Code''; and

(III) by striking ''section 4 of the Egg Products Inspection Act'' and inserting ''section 31701 of title 21, United States Code''.

(N) COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986.—

(i) Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) is amended—

(I) in subsection (b)(4), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''; and

(II) in subsection (d), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(ii) Section 9(1) of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4408(1)) is amended by striking ''section 900(18) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 21101(18) of title 21, United States Code''.

(O) STEEL AND ALUMINUM ENERGY CONSERVATION AND TECHNOLOGY COMPETITIVENESS ACT OF 1988.—Section 11 of the Steel and Aluminum Energy Conservation and Technology Competitiveness Act of 1988 (15 U.S.C. 5110) is amended—

(i) in subsection (a), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21, United States Code''; and

(ii) in subsection (b), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21, United States Code''.

(P) NATIONAL AERONAUTICS AND SPACE ADMINISTRATION AUTHORIZATION ACT.—Section 215 of the National Aeronautics and Space Administration Authorization Act, Fiscal Year 1989 (Public Law 100–685, 15 U.S.C. 5110 note) is amended—

(i) in subsection (a), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21, United States Code''; and

(ii) in subsection (b), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21, United States Code''.

(8) TITLE 16.—

(A) Section 15002(c) of the National Forest System Drug Control Act of 1986 (16

U.S.C. 559b(c)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(B) Section 15003(2) of the National Forest System Drug Control Act of 1986 (16 U.S.C. 559c(2)) is amended by striking ''section 401 of Controlled Substances Act (21 U.S.C. 841)'' and inserting ''section 50701 of title 21, United States Code,''.

(C) Section 15004 of the National Forest System Drug Control Act of 1986 (16 U.S.C. 559d) is amended—

(i) in paragraph (2), by striking ''section 401 of the Controlled Substances Act (21 U.S.C. 841)'' and inserting ''section 50701 of title 21, United States Code'';

(ii) in paragraph (3), by striking ''section 511 of the Controlled Substances Act (21 U.S.C. 881) for violations of the Controlled Substances Act'' and inserting ''section 50911 of title 21, United States Code, for violations of division A of subtitle V of title 21, United States Code,''; and

(iii) in paragraph (5), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21, United States Code,''.

(9) TITLE 18.—

(A) PART I, CRIMES.—

(i) Section 24(a)(2) of title 18, United States Code, is amended by striking ''section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331)'' and inserting '', section 10501 of title 21''.

(ii) Section 36(a) of title 18, United States Code, is amended—

(I) in paragraph (1), by striking ''section 408(c) of the Controlled Substances Act (21 U.S.C. 848(c))'' and inserting ''section 50708(a)(1) of title 21'';

(II) in paragraph (2), by striking ''section 406 of the Controlled Substances Act (21 U.S.C. 846) section 1013 of the Controlled Substances Import and Export Act (21 U.S.C. 963)'' and inserting ''section 50706 or 51714 of title 21''; and

(III) in paragraph (3), by striking ''section 401(b)(1)(A) of the Controlled Substances Act (21 U.S.C. 841(b)(1)(A)) or section 1010(b)(1) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)(1))'' and inserting ''section 50701(b)(1)(A) or 51710(b)(1) of title 21''.

(iii) Section 38(d)(2) of title 18, United States Code, is amended by striking ''section 413 of the Comprehensive Drug Abuse and Prevention Act of 1970 (21 U.S.C. 853)'' and inserting ''section 50713 of title 21''.

(iv) Section 42(a)(1) of title 18, United States Code, is amended by striking ''Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21''.

(v) Section 175b(d)(2)(D) of title 18, United States Code, is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(vi) Section 229B(b) of title 18, United States Code, is amended—

(I) in paragraph (1) (matter before subparagraph (A)), by striking ''subsections (b) through (p) of section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853)'' and inserting ''subsections (a) and (c) through (p) of section 50713 of title 21'';

(II) in paragraph (1)(A), by striking '' 'this subchapter or subchapter II' '' and inserting '' 'this division or division B' '';

(III) in paragraph (1)(B), by striking '' 'subsection (a)' shall be deemed'' and inserting '' 'subsection (b)' shall be deemed''; and

(IV) in paragraph (2)—

(aa) in subparagraph (A), by striking ''section 413(e)(2) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853(e)(2))'' and

inserting ''section 50713(e)(2) of title 21''; and

(bb) in subparagraph (C), by striking ''section 413(e)(2) and (3) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853(e)(2) and (3))'' and inserting ''paragraphs (2) and (3) of section 50713(e) of title 21''.

(vii) Section 342 of title 18, United States Code, is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(viii) Section 521 of title 18, United States Code, is amended—

(I) in subsection (c)(1), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''; and

(II) in subsection (d)(3)(B)(i), by striking ''section 102 of the Controlled Substances Act (21 U.S.C.

802)'' and inserting ''section 50101 of title 21''.

(ix) Section 670(e) of title 18, United States Code, is amended—

(I) in paragraph (3), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101 of title 21''; and

(II) in paragraph (5), by striking ''section 5(b) of the Orphan Drug Act'' and inserting ''section 49502(a) of title 21''.

(x) Section 793(h)(3) (matter before subparagraph (A)) of title 18, United States Code, is amended by striking ''subsections (b), (c), and (e) through (p) of section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853(b), (c), and (e)–(p))'' and inserting ''subsections (a), (c), and (e) through (p) of section 50713 of title 21''.

(xi) Section 794(d)(3) (matter before subparagraph (A)) of title 18, United States Code, is amended by striking ''subsections (b), (c), and (e) through (p) of

section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853(b), (c), and (e)–(p))'' and inserting ''subsections (a), (c), and (e) through (p) of section 50713 of title 21''.

(xii) Section 798(d)(3) (matter before subparagraph (A)) of title 18, United States Code, is amended by striking ''subsections (b), (c), and (e) through (p) of section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853(b), (c), and (e)–(p)),'' and inserting ''subsections (a), (c), and (e) through (p) of section 50713 of title 21''.

(xiii) Section 842 of title 18, United States Code, is amended—

(I) in subsection (d)(5), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''; and

(II) in subsection (i)(3), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(xiv) Section 922 of title 18, United States Code, is amended—

(I) in subsection (d)(3), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21'';

(II) in subsection (g)(3), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''; and

(III) in subsection (s)(3)(B)(iii), by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21''.

(xv) Section 924 of title 18, United States Code, is amended—

(I) in subsection (c)(2), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.),'' and inserting ''division A or B of subtitle V of title 21'';

(II) in subsection (d)(3)(B), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.) or the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.);'' and inserting ''division A or B of subtitle V of title 21;'';

(III) in subsection (e)(2)(A)—

(aa) in clause (i), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.),'' and inserting ''division A or B of subtitle V of title 21''; and

(bb) in clause (ii), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21'';

(IV) in subsection (g)—

(aa) in paragraph (2), by striking ''the Controlled Substances Act (21 U.S.C. 801 et

seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.),'' and inserting ''division A or B of subtitle V of title 21''; and

(bb) in paragraph (3), by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21''; and

(V) in subsection (k)(1)(A), by striking ''the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.)'' and inserting ''division B of subtitle V of title 21''.

(xvi) Section 929(a)(2) of title 18, United States Code, is amended by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.),'' and inserting ''division A or B of subtitle V of title 21''.

(xvii) Section 981 of title 18, United States Code, is amended—

(I) in subsection (a)(1)(B)(i), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21'';

(II) in subsection (b)(4)(A), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21''; and

(III) in subsection (k)(1)(A), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.),'' and inserting ''division A of subtitle V of title 21,''.

(xviii) Section 982(b)(1) of title 18, United States Code, is amended by striking ''section 413 (other than subsection (d) of that section) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853)'' and inserting ''section 50713 (other than subsection (d) of that section) of title 21''.

(xix) Section 983(i)(2)(C) of title 18, United States Code, is amended by striking ''the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21''.

(xx) Section 986 of title 18, United States Code, is amended—

(I) in subsection (a), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21''; and

(II) in subsection (d)(1) (matter before subparagraph (A)), by striking ''section 413(n) of the Controlled Substances Act (21 U.S.C. 853(n))'' and inserting ''section 50713(n) of title 21''.

(xxi) Section 1028(g) of title 18, United States Code, is amended by striking ''section 413 (other than subsection (d) of that section) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853)'' and inserting ''section 50713 (other than subsection (d) of that section) of title 21''.

(xxii) Section 1029(c)(2) of title 18, United States Code, is amended by striking ''section 413 of the Controlled Sub-

stances Act'' and inserting ''section 50713 of title 21''.

(xxiii) Section 1030(i)(2) of title 18, United States Code, is amended by striking ''section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853)'' and inserting ''section 50713 of title 21''.

(xxiv) Section 1037(c)(2) of title 18, United States Code, is amended by striking ''section 413 of the Controlled Substances Act (21 U.S.C. 853), other than subsection (d) of that section,'' and inserting ''section 50713 of title 21, other than subsection (d) of that section,''.

(xxv) Section 1365(h) of title 18, United States Code, is amended—

(I) in paragraph (1)(A), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21''; and

(II) in paragraph (2), by striking ''section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

321(m))'' and inserting ''section 10101(a)(28) of title 21''.

(xxvi) Section 1467(b) of title 18, United States Code, is amended by striking ''section 413 of the Controlled Substances Act (21 U.S.C. 853), with the exception of subsections (a) and (d),'' and inserting ''section 50713 of title 21, with the exception of subsections (b) and (d),''.

(xxvii) Section 1593(b)(4) of title 18, United States Code, is amended by striking ''section 413 (other than subsection (d) of such section) of the Controlled Substances Act (21 U.S.C. 853)'' and inserting ''section 50713 (other than subsection (d) of such section) of title 21''.

(xxviii) Section 1791(d)(3) of title 18, United States Code, is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(xxix) Section 1841(b)(2) of title 18, United States Code, is amended by striking ''Section 408(e) of the Controlled Substances Act of 1970 (21 U.S.C. 848(e))''

and inserting ''Section 50708(d) of title 21''.

(xxx) Section 1864(a)(1) of title 18, United States Code, is amended by striking ''the Controlled Substances Act,'' and inserting ''division A of subtitle V of title 21,''.

(xxxi) Section 1952(b)(i)(1) of title 18, United States Code, is amended by striking ''section 102(6) of the Controlled Substances Act'' and inserting ''section 50101(9) of title 21''.

(xxxii) Section 1956(c)(7) of title 18, United States Code, is amended—

(I) in subparagraph (B)(i), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21'';

(II) in subparagraph (C), by striking ''section 408 of the Controlled Substances Act (21 U.S.C. 848);'' and inserting ''section 50708 of title 21;''; and

(III) in subparagraph (D), by striking ''section 422 of the Con-

trolled Substances Act'' and inserting ''section 50723 of title 21''.

(xxxiii) Section 1961(1) of title 18, United States Code, is amended—

(I) in subparagraph (A), by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21''; and

(II) in subparagraph (D), by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21''.

(xxxiv) Section 2118 of title 18, United States Code, is amended—

(I) in subsection (a) (matter before paragraph (1)), by striking ''section 302 of the Controlled Substances Act (21 U.S.C. 822)'' and inserting ''section 50502 of title 21'';

(II) in subsection (b) (matter before paragraph (1)), by striking ''section 302 of the Controlled Substances Act (21 U.S.C. 822)'' and inserting ''section 50502 of title 21''; and

(III) in subsection (e)(1), by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21''.

(xxxv) Section 2253(b) of title 18, United States Code, is amended by striking ''Section 413 of the Controlled Substances Act (21 U.S.C. 853) with the exception of subsections (a) and (d)'' and inserting ''Section 50713 of title 21 with the exception of subsections (b) and (d)''.

(xxxvi) Section 2320(f)(6) of title 18, United States Code, is amended by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21''.

(xxxvii) Section 2323(b)(2)(A) of title 18, United States Code, is amended by striking ''section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853), other than subsection (d) of that section'' and inserting ''section 50713 of title 21, other than subsection (d) of that section''.

(xxxviii) Section 2328(b) of title 18, United States Code, is amended by striking ''section 413 of the Controlled Substances Act (21 U.S.C. 853), other than subsection (d) of that section,'' and inserting ''section 50713 of title 21, other than subsection (d) of that section,''.

(xxxix) Section 2332b(g)(5)(B)(iv) of title 18, United States Code, is amended by striking ''section 1010A of the Controlled Substances Import and Export Act'' and inserting ''section 51711 of title 21''.

(xl) Section 2333(e) of title 18, United States Code, is amended by striking ''section 805(b) of the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1904(b))'' and inserting ''section 61105(b) of title 21''.

(xli) Section 2429(c) of title 18, United States Code, is amended by striking ''section 413 (other than subsection (d) of such section) of the Controlled Substances Act (21 U.S.C. 853)'' and inserting ''section 50713 (other than subsection (d) of such section) of title 21''.

(B) PART II, CRIMINAL PROCEDURE.—

(i) Section 3142 of title 18, United States Code, is amended—

(I) in subsection (c)(1)(B)(ix), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21'';

(II) in subsection (e)(3)(A), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.),'' and inserting ''division A or B of subtitle V of title 21''; and

(III) in subsection (f)(1)(C), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.),'' and inserting ''division A or B of subtitle V of title 21''.

(ii) Section 7304(e) of the Anti-Drug Abuse Act of 1988 (Public Law 100–690, 18 U.S.C. 3154 note) is amended by strik-

ing ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''.

(iii) Section 3553(f) of title 18, United States Code, is amended—

(I) in the matter before paragraph (1), by striking ''section 401, 404, or 406 of the Controlled Substances Act (21 U.S.C. 841, 844, 846), section 1010 or 1013 of the Controlled Substances Import and Export Act (21 U.S.C. 960, 963),'' and inserting ''section 50701, 50704, 50706, 51710, or 51714 of title 21''; and

(II) in paragraph (4), by striking ''section 408 of the Controlled Substances Act'' and inserting ''section 50708 of title 21''.

(iv) Section 3554 of title 18, United States Code, is amended—

(I) by striking ''title II or III of the Comprehensive Drug Abuse Prevention and Control Act of 1970'' and

inserting ''division A or B of subtitle V of title 21,''; and

(II) by striking ''section 413 of the Comprehensive Drug Abuse and Control Act of 1970'' and inserting ''section 50713 of title 21''.

(v) Section 3559 of title 18, United States Code, is amended—

(I) in subsection (c)(2)(H)—

(aa) in clause (i), by striking ''section 401(b)(1)(A) or 408 of the Controlled Substances Act (21 U.S.C. 841(b)(1)(A), 848) or section 1010(b)(1)(A) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)(1)(A))'' and inserting ''section 50701(b)(1)(A), 50708, or 51710(b)(1)(A)(i) of title 21''; and

(bb) in clause (ii), by striking ''section 401(b)(1)(A) or 408 of the Controlled Substances Act (21 U.S.C. 841(b)(1)(A), 848) or section 1010(b)(1)(A) of the

Controlled Substances Import and Export Act (21 U.S.C. 960(b)(1)(A))'' and inserting ''section 50701(b)(1)(A), 50708, or 51710(b)(1)(A)(i) of title 21''; and

(II) in subsection (c)(4), by striking ''section 411(a) of the Controlled Substances Act (21 U.S.C. 851(a))'' and inserting ''section 50711(a) of title 21''.

(vi) Section 3563(b)(7) of title 18, United States Code, is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(vii) Section 3582(e) of title 18, United States Code, is amended by striking ''the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.)'' and inserting ''division A or B of subtitle V of title 21''.

(viii) Section 3591(b) of title 18, United States Code, is amended—

(I) in paragraph (1), by striking ''section 408(c)(1) of the Controlled Substances Act (21 U.S.C. 848(c)(1))'' and inserting ''section 50708(a)(1)(A) of title 21''; and

(II) in paragraph (2), by striking ''section 408(c)(1) of the Controlled Substances Act (21 U.S.C. 848(c)(1))'' and inserting ''section 50708(a)(1)(A) of title 21''.

(ix) Section 3592 of title 18, United States Code, is amended—

(I) in subsection (c)—

(aa) in paragraph (12), by striking ''title II or III of the Comprehensive Drug Abuse Prevention and Control Act of 1970'' and inserting ''division A or B of subtitle V of title 21''; and

(bb) in paragraph (13)—

(AA) by striking ''section 408(c) of the Controlled Substances Act (21 U.S.C. 848(c))'' and inserting ''sec-

tion 50708(a)(1) of title 21''; and

(BB) by striking ''section 418 of that Act (21 U.S.C. 859)'' and inserting ''section 50718 of title 21''; and

(II) in subsection (d)—

(aa) in paragraph (2), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21'';

(bb) in paragraph (3), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21'';

(cc) in paragraph (5), by striking ''section 418 of the Controlled Substances Act (21 U.S.C. 859)'' and inserting ''section 50718 of title 21'';

(dd) in paragraph (6), by striking ''section 419 of the Con-

trolled Substances Act (21 U.S.C. 860)'' and inserting ''section 50719 of title 21'';

(ee) in paragraph (7), by striking ''section 420 of the Controlled Substances Act (21 U.S.C. 861)'' and inserting ''section 50721 of title 21''; and

(ff) in paragraph (8), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(x) Section 3607 of title 18, United States Code, is amended—

(I) in subsection (a), in the matter before paragraph (1), by striking ''section 404 of the Controlled Substances Act (21 U.S.C. 844)'' and inserting ''section 50704 of title 21''; and

(II) in subsection (c), by striking ''section 404 of the Controlled Substances Act (21 U.S.C. 844)'' and inserting ''section 50704 of title 21''.

(xi) Section 3612 of title 18, United States Code, is amended—

(I) in subsection (j)—

(aa) in paragraph (1), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21''; and

(bb) in paragraph (2), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21''; and

(II) in subsection (k)—

(aa) in paragraph (1), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21'';

(bb) in paragraph (2)(A), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21''; and

(cc) in paragraph (3)(A), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21''.

(xii) Section 3632(d)(4)(D) of title 18, United States Code, is amended—

(I) in clause (lviii), by striking ''Section 401(a) of the Controlled Substances Act (21 U.S.C. 841)'' and inserting ''Section 50701(a) of title 21'';

(II) in clause (lxv), by striking ''Subparagraph (A)(i) or (B)(i) of section 401(b)(1) of the Controlled Substances Act (21 U.S.C. 841(b)(1)) or paragraph (1)(A) or (2)(A) of section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)),'' and inserting ''Subparagraph (A)(i)(I) or (B)(i)(I) of section 50701(b)(1) of title 21 or paragraph (1)(A)(i) or (2)(A)(i) of section 51710(b) of title 21,'';

(III) in clause (lxvi), by striking ''Subparagraph (A)(vi) or (B)(vi) of section 401(b)(1) of the Controlled Substances Act (21 U.S.C. 841(b)(1)) or paragraph (1)(F) or (2)(F) of section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)),'' and inserting ''Subparagraph (A)(i)(VI) or (B)(i)(VI) of section 50701(b)(1) of title 21 or paragraph (1)(A)(vi) or (2)(A)(vi) of section 51710(b) of title 21,'';

(IV) in clause (lxvii), by striking ''Subparagraph (A)(viii) or (B)(viii) of section 401(b)(1) of the Controlled Substances Act (21 U.S.C. 841(b)(1)) or paragraph (1)(H) or (2)(H) of section 1010(b) the Controlled Substances Import and Export Act (21 U.S.C. 960(b)),'' and inserting ''Subparagraph (A)(i)(VIII) or (B)(i)(VIII) of section 50701(b)(1) of title 21 or paragraph (1)(A)(viii) or (2)(A)(viii) of section 51710(b) title 21,''; and

(V) in clause (lxviii), in the matter before subclause (I), by striking ''Subparagraph (A) or (B) of section 401(b)(1) of the Controlled Substances Act (21 U.S.C. 841(b)(1)) or paragraph (1) or (2) of section 1010(b) of the Controlled Substances Import and Export Act (21 U.S.C. 960(b)),'' and inserting ''Subparagraph (A) or (B) of section 50701(b)(1) of title 21 or paragraph (1) or (2) of section 51710(b) of title 21,''.

(xiii) Section 3663 of title 18, United States Code, is amended—

(I) in subsection (a)(1)(A), by striking ''section 401, 408(a), 409, 416, 420, or 422(a) of the Controlled Substances Act (21 U.S.C. 841, 848(a), 849, 856, 861, 863)'' and inserting ''section 50701, 50708(a), 50709, 50716, 50721, or 50723(b) of title 21''; and

(II) in subsection (c)—

(aa) in paragraph (1), by striking ''section 401, 408(a), 409, 416, 420, or 422(a) of the Controlled Substances Act (21 U.S.C. 841, 848(a), 849, 856, 861, 863)'' and inserting ''section 50701, 50708(a), 50709, 50716, 50721, or 50723(b) of title 21''; and

(bb) in paragraph (4), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21''.

(xiv) Section 3663A(c)(1)(A)(ii) of title 18, United States Code, is amended by striking ''section 416(a) of the Controlled Substances Act (21 U.S.C. 856(a))'' and inserting ''section 50716(a) of title 21''.

(C) PART IV, CORRECTION OF YOUTHFUL OFFENDERS.—

(i) Section 5032 of title 18, United States Code, is amended—

(I) in the first paragraph, by striking ''section 401 of the Controlled Substances Act (21 U.S.C. 841), or section 1002(a), 1003, 1005, 1009, or 1010(b)(1), (2), or (3) of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 953, 955, 959, 960(b)(1), (2), (3)),'' and inserting ''section 50701, 51702(a), 51703, 51705, or 51709 of title 21, paragraphs (1), (2), or (3) of section 51710(b) of title 21, or''; and

(II) in the fourth paragraph—

(aa) by striking ''section 401 of the Controlled Substances Act (21 U.S.C. 841), or section 1002(a), 1005, or 1009 of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 955, 959),'' and inserting ''section 50701, 51702(a), 51705, or 51709 of title 21,''; and

(bb) by striking ''subsection (b)(1)(A), (B), or (C), (d), or (e)

of section 401 of the Controlled Substances Act, or section 1002(a), 1003, 1009, or 1010(b)(1), (2), or (3) of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 953, 959, 960(b)(1), (2), (3)),'' and inserting ''subparagraph (A), (B), or (C) of section 50701(b)(1) of title 21, subsection (d) or (h) of section 50701 of title 21, section 51702(a), 51703, or 51709 of title 21, or paragraph (1), (2), or (3) of section 51710(b) of title 21,''.

(ii) Section 5038 of title 18, United States Code, is amended—

(I) in subsection (d), by striking ''section 401 of the Controlled Substances Act or section 1001(a), 1005, or 1009 of the Controlled Substances Import and Export Act,'' and inserting ''section 50701, 51701(a), 51705, or 51709 of title 21,''; and

(II) in subsection (f), by striking ''section 401 of the Controlled Substances Act or section 1001(a), 1005, or 1009 of the Controlled Substances Import and Export Act,'' and inserting ''section 50701, 51701(a), 51705, or 51709 of title 21,''.

(10) TITLE 19.—

(A) Section 401(m) of the Tariff Act of 1930 (19 U.S.C. 1401(m)) is amended—

(i) in the matter before paragraph (1), by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21, United States Code''; and

(ii) in paragraph (2), by striking ''the Controlled Substances Import and Export Act'' and inserting ''division B of subtitle V of title 21, United States Code''.

(B) Section 583 of the Tariff Act of 1930 (19 U.S.C. 1583) is amended—

(i) in subsection (a)(2)(C), by striking ''Section 1003 of the Controlled Substances Import and Export Act (relating to exportation of controlled substances) (21

U.S.C. 953)'' and inserting ''Section 51703 of title 21, United States Code (relating to exportation of controlled substances)''; and

(ii) in subsection (c)(1)(C), by striking ''section 202 of the Controlled Substances Act (21 U.S.C. 812)'' and inserting ''section 50302 of title 21, United States Code''.

(C) Section 584(a)(2) of the Tariff Act of 1930 (19 U.S.C. 1584(a)(2)) is amended by striking ''sections 102(18) and 102(16), respectively, of the Controlled Substances Act (21 U.S.C. 802(18) and 802(16))'' and inserting ''sections 50101(39) and 50101(35), respectively, of title 21, United States Code''.

(D) Section 596(c)(1)(B) of the Tariff Act of 1930 (19 U.S.C. 1595a(c)(1)(B)) is amended by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.),'' and inserting ''division A of subtitle V of title 21, United States Code,''.

(E) Section 607(b) of the Tariff Act of 1930 (19 U.S.C. 1607(b)) is amended by striking ''section 102 of the Controlled Substances

Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(F) Section 606 of the Trade Act of 1974 (19 U.S.C. 2484) is amended by striking ''section 202 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 812)'' and inserting ''section 50302 of title 21, United States Code''.

(G) Section 492 of the Trade Agreements Act of 1979 (19 U.S.C. 2578a) is amended—

(i) in subsection (b), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code,''; and

(ii) in subsection (c), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(11) TITLE 20.—

(A) Section 892(f)(3)(A)(i) of the Higher Education Act of 1965 (20 U.S.C. 1161w(f)(3)(A)(i)) is amended by striking ''section 102 of the Controlled Substances Act (21

U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(B) Section 612(a)(25)(A) of the Individuals with Disabilities Education Act (20 U.S.C. 1412(a)(25)(A)) is amended by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21, United States Code,''.

(C) Section 615(k)(7) of the Individuals with Disabilities Education Act (20 U.S.C. 1415(k)(7)) is amended—

(i) in subparagraph (A), by striking ''section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c))'' and inserting ''section 50302(c) of title 21, United States Code''; and

(ii) in subparagraph (B), by striking ''under that Act'' and inserting ''under division A of subtitle V of title 21, United States Code,''.

(D) Section 4001(c) (matter before paragraph (1)) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7101(c) (matter before paragraph (1)) is amended by striking ''section 102 of the Controlled Sub-

stances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code,''.

(E) Section 4102(2) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7112(2)) is amended by striking ''section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c))'' and inserting ''section 50302(c) of title 21, United States Code''.

(12) TITLE 21.—

(A) 21ST CENTURY CURES ACT.—Section 3043 of the 21st Century Cures Act (21 U.S.C. 356 note) is amended by inserting after ''or an amendment made by this subtitle'' the parenthetical ''(except the amendment made by section 3042 of this Act)''.

(B) PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002.—Section 122 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (21 U.S.C. 356–1) is amended to read as follows:

**''§ 122. DEFINITIONS**

''For the purposes of this title:

''(1) PRIORITY COUNTERMEASURE.—The term 'priority countermeasure' has the meaning given such term in section 319F(e)(4) of the Public Health Service Act (42 U.S.C. 247d–6(e)(4)).

''(2) PRIORITY DRUGS OR BIOLOGICAL PRODUCTS.—The term 'priority drugs or biological products' means a drug or biological product that is the subject of a drug or biologics application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2298).''

(13) TITLE 22.—

(A) Section 22 of the Inter-American Development Bank Act (22 U.S.C. 283s) is amended by striking ''the Comprehensive Drug Abuse Prevention and Control Act of 1970'' and inserting ''division A of subtitle V of title 21, United States Code''.

(B) Section 13 of the International Development Association Act (22 U.S.C. 284k) is amended by striking ''the Comprehensive Drug Abuse Prevention and Control Act of 1970'' and inserting ''division A of subtitle V of title 21, United States Code''.

(C) Section 19 of the Asian Development Bank Act (22 U.S.C. 285p) is amended by striking ''the Comprehensive Drug Abuse Prevention and Control Act of 1970'' and inserting ''division A of subtitle V of title 21, United States Code''.

(D) Section 481(e)(6) of the Foreign Assistance Act of 1961 (22 U.S.C. 2291(e)(6)) is amended by striking ''paragraph (33) of section 102 of the Controlled Substances Act (21 U.S.C. 802(33))'' and inserting ''section 50101(32) of title 21, United States Code''.

(E) Section 599H of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1991 (Public Law 101–513, 22 U.S.C. 2291 note) is amended—

(i) in subsection (a)(2), by striking ''section 102 of the Controlled Substances Act (21 USC 802)'' and inserting ''section 50101 of title 21, United States Code''; and

(ii) in subsection (e), by striking ''the Federal Food, Drug and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(F) Section 2018(d)(3) of the International Narcotics Control Act of 1986 (Public Law 99–570, title II, 22 U.S.C. 2291 note) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(G) Section 36(k)(9) of the State Department Basic Authorities Act of 1956 (22 U.S.C. 2708(k)(9)) is amended by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21, United States Code''.

(H) Section 42(e) of the State Department Basic Authorities Act of 1956 (22 U.S.C. 2714(e)) is amended—

(i) in paragraph (1), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''; and

(ii) in paragraph (2)(A), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.) or the Controlled Substances Import and Export Act (21 U.S.C. 951 et

seq.)'' and inserting ''division A or B of subtitle V of title 21, United States Code''.

(I) Section 902 of the Trade Sanctions Reform and Export Enhancement Act of 2000 (22 U.S.C. 7201) is amended—

(i) in paragraph (4), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''; and

(ii) in paragraph (5), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(J) Section 221(b)(4) of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (22 U.S.C. 7210(4)) is amended by striking ''the Foreign Narcotics Kingpin Designation Act (Public Law 106–120)'' and inserting ''chapter 611 of title 21, United States Code''.

(K) Section 101 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (22 U.S.C. 8511) is amended—

(i) in paragraph (7), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''; and

(ii) in paragraph (8), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(L) Section 212(c) of the Iran Threat Reduction and Syria Human Rights Act of 2012 (22 U.S.C. 8722(c)) is amended—

(i) in paragraph (2), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''; and

(ii) in paragraph (3), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and insert-

ing ''section 10101 of title 21, United States Code''.

(M) Section 1242(a) of the Iran Freedom and Counter-Proliferation Act of 2012 (22 U.S.C. 8801(a)) is amended—

(i) in paragraph (10), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''; and

(ii) in paragraph (11), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(N) Section 111(d) of the Countering Iran's Destabilizing Activities Act of 2017 (22 U.S.C. 9410(d)) is amended—

(i) in paragraph (3), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''; and

(ii) in paragraph (4), by striking ''section 201 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(14) TITLE 23.—

(A) Section 159 of title 23, United States Code, is amended—

(i) in subsection (a)(3)(A)(i)(I), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21''; and

(ii) in subsection (c)(2)(A), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21''.

(B) Section 2006(d) of the Highway Safety Act of 1991 (Public Law 102–240, title II, part A, 23 U.S.C. 403 note) is amended by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21, United States Code''.

(C) Section 9005(i)(1) of the Drunk Driving Prevention Act of 1988 (Public Law 100–690, title IX, subtitle A, 23 U.S.C. 403 note) is amended by striking ''section 102(6) of the

Controlled Substance Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21, United States Code,''.

(15) TITLE 25.—

(A) Section 4(3)(D)(i)(I) of the Indian Law Enforcement Reform Act (25 U.S.C. 2803(3)(D)(i)(I)) is amended—

(i) in item (aa), by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21, United States Code''; and

(ii) in item (cc), by striking ''section 731 of the USA PATRIOT Improvement and Reauthorization Act of 2005 (21 U.S.C. 865)'' and inserting ''section 69917 of title 21, United States Code''.

(B) Section 4(3) of the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4103(3)) is amended by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''.

(16) TITLE 26.—

(A) Section 45C of the Internal Revenue Code of 1986 (26 U.S.C. 45C) is amended—

(i) in subsection (b)(2)(A)—

(I) in clause (i), by striking ''section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section),'' and inserting ''section 13510 of title 21, United States Code, or regulations issued under such section,'';

(II) in clause (ii)(I), by striking ''section 526 of such Act'' and inserting ''section 13902 of such title'';

(III) in clause (ii)(II), by striking ''section 505(b) of such Act'' and inserting ''section 13503 of such title''; and

(IV) in clause (iii), by striking ''such section 526 applies'' and inserting ''such section 13902 applies'';

(ii) in subsection (b)(2)(B), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code''; and

(iii) in subsection (d)—

(I) in paragraph (1) (matter after subparagraph (B)), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code''; and

(II) in paragraph (2)(B), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code,''.

(B) Section 170(e)(3)(A)(iv) of the Internal Revenue Code of 1986 (26 U.S.C. 170(e)(3)(A)(iv)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act, as amended,'' and inserting ''subtitle I of title 21, United States Code,''.

(C) Section 280E of the Internal Revenue Code of 1986 (26 U.S.C. 280E) is amended by striking ''the Controlled Substances Act'' and inserting ''section 50302 of title 21, United States Code''.

(D) Section 9008(e)(2) of the Patient Protection and Affordable Care Act (Public Law

111–148, 26 U.S.C. note prec. 4001) is amended—

(i) in subparagraph (A)(i), by striking ''section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b))'' and inserting ''section 13503 of title 21, United States Code''; and

(ii) in subparagraph (B), by striking ''section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b))'' and inserting ''section 13103(a) of title 21, United States Code''.

(17) TITLE 28.—

(A) Section 524(c) of title 28, United States Code, is amended—

(i) in paragraph (1)(G), by striking ''the Controlled Substances Act, the Controlled Substances Import and Export Act,'' and inserting ''division A or B of subtitle V of title 21,''; and

(ii) in paragraph (4)(D)—

(I) in clause (i), by striking ''paragraph (2) of section 413(q) of the Controlled Substances Act (21 U.S.C. 853(q))'' and inserting ''para-

graph (2) of section 50713(q) of title 21''; and

(II) in clause (ii), by striking ''paragraph (1) or (3) of section 413(q) of the Controlled Substances Act'' and inserting ''paragraph (1) or (3) of section 50713(q) of title 21''.

(B) Section 994 of title 28, United States Code, is amended—

(i) in subsection (h)—

(I) in paragraph (1)(B), by striking ''section 401 of the Controlled Substances Act (21 U.S.C. 841), sections 1002(a), 1005, and 1009 of the Controlled Substances Import and Export Act (21 U.S.C. 952(a), 955, and 959),'' and inserting ''sections 50701, 51702(a), 51705, and 51709 of title 21''; and

(II) in paragraph (2)(B), by striking ''section 401 of the Controlled Substances Act (21 U.S.C. 841), sections 1002(a), 1005, and 1009 of the Controlled Substances Import and Export Act (21 U.S.C.

952(a), 955, and 959),'' and inserting ''sections 50701, 51702(a), 51705, and 51709 of title 21''; and

(ii) in subsection (i)(5), by striking ''section 401 or 1010 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 841 and 960)'' and inserting ''section 50701 or 51710 of title 21''.

(C) Section 2201(b) of title 28, United States Code, is amended by striking ''section 505 or 512 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 or 137 of title 21''.

(D) Section 2254(h) of title 28, United States Code, is amended by striking ''section 408 of the Controlled Substances Act'' and inserting ''section 50708 of title 21''.

(E) Section 2255(g) of title 28, United States Code, is amended by striking ''section 408 of the Controlled Substances Act'' and inserting ''section 50708 of title 21''.

(F) Section 2461(c) of title 28, United States Code, is amended—

(i) by striking ''section 413 of the Controlled Substances Act (21 U.S.C. 853)'' and inserting ''section 50713 of title 21''; and

(ii) by striking ''such Act'' and inserting ''division A of subtitle V of title 21''.

(18) TITLE 29.—

(A) Section 7(10) of the Rehabilitation Act of 1973 (29 U.S.C. 705(10)) is amended—

(i) in subparagraph (A), by striking ''section 202 of the Controlled Substances Act (21 U.S.C. 812)'' and inserting ''section 50302 of title 21, United States Code''; and

(ii) in subparagraph (B)—

(I) in the first sentence, by striking ''under the Controlled Substances Act.'' and inserting ''under division A of subtitle V of title 21, United States Code.''; and

(II) in the last sentence, by striking ''by the Controlled Substances Act'' and inserting ''by division A of subtitle V of title 21, United States Code,''.

(B) Section 904(c)(2) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 29 U.S.C. 792 note) is amended by striking ''section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1))'' and inserting ''section 13103(a)(1) of title 21, United States Code''.

(C) Section 411(a) (matter before paragraph (1)) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1111(a) (matter before paragraph (1))) is amended by striking ''section 102(6) of the Comprehensive Drug Abuse Prevention and Control Act of 1970'' and inserting ''section 50101(9) of title 21, United States Code''.

(D) Section 504(e)(1)(A) of the Migrant and Seasonal Agricultural Worker Protection Act (29 U.S.C. 1854(e)(1)(A)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(E) Section 7(f)(1) of the Employee Polygraph Protection Act of 1988 (29 U.S.C. 2006(f)(1)) is amended by striking ''section 202

of the Controlled Substances Act (21 U.S.C. 812)'' and inserting ''section 50302 of title 21, United States Code''.

(F) Section 152(b)(2)(C)(i) of the Workforce Innovation and Opportunity Act (29 U.S.C. 3202(b)(2)(C)(i)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(19) TITLE 31.—

(A) Section 5317(c)(1)(B) of title 31, United States Code, is amended by striking ''section 413 of the Controlled Substances Act'' and inserting ''section 50713 of title 21''.

(B) Section 5332(b) of title 31, United States Code, is amended—

(i) in paragraph (3), by striking ''section 413 of the Controlled Substances Act'' and inserting ''section 50713 of title 21''; and

(ii) in paragraph (4), by striking ''section 413(p) of the Controlled Substances Act'' and inserting ''section 50713(p) of title 21''.

(20) TITLE 33.—Section 105(i)(1) of the Marine Protection, Research, and Sanctuaries Act of 1972 (33 U.S.C. 1415(i)(1)) is amended by striking ''sections 413 and 511 of the Controlled Substances Act (21 U.S.C. 853, 881)'' and inserting ''sections 50713 and 50911 of title 21, United States Code''.

(21) TITLE 34.—

(A) Section 3025 of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10705) is amended—

(i) in paragraph (4), by striking ''section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c))'' and inserting ''section 50302(c) of title 21, United States Code''; and

(ii) in paragraph (5), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''.

(B) Section 90102 of the Violent Crime Control and Law Enforcement Act of 1994 (34 U.S.C. 12521) is amended by striking ''section 419 of the Controlled Substances Act (21

U.S.C. 860)'' and inserting ''section 50719 of title 21, United States Code''.

(C) Section 90103(b) of the Violent Crime Control and Law Enforcement Act of 1994 (34 U.S.C. 12522(b) is amended—

(i) in paragraph (1), by striking ''section 404 of the Controlled Substances Act'' and inserting ''section 50704 of title 21, United States Code,''; and

(ii) in paragraph (2), by striking ''section 401(b) of the Controlled Substances Act'' and inserting ''section 50701(b) of title 21, United States Code,''.

(D) Section 180102(b) (matter before paragraph (1)) of the Violent Crime Control and Law Enforcement Act of 1994 (34 U.S.C. 12541(b) (matter before paragraph (1))) is amended by striking ''section 503(a) of the Controlled Substances Act (21 U.S.C. 873(a))'' and inserting ''section 50903(a) of title 21, United States Code,''.

(22) TITLE 35.—

(A) Section 156 of title 35, United States Code, is amended—

(i) in subsection (d)(2)(A)(ii), by striking ''the Federal Food, Drug, and Cosmetic Act,'' and inserting ''subtitle I of title 21,'';

(ii) in subsection (d)(2)(B)(i), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(iii) in subsection (f)(1)(B), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(iv) in subsection (f)(2)(A), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(v) in subsection (f)(2)(B), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(vi) in subsection (f)(4)(B), by striking ''Any reference to section 503, 505, 512, or 515 is a reference to section 503, 505, 512, or 515 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''Any reference to chapter 135 or 137 or

to section 13142 is a reference to chapter 135 or 137 or to section 13142, respectively, of title 21'';

(vii) in subsection (f)(5), by striking ''section 201(y) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(23) of title 21'';

(viii) in subsection (g)(1)(B)(i)—

(I) by striking ''under subsection (i) of section 505 or subsection (d) of section 507'' and inserting ''under section 13510 of title 21''; and

(II) by striking ''under section 351, 505, or 507'' and inserting ''under section 351 or under chapter 135'';

(ix) in subsection (g)(1)(B)(ii) by striking ''under section 351, subsection (b) of section 505, or section 507'' and inserting ''under section 351 or under section 13503 of title 21'';

(x) in subsection (g)(2)(B)(i), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(xi) in subsection (g)(2)(B)(ii), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(xii) in subsection (g)(3)(B)(i), by striking ''under section 515'' and inserting ''under section 13142'';

(xiii) in subsection (g)(3)(B)(ii)—

(I) by striking ''submitted with respect to the device under section 515'' and inserting ''submitted with respect to the device under section 13142'';

(II) by striking ''under such Act'' and inserting ''under subtitle I of title 21'';

(III) by striking ''initially submitted under section 515(f)(5)'' and inserting ''initially submitted under section 13142(f)(5)''; and

(IV) by striking ''completed under section 515(f)(6)'' and inserting ''completed under section 13142(f)(6)'';

(xiv) in subsection (g)(4)(B)(i)—

(I) by striking ''subsection (j) of section 512'' and inserting ''section 13711 of title 21''; and

(II) by striking ''under section 512'' and inserting under ''under chapter 137'';

(xv) in subsection (g)(4)(B)(ii)—

(I) by striking ''subsection (b) of section 512'' and inserting ''section 13703 of title 21''; and

(II) by striking ''under such section'' and inserting ''under chapter 137'';

(xvi) in subsection (g)(6)(C), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(xvii) in subsection (i)(1)—

(I) in the matter before subparagraph (A), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21''; and

(II) in subparagraph (A), by striking ''or Federal Food, Drug, and

Cosmetic Act'' and inserting ''or subtitle I of title 21''; and

(xviii) in subsection (i)(2)—

(I) in subparagraph (A)(ii), by striking ''section 505(b) or 512(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13503 or 13704 of title 21'';

(II) in subparagraph (B), by striking ''section 571(b) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14502(c) of title 21'';

(III) in subparagraph (C), by striking ''section 572(d) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14503(d) of title 21''; and

(IV) in subparagraph (D), by striking ''section 201(j) of the Controlled Substances Act'' and inserting ''section 50301(j) of title 21''.

(B) Section 257(c)(2)(A) of title 35, United States Code, is amended by striking ''under section 505(j)(2)(B)(iv)(II) of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II)),'' and inserting ''under section 13511(c)(3)(D)(ii) of title 21,''.

(C) Section 271(e) of title 35, United States Code, is amended—

(i) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21'';

(ii) in paragraph (2)(A)—

(I) by striking ''section 505(j) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13511 of title 21''; and

(II) by striking ''section 505(b)(2) of such Act'' and inserting ''section 13503(b) of title 21'';

(iii) in paragraph (2)(B), by striking ''section 512 of such Act'' and inserting ''chapter 137 of title 21''; and

(iv) in paragraph (5)—

(I) by striking ''under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355),'' and inserting ''under section

13503(b)(1)(D) or 13511(c)(1)(G)(iv) of title 21,'';

(II) by striking ''subsection (b) of such section'' and inserting ''section 13503 of title 21''; and

(III) by striking ''subsection (b)(3) or (j)(2)(B) of such section'' and inserting ''section 13503(c) or 13511(c)(3) of title 21''.

(D) Section 287(c)(3)(B) of title 35, United States Code, is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21''.

(23) TITLE 38.—

(A) Section 902 of the Jason Simcakoski Memorial and Promise Act (Public Law 114–198, 38 U.S.C. 1701 note) is amended—

(i) in paragraph (1), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''; and

(ii) in paragraph (4), by striking ''the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code,''.

(B) Section 1730B(c)(1) of title 38, United States Code, is amended by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21''.

(C) Section 1730C(e) of title 38, United States Code, is amended by striking ''the Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21''.

(D) Section 7309A(f) of title 38, United States Code, is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(E) Section 7334(b)(2) of title 38, United States Code, is amended by striking ''the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1101 et seq.)'' and inserting ''the Drug Abuse Prevention, Treatment, and Rehabilitation Act''.

(24) TITLE 40.—Section 1306(h)(3)(A) of title 40, United States Code, is amended by striking ''the

Controlled Substances Act (21 U.S.C. 801 et seq.)'' and inserting ''division A of subtitle V of title 21''.

(25) TITLE 41.—Section 8101(a)(2) of title 41, United States Code, is amended by striking ''section 202 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 812)'' and inserting ''section 50302 of title 21''.

(26) TITLE 42.—

(A) PUBLIC HEALTH SERVICE ACT.—

(i) Section 2 of the Public Health Service Act (42 U.S.C. 201) is amended—

(I) in subsection (f), by striking ''355(5),''; and

(II) in subsection (q), by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''.

(ii) Section 227 of the Public Health Service Act (42 U.S.C. 236) is amended—

(I) in subsection (c)—

(aa) in paragraph (1)(A), by striking ''subchapter B of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chap-

ter 139 of title 21, United States Code,'';

(bb) in paragraph (1)(B), by striking ''such subchapter;'' and inserting ''such chapter,''; and

(cc) in paragraph (5)—

(AA) by striking ''section 505(i) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13510 of title 21, United States Code,''; and

(BB) by striking ''section 505(c) of such Act'' and inserting ''section 13504 of such title''; and

(II) in subsection (e)—

(aa) in paragraph (1), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code,''; and

(bb) in the matter after paragraph (3), by striking ''sec-

tion 5 of the Orphan Drug Act'' and inserting ''section 49502 of title 21, United States Code,''.

(iii) Section 248(e)(2)(A)(i) of the Public Health Service Act (42 U.S.C. 238q(e)(2)(A)(i)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(iv) Section 302(a) of the Public Health Service Act (42 U.S.C. 242(a)) is amended—

(I) in the second sentence, by striking ''the Controlled Substances Act and Controlled Substances Import and Export Act,'' and inserting ''divisions A and B of subtitle V of title 21, United States Code,'';

(II) in the last sentence, by striking ''control under such Acts'' and inserting ''control under such divisions A and B''; and

(III) in the last sentence, by striking ''importation requirements under such Acts'' and inserting ''im-

portation requirements under such divisions A and B''.

(v) Section 319E of the Public Health Service Act (42 U.S.C. 247d–5) is amended—

(I) in subsection (g)—

(aa) in paragraph (1), by striking ''section 506(h) of the Federal Food, Drug, and Cosmetic Act;'' and inserting ''section 13119(i) of title 21, United States Code;''; and

(bb) in paragraph (3)(B), by striking ''section 506(h) of the Federal Food, Drug, and Cosmetic Act.'' and inserting ''section 13119(i) of title 21, United States Code.''; and

(II) in subsection (j)(1)—

(aa) in the matter before subparagraph (A), by striking ''section 506(h) of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 13119(i)

of title 21, United States Code,'';

and

(bb) in subparagraph (B)(ii), by striking ''such section 506(h)'' and inserting ''such section 13119(i)''.

(vi) Section 319F–1(a)(2)(A) (matter before clause (i)) of the Public Health Service Act (42 U.S.C. 247d–6a(a)(2)(A) (matter before clause(i))) is amended—

(I) by striking ''section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))'' and inserting ''section 10101(a)(18) of title 21, United States Code''; and

(II) by striking ''section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))'' and inserting ''section 10101(a)(16) of title 21, United States Code''.

(vii) Section 319F–2(c)(1)(B) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(1)(B)) is amended—

(I) in the matter before clause (i)—

(aa) by striking ''section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))'' and inserting ''section 10101(a)(18) of title 21, United States Code''; and

(bb) by striking ''section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))'' and inserting ''section 10101(a)(16) of title 21, United States Code'';

(II) in clause (i)(III)(aa), by striking ''chapter V of the Federal Food, Drug, and Cosmetic Act'' and inserting ''division D of subtitle I of title 21, United States Code,''; and

(III) in clause (ii), by striking ''section 564 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14306 of title 21, United States Code''.

(viii) Section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) is amended—

(I) in subsection (b)(8)(B), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code'';

(II) in subsection (c)(5)(A) (matter before clause (i)), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code'';

(III) in subsection (c)(5)(B)(i)—

(aa) by striking ''section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13510 or 13152(g) of title 21, United States Code'';

(bb) by striking ''section 564 of such Act'' and inserting ''section 14306 of such title''; and

(cc) by striking ''chapter V of such Act'' and inserting ''division D of subtitle I of such title'';

(IV) in subsection (c)(5)(B)(ii)(I)—

(aa) by striking ''section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13510 or 13152(g) of title 21, United States Code'';

(bb) by striking ''section 564 of such Act'' and inserting ''section 14306 of such title''; and

(cc) by striking ''chapter 5 of such Act'' and inserting ''division D of subtitle I of such title'';

(V) in subsection (c)(5)(C)(i)(I), by striking ''any provision of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''any provision of subtitle I of title 21, United States Code,'';

(VI) in subsection (c)(5)(C)(i)(II), by striking ''under the Federal Food, Drug, and Cosmetic Act,'' and inserting ''under sub-

title I of title 21, United States Code,'';

(VII) in subsection (i)(1)(C)—

(aa) by striking ''section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))'' and inserting ''section 10101(a)(18) of title 21, United States Code)'';

(bb) by striking ''section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))'' and inserting ''section 10101(a)(16) of title 21, United States Code)''; and

(cc) by striking ''section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act;'' and inserting ''section 14306, 14307, or 14308 of title 21, United States Code;'';

(VIII) in subsection (i)(7) (matter before subparagraph (A))—

(aa) by striking ''section 201(g)(1) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))'' and inserting ''section 10101(a)(18) of title 21, United States Code)''; and

(bb) by striking ''section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))'' and inserting ''section 10101(a)(16) of title 21, United States Code)''; and

(IX) in subsection (i)(7)(B)—

(aa) in clause (i), by striking ''chapter V of the Federal Food, Drug, and Cosmetic Act'' and inserting ''division D of subtitle I of title 21, United States Code,'';

(bb) in clause (ii), by striking ''section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13510 or 13152(g) of title 21, United States Code''; and

(cc) in clause (iii), by striking ''section 564, 564A, or 564B

of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14306, 14307, or 14308 of title 21, United States Code''.

(ix) Section 319L of the Public Health Service Act (42 U.S.C. 247d–7e) is amended—

(I) in subsection (a)(6)(A)(ii), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(II) in subsection (a)(6)(B)(i), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(III) in subsection (e)(2)(C), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(IV) in subsection (e)(4)(B)(iii), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting

''subtitle I of title 21, United States Code,''; and

(V) in subsection (c)(4)(C)(i), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(x)(I) Section 7102(a) of the Patient Protection and Affordable Care Act (Public Law 111–148, 124 Stat. 823) is amended by striking ''Subsection (d) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended to read as follows:'' and inserting ''Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following:''.

(II) The amendment made by subclause (I) shall take effect on January 1, 2010.

(xi) Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—

(I) in subsection (d)(2)(B)(v)(III), by striking ''Pre-

scription Drug Marketing Act (21 U.S.C. 353)'' and inserting ''Prescription Drug Marketing Act of 1987 (Public Law 100–293, 102 Stat. 95)''; and

(II) in subsection (e), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code,''.

(xii) Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(I) in subsection (a)—

(aa) in paragraph (2)(B), by striking ''section 505B of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13113 of title 21, United States Code'';

(bb) in paragraph (2)(D), by striking ''sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''sections 13110, 13515,

and 13516 of title 21, United States Code";

(cc) in paragraph (2)(E)(i), by striking "subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act" and inserting "section 13504(e)(3) of title 21, United States Code"; and

(dd) in paragraph (2)(E)(ii), by striking "section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act" and inserting "section 13504(e) of title 21, United States Code";

(II) in subsection (g), by striking "the Federal Food, Drug, and Cosmetic Act (U.S.C., 1940 edition, title 21, ch. 9)" and inserting "subtitle I of title 21, United States Code";

(III) in subsection (h) (matter after paragraph (3))—

(aa) by striking "the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et. seq.)"

and inserting ''subtitle I of title 21, United States Code,''; and

(bb) by striking ''section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).'' and inserting ''section 20101(e) of title 21, United States Code.'';

(IV) in subsection (j)—

(aa) by striking ''The Federal Food, Drug, and Cosmetic Act, including the requirements under sections 505(o), 505(p), and 505–1 of such Act'' and inserting ''Subtitle I of title 21, United States Code, including the requirements under sections 13111, 13515, and 13516 of such title''; and

(bb) by striking ''section 505 of such Act.'' and inserting ''chapter 135 of such title.'';

(V) in subsection (k)(5)(C), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting

''subtitle I of title 21, United States Code,'';

(VI) in subsection (k)(8)(A), by striking ''section 701(h) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 17501(h) of title 21, United States Code,'';

(VII) in subsection (m)(1)—

(aa) by striking ''subsections (a), (d), (e), (f), (h), (i), (j), (k), (l), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act'' and inserting ''subsections (a), (d), (e), (f), (h), (i), (j), (k), (l) and (n) of section 13112 of title 21, United States Code,''; and

(bb) by striking ''subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act'' and inserting ''subsection (b) or (c) of section 13112 of title 21, United States Code'';

(VIII) in subsection (m)(2)—

(aa) in the matter before subparagraph (A), by striking ''section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13112(d)(4) of title 21, United States Code''; and

(bb) in subparagraph (B)—

(AA) by striking ''section 526'' and inserting ''section 13902 of title 21, United States Code,''; and

(BB) by striking ''section 527(a)'' and inserting ''section 13903(a) of title 21, United States Code,'';

(IX) in subsection (m)(3)—

(aa) in the matter before subparagraph (A), by striking ''section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13112(d)(4) of title 21, United States Code''; and

(bb) in subparagraph (B)—

(AA) by striking ''section 526'' and inserting ''section 13902 of title 21, United States Code,''; and

(BB) by striking ''section 527(a)'' and inserting ''section 13903(a) of title 21, United States Code,'';

(X) in subsection (m)(4), by striking ''section 505A(d)(4)'' and inserting ''section 13112(d)(4) of title 21, United States Code,''; and

(XI) in subsection (n)(1)—

(aa) by striking ''under the Controlled Substances Act,'' and inserting ''under division A of subtitle V of title 21, United States Code,''; and

(bb) by striking ''section 201(j) of the Controlled Substances Act'' and inserting ''section 50301(j) of title 21, United States Code''.

(xiii) Section 351A(g)(2) of the Public Health Service Act (42 U.S.C. 262a(g)(2)) is amended—

(I) in subparagraph (A), by striking ''under any of the Acts specified in subparagraph (B),'' and inserting ''under any of the provisions specified in subparagraph (B),'';

(II) in subparagraph (B)—

(aa) in the matter before clause (i), by striking ''the Acts specified in this subparagraph'' and inserting ''the provisions specified in this subparagraph'';

(bb) in clause (i), by striking ''The Federal Food, Drug, and Cosmetic Act.'' and inserting ''Subtitle I of title 21, United States Code.''; and

(cc) in clause (iii), by striking ''; 21 U.S.C. 151–159''; and

(III) in subparagraph (C)(ii), in the matter before subclause (I), by striking ''the Acts specified in subparagraph (B),'' and inserting ''the

provisions specified in subparagraph (B),''.

(xiv) Section 392A(d)(1) of the Public Health Service Act (42 U.S.C. 280b–1(d)(1)) is amended by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''.

(xv) Section 399L(d)(3) of the Public Health Service Act (42 U.S.C. 280g(d)(3)) is amended—

(I) in subparagraph (B), by striking ''section 503(b) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13103(a) of title 21, United States Code''; and

(II) in subparagraph (C), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101 of title 21, United States Code,''.

(xvi) Section 399O(k)(1) of the Public Health Service Act (42 U.S.C. 280g–3(k)(1)) is amended—

(I) by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''; and

(II) by striking ''section 202 of such Act'' and inserting ''section 50302 of such title''.

(xvii) Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(I) in subsection (i)(3)(A), by striking ''section 505(i) of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 13510 of title 21, United States Code,'';

(II) in subsection (i)(3)(B)(i), by striking ''section 561(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14301(d) of title 21, United States Code'';

(III) in subsection (i)(5), by striking ''section 736 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 17907 of title 21, United States Code,'';

(IV) in subsection (j)(1)(A)(ii)(I), by striking ''section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13136(k), 13142, or 13152(m) of title 21, United States Code,'';

(V) in subsection (j)(1)(A)(ii)(II), by striking ''section 522 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13154 of title 21, United States Code'';

(VI) in subsection (j)(1)(A)(iii)(I), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,'';

(VII) in subsection (j)(1)(A)(vi), by striking ''section 201(h) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(16) of title 21, United States Code'';

(VIII) in subsection (j)(1)(A)(vii), by striking ''section 201(g) of the Federal Food, Drug,

and Cosmetic Act'' and inserting ''section 10101(a)(18) of title 21, United States Code,'';

(IX) in subsection (j)(2)(A)(ii)(II)(gg)—

(aa) by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,''; and

(bb) by striking ''section 561 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14301 of title 21, United States Code,'';

(X) in subsection (j)(2)(D)(ii)(I), by striking ''section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act'' and inserting ''section 13136(k) of title 21, United States Code, or approval under section 13142 or 13152(m) of such title'';

(XI) in subsection (j)(2)(D)(iv)(I), by striking ''section 503(g) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13104 of title 21, United States Code,'';

(XII) in subsection (j)(3)(A)(ii)(I)(bb), by striking ''section 505A or 505B of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 13112 or 13113 of title 21, United States Code,'';

(XIII) in subsection (j)(3)(A)(ii)(I)(dd), by striking ''section 505(l)(2) of the Federal Food, Drug, and Cosmetic Act.'' and inserting ''section 13513(b) of title 21, United States Code.'';

(XIV) in subsection (j)(3)(A)(ii)(I)(ee)—

(aa) by striking ''section 515 of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 13142 of title 21, United States Code,'';

(bb) by striking ''section 520(h)(1) of such Act,'' and inserting ''section 13152(h)(1) of such title,''; and

(cc) by striking ''report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness'' and inserting ''report under section 13136(k) of such title, the section 13136(k) summary of the safety and effectiveness'';

(XV) in subsection (j)(3)(C) (matter before clause (i))—

(aa) by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,''; and

(bb) by striking ''cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act,'' and inserting ''cleared under section

13136(k) of title 21, United States Code, or approved under section 13142 or 13152(m) of such title,'';

(XVI) in subsection (j)(3)(D)(ii)(I)(aa), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,'';

(XVII) in subsection (j)(3)(D)(ii)(I)(bb), by striking ''section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or 520(m) of such Act.'' and inserting ''section 13136(k) of title 21, United States Code, or approved under section 13142 or 13152(m) of such title.'';

(XVIII) in subsection (j)(3)(D)(ii)(II)(aa), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,'';

(XIX) in subsection (j)(3)(D)(ii)(II)(bb), by striking ''section 510(k) of the Federal Food, Drug, and Cosmetic Act and not approved under section 515 or section 520(m) of such Act'' and inserting ''section 13136(k) of title 21, United States Code, and not approved under section 13142 or section 13152(m) of such title'';

(XX) in subsection (j)(3)(E)(iv)—

(aa) by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,'';

(bb) by striking ''cleared under section 510(k) or initially approved under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''cleared under section 13136(k) of title 21, United States Code, or initially approved

under section 13142 or 13152(m) of title 21, United States Code,'';

(cc) by striking ''such section 505'' and inserting ''such chapter 135''; and

(dd) by striking ''under such section 510(k), or approved under such section 515 or 520(m), as applicable.'' and inserting ''under such section 13136(k), or approved under such section 13142 or 13152(m), as applicable.'';

(XXI) in subsection (j)(3)(E)(v)(I)—

(aa) in the matter before item (aa)—

(AA) by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code''; and

(BB) by striking ''section 510(k), or approval under section 515 or 520(m), of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13136(k), or approval under section 13142 or 13152(m), of title 21, United States Code,'';

(bb) in item (aa)—

(AA) by striking ''such section 505,'' and inserting ''such chapter 135,''; and

(BB) by striking ''cleared under such section 510(k), or approved under such section 515 or 520(m);'' and inserting ''cleared under such section 13136(k), or approved under such section 13142 or 13152(m);'';

(cc) in item (bb), by striking ''such section 505, 351, 510(k),

515, or 520(m); or'' and inserting ''such chapter 135, such section 351, or such section 13136(k), 13142, or 13152(m); or''; and

(dd) in item (cc), by striking ''such section 505, 351, 510(k), 515, or 520(m)'' and inserting ''such chapter 135, such section 351, or such section 13136(k), 13142, or 13152(m)'';

(XXII) in subsection (j)(3)(E)(v)(II), by striking ''under section 351 of this Act or section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act, as applicable'' and inserting ''under section 351 of this Act, chapter 135 of title 21, United States Code, or section 13136(k), 13142, or 13152(m) of title 21, United States Code, as applicable'';

(XXIII) in subsection (j)(4)(A), by striking ''section 505, 510(k), 515, or 520(m) of the Federal Food, Drug,

and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code, or section 13136(k), 13142, or 13152(m) of title 21, United States Code,'';

(XXIV) in subsection (j)(4)(B)(ii)(I)—

(aa) by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,'';

(bb) by striking ''section 510(k) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13136(k) of title 21, United States Code,''; and

(cc) by striking ''section 515 or section 520(m) of such Act'' and inserting ''section 13142 or section 13152(m) of such title''; and

(XXV) in subsection (j)(5)(B)—

(aa) by striking ''section 505 of the Federal Food, Drug,

and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code'';

(bb) by striking ''section 515 of such Act, section 520(m) of such Act'' and inserting ''section 13142 of such title, section 13152(m) of such title''; and

(cc) by striking ''section 510(k) of such Act'' and inserting ''section 13136(k) of such title''.

(xviii) Section 409I(c) of the Public Health Service Act (42 U.S.C. 284m(c)) is amended—

(I) in paragraph (1)—

(aa) in the matter before subparagraph (A), by striking ''subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''subsection (b) or (c) of section 13112 of title 21, United States Code,'';

(bb) in subparagraph (A)(i), by striking ''section 505(j) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13511 of title 21, United States Code,''; and

(cc) in subparagraph (B)—

(AA) by striking ''section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 13503(a) of title 21, United States Code,'';

(BB) by striking ''subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''subsection (c)(5)(A), (c)(5)(B), or (c)(5)(C) of section 13504 of title 21, United States Code, or subsection

(f)(6)(A), (f)(6)(B), or (f)(6)(C) of section 13511 of title 21, United States Code,''; and

(CC) by striking ''section 527 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13903 of title 21, United States Code,'';

(II) in paragraph (2), by striking ''subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act'' and inserting ''subsection (b) or (c) of section 13112 of title 21, United States Code,'';

(III) in paragraph (6)(B)(i) (matter before subclause (I)), by striking ''section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13112(d)(4) of title 21, United States Code'';

(IV) in paragraph (10), by striking ''the Federal Food, Drug, and

Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''; and

(V) in paragraph (11), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(xix) Section 479(b)(2) (matter before subparagraph (A)) of the Public Health Service Act (42 U.S.C. 287(b)(2) (matter before subparagraph (A))) is amended by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code''.

(xx) Section 480 of the Public Health Service Act (42 U.S.C. 287a) is amended—

(I) in subsection (a)—

(aa) in paragraph (2), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101 of title 21, United States Code''; and

(bb) in paragraph (3) (matter before subparagraph (A))—

(AA) by striking ''section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(18) of title 21, United States Code)''; and

(BB) by striking ''section 201(h) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(16) of title 21, United States Code''; and

(II) in subsection (c)(5)(C), by striking ''section 565 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14309 of title 21, United States Code''.

(xxi) Section 485C(d) of the Public Health Service Act (42 U.S.C. 287c–11(d)) is amended by striking ''section 201(ff) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section

10101(a)(17) of title 21, United States Code''.

(xxii) Section 498B(e)(2) of the Public Health Service Act (42 U.S.C. 289g–2(e)(2)) is amended by striking ''section 201(b) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(24) of title 21, United States Code''.

(xxiii) Section 519B(e)(7) of the Public Health Service Act (42 U.S.C. 290bb–25b(e)(7)) is amended by striking ''the Drug-Free Communities Act of 1997'' and inserting ''chapter 605 of title 21, United States Code''.

(xxiv) Section 520E–4(c) (matter before paragraph (1)) of the Public Health Service Act (42 U.S.C. 290bb–36d(c) (matter before paragraph (1))) is amended by striking ''information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 303(h)(2)(B) of the Controlled Substances Act'' and inserting ''information on any practitioner who prescribes

narcotic drugs in schedule III, IV, or V of section 50302 of title 21, United States Code, for the purpose of maintenance or detoxification treatment''.

(xxv) Section 544 of the Public Health Service Act (42 U.S.C. 290dd–3) is amended—

(I) in subsection (a)—

(aa) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(bb) in paragraph (4)—

(AA) in the matter before subparagraph (A), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(BB) in subparagraph (B), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act''

and inserting ''chapter 135 of title 21, United States Code,'';

(II) in subsection (c)—

(aa) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(bb) in paragraph (2), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(cc) in paragraph (3), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(dd) in paragraph (4), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(III) in subsection (d)(1)—

(aa) in subparagraph (A), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(bb) in subparagraph (B), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(cc) in subparagraph (C), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(xxvi) Section 545 of the Public Health Service Act (42 U.S.C. 290ee) is amended—

(I) in subsection (a)—

(aa) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(bb) in paragraph (3), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(cc) in paragraph (4), in the matter before subparagraph (A), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(dd) in paragraph (5), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(II) in subsection (b), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(III) in subsection (c)—

(aa) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and in-

serting ''subtitle I of title 21, United States Code,'';

(bb) in paragraph (2), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(cc) in paragraph (3), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(IV) in subsection (f), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(xxvii) Section 546 of the Public Health Service Act (42 U.S.C. 290ee–1) is amended—

(I) in subsection (a), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(II) in subsection (c)—

(aa) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(bb) in paragraph (2), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(III) in subsection (d), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(IV) in subsection (f)—

(aa) in paragraph (1), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(bb) in paragraph (2), by striking ''the Federal Food, Drug, and Cosmetic Act'' and in-

serting ''subtitle I of title 21, United States Code,''.

(xxviii) Section 548 of the Public Health Service Act (42 U.S.C. 290ee–3) is amended—

(I) in subsection (a)—

(aa) in paragraph (1), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''; and

(bb) in paragraph (4), by striking ''section 202(c) of the Controlled Substances Act'' and inserting ''section 50302(c) of title 21, United States Code''; and

(II) in subsection (b)(5)(A)—

(aa) in clause (i), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(bb) in clause (ii)(I)—

(AA) in item (aa), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(BB) in item (bb), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(xxix) Section 552(g)(1)(B)(i) of the Public Health Service Act (42 U.S.C. 290ee–7(g)(1)(B)(i)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(xxx) Section 1711(b) of the Public Health Service Act (42 U.S.C. 300u–16(b)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(xxxi) Section 2122(b)(2) of the Public Health Service Act (42 U.S.C. 300aa–22(b)(2)) is amended—

(I) in the matter before subparagraph (A), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(II) in subparagraph (B), by striking ''compliance with such Act and section'' and inserting ''compliance with such subtitle and section''.

(xxxii) Section 2123(d)(2) (matter before subparagraph (A)) of the Public Health Service Act (42 U.S.C. 300aa–23(d)(2) (matter before subparagraph (A))) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(xxxiii) Section 2312 of the Public Health Service Act (42 U.S.C. 300cc–12) is amended—

(I) in subsection (a)(1)(B), by striking ''section 505(i) of the Federal

Food, Drug, and Cosmetic Act.'' and inserting ''section 13510 of title 21, United States Code.'';

(II) in subsection (b)(1), in the matter before subparagraph (A), by striking ''section 505(i) of the Federal Food, Drug, and Cosmetic Act,'' and inserting ''section 13510 of title 21, United States Code,''; and

(III) in subsection (d), by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101 of title 21, United States Code''.

(xxxiv) Section 2313(a) of the Public Health Service Act (42 U.S.C. 300cc–13(a)) is amended by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act.'' and inserting ''chapter 135 of title 21, United States Code.''.

(xxxv) Section 2317(e)(1) of the Public Health Service Act (42 U.S.C. 300cc–17(e)(1)) is amended by striking ''section 505 of the Federal Food, Drug and Cos-

metic Act'' and inserting ''chapter 135 of title 21, United States Code,''.

(xxxvi) Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended—

(I) in subsection (b)(4)(H), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''; and

(II) in subsection (d)(2)(J), by striking ''subsections (a)(1), (b)(1), and (e) of section 564 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''subsections (b)(1), (c)(1), and (f) of section 14306 of title 21, United States Code''.

(xxxvii) Section 3000(12) of the Public Health Service Act (42 U.S.C. 300jj(12)) is amended by striking ''section 804(2) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 20104(a)(2) of title 21, United States Code''.

(B) SOCIAL SECURITY ACT.—

(i) Section 303(l)(2)(B) of the Social Security Act (42 U.S.C. 503(l)(2)(B)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(ii) Section 1128 of the Social Security Act (42 U.S.C. 1320a–7) is amended—

(I) in subsection (d)(2), in the matter before subparagraph (A), by striking ''section 304(a)(5) of the Controlled Substances Act'' and inserting ''section 50504(a)(1)(E) of title 21, United States Code,''; and

(II) in subsection (g)(3), by striking ''section 304(a)(5) of the Controlled Substances Act'' and inserting ''section 50504(a)(1)(E) of title 21, United States Code,''.

(iii) Section 1128H of the Social Security Act (42 U.S.C. 1320a–7i) is amended—

(I) in subsection (a)—

(aa) in paragraph (1) (matter before subparagraph (A)), by striking ''subsection (d)(2) of section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353),'' and inserting ''subsection (c)(3) of section 13103 of title 21, United States Code,''; and

(bb) in paragraph (2) (matter before subparagraph (A)), by striking ''subsection (d)(3) of such section 503,'' and inserting ''subsection (c)(4) of such section 13103,''; and

(II) in subsection (b)(1)(A), by striking ''subsection (b) of such section 503'' and inserting ''subsection (a) of such section 13103''.

(iv) Section 1612(b)(26) (matter before subparagraph (A)) of the Social Security Act (42 U.S.C. 1382a(b)(26)) is amended by striking ''section 5(b)(2) of the Orphan Drug Act'' and inserting ''sec-

tion 49502(a)(3) of title 21, United States Code''.

(v) Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(I) in subsection (t)—

(aa) in paragraph (2) (matter after subparagraph (H)), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code'';

(bb) in paragraph (6)(A)(i), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13902 of title 21, United States Code,''; and

(cc) in paragraph (6)(B)(iv)(II)—

(AA) by striking ''section 515 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section

13142 of title 21, United States Code,'';

(BB) by striking ''under section 510(k) of such Act,'' and inserting ''under section 13136(k) of such title,'';

(CC) by striking ''requirements of section 510(k) of such Act'' and inserting ''requirements of section 13136(k) of such title'';

(DD) by striking ''subsection (l) or (m) of section 510 of such Act'' and inserting ''subsection (l) or (m) of section 13136 of such title''; and

(EE) by striking ''section 520(g) of such Act'' and inserting ''section 13152(g) of such title''; and

(II) in subsection (bb)(3)(B), by striking ''section 202 of the Controlled Substances Act'' and inserting

''section 50302 of title 21, United States Code,''.

(vi) Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended—

(I) in subsection (a)(14)—

(aa) in subparagraph (G)(i), by striking ''section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)),'' and inserting ''section 13140(c)(1)(C) of title 21, United States Code,'';

(bb) in subparagraph (H)(i), by striking ''section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)),'' and inserting ''section 13140(c)(1)(C) of title 21, United States Code,''; and

(cc) in subparagraph (I)(i), by striking ''section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(c)(1)(C)),'' and inserting

''section 13140(c)(1)(C) of title 21, United States Code,''; and

(II) in subsection (o)(3)(C)(ii), by striking ''section 202 of the Controlled Substances Act'' and inserting ''section 50302 of title 21, United States Code,''.

(vii) Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–3(a)(2)(A)) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(viii) Section 1847B(b)(4)(C) (matter after clause (ii)) of the Social Security Act (42 U.S.C. 1395w–3b (matter after clause (ii))) is amended by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''.

(ix) Section 1860D–14A (g)(2)(A) of the Social Security Act (42 U.S.C. 1395w–114a(g)(2)(A)) is amended by striking ''section 505(b) of the Federal, Food, Drug, and Cosmetic Act or'' and inserting

''section 13503 of title 21, United States Code, or''.

(x) Section 1861(jjj)(1)(A) of the Social Security Act (42 U.S.C. 1395x(jjj)(1)(A)) is amended by striking ''section 505 of the Federal, Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,''.

(xi) Section 1862 of the Social Security Act (42 U.S.C. 1395y) is amended—

(I) in subsection (c)(1)(C), by striking ''subsection (e) of section 505 of the Federal, Food, Drug, and Cosmetic Act'' and inserting ''section 13506 of title 21, United States Code,''; and

(II) in subsection (l)(1), by striking ''section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h))'' and inserting ''section 17501(h) of title 21, United States Code''.

(xii) Section 1866F(a)(2)(A) of the Social Security Act (42 U.S.C. 1395cc–6(a)(2)(A)) is amended by striking ''sec-

tion 505 of the Federal, Food, Drug, and Cosmetic Act'' and inserting ''chapter 135 of title 21, United States Code,''.

(xiii) Section 1905(ee)(1)(A) of the Social Security Act (42 U.S.C. 1396d(ee)(1)(A)) is amended by striking ''section 505 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355),'' and inserting ''chapter 135 of title 21, United States Code,''.

(xiv) Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(I) in subsection (b)(3)(A)(i)(I), by striking ''section 505(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13504 of title 21, United States Code'';

(II) in subsection (b)(3)(A)(i)(II), by striking ''section 505(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13504 of title 21, United States Code'';

(III) in subsection (b)(3)(A)(ii), by striking ''section 505(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13504 of title 21, United States Code'';

(IV) in subsection (c)(1)(C)(i) (matter before subclause (I)), by striking ''section 505(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13504 of title 21, United States Code'';

(V) in subsection (c)(1)(C)(ii)(IV), by striking ''section 505(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13504 of title 21, United States Code'';

(VI) in subsection (d)(4)(C), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,'';

(VII) in subsection (k)(1)(C)—

(aa) in the subparagraph heading, by striking ''505(c)'' and inserting ''13504''; and

(bb) in the subparagraph text, by striking ''section 505(c) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13504 of title 21, United States Code'';

(VIII) in subsection (k)(2)(A)(i), by striking ''section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act'' and inserting ''chapter 135 of title 21, United States Code, or which is approved under section 13511 of such title'';

(IX) in subsection (k)(2)(A)(ii)(II)—

(aa) by striking ''section 201(p) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 10101(a)(34) of title 21, United States Code'';

(bb) by striking ''section 301, 302(a), or 304(a) of such Act'' and inserting ''section 10501, 10502(a), or 10504(a) of such title''; and

(cc) by striking ''section 502(f) or 505(a) of such Act'' and inserting ''section 13305 or 13502 of such title'';

(X) in subsection (k)(2)(A)(iii)(II), by striking ''section 505(e) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13506 of title 21, United States Code,'';

(XI) in subsection (k)(2)(C), by striking ''section 506 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 506 of the Federal Food, Drug, and Cosmetic Act (as in effect before November 21, 1997)''; and

(XII) in subsection (k)(6), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting

''subtitle I of title 21, United States Code,''.

(xv) Section 1944(h)(1) of the Social Security Act (42 U.S.C. 1396w–3a(h)(1)) is amended by striking ''section 202(c) of the Controlled Substances Act'' and inserting ''section 50302(c) of title 21, United States Code,''.

(xvi) Section 1945A(i)(1)(A)(ii)(II) of the Social Security Act (42 U.S.C. 1396w–4a(i)(1)(A)(ii)(II)) is amended by striking ''section 529(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(a)(3))'' and inserting ''section 13905(a)(3) of title 21, United States Code''.

(C) OTHER ACTS.—

(i) BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2009.—

(I) Section 7002(e) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148, 42 U.S.C. 262 note) is amended—

(aa) in paragraph (2) (matter before subparagraph (A)), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)'' and inserting ''chapter 135 of title 21, United States Code,'';

(bb) in paragraph (2)(A), by striking ''such section 505'' and inserting ''such chapter 135'';

(cc) in paragraph (3), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)'' and inserting ''chapter 135 of title 21, United States Code,'';

(dd) in paragraph (4)(A), by striking ''section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)'' and inserting ''chapter 135 of title 21, United States Code,'';

(ee) in paragraph (4)(B)(i)—

(AA) by striking ''subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)'' and inserting ''section 13503 or 13511 of title 21, United States Code,''; and

(BB) by striking ''such section 505'' and inserting ''chapter 135 of title 21, United States Code,'';

(ff) in paragraph (4)(B)(ii)(I), in the matter before item (aa), by striking ''section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13511(h) of title 21, United States Code'';

(gg) in paragraph (4)(B)(ii)(I)(aa), by striking ''subparagraph (C) of such section 505(j)(7)'' and inserting ''paragraph (3) of such section 13511(h)'';

(hh) in paragraph (4)(B)(ii)(III)—

(AA) by striking ''subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13504 or 13511 of title 21, United States Code,''; and

(BB) by striking ''section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13511(h) of title 21, United States Code,'';

(ii) in paragraph (4)(B)(iv)(I)(aa)—

(AA) by striking ''section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or clauses (vii) and (viii) of section 505(j)(2)(A) of such Act'' and inserting ''section 13503(b) of title 21, United

States Code, or subparagraphs (G) and (H) of section 13511(c)(1) of such title''; and

(BB) by striking '' section 505(j)(7) of such Act'' and inserting ''section 13511(h) of such title'';

(jj) in paragraph (4)(B)(iv)(I)(bb)(AA), by striking ''section 505(c)(3)(E), 505(j)(5)(B)(iv), 505(j)(5)(F), 505A, 505E, or 527 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13112, 13116, 13504(c)(5), 13511(f)(2)(D), 13511(f)(6), or 13903 of title 21, United States Code'';

(kk) in paragraph (4)(B)(iv)(I)(bb)(BB)—

(AA) by striking ''section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act'' and inserting

"section 13503(b) of title 21, United States Code,";

(BB) by striking "subparagraph (A), (B), or (C) of section 505(c)(3) of such Act" and inserting "paragraph (1), (2), or (3) of section 13504(c) of such title";

(CC) by striking "section 505(j) of such Act" and inserting "section 13511 of such title"; and

(DD) by striking "clause (i), (ii), or (iii) of section 505(j)(5)(B) of such Act" and inserting "subparagraph (A), (B), or (C) of section 13511(f)(2) of such title"; and

(ll) in paragraph (4)(B)(v)—

(AA) by striking "section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act" and inserting "section

13511(h) of title 21, United States Code''; and

(BB) by striking ''section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 13503(a)(1)(A) of title 21, United States Code,''.

(II) Section 7002(h) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148, 42 U.S.C. 262 note) is amended—

(aa) in the matter before paragraph (1), by striking ''section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)'' and inserting ''section 13902 of title 21, United States Code,''; and

(bb) in paragraph (1), by striking ''section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a));''

and inserting ''section 13903(a) of title 21, United States Code;''.

(ii) NATIONAL ORGAN TRANSPLANT ACT.—Section 301(c)(3) of the National Organ Transplant Act (42 U.S.C. 274e(c)(3)) is amended by striking ''section 201(b) of the Federal Food, Drug and Cosmetic Act'' and inserting ''section 10101(a)(24) of title 21, United States Code''.

(iii) FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007.—Section 801(d)(2) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 42 U.S.C. 282 note) is amended by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code''.

(iv) BEST PHARMACEUTICALS FOR CHILDREN ACT.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m–1) is amended—

(I) in subsection (b)(2)—

(aa) in subparagraph (A), by striking ''sections 501, 502, 505, 505A, 505B, 510(k), 515, and 520(m) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''chapters 133 and 135 of title 21, United States Code, and sections 13101, 13112, 13113, 13136(k), 13142, and 13152(m) of title 21, United States Code''; and

(bb) in subparagraph (D), by striking ''section 565(a) of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 14309(a) of title 21, United States Code''; and

(II) in subsection (d), by striking ''sections 505A, 505B, and 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c, and 360j(m))'' and inserting ''sections 13112, 13113, and 13152(m) of title 21, United States Code''.

(v) COMPREHENSIVE ADDICTION AND RECOVERY ACT OF 2016.—

(I) Section 701(c)(1)(B) of the Comprehensive Addiction and Recovery Act of 2016 (42 U.S.C. 290aa–15(1)(B)) is amended by striking ''section 103'' and inserting ''section 60703 of title 21, United States Code''.

(II) Section 701(e) of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198, 42 U.S.C. 290aa–15 note) is amended by striking ''section 103'' and inserting ''section 60703 of title 21, United States Code''.

(III) Section 701(d)(1)(A) of the Comprehensive Addiction and Recovery Act of 2016 (42 U.S.C. 290aa–16(1)(A)) is amended by striking ''section 103'' and inserting ''section 60703 of title 21, United States Code''.

(IV) Section 102(a) of the Comprehensive Addiction and Recovery

Act of 2016 (42 U.S.C. 290bb–25g(a)) is amended—

(aa) in paragraph (1)(B), by striking ''section 309(f) of the Controlled Substances Act'' and inserting ''section 50509(f) of title 21, United States Code''; and

(bb) in paragraph (2)(E), by striking ''section 309(f) of the Controlled Substances Act'' and inserting ''section 50509(f) of title 21, United States Code''.

(vi) SUBSTANCE USE-DISORDER PREVENTION THAT PROMOTES OPIOID RECOVERY AND TREATMENT FOR PATIENTS AND COMMUNITIES ACT.—Section 7081(b) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (42 U.S.C. 290dd–4(b)) is amended—

(I) in paragraph (4)(B), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)''

and inserting ''subtitle I of title 21, United States Code,''; and

(II) in paragraph (5)(A), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)'' and inserting ''subtitle I of title 21, United States Code,''.

(vii) MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003.—

(I) Section 1013(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (42 U.S.C. 299b–7(a)) is amended—

(aa) in paragraph (3)(C)(ii)(I), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code,''; and

(bb) in paragraph (4)(B), by striking ''the Federal Food, Drug, and Cosmetic Act'' and inserting ''subtitle I of title 21, United States Code''.

(II) Section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173, 42 U.S.C. 1395m note) is amended by striking ''section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C))'' and inserting ''section 13140(c)(1)(C) of title 21, United States Code,''.

(viii) NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986.—Section 313(a)(1)(A) of the National Childhood Vaccine Injury Act of 1986 (Public Law 99–660, title III, 42 U.S.C. 300aa–1 note) is amended by striking ''section 102'' and inserting ''section 20102 of title 21, United States Code''.

(ix) SAFE DRINKING WATER ACT.—Section 1457 of the Safe Drinking Water Act (42 U.S.C. 300j–17) is amended—

(I) by striking ''section 408(p)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(p)(3)(B))'' and inserting ''sec-

tion 11110(q)(3)(B) of title 21, United States Code,'';

(II) by striking ''by section 408(p) of such Act'' and inserting ''by section 11110(q) of such title''; and

(III) by striking ''of section 408(p) of such Act'' and inserting ''of section 11110(q) of such title''.

(x) UNITED STATES HOUSING ACT OF 1937.—

(I) Section 3(b)(9) of the United States Housing Act of 1937 (42 U.S.C. 1437a(b)(9)) is amended by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''.

(II) Section 6 of the United States House Act of 1937 (42 U.S.C. 1437d) is amended—

(aa) in subsection (l) (matter after paragraph (9)(2)), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''sec-

tion 50101 of title 21, United States Code''; and

(bb) in subsection (t)(7)(B), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(III) Section 8(f)(5) of the United States Housing Act of 1937 (42 U.S.C. 1437f(f)(5)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(xi) ANTI-DRUG ABUSE ACT OF 1988.—Section 3601 of the Anti-Drug Abuse Act of 1988 (42 U.S.C. 11851) is amended—

(I) in paragraph (2), by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21, United States Code''; and

(II) in paragraph (3), by striking ''section 102(32) of the Controlled Substances Act (21 U.S.C. 802(32))'' and inserting ''section 50101(10) of title 21, United States Code''.

(xii) CHILD NUTRITION ACT OF 1966.—Section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) is amended—

(I) in subsection (f)(15)(A), by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.)'' and inserting ''subtitle I of title 21, United States Code'';

(II) in subsection (f)(15)(B)—

(aa) by striking ''complies with such Act'' and inserting ''complies with subtitle I of title 21, United States Code,''; and

(bb) by striking ''pursuant to such Act'' and inserting ''pursuant to that subtitle I'';

(III) in subsection (o)(1)(B), by striking ''section 102 of the Controlled Substances Act (21 U.S.C.

802)'' and inserting ''section 50101 of title 21, United States Code''; and

(IV) in subsection (p)(4), by striking ''section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853), other than subsection (d) of that section'' and inserting ''section 50713 of title 21, United States Code, other than subsection (d) of that section''.

(xiii) NATIONAL SCIENCE FOUNDATION AUTHORIZATION ACT OF 1988.—Section 118 of the National Science Foundation Authorization Act of 1988 (Public Law 100–570, 42 U.S.C. 1875 note) is amended—

(I) in subsection (a), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21, United States Code''; and

(II) in subsection (b), by striking ''the Controlled Substances Act'' and inserting ''division A of subtitle V of title 21, United States Code''.

(xiv) CIVIL RIGHTS ACT OF 1964.—Section 703(k)(3) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2(k)(3)) is amended—

(I) by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21, United States Code''; and

(II) by striking ''by the Controlled Substances Act'' and inserting ''by division A of subtitle V of title 21, United States Code,''.

(xv) MEDICAL DEVICE AMENDMENTS OF 1976.—Section 10 of the Medical Device Amendments of 1976 (42 U.S.C. 3512) is amended by striking ''the Federal Food, Drug, and Cosmetic Act, as amended by this Act'' and inserting ''subtitle I of title 21, United States Code''.

(xvi) FAIR HOUSING ACT.—

(I) Section 802(h) (matter after paragraph (3)) of the Fair Housing Act (42 U.S.C. 3602(h) (matter after paragraph (3))) is amended by strik-

ing ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(II) Section 807(b)(4) of the Fair Housing Act (42 U.S.C. 3607(b)(4)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(xvii) ENERGY POLICY AND CONSERVATION ACT.—Section 321(36)(C)(ii)(I) of the Energy Policy and Conservation Act (42 U.S.C. 6291(36)(C)(ii)(I)) is amended by striking ''section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c);'' and inserting ''section 13140 of title 21, United States Code;''.

(xviii) CLEAN AIR ACT.—Section 601(8) (matter before subparagraph (A)) of the Clean Air Act (42 U.S.C. 7671(8) (matter before subparagraph (A))) is amended—

(I) by striking ''the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code''; and

(II) by striking ''drug (as defined in the Federal Food, Drug, and Cosmetic Act)'' and inserting ''drug (as defined in subtitle I of title 21, United States Code)''.

(xix) COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT OF 1980.—Section 101(39)(D)(ii)(I) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601(39)(D)(ii)(I)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(xx) COMMUNITY SERVICES BLOCK GRANT ACT.—Section 678G(a)(3) of the Community Services Block Grant Act (42 U.S.C. 9919(a)(3)) is amended by striking

''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(xxi) HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986.—Section 432(c) of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11152(c)) is amended by striking ''section 304 of the Controlled Substances Act'' and inserting ''section 50504 of title 21, United States Code''.

(xxii) PUBLIC AND ASSISTED HOUSING DRUG ELIMINATION ACT OF 1990.—Section 5126(1) of the Public and Assisted Housing Drug Elimination Act of 1990 (42 U.S.C. 11905(1)) is amended by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(xxiii) DRUG-FREE PUBLIC HOUSING ACT OF 1988.—Section 5145(1) of the Drug-Free Public Housing Act of 1988 (42 U.S.C. 11924(1)) is amended by strik-

ing ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''.

(xxiv) AMERICAN WITH DISABILITIES ACT OF 1990.—

(I) Section 101(6) of the American with Disabilities Act of 1990 (42 U.S.C. 12111(6)) is amended—

(aa) in subparagraph (A)—

(AA) in the first sentence, by striking ''under the Controlled Substances Act (21 U.S.C. 812)'' and inserting ''under division A of subtitle V of title 21, United States Code''; and

(BB) in the second sentence, by striking ''by the Controlled Substances Act'' and inserting ''by division A of subtitle V of title 21, United States Code,''; and

(bb) in subparagraph (B), by striking ''section 202 of the

Controlled Substances Act'' and inserting ''section 50302 of title 21, United States Code''.

(II) Section 511(d) of the American with Disabilities Act of 1990 (42 U.S.C. 12210(d)) is amended—

(aa) in paragraph (1)—

(AA) in the first sentence, by striking ''under the Controlled Substances Act (21 U.S.C. 812)'' and inserting ''under division A of subtitle V of title 21, United States Code''; and

(BB) in the second sentence, by striking ''by the Controlled Substances Act'' and inserting ''by division A of subtitle V of title 21, United States Code,''; and

(bb) in paragraph (2), by striking ''section 202 of the Controlled Substances Act'' and inserting ''section 50302 of title 21, United States Code''.

(xxv) NATIONAL AND COMMUNITY SERVICE ACT OF 1990.—Section 146(e)(4) of the National and Community Service Act of 1990 (42 U.S.C. 12602(e)(4)) is amended by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21, United States Code''.

(xxvi) Section 106(d)(2)(C) of the Medicare Access and CHIP Reauthorization Act of 2015 (42 U.S.C. 18122(2)(C)) is amended by striking ''section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)'' and inserting ''section 10101 of title 21, United States Code,''.

(27) TITLE 46.—

(A) Section 2101(8) of title 46, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(B) Section 70502(a) of title 46, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Preven-

tion and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(C) Section 70503(a)(2) of title 46, United States Code, is amended by striking ''section 511(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 881(a))'' and inserting ''section 50911(a) of title 21''.

(D) Section 70506 of title 46, United States Code, is amended—

(i) in subsection (a)—

(I) by striking ''section 1010 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 960)'' and inserting ''section 51710 of title 21'';

(II) by striking ''section 1012(b) of that Act (21 U.S.C. 962(b))'' and inserting ''section 51713(b) of title 21''; and

(III) by striking ''section 1012 of that Act (21 U.S.C. 962)'' and inserting ''section 51713 of title 21''; and

(ii) in subsection (c)(1), by striking ''the Controlled Substances Act (21 U.S.C.

812)'' and inserting ''division A of subtitle V of title 21''.

(E) Section 70507(a) of title 46, United States Code, is amended—

(i) by striking ''section 511(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 881(a))'' and inserting ''section 50911(a) of title 21''; and

(ii) by striking ''forfeited under section 511 of that Act (21 U.S.C. 881)'' and inserting ''forfeited under section 50911 of that title''.

(28) TITLE 48.—

(A) Section 5004 of the United States Insular Areas Drug Abuse Act of 1986 (48 U.S.C. 1494b) is amended—

(i) in subsection (a)(1)(C), by striking ''the Controlled Substances Import and Export Act (21 U.S.C. 951–970)'' and inserting ''division B of subtitle V of title 21, United States Code''; and

(ii) in subsection (c)(1)(C), by striking ''the Controlled Substances Import and Export Act (21 U.S.C. 951–970)'' and in-

serting ''division B of subtitle V of title 21, United States Code''.

(B) Section 102(a)(1)(B) of the Compact of Free Association Act of 1985 (48 U.S.C. 1902(a)(1)(B)) is amended by striking ''section 102(6) of the United States Controlled Substances Act'' and inserting ''section 50101(9) of title 21, United States Code,''.

(C) Section 103(a)(1)(B) of the Compact of Free Association Act of 1985 (48 U.S.C. 1903(a)(1)(B)) is amended by striking ''section 102(6) of the United States Controlled Substances Act'' and inserting ''section 50101(9) of title 21, United States Code,''.

(D) Section 201(a) of Public Law 101–219 (48 U.S.C. 1972(a)) is amended—

(i) in paragraph (1), by striking ''part C of the Controlled Substances Act (21 U.S.C. 821 et seq.)'' and inserting ''chapter 505 of title 21, United States Code,''; and

(ii) in paragraph (2), by striking ''subsection (a) of section 1003 of the Controlled Substances Act (21 U.S.C. 953)''

and inserting ''subsection (a) of section 51703 of title 21, United States Code''.

(29) TITLE 49.—

(A) Section 5331(a)(1) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(B) Section 5701(a)(1) of title 49, United States Code, is amended—

(i) in subparagraph (A), by striking ''section 416 of the Federal Food, Drug, and Cosmetic Act'' and inserting ''section 11118 of title 21'';

(ii) in subparagraph (B), by striking ''section 402 of the Federal Meat Inspection Act (21 U.S.C. 672)'' and inserting ''section 30362 of title 21''; and

(iii) in subparagraph (C), by striking ''section 19 of the Poultry Products Inspection Act (21 U.S.C. 467a)'' and inserting ''section 31317 of title 21''.

(C) Section 20140(a) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Preven-

tion and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(D) Section 30301(3) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(E) Section 31102(c)(2)(O)(iii) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(F) Section 31301(5) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(G) Section 31306(a) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(H) Section 44106(a) of title 49, United States Code, is amended by striking ''section

102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(I) Section 44111(b)(2) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(J) Section 7210(4)(B)(i) of the Federal Aviation Administration Drug Enforcement Assistance Act of 1988 (Public Law 100–690, 49 U.S.C. 44111 note) is amended by striking ''section 102 of the Controlled Substances Act'' and inserting ''section 50101 of title 21, United States Code''.

(K) Section 44703(g)(1) (matter before subparagraph (A)) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(L) Section 44710(a) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Preven-

tion and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(M) Section 44713(d)(1) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(N) Section 45101 of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(O) Section 46306(c)(1) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(P) Section 46317(b)(1) of title 49, United States Code, is amended by striking ''section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802)'' and inserting ''section 50101 of title 21''.

(Q) Section 80302(a)(1) of title 49, United States Code, is amended—

(i) by striking ''a narcotic drug (as defined in section 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 802))'' and inserting ''a narcotic drug (as defined in section 50101 of title 21)''; and

(ii) by striking ''including marihuana (as defined in section 102 of that Act (21 U.S.C. 802))'' and inserting ''including marihuana (as defined in section 50101 of that title)''.

(30) TITLE 50.—

(A) Section 4(e)(3) of the Subversive Activities Control Act of 1950 (50 U.S.C. 783(e)(3)) is amended by striking ''subsections (b), (c), and (e) through (p) of section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853(b), (c), and (e)–(p))'' and inserting ''subsections (a), (c), and (e) through (p) of section 50713 of title 21, United States Code,''.

(B) Section 3002 of the Intelligence Reform and Terrorism Prevention Act of 2004 (50 U.S.C. 3343) is amended—

(i) in subsection (a)(1), by striking ''section 102 of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101 of title 21, United States Code''; and

(ii) in subsection (b), by striking ''section 102(1) of the Controlled Substances Act (21 U.S.C. 802)'' and inserting ''section 50101(1) of title 21, United States Code''.

(C) Section 1760(d)(2) of the Export Controls Act of 2018 (50 U.S.C. 4819(d)(2)) is amended by striking ''section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853), other than subsection (d) of such section'' and inserting ''section 50713 of title 21, United States Code, other than subsection (d) of such section''.

(31) TITLE 51.—Section 31102(a) of title 51, United States Code, is amended by striking ''section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6))'' and inserting ''section 50101(9) of title 21''.

(32) FENTANYL SANCTIONS ACT.—

(A) Section 7217 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2269) is amended—

(i) by redesignating subsections (a) and (b) as subsections (b) and (c); and

(ii) by inserting before subsection (b), as redesignated, the following new subsection (a):

''(a) DEFINITIONS.—In this section, the terms defined in section 61901 of title 21, United States Code, have the meanings given the terms in that section.''; and

(B) Section 7221 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2270) is amended—

(i) by redesignating subsections (a) through (g) as subsections (b) through (h);

(ii) by inserting before subsection (b), as redesignated, the following new subsection (a):

''(a) DEFINITIONS.—In this section, the terms defined in section 61901 of title 21, United States Code, have the meanings given the terms in that section.''; and

(iii) by adding at the end the following:

''(i) AUTHORIZATION OF APPROPRIATIONS.—Of the amount authorized to be appropriated by section 1403 for fiscal year 2020 and available for Drug Interdiction and Counter-Drug Activities, Defense-wide, as specified in the funding table in section 4501, the Secretary of Defense may, notwithstanding section 2215 of title 10, United States Code, transfer $5,000,000 to the Commission on Combating Synthetic Opioid Trafficking established under section 7221 in order to carry out the duties of the Commission.''.

(33) CONSOLIDATED APPROPRIATIONS ACT, 2023.—Effective on the date of enactment of the Consolidated Appropriations Act, 2023 (Public Law 117–328, 136 Stat. 4459), section 3503(b)(2) of the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 136 Stat. 5859) is amended by striking ''as added by section 802,'' and inserting ''as added by section 3502,''.

**SEC. 5. TRANSITIONAL AND SAVINGS PROVISIONS.**

(a) DEFINITIONS.—In this section:

(1) SOURCE PROVISION.—The term ''source provision'' means a provision of law that is replaced by a title 21 provision.

(2) TITLE 21 PROVISION.—The term ''title 21 provision'' means a provision of title 21, United States Code, that is enacted by section 3.

(b) CUTOFF DATE.—The title 21 provisions replace certain provisions of law enacted on or before July 30, 2025. If a law enacted after that date amends or repeals a source provision, that law is deemed to amend or repeal, as the case may be, the corresponding title 21 provision. If a law enacted after that date is otherwise inconsistent with a title 21 provision or a provision of this Act, that law supersedes the title 21 provision or provision of this Act to the extent of the inconsistency.

(c) ORIGINAL DATE OF ENACTMENT UNCHANGED.—A title 21 provision is deemed to have been enacted on the date of enactment of the corresponding source provision.

(d) REFERENCES TO TITLE 21 PROVISIONS.—A reference to a title 21 provision is deemed to refer to the corresponding source provision.

(e) REFERENCES TO SOURCE PROVISIONS.—A reference to a source provision, including a reference in a regulation, order, or other law, is deemed to refer to the corresponding title 21 provision.

(f) REGULATIONS, ORDERS, AND OTHER ADMINISTRATIVE ACTIONS.—A regulation, order, or other admin-

istrative action in effect under a source provision continues in effect under the corresponding title 21 provision.

(g) ACTIONS TAKEN AND OFFENSES COMMITTED.—An action taken or an offense committed under a source provision is deemed to have been taken or committed under the corresponding title 21 provision.

**SEC. 6. REPEALS.**

The following provisions of law are repealed, except with respect to rights and duties that matured, penalties that were incurred, or proceedings that were begun before the date of enactment of this Act:

Schedule of Laws Repealed

| Act | Section | United States Code Former Classification |
|---|---|---|
| Act of Aug. 30, 1890, ch. 839 | 4 | 21 U.S.C. 18. |
| Act of May 9, 1902, ch. 784 | 1 | 21 U.S.C. 25. |
| Act of July 1, 1902, ch. 1357 | 1 | 21 U.S.C. 16. |
| | 2 | 21 U.S.C. 17. |
| Act of Mar. 4, 1907, ch. 2907 (Federal Meat Inspection Act) | 1 | 21 U.S.C. 601. |
| | 2 | 21 U.S.C. 602. |
| | 3 | 21 U.S.C. 603. |
| | 4 | 21 U.S.C. 604. |
| | 5 | 21 U.S.C. 605. |
| | 6 | 21 U.S.C. 606. |
| | 7 | 21 U.S.C. 607. |
| | 8 | 21 U.S.C. 608. |
| | 9 | 21 U.S.C. 609. |
| | 10 | 21 U.S.C. 610. |
| | 11 | 21 U.S.C. 611. |
| | 12 | 21 U.S.C. 612. |
| | 13 | 21 U.S.C. 613. |
| | 15 | 21 U.S.C. 615. |
| | 16 | 21 U.S.C. 616. |
| | 17 | 21 U.S.C. 617. |
| | 18 | 21 U.S.C. 618. |
| | 19 | 21 U.S.C. 619. |
| | 20 | 21 U.S.C. 620. |
| | 21 | 21 U.S.C. 621. |
| | 22 | 21 U.S.C. 622. |
| | 23 | 21 U.S.C. 623. |
| | 24 | 21 U.S.C. 624. |
| | 25 | 21 U.S.C. 625. |
| | 201 | 21 U.S.C. 641. |
| | 202 | 21 U.S.C. 642. |
| | 203 | 21 U.S.C. 643. |
| | 204 | 21 U.S.C. 644. |
| | 205 | 21 U.S.C. 645. |
| | 301 | 21 U.S.C. 661. |
| | 401 | 21 U.S.C. 671. |
| | 402 | 21 U.S.C. 672. |
| | 403 | 21 U.S.C. 673. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 404 | 21 U.S.C. 674. |
| | 405 | 21 U.S.C. 675. |
| | 406 | 21 U.S.C. 676. |
| | 407 | 21 U.S.C. 677. |
| | 408 | 21 U.S.C. 678. |
| | 409 | 21 U.S.C. 679. |
| | 410 | 21 U.S.C. 679a. |
| | 411 | 21 U.S.C. 680. |
| | 501 | 21 U.S.C. 683. |
| Act of June 30, 1914, ch. 131 | proviso in paragraph under heading "MEAT INSPECTION, BUREAU OF ANIMAL INDUSTRY", at 38 Stat. 420. | 21 U.S.C. 692. |
| Act of Mar. 3, 1915, ch. 74 | 1 | 21 U.S.C. 201, 202. |
| | 2 | 21 U.S.C. 203. |
| | 3 | 21 U.S.C. 204. |
| | 4 | 21 U.S.C. 206. |
| | 5 | 21 U.S.C. 205. |
| | 6 | 21 U.S.C. 207, 208. |
| | 7 | 21 U.S.C. 209. |
| | 8 | 21 U.S.C. 213. |
| | 9 | 21 U.S.C. 211. |
| | 10 | 21 U.S.C. 210. |
| | 11 | 21 U.S.C. 212. |
| | 12 | 21 U.S.C. 215. |
| | 13 | 21 U.S.C. 214. |
| Act of Aug. 10, 1917, ch. 52 | 9 | 21 U.S.C. 106, 107. |
| Act of July 24, 1919, ch. 26 | 13th paragraph after paragraph under heading "ERADICATION OF PINK BOLLWORM", at 41 Stat. 271. | 21 U.S.C. 321b. |
| Act of Mar. 4, 1923, ch. 262 (Filled Milk Act) | 1 | 21 U.S.C. 61. |
| | 2 | 21 U.S.C. 62. |
| | 3 | 21 U.S.C. 63. |
| | 4 | 21 U.S.C. 64. |
| Act of Mar. 4, 1923, ch. 268 | | 21 U.S.C. 321a. |
| Act of Feb. 15, 1927, ch. 155 (Import Milk Act) | 1 | 21 U.S.C. 141. |
| | 2 | 21 U.S.C. 142. |
| | 3 | 21 U.S.C. 143. |
| | 4 | 21 U.S.C. 144. |
| | 5 | 21 U.S.C. 145. |
| | 6 | 21 U.S.C. 146. |
| | 7 | 21 U.S.C. 147. |
| | 8 | 21 U.S.C. 148. |
| | 9 | 21 U.S.C. 149. |
| Act of June 14, 1930, ch. 488 | 1 | 21 U.S.C. 161. |
| | 2 | 21 U.S.C. 162. |
| | 3 | 21 U.S.C. 164. |
| | 5 | 21 U.S.C. 165. |
| Act of June 25, 1938, ch. 675 (Federal Food, Drug, and Cosmetic Act) | 201 | 21 U.S.C. 321. |
| | 301 | 21 U.S.C. 331. |
| | 302 | 21 U.S.C. 332. |
| | 303 | 21 U.S.C. 333. |
| | 304 | 21 U.S.C. 334. |
| | 305 | 21 U.S.C. 335. |
| | 306 | 21 U.S.C. 335a. |
| | 307 | 21 U.S.C. 335b. |
| | 308 | 21 U.S.C. 335e. |
| | 309 | 21 U.S.C. 336. |
| | 310 | 21 U.S.C. 337. |
| | 311 | 21 U.S.C. 337a. |
| | 401 | 21 U.S.C. 341. |
| | 402 | 21 U.S.C. 342. |
| | 403 | 21 U.S.C. 343. |
| | 403A | 21 U.S.C. 343–1. |
| | 403B | 21 U.S.C. 343–2. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 403C | 21 U.S.C. 343–3. |
| | 404 | 21 U.S.C. 344. |
| | 405 | 21 U.S.C. 345. |
| | 406 | 21 U.S.C. 346. |
| | 407 | 21 U.S.C. 347. |
| | 408 | 21 U.S.C. 346a. |
| | 409 | 21 U.S.C. 348. |
| | 410 | 21 U.S.C. 349. |
| | 411 | 21 U.S.C. 350. |
| | 412 | 21 U.S.C. 350a. |
| | 413 | 21 U.S.C. 350b. |
| | 414 | 21 U.S.C. 350c. |
| | 415 | 21 U.S.C. 350d. |
| | 416 | 21 U.S.C. 350e. |
| | 417 | 21 U.S.C. 350f. |
| | 418 | 21 U.S.C. 350g. |
| | 419 | 21 U.S.C. 350h. |
| | 420 | 21 U.S.C. 350i. |
| | 421 | 21 U.S.C. 350j. |
| | 422 | 21 U.S.C. 350k. |
| | 423 | 21 U.S.C. 350l. |
| | 424 | 21 U.S.C. 350m. |
| | 501 | 21 U.S.C. 351. |
| | 502 | 21 U.S.C. 352. |
| | 503 (except (b)(5)) | 21 U.S.C. 353 (except (b)(5)). |
| | 503A | 21 U.S.C. 353a. |
| | 503B | 21 U.S.C. 353b. |
| | 503C | 21 U.S.C. 353c. |
| | 503D | 21 U.S.C. 353d. |
| | 504 | 21 U.S.C. 354. |
| | 505 | 21 U.S.C. 355. |
| | 505–1 | 21 U.S.C. 355–1. |
| | 505A | 21 U.S.C. 355a. |
| | 505B | 21 U.S.C. 355c. |
| | 505C | 21 U.S.C. 355d. |
| | 505D | 21 U.S.C. 355e. |
| | 505E | 21 U.S.C. 355f. |
| | 505F | 21 U.S.C. 355g. |
| | 505G | 21 U.S.C. 355h. |
| | 506 | 21 U.S.C. 356. |
| | 506A | 21 U.S.C. 356a. |
| | 506B | 21 U.S.C. 356b. |
| | 506C | 21 U.S.C. 356c. |
| | 506C–1 | 21 U.S.C. 356c–1. |
| | 506D | 21 U.S.C. 356d. |
| | 506E | 21 U.S.C. 356e. |
| | 506F | 21 U.S.C. 356f. |
| | 506G | 21 U.S.C. 356g. |
| | 506H | 21 U.S.C. 356h. |
| | 506I | 21 U.S.C. 356i. |
| | 506J | 21 U.S.C. 356j. |
| | 506K | 21 U.S.C. 356k. |
| | 506L | 21 U.S.C. 356l. |
| | 507 | 21 U.S.C. 357. |
| | 508 | 21 U.S.C. 358. |
| | 509 | 21 U.S.C. 359. |
| | 510 | 21 U.S.C. 360. |
| | 511 | 21 U.S.C. 360a. |
| | 511A | 21 U.S.C. 360a–2. |
| | 512 | 21 U.S.C. 360b. |
| | 512A | 21 U.S.C. 360b–1. |
| | 513 | 21 U.S.C. 360c. |
| | 514 | 21 U.S.C. 360d. |
| | 515 | 21 U.S.C. 360e. |
| | 515A | 21 U.S.C. 360e–1. |
| | 515B | 21 U.S.C. 360e–3. |
| | 515C | 21 U.S.C. 360e–4. |
| | 516 | 21 U.S.C. 360f. |
| | 517 | 21 U.S.C. 360g. |
| | 517A | 21 U.S.C. 360g–1. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 518 | 21 U.S.C. 360h. |
| | 518A | 21 U.S.C. 360h–1. |
| | 519 | 21 U.S.C. 360i. |
| | 520 | 21 U.S.C. 360j. |
| | 521 | 21 U.S.C. 360k. |
| | 522 | 21 U.S.C. 360l. |
| | 523 | 21 U.S.C. 360m. |
| | 524 | 21 U.S.C. 360n. |
| | 524A | 21 U.S.C. 360n–1. |
| | 524B | 21 U.S.C. 360n–2. |
| | 525 | 21 U.S.C. 360aa. |
| | 526 | 21 U.S.C. 360bb. |
| | 527 | 21 U.S.C. 360cc. |
| | 528 | 21 U.S.C. 360dd. |
| | 529 | 21 U.S.C. 360ff. |
| | 529A | 21 U.S.C. 360ff–1. |
| | 531 | 21 U.S.C. 360hh. |
| | 532 | 21 U.S.C. 360ii. |
| | 533 | 21 U.S.C. 360jj. |
| | 534 | 21 U.S.C. 360kk. |
| | 535 | 21 U.S.C. 360ll. |
| | 536 | 21 U.S.C. 360mm. |
| | 537 | 21 U.S.C. 360nn. |
| | 538 | 21 U.S.C. 360oo. |
| | 539 | 21 U.S.C. 360pp. |
| | 541 | 21 U.S.C. 360rr. |
| | 542 | 21 U.S.C. 360ss. |
| | 551 | 21 U.S.C. 360aaa. |
| | 552 | 21 U.S.C. 360aaa–1. |
| | 553 | 21 U.S.C. 360aaa–2. |
| | 554 | 21 U.S.C. 360aaa–3. |
| | 555 | 21 U.S.C. 360aaa–4. |
| | 556 | 21 U.S.C. 360aaa–5. |
| | 557 | 21 U.S.C. 360aaa–6. |
| | 561 | 21 U.S.C. 360bbb. |
| | 561A | 21 U.S.C. 360bbb–0. |
| | 561B | 21 U.S.C. 360bbb–0a. |
| | 562 | 21 U.S.C. 360bbb–1. |
| | 563 | 21 U.S.C. 360bbb–2. |
| | 564 | 21 U.S.C. 360bbb–3. |
| | 564A | 21 U.S.C. 360bbb–3a. |
| | 564B | 21 U.S.C. 360bbb–3b. |
| | 565 | 21 U.S.C. 360bbb–4. |
| | 565A | 21 U.S.C. 360bbb–4a. |
| | 565B | 21 U.S.C. 360bbb–4b. |
| | 566 | 21 U.S.C. 360bbb–5. |
| | 566A | 21 U.S.C. 360bbb–5a. |
| | 567 | 21 U.S.C. 360bbb–6. |
| | 568 | 21 U.S.C. 360bbb–7. |
| | 569 | 21 U.S.C. 360bbb–8. |
| | 569A | 21 U.S.C. 360bbb–8a. |
| | 569B | 21 U.S.C. 360bbb–8b. |
| | 569C | 21 U.S.C. 360bbb–8c. |
| | 569D | 21 U.S.C. 360bbb–8d. |
| | 571 | 21 U.S.C. 360ccc. |
| | 572 | 21 U.S.C. 360ccc–1. |
| | 573 | 21 U.S.C. 360ccc–2. |
| | 575 | 21 U.S.C. 360ddd. |
| | 576 | 21 U.S.C. 360ddd–1. |
| | 577 | 21 U.S.C. 360ddd–2. |
| | 581 | 21 U.S.C. 360eee. |
| | 582 | 21 U.S.C. 360eee–1. |
| | 583 | 21 U.S.C. 360eee–2. |
| | 584 | 21 U.S.C. 360eee–3. |
| | 585 | 21 U.S.C. 360eee–4. |
| | 586 | 21 U.S.C. 360fff. |
| | 586A | 21 U.S.C. 360fff–1. |
| | 586B | 21 U.S.C. 360fff–2. |
| | 586C | 21 U.S.C. 360fff–3. |
| | 586D | 21 U.S.C. 360fff–4. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 586F | 21 U.S.C. 360fff–6. |
| | 586G | 21 U.S.C. 360fff–7. |
| | 586H | 21 U.S.C. 360fff–8. |
| | 601 | 21 U.S.C. 361. |
| | 602 | 21 U.S.C. 362. |
| | 603 | 21 U.S.C. 363. |
| | 604 | 21 U.S.C. 364. |
| | 605 | 21 U.S.C. 364a. |
| | 606 | 21 U.S.C. 364b. |
| | 607 | 21 U.S.C. 364c. |
| | 608 | 21 U.S.C. 364d. |
| | 609 | 21 U.S.C. 364e. |
| | 610 | 21 U.S.C. 364f. |
| | 611 | 21 U.S.C. 364g. |
| | 612 | 21 U.S.C. 364h. |
| | 613 | 21 U.S.C. 364i. |
| | 614 | 21 U.S.C. 364j. |
| | 701 | 21 U.S.C. 371. |
| | 702 | 21 U.S.C. 372. |
| | 703 | 21 U.S.C. 373. |
| | 704 | 21 U.S.C. 374. |
| | 705 | 21 U.S.C. 375. |
| | 706 | 21 U.S.C. 376. |
| | 707 | 21 U.S.C. 378. |
| | 708 | 21 U.S.C. 379. |
| | 709 | 21 U.S.C. 379a. |
| | 710 | 21 U.S.C. 379b. |
| | 711 | 21 U.S.C. 379d. |
| | 712 | 21 U.S.C. 379d–1. |
| | 713 | 21 U.S.C. 379d–2. |
| | 714 | 21 U.S.C. 379d–3. |
| | 714A | 21 U.S.C. 379d–3a. |
| | 714B | 21 U.S.C. 379d–3b. |
| | 715 | 21 U.S.C. 379d–4. |
| | 721 | 21 U.S.C. 379e. |
| | 731 | 21 U.S.C. 379f. |
| | 735 | 21 U.S.C. 379g. |
| | 736 | 21 U.S.C. 379h. |
| | 736A | 21 U.S.C. 379h–1. |
| | 736B | 21 U.S.C. 379h–2. |
| | 737 | 21 U.S.C. 379i. |
| | 738 | 21 U.S.C. 379j. |
| | 738A | 21 U.S.C. 379j–1. |
| | 739 | 21 U.S.C. 379j–11. |
| | 740 | 21 U.S.C. 379j–12. |
| | 740A | 21 U.S.C. 379j–13. |
| | 741 | 21 U.S.C. 379j–21. |
| | 742 | 21 U.S.C. 379j–22. |
| | 743 | 21 U.S.C. 379j–31. |
| | 744A | 21 U.S.C. 379j–41. |
| | 744B | 21 U.S.C. 379j–42. |
| | 744C | 21 U.S.C. 379j–43. |
| | 744G | 21 U.S.C. 379j–51. |
| | 744H (except (a)(1)(A)(v)) | 21 U.S.C. 379j–52 (except (a)(1)(A)(v)). |
| | 744I | 21 U.S.C. 379j–53. |
| | 744J | 21 U.S.C. 379j–61. |
| | 744K | 21 U.S.C. 379j–62. |
| | 744L | 21 U.S.C. 379j–71. |
| | 744M (except (c)(4)(A)) | 21 U.S.C. 379j–72 (except (c)(4)(A)). |
| | 744N | 21 U.S.C. 379j–73. |
| | 745 | 21 U.S.C. 379k. |
| | 745A | 21 U.S.C. 379k–1. |
| | 746 | 21 U.S.C. 379l. |
| | 749 | 21 U.S.C. 379o. |
| | 751 | 21 U.S.C. 379r. |
| | 752 | 21 U.S.C. 379s. |
| | 756 | 21 U.S.C. 379v. |
| | 760 | 21 U.S.C. 379aa. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 761 | 21 U.S.C. 379aa–1. |
| | 770 | 21 U.S.C. 379dd. |
| | 771 | 21 U.S.C. 379dd–1. |
| | 772 | 21 U.S.C. 379dd–2. |
| | 801 | 21 U.S.C. 381. |
| | 802 | 21 U.S.C. 382. |
| | 803 | 21 U.S.C. 383. |
| | 804 | 21 U.S.C. 384. |
| | 805 | 21 U.S.C. 384a. |
| | 806 | 21 U.S.C. 384b. |
| | 807 | 21 U.S.C. 384c. |
| | 808 | 21 U.S.C. 384d. |
| | 809 | 21 U.S.C. 384e. |
| | 900 | 21 U.S.C. 387. |
| | 901 | 21 U.S.C. 387a. |
| | 902 | 21 U.S.C. 387b. |
| | 903 | 21 U.S.C. 387c. |
| | 904 | 21 U.S.C. 387d. |
| | 905 | 21 U.S.C. 387e. |
| | 906 | 21 U.S.C. 387f. |
| | 907 | 21 U.S.C. 387g. |
| | 908 | 21 U.S.C. 387h. |
| | 909 | 21 U.S.C. 387i. |
| | 910 | 21 U.S.C. 387j. |
| | 911 | 21 U.S.C. 387k. |
| | 912 | 21 U.S.C. 387l. |
| | 913 | 21 U.S.C. 387m. |
| | 914 | 21 U.S.C. 387n. |
| | 915 | 21 U.S.C. 387o. |
| | 916 | 21 U.S.C. 387p. |
| | 917 | 21 U.S.C. 387q. |
| | 918 | 21 U.S.C. 387r. |
| | 919 | 21 U.S.C. 387s. |
| | 920 | 21 U.S.C. 387t. |
| | 1001 | 21 U.S.C. 391. |
| | 1002 | 21 U.S.C. 392. |
| | 1003 | 21 U.S.C. 393. |
| | 1004 | 21 U.S.C. 394. |
| | 1005 | 21 U.S.C. 395. |
| | 1006 | 21 U.S.C. 396. |
| | 1007 | 21 U.S.C. 397. |
| | 1008 | 21 U.S.C. 398. |
| | 1009 | 21 U.S.C. 399. |
| | 1010 | 21 U.S.C. 399a. |
| | 1011 | 21 U.S.C. 399b. |
| | 1012 | 21 U.S.C. 399c. |
| | 1013 | 21 U.S.C. 399d. |
| | 1014 | 21 U.S.C. 399g. |
| Act of July 12, 1943, ch. 221, title II (Federal Security Agency Appropriation Act, 1944) | matter after 5th semicolon (from "and the Administrator" through "Food and Drug Administration") under heading "Enforcement operations:", at 57 Stat. 500. | 21 U.S.C. 377. |
| Act of Mar. 2, 1944, ch. 77 | | 21 U.S.C. 321c. |
| Act of Sept. 21, 1944, ch. 412 (Department of Agriculture Organic Act of 1944) | 101(f) | 21 U.S.C. 626. |
| Act of July 30, 1947, ch. 356, title I (Department of Agriculture Appropriation Act, 1948) | title I, 1st proviso after heading "Meat inspection:", at 61 Stat. 532. | 21 U.S.C. 97a. |
| | title I, 2d proviso after heading "Meat inspection:", at 61 Stat. 532. | 21 U.S.C. 97b. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | title I, 3d proviso after heading "Meat inspection:", at 61 Stat. 532. | 21 U.S.C. 97c. |
| | title I, last proviso after heading "Meat inspection:", at 61 Stat. 532. | 21 U.S.C. 97d. |
| | title I, matter before provisos after heading "Meat inspection:", at 61 Stat. 531. | 21 U.S.C. 97. |
| Act of June 5, 1948, ch. 423 | | 21 U.S.C. 695. |
| Act of Mar. 16, 1950, ch. 61 | 3(a) | 21 U.S.C. 347a. |
| | 6 | 21 U.S.C. 347b. |
| Act of July 22, 1954, ch. 559 | 4 | 21 U.S.C. 346b. |
| Act of Aug. 11, 1955, ch. 800 | 1 | 21 U.S.C. 967. |
| | 2 | 21 U.S.C. 968. |
| | 3 | 21 U.S.C. 969. |
| Public Law 85–172 (Poultry Products Inspection Act) | 3 | 21 U.S.C. 452. |
| | 4 | 21 U.S.C. 453. |
| | 5 | 21 U.S.C. 454. |
| | 6 | 21 U.S.C. 455. |
| | 7 | 21 U.S.C. 456. |
| | 8 | 21 U.S.C. 457. |
| | 9 | 21 U.S.C. 458. |
| | 10 | 21 U.S.C. 459. |
| | 11 | 21 U.S.C. 460. |
| | 12 | 21 U.S.C. 461. |
| | 13 | 21 U.S.C. 462. |
| | 14 | 21 U.S.C. 463. |
| | 15 | 21 U.S.C. 464. |
| | 16 | 21 U.S.C. 465. |
| | 17 | 21 U.S.C. 466. |
| | 18 | 21 U.S.C. 467. |
| | 19 | 21 U.S.C. 467a. |
| | 20 | 21 U.S.C. 467b. |
| | 21 | 21 U.S.C. 467c. |
| | 22 | 21 U.S.C. 467d. |
| | 23 | 21 U.S.C. 467e. |
| | 24 | 21 U.S.C. 467f. |
| | 25 | 21 U.S.C. 468. |
| | 26 | 21 U.S.C. 469. |
| | 27 | 21 U.S.C. 470. |
| | 30 | 21 U.S.C. 471. |
| | 31 | 21 U.S.C. 472. |
| Public Law 86–537 | 2 | 21 U.S.C. 343 note. |
| Public Law 90–201 (Wholesome Meat Act) | 17 | 21 U.S.C. 691. |
| Public Law 91–513, title II (Controlled Substances Act) | 101 | 21 U.S.C. 801. |
| | 102 | 21 U.S.C. 802. |
| | 201 | 21 U.S.C. 811. |
| | 202 | 21 U.S.C. 812. |
| | 203 | 21 U.S.C. 813. |
| | 204 | 21 U.S.C. 814. |
| | 301 | 21 U.S.C. 821. |
| | 302 | 21 U.S.C. 822. |
| | 303 | 21 U.S.C. 823. |
| | 304 | 21 U.S.C. 824. |
| | 305 | 21 U.S.C. 825. |
| | 306 | 21 U.S.C. 826. |
| | 307 | 21 U.S.C. 827. |
| | 308 | 21 U.S.C. 828. |
| | 309 | 21 U.S.C. 829. |
| | 309A | 21 U.S.C. 829a. |
| | 310 | 21 U.S.C. 830. |
| | 311 | 21 U.S.C. 831. |
| | 312 | 21 U.S.C. 832. |
| | 401 | 21 U.S.C. 841. |
| | 402 | 21 U.S.C. 842. |
| | 403 | 21 U.S.C. 843. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 404 | 21 U.S.C. 844. |
| | 405 | 21 U.S.C. 844a. |
| | 406 | 21 U.S.C. 846. |
| | 407 | 21 U.S.C. 847. |
| | 408 | 21 U.S.C. 848. |
| | 409 | 21 U.S.C. 849. |
| | 410 | 21 U.S.C. 850. |
| | 411 | 21 U.S.C. 851. |
| | 412 | 21 U.S.C. 852. |
| | 413 | 21 U.S.C. 853. |
| | 414 | 21 U.S.C. 854. |
| | 415 | 21 U.S.C. 855. |
| | 417 | 21 U.S.C. 858. |
| | 418 | 21 U.S.C. 859. |
| | 419 | 21 U.S.C. 860. |
| | 419a | 21 U.S.C. 860a. |
| | 420 | 21 U.S.C. 861. |
| | 421(a) through (f) | 21 U.S.C. 862(a) through (f). |
| | 422 | 21 U.S.C. 863. |
| | 423 | 21 U.S.C. 864. |
| | 501 | 21 U.S.C. 871. |
| | 502 | 21 U.S.C. 872. |
| | 503 | 21 U.S.C. 873. |
| | 504 | 21 U.S.C. 874. |
| | 505 | 21 U.S.C. 875. |
| | 506 | 21 U.S.C. 876. |
| | 507 | 21 U.S.C. 877. |
| | 508 | 21 U.S.C. 878. |
| | 509 | 21 U.S.C. 879. |
| | 510 | 21 U.S.C. 880. |
| | 511 | 21 U.S.C. 881. |
| | 512 | 21 U.S.C. 882. |
| | 513 | 21 U.S.C. 883. |
| | 514 | 21 U.S.C. 884. |
| | 515 | 21 U.S.C. 885. |
| | 516 | 21 U.S.C. 886. |
| | 517 | 21 U.S.C. 887. |
| | 519 | 21 U.S.C. 889. |
| | 520 | 21 U.S.C. 890. |
| | 706 | 21 U.S.C. 901. |
| | 707 | 21 U.S.C. 902. |
| | 708 | 21 U.S.C. 903. |
| | 709 | 21 U.S.C. 904. |
| | 4166 | 21 U.S.C. 856. |
| Public Law 91–513, title III (Controlled Substances Import and Export Act) | 1001 | 21 U.S.C. 951. |
| | 1002 | 21 U.S.C. 952. |
| | 1003 | 21 U.S.C. 953. |
| | 1004 | 21 U.S.C. 954. |
| | 1005 | 21 U.S.C. 955. |
| | 1006 | 21 U.S.C. 956. |
| | 1007 | 21 U.S.C. 957. |
| | 1008 | 21 U.S.C. 958. |
| | 1009 | 21 U.S.C. 959. |
| | 1010 | 21 U.S.C. 960. |
| | 1010A | 21 U.S.C. 960a. |
| | 1011 | 21 U.S.C. 961. |
| | 1012 | 21 U.S.C. 962. |
| | 1013 | 21 U.S.C. 963. |
| | 1014 | 21 U.S.C. 964. |
| | 1015 | 21 U.S.C. 965. |
| | 1016 | 21 U.S.C. 966. |
| | 1017 | 21 U.S.C. 970. |
| | 1018 | 21 U.S.C. 971. |
| Public Law 91–597 (Egg Products Inspection Act) | 2 | 21 U.S.C. 1031. |
| | 3 | 21 U.S.C. 1032. |
| | 4 | 21 U.S.C. 1033. |
| | 5 | 21 U.S.C. 1034. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 6 | 21 U.S.C. 1035. |
| | 7 | 21 U.S.C. 1036. |
| | 8 | 21 U.S.C. 1037. |
| | 9 | 21 U.S.C. 1038. |
| | 10 | 21 U.S.C. 1039. |
| | 11 | 21 U.S.C. 1040. |
| | 12 | 21 U.S.C. 1041. |
| | 13 | 21 U.S.C. 1042. |
| | 14 | 21 U.S.C. 1043. |
| | 15 | 21 U.S.C. 1044. |
| | 16 | 21 U.S.C. 1045. |
| | 17 | 21 U.S.C. 1046. |
| | 18 | 21 U.S.C. 1047. |
| | 19 | 21 U.S.C. 1048. |
| | 20 | 21 U.S.C. 1049. |
| | 21 | 21 U.S.C. 1050. |
| | 22 | 21 U.S.C. 1051. |
| | 23 | 21 U.S.C. 1052. |
| | 24 | 21 U.S.C. 1053. |
| | 26 | 21 U.S.C. 1054. |
| | 27 | 21 U.S.C. 1055. |
| | 28 | 21 U.S.C. 1056. |
| Public Law 92–255 (Drug Abuse Prevention, Treatment, and Rehabilitation Act) | 102 | 21 U.S.C. 1102. |
| | 201 | 21 U.S.C. 1115. |
| | 404 | 21 U.S.C. 1171. |
| | 406 | 21 U.S.C. 1173. |
| | 410 | 21 U.S.C. 1177. |
| | 411 | 21 U.S.C. 1178. |
| | 412 | 21 U.S.C. 1179. |
| | 414 | 21 U.S.C. 1181. |
| Public Law 94–278 (Health Research and Health Services Amendments of 1976) | 501(b) | 21 U.S.C. 350 note. |
| Public Law 95–445 (Humane Methods of Slaughter Act of 1978) | 6 | 21 U.S.C. 603 note. |
| Public Law 95–633 (Psychotropic Substances Act of 1978) | 102(c) | 21 U.S.C. 812 note. |
| Public Law 97–414 (Orphan Drug Act) | 5 | 21 U.S.C. 360ee. |
| Public Law 99–570 (Anti-Drug Abuse Act of 1986) | 4304 | 21 U.S.C. 801 note. |
| Public Law 100–418, title IV, subtitle G (Pesticide Monitoring Improvements Act of 1988) | 4702 | 21 U.S.C. 1401. |
| | 4703(a) through (c) | 21 U.S.C. 1402(a) through (c). |
| | 4704 (except matter after (2)) | 21 U.S.C. 1403 (except matter after (2)). |
| Public Law 100–670 (Generic Animal Drug and Patent Term Restoration Act) | 106 | 21 U.S.C. 360b note. |
| Public Law 100–690, title I, subtitle A (National Narcotics Leadership Act of 1988) | 1022 | 21 U.S.C. 1522. |
| | 1023 | 21 U.S.C. 1523. |
| | 1024 | 21 U.S.C. 1524. |
| | 1031 | 21 U.S.C. 1531. |
| | 1032 | 21 U.S.C. 1532. |
| | 1033 | 21 U.S.C. 1533. |
| | 1034 | 21 U.S.C. 1534. |
| | 1035 | 21 U.S.C. 1535. |
| Public Law 100–690, title VI, subtitle B (Asset Forfeiture Amendments Act of 1988) | 6079 | 21 U.S.C. 881 note. |
| Public Law 101–225 (Coast Guard Authorization Act of 1989) | 210 | 21 U.S.C. 881 note. |
| Public Law 101–535 (Nutrition Labeling and Education Act of 1990) | 2(c) | 21 U.S.C. 343 note. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| Public Law 101–647, title XIX (Anabolic Steroids Control Act of 1990) | 1903 | 21 U.S.C. 802 note. |
| Public Law 102–395, title I (Department of Justice and Related Agencies Appropriations Act, 1993) | 111(b) | 21 U.S.C. 886a. |
| Public Law 104–170 (Food Quality Protection Act of 1996) | 301 | 21 U.S.C. 346a note. |
| Public Law 104–193 (Personal Responsibility and Work Opportunity Reconciliation Act of 1996) | 115 | 21 U.S.C. 862a. |
| | 902 | 21 U.S.C. 862b. |
| Public Law 104–237 (Comprehensive Methamphetamine Control Act of 1996) | 101 | 21 U.S.C. 801 note. |
| | 204(b) | 21 U.S.C. 971 note. |
| | 503 | 21 U.S.C. 872a. |
| Public Law 104–305 (Drug-Induced Rape Prevention and Punishment Act of 1996) | 4 | 21 U.S.C. 872 note. |
| Public Law 105–85 (National Defense Authorization Act for Fiscal Year 1998) | 1034 | 21 U.S.C. 1505a. |
| Public Law 105–115 (Food and Drug Administration Modernization Act of 1997) | 118 | 21 U.S.C. 355 note. |
| | 121(c) | 21 U.S.C. 355 note. |
| | 121(e) | 21 U.S.C. 355 note. |
| | 122 | 21 U.S.C. 355 note. |
| | 123(f) | 21 U.S.C. 355 note. |
| | 129 | 21 U.S.C. 393 note. |
| Public Law 105–230 (Biomaterials Access Assurance Act of 1998) | 3 | 21 U.S.C. 1602. |
| | 4 | 21 U.S.C. 1603. |
| | 5 | 21 U.S.C. 1604. |
| | 6 | 21 U.S.C. 1605. |
| | 7 | 21 U.S.C. 1606. |
| Pub. L. 105–277, div. C, title VII (Office of National Drug Control Policy Reauthorization Act of 1998) | 702 | 21 U.S.C. 1701. |
| | 703 | 21 U.S.C. 1702. |
| | 704 | 21 U.S.C. 1703. |
| | 705 | 21 U.S.C. 1704. |
| | 706 | 21 U.S.C. 1705. |
| | 707 | 21 U.S.C. 1706. |
| | 709 | 21 U.S.C. 1708. |
| | 711 | 21 U.S.C. 1710. |
| | 712 | 21 U.S.C. 1710a. |
| | 714 | 21 U.S.C. 1711. |
| | 716 (except (d)) | 21 U.S.C. 1714 (except (d)). |
| Public Law 105–277, div. C, title VIII (Western Hemisphere Drug Elimination Act) | 834 | 21 U.S.C. 1713. |
| Public Law 105–357 (Controlled Substances Trafficking Prohibition Act) | 2(b) | 21 U.S.C. 956 note. |
| | 2(c) | 21 U.S.C. 956 note. |
| Public Law 106–120, title VIII (Foreign Narcotics Kingpin Designation Act) | 802(b) | 21 U.S.C. 1901(b). |
| | 803 | 21 U.S.C. 1902. |
| | 804 | 21 U.S.C. 1903. |
| | 805 | 21 U.S.C. 1904. |
| | 806 | 21 U.S.C. 1905. |
| | 807 | 21 U.S.C. 1906. |
| | 808 | 21 U.S.C. 1907. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| Public Law 106–172 (Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000) | 3(a) | 21 U.S.C. 812 note. |
| | 6 | 21 U.S.C. 801 note. |
| | 6(a), (b) | 21 U.S.C. 801 note. |
| | 7 | 21 U.S.C. 801 note. |
| Public Law 106–310, title XXXVI (Methamphetamine Anti-Proliferation Act of 2000) | 3625 | 21 U.S.C. 873 note. |
| | 3671 | 21 U.S.C. 801 note. |
| Public Law 106–387 | 1(a) [title VII, §752] | 21 U.S.C. 455 note. |
| Public Law 106–391 (National Aeronautics and Space Administration Authorization Act of 2000) | 320 | 21 U.S.C. 801 note. |
| Public Law 107–82 | 4 | 21 U.S.C. 1521 note. |
| | 5 | 21 U.S.C. 1521 note. |
| Public Law 107–109 (Best Pharmaceuticals for Children Act) | 6 | 21 U.S.C. 393a. |
| | 17 | 21 U.S.C. 355b. |
| Public Law 107–171 (Farm Security and Rural Investment Act of 2002) | 10806(a)(1) | 21 U.S.C. 321d(a)(1). |
| | 10806(b)(1) | 21 U.S.C. 321d(b)(1). |
| | 10808(a) | 21 U.S.C. 679b. |
| Public Law 107–188 (Public Health Security and Bioterrorism Preparedness and Response Act of 2002) | 122(a) through (e) | 21 U.S.C. 356–1(a) through (e). |
| | 301 | 21 U.S.C. 341 note. |
| | 308(e) | 21 U.S.C. 381 note. |
| | 332 | 21 U.S.C. 679c. |
| Public Law 108–173 (Medicare Prescription Drug, Improvement, and Modernization Act of 2003) | 1103(b) | 21 U.S.C. 355 note. |
| | 1111 | 21 U.S.C. 355 note. |
| | 1112 | 21 U.S.C. 355 note. |
| | 1113 | 21 U.S.C. 355 note. |
| | 1114 | 21 U.S.C. 355 note. |
| | 1115 | 21 U.S.C. 355 note. |
| | 1116 | 21 U.S.C. 355 note. |
| | 1117 | 21 U.S.C. 355 note. |
| Public Law 108–282, title I (Minor Use and Minor Species Animal Health Act of 2004) | 102(b)(7) | 21 U.S.C. 393 note. |
| Public Law 108–282, title II (Food Allergen Labeling and Consumer Protection Act of 2004) | 205 | 21 U.S.C. 374a. |
| | 206 | 21 U.S.C. 343 note. |
| | 207 | 42 U.S.C. 242r. |
| Public Law 109–43 (Medical Device User Fee Stabilization Act of 2005) | 2(c)(2) | 21 U.S.C. 352 note. |
| Public Law 109–177, title VII (Combat Methamphetamine Epidemic Act of 2005) | 711(g) | 21 U.S.C. 802 note. |
| | 718 | 21 U.S.C. 826 note. |
| | 731 | 21 U.S.C. 865. |
| | 736 | 21 U.S.C. 871a. |
| Public Law 109–462 (Dietary Supplement and Nonprescription Drug Consumer Protection Act) | 2(b) | 21 U.S.C. 379aa note. |
| | 2(e)(3) | 21 U.S.C. 379aa note. |
| | 3(d)(3) | 21 U.S.C. 379aa note. |
| Public Law 109–469 (Office of National Drug Control Policy Reauthorization Act of 2006) | 701 | 21 U.S.C. 2001. |
| | 702 | 21 U.S.C. 2002. |
| | 703 | 21 U.S.C. 2003. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| Public Law 109–469, title X (National Methamphetamine Information Clearinghouse Act of 2006) .. | 1002 | 21 U.S.C. 2011. |
| | 1003 | 21 U.S.C. 2012. |
| | 1004 | 21 U.S.C. 2013. |
| | 1005 | 21 U.S.C. 2014. |
| Public Law 110–85 (Food and Drug Administration Amendments Act of 2007) | 901(d)(3)(B) | 21 U.S.C. 352 note. |
| | 905(b) | 21 U.S.C. 355 note. |
| | 907 | 21 U.S.C. 355 note. |
| | 1002 | 21 U.S.C. 2102. |
| | 1003 | 21 U.S.C. 2103. |
| | 1004 | 21 U.S.C. 2104. |
| | 1005(f) | 21 U.S.C. 350f note. |
| | 1005(g) | 21 U.S.C. 2110 note. |
| | 1006(b), (d) | 21 U.S.C. 2105(b), (d). |
| | 1007 | 21 U.S.C. 2106. |
| | 1009 | 21 U.S.C. 2108. |
| | 1010 | 21 U.S.C. 2109. |
| | 1011 | 21 U.S.C. 2110. |
| Public Law 110–234 (Food, Conservation, and Energy Act of 2008) | 14203 | 21 U.S.C. 864a. |
| Public Law 110–425 (Ryan Haight Online Pharmacy Consumer Protection Act of 2008) | 4 | 21 U.S.C. 802 note. |
| Public Law 111–31, div. A (Family Smoking Prevention and Tobacco Control Act) | 4 | 21 U.S.C. 387 note. |
| | 102 | 21 U.S.C. 387a–1. |
| | 103(q)(1), (2) | 21 U.S.C. 333 note. |
| | 105 | 21 U.S.C. 387f–1. |
| | 106 | 21 U.S.C. 387u. |
| Public Law 111–148 (Patient Protection and Affordable Care Act) | 4205(d) | 21 U.S.C. 343 note. |
| Public Law 111–353 (FDA Food Safety Modernization Act) | 102(b)(2) | 21 U.S.C. 350d note. |
| | 103(b) | 21 U.S.C. 350g note. |
| | 103(f) | 21 U.S.C. 350g note. |
| | 103(g) | 21 U.S.C. 350g note. |
| | 104 | 21 U.S.C. 2201. |
| | 105(b) | 21 U.S.C. 350h note. |
| | 105(d) | 21 U.S.C. 350h note. |
| | 106(b) | 21 U.S.C. 350i note. |
| | 106(c) | 21 U.S.C. 350i note. |
| | 108 | 21 U.S.C. 2202. |
| | 109 | 21 U.S.C. 2203. |
| | 110 | 21 U.S.C. 2204. |
| | 112 | 21 U.S.C. 2205. |
| | 113(b) | 21 U.S.C. 350b note. |
| | 116 | 21 U.S.C. 2206. |
| | 201(c) | 21 U.S.C. 350j note. |
| | 202(b) | 21 U.S.C. 2221. |
| | 203 | 21 U.S.C. 2222. |
| | 204 (except (j)) | 21 U.S.C. 2223. |
| | 205 | 21 U.S.C. 2224. |
| | 206(b) | 21 U.S.C. 350l note. |
| | 206(f) | 21 U.S.C. 350l–1. |
| | 208 | 21 U.S.C. 2225. |
| | 303(d) | 21 U.S.C. 381 note. |
| | 306(b) | 21 U.S.C. 2241. |
| | 308 | 21 U.S.C. 2242. |
| | 309 | 21 U.S.C. 2243. |
| | 403 | 21 U.S.C. 2251. |
| | 404 | 21 U.S.C. 2252. |
| Public Law 112–144 (Food and Drug Administration Safety and Innovation Act) | 508 | 21 U.S.C. 355c–1. |
| | 608(c) | 21 U.S.C. 360c–1. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| | 707(b) | 21 U.S.C. 351 note. |
| | 804 | 21 U.S.C. 360a–1. |
| | 806 | 21 U.S.C. 355 note. |
| | 1001(b) | 21 U.S.C. 356c note. |
| | 1006 | 21 U.S.C. 826a. |
| | 1113 | 21 U.S.C. 360ddd note. |
| | 1121 | 21 U.S.C. 379d–5. |
| | 1122(c) | 21 U.S.C. 355 note. |
| | 1126 | 21 U.S.C. 399e. |
| | 1132(c) | 21 U.S.C. 355–1 note. |
| | 1138 | 21 U.S.C. 399f. |
| Public Law 113–54, title I (Compounding Quality Act) | 105 | 21 U.S.C. 353a–1. |
| Public Law 113–79 (Agricultural Act of 2014) | 10015 | 21 U.S.C. 346a note. |
| Public Law 113–195 (Sunscreen Innovation Act) | 2(b) | 21 U.S.C. 360fff note. |
| Public Law 113–260 (Designer Anabolic Steroid Control Act of 2014) | 4 | 21 U.S.C. 825 note. |
| Public Law 114–198 (Comprehensive Addiction and Recovery Act of 2016) | 103 | 21 U.S.C. 1536. |
| | 106(b) | 21 U.S.C. 355–1 note. |
| | 203 | 21 U.S.C. 822a. |
| | 702(b) | 21 U.S.C. 829 note. |
| Public Law 114–255, div. A (21st Century Cures Act) | 3003 | 21 U.S.C. 360bbb–8c note. |
| | 3016 | 21 U.S.C. 399h. |
| | 3021 | 21 U.S.C. 355 note. |
| | 3035 | 21 U.S.C. 356 note. |
| | 3038(c) | 21 U.S.C. 355 note. |
| | 3043 (relating to section 3042 of subtitle E). | 21 U.S.C. 356 note. |
| | 3044(d) | 21 U.S.C. 360a–2 note. |
| | 3052(b) | 21 U.S.C. 360j note. |
| | 3060(b) | 21 U.S.C. 360j note. |
| | 3091 | 21 U.S.C. 360bbb–4 note. |
| Public Law 115–52 (FDA Reauthorization Act of 2017) | 505(d)(2) | 21 U.S.C. 355a note. |
| | 702(b) | 21 U.S.C. 374 note. |
| | 709(b), (c) | 21 U.S.C. 360j note. |
| | 902 | 21 U.S.C. 355 note. |
| Public Law 115–92 | 1(b) | 21 U.S.C. 360bbb–3c. |
| Public Law 115–141 (Consolidated Appropriations Act, 2018) | div. M, §401(c) | 21 U.S.C. 346a note. |
| Public Law 115–141, div. A (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018) | 722 | 21 U.S.C. 399i. |
| Public Law 115–176 (Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017) | 2(b) | 21 U.S.C. 360bbb–0a note. |
| Public Law 115–234 (Animal Drug and Animal Generic Drug User Fee Amendments of 2018) | 303(b) | 21 U.S.C. 352 note. |
| | 305 | 21 U.S.C. 360b note. |
| | 306(c) | 21 U.S.C. 348 note. |
| Public Law 115–271 (Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act) | 3001 | 21 U.S.C. 355 note. |
| | 3002 | 21 U.S.C. 355–1 note. |
| Public Law 115–271, title III, subtitle A, ch. 2 (Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act) | 3014 | 21 U.S.C. 384f. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| Public Law 115–271, title III, subtitle A, ch. 3 (Stop Illicit Drug Importation Act of 2018) | 3022(a) | 21 U.S.C. 384g. |
| Public Law 115–271, title III, subtitle B, ch. 2 (Empowering Pharmacists in the Fight Against Opioid Abuse Act) | 3212 | 21 U.S.C. 829 note. |
| Public Law 115–271, title III, subtitle B, ch. 3 (Safe Disposal of Unused Medication Act) | 3222(b) | 21 U.S.C. 822 note. |
| | 3222(c) | 21 U.S.C. 822 note. |
| Public Law 115–271, title III, subtitle B, ch. 6 (Access to Increased Drug Disposal Act of 2018) | 3251 | 21 U.S.C. 822a note. |
| | 3252 | 21 U.S.C. 822a note. |
| | 3253 | 21 U.S.C. 822a note. |
| | 3254 | 21 U.S.C. 822a note. |
| | 3255 | 21 U.S.C. 822a note. |
| | 3256 | 21 U.S.C. 822a note. |
| | 3257 | 21 U.S.C. 822a note. |
| | 3258 | 21 U.S.C. 822a note. |
| | 3259 | 21 U.S.C. 822a note. |
| | 3260 | 21 U.S.C. 822a note. |
| Public Law 115–271, title VIII, subtitle K (Substance Abuse Prevention Act of 2018) | 8220 | 21 U.S.C. 1715. |
| Public Law 115–334 (Agriculture Improvement Act of 2018) | 12516 | 21 U.S.C. 343 note. |
| Public Law 116–92, div. F, title LXXII (Fentanyl Sanctions Act) | 7203 | 21 U.S.C. 2302. |
| | 7211 | 21 U.S.C. 2311. |
| | 7212 | 21 U.S.C. 2312. |
| | 7213 | 21 U.S.C. 2313. |
| | 7213A | 21 U.S.C. 2313a. |
| | 7214 | 21 U.S.C. 2314. |
| | 7215 | 21 U.S.C. 2315. |
| | 7216 | 21 U.S.C. 2316. |
| | 7231 | 21 U.S.C. 2331. |
| | 7232 | 21 U.S.C. 2332. |
| | 7233 | 21 U.S.C. 2333. |
| | 7234 | 21 U.S.C. 2334. |
| | 7235 | 21 U.S.C. 2335. |
| Public Law 116–94 (Further Consolidated Appropriations Act, 2020) | div. N, §610(a) through (c) | 21 U.S.C. 355–2(a) through (c). |
| | div. N, §610(e) | 21 U.S.C. 355–2(e). |
| | div. N, §610(g) | 21 U.S.C. 355–2(g). |
| Public Law 116–136 (Coronavirus Aid, Relief, and Economic Security Act) | 3853 | 21 U.S.C. 355h note. |
| Public Law 116–136, div. A, title III, subtitle A (Coronavirus Aid, Relief, and Economic Security Act) | 3112(f) | 21 U.S.C. 356c note. |
| Public Law 116–206 (Rodchenkov Anti-Doping Act of 2019) | 2 | 21 U.S.C. 2401. |
| | 3 | 21 U.S.C. 2402. |
| | 4 | 21 U.S.C. 2403. |
| | 6 | 21 U.S.C. 2404. |
| Public Law 116–215 (Further Continuing Appropriations Act, 2021, and Other Extensions Act) | 1302 | 21 U.S.C. 829 note. |
| Public Law 116–260 (Consolidated Appropriations Act, 2021 ) | 764 | 21 U.S.C. 473. |
| Pub. L. 116–260, div. A (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2021 ) | 787 | 21 U.S.C. 2105 note. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| Public Law 117–79 (Accelerating Access to Critical Therapies for ALS Act) | 2 | 21 U.S.C. 360ee note. |
| | 3 | 42 U.S.C. 280g–7b. |
| | 4 | 21 U.S.C. 360aa note. |
| | 5 | 21 U.S.C. 360ee–1. |
| Public Law 117–99 (Methamphetamine Response Act of 2021) | 1 | 21 U.S.C. 1708 note. |
| | 2 | 21 U.S.C. 1708 note. |
| Public Law 117–103 (Consolidated Appropriations Act, 2022) | div. P, title I, §112 | 21 U.S.C. 387v. |
| Public Law 117–103, div. Q, title III (United States Anti-Doping Agency Reauthorization Act of 2022) | 305 | 21 U.S.C. 2004. |
| Public Law 117–215 | 2(a) | 21 U.S.C. 801 note. |
| | 104 | 21 U.S.C. 823 note. |
| | 105 | 21 U.S.C. 823 note. |
| | 106 | 42 U.S.C. 241 note. |
| | 201 | 21 U.S.C. 823 note. |
| | 202 | 21 U.S.C. 823 note. |
| | 301 | 21 U.S.C. 801 note. |
| | 401 | 42 U.S.C. 284 note. |
| Public Law 117–328, div. E, title II (Executive Office of the President Appropriations Act, 2023) | proviso under heading "SALARIES AND EXPENSES", under heading "OFFICE OF NATIONAL DRUG CONTROL POLICY", at 136 Stat. 4664. | 21 U.S.C. 1702 note. |
| Public Law 117–328, div. FF, title I (Restoring Hope for Mental Health and Well-Being Act of 2022) | 1252(b) | 21 U.S.C. 823 note. |
| Public Law 117–328, div. FF, title II (Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act) | 2502(b) | 21 U.S.C. 360bbb–4 note. |
| | 2503(b) | 21 U.S.C. 356k note. |
| | 2505 | 21 U.S.C. 393 note. |
| | 2512(a) | 21 U.S.C. 355 note. |
| | 2514(b), (c) | 21 U.S.C. 356j note. |
| Public Law 117–328, div. FF, title III (Food and Drug Omnibus Reform Act of 2022) | 3208(d) | 21 U.S.C. 360aa note. |
| | 3210(d) | 21 U.S.C. 356 note. |
| | 3210(e) | 21 U.S.C. 356–2. |
| | 3211 | 21 U.S.C. 355 note. |
| | 3305(c) (relating to subsections (a), (b), (e), and (f) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5832)). | 21 U.S.C. 331 note. |
| | 3305(e) | 21 U.S.C. 360n–2 note. |
| | 3305(f) | 21 U.S.C. 360n–2 note. |
| | 3307 | 21 U.S.C. 360g–2. |
| | 3401(a)(1), (b), (e), (f)(1), (g)(5), (i), (j). | 21 U.S.C. 350a–1(a)(1), (b), (e), (f)(1), (g)(5), (i), (j). |
| | 3602(a), (b) | 21 U.S.C. 355 note. |
| | 3604 | 21 U.S.C. 355 note. |
| | 3606 | 21 U.S.C. 360a–1 note. |
| | 3607 | 21 U.S.C. 360a–1 note. |
| | 3611(b)(2) | 21 U.S.C. 374 note. |
| | 3612(b)(2) | 21 U.S.C. 374 note. |
| | 3627(a) | 21 U.S.C. 393 note. |
| | 3629(a), (c) | 21 U.S.C. 355 note. |

Schedule of Laws Repealed—Continued

| Act | Section | United States Code Former Classification |
|---|---|---|
| Public Law 117–328, div. FF, title III, subtitle E (Modernization of Cosmetics Regulation Act of 2022) | 3503(c) | 21 U.S.C. 364 note. |
| | 3505 | 21 U.S.C. 364d note. |
| Public Law 118–50, div. E (Fentanyl Eradication and Narcotics Deterrence Off Fentanyl) | 3003 | 21 U.S.C. 2341. |
| | 3101(b) | 21 U.S.C. 2351(b). |
| | 3102 | 21 U.S.C. 2352. |
| | 3103 | 21 U.S.C. 2353. |
| | 3104 | 21 U.S.C. 2354. |
| | 3105 | 21 U.S.C. 2355. |
| | 3202 | 21 U.S.C. 2361. |
| | 3301 | 21 U.S.C. 2371. |