EXPLANATION OF H.R. , TO ENACT CERTAIN LAWS RELATING TO FOOD AND DRUGS AS TITLE 21, UNITED STATES CODE, "FOOD AND DRUGS"

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BACKGROUND

Over the past 100 years, numerous laws relating to food and drugs have been enacted. In the United States Code, these provisions are classified to title 21, "Food and Drugs". H.R. ___ restates these provisions as a new positive law title of the United States Code. The new positive law title replaces the former provisions, which are repealed by H.R. ___.

H.R. ___ was prepared by the Office of the Law Revision Counsel as part of the Office's ongoing responsibility under section 205(c) of House Resolution No. 988, 93d Congress, as enacted into law by Public Law 93–554 (2 U.S.C. 285b), "[t]o prepare, and submit to the Committee on the Judiciary one title at a time, a complete compilation, restatement, and revision of the general and permanent laws of the United States".

RESTATEMENT DOES NOT CHANGE MEANING OR EFFECT OF EXISTING LAW

The bill is a codification measure prepared in accordance with section 205(c) of House Resolution No. 988, 93d Congress, as enacted into law by Public Law 93–554 (2 U.S.C. 285b). The purpose of the bill is to enact a restatement of existing law relating to food and drugs as a positive law title of the United States Code. The restatement of existing law 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.

The courts have repeatedly held that the restatement of existing law in a bill such as this one does not change the meaning or effect of the existing law unless Congress explicitly expresses the intent to do so. See, e.g., the following:

Finley v. United States, 490 U.S. 545, 553–555 (1989).

Cass v. United States, 417 U.S. 72, 81–82 (1974).

Tidewater Oil Co. v. United States, 409 U.S. 151, 161–163 (1972).

United States v. Cook, 384 U.S. 257, 260 (1966).

Fourco Glass Co. v. Transmirra Products Corp., 353 U.S. 222, 226–228 (1957).

Washington–Dulles Transportation, Ltd. v. Metropolitan Washington Airports Authority, 263 F.3d 371, 378–379 (4th Cir. 2001).

Atchison, Topeka and Santa Fe Railway Co. v. United States, 617 F.2d 485, 488–491 (7th Cir. 1980).

Trailer Marine Transport Corp. v. Federal Maritime Commission, 602 F.2d 379, 383 nt. 18, 387–389 (D.C. Cir. 1979).

Scheidler v. National Organization for Women, Inc., 547 U.S. 9 (2006).

Keene Corp. v. United States, 508 U.S. 200, 209 (1993).

United States v. Sischo, 262 U.S. 165, 168–169 (1923).

United States v. Ryder, 110 U.S. 729, 740 (1884).

McDonald v. Hovey, 110 U.S. 619, 628–630 (1884).

Smythe v. Fiske, 23 U.S.. 374, 382 (1874).

See also NORMAN J. SINGER & J.D. SHAMBIE SINGER, SUTHERLAND STATUTES AND STATUTORY CONSTRUCTION, §§ 28.10, 28.11 (7th ed. 2009).

DISPOSITION TABLE

The table below shows a disposition for each section of the United States Code affected by H.R. ___.

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 1	Previously repealed.
21 U.S.C. 2	Previously repealed.
21 U.S.C. 3	Previously repealed.
21 U.S.C. 4	Previously repealed.
21 U.S.C. 5	Previously repealed.
21 U.S.C. 6	Previously transferred to 21 U.S.C. 321a.
21 U.S.C. 7	Previously repealed.
21 U.S.C. 8	Previously repealed.
21 U.S.C. 9	Previously repealed.
21 U.S.C. 10	Previously repealed.
21 U.S.C. 11	Previously repealed.
21 U.S.C. 12	Previously repealed.
21 U.S.C. 13	Previously repealed.
21 U.S.C. 14	Previously repealed.
21 U.S.C. 14a	Previously transferred to 21 U.S.C. 376.
21 U.S.C. 15	Previously repealed.
21 U.S.C. 16	21 U.S.C. 30103
21 U.S.C. 17	21 U.S.C. 30104
21 U.S.C. 18	21 U.S.C. 30101
21 U.S.C. 19	Previously repealed.

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 20	Not repealed but omitted from the text of title 21. Provides for standard grades of apples.
21 U.S.C. 21	Not repealed but omitted from the text of title 21. Requires that barrels in which apples are packed be branded in accordance with section 2 of the Act of August 3, 1912 (21 U.S.C. 20).
21 U.S.C. 22	Not repealed but omitted from the text of title 21. Provides for misbranding of barrels of apples.
21 U.S.C. 23	Not repealed but omitted from the text of title 21. Provides for penalties for selling or offering for sale barrels of apples in violation of the Act of August 3, 1912 (15 U.S.C. 231 et seq.; 21 U.S.C. 20 et seq.).
21 U.S.C. 24	Not repealed but omitted from the text of title 21. Requires payment for the cost of inspection under a provision authorizing the investigation of the character of chemical and physical tests applied to American food products in foreign countries and the inspection of the products before shipment to foreign countries.
21 U.S.C. 25	21 U.S.C. 30102
21 U.S.C. 26	Not repealed but omitted from the text of title 21. Authorizes, upon request of any branch of the Federal Government, inspections of food and other products and reimbursement for the inspection. See section 702 of the Act of September 21, 1944 (7 U.S.C. 2256).
21 U.S.C. 41	Previously repealed.
21 U.S.C. 42	Previously repealed.
21 U.S.C. 43	Previously repealed.
21 U.S.C. 44	Previously repealed.
21 U.S.C. 45	Previously repealed.
21 U.S.C. 46	Previously repealed.
21 U.S.C. 46a	Previously repealed.
21 U.S.C. 47	Previously repealed.
21 U.S.C. 48	Previously repealed.
21 U.S.C. 49	Previously repealed.
21 U.S.C. 50	Previously repealed.
21 U.S.C. 61(a)	21 U.S.C. 30701(3)
21 U.S.C. 61(b)	21 U.S.C. 30701(2)
21 U.S.C. 61(c)	21 U.S.C. 30701(1)
21 U.S.C. 62	21 U.S.C. 30702
21 U.S.C. 63	21 U.S.C. 30703
21 U.S.C. 64	21 U.S.C. 30704
21 U.S.C. 71	Previously transferred to 21 U.S.C. 603.
21 U.S.C. 72	Previously transferred to 21 U.S.C. 604.
21 U.S.C. 73	Previously transferred to 21 U.S.C. 605.
21 U.S.C. 74	Previously transferred to 21 U.S.C. 606.
21 U.S.C. 75	Previously transferred to 21 U.S.C. 607.
21 U.S.C. 76	Previously transferred to 21 U.S.C. 608.
21 U.S.C. 77	Previously transferred to 21 U.S.C. 609.
21 U.S.C. 78	Previously transferred to 21 U.S.C. 610.
21 U.S.C. 79	Previously transferred to 21 U.S.C. 611.
21 U.S.C. 80	Previously transferred to 21 U.S.C. 612 and subsequently repealed by section 10418(a)(19) of the Animal Health Protection Act (Public Law 107–171, 116 Stat. 508). See disposition of 21 U.S.C. 612 for disposition of an unrelated provision that was later enacted and classified to 21 U.S.C. 612.
21 U.S.C. 81	Previously transferred to 21 U.S.C. 613 and subsequently repealed by section 10418(a)(19) of the Animal Health Protection Act (Public Law 107–171, 116 Stat. 508). See disposition of 21 U.S.C. 613 for disposition of an unrelated provision that was later enacted and classified to 21 U.S.C. 613.

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 82	Previously transferred to 21 U.S.C. 614 and subsequently repealed by section 10418(a)(19) of the Animal Health Protection Act (Public Law 107–171, 116 Stat. 508).
21 U.S.C. 83	Previously transferred to 21 U.S.C. 615.
21 U.S.C. 84	Previously transferred to 21 U.S.C. 616.
21 U.S.C. 85	Previously transferred to 21 U.S.C. 617.
21 U.S.C. 86	Previously transferred to 21 U.S.C. 618.
21 U.S.C. 87	Previously transferred to 21 U.S.C. 619.
21 U.S.C. 88	Previously transferred to 21 U.S.C. 620.
21 U.S.C. 89	Previously transferred to 21 U.S.C. 621.
21 U.S.C. 90	Previously transferred to 21 U.S.C. 622.
21 U.S.C. 91	Previously transferred to 21 U.S.C. 623.
21 U.S.C. 92	Previously transferred to 21 U.S.C. 623.
21 U.S.C. 93	Previously repealed.
21 U.S.C. 94	Previously transferred to 21 U.S.C. 692.
21 U.S.C. 94a	Previously transferred to 21 U.S.C. 693.
21 U.S.C. 95	Previously transferred to 21 U.S.C. 694.
21 U.S.C. 96	Previously repealed.
21 U.S.C. 97	Repealed as obsolete. Set up a meat inspection fund and provided for payment by the persons or organizations for whom meat inspection was furnished. The provision is obsolete because it ceased to be effective on July 1, 1948, under the Act of June 5, 1948 (21 U.S.C. 695) which requires the cost of the inspection to be borne by the United States. The unobligated balance in the meat inspection fund was carried to the general fund of the Treasury by the Act of June 19, 1948 (ch. 543, 62 Stat. 515).
21 U.S.C. 97a	Repealed as obsolete. Authorized the Secretary of Agriculture to require assurances of payment related to meat inspection and authorized withholding or withdrawal of service for nonpayment or failure to provide assurance of payment. The provision is obsolete because it ceased to be effective on July 1, 1948, under the Act of June 5, 1948 (21 U.S.C. 695) which requires the cost of the inspection to be borne by the United States.
21 U.S.C. 97b	Repealed as obsolete. Authorized rendering of meat inspection to Government or other public agencies under the terms and conditions provided in the Act of July 30, 1947 (21 U.S.C. 97 through 97d). The provision is obsolete because it ceased to be effective on July 1, 1948, under the Act of June 5, 1948 (21 U.S.C. 695) which requires the cost of the inspection to be borne by the United States.
21 U.S.C. 97c	Repealed as obsolete. Required a schedule of obligations and reimbursements of the meat inspection fund to be included in the budget submitted to Congress annually. The provision is obsolete because it ceased to be effective on July 1, 1948, under the Act of June 5, 1948 (21 U.S.C. 695) which requires the cost of the inspection to be borne by the United States.
21 U.S.C. 97d	Repealed as obsolete. Required payments to be made for meat inspection rendered on or after July 1, 1947. The provision is obsolete because it ceased to be effective on July 1, 1948, under the Act of June 5, 1948 (21 U.S.C. 695) which requires the cost of the inspection to be borne by the United States.
21 U.S.C. 98	Previously transferred to 21 U.S.C. 695.
21 U.S.C. 99	Previously repealed.
21 U.S.C. 101	Not repealed but omitted from the text of title 21. Provides that whenever, in the opinion of the President, it is necessary for the protection of animals in the United States against infectious

Disposition Table

Former United States Code Section	Disposition
	or contagious diseases, the President may, by proclamation, suspend the importation of all or any class of animals for a limited time, and may change, modify, revoke, or renew the proclamation, as the public good may require, and during the time of the suspension, the importation of any such animals shall be unlawful.
21 U.S.C. 102	Previously repealed.
21 U.S.C. 103	Previously repealed.
21 U.S.C. 104	Previously repealed.
21 U.S.C. 105	Previously repealed.
21 U.S.C. 106	Repealed as obsolete. Authorized the Secretary of Agriculture to permit the admission into the United States, for immediate slaughter, of tick-infested cattle which were otherwise free from disease, prohibited the importation of tick-infested cattle from specified countries in which foot-and-mouth disease existed, and provided requirements relating to slaughter of the cattle. The provision is obsolete because of section 12 of the Act of August 10, 1917 (ch. 52, 40 Stat. 276), which provided for the provision to cease effect after the passing of the national emergency resulting from World War I.
21 U.S.C. 107	Repealed as obsolete. Authorized deferment of slaughter of tick-infested cattle imported into Puerto Rico in accordance with regulations prescribed by the Secretary of Agriculture, and authorized the Secretary of Agriculture, under joint regulations prescribed by the Secretary of Agriculture and the Secretary of the Treasury, to permit the exportation of tick-infested cattle from the Virgin Islands to Puerto Rico if free from disease.
21 U.S.C. 111	Previously repealed.
21 U.S.C. 112	Previously repealed.
21 U.S.C. 112a	Not repealed but omitted from the text of title 21. Amends certain Acts relating to prevention of diseases among animals (including livestock) to include live poultry.
21 U.S.C. 113	Previously repealed.
21 U.S.C. 113a	Not repealed but omitted from the text of title 21. Provides that the Secretary of Agriculture is authorized to establish research laboratories, including the acquisition of necessary land, buildings, or facilities, and also including the making of research contracts under the authority contained in section 10 of the Bankhead-Jones Act (7 U.S.C. 3105(a)), for research and study, in the United States or elsewhere, of foot-and-mouth disease and other animal diseases which in the opinion of the Secretary constitute a threat to the livestock industry of the United States.
21 U.S.C. 114	Previously repealed.
21 U.S.C. 114a	Previously repealed.
21 U.S.C. 114a–1	Previously repealed.
21 U.S.C. 114b	Previously repealed.
21 U.S.C. 114c	Previously repealed.
21 U.S.C. 114d	Previously repealed.
21 U.S.C. 114d–1	Previously repealed.
21 U.S.C. 114d–2	Previously repealed.
21 U.S.C. 114d–3	Previously repealed.
21 U.S.C. 114d–4	Previously repealed.
21 U.S.C. 114d–5	Previously repealed.
21 U.S.C. 114d–6	Previously repealed.
21 U.S.C. 114e	Previously repealed.
21 U.S.C. 114f	Previously repealed.
21 U.S.C. 114g	Previously repealed.

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 114h	Previously repealed.
21 U.S.C. 114i	Not repealed but omitted from the text of title 21. Provides that the Secretary of Agriculture shall establish and carry out a program for the eradication of pseudorabies in United States swine populations.
21 U.S.C. 115	Previously repealed.
21 U.S.C. 116	Previously repealed.
21 U.S.C. 117	Previously repealed.
21 U.S.C. 118	Previously repealed.
21 U.S.C. 119	Previously repealed.
21 U.S.C. 120	Previously repealed.
21 U.S.C. 121	Previously repealed.
21 U.S.C. 122	Previously repealed.
21 U.S.C. 123	Previously repealed.
21 U.S.C. 124	Previously repealed.
21 U.S.C. 125	Previously repealed.
21 U.S.C. 126	Previously repealed.
21 U.S.C. 127	Previously repealed.
21 U.S.C. 128	Previously repealed.
21 U.S.C. 129	Not repealed but omitted from the text of title 21. Authorizes transfer of funds for emergency arrest of animal, poultry, or plant diseases or pests.
21 U.S.C. 129a	Previously repealed.
21 U.S.C. 130	Previously repealed.
21 U.S.C. 131	Previously repealed.
21 U.S.C. 132	Previously transferred to 21 U.S.C. 693.
21 U.S.C. 133	Previously repealed.
21 U.S.C. 134	Previously repealed.
21 U.S.C. 134a	Previously repealed.
21 U.S.C. 134b	Previously repealed.
21 U.S.C. 134c	Previously repealed.
21 U.S.C. 134d	Previously repealed.
21 U.S.C. 134e	Previously repealed.
21 U.S.C. 134f	Previously repealed.
21 U.S.C. 134g	Previously repealed.
21 U.S.C. 134h	Previously repealed.
21 U.S.C. 135	Previously repealed.
21 U.S.C. 135a	Previously repealed.
21 U.S.C. 135b	Previously repealed.
21 U.S.C. 136	Not repealed but omitted from the text of title 21. Provides that the Secretary of Agriculture, in carrying out regulations prohibiting or restricting the entry of materials that may harbor pests, or diseases, may enter into agreements with operators or owners of vessels or aircraft for the purpose of providing inspection services at points of entry in the United States in addition to the regular or on-call basis currently available in connection with the vessels or aircraft.
21 U.S.C. 136a	Not repealed but omitted from the text of title 21. Provides that the Secretary of Agriculture may prescribe and collect fees sufficient to cover the cost of providing agricultural quarantine and inspection services relating to vessels, aircraft, and other transportation entering the United States.
21 U.S.C. 141	21 U.S.C. 30902
21 U.S.C. 142	21 U.S.C. 30903
21 U.S.C. 143	21 U.S.C. 30904
21 U.S.C. 144	21 U.S.C. 30905
21 U.S.C. 145	21 U.S.C. 30906
21 U.S.C. 146	21 U.S.C. 30907
21 U.S.C. 147	21 U.S.C. 30908
21 U.S.C. 148	21 U.S.C. 30909

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 149	21 U.S.C. 30901
21 U.S.C. 151	Not repealed but omitted from the text of title 21. Provides that it is unlawful for any person to prepare, sell, barter, or exchange, or to ship or deliver for shipment any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and to prepare, sell, barter, exchange, or ship any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless the virus, serum, toxin, or analogous product is prepared, under regulations prescribed by the Secretary of Agriculture, at an establishment holding a license issued by the Secretary of Agriculture.
21 U.S.C. 152	Not repealed but omitted from the text of title 21. Provides that the importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without a permit or certification.
21 U.S.C. 153	Not repealed but omitted from the text of title 21. Provides that the Secretary of Agriculture may cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, that are being imported or offered for importation into the United States, to determine whether the viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it appears that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, it shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.
21 U.S.C. 154	Not repealed but omitted from the text of title 21. Provides that the Secretary of Agriculture may make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment.
21 U.S.C. 154a	Not repealed but omitted from the text of title 21. Provides that in order to meet certain special circumstances, the Secretary of Agriculture may issue a special license under an expedited procedure on such conditions as are necessary to ensure purity, safety, and a reasonable expectation of efficacy, and that the Secretary shall exempt by regulation from the requirement of preparation pursuant to a license certain specified virus, serum, toxin, or analogous product prepared by any person, firm, or corporation.
21 U.S.C. 155	Not repealed but omitted from the text of title 21. Provides that the Secretary of Agriculture may issue permits for the importation into the United

Former United States Code Section	Disposition
	States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful.
21 U.S.C. 156	Not repealed but omitted from the text of title 21. Provides that all licenses issued under the authority of the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.) to establishments where viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment shall be issued on condition that the licensee shall permit the inspection of the establishments and of the products and their preparation, and that the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of the Act, if the Secretary of Agriculture is satisfied that the license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment, or the importation into the United States, of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals.
21 U.S.C. 157	Not repealed but omitted from the text of title 21. Provides that any officer, agent, or employee of the Department of Agriculture authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment.
21 U.S.C. 158	Not repealed but omitted from the text of title 21. Provides criminal penalties for any person, firm, or corporation that violates any of the provisions of the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.).
21 U.S.C. 159	Not repealed but omitted from the text of title 21. Provides that provisions of the Meat Inspection Act (21 U.S.C. 601 et seq.) relating to enforcement and penalties apply with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.) or a regulation promulgated under that Act. Sets forth findings of Congress relating to effect on interstate and foreign commerce of the regulation of products under the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.).
21 U.S.C. 161	Repealed as obsolete. Established a Bureau of Narcotics in the Department of the Treasury, provided for appointment of a Commissioner of Narcotics, and required the Commissioner to make an annual report to Congress. The Bureau was abolished and its functions were transferred to the Department of Justice by Reorganization Plan No. 1 of 1968 (28 U.S.C. 509 note).
21 U.S.C. 162	Repealed as obsolete. Provided for appointment and compensation of a Deputy Commissioner and other personnel for the Bureau of Narcotics, required the Deputy to be an acting Commissioner in the event that there is no Commissioner, and authorized designation of an officer or employee of the Treasury Department as an acting Commissioner in the event there is no Commissioner or Deputy Commissioner. The Bureau was abolished and its functions were transferred to the Department of Justice by Reorganization Plan No. 1 of 1968 (28 U.S.C. 509 note).

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 163	Not repealed but omitted from the text of title 21. Provides for transfer to the Secretary of the Treasury the rights, privileges, powers, and duties conferred on the Commissioner of Internal Revenue by any law relating to taxation, importation, exportation, transportation, manufacture, production, compounding, sale, exchange, dispensing, giving away, possession, or use of narcotic drugs.
21 U.S.C. 164	Repealed as obsolete. Provided for the abolition of the Federal Narcotics Control Board, transferred powers of the Board to the Commissioner of Narcotics, and provided for other related transition provisions.
21 U.S.C. 165	Repealed as obsolete. Provided for the review of decisions of the Commissioner of Narcotics by the Secretary of the Treasury.
21 U.S.C. 171	Previously repealed.
21 U.S.C. 172	Previously repealed.
21 U.S.C. 173	Previously repealed.
21 U.S.C. 173a	Previously repealed.
21 U.S.C. 174	Previously repealed.
21 U.S.C. 175	Previously repealed.
21 U.S.C. 176	Previously repealed.
21 U.S.C. 176a	Previously repealed.
21 U.S.C. 176b	Previously repealed.
21 U.S.C. 177	Previously repealed.
21 U.S.C. 178	Previously repealed.
21 U.S.C. 179	Previously repealed.
21 U.S.C. 180	Previously repealed.
21 U.S.C. 181	Previously repealed.
21 U.S.C. 182	Previously repealed.
21 U.S.C. 183	Previously repealed.
21 U.S.C. 184	Previously repealed.
21 U.S.C. 184a	Previously repealed.
21 U.S.C. 185	Previously repealed.
21 U.S.C. 186	Previously repealed.
21 U.S.C. 187	Previously repealed.
21 U.S.C. 188	Previously repealed.
21 U.S.C. 188a	Previously repealed.
21 U.S.C. 188b	Previously repealed.
21 U.S.C. 188c	Previously repealed.
21 U.S.C. 188d	Previously repealed.
21 U.S.C. 188e	Previously repealed.
21 U.S.C. 188f	Previously repealed.
21 U.S.C. 188g	Previously repealed.
21 U.S.C. 188h	Previously repealed.
21 U.S.C. 188i	Previously repealed.
21 U.S.C. 188j	Previously repealed.
21 U.S.C. 188k	Previously repealed.
21 U.S.C. 188l	Previously repealed.
21 U.S.C. 188m	Previously repealed.
21 U.S.C. 188n	Previously repealed.
21 U.S.C. 191	Previously repealed.
21 U.S.C. 192	Previously repealed.
21 U.S.C. 193	Previously repealed.
21 U.S.C. 196	Previously repealed.
21 U.S.C. 197	Previously repealed.
21 U.S.C. 198	Previously repealed.
21 U.S.C. 198a	Previously transferred to 21 U.S.C. 967.
21 U.S.C. 198b	Previously transferred to 21 U.S.C. 968.
21 U.S.C. 198c	Previously transferred to 21 U.S.C. 969.
21 U.S.C. 199	Previously repealed.
21 U.S.C. 200	Previously repealed.

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 200a	Previously repealed.
21 U.S.C. 200b	Previously repealed.
21 U.S.C. 201	21 U.S.C. 40102
21 U.S.C. 202	21 U.S.C. 40103
21 U.S.C. 203	21 U.S.C. 40104
21 U.S.C. 204	21 U.S.C. 40105
21 U.S.C. 205	21 U.S.C. 40106
21 U.S.C. 206	21 U.S.C. 40107
21 U.S.C. 207	21 U.S.C. 40108
21 U.S.C. 208	21 U.S.C. 40109
21 U.S.C. 209 (last paragraph)	21 U.S.C. 40101(b)
21 U.S.C. 209 (except last paragraph)	21 U.S.C. 40110
21 U.S.C. 210	21 U.S.C. 40111
21 U.S.C. 211	21 U.S.C. 40112
21 U.S.C. 212	21 U.S.C. 40113
21 U.S.C. 213	21 U.S.C. 40114
21 U.S.C. 214	Repealed as obsolete. Provided that nothing in the Act of March 3, 1915 (ch. 74, 38 Stat. 817) shall be construed as modifying or revoking any of the provisions of the Act of February 23, 1887 (ch. 210, 24 Stat. 409), which was subsequently repealed.
21 U.S.C. 215	21 U.S.C. 40101(a)
21 U.S.C. 221	Previously repealed.
21 U.S.C. 222	Previously repealed.
21 U.S.C. 222a	Previously repealed.
21 U.S.C. 222b	Previously repealed.
21 U.S.C. 223	Previously repealed.
21 U.S.C. 224	Previously repealed.
21 U.S.C. 225	Previously repealed.
21 U.S.C. 226	Previously repealed.
21 U.S.C. 227	Previously repealed.
21 U.S.C. 228	Previously repealed.
21 U.S.C. 229	Previously repealed.
21 U.S.C. 230	Previously repealed.
21 U.S.C. 231	Previously repealed.
21 U.S.C. 232	Previously repealed.
21 U.S.C. 233	Previously repealed.
21 U.S.C. 234	Previously repealed.
21 U.S.C. 235	Previously repealed.
21 U.S.C. 236	Previously repealed.
21 U.S.C. 237	Previously repealed.
21 U.S.C. 301	Not repealed but omitted from the text of title 21. Provided a short title for the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).
21 U.S.C. 321(a)(1)	21 U.S.C. 10101(a)(47)
21 U.S.C. 321(a)(2)	21 U.S.C. 10101(a)(48)
21 U.S.C. 321(b)	21 U.S.C. 10101(a)(24)
21 U.S.C. 321(c)	21 U.S.C. 10101(a)(15)
21 U.S.C. 321(d)	21 U.S.C. 10101(a)(44)
21 U.S.C. 321(e)	21 U.S.C. 10101(a)(37)
21 U.S.C. 321(f)	21 U.S.C. 10101(a)(19)
21 U.S.C. 321(g)(1)	21 U.S.C. 10101(a)(18)
21 U.S.C. 321(g)(2)	21 U.S.C. 10101(a)(12)
21 U.S.C. 321(h)(1)	21 U.S.C. 10101(a)(16)
21 U.S.C. 321(h)(2)	21 U.S.C. 10101(a)(11)
21 U.S.C. 321(i)	21 U.S.C. 10101(a)(10)
21 U.S.C. 321(j)	21 U.S.C. 10101(a)(35)
21 U.S.C. 321(k)	21 U.S.C. 10101(a)(27)
21 U.S.C. 321(l)	21 U.S.C. 10101(a)(21)
21 U.S.C. 321(m)	21 U.S.C. 10101(a)(28)
21 U.S.C. 321(n)	21 U.S.C. 10101(c)(1)
21 U.S.C. 321(o)	21 U.S.C. 10101(c)(2)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 321(p)	21 U.S.C. 10101(a)(34)
21 U.S.C. 321(q)(1)	21 U.S.C. 10101(a)(38)(A) through (D)
21 U.S.C. 321(q)(2)	21 U.S.C. 10101(a)(39)(A)
21 U.S.C. 321(q)(3) (relating to subparagraph (1))	21 U.S.C. 10101(a)(38)(E)
21 U.S.C. 321(q)(3) (relating to subparagraph (2))	21 U.S.C. 10101(a)(39)(B)
21 U.S.C. 321(r)	21 U.S.C. 10101(a)(42)
21 U.S.C. 321(s)	21 U.S.C. 10101(a)(20)
21 U.S.C. 321(t)(1), (3)	21 U.S.C. 10101(a)(7)
21 U.S.C. 321(t)(2)	21 U.S.C. 10101(a)(6)
21 U.S.C. 321(u)	21 U.S.C. 10101(b)(3)
21 U.S.C. 321(v)	21 U.S.C. 10101(a)(33)
21 U.S.C. 321(w)	21 U.S.C. 10101(a)(3)
21 U.S.C. 321(x)	21 U.S.C. 10101(a)(23)
21 U.S.C. 321(y)	21 U.S.C. 10101(a)(43)
21 U.S.C. 321(z)	21 U.S.C. 10101(a)(22)
21 U.S.C. 321(aa)	21 U.S.C. 10101(a)(1)
21 U.S.C. 321(bb) (relating to "knowingly")	21 U.S.C. 10101(a)(26)
21 U.S.C. 321(bb) (relating to "knew")	21 U.S.C. 10101(a)(25)
21 U.S.C. 321(cc)	21 U.S.C. 10101(b)(2)
21 U.S.C. 321(dd)	21 U.S.C. 10101(b)(1)
21 U.S.C. 321(ee)	21 U.S.C. 10101(a)(8)
21 U.S.C. 321(ff)	21 U.S.C. 10101(a)(17)
21 U.S.C. 321(gg)	21 U.S.C. 10101(a)(41)
21 U.S.C. 321(hh)	21 U.S.C. 10101(a)(2)
21 U.S.C. 321(ii)	21 U.S.C. 10101(a)(9)
21 U.S.C. 321(jj) (except 1st parenthetical)	21 U.S.C. 10101(a)(4)(A)
21 U.S.C. 321(jj) (1st parenthetical)	21 U.S.C. 10101(a)(4)(B)
21 U.S.C. 321(kk)	21 U.S.C. 10101(a)(40)
21 U.S.C. 321(ll)	21 U.S.C. 10101(a)(46)
21 U.S.C. 321(mm)(1)	21 U.S.C. 10101(a)(14)
21 U.S.C. 321(mm)(2)	21 U.S.C. 10101(a)(45)
21 U.S.C. 321(nn)	21 U.S.C. 10101(a)(30)
21 U.S.C. 321(oo)	21 U.S.C. 10101(a)(31)
21 U.S.C. 321(pp)	21 U.S.C. 10101(a)(32)
21 U.S.C. 321(qq)	21 U.S.C. 10101(a)(29)
21 U.S.C. 321(rr)(1) through (4)	21 U.S.C. 10101(a)(49) (except (B)(iii))
21 U.S.C. 321(rr)(5)	21 U.S.C. 10101(a)(49)(B)(iii)
21 U.S.C. 321(ss)	21 U.S.C. 10101(a)(13)
21 U.S.C. 321a	21 U.S.C. 10101(a)(5)
21 U.S.C. 321b	21 U.S.C. 10101(a)(36)
21 U.S.C. 321c	21 U.S.C. 10102
21 U.S.C. 321d(a)(1)	21 U.S.C. 10103(a)
21 U.S.C. 321d(a)(2)	Omitted from the Code. Amended section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343).
21 U.S.C. 321d(b)(1)	21 U.S.C. 10103(b)
21 U.S.C. 321d(b)(2)	Omitted from the Code. Amended section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343).
21 U.S.C. 331(a)	21 U.S.C. 10501(1)
21 U.S.C. 331(b)	21 U.S.C. 10501(2)
21 U.S.C. 331(c)	21 U.S.C. 10501(3)
21 U.S.C. 331(d)	21 U.S.C. 10501(4)
21 U.S.C. 331(e)	21 U.S.C. 10501(5)
21 U.S.C. 331(f)	21 U.S.C. 10501(6)
21 U.S.C. 331(g)	21 U.S.C. 10501(7)
21 U.S.C. 331(h)	21 U.S.C. 10501(8)
21 U.S.C. 331(i)	21 U.S.C. 10501(9)
21 U.S.C. 331(j)	21 U.S.C. 10501(10)
21 U.S.C. 331(k)	21 U.S.C. 10501(11)
21 U.S.C. 331(l)	Previously repealed.
21 U.S.C. 331(m)	21 U.S.C. 10501(12)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 331(n)	21 U.S.C. 10501(13)
21 U.S.C. 331(o)	21 U.S.C. 10501(14)
21 U.S.C. 331(p)	21 U.S.C. 10501(15)
21 U.S.C. 331(q)	21 U.S.C. 10501(16) (except (C)(ii))
21 U.S.C. 331(r)	21 U.S.C. 10501(17)
21 U.S.C. 331(s)	21 U.S.C. 10501(18)
21 U.S.C. 331(t)	21 U.S.C. 10501(19)
21 U.S.C. 331(u)	21 U.S.C. 10501(20)
21 U.S.C. 331(v)	21 U.S.C. 10501(21)
21 U.S.C. 331(w)	21 U.S.C. 10501(22)
21 U.S.C. 331(x)	21 U.S.C. 10501(23)
21 U.S.C. 331(y)	21 U.S.C. 10501(24)
21 U.S.C. 331(z)	Repealed as obsolete. Prohibited dissemination of information in violation of section 551 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa). The provision is obsolete because of section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 360aaa note).
21 U.S.C. 331(aa)	21 U.S.C. 10501(25)
21 U.S.C. 331(bb)	21 U.S.C. 10501(26)
21 U.S.C. 331(cc)	21 U.S.C. 10501(27)
21 U.S.C. 331(dd)	21 U.S.C. 10501(28)
21 U.S.C. 331(ee)	21 U.S.C. 10501(29)
21 U.S.C. 331(ff)	21 U.S.C. 10501(30)
21 U.S.C. 331(gg)	21 U.S.C. 10501(31)
21 U.S.C. 331(hh)	21 U.S.C. 10501(32)
21 U.S.C. 331(ii)	21 U.S.C. 10501(33)
21 U.S.C. 331(jj)	21 U.S.C. 10501(34)
21 U.S.C. 331(kk)	21 U.S.C. 10501(35)
21 U.S.C. 331(ll)	21 U.S.C. 10501(36)
21 U.S.C. 331(mm)	21 U.S.C. 10501(37)
21 U.S.C. 331(nn)	21 U.S.C. 10501(38)
21 U.S.C. 331(oo)	21 U.S.C. 10501(39)
21 U.S.C. 331(pp)	21 U.S.C. 10501(40)
21 U.S.C. 331(qq)	21 U.S.C. 10501(41)
21 U.S.C. 331(rr)	21 U.S.C. 10501(42)
21 U.S.C. 331(ss)	21 U.S.C. 10501(43)
21 U.S.C. 331(tt)	21 U.S.C. 10501(44)
21 U.S.C. 331(uu)	21 U.S.C. 10501(45)
21 U.S.C. 331(vv)	21 U.S.C. 10501(46)
21 U.S.C. 331(ww)	21 U.S.C. 10501(47)
21 U.S.C. 331(xx)	21 U.S.C. 10501(48)
21 U.S.C. 331(yy)	21 U.S.C. 10501(49)
21 U.S.C. 331(zz)	21 U.S.C. 10501(50)
21 U.S.C. 331(aaa)	21 U.S.C. 10501(51)
21 U.S.C. 331(bbb)	21 U.S.C. 10501(52)
21 U.S.C. 331(ccc)	21 U.S.C. 10501(53)
21 U.S.C. 331(ddd)	21 U.S.C. 10501(54)
21 U.S.C. 331(eee)	21 U.S.C. 10501(55)
21 U.S.C. 331(fff)	21 U.S.C. 10501(56)
21 U.S.C. 331(ggg)	21 U.S.C. 10501(57)
21 U.S.C. 331(hhh)	21 U.S.C. 10501(58)
21 U.S.C. 331(iii)	21 U.S.C. 10501(59)
21 U.S.C. 331 note (Pub. L. 117–328, div. FF, title III, §3305(c) (except 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)))	Not repealed but omitted from the text of title 21. Provides that nothing in section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5832), including the amendments made by that 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

Former United States Code Section	Disposition
	cleared prior to December 29, 2022. The provision is restated in sections of title 21, United States Code, that restate certain subsections of that section 3305 and certain provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) that were amended by that section 3305. See sections 10501(16)(C), 13158(e), 29117(c), and 49520(c) of title 21, United States Code. The provision is not repealed as it relates to subsections of the that section 3305 that are not restated in title 21, United States Code.
21 U.S.C. 331 note (Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (a) 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. 13158(e)
21 U.S.C. 331 note (Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (b) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5833)))	21 U.S.C. 10501(16)(C)(ii)
21 U.S.C. 331 note (Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (e) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5833)))	21 U.S.C. 29117(c)
21 U.S.C. 331 note (Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (f) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5834)))	21 U.S.C. 49520(c)
21 U.S.C. 332	21 U.S.C. 10502
21 U.S.C. 333(a)	21 U.S.C. 10503(a)
21 U.S.C. 333(b)	21 U.S.C. 10503(b)
21 U.S.C. 333(c)	21 U.S.C. 10503(c)
21 U.S.C. 333(d)	21 U.S.C. 10503(d)
21 U.S.C. 333(e)(1)	21 U.S.C. 10503(e)(2)
21 U.S.C. 333(e)(2)	21 U.S.C. 10503(e)(3)
21 U.S.C. 333(e)(3)	21 U.S.C. 10503(e)(4)
21 U.S.C. 333(e)(4)	21 U.S.C. 10503(e)(1)
21 U.S.C. 333(e)(5)	21 U.S.C. 10503(e)(5)
21 U.S.C. 333(f)(1)	21 U.S.C. 10503(f)(1)
21 U.S.C. 333(f)(2)	21 U.S.C. 10503(f)(2)
21 U.S.C. 333(f)(3)	21 U.S.C. 10503(f)(3)
21 U.S.C. 333(f)(4)(A) (matter before (i) ("(as such term is used in section 355–1 of this title)"))	21 U.S.C. 10503(f)(4)(A)(i)
21 U.S.C. 333(f)(4)(A) (except "(as such term is used in section 355–1 of this title)")	21 U.S.C. 10503(f)(4)(A)(ii)
21 U.S.C. 333(f)(4)(B)	21 U.S.C. 10503(f)(4)(B)
21 U.S.C. 333(f)(5)	21 U.S.C. 10503(f)(5)
21 U.S.C. 333(f)(6)	21 U.S.C. 10503(f)(6)
21 U.S.C. 333(f)(7)	21 U.S.C. 10503(f)(7)
21 U.S.C. 333(f)(8)	21 U.S.C. 10503(f)(8)
21 U.S.C. 333(f)(9)	21 U.S.C. 10503(f)(9)
21 U.S.C. 333(g)(1)	21 U.S.C. 10503(g)(1)
21 U.S.C. 333(g)(2)	21 U.S.C. 10503(g)(2)
21 U.S.C. 333(g)(3)	21 U.S.C. 10503(g)(3)
21 U.S.C. 333(g)(4)	21 U.S.C. 10503(g)(4)
21 U.S.C. 333(g)(5)	21 U.S.C. 10503(g)(5)
21 U.S.C. 333(g)(6)	21 U.S.C. 10503(g)(6)
21 U.S.C. 333(g)(7)	21 U.S.C. 10503(g)(7)
21 U.S.C. 333 note (Pub. L. 111–31, div. A, title I, §103(q)(1), (2))	21 U.S.C. 80102
21 U.S.C. 333a	Previously repealed.
21 U.S.C. 334(a)	21 U.S.C. 10504(a)
21 U.S.C. 334(b)	21 U.S.C. 10504(b)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 334(c)	21 U.S.C. 10504(c)
21 U.S.C. 334(d)	21 U.S.C. 10504(d)
21 U.S.C. 334(e)	21 U.S.C. 10504(e)
21 U.S.C. 334(f)	21 U.S.C. 10504(f)
21 U.S.C. 334(g)	21 U.S.C. 10504(g)
21 U.S.C. 334(h)	21 U.S.C. 10504(h)
21 U.S.C. 334(i)	21 U.S.C. 10504(i)
21 U.S.C. 335	21 U.S.C. 10505
21 U.S.C. 335a(a)	21 U.S.C. 10506(a)
21 U.S.C. 335a(b)(1) through (4)	21 U.S.C. 10506(b) (except (3)(A))
21 U.S.C. 335a(b)(5)	21 U.S.C. 10506(b)(3)(A)
21 U.S.C. 335a(c)	21 U.S.C. 10506(c)
21 U.S.C. 335a(d)	21 U.S.C. 10506(d)
21 U.S.C. 335a(e)	21 U.S.C. 10506(e)
21 U.S.C. 335a(f)	21 U.S.C. 10506(f)
21 U.S.C. 335a(g)	21 U.S.C. 10506(g)
21 U.S.C. 335a(h)	21 U.S.C. 10506(h)
21 U.S.C. 335a(i)	21 U.S.C. 10506(i)
21 U.S.C. 335a(j)	21 U.S.C. 10506(j)
21 U.S.C. 335a(k)	21 U.S.C. 10506(k)
21 U.S.C. 335a(l)	21 U.S.C. 10506(l)
21 U.S.C. 335a(m)	21 U.S.C. 10506(m)
21 U.S.C. 335b	21 U.S.C. 10507
21 U.S.C. 335c	21 U.S.C. 10508
21 U.S.C. 336	21 U.S.C. 10509
21 U.S.C. 337	21 U.S.C. 10510
21 U.S.C. 337a	21 U.S.C. 10511
21 U.S.C. 341 (1st sentence)	21 U.S.C. 11101(a)
21 U.S.C. 341 (2d sentence (from "No definition" through "or butter,"))	21 U.S.C. 11101(b)(1)
21 U.S.C. 341 (2d sentence (from "except that" through "and melons."))	21 U.S.C. 11101(b)(2)(A)
21 U.S.C. 341 (3d sentence)	21 U.S.C. 11101(c)
21 U.S.C. 341 (4th sentence)	21 U.S.C. 11101(d)
21 U.S.C. 341 (5th sentence)	21 U.S.C. 11101(e)
21 U.S.C. 341 (last sentence)	21 U.S.C. 11101(b)(2)(B)
21 U.S.C. 341 note (Pub. L. 107–188, title III, §301(a))	21 U.S.C. 39902
21 U.S.C. 341 note (Pub. L. 107–188, title III, §301(b))	Repealed as unnecessary. Authorized to be appropriated $750,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year, for the purpose of implementing a crisis communications and education strategy described in section 301(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (21 U.S.C. 341 note).
21 U.S.C. 342 (matter before (a))	Repealed as unnecessary. Provided introductory language for provisions describing foods deemed adulterated. The introductory language is repeated in each subsection restating the provisions.
21 U.S.C. 342(a)	21 U.S.C. 11102(a)
21 U.S.C. 342(b)	21 U.S.C. 11102(b)
21 U.S.C. 342(c)	21 U.S.C. 11102(c)
21 U.S.C. 342(d)	21 U.S.C. 11102(d)
21 U.S.C. 342(e)	21 U.S.C. 11102(e)
21 U.S.C. 342(f)	21 U.S.C. 11102(f)
21 U.S.C. 342(g)	21 U.S.C. 11102(g)
21 U.S.C. 342(h)	21 U.S.C. 11102(h)
21 U.S.C. 342(i)	21 U.S.C. 11102(i)
21 U.S.C. 343 (matter before (a))	Repealed as unnecessary. Provided introductory language for provisions describing foods deemed misbranded. The introductory language is repeated in each section restating the provisions.

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 343(a)	21 U.S.C. 11301
21 U.S.C. 343(b)	21 U.S.C. 11302
21 U.S.C. 343(c)	21 U.S.C. 11303
21 U.S.C. 343(d)	21 U.S.C. 11304
21 U.S.C. 343(e)	21 U.S.C. 11305
21 U.S.C. 343(f)	21 U.S.C. 11306
21 U.S.C. 343(g)	21 U.S.C. 11307(a)
21 U.S.C. 343(h) (matter before (1))	21 U.S.C. 11308 (matter before (1)), 21 U.S.C. 11309(a) ("if it purports to be or is represented as")
21 U.S.C. 343(h)(1)	21 U.S.C. 11308(1)
21 U.S.C. 343(h)(2)	21 U.S.C. 11308(2)
21 U.S.C. 343(h)(3) (matter before (A))	21 U.S.C. 11309(a) ("a food that is pasteurized unless")
21 U.S.C. 343(h)(3)(A)	21 U.S.C. 11309(a)(1)
21 U.S.C. 343(h)(3)(B)	21 U.S.C. 11309(a)(2)
21 U.S.C. 343(h) (matter after (3)(B)(ii))	21 U.S.C. 11309(b)
21 U.S.C. 343(i)	21 U.S.C. 11310(a) through (c)
21 U.S.C. 343(j)	21 U.S.C. 11311
21 U.S.C. 343(k) (1st sentence)	21 U.S.C. 11312(a)
21 U.S.C. 343(k) (2d sentence (relating to paragraph (k)))	21 U.S.C. 11312(b)
21 U.S.C. 343(k) (2d sentence (relating to paragraph (g)))	21 U.S.C. 11307(b)
21 U.S.C. 343(k) (2d sentence (relating to paragraph (i)))	21 U.S.C. 11310(d)
21 U.S.C. 343(k) (last sentence)	21 U.S.C. 11312(c)(1)
21 U.S.C. 343(l)	21 U.S.C. 11313(a), (b)
21 U.S.C. 343(m)	21 U.S.C. 11314
21 U.S.C. 343(n)	21 U.S.C. 11315
21 U.S.C. 343(o)	Previously repealed.
21 U.S.C. 343(p)	Previously repealed.
21 U.S.C. 343(q)(1)	21 U.S.C. 11316(a)
21 U.S.C. 343(q)(2)	21 U.S.C. 11316(b)
21 U.S.C. 343(q)(3)	21 U.S.C. 11316(c)
21 U.S.C. 343(q)(4)(A)	21 U.S.C. 11316(d)(2)
21 U.S.C. 343(q)(4)(B) through (D)	21 U.S.C. 11316(d)(3) through (5)
21 U.S.C. 343(q)(4)(E)	21 U.S.C. 11316(d)(1)
21 U.S.C. 343(q)(4)(F)	21 U.S.C. 11316(d)(6)
21 U.S.C. 343(q)(5)(A) through (D)	21 U.S.C. 11316(f)(1) through (4)
21 U.S.C. 343(q)(5)(E)(i)	21 U.S.C. 11316(f)(5)(B)
21 U.S.C. 343(q)(5)(E)(ii)	Repealed as obsolete. Provided an exemption from nutrition labeling requirements during any 12-month period following the specified dates in the provision.
21 U.S.C. 343(q)(5)(E)(iii) (except matter after (IV))	21 U.S.C. 11316(f)(5)(C)
21 U.S.C. 343(q)(5)(E)(iii) (matter after (IV))	21 U.S.C. 11316(f)(5)(D)
21 U.S.C. 343(q)(5)(E)(iv)	21 U.S.C. 11316(f)(5)(E)
21 U.S.C. 343(q)(5)(E)(v)	21 U.S.C. 11316(f)(5)(F)
21 U.S.C. 343(q)(5)(E)(vi)(I)	21 U.S.C. 11316(f)(5)(A)(iii)
21 U.S.C. 343(q)(5)(E)(vi)(II), (III)	21 U.S.C. 11316(f)(5)(A)(i), (ii)
21 U.S.C. 343(q)(5)(F)	21 U.S.C. 11316(e)
21 U.S.C. 343(q)(5)(G)	21 U.S.C. 11316(f)(6)
21 U.S.C. 343(q)(5)(H)(i) through (viii)	21 U.S.C. 11316(g)(2) through (9)
21 U.S.C. 343(q)(5)(H)(ix)(I)	21 U.S.C. 11316(g)(10)(A)
21 U.S.C. 343(q)(5)(H)(ix)(II)	Repealed as obsolete. Provided that within 120 days of March 23, 2010, the Secretary shall publish a notice in the Federal Register specifying the terms and conditions for implementation of section 403(q)(5)(H)(ix)(I) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)(ix)(I)), pending promulgation of regulations.
21 U.S.C. 343(q)(5)(H)(ix)(III)	21 U.S.C. 11316(g)(10)(B)
21 U.S.C. 343(q)(5)(H)(x)	21 U.S.C. 11316(g)(11)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 343(q)(5)(H)(xi)	21 U.S.C. 11316(g)(1)
21 U.S.C. 343(r)(1)	21 U.S.C. 11317(a)
21 U.S.C. 343(r)(2)	21 U.S.C. 11317(b)
21 U.S.C. 343(r)(3)	21 U.S.C. 11317(c)
21 U.S.C. 343(r)(4)	21 U.S.C. 11317(d)
21 U.S.C. 343(r)(5)	21 U.S.C. 11317(e)
21 U.S.C. 343(r)(6)	21 U.S.C. 11317(f)
21 U.S.C. 343(r)(7)	21 U.S.C. 11317(g)
21 U.S.C. 343(s)	21 U.S.C. 11318
21 U.S.C. 343(t)	21 U.S.C. 11320
21 U.S.C. 343(u)	21 U.S.C. 11321
21 U.S.C. 343(v)	21 U.S.C. 11322(a)
21 U.S.C. 343(w)(1)	21 U.S.C. 11323(a)(2)
21 U.S.C. 343(w)(2)	21 U.S.C. 11323(a)(1)
21 U.S.C. 343(w)(3) through (7)	21 U.S.C. 11323(b) through (f)
21 U.S.C. 343(x)	21 U.S.C. 11324
21 U.S.C. 343(y)	21 U.S.C. 11319
21 U.S.C. 343 note (Pub. L. 111–148, title IV, §4205(d))	21 U.S.C. 11316(g)(12)
21 U.S.C. 343 note (Pub. L. 115–334, title XII, §12516)	21 U.S.C. 11316(h)
21 U.S.C. 343 note (Pub. L. 108–282, title II, §206)	21 U.S.C. 32102
21 U.S.C. 343 note (Pub. L. 101–535, § 2(c))	21 U.S.C. 39901
21 U.S.C. 343 note (Pub. L. 86–537, § 2)	21 U.S.C. 11312(c)(2), 21 U.S.C. 11313(c)
21 U.S.C. 343–1	21 U.S.C. 11103
21 U.S.C. 343–2	21 U.S.C. 11104
21 U.S.C. 343–3(a)	21 U.S.C. 11105(b)
21 U.S.C. 343–3(b)	21 U.S.C. 11105(a)
21 U.S.C. 343a	Previously repealed.
21 U.S.C. 344(a) ("Whenever the Secretary finds after investigation that")	21 U.S.C. 11106(a)(1) (matter before (A) ("if the Secretary finds, after investigation, that"))
21 U.S.C. 344(a) (from "the distribution" through "entered interstate commerce,")	21 U.S.C. 11106(a)(1)(A), (B)
21 U.S.C. 344(a) ("he then, and in such case only, shall promulgate regulations providing for the issuance", "of permits")	21 U.S.C. 11106(a)(1) (matter before (A) ("The Secretary shall prescribe regulations providing for the issuance of permits described in this subsection"))
21 U.S.C. 344(a) ("to manufacturers, processors, or packers of such class of food in such locality,")	21 U.S.C. 11106(a)(2)
21 U.S.C. 344(a) (from "to which" through "public health;")	21 U.S.C. 11106(a)(3)
21 U.S.C. 344(a) (from "and after the effective date" through "as provided by such regulations.")	21 U.S.C. 11106(a)(4)
21 U.S.C. 344(b)	21 U.S.C. 11106(b)
21 U.S.C. 344(c)	21 U.S.C. 11106(c)
21 U.S.C. 345	21 U.S.C. 11107
21 U.S.C. 346	21 U.S.C. 11108
21 U.S.C. 346a(a)(1) (matter before (A))	21 U.S.C. 11110(b)(1) (matter before (A))
21 U.S.C. 346a(a)(1)(A), (B)	21 U.S.C. 11110(b)(1)(A), (B)
21 U.S.C. 346a(a)(1) (matter after (B))	21 U.S.C. 11110(a)(1)
21 U.S.C. 346a(a)(2) through (4)	21 U.S.C. 11110(b)(2) through (4)
21 U.S.C. 346a(b)(1) (matter before (A))	21 U.S.C. 11110(c)(1) (matter before (A))
21 U.S.C. 346a(b)(1)(A), (B)	21 U.S.C. 11110(c)(1)(A), (B)
21 U.S.C. 346a(b)(1) (matter after (B))	21 U.S.C. 11110(a)(2)
21 U.S.C. 346a(b)(2)(A)(i)	21 U.S.C. 11110(c)(2)(A)(i)
21 U.S.C. 346a(b)(2)(A)(ii)	21 U.S.C. 11110(a)(3)
21 U.S.C. 346a(b)(2)(A)(iii)	21 U.S.C. 11110(c)(2)(A)(ii)
21 U.S.C. 346a(b)(2)(B)	21 U.S.C. 11110(c)(2)(B)
21 U.S.C. 346a(b)(2)(C) (matter before (i))	21 U.S.C. 11110(c)(2)(C)(i) (matter before (I))
21 U.S.C. 346a(b)(2)(C)(i), (ii)	21 U.S.C. 11110(c)(2)(C)(i)(I), (II)
21 U.S.C. 346a(b)(2)(C) (matter after (ii)(II) (1st sentence))	21 U.S.C. 11110(c)(2)(C)(ii)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 346a(b)(2)(C) (matter after (ii)(II) (2d sentence, last sentence))	21 U.S.C. 11110(c)(2)(C)(iv)
21 U.S.C. 346a(b)(2)(D) through (F)	21 U.S.C. 11110(c)(2)(D) through (F)
21 U.S.C. 346a(b)(3), (4)	21 U.S.C. 11110(c)(3), (4)
21 U.S.C. 346a(c)(1)	21 U.S.C. 11110(d)(1)
21 U.S.C. 346a(c)(2)(A)(i)	21 U.S.C. 11110(d)(2)(A)
21 U.S.C. 346a(c)(2)(A)(ii)	21 U.S.C. 11110(a)(3)
21 U.S.C. 346a(c)(2)(B)	21 U.S.C. 11110(d)(2)(B)
21 U.S.C. 346a(c)(3)	21 U.S.C. 11110(d)(3)
21 U.S.C. 346a(d)	21 U.S.C. 11110(e)
21 U.S.C. 346a(e)	21 U.S.C. 11110(f)
21 U.S.C. 346a(f)	21 U.S.C. 11110(g)
21 U.S.C. 346a(g)	21 U.S.C. 11110(h)
21 U.S.C. 346a(h)	21 U.S.C. 11110(i)
21 U.S.C. 346a(i)	21 U.S.C. 11110(j)
21 U.S.C. 346a(j)	21 U.S.C. 11110(k)
21 U.S.C. 346a(k)	21 U.S.C. 11110(l)
21 U.S.C. 346a(l)	21 U.S.C. 11110(m)
21 U.S.C. 346a(m)	21 U.S.C. 11110(n)
21 U.S.C. 346a(n)	21 U.S.C. 11110(o)
21 U.S.C. 346a(o)	21 U.S.C. 11110(p)
21 U.S.C. 346a(p)(1) through (6)	21 U.S.C. 11110(q)
21 U.S.C. 346a(p)(7)	Repealed as obsolete. Required the Administrator, not later than 4 years after August 3, 1996, to prepare and submit a report to Congress relating to the Endocrine Disruptor Screening Program.
21 U.S.C. 346a(q)	Repealed as obsolete. Required the Administrator of the Environmental Protection Agency to review tolerances and tolerance exemptions for pesticide chemical residues in effect on the day before August 3, 1996, required that in the review of tolerances and exemptions, priority be given to those that pose the greatest risk to public health, and required the Administrator to publish a schedule for the review. See 73 Fed. Reg. 51473 (Sept. 8, 2008) ("The 1996 FFDCA amendments also required the reassessment of all existing tolerances (pesticide residue limits in food) and tolerance exemptions within 10 years, to ensure that they met the safety standard of the law. EPA was directed to give priority to the review of those pesticides that appeared to pose the greatest risk to public health. The Agency completed over 99% of the required tolerance reassessment decisions by August 3, 2006, and upon concluding the N-methyl carbamate cumulative risk assessment, completed all 9,721 tolerance reassessment decisions in September 2007. These decisions represent significant enhancements in public health and environmental protection. By successfully implementing this provision of FFDCA, EPA is ensuring that all pesticides used on food in the United States meet the law's safety standard. EPA's approach to tolerance reassessment under FFDCA was described fully in the Agency's document, `Raw and Processed Food Schedule for Pesticide Tolerance Reassessment' (62 FR 42020, August 4, 1997) (FRL-5734-6)."); 62 Fed. Reg. 42020 (Aug. 4, 1997) ("This notice announces EPA's schedule for reassessing tolerances for pesticide residues in or on raw and processed foods. Publication of this schedule meets the requirements of Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q)(3), as established by the Food Quality Protection Act of 1996.").
21 U.S.C. 346a(r)	21 U.S.C. 11110(r)

Disposition Table

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21 U.S.C. 346a(s)	21 U.S.C. 11110(t)
21 U.S.C. 346a note (Pub. L. 115–141, div. M, title IV, §401(c))	Repealed as obsolete. Provided that section 408(m)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m)(3)) shall be applied by substituting "September 30, 2018" for "September 30, 2017". The provision is obsolete because it has been superseded by the amendment made by section 2(c) of the Pesticide Registration Improvement Extension Act of 2018 (Public Law 116–8, 133 Stat. 485).
21 U.S.C. 346a note (Pub. L. 113–79, title X, §10015)	21 U.S.C. 11110(s)
21 U.S.C. 346a note (Pub. L. 104–170, title III, §301)	21 U.S.C. 11110(c)(2)(C)(iii)
21 U.S.C. 346b	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary for the purpose and administration of the Act of July 22, 1954 (ch. 559, 68 Stat. 511).
21 U.S.C. 347(a) through (d)	21 U.S.C. 11109(c) through (f)
21 U.S.C. 347(e)	21 U.S.C. 11109(b)
21 U.S.C. 347a	21 U.S.C. 31101
21 U.S.C. 347b	21 U.S.C. 31102
21 U.S.C. 348(a)	21 U.S.C. 11111(b)
21 U.S.C. 348(b)	21 U.S.C. 11111(c)
21 U.S.C. 348(c)	21 U.S.C. 11111(d)
21 U.S.C. 348(d)	21 U.S.C. 11111(e)
21 U.S.C. 348(e)	21 U.S.C. 11111(f)
21 U.S.C. 348(f)	21 U.S.C. 11111(g)
21 U.S.C. 348(g)	21 U.S.C. 11111(h)
21 U.S.C. 348(h)(1)	21 U.S.C. 11111(i)(1)
21 U.S.C. 348(h)(2)(A)	21 U.S.C. 11111(i)(2)(B)
21 U.S.C. 348(h)(2)(B)	21 U.S.C. 11111(i)(2)(C)
21 U.S.C. 348(h)(2)(C)	21 U.S.C. 11111(i)(2)(A)
21 U.S.C. 348(h)(3)	21 U.S.C. 11111(i)(3)
21 U.S.C. 348(h)(4)	21 U.S.C. 11111(i)(4)
21 U.S.C. 348(h)(5)(A)(i)	21 U.S.C. 11111(i)(5)(A)(i)
21 U.S.C. 348(h)(5)(A)(ii)	Repealed as obsolete. Provided the conditions on which the Secretary of Health and Human Services was to, not later than April 1, 1999, begin accepting and reviewing notifications submitted under the notification program under section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)).
21 U.S.C. 348(h)(5)(A)(iii)	Repealed as obsolete. Provided the amount applicable to the conditions set out by section 409(h)(5)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(5)(A)(ii)).
21 U.S.C. 348(h)(5)(A)(iv)	21 U.S.C. 11111(i)(5)(A)(ii)
21 U.S.C. 348(h)(5)(B)	Repealed as obsolete. Authorized to be appropriated such sums as necessary for fiscal years 1999 through 2003 to carry out the notification program under section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)).
21 U.S.C. 348(h)(5)(C)	21 U.S.C. 11111(i)(5)(B)
21 U.S.C. 348(h)(6)	21 U.S.C. 11111(a)
21 U.S.C. 348(i)	21 U.S.C. 11111(j)
21 U.S.C. 348(j)	21 U.S.C. 11111(k)
21 U.S.C. 348(k)	21 U.S.C. 11111(l)(1) through (3)
21 U.S.C. 348 note (Pub. L. 115–234, title III, §306(c))	21 U.S.C. 11111(l)(4)
21 U.S.C. 349(a)	21 U.S.C. 11112(a)
21 U.S.C. 349(b)(1) through (3)	21 U.S.C. 11112(b)(1) through (3)
21 U.S.C. 349(b)(4)(A)	21 U.S.C. 11112(b)(4)(A)
21 U.S.C. 349(b)(4)(B) (except matter before (i) ("a national primary drinking water regulation that pursuant to subparagraph (A) is	21 U.S.C. 11112(b)(4)(B)(ii)

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considered to be a standard of quality regulation,"))	
21 U.S.C. 349(b)(4)(B) (matter before (i) ("a national primary drinking water regulation that pursuant to subparagraph (A) is considered to be a standard of quality regulation,"))	21 U.S.C. 11112(b)(4)(B)(i)
21 U.S.C. 350(a)(1)	21 U.S.C. 11113(b)
21 U.S.C. 350(a)(2) (1st sentence)	21 U.S.C. 11113(c)(2)
21 U.S.C. 350(a)(2) (last sentence)	21 U.S.C. 11113(c)(1)
21 U.S.C. 350(b)	21 U.S.C. 11113(d)
21 U.S.C. 350(c)	21 U.S.C. 11113(a)
21 U.S.C. 350 note (Pub. L. 94–278, title V, §501(b))	21 U.S.C. 11113(e)
21 U.S.C. 350a(a)	21 U.S.C. 11114(a)
21 U.S.C. 350a(b)(1)	21 U.S.C. 11114(b)(1)
21 U.S.C. 350a(b)(2)	21 U.S.C. 11114(b)(2)
21 U.S.C. 350a(b)(3)(A)	21 U.S.C. 11114(b)(3)(B)
21 U.S.C. 350a(b)(3)(B)	21 U.S.C. 11114(b)(3)(C)
21 U.S.C. 350a(b)(3)(C)	21 U.S.C. 11114(b)(3)(D)
21 U.S.C. 350a(b)(3)(D)	21 U.S.C. 11114(b)(3)(E)
21 U.S.C. 350a(b)(3)(E)	21 U.S.C. 11114(b)(3)(A)
21 U.S.C. 350a(b)(4)	21 U.S.C. 11114(b)(4)
21 U.S.C. 350a(c)(1)	21 U.S.C. 11114(c)(2)
21 U.S.C. 350a(c)(2)	21 U.S.C. 11114(c)(1)
21 U.S.C. 350a(d)	21 U.S.C. 11114(d)
21 U.S.C. 350a(e)(1) (1st sentence)	21 U.S.C. 11114(e)(2)
21 U.S.C. 350a(e)(1) (last sentence)	21 U.S.C. 11114(e)(3)
21 U.S.C. 350a(e)(2)	21 U.S.C. 11114(e)(1)
21 U.S.C. 350a(f)	21 U.S.C. 11114(f)
21 U.S.C. 350a(g)	21 U.S.C. 11114(g)
21 U.S.C. 350a(h)	21 U.S.C. 11114(h)
21 U.S.C. 350a(i)	21 U.S.C. 11114(i)
21 U.S.C. 350a(j)	21 U.S.C. 11114(j)
21 U.S.C. 350a(k)	21 U.S.C. 11114(k)
21 U.S.C. 350a(l)	21 U.S.C. 11114(l)
21 U.S.C. 350a(m)(1), (2)	21 U.S.C. 11114(m)(2), (3)
21 U.S.C. 350a(m)(3)	21 U.S.C. 11114(m)(1)
21 U.S.C. 350a–1(a)(1)	21 U.S.C. 25308(a)
21 U.S.C. 350a–1(a)(2)	Omitted from the Code. Amended section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).
21 U.S.C. 350a–1(b)	21 U.S.C. 25308(b)
21 U.S.C. 350a–1(c)	Omitted from the Code. Amended section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a).
21 U.S.C. 350a–1(d)	Not repealed but omitted from the text of title 21. Required the Secretary of Health and Human Services to 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, not later than 1 year after December 29, 2022, a report that includes information relating to premarket submissions for new infant formula.
21 U.S.C. 350a–1(e)	21 U.S.C. 25308(c)
21 U.S.C. 350a–1(f)(1)	21 U.S.C. 25308(d)
21 U.S.C. 350a–1(f)(2)	Not repealed but omitted from the text of title 21. Required the Secretary of Health and Human Services, not later than 60 days after December 29, 2022, to seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to examine and report on challenges in supply, market competition, and regulation of infant formula in the United States, and required that the agreement specify that the National Academies shall, not later than 1 year after

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	December 29, 2022, complete the study and submit a report on the results of the study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.
21 U.S.C. 350a–1(g)(1)	Omitted from the Code. Amended section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a).
21 U.S.C. 350a–1(g)(2)	Omitted from the Code. Amended section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a).
21 U.S.C. 350a–1(g)(3)	Omitted from the Code. Amended section 412(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(d)).
21 U.S.C. 350a–1(g)(4)	Omitted from the Code. Amended section 412(i)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)(1)).
21 U.S.C. 350a–1(g)(5)	21 U.S.C. 25308(e)
21 U.S.C. 350a–1(g)(6)	Omitted from the Code. Amended section 412(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(c)(1)(B)).
21 U.S.C. 350a–1(h)	Not repealed but omitted from the text of title 21. Required the manufacturer of a recalled infant formula to submit information to the Secretary of Health and Human Services regarding the recall, required the Secretary to provide the submission, together with specified information, in 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, and provided that the provision is to cease to have force or effect on September 30, 2026.
21 U.S.C. 350a–1(i)	21 U.S.C. 25308(f)
21 U.S.C. 350a–1(j)	21 U.S.C. 25308(g)
21 U.S.C. 350a–1(k)	Omitted from the Code. Added section 424 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350m). That section 424 is restated as section 11126 of title 21, United States Code.
21 U.S.C. 350a–1(l)	Omitted from the Code. Amended section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a).
21 U.S.C. 350a–1(m)	Not repealed but omitted from the text of title 21. Provided that during the 90-day period beginning on December 29, 2022, an individual may import up to a 3-month supply of infant formula for personal use from certain countries, provided conditions for the authorization to import, required health care providers to report to the Commissioner of Food and Drugs adverse events which the health care provider reasonably suspects to be associated with infant formula imported under the provision, required the Commissioner of Food and Drugs to post public notice containing information on infant formula imported under the provision, and provided a sense of Congress relating to consulting with pediatricians regarding importations under the provision.
21 U.S.C. 350b(a)	21 U.S.C. 11115(b)
21 U.S.C. 350b(b)	21 U.S.C. 11115(c)
21 U.S.C. 350b(c)(1) (1st sentence)	21 U.S.C. 11115(d)(2)
21 U.S.C. 350b(c)(1) (last sentence)	21 U.S.C. 11115(d)(3)
21 U.S.C. 350b(c)(2)	21 U.S.C. 11115(d)(1)
21 U.S.C. 350b(d)	21 U.S.C. 11115(a)
21 U.S.C. 350b note (Pub. L. 111–353, title I, § 113(b))	21 U.S.C. 11115(e)
21 U.S.C. 350c	21 U.S.C. 11116
21 U.S.C. 350d(a)(1)	21 U.S.C. 11117(b)(1)

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Former United States Code Section	Disposition
21 U.S.C. 350d(a)(2)	21 U.S.C. 11117(b)(2)
21 U.S.C. 350d(a)(3)	21 U.S.C. 11117(b)(3)
21 U.S.C. 350d(a)(4)	21 U.S.C. 11117(b)(4)
21 U.S.C. 350d(a)(5)	21 U.S.C. 11117(b)(5)
21 U.S.C. 350d(b)(1)	21 U.S.C. 11117(c)(1)
21 U.S.C. 350d(b)(2) (1st sentence)	21 U.S.C. 11117(c)(2)
21 U.S.C. 350d(b)(2) (last sentence)	21 U.S.C. 11117(c)(3)
21 U.S.C. 350d(b)(3)	21 U.S.C. 11117(c)(4)
21 U.S.C. 350d(b)(4)	21 U.S.C. 11117(c)(5)
21 U.S.C. 350d(b)(5)	21 U.S.C. 11117(c)(6)(A), (B)
21 U.S.C. 350d(b)(6)	Repealed as obsolete. Provided for the date on which facilities were to be subject to the requirements of subsection (b) of section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d).
21 U.S.C. 350d(b)(7)	21 U.S.C. 11117(c)(7)
21 U.S.C. 350d(c)(1)	21 U.S.C. 11117(a)(2)
21 U.S.C. 350d(c)(2)	21 U.S.C. 11117(a)(1)
21 U.S.C. 350d(c)(3)	21 U.S.C. 11117(a)(3)
21 U.S.C. 350d(d)	21 U.S.C. 11117(d)
21 U.S.C. 350d note (Pub. L. 111–353, title I, §102(b)(2))	21 U.S.C. 11117(c)(6)(C)
21 U.S.C. 350e	21 U.S.C. 11118
21 U.S.C. 350f(b) through (n)	21 U.S.C. 11119(b) through (n)
21 U.S.C. 350f(a)(2)	21 U.S.C. 11119(a)(1)
21 U.S.C. 350f(a)(1)	21 U.S.C. 11119(a)(2)
21 U.S.C. 350f note (Pub. L. 110–85, title X, § 1005(f))	21 U.S.C. 11119(o)
21 U.S.C. 350g(a) through (k)	21 U.S.C. 11120(b) through (l)
21 U.S.C. 350g(l)(1)	21 U.S.C. 11120(m)(2)
21 U.S.C. 350g(l)(2)	21 U.S.C. 11120(m)(3)
21 U.S.C. 350g(l)(3)(A)	21 U.S.C. 11120(m)(4)
21 U.S.C. 350g(l)(3)(B)	21 U.S.C. 11120(m)(5)
21 U.S.C. 350g(l)(4)	21 U.S.C. 11120(m)(1)
21 U.S.C. 350g(l)(5)(A)	Repealed as obsolete. Required the Secretary of Health and Human Services to conduct a study of the food processing sector.
21 U.S.C. 350g(l)(5)(B) (1st sentence)	Repealed as obsolete. Required the results of the study conducted under section 418(l)(5)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(l)(5)(A)) to include the information necessary to enable the Secretary of Health and Human Services to define the terms "small business" and "very small business", for purposes of promulgating regulations under section 418(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(n)).
21 U.S.C. 350g(l)(5)(B) (last sentence)	21 U.S.C. 11120(o)(2)
21 U.S.C. 350g(l)(5)(C)	Repealed as obsolete. Provided that the Secretary of Health and Human Services submit to Congress a report describing the results of the study conducted under subparagraph (A) of section 418(l)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(l)(5)) not later than 18 months after January 4, 2011.
21 U.S.C. 350g(l)(6)	21 U.S.C. 11120(m)(6)
21 U.S.C. 350g(l)(7)	21 U.S.C. 11120(m)(7)
21 U.S.C. 350g(m)	21 U.S.C. 11120(n)
21 U.S.C. 350g(n)(1)	21 U.S.C. 11120(o)(1)
21 U.S.C. 350g(n)(2)	21 U.S.C. 11120(o)(3)
21 U.S.C. 350g(n)(3)	21 U.S.C. 11120(o)(4)
21 U.S.C. 350g(n)(4)	21 U.S.C. 11120(o)(6)
21 U.S.C. 350g(n)(5)	Repealed as obsolete. Provided that, in promulgating the regulations under section 418(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(n)(1)(A)), the

Former United States Code Section	Disposition
	Secretary of Health and Human Services review regulatory hazard analysis and preventive control programs in existence on January 4, 2011, including the Grade "A" Pasteurized Milk Ordinance, to ensure consistency of the regulations with applicable domestic and internationally recognized standards in existence on the date.
21 U.S.C. 350g(o)	21 U.S.C. 11120(a)
21 U.S.C. 350g note (Pub. L. 111–353, title I, §103(b))	21 U.S.C. 11120(o)(5)
21 U.S.C. 350g note (Pub. L. 111–353, title I, §103(f))	21 U.S.C. 11120(p)(1)
21 U.S.C. 350g note (Pub. L. 111–353, title I, §103(g))	21 U.S.C. 11120(p)(2)
21 U.S.C. 350h(a) through (e)	21 U.S.C. 11121(a) through (e)
21 U.S.C. 350h(f)(1)	21 U.S.C. 11121(f)(2)
21 U.S.C. 350h(f)(2)	21 U.S.C. 11121(f)(3)
21 U.S.C. 350h(f)(3)	21 U.S.C. 11121(f)(4)
21 U.S.C. 350h(f)(4)	21 U.S.C. 11121(f)(1)
21 U.S.C. 350h(f)(5)	21 U.S.C. 11121(f)(5)
21 U.S.C. 350h(f)(6)	21 U.S.C. 11121(f)(6)
21 U.S.C. 350h(g)	21 U.S.C. 11121(h)
21 U.S.C. 350h(h)	21 U.S.C. 11121(i)
21 U.S.C. 350h note (Pub. L. 111–353, title I, §105(b))	21 U.S.C. 11121(g)
21 U.S.C. 350h note (Pub. L. 111–353, title I, §105(d))	21 U.S.C. 11121(j)
21 U.S.C. 350i(a)	21 U.S.C. 11122(b)
21 U.S.C. 350i(b)	21 U.S.C. 11122(c)
21 U.S.C. 350i(c)	21 U.S.C. 11122(f)
21 U.S.C. 350i(d)	21 U.S.C. 11122(g)
21 U.S.C. 350i(e)	21 U.S.C. 11122(a)
21 U.S.C. 350i note (Pub. L. 111–353, title I, §106(b))	21 U.S.C. 11122(d)
21 U.S.C. 350i note (Pub. L. 111–353, title I, §106(c))	21 U.S.C. 11122(e)
21 U.S.C. 350j(a) through (d)	21 U.S.C. 11123(b) through (e)
21 U.S.C. 350j(e)	21 U.S.C. 11123(a)
21 U.S.C. 350j note (Pub. L. 111–353, title II, §201(c))	21 U.S.C. 11123(f)
21 U.S.C. 350k	21 U.S.C. 11124
21 U.S.C. 350l(a) through (h)	21 U.S.C. 11125(a) through (h)
21 U.S.C. 350l(i)	21 U.S.C. 11125(j)
21 U.S.C. 350l(j)	21 U.S.C. 11125(i)
21 U.S.C. 350l note (Pub. L. 111–353, title II, §206(b))	21 U.S.C. 11125(k)
21 U.S.C. 350l–1	21 U.S.C. 11125(l)
21 U.S.C. 350m(a)(1) through (3)	21 U.S.C. 11126(a)(2) through (4)
21 U.S.C. 350m(a)(4)	21 U.S.C. 11126(a)(1)
21 U.S.C. 350m(b), (c)	21 U.S.C. 11126(b), (c)
21 U.S.C. 351 (matter before (a))	Repealed as unnecessary. Provided introductory language for provisions describing drugs or devices deemed adulterated. The introductory language is repeated in each subsection restating the provisions.
21 U.S.C. 351(a)	21 U.S.C. 13101(a)(2)
21 U.S.C. 351(b)	21 U.S.C. 13101(b)
21 U.S.C. 351(c)	21 U.S.C. 13101(c)
21 U.S.C. 351(d)	21 U.S.C. 13101(d)
21 U.S.C. 351(e)	21 U.S.C. 13101(e)
21 U.S.C. 351(f)	21 U.S.C. 13101(f)
21 U.S.C. 351(g)	21 U.S.C. 13101(g)
21 U.S.C. 351(h)	21 U.S.C. 13101(h)
21 U.S.C. 351(i)	21 U.S.C. 13101(i)
21 U.S.C. 351(j)	21 U.S.C. 13101(j)(1)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 351 (from "For purposes of paragraph (a)(2)(B)," through "finished drug products.")	21 U.S.C. 13101(a)(1)
21 U.S.C. 351 note (Pub. L. 112–144, title VII, § 707(b))	21 U.S.C. 13101(j)(2)
21 U.S.C. 352 (matter before (a))	Repealed as unnecessary. Provided introductory language for provisions describing drugs or devices deemed misbranded. The introductory language is repeated in each section restating the provisions.
21 U.S.C. 352(a)(1)	21 U.S.C. 13301(b) through (e)
21 U.S.C. 352(a)(2)	21 U.S.C. 13301(a)
21 U.S.C. 352(b)	21 U.S.C. 13302
21 U.S.C. 352(c)	21 U.S.C. 13303
21 U.S.C. 352(d)	Previously repealed.
21 U.S.C. 352(e)(1)	21 U.S.C. 13304(a)(2) through (4)
21 U.S.C. 352(e)(2)	21 U.S.C. 13304(b)(2), (3)
21 U.S.C. 352(e)(3)	21 U.S.C. 13304(a)(1)
21 U.S.C. 352(e)(4)	21 U.S.C. 13304(b)(1)
21 U.S.C. 352(f)	21 U.S.C. 13305
21 U.S.C. 352(g)	21 U.S.C. 13306
21 U.S.C. 352(h)	21 U.S.C. 13307
21 U.S.C. 352(i)	21 U.S.C. 13308
21 U.S.C. 352(j)	21 U.S.C. 13309
21 U.S.C. 352(k)	Previously repealed.
21 U.S.C. 352(l)	Previously repealed.
21 U.S.C. 352(m)	21 U.S.C. 13310
21 U.S.C. 352(n)	21 U.S.C. 13311 (except (f)(2))
21 U.S.C. 352(o)	21 U.S.C. 13312
21 U.S.C. 352(p)	21 U.S.C. 13313
21 U.S.C. 352(q)	21 U.S.C. 13314
21 U.S.C. 352(r)	21 U.S.C. 13315
21 U.S.C. 352(s)	21 U.S.C. 13316
21 U.S.C. 352(t)	21 U.S.C. 13317
21 U.S.C. 352(u)	21 U.S.C. 13318(a), (b)
21 U.S.C. 352(v)	21 U.S.C. 13319
21 U.S.C. 352(w)	21 U.S.C. 13320(a)
21 U.S.C. 352(x)	21 U.S.C. 13321
21 U.S.C. 352(y)	21 U.S.C. 13322
21 U.S.C. 352(z)	21 U.S.C. 13323
21 U.S.C. 352(aa)	21 U.S.C. 13324
21 U.S.C. 352(bb)	21 U.S.C. 13325
21 U.S.C. 352(cc)	21 U.S.C. 13326
21 U.S.C. 352(dd)	21 U.S.C. 13327
21 U.S.C. 352(ee)	21 U.S.C. 13328
21 U.S.C. 352(ff)	21 U.S.C. 13329
21 U.S.C. 352(gg)(1)	21 U.S.C. 13330(b)
21 U.S.C. 352(gg)(2)	21 U.S.C. 13330(a)
21 U.S.C. 352 note (Pub. L. 115–234, title III, §303(b))	21 U.S.C. 13320(b)
21 U.S.C. 352 note (Pub. L. 110–85, title IX, § 901(d)(3)(B))	21 U.S.C. 13311(f)(2)
21 U.S.C. 352 note (Pub. L. 109–43, §2(c)(2))	21 U.S.C. 13318(c)
21 U.S.C. 353(a)	21 U.S.C. 13102
21 U.S.C. 353(b) (except (5))	21 U.S.C. 13103(a)
21 U.S.C. 353(b)(5)	Not repealed but omitted from the text of title 21. Provides that nothing in subsection (b) of section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) relieves any person from any requirement of law with respect to drugs within the classifications stated in section 3220 of the Internal Revenue Code of 1939 or to marihuana as defined in section 3238(b) of the Internal Revenue Code of 1939.
21 U.S.C. 353(c)(1) (1st sentence)	21 U.S.C. 13103(b)(1)(B)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 353(c)(1) (2d sentence)	21 U.S.C. 13103(b)(1)(A)
21 U.S.C. 353(c)(1) (last sentence)	21 U.S.C. 13103(b)(1)(C)
21 U.S.C. 353(c)(2) (1st sentence)	21 U.S.C. 13103(b)(2)(B)
21 U.S.C. 353(c)(2) (last sentence)	21 U.S.C. 13103(b)(2)(A)
21 U.S.C. 353(c)(3)(A)	21 U.S.C. 13103(b)(3)(B)
21 U.S.C. 353(c)(3)(B)	21 U.S.C. 13103(b)(3)(C)
21 U.S.C. 353(c)(3) (matter after (B)(v))	21 U.S.C. 13103(b)(3)(A)
21 U.S.C. 353(d)(1) (1st sentence)	21 U.S.C. 13103(c)(2)
21 U.S.C. 353(d)(1) (last sentence)	21 U.S.C. 13103(c)(1)(B)
21 U.S.C. 353(d)(2)	21 U.S.C. 13103(c)(3)
21 U.S.C. 353(d)(3)	21 U.S.C. 13103(c)(4)
21 U.S.C. 353(d)(4)	21 U.S.C. 13103(c)(1)(A)
21 U.S.C. 353(e)(1) through (3)	21 U.S.C. 13103(d)(2) through (4)
21 U.S.C. 353(e)(4)	21 U.S.C. 13103(d)(1)(B)
21 U.S.C. 353(e)(5)	21 U.S.C. 13103(d)(5)
21 U.S.C. 353(e)(6)	21 U.S.C. 13103(d)(1)(A)
21 U.S.C. 353(f)	21 U.S.C. 13103(e)
21 U.S.C. 353(g)(1)(A)	21 U.S.C. 13104(b)
21 U.S.C. 353(g)(1)(B)	21 U.S.C. 13104(c)
21 U.S.C. 353(g)(1)(C)	21 U.S.C. 13104(a)(5)
21 U.S.C. 353(g)(1)(D), (E)	21 U.S.C. 13104(d)
21 U.S.C. 353(g)(1)(F)	21 U.S.C. 13104(e)
21 U.S.C. 353(g)(2)	21 U.S.C. 13104(f)
21 U.S.C. 353(g)(3)	21 U.S.C. 13104(g)(2)
21 U.S.C. 353(g)(4)	21 U.S.C. 13104(g)(3)
21 U.S.C. 353(g)(5)(A)	21 U.S.C. 13104(g)(4)
21 U.S.C. 353(g)(5)(B)	21 U.S.C. 13104(g)(1)
21 U.S.C. 353(g)(5)(C)	21 U.S.C. 13104(g)(5)
21 U.S.C. 353(g)(5)(D)	21 U.S.C. 13104(g)(6)
21 U.S.C. 353(g)(6)	21 U.S.C. 13104(h)
21 U.S.C. 353(g)(7)	21 U.S.C. 13104(i)
21 U.S.C. 353(g)(8)(A) (parenthetical)	21 U.S.C. 13104(j)(1)
21 U.S.C. 353(g)(8)(A) (except parenthetical)	21 U.S.C. 13104(j)(2) through (5)
21 U.S.C. 353(g)(8)(B)	21 U.S.C. 13104(j)(6)(A)
21 U.S.C. 353(g)(8)(C)(i), (ii)	21 U.S.C. 13104(j)(6)(B)
21 U.S.C. 353(g)(8)(C)(iii), (iv)	21 U.S.C. 13104(j)(6)(C), (D)
21 U.S.C. 353(g)(8)(C)(v)	21 U.S.C. 13104(j)(7)
21 U.S.C. 353(g)(8)(C)(vi)	21 U.S.C. 13104(k)
21 U.S.C. 353(g)(8)(D)	21 U.S.C. 13104(j)(8)
21 U.S.C. 353(g)(8)(E)	21 U.S.C. 13104(j)(9)
21 U.S.C. 353(g)(8)(F)	21 U.S.C. 13104(j)(10)
21 U.S.C. 353(g)(8)(G)	21 U.S.C. 13104(l)
21 U.S.C. 353(g)(8)(H)	21 U.S.C. 13104(j)(11)
21 U.S.C. 353(g)(9)	21 U.S.C. 13104(a)(1) through (4)
21 U.S.C. 353(h)(1)	21 U.S.C. 13105(b)
21 U.S.C. 353(h)(2)	21 U.S.C. 13105(a)
21 U.S.C. 353(h)(3), (4)	21 U.S.C. 13105(c), (d)
21 U.S.C. 353a(a) (matter before (1) ("Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product"))	21 U.S.C. 13106(b) (matter before (1))
21 U.S.C. 353a(a) (matter before (1) (from "if the drug product is compounded" through "meets the requirements of this section,"))	21 U.S.C. 13106(b)(1), (2)
21 U.S.C. 353a(a) (matter before (1) ("and if the compounding"))	21 U.S.C. 13106(b)(3) (matter before (A))
21 U.S.C. 353a(a)(1)	21 U.S.C. 13106(b)(3)(A)
21 U.S.C. 353a(a)(2)	21 U.S.C. 13106(b)(3)(B)
21 U.S.C. 353a(b) through (d)	21 U.S.C. 13106(c) through (e)
21 U.S.C. 353a(e)	21 U.S.C. 13106(a)
21 U.S.C. 353a–1	21 U.S.C. 49510
21 U.S.C. 353b(a)	21 U.S.C. 13107(b)
21 U.S.C. 353b(b)	21 U.S.C. 13107(c)
21 U.S.C. 353b(c)	21 U.S.C. 13107(d)
21 U.S.C. 353b(d) (matter before (1))	21 U.S.C. 13107(a) (matter before (1))

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 353b(d)(1)	21 U.S.C. 13107(a)(2)
21 U.S.C. 353b(d)(2)	21 U.S.C. 13107(a)(3)
21 U.S.C. 353b(d)(3)	21 U.S.C. 13107(a)(1)
21 U.S.C. 353b(d)(4)	21 U.S.C. 13107(a)(4)
21 U.S.C. 353b(d)(5)	21 U.S.C. 13107(a)(5)
21 U.S.C. 353b(d) (relating to obligation to pay fees)	21 U.S.C. 13107(e)
21 U.S.C. 353c(a), (b)	21 U.S.C. 13108(a), (b)
21 U.S.C. 353c(c)	21 U.S.C. 13108(d)
21 U.S.C. 353c(d)	21 U.S.C. 13108(c)
21 U.S.C. 353c(e), (f)	21 U.S.C. 13108(e), (f)
21 U.S.C. 353d	21 U.S.C. 13109
21 U.S.C. 354	21 U.S.C. 13110
21 U.S.C. 355(a)	21 U.S.C. 13502
21 U.S.C. 355(b)(1) through (4)	21 U.S.C. 13503(a) through (d)
21 U.S.C. 355(b)(5)(A)	21 U.S.C. 13503(e)(1)
21 U.S.C. 355(b)(5)(B) through (F)	21 U.S.C. 13503(e)(2)(B) through (F)
21 U.S.C. 355(b)(5)(G)	21 U.S.C. 13503(e)(2)(A)
21 U.S.C. 355(b)(6)	21 U.S.C. 13503(f)
21 U.S.C. 355(c)(1)	21 U.S.C. 13504(a)
21 U.S.C. 355(c)(2)	21 U.S.C. 13504(b)
21 U.S.C. 355(c)(3) (matter before (A))	21 U.S.C. 13504(c) (matter before (1))
21 U.S.C. 355(c)(3)(A) through (D)	21 U.S.C. 13504(c)(1) through (4)
21 U.S.C. 355(c)(3)(E)(i)	Previously repealed.
21 U.S.C. 355(c)(3)(E)(ii) through (v)	21 U.S.C. 13504(c)(5)
21 U.S.C. 355(c)(4)	21 U.S.C. 13504(d)
21 U.S.C. 355(c)(5)(A) through (C)	21 U.S.C. 13504(e)(2) through (4)
21 U.S.C. 355(c)(5)(D)(i)	21 U.S.C. 13504(e)(1)(B)
21 U.S.C. 355(c)(5)(D)(ii)	21 U.S.C. 13504(e)(1)(A)
21 U.S.C. 355(d) (1st sentence, 2d sentence)	21 U.S.C. 13505(b), (c)
21 U.S.C. 355(d) (3d sentence, 4th sentence)	21 U.S.C. 13505(a)
21 U.S.C. 355(d) (5th sentence, last sentence)	21 U.S.C. 13505(d)
21 U.S.C. 355(e) (last sentence)	Repealed as obsolete. Authorized the Secretary of Health and Human Services to withdraw the approval of an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or to suspend the approval of such an application, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505–1(g)(2)(D) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355–1(g)(2)(D)). The provision is obsolete because section 505–1(g)(2)(D) of that Act was struck by section 1132(a)(2)(C) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 120).
21 U.S.C. 355(e) (except last sentence)	21 U.S.C. 13506(b) through (e)
21 U.S.C. 355(f)	21 U.S.C. 13507
21 U.S.C. 355(g)	21 U.S.C. 13508
21 U.S.C. 355(h)	21 U.S.C. 13509
21 U.S.C. 355(i)(1) through (3)	21 U.S.C. 13510(a) through (c)
21 U.S.C. 355(i)(4) (1st sentence)	21 U.S.C. 13510(d)(1)
21 U.S.C. 355(i)(4) (2d sentence)	21 U.S.C. 13510(e)
21 U.S.C. 355(i)(4) (last sentence)	21 U.S.C. 13510(d)(2)
21 U.S.C. 355(j)(1)	21 U.S.C. 13511(b)
21 U.S.C. 355(j)(2)(A) (matter before (i))	21 U.S.C. 13511(c)(1) (matter before (A))
21 U.S.C. 355(j)(2)(A)(i) ("(hereinafter in this subsection referred to as a `listed drug')")	21 U.S.C. 13511(a)(3)
21 U.S.C. 355(j)(2)(A)(i) (except "(hereinafter in this subsection referred to as a `listed drug')")	21 U.S.C. 13511(c)(1)(A)
21 U.S.C. 355(j)(2)(A)(ii) through (viii)	21 U.S.C. 13511(c)(1)(B) through (H)
21 U.S.C. 355(j)(2)(A) (matter after (viii))	21 U.S.C. 13511(c)(2)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 355(j)(2)(B)	21 U.S.C. 13511(c)(3)
21 U.S.C. 355(j)(2)(C)	21 U.S.C. 13511(c)(4)
21 U.S.C. 355(j)(2)(D)	21 U.S.C. 13511(c)(5)
21 U.S.C. 355(j)(3)(A)	21 U.S.C. 13511(d)(1)
21 U.S.C. 355(j)(3)(B) through (F)	21 U.S.C. 13511(d)(2)(B) through (F)
21 U.S.C. 355(j)(3)(G)	21 U.S.C. 13511(d)(2)(A)
21 U.S.C. 355(j)(4)	21 U.S.C. 13511(e)
21 U.S.C. 355(j)(5)(A)	21 U.S.C. 13511(f)(1)
21 U.S.C. 355(j)(5)(B) (matter before (i))	21 U.S.C. 13511(f)(2) (matter before (A))
21 U.S.C. 355(j)(5)(B)(i), (ii)	21 U.S.C. 13511(f)(2)(A), (B)
21 U.S.C. 355(j)(5)(B)(iii) (except matter after (IV))	21 U.S.C. 13511(f)(2)(C)(i), (ii)
21 U.S.C. 355(j)(5)(B)(iii) (matter after (IV))	21 U.S.C. 13511(f)(2)(C)(iii)
21 U.S.C. 355(j)(5)(B)(iv)(I)	21 U.S.C. 13511(f)(2)(D)(iii)
21 U.S.C. 355(j)(5)(B)(iv)(II)(aa)	21 U.S.C. 13511(f)(2)(D)(i)(I)
21 U.S.C. 355(j)(5)(B)(iv)(II)(bb)	21 U.S.C. 13511(f)(2)(D)(ii)(I)
21 U.S.C. 355(j)(5)(B)(iv)(II)(cc)	21 U.S.C. 13511(f)(2)(D)(ii)(II)
21 U.S.C. 355(j)(5)(B)(iv)(II)(dd)	21 U.S.C. 13511(f)(2)(D)(i)(II)
21 U.S.C. 355(j)(5)(B)(v)(I), (II)	21 U.S.C. 13511(f)(2)(E)(ii), (iii)
21 U.S.C. 355(j)(5)(B)(v)(III)	21 U.S.C. 13511(f)(2)(E)(i)
21 U.S.C. 355(j)(5)(C)	21 U.S.C. 13511(f)(3)
21 U.S.C. 355(j)(5)(D)(i)	21 U.S.C. 13511(f)(4)(A)(ii)
21 U.S.C. 355(j)(5)(D)(ii)	21 U.S.C. 13511(f)(4)(B)
21 U.S.C. 355(j)(5)(D)(iii)	21 U.S.C. 13511(f)(4)(C)
21 U.S.C. 355(j)(5)(D)(iv)	21 U.S.C. 13511(f)(4)(D)
21 U.S.C. 355(j)(5)(E)	21 U.S.C. 13511(f)(5)
21 U.S.C. 355(j)(5)(F)(i)	Previously repealed.
21 U.S.C. 355(j)(5)(F)(ii) through (v)	21 U.S.C. 13511(f)(6)
21 U.S.C. 355(j)(6)	21 U.S.C. 13511(g)
21 U.S.C. 355(j)(7)	21 U.S.C. 13511(h)
21 U.S.C. 355(j)(8)(A)	21 U.S.C. 13511(a)(1)(A), (B)
21 U.S.C. 355(j)(8)(B)	21 U.S.C. 13511(a)(2)(A)
21 U.S.C. 355(j)(8)(C)	21 U.S.C. 13511(a)(2)(B)(i)
21 U.S.C. 355(j)(9)	21 U.S.C. 13511(i)
21 U.S.C. 355(j)(10)	21 U.S.C. 13511(j)
21 U.S.C. 355(j)(11), (12)	21 U.S.C. 13511(k), (l)
21 U.S.C. 355(j)(13)	21 U.S.C. 13511(m)
21 U.S.C. 355(k)	21 U.S.C. 13512(a) through (e)
21 U.S.C. 355(l)	21 U.S.C. 13513
21 U.S.C. 355(m)	21 U.S.C. 13501(3)
21 U.S.C. 355(n) (except (2))	21 U.S.C. 13514
21 U.S.C. 355(n)(2)	21 U.S.C. 10305(b)
21 U.S.C. 355(o)(1)	21 U.S.C. 13515(b)
21 U.S.C. 355(o)(2) (matter before (A))	21 U.S.C. 13515(a) (matter before (1))
21 U.S.C. 355(o)(2)(A)	21 U.S.C. 13515(a)(3)
21 U.S.C. 355(o)(2)(B)	21 U.S.C. 13515(a)(1)
21 U.S.C. 355(o)(2)(C) (relating to new safety information)	21 U.S.C. 13515(a)(2)
21 U.S.C. 355(o)(2)(C) (relating to serious risk)	21 U.S.C. 13515(a)(4)
21 U.S.C. 355(o)(2)(C) (relating to signal of a serious risk)	21 U.S.C. 13515(a)(5)
21 U.S.C. 355(o)(3)	21 U.S.C. 13515(c)
21 U.S.C. 355(o)(4)	21 U.S.C. 13515(d)
21 U.S.C. 355(o)(5)	21 U.S.C. 13515(e)
21 U.S.C. 355(p)	21 U.S.C. 13516
21 U.S.C. 355(q)(1) through (4)	21 U.S.C. 13517(b) through (e)
21 U.S.C. 355(q)(5)	21 U.S.C. 13517(a)
21 U.S.C. 355(r) (except (4))	21 U.S.C. 13518
21 U.S.C. 355(r)(4)	Repealed as obsolete. Authorized the Secretary of Health and Human Services to implement systems or products developed by private entities to ensure development of the internet website required by paragraph (1) of section

Former United States Code Section	Disposition
	505(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(r)) by the date described in that paragraph.
21 U.S.C. 355(s)	21 U.S.C. 13519
21 U.S.C. 355(t)(1)	21 U.S.C. 13520(b)
21 U.S.C. 355(t)(2)	21 U.S.C. 13520(c)
21 U.S.C. 355(t)(3)	21 U.S.C. 13520(a)
21 U.S.C. 355(u)(1)	21 U.S.C. 13521(b)
21 U.S.C. 355(u)(2)	21 U.S.C. 13521(c)
21 U.S.C. 355(u)(3)	21 U.S.C. 13521(a)
21 U.S.C. 355(u)(4)	21 U.S.C. 13521(d)
21 U.S.C. 355(v)	21 U.S.C. 13522
21 U.S.C. 355(w)	21 U.S.C. 13523
21 U.S.C. 355(x)(1)	21 U.S.C. 13524
21 U.S.C. 355(x)(2)	21 U.S.C. 13501(1)
21 U.S.C. 355(y)	21 U.S.C. 13525
21 U.S.C. 355(z)	21 U.S.C. 13501(2), 21 U.S.C. 13526
21 U.S.C. 355 note (Pub. L. 110–85, title IX, §905(b))	21 U.S.C. 13512(f)
21 U.S.C. 355 note (Pub. L. 117–328, div. FF, title II, §2512(a))	21 U.S.C. 29112
21 U.S.C. 355 note (Pub. L. 117–328, div. FF, title III, §3211)	21 U.S.C. 29116
21 U.S.C. 355 note (Pub. L. 117–328, div. FF, title III, §3602(a), (b))	21 U.S.C. 29118
21 U.S.C. 355 note (Pub. L. 117–328, div. FF, title III, §3604)	21 U.S.C. 49522
21 U.S.C. 355 note (Pub. L. 117–328, div. FF, title III, §3629(a), (c))	21 U.S.C. 29124
21 U.S.C. 355 note (Pub. L. 117–328, div. FF, title III, §3629(b))	Not repealed but omitted from the text of title 21. Provides that not later than 2 years after the end of the public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, with respect to COVID–19, the Secretary shall 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 on certain specified applications.
21 U.S.C. 355 note (Pub. L. 115–271, title III, §3001(a), (b))	21 U.S.C. 40901(b), (c)
21 U.S.C. 355 note (Pub. L. 115–271, title III, §3001(c))	21 U.S.C. 40901(a)
21 U.S.C. 355 note (Pub. L. 115–52, title IX, §902)	21 U.S.C. 49517
21 U.S.C. 355 note (Pub. L. 114–255, div. A, title III, §3021)	21 U.S.C. 29106
21 U.S.C. 355 note (Pub. L. 114–255, div. A, title III, §3038(c))	21 U.S.C. 49513
21 U.S.C. 355 note (Pub. L. 112–144, title VIII, §806)	21 U.S.C. 29103
21 U.S.C. 355 note (Pub. L. 112–144, title XI, §1122(c))	21 U.S.C. 29105
21 U.S.C. 355 note (Pub. L. 110–85, title IX, §907)	21 U.S.C. 49505
21 U.S.C. 355 note (Pub. L. 108–173, title XI, §1103(b) (relating to amendment made by subsection (a)(1)))	21 U.S.C. 13511(a)(1)(C)
21 U.S.C. 355 note (Pub. L. 108–173, title XI, §1103(b) (relating to amendment made by subsection (a)(2)))	21 U.S.C. 13511(a)(2)(B)(ii)
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1111)	21 U.S.C. 40701
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1112)	21 U.S.C. 40702

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1113)	21 U.S.C. 40703
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1114)	21 U.S.C. 40704
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1115)	21 U.S.C. 40705
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1116)	21 U.S.C. 40706
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1117)	21 U.S.C. 40707
21 U.S.C. 355 note (Pub. L. 108–173, title XI, subtitle B, §1118)	Not repealed but omitted from the text of title 21. Provides that subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173, 117 Stat. 2461) shall take effect 30 days after December 8, 2003, and shall apply to agreements described in section 1112 of that Act that are entered into 30 days after December 8, 2003.
21 U.S.C. 355 note (Pub. L. 105–115, title I, §118)	21 U.S.C. 40301
21 U.S.C. 355 note (Pub. L. 105–115, title I, §121(c))	21 U.S.C. 40302(b), (c)
21 U.S.C. 355 note (Pub. L. 105–115, title I, §121(e))	21 U.S.C. 40302(a)
21 U.S.C. 355 note (Pub. L. 105–115, title I, §122(a)(1))	21 U.S.C. 40303(b)
21 U.S.C. 355 note (Pub. L. 105–115, title I, §122(a)(2))	21 U.S.C. 40303(c)
21 U.S.C. 355 note (Pub. L. 105–115, title I, §122(b))	21 U.S.C. 40303(a)
21 U.S.C. 355 note (Pub. L. 105–115, title I, §123(f))	21 U.S.C. 40304
21 U.S.C. 355–1(a)	21 U.S.C. 13111(b)
21 U.S.C. 355–1(b)	21 U.S.C. 13111(a) (except (5))
21 U.S.C. 355–1(c)	21 U.S.C. 13111(c)
21 U.S.C. 355–1(d)	21 U.S.C. 13111(d)
21 U.S.C. 355–1(e)	21 U.S.C. 13111(e)
21 U.S.C. 355–1(f)(1)	21 U.S.C. 13111(f)(1)
21 U.S.C. 355–1(f)(2)	21 U.S.C. 13111(f)(2)
21 U.S.C. 355–1(f)(3) (matter before (A))	21 U.S.C. 13111(f)(3)(A) (matter before (i))
21 U.S.C. 355–1(f)(3)(A) (except parenthetical)	21 U.S.C. 13111(f)(3)(A)(i)
21 U.S.C. 355–1(f)(3)(A) (parenthetical)	21 U.S.C. 13111(f)(3)(B)
21 U.S.C. 355–1(f)(3)(B) (except parenthetical)	21 U.S.C. 13111(f)(3)(A)(ii)
21 U.S.C. 355–1(f)(3)(B) (parenthetical)	21 U.S.C. 13111(f)(3)(C)
21 U.S.C. 355–1(f)(3)(C) through (F)	21 U.S.C. 13111(f)(3)(A)(iii) through (vi)
21 U.S.C. 355–1(f)(4)	21 U.S.C. 13111(f)(4)
21 U.S.C. 355–1(f)(5)	21 U.S.C. 13111(f)(5)
21 U.S.C. 355–1(f)(6)	21 U.S.C. 13111(f)(6)
21 U.S.C. 355–1(f)(7)	Previously repealed.
21 U.S.C. 355–1(f)(8)	21 U.S.C. 13111(f)(7)
21 U.S.C. 355–1(g)	21 U.S.C. 13111(g)
21 U.S.C. 355–1(h)	21 U.S.C. 13111(h) (except (2)(A)(ii)(II))
21 U.S.C. 355–1(i)	21 U.S.C. 13111(i)
21 U.S.C. 355–1(j)	21 U.S.C. 13111(j)
21 U.S.C. 355–1(k)	21 U.S.C. 13111(k)
21 U.S.C. 355–1(l)	21 U.S.C. 13111(l)
21 U.S.C. 355–1(m)	21 U.S.C. 13111(a)(5)
21 U.S.C. 355–1 note (Pub. L. 115–271, title III, §3002)	21 U.S.C. 40902
21 U.S.C. 355–1 note (Pub. L. 114–198, title I, §106(b))	21 U.S.C. 49511
21 U.S.C. 355–1 note (Pub. L. 112–144, title XI, §1132(c))	21 U.S.C. 13111(h)(2)(A)(ii)(II)
21 U.S.C. 355–2(a) through (c)	21 U.S.C. 49519(a) through (c)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 355–2(d)	Not repealed but omitted from the text of title 21. Amends section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).
21 U.S.C. 355–2(e)	21 U.S.C. 49519(d)
21 U.S.C. 355–2(f)	Not repealed but omitted from the text of title 21. Amends section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).
21 U.S.C. 355–2(g)	21 U.S.C. 49519(e)
21 U.S.C. 355a(a)	21 U.S.C. 13112(a)
21 U.S.C. 355a(b)	21 U.S.C. 13112(b)
21 U.S.C. 355a(c)	21 U.S.C. 13112(c)
21 U.S.C. 355a(d)	21 U.S.C. 13112(d)
21 U.S.C. 355a(e)	21 U.S.C. 13112(e)
21 U.S.C. 355a(f)	21 U.S.C. 13112(f)
21 U.S.C. 355a(g)	21 U.S.C. 13112(g)
21 U.S.C. 355a(h)	21 U.S.C. 13112(h)
21 U.S.C. 355a(i)	21 U.S.C. 13112(i)
21 U.S.C. 355a(j)	21 U.S.C. 13112(j)
21 U.S.C. 355a(k)	21 U.S.C. 13112(k)
21 U.S.C. 355a(l)	21 U.S.C. 13112(l)
21 U.S.C. 355a(m)	21 U.S.C. 13112(m)
21 U.S.C. 355a(n)	21 U.S.C. 13112(n)
21 U.S.C. 355a(o)	21 U.S.C. 13112(o)
21 U.S.C. 355a(p)	Previously repealed.
21 U.S.C. 355a note (Pub. L. 115–52, title V, §505(d)(2))	21 U.S.C. 29107
21 U.S.C. 355b (except (a)(3))	21 U.S.C. 49503
21 U.S.C. 355b(a)(3)	Repealed as obsolete. Provided an effective date for a rule required to be promulgated under subsection (a) of section 17 of the Best Pharmaceuticals for Children Act (21 U.S.C. 355b).
21 U.S.C. 355c(a) (except (4)(B)(ii) (5th sentence, 6th sentence))	21 U.S.C. 13113(a)
21 U.S.C. 355c(a)(4)(B)(ii) (5th sentence, 6th sentence)	Repealed as obsolete. Provided for deadlines relating to deferral extension requests by applicants and responses by the Secretary of Health and Human Services with respect to deferrals that expired prior to July 9, 2012.
21 U.S.C. 355c(b)	21 U.S.C. 13113(b)
21 U.S.C. 355c(c)	21 U.S.C. 13113(c)
21 U.S.C. 355c(d)	21 U.S.C. 13113(d)
21 U.S.C. 355c(e)	21 U.S.C. 13113(e)
21 U.S.C. 355c(f)	21 U.S.C. 13113(f)
21 U.S.C. 355c(g)	21 U.S.C. 13113(g)
21 U.S.C. 355c(h)	21 U.S.C. 13113(h)
21 U.S.C. 355c(i)	21 U.S.C. 13113(i)
21 U.S.C. 355c(j)	21 U.S.C. 13113(j)
21 U.S.C. 355c(k)	21 U.S.C. 13113(k)
21 U.S.C. 355c(l)	21 U.S.C. 13113(l)
21 U.S.C. 355c(m)	21 U.S.C. 13113(m)
21 U.S.C. 355c–1	21 U.S.C. 49506
21 U.S.C. 355d	21 U.S.C. 13114
21 U.S.C. 355e(a) through (c)	21 U.S.C. 13115(b) through (d)
21 U.S.C. 355e(d)	21 U.S.C. 13115(a)
21 U.S.C. 355f(a) through (e)	21 U.S.C. 13116(b) through (f)
21 U.S.C. 355f(f)(1)	21 U.S.C. 13116(a)(2)
21 U.S.C. 355f(f)(2)	21 U.S.C. 13116(g)
21 U.S.C. 355f(g)	21 U.S.C. 13116(a)(1)
21 U.S.C. 355g(a)	21 U.S.C. 13117(b)
21 U.S.C. 355g(b)	21 U.S.C. 13117(a)
21 U.S.C. 355g(c) through (f)	21 U.S.C. 13117(c) through (f)
21 U.S.C. 355h(a)	21 U.S.C. 13118(b)
21 U.S.C. 355h(b)(1)	21 U.S.C. 13118(c)(1)
21 U.S.C. 355h(b)(2)	21 U.S.C. 13118(c)(2)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 355h(b)(3)	21 U.S.C. 13118(c)(3)
21 U.S.C. 355h(b)(4)	21 U.S.C. 13118(c)(4)
21 U.S.C. 355h(b)(5)(A), (B)	21 U.S.C. 13118(c)(5)(A), (B)
21 U.S.C. 355h(b)(5)(C)(i) through (iv)	21 U.S.C. 13118(c)(5)(C)(ii) through (v)
21 U.S.C. 355h(b)(5)(C)(v)	21 U.S.C. 13118(c)(5)(C)(i)
21 U.S.C. 355h(b)(5)(C)(vi)	21 U.S.C. 13118(c)(5)(C)(vi)
21 U.S.C. 355h(b)(6) through (8)	21 U.S.C. 13118(c)(6) through (8)
21 U.S.C. 355h(c) through (p)	21 U.S.C. 13118(d) through (q)
21 U.S.C. 355h(q)	21 U.S.C. 13118(a)
21 U.S.C. 355h note (Pub. L. 116–136, div. A, title III, §3853)	21 U.S.C. 41101
21 U.S.C. 356(a)(1) (from "The Secretary" through "review of such drug")	21 U.S.C. 13119(b)(1)
21 U.S.C. 356(a)(1) (from "if the drug" through "a 'breakthrough therapy'.)")	21 U.S.C. 13119(a)(2)
21 U.S.C. 356(a)(2), (3)	21 U.S.C. 13119(b)(2), (3)
21 U.S.C. 356(b)(1) (from "The Secretary" through "review of such drug")	21 U.S.C. 13119(c)(1)
21 U.S.C. 356(b)(1) (from "if it is intended" through "a 'fast track product'.)")	21 U.S.C. 13119(a)(3)
21 U.S.C. 356(b)(2), (3)	21 U.S.C. 13119(c)(2), (3)
21 U.S.C. 356(c) (except (1)(A) (last sentence))	21 U.S.C. 13119(d)
21 U.S.C. 356(c)(1)(A) (last sentence)	21 U.S.C. 13119(a)(1)
21 U.S.C. 356(d) through (f)	21 U.S.C. 13119(e) through (g)
21 U.S.C. 356(g)(1) through (7)	21 U.S.C. 13119(h)(1) through (7)
21 U.S.C. 356(g)(8)	21 U.S.C. 13119(a)(4)
21 U.S.C. 356(h)	21 U.S.C. 13119(i) (except (8)(B))
21 U.S.C. 356 note (Pub. L. 114–255, div. A, title III, §3043 (relating to section 3042 of subtitle E))	21 U.S.C. 13119(i)(8)(B)
21 U.S.C. 356 note (Pub. L. 114–255, div. A, title III, §3043 (relating to other than section 3042 of subtitle E))	Not repealed but omitted from the text of title 21. Provides that nothing in subtitle E of title III of the 21st Century Cures Act (Public Law 114–255, div. A, 130 Stat. 1111), or an amendment made by the subtitle, shall be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under subsection (h) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), by health care professionals, or to limit the practice of health care. See section 4(12)(A) of the bill enacting title 21, United States Code, which makes a conforming amendment to section 3043 of the 21st Century Cures Act (Public Law 114–255, div. A, 130 Stat. 1114), which conforming amendment excepts the amendment made by section 3042 of the Act (Public Law 114–255, div. A, 130 Stat. 1112) from the reference to "an amendment made by the subtitle", because of section 13119(i)(8)(B) of title 21, United States Code.
21 U.S.C. 356 note (Pub. L. 117–328, div. FF, title III, §3210(d))	21 U.S.C. 29115
21 U.S.C. 356 note (Pub. L. 114–255, div. A, title III, §3035)	21 U.S.C. 13119(h)(8)
21 U.S.C. 356–1(a) through (c)	21 U.S.C. 49504(b) through (d)
21 U.S.C. 356–1(d)	Not repealed but omitted from the text of title 21. Provides definitions of the terms "priority countermeasure" and "priority drugs or biological products" for title I of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188, 116 Stat. 596). See section 4(12)(B) of the bill enacting title 21, United States Code, for conforming amendment to section 122 of the Act (Public Law 107–188, 116 Stat. 613).

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 356–2	21 U.S.C. 25305
21 U.S.C. 356a	21 U.S.C. 13120
21 U.S.C. 356b	21 U.S.C. 13121
21 U.S.C. 356c(a) ("A manufacturer of a drug", "shall notify the Secretary," through "for such discontinuance or interruption.")	21 U.S.C. 13122(b)(1) (matter before (A))
21 U.S.C. 356c(a)(1), (2)	21 U.S.C. 13122(b)(1)(A), (B)
21 U.S.C. 356c(a) (last sentence)	21 U.S.C. 13122(b)(2)
21 U.S.C. 356c(b) through (g)	21 U.S.C. 13122(c) through (h)
21 U.S.C. 356c(h)	21 U.S.C. 13122(a)
21 U.S.C. 356c(i)	21 U.S.C. 13122(i)
21 U.S.C. 356c(j)	21 U.S.C. 13122(j)
21 U.S.C. 356c note (Pub. L. 116–136, div. A, title III, §3112(f))	21 U.S.C. 41102
21 U.S.C. 356c note (Pub. L. 112–144, title X, §1001(b))	21 U.S.C. 13122(k)
21 U.S.C. 356c–1(a), (b)	21 U.S.C. 13123(b), (c)
21 U.S.C. 356c–1(c)	21 U.S.C. 13123(a)
21 U.S.C. 356d(a)	Repealed as obsolete. Provided that the Secretary of Health and Human Services shall establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages. The provision ceased to be effective on July 9, 2017, as provided in the 1st sentence of subsection (f) of section 506D of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356d(f)).
21 U.S.C. 356d(b) through (e)	21 U.S.C. 13124(a) through (d)
21 U.S.C. 356d(f) (1st sentence)	Repealed as obsolete. Provided that section 506D(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 365d(a)) shall cease to be effective on the date that is 5 years after July 9, 2012.
21 U.S.C. 356d(f) (2d sentence, last sentence)	21 U.S.C. 13124(e)
21 U.S.C. 356d(g)	21 U.S.C. 13124(f)
21 U.S.C. 356e	21 U.S.C. 13125
21 U.S.C. 356f	21 U.S.C. 13126
21 U.S.C. 356g(a), (b)	21 U.S.C. 13127(b), (c)
21 U.S.C. 356g(c)	21 U.S.C. 13127(a)
21 U.S.C. 356h(a) through (d)	21 U.S.C. 13128(b) through (e)
21 U.S.C. 356h(e)	21 U.S.C. 13128(a)
21 U.S.C. 356i	21 U.S.C. 13129
21 U.S.C. 356j(a) (matter before (1), matter after (2))	21 U.S.C. 13130(b)(1)
21 U.S.C. 356j(a)(1), (2)	21 U.S.C. 13130(b)(2)
21 U.S.C. 356j(b) through (g)	21 U.S.C. 13130(c) through (h)
21 U.S.C. 356j(h)	21 U.S.C. 13130(i)
21 U.S.C. 356j(i)	21 U.S.C. 13130(j)
21 U.S.C. 356j(j)	21 U.S.C. 13130(a)
21 U.S.C. 356j note (Pub. L. 117–328, div. FF, title II, §2514(b), (c))	21 U.S.C. 29113
21 U.S.C. 356k(a) through (g)	21 U.S.C. 13131(b) through (h)
21 U.S.C. 356k(h)	21 U.S.C. 13131(a)
21 U.S.C. 356k(i)	21 U.S.C. 13131(i)
21 U.S.C. 356k note (Pub. L. 117–328, div. FF, title II, §2503(b))	21 U.S.C. 29111
21 U.S.C. 356l	21 U.S.C. 13132
21 U.S.C. 357(a) through (d)	21 U.S.C. 13133(b) through (e)
21 U.S.C. 357(e)	21 U.S.C. 13133(a)
21 U.S.C. 358	21 U.S.C. 13134
21 U.S.C. 359	21 U.S.C. 13135
21 U.S.C. 360(a) through (f)	21 U.S.C. 13136(a) through (f)
21 U.S.C. 360(g) (matter before (1))	21 U.S.C. 13136(g)(2) (matter before (A))
21 U.S.C. 360(g)(1) through (5)	21 U.S.C. 13136(g)(2)(A) through (E)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360(g) (matter after (5))	21 U.S.C. 13136(g)(1)
21 U.S.C. 360(h)	21 U.S.C. 13136(h)
21 U.S.C. 360(i)	21 U.S.C. 13136(i)
21 U.S.C. 360(j)	21 U.S.C. 13136(j)
21 U.S.C. 360(k)	21 U.S.C. 13136(k)
21 U.S.C. 360(l)	21 U.S.C. 13136(l)
21 U.S.C. 360(m)	21 U.S.C. 13136(m)
21 U.S.C. 360(n)(1)	21 U.S.C. 13136(n)(1)
21 U.S.C. 360(n)(2)(A)	Repealed as obsolete. Required the Secretary of Health and Human Services to submit a report to Congress not later than 18 months after July 9, 2012.
21 U.S.C. 360(n)(2)(B)	21 U.S.C. 13136(n)(2)(A)
21 U.S.C. 360(n)(2)(C)	21 U.S.C. 13136(n)(2)(B)
21 U.S.C. 360(o)(1)	21 U.S.C. 13136(o)(1)
21 U.S.C. 360(o)(2) (except (C))	21 U.S.C. 13136(o)(2)
21 U.S.C. 360(o)(2)(C)	Repealed as obsolete. Specified deadlines on which lists relating to semi-critical devices and critical devices were to be published. See 68 Fed. Reg. 23139 (Apr. 30, 2003) and 69 Fed. Reg. 19433 (Apr. 13, 2004).
21 U.S.C. 360(p)	21 U.S.C. 13136(p)
21 U.S.C. 360(q)	21 U.S.C. 13136(q)
21 U.S.C. 360a	21 U.S.C. 13137
21 U.S.C. 360a–1(a), (b)	21 U.S.C. 49508(b), (c)
21 U.S.C. 360a–1(c)	21 U.S.C. 49508(a)
21 U.S.C. 360a–1 note (Pub. L. 117–328, div. FF, title III, §3606)	21 U.S.C. 29119
21 U.S.C. 360a–1 note (Pub. L. 117–328, div. FF, title III, §3607(a))	21 U.S.C. 29120
21 U.S.C. 360a–1 note (Pub. L. 117–328, div. FF, title III, §3607(b))	21 U.S.C. 29121
21 U.S.C. 360a–1 note (Pub. L. 117–328, div. FF, title III, §3607(c))	21 U.S.C. 25309
21 U.S.C. 360a–2(a)(1)	21 U.S.C. 13138(a)
21 U.S.C. 360a–2(a) (except (1))	21 U.S.C. 13138(c)
21 U.S.C. 360a–2(b)(1) ("(referred to in this section as the `Interpretive Criteria Website')")	21 U.S.C. 13138(b)(4)
21 U.S.C. 360a–2(b)(1) (except "(referred to in this section as the `Interpretive Criteria Website')")	21 U.S.C. 13138(d)(1)
21 U.S.C. 360a–2(b)(2)	21 U.S.C. 13138(d)(2)
21 U.S.C. 360a–2(b)(3)	Repealed as obsolete. Provided that not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register. See 82 Fed. Reg. 58617 (Dec. 13, 2017).
21 U.S.C. 360a–2(b)(4), (5)	21 U.S.C. 13138(d)(3), (4)
21 U.S.C. 360a–2(c)	21 U.S.C. 13138(e)
21 U.S.C. 360a–2(d)	21 U.S.C. 13138(f)
21 U.S.C. 360a–2(e)	21 U.S.C. 13138(g)
21 U.S.C. 360a–2(f) (matter before (1))	21 U.S.C. 13138(b) (matter before (1))
21 U.S.C. 360a–2(f)(1)	21 U.S.C. 13138(b)(2)
21 U.S.C. 360a–2(f)(2)	21 U.S.C. 13138(b)(5)
21 U.S.C. 360a–2(f)(3)	21 U.S.C. 13138(b)(6)
21 U.S.C. 360a–2(f)(4)	21 U.S.C. 13138(b)(1)
21 U.S.C. 360a–2(f)(5)	21 U.S.C. 13138(b)(3)
21 U.S.C. 360a–2(g)	21 U.S.C. 13138(h)
21 U.S.C. 360a–2 note (Pub. L. 114–255, div. A, title III, §3044(d))	21 U.S.C. 13138(i)
21 U.S.C. 360b(a)(1) through (5)	21 U.S.C. 13702(a) through (e)
21 U.S.C. 360b(a)(6) (1st sentence)	21 U.S.C. 13702(f)(2)
21 U.S.C. 360b(a)(6) (2d sentence)	21 U.S.C. 13702(f)(3)
21 U.S.C. 360b(a)(6) (3d sentence)	21 U.S.C. 13702(f)(4)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360b(a)(6) (4th sentence)	21 U.S.C. 13702(f)(1)
21 U.S.C. 360b(a)(6) (last sentence)	21 U.S.C. 13702(f)(5)
21 U.S.C. 360b(b)	21 U.S.C. 13703 (except (b)(3))
21 U.S.C. 360b(c)(1)	21 U.S.C. 13704(a)
21 U.S.C. 360b(c)(2)(A)	21 U.S.C. 13704(b)(2)
21 U.S.C. 360b(c)(2)(B)	21 U.S.C. 13704(b)(3)
21 U.S.C. 360b(c)(2)(C)	21 U.S.C. 13704(b)(4)
21 U.S.C. 360b(c)(2)(D)	21 U.S.C. 13704(b)(5)
21 U.S.C. 360b(c)(2)(E)	21 U.S.C. 13704(b)(6)
21 U.S.C. 360b(c)(2)(F)	21 U.S.C. 13704(b)(7)
21 U.S.C. 360b(c)(2)(G)	21 U.S.C. 13704(b)(8)
21 U.S.C. 360b(c)(2)(H)	21 U.S.C. 13704(b)(1)
21 U.S.C. 360b(c)(3)	21 U.S.C. 13704(c)
21 U.S.C. 360b(c)(4)	21 U.S.C. 13704(d)
21 U.S.C. 360b(d)(1), (2)	21 U.S.C. 13705(a) through (c)
21 U.S.C. 360b(d)(3)	21 U.S.C. 13701(3)
21 U.S.C. 360b(d)(4)	21 U.S.C. 13705(d)
21 U.S.C. 360b(d)(5)	21 U.S.C. 13705(e)
21 U.S.C. 360b(e)	21 U.S.C. 13706
21 U.S.C. 360b(f)	21 U.S.C. 13707
21 U.S.C. 360b(g)	21 U.S.C. 13708
21 U.S.C. 360b(h)	21 U.S.C. 13709
21 U.S.C. 360b(i)	21 U.S.C. 13710
21 U.S.C. 360b(j)	21 U.S.C. 13711
21 U.S.C. 360b(k)	21 U.S.C. 13712
21 U.S.C. 360b(l)	21 U.S.C. 13713
21 U.S.C. 360b(m)	21 U.S.C. 13714
21 U.S.C. 360b(n)(1) ("(hereinafter in this subsection referred to as an `approved new animal drug')")	21 U.S.C. 13715(a)
21 U.S.C. 360b(n)(1) (except "(hereinafter in this subsection referred to as an `approved new animal drug')")	21 U.S.C. 13715(b)
21 U.S.C. 360b(n)(2)	21 U.S.C. 13715(c)
21 U.S.C. 360b(n)(3)	21 U.S.C. 13715(d)
21 U.S.C. 360b(n)(4)	21 U.S.C. 13715(e)
21 U.S.C. 360b(n)(5)	21 U.S.C. 13715(f)
21 U.S.C. 360b(o)	21 U.S.C. 13701(2)
21 U.S.C. 360b(p)	21 U.S.C. 13716
21 U.S.C. 360b(q)(1)	21 U.S.C. 13717
21 U.S.C. 360b(q)(2)	21 U.S.C. 13701(1)
21 U.S.C. 360b note (Pub. L. 115–234, title III, §305(a) ("(referred to in this section as 'elements of investigations')"))	21 U.S.C. 29109(a)
21 U.S.C. 360b note (Pub. L. 115–234, title III, §305(a) (except "(referred to in this section as 'elements of investigations')"))	21 U.S.C. 29109(b)
21 U.S.C. 360b note (Pub. L. 115–234, title III, §305(b) through (d))	21 U.S.C. 29109(c) through (e)
21 U.S.C. 360b note (Pub. L. 100–670, title I, §106)	21 U.S.C. 13703(b)(3)
21 U.S.C. 360b–1	21 U.S.C. 13139
21 U.S.C. 360c(a)(1) (except last sentence) ...	21 U.S.C. 13140(c)(1)
21 U.S.C. 360c(a)(1) (last sentence)	21 U.S.C. 13140(c)(2)
21 U.S.C. 360c(a)(2)	21 U.S.C. 13140(c)(3)
21 U.S.C. 360c(a)(3)(A) through (C)	21 U.S.C. 13140(c)(4)(A) through (C)
21 U.S.C. 360c(a)(3)(D)(i)	21 U.S.C. 13140(c)(4)(D)(i)
21 U.S.C. 360c(a)(3)(D)(ii)	21 U.S.C. 13140(c)(4)(D)(ii)(II), (III)
21 U.S.C. 360c(a)(3)(D)(iii)	21 U.S.C. 13140(c)(4)(D)(ii)(I)
21 U.S.C. 360c(a)(3)(D)(iv), (v)	21 U.S.C. 13140(c)(4)(D)(iii), (iv)
21 U.S.C. 360c(b)(1) (1st sentence)	21 U.S.C. 13140(d)(1)(A)
21 U.S.C. 360c(b)(1) (2d sentence)	21 U.S.C. 13140(d)(1)(B)
21 U.S.C. 360c(b)(1) (last sentence)	21 U.S.C. 13140(d)(1)(C)
21 U.S.C. 360c(b)(2) through (8)	21 U.S.C. 13140(d)(2) through (8)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360c(c)(1)	21 U.S.C. 13140(e)(1)
21 U.S.C. 360c(c)(2)(A), (B)	21 U.S.C. 13140(e)(2)(A), (B)
21 U.S.C. 360c(c)(2)(C) (1st sentence)	21 U.S.C. 13140(e)(2)(C)(i)
21 U.S.C. 360c(c)(2)(C) (last sentence)	21 U.S.C. 13140(e)(2)(C)(ii)
21 U.S.C. 360c(c)(3)	Repealed as obsolete. Provided that the classification panels established under section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) were to submit to the Secretary within 1 year of the date funds were first appropriated for the implementation of that section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976.
21 U.S.C. 360c(d)	21 U.S.C. 13140(f)
21 U.S.C. 360c(e)	21 U.S.C. 13140(g)
21 U.S.C. 360c(f)(1) through (3)	21 U.S.C. 13140(h)(1) through (3)
21 U.S.C. 360c(f)(4) (matter before (A))	21 U.S.C. 13140(h)(4)(A) (matter before (i))
21 U.S.C. 360c(f)(4)(A) through (C)	21 U.S.C. 13140(h)(4)(A)(i) through (iii)
21 U.S.C. 360c(f)(4) (matter after (C))	21 U.S.C. 13140(h)(4)(B)
21 U.S.C. 360c(f)(5)	21 U.S.C. 13140(h)(5)
21 U.S.C. 360c(f)(6)	21 U.S.C. 13140(h)(6)
21 U.S.C. 360c(g)	21 U.S.C. 13140(i)
21 U.S.C. 360c(h)	21 U.S.C. 13140(a)
21 U.S.C. 360c(i)	21 U.S.C. 13140(b)
21 U.S.C. 360c(j)	21 U.S.C. 13140(j)
21 U.S.C. 360c(k)	21 U.S.C. 13140(k)
21 U.S.C. 360c–1	21 U.S.C. 49507
21 U.S.C. 360d(a)	21 U.S.C. 13141(a)
21 U.S.C. 360d(b)	21 U.S.C. 13141(b)
21 U.S.C. 360d(c)	21 U.S.C. 13141(c)
21 U.S.C. 360d(d)	21 U.S.C. 13141(d)
21 U.S.C. 360e(a) (except matter after (2))	21 U.S.C. 13142(a)(2)
21 U.S.C. 360e(a) (matter after (2))	21 U.S.C. 13142(a)(1)
21 U.S.C. 360e(b)(1)(A), (B)	21 U.S.C. 13142(b)(1)(B)
21 U.S.C. 360e(b)(1) (from "the Secretary shall" through "for premarket approval.")	21 U.S.C. 13142(b)(1)(A)
21 U.S.C. 360e(b)(1) (last sentence)	21 U.S.C. 13142(b)(1)(C)
21 U.S.C. 360e(b)(2), (3)	21 U.S.C. 13142(b)(2), (3)
21 U.S.C. 360e(c)(1) through (4)	21 U.S.C. 13142(c)(1) through (4)
21 U.S.C. 360e(c)(5)(A)	21 U.S.C. 13142(c)(5)(A)(ii)
21 U.S.C. 360e(c)(5)(B)	21 U.S.C. 13142(c)(5)(A)(i)
21 U.S.C. 360e(c)(5)(C), (D)	21 U.S.C. 13142(c)(5)(B), (C)
21 U.S.C. 360e(d)	21 U.S.C. 13142(d)
21 U.S.C. 360e(e)	21 U.S.C. 13142(e)
21 U.S.C. 360e(f)	21 U.S.C. 13142(f)
21 U.S.C. 360e(g)	21 U.S.C. 13142(g)
21 U.S.C. 360e(h)	21 U.S.C. 13142(h)
21 U.S.C. 360e(i)	21 U.S.C. 13142(i)
21 U.S.C. 360e–1(a), (b)	21 U.S.C. 13143(b), (c)
21 U.S.C. 360e–1(c)	21 U.S.C. 13143(a)
21 U.S.C. 360e–3	21 U.S.C. 13144
21 U.S.C. 360e–4	21 U.S.C. 13145
21 U.S.C. 360f	21 U.S.C. 13146
21 U.S.C. 360g(a) (1st sentence)	21 U.S.C. 13147(b)(1)
21 U.S.C. 360g(a) (last sentence)	21 U.S.C. 13147(a)
21 U.S.C. 360g(b) through (f)	21 U.S.C. 13147(c) through (g)
21 U.S.C. 360g(a) (2d sentence, 3d sentence)	21 U.S.C. 13147(b)(2), (3)
21 U.S.C. 360g–1	21 U.S.C. 13148
21 U.S.C. 360g–2	21 U.S.C. 49521
21 U.S.C. 360h(a) (1st sentence ("If the Secretary determines that", "the Secretary may issue" through "eliminate such risk."))	21 U.S.C. 13149(a)(1) (matter before (A))
21 U.S.C. 360h(a)(1), (2)	21 U.S.C. 13149(a)(1)(A), (B)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360h(a) (2d sentence through last sentence)	21 U.S.C. 13149(a)(2) through (4)
21 U.S.C. 360h(b) through (e)	21 U.S.C. 13149(b) through (e)
21 U.S.C. 360h–1(a)	21 U.S.C. 13150(b)
21 U.S.C. 360h–1(b)	21 U.S.C. 13150(c)
21 U.S.C. 360h–1(c)	21 U.S.C. 13150(a)
21 U.S.C. 360i(a)	21 U.S.C. 13151(a)
21 U.S.C. 360i(b)(1)	21 U.S.C. 13151(b)(2)
21 U.S.C. 360i(b)(2)	21 U.S.C. 13151(b)(3)
21 U.S.C. 360i(b)(3)	21 U.S.C. 13151(b)(4)
21 U.S.C. 360i(b)(4)	21 U.S.C. 13151(b)(5)
21 U.S.C. 360i(b)(5)(A) through (D)	21 U.S.C. 13151(b)(6)
21 U.S.C. 360i(b)(5)(E)	Repealed as obsolete. Provided that not later than November 21, 1999, the Secretary of Health and Human Services submit to committees in Congress a report describing the plan developed by the Secretary under section 519(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(b)(5)(A)) and the progress made toward the implementation of the plan.
21 U.S.C. 360i(b)(6)	21 U.S.C. 13151(b)(1)
21 U.S.C. 360i(c)	21 U.S.C. 13151(c)
21 U.S.C. 360i(d)	Previously repealed.
21 U.S.C. 360i(e)	21 U.S.C. 13151(d)
21 U.S.C. 360i(f)	21 U.S.C. 13151(e)
21 U.S.C. 360i(g)	21 U.S.C. 13151(f)
21 U.S.C. 360i(h)	21 U.S.C. 13151(g)
21 U.S.C. 360i(i)	21 U.S.C. 13151(h)
21 U.S.C. 360j(a) through (e)	21 U.S.C. 13152(a) through (e)
21 U.S.C. 360j(f)	21 U.S.C. 13152(f)
21 U.S.C. 360j(g)	21 U.S.C. 13152(g)
21 U.S.C. 360j(h)	21 U.S.C. 13152(h)
21 U.S.C. 360j(i)	21 U.S.C. 13152(i)
21 U.S.C. 360j(j)	21 U.S.C. 13152(j)
21 U.S.C. 360j(k)	21 U.S.C. 13152(k)
21 U.S.C. 360j(l)(1) through (3)	21 U.S.C. 13152(l)(1) through (3)
21 U.S.C. 360j(l)(4)	Previously repealed.
21 U.S.C. 360j(l)(5)	21 U.S.C. 13152(l)(4)
21 U.S.C. 360j(m)(1)	21 U.S.C. 13152(m)(1)
21 U.S.C. 360j(m)(2)	21 U.S.C. 13152(m)(2)(A), (B)
21 U.S.C. 360j(m)(3) through (5)	21 U.S.C. 13152(m)(3) through (5)
21 U.S.C. 360j(m)(6)(A) (except (ii) (2d sentence))	21 U.S.C. 13152(m)(6)(B)
21 U.S.C. 360j(m)(6)(A)(ii) (2d sentence)	21 U.S.C. 13152(m)(6)(A)(i)
21 U.S.C. 360j(m)(6)(B) through (D)	21 U.S.C. 13152(m)(6)(C) through (E)
21 U.S.C. 360j(m)(6)(E)	21 U.S.C. 13152(m)(6)(A)(ii), (iii)
21 U.S.C. 360j(m)(7), (8)	21 U.S.C. 13152(m)(7), (8)
21 U.S.C. 360j(n)	21 U.S.C. 13152(n)
21 U.S.C. 360j(o)	21 U.S.C. 13152(o)
21 U.S.C. 360j(p)(1) through (3)	21 U.S.C. 13152(p)(2) through (4)
21 U.S.C. 360j(p)(4)	21 U.S.C. 13152(p)(1)
21 U.S.C. 360j(q)	21 U.S.C. 13152(q)
21 U.S.C. 360j note (Pub. L. 115–52, title VII, §709(b), (c))	21 U.S.C. 49516
21 U.S.C. 360j note (Pub. L. 114–255, div. A, title III, §3052(b))	21 U.S.C. 13152(m)(2)(C)
21 U.S.C. 360j note (Pub. L. 114–255, div. A, title III, §3060(b))	21 U.S.C. 49514
21 U.S.C. 360k	21 U.S.C. 13153
21 U.S.C. 360l	21 U.S.C. 13154
21 U.S.C. 360m	21 U.S.C. 13155
21 U.S.C. 360n (except (b)(3)(B))	21 U.S.C. 13156
21 U.S.C. 360n(b)(3)(B)	Repealed as obsolete. Provided that the Secretary of Health and Human Services issue

Former United States Code Section	Disposition
	a priority review voucher to the sponsor of a tropical disease product no earlier than September 27, 2008.
21 U.S.C. 360n–1	21 U.S.C. 13157
21 U.S.C. 360n–2(a), (b), (d)	21 U.S.C. 13158(b) through (d)
21 U.S.C. 360n–2(c)	21 U.S.C. 13158(a)
21 U.S.C. 360n–2 note (Pub. L. 117–328, div. FF, title III, §3305(e))	21 U.S.C. 29117(b)
21 U.S.C. 360n–2 note (Pub. L. 117–328, div. FF, title III, §3305(f))	21 U.S.C. 49520(b)
21 U.S.C. 360aa	21 U.S.C. 13901
21 U.S.C. 360aa note (Pub. L. 117–328, div. FF, title III, §3208(a) through (c), (e))	Not repealed but omitted from the text of title 21. Provides that the Secretary of Health and Human Services shall establish a pilot program under which the Secretary establishes procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints for drugs intended to treat rare diseases, conduct up to 3 public workshops to discuss topics relevant to the development of endpoints for rare diseases, 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 reports, including a final report not later than September 30, 2027, relating to the pilot program and public workshops. Provides that the Secretary may not accept any new application or request to participate in the program on or after October 1, 2027.
21 U.S.C. 360aa note (Pub. L. 117–328, div. FF, title III, §3208(d))	21 U.S.C. 29114
21 U.S.C. 360aa note (Pub. L. 117–79, §4)	21 U.S.C. 41303
21 U.S.C. 360bb(a)(1)	21 U.S.C. 13902(a)(2)
21 U.S.C. 360bb(a)(2)	21 U.S.C. 13902(a)(1)
21 U.S.C. 360bb(b) through (d)	21 U.S.C. 13902(b) through (d)
21 U.S.C. 360cc	21 U.S.C. 13903
21 U.S.C. 360dd	21 U.S.C. 13904
21 U.S.C. 360ee(a), (c)	21 U.S.C. 49502(b), (c)
21 U.S.C. 360ee(b)(1)	21 U.S.C. 49502(a)(2)
21 U.S.C. 360ee(b)(2)	21 U.S.C. 49502(a)(3)
21 U.S.C. 360ee(b)(3)	21 U.S.C. 49502(a)(1)
21 U.S.C. 360ee note (Pub. L. 117–79, §2)	21 U.S.C. 41301
21 U.S.C. 360ee–1	21 U.S.C. 41304
21 U.S.C. 360ff	21 U.S.C. 13905
21 U.S.C. 360ff–1(a)	21 U.S.C. 13906(a)
21 U.S.C. 360ff–1(b)	21 U.S.C. 13906(c)
21 U.S.C. 360ff–1(c)	21 U.S.C. 13906(b)
21 U.S.C. 360ff–1(d)	21 U.S.C. 13906(d)
21 U.S.C. 360hh(1)	21 U.S.C. 14101(3)
21 U.S.C. 360hh(2)	21 U.S.C. 14101(2)
21 U.S.C. 360hh(3)	21 U.S.C. 14101(4)
21 U.S.C. 360hh(4)	21 U.S.C. 14101(1)
21 U.S.C. 360hh(5)	21 U.S.C. 14101(5)
21 U.S.C. 360ii	21 U.S.C. 14102
21 U.S.C. 360jj	21 U.S.C. 14103
21 U.S.C. 360kk(a) through (e)	21 U.S.C. 14104(a) through (e)
21 U.S.C. 360kk(f)(1)(A) (parenthetical)	21 U.S.C. 14104(f)(1)
21 U.S.C. 360kk(f) (except (1)(A) (parenthetical))	21 U.S.C. 14104(f)(2) through (6)
21 U.S.C. 360kk(g)	21 U.S.C. 14104(g)
21 U.S.C. 360kk(h)	21 U.S.C. 14104(h)
21 U.S.C. 360ll	21 U.S.C. 14105
21 U.S.C. 360mm	21 U.S.C. 14106

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360nn	21 U.S.C. 14107
21 U.S.C. 360oo	21 U.S.C. 14108
21 U.S.C. 360pp	21 U.S.C. 14109
21 U.S.C. 360qq	Previously repealed.
21 U.S.C. 360rr	21 U.S.C. 14110
21 U.S.C. 360ss	21 U.S.C. 14111
21 U.S.C. 360aaa	Repealed as obsolete. Authorized a manufacturer to disseminate information on the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device if the manufacturer met specified requirements. The provision ceased to be effective under section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. note prec. 360bbb).
21 U.S.C. 360aaa–1	Repealed as obsolete. Authorized a manufacturer to disseminate information under section 551 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa) on a new use if the information was in a specified form and if it was not false or misleading. The provision ceased to be effective under section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. note prec. 360bbb).
21 U.S.C. 360aaa–2	Repealed as obsolete. Authorized a manufacturer to disseminate information under section 551 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa) on a new use if the manufacturer submitted certain lists and required recordkeeping that may be used to take corrective action. The provision ceased to be effective under section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. note prec. 360bbb).
21 U.S.C. 360aaa–3	Repealed as obsolete. Authorized a manufacturer to disseminate information under section 551 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa) on a new use if the manufacturer met requirements relating to the submission of a supplemental application. The provision ceased to be effective under section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. note prec. 360bbb).
21 U.S.C. 360aaa–4	Repealed as obsolete. Provided that the Secretary of Health and Human Services take corrective action (including cessation of dissemination of information under section 551 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa)) if the Secretary made certain determinations. The provision ceased to be effective under section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. note prec. 360bbb).
21 U.S.C. 360aaa–5	Repealed as obsolete. Provided a definitions section for subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa et seq.). The provision ceased to be effective under section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. note prec. 360bbb).
21 U.S.C. 360aaa–6	Repealed as obsolete. Set out rules of construction for section 551 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa). The provision ceased to be effective under section 401(e) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. note prec. 360bbb).
21 U.S.C. 360bbb(a)	21 U.S.C. 14301(b)
21 U.S.C. 360bbb(b)	21 U.S.C. 14301(c)
21 U.S.C. 360bbb(c)	21 U.S.C. 14301(d)
21 U.S.C. 360bbb(d)	21 U.S.C. 14301(e)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360bbb(e)	21 U.S.C. 14301(a)
21 U.S.C. 360bbb–0	21 U.S.C. 14302
21 U.S.C. 360bbb–0a(a)(1)	21 U.S.C. 14303(a)(2)
21 U.S.C. 360bbb–0a(a)(2)	21 U.S.C. 14303(a)(1)
21 U.S.C. 360bbb–0a(a)(3)	21 U.S.C. 14303(a)(3)
21 U.S.C. 360bbb–0a(b) through (d)	21 U.S.C. 14303(b) through (d)
21 U.S.C. 360bbb–0a note (Pub. L. 115–176, §2(b))	21 U.S.C. 14303(e)
21 U.S.C. 360bbb–1 (1st sentence)	21 U.S.C. 14304(a)
21 U.S.C. 360bbb–1 (2d sentence)	21 U.S.C. 14304(b)
21 U.S.C. 360bbb–1 (last sentence)	Repealed as obsolete. Provided that the Secretary of Health and Human Services promulgate regulations under section 562 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–1) within 1 year after November 21, 1997.
21 U.S.C. 360bbb–2	21 U.S.C. 14305
21 U.S.C. 360bbb–3(a)(1) through (3)	21 U.S.C. 14306(b)
21 U.S.C. 360bbb–3(a)(4)	21 U.S.C. 14306(a)
21 U.S.C. 360bbb–3(b) through (m)	21 U.S.C. 14306(c) through (n)
21 U.S.C. 360bbb–3a	21 U.S.C. 14307
21 U.S.C. 360bbb–3b	21 U.S.C. 14308
21 U.S.C. 360bbb–3c	21 U.S.C. 49518
21 U.S.C. 360bbb–4 (except (c)(2))	21 U.S.C. 14309
21 U.S.C. 360bbb–4(c)(2)	Repealed as obsolete. Authorized the Secretary of Health and Human Services to extend the deadline for providing final guidance under section 565(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4(c)(1)) by not more than 6 months upon submission by the Secretary of a report on the status of the guidance to congressional committees.
21 U.S.C. 360bbb–4 note (Pub. L. 117–328, div. FF, title II, §2502(b))	21 U.S.C. 29110
21 U.S.C. 360bbb–4 note (Pub. L. 114–255, div. A, title III, §3091)	21 U.S.C. 49515
21 U.S.C. 360bbb–4a(a)(1)	21 U.S.C. 14310(a)(1)
21 U.S.C. 360bbb–4a(a)(2)	21 U.S.C. 14310(a)(3)
21 U.S.C. 360bbb–4a(a)(3)	21 U.S.C. 14310(a)(4)
21 U.S.C. 360bbb–4a(a)(4)	21 U.S.C. 14310(a)(2)
21 U.S.C. 360bbb–4a(b) through (g)	21 U.S.C. 14310(b) through (g)
21 U.S.C. 360bbb–4b(a) through (e)	21 U.S.C. 14311(b) through (f)
21 U.S.C. 360bbb–4b(f)	21 U.S.C. 14311(a)
21 U.S.C. 360bbb–5(a)	21 U.S.C. 14312(b)
21 U.S.C. 360bbb–5(b)	21 U.S.C. 14312(a)(1)
21 U.S.C. 360bbb–5(c)	21 U.S.C. 14312(c)
21 U.S.C. 360bbb–5(d)	21 U.S.C. 14312(d)
21 U.S.C. 360bbb–5(e)	21 U.S.C. 14312(a)(2)
21 U.S.C. 360bbb–5(f)	21 U.S.C. 14312(e)
21 U.S.C. 360bbb–5a	21 U.S.C. 14313
21 U.S.C. 360bbb–6(a)(1) (parenthetical)	21 U.S.C. 14314(a)
21 U.S.C. 360bbb–6 (except (a)(1) (parenthetical))	21 U.S.C. 14314(b), (c)
21 U.S.C. 360bbb–7(a) through (c)	21 U.S.C. 14315(b) through (d)
21 U.S.C. 360bbb–7(d)	21 U.S.C. 14315(a)
21 U.S.C. 360bbb–8	21 U.S.C. 14316
21 U.S.C. 360bbb–8a	21 U.S.C. 14317
21 U.S.C. 360bbb–8b	21 U.S.C. 14318
21 U.S.C. 360bbb–8c(a)(1) through (4)	21 U.S.C. 14319(b)
21 U.S.C. 360bbb–8c(a)(5)	21 U.S.C. 14319(a)(1)
21 U.S.C. 360bbb–8c(b)	21 U.S.C. 14319(c)
21 U.S.C. 360bbb–8c(c)	21 U.S.C. 14319(a)(2)
21 U.S.C. 360bbb–8c note (Pub. L. 114–255, div. A, title III, §3003)	21 U.S.C. 14319(d)
21 U.S.C. 360bbb–8d	21 U.S.C. 14320
21 U.S.C. 360ccc(a)	21 U.S.C. 14502(b)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360ccc(b)	21 U.S.C. 14502(c)
21 U.S.C. 360ccc(c)	21 U.S.C. 14502(d)
21 U.S.C. 360ccc(d) (except (4)(B))	21 U.S.C. 14502(e)
21 U.S.C. 360ccc(d)(4)(B)	21 U.S.C. 14502(a)
21 U.S.C. 360ccc(e)	21 U.S.C. 14502(f)
21 U.S.C. 360ccc(f)	21 U.S.C. 14502(g)
21 U.S.C. 360ccc(g)	21 U.S.C. 14502(h)
21 U.S.C. 360ccc(h)	21 U.S.C. 14502(i)
21 U.S.C. 360ccc(i)	21 U.S.C. 14502(j)
21 U.S.C. 360ccc(j)	21 U.S.C. 14501
21 U.S.C. 360ccc(k)	21 U.S.C. 14502(k)
21 U.S.C. 360ccc–1(a) through (c)	21 U.S.C. 14503(a) through (c)
21 U.S.C. 360ccc–1(d)(1)	21 U.S.C. 14503(d)(2)
21 U.S.C. 360ccc–1(d)(2)	21 U.S.C. 14503(d)(3)
21 U.S.C. 360ccc–1(d)(3)	21 U.S.C. 14503(d)(1)
21 U.S.C. 360ccc–1(d)(4)	21 U.S.C. 14503(d)(4)
21 U.S.C. 360ccc–1(e)	21 U.S.C. 14503(e)
21 U.S.C. 360ccc–1(f)	21 U.S.C. 14503(f)
21 U.S.C. 360ccc–1(g)	21 U.S.C. 14503(g)
21 U.S.C. 360ccc–1(h)	21 U.S.C. 14503(h)
21 U.S.C. 360ccc–1(i)	21 U.S.C. 14503(i)
21 U.S.C. 360ccc–1(j)	21 U.S.C. 14503(j)
21 U.S.C. 360ccc–1(k)	21 U.S.C. 14503(k)
21 U.S.C. 360ccc–2(a)	21 U.S.C. 14504(a)
21 U.S.C. 360ccc–2(b)(1)	21 U.S.C. 14504(b)(2)
21 U.S.C. 360ccc–2(b)(2)	21 U.S.C. 14504(b)(1)
21 U.S.C. 360ccc–2(c)	21 U.S.C. 14504(c)
21 U.S.C. 360ddd	21 U.S.C. 14701
21 U.S.C. 360ddd note (Pub. L. 112–144, title XI, §1113)	21 U.S.C. 14704
21 U.S.C. 360ddd–1	21 U.S.C. 14702
21 U.S.C. 360ddd–2	21 U.S.C. 14703
21 U.S.C. 360eee	21 U.S.C. 14901
21 U.S.C. 360eee–1(a)(1)	21 U.S.C. 14902(a)(1)
21 U.S.C. 360eee–1(a)(2)(A)	21 U.S.C. 14902(a)(2)
21 U.S.C. 360eee–1(a)(2)(B)	Repealed as obsolete. Provided that the Secretary of Health and Human Services gather comments and information from stakeholders and maintain the comments and information in a public docket for at least 60 days prior to issuing the guidance required to be issued under section 582(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1(a)(2)(A)).
21 U.S.C. 360eee–1(a)(2)(C)	Repealed as obsolete. Provided that the Secretary of Health and Human Services publish the standards established under section 582(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee–1(a)(2)(A)) not later than 1 year after November 27, 2013.
21 U.S.C. 360eee–1(a)(3) through (9)	21 U.S.C. 14902(a)(3) through (9)
21 U.S.C. 360eee–1(b)(1) through (3)	21 U.S.C. 14902(b)(1) through (3)
21 U.S.C. 360eee–1(b)(4) (matter before (A))	21 U.S.C. 14902(b)(4) (matter before (A))
21 U.S.C. 360eee–1(b)(4)(A)	21 U.S.C. 14902(b)(4)(A)
21 U.S.C. 360eee–1(b)(4)(B)(i)	21 U.S.C. 14902(b)(4)(B)(i)
21 U.S.C. 360eee–1(b)(4)(B)(ii)(I)	21 U.S.C. 14902(b)(4)(B)(ii)(I)
21 U.S.C. 360eee–1(b)(4)(B)(ii)(II) (1st sentence)	21 U.S.C. 14902(b)(4)(B)(ii)(II)(bb)
21 U.S.C. 360eee–1(b)(4)(B)(ii)(II) (last sentence)	21 U.S.C. 14902(b)(4)(B)(ii)(II)(aa)
21 U.S.C. 360eee–1(b)(4)(B)(iii)	21 U.S.C. 14902(b)(4)(B)(iii)
21 U.S.C. 360eee–1(b)(4)(B)(iv)	21 U.S.C. 14902(b)(4)(B)(iv)
21 U.S.C. 360eee–1(b)(4)(B)(v)	21 U.S.C. 14902(b)(4)(B)(v)
21 U.S.C. 360eee–1(b)(4)(C)	21 U.S.C. 14902(b)(4)(C)
21 U.S.C. 360eee–1(b)(4)(D)	21 U.S.C. 14902(b)(4)(D)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 360eee–1(b)(4)(E)	21 U.S.C. 14902(b)(4)(E)
21 U.S.C. 360eee–1(b)(4)(F)	21 U.S.C. 14902(b)(4)(F)
21 U.S.C. 360eee–1(c)	21 U.S.C. 14902(c)
21 U.S.C. 360eee–1(d)	21 U.S.C. 14902(d)
21 U.S.C. 360eee–1(e)	21 U.S.C. 14902(e)
21 U.S.C. 360eee–1(f)	21 U.S.C. 14902(f)
21 U.S.C. 360eee–1(g)	21 U.S.C. 14902(g)
21 U.S.C. 360eee–1(h)	21 U.S.C. 14902(h)
21 U.S.C. 360eee–1(i)	21 U.S.C. 14902(i)
21 U.S.C. 360eee–1(j)	21 U.S.C. 14902(j)
21 U.S.C. 360eee–1(k)	21 U.S.C. 14902(k)
21 U.S.C. 360eee–1(l)	21 U.S.C. 14902(l)
21 U.S.C. 360eee–1(m)	21 U.S.C. 14902(m)
21 U.S.C. 360eee–2	21 U.S.C. 14903
21 U.S.C. 360eee–3	21 U.S.C. 14904
21 U.S.C. 360eee–4	21 U.S.C. 14905
21 U.S.C. 360fff	21 U.S.C. 15101
21 U.S.C. 360fff note (Pub. L. 113–195, §2(b))	21 U.S.C. 15106
21 U.S.C. 360fff–1	21 U.S.C. 15102
21 U.S.C. 360fff–2	21 U.S.C. 15103
21 U.S.C. 360fff–3	21 U.S.C. 15104
21 U.S.C. 360fff–4 (except (a)(1)(B))	21 U.S.C. 15105
21 U.S.C. 360fff–4(a)(1)(B)	Repealed as unnecessary. Provided that the Secretary of Health and Human Services finalize the guidance described in section 586D(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–4(a)(1)(A)) not later than 2 years after November 26, 2014. The provision is unnecessary because of the wording of the restatement of section 586D(a)(1)(A) of the Act. See section 15105(a)(1)(A) of title 21, United States Code.
21 U.S.C. 360fff–5	Previously repealed.
21 U.S.C. 360fff–6 (except (b)(5))	21 U.S.C. 15107
21 U.S.C. 360fff–6(b)(5)	Repealed as unnecessary. Provided that the Secretary of Health and Human Services finalize the regulations under section 586F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–6) not later than 27 months after November 26, 2014. The provision is unnecessary because of the wording of the restatement of section 586F(b)(1) of the Act (21 U.S.C. 360fff–6(b)(1)). See section 15107(b)(1) of title 21, United States Code.
21 U.S.C. 360fff–7	21 U.S.C. 15108
21 U.S.C. 360fff–8	21 U.S.C. 15109
21 U.S.C. 361 (matter before (a))	Repealed as unnecessary. Provided introductory language for provisions describing cosmetics deemed adulterated. The introductory language is repeated in each subsection restating the provisions.
21 U.S.C. 361(a) (from "If it bears" through "customary or usual,")	21 U.S.C. 17111(b)(1)
21 U.S.C. 361(a) (from "except that" through "preliminary testing.")	21 U.S.C. 17111(b)(2)
21 U.S.C. 361(a) (last sentence)	21 U.S.C. 17111(a)
21 U.S.C. 361(b) through (e)	21 U.S.C. 17111(c) through (f)
21 U.S.C. 361(f), (g)	21 U.S.C. 17111(g), (h)
21 U.S.C. 362 (matter before (a))	Repealed as unnecessary. Provided introductory language for provisions describing cosmetics deemed misbranded. The introductory language is repeated in each subsection restating the provisions.
21 U.S.C. 362(a) through (f)	21 U.S.C. 17112
21 U.S.C. 363	21 U.S.C. 17113
21 U.S.C. 364	21 U.S.C. 17101

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 364 note (Pub. L. 117–328, div. FF, title III, §3503(c))	21 U.S.C. 70101
21 U.S.C. 364a (except (e))	21 U.S.C. 17121 (except (e))
21 U.S.C. 364a(e)(1)	21 U.S.C. 17121(e)(1)
21 U.S.C. 364a(e)(2)(A)	21 U.S.C. 17121(e)(2)(B)
21 U.S.C. 364a(e)(2)(B)	21 U.S.C. 17121(e)(2)(A)
21 U.S.C. 364b	21 U.S.C. 17122
21 U.S.C. 364c	21 U.S.C. 17123
21 U.S.C. 364d(a), (b)	21 U.S.C. 17124(b), (c)
21 U.S.C. 364d(c)	21 U.S.C. 17124(a)
21 U.S.C. 364d note (Pub. L. 117–328, div. FF, title III, §3505)	21 U.S.C. 70102
21 U.S.C. 364e	21 U.S.C. 17125
21 U.S.C. 364f	21 U.S.C. 17126
21 U.S.C. 364g	21 U.S.C. 17127
21 U.S.C. 364h	21 U.S.C. 17128
21 U.S.C. 364i	21 U.S.C. 17129
21 U.S.C. 364j	21 U.S.C. 17130
21 U.S.C. 371	21 U.S.C. 17501
21 U.S.C. 372(a)(1)	21 U.S.C. 17502(a)(2)
21 U.S.C. 372(a)(2)	21 U.S.C. 17502(a)(3)
21 U.S.C. 372(a)(3)	21 U.S.C. 17502(a)(4)
21 U.S.C. 372(a)(4)	21 U.S.C. 17502(a)(1)
21 U.S.C. 372(b) through (e)	21 U.S.C. 17502(b) through (e)
21 U.S.C. 372a	Previously transferred to 21 U.S.C. 376.
21 U.S.C. 373	21 U.S.C. 17503
21 U.S.C. 374(a) through (e)	21 U.S.C. 17504(a) through (e)
21 U.S.C. 374(f)(1)	21 U.S.C. 17504(f)(2)
21 U.S.C. 374(f)(2)	21 U.S.C. 17504(f)(3)
21 U.S.C. 374(f)(3)	21 U.S.C. 17504(f)(1)
21 U.S.C. 374(g)(1) through (9)	21 U.S.C. 17504(g)(1) through (9)
21 U.S.C. 374(g)(10)(A)	21 U.S.C. 17504(g)(10)(B)
21 U.S.C. 374(g)(10)(B)	21 U.S.C. 17504(g)(10)(C)
21 U.S.C. 374(g)(10)(C)	21 U.S.C. 17504(g)(10)(A)
21 U.S.C. 374(g)(11) through (15)	21 U.S.C. 17504(g)(11) through (15)
21 U.S.C. 374(h)	21 U.S.C. 17504(h)
21 U.S.C. 374 note (Pub. L. 117–328, div. FF, title III, §3612(b)(2))	21 U.S.C. 29123
21 U.S.C. 374 note (Pub. L. 117–328, div. FF, title III, §3611(b)(2))	21 U.S.C. 29122
21 U.S.C. 374 note (Pub. L. 115–52, title VII, §702(b))	21 U.S.C. 29108
21 U.S.C. 374a	21 U.S.C. 32101
21 U.S.C. 375	21 U.S.C. 17505
21 U.S.C. 376	21 U.S.C. 17506
21 U.S.C. 377	21 U.S.C. 49501
21 U.S.C. 378	21 U.S.C. 17507
21 U.S.C. 379	21 U.S.C. 17508
21 U.S.C. 379a	21 U.S.C. 17509
21 U.S.C. 379b(a) through (c)	21 U.S.C. 17510
21 U.S.C. 379b(d)	Repealed as obsolete. Authorized to be appropriated to carry out section 710 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379b) $100,000,000 for fiscal year 1991, and such sums as may be necessary for each subsequent fiscal year, to remain available until expended.
21 U.S.C. 379c	Previously transferred to 21 U.S.C. 379f.
21 U.S.C. 379d(a)	21 U.S.C. 17511
21 U.S.C. 379d(b)	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary to carry out section 711 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d).
21 U.S.C. 379d–1	21 U.S.C. 17512
21 U.S.C. 379d–2	21 U.S.C. 17513

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 379d–3	Repealed as obsolete. Authorized the Secretary of Health and Human Services, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, to appoint employees to positions in the Food and Drug Administration to perform specified activities if the appointments were needed to achieve specified objectives. The provision is obsolete because the authority terminated on July 9, 2015, under subsection (e) of section 714 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d-3(e)).
21 U.S.C. 379d–3a (except (c))	21 U.S.C. 17514
21 U.S.C. 379d–3a(c)	Repealed as obsolete. Provided that the authorities under section 714A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3a) shall not be construed to affect the authority provided under section 714 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3). Section 714 of the Act is repealed as obsolete by the bill.
21 U.S.C. 379d–3b	21 U.S.C. 17515
21 U.S.C. 379d–4(a)	Repealed as obsolete. Repealed as obsolete. Required to Secretary of Health and Human Services, beginning with fiscal year 2013 and ending after fiscal year 2017, to 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 certain data for all applications for approval of a generic drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), amendments to those applications, and prior approval supplements with respect to those applications filed in the previous fiscal year.
21 U.S.C. 379d–4(b)	21 U.S.C. 17516
21 U.S.C. 379d–5	21 U.S.C. 29104
21 U.S.C. 379e(a)	21 U.S.C. 17701(a)
21 U.S.C. 379e(b)(1)	21 U.S.C. 17701(b)(2)
21 U.S.C. 379e(b)(2)	21 U.S.C. 17701(b)(3)
21 U.S.C. 379e(b)(3) ("specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used;")	21 U.S.C. 17701(b)(1)
21 U.S.C. 379e(b)(3) (except "specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used;")	21 U.S.C. 17701(b)(4)
21 U.S.C. 379e(b)(4)	21 U.S.C. 17701(b)(5)
21 U.S.C. 379e(b)(5)	21 U.S.C. 17701(b)(6)
21 U.S.C. 379e(b)(6) through (8)	21 U.S.C. 17701(b)(7) through (9)
21 U.S.C. 379e(c) through (f)	21 U.S.C. 17701(c) through (f)
21 U.S.C. 379f	21 U.S.C. 17901
21 U.S.C. 379g(1)	21 U.S.C. 17906(a)(6)
21 U.S.C. 379g(2)	21 U.S.C. 17906(a)(12)
21 U.S.C. 379g(3)	21 U.S.C. 17906(a)(9)
21 U.S.C. 379g(4)	21 U.S.C. 17906(a)(5)
21 U.S.C. 379g(5)	21 U.S.C. 17906(a)(8)
21 U.S.C. 379g(6)	21 U.S.C. 17906(a)(10)
21 U.S.C. 379g(7)	21 U.S.C. 17906(a)(4)
21 U.S.C. 379g(8)	21 U.S.C. 17906(a)(2)
21 U.S.C. 379g(9)	21 U.S.C. 17906(a)(7)
21 U.S.C. 379g(10)	21 U.S.C. 17906(a)(1)
21 U.S.C. 379g(11)	21 U.S.C. 17906(a)(3)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 379g(12)	21 U.S.C. 17906(a)(11)
21 U.S.C. 379h	21 U.S.C. 17907(a) through (k)
21 U.S.C. 379h–1	Repealed as obsolete. Provided for a program to assess and collect fees related to review of direct-to-consumer television advertisements. The program never commenced pursuant to subsection (f) of this provision. See 73 Fed. Reg. 2924 (Jan. 16, 2008).
21 U.S.C. 379h–2	21 U.S.C. 17908(a) through (f)
21 U.S.C. 379i (matter before (1))	21 U.S.C. 17916(a) (matter before (1))
21 U.S.C. 379i(1)	21 U.S.C. 17916(a)(8)
21 U.S.C. 379i(2)	21 U.S.C. 17916(a)(10)
21 U.S.C. 379i(3)	21 U.S.C. 17916(a)(9)
21 U.S.C. 379i(4)	21 U.S.C. 17916(a)(13)
21 U.S.C. 379i(5)	21 U.S.C. 17916(a)(14)
21 U.S.C. 379i(6)	21 U.S.C. 17916(a)(12)
21 U.S.C. 379i(7)	21 U.S.C. 17916(a)(3)
21 U.S.C. 379i(8)	21 U.S.C. 17916(a)(5)
21 U.S.C. 379i(9)	21 U.S.C. 17916(a)(11)
21 U.S.C. 379i(10)	21 U.S.C. 17916(a)(4)
21 U.S.C. 379i(11)	21 U.S.C. 17916(a)(1)
21 U.S.C. 379i(12)	21 U.S.C. 17916(a)(7)
21 U.S.C. 379i(13)	21 U.S.C. 17916(a)(2)
21 U.S.C. 379i(14)	21 U.S.C. 17916(a)(6)
21 U.S.C. 379j(a) through (c)	21 U.S.C. 17917(a) through (c)
21 U.S.C. 379j(d)(1) (1st sentence)	21 U.S.C. 17917(d)(1)(B)
21 U.S.C. 379j(d)(1) (2d sentence)	21 U.S.C. 17917(d)(1)(A)
21 U.S.C. 379j(d)(1) (last sentence)	21 U.S.C. 17917(d)(1)(C)
21 U.S.C. 379j(d)(2)	21 U.S.C. 17917(d)(2)
21 U.S.C. 379j(e)(1)	21 U.S.C. 17917(e)(2)
21 U.S.C. 379j(e)(2)(A)	21 U.S.C. 17917(e)(1)
21 U.S.C. 379j(e)(2)(B) through (D)	21 U.S.C. 17917(e)(3)
21 U.S.C. 379j(f)	21 U.S.C. 17917(f)
21 U.S.C. 379j(g)	21 U.S.C. 17917(g)
21 U.S.C. 379j(h) through (k)	21 U.S.C. 17917(h) through (k)
21 U.S.C. 379j–1	21 U.S.C. 17918(a), (b)
21 U.S.C. 379j–11 (matter before (1))	21 U.S.C. 17926(a) (matter before (1))
21 U.S.C. 379j–11(1)	21 U.S.C. 17926(a)(3)
21 U.S.C. 379j–11(2)	21 U.S.C. 17926(a)(12)
21 U.S.C. 379j–11(3)	21 U.S.C. 17926(a)(5)
21 U.S.C. 379j–11(4)	21 U.S.C. 17926(a)(4)
21 U.S.C. 379j–11(5)	21 U.S.C. 17926(a)(9)
21 U.S.C. 379j–11(6)	21 U.S.C. 17926(a)(6)
21 U.S.C. 379j–11(7)	21 U.S.C. 17926(a)(8)
21 U.S.C. 379j–11(8)	21 U.S.C. 17926(a)(11)
21 U.S.C. 379j–11(9)	21 U.S.C. 17926(a)(7)
21 U.S.C. 379j–11(10)	21 U.S.C. 17926(a)(1)
21 U.S.C. 379j–11(11)	21 U.S.C. 17926(a)(10)
21 U.S.C. 379j–11(12)	21 U.S.C. 17926(a)(2)
21 U.S.C. 379j–12(a)	21 U.S.C. 17927(a)
21 U.S.C. 379j–12(b)	21 U.S.C. 17927(b)
21 U.S.C. 379j–12(c)	21 U.S.C. 17927(c)
21 U.S.C. 379j–12(d) (except (3)(A))	21 U.S.C. 17927(d)(2) through (5)
21 U.S.C. 379j–12(d)(3)(A)	21 U.S.C. 17927(d)(1)
21 U.S.C. 379j–12(e) through (k)	21 U.S.C. 17927(e) through (k)
21 U.S.C. 379j–13	21 U.S.C. 17928(a) through (d)
21 U.S.C. 379j–21(a) through (j)	21 U.S.C. 17937(a) through (j)
21 U.S.C. 379j–21(k)	21 U.S.C. 17936(a)
21 U.S.C. 379j–22	21 U.S.C. 17938 (except (e))
21 U.S.C. 379j–31(a)(1)	21 U.S.C. 17947(a)
21 U.S.C. 379j–31(a)(2)	21 U.S.C. 17946
21 U.S.C. 379j–31(b)(2)(B)(i)(II)	Repealed as obsolete. Provided that in establishing the fee amounts under subparagraph section 743(b)(2)(A)(iii) of the

Disposition Table

Former United States Code Section	Disposition
	Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–31(b)(2)(A)(iii)) for the first 5 fiscal years after January 4, 2011, the Secretary shall include in the fee a reasonable surcharge that would provide a recoupment of the costs expended by the Secretary to establish and implement the first year of the program under section 806 of that Act (21 U.S.C. 384b).
21 U.S.C. 379j–31(b) (except (2)(B)(i)(II))	21 U.S.C. 17947(b)
21 U.S.C. 379j–31(c) through (g)	21 U.S.C. 17947(c) through (g)
21 U.S.C. 379j–41	21 U.S.C. 17951(a)
21 U.S.C. 379j–42(a) through (d)	21 U.S.C. 17952(a) through (d)
21 U.S.C. 379j–42(e)	21 U.S.C. 17952(e)
21 U.S.C. 379j–42(f) through (o)	21 U.S.C. 17952(f) through (o)
21 U.S.C. 379j–43	21 U.S.C. 17953(a) through (f)
21 U.S.C. 379j–51	21 U.S.C. 17961(a)
21 U.S.C. 379j–52(a) (except (1)(A)(v))	21 U.S.C. 17962(a)
21 U.S.C. 379j–52(a)(1)(A)(v)	Not repealed but omitted from the text of title 21. Provided a deadline for payment of the initial biosimilar biological product development fee by each person that submitted an investigational new drug application prior to July 9, 2012.
21 U.S.C. 379j–52(b), (c)	21 U.S.C. 17962(b), (c)
21 U.S.C. 379j–52(d)(1), (2)	21 U.S.C. 17962(d)(2), (3)
21 U.S.C. 379j–52(d)(3)	21 U.S.C. 17962(d)(1)
21 U.S.C. 379j–52(e) through (h)	21 U.S.C. 17962(e) through (h)
21 U.S.C. 379j–52(i)	21 U.S.C. 17962(i)
21 U.S.C. 379j–53	21 U.S.C. 17963(a) through (f)
21 U.S.C. 379j–61	21 U.S.C. 17971
21 U.S.C. 379j–62	21 U.S.C. 17972
21 U.S.C. 379j–71(1) through (6)	21 U.S.C. 17976(1) through (6)
21 U.S.C. 379j–71(7)	21 U.S.C. 17976(9)
21 U.S.C. 379j–71(8)	21 U.S.C. 17976(13)
21 U.S.C. 379j–71(9)	21 U.S.C. 17976(14)
21 U.S.C. 379j–71(10), (11)	21 U.S.C. 17976(7), (8)
21 U.S.C. 379j–71(12)	21 U.S.C. 17976(10)
21 U.S.C. 379j–71(13) (relating to "requestor")	21 U.S.C. 17976(11)
21 U.S.C. 379j–71(13) (relating to "sponsor") .	21 U.S.C. 17976(12)
21 U.S.C. 379j–72(a) (except (1)(D)(i))	21 U.S.C. 17977(a)
21 U.S.C. 379j–72(a)(1)(D)(i)	Repealed as obsolete. Provided that for fiscal year 2021, the facility fees required under section 744M(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(a)(1)(A)) shall be due on the later of the first business day of July of 2020 or 45 calendar days after publication of the Federal Register notice provided for under section 744M(c)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(c)(4)(A)).
21 U.S.C. 379j–72(b)(1)	Repealed as obsolete. Provided that for fiscal year 2021, fees under section 744M(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(a)(1)) shall be established to generate a total facility fee revenue amount equal to the sum of the annual base revenue for fiscal year 2021 (as determined under section 744M(a)(3) of that Act (21 U.S.C. 379j–72(a)(3))), the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under section 744M(c)(2) of that Act (21 U.S.C. 379j–72(c)(2))), and additional direct cost adjustments (as determined under section 744M(c)(3) of that Act (21 U.S.C. 379j–72(c)(3))).
21 U.S.C. 379j–72(b)(2)	21 U.S.C. 17977(b)(1)
21 U.S.C. 379j–72(b)(3)	21 U.S.C. 17977(b)(2)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 379j–72(c) (except (4)(A))	21 U.S.C. 17977(c)
21 U.S.C. 379j–72(c)(4)(A)	Not repealed but omitted from the text of title 21. Provided that the Secretary shall, not later than the second Monday in May of 2020, establish OTC monograph drug facility fees for fiscal year 2021 under section 744M(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(a)), based on the revenue amount for that fiscal year under section 744M(b) of that Act (21 U.S.C. 379j–72(b)) and the adjustments provided under section 744M(c) of that Act (21 U.S.C. 379j–72(c)), and publish fee revenue, facility fees, and OTC monograph order requests in the Federal Register.
21 U.S.C. 379j–72(d) through (h)	21 U.S.C. 17977(d) through (h)
21 U.S.C. 379j–73	21 U.S.C. 17978
21 U.S.C. 379k	21 U.S.C. 18101
21 U.S.C. 379k–1	21 U.S.C. 18102
21 U.S.C. 379l	21 U.S.C. 18103
21 U.S.C. 379o	21 U.S.C. 18301
21 U.S.C. 379r	21 U.S.C. 18501
21 U.S.C. 379s	21 U.S.C. 18502
21 U.S.C. 379v (1st parenthetical)	21 U.S.C. 18701(a)
21 U.S.C. 379v (except 1st parenthetical)	21 U.S.C. 18701(b), (c)
21 U.S.C. 379aa(a)	21 U.S.C. 18901(a)
21 U.S.C. 379aa(b)(1)	21 U.S.C. 18901(b)(1)
21 U.S.C. 379aa(b)(2)	21 U.S.C. 18901(b)(2)
21 U.S.C. 379aa(c) through (h)	21 U.S.C. 18901(c) through (h)
21 U.S.C. 379aa(i)	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary to carry out section 760 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa).
21 U.S.C. 379aa note (Pub. L. 109–462, §2(b))	21 U.S.C. 18901(i)
21 U.S.C. 379aa note (Pub. L. 109–462, §2(e)(3))	21 U.S.C. 29101
21 U.S.C. 379aa note (Pub. L. 109–462, §3(d)(3))	21 U.S.C. 29102
21 U.S.C. 379aa–1(a) through (d)	21 U.S.C. 18902(a) through (d)
21 U.S.C. 379aa–1(e)(1)	21 U.S.C. 18902(e)(1)
21 U.S.C. 379aa–1(e)(2)(A)	21 U.S.C. 18902(e)(2)(B)
21 U.S.C. 379aa–1(e)(2)(B)	21 U.S.C. 18902(e)(2)(A)
21 U.S.C. 379aa–1(f) through (h)	21 U.S.C. 18902(f) through (h)
21 U.S.C. 379aa–1(i)	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary to carry out section 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa–1).
21 U.S.C. 379dd(a) ("(referred to in this part as the `Foundation')")	21 U.S.C. 19101(2)
21 U.S.C. 379dd(a) (except "(referred to in this part as the `Foundation')")	21 U.S.C. 19102(a)
21 U.S.C. 379dd(b)	21 U.S.C. 19102(b)
21 U.S.C. 379dd(c)	21 U.S.C. 19102(c)
21 U.S.C. 379dd(d)(1)(A) (except "(referred to in this part as the `Board')")	21 U.S.C. 19102(d)(1)(A)
21 U.S.C. 379dd(d)(1)(A) ("(referred to in this part as the `Board')")	21 U.S.C. 19101(1)
21 U.S.C. 379dd(d)(1)(B)	21 U.S.C. 19102(d)(1)(B)
21 U.S.C. 379dd(d)(1)(C)	21 U.S.C. 19102(d)(1)(C)
21 U.S.C. 379dd(d)(1)(D)(i)	Repealed as obsolete. Provided that not later than 30 days after September 27, 2007, the Secretary shall convene a meeting of the ex officio members of the Board to incorporate the Foundation and to appoint the members of the Board in accordance with subparagraph (C) of section 770(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)).

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 379dd(d)(1)(D)(ii)	Repealed as obsolete. Provided that on the initial appointment of the members of the Board, the terms of service of the Director of the Centers for Disease Control and Prevention and of the Director of the Agency for Healthcare Research and Quality as ex officio members of the Board shall terminate and the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board, but shall be nonvoting members.
21 U.S.C. 379dd(d)(1)(D)(iii)	21 U.S.C. 19102(d)(1)(D)
21 U.S.C. 379dd(d)(2)	21 U.S.C. 19102(d)(2)
21 U.S.C. 379dd(d)(3)	21 U.S.C. 19102(d)(3)
21 U.S.C. 379dd(d)(4)	21 U.S.C. 19102(d)(4)
21 U.S.C. 379dd(e)	Repealed as obsolete. Provided that the ex officio members of the Board of Directors of the Reagan-Udall Foundation serve as incorporators and take whatever actions necessary to incorporate the Foundation.
21 U.S.C. 379dd(f) through (n)	21 U.S.C. 19102(e) through (m)
21 U.S.C. 379dd–1	21 U.S.C. 19103
21 U.S.C. 379dd–2	21 U.S.C. 19104
21 U.S.C. 381(a) (1st sentence, 2d sentence)	21 U.S.C. 20101(a)(1), (2)
21 U.S.C. 381(a) (3d sentence)	21 U.S.C. 20101(a)(3)(A)
21 U.S.C. 381(a) (4th sentence)	21 U.S.C. 20101(a)(3)(B)
21 U.S.C. 381(a) (5th sentence)	21 U.S.C. 20101(a)(3)(C)
21 U.S.C. 381(a) (6th sentence)	21 U.S.C. 20101(a)(3)(D)
21 U.S.C. 381(a) (7th sentence)	21 U.S.C. 20101(a)(4)
21 U.S.C. 381(a) (8th sentence through 11th sentence)	21 U.S.C. 20101(a)(5)
21 U.S.C. 381(a) (last sentence)	21 U.S.C. 20101(a)(3)(E)
21 U.S.C. 381(b)	21 U.S.C. 20101(b)
21 U.S.C. 381(c)	21 U.S.C. 20101(c)
21 U.S.C. 381(d)	21 U.S.C. 20101(d)
21 U.S.C. 381(e)(1) through (3)	21 U.S.C. 20101(e)(1) through (3)
21 U.S.C. 381(e)(4)(A)	21 U.S.C. 20101(e)(4)(A)
21 U.S.C. 381(e)(4)(B)	21 U.S.C. 20101(e)(4)(B)(i) through (iii)
21 U.S.C. 381(e)(4)(C)	21 U.S.C. 20101(e)(4)(C)
21 U.S.C. 381(e)(4)(D)	21 U.S.C. 20101(e)(4)(B)(iv)
21 U.S.C. 381(e)(4)(E)	21 U.S.C. 20101(e)(4)(D)
21 U.S.C. 381(e)(4)(F)	21 U.S.C. 20101(e)(4)(E)
21 U.S.C. 381(f)	21 U.S.C. 20101(f)
21 U.S.C. 381(g)(1)	21 U.S.C. 20101(g)(2)
21 U.S.C. 381(g)(2)	21 U.S.C. 20101(g)(1)
21 U.S.C. 381(h)	21 U.S.C. 20101(h)
21 U.S.C. 381(i)	21 U.S.C. 20101(i)
21 U.S.C. 381(j)	21 U.S.C. 20101(j)
21 U.S.C. 381(k)	21 U.S.C. 20101(k)
21 U.S.C. 381(l)	21 U.S.C. 20101(l)
21 U.S.C. 381(m)	21 U.S.C. 20101(m)
21 U.S.C. 381(n)	21 U.S.C. 20101(n)(1) through (3)
21 U.S.C. 381(o)	21 U.S.C. 20101(o)
21 U.S.C. 381(p)	21 U.S.C. 20101(p)
21 U.S.C. 381(q)	21 U.S.C. 20101(q)(1) through (7)
21 U.S.C. 381(r)	21 U.S.C. 20101(r)
21 U.S.C. 381(s)	21 U.S.C. 20101(s)
21 U.S.C. 381(t)	21 U.S.C. 20101(t)
21 U.S.C. 381(u)	21 U.S.C. 20101(u)
21 U.S.C. 381 note (Pub. L. 111–353, title III, §303(d))	21 U.S.C. 20101(q)(8)
21 U.S.C. 381 note (Pub. L. 107–188, title III, §308(c) (relating to subsection (a) of "this section"))	21 U.S.C. 20101(n)(4)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 381 note (Pub. L. 107–188, title III, §308(c) (relating to subsection (b) of "this section"))	21 U.S.C. 11322(b)
21 U.S.C. 382(a)	21 U.S.C. 20102(b)
21 U.S.C. 382(b) through (g)	21 U.S.C. 20102(c) through (h)
21 U.S.C. 382(h)	21 U.S.C. 20102(a)
21 U.S.C. 382(i)	21 U.S.C. 20102(i)
21 U.S.C. 383	21 U.S.C. 20103
21 U.S.C. 384 (except (m))	21 U.S.C. 20104
21 U.S.C. 384(m)	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary to carry out section 804 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384).
21 U.S.C. 384a(a)(1)	21 U.S.C. 20105(b)
21 U.S.C. 384a(a)(2)	21 U.S.C. 20105(a)
21 U.S.C. 384a(b) through (g)	21 U.S.C. 20105(c) through (h)
21 U.S.C. 384b(a) through (f)	21 U.S.C. 20106(b) through (g)
21 U.S.C. 384b(g)	21 U.S.C. 20106(a)
21 U.S.C. 384c	21 U.S.C. 20107
21 U.S.C. 384d(a)(1)	21 U.S.C. 20108(a)(3)
21 U.S.C. 384d(a)(2)	21 U.S.C. 20108(a)(1)
21 U.S.C. 384d(a)(3)	21 U.S.C. 20108(a)(7)
21 U.S.C. 384d(a)(4)	21 U.S.C. 20108(a)(2)
21 U.S.C. 384d(a)(5)	21 U.S.C. 20108(a)(4)
21 U.S.C. 384d(a)(6)	21 U.S.C. 20108(a)(5)
21 U.S.C. 384d(a)(7)	21 U.S.C. 20108(a)(6)
21 U.S.C. 384d(b) through (h)	21 U.S.C. 20108(b) through (h)
21 U.S.C. 384e	21 U.S.C. 20109
21 U.S.C. 384f	21 U.S.C. 40903
21 U.S.C. 384g	21 U.S.C. 40904
21 U.S.C. 387 (except (19))	21 U.S.C. 21101
21 U.S.C. 387(19)	Repealed as unnecessary. Provided definitions of "State" and "Territory". The provision is unnecessary because of paragraphs (47) and (48) of section 10101(a) of title 21, United States Code.
21 U.S.C. 387 note (Pub. L. 111–31, div. A, §4)	21 U.S.C. 80105
21 U.S.C. 387a	21 U.S.C. 21102
21 U.S.C. 387a–1	21 U.S.C. 80101
21 U.S.C. 387b	21 U.S.C. 21103
21 U.S.C. 387c	21 U.S.C. 21104
21 U.S.C. 387d(a) (except (3) (last sentence))	21 U.S.C. 21105(a)(1)
21 U.S.C. 387d(a)(3) (last sentence)	21 U.S.C. 21105(a)(2)
21 U.S.C. 387d(b) through (e)	21 U.S.C. 21105(b) through (e)
21 U.S.C. 387e (except (b) (last sentence))	21 U.S.C. 21106 (except (j)(1))
21 U.S.C. 387e(b) (last sentence)	Repealed as obsolete. Provided a date by which initial registration under section 905(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(b)) shall be made.
21 U.S.C. 387f (except (e)(3))	21 U.S.C. 21107
21 U.S.C. 387f(e)(3)	Repealed as obsolete. Provided that compliance with requirements under subsection (e) of section 906 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f) shall not be required before June 22, 2012.
21 U.S.C. 387f–1	21 U.S.C. 80103
21 U.S.C. 387g(a) through (d)	21 U.S.C. 21108
21 U.S.C. 387g(e)	Repealed as obsolete. Provided that immediately on the establishment of the Tobacco Products Scientific Advisory Committee, the Secretary shall refer to the Committee for report and recommendation the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities, and that in the

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	Committee's review, it shall address certain specified considerations.
21 U.S.C. 387g(f)	Repealed as obsolete. Provided that the Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including the use among children and that in the Committee's review, it shall address certain specified considerations.
21 U.S.C. 387h	21 U.S.C. 21109
21 U.S.C. 387i	21 U.S.C. 21110
21 U.S.C. 387j(a)(1)	21 U.S.C. 21111(a)(1)
21 U.S.C. 387j(a)(2)	21 U.S.C. 21111(b)(1)
21 U.S.C. 387j(a)(3) (relating to "this section")	21 U.S.C. 21111(a)(2)
21 U.S.C. 387j(a)(3) (relating to "section 387e(j) of this title")	21 U.S.C. 21106(j)(1)
21 U.S.C. 387j(a)(4)	21 U.S.C. 21111(b)(2)
21 U.S.C. 387j(b) through (g)	21 U.S.C. 21111(c) through (h)
21 U.S.C. 387k(a)	21 U.S.C. 21112(b)
21 U.S.C. 387k(b)(1), (2)	21 U.S.C. 21112(a)
21 U.S.C. 387k(b)(3)	Repealed as obsolete. Provided for the effective date of subsection (b)(2)(A)(ii) of section 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387k), which effective date was 12 months after June 22, 2009, for products containing specified terms on June 22, 2009.
21 U.S.C. 387k(c) through (m)	21 U.S.C. 21112(c) through (m)
21 U.S.C. 387l(a)(2)(C)	21 U.S.C. 21113(a)
21 U.S.C. 387l (except (a)(2)(C))	21 U.S.C. 21113(b) through (f)
21 U.S.C. 387m	21 U.S.C. 21114
21 U.S.C. 387n	21 U.S.C. 21115
21 U.S.C. 387o	21 U.S.C. 21116
21 U.S.C. 387p	21 U.S.C. 21117
21 U.S.C. 387q(a) (parenthetical)	21 U.S.C. 21118(a)
21 U.S.C. 387q (except (a) (parenthetical))	21 U.S.C. 21118(b) through (f)
21 U.S.C. 387r(a)	21 U.S.C. 21119
21 U.S.C. 387r(b)	Repealed as obsolete. Required the Secretary of Health and Human Services, after consultation with recognized scientific, medical, and public health experts, to submit to Congress a report examining how best to regulate, promote, and encourage the development of innovative products and treatments to better achieve total abstinence from tobacco use, reductions in consumption of tobacco, and reductions in the harm associated with continued tobacco use.
21 U.S.C. 387s(a)	21 U.S.C. 21120(a)
21 U.S.C. 387s(b)	21 U.S.C. 21120(b)
21 U.S.C. 387s(c)(1)	21 U.S.C. 21120(c)(2)
21 U.S.C. 387s(c)(2)(A) (parenthetical)	21 U.S.C. 21120(c)(1)
21 U.S.C. 387s(c)(2)(A) (except parenthetical)	21 U.S.C. 21120(c)(3)(A)
21 U.S.C. 387s(c)(2)(B)(i)	21 U.S.C. 21120(c)(3)(B)
21 U.S.C. 387s(c)(2)(B)(ii)	Repealed as obsolete. Provided that until October 1, 2009, any amounts available to the Food and Drug Administration (excluding user fees) shall be available and allocated as needed to pay the costs of tobacco regulation activities.
21 U.S.C. 387s(c)(2)(C)	Repealed as obsolete. Provided for reimbursement of amounts made available for start-up costs of tobacco regulation activities.
21 U.S.C. 387s(c)(2)(D)	Repealed as obsolete. Provided that notwithstanding the first sentence of paragraph (1) of section 919(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 919(c)(1)), fees under subsection (a) of section 919 of that Act may be collected through September 30, 2009,

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	for startup costs and shall be available for obligation and remain available until expended, and provided that the offsetting collections shall be credited to the salaries and expenses account of the Food and Drug Administration.
21 U.S.C. 387s(c)(2)(E)	Repealed as obsolete. Provided that notwithstanding any other provision of law, following the enactment of an appropriation for fees under section 919 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s) for fiscal year 2010, or any portion of the fees, obligations for costs of tobacco regulation activities during the start-up period may be incurred in anticipation of the receipt of offsetting fee collections through procedures specified in section 1534 of title 31, United States Code.
21 U.S.C. 387s(c)(3)	21 U.S.C. 21120(c)(4)
21 U.S.C. 387s(d)	21 U.S.C. 21120(d)
21 U.S.C. 387s(e)	Repealed as obsolete. Provided for the amount of quarterly fees for quarters in fiscal year 2009.
21 U.S.C. 387t(a)	21 U.S.C. 21121(a)
21 U.S.C. 387t(b)	21 U.S.C. 21121(b)
21 U.S.C. 387t(c)	21 U.S.C. 21121(c)
21 U.S.C. 387t(d)(1)	21 U.S.C. 21121(d)(2)
21 U.S.C. 387t(d)(2)	21 U.S.C. 21121(d)(1)
21 U.S.C. 387t(e)	21 U.S.C. 21121(e)
21 U.S.C. 387u	21 U.S.C. 80104
21 U.S.C. 387v	21 U.S.C. 89901
21 U.S.C. 391	Repealed as unnecessary. Separability provision provided a rule that applies to laws generally in the absence of such a provision.
21 U.S.C. 392	21 U.S.C. 10321
21 U.S.C. 393	21 U.S.C. 10301
21 U.S.C. 393 note (Pub. L. 117–328, div. FF, title II, §2505)	21 U.S.C. 25306
21 U.S.C. 393 note (Pub. L. 117–328, div. FF, title III, §3627(a))	21 U.S.C. 25307
21 U.S.C. 393 note (Pub. L. 108–282, title I, §102(b)(7))	21 U.S.C. 25302
21 U.S.C. 393 note (Pub. L. 105–115, title I, §129)	21 U.S.C. 40305
21 U.S.C. 393a	21 U.S.C. 25301
21 U.S.C. 394	21 U.S.C. 10305(a)
21 U.S.C. 395(a), (b)	21 U.S.C. 10322
21 U.S.C. 395(c)	Repealed as obsolete. Authorized to be appropriated such sums as may be necessary to carry out section 1005 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 395) for each of fiscal years 1994 through 1996.
21 U.S.C. 396	21 U.S.C. 10323
21 U.S.C. 397	21 U.S.C. 10324
21 U.S.C. 398	21 U.S.C. 10325
21 U.S.C. 399(a)	21 U.S.C. 10326(b)
21 U.S.C. 399(b)(1)	21 U.S.C. 10326(a)
21 U.S.C. 399(b)(2)	21 U.S.C. 10326(c)
21 U.S.C. 399(c) through (g)	21 U.S.C. 10326(d) through (h)
21 U.S.C. 399(h)	Repealed as obsolete. Authorized to be appropriated such sums as may be necessary for the purpose of making grants under section 1009 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399) for fiscal years 2011 through 2015.
21 U.S.C. 399a	21 U.S.C. 10302(b), (c)
21 U.S.C. 399b(a) (parenthetical)	21 U.S.C. 10303(a)
21 U.S.C. 399b(a) (except parenthetical)	21 U.S.C. 10303(b)
21 U.S.C. 399b(b)	21 U.S.C. 10303(c)

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Former United States Code Section	Disposition
21 U.S.C. 399b(c)	Repealed as obsolete. Authorized to be appropriated such sums as may be necessary to carry out section 1011 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399b) for each of the fiscal years 2010 through 2014.
21 U.S.C. 399c(a) through (d)	21 U.S.C. 10327
21 U.S.C. 399c(e)	Repealed as obsolete. Authorized to be appropriated such sums as may be necessary to carry out section 1012 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399c) for fiscal years 2011 through 2015.
21 U.S.C. 399d	21 U.S.C. 10328
21 U.S.C. 399e	21 U.S.C. 25303
21 U.S.C. 399f (except (c)(1))	21 U.S.C. 49509
21 U.S.C. 399f(c)(1)	Repealed as obsolete. Provided that not later than 1 year after July 9, 2012, the Secretary of Health and Human Services issue the communication plan described section 1138 of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 399f).
21 U.S.C. 399g(a) (1st parenthetical)	21 U.S.C. 10304(a)(2)
21 U.S.C. 399g(a) (last parenthetical)	21 U.S.C. 10304(a)(1)
21 U.S.C. 399g(a) (except 1st parenthetical, last parenthetical)	21 U.S.C. 10304(b)
21 U.S.C. 399g(b)	21 U.S.C. 10304(c)
21 U.S.C. 399g(c)	Repealed as obsolete. Provided that the Secretary shall establish at least 1 Intercenter Institute under section 1014(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399g(a)) before December 13, 2017.
21 U.S.C. 399g(d)	21 U.S.C. 10304(d)
21 U.S.C. 399h(a)	21 U.S.C. 49512(b)
21 U.S.C. 399h(b)	21 U.S.C. 49512(c)
21 U.S.C. 399h(c)	21 U.S.C. 49512(d)
21 U.S.C. 399h(d)	21 U.S.C. 49512(e)
21 U.S.C. 399h(e)	21 U.S.C. 49512(f)
21 U.S.C. 399h(f)	21 U.S.C. 49512(g)
21 U.S.C. 399h(g)	21 U.S.C. 49512(h)
21 U.S.C. 399h(h)(1) through (3)	21 U.S.C. 49512(a)(1) through (3)
21 U.S.C. 399h(h)(4), (5)	21 U.S.C. 49512(a)(5), (6)
21 U.S.C. 399h(i)	21 U.S.C. 49512(i)
21 U.S.C. 399i (except (b))	21 U.S.C. 25304
21 U.S.C. 399i(b)	Repealed as obsolete. Provided that of any discretionary resources appropriated in the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018 (Public Law 115–141, div. A, 132 Stat. 380) for fiscal year 2018 for "Department of Health and Human Services, Food and Drug Administration, Salaries and Expenses", not to exceed $5,000,000 of amounts available as of September 30 may be transferred to and merged with the Working Capital Fund, notwithstanding any otherwise applicable purpose limitations.
21 U.S.C. 451	Not repealed but omitted from the text of title 21. Provides a statement of findings for the Poultry Products Inspection Act (21 U.S.C. 451 et seq.).
21 U.S.C. 452	21 U.S.C. 31302
21 U.S.C. 453 (matter before (a))	21 U.S.C. 31301 (matter before (1))
21 U.S.C. 453(a)	21 U.S.C. 31301(5)
21 U.S.C. 453(b)	21 U.S.C. 31301(30)
21 U.S.C. 453(c)	21 U.S.C. 31301(31)
21 U.S.C. 453(d)	21 U.S.C. 31301(32)
21 U.S.C. 453(e)	21 U.S.C. 31301(22)
21 U.S.C. 453(f)	21 U.S.C. 31301(23)
21 U.S.C. 453(g)	21 U.S.C. 31301(1)

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Former United States Code Section	Disposition
21 U.S.C. 453(h)	21 U.S.C. 31301(13)
21 U.S.C. 453(i)	21 U.S.C. 31301(28)
21 U.S.C. 453(j)	21 U.S.C. 31301(20)
21 U.S.C. 453(k)	21 U.S.C. 31301(10)
21 U.S.C. 453(l)	21 U.S.C. 31301(18)
21 U.S.C. 453(m)	21 U.S.C. 31301(17)
21 U.S.C. 453(n)	21 U.S.C. 31301(14)
21 U.S.C. 453(o)	21 U.S.C. 31301(15)
21 U.S.C. 453(p)	21 U.S.C. 31301(16)
21 U.S.C. 453(q)	21 U.S.C. 31301(9)
21 U.S.C. 453(r) (relating to container)	21 U.S.C. 31301(6)
21 U.S.C. 453(r) (relating to package)	21 U.S.C. 31301(19)
21 U.S.C. 453(s) (relating to label)	21 U.S.C. 31301(11)
21 U.S.C. 453(s) (relating to labeling)	21 U.S.C. 31301(12)
21 U.S.C. 453(t)	21 U.S.C. 31301(29)
21 U.S.C. 453(u)	21 U.S.C. 31301(8)
21 U.S.C. 453(v)	21 U.S.C. 31301(3)
21 U.S.C. 453(w)	21 U.S.C. 31301(25)
21 U.S.C. 453(x)	Repealed as unnecessary. Provided a definition of the term “Federal Food, Drug, and Cosmetic Act”. The term is unnecessary because of the restatement of the Act in subtitle I of title 21, United States Code, and the references made to that subtitle I in title 21, United States Code.
21 U.S.C. 453(y) (relating to color additive)	21 U.S.C. 31301(4)
21 U.S.C. 453(y) (relating to food additive)	21 U.S.C. 31301(7)
21 U.S.C. 453(y) (relating to pesticide chemical)	21 U.S.C. 31301(21)
21 U.S.C. 453(y) (relating to raw agricultural commodity)	21 U.S.C. 31301(26)
21 U.S.C. 453(z)	21 U.S.C. 31301(24)
21 U.S.C. 453(aa)	21 U.S.C. 31301(27)
21 U.S.C. 453(bb)	21 U.S.C. 31301(2)
21 U.S.C. 454(a), (b)	21 U.S.C. 31303(b), (c)
21 U.S.C. 454(c)(1) (except proviso)	21 U.S.C. 31303(d)(1)
21 U.S.C. 454(c)(1) (proviso)	Repealed as obsolete. Provided that if the Secretary of Agriculture had reason to believe that a State will have activated the requirements described in section 5(c)(1) of the Poultry Products Inspection Act (21 U.S.C. 454(c)(1)) within 1 additional year, the Secretary was authorized to delay the designation described in that section for that period, and if the Secretary had determined at the end of the year that the State then had the requirements in effective operation, the Secretary was not designate the State.
21 U.S.C. 454(c)(2)	21 U.S.C. 31303(d)(2)
21 U.S.C. 454(c)(3)	21 U.S.C. 31303(d)(3)
21 U.S.C. 454(c)(4)	21 U.S.C. 31303(d)(4)
21 U.S.C. 454(d)	21 U.S.C. 31303(a)
21 U.S.C. 455	21 U.S.C. 31304
21 U.S.C. 455 note (Pub. L. 106–387, §1(a) [title VII, §752])	21 U.S.C. 31501
21 U.S.C. 456	21 U.S.C. 31305
21 U.S.C. 457	21 U.S.C. 31306
21 U.S.C. 458	21 U.S.C. 31307
21 U.S.C. 459	21 U.S.C. 31308
21 U.S.C. 460	21 U.S.C. 31309
21 U.S.C. 461(a)	21 U.S.C. 31310(a)
21 U.S.C. 461(b)	21 U.S.C. 31310(c)
21 U.S.C. 461(c)	21 U.S.C. 31310(b)
21 U.S.C. 462	21 U.S.C. 31311
21 U.S.C. 463	21 U.S.C. 31312
21 U.S.C. 464	21 U.S.C. 31313
21 U.S.C. 465	21 U.S.C. 31314

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21 U.S.C. 466	21 U.S.C. 31315
21 U.S.C. 467	21 U.S.C. 31316
21 U.S.C. 467a	21 U.S.C. 31317
21 U.S.C. 467b	21 U.S.C. 31318
21 U.S.C. 467c	21 U.S.C. 31319
21 U.S.C. 467d	21 U.S.C. 31320
21 U.S.C. 467e	21 U.S.C. 31321
21 U.S.C. 467f	21 U.S.C. 31322
21 U.S.C. 468	21 U.S.C. 31323(b)
21 U.S.C. 469	Repealed as unnecessary. Authorized to be appropriated such sums as necessary to carry out the Poultry Products Inspection Act (21 U.S.C. 451 et seq.).
21 U.S.C. 470	Repealed as obsolete. Required the Secretary of Agriculture to annually report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate with respect to the slaughter of poultry, the preparation, storage, handling, and distribution of poultry parts and poultry products, and the inspection of establishments. The provision is obsolete because of the termination of the reporting requirement with respect to Congress, effective May 15, 2000. See section 3003 of the Federal Reports Elimination and Sunset Act of 1995 (Public Law 104–66, 31 U.S.C. 1113 note) and the 3d item on page 46 of House Document No. 103–7.
21 U.S.C. 471	21 U.S.C. 31324
21 U.S.C. 472(a) through (d)	21 U.S.C. 31325(a) through (d)
21 U.S.C. 472(e)(1)	21 U.S.C. 31325(e)
21 U.S.C. 472(e)(2)	Repealed as obsolete. Required the Comptroller General of the United States to conduct an audit of the implementation of section 11015 of the Food, Conservation, and Energy Act of 2008 (21 U.S.C. 472) not earlier than 3 years, nor later than 5 years, after June 18, 2008.
21 U.S.C. 472(f) through (i)	21 U.S.C. 31325(f) through (i)
21 U.S.C. 473 (except (d)(3)(B))	21 U.S.C. 30507
21 U.S.C. 473(d)(3)(B)	Repealed as obsolete. Provided that the Secretary shall not require any recipient of a grant under section 764 of title VII of division N of the Consolidated Appropriations Act, 2021 (21 U.S.C. 473) (restated as section 30507 of title 21, United States Code) to provide matching funds with respect to a grant awarded in fiscal year 2021 and fiscal year 2022.
21 U.S.C. 501	Previously repealed.
21 U.S.C. 502	Previously repealed.
21 U.S.C. 503	Previously repealed.
21 U.S.C. 504	Previously repealed.
21 U.S.C. 505	Previously repealed.
21 U.S.C. 506	Previously repealed.
21 U.S.C. 507	Previously repealed.
21 U.S.C. 508	Previously repealed.
21 U.S.C. 509	Previously repealed.
21 U.S.C. 510	Previously repealed.
21 U.S.C. 511	Previously repealed.
21 U.S.C. 512	Previously repealed.
21 U.S.C. 513	Previously repealed.
21 U.S.C. 514	Previously repealed.
21 U.S.C. 515	Previously repealed.
21 U.S.C. 516	Previously repealed.
21 U.S.C. 517	Previously repealed.
21 U.S.C. 601 (matter before (a))	21 U.S.C. 30301 (matter before (1))
21 U.S.C. 601(a)	21 U.S.C. 30301(22)
21 U.S.C. 601(b)	21 U.S.C. 30301(7)

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Former United States Code Section	Disposition
21 U.S.C. 601(c)	21 U.S.C. 30301(11)
21 U.S.C. 601(d)	21 U.S.C. 30301(21)
21 U.S.C. 601(e)	21 U.S.C. 30301(3)
21 U.S.C. 601(f)	21 U.S.C. 30301(23)
21 U.S.C. 601(g)	21 U.S.C. 30301(24)
21 U.S.C. 601(h)	21 U.S.C. 30301(6)
21 U.S.C. 601(i)	21 U.S.C. 30301(25)
21 U.S.C. 601(j)	21 U.S.C. 30301(12)
21 U.S.C. 601(k)	21 U.S.C. 30301(4)
21 U.S.C. 601(l)	21 U.S.C. 30301(19)
21 U.S.C. 601(m)	21 U.S.C. 30301(1)
21 U.S.C. 601(n)	21 U.S.C. 30301(13)
21 U.S.C. 601(o)	21 U.S.C. 30301(9)
21 U.S.C. 601(p)	21 U.S.C. 30301(10)
21 U.S.C. 601(q)	Repealed as unnecessary. Provided a definition of the term “Federal Food, Drug, and Cosmetic Act”. The term is unnecessary because of the restatement of the Act in subtitle I of title 21, United States Code, and the references made to that subtitle I in title 21, United States Code.
21 U.S.C. 601(r) (relating to color additive)	21 U.S.C. 30301(5)
21 U.S.C. 601(r) (relating to food additive)	21 U.S.C. 30301(8)
21 U.S.C. 601(r) (relating to pesticide chemical)	21 U.S.C. 30301(18)
21 U.S.C. 601(r) (relating to raw agricultural commodity)	21 U.S.C. 30301(20)
21 U.S.C. 601(s)	21 U.S.C. 30301(17)
21 U.S.C. 601(t)	21 U.S.C. 30301(16)
21 U.S.C. 601(u)	21 U.S.C. 30301(14)
21 U.S.C. 601(v)	21 U.S.C. 30301(15)
21 U.S.C. 601(w)	21 U.S.C. 30301(2)
21 U.S.C. 602	21 U.S.C. 30302
21 U.S.C. 603	21 U.S.C. 30303
21 U.S.C. 603 note (Pub. L. 95–445, §6)	21 U.S.C. 30504
21 U.S.C. 604	21 U.S.C. 30304
21 U.S.C. 605	21 U.S.C. 30305
21 U.S.C. 606	21 U.S.C. 30306
21 U.S.C. 607	21 U.S.C. 30307
21 U.S.C. 608	21 U.S.C. 30308
21 U.S.C. 609	21 U.S.C. 30309
21 U.S.C. 610	21 U.S.C. 30310
21 U.S.C. 611	21 U.S.C. 30311
21 U.S.C. 612	21 U.S.C. 30312
21 U.S.C. 613	21 U.S.C. 30313
21 U.S.C. 614	Previously repealed.
21 U.S.C. 615	21 U.S.C. 30314
21 U.S.C. 616	21 U.S.C. 30315
21 U.S.C. 617	21 U.S.C. 30316
21 U.S.C. 618	21 U.S.C. 30317
21 U.S.C. 619	21 U.S.C. 30318
21 U.S.C. 620 (except (e))	21 U.S.C. 30319
21 U.S.C. 620(e)	Repealed as obsolete. Required the Secretary of Agriculture to submit to certain congressional committees an annual report with respect to the administration of section 20 of the Federal Meat Inspection Act (21 U.S.C. 620). The provision is obsolete because of the termination of the reporting requirement with respect to Congress, effective May 15, 2000. See section 3003 of the Federal Reports Elimination and Sunset Act of 1995 (Public Law 104–66, 31 U.S.C. 1113 note) and the 5th item on page 46 of House Document No. 103–7.
21 U.S.C. 621	21 U.S.C. 30320
21 U.S.C. 622	21 U.S.C. 30321
21 U.S.C. 623	21 U.S.C. 30322

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 624	21 U.S.C. 30323
21 U.S.C. 625	21 U.S.C. 30324
21 U.S.C. 626	21 U.S.C. 30502
21 U.S.C. 641	21 U.S.C. 30341
21 U.S.C. 642	21 U.S.C. 30342
21 U.S.C. 643	21 U.S.C. 30343
21 U.S.C. 644	21 U.S.C. 30344
21 U.S.C. 645	21 U.S.C. 30345
21 U.S.C. 661(a) through (c)	21 U.S.C. 30356(b) through (d)
21 U.S.C. 661(d)	21 U.S.C. 30356(a)
21 U.S.C. 671	21 U.S.C. 30361
21 U.S.C. 672	21 U.S.C. 30362
21 U.S.C. 673	21 U.S.C. 30363
21 U.S.C. 674	21 U.S.C. 30364
21 U.S.C. 675	21 U.S.C. 30365
21 U.S.C. 676	21 U.S.C. 30366
21 U.S.C. 677	21 U.S.C. 30367
21 U.S.C. 678	21 U.S.C. 30368
21 U.S.C. 679	21 U.S.C. 30369
21 U.S.C. 679a(a) (parenthetical)	21 U.S.C. 30370(a)
21 U.S.C. 679a(a) (except parenthetical)	21 U.S.C. 30370(b)
21 U.S.C. 679a(b) through (i)	21 U.S.C. 30370(c) through (j)
21 U.S.C. 679b(1)	21 U.S.C. 30505
21 U.S.C. 679b(2)	Repealed as unnecessary. Authorized to be appropriated such sums as necessary to carry out section 10808(a) of the Farm Security and Rural Investment Act of 2002 (21 U.S.C. 679b).
21 U.S.C. 679c(a)	21 U.S.C. 30506
21 U.S.C. 679c(b)	Repealed as unnecessary. Authorized to be appropriated, to carry out section 332 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (21 U.S.C. 679c), $15,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.
21 U.S.C. 680	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary to carry out the provisions of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
21 U.S.C. 683(a) through (d)	21 U.S.C. 30381(a) through (d)
21 U.S.C. 683(e)(1)	21 U.S.C. 30381(e)
21 U.S.C. 683(e)(2)	Repealed as obsolete. Required the Comptroller General of the United States to conduct an audit of the implementation of section 501 of the Federal Meat Inspection Act (21 U.S.C. 683) not earlier than 3 years, nor later than 5 years, after June 18, 2008.
21 U.S.C. 683(f) through (j)	21 U.S.C. 30381(f) through (j)
21 U.S.C. 691	Repealed as obsolete. Required the Secretary of Agriculture to report annually to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate on the slaughter of animals and the processing and distribution of carcasses and products. The provision is obsolete because of the termination of the reporting requirement with respect to Congress, effective May 15, 2000. See section 3003 of the Federal Reports Elimination and Sunset Act of 1995 (Public Law 104–66, 31 U.S.C. 1113 note) and the 6th item on page 46 of House Document No. 103–7.
21 U.S.C. 692	21 U.S.C. 30501
21 U.S.C. 693	Not repealed but omitted from the text of title 21. Provides that the Act of March 3, 1891 (ch. 555, 26 Stat. 1089), which relates to the inspection of live cattle and products of live cattle, shall be deemed to include dairy

Former United States Code Section	Disposition
	products intended for exportation to any foreign country, and that the Secretary of Agriculture may apply, under regulations to be prescribed by the Secretary of Agriculture, the provisions of that Act for inspection and certification appropriate for ascertaining the purity and quality of dairy products.
21 U.S.C. 694	Not repealed but omitted from the text of title 21. Provides for annual appropriations of $3,000,000 from the general fund of the Treasury for the expenses of the inspection of cattle, sheep, swine, and goats and the meat and meat food products of those animals that enter into interstate or foreign commerce and for all expenses necessary to carry into effect certain provisions relating to meat inspection. Provides for appropriation of such other sums as may be necessary in the enforcement of the meat inspection laws.
21 U.S.C. 695	21 U.S.C. 30503(b)
21 U.S.C. 801	21 U.S.C. 50102
21 U.S.C. 801 note (Pub. L. 117–215, title III, §301)	21 U.S.C. 41531
21 U.S.C. 801 note (Pub. L. 106–391, title III, §320)	21 U.S.C. 69915(b)
21 U.S.C. 801 note (Pub. L. 106–310, div. B, title XXXVI, §3671)	21 U.S.C. 69915(a)
21 U.S.C. 801 note (Pub. L. 106–172, §6(a))	21 U.S.C. 61303(a)
21 U.S.C. 801 note (Pub. L. 106–172, §6(b)(1))	21 U.S.C. 61303(b)
21 U.S.C. 801 note (Pub. L. 106–172, §6(b)(2))	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary to carry out subsection (b) of section 6 of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000 (Public Law 106–172, 21 U.S.C. 801 note).
21 U.S.C. 801 note (Pub. L. 106–172, §6(c))	Repealed as obsolete. Provided that not later than 180 days after February 18, 2000, the Attorney General was to submit to the Committees on the Judiciary of the Senate and House of Representatives a report on mechanisms for coordinating Federal, State, and local investigations into and prosecutions related to possible violations of the Controlled Substances Act (21 U.S.C. 801 et seq.) or other Federal or State laws that result in or contribute to rape, other crimes of violence, or other crimes involving the abuse of gamma hydroxybutyric acid, other controlled substances, or "designer drugs".
21 U.S.C. 801 note (Pub. L. 106–172, §7(c))	21 U.S.C. 61304(a)
21 U.S.C. 801 note (Pub. L. 106–172, §7(a))	21 U.S.C. 61304(b)
21 U.S.C. 801 note (Pub. L. 106–172, §7(b))	21 U.S.C. 61304(c)
21 U.S.C. 801 note (Pub. L. 104–237, title I, §101)	21 U.S.C. 69909
21 U.S.C. 801 note (Pub. L. 99–570, title IV, §4304(a))	21 U.S.C. 69902
21 U.S.C. 801 note (Pub. L. 99–570, title IV, §4304(b))	Repealed as obsolete. Provided that within 1 year after October 27, 1986, the Secretary of Education, the Secretary of Health and Human Services, and the Secretary of Labor jointly submit to Congress a report concerning the extent to which States and localities were able to implement non-duplicative drug abuse prevention activities.
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(1), (2))	21 U.S.C. 41501(1), (2)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(3) (relating to controlled substance))	21 U.S.C. 41501(3)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(3) (relating to dispense))	21 U.S.C. 41501(5)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(3) (relating to distribute))	21 U.S.C. 41501(6)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(3) (relating to manufacture))	21 U.S.C. 41501(8)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(3) (relating to marijuana))	21 U.S.C. 41501(9)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(3) (relating to practitioner))	21 U.S.C. 41501(11)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(4))	21 U.S.C. 41501(4)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(5))	21 U.S.C. 41501(7)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(6))	21 U.S.C. 41501(10)
21 U.S.C. 801 note (Pub. L. 117–215, §2(a)(7))	21 U.S.C. 41501(12)
21 U.S.C. 801a	Not repealed but omitted from the text of title 21. Provides a statement of findings and declarations for the Psychotropic Substances Act of 1978 (Public Law 95–633, 92 Stat. 3768).
21 U.S.C. 802(1) through (3)	21 U.S.C. 50101(1) through (3)
21 U.S.C. 802(4)	21 U.S.C. 50101(20)
21 U.S.C. 802(5)	21 U.S.C. 50101(8)
21 U.S.C. 802(6)	21 U.S.C. 50101(9)
21 U.S.C. 802(7)	21 U.S.C. 50101(12)
21 U.S.C. 802(8)	21 U.S.C. 50101(14)
21 U.S.C. 802(9)	21 U.S.C. 50101(15)
21 U.S.C. 802(10)	21 U.S.C. 50101(17)
21 U.S.C. 802(11)	21 U.S.C. 50101(18)
21 U.S.C. 802(12)	21 U.S.C. 50101(19)
21 U.S.C. 802(13)	21 U.S.C. 50101(21)
21 U.S.C. 802(14)	21 U.S.C. 50101(29)
21 U.S.C. 802(15)	21 U.S.C. 50101(34)
21 U.S.C. 802(16)	21 U.S.C. 50101(35)
21 U.S.C. 802(17)	21 U.S.C. 50101(37)
21 U.S.C. 802(18)	21 U.S.C. 50101(39)
21 U.S.C. 802(19)	21 U.S.C. 50101(40)
21 U.S.C. 802(20)	21 U.S.C. 50101(41)
21 U.S.C. 802(21)	21 U.S.C. 50101(43)
21 U.S.C. 802(22)	21 U.S.C. 50101(44)
21 U.S.C. 802(23)	21 U.S.C. 50101(26)
21 U.S.C. 802(24)	21 U.S.C. 50101(53)
21 U.S.C. 802(25)	21 U.S.C. 50101(54)
21 U.S.C. 802(26)	21 U.S.C. 50101(58)
21 U.S.C. 802(27)	21 U.S.C. 50101(61)
21 U.S.C. 802(28)	21 U.S.C. 50101(62)
21 U.S.C. 802(29)	21 U.S.C. 50101(33)
21 U.S.C. 802(30)	21 U.S.C. 50101(16)
21 U.S.C. 802(31) (matter before semicolon)	21 U.S.C. 50101(11)
21 U.S.C. 802(31) (matter after semicolon)	21 U.S.C. 50101(57)
21 U.S.C. 802(32)	21 U.S.C. 50101(10)
21 U.S.C. 802(33)	21 U.S.C. 50101(32)
21 U.S.C. 802(34)	21 U.S.C. 50101(30)
21 U.S.C. 802(35)	21 U.S.C. 50101(31)
21 U.S.C. 802(36)	21 U.S.C. 50101(46)
21 U.S.C. 802(37)	21 U.S.C. 50101(47)
21 U.S.C. 802(38)	21 U.S.C. 50101(48)
21 U.S.C. 802(39)	21 U.S.C. 50101(50)
21 U.S.C. 802(40)	21 U.S.C. 50101(7)
21 U.S.C. 802(41)	21 U.S.C. 50101(4)
21 U.S.C. 802(42)	21 U.S.C. 50101(27)
21 U.S.C. 802(43) (relating to broker)	21 U.S.C. 50101(6)
21 U.S.C. 802(43) (relating to trader)	21 U.S.C. 50101(60)
21 U.S.C. 802(44)	21 U.S.C. 50101(22)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 802(45)	21 U.S.C. 50101(52)
21 U.S.C. 802(46)	21 U.S.C. 50101(49)
21 U.S.C. 802(47)	21 U.S.C. 50101(36)
21 U.S.C. 802(48)	21 U.S.C. 50101(5)
21 U.S.C. 802(49)	21 U.S.C. 50101(51)
21 U.S.C. 802(50)	21 U.S.C. 50101(28)
21 U.S.C. 802(51)	21 U.S.C. 50101(13)
21 U.S.C. 802(52)	21 U.S.C. 50101(38)
21 U.S.C. 802(53)	21 U.S.C. 50101(25)
21 U.S.C. 802(54)	21 U.S.C. 50101(42)
21 U.S.C. 802(55)	21 U.S.C. 50101(45)
21 U.S.C. 802(56)	21 U.S.C. 50101(24)
21 U.S.C. 802(57)	21 U.S.C. 50101(59)
21 U.S.C. 802(58)	21 U.S.C. 50101(55)
21 U.S.C. 802(59)	21 U.S.C. 50101(56)
21 U.S.C. 802(60)	21 U.S.C. 50101(23)
21 U.S.C. 802 note (Pub. L. 110–425, §4)	21 U.S.C. 51101(b)
21 U.S.C. 802 note (Pub. L. 109–177, title VII, §711(g))	21 U.S.C. 51101(c)
21 U.S.C. 802 note (Pub. L. 101–647, title XIX, §1903)	21 U.S.C. 69905
21 U.S.C. 803	Previously repealed.
21 U.S.C. 811(a)	21 U.S.C. 50301(a)
21 U.S.C. 811(b)	21 U.S.C. 50301(b)
21 U.S.C. 811(c)	21 U.S.C. 50301(c)
21 U.S.C. 811(d)	21 U.S.C. 50301(d)
21 U.S.C. 811(e)	21 U.S.C. 50301(e)
21 U.S.C. 811(f)	21 U.S.C. 50301(f)
21 U.S.C. 811(g)	21 U.S.C. 50301(g)
21 U.S.C. 811(h)	21 U.S.C. 50301(h)
21 U.S.C. 811(i)	21 U.S.C. 50301(i)
21 U.S.C. 811(j)	21 U.S.C. 50301(j)
21 U.S.C. 812	21 U.S.C. 50302
21 U.S.C. 812 note (Pub. L. 106–172, §2)	Not repealed but omitted from the text of title 21. Provides a statement of findings for the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000 (Public Law 106–172, 21 U.S.C. 812 note).
21 U.S.C. 812 note (Pub. L. 106–172, §3(a)(1))	21 U.S.C. 61302
21 U.S.C. 812 note (Pub. L. 106–172, §3(a)(2))	Repealed as obsolete. Provided that if the final order required under paragraph (1) of section 3(a) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000 (Public Law 106–172, 21 U.S.C. 812 note) were not issued within the period specified in that paragraph (1), gamma hydroxybutyric acid (together with its salts, isomers, and salts of isomers) would be deemed to be scheduled under section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) in accordance with the policies described in that paragraph (1), as if the Attorney General had issued a final order in accordance with that paragraph. The final order had been issued. See 65 Fed. Reg. 13235 (Mar. 13, 2000).
21 U.S.C. 812 note (Pub. L. 95–633, title I, §102(c))	21 U.S.C. 69901
21 U.S.C. 813	21 U.S.C. 50303
21 U.S.C. 814	21 U.S.C. 50304
21 U.S.C. 821	21 U.S.C. 50501
21 U.S.C. 822 (except (g)(5))	21 U.S.C. 50502 (except (g)(5))
21 U.S.C. 822(g)(5)(A)	21 U.S.C. 50502(g)(5)(B)
21 U.S.C. 822(g)(5)(B)(i) (relating to hospice care)	21 U.S.C. 50502(g)(5)(A)(ii)
21 U.S.C. 822(g)(5)(B)(i) (relating to hospice program)	21 U.S.C. 50502(g)(5)(A)(iii)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 822(g)(5)(B)(ii)	21 U.S.C. 50502(g)(5)(A)(i)
21 U.S.C. 822(g)(5)(B)(iii)	21 U.S.C. 50502(g)(5)(A)(iv)
21 U.S.C. 822 note (Pub. L. 115–271, title III, §3222(c))	21 U.S.C. 50502(g)(5)(D)
21 U.S.C. 822 note (Pub. L. 115–271, title III, §3222(b))	21 U.S.C. 50502(g)(5)(C)
21 U.S.C. 822a	21 U.S.C. 69921
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3251)	Repealed as unnecessary. Provided a short title for the Access to Increased Drug Disposal Act of 2018 (Public Law 115–271, title III, subtitle B, ch. 6, 21 U.S.C. 822a note).
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3252)	21 U.S.C. 40905(a)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3253)	21 U.S.C. 40905(b)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3254)	21 U.S.C. 40905(c)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3255)	21 U.S.C. 40905(d)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3256)	21 U.S.C. 40905(e)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3257)	21 U.S.C. 40905(f)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3258)	21 U.S.C. 40905(g)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3259)	21 U.S.C. 40905(h)
21 U.S.C. 822a note (Pub. L. 115–271, title III, §3260)	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary to carry out the Access to Increased Drug Disposal Act of 2018 (Public Law 115–271, title III, ch. 6, 132 Stat. 3950).
21 U.S.C. 823(a), (b)	21 U.S.C. 50503(b), (c)
21 U.S.C. 823(c)	21 U.S.C. 50503(d)
21 U.S.C. 823(d)	21 U.S.C. 50503(e)
21 U.S.C. 823(e), (f)	21 U.S.C. 50503(f), (g)
21 U.S.C. 823(g)	21 U.S.C. 50503(h)
21 U.S.C. 823(h)	21 U.S.C. 50503(i)
21 U.S.C. 823(i)	21 U.S.C. 50503(j)
21 U.S.C. 823(j)	21 U.S.C. 50503(k)
21 U.S.C. 823(k)(1) through (12)	21 U.S.C. 50503(l)(1) through (12)
21 U.S.C. 823(k)(13)	21 U.S.C. 50503(a) (except (7))
21 U.S.C. 823(l)	21 U.S.C. 50503(a)(7)
21 U.S.C. 823(m)	21 U.S.C. 50503(m)
21 U.S.C. 823(n)	21 U.S.C. 50503(n)
21 U.S.C. 823(o)	21 U.S.C. 50503(o)
21 U.S.C. 823 note (Pub. L. 117–328, div. FF, title I, §1252(b))	21 U.S.C. 69926
21 U.S.C. 823 note (Pub. L. 117–215, title I, §104)	21 U.S.C. 41511
21 U.S.C. 823 note (Pub. L. 117–215, title I, §105)	21 U.S.C. 41512
21 U.S.C. 823 note (Pub. L. 117–215, title II, §201)	21 U.S.C. 41521
21 U.S.C. 823 note (Pub. L. 117–215, title II, §202)	21 U.S.C. 41522
21 U.S.C. 824 (except (d))	21 U.S.C. 50504 (except (d))
21 U.S.C. 824(d)(1)	21 U.S.C. 50504(d)(2)
21 U.S.C. 824(d)(2)	21 U.S.C. 50504(d)(1)
21 U.S.C. 825	21 U.S.C. 50505
21 U.S.C. 825 note (Pub. L. 113–260, §4)	21 U.S.C. 69920
21 U.S.C. 826(a) through (h)	21 U.S.C. 50506(a) through (h)
21 U.S.C. 826(i)(1)(A) (parenthetical)	21 U.S.C. 50506(i)(1)
21 U.S.C. 826(i)(1)(A) (except parenthetical)	21 U.S.C. 50506(i)(2)(A)
21 U.S.C. 826(i)(1)(B), (C)	21 U.S.C. 50506(i)(2)(B), (C)
21 U.S.C. 826(i)(2), (3)	21 U.S.C. 50506(i)(3), (4)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 826 note (Pub. L. 109–177, title VII, § 718)	21 U.S.C. 69916
21 U.S.C. 826a	21 U.S.C. 50506(j)
21 U.S.C. 827	21 U.S.C. 50507
21 U.S.C. 828	21 U.S.C. 50508
21 U.S.C. 829 (except (f)(3))	21 U.S.C. 50509 (except (f)(3), (g))
21 U.S.C. 829(f)(3)	Repealed as obsolete. Provided that as of the day before July 22, 2016, in any circumstance in which, as of the day before July 22, 2016, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow the prescription to be partially filled.
21 U.S.C. 829 note (Pub. L. 114–198, title VII, §702(b))	21 U.S.C. 50509(f)(3)
21 U.S.C. 829 note (Pub. L. 116–215, div. B, title III, §1302)	21 U.S.C. 69923
21 U.S.C. 829 note (Pub. L. 115–271, title III, §3212)	21 U.S.C. 50509(g)
21 U.S.C. 829a(a)	21 U.S.C. 50510(a)
21 U.S.C. 829a(b)(1)	Repealed as obsolete. Provided that during the 2-year period beginning on October 24, 2018, the Attorney General, in coordination with the Secretary of Health and Human Services, may reduce the number of days described in section 309A(a)(5) of the Controlled Substances Act (21 U.S.C. 829a(a)(5)) if the Attorney General determines that the reduction will reduce the risk of diversion or protect the public health.
21 U.S.C. 829a(b)(2), (3)	21 U.S.C. 50510(b)
21 U.S.C. 830(a)	21 U.S.C. 50511(a)
21 U.S.C. 830(b)	21 U.S.C. 50511(b)
21 U.S.C. 830(c)	21 U.S.C. 50511(c)
21 U.S.C. 830(d)	21 U.S.C. 50511(d)
21 U.S.C. 830(e)	21 U.S.C. 50511(e)
21 U.S.C. 831 (except (d)(3))	21 U.S.C. 50512
21 U.S.C. 831(d)(3)	Repealed as obsolete. Provided that an online pharmacy that is already operational as of the effective date of section 311 of the Controlled Substances Act (21 U.S.C. 831) shall notify the Attorney General and applicable State boards of pharmacy in accordance with section 311(d) of that Act not later than 30 days after that date.
21 U.S.C. 832	21 U.S.C. 50513
21 U.S.C. 841(a)	21 U.S.C. 50701(a)
21 U.S.C. 841(b)	21 U.S.C. 50701(b)
21 U.S.C. 841(c)	21 U.S.C. 50701(c)
21 U.S.C. 841(d)	21 U.S.C. 50701(d)
21 U.S.C. 841(e)	21 U.S.C. 50701(h)
21 U.S.C. 841(f) through (h)	21 U.S.C. 50701(e) through (g)
21 U.S.C. 842(a), (b)	21 U.S.C. 50702(a), (b)
21 U.S.C. 842(c)(1)	21 U.S.C. 50702(d)(1)
21 U.S.C. 842(c)(2)(A), (B)	21 U.S.C. 50702(c)(1), (2)
21 U.S.C. 842(c)(2)(C)	21 U.S.C. 50702(d)(2)
21 U.S.C. 842(c)(2)(D)	21 U.S.C. 50702(c)(3)
21 U.S.C. 842(c)(3), (4)	21 U.S.C. 50702(d)(3), (4)
21 U.S.C. 843	21 U.S.C. 50703
21 U.S.C. 844	21 U.S.C. 50704
21 U.S.C. 844a	21 U.S.C. 50705
21 U.S.C. 845	Previously transferred to 21 U.S.C. 859.
21 U.S.C. 845a	Previously transferred to 21 U.S.C. 860.
21 U.S.C. 845b	Previously transferred to 21 U.S.C. 861.
21 U.S.C. 846	21 U.S.C. 50706
21 U.S.C. 847	21 U.S.C. 50707
21 U.S.C. 848(a)	21 U.S.C. 50708(a)(2), (3)
21 U.S.C. 848(b)	21 U.S.C. 50708(b)
21 U.S.C. 848(c)	21 U.S.C. 50708(a)(1)

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 848(d)	21 U.S.C. 50708(c)
21 U.S.C. 848(e)	21 U.S.C. 50708(d)
21 U.S.C. 848(g) through (p)	Previously repealed.
21 U.S.C. 848(q)	Previously repealed.
21 U.S.C. 848(r)	Previously repealed.
21 U.S.C. 848(s)	21 U.S.C. 50708(e)
21 U.S.C. 849	21 U.S.C. 50709
21 U.S.C. 850	21 U.S.C. 50710
21 U.S.C. 851	21 U.S.C. 50711
21 U.S.C. 852	21 U.S.C. 50712
21 U.S.C. 853	21 U.S.C. 50713
21 U.S.C. 853a	Previously transferred to 21 U.S.C. 862.
21 U.S.C. 854	21 U.S.C. 50714
21 U.S.C. 855	21 U.S.C. 50715
21 U.S.C. 856	21 U.S.C. 50716
21 U.S.C. 857	Previously repealed.
21 U.S.C. 858	21 U.S.C. 50717
21 U.S.C. 859	21 U.S.C. 50718
21 U.S.C. 860	21 U.S.C. 50719
21 U.S.C. 860a	21 U.S.C. 50720
21 U.S.C. 861	21 U.S.C. 50721
21 U.S.C. 862(a) through (f)	21 U.S.C. 50722
21 U.S.C. 862(g)	Not repealed but omitted from the text of title 21. Provides that on or before May 1, 1989, the President shall transmit to Congress a report relating to enforcement of section 421 of the Controlled Substances Act (21 U.S.C. 862) and that the Congress shall consider the report of the President and enact such changes as Congress deems appropriate to further the goals of the section.
21 U.S.C. 862(h)	Not repealed but omitted from the text of title 21. Provides that the denial of Federal benefits set forth in section 421 of the Controlled Substances Act (21 U.S.C. 862) shall take effect for convictions occurring after September 1, 1989.
21 U.S.C. 862a(a) through (d)	21 U.S.C. 69907(b) through (e)
21 U.S.C. 862a(e)	21 U.S.C. 69907(a)
21 U.S.C. 862a(f)	21 U.S.C. 69907(f)
21 U.S.C. 862b	21 U.S.C. 69908
21 U.S.C. 863(a) through (c)	21 U.S.C. 50723(b) through (d)
21 U.S.C. 863(d)	21 U.S.C. 50723(a)
21 U.S.C. 863(e)	21 U.S.C. 50723(e)
21 U.S.C. 863(f)	21 U.S.C. 50723(f)
21 U.S.C. 864	21 U.S.C. 50724
21 U.S.C. 864a(a) through (c)	21 U.S.C. 69919
21 U.S.C. 864a(d)	Repealed as obsolete. Authorized to be appropriated to the Secretary of Agriculture to make grants under section 14203 of the Food, Conservation, and Energy Act of 2008 (Public Law 110–246, 122 Stat. 2220) $15,000,000 for the period of fiscal years 2008 through 2012.
21 U.S.C. 865	21 U.S.C. 69917
21 U.S.C. 871	21 U.S.C. 50901
21 U.S.C. 871a	21 U.S.C. 69918
21 U.S.C. 872	21 U.S.C. 50902
21 U.S.C. 872 note (Pub. L. 104–305, §4)	21 U.S.C. 69911
21 U.S.C. 872a	21 U.S.C. 69910
21 U.S.C. 873 (except (d)(3))	21 U.S.C. 50903
21 U.S.C. 873(d)(3)	Repealed as obsolete. Authorized to be appropriated $6,000,000 for fiscal year 1985 and $6,000,000 for fiscal year 1986 to carry out subsection (d) of section 503 of the Controlled Substances Act (21 U.S.C. 873(d)).
21 U.S.C. 873 note (Pub. L. 106–310, div. B, title XXXVI, §3625)	21 U.S.C. 69914

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 874	21 U.S.C. 50904
21 U.S.C. 875	21 U.S.C. 50905
21 U.S.C. 876	21 U.S.C. 50906
21 U.S.C. 877	21 U.S.C. 50907
21 U.S.C. 878	21 U.S.C. 50908
21 U.S.C. 879	21 U.S.C. 50909
21 U.S.C. 880(a)	21 U.S.C. 50910(a)(1)
21 U.S.C. 880(b)(1)	21 U.S.C. 50910(b)(1)
21 U.S.C. 880(b)(2)	21 U.S.C. 50910(b)(2)
21 U.S.C. 880(b)(3)	21 U.S.C. 50910(b)(3)
21 U.S.C. 880(b)(4)	21 U.S.C. 50910(b)(4)
21 U.S.C. 880(c)	21 U.S.C. 50910(c)
21 U.S.C. 880(d) (matter before (1))	21 U.S.C. 50910(d) (matter before (1))
21 U.S.C. 880(d)(1) (last sentence)	21 U.S.C. 50910(a)(2)
21 U.S.C. 880(d)(1) (1st sentence)	21 U.S.C. 50910(d)(1)
21 U.S.C. 880(d)(2)	21 U.S.C. 50910(d)(2)
21 U.S.C. 880(d)(3)	21 U.S.C. 50910(d)(3)
21 U.S.C. 880(d)(4)	21 U.S.C. 50910(d)(4)
21 U.S.C. 881	21 U.S.C. 50911
21 U.S.C. 881 note (Pub. L. 101–225, title II, §210)	21 U.S.C. 69904
21 U.S.C. 881 note (Pub. L. 100–690, title VI, §6079(a) through (d))	21 U.S.C. 69903(b) through (e)
21 U.S.C. 881 note (Pub. L. 100–690, title VI, §6079(e))	21 U.S.C. 69903(a)
21 U.S.C. 881–1	Previously transferred to 21 U.S.C. 888 and subsequently repealed.
21 U.S.C. 881a	Previously transferred to 21 U.S.C. 889.
21 U.S.C. 882	21 U.S.C. 50912
21 U.S.C. 883	21 U.S.C. 50913
21 U.S.C. 884	21 U.S.C. 50914
21 U.S.C. 885	21 U.S.C. 50915
21 U.S.C. 886	21 U.S.C. 50916
21 U.S.C. 886a(1)	21 U.S.C. 69906(b)
21 U.S.C. 886a(2)(B)	21 U.S.C. 69906(a)(1)
21 U.S.C. 886a(2)(A)	21 U.S.C. 69906(a)(2)
21 U.S.C. 887	21 U.S.C. 50917
21 U.S.C. 888	Previously repealed.
21 U.S.C. 889 (except (a)(1))	21 U.S.C. 50918
21 U.S.C. 889(a)(1)	Repealed as unnecessary. Provided a definition of the term "controlled substances" which is unnecessary because of section 50101(9) of title 21, United States Code.
21 U.S.C. 890	21 U.S.C. 50919
21 U.S.C. 901	Repealed as unnecessary. Provided a severability clause that applies to laws generally in the absence of such a clause.
21 U.S.C. 902	21 U.S.C. 51101(a)
21 U.S.C. 903	21 U.S.C. 51102
21 U.S.C. 904	21 U.S.C. 51103
21 U.S.C. 951	21 U.S.C. 51701
21 U.S.C. 952	21 U.S.C. 51702
21 U.S.C. 953	21 U.S.C. 51703
21 U.S.C. 954	21 U.S.C. 51704
21 U.S.C. 955	21 U.S.C. 51705
21 U.S.C. 956	21 U.S.C. 51706 (except (a)(2)(B), (C))
21 U.S.C. 956 note (Pub. L. 105–357, §2(b))	21 U.S.C. 51706(a)(2)(B)
21 U.S.C. 956 note (Pub. L. 105–357, §2(c))	21 U.S.C. 51706(a)(2)(C)
21 U.S.C. 957	21 U.S.C. 51707
21 U.S.C. 958	21 U.S.C. 51708
21 U.S.C. 959	21 U.S.C. 51709
21 U.S.C. 960	21 U.S.C. 51710
21 U.S.C. 960a	21 U.S.C. 51711
21 U.S.C. 961	21 U.S.C. 51712

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 962	21 U.S.C. 51713
21 U.S.C. 963	21 U.S.C. 51714
21 U.S.C. 964	21 U.S.C. 51715
21 U.S.C. 965	21 U.S.C. 51716
21 U.S.C. 966	21 U.S.C. 51717
21 U.S.C. 967	21 U.S.C. 60101
21 U.S.C. 968	21 U.S.C. 60102
21 U.S.C. 969	21 U.S.C. 60103
21 U.S.C. 970	21 U.S.C. 51718
21 U.S.C. 971	21 U.S.C. 51719(a) through (h)
21 U.S.C. 971 note (Pub. L. 104–237, title II, §204(b))	21 U.S.C. 51719(i)
21 U.S.C. 1001	Previously repealed.
21 U.S.C. 1002	Previously repealed.
21 U.S.C. 1003	Previously repealed.
21 U.S.C. 1004	Previously repealed.
21 U.S.C. 1005	Previously repealed.
21 U.S.C. 1006	Previously repealed.
21 U.S.C. 1007	Previously repealed.
21 U.S.C. 1031	21 U.S.C. 31702
21 U.S.C. 1032	21 U.S.C. 31703
21 U.S.C. 1033(a)	21 U.S.C. 31701(1)
21 U.S.C. 1033(b)	21 U.S.C. 31701(2)
21 U.S.C. 1033(c)	21 U.S.C. 31701(4)
21 U.S.C. 1033(d) (matter before (1) relating to package)	21 U.S.C. 31701(21)
21 U.S.C. 1033(d) (matter before (1) relating to container)	21 U.S.C. 31701(5)
21 U.S.C. 1033(d)(1)	21 U.S.C. 31701(11)
21 U.S.C. 1033(d)(2)	21 U.S.C. 31701(29)
21 U.S.C. 1033(e)	21 U.S.C. 31701(7)
21 U.S.C. 1033(f)	21 U.S.C. 31701(8)
21 U.S.C. 1033(g)	21 U.S.C. 31701(6)
21 U.S.C. 1033(h)	21 U.S.C. 31701(9)
21 U.S.C. 1033(i)	Repealed as unnecessary. Provided a definition of the term “Federal Food, Drug, and Cosmetic Act”. The term is unnecessary because of the restatement of the Act in subtitle I of title 21, United States Code, and the references made to that subtitle I in title 21, United States Code.
21 U.S.C. 1033(j)	21 U.S.C. 31701(12)
21 U.S.C. 1033(k)	21 U.S.C. 31701(13)
21 U.S.C. 1033(l)	21 U.S.C. 31701(14)
21 U.S.C. 1033(m)	21 U.S.C. 31701(15)
21 U.S.C. 1033(n)	21 U.S.C. 31701(16)
21 U.S.C. 1033(o)	21 U.S.C. 31701(17)
21 U.S.C. 1033(p)	21 U.S.C. 31701(18)
21 U.S.C. 1033(q)	21 U.S.C. 31701(19)
21 U.S.C. 1033(r)	21 U.S.C. 31701(20)
21 U.S.C. 1033(s)	21 U.S.C. 31701(22)
21 U.S.C. 1033(t)	21 U.S.C. 31701(23)
21 U.S.C. 1033(u) (relating to color additive)	21 U.S.C. 31701(3)
21 U.S.C. 1033(u) (relating to food additive)	21 U.S.C. 31701(10)
21 U.S.C. 1033(u) (relating to pesticide chemical)	21 U.S.C. 31701(24)
21 U.S.C. 1033(u) (relating to raw agricultural commodity)	21 U.S.C. 31701(27)
21 U.S.C. 1033(v)	21 U.S.C. 31701(25)
21 U.S.C. 1033(w)	21 U.S.C. 31701(26)
21 U.S.C. 1033(x)	21 U.S.C. 31701(28)
21 U.S.C. 1033(y)	21 U.S.C. 31701(30)
21 U.S.C. 1033(z)	21 U.S.C. 31701(31)
21 U.S.C. 1034	21 U.S.C. 31704
21 U.S.C. 1035	21 U.S.C. 31705

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 1036	21 U.S.C. 31706
21 U.S.C. 1037	21 U.S.C. 31707
21 U.S.C. 1038	21 U.S.C. 31708
21 U.S.C. 1039	21 U.S.C. 31709
21 U.S.C. 1040	21 U.S.C. 31710
21 U.S.C. 1041	21 U.S.C. 31711
21 U.S.C. 1042	21 U.S.C. 31712
21 U.S.C. 1043	21 U.S.C. 31713
21 U.S.C. 1044(a), (c)	21 U.S.C. 31714
21 U.S.C. 1044(b)	Repealed as obsolete. Authorized exemption for plants if despite good faith efforts by plant owners, full compliance to the Egg Products Inspection Act (21 U.S.C. 1031 et seq.) had not been attained. The exemption was not to be granted for any period extending beyond December 31, 1971.
21 U.S.C. 1045	21 U.S.C. 31715
21 U.S.C. 1046	21 U.S.C. 31716
21 U.S.C. 1047	21 U.S.C. 31717
21 U.S.C. 1048	21 U.S.C. 31718(a) through (c)
21 U.S.C. 1049	21 U.S.C. 31719
21 U.S.C. 1050	21 U.S.C. 31720
21 U.S.C. 1051	21 U.S.C. 31721
21 U.S.C. 1052(a) through (c)	21 U.S.C. 31722
21 U.S.C. 1052(d)	21 U.S.C. 31718(d)
21 U.S.C. 1053(a)	21 U.S.C. 31723(b)
21 U.S.C. 1053(b) (relating to "this chapter")	21 U.S.C. 31723(a)
21 U.S.C. 1053(b) (relating to "the Wholesome Poultry Products Act")	21 U.S.C. 31323(a)
21 U.S.C. 1053(b) (relating to "the Wholesome Meat Act")	21 U.S.C. 30503(a)
21 U.S.C. 1054	21 U.S.C. 31724
21 U.S.C. 1055	Repealed as unnecessary. Authorized to be appropriated such sums as necessary to carry out the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).
21 U.S.C. 1056	Repealed as unnecessary. Provided a severability clause that applies to laws generally in the absence of such a clause.
21 U.S.C. 1101	Not repealed but omitted from the text of title 21. Provides a statement of findings for the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1101 et seq.).
21 U.S.C. 1102	21 U.S.C. 60301
21 U.S.C. 1103	Previously repealed.
21 U.S.C. 1104	Previously repealed.
21 U.S.C. 1111	Previously repealed.
21 U.S.C. 1112	Previously repealed.
21 U.S.C. 1113	Previously repealed.
21 U.S.C. 1114	Previously repealed.
21 U.S.C. 1115	21 U.S.C. 60302
21 U.S.C. 1116	Previously repealed.
21 U.S.C. 1117	Previously repealed.
21 U.S.C. 1118	Previously omitted from general amendment of title II of the Drug Abuse Prevention, Treatment, and Rehabilitation Act by section 4 of the Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (Public Law 96–181, 93 Stat. 1309).
21 U.S.C. 1119	Previously omitted from general amendment of title II of the Drug Abuse Prevention, Treatment, and Rehabilitation Act by section 4 of the Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (Public Law 96–181, 93 Stat. 1309).
21 U.S.C. 1120	Previously omitted from general amendment of title II of the Drug Abuse Prevention,

Disposition Table

Former United States Code Section	Disposition
	Treatment, and Rehabilitation Act by section 4 of the Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (Public Law 96–181, 93 Stat. 1309).
21 U.S.C. 1121	Previously repealed.
21 U.S.C. 1122	Previously repealed.
21 U.S.C. 1123	Previously repealed.
21 U.S.C. 1131	Previously omitted from general amendment of title II of the Drug Abuse Prevention, Treatment, and Rehabilitation Act by section 4 of the Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (Public Law 96–181, 93 Stat. 1309).
21 U.S.C. 1132	Previously omitted from general amendment of title II of the Drug Abuse Prevention, Treatment, and Rehabilitation Act by section 4 of the Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (Public Law 96–181, 93 Stat. 1309).
21 U.S.C. 1133	Previously omitted from general amendment of title II of the Drug Abuse Prevention, Treatment, and Rehabilitation Act by section 4 of the Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (Public Law 96–181, 93 Stat. 1309).
21 U.S.C. 1134	Previously repealed.
21 U.S.C. 1135	Previously repealed.
21 U.S.C. 1136	Previously repealed.
21 U.S.C. 1137	Previously repealed.
21 U.S.C. 1138	Previously repealed.
21 U.S.C. 1139	Previously repealed.
21 U.S.C. 1140	Previously repealed.
21 U.S.C. 1141	Previously repealed.
21 U.S.C. 1142	Previously repealed.
21 U.S.C. 1143	Previously repealed.
21 U.S.C. 1151	Previously repealed.
21 U.S.C. 1152	Previously repealed.
21 U.S.C. 1153	Previously repealed.
21 U.S.C. 1154	Previously repealed.
21 U.S.C. 1155	Previously repealed.
21 U.S.C. 1161	Previously repealed.
21 U.S.C. 1162	Previously repealed.
21 U.S.C. 1163	Previously repealed.
21 U.S.C. 1164	Previously repealed.
21 U.S.C. 1165	Previously repealed.
21 U.S.C. 1171	21 U.S.C. 60303
21 U.S.C. 1172	Previously repealed.
21 U.S.C. 1173(a)	Previously renumbered and transferred to 42 U.S.C. 290aa–2(e), and subsequently repealed.
21 U.S.C. 1173(b)	Repealed as obsolete. Provided that the Secretary of Health, Education, and Welfare carry out the functions under subsection (a) of section 406 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1173(a)) through the National Institute on Drug Abuse. Subsection (a) of that section was previously renumbered and subsequently repealed.
21 U.S.C. 1174	Previously renumbered and transferred to 42 U.S.C. 290ee–2, and then omitted as part of a general amendment.
21 U.S.C. 1175	Previously renumbered and transferred to 42 U.S.C. 290ee–3, and then omitted as part of a general amendment.
21 U.S.C. 1176	Previously repealed.
21 U.S.C. 1177 (except (b), (g)(3)(B))	21 U.S.C. 60304

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 1177(b)	Repealed as obsolete. Authorized appropriations for fiscal years 1972 through 1982 relating to drug abuse.
21 U.S.C. 1177(g)(3)(B)	Repealed as obsolete. Provided that for purposes of paragraph (3) of section 410(g) of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1177(g)(3)), no grant or contract shall be considered to have been made under the section for a fiscal year ending before September 30, 1981.
21 U.S.C. 1178	21 U.S.C. 60305
21 U.S.C. 1179	Repealed as obsolete. Provided for the establishment of a National Drug Abuse Training Center to develop, conduct, and support a full range of training programs relating to drug abuse prevention functions and authorized appropriations for carrying out section 412 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1179) for fiscal years 1972 through 1975.
21 U.S.C. 1180	Previously renumbered and transferred to 42 U.S.C. 290ee–1, and then omitted as part of a general amendment.
21 U.S.C. 1181	21 U.S.C. 60306
21 U.S.C. 1191	Previously renumbered and transferred to 42 U.S.C. 290aa–2(a) through (d), and subsequently repealed.
21 U.S.C. 1192	Previously renumbered and transferred to 42 U.S.C. 290ee, and then omitted as part of a general amendment.
21 U.S.C. 1193	Previously renumbered and transferred to 42 U.S.C. 290cc, and subsequently repealed.
21 U.S.C. 1194	Previously repealed.
21 U.S.C. 1201	Previously repealed.
21 U.S.C. 1202	Previously repealed.
21 U.S.C. 1203	Previously repealed.
21 U.S.C. 1204	Previously repealed.
21 U.S.C. 1301	Not repealed but omitted from the text of title 21. Establishes the President's Media Commission on Alcohol and Drug Abuse Prevention.
21 U.S.C. 1302	Not repealed but omitted from the text of title 21. Provides for the duties of the President's Media Commission on Alcohol and Drug Abuse Prevention.
21 U.S.C. 1303	Not repealed but omitted from the text of title 21. Requires appointment of members of the President's Media Commission on Alcohol and Drug Abuse Prevention within 30 days after October 27, 1986, and provides for the membership requirements of the Commission.
21 U.S.C. 1304	Not repealed but omitted from the text of title 21. Provides for the order of meetings of the President's Media Commission on Alcohol and Drug Abuse Prevention.
21 U.S.C. 1305	Not repealed but omitted from the text of title 21. Provides for the employment of Director and staff and the procurement of the services of experts and consultants.
21 U.S.C. 1306	Not repealed but omitted from the text of title 21. Provides for the authorities of the President's Media Commission on Alcohol and Drug Abuse Prevention.
21 U.S.C. 1307	Not repealed but omitted from the text of title 21. Requires an annual report to Congress.
21 U.S.C. 1308	Not repealed but omitted from the text of title 21. Provides for the termination of the President's Media Commission on Alcohol and Drug Abuse Prevention 3 years after the date on which members of the Commission were first appointed unless the President extended the

Former United States Code Section	Disposition
	authority of the Commission by Executive order.
21 U.S.C. 1401	21 U.S.C. 31901
21 U.S.C. 1402(a) through (c)	21 U.S.C. 31902
21 U.S.C. 1402(d)	Not repealed but omitted from the text of title 21. Provides that not later than August 23, 1989, the Secretary of Health and Human Services shall report to certain congressional committees on the activities undertaken by the Secretary to implement this section 4703 of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1402) and that the report shall be made available to appropriate Federal and State agencies and to interested persons.
21 U.S.C. 1403 (except matter after (2))	21 U.S.C. 31903
21 U.S.C. 1403 (matter after (2))	Not repealed but omitted from the text of title 21. Provides that the Secretary of Health and Human Services shall report the plan developed under section 4704(1) of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1403(1)), the resources necessary to carry out the research described in the provision, recommendations for the implementation of the research, and the result of the review conducted under section 4704(2) of the Act (21 U.S.C. 1403(2)) not later than the expiration of 240 days after August 23, 1988, to certain congressional committees.
21 U.S.C. 1501	Previously repealed.
21 U.S.C. 1502	Previously repealed.
21 U.S.C. 1502a	Previously transferred to 21 U.S.C. 1505 and subsequently repealed.
21 U.S.C. 1503	Previously repealed.
21 U.S.C. 1504	Previously repealed.
21 U.S.C. 1505	Previously repealed.
21 U.S.C. 1505a	21 U.S.C. 69912
21 U.S.C. 1506	Previously repealed.
21 U.S.C. 1507	Previously repealed.
21 U.S.C. 1508	Previously repealed.
21 U.S.C. 1509	Previously repealed.
21 U.S.C. 1521	Not repealed but omitted from the text of title 21. Provides a statement of findings for chapter 2 of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1521 et seq.).
21 U.S.C. 1521 note (Pub. L. 107–82, §4)	21 U.S.C. 60701
21 U.S.C. 1521 note (Pub. L. 107–82, §5)	21 U.S.C. 60702
21 U.S.C. 1522	21 U.S.C. 60502
21 U.S.C. 1523 (except (2))	21 U.S.C. 60501
21 U.S.C. 1523(2)	Repealed as obsolete. Provided a definition of the term "Advisory Commission". The provision is obsolete because provisions relating to the Advisory Commission (which provisions were enacted as subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988, as added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224)) were repealed by section 8203(b)(5) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4112).
21 U.S.C. 1524	21 U.S.C. 60503
21 U.S.C. 1531	21 U.S.C. 60511
21 U.S.C. 1532	21 U.S.C. 60512
21 U.S.C. 1533	21 U.S.C. 60513
21 U.S.C. 1534	21 U.S.C. 60514
21 U.S.C. 1535	21 U.S.C. 60515
21 U.S.C. 1536 (except (a)(3))	21 U.S.C. 60703
21 U.S.C. 1536(a)(3)	Repealed as unnecessary. Provided a definition of “Drug-Free Communities Act of 1997” which is

Disposition Table

Former United States Code Section	Disposition
	made unnecessary by the substitution in section 60703 of title 21, United States Code, of "chapter 605 of this title" for "Drug-Free Communities Act of 1997".
21 U.S.C. 1541	Previously repealed.
21 U.S.C. 1542	Previously repealed.
21 U.S.C. 1543	Previously repealed.
21 U.S.C. 1544	Previously repealed.
21 U.S.C. 1545	Previously repealed.
21 U.S.C. 1546	Previously repealed.
21 U.S.C. 1547	Previously repealed.
21 U.S.C. 1548	Previously repealed.
21 U.S.C. 1601	Not repealed but omitted from the text of title 21. Provides a statement of findings for the Biomaterials Access Assurance Act of 1998 (21 U.S.C. 1601 et seq.).
21 U.S.C. 1602	21 U.S.C. 40501
21 U.S.C. 1603	21 U.S.C. 40502
21 U.S.C. 1604	21 U.S.C. 40503
21 U.S.C. 1605	21 U.S.C. 40504
21 U.S.C. 1606	21 U.S.C. 40505
21 U.S.C. 1701	21 U.S.C. 60901
21 U.S.C. 1702	21 U.S.C. 60902(a) through (c)
21 U.S.C. 1702 note (Pub. L. 117–328, div. E, title II, proviso under heading "SALARIES AND EXPENSES", under heading "OFFICE OF NATIONAL DRUG CONTROL POLICY")	21 U.S.C. 60902(d)
21 U.S.C. 1703	21 U.S.C. 60903
21 U.S.C. 1704	21 U.S.C. 60904
21 U.S.C. 1705	21 U.S.C. 60905
21 U.S.C. 1706(a)(1) (parenthetical)	21 U.S.C. 60906(a)(2)
21 U.S.C. 1706(k)(1)	Repealed as obsolete. Provided that not later than 90 days after December 29, 2006, the Director shall submit a report to Congress that describes, for each designated high intensity drug trafficking area ("HIDTA"), the specific purposes for the HIDTA, the specific goals and objectives for the HIDTA, the measurements that will be used to evaluate the performance of the HIDTA in achieving the goals, and the reporting requirements needed to evaluate the performance of the HIDTA in achieving the goals.
21 U.S.C. 1706(except (a)(1) (parenthetical), (k)(1))	21 U.S.C. 60906(b) through (t)
21 U.S.C. 1707	Previously repealed.
21 U.S.C. 1708	21 U.S.C. 60907
21 U.S.C. 1708 note (Pub. L. 117–99, §1)	Repealed as unnecessary. Provided a short title for the Methamphetamine Response Act of 2021 (Public Law 117–99, 21 U.S.C. 1708 note).
21 U.S.C. 1708 note (Pub. L. 117–99, §2)	21 U.S.C. 69924
21 U.S.C. 1708a	Previously repealed.
21 U.S.C. 1709	Previously repealed.
21 U.S.C. 1710	21 U.S.C. 60908
21 U.S.C. 1710a(a)	21 U.S.C. 60909(b)
21 U.S.C. 1710a(b)	21 U.S.C. 60909(a)
21 U.S.C. 1711	21 U.S.C. 60910
21 U.S.C. 1712	Previously repealed.
21 U.S.C. 1713	21 U.S.C. 69913
21 U.S.C. 1714(a), (b)	21 U.S.C. 60911(b), (c)
21 U.S.C. 1714(c)	21 U.S.C. 60911(a)
21 U.S.C. 1714(d)	Not repealed but omitted from the text of title 21. Provides that not later than June 1, 2009, the Director shall submit to Congress a report that identifies the best practices in reducing the use of illicit drugs by chronic hard-drug users, and

Former United States Code Section	Disposition
	not later than June 1, 2010, the Director shall submit to Congress a report on the demonstration programs funded under section 716 of the Office of National Drug Control Policy Reauthorization Act of 1988 (21 U.S.C. 1714).
21 U.S.C. 1714(e)	Repealed as obsolete. Authorized to be appropriated $4,900,000 to carry out section 716 of the Office of National Drug Control Policy Reauthorization Act of 1988 (21 U.S.C. 1714) for each of fiscal years 2007 through 2009.
21 U.S.C. 1715	21 U.S.C. 69922
21 U.S.C. 1801	Previously repealed.
21 U.S.C. 1802	Previously repealed.
21 U.S.C. 1803	Previously repealed.
21 U.S.C. 1804	Previously repealed.
21 U.S.C. 1901(a)	Not repealed but omitted from the text of title 21. Provides a statement of findings for the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1901 et seq.).
21 U.S.C. 1901(b)	21 U.S.C. 61102
21 U.S.C. 1902	21 U.S.C. 61103
21 U.S.C. 1903	21 U.S.C. 61104
21 U.S.C. 1904	21 U.S.C. 61105
21 U.S.C. 1905	21 U.S.C. 61106
21 U.S.C. 1906	21 U.S.C. 61107
21 U.S.C. 1907(1)	21 U.S.C. 61101(2)
21 U.S.C. 1907(2)	21 U.S.C. 61101(3)
21 U.S.C. 1907(3)	21 U.S.C. 61101(6)
21 U.S.C. 1907(4) (relating to controlled substance)	21 U.S.C. 61101(1)
21 U.S.C. 1907(4) (relating to listed chemical)	21 U.S.C. 61101(4)
21 U.S.C. 1907(4) (relating to narcotic drug)	21 U.S.C. 61101(5)
21 U.S.C. 1907(5)	21 U.S.C. 61101(7)
21 U.S.C. 1907(6)	21 U.S.C. 61101(9)
21 U.S.C. 1907(7)	21 U.S.C. 61101(8)
21 U.S.C. 1908	Not repealed but omitted from the text of title 21. Provides for the establishment, membership, duties, authorities, and termination of the Judicial Review Commission on Foreign Asset Control.
21 U.S.C. 2001(a) (matter before (1))	21 U.S.C. 61501 (matter before (1))
21 U.S.C. 2001(a)(1)	21 U.S.C. 61501(3)
21 U.S.C. 2001(a)(2)	21 U.S.C. 61501(2)
21 U.S.C. 2001(a)(3)	21 U.S.C. 61501(1)
21 U.S.C. 2001(b), (c)	21 U.S.C. 61502
21 U.S.C. 2002	21 U.S.C. 61503
21 U.S.C. 2003	21 U.S.C. 61504
21 U.S.C. 2004	21 U.S.C. 69925
21 U.S.C. 2011	21 U.S.C. 61701
21 U.S.C. 2012	21 U.S.C. 61702
21 U.S.C. 2013	21 U.S.C. 61703
21 U.S.C. 2014	Repealed as obsolete. Authorized appropriations for the National Methamphetamine Advisory Council and the National Methamphetamine Information Clearinghouse for fiscal years 2007 through 2009.
21 U.S.C. 2101	Not repealed but omitted from the text of title 21. Provides a statement of findings for title X of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 2101 et seq.).
21 U.S.C. 2102	21 U.S.C. 32301
21 U.S.C. 2103	21 U.S.C. 32302
21 U.S.C. 2104	21 U.S.C. 32303

Disposition Table

Former United States Code Section	Disposition
21 U.S.C. 2105(a)	Not repealed but omitted from the text of title 21. Provides a statement of findings for section 1006 of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 2105).
21 U.S.C. 2105(b)	21 U.S.C. 32304(a)
21 U.S.C. 2105(c)	Not repealed but omitted from the text of title 21. Requires the Secretary of Health and Human Services to submit to Congress a report describing the aquaculture and seafood inspection program, describing the feasibility of developing a traceability system for all catfish and seafood products, and providing for an assessment of the risks associated with particular contaminants and banned substances.
21 U.S.C. 2105(d)	21 U.S.C. 32304(b)
21 U.S.C. 2105 note (Pub. L. 116–260, div. A, title VII, §787)	21 U.S.C. 39903
21 U.S.C. 2106	21 U.S.C. 32305
21 U.S.C. 2107	Not repealed but omitted from the text of title 21. Provides a sense of Congress relating to food safety, including the provision of additional resources to the Food and Drug Administration and the prioritization of entering into agreements with the trading partners of the United States with respect to food safety.
21 U.S.C. 2108	21 U.S.C. 32306
21 U.S.C. 2109	21 U.S.C. 32307
21 U.S.C. 2110	21 U.S.C. 32308(a)
21 U.S.C. 2110 note (Pub. L. 110–85, title X, §1005(g))	21 U.S.C. 32308(b)
21 U.S.C. 2201	21 U.S.C. 32511
21 U.S.C. 2202	21 U.S.C. 32512
21 U.S.C. 2203	21 U.S.C. 32513
21 U.S.C. 2204	21 U.S.C. 32514
21 U.S.C. 2205(a)(1)	21 U.S.C. 32515(a)(1)
21 U.S.C. 2205(a)(2) (relating to elementary school)	21 U.S.C. 32515(a)(2)
21 U.S.C. 2205(a)(2) (relating to local education agency)	21 U.S.C. 32515(a)(3)
21 U.S.C. 2205(a)(2) (relating to parent)	21 U.S.C. 32515(a)(4)
21 U.S.C. 2205(a)(2) (relating to secondary school)	21 U.S.C. 32515(a)(6)
21 U.S.C. 2205(a)(3)	21 U.S.C. 32515(a)(5)
21 U.S.C. 2205(a)(4)	Repealed as unnecessary. Provided a definition of "Secretary" that is made unnecessary by the parenthetical "(referred to in this chapter as the `Secretary')" in section 32511(a) of title 21, United States Code.
21 U.S.C. 2205(b)	21 U.S.C. 32515(b)
21 U.S.C. 2205(c) (except (12))	21 U.S.C. 32515(c)
21 U.S.C. 2205(c)(12)	Repealed as obsolete. Authorized to be appropriated, to carry out subsection (c) of section 112 of the FDA Food Safety Modernization Act (21 U.S.C. 2205(c)), $30,000,000 for fiscal year 2011 and such sums as may be necessary for each of the 4 succeeding fiscal years.
21 U.S.C. 2205(d)	21 U.S.C. 32515(d)
21 U.S.C. 2206	21 U.S.C. 32516
21 U.S.C. 2221	21 U.S.C. 32531
21 U.S.C. 2222	21 U.S.C. 32532
21 U.S.C. 2223	21 U.S.C. 32533
21 U.S.C. 2224(a)	21 U.S.C. 32501
21 U.S.C. 2224(b)(1), (2)	21 U.S.C. 32534(a)
21 U.S.C. 2224(b)(3)	Repealed as obsolete. Authorized to be appropriated, to carry out the activities described in paragraph (1) of section 205(b) of the FDA Food Safety Modernization Act (21

Former United States Code Section	Disposition
	U.S.C. 2224(b)), restated as paragraph (1) of section 32534(a) of title 21, United States Code, $24,000,000 for each of fiscal years 2011 through 2015.
21 U.S.C. 2224(c)	21 U.S.C. 32534(b)
21 U.S.C. 2225	21 U.S.C. 32535
21 U.S.C. 2241	21 U.S.C. 32551
21 U.S.C. 2242(a), (b)	21 U.S.C. 32552
21 U.S.C. 2242(c)	Repealed as obsolete. Provided that not later than October 1, 2011, the Secretary of Health and Human Services shall submit to Congress a report relating to the offices in foreign countries established by the Food and Drug Administration.
21 U.S.C. 2243(a) through (d)	21 U.S.C. 32553(b) through (e)
21 U.S.C. 2243(e)	21 U.S.C. 32553(a)
21 U.S.C. 2251	21 U.S.C. 32561
21 U.S.C. 2252	21 U.S.C. 32562
21 U.S.C. 2301	Not repealed but omitted from the text of title 21. Provides a sense of Congress relating to the application of economic and other financial sanctions to foreign traffickers of illicit opioids.
21 U.S.C. 2302(1) (relating to "alien")	21 U.S.C. 61901(1)
21 U.S.C. 2302(1) (relating to "national")	21 U.S.C. 61901(10)
21 U.S.C. 2302(1) (relating to "national of the United States")	21 U.S.C. 61901(11)
21 U.S.C. 2302(2)	21 U.S.C. 61901(2)
21 U.S.C. 2302(3) (relating to "controlled substance")	21 U.S.C. 61901(3)
21 U.S.C. 2302(3) (relating to "listed chemical")	21 U.S.C. 61901(8)
21 U.S.C. 2302(3) (relating to "narcotic drug")	21 U.S.C. 61901(9)
21 U.S.C. 2302(3) (relating to "opioid")	21 U.S.C. 61901(12)
21 U.S.C. 2302(4)	21 U.S.C. 61901(4)
21 U.S.C. 2302(5)	21 U.S.C. 61901(5)
21 U.S.C. 2302(6)	21 U.S.C. 61901(6)
21 U.S.C. 2302(7)	21 U.S.C. 61901(7)
21 U.S.C. 2302(8)	21 U.S.C. 61901(13)
21 U.S.C. 2302(9)	21 U.S.C. 61901(14)
21 U.S.C. 2302(10)	21 U.S.C. 61901(15)
21 U.S.C. 2311	21 U.S.C. 61911
21 U.S.C. 2312	21 U.S.C. 61912
21 U.S.C. 2313	21 U.S.C. 61913
21 U.S.C. 2313a	21 U.S.C. 61914
21 U.S.C. 2314	21 U.S.C. 61915
21 U.S.C. 2315	21 U.S.C. 61916
21 U.S.C. 2316	21 U.S.C. 61917
21 U.S.C. 2331(a), (b)	21 U.S.C. 61931(b), (c)
21 U.S.C. 2331(c)(1)(A) (1st sentence)	21 U.S.C. 61931(d)(1)(A)
21 U.S.C. 2331(c)(1)(A) (last sentence)	Repealed as obsolete. Provided that the first report under section 7231(c)(1)(A) of the Fentanyl Sanctions Act (21 U.S.C. 2331(c)(1)(A)) shall include a description of the amount of funds devoted by the intelligence community to the efforts described in subsection section 7231(a) of that Act (21 U.S.C. 2331(a)) during each of fiscal years 2017 and 2018.
21 U.S.C. 2331(c)(1)(B)	21 U.S.C. 61931(d)(1)(B)
21 U.S.C. 2331(c)(2)	21 U.S.C. 61931(d)(2)
21 U.S.C. 2331(d)	21 U.S.C. 61931(a)
21 U.S.C. 2332(a)	21 U.S.C. 61932(b)
21 U.S.C. 2332(b)	Repealed as unnecessary. Provided that of the amount authorized to be appropriated by section 1403 of the National Defense Authorization Act for Fiscal Year 2020 (Public Law 116–92, 133 Stat. 1711) for fiscal year

Disposition Table

Former United States Code Section	Disposition
	2020 and available for Drug Interdiction and Counter-Drug Activities, Defense-wide, as specified in the funding table in section 4501 of that Act (Public Law 116–92, 133 Stat. 2086), 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 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2270) in order to carry out the duties of the Commission. See section 4(32)(B)(iii) of the bill enacting title 21, United States Code; that section amends section 7221 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2270) to add a provision that tracks the language of section 7232(b) of the Act (21 U.S.C. 2332(b)).
21 U.S.C. 2332(c)	21 U.S.C. 61932(c)
21 U.S.C. 2332(d)	21 U.S.C. 61932(d)
21 U.S.C. 2332(e)	21 U.S.C. 61932(a)
21 U.S.C. 2333	21 U.S.C. 61933
21 U.S.C. 2334	21 U.S.C. 61934
21 U.S.C. 2335(a)	21 U.S.C. 61935(b)
21 U.S.C. 2335(b)	21 U.S.C. 61935(a)
21 U.S.C. 2341	21 U.S.C. 62301
21 U.S.C. 2351(a)	Not repealed but omitted from the text of title 21.
21 U.S.C. 2351(b)	21 U.S.C. 62311
21 U.S.C. 2352	21 U.S.C. 62312
21 U.S.C. 2353	21 U.S.C. 62313
21 U.S.C. 2354	21 U.S.C. 62314
21 U.S.C. 2355(a)(1), (2)	21 U.S.C. 62315(a)(2), (3)
21 U.S.C. 2355(a)(3)	21 U.S.C. 62315(a)(1)
21 U.S.C. 2355(b)	21 U.S.C. 62315(b)
21 U.S.C. 2361	21 U.S.C. 62331
21 U.S.C. 2371(a)	21 U.S.C. 62341(b)
21 U.S.C. 2371(b)	21 U.S.C. 62341(a)
21 U.S.C. 2401	21 U.S.C. 62101
21 U.S.C. 2402	21 U.S.C. 62102
21 U.S.C. 2403	21 U.S.C. 62103
21 U.S.C. 2404	21 U.S.C. 62104
42 U.S.C. 241 note (Pub. L. 117–215, title I, §106)	21 U.S.C. 41513
42 U.S.C. 242r(a)	21 U.S.C. 32103
42 U.S.C. 242r(b)	Repealed as unnecessary. Authorized to be appropriated such sums as may be necessary for the purpose of carrying out section 207 of the Food Allergen Labeling and Consumer Protection Act of 2004 (21 U.S.C. 242r).
42 U.S.C. 280g–7b(a) (except "(referred to in this section as the `Secretary')", "(to be known and referred to in this section as the `Partnership')")	21 U.S.C. 41302(b)
42 U.S.C. 280g–7b(a) ("(referred to in this section as the `Secretary')")	21 U.S.C. 41302(a)(3)
42 U.S.C. 280g–7b(a) ("(to be known and referred to in this section as the `Partnership')")	21 U.S.C. 41302(a)(2)
42 U.S.C. 280g–7b(b)	21 U.S.C. 41302(a)(1)
42 U.S.C. 280g–7b(c)	21 U.S.C. 41302(c)
42 U.S.C. 284 note (Pub. L. 117–215, title IV, §401)	21 U.S.C. 41541

SECTION-BY-SECTION EXPLANATION

SECTION 1—TABLE OF CONTENTS

Section 1 of the bill provides a table of contents for the Act.

SECTION 2—PURPOSE; RESTATEMENT DOES NOT CHANGE MEANING OR EFFECT OF EXISTING LAW

Section 2(a) of the bill provides that the purpose is to enact a restatement of existing law relating to food and drugs as a positive law title of the United States Code.

Section 2(b)(1) of the bill provides that the restatement of existing law does not change the meaning or effect of the existing law (see explanation above, under the heading "Restatement Does Not Change Meaning or Effect of Existing Law").

Section 2(b)(2) of the bill creates a rule of construction to provide that, notwithstanding the plain meaning rule or other rules of statutory construction, a change in wording made in the restatement of existing law serves to clarify the existing law, but not to change the meaning or effect of the existing law. This rule of construction applies whether or not a change in wording is explained by a revision note appearing in a congressional report accompanying the bill. The bill provides that if such a revision note does appear, a court is required to consider the revision note in interpreting the change.

SECTION 3—ENACTMENT OF TITLE 21, UNITED STATES CODE

Section 3 of the bill enacts title 21, United States Code. For each section of title 21, United States Code, the source law citations, along with any revision notes, are set out below. In the revision notes, where language is quoted from a source provision, the enacted language, as it appears in the Statutes at Large rather than in the United States Code, is shown.

SOURCE LAW CITATION TABLES AND REVISION NOTES

TITLE 21—FOOD AND DRUGS

The following revisions are made throughout the title:

The word "may" is substituted for "is authorized to" and words of like import to eliminate unnecessary words, for clarity, and for consistency in title 21, United States Code.

The word "shall" is substituted for "is authorized and directed to" and words of like import to eliminate unnecessary words, for clarity, and for consistency in title 21, United States Code.

Subtitle I—Federal Food, Drug, and Cosmetic Provisions

Division A—General Provisions

Chapter 101—Definitions Applicable to Subtitle

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10101(a)(1)	21 U.S.C. 321(aa)	June 25, 1938, ch. 675, §201(aa), formerly §201(bb), as added Pub. L. 102–282, §6, May 13, 1992, 106 Stat. 161; redesignated §201(aa), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775; Pub. L. 105–115, title I, §125(b)(2)(A), Nov. 21, 1997, 111 Stat. 2325.
10101(a)(2)	21 U.S.C. 321(hh)	June 25, 1938, ch. 675, §201(hh), as added Pub. L. 104–170, title IV, §402(c), Aug. 3, 1996, 110 Stat. 1513.
10101(a)(3)	21 U.S.C. 321(w)	June 25, 1938, ch. 675, §201(w), formerly §201(x), as added Pub. L. 90–399, §102(e), July 13, 1968, 82 Stat. 351; redesignated §201(w), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(a)(4)(A)	21 U.S.C. 321(jj) (except 1st parenthetical)	June 25, 1938, ch. 675, §201(jj) (except 1st parenthetical), as added Pub. L. 105–115, title I, §125(e), Nov. 21, 1997, 111 Stat. 2327.
10101(a)(4)(B)	21 U.S.C. 321(jj) (1st parenthetical)	June 25, 1938, ch. 675, §201(jj) (1st parenthetical), as added Pub. L. 105–115, title I, §125(e), Nov. 21, 1997, 111 Stat. 2327.
10101(a)(5)	21 U.S.C. 321a	Mar. 4, 1923, ch. 268, 42 Stat. 1500.
10101(a)(6)	21 U.S.C. 321(t)(2)	June 25, 1938, ch. 675, §201(t)(2), as added Pub. L. 86–618, title I, §101(c), July 12, 1960, 74 Stat. 397.
10101(a)(7)	21 U.S.C. 321(t)(1), (3)	June 25, 1938, ch. 675, §201(t)(1), (3), as added Pub. L. 86–618, title I, §101(c), July 12, 1960, 74 Stat. 397.
10101(a)(8)	21 U.S.C. 321(ee)	June 25, 1938, ch. 675, §201(ee), formerly §201(ff), as added Pub. L. 102–300, §6(a)(2), June 16, 1992, 106 Stat. 240; redesignated §201(ee), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(a)(9)	21 U.S.C. 321(ii)	June 25, 1938, ch. 675, §201(ii), as added Pub. L. 105–115, title I, §121(a), Nov. 21, 1997, 111 Stat. 2320.
10101(a)(10)	21 U.S.C. 321(i)	June 25, 1938, ch. 675, §201(i), 52 Stat. 1041.
10101(a)(11)	21 U.S.C. 321(h)(2)	June 25, 1938, ch. 675, §201(h)(2), as added Pub. L. 116–304, §2(b)(2)(B), Jan. 5, 2021, 134 Stat. 4916.
10101(a)(12)	21 U.S.C. 321(g)(2)	June 25, 1938, ch. 675, §201(g)(2), 52 Stat. 1041; Pub. L. 89–74, §9(b), July 15, 1965, 79 Stat. 234.
10101(a)(13)	21 U.S.C. 321(ss)	June 25, 1938, ch. 675, §201(ss), as added Pub. L. 117–328, div. FF, title III, §3401(a)(2), Dec. 29, 2022, 136 Stat. 5838.
10101(a)(14)	21 U.S.C. 321(mm)(1)	June 25, 1938, ch. 675, §201(mm)(1), as added Pub. L. 107–250, title III, §302(d), Oct. 26, 2002, 116 Stat. 1619.
10101(a)(15)	21 U.S.C. 321(c)	June 25, 1938, ch. 675, §201(c), 52 Stat. 1040; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779.
10101(a)(16)	21 U.S.C. 321(h)(1)	June 25, 1938, ch. 675, §201(h)(1), 52 Stat. 1041; Pub. L. 94–295, §3(a)(1)(A), May 28, 1976, 90 Stat. 575; Pub. L. 101–629, §16(b)(2), Nov. 28, 1990, 104 Stat. 4526; Pub. L. 102–300, §6(a)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §4(b), Aug. 13, 1993, 107 Stat. 779; Pub. L. 114–255, div. A, title III, §3060(d), Dec. 13, 2016, 130 Stat. 1133; Pub. L. 116–304, §2(b)(1), (2)(A), Jan. 5, 2021, 134 Stat. 4916.
10101(a)(17)	21 U.S.C. 321(ff)	June 25, 1938, ch. 675, §201(ff), as added Pub. L. 103–417, §3(a), Oct. 25, 1994, 108 Stat. 4327; Pub. L. 105–115, title I, §125(b)(2)(A), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 110–85, title X, §1005(c), Sept. 27, 2007, 121 Stat. 968.
10101(a)(18)	21 U.S.C. 321(g)(1)	June 25, 1938, ch. 675, §201(g)(1), 52 Stat. 1041; Pub. L. 89–74, §9(b), July 15, 1965, 79 Stat. 234; Pub. L. 101–535, §5(b), Nov. 8, 1990, 104 Stat. 2362; Pub. L. 101–629, §16(b)(1), Nov. 28, 1990, 104 Stat. 4526; Pub. L. 103–417, §10(a), Oct. 25, 1994, 108 Stat. 4332.
10101(a)(19)	21 U.S.C. 321(f)	June 25, 1938, ch. 675, §201(f), 52 Stat. 1040.
10101(a)(20)	21 U.S.C. 321(s)	June 25, 1938, ch. 675, §201(s), as added Pub. L. 85–929, §2, Sept. 6, 1958, 72 Stat. 1784; Pub. L. 86–618, title I, §101(a), July 12, 1960, 74 Stat. 397; Pub. L. 90–399, §102(c), July 13, 1968, 82 Stat.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		351; Pub. L. 103–417, §3(b), Oct. 25, 1994, 108 Stat. 4327; Pub. L. 104–170, title IV, §402(b), Aug. 3, 1996, 110 Stat. 1513.
10101(a)(21)	21 U.S.C. 321(l)	June 25, 1938, ch. 675, §201(l), 52 Stat. 1041.
10101(a)(22)	21 U.S.C. 321(z)	June 25, 1938, ch. 675, §201(z), formerly §201(aa), as added Pub. L. 96–359, §3, Sept. 26, 1980, 94 Stat. 1193; redesignated §201(z), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(a)(23)	21 U.S.C. 321(x)	June 25, 1938, ch. 675, §201(x), formerly §201(y), as added Pub. L. 94–295, §3(a)(2), May 28, 1976, 90 Stat. 575; Pub. L. 102–300, §6(b)(2), June 16, 1992, 106 Stat. 240; redesignated §201(x), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(a)(24)	21 U.S.C. 321(b)	June 25, 1938, ch. 675, §201(b), 52 Stat. 1040.
10101(a)(25)	21 U.S.C. 321(bb) (relating to "knew")	June 25, 1938, ch. 675, §201(bb) (relating to "knew"), formerly §201(cc) (relating to "knew"), as added Pub. L. 102–282, §6, May 13, 1992, 106 Stat. 162; redesignated §201(bb) (relating to "knew"), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(a)(26)	21 U.S.C. 321(bb) (relating to "knowingly")	June 25, 1938, ch. 675, §201(bb) (relating to "knowingly"), formerly §201(cc) (relating to "knowingly"), as added Pub. L. 102–282, §6, May 13, 1992, 106 Stat. 162; redesignated §201(bb) (relating to "knowingly"), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(a)(27)	21 U.S.C. 321(k)	June 25, 1938, ch. 675, §201(k), 52 Stat. 1041.
10101(a)(28)	21 U.S.C. 321(m)	June 25, 1938, ch. 675, §201(m), 52 Stat. 1041.
10101(a)(29)	21 U.S.C. 321(qq)	June 25, 1938, ch. 675, §201(qq), as added Pub. L. 108–282, title II, §203(c)(1), Aug. 2, 2004, 118 Stat. 908; Pub. L. 117–11, §2(a), Apr. 23, 2021, 135 Stat. 262.
10101(a)(30)	21 U.S.C. 321(nn)	June 25, 1938, ch. 675, §201(nn), as added Pub. L. 108–282, title I, §102(b)(1), Aug. 2, 2004, 118 Stat. 891.
10101(a)(31)	21 U.S.C. 321(oo)	June 25, 1938, ch. 675, §201(oo), as added Pub. L. 108–282, title I, §102(b)(1), Aug. 2, 2004, 118 Stat. 891.
10101(a)(32)	21 U.S.C. 321(pp)	June 25, 1938, ch. 675, §201(pp), as added Pub. L. 108–282, title I, §102(b)(1), Aug. 2, 2004, 118 Stat. 891.
10101(a)(33)	21 U.S.C. 321(v)	June 25, 1938, ch. 675, §201(v), formerly §201(w), as added Pub. L. 90–399, §102(e), July 13, 1968, 82 Stat. 351; Pub. L. 100–670, title I, §107(a)(1), Nov. 16, 1988, 102 Stat. 3984; redesignated §201(v), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775; Pub. L. 108–282, title I, §102(b)(5)(B), Aug. 2, 2004, 118 Stat. 902.
10101(a)(34)	21 U.S.C. 321(p)	June 25, 1938, ch. 675, §201(p), 52 Stat. 1041; Pub. L. 87–781, title I, §102(a), Oct. 10, 1962, 76 Stat. 781; Pub. L. 90–399, §102, July 13, 1968, 82 Stat. 351.
10101(a)(35)	21 U.S.C. 321(j)	June 25, 1938, ch. 675, §201(j), 52 Stat. 1041.
10101(a)(36)	21 U.S.C. 321b	July 24, 1919, ch. 26, 13th paragraph after paragraph under heading "ERADICATION OF PINK BOLLWORM", 41 Stat. 271.
10101(a)(37)	21 U.S.C. 321(e)	June 25, 1938, ch. 675, §201(e), 52 Stat. 1040.
10101(a)(38)(A) through (D)	21 U.S.C. 321(q)(1)	June 25, 1938, ch. 675, §201(q)(1), as added July 22, 1954, ch. 559, §1, 68 Stat. 511; Pub. L. 92–516, §3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 104–170, title IV, §402(a), Aug. 3, 1996, 110 Stat. 1513; Pub. L. 105–324, §2(a), Oct. 30, 1998, 112 Stat. 3035.
10101(a)(38)(E)	21 U.S.C. 321(q)(3) (relating to subparagraph (1))	June 25, 1938, ch. 675, §201(q)(3) (relating to subparagraph (1)), as added July 22, 1954, ch. 559, §1, 68 Stat. 511; Pub. L. 92–516, §3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 104–170, title IV, §402(a), Aug. 3, 1996, 110 Stat. 1513; Pub. L. 105–324, §2(c), Oct. 30, 1998, 112 Stat. 3037.
10101(a)(39)(A)	21 U.S.C. 321(q)(2)	June 25, 1938, ch. 675, §201(q)(2), as added July 22, 1954, ch. 559, §1, 68 Stat. 511; Pub. L. 92–516, §3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 104–170, title IV, §402(a), Aug. 3, 1996, 110 Stat. 1513.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10101(a)(39)(B)	21 U.S.C. 321(q)(3) (relating to subparagraph (2))	June 25, 1938, ch. 675, §201(q)(3) (relating to subparagraph (2)), as added July 22, 1954, ch. 559, §1, 68 Stat. 511; Pub. L. 92–516, §3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 104–170, title IV, §402(a), Aug. 3, 1996, 110 Stat. 1513; Pub. L. 105–324, §2(c), Oct. 30, 1998, 112 Stat. 3037.
10101(a)(40)	21 U.S.C. 321(kk)	June 25, 1938, ch. 675, §201(kk), as added Pub. L. 107–109, §5(b)(1), Jan. 4, 2002, 115 Stat. 1413.
10101(a)(41)	21 U.S.C. 321(gg)	June 25, 1938, ch. 675, §201(gg), as added Pub. L. 104–170, title IV, §402(c), Aug. 3, 1996, 110 Stat. 1513.
10101(a)(42)	21 U.S.C. 321(r)	June 25, 1938, ch. 675, §201(r), as added July 22, 1954, ch. 559, §1, 68 Stat. 511.
10101(a)(43)	21 U.S.C. 321(y)	June 25, 1938, ch. 675, §201(y), formerly §201(z), as added Pub. L. 95–203, §4(b)(3), Nov. 23, 1977, 91 Stat. 1453; redesignated §201(y), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(a)(44)	21 U.S.C. 321(d)	June 25, 1938, ch. 675, §201(d), 52 Stat. 1040; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779.
10101(a)(45)	21 U.S.C. 321(mm)(2)	June 25, 1938, ch. 675, §201(mm)(2), as added Pub. L. 107–250, title III, §302(d), Oct. 26, 2002, 116 Stat. 1619.
10101(a)(46)	21 U.S.C. 321(ll)	June 25, 1938, ch. 675, §201(ll), as added Pub. L. 107–250, title III, §302(d), Oct. 26, 2002, 116 Stat. 1619.
10101(a)(47)	21 U.S.C. 321(a)(1)	June 25, 1938, ch. 675, §201(a)(1), 52 Stat. 1040; Pub. L. 87–781, title III, §307(a), Oct. 10, 1962, 76 Stat. 796.
10101(a)(48)	21 U.S.C. 321(a)(2)	June 25, 1938, ch. 675, §201(a)(2), 52 Stat. 1040; Pub. L. 87–781, title III, §307(a), Oct. 10, 1962, 76 Stat. 796; Pub. L. 90–639, §4(a), Oct. 24, 1968, 82 Stat. 1362; Pub. L. 91–513, title II, §701(g), Oct. 27, 1970, 84 Stat. 1282.
10101(a)(49) (except (B)(iii))	21 U.S.C. 321(rr)(1) through (4)	June 25, 1938, ch. 675, §201(rr), as added Pub. L. 111–31, div. A, title I, §101(a), June 22, 2009, 123 Stat. 1783; Pub. L. 117–103, div. P, title I, §111(a)(1), Mar. 15, 2022, 136 Stat. 789.
10101(a)(49)(B)(iii)	21 U.S.C. 321(rr)(5)	June 25, 1938, ch. 675, §201(rr), as added Pub. L. 117–103, div. P, title I, §111(a)(2), Mar. 15, 2022, 136 Stat. 789.
10101(b)(1)	21 U.S.C. 321(dd)	June 25, 1938, ch. 675, §201(dd), formerly §201(ee), as added Pub. L. 102–282, §6, May 13, 1992, 106 Stat. 161; redesignated §201(dd), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775; Pub. L. 105–115, title I, §125(b)(2)(A), Nov. 21, 1997, 111 Stat. 2325.
10101(b)(2)	21 U.S.C. 321(cc)	June 25, 1938, ch. 675, §201(cc), formerly §201(dd), as added Pub. L. 102–282, §6, May 13, 1992, 106 Stat. 162; redesignated §201(cc), Pub. L. 103–80, §3(b), Aug. 13, 1993, 107 Stat. 775.
10101(b)(3)	21 U.S.C. 321(u)	June 25, 1938, ch. 675, §201(u), formerly §201(t), as added Pub. L. 85–929, §2, Sept. 6, 1958, 72 Stat. 1784; redesignated §201(u), Pub. L. 86–618, title I, §101(b), July 12, 1960, 74 Stat. 397; Pub. L. 90–399, §102(d), July 13, 1968, 82 Stat. 351; Pub. L. 102–571, title I, §107(1), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 108–282, title I, §102(b)(5)(A), Aug. 2, 2004, 118 Stat. 902.
10101(c)(1)	21 U.S.C. 321(n)	June 25, 1938, ch. 675, §201(n), 52 Stat. 1041; Pub. L. 94–278, title V, §502(a)(2)(A), Apr. 22, 1976, 90 Stat. 411.
10101(c)(2)	21 U.S.C. 321(o)	June 25, 1938, ch. 675, §201(o), 52 Stat. 1041.

In subparagraphs (A) and (B) of subsection (a)(1), the words "the approved application" are substituted for the words "such an application" each place they appear for clarity.

In subsection (a)(3)(A)(i), the reference to paragraph (33) is substituted for the reference to paragraph (w) to provide the correct reference to the pertinent provision. The defined term "animal feed" appears in paragraph (v) of section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), which paragraph was formerly paragraph (w) of that section 201 prior to its redesignation as paragraph (v) by section 3(b) of the Nutrition Labeling and Education Act Amendments of 1993 (Public Law 103–80, 107 Stat. 775). Paragraph (v) of section 201 of the Act is restated as paragraph (33) of section 10101(a) of title 21, United States Code.

In subsection (a)(5), the definition of "butter", which was not originally enacted as part of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), is incorporated in this section on authority of section 1002(a), formerly section 902(a), of the Federal Food, Drug, and Cosmetic Act (ch. 675, 21 U.S.C. 301 note), which made the definition applicable to the Act.

In subsection (a)(7)(C), the words "by which growth or processes the color of the produce is affected" are substituted for "and thereby affecting its color" for clarity.

In subsection (a)(11)(A), the words "or any likeness of the trademark, trade name, or other identifying mark or imprint" are substituted for "or any likeness thereof" for clarity.

In subsection (a)(11)(A), the words "or persons" are omitted as unnecessary because of section 1 of title 1, United States Code.

In subsection (a)(11)(B), the words "by the unauthorized bearing described in subparagraph (A)," are substituted for "thereby" for clarity.

In subsection (a)(12)(A), the words "or any likeness of the trademark, trade name, or other identifying mark, imprint, or device" are substituted for "or any likeness thereof" for clarity.

In subsection (a)(12)(B), the words "by the unauthorized bearing described in subparagraph (A)," are substituted for "thereby" for clarity.

In subsection (a)(17)(A)(i), in the matter before subclause (I), the words "the following dietary ingredients" are omitted as unnecessary.

In subsection (a)(17)(A)(iii)(I), the words "prior to the approval or license," are substituted for "prior to such approval, certification, or license," for consistency in the subclause.

In subsection (a)(17)(A)(iii)(II)(aa)(AA), the words "certified as an antibiotic under section 507," are omitted as obsolete because of the repeal of the former section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), which section related to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, by section 125(b)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325).

In subsection (a)(17)(A)(iii)(II)(aa)(BB), the words "as a new drug or biologic" are substituted for "as a new drug, antibiotic, or biological" for consistency with subitem (AA).

In subsection (a)(17)(A)(iii)(II)(bb), the words "before the approval, licensing, or authorization under item (aa)" are substituted for "before such approval, certification, licensing, or authorization" for consistency with item (aa).

In subsection (a)(19)(B), in the matter after the semicolon, the word "or" is substituted for "and" for clarity.

In subsection (a)(19)(C), the words "any article under subparagraph (A) or (B)" are substituted for "any such article" for clarity.

In subsection (a)(24), the words "territory of the United States" are substituted for "Territory" each place it appears for consistency with the defined term "territory of the United States" in subsection (a)(48). See revision note for subsection (a)(48).

In subsection (a)(24)(A), in the matter after the semicolon, the word "or" is substituted for "and" for clarity.

In subsection (a)(25), in the matter before subparagraph (A), the defined term "know" is substituted for "knew" for consistency in title 21, United States Code.

In subsection (a)(25), in the matter before subparagraph (A), the words "means, with respect to a person that knows information, the person" are substituted for "means that a person, with respect to information" to make the definition consistent with the defined term.

In subsection (a)(26), in the matter before subparagraph (A), the words "means, with respect to a person's knowing of information, the person" are substituted for "means that a person, with respect to information" to make the definition consistent with the defined term.

In subsection (a)(29)(A), the words "or sesame" are substituted for "and sesame" for clarity.

In subsection (a)(30), the words "or cats" are substituted for "and cats" for clarity.

In subsection (a)(33)(A)(ii), the words "the conditions prescribed, recommended, or suggested in the labeling of the drug" are substituted for "such conditions" for clarity.

In subsection (a)(33)(A)(ii), the words "has become generally recognized as described in clause (i)" are substituted for "has become so recognized" for clarity.

In subsection (a)(34)(A)(ii), the words "the conditions prescribed, recommended, or suggested in the labeling of the drug" are substituted for "such conditions" for clarity.

In subsection (a)(34)(A)(ii), the words "has become generally recognized as described in clause (i)" are substituted for "has become so recognized" for clarity.

In subsection (a)(36), the definition of "package", which was not originally enacted as part of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et

seq.), is incorporated in this section on authority of section 1002(a), formerly section 902(a), of the Federal Food, Drug, and Cosmetic Act (ch. 675, 21 U.S.C. 301 note), which made the definition applicable to the Act. The matter beginning with the words "where it occurs" and ending with the words "approved March 3, 1913," is omitted as obsolete because that matter applied the definition to the Act of June 30, 1906 (ch. 3915, 34 Stat. 768), which was repealed by section 1002(a), formerly section 902(a), of the Federal Food, Drug, and Cosmetic Act (ch. 675, 21 U.S.C. 301 note).

In subsection (a)(36), the word "includes" is substituted for "shall include and shall be construed to include" to eliminate unnecessary words.

In subsection (a)(36), the words "of the wrapped meat" are substituted for "thereof" for clarity.

In subsection (a)(46)(A)(ii), the words "for use" are added for clarity.

In subsection (a)(47), the words "or Puerto Rico" are substituted for "and the Commonwealth of Puerto Rico" for clarity.

In subsection (a)(48), the defined term "territory of the United States" is substituted for "Territory" for clarity and consistency in title 21, United States Code. Throughout the subtitle, the term "territory of the United States" is substituted for "Territory", "territory", and words of like import, as appropriate, for consistency with the defined term, in the subtitle, and in title 21, United States Code, and for clarity.

In subsection (a)(48), the words "and the Canal Zone" are omitted as obsolete.

In subsection (a)(49)(B)(i), the words "a device under paragraph (16)" are substituted for "a device under subsection (h)" to provide a more precise reference to the pertinent provision.

In subsection (a)(49)(B)(ii), the words "The articles described" are substituted for "The products described" for consistency with clause (i).

In subsection (b)(2)(B), in the matter before clause (i), the words "includes individuals" are substituted for "includes persons" for consistency with subparagraph (A) and with the definition of "person" in subsection (a)(37) of section 10101 of title 21, United States Code.

In subsection (c)(1)(A)(ii), the words "any combination of statement, word, design, or device" are substituted for "any combination thereof" for clarity.

In subsection (c)(1)(B)(ii)(I), the words "in the labeling or advertising of the article" are substituted for "in the labeling or advertising thereof" for clarity.

SECTION 10102—NONFAT DRY MILK

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10102	21 U.S.C. 321c	Mar. 2, 1944, ch. 77, 58 Stat. 108; July 2, 1956, ch. 495, 70 Stat. 486.

In subsection (b), in the matter before paragraph (1), the words "For the purposes of this subtitle" are substituted for "That for the purposes of the Federal Food, Drug, and Cosmetic Act of June 26, 1938, (ch. 675, sec. 1, 52 Stat. 1040),"

because of the incorporation of the provision in subtitle I of title 21, United States Code, which restates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SECTION 10103—MARKET NAMES FOR CATFISH AND GINSENG

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10103(a)	21 U.S.C. 321d(a)(1)	Pub. L. 107–171, title X, § 10806(a)(1), May 13, 2002, 116 Stat. 526.
10103(b)	21 U.S.C. 321d(b)(1)	Pub. L. 107–171, title X, §10806(b)(1), May 13, 2002, 116 Stat. 526.

SECTION 10104—FDA AND FDA WEBSITE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10104	(no source)	

This section is added for convenience. Throughout the subtitle, the defined term "FDA" is substituted for "Food and Drug Administration" and "Administration" (where "Administration" refers to the Food and Drug Administration) each place they appear and the defined term "FDA website" is substituted for "Internet website of the Food and Drug Administration" and words of like import each place they appear because of the addition of this section.

Chapter 103—Food and Drug Administration

Subchapter I—Establishment

SECTION 10301—FOOD AND DRUG ADMINISTRATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10301	21 U.S.C. 393	June 25, 1938, ch. 675, §1003, formerly §903, as added Pub. L. 100–607, title V, §503(a), Nov. 4, 1988, 102 Stat. 3121; Pub. L. 100–690, title II, §2631, Nov. 18, 1988, 102 Stat. 4244; Pub. L. 105–115, title IV, §§406, 414, Nov. 21, 1997, 111 Stat. 2369, 2377; redesignated §1003, Pub. L. 111–31, div. A, title I, §§101(b)(2), 103(m), June 22, 2009, 123 Stat. 1784, 1838; Pub. L. 111–353, title II, §201(b), Jan. 4, 2011, 124 Stat. 3925.

In subsection (a), the parenthetical "(hereinafter in this section referred to as the `Administration')" is omitted as unnecessary because of the definition of "FDA" in section 10104 of title 21, United States Code.

In subsection (d)(1), the parenthetical "(hereinafter in this section referred to as the 'Commissioner')" is omitted as unnecessary because of the definition of "Commissioner" in section 10101 of title 21, United States Code.

In subsection (e), the words "Federal Government" are substituted for "United States" for consistency in title 21, United States Code.

In subsection (f)(1), the words "Not later than 1 year after the date of enactment of the Food and Drug Administration Modernization Act of 1997," are omitted as obsolete.

In subsection (f)(2)(E), the words "by July 1, 1999," are omitted as obsolete.

In subsection (f)(2)(E), the words "and submitted after the date of enactment of the Food and Drug Administration Modernization Act of 1997" are omitted as obsolete.

In subsection (h)(1)(B), the words "the average cost of a non-high-risk food facility inspection and the average cost of a high-risk food facility inspection" are substituted for "the average cost of both a non-high-risk food facility inspection and a high-risk food facility inspection" for clarity.

In subsection (h)(1)(B), the words "if a difference exists between the costs" are substituted for "if such a difference exists" for clarity and because the word "difference" has no antecedent.

SECTION 10302—OFFICE OF THE CHIEF SCIENTIST

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10302(a)	(no source)	
10302(b), (c)	21 U.S.C. 399a	June 25, 1938, ch. 675, § 1010, formerly § 910, as added Pub. L. 110–85, title VI, § 602, Sept. 27, 2007, 121 Stat. 898; renumbered § 1010, Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.

In this section, subsection (a) is added for convenience.

SECTION 10303—OFFICE OF WOMEN'S HEALTH

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10303(a)	21 U.S.C. 399b(a) (parenthetical)	June 25, 1938, ch. 675, §1011(a) (parenthetical), as added Pub. L. 111–148, title III, § 3509(g), Mar. 23, 2010, 124 Stat. 536.
10303(b)	21 U.S.C. 399b(a) (except parenthetical)	June 25, 1938, ch. 675, §1011(a) (except parenthetical), as added Pub. L. 111–148, title III, § 3509(g), Mar. 23, 2010, 124 Stat. 536.
10303(c)	21 U.S.C. 399b(b)	June 25, 1938, ch. 675, §1011(b), as added Pub. L. 111–148, title III, § 3509(g), Mar. 23, 2010, 124 Stat. 536.

In subsection (c)(4), the words "FDA policy" are substituted for "Administration policy" for clarity and consistency with the definition of "FDA" in section 10104 of title 21, United States Code.

SECTION 10304—FDA INTERCENTER INSTITUTES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10304(a)(1)	21 U.S.C. 399g(a) (last parenthetical)	June 25, 1938, ch. 675, §1014(a) (last parenthetical), as added Pub. L. 114–255, div. A, title III, §3073(a), Dec. 13, 2016, 130 Stat. 1136.
10304(a)(2)	21 U.S.C. 399g(a) (1st parenthetical)	June 25, 1938, ch. 675, §1014(a) (1st parenthetical), as added Pub. L. 114–255, div. A, title III, §3073(a), Dec. 13, 2016, 130 Stat. 1136.
10304(b)	21 U.S.C. 399g(a) (except 1st parenthetical, last parenthetical)	June 25, 1938, ch. 675, §1014(a) (except 1st parenthetical, last parenthetical), as added Pub. L. 114–255, div. A, title III, §3073(a), Dec. 13, 2016, 130 Stat. 1136.
10304(c)	21 U.S.C. 399g(b)	June 25, 1938, ch. 675, §1014(b), as added Pub. L. 114–255, div. A, title III, §3073(a), Dec. 13, 2016, 130 Stat. 1137.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10304(d)	21 U.S.C. 399g(d)	June 25, 1938, ch. 675, §1014(d), as added Pub. L. 114–255, div. A, title III, §3073(a), Dec. 13, 2016, 130 Stat. 1137.

In subsection (b), in the matter before paragraph (1), the words "as applicable to the major disease area" are substituted for "as applicable to the major disease area or areas" for consistency with "With respect to a major disease area of focus of an Institute".

SECTION 10305—SCIENTIFIC REVIEW GROUPS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10305(a)	21 U.S.C. 394	June 25, 1938, ch. 675, § 1004, formerly § 903, as added Pub. L. 101–635, title III, § 301, Nov. 28, 1990, 104 Stat. 4584; renumbered § 904, Pub. L. 103–43, title XX, § 2006(1), June 10, 1993, 107 Stat. 209; renumbered § 1004, Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.
10305(b)	21 U.S.C. 355(n)(2)	June 25, 1938, ch. 675, §505(n)(2), as added Pub. L. 105–115, title I, §120, Nov. 21, 1997, 111 Stat. 2318; Pub. L. 111–31, div. A, title I, § 103(e), June 22, 2009, 123 Stat. 1837.

In subsection (a)(2), the words "Federal Government" are substituted for "United States" for consistency in title 21, United States Code.

Subchapter II—Administrative Provisions

SECTION 10321—EXEMPTION OF MEATS AND MEAT FOOD PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10321	21 U.S.C. 392	June 25, 1938, ch. 675, § 1002(b), (c), formerly § 902(b), (c), 52 Stat. 1059; Pub. L. 90–399, § 107, July 13, 1968, 82 Stat. 353; renumbered § 1002(b), (c), Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.

In subsection (b), the reference to "the Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10)" is omitted as obsolete. The repeal of part II of subchapter C of chapter 39 (relating to regulatory provisions affecting filled cheese) of the Internal Revenue Code of 1954 by section 3(a)(1) of Public Law 93–490 (88 Stat. 1466) effectively repealed the Act because provisions of the Act were generally enacted as that part.

SECTION 10322—LOAN REPAYMENT PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10322	21 U.S.C. 395(a), (b)	June 25, 1938, ch. 675, §1005(a), (b), formerly §905(a), (b), as added Pub. L. 103–43, title XX, § 2006(2), June 10, 1993, 107 Stat. 210; redesignated §1005(a), (b), Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.

SECTION 10323—PRACTICE OF MEDICINE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10323	21 U.S.C. 396	June 25, 1938, ch. 675, §1006, formerly §906, as added Pub. L. 105–115, title II, § 214, Nov. 21, 1997, 111 Stat. 2348; redesignated §1006, Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.

SECTION 10324—CONTRACTS FOR EXPERT REVIEW

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10324	21 U.S.C. 397	June 25, 1938, ch. 675, §1007, formerly §907, as added Pub. L. 105–115, title IV, §415, Nov. 21, 1997, 111 Stat. 2377; redesignated §1007, Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.

SECTION 10325—NOTICES TO STATES REGARDING IMPORTED FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10325	21 U.S.C. 398	June 25, 1938, ch. 675, §1008, formerly §908, as added Pub. L. 107–188, title III, §310, June 12, 2002, 116 Stat. 673; redesignated §1008, Pub. L. 111–31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.

SECTION 10326—GRANTS TO ENHANCE FOOD SAFETY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10326(a)	21 U.S.C. 399(b)(1)	June 25, 1938, ch. 675, §1009(b)(1), formerly § 909, as added Pub. L. 107–188, title III, § 311, June 12, 2002, 116 Stat. 673; renumbered § 1009 and amended Pub. L. 111–31, div. A, title I, §§ 101(b)(2), 103(n), June 22, 2009, 123 Stat. 1784, 1838; Pub. L. 111–353, title II, § 210(a), Jan. 4, 2011, 124 Stat. 3948.
10326(b)	21 U.S.C. 399(a)	June 25, 1938, ch. 675, §1009(a), formerly § 909, as added Pub. L. 107–188, title III, § 311, June 12, 2002, 116 Stat. 673; renumbered § 1009 and amended Pub. L. 111–31, div. A, title I, §§ 101(b)(2), 103(n), June 22, 2009, 123 Stat. 1784, 1838; Pub. L. 111–353, title II, § 210(a), Jan. 4, 2011, 124 Stat. 3948.
10326(c)	21 U.S.C. 399(b)(2)	June 25, 1938, ch. 675, §1009(b)(2), formerly § 909, as added Pub. L. 107–188, title III, § 311, June 12, 2002, 116 Stat. 673; renumbered § 1009 and amended Pub. L. 111–31, div. A, title I, §§ 101(b)(2), 103(n), June 22, 2009, 123 Stat. 1784, 1838; Pub. L. 111–353, title II, § 210(a), Jan. 4, 2011, 124 Stat. 3948.
10326(d) through (h) ...	21 U.S.C. 399(c) through (g)	June 25, 1938, ch. 675, §1009(a) through (g), formerly § 909, as added Pub. L. 107–188, title III, § 311, June 12, 2002, 116 Stat. 673; renumbered § 1009 and amended Pub. L. 111–31, div. A, title I, §§ 101(b)(2), 103(n), June 22, 2009, 123 Stat. 1784, 1838; Pub. L. 111–353, title II, § 210(a), Jan. 4, 2011, 124 Stat. 3948.

In subsection (f), the words “if applicable” are substituted for “where applicable” to use the more appropriate word.

SECTION 10327—IMPROVING THE TRAINING OF STATE, LOCAL, TERRITORIAL, AND TRIBAL FOOD SAFETY OFFICIALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10327	21 U.S.C. 399c(a) through (d)	June 25, 1938, ch. 675, §1012(a) through (d), formerly §1011(a) through (d), as added Pub. L. 111–353, title II, §209(a), Jan. 4, 2011, 124 Stat. 3945; redesignated §1012(a) through (d), Pub. L. 114–255, div. A, title III, §3073(b)(2), Dec. 13, 2016, 130 Stat. 1137.

In subsection (c), the reference to the FDA Food Safety Modernization Act is retained in text for clarity. The Act amended the Federal Food, Drug, and Cosmetic Act (generally restated as subtitle I of title 21, United States Code), title IV of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7621 et seq.), and part P of the Public Health Service Act (42 U.S.C. 280g et seq.), and enacted the source provisions for chapter 325 of title 21, United States Code.

In subsection (d)(1), in the matter before subparagraph (A), the words "not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

SECTION 10328—EMPLOYEE PROTECTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10328	21 U.S.C. 399d	June 25, 1938, ch. 675, §1013, formerly §1012, as added Pub. L. 111–353, title IV, §402, Jan. 4, 2011, 124 Stat. 3968; redesignated §1013, Pub. L. 114–255, div. A, title III, §3073(b)(1), Dec. 13, 2016, 130 Stat. 1137.

In subsection (b)(1)(A), the words "An individual" are substituted for "A person" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (b)(5)(A)(ii), the words "shall be filed" are substituted for "must be filed" for consistency in title 21, United States Code.

Division B—Procedure and Prohibited Acts and Penalties

Chapter 105—Procedure and Prohibited Acts and Penalties

SECTION 10501—PROHIBITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10501(1)	21 U.S.C. 331(a)	June 25, 1938, ch. 675, §301(a), 52 Stat. 1042; Pub. L. 111–31, div. A, title I, §103(b)(1), June 22, 2009, 123 Stat. 1833.
10501(2)	21 U.S.C. 331(b)	June 25, 1938, ch. 675, §301(b), 52 Stat. 1042; Pub. L. 111–31, div. A, title I, §103(b)(2), June 22, 2009, 123 Stat. 1833.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10501(3)	21 U.S.C. 331(c)	June 25, 1938, ch. 675, §301(c), 52 Stat. 1042; Pub. L. 111–31, div. A, title I, §103(b)(3), June 22, 2009, 123 Stat. 1833.
10501(4)	21 U.S.C. 331(d)	June 25, 1938, ch. 675, §301(d), 52 Stat. 1042; Pub. L. 108–136, div. A, title XVI, §1603(c), Nov. 24, 2003, 117 Stat. 1690; Pub. L. 111–353, title I, §102(d)(1), Jan. 4, 2011, 124 Stat. 3889; Pub. L. 117–328, div. FF, title III, §3503(a)(1)(B), Dec. 29, 2022, 136 Stat. 5858.
10501(5)	21 U.S.C. 331(e)	June 25, 1938, ch. 675, §301(e), 52 Stat. 1042; Pub. L. 87–781, title I, §§103(c), 106(c), Oct. 10, 1962, 76 Stat. 784, 788; Pub. L. 90–399, §103(1), July 13, 1968, 82 Stat. 352; Pub. L. 94–295, §3(b)(2), May 28, 1976, 90 Stat. 576; Pub. L. 96–359, §5(b), Sept. 26, 1980, 94 Stat. 1193; Pub. L. 101–502, §5(j), Nov. 3, 1990, 104 Stat. 1289; Pub. L. 103–396, §2(b)(1)(A), Oct. 22, 1994, 108 Stat. 4154; Pub. L. 104–250, §5(d), Oct. 9, 1996, 110 Stat. 3156; Pub. L. 105–115, title I, §125(b)(2)(B), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 107–188, title III, §306(c)(1), June 12, 2002, 116 Stat. 670; Pub. L. 108–136, div. A, title XVI, §1603(c), Nov. 24, 2003, 117 Stat. 1690; Pub. L. 108–282, title I, §102(b)(5)(C), Aug. 2, 2004, 118 Stat. 902; Pub. L. 109–59, title VII, §7202(d), Aug. 10, 2005, 119 Stat. 1913; Pub. L. 109–462, §§2(c), 3(b), Dec. 22, 2006, 120 Stat. 3472, 3475; Pub. L. 110–85, title X, §1005(d)(1), Sept. 27, 2007, 121 Stat. 968; Pub. L. 111–31, div. A, title I, §103(b)(4), June 22, 2009, 123 Stat. 1833; Pub. L. 111–353, title II, §204(j)(1), 211(c), Jan. 4, 2011, 124 Stat. 3937, 3953; Pub. L. 117–328, div. FF, title III, §3503(a)(4)(A), Dec. 29, 2022, 136 Stat. 5858.
10501(6)	21 U.S.C. 331(f)	June 25, 1938, ch. 675, §301(f), 52 Stat. 1042.
10501(7)	21 U.S.C. 331(g)	June 25, 1938, ch. 675, §301(g), 52 Stat. 1042; Pub. L. 111–31, div. A, title I, §103(b)(5), June 22, 2009, 123 Stat. 1833.
10501(8)	21 U.S.C. 331(h)	June 25, 1938, ch. 675, §301(h), 52 Stat. 1042; Pub. L. 111–31, div. A, title I, §103(b)(6), June 22, 2009, 123 Stat. 1833.
10501(9)	21 U.S.C. 331(i)	June 25, 1938, ch. 675, §301(i), 52 Stat. 1042; Dec. 22, 1941, ch. 613, §1, 55 Stat. 851; July 6, 1945, ch. 281, §1, 59 Stat. 463; Pub. L. 86–618, title I, §105(a), July 12, 1960, 74 Stat. 403; Pub. L. 89–74, §9(c), July 15, 1965, 79 Stat. 235; Pub. L. 102–571, title I, §107(2), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 105–115, title I, §125(a)(2)(C), Nov. 21, 1997, 111 Stat. 2325.
10501(10)	21 U.S.C. 331(j)	June 25, 1938, ch. 675, §301(j), 52 Stat. 1042; Mar. 10, 1947, ch. 16, §1, 61 Stat. 11; Pub. L. 85–929, §5, Sept. 6, 1958, 72 Stat. 1788; Pub. L. 86–618, title I, §104, July 12, 1960, 74 Stat. 403; Pub. L. 90–399, §103(2), July 13, 1968, 82 Stat. 352; Pub. L. 94–295, §3(b)(3), May 28, 1976, 90 Stat. 576; Pub. L. 96–359, §5(c), Sept. 26, 1980, 94 Stat. 1193; Pub. L. 101–508, title IV, §4755(c)(2), Nov. 5, 1990, 104 Stat. 1388–210; Pub. L. 102–571, title I, §107(3), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, §3(c)(1), Aug. 13, 1993, 107 Stat. 775; Pub. L. 104–170, title IV, §403, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 105–115, title I, §125(a)(2)(A), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 107–188, title III, §306(c)(2), June 12, 2002, 116 Stat. 670; Pub. L. 108–282, title I, §102(b)(5)(D), Aug. 2, 2004, 118 Stat. 902; Pub. L. 111–31, div. A, title I, §103(b)(7), June 22, 2009, 123 Stat. 1833.
10501(11)	21 U.S.C. 331(k)	June 25, 1938, ch. 675, §301(k), 52 Stat. 1042; June 24, 1948, ch. 613, §1, 62 Stat. 582; Pub. L. 111–31, div. A, title I, §103(b)(8), June 22, 2009, 123 Stat. 1834.
10501(12)	21 U.S.C. 331(m)	June 25, 1938, ch. 675, §301(m), as added Mar. 16, 1950, ch. 61, §3(b), 64 Stat. 20.
10501(13)	21 U.S.C. 331(n)	June 25, 1938, ch. 675, §301(n), as added Aug. 7, 1953, ch. 350, §2, 67 Stat. 477.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10501(14)	21 U.S.C. 331(o)	June 25, 1938, ch. 675, §301(o), as added Pub. L. 87–781, title I, §114(a), Oct. 10, 1962, 76 Stat. 791.
10501(15)	21 U.S.C. 331(p)	June 25, 1938, ch. 675, §301(p), as added Pub. L. 87–781, title III, §304, Oct. 10, 1962, 76 Stat. 795; Pub. L. 92–387, §4(e), Aug. 16, 1972, 86 Stat. 562; Pub. L. 94–295, §4(b)(1), May 28, 1976, 90 Stat. 580; Pub. L. 111–31, div. A, title I, §103(b)(9), June 22, 2009, 123 Stat. 1834.
10501(16) (except (C)(ii))	21 U.S.C. 331(q)	June 25, 1938, ch. 675, §301(q), as added Pub. L. 94–295, §3(b)(1), May 28, 1976, 90 Stat. 576; Pub. L. 102–300, §3(a)(1), June 16, 1992, 106 Stat. 238; Pub. L. 111–31, div. A, title I, §103(b)(10), (11), June 22, 2009, 123 Stat. 1834; Pub. L. 117–328, div. FF, title III, §3305(b), Dec. 29, 2022, 136 Stat. 5833.
10501(16)(C)(ii)	21 U.S.C. 331 note	Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (b) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5833)), Dec. 29, 2022, 136 Stat. 5833.
10501(17)	21 U.S.C. 331(r)	June 25, 1938, ch. 675, §301(r), as added Pub. L. 94–295, §7(b), May 28, 1976, 90 Stat. 582; Pub. L. 111–31, div. A, title I, §103(b)(12), June 22, 2009, 123 Stat. 1834; Pub. L. 114–255, div. A, title III, §3101(a)(2)(A), Dec. 13, 2016, 130 Stat. 1152.
10501(18)	21 U.S.C. 331(s)	June 25, 1938, ch. 675, §301(s), as added Pub. L. 96–359, §5(a), Sept. 26, 1980, 94 Stat. 1193; Pub. L. 99–570, title IV, §4014(b)(2), Oct. 27, 1986, 100 Stat. 3207–120; Pub. L. 103–80, §3(c)(2), Aug. 13, 1993, 107 Stat. 775.
10501(19)	21 U.S.C. 331(t)	June 25, 1938, ch. 675, §301(t), as added Pub. L. 100–293, §7(a), Apr. 22, 1988, 102 Stat. 99; Pub. L. 113–54, title II, §206(a), Nov. 27, 2013, 127 Stat. 639.
10501(20)	21 U.S.C. 331(u)	June 25, 1938, ch. 675, §301(u), as added Pub. L. 103–396, §2(b)(1)(B), Oct. 22, 1994, 108 Stat. 4154.
10501(21)	21 U.S.C. 331(v)	June 25, 1938, ch. 675, §301(v), formerly §301(u), as added Pub. L. 103–417, §10(b), Oct. 25, 1994, 108 Stat. 4332; renumbered §301(v), Pub. L. 104–134,title II, §2103(1), Apr. 26, 1996, 110 Stat. 1321–319.
10501(22)	21 U.S.C. 331(w)	June 25, 1938, ch. 675, §301(w), as added Pub. L. 104–134, title II, §2103(2), Apr. 26, 1996, 110 Stat. 1321–319; Pub. L. 107–188, title III, §322(b), June 12, 2002, 116 Stat. 677.
10501(23)	21 U.S.C. 331(x)	June 25, 1938, ch. 675, §301(x), as added Pub. L. 105–115, title II, §204(b), Nov. 21, 1997, 111 Stat. 2336.
10501(24)	21 U.S.C. 331(y)	June 25, 1938, ch. 675, §301(y), as added Pub. L. 105–115, title II, §210(c), Nov. 21, 1997, 111 Stat. 2345.
10501(25)	21 U.S.C. 331(aa)	June 25, 1938, ch. 675, §301(aa), as added Pub. L. 106–387, §1(a) [title VII, § 745(d)(1)], Oct. 28, 2000, 114 Stat. 1549, 1549A–39; Pub. L. 108–173, title XI, §1121(b)(1), Dec. 8, 2003, 117 Stat. 2469.
10501(26)	21 U.S.C. 331(bb)	June 25, 1938, ch. 675, §301(bb), as added Pub. L. 107–188, title III, §303(b), June 12, 2002, 116 Stat. 664.
10501(27)	21 U.S.C. 331(cc)	June 25, 1938, ch. 675, §301(cc), as added Pub. L. 107–188, title III, §304(d), June 12, 2002, 116 Stat. 666; Pub. L. 115–271, title III, §3022(b)(1), Oct. 24, 2018, 132 Stat. 3938.
10501(28)	21 U.S.C. 331(dd)	June 25, 1938, ch. 675, §301(dd), as added Pub. L. 107–188, title III, §305(b), June 12, 2002, 116 Stat. 668.
10501(29)	21 U.S.C. 331(ee)	June 25, 1938, ch. 675, §301(ee), as added Pub. L. 107–188, title III, §307(b), June 12, 2002, 116 Stat. 672.
10501(30)	21 U.S.C. 331(ff)	June 25, 1938, ch. 675, §301(ff), as added Pub. L. 107–188, title III, §321(b)(2), June 12, 2002, 116 Stat. 676.
10501(31)	21 U.S.C. 331(gg)	June 25, 1938, ch. 675, §301(gg), as added Pub. L. 107–250, title II, §201(d), Oct. 26, 2002, 116 Stat. 1609; Pub. L. 108–214, §2(b)(2)(A), Apr. 1, 2004, 118 Stat. 575.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10501(32)	21 U.S.C. 331(hh)	June 25, 1938, ch. 675, §301(hh), as added Pub. L. 109–59, title VII, §7202(e), Aug. 10, 2005, 119 Stat. 1913.
10501(33)	21 U.S.C. 331(ii)	June 25, 1938, ch. 675, §301(ii), as added Pub. L. 109–462, §4(a), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 117–328, div. FF, title III, §3503(a)(4)(B), Dec. 29, 2022, 136 Stat. 5858.
10501(34)	21 U.S.C. 331(jj)	June 25, 1938, ch. 675, §301(jj), as added Pub. L. 110–85, title VIII, §801(b)(1), Sept. 27, 2007, 121 Stat. 920.
10501(35)	21 U.S.C. 331(kk)	June 25, 1938, ch. 675, §301(kk), as added Pub. L. 110–85, title IX, §901(d)(1), Sept. 27, 2007, 121 Stat. 939.
10501(36)	21 U.S.C. 331(ll)	June 25, 1938, ch. 675, §301(ll), as added Pub. L. 110–85, title IX, §912(a), Sept. 27, 2007, 121 Stat. 951.
10501(37)	21 U.S.C. 331(mm)	June 25, 1938, ch. 675, §301(mm), as added Pub. L. 110–85, title X, §1005(d)(2), Sept. 27, 2007, 121 Stat. 968.
10501(38)	21 U.S.C. 331(nn)	June 25, 1938, ch. 675, §301(nn), as added Pub. L. 110–85, title X, §1005(d)(2), Sept. 27, 2007, 121 Stat. 968.
10501(39)	21 U.S.C. 331(oo)	June 25, 1938, ch. 675, §301(oo), as added Pub. L. 111–31, div. A, title I, §103(b)(13), June 22, 2009, 123 Stat. 1834.
10501(40)	21 U.S.C. 331(pp)	June 25, 1938, ch. 675, §301(pp), as added Pub. L. 111–31, div. A, title I, §103(b)(13), June 22, 2009, 123 Stat. 1834.
10501(41)	21 U.S.C. 331(qq)	June 25, 1938, ch. 675, §301(qq), as added Pub. L. 111–31, div. A, title I, §103(b)(13), June 22, 2009, 123 Stat. 1834.
10501(42)	21 U.S.C. 331(rr)	June 25, 1938, ch. 675, §301(rr), as added Pub. L. 111–31, div. A, title I, §103(b)(13), June 22, 2009, 123 Stat. 1834.
10501(43)	21 U.S.C. 331(ss)	June 25, 1938, ch. 675, §301(ss), as added Pub. L. 111–31, div. A, title I, §103(b)(13), June 22, 2009, 123 Stat. 1834.
10501(44)	21 U.S.C. 331(tt)	June 25, 1938, ch. 675, §301(tt), as added Pub. L. 111–31, div. A, title I, §103(b)(13), June 22, 2009, 123 Stat. 1834.
10501(45)	21 U.S.C. 331(uu)	June 25, 1938, ch. 675, §301(uu), as added Pub. L. 111–353, title I, §103(e), Jan. 4, 2011, 124 Stat. 3898.
10501(46)	21 U.S.C. 331(vv)	June 25, 1938, ch. 675, §301(vv), as added Pub. L. 111–353, title I, §105(c), Jan. 4, 2011, 124 Stat. 3904.
10501(47)	21 U.S.C. 331(ww)	June 25, 1938, ch. 675, §301(ww), as added Pub. L. 111–353, title I, §106(d), Jan. 4, 2011, 124 Stat. 3906.
10501(48)	21 U.S.C. 331(xx)	June 25, 1938, ch. 675, §301(xx), as added Pub. L. 111–353, title I, §206(d), Jan. 4, 2011, 124 Stat. 3943.
10501(49)	21 U.S.C. 331(yy)	June 25, 1938, ch. 675, §301(yy), as added Pub. L. 111–353, title II, §211(b), Jan. 4, 2011, 124 Stat. 3953.
10501(50)	21 U.S.C. 331(zz)	June 25, 1938, ch. 675, §301(zz), as added Pub. L. 111–353, title III, §301(b), Jan. 4, 2011, 124 Stat. 3954.
10501(51)	21 U.S.C. 331(aaa)	June 25, 1938, ch. 675, §301(aaa), as added Pub. L. 112–144, title VII, §714(a), July 9, 2012, 126 Stat. 1073.
10501(52)	21 U.S.C. 331(bbb)	June 25, 1938, ch. 675, §301(bbb), as added Pub. L. 112–144, title VII, §715(a), July 9, 2012, 126 Stat. 1075.
10501(53)	21 U.S.C. 331(ccc)	June 25, 1938, ch. 675, §301(ccc), as added Pub. L. 113–54, title I, §103(a), Nov. 27, 2013, 127 Stat. 597.
10501(54)	21 U.S.C. 331(ddd)	June 25, 1938, ch. 675, §301(ddd), as added Pub. L. 114–114, §2(a), Dec. 28, 2015, 129 Stat. 3129.
10501(55)	21 U.S.C. 331(eee)	June 25, 1938, ch. 675, §301(eee), as added Pub. L. 115–271, title III, §3012(a), Oct. 24, 2018, 132 Stat. 3935.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10501(56)	21 U.S.C. 331(fff)	June 25, 1938, ch. 675, §301(fff), as added Pub. L. 117–328, div. FF, title II, §2513(a), Dec. 29, 2022, 136 Stat. 5805.
10501(57)	21 U.S.C. 331(ggg)	June 25, 1938, ch. 675, §301(ggg), as added Pub. L. 117–328, div. FF, title III, §3210(c), Dec. 29, 2022, 136 Stat. 5824.
10501(58)	21 U.S.C. 331(hhh)	June 25, 1938, ch. 675, §301(ggg), as added Pub. L. 117–328, div. FF, title III, §3503(a)(1)(A), Dec. 29, 2022, 136 Stat. 5858.
10501(59)	21 U.S.C. 331(iii)	June 25, 1938, ch. 675, §301(iii), as added Pub. L. 117–328, div. FF, title III, §3503(a)(1)(A), Dec. 29, 2022, 136 Stat. 5858.

In paragraph (5)(C), the words "section 32533 of this title" are substituted for "section 204 of the FDA Food Safety Modernization Act" to provide a more precise reference to the pertinent provision. Section 204 of the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3937) is composed of the source law for section 32533 of title 21, United States Code, and amendments to certain provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

In paragraph (8)(A), the words "the name and address of, another person" are substituted for "the name and address of, the person" for clarity.

In paragraph (8)(A), the words "from whom the former" are substituted for "from whom he" for clarity.

In paragraph (16)(C)(ii), the reference to "clause (i)" is substituted for "this section, including the amendments made by this section," for clarity. The words "the amendments by this section" in the source provision are translated in the restatement as "clause (i)" because clause (i) restates paragraph (3) of section 301(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)), which was added to that section by the amendment made by section 3305(b) of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5833). See sections 13158(e), 29117(c), and 49520(c) of title 21, United States Code, for identical provisions, except for the reference to "clause (i)".

In paragraph (19), in subparagraph (E), the words "failure to otherwise comply with the requirements of section 503(e)." in the source law are restated to follow the restatement of the words "the distribution of drugs in violation of section 503(e)" in the source law, and the words "failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable," in the source law are restated as subparagraph (F), for clarity.

In paragraph (35), the words "with section 13108 of this title" are substituted for "with section 503B" because that reference to section 503B refers to a provision renumbered as section 503C of the Federal Food Drug and Cosmetic Act (21 U.S.C. 353c) by section 102(a)(2) of the Drug Quality and Security Act (Public Law 113–54, 127 Stat. 587), which section 503C is restated as section 13108 of title 21, United States Code.

In paragraph (44)(A)(ii), the word "considers" is substituted for "deems" to use the more appropriate word.

In paragraph (44)(B), the words "Making . . . any statement or representation described in subparagraph (A)" are substituted for "including any such statement or representation" for clarity.

SECTION 10502—INJUNCTION PROCEEDINGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10502	21 U.S.C. 332	June 25, 1938, ch. 675, §302, 52 Stat. 1043; Pub. L. 87–781, title I, §103(d), title II, §201(c), Oct. 10, 1962, 76 Stat. 784 , 793; Pub. L. 103–80, §3(d), Aug. 13, 1993, 107 Stat. 775.

In subsection (a), the words "to issue an injunction or restraining order for a violation of" are substituted for "to restrain violations of" for clarity and for consistency with subsection (b).

SECTION 10503—PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10503(a)	21 U.S.C. 333(a)	June 25, 1938, ch. 675, §303(a), 52 Stat. 1043; Pub. L. 89–74, §7(a), July 15, 1965, 79 Stat. 233; Pub. L. 90–639, §3, Oct. 24, 1968, 82 Stat. 1361; Pub. L. 91–513, title II, §701(b), Oct. 27, 1970, 84 Stat. 1281; Pub. L. 100–293, §7(b)(1), (2), Apr. 22, 1988, 102 Stat. 99.
10503(b)	21 U.S.C. 333(b)	June 25, 1938, ch. 675, §303(b) , as added Pub. L. 100–293, §7(b), Apr. 22, 1988, 102 Stat. 99; Pub. L. 102–353, §3(a), (b)(1) through (3), Aug. 26, 1992, 106 Stat. 941; Pub. L. 106–387, §1(a) [title VII, §745(d)(2)], Oct. 28, 2000, 114 Stat. 1549, 1549A-40; Pub. L. 108–173, title XI, §1121(b)(2), Dec. 8, 2003, 117 Stat. 2469; Pub. L. 112–144, title VII, §716, July 9, 2012, 126 Stat. 1075; Pub. L. 113–54, title II, §207(a), Nov. 27, 2013, 127 Stat. 640; Pub. L. 115–52, title VI, §604(b), Aug. 18, 2017, 131 Stat. 1048; Pub. L. 117–328, div. FF, title II, §2513(b)(1), Dec. 29, 2022, 136 Stat. 5805.
10503(c)	21 U.S.C. 333(c)	June 25, 1938, ch. 675, §303(c), 52 Stat. 1043; Oct. 26, 1951, ch. 578, §2, 65 Stat. 649; Pub. L. 86–618, title I, §105(b), July 12, 1960, 74 Stat. 403; Pub. L. 89–74, §9(d), July 15, 1965, 79 Stat. 235; Pub. L. 102–353, §3(b)(4), Aug. 26, 1992, 106 Stat. 942; Pub. L. 117–328, div. FF, title II, §2513(b)(2), Dec. 29, 2022, 136 Stat. 5805.
10503(d)	21 U.S.C. 333(d)	June 25, 1938, ch. 675, §303(d), as added Pub. L. 94–278, title V, §502(a)(2)(B), Apr. 22, 1976, 90 Stat. 411; Pub. L. 102–353, §3(b)(4), (5), Aug. 26, 1992, 106 Stat. 942.
10503(e)(1)	21 U.S.C. 333(e)(4)	June 25, 1938, ch. 675, §303(e)(4), as added Pub. L. 100–690, title II, §2403, Nov. 18, 1988, 102 Stat. 4230; Pub. L. 101–647, title XIX, §1904, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103–322, title XXXIII, §330015, Sept. 13, 1994, 108 Stat. 2146.
10503(e)(2)	21 U.S.C. 333(e)(1)	June 25, 1938, ch. 675, §303(e)(1), as added Pub. L. 100–690, title II, §2403, Nov. 18, 1988, 102 Stat. 4230; Pub. L. 101–647, title XIX, §1904, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103–322, title XXXIII, §330015, Sept. 13, 1994, 108 Stat. 2146.
10503(e)(3)	21 U.S.C. 333(e)(2)	June 25, 1938, ch. 675, §303(e)(2), as added Pub. L. 100–690, title II, §2403, Nov. 18, 1988, 102 Stat. 4230; Pub. L. 101–647, title XIX, §1904, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103–322, title XXXIII, §330015, Sept. 13, 1994, 108 Stat. 2146.
10503(e)(4)	21 U.S.C. 333(e)(3)	June 25, 1938, ch. 675, §303(e)(3), as added Pub. L. 100–690, title II, §2403, Nov. 18, 1988, 102 Stat. 4230; Pub. L. 101–647, title XIX, §1904, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 103–80, §3(e), Aug.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		13, 1993, 107 Stat. 775; Pub. L. 103–322, title XXXIII, §330015, Sept. 13, 1994, 108 Stat. 2146.
10503(e)(5)	21 U.S.C. 333(e)(5)	June 25, 1938, ch. 675, §303(e)(5), as added Pub. L. 100–690, title II, §2403, Nov. 18, 1988, 102 Stat. 4230; Pub. L. 101–647, title XIX, §1904, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103–322, title XXXIII, §330015, Sept. 13, 1994, 108 Stat. 2146.
10503(f)(1)	21 U.S.C. 333(f)(1)	June 25, 1938, ch. 675, §303(f)(1), as added Pub. L. 101–629, §17(a), Nov. 28, 1990, 104 Stat. 4527; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 107–250, title II, §201(c), Oct. 26, 2002, 116 Stat. 1609; Pub. L. 110–85, title II, §226(b), title VIII, §801(b)(2), Sept. 27, 2007, 121 Stat. 920, 854.
10503(f)(2)	21 U.S.C. 333(f)(2)	June 25, 1938, ch. 675, §303(f)(2), as added Pub. L. 104–170, title IV, §407(2), Aug. 3, 1996, 110 Stat. 1535; Pub. L. 110–85, title II, §226(b)(1), title VIII, §801(b)(2)(C), Sept. 27, 2007, 121 Stat. 854, 920; Pub. L. 111–353, title II, §206(c), Jan. 4, 2011, 124 Stat. 3943.
10503(f)(3)	21 U.S.C. 333(f)(3)	June 25, 1938, ch. 675, §303(f)(3), as added Pub. L. 110–85, title VIII, §801(b)(2)(B), Sept. 27, 2007, 121 Stat. 920.
10503(f)(4)(A)(i)	21 U.S.C. 333(f)(4)(A) (matter before (i) ("(as such term is used in section 355–1 of this title)"))	June 25, 1938, ch. 675, §303(f)(4)(A) (matter before (i) ("(as such term is used in section 505–1)")), as added Pub. L. 110–85, title IX, §902(b), Sept. 27, 2007, 121 Stat. 943.
10503(f)(4)(A)(ii)	21 U.S.C. 333(f)(4)(A) (except "(as such term is used in section 355–1 of this title)")	June 25, 1938, ch. 675, §303(f)(4)(A) (except "(as such term is used in section 505–1)"), as added Pub. L. 110–85, title IX, §902(b), Sept. 27, 2007, 121 Stat. 943.
10503(f)(4)(B)	21 U.S.C. 333(f)(4)(B)	June 25, 1938, ch. 675, §303(f)(4)(B), as added Pub. L. 110–85, title IX, §902(b), Sept. 27, 2007, 121 Stat. 943.
10503(f)(5)	21 U.S.C. 333(f)(5)	June 25, 1938, ch. 675, §303(f)(5), formerly §303(f)(2), as added Pub. L. 101–629, §17(a), Nov. 28, 1990, 104 Stat. 4527; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 104–170, title IV, §407(1), (3), Aug. 3, 1996, 110 Stat. 1535, 1536; Pub. L. 110–85, title II, §226(b)(1), title VIII, §801(b)(2)(A), (D), Sept. 27, 2007, 121 Stat. 854 , 920, 921; Pub. L. 111–31, div. A, title I, §103(c)(1), June 22, 2009, 123 Stat. 1835.
10503(f)(6)	21 U.S.C. 333(f)(6)	June 25, 1938, ch. 675, § 303(f)(6), formerly §303(f)(3) as added Pub. L. 101–629, § 17(a), Nov. 28, 1990, 104 Stat. 4527; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 104–170, title IV, §407(1), (4), Aug. 3, 1996, 110 Stat. 1535; Pub. L. 110–85, title II, §226(b)(1), title VIII, §801(b)(2)(A), (E), Sept. 27, 2007, 121 Stat. 854 , 920, 921; Pub. L. 111–31, div. A, title I, §103(c)(2), June 22, 2009, 123 Stat. 1835.
10503(f)(7)	21 U.S.C. 333(f)(7)	June 25, 1938, ch. 675, §303(f)(7), formerly §303(f)(4), as added Pub. L. 101–629, §17(a), Nov. 28, 1990, 104 Stat. 4527; Pub. L. 103–80, §3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 104–170, title IV, §407(1), (5), Aug. 3, 1996, 110 Stat. 1535, 1536; Pub. L. 110–85, title II, §226(b)(1), title VIII, §801(b)(2)(A), (F), Sept. 27, 2007, 121 Stat. 854, 920, 921.
10503(f)(8)	21 U.S.C. 333(f)(8)	June 25, 1938, ch. 675, §303(f)(8), as added Pub. L. 111–31, div. A, title I, §103(c)(3), June 22, 2009, 123 Stat. 1835; Pub. L. 116–94, div. N, title I, §603(d)(2), Dec. 20, 2019, 133 Stat. 3124.
10503(f)(9)	21 U.S.C. 333(f)(9)	June 25, 1938, ch. 675, §303(f)(9), as added Pub. L. 111–31, div. A, title I, §103(c)(3), June 22, 2009, 123 Stat. 1836.
10503(g)(1)	21 U.S.C. 333(g)(1)	June 25, 1938, ch. 675, § 303(g)(1), as added Pub. L. 110–85, title IX, § 901(d)(4), Sept. 27, 2007, 121 Stat. 940.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10503(g)(2)	21 U.S.C. 333(g)(2)	June 25, 1938, ch. 675, §303(g)(2), as added Pub. L. 110–85, title IX, § 901(d)(4), Sept. 27, 2007, 121 Stat. 940.
10503(g)(3)	21 U.S.C. 333(g)(3)	June 25, 1938, ch. 675, §303(g)(3), as added Pub. L. 110–85, title IX, §901(d)(4), Sept. 27, 2007, 121 Stat. 940.
10503(g)(4)	21 U.S.C. 333(g)(4)	June 25, 1938, ch. 675, §303(g)(4), as added Pub. L. 110–85, title IX, §901(d)(4), Sept. 27, 2007, 121 Stat. 940.
10503(g)(5)	21 U.S.C. 333(g)(5)	June 25, 1938, ch. 675, §303(g)(5), as added Pub. L. 110–85, title IX, §901(d)(4), Sept. 27, 2007, 121 Stat. 940.
10503(g)(6)	21 U.S.C. 333(g)(6)	June 25, 1938, ch. 675, §303(g)(6), as added Pub. L. 110–85, title IX, § 901(d)(4), Sept. 27, 2007, 121 Stat. 940.
10503(g)(7)	21 U.S.C. 333(g)(7)	June 25, 1938, ch. 675, §303(g)(7), as added Pub. L. 110–85, title IX, §901(d)(4), Sept. 27, 2007, 121 Stat. 940.

In this section, the words "civil penalty" are substituted for "civil monetary penalty" and words of like import each place they appear to eliminate an unnecessary word and for consistency in the title.

In subsection (a)(1), the words "fined under title 18" are substituted for "fined not more than $1,000" for consistency with chapter 227 of title 18, United States Code.

In subsection (a)(2), in the matter before subparagraph (A), the words "fined under title 18" are substituted for "fined not more than $10,000" for consistency with chapter 227 of title 18, United States Code.

In subsection (b), the amendment made by section 1121(b)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173, 117 Stat. 2469) to section 303(a)(6) of the Federal Food, Drug, and Cosmetic Act is executed as an amendment to section 303(b)(6) of the Act (21 U.S.C. 333(b)(6)) to reflect the probable intent of Congress. Section 303(a) of the Act did not contain a paragraph (6), and the words stricken by the amendment appeared in section 303(b)(6) of the Act.

In subsection (b)(1), in the matter before subparagraph (A), the words "fined not more than $250,000," are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (b)(6), the words "fined not more than $250,000," are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (b)(7), the words "fined not more than $1,000,000," are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (c)(1)(A), the words "name and address of the source" are substituted for "name and address of the person" for clarity.

In subsection (c)(2)(A), the words "the source residing in the United States" are substituted for "the person residing in the United States" for clarity.

In subsection (e), the amendment made by section 3(e) of the Nutrition Labeling and Education Act Amendments of 1993 (Public Law 103–80, 107 Stat. 775) redesignating the second subsection (e) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) could not be executed because section 303 of the Act no longer contained a second subsection (e) after the enactment of section 330015 of Public Law 103–322 (108 Stat. 2146).

In subsection (e)(2), the words "a person that" are substituted for "whoever" for consistency in the section and because of section 1 of title 1, United States Code.

In subsection (e)(2), the words "shall be imprisoned for not more than 5 years, fined under title 18, or both" are substituted for "is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, or both" to eliminate unnecessary words and for consistency in the section.

In subsection (e)(3), the words "A person that" are substituted for "Whoever" for consistency in the section and because of section 1 of title 1, United States Code.

In subsection (e)(3), the words "shall be imprisoned not more than 10 years, fined under title 18, or both" are substituted for "is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, or both" to eliminate unnecessary words and for consistency in the section.

In subsection (f)(3)(B), the words "section 402(j)(5)(C)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(5)(C)(ii))" are substituted for "section 402(j)(5)(C)(ii)" to clarify that the reference is not to section 402(j)(5)(C)(ii) of the Federal Food, Drug, and Cosmetic Act, which section does not exist, but to section 402(j)(5)(C)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(5)(C)(ii)).

In subsection (f)(4)(A)(ii)(II), the words "after the first 30-day period" are substituted for "thereafter" for clarity.

In subsection (f)(7)(A), in the matter before clause (i), the words "against a person" are added for clarity.

In subsection (g)(3), subparagraph (A) of the source law, which contains the words "Whether the person submitted the advertisement or a similar advertisement for review under section 736A", is omitted as obsolete because section 736A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–1) is repealed as obsolete by the bill enacting title 21, United States Code. See 73 Fed. Reg. 2924 (Jan. 16, 2008).

In subsection (g)(3)(A), the words "under section 13108 of this title" are substituted for "under section 503B" because that reference to section 503B refers to a provision renumbered as section 503C of the Federal Food Drug and Cosmetic Act (21 U.S.C. 353c) by section 102(a)(2) of the Drug Quality and

Security Act (Public Law 113–54, 127 Stat. 587), which section 503C is restated as section 13108 of title 21, United States Code.

In subsection (g)(3)(B), the words "described in subparagraph (A)" are substituted for "described in subparagraph (A) or (B)" because subparagraph (A) of the source law is omitted as obsolete. See revision note for subsection (g)(3) relating to the omission of subparagraph (A) of the source law.

In subsection (g)(3)(H), the words "under this subsection" are substituted for "under this provision" for clarity.

In subsection (g)(7)(A), in the matter before clause (i), the words "against a person" are added for clarity.

SECTION 10504—SEIZURE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10504(a)	21 U.S.C. 334(a)	June 25, 1938, ch. 675, §304(a), 52 Stat. 1044; June 24, 1948, ch. 613, §2, 62 Stat. 582; Pub. L. 89–74, §6(a), July 15, 1965, 79 Stat. 232; Pub. L. 90–639, §4(b), Oct. 24, 1968, 82 Stat. 1362; Pub. L. 91–513, title II, §701(c), Oct. 27, 1970, 84 Stat. 1281; Pub. L. 94–278, title V, §502(a)(2)(C), Apr. 22, 1976, 90 Stat. 411; Pub. L. 94–295, §3(c), May 28, 1976, 90 Stat. 576; Pub. L. 103–80, §3(f)(1), Aug. 13, 1993, 107 Stat. 775; Pub. L. 110–85, title IX, §912(b)(1), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(d)(1), June 22, 2009, 123 Stat. 1836; Pub. L. 117–328, div. FF, title II, §2513(c), Dec. 29, 2022, 136 Stat. 5805.
10504(b)	21 U.S.C. 334(b)	June 25, 1938, ch. 675, §304(b), 52 Stat. 1044; Pub. L. 89–74, § 6(b)(1), July 15, 1965, 79 Stat. 233.
10504(c)	21 U.S.C. 334(c)	June 25, 1938, ch. 675, §304(c), 52 Stat. 1045; Aug. 7, 1953, ch. 350, § 3, 67 Stat. 477.
10504(d)	21 U.S.C. 334(d)	June 25, 1938, ch. 675, § 304(d), 52 Stat. 1045; Pub. L. 85–250, Aug. 31, 1957, 71 Stat. 567; Pub. L. 89–74, § 6(b)(2), July 15, 1965, 79 Stat. 233; Pub. L. 91–513, title II, §701(d), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 102–300, § 6(c), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(f)(2), Aug. 13, 1993, 107 Stat. 775; Pub. L. 105–115, title IV, §418, Nov. 21, 1997, 111 Stat. 2379; Pub. L. 111–31, div. A, title I, §103(d)(2), June 22, 2009, 123 Stat. 1836.
10504(e)	21 U.S.C. 334(e)	June 25, 1938, ch. 675, § 304(e), 52 Stat. 1045.
10504(f)	21 U.S.C. 334(f)	June 25, 1938, ch. 675, § 304(f), 52 Stat. 1045.
10504(g)	21 U.S.C. 334(g)	June 25, 1938, ch. 675, §304(g), as added Pub. L. 94–295, § 7(a), May 28, 1976, 90 Stat. 582; Pub. L. 111–31, div. A, title I, §103(d)(3), (4), June 22, 2009, 123 Stat. 1836; Pub. L. 112–144, title VII, §709(a), July 9, 2012, 126 Stat. 1069.
10504(h)	21 U.S.C. 334(h)	June 25, 1938, ch. 675, §304(h), as added Pub. L. 107–188, title III, § 303(a), June 12, 2002, 116 Stat. 663; Pub. L. 111–353, title II, §207(a), Jan. 4, 2011, 124 Stat. 3944.
10504(i)	21 U.S.C. 334(i)	June 25, 1938, ch. 675, § 304(i), as added Pub. L. 112–144, title VII, § 709(b)(2), July 9, 2012, 126 Stat. 1069.

In subsection (a)(1)(A), in the matter before clause (i), the words "shall be subject to an action for condemnation proceeding" are substituted for "shall be liable to be proceeded against . . . on libel of information" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(1)(B)(i)(I), the words "An action for condemnation proceeding" are substituted for "A libel for condemnation" and the words "an action for condemnation proceeding" are substituted for "a libel for

condemnation proceeding" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(1)(B)(ii)(I), the words "or action" are substituted for "or libel" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(1)(C)(i), the words "the number of condemnation proceedings" are substituted for "the number of libel for condemnation proceedings" for consistency in the section.

In subsection (a)(1)(C)(i), the words "as provided in subparagraph (B)" are substituted for "as above provided" for clarity.

In subsection (a)(2), in the matter before subparagraph (A), the words "subject to condemnation proceedings at any time and condemned" are substituted for "liable to be proceeded against at any time on libel of information and condemned" for consistency in the section.

In subsection (a)(2)(H), the word "device" is substituted for "device or devices" because of section 1 of title 1, United States Code.

In subsection (a)(3)(A), in the matter before clause (i), the words "an action for condemnation proceeding" are substituted for "libel for condemnation" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(3)(B), in the matter before clause (i), the words "An action for condemnation proceeding" are substituted for "A libel for condemnation" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (b)(1), the words "pursuant to the action for condemnation proceeding" are substituted for "pursuant to the libel" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (b)(2), in the matter before subparagraph (A), the words "If actions for condemnation proceedings under this section" are substituted for "When libel for condemnation proceedings under this section" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (b)(2), in the matter before subparagraph (A), the words "the pending actions" are substituted for "such pending proceedings" for consistency in the section.

In subsection (b)(2)(A), the words "one of the actions" are substituted for "one of such proceedings" for consistency in the section.

In subsection (d)(1)(D)(ii), in the matter before subclause (I), the words "Clause (i) shall not apply if" are substituted for "The provisions of this sentence shall not apply where" to correct an error in the law. As originally enacted by Public Law 85–250 (71 Stat. 567), the words "[t]he provisions of this sentence shall not apply" were contained in a proviso in a sentence that included the matter restated in clause (i) of subsection (d)(1)(D). Subsequently, section 3(f)(2)(B) of the Nutrition Labeling and Education Act Amendments of 1993 (Public Law 103-80, 107 Stat. 775) made a technical amendment to separate the proviso into its own sentence, but the technical amendment failed to update the reference to "this sentence" to refer instead to the preceding sentence.

In subsection (d)(2), the words "to the extent considered appropriate" are substituted for "to the extent deemed appropriate" to use the more appropriate word.

SECTION 10505—HEARING BEFORE REPORT OF CRIMINAL VIOLATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10505	21 U.S.C. 335	June 25, 1938, ch. 675, §305, 52 Stat. 1045.

SECTION 10506—DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10506(a)	21 U.S.C. 335a(a)	June 25, 1938, ch. 675, §306(a), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 150; Pub. L. 107–188, title III, §304(b)(1), June 12, 2002, 116 Stat. 666.
10506(b) (except (3)(A))	21 U.S.C. 335a(b)(1) through (4)	June 25, 1938, ch. 675, §306(b)(1) through (4), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 150; Pub. L. 107–188, title III, §304(a), (b)(2), June 12, 2002, 116 Stat. 665, 666; Pub. L. 115–271, title III, §3022(b)(2)(A), (B), Oct. 24, 2018, 132 Stat. 3938.
10506(b)(3)(A)	21 U.S.C. 335a(b)(5)	June 25, 1938, ch. 675, §306(b)(5), as added Pub. L. 115–271, title III, §3022(b)(2)(C), Oct. 24, 2018, 132 Stat. 3939.
10506(c)	21 U.S.C. 335a(c)	June 25, 1938, ch. 675, §306(c), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 152; Pub. L. 107–188, title III, §304(b)(3), June 12, 2002, 116 Stat. 666.
10506(d)	21 U.S.C. 335a(d)	June 25, 1938, ch. 675, §306(d), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 153; Pub. L. 105–115, title I, §125(b)(2)(C), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 107–188, title III, §304(b)(4), June 12, 2002, 116 Stat. 666.
10506(e)	21 U.S.C. 335a(e)	June 25, 1938, ch. 675, §306(e), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 155.
10506(f)	21 U.S.C. 335a(f)	June 25, 1938, ch. 675, §306(f), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 155.
10506(g)	21 U.S.C. 335a(g)	June 25, 1938, ch. 675, §306(g), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 156.
10506(h)	21 U.S.C. 335a(h)	June 25, 1938, ch. 675, §306(h), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 157.
10506(i)	21 U.S.C. 335a(i)	June 25, 1938, ch. 675, §306(i), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 157.
10506(j)	21 U.S.C. 335a(j)	June 25, 1938, ch. 675, §306(j), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 158.
10506(k)	21 U.S.C. 335a(k)	June 25, 1938, ch. 675, §306(k), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 158.
10506(l)	21 U.S.C. 335a(l)	June 25, 1938, ch. 675, §306(l), as added Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 158; Pub. L. 107–188, title III, §304(c), June 12, 2002, 116 Stat. 666.
10506(m)	21 U.S.C. 335a(m)	June 25, 1938, ch. 675, §306(m), as added Pub. L. 107–250, title II, §203, Oct. 26, 2002, 116 Stat. 1610.

SECTION 10507—CIVIL PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10507	21 U.S.C. 335b	June 25, 1938, ch. 675, §307, as added Pub. L. 102–282, § 3, May 13, 1992, 106 Stat. 159; Pub. L. 103–80, § 3(g), Aug. 13, 1993, 107 Stat. 776.

In subsection (b)(1)(B), the words "civil penalty" are substituted for "civil money penalty" to eliminate an unnecessary word and for consistency in the title.

In subsection (b)(3), subparagraph (A) of section 307(b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335b(b)(3)), which read "with respect to any act described in subsection (a) that occurred before the date of the enactment of this Act, or", is omitted to eliminate obsolete words.

In subsection (b)(3), the words "material to the act described in subsection (a)" are substituted for "material to the act" for clarity because of the omission of subparagraph (A) of section 307(b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335b(b)(3)) in the restatement. See previous revision note.

In subsection (b)(3), the words "but not more than" are substituted for "but in no event more than" to eliminate unnecessary words.

In subsection (e)(1), the words "an individual who materially" are substituted for "a person who materially" for consistency in the paragraph.

SECTION 10508—AUTHORITY TO WITHDRAW APPROVAL OF ABBREVIATED DRUG APPLICATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10508	21 U.S.C. 335c	June 25, 1938, ch. 675, §308, as added Pub. L. 102–282, § 4, May 13, 1992, 106 Stat. 160.

SECTION 10509—REPORT OF MINOR VIOLATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10509	21 U.S.C. 336	June 25, 1938, ch. 675, §309, formerly §306, 52 Stat. 1045; renumbered §309, Pub. L. 102–282, § 2, May 13, 1992, 106 Stat. 150.

In this section, the words "civil action or injunction proceedings" are substituted for "libel or injunction proceedings" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

SECTION 10510—PROCEEDINGS IN NAME OF UNITED STATES OR A STATE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10510	21 U.S.C. 337	June 25, 1938, ch. 675, §310, formerly § 307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, § 37, 68 Stat. 1239; Pub. L. 101–535, §4, Nov. 8, 1990, 104 Stat. 2362; renumbered §310, Pub. L. 102–282, §2, May 13, 1992, 106 Stat. 150.

SECTION 10511—EXTRATERRITORIAL JURISDICTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
10511	21 U.S.C. 337a	June 25, 1938, ch. 675, §311, as added Pub. L. 112–144, title VII, §718, July 9, 2012, 126 Stat. 1077.

Division C—Food

Chapter 111—General Provisions

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11101(a)	21 U.S.C. 341 (1st sentence)	June 25, 1938, ch. 675, §401 (1st sentence), 52 Stat. 1046; Apr. 15, 1954, ch. 143, §1, 68 Stat. 54; Aug. 1, 1956, ch. 861, §1, 70 Stat. 919; Pub. L. 103–80, §3(h), Aug. 13, 1993, 107 Stat. 776.
11101(b)(1)	21 U.S.C. 341 (2d sentence (from "No definition" through "or butter,"))	June 25, 1938, ch. 675, §401 (2d sentence (from "No definition" through "or butter,")), 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, §1, 70 Stat. 919; Pub. L. 103–80, § 3(h), Aug. 13, 1993, 107 Stat. 776.
11101(b)(2)(A)	21 U.S.C. 341 (2d sentence (from "except that" through "and melons."))	June 25, 1938, ch. 675, § 401 (2d sentence (from "except that" through "and melons.")), 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919; Pub. L. 103–80, § 3(h), Aug. 13, 1993, 107 Stat. 776.
11101(b)(2)(B)	21 U.S.C. 341 (last sentence)	June 25, 1938, ch. 675, § 401 (last sentence), 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919; Pub. L. 103–80, § 3(h), Aug. 13, 1993, 107 Stat. 776.
11101(c)	21 U.S.C. 341 (3d sentence)	June 25, 1938, ch. 675, § 401 (3d sentence), 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919; Pub. L. 103–80, § 3(h), Aug. 13, 1993, 107 Stat. 776.
11101(d)	21 U.S.C. 341 (4th sentence)	June 25, 1938, ch. 675, § 401 (4th sentence), 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919; Pub. L. 103–80, § 3(h), Aug. 13, 1993, 107 Stat. 776.
11101(e)	21 U.S.C. 341 (5th sentence)	June 25, 1938, ch. 675, § 401 (5th sentence), 52 Stat. 1046; Apr. 15, 1954, ch. 143, § 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, § 1, 70 Stat. 919; Pub. L. 103–80, § 3(h), Aug. 13, 1993, 107 Stat. 776.

In subsection (a), the words "to the extent practicable" are substituted for "so far as practicable" for consistency in title 21, United States Code.

In subsection (a), the words "promulgating the regulations" are substituted for "such action" for clarity.

In subsection (c), in the matter before paragraph (1), the words "shall consider" are substituted for "shall give due consideration" to eliminate unnecessary words.

In subsection (d), the words "the Secretary shall consider and allow for" are substituted for "consideration shall be given and due allowance made for" for consistency with subsection (a) and to eliminate unnecessary words.

SECTION 11102—ADULTERATED FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11102(a)	21 U.S.C. 342(a)	June 25, 1938, ch. 675, §402(a), 52 Stat. 1046; July 22, 1954, ch. 559, §2, 68 Stat. 511; Pub. L. 85–929, §3(a), (b), Sept. 6, 1958, 72 Stat. 1784; Pub. L. 86–618, title I, §102(a)(1), (2), July 12, 1960, 74 Stat. 397, 398; Pub. L. 90–399, §104, July 13, 1968, 82 Stat. 352; Pub. L. 103–80, §3(i), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, §404, Aug. 3, 1996, 110 Stat. 1514.
11102(b)	21 U.S.C. 342(b)	June 25, 1938, ch. 675, § 402(b), 52 Stat. 1046.
11102(c)	21 U.S.C. 342(c)	June 25, 1938, ch. 675, § 402(c), 52 Stat. 1046; July 9, 1956, ch. 530, 70 Stat. 512; Pub. L. 86–2, Mar. 17, 1959, 73 Stat. 3; Pub. L. 86–618, title I, §102(a)(2), July 12, 1960, 74 Stat. 398; Pub. L. 102–571, title I, §107(4), Oct. 29, 1992, 106 Stat. 4499.
11102(d)	21 U.S.C. 342(d)	June 25, 1938, ch. 675, §402(d), 52 Stat. 1046; Pub. L. 86–618, title I, §105(c), July 12, 1960, 74 Stat. 404;

SECTION 11102—ADULTERATED FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Pub. L. 89–477, June 29, 1966, 80 Stat. 231; Pub. L. 99–252, §10, Feb. 27, 1986, 100 Stat. 35; Pub. L. 103–80, §3(i)(2), (3), Aug. 13, 1993, 107 Stat. 776.
11102(e)	21 U.S.C. 342(e)	June 25, 1938, ch. 675, §402(e), as added Mar. 16, 1950, ch. 61, §3(d), 64 Stat. 21.
11102(f)	21 U.S.C. 342(f)	June 25, 1938, ch. 675, §402(f), as added Pub. L. 103–417, §4, Oct. 25, 1994, 108 Stat. 4328.
11102(g)	21 U.S.C. 342(g)	June 25, 1938, ch. 675, §402(g), as added Pub. L. 103–417, §9, Oct. 25, 1994, 108 Stat. 4332.
11102(h)	21 U.S.C. 342(h)	June 25, 1938, ch. 675, §402(h), as added Pub. L. 107–188, title III, §309, June 12, 2002, 116 Stat. 673.
11102(i)	21 U.S.C. 342(i)	June 25, 1938, ch. 675, §402(i), as added Pub. L. 109–59, title VII, §7202(a), Aug. 10, 2005, 119 Stat. 1911.

In this section, the words "A food shall be deemed to be adulterated" are added at the beginning of each subsection to carry forward the matter before subsection (a) of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342).

In subsection (a)(1), the words "this paragraph" are substituted for "this clause" to provide the correct reference to the pertinent provision.

In subsection (d)(2)(B), the words "This paragraph" are substituted for "this clause" to provide the correct reference to the pertinent provision.

SECTION 11103—NATIONAL UNIFORM NUTRITION LABELING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11103	21 U.S.C. 343–1	June 25, 1938, ch. 675, § 403A, as added Pub. L. 101–535, § 6(a), Nov. 8, 1990, 104 Stat. 2362; amended Pub. L. 102–108, § 2(b), Aug. 17, 1991, 105 Stat. 549; Pub. L. 103–396, § 3(a), Oct. 22, 1994, 108 Stat. 4154; Pub. L. 108–282, title II, § 203(c)(2), Aug. 2, 2004, 118 Stat. 908; Pub. L. 111–148, title IV, § 4205(c), Mar. 23, 2010, 124 Stat. 576.

In subsection (a)(1), the references to section 403(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(g)) are translated as section 11307 of title 21, United States Code, even though those references to section 11307 are broader because section 11307 of that title also restates the part of section 403(k) of the Act that relates to section 403(g) of the Act. The broader translation is done for convenience and does not affect the meaning or effect of the source provision.

In subsection (a)(3), the reference to section 403(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(k)) is translated as section 11312 of title 21, United States Code, even though the reference to section 11312 is narrower because section 11312 of that title does not restate the matter in the 2d sentence of section 403(k) of the Act that relates paragraphs (g) and (i) of section 403 of the Act. The matter relating to paragraph (g) is restated as section 11307(g) of title 21, United States Code. The matter relating to paragraph (i) is restated as section 11310(d) of title 21, United States Code. The narrower translation is done for convenience and does not affect the meaning or effect of the source provision.

SECTION 11104—DIETARY SUPPLEMENT LABELING EXEMPTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11104	21 U.S.C. 343–2	June 25, 1938, ch. 675, § 403B, as added Pub. L. 103–417, § 5, Oct. 25, 1994, 108 Stat. 4328.

In subsection (a)(3), the words "with other publications" are substituted for "with other such items" for clarity.

In subsection (b), the words "in any way whatsoever" are omitted as unnecessary.

In subsection (c), the words "a publication" are substituted for "an article or other such matter" for consistency in the section.

SECTION 11105—DISCLOSURE RELATING TO RADIATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11105(a)	21 U.S.C. 343–3(b)	June 25, 1938, ch. 675, § 403C(b), as added Pub. L. 105–115, title III, § 306, Nov. 21, 1997, 111 Stat. 2353.
11105(b)	21 U.S.C. 343–3(a)	June 25, 1938, ch. 675, § 403C(a), as added Pub. L. 105–115, title III, § 306, Nov. 21, 1997, 111 Stat. 2353.

SECTION 11106—EMERGENCY PERMIT RELATING TO CONTAMINATED FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11106(a)(1) (matter before (A) ("if the Secretary finds, after investigation, that"))	21 U.S.C. 344(a) ("Whenever the Secretary finds after investigation that")	June 25, 1938, ch. 675, § 404(a) ("Whenever the Secretary finds after investigation that"), 52 Stat. 1048.
11106(a)(1) (matter before (A) ("The Secretary shall prescribe regulations providing for the issuance of permits described in this subsection"))	21 U.S.C. 344(a) ("he then, and in such case only, shall promulgate regulations providing for the issuance", "of permits")	June 25, 1938, ch. 675, § 404(a) ("he then, and in such case only, shall promulgate regulations providing for the issuance"), ("of permits"), 52 Stat. 1048.
11106(a)(1)(A), (B)	21 U.S.C. 344(a) (from "the distribution" through "entered interstate commerce,")	June 25, 1938, ch. 675, § 404(a) (from "the distribution" through "entered interstate commerce,"), 52 Stat. 1048.
11106(a)(2)	21 U.S.C. 344(a) ("to manufacturers, processors, or packers of such class of food in such locality,")	June 25, 1938, ch. 675, § 404(a) ("to manufacturers, processors, or packers of such class of food in such locality,"), 52 Stat. 1048.
11106(a)(3)	21 U.S.C. 344(a) (from "to which" through "public health;")	June 25, 1938, ch. 675, § 404(a) (from "to which" through "public health;"), 52 Stat. 1048.
11106(a)(4)	21 U.S.C. 344(a) (from "and after the effective date" through "as provided by such regulations.")	June 25, 1938, ch. 675, § 404(a) (from "and after the effective date" through "as provided by such regulations."), 52 Stat. 1048.
11106(b)	21 U.S.C. 344(b)	June 25, 1938, ch. 675, § 404(b), 52 Stat. 1048.
11106(c)	21 U.S.C. 344(c)	June 25, 1938, ch. 675, § 404(c), 52 Stat. 1048.

In subsection (a)(1), in the matter before subparagraph (A), the words "The Secretary shall prescribe regulations providing for the issuance of permits" are

substituted for "he then, and in such case only, shall promulgate regulations providing for the issuance . . . of permits" for clarity.

In subsection (a)(1)(A), the words "of articles of food within the class" are substituted for "thereof" for clarity and to provide an antecedent for "the articles" in subparagraph (B).

In subsection (a)(2), the words "of the class of food described in paragraph (1) in the locality" are substituted for "of such class of food in such locality" for clarity.

In subsection (a)(4), the words "any article of food within the class described in paragraph (1)" are substituted for "any such food" for clarity.

In subsection (a)(4), the words "any manufacturer, processor, or packer of the class of food described in paragraph (1) in the locality" are substituted for "any such manufacturer, processor, or packer" for clarity.

In subsection (b)(1), the words "if the Secretary finds" are substituted for "if it is found" for clarity.

In subsection (b)(2)(B), the words "manufacturing, processing, or packing establishment" are substituted for "establishment" for clarity and consistency in the section.

In subsection (b)(2)(B), the words "if the Secretary finds" are substituted for "if it is found" for clarity.

SECTION 11107—REGULATIONS MAKING LABELING EXEMPTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11107	21 U.S.C. 345	June 25, 1938, ch. 675, § 405, 52 Stat. 1049; Pub. L. 101–535, § 5(a), Nov. 8, 1990, 104 Stat. 2362.

SECTION 11108—ADDED POISONOUS OR DELETERIOUS SUBSTANCES DEEMED UNSAFE; TOLERANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11108	21 U.S.C. 346	June 25, 1938, ch. 675, § 406, 52 Stat. 1049; Pub. L. 85–929, § 3(c), Sept. 6, 1958, 72 Stat. 1785; Pub. L. 86–618, title I, § 103(a)(1), July 12, 1960, 74 Stat. 398.

In this section, the words "or the Administrator, as applicable pursuant to section 2(a)(4) of Reorganization Plan No. 3 of 1970 (42 U.S.C. 4321 note)," are added each place they appear for clarity and consistency with section 2(a)(4) of Reorganization Plan No. 3 of 1970 (42 U.S.C. 4321 note).

In subsection (b)(1), the words "production of the food" are substituted for "production thereof" for clarity.

In subsection (c), the words "in or on the food" are substituted for "therein or thereon" for clarity.

In subsection (c), the words the words "the Secretary or Administrator finds necessary" are substituted for "as he finds necessary" for clarity and consistency with section 2(a)(4) of Reorganization Plan No. 3 of 1970 (42 U.S.C. 4321 note).

In subsection (d), the words "prescribed by regulation under subsection (c)" are substituted for "so fixed" for consistency with subsection (c).

SECTION 11109—INTRASTATE SALES OF COLORED OLEOMARGARINE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11109(a)	(no source)	
11109(b)	21 U.S.C. 347(e)	June 25, 1938, ch. 675, § 407(e), as added Mar. 16, 1950, ch. 61, § 3(c), 64 Stat. 20.
11109(c) through (f)	21 U.S.C. 347(a) through (d)	June 25, 1938, ch. 675, § 407(a) through (d), as added Mar. 16, 1950, ch. 61, § 3(c), 64 Stat. 20.

Subsection (a) is added to carry forward the matter relating to section 407 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 347) in subsection (f) of section 15 of the Federal Trade Commission Act (15 U.S.C. 55(f)). See section 4(7)(A)(ii) of the bill enacting title 21, United States Code. In carrying the provision forward, subsection (a) provides for the inclusions in the terms "margarine" and "oleomargarine" separately, as paragraphs (1) and (2) respectively, for clarity. In both provisions, the word "consistency" is substituted for "consistence" to use a more modern word.

SECTION 11110—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11110(a)(1)	21 U.S.C. 346a(a)(1) (matter after (B))	June 25, 1938, ch. 675, § 408(a)(1) (matter after (B)), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514.
11110(a)(2)	21 U.S.C. 346a(b)(1) (matter after (B))	June 25, 1938, ch. 675, § 408(b)(1) (matter after (B)), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1515.
11110(a)(3)	21 U.S.C. 346a(b)(2)(A)(ii)	June 25, 1938, ch. 675, § 408(b)(2)(A)(ii), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1516.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
	21 U.S.C. 346a(c)(2)(A)(ii)	June 25, 1938, ch. 675, § 408(c)(2)(A)(ii), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1520.
11110(b)(1) (matter before (A))	21 U.S.C. 346a(a)(1) (matter before (A))	June 25, 1938, ch. 675, § 408(a)(1) (matter before (A)), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514.
11110(b)(1)(A), (B)	21 U.S.C. 346a(a)(1)(A), (B)	June 25, 1938, ch. 675, § 408(a)(1)(A), (B), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514.
11110(b)(2) through (4)	21 U.S.C. 346a(a)(2) through (4)	June 25, 1938, ch. 675, § 408(a)(2) through (4), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514.
11110(c)(1) (matter before (A))	21 U.S.C. 346a(b)(1) (matter before (A))	June 25, 1938, ch. 675, § 408(b)(1) (matter before (A)), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1515.
11110(c)(1)(A), (B)	21 U.S.C. 346a(b)(1)(A), (B)	June 25, 1938, ch. 675, § 408(b)(1)(A), (B), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240;

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1515.
11110(c)(2)(A)(i)	21 U.S.C. 346a(b)(2)(A)(i)	June 25, 1938, ch. 675, § 408(b)(2)(A)(i), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1516.
11110(c)(2)(A)(ii)	21 U.S.C. 346a(b)(2)(A)(iii)	June 25, 1938, ch. 675, § 408(b)(2)(A)(iii), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1516.
11110(c)(2)(B)	21 U.S.C. 346a(b)(2)(B)	June 25, 1938, ch. 675, § 408(b)(2)(B), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1516.
11110(c)(2)(C)(i) (matter before (I)) ..	21 U.S.C. 346a(b)(2)(C) (matter before (i))	June 25, 1938, ch. 675, § 408(b)(2)(C) (matter before (i)), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1517.
11110(c)(2)(C)(i)(I), (II)	21 U.S.C. 346a(b)(2)(C)(i), (ii)	June 25, 1938, ch. 675, § 408(b)(2)(C)(i), (ii), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1517.
11110(c)(2)(C)(ii)	21 U.S.C. 346a(b)(2)(C) (matter after (ii)(II) (1st sentence))	June 25, 1938, ch. 675, § 408(b)(2)(C) (matter after (ii)(II) (1st sentence)), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§ 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1518.
11110(c)(2)(C)(iii)	21 U.S.C. 346a note	Pub. L. 104–170, title III, §301, Aug. 3, 1996, 110 Stat. 1511.
11110(c)(2)(C)(iv)	21 U.S.C. 346a(b)(2)(C) (matter after (ii)(II) (2d sentence, last sentence))	June 25, 1938, ch. 675, § 408(b)(2)(C) (matter after (ii)(II) (2d sentence, last sentence)), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1518.
11110(c)(2)(D) through (F)	21 U.S.C. 346a(b)(2)(D) through (F)	June 25, 1938, ch. 675, § 408(b)(2)(D) through (F), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1518.
11110(c)(3), (4)	21 U.S.C. 346a(b)(3), (4)	June 25, 1938, ch. 675, § 408(b)(3), (4), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1519.
11110(d)(1)	21 U.S.C. 346a(c)(1)	June 25, 1938, ch. 675, § 408(c)(1), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1520.
11110(d)(2)(A)	21 U.S.C. 346a(c)(2)(A)(i)	June 25, 1938, ch. 675, § 408(c)(2)(A)(i), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§ 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1520.
11110(d)(2)(B)	21 U.S.C. 346a(c)(2)(B)	June 25, 1938, ch. 675, § 408(c)(2)(B), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1520.
11110(d)(3)	21 U.S.C. 346a(c)(3)	June 25, 1938, ch. 675, § 408(c)(3), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1520.
11110(e)	21 U.S.C. 346a(d)	June 25, 1938, ch. 675, § 408(d), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1521.
11110(f)	21 U.S.C. 346a(e)	June 25, 1938, ch. 675, § 408(e), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1523.
11110(g)	21 U.S.C. 346a(f)	June 25, 1938, ch. 675, § 408(f), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1523.
11110(h)	21 U.S.C. 346a(g)	June 25, 1938, ch. 675, § 408(g), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1524.
11110(i)	21 U.S.C. 346a(h)	June 25, 1938, ch. 675, § 408(h), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1525.
11110(j)	21 U.S.C. 346a(i)	June 25, 1938, ch. 675, § 408(i), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1526.
11110(k)	21 U.S.C. 346a(j)	June 25, 1938, ch. 675, § 408(j), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 105–324, § 2(b), Oct. 30, 1998, 112 Stat. 3036.
11110(l)	21 U.S.C. 346a(k)	June 25, 1938, ch. 675, § 408(k), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1527.
11110(m)	21 U.S.C. 346a(l)	June 25, 1938, ch. 675, § 408(l), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107

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		Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1527.
11110(n)	21 U.S.C. 346a(m)	June 25, 1938, ch. 675, § 408(m), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 110–94, § 4(d)(2), Oct. 9, 2007, 121 Stat. 1002; Pub. L. 112–177, § 2(a)(3), Sept. 28, 2012, 126 Stat. 1329; Pub. L. 116–8, §2(c), Mar. 8, 2019, 133 Stat. 485; Pub. L. 117–328, div. HH, title VI, §703(b), Dec. 29, 2022, 136 Stat. 6002.
11110(o)	21 U.S.C. 346a(n)	June 25, 1938, ch. 675, § 408(n), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1530.
11110(p)	21 U.S.C. 346a(o)	June 25, 1938, ch. 675, § 408(o), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1532.
11110(q)	21 U.S.C. 346a(p)(1) through (6)	June 25, 1938, ch. 675, § 408(p)(1) through (6), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1532.
11110(r)	21 U.S.C. 346a(r)	June 25, 1938, ch. 675, § 408(r), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1535.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11110(s)	21 U.S.C. 346a note	Pub. L. 113–79, title X, §10015, Feb. 7, 2014, 128 Stat. 952.
11110(t)	21 U.S.C. 346a(s)	June 25, 1938, ch. 675, § 408(s), as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1535.

In subsection (a)(2), the words "with respect to a tolerance," are added for clarity.

In subsection (b)(3), the words "exemption from the requirement" are substituted for the words "exemption from the need" each place they appear for consistency in the section.

In subsection (b)(3), in the matter before subparagraph (A), the words "the pesticide chemical residue present in or on the food" are substituted for "such a residue" for clarity.

In subsection (c)(2)(B)(v)(I), in the matter before item (aa), the words "as the Administrator considers appropriate" are substituted for "as the Administrator deems appropriate" to use the more appropriate word.

In subsection (c)(2)(E)(ii)(I), the words "as the Administrator considers appropriate" are substituted for "as the Administrator deems appropriate" to use the more appropriate word.

In subsection (c)(2)(E)(ii)(I), the words "relied on by the Administrator" are substituted for "so relied on" for clarity.

In subsection (c)(2)(F)(i), the words "crop that is treated with the pesticide chemical" are substituted for "such crop" for clarity because "such crop" has no antecedent.

In subsection (e)(2)(A)(viii), the words "the processing methods" are substituted for "the processing method(s)" for consistency in title 21, United States Code, and because of section 1 of title 1, United States Code.

In subsection (e)(4)(C)(ii)(II), the words "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," are substituted for "If such condition does not continue to exist," for clarity and consistency in the clause.

In subsection (e)(4)(C)(ii)(II), the words "the determination is made" are substituted for "the determination under the preceding sentence is made" because of the addition of the words "the Administrator determines" in the first part of the subclause. See previous revision note.

In subsection (g)(1)(C)(i), the words "by any interested person" are substituted for "by 1 or more interested persons" to eliminate unnecessary words because of section 1 of title 1, United States Code.

In subsection (g)(1)(C)(i), the words, "the person" are substituted for "the person or persons" to eliminate unnecessary words because of section 1 of title 1, United States Code.

In subsection (h)(2)(A)(i), the words "to the regulation or order" are substituted for "thereto" for clarity.

In subsection (h)(2)(A)(i), the words "considered objectionable" are substituted for "deemed objectionable" to use the more appropriate word.

In subsection (h)(2)(A)(i), the words "for considering the provisions objectionable" are substituted for "therefor" for clarity.

In subsection (h)(2)(B)(v), the words "a subpoena under clause (iii)" are substituted for "such a subpoena" for clarity.

In subsection (h)(2)(C)(i)(I), the words "each objection under this paragraph" are substituted for "each such objection" for clarity.

In subsection (i)(1), the words "subject of an order issued under subsection (g)(1)(C) or (h)(2)(C)" are substituted for "subject of such an order" for clarity.

In subsection (i)(2)(A), the words "immediately transmitted" are substituted for "forthwith transmitted" for consistency in title 21, United States Code.

In subsection (i)(2)(A), the words "on the transmittal," are substituted for "thereupon" for clarity.

In subsection (i)(2)(B), the words "that is petitioned to be set aside" are substituted for "complained of" for clarity and consistency in the subsection.

In subsection (i)(3)(A), the words "the court may order the additional evidence . . . to be taken" are substituted for "the court may order that the additional evidence . . . shall be taken" to eliminate unnecessary words.

In subsection (i)(3)(A), the words "the court considers proper" are substituted for "the court deems proper" to use the more appropriate word.

In subsection (j)(2)(A)(i), the words "Federal employees" are substituted for "employees of the United States" to eliminate unnecessary words.

In subsection (j)(2)(B)(i), the words "the Senate or the House of Representatives" are substituted for "either House of Congress" for consistency in title 21, United States Code.

In paragraphs (1) through (3) of subsection (k), the words "and shall be subject to review under subsection (q)" are omitted each place they appear to eliminate obsolete words. Subsection (q) of section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(q)) is repealed as obsolete by the bill enacting title 21, United States Code. See Disposition Table entry for 21 U.S.C. 346a(q).

In subsection (k)(1), the words "section 11108 of this title" are substituted for "section 406(a)" to provide the correct reference to the pertinent provision. Section 406 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346) is restated as section 11108 of title 21, United States Code. There is no subsection (a) in section 406 of the Act.

In subsection (k)(4)(B), the words "on the day before October 30, 1998," are substituted for "on such day" for clarity.

In subsection (m)(1), the words "and consistent with the review deadlines in subsection (q)" are omitted as obsolete. Subsection (q) of section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(q)) is repealed as obsolete by the bill enacting title 21, United States Code. See Disposition Table entry for 21 U.S.C. 346a(q).

In subsection (m)(6)(D)(i), the words "within 365 days after the date of the enactment of this paragraph" are omitted as obsolete. See 65 Fed. Reg. 64126 (Oct. 25, 2000).

In subsection (n)(3), the words "on December 29, 2022" are substituted for "on the effective date of the Pesticide Registration Improvement Act of 2022" for clarity.

In subsection (o)(3)(B), the words "contains a pesticide chemical residue" are substituted for "contains a pesticide residue" for consistency in the subsection.

In subsection (o)(4)(C)(ii), the words "in violation of Federal law" are substituted for "a violation of Federal law" to use the more appropriate word.

In subsection (o)(4)(D)(ii), the word "act" is substituted for "thereafter act" to eliminate an unnecessary word.

In subsection (o)(5)(A), the words "pesticide chemical residue level" are substituted for "pesticide residue level" for consistency in the subsection.

In subsection (p)(1), in the matter before subparagraph (A), the words "The Administrator shall annually," are substituted for "Not later than 2 years after the date of enactment of this section, the Administrator shall" to eliminate obsolete words.

In subsection (q)(1), the words "Not later than 2 years after the date of enactment of this section," are omitted as obsolete.

In subsection (q)(2), the words "Not later than 3 years after the date of enactment of this section," are omitted as obsolete.

In subsection (q)(2), the words "section 8 of the Environmental Research, Development, and Demonstration Authorization Act of 1978 (42 U.S.C. 4365)" are substituted for "section 8 of the Environmental Research, Development, and Demonstration Act of 1978 (42 U.S.C. 4365)" to provide the correct reference to the pertinent provision.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11111(a)	21 U.S.C. 348(h)(6)	June 25, 1938, ch. 675, § 409(h)(6), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2356.
11111(b)	21 U.S.C. 348(a)	June 25, 1938, ch. 675, § 409(a), as added Pub. L. 85–929, §4, Sept. 6, 1958, 72 Stat. 1785; Pub. L. 105–115, title III, §309, Nov. 21, 1997, 111 Stat. 2354.
11111(c)	21 U.S.C. 348(b)	June 25, 1938, ch. 675, § 409(b), as added Pub. L. 85–929, § 4, Sept. 6, 1958, 72 Stat. 1785.
11111(d)	21 U.S.C. 348(c)	June 25, 1938, ch. 675, § 409(c), as added Pub. L. 85–929, §4, Sept. 6, 1958, 72 Stat. 1786; Pub. L. 87–781, title I, §104(f)(1), Oct. 10, 1962, 76 Stat. 785.
11111(e)	21 U.S.C. 348(d)	June 25, 1938, ch. 675, § 409(d), as added Pub. L. 85–929, § 4, Sept. 6, 1958, 72 Stat. 1787.
11111(f)	21 U.S.C. 348(e)	June 25, 1938, ch. 675, § 409(e), as added Pub. L. 85–929, § 4, Sept. 6, 1958, 72 Stat. 1787.
11111(g)	21 U.S.C. 348(f)	June 25, 1938, ch. 675, §409(f), as added Pub. L. 85–929, § 4, Sept. 6, 1958, 72 Stat. 1787.
11111(h)	21 U.S.C. 348(g)	June 25, 1938, ch. 675, § 409(g), as added Pub. L. 85–929, § 4, Sept. 6, 1958, 72 Stat. 1785; Pub. L. 86–546, § 2, June 29, 1960, 74 Stat. 255; Pub. L. 98–620, title IV, § 402(25)(B), Nov. 8, 1984, 98 Stat. 3359.
11111(i)(1)	21 U.S.C. 348(h)(1)	June 25, 1938, ch. 675, § 409(h)(1), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2354.
11111(i)(2)(A)	21 U.S.C. 348(h)(2)(C)	June 25, 1938, ch. 675, § 409(h)(2)(C), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2355.
11111(i)(2)(B)	21 U.S.C. 348(h)(2)(A)	June 25, 1938, ch. 675, § 409(h)(2)(A), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2354.
11111(i)(2)(C)	21 U.S.C. 348(h)(2)(B)	June 25, 1938, ch. 675, § 409(h)(2)(B), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2355.
11111(i)(3)	21 U.S.C. 348(h)(3)	June 25, 1938, ch. 675, § 409(i)(3), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2355.
11111(i)(4)	21 U.S.C. 348(h)(4)	June 25, 1938, ch. 675, § 409(h)(4), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2355.
11111(i)(5)(A)(i)	21 U.S.C. 348(h)(5)(A)(i)	June 25, 1938, ch. 675, § 409(h)(5)(A)(i), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2355.
11111(i)(5)(A)(ii)	21 U.S.C. 348(h)(5)(A)(iv)	June 25, 1938, ch. 675, § 409(h)(5)(A)(iv), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2356.
11111(i)(5)(B)	21 U.S.C. 348(h)(5)(C)	June 25, 1938, ch. 675, § 409(h)(5)(C), as added Pub. L. 105–115, title III, § 309(b)(2), Nov. 21, 1997, 111 Stat. 2356.
11111(j)	21 U.S.C. 348(i)	June 25, 1938, ch. 675, §409(i), formerly §409(h), as added Pub. L. 85–929, §4, Sept. 6, 1958, 72 Stat. 1785; redesignated §409(i), Pub. L. 105–115, title III, §309(b)(1), (3), Nov. 21, 1997, 111 Stat. 2354, 2356.
11111(k)	21 U.S.C. 348(j)	June 25, 1938, ch. 675, §409(j), formerly §409(i), as added Pub. L. 85–929, §4, Sept. 6, 1958, 72 Stat. 1785; redesignated §409(j), Pub. L. 105–115, title III, §309(b)(1), (3), Nov. 21, 1997, 111 Stat. 2354, 2356.
11111(l)(1) through (3)	21 U.S.C. 348(k)	June 25, 1938, ch. 675, §409(k), as added Pub. L. 115–234, title III, §306(a), Aug. 14, 2018, 132 Stat. 2440.
11111(l)(4)	21 U.S.C. 348 note	Pub. L. 115–234, title III, §306(c), Aug. 14, 2018, 132 Stat. 2441.

In subsection (b)(1)(C), in the matter before clause (i), the words "food additive" are substituted for "food additive as defined in this Act" to eliminate unnecessary words.

In subsection (d), the word “humans” is substituted for “man” each place it appears to use a gender-neutral term.

In subsection (d)(1)(A)(i), the words “classes of food in or on which the food” are substituted for “classes of food in or in which the food” to correct an error in the law.

In subsection (d)(1(A)(i), the words “that the Secretary considers necessary” are substituted for “deemed necessary by him” to use the more appropriate word.

In subsection (d)(1)(A)(i), the words “ensure the safety” are substituted for “assure the safety” to use the more appropriate word.

In subsection (d)(2), the words “as the Secretary considers necessary” are substituted for “as the Secretary deems necessary” to use the more appropriate word.

In subsection (d)(3), in the matter before subparagraph (A), the words “A regulation proposed to be issued under this subsection shall not be issued if either subparagraph (A) or (B) applies” are substituted for “No such regulation shall issue” for clarity.

In subsection (d)(4), in the matter before subparagraph (A), the words “ensure that the proposed use” are substituted for “assure that the proposed use” to use the more appropriate word.

In subsection (d)(5)(B), the words “related substance” are substituted for “related substance or substances” because under section 1 of title 1, United States Code, the singular includes the plural.

In subsection (e)(1), the words “for the conditions” are substituted for “therefor” for clarity.

In subsection (g)(1)(A), the words “considered objectionable” are substituted for “deemed objectionable” to use the more appropriate word.

In subsection (g)(1)(A), the words “reasonable grounds for the objections” are substituted for “reasonable grounds therefor” for clarity.

In subsection (h)(2)(A), the words “immediately transmitted” are substituted for “forthwith transmitted” for consistency in title 21, United States Code.

In subsection (h)(2)(A), the words “on the transmittal,” are substituted for “thereupon” for clarity.

In subsection (h)(4)(A), the words “prior proceedings before the Secretary” are substituted for “proceedings below” for clarity.

In subsection (i)(5)(A)(i), the words “Except as provided in clause (ii)” are omitted as obsolete.

In subsection (i)(5)(A)(ii), the words “For fiscal year 2000 and subsequent fiscal years,” are omitted as obsolete.

In subsection (i)(5)(B), the words "Not later than February 1 of each fiscal year," are substituted for "Not later than April 1 of fiscal year 1998 and February 1 of each subsequent fiscal year," to eliminate obsolete words.

In subsection (i)(5)(B), the words "Committee on Energy and Commerce of the House of Representatives" are substituted for "Committee on Commerce of the House of Representatives" on authority of Rule X(1)(f) of the Rules of House of Representatives, adopted by House Resolution No. 5 (107th Congress, January 3, 2001).

In subsection (i)(5)(B), the words "Committee on Health, Education, Labor, and Pensions of the Senate" are substituted for "Committee on Labor and Human Resources of the Senate" on authority of Rule XXV(1)(m) of the Standing Rules of the Senate. See S. Res. 20, adopted January 19, 1999 (changing Committee name).

In subsection (j), the words "subsections (a) through (i)" are substituted for "the foregoing provisions of this section" for clarity.

In subsection (k), the reference to subsections (c) through (j) is translated from the reference to subsections (b) to (i) in the source law for convenience, even though subsection (h)(6) of the source law is restated as subsection (a) in the restatement.

In subsection (k), the words "inclusive, of this section," are omitted as unnecessary.

SECTION 11112—BOTTLED DRINKING WATER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11112(a)	21 U.S.C. 349(a)	June 25, 1938, ch. 675, § 410(a), as added Pub. L. 104–182, title III, § 305(1), Aug. 6, 1996, 110 Stat. 1684.
11112(b)(1) through (3)	21 U.S.C. 349(b)(1) through (3)	June 25, 1938, ch. 675, § 410(b)(1) through (3), as added Pub. L. 104–182, title III, § 305(2), Aug. 6, 1996, 110 Stat. 1684.
11112(b)(4)(A)	21 U.S.C. 349(b)(4)(A)	June 25, 1938, ch. 675, § 410(b)(4)(A), as added Pub. L. 104–182, title III, § 305(2), Aug. 6, 1996, 110 Stat. 1685.
11112(b)(4)(B)(i)	21 U.S.C. 349(b)(4)(B) (matter before (i) ("a national primary drinking water regulation that pursuant to subparagraph (A) is considered to be a standard of quality regulation,"))	June 25, 1938, ch. 675, § 410(b)(4)(B) (matter before (i) ("a national primary drinking water regulation that pursuant to subparagraph (A) is considered to be a standard of quality regulation,")), as added Pub. L. 104–182, title III, § 305(2), Aug. 6, 1996, 110 Stat. 1685.
11112(b)(4)(B)(ii)	21 U.S.C. 349(b)(4)(B) (except matter before (i) ("a national primary drinking water regulation that pursuant to subparagraph (A) is considered to be a standard of quality regulation,"))	June 25, 1938, ch. 675, § 410(b)(4)(B) (except matter before (i) ("a national primary drinking water regulation that pursuant to subparagraph (A) is considered to be a standard of quality regulation,")), as added Pub. L. 104–182, title III, § 305(2), Aug. 6, 1996, 110 Stat. 1685.

In subsection (a), in the matter before paragraph (1), the words "Safe Drinking Water Act" are substituted for "Public Health Service Act" to provide the correct reference to the pertinent provision.

In subsection (b), the word "deemed" is substituted for "considered" each place it appears to use the more appropriate word.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11113(a)	21 U.S.C. 350(c)	June 25, 1938, ch. 675, §411(c), as added Pub. L. 94–278, title V, §501(a), Apr. 22, 1976, 90 Stat. 410; Pub. L. 103–417, §3(c), Oct. 25, 1994, 108 Stat. 4328.
11113(b)	21 U.S.C. 350(a)(1)	June 25, 1938, ch. 675, § 411(a)(1), as added Pub. L. 94–278, title V, § 501(a), Apr. 22, 1976, 90 Stat. 410.
11113(c)(1)	21 U.S.C. 350(a)(2) (last sentence)	June 25, 1938, ch. 675, § 411(a)(2) (last sentence), as added Pub. L. 94–278, title V, § 501(a), Apr. 22, 1976, 90 Stat. 410.
11113(c)(2)	21 U.S.C. 350(a)(2) (1st sentence)	June 25, 1938, ch. 675, § 411(a)(2) (1st sentence), as added Pub. L. 94–278, title V, § 501(a), Apr. 22, 1976, 90 Stat. 410.
11113(d)	21 U.S.C. 350(b)	June 25, 1938, ch. 675, § 411(b), as added Pub. L. 94–278, title V, § 501(a), Apr. 22, 1976, 90 Stat. 410; Pub. L. 103–417, §7(d), Oct. 25, 1994, 108 Stat. 4331.
11113(e)	21 U.S.C. 350 note	Pub. L. 94–278, title V, §501(b), Apr. 22, 1976, 90 Stat. 411; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.

In subsection (a)(3), in the matter before paragraph (1), the words "as applied to food used by man" are omitted as unnecessary because of the words "for humans" in subsection (a)(1)(A).

In subsection (b)(2), in the matter after the semicolon, the word "and" is added for clarity.

In subsection (d)(1), in the matter before subparagraph (A), the words "shall not be considered" are substituted for "shall not be deemed" to use the more appropriate word.

SECTION 11114—INFANT FORMULAS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11114(a)	21 U.S.C. 350a(a)	June 25, 1938, ch. 675, § 412(a), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–116.
11114(b)(1)	21 U.S.C. 350a(b)(1)	June 25, 1938, ch. 675, § 412(b)(1), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–116.
11114(b)(2)	21 U.S.C. 350a(b)(2)	June 25, 1938, ch. 675, § 412(b)(2), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–116.
11114(b)(3)(A)	21 U.S.C. 350a(b)(3)(E)	June 25, 1938, ch. 675, § 412(b)(3)(E), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–117.
11114(b)(3)(B)	21 U.S.C. 350a(b)(3)(A)	June 25, 1938, ch. 675, § 412(b)(3)(A), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–117.
11114(b)(3)(C)	21 U.S.C. 350a(b)(3)(B)	June 25, 1938, ch. 675, § 412(b)(3)(B), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–117.
11114(b)(3)(D)	21 U.S.C. 350a(b)(3)(C)	June 25, 1938, ch. 675, § 412(b)(3)(C), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–117.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11114(b)(3)(E)	21 U.S.C. 350a(b)(3)(D)	June 25, 1938, ch. 675, § 412(b)(3)(D), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–117.
11114(b)(4)	21 U.S.C. 350a(b)(4)	June 25, 1938, ch. 675, § 412(b)(4), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–117.
11114(c)(1)	21 U.S.C. 350a(c)(2)	June 25, 1938, ch. 675, § 412(c)(2), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–118.
11114(c)(2)	21 U.S.C. 350a(c)(1)	June 25, 1938, ch. 675, § 412(c)(1), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–118; Pub. L. 117–328, div. FF, title III, §3401(g)(6), Dec. 29, 2022, 136 Stat. 5841.
11114(d)	21 U.S.C. 350a(d)	June 25, 1938, ch. 675, § 412(d), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–118; Pub. L. 117–328, div. FF, title III, §3401(g)(3), Dec. 29, 2022, 136 Stat. 5841.
11114(e)(1)	21 U.S.C. 350a(e)(2)	June 25, 1938, ch. 675, § 412(e)(2), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–119.
11114(e)(2)	21 U.S.C. 350a(e)(1) (1st sentence)	June 25, 1938, ch. 675, § 412(e)(1) (1st sentence), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–119.
11114(e)(3)	21 U.S.C. 350a(e)(1) (last sentence)	June 25, 1938, ch. 675, § 412(e)(1) (last sentence), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–119.
11114(f)	21 U.S.C. 350a(f)	June 25, 1938, ch. 675, § 412(f), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; Pub. L. 99–570, title IV, § 4014(a)(7), Oct. 27, 1986, 100 Stat. 3207–119.
11114(g)	21 U.S.C. 350a(g)	June 25, 1938, ch. 675, § 412(g), formerly §412(e), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; redesignated §412(g), Pub. L. 99–570, title IV, § 4014(a)(1), (2), Oct. 27, 1986, 100 Stat. 3207–116.
11114(h)	21 U.S.C. 350a(h)	June 25, 1938, ch. 675, §412(h), formerly §412(f), as added Pub. L. 96–359, §2, Sept. 26, 1980, 94 Stat. 1192; redesignated §412(h), Pub. L. 99–570, title IV, § 4014(a)(1), (3) through (6), Oct. 27, 1986, 100 Stat. 3207–116; Pub. L. 103–80, §3(l), Aug. 13, 1993, 107 Stat. 777.
11114(i)	21 U.S.C. 350a(i)	June 25, 1938, ch. 675, § 412(i), formerly §412(g), as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; redesignated §412(i), Pub. L. 99–570, title IV, § 4014(a)(1), (b)(1), Oct. 27, 1986, 100 Stat. 3207–116, 3207–120; Pub. L. 117–328, div. FF, title III, §3401(g)(4), Dec. 29, 2022, 136 Stat. 5841.
11114(j)	21 U.S.C. 350a(j)	June 25, 1938, ch. 675, § 412(j), as added Pub. L. 117–328, div. FF, title III, §3401(c), Dec. 29, 2022, 136 Stat. 5838.
11114(k)	21 U.S.C. 350a(k)	June 25, 1938, ch. 675, § 412(k), as added Pub. L. 117–328, div. FF, title III, §3401(g)(1), Dec. 29, 2022, 136 Stat. 5840.
11114(l)	21 U.S.C. 350a(l)	June 25, 1938, ch. 675, § 412(l), as added Pub. L. 117–328, div. FF, title III, §3401(g)(2), Dec. 29, 2022, 136 Stat. 5840.
11114(m)(1)	21 U.S.C. 350a(m)(3)	June 25, 1938, ch. 675, § 412(m)(3), as added Pub. L. 117–328, div. FF, title III, §3401(l), Dec. 29, 2022, 136 Stat. 5846.
11114(m)(2), (3)	21 U.S.C. 350a(m)(1), (2)	June 25, 1938, ch. 675, § 412(m)(1), (2), as added Pub. L. 117–328, div. FF, title III, §3401(l), Dec. 29, 2022, 136 Stat. 5845.

In subsection (b)(2)(A), in the matter before clause (i), the words "ensure that an infant formula" are substituted for "assure that an infant formula" to use the more appropriate word.

SECTION 11115—NEW DIETARY INGREDIENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11115(a)	21 U.S.C. 350b(d)	June 25, 1938, ch. 675, § 413(d), as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331; Pub. L. 111–353, title I, § 113(a)(1), Jan. 4, 2011, 124 Stat. 3920.
11115(b)	21 U.S.C. 350b(a)	June 25, 1938, ch. 675, § 413(a), as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331.
11115(c)	21 U.S.C. 350b(b)	June 25, 1938, ch. 675, § 413(b), as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331.
11115(d)(1)	21 U.S.C. 350b(c)(2)	June 25, 1938, ch. 675, § 413(c)(2), as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331; Pub. L. 111–353, title I, § 113(a)(2), Jan. 4, 2011, 124 Stat. 3920.
11115(d)(2)	21 U.S.C. 350b(c)(1) (1st sentence)	June 25, 1938, ch. 675, § 413(c)(1) (1st sentence), as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331; Pub. L. 111–353, title I, § 113(a)(2), Jan. 4, 2011, 124 Stat. 3920.
11115(d)(3)	21 U.S.C. 350b(c)(1) (last sentence)	June 25, 1938, ch. 675, § 413(c)(1) (last sentence), as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331; Pub. L. 111–353, title I, § 113(a)(2), Jan. 4, 2011, 124 Stat. 3920.
11115(e)	21 U.S.C. 350b note	Pub. L. 111–353, title I, § 113(b), Jan. 4, 2011, 124 Stat. 3921.

In subsection (e)(4), the words "the identity" are substituted for "the identify" to correct an error in the law.

SECTION 11116—MAINTENANCE AND INSPECTION OF RECORDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11116	21 U.S.C. 350c	June 25, 1938, ch. 675, § 414, as added Pub. L. 107–188, title III, § 306(a), June 12, 2002, 116 Stat. 669; amended Pub. L. 111–353, title I, § 101(a), Jan. 4, 2011, 124 Stat. 3886.

In paragraphs (1) and (2) of subsection (a), the words "and to have access to any other article of food" are substituted for "and to any other article of food" for clarity.

In subsection (b)(1), the words "Federal agencies" are substituted for "Federal departments and agencies" to eliminate unnecessary words.

In subsection (b)(2), the words "this subsection" are substituted for "this section" to provide a more precise reference to the pertinent provision.

SECTION 11117—REGISTRATION OF FOOD FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11117(a)(1)	21 U.S.C. 350d(c)(2)	June 25, 1938, ch. 675, §415(c)(2), formerly §415(b)(2), as added Pub. L. 107–188, title III, § 305(a), June 12, 2002, 116 Stat. 667; redesignated §415(c)(2), Pub. L. 111–353, title I, § 102(b)(1)(B), Jan. 4, 2011, 124 Stat. 3887.
11117(a)(2)	21 U.S.C. 350d(c)(1)	June 25, 1938, ch. 675, § 415(c)(1), formerly §415(b)(1), as added Pub. L. 107–188, title III, § 305(a), June 12, 2002, 116 Stat. 667; redesignated §415(c)(1), Pub. L. 111–353, title I, § 102(b)(1)(B), Jan. 4, 2011, 124 Stat. 3887.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11117(a)(3)	21 U.S.C. 350d(c)(3)	June 25, 1938, ch. 675, §415(c)(3), formerly §415(b)(3), as added Pub. L. 107–188, title III, § 305(a), June 12, 2002, 116 Stat. 667; redesignated §415(c)(3), Pub. L. 111–353, title I, § 102(b)(1)(B), Jan. 4, 2011, 124 Stat. 3887.
11117(b)(1)	21 U.S.C. 350d(a)(1)	June 25, 1938, ch. 675, § 415(a)(1), as added Pub. L. 107–188, title III, § 305(a), June 12, 2002, 116 Stat. 667.
11117(b)(2)	21 U.S.C. 350d(a)(2)	June 25, 1938, ch. 675, § 415(a)(2), as added Pub. L. 107–188, title III, § 305(a), June 12, 2002, 116 Stat. 667; Pub. L. 111–353, title I, § 102(a)(1), (b)(1)(A), Jan. 4, 2011, 124 Stat. 3887.
11117(b)(3)	21 U.S.C. 350d(a)(3)	June 25, 1938, ch. 675, § 415(a)(3), as added Pub. L. 111–353, title I, § 102(a)(3), Jan. 4, 2011, 124 Stat. 3887.
11117(b)(4)	21 U.S.C. 350d(a)(4)	June 25, 1938, ch. 675, §415(a)(4), formerly §415(a)(3), as added Pub. L. 107–188, title III, §305(a), June 12, 2002, 116 Stat. 667; redesignated §415(a)(4), Pub. L. 111–353, title I, §102(a)(2), Jan. 4, 2011, 124 Stat. 3887.
11117(b)(5)	21 U.S.C. 350d(a)(5)	June 25, 1938, ch. 675, §415(a)(5), formerly §415(a)(4), as added Pub. L. 107–188, title III, § 305(a), June 12, 2002, 116 Stat. 667; redesignated §415(a)(5), Pub. L. 111–353, title I, § 102(a)(2), Jan. 4, 2011, 124 Stat. 3887.
11117(c)(1)	21 U.S.C. 350d(b)(1)	June 25, 1938, ch. 675, § 415(b)(1), as added Pub. L. 111–353, title I, § 102(b)(1)(C), Jan. 4, 2011, 124 Stat. 3887.
11117(c)(2)	21 U.S.C. 350d(b)(2) (1st sentence)	June 25, 1938, ch. 675, § 415(b)(2) (1st sentence), as added Pub. L. 111–353, title I, § 102(b)(1)(C), Jan. 4, 2011, 124 Stat. 3888.
11117(c)(3)	21 U.S.C. 350d(b)(2) (last sentence)	June 25, 1938, ch. 675, § 415(b)(2) (last sentence), as added Pub. L. 111–353, title I, § 102(b)(1)(C), Jan. 4, 2011, 124 Stat. 3888.
11117(c)(4)	21 U.S.C. 350d(b)(3)	June 25, 1938, ch. 675, § 415(b)(3), as added Pub. L. 111–353, title I, § 102(b)(1)(C), Jan. 4, 2011, 124 Stat. 3888.
11117(c)(5)	21 U.S.C. 350d(b)(4)	June 25, 1938, ch. 675, § 415(b)(4), as added Pub. L. 111–353, title I, § 102(b)(1)(C), Jan. 4, 2011, 124 Stat. 3888.
11117(c)(6)(A), (B)	21 U.S.C. 350d(b)(5)	June 25, 1938, ch. 675, § 415(b)(5), as added Pub. L. 111–353, title I, § 102(b)(1)(C), Jan. 4, 2011, 124 Stat. 3888.
11117(c)(6)(C)	21 U.S.C. 350d note	Pub. L. 111–353, title I, §102(b)(2), Jan. 4, 2011, 124 Stat. 3888.
11117(c)(7)	21 U.S.C. 350d(b)(7)	June 25, 1938, ch. 675, § 415(b)(7), as added Pub. L. 111–353, title I, § 102(b)(1)(C), Jan. 4, 2011, 124 Stat. 3888.
11117(d)	21 U.S.C. 350d(d)	June 25, 1938, ch. 675, §415(d), formerly §415(c), as added Pub. L. 107–188, title III, §305(a), June 12, 2002, 116 Stat. 667; redesignated §415(d), Pub. L. 111–353, title I, §102(b)(1)(B), (d)(2), Jan. 4, 2011, 124 Stat. 3887, 3889.

In subsection (a)(2)(B)(ii), the words "restaurants or other retail food establishments;" are substituted for "restaurants; other retail food establishments;" for clarity.

In subsection (a)(3)(A), the word "manufactures" is substituted for "manufacturers" to correct an error in the law.

In subsection (c)(6)(B), the second sentence of the source law, which provides that a requirement under section 415(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(b)(5)(B)), which relates to electronic submission of registration of food facilities, shall not take effect before 5 years after January 4, 2011, is omitted as obsolete.

In subsection (c)(6)(C), the words "Not later than 180 days after the issuance of the regulations promulgated under section 415(b)(5) of the Federal Food, Drug, and Cosmetic Act (as added by this section)," are omitted as obsolete.

In subsection (c)(6)(C), the words "the requirements of the regulations under this paragraph" are substituted for "the requirements of such regulations" and the words "required under this paragraph" are substituted for "required under such section" for clarity.

SECTION 11118—SANITARY TRANSPORTATION PRACTICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11118	21 U.S.C. 350e	June 25, 1938, ch. 675, §416, as added Pub. L. 109–59, title VII, §7202(b), Aug. 10, 2005, 119 Stat. 1911.

In subsection (a)(1), the words "and hopper bin" are substituted for "or hopper bin" to use the more appropriate word.

SECTION 11119—REPORTABLE FOOD REGISTRY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11119(a)(1)	21 U.S.C. 350f(a)(2)	June 25, 1938, ch. 675, § 417(a)(2), as added Pub. L. 110–85, title X, § 1005(b), Sept. 27, 2007, 121 Stat. 965.
11119(a)(2)	21 U.S.C. 350f(a)(1)	June 25, 1938, ch. 675, § 417(a)(1), as added Pub. L. 110–85, title X, § 1005(b), Sept. 27, 2007, 121 Stat. 965.
11119(b) through (n) ...	21 U.S.C. 350f(b) through (n)	June 25, 1938, ch. 675, § 417(b) through (n), as added Pub. L. 110–85, title X, § 1005(b), Sept. 27, 2007, 121 Stat. 965; amended Pub. L. 111–353, title II, § 211(a), Jan. 4, 2011, 124 Stat. 3951.
11119(o)	21 U.S.C. 350f note	Pub. L. 110–85, title X, § 1005(f), Sept. 27, 2007, 121 Stat. 969.

In subsection (b)(1), the words "Not later than 1 year after the date of the enactment of this section," are omitted as obsolete.

In subsections (c) and (d), the words "considers necessary" are substituted for the words "deems necessary" each place they appear to use the more appropriate word.

In subsection (d)(1), in the matter before subparagraph (A), the words "but not later than 24 hours" are substituted for "but in no case later than 24 hours" to eliminate unnecessary words.

In subsection (d)(6), in the matter before subparagraph (A), the words "but not later than a time" are substituted for "but in no case later than a time" to eliminate unnecessary words.

In subsection (d)(7), in the matter before subparagraph (A), the words "but not later than a time" are substituted for "but in no case later than a time" to eliminate unnecessary words.

In subsection (d)(8)(B), the words "paragraph (9) of subsection (e)" are substituted for "paragraph (9)" for clarity.

In subsection (e)(1), the words "section 11117(b)(4) of this title" are substituted for "section 415(a)(3)" to provide the correct reference to the

pertinent provision. Section 102(a)(2) of the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3951) redesignated paragraph (3) of section 415(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(a)(3)) as paragraph (4), and paragraph (4) of that section, as redesignated, is restated as section 11117(b)(4) of title 21, United States Code.

In subsection (g)(1)(A), in the matter after the semicolon, the word "and" is added for clarity.

In subsection (g)(2), the words "printed by a grocery store" are added for clarity.

In subsection (k), the words "section 11117(b)(5) of this title" are substituted for "section 415(a)(4)" to provide the correct reference to the pertinent provision. Section 102(a)(2) of the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3951) redesignated paragraph (4) of section 415(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(a)(4)) as paragraph (5), and paragraph (5) of that section, as redesignated, is restated as section 11117(b)(5) of title 21, United States Code.

In subsection (o), the words "Not later than 9 months after the date of the enactment of this Act," are omitted as obsolete.

SECTION 11120—HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11120(a)	21 U.S.C. 350g(o)	June 25, 1938, ch. 675, §418(o), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3896.
11120(b) through (l)	21 U.S.C. 350g(a) through (k)	June 25, 1938, ch. 675, §418(a) through (k), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3889.
11120(m)(1)	21 U.S.C. 350g(l)(4)	June 25, 1938, ch. 675, §418(l)(4), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3893.
11120(m)(2)	21 U.S.C. 350g(l)(1)	June 25, 1938, ch. 675, §418(l)(1), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3892.
11120(m)(3)	21 U.S.C. 350g(l)(2)	June 25, 1938, ch. 675, §418(l)(2), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3892.
11120(m)(4)	21 U.S.C. 350g(l)(3)(A)	June 25, 1938, ch. 675, §418(l)(3)(A), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3893.
11120(m)(5)	21 U.S.C. 350g(l)(3)(B)	June 25, 1938, ch. 675, §418(l)(3)(B), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3893.
11120(m)(6)	21 U.S.C. 350g(l)(6)	June 25, 1938, ch. 675, §418(l)(6), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3894.
11120(m)(7)	21 U.S.C. 350g(l)(7)	June 25, 1938, ch. 675, §418(l)(7), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3894.
11120(n)	21 U.S.C. 350g(m)	June 25, 1938, ch. 675, §418(m), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3895.
11120(o)(1)	21 U.S.C. 350g(n)(1)	June 25, 1938, ch. 675, §418(n)(1), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3895.
11120(o)(2)	21 U.S.C. 350g(l)(5)(B) (last sentence)	June 25, 1938, ch. 675, §418(l)(5)(B) (last sentence), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3894.
11120(o)(3)	21 U.S.C. 350g(n)(2)	June 25, 1938, ch. 675, §418(n)(2), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3895.
11120(o)(4)	21 U.S.C. 350g(n)(3)	June 25, 1938, ch. 675, § 418(n)(3), as added Pub. L. 111–353, title I, § 103(a), Jan. 4, 2011, 124 Stat. 3895.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11120(o)(5)	21 U.S.C. 350g note	Pub. L. 111–353, title I, §103(b), Jan. 4, 2011, 124 Stat. 3896.
11120(o)(6)	21 U.S.C. 350g(n)(4)	June 25, 1938, ch. 675, §418(n)(4), as added Pub. L. 111–353, title I, §103(a), Jan. 4, 2011, 124 Stat. 3895.
11120(p)(1)	21 U.S.C. 350g note	Pub. L. 111–353, title I, §103(f), Jan. 4, 2011, 124 Stat. 3898.
11120(p)(2)	21 U.S.C. 350g note	Pub. L. 111–353, title I, §103(g), Jan. 4, 2011, 124 Stat. 3898.

In subsection (k)(2), the words "part 113 of title 21" are substituted for "part 113 of chapter 21" to provide the correct reference to the pertinent provisions.

In subsection (m)(2)(C)(ii)(I), in the 2d parenthetical, the words "as described in clause (i)" are substituted for "as so described" for clarity.

In subsection (m)(3)(B)(ii), the words "issued not later than 1 year after the date of enactment of this section" are omitted as obsolete.

In subsection (o)(1), in the matter before subparagraph (A), the words "Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

In subsection (o)(4)(D), the words "audit preventive controls" are substituted for "audit preventative controls" for consistency with the defined term "preventive controls" in subsection (a).

In subsection (o)(5), the words "under paragraph (1)(A)" are substituted for "under subsection (b)(1)" to provide the correct reference to the pertinent provision. The source provision, which is subsection (b) of section 103 of the FDA Food Safety Modernization Act (Public Law 111–353, 21 U.S.C. 350g note), does not contain a paragraph (1). The reference to subsection (b)(1) in the source law is translated as subsection (n)(1) of section 418 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350g(n)(1)), which is restated as subsection (o)(1) of section 11120 of title 21, United States Code. The reference to "paragraph (1)(A)" in the restatement refers to subsection (o)(1)(A) of that section 11120.

In paragraphs (1) and (2) of subsection (p), the words "Nothing in this section and section 10501(45) of this title" are substituted for "Nothing in the amendments made by this section" for clarity.

In subsection (p)(1), the words "Hazard Analysis Critical Control Points programs" are substituted for "Hazard Analysis Critical Control programs" to provide the missing word.

SECTION 11121—STANDARDS FOR PRODUCE SAFETY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11121(a) through (e) ...	21 U.S.C. 350h(a) through (e)	June 25, 1938, ch. 675, §419(a) through (e), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3899.
11121(f)(1)	21 U.S.C. 350h(f)(4)	June 25, 1938, ch. 675, §419(f)(4), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3904.

SECTION 11121—STANDARDS FOR PRODUCE SAFETY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11121(f)(2)	21 U.S.C. 350h(f)(1)	June 25, 1938, ch. 675, §419(f)(1), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3903.
11121(f)(3)	21 U.S.C. 350h(f)(2)	June 25, 1938, ch. 675, §419(f)(2), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3903.
11121(f)(4)	21 U.S.C. 350h(f)(3)	June 25, 1938, ch. 675, §419(f)(3), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3904.
11121(f)(5)	21 U.S.C. 350h(f)(5)	June 25, 1938, ch. 675, §419(f)(5), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3904.
11121(f)(6)	21 U.S.C. 350h(f)(6)	June 25, 1938, ch. 675, §419(f)(6), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3904.
11121(g)	21 U.S.C. 350h note	Pub. L. 111–353, title I, §105(b), Jan. 4, 2011, 124 Stat. 3904.
11121(h)	21 U.S.C. 350h(g)	June 25, 1938, ch. 675, §419(g), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3904.
11121(i)	21 U.S.C. 350h(h)	June 25, 1938, ch. 675, §419(h), as added Pub. L. 111–353, title I, §105(a), Jan. 4, 2011, 124 Stat. 3904.
11121(j)	21 U.S.C. 350h note	Pub. L. 111–353, title I, §105(d), Jan. 4, 2011, 124 Stat. 3905.

In subsection (b)(1), the words "which standards shall be based on" are substituted for "based on" for clarity.

In subsection (c)(1)(E), the words "or certify compliance" are substituted for "certify, compliance" to correct an error in the law.

In subsection (c)(2)(A)(iii), the words "requests for variance" are substituted for "such requests" for clarity.

In subsection (g), the words "to assist" are substituted for "and to assist" to eliminate an unnecessary word.

In subsection (j), the words "Nothing in this section and section 10501(46) of this title" are substituted for "Nothing in the amendments made by this section" for clarity.

In subsection (j), the words "Juice Hazard Analysis Critical Control Points Program" are substituted for "Juice Hazard Analysis Critical Control Program" to provide the missing word.

SECTION 11122—PROTECTION AGAINST INTENTIONAL ADULTERATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11122(a)	21 U.S.C. 350i(e)	June 25, 1938, ch. 675, §420(e), as added Pub. L. 111–353, title I, §106(a), Jan. 4, 2011, 124 Stat. 3906.
11122(b)	21 U.S.C. 350i(a)	June 25, 1938, ch. 675, §420(a), as added Pub. L. 111–353, title I, §106(a), Jan. 4, 2011, 124 Stat. 3905.
11122(c)	21 U.S.C. 350i(b)	June 25, 1938, ch. 675, §420(b), as added Pub. L. 111–353, title I, §106(a), Jan. 4, 2011, 124 Stat. 3905.
11122(d)	21 U.S.C. 350i note	Pub. L. 111–353, title I, §106(b), Jan. 4, 2011, 124 Stat. 3906.
11122(e)	21 U.S.C. 350i note	Pub. L. 111–353, title I, §106(c), Jan. 4, 2011, 124 Stat. 3906.
11122(f)	21 U.S.C. 350i(c)	June 25, 1938, ch. 675, §420(c), as added Pub. L. 111–353, title I, §106(a), Jan. 4, 2011, 124 Stat. 3905.

SECTION 11122—PROTECTION AGAINST INTENTIONAL ADULTERATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11122(g)	21 U.S.C. 350i(d)	June 25, 1938, ch. 675, § 420(d), as added Pub. L. 111–353, title I, § 106(a), Jan. 4, 2011, 124 Stat. 3906.

In subsection (c)(1), the words "Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act" are omitted as obsolete.

In subsection (d)(1), the words "Not later than 1 year after the date of enactment of this Act," are omitted as obsolete.

In subsection (f)(1), the words "which intentional contamination could cause" are substituted for "that could cause" for clarity.

In subsection (f)(2), in the matter before subparagraph (A), the words "The food to which the regulations under subsection (c) apply as described in paragraph (1) shall include food" are substituted for "and shall include those foods" for clarity.

SECTION 11123—TARGETING OF INSPECTION RESOURCES FOR DOMESTIC FACILITIES, FOREIGN FACILITIES, AND PORTS OF ENTRY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11123(a)	21 U.S.C. 350j(e)	June 25, 1938, ch. 675, §421(e), as added Pub. L. 111–353, title II, §201(a), Jan. 4, 2011, 124 Stat. 3925.
11123(b) through (e) ...	21 U.S.C. 350j(a) through (d)	June 25, 1938, ch. 675, §421(a) through (d), as added Pub. L. 111–353, title II, §201(a), Jan. 4, 2011, 124 Stat. 3923.
11123(f)	21 U.S.C. 350j note	Pub. L. 111–353, title II, §201(c), Jan. 4, 2011, 124 Stat. 3926.

In subsections (b)(1)(F) and (c)(8), the words "considered necessary and appropriate" are substituted for "deemed necessary and appropriate" to use the more appropriate word.

In subsection (d)(2)(E), the words "section 11323, 11324, or 20101 of this title" are substituted for "section 801 of this Act or section 203 of the Food Allergen Labeling and Consumer Protection Act of 2004" for clarity.

SECTION 11124—LABORATORY ACCREDITATION FOR ANALYSES OF FOODS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11124	21 U.S.C. 350k	June 25, 1938, ch. 675, §422, as added Pub. L. 111–353, title II, §202(a), Jan. 4, 2011, 124 Stat. 3926.

In subsection (a)(1), in the matter before subparagraph (A), the words "Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

In subsection (a)(1)(B), the words "information considered appropriate" are substituted for "information deemed appropriate" to use the more appropriate word.

In subsection (a)(3), the words "under subsection (b)" are substituted for "under subparagraph (b)" to provide the correct reference to the law.

In subsection (a)(7)(A), the words "but not less than once every 5 years" are substituted for "and in no case less than once every 5 years" to eliminate unnecessary words.

In subsection (b)(1), in the matter before subparagraph (A), the words "Not later than 30 months after the date of enactment of the FDA Food Safety Modernization Act" are omitted as obsolete.

In subsection (b)(1)(A)(ii), the words "as the Secretary considers appropriate" are substituted for "as the Secretary deems appropriate" to use the more appropriate word.

SECTION 11125—MANDATORY RECALL AUTHORITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11125(a) through (h) ...	21 U.S.C. 350l(a) through (h)	June 25, 1938, ch. 675, §423(a) through (h), as added Pub. L. 111–353, title II, §206(a), Jan. 4, 2011, 124 Stat. 3939.
11125(i)	21 U.S.C. 350l(j)	June 25, 1938, ch. 675, §423(j), as added Pub. L. 111–353, title II, §206(a), Jan. 4, 2011, 124 Stat. 3942.
11125(j)	21 U.S.C. 350l(i)	June 25, 1938, ch. 675, §423(i), as added Pub. L. 111–353, title II, §206(a), Jan. 4, 2011, 124 Stat. 3942.
11125(k)	21 U.S.C. 350l note	Pub. L. 111–353, title II, §206(b), Jan. 4, 2011, 124 Stat. 3942.
11125(l)	21 U.S.C. 350l–1	Pub. L. 111–353, title II, §206(f), Jan. 4, 2011, 124 Stat. 3943.

In subsection (b)(1), in the matter before subparagraph (A), the words "that the Secretary may prescribe" are substituted for "prescribed by the Secretary (if so prescribed)" for consistency in title 21, United States Code.

In subsection (b)(1), in the matter before subparagraph (A), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

In subsection (b)(1), in the matter before subparagraph (A), the words "the responsible party to" are substituted for "such person to" for consistency with the antecedent.

In subsection (k), in the matter before paragraph (1), the words "The Secretary shall include in the FDA website a search engine that" are substituted for "Not later than 90 days after the date of enactment of this Act, the Secretary shall modify the Internet Web site of the Food and Drug Administration to include a search engine that" to eliminate obsolete words.

In subsection (l)(1), in the matter before subparagraph (A), the words "The Secretary shall annually submit" are substituted for "Not later than 2 years after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall submit" to eliminate obsolete and unnecessary words.

SECTION 11126—REQUIREMENTS FOR CRITICAL FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11126(a)(1)	21 U.S.C. 350m(a)(4)	June 25, 1938, ch. 675, §424(a)(4), as added Pub. L. 117–328, div. FF, title III, §3401(k), Dec. 29, 2022, 136 Stat. 5844.

SECTION 11126—REQUIREMENTS FOR CRITICAL FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11126(a)(2) through (4)	21 U.S.C. 350m(a)(1) through (3)	June 25, 1938, ch. 675, §424(a)(1) through (3), as added Pub. L. 117–328, div. FF, title III, §3401(k), Dec. 29, 2022, 136 Stat. 5844.
11126(b), (c)	21 U.S.C. 350m(b), (c)	June 25, 1938, ch. 675, §424(b), (c), as added Pub. L. 117–328, div. FF, title III, §3401(k), Dec. 29, 2022, 136 Stat. 5845.

In subsection (a)(2), the words "(as defined in section 201(ss))" are omitted as unnecessary.

Chapter 113—Misbranded Food

This chapter restates section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343). In restating that section 403 as this chapter, the words "A food shall be deemed to be misbranded" are added in sections 11301 through 11323 of title 21, United States Code, to carry forward the matter before subsection (a) of section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343).

SECTION 11301—FALSE OR MISLEADING LABEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11301	21 U.S.C. 343(a)	June 25, 1938, ch. 675, §403(a), 52 Stat. 1047; Pub. L. 94–278, title V, §502(a)(1), Apr. 22, 1976, 90 Stat. 411.

SECTION 11302—OFFER FOR SALE UNDER ANOTHER NAME

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11302	21 U.S.C. 343(b)	June 25, 1938, ch. 675, §403(b), 52 Stat. 1047.

SECTION 11303—IMITATION OF ANOTHER FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11303	21 U.S.C. 343(c)	June 25, 1938, ch. 675, §403(c), 52 Stat. 1047.

SECTION 11304—MISLEADING CONTAINER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11304	21 U.S.C. 343(d)	June 25, 1938, ch. 675, §403(d), 52 Stat. 1047.

SECTION 11305—PACKAGE FORM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11305	21 U.S.C. 343(e)	June 25, 1938, ch. 675, §403(e), 52 Stat. 1047; Pub. L. 103–80, §3(j)(1), Aug. 13, 1993, 107 Stat. 776.

SECTION 11306—PROMINENCE OF INFORMATION ON LABEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11306	21 U.S.C. 343(f)	June 25, 1938, ch. 675, §403(f), 52 Stat. 1047.

SECTION 11307—REPRESENTATION AS TO DEFINITION AND STANDARD OF IDENTITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11307(a)	21 U.S.C. 343(g)	June 25, 1938, ch. 675, §403(g), 52 Stat. 1047.
11307(b)	21 U.S.C. 343(k) (2d sentence (relating to paragraph (g)))	June 25, 1938, ch. 675, § 403(k) (2d sentence (relating to paragraph (g))), 52 Stat. 1048.

In subsection (a)(2)(B), the words "to the extent that the regulations may require," are substituted for "insofar as may be required by such regulations," for clarity.

SECTION 11308—REPRESENTATION AS TO STANDARDS OF QUALITY AND FILL OF CONTAINER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11308 (matter before (1))	21 U.S.C. 343(h) (matter before (1))	June 25, 1938, ch. 675, §403(h) (matter before (1)), 52 Stat. 1047.
11308(1)	21 U.S.C. 343(h)(1)	June 25, 1938, ch. 675, §403(h)(1), 52 Stat. 1047; Pub. L. 107–171, title X, §10808(b)(1), May 13, 2002, 116 Stat. 530.
11308(2)	21 U.S.C. 343(h)(2)	June 25, 1938, ch. 675, §403(h)(2), 52 Stat. 1047; Pub. L. 107–171, title X, §10808(b)(2), May 13, 2002, 116 Stat. 530.

In paragraph (2), the words "or standards" are omitted as unnecessary because of section 1 of title 1, United States Code.

SECTION 11309—REPRESENTATION AS TO PASTEURIZATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11309(a) ("if it purports to be or is represented as")	21 U.S.C. 343(h) (matter before (1))	June 25, 1938, ch. 675, §403(h) (matter before (1)), 52 Stat. 1047.
11309(a) ("a food that is pasteurized unless")	21 U.S.C. 343(h)(3) (matter before (A))	June 25, 1938, ch. 675, § 403(h)(3) (matter before (A)), as added Pub. L. 107–171, title X, §10808(b)(3), May 13, 2002, 116 Stat. 530.
11309(a)(1)	21 U.S.C. 343(h)(3)(A)	June 25, 1938, ch. 675, §403(h)(3)(A), as added Pub. L. 107–171, title X, §10808(b)(3), May 13, 2002, 116 Stat. 530.
11309(a)(2)	21 U.S.C. 343(h)(3)(B)	June 25, 1938, ch. 675, §403(h)(3)(B), as added Pub. L. 107–171, title X, §10808(b)(3), May 13, 2002, 116 Stat. 530.
11309(b)	21 U.S.C. 343(h) (matter after (3)(B)(ii))	June 25, 1938, ch. 675, §403(h) (matter after (3)(B)(ii)), as added Pub. L. 107–171, title X, §10808(b)(3), May 13, 2002, 116 Stat. 531.

SECTION 11310—LABEL TO BEAR COMMON OR USUAL NAME

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11310(a) through (c) ...	21 U.S.C. 343(i)	June 25, 1938, ch. 675, §403(i), 52 Stat. 1048; Pub. L. 101–535, §7, Nov. 8, 1990, 104 Stat. 2364; Pub. L. 102–108, §2(c), Aug. 17, 1991, 105 Stat. 549; Pub. L. 102–571, title I, §107(5), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, §3(j)(2), Aug. 13, 1993, 107 Stat. 776.
11310(d)	21 U.S.C. 343(k) (2d sentence (relating to paragraph (i)))	June 25, 1938, ch. 675, § 403(k) (2d sentence (relating to paragraph (i))), 52 Stat. 1048.

SECTION 11311—REPRESENTATION FOR SPECIAL DIETARY USE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11311	21 U.S.C. 343(j)	June 25, 1938, ch. 675, §403(j), 52 Stat. 1048.

SECTION 11312—ARTIFICIAL FLAVORING, ARTIFICIAL COLORING, OR CHEMICAL PRESERVATIVES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11312(a)	21 U.S.C. 343(k) (1st sentence)	June 25, 1938, ch. 675, §403(k) (1st sentence), 52 Stat. 1048; Pub. L. 103–80, §3(j)(3), Aug. 13, 1993, 107 Stat. 776.
11312(b)	21 U.S.C. 343(k) (2d sentence (relating to paragraph (k)))	June 25, 1938, ch. 675, § 403(k) (2d sentence (relating to paragraph (k))), 52 Stat. 1048.
11312(c)(1)	21 U.S.C. 343(k) (last sentence)	June 25, 1938, ch. 675, § 403(k) (last sentence), as added Pub. L. 86–537, § 1, June 29, 1960, 74 Stat. 251.
11312(c)(2)	21 U.S.C. 343 note	Pub. L. 86–537, § 2, June 29, 1960, 74 Stat. 251.

In subsection (c)(2), the words "Nothing in paragraph (1)" are substituted for "Nothing in the amendments made by the first section of this Act" for clarity.

SECTION 11313—PESTICIDE CHEMICALS ON RAW AGRICULTURAL COMMODITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11313(a), (b)	21 U.S.C. 343(l)	June 25, 1938, ch. 675, §403(l), as added Pub. L. 86–537, §1, June 29, 1960, 74 Stat. 251; Pub. L. 103–80, §3(j)(4), Aug. 13, 1993, 107 Stat. 776.
11313(c)	21 U.S.C. 343 note	Pub. L. 86–537, § 2, June 29, 1960, 74 Stat. 251.

In subsection (c), the words "Nothing in this section" are substituted for "Nothing in the amendments made by the first section of this Act" for clarity.

SECTION 11314—COLOR ADDITIVES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11314	21 U.S.C. 343(m)	June 25, 1938, ch. 675, §403(m), as added Pub. L. 86–618, title I, §102(a)(3), July 12, 1960, 74 Stat. 398; Pub. L. 102–571, title I, §107(6), Oct. 29, 1992, 106 Stat. 4499.

SECTION 11315—PACKAGING OR LABELING OF DRUGS IN VIOLATION OF REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11315	21 U.S.C. 343(n)	June 25, 1938, ch. 675, §403(n), as added Pub. L. 91–601, §6(c), formerly §7(c), Dec. 30, 1970, 84 Stat. 1673, renumbered Pub. L. 97–35, title XII, § 1205(c), Aug. 13, 1981, 95 Stat. 716.

SECTION 11316—NUTRITION INFORMATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11316(a)	21 U.S.C. 343(q)(1)	June 25, 1938, ch. 675, §403(q)(1), as added Pub. L. 101–535, §2(a), Nov. 8, 1990, 104 Stat. 2353.
11316(b)	21 U.S.C. 343(q)(2)	June 25, 1938, ch. 675, §403(q)(2), as added Pub. L. 101–535, §2(a), Nov. 8, 1990, 104 Stat. 2354.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11316(c)	21 U.S.C. 343(q)(3)	June 25, 1938, ch. 675, §403(q)(3), as added Pub. L. 101–535, §2(a), Nov. 8, 1990, 104 Stat. 2354.
11316(d)(1)	21 U.S.C. 343(q)(4)(E)	June 25, 1938, ch. 675, §403(q)(4)(E), as added Pub. L. 101–535, § 2(a), Nov. 8, 1990, 104 Stat. 2355.
11316(d)(2)	21 U.S.C. 343(q)(4)(A)	June 25, 1938, ch. 675, §403(q)(4)(A), as added Pub. L. 101–535, §2(a), Nov. 8, 1990, 104 Stat. 2354; Pub. L. 102–108, §2(a), Aug. 17, 1991, 105 Stat. 549.
11316(d)(3) through (5)	21 U.S.C. 343(q)(4)(B) through (D)	June 25, 1938, ch. 675, §403(q)(4)(B) through (D), as added Pub. L. 101–535, §2(a), Nov. 8, 1990, 104 Stat. 2354.
11316(d)(6)	21 U.S.C. 343(q)(4)(F)	June 25, 1938, ch. 675, §403(q)(4)(F), as added Pub. L. 101–535, §2(a), Nov. 8, 1990, 104 Stat. 2355.
11316(e)	21 U.S.C. 343(q)(5)(F)	June 25, 1938, ch. 675, § 403(q)(5)(F), formerly § 403(q)(5)(E), as added Pub. L. 101–535, § 2(a), Nov. 8, 1990, 104 Stat. 2356; redesignated § 403(q)(5)(F), Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 773; Pub. L. 103–417, § 7(b), Oct. 25, 1994, 108 Stat. 4330.
11316(f)(1) through (4)	21 U.S.C. 343(q)(5)(A) through (D)	June 25, 1938, ch. 675, § 403(q)(5)(A) through (D), as added Pub. L. 101–535, § 2(a), Nov. 8, 1990, 104 Stat. 2355; Pub. L. 111–148, title IV, § 4205(a), Mar. 23, 2010, 124 Stat. 573.
11316(f)(5)(A)(i), (ii)	21 U.S.C. 343(q)(5)(E)(vi)(II), (III)	June 25, 1938, ch. 675, § 403(q)(5)(E)(vi)(II), (III), as added Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 775.
11316(f)(5)(A)(iii)	21 U.S.C. 343(q)(5)(E)(vi)(I)	June 25, 1938, ch. 675, § 403(q)(5)(E)(vi)(I), as added Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 775.
11316(f)(5)(B)	21 U.S.C. 343(q)(5)(E)(i)	June 25, 1938, ch. 675, §403(q)(5)(E)(i), as added Pub. L. 103–80, §2(b), Aug. 13, 1993, 107 Stat. 773.
11316(f)(5)(C)	21 U.S.C. 343(q)(5)(E)(iii) (except matter after (IV))	June 25, 1938, ch. 675, § 403(q)(5)(E)(iii) (except matter after (IV)), as added Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 774.
11316(f)(5)(D)	21 U.S.C. 343(q)(5)(E)(iii) (matter after (IV))	June 25, 1938, ch. 675, § 403(q)(5)(E)(iii) (matter after (IV)), as added Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 774.
11316(f)(5)(E)	21 U.S.C. 343(q)(5)(E)(iv)	June 25, 1938, ch. 675, § 403(q)(5)(E)(iv), as added Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 774.
11316(f)(5)(F)	21 U.S.C. 343(q)(5)(E)(v)	June 25, 1938, ch. 675, § 403(q)(5)(E)(v), as added Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 775.
11316(f)(6)	21 U.S.C. 343(q)(5)(G)	June 25, 1938, ch. 675, § 403(q)(5)(G), formerly § 403(q)(5)(F), as added Pub. L. 101–535, § 2(a), Nov. 8, 1990, 104 Stat. 2356; redesignated § 403(q)(5)(G), Pub. L. 103–80, § 2(b), Aug. 13, 1993, 107 Stat. 773.
11316(g)(1)	21 U.S.C. 343(q)(5)(H)(xi)	June 25, 1938, ch. 675, § 403(q)(5)(H)(xi), as added Pub. L. 111–148, title IV, § 4205(b), Mar. 23, 2010, 124 Stat. 576.
11316(g)(2) through (9)	21 U.S.C. 343(q)(5)(H)(i) through (viii)	June 25, 1938, ch. 675, § 403(q)(5)(H)(i) through (viii), as added Pub. L. 111–148, title IV, § 4205(b), Mar. 23, 2010, 124 Stat. 573.
11316(g)(10)(A)	21 U.S.C. 343(q)(5)(H)(ix)(I)	June 25, 1938, ch. 675, § 403(q)(5)(H)(ix)(I), as added Pub. L. 111–148, title IV, § 4205(b), Mar. 23, 2010, 124 Stat. 575.
11316(g)(10)(B)	21 U.S.C. 343(q)(5)(H)(ix)(III)	June 25, 1938, ch. 675, § 403(q)(5)(H)(ix)(III), as added Pub. L. 111–148, title IV, § 4205(b), Mar. 23, 2010, 124 Stat. 575.
11316(g)(11)	21 U.S.C. 343(q)(5)(H)(x)	June 25, 1938, ch. 675, § 403(q)(5)(H)(x), as added Pub. L. 111–148, title IV, § 4205(b), Mar. 23, 2010, 124 Stat. 575.
11316(g)(12)	21 U.S.C. 343 note	Pub. L. 111–148, title IV, §4205(d), Mar. 23, 2010, 124 Stat. 576.
11316(h)	21 U.S.C. 343 note	Pub. L. 115–334, title XII, §12516, Dec. 20, 2018, 132 Stat. 5000.

In subsection (d)(5)(B)(iv), the words "the varieties of food described in clause (i)" are substituted for "such food" for clarity.

In subsection (e)(2), the words "each of the dietary ingredients" are substiuted for "each such ingredient" and the words "the quantity of a proprietary blend of the dietary ingredients" are substituted for "of a proprietary blend of such ingredients" for clarity.

In subsection (g)(1)(B), the words "on a board," are added for clarity.

In subsection (g)(3)(A)(ii), the words "on the menu board, designed to enable" are substituted for "on the menu and designed to enable" for consistency with subsection (g)(3)(B)(ii).

In subsection (g)(10)(C), the words "as described in subparagraph (A)" are substituted for "as described in such item" for clarity.

In subsection (g)(11)(A), the words "Not later than 1 year after the date of enactment of this clause" are omitted as obsolete.

In subsection (g)(11)(C), the words "under this subsection" are substituted for "under this subparagraph" to provide a more precise reference to the pertinent provision. The provision to which "this subparagraph" refers in the source law is the provision in subparagraph (5) of section 403(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)), which is restated in subsections (e), (f), and (g) of section 11316 of title 21, United States Code. The reference to "this subsection" in the restatement refers only to the restatement of clause (H) of subparagraph (5) of section 403(q) of the Act, which restatement is in subsection (g) of section 11316 of title 21, United States Code.

In subsection (g)(12), in the matter before subparagraph (A), the words "Nothing in this subsection" are substituted for "Nothing in the amendments made by this section" for clarity and to incorporate section 4205(d) of the Patient Protection and Affordable Care Act (Public Law 111–148, 21 U.S.C. 343 note) into section 11316(g) of title 21, United States Code, the source law of which is section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)).

In subsection (g)(12)(A)(ii), the words "section 11103(a)(4) of this title" are substituted for "subsection (a)(4) of such section" to provide the correct reference to the pertinent provision. The antecedent of "such section" in the source law is "section 403(q)(5)(H) of the Federal food, Drug, and Cosmetic Act". Section 403 of that Act (21 U.S.C. 343) does not contain a subsection (a)(4). Section 403A of that Act (21 U.S.C. 343–1) contains a subsection (a)(4) which relates to preemption. That subsection (a)(4) is restated as section 11103(a)(4) of title 21, United States Code.

SECTION 11317—NUTRITION LEVELS AND HEALTH-RELATED CLAIMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11317(a)	21 U.S.C. 343(r)(1)	June 25, 1938, ch. 675, §403(r)(1), as added Pub. L. 101–535, § 3(a), Nov. 8, 1990, 104 Stat. 2357; Pub. L. 103–80, §3(j)(5), Aug. 13, 1993, 107 Stat. 776.
11317(b)	21 U.S.C. 343(r)(2)	June 25, 1938, ch. 675, §403(r)(2), as added Pub. L. 101–535, § 3(a), Nov. 8, 1990, 104 Stat. 2358; Pub. L. 103–417, §7(c), Oct. 25, 1994, 108 Stat. 4330; Pub. L. 105–115, title III, §§304, 305, Nov. 21, 1997, 111 Stat. 2352, 2353.

SECTION 11317—NUTRITION LEVELS AND HEALTH-RELATED CLAIMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11317(c)	21 U.S.C. 343(r)(3)	June 25, 1938, ch. 675, §403(r)(3), as added Pub. L. 101–535, § 3(a), Nov. 8, 1990, 104 Stat. 2359; Pub. L. 105–115, title III, §303, Nov. 21, 1997, 111 Stat. 2350.
11317(d)	21 U.S.C. 343(r)(4)	June 25, 1938, ch. 675, §403(r)(4), as added Pub. L. 101–535, § 3(a), Nov. 8, 1990, 104 Stat. 2360; Pub. L. 103–80, §3(j)(6), Aug. 13, 1993, 107 Stat. 776; Pub. L. 105–115, title III, §302, Nov. 21, 1997, 111 Stat. 2350.
11317(e)	21 U.S.C. 343(r)(5)	June 25, 1938, ch. 675, § 403(r)(5), as added Pub. L. 101–535, § 3(a), Nov. 8, 1990, 104 Stat. 2360.
11317(f)	21 U.S.C. 343(r)(6)	June 25, 1938, ch. 675, §403(r)(6), as added Pub. L. 103–417, §6, Oct. 25, 1994, 108 Stat. 4329.
11317(g)	21 U.S.C. 343(r)(7)	June 25, 1938, ch. 675, §403(r)(7), as added Pub. L. 105–115, title III, §301, Nov. 21, 1997, 111 Stat. 2350.

In subparagraphs (B)(i) and (C)(i)(I) of subsection (b)(1), the words "or in another food" are substituted for "or in a food" for clarity.

In subsection (b)(1)(C), in the matter before clause (i), the word "individuals" is substituted for "persons" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (c)(2)(A), the words "that the claims to be authorized are supported by the evidence" are substituted for "that the claim is supported by such evidence" for consistency in the subparagraph.

In subsection (d)(1)(A)(viii), the words "Committee on Energy and Commerce of the House of Representatives" are substituted for "Committee on Commerce of the House of Representatives" on authority of Rule X(1)(f) of the Rules of House of Representatives, adopted by House Resolution No. 5 (107th Congress, January 3, 2001).

In subsection (d)(1)(A)(viii), the words "Committee on Health, Education, Labor, and Pensions of the Senate" are substituted for "Committee on Labor and Human Resources of the Senate" on authority of Rule XXV(1)(m) of the Standing Rules of the Senate. See S. Res. 20, adopted January 19, 1999 (changing Committee name).

SECTION 11318—DIETARY SUPPLEMENTS; GENERAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11318	21 U.S.C. 343(s)	June 25, 1938, ch. 675, § 403(s), as added Pub. L. 103–417, §§ 7(a), 10(c), Oct. 25, 1994, 108 Stat. 4329, 4332.

SECTION 11319—DIETARY SUPPLEMENTS; SERIOUS ADVERSE EVENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11319	21 U.S.C. 343(y)	June 25, 1938, ch. 675, § 403(y), as added Pub. L. 109–462, § 3(c), Dec. 22, 2006, 120 Stat. 3475.

SECTION 11320—CATFISH

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11320	21 U.S.C. 343(t)	June 25, 1938, ch. 675, § 403(t), as added Pub. L. 107–171, title X, § 10806(a)(2), May 13, 2002, 116 Stat. 526.

SECTION 11321—GINSENG

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11321	21 U.S.C. 343(u)	June 25, 1938, ch. 675, § 403(u), as added Pub. L. 107–171, title X, § 10806(b)(2), May 13, 2002, 116 Stat. 527.

SECTION 11322—FAILURE TO LABEL; HEALTH THREAT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11322(a)	21 U.S.C. 343(v)	June 25, 1938, ch. 675, § 403(v), as added Pub. L. 107–188, title III, § 308(b), June 12, 2002, 116 Stat. 672.
11322(b)	21 U.S.C. 381 note	Pub. L. 107–188, title III, §308(c) (relating to subsection (b) of "this section"), June 12, 2002, 116 Stat. 673.

In subsection (b), the reference to the Secretary of the Treasury is retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

SECTION 11323—MAJOR FOOD ALLERGEN LABELING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11323(a)(1)	21 U.S.C. 343(w)(2)	June 25, 1938, ch. 675, § 403(w)(2), as added Pub. L. 108–282, title II, § 203(a), Aug. 2, 2004, 118 Stat. 907.
11323(a)(2)	21 U.S.C. 343(w)(1)	June 25, 1938, ch. 675, § 403(w)(1), as added Pub. L. 108–282, title II, § 203(a), Aug. 2, 2004, 118 Stat. 906.
11323(b) through (f)	21 U.S.C. 343(w)(3) through (7)	June 25, 1938, ch. 675, § 403(w)(3) through (7), as added Pub. L. 108–282, title II, § 203(a), Aug. 2, 2004, 118 Stat. 907.

In subparagraphs (A) and (B) of subsection (a)(2), the references to subsection (g), which are references to section 403(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(g)), are translated as section 11307 of title 21, United States Code, even though the references to section 11307 are broader because section 11307 of that title also restates the part of section 403(k) of the Act that relates to section 403(g) of the Act. The broader translation is done for convenience and does not affect the meaning or effect of the source provision.

In subparagraphs (A) and (B) of subsection (a)(2), the references to subsection (i), which are references to section 403(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(i)), are translated as section 11310 of title 21, United States Code, even though the references to section 11310 are broader because section 11310 of that title also restates the part of section 403(k) of the

Act that relates to section 403(i) of the Act. The broader translation is done for convenience and does not affect the meaning or effect of the source provision.

SECTION 11324—NONMAJOR FOOD ALLERGEN LABELING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
11324	21 U.S.C. 343(x)	June 25, 1938, ch. 675, § 403(x), as added Pub. L. 108–282, title II, § 203(a), Aug. 2, 2004, 118 Stat. 908.

Division D—Drugs and Devices

Chapter 131—Drugs and Devices Generally

SECTION 13101—ADULTERATED DRUGS AND DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13101(a)(1)	21 U.S.C. 351 (from "For purposes of paragraph (a)(2)(B)," through "finished drug products.")	June 25, 1938, ch. 675, §501 (from "For purposes of paragraph (a)(2)(B)," through "finished drug products."), 52 Stat. 1049; Pub. L. 112–144, title VII, §711, July 9, 2012, 126 Stat. 1071.
13101(a)(2)	21 U.S.C. 351(a)	June 25, 1938, ch. 675, §501(a), 52 Stat. 1049; Pub. L. 86–618, title I, §102(b)(1), July 12, 1960, 74 Stat. 398; Pub. L. 87–781, title I, §101, Oct. 10, 1962, 76 Stat. 780; Pub. L. 90–399, §101(a), July 13, 1968, 82 Stat. 343; Pub. L. 94–295, §9(b)(1)(A), (2), (3), May 28, 1976, 90 Stat. 583; Pub. L. 102–571, title I, §107(8), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 105–115, title I, §121(b)(1), Nov. 21, 1997, 111 Stat. 2320.
13101(b)	21 U.S.C. 351(b)	June 25, 1938, ch. 675, §501(b), 52 Stat. 1049.
13101(c)	21 U.S.C. 351(c)	June 25, 1938, ch. 675, §501(c), 52 Stat. 1050.
13101(d)	21 U.S.C. 351(d)	June 25, 1938, ch. 675, §501(d), 52 Stat. 1050.
13101(e)	21 U.S.C. 351(e)	June 25, 1938, ch. 675, §501(e), as added Pub. L. 94–295, §3(d), May 28, 1976, 90 Stat. 576; Pub. L. 105–115, title II, §204(c), Nov. 21, 1997, 111 Stat. 2336.
13101(f)	21 U.S.C. 351(f)	June 25, 1938, ch. 675, §501(f), as added Pub. L. 94–295, §3(d), May 28, 1976, 90 Stat. 576; Pub. L. 101–629, §9(b), Nov. 28, 1990, 104 Stat. 4521; Pub. L. 112–144, title VI, §608(b)(2), July 9, 2012, 126 Stat. 1058.
13101(g)	21 U.S.C. 351(g)	June 25, 1938, ch. 675, §501(g), as added Pub. L. 94–295, §3(d), May 28, 1976, 90 Stat. 577.
13101(h)	21 U.S.C. 351(h)	June 25, 1938, ch. 675, §501(h), as added Pub. L. 94–295, §3(d), May 28, 1976, 90 Stat. 577.
13101(i)	21 U.S.C. 351(i)	June 25, 1938, ch. 675, §501(i), as added Pub. L. 94–295, §3(d), May 28, 1976, 90 Stat. 577.
13101(j)(1)	21 U.S.C. 351(j)	June 25, 1938, ch. 675, §501(j), 52 Stat. 1049; Pub. L. 112–144, title VII, §707(a), July 9, 2012, 126 Stat. 1068; Pub. L. 115–52, title VII, §702(c), Aug. 18, 2017, 131 Stat. 1056.
13101(j)(2)	21 U.S.C. 351 note	Pub. L. 112–144, title VII, § 707(b), July 9, 2012, 126 Stat. 1068.

In this section, the words “A drug or device shall be deemed to be adulterated”, “A drug shall be deemed to be adulterated”, or “A device shall be deemed to be adulterated” are added as appropriate each place they appear to carry forward the matter before subsection (a) of section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351). The words “drug or” or “or device” are omitted as appropriate in the matter carried forward for consistency in the applicable provision.

In clauses (ii) and (iii) of subsection (a)(2)(B), the words "ensure that the drug" are substituted for "assure that such drug" to use the more appropriate word.

In subsection (b)(2)(D), the words "set forth for the drug" are substituted for "therefor set forth" for clarity.

In subsection (d), in the matter before paragraph (1), the words "if any substance has been" are substituted for "If it is a drug and any substance has been" to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be adulterated" as described in the first revision note.

In subsection (h), the words "if the methods used in" are substituted for "If it is a device and the methods used in" to eliminate unnecessary words because of the addition of the words "A device shall be deemed to be adulterated" as described in the first revision note.

In subsection (j)(1), in the matter before subparagraph (A), the words "if it has been" are substituted for "If it is a drug or device and it has been" to eliminate unnecessary words because of the addition of the words "A drug or device shall be deemed to be adulterated" as described in the first revision note.

In subsection (j)(2), the words "Not later than 1 year after the date of enactment of this section" are omitted as obsolete.

SECTION 13102—EXEMPTION FROM LABELING AND PACKAGING REQUIREMENTS FOR DRUGS AND DEVICES TO BE PROCESSED, LABELED, OR REPACKED ELSEWHERE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13102	21 U.S.C. 353(a)	June 25, 1938, ch. 675, §503(a), 52 Stat. 1051.

In this section, the words "shall promulgate" are substituted for "is directed to promulgate" to eliminate unnecessary words.

SECTION 13103—PRESCRIPTION DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13103(a)	21 U.S.C. 353(b) (except (5))	June 25, 1938, ch. 675, §503(b) (except (5)), 52 Stat. 1051; Oct. 26, 1951, ch. 578, §1, 65 Stat. 648; Pub. L. 87–781, title I, §104(e)(2), Oct. 10, 1962, 76 Stat. 785; Pub. L. 91–601, §6(e), formerly §7(e), Dec. 30, 1970, 84 Stat. 1673, renumbered Pub. L. 97–35, title XII, §1205(c), Aug. 13, 1981, 95 Stat. 716; Pub. L. 105–115, title I, §126(a), (c)(1), (2), Nov. 21, 1997, 111 Stat. 2327, 2328.
13103(b)(1)(A)	21 U.S.C. 353(c)(1) (2d sentence)	June 25, 1938, ch. 675, §503(c)(1) (2d sentence), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 96.
13103(b)(1)(B)	21 U.S.C. 353(c)(1) (1st sentence)	June 25, 1938, ch. 675, §503(c)(1) (1st sentence), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 96.
13103(b)(1)(C)	21 U.S.C. 353(c)(1) (last sentence)	June 25, 1938, ch. 675, §503(c)(1) (last sentence), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 96.
13103(b)(2)(A)	21 U.S.C. 353(c)(2) (last sentence)	June 25, 1938, ch. 675, §503(c)(2) (last sentence), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 96; Pub. L. 102–108, §2(d)(1), Aug. 17, 1991, 105 Stat. 550.
13103(b)(2)(B)	21 U.S.C. 353(c)(2) (1st sentence)	June 25, 1938, ch. 675, §503(c)(2) (1st sentence), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 96.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13103(b)(3)(A)	21 U.S.C. 353(c)(3) (matter after (B)(v))	June 25, 1938, ch. 675, §503(c)(3) (matter after (B)(v)), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 97.
13103(b)(3)(B)	21 U.S.C. 353(c)(3)(A)	June 25, 1938, ch. 675, §503(c)(3)(A), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 96.
13103(b)(3)(C)	21 U.S.C. 353(c)(3)(B)	June 25, 1938, ch. 675, §503(c)(3)(B), as added Pub. L. 100–293, §4, Apr. 22, 1988, 102 Stat. 96; Pub. L. 102–108, §2(d)(1), Aug. 17, 1991, 105 Stat. 550.
13103(c)(1)(A)	21 U.S.C. 353(d)(4)	June 25, 1938, ch. 675, §503(d)(4), as added Pub. L. 113–54, title II, §204(b), Nov. 27, 2013, 127 Stat. 635.
13103(c)(1)(B)	21 U.S.C. 353(d)(1) (last sentence)	June 25, 1938, ch. 675, §503(d)(1) (last sentence), as added Pub. L. 100–293, §5, Apr. 22, 1988, 102 Stat. 97; Pub. L. 102–353, §4(1), Aug. 26, 1992, 106 Stat. 942.
13103(c)(1)(C)	(no source)	
13103(c)(1)(D)	(no source)	
13103(c)(2)	21 U.S.C. 353(d)(1) (1st sentence)	June 25, 1938, ch. 675, §503(d)(1) (1st sentence), as added Pub. L. 100–293, §5, Apr. 22, 1988, 102 Stat. 97; Pub. L. 102–353, §4(1), Aug. 26, 1992, 106 Stat. 942.
13103(c)(3)	21 U.S.C. 353(d)(2)	June 25, 1938, ch. 675, §503(d)(2), as added Pub. L. 100–293, §5, Apr. 22, 1988, 102 Stat. 97; Pub. L. 102–353, §4(2), Aug. 26, 1992, 106 Stat. 942.
13103(c)(4)	21 U.S.C. 353(d)(3)	June 25, 1938, ch. 675, §503(d)(3), as added Pub. L. 100–293, §5, Apr. 22, 1988, 102 Stat. 97; Pub. L. 102–108, §2(d)(2), Aug. 17, 1991, 105 Stat. 550; Pub. L. 102–353, §4(2), Aug. 26, 1992, 106 Stat. 942.
13103(d)(1)(A)	21 U.S.C. 353(e)(6)	June 25, 1938, ch. 675, §503(e)(6), as added Pub. L. 113–54, title II, §204(a)(4), Nov. 27, 2013, 127 Stat. 634.
13103(d)(1)(B)	21 U.S.C. 353(e)(4)	June 25, 1938, ch. 675, §503(e)(4), as added Pub. L. 113–54, title II, §204(a)(2), Nov. 27, 2013, 127 Stat. 632.
13103(d)(2) through (4)	21 U.S.C. 353(e)(1) through (3)	June 25, 1938, ch. 675, §503(e)(1) through (3), as added Pub. L. 100–293, §6, Apr. 22, 1988, 102 Stat. 98; Pub. L. 102–353, §§2(a), (b), (d), 4(3), (4), Aug. 26, 1992, 106 Stat. 941, 942; Pub. L. 113–54, title II, §204(a)(1), Nov. 27, 2013, 127 Stat. 630.
13103(d)(5)	21 U.S.C. 353(e)(5)	June 25, 1938, ch. 675, §503(e)(5), as added Pub. L. 113–54, title II, §204(a)(3), Nov. 27, 2013, 127 Stat. 634.
13103(e)	21 U.S.C. 353(f)	June 25, 1938, ch. 675, §503(f), formerly §503(c), as added Pub. L. 100–670, title I, §105, Nov. 16, 1988, 102 Stat. 3983; redesignated §503(f), Pub. L. 102–108, §2(d)(3), Aug. 17, 1991, 105 Stat. 550; Pub. L. 102–353, §2(c), Aug. 26, 1992, 106 Stat. 941; Pub. L. 104–250, §5(a), Oct. 9, 1996, 110 Stat. 3155; Pub. L. 108–282, title I, §102(b)(5)(F), Aug. 2, 2004, 118 Stat. 903.

In subsection (a)(2)(A)(i), the reference to subsection (k) of section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is omitted as obsolete because that subsection was previously repealed by section 125(a)(2)(B) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325). The reference to subsection (l) of section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is omitted as obsolete because that subsection was struck by section 125(b)(2)(D) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325).

In subsection (a)(3), the word "exempt" is substituted for "remove" for consistency in the subsection.

In subsection (b)(1)(A), in the matter before clause (i), the words "In this paragraph," are substituted for "For purposes of this paragraph and subsection (d)," to eliminate unnecessary words and because of the addition of subparagraph (C) in section 13103(c)(1) of title 21, United States Code.

In subsection (c)(1), subparagraph (C) is added to carry forward the words "For purposes of this paragraph and subsection (d)," in section 503(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(c)(1)) and subparagraph (D) is added to carry forward the words "For the purposes of this subsection and subsection (d)," in section 503(e)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(4)).

In subsection (c)(4)(A)(ii)(II), the words "A written request for drug samples under subclause (I)" are substituted for "A written request for drug samples" for clarity.

In subsection (c)(4)(B), the words "ensure that the drug samples" are substituted for "assure that the drug samples" to use the more appropriate word.

In subsection (d)(1)(B)(i), the words "For the purposes of this subsection and subsection (d)," are omitted because of the words "In this subsection" in subsection (d)(1) (matter before subparagraph (A)) and because of the addition of subparagraph (D) in section 13103(c)(1) of title 21, United States Code.

In subsection (d)(1)(B)(ii)(X), the words "the transportation, by a common carrier, of a drug" are substituted for "a common carrier that transports a drug" for consistency in the clause.

In subsection (d)(1)(B)(ii)(XIII)(bb), the words "division A of subtitle V of this title" are substituted for "Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.)" to provide a more precise reference to the pertinent provision.

In subsection (d)(3)(A), in the matter before clause (i), the words "Beginning January 1, 2015," are omitted as obsolete.

In subsection (d)(3)(B), in the matter before clause (i), the words "Not later than January 1, 2015," are omitted as obsolete.

In subsection (d)(4)(A)(ii), the words "under this section" are retained, even though the reference to "section" in the source law is broader than the reference to "section" in the restatement, for convenience.

SECTION 13104—COMBINATION PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13104(a)(1) through (4)	21 U.S.C. 353(g)(9)	June 25, 1938, ch. 675, §503(g)(9), formerly §503(f)(4), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g)(4), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 105–115, title I, §123(e), Nov. 21, 1997, 111 Stat. 2324; redesignated §503(g)(5), Pub. L. 107–250, title II, §204((2), 4), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(9), Pub. L. 114–255, div. A, title III, §3038(a)(3), (6), Dec. 13, 2016, 130 Stat. 1105.
13104(a)(5)	21 U.S.C. 353(g)(1)(C)	June 25, 1938, ch. 675, §503(g)(1)(C), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g),

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 107–250, title II, §204(1), Oct. 26, 2002, 116 Stat. 1611; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(b)	21 U.S.C. 353(g)(1)(A)	June 25, 1938, ch. 675, §503(g)(1)(A), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 107–250, title II, §204(1), Oct. 26, 2002, 116 Stat. 1611; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(c)	21 U.S.C. 353(g)(1)(B)	June 25, 1938, ch. 675, §503(g)(1)(B), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 107–250, title II, §204(1), Oct. 26, 2002, 116 Stat. 1611; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(d)	21 U.S.C. 353(g)(1)(D), (E)	June 25, 1938, ch. 675, §503(g)(1)(D), (E), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 107–250, title II, §204(1), Oct. 26, 2002, 116 Stat. 1611; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(e)	21 U.S.C. 353(g)(1)(F)	June 25, 1938, ch. 675, §503(g)(1)(F), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 107–250, title II, §204(1), Oct. 26, 2002, 116 Stat. 1611; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(f)	21 U.S.C. 353(g)(2)	June 25, 1938, ch. 675, §503(g)(2), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(g)(1)	21 U.S.C. 353(g)(5)(B)	June 25, 1938, ch. 675, §503(g)(5)(B), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(g)(2)	21 U.S.C. 353(g)(3)	June 25, 1938, ch. 675, §503(g)(3), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 114–255, div. A, title III, §3038(a)(1), (4), Dec. 13, 2016, 130 Stat. 1105.
13104(g)(3)	21 U.S.C. 353(g)(4)	June 25, 1938, ch. 675, §503(g)(4), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(g)(4)	21 U.S.C. 353(g)(5)(A)	June 25, 1938, ch. 675, §503(g)(5)(A), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(g)(5)	21 U.S.C. 353(g)(5)(C)	June 25, 1938, ch. 675, §503(g)(5)(C), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(g)(6)	21 U.S.C. 353(g)(5)(D)	June 25, 1938, ch. 675, §503(g)(5)(D), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		550; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(h)	21 U.S.C. 353(g)(6)	June 25, 1938, ch. 675, §503(g)(6), formerly §503(f), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; Pub. L. 114–255, div. A, title III, §3038(a)(4), Dec. 13, 2016, 130 Stat. 1105.
13104(i)	21 U.S.C. 353(g)(7)	June 25, 1938, ch. 675, §503(g)(7), formerly §503(f)(2), as added Pub. L. 101–629, §16(a)(2), Nov. 28, 1990, 104 Stat. 4526; redesignated §503(g)(2), Pub. L. 102–108, §2(d)(4), Aug. 17, 1991, 105 Stat. 550; redesignated §503(g)(7), Pub. L. 114–255, div. A, title III, §3038(a)(2), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(1)	21 U.S.C. 353(g)(8)(A) (parenthetical)	June 25, 1938, ch. 675, §503(g)(8)(A) (parenthetical), formerly §503(g)(4)(A) (parenthetical), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(A) (parenthetical), Pub. L. 114–255, div. A, title III, §3038(a)(3), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(2) through (5)	21 U.S.C. 353(g)(8)(A) (except parenthetical)	June 25, 1938, ch. 675, §503(g)(8)(A) (except parenthetical), formerly §503(g)(4)(A) (except parenthetical), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(A) (except parenthetical), Pub. L. 114–255, div. A, title III, §3038(a)(3), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(6)(A)	21 U.S.C. 353(g)(8)(B)	June 25, 1938, ch. 675, §503(g)(8)(B), formerly §503(g)(4)(B), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(B), Pub. L. 114–255, div. A, title III, §3038(a)(3), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(6)(B)	21 U.S.C. 353(g)(8)(C)(i), (ii)	June 25, 1938, ch. 675, §503(g)(8)(C)(i), (ii), formerly §503(g)(4)(C)(i), (ii), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(C)(i), (ii), Pub. L. 114–255, div. A, title III, §3038(a)(3), (5)(A)(i), (ii), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(6)(C), (D)	21 U.S.C. 353(g)(8)(C)(iii), (iv)	June 25, 1938, ch. 675, §503(g)(8)(C)(iii), (iv), as added Pub. L. 114–255, div. A, title III, §3038(a)(5)(A)(iii), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(7)	21 U.S.C. 353(g)(8)(C)(v)	June 25, 1938, ch. 675, §503(g)(8)(C)(v), as added Pub. L. 114–255, div. A, title III, §3038(a)(5)(A)(iii), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(8)	21 U.S.C. 353(g)(8)(D)	June 25, 1938, ch. 675, §503(g)(8)(D), formerly §503(g)(4)(D), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(D), Pub. L. 114–255, div. A, title III, §3038(a)(3), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(9)	21 U.S.C. 353(g)(8)(E)	June 25, 1938, ch. 675, §503(g)(8)(E), formerly §503(g)(4)(E), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(E), Pub. L. 114–255, div. A, title III, §3038(a)(3), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(10)	21 U.S.C. 353(g)(8)(F)	June 25, 1938, ch. 675, §503(g)(8)(F), formerly §503(g)(4)(F), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(F), Pub. L. 114–255, div. A, title III, §3038(a)(3), Dec. 13, 2016, 130 Stat. 1105.
13104(j)(11)	21 U.S.C. 353(g)(8)(H)	June 25, 1938, ch. 675, §503(g)(8)(H), formerly §503(g)(4)(H), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(H), Pub. L. 114–255, div. A, title III, §3038(a)(3), Dec. 13, 2016, 130 Stat. 1105.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13104(k)	21 U.S.C. 353(g)(8)(C)(vi)	June 25, 1938, ch. 675, §503(g)(8)(C)(vi), as added Pub. L. 114–255, div. A, title III, §3038(a)(5)(A)(iii), Dec. 13, 2016, 130 Stat. 1105.
13104(l)	21 U.S.C. 353(g)(8)(G)	June 25, 1938, ch. 675, §503(g)(8)(G), formerly §503(g)(4)(G), as added Pub. L. 107–250, title II, §204(3), Oct. 26, 2002, 116 Stat. 1611; redesignated §503(g)(8)(G), Pub. L. 114–255, div. A, title III, §3038(a)(3), (5)(B), Dec. 13, 2016, 130 Stat. 1105.

In subsection (a)(3)(A), the reference to "507" is omitted as obsolete because of the repeal of the former section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), which section related to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, by section 125(b)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325).

In subsection (a)(3)(B), the reference to "this chapter" is substituted for "this subchapter" for convenience, even though the reference to "this chapter" in the restatement is narrower in that the chapter to which the reference is made (chapter 131 of title 21, United States Code) does not include certain provisions of subchapter A of chapter V of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), to which "this subchapter" in the source law refers. The provisions of that subchapter A that are not included in chapter 131 of title 21, United States Code, are sections 502, 505, and 512 of the Act (21 U.S.C. 352, 355, 360b). Because those provisions do not provide for findings of substantial equivalence, referring to their restated provisions is not necessary.

In subsection (e)(1), in the matter before subparagraph (A), and in subsection (e)(3), the reference to subsection (d) is translated from the reference to subparagraph (D) in the source law (which is a reference to subparagraph (D) of section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)(1))), even though the reference to subsection (d) in the restatement includes subparagraph (E) of section 503(g)(1) of that Act (21 U.S.C. 353(g)(1)), for convenience.

In subsections (f)(2) and (g)(4) (matter before subparagraph (A)), the reference to subsection (d) is translated from the reference to paragraph (1)(D) in the source law (which is a reference to paragraph (1)(D) of section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g))), even though the reference to subsection (d) in the restatement includes paragraph (1)(E) of section 503(g) of that Act (21 U.S.C. 353(g)), for convenience.

In subsection (j)(2), in the matter before subparagraph (A), the words "Not later than 60 days after the date of the enactment of this paragraph," are omitted as obsolete.

In subsection (k), in the matter before paragraph (1), the words "and after a public comment period of not less than 60 calendar days," are omitted as obsolete.

In subsection (l)(1), the words "The Secretary shall annually report" are substituted for "Not later than one year after the date of the enactment of this

paragraph (except with respect to clause (iv), beginning not later than one year after the date of the enactment of the 21st Century Cures Act) and annually thereafter, the Secretary shall report" to eliminate obsolete words.

SECTION 13105—REGULATION OF CERTAIN PRODUCTS AS DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13105(a)	21 U.S.C. 353(h)(2)	June 25, 1938, ch. 675, §503(h)(2), as added Pub. L. 117–328, div. FF, title III, §3621, Dec. 29, 2022, 136 Stat. 5877.
13105(b)	21 U.S.C. 353(h)(1)	June 25, 1938, ch. 675, §503(h)(1), as added Pub. L. 117–328, div. FF, title III, §3621, Dec. 29, 2022, 136 Stat. 5877.
13105(c), (d)	21 U.S.C. 353(h)(3), (4)	June 25, 1938, ch. 675, §503(h)(3), (4), as added Pub. L. 117–328, div. FF, title III, §3621, Dec. 29, 2022, 136 Stat. 5877.

SECTION 13106—PHARMACY COMPOUNDING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13106(a)	21 U.S.C. 353a(e)	June 25, 1938, ch. 675, §503A(e), formerly §503A(f), as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328; redesignated §503A(e), Pub. L. 113–54, title I, § 106(a)(3), Nov. 27, 2013, 127 Stat. 598.
13106(b) (matter before (1))	21 U.S.C. 353a(a) (matter before (1) ("Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product"))	June 25, 1938, ch. 675, §503A(a) (matter before (1) ("Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product")), as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328.
13106(b)(1), (2)	21 U.S.C. 353a(a) (matter before (1) (from "if the drug product is compounded" through "meets the requirements of this section,"))	June 25, 1938, ch. 675, § 503A(a) (matter before (1) (from "if the drug product is compounded" through "meets the requirements of this section,")), as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328; Pub. L. 113–54, title I, § 106(a)(1), Nov. 27, 2013, 127 Stat. 598.
13106(b)(3) (matter before (A))	21 U.S.C. 353a(a) (matter before (1) ("and if the compounding"))	June 25, 1938, ch. 675, §503A(a) (matter before (1) ("and if the compounding")), as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328.
13106(b)(3)(A)	21 U.S.C. 353a(a)(1)	June 25, 1938, ch. 675, §503A(a)(1), as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328.
13106(b)(3)(B)	21 U.S.C. 353a(a)(2)	June 25, 1938, ch. 675, §503A(a)(2), as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328.
13106(c) through (e) ...	21 U.S.C. 353a(b) through (d)	June 25, 1938, ch. 675, §503A(b) through (d), as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328; Pub. L. 113–54, title I, § 106(a)(2) through (4), Nov. 27, 2013, 127 Stat. 598.

SECTION 13107—OUTSOURCING FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13107(a) (matter before (1))	21 U.S.C. 353b(d) (matter before (1))	June 25, 1938, ch. 675, §503B(d) (matter before (1)), as added Pub. L. 113–54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 592.
13107(a)(1)	21 U.S.C. 353b(d)(3)	June 25, 1938, ch. 675, § 503B(d)(3), as added Pub. L. 113–54, title I, § 102(a)(2), Nov. 27, 2013, 127 Stat. 593.
13107(a)(2)	21 U.S.C. 353b(d)(1)	June 25, 1938, ch. 675, §503B(d)(1), as added Pub. L. 113–54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 592.
13107(a)(3)	21 U.S.C. 353b(d)(2)	June 25, 1938, ch. 675, § 503B(d)(2), as added Pub. L. 113–54, title I, § 102(a)(2), Nov. 27, 2013, 127 Stat. 592.
13107(a)(4)	21 U.S.C. 353b(d)(4)	June 25, 1938, ch. 675, § 503B(d)(4), as added Pub. L. 113–54, title I, § 102(a)(2), Nov. 27, 2013, 127 Stat. 593.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13107(a)(5)	21 U.S.C. 353b(d)(5)	June 25, 1938, ch. 675, §503B(d)(5), as added Pub. L. 113–54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 593.
13107(b)	21 U.S.C. 353b(a)	June 25, 1938, ch. 675, §503B(a), as added Pub. L. 113–54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 588.
13107(c)	21 U.S.C. 353b(b)	June 25, 1938, ch. 675, §503B(b), as added Pub. L. 113–54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 590.
13107(d)	21 U.S.C. 353b(c)	June 25, 1938, ch. 675, § 503B(c), as added Pub. L. 113–54, title I, § 102(a)(2), Nov. 27, 2013, 127 Stat. 592.
13107(e)	21 U.S.C. 353b(d) (relating to obligation to pay fees)	June 25, 1938, ch. 675, §503B(d) (relating to obligation to pay fees), as added Pub. L. 113–54, title I, §102(a)(2), Nov. 27, 2013, 127 Stat. 593.

In subsection (a)(1), the words "on the list described in subsection (b)(4)" are substituted for "on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective" to eliminate unnecessary words.

In subsection (b), in the matter before paragraph (1), the words "in an outsourcing facility" are substituted for "in a facility that elects to register as an outsourcing facility" to eliminate unnecessary words because of subsection (a)(4)(A)(ii).

In subsection (b)(5), the words "not essentially a copy of an approved drug" are substituted for "not essentially a copy of one or more approved drugs" for consistency with subsection (a)(3).

In subsection (b)(6)(A), the words "which difficulties are reasonably likely" are substituted for "that are reasonably likely" for clarity.

In subsection (b)(7), the words "ensure safe use" are substituted for "assure safe use" to use the more appropriate word.

In subsection (c)(1)(A), in the matter before clause (i), the words "after becoming an outsourcing facility" are substituted for "thereafter" for clarity.

In subsection (c)(3), the words "a request for waiver of the electronic submission requirement" are substituted for "a request for waiver of such requirement" for clarity.

In subsection (c)(4)(C), in the matter before clause (i), the words "which safety risks shall be based on" are substituted for "which shall be based on" for clarity.

In subsection (c)(4)(C)(vi), the words "considered necessary and appropriate" are substituted for "deemed necessary and appropriate" to use the more appropriate word.

SECTION 13108—PREREVIEW OF TELEVISION ADVERTISEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13108(a), (b)	21 U.S.C. 353c(a), (b)	June 25, 1938, ch. 675, §503C(a), (b), formerly §503B(a), (b), as added Pub. L. 110–85, title IX, §901(d)(2), Sept. 27, 2007, 121 Stat. 939, renumbered §503C(a), (b), Pub. L. 113–54, title I, §102(a)(1), Nov. 27, 2013, 127 Stat. 587.
13108(c)	21 U.S.C. 353c(d)	June 25, 1938, ch. 675, § 503C(d), formerly §503B(d), as added Pub. L. 110–85, title IX, §901(d)(2), Sept. 27, 2007, 121 Stat. 939, renumbered §503C(d), Pub. L. 113–54, title I, §102(a)(1), Nov. 27, 2013, 127 Stat. 587.
13108(d)	21 U.S.C. 353c(c)	June 25, 1938, ch. 675, §503C(c), formerly §503B(c), as added Pub. L. 110–85, title IX, §901(d)(2), Sept. 27, 2007, 121 Stat. 939, renumbered §503C(c), Pub. L. 113–54, title I, §102(a)(1), Nov. 27, 2013, 127 Stat. 587.
13108(e), (f)	21 U.S.C. 353c(e), (f)	June 25, 1938, ch. 675, §503C(e), (f), formerly §503B(e), (f), as added Pub. L. 110–85, title IX, §901(d)(2), Sept. 27, 2007, 121 Stat. 939, renumbered §503C(e), (f), Pub. L. 113–54, title I, §102(a)(1), Nov. 27, 2013, 127 Stat. 587.

SECTION 13109—PROCESS TO UPDATE LABELING FOR CERTAIN GENERIC DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13109	21 U.S.C. 353d	June 25, 1938, ch. 675, §503D, as added Pub. L. 116–260, div. BB, title III, §324, Dec. 27, 2020, 134 Stat. 2933.

In subsection (j)(1)(B), the words "or holders" are omitted as unnecessary because of section 1 of title 1, United States Code.

SECTION 13110—VETERINARY FEED DIRECTIVE DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13110	21 U.S.C. 354	June 25, 1938, ch. 675, §504, as added Pub. L. 104–250, §5(b), Oct. 9, 1996, 110 Stat. 3155; amended Pub. L. 108–282, title I, §102(b)(5)(G), (H), Aug. 2, 2004, 118 Stat. 903.

SECTION 13111—RISK EVALUATION AND MITIGATION STRATEGIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13111(a) (except (5)) ...	21 U.S.C. 355–1(b)	June 25, 1938, ch. 675, §505–1(b), as added Pub. L. 110–85, title IX, §901(b), Sept. 27, 2007, 121 Stat. 927; Pub. L. 115–271, title III, §3041(a), Oct. 24, 2018, 132 Stat. 3942.
13111(a)(5)	21 U.S.C. 355–1(m)	June 25, 1938, ch. 675, §505–1(m), as added Pub. L. 116–94, div. N, title I, §610(f)(4), Dec. 20, 2019, 133 Stat. 3136.
13111(b)	21 U.S.C. 355–1(a)	June 25, 1938, ch. 675, § 505–1(a), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 926.
13111(c)	21 U.S.C. 355–1(c)	June 25, 1938, ch. 675, §505–1(c), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 928.
13111(d)	21 U.S.C. 355–1(d)	June 25, 1938, ch. 675, § 505–1(d), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 929.
13111(e)	21 U.S.C. 355–1(e)	June 25, 1938, ch. 675, §505–1(e), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 929; Pub. L. 115–52, title VI, §606, Aug. 18, 2017, 131 Stat. 1049; Pub. L. 115–271, title III, §3032(a),

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Oct. 24, 2018, 132 Stat. 3940; Pub. L. 117–328, div. FF, title III, §3221, Dec. 29, 2022, 136 Stat. 5829.
13111(f)(1)	21 U.S.C. 355–1(f)(1)	June 25, 1938, ch. 675, §505–1(f)(1), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 930.
13111(f)(2)	21 U.S.C. 355–1(f)(2)	June 25, 1938, ch. 675, §505–1(f)(2), as added Pub. L. 110–85, title IX, §901(b), Sept. 27, 2007, 121 Stat. 930; Pub. L. 115–271, title III, §3032(b), Oct. 24, 2018, 132 Stat. 3941.
13111(f)(3)(A) (matter before (i))	21 U.S.C. 355–1(f)(3) (matter before (A))	June 25, 1938, ch. 675, § 505–1(f)(3) (matter before (A)), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 930.
13111(f)(3)(A)(i)	21 U.S.C. 355–1(f)(3)(A) (except parenthetical)	June 25, 1938, ch. 675, §505–1(f)(3)(A) (except parenthetical), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 930.
13111(f)(3)(A)(ii)	21 U.S.C. 355–1(f)(3)(B) (except parenthetical)	June 25, 1938, ch. 675, § 505–1(f)(3)(B) (except parenthetical), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 931.
13111(f)(3)(A)(iii) through (vi)	21 U.S.C. 355–1(f)(3)(C) through (F)	June 25, 1938, ch. 675, § 505–1(f)(3)(C) through (F), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 931.
13111(f)(3)(B)	21 U.S.C. 355–1(f)(3)(A) (parenthetical)	June 25, 1938, ch. 675, § 505–1(f)(3)(A) (parenthetical), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 930.
13111(f)(3)(C)	21 U.S.C. 355–1(f)(3)(B) (parenthetical)	June 25, 1938, ch. 675, § 505–1(f)(3)(B) (parenthetical), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 931.
13111(f)(4)	21 U.S.C. 355–1(f)(4)	June 25, 1938, ch. 675, §505–1(f)(4), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 931.
13111(f)(5)	21 U.S.C. 355–1(f)(5)	June 25, 1938, ch. 675, §505–1(f)(5), as added Pub. L. 110–85, title IX, §901(b), Sept. 27, 2007, 121 Stat. 931; Pub. L. 114–255, div. A, title III, §3075(c), Dec. 13, 2016, 130 Stat. 1139.
13111(f)(6)	21 U.S.C. 355–1(f)(6)	June 25, 1938, ch. 675, § 505–1(f)(6), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 931.
13111(f)(7)	21 U.S.C. 355–1(f)(8)	June 25, 1938, ch. 675, § 505–1(f)(8), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 932.
13111(g)	21 U.S.C. 355–1(g)	June 25, 1938, ch. 675, §505–1(g), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 932; Pub. L. 112–144, title XI, §1132(a), July 9, 2012, 126 Stat. 1119; Pub. L. 116–94, div. N, title I, §610(f)(1), Dec. 20, 2019, 133 Stat. 3136.
13111(h) (except (2)(A)(ii)(II))	21 U.S.C. 355–1(h)	June 25, 1938, ch. 675, §505–1(h), as added Pub. L. 110–85, title IX, §901(b), Sept. 27, 2007, 121 Stat. 933; Pub. L. 112–144, title XI, §1132(b), July 9, 2012, 126 Stat. 1120; Pub. L. 114–255, div. A, title III, §3101(a)(2)(C), Dec. 13, 2016, 130 Stat. 1153.
13111(h)(2)(A)(ii)(II) ..	21 U.S.C. 355–1 note	Pub. L. 112–144, title XI, §1132(c), July 9, 2012, 126 Stat. 1122.
13111(i)	21 U.S.C. 355–1(i)	June 25, 1938, ch. 675, § 505–1(i), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 937; Pub. L. 115–271, title III, §3032(c), Oct. 24, 2018, 132 Stat. 3941; Pub. L. 116–94, div. N, title I, §610(f)(2), (3), Dec. 20, 2019, 133 Stat. 3136.
13111(j)	21 U.S.C. 355–1(j)	June 25, 1938, ch. 675, §505–1(j), as added Pub. L. 110–85, title IX, § 901(b), Sept. 27, 2007, 121 Stat. 938.
13111(k)	21 U.S.C. 355–1(k)	June 25, 1938, ch. 675, § 505–1(k), as added Pub. L. 113–5, title III, §302(c)(2), Mar. 13, 2013, 127 Stat. 185.
13111(l)	21 U.S.C. 355–1(l)	June 25, 1938, ch. 675, § 505–1(l), as added Pub. L. 116–94, div. N, title I, §610(d), Dec. 20, 2019, 133 Stat. 3135.

In subsection (a)(3)(A)(iii), the words "considered appropriate" are substituted for "deemed appropriate" to use the more appropriate word.

In subsection (a)(5), in the matter before subparagraph (A), the words "to ensure safe use" are substituted for "to assure safe use" to use the more appropriate word.

In subsection (a)(5)(A), the words "but achieves the same level of safety as the strategy for the listed drug" are added for clarity.

In subsection (a)(5)(B), the words "another application" are substituted for "other application" to use the more appropriate word.

In subsection (a)(5)(B), the words "as the strategy for the listed drug" are substituted for "as such strategy" for clarity.

In subsection (a)(7)(F), the words "data considered appropriate" are substituted for "data deemed appropriate" to use the more appropriate word.

In subsection (d)(4)(C), the words "3-year period described in paragraph (2)" are substituted for "3-year period described in paragraph (1)" to provide the correct reference to the pertinent provision. The 3-year period is described in paragraph (2) and not in paragraph (1).

In subsections (e)(3)(C), (f), (g)(4)(B)(iii), and (i), the words "ensure safe use" are substituted for the words "assure safe use" each place they appear to use the more appropriate word.

In subsection (g)(2)(B), in the matter after the semicolon, the word "and" is added for clarity.

In subsection (h)(2)(A)(ii)(II), the words "Not later than 1 year after the date of enactment of this Act," are omitted as obsolete.

In paragraphs (3) and (4)(C)(i)(I) of subsection (h), the words "section 101(c) of the Prescription Drug User Fee Amendments of 2007 (Public Law 110–85, title I, 121 Stat. 825)" are substituted for "section 101(c) of the Food and Drug Administration Amendments Act of 2007" to provide a more precise reference to the pertinent provision. The short title for title I of the Food and Drug Administration Amendments Act of 2007 is Prescription Drug User Fee Amendments of 2007, and section 101(c) is under that title.

In subsection (h)(4)(G)(ii), the words "under subparagraph (B) or (C) of subsection (g)(2)" are substituted for "under any of subparagraphs (B) through (D) of subsection (g)(2)" to eliminate an obsolete reference. Subsection (g)(2) of the source law does not contain a subparagraph (D). That subparagraph was struck by section 1132(a)(2)(C) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1120).

In subsection (h)(4)(K), the words "Office of Pediatric Therapeutics" are substituted for "Office of Pediatrics" for consistency with section 25301 of title 21, United States Code.

In subsection (h)(4)(K), the words "meeting under subparagraph (D)" are substituted for "meeting under subparagraph (D) of the Drug Safety Oversight Board" to eliminate unnecessary words.

In subsection (h)(6)(C)(ii), the words "as provided for under paragraph (5)" are substituted for "as provided for under paragraph (6)" to provide the correct

reference to the pertinent provision. Meetings of advisory committees are provided for in paragraph (5) of the source law, which is restated as paragraph (5) of section 13111(h)(6) of title 21, United States Code.

In subsection (h)(7)(A), the words "the Secretary considers comparable" are substituted for "the Secretary deems comparable" to use the more appropriate word.

In subsection (i)(2)(C), the words "that is approved under section 13511 of this title" are substituted for "that is so approved" for clarity.

SECTION 13112—PEDIATRIC STUDIES OF DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13112(a)	21 U.S.C. 355a(a)	June 25, 1938, ch. 675, §505A(a), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876.
13112(b)	21 U.S.C. 355a(b)	June 25, 1938, ch. 675, §505A(b), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 115–52, title V, §505(b)(2)(A), Aug. 18, 2017, 131 Stat. 1046.
13112(c)	21 U.S.C. 355a(c)	June 25, 1938, ch. 675, §505A(c), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 115–52, title V, §505(b)(2)(A), Aug. 18, 2017, 131 Stat. 1046; Pub. L. 117–9, §1(b)(2), Apr. 23, 2021, 135 Stat. 258.
13112(d)	21 U.S.C. 355a(d)	June 25, 1938, ch. 675, §505A(d), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 113–5, title III, §307(a)(1), Mar. 13, 2013, 127 Stat. 191; Pub. L. 115–52, title V, §505(b)(1), Aug. 18, 2017, 131 Stat. 1046.
13112(e)	21 U.S.C. 355a(e)	June 25, 1938, ch. 675, §505A(e), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876.
13112(f)	21 U.S.C. 355a(f)	June 25, 1938, ch. 675, §505A(f), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 115–52, title V, §505(a), (b)(2)(A), Aug. 18, 2017, 131 Stat. 1046.
13112(g)	21 U.S.C. 355a(g)	June 25, 1938, ch. 675, §505A(g), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876.
13112(h)	21 U.S.C. 355a(h)	June 25, 1938, ch. 675, § 505A(h), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 112–144, title V, §502(a)(1), July 9, 2012, 126 Stat. 1040; Pub. L. 115–52, title V, §505(b)(2)(A), Aug. 18, 2017, 131 Stat. 1046.
13112(i)	21 U.S.C. 355a(i)	June 25, 1938, ch. 675, §505A(i), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876.
13112(j)	21 U.S.C. 355a(j)	June 25, 1938, ch. 675, §505A(j), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876.
13112(k)	21 U.S.C. 355a(k)	June 25, 1938, ch. 675, §505A(k), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 112–144, title V, §509(a)(1), July 9, 2012, 126 Stat. 1047.
13112(l)	21 U.S.C. 355a(l)	June 25, 1938, ch. 675, § 505A(l), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 112–144, title V, §509(a)(2), July 9, 2012, 126 Stat. 1047.
13112(m)	21 U.S.C. 355a(m)	June 25, 1938, ch. 675, §505A(m), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13112(n)	21 U.S.C. 355a(n)	June 25, 1938, ch. 675, § 505A(n), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 112–144, title V, §509(a)(3), July 9, 2012, 126 Stat. 1047; Pub. L. 113–5, title III, §307(a)(2), Mar. 13, 2013, 127 Stat. 191.
13112(o)	21 U.S.C. 355a(o)	June 25, 1938, ch. 675, §505A(o), as added Pub. L. 105–115, title I, §111, Nov. 21, 1997, 111 Stat. 2305; Pub. L. 107–109, §§2, 4, 5(b)(2), 7 through 11(a), 18(a), 19, Jan. 4, 2002, 115 Stat. 1408, 1411, 1413 through 1415, 1423, 1424; Pub. L. 108–155, §§2(b)(2), 3(a), (b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1104, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 110–85, title V, §502(a)(1), Sept. 27, 2007, 121 Stat. 876; Pub. L. 112–144, title V, §509(a)(4), July 9, 2012, 126 Stat. 1048; Pub. L. 115–52, title VI, §608, Aug. 18, 2017, 131 Stat. 1050.

In subsection (a), the defined term "studies" is omitted as unnecessary. Throughout the section, the term "pediatric studies" is substituted for "studies" for consistency in the section.

In subsection (b)(1)(A)(v), the words "reports of the pediatric studies" are substituted for "reports thereof" for clarity.

In subsection (b)(1)(B), in the matter before clause (i), the words "With regard to the drug concerned under subparagraph (A)" are added for clarity because of the structure of the restatement of section 505A(b) of the Federal Food, Drug, and Cosmetic Law (21 U.S.C. 355a(b)).

In subsection (c)(1)(A)(v), the words "reports of the pediatric studies" are substituted for "reports thereof" for clarity.

In subsection (c)(1)(B), in the matter before clause (i), the words "With regard to the drug concerned under subparagraph (A)" are added for clarity because of the structure of the restatement of section 505A(c) of the Federal Food, Drug, and Cosmetic Law (21 U.S.C. 355a(c)).

In subsection (d)(1)(A)(i), the words "a written request to conduct pediatric studies for the drug" are substituted for "a written request for the conduct of pediatric studies for such drug" for clarity.

In subsection (d)(2)(A)(ii), the words "on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (d)(2)(B), in the matter before clause (i), the words "on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (d)(2)(B)(ii), the words "submission of the reports of the pediatric studies" are substituted for "submission of the reports" for clarity.

In subsection (d)(4)(A), the words "notify the sponsor or holder of the acceptance or rejection" are substituted for "so notify the sponsor or holder" for clarity.

In subsection (e)(1)(A), the words "made on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (e)(2)(A), the words "on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (f)(1), the words "internal committee" are substituted for "internal review committee" for consistency with section 13114 of title 21, United States Code.

In subsection (f)(1), the words "issued in accordance with" are substituted for "issued on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, in accordance with" to eliminate obsolete words.

In subsection (i)(2)(A), in the matter before clause (i), the words "on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (j), the words "on or after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (k)(2), the words "Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (l)(1)(A), the words "Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (l)(1)(A), the words "established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109)" are omitted as unnecessary and for consistency in title 21, United States Code.

In subsection (n)(1), in the matter before subparagraph (A), the words "Beginning on the date of the enactment of the Best Pharmaceuticals for Children Act of 2007," are omitted as obsolete.

In subsection (n)(1)(A), the words "the Secretary shall make a determination" are substituted for "make a determination" for clarity.

In subsection (o)(2)(B), the words "ensure safe use" are substituted for "assure safe use" to use the more appropriate word.

SECTION 13113—RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13113(a)	21 U.S.C. 355c(a) (except (4)(B)(ii) (5th sentence, 6th sentence))	June 25, 1938, ch. 675, §505B(a) (except (4)(B)(ii) (5th sentence), (6th sentence)), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §§505(a)(1), 506(b)(1), 509(b)(1), July 9, 2012, 126 Stat. 1041, 1044, 1048; Pub. L. 115–52, title V, §504(a)(1), Aug. 18, 2017, 131 Stat. 1039.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13113(b)	21 U.S.C. 355c(b)	June 25, 1938, ch. 675, §505B(b), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §509(b)(2), July 9, 2012, 126 Stat. 1048.
13113(c)	21 U.S.C. 355c(c)	June 25, 1938, ch. 675, §505B(c), as added Pub. L. 108–155, § 2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, § 402(a), Sept. 27, 2007, 121 Stat. 866.
13113(d)	21 U.S.C. 355c(d)	June 25, 1938, ch. 675, §505B(d), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §505(c)(1), July 9, 2012, 126 Stat. 1042; Pub. L. 115–52, title V, §§504(a)(2), 505(e), Aug. 18, 2017, 131 Stat. 1040 , 1047.
13113(e)	21 U.S.C. 355c(e)	June 25, 1938, ch. 675, §505B(e), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §506(a), July 9, 2012, 126 Stat. 1043; Pub. L. 114–255, div. A, title III, §3101(a)(2)(D)(i), Dec. 13, 2016, 130 Stat. 1153; Pub. L. 115–52, title V, §§503, 504(a)(3), Aug. 18, 2017, 131 Stat. 1038, 1040.
13113(f)	21 U.S.C. 355c(f)	June 25, 1938, ch. 675, §505B(f), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §§505(a)(2), (b), (c)(2), 506(b)(2), July 9, 2012, 126 Stat. 1042, 1044; Pub. L. 114–255, div. A, title III, §3101(a)(2)(D)(ii), Dec. 13, 2016, 130 Stat. 1153; Pub. L. 117–328, div. FF, title II, §2515(c), Dec. 29, 2022, 136 Stat. 5806.
13113(g)	21 U.S.C. 355c(g)	June 25, 1938, ch. 675, §505B(g), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §509(b)(3), July 9, 2012, 126 Stat. 1048.
13113(h)	21 U.S.C. 355c(h)	June 25, 1938, ch. 675, §505B(h), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §509(b)(4), July 9, 2012, 126 Stat. 1048.
13113(i)	21 U.S.C. 355c(i)	June 25, 1938, ch. 675, §505B(i), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 112–144, title V, §509(b)(5), July 9, 2012, 126 Stat. 1048.
13113(j)	21 U.S.C. 355c(j)	June 25, 1938, ch. 675, §505B(j), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866.
13113(k)	21 U.S.C. 355c(k)	June 25, 1938, ch. 675, §505B(k), as added Pub. L. 108–155, §2(a), Dec. 3, 2003, 117 Stat. 1936; Pub. L. 110–85, title IV, §402(a), Sept. 27, 2007, 121 Stat. 866; Pub. L. 115–52, title V, §504(b), Aug. 18, 2017, 131 Stat. 1041.
13113(l)	21 U.S.C. 355c(l)	June 25, 1938, ch. 675, §505B(l), formerly 505B(n), as added Pub. L. 111–148, title VII, § 7002(d)(2), Mar. 23, 2010, 124 Stat. 816; redesignated §505B(m), Pub. L. 112–144, title V, §501(b)(2), July 9, 2012, 126 Stat. 1040; redesignated §505B(l), Pub. L. 114–255, div. A, title III, §3102(3)(B), Dec. 13, 2016, 130 Stat. 1156.
13113(m)	21 U.S.C. 355c(m)	June 25, 1938, ch. 675, §505B(m), as added Pub. L. 115–52, title V, §504(a)(4), Aug. 18, 2017, 131 Stat. 1040.

In subsection (a)(1)(A)(i), the words "on or after the date of the enactment of the Pediatric Research Equity Act of 2007" are omitted as obsolete.

In subsection (c), in the matter before paragraph (1), the words "paragraph (5)(A)(iii)(I) and (5)(B)(iii)(I) of subsection (a)" are substituted for "paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a)" to reflect the redesignation of former paragraph (4) of section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) to paragraph (5) of that section. The redesignation was made by section 504(a)(1)(C) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1040). The redesignated paragraph is restated as paragraph (5) of section 13113(a) of title 21, United States Code.

In subsection (d), in the matter before paragraph (1), the words "or report on the investigation described in subsection (a)(3)," are substituted for "or the investigation described in subsection (a)(3)," for clarity and consistency in the section.

In subsection (d)(1)(A), the words "Beginning 270 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act," are omitted as obsolete.

In subsection (d)(1)(A), the words "informing the person" are substituted for "informing them" for consistency with the antecedent "person".

In subsection (d)(2), in the matter before subparagraph (A), the words "request for approval of a pediatric formulation described in subsection (a) or (b)" are substituted for "request for approval of a pediatric formulation" for clarity and consistency with paragraph (1).

In subsection (e)(1), the words "prior to the submission of the assessments described under subsection (a)(2) or the investigation described in subsection (a)(3)" are omitted as unnecessary because of paragraph (2)(A)(i)(I).

In subsection (e)(2)(A)(i)(I), the words "or reports on the investigation described in subsection (a)(3)," are substituted for "or the investigation described in subsection (a)(3)," for clarity and consistency in the section.

In subsection (e)(2)(C)(iii), the words "shall notify the applicant of the determination" are substituted for "shall so notify the applicant" for clarity.

In subsection (e)(4), the words "under paragraph (4) or (5) of subsection (a)" are substituted for "under paragraphs (3) or (4) of subsection (a)" to reflect the redesignation of former paragraphs (3) and (4) of section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) to paragraphs (4) and (5) of that section. The redesignation was made by section 504(a)(1)(C) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1040). The redesignated paragraphs are restated as paragraphs (4) and (5) of section 13113(a) of title 21, United States Code.

In subsection (f)(1), in the matter before subparagraph (A), the words "Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007," are omitted as obsolete.

In subsection (g)(1)(A), in the matter before clause (i), the words "on or after the date of the enactment of the Pediatric Research Equity Act of 2007," are omitted as obsolete.

In subsection (g)(2), the words "on or after the date of the enactment of the Pediatric Research Equity Act of 2007," are omitted as obsolete.

In subsection (h)(2), the words "Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007," are omitted as obsolete.

In subsection (i)(1)(A), the words "Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007," are omitted as obsolete.

In subsection (m)(1), in the matter before subparagraph (A), the words "The Secretary shall update" are substituted for "Within one year of the date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall establish and update" to eliminate obsolete words.

In subsection (m)(2), the words "meeting under section 504(c) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1041)" are substituted for "meeting under subsection (c)" to provide the correct reference to the pertinent provision.

SECTION 13114—INTERNAL COMMITTEE FOR REVIEW OF PEDIATRIC PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13114	21 U.S.C. 355d	June 25, 1938, ch. 675, §505C, as added Pub. L. 110–85, title IV, §403, Sept. 27, 2007, 121 Stat. 875; amended Pub. L. 112–144, title V, §509(c), July 9, 2012, 126 Stat. 1049; Pub. L. 115–52, title V, §505(f), Aug. 18, 2017, 131 Stat. 1047.

SECTION 13115—PHARMACEUTICAL SECURITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13115(a)	21 U.S.C. 355e(d)	June 25, 1938, ch. 675, §505D(d), as added Pub. L. 110–85, title IX, § 913, Sept. 27, 2007, 121 Stat. 952.
13115(b) through (d) ...	21 U.S.C. 355e(a) through (c)	June 25, 1938, ch. 675, §505D(a) through (c), as added Pub. L. 110–85, title IX, § 913, Sept. 27, 2007, 121 Stat. 952.

In subsection (c)(2), the words "Not later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007" are omitted as obsolete.

SECTION 13116—EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13116(a)(1)	21 U.S.C. 355f(g)	June 25, 1938, ch. 675, §505E(g), as added Pub. L. 112–144, title VIII, § 801(a), July 9, 2012, 126 Stat. 1077; Pub. L. 117–328, div. FF, title III, §3212(a)(3), Dec. 29, 2022, 136 Stat. 5826.
13116(a)(2)	21 U.S.C. 355f(f)(1)	June 25, 1938, ch. 675, §505E(f)(1), as added Pub. L. 112–144, title VIII, § 801(a), July 9, 2012, 126 Stat. 1077.
13116(b) through (f)	21 U.S.C. 355f(a) through (e)	June 25, 1938, ch. 675, §505E(a) through (e), as added Pub. L. 112–144, title VIII, § 801(a), July 9, 2012, 126 Stat. 1077; Pub. L. 117–328, div. FF, title III, §3212(a)(1), (2), Dec. 29, 2022, 136 Stat. 5826.
13116(g)	21 U.S.C. 355f(f)(2)	June 25, 1938, ch. 675, §505E(f)(2), as added Pub. L. 112–144, title VIII, § 801(a), July 9, 2012, 126 Stat. 1077.

In subsection (a), in the matter before paragraph (1), the words "In this section:" are added to make the defined term in paragraph (1) applicable to the

section, for clarity. The source provision of paragraph (1) does not specify to which provisions the defined term is applicable.

In subsection (f)(1), the words "The Secretary shall promulgate regulations" are substituted for "Not later than 2 years after the date of the enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations" to eliminate obsolete words.

SECTION 13117—UTILIZING REAL-WORLD EVIDENCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13117(a)	21 U.S.C. 355g(b)	June 25, 1938, ch. 675, §505F(b), as added Pub. L. 114–255, div. A, title III, §3022, Dec. 13, 2016, 130 Stat. 1096; Pub. L. 115–52, title IX, §901(c), Aug. 18, 2017, 131 Stat. 1076.
13117(b)	21 U.S.C. 355g(a)	June 25, 1938, ch. 675, §505F(a), as added Pub. L. 114–255, div. A, title III, §3022, Dec. 13, 2016, 130 Stat. 1096.
13117(c) through (f)	21 U.S.C. 355g(c) through (f)	June 25, 1938, ch. 675, §505F(c) through (f), as added Pub. L. 114–255, div. A, title III, §3022, Dec. 13, 2016, 130 Stat. 1096; Pub. L. 115–52, title IX, §901(d), Aug. 18, 2017, 131 Stat. 1076.

SECTION 13118—REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED DRUG APPLICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13118(a)	21 U.S.C. 355h(q)	June 25, 1938, ch. 675, §505G(q), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 452.
13118(b)	21 U.S.C. 355h(a)	June 25, 1938, ch. 675, §505G(a), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 435.
13118(c)(1)	21 U.S.C. 355h(b)(1)	June 25, 1938, ch. 675, §505G(b)(1), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 437.
13118(c)(2)	21 U.S.C. 355h(b)(2)	June 25, 1938, ch. 675, §505G(b)(2), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 438.
13118(c)(3)	21 U.S.C. 355h(b)(3)	June 25, 1938, ch. 675, §505G(b)(3), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 439.
13118(c)(4)	21 U.S.C. 355h(b)(4)	June 25, 1938, ch. 675, §505G(b)(4), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 441.
13118(c)(5)(A), (B)	21 U.S.C. 355h(b)(5)(A), (B)	June 25, 1938, ch. 675, §505G(b)(5)(A), (B), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 443.
13118(c)(5)(C)(i)	21 U.S.C. 355h(b)(5)(C)(v)	June 25, 1938, ch. 675, §505G(b)(5)(C)(v), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 445.
13118(c)(5)(C)(ii) through (v)	21 U.S.C. 355h(b)(5)(C)(i) through (iv)	June 25, 1938, ch. 675, §505G(b)(5)(C)(i) through (iv), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 444.
13118(c)(5)(C)(vi)	21 U.S.C. 355h(b)(5)(C)(vi)	June 25, 1938, ch. 675, §505G(b)(5)(C)(vi), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 445.
13118(c)(6) through (8)	21 U.S.C. 355h(b)(6) through (8)	June 25, 1938, ch. 675, §505G(b)(6) through (8), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 446.
13118(d) through (q) ...	21 U.S.C. 355h(c) through (p)	June 25, 1938, ch. 675, §505G(c) through (p), as added Pub. L. 116–136, div. A, title III, §3851(a), Mar. 27, 2020, 134 Stat. 447.

In this section, the reference to "section 10101(a)(34)(A)(i) of this title" is substituted for the reference to "section 201(p)(1)" each place it appears to provide a more precise reference to the pertinent provision.

In subsection (c)(3)(A)(ii), the words "A person seeking a hearing shall submit a request for a hearing," are substituted for "If a hearing is sought, the person must submit a request for a hearing," to eliminate unnecessary words and for clarity.

In subsection (c)(5)(C)(v)(II)(bb), the words "to ensure safe use" are substituted for "to assure safe use" to use the more appropriate word.

In subsection (m)(4), the words "procedures for the consolidated proceedings" are substituted for "procedures for such proceedings" for clarity.

SECTION 13119—EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13119(a)(1)	21 U.S.C. 356(c)(1)(A) (last sentence)	June 25, 1938, ch. 675, §506(c)(1)(A) (last sentence), formerly §506(b)(1)(A) (last sentence), as added Pub. L. 105–115, title I, § 112(a), Nov. 21, 1997, 111 Stat. 2309; redesignated §506(c)(1)(A) (last sentence), Pub. L. 112–144, title IX, §§901(b), 902(a)(1), July 9, 2012, 126 Stat. 1083, 1086.
13119(a)(2)	21 U.S.C. 356(a)(1) (from "if the drug" through "a 'breakthrough therapy'.)")	June 25, 1938, ch. 675, §506(a)(1) (from "if the drug" through "a 'breakthrough therapy'.)"), as added Pub. L. 112–144, title IX, §902(a)(3), July 9, 2012, 126 Stat. 1083.
13119(a)(3)	21 U.S.C. 356(b)(1) (from "if it is intended" through "a 'fast track product'.)")	June 25, 1938, ch. 675, §506(b)(1) (from "if it is intended" through "a 'fast track product'.)"), formerly §506(a)(1) (from "if it is intended" through "a 'fast track product'.)"), as added Pub. L. 105–115, title I, § 112(a), Nov. 21, 1997, 111 Stat. 2309; redesignated §506(b)(1) (from "if it is intended" through "a 'fast track product'.)"), Pub. L. 112–144, title VIII, §803, title IX, §§901(b), 902(a)(1), July 9, 2012, 126 Stat. 1079, 1083, 1086.
13119(a)(4)	21 U.S.C. 356(g)(8)	June 25, 1938, ch. 675, §506(g)(8), as added Pub. L. 114–255, div. A, title III, §3033(a)(2), Dec. 13, 2016, 130 Stat. 1101.
13119(b)(1)	21 U.S.C. 356(a)(1) (from "The Secretary" through "review of such drug")	June 25, 1938, ch. 675, §506(a)(1) (from "The Secretary" through "review of such drug"), as added Pub. L. 112–144, title IX, §902(a)(3), July 9, 2012, 126 Stat. 1083.
13119(b)(2), (3)	21 U.S.C. 356(a)(2), (3)	June 25, 1938, ch. 675, §506(a)(2), (3), as added Pub. L. 112–144, title IX, §902(a)(3), July 9, 2012, 126 Stat. 1083.
13119(c)(1)	21 U.S.C. 356(b)(1) (from "The Secretary" through "review of such drug")	June 25, 1938, ch. 675, §506(b)(1) (from "The Secretary" through "review of such drug"), formerly §506(a)(1) (from "The Secretary" through "review of such drug"), as added Pub. L. 105–115, title I, § 112(a), Nov. 21, 1997, 111 Stat. 2309; redesignated §506(b)(1) (from "The Secretary" through "review of such drug"), Pub. L. 112–144, title VIII, §803, title IX, §§901(b), 902(a)(1), July 9, 2012, 126 Stat. 1079, 1083, 1086.
13119(c)(2), (3)	21 U.S.C. 356(b)(2), (3)	June 25, 1938, ch. 675, §506(b)(2), (3), formerly §506(a)(2), (3), as added Pub. L. 105–115, title I, § 112(a), Nov. 21, 1997, 111 Stat. 2309; redesignated §506(b)(2), (3), Pub. L. 112–144, title VIII, §803, title IX, §§901(b), 902(a)(1), July 9, 2012, 126 Stat. 1079, 1083, 1086.
13119(d)	21 U.S.C. 356(c) (except (1)(A) (last sentence))	June 25, 1938, ch. 675, §506(c) (except (1)(A) (last sentence)), formerly §506(b) (except (1)(A) (last sentence)), as added Pub. L. 105–115, title I, § 112(a), Nov. 21, 1997, 111 Stat. 2309; redesignated §506(c) (except (1)(A) (last sentence)), Pub. L. 112–144, title IX, §§901(b), 902(a)(1), July 9, 2012, 126 Stat. 1083, 1086.
13119(e) through (g) ...	21 U.S.C. 356(d) through (f)	June 25, 1938, ch. 675, §506(d) through (f), as added Pub. L. 105–115, title I, §112(a), Nov. 21, 1997, 111 Stat. 2309; Pub. L. 112–144, title IX, §§901(b), 902(a)(1), (2), (4), July 9, 2012, 126 Stat. 1083, 1086; Pub. L. 114–255, div. A, title III, §3033(a)(1), (c), Dec. 13, 2016, 130 Stat. 1101, 1103.

SECTION 13119—EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13119(h)(1) through (7)	21 U.S.C. 356(g)(1) through (7)	June 25, 1938, ch. 675, §506(g)(1) through (7), as added Pub. L. 114–255, div. A, title III, §3033(a)(2), Dec. 13, 2016, 130 Stat. 1101.
13119(h)(8)	21 U.S.C. 356 note	Pub. L. 114–255, div. A, title III, §3035, Dec. 13, 2016, 130 Stat. 1103.
13119(i) (except (8)(B))	21 U.S.C. 356(h)	June 25, 1938, ch. 675, §506(h), as added Pub. L. 114–255, div. A, title III, §3042, Dec. 13, 2016, 130 Stat. 1112.
13119(i)(8)(B)	21 U.S.C. 356 note	Pub. L. 114–255, div. A, title III, §3043 (relating to section 3042 of subtitle E), Dec. 13, 2016, 130 Stat. 1114.

In subsection (d)(1)(A), the words "mortality and that is reasonably" are substituted for "mortality, that is reasonably" for clarity.

In subsection (d)(2)(B), the words "following approval and for the period after approval" are substituted for "following approval and for such period thereafter" for clarity.

In subsection (f)(2)(C), the words "as described in subsection (d)(1)(B)" are substituted for "as described in subsection (b)(1)(B)" to reflect the redesignations made by section 902 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1086).

In subsection (h)(2)(A), the parenthetical "(as defined in paragraph (8))" is omitted as unnecessary.

In subsection (h)(8), subsection (b) of section 3035 of the 21st Century Cures Act (Public Law 114–255, 130 Stat. 1103) is omitted as unnecessary because of the incorporation of subsection (a) of that section in section 13119 of title 21, United States Code.

In subsection (i)(3)(A)(i)(II), the words "as defined in section 13304(a)(1) of this title" are substituted for "as defined in section 503(e)(3)" to provide the correct reference to the pertinent provision. Section 503(e)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(3)), referred to in the source law and restated as section 13103(d)(4) of title 21, United States Code, does not define the term "established name". That term is defined in section 502(e)(3) of the Act (21 U.S.C. 352(e)(3)), which is restated as section 13304(a)(1) of title 21, United States Code.

In subsection (i)(8)(A)(i)(I), in the matter after the semicolon, the word "and" is added for clarity.

SECTION 13120—MANUFACTURING CHANGES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13120	21 U.S.C. 356a	June 25, 1938, ch. 675, § 506A, as added Pub. L. 105–115, title I, § 116(a), Nov. 21, 1997, 111 Stat. 2313.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13121	21 U.S.C. 356b	June 25, 1938, ch. 675, § 506B, as added Pub. L. 105–115, title I, § 130(a), Nov. 21, 1997, 111 Stat. 2331; amended Pub. L. 107–188, title V, § 506, June 12, 2002, 116 Stat. 693; Pub. L. 112–144, title IX, § 902(c), July 9, 2012, 126 Stat. 1088; Pub. L. 117–328, div. FF, title III, §3210(b), Dec. 29, 2022, 136 Stat. 5823.

In subsection (e)(1), the words "on September 30, 2002," are substituted for "on the day before the effective date of this subsection," for clarity.

SECTION 13122—DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIFE-SAVING DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13122(a)	21 U.S.C. 356c(h)	June 25, 1938, ch. 675, §506C(h), as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332; Pub. L. 112–144, title X, § 1001(a), July 9, 2012, 126 Stat. 1099.
13122(b)(1) (matter before (A))	21 U.S.C. 356c(a) ("A manufacturer of a drug", "shall notify the Secretary," through "for such discontinuance or interruption.")	June 25, 1938, ch. 675, §506C(a) ("A manufacturer of a drug", "shall notify the Secretary," through "for such discontinuance or interruption."), as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332; Pub. L. 112–144, title X, § 1001(a), July 9, 2012, 126 Stat. 1099; Pub. L. 116–136, div. A, title III, §3112(a)(2)(A), Mar. 27, 2020, 134 Stat. 362; Pub. L. 117–328, div. FF, title II, §2515(b)(1), Dec. 29, 2022, 136 Stat. 5806.
13122(b)(1)(A), (B)	21 U.S.C. 356c(a)(1), (2)	June 25, 1938, ch. 675, §506C(a)(1), (2), as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332; Pub. L. 112–144, title X, § 1001(a), July 9, 2012, 126 Stat. 1099; Pub. L. 116–136, div. A, title III, §3112(a)(1), Mar. 27, 2020, 134 Stat. 362.
13122(b)(2)	21 U.S.C. 356c(a) (last sentence)	June 25, 1938, ch. 675, §506C(a) (last sentence), as added Pub. L. 116–136, div. A, title III, §3112(a)(2)(B), Mar. 27, 2020, 134 Stat. 362.
13122(c) through (h) ...	21 U.S.C. 356c(b) through (g)	June 25, 1938, ch. 675, §506C(b) through (g), as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332; Pub. L. 112–144, title X, § 1001(a), July 9, 2012, 126 Stat. 1099; Pub. L. 114–255, div. A, title III, §3101(a)(2)(E), Dec. 13, 2016, 130 Stat. 1153; Pub. L. 116–136, div. A, title III, §3111, Mar. 27, 2020, 134 Stat. 361; Pub. L. 117–328, div. FF, title II, §2515(a)(1), Dec. 29, 2022, 136 Stat. 5806.
13122(i)	21 U.S.C. 356c(i)	June 25, 1938, ch. 675, §506C(i), as added Pub. L. 105–115, title I, § 131(a), Nov. 21, 1997, 111 Stat. 2332; Pub. L. 112–144, title X, § 1001(a), July 9, 2012, 126 Stat. 1099.
13122(j)	21 U.S.C. 356c(j)	June 25, 1938, ch. 675, §506C(j), as added Pub. L. 116–136, div. A, title III, §3112(b), Mar. 27, 2020, 134 Stat. 362.
13122(k)	21 U.S.C. 356c note	Pub. L. 112–144, title X, §1001(b), July 9, 2012, 126 Stat. 1101.

In subsection (a)(2), the words "or 'shortage'" are omitted as unnecessary and for clarity. Throughout the section, the defined term "drug shortage" is substituted for "shortage", where applicable, because of the omission.

In subsection (b)(2)(A)(ii), the words "that is a reason for" are substituted for "is a reason for" for clarity.

In subsection (d), the words "as the Secretary considers appropriate" are substituted for "as the Secretary deems appropriate" to use the more appropriate word.

In subsection (f)(1)(B)(ii), the words "the Secretary considers necessary" are substituted for "the Secretary deems necessary" to use the more appropriate word.

In subsection (i)(1), the words "Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act," are omitted as obsolete.

SECTION 13123—ANNUAL REPORTING ON DRUG SHORTAGES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13123(a)	21 U.S.C. 356c–1(c)	June 25, 1938, ch. 675, §506C–1(c), as added Pub. L. 112–144, title X, § 1002, July 9, 2012, 126 Stat. 1102.
13123(b), (c)	21 U.S.C. 356c–1(a), (b)	June 25, 1938, ch. 675, §506C–1(a), (b), as added Pub. L. 112–144, title X, § 1002, July 9, 2012, 126 Stat. 1102; Pub. L. 114–255, div. A, title III, §3101(a)(2)(F), Dec. 13, 2016, 130 Stat. 1153; Pub. L. 117–328, div. FF, title III, §3616(b)(1), Dec. 29, 2022, 136 Stat. 5875.

In subsection (a), the words "or 'shortage'" are omitted as unnecessary. Only the defined term "drug shortage" appears in the source law; the term "shortage" does not.

SECTION 13124—COORDINATION RELATING TO DRUG SHORTAGES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13124(a) through (d) ...	21 U.S.C. 356d(b) through (e)	June 25, 1938, ch. 675, §506D(b) through (e), as added Pub. L. 112–144, title X, §1003, July 9, 2012, 126 Stat. 1104.
13124(e)	21 U.S.C. 356d(f) (2d sentence, last sentence)	June 25, 1938, ch. 675, §506D(f) (2d sentence, last sentence), as added Pub. L. 112–144, title X, §1003, July 9, 2012, 126 Stat. 1104; Pub. L. 117–328, div. FF, title III, §3616(a)(2), Dec. 29, 2022, 136 Stat. 5874.
13124(f)	21 U.S.C. 356d(g)	June 25, 1938, ch. 675, §506D(g), as added Pub. L. 117–328, div. FF, title III, §3616(a)(1), Dec. 29, 2022, 136 Stat. 5874.

SECTION 13125—DRUG SHORTAGE LIST

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13125	21 U.S.C. 356e	June 25, 1938, ch. 675, §506E, as added Pub. L. 112–144, title X, § 1004, July 9, 2012, 126 Stat. 1104; Pub. L. 114–255, div. A, title III, §3101(a)(2)(G), Dec. 13, 2016, 130 Stat. 1153; Pub. L. 116–136, div. A, title III, §3112(c), Mar. 27, 2020, 134 Stat. 362.

SECTION 13126—HOSPITAL REPACKAGING OF DRUGS IN SHORTAGE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13126	21 U.S.C. 356f	June 25, 1938, ch. 675, §506F, as added Pub. L. 112–144, title X, § 1007, July 9, 2012, 126 Stat. 1106.

In subsection (a)(3), in the matter before subparagraph (A), the words "For the purposes of this section only," are omitted as unnecessary.

SECTION 13127—STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13127(a)	21 U.S.C. 356g(c)	June 25, 1938, ch. 675, §506G(c), as added Pub. L. 114–255, div. A, title III, §3036, Dec. 13, 2016, 130 Stat. 1104.
13127(b), (c)	21 U.S.C. 356g(a), (b)	June 25, 1938, ch. 675, §506G(a), (b), as added Pub. L. 114–255, div. A, title III, §3036, Dec. 13, 2016, 130 Stat. 1104; Pub. L. 115–52, title IX, §901(b), Aug. 18, 2017, 131 Stat. 1076.

SECTION 13128—COMPETITIVE GENERIC THERAPIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13128(a)	21 U.S.C. 356h(e)	June 25, 1938, ch. 675, §506H(e), as added Pub. L. 115–52, title VIII, §803(a), Aug. 18, 2017, 131 Stat. 1070.
13128(b) through (e) ...	21 U.S.C. 356h(a) through (d)	June 25, 1938, ch. 675, §506H(a) through (d), as added Pub. L. 115–52, title VIII, §803(a), Aug. 18, 2017, 131 Stat. 1070.

SECTION 13129—PROMPT REPORTS OF MARKETING STATUS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13129	21 U.S.C. 356i	June 25, 1938, ch. 675, §506I, as added Pub. L. 115–52, title VIII, §804, Aug. 18, 2017, 131 Stat. 1071; Pub. L. 117–328, div. FF, title III, §3201, Dec. 29, 2022, 136 Stat. 5808.

SECTION 13130—DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF MEDICAL DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13130(a)	21 U.S.C. 356j(j)	June 25, 1938, ch. 675, §506J(j), formerly §506J(i), as added Pub. L. 116–136, div. A, title III, §3121, Mar. 27, 2020, 134 Stat. 363; redesignated §506J(j), Pub. L. 117–328, div. FF, title II, §2514(a)(2), Dec. 29, 2022, 136 Stat. 5805.
13130(b)(1)	21 U.S.C. 356j(a) (matter before (1), matter after (2))	June 25, 1938, ch. 675, §506J(a) (matter before (1), matter after (2)), as added Pub. L. 116–136, div. A, title III, §3121, Mar. 27, 2020, 134 Stat. 363.
13130(b)(2)	21 U.S.C. 356j(a)(1), (2)	June 25, 1938, ch. 675, §506J(a)(1), (2), as added Pub. L. 116–136, div. A, title III, §3121, Mar. 27, 2020, 134 Stat. 363.
13130(c) through (h) ...	21 U.S.C. 356j(b) through (g)	June 25, 1938, ch. 675, §506J(b) through (g), as added Pub. L. 116–136, div. A, title III, §3121, Mar. 27, 2020, 134 Stat. 363; Pub. L. 117–328, div. FF, title II, §2514(a)(1), Dec. 29, 2022, 136 Stat. 5805.
13130(i)	21 U.S.C. 356j(h)	June 25, 1938, ch. 675, §506J(h), as added Pub. L. 117–328, div. FF, title II, §2514(a)(3), Dec. 29, 2022, 136 Stat. 5805.
13130(j)	21 U.S.C. 356j(i)	June 25, 1938, ch. 675, §506J(i), formerly §506J(h), as added Pub. L. 116–136, div. A, title III, §3121, Mar. 27, 2020, 134 Stat. 363; redesignated Š506J(i), Pub. L. 117–328, div. FF, title II, §2514(a)(2), Dec. 29, 2022, 136 Stat. 5805.

In subsection (a)(1)(B)(ii), in the matter after the semicolon, the word "or" is substituted for "and" for clarity.

In subsection (d)(1), the words "to appropriate organizations (including physician, health provider, and patient organizations) and supply chain

partners," are substituted for "to appropriate organizations, including physician, health provider, patient organizations, and supply chain partners," for clarity.

In subsection (g)(1), the words "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" are substituted for "prioritize and expedite the review of a submission under section 513(f)(2), 515, review of a notification under section 510(k), or 520(m) for a device" for clarity.

SECTION 13131—PLATFORM TECHNOLOGIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13131(a)	21 U.S.C. 356k(h)	June 25, 1938, ch. 675, §506K(h), as added Pub. L. 117–328, div. FF, title II, §2503(a), Dec. 29, 2022, 136 Stat. 5800.
13131(b) through (h) ...	21 U.S.C. 356k(a) through (g)	June 25, 1938, ch. 675, §506K(a) through (g), as added Pub. L. 117–328, div. FF, title II, §2503(a), Dec. 29, 2022, 136 Stat. 5798.
13131(i)	21 U.S.C. 356k(i)	June 25, 1938, ch. 675, §506K(i), as added Pub. L. 117–328, div. FF, title II, §2503(a), Dec. 29, 2022, 136 Stat. 5801.

In subsection (c)(3), the words "applicable sponsor" are substituted for "applicable person" for consistency with subsection (c)(2).

In subsection (d), the words "request the Secretary to designate" are substituted for "request the Secretary designate" to supply a missing word.

In subsection (g), in the matter before paragraph (1), the word "if" is substituted for "provided that" for consistency in title 21, United States Code.

SECTION 13132—ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13132	21 U.S.C. 356l	June 25, 1938, ch. 675, §506L, as added Pub. L. 117–328, div. FF, title III, §3213, Dec. 29, 2022, 136 Stat. 5826.

SECTION 13133—QUALIFICATION OF DRUG DEVELOPMENT TOOLS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13133(a)	21 U.S.C. 357(e)	June 25, 1938, ch. 675, §507(e), as added Pub. L. 114–255, div. A, title III, §3011(a), Dec. 13, 2016, 130 Stat. 1086.
13133(b) through (e) ...	21 U.S.C. 357(a) through (d)	June 25, 1938, ch. 675, §507(a) through (d), as added Pub. L. 114–255, div. A, title III, §3011(a), Dec. 13, 2016, 130 Stat. 1086; Pub. L. 116–22, title VII, §705(e), June 24, 2019, 133 Stat. 964.

In subsection (a)(7), the words "The term 'qualification' means" are substituted for "The terms 'qualification' and 'qualified' mean" because it is not necessary to define the term in more than 1 part of speech.

SECTION 13134—AUTHORITY TO DESIGNATE OFFICIAL NAMES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13134	21 U.S.C. 358	June 25, 1938, ch. 675, § 508, as added Pub. L. 87–781, title I, § 111(a), Oct. 10, 1962, 76 Stat. 789;

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		amended Pub. L. 94–295, § 5(b), May 28, 1976, 90 Stat. 581; Pub. L. 103–80, § 3(q), Aug. 13, 1993, 107 Stat. 777.

In subsection (a)(3), the words "The Secretary shall not establish an official name" are substituted for "In no event, however, shall the Secretary establish an official name" to eliminate unnecessary words.

In subsection (b)(1), the words "At such times as the Secretary" are substituted for "Within a reasonable time after October 10, 1962, and at such other times as he" to eliminate obsolete words.

In subsection (b)(1), the words "may consider necessary" are substituted for "may deem necessary" to use the more appropriate word.

In paragraphs (1) and (2) of subsection (b), the words "shall review the official names" are substituted for "shall cause a review to be made of the official names" to eliminate unnecessary words.

In subsection (b)(1), the words "to those compendia," are substituted for "thereto," for clarity.

In subsection (b)(2), the words "may consider necessary" are substituted for "may deem necessary" to use the more appropriate word.

In subsection (d), in the matter before paragraph (1), the words "the Secretary shall compile, publish, and publicly distribute" are substituted for "the Secretary shall cause to be compiled, published, and publicly distributed" to eliminate unnecessary words.

SECTION 13135—INAPPLICABILITY OF DIVISION TO COSMETICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13135	21 U.S.C. 359	June 25, 1938, ch. 675, § 509, as added Pub. L. 87–781, title I, § 113, Oct. 10, 1962, 76 Stat. 791.

SECTION 13136—REGISTRATION OF PRODUCERS OF DRUGS OR DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13136(a) through (f)	21 U.S.C. 360(a) through (f)	June 25, 1938, ch. 675, §510(a) through (f), as added Pub. L. 87–781, title III, §302, Oct. 10, 1962, 76 Stat. 794; Pub. L. 89–74, §4(a) through (d), July 15, 1965, 79 Stat. 231; Pub. L. 91–513, title II, §701(e)(1) through (6), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 92–387, §4(a), (b), Aug. 16, 1972, 86 Stat. 561; Pub. L. 94–295, §4(a)(2) through (4), May 28, 1976, 90 Stat. 579; Pub. L. 110–85, title II, §222(a), Sept. 27, 2007, 121 Stat. 853; Pub. L. 112–144, title VII, §701, July 9, 2012, 126 Stat. 1064.
13136(g)(1)	21 U.S.C. 360(g) (matter after (5))	June 25, 1938, ch. 675, §510(g) (matter after (5)), as added Pub. L. 87–781, title III, §302, Oct. 10, 1962, 76 Stat. 794; Pub. L. 94–295, §4(a)(5), May 28, 1976, 90 Stat. 579; Pub. L. 105–115, title II, §213(b), Nov. 21, 1997, 111 Stat. 2347.
13136(g)(2) (matter before (A))	21 U.S.C. 360(g) (matter before (1))	June 25, 1938, ch. 675, §510(g) (matter before (1)), as added Pub. L. 87–781, title III, §302, Oct. 10, 1962, 76 Stat. 794; Pub. L. 94–295, §4(a)(5), May 28,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		1976, 90 Stat. 579; Pub. L. 105–115, title II, §213(b), Nov. 21, 1997, 111 Stat. 2347.
13136(g)(2)(A) through (E)	21 U.S.C. 360(g)(1) through (5)	June 25, 1938, ch. 675, §510(g)(1) through (5), as added Pub. L. 87–781, title III, §302, Oct. 10, 1962, 76 Stat. 794; Pub. L. 94–295, §4(a)(5), May 28, 1976, 90 Stat. 579; Pub. L. 105–115, title II, §213(b), Nov. 21, 1997, 111 Stat. 2347.
13136(h)	21 U.S.C. 360(h)	June 25, 1938, ch. 675, §510(h), as added Pub. L. 87–781, title III, §302, Oct. 10, 1962, 76 Stat. 794; Pub. L. 94–295, §4(a)(6), May 28, 1976, 90 Stat. 579; Pub. L. 107–250, title II, §201(e), 211, Oct. 26, 2002, 116 Stat. 1609; Pub. L. 112–144, title VII, §705, July 9, 2012, 126 Stat. 1066; Pub. L. 114–255, div. A, title III, §3101(a)(2)(H), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 115–52, title VII, §701(a), title IX, §901(e), Aug. 18, 2017, 131 Stat. 1054, 1076; Pub. L. 117–328, div. FF, title III, §§3613(a), 3616(c), Dec. 29, 2022, 136 Stat. 5875.
13136(i)	21 U.S.C. 360(i)	June 25, 1938, ch. 675, §510(i), as added Pub. L. 87–781, title III, §302, Oct. 10, 1962, 76 Stat. 794; Pub. L. 92–387, §4(c), Aug. 16, 1972, 86 Stat. 562; Pub. L. 94–295, §4(a)(7), May 28, 1976, 90 Stat. 579; Pub. L. 105–115, title I, §125(a)(2)(C), title IV, §417, Nov. 21, 1997, 111 Stat. 2325, 2379; Pub. L. 107–188, title III, §321(a)(1), June 12, 2002, 116 Stat. 675; Pub. L. 110–85, title II, §222(b), Sept. 27, 2007, 121 Stat. 853; Pub. L. 112–144, title VII, §702(b), July 9, 2012, 126 Stat. 1065; Pub. L. 117–328, div. FF, title II, §2511(a), Dec. 29, 2022, 136 Stat. 5803.
13136(j)	21 U.S.C. 360(j)	June 25, 1938, ch. 675, §510(j), as added Pub. L. 92–387, §3, Aug. 16, 1972, 86 Stat. 560; Pub. L. 94–295, §4(a)(8), May 28, 1976, 90 Stat. 579; Pub. L. 105–115, title I, §125(a)(2)(C), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 107–188, title III, §321(a)(2), June 12, 2002, 116 Stat. 675; Pub. L. 110–85, title II, §223, Sept. 27, 2007, 121 Stat. 853; Pub. L. 112–144, title VII, §703, July 9, 2012, 126 Stat. 1065; Pub. L. 116–136, div. A, title III, §3112(e), Mar. 27, 2020, 134 Stat. 363; Pub. L. 117–328, div. FF, title II, §2515(a)(3), Dec. 29, 2022, 136 Stat. 5806.
13136(k)	21 U.S.C. 360(k)	June 25, 1938, ch. 675, §510(k), as added Pub. L. 94–295, §4(a)(9), May 28, 1976, 90 Stat. 579; Pub. L. 105–115, title II, §206(a)(1), Nov. 21, 1997, 111 Stat. 2338; Pub. L. 110–85, title VIII, §801(b)(3)(C), Sept. 27, 2007, 121 Stat. 921.
13136(l)	21 U.S.C. 360(l)	June 25, 1938, ch. 675, §510(l), as added Pub. L. 105–115, title II, §206(a)(2), Nov. 21, 1997, 111 Stat. 2339; Pub. L. 114–255, div. A, title III, §3054(a), Dec. 13, 2016, 130 Stat. 1126; Pub. L. 117–328, div. FF, title III, §3308(b)(1), Dec. 29, 2022, 136 Stat. 5836.
13136(m)	21 U.S.C. 360(m)	June 25, 1938, ch. 675, §510(m), as added Pub. L. 105–115, title II, §206(a)(2), Nov. 21, 1997, 111 Stat. 2339; Pub. L. 107–250, title II, §211, Oct. 26, 2002, 116 Stat. 1614; Pub. L. 114–255, div. A, title III, §3054(b), Dec. 13, 2016, 130 Stat. 1126.
13136(n)(1)	21 U.S.C. 360(n)(1)	June 25, 1938, ch. 675, §510(n)(1), as added Pub. L. 105–115, title II, §209(a), Nov. 21, 1997, 111 Stat. 2341; Pub. L. 112–144, title VI, §604(1), July 9, 2012, 126 Stat. 1052.
13136(n)(2)(A)	21 U.S.C. 360(n)(2)(B)	June 25, 1938, ch. 675, §510(n)(2)(B), as added Pub. L. 112–144, title VI, §604(2), July 9, 2012, 126 Stat. 1053.
13136(n)(2)(B)	21 U.S.C. 360(n)(2)(C)	June 25, 1938, ch. 675, §510(n)(2)(C), as added Pub. L. 112–144, title VI, §604(2), July 9, 2012, 126 Stat. 1053.
13136(o)(1)	21 U.S.C. 360(o)(1)	June 25, 1938, ch. 675, §510(o)(1), as added Pub. L. 107–250, title III, §302(b), Oct. 26, 2002, 116 Stat. 1616; Pub. L. 108–214, §2(c)(2)(A), Apr. 1, 2004, 118 Stat. 576.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13136(o)(2)	21 U.S.C. 360(o)(2) (except (C))	June 25, 1938, ch. 675, §510(o)(2) (except (C)), as added Pub. L. 107–250, title III, §302(b), Oct. 26, 2002, 116 Stat. 1616; Pub. L. 108–214, §2(c)(2)(B), Apr. 1, 2004, 118 Stat. 576.
13136(p)	21 U.S.C. 360(p)	June 25, 1938, ch. 675, §510(p), as added Pub. L. 107–250, title II, §207, Oct. 26, 2002, 116 Stat. 1613; Pub. L. 110–85, title II, §224, Sept. 27, 2007, 121 Stat. 853; Pub. L. 112–144, §704, July 9, 2012, 126 Stat. 1066.
13136(q)	21 U.S.C. 360(q)	June 25, 1938, ch. 675, §510(q), as added Pub. L. 114–255, div. A, title III, §3059(a), Dec. 13, 2016, 130 Stat. 1130.

In subsection (f)(2), the words "pursuant to paragraph (4) of subsection (j)" are substituted for "pursuant to paragraph (3) of subsection (j)" to reflect the redesignation of paragraph (3) of section 510(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)) to paragraph (4) of that section by section 3112(e)(1) of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136, div. A, title III, 134 Stat. 363).

In subsection (h)(2)(A), the words "engaged in the manufacture, preparation, propagation, compounding, or processing" are substituted for "engaged in the manufacture, propagation, compounding, or processing" for consistency in the section.

In subsection (h)(3), the parenthetical "(referred to in this subsection as 'drug establishments')" is omitted as unnecessary. The term "drug establishments" is not referred to anywhere in subsection (h).

In subsection (h)(4)(F), the words "establishments in the country or region in which the establishment is located, which establishments are subject to regulation" are substituted for "establishments in the country or region in which the establishment is located that are subject to regulation" and "products exported from the country or region, which products are subject to the regulation" are substituted for "products exported from the country or region that are subject to the regulation" for clarity.

In subsection (h)(4)(G), the words "other criteria considered necessary" are substituted for "other criteria deemed necessary" to use the more appropriate word.

In subsection (i)(1)(A)(i)(II), the words "all establishments owned or operated by the person" are substituted for "all such establishments" for clarity.

In subsection (i)(1)(A)(i)(VI), the words "which importer is known to the establishment" are substituted for "that is known to the establishment" for clarity.

In subsection (i)(1)(A)(ii)(III), the words "which importer is known to the establishment" are substituted for "that is known to the establishment" for clarity.

In subsection (i)(1)(B), the words "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)" are substituted for "each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year" for clarity.

In subsection (m)(1)(B), the words "have published" are substituted for "publish" and the words "original final determination" are substituted for "final determination" for consistency in the paragraph.

In subsection (m)(2)(A), the words "ensure the safety and effectiveness" are substituted for "assure the safety and effectiveness" to use the more appropriate word.

In subsection (m)(2)(D), the words "respond to a petition under this paragraph" are substituted for "respond to a petition" for clarity.

In subsection (o)(1)(A)(ii), the words "Within six months after enactment of this subsection," are omitted as obsolete.

In subsection (o)(1)(B)(i), the words "of the list" are substituted for "thereof" for clarity.

In subsection (q)(1), in the matter before subparagraph (A), the words "Not later than 180 days after the date of enactment of the 21st Century Cures Act," are omitted as obsolete.

In subsection (q)(2), the words "under paragraph (1)" are substituted for "under paragraph (2)" to provide the correct reference to the pertinent provision.

SECTION 13137—CLINICAL TRIAL GUIDANCE FOR ANTIBIOTIC DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13137	21 U.S.C. 360a	June 25, 1938, ch. 675, §511, as added Pub. L. 110–85, title IX, § 911, Sept. 27, 2007, 121 Stat. 951.

In subsection (a), the words "Not later than 1 year after the date of the enactment of this section," are omitted as obsolete.

In subsection (b), the words "Not later than 5 years after the date of the enactment of this section," are omitted as obsolete.

SECTION 13138—SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13138(a)	21 U.S.C. 360a–2(a)(1)	June 25, 1938, ch. 675, §511A(a)(1), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1114.
13138(b) (matter before (1))	21 U.S.C. 360a–2(f) (matter before (1))	June 25, 1938, ch. 675, §511A(f) (matter before (1)), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1120.
13138(b)(1)	21 U.S.C. 360a–2(f)(4)	June 25, 1938, ch. 675, §511A(f)(4), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1120.
13138(b)(2)	21 U.S.C. 360a–2(f)(1)	June 25, 1938, ch. 675, §511A(f)(1), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1120.
13138(b)(3)	21 U.S.C. 360a–2(f)(5)	June 25, 1938, ch. 675, §511A(f)(5), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1120.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13138(b)(4)	21 U.S.C. 360a–2(b)(1) ("(referred to in this section as the `Interpretive Criteria Website')")	June 25, 1938, ch. 675, §511A(b)(1) ("(referred to in this section as the `Interpretive Criteria Website')"), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1115.
13138(b)(5)	21 U.S.C. 360a–2(f)(2)	June 25, 1938, ch. 675, §511A(f)(2), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1120.
13138(b)(6)	21 U.S.C. 360a–2(f)(3)	June 25, 1938, ch. 675, §511A(f)(3), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1120.
13138(c)	21 U.S.C. 360a–2(a) (except (1))	June 25, 1938, ch. 675, §511A(a) (except (1)), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1114.
13138(d)(1)	21 U.S.C. 360a–2(b)(1) (except "(referred to in this section as the `Interpretive Criteria Website')")	June 25, 1938, ch. 675, §511A(b)(1) (except "(referred to in this section as the `Interpretive Criteria Website')"), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1115.
13138(d)(2)	21 U.S.C. 360a–2(b)(2)	June 25, 1938, ch. 675, §511A(b)(2), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1115.
13138(d)(3), (4)	21 U.S.C. 360a–2(b)(4), (5)	June 25, 1938, ch. 675, §511A(b)(4), (5), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1117.
13138(e)	21 U.S.C. 360a–2(c)	June 25, 1938, ch. 675, §511A(c), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1117.
13138(f)	21 U.S.C. 360a–2(d)	June 25, 1938, ch. 675, §511A(d), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1118.
13138(g)	21 U.S.C. 360a–2(e)	June 25, 1938, ch. 675, §511A(e), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1119.
13138(h)	21 U.S.C. 360a–2(g)	June 25, 1938, ch. 675, §511A(g), as added Pub. L. 114–255, div. A, title III, §3044(a), Dec. 13, 2016, 130 Stat. 1120.
13138(i)	21 U.S.C. 360a–2 note	Pub. L. 114–255, div. A, title III, §3044(d), Dec. 13, 2016, 130 Stat. 1121.

In subsection (d)(1), the words “Not later than 1 year after the date of the enactment of the 21st Century Cures Act,” are omitted as obsolete.

In subsection (d)(1), the words “after the establishment” are substituted for “thereafter” for clarity.

In subsection (e)(1)(A), in the matter before clause (i), the words “At least every 6 months,” are substituted for “Beginning on the date of the establishment of the Interpretive Criteria Website, and at least every 6 months thereafter,” to eliminate obsolete words.

In subsection (f)(1)(A), the words “for the drug” are substituted for “for each such drug” for consistency with the antecedent “an antimicrobial drug”.

In subsection (h)(1)(B), the words “(as applicable)” are omitted as unnecessary.

In subsection (i), the words “established under subsection (d)” are substituted for “established under section 511A(c) of such Act” to provide the correct reference to the pertinent provision. Section 511A(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a–2(c)), referred to in the source provision, is restated as subsection (e) of section 13138 of title 21, United States Code.

However, section 511A(b) of that Act (21 U.S.C. 360a–2(b)) contains the provision relating to establishment of the Interpretive Criteria Website, which is restated as subsection (d) of section 13138 of title 21, United States Code.

SECTION 13139—PRIORITY ZOONOTIC ANIMAL DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13139	21 U.S.C. 360b–1	June 25, 1938, ch. 675, §512A, as added Pub. L. 116–136, div. A, title III, §3302, Mar. 27, 2020, 134 Stat. 384.

SECTION 13140—CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13140(a)	21 U.S.C. 360c(h)	June 25, 1938, ch. 675, § 513(h), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 546.
13140(b)	21 U.S.C. 360c(i)	June 25, 1938, ch. 675, §513(i), as added Pub. L. 101–629, §12(a), Nov. 28, 1990, 104 Stat. 4523; Pub. L. 105–115, title II, §§205(b), 206(c), Nov. 21, 1997, 111 Stat. 2337, 2339; Pub. L. 107–250, title II, §208, Oct. 26, 2002, 116 Stat. 1613; Pub. L. 112–144, title VI, §602(b), July 9, 2012, 126 Stat. 1051.
13140(c)(1)	21 U.S.C. 360c(a)(1) (except last sentence)	June 25, 1938, ch. 675, §513(a)(1) (except last sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 540; Pub. L. 101–629, §5(a), Nov. 28, 1990, 104 Stat. 4517.
13140(c)(2)	21 U.S.C. 360c(a)(1) (last sentence)	June 25, 1938, ch. 675, §513(a)(1) (last sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 540.
13140(c)(3)	21 U.S.C. 360c(a)(2)	June 25, 1938, ch. 675, §513(a)(2), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 540.
13140(c)(4)(A) through (C)	21 U.S.C. 360c(a)(3)(A) through (C)	June 25, 1938, ch. 675, §513(a)(3)(A) through (C), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 540; Pub. L. 105–115, title II, §§205(a), 217, Nov. 21, 1997, 111 Stat. 2336, 2350.
13140(c)(4)(D)(i)	21 U.S.C. 360c(a)(3)(D)(i)	June 25, 1938, ch. 675, §513(a)(3)(D)(i), as added Pub. L. 105–115, title II, §205(a), Nov. 21, 1997, 111 Stat. 2336.
13140(c)(4)(D)(ii)(I) ...	21 U.S.C. 360c(a)(3)(D)(iii)	June 25, 1938, ch. 675, §513(a)(3)(D)(iii), as added Pub. L. 112–144, title VI, §602(a)(2), July 9, 2012, 126 Stat. 1051.
13140(c)(4)(D)(ii)(II), (III)	21 U.S.C. 360c(a)(3)(D)(ii)	June 25, 1938, ch. 675, §513(a)(3)(D)(ii), as added Pub. L. 105–115, title II, §205(a), Nov. 21, 1997, 111 Stat. 2336.
13140(c)(4)(D)(iii), (iv)	21 U.S.C. 360c(a)(3)(D)(iv), (v)	June 25, 1938, ch. 675, §513(a)(3)(D)(iv), (v), as added Pub. L. 105–115, title II, §205(a), Nov. 21, 1997, 111 Stat. 2336; Pub. L. 112–144, title VI, §602(a), July 9, 2012, 126 Stat. 1051.
13140(d)(1)(A)	21 U.S.C. 360c(b)(1) (1st sentence)	June 25, 1938, ch. 675, §513(b)(1) (1st sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 542.
13140(d)(1)(B)	21 U.S.C. 360c(b)(1) (2d sentence)	June 25, 1938, ch. 675, §513(b)(1) (2d sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 542.
13140(d)(1)(C)	21 U.S.C. 360c(b)(1) (last sentence)	June 25, 1938, ch. 675, §513(b)(1) (last sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 542; Pub. L. 117–286, §4(a)(155)(A), Dec. 27, 2022, 136 Stat. 4323.
13140(d)(2) through (8)	21 U.S.C. 360c(b)(2) through (8)	June 25, 1938, ch. 675, §513(b)(2) through (8), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 540; Pub. L. 103–80, §3(s), Aug. 13, 1993, 107 Stat. 778; Pub. L. 105–115, title II, §208, Nov. 21, 1997, 111 Stat. 2340; Pub. L. 114–255, div. A, title III, §3055, Dec. 13, 2016, 130 Stat. 1127; Pub. L. 115–52, title IX, §901(h), Aug. 18, 2017, 131 Stat. 1077; Pub. L. 117–286, §4(a)(155)(B), Dec. 27, 2022, 136 Stat. 4323.
13140(e)(1)	21 U.S.C. 360c(c)(1)	June 25, 1938, ch. 675, §513(c)(1), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 543.
13140(e)(2)(A), (B)	21 U.S.C. 360c(c)(2)(A), (B)	June 25, 1938, ch. 675, §513(c)(2)(A), (B), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 543.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13140(e)(2)(C)(i)	21 U.S.C. 360c(c)(2)(C) (1st sentence)	June 25, 1938, ch. 675, §513(c)(2)(C) (1st sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 543.
13140(e)(2)(C)(ii)	21 U.S.C. 360c(c)(2)(C) (last sentence)	June 25, 1938, ch. 675, §513(c)(2)(C) (last sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 543.
13140(f)	21 U.S.C. 360c(d)	June 25, 1938, ch. 675, §513(d), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 544.
13140(g)	21 U.S.C. 360c(e)	June 25, 1938, ch. 675, §513(e), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 544; Pub. L. 101–629, §5(b), Nov. 28, 1990, 104 Stat. 4518; Pub. L. 112–144, title VI, §608(a)(1), (2)(A), July 9, 2012, 126 Stat. 1055.
13140(h)(1) through (3)	21 U.S.C. 360c(f)(1) through (3)	June 25, 1938, ch. 675, §513(f)(1) through (3), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 544; Pub. L. 101–629, §§4(a), 5(c)(1), (3), 18(a), Nov. 28, 1990, 104 Stat. 4515, 4518, 4528; Pub. L. 102–300, §6(e), June 16, 1992, 106 Stat. 240; Pub. L. 105–115, title II, §207, Nov. 21, 1997, 111 Stat. 2340; Pub. L. 112–144, title VI, §607, July 9, 2012, 126 Stat. 1054; Pub. L. 114–255, div. A, title III, §3101(a)(2)(I), Dec. 13, 2016, 130 Stat. 1154.
13140(h)(4)(A) (matter before (i))	21 U.S.C. 360c(f)(4) (matter before (A))	June 25, 1938, ch. 675, §513(f)(4) (matter before (A)), formerly §513(f)(3) (matter before (A)), as added Pub. L. 101–629, §§4(a), 5(c)(3), Nov. 28, 1990, 104 Stat. 4515, 4518; Pub. L. 102–300, §6(e), June 16, 1992, 106 Stat. 240; redesignated §513(f)(4) (matter before (A)), Pub. L. 105–115, title II, §207(2), Nov. 21, 1997, 111 Stat. 2340.
13140(h)(4)(A)(i) through (iii)	21 U.S.C. 360c(f)(4)(A) through (C)	June 25, 1938, ch. 675, §513(f)(4)(A) through (C), formerly §513(f)(3)(A) through (C), as added Pub. L. 101–629, §§4(a), 5(c)(3), Nov. 28, 1990, 104 Stat. 4515, 4518; Pub. L. 102–300, §6(e), June 16, 1992, 106 Stat. 240; redesignated §513(f)(4)(A) through (C), Pub. L. 105–115, title II, §207(2), Nov. 21, 1997, 111 Stat. 2340.
13140(h)(4)(B)	21 U.S.C. 360c(f)(4) (matter after (C))	June 25, 1938, ch. 675, §513(f)(4) (matter after (C)), formerly §513(f)(3) (matter after (C)), as added Pub. L. 101–629, §§4(a), 5(c)(3), Nov. 28, 1990, 104 Stat. 4515, 4518; Pub. L. 102–300, §6(e), June 16, 1992, 106 Stat. 240; redesignated §513(f)(4) (matter after (C)), Pub. L. 105–115, title II, §207(2), Nov. 21, 1997, 111 Stat. 2340.
13140(h)(5)	21 U.S.C. 360c(f)(5)	June 25, 1938, ch. 675, §513(f)(5), as added Pub. L. 105–115, title II, §206(b), Nov. 21, 1997, 111 Stat. 2339.
13140(h)(6)	21 U.S.C. 360c(f)(6)	June 25, 1938, ch. 675, §513(f)(6), as added Pub. L. 115–52, title VII, §707(a), Aug. 18, 2017, 131 Stat. 1060.
13140(i)	21 U.S.C. 360c(g)	June 25, 1938, ch. 675, §513(g), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 546.
13140(j)	21 U.S.C. 360c(j)	June 25, 1938, ch. 675, §513(j), as added Pub. L. 114–255, div. A, title III, §3058(a), Dec. 13, 2016, 130 Stat. 1128.
13140(k)	21 U.S.C. 360c(k)	June 25, 1938, ch. 675, §513(k), as added Pub. L. 117–328, div. FF, title III, §3301, Dec. 29, 2022, 136 Stat. 5831.

In subsection (b)(1)(A), in the matter before clause (i), the words "a device is substantially equivalent to a predicate device if the device has the same intended use" are substituted for "the term `substantially equivalent' or `substantial equivalence' means, with respect to a device being compared to a predicate device, that the device has the same intended use" for clarity.

In subsection (b)(1)(A)(ii)(I), the words "the information submitted showing that the device is substantially equivalent" are substituted for "the information submitted that the device is substantially equivalent" for clarity.

In subsection (b)(1)(A)(ii)(I), the words "if considered necessary" are substituted for "if deemed necessary" to use the more appropriate word.

In subsection (b)(1)(E)(ii), in the matter before subclause (I), the words "A determination of substantial equivalence under clause (i)" are substituted for "Such determination" for clarity.

In subsection (b)(1)(F), the words "Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997," are omitted as obsolete.

In subsection (c)(1)(B)(i)(VI), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

In subsection (c)(3)(C), the words "by weighing any" are substituted for "weighing any" for clarity.

In subsection (d)(2)(A), the word "individuals" is substituted for "persons" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (d)(2)(E), the word "chairperson" is substituted for "chairman" for gender neutrality.

In subsection (d)(3)(A), the words "the maximum rate payable under section 5376 of title 5" are substituted for "the rate in effect for grade GS–18 of the General Schedule" for clarity and because of section 101(c) of the Federal Employees Pay Comparability Act of 1990 (enacted by section 529 of Public Law 101−509) (5 U.S.C. 5376 note)).

In subsection (d)(3)(B), the words "individuals in the Government service" are substituted for "persons in the Government service" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

In subsection (d)(5)(C), in the matter before clause (i), the words "adequate expertise is represented on the classification panel if the membership of the classification panel" are substituted for "the term `adequate expertise' means that the membership of the classification panel" for clarity.

In subsection (d)(7)(C)(ii), the words "include in the notification under clause (i)" are substituted for "include" for clarity.

In subsection (h)(2)(A)(ii), the words "a determination of substantial equivalence under subsection (b)" are substituted for "a determination of substantial equivalence (as defined in subsection (i))" for consistency with subsection (b).

In subsection (h)(2)(B)(i)(I), the words "the device that is the subject of a request under subparagraph (A)" are substituted for "the device involved" for clarity.

In subsection (h)(4)(A)(iii), the parenthetical "(as in effect prior to July 9, 2012)" is added to reflect the amendment to section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)) made by section 608(b)(1) of the

Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1057).

In subsection (j)(2)(B), the words "interviews of individuals who" are substituted for "interviews of persons who" for consistency with the word "representative" in the subparagraph and with the definition of the term "person" in section 10101 of title 21, United States Code.

SECTION 13141—PERFORMANCE STANDARDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13141(a)	21 U.S.C. 360d(a)	June 25, 1938, ch. 675, §514(a), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 546; Pub. L. 94–460, title III, §304, Oct. 8, 1976, 90 Stat. 1960; Pub. L. 101–629, §6(a)(1), Nov. 28, 1990, 104 Stat. 4519; Pub. L. 105–115, title II, §204(d), Nov. 21, 1997, 111 Stat. 2336; Pub. L. 112–144, title VI, §608(a)(2)(B), July 9, 2012, 126 Stat. 1056.
13141(b)	21 U.S.C. 360d(b)	June 25, 1938, ch. 675, §514(b), formerly §514(g), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 546; redesignated §514(b), Pub. L. 101–629, §§6(a)(3), (4), (b)(1), 18(b), Nov. 28, 1990, 104 Stat. 4519 , 4528; Pub. L. 102–300, §6(g), June 16, 1992, 106 Stat. 241; Pub. L. 103–80, §4(a)(1), Aug. 13, 1993, 107 Stat. 779.
13141(c)	21 U.S.C. 360d(c)	June 25, 1938, ch. 675, §514(c), as added Pub. L. 105–115, title II, §204(a), Nov. 21, 1997, 111 Stat. 2335; Pub. L. 114–255, div. A, title III, §§3044(b)(3), 3053(a), Dec. 13, 2016, 130 Stat. 1121, 1125.
13141(d)	21 U.S.C. 360d(d)	June 25, 1938, ch. 675, §514(d), as added Pub. L. 115–52, title II, §205(a), Aug. 18, 2017, 131 Stat. 1016; Pub. L. 117–180, div. F, title II, §2005, Sept. 30, 2022, 136 Stat. 2153.

In subsection (a)(2)(B)(ii), the words "ensure the conformity" are substituted for "assure the conformity" to use the more appropriate word.

In subsection (a)(4)(C), the words "informed individuals" are substituted for "informed persons" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (b)(5)(B)(ii), the words "individuals who are qualified" are substituted for "persons qualified" for consistency with the words "any individual who is in the regular full-time employ" in the clause and with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (b)(5)(B)(iv)(I), the words "the maximum rate payable under section 5376 of title 5" are substituted for "the rate in effect for grade GS–18 of the General Schedule" for clarity and because of section 101(c) of the Federal Employees Pay Comparability Act of 1990 (enacted by section 529 of Public Law 101−509) (5 U.S.C. 5376 note)).

In subsection (b)(5)(B)(iv)(II), the words "individuals in the Government service" are substituted for "persons in the Government service" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

In subsection (b)(5)(B)(v), the word "chairperson" is substituted for "chairman" for gender neutrality.

In subsection (c)(1)(B), the words "to use data, or information other than data," are substituted for "to use data, or information, other than data" for clarity.

In subsection (c)(1)(C)(i), the words "nationally or internationally recognized standard development organization" are substituted for "nationally or internationally recognized standard organization" for consistency with subsection (c)(1)(A).

SECTION 13142—PREMARKET APPROVAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13142(a)(1)	21 U.S.C. 360e(a) (matter after (2))	June 25, 1938, ch. 675, §515(a) (matter after (2)), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 107–250, title III, §302(c)(1), Oct. 26, 2002, 116 Stat. 1618; Pub. L. 112–144, title VI, §608(b)(1)(A), July 9, 2012, 126 Stat. 1056; Pub. L. 114–255, div. A, title III, §3101(a)(2)(J), Dec. 13, 2016, 130 Stat. 1154.
13142(a)(2)	21 U.S.C. 360e(a) (except matter after (2))	June 25, 1938, ch. 675, §515(a) (except matter after (2)), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 107–250, title III, §302(c)(1), Oct. 26, 2002, 116 Stat. 1618; Pub. L. 112–144, title VI, §608(b)(1)(A), July 9, 2012, 126 Stat. 1056; Pub. L. 114–255, div. A, title III, §3101(a)(2)(J), Dec. 13, 2016, 130 Stat. 1154.
13142(b)(1)(A)	21 U.S.C. 360e(b)(1) (from "the Secretary shall" through "for premarket approval.")	June 25, 1938, ch. 675, §515(b)(1) (from "the Secretary shall" through "for premarket approval."), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 112–144, title VI, §608(b)(1)(B)(i), July 9, 2012, 126 Stat. 1057.
13142(b)(1)(B)	21 U.S.C. 360e(b)(1)(A), (B)	June 25, 1938, ch. 675, §515(b)(1)(A), (B), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 112–144, title VI, §608(b)(1)(B)(i), July 9, 2012, 126 Stat. 1057.
13142(b)(1)(C)	21 U.S.C. 360e(b)(1) (last sentence)	June 25, 1938, ch. 675, §515(b)(1) (last sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 112–144, title VI, §608(b)(1)(B)(i), July 9, 2012, 126 Stat. 1057.
13142(b)(2), (3)	21 U.S.C. 360e(b)(2), (3)	June 25, 1938, ch. 675, §515(b)(2), (3), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 112–144, title VI, §608(b)(1)(B)(ii), (iii), July 9, 2012, 126 Stat. 1057.
13142(c)(1) through (4)	21 U.S.C. 360e(c)(1) through (4)	June 25, 1938, ch. 675, §515(c)(1) through (4), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 101–629, §18(c), Nov. 28, 1990, 104 Stat. 4528; Pub. L. 103–80, §3(t), Aug. 13, 1993, 107 Stat. 778; Pub. L. 107–250, title II, §§209, 210, title III, §302(c)(2), Oct. 26, 2002, 116 Stat. 1613, 1614, 1618; Pub. L. 108–214, §2(d)(1), Apr. 1, 2004, 118 Stat. 576; Pub. L. 110–85, title VIII, §801(b)(3)(D), Sept. 27, 2007, 121 Stat. 921; Pub. L. 112–144, title II, §203(g), July 9, 2012, 126 Stat. 1006; Pub. L. 115–52, title II, §203(f)(2)(A), Aug. 18, 2017, 131 Stat. 1015.
13142(c)(5)(A)(i)	21 U.S.C. 360e(c)(5)(B)	June 25, 1938, ch. 675, §515(c)(5)(B), as added Pub. L. 114–255, div. A, title III, §3058(b), Dec. 13, 2016, 130 Stat. 1129.
13142(c)(5)(A)(ii)	21 U.S.C. 360e(c)(5)(A)	June 25, 1938, ch. 675, §515(c)(5)(A), as added Pub. L. 114–255, div. A, title III, §3058(b), Dec. 13, 2016, 130 Stat. 1129.
13142(c)(5)(B), (C)	21 U.S.C. 360e(c)(5)(C), (D)	June 25, 1938, ch. 675, §515(c)(5)(C), (D), as added Pub. L. 114–255, div. A, title III, §3058(b), Dec. 13, 2016, 130 Stat. 1129.
13142(d)	21 U.S.C. 360e(d)	June 25, 1938, ch. 675, §515(d), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 552; Pub. L. 105–115, title II, §§201(b), 202, 205(c), 209(b), Nov. 21, 1997, 111 Stat. 2334, 2338, 2341; Pub. L. 114–255, div. A, title III, §3051(c)(1), Dec. 13, 2016, 130 Stat. 1124; Pub. L. 117–328, div. FF, title III, §3308(b)(2), Dec. 29, 2022, 136 Stat. 5836.
13142(e)	21 U.S.C. 360e(e)	June 25, 1938, ch. 675, §515(e), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 101–629, §9(a), Nov. 28, 1990, 104 Stat. 4521.
13142(f)	21 U.S.C. 360e(f)	June 25, 1938, ch. 675, §515(f), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552; Pub. L. 105–115, title II, §216(b), Nov. 21, 1997, 111 Stat. 2349.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13142(g)	21 U.S.C. 360e(g)	June 25, 1938, ch. 675, §515(g), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552.
13142(h)	21 U.S.C. 360e(h)	June 25, 1938, ch. 675, §515(h), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 552.
13142(i)	21 U.S.C. 360e(i)	June 25, 1938, ch. 675, §515(i), as added Pub. L. 101–629, §4(b)(1), Nov. 28, 1990, 104 Stat. 4515; Pub. L. 112–144, title VI, §608(b)(1)(C), July 9, 2012, 126 Stat. 1056.

In subsection (c)(4)(A), the words "the Secretary may" are substituted for "the Secretary has discretion whether to" to eliminate unnecessary words and for consistency in title 21, United States Code.

In subsection (d)(1)(A)(i), in the matter before subclause (I), the words "but not later than" are substituted for "but in no event later than" to eliminate unnecessary words.

In subsection (d)(1)(B)(i), the words "for a device subject to an order issued under subsection (b)" are substituted for "for a device subject to a regulation promulgated under subsection (b)" to reflect the amendment to section 515(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)) by section 608(b)(1)(B) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1057).

In subsections (e)(1) (matter before subparagraph (A)) and (f)(7), the words "informal hearing provided to" are substituted for "informal hearing to" for clarity.

In subsection (f)(7), the words "as provided in paragraph (6)(B)" are substituted for "as provided in subparagraph (B)" to provide the correct reference to the pertinent provision.

In subsection (g)(2)(B)(ii), the words "individuals who are qualified" are substituted for "persons qualified" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (g)(2)(B)(iii)(I), the words "the maximum rate payable under section 5376 of title 5" are substituted for "grade GS–18 of the General Schedule" for clarity and because of section 101(c) of the Federal Employees Pay Comparability Act of 1990 (enacted by section 529 of Public Law 101−509) (5 U.S.C. 5376 note)).

In subsection (g)(2)(B)(iii)(II), the words "individuals in the Government service" are substituted for "persons in the Government service" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

In subsection (g)(2)(B)(iv), the word "chairperson" is substituted for "chairman" for gender neutrality.

SECTION 13143—PEDIATRIC USES OF DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13143(a)	21 U.S.C. 360e–1(c)	June 25, 1938, ch. 675, §515A(c), as added Pub. L. 110–85, title III, §302, Sept. 27, 2007, 121 Stat. 859.
13143(b), (c)	21 U.S.C. 360e–1(a), (b)	June 25, 1938, ch. 675, §515A(a), (b), as added Pub. L. 110–85, title III, §302, Sept. 27, 2007, 121 Stat. 859; Pub. L. 115–52, title V, §502(a), Aug. 18, 2017, 131 Stat. 1037.

In subsection (b)(3)(A), in the matter before clause (i), the words "The Secretary shall annually submit" are substituted for "Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary shall submit" to eliminate obsolete words.

SECTION 13144—BREAKTHROUGH DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13144	21 U.S.C. 360e–3	June 25, 1938, ch. 675, §515B, formerly §515C, as added Pub. L. 114–255, div. A, title III, §3051(a), Dec. 13, 2016, 130 Stat. 1121; renumbered §515B and amended Pub. L. 115–52, title IX, §901(f), (g), Aug. 18, 2017, 131 Stat. 1076, 1077.

SECTION 13145—PREDETERMINED CHANGE CONTROL PLANS FOR DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13145	21 U.S.C. 360e–4	June 25, 1938, ch. 675, §515C, as added Pub. L. 117–328, div. FF, title III, §3308(a), Dec. 29, 2022, 136 Stat. 5835.

SECTION 13146—BANNED DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13146	21 U.S.C. 360f	June 25, 1938, ch. 675, §516, as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 560; Pub. L. 101–629, § 18(d), Nov. 28, 1990, 104 Stat. 4529; Pub. L. 117–328, div. FF, title III, §3306(a), Dec. 29, 2022, 136 Stat. 5834.

SECTION 13147—JUDICIAL REVIEW

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13147(a)	21 U.S.C. 360g(a) (last sentence)	June 25, 1938, ch. 675, §517(a) (last sentence), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 560.
13147(b)(1)	21 U.S.C. 360g(a) (1st sentence)	June 25, 1938, ch. 675, §517(a) (1st sentence), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 560; Pub. L. 101–629, § 13, Nov. 28, 1990, 104 Stat. 4524; Pub. L. 102–300, § 6(f), June 16, 1992, 106 Stat. 240; Pub. L. 105–115, title II, § 216(a)(2), Nov. 21, 1997, 111 Stat. 2349; Pub. L. 112–144, title VI, § 608(a)(2)(C), July 9, 2012, 126 Stat. 1056.
13147(b)(2), (3)	21 U.S.C. 360g(a) (2d sentence, 3d sentence)	June 25, 1938, ch. 675, §517(a) (2d sentence, 3d sentence), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 561.
13147(c) through (g)	21 U.S.C. 360g(b) through (f)	June 25, 1938, ch. 675, §517(b) through (f), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 561.

In subsection (b)(1)(A)(iii), the reference to "515(b)(2)(B)" is omitted as obsolete because of the amendment of section 515(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)(2)) by section 608(b)(1)(B)(ii) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1057).

In subsection (b)(1)(A)(iv), the words "issuance of an order under section 13142(b)(3) of this title" are substituted for "promulgation of a regulation under paragraph (3) of section 515(b)" to reflect the amendment to section 515(b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)(3)) by section 608(b)(1)(B)(iii) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1057).

In subsection (b)(1)(A)(iv), the words "a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3)," are omitted as obsolete because section 515(b)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(b)(4)) was struck by section 608(b)(1)(B)(iv) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1058).

In subsection (d), the words "or an order issued after the review" are substituted for "and an order issued after the review" for clarity.

SECTION 13148—AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13148	21 U.S.C. 360g–1	June 25, 1938, ch. 675, §517A, as added Pub. L. 112–144, title VI, §603, July 9, 2012, 126 Stat. 1051; Pub. L. 114–255, div. A, title III, §§3051(b), 3058(c), Dec. 13, 2016, 130 Stat. 1124, 1129; Pub. L. 117–328, div. FF, title III, §3308(b)(3), Dec. 29, 2022, 136 Stat. 5836.

In subsection (a)(1), the words "section 13144 of this title" are substituted for "section 515C" to provide the correct reference to the pertinent provision. Section 13144 of title 21, United States Code, restates section 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3). Section 515B of the Act was formerly section 515C of the Act, and was redesignated as section 515B by section 901(f)(2) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1077).

SECTION 13149—NOTIFICATION AND OTHER REMEDIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13149(a)(1) (matter before (A))	21 U.S.C. 360h(a) (1st sentence ("If the Secretary determines that", "the Secretary may issue" through "eliminate such risk."))	June 25, 1938, ch. 675, §518(a)(1), (2), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 562.
13149(a)(1)(A), (B)	21 U.S.C. 360h(a)(1), (2)	June 25, 1938, ch. 675, §518(a)(1), (2), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 562.
13149(a)(2) through (4)	21 U.S.C. 360h(a) (2d sentence through last sentence)	June 25, 1938, ch. 675, §518(a) (2d sentence through last sentence), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 562.
13149(b) through (e) ...	21 U.S.C. 360h(b) through (e)	June 25, 1938, ch. 675, § 518(b) through (e), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 562; amended Pub. L. 101–629, § 8, Nov. 28, 1990, 104 Stat. 4520; Pub. L. 102–300, § 4, June 16, 1992, 106 Stat. 239.

In subsection (a)(1), in the matter before subparagraph (A), the words "ensure that adequate notification" are substituted for "assure that adequate notification" to use the more appropriate word.

In subsection (b)(1)(B)(i), in the matter before subparagraph (A), the words "ensure that the unreasonable risk" are substituted for "assure that the unreasonable risk" to use the more appropriate word.

In subsection (b)(3), the words "itself or one's self" are substituted for "himself" each place it appears for consistency with the definition of "person" in section 10101 of title 21, United States Code, and for gender neutrality.

In subsection (e)(2)(A), the words "except as provided in subclauses (I) and (II) of subparagraph (B)(i)" are substituted for "except as provided in subparagraphs (B) and (C)" to provide the correct reference to the pertinent provisions. Subclauses (I) and (II) of subparagraph (B)(i) restate subclauses (I) and (II) of section 518(e)(2)(B)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)(2)(B)(i)), which subclauses provide for exceptions to the requirement for recall. Subparagraph (B) of section 518(e)(2) of that Act (21 U.S.C. 360h(e)(2)) contains those exceptions and provisions that are not exceptions to the requirement for recall. There is no subparagraph (C) in section 518(e)(2)) of that Act (21 U.S.C. 360h(e)(2)).

SECTION 13150—PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13150(a)	21 U.S.C. 360h–1(c)	June 25, 1938, ch. 675, §518A(c), as added Pub. L. 112–144, title VI, § 605, July 9, 2012, 126 Stat. 1053; Pub. L. 114–255, div. A, title III, §3101(a)(2)(K), Dec. 13, 2016, 130 Stat. 1154.
13150(b)	21 U.S.C. 360h–1(a)	June 25, 1938, ch. 675, §518A(a), as added Pub. L. 112–144, title VI, § 605, July 9, 2012, 126 Stat. 1053.
13150(c)	21 U.S.C. 360h–1(b)	June 25, 1938, ch. 675, §518A(b), as added Pub. L. 112–144, title VI, § 605, July 9, 2012, 126 Stat. 1053.

SECTION 13151—RECORDS AND REPORTS ON DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13151(a)	21 U.S.C. 360i(a)	June 25, 1938, ch. 675, §519(a), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 564; Pub. L. 101–629, §3(a)(1), 7, Nov. 28, 1990, 104 Stat. 4513; Pub. L. 102–300, §5(a)(1), June 16, 1992, 106 Stat. 239; Pub. L. 103–80, §3(u), Aug. 13, 1993, 107 Stat. 778; Pub. L. 105–115, title II, §213(a)(1), Nov. 21, 1997, 111 Stat. 2346; Pub. L. 110–85, title II, §227, Sept. 27, 2007, 121 Stat. 854.
13151(b)(1)	21 U.S.C. 360i(b)(6)	June 25, 1938, ch. 675, §519(b)(6), formerly §519(b)(5), as added Pub. L. 101–629, §2(a), Nov. 28, 1990, 104 Stat. 4511; Pub. L. 102–300, §5(a)(2)(C), June 16, 1992, 106 Stat. 239; redesignated §519(b)(6), Pub. L. 105–115, title II, §213(c)(2)(A), Nov. 21, 1997, 111 Stat. 2347.
13151(b)(2)	21 U.S.C. 360i(b)(1)	June 25, 1938, ch. 675, §519(b)(1), as added Pub. L. 101–629, §2(a), Nov. 28, 1990, 104 Stat. 4511; Pub. L. 102–300, §5(a)(2)(A), (B), June 16, 1992, 106 Stat. 239; Pub. L. 105–115, title II, §213(c)(1)(A), Nov. 21, 1997, 111 Stat. 2347.
13151(b)(3)	21 U.S.C. 360i(b)(2)	June 25, 1938, ch. 675, §519(b)(2), as added Pub. L. 101–629, §2(a), Nov. 28, 1990, 104 Stat. 4511; Pub. L. 105–115, title II, §213(c)(1)(B), Nov. 21, 1997, 111 Stat. 2347.
13151(b)(4)	21 U.S.C. 360i(b)(3)	June 25, 1938, ch. 675, §519(b)(3), as added Pub. L. 101–629, §2(a), Nov. 28, 1990, 104 Stat. 4511.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13151(b)(5)	21 U.S.C. 360i(b)(4)	June 25, 1938, ch. 675, §519(b)(4), as added Pub. L. 101–629, §2(a), Nov. 28, 1990, 104 Stat. 4511.
13151(b)(6)	21 U.S.C. 360i(b)(5)(A) through (D)	June 25, 1938, ch. 675, §519(b)(5)(A) through (D), as added Pub. L. 105–115, title II, §213(c)(2)(B), Nov. 21, 1997, 111 Stat. 2347.
13151(c)	21 U.S.C. 360i(c)	June 25, 1938, ch. 675, §519(c), formerly §519(b), as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 564; redesignated §519(c), Pub. L. 101–629, §2(a), Nov. 28, 1990, 104 Stat. 4511.
13151(d)	21 U.S.C. 360i(e)	June 25, 1938, ch. 675, §519(e), as added Pub. L. 101–629, §3(b)(1), Nov. 28, 1990, 104 Stat. 4514; Pub. L. 105–115, title II, §211, Nov. 21, 1997, 111 Stat. 2345.
13151(e)	21 U.S.C. 360i(f)	June 25, 1938, ch. 675, §519(f), as added Pub. L. 110–85, title II, §226(a)(2), Sept. 27, 2007, 121 Stat. 854; Pub. L. 112–144, title VI, §614, July 9, 2012, 126 Stat. 1061; Pub. L. 114–255, div. A, title III, §3101(a)(2)(L), Dec. 13, 2016, 130 Stat. 1154.
13151(f)	21 U.S.C. 360i(g)	June 25, 1938, ch. 675, §519(g), formerly §519(f), as added Pub. L. 101–629, §7, Nov. 28, 1990, 104 Stat. 4520; Pub. L. 105–115, title II, §213(a)(3), Nov. 21, 1997, 111 Stat. 2347; redesignated §519(g), Pub. L. 110–85, title II, §226(a)(1), Sept. 27, 2007, 121 Stat. 854.
13151(g)	21 U.S.C. 360i(h)	June 25, 1938, ch. 675, §519(h), as added Pub. L. 112–144, title VI, §615, July 9, 2012, 126 Stat. 1061.
13151(h)	21 U.S.C. 360i(i)	June 25, 1938, ch. 675, § 519(i), as added Pub. L. 115–52, title VII, §708(a), Aug. 18, 2017, 131 Stat. 1062.

In subsection (a)(1), in the matter before subparagraph (A), the word "Each" is substituted for "Every" for clarity.

In subsection (a)(1) (matter before subparagraph (A)) and in subparagraphs (A) and (B) of subsection (c)(3), the word "ensure" is substituted for "assure" each place it appears to use the more appropriate word.

In subsection (b)(2)(B), in the matter before clause (i), the words "after becoming aware of information or experience described in clause (i) or (ii), respectively" are substituted for "after becoming aware of the information" for clarity and consistency in the subparagraph.

In subsection (b)(2)(B), in the matter before clause (i), the words "report the information or experience" are substituted for "report the information" for clarity and consistency in the subparagraph.

In subsection (e), the words "Not later than December 31, 2012," are omitted as obsolete.

In subsection (e), the words "shall issue regulations" are substituted for "shall issue proposed regulations" to eliminate obsolete words.

In subsection (e), the last sentence of the source provision is omitted as obsolete.

In subsection (f)(1)(A)(ii), the words "which violation may" are substituted for "which may" for clarity.

In subsection (g)(2), the words “other data considered appropriate” are substituted for “other data deemed appropriate” to use the more appropriate word.

In subsection (h)(5), in the matter before subparagraph (A), the words “carried out under this section” are substituted for “carried out under this section 519” eliminate the unnecessary reference to “519”.

SECTION 13152—GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13152(a) through (e) ...	21 U.S.C. 360j(a) through (e)	June 25, 1938, ch. 675, §520(a) through (e), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 565; Pub. L. 101–629, §11(1), Nov. 28, 1990, 104 Stat. 4522; Pub. L. 112–144, title VI, §617, July 9, 2012, 126 Stat. 1062.
13152(f)	21 U.S.C. 360j(f)	June 25, 1938, ch. 675, §520(f), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 567; Pub. L. 101–629, §18(e), Nov. 28, 1990, 104 Stat. 4529; Pub. L. 105–115, title IV, §410(a), Nov. 21, 1997, 111 Stat. 2372; Pub. L. 117–286, §4(a)(156), Dec. 27, 2022, 136 Stat. 4323.
13152(g)	21 U.S.C. 360j(g)	June 25, 1938, ch. 675, §520(g), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 569; Pub. L. 102–571, title I, §107(10), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 105–115, title II, §201(a), Nov. 21, 1997, 111 Stat. 2332; Pub. L. 112–144, title VI, §§601, 606, July 9, 2012, 126 Stat. 1051, 1054; Pub. L. 114–255, div. A, title III, §§3024(a), 3056(1), Dec. 13, 2016, 130 Stat. 1099, 1128; Pub. L. 117–328, div. FF, title III, §3601(b), Dec. 29, 2022, 136 Stat. 5861.
13152(h)	21 U.S.C. 360j(h)	June 25, 1938, ch. 675, §520(h), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 571; Pub. L. 101–629, §11(2), Nov. 28, 1990, 104 Stat. 4522; Pub. L. 105–115, title II, §216(a)(1), Nov. 21, 1997, 111 Stat. 2349; Pub. L. 114–255, div. A, title III, §3038(b), Dec. 13, 2016, 130 Stat. 1110.
13152(i)	21 U.S.C. 360j(i)	June 25, 1938, ch. 675, §520(i), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 571; Pub. L. 101–629, §6(b)(2), Nov. 28, 1990, 104 Stat. 4519.
13152(j)	21 U.S.C. 360j(j)	June 25, 1938, ch. 675, §520(j), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 572; Pub. L. 101–629,§3(b)(2), Nov. 28, 1990, 104 Stat. 4514.
13152(k)	21 U.S.C. 360j(k)	June 25, 1938, ch. 675, §520(k), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 572.
13152(l)(1) through (3)	21 U.S.C. 360j(l)(1) through (3)	June 25, 1938, ch. 675, §520(l)(1) through (3), as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 565; Pub. L. 101–629, §§ 5(c)(2), 18(f), Nov. 28, 1990, 104 Stat. 4518, 4529; Pub. L. 105–115, title I, §125(b)(2)(E), Nov. 21, 1997, 111 Stat. 2325.
13152(l)(4)	21 U.S.C. 360j(l)(5)	June 25, 1938, ch. 675, §520(l)(5), as added Pub. L. 101–629, §4(b)(2), Nov. 28, 1990, 104 Stat. 4516; Pub. L. 105–115, title I, §125(b)(2)(E), Nov. 21, 1997, 111 Stat. 2325.
13152(m)(1)	21 U.S.C. 360j(m)(1)	June 25, 1938, ch. 675, §520(m)(1), as added Pub. L. 101–629, §14(a), Nov. 28, 1990, 104 Stat. 4524; Pub. L. 114–255, div. A, title III, §3052(a)(1), Dec. 13, 2016, 130 Stat. 1124.
13152(m)(2)(A), (B) ...	21 U.S.C. 360j(m)(2)	June 25, 1938, ch. 675, §520(m)(2), as added Pub. L. 101–629, §14(a), Nov. 28, 1990, 104 Stat. 4524; Pub. L. 105–115, title II, §203(1), Nov. 21, 1997, 111 Stat. 2334; Pub. L. 110–85, title VIII, §801(b)(3)(E), Sept. 27, 2007, 121 Stat. 921; Pub. L. 114–255, div. A, title III, §3052(a)(2), Dec. 13, 2016, 130 Stat. 1125.
13152(m)(2)(C)	21 U.S.C. 360j note	Pub. L. 114–255, div. A, title III, §3052(b), Dec. 13, 2016, 130 Stat. 1125.
13152(m)(3) through (5)	21 U.S.C. 360j(m)(3) through (5)	June 25, 1938, ch. 675, §520(m)(3) through (5), as added Pub. L. 101–629, §14(a), Nov. 28, 1990, 104 Stat. 4524; Pub. L. 105–115, title II, §203(2), (3), Nov. 21, 1997, 111 Stat. 2334; Pub. L. 110–85, title

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		III, §303(a)(1), (2), title VIII, §801(b)(3)(E), Sept. 27, 2007, 121 Stat. 860, 921; Pub. L. 114–255, div. A, title III, §3056(2), Dec. 13, 2016, 130 Stat. 1128; Pub. L. 115–52, title V, §502(b)(1), Aug. 18, 2017, 131 Stat. 1037.
13152(m)(6)(A)(i)	21 U.S.C. 360j(m)(6)(A)(ii) (2d sentence)	June 25, 1938, ch. 675, §520(m)(6)(A)(ii) (2d sentence), as added Pub. L. 110–85, title III, §303(a)(3), Sept. 27, 2007, 121 Stat. 860; Pub. L. 112–144, title VI, §613(a)(1)(A), July 9, 2012, 126 Stat. 1060; Pub. L. 114–255, div. A, title III, §3052(a)(3), Dec. 13, 2016, 130 Stat. 1125.
13152(m)(6)(A)(ii), (iii)	21 U.S.C. 360j(m)(6)(E)	June 25, 1938, ch. 675, §520(m)(6)(E), as added Pub. L. 110–85, title III, §303(a)(3), Sept. 27, 2007, 121 Stat. 860.
13152(m)(6)(B)	21 U.S.C. 360j(m)(6)(A) (except (ii) (2d sentence))	June 25, 1938, ch. 675, §520(m)(6)(A) (except (ii) (2d sentence)), as added Pub. L. 110–85, title III, §303(a)(3), Sept. 27, 2007, 121 Stat. 860; Pub. L. 112–144, title V, §507(c), title VI, §613(a)(1)(A), July 9, 2012, 126 Stat. 1045, 1060; Pub. L. 114–255, div. A, title III, §3052(a)(3), Dec. 13, 2016, 130 Stat. 1125; Pub. L. 115–52, title V, §502(b)(2), Aug. 18, 2017, 131 Stat. 1037; Pub. L. 117–180, div. F, title V, §5002, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, §303, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3103, Dec. 29, 2022, 136 Stat. 5807.
13152(m)(6)(C) through (E)	21 U.S.C. 360j(m)(6)(B) through (D)	June 25, 1938, ch. 675, §520(m)(6)(B) through (D), as added Pub. L. 110–85, title III, §303(a)(3), Sept. 27, 2007, 121 Stat. 860.
13152(m)(7), (8)	21 U.S.C. 360j(m)(7), (8)	June 25, 1938, ch. 675, §520(m)(7), (8), as added Pub. L. 110–85, title III, §303(a)(3), Sept. 27, 2007, 121 Stat. 860; Pub. L. 112–144, title VI, §613(a)(2), (3), July 9, 2012, 126 Stat. 1061.
13152(n)	21 U.S.C. 360j(n)	June 25, 1938, ch. 675, §520(n), as added Pub. L. 109–96, §1, Nov. 9, 2005, 119 Stat. 2119.
13152(o)	21 U.S.C. 360j(o)	June 25, 1938, ch. 675, §520(o), as added Pub. L. 114–255, div. A, title III, §3060(a), Dec. 13, 2016, 130 Stat. 1130.
13152(p)(1)	21 U.S.C. 360j(p)(4)	June 25, 1938, ch. 675, §520(p)(4), as added Pub. L. 115–52, title VII, §706(a), Aug. 18, 2017, 131 Stat. 1058.
13152(p)(2) through (4)	21 U.S.C. 360j(p)(1) through (3)	June 25, 1938, ch. 675, §520(p)(1) through (3), as added Pub. L. 115–52, title VII, §706(a), Aug. 18, 2017, 131 Stat. 1058.
13152(q)	21 U.S.C. 360j(q)	June 25, 1938, ch. 675, §520(q), as added Pub. L. 115–52, title VII, §709(a), Aug. 18, 2017, 131 Stat. 1065.

In subsection (b)(3), the words "Not later than 2 years after the date of enactment of this section," are omitted as obsolete.

In subsection (e)(1)(B)(ii)(II), the words "a certifying board described in subclause (I)" are substituted for "such a Board" for clarity.

In subsection (f)(1)(A), the words "ensure that the device" are substituted for "assure that the device" to use the more appropriate word.

In subsection (f)(2)(A)(i), the words "ensure that the device" are substituted for "assure that the device" to use the more appropriate word.

In subsection (f)(2)(C)(i)(I), the words "ensure that the device" are substituted for "assure that the device" to use the more appropriate word.

In subsection (f)(2)(C)(i)(II), the words "ensure that the device" are substituted for "assure that the device" to use the more appropriate word.

In subsection (f)(2)(C)(ii), the words "ensure that the device" are substituted for "assure that the device" to use the more appropriate word.

In clauses (i) and (ii) of subsection (f)(3)(B), the words "from individuals" are substituted for the words "from persons" each place they appear for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (f)(3)(C)(i), the words "the maximum rate payable under section 5376 of title 5" are substituted for "the rate in effect for grade GS–18 of the General Schedule" for clarity and because of section 101(c) of the Federal Employees Pay Comparability Act of 1990 (enacted by section 529 of Public Law 101−509) (5 U.S.C. 5376 note)).

In subsection (f)(3)(C)(ii), the words "individuals in the Government service" are substituted for "persons in the Government service" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

In subsection (f)(3)(D), the word "chairperson" is substituted for "chairman" for gender neutrality.

In subsection (g)(2)(A), the words "within the one hundred and twenty-day period beginning on the date of the enactment of this section" are omitted as obsolete.

In subsection (g)(2)(B)(ii), the words "ensure the establishment" are substituted for "assure the establishment" to use the more appropriate word.

In subsection (g)(2)(B)(ii), the words "ensure compliance" are substituted for "assure compliance" to use the more appropriate word.

In subsection (g)(3)(A)(i)(II), the words "if the plan and report are not submitted to the Secretary under subclause (I)(bb)," are substituted for "unless the plan and report are submitted to the Secretary," for clarity.

In subsection (g)(3)(A)(iv), in the matter before subclause (I), the words "ensure that informed consent" are substituted for "assure that informed consent" to use the more appropriate word.

In subsection (g)(6)(A), in the matter before clause (i), the words "Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997," are omitted as obsolete.

In subsection (g)(8)(B)(i), in the matter before subclause (I), the words "of the individuals" are substituted for "of the persons" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (j), the words "ensure the protection" are substituted for "assure the protection" to use the more appropriate word.

In subsection (k), the words "subsections (a) and (b) of section 3324 of title 31 and section 6101 of title 41" are substituted for "sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5)" on authority of section 4(b)

of Public Law 97–258 (96 Stat. 1067), which Act enacted title 31, United States Code, and section 6(c) of Public Law 111–350 (124 Stat. 3854), which Act enacted title 41, United States Code.

In subsection (m)(2)(C), the words "Not later than 18 months after the date of enactment of this Act," are omitted as obsolete.

In subsection (m)(6)(A), in the matter before clause (i), the reference to "this paragraph" is a translation from the references to "this subsection" in clauses (i) and (ii) of section 520(m)(6)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(E)) to provide a more precise reference to the pertinent provision.

In subsection (m)(6)(E), the words "after the notification or determination" are substituted for "after such notification" for consistency in the subparagraph.

In subsection (m)(7), the words "established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109)" are omitted as unnecessary and for consistency in title 21, United States Code.

SECTION 13153—STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13153	21 U.S.C. 360k	June 25, 1938, ch. 675, § 521, as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 574.

SECTION 13154—POSTMARKET SURVEILLANCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13154	21 U.S.C. 360l	June 25, 1938, ch. 675, § 522, as added Pub. L. 101–629, § 10, Nov. 28, 1990, 104 Stat. 4521; amended Pub. L. 102–300, § 3(b), June 16, 1992, 106 Stat. 239; Pub. L. 105–115, title II, § 212, Nov. 21, 1997, 111 Stat. 2346; Pub. L. 110–85, title III, § 307, Sept. 27, 2007, 121 Stat. 865; Pub. L. 112–144, title VI, § 616, July 9, 2012, 126 Stat. 1062.

In subsection (c)(2), the words "considered necessary" are substituted for "deemed necessary" to use the more appropriate word.

SECTION 13155—ACCREDITED PERSONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13155	21 U.S.C. 360m	June 25, 1938, ch. 675, § 523, as added Pub. L. 105–115, title II, § 210(a), Nov. 21, 1997, 111 Stat. 2342; amended Pub. L. 107–250, title II, § 202, Oct. 26, 2002, 116 Stat. 1609; Pub. L. 110–85, title II, § 221, Sept. 27, 2007, 121 Stat. 852; Pub. L. 111–31, div. A, title I, § 103(f), June 22, 2009, 123 Stat. 1837; Pub. L. 112–144, title VI, § 611, July 9, 2012, 126 Stat. 1059; Pub. L. 114–255, div. A, title III, §3102(4), Dec. 13, 2016, 130 Stat. 1156; Pub. L. 115–52, title II, §206, Aug. 18, 2017, 131 Stat. 1018; Pub. L. 117–180, div. F, title II, §2006, Sept. 30, 2022, 136 Stat. 2154; Pub. L. 117–229, div. C, title III, §309, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3109, Dec. 29, 2022, 136 Stat. 5808.

In subsection (a)(1), the words "Not later than 1 year after the date of the enactment of the Food and Drug Modernization Act of 1997," are omitted as obsolete.

In subsection (a)(3)(A)(ii), the words "section 13144(d) of this title" are substituted for "section 515C(d)" to provide the correct reference to the pertinent provision. Section 13144(d) of title 21, United States Code, restates section 515B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3(d)). Section 515B of the Act was formerly section 515C of the Act, and was redesignated as section 515B by section 901(f)(2) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1077).

In subsection (b)(2)(A)(i), the words "Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997," are omitted as obsolete.

In subsection (b)(2)(D)(iii), the words "Not later than 120 days after the date of the enactment of this subparagraph," are omitted as obsolete.

SECTION 13156—PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13156	21 U.S.C. 360n (except (b)(3)(B))	June 25, 1938, ch. 675, §524 (except (b)(3)(B)), as added Pub. L. 110–85, title XI, §1102, Sept. 27, 2007, 121 Stat. 972; Pub. L. 113–233, §2, Dec. 16, 2014, 128 Stat. 2127; Pub. L. 114–146, §2, Apr. 19, 2016, 130 Stat. 357; Pub. L. 114–255, div. A, title III, §3101(a)(2)(M), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 115–52, title VI, §611(a), Aug. 18, 2017, 131 Stat. 1054; Pub. L. 117–9, §1(a)(3), Apr. 23, 2021, 135 Stat. 257.

In subsection (a)(1), the words "section 101(c) of the Prescription Drug User Fee Amendments of 2007 (Public Law 110–85, title I, 121 Stat. 825)" are substituted for "section 101(c) of the Food and Drug Administration Amendments Act of 2007" to provide a more precise reference to the pertinent provision. The short title for title I of the Food and Drug Administration Amendments Act of 2007 is Prescription Drug User Fee Amendments of 2007, and section 101(c) is under that title.

In subsection (a)(4)(A)(ii), the words "considers eligible" are substituted for "deems eligible" to use the more appropriate word.

In subsection (c)(1), the words "chapter 179 of this title" are substituted for "chapter VII" to provide a more precise reference to the pertinent provision.

In subsection (c)(3), the words "beginning after September 30, 2007" are omitted as obsolete.

SECTION 13157—PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13157	21 U.S.C. 360n–1	June 25, 1938, ch. 675, § 524A, as added Pub. L. 112–144, title VIII, §802(a), July 9, 2012, 126 Stat. 1079; Pub. L. 114–255, div. A, title III, §3101(a)(2)(N), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 117–328, div. FF, title III, §3212(b), Dec. 29, 2022, 136 Stat. 5826.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13158(a)	21 U.S.C. 360n–2(c)	June 25, 1938, ch. 675, §524B(c), as added Pub. L. 117–328, div. FF, title III, §3305(a), Dec. 29, 2022, 136 Stat. 5832.
13158(b) through (d) ...	21 U.S.C. 360n–2(a), (b), (d)	June 25, 1938, ch. 675, §524B(a), (b), (d), as added Pub. L. 117–328, div. FF, title III, §3305(a), Dec. 29, 2022, 136 Stat. 5832.
13158(e)	21 U.S.C. 331 note	Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (a) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5832)), Dec. 29, 2022, 136 Stat. 5833.

In subsection (e), the words "this section" are substituted for "this section, including the amendments made by this section," for clarity. The words "the amendments by this section" in the source provision are translated in the restatement as "this section" because section 13158 of title 21, United States Code, to which "this section" refers, restates section 524B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n–2), which was added to that Act by the amendment made by section 3305(a) of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5832). See sections 10501(16)(C)(ii), 29117(c), and 49520(c) of title 21, United States Code, for identical provisions, except for the reference to "this section".

Chapter 133—Misbranded Drugs and Devices

In this chapter, the words "A drug or device shall be deemed to be misbranded", "A drug shall be deemed to be misbranded", "A device shall be deemed to be misbranded", or words of like import are added as appropriate each place they appear to carry forward the matter before subsection (a) of section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352). The words "drug or" or "or device" in the matter carried forward are omitted as appropriate for consistency in the applicable provision.

SECTION 13301—FALSE OR MISLEADING LABEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13301(a)	21 U.S.C. 352(a)(2)	June 25, 1938, ch. 675, §502(a)(2), 52 Stat. 1050; Pub. L. 105–115, title I, §114(a), Nov. 21, 1997, 111 Stat. 2312; Pub. L. 114–255, div. A, title III, §3037, Dec. 13, 2016, 130 Stat. 1105; Pub. L. 117–328, div. FF, title III, §3630(a)(1)(B), (2), Dec. 29, 2022, 136 Stat. 5893.
13301(b) through (e) ...	21 U.S.C. 352(a)(1)	June 25, 1938, ch. 675, §502(a)(1), 52 Stat. 1050; Pub. L. 105–115, title I, §114(a), Nov. 21, 1997, 111 Stat. 2312; Pub. L. 114–255, div. A, title III, §3037, Dec. 13, 2016, 130 Stat. 1105; Pub. L. 117–328, div. FF, title III, §3630(a), Dec. 29, 2022, 136 Stat. 5893.

SECTION 13302—PACKAGE FORM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13302	21 U.S.C. 352(b)	June 25, 1938, ch. 675, §502(b), 52 Stat. 1050.

SECTION 13303—PROMINENCE OF INFORMATION ON LABEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13303	21 U.S.C. 352(c)	June 25, 1938, ch. 675, §502(c), 52 Stat. 1050.

SECTION 13304—DESIGNATION OF DRUGS OR DEVICES BY ESTABLISHED NAMES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13304(a)(1)	21 U.S.C. 352(e)(3)	June 25, 1938, ch. 675, §502(e)(3), formerly §502(e)(2), as added Pub. L. 87–781, title I, §112(a)(6), Oct. 10, 1962, 76 Stat. 790; redesignated §502(e)(3), Pub. L. 94–295, §5(a)(2), May 28, 1976, 90 Stat. 580; Pub. L. 103–80, § 3(m)(1), Aug. 13, 1993, 107 Stat. 777.
13304(a)(2) through (4)	21 U.S.C. 352(e)(1)	June 25, 1938, ch. 675, §502(e)(1), 52 Stat. 1050; Pub. L. 87–781, title I, §112(a), Oct. 10, 1962, 76 Stat. 790; Pub. L. 94–295, §5(a)(1), May 28, 1976, 90 Stat. 580; Pub. L. 105–115, title IV, §412(c), Nov. 21, 1997, 111 Stat. 2375.
13304(b)(1)	21 U.S.C. 352(e)(4)	June 25, 1938, ch. 675, §502(e)(4), as added Pub. L. 94–295, §5(a)(4), May 28, 1976, 90 Stat. 581.
13304(b)(2), (3)	21 U.S.C. 352(e)(2)	June 25, 1938, ch. 675, §502(e)(2), as added Pub. L. 94–295, §5(a)(3), May 28, 1976, 90 Stat. 580.

In subsection (a)(2), in the matter before subparagraph (A), the words "unless its label bears," are substituted for "If it is a drug, unless its label bears," to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be misbranded" as described in the previous revision note.

In subsection (a)(2)(A), the parenthetical "(as defined in subparagraph (3))" is omitted as unnecessary because of subsection (a)(1).

In subsection (b)(2), the words "if it has an established name," are substituted for "If it is a device and it has an established name," to eliminate unnecessary words because of the addition of the words "A device shall be deemed to be misbranded" as described in the previous revision note.

In subsection (b)(2), the parenthetical "(as defined in subparagraph (4))" is omitted as unnecessary because of subsection (b)(1).

SECTION 13305—DIRECTIONS FOR USE AND WARNINGS ON LABEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13305	21 U.S.C. 352(f)	June 25, 1938, ch. 675, §502(f), 52 Stat. 1051; Pub. L. 103–80, § 3(m)(2), Aug. 13, 1993, 107 Stat. 777; Pub. L. 107–250, title II, §206, Oct. 26, 2002, 116 Stat. 1613; Pub. L. 108–214, § 2(b)(2)(B), Apr. 1, 2004, 118 Stat. 575.

SECTION 13306—REPRESENTATIONS AS RECOGNIZED DRUG

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13306	21 U.S.C. 352(g)	June 25, 1938, ch. 675, §502(g), 52 Stat. 1051; Pub. L. 87–781, title I, §112(b), Oct. 10, 1962, 76 Stat. 791; Pub. L. 103–80, § 3(m)(3), Aug. 13, 1993, 107 Stat. 777.

In subsection (b), the words "for a drug described in subsection (a)" are added for clarity.

SECTION 13307—DETERIORATIVE DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13307	21 U.S.C. 352(h)	June 25, 1938, ch. 675, §502(h), 52 Stat. 1051.

In subsection (b), in the matter before paragraph (1), the words "The Secretary shall not establish any regulation under subsection (a) for any drug" are substituted for "No such regulation shall be established for any drug" for clarity.

SECTION 13308—MISLEADING CONTAINER; IMITATION; OFFERED FOR SALE UNDER ANOTHER NAME

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13308	21 U.S.C. 352(i)	June 25, 1938, ch. 675, §502(i), 52 Stat. 1051.

In paragraph (1), the words "if its container is made," are substituted for "If it is a drug and its container is so made," to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be misbranded" as described in the previous revision note.

SECTION 13309—HEALTH-ENDANGERING WHEN USED AS PRESCRIBED

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13309	21 U.S.C. 352(j)	June 25, 1938, ch. 675, §502(j), 52 Stat. 1051; Pub. L. 94–295, §3(e)(2), May 28, 1976, 90 Stat. 578.

SECTION 13310—COLOR ADDITIVES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13310	21 U.S.C. 352(m)	June 25, 1938, ch. 675, §502(m), as added Pub. L. 86–618, title I, §102(b)(2), July 12, 1960, 74 Stat. 398; Pub. L. 94–295, §9(b)(2), May 28, 1976, 90 Stat. 583; Pub. L. 102–571, title I, §107(9), Oct. 29, 1992, 106 Stat. 4499.

SECTION 13311—PRESCRIPTION DRUG ADVERTISEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13311 (except (f)(2)) ...	21 U.S.C. 352(n)	June 25, 1938, ch. 675, §502(n), as added Pub. L. 87–781, title I, §131(a), Oct. 10, 1962, 76 Stat. 791; Pub. L. 95–633, title I, § 111, Nov. 10, 1978, 92 Stat. 3773; Pub. L. 103–80, §3(m)(4), Aug. 13, 1993, 107 Stat. 777; Pub. L. 110–85, title IX, §§901(d)(3)(A), (6), 906(a), Sept. 27, 2007, 121 Stat. 940, 942, 949.
13311(f)(2)	21 U.S.C. 352 note	Pub. L. 110–85, title IX, § 901(d)(3)(B), Sept. 27, 2007, 121 Stat. 940.

In subsection (a), in the matter before paragraph (1), the words "if it is a prescription drug" are substituted for "In the case of any prescription drug" for consistency in the chapter.

In subsection (f)(2), the words "described in paragraph (1)," are substituted for "described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by subparagraph (A))" to provide a more precise reference to the pertinent provision. The provision in section 502(n) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) that relates to the manner in which a major statement relating to side effects and contraindications shall be presented is set out in the last sentence of that section 502(n). The last sentence of that section 502(n) is restated as paragraph (1) of section 13311(f) of title 21, United States Code.

SECTION 13312—DRUGS OR DEVICES FROM NONREGISTERED ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13312	21 U.S.C. 352(o)	June 25, 1938, ch. 675, §502(o), as added Pub. L. 87–781, title III, §305, Oct. 10, 1962, 76 Stat. 795; Pub. L. 94–295, §4(b)(2), May 28, 1976, 90 Stat. 580; Pub. L. 112–144, title VII, §§702(a), 714(c), July 9, 2012, 126 Stat. 1065, 1074.

In paragraph (5), the words "if it is a device and it does not" are substituted for "if it does not" for consistency in the section and in the paragraph.

SECTION 13313—PACKAGING OR LABELING OF DRUGS IN VIOLATION OF REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13313	21 U.S.C. 352(p)	June 25, 1938, ch. 675, §502(p), as added Pub. L. 91–601, § 6(d), formerly §7(d), Dec. 30, 1970, 84 Stat. 1673, renumbered Pub. L. 97–35, title XII, §1205(c), Aug. 13, 1981, 95 Stat. 716.

In this section, the words "if its packaging or labeling" are substituted for "If it is a drug and its packaging or labeling" to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be misbranded" as described in the previous revision note.

SECTION 13314—RESTRICTED DEVICES USING FALSE OR MISLEADING ADVERTISING OR USED IN VIOLATION OF REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13314	21 U.S.C. 352(q)	June 25, 1938, ch. 675, §502(q), as added Pub. L. 94–295, §3(e)(1), May 28, 1976, 90 Stat. 577.

SECTION 13315—RESTRICTED DEVICE ADVERTISEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13315	21 U.S.C. 352(r)	June 25, 1938, ch. 675, §502(r), as added Pub. L. 94–295, §§ 3(e)(1), May 28, 1976, 90 Stat. 577.

In subsection (c), the words "published after May 28, 1976," are substituted for "published after the effective date of this paragraph" for clarity.

SECTION 13316—DEVICES SUBJECT TO PERFORMANCE STANDARDS NOT BEARING REQUISITE LABELING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13316	21 U.S.C. 352(s)	June 25, 1938, ch. 675, §502(s), as added Pub. L. 94–295, §3(e)(1), May 28, 1976, 90 Stat. 578.

In this section, the words "if it is subject to a performance standard" are substituted for "If it is a device subject to a performance standard" to eliminate

unnecessary words because of the addition of the words "A device shall be deemed to be misbranded" as described in the previous revision note.

SECTION 13317—DEVICES FOR WHICH THERE HAS BEEN A FAILURE OR REFUSAL TO GIVE REQUIRED NOTIFICATION OR TO FURNISH REQUIRED MATERIAL OR INFORMATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13317	21 U.S.C. 352(t)	June 25, 1938, ch. 675, §502(t), as added Pub. L. 94–295, §3(e)(1), May 28, 1976, 90 Stat. 578; Pub. L. 102–300, §3(a)(2), June 16, 1992, 106 Stat. 239.

In this section, the words "if there was a failure or refusal" are substituted for "If it is a device and there was a failure or refusal" to eliminate unnecessary words because of the addition of the words "A device shall be deemed to be misbranded" as described in the previous revision note.

In paragraph (3), the words "respecting the device" are added for consistency with paragraphs (1) and (2).

SECTION 13318—IDENTIFICATION OF MANUFACTURER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13318(a), (b)	21 U.S.C. 352(u)	June 25, 1938, ch. 675, §502(u), as added Pub. L. 107–250, title III, §301(a), Oct. 26, 2002, 116 Stat. 1616; Pub. L. 109–43, §2(c)(1), Aug. 1, 2005, 119 Stat. 441.
13318(c)	21 U.S.C. 352 note	Pub. L. 109–43, §2(c)(2), Aug. 1, 2005, 119 Stat. 441.

In subsection (c), the words "Not later than 180 days after the date of enactment of this Act" are omitted as obsolete.

SECTION 13319—REPROCESSED SINGLE-USE DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13319	21 U.S.C. 352(v)	June 25, 1938, ch. 675, §502(v), as added Pub. L. 107–250, title III, §302(a)(1), Oct. 26, 2002, 116 Stat. 1616.

SECTION 13320—NEW ANIMAL DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13320(a)	21 U.S.C. 352(w)	June 25, 1938, ch. 675, §502(w), as added Pub. L. 108–282, title I, §102(b)(5)(E), Aug. 2, 2004, 118 Stat. 902; Pub. L. 115–234, title III, §303(a), Aug. 14, 2018, 132 Stat. 2436.
13320(b)	21 U.S.C. 352 note	Pub. L. 115–234, title III, §303(b), Aug. 14, 2018, 132 Stat. 2436.

SECTION 13321—NONPRESCRIPTION DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13321	21 U.S.C. 352(x)	June 25, 1938, ch. 675, §502(x), as added Pub. L. 109–462, §2(d), Dec. 22, 2006, 120 Stat. 3472.

SECTION 13322—DRUGS SUBJECT TO APPROVED RISK EVALUATION AND MITIGATION STRATEGY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13322	21 U.S.C. 352(y)	June 25, 1938, ch. 675, §502(y), as added Pub. L. 110–85, title IX, §902(a), Sept. 27, 2007, 121 Stat. 943.

In this section, the words "if it is subject to an approved risk evaluation and mitigation strategy" are substituted for "If it is a drug subject to an approved risk evaluation and mitigation strategy" to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be misbranded" as described in the previous revision note.

SECTION 13323—POSTMARKET STUDIES AND CLINICAL TRIALS; NEW SAFETY INFORMATION IN LABELING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13323	21 U.S.C. 352(z)	June 25, 1938, ch. 675, §502(z), as added Pub. L. 110–85, title IX, §902(a), Sept. 27, 2007, 121 Stat. 943.

In this section, the words "if the responsible person" are substituted for "If it is a drug, and the responsible person" to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be misbranded" as described in the previous revision note.

In this section, the parentheticals "(relating to postmarket studies and clinical trials)" and "(relating to labeling)" are omitted as unnecessary.

SECTION 13324—UNPAID FEES; FAILURE TO SUBMIT IDENTIFYING INFORMATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13324	21 U.S.C. 352(aa)	June 25, 1938, ch. 675, §502(aa), as added Pub. L. 112–144, title III, §306, July 9, 2012, 126 Stat. 1024; Pub. L. 112–193, § 2(a), Oct. 5, 2012, 126 Stat. 1443.

SECTION 13325—FALSE OR MISLEADING ADVERTISEMENT OR PROMOTION OF COMPOUNDED DRUG

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13325	21 U.S.C. 352(bb)	June 25, 1938, ch. 675, §502(bb), as added Pub. L. 113–54, title I, §103(b), Nov. 27, 2013, 127 Stat. 597.

In this section, the words "if it is a compounded drug and its advertising or promotion" are substituted for "If the advertising or promotion of a compounded drug" for clarity.

SECTION 13326—FAILURE TO BEAR PRODUCT IDENTIFIER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13326	21 U.S.C. 352(cc)	June 25, 1938, ch. 675, § 502(cc), as added Pub. L. 113–54, title II, §206(b), Nov. 27, 2013, 127 Stat. 639.

In this section, the words "if it fails to bear the product identifier" are substituted for "If it is a drug and it fails to bear the product identifier" to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be misbranded" as described in the previous revision note.

SECTION 13327—IMPROPER LABELING OF ANTIMICROBIAL DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13327	21 U.S.C. 352(dd)	June 25, 1938, ch. 675, § 502(dd), as added Pub. L. 114–255, div. A, title III, §3044(b)(2), Dec. 13, 2016, 130 Stat. 1121.

SECTION 13328—NONPRESCRIPTION DRUG SUBJECT TO REGULATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13328	21 U.S.C. 352(ee)	June 25, 1938, ch. 675, § 502(ee), as added Pub. L. 116–136, div. A, title III, §3852, Mar. 27, 2020, 134 Stat. 454.

SECTION 13329—DRUGS MANUFACTURED, PREPARED, PROPAGATED, COMPOUNDED, OR PROCESSED IN FACILITIES FOR WHICH FEES HAVE NOT BEEN PAID

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13329	21 U.S.C. 352(ff)	June 25, 1938, ch. 675, § 502(ff), as added Pub. L. 116–136, div. A, title III, §3852, Mar. 27, 2020, 134 Stat. 454.

In this section, the words "if it was manufactured" are substituted for "If it is a drug and it was manufactured" to eliminate unnecessary words because of the addition of the words "A drug shall be deemed to be misbranded" as described in the previous revision note.

SECTION 13330—PRODUCT INFORMATION PRIOR TO APPROVAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13330(a)	21 U.S.C. 352(gg)(2)	June 25, 1938, ch. 675, § 502(gg)(2), as added Pub. L. 117–328, div. FF, title III, §3630(a)(4), Dec. 29, 2022, 136 Stat. 5894.
13330(b)	21 U.S.C. 352(gg)(1)	June 25, 1938, ch. 675, § 502(gg)(1), as added Pub. L. 117–328, div. FF, title III, §3630(a)(4), Dec. 29, 2022, 136 Stat. 5893.

In subsection (a), in the matter before paragraph (1), the reference to "this section" is substituted for "this paragraph" to provide the correct reference to the pertinent provision. Paragraph (2) of section 502(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(gg)(2)), to which "this paragraph" refers, defines "product information" and does not contain other provisions that use the defined term. To make the defined term applicable to all relevant provisions, the restatement refers to "this section", which restates subsection (gg) of section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(gg)).

In subsection (b)(1)(B)(iii), the words "or when such a submission" are substituted for "and when such a submission" for clarity.

Chapter 135—New Drugs

SECTION 13501—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13501(1)	21 U.S.C. 355(x)(2)	June 25, 1938, ch. 675, §505(x)(2), as added Pub. L. 114–89, §2(a)(1), Nov. 25, 2015, 129 Stat. 698.
13501(2)	21 U.S.C. 355(z)	June 25, 1938, ch. 675, §505(z), as added Pub. L. 117–328, div. FF, title III, §3209(a)(2), Dec. 29, 2022, 136 Stat. 5821.
13501(3)	21 U.S.C. 355(m)	June 25, 1938, ch. 675, §505(m), as added Pub. L. 98–417, title I, §104, Sept. 24, 1984, 98 Stat. 1597; Pub. L. 106–113, div. B, § 1000(a)(9) [title IV, § 4732(b)(11)], Nov. 29, 1999, 113 Stat. 1536, 1501A–584.

SECTION 13502—NECESSITY OF EFFECTIVE APPROVAL OF APPLICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13502	21 U.S.C. 355(a)	June 25, 1938, ch. 675, §505(a), 52 Stat. 1052; Pub. L. 87–781, title I, §104(a), Oct. 10, 1962, 76 Stat. 784; Pub. L. 98–417, title I, §102(b)(1), Sept. 24, 1984, 98 Stat. 1593.

SECTION 13503—FILING APPLICATION; CONTENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13503(a) through (d) ...	21 U.S.C. 355(b)(1) through (4)	June 25, 1938, ch. 675, §505(b)(1) through (4), 52 Stat. 1052; Pub. L. 87–781, title I, §102(b), Oct. 10, 1962, 76 Stat. 781; Pub. L. 98–417, title I, §103(a), Sept. 24, 1984, 98 Stat. 1593; Pub. L. 105–115, title I, §115(b), Nov. 21, 1997, 111 Stat. 2313; Pub. L. 108–155, §2(b)(1), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 108–173, title XI, §1101(b)(1)(A), (B), Dec. 8, 2003, 117 Stat. 2452, 2453; Pub. L. 116–290, §2(a)(1), Jan. 5, 2021, 134 Stat. 4889.
13503(e)(1)	21 U.S.C. 355(b)(5)(A)	June 25, 1938, ch. 675, §505(b)(5)(A), formerly §505(b)(4)(A), as added Pub. L. 105–115, title I, §119(a), Nov. 21, 1997, 111 Stat. 2316; redesignated §505(b)(5)(A), Pub. L. 108–173, title XI, §1101(b)(1)(B)(i), Dec. 8, 2003, 117 Stat. 2453.
13503(e)(2)(A)	21 U.S.C. 355(b)(5)(G)	June 25, 1938, ch. 675, §505(b)(5)(G), formerly §505(b)(4)(G), as added Pub. L. 105–115, title I, §119(a), Nov. 21, 1997, 111 Stat. 2316; redesignated §505((b)(5)(G), Pub. L. 108–173, title XI, §1101(b)(1)(B)(i), Dec. 8, 2003, 117 Stat. 2453.
13503(e)(2)(B) through (F)	21 U.S.C. 355(b)(5)(B) through (F)	June 25, 1938, ch. 675, §505(b)(5)(B) through (F), formerly §505(b)(4)(B) through (F), as added Pub. L. 105–115, title I, §119(a), Nov. 21, 1997, 111 Stat. 2316; redesignated §505((b)(5)(B) through (F), Pub. L. 108–173, title XI, §1101(b)(1)(B)(i), Dec. 8, 2003, 117 Stat. 2453; Pub. L. 111–148, title VII, §7002(d)(1), Mar. 23, 2010, 124 Stat. 816; Pub. L. 113–5, title III, § 301, Mar. 13, 2013, 127 Stat. 179.
13503(f)	21 U.S.C. 355(b)(6)	June 25, 1938, ch. 675, §505(b)(6), as added Pub. L. 110–85, title VIII, §801(b)(3)(B), Sept. 27, 2007, 121 Stat. 921.

In subsection (b), in the matter before paragraph (1), the words "(which investigations were relied on by the applicant for approval of the application)" are substituted for "and relied upon by the applicant for approval of the application" for clarity.

In subsection (b), in the matter before paragraph (1), the words "and for which drug the applicant has not obtained a right of reference" are substituted for "and for which the applicant has not obtained a right of reference" for clarity.

In subsection (e)(2)(A), the words "In this paragraph" are substituted for "For purposes of this paragraph", even though the reference to "this paragraph" in the source law is broader than the reference to "this paragraph" in the restatement, to provide a more precise reference to the pertinent provisions. In the restatement, the reference to "this paragraph" refers to paragraph (2) of section 13503(e) of title 21, United States Code, the source provisions of which are only subparagraphs (B) through (G) of section 505(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)). In the source law, the reference to "this paragraph" refers to paragraph (5) of section 505(b) of the Act (21 U.S.C. 355(b)), which includes all subparagraphs in that paragraph.

In subsection (e)(2)(C)(i), the words "design and size of clinical trials of a new drug under this paragraph" are retained, even though the reference to "this paragraph" in the source law is broader than the reference to "this paragraph" in the restatement, to provide a more precise reference to the pertinent provisions. In the restatement, the reference to "this paragraph" refers to paragraph (2) of section 13503(e) of title 21, United States Code, the source provisions of which are only subparagraphs (B) through (G) of section 505(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)). In the source law, the reference to "this paragraph" refers to paragraph (5) of section 505(b) of the Act (21 U.S.C. 355(b)), which includes all subparagraphs in that paragraph.

In subsection (e)(2)(F), the words "ensure the marketing" are substituted for "assure the marketing" to use the more appropriate word.

SECTION 13504—PERIOD FOR APPROVAL OF APPLICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13504(a)	21 U.S.C. 355(c)(1)	June 25, 1938, ch. 675, §505(c)(1), 52 Stat. 1052; Pub. L. 87–781, title I, §104(b), Oct. 10, 1962, 76 Stat. 784; Pub. L. 98–417, title I, §102(a)(2), (b)(2), Sept. 24, 1984, 98 Stat. 1592, 1593.
13504(b)	21 U.S.C. 355(c)(2)	June 25, 1938, ch. 675, §505(c)(2), as added Pub. L. 98–417, title I, §102(a)(2), Sept. 24, 1984, 98 Stat. 1592; Pub. L. 116–290, §2(b)(1), Jan. 5, 2021, 134 Stat. 4890.
13504(c) (matter before (1))	21 U.S.C. 355(c)(3) (matter before (A))	June 25, 1938, ch. 675, §505(c)(3) (matter before (A)), as added Pub. L. 98–417, title I, §103(b), Sept. 24, 1984, 98 Stat. 1594; Pub. L. 108–173, title XI, §1101(b)(2)(A), Dec. 8, 2003, 117 Stat. 2453.
13504(c)(1) through (4)	21 U.S.C. 355(c)(3)(A) through (D)	June 25, 1938, ch. 675, §505(c)(3)(A) through (D), as added Pub. L. 98–417, title I, §103(b), Sept. 24, 1984, 98 Stat. 1594; Pub. L. 108–173, title XI, §1101(b)(2), Dec. 8, 2003, 117 Stat. 2453.
13504(c)(5)	21 U.S.C. 355(c)(3)(E)(ii) through (v)	June 25, 1938, ch. 675, §505(c)(3)(E)(ii) through (v), formerly §505(c)(3)(D)((ii) through (v), as added Pub. L. 98–417, title I, §103(b), Sept. 24, 1984, 98 Stat. 1594; redesignated §505(c)(3)(E)(ii) through (v), Pub. L. 108–173, title XI, §1101(b)(2)(C), Dec. 8, 2003, 117 Stat. 2454; Pub. L. 116–290, §2(g)(1), Jan. 5, 2021, 134 Stat. 4892; Pub. L. 117–9, §1(a)(1)(A), Apr. 23, 2021, 135 Stat. 256.
13504(d)	21 U.S.C. 355(c)(4)	June 25, 1938, ch. 675, §505(c)(4), as added Pub. L. 105–115, title I, §124(a), Nov. 21, 1997, 111 Stat. 2324.
13504(e)(1)(A)	21 U.S.C. 355(c)(5)(D)(ii)	June 25, 1938, ch. 675, §505(c)(5)(D)(ii), as added Pub. L. 114–255, div. A, title III, §3031(a), Dec. 13, 2016, 130 Stat. 1100.
13504(e)(1)(B)	21 U.S.C. 355(c)(5)(D)(i)	June 25, 1938, ch. 675, §505((c)(5)(D)(i), as added Pub. L. 114–255, div. A, title III, §3031(a), Dec. 13, 2016, 130 Stat. 1100.
13504(e)(2) through (4)	21 U.S.C. 355(c)(5)(A) through (C)	June 25, 1938, ch. 675, §505(c)(5)(A) through (C), as added Pub. L. 114–255, div. A, title III, §3031(a), Dec. 13, 2016, 130 Stat. 1099.

In subsection (c)(4)(A)(i)(III), the reference to section 13503(c) of title 21, United States Code, is a translation from the reference in the source law to paragraph (2)(B). Paragraph (2) of subsection (c) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) does not contain subparagraphs. The provision that relates to notices of noninfringement appears in subsection (b)(3) of section 505 of the Act, which is restated as section 13503(c) of title 21, United States Code.

In subsection (c)(5)(A), the words "(referred to in this subparagraph as 'approved application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (c)(5)(A): the words "for which the approved application" are substituted for "for which the subsection (b) application"; the words "5 years from the date of the approval of the approved application" are substituted for "five years from the date of the approval of the application under subsection (b)"; the words "4 years from the date of the approval of the approved application" are substituted for "four years from the date of the approval of the subsection (b) application"; the words "48 months after the date of the approval of the approved application" are substituted for "forty-eight months after the date of the approval of the subsection (b) application"; and the words "elapsed from the date of approval of the approved application" are substituted for "elapsed from the date of approval of the subsection (b) application".

In subsection (c)(5)(A), the words "(referred to in this subparagraph as 'referring application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (c)(5)(A): the words "approval of the referring application" are substituted for "approval of the application"; the words "the referring application may be submitted" are substituted for "such an application may be submitted"; the words "if the referring application contains" are substituted for "if it contains"; and the words "approval of the referring application" are substituted for "approval of such an application".

In subsection (c)(5)(B), the words "(referred to in this subparagraph as 'approved application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (c)(5)(B): the words "if the approved application contains" are substituted for "if such application contains"; the words "essential to the approval of the approved application" are substituted for "essential to the approval of the application"; the words "conditions of approval of the drug in the approved application" are substituted for "conditions of approval of such drug in the approved subsection (b) application"; and the words "3 years from the date of the approval of the approved application" are substituted for "three years from the date of the approval of the application under subsection (b)".

In subsection (c)(5)(B), the words "(referred to in this subparagraph as 'submitted application')" are added for clarity. Because of the addition of those words, the words "approval of the submitted application" are substituted for "approval of the application" in subsection (c)(5)(B).

In subsection (c)(5)(D), the words "(referred to in this subparagraph as 'approved application or supplement')" are added for clarity. Because of the addition of those words, the words "for which the approved application or supplement was submitted" are substituted for "for which the subsection (b) application was submitted" in subsection (c)(5)(D).

In subsection (c)(5)(D), the words "(referred to in this subparagraph as 'submitted application')" are added for clarity. Because of the addition of those words, the words "approval of the submitted application" are substituted for "approval of the application" in subsection (c)(5)(D).

SECTION 13505—GROUNDS FOR REFUSING TO APPROVE APPLICATION; APPROVAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13505(a)	21 U.S.C. 355(d) (3d sentence, 4th sentence)	June 25, 1938, ch. 675, §505(d) (3d sentence, 4th sentence), 52 Stat. 1052; Pub. L. 87–781, title I, §102(c), Oct. 10, 1962, 76 Stat. 781; Pub. L. 105–115, title I, §115(a), Nov. 21, 1997, 111 Stat. 2313.
13505(b), (c)	21 U.S.C. 355(d) (1st sentence, 2d sentence)	June 25, 1938, ch. 675, §505(d) (1st sentence, 2d sentence), 52 Stat. 1052; Pub. L. 87–781, title I, §102(c), Oct. 10, 1962, 76 Stat. 781; Pub. L. 98–417, title I, §102(a)(3)(A), Sept. 24, 1984, 98 Stat. 1593.
13505(d)	21 U.S.C. 355(d) (5th sentence, last sentence)	June 25, 1938, ch. 675, §505(d) (5th sentence, last sentence), as added Pub. L. 112–144, title IX, §905, July 9, 2012, 126 Stat. 1092; Pub. L. 114–255, div. A, title III, §3101(a)(2)(B)(i), Dec. 13, 2016, 130 Stat. 1153.

In subsection (a), in the matter before paragraph (1), the words "In this section" are substituted for "As used in this subsection and subsection (e)" to provide the precise reference to the pertinent provision. The reference to "this section" in the restatement is a translation from "this subsection" in the source law. The reference to "subsection (e)" in the source law is reflected in subsection (a) of section 13506 of title 21, United States Code.

In subsection (b), in the matter before paragraph (1), the words "an application under section 13503 of this title" are substituted for "the application" for clarity.

In subsection (c), the words "that paragraphs (1) through (7) of subsection (b)" are substituted for "that clauses (1) through (6)" to incorporate the amendment made by section 102(a)(3)(A) of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417, 98 Stat. 1593), which amendment added a new clause (6), and redesignated the former clause (6) as clause (7), in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)).

SECTION 13506—WITHDRAWAL OF AND SUSPENSION OF APPROVAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13506(a)	(no source)	
13506(b) through (e) ...	21 U.S.C. 355(e) (except last sentence)	June 25, 1938, ch. 675, §505(e) (except last sentence), 52 Stat. 1052; Pub. L. 87–781, title I, §102(d), Oct. 10, 1962, 76 Stat. 781; Pub. L. 92–387, §4(d), Aug. 16, 1972, 86 Stat. 562; Pub. L. 98–417, title I, §102(a)(3)(B), (b)(3), (4), Sept. 24, 1984, 98 Stat. 1593; Pub. L. 110–85, title IX, §903, Sept. 27, 2007, 121 Stat. 943.

In this section, subsection (a) is added to carry forward the 3d and 4th sentences of section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) because of the reference to "subsection (e)" in the 3d sentence of section 505(d) of that Act. See revision note for section 13505(a) of title 21, United States Code.

In subsection (b)(2), the words "considered reasonably applicable" are substituted for "deemed reasonably applicable" to use the more appropriate word.

In subsection (d)(1), the words "section 13136(j)(2) of this title" are substituted for "section 510(k)(2)" to provide the correct reference to the pertinent provision. Section 510(k)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)(2)), referred to in the source law, relates to premarket reporting, with respect to devices, of action taken to comply with certain requirements, whereas the source provision of subsection (d)(1) (section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), which makes the reference to that section 510(k)(2), relates to drugs and not to devices. Prior to the amendment of section 505(e) of the Act by paragraph (4) of section 102(b) of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417, 98 Stat. 1593), the reference in that section 505(e) was to section 510(j)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(2)). That section 510(j)(2) relates to reporting requirements with respect to drugs, and is restated as section 13136(j)(2) of title 21, United States Code. Thus, the substitution is made in subsection (d)(1), notwithstanding the amendment made by paragraph (4) of section 102(b) of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417, 98 Stat. 1593), in order to make the reference refer to reporting requirements with respect to drugs, and not with respect to devices.

In subsection (d)(1), the words "as required by section 13512(b) of this title" are substituted for "as required by paragraph (2) of such subsection" for clarity.

In subsection (d)(2), the words "ensure and preserve" are substituted for "assure and preserve" to use the more appropriate word.

SECTION 13507—REVOCATION OF ORDER REFUSING, WITHDRAWING, OR SUSPENDING APPROVAL OF APPLICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13507	21 U.S.C. 355(f)	June 25, 1938, ch. 675, §505(f), 52 Stat. 1053; Pub. L. 87–781, title I, §104(c), Oct. 10, 1962, 76 Stat. 784.

SECTION 13508—SERVICE OF ORDERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13508	21 U.S.C. 355(g)	June 25, 1938, ch. 675, §505(g), 52 Stat. 1053; Pub. L. 86–507, §1(18), June 11, 1960, 74 Stat. 201.

SECTION 13509—APPEAL FROM ORDER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13509	21 U.S.C. 355(h)	June 25, 1938, ch. 675, §505(h), 52 Stat. 1053; Pub. L. 87–781, title I, §104(d)(1), Oct. 10, 1962, 76 Stat. 784.

In subsection (b)(2), the word "immediately" is substituted for "forthwith" for consistency in title 21, United States Code.

In subsection (b)(7), the words "the original order" are substituted for "any such order" for clarity.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13510(a) through (c) ...	21 U.S.C. 355(i)(1) through (3)	June 25, 1938, ch. 675, §505(i)(1) through (3), 52 Stat. 1052; Pub. L. 87–781, title I, §103(b), Oct. 10, 1962, 76 Stat. 783; Pub. L. 105–115, title I, §117, Nov. 21, 1997, 111 Stat. 2315; Pub. L. 107–109, § 15(c)(1), Jan. 4, 2002, 115 Stat. 1420; Pub. L. 117–328, div. FF, title III, §3209(a)(1), Dec. 29, 2022, 136 Stat. 5821.
13510(d)(1)	21 U.S.C. 355(i)(4) (1st sentence)	June 25, 1938, ch. 675, §505(i)(4) (1st sentence), as added Pub. L. 105–115, title I, §117(4), Nov. 21, 1997, 111 Stat. 2315; Pub. L. 114–255, div. A, title III, §3024(b), Dec. 13, 2016, 130 Stat. 1099.
13510(d)(2)	21 U.S.C. 355(i)(4) (last sentence)	June 25, 1938, ch. 675, §505(i)(4) (last sentence), as added Pub. L. 105–115, title I, §117(4), Nov. 21, 1997, 111 Stat. 2315; as added Pub. L. 110–85, title VIII, §801(b)(3)(A), Sept. 27, 2007, 121 Stat. 921.
13510(e)	21 U.S.C. 355(i)(4) (2d sentence)	June 25, 1938, ch. 675, §505(i)(4) (2d sentence), as added Pub. L. 105–115, title I, §117(4), Nov. 21, 1997, 111 Stat. 2315.

In subsection (a)(1), the words "sections 13502 through 13509 of this title" are substituted for "the foregoing subsections of this section" for clarity.

In subsection (a)(2), in the matter before subparagraph (A), the words "In the regulations, the Secretary may provide for, among other conditions relating to the protection of public health, conditioning the exemption on" are substituted for "Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon" for clarity.

In subsection (c)(2)(A), in the matter before clause (i), the words "safety of the individuals" are substituted for "safety of the persons" for clarity and consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (d)(2), the words "The Secretary shall require in the regulations under subsection (a) the inclusion," are substituted for "The Secretary shall update such regulations to require inclusion" to eliminate obsolete words.

SECTION 13511—ABBREVIATED NEW DRUG APPLICATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13511(a)(1)(A), (B)	21 U.S.C. 355(j)(8)(A)	June 25, 1938, ch. 675, §505(j)(8)(A), formerly §505(j)(7), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(8), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1103(a)(1), Dec. 8, 2003, 117 Stat. 2460.
13511(a)(1)(C)	21 U.S.C. 355 note	Pub. L. 108–173, title XI, §1103(b) (relating to amendment made by subsection (a)(1)), Dec. 8, 2003, 117 Stat. 2461.
13511(a)(2)(A)	21 U.S.C. 355(j)(8)(B)	June 25, 1938, ch. 675, §505(j)(8)(B), formerly §505(j)(7), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(8), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317.
13511(a)(2)(B)(i)	21 U.S.C. 355(j)(8)(C)	June 25, 1938, ch. 675, §505(j)(8)(C), as added Pub. L. 108–173, title XI, §1103(a)(2), Dec. 8, 2003, 117 Stat. 2460.
13511(a)(2)(B)(ii)	21 U.S.C. 355 note	Pub. L. 108–173, title XI, §1103(b) (relating to amendment made by subsection (a)(2)), Dec. 8, 2003, 117 Stat. 2461.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13511(a)(3)	21 U.S.C. 355(j)(2)(A)(i) ("(hereinafter in this subsection referred to as a `listed drug')")	June 25, 1938, ch. 675, §505(j)(2)(A)(i) ("(hereinafter in this subsection referred to as a `listed drug')"), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585.
13511(b)	21 U.S.C. 355(j)(1)	June 25, 1938, ch. 675, §505(j)(1), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585.
13511(c)(1) (matter before (A))	21 U.S.C. 355(j)(2)(A) (matter before (i))	June 25, 1938, ch. 675, §505(j)(2)(A) (matter before (i)), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585.
13511(c)(1)(A)	21 U.S.C. 355(j)(2)(A)(i) (except "(hereinafter in this subsection referred to as a `listed drug')")	June 25, 1938, ch. 675, §505(j)(2)(A)(i) (except "(hereinafter in this subsection referred to as a `listed drug')"), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585.
13511(c)(1)(B) through (H)	21 U.S.C. 355(j)(2)(A)(ii) through (viii)	June 25, 1938, ch. 675, §505(j)(2)(A)(ii) through (viii), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; Pub. L. 116–290, §2(g)(2), Jan. 5, 2021, 134 Stat. 4893.
13511(c)(2)	21 U.S.C. 355(j)(2)(A) (matter after (viii))	June 25, 1938, ch. 675, §505(j)(2)(A) (matter after (viii)), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585.
13511(c)(3)	21 U.S.C. 355(j)(2)(B)	June 25, 1938, ch. 675, §505(j)(2)(B), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; Pub. L. 108–173, title XI, §1101(a)(1)(A), Dec. 8, 2003, 117 Stat. 2448.
13511(c)(4)	21 U.S.C. 355(j)(2)(C)	June 25, 1938, ch. 675, §505(j)(2)(C), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585.
13511(c)(5)	21 U.S.C. 355(j)(2)(D)	June 25, 1938, ch. 675, §505(j)(2)(D), as added Pub. L. 108–173, title XI, §1101(a)(1)(B), Dec. 8, 2003, 117 Stat. 2449.
13511(d)(1)	21 U.S.C. 355(j)(3)(A)	June 25, 1938, ch. 675, §505(j)(3)(A), as added Pub. L. 105–115, title I, §119(b)(1)(B), Nov. 21, 1997, 111 Stat. 2317.
13511(d)(2)(A)	21 U.S.C. 355(j)(3)(G)	June 25, 1938, ch. 675, §505(j)(3)(G), as added Pub. L. 105–115, title I, §119(b)(1)(B), Nov. 21, 1997, 111 Stat. 2317.
13511(d)(2)(B) through (F)	21 U.S.C. 355(j)(3)(B) through (F)	June 25, 1938, ch. 675, §505(j)(3)(B) through (F), as added Pub. L. 105–115, title I, §119(b)(1)(B), Nov. 21, 1997, 111 Stat. 2317.
13511(e)	21 U.S.C. 355(j)(4)	June 25, 1938, ch. 675, §505(j)(4), formerly §505(j)(3), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1587; redesignated §505(j)(4), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317.
13511(f)(1)	21 U.S.C. 355(j)(5)(A)	June 25, 1938, ch. 675, §505(j)(5)(A), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1587; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317.
13511(f)(2) (matter before (A))	21 U.S.C. 355(j)(5)(B) (matter before (i))	June 25, 1938, ch. 675, §505(j)(5)(B) (matter before (i)), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1587; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1102(a)(2)(A)(i), Dec. 8, 2003, 117 Stat. 2449.
13511(f)(2)(A), (B)	21 U.S.C. 355(j)(5)(B)(i), (ii)	June 25, 1938, ch. 675, §505(j)(5)(B)(i), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1587; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317.
13511(f)(2)(C)(i), (ii) ..	21 U.S.C. 355(j)(5)(B)(iii) (except matter after (IV))	June 25, 1938, ch. 675, §505(j)(5)(B)(iii) (except matter after (IV)), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1101(a)(2)(A)(ii) (except (II)(ee)), Dec. 8, 2003, 117 Stat. 2449.
13511(f)(2)(C)(iii)	21 U.S.C. 355(j)(5)(B)(iii) (matter after (IV))	June 25, 1938, ch. 675, §505(j)(5)(B)(iii) (matter after (IV)), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5), Pub. L. 105–115, title I,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1101(a)(2)(A)(ii)(II)(ee), Dec. 8, 2003, 117 Stat. 2449.
13511(f)(2)(D)(i)(I)	21 U.S.C. 355(j)(5)(B)(iv)(II)(aa)	June 25, 1938, ch. 675, §505(j)(5)(B)(iv)(II)(aa), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1102(a)(1), Dec. 8, 2003, 117 Stat. 2457.
13511(f)(2)(D)(i)(II) ...	21 U.S.C. 355(j)(5)(B)(iv)(II)(dd)	June 25, 1938, ch. 675, §505(j)(5)(B)(iv)(II)(dd), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1102(a)(1), Dec. 8, 2003, 117 Stat. 2457.
13511(f)(2)(D)(ii)(I)	21 U.S.C. 355(j)(5)(B)(iv)(II)(bb)	June 25, 1938, ch. 675, §505(j)(5)(B)(iv)(II)(bb), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1102(a)(1), Dec. 8, 2003, 117 Stat. 2457.
13511(f)(2)(D)(ii)(II) ..	21 U.S.C. 355(j)(5)(B)(iv)(II)(cc)	June 25, 1938, ch. 675, §505(j)(5)(B)(iv)(II)(cc), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1102(a)(1), Dec. 8, 2003, 117 Stat. 2457.
13511(f)(2)(D)(iii)	21 U.S.C. 355(j)(5)(B)(iv)(I)	June 25, 1938, ch. 675, §505(j)(5)(B)(iv)(I), formerly §505(j)(4), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 108–173, title XI, §1102(a)(1), Dec. 8, 2003, 117 Stat. 2457.
13511(f)(2)(E)(i)	21 U.S.C. 355(j)(5)(B)(v)(III)	June 25, 1938, ch. 675, §505(j)(5)(B)(v)(III), formerly §505(j)(4), as added Pub. L. 115–52, title VIII, §808(1), Aug. 18, 2017, 131 Stat. 1074.
13511(f)(2)(E)(ii), (iii)	21 U.S.C. 355(j)(5)(B)(v)(I), (II)	June 25, 1938, ch. 675, §505(j)(5)(B)(v)(I), (II), formerly §505(j)(4), as added Pub. L. 115–52, title VIII, §808(1), Aug. 18, 2017, 131 Stat. 1074.
13511(f)(3)	21 U.S.C. 355(j)(5)(C)	June 25, 1938, ch. 675, §505(j)(5)(C), as added Pub. L. 108–173, title XI, §1101(a)(2)(C), Dec. 8, 2003, 117 Stat. 2450.
13511(f)(4)(A)(i)	(no source)	
13511(f)(4)(A)(ii)	21 U.S.C. 355(j)(5)(D)(i)	June 25, 1938, ch. 675, §505(j)(5)(D)(i), as added Pub. L. 108–173, title XI, §1102(a)(2), Dec. 8, 2003, 117 Stat. 2458.
13511(f)(4)(B)	21 U.S.C. 355(j)(5)(D)(ii)	June 25, 1938, ch. 675, §505(j)(5)(D)(ii), as added Pub. L. 108–173, title XI, §1102(a)(2), Dec. 8, 2003, 117 Stat. 2458.
13511(f)(4)(C)	21 U.S.C. 355(j)(5)(D)(iii)	June 25, 1938, ch. 675, §505(j)(5)(D)(iii), as added Pub. L. 108–173, title XI, §1102(a)(2), Dec. 8, 2003, 117 Stat. 2458.
13511(f)(4)(D)	21 U.S.C. 355(j)(5)(D)(iv)	June 25, 1938, ch. 675, §505(j)(5)(D)(iv), as added Pub. L. 115–52, title VIII, §808(2), Aug. 18, 2017, 131 Stat. 1075.
13511(f)(5)	21 U.S.C. 355(j)(5)(E)	June 25, 1938, ch. 675, §505(j)(5)(E), formerly §505(j)(4)(C), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(5)(C), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; redesignated §505(j)(5)(E), Pub. L. 108–173, title XI, §1101(a)(2)(B), Dec. 8, 2003, 117 Stat. 2450.
13511(f)(6)	21 U.S.C. 355(j)(5)(F)(ii) through (v)	June 25, 1938, ch. 675, §505(j)(5)(F)(ii) through (v), formerly §505(j)(4)(D)(ii) through (v), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1590; redesignated §505(j)(5)(D)(ii) through (v), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; redesignated §505(j)(5)(F)(ii) through (v), Pub. L. 108–173, title XI, §1101(a)(2)(B), Dec. 8, 2003, 117 Stat. 2450; Pub. L. 117–9, §1(a)(1)(B), Apr. 23, 2021, 135 Stat. 256.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13511(g)	21 U.S.C. 355(j)(6)	June 25, 1938, ch. 675, §505(j)(6), formerly §505(j)(5), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; redesignated §505(j)(6), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317.
13511(h)	21 U.S.C. 355(j)(7)	June 25, 1938, ch. 675, §505(j)(7), formerly §505(j)(6), as added Pub. L. 98–417, title I, §101, Sept. 24, 1984, 98 Stat. 1585; Pub. L. 103–80, § 3(n)(1), Aug. 13, 1993, 107 Stat. 777; redesignated §505(j)(7), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317; Pub. L. 116–290, §2(b)(2), (d)(1), Jan. 5, 2021, 134 Stat. 4890, 4891; Pub. L. 117–328, div. FF, title III, §3222, Dec. 29, 2022, 136 Stat. 5829.
13511(i)	21 U.S.C. 355(j)(9)	June 25, 1938, ch. 675, §505(j)(9), formerly §505(j)(8), as added Pub. L. 102–282, §5, May 13, 1992, 106 Stat. 161; redesignated §505(j)(9), Pub. L. 105–115, title I, §119(b)(1)(A), Nov. 21, 1997, 111 Stat. 2317.
13511(j)	21 U.S.C. 355(j)(10)	June 25, 1938, ch. 675, §505(j)(10), as added Pub. L. 111–148, title X, §10609, Mar. 23, 2010, 124 Stat. 1014; Pub. L. 117–328, div. FF, title III, §3224, Dec. 29, 2022, 136 Stat. 5831.
13511(k), (l)	21 U.S.C. 355(j)(11), (12)	June 25, 1938, ch. 675, §505(j)(11), (12), as added Pub. L. 115–52, title VIII, §801, Aug. 18, 2017, 131 Stat. 1068.
13511(m)	21 U.S.C. 355(j)(13)	June 25, 1938, ch. 675, §505(j)(13), as added Pub. L. 115–52, title VIII, §802, Aug. 18, 2017, 131 Stat. 1069.

In subsection (a)(1)(C), the words "This paragraph" are substituted for "The amendment made by subsection (a)" for clarity.

In subsection (a)(2)(B)(ii), the words "This subparagraph" are substituted for "The amendment made by subsection (a)" for clarity.

In subsection (c)(5)(C), the words "Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," are omitted as obsolete.

In subsection (d)(2)(A), the words "In this paragraph" are substituted for "For purposes of this paragraph", even though the reference to "this paragraph" in the source law is broader than the reference to "this paragraph" in the restatement, to provide a more precise reference to the pertinent provision. In the restatement, the reference to "this paragraph" refers to paragraph (2) of section 13511(d) of title 21, United States Code, the source provisions of which are only subparagraphs (B) through (G) of section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)). In the source law, the reference to "this paragraph" refers to paragraph (3) of section 505(j) of the Act (21 U.S.C. 355(j)), which includes all subparagraphs in that paragraph.

In subsection (d)(2)(C)(i), the words "design and size of bioavailability and bioequivalence studies of a drug under this paragraph" are retained, even though the reference to "this paragraph" in the source law is broader than the reference to "this paragraph" in the restatement, to provide a more precise reference to the pertinent provision. In the restatement, the reference to "this paragraph" refers to paragraph (2) of section 13511(d) of title 21, United States Code, the source provisions of which are only subparagraphs (B) through (G) of section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)). In the source

law, the reference to "this paragraph" refers to paragraph (3) of section 505(j) of the Act (21 U.S.C. 355(j)), which includes all subparagraphs in that paragraph.

In subsection (d)(2)(F), the words "ensure the marketing" are substituted for "assure the marketing" to use the more appropriate word.

In subsection (e)(1), the words "ensure and preserve" are substituted for "assure and preserve" to use the more appropriate word.

In subsection (e)(9)(A), the words "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" are substituted for "has been withdrawn or suspended for grounds described in the first sentence of subsection (e)" because of the structure of the restatement of subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). See section 13506 of title 21, United States Code.

In subsection (e)(9)(B), the words "for grounds described in section 13506(b) of this title" are substituted for "for grounds described in the first sentence of subsection (e)" to provide a more precise reference to the pertinent provision. The reference to the "first sentence of subsection (e)" in the source law is broader than the reference to "section 13506(b) of this title" because section 13506(b) of title 21, United States Code, restates only part of the first sentence of subsection (e) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). The proviso in the first sentence of subsection (e) of section 505 of the Act, which relates to grounds for suspension of approval, is restated as section 13506(c) of title 21, United States Code.

In subsection (f)(2)(C)(i)(II), the words "later determines to be a substantially complete application" are substituted for "later determines to be substantially complete" for consistency with the defined term "substantially complete application" in item (cc) of section 505(j)(5)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)(II)), which is restated as subclause (II) of section 13511(f)(2)(D)(ii) of title 21, United States Code. See revision note that follows for addition of clarifying parenthetical after the defined term "substantially complete application" in the restatement.

In subsection (f)(2)(C)(i)(II), the parenthetical "(as defined in subparagraph (D)(ii)(II)" is added because the applicability of the defined term "substantially complete application" in item (cc) of section 505(j)(5)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)(II)) is made narrower in the restatement of that item. See restatement of that item in subclause (II) of section 13511(f)(2)(D)(ii) of title 21, United States Code, which restatement substitutes "In subclause (I)" for "As used in this subsection". The addition of the parenthetical supports the substitution described in the immediately preceding revision note.

In subsection (f)(2)(D)(ii)(I), the words "In this subparagraph" are substituted for "As used in this subsection" because the structure of the restatement is made to make the defined term closer to the provisions to which it applies, for clarity. The defined term "first applicant" appears only in subparagraphs (B)(iv) and (D) of section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)). Those subparagraphs are restated in subparagraph (D) of section 13511(f)(2) of title 21, United States Code, and in paragraph (4) of section 13511(f) of title 21, United States Code, respectively. For clarity, the defined term is restated only in that subparagraph (D) (to which "this subparagraph"

refers) and is carried forward in that paragraph (4) (see paragraph (4)(A)(i) of section 13511(f) of title 21, United States Code).

In subsection (f)(2)(D)(ii)(II), the words "In subclause (I)" are substituted for "As used in this subsection" to provide a more precise reference to the pertinent provision. The term "substantially complete application" appears only in item (bb) of section 505(j)(5)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)(II)), which is restated as subclause (I) of section 13511(f)(2)(D)(ii) of title 21, United States Code. For additional applicability of the defined term "substantially complete application" in the restatement, see revision notes above for subsection (f)(2)(C)(i)(II).

In subsection (f)(4)(A)(i), a definition of "first applicant" is added to carry forward the applicability of the defined term "first applicant" to subsection (f)(4). See revision note for subsection (f)(2)(D)(ii)(I) above.

In subsection (f)(6)(A), the words "(referred to in this subparagraph as 'approved application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (f)(6)(A): the words "for which the approved application was submitted" are substituted for "for which the subsection (b) application"; the words "5 years from the date of the approval of the approved application" are substituted for "five years from the date of the approval of the application under subsection (b)"; the words "4 years from the date of the approval of the approved application" are substituted for "four years from the date of the approval of the subsection (b) application"; the words "48 months after the date of the approval of the approved application" are substituted for "forty-eight months after the date of the approval of the subsection (b) application"; and the words "elapsed from the date of approval of the approved application" are substituted for "elapsed from the date of approval of the subsection (b) application".

In subsection (f)(6)(A), the words "(referred to in this subparagraph as 'referring application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (f)(6)(A): the words "the referring application may" are substituted for "such an application may"; the words "if the referring application contains" are substituted for "if it contains"; and the words "The approval of the referring application" are substituted for "The approval of such an application".

In subsection (f)(6)(B), the words "(referred to in this subparagraph as 'approved application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (c)(5)(B): the words "if the approved application contains" are substituted for "if such application contains"; the words "essential to the approval of the approved application" are substituted for "essential to the approval of the application"; the words "conditions of approval of the drug in the approved application" are substituted for "conditions of approval of such drug in the subsection (b) application"; and the words "3 years from the date of the approval of the approved application" are substituted for "three years from the date of the approval of the application under subsection (b)".

In subsection (f)(6)(D), the words "(referred to in this subparagraph as 'approved application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (f)(6)(D): the words "for which the approved application" are substituted for "for which the subsection (b) application"; and the words "supplement to the approved application" are substituted for "supplement to the subsection (b) application".

In subsection (g), in the matter before paragraph (1), the words "withdrawn for grounds described in section 13506(b) of this title or suspended for grounds described in section 13506(c) of this title" are substituted for "withdrawn or suspended for grounds described in the first sentence of subsection (e)" for clarity.

In subsection (g)(1), the words "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" are substituted for "for the same period as the withdrawal or suspension under subsection (e) or this paragraph" for clarity and consistency in the paragraph.

In subsection (h)(1)(A), in the matter before clause (i), the words "Within sixty days of the date of the enactment of this subsection," are omitted as obsolete.

In subsection (h)(1)(E)(i)(I), the words "if the request" are substituted for "provided that the request" for consistency in title 21, United States Code.

In subsection (h)(1)(E)(i)(II), in the matter before item (aa), the words "and if—" are substituted for "provided that—" for consistency in title 21, United States Code.

In subsection (h)(3)(A), in the matter before clause (i), the words "withdrawn for grounds described in section 13506(b) of this title or suspended for grounds described in section 13506(c) of this title" are substituted for "withdrawn or suspended for grounds described in the first sentence of subsection (e)" for clarity.

In subsection (h)(3)(A)(i), the words "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)" are substituted for "for the same period as the withdrawal or suspension under subsection (e) or paragraph (6)" for clarity and consistency in the subparagraph.

SECTION 13512—RECORDS AND REPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13512(a) through (e) ...	21 U.S.C. 355(k)	June 25, 1938, ch. 675, §505(k), formerly §505(j), as added Pub. L. 87–781, title I, §103(a), Oct. 10, 1962, 76 Stat. 782; redesignated §505(k), Pub. L. 98–417, title I, §§101, 102(b)(5), Sept. 24, 1984, 98 Stat. 1585, 1593; Pub. L. 103–80, §3(n)(2), Aug. 13, 1993, 107 Stat. 777; Pub. L. 110–85, title IX, §§905(a), 921, Sept. 27, 2007, 121 Stat. 944, 962; Pub. L. 114–255, div. A, title III, §§3075(a), 3102(1), Dec. 13, 2016, 130 Stat. 1138, 1156; Pub. L. 115–52, title IX, §901(a), Aug. 18, 2017, 131 Stat. 1076.
13512(f)	21 U.S.C. 355 note	Pub. L. 110–85, title IX, §905(b), Sept. 27, 2007, 121 Stat. 949.

In subsection (a)(2)(B), the words "considers it to be appropriate" are substituted for "deems it to be appropriate" to use the more appropriate word.

In subsection (c)(1)(D), the words "considered appropriate" are substituted for "deemed appropriate" to use the more appropriate word.

In subsection (c)(2), in the matter before subparagraph (A), the words "not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007," are omitted as obsolete.

In subsection (c)(3)(A)(iii)(III), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

In subsection (d)(4)(A), in the matter before clause (i), the words "Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection," are omitted as obsolete.

In subsection (d)(4)(A)(v), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

In subsection (d)(6)(B)(v), the words "the Secretary considers necessary" are substituted for "the Secretary deems necessary" to use the more appropriate word.

In subsection (d)(8), the words "section 132 of title 41" are substituted for "section 4(5) of the Federal Procurement Policy Act" on authority of section 6(c) of Public Law 111–350 (124 Stat. 3854), which Act enacted title 41, United States Code.

In subsection (d)(10), the words "shall coordinate activities with private entities," are substituted for "shall coordinate with the activities of private entities," for clarity.

In subsection (f), the words "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)" are substituted for "Nothing in this section or the amendment made by this section" for clarity.

SECTION 13513—PUBLIC DISCLOSURE OF SAFETY AND EFFECTIVENESS DATA AND ACTION PACKAGE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13513	21 U.S.C. 355(l)	June 25, 1938, ch. 675, §505(l), as added Pub. L. 98–417, title I, §104, Sept. 24, 1984, 98 Stat. 1597; Pub. L. 110–85, §916, Sept. 27, 2007, 121 Stat. 958; Pub. L. 117–9, §1(a)(1)(C), Apr. 23, 2021, 135 Stat. 256.

In subsection (b)(1)(A), in the matter before clause (i), the word "application" is substituted for "applications" for consistency in the subparagraph.

SECTION 13514—SCIENTIFIC ADVISORY PANELS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13514	21 U.S.C. 355(n) (except (2))	June 25, 1938, ch. 675, §505(n) (except (2)), as added Pub. L. 105–115, title I, §120, Nov. 21, 1997, 111 Stat. 2318; Pub. L. 110–85, title VII, §701(b), Sept. 27, 2007, 121 Stat. 903.

In subsection (b)(3), the words "full-time employ of the Federal Government" are substituted for "full-time employ of the United States" for consistency in title 21, United States Code.

In subsection (b)(4), the word "chairperson" is substituted for "chairman" for gender neutrality.

In subsection (d)(1), in the parenthetical, the words "Federal Government" are substituted for "United States" for consistency in title 21, United States Code.

In subsection (d)(1), the words "of attendance or engagement" are substituted for "so engaged" for clarity and consistency in the paragraph.

In subsection (d)(2), the words "individuals in the Government service" are substituted for "persons in the Government service" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

SECTION 13515—POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING CHANGES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13515(a) (matter before (1))	21 U.S.C. 355(o)(2) (matter before (A))	June 25, 1938, ch. 675, §505(o)(2) (matter before (A)), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(a)(1)	21 U.S.C. 355(o)(2)(B)	June 25, 1938, ch. 675, §505(o)(2)(B), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(a)(2)	21 U.S.C. 355(o)(2)(C) (relating to new safety information)	June 25, 1938, ch. 675, §505(o)(2)(C) (relating to new safety information), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(a)(3)	21 U.S.C. 355(o)(2)(A)	June 25, 1938, ch. 675, §505(o)(2)(A), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(a)(4)	21 U.S.C. 355(o)(2)(C) (relating to serious risk)	June 25, 1938, ch. 675, §505(o)(2)(C) (relating to serious risk), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(a)(5)	21 U.S.C. 355(o)(2)(C) (relating to signal of a serious risk)	June 25, 1938, ch. 675, §505(o)(2)(C) (relating to signal of a serious risk), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(b)	21 U.S.C. 355(o)(1)	June 25, 1938, ch. 675, §505(o)(1), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(c)	21 U.S.C. 355(o)(3)	June 25, 1938, ch. 675, §505(o)(3), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.
13515(d)	21 U.S.C. 355(o)(4)	June 25, 1938, ch. 675, §505(o)(4), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922; Pub. L. 115–271, title III, §3041(b), Oct. 24, 2018, 132 Stat. 3942.
13515(e)	21 U.S.C. 355(o)(5)	June 25, 1938, ch. 675, §505(o)(5), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.

In subsection (c)(1), the words "data considered appropriate" are substituted for "data deemed appropriate" to use the more appropriate word.

In subsection (c)(5)(A), the words "section 101(c) of the Prescription Drug User Fee Amendments of 2007 (Public Law 110–85, title I, 121 Stat. 825)" are substituted for "section 101(c) of the Food and Drug Administration Amendments Act of 2007" to provide a more precise reference to the pertinent provision. The short title for title I of the Food and Drug Administration Amendments Act of 2007 is Prescription Drug User Fee Amendments of 2007, and section 101(c) is under that title.

In subsection (d)(5)(A), the words "as the Secretary considers appropriate" are substituted for "as the Secretary deems appropriate" to use the more appropriate word.

SECTION 13516—RISK EVALUATION AND MITIGATION STRATEGY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13516	21 U.S.C. 355(p)	June 25, 1938, ch. 675, §505(p), as added Pub. L. 110–85, title IX, §901(a), Sept. 27, 2007, 121 Stat. 922.

SECTION 13517—PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13517(a)	21 U.S.C. 355(q)(5)	June 25, 1938, ch. 675, §505(q)(5), as added Pub. L. 110–85, title IX, §914(a), Sept. 27, 2007, 121 Stat. 953; Pub. L. 112–144, title XI, §1135(4), July 9, 2012, 126 Stat. 1123; Pub. L. 114–255, div. A, title III, §3101(a)(2)(B)(ii), Dec. 13, 2016, 130 Stat. 1153.
13517(b) through (e) ...	21 U.S.C. 355(q)(1) through (4)	June 25, 1938, ch. 675, §505(q)(1) through (4), as added Pub. L. 110–85, title IX, §914(a), Sept. 27, 2007, 121 Stat. 953; Pub. L. 110–316, title III, §301, Aug. 14, 2008, 122 Stat. 3524; Pub. L. 112–144, title XI, §1135(1) through (3), July 9, 2012, 126 Stat. 1123.

In subsection (b)(1)(A), in the matter before clause (i), the words "pending application" are substituted for "pending application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act" to eliminate unnecessary words because of the definition of "application" in subsection (a)(1).

In paragraphs (2) and (4) of subsection (d), the words "during the 12-month period" are substituted for "during such period" for clarity.

SECTION 13518—POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13518	21 U.S.C. 355(r) (except (4))	June 25, 1938, ch. 675, §505(r) (except (4)), as added Pub. L. 110–85, title IX, §915, Sept. 27, 2007, 121 Stat. 957; Pub. L. 114–255, div. A, title III, §3075(b), Dec. 13, 2016, 130 Stat. 1138.

In subsection (a), in the matter before paragraph (1), the words "Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007," are omitted as obsolete.

In subsection (c), the words "developed and maintained" are substituted for "established" for consistency with subsection (a).

In subsection (e)(1), the words the words "developed and maintained" are substituted for "established" for consistency with subsection (a).

SECTION 13519—REFERRAL TO ADVISORY COMMITTEE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13519	21 U.S.C. 355(s)	June 25, 1938, ch. 675, §505(s), as added Pub. L. 110–85, title IX, §918, Sept. 27, 2007, 121 Stat. 960; Pub. L. 117–9, §1(a)(1)(D), Apr. 23, 2021, 135 Stat. 256.

In paragraph (1), in the matter before subparagraph (A), the words "approval of the drug or biological product" are substituted for "approval of such drug or biological" for consistency in the subsection.

SECTION 13520—DATABASE FOR AUTHORIZED GENERIC DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13520(a)	21 U.S.C. 355(t)(3)	June 25, 1938, ch. 675, §505(t)(3), as added Pub. L. 110–85, title IX, §920, Sept. 27, 2007, 121 Stat. 961.
13520(b)	21 U.S.C. 355(t)(1)	June 25, 1938, ch. 675, §505(t)(1), as added Pub. L. 110–85, title IX, §920, Sept. 27, 2007, 121 Stat. 961.
13520(c)	21 U.S.C. 355(t)(2)	June 25, 1938, ch. 675, §505(t)(2), as added Pub. L. 110–85, title IX, §920, Sept. 27, 2007, 121 Stat. 961.

In subsection (a), in the matter before paragraph (1), the words "In this section" are retained even though the reference to "this section" in the source provision is broader than the reference to "this section" in the restatement. The defined term "authorized generic drug" appears only in section 13520 of title 21, United States Code, the source law of which is subsection (t) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and does not appear anywhere else in that section.

In subsection (b)(1)(A), the words "not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007," are omitted as obsolete.

SECTION 13521—CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13521(a)	21 U.S.C. 355(u)(3)	June 25, 1938, ch. 675, §505(u)(3), as added Pub. L. 110–85, title XI, §1113, Sept. 27, 2007, 121 Stat. 976.
13521(b)	21 U.S.C. 355(u)(1)	June 25, 1938, ch. 675, §505(u)(1), as added Pub. L. 110–85, title XI, §1113, Sept. 27, 2007, 121 Stat. 976; Pub. L. 112–144, title XI, §1101(b), July 9, 2012, 126 Stat. 1108; Pub. L. 117–9, §1(a)(1)(E), Apr. 23, 2021, 135 Stat. 257; Pub. L. 117–328, div. FF, title III, §3105(1), Dec. 29, 2022, 136 Stat. 5807.
13521(c)	21 U.S.C. 355(u)(2)	June 25, 1938, ch. 675, §505(u)(2), as added Pub. L. 110–85, title XI, §1113, Sept. 27, 2007, 121 Stat. 976.
13521(d)	21 U.S.C. 355(u)(4)	June 25, 1938, ch. 675, §505(u)(4), as added Pub. L. 110–85, title XI, §1113, Sept. 27, 2007, 121 Stat. 976; Pub. L. 112–144, title XI, §1101(a), July 9, 2012, 126 Stat. 1108; Pub. L. 115–52, title VI, §601, Aug. 18, 2017, 131 Stat. 1048; Pub. L. 117–180, div. F, title V, §5004, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, §305, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3105(2), Dec. 29, 2022, 136 Stat. 5807.

SECTION 13522—ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13522	21 U.S.C. 355(v)	June 25, 1938, ch. 675, §505(v), as added Pub. L. 110–379, § 4(a), Oct. 8, 2008, 122 Stat. 4076.

In subsection (a)(1) and (b)(1), the words "Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law," are retained and a reference to chapter 403 of title 21, United States Code, is not added even though that chapter restates certain provisions of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2296), because of the words "any other provision of law" and because nothing in that chapter 403 purports to affect exclusivity periods relating to drugs containing antibiotic drugs.

In subsection (d), the words "Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law," are retained and a reference to chapter 403 of title 21, United States Code, is not added even though that chapter restates certain provisions of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2296), because of the words "any other provision of law".

SECTION 13523—DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13523	21 U.S.C. 355(w)	June 25, 1938, ch. 675, §505(w), as added Pub. L. 112–144, title XI, §1134(a), July 9, 2012, 126 Stat. 1123.

SECTION 13524—DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER DIVISION A OF SUBTITLE V OF THIS TITLE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13524	21 U.S.C. 355(x)(1)	June 25, 1938, ch. 675, §505(x)(1), as added Pub. L. 114–89, §2(a)(1), Nov. 25, 2015, 129 Stat. 698.

SECTION 13525—CONTRAST AGENTS INTENDED FOR USE WITH APPLICABLE MEDICAL IMAGING DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13525	21 U.S.C. 355(y)	June 25, 1938, ch. 675, §505(y), as added Pub. L. 115–52, title VII, §706(b), Aug. 18, 2017, 131 Stat. 1059.

SECTION 13526—DIVERSITY ACTION PLAN FOR CLINICAL STUDIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13526	21 U.S.C. 355(z)	June 25, 1938, ch. 675, §505(z), as added Pub. L. 117–328, div. FF, title III, §3601(a), Dec. 29, 2022, 136 Stat. 5860.

Chapter 137—New Animal Drugs

SECTION 13701—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13701(1)	21 U.S.C. 360b(q)(2)	June 25, 1938, ch. 675, §512(q)(2), as added Pub. L. 114–89, §2(a)(3)(A), Nov. 25, 2015, 129 Stat. 699.
13701(2)	21 U.S.C. 360b(o)	June 25, 1938, ch. 675, §512(o), as added Pub. L. 100–670, title I, §101(b), Nov. 16, 1988, 102 Stat. 3975; Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4732(b)(11)], Nov. 29, 1999, 113 Stat. 1536, 1501A–584.
13701(3)	21 U.S.C. 360b(d)(3)	June 25, 1938, ch. 675, §512(d)(3), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 345; Pub. L. 104–250, §2(a), Oct. 9, 1996, 110 Stat. 3151.

SECTION 13702—UNSAFE NEW ANIMAL DRUGS AND ANIMAL FEED

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13702(a) through (e) ...	21 U.S.C. 360b(a)(1) through (5)	June 25, 1938, ch. 675, §512(a)(1) through (5), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §107(a)(2), Nov. 16, 1988, 102 Stat. 3984; Pub. L. 103–396, §2(a), Oct. 22, 1994, 108 Stat. 4153; Pub. L. 104–250, §6(a), Oct. 9, 1996, 110 Stat. 3157; Pub. L. 108–282, title I, §102(b)(5)(I), Aug. 2, 2004, 118 Stat. 892, 903; Pub. L. 114–255, div. A, title III, §3088(b), Dec. 13, 2016, 130 Stat. 1149.
13702(f)(1)	21 U.S.C. 360b(a)(6) (4th sentence)	June 25, 1938, ch. 675, §512(a)(6) (4th sentence), as added Pub. L. 104–250, §4, Oct. 9, 1996, 110 Stat. 3155.
13702(f)(2)	21 U.S.C. 360b(a)(6) (1st sentence)	June 25, 1938, ch. 675, §512(a)(6) (1st sentence), as added Pub. L. 104–250, §4, Oct. 9, 1996, 110 Stat. 3155.
13702(f)(3)	21 U.S.C. 360b(a)(6) (2d sentence)	June 25, 1938, ch. 675, §512(a)(6) (2d sentence), as added Pub. L. 104–250, §4, Oct. 9, 1996, 110 Stat. 3155.
13702(f)(4)	21 U.S.C. 360b(a)(6) (3d sentence)	June 25, 1938, ch. 675, §512(a)(6) (3d sentence), as added Pub. L. 104–250, §4, Oct. 9, 1996, 110 Stat. 3155.
13702(f)(5)	21 U.S.C. 360b(a)(6) (last sentence)	June 25, 1938, ch. 675, §512(a)(6) (last sentence), as added Pub. L. 104–250, §4, Oct. 9, 1996, 110 Stat. 3155.

In subsection (a)(1)(D), the words "all conditions" are substituted for "any conditions" for clarity.

In subsection (c), the words "with respect to the new animal drug or the animal feed" are substituted for "with respect thereto" for clarity.

In subsection (f)(1), the words "Codex Alimentarius Commission" are substituted for "Codex Alimenterius Commission" to provide the correct spelling of the name of the Commission.

In subsection (f)(1), the words "considered appropriate" are substituted for "deemed appropriate" to use the more appropriate word.

In subsection (f)(2), in the matter before subparagraph (A), the words "For purposes of section 11102(a)(2)(C)(ii) of this title" are substituted for "For the purposes of section 402(a)(2)(D)" to provide the correct reference to the pertinent provision. Section 402(a)(2) of the Federal Food, Drug, and Cosmetic Act no longer contains a subparagraph (D) as that subparagraph was struck by section 404 of the Food Quality Protection Act of 1996 (Public Law 104–170, 110 Stat. 1514). Section 404 of that Act also enacted paragraph (2)(C)(ii) of section 402(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)),

which paragraph contains language that is similar to the former subparagraph (D). Paragraph (2)(C)(ii) of section 402(a) of the Act is restated as section 11102(a)(2)(C)(ii) of title 21, United States Code.

SECTION 13703—APPLICATION PROCEDURES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13703 (except (b)(3)) ..	21 U.S.C. 360b(b)	June 25, 1938, ch. 675, §512(b), as added Pub. L. 90–399, § 101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §§101(a), 102(a), Nov. 16, 1988, 102 Stat. 3971, 3981; Pub. L. 104–250, §2(d), Oct. 9, 1996, 110 Stat. 3153; Pub. L. 108–282, title I, §102(b)(5)(J), Aug. 2, 2004, 118 Stat. 904; Pub. L. 115–234, title III, §301(a), Aug. 14, 2018, 132 Stat. 2436.
13703(b)(3)	21 U.S.C. 360b note	Pub. L. 100–670, title I, §106, Nov. 16, 1988, 102 Stat. 3984.

In subsection (a)(2)(H), the words "ensure that the proposed use" are substituted for "assure that the proposed use" to use the more appropriate word.

In subsection (d), the words "Beginning on October 1, 2018," are omitted as obsolete.

SECTION 13704—APPROVAL OF APPLICATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13704(a)	21 U.S.C. 360b(c)(1)	June 25, 1938, ch. 675, §512(c)(1), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975.
13704(b)(1)	21 U.S.C. 360b(c)(2)(H)	June 25, 1938, ch. 675, §512(c)(2)(H), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975; Pub. L. 103–80, §3(r)(3), Aug. 13, 1993, 107 Stat. 777.
13704(b)(2)	21 U.S.C. 360b(c)(2)(A)	June 25, 1938, ch. 675, §512(c)(2)(A), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975; Pub. L. 103–80, §3(r)(1), Aug. 13, 1993, 107 Stat. 777.
13704(b)(3)	21 U.S.C. 360b(c)(2)(B)	June 25, 1938, ch. 675, §512(c)(2)(B), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975.
13704(b)(4)	21 U.S.C. 360b(c)(2)(C)	June 25, 1938, ch. 675, §512(c)(2)(C), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975.
13704(b)(5)	21 U.S.C. 360b(c)(2)(D)	June 25, 1938, ch. 675, §512(c)(2)(D), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975.
13704(b)(6)	21 U.S.C. 360b(c)(2)(E)	June 25, 1938, ch. 675, §512(c)(2)(E), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975.
13704(b)(7)	21 U.S.C. 360b(c)(2)(F)	June 25, 1938, ch. 675, §512(c)(2)(F), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975; Pub. L. 103–80, §3(r)(2), Aug. 13, 1993, 107 Stat. 777; Pub. L. 104–250, §2(b), Oct. 9, 1996, 110 Stat. 3151; Pub. L. 108–282, title I, §102(b)(2), Aug. 2, 2004, 118 Stat. 892; Pub. L. 117–9, §1(a)(2), Apr. 23, 2021, 135 Stat. 257.
13704(b)(8)	21 U.S.C. 360b(c)(2)(G)	June 25, 1938, ch. 675, §512(c)(2)(G), as added Pub. L. 100–670, title I, §101(c), Nov. 16, 1988, 102 Stat. 3975.
13704(c)	21 U.S.C. 360b(c)(3)	June 25, 1938, ch. 675, §512(c)(3), as added Pub. L. 100–670, title I, §102(b)(1), Nov. 16, 1988, 102 Stat. 3981.
13704(d)	21 U.S.C. 360b(c)(4)	June 25, 1938, ch. 675, §512(c)(4), as added Pub. L. 105–115, title I, §124(b), Nov. 21, 1997, 111 Stat. 2325.

In subsection (a)(1), in the matter before subparagraph (A), the words "pursuant to section 13703(a) of this title" are substituted for "pursuant to subsection (b)" to provide a more precise reference to the pertinent provision. Prior to the amendment made by section 101(a) of the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670, 102 Stat. 3971) to section 512(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)), the reference to "subsection (b)" in the source provision referred only to the provisions that, because of the amendment, were redesignated as paragraph (1) of that subsection (b). Thus, for the restatement to reflect the amendment and refer only to paragraph (1) of that subsection (b), the restatement substitutes "section 13703(a) of this title" for "subsection (b)".

In subsection (b)(1)(B)(iii), the word "considered" is substituted for "deemed" to use the more appropriate word.

In subsection (b)(1)(C)(i), the words "considers appropriate" are substituted for "deems appropriate" to use the more appropriate word.

In subsection (b)(1)(C)(iii), the words "To ensure that" are substituted for "To assure that" to use the more appropriate word.

In subsection (b)(1)(C)(v), the words "considers appropriate" are substituted for "deems appropriate" to use the more appropriate word.

In subsection (b)(2)(A), the words "ensure and preserve" are substituted for "assure and preserve" to use the more appropriate word.

In subsection (b)(5)(A), the words "certification described in clause (i) or (ii) of section 13715(b)(1)(H) of this title" are substituted for "certification described in clause (i) or (ii) of subsection (n)(1)(G)", in subsection (b)(5)(B), the words "certification described in clause (iii) of section 13715(b)(1)(H) of this title" are substituted for "certification described in clause (iii) of subsection (n)(1)(G)", in subsection (b)(5)(C)(i), the words "certification described in clause (iv) of section 13715(b)(1)(H) of this title" are substituted for "certification described in clause (iv) of subsection (n)(1)(G)", and in subsection (b)(5)(D), in the matter before clause (i), the words "certification described in clause (iv) of section 13715(b)(1)(H) of this title" are substituted for "certification described in clause (iv) of subsection (n)(1)(G)" to provide the correct reference to the pertinent provisions. Provisions relating to the relevant certifications are in subparagraph (H) of section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)), not in subparagraph (G) of that section. Subparagraph (H) of that section is restated as subparagraph (H) of section 13715(b)(1) of title 21, United States Code.

In subsection (b)(5)(B), the words "under clause (iii) of subsection (b)(1)(H) of section 13715 of this title" are substituted for "under clause (iii)" for clarity.

In subsection (b)(5)(C)(i), the words "notice provided under section 13715(c)(1)(A) of this title" are substituted for "notice provided under subsection (n)(2)(B)(i)" to provide the correct reference to the pertinent provision. The provision relating to giving notice to a patent owner is in subsection (n)(2)(A)(i) of section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), not in subsection (n)(2)(B)(i) of that section. Subsection (n)(2)(B) of that section does not contain clauses. Subsection (n)(2)(A)(i) of that section is restated as subsection (c)(1)(A) of section 13715 of title 21, United States Code.

In subsection (b)(5)(C)(ii), in the matter before subclause (I), the words "notice provided under section 13715(c)(1) of this title" are substituted for "notice provided under subsection (n)(2)(B)" to provide the correct reference to the pertinent provision. The provision relating to notice recipients is in subsection (n)(2)(A) of section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), not in subsection (n)(2)(B) of that section. Subsection (n)(2)(A) of that section is restated as subsection (c)(1) of section 13715 of title 21, United States Code.

In subsection (b)(5)(D)(ii), the words "action described in subparagraph (C)(ii)(III)" are substituted for "action described in subclause (III)" to provide the correct reference to the pertinent provision. There is no subclause (III) in clause (iv) of section 512(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(D)), which clause is the provision in the source law in which the reference to subclause (III) appears. Provisions relating to actions for patent infringement are in clause (iii) of section 512(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(D)), which contains a subclause (III), and which subclause is restated as subclause (III) of section 13704(b)(5)(C)(ii) of title 21, United States Code.

In subsection (b)(7)(A)(i), the words "(referred to in this subparagraph as 'approved application')" are added for clarity. Because of the addition of those words, the following substitutions are made in clauses (i) and (ii) of subsection (b)(7)(A): the words "for which the approved application was submitted" are substituted for "for which the subsection (b)(1) application was submitted"; the words "5 years from the date of the approval of the approved application" are substituted for "5 years from the date of the approval of the application under subsection (b)(1)"; the words "4 years from the date of the approval of the approved application" are substituted for "4 years from the date of the approval of the subsection (b)(1) application"; and the words "7½ years to have elapsed from the date of approval of the approved application" are substituted for "seven and one-half years to have elapsed from the date of approval of the subsection (b) application".

In subsection (b)(7)(A)(i), the words "(referred to in this subparagraph as 'abbreviated application')" are added for clarity. Because of the addition of those words, the following substitutions are made in clauses (i) and (ii) of subsection (b)(7)(A): the words "except that an abbreviated application" are substituted for "except that such an application"; and the words "The approval of such an abbreviated application" are substituted for "The approval of such an application".

In subsection (b)(7)(A)(i), the words "certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(1)(H) of section 13715 of this title" are substituted for "certification of patent invalidity or noninfringement described in clause (iv) of subsection (n)(1)(G)" to provide the correct reference to the pertinent provision. Provisions relating to certifications relating to patents are in subparagraph (H) of section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)), not in subparagraph (G) of that section. Subparagraph (H) of that section is restated as subparagraph (H) of section 13715(b)(1) of title 21, United States Code.

In subsection (b)(7)(A)(ii), the words "in accordance with paragraph (5)" are substituted for "in accordance with subparagraph (B)" to provide the correct reference to the pertinent provision. Provisions relating to effective dates of approval are in subparagraph (D) of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)), which is restated as paragraph (5) of

section 13704(b) of title 21, United States Code, and not in subparagraph (B) of section 512(c)(2) of the Act as referred to in the source provision. Compare with similar provisions in subparagraphs (B) and (F)(ii) of section 505(j)(5) of the Act (21 U.S.C. 355(j)(5)).

In subsection (b)(7)(A)(ii), the words "48 months after the date of the approval of the approved application" are substituted for "48 months after the date of the approval of the subsection (b) application" for clarity. The words "approved application" in the restated words effectively narrow the reference to "subsection (b)" in the source provision because of the addition of the parenthetical "(referred to in this subparagraph as 'approved application')" in subsection (b)(7)(A)(i), which parenthetical provides a term for an application approved under subsection (b)(1) of section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(1)), which is a narrower than the "subsection (b)" reference in the source provision.

In subsection (b)(7)(B), the words "(referred to in this subparagraph as 'approved application')" are added for clarity. Because of the addition of those words, the following substitutions are made in subsection (b)(7)(B): the words "and if the approved application contains" are substituted for "and if such application contains"; the words "required for the approval of the approved application" are substituted for "required for the approval of the application"; the words "conditions of approval of the drug in the approved application" are substituted for "conditions of approval of such drug in the subsection (b)(1) application"; and the words "3 years from the date of the approval of the approved application for the drug" are substituted for "3 years from the date of the approval of the application under subsection (b)(1) for such drug".

In subsection (c)(1), in the matter before subparagraph (A), the words "the application was filed before the patent information was required under subsection (b)(1) or" are omitted as obsolete.

In subsection (c)(2), the words "If the holder of an approved application could not file patent information under subsection (b)(1) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than 30 days after the date of the enactment of this sentence, and" are omitted as obsolete.

SECTION 13705—GROUNDS FOR REFUSING APPLICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13705(a) through (c) ...	21 U.S.C. 360b(d)(1), (2)	June 25, 1938, ch. 675, §512(d)(1), (2), as added Pub. L. 90–399, § 101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §102(b)(2), (3), Nov. 16, 1988, 102 Stat. 3981, 3982; Pub. L. 104–250, §3, Oct. 9, 1996, 110 Stat. 3155.
13705(d)	21 U.S.C. 360b(d)(4)	June 25, 1938, ch. 675, §512(d)(4), as added Pub. L. 104–250, §2(c), Oct. 9, 1996, 110 Stat. 3152; Pub. L. 105–277, div. A, § 101(a) [title VII, § 737], Oct. 21, 1998, 112 Stat. 2681, 2681–30; Pub. L. 108–282, title I, §102(b)(5)(K), Aug. 2, 2004, 118 Stat. 904.
13705(e)	21 U.S.C. 360b(d)(5)	June 25, 1938, ch. 675, §512(d)(5), as added Pub. L. 108–282, title I, §102(b)(3), Aug. 2, 2004, 118 Stat. 892.

In subsection (a)(1), in the matter before subparagraph (A), the words "refusing to approve an application under section 13703(a) of this title" are substituted for "refusing to approve the application" for clarity and consistency with section 13704(a)(1)(A) of title 21, United States Code.

In subsection (a)(1)(A), the words "pursuant to section 13703(a) of this title" are substituted for "pursuant to subsection (b)" to provide a more precise reference to the pertinent provision.

In subsection (a)(1)(I), in the matter before clause (i), the words "except that this subparagraph" are substituted for "except that the foregoing provisions of this subparagraph" to eliminate unnecessary words and for consistency in title 21, United States Code.

SECTION 13706—WITHDRAWAL AND SUSPENSION OF APPROVAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13706	21 U.S.C. 360b(e)	June 25, 1938, ch. 675, §512(e), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §102(b)(4), Nov. 16, 1988, 102 Stat. 3982; Pub. L. 102–108, §2(e), Aug. 17, 1991, 105 Stat. 550; Pub. L. 103–396, §2(b)(2), Oct. 22, 1994, 108 Stat. 4154.

In subsection (a), in the matter before paragraph (1), the words "pursuant to section 13703(a) of this title" are substituted for "pursuant to subsection (b)" to provide a more precise reference to the pertinent provision. Prior to the amendment made by section 101(a) of the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670, 102 Stat. 3971) to section 512(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)), the reference to "subsection (b)" in the source provision referred only to the provisions that, because of the amendment, were redesignated as paragraph (1) of that subsection (b). Thus, for the restatement to reflect the amendment and refer only to paragraph (1) of that subsection (b), the restatement substitutes "section 13703(a) of this title" for "subsection (b)".

In subsection (a)(2), in the matter before subparagraph (A), the words "considered reasonably applicable" are substituted for "deemed reasonably applicable" to use the more appropriate word.

In subsection (c)(2), the words "ensure and preserve" are substituted for "assure and preserve" to use the more appropriate word.

SECTION 13707—REVOCATION OF ORDER REFUSING, WITHDRAWING, OR SUSPENDING APPROVAL OF APPLICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13707	21 U.S.C. 360b(f)	June 25, 1938, ch. 675, §512(f), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 108–282, title I, §102(b)(5)(L), Aug. 2, 2004, 118 Stat. 904.

SECTION 13708—SERVICE OF ORDERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13708	21 U.S.C. 360b(g)	June 25, 1938, ch. 675, §512(g), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 108–282, title I, §102(b)(5)(M), Aug. 2, 2004, 118 Stat. 904.

SECTION 13709—APPEALS FROM ORDERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13709	21 U.S.C. 360b(h)	June 25, 1938, ch. 675, §512(h), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343.

SECTION 13710—PUBLICATION OF APPROVAL IN FEDERAL REGISTER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13710	21 U.S.C. 360b(i)	June 25, 1938, ch. 675, §512(i), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 104–250, §5(c), Oct. 9, 1996, 110 Stat. 3156; Pub. L. 108–282, title I, §102(b)(5)(N), Aug. 2, 2004, 118 Stat. 904.

In subsection (a)(3), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

In subsection (a)(3), the words "ensure the safe and effective" are substituted for "assure the safe and effective" to use the more appropriate word.

In subsection (b), the word "immediately" is substituted for "forthwith" for consistency in title 21, United States Code.

SECTION 13711—EXEMPTION FOR DRUGS FOR INVESTIGATIONAL USE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13711	21 U.S.C. 360b(j)	June 25, 1938, ch. 675, §512(j), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343.

SECTION 13712—FOOD CONTAINING APPROVED NEW ANIMAL DRUG CONSIDERED UNADULTERATED

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13712	21 U.S.C. 360b(k)	June 25, 1938, ch. 675, §512(k), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343.

SECTION 13713—RECORDS AND REPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13713	21 U.S.C. 360b(l)	June 25, 1938, ch. 675, §512(l), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 103–396, §2(b)(3), Oct. 22, 1994, 108 Stat. 4154; Pub. L. 108–282, title I, §102(b)(5)(O), Aug. 2, 2004, 118 Stat. 904; Pub. L. 110–316, title I, §105(a), Aug. 14, 2008, 122 Stat. 3513.

In subsection (a)(2), the words "considers it to be appropriate" are substituted for "deems it to be appropriate" to use the more appropriate word.

In subsection (b), the words "Each person" are substituted for "Every person" for clarity.

In subsection (b), the words "and each person" are substituted for "and every person" for clarity.

In subsection (c)(2)(B)(iii), the words “of the preceding calendar year” are substituted for “of such calendar year” for clarity.

SECTION 13714—FEED MILL LICENSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13714	21 U.S.C. 360b(m)	June 25, 1938, ch. 675, §512(m), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 104–250, §6(b), Oct. 9, 1996, 110 Stat. 3157; Pub. L. 108–282, title I, §102(b)(5)(P), (Q), Aug. 2, 2004, 118 Stat. 904.

In subsection (c)(1), in the matter before subparagraph (A), the words “refusing to approve an application under subsection (a)” are substituted for “refusing to approve the application” for clarity.

In subsection (d)(3)(B), the words “ensure and preserve” are substituted for “assure and preserve” to use the more appropriate word.

In subsection (e)(2), the words “each person” are substituted for the words “every person” each place they appear for clarity.

SECTION 13715—ABBREVIATED APPLICATIONS FOR NEW ANIMAL DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13715(a)	21 U.S.C. 360b(n)(1) ("(hereinafter in this subsection referred to as an `approved new animal drug')")	June 25, 1938, ch. 675, §512(n)(1) ("(hereinafter in this subsection referred to as an `approved new animal drug')"), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §101(b), Nov. 16, 1988, 102 Stat. 3971.
13715(b)	21 U.S.C. 360b(n)(1) (except "(hereinafter in this subsection referred to as an `approved new animal drug')")	June 25, 1938, ch. 675, §512(n)(1)(except "(hereinafter in this subsection referred to as an `approved new animal drug')"), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §101(b), Nov. 16, 1988, 102 Stat. 3971.
13715(c)	21 U.S.C. 360b(n)(2)	June 25, 1938, ch. 675, §512(n)(2), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §101(b), Nov. 16, 1988, 102 Stat. 3971.
13715(d)	21 U.S.C. 360b(n)(3)	June 25, 1938, ch. 675, §512(n)(3), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §101(b), Nov. 16, 1988, 102 Stat. 3971.
13715(e)	21 U.S.C. 360b(n)(4)	June 25, 1938, ch. 675, §512(n)(4), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §101(b), Nov. 16, 1988, 102 Stat. 3971.
13715(f)	21 U.S.C. 360b(n)(5)	June 25, 1938, ch. 675, §512(n)(5), as added Pub. L. 90–399, §101(b), July 13, 1968, 82 Stat. 343; Pub. L. 100–670, title I, §101(b), Nov. 16, 1988, 102 Stat. 3971.

In paragraphs (1) and (3) of subsection (c), the words “a certification described in subsection (b)(1)(H)(iv)” are substituted for “a certification described in paragraph (1)(G)(iv)” to provide the correct reference to the pertinent provision. Provisions relating to the relevant certification are in subparagraph (H) of section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)), not in subparagraph (G) of that section. Subparagraph (H) of that section is restated as subparagraph (H) of section 13715(b)(1) of title 21, United States Code.

In subsection (d)(2)(B)(ii), in the matter after the semicolon, the word “or” is added for clarity.

In subsection (e)(1)(A), the words "Within 60 days after the date of the enactment of this subsection" are omitted as obsolete.

In subsection (e)(1)(B), the words "Every 30 days, the Secretary" are substituted for "Every 30 days after the publication of the first list under clause (i) the Secretary" to eliminate obsolete words.

In subsection (f), in the matter before paragraph (1), the words "shall be deemed to be an application" are substituted for "shall be considered to be an application" to use the more appropriate word.

SECTION 13716—SAFETY AND EFFECTIVENESS DATA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13716	21 U.S.C. 360b(p)	June 25, 1938, ch. 675, §512(p), as added Pub. L. 100–670, title I, §104, Nov. 16, 1988, 102 Stat. 3982; Pub. L. 108–282, title I, §102(b)(5)(R), (S), Aug. 2, 2004, 118 Stat. 904.

SECTION 13717—DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13717	21 U.S.C. 360b(q)(1)	June 25, 1938, ch. 675, §512(q)(1), as added Pub. L. 114–89, §2(a)(3)(A), Nov. 25, 2015, 129 Stat. 699.

Chapter 139—Drugs for Rare Diseases or Conditions

SECTION 13901—RECOMMENDATIONS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13901	21 U.S.C. 360aa	June 25, 1938, ch. 675, § 525, as added Pub. L. 97–414, § 2(a), Jan. 4, 1983, 96 Stat. 2049; amended Pub. L. 99–91, § 3(a)(1), Aug. 15, 1985, 99 Stat. 387; Pub. L. 105–115, title I, § 125(b)(2)(F), (G), Nov. 21, 1997, 111 Stat. 2325, 2326.

SECTION 13902—DESIGNATION OF DRUGS FOR RARE DISEASES OR CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13902(a)(1)	21 U.S.C. 360bb(a)(2)	June 25, 1938, ch. 675, §526(a)(2), as added Pub. L. 97–414, §2(a), Jan. 4, 1983, 96 Stat. 2050; Pub. L. 98–551, §4(a), Oct. 30, 1984, 98 Stat. 2817.
13902(a)(2)	21 U.S.C. 360bb(a)(1)	June 25, 1938, ch. 675, §526(a)(1), as added Pub. L. 97–414, §2(a), Jan. 4, 1983, 96 Stat. 2050; Pub. L. 99–91, § 3(a)(2), Aug. 15, 1985, 99 Stat. 387; Pub. L. 100–290, §2(a), Apr. 18, 1988, 102 Stat. 90; Pub. L. 105–115, title I, §125(b)(2)(H), Nov. 21, 1997, 111 Stat. 2326.
13902(b) through (d) ...	21 U.S.C. 360bb(b) through (d)	June 25, 1938, ch. 675, §526(b) through (d), as added Pub. L. 97–414, §2(a), Jan. 4, 1983, 96 Stat. 2050; Pub. L. 100–290, §2(b), Apr. 18, 1988, 102 Stat. 90; Pub. L. 105–115, title I, §125(b)(2)(I), Nov. 21, 1997, 111 Stat. 2326.

In subsection (a)(2)(C)(i), the restatement of the words "the approval, certification, or license would be for use for such disease or condition" in subclauses (I) and (II) omits the word "certification" in conformity with the amendment made by section 125(b)(2)(H) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115, 111 Stat. 2326), which struck provisions relating to certifications under former section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357).

In subsection (a)(2)(C)(ii), the words "under subsection (c)" are substituted for "under subsection (b)" to provide the correct reference to the pertinent provision because of the redesignations made by section 2(b) of the Orphan Drug Amendments of 1988 (Public Law 100–290, 102 Stat. 90).

SECTION 13903—PROTECTION FOR DRUGS FOR RARE DISEASES OR CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13903	21 U.S.C. 360cc	June 25, 1938, ch. 675, §527, as added Pub. L. 97–414, § 2(a), Jan. 4, 1983, 96 Stat. 2050; amended Pub. L. 98–417, title I, § 102(b)(6), Sept. 24, 1984, 98 Stat. 1593; Pub. L. 99–91, §§ 2, 3(a)(3), Aug. 15, 1985, 99 Stat. 387, 388; Pub. L. 103–80, § 3(v), Aug. 13, 1993, 107 Stat. 778; Pub. L. 105–115, title I, § 125(b)(2)(J), (K), Nov. 21, 1997, 111 Stat. 2326; Pub. L. 107–281, § 4, Nov. 6, 2002, 116 Stat. 1993; Pub. L. 115–52, title VI, §607(a), Aug. 18, 2017, 131 Stat. 1049; Pub. L. 116–260, div. BB, title III, §323, Dec. 27, 2020, 134 Stat. 2933.

In subsection (a)(2), the words "Section 13504(a)(1)(B) of this title" are substituted for "Section 505(c)(2)" to provide the correct reference to the pertinent provision. On the enactment of the source provision in 1983, section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(2)) related to an opportunity for a hearing. That provision was redesignated as section 505(c)(1)(B) of the Act by section 102(a)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417, 98 Stat. 1592), which section 102(a)(2) also enacted a new section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(2)) relating to filing of patent information. Thus, the restatement is made to refer to section 13504(a)(1)(B) of title 21, United States Code, the source provision of which is section 505(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(1)(B)), to reflect the redesignation.

In subsection (b)(1), the words "individuals with the disease" are substituted for "persons with the disease" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (d), the words "with the terms of this section" are substituted for "with the terms of this section, as amended by such Act" to eliminate unnecessary words.

SECTION 13904—OPEN PROTOCOLS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13904	21 U.S.C. 360dd	June 25, 1938, ch. 675, § 528, as added Pub. L. 97–414, § 2(a), Jan. 4, 1983, 96 Stat. 2051.

In this section, the words “individuals with the disease” are substituted for “persons with the disease” for consistency with the definition of “person” in section 10101 of title 21, United States Code.

SECTION 13905—PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13905	21 U.S.C. 360ff	June 25, 1938, ch. 675, § 529, as added Pub. L. 112–144, title IX, § 908, July 9, 2012, 126 Stat. 1094; Pub. L. 114–113, div. A, title VII, §765, Dec. 18, 2015, 129 Stat. 2286; Pub. L. 114–229, §2(a), Sept. 30, 2016, 130 Stat. 943; Pub. L. 114–255, div. A, title III, §3013(a), Dec. 13, 2016, 130 Stat. 1093; Pub. L. 116–159, div. C, title I, §2105, Oct. 1, 2020, 134 Stat. 729; Pub. L. 116–215, div. B, title II, §1211, Dec. 11, 2020, 134 Stat. 1045; Pub. L. 116–260, div. BB, title III, §321, Dec. 27, 2020, 134 Stat. 2932; Pub. L. 117–9, §1(a)(4), Apr. 23, 2021, 135 Stat. 257; Pub. L. 118–83, div. B, title II, §202, Sept. 26, 2024, 138 Stat. 1538.

In subsection (a)(4)(C), the words “considers eligible” are substituted for “deems eligible” to use the more appropriate word.

In subsection (c)(1), the words “chapter 179 of this title” are substituted for “chapter VII” to provide a more precise reference to the pertinent provision.

In subsection (c)(3), the words “beginning after September 30, 2012” are omitted as obsolete.

In subsection (c)(4)(A), the reference to “subsection (b)(4)(B)” is a translation from the reference to “subsection (b)(4)(A)” because of the amendment made by section 2(a)(2) of Advancing Hope Act of 2016 (Public Law 114–229, 130 Stat. 943).

SECTION 13906—TARGETED DRUGS FOR RARE DISEASES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
13906(a)	21 U.S.C. 360ff–1(a)	June 25, 1938, ch. 675, §529A(a), as added Pub. L. 114–255, div. A, title III, §3012, Dec. 13, 2016, 130 Stat. 1091.
13906(b)	21 U.S.C. 360ff–1(c)	June 25, 1938, ch. 675, §529A(c), as added Pub. L. 114–255, div. A, title III, §3012, Dec. 13, 2016, 130 Stat. 1091.
13906(c)	21 U.S.C. 360ff–1(b)	June 25, 1938, ch. 675, §529A(b), as added Pub. L. 114–255, div. A, title III, §3012, Dec. 13, 2016, 130 Stat. 1091.
13906(d)	21 U.S.C. 360ff–1(d)	June 25, 1938, ch. 675, §529A(d), as added Pub. L. 114–255, div. A, title III, §3012, Dec. 13, 2016, 130 Stat. 1091.

Chapter 141—Electronic Product Radiation Control

In this chapter, the words “electronic product” are substituted, whenever appropriate, for “product” each place it appears for consistency with the defined term “electronic product” in section 14101(2) of title 21, United States Code.

SECTION 14101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14101(1)	21 U.S.C. 360hh(4)	June 25, 1938, ch. 675, §531(4), formerly act July 1, 1944, ch. 373, title III, §531(4), formerly §355(4), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1174; renumbered §531(4), Pub. L. 101–629, §19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.
14101(2)	21 U.S.C. 360hh(2)	June 25, 1938, ch. 675, §531(2), formerly act July 1, 1944, ch. 373, title III, §531(2), formerly §355(2), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1174; renumbered §531(2), Pub. L. 101–629, §19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.
14101(3)	21 U.S.C. 360hh(1)	June 25, 1938, ch. 675, §531(1), formerly act July 1, 1944, ch. 373, title III, §531(1), formerly §355(1), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1174; renumbered §531(1), Pub. L. 101–629, §19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.
14101(4)	21 U.S.C. 360hh(3)	June 25, 1938, ch. 675, §531(3), formerly act July 1, 1944, ch. 373, title III, §531(3), formerly §355(3), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1174; renumbered §531(3), Pub. L. 101–629, §19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.
14101(5)	21 U.S.C. 360hh(5)	June 25, 1938, ch. 675, §531(5), formerly act July 1, 1944, ch. 373, title III, §531(5), formerly §355(5), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1174; Pub. L. 94–484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325; renumbered §531(5), Pub. L. 101–629, §19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.

SECTION 14102—PROGRAM OF CONTROL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14102	21 U.S.C. 360ii	June 25, 1938, ch. 675, § 532, formerly act July 1, 1944, ch. 373, title III, § 532, formerly § 356, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1174; renumbered § 532 and amended Pub. L. 101–629, § 19(a)(1)(B), (2)(A), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

In subsection (a)(6), in the matter before subparagraph (A), the words "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" are substituted for "the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on" to eliminate obsolete words. The Atomic Energy Commission was abolished and its functions were transferred to the Energy Research and Development Administration and the Nuclear Regulatory Commission by sections 104 and 201 of the Energy Reorganization Act of 1974 (42 U.S.C. 5814, 5841). The Energy Research and Development Administration was subsequently terminated and its functions were transferred to the Secretary of Energy by sections 301(a) and 703 of the Department of Energy Organization Act (42 U.S.C. 7151(a), 7293).

In subsection (b)(3), the words "section 6101 of title 41" are substituted for "section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)" on authority of section 6(c) of Public Law 111–350 (41 U.S.C. note prec. 101).

SECTION 14103—STUDIES BY SECRETARY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14103	21 U.S.C. 360jj	June 25, 1938, ch. 675, § 533, formerly act July 1, 1944, ch. 373, title III, § 533, formerly § 357, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1176; renumbered § 533 and amended Pub. L. 101–629, § 19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

In subsection (a), in the matter before paragraph (1), the words "from time to time" are substituted for "on or before January 1, 1970, and from time to time thereafter" to eliminate obsolete words.

In subsection (a), in the matter before paragraph (1), the words "may consider appropriate" are substituted for "may deem appropriate" to use the more appropriate word.

In subsection (a)(1)(D), the words "ensure consistent and effective control" are substituted for "assure consistent and effective control" to use the more appropriate word.

In subsection (b), the words "Federal agencies" are substituted for "Federal departments and agencies" to eliminate unnecessary words.

In subsection (c), the words "The Secretary shall" are substituted for "The Secretary or his designee shall" to eliminate unnecessary words.

In subsection (c), the words "considers best" are substituted for "deems best" to use the more appropriate word.

In subsection (c), the words "if the inclusion is requested by the dissenter" are substituted for "if so requested by the dissenter" for clarity.

SECTION 14104—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14104(a) through (e) ...	21 U.S.C. 360kk(a) through (e)	June 25, 1938, ch. 675, §534(a) through (e), formerly act July 1, 1944, ch. 373, title III, §534(a) through (e), formerly §358(a) through (e), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1177; renumbered § 534(a) through (e), Pub. L. 101–629, §19(a)(1)(B), (2)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.
14104(f)(1)	21 U.S.C. 360kk(f)(1)(A) (parenthetical)	June 25, 1938, ch. 675, §534(f)(1)(A) (parenthetical), formerly act July 1, 1944, ch. 373, title III, §534(f)(1)(A) (parenthetical), formerly §358(f)(1)(A) (parenthetical), as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1177; renumbered §534(f)(1)(A) (parenthetical), Pub. L. 101–629, §19(a)(3), (4), Nov. 28, 1990, 104 Stat. 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.
14104(f)(2) through (6)	21 U.S.C. 360kk(f) (except (1)(A) (parenthetical))	June 25, 1938, ch. 675, §534(f) (except (1)(A) (parenthetical)), formerly act July 1, 1944, ch. 373, title III, §534(f) (except (1)(A) (parenthetical)), formerly §358(f) (except (1)(A) (parenthetical)), as

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1177; Pub. L. 91–515, title VI, §601(b)(2), (3), Oct. 30, 1970, 84 Stat. 1311; renumbered §534(f) (except (1)(A) (parenthetical)), Pub. L. 101–629, §19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §§3(w), 4(a)(2), Aug. 13, 1993, 107 Stat. 778, 779.
14104(g)	21 U.S.C. 360kk(g)	June 25, 1938, ch. 675, §534(g), formerly act July 1, 1944, ch. 373, title III, §534(g), formerly §358(g), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1177; renumbered §534(g), Pub. L. 101–629, §19(a)(3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.
14104(h)	21 U.S.C. 360kk(h)	June 25, 1938, ch. 675, §534(h), formerly act July 1, 1944, ch. 373, title III, §534(h), formerly §358(h), as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1177; renumbered §534(h), Pub. L. 101–629, §19(a)(3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.

In subsection (a)(1)(C), the words "but the first of such standards shall be prescribed prior to January 1, 1970" are omitted as obsolete.

In subsection (a)(1)(D), in the matter before clause (i), the words "Federal and State agencies" are substituted for "Federal and State departments and agencies" to eliminate unnecessary words.

In subsection (a)(5), the words "any Federal agency, provided that the Federal agency" are substituted for "departments or agencies of the United States provided such department or agency" for clarity, for consistency in the paragraph, and to eliminate unnecessary words.

In subsection (a)(5), the words "predominantly by Federal agencies" are substituted for "predominantly by departments or agencies of the United States" to eliminate unnecessary words.

In subsection (d)(1)(B), the word "immediately" is substituted for "forthwith" for consistency in title 21, United States Code.

In subsection (d)(2)(A), the words "rebuttal of the additional evidence" are substituted for "rebuttal thereof" for clarity.

In subsection (d)(5), the word "individual" is substituted for "person" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (g), the words "ensure the adequacy" are substituted for "assure the adequacy" to use the more appropriate word.

In subsection (g), the words "ensure that electronic products" are substituted for "assure that electronic products" to use the more appropriate word.

In subsection (h)(2), the words "with the standard in effect described in paragraph (1)" are substituted for "with such standard" for clarity.

In subsection (h)(2), the words "to which the certification is attached" are substituted for "to which it is attached" for clarity.

In subsection (h)(2), the words "on the grounds that the testing program" are substituted for "on the grounds that it" for clarity.

In subsection (h)(2), the words "ensure the adequacy" are substituted for "assure the adequacy" to use the more appropriate word.

In subsection (h)(2), the words "or that the testing program does not" are substituted for "or that it does not" for clarity.

In subsection (h)(2), the words "ensure that electronic products" are substituted for "assure that electronic products" to use the more appropriate word.

SECTION 14105—NOTIFICATION OF DEFECTS IN AND REPAIR OR REPLACEMENT OF ELECTRONIC PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14105	21 U.S.C. 360ll	June 25, 1938, ch. 675, § 535, formerly act July 1, 1944, ch. 373, title III, § 535, formerly § 359, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1180; renumbered § 535 and amended Pub. L. 101–629, § 19(a)(1)(B), (2)(C), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

In subparagraphs (A) and (C) of subsection (a)(2), the words "does not create" are substituted for "is not such as to create" to eliminate unnecessary words.

In subsection (d)(1), the words "regarding the defect or failure to comply" are substituted for "regarding any such defect in such product or any such failure to comply with a standard applicable to such product" to eliminate unnecessary words and for consistency with subsections (a) and (c).

In subsection (d)(2), the words "considers will assist" are substituted for "deems will assist" to use the more appropriate word.

In subsection (e)(4), the words "does not create" are substituted for "is not such as to create" to eliminate unnecessary words.

SECTION 14106—IMPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14106	21 U.S.C. 360mm	June 25, 1938, ch. 675, § 536, formerly act July 1, 1944, ch. 373, title III, § 536, formerly § 360, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1181; renumbered § 536 and amended Pub. L. 101–629, § 19(a)(1)(B), (2)(D), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

In paragraphs (2) and (3) of subsection (a), references to the Secretary of the Treasury are retained to ensure that no change in the meaning or effect of the source provisions is made by the restatement of the provisions in title 21, United States Code. For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to

customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

In subsection (a)(2), the words "giving to the owner or consignee notice of the delivery," are substituted for "giving notice thereof to the owner or consignee," for clarity.

In subsection (d)(1), the words "Each manufacturer offering an electronic product for importation into the United States shall designate in writing" are substituted for "It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing" for consistency in title 21, United States Code, and to eliminate unnecessary words.

In subsection (d)(2), the words "be changed in writing, filed with the Secretary" are substituted for "be changed by like writing, similarly filed" for clarity.

In subsection (d)(3)(A), the words "the effect of which is as if service was made personally on the manufacturer" are substituted for "with like effect as if made personally upon the manufacturer" for clarity.

In subsection (d)(3)(B), the words "If designation of an agent under this subsection is not made," are substituted for "in default of the designation of the agent," for clarity.

SECTION 14107—INSPECTION, RECORDS, AND REPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14107	21 U.S.C. 360nn	June 25, 1938, ch. 675, § 537, formerly act July 1, 1944, ch. 373, title III, § 537, formerly § 360A, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1182; renumbered § 537 and amended Pub. L. 101–629, § 19(a)(1)(B), (2)(E), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

In subsection (a)(1), in the matter before subparagraph (A), the words "are authorized" are substituted for "are thereafter authorized" to eliminate an unnecessary word.

In subsection (f)(2)(B), the words "of the need for the required information" are substituted for "of the need therefor" for clarity.

SECTION 14108—PROHIBITED ACTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14108	21 U.S.C. 360oo	June 25, 1938, ch. 675, § 538, formerly act July 1, 1944, ch. 373, title III, § 538, formerly § 360B, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1184; renumbered § 538 and amended Pub. L. 101–629, § 19(a)(1)(B), (2)(F), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

SECTION 14109—ENFORCEMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14109	21 U.S.C. 360pp	June 25, 1938, ch. 675, § 539, formerly act July 1, 1944, ch. 373, title III, § 539, formerly § 360C, as

SECTION 14109—ENFORCEMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1184; renumbered § 539 and amended Pub. L. 101–629, § 19(a)(1)(B), (2)(G), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

SECTION 14110—FEDERAL-STATE COOPERATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14110	21 U.S.C. 360rr	June 25, 1938, ch. 675, § 541, formerly act July 1, 1944, ch. 373, title III, § 541, formerly § 360E, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1186; renumbered § 541 and amended Pub. L. 101–629, § 19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

SECTION 14111—PREEMPTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14111	21 U.S.C. 360ss	June 25, 1938, ch. 675, § 542, formerly act July 1, 1944, ch. 373, title III, § 542, formerly § 360F, as added Pub. L. 90–602, § 2(3), Oct. 18, 1968, 82 Stat. 1186; renumbered § 542 and amended Pub. L. 101–629, § 19(a)(1)(B), (2)(H), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.

Chapter 143—General Provisions Relating to Drugs and Devices

SECTION 14301—EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14301(a)	21 U.S.C. 360bbb(e)	June 25, 1938, ch. 675, §561(e), as added Pub. L. 105–115, title IV, § 402, Nov. 21, 1997, 111 Stat. 2365.
14301(b)	21 U.S.C. 360bbb(a)	June 25, 1938, ch. 675, §561(a), as added Pub. L. 105–115, title IV, § 402, Nov. 21, 1997, 111 Stat. 2365.
14301(c)	21 U.S.C. 360bbb(b)	June 25, 1938, ch. 675, §561(b), as added Pub. L. 105–115, title IV, § 402, Nov. 21, 1997, 111 Stat. 2365.
14301(d)	21 U.S.C. 360bbb(c)	June 25, 1938, ch. 675, §561(c), as added Pub. L. 105–115, title IV, § 402, Nov. 21, 1997, 111 Stat. 2365; Pub. L. 109–482, title I, § 102(f)(2), Jan. 15, 2007, 120 Stat. 3685.
14301(e)	21 U.S.C. 360bbb(d)	June 25, 1938, ch. 675, §561(d), as added Pub. L. 105–115, title IV, § 402, Nov. 21, 1997, 111 Stat. 2365.

In subsection (c), the word “individual” is substituted for “person” each place it appears for consistency with the definition of “person” in section 10101 of title 21, United States Code.

SECTION 14302—EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14302	21 U.S.C. 360bbb–0	June 25, 1938, ch. 675, §561A, as added Pub. L. 114–255, div. A, title III, §3032, Dec. 13, 2016, 130 Stat. 1100; Pub. L. 115–52, title VI, §610(c), Aug. 18, 2017, 131 Stat. 1053.

SECTION 14303—INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14303(a)(1)	21 U.S.C. 360bbb–0a(a)(2)	June 25, 1938, ch. 675, §561B(a)(2), as added Pub. L. 115–176, §2(a), May 30, 2018, 132 Stat. 1372.
14303(a)(2)	21 U.S.C. 360bbb–0a(a)(1)	June 25, 1938, ch. 675, §561B(a)(1), as added Pub. L. 115–176, §2(a), May 30, 2018, 132 Stat. 1372.
14303(a)(3)	21 U.S.C. 360bbb–0a(a)(3)	June 25, 1938, ch. 675, §561B(a)(3), as added Pub. L. 115–176, §2(a), May 30, 2018, 132 Stat. 1372.
14303(b) through (d) ...	21 U.S.C. 360bbb–0a(b) through (d)	June 25, 1938, ch. 675, §561B(b) through (d), as added Pub. L. 115–176, §2(a), May 30, 2018, 132 Stat. 1372.
14303(e)	21 U.S.C. 360bbb–0a note	Pub. L. 115–176, §2(b), May 30, 2018, 132 Stat. 1374.

In this section, references to "this section" are retained for convenience, even though "this section" refers to section 14303 of title 21, United States Code, which section restates 2 sections, each from a separate Act. Section 561B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a) is restated as subsections (a) through (d) of section 14303 of title 21, United States Code, and section 2(b) of the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (21 U.S.C. 360bbb–0a note) is restated as subsection (e) of section 14303 of title 21, United States Code.

In subsection (e)(2), the words "a sponsor, manufacturer," are substituted for "a sponsor manufacturer," for consistency in the subsection.

SECTION 14304—DISPUTE RESOLUTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14304(a)	21 U.S.C. 360bbb–1 (1st sentence)	June 25, 1938, ch. 675, §562 (1st sentence), as added Pub. L. 105–115, title IV, § 404, Nov. 21, 1997, 111 Stat. 2368.
14304(b)	21 U.S.C. 360bbb–1 (2d sentence)	June 25, 1938, ch. 675, §562 (2d sentence), as added Pub. L. 105–115, title IV, § 404, Nov. 21, 1997, 111 Stat. 2368.

SECTION 14305—CLASSIFICATION OF PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14305	21 U.S.C. 360bbb–2	June 25, 1938, ch. 675, § 563, as added Pub. L. 105–115, title IV, § 416, Nov. 21, 1997, 111 Stat. 2378.

SECTION 14306—AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14306(a)	21 U.S.C. 360bbb–3(a)(4)	June 25, 1938, ch. 675, §564(a)(4), as added Pub. L. 108–136, div. A, title XVI, §1603(a), Nov. 24, 2003, 117 Stat. 1684; Pub. L. 108–276, §4(a), July 21, 2004, 118 Stat. 853.
14306(b)	21 U.S.C. 360bbb–3(a)(1) through (3)	June 25, 1938, ch. 675, §564(a)(1) through (3), as added Pub. L. 108–136, div. A, title XVI, §1603(a),

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Nov. 24, 2003, 117 Stat. 1684; Pub. L. 108–276, §4(a), July 21, 2004, 118 Stat. 853; Pub. L. 113–5, title III, §302(a)(1), Mar. 13, 2013, 127 Stat. 179; Pub. L. 114–255, div. A, title III, §3088(a)(1), Dec. 13, 2016, 130 Stat. 1148.
14306(c) through (n) ...	21 U.S.C. 360bbb–3(b) through (m)	June 25, 1938, ch. 675, §564(b) through (m), as added Pub. L. 108–136, div. A, title XVI, §1603(a), Nov. 24, 2003, 117 Stat. 1684; Pub. L. 108–276, §4(a), July 21, 2004, 118 Stat. 853; Pub. L. 113–5, title III, §302(a)(2) through (9), Mar. 13, 2013, 127 Stat. 179; Pub. L. 114–255, div. A, title III, §3088(a)(2) through (7), Dec. 13, 2016, 130 Stat. 1148; Pub. L. 115–92, §1(a), Dec. 12, 2017, 131 Stat. 2023; Pub. L. 117–328, div. FF, title II, §2504, Dec. 29, 2022, 136 Stat. 5802.

In subsection (a)(2), the words "means use in an actual or potential emergency" are substituted for "has the meaning indicated for the term in paragraph (1)" for clarity.

In subsection (a)(4), the words "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)" are substituted for "has the meaning indicated for the term in paragraph (2)(A)" for clarity.

In subsection (a)(5), the words "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)" are substituted for "has the meaning indicated for the term in paragraph (2)(B)" for clarity.

In subsection (b)(2)(B), the words "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," are substituted for "is approved, conditionally approved under section 571, licensed, or cleared under such a provision," for clarity.

In subsection (b)(2)(B), the words "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" are substituted for "which use is not under such provision an approved, conditionally approved under section 571, licensed, or cleared use of the product" for clarity.

In subsection (c)(1)(B), in the matter before clause (i), the words "the provisions classified to title 50" are substituted for "title 50" for clarity because title 50 of the United States Code has not been enacted as a positive law title of the United States Code.

In subsection (h)(1), in the matter before subparagraph (A), the words "the approval, licensure, or clearance of, or the conditional approval under section

14502 of this title of" are substituted for "the approval, conditional approval under section 571, licensure, or clearance of" for clarity.

In subsection (i)(1)(A), the words "of the reasons for the authorization, termination, or revocation" are substituted for "of the reasons therefor" for clarity.

SECTION 14307—EMERGENCY USE OF MEDICAL PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14307	21 U.S.C. 360bbb–3a	June 25, 1938, ch. 675, § 564A, as added Pub. L. 113–5, title III, § 302(b), Mar. 13, 2013, 127 Stat. 183; Pub. L. 114–255, div. A, title III, §3088(c), Dec. 13, 2016, 130 Stat. 1149; Pub. L. 116–22, title VII, §705(c), June 24, 2019, 133 Stat. 964.

In subsection (b)(3)(C), the words "may consider appropriate" are substituted for "may deem appropriate" to use the more appropriate word.

SECTION 14308—PRODUCTS HELD FOR EMERGENCY USE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14308	21 U.S.C. 360bbb–3b	June 25, 1938, ch. 675, §564B, as added Pub. L. 113–5, title III, §302(d), Mar. 13, 2013, 127 Stat. 185; Pub. L. 114–255, div. A, title III, §3088(d), Dec. 13, 2016, 130 Stat. 1149; Pub. L. 116–22, title VII, §705(d), June 24, 2019, 133 Stat. 964.

SECTION 14309—COUNTERMEASURE DEVELOPMENT, REVIEW, AND TECHNICAL ASSISTANCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14309	21 U.S.C. 360bbb–4 (except (c)(2))	June 25, 1938, ch. 675, §565 (except (c)(2)), as added Pub. L. 109–417, title IV, §404, Dec. 19, 2006, 120 Stat. 2875; amended Pub. L. 113–5, title III, §§303 through 306, Mar. 13, 2013, 127 Stat. 185 through 190; Pub. L. 116–22, title V, §503, June 24, 2019, 133 Stat. 951; Pub. L. 117–328, div. FF, title II, §§2501, 2502(a), Dec. 29, 2022, 136 Stat. 5796, 5797.

In subsection (b)(4), in the matter before subparagraph (A), the words "which teams shall" are substituted for "that shall" for clarity.

In subsection (c), the words "Not later than 1 year after the date of the enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013," are omitted as obsolete.

In subsection (d)(1), in the matter before subparagraph (A), the words "not later than 180 days after the enactment of this subsection" are omitted as obsolete.

In subsection (g), in the matter before paragraph (1), the words "The Secretary shall annually" are substituted for "Not later than 180 days after the date of enactment of this subsection, and annually thereafter, the Secretary" to eliminate obsolete words.

In subsection (g)(2), in the matter before subparagraph (A), the words "set forth in subsection (f)(5)(B)" are substituted for "set forth in subsection

(f)(4)(B)" to provide the correct reference to the pertinent provision because of the amendment made by section 503(1) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (Public Law 116–22, 133 Stat. 951).

In subsection (g)(6), the words "submitted under subsection (f)(4)(A)" are substituted for "submitted under subsection (f)(3)(A)" to provide the correct reference to the pertinent provision because of the amendment made by section 503(1) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (Public Law 116–22, 133 Stat. 951).

In subsection (g)(7)(A), the words "as defined in subsection (a)" are omitted as unnecessary.

In subsection (i)(1), the words "and make recommendations" are substituted for "and make such recommendations" to eliminate an unnecessary word because the word "recommendations" has no antecedent.

SECTION 14310—PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14310(a)(1)	21 U.S.C. 360bbb–4a(a)(1)	June 25, 1938, ch. 675, §565A(a)(1), as added Pub. L. 114–255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144.
14310(a)(2)	21 U.S.C. 360bbb–4a(a)(4)	June 25, 1938, ch. 675, §565A(a)(4), as added Pub. L. 114–255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144; Pub. L. 117–9, §1(a)(5), Apr. 23, 2021, 135 Stat. 258.
14310(a)(3)	21 U.S.C. 360bbb–4a(a)(2)	June 25, 1938, ch. 675, §565A(a)(2), as added Pub. L. 114–255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144.
14310(a)(4)	21 U.S.C. 360bbb–4a(a)(3)	June 25, 1938, ch. 675, §565A(a)(3), as added Pub. L. 114–255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144.
14310(b) through (g) ...	21 U.S.C. 360bbb–4a(b) through (g)	June 25, 1938, ch. 675, §565A(b) through (g), as added Pub. L. 114–255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144.

In subsection (a)(3), the words "section 101(b) of the Prescription Drug User Fee Amendments of 2012 (Public Law 112–144, title I, 126 Stat. 996)" are substituted for "section 101(b) of the Food and Drug Administration Safety and Innovation Act" to provide a more precise reference to the pertinent provision. The short title for title I of the Food and Drug Administration Safety and Innovation Act is Prescription Drug User Fee Amendments of 2012, and section 101(b) is under that title.

In subsection (c)(3), the words "beginning after September 30, 2016" are omitted as obsolete.

SECTION 14311—MEDICAL COUNTERMEASURE MASTER FILES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14311(a)	21 U.S.C. 360bbb–4b(f)	June 25, 1938, ch. 675, §565B(f), as added Pub. L. 116–22, title VI, §603(b), June 24, 2019, 133 Stat. 953.
14311(b) through (f)	21 U.S.C. 360bbb–4b(a) through (e)	June 25, 1938, ch. 675, §565B(a) through (e), as added Pub. L. 116–22, title VI, §603(b), June 24, 2019, 133 Stat. 953.

In subsection (b)(1), the words "the person authorized" are substituted for "any such persons" for clarity and consistency in the paragraph.

In subsection (e)(2), the words "section 13701(3) of this title" are substituted for "subsection (d) of section 512" to provide a more precise reference to the pertinent provision.

In subsection (e)(2), the words "which written description shall not include any trade secret" are substituted for "which shall not include any trade secret" for clarity.

In subsection (f)(1), the words "as the subtitle or Act, as applicable, is in effect on the day before June 24, 2019" are substituted for "as such applicable Act is in effect on the day before the date of enactment of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019" for clarity because of the substitution of "this subtitle" for "this Act".

In subsection (f)(1), the words "for approval under the subtitle or Act, as applicable" are substituted for "for approval under the applicable Act" for clarity because of the substitution of "this subtitle" for "this Act".

In subsection (f)(2), the words "and 13701(3) of this title" are substituted for "and 512(d) of this Act" to provide a more precise reference to the pertinent provision.

SECTION 14312—CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14312(a)(1)	21 U.S.C. 360bbb–5(b)	June 25, 1938, ch. 675, §566(b), as added Pub. L. 110–85, title VI, §603, Sept. 27, 2007, 121 Stat. 898.
14312(a)(2)	21 U.S.C. 360bbb–5(e)	June 25, 1938, ch. 675, §566(e), as added Pub. L. 110–85, title VI, §603, Sept. 27, 2007, 121 Stat. 898.
14312(b)	21 U.S.C. 360bbb–5(a)	June 25, 1938, ch. 675, §566(a), as added Pub. L. 110–85, title VI, §603, Sept. 27, 2007, 121 Stat. 898.
14312(c)	21 U.S.C. 360bbb–5(c)	June 25, 1938, ch. 675, § 566(c), as added Pub. L. 110–85, title VI, §603, Sept. 27, 2007, 121 Stat. 898.
14312(d)	21 U.S.C. 360bbb–5(d)	June 25, 1938, ch. 675, §566(d), as added Pub. L. 110–85, title VI, §603, Sept. 27, 2007, 121 Stat. 898.
14312(e)	21 U.S.C. 360bbb–5(f)	June 25, 1938, ch. 675, §566(f), as added Pub. L. 110–85, title VI, §603, Sept. 27, 2007, 121 Stat. 898; Pub. L. 112–144, title XI, §1102, July 9, 2012, 126 Stat. 1108; Pub. L. 115–52, title VI, §602, Aug. 18, 2017, 131 Stat. 1048; Pub. L. 117–180, div. F, title V, §5005, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, §301, Dec. 16, 2022, 136 Stat. 2311; Pub. L. 117–328, div. FF, title III, §3101, Dec. 29, 2022, 136 Stat. 5807.

In subsection (d), in the matter before paragraph (1), the words "The Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall annually submit" are substituted for "Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit" to eliminate obsolete words.

In subsection (e), the words "$6,000,000 for each of fiscal years 2023 through 2027" are substituted for "$1,380,822 for the period beginning on October 1, 2022 and ending on December 23, 2022" to reflect the amendment made by section 3101 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807). That section 3101 struck "$1,265,753 for the period beginning on October 1, 2022 and ending on December 23, 2022",

which did not appear in the law at the time of enactment of that section because of the intervening amendment made by section 301 of the Further Continuing Appropriations and Extensions Act, 2023 (Public Law 117–229, 136 Stat. 2312), which struck "$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022" and inserted "$1,380,822 for the period beginning on October 1, 2022 and ending on December 23, 2022".

SECTION 14313—EMERGING TECHNOLOGY PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14313	21 U.S.C. 360bbb–5a	June 25, 1938, ch. 675, §566A, as added Pub. L. 117–328, div. FF, title III, §3203, Dec. 29, 2022, 136 Stat. 5814.

SECTION 14314—RISK COMMUNICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14314(a)	21 U.S.C. 360bbb–6(a)(1) (parenthetical)	June 25, 1938, ch. 675, §567(a)(1) (parenthetical), as added Pub. L. 110–85, title IX, §917, Sept. 27, 2007, 121 Stat. 960.
14314(b), (c)	21 U.S.C. 360bbb–6 (except (a)(1) (parenthetical))	June 25, 1938, ch. 675, §567 (except (a)(1) (parenthetical)), as added Pub. L. 110–85, title IX, §917, Sept. 27, 2007, 121 Stat. 960; Pub. L. 117–286, §4(a)(157), Dec. 27, 2022, 136 Stat. 4323.

SECTION 14315—NOTIFICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14315(a)	21 U.S.C. 360bbb–7(d)	June 25, 1938, ch. 675, §568(d), as added Pub. L. 112–144, title VII, §715(b), July 9, 2012, 126 Stat. 1075.
14315(b) through (d) ...	21 U.S.C. 360bbb–7(a) through (c)	June 25, 1938, ch. 675, §568(a) through (c), as added Pub. L. 112–144, title VII, §715(b), July 9, 2012, 126 Stat. 1075.

SECTION 14316—CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14316	21 U.S.C. 360bbb–8	June 25, 1938, ch. 675, §569, as added Pub. L. 112–144, title IX, §903, July 9, 2012, 126 Stat. 1088; Pub. L. 114–255, div. A, title III, §3101(a)(2)(O), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 117–328, div. FF, title III, §3202(e), Dec. 29, 2022, 136 Stat. 5812.

SECTION 14317—OPTIMIZING GLOBAL CLINICAL TRIALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14317	21 U.S.C. 360bbb–8a	June 25, 1938, ch. 675, § 569A, as added Pub. L. 112–144, title XI, § 1123, July 9, 2012, 126 Stat. 1113; Pub. L. 114–255, div. A, title III, §3101(a)(2)(P), Dec. 13, 2016, 130 Stat. 1154.

In subsection (a), the words "as defined in subsection (g) of section 201" and "as defined in subsection (h) of such section" are omitted as unnecessary.

SECTION 14318—USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14318	21 U.S.C. 360bbb–8b	June 25, 1938, ch. 675, §569B, as added Pub. L. 112–144, title XI, §1123, July 9, 2012, 126 Stat. 1113; Pub. L. 114–255, div. A, title III, §3101(a)(2)(Q), Dec. 13, 2016, 130 Stat. 1155.

SECTION 14319—PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14319(a)(1)	21 U.S.C. 360bbb–8c(a)(5)	June 25, 1938, ch. 675, §569C(a)(5), formerly §569C(e), as added Pub. L. 112–144, title XI, § 1137, July 9, 2012, 126 Stat. 1124; redesignated §569C(a)(5), Pub. L. 114–255, div. A, title III, §3001(2), Dec. 13, 2016, 130 Stat. 1083.
14319(a)(2)	21 U.S.C. 360bbb–8c(c)	June 25, 1938, ch. 675, § 569C(c), as added Pub. L. 114–255, div. A, title III, §3001(3), Dec. 13, 2016, 130 Stat. 1083; Pub. L. 115–52, title VI, §605, Aug. 18, 2017, 131 Stat. 1048.
14319(b)	21 U.S.C. 360bbb–8c(a)(1) through (4)	June 25, 1938, ch. 675, §569C(a)(1) through (4), as added Pub. L. 112–144, title XI, §1137, July 9, 2012, 126 Stat. 1124; Pub. L. 114–255, div. A, title III, §3001(1), (2), Dec. 13, 2016, 130 Stat. 1083.
14319(c)	21 U.S.C. 360bbb–8c(b)	June 25, 1938, ch. 675, §569C(b), as added Pub. L. 114–255, div. A, title III, §3001(3), Dec. 13, 2016, 130 Stat. 1083.
14319(d)	21 U.S.C. 360bbb–8c note	Pub. L. 114–255, div. A, title III, §3003, Dec. 13, 2016, 130 Stat. 1085.

In subsection (b)(1)(A), the words "special Government employee (as defined under section 202 of title 18)" are substituted for "special government employee" for clarity.

SECTION 14320—NOTIFICATION, NONDISTRIBUTION, AND RECALL OF CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14320	21 U.S.C. 360bbb–8d	June 25, 1938, ch. 675, §569D, as added Pub. L. 115–271, title III, §3012(b), Oct. 24, 2018, 132 Stat. 3935.

In subsection (b)(1), the words "an order pursuant to subsection (a)(1)" are substituted for "an order pursuant to paragraph (1)" to provide the correct reference to the pertinent provision.

In subsection (b)(1), the words "an amended order pursuant to subparagraph (B) or (C) of subsection (a)(3)" are substituted for "an amended order pursuant to subparagraph (B) or (C) of paragraph (3)" to provide the correct reference to the pertinent provision.

In subsection (c)(2), the words "An official may not be designated under paragraph (1)" are substituted for "An official may not be so designated under this section" to provide a more precise reference to the pertinent provision.

Chapter 145—New Animal Drugs for Minor Use and Minor Species

SECTION 14501—DEFINITION OF TRANSGENIC ANIMAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14501	21 U.S.C. 360ccc(j)	June 25, 1938, ch. 675, §571(j), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892.

SECTION 14502—CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES AND CERTAIN NEW ANIMAL DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14502(a)	21 U.S.C. 360ccc(d)(4)(B)	June 25, 1938, ch. 675, § 571(d)(4)(B), as added Pub. L. 114–89, §2(a)(3)(B), Nov. 25, 2015, 129 Stat. 699.
14502(b)	21 U.S.C. 360ccc(a)	June 25, 1938, ch. 675, §571(a), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892; Pub. L. 115–234, title III, §§301(b), 304(a)(2), Aug. 14, 2018, 132 Stat. 2436, 2437.
14502(c)	21 U.S.C. 360ccc(b)	June 25, 1938, ch. 675, §571(b), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892.
14502(d)	21 U.S.C. 360ccc(c)	June 25, 1938, ch. 675, §571(c), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892.
14502(e)	21 U.S.C. 360ccc(d) (except (4)(B))	June 25, 1938, ch. 675, §571(d) (except (4)(B)), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892; Pub. L. 114–89, §2(a)(3)(B), Nov. 25, 2015, 129 Stat. 699.
14502(f)	21 U.S.C. 360ccc(e)	June 25, 1938, ch. 675, §571(e), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892.
14502(g)	21 U.S.C. 360ccc(f)	June 25, 1938, ch. 675, §571(f), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892; Pub. L. 115–234, title III, §304(a)(3), Aug. 14, 2018, 132 Stat. 2437.
14502(h)	21 U.S.C. 360ccc(g)	June 25, 1938, ch. 675, §571(g), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892.
14502(i)	21 U.S.C. 360ccc(h)	June 25, 1938, ch. 675, §571(h), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892.
14502(j)	21 U.S.C. 360ccc(i)	June 25, 1938, ch. 675, §571(i), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 892.
14502(k)	21 U.S.C. 360ccc(k)	June 25, 1938, ch. 675, §571(k), as added Pub. L. 115–234, title III, §304(a)(4), Aug. 14, 2018, 132 Stat. 2437.

In subsection (b)(1)(B), the words "not later than September 30, 2019," are omitted as obnsolete.

In subsection (d)(1), in the matter before subparagraph (A), the words "an application under subsection (b)" are substituted for "the application" for clarity.

In subsection (d)(1)(C), the words "ensure the availability" are substituted for "assure the availability" to use the more appropriate word.

In subsection (e)(1)(C)(ii), in the matter before subclause (I), the words "at the Secretary's discretion," are omitted as unnecessary.

In subsection (e)(1)(C)(ii)(II)(cc), the words "ensure the availability" are substituted for "assure the availability" to use the more appropriate word.

In subsection (e)(2)(B), the words "after the issuance under subparagraph (A)," are substituted for "thereafter" for clarity.

In subsection (f)(1), the words "ensure the availability" are substituted for "assure the availability" to use the more appropriate word.

SECTION 14503—INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14503(a) through (c) ...	21 U.S.C. 360ccc–1(a) through (c)	June 25, 1938, ch. 675, §572(a) through (c), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(d)(1)	21 U.S.C. 360ccc–1(d)(3)	June 25, 1938, ch. 675, §572(d)(3), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896; Pub. L. 117–286, §4(a)(158), Dec. 27, 2022, 136 Stat. 4323.
14503(d)(2)	21 U.S.C. 360ccc–1(d)(1)	June 25, 1938, ch. 675, §572(d)(1), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(d)(3)	21 U.S.C. 360ccc–1(d)(2)	June 25, 1938, ch. 675, §572(d)(2), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(d)(4)	21 U.S.C. 360ccc–1(d)(4)	June 25, 1938, ch. 675, §572(d)(4), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(e)	21 U.S.C. 360ccc–1(e)	June 25, 1938, ch. 675, §572(e), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(f)	21 U.S.C. 360ccc–1(f)	June 25, 1938, ch. 675, §572(f), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(g)	21 U.S.C. 360ccc–1(g)	June 25, 1938, ch. 675, §572(g), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(h)	21 U.S.C. 360ccc–1(h)	June 25, 1938, ch. 675, §572(h), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896; Pub. L. 115–234, title III, §302, Aug. 14, 2018, 132 Stat. 2436.
14503(i)	21 U.S.C. 360ccc–1(i)	June 25, 1938, ch. 675, §572(i), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(j)	21 U.S.C. 360ccc–1(j)	June 25, 1938, ch. 675, §572(j), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896.
14503(k)	21 U.S.C. 360ccc–1(k)	June 25, 1938, ch. 675, §572(k), as added Pub. L. 114–89, §2(a)(3)(C), Nov. 25, 2015, 129 Stat. 699.

In subsection (c)(1)(G), the words "may consider necessary" are substituted for "may deem necessary" to use the more appropriate word.

In subsection (e)(1)(D), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

In subsection (g)(2), the words "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" are substituted for "Such regulations may, at the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon" for clarity.

In subsection (i)(1)(B), the words "the Secretary considers" are substituted for "the Secretary deems" to use the more appropriate word.

SECTION 14504—DESIGNATED NEW ANIMAL DRUGS FOR MINOR USE OR MINOR SPECIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14504(a)	21 U.S.C. 360ccc–2(a)	June 25, 1938, ch. 675, §573(a), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 900.
14504(b)(1)	21 U.S.C. 360ccc–2(b)(2)	June 25, 1938, ch. 675, §573(b)(2), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 900.
14504(b)(2)	21 U.S.C. 360ccc–2(b)(1)	June 25, 1938, ch. 675, §573(b)(1), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 900.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14504(c)	21 U.S.C. 360ccc–2(c)	June 25, 1938, ch. 675, §573(c), as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 900; Pub. L. 114–89, §2(a)(4), Nov. 25, 2015, 129 Stat. 700.

In subsection (c)(2)(A), the words "ensure the availability" are substituted for "assure the availability" to use the more appropriate word.

Chapter 147—Medical Gases

SECTION 14701—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14701	21 U.S.C. 360ddd	June 25, 1938, ch. 675, §575, as added Pub. L. 112–144, title XI, §1111, July 9, 2012, 126 Stat. 1108; Pub. L. 114–255, div. A, title III, §3101(a)(2)(R), Dec. 13, 2016, 130 Stat. 1155.

In paragraph (1)(H), the words "considered appropriate" are substituted for "deemed appropriate" to use the more appropriate word.

SECTION 14702—REGULATION OF MEDICAL GASES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14702	21 U.S.C. 360ddd–1	June 25, 1938, ch. 675, §576, as added Pub. L. 112–144, title XI, §1111, July 9, 2012, 126 Stat. 1109; Pub. L. 114–255, div. A, title III, §3101(a)(2)(S), Dec. 13, 2016, 130 Stat. 1155.

In subsection (a)(1), in the matter before subparagraph (A), the words "Beginning 180 days after the date of enactment of this section," are omitted as obsolete.

In subsection (a)(1)(D), the words "considered appropriate" are substituted for "deemed appropriate" to use the more appropriate word.

In subsection (a)(3)(A)(i)(VIII), the words "considered appropriate" are substituted for "deemed appropriate" to use the more appropriate word.

SECTION 14703—INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14703	21 U.S.C. 360ddd–2	June 25, 1938, ch. 675, §577, as added Pub. L. 112–144, title XI, §1111, July 9, 2012, 126 Stat. 1111; Pub. L. 114–255, div. A, title III, §3101(a)(2)(T), Dec. 13, 2016, 130 Stat. 1155.

SECTION 14704—RULES OF CONSTRUCTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14704	21 U.S.C. 360ddd note	Pub. L. 112–144, title XI, §1113, July 9, 2012, 126 Stat. 1112.

In this section, in the matter before paragraph (1), the words “this chapter” are substituted for “this subtitle and the amendments made by this subtitle” to provide a more precise reference to the pertinent provision.

Chapter 149—Pharmaceutical Distribution Supply Chain

SECTION 14901—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14901	21 U.S.C. 360eee	June 25, 1938, ch. 675, § 581, as added Pub. L. 113–54, title II, § 202, Nov. 27, 2013, 127 Stat. 599.

In paragraph (5)(A), the words “The term ‘distribution’” are substituted for “The term `distribute’ or `distribution’” to eliminate unnecessary words because it is not necessary to define the term in more than 1 part of speech.

In paragraph (9)(B), in the matter after the semicolon, the word “or” is substituted for “and” for clarity.

In paragraph (17), the words “a returns processor” are substituted for “a returns processor or reverse logistics provider” to eliminate unnecessary words. See restatement of the definition of “returns processor” in paragraph (18) and accompanying revision note.

In paragraph (18), the defined term “reverse logistics provider” is eliminated as unnecessary. In the source law, the term appears only in paragraph (17) of section 581 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee), which is restated as paragraph (17) of section 14901 of title 21, United States Code. See revision note for paragraph (17) which reflects the elimination of the defined term “reverse logistics provider” in the restatement.

In paragraph (19)(A), the words “the need for the transfer” are substituted for “the transfer” to make the definition consistent with the defined term.

In paragraph (19)(B), the words “the need for the transfer” are substituted for “the transfer” to make the definition consistent with the defined term.

In paragraph (24)(B)(xi), the words “the transfer of products” are substituted for “products transferred” for consistency in the subparagraph.

In paragraph (24)(B)(xiii)(II), the words “division A of subtitle V of this title” are substituted for “Comprehensive Drug Abuse Prevention and Control Act of 1970” to provide a more precise reference to the pertinent provision.

In paragraph (24)(B)(xiii)(III), in the matter before item (aa), the word “manufactures” is substituted for “manufacturers” to correct an error in the law.

In paragraph (27)(A), the words “this chapter” are substituted for “the Drug Supply Chain Security Act” to provide a more precise reference to the pertinent provisions.

In paragraph (27)(B), the words “this chapter” are substituted for “the Drug Supply Chain Security Act” to provide a more precise reference to the pertinent provisions.

In paragraph (27)(D), the words “suspect product or illegitimate product” are substituted for “suspect or illegitimate product” for consistency with the defined term “suspect product” in paragraph (21).

In paragraph (28), the words “The term ‘verification’” are substituted for “The term `verification’ or `verify’” to eliminate unnecessary words because it is not necessary to define the term in more than 1 part of speech.

In paragraph (28), the words “the determination of whether” are substituted for “determining whether” for consistency of the definition with the defined term.

SECTION 14902—REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14902(a)(1)	21 U.S.C. 360eee–1(a)(1)	June 25, 1938, ch. 675, §582(a)(1), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 605.
14902(a)(2)	21 U.S.C. 360eee–1(a)(2)(A)	June 25, 1938, ch. 675, §582(a)(2)(A), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 605.
14902(a)(3) through (9)	21 U.S.C. 360eee–1(a)(3) through (9)	June 25, 1938, ch. 675, §582(a)(3) through (9), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 606.
14902(b)(1) through (3)	21 U.S.C. 360eee–1(b)(1) through (3)	June 25, 1938, ch. 675, §582(b)(1) through (3), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 608.
14902(b)(4) (matter before (A))	21 U.S.C. 360eee–1(b)(4) (matter before (A))	June 25, 1938, ch. 675, §582(b)(4) (matter before (A)), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 609.
14902(b)(4)(A)	21 U.S.C. 360eee–1(b)(4)(A)	June 25, 1938, ch. 675, §582(b)(4)(A), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 609.
14902(b)(4)(B)(i)	21 U.S.C. 360eee–1(b)(4)(B)(i)	June 25, 1938, ch. 675, §582(b)(4)(B)(i), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 609.
14902(b)(4)(B)(ii)(I) ...	21 U.S.C. 360eee–1(b)(4)(B)(ii)(I)	June 25, 1938, ch. 675, §582(b)(4)(B)(ii)(I), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 610.
14902(b)(4)(B)(ii)(II)(aa)	21 U.S.C. 360eee–1(b)(4)(B)(ii)(II) (last sentence)	June 25, 1938, ch. 675, §582(b)(4)(B)(ii)(II) (last sentence), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 610.
14902(b)(4)(B)(ii)(II)(bb)	21 U.S.C. 360eee–1(b)(4)(B)(ii)(II) (1st sentence)	June 25, 1938, ch. 675, §582(b)(4)(B)(ii)(II) (1st sentence), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 610.
14902(b)(4)(B)(iii)	21 U.S.C. 360eee–1(b)(4)(B)(iii)	June 25, 1938, ch. 675, §582(b)(4)(B)(iii), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 610.
14902(b)(4)(B)(iv)	21 U.S.C. 360eee–1(b)(4)(B)(iv)	June 25, 1938, ch. 675, §582(b)(4)(B)(iv), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 610.
14902(b)(4)(B)(v)	21 U.S.C. 360eee–1(b)(4)(B)(v)	June 25, 1938, ch. 675, §582(b)(4)(B)(v), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 610.
14902(b)(4)(C)	21 U.S.C. 360eee–1(b)(4)(C)	June 25, 1938, ch. 675, §582(b)(4)(C), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 610.
14902(b)(4)(D)	21 U.S.C. 360eee–1(b)(4)(D)	June 25, 1938, ch. 675, §582(b)(4)(D), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 611.
14902(b)(4)(E)	21 U.S.C. 360eee–1(b)(4)(E)	June 25, 1938, ch. 675, §582(b)(4)(E), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 611.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14902(b)(4)(F)	21 U.S.C. 360eee–1(b)(4)(F)	June 25, 1938, ch. 675, §582(b)(4)(F), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 611.
14902(c)	21 U.S.C. 360eee–1(c)	June 25, 1938, ch. 675, §582(c), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 611.
14902(d)	21 U.S.C. 360eee–1(d)	June 25, 1938, ch. 675, §582(d), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 616.
14902(e)	21 U.S.C. 360eee–1(e)	June 25, 1938, ch. 675, §582(e), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 619.
14902(f)	21 U.S.C. 360eee–1(f)	June 25, 1938, ch. 675, §582(f), as added Pub. L. 113–54, title II, §202, Nov. 27, 2013, 127 Stat. 623.
14902(g)	21 U.S.C. 360eee–1(g)	June 25, 1938, ch. 675, §582(g), as added Pub. L. 113–54, title II, §203, Nov. 27, 2013, 127 Stat. 623.
14902(h)	21 U.S.C. 360eee–1(h)	June 25, 1938, ch. 675, §582(h), as added Pub. L. 113–54, title II, §203, Nov. 27, 2013, 127 Stat. 626.
14902(i)	21 U.S.C. 360eee–1(i)	June 25, 1938, ch. 675, §582(i), as added Pub. L. 113–54, title II, §203, Nov. 27, 2013, 127 Stat. 628.
14902(j)	21 U.S.C. 360eee–1(j)	June 25, 1938, ch. 675, §582(j), as added and amended Pub. L. 113–54, title II, §203, Nov. 27, 2013, 127 Stat. 629.
14902(k)	21 U.S.C. 360eee–1(k)	June 25, 1938, ch. 675, §582(k), as added and amended Pub. L. 113–54, title II, §203, Nov. 27, 2013, 127 Stat. 630.
14902(l)	21 U.S.C. 360eee–1(l)	June 25, 1938, ch. 675, §582(l), as added and amended Pub. L. 113–54, title II, §203, Nov. 27, 2013, 127 Stat. 630.
14902(m)	21 U.S.C. 360eee–1(m)	June 25, 1938, ch. 675, §582(m), as added and amended Pub. L. 113–54, title II, §203, Nov. 27, 2013, 127 Stat. 630.

In subsection (a)(3)(A), in the matter before clause (i), the words "Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (a)(5)(A), the words "Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (b)(1)(A), in the matter before clause (i), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (b)(1)(C)(i), the words "Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (b)(2)(A), the words "Beginning not later than 4 years after the date of enactmentof the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (b)(3), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (b)(4), in the matter before subparagraph (A), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (b)(4)(A)(i)(II), the words "beginning 4 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (b)(4)(C)(i), the words "Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (b)(4)(C)(i), the words "that the authorized repackager, wholesale distributor, or dispenser believes" are substituted for "such person believes" for clarity.

In subsection (b)(4)(C)(i), the words "notify the authorized repackager, wholesale distributor, or dispenser" are substituted for "notify the person" for clarity.

In subsection (b)(4)(E), the words "Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act" are omitted as obsolete.

In subsection (c)(1)(A), in the matter before clause (i), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (c)(1)(B)(ii), the words "the manufacturer, repackager, or wholesale distributor from whom the product was purchased" are substituted for "such a person" for clarity.

In subsection (c)(1)(D)(i), the words "Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (c)(2), the words "Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (c)(3), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (c)(4), in the matter before subparagraph (A), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (c)(4)(A)(i)(II), the words "beginning 6 years after the date of enactment of the Drug Supply Chain Security Act" are omitted as obsolete.

In subsection (c)(4)(D), the words "Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (d)(1)(A), in the matter before clause (i), the words "Beginning July 1, 2015," are omitted as obsolete.

In subsection (d)(1)(C)(ii), the words "the manufacturer, repackager, wholesale distributor from whom the product was purchased, or returns processor" are substituted for "such a person" for clarity.

In subsection (d)(2), the words "Beginning not later than 7 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (d)(3), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (d)(4), in the matter before subparagraph (A), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (d)(4)(A)(ii)(I), the words "beginning 7 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (d)(4)(A)(ii)(II), the words "beginning 7 years after the date of enactment of such Act," are omitted as obsolete.

In subsection (e)(1)(A), in the matter before clause (i), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (e)(1)(B)(i), the words "the manufacturer, repackager, or wholesale distributor from whom the product was purchased" are substituted for "such a person" for clarity.

In subsection (e)(2)(A), in the matter before clause (i), the words "Beginning not later than 5 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (e)(3), the words "Beginning January 1, 2015," are omitted as obsolete.

In subsection (e)(4), in the matter before subparagraph (A), the words "Beginning not later than January 1, 2015," are omitted as obsolete.

In subsection (e)(4)(A)(i)(II)(bb), the words "beginning 5 years after the date of enactment of the Drug Supply Chain Security Act" are omitted as obsolete.

In subsection (e)(4)(C)(i), the words "Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (e)(4)(C)(i), the words "notify the authorized manufacturer, wholesale distributor, or dispenser" are substituted for "notify the person" for clarity.

In subsection (e)(4)(E), the words "Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (h)(2)(A), in the matter before clause (i), the words "Not later than 180 days after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

SECTION 14903—NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14903	21 U.S.C. 360eee–2	June 25, 1938, ch. 675, § 583, as added Pub. L. 113–54, title II, § 204(a)(5), Nov. 27, 2013, 127 Stat. 634.

SECTION 14904—NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14904	21 U.S.C. 360eee–3	June 25, 1938, ch. 675, § 584, as added Pub. L. 113–54, title II, § 205, Nov. 27, 2013, 127 Stat. 636.

In subsection (b), in the matter before paragraph (1), the words "Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
14905	21 U.S.C. 360eee–4	June 25, 1938, ch. 675, § 585, as added Pub. L. 113–54, title II, § 205, Nov. 27, 2013, 127 Stat. 638.

In subsection (a), in the matter before paragraph (1), the words "Beginning on the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (a)(1), the words "(or regulations issued under this chapter or section 13103(d) of this title)" are substituted for "(or regulations issued thereunder)" for clarity.

In subsection (b)(1), the words "Beginning on the date of enactment of the Drug Supply Chain Security Act," are omitted as obsolete.

In subsection (c), the words "(or regulations issued under this chapter or section 13103(d) of this title)" are substituted for "(or regulations issued thereunder)" for clarity.

Chapter 151—Nonprescription Sunscreen and Other Active Ingredients

SECTION 15101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15101	21 U.S.C. 360fff	June 25, 1938, ch. 675, § 586, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2035.

SECTION 15102—SUBMISSION OF REQUESTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15102	21 U.S.C. 360fff–1	June 25, 1938, ch. 675, § 586A, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2036.

In this section, the words "of the ingredient or combination of ingredients" are substituted for "thereof" for clarity.

SECTION 15103—ELIGIBILITY DETERMINATIONS; DATA SUBMISSION; FILING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15103	21 U.S.C. 360fff–2	June 25, 1938, ch. 675, § 586B, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2036.

In subsection (a)(2)(A), in the matter before clause (i), the words "of the ingredient or combination of ingredients" are substituted for "thereof" for clarity.

SECTION 15104—GRASE DETERMINATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15104	21 U.S.C. 360fff–3	June 25, 1938, ch. 675, §586C, as added Pub. L. 113–195, §2(a), Nov. 26, 2014, 128 Stat. 2039; Pub. L. 116–136, div. A, title III, §3854(b)(1) through (3), Mar. 27, 2020, 134 Stat. 455, 456.

SECTION 15105—GUIDANCE; OTHER PROVISIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15105	21 U.S.C. 360fff–4 (except (a)(1)(B))	June 25, 1938, ch. 675, § 586D (except (a)(1)(B)), as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2044.

In subsection (a)(1)(A), in the matter before clause (i), the words "The Secretary shall issue final guidance on" are substituted for "Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, the Secretary shall issue draft guidance on" to eliminate obsolete words and on authority of section 586D(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–4(a)(1)(B)) which is repealed as unnecessary by the bill enacting title 21, United States Code.

In subsection (a)(2)(A), the words "beginning on the date of enactment of the Sunscreen Innovation Act," are omitted as obsolete.

SECTION 15106—EFFECT OF SECTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15106	21 U.S.C. 360fff note	Pub. L. 113–195, §2(b), Nov. 26, 2014, 128 Stat. 2045.

In paragraphs (1) and (2), the words "a sponsor" are substituted for "a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a))" because the restatement of section 15106 of title 21, United States Code, in chapter 151 of title 21, United States Code, makes section 15101 of that title applicable to section 15106 that title.

SECTION 15107—NON-SUNSCREEN TIME AND EXTENT APPLICATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15107	21 U.S.C. 360fff–6 (except (b)(5))	June 25, 1938, ch. 675, § 586F (except (b)(5)), as added Pub. L. 113–195, § 3, Nov. 26, 2014, 128 Stat. 2046.

In subsection (b)(1), in the matter before subparagraph (A), the words "The Secretary shall issue final regulations" are substituted for "Not later than 18 months after the date of enactment of the Sunscreen Innovation Act, the Secretary shall issue proposed regulations" to eliminate obsolete words and on authority of section 586F(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–6(b)(5)) which is repealed as unnecessary by the bill enacting title 21, United States Code.

SECTION 15108—REPORT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15108	21 U.S.C. 360fff–7	June 25, 1938, ch. 675, § 586G, as added Pub. L. 113–195, § 4(c), Nov. 26, 2014, 128 Stat. 2050.

SECTION 15109—SUNSET

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
15109	21 U.S.C. 360fff–8	June 25, 1938, ch. 675, §586H, as added Pub. L. 116–136, div. A, title III, §3854(b)(4), Mar. 27, 2020, 134 Stat. 456.

Division E—Cosmetics

Chapter 171—Cosmetics

Subchapter I—General Provisions

SECTION 17101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17101	21 U.S.C. 364	June 25, 1938, ch. 675, §604, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5847.

Subchapter II—Adulterated and Misbranded Cosmetics

SECTION 17111—ADULTERATED COSMETICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17111(a)	21 U.S.C. 361(a) (last sentence)	June 25, 1938, ch. 675, §601(a) (last sentence), 52 Stat. 1054; Pub. L. 103–80, § 3(x), Aug. 13, 1993, 107 Stat. 778.
17111(b)(1)	21 U.S.C. 361(a) (from "If it bears" through "customary or usual,")	June 25, 1938, ch. 675, §601(a) (from "If it bears" through "customary or usual,"), 52 Stat. 1054; Pub. L. 103–80, § 3(x), Aug. 13, 1993, 107 Stat. 778.
17111(b)(2)	21 U.S.C. 361(a) (from "except that" through "preliminary testing.")	June 25, 1938, ch. 675, §601(a) (from "except that" through "preliminary testing."), 52 Stat. 1054; Pub. L. 103–80, § 3(x), Aug. 13, 1993, 107 Stat. 778.
17111(c) through (f)	21 U.S.C. 361(b) through (e)	June 25, 1938, ch. 675, §601(b) through (e), 52 Stat. 1054; Pub. L. 86–618, title I, § 102(c)(1), July 12, 1960, 74 Stat. 398; Pub. L. 102–571, title I, § 107(11), Oct. 29, 1992, 106 Stat. 4499.
17111(g), (h)	21 U.S.C. 361(f), (g)	June 25, 1938, ch. 675, §601(f), (g), as added Pub. L. 117–328, div. FF, title III, §3503(a)(2), Dec. 29, 2022, 136 Stat. 5858.

In subsection (a), the words “this section” are substituted for “this paragraph and paragraph (e)” for convenience.

In subsections (b)(1), (c), (d), (e), (f), (g), and (h), the words "A cosmetic shall be deemed to be adulterated" are added to carry forward the matter before subsection (a) of section 601 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361).

In subsection (b)(2)(A), the words "bears the statement, conspicuously displayed on the label," are substituted for "bears the following legend conspicuously displayed thereon:" for clarity and consistency in title 21, United States Code.

In subsection (b)(2)(B), the words "for the preliminary testing referred to in the statement under subparagraph (A)" are substituted for "for such preliminary testing" for clarity.

SECTION 17112—MISBRANDED COSMETICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17112	21 U.S.C. 362(a) through (f)	June 25, 1938, ch. 675, §602(a) through (f), 52 Stat. 1054; Pub. L. 86–618, title I, § 102(c)(2), July 12, 1960, 74 Stat. 398; Pub. L. 91–601, § 6(f), formerly § 7(f), Dec. 30, 1970, 84 Stat. 1673, renumbered Pub. L. 97–35, title XII, § 1205(c), Aug. 13, 1981, 95 Stat. 716; Pub. L. 102–571, title I, § 107(12), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 117–328, div. FF, title III, §3503(a)(3), Dec. 29, 2022, 136 Stat. 5858.

In subsections (a), (b)(1), (c), (d). (e)(1), and (f), the words "A cosmetic shall be deemed to be misbranded" are added to carry forward the matter before subsection (a) of section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362).

In subsection (d), the words "if its container is made, formed, or filled in a manner that is misleading" are substituted for "if its container is so made, formed, or filled as to be misleading" for clarity.

SECTION 17113—REGULATIONS MAKING EXEMPTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17113	21 U.S.C. 363	June 25, 1938, ch. 675, § 603, 52 Stat. 1054.

Subchapter III—General Safety Regulations

SECTION 17121—ADVERSE EVENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17121 (except (e))	21 U.S.C. 364a (except (e))	June 25, 1938, ch. 675, §605 (except (e)), as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5848.
17121(e)(1)	21 U.S.C. 364a(e)(1)	June 25, 1938, ch. 675, §605(e)(1), as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5849.
17121(e)(2)(A)	21 U.S.C. 364a(e)(2)(B)	June 25, 1938, ch. 675, §605(e)(2)(B), as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5849.
17121(e)(2)(B)	21 U.S.C. 364a(e)(2)(A)	June 25, 1938, ch. 675, §605(e)(2)(A), as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5849.

In subsection (e)(2)(A), the defined term "authorized individual" is substituted for "authorized person" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (e)(2)(A), in the matter before clause (i), the word "Department" is substituted for "Department of Health and Human Services" because of the definition of "Department" in section 10101 of title 21, United States Code.

In subsection (e)(2)(B), the words "authorized individual" are substituted for "authorized person" because of the substitution made in subsection (e)(2)(A) as described in a previous revision note.

In subsection (g)(2), the parentheticals "(commonly referred to as the 'Privacy Act of 1974')" and "(commonly referred to as the `Freedom of Information Act')" are omitted as unnecessary.

SECTION 17122—GOOD MANUFACTURING PRACTICE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17122	21 U.S.C. 364b	June 25, 1938, ch. 675, §606, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5850.

In subsection (a)(3), the words "under this subsection" are substituted for "under this paragraph" to correct an error in the law.

In subsection (c), the words "shall publish final regulations under this section" are substituted for "shall publish a final such rule" for clarity and consistency in the section.

SECTION 17123—REGISTRATION AND PRODUCT LISTING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17123	21 U.S.C. 364c	June 25, 1938, ch. 675, §607, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5851.

In subsection (c)(2), the word "Thereafter," is omitted as unnecessary.

SECTION 17124—SAFETY SUBSTANTIATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17124(a)	21 U.S.C. 364d(c)	June 25, 1938, ch. 675, §608(c), as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5854.
17124(b), (c)	21 U.S.C. 364d(a), (b)	June 25, 1938, ch. 675, §608(a), (b), as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5854.

SECTION 17125—LABELING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17125	21 U.S.C. 364e	June 25, 1938, ch. 675, §609, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5854.

Subsection (a) restates section 609(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 364e(a)), the effective date of which is provided in section 3503(b)(2) of the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 21 U.S.C. 364e note). Under that section 3503(b)(2), the effective date of that section 609(a), "as added by section 802", is the date that is 2 years after the date of enactment of the Modernization of Cosmetics Regulation Act of 2022 (Public Law 117-328, div. FF, title III, subtitle E, 136 Stat. 5847). Section 4(33) of the bill amending title 21, United States Code amends that section 3502(b)(2) by striking "as added by section 802," and inserting "as added by section 3502," to correct an error in the law.

In subsection (b)(3)(A), the words "implementing this subsection" are substituted for "implementing this requirement" for clarity and consistency with subsection (b)(4).

In subsection (c)(2)(A), the words "only by professionals" are substituted for "only by licensed professionals" to eliminate an unnecessary word because of the definition of "professional" in subsection (c)(1).

SECTION 17126—RECORDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17126	21 U.S.C. 364f	June 25, 1938, ch. 675, §610, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5855.

SECTION 17127—MANDATORY RECALL AUTHORITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17127	21 U.S.C. 364g	June 25, 1938, ch. 675, §611, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5855.

In subsection (a)(1), the words "recall the cosmetic" are substituted for "recall such article" for consistency in the subsection.

In subsection (a)(2), the words "distribution of the cosmetic" are substituted for "distribution of such article" for consistency in the subsection.

In subsection (e)(1), the words "the cosmetic" are substituted for "such product" for consistency in the subsection.

In subsection (f)(1)(B)(ii), the words "the cosmetic" are substituted for "such article" for consistency in the subsection.

SECTION 17128—SMALL BUSINESSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17128	21 U.S.C. 364h	June 25, 1938, ch. 675, §612, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5857.

SECTION 17129—EXEMPTION FOR CERTAIN PRODUCTS AND FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17129	21 U.S.C. 364i	June 25, 1938, ch. 675, §613, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5857.

SECTION 17130—PREEMPTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17130	21 U.S.C. 364j	June 25, 1938, ch. 675, §614, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5857.

Division F—General Authorities

Chapter 175—General Administrative Provisions

SECTION 17501—REGULATIONS AND HEARINGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17501	21 U.S.C. 371	June 25, 1938, ch. 675, § 701, 52 Stat. 1055; June 25, 1948, ch. 646, § 32, 62 Stat. 991; Apr. 15, 1954, ch. 143, § 2, 68 Stat. 55; Aug. 1, 1956, ch. 861, § 2, 70 Stat. 919; Pub. L. 85–791, § 21, Aug. 28, 1958, 72 Stat. 948; Pub. L. 86–618, title I, § 103(a)(4), July 12, 1960, 74 Stat. 398; Pub. L. 101–535, § 8, Nov. 8, 1990, 104 Stat. 2365; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §§ 3(y), (dd)(1), 4(c), Aug. 13, 1993, 107 Stat. 778, 779; Pub. L. 103–396, § 3(b), Oct. 22, 1994, 108 Stat. 4155; Pub. L. 105–115, title IV, § 405, Nov. 21, 1997, 111 Stat. 2368; Pub. L. 112–144, title VI, § 619, July 9, 2012, 126 Stat. 1063.

In subsection (b), the reference to the Secretary of the Treasury is retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

In subsection (e)(1)(A), in the matter before clause (i), the reference to section 502(d) is omitted because that provision was repealed by section 126(b) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2327).

In subsection (e)(1)(A), in the matter before clause (i), the words "shall be initiated" are substituted for "shall be begun" for consistency in title 21, United States Code.

In subsection (e)(1)(C)(i), the words "after the presentation of views under subparagraph (B)" are substituted for "thereafter" for clarity.

In subsection (e)(2)(A), the words "considered objectionable" are substituted for "deemed objectionable" to use the more appropriate word.

In subsection (f)(1)(B), the words "immediately transmitted" are substituted for "forthwith transmitted" for consistency in title 21, United States Code.

In subsection (f)(3)(B), the words "If the Secretary, in the Secretary's order," are substituted for "If the order of the Secretary" for clarity.

In subsection (f)(5), the word "in the individual" are substituted for "in the person" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (g)(2), the words "action for condemnation" are substituted for "libel for condemnation" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

SECTION 17502—EXAMINATIONS AND INVESTIGATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17502(a)(1)	21 U.S.C. 372(a)(4)	June 25, 1938, ch. 675, §702(a)(4), 52 Stat. 1056; Pub. L. 87–781, title III, §307(b), Oct. 10, 1962, 76 Stat. 796; Pub. L. 107–188, title III, §314(3), June 12, 2002, 116 Stat. 674.
17502(a)(2)	21 U.S.C. 372(a)(1)	June 25, 1938, ch. 675, §702(a)(1), 52 Stat. 1056; Pub. L. 87–781, title III, §307(b), Oct. 10, 1962, 76 Stat. 796; Pub. L. 107–188, title III, §314(1), June 12, 2002, 116 Stat. 674; Pub. L. 111–31, div. A, title I, §103(g), June 22, 2009, 123 Stat. 1837.
17502(a)(3)	21 U.S.C. 372(a)(2)	June 25, 1938, ch. 675, §702(a)(2), as added Pub. L. 107–188, title III, §314(4), June 12, 2002, 116 Stat. 674.
17502(a)(4)	21 U.S.C. 372(a)(3)	June 25, 1938, ch. 675, §702(a)(3), 52 Stat. 1056; Pub. L. 87–781, title III, §307(b), Oct. 10, 1962, 76 Stat. 796; Pub. L. 107–188, title III, §314(2), June 12, 2002, 116 Stat. 674.
17502(b) through (e) ...	21 U.S.C. 372(b) through (e)	June 25, 1938, ch. 675, §702(b) through (e), 52 Stat. 1056; Pub. L. 87–781, title III, §308, Oct. 10, 1962, 76 Stat. 796; Pub. L. 89–74, §8(a), July 15, 1965, 79 Stat. 234; Pub. L. 91–513, title II, §701(f), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 102–300, §6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(2), Aug. 13, 1993, 107 Stat. 779; Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4732(b)(12)], Nov. 29, 1999, 113 Stat. 1536, 1501A–584.

In subsection (a)(2)(A), the words "or political subdivision of a State or territory of the United States" are substituted for "or political subdivision thereof" for clarity.

In subsection (a)(2)(B)(i), the words "contract with a State" are substituted for "contract with the States" for consistency in the clause.

In subsection (a)(3)(A)(i), the words "another Federal agency" are substituted for "another Federal department or agency" and the words "the other Federal agency" are substituted for "such other department or agency" to eliminate unnecessary words.

In subsection (a)(3)(A)(iii), the words "the head of the other Federal agency" are substituted for "the head of the other department or agency" and the words "the other Federal agency" are substituted for "such other department or agency" to eliminate unnecessary words.

In subsection (a)(3)(B), the words "another Federal agency" are substituted for "another Federal department or agency" and the words "the other Federal agency" are substituted for "such department or agency" to eliminate unnecessary words.

In subsection (a)(3)(C), in the matter before clause (i), the words "another Federal agency" are substituted for "another Federal department or agency" and the words "the other Federal agency" are substituted for "such department or agency" to eliminate unnecessary words.

In subsection (a)(3)(C), in the matter before clause (i), the words "with respect to their respective agencies" are substituted for "with respect to their respective departments or agencies" to eliminate unnecessary words.

In subsection (b)(1), the words "If a sample" are substituted for "Where a sample" for consistency in title 21, United States Code.

In subsection (b)(1), the words "or the owner of the article" are substituted for "or the owner thereof" for clarity.

In subsection (b)(1), the words "or the person's or owner's attorney or agent" are substituted for "or his attorney or agent" for clarity.

In subsection (c), the words "records of any agency" are substituted for "records of any department" for consistency in the section.

In subsection (e)(1)(C), the words "pursuant to an action" are substituted for "pursuant to libel" for consistency with section 10504 of title 21, United States Code, and with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (e)(1)(E), the words "institution of an action for condemnation proceeding" are substituted for "institution of libel proceedings" for consistency with section 10504(a)(2) of title 21, United States Code, and with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (e)(2), the words "an action for condemnation proceeding" are substituted for "libel proceedings" for consistency with paragraph (1)(E), with section 10504(a)(2) of title 21, United States Code, and with the Federal Rules of Civil Procedure (28 U.S.C. App.).

SECTION 17503—RECORDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17503	21 U.S.C. 373	June 25, 1938, ch. 675, § 703, 52 Stat. 1057; Pub. L. 91–452, title II, § 230, Oct. 15, 1970, 84 Stat. 930; Pub. L. 103–80, § 3(z), Aug. 13, 1993, 107 Stat. 778; Pub. L. 109–59, title VII, § 7202(c), Aug. 10, 2005, 119 Stat. 1913; Pub. L. 111–31, div. A, title I, § 103(h), June 22, 2009, 123 Stat. 1837.

SECTION 17504—INSPECTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17504(a) through (e) ...	21 U.S.C. 374(a) through (e)	June 25, 1938, ch. 675, §704(a) through (e), 52 Stat. 1057; Aug. 7, 1953, ch. 350, §1, 67 Stat. 476; Pub. L. 87–781, title II, §201(a), (b), Oct. 10, 1962, 76 Stat. 792, 793; Pub. L. 94–295, §6, May 28, 1976, 90 Stat. 581; Pub. L. 96–359, §4, Sept. 26, 1980, 94

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Stat. 1193; Pub. L. 103–80, §3(aa), Aug. 13, 1993, 107 Stat. 778; Pub. L. 105–115, title I, §125(b)(2)(L), title IV, §412(b), Nov. 21, 1997, 111 Stat. 2326, 2375; Pub. L. 107–188, title III, § 306(b), June 12, 2002, 116 Stat. 670; Pub. L. 111–31, div. A, title I, §103(i)(1), (2), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title I, §101(b), Jan. 4, 2011, 124 Stat. 3887; Pub. L. 112–144, title VII, §706, July 9, 2012, 126 Stat. 1067; Pub. L. 116–136, div. A, title III, §3112(d), Mar. 27, 2020, 134 Stat. 362; Pub. L. 117–328, div. FF, title II, §2515(a)(2), title III, §§3611(a), (b)(1), 3612(a), 3613(b), Dec. 29, 2022, 136 Stat. 5806, 5869, 5872.
17504(f)(1)	21 U.S.C. 374(f)(3)	June 25, 1938, ch. 675, §704(f)(3), as added Pub. L. 107–250, title II, § 201(b)(3), Oct. 26, 2002, 116 Stat. 1602, 1609.
17504(f)(2)	21 U.S.C. 374(f)(1)	June 25, 1938, ch. 675, §704(f)(1), as added Pub. L. 105–115, title II, §210(b), Nov. 21, 1997, 111 Stat. 2344; Pub. L. 107–250, title II, §201(b)(1), Oct. 26, 2002, 116 Stat. 1609.
17504(f)(3)	21 U.S.C. 374(f)(2)	June 25, 1938, ch. 675, §704(f)(2), as added Pub. L. 105–115, title II, § 210(b), Nov. 21, 1997, 111 Stat. 2344; Pub. L. 107–250, title II, §201(b)(2), Oct. 26, 2002, 116 Stat. 1609.
17504(g)(1) through (9)	21 U.S.C. 374(g)(1) through (9)	June 25, 1938, ch. 675, §704(g)(1) through (9), as added Pub. L. 107–250, title II, §201(a), Oct. 26, 2002, 116 Stat. 1602; Pub. L. 108–214, §2(b)(1)(A) through (F), Apr. 1, 2004, 118 Stat. 573; Pub. L. 110–85, title II, §228(1) through (5), Sept. 27, 2007, 121 Stat. 855.
17504(g)(10)(A)	21 U.S.C. 374(g)(10)(C)	June 25, 1938, ch. 675, §704(g)(10)(C), as added Pub. L. 107–250, title II, §201(a), Oct. 26, 2002, 116 Stat. 1602; Pub. L. 110–85, title II, §228(6), Sept. 27, 2007, 121 Stat. 855.
17504(g)(10)(B)	21 U.S.C. 374(g)(10)(A)	June 25, 1938, ch. 675, §704(g)(10)(A), as added Pub. L. 107–250, title II, §201(a), Oct. 26, 2002, 116 Stat. 1602.
17504(g)(10)(C)	21 U.S.C. 374(g)(10)(B)	June 25, 1938, ch. 675, §704(g)(10)(B), as added Pub. L. 107–250, title II, §201(a), Oct. 26, 2002, 116 Stat. 1602; Pub. L. 108–214, §2(b)(1)(G), Apr. 1, 2004, 118 Stat. 573.
17504(g)(11) through (15)	21 U.S.C. 374(g)(11) through (15)	June 25, 1938, ch. 675, §704(g)(11) through (15), as added Pub. L. 107–250, title II, §201(a), Oct. 26, 2002, 116 Stat. 1602; Pub. L. 108–214, §2(b)(1)(H), Apr. 1, 2004, 118 Stat. 573; Pub. L. 111–31, div. A, title I, §103(i)(3), June 22, 2009, 123 Stat. 1837; Pub. L. 112–144, title VI, §612, July 9, 2012, 126 Stat. 1060; Pub. L. 115–52, title VII, §§703, 705, Aug. 18, 2017, 131 Stat. 1056, 1057; Pub. L. 117–180, div. F, title V, §5007, Sept. 30, 2022, 136 Stat. 2168; Pub. L. 117–229, div. C, title III, §306, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3106, Dec. 29, 2022, 136 Stat. 5807.
17504(h)	21 U.S.C. 374(h)	June 25, 1938, ch. 675, §704(h), as added Pub. L. 115–52, title VII, §702(a), Aug. 18, 2017, 131 Stat. 1055.

In subsection (a)(1)(F), the words "for each inspection under this paragraph" are substituted for "for each such inspection" for clarity.

In subsection (a)(1)(G), the words "Each inspection under this paragraph" are substituted for "Each such inspection" for clarity.

In subsection (a)(2), in the matter before subparagraph (A), the words "Paragraph (1)(D) shall not apply to" are substituted for "The provisions of the third sentence of paragraph (1) shall not apply to" to provide the correct reference to the pertinent provision. Prior to the amendment made by section 3504 of the Modernization of Cosmetics Regulation Act of 2022 (Public Law

117-328, div. FF, title III, subtitle E, 136 Stat. 5847), the reference to the "third sentence" in the source provision referred to the provision that relates to the scope of inspection relating to drugs, devices, and tobacco products. After enactment of that section 3504, that provision became the 4th sentence of section 374(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)), which is restated as subparagraph (D) of subsection (a)(1) of the restatement; the substituted reference conforms the restatement to the amendment made by that section 3504.

In subsection (a)(2)(C), in the matter after the semicolon, the word "or" is added for clarity and for consistency in the title.

In subsection (b)(2), for clarity, subparagraph (B) is restated to contain clauses and in subparagraph (B)(ii), the words "that is, or has been" are substituted for "is, or has been".

In subsection (e), the words "Each person" are substituted for "Every person" for clarity.

In subsection (e), the words "each person" are substituted for "every person" for clarity.

In subsection (g)(2)(B), the word "Thereafter" is omitted as unnecessary.

In subsection (g)(2)(B), the words "a person requesting accreditation" are substituted for "those requesting accreditation" for clarity.

In subsection (g)(5)(B)(i)(I)(bb), in the matter after the semicolon, the word "or" is added for clarity and for consistency in the title.

In subsection (g)(6)(B)(iii)(I)(bb), the words "the Secretary considers necessary" are substituted for "the Secretary deems necessary" to use the more appropriate word.

In subsection (g)(7)(C), the words "but not later than" are substituted for "but under no circumstances later than" to eliminate unnecessary words.

SECTION 17505—PUBLICITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17505	21 U.S.C. 375	June 25, 1938, ch. 675, §705, 52 Stat. 1057; Pub. L. 111–31, div. A, title I, § 103(j), June 22, 2009, 123 Stat. 1837.

In subsection (a), the words "The Secretary shall publish" are substituted for "The Secretary shall cause to be published" for consistency in title 21, United States Code, and to eliminate unnecessary words.

In subsection (a), the words "disposition of all such judgments, decrees, and court orders" are substituted for "disposition thereof" for clarity.

In subsection (b), the words "The Secretary may disseminate" are substituted for "The Secretary may also cause to be disseminated" for consistency in title 21, United States Code, and to eliminate unnecessary words.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17506	21 U.S.C. 376	June 25, 1938, ch. 675, §706, formerly § 702A, formerly June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204; amended Aug. 27, 1935, ch. 739, 49 Stat. 871; June 25, 1938, ch. 675, § 1002(a), formerly § 902(a), 52 Stat. 1059, renumbered § 1002(a), Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784; renumbered § 702A of act June 25, 1938, July 12, 1943, ch. 221, title II, 57 Stat. 500; Pub. L. 102–300, § 6(b)(2), June 16, 1992, 106 Stat. 240; renumbered § 706, Pub. L. 102–571, title I, § 106(3), Oct. 29, 1992, 106 Stat. 4498; Pub. L. 103–80, § 3(dd)(2), Aug. 13, 1993, 107 Stat. 779.

In subsection (a), the words "for shipment or sale subject to this subtitle" are substituted "for shipment or sale within the jurisdiction of this Act" for consistency in title 21, United States Code.

In subsection (a), the words "at his discretion," are omitted as unnecessary.

In subsection (d), the words "deposited in" are substituted for "covered into" for clarity.

In subsection (e), the words "provided under this section" are substituted for "herein provided" for clarity.

In subsection (f), the words "shall be imprisoned for not more than 1 year, fined under title 18 but not less than $1,000, or both" are substituted for "shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than $1,000 nor more than $5,000, or both such imprisonment and fine" for consistency with title 18, United States Code, and to eliminate unnecessary words.

SECTION 17507—ADVERTISING OF FOODS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17507	21 U.S.C. 378	June 25, 1938, ch. 675, § 707, as added Pub. L. 94–278, title V, § 502(b), Apr. 22, 1976, 90 Stat. 412.

In subsection (a)(1), in the matter before subparagraph (A), the words "with respect to any food or advertising of food" are added for clarity.

In subsection (a)(1)(B), the words "causes the food to be misbranded under section 11301(2) of this title" are substituted for "causes the food to be so misbranded" for clarity.

In subsection (a)(2)(A)(i), in the matter after the semicolon, the word "and" is added for clarity.

In subsection (b)(1), in the matter before subparagraph (A), the words "receipt of the Secretary's notice" are substituted for "receipt of such notice" for clarity.

SECTION 17508—CONFIDENTIAL INFORMATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17508	21 U.S.C. 379	June 25, 1938, ch. 675, § 708, as added Pub. L. 94–295, § 8, May 28, 1976, 90 Stat. 582; amended Pub. L. 112–144, title VII, § 710, July 9, 2012, 126 Stat. 1070.

In subsection (a)(1), the words "determines that the person requires" are substituted for "determines such other person requires" for clarity.

In subsection (b)(1), in the matter before subparagraph (A), the words "(commonly referred to as the 'Freedom of Information Act')" are omitted as unnecessary.

SECTION 17509—EXISTENCE OF JURISDICTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17509	21 U.S.C. 379a	June 25, 1938, ch. 675, § 709, as added Pub. L. 94–295, § 8, May 28, 1976, 90 Stat. 583; amended Pub. L. 105–115, title IV, § 419, Nov. 21, 1997, 111 Stat. 2379; Pub. L. 111–31, div. A, title I, § 103(k), June 22, 2009, 123 Stat. 1837.

In this section, the word "deemed" is substituted for "presumed" for consistency in the title.

SECTION 17510—CONSOLIDATED ADMINISTRATIVE AND LABORATORY FACILITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17510	21 U.S.C. 379b(a) through (c)	June 25, 1938, ch. 675, § 710(a) through (c), as added Pub. L. 101–635, title I, § 101, Nov. 28, 1990, 104 Stat. 4583.

SECTION 17511—AUTOMATION OF FDA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17511	21 U.S.C. 379d(a)	June 25, 1938, ch. 675, §711(a), formerly §712, as added Pub. L. 101–635, title IV, § 401, Nov. 28, 1990, 104 Stat. 4585; renumbered § 711, Pub. L. 102–571, title I, § 106(3), Oct. 29, 1992, 106 Stat. 4498.

SECTION 17512—CONFLICTS OF INTEREST

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17512	21 U.S.C. 379d–1	June 25, 1938, ch. 675, § 712, as added Pub. L. 110–85, title VII, § 701(a), Sept. 27, 2007, 121 Stat. 900; amended Pub. L. 112–144, title XI, § 1142(a), July 9, 2012, 126 Stat. 1127; Pub. L. 114–255, div. A, title III, §3101(a)(2)(U), Dec. 13, 2016, 130 Stat. 1155; Pub. L. 117–286, §4(a)(159), (c)(29), Dec. 27, 2022, 136 Stat. 4323, 4357.

In subsection (c)(2), the words "but not later than" are substituted for "but in no case later than" to eliminate unnecessary words.

In subsection (c)(1), in the matter before subparagraph (A), the words "(popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)" are omitted as unnecessary.

In subsection (d), the words "section 552 or 552a of title 5" are substituted for "section 552 of title 5, United States Code, and section 552a of title 5, United States Code" for consistency in the section.

In subparagraphs (A) and (B) of subsection (e)(1), the word "individuals" is substituted for "persons" each place it appears for consistency with subsections (b)(2)(C) and (e)(1)(D), and with the definition of "person" in section 10101 of title 21, United States Code.

In subparagraphs (B), (C), and (D) of subsection (e)(1), the words "with respect to the fiscal year described in subparagraph (A)" are substituted for "with respect to such year" for clarity.

In subsection (e)(2), the words "the congressional committees" are substituted for "the committees" for clarity.

SECTION 17513—POLICY ON THE REVIEW AND CLEARANCE OF SCIENTIFIC ARTICLES PUBLISHED BY FDA EMPLOYEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17513	21 U.S.C. 379d–2	June 25, 1938, ch. 675, § 713, as added Pub. L. 110–85, title XI, § 1101, Sept. 27, 2007, 121 Stat. 971.

In subsection (c), the words "or a contractor" are substituted for "and a contractor" for clarity.

SECTION 17514—HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17514	21 U.S.C. 379d–3a (except (c))	June 25, 1938, ch. 675, §714A (except (c)), as added Pub. L. 114–255, div. A, title III, §3072(a), Dec. 13, 2016, 130 Stat. 1134; Pub. L. 117–328, div. FF, title III, §3624, Dec. 29, 2022, 136 Stat. 5879.

SECTION 17515—STRATEGIC WORKFORCE PLAN AND REPORT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17515	21 U.S.C. 379d–3b	June 25, 1938, ch. 675, §714B, as added Pub. L. 117–328, div. FF, title III, §3623, Dec. 29, 2022, 136 Stat. 5878.

In subsection (c)(5), the words "gaps in the FDA workforce" are substituted for "gaps in such workforce" for clarity.

In subsection (e)(2), the word "previous" is added for clarity.

SECTION 17516—REPORTING REQUIREMENTS FOR BIOSIMILAR BIOLOGICAL PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17516	21 U.S.C. 379d–4(b)	June 25, 1938, ch. 675, § 715(b), as added Pub. L. 112–144, title IV, § 408, July 9, 2012, 126 Stat. 1039.

In subsection (a), in the matter before paragraph (1), the words “Beginning with fiscal year 2014” are omitted as obsolete.

In subsection (b), the words “subchapter II of chapter 179 of this title” are substituted for “part 2” for clarity.

Chapter 177—Colors

SECTION 17701—LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, DEVICES, AND COSMETICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17701(a)	21 U.S.C. 379e(a)	June 25, 1938, ch. 675, §721(a), formerly § 706(a), 52 Stat. 1058; Pub. L. 86–618, title I, § 103(b), July 12, 1960, 74 Stat. 399; Pub. L. 94–295, § 9(a), May 28, 1976, 90 Stat. 583; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; renumbered §721(a), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.
17701(b)(1)	21 U.S.C. 379e(b)(3) ("specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used;")	June 25, 1938, ch. 675, §721(b)(3) ("specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used;"), formerly §706(b)(3), 52 Stat. 1058; Pub. L. 86–618, title I, § 103(b), July 12, 1960, 74 Stat. 399; renumbered §721(b)(3), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.
17701(b)(2)	21 U.S.C. 379e(b)(1)	June 25, 1938, ch. 675, §721(b)(1), formerly §706(b)(1), 52 Stat. 1058; Pub. L. 86–618, title I, § 103(b), July 12, 1960, 74 Stat. 399; Pub. L. 94–295, §9(a)(2), May 28, 1976, 90 Stat. 583; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; renumbered §721(b)(1), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.
17701(b)(3)	21 U.S.C. 379e(b)(2)	June 25, 1938, ch. 675, §721(b)(2), formerly §706(b)(2), 52 Stat. 1058; Pub. L. 86–618, title I, §103(b), July 12, 1960, 74 Stat. 399; Pub. L. 94–295, §9(a)(2), May 28, 1976, 90 Stat. 583; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; renumbered §721(b)(2), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.
17701(b)(4)	21 U.S.C. 379e(b)(3) (except "specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used;")	June 25, 1938, ch. 675, §721(b)(3) (except "specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used;"), formerly §706(b)(3), 52 Stat. 1058; Pub. L. 86–618, title I, § 103(b), July 12, 1960, 74 Stat. 399; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; renumbered §721(b)(3), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.
17701(b)(5)	21 U.S.C. 379e(b)(4)	June 25, 1938, ch. 675, §721(b)(4), formerly §706(b)(4), 52 Stat. 1058; Pub. L. 86–618, title I, § 103(b), July 12, 1960, 74 Stat. 399; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; renumbered §721(b)(4), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.
17701(b)(6)	21 U.S.C. 379e(b)(5)	June 25, 1938, ch. 675, §721(b)(5), formerly §706(b)(5), 52 Stat. 1058; Pub. L. 86–618, title I, §103(b), July 12, 1960, 74 Stat. 399; Pub. L. 87–781, title I, §104(f)(2), Oct. 10, 1962, 76 Stat. 785; Pub. L. 91–515, title VI, §601(d)(2), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 94–295, §9(a)(1), (2), May 28, 1976, 90 Stat. 583; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–300, § 6(b)(2), June 16, 1992, 106 Stat. 240; renumbered §721(b)(5), Pub. L. 102–571, title I,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§106(4), Oct. 29, 1992, 106 Stat. 4498; Pub. L. 103–80, § 3(bb), Aug. 13, 1993, 107 Stat. 778.
17701(b)(7) through (9)	21 U.S.C. 379e(b)(6) through (8)	June 25, 1938, ch. 675, §721(b)(6) through (8), formerly §706(b)(6) through (8), 52 Stat. 1058; Pub. L. 86–618, title I, § 103(b), July 12, 1960, 74 Stat. 399; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; renumbered §721(b)(6) through (8), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.
17701(c) through (f)	21 U.S.C. 379e(c) through (f)	June 25, 1938, ch. 675, §721(c) through (f), formerly §706(c) through (f), 52 Stat. 1058; Pub. L. 86–618, title I, §103(b), July 12, 1960, 74 Stat. 399; Pub. L. 94–295, §9(a)(1), May 28, 1976, 90 Stat. 583; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; renumbered §721(c) through (f), Pub. L. 102–571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498.

In subsection (b)(1), the words "this subsection" are substituted for "this section" to provide a more precise reference to the pertinent provision.

In subsection (b)(1), the words "as to the maximum quantity or quantities of a color additive" are substituted for "as to the maximum quantity or quantities" for clarity.

In subsection (b)(1), the words "the color additive is used" are substituted for "it is used" for clarity.

In subsection (b)(4), in the matter before subparagraph (A), the words "considered necessary" are substituted for "deemed necessary" to use the more appropriate word.

In subsection (b)(4), in the matter before subparagraph (A), the words "ensure the safety" are substituted for "assure the safety" to use the more appropriate word.

In subsection (b)(4)(A), the words "tolerance limitations" are substituted for "specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used" to eliminate unnecessary words because of paragraph (1).

In subsection (b)(5)(B), the words "declaring the color additive" are substituted for "declaring the substance" for consistency in the subparagraph.

In subsection (b)(6)(C)(i)(I), the words "within the time specified in subclause (IV)" are substituted for "within the time specified in this subparagraph" to provide a more precise reference to the pertinent provision.

In subsection (b)(6)(C)(i)(I), the words "that the petition or order on the petition" are substituted for "that the petition or order thereon" for clarity.

In subsection (b)(6)(C)(i)(II), in the matter before item (aa), the words "within the time specified in subclause (IV)" are substituted for "within such time" for clarity.

In subsection (b)(6)(C)(i)(II), in the matter before item (aa), the words "considers such a referral necessary" are substituted for "deems such a referral necessary" to use the more appropriate word.

In subsection (b)(6)(C)(i)(II)(aa), the word "immediately" is substituted for "forthwith" for consistency in title 21, United States Code.

In subsection (b)(6)(C)(ii)(I), in the matter before item (aa), the words "considers the additional time necessary" are substituted for "deems such additional time necessary" to use the more appropriate word.

In subsection (b)(6)(C)(ii)(II), the words "A copy of the items described in items (aa) and (bb) of subclause (I)" are substituted for "A copy of the foregoing" for clarity.

In subsection (b)(6)(C)(ii)(III), the words "previously issued" are substituted for "theretofore issued" for consistency in title 21, United States Code.

In subsection (b)(6)(D)(iii)(I), the words "the daily equivalent, at the time of service, of the maximum rate payable under section 5376 of title 5," are substituted for "the daily equivalent of the rate specified at the time of the service for grade GS–18 of the General Schedule," for clarity and because of section 101(c) of the Federal Employees Pay Comparability Act of 1990 (enacted by section 529 of Public Law 101−509) (5 U.S.C. 5376 note)).

In subsection (b)(6)(D)(iii)(II), the words "individuals in the Government service" are substituted for "persons in the Government service" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

In subsection (b)(8), in the matter before subparagraph (A), the words "ensure that a proposed use" are substituted for "assure that a proposed use" to use the more appropriate word.

In subsection (c)(1), in the matter before subparagraph (A), the words "The Secretary shall, by regulation," are substituted for "The Secretary shall further, by regulation," to eliminate an unnecessary word.

In subsection (d)(1)(A), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

Chapter 179—Fees

Subchapter I—Freedom of Information Fees

SECTION 17901—RECOVERY AND RETENTION OF FEES FOR FREEDOM OF INFORMATION REQUESTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17901	21 U.S.C. 379f	June 25, 1938, ch. 675, § 731, formerly § 711, as added Pub. L. 101–635, title II, § 201, Nov. 28, 1990, 104 Stat. 4584; renumbered § 731, Pub. L. 102–571, title I, § 106(6), Oct. 29, 1992, 106 Stat. 4499.

Subchapter II—Fees Relating to Drugs

SECTION 17906—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17906(a)(1)	21 U.S.C. 379g(10)	June 25, 1938, ch. 675, §735(10), as added Pub. L. 110–85, title I, §102(8), Sept. 27, 2007, 121 Stat. 826.
17906(a)(2)	21 U.S.C. 379g(8)	June 25, 1938, ch. 675, §735(8), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; Pub. L. 105–115, title I, §102(6), Nov. 21, 1997, 111 Stat. 2298; Pub. L. 107–188, title V, §503(4), June 12, 2002, 116 Stat. 688; Pub. L. 110–85, title I, §102(6), Sept. 27, 2007, 121 Stat. 825.
17906(a)(3)	21 U.S.C. 379g(11)	June 25, 1938, ch. 675, §735(11), formerly §735(9), as added Pub. L. 105–115, title I, §102(7), Nov. 21, 1997, 111 Stat. 2298; redesignated §735(11), Pub. L. 110–85, title I, § 102, Sept. 27, 2007, 121 Stat. 825.
17906(a)(4)	21 U.S.C. 379g(7)	June 25, 1938, ch. 675, §735(7), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; Pub. L. 105–115, title I, §102(5), Nov. 21, 1997, 111 Stat. 2298; Pub. L. 112–144, title I, §102, July 9, 2012, 126 Stat. 996.
17906(a)(5)	21 U.S.C. 379g(4)	June 25, 1938, ch. 675, §735(4), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; Pub. L. 105–115, title I, §102(3), Nov. 21, 1997, 111 Stat. 2298; Pub. L. 110–85, title I, §102(4), Sept. 27, 2007, 121 Stat. 825.
17906(a)(6)	21 U.S.C. 379g(1)	June 25, 1938, ch. 675, §735(1), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; Pub. L. 105–115, title I, §102(1), Nov. 21, 1997, 111 Stat. 2298; Pub. L. 107–188, title V, §503(1), June 12, 2002, 116 Stat. 688; Pub. L. 110–85, title I, §102(1), (2), Sept. 27, 2007, 121 Stat. 825; Pub. L. 111–148, title VII, §7002(f)(3)(A), Mar. 23, 2010, 124 Stat. 818; Pub. L. 112–144, title IV, §407, July 9, 2012, 126 Stat. 1039; Pub. L. 117–180, div. F, title I, §1002(a), Sept. 30, 2022, 136 Stat. 2140.
17906(a)(7)	21 U.S.C. 379g(9)	June 25, 1938, ch. 675, §735(9), as added Pub. L. 110–85, title I, §102(8), Sept. 27, 2007, 121 Stat. 826.
17906(a)(8)	21 U.S.C. 379g(5)	June 25, 1938, ch. 675, §735(5), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; Pub. L. 105–115, title I, §102(4), Nov. 21, 1997, 111 Stat. 2298.
17906(a)(9)	21 U.S.C. 379g(3)	June 25, 1938, ch. 675, §735(3), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; Pub. L. 105–115, title I, §102(3), Nov. 21, 1997, 111 Stat. 2298; Pub. L. 107–188, title V, §503(2), June 12, 2002, 116 Stat. 688; Pub. L. 110–85, title I, §102(3), Sept. 27, 2007, 121 Stat. 825; Pub. L. 117–180, div. F, title I, §1002(b), Sept. 30, 2022, 136 Stat. 2141.
17906(a)(10)	21 U.S.C. 379g(6)	June 25, 1938, ch. 675, §735(6), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491; Pub. L. 107–188, title V, §503(3), June 12, 2002, 116 Stat. 688; Pub. L. 110–85, title I, §102(5), Sept. 27, 2007, 121 Stat. 825.
17906(a)(11)	21 U.S.C. 379g(12)	June 25, 1938, ch. 675, §735(2), as added Pub. L. 117–180, div. F, title I, §1002(c), Sept. 30, 2022, 136 Stat. 2141.
17906(a)(12)	21 U.S.C. 379g(2)	June 25, 1938, ch. 675, §735(2), as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4491.
17906(b)	(no source)	

In subsection (a)(10)(F)(iv), the words "(relating to postapproval studies and clinical trials and labeling changes)" and "(relating to risk evaluation and mitigation strategies)" are omitted as unnecessary.

In subsection (a)(10)(F)(v), the words "(relating to adverse event reports and postmarket safety activities)" are omitted as unnecessary.

Subsection (b) is added on authority of section 1005(a) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2147).

SECTION 17907—AUTHORITY TO ASSESS AND USE DRUG FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17907(a) through (k) ...	21 U.S.C. 379h	June 25, 1938, ch. 675, §736, as added Pub. L. 102–571, title I, §103, Oct. 29, 1992, 106 Stat. 4494; Pub. L. 105–115, title I, §103(a) through (g), Nov. 21, 1997, 111 Stat. 2299 through 2304; Pub. L. 107–109, §5(a), Jan. 4, 2002, 115 Stat. 1413; Pub. L. 107–188, title V, §504, June 12, 2002, 116 Stat. 689; Pub. L. 110–85, title I, §103(a) through (h)(1), Sept. 27, 2007, 121 Stat. 826 through 832; Pub. L. 112–144, title I, §103, July 9, 2012, 126 Stat. 996; Pub. L. 115–52, title I, §102(a)(1), (b) through (h), title IX, §905(b)(1), Aug. 18, 2017, 131 Stat. 1007 through 1012, 1090; Pub. L. 117–180, div. F, title I, §1003, Sept. 30, 2022, 136 Stat. 2142; Pub. L. 117–328, div. FF, title III, §3625(a), Dec. 29, 2022, 136 Stat. 5880.
17907(l)	(no source)	

In subsection (a), in the matter before paragraph (1), the words "Beginning in fiscal year 2023," are omitted as obsolete.

In subsection (a)(1)(A), in the matter before clause (i), the words "on or after September 1, 1992," are omitted as obsolete.

In subsection (a)(2)(A)(ii), the words "each prescription drug product described in this clause" are substituted for "each such product" for clarity.

In subsection (b)(1)(G), clause (i) of section 736(b)(1)(G) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)(1)(G)(i)), which provides a dollar amount for fiscal year 2023, is omitted as obsolete.

In subsection (c)(1)(B)(i), the words "(as defined in section 735(6))" are omitted as unnecessary.

In subsection (c)(1)(B)(ii), the words "(as defined in section 735(6))" are omitted as unnecessary.

In subsection (c)(2), subparagraph (A) of section 736(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(2)(A)), which provides an amount for fiscal year 2023, is omitted as obsolete.

In subsection (c)(3)(C), the words "An adjustment under this paragraph shall not result" are substituted for "Under no circumstances shall an adjustment under this paragraph result" to eliminate unnecessary words.

In subsection (c)(3)(C), the words "(the annual base revenue for the fiscal year)", "(the dollar amount of the inflation adjustment for the fiscal year)", and "(the dollar amount of the strategic hiring and retention adjustment for the fiscal year)" are omitted as unnecessary.

In subsection (c)(3)(D), the words "publish, in the Federal Register notice under paragraph (6), the fee revenue" are substituted for "publish in the Federal Register notice under paragraph (6) of the fee revenue" to correct an error in the law.

In subsection (c)(4)(A), in the matter before clause (i), the words "For fiscal year 2023 and subsequent fiscal years," are omitted as obsolete and unnecessary.

In subsection (c)(4)(A), in the matter before clause (i), the words "if the increase" are substituted for "if such an adjustment" for consistency in the subparagraph.

In subsection (c)(4)(A), clause (i) of section 736(c)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(4)(A)(i)), which provides the required amount of operating reserves for fiscal year 2023 based on which fee revenue and fee increases were to be made, is omitted as obsolete.

In subsection (c)(5)(A), clause (i) of section 736(c)(5)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(5)(A)(i)), which provides an amount for fiscal year 2023 based on which fee revenues and fees were to be increased, is omitted as obsolete.

In subsection (c)(6), in the matter before subparagraph (A), the words "that begins after September 30, 2022" are omitted as obsolete.

In subsection (c)(7), the words "may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of human drug applications" are substituted for "may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications" for consistency with section 17906(a)(4) of title 21, United States Code.

In subsection (f)(3), the words "Beginning on October 1, 2023," are omitted as obsolete.

In subsection (g)(2)(A)(ii), subclause (I) of section 736(g)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379(g)(2)(A)(ii)), which provides the purpose for which authorized fees were to be made available for fiscal year 2023, is omitted as obsolete.

In subsection (g)(2)(A)(ii), the words "for each fiscal year" are substituted for "for fiscal year 2024 and each subsequent fiscal year" to eliminate unnecessary words.

In subsection (j), the words "for officers, employees," are substituted for "for officers, employers," to use the correct word.

Subsection (l) is added on authority of section 1005(a) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2147).

SECTION 17908—REAUTHORIZATION; REPORTING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17908(a) through (f)	21 U.S.C. 379h–2	June 25, 1938, ch. 675, § 736B, as added Pub. L. 110–85, title I, § 105, Sept. 27, 2007, 121 Stat. 840; Pub.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		L. 112–144, title I, § 104, July 9, 2012, 126 Stat. 1000; Pub. L. 115–52, title I, §103, title IX, §§903(a), 904(a), Aug. 18, 2017, 131 Stat. 1012, 1077, 1082; Pub. L. 117–180, div. F, title I, §1004, Sept. 30, 2022, 136 Stat. 2146; Pub. L. 117–328, div. FF, title III, §3626(a), Dec. 29, 2022, 136 Stat. 5883.
17908(g)	(no source)	

In this section, the reference to "section 1001(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2140)" is substituted for "section 101(b) of the Prescription Drug User Fee Amendments of 2022" each place it appears to provide the correct reference to the pertinent provision.

In subsection (a)(3)(B)(i), the words "whether the guidance documents" are substituted for "whether such guidances" for clarity.

In subsection (a)(4)(B), in the matter before clause (i), the words "costs of resources allocated for the process for the review of human drug applications" are substituted for "costs for the process for the review of human drug applications" for consistency with section 17906 of title 21, United States Code.

Subsection (g) is added on authority of section 1005(b) of the Prescription Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title I, 136 Stat. 2147).

Subchapter III—Fees Relating to Devices

SECTION 17916—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17916(a) (matter before (1))	21 U.S.C. 379i (matter before (1))	June 25, 1938, ch. 675, §737 (matter before (1)), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 110–85, title II, §211(1), Sept. 27, 2007, 121 Stat. 843.
17916(a)(1)	21 U.S.C. 379i(11)	June 25, 1938, ch. 675, §737(11), formerly §737(10), formerly §737(7), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(d)(3)(A), Apr. 1, 2004, 118 Stat. 577; redesignated §737(10), Pub. L. 110–85, title II, §211(2), (4), Sept. 27, 2007, 121 Stat. 843; Pub. L. 112–144, title II, §202(2), July 9, 2012, 126 Stat. 1002; redesignated §737(11), Pub. L. 115–52, title II, §202(a)(1), (4), Aug. 18, 2017, 131 Stat. 1013; Pub. L. 117–180, div. F, title II, §2002(2), Sept. 30, 2022, 136 Stat. 2148.
17916(a)(2)	21 U.S.C. 379i(13)	June 25, 1938, ch. 675, §737(13), formerly §737(12), formerly §737(8), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(d)(3)(A), Apr. 1, 2004, 118 Stat. 577; redesignated §737(12), Pub. L. 110–85, title II, § 211, Sept. 27, 2007, 121 Stat. 843; redesignated §737(13), Pub. L. 115–52, title II, §202(a)(1), Aug. 18, 2017, 131 Stat. 1013.
17916(a)(3)	21 U.S.C. 379i(7)	June 25, 1938, ch. 675, §737(7), as added Pub. L. 110–85, title II, §211(3), Sept. 27, 2007, 121 Stat. 843.
17916(a)(4)	21 U.S.C. 379i(10)	June 25, 1938, ch. 675, §737(10), formerly §737(9), formerly §737(6), as added Pub. L. 107–250, title I,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(d)(3)(A), Apr. 1, 2004, 118 Stat. 577; redesignated §737(9), Pub. L. 110–85, title II, § 211, Sept. 27, 2007, 121 Stat. 843; Pub. L. 112–144, title II, §202(1), July 9, 2012, 126 Stat. 1002; redesignated §737(10), Pub. L. 115–52, title II, §202(a)(1), (3), Aug. 18, 2017, 131 Stat. 1013.
17916(a)(5)	21 U.S.C. 379i(8)	June 25, 1938, ch. 675, §737(8), as added Pub. L. 115–52, title II, §202(a)(2), Aug. 18, 2017, 131 Stat. 1013.
17916(a)(6)	21 U.S.C. 379i(14)	June 25, 1938, ch. 675, §737(14), formerly §737(13), as added Pub. L. 110–85, title II, §211(6), Sept. 27, 2007, 121 Stat. 843; Pub. L. 112–144, title II, §202(3), July 9, 2012, 126 Stat. 1002; redesignated §737(14), Pub. L. 115–52, title II, §202(a)(1), Aug. 18, 2017, 131 Stat. 1013.
17916(a)(7)	21 U.S.C. 379i(12)	June 25, 1938, ch. 675, §737(12), formerly §737(11), as added Pub. L. 110–85, title II, §211(5), Sept. 27, 2007, 121 Stat. 843; redesignated §737(12), Pub. L. 115–52, title II, §202(a)(1), Aug. 18, 2017, 131 Stat. 1013.
17916(a)(8)	21 U.S.C. 379i(1)	June 25, 1938, ch. 675, §737(1), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(d)(3)(A), Apr. 1, 2004, 118 Stat. 577.
17916(a)(9)	21 U.S.C. 379i(3)	June 25, 1938, ch. 675, §737(3), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(d)(3)(A), Apr. 1, 2004, 118 Stat. 577.
17916(a)(10)	21 U.S.C. 379i(2)	June 25, 1938, ch. 675, §737(2), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(d)(3)(A), Apr. 1, 2004, 118 Stat. 577.
17916(a)(11)	21 U.S.C. 379i(9)	June 25, 1938, ch. 675, §737(9), formerly §737(8), formerly §737(5), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(a)(1)(C), (d)(3)(A), Apr. 1, 2004, 118 Stat. 572, 577; redesignated §737(8), Pub. L. 110–85, title II, §211(2), Sept. 27, 2007, 121 Stat. 843; redesignated §737(9), Pub. L. 115–52, title II, §202(a)(1), Aug. 18, 2017, 131 Stat. 1013; Pub. L. 117–180, div. F, title II, §2002(1), Sept. 30, 2022, 136 Stat. 2148.
17916(a)(12)	21 U.S.C. 379i(6)	June 25, 1938, ch. 675, §737(6), as added Pub. L. 110–85, title II, §211(3), Sept. 27, 2007, 121 Stat. 843.
17916(a)(13)	21 U.S.C. 379i(4)	June 25, 1938, ch. 675, §737(4), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1589; Pub. L. 108–214, §2(a)(1)(A), (B), (d)(3)(A), Apr. 1, 2004, 118 Stat. 572, 577.
17916(a)(14)	21 U.S.C. 379i(5)	June 25, 1938, ch. 675, §737(5), as added Pub. L. 110–85, title II, §211(3), Sept. 27, 2007, 121 Stat. 843; Pub. L. 114–255, div. A, title III, §3051(c)(2), Dec. 13, 2016, 130 Stat. 1124.
17916(b)	(no source)	

Subsection (b) is added on authority of section 2007(a) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2154).

SECTION 17917—AUTHORITY TO ASSESS AND USE DEVICE FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17917(a) through (c) ...	21 U.S.C. 379j(a) through (c)	June 25, 1938, ch. 675, §738(a) through (c), as added Pub. L. 107–250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, § 2(a)(2)(A), (d)(2)(A), (3)(A), Apr. 1, 2004, 118 Stat. 572, 576, 577; Pub. L. 109–43, §2(a)(1), (2), Aug. 1, 2005, 119 Stat. 439; Pub. L. 110–85, title II, §212(a)

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		through (c), Sept. 27, 2007, 121 Stat. 844; Pub. L. 112–144, title II, §203(a) through (c), July 9, 2012, 126 Stat. 1002; Pub. L. 115–52, title II, §203(a), (b), (c), (f)(2)(B)(ii), (iii), Aug. 18, 2017, 131 Stat. 1013 through 1015; Pub. L. 117–180, div. F, title II, §2003(a) through (c), Sept. 30, 2022, 136 Stat. 2148; Pub. L. 117–328, div. FF, title III, §3309(a), Dec. 29, 2022, 136 Stat. 5836.
17917(d)(1)(A)	21 U.S.C. 379j(d)(1) (2d sentence)	June 25, 1938, ch. 675, §738(d)(1) (2d sentence), as added Pub. L. 109–43, §2(a)(3)(A), Aug. 1, 2005, 119 Stat. 439; Pub. L. 110–85, title II, §212(d)(1)(A), Sept. 27, 2007, 121 Stat. 846.
17917(d)(1)(B)	21 U.S.C. 379j(d)(1) (1st sentence)	June 25, 1938, ch. 675, §738(d)(1) (1st sentence), as added Pub. L. 107–250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1591.
17917(d)(1)(C)	21 U.S.C. 379j(d)(1) (last sentence)	June 25, 1938, ch. 675, §738(d)(1) (last sentence), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, § 2(d)(2)(B)(i), Apr. 1, 2004, 118 Stat. 576; Pub. L. 110–85, title II, §212(d)(1)(B), Sept. 27, 2007, 121 Stat. 846; Pub. L. 115–52, title II, §203(d)(1), Aug. 18, 2017, 131 Stat. 1015.
17917(d)(2)	21 U.S.C. 379j(d)(2)	June 25, 1938, ch. 675, §738(d)(2), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, § 2(a)(2)(B), (d) (3)(A), Apr. 1, 2004, 118 Stat. 572, 577; Pub. L. 109–43, §2(a)(3)(B),(7), Aug. 1, 2005, 119 Stat. 440, 441; Pub. L. 110–85, title II, §212(d)(2), (3), Sept. 27, 2007, 121 Stat. 846. 847; Pub. L. 115–52, title II, §203(d)(2), Aug. 18, 2017, 131 Stat. 1015; Pub. L. 117–328, div. FF, title III, §3309(b), Dec. 29, 2022, 136 Stat. 5838.
17917(e)(1)	21 U.S.C. 379j(e)(2)(A)	June 25, 1938, ch. 675, §738(e)(2)(A), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, §2(a)(2)(C)(ii)(II), (d)(3)(A), Apr. 1, 2004, 118 Stat. 573, 577; Pub. L. 109–43, §2(a)(4), Aug. 1, 2005, 119 Stat. 440; Pub. L. 110–85, title II, §212(e)(2)(A), Sept. 27, 2007, 121 Stat. 848.
17917(e)(2)	21 U.S.C. 379j(e)(1)	June 25, 1938, ch. 675, §738(e)(1), as added Pub. L. 107–250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, §2(d)(2)(B)(ii), (3)(A), Apr. 1, 2004, 118 Stat. 576, 577; Pub. L. 110–85, title II, §212(e)(1), Sept. 27, 2007, 121 Stat. 847.
17917(e)(3)	21 U.S.C. 379j(e)(2)(B) through (D)	June 25, 1938, ch. 675, §738(e)(2)(B) through (D), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, §2(a)(2)(C)(ii), (d)(2)(B)(iii), (d)(3)(A), Apr. 1, 2004, 118 Stat. 573, 576, 577; Pub. L. 109–43, §2(a)(7), Aug. 1, 2005, 119 Stat. 441; Pub. L. 110–85, title II, §212(e)(2)(B), (3), Sept. 27, 2007, 121 Stat. 848; Pub. L. 115–52, title II, §203(e), Aug. 18, 2017, 131 Stat. 1015; Pub. L. 117–328, div. FF, title III, §3625(d)(1), Dec. 29, 2022, 136 Stat. 5882.
17917(f)	21 U.S.C. 379j(f)	June 25, 1938, ch. 675, §738(f), formerly §738(g), formerly §738(f), as added Pub. L. 107–250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, §2(a)(2)(D), (d)(3)(A), Apr. 1, 2004, 118 Stat. 573, 577; Pub. L. 110–85, title II, §212(f), Sept. 27, 2007, 121 Stat. 848; redesignated §738(g), Pub. L. 112–144, title II, §203(d)(1), July 9, 2012, 126 Stat. 1005; redesignated §738(f), Pub. L. 115–52, title II, §203(f)(2)(B)(i), (g), Aug. 18, 2017, 131 Stat. 1015.
17917(g)	21 U.S.C. 379j(g)	June 25, 1938, ch. 675, §738(g), formerly §738(h), formerly §738(g), as added Pub. L. 107–250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, §2(d)(3)(A), Apr. 1, 2004, 118 Stat. 577; Pub. L. 109–43, §2(a)(5), Aug. 1, 2005, 119 Stat. 440; Pub. L. 110–85, title II, §212(g), Sept. 27, 2007, 121 Stat. 849; redesignated §738(h), Pub. L. 112–144, title II, §203(d)(1), (e), July 9, 2012, 126 Stat. 1005; redesignated §203(g), Pub. L. 115–52,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		title II, §203(f)(2)(B)(i), (h), Aug. 18, 2017, 131 Stat. 1015; Pub. L. 117–180, div. F, title II, §2003(d), Sept. 30, 2022, 136 Stat. 2152; Pub. L. 117–328, div. FF, title III, §3625(e)(1), Dec. 29, 2022, 136 Stat. 5882.
17917(h) through (k) ...	21 U.S.C. 379j(h) through (k)	June 25, 1938, ch. 675, §738(h) through (k), as added Pub. L. 107–250, title I, §102(a), Oct. 26, 2002, 116 Stat. 1591; Pub. L. 108–214, §2(d)(2)(B)(iv), (3)(A), Apr. 1, 2004, 118 Stat. 577; Pub. L. 109–43, §2(a)(6), Aug. 1, 2005, 119 Stat. 440; Pub. L. 110–85, title II, §212(h), Sept. 27, 2007, 121 Stat. 849; Pub. L. 112–144, title II, § 203(d)(1), (f), July 9, 2012, 126 Stat. 1005; Pub. L. 112–193, §2(b)(1), Oct. 5, 2012, 126 Stat. 1443; Pub. L. 115–52, title II, §203(f)(2)(B)(i), (i), title IX, §905(b)(2), Aug. 18, 2017, 131 Stat. 1015, 1016, 1090; Pub. L. 117–180, div. F, title II, §2003(e), Sept. 30, 2022, 136 Stat. 2152; Pub. L. 117–328, div. FF, title III, §3625(d)(2), (3), Dec. 29, 2022, 136 Stat. 5882.
17917(l)	(no source)	

In subsection (a)(1), the words "Beginning in fiscal year 2023," are omitted as obsolete.

In subsection (a)(2)(A), in the matter before clause (i), the words "on or after October 1, 2022," are omitted as obsolete.

In subsection (a)(3)(A), the words "beginning with its registration for fiscal year 2008" are omitted as obsolete.

In subsection (a)(3)(B), the words "as defined in the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.)" are substituted for "as defined in the Indian Self Determination and Educational Assistance Act" for clarity.

In subsection (c)(1), the words "after September 30, 2022" are omitted as obsolete.

In subsection (c)(2)(A), the words "For fiscal year 2023 and each subsequent fiscal year," are omitted as obsolete.

In subsection (c)(2)(B), in the matter before clause (i), the words "for fiscal year 2023 and each subsequent fiscal year" are omitted as obsolete.

In subsection (c)(2)(C)(ii)(I), the word "deemed" is substituted for "considered" to use the more appropriate word.

In subsection (c)(2)(C)(ii)(II), the word "deemed" is substituted for "considered" to use the more appropriate word.

In subsection (c)(7), the words "may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of device applications" are substituted for "may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications" for consistency with section 17916(a)(4) of title 21, United States Code.

In subsection (e)(2), the words "For fiscal year 2008 and each subsequent fiscal year," are omitted as obsolete.

In subsection (e)(3)(B), the words "For fiscal year 2008 and each subsequent fiscal year," are omitted as obsolete.

In subsection (g)(3), the words "Beginning on October 1, 2023," are omitted as obsolete.

In subsection (h)(2)(A)(ii), subclause (I) of section 738(h)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)(2)(A)(ii)), which provides the purpose for which authorized fees were to be made available for fiscal year 2023, is omitted as obsolete.

Subsection (l) is added on authority of section 2007(a) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2154).

SECTION 17918—REAUTHORIZATION; REPORTING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17918(a), (b)	21 U.S.C. 379j–1	June 25, 1938, ch. 675, § 738A, as added Pub. L. 110–85, title II, § 213, Sept. 27, 2007, 121 Stat. 850; amended Pub. L. 112–144, title II, § 204, July 9, 2012, 126 Stat. 1006; Pub. L. 115–52, title II, §204, title IX, §§903(b), 904(b), Aug. 18, 2017, 131 Stat. 1016, 1078, 1083; Pub. L. 117–180, div. F, title II, §2004, Sept. 30, 2022, 136 Stat. 2153; Pub. L. 117–328, div. FF, title III, §3626(b), Dec. 29, 2022, 136 Stat. 5884.
17918(c)	(no source)	

In subsection (a), the reference to "section 2001(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2147)" is substituted for "section 201(b) of the Medical Device User Fee Amendments of 2022" each place it appears to provide the correct reference to the pertinent provision.

In subsection (a)(1)(A)(i), the words "Beginning with fiscal year 2023," are omitted as obsolete.

In subsection (a)(1)(A)(ii)(I), in the matter before item (aa), the words "Beginning with fiscal year 2023," are omitted as obsolete.

In subsection (a)(1)(A)(ii)(I)(cc), the words "section 13144 of this title" are substituted for "section 515C" to provide the correct reference to the pertinent provision. Section 13144 of title 21, United States Code, restates section 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3). Section 515B of the Act was formerly section 515C of the Act, and was redesignated as section 515B by section 901(f)(2) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1077).

In subsection (a)(1)(A)(iii)(II)(aa), the words "whether the guidance documents" are substituted for "whether such guidances" for clarity.

In subsection (a)(1)(A)(iv), in the matter before subclause (I), the words "Beginning with fiscal year 2023," are omitted as obsolete.

In subsection (a)(1)(A)(iv), in the matter before subclause (I), the words "annual report under clause (i)" are substituted for "annual report under paragraph (1)" to provide a more precise reference to the pertinent provision.

In subsection (a)(1)(A)(iv)(II), in the matter before item (aa), the words "costs of resources allocated for the process for the review of device applications" are substituted for "costs for the process for the review of device applications" for consistency with section 17916 of title 21, United States Code.

In subsection (a)(2), in the matter before subparagraph (A), the words "Beginning with fiscal year 2023," are omitted as obsolete.

In subsection (a)(2)(A), the words "under paragraph (1)(A)(v)" are substituted for "under paragraph (1)(A)(iv)" because of the redesignation made by section 2004(a)(3)(A) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2153).

Subsection (c) is added on authority of section 2007(b) of the Medical Device User Fee Amendments of 2022 (Public Law 117–180, div. F, title II, 136 Stat. 2154).

Subchapter IV—Fees Relating to Animal Drugs

SECTION 17926—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17926(a) (matter before (1))	21 U.S.C. 379j–11 (matter before (1))	June 25, 1938, ch. 675, §739 (matter before (1)), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(1)	21 U.S.C. 379j–11(10)	June 25, 1938, ch. 675, §739(10), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(2)	21 U.S.C. 379j–11(12)	June 25, 1938, ch. 675, §739(12), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(3)	21 U.S.C. 379j–11(1)	June 25, 1938, ch. 675, §739(1), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452; Pub. L. 115–234, title I, §102(1), Aug. 14, 2018, 132 Stat. 2428.
17926(a)(4)	21 U.S.C. 379j–11(4)	June 25, 1938, ch. 675, §739(4), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(5)	21 U.S.C. 379j–11(3)	June 25, 1938, ch. 675, §739(3), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452; Pub. L. 118–15, div. B, title III, §2302(1), Sept. 30, 2023, 137 Stat. 86.

SECTION 17926—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17926(a)(6)	21 U.S.C. 379j–11(6)	June 25, 1938, ch. 675, §739(6), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(7)	21 U.S.C. 379j–11(9)	June 25, 1938, ch. 675, §739(9), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(8)	21 U.S.C. 379j–11(7)	June 25, 1938, ch. 675, §739(7), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(9)	21 U.S.C. 379j–11(5)	June 25, 1938, ch. 675, §739(5), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(10)	21 U.S.C. 379j–11(11)	June 25, 1938, ch. 675, §739(11), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(a)(11)	21 U.S.C. 379j–11(8)	June 25, 1938, ch. 675, §739(8), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452; Pub. L. 115–234, title I, §102(2), Aug. 14, 2018, 132 Stat. 2428; Pub. L. 118–15, div. B, title III, §2302(2), Sept. 30, 2023, 137 Stat. 86.
17926(a)(12)	21 U.S.C. 379j–11(2)	June 25, 1938, ch. 675, §739(2), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1361; Pub. L. 110–85, title I, § 109, Sept. 27, 2007, 121 Stat. 842; Pub. L. 110–316, title I, § 102, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 102, June 13, 2013, 127 Stat. 452.
17926(b)	(no source)	

Subsection (b) is added on authority of section 2307(a) of the Animal Drug User Fee Amendments of 2023 (Public Law 118–15, div. B, title III, subtitle A, chapter 1, 137 Stat. 89).

SECTION 17927—AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17927(a)	21 U.S.C. 379j–12(a)	June 25, 1938, ch. 675, §740(a), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1363; Pub. L. 110–316, title I, § 103, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 103, June 13, 2013, 127 Stat. 454; Pub. L. 115–52, title I, §102(a)(2), Aug. 18, 2017, 131 Stat. 1008; Pub. L. 115–234, title III, §304(b), Aug. 14, 2018, 132 Stat. 2438; Pub. L. 118–15, div. B, title III, §2303(a), Sept. 30, 2023, 137 Stat. 87.
17927(b)	21 U.S.C. 379j–12(b)	June 25, 1938, ch. 675, §740(b), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1363; Pub. L. 110–316, title I, §103, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, §103, June 13, 2013, 127 Stat. 454; Pub. L. 115–234, title I, §103(a),

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Aug. 14, 2018, 132 Stat. 2428; Pub. L. 118–15, div. B, title III, §2303(b), Sept. 30, 2023, 137 Stat. 87.
17927(c)	21 U.S.C. 379j–12(c)	June 25, 1938, ch. 675, §740(c), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1363; Pub. L. 110–316, title I, § 103, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 103, June 13, 2013, 127 Stat. 454; Pub. L. 115–234, title I, §103(b), Aug. 14, 2018, 132 Stat. 2428; Pub. L. 118–15, div. B, title III, §2303(c), Sept. 30, 2023, 137 Stat. 87.
17927(d)(1)	21 U.S.C. 379j–12(d)(3)(A)	June 25, 1938, ch. 675, §740(d)(3)(A), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1363; Pub. L. 110–316, title I, § 103, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 103, June 13, 2013, 127 Stat. 454.
17927(d)(2) through (5)	21 U.S.C. 379j–12(d) (except (3)(A))	June 25, 1938, ch. 675, §740(d) (except (3)(A)), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1363; Pub. L. 110–316, title I, § 103, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 103, June 13, 2013, 127 Stat. 454; Pub. L. 115–234, title I, §103(c), Aug. 14, 2018, 132 Stat. 2430; Pub. L. 118–15, div. B, title III, §2303(d), Sept. 30, 2023, 137 Stat. 88.
17927(e) through (k) ...	21 U.S.C. 379j–12(e) through (k)	June 25, 1938, ch. 675, §740(e) through (k), as added Pub. L. 108–130, § 3, Nov. 18, 2003, 117 Stat. 1363; Pub. L. 110–316, title I, § 103, Aug. 14, 2008, 122 Stat. 3510; Pub. L. 113–14, title I, § 103, June 13, 2013, 127 Stat. 454; Pub. L. 115–234, title I, §103(d), Aug. 14, 2018, 132 Stat. 2430; Pub. L. 118–15, div. B, title III, §2303(e), Sept. 30, 2023, 137 Stat. 88.
17927(l)	(no source)	

In subsection (a), in the matter before paragraph (1), the words "Beginning in fiscal year 2004," are omitted as obsolete.

In subsection (a)(1)(C)(ii), the words "Beginning with fiscal year 2019," are omitted as obsolete.

In subsection (a)(1)(A), in the matter before clause (i), the words "on or after September 1, 2003," are omitted as obsolete.

In subsection (b)(2)(A), the words "(relating to animal drug applications and supplements)" are omitted as unnecessary.

In subsection (b)(2)(B), the words "(relating to animal drug products)" are omitted as unnecessary.

In subsection (b)(2)(C), the words "(relating to animal drug establishments)" are omitted as unnecessary.

In subsection (b)(2)(D), the words "(relating to animal drug sponsors)" are omitted as unnecessary.

In subsection (c)(3)(A)(iii), the words "publish, in the Federal Register notice under paragraph (1), the amount" are substituted for "publish in the Federal Register notice under paragraph (1) the amount" for clarity.

In subsection (c)(3)(B), the words "The workload adjustments under this paragraph shall not result" are substituted for "Under no circumstances shall the

workload adjustments under this paragraph result" to eliminate unnecessary words.

In subsection (c)(5), the words "may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of animal drug applications" are substituted for "may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications" for consistency with section 17926(a)(7) of title 21, United States Code.

In subsection (d)(1), the words "this subsection" are substituted for "paragraph (1)(E)" for convenience.

In subsection (f)(1), the words "beginning after fiscal year 2003" are omitted as obsolete.

In subsection (g)(2)(A)(ii), the words "to the extent that those costs exceed the costs (excluding costs paid from fees collected under this section) for fiscal year 2003" are substituted for "over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003" for clarity.

Subsection (l) is added on authority of section 2307(a) of the Animal Drug User Fee Amendments of 2023 (Public Law 118–15, div. B, title III, subtitle A, chapter 1, 137 Stat. 89).

SECTION 17928—REAUTHORIZATION; REPORTING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17928(a) through (d) ...	21 U.S.C. 379j–13	June 25, 1938, ch. 675, § 740A, as added Pub. L. 110–316, title I, § 104, Aug. 14, 2008, 122 Stat. 3511; Pub. L. 113–14, title I, § 104, June 13, 2013, 127 Stat. 462; Pub. L. 115–234, title I, §104, Aug. 14, 2018, 132 Stat. 2431; Pub. L. 118–15, div. B, title III, §2304, Sept. 30, 2023, 137 Stat. 89.
17928(e)	(no source)	

In subsection (a), the words "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)" are substituted for "section 101(b) of the Animal Drug User Fee Amendments of 2023" to provide the correct reference to the pertinent provision.

Subsection (e) is added on authority of section 2307(b) of the Animal Drug User Fee Amendments of 2023 (Public Law 118–15, div. B, title III, subtitle A, chapter 1, 137 Stat. 89).

Subchapter V—Fees Relating to Generic New Animal Drugs

SECTION 17936—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17936(a)	21 U.S.C. 379j–21(k)	June 25, 1938, ch. 675, §741(k), as added Pub. L. 110–316, title II, § 202(b), Aug. 14, 2008, 122 Stat. 3515; amended Pub. L. 113–14, title II, § 202, June

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17936(b)	(no source)	13, 2013, 127 Stat. 465; Pub. L. 118–15, div. B, title III, §2312(h), Sept. 30, 2023, 137 Stat. 93.

In subsection (a)(1)(A), the defined term "abbreviated application for a generic new animal drug" is omitted as unnecessary. Throughout the subchapter, the term "abbreviated application" is substituted for "abbreviated application for a generic new animal drug" and terms of like import each place they appear.

In subsection (a)(3), in the matter before subparagraph (A), the defined term "costs of resources allocated for the process for the review of abbreviated applications" is substituted for "costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs" for consistency with paragraph (1). Throughout the subchapter, the term "costs of resources allocated for the process for the review of abbreviated applications" is substituted for the term "costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs" each place it appears.

In subsection (a)(9), in the matter before subparagraph (A), the defined term "investigational submission for a generic new animal drug" is omitted as unnecessary. Throughout the subchapter, the term "investigational submission" is substituted for the term "investigational submission for a generic new animal drug" each place it appears.

In subsection (a)(11), in the matter before subparagraph (A), the defined term "process for the review of abbreviated applications" is substituted for "process for the review of abbreviated applications for generic new animal drugs" for consistency with paragraph (1). Throughout the subchapter, the term "process for the review of abbreviated applications" is substituted for the term "process for the review of abbreviated applications for generic new animal drugs" each place it appears.

In subsection (a)(11)(B), the words "the actions necessary to place the abbreviated applications, supplemental abbreviated applications, or investigational submissions" are substituted for "the actions necessary to place such applications, supplemental applications, or submissions" for consistency in the subparagraph.

In subsection (a)(13), the defined term "supplemental abbreviated application for a generic new animal drug" is omitted as unnecessary. Throughout the subchapter, the term "supplemental abbreviated application" is substituted for the term "supplemental abbreviated application for a generic new animal drug" and terms of like import each place they appear.

Subsection (b) is added on authority of section 2316(a) of the Animal Generic Drug User Fee Amendments of 2023 (Public Law 118–15, div. B, title III, subtitle A, chapter 2, 137 Stat. 94).

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17937(a) through (j)	21 U.S.C. 379j–21(a) through (j)	June 25, 1938, ch. 675, §741(a) through (j), as added Pub. L. 110–316, title II, § 202(b), Aug. 14, 2008, 122 Stat. 3515; Pub. L. 113–14, title II, § 202, June 13, 2013, 127 Stat. 465; Pub. L. 115–234, title II, §202, Aug. 14, 2018, 132 Stat. 2432; Pub. L. 118–15, div. B, title III, §2312(a) through (g), Sept. 30, 2023, 137 Stat. 90.
17937(k)	(no source)	

In subsection (a), in the matter before paragraph (1), the words "Beginning with respect to fiscal year 2009," are omitted as obsolete.

In subsection (a)(1)(A), the words "on or after July 1, 2008," are omitted as obsolete.

In subsection (a)(1)(C)(ii), the words "and submitted on or after October 1, 2013" are omitted as obsolete.

In subsection (a)(3)(C), in the matter before clause (i), the words "the fee under subparagraph (A) only once per year" are substituted for "only 1 such fee each fiscal year" for clarity.

In subsection (b)(2)(A), the parentheticals "(relating to abbreviated applications for a generic new animal drug)" and "(relating to generic investigational new animal drug files)" are omitted as unnecessary.

In subsection (b)(2)(B), the parenthetical "(relating to generic new animal drug products)" is omitted as unnecessary.

In subsection (b)(2)(C), the parenthetical "(relating to generic new animal drug sponsors)" is omitted as unnecessary.

In subsection (c)(1), in the matter before subparagraph (A), the words "beginning after September 30, 2023" are omitted as obsolete.

In subsection (c)(3)(C), the words "The workload adjustments under this paragraph shall not result" are substituted for "Under no circumstances shall workload adjustments under this paragraph result" to eliminate unnecessary words.

In subsection (c)(5), the words "may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of abbreviated applications" are substituted for "may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of abbreviated applications for generic new animal drugs" for consistency with section 17936(a)(3) of title 21, United States Code.

In subsection (f)(1), the words "beginning after fiscal year 2008" are omitted as obsolete.

In subsection (g)(2)(A)(ii), the words "to the extent that those costs exceed the costs (excluding costs paid from fees collected under this section) for fiscal year 2008" are substituted for "over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008" for clarity.

Subsection (k) is added on authority of section 2316(a) of the Animal Generic Drug User Fee Amendments of 2023 (Public Law 118–15, div. B, title III, subtitle A, chapter 2, 137 Stat. 94).

SECTION 17938—REAUTHORIZATION; REPORTING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17938 (except (e))	21 U.S.C. 379j–22	June 25, 1938, ch. 675, § 742, as added Pub. L. 110–316, title II, § 203, Aug. 14, 2008, 122 Stat. 3522; amended Pub. L. 113–14, title II, § 203, June 13, 2013, 127 Stat. 472; Pub. L. 115–234, title II, §203, Aug. 14, 2018, 132 Stat. 2435; Pub. L. 118–15, div. B, title III, §2313, Sept. 30, 2023, 137 Stat. 93.
17938(e)	(no source)	

In subsection (a), the words "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)" are substituted for "section 201(b) of the Animal Generic Drug User Fee Amendments of 2023" to provide the correct reference to the pertinent provision.

Subsection (e) is added on authority of section 2316(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. 94).

Subchapter VI—Fees Relating to Food

SECTION 17946—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17946	21 U.S.C. 379j–31(a)(2)	June 25, 1938, ch. 675, §743(a)(2), as added Pub. L. 111–353, title I, § 107(a), Jan. 4, 2011, 124 Stat. 3906.

In paragraph (1)(A), the words "section 11117(a) of this title" are substituted for "section 415(b)" to provide the correct reference to the pertinent provision. The term "domestic facility" is defined in section 415(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(c)), not in section 415(b) of the Act. Section 415(c) of the Act is restated as section 11117(a) of title 21, United States Code.

SECTION 17947—AUTHORITY TO COLLECT AND USE FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17947(a)	21 U.S.C. 379j–31(a)(1)	June 25, 1938, ch. 675, §743(a)(1), as added Pub. L. 111–353, title I, § 107(a), Jan. 4, 2011, 124 Stat. 3906.
17947(b)	21 U.S.C. 379j–31(b) (except (2)(B)(i)(II))	June 25, 1938, ch. 675, §743(b) (except (2)(B)(i)(II)), as added Pub. L. 111–353, title I, § 107(a), Jan. 4, 2011, 124 Stat. 3907.
17947(c) through (g) ...	21 U.S.C. 379j–31(c) through (g)	June 25, 1938, ch. 675, §743(c) through (g), as added Pub. L. 111–353, title I, § 107(a), Jan. 4, 2011, 124 Stat. 3908.

In subsection (a), in the matter before paragraph (1), the words "For each fiscal year," are substituted for "For fiscal year 2010 and each subsequent fiscal year," to eliminate obsolete words.

In paragraphs (1) and (2) of subsection (a), the words "section 11117(a) of this title" are substituted for "section 415(b)" to provide the correct reference to the pertinent provision. The term "domestic facility" is defined in section 415(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(c)), not in section 415(b) of that Act. Section 415(c) of the Act is restated as section 11117(a) of title 21, United States Code.

In subsection (b)(1), the words "specified in subsection (a)(1)" are omitted as obsolete.

In subsection (b)(2)(B)(iii)(I), the words "Not later than 180 days after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

In subsection (c)(1), the words "beginning after fiscal year 2010" are omitted as obsolete.

In subsection (c)(3)(A), the words "but the adjustment factor shall not be" are substituted for "but in no case shall the adjustment factor be" to eliminate unnecessary words.

In subsection (c)(4)(B), the words "section 11117(a) of this title" are substituted for "section 415(b)" to provide the correct reference to the pertinent provision. The term "domestic facility" is defined in section 415(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d(c)), not in section 415(b) of that Act. Section 415(c) of the Act is restated as section 11117(a) of title 21, United States Code.

In subsection (d)(3), the words "fees under subsection (a)" are substituted for "these food safety fees" for clarity and consistency in the subsection.

In subsection (g), the words "For each fiscal year," are substituted for "For fiscal year 2010 and each fiscal year thereafter," to eliminate obsolete words.

Subchapter VII—Fees Relating to Generic Drugs

SECTION 17951—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17951(a)	21 U.S.C. 379j–41	June 25, 1938, ch. 675, § 744A, as added Pub. L. 112–144, title III, § 302, July 9, 2012, 126 Stat. 1008; Pub. L. 115–52, title III, §302, Aug. 18, 2017, 131 Stat. 1020.
17951(b)	(no source)	

In subsection (a)(1)(A), the words "on November 20, 1997" are substituted for "on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997" for clarity.

In subsection (a)(9)(F)(iv), the parentheticals "(relating to postapproval studies and clinical trials and labeling changes)" and "(relating to risk evaluation and mitigation strategies)" are omitted as unnecessary.

In subsection (a)(9)(F)(v), the words "(relating to adverse-event reports and postmarket safety activities)" are omitted as unnecessary.

In subsection (a)(12)(A)(iv), the words "section 17952 of this title" are substituted for "subsection (a)" to provide the correct reference to the pertinent provision.

Subsection (b) is added on authority of section 3004(a) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2159).

SECTION 17952—AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17952(a) through (d) ...	21 U.S.C. 379j–42(a) through (d)	June 25, 1938, ch. 675, §744B(a) through (d), as added Pub. L. 112–144, title III, §302, July 9, 2012, 126 Stat. 1011; Pub. L. 112–193, §2(b)(2), Oct. 5, 2012, 126 Stat. 1443; Pub. L. 115–52, title III, §303(a) through (d), Aug. 18, 2017, 131 Stat. 1021; Pub. L. 117–180, div. F, title III, §3002(a) through (d), Sept. 30, 2022, 136 Stat. 2155.
17952(e)	21 U.S.C. 379j–42(e)	June 25, 1938, ch. 675, §744B(e), as added Pub. L. 112–144, title III, §302, July 9, 2012, 126 Stat. 1011; Pub. L. 115–52, title IX, §905(b)(3), Aug. 18, 2017, 131 Stat. 1090; Pub. L. 117–328, div. FF, title III, §3625(c)(1), Dec. 29, 2022, 136 Stat. 5881.
17952(f) through (o)	21 U.S.C. 379j–42(f) through (o)	June 25, 1938, ch. 675, § 744B(f) through (o), as added Pub. L. 112–144, title III, §302, July 9, 2012, 126 Stat. 1011; Pub. L. 112–193, §2(b)(3), Oct. 5, 2012, 126 Stat. 1443; Pub. L. 115–52, title III, §303(e) through (i), Aug. 18, 2017, 131 Stat. 1025; Pub. L. 117–180, div. F, title III, §3002(e), (f), Sept. 30, 2022, 136 Stat. 2158; Pub. L. 117–328, div. FF, title III, §3625(c)(2), Dec. 29, 2022, 136 Stat. 5881.
17952(p)	(no source)	

In subsection (a)(1), subparagraph (E) is omitted as unnecessary because of subsection (p).

In subsection (a)(2)(D)(i), the words "shall be deemed" are substituted for "must be deemed" for consistency in title 21, United States Code.

In subsection (a)(3)(A), the words "on or after October 1, 2012," are omitted as obsolete.

In subsection (a)(3)(E), the words "on or after October 1, 2012," are omitted as obsolete.

In subsection (a)(6), in the matter before subparagraph (A), the words "Type II active pharmaceutical ingredient drug master file" are substituted for "Type II pharmaceutical master file" for consistency with section 17951(a)(13) of title 21, United States Code.

In subparagraphs (C) and (D) of subsection (b)(2), and in subsection (f)(2)(C), the words "territories of the United States" are substituted for "its territories and possessions" to eliminate unnecessary words because of section 10101(a)(48) of title 21, United States Code.

In subsection (c)(2)(C), the words "An adjustment under this paragraph shall not result" are substituted for "Under no circumstances shall an adjustment under this paragraph result" to eliminate unnecessary words.

In subsection (c)(3)(A), the words "if the increase" are substituted for "if such an adjustment" for consistency in the subparagraph.

In subsection (g)(1), the words "on or after October 1, 2012," are omitted as obsolete.

In subsection (g)(1), the words "This paragraph shall cease to be effective on October 1, 2022" are omitted as unnecessary because of subsection (p).

In subsection (g)(2)(B)(i), the words "on or after October 1, 2012," are omitted as obsolete.

In subsection (g)(4)(A)(i), the words "on or after October 1, 2012," are omitted as obsolete.

In subsection (g)(4)(A)(ii), the words "on or after October 1, 2012," are omitted as obsolete.

In subsection (g)(4)(C)(i), the words "on or after October 1, 2012," are omitted as obsolete.

In subsection (h)(1), the words "beginning after fiscal year 2012" are omitted as obsolete.

In subsection (i)(2)(A)(ii), subclause (I) of section 744B(i)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(i)(2)(A)(ii)(I)), which provides the purpose for which authorized fees were to be made available for fiscal year 2023, is omitted as obsolete.

In subsection (i)(2)(A)(ii), the words "for each fiscal year" are substituted for "for fiscal year 2024 and each subsequent fiscal year" to eliminate unnecessary words.

In subsection (n)(1), the words "because of failure to pay an applicable fee under this section" are substituted for "because of failure to pay an applicable fee under this provision" for clarity.

Subsection (p) is added on authority of section 3004(a) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2159).

SECTION 17953—REAUTHORIZATION; REPORTING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17953(a) through (f)	21 U.S.C. 379j–43	June 25, 1938, ch. 675, §744C, as added Pub. L. 112–144, title III, §303, July 9, 2012, 126 Stat. 1022; Pub. L. 115–52, title III, §304, title IX, §§903(c), 904(c), Aug. 18, 2017, 131 Stat. 1027, 1080, 1085; Pub. L. 117–180, div. F, title III, §3003, Sept. 30, 2022, 136 Stat. 2158; Pub. L. 117–328, div. FF, title III, §3626(c), Dec. 29, 2022, 136 Stat. 5885.
17953(g)	(no source)	

In this section, the reference to "section 3001(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2155)" is substituted for "section 301(b) of the Generic Drug User Fee Amendments of 2022" each place it appears to provide the correct reference to the pertinent provision.

In subsection (a)(2)(B)(i), the words "whether the guidance documents" are substituted for "whether such guidances" for clarity.

Subsection (g) is added on authority of section 3004(b) of the Generic Drug User Fee Amendments of 2022 (Public Law 117–180, div. F, title III, 136 Stat. 2159).

Subchapter VIII—Fees Relating to Biosimilar Biological Products

SECTION 17961—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17961(a)	21 U.S.C. 379j–51	June 25, 1938, ch. 675, §744G, as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1026; Pub. L. 115–52, title IV, §402, Aug. 18, 2017, 131 Stat. 1028; Pub. L. 117–180, div. F, title IV, §4002, Sept. 30, 2022, 136 Stat. 2160.
17961(b)	(no source)	

In subsection (a)(8)(A)(ii), the words "if licensure may be feasible as described in clause (i)" are substituted for "if so" for clarity.

In subsection (a)(13)(F)(iv), the parentheticals "(relating to postapproval studies and clinical trials and labeling changes)" and "(relating to risk evaluation and mitigation strategies)" are omitted as unnecessary.

In subsection (a)(13)(F)(v), the parenthetical "(relating to adverse-event reports and postmarket safety activities)" is omitted as unnecessary.

Subsection (b) is added on authority of section 4005(a) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2166).

SECTION 17962—AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17962(a)	21 U.S.C. 379j–52(a) (except (1)(A)(v))	June 25, 1938, ch. 675, §744H(a) (except (1)(A)(v)), as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1029; Pub. L. 114–255, div. A, title III, §3101(a)(2)(V), Dec. 13, 2016, 130 Stat. 1155; Pub. L. 115–52, title IV, §403(a), (c)(2), (3), Aug. 18, 2017, 131 Stat. 1028; Pub. L. 117–180, div. F, title IV, §4003(a), Sept. 30, 2022, 136 Stat. 2160.
17962(b), (c)	21 U.S.C. 379j–52(b), (c)	June 25, 1938, ch. 675, §744H(b), (c), as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1034; Pub. L. 115–52, title IV, §403(b), (c)(1), (4), Aug. 18, 2017, 131 Stat. 1030, 1031, 1032; Pub. L. 117–180, div. F, title IV, §4003(b), (c), Sept. 30, 2022, 136 Stat. 2163.
17962(d)(1)	21 U.S.C. 379j–52(d)(3)	June 25, 1938, ch. 675, §744H(d)(3), formerly 744H(c)(3), as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1036; redesignated §744H(d)(3), Pub. L. 115–52, title IV, §403(c)(1), Aug. 18, 2017, 131 Stat. 1028.
17962(d)(2), (3)	21 U.S.C. 379j–52(d)(1), (2)	June 25, 1938, ch. 675, §744H(d)(1), (2), formerly §744H(c)(1), (2), as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1035; redesignated §744H(d)(1), (2), Pub. L. 115–52, title IV, §403(c)(1), (d), Aug. 18, 2017, 131 Stat. 1031, 1034.
17962(e) through (h)	21 U.S.C. 379j–52(e) through (h)	June 25, 1938, ch. 675, §744H(e) through (h), formerly §744H(d) through (g), as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1036; redesignated §744H(e) through (h), Pub. L. 115–52, title IV, §403(c) through (f), title IX, §905(b)(4),

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Aug. 18, 2017, 131 Stat. 1031, 1090; Pub. L. 116–136, div. A, title III, §3856(b)(1), Mar. 27, 2020, 134 Stat. 458; Pub. L. 117–180, div. F, title IV, §4003(d), (e), Sept. 30, 2022, 136 Stat. 2165; Pub. L. 117–328, div. FF, title III, §3625(b), Dec. 29, 2022, 136 Stat. 5880.
17962(i)	21 U.S.C. 379j–52(i)	June 25, 1938, ch. 675, §744H(i), formerly §744H(h), as added Pub. L. 112–144, title IV, §402, July 9, 2012, 126 Stat. 1037; redesignated §744H(i), Pub. L. 115–52, title IV, §403(c)(1), Aug. 18, 2017, 131 Stat. 1031.
17962(j)	(no source)	

In subsection (a), in the matter before paragraph (1), the words "Beginning in fiscal year 2023," are omitted as obsolete.

In subsection (a)(2)(A), in the matter before clause (i), the words "on or after October 1, 2017," are omitted as obsolete.

In subsection (c)(1)(B)(i), the words "(as defined in section 744G(13))" are omitted as unnecessary.

In subsection (c)(1)(B)(ii), the words "(as defined in section 744G(13))" are omitted as unnecessary.

In subsection (c)(3)(C), the words "An adjustment under this paragraph shall not result" are substituted for "Under no circumstances shall an adjustment under this paragraph result" to eliminate unnecessary words.

In subsection (c)(3)(C), the parentheticals "(the annual base revenue for the fiscal year)", "(the dollar amount of the inflation adjustment for the fiscal year)", and "(the dollar amount of the strategic hiring and retention adjustment)" are omitted as unnecessary.

In subsection (c)(4)(A), the words "For each fiscal year," are substituted for "For fiscal year 2023 and subsequent fiscal years," to eliminate obsolete words.

In subsection (c)(4)(A), the words "if the increase" are substituted for "if such an adjustment" for consistency in the subparagraph.

In subsection (c)(4)(B), clause (i) of section 744H(c)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(c)(5)(B)), which provides an amount for fiscal year 2023 based on which fee revenues and fees were to be decreased, is omitted as obsolete.

In subsection (c)(5), in the matter before subparagraph (A), the words "For each fiscal year" are substituted for "For fiscal year 2023 and each subsequent fiscal year," to eliminate obsolete words.

In subsection (c)(5)(A), the words "for the fiscal year," are omitted as unnecessary.

In subsection (c)(6), the words "may not exceed, for the fiscal year, the total costs of resources allocated for the process for the review of biosimilar

biological product applications" are substituted for "may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of biosimilar biological product applications" for consistency with section 17961(a)(9) of title 21, United States Code.

In subsection (d)(1)(B)(i), the words "(as defined in section 744G(4))" are omitted as unnecessary.

In subsection (f)(2)(B)(i), subclause (I) of section 744H(f)(2)(B)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(f)(2)(B)(i)(I)), which provides the purpose for which authorized fees were to be made available for fiscal year 2023, is omitted as obsolete.

In subsection (f)(2)(B)(i), the words "for each fiscal year" are substituted for "for fiscal year 2024 and each subsequent fiscal year" to eliminate unnecessary words.

In subsection (f)(2)(B)(i), the words "costs of resources allocated for the process for the review of biosimilar biological product applications" are substituted for "costs of the process for the review of biosimilar biological product applications" for consistency with section 17961(a) of title 21, United States Code.

In subsection (f)(2)(B)(ii), the words "Beginning on October 1, 2023," are omitted as obsolete.

In subsection (f)(2)(C), the words "if the amount allocated under subparagraph (B)(i)(I) or the sum of amounts allocated under subparagraph (B)(i)(II)," are substituted for "if the costs allocated as described in subclause (I) or (II) of such subparagraph," for clarity and consistency with subclauses (I) and (II) of subsection (f)(2)(B)(i).

In subsection (i), the words "for officers, employees," are substituted for "for officers, employers," to use the correct word.

Subsection (j) is added on authority of section 4005(a) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2166).

SECTION 17963—REAUTHORIZATION; REPORTING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17963(a) through (f)	21 U.S.C. 379j–53	June 25, 1938, ch. 675, § 744I, as added Pub. L. 112–144, title IV, § 403, July 9, 2012, 126 Stat. 1037; Pub. L. 115–52, title IV, §404, title IX, §§903(d), 904(d), Aug. 18, 2017, 131 Stat. 1035, 1081, 1087; Pub. L. 117–180, div. F, title IV, §4004, Sept. 30, 2022, 136 Stat. 2166; Pub. L. 117–328, div. FF, title III, §3626(d), Dec. 29, 2022, 136 Stat. 5886.
17963(g)	(no source)	

In paragraph (1), in clauses (i) and (ii) of paragraph (3)(B), and in subparagraphs (A)(ii), (B), and (C) of paragraph (5), of subsection (a), and in paragraphs (1) and (2) of subsection (c), the words "section 4001(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2160)" are substituted for "section 401(b) of the Biosimilar User Fee Amendments of 2017" to provide the correct reference to the pertinent provision.

In subsection (a)(1), the words "The report for a fiscal year shall include 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." are omitted as unnecessary because of subsection (a)(2)(A).

In subsection (a)(3)(B)(i), the words "process for the review of biosimilar biological product applications" are substituted for "process for the review of biosimilars" for consistency with section 17961(a)(13) of title 21, United States Code.

In subsection (a)(3)(B)(i), the words "whether the guidance documents" are substituted for "whether such guidances" for clarity.

In subsection (a)(3)(B)(ii), the words "process for the review of biosimilar biological product applications" are substituted for "process for the review of biosimilars" for consistency with section 17961(a)(13) of title 21, United States Code.

In subsection (a)(4), in the matter before subparagraph (A), the words "Beginning with fiscal year 2020," are omitted as obsolete.

In subsection (a)(4)(B), in the matter before clause (i), the words "costs of resources allocated for the process for the review of biosimilar biological product applications" are substituted for "costs for the process for the review of biosimilar biological product applications" for consistency with section 17961(a)(9) of title 21, United States Code.

Subsection (g) is added on authority of section 4005(b) of the Biosimilar User Fee Amendments of 2022 (Public Law 117–180, div. F, title IV, 136 Stat. 2166).

Subchapter IX—Fees Relating to Outsourcing Facilities

SECTION 17971—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17971	21 U.S.C. 379j–61	June 25, 1938, ch. 675, § 744J, as added Pub. L. 113–54, title I, § 102(b), Nov. 27, 2013, 127 Stat. 593.

SECTION 17972—AUTHORITY TO ASSESS AND USE OUTSOURCING FACILITY FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17972	21 U.S.C. 379j–62	June 25, 1938, ch. 675, § 744K, as added Pub. L. 113–54, title I, § 102(b), Nov. 27, 2013, 127 Stat. 594.

In subsection (a)(1), in the matter before subparagraph (A), the words "For each fiscal year," are substituted for "For fiscal year 2015 and each subsequent fiscal year," to eliminate obsolete words.

In subsection (c)(2)(A), in the matter before clause (i), the words "For each fiscal year," are substituted for "For fiscal year 2015 and subsequent fiscal years," to eliminate obsolete words.

In subsection (c)(4)(B), the words “an application for the exception, in the form of a written request and in a format specified” are substituted for “a written request for such exception, in a format specified” for consistency in the subparagraph.

In subsection (i), in the matter before clause (i), the words “For each fiscal year,” are substituted for “For fiscal year 2014 and each subsequent fiscal year,” to eliminate obsolete words.

Subchapter X—Fees Relating to Over-the-Counter Drugs

SECTION 17976—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17976(1) through (6) ...	21 U.S.C. 379j–71(1) through (6)	June 25, 1938, ch. 675, §744L(1) through (6), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 459.
17976(7), (8)	21 U.S.C. 379j–71(10), (11)	June 25, 1938, ch. 675, §744L(10), (11), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.
17976(9)	21 U.S.C. 379j–71(7)	June 25, 1938, ch. 675, §744L(7), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 460.
17976(10)	21 U.S.C. 379j–71(12)	June 25, 1938, ch. 675, §744L(12), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.
17976(11)	21 U.S.C. 379j–71(13) (relating to "requestor")	June 25, 1938, ch. 675, §744L(13) (relating to "requestor"), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.
17976(12)	21 U.S.C. 379j–71(13) (relating to "sponsor")	June 25, 1938, ch. 675, §744L(13) (relating to "sponsor"), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.
17976(13)	21 U.S.C. 379j–71(8)	June 25, 1938, ch. 675, §744L(8), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 460.
17976(14)	21 U.S.C. 379j–71(9)	June 25, 1938, ch. 675, §744L(9), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 460.

In paragraph (6), in the matter before subparagraph (A), the words “associated with the OTC monograph drugs” are substituted for “associated with such products” for consistency in the paragraph.

In paragraph (14)(A)(iii), the words “if the modification conforms” are substituted for “if such changes conform” for consistency in the clause.

SECTION 17977—AUTHORITY TO ASSESS AND USE OTC MONOGRAPH FEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17977(a)	21 U.S.C. 379j–72(a) (except (1)(D)(i))	June 25, 1938, ch. 675, §744M, as added Pub. L. 116–136, div. A, title III, §3862(a) (except (1)(D)(i)), Mar. 27, 2020, 134 Stat. 461.
17977(b)(1)	21 U.S.C. 379j–72(b)(2)	June 25, 1938, ch. 675, §744M(b)(2), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.
17977(b)(2)	21 U.S.C. 379j–72(b)(3)	June 25, 1938, ch. 675, §744M(b)(3), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.
17977(c)	21 U.S.C. 379j–72(c) (except (4)(A))	June 25, 1938, ch. 675, §744M(c) (except (4)(A)), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17977(d) through (h) ...	21 U.S.C. 379j–72(d) through (h)	June 25, 1938, ch. 675, §744M(d) through (h), as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.

In subsection (a), in the matter before paragraph (1), the words "Beginning with fiscal year 2021," are omitted as obsolete.

In subsection (b)(2), subparagraph (A) of section 744M(b)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(b)(3)(A)), which provides an amount for fiscal year 2021, is omitted as obsolete.

In subsection (c)(1)(A), in the matter before clause (i), the words "for each fiscal year" are substituted for "fiscal year 2022 and each subsequent fiscal year" to eliminate obsolete words.

In subsection (c)(1)(B), in the matter before clause (i), the words "for each fiscal year" are substituted for "for fiscal year 2022 and each subsequent fiscal year" to eliminate obsolete words.

In subsection (c)(1)(C), clause (i) of section 744M(c)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(c)(1)(C)(i)), which provides to which number the inflation adjustment percentage for fiscal years 2022 and 2023 shall be equal, is omitted to eliminate obsolete words.

In subsection (c)(2)(A), the words "For each fiscal year" are substituted for "For fiscal year 2021 and subsequent fiscal years," to eliminate obsolete words.

In subsection (c)(2)(B), clauses (i) through (iii) of section 744M(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(c)(2)(B)(i) through (iii)), which specify the number of weeks for fiscal 2021 through 2023 referred to in section 744M(c)(2)(A) of that Act (21 U.S.C. 379j–72(c)(2)(A)), are omitted to eliminate obsolete words.

In subsection (c)(2)(C), the words "for OTC monograph drug activities" are substituted for "for the process" for consistency with subparagraph (A).

In subsection (c)(3), subparagraph (A) of section 744M(c)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–72(c)(3)), which provides the amount of additional direct cost adjustment for fiscal year 2021, is omitted to eliminate unnecessary words.

In subsection (c)(4), in the matter before subparagraph (A), the words "that begins after September 30, 2021" are omitted as unnecessary.

In subsection (f)(2)(D), the words "(after fiscal year 2021)" are omitted as obsolete.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
17978	21 U.S.C. 379j–73	June 25, 1938, ch. 675, §744N, as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 468.

In subsection (a), the words "Beginning with fiscal year 2021, and" and "thereafter" are omitted as obsolete.

In subsection (a), the words "section 3861 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136, div. A, title III, 134 Stat. 458)" are substituted for "section 3861(b) of the CARES Act" to provide the correct reference to the pertinent provision. Section 3861 of the CARES Act does not contain subsections. Also, the short title "Coronavirus Aid, Relief, and Economic Security Act" is used instead of the "CARES Act" for consistency in the title.

In subsection (b), the words "Not later than 120 calendar days after the end of each fiscal year" are substituted for "Not later than 120 calendar days after the end of fiscal year 2021 and each subsequent fiscal year" to eliminate obsolete words.

Chapter 181—Information and Education

SECTION 18101—INFORMATION SYSTEM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18101	21 U.S.C. 379k	June 25, 1938, ch. 675, § 745, formerly § 741, as added Pub. L. 105–115, title IV, § 407(a), Nov. 21, 1997, 111 Stat. 2370; renumbered § 745, Pub. L. 110–316, title II, § 202(a), Aug. 14, 2008, 122 Stat. 3515.

SECTION 18102—ELECTRONIC FORMAT FOR SUBMISSIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18102	21 U.S.C. 379k–1	June 25, 1938, ch. 675, § 745A, as added Pub. L. 112–144, title XI, § 1136, July 9, 2012, 126 Stat. 1123; Pub. L. 115–52, title II, §207, Aug. 18, 2017, 131 Stat. 1019.

SECTION 18103—EDUCATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18103	21 U.S.C. 379l	June 25, 1938, ch. 675, § 746, formerly § 742, as added Pub. L. 105–115, title IV, § 408(a), Nov. 21, 1997, 111 Stat. 2371; amended Pub. L. 110–85, title VI, § 601(c), Sept. 27, 2007, 121 Stat. 897; renumbered § 746, Pub. L. 110–316, title II, § 202(a), Aug. 14, 2008, 122 Stat. 3515.

Chapter 183—Environmental Impact Review

SECTION 18301—ENVIRONMENTAL IMPACT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18301	21 U.S.C. 379o	June 25, 1938, ch. 675, § 749, formerly § 746, as added Pub. L. 105–115, title IV, § 411, Nov. 21, 1997, 111 Stat. 2373; renumbered § 749, Pub. L. 110–316, title II, § 202(a), Aug. 14, 2008, 122 Stat. 3515.

In this section, the word "deemed" is substituted for "considered" to use the more appropriate word.

Chapter 185—National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics

SECTION 18501—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18501	21 U.S.C. 379r	June 25, 1938, ch. 675, § 751, as added Pub. L. 105–115, title IV, § 412(a), Nov. 21, 1997, 111 Stat. 2373; Pub. L. 116–136, div. A, title III, §3851(c), Mar. 27, 2020, 134 Stat. 454.

In subsection (a)(2), the words "that is not identical with or that is in addition to" are substituted for "that is different from or in addition to, or that is otherwise not identical with," to eliminate unnecessary words.

In subsection (d)(1), in the matter before subparagraph (A), the words "but is not identical with or is in addition to" are substituted for "but is different from or in addition to, or that is otherwise not identical with" to eliminate unnecessary words.

SECTION 18502—PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18502	21 U.S.C. 379s	June 25, 1938, ch. 675, § 752, as added Pub. L. 105–115, title IV, § 412(d), Nov. 21, 1997, 111 Stat. 2376.

In subsection (a), the words "that is not identical with or that is in addition to" are substituted for "that is different from or in addition to, or that is otherwise not identical with," to eliminate unnecessary words.

Chapter 187—Safety Reports

SECTION 18701—SAFETY REPORTS AS ADMISSION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18701(a)	21 U.S.C. 379v (1st parenthetical)	June 25, 1938, ch. 675, §756 (1st parenthetical), as added Pub. L. 105–115, title IV, §420, Nov. 21, 1997, 111 Stat. 2379.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18701(b), (c)	21 U.S.C. 379v (except 1st parenthetical)	June 25, 1938, ch. 675, §756 (except 1st parenthetical), as added Pub. L. 105–115, title IV, §420, Nov. 21, 1997, 111 Stat. 2379.

Chapter 189—Serious Adverse Event Reports

SECTION 18901—SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18901(a)	21 U.S.C. 379aa(a)	June 25, 1938, ch. 675, §760(a), as added Pub. L. 109–462, § 2(a), Dec. 22, 2006, 120 Stat. 3469.
18901(b)(1)	21 U.S.C. 379aa(b)(1)	June 25, 1938, ch. 675, §760(b)(1), as added Pub. L. 109–462, § 2(a), Dec. 22, 2006, 120 Stat. 3469.
18901(b)(2)	21 U.S.C. 379aa(b)(2)	June 25, 1938, ch. 675, §760(b)(2), as added Pub. L. 109–462, § 2(a), Dec. 22, 2006, 120 Stat. 3469.
18901(c) through (h) ...	21 U.S.C. 379aa(c) through (h)	June 25, 1938, ch. 675, §760(c) through (h), as added Pub. L. 109–462, § 2(a), Dec. 22, 2006, 120 Stat. 3469.
18901(i)	21 U.S.C. 379aa note	Pub. L. 109–462, §2(b), Dec. 22, 2006, 120 Stat. 3472.

In subsection (e)(2)(A), in the matter before clause (i), the defined term "authorized individual" is substituted for "authorized person" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (f)(2), the words "(commonly referred to as the 'Privacy Act of 1974')" and "(commonly referred to as the 'Freedom of Information Act')" are omitted as unnecessary.

In subsection (h)(1), the words "that is not identical to or that is in addition to this section" are substituted for "that is different from, in addition to, or otherwise not identical to, this section" to eliminate unnecessary words.

SECTION 18902—SERIOUS ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
18902(a) through (d) ...	21 U.S.C. 379aa–1(a) through (d)	June 25, 1938, ch. 675, § 761(a) through (d), as added Pub. L. 109–462, § 3(a), Dec. 22, 2006, 120 Stat. 3472.
18902(e)(1)	21 U.S.C. 379aa–1(e)(1)	June 25, 1938, ch. 675, §761(e)(1), as added Pub. L. 109–462, § 3(a), Dec. 22, 2006, 120 Stat. 3472.
18902(e)(2)(A)	21 U.S.C. 379aa–1(e)(2)(B)	June 25, 1938, ch. 675, §761(e)(2)(B), as added Pub. L. 109–462, § 3(a), Dec. 22, 2006, 120 Stat. 3472.
18902(e)(2)(B)	21 U.S.C. 379aa–1(e)(2)(A)	June 25, 1938, ch. 675, §761(e)(2)(A), as added Pub. L. 109–462, § 3(a), Dec. 22, 2006, 120 Stat. 3472.
18902(f) through (h)	21 U.S.C. 379aa–1(f) through (h)	June 25, 1938, ch. 675, §761(f) through (h), as added Pub. L. 109–462, § 3(a), Dec. 22, 2006, 120 Stat. 3472.

In subsection (e)(2)(A), in the matter before clause (i), the defined term "authorized individual" is substituted for "authorized person" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (f)(2), the words "(commonly referred to as the 'Privacy Act of 1974')" and "(commonly referred to as the 'Freedom of Information Act')" are omitted as unnecessary.

In subsection (h)(1), the words “that is not identical to or that is in addition to this section” are substituted for “that is different from, in addition to, or otherwise not identical to, this section” to eliminate unnecessary words.

Chapter 191—Reagan-Udall Foundation for the Food and Drug Administration

SECTION 19101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
19101(1)	21 U.S.C. 379dd(d)(1)(A) ("(referred to in this part as the `Board')")	June 25, 1938, ch. 675, §770(d)(1)(A) ("(referred to in this part as the `Board')"), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 892.
19101(2)	21 U.S.C. 379dd(a) ("(referred to in this part as the `Foundation')")	June 25, 1938, ch. 675, §770(a) ("(referred to in this part as the `Foundation')"), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890.

SECTION 19102—ESTABLISHMENT AND FUNCTIONS OF THE FOUNDATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
19102(a)	21 U.S.C. 379dd(a) (except "(referred to in this part as the `Foundation')")	June 25, 1938, ch. 675, §770(a) (except "(referred to in this part as the `Foundation')"), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890.
19102(b)	21 U.S.C. 379dd(b)	June 25, 1938, ch. 675, §770(b), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890.
19102(c)	21 U.S.C. 379dd(c)	June 25, 1938, ch. 675, § 770(c), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890.
19102(d)(1)(A)	21 U.S.C. 379dd(d)(1)(A) (except "(referred to in this part as the `Board')")	June 25, 1938, ch. 675, §770(d)(1)(A) (except "(referred to in this part as the `Board')"), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 892.
19102(d)(1)(B)	21 U.S.C. 379dd(d)(1)(B)	June 25, 1938, ch. 675, §770(d)(1)(B), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 892.
19102(d)(1)(C)	21 U.S.C. 379dd(d)(1)(C)	June 25, 1938, ch. 675, §770(d)(1)(C), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 892; Pub. L. 114–255, div. A, title III, §3076(a)(1), (2), Dec. 13, 2016, 130 Stat. 1139.
19102(d)(1)(D)	21 U.S.C. 379dd(d)(1)(D)(iii)	June 25, 1938, ch. 675, §770(d)(1)(D)(iii), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 893.
19102(d)(2)	21 U.S.C. 379dd(d)(2)	June 25, 1938, ch. 675, §770(d)(2), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890.
19102(d)(3)	21 U.S.C. 379dd(d)(3)	June 25, 1938, ch. 675, §770(d)(3), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890; Pub. L. 114–255, div. A, title III, §3076(a)(3), Dec. 13, 2016, 130 Stat. 1139.
19102(d)(4)	21 U.S.C. 379dd(d)(4)	June 25, 1938, ch. 675, §770(d)(4), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890.
19102(e) through (m)	21 U.S.C. 379dd(f) through (n)	June 25, 1938, ch. 675, §770(f) through (n), as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890; Pub. L. 114–255, div. A, title III, §3076(b), (c), Dec. 13, 2016, 130 Stat. 1139; Pub. L. 117–101, §2(a), Mar. 15, 2022, 136 Stat. 47.

In subsection (a)(2), the words “under subsection (f)” are substituted for “under subsection (e)” to provide the correct reference to the pertinent provision.

In subsection (c)(1)(B), the words “including the incorporation” are substituted for “and including the incorporation” for clarity.

In subsection (c)(7)(C), the words “other like instruments” are substituted for “other such instruments” for clarity.

In subsection (d)(1)(B), in the matter before clause (i), the words “who shall be nonvoting members of the Board,” are added on authority of section 770(d)(1)(D)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(D)(ii)), which is repealed as obsolete by the bill enacting title 21, United States Code, because it provided that on the appointment of the members of the Board, the Commissioner and the Director of the National Institutes of Health shall continue to serve as ex officio members of the Board.

In subsection (d)(1)(B), clauses (iii) and (iv) of section 770(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(B)(iii), (iv)), which listed the Director of the Centers for Disease Control and Prevention and the Director of the Agency for Healthcare Research and Quality as ex officio members, are omitted as obsolete because of section 770(d)(1)(D)(ii)(I) of that Act (21 U.S.C. 379dd(d)(1)(D)(ii)(I)). That section 770(d)(1)(D)(ii)(I) is repealed as obsolete by the bill enacting title 21, United States Code.

In subsection (d)(1)(C)(i), the words “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,” are substituted for “The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 14 individuals,” to eliminate obsolete words and for clarity. As in effect on the day before the enactment of title 21, United States Code, subsection (d)(1)(B) was designated as section 770(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(B)), which listed the Director of the Centers for Disease Control and Prevention and the Director of the Agency for Healthcare Research and Quality as ex officio members; those Directors are omitted in restating that section 770(d)(1)(B) as subsection (d)(1)(B) (see previous revision note), making the parenthetical "(as in effect on the day before the enactment of this title)" necessary to clarify the ex officio members that appointed the initial members of the Board.

In subsection (d)(1)(C)(ii)(I), the words “through an amendment” are substituted for “through amendments” for consistency in the subclause.

In subsection (d)(1)(C)(ii)(II), the words “individuals appointed under this subclause” are substituted for “persons so appointed” for clarity.

In subsection (d)(1)(C)(iii)(I), the words “shall ensure that the Board” are substituted for “shall ensure the Board” for clarity.

In subsection (d)(1)(C)(iii)(II)(aa), the words “this subclause” are substituted for “this section” to provide a more precise reference to the pertinent provision. The term “employee of the Federal Government” appears only in subclause (II) of subsection (d)(1)(C)(iii).

In subsection (d)(3)(A)(i), the words “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 expiration of terms under this clause as in effect on the day before the enactment of this title)” are substituted for “the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members” to eliminate obsolete words.

In subsection (d)(3)(A)(ii), the words "individuals initially appointed" are substituted for "persons initially appointed" for clarity.

In subsection (i), the words "Federal employees" are substituted for "Federal Government employees" to eliminate an unnecessary word.

In subsection (j)(1), the words "Federal employees" are substituted for "Federal Government employees" to eliminate an unnecessary word.

In subsection (k)(2), in the matter before subparagraph (A), the words "Beginning with fiscal year 2009," are omitted as obsolete.

SECTION 19103—LOCATION OF FOUNDATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
19103	21 U.S.C. 379dd–1	June 25, 1938, ch. 675, § 771, as added Pub. L. 110–85, title VI, § 601(b), Sept. 27, 2007, 121 Stat. 897.

SECTION 19104—ACTIVITIES OF THE FDA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
19104	21 U.S.C. 379dd–2	June 25, 1938, ch. 675, § 772, as added Pub. L. 110–85, title VI, § 601(b), Sept. 27, 2007, 121 Stat. 897.

In subsection (b), the words "Beginning with fiscal year 2009," are omitted as obsolete.

Division G—Imports and Exports

Chapter 201—Imports and Exports

SECTION 20101—IMPORTS AND EXPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20101(a)(1), (2)	21 U.S.C. 381(a) (1st sentence, 2d sentence)	June 25, 1938, ch. 675, §801(a) (1st sentence), (2d sentence), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §1, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f)(2), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 109–462, §5(a)(1), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, § 912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(l)(1), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title II, §204(j)(2), title III, §§301(c), 303(a), (c), Jan. 4, 2011, 124 Stat. 3937, 3955 through 3957; Pub. L. 112–144, title VII, §708(a), (b), July 9, 2012, 126 Stat. 1068.
20101(a)(3)(A)	21 U.S.C. 381(a) (3d sentence)	June 25, 1938, ch. 675, §801(a) (3d sentence), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §1, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f)(2), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 109–462, §5(a)(1), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, § 912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§103(l)(1), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title II, §204(j)(2), title III, §§301(c), 303(a), (c), Jan. 4, 2011, 124 Stat. 3937, 3955 through 3957; Pub. L. 112–144, title VII, §708(a), (b), July 9, 2012, 126 Stat. 1068; Pub. L. 115–271, title III, §§3012(c), 3022(c)(1), Oct. 24, 2018, 132 Stat. 3936, 3939.
20101(a)(3)(B)	21 U.S.C. 381(a) (4th sentence)	June 25, 1938, ch. 675, §801(a) (4th sentence), as added Pub. L. 115–271, title III, §3022(c)(2), Oct. 24, 2018, 132 Stat. 3939; Pub. L. 116–304, §2(a)(1), Jan. 5, 2021, 134 Stat. 4915.
20101(a)(3)(C)	21 U.S.C. 381(a) (5th sentence)	June 25, 1938, ch. 675, §801(a) (5th sentence), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §1, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f)(2), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 109–462, §5(a)(1), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, § 912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(l)(1), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title II, §204(j)(2), title III, §§301(c), 303(a), (c), Jan. 4, 2011, 124 Stat. 3937, 3955 through 3957; Pub. L. 112–144, title VII, §708(a), (b), July 9, 2012, 126 Stat. 1068.
20101(a)(3)(D)	21 U.S.C. 381(a) (6th sentence)	June 25, 1938, ch. 675, §801(a) (6th sentence), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §1, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f)(2), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 109–462, §5(a)(1), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, § 912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(l)(1), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title II, §204(j)(2), title III, §§301(c), 303(a), (c), Jan. 4, 2011, 124 Stat. 3937, 3955 through 3957; Pub. L. 112–144, title VII, §708(a), (b), July 9, 2012, 126 Stat. 1068; Pub. L. 117–328, div. FF, title III, §3503(a)(4)(C), Dec. 29, 2022, 136 Stat. 5858.
20101(a)(3)(E)	21 U.S.C. 381(a) (last sentence)	June 25, 1938, ch. 675, §801(a) (last sentence), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §1, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f)(2), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 109–462, §5(a)(1), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, § 912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(l)(1), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title II, §204(j)(2), title III, §§301(c), 303(a), (c), Jan. 4, 2011, 124 Stat. 3937, 3955 through 3957; Pub. L. 112–144, title VII, §708(a), (b), July 9, 2012, 126 Stat. 1068; Pub. L. 115–271, title III, §3022(c)(3), Oct. 24, 2018, 132 Stat. 3939.
20101(a)(4)	21 U.S.C. 381(a) (7th sentence)	June 25, 1938, ch. 675, §801(a) (7th sentence), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §1, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f)(2), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 109–462, §5(a)(1), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, § 912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(l)(1), June 22, 2009, 123 Stat. 1837; Pub. L.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		111–353, title II, §204(j)(2), title III, §§301(c), 303(a), (c), Jan. 4, 2011, 124 Stat. 3937, 3955 through 3957; Pub. L. 112–144, title VII, §708(a), (b), July 9, 2012, 126 Stat. 1068; Pub. L. 116–304, §2(a)(2), Jan. 5, 2021, 134 Stat. 4915.
20101(a)(5)	21 U.S.C. 381(a) (8th sentence through 11th sentence)	June 25, 1938, ch. 675, §801(a) (8th sentence through 11th sentence), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §1, 63 Stat. 882; Pub. L. 87–781, title III, §306, Oct. 10, 1962, 76 Stat. 796; Pub. L. 91–513, title II, §701(h), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 94–295, §§3(f)(2), 4(b)(3), May 28, 1976, 90 Stat. 578, 580; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 109–462, §5(a)(1), Dec. 22, 2006, 120 Stat. 3475; Pub. L. 110–85, title IX, § 912(b)(2), Sept. 27, 2007, 121 Stat. 952; Pub. L. 111–31, div. A, title I, §103(l)(1), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title II, §204(j)(2), title III, §§301(c), 303(a), (c), Jan. 4, 2011, 124 Stat. 3937, 3955 through 3957; Pub. L. 112–144, title VII, §708(a), (b), July 9, 2012, 126 Stat. 1068; Pub. L. 116–304, §2(a)(2), Jan. 5, 2021, 134 Stat. 4915.
20101(b)	21 U.S.C. 381(b)	June 25, 1938, ch. 675, §801(b), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §2, 63 Stat. 882; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(cc), Aug. 13, 1993, 107 Stat. 778; Pub. L. 109–462, §5(a)(2), Dec. 22, 2006, 120 Stat. 3476; Pub. L. 117–328, div. FF, title III, §3503(a)(4)(D), Dec. 29, 2022, 136 Stat. 5858.
20101(c)	21 U.S.C. 381(c)	June 25, 1938, ch. 675, §801(c), 52 Stat. 1058; Oct. 18, 1949, ch. 696, §3, 63 Stat. 883.
20101(d)	21 U.S.C. 381(d)	June 25, 1938, ch. 675, §801(d), as added Pub. L. 100–293, §3, Apr. 22, 1988, 102 Stat. 96; Pub. L. 102–353, § 5, Aug. 26, 1992, 106 Stat. 943; Pub. L. 104–134, title II, §2102(a), Apr. 26, 1996, 110 Stat. 1321–313; Pub. L. 104–180, title VI, §603(a), Aug. 6, 1996, 110 Stat. 1594; Pub. L. 105–115, title I, § 125(a)(2)(D), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 106–387, §1(a) [title VII, §745(c)(1)], Oct. 28, 2000, 114 Stat. 1549, 1549A–36; Pub. L. 107–188, title III, §322(a), June 12, 2002, 116 Stat. 676; Pub. L. 115–52, title VI, §604(a), Aug. 18, 2017, 131 Stat. 1048.
20101(e)(1) through (3)	21 U.S.C. 381(e)(1) through (3)	June 25, 1938, ch. 675, §801(e)(1) through (3), formerly §801(d), 52 Stat. 1058; Pub. L. 90–399, § 106, July 13, 1968, 82 Stat. 353; Pub. L. 94–295, §§ 3(f)(1), May 28, 1976, 90 Stat. 578; redesignated §801(e), Pub. L. 100–293, § 3, Apr. 22, 1988, 102 Stat. 96; Pub. L. 104–134, title II, § 2102(b)(1) through (3), Apr. 26, 1996, 110 Stat. 1321–314; Pub. L. 111–31, div. A, title I, § 103(l)(2), June 22, 2009, 123 Stat. 1837.
20101(e)(4)(A)	21 U.S.C. 381(e)(4)(A)	June 25, 1938, ch. 675, §801(e)(4)(A), as added Pub. L. 104–134, title II, §2102(b)(3), Apr. 26, 1996, 110 Stat. 1321–314; Pub. L. 111–353, title I, §107(b)(1), Jan. 4, 2011, 124 Stat. 3910.
20101(e)(4)(B)(i) through (iii)	21 U.S.C. 381(e)(4)(B)	June 25, 1938, ch. 675, §801(e)(4)(B), as added Pub. L. 104–134, title II, §2102(b)(3), Apr. 26, 1996, 110 Stat. 1321–314.
20101(e)(4)(B)(iv)	21 U.S.C. 381(e)(4)(D)	June 25, 1938, ch. 675, §801(e)(4)(D), as added Pub. L. 111–353, title I, §107(b)(3), Jan. 4, 2011, 124 Stat. 3889, 3910; Pub. L. 115–52, title VII, §704(2), Aug. 18, 2017, 131 Stat. 1056.
20101(e)(4)(C)	21 U.S.C. 381(e)(4)(C)	June 25, 1938, ch. 675, §801(e)(4)(C), as added Pub. L. 111–353, title I, §107(b)(2), Jan. 4, 2011, 124 Stat. 3910; Pub. L. 115–52, title VII, §704(2), Aug. 18, 2017, 131 Stat. 1056.
20101(e)(4)(D)	21 U.S.C. 381(e)(4)(E)	June 25, 1938, ch. 675, §801(e)(4)(E), as added Pub. L. 115–52, title VII, §704(1), Aug. 18, 2017, 131 Stat. 1056; Pub. L. 116–136, div. A, title III, §3856(a), Mar. 27, 2020, 134 Stat. 458; Pub. L. 117–328, div. FF, title III, §3304(1), Dec. 29, 2022, 136 Stat. 5832.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20101(e)(4)(E)	21 U.S.C. 381(e)(4)(F)	June 25, 1938, ch. 675, §801(e)(4)(F), as added Pub. L. 117–328, div. FF, title III, §3304(2), Dec. 29, 2022, 136 Stat. 5832.
20101(f)	21 U.S.C. 381(f)	June 25, 1938, ch. 675, §801(f), as added Pub. L. 104–134, title II, §2102(c), Apr. 26, 1996, 110 Stat. 1321–314; Pub. L. 104–180, title VI, §603(b), Aug. 6, 1996, 110 Stat. 1595.
20101(g)(1)	21 U.S.C. 381(g)(2)	June 25, 1938, ch. 675, §801(g)(2), as added Pub. L. 106–387, § 1(a) [title VII, §746(c)], Oct. 28, 2000, 114 Stat. 1549, 1549A–40.
20101(g)(2)	21 U.S.C. 381(g)(1)	June 25, 1938, ch. 675, §801(g)(1), as added Pub. L. 106–387, § 1(a) [title VII, §746(c)], Oct. 28, 2000, 114 Stat. 1549, 1549A–40.
20101(h)	21 U.S.C. 381(h)	June 25, 1938, ch. 675, §801(h), as added Pub. L. 107–188, title III, §302(a) through (c), June 12, 2002, 116 Stat. 662.
20101(i)	21 U.S.C. 381(i)	June 25, 1938, ch. 675, §801(i), as added Pub. L. 107–188, title III, §302(d), June 12, 2002, 116 Stat. 663.
20101(j)	21 U.S.C. 381(j)	June 25, 1938, ch. 675, §801(j), as added Pub. L. 107–188, title III, §303(c), June 12, 2002, 116 Stat. 665.
20101(k)	21 U.S.C. 381(k)	June 25, 1938, ch. 675, §801(k), as added Pub. L. 107–188, title III, §304(e), June 12, 2002, 116 Stat. 667.
20101(l)	21 U.S.C. 381(l)	June 25, 1938, ch. 675, §801(l), as added Pub. L. 107–188, title III, §305(c), June 12, 2002, 116 Stat. 668; Pub. L. 111–353, title I, §102(b)(3), 107(b), Jan. 4, 2011, 124 Stat. 3889.
20101(m)	21 U.S.C. 381(m)	June 25, 1938, ch. 675, §801(m), as added Pub. L. 107–188, title III, §307(a), June 12, 2002, 116 Stat. 670; Pub. L. 111–353, title III, §304(a), Jan. 4, 2011, 124 Stat. 3957.
20101(n)(1) through (3)	21 U.S.C. 381(n)	June 25, 1938, ch. 675, §801(n), as added Pub. L. 107–188, title III, §308(a), June 12, 2002, 116 Stat. 672.
20101(n)(4)	21 U.S.C. 381 note	Pub. L. 107–188, title III, §308(c) (relating to subsection (a) of "this section"), June 12, 2002, 116 Stat. 673.
20101(o)	21 U.S.C. 381(o)	June 25, 1938, ch. 675, §801(o), as added Pub. L. 107–188, title III, §321(b)(1), June 12, 2002, 116 Stat. 676; Pub. L. 112–144, title VII, §713(1), July 9, 2012, 126 Stat. 1072.
20101(p)	21 U.S.C. 381(p)	June 25, 1938, ch. 675, §801(p), as added Pub. L. 111–31, div. A, title I, §103(l)(3), June 22, 2009, 123 Stat. 1838.
20101(q)(1) through (7)	21 U.S.C. 381(q)	June 25, 1938, ch. 675, §801(q), as added Pub. L. 111–353, title III, §303(b), Jan. 4, 2011, 124 Stat. 3956.
20101(q)(8)	21 U.S.C. 381 note	Pub. L. 111–353, title III, §303(d), Jan. 4, 2011, 124 Stat. 3957.
20101(r)	21 U.S.C. 381(r)	June 25, 1938, ch. 675, §801(r), as added Pub. L. 112–144, title VII, §713(2), July 9, 2012, 126 Stat. 1072.
20101(s)	21 U.S.C. 381(s)	June 25, 1938, ch. 675, §801(s), as added Pub. L. 112–144, title VII, §714(b), July 9, 2012, 126 Stat. 1073; Pub. L. 114–255, div. A, title III, §3101(a)(2)(W)(i), Dec. 13, 2016, 130 Stat. 1155.
20101(t)	21 U.S.C. 381(t)	June 25, 1938, ch. 675, §801(t), as added Pub. L. 115–271, title III, §3013, Oct. 24, 2018, 132 Stat. 3936.
20101(u)	21 U.S.C. 381(u)	June 25, 1938, ch. 675, §801(u), as added Pub. L. 115–271, title III, §3022(d), Oct. 24, 2018, 132 Stat. 3940.

In this section, references to the Secretary of the Treasury and the Department of the Treasury are retained each place they appear to ensure that no change in the meaning or effect of the source provisions in which they appear is made by the restatement of the provisions in title 21, United States Code. For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

In subsection (a)(1), the words "giving notice of the delivery" are substituted for "giving notice thereof" for clarity.

In subsection (a)(2)(B), the words "not registered pursuant to the provisions referred to in subparagraph (A)" are substituted for "not so registered" for clarity.

In subsection (a)(4)(A), the words "any article refused admission under this subsection" are substituted for "any such article refused admission" for clarity.

In subsection (b)(2)(A)(ii), the words "an article described in subsection (a)(3)(D)," are substituted for "an article described in subsection (a) relating to the requirements of section 605, 760, or 761," for clarity, to eliminate unnecessary words, and to provide a more precise reference to the pertinent provision.

In subsection (b)(2)(A)(ii), the words "that would ensure" are substituted for "that would assure" to use the more appropriate word.

In subsection (b)(2)(B)(ii), the words "as provided in paragraph (1)," are substituted for "as provided in the preceding provisions of this subsection," to provide a more precise reference to the pertinent provision.

In subsection (e)(4)(A)(i)(II), the words "food, drug, animal drug, or device meets" are substituted for "food, drug or device meets" for consistency in the subclause.

In subsection (e)(4)(B)(i), the words "a fee not to exceed $175 may be charged for the certification" are substituted for "a fee for such certification may be charged but shall not exceed $175 for each certification" to eliminate unnecessary words.

In subsection (e)(4)(D)(ii)(III), the words "The Secretary shall issue final guidance providing for a process to carry out this subparagraph." are substituted for "Not later than 1 year after the date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall issue guidance providing for a process to carry out this subparagraph. Not later than 1 year after the close of the comment period for such guidance, the Secretary shall issue final guidance." to eliminate obsolete words.

In subsection (f)(2)(A), the words "shall state" are substituted for "must state" for consistency in title 21, United States Code.

In subsection (g)(1), the words "this subsection" are substituted for "this section" to provide a more precise reference to the pertinent provision.

In subsection (j)(2)(B), the words "held under paragraph (1) (including after removal under subparagraph (A))" are substituted for "so held" for clarity.

In subsection (j)(2)(C), the words "held under paragraph (1) (including after removal under subparagraph (A))" are substituted for "so held" for clarity.

In subsection (k)(1)(D), the words "held under this paragraph (including after removal under subparagraph (C))" are substituted for "so held" for clarity.

In subsection (l)(4), the words "held under this subsection (including after removal under paragraph (3))" are substituted for "so held" for clarity.

In subsection (m)(2)(B)(i)(IV), the words "held under this clause (including after removal under subclause (III))" are substituted for "so held" for clarity.

In subsection (o)(5), the words "held under this subsection (including after removal under paragraph (4))" are substituted for "so held" for clarity.

In subsection (p)(1), in the matter before subparagraph (A), the words "The Secretary shall annually" are substituted for "Not later than 36 months after June 22, 2009, and annually thereafter, the Secretary shall" to eliminate obsolete words.

In subsection (q)(4)(A), the words "specified in paragraph (3)" are substituted for "specified in paragraph (2)" to provide the correct reference to the pertinent provision.

In subsection (q)(6), the words "entity described in paragraph (3)" are substituted for "entity described in paragraph (2)" to provide the correct reference to the pertinent provision.

In subsection (q)(8), the words "considers appropriate" are substituted for "deems appropriate" to use the more appropriate word.

In subsection (r)(2)(D), the words "considered necessary and appropriate" are substituted for "deemed necessary and appropriate" to use the more appropriate word.

In subsection (r)(4)(A)(i), the words "Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act," are omitted as obsolete.

In subsection (t), the words "as offering for import from the same manufacturer, distributor, or importer the controlled substances or drugs," are substituted for "as being offered for import from the same manufacturer, distributor, or importer," for clarity.

SECTION 20102—EXPORTS OF CERTAIN UNAPPROVED PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20102(a)	21 U.S.C. 382(h)	June 25, 1938, ch. 675, §802(h), as added Pub. L. 99–660, title I, § 102(2), Nov. 14, 1986, 100 Stat. 3743; Pub. L. 104–134, title III, § 2102(d)(1), Apr. 26, 1996, 110 Stat. 1321–315.
20102(b)	21 U.S.C. 382(a)	June 25, 1938, ch. 675, §802(a), as added Pub. L. 99–660, title I, § 102(2), Nov. 14, 1986, 100 Stat. 3743; Pub. L. 104–134, title III, § 2102(d)(1), Apr. 26, 1996, 110 Stat. 1321–315.
20102(c) through (h)	21 U.S.C. 382(b) through (g)	June 25, 1938, ch. 675, §802(b) through (g), as added Pub. L. 99–660, title I, § 102(2), Nov. 14, 1986, 100 Stat. 3743; Pub. L. 104–134, title III, § 2102(d)(1), Apr. 26, 1996, 110 Stat. 1321–315; Pub. L. 104–180, title VI, § 603(c), Aug. 6, 1996, 110 Stat. 1595.
20102(i)	21 U.S.C. 382(i)	June 25, 1938, ch. 675, §802(i), as added Pub. L. 105–115, title I, § 125(c), Nov. 21, 1997, 111 Stat. 2326.

In subsection (b)(1), the words "the provisions referred to in paragraph (2)" are substituted for "such sections or Act" for clarity.

In subsection (b)(2)(A)(i)(II), the words "(known as the Virus-Serum Toxin Act)" are omitted as unnecessary.

In subsection (c)(1)(B)(i)(II)(bb), the words "ensure that the device" are substituted for "assure that the device" to use the more appropriate word.

In subsection (c)(1)(B)(i)(V), the words "in the country" are substituted for "in the country or countries" for consistency with the matter before subclause (I) of subsection (c)(1)(B)(i) and with section 1 of title 1, United States Code.

In subsection (f)(2)(A), the words "under paragraph (1)" are substituted for "under paragraph (1)(A)" to provide the correct reference to the pertinent provision. There is no subparagraph (A) in section 802(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 382(e)(1)).

SECTION 20103—OFFICE OF INTERNATIONAL RELATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20103	21 U.S.C. 383	June 25, 1938, ch. 675, § 803, as added Pub. L. 101–629, § 15(a), Nov. 28, 1990, 104 Stat. 4525; amended Pub. L. 105–115, title IV, § 410(b), Nov. 21, 1997, 111 Stat. 2373; Pub. L. 112–144, title VI, §§ 609, 610, July 9, 2012, 126 Stat. 1059.

In subsection (c)(3)(B)(iii), the words "and other activities" are substituted for "and other activities of such fora" to eliminate unnecessary words because of the word "forum's" before "strategies".

SECTION 20104—IMPORTATION OF PRESCRIPTION DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20104	21 U.S.C. 384 (except (m))	June 25, 1938, ch. 675, §804 (except (m)), as added Pub. L. 108–173, title XI, §1121(a), Dec. 8, 2003, 117 Stat. 2464; Pub. L. 114–125, title VIII, §802(d)(2), Feb. 24, 2016, 130 Stat. 210.

In subsection (a)(5)(A), the words "under section 13103(d)(2)(A) of this title" are substituted for "under section 503(e)(2)(A)" to provide the correct reference to the pertinent provision. Section 503(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(2)(A)) relates to reporting requirements for persons that own or operate an establishment that engages in wholesale distribution. The provision that relates to licensing requirements of persons that engage in wholesale distribution is set out in section 503(e)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)(1)(A)), which is restated as section 13103(d)(2)(A) of title 21, United States Code.

In subsection (b), the words "Commissioner of U.S. Customs and Border Protection" are substituted for "Commissioner of Customs" because of section 802(d)(2) of the U.S. Customs and Border Protection Authorization Act (6 U.S.C. 211 note).

SECTION 20105—FOREIGN SUPPLIER VERIFICATION PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20105(a)	21 U.S.C. 384a(a)(2)	June 25, 1938, ch. 675, §805(a)(2), as added Pub. L. 111–353, title III, § 301(a), Jan. 4, 2011, 124 Stat. 3953.

SECTION 20105—FOREIGN SUPPLIER VERIFICATION PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20105(b)	21 U.S.C. 384a(a)(1)	June 25, 1938, ch. 675, §805(a)(1), as added Pub. L. 111–353, title III, § 301(a), Jan. 4, 2011, 124 Stat. 3953.
20105(c) through (h) ...	21 U.S.C. 384a(b) through (g)	June 25, 1938, ch. 675, §805(b) through (g), as added Pub. L. 111–353, title III, § 301(a), Jan. 4, 2011, 124 Stat. 3953.

In subsection (c), the words "Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

In subsection (d)(1), the words "Not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

In subsection (d)(2)(B), the words "considers necessary and appropriate" are substituted for "deems necessary and appropriate" to use the more appropriate word.

In subsection (h), the words "considered necessary" are substituted for "deemed necessary" to use the more appropriate word.

SECTION 20106—VOLUNTARY QUALIFIED IMPORTER PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20106(a)	21 U.S.C. 384b(g)	June 25, 1938, ch. 675, §806(g), as added Pub. L. 111–353, title III, § 302, Jan. 4, 2011, 124 Stat. 3955.
20106(b) through (g) ...	21 U.S.C. 384b(a) through (f)	June 25, 1938, ch. 675, §806(a) through (f), as added Pub. L. 111–353, title III, § 302, Jan. 4, 2011, 124 Stat. 3955.

In subsection (b), in the matter before paragraph (1), the words "Beginning not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

SECTION 20107—INSPECTION OF FOREIGN FOOD FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20107	21 U.S.C. 384c	June 25, 1938, ch. 675, § 807, as added Pub. L. 111–353, title III, § 306(a), Jan. 4, 2011, 124 Stat. 3958.

SECTION 20108—ACCREDITATION OF THIRD-PARTY AUDITORS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20108(a)(1)	21 U.S.C. 384d(a)(2)	June 25, 1938, ch. 675, §808(a)(2), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.
20108(a)(2)	21 U.S.C. 384d(a)(4)	June 25, 1938, ch. 675, §808(a)(4), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.
20108(a)(3)	21 U.S.C. 384d(a)(1)	June 25, 1938, ch. 675, §808(a)(1), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.
20108(a)(4)	21 U.S.C. 384d(a)(5)	June 25, 1938, ch. 675, §808(a)(5), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.
20108(a)(5)	21 U.S.C. 384d(a)(6)	June 25, 1938, ch. 675, §808(a)(6), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20108(a)(6)	21 U.S.C. 384d(a)(7)	June 25, 1938, ch. 675, §808(a)(7), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.
20108(a)(7)	21 U.S.C. 384d(a)(3)	June 25, 1938, ch. 675, §808(a)(3), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.
20108(b) through (h) ...	21 U.S.C. 384d(b) through (h)	June 25, 1938, ch. 675, §808(b) through (h), as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.

In subsection (a)(7)(B), the words "an individual" are substituted for "a single individual" to eliminate an unnecessary word.

In subsection (b)(1)(A)(i), the words "Not later than 2 years after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

In subsection (b)(2)(A), the words "Not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act," are omitted as obsolete.

In subsection (c)(1)(A), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

In subsection (c)(1)(B), the words "as the Secretary considers necessary" are substituted for "as the Secretary deems necessary" to use the more appropriate word.

In subsection (c)(2)(C)(i), the words, "section 20106(b) of this title" are substituted for "subparagraph (B)" for clarity and consistency in the clause and with clause (ii).

In subsection (c)(2)(C)(ii), the words "section 20101(q) of this title" are substituted for "301(g)" to provide the correct reference to the pertinent provision.

In subsection (c)(5)(C), in the matter before clause (i), the words "not later than 18 months after the date of enactment of the FDA Food Safety Modernization Act" to eliminate unnecessary words.

In subsection (c)(6)(A)(i), the words "section 20106(b) of this title" are substituted for "paragraph (2)(B)" for clarity and consistency in the clause.

In subsection (c)(6)(C)(ii), the words "section 20106(b) of this title" are substituted for "paragraph (2)(B)" for clarity and consistency in the clause.

In subsection (c)(8)(A), the words "section 203(h) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1622(h))," are substituted for "section 203(h) of the Agriculture Marketing Act of 1946," to correct a technical error.

In subsection (f)(2), the words "measures considered necessary" are substituted for "measures deemed necessary" to use the more appropriate word.

In subsection (f)(4), the words "measures considered necessary" are substituted for "measures deemed necessary" to use the more appropriate word.

In subsection (g), the words "information considered necessary" are substituted for "information deemed necessary" to use the more appropriate word.

SECTION 20109—RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
20109	21 U.S.C. 384e	June 25, 1938, ch. 675, § 809, as added Pub. L. 112–144, title VII, § 712, July 9, 2012, 126 Stat. 1072; Pub. L. 114–255, div. A, title III, §3101(a)(2)(X), Dec. 13, 2016, 130 Stat. 1156; Pub. L. 115–52, title VII, §701(b), Aug. 18, 2017, 131 Stat. 1055; Pub. L. 117–328, div. FF, title III, §3613(c), Dec. 29, 2022, 136 Stat. 5872.

In subsection (a)(2), the words "may enter into arrangements and agreements under this section" are substituted for "may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section" to eliminate unnecessary words.

In subsection (a)(3), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

Division H—Tobacco Products

Chapter 211—Tobacco Products

SECTION 21101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21101	21 U.S.C. 387 (except (19))	June 25, 1938, ch. 675, §900 (except (19)), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1784.

SECTION 21102—FDA AUTHORITY OVER TOBACCO PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21102	21 U.S.C. 387a	June 25, 1938, ch. 675, § 901, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1786; Pub. L. 117–103, div. P, title I, §111(b), Mar. 15, 2022, 136 Stat. 789.

In subsection (b), the words "considers to be subject" are substituted for "deems to be subject" to use the more appropriate word.

In subsection (c)(1), the words "Nothing in this chapter, or any policy issued or regulation promulgated under this chapter, or in section 80101 or 80102 of this title, or in section 101(a) or 103 of the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1783, 1833), or in title II or title III of the Act (Public Law 111–31, 123 Stat. 1842, 1850)," are substituted for "Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of title I, title II, or title III of the Family Smoking Prevention and Tobacco Control Act," for clarity.

In subsection (e), the words "Not later than 90 days after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

SECTION 21103—ADULTERATED TOBACCO PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21103	21 U.S.C. 387b	June 25, 1938, ch. 675, § 902, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1787.

SECTION 21104—MISBRANDED TOBACCO PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21104	21 U.S.C. 387c	June 25, 1938, ch. 675, § 903, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1788; Pub. L. 116–94, div. N, title I, §603(d)(3), Dec. 20, 2019, 133 Stat. 3124.

In subsection (b)(1), the words "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" are substituted for "with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act)" for clarity.

SECTION 21105—SUBMISSION OF HEALTH INFORMATION TO THE SECRETARY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21105(a)(1)	21 U.S.C. 387d(a) (except (3) (last sentence))	June 25, 1938, ch. 675, § 904(a) (except (3) (last sentence)), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1790.
21105(a)(2)	21 U.S.C. 387d(a)(3) (last sentence)	June 25, 1938, ch. 675, §904(a)(3) (last sentence), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1790.
21105(b) through (e) ...	21 U.S.C. 387d(b) through (e)	June 25, 1938, ch. 675, §904(b) through (e), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1790.

In subsection (a)(1)(A), the words "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" are substituted for "Not later than 6 months after June 22, 2009, a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added" to eliminate obsolete words.

In subsection (a)(1)(C), the words "Beginning 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

In subsection (a)(1)(D), the words "Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

In subsection (a)(1)(D), the words "after June 22, 2009," are substituted for "after such date of enactment" for clarity.

In subsection (a)(2), the words "Effective beginning 3 years after such date of enactment," are omitted as obsolete.

In subsection (c)(3), the words “advise the Secretary of the action” are substituted for “so advise the Secretary” for clarity.

In subsection (d)(1), the words “The Secretary shall annually publish” are substituted for “Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish” to eliminate obsolete words.

In subsection (e), the words “Not later than 24 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act,” are omitted as obsolete.

SECTION 21106—ANNUAL REGISTRATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21106 (except (j)(1)) ...	21 U.S.C. 387e (except (b) (last sentence))	June 25, 1938, ch. 675, §905 (except (b) (last sentence)), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1792.
21106(j)(1)	21 U.S.C. 387j(a)(3) (relating to "section 387e(j) of this title")	June 25, 1938, ch. 675, §910(a)(3) (relating to "section 905(j)"), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1807.

In subsections (b), (c), (d), (g), and (h)(1), the words “a tobacco product” are substituted for “a tobacco product or tobacco products” to eliminate unnecessary words and for consistency with section 1 of title 1, United States Code.

In subsection (g), the words “engaged in the manufacture, preparation, compounding, or processing” are substituted for “engaged in the manufacture, compounding, or processing” for consistency with subsection (a)(1).

In subsection (g), the word “thereafter” is omitted as unnecessary.

In subsection (i)(3)(A)(ii), the words “the registrant has discontinued” are substituted for “that person has discontinued” for consistency in the clause.

In subsection (i)(3)(A)(iii), the words “the registrant has resumed” are substituted for “that person has resumed” for consistency in the clause.

In subsection (j)(1)(A), in the matter before clause (i), the defined term “substantial equivalence” is eliminated as unnecessary. That term is not used in section 21106 of title 21, United States Code.

In subsection (j)(1)(A)(ii), the words “considered necessary” are substituted for “deemed necessary” to use the more appropriate word.

In subsection (j)(4)(B), the words “Not later than 15 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act,” are omitted as obsolete.

SECTION 21107—GENERAL PROVISIONS RESPECTING CONTROL OF TOBACCO PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21107	21 U.S.C. 387f (except (e)(3))	June 25, 1938, ch. 675, §906 (except (e)(3)), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1795; Pub. L. 116–94, div. N, title I, §603(a), Dec. 20, 2019, 133 Stat. 3123.

In subsection (b)(2), the words "cause for the extension" are substituted for "cause therefore" for clarity.

In subsection (d)(5), the word "individual" is substituted for "person" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (e)(1)(A)(i), the words "ensure that the public health" are substituted for "assure that the public health" to use the more appropriate word.

In subparagraph (A)(i), clauses (i) and (ii) of subparagraph (D), and subparagraph (E) of subsection (e)(2), the words "ensure that the tobacco product" are substituted for "assure that the tobacco product" to use the more appropriate word.

In subsection (e)(2)(F), the words "under subparagraph (C)" are substituted for "under subparagraph (B)" to provide a more precise reference to the pertinent provision.

SECTION 21108—TOBACCO PRODUCT STANDARDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21108	21 U.S.C. 387g(a) through (d)	June 25, 1938, ch. 675, § 907(a) through (d), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1799; Pub. L. 117–103, div. P, title I, §111(f), Mar. 15, 2022, 136 Stat. 790.

In subsection (a)(1)(A)(i), the words "Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

In subsection (a)(1)(B), the words "Beginning 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

SECTION 21109—NOTIFICATION AND OTHER REMEDIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21109	21 U.S.C. 387h	June 25, 1938, ch. 675, § 908, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1804.

In subsection (a)(2), the words "ensure that adequate notification" are substituted for "assure that adequate notification" to use the more appropriate word.

SECTION 21110—RECORDS AND REPORTS ON TOBACCO PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21110	21 U.S.C. 387i	June 25, 1938, ch. 675, § 909, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1805.

In subsection (a)(1), the words "ensure that the tobacco product" are substituted for "assure that such tobacco product" to use the more appropriate word.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21111(a)(1)	21 U.S.C. 387j(a)(1)	June 25, 1938, ch. 675, §910(a)(1), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1807.
21111(a)(2)	21 U.S.C. 387j(a)(3) (relating to "this section")	June 25, 1938, ch. 675, §910(a)(3) (relating to "this section"), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1807.
21111(b)(1)	21 U.S.C. 387j(a)(2)	June 25, 1938, ch. 675, §910(a)(2), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1807.
21111(b)(2)	21 U.S.C. 387j(a)(4)	June 25, 1938, ch. 675, §910(a)(4), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1807.
21111(c) through (h) ...	21 U.S.C. 387j(b) through (g)	June 25, 1938, ch. 675, §910(b) through (g), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1807.

In subsection (a)(2), the defined term "substantial equivalence" is eliminated as unnecessary. That term is not used in section 21111 of title 21, United States Code.

In subsection (a)(2)(A)(ii), the words "considered necessary" are substituted for "deemed necessary" to use the more appropriate word.

SECTION 21112—MODIFIED RISK TOBACCO PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21112(a)	21 U.S.C. 387k(b)(1), (2)	June 25, 1938, ch. 675, §911(b)(1), (2), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1812.
21112(b)	21 U.S.C. 387k(a)	June 25, 1938, ch. 675, §911(a), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1812.
21112(c) through (m) ..	21 U.S.C. 387k(c) through (m)	June 25, 1938, ch. 675, §911(c) through (m), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1812.

In subsection (a)(2)(A)(iii), the words "respecting the tobacco product, which action would be reasonably expected" are substituted for "respecting the product that would be reasonably expected" for clarity.

In subsection (g)(1)(B), the words "individuals who do not currently use" are substituted for "persons who do not currently use" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (g)(2)(B), in the matter before clause (i), the words "shall also find" are substituted for "must also find" for consistency in title 21, United States Code.

In subsection (g)(2)(B)(iv), the words "individuals who do not currently use" are substituted for "persons who do not currently use" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (g)(4)(C), the words "that individuals who do not use" are substituted for "that persons who do not use" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (g)(4)(D), the words "the risks and benefits to individuals" are substituted for "the risks and benefits to persons" for consistency with the definition of "person" in section 10101 of title 21, United States Code.

In subsection (l)(1), in the matter before subparagraph (A), the words "Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

In subsection (l)(2), the words "National Academy of Medicine" are substituted for "Institute of Medicine" to reflect the current name of the entity.

In subsection (l)(4), the words "Not later than 2 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

In subsection (m), the words "after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

SECTION 21113—JUDICIAL REVIEW

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21113(a)	21 U.S.C. 387l(a)(2)(C)	June 25, 1938, ch. 675, §912(a)(2)(C), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1819.
21113(b) through (f)	21 U.S.C. 387l (except (a)(2)(C))	June 25, 1938, ch. 675, §912 (except (a)(2)(C)), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1819.

In subsection (a)(1), the words "a regulation or order reviewed under this section" are substituted for "the regulation or order reviewed" for clarity.

In clauses (i) and (ii) of subsection (b)(2)(B), and in subsections (c) and (d), the words "denial order" are substituted for "order" each place it appears for clarity.

SECTION 21114—EQUAL TREATMENT OF RETAIL OUTLETS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21114	21 U.S.C. 387m	June 25, 1938, ch. 675, § 913, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1820.

SECTION 21115—JURISDICTION OF AND COORDINATION WITH THE FEDERAL TRADE COMMISSION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21115	21 U.S.C. 387n	June 25, 1938, ch. 675, § 914, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1820.

In subsection (b)(1), the words "enforcement of the Acts" are substituted for "enforcement of such Act" for consistency in the paragraph.

SECTION 21116—REGULATION REQUIREMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21116	21 U.S.C. 387o	June 25, 1938, ch. 675, § 915, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1820.

In subsection (d)(1)(A), in the matter after the semicolon, the word "or" is substituted for "and" to use the more appropriate word.

In subsection (f), the words "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)" are substituted for "under any provision of this Act or the Family Smoking Prevention and Tobacco Control Act other than this section" for clarity.

SECTION 21117—PRESERVATION OF STATE AND LOCAL AUTHORITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21117	21 U.S.C. 387p	June 25, 1938, ch. 675, § 916, as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1823.

SECTION 21118—TOBACCO PRODUCTS SCIENTIFIC ADVISORY COMMITTEE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21118(a)	21 U.S.C. 387q(a) (parenthetical)	June 25, 1938, ch. 675, §917(a) (parenthetical), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1824.
21118(b) through (f)	21 U.S.C. 387q (except (a) (parenthetical))	June 25, 1938, ch. 675, §917 (except (a) (parenthetical)), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1824; Pub. L. 117–286, §4(a)(160), Dec. 27, 2022, 136 Stat. 4323.

In subsection (b), the words "Not later than 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

In subsection (e)(1)(B), the words "individuals in the Government service" are substituted for "persons in the Government service" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

In subsection (f), the words "proceeding of the Advisory Committee" are substituted for "proceeding of the panel or committee" and the words "The Advisory Committee" are substituted for "Each such panel and committee" for consistency in the subsection.

SECTION 21119—DRUG PRODUCTS USED TO TREAT TOBACCO DEPENDENCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21119	21 U.S.C. 387r(a)	June 25, 1938, ch. 675, §918(a), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1825.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21120(a)	21 U.S.C. 387s(a)	June 25, 1938, ch. 675, §919(a), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.
21120(b)	21 U.S.C. 387s(b)	June 25, 1938, ch. 675, §919(b), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.
21120(c)(1)	21 U.S.C. 387s(c)(2)(A) (parenthetical)	June 25, 1938, ch. 675, §919(c)(2)(A) (parenthetical), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.
21120(c)(2)	21 U.S.C. 387s(c)(1)	June 25, 1938, ch. 675, §919(c)(1), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.
21120(c)(3)(A)	21 U.S.C. 387s(c)(2)(A) (except parenthetical)	June 25, 1938, ch. 675, §919(c)(2)(A) (except parenthetical), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.
21120(c)(3)(B)	21 U.S.C. 387s(c)(2)(B)(i)	June 25, 1938, ch. 675, §919(c)(2)(B)(i), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.
21120(c)(4)	21 U.S.C. 387s(c)(3)	June 25, 1938, ch. 675, §919(c)(3), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.
21120(d)	21 U.S.C. 387s(d)	June 25, 1938, ch. 675, §919(d), as added Pub. L. 111–31, div. A, title I, § 101(b)(3), June 22, 2009, 123 Stat. 1826.

In subsection (a), the words "Beginning on the date of enactment of the Family Smoking Prevention and Tobacco Control Act," are omitted as obsolete.

In subsection (b)(1), subparagraphs (A) through (J) of section 919(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(b)(1)) are omitted as obsolete.

In subsection (b)(1), the words "for each fiscal year" are substituted for "For fiscal year 2019 and each subsequent fiscal year," to eliminate obsolete words.

In subsection (b)(7)(B), the words "For each fiscal year" are substituted for "Beginning not later than fiscal year 2015, and for each subsequent fiscal year," to eliminate obsolete words.

In subsection (c)(1), the words "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)" are substituted for "under this chapter and the Family Smoking Prevention and Tobacco Control Act" for clarity.

In subsection (c)(2)(A), the words "subject to paragraph (2)(D)" are omitted as obsolete. Paragraph (2)(D) of section 919(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(c)) is repealed by the bill enacting title 21, United States Code.

In subsection (c)(3)(A), the words "except that such fees may be used for the reimbursement specified in subparagraph (C)" are omitted as obsolete. Subparagraph (C) of section 919(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387s(c)(2)) is repealed by the bill enacting title 21, United States Code.

In subsection (c)(3)(B), the words "Except as provided in clause (ii)," are omitted as obsolete. Clause (ii) of section 919(c)(2)(B) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 387s(c)(2)(B)) is repealed by the bill enacting title 21, United States Code.

In subsection (c)(4), the words "For each fiscal year," are substituted for "For fiscal year 2009 and each subsequent fiscal year," to eliminate obsolete words.

SECTION 21121—LABELING, RECORDKEEPING, RECORDS INSPECTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
21121(a)	21 U.S.C. 387t(a)	June 25, 1938, ch. 675, §920(a), as added Pub. L. 111–31, div. A, title III, § 301, June 22, 2009, 123 Stat. 1850.
21121(b)	21 U.S.C. 387t(b)	June 25, 1938, ch. 675, §920(b), as added Pub. L. 111–31, div. A, title III, § 301, June 22, 2009, 123 Stat. 1850.
21121(c)	21 U.S.C. 387t(c)	June 25, 1938, ch. 675, §920(c), as added Pub. L. 111–31, div. A, title III, § 301, June 22, 2009, 123 Stat. 1850.
21121(d)(1)	21 U.S.C. 387t(d)(2)	June 25, 1938, ch. 675, §920(d)(2), as added Pub. L. 111–31, div. A, title III, § 301, June 22, 2009, 123 Stat. 1850.
21121(d)(2)	21 U.S.C. 387t(d)(1)	June 25, 1938, ch. 675, §920(d)(1), as added Pub. L. 111–31, div. A, title III, § 301, June 22, 2009, 123 Stat. 1850.
21121(e)	21 U.S.C. 387t(e)	June 25, 1938, ch. 675, §920(e), as added Pub. L. 111–31, div. A, title III, § 301, June 22, 2009, 123 Stat. 1850.

In subsection (d)(2) (matter before subparagraph (A)) and (e), the reference to the Secretary of the Treasury is retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

Subtitle II—Supplemental Food and Drug Administration Provisions

Chapter 251—General Provisions

SECTION 25101—SUBTITLE DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25101	(no source)	

This section is added for convenience.

Chapter 253—Organization and Administration

SECTION 25301—OFFICE OF PEDIATRIC THERAPEUTICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25301	21 U.S.C. 393a	Pub. L. 107–109, §6, Jan. 4, 2002, 115 Stat. 1414; Pub. L. 110–85, title III, §306(a), Sept. 27, 2007, 121 Stat. 864; Pub. L. 112–144, title V, §511, July 9, 2012, 126 Stat. 1050; Pub. L. 115–52, title V, §505(d)(1), Aug. 18, 2017, 131 Stat. 1047.

In this section, the words "Secretary", "FDA", and "Department" are substituted for "Secretary of Health and Human Services", "Food and Drug Administration", and "Department of Health and Human Services", respectively, each place they appear because of section 25101 of title 21, United States Code.

In subsection (c)(2)(B), the words "National Academy of Medicine" are substituted for "Institute of Medicine" to reflect the current name of the entity.

SECTION 25302—OFFICE OF MINOR USE AND MINOR SPECIES ANIMAL DRUG DEVELOPMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25302	21 U.S.C. 393 note	Pub. L. 108–282, title I, §102(b)(7), Aug. 2, 2004, 118 Stat. 905.

In this section, the words "Secretary" and "FDA" are substituted for "Secretary of Health and Human Services'' and "Food and Drug Administration", respectively, each place they appear because of section 25101 of title 21, United States Code.

In this section, the last sentence of section 102(b)(7) of the Minor Use and Minor Species Animal Health Act of 2004 (Public Law 108–282, 118 Stat. 905), which authorized to be appropriated $1,200,000 for fiscal year 2004 and such sums as may be necessary for each fiscal year after fiscal year 2004 to carry out subsection (b) of section 102 of that Act, is omitted as unnecessary.

SECTION 25303—NANOTECHNOLOGY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25303	21 U.S.C. 399e	Pub. L. 112–144, title XI, § 1126, July 9, 2012, 126 Stat. 1116.

In this section, the word "FDA" is substituted for the words "Food and Drug Administration" each place they appear because of section 25101 of title 21, United States Code.

In subsection (a), the words "The Secretary" are substituted for "The Secretary of Health and Human Services (referred to in this section as the 'Secretary')" because of section 25101 of title 21, United States Code.

SECTION 25304—FDA WORKING CAPITAL FUND

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25304	21 U.S.C. 399i (except (b))	Pub. L. 115–141, div. A, title VII, §722 (except (b)), Mar. 23, 2018, 132 Stat. 387.

Subsection (a) is added to carry forward the parenthetical "(the Fund)" in section 722(a) of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018 (21 U.S.C. 399i(a)). The parenthetical is omitted in the restatement of section 722(a) of the Act. See revision note for subsection (b)(1) (matter before subparagraph (A)).

In subsection (b)(1), in the matter before subparagraph (A), the parentheticals "(the Fund)" and "(FDA)" are omitted because of subsection (a) and section 25101 of title 21, United States Code.

In subsection (b)(1)(B), the words "Commissioner of Food and Drugs" are substituted for "Commissioner of the FDA" for clarity and consistency with section 10301(d) of title 21, United States Code.

In subsection (b)(1)(B), the word "Secretary" is substituted for "Secretary of Health and Human Services'' because of section 25101 of title 21, United States Code.

SECTION 25305—ACCELERATED APPROVAL COUNCIL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25305	21 U.S.C. 356–2	Pub. L. 117–328, div. FF, title III, §3210(e), Dec. 29, 2022, 136 Stat. 5824.

In this section, the word "FDA" is substituted for "Food and Drug Administration" each place it appears because of section 25101 of title 21, United States Code.

In subsection (a), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 25306—IMPROVING FDA GUIDANCE AND COMMUNICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25306	21 U.S.C. 393 note	Pub. L. 117–328, div. FF, title II, §2505, Dec. 29, 2022, 136 Stat. 5802.

In this section, the word "FDA" is substituted for "Food and Drug Administration" each place it appears because of section 25101 of title 21, United States Code.

In subsection (a), in the matter before paragraph (1), the words "The Secretary" are substituted for "The Secretary of Health and Human Services (referred to in this section as the 'Secretary')" because of section 25101 of title 21, United States Code.

In subsections (a) (matter before paragraph (1)) and (b), the words "FDA website" are substituted for "website of the Food and Drug Administration" because of section 25101 of title 21, United States Code.

SECTION 25307—FOOD AND DRUG ADMINISTRATION STRATEGIC INFORMATION TECHNOLOGY PLAN

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25307	21 U.S.C. 393 note	Pub. L. 117–328, div. FF, title III, §3627(a), Dec. 29, 2022, 136 Stat. 5888.

In this section, the word "Secretary" is retained each place it appears because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 25308—OFFICE OF CRITICAL FOODS; INFANT SUPPLY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25308(a)	21 U.S.C. 350a–1(a)(1)	Public Law 117–328, div. FF, title III, §3401(a)(1), Dec. 29, 2022, 136 Stat. 5838.
25308(b)	21 U.S.C. 350a–1(b)	Pub. L. 117–328, div. FF, title III, §3401(b), Dec. 29, 2022, 136 Stat. 5838.
25308(c)	21 U.S.C. 350a–1(e)	Pub. L. 117–328, div. FF, title III, §3401(e), Dec. 29, 2022, 136 Stat. 5838.
25308(d)	21 U.S.C. 350a–1(f)(1)	Pub. L. 117–328, div. FF, title III, §3401(f)(1), Dec. 29, 2022, 136 Stat. 5838.
25308(e)	21 U.S.C. 350a–1(g)(5)	Pub. L. 117–328, div. FF, title III, §3401(g)(5), Dec. 29, 2022, 136 Stat. 5840.
25308(f)	21 U.S.C. 350a–1(i)	Pub. L. 117–328, div. FF, title III, §3401(i), Dec. 29, 2022, 136 Stat. 5838.
25308(g)	21 U.S.C. 350a–1(j)	Pub. L. 117–328, div. FF, title III, §3401(j), Dec. 29, 2022, 136 Stat. 5843.

In this section, the word "Secretary" is retained each place it appears because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

In subsection (e), the words "each of the requirements of paragraphs (1), (2), and (3) of section 11114(d) of this title" are substituted for "each of the requirements of paragraphs (1), (2), and (3) of subsection (d)" for clarity.

SECTION 25309—INTERNATIONAL HARMONIZATION RELATING TO MODERNIZING CLINICAL TRIALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
25309	21 U.S.C. 360a–1 note	Pub. L. 117–328, div. FF, title III, §3607(c), Dec. 29, 2022, 136 Stat. 5868.

In this section, the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

Chapters 255 Through 289—Reserved

Chapter 291—Guidance Documents

SECTION 29101—GUIDANCE RELATING TO SERIOUS ADVERSE REPORTING FOR NONPRESCRIPTION DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29101	21 U.S.C. 379aa note	Pub. L. 109–462, §2(e)(3), Dec. 22, 2006, 120 Stat. 3472.

In this section, the words "Not later than 270 days after the date of enactment of this Act," are omitted as obsolete.

In this section, the word "Secretary" is substituted for "Secretary of Health and Human Services" because of section 25101 of title 21, United States Code.

In this section, the words "described in section 18901 of this title" are substituted for "described under the amendments made by this Act" for clarity. There are only 2 serious adverse event reports described in the amendments made by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462, 120 Stat. 3469); sections 2(a) and 3(a) of that Act amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to add provisions relating to serious adverse event reporting for nonprescription drugs and serious adverse event reporting for dietary supplements, respectively. The substitution clarifies to which serious adverse event report the source law refers. See revision note for section 29102 of title 21, United States Code, for similar revision to similar provision.

SECTION 29102—GUIDANCE RELATING TO SERIOUS ADVERSE REPORTING FOR DIETARY SUPPLEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29102	21 U.S.C. 379aa note	Pub. L. 109–462, §3(d)(3), Dec. 22, 2006, 120 Stat. 3475.

In this section, the words "Not later than 270 days after the date of enactment of this Act," are omitted as obsolete.

In this section, the word "Secretary" is substituted for "Secretary of Health and Human Services" because of section 25101 of title 21, United States Code.

In this section, the words "described in section 18902 of this title" are substituted for "as described under the amendments made by this Act" for clarity. There are only 2 serious adverse event reports described in the amendments made by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462, 120 Stat. 3469); sections 2(a) and 3(a) of that Act amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to add provisions relating to serious adverse event reporting for nonprescription drugs and serious adverse event reporting for dietary supplements, respectively. The substitution clarifies to which serious adverse event report the source law refers. See revision note for section 29101 of title 21, United States Code, for similar revision to similar provision.

SECTION 29103—GUIDANCE ON PATHOGEN-FOCUSED ANTIBACTERIAL DRUG DEVELOPMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29103	21 U.S.C. 355 note	Pub. L. 112–144, title VIII, §806, July 9, 2012, 126 Stat. 1082.

In this section, the words "Secretary" and "FDA" are substituted for "Secretary of Health and Human Services" and "Food and Drug Administration", respectively, each place they appear because of section 25101 of title 21, United States Code.

In subsection (a), in the matter before paragraph (1), the words "Not later than June 30, 2013," are omitted as obsolete.

In subsection (b), the words "Not later than December 31, 2014," are omitted as obsolete.

SECTION 29104—GUIDANCE DOCUMENT REGARDING PRODUCT PROMOTION USING THE INTERNET

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29104	21 U.S.C. 379d–5	Pub. L. 112–144, title XI, § 1121, July 9, 2012, 126 Stat. 1112.

In this section, the words "Not later than 2 years after the date of enactment of this Act," are omitted as obsolete.

In this section, the word "Secretary" is substituted for "Secretary of Health and Human Services" and the word "FDA" is substituted for "Food and Drug Administration" and "such Administration" because of section 25101 of title 21, United States Code.

SECTION 29105—GUIDANCE ON ABUSE-DETERRENT PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29105	21 U.S.C. 355 note	Pub. L. 112–144, title XI, §1122(c), July 9, 2012, 126 Stat. 1113.

In this section, the words "Not later than 6 months after the date of enactment of this Act," are omitted as obsolete.

In this section, the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of the words "the Secretary of Health and Human Services (referred to in this section as the 'Secretary')" in section 1122(a) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1112).

SECTION 29106—GUIDANCE RELATING TO NOVEL CLINICAL TRIAL DESIGNS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29106	21 U.S.C. 355 note	Pub. L. 114–255, div. A, title III, §3021, Dec. 13, 2016, 130 Stat. 1095.

In subsection (a), the word “Secretary” is substituted for “Secretary of Health and Human Services (referred to in this section as the ‘Secretary’)” because of section 25101 of title 21, United States Code.

SECTION 29107—GUIDANCE RELATING TO NEONATAL STUDIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29107	21 U.S.C. 355a note	Pub. L. 115–52, title V, §505(d)(2), Aug. 18, 2017, 131 Stat. 1047.

In this section, the words “Not later than 2 years after the date of enactment of this Act,” are omitted as obsolete.

In this section, the word “Secretary” is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to “Secretary” means the Secretary of Health and Human Services. See section 505(c) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1046) (referring to the Secretary of Health and Human Services).

SECTION 29108—GUIDANCE RELATING TO INSPECTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29108	21 U.S.C. 374 note	Pub. L. 115–52, title VII, §702(b), Aug. 18, 2017, 131 Stat. 1055.

In this section, the word “Secretary” is substituted for “Secretary of Health and Human Services” and the word “FDA” is substituted for “Food and Drug Administration” each place they appear because of section 25101 of title 21, United States Code.

In subsection (a)(3)(B), the words “to conduct the inspection” are substituted for “to conduct such investigation” for consistency in the paragraph.

SECTION 29109—GUIDANCE RELATING TO USE OF ELEMENTS OF INVESTIGATIONS IN THE DEVELOPMENT OF NEW ANIMAL DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29109(a)	21 U.S.C. 360b note	Pub. L. 115–234, title III, §305(a) ("(referred to in this section as 'elements of investigations')"), Aug. 14, 2018, 132 Stat. 2440.
29109(b)	21 U.S.C. 360b note	Pub. L. 115–234, title III, §305(a) (except "(referred to in this section as 'elements of investigations')"), Aug. 14, 2018, 132 Stat. 2440.
29109(c) through (e) ...	21 U.S.C. 360b note	Pub. L. 115–234, title III, §305(b) through (d), Aug. 14, 2018, 132 Stat. 2440.

In subsection (b), the word “Secretary” is substituted for “Secretary of Health and Human Services (referred to in this section as the ‘Secretary’)” because of section 25101 of title 21, United States Code.

SECTION 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

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29110	21 U.S.C. 360bbb–4 note	Pub. L. 117–328, div. FF, title II, §2502(b), Dec. 29, 2022, 136 Stat. 5798.

In this section, the words "the Secretary" are substituted for "the Secretary of Health and Human Services (referred to in this section as the 'Secretary')" because of section 25101 of title 21, United States Code.

SECTION 29111—GUIDANCE RELATING TO PLATFORM TECHNOLOGIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29111	21 U.S.C. 356k note	Pub. L. 117–328, div. FF, title II, §2503(b), Dec. 29, 2022, 136 Stat. 5801.

In subsection (a), the word "Secretary" is substituted for "Secretary of Health and Human Services (referred to in this section as the 'Secretary')" because if section 25101 of title 21, United States Code.

In subsection (a), the words "implementation of section 13131 of this title" are substituted for "implementation of this section" to provide a more precise reference to the pertinent provision. The reference to "this section" in the source provision refers to section 2503 of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (Public Law 117–328, div. FF, title II, 136 Stat. 5798). That section comprises the addition of section 506K of the Federal Food, Drug, and Cosmetic Act (restated in title 21, United States Code, as section 13131), a requirement for the Secretary to issue draft guidance (restated in this section), and a reporting requirement, which is neither restated nor repealed in title 21, United States Code.

SECTION 29112—GUIDANCE RELATING TO EXTENDING EXPIRATION DATES FOR CERTAIN DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29112	21 U.S.C. 355 note	Pub. L. 117–328, div. FF, title II, §2512(a), Dec. 29, 2022, 136 Stat. 5804.

In this section, the words "the Secretary" are substituted for "the Secretary of Health and Human Services (referred to in this section as the 'Secretary')" because of section 25101 of title 21, United States Code.

SECTION 29113—GUIDANCE RELATING TO DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF MEDICAL DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29113	21 U.S.C. 356j note	Pub. L. 117–328, div. FF, title II, §2514(b), (c), Dec. 29, 2022, 136 Stat. 5806.

In this section, the word "Secretary" is retained for clarity because section 25101 of title 21, United States Code, defines "Secretary" as the Secretary of Health and Human Services. The word "Secretary" is not defined in the source provision, but the subject matter of the draft guidance to be issued under this section relates to subject matter under the authority of the Secretary of Health and Human Services.

SECTION 29114—GUIDANCE RELATING TO BEST PRACTICES AND STRATEGIES FOR DEVELOPMENT OF EFFICACY ENDPOINTS FOR RARE DISEASES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29114	21 U.S.C. 360aa note	Pub. L. 117–328, div. FF, title III, §3208(d), Dec. 29, 2022, 136 Stat. 5821.

In this section, the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 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

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29115	21 U.S.C. 356 note	Pub. L. 117–328, div. FF, title III, §3210(d), Dec. 29, 2022, 136 Stat. 5824.

In subsection (a), in the matter before paragraph (1), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

In subsection (a)(1), the word "FDA" is substituted for "Food and Drug Administration" because of section 25101 of title 21, United States Code.

SECTION 29116—GUIDANCE RELATING TO APPROVAL OR LICENSURE OF ANTIFUNGAL THERAPIES DESIGNED TO TREAT VALLEY FEVER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29116	21 U.S.C. 355 note	Pub. L. 117–328, div. FF, title III, §3211, Dec. 29, 2022, 136 Stat. 5825.

In subsection (a), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 29117—GUIDANCE ON DEVICE CYBERSECURITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29117(a)	(no source)	
29117(b)	21 U.S.C. 360n–2 note	Pub. L. 117–328, div. FF, title III, §3305(e), Dec. 29, 2022, 136 Stat. 5833.
29117(c)	21 U.S.C. 331 note	Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (e) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5833)), Dec. 29, 2022, 136 Stat. 5833.

Subsection (a) is added to carry forward the definition of "device" in section 3305(h) of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5834). In carrying forward the definition, the reference to "section 10101(a) of this title" is substituted for "section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" to provide a more precise reference to the pertinent provision.

In subsection (b), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of

section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

In subsection (c), the words "this section" are substituted for "this section, including the amendments made by this section," for clarity. The words "this section" in the source provision is retained, even though "this section" in the restatement refers only to the restatement of subsection (e) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5833), because the source provision is identically restated in other relevant provisions. See sections 10501(16)(C)(ii), 13158(e), and 49520(c) of title 21, United States Code, for identical provisions, except for the reference to "this section".

SECTION 29118—GUIDANCE RELATING TO DIVERSITY ACTION PLANS FOR CLINICAL STUDIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29118	21 U.S.C. 355 note	Pub. L. 117–328, div. FF, title III, §3602(a), (b), Dec. 29, 2022, 136 Stat. 5861.

In subsection (a), in the matter before paragraph (1), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 29119—GUIDANCE RELATING TO DECENTRALIZED CLINICAL STUDIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29119	21 U.S.C. 360a–1 note	Pub. L. 117–328, div. FF, title III, §3606, Dec. 29, 2022, 136 Stat. 5865.

In subsection (b), in the matter before paragraph (1), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 29120—GUIDANCE RELATING TO CLARIFYING THE USE OF DIGITAL HEALTH TECHNOLOGIES IN CLINICAL TRIALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29120	21 U.S.C. 360a–1 note	Pub. L. 117–328, div. FF, title III, §3607(a), Dec. 29, 2022, 136 Stat. 5866.

In subsection (a), in the matter before paragraph (1), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 29121—GUIDANCE RELATING TO SEAMLESS AND CONCURRENT CLINICAL TRIALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29121	21 U.S.C. 360a–1 note	Pub. L. 117–328, div. FF, title III, §3607(b), Dec. 29, 2022, 136 Stat. 5868.

In subsection (a), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 29122—GUIDANCE RELATING TO PROVISION OF RECORDS OR OTHER INFORMATION IN ADVANCE OF INSPECTION OF CERTAIN ESTABLISHMENTS, SITES, OR FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29122	21 U.S.C. 374 note	Pub. L. 117–328, div. FF, title III, §3611(b)(2), Dec. 29, 2022, 136 Stat. 5869.

In subsection (a), in the matter before paragraph (1), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 29123—GUIDANCE RELATING TO PROCESSES AND PRACTICES APPLICABLE TO INSPECTIONS OF CERTAIN SITES AND FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29123	21 U.S.C. 374 note	Pub. L. 117–328, div. FF, title III, §3612(b)(2), Dec. 29, 2022, 136 Stat. 5871.

In subsection (a), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 29124—GUIDANCE RELATING TO FACILITATING THE USE OF REAL WORLD EVIDENCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
29124	21 U.S.C. 355 note	Pub. L. 117–328, div. FF, title III, §3629(a), (c), Dec. 29, 2022, 136 Stat. 5891.

In subsection (a), the word "Secretary" is retained because of section 25101 of title 21, United States Code. In the source provision, the reference to "Secretary" means the Secretary of Health and Human Services because of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

Chapters 293 through 299—Reserved

Subtitle III—Food

Chapter 301—Adulterated or Misbranded Foods

SECTION 30101—SUSPENSION OF IMPORTATION OF ADULTERATED ARTICLES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30101	21 U.S.C. 18	Aug. 30, 1890, ch. 839, § 4, 26 Stat. 415.

In subsection (b), the words "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" are substituted for "and during such period it shall be unlawful to import into the United States from the countries designated in the proclamation of the President any of the articles the importation of which is so suspended" for clarity.

SECTION 30102—OLEOMARGARINE, BUTTERINE, OR IMITATION BUTTER OR CHEESE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30102	21 U.S.C. 25	May 9, 1902, ch. 784, § 1, 32 Stat. 193.

In this section, the words "in the State, territory of the United States, or the District of Columbia" are substituted for "therein" each place it appears and the word "respectively" is added after each of those substitutions for clarity.

SECTION 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

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30103	21 U.S.C. 16	July 1, 1902, ch. 1357, § 1, 32 Stat. 632.

In this section, in the matter before paragraph (1), the words "A person" are substituted for "That no person or persons, company or corporation," to eliminate unnecessary words because of section 1 of title 1, United States Code.

In paragraph (1), the words "that are falsely labeled" are substituted for "which shall be falsely labeled" for clarity.

In paragraph (2), the words "cause an action described in paragraph (1)" are substituted for "cause or procure the same" for clarity and to eliminate unnecessary words.

SECTION 30104—CRIMINAL PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30104	21 U.S.C. 17	July 1, 1902, ch. 1357, §2, 32 Stat. 632.

In subsection (a), the words "Any person" are substituted for "any person or persons" to eliminate unnecessary words because of section 1 of title 1, United States Code.

In subsection (a), the words "or causes another to violate section 30103 of this title" are substituted for "either in person or through another" for clarity and consistency in title 21, United States Code.

In subsection (a), the words "shall be fined under title 18 but not less than $500" are substituted for "shall be guilty of a misdemeanor and shall be punished by a fine of not less than $500 nor more than $2,000" for consistency with title 18, United States Code.

In subsection (b), the words "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" are substituted for "The jurisdiction for the prosecution of said misdemeanor shall be within the district of the United States court in which it is committed" for clarity and for consistency with subsection (a) and in title 21, United States Code.

Chapter 303—Meat Inspection

Throughout this chapter, the words "person, firm, or corporation" are retained, even though under section 1 of title 1, United States Code, the term "person" includes firms and corporations, to ensure that no change in the meaning or effect of the source provisions in which those words appear is made by the restatement of the provisions in title 21, United States Code. Retaining the words "person, firm, or corporation" throughout the chapter preserves the word "firm", which is a defined term for purposes of the chapter in section 30301(7) of title 21, United States Code.

Subchapter I—Inspection Requirements; Adulteration and Misbranding

SECTION 30301—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30301 (matter before (1))	21 U.S.C. 601 (matter before (a))	Mar. 4, 1907, ch. 2907, title I, §1 (matter before (a)), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(1)	21 U.S.C. 601(m)	Mar. 4, 1907, ch. 2907, title I, §1(m), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 585; Pub. L. 102–571, title I, § 107(14), Oct. 29, 1992, 106 Stat. 4499.
30301(2)	21 U.S.C. 601(w)	Mar. 4, 1907, ch. 2907, title I, §1(w), as added Pub. L. 109–97, title VII, § 798[(a)](2), Nov. 10, 2005, 119 Stat. 2166; Pub. L. 110–234, title XI, § 11016(b)(1)(A), May 22, 2008, 122 Stat. 1369; Pub. L. 110–246, § 4(a), title XI, § 11016(b)(1)(A), June 18, 2008, 122 Stat. 1664, 2130; Pub. L. 113–79, title XII, § 12106(a)(1), Feb. 7, 2014, 128 Stat. 980.
30301(3)	21 U.S.C. 601(e)	Mar. 4, 1907, ch. 2907, title I, §1(e), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(4)	21 U.S.C. 601(k)	Mar. 4, 1907, ch. 2907, title I, §1(k), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 585.
30301(5)	21 U.S.C. 601(r) (relating to color additive)	Mar. 4, 1907, ch. 2907, title I, §1(r) (relating to color additive), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(6)	21 U.S.C. 601(h)	Mar. 4, 1907, ch. 2907, title I, §1(h), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(7)	21 U.S.C. 601(b)	Mar. 4, 1907, ch. 2907, title I, §1(b), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30301(8)	21 U.S.C. 601(r) (relating to food additive)	Mar. 4, 1907, ch. 2907, title I, §1(r) (relating to food additive), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(9)	21 U.S.C. 601(o)	Mar. 4, 1907, ch. 2907, title I, §1(o), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 586.
30301(10)	21 U.S.C. 601(p)	Mar. 4, 1907, ch. 2907, title I, §1(p), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 586.
30301(11)	21 U.S.C. 601(c)	Mar. 4, 1907, ch. 2907, title I, §1(c), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(12)	21 U.S.C. 601(j)	Mar. 4, 1907, ch. 2907, title I, §1(j), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(13)	21 U.S.C. 601(n)	Mar. 4, 1907, ch. 2907, title I, §1(n), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 586; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.
30301(14)	21 U.S.C. 601(u)	Mar. 4, 1907, ch. 2907, title I, §1(u), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(15)	21 U.S.C. 601(v)	Mar. 4, 1907, ch. 2907, title I, §1(v), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(16)	21 U.S.C. 601(t)	Mar. 4, 1907, ch. 2907, title I, §1(t), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(17)	21 U.S.C. 601(s)	Mar. 4, 1907, ch. 2907, title I, §1(s), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(18)	21 U.S.C. 601(r) (relating to pesticide chemical)	Mar. 4, 1907, ch. 2907, title I, §1(r) (relating to pesticide chemical), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(19)	21 U.S.C. 601(l)	Mar. 4, 1907, ch. 2907, title I, §1(l), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 585.
30301(20)	21 U.S.C. 601(r) (relating to raw agricultural commodity)	Mar. 4, 1907, ch. 2907, title I, §1(r) (relating to raw agricultural commodity), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(21)	21 U.S.C. 601(d)	Mar. 4, 1907, ch. 2907, title I, §1(d), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(22)	21 U.S.C. 601(a)	Mar. 4, 1907, ch. 2907, title I, §1(a), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(23)	21 U.S.C. 601(f)	Mar. 4, 1907, ch. 2907, title I, §1(f), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(24)	21 U.S.C. 601(g)	Mar. 4, 1907, ch. 2907, title I, §1(g), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.
30301(25)	21 U.S.C. 601(i)	Mar. 4, 1907, ch. 2907, title I, §1(i), as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 584.

In paragraph (1)(A)(i), the words "under this clause" are retained, even though there are no clauses in the source provision which is paragraph (1) of section 1(m) of the Federal Meat Inspection Act (21 U.S.C. 601(m)), to provide the correct reference to the pertinent provision. The reference to "this clause" in the restatement is a reference to clause (i) of paragraph (1)(A) of section 30101 of title 21, United States Code, the source law of which is paragraph (1) of that section 1(m) of the Act.

In paragraph (1)(A)(ix), the words "in the margarine" are substituted for "therein" for clarity.

In paragraph (6), the words "territory of the United States" are substituted for "Territory" each place it appears for consistency with the defined term "territory of the United States" in paragraph (24). See revision note for paragraph (24).

In paragraph (12)(A)(ii), the words "ensure that the meat" are substituted for "assure that the meat" to use the more appropriate word.

In paragraph (13)(A)(viii), the words "or standards" are omitted as unnecessary because of section 1 of title 1, United States Code.

In paragraph (13)(A)(xii), the words "ensure that it will not have" are substituted for "assure that it will not have" to use the more appropriate word.

In paragraph (23), the words "or Puerto Rico" are substituted for "and the Commonwealth of Puerto Rico" to eliminate unnecessary words and for clarity.

In paragraph (24), the defined term "territory of the United States" is substituted for "Territory" for clarity and consistency in title 21, United States Code. Throughout the chapter, the term "territory of the United States" is substituted for "Territory", "territory", and words of like import, as appropriate, for consistency with the defined term, in the chapter, and in title 21, United States Code, and for clarity.

In paragraph (24), the words "or any other territory" are substituted for "and any other territory" for clarity.

In paragraph (24), the words "excluding the Canal Zone" are omitted as obsolete.

SECTION 30302—CONGRESSIONAL STATEMENT OF FINDINGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30302	21 U.S.C. 602	Mar. 4, 1907, ch. 2907, title I, § 2, as added Pub. L. 90–201, § 2, Dec. 15, 1967, 81 Stat. 587.

In subsection (a), in the matter before paragraph (1), the words "Congress finds the following:" are added for consistency in title 21, United States Code, and for clarity.

In subsection (a)(3), the words "ensuring that meat" are substituted for "assuring that meat" to use the more appropriate word.

In subsection (b), the words "Because of the findings in subsection (a), Congress finds" are substituted for "It is hereby found" for clarity.

SECTION 30303—EXAMINATION OF ANIMALS PRIOR TO SLAUGHTER; USE OF HUMANE METHODS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30303	21 U.S.C. 603	Mar. 4, 1907, ch. 2907, title I, § 3, formerly 1st par., 34 Stat. 1260; renumbered § 3 and amended Pub. L. 90–201, §§ 1, 3, 12(a), (b), Dec. 15, 1967, 81 Stat. 584, 588, 592; Pub. L. 95–445, § 2, Oct. 10, 1978, 92 Stat. 1069; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In subsection (a)(1), the words "the Secretary shall examine and inspect, through inspectors appointed for that purpose," are substituted for "the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of" for clarity and to eliminate unnecessary words.

In subsection (a)(1), the words "and in which the meat and meat food products of the amenable species" are substituted for "and the meat and meat food products thereof" for clarity.

In subsection (b)(1), the words "the Secretary shall examine and inspect, through inspectors appointed for that purpose," are substituted for "the Secretary

shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of" for clarity and to eliminate unnecessary words.

In subsection (b)(2), the words "or may temporarily suspend inspection at a slaughtering establishment" are substituted for "or may cause inspection to be temporarily suspended at a slaughtering establishment" for clarity and to eliminate unnecessary words.

SECTION 30304—POST MORTEM EXAMINATION OF CARCASSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30304	21 U.S.C. 604	Mar. 4, 1907, ch. 2907, title I, § 4, formerly 2nd par., 34 Stat. 1260; renumbered § 4 and amended Pub. L. 90–201, §§ 1, 3, 4, 12(a)–(d), Dec. 15, 1967, 81 Stat. 584, 588, 592; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In subsection (a), the words "For the purpose of preventing the use in commerce of meat and meat food products that are adulterated," are substituted for "For the purposes hereinbefore set forth" for clarity.

In subsection (a), the words "the Secretary shall conduct, through inspectors appointed for that purpose, a post mortem examination and inspection" are substituted for "the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection" for clarity.

In subsection (d)(1), the words "consider it necessary" are substituted for "deem it necessary" to use the more appropriate word.

SECTION 30305—EXAMINATION OF CARCASSES BROUGHT INTO SLAUGHTERING OR PACKING ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30305	21 U.S.C. 605	Mar. 4, 1907, ch. 2907, title I, § 5, formerly 3rd par., 34 Stat. 1261; renumbered § 5 and amended Pub. L. 90–201, §§ 1, 5, 12(a), Dec. 15, 1967, 81 Stat. 584, 588, 592; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In subsection (a), the words "Sections 30301 through 30304 of this title" are substituted for "The foregoing provisions" for clarity.

In subsection (b), the words "Sections 30301 through 30304 of this title" are substituted for "and the foregoing provisions" for clarity.

In subsection (c), the words "ensure that allowing the entry" are substituted for "assure that allowing the entry" to use the more appropriate word.

SECTION 30306—INSPECTION AND LABELING OF MEAT FOOD PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30306	21 U.S.C. 606	Mar. 4, 1907, ch. 2907, title I, § 6, as added Pub. L. 110–234, title XI, § 11016(b)(1)(B), May 22, 2008, 122 Stat. 1369, and Pub. L. 110–246, § 4(a), title XI, § 11016(b)(1)(B), June 18, 2008, 122 Stat. 1664, 2131; amended Pub. L. 113–79, title XII, § 12106(a)(2), Feb. 7, 2014, 128 Stat. 981.

In subsection (a)(1), the words "For the purpose of preventing the use in commerce of meat and meat food products that are adulterated," are substituted for "For the purposes hereinbefore set forth" for clarity.

In subsection (a)(1), the words "the Secretary shall examine and inspect, through inspectors appointed for that purpose," are substituted for "the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of" for clarity and to eliminate unnecessary words.

In subsection (a)(2), the words "For the purposes of any examination and inspection under paragraph (1)," are substituted for "and for the purposes of any examination and inspection" for clarity.

In subsection (a)(2), the words "inspectors shall have access" are substituted for "and inspectors shall have access" to correct a technical error.

In subsection (a)(2), the words "is being operated" are substituted for "be operated" for clarity.

In subsection (a)(3), the words "all meat food products examined and inspected under paragraph (1)" are substituted for "all such products" for clarity.

In subsection (a)(4)(A), the words "all meat food products examined and inspected under paragraph (1)" are substituted for "all such products" for clarity.

In subsection (a)(4)(B), the words "by the establishment described in paragraph (1) in the presence of an inspector" are substituted for "as hereinbefore provided" for clarity.

In subsection (a)(5)(B), the words "If the meat food products under subparagraph (A) are to be sold or offered for sale" are substituted for "but if said article shall be in fact sold or offered for sale" for clarity and consistency with subparagraph (A).

In subsection (a)(5)(B), the words "all the other provisions of this chapter" are retained to provide the correct reference to the pertinent provisions. The reference to "this chapter" in the restatement refers to chapter 303 of title 21, United States Code, which chapter restates the Federal Meat Inspection Act (21 U.S.C. 601 et seq.). The Federal Meat Inspection Act does not contain chapters.

SECTION 30307—LABELING, MARKING, AND CONTAINER REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30307	21 U.S.C. 607	Mar. 4, 1907, ch. 2907, title I, § 7, formerly 5th par., 34 Stat. 1262; renumbered § 7 and amended Pub. L. 90–201, §§ 1, 3(a), 6, Dec. 15, 1967, 81 Stat. 584, 588; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 104–127, title II, § 279, Apr. 4, 1996, 110 Stat. 979.

In subsection (a)(1), the words "as provided in sections 30303 through 30306 of this title" are substituted for "as hereinbefore provided" for clarity and to provide a more precise reference to the pertinent provisions.

In subsection (a)(1), the words "shall attach a label" are substituted for "shall cause a label to be attached" to eliminate unnecessary words.

In subsection (c)(1)(A)(ii), the word "and" is added in the matter after the semicolon for clarity.

In subsection (c)(2), the words "under this subchapter or subtitle I of this title" are substituted for "under either Act" for clarity.

In subsection (c)(2), the words "administration of this chapter and subtitle I of this title" are substituted for "administration of these Acts" for clarity.

In subsection (e)(2), the words "determination of withholding of the Secretary under paragraph (1)" are substituted for "the determination of the Secretary" for clarity.

SECTION 30308—SANITARY INSPECTION AND REGULATION OF SLAUGHTERING AND PACKING ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30308	21 U.S.C. 608	Mar. 4, 1907, ch. 2907, title I, § 8, formerly 6th par., 34 Stat. 1262; renumbered § 8 and amended Pub. L. 90–201, §§ 1, 3, 12(a), (f), Dec. 15, 1967, 81 Stat. 584, 588, 592; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In subsection (a)(1), the words "inspect, through experts in sanitation or other competent inspectors," are substituted for "cause to be made, by experts in sanitation or by other competent inspectors, such inspection of" for clarity and to eliminate unnecessary words.

In subsection (a)(1), the words "and in which the meat and meat food products of the amenable species" are substituted for "and the meat and meat food products thereof" for clarity.

SECTION 30309—EXAMINATION OF ANIMALS AND FOOD PRODUCTS OF THE ANIMALS SLAUGHTERED AND PREPARED DURING NIGHTTIME

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30309	21 U.S.C. 609	Mar. 4, 1907, ch. 2907, title I, § 9, formerly 7th par., 34 Stat. 1262; renumbered § 9 and amended Pub. L. 90–201, §§ 1, 3, 12(a), Dec. 15, 1967, 81 Stat. 584, 588, 592; Pub. L. 99–641, title IV, § 403(d)(1), Nov. 10, 1986, 100 Stat. 3570; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In this section, in the matter before paragraph (1), the words "shall examine and inspect all amenable species" are substituted for "shall cause an examination and inspection of all amenable species" to eliminate unnecessary words.

In this section, in the matter before paragraph (1), the words "described in section 30308 of this title" are substituted for "hereinbefore described" for clarity.

In this section, in the matter before paragraph (1), the words "which examination and inspection are to be made" are substituted for "to be made" for clarity.

SECTION 30310—PROHIBITED ACTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30310	21 U.S.C. 610	Mar. 4, 1907, ch. 2907, title I, § 10, formerly 8th par., 34 Stat. 1262; renumbered § 10 and amended Pub. L. 90–201, §§ 1, 7, Dec. 15, 1967, 81 Stat. 584, 589; Pub. L. 95–445, § 3, Oct. 10, 1978, 92 Stat. 1069.

SECTION 30311—DEVICES, MARKS, LABELS, AND CERTIFICATES; SIMULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30311	21 U.S.C. 611	Mar. 4, 1907, ch. 2907, title I, § 11, formerly 9th par., 34 Stat. 1263; renumbered § 11 and amended Pub. L. 90–201, §§ 1, 8, Dec. 15, 1967, 81 Stat. 584, 589.

In subsection (b)(3), the words "detach, deface, or destroy, or fail to use," are substituted for "fail to use, or to detach, deface, or destroy" for clarity.

SECTION 30312—NOTIFICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30312	21 U.S.C. 612	Mar. 4, 1907, ch. 2907, title I, § 12, as added Pub. L. 110–234, title XI, § 11017(a), May 22, 2008, 122 Stat. 1370, and Pub. L. 110–246, § 4(a), title XI, § 11017(a), June 18, 2008, 122 Stat. 1664, 2132.

SECTION 30313—PLANS AND REASSESSMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30313	21 U.S.C. 613	Mar. 4, 1907, ch. 2907, title I, § 13, as added Pub. L. 110–234, title XI, § 11017(a), May 22, 2008, 122 Stat. 1370, and Pub. L. 110–246, § 4(a), title XI, § 11017(a), June 18, 2008, 122 Stat. 1664, 2132.

SECTION 30314—INSPECTION OF CARCASSES, MEAT OF WHICH IS INTENDED FOR EXPORT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30314	21 U.S.C. 615	Mar. 4, 1907, ch. 2907, title I, § 15, formerly 13th par., 34 Stat. 1263; renumbered § 15 and amended Pub. L. 90–201, §§ 1, 3(b), 12(a), Dec. 15, 1967, 81 Stat. 584, 588, 592; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In this section, the words "shall carefully inspect" are substituted for "shall also cause to be made a careful inspection of" to eliminate unnecessary words.

In this section, the words "consider proper" are substituted for "deem proper" to use the more appropriate word.

SECTION 30315—CERTIFICATES OF CONDITION FROM INSPECTORS OF MEAT FOR EXPORT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30315	21 U.S.C. 616	Mar. 4, 1907, ch. 2907, title I, § 16, formerly 14th par., 34 Stat. 1263; renumbered § 16 and amended Pub. L. 90–201, §§ 1, 3(b), 12(a), Dec. 15, 1967, 81 Stat. 584, 588, 592.

SECTION 30316—CLEARANCE PROHIBITED TO VESSEL CARRYING MEAT FOR EXPORT WITHOUT INSPECTOR'S CERTIFICATE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30316	21 U.S.C. 617	Mar. 4, 1907, ch. 2907, title I, § 17, formerly 15th par., 34 Stat. 1263; renumbered § 17 and amended Pub. L. 90–201, §§ 1, 3(b), 12(a), (g), Dec. 15, 1967, 81 Stat. 584, 588, 592; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

SECTION 30317—DELIVERY OF INSPECTORS' CERTIFICATES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30317	21 U.S.C. 618	Mar. 4, 1907, ch. 2907, title I, § 18, formerly 16th par., 34 Stat. 1263; renumbered § 18 and amended Pub. L. 90–201, §§ 1, 12(a), (h), Dec. 15, 1967, 81 Stat. 584, 592; Pub. L. 107–171, title X, § 10418(b)(4), May 13, 2002, 116 Stat. 508; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In subsection (a), the words "this subchapter" are substituted for "herein" for clarity.

SECTION 30318—MARKING, LABELING, OR OTHER IDENTIFICATION OF ARTICLES RELATING TO THE KINDS OF ANIMALS FROM WHICH DERIVED; SEPARATE PREPARATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30318	21 U.S.C. 619	Mar. 4, 1907, ch. 2907, title I, § 19, formerly 17th par., 34 Stat. 1264; renumbered § 19 and amended Pub. L. 90–201, §§ 1, 9, Dec. 15, 1967, 81 Stat. 584, 590; Pub. L. 109–97, title VII, § 798[(a)](3), Nov. 10, 2005, 119 Stat. 2166.

SECTION 30319—IMPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30319	21 U.S.C. 620 (except (e))	Mar. 4, 1907, ch. 2907, title I, §20 (except (e)), formerly 18th par., 34 Stat. 1264; renumbered § 20 and amended Pub. L. 90–201, §§ 1, 10, Dec. 15, 1967, 81 Stat. 584, 590; Pub. L. 95–445, § 4, Oct. 10, 1978, 92 Stat. 1069; Pub. L. 97–98, title XI, § 1122, Dec. 22, 1981, 95 Stat. 1273; Pub. L. 99–198, title XVII, § 1702, Dec. 23, 1985, 99 Stat. 1634; Pub. L. 100–418, title IV, § 4604, Aug. 23, 1988, 102 Stat. 1408; Pub. L. 103–182, title III, § 361(f), Dec. 8, 1993, 107 Stat. 2124; Pub. L. 103–437, § 8(2), Nov. 2, 1994, 108 Stat. 4588; Pub. L. 103–465, title IV, § 431(l), Dec. 8, 1994, 108 Stat. 4970; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In subsection (a)(1)(B), the words "inspection and building construction standards," are substituted for "inspection, building, construction standards," for consistency with subsection (g)(1)(B).

In subsection (b), in the matter before paragraph (1), the words "all articles described in subsection (a) that are imported contrary to this section" are substituted for "all such articles which are imported contrary to this section" for clarity.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30320	21 U.S.C. 621	Mar. 4, 1907, ch. 2907, title I, § 21, formerly 19th par., 34 Stat. 1264; renumbered § 21 and amended Pub. L. 90–201, §§ 1, 3(b), 12(a), (i), Dec. 15, 1967, 81 Stat. 584, 588, 592, 593; Pub. L. 99–641, title IV, § 403(d)(2), Nov. 10, 1986, 100 Stat. 3570; Pub. L. 109–97, title VII, § 798[(a)](1), Nov. 10, 2005, 119 Stat. 2166.

In subsection (a), in the matter before paragraph (1), the words "examine and inspect" are substituted for "make examination and inspection of" to eliminate unnecessary words.

In subsection (a)(1), the words "is provided under this subchapter" are substituted for "is hereby provided" for clarity.

In subsection (a)(4), the words "described in paragraph (3)" are substituted for "hereinbefore described" for clarity.

In subsection (b), the words "described in subsection (a)" are substituted for "hereinbefore mentioned" for clarity.

In subsection (b), the words "until the article is inspected" are substituted for "until the same shall have actually been inspected" to eliminate unnecessary words.

In subsection (e), the words "shall be made according to this chapter" are substituted for "shall be such" for clarity.

SECTION 30321—BRIBERY OF OR GIFTS TO INSPECTORS OR OTHER OFFICERS AND ACCEPTANCE OF GIFTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30321	21 U.S.C. 622	Mar. 4, 1907, ch. 2907, title I, § 22, formerly 20th par., 34 Stat. 1264; renumbered § 22 and amended Pub. L. 90–201, §§ 1, 3, Dec. 15, 1967, 81 Stat. 584, 588.

In subsection (a), the words "on conviction, imprisoned not less than 1 year nor more than 3 years and fined under title 18 but not less than $5,000" are substituted for "deemed guilty of a felony, and, upon conviction thereof, shall be punished by a fine not less than $5,000 nor more than $10,000 and by imprisonment not less than one year nor more than three years" for consistency with title 18, United States Code.

In subsection (b), the words "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" are substituted for "deemed guilty of a felony and shall, upon conviction thereof, be summarily discharged from office and shall be punished by a fine not less than $1,000 nor more than $10,000 and by imprisonment not less than 1 year nor more than 3 years" for consistency with title 18, United States Code.

SECTION 30322—EXEMPTIONS FROM INSPECTION REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30322	21 U.S.C. 623	Mar. 4, 1907, ch. 2907, title I, § 23, formerly 21st, 22nd pars., 34 Stat. 1265; June 29, 1938, ch. 810, 52 Stat. 1235; renumbered § 23 and amended Pub. L. 90–201, §§ 1, 11, Dec. 15, 1967, 81 Stat. 584, 591; Pub. L. 91–342, July 18, 1970, 84 Stat. 438; Pub. L. 102–237, title X, § 1016(a), Dec. 13, 1991, 105 Stat. 1902.

In subsection (a)(1)(A), the word "individual" is substituted for "person" each place it appears for consistency with section 1 of title 1, United States Code.

In subsection (a)(1)(C)(i), the words "from the slaughter by any individual" are substituted for "from the slaughter by any person" for consistency with section 1 of title 1, United States Code.

In subsection (a)(3), in the matter before subparagraph (A), the words "promulgate to ensure" are substituted for "promulgate to assure" to use the more appropriate word.

SECTION 30323—STORAGE AND HANDLING REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30323	21 U.S.C. 624	Mar. 4, 1907, ch. 2907, title I, § 24, as added Pub. L. 90–201, § 13, Dec. 15, 1967, 81 Stat. 593.

In subsection (a), the words "considers the action necessary" are substituted for "deems such action necessary" to use the more appropriate word.

In subsection (a), the words "ensure that the articles" are substituted for "assure that such articles" to use the more appropriate word.

SECTION 30324—INAPPLICABILITY OF CERTAIN REQUIREMENTS TO CATFISH

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30324	21 U.S.C. 625	Mar. 4, 1907, ch. 2907, title I, § 25, as added Pub. L. 110–234, title XI, § 11016(b)(1)(C), May 22, 2008, 122 Stat. 1369, and Pub. L. 110–246, § 4(a), title XI, § 11016(b)(1)(C), June 18, 2008, 122 Stat. 1664, 2131; amended Pub. L. 113–79, title XII, § 12106(a)(3), Feb. 7, 2014, 128 Stat. 981.

Subchapter II—Meat Processors and Related Industries

SECTION 30341—PROHIBITION OF SUBCHAPTER I INSPECTION OF ARTICLES NOT INTENDED FOR USE AS HUMAN FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30341	21 U.S.C. 641	Mar. 4, 1907, ch. 2907, title II, § 201, as added Pub. L. 90–201, § 14, Dec. 15, 1967, 81 Stat. 593.

SECTION 30342—RECORDKEEPING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30342	21 U.S.C. 642	Mar. 4, 1907, ch. 2907, title II, § 202, as added Pub. L. 90–201, § 14, Dec. 15, 1967, 81 Stat. 593.

In subsection (a)(2), the words "records of inventory" are substituted for "records thereof" for clarity.

SECTION 30343—REGISTRATION OF BUSINESS, NAME OF PERSON, AND TRADE NAMES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30343	21 U.S.C. 643	Mar. 4, 1907, ch. 2907, title II, § 203, as added Pub. L. 90–201, § 14, Dec. 15, 1967, 81 Stat. 594.

In paragraph (4), the words "of the specified kinds under paragraph (2)" are substituted for "of the specified kinds" for clarity.

SECTION 30344—REGULATION OF TRANSACTIONS, TRANSPORTATION, OR IMPORTATION OF ANIMALS TO PREVENT USE AS HUMAN FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30344	21 U.S.C. 644	Mar. 4, 1907, ch. 2907, title II, § 204, as added Pub. L. 90–201, § 14, Dec. 15, 1967, 81 Stat. 594.

In this section, the words "ensure that the animals" are substituted for "assure that such animals" to use the more appropriate word.

SECTION 30345—FEDERAL PROVISIONS APPLICABLE TO STATE OR TERRITORIAL BUSINESS TRANSACTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30345	21 U.S.C. 645	Mar. 4, 1907, ch. 2907, title II, § 205, as added Pub. L. 90–201, § 14, Dec. 15, 1967, 81 Stat. 594.

In subsection (a), the words "including the State or territory of the United States providing for" are substituted for "including the State providing for" for consistency in the section.

In subsection (a), the words "records of the inventories" are substituted for "records thereof" for clarity.

Subchapter III—Federal and State Cooperation

SECTION 30356—FEDERAL AND STATE COOPERATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30356(a)	21 U.S.C. 661(d)	Mar. 4, 1907, ch. 2907, title III §301(d), as added Pub. L. 90–201, § 15, Dec. 15, 1967, 81 Stat. 597.
30356(b) through (d) ...	21 U.S.C. 661(a) through (c)	Mar. 4, 1907, ch. 2907, title III § 301, as added Pub. L. 90–201, §15(a) through (c), Dec. 15, 1967, 81 Stat. 595; Pub. L. 98–487, § 1, Oct. 17, 1984, 98 Stat. 2264; Pub. L. 103–437, § 8(2), Nov. 2, 1994, 108 Stat. 4588.

In subsection (b)(2)(C)(iv), the words "considers adequate" are substituted for "deems adequate" to use the more appropriate word.

In subsection (d)(1)(E), the word "Thereafter," is omitted as unnecessary.

In subsection (d)(1)(F)(ii), the word "immediately" is substituted for "forthwith" for consistency in title 21, United States Code.

In subsection (d)(2)(B)(iii), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

In subsection (d)(4), the words "shall periodically, but at least annually," are substituted for "shall promptly upon enactment of the Wholesome Meat Act and periodically thereafter, but at least annually," to eliminate obsolete words.

In subsection (d)(4), the words "and annually report thereon to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate in the report required under section 17 of the Wholesome Meat Act" are omitted because of the termination of the reporting requirement with respect to Congress, effective May 15, 2000. See section 3003 of the Federal Reports Elimination and Sunset Act of 1995 (Public Law 104–66, 31 U.S.C. 1113 note) and the 6th item on page 46 of House Document No. 103–7 (the 6th item lists the report required by section 17 of the Wholesome Meat Act (21 U.S.C. 691), in which report the reporting requirement to Congress under subsection (d)(4) was required to be incorporated).

Subchapter IV—Other Provisions

SECTION 30361—REFUSAL OR WITHDRAWAL OF INSPECTION SERVICES BASED ON CERTAIN CONVICTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30361	21 U.S.C. 671	Mar. 4, 1907, ch. 2907, title IV, § 401, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 597; amended Pub. L. 99–641, title IV, § 403(b), Nov. 10, 1986, 100 Stat. 3568.

In subsection (a)(1), in the matter before subparagraph (A), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

In subsection (a)(2), the words "an individual shall be deemed to be responsibly connected" are substituted for "a person shall be deemed to be responsibly connected" for consistency in the paragraph and with section 1 of title 1, United States Code.

In subsection (c), the words "in any way" are omitted as unnecessary.

SECTION 30362—ADMINISTRATIVE DETENTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30362	21 U.S.C. 672	Mar. 4, 1907, ch. 2907, title IV, § 402, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 598.

In subsection (b), the words “The article or animal” are substituted for “The article” for consistency with subsection (a).

SECTION 30363—SEIZURE AND CONDEMNATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30363	21 U.S.C. 673	Mar. 4, 1907, ch. 2907, title IV, § 403, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 598; amended Pub. L. 101–205, § 1, Dec. 7, 1989, 103 Stat. 1829.

In subsection (a)(1)(A), the words “on a filing of an action” are substituted for “on a libel of information” for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(2)(B), the words “ensure compliance” are substituted for “insure compliance” to use the more appropriate word.

In subsection (a)(4), the words “Proceedings under this section” are substituted for “The proceedings in such libel cases” for consistency with subsection (a)(1)(A) and with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(4), the words “brought by” are substituted for “at the suit of” for clarity.

In subsection (b), the words “shall not derogate” are substituted for “shall in no way derogate” to eliminate unnecessary words.

SECTION 30364—FEDERAL COURT JURISDICTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30364	21 U.S.C. 674	Mar. 4, 1907, ch. 2907, title IV, § 404, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 599.

SECTION 30365—ASSAULTING, RESISTING, OR IMPEDING CERTAIN PERSONS; MURDER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30365	21 U.S.C. 675	Mar. 4, 1907, ch. 2907, title IV, § 405, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 599.

In this section, the word “individual” is substituted for “person” each place it appears for consistency with section 1 of title 1, United States Code.

In this section, the words “Any individual who” are substituted for “Whoever” each place it appears for consistency with section 1 of title 1, United States Code.

In subsection (a), the words “imprisoned not more than 3 years, fined under title 18, or both” are substituted for “fined not more than $5,000 or imprisoned not more than three years, or both” for consistency with chapter 227 of title 18, United States Code.

In subsection (b), the words “imprisoned not more than 10 years, fined under title 18, or both” are substituted for “fined not more than $10,000 or imprisoned not more than ten years, or both” for consistency with chapter 227 of title 18, United States Code.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30366	21 U.S.C. 676	Mar. 4, 1907, ch. 2907, title IV, §406, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 599; amended Pub. L. 99–641, title IV, § 403(c), Nov. 10, 1986, 100 Stat. 3570.

In subsection (a), the words "imprisoned not more than 1 year, fined under title 18, or both" are substituted for "subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine" for consistency with chapter 227 of title 18, United States Code.

In subsection (b), the words "imprisoned not more than 3 years, fined under title 18, or both" are substituted for "subject to imprisonment for not more than three years or a fine of not more than $10,000, or both" for consistency with chapter 227 of title 18, United States Code.

In subsection (c)(1), the words "name and address of the individual from whom the person, firm, or corporation received" are substituted for "name and address of the person from whom he received" for clarity and consistency in the subsection and with section 1 of title 1, United States Code.

In subsection (c)(2), the words "delivery of the article or animal to the person, firm, or corporation" are substituted for "delivery of the article or animal to him" for clarity and consistency in the subsection.

In subsection (d), the words "civil action or injunction proceedings" are substituted for "libel or injunction proceedings" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

SECTION 30367—OTHER FEDERAL LAWS APPLICABLE TO ADMINISTRATION AND ENFORCEMENT OF CHAPTER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30367	21 U.S.C. 677	Mar. 4, 1907, ch. 2907, title IV, § 407, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 599.

In subsection (a), the words "and the last paragraph of section 9" are omitted as obsolete because the last paragraph of section 9 of the Federal Trade Commission Act (15 U.S.C. 49) was struck by section 211 of the Organized Crime Control Act of 1970 (Public Law 91–452, 84 Stat. 929).

In subsection (a), the words "and the provisions of subsection 409(l) of the Communications Act of 1934 (48 Stat. 1096, as amended; 47 U.S.C. 409(l))," are omitted as obsolete because that provision was repealed by section 242 of the Organized Crime Control Act of 1970 (Public Law 91–452, 84 Stat. 930).

SECTION 30368—PROHIBITION OF ADDITIONAL OR DIFFERENT REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30368	21 U.S.C. 678	Mar. 4, 1907, ch. 2907, title IV, § 408, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 600.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30369	21 U.S.C. 679	Mar. 4, 1907, ch. 2907, title IV, § 409, as added Pub. L. 90–201, § 16, Dec. 15, 1967, 81 Stat. 600; amended Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 111–31, div. A, title I, § 103(o), June 22, 2009, 123 Stat. 1838.

SECTION 30370—SAFE MEAT AND POULTRY INSPECTION PANEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30370(a)	21 U.S.C. 679a(a) (parenthetical)	Mar. 4, 1907, ch. 2907, title IV, §410(a) (parenthetical), as added Pub. L. 104–127, title IX, § 918(a)(1)(B), Apr. 4, 1996, 110 Stat. 1188.
30370(b)	21 U.S.C. 679a(a) (except parenthetical)	Mar. 4, 1907, ch. 2907, title IV, §410(a) (except parenthetical), as added Pub. L. 104–127, title IX, § 918(a)(1)(B), Apr. 4, 1996, 110 Stat. 1188.
30370(c) through (j)	21 U.S.C. 679a(b) through (i)	Mar. 4, 1907, ch. 2907, title IV, §410(b) through (i), as added Pub. L. 104–127, title IX, § 918(a)(1)(B), Apr. 4, 1996, 110 Stat. 1188; Pub. L. 117–286, §4(a)(161), Dec. 27, 2022, 136 Stat. 4323.

In subsection (g), the words "as an individual" are substituted for "as a person" for consistency with the definition of "person" in section 10101 of title 21, United States Code, and with sections 5701 and 5703 of title 5, United States Code.

Subchapter V—Inspections by Federal and State Agencies

SECTION 30381—INTERSTATE SHIPMENT OF MEAT INSPECTED BY FEDERAL AND STATE AGENCIES FOR CERTAIN SMALL ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30381(a) through (d) ...	21 U.S.C. 683(a) through (d)	Mar. 4, 1907, ch. 2907, title V, §501(a) through (d), as added Pub. L. 110–234, title XI, § 11015(a), May 22, 2008, 122 Stat. 1362, and Pub. L. 110–246, § 4(a), title XI, § 11015(a), June 18, 2008, 122 Stat. 1664, 2124.
30381(e)	21 U.S.C. 683(e)(1)	Mar. 4, 1907, ch. 2907, title V, §501(e)(1), as added Pub. L. 110–234, title XI, § 11015(a), May 22, 2008, 122 Stat. 1362, and Pub. L. 110–246, § 4(a), title XI, § 11015(a), June 18, 2008, 122 Stat. 1664, 2124.
30381(f) through (j)	21 U.S.C. 683(f) through (j)	Mar. 4, 1907, ch. 2907, title V, §501(f) through (j), as added Pub. L. 110–234, title XI, § 11015(a), May 22, 2008, 122 Stat. 1362, and Pub. L. 110–246, § 4(a), title XI, § 11015(a), June 18, 2008, 122 Stat. 1664, 2124.

In subsection (a)(4)(A), in the matter after the semicolon, the word "or" is substituted for "and" for clarity.

In subsection (b)(2)(B), the words "as of June 18, 2008" are substituted for "as of the date of the enactment of this section" for clarity.

In subsection (b)(2)(C)(ii), the words "as of June 18, 2008" are substituted for "as of the date of the enactment of this section" for clarity.

In subsection (b)(2)(C)(iii), in the matter before subclause (I), the words "as of June 18, 2008," are substituted for "as of the date of the enactment of this section" for clarity.

In subsection (b)(2)(C)(iii)(I), the words "as of June 18, 2008" are substituted for "as of the date of the enactment of this section" for clarity.

In subsection (b)(2)(C)(iii)(II), the words "as of June 18, 2008" are substituted for "as of the date of the enactment of this section" for clarity.

In subsection (b)(3)(B)(i), the words "as of June 18, 2008," are substituted for "as of the date of the enactment of this section" for clarity.

In subsection (b)(3)(B)(ii), the words "beginning on the date that is 3 years after the effective date described in subsection (j)" are omitted as obsolete.

In subsection (f)(1), in the matter before subparagraph (A), the words "Not later than 180 days after the effective date described in subsection (j)," are omitted as obsolete.

In subsection (j)(2), the words "Not later than 18 months after the date of the enactment of this section," are omitted as obsolete.

Chapter 305—Supplemental Federal Meat Inspection Provisions

SECTION 30501—INSPECTION EXTENDED TO REINDEER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30501	21 U.S.C. 692	June 30, 1914, ch. 131, proviso under heading "MEAT INSPECTION, BUREAU OF ANIMAL INDUSTRY", 38 Stat. 420.

SECTION 30502—PURCHASE OF TAGS, LABELS, STAMPS, AND CERTIFICATES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30502	21 U.S.C. 626	Sept. 21, 1944, ch. 412, title I, §101(f), 58 Stat. 734.

SECTION 30503—INSPECTION COSTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30503(a)	21 U.S.C. 1053(b) (relating to "the Wholesome Meat Act")	Pub. L. 91–597, §24(b) (relating to "the Wholesome Meat Act"), Dec. 29, 1970, 84 Stat. 1633.
30503(b)	21 U.S.C. 695	June 5, 1948, ch. 423, 62 Stat. 344; Pub. L. 107–171, title X, § 10703(c)(2), May 13, 2002, 116 Stat. 517.

In subsection (a), the words "chapter 303 of this title" are substituted for "the Wholesome Meat Act" for clarity. The Wholesome Meat Act (Public Law 90–201, 81 Stat. 584) designated provisions appearing under the subheading "FOR MEAT INSPECTION:" under the heading "BUREAU OF ANIMAL INDUSTRY" in the Act of March 4, 1907 (ch. 2907, 34 Stat. 1260) as the Federal Meat Inspection Act (21 U.S.C. 601 et seq.). Also, the Wholesome Meat Act (Public Law 90–201, 81 Stat. 584) amended certain provisions that it designated as the

Federal Meat Inspection Act and added to the Federal Meat Inspection Act. The substitution is made because inspections under the Wholesome Meat Act are inspections under the Federal Meat Inspection Act, and the Federal Meat Inspection Act is restated as chapter 303 of title 21, United States Code.

In subsection (b), the words "on and after July 1, 1948," are omitted as obsolete.

SECTION 30504—PROTECTION OF RELIGIOUS FREEDOM AND RITUAL SLAUGHTER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30504	21 U.S.C. 603 note	Pub. L. 95–445, §6, Oct. 10, 1978, 92 Stat. 1070.

In subsection (b), the words "or hinder" are substituted for "or in any way hinder" to eliminate unnecessary words.

SECTION 30505—PASTEURIZATION OF MEAT AND POULTRY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30505	21 U.S.C. 679b(1)	Pub. L. 107–171, title X, § 10808(a)(1), May 13, 2002, 116 Stat. 530.

In this section, the words "Effective beginning not later than 30 days after the date of enactment of this Act" are omitted as obsolete.

SECTION 30506—EXPANSION OF FOOD SAFETY INSPECTION SERVICE ACTIVITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30506	21 U.S.C. 679c(a)	Pub. L. 107–188, title III, § 332(a), June 12, 2002, 116 Stat. 679.

SECTION 30507—GRANTS FOR IMPROVEMENTS TO MEAT AND POULTRY FACILITIES TO ALLOW FOR INTERSTATE SHIPMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30507	21 U.S.C. 473 (except (d)(3)(B))	Pub. L. 116–260, div. N, title VII, §764 (except (d)(3)(B)), Dec. 27, 2020, 134 Stat. 2115; Pub. L. 117–103, div. A, title VII, §776, Mar. 15, 2022, 136 Stat. 99.

In subsection (e)(2), the words "Beginning not later than 1 year after the date of the enactment of this section," are omitted as obsolete.

Chapter 307—Filled Milk

SECTION 30701—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30701(1)	21 U.S.C. 61(c)	Mar. 4, 1923, ch. 262, §1(c), 42 Stat. 1486.
30701(2)	21 U.S.C. 61(b)	Mar. 4, 1923, ch. 262, §1(b), 42 Stat. 1486.
30701(3)	21 U.S.C. 61(a)	Mar. 4, 1923, ch. 262, §1(a), 42 Stat. 1486.

In paragraph (1)(B)(ii), the words "for feeding infants and young children" are substituted for "for said purpose" for clarity.

In paragraph (1)(B)(ii), in the matter after the semicolon, the word “and” is added for clarity.

SECTION 30702—MANUFACTURE, SHIPMENT, OR DELIVERY FOR SHIPMENT IN INTERSTATE OR FOREIGN COMMERCE PROHIBITED

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30702	21 U.S.C. 62	Mar. 4, 1923, ch. 262, § 2, 42 Stat. 1487.

SECTION 30703—CRIMINAL PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30703	21 U.S.C. 63	Mar. 4, 1923, ch. 262, §3, 42 Stat. 1487.

In subsection (a), the words “imprisoned not more than 1 year, fined under title 18, or both” are substituted for “subject to a fine of not more than $1,000 or imprisonment of not more than one year, or both” for consistency with chapter 227 of title 18, United States Code.

In subsection (a), the words “except that no penalty shall be enforced for any such violation occurring within thirty days after this Act becomes law” are omitted as obsolete.

In subsection (b), the words “shall be deemed” are substituted for “shall in every case be deemed ” to eliminate unnecessary words.

SECTION 30704—REGULATIONS FOR ENFORCEMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30704	21 U.S.C. 64	Mar. 4, 1923, ch. 262, § 4, as added Aug. 27, 1935, ch. 743, 49 Stat. 885.

In this section, the words “Secretary of Health and Human Services” are substituted for “Secretary of Agriculture” because of section 12 of Reorganization Plan No. IV of 1940 (5 U.S.C. App.), which transferred the functions of the Food and Drug Administration in the Department of Agriculture to the Federal Security Agency and placed those functions under the direction and supervision of the Federal Security Administrator. Subsequently, section 5 of Reorganization Plan No. 1 of 1953 (42 U.S.C. 3501 note) transferred the functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare. References to the Secretary of Health, Education, and Welfare were deemed to refer to the Secretary of Health and Human Services by section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

Chapter 309—Importation of Milk and Cream

SECTION 30901—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30901	21 U.S.C. 149	Feb. 15, 1927, ch. 155, §9, 44 Stat. 1103; Pub. L. 86–70, §19, June 25, 1959, 73 Stat. 145; Pub. L. 86–624, §15, July 12, 1960, 74 Stat. 415.

SECTION 30902—PROHIBITION OF IMPORTATION WITHOUT PERMIT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30902	21 U.S.C. 141	Feb. 15, 1927, ch. 155, §1, 44 Stat. 1101.

In this section, the words "That on and after the date on which this Act takes effect" are omitted as obsolete.

In this section, the words "Secretary of Health and Human Services" are substituted for "Secretary of Agriculture" because of section 12 of Reorganization Plan No. IV of 1940 (5 U.S.C. App.), which transferred the functions of the Food and Drug Administration in the Department of Agriculture to the Federal Security Agency and placed those functions under the direction and supervision of the Federal Security Administrator. Subsequently, section 5 of Reorganization Plan No. 1 of 1953 (42 U.S.C. 3501 note) transferred the functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare. References to the Secretary of Health, Education, and Welfare were deemed to refer to the Secretary of Health and Human Services by section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

SECTION 30903—MILK OR CREAM UNFIT FOR IMPORTATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30903	21 U.S.C. 142	Feb. 15, 1927, ch. 155, §2, 44 Stat. 1101.

In paragraph (3), the words "Secretary of Health and Human Services" are substituted for "Bureau of Dairy Industry of the United States Department of Agriculture" because the Bureau of Dairy Industry no longer exists. See Secretary of Agriculture's Memorandum 1320, Supplement 4, November 2, 1953, for transfer of functions of the Bureau of Dairy Industry to the Agricultural Research Service. The substitution is made on authority of sections 1210.11 and 1210.14 of title 21, Code of Federal Regulations.

In paragraph (4)(D), in the matter after the semicolon, the word "or" is added for clarity.

SECTION 30904—COMPLIANCE; PERMITS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30904	21 U.S.C. 143	Feb. 15, 1927, ch. 155, §3, 44 Stat. 1102.

In this section, the words "Secretary of Health and Human Services" are substituted for the words "Secretary of Agriculture" each place they appear because of section 12 of Reorganization Plan No. IV of 1940 (5 U.S.C. App.), which transferred the functions of the Food and Drug Administration in the Department of Agriculture to the Federal Security Agency and placed those functions under the direction and supervision of the Federal Security Administrator. Subsequently, section 5 of Reorganization Plan No. 1 of 1953 (42 U.S.C. 3501 note) transferred the functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare. References to the Secretary of Health, Education, and Welfare were deemed to refer to the Secretary of Health and Human Services by section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

In subsection (a)(1), the words "ensure that milk" are substituted for "insure that milk" to use the more appropriate word.

In subsection (a)(2), the words "applying for importation" are substituted for "making application therefor" for clarity.

In subsection (a)(3), the words "In lieu of inspections under this subsection, the Secretary of Health and Human Services may" are substituted for "in lieu of the inspections to be made by or under the direction of the Secretary he may, in his discretion," to eliminate unnecessary words.

In subsection (a)(3), the words "municipality of the foreign government or the State" are substituted for "municipality thereof" for clarity.

In subsection (a)(4), the words "who shall prescribe the form and the rules and regulations regulating the issuance of permits" are substituted for "who is authorized and directed to prescribe such form as well as rules and regulations regulating the issuance of permits" to eliminate unnecessary words.

In subsection (b)(1)(B), the words "Notwithstanding subparagraph (A)," are substituted for "Provided, however," for consistency in title 21, United States Code.

In subsection (b)(1)(C), the words "Notwithstanding subparagraph (A), paragraph (4) of section 30903 of this title" are substituted for "Provided further, That such requirements" for clarity.

In subsection (b)(1)(D), the words "If milk or cream imported under a waiver authorized under this paragraph" are substituted for "Provided further, That if milk and/or cream imported when the requirements of section 2, paragraph (4), have been so waived," to eliminate unnecessary words.

In subsection (b)(2)(A), the words "with regard to milk" are substituted for "insofar as the same relate to milk" for clarity.

In subsection (b)(2)(B), the words "If milk imported under a waiver authorized under this paragraph" are substituted for "Provided, That if milk imported when the requirements of paragraphs 2 and 5 of section 2 have been so waived" to eliminate unnecessary words.

In subsection (c)(1)(A), in the matter after the semicolon, the word "and" is added for clarity.

SECTION 30905—UNLAWFUL RECEIVING OF IMPORTED MILK OR CREAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30905	21 U.S.C. 144	Feb. 15, 1927, ch. 155, §4, 44 Stat. 1103.

SECTION 30906—CRIMINAL PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30906	21 U.S.C. 145	Feb. 15, 1927, ch. 155, §5, 44 Stat. 1103.

In this section, the words "be imprisoned for not more than 1 year, fined under title 18 but not less than $50, or both" are substituted for "be punished by a fine

of not less than $50 nor more than $2,000, or by imprisonment for not more than one year, or by both such fine and imprisonment" for consistency with chapter 227 of title 18, United States Code.

SECTION 30907—AUTHORIZATION OF APPROPRIATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30907	21 U.S.C. 146	Feb. 15, 1927, ch. 155, §6, 44 Stat. 1103.

In this section, the words "Secretary of Health and Human Services" are substituted for "Secretary of Agriculture" because of section 12 of Reorganization Plan No. IV of 1940 (5 U.S.C. App.), which transferred the functions of the Food and Drug Administration in the Department of Agriculture to the Federal Security Agency and placed those functions under the direction and supervision of the Federal Security Administrator. Subsequently, section 5 of Reorganization Plan No. 1 of 1953 (42 U.S.C. 3501 note) transferred the functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare. References to the Secretary of Health, Education, and Welfare were deemed to refer to the Secretary of Health and Human Services by section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

SECTION 30908—REPEAL OF INCONSISTENT LAWS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30908	21 U.S.C. 147	Feb. 15, 1927, ch. 155, §7, 44 Stat. 1103.

SECTION 30909—NONPREEMPTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
30909	21 U.S.C. 148	Feb. 15, 1927, ch. 155, §8, 44 Stat. 1103.

Chapter 311—Oleomargarine

SECTION 31101—CONGRESSIONAL DECLARATION OF POLICY REGARDING OLEOMARGARINE SALES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31101	21 U.S.C. 347a	Mar. 16, 1950, ch. 61, § 3(a), 64 Stat. 20.

SECTION 31102—CONTRAVENTION OF STATE LAWS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31102	21 U.S.C. 347b	Mar. 16, 1950, ch. 61, § 6, 64 Stat. 22.

Chapter 313—Poultry and Poultry Products Inspection

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31301 (matter before (1))	21 U.S.C. 453 (matter before (a))	Pub. L. 85–172, §4 (matter before (a)), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–571, title I, § 107(13), Oct. 29, 1992, 106 Stat. 4499.
31301(1)	21 U.S.C. 453(g)	Pub. L. 85–172, §4(g), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792; Pub. L. 102–571, title I, § 107(13), Oct. 29, 1992, 106 Stat. 4499.
31301(2)	21 U.S.C. 453(bb)	Pub. L. 85–172, §4(bb), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(3)	21 U.S.C. 453(v)	Pub. L. 85–172, §4(v), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(4)	21 U.S.C. 453(y) (relating to color additive)	Pub. L. 85–172, §4(y) (relating to color additive), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(5)	21 U.S.C. 453(a)	Pub. L. 85–172, §4(a), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(6)	21 U.S.C. 453(r) (relating to container)	Pub. L. 85–172, §4(r) (relating to container), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(7)	21 U.S.C. 453(y) (relating to food additive)	Pub. L. 85–172, §4(y) (relating to food additive), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(8)	21 U.S.C. 453(u)	Pub. L. 85–172, §4(u), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(9)	21 U.S.C. 453(q)	Pub. L. 85–172, §4(q), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(10)	21 U.S.C. 453(k)	Pub. L. 85–172, §4(k), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(11)	21 U.S.C. 453(s) (relating to label)	Pub. L. 85–172, §4(s) (relating to label), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(12)	21 U.S.C. 453(s) (relating to labeling)	Pub. L. 85–172, §4(s) (relating to labeling), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(13)	21 U.S.C. 453(h)	Pub. L. 85–172, §4(h), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.
31301(14)	21 U.S.C. 453(n)	Pub. L. 85–172, §4(n), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(15)	21 U.S.C. 453(o)	Pub. L. 85–172, §4(o), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(16)	21 U.S.C. 453(p)	Pub. L. 85–172, §4(p), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(17)	21 U.S.C. 453(m)	Pub. L. 85–172, §4(m), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(18)	21 U.S.C. 453(l)	Pub. L. 85–172, §4(l), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(19)	21 U.S.C. 453(r) (relating to package)	Pub. L. 85–172, §4(r) (relating to package), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(20)	21 U.S.C. 453(j)	Pub. L. 85–172, §4(j), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(21)	21 U.S.C. 453(y) (relating to pesticide chemical)	Pub. L. 85–172, §4(y) (relating to pesticide chemical), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(22)	21 U.S.C. 453(e)	Pub. L. 85–172, §4(e), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(23)	21 U.S.C. 453(f)	Pub. L. 85–172, §4(f), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(24)	21 U.S.C. 453(z)	Pub. L. 85–172, §4(z), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(25)	21 U.S.C. 453(w)	Pub. L. 85–172, §4(w), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(26)	21 U.S.C. 453(y) (relating to raw agricultural commodity)	Pub. L. 85–172, §4(y) (relating to raw agricultural commodity), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(27)	21 U.S.C. 453(aa)	Pub. L. 85–172, §4(aa), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(28)	21 U.S.C. 453(i)	Pub. L. 85–172, §4(i), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(29)	21 U.S.C. 453(t)	Pub. L. 85–172, §4(t), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(30)	21 U.S.C. 453(b)	Pub. L. 85–172, §4(b), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(31)	21 U.S.C. 453(c)	Pub. L. 85–172, §4(c), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.
31301(32)	21 U.S.C. 453(d)	Pub. L. 85–172, §4(d), Aug. 28, 1957, 71 Stat. 441; Pub. L. 87–498, June 25, 1962, 76 Stat. 110; Pub. L. 90–492, § 4, Aug. 18, 1968, 82 Stat. 792.

In paragraph (1)(A)(i), the words "under this clause" are retained, even though there are no clauses in the source provision which is paragraph (1) of subsection (g) of the Poultry Products Inspection Act (21 U.S.C. 451), to provide the correct reference to the pertinent provision. The reference to "this clause" in the restatement is a reference to clause (i) of paragraph (1)(A) of section 31301 of title 21, United States Code, the source law of which is paragraph (1) of that subsection (g) of the Act.

In paragraph (13)(A)(xii), the words "regulations to ensure" are substituted for "regulations to assure" to use the more appropriate word.

In paragraph (23)(B)(ii), the words "ensure that the poultry ingredients" are substituted for "assure that the poultry ingredients" to use the more appropriate word.

In paragraph (30), the word "or" is substituted for "and" for clarity.

In paragraph (31), the defined term "territory of the United States" is substituted for "territory" for clarity and consistency in title 21, United States

Code. Throughout the chapter, the term "territory of the United States" is substituted for "territory", "Territory", and words of like import, as appropriate, for consistency with the defined term, in the chapter, and in title 21, United States Code, and for clarity.

In paragraph (31), the words "or any other" are substituted for "and any other" for clarity.

In paragraph (31), the words "excluding the Canal Zone" are omitted as obsolete.

SECTION 31302—CONGRESSIONAL DECLARATION OF POLICY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31302	21 U.S.C. 452	Pub. L. 85–172, § 3, Aug. 28, 1957, 71 Stat. 441; Pub. L. 90–492, § 3, Aug. 18, 1968, 82 Stat. 792.

In subsection (a), the words "It is the policy of Congress" are substituted for "It is hereby declared to be the policy of the Congress" to eliminate unnecessary words.

In subsection (a), the words "as prescribed in this chapter" are substituted for "as hereinafter prescribed" for clarity.

SECTION 31303—FEDERAL AND STATE COOPERATION IN DEVELOPMENT AND ADMINISTRATION OF STATE POULTRY PRODUCT INSPECTION PROGRAMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31303(a)	21 U.S.C. 454(d)	Pub. L. 85–172, §5(d), Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, § 5, Aug. 18, 1968, 82 Stat. 796.
31303(b), (c)	21 U.S.C. 454(a), (b)	Pub. L. 85–172, §5(a), (b), Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, § 5, Aug. 18, 1968, 82 Stat. 796.
31303(d)(1)	21 U.S.C. 454(c)(1) (except proviso)	Pub. L. 85–172, §5(c)(1) (except proviso), Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, §5, Aug. 18, 1968, 82 Stat. 797.
31303(d)(2)	21 U.S.C. 454(c)(2)	Pub. L. 85–172, §5(c)(2), Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, §5, Aug. 18, 1968, 82 Stat. 798; Pub. L. 98–487, §2, Oct. 17, 1984, 98 Stat. 2264.
31303(d)(3)	21 U.S.C. 454(c)(3)	Pub. L. 85–172, §5(c)(3), Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, §5, Aug. 18, 1968, 82 Stat. 798.
31303(d)(4)	21 U.S.C. 454(c)(4)	Pub. L. 85–172, §5(c)(4), Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, §5, Aug. 18, 1968, 82 Stat. 798; Pub. L. 103–437, §8(1), Nov. 2, 1994, 108 Stat. 4588.

In subsection (b)(3)(C), the words "considers adequate" are substituted for "deems adequate" to use the more appropriate word.

In subsection (d)(1)(A), the words "by thirty days prior to the expiration of two years after enactment of the Wholesome Poultry Products Act," are omitted as obsolete.

In subsection (d)(1)(A), the list of references in the restated provision does not include references to section 1 of the Poultry Products Inspection Act (21 U.S.C. 451 note) and section 2 of the Act (21 U.S.C. 451) because neither of those provisions impose any requirement. Section 1 of the Act sets out the short title of the Act and section 2 of the Act sets out congressional findings.

In subsection (d)(1)(B), the words "after the expiration of such two-year period" are omitted as obsolete.

In subsection (d)(1)(E)(ii), the word "immediately" is substituted for "forthwith" for consistency in title 21, United States Code.

In subsection (d)(2)(B)(iii), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

In subsection (d)(4), the words "shall periodically, but at least annually, review the requirements" are substituted for "shall promptly upon enactment of the Wholesome Poultry Products Act, and periodically thereafter, but at least annually, review the requirements" to eliminate obsolete words.

In subsection (d)(4), the words "and annually report thereon to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate in the report required in section 27 of the Act" are omitted because of the termination of the reporting requirement with respect to Congress, effective May 15, 2000. See section 3003 of the Federal Reports Elimination and Sunset Act of 1995 (Public Law 104–66, 31 U.S.C. 1113 note) and the 3d item on page 46 of House Document No. 103–7 (the 3d item lists the report required by section 27 of the Poultry Products Inspection Act (21 U.S.C. 470), in which report the reporting requirement to Congress under subsection (d)(4) was required to be incorporated).

SECTION 31304—INSPECTION IN OFFICIAL ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31304	21 U.S.C. 455	Pub. L. 85–172, § 6, Aug. 28, 1957, 71 Stat. 443; Pub. L. 90–492, § 6, Aug. 18, 1968, 82 Stat. 798.

In subsection (a), the words "the Secretary shall conduct (if and to the extent considered by the Secretary necessary), through inspectors, ante mortem inspection" are substituted for "the Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection" for clarity and to eliminate unnecessary words.

In subsection (b), in the matter before paragraph (1), the words "shall conduct" are substituted for "shall cause to be made" to eliminate unnecessary words.

In subsection (b)(2), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

SECTION 31305—OPERATION OF PREMISES, FACILITIES, AND EQUIPMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31305	21 U.S.C. 456	Pub. L. 85–172, § 7, Aug. 28, 1957, 71 Stat. 444; Pub. L. 90–492, § 7, Aug. 18, 1968, 82 Stat. 799.

SECTION 31306—LABELING AND CONTAINER STANDARDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31306	21 U.S.C. 457	Pub. L. 85–172, § 8, Aug. 28, 1957, 71 Stat. 444; Pub. L. 90–492, § 8, Aug. 18, 1968, 82 Stat. 799; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.

In subsection (b)(1)(A), in the matter after the semicolon, the word "and" is added for clarity.

In subsection (b)(1)(B), the words "definitions and standards of identity or composition for articles" are substituted for "definitions and standards of identity or composition or articles" to use the correct word.

In subsection (b)(2)(A), the words "standards under this chapter or subtitle I of this title" are substituted for "standards under either Act" for clarity.

SECTION 31307—PROHIBITED ACTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31307	21 U.S.C. 458	Pub. L. 85–172, § 9, Aug. 28, 1957, 71 Stat. 445; Pub. L. 90–492, § 9, Aug. 18, 1968, 82 Stat. 800.

In subsection (a)(4), in the matter after the semicolon, the word "or" is added for clarity.

In subsection (c)(3), the words "detach, deface, or destroy, or fail to use," are substituted for "fail to use, or to detach, deface, or destroy" for clarity.

SECTION 31308—COMPLIANCE BY ALL ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31308	21 U.S.C. 459	Pub. L. 85–172, § 10, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 10, Aug. 18, 1968, 82 Stat. 801; Pub. L. 110–234, title XI, § 11017(b), May 22, 2008, 122 Stat. 1370; Pub. L. 110–246, § 4(a), title XI, § 11017(b), June 18, 2008, 122 Stat. 1664, 2132.

SECTION 31309—MISCELLANEOUS ACTIVITIES SUBJECT TO REGULATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31309	21 U.S.C. 460	Pub. L. 85–172, § 11, Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 11, Aug. 18, 1968, 82 Stat. 801.

In subsection (b)(1)(A), the words "ensure against adulterated or misbranded poultry products" are substituted for "insure against adulterated or misbranded poultry products" to use the more appropriate word.

In subsection (b)(1)(B), the words "records of inventory" are substituted for "records thereof" for clarity.

In subsection (d), the words "ensure that the poultry" are substituted for "assure that such poultry" to use the more appropriate word.

In subsection (e)(1), the words "records of inventories" are substituted for "records thereof" for clarity.

SECTION 31310—OFFENSES AND PUNISHMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31310(a)	21 U.S.C. 461(a)	Pub. L. 85–172, §12(a), Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 12, Aug. 18, 1968, 82 Stat. 802.
31310(b)	21 U.S.C. 461(c)	Pub. L. 85–172, § 12(c), Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 12, Aug. 18, 1968, 82 Stat. 802.
31310(c)	21 U.S.C. 461(b)	Pub. L. 85–172, §12(b), Aug. 28, 1957, 71 Stat. 446; Pub. L. 90–492, § 12, Aug. 18, 1968, 82 Stat. 802.

In subsection (a)(1), the words "imprisoned not more than 1 year, fined under title 18, or both" are substituted for "fined not more than $1,000 or imprisoned not more than one year, or both" for consistency with chapter 227 of title 18, United States Code.

In subsection (a)(2), the words "imprisoned not more than 3 years, fined under title 18, or both" are substituted for "fined not more than $10,000 or imprisoned not more than three years, or both" for consistency with chapter 227 of title 18, United States Code.

In subsection (a)(3), the words "shall be deemed" are substituted for "shall in every case be deemed" to eliminate unnecessary words.

In subsection (b)(1), the words "individual while engaged in or on account of the performance of the individual's official duties" are substituted for "person while engaged in or on account of the performance of his official duties" for clarity.

In subsection (b)(1), the words "imprisoned not more than 3 years, fined under title 18, or both" are substituted for "fined not more than $5,000 or imprisoned not more than three years, or both" for consistency with chapter 227 of title 18, United States Code.

In subsection (b)(2), the words "imprisoned not more than 10 years, fined under title 18, or both" are substituted for "fined not more than $10,000 or imprisoned not more than ten years, or both" for consistency with chapter 227 of title 18, United States Code.

In subsection (b)(3), the words "kills an individual while engaged in or on account of the performance of the individual's official duties" are substituted for "kills any person while engaged in or on account of the performance of his official duties" for clarity and consistency with sections 1111 and 1114 of title 18, United States Code.

SECTION 31311—REPORTING OF VIOLATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31311	21 U.S.C. 462	Pub. L. 85–172, § 13, Aug. 28, 1957, 71 Stat. 447.

SECTION 31312—RULES AND REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31312	21 U.S.C. 463	Pub. L. 85–172, § 14, Aug. 28, 1957, 71 Stat. 447; Pub. L. 90–492, § 13, Aug. 18, 1968, 82 Stat. 803.

In subsection (a), the words "considers the action necessary" are substituted for "deems such action necessary" to use the more appropriate word.

In subsection (a), the words "ensure that the articles" are substituted for "assure that such articles" to use the more appropriate word.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31313	21 U.S.C. 464	Pub. L. 85–172, § 15, Aug. 28, 1957, 71 Stat. 447; Pub. L. 90–492, § 14, Aug. 18, 1968, 82 Stat. 803; Pub. L. 97–206, June 30, 1982, 96 Stat. 136; Pub. L. 102–237, title X, § 1016(b), Dec. 13, 1991, 105 Stat. 1903.

In subsection (a), in the matter before paragraph (1), the words "relating to sanitary standards" are substituted for "as to sanitary standards" for clarity.

In subsection (a), paragraph (2) of section 15(a) of the Poultry Products Inspection Act (21 U.S.C. 464(a)) is omitted as obsolete. Any exemption provided for by that paragraph was to cease be in effect on and after January 1, 1970.

In subsection (c)(1)(A)(iii), the words "the slaughtering of poultry and processing of poultry products" are substituted for "the slaughtering and processing of poultry products" for clarity.

In subsection (c)(1)(A)(iii), the words "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," are substituted for "and the distribution by any person solely within such jurisdiction of the poultry products derived from such operations," for clarity.

In subsection (c)(1)(A)(iv), the words "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" are substituted for "by him solely within such jurisdiction directly to" for clarity.

In subsection (c)(2), the words "In addition to the specific exemptions provided under this subsection" are substituted for "In addition to the specific exemptions provided herein" for clarity.

In subsection (c)(2), the words "considers appropriate" are substituted for "deems appropriate" to use the more appropriate word.

In subsection (d)(1), in the matter before subparagraph (A), the words "which terms and conditions may be necessary to ensure food safety and protect public health, such as special handling procedures," are substituted for "that may be necessary to ensure food safety and protect public health such as special handling procedures," for clarity.

SECTION 31314—LIMITATIONS ON ENTRY OF POULTRY PRODUCTS AND OTHER MATERIALS INTO OFFICIAL ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31314	21 U.S.C. 465	Pub. L. 85–172, § 16, Aug. 28, 1957, 71 Stat. 448; Pub. L. 90–492, § 15, Aug. 18, 1968, 82 Stat. 805.

In this section, the words "ensure that allowing" are substituted for "assure that allowing" to use the more appropriate word.

SECTION 31315—IMPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31315	21 U.S.C. 466	Pub. L. 85–172, § 17, Aug. 28, 1957, 71 Stat. 448; Pub. L. 99–198, title XVII, § 1701(a), Dec. 23, 1985, 99 Stat. 1633; Pub. L. 103–182, title III, § 361(e), Dec. 8, 1993, 107 Stat. 2123; Pub. L. 103–465, title IV, § 431(k), Dec. 8, 1994, 108 Stat. 4969.

In subsection (a)(1), the words "ensure that imported poultry" are substituted for "assure that imported poultry" to use the more appropriate word.

In subsection (d)(4), the words "that does not meet the standards that achieve the level of sanitary protection equivalent to that achieved under United States standards" are substituted for "that does not meet such standards" for clarity.

SECTION 31316—REFUSAL OR WITHDRAWAL OF INSPECTION SERVICES BASED ON CERTAIN CONVICTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31316	21 U.S.C. 467	Pub. L. 85–172, § 18, Aug. 28, 1957, 71 Stat. 448; Pub. L. 90–492, § 16, Aug. 18, 1968, 82 Stat. 805.

In subsection (a)(1), in the matter before subparagraph (A), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

In subsection (c)(2), the words "shall be based on" are substituted for "shall be upon" for clarity.

SECTION 31317—ADMINISTRATIVE DETENTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31317	21 U.S.C. 467a	Pub. L. 85–172, § 19, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 805.

SECTION 31318—SEIZURE AND CONDEMNATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31318	21 U.S.C. 467b	Pub. L. 85–172, § 20, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 806; amended Pub. L. 101–205, § 2, Dec. 7, 1989, 103 Stat. 1830.

In subsection (a)(1)(A), the words "on a filing of an action" are substituted for "on a libel of information" for consistency with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(2)(B), the words "ensure compliance" are substituted for "insure compliance" to use the more appropriate word.

In subsection (a)(4), the words "The procedure for actions under this section" are substituted for "The proceedings in such libel cases" for consistency with subsection (a)(1) and with the Federal Rules of Civil Procedure (28 U.S.C. App.).

In subsection (a)(4), the words "procedure in admiralty" are substituted for "proceedings in admiralty" for consistency in the paragraph.

In subsection (a)(4), the words "all such actions" are substituted for "all such proceedings" for consistency in the paragraph.

In subsection (a)(4), the words "brought by" are substituted for "at the suit of" for clarity.

In subsection (b), the words "shall not derogate" are substituted for "shall in no way derogate" to eliminate unnecessary words.

SECTION 31319—FEDERAL COURT JURISDICTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31319	21 U.S.C. 467c	Pub. L. 85–172, § 21, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 806.

SECTION 31320—OTHER FEDERAL LAWS APPLICABLE FOR ADMINISTRATION AND ENFORCEMENT OF CHAPTER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31320	21 U.S.C. 467d	Pub. L. 85–172, § 22, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807.

In subsection (a), the words "and the last paragraph of section 9" are omitted as obsolete because the last paragraph of section 9 of the Federal Trade Commission Act (15 U.S.C. 49) was struck by section 211 of the Organized Crime Control Act of 1970 (Public Law 91–452, 84 Stat. 929).

In subsection (a), the words "and the provisions of subsection 409(l) of the Communications Act of 1934 (48 Stat. 1096, as amended; 47 U.S.C. 409(l))," are omitted as obsolete because that provision was repealed by section 242 of the Organized Crime Control Act of 1970 (Public Law 91–452, 84 Stat. 930).

SECTION 31321—STATE OR LOCAL REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31321	21 U.S.C. 467e	Pub. L. 85–172, § 23, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807.

In subsection (b)(2), the words "In the case of imported articles that are not at an official establishment, concurrent jurisdiction maybe be exercised" are substituted for "or, in the case of imported articles which are not at such an establishment," for clarity.

SECTION 31322—APPLICABILITY OF SUBTITLE I

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31322	21 U.S.C. 467f	Pub. L. 85–172, § 24, as added Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 807; amended Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31323(a)	21 U.S.C. 1053(b) (relating to "the Wholesome Poultry Products Act")	Pub. L. 91–597, §24(b) (relating to "the Wholesome Poultry Products Act"), Dec. 29, 1970, 84 Stat. 1633.
31323(b)	21 U.S.C. 468	Pub. L. 85–172, § 25, formerly § 19, Aug. 28, 1957, 71 Stat. 448, renumbered Pub. L. 90–492, § 17, Aug. 18, 1968, 82 Stat. 805; Pub. L. 107–171, title X, § 10703(c)(1), May 13, 2002, 116 Stat. 517.

In subsection (a), the words "this chapter" are substituted for "the Wholesome Poultry Products Act" for clarity. The Wholesome Poultry Products Act (Public Law 90–492, 82 Stat. 791) amended the Poultry Products Inspection Act (21 U.S.C. 451 et seq.). The substitution is made because inspections under the Wholesome Poultry Products Act are inspections under the Poultry Products Inspection Act, and the Poultry Products Inspection Act is restated as chapter 313 of title 21, United States Code, to which "this chapter" in the restatement refers.

SECTION 31324—SAFE MEAT AND POULTRY INSPECTION PANEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31324	21 U.S.C. 471	Pub. L. 85–172, § 30, as added Pub. L. 104–127, title IX, § 918(a)(2), Apr. 4, 1996, 110 Stat. 1190.

In subsection (b)(1), the words "under subsection (a)" are substituted for "under paragraph (1)" to provide the correct reference to the pertinent provision.

SECTION 31325—INTERSTATE SHIPMENT OF POULTRY INSPECTED BY FEDERAL AND STATE AGENCIES FOR CERTAIN SMALL ESTABLISHMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31325(a) through (d)	21 U.S.C. 472(a) through (d)	Pub. L. 85–172, §31(a) through (d), as added Pub. L. 110–234, title XI, § 11015(b), May 22, 2008, 122 Stat. 1365, and Pub. L. 110–246, § 4(a), title XI, § 11015(b), June 18, 2008, 122 Stat. 1664, 2127.
31325(e)	21 U.S.C. 472(e)(1)	Pub. L. 85–172, §31(e)(1), as added Pub. L. 110–234, title XI, § 11015(b), May 22, 2008, 122 Stat. 1365, and Pub. L. 110–246, § 4(a), title XI, § 11015(b), June 18, 2008, 122 Stat. 1664, 2127.
31325(f) through (i)	21 U.S.C. 472(f) through (i)	Pub. L. 85–172, §31(f) through (i), as added Pub. L. 110–234, title XI, § 11015(b), May 22, 2008, 122 Stat. 1365, and Pub. L. 110–246, § 4(a), title XI, § 11015(b), June 18, 2008, 122 Stat. 1664, 2127.

In subsection (a)(4)(A), in the matter after the semicolon, the word "or" is substituted for "and" for clarity.

In subsection (b), the words "as of June 18, 2008" are substituted for the words "as of the date of the enactment of this section" each place they appear for clarity.

In subsection (i)(2), the words "Not later than 18 months after the date of the enactment of this section" are omitted as obsolete.

Chapter 315—Supplemental Poultry and Poultry Products Inspection Provisions

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31501	21 U.S.C. 455 note	Pub. L. 106–387, §1(a) [title VII, §752], Oct. 28, 2000, 114 Stat. 1549, 1549A–41.

In this section, the words "Effective 180 days after the date of the enactment of this Act and continuing for the remainder of fiscal year 2001 and each subsequent fiscal year" are omitted as obsolete.

Chapter 317—Egg Products Inspection

SECTION 31701—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31701(1)	21 U.S.C. 1033(a)	Pub. L. 91–597, §4(a), Dec. 29, 1970, 84 Stat. 1621; Pub. L. 102–571, title I, § 107(15), Oct. 29, 1992, 106 Stat. 4499.
31701(2)	21 U.S.C. 1033(b)	Pub. L. 91–597, §4(b), Dec. 29, 1970, 84 Stat. 1621.
31701(3)	21 U.S.C. 1033(u) (relating to color additive)	Pub. L. 91–597, §4(u) (relating to color additive), Dec. 29, 1970, 84 Stat. 1621.
31701(4)	21 U.S.C. 1033(c)	Pub. L. 91–597, §4(c), Dec. 29, 1970, 84 Stat. 1621.
31701(5)	21 U.S.C. 1033(d) (matter before (1) relating to container)	Pub. L. 91–597, §4(d) (matter before (1) relating to container), Dec. 29, 1970, 84 Stat. 1621.
31701(6)	21 U.S.C. 1033(g)	Pub. L. 91–597, §4(g), Dec. 29, 1970, 84 Stat. 1621.
31701(7)	21 U.S.C. 1033(e)	Pub. L. 91–597, §4(e), Dec. 29, 1970, 84 Stat. 1621.
31701(8)	21 U.S.C. 1033(f)	Pub. L. 91–597, §4(f), Dec. 29, 1970, 84 Stat. 1621.
31701(9)	21 U.S.C. 1033(h)	Pub. L. 91–597, §4(h), Dec. 29, 1970, 84 Stat. 1621.
31701(10)	21 U.S.C. 1033(u) (relating to food additive)	Pub. L. 91–597, §4(u) (related to food additive), Dec. 29, 1970, 84 Stat. 1621.
31701(11)	21 U.S.C. 1033(d)(1)	Pub. L. 91–597, §4(d)(1), Dec. 29, 1970, 84 Stat. 1621.
31701(12)	21 U.S.C. 1033(j)	Pub. L. 91–597, §4(j), Dec. 29, 1970, 84 Stat. 1621.
31701(13)	21 U.S.C. 1033(k)	Pub. L. 91–597, §4(k), Dec. 29, 1970, 84 Stat. 1621.
31701(14)	21 U.S.C. 1033(l)	Pub. L. 91–597, §4(l), Dec. 29, 1970, 84 Stat. 1621.
31701(15)	21 U.S.C. 1033(m)	Pub. L. 91–597, §4(m), Dec. 29, 1970, 84 Stat. 1621.
31701(16)	21 U.S.C. 1033(n)	Pub. L. 91–597, §4(n), Dec. 29, 1970, 84 Stat. 1621.
31701(17)	21 U.S.C. 1033(o)	Pub. L. 91–597, §4(o), Dec. 29, 1970, 84 Stat. 1621.
31701(18)	21 U.S.C. 1033(p)	Pub. L. 91–597, §4(p), Dec. 29, 1970, 84 Stat. 1621.
31701(19)	21 U.S.C. 1033(q)	Pub. L. 91–597, §4(q), Dec. 29, 1970, 84 Stat. 1621.
31701(20)	21 U.S.C. 1033(r)	Pub. L. 91–597, §4(r), Dec. 29, 1970, 84 Stat. 1621.
31701(21)	21 U.S.C. 1033(d) (matter before (1) relating to package)	Pub. L. 91–597, §4(d) (matter before (1) relating to package), Dec. 29, 1970, 84 Stat. 1621.
31701(22)	21 U.S.C. 1033(s)	Pub. L. 91–597, §4(s), Dec. 29, 1970, 84 Stat. 1621.
31701(23)	21 U.S.C. 1033(t)	Pub. L. 91–597, §4(t), Dec. 29, 1970, 84 Stat. 1621.
31701(24)	21 U.S.C. 1033(u) (relating to pesticide chemical)	Pub. L. 91–597, §4(u) (relating to pesticide chemical), Dec. 29, 1970, 84 Stat. 1621.
31701(25)	21 U.S.C. 1033(v)	Pub. L. 91–597, §4(v), Dec. 29, 1970, 84 Stat. 1621.
31701(26)	21 U.S.C. 1033(w)	Pub. L. 91–597, §4(w), Dec. 29, 1970, 84 Stat. 1621.
31701(27)	21 U.S.C. 1033(u) (relating to raw agricultural commodity)	Pub. L. 91–597, §4(u) (relating to raw agricultural commodity), Dec. 29, 1970, 84 Stat. 1621.
31701(28)	21 U.S.C. 1033(x)	Pub. L. 91–597, §4(x), Dec. 29, 1970, 84 Stat. 1621.
31701(29)	21 U.S.C. 1033(d)(2)	Pub. L. 91–597, §4(d)(2), Dec. 29, 1970, 84 Stat. 1621.
31701(30)	21 U.S.C. 1033(y)	Pub. L. 91–597, §4(y), Dec. 29, 1970, 84 Stat. 1621.
31701(31)	21 U.S.C. 1033(z)	Pub. L. 91–597, §4(z), Dec. 29, 1970, 84 Stat. 1621.

In paragraph (1)(A)(i), the words "under this clause" are retained, even though there are no clauses in the source provision which is paragraph (1) of subsection (a) of the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), to provide the

correct reference to the pertinent provision. The reference to "this clause" in the restatement is a reference to clause (i) of paragraph (1)(A) of section 31701 of title 21, United States Code, the source law of which is paragraph (1) of that subsection (a) of the Act.

In paragraph (3), the words "section 10101 of this title" are substituted for "the Federal Food, Drug, and Cosmetic Act" to provide a more precise reference to the pertinent provision.

In paragraph (8), the words "ensure that the egg ingredients" are substituted for "assure that the egg ingredients" to use the more appropriate word.

In paragraph (10), the words "section 10101 of this title" are substituted for "the Federal Food, Drug, and Cosmetic Act" to provide a more precise reference to the pertinent provision.

In paragraph (12), the words "considered necessary" are substituted for "deemed necessary" to use the more appropriate word.

In paragraph (24), the words "section 10101 of this title" are substituted for "the Federal Food, Drug, and Cosmetic Act" to provide a more precise reference to the pertinent provision.

In paragraph (27), the words "section 10101 of this title" are substituted for "the Federal Food, Drug, and Cosmetic Act" to provide a more precise reference to the pertinent provision.

SECTION 31702—CONGRESSIONAL STATEMENT OF FINDINGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31702	21 U.S.C. 1031	Pub. L. 91–597, § 2, Dec. 29, 1970, 84 Stat. 1620; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.

In subsection (a), in the matter before paragraph (1), the words "Congress finds the following:" are added for consistency in title 21, United States Code, and for clarity.

In subsection (a)(3), the words "prescribed in this chapter" are substituted for "prescribed herein" for clarity.

In subsection (a)(3), the words "ensuring that eggs" are substituted for "assuring that eggs" to use the more appropriate word.

In subsection (b), the words "Because of the findings in subsection (a), Congress finds" are substituted for "It is hereby found" for clarity.

SECTION 31703—CONGRESSIONAL DECLARATION OF POLICY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31703	21 U.S.C. 1032	Pub. L. 91–597, § 3, Dec. 29, 1970, 84 Stat. 1621.

In this section, the words "It is the policy of Congress" are substituted for "It is hereby declared to be the policy of the Congress" to eliminate unnecessary words.

In this section, the words "as prescribed in this chapter" are substituted for "as hereinafter prescribed" for clarity.

SECTION 31704—INSPECTION OF EGG PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31704	21 U.S.C. 1034	Pub. L. 91–597, § 5, Dec. 29, 1970, 84 Stat. 1624; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–237, title X, § 1012(b), Dec. 13, 1991, 105 Stat. 1899.

In subsection (b), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

In subsection (d)(1), the words "considers appropriate" are substituted for "deems appropriate" to use the more appropriate word.

In subsection (d)(1), the words "ensure that only eggs" are substituted for "assure that only eggs" to use the more appropriate word.

In subsection (d)(1), the words "ensure compliance" are substituted for "assure compliance" to use the more appropriate word.

In subsection (d)(2), the words "considers appropriate" are substituted for "deems appropriate" to use the more appropriate word.

In subsection (d)(2), the words "ensure compliance" are substituted for "assure compliance" to use the more appropriate word.

In subsection (e)(5), the words "Any representative of the Secretary or the Secretary of Health and Human Services" are substituted for "A representative of the Secretary and the Secretary of Health and Human Services" for clarity.

SECTION 31705—SANITARY OPERATING PRACTICES IN OFFICIAL PLANTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31705	21 U.S.C. 1035	Pub. L. 91–597, § 6, Dec. 29, 1970, 84 Stat. 1625.

SECTION 31706—PASTEURIZATION AND LABELING OF EGG PRODUCTS AT OFFICIAL PLANTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31706	21 U.S.C. 1036	Pub. L. 91–597, § 7, Dec. 29, 1970, 84 Stat. 1625.

In subsection (a)(2)(B), the words "ensure that they will not" are substituted for "assure that they will not" to use the more appropriate word.

In subsection (b)(3), the words "the determination of the Secretary under paragraph (1)" are substituted for "the determination of the Secretary" for clarity.

In subsection (b)(4)(A), the words "Any final determination by the Secretary under paragraph (3)" are substituted for "Any such determination by the Secretary" for clarity.

SECTION 31707—PROHIBITED ACTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31707	21 U.S.C. 1037	Pub. L. 91–597, § 8, Dec. 29, 1970, 84 Stat. 1626; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–237, title X, § 1012(c), Dec. 13, 1991, 105 Stat. 1899.

In subsection (a)(1), the words "ensure that only eggs" are substituted for "assure that only eggs" to use the more appropriate word.

In subsection (a)(2), the words "ensure that only eggs" are substituted for "assure that only eggs" to use the more appropriate word.

In subsection (e)(4), the words "detach, deface, or destroy, or fail to use," are substituted for "fail to use, or to detach, deface, or destroy" for clarity.

In subsection (e)(7), in the matter after the semicolon, the word "or" is substituted for "and" for clarity.

In subsection (f), the word "individual" is substituted for "person" for consistency with section 31701(23) of title 21, United States Code.

SECTION 31708—COOPERATION WITH APPROPRIATE STATE AND OTHER GOVERNMENTAL AGENCIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31708	21 U.S.C. 1038	Pub. L. 91–597, § 9, Dec. 29, 1970, 84 Stat. 1627.

SECTION 31709—EGGS AND EGG PRODUCTS NOT INTENDED FOR USE AS HUMAN FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31709	21 U.S.C. 1039	Pub. L. 91–597, § 10, Dec. 29, 1970, 84 Stat. 1627.

SECTION 31710—RECORDKEEPING REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31710	21 U.S.C. 1040	Pub. L. 91–597, § 11, Dec. 29, 1970, 84 Stat. 1627; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.

SECTION 31711—ENFORCEMENT PROVISIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31711	21 U.S.C. 1041	Pub. L. 91–597, §12, Dec. 29, 1970, 84 Stat. 1628; Pub. L. 102–237, title X, § 1012(d), Dec. 13, 1991, 105 Stat. 1899.

In subsection (a)(1), the words "not more than $5,000" are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (a)(2), the words "not more than $10,000" are retained to ensure that no change in the meaning or effect of the source provision is made by the

restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (b)(1), the words "individual while engaged in or on account of the performance of the individual's official duties" are substituted for "person while engaged in or on account of the performance of his official duties" for clarity.

In subsection (b)(1), the words "fined under title 18" are substituted for "fined not more than $5,000" for consistency with chapter 227 of title 18, United States Code.

In subsection (b)(2), the words "fined under title 18" are substituted for "fined not more than $10,000" for consistency with chapter 227 of title 18, United States Code.

In subsection (b)(3), the words "kills an individual while engaged in or on account of the performance of the individual's official duties" are substituted for "kills any person while engaged in or on account of the performance of his official duties" for clarity and consistency with sections 1111 and 1112 of title 18, United States Code.

In subsection (c)(1)(B), the words "civil penalty" are substituted for "penalty" for clarity.

SECTION 31712—PROCEDURES PRIOR TO REPORTING TO ATTORNEY GENERAL FOR INSTITUTION OF CRIMINAL PROCEEDING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31712	21 U.S.C. 1042	Pub. L. 91–597, § 13, Dec. 29, 1970, 84 Stat. 1628; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–237, title X, § 1012(e), Dec. 13, 1991, 105 Stat. 1900.

SECTION 31713—RULES AND REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31713	21 U.S.C. 1043	Pub. L. 91–597, § 14, Dec. 29, 1970, 84 Stat. 1629.

In this section, the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

SECTION 31714—EXEMPTION OF CERTAIN ACTIVITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31714	21 U.S.C. 1044(a), (c)	Pub. L. 91–597, §15(a), (c), Dec. 29, 1970, 84 Stat. 1629; Pub. L. 92–67, Aug. 6, 1971, 85 Stat. 173.

In paragraphs (3), (4), and (5) of subsection (a), the words "this subsection" are substituted for "this paragraph" to provide the correct reference to the pertinent provision. In the original enactment of the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), references to subsections were referred to as paragraphs. The substitution is made to effectuate in the restatement the intended references of the original enactment.

In subsection (c), the words "considers the action" are substituted for "deems such action" to use the more appropriate word.

SECTION 31715—LIMITATION ON ENTRY OF EGGS AND EGG PRODUCTS AND OTHER MATERIALS INTO OFFICIAL PLANTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31715	21 U.S.C. 1045	Pub. L. 91–597, § 16, Dec. 29, 1970, 84 Stat. 1630.

In this section, the words "ensure that allowing the entry" are substituted for "assure that allowing the entry" to use the more appropriate word.

SECTION 31716—IMPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31716	21 U.S.C. 1046	Pub. L. 91–597, § 17, Dec. 29, 1970, 84 Stat. 1630; Pub. L. 102–237, title X, § 1012(f), Dec. 13, 1991, 105 Stat. 1901.

SECTION 31717—REFUSAL OR WITHDRAWAL OF INSPECTION SERVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31717	21 U.S.C. 1047	Pub. L. 91–597, § 18, Dec. 29, 1970, 84 Stat. 1630.

In subsection (a), in the matter before paragraph (1), the words "considers necessary" are substituted for "deems necessary" to use the more appropriate word.

In subsection (d), the words "in any way" are omitted as unnecessary.

SECTION 31718—DETENTION OF ARTICLES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31718(a) through (c) ...	21 U.S.C. 1048	Pub. L. 91–597, § 19, Dec. 29, 1970, 84 Stat. 1631.
31718(d)	21 U.S.C. 1052(d)	Pub. L. 91–597, §23(d), Dec. 29, 1970, 84 Stat. 1632; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695.

SECTION 31719—SEIZURE AND CONDEMNATION PROCEEDINGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31719	21 U.S.C. 1049	Pub. L. 91–597, § 20, Dec. 29, 1970, 84 Stat. 1631.

In subsection (c), the words "ensure compliance" are substituted for "insure compliance" to use the more appropriate word.

In subsection (e), the words "brought by" are substituted for "at the suit of" for clarity.

SECTION 31720—JURISDICTION OF DISTRICT COURTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31720	21 U.S.C. 1050	Pub. L. 91–597, § 21, Dec. 29, 1970, 84 Stat. 1632.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31721	21 U.S.C. 1051	Pub. L. 91–597, § 22, Dec. 29, 1970, 84 Stat. 1632.

In subsection (a), the words "and the last paragraph of section 9" are omitted as obsolete because the last paragraph of section 9 of the Federal Trade Commission Act (15 U.S.C. 49) was struck by section 211 of the Organized Crime Control Act of 1970 (Public Law 91–452, 84 Stat. 929).

In subsection (a), the words "and the provisions of subsection 409(l) of the Communications Act of 1934 (48 Stat. 1096, as amended; 47 U.S.C. 409(l))," are omitted as obsolete because that provision was repealed by section 242 of the Organized Crime Control Act of 1970 (Public Law 91–452, 84 Stat. 930).

SECTION 31722—STATE OR LOCAL REGULATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31722	21 U.S.C. 1052(a) through (c)	Pub. L. 91–597, §23(a) through (c), Dec. 29, 1970, 84 Stat. 1632; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–237, title X, § 1012(g), Dec. 13, 1991, 105 Stat. 1901.

In subsection (b)(2), the words "Paragraph (1) shall not preclude" are substituted for "*Provided*, *however*, That this shall not preclude" for clarity.

In subsection (d), the words "Notwithstanding this section" are substituted for "However" for clarity.

In subsection (d), the words "this chapter, subtitle I of this title, and the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.)" are substituted for "said Federal Acts" and "therewith" for clarity.

In subsection (e), the words "Except as provided in this section" are substituted for "Otherwise" for clarity.

SECTION 31723—INSPECTION AND ADMINISTRATION COSTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31723(a)	21 U.S.C. 1053(b) (relating to "this chapter")	Pub. L. 91–597, §24(b) (relating to "this Act"), Dec. 29, 1970, 84 Stat. 1633.
31723(b)	21 U.S.C. 1053(a)	Pub. L. 91–597, §24(a), Dec. 29, 1970, 84 Stat. 1633.

SECTION 31724—ANNUAL REPORT TO CONGRESSIONAL COMMITTEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31724	21 U.S.C. 1054	Pub. L. 91–597, § 26, Dec. 29, 1970, 84 Stat. 1634; Pub. L. 103–437, § 8(4), Nov. 2, 1994, 108 Stat. 4588.

In this section, in the matter before paragraph (1), the words "following the enactment of this Act" are omitted as obsolete.

In paragraph (2), in the matter before subparagraph (A), the words "(relating to imports)" are omitted as unnecessary.

Chapter 319—Pesticide Monitoring Improvement

SECTION 31901—PESTICIDE MONITORING AND ENFORCEMENT INFORMATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31901	21 U.S.C. 1401	Pub. L. 100–418, title IV, § 4702, Aug. 23, 1988, 102 Stat. 1412.

In subsection (a)(1), the words "Not later than 480 days after the date of the enactment of this Act," are omitted as obsolete.

In subsection (d)(1), the words "The Secretary of Health and Human Services shall annually compile" are substituted for "Not later than 90 days after the expiration of 1 year after the data management systems are placed into effect under subsection (a) and annually thereafter, the Secretary of Health and Human Services shall compile" to eliminate obsolete words.

SECTION 31902—FOREIGN PESTICIDE INFORMATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31902	21 U.S.C. 1402(a) through (c)	Pub. L. 100–418, title IV, §4703(a) through (c), Aug. 23, 1988, 102 Stat. 1413.

In subsection (a), the words "ensure compliance" are substituted for "assure compliance" to use the more appropriate word.

In subsection (b)(2), the words "ensure an effective pesticide monitoring program" are substituted for "assure an effective pesticide monitoring program" to use the more appropriate word.

In subsection (b)(3), the words "ensure that appropriate offices" are substituted for "assure that appropriate offices" to use the more appropriate word.

In subsection (c)(2), the words "the agencies referred to in paragraph (1)" are substituted for "those departments and agencies" for clarity.

SECTION 31903—PESTICIDE ANALYTICAL METHODS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
31903	21 U.S.C. 1403 (except matter after (2))	Pub. L. 100–418, title IV, §4704 (except matter after (2)), Aug. 23, 1988, 102 Stat. 1414.

Chapter 321—Food Allergen Labeling and Consumer Protection

SECTION 32101—INSPECTIONS RELATING TO FOOD ALLERGENS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32101	21 U.S.C. 374a	Pub. L. 108–282, title II, § 205, Aug. 2, 2004, 118 Stat. 909.

SECTION 32102—GLUTEN-FREE LABELING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32102	21 U.S.C. 343 note	Pub. L. 108–282, title II, §206, Aug. 2, 2004, 118 Stat. 910.

In this section, the first sentence of the source provision, which required the Secretary of Health and Human Services to issue a proposed rule to define, and permit use of, the term "gluten-free" on the labeling of foods, is omitted as obsolete. The words "Not later than 4 years after the date of enactment of this Act," are also omitted as obsolete.

SECTION 32103—IMPROVEMENT AND PUBLICATION OF DATA ON FOOD-RELATED ALLERGIC RESPONSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32103	42 U.S.C. 242r(a)	Pub. L. 108–282, title II, §207(a), Aug. 2, 2004, 118 Stat. 910.

Chapter 323—Food Safety

SECTION 32301—ENSURING THE SAFETY OF PET FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32301	21 U.S.C. 2102	Pub. L. 110–85, title X, §1002, Sept. 27, 2007, 121 Stat. 963; Pub. L. 115–234, title III, §306(b), Aug. 14, 2018, 132 Stat. 2441.

In subsection (a), in the matter before paragraph (1), the words "Not later than 2 years after the date of the enactment of this Act," are omitted as obsolete.

In subsection (b), in the matter before paragraph (1), the words "Not later than 1 year after the date of the enactment of this Act," are omitted as obsolete.

In subsection (b)(4), the words "considers appropriate" are substituted for "deems appropriate" to use the more appropriate word.

SECTION 32302—ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32302	21 U.S.C. 2103	Pub. L. 110–85, title X, § 1003, Sept. 27, 2007, 121 Stat. 963.

SECTION 32303—STATE AND FEDERAL COOPERATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32303	21 U.S.C. 2104	Pub. L. 110–85, title X, § 1004, Sept. 27, 2007, 121 Stat. 964.

SECTION 32304—ENHANCED AQUACULTURE AND SEAFOOD INSPECTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32304(a)	21 U.S.C. 2105(b)	Pub. L. 110–85, title X, §1006(b), Sept. 27, 2007, 121 Stat. 969.
32304(b)	21 U.S.C. 2105(d)	Pub. L. 110–85, title X, §1006(d), Sept. 27, 2007, 121 Stat. 969.

SECTION 32305—CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32305	21 U.S.C. 2106	Pub. L. 110–85, title X, § 1007, Sept. 27, 2007, 121 Stat. 969.

SECTION 32306—ANNUAL REPORT TO CONGRESS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32306	21 U.S.C. 2108	Pub. L. 110–85, title X, § 1009, Sept. 27, 2007, 121 Stat. 970.

SECTION 32307—PUBLICATION OF ANNUAL REPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32307	21 U.S.C. 2109	Pub. L. 110–85, title X, § 1010, Sept. 27, 2007, 121 Stat. 970.

In subsection (a)(3)(A)(i), in the matter after the semicolon, the word "and" is added for clarity.

In subsection (b), the words "Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a)" are omitted as obsolete.

In subsection (c), the words "which data relates to" are substituted for "relating to" for clarity.

SECTION 32308—RULE OF CONSTRUCTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32308(a)	21 U.S.C. 2110	Pub. L. 110–85, title X, § 1011, Sept. 27, 2007, 121 Stat. 971.
32308(b)	21 U.S.C. 2110 note	Pub. L. 110–85, title X, §1005(g), Sept. 27, 2007, 121 Stat. 969.

In subsection (a)(2), the words "under section 18902 of this title" are substituted for "created under the Dietary Supplement and Nonprescription Drug

Consumer Protection Act (Public Law 109–462)" to provide a more precise reference to the pertinent provision.

Chapter 325—Food Safety Modernization

Subchapter I—General Provisions

SECTION 32501—DEFINITION OF FOODBORNE ILLNESS OUTBREAK

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32501	21 U.S.C. 2224(a)	Pub. L. 111–353, title II, §205(a), Jan. 4, 2011, 124 Stat. 3937.

Subchapter II—Improving Capacity To Prevent Food Safety Problems

SECTION 32511—PERFORMANCE STANDARDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32511	21 U.S.C. 2201	Pub. L. 111–353, title I, § 104, Jan. 4, 2011, 124 Stat. 3899.

In subsection (a), the parenthetical "(referred to in this chapter as the 'Secretary')" is added for clarity. Throughout the chapter, the term "Secretary" is substituted for "Secretary of Health and Human Services" for consistency with the parenthetical and in the chapter and for clarity.

SECTION 32512—NATIONAL AGRICULTURE AND FOOD DEFENSE STRATEGY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32512	21 U.S.C. 2202	Pub. L. 111–353, title I, § 108, Jan. 4, 2011, 124 Stat. 3910.

In subsection (a)(1), the words "Not later than 1 year after the date of enactment of this Act," are omitted as obsolete.

In subsection (a)(1) , the word "submit" is substituted for "transmit" for consistency with subsection (a)(4).

In subsection (a)(1), the parenthetical "(referred to in this section as the 'Strategy')" is added for convenience.

SECTION 32513—FOOD AND AGRICULTURE COORDINATING COUNCILS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32513	21 U.S.C. 2203	Pub. L. 111–353, title I, § 109, Jan. 4, 2011, 124 Stat. 3912.

In paragraph (2), the words "each Council" are substituted for "each council" for consistency in the section.

In paragraph (2), the words “which information relates to” are substituted for “relating to” for clarity.

SECTION 32514—BUILDING DOMESTIC CAPACITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32514	21 U.S.C. 2204	Pub. L. 111–353, title I, § 110, Jan. 4, 2011, 124 Stat. 3913.

In this section, the word “Secretary”, each place it appears in the source law except when appearing in references to the Secretary of Agriculture and the Secretary of Homeland Security, is translated as “Secretary of Health and Human Services” through the applicability of the parenthetical “(referred to in this chapter as the `Secretary')” in section 32511 of title 21, United States Code, for clarity.

In subsection (a)(1), in the matter before subparagraph (A), the words “not later than 2 years after the date of enactment of this Act,” are omitted as obsolete.

In subsection (a)(1)(F), the words “progress in implementing” are substituted for “progress implementing” to supply a missing word.

In subsection (a)(1)(I), the words “(as added by section 201)” are omitted as unnecessary.

In subsection (c), the words “(as added by section 202)” are omitted as unnecessary.

In subsection (h)(1), in the matter before subparagraph (A), the words “beginning not later than 1 year after the date of enactment of this Act” are omitted as obsolete.

SECTION 32515—FOOD ALLERGY AND ANAPHYLAXIS MANAGEMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32515(a)(1)	21 U.S.C. 2205(a)(1)	Pub. L. 111–353, title I, §112(a)(1), Jan. 4, 2011, 124 Stat. 3916.
32515(a)(2)	21 U.S.C. 2205(a)(2) (relating to elementary school)	Pub. L. 111–353, title I, §112(a)(2) (relating to elementary school), Jan. 4, 2011, 124 Stat. 3916; Pub. L. 114–95, title IX, §9215(jj), Dec. 10, 2015, 129 Stat. 2175.
32515(a)(3)	21 U.S.C. 2205(a)(2) (relating to local education agency)	Pub. L. 111–353, title I, §112(a)(2) (relating to local education agency), Jan. 4, 2011, 124 Stat. 3916; Pub. L. 114–95, title IX, §9215(jj), Dec. 10, 2015, 129 Stat. 2175.
32515(a)(4)	21 U.S.C. 2205(a)(2) (relating to parent)	Pub. L. 111–353, title I, §112(a)(2) (relating to parent), Jan. 4, 2011, 124 Stat. 3916; Pub. L. 114–95, title IX, §9215(jj), Dec. 10, 2015, 129 Stat. 2175.
32515(a)(5)	21 U.S.C. 2205(a)(3)	Pub. L. 111–353, title I, §112(a)(3), Jan. 4, 2011, 124 Stat. 3916.
32515(a)(6)	21 U.S.C. 2205(a)(2) (relating to secondary school)	Pub. L. 111–353, title I, §112(a)(2) (relating to secondary school), Jan. 4, 2011, 124 Stat. 3916; Pub. L. 114–95, title IX, §9215(jj), Dec. 10, 2015, 129 Stat. 2175.
32515(b)	21 U.S.C. 2205(b)	Pub. L. 111–353, title I, §112(b), Jan. 4, 2011, 124 Stat. 3916.
32515(c)	21 U.S.C. 2205(c) (except (12))	Pub. L. 111–353, title I, §112(c) (except (12)), Jan. 4, 2011, 124 Stat. 3916.
32515(d)	21 U.S.C. 2205(d)	Pub. L. 111–353, title I, §112(d), Jan. 4, 2011, 124 Stat. 3916.

In subsection (a)(1)(B), the words “State-licensed or State-regulated” are substituted for “State licensed or regulated” for clarity.

In subsection (b)(1)(A), in the matter before clause (i), the words “Not later than 1 year after the date of enactment of this Act,” are omitted as obsolete.

In subsection (b)(1)(B), the parenthetical “(commonly referred to as the ‘Family Educational Rights and Privacy Act of 1974’)” is omitted as unnecessary.

SECTION 32516—ALCOHOL-RELATED FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32516	21 U.S.C. 2206	Pub. L. 111–353, title I, § 116, Jan. 4, 2011, 124 Stat. 3922.

In subsection (b), in the matter before paragraph (1), the words “except that subsection (a)” are substituted for “except that such paragraph” for clarity and consistency in the subsection.

In subsection (b), in the matter before paragraph (1), the words “described in subsection (a)” are substituted for “described in such paragraph” for clarity and consistency in the subsection.

In subsection (c), the words “as defined in section 203” are substituted for “as defined in section 214” to provide the correct reference to the pertinent provision.

Subchapter III—Improving Capacity To Detect and Respond to Food Safety Problems

SECTION 32531—FOOD EMERGENCY RESPONSE NETWORK

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32531	21 U.S.C. 2221	Pub. L. 111–353, title II, § 202(b), Jan. 4, 2011, 124 Stat. 3929.

In this section, in the matter before paragraph (1), the word “Secretary” in the source law (except when appearing in references to the Secretary of Agriculture and the Secretary of Homeland Security) is translated as “Secretary of Health and Human Services” through the applicability of the parenthetical “(referred to in this chapter as the `Secretary')” in section 32511 of title 21, United States Code, for clarity.

In this section, in the matter before paragraph (1), the words “shall biennially” are substituted for “shall, not later than 180 days after the date of enactment of this Act, and biennially thereafter,” to eliminate obsolete words.

SECTION 32532—INTEGRATED CONSORTIUM OF LABORATORY NETWORKS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32532	21 U.S.C. 2222	Pub. L. 111–353, title II, § 203, Jan. 4, 2011, 124 Stat. 3929.

SECTION 32533—ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32533	21 U.S.C. 2223	Pub. L. 111–353, title II, § 204 (except (j)), Jan. 4, 2011, 124 Stat. 3930.

In subsection (i)(1), in the parenthetical, the words "not later than 90 days after the date of enactment of this Act" are omitted as unnecessary. See section 11120(o)(1)(B) of title 21, United States Code.

In subsection (i)(2), in the parenthetical, the words "not later than 90 days after the date of enactment of this Act" are omitted as unnecessary. See section 11120(o)(1)(B) of title 21, United States Code.

SECTION 32534—SURVEILLANCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32534(a)	21 U.S.C. 2224(b)(1), (2)	Pub. L. 111–353, title II, §205(b)(1), (2), Jan. 4, 2011, 124 Stat. 3937.
32534(b)	21 U.S.C. 2224(c)	Pub. L. 111–353, title II, §205(c), Jan. 4, 2011, 124 Stat. 3939.

In this section, the word "Secretary", each place it appears in the source law, is translated as "Secretary of Health and Human Services" through the applicability of the parenthetical "(referred to in this chapter as the `Secretary')" in section 32511 of title 21, United States Code, for clarity.

In subsection (a)(1)(J), the words "performing other activities" are substituted for "other activities" for consistency in the paragraph.

In subsection (b)(2), in the matter before subparagraph (A), the word "of" is omitted from the phrase "In developing of the strategies" to correct an error in the law.

SECTION 32535—DECONTAMINATION AND DISPOSAL STANDARDS AND PLANS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32535	21 U.S.C. 2225	Pub. L. 111–353, title II, § 208, Jan. 4, 2011, 124 Stat. 3944.

In subsection (d), the word "in" is substituted for "under" in the phrase "entities described in subsection (b)" for clarity and for consistency with subsection (e).

Subchapter IV—Improving the Safety of Imported Food

SECTION 32551—INSPECTION BY THE SECRETARY OF COMMERCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32551	21 U.S.C. 2241	Pub. L. 111–353, title III, § 306(b), Jan. 4, 2011, 124 Stat. 3959.

SECTION 32552—FOREIGN OFFICES OF THE FOOD AND DRUG ADMINISTRATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32552	21 U.S.C. 2242(a), (b)	Pub. L. 111–353, title III, §308(a), (b), Jan. 4, 2011, 124 Stat. 3966.

In this section, the word "Secretary", each place it appears in the source law except when appearing in references to the Secretary of State and the Secretary of Homeland Security, is translated as "Secretary of Health and Human Services" through the applicability of the parenthetical "(referred to in this chapter as the `Secretary')" in section 32511 of title 21, United States Code, for clarity.

SECTION 32553—SMUGGLED FOOD

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32553(a)	21 U.S.C. 2243(e)	Pub. L. 111–353, title III, §309(e), Jan. 4, 2011, 124 Stat. 3966.
32553(b) through (e) ...	21 U.S.C. 2243(a) through (d)	Pub. L. 111–353, title III, §309(a) through (d), Jan. 4, 2011, 124 Stat. 3966.

In this section, the word "Secretary", each place it appears in the source law except when appearing in references to the Secretary of Homeland Security, is translated as "Secretary of Health and Human Services" through the applicability of the parenthetical "(referred to in this chapter as the `Secretary')" in section 32511 of title 21, United States Code, for clarity.

In subsection (b), the words "Not later than 180 days after the enactment of this Act," are omitted as obsolete.

Subchapter V—Miscellaneous Provisions

SECTION 32561—EFFECT OF FOOD SAFETY MODERNIZATION PROVISIONS ON JURISDICTION AND AUTHORITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32561	21 U.S.C. 2251	Pub. L. 111–353, title IV, § 403, Jan. 4, 2011, 124 Stat. 3972.

In paragraph (3)(A), the words "subtitle I of this title (as the Federal Food, Drug, and Cosmetic Act was in effect on January 3, 2011)" are substituted for "the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act" for clarity. In the source law, the words "the date of enactment of this Act" mean the date of enactment of the FDA Food Safety Modernization Act (Public Law 111–353, 124 Stat. 3885), which was enacted January 4, 2011. The Federal Food, Drug, and Cosmetic Act was classified to chapter 9 (§301 et seq.) of former title 21, United States Code, and is now restated as subtitle I (§10101 et seq.) of title 21, United States Code. The reference to "subtitle I of this title" is deemed to refer to the Federal Food, Drug, and Cosmetic Act under section 5(d) of the bill enacting title 21, United States Code.

SECTION 32562—EFFECT OF FOOD SAFETY MODERNIZATION PROVISIONS ON COMPLIANCE WITH INTERNATIONAL AGREEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
32562	21 U.S.C. 2252	Pub. L. 111–353, title IV, § 404, Jan. 4, 2011, 124 Stat. 3972.

Chapters 327 Through 397—Reserved

Chapter 399—Miscellaneous

SECTION 39901—CONSUMER EDUCATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
39901	21 U.S.C. 343 note	Pub. L. 101–535, § 2(c), Nov. 8, 1990, 104 Stat. 2357.

SECTION 39902—FOOD SAFETY AND SECURITY STRATEGY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
39902	21 U.S.C. 341 note	Pub. L. 107–188, title III, §301(a), June 12, 2002, 116 Stat. 662.

SECTION 39903—REGULATION OF EXPORT OF SHRIMP TO THE UNITED STATES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
39903	21 U.S.C. 2105 note	Pub. L. 116–260, div. A, title VII, §787, Dec. 27, 2020, 134 Stat. 1230.

In subsection (a), the words "if the Secretary determines it feasible," are substituted for "if it determines feasible," for clarity.

In subsection (b)(3), references to "the Committee" are retained to ensure that no change in meaning or effect of the law is made by the restatement of the provision in title 21, United States Code. Section 787 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2021 (Public Law 116–260, div. A, 21 U.S.C. 2105 note), which is the source provision for section 39903 of title 21, United States Code, does not contain any antecedent for its reference to "the Committee". Elsewhere in title VII of the Act are several references to "Committees on Appropriations of both Houses of Congress", but section 787 of the Act, as enacted, refers only to "the Committee".

Subtitle IV—Pharmacology, Drugs, and Devices

Chapter 401—Practice of Pharmacy and Sale of Poisons in Consular Districts in China

SECTION 40101—GENERAL PROVISIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40101(a)	21 U.S.C. 215	Mar. 3, 1915, ch. 74, § 12, 38 Stat. 822.
40101(b)	21 U.S.C. 209 (last paragraph)	Mar. 3, 1915, ch. 74, §7 (last paragraph), 38 Stat. 821.

SECTION 40102—UNLAWFUL ACTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40102	21 U.S.C. 201	Mar. 3, 1915, ch. 74, §1 (from "That on and after" through 1st proviso), 38 Stat. 817.

In this section, the word “individual” is substituted for “person” each place it appears for clarity and consistency with section 1 of title 1, United States Code.

In subsection (a), in the matter before paragraph (1), the words “That on and after the first day of January, nineteen hundred and sixteen,” are omitted as obsolete.

In subsection (a), in the matter before paragraph (1), the words “Except as provided in this chapter,” are substituted for “except as hereinafter provided, or, except as hereinafter provided, ”to eliminate unnecessary words and for clarity.

In subsection (a), the 2d instance of the words “for any person whose permanent allegiance is due to the United States not licensed as a pharmacist within the meaning of this Act” are omitted as unnecessary.

SECTION 40103—PRACTITIONERS AND OTHER BUSINESSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40103	21 U.S.C. 202	Mar. 3, 1915, ch. 74, §1 (last proviso), 38 Stat. 818.

In this section, the word “individual” is substituted for “person” each place it appears for clarity and consistency with section 1 of title 1, United States Code.

In paragraph (1), the words “may consider proper” are substituted for “may deem proper” to use the more appropriate word.

In paragraph (1), the words “except as provided in the other provisions of this chapter” are substituted for “except as hereinafter provided” for clarity.

In paragraph (2), the words “except as provided in the other provisions of this chapter” are substituted for “except as hereinafter provided” for clarity.

SECTION 40104—APPLICATION FOR LICENSE; QUALIFICATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40104	21 U.S.C. 203	Mar. 3, 1915, ch. 74, §2, 38 Stat. 818.

In subsection (a), in the matter before paragraph (1), the word “individual” is substituted for “person” for clarity and consistency with section 1 of title 1, United States Code.

In subsection (a), in the matter before paragraph (1), the words "now practicing as a pharmacist or" are omitted as obsolete.

SECTION 40105—ISSUANCE OF LICENSE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40105	21 U.S.C. 204	Mar. 3, 1915, ch. 74, §3, 38 Stat. 819.

SECTION 40106—DISPLAY OF LICENSE IN PHARMACY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40106	21 U.S.C. 205	Mar. 3, 1915, ch. 74, §5, 38 Stat. 819.

In this section, the word "individual" is substituted for "person" each place it appears for clarity and consistency with section 1 of title 1, United States Code.

SECTION 40107—REVOCATION OF LICENSE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40107	21 U.S.C. 206	Mar. 3, 1915, ch. 74, §4, 38 Stat. 819.

In this section, the word "individual" is substituted for "person" each place it appears for clarity and consistency with section 1 of title 1, United States Code.

SECTION 40108—UNLAWFUL SALES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40108	21 U.S.C. 207	Mar. 3, 1915, ch. 74, §6 (except from 1st proviso through last sentence), 38 Stat. 819.

In this section, the word "individual" is substituted for "person" each place it appears for clarity and consistency with section 1 of title 1, United States Code.

In subsection (a), in the matter before paragraph (1), the words "or by an agent or as the agent" are substituted for "or by servant or agent or as the servant or agent" to eliminate unnecessary words.

SECTION 40109—INAPPLICABILITY OF SECTION 40108

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40109	21 U.S.C. 208	Mar. 3, 1915, ch. 74, § 6 (1st proviso through last sentence), 38 Stat. 819.

In subsection (a)(3), the words "as liniments or ointments, respectively," are substituted for "as such" for clarity.

In subsection (b)(2), the words "may consider necessary" are substituted for "may deem necessary" to use the more appropriate word.

In subsection (b)(2), the words "or the substances are not furnished" are substituted for "or substances furnished" for clarity.

SECTION 40110—POISONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40110	21 U.S.C. 209 (except last paragraph)	Mar. 3, 1915, ch. 74, §7 (except last paragraph), 38 Stat. 820.

In this section, the word "individual" is substituted for "person" each place it appears for clarity and consistency with section 1 of title 1, United States Code.

In subsection (b), in the matter before paragraph (1), the words "Prior to sale or delivery of a substance described in subsection (a)" are added for clarity.

In subsection (c)(1), in the matter before subparagraph (A), the words "kept for that purpose" are omitted as unnecessary.

In subsection (c)(2), the words "owner of the book" are substituted for "owner thereof" for clarity.

In subsection (d), the words "Subsections (a) through (c) shall not apply" are substituted for "The foregoing provisions shall not apply" for clarity.

In subsection (f), the words "record of sale and delivery described in subsection (c)" are substituted for "record of sale and delivery above mentioned" for clarity.

In subsection (g)(3), the words "as liniments or ointments, respectively" are substituted for "as such" for clarity.

SECTION 40111—PHARMACIST; UNAUTHORIZED USE OF TITLE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40111	21 U.S.C. 210	Mar. 3, 1915, ch. 74, §10, 38 Stat. 821.

In this section, the word "individual" is substituted for "person" for clarity and consistency with section 1 of title 1, United States Code.

SECTION 40112—PRESCRIPTION RECORDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40112	21 U.S.C. 211	Mar. 3, 1915, ch. 74, §9, 38 Stat. 821.

In this section, the word "individual" is substituted for "person" each place it appears for clarity and consistency with section 1 of title 1, United States Code.

In subsection (b), the words "the drug store or pharmacy under subsection (a)" are substituted for "such store" for clarity.

SECTION 40113—CRIMINAL PENALTIES; ENFORCEMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40113	21 U.S.C. 212	Mar. 3, 1915, ch. 74, §11, 38 Stat. 821.

In subsection (a)(1), the word "individual" is substituted for "person" for clarity and consistency with section 1 of title 1, United States Code.

In subsection (a)(1), the words "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" are substituted for "shall be deemed guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than $50 and not more than $100 or by imprisonment for not less than one month and not more than sixty days, or by both such fine and imprisonment, in the discretion of the court," for consistency with chapter 227 of title 18, United States Code, and to eliminate unnecessary words.

In subsection (b), the words "Consular and judicial officers of the United States in China shall enforce" are substituted for "it shall be the duty of the consular and judicial officers of the United States in China to enforce" for clarity.

SECTION 40114—FRAUDULENT REPRESENTATIONS TO EVADE OR DEFEAT RESTRICTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40114	21 U.S.C. 213	Mar. 3, 1915, ch. 74, §8, 38 Stat. 821.

In this section, the word "individual" is substituted for "person" for clarity and consistency with section 1 of title 1, United States Code.

Chapter 403—Improvements on Regulation of Drugs

SECTION 40301—DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40301	21 U.S.C. 355 note	Pub. L. 105–115, title I, §118, Nov. 21, 1997, 111 Stat. 2316.

In this section, the words "Within 12 months after the date of enactment of this Act," are omitted as obsolete.

SECTION 40302—APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING REQUIREMENTS FOR POSITRON EMISSION TOMOGRAPHY DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40302(a)	21 U.S.C. 355 note	Pub. L. 105–115, title I, §121(e), Nov. 21, 1997, 111 Stat. 2321.
40302(b), (c)	21 U.S.C. 355 note	Pub. L. 105–115, title I, §121(c), Nov. 21, 1997, 111 Stat. 2321.

SECTION 40303—APPROVAL OF RADIOPHARMACEUTICALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40303(a)	21 U.S.C. 355 note	Pub. L. 105–115, title I, §122(b), Nov. 21, 1997, 111 Stat. 2322.
40303(b)	21 U.S.C. 355 note	Pub. L. 105–115, title I, §122(a)(1), Nov. 21, 1997, 111 Stat. 2322.
40303(c)	21 U.S.C. 355 note	Pub. L. 105–115, title I, §122(a)(2), Nov. 21, 1997, 111 Stat. 2322.

Subsection (b) is substituted for section 122(a)(1) of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 355 note) to eliminate obsolete words. See section 6 of the bill enacting title 21, United States Code, which repeals section 122 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 355 note) in its entirety.

SECTION 40304—MINIMIZING DIFFERENCES IN THE REVIEW AND APPROVAL OF BIOLOGICS LICENSE APPLICATIONS AND NEW DRUG APPLICATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40304	21 U.S.C. 355 note	Pub. L. 105–115, title I, §123(f), Nov. 21, 1997, 111 Stat. 2324.

SECTION 40305—REGULATIONS FOR OVER-THE-COUNTER SUNSCREEN PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40305	21 U.S.C. 393 note	Pub. L. 105–115, title I, §129, Nov. 21, 1997, 111 Stat. 2331.

In this section, the words "Not later than 18 months after the date of enactment of this Act" are omitted as obsolete.

Chapter 405—Biomaterials Access Assurance

SECTION 40501—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40501	21 U.S.C. 1602	Pub. L. 105–230, §3, Aug. 13, 1998, 112 Stat. 1520.

In paragraph (2)(A), the words "including a person other than the individual into whose body the implant was placed or with whose blood or tissue the implant was in contact," are substituted for "including a person other than the individual into whose body, or in contact with whose blood or tissue, the implant is placed," for clarity.

In paragraph (2)(B), the words "of a deceased individual into whose body the implant was placed or with whose blood or tissue the implant was in contact," are substituted for "of a deceased individual into whose body, or in contact with whose blood or tissue the implant was placed," for clarity.

SECTION 40502—GENERAL REQUIREMENTS; APPLICABILITY; PREEMPTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40502	21 U.S.C. 1603	Pub. L. 105–230, § 4, Aug. 13, 1998, 112 Stat. 1523.

SECTION 40503—LIABILITY OF BIOMATERIALS SUPPLIERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40503	21 U.S.C. 1604	Pub. L. 105–230, § 5, Aug. 13, 1998, 112 Stat. 1524.

In subsection (d)(1)(B)(v), the words "which specifications received clearance" are substituted for "and received clearance" for clarity.

SECTION 40504—PROCEDURES FOR DISMISSAL OF CIVIL ACTIONS AGAINST BIOMATERIALS SUPPLIERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40504	21 U.S.C. 1605	Pub. L. 105–230, § 6, Aug. 13, 1998, 112 Stat. 1526.

SECTION 40505—SUBSEQUENT IMPLEADER OF DISMISSED BIOMATERIALS SUPPLIER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40505	21 U.S.C. 1606	Pub. L. 105–230, § 7, Aug. 13, 1998, 112 Stat. 1528.

Chapter 407—Federal Trade Commission Review of Agreements Relating to Generic Drugs and Brand Name Drugs

SECTION 40701—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40701	21 U.S.C. 355 note	Pub. L. 108–173, title XI, subtitle B, §1111, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 115–263, §3(1), Oct. 10, 2018, 132 Stat. 3673; Pub. L. 115–271, title IV, §4004(1), Oct. 24, 2018, 132 Stat. 3960.

SECTION 40702—NOTIFICATION OF AGREEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40702	21 U.S.C. 355 note	Pub. L. 108–173, title XI, subtitle B, §1112, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 115–263, §3(2), Oct. 10, 2018, 132 Stat. 3673; Pub. L. 115–271, title IV, §4004(2), Oct. 24, 2018, 132 Stat. 3960.

In subsection (b)(1)(A), the words "where the generic drug applicants enter into an agreement described in paragraph (2), shall each file the agreement in accordance with subsection (c)" are substituted for "shall each file the agreement in accordance with subsection (c)" for clarity.

In subsection (b)(1)(B), the words "where the biosimilar biological product applicants enter into an agreement described in paragraph (2), shall each file the agreement in accordance with subsection (c)" are substituted for "shall each file the agreement in accordance with subsection (c)" for clarity.

SECTION 40703—FILING DEADLINE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40703	21 U.S.C. 355 note	Pub. L. 108–173, title XI, subtitle B, §1113, Dec. 8, 2003, 117 Stat. 2461.

SECTION 40704—DISCLOSURE EXEMPTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40704	21 U.S.C. 355 note	Pub. L. 108–173, title XI, subtitle B, §1114, Dec. 8, 2003, 117 Stat. 2461.

SECTION 40705—ENFORCEMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40705	21 U.S.C. 355 note	Pub. L. 108–173, title XI, subtitle B, §1115, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 115–263, §3(3), Oct. 10, 2018, 132 Stat. 3675.

In subsection (a)(2), the parenthetical "(15 U.S.C. 56(a)(1))" is substituted for "(15 U.S.C. 56(a))" for consistency with the reference to "section 16(a)(1) of the Federal Trade Commission Act".

SECTION 40706—RULEMAKING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40706	21 U.S.C. 355 note	Pub. L. 108–173, title XI, subtitle B, §1116, Dec. 8, 2003, 117 Stat. 2461.

SECTION 40707—EFFECT OF CHAPTER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40707	21 U.S.C. 355 note	Pub. L. 108–173, title XI, subtitle B, §1117, Dec. 8, 2003, 117 Stat. 2461; Pub. L. 115–263, §3(4), Oct. 10, 2018, 132 Stat. 3675.

Chapter 409—Substance Use Disorder Prevention

SECTION 40901—CLARIFYING FDA REGULATION OF NON-ADDICTIVE PAIN PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40901(a)	21 U.S.C. 355 note	Pub. L. 115–271, title III, §3001(c), Oct. 24, 2018, 132 Stat. 3932.
40901(b), (c)	21 U.S.C. 355 note	Pub. L. 115–271, title III, §3001(a), (b), Oct. 24, 2018, 132 Stat. 3932.

SECTION 40902—EVIDENCE-BASED OPIOID ANALGESIC PRESCRIBING GUIDELINES AND REPORT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40902	21 U.S.C. 355–1 note	Pub. L. 115–271, title III, §3002, Oct. 24, 2018, 132 Stat. 3934

In subsection (b)(1), the words "medical specialties (including pain medicine specialty) societies" are substituted for "medical specialties including pain medicine specialty societies" for clarity.

SECTION 40903—STRENGTHENING FDA AND CBP COORDINATION AND CAPACITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40903	21 U.S.C. 384f	Pub. L. 115–271, title III, §3014, Oct. 24, 2018, 132 Stat. 3937.

In subsection (a)(1), the words "which activities will provide improvements" are substituted for "that will provide improvements" for clarity.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40904	21 U.S.C. 384g	Pub. L. 115–271, title III, §3022(a), Oct. 24, 2018, 132 Stat. 3938.

SECTION 40905—ACCESS TO INCREASED DRUG DISPOSAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
40905(a)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3252, Oct. 24, 2018, 132 Stat. 3950.
40905(b)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3253, Oct. 24, 2018, 132 Stat. 3951.
40905(c)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3254, Oct. 24, 2018, 132 Stat. 3951.
40905(d)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3255, Oct. 24, 2018, 132 Stat. 3951.
40905(e)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3256, Oct. 24, 2018, 132 Stat. 3951.
40905(f)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3257, Oct. 24, 2018, 132 Stat. 3951.
40905(g)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3258, Oct. 24, 2018, 132 Stat. 3951.
40905(h)	21 U.S.C. 822a note	Pub. L. 115–271, title III, §3259, Oct. 24, 2018, 132 Stat. 3952.

In subsection (a)(3), the words "under subsection (b)" are substituted for "under section 3003" to provide the correct reference to the pertinent provision. Neither the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Public Law 115–271, 132 Stat. 3894) nor the Access to Increased Drug Disposal Act of 2018 (Public Law 115–271, title III, ch. 6, 21 U.S.C. 822a note) contains a provision designated as section 3003. The authority to award grants is provided in section 3253 of the Access to Increased Drug Disposal Act of 2018 (Public Law 115–271, title III, ch. 6, 21 U.S.C. 822a note) and is restated in subsection (b).

Chapter 411—Coronavirus Aid, Relief, and Economic Security

SECTION 41101—DRUGS EXCLUDED FROM THE OVER-THE-COUNTER DRUG REVIEW

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41101	21 U.S.C. 355h note	Pub. L. 116–136, div. A, title III, §3853, Mar. 27, 2020, 134 Stat. 454.

In subsection (a), the words "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)" are substituted for "Nothing in this Act (or the amendments made by this Act)" to provide a more precise reference to the pertinent provisions.

In subsection (b), the words "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))" are substituted for "any other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)" for clarity.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41102	21 U.S.C. 356c note	Pub. L. 116–136, div. A, title III, §3112(f), Mar. 27, 2020, 134 Stat. 363.

Chapter 413—Accelerating Access to Critical Therapies for ALS

SECTION 41301—GRANTS FOR RESEARCH ON THERAPIES FOR ALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41301	21 U.S.C. 360ee note	Pub. L. 117–79, §2, Dec. 23, 2021, 135 Stat. 1533.

In subsection (a)(3), the word “site” is substituted for “site or sites” to eliminate unnecessary words because of section 1 of title 1, United States Code.

SECTION 41302—HHS PUBLIC-PRIVATE PARTNERSHIP FOR RARE NEURODEGENERATIVE DISEASES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41302(a)(1)	42 U.S.C. 280g–7b(b)	Pub. L. 117–79, §3(b), Dec. 23, 2021, 135 Stat. 1535.
41302(a)(2)	42 U.S.C. 280g–7b(a) ("(to be known and referred to in this section as the `Partnership')")	Pub. L. 117–79, §3(a) ("(to be known and referred to in this section as the `Partnership')"), Dec. 23, 2021, 135 Stat. 1535.
41302(a)(3)	42 U.S.C. 280g–7b(a) ("(referred to in this section as the `Secretary')")	Pub. L. 117–79, §3(a) ("(referred to in this section as the `Secretary')"), Dec. 23, 2021, 135 Stat. 1535.
41302(b)	42 U.S.C. 280g–7b(a) (except "(referred to in this section as the `Secretary')", "(to be known and referred to in this section as the `Partnership')")	Pub. L. 117–79, §3(a) (except "(referred to in this section as the `Secretary')", "(to be known and referred to in this section as the `Partnership')"), Dec. 23, 2021, 135 Stat. 1535.
41302(c)	42 U.S.C. 280g–7b(c)	Pub. L. 117–79, §3(c), Dec. 23, 2021, 135 Stat. 1535.

In subsection (a)(1)(A)(i), the words “section 101 of the Higher Education Act of 1965” are substituted for “section 1001 of the Higher Education Act of 1965” to provide the correct reference to the pertinent provision. The Higher Education Act of 1965 does not contain a section 1001; the term “institution of higher education” is defined in section 101 of that Act (20 U.S.C. 1001).

In subsection (a)(1)(A)(ii), the words “subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 (26 U.S.C. 501)” are substituted for “section 501(c)(3) of the Internal Revenue Code of 1986” for clarity, because of the reference to “subsection (a) of that section” at the end of the provision.

In subsection (b), in the matter before paragraph (1), the words “There Secretary shall implement” are substituted for “Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish and implement” to eliminate obsolete words.

In subsection (b), in the matter before paragraph (1), the word “amyotrophic” is substituted for “amytrophic” to correct a technical error.

SECTION 41303—ALS AND OTHER RARE NEURODEGENERATIVE DISEASE ACTION PLAN

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41303	21 U.S.C. 360aa note	Pub. L. 117–79, §4, Dec. 23, 2021, 135 Stat. 1536.

SECTION 41304—FDA RARE NEURODEGENERATIVE DISEASE GRANT PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41304	21 U.S.C. 360ee–1	Pub. L. 117–79, §5, Dec. 23, 2021, 135 Stat. 1537.

Chapter 415—Medical Marijuana and Cannabidiol Research Expansion

Subchapter I—General Provisions

SECTION 41501—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41501(1), (2)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(1), (2), Dec. 2, 2022, 136 Stat. 2257.
41501(3)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(3) (relating to controlled substance), Dec. 2, 2022, 136 Stat. 2258.
41501(4)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(4), Dec. 2, 2022, 136 Stat. 2258.
41501(5)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(3) (relating to dispense), Dec. 2, 2022, 136 Stat. 2258.
41501(6)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(3) (relating to distribute), Dec. 2, 2022, 136 Stat. 2258.
41501(7)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(5) , Dec. 2, 2022, 136 Stat. 2258.
41501(8)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(3) (relating to manufacture) , Dec. 2, 2022, 136 Stat. 2258.
41501(9)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(3) (relating to marijuana) , Dec. 2, 2022, 136 Stat. 2258.
41501(10)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(6) , Dec. 2, 2022, 136 Stat. 2258.
41501(11)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(3) (relating to practitioner), Dec. 2, 2022, 136 Stat. 2258.
41501(12)	21 U.S.C. 801 note	Pub. L. 117–215, §2(a)(7), Dec. 2, 2022, 136 Stat. 2258.

In paragraph (1), the words “with respect to an individual or entity,” are added for clarity.

Subchapter II—Registrations for Marijuana Research

SECTION 41511—ADEQUATE AND UNINTERRUPTED SUPPLY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41511	21 U.S.C. 823 note	Pub. L. 117–215, title I, §104, Dec. 2, 2022, 136 Stat. 2263.

SECTION 41512—SECURITY REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41512	21 U.S.C. 823 note	Pub. L. 117–215, title I, §105, Dec. 2, 2022, 136 Stat. 2264.

SECTION 41513—PROHIBITION AGAINST REINSTATING INTERDISCIPLINARY REVIEW PROCESS FOR NON-NIH-FUNDED RESEARCHERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41513	42 U.S.C. 241 note	Pub. L. 117–215, title I, §106, Dec. 2, 2022, 136 Stat. 2264.

Subchapter III—Development of Food and Drug Administration-Approved Drugs Using Cannabidiol and Marijuana

SECTION 41521—MEDICAL RESEARCH ON CANNABIDIOL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41521	21 U.S.C. 823 note	Pub. L. 117–215, title II, §201, Dec. 2, 2022, 136 Stat. 2264.

In this section, the words "the Safe and Drug-Free Schools and Communities Act (20 U.S.C. 7101 et seq.)" are omitted as obsolete. The Safe and Drug-Free Schools and Communities Act, as enacted by section 401 of the No Child Left Behind Act of 2001 (Public Law 107–110, 115 Stat. 1734), was formerly part A of title IV of Public Law 89–10 and was classified to 20 U.S.C. 7101 et seq., until the general amendment of that part A by title IV of the Every Student Succeeds Act (Public Law 114–95, 129 Stat. 1966), which made the reference to the Safe and Drug-Free Schools and Communities Act (20 U.S.C. 7101 et seq.) obsolete.

SECTION 41522—REGISTRATION FOR THE COMMERCIAL PRODUCTION AND DISTRIBUTION OF FDA-APPROVED DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41522	21 U.S.C. 823 note	Pub. L. 117–215, title II, §202, Dec. 2, 2022, 136 Stat. 2264.

Subchapter IV—Doctor-Patient Relationship

SECTION 41531—DISCUSSING HARMS AND BENEFITS OF MARIJUANA AND MARIJUANA DERIVATIVES AS A TREATMENT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41531	21 U.S.C. 801 note	Pub. L. 117–215, title III, §301, Dec. 2, 2022, 136 Stat. 2265.

Subchapter V—Federal Research

SECTION 41541—FEDERAL RESEARCH

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
41541	42 U.S.C. 284 note	Pub. L. 117–215, title IV, §401, Dec. 2, 2022, 136 Stat. 2265.

In subsection (a)(3)(B)(ii), the words "that the levels of tetrahydrocannabinol, cannabidiol, or other cannabinoids . . . are accurate" are substituted for "the levels of tetrahydrocannabinol, cannabidiol, or other cannabinoids . . . is accurate" for clarity.

Chapters 417 Through 493—Reserved

Chapter 495—Miscellaneous

SECTION 49501—REVISION OF UNITED STATES PHARMACOPEIA; DEVELOPMENT OF ANALYSIS AND MECHANICAL AND PHYSICAL TESTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49501	21 U.S.C. 377	July 12, 1943, ch. 221, title II, matter after 5th semicolon (from "and the Administrator" through "Food and Drug Administration") under heading "Enforcement operations:", 57 Stat. 500.

In this section, the words "The Secretary of Health and Human Services" are substituted for "the Administrator" because of Reorganization Plan No. 1 of 1953 (42 U.S.C. 3501 note) and section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

In this section, the word "hereafter" is omitted as obsolete.

SECTION 49502—GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49502(a)(1)	21 U.S.C. 360ee(b)(3)	Pub. L. 97–414, §5(b)(3), as added Pub. L. 100–290, §3(b)(3), Apr. 18, 1988, 102 Stat. 91.
49502(a)(2)	21 U.S.C. 360ee(b)(1)	Pub. L. 97–414, §5(b)(1), Jan. 4, 1983, 96 Stat. 2056; Pub. L. 99–91, §5(a)(2), Aug. 15, 1985, 99 Stat. 391; Pub. L. 105–115, title I, §125(b)(2)(N), Nov. 21, 1997, 111 Stat. 2326; Pub. L. 112–144, title IX, §906(a), July 9, 2012, 126 Stat. 1092; Pub. L. 114–255, div. A, title III, §3015(2), Dec. 13, 2016, 130 Stat. 1094.
49502(a)(3)	21 U.S.C. 360ee(b)(2)	Pub. L. 97–414, §5(b)(2), Jan. 4, 1983, 96 Stat. 2056; Pub. L. 98–551, §4(b), Oct. 30, 1984, 98 Stat. 2817; Pub. L. 100–290, §3(a)(2), (b)(2), Apr. 18, 1988, 102 Stat. 91.
49502(b), (c)	21 U.S.C. 360ee(a), (c)	Pub. L. 97–414, §5(a), (c), Jan. 4, 1983, 96 Stat. 2056; Pub. L. 99–91, §5(a)(1), (b), Aug. 15, 1985, 99 Stat. 391; Pub. L. 100–290, §3(a)(1), (b)(1), (c), Apr. 18, 1988, 102 Stat. 90, 91; Pub. L. 107–281, § 3, Nov. 6, 2002, 116 Stat. 1993; Pub. L. 110–85, title XI, § 1112(b), Sept. 27, 2007, 121 Stat. 976; Pub. L. 112–144, title IX, §906(b), July 9, 2012, 126 Stat. 1092; Pub. L. 114–255, div. A, title III, §3015(1),

SECTION 49502—GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Dec. 13, 2016, 130 Stat. 1094; Pub. L. 115–52, title VI, §603, Aug. 18, 2017, 131 Stat. 1048; Pub. L. 117–180, div. F, title V, §5006, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, §307, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3107, Dec. 29, 2022, 136 Stat. 5808.

In subsection (b), the words "Secretary of Health and Human Services" are substituted for "Secretary" for clarity.

In subsection (c), the words "$30,000,000 for each of fiscal years 2023 through 2027" are substituted for "$6,904,110 for the period beginning on October 1, 2022 and ending on December 23, 2022" to reflect the amendment made by section 3107(2) of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5808). That section 3107(2) struck "$6,328,767 for the period beginning on October 1, 2022, and ending on December 23, 2022", which no longer appeared in the law at the time of enactment of that section because of the intervening amendment made by section 307 of the Further Continuing Appropriations and Extensions Act, 2023 (Public Law 117–229, 136 Stat. 2312), which struck the same words and inserted "$6,904,110 for the period beginning on October 1, 2022 and ending on December 23, 2022".

SECTION 49503—ADVERSE-EVENT REPORTING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49503	21 U.S.C. 355b (except (a)(3))	Pub. L. 107–109, §17 (except (a)(3)), Jan. 4, 2002, 115 Stat. 1422; Pub. L. 108–155, §3(b)(5), Dec. 3, 2003, 117 Stat. 1942.

In subsection (a)(1), the words "Not later than one year after the date of the enactment of this Act," are omitted as obsolete.

In subsection (a)(1), the words "Secretary of Health and Human Services (referred to in this section as the 'Secretary')" are substituted for "Secretary of Health and Human Services" for clarity. Throughout the rest of the section, the word "Secretary" is substituted for the words "Secretary of Health and Human Services" each place they appear because of the parenthetical "(referred to in this section as the 'Secretary')".

In subsection (a)(2), in the matter before subparagraph (A), the words "With respect to the final rule:" are omitted as unnecessary.

In subsection (b)(1)(A), the words "established under section 6 of this Act" are omitted as unnecessary and for consistency in title 21, United States Code.

In subsection (b)(1)(B), the words "recommendations of the Pediatric Advisory Committee" are substituted for "recommendations of such subcommittee" for consistency in the subparagraph.

SECTION 49504—ACCELERATED APPROVAL OF PRIORITY COUNTERMEASURES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49504(a)	(no source)	
49504(b) through (d) ...	21 U.S.C. 356–1(a) through (c)	Pub. L. 107–188, title I, §122(a) through (c) , June 12, 2002, 116 Stat. 613.

In this section, subsection (a) is added to carry forward section 122(d) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (21 U.S.C. 356–1)(d)). See section 4(12)(B) of the bill enacting title 21, United States Code, which makes a conforming amendment to section 122 of the Act; the amendment is made because of the restatement (and repeal by the bill) of subsections (a) through (c) of section 122 of the Act.

In subsection (a)(1), the words "section 319F(e)(4) of the Public Health Service Act (42 U.S.C. 247d–6(e)(4))" are substituted for "section 319F(h)(4) of the Public Health Service Act" to provide the correct reference to the pertinent provision and to execute the redesignation made by section 304(3) of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417, 120 Stat. 2861).

In subsection (b)(1), the words "or as a device granted review priority pursuant to section 515(d)(5) of such Act (21 U.S.C. 360e(d)(5))" are omitted as obsolete because paragraph (5) of section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)), as in effect prior to the enactment of the 21st Century Cures Act (Public Law 114–255, 130 Stat. 1033), was struck by section 3051(c)(1) of that Act (Public Law 114–255, 130 Stat. 1124).

SECTION 49505—EFFECT OF PROVISIONS ON DRUGS USED BY LICENSED VETERINARIANS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49505	21 U.S.C. 355 note	Pub. L. 110–85, title IX, §907, Sept. 27, 2007, 121 Stat. 950.

In this section, references to sections 13311(f)(2) and 13512(f) of title 21, United States Code, are omitted as unnecessary and for convenience, even though their source provisions are sections 901(d)(3)(B) and 905(b), respectively, of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 121 Stat. 940, 949), both of which are in subtitle A of title IX of that Act. Neither provision purports to have any effect on the use of the drugs described in this section.

SECTION 49506—REPORTS RELATING TO PEDIATRIC USES OF DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49506	21 U.S.C. 355c–1	Pub. L. 112–144, title V, §508, July 9, 2012, 126 Stat. 1045; Pub. L. 115–52, title V, §504(d), Aug. 18, 2017, 131 Stat. 1044.

In subsection (a), the words "Secretary of Health and Human Services (referred to in this section as the 'Secretary')" are substituted for "Secretary" on authority of the words "Secretary of Health and Human Services (referred to in this title as the 'Secretary')" in section 503 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144, 126 Stat. 1040).

In subsection (b)(12), in the matter before subparagraph (A), the words "developed under section 505(c) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1046)" are substituted for "developed under section 505C–1 of the Federal Food, Drug, and Cosmetic Act" to provide the correct reference to the pertinent provision. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) does not contain any provision designated as section 505C–1. Section 505(c) of the FDA Reauthorization Act of 2017 (Public Law 115–52, 131 Stat. 1046) contains provisions relating to a plan regarding earlier submission of pediatric studies.

In subsection (b)(15), the words "the number of requests under section 13112 of this title for molecular targeted cancer drugs (as defined by subsection (a)(1)(B) of section 13116 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" are substituted for "how many requests under such section 505A for molecular targeted cancer drugs, as defined by subsection (a)(1)(B) of such section 505B, approved prior to 3 years after the date of enactment of the FDA Reauthorization Act of 2017, have been issued by the Food and Drug Administration, and how many such requests have been completed; and" for clarity and for consistency in the subsection.

SECTION 49507—REPORT ON RECLASSIFICATION OF DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49507	21 U.S.C. 360c–1	Pub. L. 112–144, title VI, § 608(c), July 9, 2012, 126 Stat. 1059.

SECTION 49508—CLINICAL TRIALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49508(a)	21 U.S.C. 360a–1(c)	Pub. L. 112–144, title VIII, §804(c), July 9, 2012, 126 Stat. 1080.
49508(b), (c)	21 U.S.C. 360a–1(a), (b)	Pub. L. 112–144, title VIII, §804(a), (b), July 9, 2012, 126 Stat. 1080.

SECTION 49509—COMMUNICATION PLAN RELATING TO BENEFITS AND RISKS OF MEDICAL PRODUCTS PARTICULARLY ON UNDERREPRESENTED POPULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49509	21 U.S.C. 399f (except (c)(1))	Pub. L. 112–144, title XI, §1138 (except (c)(1)), July 9, 2012, 126 Stat. 1125.

SECTION 49510—ENHANCED COMMUNICATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49510	21 U.S.C. 353a–1	Pub. L. 113–54, title I, § 105, Nov. 27, 2013, 127 Stat. 597.

SECTION 49511—RECOMMENDATIONS REGARDING EDUCATION PROGRAMS FOR PRESCRIBERS OF OPIOIDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49511	21 U.S.C. 355–1 note	Pub. L. 114–198, title I, §106(b), July 22, 2016, 130 Stat. 703.

In this section, in the matter before paragraph (1), the words "Not later than 1 year after the date of the enactment of this Act," are omitted as obsolete.

In this section, in the matter before paragraph (1), the words "Secretary of Health and Human Services" are substituted for "Secretary" on authority of the words "Secretary of Health and Human Services (referred to in this section as the 'Secretary')" in section 106(a)(1)(A) of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198, 130 Stat. 702).

SECTION 49512—NATIONAL CENTERS OF EXCELLENCE IN ADVANCED AND CONTINUOUS PHARMACEUTICAL MANUFACTURING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49512(a)(1) through (3)	21 U.S.C. 399h(h)(1) through (3)	Pub. L. 114–255, div. A, title III, §3016(h)(1) through (3), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5819.
49512(a)(4)	(no source)	
49512(a)(5), (6)	21 U.S.C. 399h(h)(4), (5)	Pub. L. 114–255, div. A, title III, §3016(h)(4), (5), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5819.
49512(b)	21 U.S.C. 399h(a)	Pub. L. 114–255, div. A, title III, §3016(a), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5815.
49512(c)	21 U.S.C. 399h(b)	Pub. L. 114–255, div. A, title III, §3016(b), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5816.
49512(d)	21 U.S.C. 399h(c)	Pub. L. 114–255, div. A, title III, §3016(c), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5816.
49512(e)	21 U.S.C. 399h(d)	Pub. L. 114–255, div. A, title III, §3016(d), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5816.
49512(f)	21 U.S.C. 399h(e)	Pub. L. 114–255, div. A, title III, §3016(e), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5817.
49512(g)	21 U.S.C. 399h(f)	Pub. L. 114–255, div. A, title III, §3016(f), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5817.
49512(h)	21 U.S.C. 399h(g)	Pub. L. 114–255, div. A, title III, §3016(g), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5818.
49512(i)	21 U.S.C. 399h(i)	Pub. L. 114–255, div. A, title III, §3016(i), Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117–328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5819.

In subsection (a)(1), in the matter before subparagraph (A), the words "refers to a method, or a combination of methods, of pharmaceutical manufacturing, which method or combination—" are substituted for "refers to a method of pharmaceutical manufacturing, or a combination of pharmaceutical manufacturing methods—" for clarity.

In subsection (a)(3), the words "section 10101(a)(18) of this title" are substituted for "section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))" to provide a more precise reference to the pertinent provision.

In subsection (a)(4), a definition of "FDA" is added for convenience.

In subsection (i)(1), the words "for fiscal years 2026 and 2027" are substituted for "for the period of fiscal years 2023 through 2027" to eliminate obsolete words.

SECTION 49513—VARIATIONS FROM CURRENT GOOD MANUFACTURING PRACTICES RELATING TO COMBINATION PRODUCTS AND MANUFACTURING PROCESSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49513	21 U.S.C. 355 note	Pub. L. 114–255, div. A, title III, §3038(c), Dec. 13, 2016, 130 Stat. 1110.

In subsection (a), in the matter before paragraph (1), the words "proposes that good manufacturing practices" are substituted for "proposes that good manufacturing processes" for consistency in the section.

SECTION 49514—REPORT RELATING TO SOFTWARE FUNCTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49514	21 U.S.C. 360j note	Pub. L. 114–255, div. A, title III, §3060(b), Dec. 13, 2016, 130 Stat. 1132.

SECTION 49515—PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49515	21 U.S.C. 360bbb–4 note	Pub. L. 114–255, div. A, title III, §3091, Dec. 13, 2016, 130 Stat. 1149.

SECTION 49516—REGULATIONS RELATING TO OVER-THE-COUNTER HEARING AIDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49516	21 U.S.C. 360j note	Pub. L. 115–52, title VII, §709(b), (c), Aug. 18, 2017, 131 Stat. 1066, 1067.

In subsection (a)(1), the words "shall issue final regulations to establish a category of over-the-counter hearing aids (as defined in section 13152(q) of this title)" are substituted for "not later than 3 years after the date of enactment of this Act, shall promulgate proposed regulations to establish a category of over-the-counter hearing aids, as defined in subsection (q) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) as amended by subsection (a), and, not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations" to eliminate obsolete words. See 87 Fed. Reg. 50698 (Aug. 17, 2022).

Subsection (b) is substituted for section 709(c) of the FDA Reauthorization Act of 2017 to eliminate obsolete words. See 87 Fed. Reg. 50568 (Aug. 17, 2022).

SECTION 49517—ANNUAL REPORT ON INSPECTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49517	21 U.S.C. 355 note	Pub. L. 115–52, title IX, §902, Aug. 18, 2017, 131 Stat. 1077; Pub. L. 117–328, div. FF, title III, §3617, Dec. 29, 2022, 136 Stat. 5876.

SECTION 49518—EXPEDITED DEVELOPMENT AND REVIEW OF MEDICAL PRODUCTS FOR EMERGENCY USES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49518	21 U.S.C. 360bbb–3c	Pub. L. 115–92, §1(b), Dec. 12, 2017, 131 Stat. 2023.

SECTION 49519—ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49519(a) through (c) ...	21 U.S.C. 355–2(a) through (c)	Pub. L. 116–94, div. N, title I, §610(a) through (c), Dec. 20, 2019, 133 Stat. 3130.
49519(d)	21 U.S.C. 355–2(e)	Pub. L. 116–94, div. N, title I, §610(e), Dec. 20, 2019, 133 Stat. 3136.
49519(e)	21 U.S.C. 355–2(g)	Pub. L. 116–94, div. N, title I, §610(g), Dec. 20, 2019, 133 Stat. 3137.

In subsection (a)(2)(A)(iii), the words "or otherwise to meet" are substituted for "or otherwise meet" for clarity.

In subsection (a)(9), the words "elements to ensure safe use" are substituted for the words "elements to assure safe use" each place they appear to use the more appropriate word.

In subsection (a)(10), in the matter before subparagraph (A), the words "allows the eligible product developer" are substituted for "allows it" for clarity.

In subsection (c), the words "to ensure safe use" are substituted for "to assure safe use" to use the more appropriate word.

In subsection (e), in the matter before paragraph (1), the words "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)" are substituted for "the amendments made by this section," for clarity.

SECTION 49520—RESOURCES REGARDING CYBERSECURITY OF DEVICES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49520(a)	(no source)	
49520(b)	21 U.S.C. 360n–2 note	Pub. L. 117–328, div. FF, title III, §3305(f), Dec. 29, 2022, 136 Stat. 5834.
49520(c)	21 U.S.C. 331 note	Pub. L. 117–328, div. FF, title III, §3305(c) (relating to subsection (f) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5834)), Dec. 29, 2022, 136 Stat. 5833.

Subsection (a) is added to carry forward the definition of "device" in section 3305(h) of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5834). In carrying forward the definition, the reference to "section 10101(a)(16) of this title" is substituted for "section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" to provide a more precise reference to the pertinent provision.

In subsection (b), in the matter before paragraph (1), the words "Secretary of Health and Human Services" are substituted for "Secretary" on authority of

section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

In subsection (c), the words "this section" are substituted for "this section, including the amendments made by this section," for clarity. The words "this section" in the source provision is retained, even though "this section" in the restatement refers only to the restatement of subsection (f) of section 3305 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5834), because the source provision is identically restated in other relevant provisions. See sections 10501(16)(C)(ii), 13158(e), and 29117(c) of title 21, United States Code, for identical provisions, except for the reference to "this section".

SECTION 49521—THIRD PARTY DATA TRANSPARENCY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49521	21 U.S.C. 360g–2	Pub. L. 117–328, div. FF, title III, §3307, Dec. 29, 2022, 136 Stat. 5834.

In subsection (a), in the matter before paragraph (1), the words "Secretary of Health and Human Services" are substituted for "Secretary" on authority of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 49522—ANNUAL SUMMARY REPORT ON PROGRESS TO INCREASE DIVERSITY IN CLINICAL STUDIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
49522	21 U.S.C. 355 note	Pub. L. 117–328, div. FF, title III, §3604, Dec. 29, 2022, 136 Stat. 5864.

In subsection (a), in the matter before paragraph (1), the words "Secretary of Health and Human Services" are substituted for "Secretary" on authority of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

Subtitle V—Comprehensive Drug Abuse Prevention and Control

Division A—Controlled Substances

Chapter 501—General Provisions

SECTION 50101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50101(1) through (3) ...	21 U.S.C. 802(1) through (3)	Pub. L. 91–513, title II, §102(1) through (3), Oct. 27, 1970, 84 Stat. 1242.
50101(4)	21 U.S.C. 802(41)	Pub. L. 91–513, title II, §102(41), as added Pub. L. 101–647, title XIX, §1902(b), Nov. 29, 1990, 104 Stat. 4852; Pub. L. 108–358, §2(a), Oct. 22, 2004, 118 Stat. 1661; Pub. L. 109–162, title XI, §1180, Jan. 5, 2006, 119 Stat. 3126; Pub. L. 113–260, §2(a), Dec. 18, 2014, 128 Stat. 2929.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50101(5)	21 U.S.C. 802(48)	Pub. L. 91–513, title II, §102(48), as added Pub. L. 109–177, title VII, §711(a)(1)(B), Mar. 9, 2006, 120 Stat. 257.
50101(6)	21 U.S.C. 802(43) (relating to broker)	Pub. L. 91–513, title II, §102(43) (relating to broker), as added Pub. L. 103–200, §2(a)(8), Dec. 17, 1993, 107 Stat. 2334.
50101(7)	21 U.S.C. 802(40)	Pub. L. 91–513, title II, §102(40), as added Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316; Pub. L. 103–200, §2(a)(7), Dec. 17, 1993, 107 Stat. 2333.
50101(8)	21 U.S.C. 802(5)	Pub. L. 91–513, title II, §102(5), Oct. 27, 1970, 84 Stat. 1243.
50101(9)	21 U.S.C. 802(6)	Pub. L. 91–513, title II, §102(6), Oct. 27, 1970, 84 Stat. 1243; Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095.
50101(10)	21 U.S.C. 802(32)	Pub. L. 91–513, title II, §102(32), as added Pub. L. 99–570, title I, §1203, Oct. 27, 1986, 100 Stat. 3207–13; Pub. L. 106–172, §5(a), Feb. 18, 2000, 114 Stat. 10.
50101(11)	21 U.S.C. 802(31) (matter before semicolon)	Pub. L. 91–513, title II, §102(31) (matter before semicolon), formerly §102(29) (matter before semicolon), formerly §102(30) (matter before semicolon), as added Pub. L. 95–633, title I, §102(b), Nov. 10, 1978, 92 Stat. 3772; redesignated §102(30) (matter before semicolon), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; redesignated §102(31) (matter before semicolon), Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.
50101(12)	21 U.S.C. 802(7)	Pub. L. 91–513, title II, §102(7), Oct. 27, 1970, 84 Stat. 1243.
50101(13)	21 U.S.C. 802(51)	Pub. L. 91–513, title II, §102(51), as added Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821.
50101(14)	21 U.S.C. 802(8)	Pub. L. 91–513, title II, §102(8), Oct. 27, 1970, 84 Stat. 1243; Pub. L. 100–690, title VI, §6054(1), Nov. 18, 1988, 102 Stat. 4316.
50101(15)	21 U.S.C. 802(9)	Pub. L. 91–513, title II, §102(9), Oct. 27, 1970, 84 Stat. 1243; Pub. L. 105–115, title I, §126(c)(3), Nov. 21, 1997, 111 Stat. 2328.
50101(16)	21 U.S.C. 802(30)	Pub. L. 91–513, title II, §102(30), formerly §102(28), formerly §102(29), as added Pub. L. 93–281, §2, May 14, 1974, 88 Stat. 124; redesignated §102(29), Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 98–509, title III, §301(a), Oct. 19, 1984, 98 Stat. 2364; redesignated §102(30), Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.
50101(17)	21 U.S.C. 802(10)	Pub. L. 91–513, title II, §102(10), Oct. 27, 1970, 84 Stat. 1243.
50101(18)	21 U.S.C. 802(11)	Pub. L. 91–513, title II, §102(11), Oct. 27, 1970, 84 Stat. 1243; Pub. L. 100–690, title VI, §6054(2), Nov. 18, 1988, 102 Stat. 4316.
50101(19)	21 U.S.C. 802(12)	Pub. L. 91–513, title II, §102(12), Oct. 27, 1970, 84 Stat. 1244.
50101(20)	21 U.S.C. 802(4)	Pub. L. 91–513, title II, §102(4), Oct. 27, 1970, 84 Stat. 1243; Pub. L. 96–132, §16(a), Nov. 30, 1979, 93 Stat. 1049.
50101(21)	21 U.S.C. 802(13)	Pub. L. 91–513, title II, §102(13), Oct. 27, 1970, 84 Stat. 1244.
50101(22)	21 U.S.C. 802(44)	Pub. L. 91–513, title II, §102(44), as added Pub. L. 103–322, title IX, §90105(d), Sept. 13, 1994, 108 Stat. 1988; Pub. L. 104–237, title IV, §401(b)(3), Oct. 3, 1996, 110 Stat. 3107; Pub. L. 104–294, title VI, §§604(b)(4), 607(j)(2), Oct. 11, 1996, 110 Stat. 3506, 3512; Pub. L. 107–273, div. B, title IV, §4002(c)(1), Nov. 2, 2002, 116 Stat. 1808; Pub. L. 108–358, §2(a)(2), Oct. 22, 2004, 118 Stat. 1661.
50101(23)	21 U.S.C. 802(60)	Pub. L. 91–513, title II, §102(60), as added Pub. L. 119–26, §6(c), July 16, 2025, 139 Stat. 418.
50101(24)	21 U.S.C. 802(56)	Pub. L. 91–513, title II, §102(56), as added Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821.

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50101(25)	21 U.S.C. 802(53)	Pub. L. 91–513, title II, §102(53), as added Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821.
50101(26)	21 U.S.C. 802(23)	Pub. L. 91–513, title II, §102(23), formerly §102(22), Oct. 27, 1970, 84 Stat. 1245; redesignated §102(23), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071.
50101(27)	21 U.S.C. 802(42)	Pub. L. 91–513, title II, §102(42), as added Pub. L. 103–200, §2(a)(8), Dec. 17, 1993, 107 Stat. 2334.
50101(28)	21 U.S.C. 802(50)	Pub. L. 91–513, title II, §102(50), as added Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821.
50101(29)	21 U.S.C. 802(14)	Pub. L. 91–513, title II, §102(14), as added Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 99–570, title I, §1870, Oct. 27, 1986, 100 Stat. 3207–56; Pub. L. 99–646, §83, Nov. 10, 1986, 100 Stat. 3619.
50101(30)	21 U.S.C. 802(34)	Pub. L. 91–513, title II, §102(34), as added Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316; Pub. L. 101–647, title XXIII, §2301, Nov. 29, 1990, 104 Stat. 4858; Pub. L. 103–200, §§2(a)(2), 8, Dec. 17, 1993, 107 Stat. 2333, 2340; Pub. L. 103–322, title XXXIII, §330024(b), Sept. 13, 1994, 108 Stat. 2150; Pub. L. 104–237, title II, §209(1), Oct. 3, 1996, 110 Stat. 3104; Pub. L. 106–172, §3(c), Feb. 18, 2000, 114 Stat. 9.
50101(31)	21 U.S.C. 802(35)	Pub. L. 91–513, title II, §102(35), as added Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316; Pub. L. 103–200, §2(a)(4), Dec. 17, 1993, 107 Stat. 2333; Pub. L. 103–322, title XXXIII, §330024(d)(1), Sept. 13, 1994, 108 Stat. 2150; Pub. L. 104–237, title II, §§204(a), 209(2), Oct. 3, 1996, 110 Stat. 3102, 3104.
50101(32)	21 U.S.C. 802(33)	Pub. L. 91–513, title II, §102(33), as added Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316; Pub. L. 103–200, §2(a)(1), Dec. 17, 1993, 107 Stat. 2333.
50101(33)	21 U.S.C. 802(29)	Pub. L. 91–513, title II, §102(29), formerly §102(27), formerly §102(28), as added Pub. L. 93–281, §2, May 14, 1974, 88 Stat. 124; redesignated §102(28), Pub. L. 98–473, title II, § 507(a), (b), Oct. 12, 1984, 98 Stat. 2071; redesignated §102(29), Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.
50101(34)	21 U.S.C. 802(15)	Pub. L. 91–513, title II, §102(15), formerly §102(14), Oct. 27, 1970, 84 Stat. 1244; redesignated §102(15), Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071.
50101(35)	21 U.S.C. 802(16)	Pub. L. 91–513, title II, §102(16), formerly §102(15), Oct. 27, 1970, 84 Stat. 1244; redesignated §102(16), Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 115–334, title XII, §12619(a), Dec. 20, 2018, 132 Stat. 5018.
50101(36)	21 U.S.C. 802(47)	Pub. L. 91–513, title II, §102(47), as added Pub. L. 109–177, title VII, §711(a)(1)(B), Mar. 9, 2006, 120 Stat. 257.
50101(37)	21 U.S.C. 802(17)	Pub. L. 91–513, title II, §102(17), formerly §102(16), Oct. 27, 1970, 84 Stat. 1244; redesignated §102(17), Pub. L. 98–473, title II, § 507(a), (b), Oct. 12, 1984, 98 Stat. 2071.
50101(38)	21 U.S.C. 802(52)	Pub. L. 91–513, title II, §102(52), as added Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821; Pub. L. 117–215, title I, §103(b)(1)(A)(i), Dec. 2, 2022, 136 Stat. 2262.
50101(39)	21 U.S.C. 802(18)	Pub. L. 91–513, title II, §102(18), formerly §102(17), Oct. 27, 1970, 84 Stat. 1244; redesignated §102(18), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 114–198, title III, §303(a)(2), July 22, 2016, 130 Stat. 722.
50101(40)	21 U.S.C. 802(19)	Pub. L. 91–513, title II, §102(19), formerly §102(18), Oct. 27, 1970, 84 Stat. 1244; redesignated §102(19), Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50101(41)	21 U.S.C. 802(20)	Pub. L. 91–513, title II, §102(20), formerly §102(19), Oct. 27, 1970, 84 Stat. 1244; redesignated §102(20), Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071.
50101(42)	21 U.S.C. 802(54)	Pub. L. 91–513, title II, §102(54), as added Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821; Pub. L. 117–215, title I, §103(b)(1)(A)(ii), Dec. 2, 2022, 136 Stat. 2262.
50101(43)	21 U.S.C. 802(21)	Pub. L. 91–513, title II, §102(21), formerly §102(20), Oct. 27, 1970, 84 Stat. 1244; redesignated §102(21), Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071.
50101(44)	21 U.S.C. 802(22)	Pub. L. 91–513, title II, §102(22), formerly §102(21), Oct. 27, 1970, 84 Stat. 1245; redesignated §102(22), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071.
50101(45)	21 U.S.C. 802(55)	Pub. L. 91–513, title II, §102(55), as added Pub. L. 110–425, §3(a), Oct. 15, 2008, 122 Stat. 4821.
50101(46)	21 U.S.C. 802(36)	Pub. L. 91–513, title II, §102(36), Oct. 27, 1970, Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316.
50101(47)	21 U.S.C. 802(37)	Pub. L. 91–513, title II, §102(37), as added Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316; Pub. L. 103–200, §9(a), Dec. 17, 1993, 107 Stat. 2340.
50101(48)	21 U.S.C. 802(38)	Pub. L. 91–513, title II, §102(38), as added Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316; Pub. L. 103–200, §2(a)(5), Dec. 17, 1993, 107 Stat. 2333.
50101(49)	21 U.S.C. 802(46)	Pub. L. 91–513, title II, §102(46), as added Pub. L. 109–177, title VII, §711(a)(1)(B), Mar. 9, 2006, 120 Stat. 257.
50101(50)	21 U.S.C. 802(39)	Pub. L. 91–513, title II, §102(39), as added Pub. L. 100–690, title VI, §6054(3), Nov. 18, 1988, 102 Stat. 4316; Pub. L. 103–200, §§2(a)(6), 7, Dec. 17, 1993, 107 Stat. 2333, 2340; Pub. L. 103–322, title XXXIII, §330024(a), Sept. 13, 1994, 108 Stat. 2150; Pub. L. 104–237, title IV, §401(a), (b)(1), (2), Oct. 3, 1996, 110 Stat. 3106, 3107; Pub. L. 106–310, div. B, title XXXVI, §3622(a), Oct. 17, 2000, 114 Stat. 1231; Pub. L. 109–177, title VII, §712(a)(1)(A), Mar. 9, 2006, 120 Stat. 263.
50101(51)	21 U.S.C. 802(49)	Pub. L. 91–513, title II, §102(49), formerly §102(46), as added Pub. L. 104–237, title IV, §401(b)(4), Oct. 3, 1996, 110 Stat. 3107; redesignated §102(49), Pub. L. 109–177, title VII, §711(a)(1)(A), (2)(A), Mar. 9, 2006, 120 Stat. 256, 257.
50101(52)	21 U.S.C. 802(45)	Pub. L. 91–513, title II, §102(45), as added Pub. L. 109–177, title VII, §711(a)(1)(B), Mar. 9, 2006, 120 Stat. 257.
50101(53)	21 U.S.C. 802(24)	Pub. L. 91–513, title II, §102(24), formerly §102(23), Oct. 27, 1970, 84 Stat. 1245; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; redesignated §102(24), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; Pub. L. 115–271, title III, §3202(c), Oct. 24, 2018, 132 Stat. 3945.
50101(54)	21 U.S.C. 802(25)	Pub. L. 91–513, title II, §102(25), as added Pub. L. 99–570, title I, §1003(b)(1), Oct. 27, 1986, 100 Stat. 3207–6.
50101(55)	21 U.S.C. 802(58)	Pub. L. 91–513, title II, §102(58), as added Pub. L. 115–391, title IV, §401(a)(1), Dec. 21, 2018, 132 Stat. 5220; Pub. L. 118–189, §1(2), (3), Dec. 23, 2024, 138 Stat. 2652.
50101(56)	21 U.S.C. 802(59)	Pub. L. 91–513, title II, §102(59), as added Pub. L. 115–391, title IV, §401(a)(1), Dec. 21, 2018, 132 Stat. 5220; Pub. L. 118–189, §1(1), (3), Dec. 23, 2024, 138 Stat. 2652.
50101(57)	21 U.S.C. 802(31) (matter after semicolon)	Pub. L. 91–513, title II, §102(31) (matter after semicolon), formerly §102(29) (matter after semicolon), formerly §102(30) (matter after semicolon), as added Pub. L. 95–633, title I, §102(b), Nov. 10, 1978, 92 Stat. 3772; redesignated

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§102(30) (matter after semicolon), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; redesignated §102(31) (matter after semicolon), Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.
50101(58)	21 U.S.C. 802(26)	Pub. L. 91–513, title II, §102(26), formerly §102(24), formerly §102(25), Oct. 27, 1970, 84 Stat. 1245; redesignated §102(25), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; redesignated §102(26), Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6; Pub. L. 104–294, title VI, §607(j)(1), Oct. 11, 1996, 110 Stat. 3512.
50101(59)	21 U.S.C. 802(57)	Pub. L. 91–513, title II, §102(57), as added Pub. L. 115–271, title III, §3292(a), Oct. 24, 2018, 132 Stat. 3956; Pub. L. 118–189, §1(3), Dec. 23, 2024, 138 Stat. 2652.
50101(60)	21 U.S.C. 802(43) (relating to trader)	Pub. L. 91–513, title II, §102(43) (relating to trader), as added Pub. L. 103–200, §2(a)(8), Dec. 17, 1993, 107 Stat. 2334.
50101(61)	21 U.S.C. 802(27)	Pub. L. 91–513, title II, §102(27), formerly §102(25), formerly §102(26), Oct. 27, 1970, 84 Stat. 1245; redesignated §102(26), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; redesignated §102(27), Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.
50101(62)	21 U.S.C. 802(28)	Pub. L. 91–513, title II, §102(28), formerly §102(26), formerly §102(27), Oct. 27, 1970, 84 Stat. 1245; redesignated §102(27), Pub. L. 98–473, title II, §507(a), Oct. 12, 1984, 98 Stat. 2071; redesignated §102(28), Pub. L. 99–570, title I, §1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.

In paragraph (3)(A), the words "when referring to an agent of a manufacturer, distributor, or dispenser," are added for clarity because in certain provisions of division A of subtitle V of title 21, United States Code, the term "agent" is used in a manner that does not refer to an agent of a manufacturer, distributor, or dispenser. See, e.g., sections 50101(2)(A) and 50911(d)(3) of title 21, United States Code.

In paragraph (4)(E)(i), in the matter before subclause (I), the words "listed in subparagraph (B)" are substituted for the words "listed in subparagraph (A)" each place they appear to provide a more precise reference to the pertinent provision. Subparagraph (A) of section 102(41) of the Controlled Substances Act (21 U.S.C. 802(41)) is restated as subparagraphs (A) through (C) of section 50101(4) of title 21, United States Code. The provision in subparagraph (A) of section 102(41) of the Act relating to a list is restated as subparagraph (B) of section 50101(4) of title 21, United States Code.

In paragraph (4)(E)(i), in the matter before subclause (I), the words "for purposes of this division" are substituted for "for purposes of this Act" to provide a more precise reference to the pertinent provision and for consistency in the section. The reference to "this division" in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.), not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236). In the matter before subclause (I), the definition of "anabolic steroid" applies only to "this division".

In paragraph (14), the words "The term 'delivery' means" are substituted for "The terms 'deliver' or 'delivery' mean" because it is not necessary to define the term in more than 1 part of speech.

In paragraph (16), the amendment made by section 301(a) of the Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984 (Public Law 98–509, 98 Stat. 2364), which substituted the words "one hundred and eighty" for "twenty-one", was executed to the source provision of paragraph (16), which is paragraph (30) of section 102 of the Controlled Substances Act (21 U.S.C. 802(30)). Though the amendment directed the substitution to be made to paragraph (28) of that section 102, the restatement executes the amendment as if the amendment was made to paragraph (29) of that section 102 (subsequently redesignated as paragraph (30) by section 1003(b)(2) of the Narcotics Penalties and Enforcement Act of 1986 (Public Law 99–570, 100 Stat. 3207–6)) to reflect the intent of Congress. See H.R. Rep. No. 98–1123, at 28 (1984) (Conf. Rep.) ("The Conference Agreement incorporates the House provisions amending the Controlled Substances Act to revise the definition of 'detoxification treatment' as it applies to the treatment of heroin addiction. The amendment would extend from 28 [sic] to 180 days the maximum period a patient may participate in a detoxification program.").

In paragraph (42), in the matter before subparagraph (A), the words "for purposes of this title" are omitted as unnecessary.

In paragraph (61), the word "individual" is substituted for "person" for clarity and consistency with section 1 of title 1, United States Code.

SECTION 50102—CONGRESSIONAL FINDINGS AND DECLARATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50102	21 U.S.C. 801	Pub. L. 91–513, title II, § 101, Oct. 27, 1970, 84 Stat. 1242.

Chapter 503—Authority To Control; Standards and Schedules

SECTION 50301—AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50301(a)	21 U.S.C. 811(a)	Pub. L. 91–513, title II, § 201(a), Oct. 27, 1970, 84 Stat. 1245.
50301(b)	21 U.S.C. 811(b)	Pub. L. 91–513, title II, § 201(b), Oct. 27, 1970, 84 Stat. 1246.
50301(c)	21 U.S.C. 811(c)	Pub. L. 91–513, title II, § 201(c), Oct. 27, 1970, 84 Stat. 1246.
50301(d)	21 U.S.C. 811(d)	Pub. L. 91–513, title II, §201(d), Oct. 27, 1970, 84 Stat. 1246; Pub. L. 95–633, title I, §102(a), Nov. 10, 1978, 92 Stat. 3769; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.
50301(e)	21 U.S.C. 811(e)	Pub. L. 91–513, title II, §201(e), Oct. 27, 1970, 84 Stat. 1246.
50301(f)	21 U.S.C. 811(f)	Pub. L. 91–513, title II, §201(f), Oct. 27, 1970, 84 Stat. 1247.
50301(g)	21 U.S.C. 811(g)	Pub. L. 91–513, title II, §201(g), Oct. 27, 1970, 84 Stat. 1247; Pub. L. 98–473, title II, §509(a), Oct. 12, 1984, 98 Stat. 2072; Pub. L. 108–358, §2(b), Oct. 22, 2004, 118 Stat. 1663.
50301(h)	21 U.S.C. 811(h)	Pub. L. 91–513, title II, §201(h), as added Pub. L. 98–473, title II, §508, Oct. 12, 1984, 98 Stat. 2071; Pub. L. 112–144, title XI, §1153, July 9, 2012, 126 Stat. 1132.
50301(i)	21 U.S.C. 811(i)	Pub. L. 91–513, title II, §201(i), as added Pub. L. 113–260, § 2(b), Dec. 18, 2014, 128 Stat. 2930.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50301(j)	21 U.S.C. 811(j)	Pub. L. 91–513, title II, §201(j), as added Pub. L. 114–89, §2(b), Nov. 25, 2015, 129 Stat. 700.

In subsection (d)(1), in the matter before subparagraph (A), the words "considers most appropriate" are substituted for "deems most appropriate" to use the more appropriate word.

In subsection (d)(3)(A), the words "to apply the more stringent controls" are substituted for "to apply to such controls" for clarity.

In subsection (d)(3)(C)(i), the words "if the Secretary determines" are substituted for "if the Secretary deems" to use the more appropriate word.

In subsection (d)(4)(A)(ii), the words "that the Attorney General finds is not required" are substituted for "which he finds is not required" for clarity.

In subsection (d)(4)(B)(iii)(I)(aa), the words "scheduling decision is reversed" are substituted for "decision is reversed" for clarity.

In subsection (d)(4)(B)(iii)(I)(bb), the words "subject to the scheduling decision" are substituted for "subject to such decision" for clarity.

In subsection (d)(4)(B)(iii)(II), the words "of the decision to reverse under subclause (I)(aa)" are substituted for "of the review decision" for clarity.

In subsection (d)(4)(B)(iv), the words "the order issued under this subparagraph" are substituted for "the order issued under this paragraph" to provide a more precise reference to the pertinent provision.

In subsection (g)(1), the words "application of this division and division B" are substituted for "application of titles II and III of the Comprehensive Drug Abuse Prevention and Control Act (21 U.S.C. 801 et seq.)" for clarity. The reference to "this division" in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.), which was enacted as title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.). The reference to "division B" in the restatement refers to restated provisions of the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), which was enacted as part A of title III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 951 et seq.).

In subsection (g)(2), the words "after the date of such enactment" are omitted as obsolete.

In subsection (g)(2), the words "pursuant to subsections (a) through (f)" are substituted for "pursuant to the foregoing provisions of this section" for clarity.

In subsection (g)(3)(A), the words "that are included in a schedule" are substituted for "which are included therein" for clarity.

In subsection (j)(3), the words "for the regulation" are substituted for "therefor" for clarity.

SECTION 50302—SCHEDULES OF CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50302	21 U.S.C. 812	Pub. L. 91–513, title II, § 202, Oct. 27, 1970, 84 Stat. 1247; Pub. L. 95–633, title I, § 103, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, §§ 507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub. L. 99–570, title I, § 1867, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, § 84, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 101–647, title XIX, § 1902(a), Nov. 29, 1990, 104 Stat. 4851; Pub. L. 112–144, title XI, § 1152, July 9, 2012, 126 Stat. 1130; Pub. L. 115–334, title XII, §12619(b), Dec. 20, 2018, 132 Stat. 5018; Pub. L. 119–26, §2, July 16, 2025, 139 Stat. 410.

In subsection (a)(3), the words "The schedules established by this section shall be updated and republished on an annual basis" are substituted for "The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after the date of enactment of this title and shall be updated and republished on an annual basis thereafter" to eliminate obsolete words.

In subsection (c)(1)(A)(iii), the word "Alphacetylmethadol" is substituted for "Alphacetylmathadol" to provide the commonly used spelling of the term.

In subsection (c)(2)(A)(ii), the words "preparation of the salt, compound, or derivative" are substituted for "preparation thereof" for clarity.

SECTION 50303—TREATMENT OF CONTROLLED SUBSTANCE ANALOGUES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50303	21 U.S.C. 813	Pub. L. 91–513, title II, § 203, as added Pub. L. 99–570, title I, § 1202, Oct. 27, 1986, 100 Stat. 3207–13; amended Pub. L. 100–690, title VI, § 6470(c), Nov. 18, 1988, 102 Stat. 4378; Pub. L. 115–271, title III, §3241, Oct. 24, 2018, 132 Stat. 3950.

SECTION 50304—REMOVAL OF EXEMPTION OF CERTAIN DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50304	21 U.S.C. 814	Pub. L. 91–513, title II, § 204, as added Pub. L. 103–200, § 2(b)(1), Dec. 17, 1993, 107 Stat. 2334; amended Pub. L. 104–237, title IV, § 401(c), Oct. 3, 1996, 110 Stat. 3108; Pub. L. 109–177, title VII, § 712(a)(2), Mar. 9, 2006, 120 Stat. 263.

Chapter 505—Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

SECTION 50501—RULES AND REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50501	21 U.S.C. 821	Pub. L. 91–513, title II, § 301, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 103–200, § 3(a), Dec. 17, 1993, 107

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Stat. 2336; Pub. L. 108–447, div. B, title VI, § 633(b), Dec. 8, 2004, 118 Stat. 2922.

SECTION 50502—PERSONS REQUIRED TO REGISTER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50502 (except (g)(5)) ..	21 U.S.C. 822 (except (g)(5))	Pub. L. 91–513, title II, §302 (except (g)(5)), Oct. 27, 1970, 84 Stat. 1253; Pub. L. 98–473, title II, § 510, Oct. 12, 1984, 98 Stat. 2072; Pub. L. 103–200, § 3(b), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 111–273, § 3(a), Oct. 12, 2010, 124 Stat. 2859; Pub. L. 113–143, § 2, Aug. 1, 2014, 128 Stat. 1750; Pub. L. 117–53, §2, Nov. 10, 2021, 135 Stat. 411; Pub. L. 117–328, div. FF, title I, §1252(a), Dec. 29, 2022, 136 Stat. 5681, as amended Pub. L. 119–26, §4(1), July 16, 2025, 139 Stat. 416; Pub. L. 119–26, §3(b) through (f), July 16, 2025, 139 Stat. 413.
50502(g)(5)(A)(i)	21 U.S.C. 822(g)(5)(B)(ii)	Pub. L. 91–513, title II, §302(g)(5)(B)(ii), as added Pub. L. 115–271, title III, §3222(a), Oct. 24, 2018, 132 Stat. 3948.
50502(g)(5)(A)(ii)	21 U.S.C. 822(g)(5)(B)(i) (relating to hospice care)	Pub. L. 91–513, title II, §302(g)(5)(B)(i) (relating to hospice care), as added Pub. L. 115–271, title III, §3222(a), Oct. 24, 2018, 132 Stat. 3948.
50502(g)(5)(A)(iii)	21 U.S.C. 822(g)(5)(B)(i) (relating to hospice program)	Pub. L. 91–513, title II, §302(g)(5)(B)(i) (relating to hospice program), as added Pub. L. 115–271, title III, §3222(a), Oct. 24, 2018, 132 Stat. 3948.
50502(g)(5)(A)(iv)	21 U.S.C. 822(g)(5)(B)(iii)	Pub. L. 91–513, title II, §302(g)(5)(B)(iii), as added Pub. L. 115–271, title III, §3222(a), Oct. 24, 2018, 132 Stat. 3948.
50502(g)(5)(B)	21 U.S.C. 822(g)(5)(A)	Pub. L. 91–513, title II, §302(g)(5)(A), as added Pub. L. 115–271, title III, §3222(a), Oct. 24, 2018, 132 Stat. 3948; Pub. L. 117–215, title I, §103(b)(1)(B), Dec. 2, 2022, 136 Stat. 2263.
50502(g)(5)(C)	21 U.S.C. 822 note	Pub. L. 115–271, title III, §3222(b), Oct. 24, 2018, 132 Stat. 3949.
50502(g)(5)(D)	21 U.S.C. 822 note	Pub. L. 115–271, title III, §3222(c), Oct. 24, 2018, 132 Stat. 3949.

In subsection (a)(2), the words "A registration under this paragraph shall not" are substituted for "In no event, however, shall such registrations" to eliminate unnecessary words.

In subsection (a)(3)(C), the words "conferred by the registration" are substituted for "conferred thereby" for clarity.

In subsection (g)(1)(A), the words "to engage in the disposal" are substituted for "to engage in the activity" for consistency in the subsection.

In subsection (g)(4), the words "If an individual dies" are substituted for "If a person dies" for consistency with section 1 of title 1, United States Code.

In subsection (g)(5)(A)(i), in the matter before subclause (I), the words "other individual" are substituted for "other person" for consistency with section 1 of title 1, United States Code.

In subsection (g)(5)(A)(iv)(I), the words "of an individual receiving hospice care after the individual's death" are substituted for "of a person receiving hospice care after the person's death" for consistency with section 1 of title 1, United States Code.

In subsection (g)(5)(B), the words "individual receiving hospice care" are substituted for the words "person receiving hospice care" each place they appear for consistency with section 1 of title 1, United States Code.

In subsection (g)(5)(B)(iii)(II), the words "the individual" are substituted for the words "the hospice patient" each place they appear for consistency in the subparagraph.

In subsection (g)(5)(D), the words "in this paragraph" are substituted for "in this section or the amendments made by this section" to provide a more precise reference to the pertinent provision.

SECTION 50503—REGISTRATION REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50503(a) (except (7)) ...	21 U.S.C. 823(k)(13)	Pub. L. 91–513, title II, §303(k)(13), formerly §303(j)(13), as added Pub. L. 115–83, §2(2), Nov. 17, 2017, 131 Stat. 1267; redesignated §303(k)(13), Pub. L. 117–215, title I, §103(a)(1), (5), Dec. 2, 2022, 136 Stat. 2261, 2262.
50503(a)(7)	21 U.S.C. 823(l)	Pub. L. 91–513, title II, §303(l), formerly §303(k), formerly §303(j), as added Pub. L. 114–145, §2(a)(1), Apr. 19, 2016, 130 Stat. 354; redesignated §303(k), Pub. L. 115–83, §2(1), Nov. 17, 2017, 131 Stat. 1267; redesignated §303(l), Pub. L. 117–215, title I, §103(a)(1), Dec. 2, 2022, 136 Stat. 2261.
50503(b), (c)	21 U.S.C. 823(a), (b)	Pub. L. 91–513, title II, §303(a), (b), Oct. 27, 1970, 84 Stat. 1253.
50503(d)	21 U.S.C. 823(c)	Pub. L. 91–513, title II, §303(c), as added Pub. L. 117–215, title I, §103(a)(2), Dec. 2, 2022, 136 Stat. 2261.
50503(e)	21 U.S.C. 823(d)	Pub. L. 91–513, title II, §303(d), formerly §303(c), Oct. 27, 1970, 84 Stat. 1253; redesignated §303(d), Pub. L. 117–215, title I, §103(a)(1), Dec. 2, 2022, 136 Stat. 2261.
50503(f), (g)	21 U.S.C. 823(e), (f)	Pub. L. 91–513, title II, §303(e), (f), formerly §303(d), (e), Oct. 27, 1970, 84 Stat. 1253; redesignated §303(e), (f), Pub. L. 117–215, title I, §103(a)(1), Dec. 2, 2022, 136 Stat. 2261.
50503(h)	21 U.S.C. 823(g)	Pub. L. 91–513, title II, §303(g), formerly §303(f), Oct. 27, 1970, 84 Stat. 1253; Pub. L. 95–633, title I, §109, Nov. 10, 1978, 92 Stat. 3773; Pub. L. 98–473, title II, §511, Oct. 12, 1984, 98 Stat. 2073; Pub. L. 110–425, §3(b), Oct. 15, 2008, 122 Stat. 4824; redesignated §303(g), Pub. L. 117–215, title I, §§101, 102(a), 103(a)(1), Dec. 2, 2022, 136 Stat. 2258, 2260, 2261.
50503(i)	21 U.S.C. 823(h)	Pub. L. 91–513, title II, §303(h), formerly §303(g), as added Pub. L. 93–281, §3, May 14, 1974, 88 Stat. 124; Pub. L. 106–310, div. B, title XXXV, §3502(a), Oct. 17, 2000, 114 Stat. 1222; redesignated §303(h), Pub. L. 117–215, title I, §103(a)(1), (3), Dec. 2, 2022, 136 Stat. 2261, 2262; Pub. L. 117–328, div. FF, title I, §1262(a), Dec. 29, 2022, 136 Stat. 5681, as amended Pub. L. 119–26, §4(2)(A), July 16, 2025, 139 Stat. 416.
50503(j)	21 U.S.C. 823(i)	Pub. L. 91–513, title II, §303(i), formerly §303(h), as added Pub. L. 103–200, §3(c), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 109–177, title VII, §712(a)(3), Mar. 9, 2006, 120 Stat. 263; redesignated §303(i), Pub. L. 117–215, title I, §103(a)(1), Dec. 2, 2022, 136 Stat. 2261; Pub. L. 119–26, §4(2)(A), July 16, 2025, 139 Stat. 416.
50503(k)	21 U.S.C. 823(j)	Pub. L. 91–513, title II, §303(j), formerly §303(i), as added Pub. L. 114–89, §3, Nov. 25, 2015, 129 Stat. 701; redesignated §303(j), Pub. L. 117–215, title I, §103(a)(1), (4), Dec. 2, 2022, 136 Stat. 2261, 2262.
50503(l)(1) through (12)	21 U.S.C. 823(k)(1) through (12)	Pub. L. 91–513, title II, §303(k)(1) through (12), formerly §303(j)(1) through (12), as added Pub. L. 115–83, §2(2), Nov. 17, 2017, 131 Stat. 1267; redesignated §303(k)(1) through (12), Pub. L. 117–215, title I, §103(a)(1), (5), Dec. 2, 2022, 136 Stat. 2261, 2262.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50503(m)	21 U.S.C. 823(m)	Pub. L. 91–513, title II, §303(m), formerly §303(l), as added Pub. L. 117–328, div. FF, title I, §1263(a), Dec. 29, 2022, 136 Stat. 5683; redesignated §303(m), Pub. L. 119–26, §3(a)(1), July 16, 2025, 139 Stat. 411.
50503(n)	21 U.S.C. 823(n)	Pub. L. 91–513, title II, §303(n), as added Pub. L. 119–26, §3(a)(2), July 16, 2025, 139 Stat. 411.
50503(o)	21 U.S.C. 823(o)	Pub. L. 91–513, title II, §303(o), as added Pub. L. 119–26, §3(g), July 16, 2025, 139 Stat. 416.

In subsection (a)(1)(A), the words "under this division" are substituted for "under this Act" for clarity. The reference to "this division" in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.), not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236). The registration required under the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), which was enacted as title III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 951 et seq.), is for import and export of controlled substances.

In subsection (b)(1), the words "compounded from the particular controlled substances" are substituted for "compounded therefrom" for clarity.

In subsection (d)(1)(A), the words "under this division" are substituted for the words "under this Act" each place they appear for clarity. The reference to "this division" in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.), which was enacted as title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236), and not to restated provisions of that Act, which would have included a reference to division B o f subtitle V of title 21, United States Code, because that division B restates title III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 951 et seq.).

In subsection (f)(1), the words "compounded from the particular controlled substances" are substituted for "compounded therefrom" for clarity.

In subsection (h)(2)(B)(i)(II), the words "diversion of the marijuana" are substituted for "diversion of the controlled substance" for consistency in the subparagraph.

In subsection (j)(5), the words "factors as may be relevant to and consistent with the public health and safety" are substituted for "factors as are relevant to and consistent with the public health and safety" for consistency with subsection (a)(7) and in the section.

In subsection (m)(1), in the matter before subparagraph (A), the words "In this subsection" are substituted for "In this section" to provide the more precise reference to the pertinent provision.

In subsection (m)(2)(A), in the matter before clause (i), the words "If the practitioner is a physician . . . , the practitioner meets" are substituted for "If the practitioner is a physician . . . and the practitioner meets" for clarity and consistency with subsection (m)(2)(B) (matter before clause (i)).

In subsection (n)(3)(A)(ii), the words "the Secretary of Defense" are substituted for "the Department of Defense" for consistency in the clause.

SECTION 50504—DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50504 (except (d))	21 U.S.C. 824 (except (d))	Pub. L. 91–513, title II, §304 (except (d)), Oct. 27, 1970, 84 Stat. 1255; Pub. L. 93–281, §4(a), May 14, 1974, 88 Stat. 125; Pub. L. 98–473, title II, §§304, 512, 513, Oct. 12, 1984, 98 Stat. 2050, 2073; Pub. L. 100–93, §8(j), Aug. 18, 1987, 101 Stat. 695; Pub. L. 103–200, §3(d), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103–322, title XXXIII, §330024(e), Sept. 13, 1994, 108 Stat. 2151; Pub. L. 106–310, div. B, title XXXV, §3502(b)(1), Oct. 17, 2000, 114 Stat. 1227; Pub. L. 114–145, §2(b), Apr. 19, 2016, 130 Stat. 354; Pub. L. 117–36, §2, Aug. 6, 2021, 135 Stat. 328; Pub. L. 117–215, title I, §103(b)(1)(C), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §1262(b)(1), Dec. 29, 2022, 136 Stat. 5682, as amended Pub. L. 119–26, §4(2)(B)(i), (ii), July 16, 2025, 139 Stat. 416.
50504(d)(1)	21 U.S.C. 824(d)(2)	Pub. L. 91–513, title II, §304(d)(2), as added Pub. L. 114–145, §2(a)(2)(B), Apr. 19, 2016, 130 Stat. 354.
50504(d)(2)	21 U.S.C. 824(d)(1)	Pub. L. 91–513, title II, §304(d)(1), Oct. 27, 1970, 84 Stat. 1256; Pub. L. 93–281, §4(b), May 14, 1974, 88 Stat. 125; Pub. L. 106–310, div. B, title XXXV, §3502(b)(2), Oct. 17, 2000, 114 Stat. 1227; Pub. L. 114–145, §2(a)(2)(A), Apr. 19, 2016, 130 Stat. 354; Pub. L. 117–215, title I, §103(b)(1)(C), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §1262(b)(1), Dec. 29, 2022, 136 Stat. 5682, as amended Pub. L. 119–26, §4(2)(B)(i), (ii), July 16, 2025, 139 Stat. 416.

In subsection (d)(2)(C), the words "including judicial review of the suspension" are substituted for "including judicial review thereof" for clarity.

In subsection (f)(2), the words "on application for the sale" are substituted for "upon application therefor" for clarity.

SECTION 50505—LABELING AND PACKAGING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50505	21 U.S.C. 825	Pub. L. 91–513, title II, § 305, Oct. 27, 1970, 84 Stat. 1256; Pub. L. 113–260, § 3(a), Dec. 18, 2014, 128 Stat. 2931.

SECTION 50506—PRODUCTION QUOTAS FOR CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50506(a) through (h) ...	21 U.S.C. 826(a) through (h)	Pub. L. 91–513, title II, § 306(a) through (h), Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94–273, § 3(16), Apr. 21, 1976, 90 Stat. 377; Pub. L. 109–177, title VII, § 713, Mar. 9, 2006, 120 Stat. 264; Pub. L. 112–144, title X, § 1005, July 9, 2012, 126 Stat. 1105; Pub. L. 115–271, title III, §3282(a)(1) through (3), Oct. 24, 2018, 132 Stat. 3954.
50506(i)(1)	21 U.S.C. 826(i)(1)(A) (parenthetical)	Pub. L. 91–513, title II, § 306(i)(1)(A) (parenthetical), as added Pub. L. 115–271, title III, §3282(a)(4), Oct. 24, 2018, 132 Stat. 3954.
50506(i)(2)(A)	21 U.S.C. 826(i)(1)(A) (except parenthetical)	Pub. L. 91–513, title II, § 306(i)(1)(A) (except parenthetical), as added Pub. L. 115–271, title III, §3282(a)(4), Oct. 24, 2018, 132 Stat. 3954.
50506(i)(2)(B), (C)	21 U.S.C. 826(i)(1)(B), (C)	Pub. L. 91–513, title II, §306(i)(1)(B), (C), as added Pub. L. 115–271, title III, §3282(a)(4), Oct. 24, 2018, 132 Stat. 3955.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50506(i)(3), (4)	21 U.S.C. 826(i)(2), (3)	Pub. L. 91–513, title II, §306(i)(2), (3), as added Pub. L. 115–271, title III, §3282(a)(4), Oct. 24, 2018, 132 Stat. 3955.
50506(j)	21 U.S.C. 826a	Pub. L. 112–144, title X, § 1006, July 9, 2012, 126 Stat. 1105.

In subsection (c)(1), the words "on application for a manufacturing quota" are substituted for "upon application therefor" for clarity.

In subsection (j), in the matter before paragraph (1), the words "The Attorney General shall annually submit" are substituted for "Not later than 6 months after the date of the enactment of this Act, and annually thereafter, the Attorney General shall submit" to eliminate obsolete words.

SECTION 50507—RECORDS AND REPORTS OF REGISTRANTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50507	21 U.S.C. 827	Pub. L. 91–513, title II, § 307, Oct. 27, 1970, 84 Stat. 1258; Pub. L. 93–281, § 5, May 14, 1974, 88 Stat. 125; Pub. L. 95–633, title I, §§ 104, 110, Nov. 10, 1978, 92 Stat. 3772, 3773; Pub. L. 98–473, title II, §§ 514, 515, Oct. 12, 1984, 98 Stat. 2074; Pub. L. 106–172, § 4, Feb. 18, 2000, 114 Stat. 9; Pub. L. 110–425, § 3(c), Oct. 15, 2008, 122 Stat. 4824; Pub. L. 115–271, title III, §3273(a), Oct. 24, 2018, 132 Stat. 3952; Pub. L. 117–215, title I, §103(b)(1)(D), Dec. 2, 2022, 136 Stat. 2263.

In subsection (a)(1), the words "each registrant shall, as soon as the registrant first engages" are substituted for "every registrant under this title shall, on the effective date of this section, or soon thereafter as such registrant first engages" to eliminate obsolete words.

In subsection (a)(1), the words "(following the initial inventory required by this paragraph)" are omitted as unnecessary.

In subsection (a)(3), the words "on and after the effective date of this section" are omitted as obsolete.

In subsection (a)(3), the words "a controlled substance" are substituted for "a controlled substance or substances" for consistency with section 1 of title 1, United States Code.

In subsection (a)(3), the words "record of each controlled substance" are substituted for "record of each such substance" for clarity.

In subsection (d)(1), the words "at such time" are substituted for "at such time or times" for consistency with section 1 of title 1, United States Code.

In subsection (g), the words "ensure the security" are substituted for "insure the security" to use the more appropriate word.

In subsection (i)(1), the words "as a manufacturer of bulk or dosage form, or as a packager, repackager, labeler, relabeler, or distributor," are substituted for

"as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor" to supply a missing word.

In subsection (i)(6), the words "(relating to mail order reporting)" are omitted as unnecessary.

SECTION 50508—ORDER FORMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50508	21 U.S.C. 828	Pub. L. 91–513, title II, § 308, Oct. 27, 1970, 84 Stat. 1259; Pub. L. 111–273, § 3(b), Oct. 12, 2010, 124 Stat. 2860.

In subsection (d)(1)(B), the words "with intent" are substituted for "with intent thereby" to eliminate an unnecessary word.

SECTION 50509—PRESCRIPTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50509 (except (f)(3), (g))	21 U.S.C. 829 (except (f)(3))	Pub. L. 91–513, title II, § 309 (except (f)(3)), Oct. 27, 1970, 84 Stat. 1260; Pub. L. 110–425, § 2, Oct. 15, 2008, 122 Stat. 4820; Pub. L. 114–198, title VII, §702(a), July 22, 2016, 130 Stat. 740.
50509(f)(3)	21 U.S.C. 829 note	Pub. L. 114–198, title VII, §702(b), July 22, 2016, 130 Stat. 741.
50509(g)	21 U.S.C. 829 note	Pub. L. 115–271, title III, §3212, Oct. 24, 2018, 132 Stat. 3947; Pub. L. 117–328, div. FF, title I, §1271(a), Dec. 29, 2022, 136 Stat. 5685.

SECTION 50510—DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO AN ADMINISTERING PRACTITIONER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50510(a)	21 U.S.C. 829a(a)	Pub. L. 91–513, title II, § 309A(a), as added Pub. L. 115–271, title III, §3204(a), Oct. 24, 2018, 132 Stat. 3945; Pub. L. 117–215, title I, §103(b)(1)(E), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §§1262(b)(2), 1264, Dec. 29, 2022, 136 Stat. 5682, 5685, as amended Pub. L. 119–26, §4(2)(B)(iii), July 16, 2025, 139 Stat. 416.
50510(b)	21 U.S.C. 829a(b)(2), (3)	Pub. L. 91–513, title II, § 309A(b)(2), (3), as added Pub. L. 115–271, title III, §3204(a), Oct. 24, 2018, 132 Stat. 3945; Pub. L. 117–215, title I, §103(b)(1)(E), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §§1262(b)(2), 1264, Dec. 29, 2022, 136 Stat. 5682, 5685.

In subsection (b), the words "After the date on which the report described in section 3204(b) of the SUPPORT for Patients and Communities Act is submitted," are omitted as obsolete.

SECTION 50511—REGULATION OF LISTED CHEMICALS AND CERTAIN MACHINES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50511(a)	21 U.S.C. 830(a)	Pub. L. 91–513, title II, §310(a), as added Pub. L. 95–633, title II, §202(a), Nov. 10, 1978, 92 Stat. 3774; Pub. L. 100–690, title VI, §6052(a), Nov. 18, 1988, 102 Stat. 4312; Pub. L. 103–200, §2(c)(1), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 104–237, title II, §208, Oct. 3, 1996, 110 Stat. 3104.
50511(b)	21 U.S.C. 830(b)	Pub. L. 91–513, title II, §310(b), as added Pub. L. 95–633, title II, §202(a), Nov. 10, 1978, 92 Stat. 3774; Pub. L. 100–690, title VI, §6052(a), Nov. 18, 1988,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		102 Stat. 4312; Pub. L. 103–200, §10, Dec. 17, 1993, 107 Stat. 2341; Pub. L. 104–237, title IV, §402, Oct. 3, 1996, 110 Stat. 3111; Pub. L. 106–310, div. B, title XXXVI, §3652, Oct. 17, 2000, 114 Stat. 1239; Pub. L. 109–177, title VII, §§711(a)(2)(B), (c)(2), 716(b)(2), Mar. 9, 2006, 120 Stat. 257, 261, 267.
50511(c)	21 U.S.C. 830(c)	Pub. L. 91–513, title II, §310(c), as added Pub. L. 95–633, title II, §202(a), Nov. 10, 1978, 92 Stat. 3774; Pub. L. 100–690, title VI, §6052(a), Nov. 18, 1988, 102 Stat. 4312; Pub. L. 103–200, §2(c)(2), Dec. 17, 1993, 107 Stat. 2336.
50511(d)	21 U.S.C. 830(d)	Pub. L. 91–513, title II, §310(d), as added Pub. L. 109–177, title VII, §711(b)(1), Mar. 9, 2006, 120 Stat. 257.
50511(e)	21 U.S.C. 830(e)	Pub. L. 91–513, title II, §310(e), as added Pub. L. 109–177, title VII, §711(b)(1), (c)(1), (d), Mar. 9, 2006, 120 Stat. 257 , 261; Pub. L. 110–415, §2, Oct. 14, 2008, 122 Stat. 4349; Pub. L. 111–268, §§2, 3, Oct. 12, 2010, 124 Stat. 2847.

In subsection (e)(1)(A)(iv)(III)(aa)(BB), the words "a unique identifier which can be linked to the information listed in subitem (AA) in electronic form" are substituted for "a unique identifier which can be linked to that electronic information" for clarity.

In subsection (e)(1)(A)(iv)(III)(bb), the words "a unique identifier that can be linked to the information under item (aa)" are substituted for "a unique identifier which can be linked to that information" for clarity.

In subsection (e)(1)(B)(iii)(V), the words "Department of Justice" are substituted for "Department" each place it appears for clarity.

SECTION 50512—ADDITIONAL REQUIREMENTS RELATING TO ONLINE PHARMACIES AND TELEMEDICINE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50512	21 U.S.C. 831 (except (d)(3))	Pub. L. 91–513, title II, § 311 (except (d)(3)), as added Pub. L. 110–425, § 3(d)(1), Oct. 15, 2008, 122 Stat. 4825; Pub. L. 115–271, title III, §3232, Oct. 24, 2018, 132 Stat. 3950; Pub. L. 117–215, title I, §103(b)(1)(F), Dec. 2, 2022, 136 Stat. 2263.

In subsection (i)(2), the words "described in paragraph (1)" are substituted for "described in subparagraph (A)" to provide the correct reference to the pertinent provision.

In subsection (j), the words "under this division" are substituted for "under this Act" for clarity. The reference to "this division" in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.), not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236), which includes, as title III of that Act, the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.).

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50513	21 U.S.C. 832	Pub. L. 91–513, title II, § 312, as added Pub. L. 115–271, title III, §3292(b), Oct. 24, 2018, 132 Stat. 3956.

In subsection (b)(1), the words "Not later than 1 year after the date of enactment of this section," are omitted as obsolete.

Chapter 507—Offenses and Penalties

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50701(a)	21 U.S.C. 841(a)	Pub. L. 91–513, title II, §401(a), Oct. 27, 1970, 84 Stat. 1260.
50701(b)	21 U.S.C. 841(b)	Pub. L. 91–513, title II, §401(b), Oct. 27, 1970, 84 Stat. 1261; Pub. L. 95–633, title II, §201(1), (2), Nov. 10, 1978, 92 Stat. 3774; Pub. L. 96–359, §8(c), Sept. 26, 1980, 94 Stat. 1194; Pub. L. 98–473, title II, §§224(a)(1) through (5), 502, 503(b)(1), Oct. 12, 1984, 98 Stat. 2030, 2068, 2070; Pub. L. 99–570, title I, §§1002, 1003(a)(1) through (5), 1004(a), 1005(a), 1103(a), Oct. 27, 1986, 100 Stat. 3207–2, 3207–5, 3207–6, 3207–11; Pub. L. 100–690, title VI, §§6254(h), 6452(a), 6470(g), (h), 6479, Nov. 18, 1988, 102 Stat. 4367, 4371, 4378, 4381; Pub. L. 101–647, title X, §1002(e), title XII, §1202, title XXXV, §3599K, Nov. 29, 1990, 104 Stat. 4828, 4830, 4932; Pub. L. 103–322, title IX, §90105(a), (c), title XVIII, §180201(b)(2)(A), Sept. 13, 1994, 108 Stat. 1987, 1988, 2047; Pub. L. 104–305, §2(a), (b)(1), Oct. 13, 1996, 110 Stat. 3807; Pub. L. 105–277, div. E, §2(a), Oct. 21, 1998, 112 Stat. 2681–759; Pub. L. 106–172, §§3(b)(1), 5(b), Feb. 18, 2000, 114 Stat. 9, 10; Pub. L. 107–273, div. B, title III, §3005(a), Nov. 2, 2002, 116 Stat. 1805; Pub. L. 109–177, title VII, §732, Mar. 9, 2006, 120 Stat. 270; Pub. L. 110–425, §3(e), Oct. 15, 2008, 122 Stat. 4828; Pub. L. 111–220, §§2(a), 4(a), Aug. 3, 2010, 124 Stat. 2372; Pub. L. 115–391, title IV, §401(a)(2), Dec. 21, 2018, 132 Stat. 5220; Pub. L. 119–26, §6(a), July 16, 2025, 139 Stat. 417.
50701(c)	21 U.S.C. 841(c)	Pub. L. 91–513, title II, §401(c), formerly §401(d), as added Pub. L. 95–633, title II, §201(3), Nov. 10, 1978, 92 Stat. 3774; Pub. L. 99–570, title I, §1003(a)(6), Oct. 27, 1986, 100 Stat. 3207–6; Pub. L. 100–690, title VI, §6055(a), Nov. 18, 1988, 102 Stat. 4318; Pub. L. 104–237, title III, §302(a), Oct. 3, 1996, 110 Stat. 3105; redesignated §401(c), Pub. L. 106–172, §9, Feb. 18, 2000, 114 Stat. 13.
50701(d)	21 U.S.C. 841(d)	Pub. L. 91–513, title II, §401(d), formerly §401(e), as added Pub. L. 99–570, title XV, §15005, Oct. 27, 1986, 100 Stat. 3207–192; redesignated §401(d), Pub. L. 106–172, §9, Feb. 18, 2000, 114 Stat. 13; Pub. L. 107–273, div. B, title IV, §4002(d)(2)(A), Nov. 2, 2002, 116 Stat. 1809.
50701(e) through (g)	21 U.S.C. 841(f) through (h)	Pub. L. 91–513, title II, §401(f) through (h), as added Pub. L. 100–690, title VI, §6055(b), Nov. 18, 1988, 102 Stat. 4318; Pub. L. 106–172, §9, Feb. 18, 2000, 114 Stat. 13; Pub. L. 109–177, title VII, §711(f)(1)(B), Mar. 9, 2006, 120 Stat. 262; Pub. L. 109–248, title II, § 201, July 27, 2006, 120 Stat. 611; Pub. L. 110–425, §3(f), Oct. 15, 2008, 122 Stat. 4829; Pub. L. 117–215, title I, §103(b)(1)(G), Dec. 2, 2022, 136 Stat. 2263.
50701(h)	21 U.S.C. 841(e)	Pub. L. 91–513, title II, §401(e), formerly §401(f), as added Pub. L. 100–690, title VI, §6055(b), Nov. 18,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		1988, 102 Stat. 4318; Pub. L. 104–237, title II, § 206(a), Oct. 3, 1996, 110 Stat. 3103; redesignated §401(e), Pub. L. 106–172, §9, Feb. 18, 2000, 114 Stat. 13.

In subsection (b)(1)(A)(iii), the words "in the absence of a prior conviction described in clause (ii)" are substituted for "in the absence of such a prior conviction" for clarity.

In subsection (b)(1)(B)(iii), the words "in the absence of a prior conviction described in clause (ii)" are substituted for "in the absence of such a prior conviction" for clarity.

In subsection (b)(1)(C)(i), the words "In the case of a person's violation of subsection (a) involving a controlled substance" are substituted for "In the case of a controlled substance" for consistency with subparagraphs (A)(i) and (B)(i).

In subsection (b)(1)(C)(iii), the words "any sentence imposing a term of imprisonment under this subparagraph" are substituted for "any sentence imposing a term of imprisonment under this paragraph" to provide a more precise reference to the pertinent provision.

In subsection (b)(1)(C)(iii), the words "in the absence of a prior conviction described in clause (ii)" are substituted for "in the absence of such a prior conviction" for clarity.

In subsection (b)(1)(D)(i), the words "In the case of a person's violation of subsection (a) involving less than 50 kilograms of marihuana," are substituted for "In the case of less than 50 kilograms of marihuana," for consistency with subparagraphs (A)(i) and (B)(i).

In subsection (b)(1)(D)(iii), the words "any sentence imposing a term of imprisonment under this subparagraph" are substituted for "any sentence imposing a term of imprisonment under this paragraph" to provide a more precise reference to the pertinent provision.

In subsection (b)(1)(D)(iii), the words "in the absence of a prior conviction described in clause (ii)" are substituted for "in the absence of such a prior conviction" for clarity.

In subsection (b)(1)(E)(i), the words "in the case of a person's violation of subsection (a) involving any controlled substance" are substituted for "in the case of any controlled substance" for consistency with subparagraphs (A)(i) and (B)(i).

In subsection (b)(1)(E)(iii), the words "in the absence of a prior conviction described in clause (ii)" are substituted for "in the absence of such a prior conviction" for clarity.

In subsection (b)(2)(A), the words "In the case of a person's violation of subsection (a) involving a controlled substance" are substituted for "In the case of a controlled substance" for consistency with subparagraphs (A)(i) and (B)(i) of paragraph (1).

In subsection (b)(2)(C), the words “in the absence of a prior conviction described in subparagraph (B)” are substituted for “in the absence of such a prior conviction” for clarity.

In subsection (b)(3)(A), the words “In the case of a person's violation of subsection (a) involving a controlled substance” are substituted for “In the case of a controlled substance” for consistency with subparagraphs (A)(i) and (B)(i) of paragraph (1).

In subsection (b)(5)(A), the words “shall be imprisoned as provided in this subsection, shall be fined” are substituted for “shall be imprisoned as provided in this subsection and shall be fined” for clarity.

In subsection (f)(1)(A), in the matter before clause (i), the words “in accordance with this division and division B” are substituted for “in accordance with this Act” to provide a more precise reference to the pertinent provisions. The reference to “this division and division B” in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236). Titles II and III of that Act comprises the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, among other provisions.

In subsection (f)(1)(A)(i), the words “An individual with a valid prescription” are substituted for “A person with a valid prescription” for consistency with section 1 of title 1, United States Code.

In subsection (f)(1)(A)(ii), the words “under this division or division B” are substituted for “under this Act” to provide a more precise reference to the pertinent provisions. The reference to “this division or division B” in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236). Titles II and III of that Act comprises the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, among other provisions.

In subsection (f)(2)(B), in the matter before clause (i), the words “to another person” are substituted for “to any person” for clarity.

In subsection (f)(2)(B)(ii), the words “the other person is not an authorized purchaser” are substituted for “the person is not an authorized purchaser” for clarity.

In subsection (f)(3), the words “under this division or division B” are substituted for “under this Act” to provide a more precise reference to the pertinent provisions. The reference to “this division or division B” in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236). Titles II and III of that Act comprises the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, among other provisions.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50702(a), (b)	21 U.S.C. 842(a), (b)	Pub. L. 91–513, title II, §402(a), (b), Oct. 27, 1970, 84 Stat. 1262; Pub. L. 95–633, title II, §202(b)(1), Nov. 10, 1978, 92 Stat. 3776; Pub. L. 100–690, title VI, §6056(a), (b), (d), Nov. 18, 1988, 102 Stat. 4318; Pub. L. 104–237, title II, §205(a), Oct. 3, 1996, 110 Stat. 3103; Pub. L. 105–277, div. A, § 101(b) [title I, §117(1), (2)], Oct. 21, 1998, 112 Stat. 2681–50, 2681–68; Pub. L. 109–177, title VII, §§711(f)(1)(A), 714, Mar. 9, 2006, 120 Stat. 262, 264; Pub. L. 111–268, §§4, 5, Oct. 12, 2010, 124 Stat. 2847, 2848; Pub. L. 113–260, §3(c)(1), Dec. 18, 2014, 128 Stat. 2931; Pub. L. 115–271, title III, §3273(c)(1), Oct. 24, 2018, 132 Stat. 3953.
50702(c)(1), (2)	21 U.S.C. 842(c)(2)(A), (B)	Pub. L. 91–513, title II, §402(c)(2)(A), (B), Oct. 27, 1970, 84 Stat. 1262; Pub. L. 107–273, div. B, title IV, §4002(d)(2)(B), Nov. 2, 2002, 116 Stat. 1809; Pub. L. 115–271, title III, §3273(c)(2)(B)(i), Oct. 24, 2018, 132 Stat. 3954.
50702(c)(3)	21 U.S.C. 842(c)(2)(D)	Pub. L. 91–513, title II, §402(c)(2)(D), as added Pub. L. 115–271, title III, §3273(c)(2)(B)(ii), Oct. 24, 2018, 132 Stat. 3954.
50702(d)(1)	21 U.S.C. 842(c)(1)	Pub. L. 91–513, title II, §402(c)(1), Oct. 27, 1970, 84 Stat. 1262; Pub. L. 105–277, div. A, §101(b) [title I, §117(3)], Oct. 21, 1998, 112 Stat. 2681–50, 2681–69; Pub. L. 113–260, §3(c)(2), Dec. 18, 2014, 128 Stat. 2931; Pub. L. 115–271, title III, §3273(c)(2)(A), Oct. 24, 2018, 132 Stat. 3953.
50702(d)(2)	21 U.S.C. 842(c)(2)(C)	Pub. L. 91–513, title II, §402(c)(2)(C), as added Pub. L. 104–237, title II, §205(b), Oct. 3, 1996, 110 Stat. 3103; Pub. L. 107–273, div. B, title IV, §4002(b)(16), Nov. 2, 2002, 116 Stat. 1808.
50702(d)(3), (4)	21 U.S.C. 842(c)(3), (4)	Pub. L. 91–513, title II, §402(c)(3), (4), Oct. 27, 1970, 84 Stat. 1262; Pub. L. 109–177, title VII, §711(f)(2), Mar. 9, 2006, 120 Stat. 263.

In subsection (a)(1)(P), the words "section 50505(e) of this title" are substituted for "subsection (e) of section 825 of this title" to provide the correct reference to the pertinent provision. Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) does not contain a section 825. Section 305 of the Controlled Substances Act is classified to 21 U.S.C. 825; that section is restated as section 50505 of title 21, United States Code, and section 305(e) of that Act (21 U.S.C. 825(e)) is restated as section 50505(e) of title 21, United States Code.

In subsection (c)(2), the words "for an offense punishable under this subsection" are substituted for "for an offense punishable under this paragraph (2)" to provide a more precise reference to the pertinent provision.

In subsection (d)(1)(A), the words "and paragraph (2)" are retained even though paragraph (2) of the restatement includes only the provision in paragraph (2)(C) of section 402(c) of the Controlled Substances Act (21 U.S.C. 842(c)) to provide a more precise reference to the pertinent provision.

In subsection (d)(1)(C), the words "the civil penalty shall not exceed $500,000" are substituted for "up to $500,000" to supply missing words.

In subsection (d)(1)(D)(i), the words "this subparagraph" are substituted for "this paragraph" to provide a more precise reference to the pertinent provision.

In subsection (d)(1)(D)(ii), the words "the civil penalty shall not exceed $1000" are substituted for "up to $1000" to supply missing words.

In subsection (d)(2), the words "for any succeeding violation, be subject to a civil penalty" are substituted for "for any succeeding violation, be subject to a civil fine" for consistency in the paragraph.

In subsection (d)(3), the words "Except under the conditions specified in subsection (c)" are substituted for "Except under the conditions specified in paragraph (2) of this subsection", even though the reference to subsection (c) in the restatement includes only the provisions in subparagraphs (A), (B), and (D) of section (c)(2) of the Controlled Substances Act (21 U.S.C.(c)(2)), to provide a more precise reference to the pertinent provisions.

SECTION 50703—PROHIBITED ACTS C

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50703	21 U.S.C. 843	Pub. L. 91–513, title II, §403, Oct. 27, 1970, 84 Stat. 1263; Pub. L. 95–633, title II, § 202(b)(3), Nov. 10, 1978, 92 Stat. 3776; Pub. L. 98–473, title II, § 516, Oct. 12, 1984, 98 Stat. 2074; Pub. L. 99–570, title I, § 1866(a), Oct. 27, 1986, 100 Stat. 3207–54; Pub. L. 100–690, title VI, § 6057, Nov. 18, 1988, 102 Stat. 4319; Pub. L. 103–200, § 3(g), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103–322, title IX, § 90106, Sept. 13, 1994, 108 Stat. 1988; Pub. L. 104–237, title II, §§ 203(a), 206(b), Oct. 3, 1996, 110 Stat. 3102, 3103; Pub. L. 107–273, div. B, title IV, § 4002(d)(2)(C), Nov. 2, 2002, 116 Stat. 1810; Pub. L. 108–21, title VI, § 608(d), Apr. 30, 2003, 117 Stat. 691; Pub. L. 110–425, § 3(g), Oct. 15, 2008, 122 Stat. 4830; Pub. L. 117–215, title I, §103(b)(1)(H), Dec. 2, 2022, 136 Stat. 2263.

In subsection (c)(1), in the matter before subparagraph (A), the words "this subsection" are substituted for "this section" to provide a more precise reference to the pertinent provision.

SECTION 50704—PENALTIES FOR SIMPLE POSSESSION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50704	21 U.S.C. 844	Pub. L. 91–513, title II, § 404, Oct. 27, 1970, 84 Stat. 1264; Pub. L. 98–473, title II, § 219, Oct. 12, 1984, 98 Stat. 2027; Pub. L. 99–570, title I, § 1052, Oct. 27, 1986, 100 Stat. 3207–8; Pub. L. 100–690, title VI, §§ 6371, 6480, Nov. 18, 1988, 102 Stat. 4370, 4382; Pub. L. 101–647, title XII, § 1201, title XIX, § 1907, Nov. 29, 1990, 104 Stat. 4829, 4854; Pub. L. 104–237, title II, § 201(a), Oct. 3, 1996, 110 Stat. 3101; Pub. L. 104–305, § 2(c), Oct. 13, 1996, 110 Stat. 3808; Pub. L. 109–177, title VII, § 711(e)(1), Mar. 9, 2006, 120 Stat. 262; Pub. L. 111–220, § 3, Aug. 3, 2010, 124 Stat. 2372.

In subsection (b)(2), the words "or if the person" are substituted for "or if the registrant" for consistency in the paragraph.

In subsection (b)(4), the words "sentenced to a term of imprisonment of not more than 1 year, shall be fined a minimum of $1,000, or both" are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (b)(5), the words "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" are retained to ensure that no change in the meaning or effect of the

source provision is made by the restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (b)(6), the words "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" are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. See chapter 227 of title 18, United States Code, for general sentencing provisions.

In subsection (b)(9), the words "if the court determines under title 18" are substituted for "if the court determines under the provision of title 18" for clarity and to eliminate unnecessary words.

SECTION 50705—CIVIL PENALTY FOR POSSESSION OF SMALL AMOUNTS OF CERTAIN CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50705	21 U.S.C. 844a	Pub. L. 91–513, title II, § 405, formerly Pub. L. 100–690, title VI, § 6486, Nov. 18, 1988, 102 Stat. 4384, renumbered § 405 of Pub. L. 91–513, and amended Pub. L. 101–647, title X, § 1002(g)(1), (2), Nov. 29, 1990, 104 Stat. 4828.

In subsection (i), the words "under this section" are substituted for "under this subsection" to provide the correct reference to the pertinent provision.

SECTION 50706—ATTEMPT AND CONSPIRACY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50706	21 U.S.C. 846	Pub. L. 91–513, title II, § 406, Oct. 27, 1970, 84 Stat. 1265; Pub. L. 100–690, title VI, § 6470(a), Nov. 18, 1988, 102 Stat. 4377.

SECTION 50707—ADDITIONAL PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50707	21 U.S.C. 847	Pub. L. 91–513, title II, § 407, Oct. 27, 1970, 84 Stat. 1265.

SECTION 50708—CONTINUING CRIMINAL ENTERPRISE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50708(a)(1)	21 U.S.C. 848(c)	Pub. L. 91–513, title II, §408(c), formerly §408(b), formerly §408(d), Oct. 27, 1970, 84 Stat. 1266; redesignated §408(d), Pub. L. 99–570, title I, §1253(1), Oct. 27, 1986, 100 Stat. 3207–14; redesignated §408(c), Pub. L. 100–690, title VI, §6481(b), Nov. 18, 1988, 102 Stat. 4382.
50708(a)(2), (3)	21 U.S.C. 848(a)	Pub. L. 91–513, title II, § 408(a), Oct. 27, 1970, 84 Stat. 1265; Pub. L. 98–473, title II, §305(a), Oct. 12, 1984, 98 Stat. 2050; Pub. L. 99–570, title I, §1252, Oct. 27, 1986, 100 Stat. 3207–14; Pub. L. 100–690, title VI, §6481(a), Nov. 18, 1988, 102 Stat. 4382.
50708(b)	21 U.S.C. 848(b)	Pub. L. 91–513, title II, § 408(b), as added Pub. L. 99–570, title I, §1253(2), Oct. 27, 1986, 100 Stat. 3207–15; Pub. L. 103–322, title XXXIII, §330003(e), Sept. 13, 1994, 108 Stat. 2141.
50708(c)	21 U.S.C. 848(d)	Pub. L. 91–513, title II, § 408(d), formerly §408(c), formerly §408(e), Oct. 27, 1970, 84 Stat. 1265; Pub.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		L. 98–473, title II, §224(b), formerly §224(c), Oct. 12, 1984, 98 Stat. 2030; redesignated §408(e), Pub. L. 99–570, title I, §§1005(b)(2), 1253(1), Oct. 27, 1986, 100 Stat. 3207–6, 3207–14; redesignated §408(d), Pub. L. 100–690, title VI, §6481(b), title VII, § 7001, Nov. 18, 1988, 102 Stat. 4382.
50708(d)	21 U.S.C. 848(e)	Pub. L. 91–513, title II, §408(e), as added Pub. L. 100–690, title VII, §7001(a)(2), Nov. 18, 1988, 102 Stat. 4382, 4387; Pub. L. 109–177, title II, §221(1), Mar. 9, 2006, 120 Stat. 231.
50708(e)	21 U.S.C. 848(s)	Pub. L. 91–513, title II, § 408(s), as added Pub. L. 109–177, title VII, § 733, Mar. 9, 2006, 120 Stat. 270.

In subsection (c), the words "the Act of July 15, 1932 (ch. 492, D.C. Code §§24–403 through 24–407)" are substituted for "the Act of July 15, 1932 (D.C. Code, secs. 24–203-24–207)" for clarity and to eliminate obsolete references.

In subsection (d)(2)(A), the reference to section 50701(b)(1)(A) of title 21, United States Code, is substituted for "under section 841(b)(1)(A)" to provide the correct reference to the pertinent provision. The Controlled Substances Act (21 U.S.C. 801 et seq.) does not contain a section 841. Section 401 of the Controlled Substances Act is classified to 21 U.S.C. 841; that section is restated as section 50701 of title 21, United States Code, and section 401(b)(1)(A) of that Act (21 U.S.C. 841(b)(1)(A)) is restated as section 50701(b)(1)(A) of title 21, United States Code.

In subsection (d)(2)(A), the reference to section 51710(b)(1) of title 21, United States Code, is substituted for "or section 960(b)(1)" to provide the correct reference to the pertinent provision. The Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.) does not contain a section 960. Section 1010 of the Controlled Substances Import and Export Act is classified to 21 U.S.C. 960; that section is restated as section 51710 of title 21, United States Code, and section 1010(b)(1) of that Act (21 U.S.C. 960(b)(1)) is restated as section 51710(b)(1) of title 21, United States Code.

In subparagraphs (A) and (B) of subsection (d)(2), the words "(and the counseling, commanding, inducing, procuring, or causing results in the killing)" are substituted for "and such killing results" for clarity.

SECTION 50709—TRANSPORTATION SAFETY OFFENSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50709	21 U.S.C. 849	Pub. L. 91–513, title II, § 409, as added Pub. L. 103–322, title XVIII, § 180201(b)(1), Sept. 13, 1994, 108 Stat. 2046.

In subsection (b), in the matter before paragraph (1), the words "except as provided in subsection (c)" are substituted for "except as provided in subsection (b)" to provide the correct reference to the pertinent provision.

In subsection (c), in the matter before paragraph (1), the words "under subsection (b)" are substituted for "under subsection (a)" to provide the correct reference to the pertinent provision.

SECTION 50710—INFORMATION FOR SENTENCING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50710	21 U.S.C. 850	Pub. L. 91–513, title II, § 410, Oct. 27, 1970, 84 Stat. 1269.

In this section, the words "or section 303(a) of the Public Health Service Act" are omitted as obsolete because that provision was repealed by section 3201(b)(1) of the Youth Drug and Mental Health Services Act (Public Law 106–310, 114 Stat. 1190).

SECTION 50711—PROCEEDINGS TO ESTABLISH PRIOR CONVICTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50711	21 U.S.C. 851	Pub. L. 91–513, title II, § 411, Oct. 27, 1970, 84 Stat. 1269.

In subsection (b), the words "may not be" are substituted for "may not thereafter be" to eliminate an unnecessary word.

SECTION 50712—APPLICATION OF TREATIES AND OTHER INTERNATIONAL AGREEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50712	21 U.S.C. 852	Pub. L. 91–513, title II, § 412, as added Pub. L. 95–633, title I, § 107(a), Nov. 10, 1978, 92 Stat. 3773.

SECTION 50713—CRIMINAL FORFEITURES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50713	21 U.S.C. 853	Pub. L. 91–513, title II, § 413, as added and amended Pub. L. 98–473, title II, §§ 303, 2301(d)–(f), Oct. 12, 1984, 98 Stat. 2044, 2192, 2193; Pub. L. 99–570, title I, §§ 1153(b), 1864, Oct. 27, 1986, 100 Stat. 3207–13, 3207–54; Pub. L. 104–237, title II, § 207, Oct. 3, 1996, 110 Stat. 3104; Pub. L. 106–310, div. B, title XXXVI, § 3613(a), Oct. 17, 2000, 114 Stat. 1229; Pub. L. 107–56, title III, § 319(d), Oct. 26, 2001, 115 Stat. 314; Pub. L. 109–177, title VII, § 743(a), Mar. 9, 2006, 120 Stat. 272; Pub. L. 111–16, § 5, May 7, 2009, 123 Stat. 1608.

In subsection (f), the words "The United States" are substituted for "The Government" for consistency in the section.

In subsection (f), the words "ensure the availability" are substituted for "assure the availability" to use the more appropriate word.

In subsection (g)(1), the words "as the court considers proper" are substituted for "as the court shall deem proper" to use the more appropriate word.

In subsection (n)(1), the words "The United States" are substituted for "The Government" for consistency in the section.

SECTION 50714—INVESTMENT OF ILLICIT DRUG PROFITS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50714	21 U.S.C. 854	Pub. L. 91–513, title II, § 414, as added Pub. L. 98–473, title II, § 303, Oct. 12, 1984, 98 Stat. 2049.

In subsection (c), the words "fined under title 18" are substituted for "fined not more than $50,000" for consistency with chapter 227 of title 18, United States Code.

SECTION 50715—ALTERNATIVE FINE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50715	21 U.S.C. 855	Pub. L. 91–513, title II, § 415, as added Pub. L. 98–473, title II, § 2302, Oct. 12, 1984, 98 Stat. 2193.

SECTION 50716—MAINTAINING DRUG-INVOLVED PREMISES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50716	21 U.S.C. 856	Pub. L. 91–513, title II, §416, as added Pub. L. 99–570, title I, § 1841(a), Oct. 27, 1986, 100 Stat. 3207–52; amended Pub. L. 106–310, div. B, title XXXVI, § 3613(e), Oct. 17, 2000, 114 Stat. 1230; Pub. L. 108–21, title VI, § 608(b)(1), (2), (c), Apr. 30, 2003, 117 Stat. 691.

In subsection (a)(1), in the matter after the semicolon, the word "or" is added for clarity.

In subsection (b), the words "or an alternative amount provided under title 18" are added in 2 places for consistency with title 18, United States Code.

SECTION 50717—CREATING SUBSTANTIAL RISK OF HARM TO HUMAN LIFE WHILE ILLEGALLY MANUFACTURING CONTROLLED SUBSTANCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50717	21 U.S.C. 858	Pub. L. 91–513, title II, § 417, as added Pub. L. 100–690, title VI, § 6301(a), Nov. 18, 1988, 102 Stat. 4370.

SECTION 50718—DISTRIBUTION TO INDIVIDUALS UNDER AGE 21

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50718	21 U.S.C. 859	Pub. L. 91–513, title II, § 418, formerly § 405, Oct. 27, 1970, 84 Stat. 1265; Pub. L. 98–473, title II, §§ 224(b), 503(b)(3), Oct. 12, 1984, 98 Stat. 2030, 2070; Pub. L. 99–570, title I, §§ 1004(a), 1005(b)(1), 1105(a), (b), Oct. 27, 1986, 100 Stat. 3207–6, 3207–11; Pub. L. 100–690, title VI, §§ 6452(b), 6455, 6456, Nov. 18, 1988, 102 Stat. 4371, 4372; renumbered § 418 and amended Pub. L. 101–647, title X, §§ 1002(a), 1003(a), title XXXV, § 3599L, Nov. 29, 1990, 104 Stat. 4827, 4828, 4932.

In subsection (a)(1), in the matter before subparagraph (A), the words "any individual at least 18 years of age, or any other person other than an individual, that violates" are substituted for "any person at least eighteen years of age who

violates" for consistency with section 50701(a)(1) of title 21, United States Code, and section 1 of title 1, United States Code.

In subsection (a)(1), in the matter before subparagraph (A), the words "individual under 21 years of age" are substituted for "person under twenty-one years of age" for consistency with section 1 of title 1, United States Code.

In subsection (b)(1), in the matter before subparagraph (A), the words "any individual at least 18 years of age, or any other person other than an individual, that violates" are substituted for "any person at least eighteen years of age who violates" for consistency with section 50701(a)(1) of title 21, United States Code, and section 1 of title 1, United States Code.

In subsection (b)(1), in the matter before subparagraph (A), the words "individual under 21 years of age" are substituted for "person under twenty-one years of age" for consistency with section 1 of title 1, United States Code.

In subsection (b)(1), the words "(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)" are substituted for "(or under section 303(b)(2) of the Federal Food, Drug, and Cosmetic Act as in effect prior to the effective date of section 701(b) of this Act)" for clarity. Section 704(a) of the Controlled Substances Act (21 U.S.C. 801 note) provides that, except as otherwise provided, the effective date for the Act is "the first day of the seventh calendar month that begins after the day immediately preceding the date of enactment", which is translated as May 1, 1971, in the restated provision. The language of section 303(b)(2) of the Federal Food, Drug, and Cosmetic Act that was in effect prior to May 1, 1971, is set out in the amendment made by section 3 of Public Law 90–639 (82 Stat. 1362).

SECTION 50719—DISTRIBUTION OR MANUFACTURING IN OR NEAR SCHOOLS AND COLLEGES AND OTHER FACILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50719	21 U.S.C. 860	Pub. L. 91–513, title II, § 419, formerly § 405A, as added Pub. L. 98–473, title II, § 503(a), Oct. 12, 1984, 98 Stat. 2069; amended Pub. L. 99–570, title I, §§ 1004(a), 1104, 1105(c), 1841(b), 1866(b), (c), Oct. 27, 1986, 100 Stat. 3207–6, 3207–11, 3207–52, 3207–55; Pub. L. 99–646, § 28, Nov. 10, 1986, 100 Stat. 3598; Pub. L. 100–690, title VI, §§ 6452(b)(1), 6457, 6458, Nov. 18, 1988, 102 Stat. 4371, 4373; renumbered § 419 and amended Pub. L. 101–647, title X, §§ 1002(b), 1003(b), title XII, § 1214, title XV, § 1502, title XXXV, § 3599L, Nov. 29, 1990, 104 Stat. 4827, 4829, 4833, 4836, 4932; Pub. L. 103–322, title XIV, § 140006, title XXXII, § 320107, title XXXIII, § 330009(a), Sept. 13, 1994, 108 Stat. 2032, 2111, 2143.

In paragraphs (2) and (3) of subsection (a), the word "individuals" is substituted for "persons" for consistency with section 1 of title 1, United States Code.

In subsection (b)(4), the words "provisions of this subsection" are substituted for "provisions of this paragraph" to provide the correct reference to the pertinent provisions. There are no paragraphs in the source provision. The reference to "this subsection" in the restatement refers to restated provisions of subsection (a) of section 419 of the Controlled Substances Act (21 U.S.C. 860).

In subsection (d)(1), the words "is subject to" are substituted for "is punishable by" to use the more appropriate words.

In subparagraphs (A) and (B) of subsection (d)(2), the word "individual" is substituted for "person" for consistency with section 1 of title 1, United States Code.

In subsection (d)(2), in the matter before subparagraph (A), the words "if the person is an individual at least 18 years of age, or any other person other than an individual, that knowingly and intentionally" are substituted for "any person at least 21 years of age who knowingly and intentionally" for consistency with section 1 of title 1, United States Code.

SECTION 50720—CONSECUTIVE SENTENCE FOR MANUFACTURING OR DISTRIBUTING METHAMPHETAMINE ON PREMISES WHERE CHILDREN ARE PRESENT OR RESIDE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50720	21 U.S.C. 860a	Pub. L. 91–513, title II, § 419a, as added Pub. L. 109–177, title VII, § 734(a), Mar. 9, 2006, 120 Stat. 270.

SECTION 50721—EMPLOYMENT OR USE OF PERSONS UNDER 18 YEARS OF AGE IN DRUG OPERATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50721	21 U.S.C. 861	Pub. L. 91–513, title II, § 420, formerly § 405B, as added Pub. L. 99–570, title I, § 1102, Oct. 27, 1986, 100 Stat. 3207–10; amended Pub. L. 100–690, title VI, §§ 6452(b)(1), 6459, 6470(d), Nov. 18, 1988, 102 Stat. 4371, 4373, 4378; renumbered § 420 and amended Pub. L. 101–647, title X, §§ 1002(c), 1003(c), title XXXV, § 3599L, Nov. 29, 1990, 104 Stat. 4827, 4829, 4932.

In subsection (a), in the matter before paragraph (1), the words "any individual at least 18 years of age, or any other person other than an individual, to knowingly and intentionally" are substituted for "any person at least eighteen years of age to knowingly and intentionally" for consistency with section 1 of title 1, United States Code.

In paragraphs (1) through (3) of subsection (a), the word "individual" is substituted for "person" for consistency with section 1 of title 1, United States Code.

In subsection (b), the words "Any individual at least 18 years of age, or any other person other than an individual, that violates subsection (a)" are substituted for "Any person who violates subsection (a)" for consistency with subsection (a) and with section 1 of title 1, United States Code.

In subsection (c), the words "Any individual at least 18 years of age, or any other person other than an individual, that violates subsection (a)," are substituted for "Any person who violates subsection (a)" for consistency with subsection (a) and with section 1 of title 1, United States Code.

In subsection (d)(1), the words "a fine under title 18" are substituted for "a fine of not more than $50,000" for consistency with chapter 227 of title 18, United States Code.

In subsection (d)(2), in the matter before subparagraph (A), the words "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)" are substituted for "Any person who violates subsection (a)(1) or (2)" for consistency with subsection (a) and with section 1 of title 1, United States Code.

In subsection (d)(2)(A), the words "any individual" are substituted for "any person" for consistency with section 1 of title 1, United States Code.

In subsection (d)(2)(B), the words "if the individual" are substituted for "if the person" for consistency with section 1 of title 1, United States Code.

In subsection (e), the words "under section 4202 of title 18, United States Code," are omitted as obsolete because that section was repealed by section 2 of the Parole Commission and Reorganization Act (Public Law 94–233, 90 Stat. 219). Section 2 of that Act also enacted a new section 4202 of title 18, United States Code, but that section 4202 was subsequently repealed by section 218(a)(5) of the Comprehensive Crime Control Act of 1984 (Public Law 98–473, 98 Stat. 2027) by the repeal of chapter 311 of title 18, United States Code.

SECTION 50722—DENIAL OF FEDERAL BENEFITS TO DRUG TRAFFICKERS AND POSSESSORS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50722	21 U.S.C. 862(a) through (f)	Pub. L. 91–513, title II, §421(a) through (f), formerly Pub. L. 100–690, title V, § 5301, Nov. 18, 1988, 102 Stat. 4310; renumbered § 421 of Pub. L. 91–513 and amended Pub. L. 101–647, title X, § 1002(d), Nov. 29, 1990, 104 Stat. 4827.

In subsection (b)(2), the words "for any individual who" are substituted for "for any person who" for consistency with section 1 of title 1, United States Code.

In subsection (c)(1)(A), in the matter before clause (i), the words "(as such term is defined for purposes of the Controlled Substances Act)" are omitted as unnecessary.

In subsection (c)(1)(A)(i)(II), the words "ensure that the individual" are substituted for "insure that the individual" to use the more appropriate word.

In subsection (c)(1)(A)(i)(IV), the words "be subject to" are added to supply missing words.

In subsection (c)(2), the words "in the case of an individual who" are substituted for "in the case of a person who" for consistency with section 1 of title 1, United States Code.

SECTION 50723—DRUG PARAPHERNALIA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50723(a)	21 U.S.C. 863(d)	Pub. L. 91–513, title II, §422(d), as added and amended Pub. L. 101–647, title XXIV, § 2401(a), (b), Nov. 29, 1990, 104 Stat. 4858, 4859; Pub. L. 106–310, div. B, title XXXVI, § 3614, Oct. 17, 2000, 114 Stat. 1230.
50723(b) through (d) ...	21 U.S.C. 863(a) through (c)	Pub. L. 91–513, title II, §422(a) through (c), as added and amended Pub. L. 101–647, title XXIV,

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		§ 2401(a) through (c), Nov. 29, 1990, 104 Stat. 4858, 4859.
50723(e)	21 U.S.C. 863(e)	Pub. L. 91–513, title II, §422(e), as added and amended Pub. L. 101–647, title XXIV, § 2401(a), (b), Nov. 29, 1990, 104 Stat. 4858, 4859.
50723(f)	21 U.S.C. 863(f)	Pub. L. 91–513, title II, §422(f), as added and amended Pub. L. 101–647, title XXIV, § 2401(a) through (c), Nov. 29, 1990, 104 Stat. 4858, 4859.

In subsection (c), the words "Any person" are substituted for "Anyone" for consistency in the section.

In subsection (d), the words "Administrator of General Services" are substituted for "Administrator of General Services, General Services Administration" to eliminate unnecessary words.

SECTION 50724—STEALING OR TRANSPORTING ANHYDROUS AMMONIA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50724	21 U.S.C. 864	Pub. L. 91–513, title II, §423, as added Pub. L. 106–310, div. B, title XXXVI, § 3653(a), Oct. 17, 2000, 114 Stat. 1240.

Chapter 509—Administrative and Enforcement Provisions

SECTION 50901—ATTORNEY GENERAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50901	21 U.S.C. 871	Pub. L. 91–513, title II, § 501, Oct. 27, 1970, 84 Stat. 1270.

In subsection (b), the words "consider necessary and appropriate" are substituted for "deem necessary and appropriate" to use the more appropriate word.

SECTION 50902—EDUCATION AND RESEARCH PROGRAMS OF ATTORNEY GENERAL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50902	21 U.S.C. 872	Pub. L. 91–513, title II, § 502, Oct. 27, 1970, 84 Stat. 1271; Pub. L. 95–633, title I, § 108(a), Nov. 10, 1978, 92 Stat. 3773; Pub. L. 100–690, title VI, § 6060, Nov. 18, 1988, 102 Stat. 4320; Pub. L. 111–211, title II, § 232(a), July 29, 2010, 124 Stat. 2278.

SECTION 50903—COOPERATIVE ARRANGEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50903	21 U.S.C. 873 (except (d)(3))	Pub. L. 91–513, title II, §503 (except (d)(3)), Oct. 27, 1970, 84 Stat. 1271; Pub. L. 96–359, § 8(a)Sept. 26, 1980, 94 Stat. 1194; Pub. L. 98–473, title II, § 517, Oct. 12, 1984, 98 Stat. 2074; Pub. L. 99–570, title I, § 1868, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L.

SECTION 50903—COOPERATIVE ARRANGEMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		99–646, § 85, Nov. 10, 1986, 100 Stat. 3620; Pub. L. 111–211, title II, § 232(c), July 29, 2010, 124 Stat. 2278; Pub. L. 115–271, title III, §3273(b), Oct. 24, 2018, 132 Stat. 3953.

In subsection (a), in the matter before paragraph (1), the words "To carry out this subsection" are substituted for "To this end" for consistency in title 21, United States Code.

In subsection (a)(7), the words "under this division and division B" are substituted for "under this Act" to provide a more precise reference to the pertinent provisions. The reference to "this division and division B" in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236). Titles II and III of that Act comprises the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, among other provisions.

In subsection (c)(2), the words "shall be construed to create a cause of action" are substituted for "shall be construed to bring an action" for clarity.

SECTION 50904—ADVISORY COMMITTEES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50904	21 U.S.C. 874	Pub. L. 91–513, title II, § 504, Oct. 27, 1970, 84 Stat. 1272.

SECTION 50905—ADMINISTRATIVE HEARINGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50905	21 U.S.C. 875	Pub. L. 91–513, title II, § 505, Oct. 27, 1970, 84 Stat. 1272.

SECTION 50906—SUBPOENAS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50906	21 U.S.C. 876	Pub. L. 91–513, title II, § 506, Oct. 27, 1970, 84 Stat. 1272; Pub. L. 100–690, title VI, § 6058, Nov. 18, 1988, 102 Stat. 4319.

SECTION 50907—JUDICIAL REVIEW

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50907	21 U.S.C. 877	Pub. L. 91–513, title II, § 507, Oct. 27, 1970, 84 Stat. 1273.

SECTION 50908—POWERS OF ENFORCEMENT PERSONNEL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50908	21 U.S.C. 878	Pub. L. 91–513, title II, § 508, Oct. 27, 1970, 84 Stat. 1273; Pub. L. 96–132, § 16(b), Nov. 30, 1979, 93 Stat. 1049; Pub. L. 99–570, title I, § 1869, Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 99–646, § 86, Nov. 10, 1986, 100 Stat. 3620; Pub. L. 111–211, title II, § 232(d), July 29, 2010, 124 Stat. 2278.

SECTION 50909—SEARCH WARRANTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50909	21 U.S.C. 879	Pub. L. 91–513, title II, § 509, Oct. 27, 1970, 84 Stat. 1274; Pub. L. 93–481, § 3, Oct. 26, 1974, 88 Stat. 1455; Pub. L. 101–650, title III, § 321, Dec. 1, 1990, 104 Stat. 5117.

SECTION 50910—ADMINISTRATIVE INSPECTIONS AND WARRANTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50910(a)(1)	21 U.S.C. 880(a)	Pub. L. 91–513, title II, §510(a), Oct. 27, 1970, 84 Stat. 1274; Pub. L. 103–200, §6(1), Dec. 17, 1993, 107 Stat. 2340.
50910(a)(2)	21 U.S.C. 880(d)(1) (last sentence)	Pub. L. 91–513, title II, §510(d)(1) (last sentence), Oct. 27, 1970, 84 Stat. 1275.
50910(b)(1)	21 U.S.C. 880(b)(1)	Pub. L. 91–513, title II, §510(b)(1), Oct. 27, 1970, 84 Stat. 1274.
50910(b)(2)	21 U.S.C. 880(b)(2)	Pub. L. 91–513, title II, §510(b)(2), Oct. 27, 1970, 84 Stat. 1274.
50910(b)(3)	21 U.S.C. 880(b)(3)	Pub. L. 91–513, title II, §510(b)(3), Oct. 27, 1970, 84 Stat. 1274; Pub. L. 101–647, title XXXV, §3599M, Nov. 29, 1990, 104 Stat. 4932; Pub. L. 103–200, §6(2), Dec. 17, 1993, 107 Stat. 2340.
50910(b)(4)	21 U.S.C. 880(b)(4)	Pub. L. 91–513, title II, §510(b)(4), Oct. 27, 1970, 84 Stat. 1275.
50910(c)	21 U.S.C. 880(c)	Pub. L. 91–513, title II, §510(c), Oct. 27, 1970, 84 Stat. 1275.
50910(d) (matter before (1))	21 U.S.C. 880(d) (matter before (1))	Pub. L. 91–513, title II, §510(d) (matter before (1)), Oct. 27, 1970, 84 Stat. 1275.
50910(d)(1)	21 U.S.C. 880(d)(1) (1st sentence)	Pub. L. 91–513, title II, §510(d)(1) (1st sentence), Oct. 27, 1970, 84 Stat. 1275; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117.
50910(d)(2)	21 U.S.C. 880(d)(2)	Pub. L. 91–513, title II, §510(d)(2), Oct. 27, 1970, 84 Stat. 1275; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117.
50910(d)(3)	21 U.S.C. 880(d)(3)	Pub. L. 91–513, title II, §510(d)(3), Oct. 27, 1970, 84 Stat. 1275; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117.
50910(d)(4)	21 U.S.C. 880(d)(4)	Pub. L. 91–513, title II, §510(d)(4), Oct. 27, 1970, 84 Stat. 1275; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117.

In subsection (d)(3)(A), the words “shall be executed” are substituted for “must be executed” for consistency in title 21, United States Code.

SECTION 50911—FORFEITURES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50911	21 U.S.C. 881	Pub. L. 91–513, title II, § 511, Oct. 27, 1970, 84 Stat. 1276; Pub. L. 95–633, title III, § 301(a), Nov. 10, 1978, 92 Stat. 3777; Pub. L. 96–132, § 14, Nov. 30, 1979, 93 Stat. 1048; Pub. L. 98–473, title II, §§ 306, 309, 518, Oct. 12, 1984, 98 Stat. 2050, 2051, 2075; Pub. L. 99–570, title I, §§ 1006(c), 1865, 1992, Oct.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		27, 1986, 100 Stat. 3207–7, 3207–54, 3207–59; Pub. L. 99–646, § 74, Nov. 10, 1986, 100 Stat. 3618; Pub. L. 100–690, title V, § 5105, title VI, §§ 6059, 6074, 6075, 6077(a), (b), 6253, Nov. 18, 1988, 102 Stat. 4301, 4319, 4323–4325, 4363; Pub. L. 101–189, div. A, title XII, § 1215(a), Nov. 29, 1989, 103 Stat. 1569; Pub. L. 101–647, title XX, §§ 2003, 2004, 2007, 2008, Nov. 29, 1990, 104 Stat. 4855, 4856; Pub. L. 102–239, § 2, Dec. 17, 1991, 105 Stat. 1912; Pub. L. 103–447, title I, § 102(d), Nov. 2, 1994, 108 Stat. 4693; Pub. L. 104–237, title II, § 201(b), Oct. 3, 1996, 110 Stat. 3101; Pub. L. 106–185, §§ 2(c)(2), 5(b), 8(b), Apr. 25, 2000, 114 Stat. 210, 214, 216; Pub. L. 107–273, div. B, title IV, § 4002(e)(3), Nov. 2, 2002, 116 Stat. 1810.

In subsection(d)(1), the words "with the provisions of this section" are substituted for "with the provisions hereof" for clarity.

In subsection (e)(1)(D), the words "Drug Enforcement Administration" are substituted for "Bureau of Narcotics and Dangerous Drugs" because the Bureau of Narcotics and Dangerous Drugs was abolished by section 3 of Reorganization Plan No. 2 of 1973 (28 U.S.C. 509 note). Section 4 of the Reorganization Plan provides for the establishment of the Drug Enforcement Administration and section 5 provides for the appointment of the Administrator of Drug Enforcement as head of the Drug Enforcement Administration. Section 7 provides that the Attorney General, acting through the Administrator and other designated officials, shall provide for the coordination of all drug law enforcement functions vested in the Attorney General.

In subsection (e)(2)(B), the words "Secretary of the Treasury" are substituted for "Treasurer of the United States" for clarity.

In subsection (e)(3), in the matter before subparagraph (A), the words "ensure that any property" are substituted for "assure that any property" to use the more appropriate word.

In subsection (f)(2)(C), the words "consider necessary" are substituted for "deem necessary" to use the more appropriate word.

SECTION 50912—INJUNCTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50912	21 U.S.C. 882	Pub. L. 91–513, title II, § 512, Oct. 27, 1970, 84 Stat. 1278; Pub. L. 110–425, § 3(h), Oct. 15, 2008, 122 Stat. 4830; Pub. L. 117–215, title I, §103(b)(1)(I), Dec. 2, 2022, 136 Stat. 2263.

In subsection (c)(3), the words "nothing in this division" are substituted for "nothing in this Act" to provide a more precise reference to the pertinent provision and for consistency with paragraph (1), which provides for a State's authority to bring a civil action for violations of provisions in division A, to which "this division" refers. The reference to "this division" in the restatement refers to restated provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.), not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236).

In subsection (c)(6)(C), the words "provided the employee" are substituted for "provided such agent or employee" to eliminate unnecessary words and for consistency in the subparagraph.

In subsection (c)(6)(C), the words "the official duties of the employee" are substituted for "the official duties of such agent or employee" to eliminate unnecessary words and for consistency in the subparagraph.

In subsection (c)(6)(C), the words "relating to the business or employment" are substituted for "therewith" for clarity.

SECTION 50913—NOTICE AND OPPORTUNITY TO PRESENT VIEWS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50913	21 U.S.C. 883	Pub. L. 91–513, title II, § 513, Oct. 27, 1970, 84 Stat. 1278; Pub. L. 96–132, § 16(c), Nov. 30, 1979, 93 Stat. 1049.

SECTION 50914—IMMUNITY AND PRIVILEGE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50914	21 U.S.C. 884	Pub. L. 91–513, title II, § 514, Oct. 27, 1970, 84 Stat. 1278; Pub. L. 100–690, title VII, § 7020(f), Nov. 18, 1988, 102 Stat. 4396.

SECTION 50915—BURDEN OF PROOF; LIABILITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50915	21 U.S.C. 885	Pub. L. 91–513, title II, § 515, Oct. 27, 1970, 84 Stat. 1279.

SECTION 50916—PAYMENTS AND ADVANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50916	21 U.S.C. 886	Pub. L. 91–513, title II, § 516, Oct. 27, 1970, 84 Stat. 1279; Pub. L. 96–132, § 16(b), Nov. 30, 1979, 93 Stat. 1049; Pub. L. 100–690, title VI, § 6254(i), Nov. 18, 1988, 102 Stat. 4367.

In subsection (a), the words "consider appropriate" are substituted for "deem appropriate" to use the more appropriate word.

In subsection (b), the words "appropriation for the Administration" are substituted for "appropriation for the Bureau" for consistency in the subsection.

In subsection (d)(5), the words "under this subsection" are substituted for "under this paragraph" to provide the correct reference to the pertinent provision.

SECTION 50917—COORDINATION AND CONSOLIDATION OF POST-SEIZURE ADMINISTRATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50917	21 U.S.C. 887	Pub. L. 91–513, title II, § 517, as added Pub. L. 100–690, title VI, § 6078(a), Nov. 18, 1988, 102 Stat. 4325.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50918	21 U.S.C. 889 (except (a)(1))	Pub. L. 91–513, title II, §519 (except (a)(1)), formerly Pub. L. 99–198, title XVII, § 1764, Dec. 23, 1985, 99 Stat. 1652; renumbered § 519 of Pub. L. 91–513, Pub. L. 101–647, title X, § 1002(h)(2), Nov. 29, 1990, 104 Stat. 4828.

In subsection (a)(2), the words "or the Trust Territory of the Pacific Islands" are omitted as obsolete. See note at 48 U.S.C. prec. 1681. For continued application of certain laws of the United States in certain cases, see the Compact of Free Association between the Government of the United States of America and the Governments of the Marshall Islands and the Federated States of Micronesia (48 U.S.C. 1901 note), and the Compact of Free Association between the Government of the United States of America and the Government of Palau (48 U.S.C. 1931 note).

In subsection (b), in the matter before paragraph (1), the words "following the date of enactment of this Act" are omitted as obsolete.

In subsection (c), in the matter before paragraph (1), the words "Not later than 180 days after the date of enactment of this Act," are omitted as obsolete.

SECTION 50919—REVIEW OF FEDERAL SALES OF CHEMICALS USABLE TO MANUFACTURE CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
50919	21 U.S.C. 890	Pub. L. 91–513, title II, § 520, as added Pub. L. 104–201, div. A, title X, § 1034(a), Sept. 23, 1996, 110 Stat. 2640.

In this section, the word "agency" is substituted for the words "department or agency" each place they appear to eliminate unnecessary words.

Chapter 511—Miscellaneous

SECTION 51101—EFFECT OF PROVISIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51101(a)	21 U.S.C. 902	Pub. L. 91–513, title II, § 707, Oct. 27, 1970, 84 Stat. 1284.
51101(b)	21 U.S.C. 802 note	Pub. L. 110–425, §4, Oct. 15, 2008, 122 Stat. 4834.
51101(c)	21 U.S.C. 802 note	Pub. L. 109–177, title VII, §711(g), Mar. 9, 2006, 120 Stat. 263.

In subsection (a), the words "as affecting" are substituted for "as in any way affecting" to eliminate unnecessary words.

In subsection (c), the words "scheduled listed chemical products" are substituted for "scheduled listed chemicals (as defined in section 102(45) of such Act)" for consistency with section 50101(52) of title 21, United States Code, the source law of which is section 102(45) of the Controlled Substances Act (21 U.S.C. 802(45)).

SECTION 51102—PREEMPTION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51102	21 U.S.C. 903	Pub. L. 91–513, title II, § 708, Oct. 27, 1970, 84 Stat. 1284.

SECTION 51103—PAYMENT OF TORT CLAIMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51103	21 U.S.C. 904	Pub. L. 91–513, title II, § 709, Oct. 27, 1970, 84 Stat. 1284; Pub. L. 93–481, § 1, Oct. 26, 1974, 88 Stat. 1455; Pub. L. 95–137, § 1(a), Oct. 18, 1977, 91 Stat. 1169; Pub. L. 96–132, §§ 13, 15, Nov. 30, 1979, 93 Stat. 1048; Pub. L. 97–414, § 9(g)(1), Jan. 4, 1983, 96 Stat. 2064.

Division B—Controlled Substances Import and Export

Chapter 517—Importation and Exportation

SECTION 51701—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51701	21 U.S.C. 951	Pub. L. 91–513, title III, § 1001, Oct. 27, 1970, 84 Stat. 1285; Pub. L. 100–418, title I, § 1214(m), Aug. 23, 1988, 102 Stat. 1158.

SECTION 51702—IMPORTATION OF CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51702	21 U.S.C. 952	Pub. L. 91–513, title III, § 1002, Oct. 27, 1970, 84 Stat. 1285; Pub. L. 95–633, title I, § 105, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, §§ 519–521, Oct. 12, 1984, 98 Stat. 2075; Pub. L. 109–177, title VII, § 715, Mar. 9, 2006, 120 Stat. 264.

In subsection (a), in the matter before paragraph (1), and in subsection (b), in the matter before paragraph (1), the words "from any place outside of the customs territory of the United States" are substituted for "from any place outside thereof" for clarity.

SECTION 51703—EXPORTATION OF CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51703	21 U.S.C. 953	Pub. L. 91–513, title III, § 1003, Oct. 27, 1970, 84 Stat. 1286; Pub. L. 95–633, title I, § 106, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98–473, title II, § 522, Oct. 12, 1984, 98 Stat. 2076; Pub. L. 109–57, § 1(b), Aug. 2, 2005, 119 Stat. 592; Pub. L. 114–89, §4, Nov. 25, 2015, 129 Stat. 701.

In subsection (a)(1)(C), the words "Single Convention on Narcotic Drugs" are substituted for "Single Convention on Narcotic Drugs, 1961, signed at New

York, March 30, 1961" because of sections 50101(57) and 51701(b) of title 21, United States Code.

In subsections (a)(2), (c)(1), and (f)(2), the words "considers adequate" are substituted for "deems adequate" to use the more appropriate word.

SECTION 51704—TRANSSHIPMENT AND IN-TRANSIT SHIPMENT OF CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51704	21 U.S.C. 954	Pub. L. 91–513, title III, § 1004, Oct. 27, 1970, 84 Stat. 1287.

SECTION 51705—POSSESSION ON BOARD VESSELS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51705	21 U.S.C. 955	Pub. L. 91–513, title III, § 1005, Oct. 27, 1970, 84 Stat. 1287.

SECTION 51706—EXEMPTION AUTHORITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51706 (except (a)(2)(B), (C))	21 U.S.C. 956	Pub. L. 91–513, title III, § 1006, Oct. 27, 1970, 84 Stat. 1288; Pub. L. 105–277, div. C, title VIII, § 872(a), Oct. 21, 1998, 112 Stat. 2681–707; Pub. L. 105–357, § 2(a), Nov. 10, 1998, 112 Stat. 3271.
51706(a)(2)(B)	21 U.S.C. 956 note	Pub. L. 105–357, §2(b), Nov. 10, 1998, 112 Stat. 3271.
51706(a)(2)(C)	21 U.S.C. 956 note	Pub. L. 105–357, §2(c), Nov. 10, 1998, 112 Stat. 3271.

In subsection (a)(2)(A), the parenthetical "(as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802))" is omitted as unnecessary because of section 51701(b) of title 21, United States Code.

In subsection (b), in the matter before paragraph (1), the words "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)" are substituted for "listed in paragraph (a) or (b) of schedule III or in schedule IV or V" for clarity and consistency in the subsection.

SECTION 51707—PERSONS REQUIRED TO REGISTER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51707	21 U.S.C. 957	Pub. L. 91–513, title III, § 1007, Oct. 27, 1970, 84 Stat. 1288; Pub. L. 98–473, title II, § 523, Oct. 12, 1984, 98 Stat. 2076; Pub. L. 103–200, § 3(e), Dec. 17, 1993, 107 Stat. 2337.

In subsection (b)(1)(C), the words "section 50101(61) of this title" are substituted for "section 102(25)" to provide the correct reference to the pertinent provision. Section 102(25) of the Controlled Substances Act, referred to in the source law, was redesignated as section 102(26) by section 507(a) of Public L. 98–473 (98 Stat. 2071) and was further redesignated as section 102(27) by section 1003(b)(2) of the Narcotics Penalties and Enforcement Act of 1986 (Public Law 99–570, title I, 100 Stat. 3207–6). Section 50101(61) of title 21, United States Code, restates section 102(27) of the source law.

SECTION 51708—REGISTRATION REQUIREMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51708	21 U.S.C. 958	Pub. L. 91–513, title III, § 1008, Oct. 27, 1970, 84 Stat. 1289; Pub. L. 98–473, title II, §§ 524, 525, Oct. 12, 1984, 98 Stat. 2076; Pub. L. 99–570, title I, § 1866(d), Oct. 27, 1986, 100 Stat. 3207–55; Pub. L. 103–200, § 3(f), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 108–447, div. B, title VI, § 633(c), Dec. 8, 2004, 118 Stat. 2922; Pub. L. 117–215, title I, §103(b)(2), Dec. 2, 2022, 136 Stat. 2263.

In subsection (g), the words "substances or chemicals to the extent" are substituted for "substances to the extent" for consistency in the subsection.

SECTION 51709—POSSESSION, MANUFACTURE, OR DISTRIBUTION OF CONTROLLED SUBSTANCE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51709	21 U.S.C. 959	Pub. L. 91–513, title III, § 1009, Oct. 27, 1970, 84 Stat. 1289; Pub. L. 99–570, title III, § 3161(a), Oct. 27, 1986, 100 Stat. 3207–94; Pub. L. 104–237, title I, § 102(a), (b), Oct. 3, 1996, 110 Stat. 3100; Pub. L. 104–305, § 2(b)(2)(A), Oct. 13, 1996, 110 Stat. 3807; Pub. L. 114–154, §2, May 16, 2016, 130 Stat. 387; Pub. L. 115–91, div. A, title X, §1012(b), Dec. 12, 2017, 131 Stat. 1546.

SECTION 51710—PROHIBITED ACTS A

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51710	21 U.S.C. 960	Pub. L. 91–513, title III, § 1010, Oct. 27, 1970, 84 Stat. 1290; Pub. L. 98–473, title II, §§ 225, formerly § 225(a), 504, Oct. 12, 1984, 98 Stat. 2030, 2070; Pub. L. 99–570, title I, §§ 1004(a), 1005(c), 1302, 1866(e), Oct. 27, 1986, 100 Stat. 3207–6, 3207–15, 3207–55; Pub. L. 100–690, title VI, §§ 6053(c), 6475, Nov. 18, 1988, 102 Stat. 4315, 4380; Pub. L. 101–647, title XII, § 1204, title XXXV, § 3599J, Nov. 29, 1990, 104 Stat. 4830, 4932; Pub. L. 103–200, §§ 4(b), 5(b), Dec. 17, 1993, 107 Stat. 2338, 2339; Pub. L. 103–322, title IX, § 90105(a), title XXXIII, § 330024(d)(2), Sept. 13, 1994, 108 Stat. 1987, 2151; Pub. L. 104–237, title I, § 102(c), title III, § 302(b), Oct. 3, 1996, 110 Stat. 3100, 3105; Pub. L. 104–305, § 2(b)(2)(B), (C), Oct. 13, 1996, 110 Stat. 3807; Pub. L. 105–277, div. E, § 2(b), Oct. 21, 1998, 112 Stat. 2681–759; Pub. L. 106–172, § 3(b)(2), Feb. 18, 2000, 114 Stat. 9; Pub. L. 107–273, div. B, title III, § 3005(b), Nov. 2, 2002, 116 Stat. 1806; Pub. L. 109–177, title VII, §§ 716(b)(1)(A), 717, Mar. 9, 2006, 120 Stat. 267; Pub. L. 110–425, § 3(i), Oct. 15, 2008, 122 Stat. 4832; Pub. L. 111–220, §§ 2(b), 4(b), Aug. 3, 2010, 124 Stat. 2372; Pub. L. 113–260, § 3(b), Dec. 18, 2014, 128 Stat. 2931; Pub. L. 115–391, title IV, §401(b), Dec. 21, 2018, 132 Stat. 5221; Pub. L. 119–26, §6(b), July 16, 2025, 139 Stat. 417.

SECTION 51711—FOREIGN TERRORIST ORGANIZATIONS AND TERRORIST PERSONS AND GROUPS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51711	21 U.S.C. 960a	Pub. L. 91–513, title III, § 1010A, as added Pub. L. 109–177, title I, § 122, Mar. 9, 2006, 120 Stat. 225.

In subsection (b)(1), the words "section 50701(a) of this title" are substituted for "section 841(a) of this title" to provide the correct reference to the pertinent provision. Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) does not contain a section 841. Section 401 of the Controlled Substances Act is classified to 21 U.S.C. 841; that section is restated as section 50701 of title 21, United States Code, and section 401(a) of that Act (21 U.S.C. 841(a)) is restated as section 50701(a) of title 21, United States Code.

In subsection (b)(1), the words "section 50701(b)(1) of this title" are substituted for "section 841(b)(1)" to provide the correct reference to the pertinent provision. Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) does not contain a section 841. Section 401 of the Controlled Substances Act is classified to 21 U.S.C. 841; that section is restated as section 50701 of title 21, United States Code, and section 401(b)(1) of that Act (21 U.S.C. 841(b)(1)) is restated as section 50701(b)(1) of title 21, United States Code.

SECTION 51712—PROHIBITED ACTS B

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51712	21 U.S.C. 961	Pub. L. 91–513, title III, §1011, Oct. 27, 1970, 84 Stat. 1290; Pub. L. 100–690, title VI, § 6053(d), Nov. 18, 1988, 102 Stat. 4316.

In paragraph (2), the words "a fine under title 18" are substituted for "a fine of not more than $25,000" for consistency with title 18, United States Code.

SECTION 51713—SECOND OR SUBSEQUENT OFFENSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51713	21 U.S.C. 962	Pub. L. 91–513, title III, § 1012, Oct. 27, 1970, 84 Stat. 1290; Pub. L. 98–473, title II, §§ 225(b), 505, Oct. 12, 1984, 98 Stat. 2030, 2070; Pub. L. 99–570, title I, §§ 1004(a), 1005(c), Oct. 27, 1986, 100 Stat. 3207–6; Pub. L. 103–322, title IX, § 90105(b), Sept. 13, 1994, 108 Stat. 1988.

SECTION 51714—ATTEMPT AND CONSPIRACY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51714	21 U.S.C. 963	Pub. L. 91–513, title III, § 1013, Oct. 27, 1970, 84 Stat. 1291; Pub. L. 100–690, title VI, § 6470(a), Nov. 18, 1988, 102 Stat. 4377.

SECTION 51715—ADDITIONAL PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51715	21 U.S.C. 964	Pub. L. 91–513, title III, § 1014, Oct. 27, 1970, 84 Stat. 1291.

SECTION 51716—APPLICABILITY OF CHAPTER 509 OF THIS TITLE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51716	21 U.S.C. 965	Pub. L. 91–513, title III, § 1015, Oct. 27, 1970, 84 Stat. 1291; Pub. L. 95–633, title III, § 301(b), Nov. 10, 1978, 92 Stat. 3778.

In subsection (a), the words "Drug Enforcement Administration" are substituted for "Bureau of Narcotics and Dangerous Drugs" because the Bureau of Narcotics and Dangerous Drugs was abolished by section 3 of Reorganization Plan No. 2 of 1973 (28 U.S.C. 509 note). Section 4 of the Reorganization Plan established the Drug Enforcement Administration and section 5 provided for the appointment of the Administrator of Drug Enforcement as head of the Drug Enforcement Administration. Section 7 provides that the Attorney General, acting through the Administrator and other designated officials, shall provide for the coordination of all drug law enforcement functions vested in the Attorney General.

SECTION 51717—AUTHORITY OF SECRETARY OF THE TREASURY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51717	21 U.S.C. 966	Pub. L. 91–513, title III, § 1016, Oct. 27, 1970, 84 Stat. 1291.

In this section, the words "Nothing in this division and division A" are substituted for "Nothing in this Act" to provide a more precise reference to the pertinent provisions. The reference to "this division and division A" in the restatement refers to restated provisions of the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.) and the Controlled Substances Act (21 U.S.C. 801 et seq.), respectively, not to the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236). Titles II and III of that Act comprises the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), respectively, among other provisions.

In this section, the reference to the Secretary of the Treasury is retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

SECTION 51718—CRIMINAL FORFEITURES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51718	21 U.S.C. 970	Pub. L. 91–513, title III, § 1017, as added Pub. L. 98–473, title II, § 307, Oct. 12, 1984, 98 Stat. 2051.

SECTION 51719—NOTIFICATION, SUSPENSION OF SHIPMENT, AND PENALTIES WITH RESPECT TO IMPORTATION AND EXPORTATION OF LISTED CHEMICALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
51719(a) through (h) ...	21 U.S.C. 971	Pub. L. 91–513, title III, § 1018, as added Pub. L. 100–690, title VI, § 6053(a), Nov. 18, 1988, 102 Stat. 4314; amended Pub. L. 103–200, §§ 4(a), 5(a), 9(b), Dec. 17, 1993, 107 Stat. 2338–2340; Pub. L. 103–322, title XXXIII, § 330024(c), Sept. 13, 1994, 108 Stat. 2150; Pub. L. 109–177, title VII, §§ 716(a), (b)(1)(B), 721, Mar. 9, 2006, 120 Stat. 265, 267.
51719(i)	21 U.S.C. 971 note	Pub. L. 104–237, title II, §204(b), Oct. 3, 1996, 110 Stat. 3102.

In subsection (h)(2), the words "request that the foreign-chain distributor" are substituted for "request that such distributor" for clarity and consistency with

the parenthetical "(which person is referred to in this subsection as a 'foreign-chain distributor')".

In subsection (h)(2), the words "known to the foreign-chain distributor" are substituted for "known to the distributor" for clarity and consistency with the parenthetical "(which person is referred to in this subsection as a 'foreign-chain distributor')".

In subsection (h)(3)(A), the words "in which the foreign-chain distributor" are substituted for "in which such distributor" for clarity and consistency in the subparagraph.

In subsection (h)(3)(C), the words "with respect to the foreign-chain distributor" are substituted for "with respect to such distributor" for clarity and consistency with subparagraph (A).

Subtitle VI—Drug Control and Enforcement

Chapter 601—Smuggling of Controlled Substances

SECTION 60101—SMUGGLING OF CONTROLLED SUBSTANCES; INVESTIGATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60101	21 U.S.C. 967	Aug. 11, 1955, ch. 800, § 1, 69 Stat. 684; Pub. L. 91–513, title III, § 1102(t), Oct. 27, 1970, 84 Stat. 1294.

In this section, references to the Secretary of the Treasury are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. For intelligence, investigative, and law enforcement functions relating to the suppression of illicit traffic in narcotics, dangerous drugs, or marihuana transferred to the Attorney General or retained by the Secretary of the Treasury, see Reorganization Plan No. 2 of 1973 (28 U.S.C. 509 note). For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

SECTION 60102—SERVICE OF SUBPOENA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60102	21 U.S.C. 968	Aug. 11, 1955, ch. 800, § 2, 69 Stat. 685.

In this section, the reference to the Secretary of the Treasury is retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. For intelligence, investigative, and law enforcement functions relating to the suppression of illicit traffic in narcotics, dangerous drugs, or marihuana transferred to the Attorney General or retained by the Secretary of the Treasury, see Reorganization Plan No. 2 of 1973 (28 U.S.C. 509 note). For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the

Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

SECTION 60103—CONTEMPT PROCEEDINGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60103	21 U.S.C. 969	Aug. 11, 1955, ch. 800, § 3, 69 Stat. 685.

In this section, references to the Secretary of the Treasury are retained to ensure that no change in the meaning or effect of the source provision is made by the restatement of the provision in title 21, United States Code. For intelligence, investigative, and law enforcement functions relating to the suppression of illicit traffic in narcotics, dangerous drugs, or marihuana transferred to the Attorney General or retained by the Secretary of the Treasury, see Reorganization Plan No. 2 of 1973 (28 U.S.C. 509 note). For potential applicability of authorities relating to customs transferred to the Secretary of Homeland Security, and of authorities relating to customs retained by the Secretary of the Treasury, see sections 403, 411, and 412 of the Homeland Security Act of 2002 (6 U.S.C. 203, 211, 212).

In subsection (b), the words "to produce records" are substituted for "there to produce records" to eliminate an unnecessary word.

Chapter 603—Drug Abuse Prevention, Treatment, and Rehabilitation

SECTION 60301—CONGRESSIONAL DECLARATION OF NATIONAL POLICY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60301	21 U.S.C. 1102	Pub. L. 92–255, title I, § 102, Mar. 21, 1972, 86 Stat. 66; Pub. L. 94–237, § 2, Mar. 19, 1976, 90 Stat. 241; Pub. L. 96–181, § 3, Jan. 2, 1980, 93 Stat. 1309.

In subsection (a)(2), the words "ensure the implementation" are substituted for "assure the implementation" to use the more appropriate word.

SECTION 60302—NOTICE RELATING TO THE CONTROL OF DANGEROUS DRUGS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60302	21 U.S.C. 1115	Pub. L. 92–255, title II, § 201, formerly § 205, as added Pub. L. 96–181, § 4, Jan. 2, 1980, 93 Stat. 1311; amended Pub. L. 97–35, title IX, § 973(a), Aug. 13, 1981, 95 Stat. 598; renumbered § 201, Pub. L. 100–690, title I, § 1007(c)(1), Nov. 18, 1988, 102 Stat. 4187.

SECTION 60303—DRUG ABUSE PREVENTION FUNCTION APPROPRIATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60303	21 U.S.C. 1171	Pub. L. 92–255, title IV, § 404, Mar. 21, 1972, 86 Stat. 77.

In this section, in the matter before paragraph (1), the words "Federal agency" are substituted for "department or agency of the Government" for clarity and to eliminate unnecessary words.

In this section, in the matter before paragraph (1), the words "submitted after the date of enactment of this Act" are omitted as obsolete.

SECTION 60304—SPECIAL PROJECT GRANTS AND CONTRACTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60304	21 U.S.C. 1177 (except (b), (g)(3)(B))	Pub. L. 92–255, title IV, §410 (except (b), (g)(3)(B)), Mar. 21, 1972, 86 Stat. 82; Pub. L. 94–237, §11, Mar. 19, 1976, 90 Stat. 247; Pub. L. 94–371, §10(c)(1), July 26, 1976, 90 Stat. 1040; Pub. L. 95–461, §6(a), Oct. 14, 1978, 92 Stat. 1270; Pub. L. 96–181, §7(a), (c), (d), Jan. 2, 1980, 93 Stat. 1312; Pub. L. 97–35, title IX, §970(b), (d), (e), (f), Aug. 13, 1981, 95 Stat. 596, 597; Pub. L. 98–24, § 5(a)(3), Apr. 26, 1983, 97 Stat. 183.

In subsection (a)(1), in the matter before subparagraph (A), the words "The Secretary of Health and Human Services (referred to in this section as the 'Secretary')," are substituted for "The Secretary" for clarity, on authority of section 405 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (Public Law 92–255, 86 Stat. 77), as amended by section 973(c)(1) of Public Law 97–35 (95 Stat. 598), which section 405 was repealed by section 2(c)(2) of the Alcohol and Drug Abuse Amendments of 1983 (Public Law 98–24, 97 Stat. 182). That section 405 provided that references to the Secretary of Health, Education, and Welfare in title IV of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1171 et seq.) were referred to as "Secretary" in that title. Subsequently, references to the Secretary of Health, Education, and Welfare were deemed to refer to the Secretary of Health and Human Services on authority of section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

In subsection (b)(3)(C), the words "ensure proper disbursement" are substituted for "assure proper disbursement" to use the more appropriate word.

In subsection (e)(2), the words "ensure care of good quality" are substituted for "insure care of good quality" to use the more appropriate word.

SECTION 60305—RECORDS AND AUDIT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60305	21 U.S.C. 1178	Pub. L. 92–255, title IV, § 411, Mar. 21, 1972, 86 Stat. 83; Pub. L. 97–35, title IX, § 971, Aug. 13, 1981, 95 Stat. 597.

In this section, the words "Secretary of Health and Human Services" are substituted for "Secretary" each place it appears for clarity, on authority of section 405 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (Public Law 92–255, 86 Stat. 77), as amended by section 973(c)(1) of Public Law 97–35 (95 Stat. 598), which section 405 was repealed by section 2(c)(2) of the Alcohol and Drug Abuse Amendments of 1983 (Public Law 98–24, 97 Stat. 182). That section 405 provided that references to the Secretary of Health, Education, and Welfare in title IV of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1171 et seq.) were referred to as "Secretary" in that title. Subsequently, references to the Secretary of Health, Education, and

Welfare were deemed to refer to the Secretary of Health and Human Services on authority of section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

SECTION 60306—CONTRACT AUTHORITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60306	21 U.S.C. 1181	Pub. L. 92–255, title IV, § 414, as added Pub. L. 96–181, § 9(a), Jan. 2, 1980, 93 Stat. 1314.

In this section, the words "Secretary of Health and Human Services" are substituted for "Secretary" for clarity, on authority of section 405 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (Public Law 92–255, 86 Stat. 77), as amended by section 973(c)(1) of Public Law 97–35 (95 Stat. 598), which section 405 was repealed by section 2(c)(2) of the Alcohol and Drug Abuse Amendments of 1983 (Public Law 98–24, 97 Stat. 182). That section 405 provided that references to the Secretary of Health, Education, and Welfare in title IV of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1171 et seq.) were referred to as "Secretary" in that title. Subsequently, references to the Secretary of Health, Education, and Welfare were deemed to refer to the Secretary of Health and Human Services on authority of section 509 of the Department of Education Organization Act (20 U.S.C. 3508).

In this section, the words "under section 60304 of this title" are substituted for "under this title and title V" to eliminate obsolete references and to provide a more precise reference to the pertinent provision.

Chapter 605—Drug Free Communities

This chapter restates chapter 2 of the National Narcotics Leadership Act of 1988 (Pub. L. 100–690, title I, subtitle A, 102 Stat. 4181), which chapter 2 was added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224). Section 1009 of the National Narcotics Leadership Act of 1988 (Pub. L. 100–690, title I, subtitle A, 102 Stat. 4188), formerly classified to 21 U.S.C. 1506, as amended by section 90208(a) of the Violent Crime Control and Law Enforcement Act of 1994 (Pub. L. 103–322, 108 Stat. 1995), repealed subtitle A of title I of Public Law 100–690 (which subtitle A is the National Narcotics Leadership Act) effective Sept. 30, 1997. Section 2(b) of the Drug-Free Communities Act of 1997 effectively amended that section 1009 repeal so that only chapter 1 of that subtitle A is repealed, and not subtitle A in its entirety, thus enabling chapter 2 of that subtitle A to have continued force and effect after the prospective repeal by that section 1009. Nevertheless, paragraphs (1) and (2) of subsection (a) of section 8203 of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4111) directed the revival and restoration of chapter 2 of that subtitle A, except for subchapter II of that chapter 2 (which was repealed by paragraph (5) of subsection (b) of that section 8203), as in effect on September 29, 1997, and as amended by Public Law 107–82 (115 Stat. 814) and the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469, 120 Stat. 3502), as amended by paragraph (4) of section 8203(a) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4111).

Subchapter I—General Provisions

SECTION 60501—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60501	21 U.S.C. 1523 (except (2))	Pub. L. 100–690, title I, § 1023 (except (2)), as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 225; Pub. L. 115–271, title VIII, §8203(b)(2), Oct. 24, 2018, 132 Stat. 4111; Pub. L. 116–74, §2(c)(1)(A)(ii)(II), Nov. 27, 2019, 133 Stat. 1157.

In paragraph (2), the words "in consultation with the Advisory Commission" are omitted as obsolete because provisions relating to the Advisory Commission (which provisions were enacted as subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988, as added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224)) were repealed by section 8203(b)(5) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4112).

In paragraph (3), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

In paragraph (8)(A), the words "is in effect" are substituted for "is effect" to supply a missing word.

In paragraph (9), the words "in consultation with the Advisory Commission" are omitted as obsolete because provisions relating to the Advisory Commission (which provisions were enacted as subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988, as added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224)) were repealed by section 8203(b)(5) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4112).

SECTION 60502—PURPOSES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60502	21 U.S.C. 1522	Pub. L. 100–690, title I, §1022, as added Pub. L. 105–20, §2(a)(2), June 27, 1997, 111 Stat. 225; Pub. L. 115–271, title VIII, §8203(b)(1), Oct. 24, 2018, 132 Stat. 4111; Pub. L. 116–74, §2(c)(1)(A)(ii)(II), Nov. 27, 2019, 133 Stat. 1157.

SECTION 60503—AUTHORIZATION OF APPROPRIATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60503	21 U.S.C. 1524	Pub. L. 100–690, title I, § 1024, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 226; amended Pub. L. 107–82, § 1(b), (c), Dec. 14, 2001, 115 Stat. 817; Pub. L. 109–469, title VIII, § 801, Dec. 29, 2006, 120 Stat. 3535; Pub. L. 115–271, title VIII, §8203(a)(4)(A), (b)(3), Oct. 24, 2018, 132 Stat. 4111; Pub. L. 116–74, §2(c)(1)(A)(i)(IV), (V), (ii)(II), Nov. 27, 2019, 133 Stat. 1157.

Subchapter II—Drug-Free Communities Support Program

SECTION 60511—ESTABLISHMENT OF DRUG-FREE COMMUNITIES SUPPORT PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60511	21 U.S.C. 1531	Pub. L. 100–690, title I, § 1031, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 226; Pub. L. 115–271, title VIII, §8203(b)(4)(A), Oct. 24, 2018, 132 Stat. 4111; Pub. L. 116–74, §2(c)(1)(A)(ii)(II), Nov. 27, 2019, 133 Stat. 1157.

In subsection (c), the words "Not later than 30 days after receiving recommendations from the Advisory Commission under section 1042(a)(1)," are omitted as obsolete because provisions relating to the Advisory Commission (which provisions were enacted as subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988, as added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224)) were repealed by section 8203(b)(5) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4112).

SECTION 60512—PROGRAM AUTHORIZATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60512	21 U.S.C. 1532	Pub. L. 100–690, title I, § 1032, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 227; amended Pub. L. 107–82, § 1(d), (g), (h), Dec. 14, 2001, 115 Stat. 818, 819; Pub. L. 109–469, title VIII, §§ 802(a), 803, 804, Dec. 29, 2006, 120 Stat. 3535; Pub. L. 115–271, title VIII, §8203(a)(4)(A), (b)(4), Oct. 24, 2018, 132 Stat. 4111; Pub. L. 116–74, §2(c)(1)(A)(i)(IV), (V), (ii)(II), (III), (iii), (3), Nov. 27, 2019, 133 Stat. 1157 , 1158.

In subsection (a)(2)(B)(ii), the words "of the Indian Self-Determination and Education Assistance Act" are substituted for "of the Indian Self-Determination Act" to provide the correct reference to the pertinent Act.

In subsection (b)(2)(A)(i), the words "in consultation with the Advisory Commission," are omitted as obsolete because provisions relating to the Advisory Commission (which provisions were enacted as subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988, as added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224)) were repealed by section 8203(b)(5) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4112).

In subsection (b)(3)(D), in the matter before clause (i), the words "Subject to subparagraph (F)" are substituted for "Subject to clause (iv)" and the words "under this paragraph" are substituted for "under this subparagraph" to provide the correct references to the pertinent provisions. Section 2(c)(1)(A)(ii)(III) of the ONDCP Technical Corrections Act of 2019 (Public Law 116–74, 133 Stat. 1158) amended section 8203(b)(4)(B) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K) so that the amendment made by that section 8203(b)(4)(B) is applied to section 1032(b)(3)(D) of chapter 2 of subtitle A of title I of the Anti-Drug Abuse Act of 1988 (21 U.S.C. 1521 et seq.), not to section 1032(b)(1)(A) of chapter 2 of subtitle A of title I of that Act. The substitutions conform the references to the amendment made by section 2(c)(1)(A)(ii)(III) of the ONDCP Technical Corrections Act of 2019 (Public Law 116–74, 133 Stat. 1158).

SECTION 60513—INFORMATION COLLECTION AND DISSEMINATION WITH RESPECT TO GRANT RECIPIENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60513	21 U.S.C. 1533	Pub. L. 100–690, title I, § 1033, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 230; amended Pub. L. 107–82, § 1(e), (f), Dec. 14, 2001, 115 Stat. 818; Pub. L. 115–271, title VIII, §8203(b)(4)(A), Oct. 24, 2018, 132 Stat. 4111; Pub. L. 116–74, §2(c)(1)(A)(ii)(II), Nov. 27, 2019, 133 Stat. 1157.

In subsection (b)(1)(A), the words "Federal agencies" are substituted for "departments or agencies of the Federal Government" to eliminate unnecessary words.

In subsection (b)(3), the words "in consultation with the National Community Antidrug Coalition Institute" are substituted for "in consultation with the Advisory Commission and the National Community Antidrug Coalition Institute" to eliminate obsolete words because provisions relating to the Advisory Commission (which provisions were enacted as subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988, as added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224)) were repealed by section 8203(b)(5) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4112).

SECTION 60514—TECHNICAL ASSISTANCE AND TRAINING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60514	21 U.S.C. 1534	Pub. L. 100–690, title I, § 1034, as added Pub. L. 105–20, § 2(a)(2), June 27, 1997, 111 Stat. 231.

SECTION 60515—SUPPLEMENTAL GRANTS FOR COALITION MENTORING ACTIVITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60515	21 U.S.C. 1535	Pub. L. 100–690, title I, § 1035, as added Pub. L. 107–82, § 2, Dec. 14, 2001, 115 Stat. 819; Pub. L. 115–271, title VIII, §8203(b)(4)(A), Oct. 24, 2018, 132 Stat. 4111; Pub. L. 116–74, §2(c)(1)(A)(ii)(II), Nov. 27, 2019, 133 Stat. 1157.

Chapter 607—Other Coalition Grants

SECTION 60701—NATIONAL COMMUNITY ANTIDRUG COALITION INSTITUTE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60701	21 U.S.C. 1521 note	Pub. L. 107–82, §4, Dec. 14, 2001, 115 Stat. 821; Pub. L. 109–469, title VIII, §805, Dec. 29, 2006, 120 Stat. 3535; Pub. L. 115–271, title VIII, §8204, Oct. 24, 2018, 132 Stat. 4112.

In subsection (a), the words "Beginning in fiscal year 2020," are omitted as obsolete.

In subsections (a) and (d)(2), the words "Director of National Drug Control Policy" are substituted for "Director" for clarity.

In subsection (b), the words "chapter 605 of this title" are substituted for "this subchapter" to provide the correct reference to the pertinent provision. There are no subchapters in Public Law 107–82 (115 Stat. 814). Provisions relating to community antidrug coalitions are in chapter 2 of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1521 et seq.), which is restated as chapter 605 of title 21, United States Code.

SECTION 60702—PROHIBITION AGAINST DUPLICATION OF EFFORT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60702	21 U.S.C. 1521 note	Pub. L. 107–82, §5, Dec. 14, 2001, 115 Stat. 821.

In this section, the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

In this section, the words "provided under subchapter II of chapter 605 of this title" are substituted for "provided under subchapter II of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1521 et seq.)" for clarity and to provide the correct reference to the pertinent provision. Subchapter II of chapter 2 of the National Narcotics Leadership Act of 1988 (which subchapter II was added to the National Narcotics Leadership Act of 1988 by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 231), and which subchapter II was previously classified to 21 U.S.C. 1541 et seq.) contained provisions relating to the Advisory Commission on Drug-Free Communities, prior to their repeal by section 8203(b)(5) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4112). Provisions relating to funds for administrative costs are in subchapter I of chapter 2 of that Act, which subchapter is restated as subchapter II of section 605 of title 21, United States Code.

SECTION 60703—COMMUNITY-BASED COALITION ENHANCEMENT GRANTS TO ADDRESS LOCAL DRUG CRISES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60703	21 U.S.C. 1536 (except (a)(3))	Pub. L. 114–198, title I, §103 (except (a)(3)), July 22, 2016, 130 Stat. 699.

In this section, any reference to "Drug-Free Communities Act of 1997" in the source provision is translated as "chapter 605 of this title", which chapter 605 restates chapter 2 of the National Narcotics Leadership Act of 1988, which chapter 2 was added by section 2(a)(2) of the Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224). See paragraph (3) of section 103(a) of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198, 130 Stat. 699), defining "Drug-Free Communities Act of 1997", which paragraph (3) is repealed as unnecessary by the bill enacting title 21, United States Code.

In subsection (a)(2), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

In subsection (f), the words "Evaluation requirements to which a grant under this section is subject may also include" are substituted for "and may also include" for clarity.

Chapter 609—Office of National Drug Control Policy

This chapter restates the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1701 et seq.). The Act as a whole was slated to be repealed, effective September 30, 2010, by section 715 of the Act (21 U.S.C. 1712). However, section 715 of the Act (i.e., the repealing provision) was itself repealed by section 8202(b)(2) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4110). In addition, section 8202(a) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4110) revived and restored the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1701 et seq.) as in effect on September 29, 2003, and as amended by the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469, 120 Stat. 3502) and the Presidential Appointment Efficiency and Streamlining Act of 2011 (Public Law 112–166, 126 Stat. 1283).

SECTION 60901—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60901	21 U.S.C. 1701	Pub. L. 105–277, div. C, title VII, §§702, 715, Oct. 21, 1998, 112 Stat. 2681–670, 2681–693; Pub. L. 109–469, title I, §101, title VI, §602, Dec. 29, 2006, 120 Stat. 3503, 3533; Pub. L. 115–271, title VIII, §§8202(a), (b)(2), 8216, Oct. 24, 2018, 132 Stat. 4110, 4117; Pub. L. 116–74, §2(a)(1), (3), Nov. 27, 2019, 133 Stat. 1155.

In paragraph (7), the words "supply of or demand for the drug or class of drugs" are substituted for "supply of or demand for such drug" for consistency in the paragraph.

SECTION 60902—OFFICE OF NATIONAL DRUG CONTROL POLICY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60902(a) through (c) ...	21 U.S.C. 1702	Pub. L. 105–277, div. C, title VII, §§703, 715, Oct. 21, 1998, 112 Stat. 2681–672, 2681–693; Pub. L. 109–469, title I, §102, title VI, §602, title XI, §1120, Dec. 29, 2006, 120 Stat. 3505, 3533, 3548; Pub. L. 115–271, title VIII, §§8202(a), (b)(2), 8217(a), (b), 8222(1), Oct. 24, 2018, 132 Stat. 4110, 4119, 4142; Pub. L. 116–74, §2(a)(2), (4), Nov. 27, 2019, 133 Stat. 1155.
60902(d)	21 U.S.C. 1702 note	Pub. L. 117–328, div. E, title II, proviso under heading "SALARIES AND EXPENSES", under heading "OFFICE OF NATIONAL DRUG CONTROL POLICY", Dec. 29, 2022, 136 Stat. 4664.

SECTION 60903—APPOINTMENT AND DUTIES OF DIRECTOR AND DEPUTY DIRECTORS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60903	21 U.S.C. 1703	Pub. L. 105–277, div. C, title VII, §§704, 715, Oct. 21, 1998, 112 Stat. 2681–672, 2681–693; Pub. L. 109–469, title I, §§103(a)–(e), (f)(3), 105, title VI, §602, Dec. 29, 2006, 120 Stat. 3506, 3507, 3510, 3511, 3533; Pub. L. 112–166, §2(t), Aug. 10, 2012, 126

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		Stat. 1288; Pub. L. 115–271, title VIII, §§8202(a), (b)(2), 8217(c)–(f), 8221(b)(1), 8222(2), Oct. 24, 2018, 132 Stat. 4110, 4120 through 4122, 4142; Pub. L. 116–74, §2(a)(1), (2), (5), Nov. 27, 2019, 133 Stat. 1155.

In subsection (a)(4), the word "individual" is substituted for "person" for consistency with section 1 of title 1, United States Code.

In subsection (b), paragraph (20) of section 704(b) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1703(b)) is omitted as obsolete. That paragraph required the Director of National Drug Control Policy to report to Congress, within 1 year after December 29, 2006, on the impact of each Federal drug reduction strategy on the availability, addiction rate, use rate, and other harms of illegal drugs.

In subsection (b)(2), the words "and submit each report under section 60905(g)(1) of this title" are substituted for "and each report under section 706(b)" for clarity and to provide the correct reference to the pertinent provision. Section 706(b) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1705(b)), as amended by section 8221(a) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4134), does not relate to reports. As amended by section 8221(a) of that Act, section 706 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1705) requires the submission of an annual assessment report under subsection (g)(1) of that section 706. No other provision in that section 706 pertains to a submission of a report by the Director of National Drug Control Policy.

In subsection (b)(4), the words "those National Drug Control Program agencies" are substituted for "those departments and agencies" for consistency in the paragraph.

In subsection (b)(11), the words "spokesperson of the Administration of the President" are substituted for "spokesperson of the Administration" for clarity.

In subsection (b)(13)(B), the words "developed under this chapter" are substituted for "developed under section 706(c)" to eliminate an obsolete reference and for consistency with section 60905(g)(2) of title 21, United States Code. Section 706(c) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1705(c)), as amended by section 8221(a) of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, title VIII, subtitle K, 132 Stat. 4134), does not relate to development of performance measures. As amended by section 8221(a) of that Act, section 706(c) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1705(c)) relates to performance measures only as an item required to be included in a National Drug Control Strategy.

In subsection (c)(1)(C), the words "State, local, and Tribal affairs" are substituted for "State, local, and tribal affairs" for consistency with section 60901(15) of title 21, United States Code.

In subsection (c)(2)(A), in the matter before clause (i), the words "State, local, and Tribal affairs" are substituted for "State, local, and tribal affairs" for consistency with section 60901(15) of title 21, United States Code.

In subsection (c)(3)(C), in the matter before clause (i), the words "including any budget request that" are substituted for "including" for clarity.

In subsection (c)(5)(A)(i), the words "budget request of each National Drug Control Program agency" are substituted for "budget request of each agency" for consistency in the clause.

In subsection (c)(5)(A)(iii), the words "perform other duties" are substituted for "other duties" to supply a missing word.

In subsection (d)(2), the words "the department, agency, or program shall comply" are substituted for "the department or agency shall comply" for consistency in the paragraph.

In subsection (i)(1)(B), the words "revise model State drug laws" are substituted for "revise such model State drug laws" to eliminate an unnecessary word.

SECTION 60904—COORDINATION WITH NATIONAL DRUG CONTROL PROGRAM AGENCIES IN DEMAND REDUCTION, SUPPLY REDUCTION, AND STATE AND LOCAL AFFAIRS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60904	21 U.S.C. 1704	Pub. L. 105–277, div. C, title VII, §§705, 715, Oct. 21, 1998, 112 Stat. 2681–680, 2681–693; Pub. L. 109–469, title I, §104, title VI, §602, Dec. 29, 2006, 120 Stat. 3510, 3533; Pub. L. 115–271, title VIII, §§8202(a), (b)(2), 8207, 8217(g), Oct. 24, 2018, 132 Stat. 4110, 4113, 4124; Pub. L. 116–74, §2(a)(1), (6), Nov. 27, 2019, 133 Stat. 1155, 1156.

SECTION 60905—DEVELOPMENT, SUBMISSION, IMPLEMENTATION, AND ASSESSMENT OF NATIONAL DRUG CONTROL STRATEGY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60905	21 U.S.C. 1705	Pub. L. 105–277, div. C, title VII, §§706, 715, Oct. 21, 1998, 112 Stat. 2681–681, 2681–693; Pub. L. 109–469, title II, §§201, 202, title VI, §602, Dec. 29, 2006, 120 Stat. 3513, 3517, 3533; Pub. L. 115–271, title VIII, §§8202(a), (b)(2), 8221(a), Oct. 24, 2018, 132 Stat. 4110, 4134; Pub. L. 116–74, §2(a)(1), (2), (c)(1)(B), (d), Nov. 27, 2019, 133 Stat. 1155, 1158; Pub. L. 117–263, div. E, title LIII, §5302, Dec. 23, 2022, 136 Stat. 3249.

In subsection (a)(2), the parenthetical "(through the Director)" is added for consistency with subsection (e).

In subsection (c)(1)(M), in the matter before clause (i), the words "and National Drug Control Program" are substituted for "and Program" for clarity.

In clauses (i) and (iii) of subsection (c)(1)(M), the words "the National Drug Control Program and the National Drug Control Strategy" are substituted for "the National Drug Control Program and Strategy" for clarity.

In subsection (c)(3)(A)(ii), the words "the government of any other relevant country" are substituted for "the government of other relevant countries" to make the word "government" consistent with "countries" in the source law.

In subsection (c)(3)(B)(i)(I), the words "the Federal Government's strategy" are substituted for "the Government's strategy" for clarity and consistency in the title.

In subsection (f)(2), the words "when establishing the Drug Control Data Dashboard" are substituted for "when establishing the Drug Control Dashboard" for consistency in the subsection.

In subsection (f)(3)(A)(i)(VI), in the matter after the semicolon, the word "and" is added for clarity.

In subsection (g)(3)(C), the words "National Drug Control Program agency and National Drug Control Program" are substituted for "National Drug Control Program agency and program" for clarity.

In subsection (g), paragraph (4) is restated as a separate provision from paragraph (3), even though the source provision of paragraph (4) is included in the source provision of paragraph (3) as a subparagraph (D), because the source provision of paragraph (4) expresses a complete idea and is set out as a complete sentence.

In subsection (g)(4), the words "on the performance measurement system described in subsection (h)" are substituted for "on the Performance Measurement System" for clarity.

In subsection (h)(4), the words "activities as defined in section 702" are omitted as necessary because of the applicability of the defined terms in paragraphs (3) and (17) of section 60901 of tile 21, United States Code. The word "activities" is included in the omitted words because each of the defined terms in those paragraphs is defined as an activity.

In subsection (h)(6)(A), the word "activities" is omitted because the terms "demand reduction" and "supply reduction" in paragraphs (3) and (17), respectively, of section 60901 of tile 21, United States Code, are each defined as an activity.

In subsection (h)(7), the words "and to the extent" are substituted for "to the extent" and the words "effectiveness of the supplemental strategies" are substituted for "effectiveness of the strategies" for clarity.

In subsection (i), the words "described in subsection (h)" are substituted for "described in subsection (c)" to provide the correct reference to the pertinent provision. Section 8221(a)(2) of the Substance Abuse Prevention Act of 2018, as amended by section 2(c)(1)(B)(ii) of the ONDCP Technical Corrections Act of 2019 (Public Law 116–74, 133 Stat. 1158), redesignated subsection (c) of section 706 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1705) as subsection (h) of that section.

In subsection (i), the words "submitted under subsection (g)" are substituted for "submitted under subsection (b)" to make the reference refer to the subsection that provides for the submission of reports. On the enactment of the source provision, which is subsection (i) (formerly subsection (d)) of section 706

of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1705), subsection (b) of that section provided for the submission of an annual report. See section 706(b) of the Office of National Drug Control Policy Reauthorization Act of 1998, as enacted on October 21, 1998 (Public Law 105–277, 112 Stat. 2681–683). Subsequent amendments to section 706 of that Act that amended the content of subsection (b) of that section did not provide for an amendment to the reference to subsection (b) in subsection (i) (formerly subsection d)). See amendatory history in the source credit table above.

SECTION 60906—HIGH INTENSITY DRUG TRAFFICKING AREAS PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60906(a)(1)	(no source)	
60906(a)(2)	21 U.S.C. 1706(a)(1) (parenthetical)	Pub. L. 105–277, div. C, title VII, §§707(a)(1) (parenthetical), 715, Oct. 21, 1998, 112 Stat. 2681–686 , 2681-693; Pub. L. 109–469, title III, §§301, §302(c), title VI, §602, Dec. 29, 2006, 120 Stat. 3518 , 3525, 3533; Pub. L. 115–271, title VIII, §§8202(a), 8202(b)(2), 8205, 8208, 8209, Oct. 24, 2018, 132 Stat. 4110 , 4113, 4114; Pub. L. 116–74, §2(a)(7), Nov. 27, 2019, 133 Stat. 1157.
60906(b) through (t)	21 U.S.C. 1706(except (a)(1) (parenthetical), (k)(1))	Pub. L. 105–277, div. C, title VII, § 707(except (a)(1) (parenthetical), (k)(1)), Oct. 21, 1998, 112 Stat. 2681–686; Pub. L. 109–469, title III, §§ 301, § 302(c), Dec. 29, 2006, 120 Stat. 3518, 3525.

In this section, subsection (a)(1) is added for convenience. Throughout the section, the term "HIDTA" is substituted for "high intensity drug trafficking area" for consistency in the section.

In subsection (f)(3), the words "the HIDTA" is substituted for "such area" for clarity.

In subsection (j)(2)(A), the word "including" is added before "how the funding the level" for clarity.

In subsection (m), in the matter before paragraph (1), the words "Not later than 1 year after the date of enactment of this subsection," and "subsequent" are omitted as obsolete.

In subsection (n), in the matter before paragraph (1), the words "Not later than 180 days after the date of enactment of this section," and "subsequent" are omitted as obsolete.

In subsection (n), the word "evaluating" is added in the matter before paragraph (1) and omitted in paragraph (1) to supply a missing word in the matter before paragraph (1).

In subsection (q), paragraphs (1) through (5) are omitted as obsolete.

In subsection (q), the words "for fiscal year 2023" are substituted for "for each of fiscal years 2018 through 2023" to eliminate obsolete words.

SECTION 60907—EMERGING THREATS COMMITTEE, EMERGING THREAT RESPONSE PLANS, AND MEDIA CAMPAIGN

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60907	21 U.S.C. 1708	Pub. L. 105–277, div. C, title VII, §§709, 715, Oct. 21, 1998, 112 Stat. 2681–688, 2681–693; Pub. L. 109–

SECTION 60907—EMERGING THREATS COMMITTEE, EMERGING THREAT RESPONSE PLANS, AND MEDIA CAMPAIGN

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
		469, title V, §501(a), title VI, §602, Dec. 29, 2006, 120 Stat. 3527, 3533; Pub. L. 115–271, title VIII, §§8202(a), (b)(2), 8218(a), Oct. 24, 2018, 132 Stat. 4110, 4125; Pub. L. 116–74, §2(a)(1), (2), (8), Nov. 27, 2019, 133 Stat. 1155 , 1157.

In subsection (b)(6), the words "Not later than 180 days after the date on which the Committee first meets," are omitted as obsolete.

In subsection (f)(5)(D), the word "individuals" is substituted for "persons" for consistency with section 1 of title 1, United States Code.

In subsection (f)(5)(D), the words "Schedule C under subpart C of part 213 of title 5, Code of Federal Regulations" are substituted for "section 213 of Schedule C of title 5, Code of Federal Regulations" to provide the correct reference to the pertinent provision.

In subsection (g), the words "for fiscal year 2023" are substituted for "for each of fiscal years 2018 through 2023" to eliminate obsolete words.

SECTION 60908—UNITED STATES INTERDICTION COORDINATOR AND INTERDICTION COMMITTEE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60908	21 U.S.C. 1710	Pub. L. 105–277, div. C, title VII, § 711, Oct. 21, 1998, 112 Stat. 2681–691; Pub. L. 109–469, title I, §103(f)(1), Dec. 29, 2006, 120 Stat. 3507; Pub. L. 115–271, title VIII, §8219(b), Oct. 24, 2018, 132 Stat. 4132.

SECTION 60909—REQUIREMENT FOR DISCLOSURE OF FEDERAL SPONSORSHIP OF ALL FEDERAL ADVERTISING OR OTHER COMMUNICATION MATERIALS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60909(a)	21 U.S.C. 1710a(b)	Pub. L. 105–277, div. C, title VII, §712(b), as added Pub. L. 109–469, title XI, §1118, Dec. 29, 2006, 120 Stat. 3546; amended Pub. L. 105–277, div. C. title VII, §715, Oct. 21, 1998, 112 Stat. 2681–693; Pub. L. 109–469, title VI, §602, Dec. 29, 2006, 120 Stat. 3533; Pub. L. 115–271, title VIII, §8202(a), (b)(2), Oct. 24, 2018, 132 Stat. 4110.
60909(b)	21 U.S.C. 1710a(a)	Pub. L. 105–277, div. C, title VII, §712(a), as added Pub. L. 109–469, title XI, §1118, Dec. 29, 2006, 120 Stat. 3546; amended Pub. L. 105–277, div. C. title VII, §715, Oct. 21, 1998, 112 Stat. 2681–693; Pub. L. 109–469, title VI, §602, Dec. 29, 2006, 120 Stat. 3533; Pub. L. 115–271, title VIII, §8202(a), (b)(2), Oct. 24, 2018, 132 Stat. 4110.

In subsection (a)(1), the words "including by print or any electronic means" are substituted for "including print or by any electronic means" for clarity.

In subsection (a)(2), the words "including by speech, print, or any electronic means" are substituted for "including speech, print, or by any electronic means" for clarity.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60910	21 U.S.C. 1711	Pub. L. 105–277, div. C, title VII, § 714, Oct. 21, 1998, 112 Stat. 2681–693; Pub. L. 109–469, title VI, § 601, Dec. 29, 2006, 120 Stat. 3533; Pub. L. 115–271, title VIII, §8202(b)(1), Oct. 24, 2018, 132 Stat. 4110.

In this section, the words "for fiscal year 2023" are substituted for "for each of fiscal years 2018 through 2023" to eliminate obsolete words.

SECTION 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

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
60911(a)	21 U.S.C. 1714(c)	Pub. L. 105–277, div. C, title VII, §716(c), as added Pub. L. 109–469, title XI, §1119, Dec. 29, 2006, 120 Stat. 3547; amended Pub. L. 105–277, div. C. title VII, §715, Oct. 21, 1998, 112 Stat. 2681–693; Pub. L. 109–469, title VI, §602, Dec. 29, 2006, 120 Stat. 3533; Pub. L. 115–271, title VIII, §8202(a), (b)(2), Oct. 24, 2018, 132 Stat. 4110.
60911(b), (c)	21 U.S.C. 1714(a), (b)	Pub. L. 105–277, div. C, title VII, §716(a), (b), as added Pub. L. 109–469, title XI, §1119, Dec. 29, 2006, 120 Stat. 3547; amended Pub. L. 105–277, div. C. title VII, §715, Oct. 21, 1998, 112 Stat. 2681–693; Pub. L. 109–469, title VI, §602, Dec. 29, 2006, 120 Stat. 3533; Pub. L. 115–271, title VIII, §8202(a), (b)(2), Oct. 24, 2018, 132 Stat. 4110.

In subsection (a)(5), in the matter after the semicolon, the word "and" is added for clarity.

Chapter 611—Foreign Narcotics Kingpin Designation

SECTION 61101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61101(1)	21 U.S.C. 1907(4) (relating to controlled substance)	Pub. L. 106–120, title VIII, §808(4) (relating to controlled substance), Dec. 3, 1999, 113 Stat. 1632.
61101(2)	21 U.S.C. 1907(1)	Pub. L. 106–120, title VIII, §808(1), Dec. 3, 1999, 113 Stat. 1632.
61101(3)	21 U.S.C. 1907(2)	Pub. L. 106–120, title VIII, §808(2), Dec. 3, 1999, 113 Stat. 1632.
61101(4)	21 U.S.C. 1907(4) (relating to listed chemical)	Pub. L. 106–120, title VIII, §808(4) (relating to listed chemical), Dec. 3, 1999, 113 Stat. 1632.
61101(5)	21 U.S.C. 1907(4) (relating to narcotic drug)	Pub. L. 106–120, title VIII, §808(4) (relating to narcotic drug), Dec. 3, 1999, 113 Stat. 1632.
61101(6)	21 U.S.C. 1907(3)	Pub. L. 106–120, title VIII, §808(3), Dec. 3, 1999, 113 Stat. 1632.
61101(7)	21 U.S.C. 1907(5)	Pub. L. 106–120, title VIII, §808(5), Dec. 3, 1999, 113 Stat. 1632.
61101(8)	21 U.S.C. 1907(7)	Pub. L. 106–120, title VIII, §808(7), Dec. 3, 1999, 113 Stat. 1632.
61101(9)	21 U.S.C. 1907(6)	Pub. L. 106–120, title VIII, §808(6), Dec. 3, 1999, 113 Stat. 1632.

SECTION 61102—POLICY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61102	21 U.S.C. 1901(b)	Pub. L. 106–120, title VIII, § 802(b), Dec. 3, 1999, 113 Stat. 1626.

In this section, the words "from the threat of the activities of international narcotics traffickers and their organizations" are substituted for "from the threat described in subsection (a)(4)" for clarity and consistency with subsection (a)(4) of section 802 of the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1901) and in the section.

SECTION 61103—PURPOSE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61103	21 U.S.C. 1902	Pub. L. 106–120, title VIII, § 803, Dec. 3, 1999, 113 Stat. 1626.

SECTION 61104—PUBLIC IDENTIFICATION OF SIGNIFICANT FOREIGN NARCOTICS TRAFFICKERS AND REQUIRED REPORTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61104	21 U.S.C. 1903	Pub. L. 106–120, title VIII, § 804, Dec. 3, 1999, 113 Stat. 1626; Pub. L. 114–198, title VIII, §801, July 22, 2016, 130 Stat. 755.

In this section, the words "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))" are substituted for the words "the Director of Central Intelligence" each place they appear for clarity because of section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note).

In subsection (a), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

In subsection (b)(1)(A), in the matter before clause (i), the words "Not later than June 1 of each year," are substituted for "Not later than June 1, 2000, and not later than June 1 of each year thereafter," to eliminate obsolete words.

In subsection (b)(1)(A)(ii), the words "Foreign Relations" are substituted for "International Relations" on authority of Rule X(1)(i) of the Rules of House of Representatives, adopted by House Resolution No. 6 (110th Congress, January 5, 2007).

In subsection (d)(1), the words "Not later than July 1 of each year," are substituted for "Not later than July 1, 2000, and not later than July 1 of each year thereafter," to eliminate obsolete words.

In subsection (f)(2), the words "on an annual basis" are substituted for "not later than July 1, 2000, and on an annual basis thereafter" to eliminate obsolete words.

In subsection (g)(2)(B), the words "Foreign Relations" are substituted for "International Relations" on authority of Rule X(1)(i) of the Rules of House of Representatives, adopted by House Resolution No. 6 (110th Congress, January 5, 2007).

In paragraphs (1)(A)(ii) and (2)(B)(ii) of subsection (h), the words "Foreign Relations" are substituted for "International Relations" on authority of Rule X(1)(i) of the Rules of House of Representatives, adopted by House Resolution No. 6 (110th Congress, January 5, 2007).

SECTION 61105—BLOCKING ASSETS AND PROHIBITING TRANSACTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61105	21 U.S.C. 1904	Pub. L. 106–120, title VIII, § 805, Dec. 3, 1999, 113 Stat. 1629; Pub. L. 107–108, title III, § 307, Dec. 28, 2001, 115 Stat. 1399.

In paragraphs (2), (3), and (4) of subsection (b), the words "the Director of 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))" are substituted for "the Director of Central Intelligence" for clarity because of section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note).

In subsection (e)(1), in the matter before subparagraph (A), the words "the Director of 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))" are substituted for "the Director of Central Intelligence" for clarity because of section 1081 of the National Security Intelligence Reform Act of 2004 (50 U.S.C. 3001 note).

SECTION 61106—AUTHORITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61106	21 U.S.C. 1905	Pub. L. 106–120, title VIII, § 806, Dec. 3, 1999, 113 Stat. 1631.

In subsection (a)(1)(A), the words "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" are added to clarify the applicability of "by any person, or with respect to any property, subject to the jurisdiction of the United States" which appear in the source law as matter after paragraph (2).

In subsection (a)(1)(B), the words "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" are added to clarify the applicability of "by any person, or with respect to any property, subject to the jurisdiction of the United States" which appear in the source law as matter after paragraph (2).

In subsection (a)(2), the words "which acquisition, holding, withholding, use, transfer, withdrawal, transportation, placement, dealing, exercising, or transaction is by any person, or is with respect to any property, subject to the jurisdiction of the United States" are added to clarify the applicability of "by any

person, or with respect to any property, subject to the jurisdiction of the United States" which appear in the source law as matter after paragraph (2).

SECTION 61107—PENALTIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61107	21 U.S.C. 1906	Pub. L. 106–120, title VIII, §807, Dec. 3, 1999, 113 Stat. 1631.

In subsection (a)(1), in the matter before subparagraph (A), the words "A person that" are substituted for "Whoever" for consistency with section 61101(7) of title 21, United States Code, and section 1 of title 1, United States Code.

In subsection (a)(1), in the matter before subparagraph (A), the words "license, rule" are substituted for "license rule" to supply a missing comma.

Chapter 613—Date-Rape Drug Prohibition

SECTION 61301—DEFINITION OF GHB

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61301	(no source)	

This section is added for convenience and on authority of the parenthetical in section 2(2) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000 (21 U.S.C. 812 note).

SECTION 61302—EMERGENCY SCHEDULING OF GHB

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61302	21 U.S.C. 812 note	Pub. L. 106–172, §3(a)(1), Feb. 18, 2000, 114 Stat. 8.

In this section, in the matter before paragraph (1), the words "not later than 60 days after the date of the enactment of this Act," are omitted as obsolete.

In this section, in the matter before paragraph (1), the term "GHB" is substituted for "such drug" for clarity.

In paragraph (1)(A), the term "GHB" is substituted for "such drug" for clarity.

In paragraph (2)(B), the words "of the letter (transmitted on May 19, 1999) referred to in paragraph (1)" are substituted for "of the letter referred to in subparagraph (A) with respect to May 19, 1999" for clarity.

SECTION 61303—INVESTIGATIONS AND PROSECUTIONS RELATING TO VIOLATIONS THAT RESULT IN OR CONTRIBUTE TO RAPE AND OTHER CRIMES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61303(a)	21 U.S.C. 801 note	Pub. L. 106–172, §6(a), Feb. 18, 2000, 114 Stat. 11.
61303(b)	21 U.S.C. 801 note	Pub. L. 106–172, §6(b)(1), Feb. 18, 2000, 114 Stat. 11.

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61304(a)	21 U.S.C. 801 note	Pub. L. 106–172, §7(c), Feb. 18, 2000, 114 Stat. 11.
61304(b)	21 U.S.C. 801 note	Pub. L. 106–172, §7(a), Feb. 18, 2000, 114 Stat. 11.
61304(c)	21 U.S.C. 801 note	Pub. L. 106–172, §7(b), Feb. 18, 2000, 114 Stat. 11.

In subsection (b), the words "The Secretary shall annually submit" are substituted for "The Secretary shall periodically submit" and the words "The first such report shall be submitted not later than January 15, 2000, and subsequent reports shall be submitted annually thereafter" are omitted to eliminate obsolete and unnecessary words.

Chapter 615—United States Anti-Doping Agency

SECTION 61501—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61501 (matter before (1))	21 U.S.C. 2001(a) (matter before (1))	Pub. L. 109–469, title VII, §701(a) (matter before (1)), Dec. 29, 2006, 120 Stat. 3533; Pub. L. 113–280, § 2(1), Dec. 18, 2014, 128 Stat. 3020.
61501(1)	21 U.S.C. 2001(a)(3)	Pub. L. 109–469, title VII, §701(a)(3), Dec. 29, 2006, 120 Stat. 3534.
61501(2)	21 U.S.C. 2001(a)(2)	Pub. L. 109–469, title VII, §701(a)(2), Dec. 29, 2006, 120 Stat. 3534.
61501(3)	21 U.S.C. 2001(a)(1)	Pub. L. 109–469, title VII, §701(a)(1), Dec. 29, 2006, 120 Stat. 3533.

In paragraph (1), the words "has the meaning given the term in section 220501(b)(1) of title 36" are substituted for "means an athlete who meets the eligibility standards established by the national governing body or paralympic sports organization for the sport in which the athlete competes (36 U.S.C. 22501(b)(1))" to eliminate unnecessary words, to correct a technical error, and for consistency with section 220501(b)(1) of title 36, United States Code.

In paragraph (2), the words "has the meaning given the term in section 220501(b)(2) of title 36" are substituted for "means a contest, game, meet, match, tournament, regatta, or other event in which amateur athletes compete (36 U.S.C. 220501(b)(2))" to eliminate unnecessary words and for consistency with section 220501(b)(2) of title 36, United States Code.

In paragraph (3), the words "United States Olympic and Paralympic Committee" are substituted for "United States Olympic Committee" for consistency with chapter 2205 of title 36, United States Code.

SECTION 61502—DESIGNATION OF UNITED STATES ANTI-DOPING AGENCY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61502	21 U.S.C. 2001(b), (c)	Pub. L. 109–469, title VII, §701(b), (c), Dec. 29, 2006, 120 Stat. 3533; Pub. L. 113–280, § 2(2), Dec. 18, 2014, 128 Stat. 3020; Pub. L. 117–103, div. Q, title III, §303, Mar. 15, 2022, 136 Stat. 817.

In paragraphs (2), (3), and (4) of subsection (a), the words "United States Olympic and Paralympic Committee" are substituted for "United States Olympic Committee" for consistency with chapter 2205 of title 36, United States Code.

SECTION 61503—RECORDS, AUDIT, AND REPORT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61503	21 U.S.C. 2002	Pub. L. 109–469, title VII, § 702, Dec. 29, 2006, 120 Stat. 3534.

SECTION 61504—AUTHORIZATION OF APPROPRIATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61504	21 U.S.C. 2003	Pub. L. 109–469, title VII, § 703, Dec. 29, 2006, 120 Stat. 3534; Pub. L. 113–280, § 3, Dec. 18, 2014, 128 Stat. 3020; Pub. L. 117–103, div. Q, title III, §304, Mar. 15, 2022, 136 Stat. 817.

In this section, paragraphs (1) and (2) of section 703 of the Office of National Drug Control Policy Reauthorization Act of 2006 (21 U.S.C. 2003) are omitted as obsolete.

Chapter 617—National Methamphetamine Information Clearinghouse

SECTION 61701—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61701	21 U.S.C. 2011	Pub. L. 109–469, title X, § 1002, Dec. 29, 2006, 120 Stat. 3537.

SECTION 61702—ESTABLISHMENT OF CLEARINGHOUSE AND ADVISORY COUNCIL

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61702	21 U.S.C. 2012	Pub. L. 109–469, title X, § 1003, Dec. 29, 2006, 120 Stat. 3538.

SECTION 61703—NMIC REQUIREMENTS AND REVIEW

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61703	21 U.S.C. 2013	Pub. L. 109–469, title X, § 1004, Dec. 29, 2006, 120 Stat. 3538.

In subsection (b)(1)(B), in the matter before clause (i), the words "which website" are substitute for "which" for clarity.

In subsection (b)(1)(B)(v), the words "and that contains" are substituted for "that contains" for clarity.

In subsection (c)(1), in the matter before subparagraph (A), the words "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" are substituted for "Not later than 30 days after the date of submission of an item by a qualified entity, the Council shall review an item submitted for posting on the website described in subsection (b)(2)" for clarity.

In subsection (c)(1)(B), the words "to determine, in consultation with the Attorney General," are substituted for "in consultation with the Attorney General, to determine" for clarity.

In subsection (c)(2), in the matter before subparagraph (A), the words "of the item" are substituted for "of an item" for clarity.

Chapter 619—Sanctions With Respect to Foreign Traffickers of Illicit Synthetic Opioids

Subchapter I—General Provisions

SECTION 61901—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61901(1)	21 U.S.C. 2302(1) (relating to "alien")	Pub. L. 116–92, div. F, title LXXII, §7203(1) (relating to "alien"), Dec. 20, 2019, 133 Stat. 2262.
61901(2)	21 U.S.C. 2302(2)	Pub. L. 116–92, div. F, title LXXII, §7203(2), Dec. 20, 2019, 133 Stat. 2262.
61901(3)	21 U.S.C. 2302(3) (relating to "controlled substance")	Pub. L. 116–92, div. F, title LXXII, §7203(3) (relating to "controlled substance"), Dec. 20, 2019, 133 Stat. 2263.
61901(4)	21 U.S.C. 2302(4)	Pub. L. 116–92, div. F, title LXXII, §7203(4), Dec. 20, 2019, 133 Stat. 2263.
61901(5)	21 U.S.C. 2302(5)	Pub. L. 116–92, div. F, title LXXII, §7203(5), Dec. 20, 2019, 133 Stat. 2263.
61901(6)	21 U.S.C. 2302(6)	Pub. L. 116–92, div. F, title LXXII, §7203(6), Dec. 20, 2019, 133 Stat. 2263.
61901(7)	21 U.S.C. 2302(7)	Pub. L. 116–92, div. F, title LXXII, §7203(7), Dec. 20, 2019, 133 Stat. 2263.
61901(8)	21 U.S.C. 2302(3) (relating to "listed chemical")	Pub. L. 116–92, div. F, title LXXII, §7203(3) (relating to "listed chemical"), Dec. 20, 2019, 133 Stat. 2263.
61901(9)	21 U.S.C. 2302(3) (relating to "narcotic drug")	Pub. L. 116–92, div. F, title LXXII, §7203(3) (relating to "narcotic drug"), Dec. 20, 2019, 133 Stat. 2263.
61901(10)	21 U.S.C. 2302(1) (relating to "national")	Pub. L. 116–92, div. F, title LXXII, §7203(1) (relating to "national"), Dec. 20, 2019, 133 Stat. 2262.
61901(11)	21 U.S.C. 2302(1) (relating to "national of the United States")	Pub. L. 116–92, div. F, title LXXII, §7203(1) (relating to "national of the United States"), Dec. 20, 2019, 133 Stat. 2262.
61901(12)	21 U.S.C. 2302(3) (relating to "opioid")	Pub. L. 116–92, div. F, title LXXII, §7203(3) (relating to "opioid"), Dec. 20, 2019, 133 Stat. 2263.
61901(13)	21 U.S.C. 2302(8)	Pub. L. 116–92, div. F, title LXXII, §7203(8), Dec. 20, 2019, 133 Stat. 2263.
61901(14)	21 U.S.C. 2302(9)	Pub. L. 116–92, div. F, title LXXII, §7203(9), Dec. 20, 2019, 133 Stat. 2263.
61901(15)	21 U.S.C. 2302(10)	Pub. L. 116–92, div. F, title LXXII, §7203(10), Dec. 20, 2019, 133 Stat. 2263.

Subchapter II—Sanctions With Respect to Foreign Opioid Traffickers

SECTION 61911—IDENTIFICATION OF FOREIGN OPIOID TRAFFICKERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61911	21 U.S.C. 2311	Pub. L. 116–92, div. F, title LXXII, §7211, Dec. 20, 2019, 133 Stat. 2263.

In subsection (a)(3), the words "the United States has imposed, before the date of the report, sanctions under this subchapter" are substituted for "the United States has imposed sanctions before the date of the report under this subchapter" for clarity.

In subsection (b)(2), the words "and does not delimit or restrict," are substituted for "and in no way delimits or restricts," to eliminate unnecessary words.

In subsection (c), the words "and annually thereafter until December 20, 2024," are substituted for "and annually thereafter until the date that is 5 years after such date of enactment," for clarity.

In subsection (d)(2)(C), the word "individual" is substituted for "person" for clarity and consistency with section 61901 of title 21, United States Code.

In subsection (e), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

SECTION 61912—IMPOSITION OF SANCTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61912	21 U.S.C. 2312	Pub. L. 116–92, div. F, title LXXII, §7212, Dec. 20, 2019, 133 Stat. 2265.

SECTION 61913—DESCRIPTION OF SANCTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61913	21 U.S.C. 2313	Pub. L. 116–92, div. F, title LXXII, §7213, Dec. 20, 2019, 133 Stat. 2266.

In subsection (a)(9), the words "on a principal executive officer of the foreign person" are substituted for "on the principal executive officer or officers of the foreign person" because of section 1 of title 1, United States Code.

In subsection (a)(9), the words "on an individual performing similar functions and with similar authorities as the officer" are substituted for "on individuals performing similar functions and with similar authorities as such officer or officers" because of section 1 of title 1, United States Code.

SECTION 61914—DESIGNATION OF TRANSACTIONS OF SANCTIONED PERSONS AS OF PRIMARY MONEY LAUNDERING CONCERN

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61914	21 U.S.C. 2313a	Pub. L. 116–92, div. F, title LXXII, §7213A, as added Pub. L. 118–50, div. E, title II, §3201(a), Apr. 24, 2024, 138 Stat. 940.

SECTION 61915—WAIVERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61915	21 U.S.C. 2314	Pub. L. 116–92, div. F, title LXXII, §7214, Dec. 20, 2019, 133 Stat. 2267.

SECTION 61916—PROCEDURES FOR JUDICIAL REVIEW OF CLASSIFIED INFORMATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61916	21 U.S.C. 2315	Pub. L. 116–92, div. F, title LXXII, §7215, Dec. 20, 2019, 133 Stat. 2268.

SECTION 61917—BRIEFINGS ON IMPLEMENTATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61917	21 U.S.C. 2316	Pub. L. 116–92, div. F, title LXXII, §7216, Dec. 20, 2019, 133 Stat. 2269.

In this section, the words "every 180 days thereafter until the December 20, 2024," are substituted for "every 180 days thereafter until the date that is 5 years after such date of enactment," for clarity.

Subchapter III—Other Matters

SECTION 61931—DIRECTOR OF NATIONAL INTELLIGENCE PROGRAM ON USE OF INTELLIGENCE RESOURCES IN EFFORTS TO SANCTION FOREIGN OPIOID TRAFFICKERS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61931(a)	21 U.S.C. 2331(d)	Pub. L. 116–92, div. F, title LXXII, §7231(d), Dec. 20, 2019, 133 Stat. 2273.
61931(b), (c)	21 U.S.C. 2331(a), (b)	Pub. L. 116–92, div. F, title LXXII, §7231(a), (b), Dec. 20, 2019, 133 Stat. 2273.
61931(d)(1)(A)	21 U.S.C. 2331(c)(1)(A) (1st sentence)	Pub. L. 116–92, div. F, title LXXII, §7231(c)(1)(A) (1st sentence), Dec. 20, 2019, 133 Stat. 2273; Pub. L. 117–263, div. F, title LXVIII, §6811(h), Dec. 23, 2022, 136 Stat. 3601.
61931(d)(1)(B)	21 U.S.C. 2331(c)(1)(B)	Pub. L. 116–92, div. F, title LXXII, §7231(c)(1)(B), Dec. 20, 2019, 133 Stat. 2273; Pub. L. 117–263, div. F, title LXVIII, §6811(h), Dec. 23, 2022, 136 Stat. 3601.
61931(d)(2)	21 U.S.C. 2331(c)(2)	Pub. L. 116–92, div. F, title LXXII, §7231(c)(2), Dec. 20, 2019, 133 Stat. 2273; Pub. L. 117–263, div. F, title LXVIII, §6811(h), Dec. 23, 2022, 136 Stat. 3601.

In this section, the words "Director of National Drug Control Policy" are substituted for the words "Director of the Office of National Drug Control Policy" each place they appear for consistency with chapter 609 of title 21, United States Code.

SECTION 61932—AUTHORIZATION OF APPROPRIATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61932(a)	21 U.S.C. 2332(e)	Pub. L. 116–92, div. F, title LXXII, §7232(e), Dec. 20, 2019, 133 Stat. 2274.
61932(b)	21 U.S.C. 2332(a)	Pub. L. 116–92, div. F, title LXXII, §7232(a), Dec. 20, 2019, 133 Stat. 2274.

SECTION 61932—AUTHORIZATION OF APPROPRIATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61932(c)	21 U.S.C. 2332(c)	Pub. L. 116–92, div. F, title LXXII, §7232(c), Dec. 20, 2019, 133 Stat. 2274.
61932(d)	21 U.S.C. 2332(d)	Pub. L. 116–92, div. F, title LXXII, §7232(d), Dec. 20, 2019, 133 Stat. 2274.

In subsection (c), the words "the subsection" are substituted for "such subsections" for consistency with the reference to "subsection (b)".

SECTION 61933—REGULATORY AUTHORITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61933	21 U.S.C. 2333	Pub. L. 116–92, div. F, title LXXII, §7233, Dec. 20, 2019, 133 Stat. 2275.

SECTION 61934—TERMINATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61934	21 U.S.C. 2334	Pub. L. 116–92, div. F, title LXXII, §7234, Dec. 20, 2019, 133 Stat. 2275.

In this section, the words "sanctions imposed pursuant to this chapter" are substituted for "sanctions imposed pursuant to this title" to provide a more precise reference to the pertinent provisions. Chapter 619 of title 21, United States Code, to which "this chapter" in the restatement refers, does not restate sections 7217 and 7221 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2269, 2270), which sections are included in the title referred to by "this title" in the source provision, but which sections do not impose the sanctions described. The sections that impose the sanctions described are restated in this chapter.

In this section, the words "shall terminate on December 20, 2026" are substituted for "shall terminate on the date that is 7 years after the date of the enactment of this Act".

SECTION 61935—EXCEPTION RELATING TO IMPORTATION OF GOODS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
61935(a)	21 U.S.C. 2335(b)	Pub. L. 116–92, div. F, title LXXII, §7235(b), Dec. 20, 2019, 133 Stat. 2274.
61935(b)	21 U.S.C. 2335(a)	Pub. L. 116–92, div. F, title LXXII, §7235(a), Dec. 20, 2019, 133 Stat. 2274.

In this section, the words "authorities and requirements to impose sanctions under this chapter" are substituted for "authorities and requirements to impose sanctions under this title" to provide a more precise reference to the pertinent provisions. Chapter 619 of title 21, United States Code, to which "this chapter" in the restatement refers, does not restate sections 7217 and 7221 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2269, 2270), which sections are included in the title referred to by "this title" in the source provision, but which sections do not provide for authorities and requirements to impose the sanctions described. The sections that provide for authorities and requirements

to impose the sanctions described are restated in chapter 619 of title 21, United States Code.

Chapter 621—International Sports Doping

SECTION 62101—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62101	21 U.S.C. 2401	Pub. L. 116–206, §2, Dec. 4, 2020, 134 Stat. 998.

In paragraph (5), in the matter before subparagraph (A), the defined term "major international sports competition" is substituted for "Major International Sport Competition" for consistency in the chapter.

SECTION 62102—MAJOR INTERNATIONAL DOPING FRAUD CONSPIRACIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62102	21 U.S.C. 2402	Pub. L. 116–206, §3, Dec. 4, 2020, 134 Stat. 999.

SECTION 62103—CRIMINAL PENALTIES AND STATUTE OF LIMITATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62103	21 U.S.C. 2403	Pub. L. 116–206, §4, Dec. 4, 2020, 134 Stat. 999.

In subsection (a)(1), the words "A person that violates" are substituted for "Whoever violates" for consistency with section 62101(6) of this title and section 1 of title 1, United States Code.

In subsection (b)(2), the words "the statute of limitations under this section" are substituted for "this statute of limitation" for clarity.

SECTION 62104—COORDINATION AND SHARING OF INFORMATION WITH USADA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62104	21 U.S.C. 2404	Pub. L. 116–206, §6, Dec. 4, 2020, 134 Stat. 1000.

Chapter 623—Fentanyl Eradication and Narcotics Deterrence

Subchapter I—General Provisions

SECTION 62301—DEFINITIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62301	21 U.S.C. 2341	Pub. L. 118–50, div. E, §3003, Apr. 24, 2024, 138 Stat. 935.

Subchapter II—Sanctions in Response to National Emergency Relating to Fentanyl Trafficking

SECTION 62311—POLICY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62311	21 U.S.C. 2351(b)	Pub. L. 118–50, div. E, title I, §3101(b), Apr. 24, 2024, 138 Stat. 936.

SECTION 62312—USE OF NATIONAL EMERGENCY AUTHORITIES; REPORTING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62312	21 U.S.C. 2352	Pub. L. 118–50, div. E, title I, §3102, Apr. 24, 2024, 138 Stat. 936.

In subsection (b)(1), in the matter before subparagraph (A), the words "The President shall annually submit" are substituted for "Not later than 180 days after the date of the enactment of this division, and annually thereafter, the President shall submit" to eliminate obsolete words.

SECTION 62313—IMPOSITION OF SANCTIONS WITH RESPECT TO FENTANYL TRAFFICKING BY TRANSNATIONAL CRIMINAL ORGANIZATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62313	21 U.S.C. 2353	Pub. L. 118–50, div. E, title I, §3103, Apr. 24, 2024, 138 Stat. 936.

In subsection (c), the words "The President shall annually submit" are substituted for "Not later than 180 days after the date of the enactment of this division, and annually thereafter, the President shall submit" to eliminate obsolete words.

SECTION 62314—PENALTIES; WAIVERS; EXCEPTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62314	21 U.S.C. 2354	Pub. L. 118–50, div. E, title I, §3104, Apr. 24, 2024, 138 Stat. 937.

SECTION 62315—TREATMENT OF FORFEITED PROPERTY OF TRANSNATIONAL CRIMINAL ORGANIZATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62315(a)(1)	21 U.S.C. 2355(a)(3)	Pub. L. 118–50, div. E, title I, §3105(a)(3), Apr. 24, 2024, 138 Stat. 938.
62315(a)(2), (3)	21 U.S.C. 2355(a)(1), (2)	Pub. L. 118–50, div. E, title I, §3105(a)(1), (2), Apr. 24, 2024, 138 Stat. 938.
62315(b)	21 U.S.C. 2355(b)	Pub. L. 118–50, div. E, title I, §3105(b), Apr. 24, 2024, 138 Stat. 938.

In subsection (a)(1)(B)(iii), the words "relating to imposing sanctions on foreign persons involved in the global illicit drug trade" are omitted as unnecessary.

Subchapter III— Anti-Money Laundering Reports

SECTION 62331—TREATMENT OF TRANSNATIONAL CRIMINAL ORGANIZATIONS IN SUSPICIOUS TRANSACTIONS REPORTS OF THE FINANCIAL CRIMES ENFORCEMENT NETWORK

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62331	21 U.S.C. 2361	Pub. L. 118–50, div. E, title II, §3202, Apr. 24, 2024, 138 Stat. 941.

Subchapter IV—Exception Relating to Importation of Goods

SECTION 62341—EXCEPTION RELATING TO IMPORTATION OF GOODS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
62341(a)	21 U.S.C. 2371(b)	Pub. L. 118–50, div. E, title III, §3301(b), Apr. 24, 2024, 138 Stat. 941.
62341(b)	21 U.S.C. 2371(a)	Pub. L. 118–50, div. E, title III, §3301(a), Apr. 24, 2024, 138 Stat. 941.

Chapters 625 Through 697—Reserved

Chapter 699—Miscellaneous Drug Control and Enforcement Provisions

SECTION 69901—PLACEMENT OF PIPRADROL AND SPA IN SCHEDULE IV TO CARRY OUT OBLIGATION UNDER CONVENTION ON PSYCHOTROPIC SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69901	21 U.S.C. 812 note	Pub. L. 95–633, title I, §102(c), Nov. 10, 1978, 92 Stat. 3772.

In this section, the words “schedule IV of section 50302(c) of this title” are substituted for “schedule IV of such Act” to provide a more precise reference to the pertinent provision.

SECTION 69902—INTERAGENCY COORDINATION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69902	21 U.S.C. 801 note	Pub. L. 99–570, title IV, §4304(a), Oct. 27, 1986, 100 Stat. 3207–154.

SECTION 69903—REGULATIONS FOR EXPEDITED ADMINISTRATIVE FORFEITURE PROCEDURES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69903(a)	21 U.S.C. 881 note	Pub. L. 100–690, title VI, §6079(e), Nov. 18, 1988, 102 Stat. 4325.
69903(b) through (e) ...	21 U.S.C. 881 note	Pub. L. 100–690, title VI, §6079(a) through (d), Nov. 18, 1988, 102 Stat. 4325.

In subsection (b), the words "The Attorney General and the Secretary of the Treasury shall prescribe regulations" are substituted for "Not later than 90 days after the date of enactment of this Act, the Attorney General and the Secretary of the Treasury shall consult, and after providing a 30-day public comment period, shall prescribe regulations" to eliminate obsolete words.

In subsection (b), the words "section 80303 of title 49" are substituted for "section 2 of the Act of August 9, 1939 (53 Stat. 1291; 49 U.S.C. App. 782)" to provide an updated reference to the pertinent provision.

In subsection (d), the words "the head of the agency" are substituted for "the head of the department or agency" to eliminate unnecessary words.

In subsection (e)(1), the words "The Attorney General, the Secretary of the Treasury, and the Secretary of Transportation shall prescribe joint regulations providing for issuance of a summons" are substituted for "Not later than 90 days after the enactment of this Act, the Attorney General, the Secretary of the Treasury, and the Secretary of Transportation shall prescribe joint regulations, after a public comment period of at least 30 days, providing for issuance of a summons" to eliminate obsolete words.

In subsection (e)(1), the words "paragraph (12), (13), or (14) of section 2101 of title 46" are substituted for "section 2101(11a), (11b), and (11c) of title 46, United States Code," on authority of section 3541(a)(1)(C) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115–232, 132 Stat. 2322).

SECTION 69904—CONSTRUCTIVE SEIZURE PROCEDURES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69904	21 U.S.C. 881 note	Pub. L. 101–225, title II, §210, Dec. 12, 1989, 103 Stat. 1913.

In this section, in the matter before paragraph (1), the words "Not later than 6 months after the date of enactment of this Act" are omitted as obsolete.

SECTION 69905—EXEMPTION OF CERTAIN SUBSTANCES FROM PRODUCTION REGULATIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69905	21 U.S.C. 802 note	Pub. L. 101–647, title XIX, §1903, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 108–358, §2(c), Oct. 22, 2004, 118 Stat. 1663.

In subsection (b), the words "not later than 45 days after the date of enactment of this Act, except that the regulations required under section 3(a) shall be issued not later than 180 days after the date of enactment of this Act" are omitted as obsolete.

SECTION 69906—DIVERSION CONTROL FEE ACCOUNT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69906(a)(1)	21 U.S.C. 886a(2)(B)	Pub. L. 102–395, title I, § 111(b)(2)(B), as added Pub. L. 108–447, div. B, title VI, § 633(a), Dec. 8, 2004, 118 Stat. 2922.

SECTION 69906—DIVERSION CONTROL FEE ACCOUNT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69906(a)(2)	21 U.S.C. 886a(2)(A)	Pub. L. 102–395, title I, § 111(b)(2)(A), as added Pub. L. 108–447, div. B, title VI, § 633(a), Dec. 8, 2004, 118 Stat. 2921.
69906(b)	21 U.S.C. 886a(1)	Pub. L. 102–395, title I, § 111(b)(1), Oct. 6, 1992, 106 Stat. 1843; Pub. L. 105–362, title X, § 1001(b), Nov. 10, 1998, 112 Stat. 3291; Pub. L. 108–447, div. B, title VI, § 633(a), Dec. 8, 2004, 118 Stat. 2921.

In subsection (b), in the matter before paragraph (1), the words "For each fiscal year, the following shall apply" are substituted for "For fiscal year 1993 and thereafter" to eliminate obsolete words.

In subsection (b)(4), the words "for each fiscal year" are substituted for "for fiscal year 1994 and thereafter" to eliminate obsolete words.

SECTION 69907—DENIAL OF ASSISTANCE AND BENEFITS FOR CERTAIN DRUG-RELATED CONVICTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69907(a)	21 U.S.C. 862a(e)	Pub. L. 104–193, title I, §115(e), Aug. 22, 1996, 110 Stat. 2180; Pub. L. 110–234, title IV, §4115(c)(2)(C), May 22, 2008, 122 Stat. 1109; Pub. L. 110–246, §4(a), title IV, §4115(c)(2)(C), June 18, 2008, 122 Stat. 1664, 1871; Pub. L. 113–79, title IV, §4030(n)(3), Feb. 7, 2014, 128 Stat. 815.
69907(b) through (e) ...	21 U.S.C. 862a(a) through (d)	Pub. L. 104–193, title I, § 115(a) through (d), Aug. 22, 1996, 110 Stat. 2180; Pub. L. 105–33, title V, § 5516(a), Aug. 5, 1997, 111 Stat. 620; Pub. L. 110–234, title IV, §4115(c)(2)(C)(i), May 22, 2008, 122 Stat. 1109; Pub. L. 110–246, § 4(a), title IV, §4115(c)(2)(C)(i), June 18, 2008, 122 Stat. 1664, 1871; Pub. L. 113–79, title IV, §4030(n)(1), (2), Feb. 7, 2014, 128 Stat. 814.
69907(f)	21 U.S.C. 862a(f)	Pub. L. 104–193, title I, 115(f), Aug. 22, 1996, 110 Stat. 2181.

SECTION 69908—SANCTIONING FOR TESTING POSITIVE FOR CONTROLLED SUBSTANCES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69908	21 U.S.C. 862b	Pub. L. 104–193, title IX, § 902, Aug. 22, 1996, 110 Stat. 2347.

SECTION 69909—SUPPORT FOR INTERNATIONAL EFFORTS TO CONTROL METHAMPHETAMINE AND PRECURSORS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69909	21 U.S.C. 801 note	Pub. L. 104–237, title I, §101, Oct. 3, 1996, 110 Stat. 3100.

SECTION 69910—PUBLIC-PRIVATE EDUCATION PROGRAM

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69910	21 U.S.C. 872a	Pub. L. 104–237, title V, § 503, Oct. 3, 1996, 110 Stat. 3112; Pub. L. 111–211, title II, § 232(b), July 29, 2010, 124 Stat. 2278.

SECTION 69911—EDUCATIONAL PROGRAM FOR POLICE DEPARTMENTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69911	21 U.S.C. 872 note	Pub. L. 104–305, §4, Oct. 13, 1996, 110 Stat. 3809.

SECTION 69912—ANNUAL REPORT ON DEVELOPMENT AND DEPLOYMENT OF NARCOTICS DETECTION TECHNOLOGIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69912	21 U.S.C. 1505a	Pub. L. 105–85, div. A, title X, § 1034, Nov. 18, 1997, 111 Stat. 1884; Pub. L. 107–296, title XVII, § 1704(e)(10), Nov. 25, 2002, 116 Stat. 2315.

In subsection (a), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

SECTION 69913—AUTHORIZATION OF USE OF ENVIRONMENTALLY APPROVED HERBICIDES TO ELIMINATE ILLICIT NARCOTICS CROPS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69913	21 U.S.C. 1713	Pub. L. 105–277, div. C, title VIII, § 834, Oct. 21, 1998, 112 Stat. 2681–702.

In subsection (a), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

SECTION 69914—COMBATING AMPHETAMINE AND METHAMPHETAMINE MANUFACTURING AND TRAFFICKING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69914	21 U.S.C. 873 note	Pub. L. 106–310, div. B, title XXXVI, §3625, Oct. 17, 2000, 114 Stat. 1233.

In subsection (a), in the matter before paragraph (1), the parentheticals "(referred to in this section as 'Administrator')" and "(referred to in this section as 'Administration')" are added for clarity.

In subsection (c), the word "Administration" is substituted for "Drug Enforcement Administration" because of the parenthetical "(referred to in this section as 'Administration')" added in subsection (a) (matter before paragraph (1)).

In subsection (c), the words "after fiscal year 1999," are omitted as obsolete.

SECTION 69915—ANTIDRUG MESSAGES ON FEDERAL GOVERNMENT INTERNET WEBSITES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69915(a)	21 U.S.C. 801 note	Pub. L. 106–310, div. B, title XXXVI, §3671, Oct. 17, 2000, 114 Stat. 1245.
69915(b)	21 U.S.C. 801 note	Pub. L. 106–391, title III, §320, Oct. 30, 2000, 114 Stat. 1597.

In this section, the words "Director of National Drug Control Policy" are substituted for the words "Director of the Office of National Drug Control Policy" each place they appear for consistency with chapter 609 of title 21, United States Code.

In subsection (a), the words "Not later than 90 days after the date of the enactment of this Act," are omitted as obsolete.

In subsection (a), the words "each agency and establishment" are substituted for "each department, agency, and establishment" to eliminate an unnecessary word.

In subsection (a), the words "controlled by the agency or establishment" are substituted for "controlled by such department, agency, or establishment" to eliminate an unnecessary word.

In subsection (b), the words "Not later than 90 days after the date of the enactment of this Act," are omitted as obsolete.

In subsection (b), the words "The Administrator of the National Aeronautics and Space Administration" are substituted for "the Administrator" to carry forward the definition of the term "Administrator" in section 3(1) of the National Aeronautics and Space Administration Authorization Act of 2000 (51 U.S.C. 10101 note).

SECTION 69916—COORDINATION WITH UNITED STATES TRADE REPRESENTATIVE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69916	21 U.S.C. 826 note	Pub. L. 109–177, title VII, § 718

SECTION 69917—SMUGGLING METHAMPHETAMINE OR METHAMPHETAMINE PRECURSOR CHEMICALS INTO THE UNITED STATES WHILE USING FACILITATED ENTRY PROGRAMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69917	21 U.S.C. 865	Pub. L. 109–177, title VII, §731, Mar. 9, 2006, 120 Stat. 270.

SECTION 69918—SEMIANNUAL REPORTS TO CONGRESS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69918	21 U.S.C. 871a	Pub. L. 109–177, title VII, § 736, Mar. 9, 2006, 120 Stat. 271.

In subsection (a)(2)(A), the words "scheduled listed chemical products" are substituted for "scheduled listed chemicals (as defined pursuant to the amendment made by section 711(a)(1))" for consistency with paragraph (52) of section 50101 of title 21, United States Code. The amendment made by section 711(a)(1) of the Combat Methamphetamine Epidemic Act of 2005 (Public Law 109–177, title VII, 120 Stat. 256) added a new paragraph (45) (among other provisions) to section 102 of the Controlled Substances Act (21 U.S.C. 802). That paragraph (45) defined the term "scheduled listed chemical product." The amendment made by section 711(a)(1) of the Combat Methamphetamine Epidemic Act of 2005 (Public Law 109–177, title VII, 120 Stat. 256) neither defined nor added a definition of "scheduled listed chemicals".

In subsection (b)(1), the words "Committee on Oversight and Government Reform" are substituted for "Committee on Government Reform" on authority of Rule X(1)(n) of the Rules of House of Representatives, adopted by House Resolution No. 6 (110th Congress, January 5, 2007).

SECTION 69919—GRANTS TO REDUCE PRODUCTION OF METHAMPHETAMINES FROM ANHYDROUS AMMONIA

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69919	21 U.S.C. 864a(a) through (c)	Pub. L. 110–234, title XIV, §14203(a) through (c), May 22, 2008, 122 Stat. 1458; Pub. L. 110–246, § 4(a), title XIV, § 14203, June 18, 2008, 122 Stat. 1664, 2220.

SECTION 69920—IDENTIFICATION AND PUBLICATION OF LIST OF PRODUCTS CONTAINING ANABOLIC STEROIDS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69920	21 U.S.C. 825 note	Pub. L. 113–260, §4, Dec. 18, 2014, 128 Stat. 2932.

In subsection (a), the words "section 50505(e) of this title" are substituted for the words "this Act and the amendments made by this Act" each place they appear to provide a more precise reference to the pertinent provision. The reference to "This Act" in the source law refers to the Designer Anabolic Steroid Control Act of 2014 (Public Law 113–260, 128 Stat. 2929). Labeling requirements in that Act are set out in section 3 of that Act (Public Law 113–260, 128 Stat. 2931) (see addition of subsection (e) to section 305 of the Controlled Substances Act (21 U.S.C. 825), restated as section 50505 of title 21, United States Code).

SECTION 69921—PRESCRIPTION DRUG TAKE BACK EXPANSION

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69921	21 U.S.C. 822a	Pub. L. 114–198, title II, §203, July 22, 2016, 130 Stat. 717.

In subsection (b), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

SECTION 69922—GAO AUDIT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69922	21 U.S.C. 1715	Pub. L. 115–271, title VIII, §8220, Oct. 24, 2018, 132 Stat. 4134 .

In this section, the words "Office of National Drug Control Policy" are substituted for "Office" each place it appears for clarity. See section 60901 of title 21, United States Code.

In paragraph (2), in the matter before subparagraph (A), the words "Director of National Drug Control Policy" are substituted for "Director" for clarity. See section 60901 of title 21, United States Code.

In paragraph (2), in the matter before subparagraph (A), the words "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" are substituted for "the appropriate congressional committees" for clarity. See section 60901 of title 21, United States Code.

SECTION 69923—DISPENSATION OF NARCOTIC DRUGS FOR THE PURPOSE OF RELIEVING ACUTE WITHDRAWAL SYMPTOMS FROM OPIOID USE DISORDER

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69923	21 U.S.C. 829 note	Pub. L. 116–215, div. B, title III, §1302, Dec. 11, 2020, 134 Stat. 1046.

SECTION 69924—METHAMPHETAMINE AS AN EMERGING DRUG THREAT

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69924	21 U.S.C. 1708 note	Pub. L. 117–99, §2, Mar. 14, 2022, 136 Stat. 43.

In subsection (b), the words "Director of National Drug Control Policy" are substituted for "Director of the Office of National Drug Control Policy" for consistency with chapter 609 of title 21, United States Code.

SECTION 69925—INFORMATION SHARING

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69925	21 U.S.C. 2004	Pub. L. 117–103, div. Q, title III, §305, Mar. 15, 2022, 136 Stat. 817.

SECTION 69926—ELIMINATING REQUIREMENT RELATING TO OPIOID TREATMENT PROGRAMS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
69926	21 U.S.C. 823 note	Pub. L. 117–328, div. FF, title I, §1252(b), Dec. 29, 2022, 136 Stat. 5681.

Subtitle VII—Cosmetics

Chapter 701—Modernization of Cosmetics Regulation

SECTION 70101—CONFIDENTIALITY

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
70101	21 U.S.C. 364 note	Pub. L. 117–328, div. FF, title III, §3503(c), Dec. 29, 2022, 136 Stat. 5859.

In subsection (a), the words "Secretary of Health and Human Services" are substituted for "Secretary" on authority of section 3002 of the Food and Drug Omnibus Reform Act of 2022 (Public Law 117–328, div. FF, title III, 136 Stat. 5807).

SECTION 70102—TALC-CONTAINING COSMETICS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
70102	21 U.S.C. 364d note	Pub. L. 117–328, div. FF, title III, §3505, Dec. 29, 2022, 136 Stat. 5859.

Subtitle VIII—Tobacco

Chapter 801—Family Smoking Prevention and Tobacco Control

SECTION 80101—FINAL RULE

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
80101	21 U.S.C. 387a–1	Pub. L. 111–31, div. A, title I, § 102, June 22, 2009, 123 Stat. 1830.

In subsection (a)(1), in the matter before subparagraph (A), the words "On the first day of publication of the Federal Register that is 180 days or more after the date of enactment of this Act," are omitted as obsolete.

In subsection (a)(1), in the matter before subparagraph (A), the words "(referred to in this section as the `Secretary')" are added for clarity.

In subsection (a)(2)(A), the words "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" are substituted for "with this subsection in accordance with this division and the amendments made by this division" for clarity.

In subsection (a)(2)(F), the words "effective on June 22, 2010" are substituted for "effective on the date that is 1 year after the date of enactment of this Act" for clarity.

In subsection (a)(5), the words "the provisions of this chapter, the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776)" are substituted for "the provisions of this division" for clarity.

In subsection (a)(6), the words "section 1140.16(d) of title 21, Code of Federal Regulations" are substituted for "section 897.16(d) of the final rule published under paragraph (1)" to provide the correct reference to the pertinent provision.

In subsection (a)(6), the words "section 80102 of this title" are substituted for "section 103(q)" to provide a more precise reference to the pertinent provision.

SECTION 80102—GUIDANCE RELATING TO CIVIL PENALTIES FOR VIOLATIONS RELATING TO SALE OF TOBACCO PRODUCTS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
80102	21 U.S.C. 333 note	Pub. L. 111–31, div. A, title I, §103(q)(1), (2), June 22, 2009, 123 Stat. 1838, 1839; Pub. L. 116–94, div. N, title I, §603(d)(1), Dec. 20, 2019, 133 Stat. 3124.

In subsection (a), in the matter before paragraph (1), the words "(referred to in this section as the `Secretary')" are added for clarity.

In subsection (a)(2), the words "has provided" are substituted for "has provider" to correct an error in the law.

In subsection (b)(1), in the matter before subparagraph (A), the reference "section 21107(d) of this title" is substituted for "section 906(d)" to provide the correct reference to the pertinent provision. The Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776) does not have a section 906(d). Section 21107(d) of title 21, United States Code, restates section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)).

In subsection (b)(2), in the matter before subparagraph (A), the words "section 21107(d)(5) of this title" are substituted for "section 906(d)(5)" to provide the correct reference to the pertinent provision. The Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776) does not have a section 906(d)(5). Section 21107(d)(5) of title 21, United States Code, restates section 906(d)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)(5)).

In subsection (b)(3), the words "in enforcing the provisions of this chapter and the Family Smoking Prevention and Tobacco Act (Public Law 111–31, div. A, 123 Stat. 1776)" are substituted for "in enforcing the provisions of this Act" for clarity.

In subsection (b)(3), the words "section 21107(d)(5) of this title" are substituted for "section 906(d)(5)" to provide the correct reference to the pertinent provision. The Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776) does not have a section 906(d)(5). Section 21107(d)(5) of title 21, United States Code, restates section 906(d)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)(5)).

In subsection (b)(3), the reference "section 21107(d) of this title" is substituted for "section 906(d)" to provide the correct reference to the pertinent provision. The Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, div. A, 123 Stat. 1776) does not have a section 906(d). Section 21107(d) of title 21, United States Code, restates section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)).

SECTION 80103—ENFORCEMENT ACTION PLAN FOR ADVERTISING AND PROMOTION RESTRICTIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
80103	21 U.S.C. 387f–1	Pub. L. 111–31, div. A, title I, § 105, June 22, 2009, 123 Stat. 1841.

In subsection (a)(1), the words "Not later than 6 months after the date of enactment of this Act," are omitted as obsolete.

In subsection (b)(1), the words "Not later than 3 months after the date of enactment of this Act," are omitted as obsolete.

In subsection (b)(1), the words "to those governments" are substituted for "to such entities" for clarity.

In subsection (b)(1), the words “by those governments” are substituted for “by such entities” for clarity.

SECTION 80104—STUDIES OF PROGRESS AND EFFECTIVENESS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
80104	21 U.S.C. 387u	Pub. L. 111–31, div. A, title I, § 106, June 22, 2009, 123 Stat. 1841.

In subsection (a), in the matter before paragraph (1), the words “(referred to in this section as the `Secretary')” are added for clarity.

In paragraphs (1), (2), and (4) of subsection (a), and in subsection (b)(1), the words “this chapter and the Family Smoking Prevention and Tobacco Control Act (Public Law 111–31, 123 Stat. 1776)” are substituted for “this division” for clarity.

In subsection (b), in the matter before paragraph (1), the words “Not later than 5 years after the date of enactment of this Act,” are omitted as obsolete.

SECTION 80105—EFFECT OF CHAPTER AND OTHER RELATED PROVISIONS

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
80105	21 U.S.C. 387 note	Pub. L. 111–31, div. A, §4, June 22, 2009, 123 Stat. 1782.

In subsections (a) (matter before paragraph (1)), (b), and (c), the words “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)” are substituted for “this division (or an amendment made by this division)” for clarity.

In subsection (b), the words “authorize the Secretary of Health and Human Services (referred to in this section as the ‘Secretary’)” are substituted for “authorize the Secretary” for clarity.

Chapters 803 through 897—Reserved

Chapter 899—Miscellaneous

SECTION 89901—REPORTING ON TOBACCO REGULATION ACTIVITIES

Revised Section	*Source (U.S. Code)*	*Source (Pub. L.)*
89901	21 U.S.C. 387v	Pub. L. 117–103, div. P, title I, §112, Mar. 15, 2022, 136 Stat. 790.

In subsection (a), the words “For each fiscal year” are substituted for “For fiscal year 2022 and each subsequent fiscal year” to eliminate obsolete words.

In subsection (d), the words “reporting with precise calculations” are substituted for “such reporting” for clarity.

SECTION 4—CONFORMING AMENDMENTS

Section 4 of the bill makes conforming amendments to certain provisions of law.

In paragraph (2), the words "(as last in effect)" are struck as unnecessary because on the date of enactment of section 843(b)(1)(A) of the Homeland Security Act of 2002 (6 U.S.C. 413(b)(1)(A)), which is December 17, 2004, section 702(7) of the Office of National Drug Control Policy Reauthorization Act of 1998 (formerly 21 U.S.C. 1701(7)) was no longer in effect pursuant to a prospective repeal that had taken into effect under section 715 of that Act (formerly 21 U.S.C. 1712). The prospective repeal was delayed pursuant to section 602 of the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469, 120 Stat. 3533). Upon the enactment of section 8202 of the Substance Abuse Prevention Act of 2018 (Public Law 115–271, 132 Stat. 4110), that section 702(7) (along with the rest of the Office of National Drug Control Policy Reauthorization Act of 1998) was revived and restored, making the words "(as last in effect)" unnecessary.

In paragraph (3)(A)(i)(III), the parenthetical "(21 U.S.C. 346a and 348)", which appears as a parenthetical citation for "section 408 of the Federal Food, Drug, and Cosmetic Act" in section 2(mm)(1)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(mm)(1)(B)), is treated in the amendment as a parenthetical citation for the references to sections 408 and 409 of the Federal Food, Drug, and Cosmetic Act in that section 2(mm)(1)(B). That treatment is reflected in the inserted language in the amendment (i.e., "a tolerance under section 11110 . . . or a food additive regulation under section 11111 . . .").

In paragraph (3)(F)(ii), the reference to "section 802 of title 21, United States Code" in section 12(b)(3)(C) of the Food and Nutrition Act of 2008 (7 U.S.C. 2021(b)(3)(C)) is translated as "section 50101 of title 21, United States Code", which is a restatement of section 102 of the Controlled Substances Act (21 U.S.C. 802).

In paragraph (3)(L)(i), the reference to "section 1011(d) of the Federal Food, Drug, and Cosmetic Act" in section 405(a) of the Agricultural Research Extension, and Education Reform Act of 1998 (7 U.S.C. 7625(a)) is translated as "section 10327(d) of title 21, United States Code", which is a restatement of section 1012(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399c(d)), to reflect the renumbering made by section 3073(b) of the 21st Century Cures Act (Public Law 114–255, 130 Stat. 1137). Section 1011 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399b), which was added by section 3509(g) of the Patient Protection and Affordable Care Act (Public Law 114–148, 124 Stat. 536), does not contain a subsection (d).

In subclauses (I) and (IV) of paragraph (5)(E)(i), the reference to "section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4))" in section 1107(f)(1) of title 10, United States Code, is translated as "section 13510(d) of title 21" for convenience, even though the second sentence of section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is restated as section 13510(e) of title 21, United States Code.

In paragraph (5)(A)(ii)(II), the reference to "section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" in section 1602(e)(2) (matter before subparagraph (A)) of the National Defense Authorization Act for Fiscal Year 2004 (Public Law 108–136, 10 U.S.C. 113 note) is translated as "section 10101(a)(16) of title 21, United States Code", which restates section 201(h)(1)

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (7)(A)(ii), the words "and section 407 of the Federal Food, Drug, and Cosmetic Act, as amended" are stricken in section 15(f) (matter before paragraph (1)) of the Federal Trade Commission Act (15 U.S.C. 55(f) (matter before paragraph (1)) because those words are carried forward in title 21, United States Code, by adding the provision in subsection (a) of section 11109 of title 21, United States Code.

In paragraph (7)(F)(ii), the reference to "section 903(a)(2)" of the Federal Food, Drug, and Cosmetic Act is translated as "section 21104(a)(1)(B)" of title 21, United States Code, for convenience, even though the matter after subparagraph (D) of section 903(a)(2) of the Act is restated as section 21104(a)(2) of title 21, United States Code.

In paragraph (7)(G)(v)(II), the reference to section "506 of the Federal Food, Drug, and Cosmetic Act" in section 10(a)(3) of the Fair Packaging and Labeling Act (15 U.S.C. 1459(a)) is not carried forward in the translation "section 13103(a)(1) of title 21, United States Code" because a prior section 506 of the Federal Food, Drug, and Cosmetic Act (which related to certification of drugs containing insulin) was in effect on the date of enactment of section 10(a)(3) of the Fair Packaging and Labeling Act (15 U.S.C. 1459(a)). That prior section 506 was repealed by section 125(a)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325). Later enactments amended the Federal Food, Drug, and Cosmetic Act by adding, and subsequently amending, a new section 506 of that Act (21 U.S.C. 356), which currently relates to expedited approval of drugs for serious or life-threatening diseases or conditions.

In paragraph (7)(J)(i)(I), the reference to section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) in section 3(a)(5)(H) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(5)(H)) is translated as section 10101(a)(18) of title 21, United States Code, for convenience, even though section 201(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(2)) is restated as section 10101(11) of title 21, United States Code, and because referring to section 10101(11) of that title is unnecessary because it provides a definition of "counterfeit drug" which is not referred to in section 3(a)(5)(H) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(5)(H)).

In paragraph (7)(J)(i)(I), the reference to section 201(h) of the Federal Food, Drug, and Cosmetic Act in section 3(a)(5)(H) of the Consumer Product Safety Act (15 U.S.C. 2052(a)(5)(H)) is translated as section 10101(a)(16) of title 21, United States Code, which restates section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (7)(J)(iii)(I), the reference to "sections 355 (1) and (2) of the Public Health Service Act" in section 31(a) of the Consumer Product Safety Act (15 U.S.C. 2080(a)) is translated as "paragraphs (2) and (3) of section 14101 of title 21, United States Code" because of the redesignation made by section 19(a)(4) of the Safe Medical Devices Act of 1990 (Public Law 101–629, 104 Stat. 4530), as amended by section 4(a)(2) of the Nutrition Labeling and Education Act Amendments of 1993 (Public Law 103–80, 107 Stat. 779).

In paragraph (7)(J)(iii)(II), the reference to "subpart 3 of part F of title III of the Public Health Service Act" in section 31(a) of the Consumer Product Safety Act (15 U.S.C. 2080(a)) is translated as "chapter 141 of title 21, United States Code" because of the redesignation made by section 19(a)(4) of the Safe Medical Devices Act of 1990 (Public Law 101–629, 104 Stat. 4530), as amended by section 4(a)(2) of the Nutrition Labeling and Education Act Amendments of 1993 (Public Law 103–80, 107 Stat. 779).

In paragraph (9)(A)(vi)(II), the reference to "'this subchapter or subchapter II'" in section 229B(b)(1)(A) of title 18, United States Code, is translated as "'this division or division B'" to correct a technical error. Subsections (b) through (p) of section 413 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 853) do not contain any reference to "'this subchapter or subchapter II'". In the restatement of those subsections (see subsections (a) and (c) through (p) of section 50713 of title 21, United States Code), the translation to "'this division or division B'" is made to clarify that the reference to "'this subchapter or subchapter II'" was intended to refer to "'this title or title III'", which refers to title II or III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1236), which titles may be cited as the Controlled Substances Act (21 U.S.C. 801 et seq.) and the Controlled Substances Import and Export Act)21 U.S.C. 951 et seq.), respectively.

In paragraph (9)(B)(vii), the reference to "the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.)" in section 3582(e) of title 18, United States Code, is translated as "division A or B of title 21" to provide a more precise reference to the pertinent provisions. Provisions relating to felonies appear only in titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.).

In paragraph (9)(B)(xiii)(I), the reference to section 408(a) of the Controlled Substances Act (21 U.S.C. 848(a)) in section 3663(a)(1)(A) of title 18, United States Code, is translated as section 50708(a) of title 21, United States Code, for convenience, even though section 408(c) of the Act is restated as paragraph (1) of section 50708(a) of title 21, United States Code.

In paragraph (9)(B)(xiii)(II)(aa), the reference to section 408(a) of the Controlled Substances Act (21 U.S.C. 848(a)) in section 3663(c)(1) of title 18, United States Code, is translated as section 50708(a) of title 21, United States Code, for convenience, even though section 408(c) of the Act is restated as paragraph (1) of section 50708(a) of title 21, United States Code.

In paragraph (12)(A), the parenthetical "(except the amendment made by section 3042 of this Act)" is added after the words "or an amendment made by this subtitle" in section 3043 of the 21st Century Cures Act (21 U.S.C. 356 note) because of the restatement of that section 3043, as it relates to the amendment made by section 3042 of the 21st Century Cures Act (Public Law 114–255, 130 Stat. 1112) in title 21, United States Code. See section 13118(i)(8)(B) of title 21, United States Code.

In paragraph (12)(B), section 122 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (21 U.S.C. 356–1) is amended generally to reflect the restatement of subsections (a) through (c) of that section in title 21, United States Code. See section 49904 of title 21, United States Code.

In paragraph (13)(A), the reference to "the Comprehensive Drug Abuse Prevention and Control Act of 1970" in section 22 of the Inter-American Development Bank Act (22 U.S.C. 283s) is translated as "division A of subtitle V of title 21, United States Code", even though division A of subtitle V of title 21, United States Code, restates only title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) to provide a more precise reference to the pertinent provision because the term "controlled substance" is defined in that title II.

In paragraph (13)(B), the reference to "the Comprehensive Drug Abuse Prevention and Control Act of 1970" in section 13 of the International Development Association Act (22 U.S.C. 284k) is translated as "division A of subtitle V of title 21, United States Code", even though division A of subtitle V of title 21, United States Code, restates only title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) to provide a more precise reference to the pertinent provision because the term "controlled substance" is defined in that title II.

In paragraph (13)(C), the reference to "the Comprehensive Drug Abuse Prevention and Control Act of 1970" in section 19 of the Asian Development Bank Act (22 U.S.C. 285p) is translated as "division A of subtitle V of title 21, United States Code", even though division A of subtitle V of title 21, United States Code, restates only title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.) to provide a more precise reference to the pertinent provision because the term "controlled substance" is defined in that title II.

In paragraph (15)(A), the amendments to section 4(3)(D)(i)(I) of the Indian Law Enforcement Reform Act (25 U.S.C. 2803(3)(D)(i)(I)) are only to items (aa) and (cc) of that section. Item (bb) of that section 4(3)(D)(i)(I) refers to "title IX of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (21 U.S.C. 862a et seq.)". The provisions of title IX of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (21 U.S.C. 862a et seq.) are classified to various titles of the Code (see Table III (Statutes at Large) of the United States Code). Section 902 of the Act is the only provision in title IX of the Act that is classified to title 21 (see 21 U.S.C. 862b). The provision that is classified to 21 U.S.C. 862a is section 115 of the Act, which does not belong to title IX of the Act. Though sections 115 and 902 of the Act are restated as sections 69907 and 69908, respectively, of title 21, United States Code, the reference to "title IX of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (21 U.S.C. 862a et seq.)" in section 4(3)(D)(i)(I)(bb) of the Indian Law Enforcement Reform Act (25 U.S.C. 2803(3)(D)(i)(I)(bb)) is retained because the reference could not be translated in a way that ensures that no change in the meaning or effect of that section 4(3)(D)(i)(I)(bb) is effectuated by the translation.

In paragraph (16)(C), the reference to "the Controlled Substances Act" in section 280E of the Internal Revenue Code of 1986 (26 U.S.C. 280E) is translated as "section 50302 of title 21, United States Code" to provide a more precise reference to the pertinent provision.

In paragraph (22)(A)(vi), the words "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" in section 156(f)(4)(B) of title 35, United States Code, are struck and in lieu of those words, the words "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" are inserted. In the inserted words, section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is translated as chapter 135 of title 21, United States Code, section 512 of the Act (21 U.S.C. 360b) is translated as chapter 137 of title 21, United States Code, and section 515 of the Act (21 U.S.C. 360e) is translated as section 13142 of title 21, United States Code. The reference to section 503 of the Act is omitted because there is no reference to section 503 in section 156 of title 35, United States Code.

In paragraph (22)(A)(vii), the reference to "section 201(y) of the Federal Food, Drug, and Cosmetic Act" is translated as "section 10101(a)(23) of title 21", even though section 10101(a)(23) of title 21, United States Code, restates section 201(x) of the Federal Food, Drug, and Cosmetic Act. See redesignation made by section 3(b) of the Nutrition Labeling and Education Act Amendments of 1993 (Public Law 103–80, 107 Stat. 775).

In paragraph (22)(A)(viii)(I), the reference to "subsection (d) of section 507" in section 156 of title 35, United States Code, is omitted as obsolete because of the repeal of the former section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), which section related to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, by section 125(b)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325).

In paragraph (22)(A)(viii)(II), the reference to section "507" in section 156 of title 35, United States Code, is omitted as obsolete because of the repeal of the former section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), which section related to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, by section 125(b)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325).

In paragraph (22)(A)(ix), the reference to "section 507" in section 156 of title 35, United States Code, is omitted as obsolete because of the repeal of the former section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), which section related to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, by section 125(b)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325).

In paragraph (22)(A)(xiii)(II), the reference to "such Act" in section 156(g)(3)(B)(ii) of title 35, United States Code, is translated as "subtitle I of title 21" for clarity.

In paragraph (22)(A)(xv)(II), the reference to "such section" in section 156(g)(4)(B)(ii) of title 35, United States Code, is translated as "chapter 137" for clarity.

In paragraph (23)(E), the reference to "the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1101 et seq.)" is translated as "the Drug Abuse Prevention, Treatment, and Rehabilitation Act" because of the amendment made by section 15(a) of the Drug Abuse Prevention, Treatment, and Rehabilitation Amendments of 1979 (Public Law 96–181, 93 Stat. 1316). Though sections of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1101 et seq.) are restated as chapter 603 of title 21, United States Code, no reference

to the chapter is made in the translation because the provisions restated in the chapter do not contain provisions relating to regulations governing the confidentiality of drug and alcohol abuse medical records and the admission of drug and alcohol abusers to private and public hospitals.

In paragraph (26)(A)(i)(I), the reference to section "355(5)," is stricken as obsolete in section 2(f) of the Public Health Service Act (42 U.S.C. 201(f)) because of the redesignation made by paragraphs (3) and (4) of section 19 of the Safe Medical Devices Act of 1990 (Public Law 101–629, 104 Stat. 4530). Those paragraphs redesignated section 355(5) of the Public Health Service Act (previously classified to 42 U.S.C. 263c(5)) as section 531(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh(5)) (restated as section 14101(5) of title 21, United States Code). The redesignation made the reference to section "355(5)," obsolete.

In paragraph (26)(A)(ii)(I)(aa), the reference to section "subchapter B of the Federal Food, Drug, and Cosmetic Act" in section 227(c)(1)(A) of the Public Health Service Act (42 U.S.C. 236(c)(1)(A)) is translated as chapter 139 of title 21, United States Code, which restates subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.). There is no other subchapter B that relates to drugs for rare diseases or conditions in the Act other than subchapter B of chapter V of the Act.

In items (aa) and (bb) of paragraph (26)(A)(v)(I), the references to "section 506(h) of the Federal Food, Drug, and Cosmetic Act" in paragraphs (1) and (3)(B) of section 319E(g) of the Public Health Service Act (42 U.S.C. 247d–5(g)) are translated as "section 13119(i) of title 21, United States Code" for convenience, even though section 3043 (matter relating to the amendment made by section 3042 of the 21st Century Cures Act) of the 21st Century Cures Act (21 U.S.C. 356 note) is restated as section 13119(i)(8)(B) of title 21, United States Code.

In paragraph (26)(A)(v)(II)(aa), the reference to "section 506(h) of the Federal Food, Drug, and Cosmetic Act" in section 319E(j)(1) (matter before subparagraph (A)) of the Public Health Service Act (42 U.S.C. 247d–5(j)(1) (matter before subparagraph (A))) is translated as "section 13119(i) of title 21, United States Code" for convenience, even though section 3043 (matter relating to the amendment made by section 3042 of the 21st Century Cures Act) of the 21st Century Cures Act (21 U.S.C. 356 note) is restated as section 13119(i)(8)(B) of title 21, United States Code.

In paragraph (26)(A)(v)(II)(bb), the reference to "such section 506(h)" in section 319E(j)(1)(B)(ii) of the Public Health Service Act (42 U.S.C. 247d–5(j)(1)(B)(ii)) is translated as "such section 13119(i)" for convenience, even though section 3043 (matter relating to the amendment made by section 3042 of the 21st Century Cures Act) of the 21st Century Cures Act (21 U.S.C. 356 note) is restated as section 13119(i)(8)(B) of title 21, United States Code.

In paragraph (26)(A)(vi)(II), the reference to "section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" in 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 translated as "section 10101(a)(16) of title 21, United States Code", which restates section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (26)(A)(vii)(I)(bb), the reference to "section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" in section 319F–2(c)(1)(B) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(1)(B)) is translated as "section 10101(a)(16) of title 21, United States Code", which restates section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (26)(A)(viii)(VII)(bb), the reference to "section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" in section 319F–3(i)(1)(C) of the Public Health Service Act (42 U.S.C. 247d–6d(i)(1)(C)) is translated as "section 10101(a)(16) of title 21, United States Code", which restates section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (26)(A)(viii)(VIII)(bb), the reference to "section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))" in section 319F–3(i)(7) of the Public Health Service Act (42 U.S.C. 247d–6d(i)(7)) is translated as "section 10101(a)(16) of title 21, United States Code", which restates section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (26)(A)(x)(I), the directory language of section 7102(a) of the Patient Protection and Affordable Care Act (Public Law 111–148, 124 Stat. 823) is amended to make the directory language executable. Section 2501(f)(1)(C) of the Patient Protection and Affordable Care Act (Public Law 111–148, 124 Stat. 309) redesignated the former subsection (d) of section 340B of the Public Health Service Act (42 U.S.C. 256b) as subsection (c), but section 7102(a) of the Patient Protection and Affordable Care Act (124 Stat. 823) generally amended subsection (d) of that section 340B, making the general amendment not executable because of the redesignation made by section 2501(f)(1)(C) of the Patient Protection and Affordable Care Act (Public Law 111–148, 124 Stat. 309).

In paragraph (26)(A)(x)(II), the amendment by paragraph (26)(A)(x)(II) is made effective on the same date that the amendment made by section 7102 of the Patient Protection and Affordable Care Act (Public Law 111-48, 124 Stat. 823) became effective. See section 7101(e)(1) of the Patient Protection and Affordable Care Act (Public Law 111-48, 124 Stat. 823).

In paragraph (26)(A)(xi)(I), the reference to "Prescription Drug Marketing Act (21 U.S.C. 353)" in section 340B(d)(2)(B)(v)(III) of the Public Health Service Act (42 U.S.C. 256b(d)(2)(B)(v)(III)) is translated as "Prescription Drug Marketing Act of 1987 (Public Law 100–293, 102 Stat. 95)" to provide the correct short title of the Act to which the reference is made. In the translation, the parenthetical "(21 U.S.C. 353)" is not carried forward. The Prescription Drug Marketing Act of 1987 (Public Law 100–293, 102 Stat. 95) is not classified to 21 U.S.C. 353; instead, it amended provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), among which is section 503 of that Act, which is classified to 21 U.S.C. 353.

In paragraph (26)(A)(xii)(VII)(aa), the reference to subsection (p) of section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) in section 351(k)(8)(A) of the Public Health Service Act (42 U.S.C. 262(k)(8)(A)) is

omitted as obsolete because that subsection was struck by section 3102(2) of the 21st Century Cures Act (Public Law 114–255, 130 Stat. 1156).

In paragraph (26)(A)(xii)(VIII)(bb)(AA), to clarify that the reference to "section 526" in section 351(m)(2)(B) of the Public Health Service Act (42 U.S.C. 262(m)(2)(B)) is a reference to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.360bb), the reference to "section 526" is translated as "section 13902 of title 21, United States Code,", which section 13902 restates section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb).

In paragraph (26)(A)(xii)(VIII)(bb)(BB), to clarify that the reference to "section 527(a)" in section 351(m)(2)(B) of the Public Health Service Act (42 U.S.C. 262(m)(2)(B)) is a reference to section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.360cc(a)), the reference to "section 527(a)" is translated as "section 13903(a) of title 21, United States Code,", which section 13903(a) restates section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)).

In paragraph (26)(A)(xii)(IX)(bb)(AA), to clarify that the reference to "section 526" in section 351(m)(3)(B) of the Public Health Service Act (42 U.S.C. 262(m)(3)(B)) is a reference to section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.360bb), the reference to "section 526" is translated as "section 13902 of title 21, United States Code,", which section 13902 restates section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb).

In paragraph (26)(A)(xii)(IX)(bb)(BB), to clarify that the reference to "section 527(a)" in section 351(m)(3)(B) of the Public Health Service Act (42 U.S.C. 262(m)(3)(B)) is a reference to section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.360cc(a)), the reference to "section 527(a)" is translated as "section 13903(a) of title 21, United States Code,", which section 13903(a) restates section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)).

In paragraph (26)(A)(xii)(X), to clarify that the reference to "section 505A(d)(4)" in section 351(m)(4) of the Public Health Service Act (42 U.S.C. 262(m)(4)) is a reference to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355a(d)(4)), the reference to "section 505A(d)(4)" is translated as "section 13112(d)(4) of title 21, United States Code,", which section 13112(d)(4) restates section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)).

In paragraph (26)(A)(xvii)(VII), the reference to "section 201(h) of the Federal Food, Drug, and Cosmetic Act" in section 402(j)(1)(A)(vi) of the Public Health Service Act (42 U.S.C. 282(j)(1)(A)(vi)) is translated as "section 10101(a)(16) of title 21, United States Code", which restates section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (26)(A)(xvii)(VIII), the reference to section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) in section 402(j)(1)(A)(vii) of the Public Health Service Act (21 U.S.C. 282(j)(1)(A)(vii)) is translated as section 10101(a)(18) of title 21, United States Code, for convenience, even though section 201(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(2)) is restated as section 10101(a)(12) of title

21, United States Code, and because referring to section 10101(a)(12) of that title is unnecessary because it provides a definition of "counterfeit drug" which is not referred to in section 402(j)(1)(A)(vii) of the Public Health Service Act (21 U.S.C. 282(j)(1)(A)(vii)).

In paragraph (26)(A)(xx)(I)(bb)(BB), the reference to "section 201(h) of the Federal Food, Drug, and Cosmetic Act" in section 480(a)(3) (matter before subparagraph (A)) of the Public Health Service Act (42 U.S.C. 287a(a)(3) (matter before subparagraph (A))) is translated as "section 10101(a)(16) of title 21, United States Code", which restates section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1)), because of the redesignations made by section 2(b) of the Safeguarding Therapeutics Act (Public Law 116–304, 134 Stat. 4916).

In paragraph (26)(A)(xxiii), the reference to "the Drug-Free Communities Act of 1997" in section 519B(e)(7) of the Public Health Service Act (42 U.S.C. 290bb–25b(e)(7)) is translated as "chapter 605 of title 21, United States Code". The Drug-Free Communities Act of 1997 (Public Law 105–20, 111 Stat. 224) redesignated certain sections of the National Narcotics Leadership Act of 1988 (Pub. L. 100–690, title I, subtitle A, 102 Stat. 4181) as chapter 1 of that Act (which chapter 1 was previously classified to 21 U.S.C. 1501 et seq.) and enacted chapter 2 of that Act, which chapter 2 is restated as chapter 605 of title 21, United States Code.

In paragraph (26)(A)(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 to reflect the intent of Congress in enacting section 1262(b)(3) of the Restoring Hope for Mental Health and Well-Being Act of 2022 (Pub. L. 117–328, div. FF, title I, 136 Stat. 5682). That amendment in that section struck words that do not appear in the law. The amendment in paragraph (26)(A)(xxiii) strikes words that Congress intended to strike and inserts the words that Congress intended to insert.

In paragraph (26)(A)(xxxvii), the reference to "section 804(2) of the Federal Food, Drug, and Cosmetic Act" in section 3000(12) of the Public Health Service Act (42 U.S.C. 300jj(12)) is translated as "section 20104(a)(2) of title 21, United States Code", which restates section 804(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384(a)(2)).

In paragraph (26)(B)(xiv)(VIII), the reference to section "507" of the Federal Food, Drug, and Cosmetic Act in section 1927(k)(2)(A)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)(A)(i)) is omitted as obsolete because of the repeal of the former section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), which section related to the certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, by section 125(b)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325).

In paragraph (26)(B)(xiv)(XI), the reference in section 1927(k)(2)(C) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)(C)) to "section 506 of the Federal Food, Drug, and Cosmetic Act" is translated as "section 506 of the Federal Food, Drug, and Cosmetic Act (as in effect before November 21, 1997)" because of the repeal of a prior section 506 of the Federal Food, Drug, and Cosmetic Act (which related to certification of drugs containing insulin) by section 125(a)(1) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115, 111 Stat. 2325). Later enactments amended the Federal Food, Drug,

and Cosmetic Act by adding, and subsequently amending, a new section 506 of that Act (21 U.S.C. 356), which currently relates to expedited approval of drugs for serious or life-threatening diseases or conditions.

In paragraph (26)(C)(i)(I)(ll), the reference to "section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act" in section 7002(e) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148, 42 U.S.C. 262 note) is translated as "section 13503(a)(1)(A) of title 21, United States Code", which restates clause (i) of that section 505(b)(1)(A), because of the amendment made by section 2(a)(1) of the Orange Book Transparency Act of 2020 (Public Law 116–290, 134 Stat. 4889).

In paragraph (26)(C)(viii), the reference to "section 102" in 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 translated as "section 20102 of title 21, United States Code" because section 102 of Public Law 99–660 (100 Stat. 3743) enacted section 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 382), which is restated as section 20102 of title 21, United States Code.

In paragraph (26)(C)(xv), the words "amended by this Act" in section 10 of the Medical Device Amendments of 1976 (42 U.S.C. 3512) are not carried forward in the translation "subtitle I of title 21, United States Code" to eliminate unnecessary words.

In paragraph (26)(C)(xxiv)(I)(aa)(AA), the parenthetical "(21 U.S.C. 812)" in section 101(6)(A) of the American with Disabilities Act of 1990 (42 U.S.C. 12111(6)(A)), which parenthetical follows the reference "the Controlled Substances Act", is not carried forward in the translation "division A of subtitle V of title 21, United States Code" because the reference is to the Act, and not to section 202 of the Act (21 U.S.C. 812).

In paragraph (26)(C)(xxiv)(II)(aa)(AA), the parenthetical "(21 U.S.C. 812)" in section 511(d)(1) of the American with Disabilities Act of 1990 (42 U.S.C. 12210(d)(1)), which parenthetical follows the reference "the Controlled Substances Act", is not carried forward in the translation "division A of subtitle V of title 21, United States Code" because the reference is to the Act, and not to section 202 of the Act (21 U.S.C. 812).

In paragraph (27)(D)(ii), the parenthetical "(21 U.S.C. 812)" in section 70506(c)(1) of title 46, United States Code, which parenthetical follows the reference "the Controlled Substances Act", is not carried forward in the translation "division A of subtitle V of title 21, United States Code" because the reference is to the Act, and not to section 202 of the Act (21 U.S.C. 812).

In paragraph (28)(B), the reference to "section 102(6) of the United States Controlled Substances Act" is translated as "section 50101(9) of title 21, United States Code,", which restates section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6)). See section 100 of title II of Public Law 91–513 (84 Stat. 1242), which provided for the short title "Controlled Substances Act".

In paragraph (28)(C), the reference to "section 102(6) of the United States Controlled Substances Act" is translated as "section 50101(9) of title 21, United States Code,", which restates section 102(6) of the Controlled Substances Act (21 U.S.C. 802(6)). See section 100 of title II of Public Law 91–513 (84 Stat. 1242) which provided for the short title "Controlled Substances Act".

In paragraph (28)(D)(ii), the reference to "subsection (a) of section 1003 of the Controlled Substances Act (21 U.S.C. 953)" in section 201(a)(2) of Public Law 101–219 (48 U.S.C. 1972(a)(2)) is translated as "subsection (a) of section 51703 of title 21, United States Code", the source provision of which is subsection (a) of section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953), for clarity.

In paragraph (32)(A)(ii), a new subsection (a) is added to section 7217 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2269) to carry forward section 7203 of the Act (21 U.S.C 2302), which is restated in the bill enacting title 21, United States Code, as section 61901 of title 21, United States Code.

In paragraph (32)(B)(ii), a new subsection (a) is added to section 7221 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2270) to carry forward section 7203 of the Act (21 U.S.C 2302), which is restated in the bill enacting title 21, United States Code, as section 61901 of title 21, United States Code.

In paragraph (32)(B)(iii), subsection (i) is added to section 7221 of the Fentanyl Sanctions Act (Public Law 116–92, title LXXII, 133 Stat. 2270) to carry forward section 7232(b) of that Act (21 U.S.C. 2332(b)), which is repealed by the bill enacting title 21, United States Code. See Disposition Table for 21 U.S.C. 2332(b)).

SECTION 5—TRANSITIONAL AND SAVINGS PROVISIONS

Section 5 of the bill contains transitional and savings provisions.

SECTION 6—REPEALS

Section 6 of the bill repeals provisions replaced by the bill, along with unnecessary and obsolete provisions (see "Disposition Table" above).