

Public Law 100-290  
100th Congress

An Act

Apr. 18, 1988  
[H.R. 3459]

To amend the Federal Food, Drug, and Cosmetic Act to revise the provisions respecting orphan drugs, and for other purposes.

Orphan Drug  
Amendments of  
1988.  
Diseases.  
21 USC 301 note.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Orphan Drug Amendments of 1988".

SEC. 2. DESIGNATION AS AN ORPHAN DRUG.

(a) **REQUEST.**—Section 526(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(1)) is amended by adding after the first sentence the following: "A request for designation of a drug shall be made before the submission of an application under section 505(b) for the drug, the submission of an application for certification of the drug under section 507, or the submission of an application for licensing of the drug under section 351 of the Public Health Service Act."

(b) **DISCONTINUANCE.**—Section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) is amended by redesignating subsections (b) and (c) as subsections (c) and (d), respectively, and by adding after subsection (a) the following:

"(b) A designation of a drug under subsection (a) shall be subject to the condition that—

"(1) if an application was approved for the drug under section 505(b), a certificate was issued for the drug under section 507, or a license was issued for the drug under section 351 of the Public Health Service Act, the manufacturer of the drug will notify the Secretary of any discontinuance of the production of the drug at least one year before discontinuance, and

"(2) if an application has not been approved for the drug under section 505(b), a certificate has not been issued for the drug under section 507, or a license has not been issued for the drug under section 351 of the Public Health Service Act and if preclinical investigations or investigations under section 505(i) are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 505(b), approval of an application for certification under section 507, or approval of a license under section 351 of the Public Health Service Act."

SEC. 3. FINANCIAL ASSISTANCE.

(a) **MEDICAL DEVICES.**—Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a), by inserting "(1)" after "assist in" and by inserting before the period a comma and "(2) defraying the costs

of developing medical devices for rare diseases or conditions”, and

(2) in subsection (b)(2)—

(A) by inserting “(1) in the case of a drug,” after “means” in the first sentence and by adding before the period in that sentence a comma and “(2) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance under subsection (a)”, and

(B) by striking out “under this subsection” in the last sentence and inserting in lieu thereof “under section 526 of the Federal Food, Drug, and Cosmetic Act”.

(b) **MEDICAL FOODS.**—Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a) (as amended by subsection (a)), by inserting before the period a comma and “and (3) defraying the costs of developing medical foods for rare diseases or conditions”,

(2) in subsection (b)(2) (as amended by subsection (a)), by inserting before the period at the end of the first sentence a comma and “and (3) in the case of a medical food, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such disease or condition will be developed without assistance under subsection (a)”, and

(3) by adding at the end of subsection (b) the following:

“(3) The term ‘medical food’ means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”.

(c) **AUTHORIZATION.**—Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

“(c) For grants and contracts under subsection (a) there are authorized to be appropriated \$10,000,000 for fiscal year 1988, \$12,000,000 for fiscal year 1989, \$14,000,000 for fiscal year 1990.”.

(d) **STUDY.**—The Secretary of Health and Human Services shall conduct a study to determine whether the application of subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (relating to drugs for rare diseases and conditions) and section 28 of the Internal Revenue Code of 1986 (relating to tax credit) to medical devices or medical foods for rare diseases or conditions or to both is needed to encourage the development of such devices and foods. The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than one year after the date of the enactment of this Act. For purposes of this section, the term “rare diseases or conditions” has the meaning prescribed by section 5 of the Orphan Drug Act (21 U.S.C. 360ee).

Taxes.  
21 USC 360aa  
note.

Reports.

## SEC. 4. NATIONAL COMMISSION ON ORPHAN DISEASES.

Section 4(n) of the Orphan Drug Amendments of 1985 (42 U.S.C. 236 note) is amended by striking out "September 30, 1987" and inserting in lieu thereof "February 1, 1989".

Approved April 18, 1988.

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LEGISLATIVE HISTORY—H.R. 3459:

HOUSE REPORTS: No. 100-473 (Comm. on Energy and Commerce).  
CONGRESSIONAL RECORD, Vol. 134 (1988):  
Mar. 22, considered and passed House.  
Mar. 31, considered and passed Senate.