

## EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99-91 effective Aug. 15, 1985, see section 8(b) of Pub. L. 99-91, set out as a note under section 360aa of this title.

**§ 360dd. Open protocols for investigations of drugs for rare diseases or conditions**

If a drug is designated under section 360bb of this title as a drug for a rare disease or condition and if notice of a claimed exemption under section 355(i) of this title or regulations issued thereunder is filed for such drug, the Secretary shall encourage the sponsor of such drug to design protocols for clinical investigations of the drug which may be conducted under the exemption to permit the addition to the investigations of persons with the disease or condition who need the drug to treat the disease or condition and who cannot be satisfactorily treated by available alternative drugs.

(June 25, 1938, ch. 675, §528, as added Pub. L. 97-414, §2(a), Jan. 4, 1983, 96 Stat. 2051.)

**§ 360ee. Grants and contracts for development of drugs for rare diseases and conditions**

**(a) Authority of Secretary**

The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the costs of qualified testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions.

**(b) Definitions**

For purposes of subsection (a) of this section:

(1) The term “qualified testing” means—

(A) human clinical testing—

(i) which is carried out under an exemption for a drug for a rare disease or condition under section 355(i) of this title (or regulations issued under such section); and

(ii) which occurs before the date on which an application with respect to such drug is submitted under section 355(b) of this title or under section 262 of title 42; and

(B) preclinical testing involving a drug for a rare disease or condition which occurs after the date such drug is designated under section 360bb of this title and before the date on which an application with respect to such drug is submitted under section 355(b) of this title or under section 262 of title 42.

(2) The term “rare disease or condition” means (1) in the case of a drug, any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug, (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) of this section, 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) of this section. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 360bb of this title is made.

(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 of appropriations**

For grants and contracts under subsection (a), there is authorized to be appropriated \$30,000,000 for each of fiscal years 2013 through 2017.

(Pub. L. 97-414, §5, Jan. 4, 1983, 96 Stat. 2056; Pub. L. 98-551, §4(b), Oct. 30, 1984, 98 Stat. 2817; Pub. L. 99-91, §5, Aug. 15, 1985, 99 Stat. 391; Pub. L. 100-290, §3(a)-(c), Apr. 18, 1988, 102 Stat. 90, 91; Pub. L. 105-115, title I, §125(b)(2)(N), Nov. 21, 1997, 111 Stat. 2326; 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, July 9, 2012, 126 Stat. 1092.)

CODIFICATION

Section was enacted as part of the Orphan Drug Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

AMENDMENTS

2012—Subsec. (b)(1)(A)(ii). Pub. L. 112-144, §906(a), struck out “after the date such drug is designated under section 360bb of this title and” after “which occurs”.

Subsec. (c). Pub. L. 112-144, §906(b), amended subsec. (c) generally. Prior to amendment, text read as follows: “For grants and contracts under subsection (a), there is authorized to be appropriated \$30,000,000 for each of fiscal years 2008 through 2012.”

2007—Subsec. (c). Pub. L. 110-85 amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: “For grants and contracts under subsection (a) of this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$25,000,000 for each of the fiscal years 2003 through 2006.”

2002—Subsec. (c). Pub. L. 107-281 amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: “For grants and contracts under subsection (a) of this section 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.”

1997—Subsec. (b)(1)(A)(ii), (B). Pub. L. 105-115 struck out “or 357” after “355(b)”.

1988—Subsec. (a). Pub. L. 100-290, §3(a)(1), (b)(1), inserted “(1)” after “assist in” and added cls. (2) and (3).

Subsec. (b)(2). Pub. L. 100-290, §3(a)(2), (b)(2), inserted “(1) in the case of a drug,” after “means”, added cls. (2) and (3), and substituted “under section 360bb of this title” for “under this subsection” in last sentence.