

AMENDMENTS

2002—Subsec. (a). Pub. L. 107-281, in concluding provisions, struck out “, of such certification,” after “such approved application” and “, the issuance of the certification,” after “approval of the approved application”.

1997—Subsec. (a). Pub. L. 105-115, §125(b)(2)(J), struck out “, issue another certification under section 357 of this title,” before “or issue another license” in closing provisions, inserted “or” at end of par. (1), redesignated par. (3) as (2), and struck out former par. (2) which read as follows: “issues a certification under section 357 of this title, or”.

Subsec. (b). Pub. L. 105-115, §125(b)(2)(K), in introductory provisions, struck out “, if a certification is issued under section 357 of this title for such a drug,” after “rare disease or condition”, “, of the issuance of the certification under section 357 of this title,” after “application approval”, “, issue another certification under section 357 of this title,” after “application under section 355 of this title”, and “, of such certification,” after “approved application”.

Subsec. (b)(1). Pub. L. 105-115, §125(b)(2)(K), struck out “, of the certification,” after “holder of the approved application”.

Subsec. (b)(2). Pub. L. 105-115, §125(b)(2)(K), struck out “, issuance of other certifications,” after “approval of other applications”.

1993—Subsec. (b). Pub. L. 103-80 struck out extraneous comma before “or issue a license under section 262” in introductory provisions and substituted “the” for “The” at beginning of par. (1).

1985—Pub. L. 99-91, §2(3), struck out “unpatented” before “drugs” in section catchline.

Subsec. (a). Pub. L. 99-91, §§2(1), 3(a)(3)(A)–(D), struck out “or” at end of par. (1), added par. (2), redesignated former par. (2) as (3), struck out “and for which a United States Letter of Patent may not be issued” after “rare disease or condition”, inserted in first sentence “, issue another certification under section 357 of this title,” after “section 355 of this title” the second time it appeared, inserted “, of such certification,” after “holder of such approved application”, and inserted “, the issuance of the certification,” after “approval of the approved application”.

Subsec. (b). Pub. L. 99-91, §§2(2), 3(a)(3)(E)–(K), struck out “and if a United States Letter of Patent may not be issued for the drug” after “such a drug”, substituted “, if a certification is issued under section 357 of this title for such a drug, or if a license” for “or a license”, inserted “, of the issuance of the certification under section 357 of this title,” after “application approval”, struck out “, if the drug is a biological product,” before “issue a license”, inserted “, issue another certification under section 357 of this title,” after “section 355 of this title”, inserted “, of such certification,” after “holder of such approved application”, inserted “, of such certification,” after “application” in par. (1), and inserted “, issuance of other certifications,” after “other applications” in par. (2).

1984—Subsecs. (a), (b). Pub. L. 98-417 substituted “section 355” for “section 355(b)” wherever appearing.

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 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; 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