

21 USC 360aa, 360bb, 360cc, 360dd

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TITLE 21--FOOD AND DRUGS

CHAPTER 9--FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V--DRUGS AND DEVICES

Part B--Drugs for Rare Diseases or Conditions

Sec. 360aa. Recommendations for investigations of drugs for rare diseases or conditions

(a) Request by sponsor; response by Secretary

The sponsor of a drug for a disease or condition which is rare in the States may request the Secretary to provide written recommendations for the non-clinical and clinical investigations which must be conducted with the drug before--

(1) it may be approved for such disease or condition under section 355 of this title, or

(2) if the drug is a biological product, it may be licensed for such disease or condition under section 262 of title 42.

If the Secretary has reason to believe that a drug for which a request is made under this section is a drug for a disease or condition which is rare in the States, the Secretary shall provide the person making the request written recommendations for the non-clinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval of such drug for such disease or condition under section 355 of this title or licensing of such drug for such disease or condition under section 262 of title 42.

(b) Regulations

The Secretary shall by regulation promulgate procedures for the implementation of subsection (a) of this section.

(June 25, 1938, ch. 675, Sec. 525, as added Pub. L. 97-414, Sec. 2(a), Jan. 4, 1983, 96 Stat. 2049; amended Pub. L. 99-91, Sec. 3(a)(1), Aug. 15, 1985, 99 Stat. 387; Pub. L. 105-115, title I, Sec. 125(b)(2)(F), (G), Nov. 21, 1997, 111 Stat. 2325, 2326.)

Amendments

1997--Subsec. (a). Pub. L. 105-115, Sec. 125(b)(2)(G), struck out `` , certification of such drug for such disease or condition under section 357 of this title, ' before ``or licensing of such drug'' in closing provisions.

Subsec. (a)(1) to (3). Pub. L. 105-115, Sec. 125(b)(2)(F), inserted ``or'' at end of par. (1), redesignated par. (3) as (2), and struck out former par. (2), which read as follows: ``if the drug is an antibiotic, it may be certified for such disease or condition under section 357 of

this title, or''.

1985--Subsec. (a). Pub. L. 99-91 struck out ``or'' at end of par. (1), inserted par. (2), redesignated former par. (2) as (3) and struck out ``before'' after ``product'', and in last sentence inserted provisions relating to certification of such drug for disease or condition under section 357 of this title and substituted ``licensing of such drug for such disease or condition under section 262 of title 42'' for ``licensing under section 262 of title 42 for such disease or condition''.

Effective Date of 1985 Amendment

Section 8 of Pub. L. 99-91 provided that:

``(a) General Rule.--Except as provided in subsection (b), this Act and the amendments made by this Act [amending this section, sections 360bb, 360cc, and 360ee of this title, and sections 295g-1 and 6022 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under section 301 of this title and section 236 of Title 42] shall take effect October 1, 1985.

``(b) Exception.--The amendments made by sections 2, 3, and 6(a) [amending this section and sections 360bb and 360cc of this title] shall take effect on the date of the enactment of this Act [Aug. 15, 1985]. The amendment made by section 6(b) [amending section 6022 of Title 42] shall take effect October 19, 1984. The amendments made by section 7 [amending section 295g-1 of Title 42] shall take effect October 1, 1984 and shall cease to be in effect after September 30, 1985.''

Study

Pub. L. 100-290, Sec. 3(d), Apr. 18, 1988, 102 Stat. 91, directed Secretary of Health and Human Services to conduct a study to determine whether the application of subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360aa et seq. (relating to drugs for rare diseases and conditions), and 26 U.S.C. 28 (relating to tax credit) to medical devices or medical foods for rare diseases or conditions or to both was needed to encourage development of such devices and foods and report results of the study to Congress not later than one year after Apr. 18, 1988.

Congressional Findings

Section 1(b) of Pub. L. 97-414 provided that: ``The Congress finds that--

``(1) there are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which affect such small numbers of individuals residing in the United States that the diseases and conditions are considered rare in the United States;

``(2) adequate drugs for many of such diseases and conditions have not been developed;

``(3) drugs for these diseases and conditions are commonly referred to as `orphan drugs';

``(4) because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss;

``(5) there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs; and

``(6) it is in the public interest to provide such changes and incentives for the development of orphan drugs.''

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TITLE 21--FOOD AND DRUGS

CHAPTER 9--FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V--DRUGS AND DEVICES

Part B--Drugs for Rare Diseases or Conditions

Sec. 360bb. Designation of drugs for rare diseases or conditions

(a) Request by sponsor; preconditions; ``rare disease or condition'' defined

(1) The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition. A request for designation of a drug shall be made before the submission of an application under section 355(b) of this title for the drug, or the submission of an application for licensing of the drug under section 262 of title 42. If the Secretary finds that a drug for which a request is submitted under this subsection is being or will be investigated for a rare disease or condition and--

(A) if an application for such drug is approved under section 355 of this title, or

(B) if a license for such drug is issued under section 262 of title 42,

the approval, certification, or license would be for use for such disease or condition, the Secretary shall designate the drug as a drug for such disease or condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) of this section respecting the designation of the drug.

(2) For purposes of paragraph (1), the term ``rare disease or condition'' means 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. 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 this subsection is made.

(b) Notification of discontinuance of drug or application as condition

A designation of a drug under subsection (a) of this section shall be subject to the condition that--

(1) if an application was approved for the drug under section 355(b) of this title or a license was issued for the drug under section 262 of title 42, 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 355(b) of this title or a license has not been issued for the drug under section 262 of title 42 and if preclinical investigations or investigations under section 355(i) of this title are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 355(b) of this title or approval of a license under section 262 of title 42.

(c) Notice to public

Notice respecting the designation of a drug under subsection (a) of this section shall be made available to the public.

(d) Regulations

The Secretary shall by regulation promulgate procedures for the implementation of subsection (a) of this section.

(June 25, 1938, ch. 675, Sec. 526, as added Pub. L. 97-414, Sec. 2(a), Jan. 4, 1983, 96 Stat. 2050; amended Pub. L. 98-551, Sec. 4(a), Oct. 30, 1984, 98 Stat. 2817; Pub. L. 99-91, Sec. 3(a)(2), Aug. 15, 1985, 99 Stat. 387; Pub. L. 100-290, Sec. 2, Apr. 18, 1988, 102 Stat. 90; Pub. L. 105-115, title I, Sec. 125(b)(2)(H), (I), Nov. 21, 1997, 111 Stat. 2326.)

Amendments

1997--Subsec. (a)(1). Pub. L. 105-115, Sec. 125(b)(2)(H), struck out ``the submission of an application for certification of the drug under section 357 of this title,' before ``or the submission of an application for licensing of the drug'' in introductory provisions, inserted ``or'' at end of subpar. (A), redesignated subpar. (C) as (B), and struck out former subpar. (B) which read as follows: ``if a certification for such drug is issued under section 357 of this title, or''.

Subsec. (b)(1). Pub. L. 105-115, Sec. 125(b)(2)(I)(i), struck out ``, a certificate was issued for the drug under section 357 of this title,' before ``or a license was issued''.

Subsec. (b)(2). Pub. L. 105-115, Sec. 125(b)(2)(I)(ii), struck out ``, a certificate has not been issued for the drug under section 357 of this title,' before ``or a license has not been issued'' and ``, approval of an application for certification under section 357 of this title,' before ``or approval of a license''.

1988--Subsec. (a)(1). Pub. L. 100-290, Sec. 2(a), inserted after first sentence ``A request for designation of a drug shall be made before the submission of an application under section 355(b) of this title for the drug, the submission of an application for certification of the drug under section 357 of this title, or the submission of an application for licensing of the drug under section 262 of title 42.''

Subsecs. (b) to (d). Pub. L. 100-290, Sec. 2(b), added subsec. (b) and redesignated former subsecs. (b) and (c) as (c) and (d), respectively.

1985--Subsec. (a)(1). Pub. L. 99-91 struck out ``or'' at end of subpar. (A), struck out subpar. (B) and substituted subpars. (B) and (C), and inserted ``, certification,' after ``approval''.

1984--Subsec. (a)(2). Pub. L. 98-551 substituted ``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'' for ``which occurs so infrequently in the United States that''.

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.

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TITLE 21--FOOD AND DRUGS

CHAPTER 9--FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V--DRUGS AND DEVICES

Part B--Drugs for Rare Diseases or Conditions

Sec. 360cc. Protection for drugs for rare diseases or conditions

(a) Exclusive approval, certification, or license

Except as provided in subsection (b) of this section, if the Secretary--

- (1) approves an application filed pursuant to section 355 of this title, or
- (2) issues a license under section 262 of title 42

for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application under section 355 of this title or issue another license under section 262 of title 42 for such drug for such disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 355(c)(2) of this title does not apply to the refusal to approve an application under the preceding sentence.

(b) Exceptions

If an application filed pursuant to section 355 of this title is approved for a drug designated under section 360bb of this title for a rare disease or condition or if a license is issued under section 262 of title 42 for such a drug, the Secretary may, during the seven-year period beginning on the date of the application approval or of the issuance of the license, approve another application under section 355 of this title or issue a license under section 262 of title 42, for such drug for such disease or condition for a person who is not the holder of such approved application or of such license if--

- (1) the Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or
- (2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

(June 25, 1938, ch. 675, Sec. 527, as added Pub. L. 97-414, Sec. 2(a), Jan. 4, 1983, 96 Stat. 2050; amended Pub. L. 98-417, title I, Sec. 102(b)(6), Sept. 24, 1984, 98 Stat. 1593; Pub. L. 99-91, Secs. 2, 3(a)(3), Aug. 15, 1985, 99 Stat. 387, 388; Pub. L. 103-80, Sec. 3(v), Aug. 13, 1993, 107 Stat. 778; Pub. L. 105-115, title I, Sec. 125(b)(2)(J), (K), Nov. 21, 1997, 111 Stat. 2326; Pub. L. 107-281, Sec. 4, Nov. 6, 2002, 116 Stat. 1993.)

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, Sec. 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, Sec. 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, Sec. 125(b)(2)(K), struck out `` , of the certification,' ' after ``holder of the approved application' '.

Subsec. (b)(2). Pub. L. 105-115, Sec. 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, Sec. 2(3), struck out ``unpatented' ' before ``drugs' ' in section catchline.

Subsec. (a). Pub. L. 99-91, Secs. 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, Secs. 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.

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TITLE 21--FOOD AND DRUGS

CHAPTER 9--FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER V--DRUGS AND DEVICES

Part B--Drugs for Rare Diseases or Conditions

Sec. 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, Sec. 528, as added Pub. L. 97-414, Sec. 2(a), Jan. 4, 1983, 96 Stat. 2051.)