

(A) is a human drug application as defined in section 379g(1) of this title—

- (i) for prevention or treatment of a tropical disease; and
- (ii) the Secretary deems eligible for priority review;

(B) is approved after September 27, 2007, by the Secretary for use in the prevention, detection, or treatment of a tropical disease; and

(C) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 355(b)(1) of this title or section 262 of title 42.

(b) Priority review voucher

(1) In general

The Secretary shall award a priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such tropical disease product application.

(2) Transferability

The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 355(b)(1) of this title or section 262 of title 42 will be submitted after the date of the approval of the tropical disease product application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(3) Limitation

(A) No award for prior approved application

A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product application was submitted to the Secretary prior to September 27, 2007.

(B) One-year waiting period

The Secretary shall issue a priority review voucher to the sponsor of a tropical disease product no earlier than the date that is 1 year after September 27, 2007.

(4) Notification

The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(c) Priority review user fee

(1) In general

The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under subchapter VII.

(2) Fee amount

The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

(3) Annual fee setting

The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

(4) Payment

(A) In general

The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 355(b)(1) of this title or section 262 of title 42 for which the priority review voucher is used.

(B) Complete application

An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) No waivers, exemptions, reductions, or refunds

The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) Offsetting collections

Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

(June 25, 1938, ch. 675, §524, as added Pub. L. 110-85, title XI, §1102, Sept. 27, 2007, 121 Stat. 972; amended Pub. L. 113-233, §2, Dec. 16, 2014, 128 Stat. 2127.)

REFERENCES IN TEXT

Section 101(c) of the Food and Drug Administration Amendments Act of 2007, referred to in subsec. (a)(1), is section 101(c) of Pub. L. 110-85, which is set out as a note under section 379g of this title.

AMENDMENTS

2014—Subsec. (a)(3)(Q), (R). Pub. L. 113-233, §2(1), added subpar. (Q), redesignated former subpar. (Q) as (R), and in subpar. (R) substituted “order of” for “regulation by”.

Subsec. (b)(2). Pub. L. 113-233, §2(2)(A), inserted at end “There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.”

Subsec. (b)(4). Pub. L. 113-233, §2(2)(B), substituted “90 days” for “365 days”.

§ 360n-1. Priority review for qualified infectious disease products

If the Secretary designates a drug under section 355f(d) of this title as a qualified infectious

disease product, then the Secretary shall give priority review to any application submitted for approval for such drug under section 355(b) of this title.

(June 25, 1938, ch. 675, §524A, as added Pub. L. 112-144, title VIII, §802(a), July 9, 2012, 126 Stat. 1079.)

EFFECTIVE DATE

Pub. L. 112-144, title VIII, §802(b), July 9, 2012, 126 Stat. 1079, provided that: “Section 524A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360n-1], as added by subsection (a), applies only with respect to an application that is submitted under section 505(b) of such Act (21 U.S.C. 355(b)) on or after the date of the enactment of this Act [July 9, 2012].”

PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

§ 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, §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.)

AMENDMENTS

1997—Subsec. (a). Pub. L. 105-115, §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, §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 certifi-

cation 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

Pub. L. 99-91, §8, Aug. 15, 1985, 99 Stat. 392, 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.”

REVIEW GROUPS ON RARE DISEASES AND NEGLECTED DISEASES OF THE DEVELOPING WORLD; REPORT; GUIDANCE; STANDARDS

Pub. L. 111-80, title VII, §740, Oct. 21, 2009, 123 Stat. 2127, provided that:

“(a) The Commissioner of Food and Drugs shall establish within the Food and Drug Administration a review group which shall recommend to the Commissioner of Food and Drugs appropriate preclinical, trial design, and regulatory paradigms and optimal solutions for the prevention, diagnosis, and treatment of rare diseases: *Provided*, That the Commissioner of Food and Drugs shall appoint individuals employed by the Food and Drug Administration to serve on the review group: *Provided further*, That members of the review group shall have specific expertise relating to the development of articles for use in the prevention, diagnosis, or treatment of rare diseases, including specific expertise in developing or carrying out clinical trials.

“(b) The Commissioner of Food and Drugs shall establish within the Food and Drug Administration a review group which shall recommend to the Commissioner of Food and Drugs appropriate preclinical, trial design, and regulatory paradigms and optimal solutions for the prevention, diagnosis, and treatment of neglected diseases of the developing world: *Provided*, That the Commissioner of Food and Drugs shall appoint individuals employed by the Food and Drug Administration to serve on the review group: *Provided further*, That members of the review group shall have specific expertise relating to the development of articles for use in the prevention, diagnosis, or treatment of neglected diseases of the developing world, including specific expertise in developing or carrying out clinical trials: *Provided further*, That for the purposes of this section the term ‘neglected disease of the developing world’ means a tropical disease, as defined in section 524(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(3)).

“(c) The Commissioner of Food and Drugs shall—

“(1) submit, not later than 1 year after the date of the establishment of review groups under subsections (a) and (b), a report to Congress that describes both the findings and recommendations made by the review groups under subsections (a) and (b);

“(2) issue, not later than 180 days after submission of the report to Congress under paragraph (1), guidance based on such recommendations for articles for use in the prevention, diagnosis, and treatment of rare diseases and for such uses in neglected diseases of the developing world; and

“(3) develop, not later than 180 days after submission of the report to Congress under paragraph (1), in-