

section (c) of section 523 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360m(c)] (as added by subsection (a)), the authority provided under subsection (a) of such section will terminate, the Comptroller General shall submit to the Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives and the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate a report describing the use of accredited persons under such section 523, including an evaluation of the extent to which such use assisted the Secretary in carrying out the duties of the Secretary under such Act [21 U.S.C. 301 et seq.] with respect to devices, and the extent to which such use promoted actions which are contrary to the purposes of such Act.

“(2) INCLUSION OF CERTAIN DEVICES WITHIN PROGRAM.— Not later than 3 years after the date of the enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate a report providing a determination by the Secretary of whether, in the program of accreditation established pursuant to the amendment made by subsection (a), the limitation established in clause (iii) of section 523(a)(3)(A) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360m(a)(3)(A)] (relating to class II devices for which clinical data are required in reports under section 510(k) [21 U.S.C. 360(k)]) should be removed.”

§ 360n. Priority review to encourage treatments for tropical diseases

(a) Definitions

In this section:

(1) Priority review

The term “priority review”, with respect to a human drug application as defined in section 379g(1) of this title, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(2) Priority review voucher

The term “priority review voucher” means a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 355(b)(1) of this title or section 262 of title 42 after the date of approval of the tropical disease product application.

(3) Tropical disease

The term “tropical disease” means any of the following:

- (A) Tuberculosis.
- (B) Malaria.
- (C) Blinding trachoma.
- (D) Buruli Ulcer.
- (E) Cholera.
- (F) Dengue/dengue haemorrhagic fever.
- (G) Dracunculiasis (guinea-worm disease).
- (H) Fascioliasis.
- (I) Human African trypanosomiasis.
- (J) Leishmaniasis.
- (K) Leprosy.

- (L) Lymphatic filariasis.
- (M) Onchocerciasis.
- (N) Schistosomiasis.
- (O) Soil transmitted helminthiasis.
- (P) Yaws.
- (Q) Filovirus Diseases.
- (R) Zika Virus Disease.

(S) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by order of the Secretary.

(4) Tropical disease product application

The term “tropical disease product application” means an application that—

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

- (i) for prevention or treatment of a tropical disease;
- (ii) the Secretary deems eligible for priority review;
- (iii) that contains reports of one or more new clinical investigations (other than bioavailability studies) that are essential to the approval of the application and conducted or sponsored by the sponsor of such application; and

(iv) that contains an attestation from the sponsor of the application that such reports were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007.¹

(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.

¹ So in original. The period probably should be a semicolon.

(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; Pub. L. 114-146, §2, Apr. 19, 2016, 130 Stat. 357; Pub. L. 114-255, div. A, title III, §3101(a)(2)(M), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 115-52, title VI, §611(a), Aug. 18, 2017, 131 Stat. 1054.)

Editorial Notes

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

2017—Subsec. (a)(4)(A)(iii), (iv). Pub. L. 115-52 added cls. (iii) and (iv).

2016—Subsec. (a)(3)(Q). Pub. L. 114-146, §2(2), substituted "Filovirus Diseases" for "Filoviruses".

Subsec. (a)(3)(R), (S). Pub. L. 114-146, §2(1), (3), added subpar. (R) and redesignated former subpar. (R) as (S).

Subsec. (c)(4)(A). Pub. L. 114-255 made technical amendment to reference in original act which appears in text as reference to section 262 of title 42.

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".

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2017 AMENDMENT

Pub. L. 115-52, title VI, §611(b), Aug. 18, 2017, 131 Stat. 1054, provided that: "The amendments made by subsection (a) [amending this section] shall apply to human drug applications submitted after September 30, 2017."

§ 360n-1. Priority review for qualified infectious disease products**(a) In general**

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 the first application submitted for approval for such drug under section 355(b) of this title.

(b) Construction

Nothing in this section shall prohibit the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 355(b) of this title that otherwise meets the criteria for the Secretary to grant priority review.