

AMENDMENTS

2009—Subsec. (b)(2)(D). Pub. L. 111-31 made technical amendment to reference in original act which appears in text as reference to section 393(g) of this title.

2007—Subsec. (c). Pub. L. 110-85 substituted “2012” for “2007”.

2002—Subsec. (c). Pub. L. 107-250, §202(1), substituted “The authority provided by this section terminates October 1, 2007.” for “The authority provided by this section terminates—

“(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) of this section are available to review at least 60 percent of the submissions under section 360(k) of this title, or

“(2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (2)(B) of subsection (a) of this section for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection,

whichever occurs first.”

Subsec. (d). Pub. L. 107-250, §202(2), added subsec. (d).

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as a note under section 321 of this title.

REPORTS ON PROGRAM OF ACCREDITATION

Pub. L. 105-115, title II, §210(d), Nov. 21, 1997, 111 Stat. 2345, provided that:

“(1) COMPTROLLER GENERAL.—

“(A) IMPLEMENTATION OF PROGRAM.—Not later than 5 years after the date of the enactment of this Act [Nov. 21, 1997], the Comptroller General of the United States 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 extent to which the program of accreditation required by the amendment made by subsection (a) [enacting this section] has been implemented.

“(B) EVALUATION OF PROGRAM.—Not later than 6 months prior to the date on which, pursuant to subsection (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) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by 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; 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.

(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 365 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 sub-

mission 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.)

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.

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.