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 helmithiasis.
(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—

(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 355(b)(1) of this title; or

(ii) a biological product, no active ingredient of which has been approved in any other application under section 262 of title 42.

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

**(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; 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; Pub. L. 117–9, §1(a)(3), Apr. 23, 2021, 135 Stat. 257.)

**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

2021—Subsec. (a)(4)(C). Pub. L. 117–9 amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: ''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.''

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, or section 262(a) of title 42, that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness.

**(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.

(June 25, 1938, ch. 675, § 524A, as added Pub. L. 112–144, title VIII, § 802(a), July 9, 2012, 126 Stat. 1079; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(N), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 117–328, div. FF, title III, § 3212(b), Dec. 29, 2022, 136 Stat. 5826.)

**Editorial Notes**

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328 inserted '', or section 262(a) of title 42, that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness'' before period at end.

2016—Pub. L. 114–255 designated existing provisions as subsec. (a), inserted heading, substituted ''the first application'' for ''any application'', and added subsec. (b).

**Statutory Notes and Related Subsidiaries**

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].''

### § 360n–2. Ensuring cybersecurity of devices

**(a) In general**

A person who submits an application or submission under section 360(k), 360c, 360e(c), 360e(f), or 360j(m) of this title for a device that meets the definition of a cyber device under this section shall include such information as the Secretary may require to ensure that such cyber device meets the cybersecurity requirements under subsection (b).

**(b) Cybersecurity requirements**

The sponsor of an application or submission described in subsection (a) shall—

(1) submit to the Secretary a plan to monitor, identify, and address, as appropriate, in a reasonable time, postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures;

(2) design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and make available postmarket updates and patches to the device and related systems to address—

(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and

(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks;

(3) provide to the Secretary a software bill of materials, including commercial, open-source, and off-the-shelf software components; and

(4) comply with such other requirements as the Secretary may require through regulation to demonstrate reasonable assurance that the device and related systems are cybersecure.

**(c) Definition**

In this section, the term ''cyber device'' means a device that—

(1) includes software validated, installed, or authorized by the sponsor as a device or in a device;

(2) has the ability to connect to the internet; and

(3) contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats.

**(d) Exemption**

The Secretary may identify devices, or categories or types of devices, that are exempt from meeting the cybersecurity requirements established by this section and regulations promulgated pursuant to this section. The Secretary shall publish in the Federal Register, and update, as appropriate, a list of the devices, or categories or types of devices, so identified by the Secretary.

(June 25, 1938, ch. 675, § 524B, as added Pub. L. 117–328, div. FF, title III, § 3305(a), Dec. 29, 2022, 136 Stat. 5832.)

**Statutory Notes and Related Subsidiaries**

EFFECTIVE DATE

Section effective 90 days after Dec. 29, 2022, see section 3305(d) of Pub. L. 117–328, set out as an Effective Date of 2022 Amendment note under section 331 of this title.

CONSTRUCTION

Nothing in section 3305(a) of Pub. L. 117–328, which enacted this section, to be construed to affect the Secretary's of Health and Human Services authority related to ensuring that there is a reasonable assurance of the safety and effectiveness of devices, which may include ensuring that there is a reasonable assurance of the cybersecurity of certain cyber devices, including for devices approved or cleared prior to Dec. 29, 2022, see section 3305(c) of Pub. L. 117–328, set out as a Construction of 2022 Amendment note under section 331 of this title.