surveillance order or condition shall not, because of noncompliance with such order or condition, be deemed in violation of section 331(q)(1)(C) of this title, adulterated under section 351(f)(1) of this title, misbranded under section 352(t)(3) of this title, or in violation of, as applicable, section 360(k) of this title or section 360e of this title, unless deemed necessary to protect the public health.

(June 25, 1938, ch. 675, §522, as added Pub. L. 101–629, §10, Nov. 28, 1990, 104 Stat. 4521; amended Pub. L. 102–300, §3(b), June 16, 1992, 106 Stat. 239; Pub. L. 105–115, title II, §212, Nov. 21, 1997, 111 Stat. 2346; Pub. L. 110–85, title III, §307, Sept. 27, 2007, 121 Stat. 865; Pub. L. 112–144, title VI, §616, July 9, 2012, 126 Stat. 1062.)

Editorial Notes

AMENDMENTS

2012—Subsec. (a)(1)(A). Pub. L. 112–144, §616(1), inserted '', at the time of approval or clearance of a device or at any time thereafter,'' after ''by order'' in introductory provisions.

Subsec. (b)(1). Pub. L. 112–144, §616(2), inserted ''The manufacturer shall commence surveillance under this section not later than 15 months after the day on which the Secretary issues an order under this section.'' after ''the public health.''

2007—Pub. L. 110–85, §307(1), made technical amendment to section catchline.

Subsec. (a). Pub. L. 110–85, §307(2), added subsec. (a) and struck out former subsec. (a). Prior to amendment, text read as follows: ''The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

''(1) implanted in the human body for more than one year, or

''(2) a life sustaining or life supporting device used outside a device user facility.''

Subsec. (b). Pub. L. 110–85, §307(3), designated existing provisions as par. (1), inserted par. heading, substituted ''Except as provided in paragraph (2), the Secretary, in consultation'' for ''The Secretary, in consultation'' and ''Except as provided in paragraph (2), any determination'' for ''Any determination'', and added par. (2).

Subsec. (c). Pub. L. 110–85, §307(3)(D), added subsec. (c).

1997—Pub. L. 105–115 amended section generally, substituting present provisions for former provisions which related to required surveillance, discretionary surveillance, and surveillance approval.

1992—Subsec. (b). Pub. L. 102–300 substituted ''(a)(1)'' for ''(a)'', inserted comma after ''commerce'', and inserted after first sentence ''Each manufacturer required to conduct a surveillance of a device under subsection (a)(2) of this section shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance.''

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1997 AMENDMENT

Pub. L. 105–115, title II, §212, Nov. 21, 1997, 111 Stat. 2346, provided in part that the amendment made by that section is effective 90 days after Nov. 21, 1997.

STUDY BY INSTITUTE OF MEDICINE OF POSTMARKET SURVEILLANCE REGARDING PEDIATRIC POPULATIONS

Pub. L. 107–250, title II, §212, Oct. 26, 2002, 116 Stat. 1614, as amended by Pub. L. 108–214, §2(d)(3)(C), Apr. 1, 2004, 118 Stat. 577, provided that the Secretary of Health and Human Services would request the Institute of Medicine to study whether the system under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) for the postmarket surveillance of medical devices provides adequate safeguards regarding the use of devices in pediatric populations, and provided that the Secretary, not later than four years after Oct. 26, 2002, would submit to Congress a report on the study and legislative and administrative recommendations.

§360m. Accredited persons

(a) In general

(1) Review and classification of devices

Not later than 1 year after November 21, 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 360(k) of this title and making recommendations to the Secretary regarding the initial classification of devices under section 360c(f)(1) of this title.

(2) Requirements regarding review

(A) In general

In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

(B) Time period for review

Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

(C) Special rule

The Secretary may change the initial classification under section 360c(f)(1) of this title that is recommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 360(k) of this title for the device, a statement explaining in detail the reasons for the change.

(3) Certain devices

(A) In general

An accredited person may not be used to perform a review of—

(i) a class III device;

(ii) a device classified under section 360c(f)(2) of this title or designated under section 360e–3(d)[1] of this title;

(iii) a device that is intended to be permanently implantable, life sustaining, or life supporting, unless otherwise determined by the Secretary in accordance with subparagraph (B)(i)(II) and listed as eligible for review under subparagraph (B)(iii); or

(iv) a device that is of a type, or subset of a type, listed as not eligible for review under subparagraph (B)(iii).

(B) Designation for review

The Secretary shall—

(i) issue draft guidance on the factors the Secretary will use in determining whether

[1] See References in Text note below.

a class I or class II device type, or subset of such device types, is eligible for review by an accredited person, including—

(I) the risk of the device type, or subset of such device type; and

(II) whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting, and whether there is a detailed public health justification for permitting the review by an accredited person of such device type or subset;

(ii) not later than 24 months after the date on which the Secretary issues such draft guidance, finalize such guidance; and

(iii) beginning on the date such guidance is finalized, designate and post on the internet website of the Food and Drug Administration, an updated list of class I and class II device types, or subsets of such device types, and the Secretary's determination with respect to whether each such device type, or subset of a device type, is eligible or not eligible for review by an accredited person under this section based on the factors described in clause (i).

(C) Interim rule

Until the date on which the updated list is designated and posted in accordance with subparagraph (B)(iii), the list in effect on August 18, 2017, shall be in effect.

(b) Accreditation

(1) Programs

The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

(2) Accreditation

(A) In general

Not later than 180 days after November 21, 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

(B) Withdrawal of accreditation

The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

(C) Performance auditing

To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

(ii) take such additional measures as the Secretary determines to be appropriate.

(D) Periodic reaccreditation

(i) Period

Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

(ii) Response to reaccreditation request

Upon the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

(iii) Criteria

Not later than 120 days after July 9, 2012, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a), and the devices, for which such persons are reaccredited.

(3) Qualifications

An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices.

(F) Such person shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to this section—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as proprietary information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements

under this clause relating to financial conflicts of interest.

(4) Selection of accredited persons

The Secretary shall provide each person who chooses to use an accredited person to receive a section 360(k) of this title report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function.

(5) Compensation of accredited persons

Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(c) Duration

The authority provided by this section terminates on October 1, 2027.

(June 25, 1938, ch. 675, §523, as added Pub. L. 105–115, title II, §210(a), Nov. 21, 1997, 111 Stat. 2342; amended Pub. L. 107–250, title II, §202, Oct. 26, 2002, 116 Stat. 1609; Pub. L. 110–85, title II, §221, Sept. 27, 2007, 121 Stat. 852; Pub. L. 111–31, div. A, title I, §103(f), June 22, 2009, 123 Stat. 1837; Pub. L. 112–144, title VI, §611, July 9, 2012, 126 Stat. 1059; Pub. L. 114–255, div. A, title III, §3102(4), Dec. 13, 2016, 130 Stat. 1156; Pub. L. 115–52, title II, §206, Aug. 18, 2017, 131 Stat. 1018; Pub. L. 117–180, div. F, title II, §2006, Sept. 30, 2022, 136 Stat. 2154; Pub. L. 117–229, div. C, title III, §309, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3109, Dec. 29, 2022, 136 Stat. 5808.)

Editorial Notes

REFERENCES IN TEXT

Section 360e–3 of this title, referred to in subsec. (a)(3)(A)(ii), was in the original a reference to section 515C of act June 25, 1938, which was renumbered section 515B by Pub. L. 115–52, title IX, §901(f)(2), Aug. 18, 2017, 131 Stat. 1077.

AMENDMENTS

2022—Subsec. (c). Pub. L. 117–328 substituted ''on October 1, 2027'' for ''December 24, 2022''.

Pub. L. 117–229 substituted ''December 24, 2022'' for ''December 17, 2022''.

Pub. L. 117–180 substituted ''December 17'' for ''October 1''.

2017—Subsec. (a)(3)(A)(ii) to (iv). Pub. L. 115–52, §206(1)(A), added cls. (ii) to (iv) and struck out former cls. (ii) and (iii) which read as follows:

''(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting; or

''(iii) a class II device which requires clinical data in the report submitted under section 360(k) of this title for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.''

Subsec. (a)(3)(B). Pub. L. 115–52, §206(1)(B), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text read as follows: ''In determining for a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary reclassified into class II, and the Secretary shall include in the denominator class II devices for which reports under section 360(k) of this title were not required to be submitted by reason of the operation of section 360(m) of this title.''

Subsec. (a)(3)(C). Pub. L. 115–52, §206(1)(C), added subpar. (C).

Subsec. (b)(2)(D), (E). Pub. L. 115–52, §206(2)(A), redesignated subpar. (E) as (D) and struck out former subpar. (D). Prior to amendment, text of subpar. (D) read as follows: ''The Secretary shall include in the annual report required under section 393(g) of this title the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.''

Subsec. (b)(3)(E). Pub. L. 115–52, §206(2)(B)(iii), added subpar. (E). Former subpar. (E) redesignated (F).

Subsec. (b)(3)(F). Pub. L. 115–52, §206(2)(B)(i), (ii), redesignated subpar. (E) as (F) and substituted ''Such person shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to this section'' for ''The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will'' in introductory provisions.

Subsec. (c). Pub. L. 115–52, §206(3), substituted ''2022' for ''2017''.

2016—Subsec. (d). Pub. L. 114–255 struck out subsec. (d) which related to report to Congress.

2012—Subsec. (b)(2)(E). Pub. L. 112–144, §611(a), added subpar. (E).

Subsec. (c). Pub. L. 112–144, §611(b), substituted ''October 1, 2017'' for ''October 1, 2012''.

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).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–180 effective Oct. 1, 2022, with fees under subpart 3 of part C of subchapter VII of this chapter to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2022, see section 2008 of Pub. L. 117–180, set out as a note under section 360d of this title.

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by Pub. L. 115–52 effective Oct. 1, 2017, with fees under subpart 3 of part C of subchapter VII of this chapter to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i of this title.

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 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.