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 OF 2012 AMENDMENT

Amendment by section 203(g) of Pub. L. 112–144 effective Oct. 1, 2012, with additional provision for assessment of certain fees, see section 206 of Pub. L. 112–144, set out as a note under section 379i of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 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.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

REPORT ON CERTAIN DEVICES

Pub. L. 107–250, title II, §205, Oct. 26, 2002, 116 Stat. 1612, directed the Secretary of Health and Human Services, not later than one year after Oct. 26, 2002, to report to the appropriate committees of Congress on the timeliness and effectiveness of device premarket reviews by centers other than the Center for Devices and Radiological Health, including information on the times required to log in and review original submissions and supplements, times required to review manufacturers' replies to submissions, times to approve or clear such devices, and recommendations on improvement of performance and reassignment of responsibility for regulating such devices.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§ 360e–1. Pediatric uses of devices

(a) New devices

(1) In general

A person that submits to the Secretary an application under section 360j(m) of this title, or an application (or supplement to an application) or a product development protocol under section 360e of this title, shall include in the application or protocol the information described in paragraph (2).

(2) Required information

The application or protocol described in paragraph (1) shall include, with respect to the device for which approval is sought and if readily available—

(A) a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(B) the number of affected pediatric patients.

(3) Annual report

Not later than 18 months after September 27, 2007, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;

(B) any information, based on a review of data available to the Secretary, regarding devices used in pediatric patients but not labeled for such use for which the Secretary determines that approved pediatric labeling could confer a benefit to pediatric patients;

(C) the number of pediatric devices that receive a humanitarian use exemption under section 360j(m) of this title;

(D) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

(E) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 379j(a)(2)(B)(v) of this title;

(F) the review time for each device described in subparagraphs (A), (C), (D), and (E);

(G) the number of devices for which the Secretary relied on data with respect to adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients; and

(H) the number of devices for which the Secretary relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.

For the items described in this paragraph, such report shall disaggregate the number of devices by pediatric subpopulation.

(b) Determination of pediatric effectiveness based on similar course of disease or condition or similar effect of device on adults

(1) In general

If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

(2) Extrapolation between subpopulations

A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

(c) Pediatric subpopulation

For purposes of this section, the term ''pediatric subpopulation'' has the meaning given the term in section 360j(m)(6)(E)(ii) of this title.

(June 25, 1938, ch. 675, § 515A, as added Pub. L. 110–85, title III, § 302, Sept. 27, 2007, 121 Stat. 859; amended Pub. L. 115–52, title V, § 502(a), Aug. 18, 2017, 131 Stat. 1037.)

Editorial Notes

AMENDMENTS

2017—Subsec. (a)(3). Pub. L. 115–52 added subpars. (B), (C), (G), and (H), redesignated former subpars. (B) to (D) as (D) to (F), respectively, substituted ''(C), (D), and (E);'' for ''(B), and (C).'' in subpar. (F), and inserted concluding provisions.

Statutory Notes and Related Subsidiaries

FINAL RULE RELATING TO TRACKING OF PEDIATRIC USES OF DEVICES

Pub. L. 112–144, title VI, § 620(b), July 9, 2012, 126 Stat. 1064, provided that: ''The Secretary of Health and Human Services shall issue—

''(1) a proposed rule implementing section 515A(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(a)(2)) not later than December 31, 2012; and

''(2) a final rule implementing such section not later than December 31, 2013.''

§ 360e–3. Breakthrough devices

(a) Purpose

The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

(b) Establishment of program

The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

(2)(A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients.

(c) Request for designation

A sponsor of a device may request that the Secretary designate such device for expedited development and priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 360e(c) of this title, a notification under section 360(k) of this title, or a petition for classification under section 360c(f)(2) of this title.

(d) Designation process

(1) In general

Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

(2) Review

Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

(3) Withdrawal

The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

(A) was designated under this section; or

(B) was given priority review under section 360e(d)(5) of this title, as in effect prior to December 13, 2016.

(e) Expedited development and priority review

(1) Actions

For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (c) for the device;

(C) adopt an efficient process for timely dispute resolution;

(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 360e(c) of this title; and

(H) assign staff to be available within a reasonable time to address questions by in-