

Subsec. (c)(2). Pub. L. 107-250, §302(c)(2)(B), added par. (2). Former par. (2) redesignated (3).

Subsec. (c)(3). Pub. L. 107-250, §302(c)(2)(A), redesignated par. (2) relating to Secretary's referral of application to appropriate panel as (3).

Pub. L. 107-250, §210, as amended by Pub. L. 108-214, §2(d)(1)(B), inserted "Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts." at the end of the concluding provisions of par. (3) as redesignated by Pub. L. 107-250, §302(c)(2)(A).

Pub. L. 107-250, §209, added par. (3) relating to acceptance and review of any portion of the application prior to submission.

1997—Subsec. (d)(1)(A). Pub. L. 105-115, §205(c)(1), inserted at end "In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling."

Subsec. (d)(1)(B)(iii). Pub. L. 105-115, §201(b), added cl. (iii).

Subsec. (d)(3), (4). Pub. L. 105-115, §202(1), 209(b), added par. (3) and redesignated former par. (3) as (4).

Subsec. (d)(5). Pub. L. 105-115, §202(2), added par. (5).

Subsec. (d)(6). Pub. L. 105-115, §205(c)(2), added par. (6).

Subsec. (f)(2). Pub. L. 105-115, §216(b), substituted "the Secretary—" and subpars. (A) and (B) for "he shall refer the proposed protocol to the appropriate panel under section 360c of this title for its recommendation respecting approval of the protocol."

1993—Subsec. (c)(2)(A). Pub. L. 103-80 struck out "refer such application" after "own initiative".

1990—Subsec. (c)(2). Pub. L. 101-629, §18(c), substituted "the Secretary—" for "the Secretary shall" and added subpars. (A) and (B).

Subsec. (e). Pub. L. 101-629, §9(a)(2), inserted "and temporary suspension" after "Withdrawal" in heading.

Subsec. (e)(3). Pub. L. 101-629, §9(a)(1), added par. (3).

Subsec. (i). Pub. L. 101-629, §4(b)(1), added subsec. (i).

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 14 of Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to 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) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

(C) 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; and

(D) the review time for each device described in subparagraphs (A), (B), and (C).

(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 simi-

lar 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.)

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.”

§ 360f. Banned devices

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information, that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

(b) Special effective date

The Secretary may declare a proposed regulation under subsection (a) of this section to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide

reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

(June 25, 1938, ch. 675, §516, as added Pub. L. 94-295, §2, May 28, 1976, 90 Stat. 560; amended Pub. L. 101-629, §18(d), Nov. 28, 1990, 104 Stat. 4529.)

AMENDMENTS

1990—Subsec. (a). Pub. L. 101-629 struck out “and after consultation with the appropriate panel or panels under section 360c of this title” after “data and information” in introductory provisions and struck out at end “The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection.”

§ 360g. Judicial review

(a) Petition; record

Not later than thirty days after—

(1) the promulgation of a regulation under section 360c of this title classifying a device in class I, an administrative order changing the classification of a device to class I, or an order under subsection (f)(2) of such section reclassifying a device or denying a petition for reclassification of a device,

(2) the promulgation of a regulation under section 360d of this title establishing, amending, or revoking a performance standard for a device,

(3) the issuance of an order under section 360d(b)(2) or 360e(b)(2)(B) of this title denying a request for reclassification of a device,

(4) the promulgation of a regulation under paragraph (3) of section 360e(b) of this title requiring a device to have an approval of a pre-market application, a regulation under paragraph (4) of that section amending or revoking a regulation under paragraph (3), or an order pursuant to section 360e(g)(1) or 360e(g)(2)(C) of this title,

(5) the promulgation of a regulation under section 360f of this title (other than a proposed regulation made effective under subsection (b) of such section upon the regulation’s publication) making a device a banned device,

(6) the issuance of an order under section 360j(f)(2) of this title,

(7) an order under section 360j(g)(4) of this title disapproving an application for an exemption of a device for investigational use or an order under section 360j(g)(5) of this title withdrawing such an exemption for a device,

(8) an order pursuant to section 360c(i) of this title, or

(9) a regulation under section 360e(i)(2) or 360j(l)(5)(B) of this title,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of