

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 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.)

§ 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 regula-