(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, ch. 675, §521, as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 574.)

§360*l*. Postmarket surveillance

(a) Postmarket surveillance

(1) In general

(A) Conduct

The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer that is a class II or class III device—

(i) the failure of which would be reasonably likely to have serious adverse health consequences;

(ii) that is expected to have significant use in pediatric populations; or

(iii) that is intended to be—

(I) implanted in the human body for more than 1 year; or

(II) a life-sustaining or life-supporting device used outside a device user facility.

(B) Condition

The Secretary may order a postmarket surveillance under subparagraph (A) as a condition to approval or clearance of a device described in subparagraph (A)(ii).

(2) Rule of construction

The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the[1] chapter or regulations issued under this chapter.

(b) Surveillance approval

(1) In general

Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. Except as provided in paragraph (2), the Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Except as provided in paragraph (2), any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 360bbb–1 of this title.

(2) Longer surveillance for pediatric devices

The Secretary may by order require a prospective surveillance period of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety or efficacy of the device.

(c) Dispute resolution

A manufacturer may request review under section 360bbb–1 of this title of any order or condition requiring postmarket surveillance under this section. During the pendency of such review, the device subject to such a postmarket 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.)

AMENDMENTS

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.''

EFFECTIVE DATE OF 1997 AMENDMENT

Section 212 of Pub. L. 105–115 provided in part that the amendment made by that section is effective 90 days after Nov. 21, 1997.

[1] So in original. Probably should be ''this''.

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:

''(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall request the Institute of Medicine to enter into an agreement with the Secretary under which such Institute conducts a study for the purpose of determining 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.

''(b) CERTAIN MATTERS.—The Secretary shall ensure that determinations made in the study under subsection (a) include determinations of—

''(1) whether postmarket surveillance studies of implanted medical devices are of long enough duration to evaluate the impact of growth and development for the number of years that the child will have the implant, and whether the studies are adequate to evaluate how children's active lifestyles may affect the failure rate and longevity of the implant; and

''(2) whether the postmarket surveillance by the Food and Drug Administration of medical devices used in pediatric populations is sufficient to provide adequate safeguards for such populations, taking into account the Secretary's monitoring of commitments made at the time of approval of medical devices and the Secretary's monitoring and use of adverse reaction reports, registries, and other postmarket surveillance activities.

''(c) REPORT TO CONGRESS.—The Secretary shall ensure that, not later than four years after the date of the enactment of this Act [Oct. 26, 2002], a report describing the findings of the study under subsection (a) is submitted to the Congress. The report shall include any recommendations of the Secretary for administrative or legislative changes to the system of postmarket surveillance referred to in such subsection.''

§ 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 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.

(B) Adjustment

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.

(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) of this section. 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) of this section 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.