into class III under paragraph (1) of this subsection or the manufacturer'' for ''The manufacturer''.

Subsec. (*l*)(5). Pub. L. 101–629, § 4(b)(2), added par. (5).

Subsec. (m). Pub. L. 101–629, § 14(a), added subsec. (m).

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by sections 201(a), 203, 216(a)(1), and 410(a) of 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.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–629, § 14(b), Nov. 28, 1990, 104 Stat. 4525, provided that: ''Subsection (m) of section 520 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(m)], as added by the amendment made by subsection (a), shall take effect on the effective date of the regulations issued by the Secretary under paragraph (6) of such subsection.''

GUIDANCE DOCUMENT ON PROBABLE BENEFIT

Pub. L. 114–255, div. A, title III, § 3052(b), Dec. 13, 2016, 130 Stat. 1125, provided that: ''Not later than 18 months after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that defines the criteria for establishing 'probable benefit' as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).''

REPORTS

Pub. L. 114–255, div. A, title III, § 3060(b), Dec. 13, 2016, 130 Stat. 1132, provided that: ''The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary'), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after the date of enactment of this Act [Dec. 13, 2016] and every 2 years thereafter, that—

''(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;

''(2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(*o*)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j[(*o*)(1)]) (as amended by subsection (a)); and

''(3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.''

APPLICABILITY TO EXISTING DEVICES

Pub. L. 112–144, title VI, § 613(b), July 9, 2012, 126 Stat. 1061, provided that: ''A sponsor of a device for which an exemption was approved under paragraph (2) of section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the date of enactment of this Act [July 9, 2012] may seek a determination under subclause (I) or (II) of section 520(m)(6)(A)(i) (as amended by subsection (a)). If the Secretary of Health and Human Services determines that such subclause (I) or (II) applies with respect to a device, clauses (ii), (iii), and (iv) of subparagraph (A) and subparagraphs (B), (C), (D), and (E) of paragraph (6) of such section 520(m) shall apply to such device, and the Secretary shall determine the annual distribution number for purposes of clause (ii) of such subparagraph (A) when making the determination under this subsection.''

GUIDANCE

Pub. L. 110–85, title III, § 303(c), Sept. 27, 2007, 121 Stat. 862, provided that: ''Not later than 180 days after the date of the enactment of this Act [Sept. 27, 2007], the Commissioner of Food and Drugs shall issue guidance for institutional review committees on how to evaluate requests for approval for devices for which a humanitarian device exemption under section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)) has been granted.''

Pub. L. 107–250, title II, § 213, Oct. 26, 2002, 116 Stat. 1614, provided that: ''Not later than 270 days after the date of the enactment of this Act [Oct. 26, 2002], the Secretary of Health and Human Services shall issue guidance on the following:

''(1) The type of information necessary to provide reasonable assurance of the safety and effectiveness of medical devices intended for use in pediatric populations.

''(2) Protections for pediatric subjects in clinical investigations of the safety or effectiveness of such devices.''

REPORT ON HUMANITARIAN DEVICE EXEMPTIONS

Pub. L. 101–629, § 14(c), Nov. 28, 1990, 104 Stat. 4525, directed Secretary of Health and Human Services, within 4 years after issuance of regulations under 21 U.S.C. 360j(m)(6), to report to Congress on types of devices exempted, an evaluation of effects of such section, and a recommendation on extension of the section.

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.

§ 360k. State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(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, at the time of approval or clearance of a device or at any time thereafter, 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. 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. 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; Pub. L. 112–144, title VI, §616, July 9, 2012, 126 Stat. 1062.)

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.’’

[1] So in original. Probably should be ‘‘this’’.