

Subsec. (h)(3). Pub. L. 101-629, §11(2)(A), substituted “Except as provided in paragraph (4), any” for “Any”.

Subsec. (h)(4). Pub. L. 101-629, §11(2)(B), added par. (4).

Subsec. (i). Pub. L. 101-629, §6(b)(2), substituted “section 360d(b)(5)(B)” for “section 360d(g)(5)(B)”.

Subsec. (j). Pub. L. 101-629, §3(b)(2), substituted “Except as provided in section 360i(e) of this title, no” for “No”.

Subsec. (l)(2). Pub. L. 101-629, §18(f), struck out “and after affording the petitioner an opportunity for an informal hearing” after “under this paragraph”.

Pub. L. 101-629, §5(c)(2), substituted “The Secretary may initiate the reclassification of a device classified 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.”

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) of this section, 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) of this section, 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.)

§ 360l. 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