(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

(2) Process

Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

(g) Rule of construction

Nothing in this section shall be construed to affect—

(1) the criteria and standards for evaluating an application pursuant to section 360e(c) of this title, a report and request for classification under section 360c(f)(2) of this title, or a report under section 360(k) of this title, including the recognition of valid scientific evidence as described in section 360c(a)(3)(B) of this title and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

(2) the authority of the Secretary with respect to clinical holds under section 360j(g)(8)(A) of this title;

(3) the authority of the Secretary to act on an application pursuant to section 360e(d) of this title before completion of an establishment inspection, as the Secretary determines appropriate; or

(4) the authority of the Secretary with respect to postmarket surveillance under sections 360i(h) and 360*l* of this title.

(June 25, 1938, ch. 675, § 515C, as added Pub. L. 114–255, div. A, title III, § 3051(a), Dec. 13, 2016, 130 Stat. 1121.)

CODIFICATION

Section 3051(a) of Pub. L. 114–255, which directed amendment of chapter V of the Federal Food, Drug, and Cosmetic Act by adding section 515C ''after section 515B, as added by section 3034(b)'', was executed by adding section 515C after section 515A of such Act to reflect the probable intent of Congress. Neither section 3034(b) nor any other provision of Pub. L. 114–255 added a section 515B.

§ 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) 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 premarket 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 title 28. For purposes of this section, the term ''record'' means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) Additional data, views, and arguments

If the petitioner applies to the court for leave to adduce additional data, views, or arguments respecting the regulation or order being reviewed and shows to the satisfaction of the court that such additional data, views, or arguments are material and that there were reasonable grounds for the petitioner's failure to adduce such data, views, or arguments in the proceedings before the Secretary, the court may order the Secretary to provide additional opportunity for the oral presentation of data, views, or arguments and for written submissions. The Secretary may modify his findings, or make new findings by reason of the additional data, views, or arguments so taken and shall file with the court such modified or new findings, and his recommendation, if any, for the modification or setting aside of the regulation or order being reviewed, with the return of such additional data, views, or arguments.

(c) Standard for review

Upon the filing of the petition under subsection (a) of this section for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided in such chapter. A regulation described in paragraph (2) or (5) of subsection (a) and an order issued after the review provided by section 360e(g) of this title shall not be affirmed if it is found to be unsupported by substantial evidence on the record taken as a whole.

(d) Finality of judgments

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

(e) Remedies

The remedies provided for in this section shall be in addition to and not in lieu of any other remedies provided by law.

(f) Statement of reasons

To facilitate judicial review under this section or under any other provision of law of a regulation or order issued under section 360c, 360d, 360e, 360f, 360h, 360i, 360j, or 360k of this title each such regulation or order shall contain a statement of the reasons for its issuance and the basis, in the record of the proceedings held in connection with its issuance, for its issuance.

(June 25, 1938, ch. 675, § 517, as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 560; amended Pub. L. 101–629, § 13, Nov. 28, 1990, 104 Stat. 4524; Pub. L. 102–300, § 6(f), June 16, 1992, 106 Stat. 240; Pub. L. 105–115, title II, § 216(a)(2), Nov. 21, 1997, 111 Stat. 2349; Pub. L. 112–144, title VI, § 608(a)(2)(C), July 9, 2012, 126 Stat. 1056.)

AMENDMENTS

2012—Subsec. (a)(1). Pub. L. 112–144 substituted '', an administrative order changing the classification of a device to class I,'' for ''or changing the classification of a device to class I''.

1997—Subsec. (a)(8). Pub. L. 105–115, § 216(a)(2)(A), inserted ''or'' at end.

Subsec. (a)(9). Pub. L. 105–115, § 216(a)(2)(B), substituted comma for '', or'' at end.

Subsec. (a)(10). Pub. L. 105–115, § 216(a)(2)(C), struck out par. (10) which read as follows: ''an order under section 360j(h)(4)(B) of this title,''.

1992—Subsec. (a)(10). Pub. L. 102–300 substituted ''360j(h)(4)(B)'' for ''360j(c)(4)(B)''.

1990—Subsec. (a)(8) to (10). Pub. L. 101–629 added pars. (8) to (10).

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.

§ 360g–1. Agency documentation and review of significant decisions regarding devices

(a) Documentation of rationale for significant decisions

(1) In general

The Secretary shall provide a substantive summary of the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding submission or review of a report under section 360(k) of this title, an application under section 360e of this title, a request for designation under section 360e–3 of this title, or an application for an exemption under section 360j(g) of this title, including documenta-