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-

tion of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

**(2) Provision of documentation**

Upon request, the Secretary shall furnish such substantive summary to the person who is seeking to submit, or who has submitted, such report or application.

**(3) Application of least burdensome requirements**

The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 360c(i)(1)(D) of this title, section 360c(a)(3)(D) of this title, and section 360e(c)(5) of this title, as applicable.

**(b) Review of significant decisions**

**(1) Request for supervisory review of significant decision**

Any person may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be conducted at the next supervisory level or higher above the individual who made the significant decision.

**(2) Submission of request**

A person requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference review.

**(3) Timeframe**

**(A) In general**

Except as provided in subparagraph (B), the Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the person requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a person who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

**(B) Exception**

Subparagraph (A) shall not apply in cases that are referred to experts outside of the Food and Drug Administration.

(June 25, 1938, ch. 675, § 517A, as added Pub. L. 112–144, title VI, § 603, July 9, 2012, 126 Stat. 1051; amended Pub. L. 114–255, div. A, title III, §§ 3051(b), 3058(c), Dec. 13, 2016, 130 Stat. 1124, 1129.)

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255, § 3051(b), inserted ''a request for designation under section 360e–3 of this title,'' after ''application under section 360e of this title,''.

Subsec. (a)(3). Pub. L. 114–255, § 3058(c), added par. (3).

**§ 360h. Notification and other remedies**

**(a) Notification**

If the Secretary determines that—

(1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and

(2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,

the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturers, importers, distributors, retailers, and device users) who should properly receive such notification in order to eliminate such risk. An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notification. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribe or use the device provide for the notification of the individuals whom the health professionals treated with the device of the risk presented by the device and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

**(b) Repair, replacement, or refund**

(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

(i) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health,

(ii) there are reasonable grounds to believe that the device was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture,

(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a manufacturer, importer, distributor, or retailer of the device to exercise due care in the installation, maintenance, repair, or use of the device, and

(iv) the notification authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the manufacturer, importer, or any distributor of such device, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sen-