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).

Statutory Notes and Related Subsidiaries

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, a petition for classification under section 360c(f) of this title, an application under section 360e of this title, or an application for an exemption under section 360j(g) of this title, including documentation 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; Pub. L. 117–328, div. FF, title III, § 3308(b)(3), Dec. 29, 2022, 136 Stat. 5836.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328 amended par. (1) generally. Prior to amendment, text read as follows: ''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 documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.''

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).

§ 360g–2. Third party data transparency

(a) In general

To the extent the Secretary relies on any data, analysis, or other information or findings provided by entities that has been funded in whole or in part by, or otherwise performed under contract with, the Food and Drug Administration, in regulatory decision-making with respect to devices, the Secretary shall—

(1) request access to the datasets, inputs, clinical or other assumptions, methods, analytical code, results, and other components underlying or comprising the analysis, conclusions, or other findings upon which the Secretary seeks to rely; and

(2) in the event that information described in paragraph (1) is used to support regulatory decision-making, and as otherwise appropriate, to the extent practicable, provide the manufacturer or manufacturers subject to such decision a summary of such information, subject to protection of confidential commercial information or trade secret information or personally identifiable information.

(b) Report

Not later than September 30, 2023, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and publish on the website of the Food and Drug Administration, a report on the number of postmarket device signals communications issued by the Secretary, the sources of data for such signals, and how such signals were revised or resolved.

(c) Rule of construction

Nothing in this section shall be construed to require the delay of any regulatory decision-making or other action of the Food and Drug Administration.

(Pub. L. 117–328, div. FF, title III, § 3307, Dec. 29, 2022, 136 Stat. 5834.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Food and Drug Omnibus Reform Act of 2022, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Statutory Notes and Related Subsidiaries

DEFINITION OF ''SECRETARY''

Secretary as used in this section means the Secretary of Health and Human Services, see section 3002 of div. FF of Pub. L. 117–328, set out as a note under section 350a–1 of this title.

§ 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 sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a device user or health professional) other than the person he determines bears such responsibility.

(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines (after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons