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.