

“(2) DETERMINATION NOT TO PROVIDE DRUG.—No liability shall lie against a sponsor manufacturer, prescriber, dispenser or other individual entity for its determination not to provide access to an eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

“(3) LIMITATION.—Except as set forth in paragraphs (1) and (2), nothing in this section shall be construed to modify or otherwise affect the right of any person to bring a private action under any State or Federal product liability, tort, consumer protection, or warranty law.”

§ 360bbb-1. Dispute resolution

If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Public Health Service Act [42 U.S.C. 262], there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 355(n) of this title or an advisory committee described in section 360e(g)(2)(B) of this title. Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after November 21, 1997.

(June 25, 1938, ch. 675, §562, as added Pub. L. 105-115, title IV, §404, Nov. 21, 1997, 111 Stat. 2368.)

REFERENCES IN TEXT

This Act, referred to in text, is the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 360bbb-2. Classification of products

(a) Request

A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this chapter for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 353(g) of this title or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

(b) Statement

Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the product under subsection (a), or the component of the Food and Drug Administration that will

regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

(c) Inaction of Secretary

If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

(June 25, 1938, ch. 675, §563, as added Pub. L. 105-115, title IV, §416, Nov. 21, 1997, 111 Stat. 2378.)

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 360bbb-3. Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an “emergency use”).

(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title (referred to in this section as an “unapproved product”); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an “unapproved use of an approved product”).

(3) Relation to other uses

An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section of this chapter or the Public