

trolled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 355(i) of this title or investigational device exemption in effect under section 360j(g) of this title; or

(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

(5) in the case of an investigational drug or investigational device described in paragraph (3)(A), the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 355(i) or 360j(g) of this title;

(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 355(i) or 360j(g) of this title, including regulations promulgated under section 355(i) or 360j(g) of this title. The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be the same type of information that is required by section 282(i)(3) of title 42.

#### (d) Termination

The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

#### (e) Definitions

In this section, the terms “investigational drug”, “investigational device”, “treatment investigational new drug application”, and “treatment investigational device exemption” shall have the meanings given the terms in regulations prescribed by the Secretary.

(June 25, 1938, ch. 675, §561, as added Pub. L. 105-115, title IV, §402, Nov. 21, 1997, 111 Stat. 2365; amended Pub. L. 109-482, title I, §102(f)(2), Jan. 15, 2007, 120 Stat. 3685.)

#### AMENDMENTS

2007—Subsec. (c). Pub. L. 109-482 substituted “section 282(i)(3)” for “section 282(j)(3)” in concluding provisions.

#### EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109-482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109-482, set out as a note under section 281 of Title 42, The Public Health and Welfare.

#### 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-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) of this section, the Secretary shall determine the classification of the product under subsection (a) of this section, 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) of this section, the recommendation made by the person under subsection (a) of this section 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 this section, 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), or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] (referred to in this section as an “unapproved product”); or

(B) is approved, licensed, or cleared under such a provision, but which use is not under such provision an approved, 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 Health Service Act [42 U.S.C. 201 et seq.] referred to in paragraph (2)(A).

**(4) Definitions**

For purposes of this section:

(A) The term “biological product” has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262].

(B) The term “emergency use” has the meaning indicated for such term in paragraph (1).

(C) The term “product” means a drug, device, or biological product.

(D) The term “unapproved product” has the meaning indicated for such term in paragraph (2)(A).

(E) The term “unapproved use of an approved product” has the meaning indicated for such term in paragraph (2)(B).

**(b) Declaration of emergency or threat justifying emergency authorized use**

**(1) In general**

The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a biological, chemical, radiological, or nuclear agent or agents;

(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or

(D) the identification of a material threat pursuant to section 319F-2 of the Public Health Service Act [42 U.S.C. 247d-6b] sufficient to affect national security or the health and security of United States citizens living abroad.

**(2) Termination of declaration**

**(A) In general**

A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

**(B) Disposition of product**

If an authorization under this section with respect to an unapproved product ceases to