

evaluating and responding to requests submitted under section 360bbb(b) of this title for provision of such a drug.

**(b) Public availability of expanded access policy**

The policies under subsection (a) shall be made public and readily available, such as by posting such policies on a publicly available Internet website. Such policies may be generally applicable to all investigational drugs of such manufacturer or distributor.

**(c) Content of policy**

A policy described in subsection (a) shall include—

- (1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);
- (2) procedures for making such requests;
- (3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests;
- (4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and
- (5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for such drug that is required under section 282(j)(2)(A)(ii)(II)(gg) of title 42.

**(d) No guarantee of access**

The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

**(e) Revised policy**

Nothing in this section shall prevent a manufacturer or distributor from revising a policy required under this section at any time.

**(f) Application**

This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the earlier of—

- (1) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational drug; or
- (2) as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy under subsection (a), (b), or (g), respectively, of section 356 of this title.

(June 25, 1938, ch. 675, §561A, as added Pub. L. 114–255, div. A, title III, §3032, Dec. 13, 2016, 130 Stat. 1100; amended Pub. L. 115–52, title VI, §610(c), Aug. 18, 2017, 131 Stat. 1053.)

AMENDMENTS

2017—Subsec. (f). Pub. L. 115–52 substituted “earlier” for “later” in introductory provisions, added par. (2), redesignated former par. (2) as (1), and struck out former par. (1) which read as follows: “the date that is 60 calendar days after December 13, 2016; or”.

**§ 360bbb–1. Dispute resolution**

If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Pub-

lic 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 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, including personnel operating under the authority of title 10 or title 50, of attack with—

(i) a biological, chemical, radiological, or nuclear agent or agents; or

(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

(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 be effective as a result of a termination under subparagraph (A) of this paragraph, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

#### (3) Advance notice of termination

The Secretary shall provide advance notice that a declaration under this subsection will