

ment 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-0. Expanded access policy required for investigational drugs

(a) In general

The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make available the policy of the manufacturer or distributor on 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 later of—

- (1) the date that is 60 calendar days after December 13, 2016; or
- (2) 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.

(June 25, 1938, ch. 675, §561A, as added Pub. L. 114-255, div. A, title III, §3032, Dec. 13, 2016, 130 Stat. 1100.)

§ 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