

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.)

Editorial Notes

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-0a. Investigational drugs for use by eligible patients

(a) Definitions

For purposes of this section—

(1) the term “eligible patient” means a patient—

(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

(i) is in good standing with the physician’s licensing organization or board; and

(ii) will not be compensated directly by the manufacturer for so certifying; and

(C) who has provided to the treating physician written informed consent regarding the

eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent;

(2) the term “eligible investigational drug” means an investigational drug (as such term is used in section 360bbb of this title)—

(A) for which a Phase 1 clinical trial has been completed;

(B) that has not been approved or licensed for any use under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262];

(C)(i) for which an application has been filed under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)]; or

(ii) that is under investigation in a clinical trial that—

(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262]; and

(II) is the subject of an active investigational new drug application under section 355(i) of this title or section 351(a)(3) of the Public Health Service Act [42 U.S.C. 262(a)(3)], as applicable; and

(D) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 355(i) of this title; and

(3) the term “phase 1 trial” means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

(b) Exemptions

Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 352(f), 353(b)(4), 355(a), and 355(i) of this title, section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)], and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.

(c) Use of clinical outcomes

(1) In general

Notwithstanding any other provision of this chapter, the Public Health Service Act [42 U.S.C. 201 et seq.], or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] unless—

(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

(B) the sponsor requests use of such outcomes.

(2) Limitation

If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

(d) Reporting

(1) In general

The manufacturer or sponsor of an eligible investigational drug shall submit to the Secretary an annual summary of any use of such drug under this section. The summary shall include the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events. The Secretary shall specify by regulation the deadline of submission of such annual summary and may amend section 312.33 of title 21, Code of Federal Regulations (or any successor regulations) to require the submission of such annual summary in conjunction with the annual report for an applicable investigational new drug application for such drug.

(2) Posting of information

The Secretary shall post an annual summary report of the use of this section on the internet website of the Food and Drug Administration, including the number of drugs for which clinical outcomes associated with the use of an eligible investigational drug pursuant to this section was—

(A) used in accordance with subsection (c)(1)(A);

(B) used in accordance with subsection (c)(1)(B); and

(C) not used in the review of an application under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262].

(June 25, 1938, ch. 675, §561B, as added Pub. L. 115–176, §2(a), May 30, 2018, 132 Stat. 1372.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (c)(1), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Statutory Notes and Related Subsidiaries

LIMITATION OF LIABILITY

Pub. L. 115–176, §2(b), May 30, 2018, 132 Stat. 1374, provided that:

“(1) ALLEGED ACTS OR OMISSIONS.—With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to section 561B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–0a] and in compliance with such section, no liability in a cause of action shall lie against—

“(A) a sponsor or manufacturer; or

“(B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

“(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.)

Editorial Notes

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, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

Statutory Notes and Related Subsidiaries

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