

- (B) the Department of Homeland Security;
- (C) the Department of Commerce; and
- (D) other appropriate Federal and State agencies.

(c) Inspection and enforcement

(1) In general

The Secretary shall expand and enhance the resources and facilities of agency components of the Food and Drug Administration involved with regulatory and criminal enforcement of this chapter to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs including biological products and active pharmaceutical ingredients from domestic and foreign sources.

(2) Activities

The Secretary shall undertake enhanced and joint enforcement activities with other Federal and State agencies, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain.

(d) Definition

In this section, the term “prescription drug” means a drug subject to section 353(b)(1) of this title.

(June 25, 1938, ch. 675, §505D, as added Pub. L. 110-85, title IX, §913, Sept. 27, 2007, 121 Stat. 952.)

§ 356. Fast track products

(a) Designation of drug as fast track product

(1) In general

The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition. (In this section, such a drug is referred to as a “fast track product”.)

(2) Request for designation

The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 355(i) of this title or section 262(a)(3) of title 42.

(3) Designation

Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(b) Approval of application for fast track product

(1) In general

The Secretary may approve an application for approval of a fast track product under sec-

tion 355(c) of this title or section 262 of title 42 upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

(2) Limitation

Approval of a fast track product under this subsection may be subject to the requirements—

(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint; and

(B) that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(3) Expedited withdrawal of approval

The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;

(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

(c) Review of incomplete applications for approval of fast track product

(1) In general

If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 379h of this title.

(2) Exception

Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 379h of this title to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

(d) Awareness efforts

The Secretary shall—

(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.

(June 25, 1938, ch. 675, §506, as added Pub. L. 105-115, title I, §112(a), Nov. 21, 1997, 111 Stat. 2309.)

PRIOR PROVISIONS

A prior section 356, act June 25, 1938, ch. 675, §506, as added Dec. 22, 1941, ch. 613, §3, 55 Stat. 851; amended Pub. L. 102-300, §6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103-80, §3(o), Aug. 13, 1993, 107 Stat. 777, related to certification of drugs containing insulin, prior to repeal by Pub. L. 105-115, title I, §125(a)(1), Nov. 21, 1997, 111 Stat. 2325.

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.

GUIDANCE

Section 112(b) of Pub. L. 105-115 provided that: "Within 1 year after the date of enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall issue guidance for fast track products (as defined in section 506(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 356(a)(1)]) that describes the policies and procedures that pertain to section 506 of such Act."

§ 356-1. Accelerated approval of priority countermeasures

(a) In general

The Secretary of Health and Human Services may designate a priority countermeasure as a fast-track product pursuant to section 356 of this title or as a device granted review priority pursuant to section 360e(d)(5) of this title. Such a designation may be made prior to the submission of—

- (1) a request for designation by the sponsor or applicant; or
- (2) an application for the investigation of the drug under section 355(i) of this title or section 262(a)(3) of title 42.

Nothing in this subsection shall be construed to prohibit a sponsor or applicant from declining such a designation.

(b) Use of animal trials

A drug for which approval is sought under section 355(b) of this title or section 262 of title 42 on the basis of evidence of effectiveness that is derived from animal studies pursuant to section 123¹ may be designated as a fast track product for purposes of this section.

(c) Priority review of drugs and biological products

A priority countermeasure that is a drug or biological product shall be considered a priority

drug or biological product for purposes of performance goals for priority drugs or biological products agreed to by the Commissioner of Food and Drugs.

(d) Definitions

For purposes of this title:¹

(1) The term "priority countermeasure" has the meaning given such term in section 247d-6(h)(4) of title 42.

(2) The term "priority drugs or biological products" means a drug or biological product that is the subject of a drug or biologics application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997.

(Pub. L. 107-188, title I, §122, June 12, 2002, 116 Stat. 613.)

REFERENCES IN TEXT

Section 123, referred to in subsec. (b), is section 123 of Pub. L. 107-188, title I, June 12, 2002, 116 Stat. 613, which is not classified to the Code.

This title, referred to in subsec. (d), is title I of Pub. L. 107-188, June 12, 2002, 116 Stat. 596, which enacted this section, section 669a of Title 29, Labor, and sections 244, 245, 247d-3a, 247d-3b, 247d-7a to 247d-7d, 300hh, 300hh-11 to 300hh-13, 1320b-5, and 7257d of Title 42, The Public Health and Welfare, amended sections 247d to 247d-6, 264, 266, 290hh-1, and 5196b of Title 42, and enacted provisions set out as notes preceding section 8101 of Title 38, Veterans' Benefits, and under sections 201, 244, 247d, 247d-6, 300hh, 300hh-12, and 1320b-5 of Title 42. For complete classification of this title to the Code, see Tables.

Section 101(4) of the Food and Drug Administration Modernization Act of 1997, referred to in subsec. (d)(2), is section 101(4) of Pub. L. 105-115, which is set out as a note under section 379g of this title.

CODIFICATION

Section was enacted as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 356a. Manufacturing changes

(a) In general

With respect to a drug for which there is in effect an approved application under section 355 or 360b of this title or a license under section 262 of title 42, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

(1) the holder of the approved application or license (referred to in this section as a "holder") has validated the effects of the change in accordance with subsection (b) of this section; and

(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c) of this section; or

(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d) of this section.

(b) Validation of effects of changes

For purposes of subsection (a)(1) of this section, a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before dis-

¹ See References in Text note below.