

(Pub. L. 112-144, title V, §508, July 9, 2012, 126 Stat. 1045.)

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

DEFINITION OF “SECRETARY”

The term “Secretary” as used in this section means the Secretary of Health and Human Services, see section 503 of Pub. L. 112-144, set out as a note under section 355a of this title.

§ 355d. Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers

The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 355a(f) and 355c(f) of this title. Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, neonatology, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry, and other individuals designated by the Secretary.

(June 25, 1938, ch. 675, §505C, as added Pub. L. 110-85, title IV, §403, Sept. 27, 2007, 121 Stat. 875; amended Pub. L. 112-144, title V, §509(c), July 9, 2012, 126 Stat. 1049.)

AMENDMENTS

2012—Pub. L. 112-144 inserted “deferral extensions,” after “deferrals,” in section catchline and “neonatology,” after “pediatric ethics,” in text.

§ 355e. Pharmaceutical security

(a) In general

The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

(b) Standards development

(1) In general

The Secretary shall, in consultation with the agencies specified in paragraph (4), manufacturers, distributors, pharmacies, and other supply chain stakeholders, prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs.

(2) Standardized numeral identifier

Not later than 30 months after September 27, 2007, the Secretary shall develop a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied

at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.

(3) Promising technologies

The standards developed under this subsection shall address promising technologies, which may include—

- (A) radio frequency identification technology;
- (B) nanotechnology;
- (C) encryption technologies; and
- (D) other track-and-trace or authentication technologies.

(4) Interagency collaboration

In carrying out this subsection, the Secretary shall consult with Federal health and security agencies, including—

- (A) the Department of Justice;
- (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.)

§ 355f. Extension of exclusivity period for new qualified infectious disease products

(a) Extension

If the Secretary approves an application pursuant to section 355 of this title for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 355 of this title, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 355 of this title, or the 7-year period described in section 360cc of this title, as applicable, shall be extended by 5 years.

(b) Relation to pediatric exclusivity

Any extension under subsection (a) of a period shall be in addition to any extension of the pe-

riod under section 355a of this title with respect to the drug.

(c) Limitations

Subsection (a) does not apply to the approval of—

(1) a supplement to an application under section 355(b) of this title for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

(2) a subsequent application filed with respect to a product approved under section 355 of this title for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(3) a product that does not meet the definition of a qualified infectious disease product under subsection (g) based upon its approved uses.

(d) Designation

(1) In general

The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 355(b) of this title for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

(2) Limitation

Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

(3) Revocation of designation

The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

(e) Regulations

(1) In general

Not later than 2 years after July 9, 2012, the Secretary shall adopt final regulations implementing this section, including developing the list of qualifying pathogens described in subsection (f).

(2) Procedure

In promulgating a regulation implementing this section, the Secretary shall—

(A) issue a notice of proposed rulemaking that includes the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) publish the final regulation not less than 30 days before the effective date of the regulation.

(3) Restrictions

Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may

issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

(4) Designation prior to regulations

The Secretary shall designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection, if such drugs meet the definition of a qualified infectious disease product described in subsection (g).

(f) Qualifying pathogen

(1) Definition

In this section, the term “qualifying pathogen” means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

(A) resistant gram positive pathogens, including methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Staphylococcus aureus*, and vancomycin-resistant *enterococcus*;

(B) multi-drug resistant gram negative bacteria, including *Acinetobacter*, *Klebsiella*, *Pseudomonas*, and *E. coli* species;

(C) multi-drug resistant tuberculosis; and

(D) *Clostridium difficile*.

(2) List of qualifying pathogens

(A) In general

The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

(B) Considerations

In establishing and maintaining the list of pathogens described under this section, the Secretary shall—

(i) consider—

(I) the impact on the public health due to drug-resistant organisms in humans;

(II) the rate of growth of drug-resistant organisms in humans;

(III) the increase in resistance rates in humans; and

(IV) the morbidity and mortality in humans; and

(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

(C) Review

Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

(g) Qualified infectious disease product

The term “qualified infectious disease product” means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

(2) qualifying pathogens listed by the Secretary under subsection (f).

(June 25, 1938, ch. 675, §505E, as added Pub. L. 112-144, title VIII, §801(a), July 9, 2012, 126 Stat. 1077.)

EFFECTIVE DATE

Pub. L. 112-144, title VIII, §801(b), July 9, 2012, 126 Stat. 1079, provided that: “Section 505E of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355f], as added by subsection (a), applies only with respect to a drug that is first approved under section 505(c) of such Act (21 U.S.C. 355(c)) on or after the date of the enactment of this Act [July 9, 2012].”

§ 356. Expedited approval of drugs for serious or life-threatening diseases or conditions

(a) Designation of a drug as a breakthrough therapy

(1) In general

The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a “breakthrough therapy”.)

(2) Request for designation

The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the 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

(A) In general

Not later than 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 breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

(B) Actions

The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

(i) holding meetings with the sponsor and the review team throughout the development of the drug;

(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to

ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

(b) 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, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition, or if the Secretary designates the drug as a qualified infectious disease product under section 355f(d) of this title. (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.

(c) Accelerated approval of a drug for a serious or life-threatening disease or condition, including a fast track product

(1) In general

(A) Accelerated approval

The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 355(c) of this title or section 262(a) of title 42 upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on