section 262(m) of title 42 are completed, submitted, and incorporated into labeling;

(B) the average length of time after the receipt of a proposed pediatric study request before the Secretary responds to such request;

(C) the average length of time after the submission of a proposed pediatric study request before the Secretary issues a written request for such studies;

(D) the number of written requests issued for each investigational new drug or biological product prior to the submission of an application under section 355(b)(1) of this title or section 262(a) of title 42; and

(E) the average number, and range of numbers, of amendments to written requests issued, and the time the Secretary requires to review and act on proposed amendments to written requests;

(13) a list of sponsors of applications or holders of approved applications who received exclusivity under such section 355a of this title or such section 262(m) of title 42 after receiving a letter issued under such section 355c(d)(1) of this title for any drug or biological product before the studies referred to in such letter were completed and submitted;

(14) a list of assessments and investigations required under such section 355c of this title;

(15) how many requests under such section 355a of this title for molecular targeted cancer drugs, as defined by subsection (a)(1)(B) of such section 355c of this title, approved prior to 3 years after August 18, 2017, have been issued by the Food and Drug Administration, and how many such requests have been completed; and

(16) the Secretary's assessment of the overall impact of the amendments made by section 504 of the FDA Reauthorization Act of 2017 on the conduct and effectiveness of pediatric cancer research and the orphan drug program, as well any subsequent recommendations.

(c) Stakeholder comment

At least 180 days prior to the submission of each report under subsection (a), the Secretary shall consult with representatives of patient groups (including pediatric patient groups), consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products.

(Pub. L. 112–144, title V, § 508, July 9, 2012, 126 Stat. 1045; Pub. L. 115–52, title V, § 504(d), Aug. 18, 2017, 131 Stat. 1044.)

Editorial Notes

REFERENCES IN TEXT

The FDA Reauthorization Act of 2017, referred to in subsec. (b)(11), (16), is Pub. L. 115–52, Aug. 18, 2017, 131 Stat. 1005. Section 504 of the Act amended this section and section 355c of this title. For complete classification of this Act to the Code, see Short Title of 2017 Amendment note set out under section 301 of this title and Tables.

Section 505C–1 of the Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(12), probably means section 505(c) of Pub. L. 115–52, the FDA Reauthorization Act of 2017, which is set out as a note under section 355a of this title. The Federal Food, Drug, and Cosmetic Act does not contain a section 505C–1, and section 505(c) of the FDA Reauthorization Act of 2017 relates to the development and implementation of a plan for earlier submission of pediatric studies under sections 355a and 355c of this title and section 262(m) of Title 42, The Public Health and Welfare.

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.

AMENDMENTS

2017—Subsec. (b)(11) to (16). Pub. L. 115–52 added pars. (11) to (16) and struck out former par. (11) which read as follows: ''an assessment of the Secretary's efforts to address the suggestions and options described in any prior report issued by the Comptroller General, Institute of Medicine, or the Secretary, and any subsequent reports, including recommendations therein, regarding the topics addressed in the reports under this section, including with respect to—

''(A) improving public access to information from pediatric studies conducted under such sections 355a and 355c of this title; and

''(B) improving the timeliness of pediatric studies and pediatric study planning under such sections 355a and 355c of this title.''

Statutory Notes and Related Subsidiaries

RULE OF CONSTRUCTION

Nothing in amendment by Pub. L. 115–52 to limit the authority of the Secretary of Health and Human Services to issue written requests under section 355a of this title or section 262(m) of Title 42, The Public Health and Welfare, or to negotiate or implement amendments to such requests proposed by applicants, see section 504(e) of Pub. L. 115–52, set out as a note under section 355c of this title.

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 or pediatric rare diseases, 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; Pub. L. 115–52, title V, § 505(f), Aug. 18, 2017, 131 Stat. 1047.)

Editorial Notes

AMENDMENTS

2017—Pub. L. 115–52 inserted ''or pediatric rare diseases'' after ''psychiatry''.

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 period 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.