''(E) the process the Secretary shall utilize to update regularly a list of molecular targets that may trigger a pediatric study under section 505B of the Federal Food, Drug, and Cosmetic Act, as so amended, and how often such updates shall occur;

''(F) how to overcome the challenges related to pediatric cancer drug and biological product development, including issues related to the ethical, practical, and other barriers to conducting clinical trials in pediatric cancer with small patient populations;

''(G) scientific or operational challenges associated with performing an investigation described in section 505B(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c(a)(1)(B)], including the effect on pediatric studies currently underway in a pediatric patient population, treatment of a pediatric patient population, and the ability to complete adult clinical trials;

''(H) the advantages and disadvantages of innovative clinical trial designs in addressing the development of cancer drugs or biological products directed at molecular targets in pediatric cancer patients;

''(I) the ways in which the Secretary can improve the current process outlined under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) to encourage additional research and development of pediatric cancer treatments;

''(J) the ways in which the Secretary might streamline and improve the written request process, including when studies contained in a request under such section 505A are not feasible due to the ethical, practical, or other barriers to conducting clinical trials in pediatric cancer populations;

''(K) how the Secretary will facilitate collaboration among pediatric networks, academic centers and experts in pediatric cancer to conduct an investigation described in such section 505B(a)(3);

''(L) how the Secretary may facilitate collaboration among sponsors of same-in-class drugs and biological products that would be subject to the requirements for an investigation under such section 505B based on shared molecular targets; and

''(M) the ways in which the Secretary will help to mitigate the risks, if any, of discouraging the research and development of orphan drugs when implementing such section 505B as amended.

''(2) GUIDANCE.—Not later than 2 years after the date of enactment of this Act [Aug. 18, 2017], the Secretary, acting through the Commissioner of Food and Drugs, shall issue final guidance on implementation of the amendments to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) regarding molecularly targeted cancer drugs made by this section, including—

''(A) the scientific criteria, types of data, and regulatory considerations for determining whether a molecular target is substantially relevant to the growth or progression of a pediatric cancer and would trigger an investigation under section 505B of the Federal Food, Drug, and Cosmetic Act, as amended;

''(B) the process by which the Secretary will engage with sponsors to discuss determinations, investigation requirements, deferrals, waivers, and any other issues that need to be resolved to ensure that any required investigation based on a molecular target can be reasonably conducted;

''(C) the scientific or operational challenges for which the Secretary may issue deferrals or waivers for an investigation described in subsection (a)(3) of such section 505B, including adverse impacts on current pediatric studies underway in a pediatric patient population, studies involving drugs designated as orphan drugs, treatment of a pediatric patient population, or the ability to complete adult clinical trials;

''(D) how the Secretary and sponsors will facilitate collaboration among pediatric networks, academic centers, and experts in pediatric cancer to conduct an investigation described in subsection (a)(3) of such section 505B;

''(E) scientific and regulatory considerations for study designs, including the applicability of innovative clinical trial designs for pediatric cancer drug and biological product developments under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c);

''(F) approaches to streamline and improve the amendment process, including when studies contained in a request under such section 505A are not feasible due to the ethical, practical, or other barriers to conducting clinical trials in pediatric cancer populations;

''(G) the process for submission of an initial pediatric study plan for the investigation described in section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)), including the process for a sponsor to meet and reach agreement with the Secretary on the initial pediatric study plan; and

''(H) considerations for implementation of such section 505B, as so amended, and waivers of the requirements of such section 505B with regard to molecular targets for which several drugs or biological products may be under investigation.''

§ 355c–1. Report

(a) In general

Not later than four years after July 9, 2012, and every five years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the Internet Web site of the Food and Drug Administration, a report on the implementation of sections 355a and 355c of this title.

(b) Contents

Each report under subsection (a) shall include—

(1) an assessment of the effectiveness of sections 355a and 355c of this title in improving information about pediatric uses for approved drugs and biological products, including the number and type of labeling changes made since July 9, 2012, and the importance of such uses in the improvement of the health of children;

(2) the number of required studies under such section 355c of this title that have not met the initial deadline provided under such section 355c of this title, including—

(A) the number of deferrals and deferral extensions granted and the reasons such extensions were granted;

(B) the number of waivers and partial waivers granted; and

(C) the number of letters issued under subsection (d) of such section 355c of this title;

(3) an assessment of the timeliness and effectiveness of pediatric study planning since July 9, 2012, including the number of initial pediatric study plans not submitted in accordance with the requirements of subsection (e) of such section 355c of this title and any resulting rulemaking;

(4) the number of written requests issued, accepted, and declined under such section 355a of this title since July 9, 2012, and a listing of any important gaps in pediatric information as a result of such declined requests;

(5) a description and current status of referrals made under subsection (n) of such section 355a of this title;

(6) an assessment of the effectiveness of studying biological products in pediatric popu-

lations under such sections 355a and 355c of this title and section 284m of title 42;

(7)(A) the efforts made by the Secretary to increase the number of studies conducted in the neonatal population (including efforts made to encourage the conduct of appropriate studies in neonates by companies with products that have sufficient safety and other information to make the conduct of the studies ethical and safe); and

(B) the results of such efforts;

(8)(A) the number and importance of drugs and biological products for children with cancer that are being tested as a result of the programs under such sections 355a and 355c of this title and under section 284m of title 42; and

(B) any recommendations for modifications to such programs that would lead to new and better therapies for children with cancer, including a detailed rationale for each recommendation;

(9) any recommendations for modification to such programs that would improve pediatric drug research and increase pediatric labeling of drugs and biological products;

(10) an assessment of the successes of and limitations to studying drugs for rare diseases under such sections 355a and 355c of this title;

(11) an assessment of the impact of the amendments to such section 355c of this title made by the FDA Reauthorization Act of 2017 on pediatric research and labeling of drugs and biological products and pediatric labeling of molecularly targeted drugs and biological products for the treatment of cancer;

(12) an assessment of the efforts of the Secretary to implement the plan developed under section 505C–1 of the Federal Food, Drug, and Cosmetic Act,[1] regarding earlier submission of pediatric studies under sections 355a and 355c of this title and section 262(m) of title 42, including—

(A) the average length of time after the approval of an application under section 355(b)(1) of this title or section 262(a) of title 42 before studies conducted pursuant to such section 355a of this title, 355c of this title, or 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

[1] See References in Text note below.

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