

ucts 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; and

(11) 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.

**(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.)

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 in-

ternal 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;