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 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 infec-