capital fund, narcotic hospitals, to surplus fund, was transferred and is set out as a note under section 290aa of this title.

§§ 259 to 261a. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221, as amended by Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710

Section 259, acts July 1, 1944, ch. 373, title III, § 343, 58 Stat. 699; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–293, § 3, May 11, 1972, 86 Stat. 136; Pub. L. 98–473, title II, § 232(b), Oct. 12, 1984, 98 Stat. 2031, related to convict addicts or other persons with drug abuse or drug dependence problems.

Section 260, acts July 1, 1944, ch. 373, title III, § 344, 58 Stat. 701; June 25, 1948, ch. 654, § 5, 62 Stat. 1018; July 24, 1956, ch. 676, title III, § 302(b), 70 Stat. 622; Pub. L. 91–513, title I, § 2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240, related to addicts and persons with drug abuse or drug dependence problems.

Section 260a, act July 1, 1944, ch. 373, title III, § 345, as added May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended July 24, 1956, ch. 676, title III, § 302(c), 70 Stat. 622; Pub. L. 91–358, title I, § 155(c)(32), July 29, 1970, 84 Stat. 572, related to admission of addicts committed from District of Columbia.

Section 261, acts July 1, 1944, ch. 373, title III, § 346, formerly § 345, 58 Stat. 701; renumbered § 346, May 8, 1954, ch. 195, § 2, 68 Stat. 79; amended Pub. L. 91–513, title I, § 2(a)(2)(A), (5), Oct. 27, 1970, 84 Stat. 1240, related to penalties for introducing prohibited articles and substances into hospitals and escaping from, or aiding and abetting escape from hospitals.

Section 261a, act July 1, 1944, ch. 373, title III, § 347, as added May 8, 1954, ch. 195, § 4, 68 Stat. 80; amended Pub. L. 91–513, title I, § 2(a)(4), Oct. 27, 1970, 84 Stat. 1240, related to release of patients and determination by Surgeon General.

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title I, § 110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106–310, which repealed sections 259 to 261a of this title) is effective as if included in the enactment of Pub. L. 106–310.

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(*o*), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(*o*), (p), 355–1].

(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)(5)].

(ii) In this subparagraph, the terms ''qualified indication'' and ''qualified data summary'' have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.