

TITLE 42 - THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A - PUBLIC HEALTH SERVICE
SUBCHAPTER II - GENERAL POWERS AND DUTIES
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 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) of this section.

(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].

(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

NB: This unofficial compilation of the U.S. Code is current as of Jan. 5, 2009 (see <http://www.law.cornell.edu/uscode/uscpri.html>).

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.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to \$100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term “base quarter”, as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding \$500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(h) Exportation of partially processed biological products

A partially processed biological product which—

- (1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;
- (2) is not intended for sale in the United States; and
- (3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 (e)).

(i) “Biological product” defined

In this section, the term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(o), 505(p), and 505–1 of such Act [21 U.S.C. 355 (o), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(July 1, 1944, ch. 373, title III, § 351, 58 Stat. 702; 1953 Reorg. Plan No. 1, §§ 5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 85–881, § 2, Sept. 2, 1958, 72 Stat. 1704; Pub. L. 91–515, title II, § 291, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 96–88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99–660, title I, § 105(a), title III, § 315, Nov. 14, 1986, 100 Stat. 3751, 3783; Pub. L. 102–300, § 6(b)(1),

June 16, 1992, 106 Stat. 240; Pub. L. 104–134, title II, §§ 2102(d)(2), 2104, Apr. 26, 1996, 110 Stat. 1321–319, 1321–320; Pub. L. 105–115, title I, § 123(a)–(d), (g), Nov. 21, 1997, 111 Stat. 2323, 2324; Pub. L. 108–155, § 2(b)(3), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title IX, § 901(c), Sept. 27, 2007, 121 Stat. 939.)

References in Text

The effective date of this paragraph, referred to in subsec. (d)(2), is the effective date of section 315 of Pub. L. 99–660 which added subsec. (d)(2). See Effective Date of 1986 Amendment note set out below.

The Federal Food, Drug, and Cosmetic Act, referred to in subsections (g), (h), and (j), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Amendments

2007—Subsec. (a)(2)(D). Pub. L. 110–85, § 901(c)(1), added subpar. (D).

Subsec. (j). Pub. L. 110–85, § 901(c)(2), inserted “, including the requirements under sections 505(o), 505(p), and 505–1 of such Act,” after “and Cosmetic Act”.

2003—Subsec. (a)(2)(B), (C). Pub. L. 108–155 added subpar. (B) and redesignated former subpar. (B) as (C).

1997—Subsec. (a). Pub. L. 105–115, § 123(a)(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) related to intrastate and interstate traffic in biological products and suspension or revocation of licenses as affecting prior sales.

Subsec. (b). Pub. L. 105–115, § 123(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: “No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.”

Subsec. (c). Pub. L. 105–115, § 123(c), substituted “biological product.” for “virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession.”

Subsec. (d). Pub. L. 105–115, § 123(a)(2), designated par. (2) as subsec. (d), redesignated subpars. (A) and (B) of par. (2) as pars. (1) and (2), respectively, in par. (2), substituted “Any violation of paragraph (1)” for “Any violation of subparagraph (A)” and substituted “this paragraph” for “this subparagraph” wherever appearing, and struck out former par. (1) which read as follows: “Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.”

Subsec. (i). Pub. L. 105–115, § 123(d), added subsec. (i).

Subsec. (j). Pub. L. 105–115, § 123(g), added subsec. (j).

1996—Subsec. (h). Pub. L. 104–134, § 2104, amended subsec. (h) generally, revising and restating former provisions, which also related to exportation of partially processed biological products.

Subsec. (h)(1)(A). Pub. L. 104–134, § 2102(d)(2), substituted “in a country listed under section 802 (b)(1)” for “in a country listed under section 802 (b)(A)” and “to a country listed under section 802 (b)(1)” for “to a country listed under section 802 (b)(4)”.

1992—Subsec. (c). Pub. L. 102–300, which directed substitution of “Health and Human Services” for “Health, Education, and Welfare”, could not be executed because the words “Health, Education, and Welfare” did not appear in original statutory text. Previously, references to Department and Secretary of Health and Human Services were substituted for references to Federal Security Agency and its Administrator pursuant to provisions cited in Transfer of Functions note below.

NB: This unofficial compilation of the U.S. Code is current as of Jan. 5, 2009 (see <http://www.law.cornell.edu/uscode/uscprint.html>).

1986—Subsec. (d). Pub. L. 99–660, § 315, designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 99–660, § 105(a), added subsec. (h).

1970—Subsecs. (a) to (c). Pub. L. 91–515 inserted “vaccine, blood, blood component or derivative, allergenic product,” after “antitoxin” wherever appearing.

1958—Subsec. (d). Pub. L. 85–881 struck out “made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Secretary” after “regulations” in first sentence.

Effective Date of 2007 Amendment

Amendment by Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of Title 21, Food and Drugs.

Effective Date of 2003 Amendment

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

Effective Date of 1997 Amendment

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

Effective Date of 1986 Amendment

Section 105(b) of Pub. L. 99–660 provided that: “Paragraph (1) of section 351(h) of the Public Health Service Act [former subsec. (h)(1) of this section] as added by subsection (a) shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Nov. 14, 1986].”

Amendment by section 315 of Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Transfer of Functions

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508 (b) of Title 20, Education.

References to Secretary and Department of Health, Education, and Welfare substituted for references to Federal Security Administrator and Federal Security Agency, respectively, pursuant to Reorg. Plan No. 1 of 1953, § 5, set out as a note under section 3501 of this title, which transferred all functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953. Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508 (b) of Title 20.

Enhanced Penalties and Control of Biological Agents

Pub. L. 104–132, title V, § 511, Apr. 24, 1996, 110 Stat. 1284, as amended by Pub. L. 107–188, title II, § 204, June 12, 2002, 116 Stat. 647, provided that:

“(a) Findings.—The Congress finds that—

“(1) certain biological agents have the potential to pose a severe threat to public health and safety;

“(2) such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

“(3) the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and

“(4) efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes.

“(b) Criminal Enforcement.—[Amended sections 175, 177, and 178 of Title 18, Crimes and Criminal Procedure.]

“(c) Terrorism.—[Amended section 2332a of Title 18.]”