

Stat. 77; Pub. L. 93-198, title IV, §421, Dec. 24, 1973, 87 Stat. 789; Pub. L. 98-473, title II, §232(a), Oct. 12, 1984, 98 Stat. 2031; Pub. L. 99-646, §22(a), Nov. 10, 1986, 100 Stat. 3597; Pub. L. 102-54, §13(q)(1)(B)(i), June 13, 1991, 105 Stat. 278, related to care and treatment of narcotic addicts.

#### § 257a. Transferred

##### CODIFICATION

Section, Pub. L. 91-513, title I, §4, Oct. 27, 1970, 84 Stat. 1241; Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, which related to medical treatment of narcotics addiction, was transferred to section 290bb-2a of this title.

#### § 258. Repealed. Pub. L. 106-310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section, acts July 1, 1944, ch. 373, title III, §342, 58 Stat. 699; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 91-513, title I, §2(a)(2)(A), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, related to employment, establishment of industries, plants, etc., sale of commodities, and disposition of proceeds.

#### § 258a. Transferred

##### CODIFICATION

Section, act July 8, 1947, ch. 210, title II, §201, 61 Stat. 269, which related to transfer of balances in working 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 Repealed.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

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.

#### 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 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  $\frac{1}{10}$  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 com-

pound), 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 subssecs. (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.

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.]"

#### § 262a. Enhanced control of dangerous biological agents and toxins

##### (a) Regulatory control of certain biological agents and toxins

##### (1) List of biological agents and toxins

##### (A) In general

The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

##### (B) Criteria

In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) consider—

(I) the effect on human health of exposure to the agent or toxin;

(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

**(2) Biennial review**

The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

**(b) Regulation of transfers of listed agents and toxins**

The Secretary shall by regulation provide for—

(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure—

(A) proper training and appropriate skills to handle such agents and toxins; and

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

**(c) Possession and use of listed agents and toxins**

The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b) of this section, in order to protect the public health and safety.

**(d) Registration; identification; database**

**(1) Registration**

Regulations under subsections (b) and (c) of this section shall require registration with the Secretary of the possession, use, and transfer

of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6) of this section.

**(2) Identification; database**

Regulations under subsections (b) and (c) of this section shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

**(e) Safeguard and security requirements for registered persons**

**(1) In general**

Regulations under subsections (b) and (c) of this section shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in collaboration with the Secretary of Homeland Security and the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

**(2) Limiting access to listed agents and toxins**

Requirements under paragraph (1) shall include provisions to ensure that registered persons—

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

**(3) Submitted names; use of databases by attorney general**

**(A) In general**

Upon the receipt of names and other identifying information under paragraph (2)(B),

the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

**(B) Certain individuals**

For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

(i) the individual is a restricted person; or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

(I) committing a crime set forth in section 2332b(g)(5) of title 18;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50).

**(C) Notification by Attorney General regarding submitted names**

After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

**(4) Notifications by Secretary**

The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

**(5) Expedited review**

Regulations under subsections (b) and (c) of this section shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

(B) expedite the notification of the registered person by the Secretary under paragraph (4).

**(6) Process regarding persons seeking to register**

**(A) Individuals**

Regulations under subsections (b) and (c) of this section shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4)

as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

**(B) Other persons**

Regulations under subsections (b) and (c) of this section shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

**(7) Review**

**(A) Administrative review**

**(i) In general**

Regulations under subsections (b) and (c) of this section shall provide for an opportunity for a review by the Secretary—

(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

**(ii) Ex parte review**

During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

**(iii) Final agency action**

The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5.

**(B) Certain procedures**

**(i) Submission of ex parte materials in judicial proceedings**

When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex

parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18 (relating to interlocutory appeal and expedited consideration).

**(ii) Disclosure of information**

In a review under subparagraph (A), and in any judicial<sup>1</sup> proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) of this section shall not be disclosed under section 552 of title 5.

**(8) Notifications regarding theft or loss of agents**

Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

**(9) Technical assistance for registered persons**

The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

**(f) Inspections**

The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) of this section to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e) of this section.

**(g) Exemptions**

**(1) Clinical or diagnostic laboratories**

Regulations under subsections (b) and (c) of this section shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

(A) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

(B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

**(2) Products**

**(A) In general**

Regulations under subsections (b) and (c) of this section shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) of this section to a specific product is necessary to protect public health and safety.

**(B) Relevant laws**

For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:

(i) The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(ii) Section 262 of this title.

(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading “Bureau of Animal Industry” in the Act of March 4, 1913; 21 U.S.C. 151–159).

(iv) The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

**(C) Investigational use**

**(i) In general**

The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) of this section when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection (b) or (c) of this section to such product is not necessary to protect public health and safety.

**(ii) Certain processes**

Regulations under subsections (b) and (c) of this section shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:

(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

**(3) Public health emergencies**

The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domes-

<sup>1</sup> So in original. Probably should be “judicial”.

tic or foreign public health emergency (whether determined under section 247d(a) of this title or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

**(4) Agricultural emergencies**

Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 8401(g)(1)(D) of title 7 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

**(h) Disclosure of information**

**(1) Nondisclosure of certain information**

No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5 any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c) of this section for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

(B) The national database developed pursuant to subsection (d) of this section, or any other compilation of the registration or transfer information submitted under subsections (b) and (c) of this section to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c) of this section, or any notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) of this section that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

**(2) Covered agencies**

For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

**(3) Other exemptions**

This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, except as to subsection<sup>2</sup> 552(b)(3) of such title, to any of the information specified in paragraph (1).

**(4) Rule of construction**

Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, or the obligation of any Federal agency to disclose under section 552 of title 5, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c) of this section; or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

**(5) Disclosures to Congress; other disclosures**

This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

**(i) Civil money penalty**

**(1) In general**

In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) of this section shall be subject to the United States for a civil money penalty in an amount not exceeding \$250,000 in the case of an

<sup>2</sup>So in original. Probably should be "section".

individual and \$500,000 in the case of any other person.

**(2) Applicability of certain provisions**

The provisions of section 1320a-7a of this title (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title. The Secretary may delegate authority under this subsection in the same manner as provided in section 1320a-7a(j)(2) of this title, and such authority shall include all powers as contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

**(j) Notification in event of release**

Regulations under subsections (b) and (c) of this section shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (l) of this section), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

**(k) Reports**

The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) of this section (relating to theft or loss) and subsection (j) of this section (relating to releases).

**(l) Definitions**

For purposes of this section:

(1) The terms “biological agent” and “toxin” have the meanings given such terms in section 178 of title 18.

(2) The term “listed agents and toxins” means biological agents and toxins listed pursuant to subsection (a)(1) of this section.

(3) The term “listed agents or toxins” means biological agents or toxins listed pursuant to subsection (a)(1) of this section.

(4) The term “overlap agents and toxins” means biological agents and toxins that—

(A) are listed pursuant to subsection (a)(1) of this section; and

(B) are listed pursuant to section 8401(a)(1) of title 7.

(5) The term “overlap agent or toxin” means a biological agent or toxin that—

(A) is listed pursuant to subsection (a)(1) of this section; and

(B) is listed pursuant to section 8401(a)(1) of title 7.

(6) The term “person” includes Federal, State, and local governmental entities.

(7) The term “registered person” means a person registered under regulations under subsection (b) or (c) of this section.

(8) The term “restricted person” has the meaning given such term in section 175b of title 18.

**(m) Authorization of appropriations**

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007.

(July 1, 1944, ch. 373, title III, §351A, as added Pub. L. 107-188, title II, §201(a), June 12, 2002, 116 Stat. 637; amended Pub. L. 107-296, title XVII, §1709(a), Nov. 25, 2002, 116 Stat. 2318.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec.(g)(2)(B)(i), 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.

The Act commonly known as the Virus-Serum-Toxin Act, referred to in subsec. (g)(2)(B)(iii), is the eighth paragraph under the heading “Bureau of Animal Industry” of act Mar. 4, 1913, ch. 145, 37 Stat. 832, as amended, which is classified generally to chapter 5 (§151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (g)(2)(B)(iv), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

Section 6 of the Inspector General Act of 1978, referred to in subsec. (i)(2), is section 6 of Pub. L. 95-452, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2002—Subsec. (e)(1). Pub. L. 107-296 substituted “collaboration with the Secretary of Homeland Security and” for “consultation with”.

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107-296 effective 60 days after Nov. 25, 2002, see section 4 of Pub. L. 107-296, set out as an Effective Date note under section 101 of Title 6, Domestic Security.

EFFECTIVE DATE

Pub. L. 107-188, title II, §203(b), June 12, 2002, 116 Stat. 647, provided that: “Subsection (h) of section 351A of the Public Health Service Act [subsec. (h) of this section], as added by section 201 of this Act, is deemed to have taken effect on the effective date of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104-132, Apr. 24, 1996, 110 Stat. 1214].”

REGULATIONS

Pub. L. 107-188, title II, §203(a), June 12, 2002, 116 Stat. 647, provided that: “Regulations promulgated by the Secretary of Health and Human Services under section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104-132, set out as a note under section 262 of this title] are deemed to have been promulgated under section 351A of the Public Health Service Act [this section], as added by section 201 of this Act. Such regulations, including the list under [former] subsection (d)(1) of such section 511, that were in effect on

the day before the date of the enactment of this Act [June 12, 2002] remain in effect until modified by the Secretary in accordance with such section 351A and with section 202 of this Act [set out as a note below].”

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Pub. L. 109-417, title II, §205, Dec. 19, 2006, 120 Stat. 2851, provided that: “The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of Health and Human Services, provide to relevant Federal departments and agencies, advice, guidance, or recommendations concerning—

“(1) a core curriculum and training requirements for workers in maximum containment biological laboratories; and

“(2) periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity.”

REPORT TO CONGRESS

Pub. L. 107-188, title II, §201(b), June 12, 2002, 116 Stat. 646, required the Secretary of Health and Human Services to report to Congress not later than one year after June 12, 2002, on the implementation, compliance, and future plans under this section.

IMPLEMENTATION BY DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pub. L. 107-188, title II, §202, June 12, 2002, 116 Stat. 646, provided that:

“(a) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 90 days after the date of the enactment of this Act [June 12, 2002], all persons (unless exempt under subsection (g) of section 351A of the Public Health Service Act [subsec. (g) of this section], as added by section 201 of this Act) in possession of biological agents or toxins listed under such section 351A of the Public Health Service Act [this section] shall notify the Secretary of Health and Human Services of such possession. Not later than 30 days after such date of enactment, the Secretary shall provide written guidance on how such notice is to be provided to the Secretary.

“(b) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—Not later than 180 days after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services shall promulgate an interim final rule for carrying out section 351A of the Public Health Service Act [this section], subject to subsection (c). Such interim final rule shall take effect 60 days after the date on which such rule is promulgated, including for purposes of—

“(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

“(2) section 351A(i) of the Public Health Service Act [subsec. (i) of this section] (relating to civil penalties).

“(c) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.—The interim final rule under subsection (b) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act [subsec. (a)(1) of this section] and that were underway as of the effective date of such rule.”

**§ 263. Preparation of biological products by Service**

(a) The Service may prepare for its own use any product described in section 262 of this title and any product necessary to carrying out any of the purposes of section 241 of this title.

(b) The Service may prepare any product described in section 262 of this title for the use of

other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

(July 1, 1944, ch. 373, title III, §352, 58 Stat. 703.)

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.

SUBPART 2—CLINICAL LABORATORIES

**§ 263a. Certification of laboratories**

**(a) “Laboratory” or “clinical laboratory” defined**

As used in this section, the term “laboratory” or “clinical laboratory” means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

**(b) Certificate requirement**

No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

**(c) Issuance and renewal of certificates**

**(1) In general**

The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d) of this section.

**(2) Term**

A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

**(d) Requirements for certificates**

**(1) In general**

A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e) of this section, the accreditation body which accredited the laboratory submits), an application—

(i) in such form and manner as the Secretary shall prescribe,

(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(I) the number and types of laboratory examinations and other procedures performed,