(c) Application

(1) Application

A network described in subsection (b) shall submit an application to the Secretary.

(2) Renewal

In subsequent years, based on the performance of grantees, the Secretary may provide renewal grants to prior year grant recipients.

(d) Use of funds

(1) Use by grantees

Grant funds may be used for the following activities:

(A) Assist low-income individuals to—

(i) access and appropriately use health services;

(ii) enroll in health coverage programs; and

(iii) obtain a regular primary care provider or a medical home.

(B) Provide case management and care management.

(C) Perform health outreach using neighborhood health workers or through other means.

(D) Provide transportation.

(E) Expand capacity, including through telehealth, after-hours services or urgent care.

(F) Provide direct patient care services.

(2) Grant funds to HRSA grantees

The Secretary may limit the percent of grant funding that may be spent on direct care services provided by grantees of programs administered by the Health Resources and Services Administration or impose other requirements on such grantees deemed necessary.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, § 340H, as added Pub. L. 111–148, title X, § 10333, Mar. 23, 2010, 124 Stat. 970.)

CODIFICATION

Another section 340H of act July 1, 1944, ch. 373, as added by Pub. L. 111–148, title V, § 5508(c), March 23, 2010, 124 Stat. 670, is classified to section 256h of this title.

PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS

§ 257. Repealed.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, § 341, 58 Stat. 698; May 8, 1954, ch. 195, § 3, 68 Stat. 80; July 24, 1956, ch. 676, title III, § 302(a), 70 Stat. 622; Pub. L. 89–793, title VI, § 601, Nov. 8, 1966, 80 Stat. 1449; 1967 Reorg. Plan No. 3, § 401, eff. Nov. 3, 1967 (in part), 32 F.R. 11669, 81 Stat. 951; Pub. L. 91–513, title I, § 2(a)(1), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–255, title IV, § 402, Mar. 21, 1972, 86 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 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) 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 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:

(1) The term ''biological product'' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), 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.

(2) The term ''biosimilar'' or ''biosimilarity'', in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term ''interchangeable'' or ''interchangeability'', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term ''reference product'' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(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.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) 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.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) 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).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term ''final court decision'' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(*l*) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the ''subsection (k) applicant'') and the sponsor of the application for the reference product (referred to in this subsection as the ''reference product sponsor''), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the ''confidential information'').

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the ''outside counsel''), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to

or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each pat-

ent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference

product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (*l*), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (i), (j), (k), (*l*), (p), (q)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder

[1] See References in Text note below.

agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526[1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a)[1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3)[1] [21 U.S.C. 355a(d)(3)] is made later than 9 months prior to the expiration of such period.

(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; Pub. L. 111–148, title VII, § 7002(a), (b), (g)(1), Mar. 23, 2010, 124 Stat. 804, 814, 819.)

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 subsecs. (g), (h), (j), and (k)(5)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, 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.

Sections 526, 527(a), and 505A(d)(3), referred to in subsec. (m)(2)(B), (3)(B), (4), probably mean sections 526, 527(a), and 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, which are classified to sections 360bb, 360cc(a), and 355a(d)(3), respectively, of Title 21, Food and Drugs.

AMENDMENTS

2010—Subsec. (a)(1)(A). Pub. L. 111–148, § 7002(a)(1), inserted ''under this subsection or subsection (k)'' after ''biologics license''.

Subsec. (i). Pub. L. 111–148, § 7002(b), substituted ''In this section:'' for ''In this section,'', designated remainder of existing provisions as par. (1), substituted ''The term'' for ''the term'', inserted ''protein (except any chemically synthesized polypeptide),'' after ''allergenic product,'', and added pars. (2) to (4).

Subsecs. (k), (*l*). Pub. L. 111–148, § 7002(a)(2), added subsecs. (k) and (*l*).

Subsec. (m). Pub. L. 111–148, § 7002(g)(1), added subsec. (m).

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.

PRODUCTS PREVIOUSLY APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Pub. L. 111–148, title VII, §7002(e), Mar. 23, 2010, 124 Stat. 817, provided that:

''(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

''(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

''(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act [Mar. 23, 2010]; and

''(B) such application—

''(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle [subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the 'Secretary') before the date of enactment of this Act; or

''(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

''(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act [42 U.S.C. 262] that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

''(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

''(5) DEFINITIONS.—For purposes of this subsection, the term 'biological product' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).''

COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Pub. L. 111–148, title VII, §7002(f)(3)(B), (C), Mar. 23, 2010, 124 Stat. 818, 819, provided that:

''(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act [Mar. 23, 2010] and ending on October 1, 2010, the Secretary [of Health and Human Services] shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act) during such period.

''(C) AUDIT.—

''(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

''(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

''(II)(aa) such ratio determined under subclause (I); to

''(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act [42 U.S.C. 262(a)] (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

''(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) [42 U.S.C. 262(k)] to more appropriately account for the costs of reviewing such applications.

''(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of

the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.''

LICENSING OF ORPHAN PRODUCTS

Pub. L. 111–148, title VII, § 7002(h), Mar. 23, 2010, 124 Stat. 821, provided that: ''If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary [of Health and Human Services] only after the expiration for such reference product of the later of—

''(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

''(2) the 12-year period described in subsection (k)(7) of such section 351.''

SAVINGS GENERATED BY 2010 AMENDMENT

Pub. L. 111–148, title VII, § 7003, Mar. 23, 2010, 124 Stat. 821, provided that:

''(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle [subtitle A (§§ 7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title].

''(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.''

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 individ-

ual 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 judical[1] 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

[1] So in original. Probably should be ''judicial''.

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 domestic 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[2] 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 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

[2] So in original. Probably should be ''section''.

(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.''

EX. ORD. NO. 13546. OPTIMIZING THE SECURITY OF BIOLOGICAL SELECT AGENTS AND TOXINS IN THE UNITED STATES

Ex. Ord. No. 13546, July 2, 2010, 75 F.R. 39439, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of the United States that:

(a) A robust and productive scientific enterprise that utilizes biological select agents and toxins (BSAT) is essential to national security;

(b) BSAT shall be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release; and

(c) Security measures shall be taken in a coordinated manner that balances their efficacy with the need to minimize the adverse impact on the legitimate use of BSAT.

SEC. 2. *Definitions*. (a) ''Select Agent Program'' (SAP) means the regulatory oversight and administrative activities conducted by the Secretaries of Health and Human Services and Agriculture and the Attorney General to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002.

(b) ''Select Agent Regulations'' (SAR) means the Federal regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations.

(c) ''Biological Select Agents and Toxins'' means biological agents and toxins with the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products and whose possession, use, and transfer are regulated by the Department of Health and Human Services and the Department of Agriculture under the SAR.

SEC. 3. *Findings*. (a) The use of BSAT presents the risk that BSAT might be lost, stolen, or diverted for malicious purpose. The SAP exists to provide effective regulatory oversight of the possession, use, and transfer of BSAT that reduces the risk of their misuse or mishandling. The absence of clearly defined, risk-based security measures in the SAR/SAP has raised concern about the need for optimized security and for risk management.

(b) In addition, variations in, and limited coordination of, individual executive departments' and agencies' oversight, security practices, and inspections have raised concerns that the cost and complexity of compliance for those who are registered to work with BSAT could discourage research or other legitimate activities.

(c) Understanding that research and laboratory work on BSAT is essential to both public health and national security, it is in the interest of the United States to address these issues.

SEC. 4. *Risk-based Tiering of the Select Agent List*. To help ensure that BSAT are secured according to level of risk, the Secretaries of Health and Human Services and Agriculture shall, through their ongoing review of the biological Select Agents and Toxins List (''Select Agent List'') contained in regulations, and no later than 18 months from the date of this order:

(a) designate a subset of the Select Agent List (Tier 1) that presents the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence;

(b) explore options for graded protection of Tier 1 agents and toxins as described in subsection (a) of this section to permit tailored risk management practices based upon relevant contextual factors; and

(c) consider reducing the overall number of agents and toxins on the Select Agent List.

SEC. 5. *Revision of Regulations, Rules, and Guidance to Accommodate a Tiered Select Agent List*. Consistent with section 4 of this order, I request that:

(a) The Secretaries of Health and Human Services and Agriculture, no later than 15 months from the date of this order, propose amendments to their respective parts of the SAR that would establish security standards specific to Tier 1 agents and toxins.

(b) The Secretaries of Health and Human Services and Agriculture each, no later than 27 months from the date of this order, promulgate final rules and guidance that clearly articulate security actions for registrants who possess, use, or transfer Tier 1 agents and toxins.

SEC. 6. *Coordination of Federal Oversight for BSAT Security*. To ensure that the policies and practices used to secure BSAT are harmonized and that the related oversight activities of the Federal Government are coordinated, the heads of executive departments and agencies identified in section 7(a)(ii) of this order shall:

(a) no later than 6 months from the date of this order, develop and implement a plan for the coordination of BSAT security oversight that:

(i) articulates a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP;

(ii) ensures consistent and timely identification and resolution of BSAT security and compliance issues;

(iii) facilitates information sharing among departments and agencies regarding ongoing oversight and inspection activities; and

(iv) provides for comprehensive and effective Federal oversight of BSAT security; and

(b) no later than 6 months from the issuance of final rules and guidance as described in section 5 of this order, and annually thereafter, review for inconsistent requirements and revise or rescind, as appropriate, any regulations, directives, guidance, or policies regarding BSAT security within their department or agency that exceed those in the updated SAR and guidance as described in section 5 of this order.

SEC. 7. *Implementation*. (a) Establishment, Operation, and Functions of the Federal Experts Security Advisory Panel.

(i) There is hereby established, within the Department of Health and Human Services for administrative purposes only, the Federal Experts Security Advisory Panel (Panel), which shall make technical and substantive recommendations on BSAT security concerning the SAP.

(ii) The Panel shall consist of representatives from the following, who may consult with additional experts from their department or agency as required:

1. the Department of State;
2. the Department of Defense;
3. the Department of Justice;
4. the Department of Agriculture (Co-Chair);
5. the Department of Commerce;
6. the Department of Health and Human Services (Co-Chair);
7. the Department of Transportation;
8. the Department of Labor;
9. the Department of Energy;
10. the Department of Veterans Affairs;
11. the Department of Homeland Security;
12. the Environmental Protection Agency;
13. the Office of the Director of National Intelligence;
14. the Office of Science and Technology Policy;
15. the Joint Chiefs of Staff; and
16. any other department or agency designated by the Co-Chairs.

(iii) To assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policies set forth in sections 1, 4, 5, and 6 of this order, the Panel shall, no later than 4 months from the date of this order, provide consensus recommendations concerning the SAP on:

1. the designation of Tier 1 agents and toxins;
2. reduction in the number of agents on the Select Agent List;
3. the establishment of appropriate practices to ensure reliability of personnel with access to Tier 1 agents and toxins at registered facilities;
4. the establishment of appropriate practices for physical security and cyber security for facilities that possess Tier 1 agents. The Department of Homeland Security shall Chair a Working Group of the Panel that develops recommended laboratory critical infrastructure security standards in these areas; and

5. other emerging policy issues relevant to the security of BSAT.

Thereafter, the Panel shall continue to provide technical advice concerning the SAP on request.

(iv) If the Panel is unable to reach consensus on recommendations for an issue within its charge, the matter shall be resolved through the interagency policy committee process led by the National Security Staff.

(v) The Secretaries of Health and Human Services and Agriculture and the Attorney General shall report to the Assistant to the President for Homeland Security and Counterterrorism on the consideration and implementation of Panel recommendations concerning the SAP, including a rationale for failure to implement any recommendations.

(vi) The Panel shall be chartered for a period of 4 years subject to renewal through the interagency policy committee process led by the National Security Staff.

(b) To further assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policy set forth in sections 1, 4, 5, and 6 of this order, the National Science Advisory Board for Biosecurity shall provide technical advice and serve as a conduit for public consultation, as needed, on topics of relevance to the SAP.

SEC. 8. *Sharing of Select Agent Program Information*. (a) Consistent with applicable laws and regulations, the Secretaries of Health and Human Services and Agriculture and the Attorney General shall, no later than 6 months from the date of this order, develop a process and the criteria for making SAP information available to executive departments and agencies when such information is necessary for furthering a public health, safety, security, law enforcement, or national security mission.

(b) SAP information shall continue to be safeguarded properly and handled securely to minimize the risk of disclosing sensitive, personal, and other information protected by the Privacy Act, 5 U.S.C. 552a.

SEC. 9. *General Provisions*. (a) The National Security Staff shall, on a biennial basis, review the implementation and effectiveness of this order and refer to the interagency policy committee process any issues that require further deliberation or adjudication.

(b) Nothing in this order shall be construed to impair or otherwise affect the authority granted by law to a department or agency, or the head thereof, or functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

§ 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,

(II) the methodologies for laboratory examinations and other procedures employed, and

(III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and