

21 USC Ch. 5: VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS**From Title 21—FOOD AND DRUGS****CHAPTER 5—VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS**

Sec.	
151.	Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments.
152.	Importation regulated and prohibited.
153.	Inspection of imports; denial of entry and destruction.
154.	Regulations for preparation and sale; licenses.
154a.	Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria.
155.	Permits for importation.
156.	Licenses conditioned on permitting inspection; suspension of licenses.
157.	Inspection.
158.	Offenses; punishment.
159.	Enforcement; penalties applicable; Congressional findings.

FEDERAL FOOD, DRUG, AND COSMETIC ACT

Nothing contained in chapter 9 (§301 et seq.) of this title shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of this chapter, see section 392(b) of this title.

§151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

(Mar. 4, 1913, ch. 145, §1 (part), 37 Stat. 832; Pub. L. 99–198, title XVII, §1768(a), Dec. 23, 1985, 99 Stat. 1654.)

CODIFICATION

The sections of this chapter are comprised of the sentences of the eighth paragraph under the heading "Bureau of Animal Industry," in the Department of Agriculture Appropriation Act, 1914, as amended.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

AMENDMENTS

1985—Pub. L. 99–198 substituted "in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States" for "from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia".

EFFECTIVE DATE OF 1985 AMENDMENT

Pub. L. 99–198, title XVII, §1768(f), Dec. 23, 1985, 99 Stat. 1655, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [enacting sections 154a and 159 of this title and amending this section and sections 154 and 157 of this title] shall become effective on the date of enactment of this Act [Dec. 23, 1985].

"(2)(A) Subject to subparagraphs (B) through (D), in the case of a person, firm, or corporation preparing, selling, bartering, exchanging, or shipping a virus, serum, toxin, or analogous product during the 12-month period ending on the date of enactment of this Act [Dec. 23, 1985] solely for intrastate commerce or for exportation, such product shall not after such date of enactment, as a result of its not

having been licensed or produced in a licensed establishment, be considered in violation of the eighth paragraph of the matter under the heading 'BUREAU OF ANIMAL INDUSTRY' of the Act entitled 'An Act making appropriations for the Department of Agriculture for the fiscal year ending June thirtieth, nineteen hundred and fourteen', approved March 14, 1913 (as amended by this section) [this chapter], until the first day of the 49th month following the date of enactment of this Act.

"(B) The exemption granted by subparagraph (A) may be extended by the Secretary of Agriculture for a period up to 12 months in an individual case on a showing by a person, firm, or corporation of good cause and a good faith effort to comply with such eighth paragraph with due diligence.

"(C) The exemption granted by subparagraph (A) must be claimed by the person, firm, or corporation preparing such product by the first day of the 13th month following the date of enactment of this Act [Dec. 23, 1985], in the form and manner prescribed by the Secretary, unless the Secretary grants an extension of the time to claim such exemption in an individual case for good cause shown.

"(D) On the issuance by the Secretary of a license to such person, firm, or corporation for such product prior to the first day of the 49th month following the date of enactment of this Act [Dec. 23, 1985], or the end of an extension of the exemption granted by the Secretary, the exemption granted by subparagraph (A) shall terminate with respect to such product."

SHORT TITLE

Act [Mar. 4, 1913, ch. 145, §1 \[part\]](#), 37 Stat. 832, which is classified to this chapter, is popularly known as the "Virus-Serum-Toxin Act".

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

APPROPRIATIONS

An appropriation of \$25,000 was made by act [Mar. 4, 1913](#), for the purpose of carrying into effect these provisions. The appropriation for the fiscal year 1926 was by act [Feb. 10, 1925, ch. 200](#), 43 Stat. 827.

§152. Importation regulated and prohibited

The importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without (1) a permit from the Secretary of Agriculture, or (2) in the case of an article originating in Canada, such permit or, in lieu of such permit, such certification by Canada as may be prescribed by the Secretary of Agriculture.

([Mar. 4, 1913, ch. 145, §1 \(part\)](#), 37 Stat. 832; [Pub. L. 100–449, title III, §301\(d\), Sept. 28, 1988](#), 102 Stat. 1868.)

AMENDMENT OF SECTION

For termination of amendment by section 501(c) of [Pub. L. 100–449](#), see [Effective and Termination Dates of 1988 Amendment](#) note below.

CODIFICATION

See note set out under section 151 of this title.

AMENDMENTS

1988—[Pub. L. 100–449](#) temporarily amended section generally. Prior to amendment, section read as follows: "The importation into the United States, without a permit from the Secretary of Agriculture, of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, are prohibited." See [Effective and Termination Dates of 1988 Amendment](#) note below.

EFFECTIVE AND TERMINATION DATES OF 1988 AMENDMENT

Amendment by [Pub. L. 100–449](#) effective on the date the United States-Canada Free-Trade Agreement enters into force (Jan. 1, 1989), and to cease to have effect on the date the Agreement ceases to be in force, see section 501(a), (c) of [Pub. L. 100–449](#), set out in a note under section 2112 of Title 19, Customs Duties.

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§153. Inspection of imports; denial of entry and destruction

The Secretary of Agriculture is authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.

(Mar. 4, 1913, ch. 145, §1 (part), 37 Stat. 832.)

CODIFICATION

See note set out under section 151 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, or otherwise to carry out this chapter, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid.

(Mar. 4, 1913, ch. 145, §1 (part), 37 Stat. 832; Pub. L. 99–198, title XVII, §1768(b), Dec. 23, 1985, 99 Stat. 1654.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

AMENDMENTS

1985—Pub. L. 99–198 inserted "or otherwise to carry out this chapter," after "domestic animals,".

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–198 effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as a note under section 151 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§154a. Special licenses for special circumstances; expedited procedure; conditions; exemptions; criteria

In order to meet an emergency condition, limited market or local situation, or other special circumstance (including production solely for intrastate use under a State-operated program), the Secretary may issue a special license under an expedited procedure on such conditions as are necessary to assure purity, safety, and a

reasonable expectation of efficacy. The Secretary shall exempt by regulation from the requirement of preparation pursuant to an unsuspended and unrevoked license any virus, serum, toxin, or analogous product prepared by any person, firm, or corporation—

- (1) solely for administration to animals of such person, firm, or corporation;
- (2) solely for administration to animals under a veterinarian-client-patient relationship in the course of the State licensed professional practice of veterinary medicine by such person, firm, or corporation; or
- (3) solely for distribution within the State of production pursuant to a license granted by such State under a program determined by the Secretary to meet criteria under which the State—
 - (A) may license virus, serum, toxin, and analogous products and establishments that produce such products;
 - (B) may review the purity, safety, potency, and efficacy of such products prior to licensure;
 - (C) may review product test results to assure compliance with applicable standards for purity, safety, and potency, prior to release to the market;
 - (D) may deal effectively with violations of State law regulating virus, serum, toxin, and analogous products; and
 - (E) exercises the authority referred to in subclauses (A) through (D) consistent with the intent of this chapter of prohibiting the preparation, sale, barter, exchange, or shipment of worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous products.

(Mar. 4, 1913, ch. 145, §1 [part], as added Pub. L. 99–198, [title XVII](#), [§1768\(c\)](#), [Dec. 23, 1985](#), 99 Stat. 1654.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

EFFECTIVE DATE

Section effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as an Effective Date of 1985 Amendment note under section 151 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§155. Permits for importation

The Secretary of Agriculture is authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful.

(Mar. 4, 1913, ch. 145, §1 (part), 37 Stat. 833.)

CODIFICATION

See note set out under section 151 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§156. Licenses conditioned on permitting inspection; suspension of licenses

All licenses issued under authority of this chapter to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of said chapter, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals.

(Mar. 4, 1913, ch. 145, §1 (part), 37 Stat. 833.)

REFERENCES IN TEXT

This chapter, referred to in text, was in the original "this Act", meaning act [Mar. 4, 1913, ch. 145](#), 37 Stat. 828, which enacted this chapter, sections 155 and 393 of Title 7, Agriculture, section 316 of Title 15, Commerce and Trade, sections 501, 502, 512, 558, and 560 of Title 16, Conservation, and section 630 of former Title 31, Money and Finance, and amended section 83 of former Title 5, Executive Departments and Government Officers and Employees, and sections 518 and 673 of Title 16.

Section 316 of Title 15 was omitted from the Code as superseded by section 5701 et seq. of Title 5, Government Organization and Employees. Section 630 of former Title 31 was repealed by act [Sept. 12, 1950, ch. 946, title III, §301\(64\)](#), 64 Stat. 842. Section 83 of former Title 5 was repealed and reenacted as section 5946 of Title 5 by Pub. L. 89–554, [Sept. 6, 1966](#), 80 Stat. 514. For complete classification of act [Mar. 4, 1913](#), to the Code, see Tables.

CODIFICATION

See note set out under section 151 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§157. Inspection

Any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid.

([Mar. 4, 1913, ch. 145, §1 \(part\)](#), 37 Stat. 833; Pub. L. 99–198, [title XVII, §1768\(d\)](#), [Dec. 23, 1985](#), 99 Stat. 1655.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

AMENDMENTS

1985—Pub. L. 99–198 struck out "licensed under this chapter" after "enter and inspect any establishment".

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–198 effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as a note under section 151 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of the Secretary of Agriculture relating to agricultural import and entry inspection activities under this chapter to the Secretary of Homeland Security, and for treatment of related references, see sections 231, 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§158. Offenses; punishment

Any person, firm, or corporation who shall violate any of the provisions of this chapter shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding \$1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

([Mar. 4, 1913, ch. 145, §1 \(part\)](#), 37 Stat. 833.)

REFERENCES IN TEXT

For explanation of "this chapter", referred to in text, see References in Text note set out under section 156 of this title.

CODIFICATION

See note set out under section 151 of this title.

§159. Enforcement; penalties applicable; Congressional findings

The procedures of sections 672, 673, and 674 of this title (relating to detentions, seizures and condemnations, and injunctions, respectively) shall apply to the enforcement of this chapter with respect to any product prepared, sold, bartered, exchanged, or shipped in violation of this chapter or a regulation promulgated under this chapter. The provisions (including penalties) of section 675 of this title shall apply to the performance of official duties under this chapter. Congress finds that (i) the products and activities that are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce or the free flow thereof, and (ii) regulation of the products and activities as provided in this chapter is necessary to prevent and eliminate burdens on such commerce and to effectively regulate such commerce.

(Mar. 4, 1913, ch. 145, §1 (part), as added Pub. L. 99–198, [title XVII](#), [§1768\(e\)](#), [Dec. 23, 1985](#), 99 Stat. 1655.)

CODIFICATION

See note set out under section 151 of this title.

Another section 1768 of Pub. L. 99–198, cited as a credit to this section, amended section 136y of Title 7, Agriculture.

EFFECTIVE DATE

Section effective Dec. 23, 1985, except as otherwise provided, see section 1768(f) of Pub. L. 99–198, set out as an Effective Date of 1985 Amendment note under section 151 of this title.