

**§ 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,