

## TITLE 21 - FOOD AND DRUGS

### CHAPTER 5 - VIRUSES, SERUMS, TOXINS, ANTITOXINS, AND ANALOGOUS PRODUCTS

#### § 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.