

§ 104.8

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Distribution and Sale, or Transit Shipment Only.

(c) A permit shall not be used after the date specified.

[38 FR 32916, Nov. 29, 1973, as amended at 56 FR 66783, Dec. 26, 1991; 62 FR 13294, Mar. 20, 1997]

§ 104.8 Illegal shipments.

(a) Biological products which are presented for importation without a permit having been issued shall be returned to the country of origin at the expense of the importer or in lieu thereof, destroyed by Department personnel.

(b) Biological products for Distribution and Sale presented for importation under a permit and found to be worthless, contaminated, dangerous, or harmful shall, within a period of 30 days after such finding, be returned to the country of origin at the expense of the importer or in lieu thereof, destroyed by Department personnel: *Provided*, That such product shall not be returned to the country of origin while bearing a U.S. permit number on the label.

PART 105—SUSPENSION, REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS

Sec.

105.1 Suspension or revocation.

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105.4 Termination of licenses and permits for inactivity.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

§ 105.1 Suspension or revocation.

(a) An establishment license, product license, or permit issued under the Virus-Serum-Toxin Act may be formally suspended or revoked after opportunity for hearing has been accorded the licensee or permittee as provided in part 123 of this subchapter if the Secretary is satisfied that the license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation contrary to said Act of any worthless, contaminated, dangerous, or

harmful biological product. Such use may be found to exist if:

(1) The construction of the establishment in which the biological product is prepared is defective, or the establishment is not conducted as required by the regulations in parts 101 through 118 of this subchapter;

(2) The methods of preparation of the product are faulty, or the product contains impurities or lacks potency;

(3) The product is so labeled or advertised as to mislead or deceive the purchaser in any particular;

(4) The licensee, permittee, or the foreign manufacturer has failed to maintain and make available for inspection records in connection with the development and preparation of product, has failed to provide complete and accurate information when requested, or has failed to provide complete and accurate information in the Outline of Production or in reports and records;

(5) The licensee or permittee has violated or failed to comply with any provision of the Virus-Serum-Toxin Act or the regulations in this subchapter;

(6) The license or permit is otherwise used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation, contrary to the Virus-Serum-Toxin Act, of any worthless, contaminated, dangerous, or harmful biological product.

(b) In case of willfulness or where the public health, interest, or safety so required the Secretary may, without hearing, informally suspend such establishment license, product license, or permit upon the grounds set forth in paragraph (a) of this section pending determination of formal proceedings under part 123 of this subchapter for suspension or revocation of the license or permit.

[38 FR 23512, Aug. 31, 1973, as amended at 41 FR 44359, Oct. 8, 1976; 61 FR 52874, Oct. 9, 1996; 64 FR 43044, Aug. 9, 1999]

§ 105.2 Notification of infractions.

If an infraction of a requirement of a product license is brought to the attention of the licensee by written notification thereof by Animal and Plant Health Inspection Service, a subsequent violation of similar nature occurring with the same licensed biological product within 6 months of the said

written notification shall be prima facie evidence of willful violation and the license for the product shall be subject to suspension or revocation under the provisions of § 105.1(b).

[42 FR 31430, June 21, 1977, as amended at 56 FR 66783, Dec. 26, 1991]

§ 105.3 Notices re: worthless, contaminated, dangerous, or harmful biological products.

(a) If at any time it appears that the preparation, sale, barter, exchange, shipment, or importation, as provided in the Virus-Serum-Toxin Act, of any biological product by any person holding a license or permit may be dangerous in the treatment of domestic animals, the Secretary may without hearing notify the licensee or permittee, and pending determination of formal proceedings instituted under part 123 of this subchapter for suspension or revocation of the license or permit insofar as it authorizes the manufacture or importation of the particular product, no person so notified shall thereafter so prepare, sell, barter, exchange, ship, deliver for shipment, or import such product.

(b) If a serial of biological product is found to be unsatisfactory according to applicable Standard Requirements, the Administrator may notify the licensee to stop distribution and sale of the serial.

(c) When notified to stop distribution and sale of a serial or subserial of a veterinary biological product under the provisions of paragraph (a) or (b) of this section, veterinary biologics licensees or permittees shall:

(1) Stop the preparation, distribution, sale, barter, exchange, shipment, or importation of the affected serial(s) or subserial(s) of any veterinary biological product pending further instructions from APHIS.

(2) Immediately, but no later than 2 days, send stop distribution and sale notifications to any wholesalers, jobbers, dealers, foreign consignees, or other persons known to have any such veterinary biological product in their possession, which instruct them to stop the preparation, distribution, sale, barter, exchange, shipment, or importation of any such veterinary biological product. All notifications shall be doc-

umented in writing by the licensee or permittee.

(3) Account for the remaining quantity of each serial(s) or subserial(s) of any such veterinary biological product at each location in the distribution channel known to the manufacturer (licensee) or importer (permittee).

(4) When required by the Administrator, submit complete and accurate reports of all notifications concerning stop distribution and sale actions to the Animal and Plant Health Inspection Service pursuant to § 116.5 of this subchapter.

(Approved by the Office of Management and Budget under control number 0579-0318)

[38 FR 23512, Aug. 31, 1973, as amended at 56 FR 66783, Dec. 26, 1991; 72 FR 17798, Apr. 10, 2007]

§ 105.4 Termination of licenses and permits for inactivity.

(a) If a biological product has not been prepared by a licensee, or imported by a permittee for a period of 5 years or more, the Administrator may require the licensee to show intent to resume production, or the permittee to show intent to resume importation, within 6 months of notification. If the licensee does not resume preparation, or the permittee does not resume importation, within 6 months of notification, or within a mutually agreeable period, the product license, or permit, may be terminated by the Administrator.

(b) When a license or permit is terminated, the licensee or permittee shall continue to be subject to the applicable records provisions of § 116.8.

[61 FR 52874, Oct. 9, 1996]

PART 106—EXEMPTION FOR BIOLOGICAL PRODUCTS USED IN DEPARTMENT PROGRAMS OR UNDER DEPARTMENT CONTROL OR SUPERVISION

AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

§ 106.1 Biological products; exemption.

The Administrator may exempt any biological product from one or more of the requirements of this subchapter if