Animal and Plant Health Inspection Service, USDA

§ 105.2

Distribution and Sale, or Transit Ship-
ment 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 pre-
sented for importation without a per-
mit having been issued shall be re-
turned to the country of origin at the
expense of the importer or in lieu
thereof, destroyed by Department per-
sonnel.

(b) Biological products for Distribu-
tion and Sale presented for importa-
tion 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, de-
stroyed by Department personnel: Pro-
vided, 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, REVOCA-
TION, OR TERMINATION OF BIO-
LOGICAL LICENSES OR PERMITS

Sec.
105.1 Suspension or revocation.
105.2 Notification of infractions.
105.3 Notices re: worthless, contaminated,
dangerous, or harmful biological products.
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 for-
ormally suspended or revoked after op-
portunity for hearing has been ac-
corded the licensee or permittee as pro-
vided in part 123 of this subchapter if
the Secretary is satisfied that the li-
cense or permit is being used to facili-
tate or effect the preparation, sale,
barter, exchange, shipment, or impor-
tation 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 establish-
ment in which the biological product is
prepared is defective, or the establish-
ment 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 con-
tains impurities or lacks potency;

3. The product is so labeled or adver-
tised as to mislead or deceive the pur-
chaser in any particular;

4. The licensee, permittee, or the
foreign manufacturer has failed to
maintain and make available for in-
spection records in connection with the
development and preparation of prod-
uct, 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 vio-
lated or failed to comply with any pro-
vision 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 prepara-
tion, 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 re-
quired the Secretary may, without
hearing, informally suspend such es-
tablishment 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 infracton of a requirement of a
product license is brought to the atten-
tion of the licensee by written notifica-
tion thereof by Animal and Plant
Health Inspection Service, a subse-
quent violation of similar nature oc-
curring with the same licensed biologi-
cal 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).


§ 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 documented 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)


§ 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 52674, Oct. 9, 1996]

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


§ 106.1 Biological products; exemption.

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