

the Animal and Plant Health Inspection Service.

(f) Data acceptable to the Administrator demonstrating that use of the experimental biological product in meat animals is not likely to result in the presence of any unwholesome condition in the edible parts of animals subsequently presented for slaughter.

(g) A statement from the research investigator or research sponsor agreeing to furnish, upon the Administrator's request, additional information concerning each group of meat animals involved prior to movement of these animals from the premises where the test is to be conducted. Such information shall include the owner's name and address; number, species, class and location of animals involved; date shipment is anticipated; along with name and address of consignee, buyer, commission firm or abattoir.

(h) Any information the Administrator may require in order to assess the product's impact on the environment.

[26 FR 7726, Aug. 18, 1961, as amended at 30 FR 11848, Sept. 16, 1965; 52 FR 30131, Aug. 13, 1987; 56 FR 66783, Dec. 26, 1991; 75 FR 20772, Apr. 21, 2010; 81 FR 59433, Aug. 30, 2016]

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

Sec.

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

SOURCE: 38 FR 32916, Nov. 29, 1973, unless otherwise noted.

§ 104.1 Permit required.

Unless otherwise authorized or directed by the Administrator, each permit to import a biological product into the United States shall be issued in accordance with the regulations in this part.

(a) No biological product shall be brought into the United States unless a permit has been issued for such prod-

uct. A separate U.S. Veterinary Biological Product Permit shall be required for each shipment of biological product to be imported: *Provided*, That, a permit shall also be required for each transit shipment of biological products moved through the United States.

(b) Each person importing biological products shall hold an unexpired, unsuspended, and unrevoked permit issued by Animal and Plant Health Inspection Service. Such person shall reside within the United States, or operate a business establishment within the United States, or both.

[38 FR 32916, Nov. 29, 1973, as amended at 56 FR 66783, Dec. 26, 1991; 56 FR 66783, Dec. 26, 1991]

§ 104.2 Permit authorized.

(a) Animal and Plant Health Inspection Service is authorized to issue three types of permits for importing biological products. They shall be:

(1) U.S. Veterinary Biological Product Permit for Research and Evaluation;

(2) U.S. Veterinary Biological Product Permit for Distribution and Sale; or

(3) U.S. Veterinary Biological Product Permit for Transit Shipment Only.

(b) A permit shall not be issued for a biological product from countries known to have exotic diseases, including but not limited to foot-and-mouth disease, highly pathogenic avian influenza, swine vesicular disease, Newcastle disease, and African swine fever, if in the opinion of the Administrator, such products may endanger the livestock or poultry of this country.

(c) A permit shall not be issued until an inspector has determined the condition of the equipment and facilities of the producer, of the applicant, or of both if such a determination is considered necessary by the Administrator.

(d) A permit shall not be issued for a biological product prepared in the United States, exported, and presented for reentry except as provided in § 104.4(d).

[38 FR 32916, Nov. 29, 1973, as amended at 56 FR 66783, Dec. 26, 1991; 56 FR 66783, Dec. 26, 1991; 78 FR 19085, Mar. 29, 2013; 83 FR 15495, Apr. 11, 2018]

Animal and Plant Health Inspection Service, USDA**§ 104.5****§ 104.3 Permit application.**

(a) Each person desiring to import a biological product shall make written application to Animal and Plant Health Inspection Service for a permit. Application forms are available on the Internet at (http://www.aphis.usda.gov/animal_health/vet_biolics/vb_forms.shtml) and application for a permit to import a veterinary biologic for research and evaluation or transit shipment may be made on the Internet at (http://www.aphis.usda.gov/animal_health/permits/vet_bio_permits.shtml).

(b) The application shall specify the type of permit required, the port of entry at which the product shall be cleared through Customs, the estimated quantity involved, and the anticipated date on which the importation shall be made.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66783, Dec. 26, 1991; 75 FR 20772, Apr. 21, 2010]

§ 104.4 Products for research and evaluation.

(a) An application for a U.S. Veterinary Biological Product Permit to import a biological product for research and evaluation shall be accompanied by a brief description of such product, methods of propagating antigens including composition of medium, species of animals or cell cultures involved, degree of inactivation or attenuation, recommendations for use, and the proposed plan of evaluation. The applicant shall also provide any information the Administrator may require in order to assess the product's impact on the environment.

(b)(1) A permit to import a biological product for research and evaluation shall not be issued unless the scientific capabilities of the investigator are determined to be adequate to safeguard domestic animals and protect public health, interest, or safety from any deleterious effects which might result from use of such product. Special restrictions or tests may be specified as part of the permit when they are deemed necessary or advisable by the Administrator.

(2) No person shall ship a product imported under this section for research and evaluation anywhere in or from the United States unless authorized by the Administrator in accordance with the provisions of §103.3 of this subchapter.

(c) A biological product shall not be imported for Research and Evaluation which is not packaged and labeled in accordance with §112.9 of this subchapter.

(d) When a licensed product has been exported from the United States, a permit may be issued to the producer for a small quantity of such product for in vitro Research and Evaluation tests: *Provided*, That, the importation of such product will not endanger the livestock or poultry of this country.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 52 FR 30131, Aug. 13, 1987; 56 FR 66783, Dec. 26, 1991]

§ 104.5 Products for distribution and sale.

An application for a U.S. Veterinary Biological Product Permit to import a biological product for Distribution and Sale shall be accompanied by supporting material necessary to satisfy the requirements provided in this section.

(a) A permit shall not be issued unless the conditions under which the biological product is to be prepared or the methods to be used are such as to reasonably insure that the product is pure, safe, potent, and efficacious.

(1) Two copies of blueprints of the producing foreign establishment shall be submitted with the application unless satisfactory plans are on file with Animal and Plant Health Inspection Service from a previous application. The production facilities to be used for each product prepared at the establishment shall be designated.

(2) The manufacturer shall submit written authorization for properly accredited inspectors to inspect without previous notification, and at such times as may be demanded by the aforesaid inspectors, all parts of the establishment in which biological products shall be prepared, all processes of

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preparation, and all records relative to such preparation.

(3) The manufacturer shall furnish written assurance that a biological product to be imported for Distribution and Sale shall be prepared under the supervision of a person competent by education and experience to handle all matters pertaining to the preparation of such product and that each biological product shall be prepared in accordance with the regulations applicable to the product or in a manner acceptable to the Administrator so as to carry out the purposes of the Act.

(4) The methods to be used in the preparation of each biological product shall be written into an approved Outline of Production prepared in accordance with the applicable provisions of part 114 of this subchapter. Two copies of such Outlines of Production shall be submitted to Animal and Plant Health Inspection Service and be approved before the permit is issued.

(5) Data shall be furnished by the applicant which establishes that the product involved complies with the provisions of the Act and the regulations issued pursuant thereto. When deemed necessary to obtain required information, Animal and Plant Health Inspection Service may require that the product be tested under field conditions within or outside the United States as the occasion demands.

(b) The permittee shall furnish the following:

(1) Adequate facilities for storing all imported biological products. An inspection of such facilities shall be made by inspectors before a permit is issued and additional inspections shall be made at any time subsequent to the importation of the biological products if deemed necessary by the Administrator;

(2) Information regarding all claims to be made on labels and advertising matter used in connection with or related to the biological product to be imported;

(3) Mounted copies of final container labels, carton labels, and enclosures to be used with the imported product as provided in part 112 of this subchapter; and

(4) Samples of each serial from each shipment of biological products im-

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ported or offered for importation. Such samples shall be collected, examined, and tested in a manner specified by the Administrator. The biological products being sampled shall not be further distributed by the permittee until released by Animal and Plant Health Inspection Service.

(Approved by the Office of Management and Budget under control number 0579-0013)

[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 49 FR 21044, May 18, 1984; 56 FR 66783, Dec. 26, 1991; 75 FR 20772, Apr. 21, 2010]

§ 104.6 Products for transit shipment only.

An application for a permit for Transit Shipment Only shall be required when a biological product is being shipped from one foreign country to another foreign country by way of the United States. The shipment shall move under a permit subject to the following restrictions:

(a) The shipment shall be confined to the carrier at all times when such shipment is to transit the United States on the same carrier on which it arrived. If the shipment is to be transferred to a carrier other than the one on which it shall arrive into the United States, a schedule of arrival and departure of each shipment shall be furnished by the permittee to Animal and Plant Health Inspection Service prior to arrival in the United States.

(b) The permittee shall be responsible to Animal and Plant Health Inspection Service for handling, storing, and forwarding of the biological product. Animal and Plant Health Inspection Service shall be notified of all shipments received and forwarded by the permittee and an accurate accounting shall be made.

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[38 FR 32916, Nov. 29, 1973, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991; 61 FR 52873, Oct. 9, 1996]

§ 104.7 Product permit.

(a) A permit shall be numbered and dated.

(b) The purpose for which the product is imported shall be specified on the permit as for Research and Evaluation,

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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 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, 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-
mally 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 provi-
sion 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 infraction 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