

of the United States any unlicensed biological product for experimental use in animals. For the benefit of license applicants and to permit and encourage research, a person may be authorized by the Administrator to ship unlicensed biological products for the purpose of evaluating such experimental products by treating limited numbers of animals, *Provided*, that, the Administrator determines that the conditions under which the experiment is to be conducted are adequate to prevent the spread of disease and approves the procedures set forth in the request for such authorization. Special restrictions or tests may be imposed, especially in the case of products containing live organisms, when they are deemed necessary or advisable by the Administrator. A request for authorization to ship an unlicensed biological product for experimental study and evaluation shall be accompanied by the following:

(a) One copy of a permit or letter of permission from the proper State or foreign animal health authorities of each State or foreign country involved.

(b) Two copies of a tentative list of the names of the proposed recipients and quantity of experimental product that is to be shipped to each individual. In the event of subsequent changes, additional information shall be furnished when such facts are known;

(c) Two copies of a description of the product, recommendations for use, and results of preliminary research work;

(d) Two copies of labels or label sketches which show the name or identification of the product and bear a statement, "Notice! For Experimental Use Only—Not For Sale," or equivalent. The U.S. Veterinary License legend shall not appear on such labels; and

(e) Two copies of a proposed general plan covering the methods and procedures for evaluating the product and for maintaining records of the quantities of experimental product prepared, shipped and used. At the conclusion of field studies, results shall be obtained, summarized, and submitted to 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]

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

Sec.

- 104.1 Permit required.
- 104.2 Permit authorized.
- 104.3 Permit application.
- 104.4 Products for research and evaluation.
- 104.5 Products for distribution and sale.
- 104.6 Products for transit shipment only.
- 104.7 Product permit.
- 104.8 Illegal shipments.

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 product. 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, rinderpest, 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]

§ 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_biologics/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