

§ 104.2

transit shipment of biological products moved through the United States.

(b) Each person importing biological products shall hold an unexpired, un-suspended, 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, fowl pest (fowl plague), 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]

§ 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. Blank forms of application shall be furnished upon request.

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(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]

§ 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