

(1) Licensed biological products shall be prepared as required by the regulations and in accordance with a filed Outline of Production as prescribed in §§114.8 and 114.9 of this subchapter. No change shall be made in the preparation of a biological product without prior approval of the Administrator.

(2) In addition to restrictions imposed by the Administrator pursuant to paragraph (e) of this section, biological products may be subject to restrictions which are imposed by any State or other jurisdiction pertaining to the distribution and use of such products, based on local disease conditions.

(3) When requested by the Administrator, a licensee shall submit a list of licensed biological products prepared in the licensed establishment.

(d) Where the Administrator determines that the protection of domestic animals or the public health, interest, or safety, or both, necessitates restrictions on the use of a product, the product shall be subject to such additional restrictions as are prescribed on the license. Such restrictions may include, but are not limited to, limits on distribution of the product or provisions that the biological product is restricted to use by veterinarians, or under the supervision of veterinarians, or both.

(e) Any person may request that the distribution and use of a veterinary biological product be restricted if the restriction pertains to the protection of domestic animals or the public health, interest, or safety, or both. All requests must be sent, in writing, to the Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, Maryland 20737-1237. Requests must specify the restriction(s) being requested and must explain why the restrictions are needed. Copies of any supporting documents, such as scientific literature, published or unpublished articles, or data from tests, should be attached to the request. When a decision is reached regarding the request, the person submitting the

request will be sent written notification of such decision.

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[39 FR 37763, Oct. 24, 1974, as amended at 48 FR 57472, Dec. 30, 1983; 50 FR 50764, Dec. 12, 1985; 52 FR 11026, Apr. 7, 1987; 56 FR 66783, Dec. 26, 1991; 57 FR 38760, Aug. 27, 1992; 59 FR 67616, Dec. 30, 1994; 62 FR 13294, Mar. 20, 1997]

§102.6 Conditional licenses.

In order to meet an emergency condition, limited market, local situation, or other special circumstance, including production solely for intrastate use under a State-operated program, the Administrator may, in response to an application submitted as specified in §102.3(b) of this part, issue a conditional U.S. Veterinary Biological Product License to an establishment under an expedited procedure which assures purity and safety, and a reasonable expectation of efficacy. Preparation of products under a conditional license shall be in compliance with all applicable regulations and standards and may be restricted as follows:

(a) The preparation may be limited to a predetermined time period which shall be established at the time of issuance and specified on the license. Prior to termination of the license, the licensee may request reissuance. Such requests shall be substantiated with data and information obtained since the license was issued. After considering all data and information available, the Administrator shall either reissue the U.S. Veterinary Biological Product License or allow it to terminate.

(b) Distribution may be limited to the extent necessary to assure that the product will meet the basic criteria for issuance of the conditional license.

(c) Labeling for the product may be required to contain information on the conditional status of the license.

[52 FR 11026, Apr. 7, 1987, as amended at 60 FR 48021; Sept. 18, 1995]

PART 103—EXPERIMENTAL PRODUCTION, DISTRIBUTION, AND EVALUATION OF BIOLOGICAL PRODUCTS PRIOR TO LICENSING

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103.1 Preparation of experimental biological

§ 103.1

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- products.
- 103.2 Disposition of animals administered experimental biological products or live organisms.
- 103.3 Shipment of experimental biological products.

AUTHORITY: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

§ 103.1 Preparation of experimental biological products.

Except as otherwise provided in this section, experimental biological products which are neither composed of nor prepared with organisms or antigens used in biologicals already licensed, shall not be prepared in the production facilities of a licensed establishment. Upon application therefor, the Administrator may authorize the preparation of experimental products on the premises of a licensed establishment if he determines that such preparation will not result in contamination of the licensed products. Each request for permission to prepare an experimental biological product on licensed premises shall indicate the nature of the unlicensed product, designate facilities to be used, and specify precautions which will be taken to prevent contamination of licensed products. Such requests shall be submitted to the Administrator. Research facilities that are entirely separate and apart from facilities used for the preparation of licensed biological products will not be considered a part of the licensed premises for purposes of this section.

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[30 FR 11848, Sept. 16, 1965, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66783, Dec. 26, 1991]

§ 103.2 Disposition of animals administered experimental biological products or live organisms.

Safeguards as herein provided shall be established by the research investigator or research sponsor to control disposition of all animals administered experimental biological products or live organisms.

(a) Surviving test animals (including challenged control animals) shall not be removed from the premises on which the tests are conducted for at least 14 days after administration of an experi-

mental biological product or live organisms: *Provided, however,* That this holding period may be increased or decreased as permitted or requested by the Administrator following review of all relevant information or data available.

(b) All animals administered experimental biological products which are to be slaughtered at establishments subject to the Federal Meat Inspection Act, as amended and extended (21 U.S.C. 601 *et. seq.*) are subject to the applicable requirements of § 309.16 of this title (Meat Inspection Regulations).

(c) Except as otherwise provided in this paragraph, the research investigator or research sponsor shall maintain adequate records relative to the disposition of each animal administered experimental biological products. These records shall be maintained for a minimum period of two years from the date that an experimental product was administered to such animal, and shall show the name and address of the owner; number, species, class and location of the animals; and if sold, the name and address of the consignee, buyer, commission, firm or abattoir: *Provided, however,* That a research investigator or research sponsor may be exempted from these recordkeeping requirements by the Administrator on the basis of acceptable data demonstrating that use of the experimental biological product will not result in the presence of any unwholesome condition in the edible parts of animals subsequently presented for slaughter.

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(44 U.S.C. 3506)

[30 FR 11848, Sept. 16, 1965, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66783, Dec. 26, 1991]

§ 103.3 Shipment of experimental biological products.

Except as provided in this section, no person shall ship or deliver for shipment in or from the United States, the District of Columbia, or any Territory 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) Three 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]

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

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- 104.3 Permit application.
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AUTHORITY: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.2(d.)

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