

§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 re-issue 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

Sec.

103.1 Preparation of experimental biological 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 371.4.

§ 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.

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

[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 experimental 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).