

March 20, 2003

VETERINARY SERVICES MEMORANDUM NO. 800.67

Subject: Shipment of Experimental Veterinary Biological Products
To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum establishes procedures for complying with 9 CFR 103.3 concerning shipment of experimental biological products for evaluation.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.67, dated December 27, 2002.

III. BACKGROUND

The shipment of unlicensed veterinary biological products in or from the United States for experimental use in animals is prohibited by the Virus-Serum-Toxin Act unless authorized under 9 CFR 103.3. To permit and encourage research, APHIS may authorize a person to ship unlicensed veterinary biological products for the treatment of limited numbers of animals under certain conditions. Information required by APHIS to support requests to ship unlicensed veterinary biological products for experimental studies is listed in 9 CFR 103.3. Further instructions for submission of requests are provided below.

IV. PROCEDURES

A. Requests for Authorization

Submit letters requesting authorization to ship unlicensed veterinary biological products for experimental purposes to:

Center for Veterinary Biologics
Licensing and Policy Development
510 South 17th Street, Suite 104
Ames, IA 50010-8197

B. Information Required in Requests

All pertinent information specified in 9 CFR 103.3(a)-(h), except the summary report of results, must accompany a request for permission to ship unlicensed product for evaluation. See Veterinary Services Memorandum No. 800.50, section IV, D, for guidance. For importing experimental products, all pertinent information specified in 9 CFR 104.4 must accompany a request for a United States Veterinary Biological Product Permit.

C. Description of the Product

1. *Products Pending Licensure* - If data from the study are to be used in support of a U.S. Veterinary Biological Product License, describe the product according to the appropriate Outline of Production guidelines in 9 CFR 114.9 and identify the serial(s) of product to be shipped.

2. *Products Not Intended for Licensure* - If data from the study are not intended for support of a license, provide the following information concerning the product:

- a. The method of preparation,
- b. The methods of testing, and
- c. The identity of the serial(s) to be shipped.

D. Test Results on Experimental Serials

For each serial of product identified to be shipped, perform the following tests and submit a summary of serial test results on the APHIS Form 2008, Veterinary Biologics Production and Test Report.

1. *Purity Tests* - All serials of product must be tested and found satisfactory for purity.

2. *Safety Tests* - Products administered to animals must have been found satisfactory in applicable safety tests.

3. *Additional Tests* - The Center for Veterinary Biologics may require additional tests, if appropriate.

E. APHIS Authorizations

When all requirements have been met, the Center for Veterinary Biologics will issue APHIS authorization to ship unlicensed, experimental product with a letter. Authorizations will identify the name of the product to be shipped, list the serial numbers of the product to be used, describe all restrictions, and specify the State(s) where permission has been granted. Date-stamped copies of experimental labels will be returned. Each authorization will usually have a time limit of 1 year. If more time is needed, request an extension supported by an interim report of results. Submit a summary report of results at the end of the experimental trial.

/s/ W. Ron DeHaven

W. Ron DeHaven
Deputy Administrator
Veterinary Services