



VETERINARY SERVICES MEMORANDUM NO. 800.67

Animal and Plant
Health Inspection
Service

Veterinary Services

1400 Independence
Ave., SW

Washington, DC
20250

TO: Veterinary Services Leadership Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: Jack A. Shere
Deputy Administrator

SUBJECT: Shipment of Experimental Veterinary Biological Products

I. PURPOSE

This memorandum establishes procedures to comply with title 9, *Code of Federal Regulations* (CFR), part 103.3, concerning shipment of all experimental veterinary biological products.

II. CANCELLATION

This memorandum replaces Veterinary Services (VS) Memorandum No. 800.67 dated November 16, 2011.

III. BACKGROUND

The shipment of experimental veterinary biological products, including unlicensed products intended for licensure, within or from the United States for use in animals, is prohibited by the Virus-Serum-Toxin Act unless authorized under 9 CFR 103.3. To permit and encourage research and to allow required licensing activities, the Animal and Plant Health Inspection Service (APHIS) may authorize shipment of such products under certain conditions. The regulations at [9 CFR 103.3](#) list information APHIS requires to support requests to ship experimental veterinary biological products. This requirement also applies to shipment of experimental veterinary diagnostic test kits.

IV. PROCEDURES

A. Requests for Authorization

Submit a request for authorization to ship experimental veterinary biological products, using an [APHIS Form 2071](#), to:

The Center for Veterinary Biologics (CVB)
Policy, Evaluation, and Licensing
The National Centers for Animal Health (NCAH)
1920 N. Dayton Avenue

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P.O. Box 844
Ames, IA 50010

Authorized NCAH portal users should submit requests via the portal.

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 authorization to ship experimental products for evaluation. See [VS Memorandum No. 800.50](#), section IV.D, for guidance. In order to import experimental products, apply for a U.S. Veterinary Biological Product Permit for Research and Evaluation, and provide all pertinent information specified in 9 CFR 104.4. You can find guidance regarding this CVB import permit in the [Import-Export section](#) of the CVB web site.

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, specify and describe the product according to the appropriate Outline of Production guidelines in 9 CFR 114.9 and identify the serial of product to be shipped.
2. *Products Not Intended for Licensure.* If data from the study are not intended to support licensure, provide the following information concerning the product:
 - a. The method of preparation.
 - b. The methods of testing and results.
 - c. The identity of the serial or serials.

D. Testing Experimental Serials

For each serial of product, perform the following tests and submit a summary of the results on an [APHIS Form 2008](#), the “Veterinary Biologics Production and Test Report,” or in another format acceptable to APHIS.

1. *Purity Tests.* All serials of product must be tested and found satisfactory for purity. Conduct this testing as specified in pertinent parts of 9 CFR 113, where applicable, or as required by the CVB. This testing is not required for test kits.
2. *Safety Tests.* Products administered to animals must have satisfactory safety test results. Conduct testing as specified in pertinent parts of the

9 CFR, where applicable, or as required by the CVB. This testing is not required for test kits.

3. *Additional Tests.* The CVB may require additional testing.

E. Experimental Labels

9 CFR 103.3 lists required elements of experimental labels. The name, identification, or description of the product must clearly identify the agent, whether it is live or killed, and the nature of the product, and be clearly understandable to those who may come into contact with the product. Do not use trade names, internal jargon, or other identifiers that do not disclose the composition and nature of the product. The experimental label should not be styled as for a product to be distributed and sold; that is, it should be clear that the product is experimental, and the label should prominently display the required warning, "Notice! For experimental use only – Not For Sale". For test kits, place the experimental label on the carton.

F. APHIS Authorization

If APHIS authorizes shipment of the experimental product, the CVB issues a letter or an APHIS Form 2071. Authorizations identify the name of the product, the serial number or numbers, the recipient's name and address, describe all restrictions, and specify the State or States granting permission. APHIS returns date-stamped copies of the experimental labels. Authorizations usually have an expiration date of 1 year past the date of CVB approval, unless the expiration date of the State authorization falls before that time.

If the product is compromised during shipment, one repeat shipment for the specified purpose may be made under the same CVB authorization. In such an instance, notify the CVB of the repeat shipment. If you need additional time, request an extension and submit, concurrently, an interim report of study results. Submit a summary report of results after the end of the experimental study.

V. IMPLEMENTATION/APPLICABILITY

Find additional guidance regarding the need for permission to ship experimental product under 9 CFR 103.3 at the CVB web site
https://www.aphis.usda.gov/animal_health/vet_biologics/publications/pel_6_1.pdf.

This update is effective immediately.