November 16, 2011

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.67

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

FROM: John R. Clifford */s/ John R. Clifford*
Deputy Administrator

SUBJECT: Shipment of Experimental Veterinary Biological Products

I. PURPOSE

This memorandum establishes procedures for complying with title 9, *Code of Federal Regulations* (9 CFR), section 103.3 concerning shipment of experimental biological products for evaluation.

II. CANCELLATION

This memorandum replaces Veterinary Services (VS) Memorandum No. 800.67, dated March 20, 2003, which is cancelled.

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 by 9 CFR 103.3. To permit and encourage research, the Animal and Plant Health Inspection Service (APHIS) may authorize a person to ship unlicensed veterinary biological products for the treatment of limited numbers of animals under certain conditions. The information APHIS requires 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

Biologics licensees, permittees, and applicants should submit letters requesting authorization to ship unlicensed veterinary biological products for experimental purposes to:

Center for Veterinary Biologics
Policy, Evaluation, and Licensing
1920 Dayton Avenue
Ames, IA 50010

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 VS Memorandum 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 U.S. Veterinary Biological Product Permit.

C. Description of the Product

1. *Products Pending Licensure.* If data from the study are to be used to support 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 to support a license, provide the following information concerning the product:

   a. The method of preparation
   b. The methods of testing
   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, the following tests must be performed and a summary of test results submitted on 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 (CVB) may require additional tests, if appropriate.

E. APHIS Authorization

When all requirements have been met, CVB will issue a letter with APHIS authorization to ship unlicensed, experimental product. Authorizations will identify the names of the products to be shipped, list the serial numbers of the products to be used, describe all restrictions, and specify the States where permission has been granted. CVB will return date-stamped copies of experimental labels. Each authorization will usually have a time limit of 1 year. If more time is needed, a request for an extension should be submitted and supported by an interim report of results. At the end of the experimental trial a summary report of results must also be submitted.

V. IMPLEMENTATION AND APPLICABILITY

This update, including the current CVB address, will be effective immediately. This policy applies to all experimental products.