March 14, 2012

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.64

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

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

SUBJECT: Preparation of Experimental Products at Licensed Establishments

I. PURPOSE

Under title 9, *Code of Federal Regulations* (9 CFR), section 103.1, the Animal and Plant Health Inspection Service may authorize the preparation of experimental products on the premises of a licensed establishment if such preparation will not result in contamination of the licensed products. This memorandum provides directions to licensees regarding the introduction of any unapproved organisms or fractions into licensed production facilities.

II. CANCELLATION

This memorandum cancels Veterinary Services (VS) Memorandum 800.64, dated October 1, 1999.

III. GENERAL

A. Production is considered any step in the preparation of a product, as defined in 9 CFR 101.2 under *prepare or preparation*. Production includes processing, testing, packaging, labeling, and storing the biological product.

B. In general, licensees must request permission to introduce **all** organisms into their licensed production facilities, regardless of the use of the organisms. Licensees must receive permission before introducing the organisms into the facilities.

C. A licensee must request permission if the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) determines that the licensed firm's research facility is not separate and apart from the production facility.

D. A licensee is not required to request permission if CVB-IC determines that the licensed firm's research facility is separate and apart from the production facility. However, we suggest that the licensee notify CVB-Policy, Evaluation, and Licensing (CVB-PEL) when isolates or experimental product is transferred to

these research facilities. In some cases, especially for select agents or high profile seeds or killed antigens, it may be prudent to inform CVB.

If the licensee elects to notify CVB of these transfers, the licensee can notify CVB of its intention via a letter that describes what is being transferred, the amount, locations, the recipient, the preparation, shipping conditions, and purpose of the shipment.

In addition, maintaining an inventory could make it easier to show compliance with National Center for Import and Export (NCIE) permits. Although CVB approval is not required for these permits, the recipient must comply with NCIE requirements regarding the receipt of animal pathogens.

IV. PROCEDURES

A. Request permission

1. Submit requests for permission to prepare an experimental veterinary biological product in production facilities of a licensed firm to:

   Center for Veterinary Biologics
   Policy, Evaluation, and Licensing
   1920 Dayton Avenue
   Box 844
   Ames, IA 50010

2. Include the supporting information specified in 9 CFR 103.1:

   a. Methods used to ensure the introduction of the organism or fraction will not result in contamination of a licensed product.

   b. The nature of the experimental product to be prepared from the organism or fraction.

   c. The location (building and room) to be used to prepare the experimental product.

B. Limit production

The CVB-PEL will limit the quantity of experimental product prepared to the amount the licensee needs for the experiment.

C. Revise facility documents

1. After the CVB-PEL authorizes the introduction of an organism or fraction, CVB-IC will require the licensee to:

   a. Submit the revised blueprint legends identifying the organism or fraction and the location where the experimental product will be prepared.

   b. Describe, if required, any additional precautions needed to prevent cross contamination of licensed products, prepared in accordance with VS Memorandum 800.78.

   c. Submit a copy of the letter received from the CVB-PEL authorizing the production of the experimental product in licensed production facilities or introduction of the organism or fraction into licensed production facilities.

2. Send this information to:

   Center for Veterinary Biologics
   Inspection and Compliance
   1920 Dayton Avenue
   Box 844
   Ames, IA 50010