



June 27, 2011

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-15**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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

**FROM:** Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*  
Director  
Center for Veterinary Biologics

**SUBJECT:** Discontinued Reagents: Standard Reference Preparations and Test  
Reagents for Virus Biological Products

**I. PURPOSE**

The purpose of this document is to notify veterinary biologics manufacturers that all Standard Reference Preparations and Test Reagents for Virus Biological Products listed in Veterinary Services Memorandum No. (VS Memo) 800.97 will be discontinued with the following exceptions:

- Veterinary Rabies Reference Vaccine Killed Virus
- Avian Leukosis Virus Subgroup A
- Avian Leukosis Virus Subgroup B
- Infectious Laryngotracheitis Challenge Virus
- Rabies Street Challenge Virus (Dogs, Cats, Sheep, Cattle, Horses)
- Rabies NIH Challenge Virus

All challenge viruses and positive control viruses currently listed in VS Memo 800.97 will be discontinued. Current inventory will be available to veterinary biologics manufacturers in limited quantities for propagation and generation of stock supplies until the supply is exhausted. Each reagent request will be evaluated based on inventory and an appropriate quantity will be supplied to manufacturers. Challenge viruses, positive control viruses, and antisera acceptable to the Animal and Plant Health Inspection Service may be obtained from other vendors, including the National Veterinary Services Laboratories. Antisera obtained from other vendors for neutralization of Master Seed Viruses (MSV) must be characterized for blocking titer and tested for extraneous antibodies, and the results of antiserum testing should be reported with MSV test results. Confirmatory testing of the antisera may be conducted by The Center for Veterinary Biologics (CVB) laboratory.



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### **II. BACKGROUND**

The CVB laboratory routinely provides Standard Reference Preparations and Test Reagents to veterinary biologics manufacturers. Due to reduced resources, the CVB is unable to replenish depleted reagent supplies. Based on information received from biologics manufacturers, Reference Preparations and Test Reagents considered critical will be sustained.

### **III. ACTION**

Procedures for obtaining reagents are described in VS Memo 800.97, Section VI. Specific information regarding production methods are provided by the CVB in all reagent shipments.

### **IV. IMPLEMENTATION/ APPLICABILITY**

This Notice will be effective immediately. Contact the reviewer assigned to your firm if interested in obtaining additional information.