



June 16, 2010

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 10-04

**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: Replacement of the Center for Veterinary Biologics Killed Veterinary Rabies References

I. PURPOSE

This Notice provides information on the availability of the Center for Veterinary Biologics' (CVB) new Killed Veterinary Rabies Reference, Lot 08-14. This reference is used in the National Institutes of Health (NIH) rabies potency test for killed veterinary rabies vaccines and replaces the previous Veterinary Rabies Reference, Lot 06-01.

II. BACKGROUND

The CVB contracted the production of the Veterinary Rabies Reference, Lot 08-14, using the Pasteur Virus strain of rabies propagated on baby hamster kidney cells. The reference was beta-propiolactone inactivated and lyophilized. The reference is nonadjuvanted.

A cooperative study was conducted with four veterinary biologics firms comparing Reference 08-14 and the 6th World Health Organization rabies reference vaccine. Based on the results of the study, each vial of Veterinary Rabies Reference, Lot 08-14, was determined to contain 9.1 international units (IU). When reconstituted with 13 mL of sterile water, Veterinary Rabies Reference, Lot 08-14, will contain 0.7 IU per mL, which is equivalent to the historical mean of Veterinary Rabies Reference, Lot 06-01.

III. POLICY

Veterinary Rabies Reference, Lot 08-14, is available upon request from the CVB. Please follow the procedures outlined in Veterinary Services Memorandum 800.97 for requesting this reagent.



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Effective August 1, 2010, U. S. veterinary biologics manufacturers should conduct the NIH rabies test using Veterinary Rabies Reference, Lot 08-14. If a serial has already been tested with Veterinary Rabies Reference, Lot 06-01, before April 1, 2010, and subsequent testing is required, the subsequent testing should be conducted with Veterinary Rabies Reference, Lot 08-14. Veterinary Rabies Reference, Lot 08-14, may be used prior to August 1, 2010, at the veterinary biologics manufacturer's discretion.

The relative potency values stated in the approved Outlines of Production shall be the serial release value when conducting the NIH rabies potency test using Veterinary Rabies Reference, Lot 08-14. The reconstitution procedure to be followed is included with the Reference and Reagent Data Sheet supplied with the reagent. The initial starting dilution of the reference shall be adequate to meet Title 9, Code of Federal Regulations, Part 113.209 criteria and the validity requirements in the Supplemental Assay Method (SAM) for Potency Testing of Inactivated Rabies Vaccine in Mice Using the National Institutes of Health Test (SAM 308).