



October 4, 2006

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-21

Animal and Plant
Health Inspection
Service

Subject: Replacement of the Center for Veterinary Biologics' Killed Veterinary Rabies Reference

Veterinary Services

Center for Veterinary
Biologics

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

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

I. PURPOSE

This notice provides information on the availability of the Center for Veterinary Biologics' (CVB) new Killed Veterinary Rabies Reference, Lot 06-01. 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 99-02.

II. BACKGROUND

The CVB contracted the production of the Veterinary Rabies Reference, Lot 06-01, using the Pasteur Virus strain of rabies propagated on baby hamster kidney cells. The reference was beta-propiolactone inactivated and lyophilized. The reference does not contain an adjuvant. A cooperative study was conducted with four veterinary biologics firms comparing Reference Lot 06-01 and the 5th World Health Organization (WHO) rabies reference vaccine. Based on the results of that study, each vial of Veterinary Rabies Reference, Lot 06-01 was determined to contain 9.2 international units (IU). When reconstituted with 13 mL of sterile water, Veterinary Rabies Reference, Lot 06-01 will contain 0.7 IU per mL, which is equivalent to the historical mean of Veterinary Rabies Reference, Lot 99-02.

III. ACTION

Reference Lot 06-01 is available upon request from the CVB. Please follow the procedures outlined in Veterinary Services Memorandum 800.97 for requesting this reagent. Effective November 1, 2006, United States veterinary biologics manufacturers should conduct the NIH rabies test using Veterinary Rabies Reference, Lot 06-01. If a serial has already been tested with Veterinary Rabies Reference, Lot 99-02 before November 1, 2006, and subsequent testing is required, then that testing should be conducted with Veterinary Rabies Reference, Lot 06-01.

Relative potency values presently in approved Outlines of Production shall be the release value when using Veterinary Rabies Reference, Lot 06-01. 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 user determined and



Safeguarding American Agriculture
APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339

adequate to meet the Title 9, Code of Federal Regulations, Part 113.209 criteria and the validity requirements in the Supplemental Assay Method for Potency Testing of Inactivated Rabies Vaccine in Mice Using the National Institutes of Health Test (SAM 308).

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director