USDA
United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 19-15

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

FROM: Byron E. Rippke
Director

BYRON RIPPKE Digitally signed by BYRON RIPPKE Date: 2019.12.19 12:36:33 -06'00'

SUBJECT: Availability of New Inactivated Veterinary Rabies Reference

I. PURPOSE

This notice provides information on the availability of the Center for Veterinary Biologics' (CVB) new Inactivated Veterinary Rabies Reference, Lot 17-06. The National Institutes of Health (NIH) rabies potency test for killed veterinary rabies vaccines uses this reference. It replaces the previous Veterinary Rabies Reference, Lot 08-14. Use the new reference in rabies potency testing, as per title 9, *Code of Federal Regulations* (9 CFR), part 113.209.

II. BACKGROUND

CVB contracted the production of Veterinary Rabies Reference, Lot 17-06 using the Pitman-Moore strain of rabies propagated on hamster cells. The reference was beta-propiolactone inactivated and lyophilized. The reference is nonadjuvanted.

Two veterinary biologics firms conducted a cooperative study comparing Reference 17-06 and the 6th World Health Organization International Standard. Based on the results of the study, each vial of Veterinary Rabies Reference Lot 17-06 was determined to contain 1 international unit (IU) when reconstituted with 55.8 mL of sterile water.

It is CVB's intent to set Reference Lot 17-06 to 1 IU for testing. This authority is given to the CVB in accordance with 9 CFR 113.209(b)(1), under the provisions of chapter 37 of "Laboratory Techniques in Rabies", Fourth Edition (1996). This chapter identifies the final potency value of the reference vaccine for use in the NIH test as 1 IU/ml. Firms have 24 months to conform to the change of setting the Rabies product potency release level at 1 IU/mL. For 24 months from the date of this notice, veterinary biologics manufacturers may reconstitute Reference Lot 17-06 with 79.8 mL to contain 0.7 IU/mL. After this transition period, firms must reconstitute Reference 17-06 with 55.8 mL of sterile water to contain 1 IU/ml and use in the NIH test for rabies potency.

III. ACTION (or POLICY)

Veterinary Rabies Reference Lot 17-06 is available upon request from CVB. Please follow the procedures outlined in Veterinary Services Memorandum 800.97 for requesting this reagent.

Effective as of the date of this notice, U.S. veterinary biologics manufacturers should conduct the NIH rabies test using Veterinary Rabies Reference, Lot 17-06. If firms have already tested a serial with Veterinary Rabies Reference Lot 08-14 before the date of this notice, and subsequent testing is required, then firms may conduct subsequent testing (including confirmation of dating) with Veterinary Rabies Reference Lot 08-14. Serials of vaccine tested at release using Veterinary Rabies Reference, Lot 17-06 at the 0.7 IU/ml dilution during the 24 month transition may use the same reference, and reference dilution, for confirmation of dating.

The relative potency values in the approved Outlines of Production shall be the release value when conducting the NIH rabies potency test using Veterinary Rabies Reference, Lot 17-06. Follow the reconstitution procedure included with the Reference and Reagent Data Sheet provided with the reagent. The initial starting dilution of the reference shall be adequate to meet 9 CFR, part 113.209 criteria and the validity requirements in the Supplemental Assay Method for Potency Testing of Inactivated Rabies Vaccine in Mice Using the NIH Test (SAM 308).

IV. IMPLEMENTATION/APPLICABILITY

This action is effective immediately.

V. REFERENCE

Wilbur LA, Aubert MFA. The NIH test for potency. In *Meslin FX, Kaplan MM, Koprowski H, editors. Laboratory techniques in rabies. fourth ed. Geneva: WHO; 1996 p. 360-8.*