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. 12-03

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

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

SUBJECT: Exemption to Shipping a Sample of Inactivated Lot or Bulk Rabies Antigen to the Center for Veterinary Biologics

I. PURPOSE

The purpose of this Notice is to clarify how to request an exemption from shipping a sample of inactivated lot or bulk rabies antigen to the Center for Veterinary Biologics (CVB).

II. BACKGROUND

The CVB Notice published on October 12, 1994, regarding safety testing of Rabies Vaccine, Killed Virus, provided clarification regarding the procedures for conducting and reporting the safety testing defined in Title 9, Code of Federal Regulations (9 CFR) , Part 113.209(d)(2). The Notice indicated that each serial must have samples submitted of each inactivated lot or bulk used to produce a serial. The Notice also indicated that if the finished vaccine is lethal to mice by the intracerebral route, the firm must collect 4 samples of 2 to 5 mL of the inactivated lot or bulk before the addition of the adjuvant or any other chemical, component, or fraction. The firm must conduct the safety testing described in 9 CFR 113.209(d)(2)(i) with one sample, submit an additional sample to the CVB with serial samples, and retain the remaining 2 samples. The Notice indicated each serial must have samples submitted of each inactivated lot or bulk used to produce a serial. Additional clarifications in reference to testing expectations were published in CVB Notice 11-18 dated July 20, 2011.

Since the bulk samples submitted to the CVB are rarely tested, CVB will consider exemption requests to shipping bulk samples to the CVB.

III. ACTION

Firms may request an exemption from shipping the inactivated lot or bulk sample to the CVB with serial samples. Firms should continue to collect at least 3 inactivated lot or bulk samples. Safety testing described in 9 CFR 113.209(d)(2)(i) should be conducted on one sample. Two of these bulk samples should continue to be maintained on site and these samples must be provided to the CVB upon request, in accordance with 9 CFR 113.3(c).

Firms should address requests for an exemption to shipping inactivated lot or bulk sample to their Reviewer in writing. Within one year of the exemption approval, Section VI.B. of the applicable Outlines of Production should be updated to describe the exemption and the date of CVB approval.

IV. IMPLEMENTATION/ APPLICABILITY

This change will be effective 30 days from the date of this Notice. This policy applies to all products containing killed Rabies Virus.