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United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.79

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

FROM: John R. Clifford */s/ John R. Clifford*
Deputy Administrator

SUBJECT: Submission of Host Animal Serum Samples for In Vitro Potency Tests

I. PURPOSE

This memorandum provides guidance to licensees, permittees, and applicants concerning the Center for Veterinary Biologics (CVB) policy on submitting serum samples for in vitro potency testing. This document describes procedures for selecting, authenticating, and submitting serum samples to the CVB from host animals used in the potency evaluation of biological products.

II. REPLACEMENT

This document replaces Veterinary Services (VS) Memorandum No. 800.79 dated October 1, 1990, which is cancelled.

III. BACKGROUND

The regulations at title 9, *Code of Federal Regulations* (9 CFR) 113.6 authorize the testing of biological products. The Standard Requirements in 9 CFR part 113 provide for the submission of serum samples from host animals used in potency tests for confirmatory testing according to the Outline of Production or Standard Requirement. Compliance with this memorandum should preclude the use of additional host animals in evaluating the potency of biological products.

IV. POLICY

A. At least one sample of pre-vaccination and post-vaccination serum from each animal used in the Standard Requirement or Outline of Production potency test for each serial should be retained after in-house testing. The minimum serum sample size should be documented in an approved Outline of Production.

B. The licensee or permittee will hold retained serum samples for potential pre-marketing release confirmatory testing by the CVB. Serum samples should be held at or below -20°C and retained throughout product dating.

C. On selection of a serial for confirmatory testing, the CVB will request corresponding serum samples. The firm's official government sampler should authenticate the origin of the serum samples, their packaging, and the shipment of the samples to the CVB. It is the responsibility of the licensee or permittee to ensure bleeding procedures, blood processing, and in-house testing comply with the regulations. Samples should be submitted in accordance with VS Memorandum No. 800.59.

V. IMPLEMENTATION AND APPLICABILITY

This policy is effective immediately for serum samples from host animals used in potency tests for evaluation of biological products. This memorandum differs from the previous version in that it is no longer necessary to ship accompanying serum samples with every product serial. The policy to ship serum only on request is a privilege for the licensee or permittee. At any time, the CVB may notify a licensee or permittee that serum samples from each serial must be submitted with product samples. The CVB will identify the basis for the changes which may be prompted by inspection, investigation findings, or regulatory compliance concerns.