



Comments due November 23, 2009

United States  
Department of  
Agriculture

**VETERINARY SERVICES MEMORANDUM NO 800.55 (DRAFT DOC 375)**

Animal and Plant  
Health Inspection  
Service

**TO:** Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics  
VS Management Team (VSMT)

Veterinary Services

Center for Veterinary  
Biologics

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**SUBJECT:** Concurrent and Confirmatory Tests of Market Serials

**I. PURPOSE**

The purpose is to establish policies for onset of tests at the Center for Veterinary Biologics (CVB) to ensure appropriate rates of testing licensed veterinary biological products.

**II. CANCELLATION**

This memorandum cancels Veterinary Services Memorandum No. 800.55 dated February 17, 1986.

**III. BACKGROUND**

Prerelease tests of animal biological products are specified in Title 9, Code of Federal Regulations (9 CFR), Part 113.6. The Center for Veterinary Biologics may find it necessary to take corrective action when test results are unsatisfactory.

**IV. POLICY AND PROCEDURES**

- A. Concurrent testing: The CVB initiates testing prior to submission of the licensee or permittee testing results.

To expedite release, CVB may select and schedule serials for concurrent testing within three (diagnostic products) or fourteen (all other biological products) calendar days from receipt of samples. Selection of serials is independent of the receipt of an APHIS Form 2008. In nearly all situations, concurrent testing is adequate to ensure continued product quality. When a serial or subserial is found unsatisfactory at CVB but reported as satisfactory by the firm, the rate of testing may be increased until satisfactory quality of the product can be assured.



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Concurrent testing will be discontinued and confirmatory testing initiated for products or fractions when:

1. Three of five consecutively tested serials or subserials from a single product code are found unsatisfactory by a specific required test.
2. Satisfactory outcome of concurrent tests is in doubt.

B. Confirmatory testing: The CVB verifies test results the firm has submitted.

1. Confirmatory tests will be initiated only after CVB receipt of a VS Form 2008 reporting satisfactory results from the licensee or permittee.
2. Confirmatory tests will be initiated within 60 days of receipt of the VS Form 2008 for any serial.
3. The confirmatory test requirement will be rescinded if the licensee or permittee can demonstrate satisfactory test results for three consecutive serials or subserials. Results will be verified by confirmatory testing or accepted based on review of licensee or permittee results.

C. Regulatory Action

The Biologist Specialist will make all official notifications to the firm regarding regulatory action.