

February 17, 1986

VETERINARY SERVICES MEMORANDUM NO. 800.55

SUBJECT: Concurrent and Confirmatory Tests of Market Serials

To: Biologics Licensees and Permittees
Directors, National Veterinary Services Laboratories
Directors, VS Regions
Biologics Specialists, VS
Area Veterinarians in Charge, VS

I. PURPOSE

The purpose is to establish policies for onset of tests at National Veterinary Services Laboratories (NVSL) to ensure appropriate rates of testing licensed veterinary biological products.

II. BACKGROUND

Prerelease tests of animal biological products are specified in Title 9, Code of Federal Regulations, Part 113.6. To expedite release, NVSL routinely initiates tests on a concurrent basis within 14 calendar days from receipt of samples. In nearly all situations, this concurrent testing is adequate to ensure continued product quality. Under the Average Outgoing Quality Level Concept, when a serial or subserial is found unsatisfactory at NVSL but reported as satisfactory by the firm, the rate of testing is increased. These tests continue on a concurrent basis until satisfactory quality can be assured by testing at the normal rate. However, expenditure of NVSL resources is inappropriate when satisfactory outcome of concurrent tests is in serious doubt. Therefore, a change to confirmatory testing is occasionally indicated for certain products or fractions.

II. POLICY AND PROCEDURES

A. Discontinuance of concurrent testing will only apply to products reported on a VS Form 14-8, Veterinary Biologics Production and Test Report, as satisfactory by the licensee or permittee, but found unsatisfactory by NVSL.

B. Concurrent testing will be discontinued and confirmatory testing initiated when three of five consecutively tested serials or subserials are found unsatisfactory by a specific required test.

C. The Veterinary Biologics Field Office (VBFO) will make all official notifications.

D. During the confirmatory test period, NVSL tests will be initiated only after receipt of a VS Form 14-8 report of satisfactory results at the VBFO from the licensee or permittee.

E. Time for initiating confirmatory tests will not exceed 60 days from receipt of the VS form 14-8 for any serial.

F. The confirmatory test requirement will be rescinded after eight consecutive satisfactory serials or subserials have been found satisfactory for the specific test by the licensee or permittee and NVSL has confirmed these results on at least four of the eight serials or subserials.

/s/

J. K. Atwell
Deputy Administrator
Veterinary Services