

July 14, 1986

VETERINARY SERVICES MEMORANDUM NO. 800.77

Subject: Unsatisfactory Product Stability

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

I. PURPOSE

The purpose of this memorandum is to describe policies and procedures to assure appropriate action when tests by Veterinary Services reveal that a product may not be efficacious throughout the expiration dating period.

II. BACKGROUND

The regulations in Title 9, Code of Federal Regulations (9 CFR), Part 101, Paragraph 101.4(f), and Part 114, Section 114.13, provide for establishment and confirmation of a date designating the end of the period during which a biological product, when properly stored and handled, can be expected with reasonable certainty, to be efficacious. Veterinary Services may find it necessary to take corrective action when stability test results at National Veterinary Services Laboratories are unsatisfactory.

III. POLICIES AND PROCEDURES

A. Test rate

1. Prerelease testing will ordinarily have priority over stability testing.
2. Routine stability tests will be started within the last month of dating.
3. An increase in the stability test rate will be initiated for products found unsatisfactory.

B. Test Reports

Licensees and permittees will be promptly notified of the results of each test using a National Veterinary Services Laboratories Biologics Test Report.

C. Regulatory actions

1. The Veterinary Biologics Field Office will initiate all regulatory actions and make all notifications regarding unsatisfactory stability tests.

2. If three serials (or 20 percent of the serials produced) in a 12-month period are found unsatisfactory for potency within the dating period, the following will apply:

a. The licensee or permittee may continue to use the authorized dating period with the provision that each serial or subserial be tested at mid-dating and at the end of the dating period. The results of each test must be promptly reported to Veterinary Services on a VS Form 14-8, Veterinary Biologics Production and Test Report.

b. Any serial found unsatisfactory at mid-dating must be promptly removed from the market.

c. In lieu of testing at mid-dating, the licensee or permittee may reduce the dating period by one-half.

3. The requirement for mid-dating retest or reduced dating will be rescinded if the licensee or permittee demonstrates that eight consecutive serials are satisfactory when tested for potency at the end of the original dating period and the results are confirmed by Veterinary Services on at least four of the serials. Initiation of confirmatory tests by Veterinary Services may extend past the expiration date of the serial. If a reduced dating period is requested, an outline page revision supported by data specified in 9 CFR 114.13 will be required.

/s/

J. K. Atwell
Deputy Administrator
Veterinary Services