



March 11, 2008

United States
Department of
Agriculture

VETERINARY SERVICES MEMORANDUM NO. 800.60

Animal and Plant
Health Inspection
Service

TO: VS Management Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

Veterinary Services

Washington, DC
20250

FROM: /s/ Andrea M. Morgan for John R. Clifford
Deputy Administrator

SUBJECT: Biological Products Returned to Licensed or Permitted Establishments

I. PURPOSE

This memorandum provides guidance to licensees and permittees on procedures for handling biological products returned to licensed or permitted establishments to ensure compliance with Title 9 Code of Federal Regulations (9 CFR) Part 114.11.

II. CANCELLATION

This memorandum cancels Veterinary Services (VS) Memorandum No. 800.60, dated September 17, 1999.

III. GENERAL

The Center for Veterinary Biologics (CVB) acknowledges that licensees and permittees may occasionally accept the return of veterinary biological products to the licensed or permitted establishment for resale or redistribution. It should be noted that once a product has left the licensed or permitted establishment, it is often difficult to determine if it has been maintained under proper conditions of storage and handling in compliance with 9 CFR 114.11. To ensure that all products that are distributed meet APHIS standards, use the following procedures to handle returned products.

IV. PROCEDURES

- A. Identify and Separate Returned Products - Properly identify all products returned to the licensed or permitted establishment and keep them separate from other products.



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- B. Resale and Redistribution - Licensees and permittees may ship a returned veterinary biological product for resale and redistribution only when adequate documentation is available to ensure that the entire quantity of product returned has been handled and stored in a uniform, acceptable manner compliant with the regulations and the applicable Outline of Production. Preferably, firms should support such documentation by a satisfactory retest of the product for potency and submit the results to CVB on the APHIS Form 2008. The submitted APHIS Form 2008 should be marked as "Other" in Block 12 (Disposition by Firm), with the comment that the report is for information. The firm should indicate in Block 11 (Remarks) that the testing was performed to support redistribution.

- C. Product Not Eligible for Release - Destroy all returned products which do not meet these guidelines, since they are not eligible for release for resale and redistribution. See Veterinary Services Memorandum 800.56 for acceptable methods of disposal.