



November 14, 2011

United States
Department of
Agriculture

VETERINARY SERVICES MEMORANDUM NO. 800.83

Animal and Plant
Health Inspection
Service

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

Veterinary Services

Washington, DC
20250

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

SUBJECT: Export of Serials Before Completion of Serial Release Testing

I. PURPOSE

This memorandum provides guidance concerning the export of veterinary biological products before completion of serial release testing.

II. CANCELLATION

This memorandum cancels Veterinary Services (VS) Memorandum 800.83 dated July 23, 1999.

III. BACKGROUND

According to title 9, *Code of Federal Regulations* (9 CFR), sections 113.5, 113.6, and 116.7, a firm may not export a product serial for distribution and sale before test completion and serial release. VS Memoranda 800.53 and 800.61 provide additional guidance concerning the testing and release of biological products.

In the past, the Animal and Plant Health Inspection Service (APHIS) has occasionally granted exemptions to facilitate concurrent testing in a foreign country. To further expedite such testing, APHIS will now permit the shipment of samples of a completed serial to foreign facilities under the conditions given below.

IV. SERIAL EXPORTS

A. Products for Further Manufacture

APHIS does not require testing before release of serials for further manufacture, except when the Outline of Production specifically includes such a test requirement. Further details concerning the export of such serials before release are provided in VS Memorandum 800.61, section V.H. Requests for release should include a completed APHIS Form 2008, "Veterinary Biologics Production and Test Report".



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B. Products in Final Form, Composition, and Containers

1. Entire Serials. A firm may export a product serial only after tests required by APHIS have been satisfactorily completed and APHIS has released the serial for shipment.
2. Serial Samples. Outlines of Production may include a statement allowing the firm to export serial samples sufficient for any firm-recipient concurrent testing before serial release. The Outline should specify the quantity of serial samples the firm will ship and the name and location of the recipient facility. This information should be included in section VI.B of the Outline of Production.

V. IMPLEMENTATION AND APPLICABILITY

This change is effective as of the date of this memorandum. All current Outlines of Production for applicable products and future Outlines of Production written for such products should conform with this memorandum.