



September 28, 2011

United States  
Department of  
Agriculture

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-20**

Animal and Plant  
Health Inspection  
Service

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

Veterinary Services

Center for Veterinary  
Biologics

**FROM:** Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*  
Director  
Center for Veterinary Biologics

1920 Dayton Avenue  
PO Box 844  
Ames, IA 50010  
(515) 337- 6100

**SUBJECT:** Supplemental Assay Methods

**I. PURPOSE**

The purpose of this Notice is to present a current list of Supplemental Assay Methods (SAMs) which describe procedures, methods, and techniques used by the Center for Veterinary Biologics (CVB) for official assays of biological products according to Title 9, Code of Federal Regulations (9 CFR) Part 113.2(a).

**II. CANCELLATION**

This Notice cancels Veterinary Services Memorandum No. 800.93 dated September 6, 2006, and the Listing of Supplemental Assay Methods dated August 2006.

**III. APPLICATION**

SAMs contain detailed instructions for conducting officially required tests following the requirements in the 9 CFR. They are not intended to supersede procedures in filed Outlines of Production that state alternative procedures. CVB protocols referenced in SAMs can be found on the CVB website.

**IV. IDENTIFICATION OF SAMs**

- A. The CVB will utilize a standardized title page format on all SAMs which includes the testing protocol heading, the descriptive title of the document, the date of the most recent version, the number, the standard requirement to which it applies, and the name of a person who has agreed to act as primary contact for comments and questions about the document.
- B. Reference to SAMs should be made by the letters "SAM" and the applicable number.

## **CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-20**

Page 2

- C. CVB will number revisions of SAMs the same as the original and show the new date of issuance with the date of the one being superseded.

### **V. PREPARATION AND DISTRIBUTION**

The CVB will prepare and distribute SAMs. Initial distribution will be made electronically or by hardcopy to licensees, permittees, applicants, and appropriate Veterinary Services personnel. You may obtain current SAMs by accessing the Center for Veterinary Biologics web site at:

[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/vb\\_sams.shtml](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_sams.shtml)

### **VI. AVAILABILITY**

The CVB will periodically issue notices of the addition, revision, or deletion of SAMs. CVB will maintain a current listing of SAMs on the Center for Veterinary Biologics website at:

[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/publications/CurrentSAMs.pdf](http://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentSAMs.pdf)