



July 12, 2011

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-17

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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

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

SUBJECT: Withdrawal of Supplemental Assay Method (SAM) for the Mikrozone
Electrophoretic Separation of Blood Fractions Used in Veterinary
Biologics, SAM 509

I. PURPOSE

This Notice is to inform interested parties that the Center for Veterinary Biologics (CVB) will be inactivating Supplemental Assay Method (SAM) 509, "Supplemental Assay Method for the Mikrozone Electrophoretic Separation of Blood Fractions Used in Veterinary Biologics".

II. BACKGROUND

A SAM is a technical bulletin containing detailed instructions for conducting a test. Such instructions are in accordance with the test procedures currently followed at the CVB. When they pertain to procedures that are no longer conducted, the documents are inactivated. SAM 509 was originally published December 15, 1970. As part of the most recent review of SAM 509, it was determined that the procedure outlined in SAM 509 has not been conducted at the CVB for a number of years, and the equipment specified in the SAM is no longer commercially available.

Firms may reference CVB SAMs in their Outlines of Production if they also use that method. When a SAM is inactivated by the CVB, the firm needs to create their own document to provide the details of the procedure.

III. ACTION

SAM 509 has been inactivated. Firms referring to this document in their Outlines of Production will need to replace the reference with the details of the test.



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IV. IMPLEMENTATION/ APPLICABILITY

As firms conduct annual reviews of their Outlines of Production, they should note if this SAM is referenced and replace the reference with testing details. New Outlines, Special Outlines, or ammended Outline pages should be submitted to the assigned Reviewer for filing.