



June 16, 2010

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 10-06

**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 216

I. PURPOSE

The purpose of this document is to notify veterinary biologics manufacturers that Supplemental Assay Method (SAM) 216 will be removed from the list of approved SAMs, effective immediately.

II. BACKGROUND

SAM 216 describes an indirect enzyme-linked immunosorbent assay (ELISA) that is used to determine the potency of commercial equine tetanus antitoxin.

III. ACTION

Biologics manufacturers who utilized SAM 216, as an assay method in studies currently in progress, may complete those studies as planned. Protocols and reports of future studies should not reference this document but provide testing details or a reference to an Outline of Production or Special Outline which contains the details.

Biologics manufacturers who utilize this SAM as a procedure in the current Outlines of Production should update these Outlines to refer to their own Special Outline or provide testing details within the Outline of Production. This Special Outline or amended Outline of Production should provide a complete description of the testing protocol. These changes should be in place within 1 year of the date of this Notice as the relevant Outlines of Production undergo their annual review.



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