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United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-14

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 Methods 101, 102, 105, and 125

I. PURPOSE

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

- Titration of Bovine Viral Diarrhea Virus in Vaccines (SAM 101)
- Titration of Parainfluenza-3 Virus in Vaccines (SAM 102)
- Titration of Infectious Bovine Rhinotracheitis Virus in Vaccines (SAM 105)
- Titration of Bovine Rotavirus in Vaccines (SAM 125)

II. BACKGROUND

SAM 101 describes an *in vitro* assay method which employs a cell culture system utilizing cytopathic effect (CPE), direct fluorescent antibody (FA), and/or indirect FA (IFA) staining to determine the Bovine Viral Diarrhea Virus content of modified live veterinary vaccines. SAM 102 describes an *in vitro* assay which employs a cell culture system and uses CPE and/or hemadsorption of guinea pig erythrocytes to determine the Parainfluenza-3 viral content of vaccines. SAM 105 describes an in *vitro test* method which utilizes viral plaque forming units in a cell culture system to titer Infectious Bovine Rhinotracheitis in modified live veterinary vaccines. SAM 125 describes an *in vitro* assay method which employs a cell culture system and CPE, or alternatively IFA, to determine the Group A Bovine Rotavirus content of vaccines. The processes described in these SAMS are very similar and have been combined into SAM 128. SAM 128 reduces redundancy, provides specific details regarding these procedures, and includes procedures for titration of additional bovine viruses not currently described in approved SAMs, including Bovine Bluetongue virus, Bovine Adenovirus, Bovine Parvovirus, and Bovine Respiratory Syncytial Virus.

III. ACTION

Biologic manufacturers who utilized SAMs 101, 102, 105, and/or 125 as assay method(s) in studies currently in progress may complete those studies as planned. Protocols and reports of future studies should not reference these documents, but should instead refer to SAM 128. Biologics manufacturers who utilize these SAMs as procedures in current Outlines of Production should updates these Outlines to refer to SAM 128 within one year of the date of this notice.