



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-15

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

FROM: Byron E. Rippke
Director

SUBJECT: Center for Veterinary Biologics Laboratory-supplied Reagents

I. PURPOSE

The purpose of this Notice is to inform veterinary biologics manufacturers and other interested parties of the process for requesting reagents from the Center for Veterinary Biologics (CVB) and guidance regarding use of these reagents.

II. BACKGROUND

The CVB provides standardized reagents to conduct serial release potency testing according to title 9, *Code of Federal Regulations*, corresponding Supplemental Assay Methods, and CVB Protocols.

The CVB Reagents Catalog lists currently available reagents. Each reagent is requested by completing an APHIS Form 2018. The fillable PDF form and instructions are available via the CVB Website at https://www.aphis.usda.gov/library/forms/pdf/APHIS_2018.pdf.

Each reagent is supplied with a Reagent Data Sheet (DAT) indicating testing use instructions, expiration date, and lot preparation information.

III. ACTION

To help expedite filling reagent requests, the updated APHIS Form 2018 indicates to now submit the completed forms directly to the reagents email group at VS.STAS.CVB.Reagent.Requests@aphis.usda.gov.

As replacement reagent lots are cleared for use, the CVB Reagent Catalog is updated. The reagent lot being replaced is tested a final time and, if results warrant, the expiration date extended. After this time, the lot will no longer be monitored by the CVB. The final extension allows biologics manufacturers to use stored supplies of the reagent lot. As DATs are updated to reflect use instruction changes or

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-15

Page 2

expiration dates, they are posted to the CVB Website (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/biologics-regulations-and-guidance/ct_vb_dats). Firm personnel are responsible for following the most recent information. The DATs will be removed from the Website after the final expiration date. Any reagents previously supplied by the CVB that did not have an expiration date included are considered expired.

When CVB-supplied reagents are stored or used differently than stated in the DAT use instructions, the changes must be supported by data that has been approved by the CVB.

IV. IMPLEMENTATION/APPLICABILITY

This process is effective immediately.