USDA
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. 18-09

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

FROM: Byron Rippke
Director

USDA

Digitally signed by PAUL HAUER
DN: c=US, o=U.S. Government, ou=Department of Agriculture, cn=PAUL HAUER, 0.9.2342.19200300.100.1.1=12001000004315
Date: 2018.06.25 12:45:45 -05'00'

SUBJECT: Implementation Period for the Submission of Adverse Event Reports

I. PURPOSE

The purpose of this notice is to inform all licensees and permittees that there will be a phase-in period for implementation of the amended Virus-Serum-Toxin Act regulations that require all veterinary biologics licensees and permittees to record and submit reports to the Center for Veterinary Biologics (CVB) concerning adverse events associated with the use of the biological products they produce or distribute.

II. BACKGROUND

On May 17, 2018, Docket Number APHIS-2014-0063, VSTA Records and Reports Specific to International Standards for Pharmacovigilance was published in the Federal Register, Volume 83, Number 96. The Federal Register publication included background information, along with the description of the changes to title 9 *Code of Federal Regulations* (9 CFR) including:

a) 9 CFR Part 101 - DEFINITIONS, adding the definitions for “adverse event” and “adverse event report”; and
b) 9 CFR Part 116 - RECORDS and REPORTS, describing the requirements for recording adverse events and submitting adverse event reports.

III. ACTION

The effective date of the new regulation is June 18, 2018. There will be a minimum 18 month phase-in period for the implementation of the regulations during which the CVB will not require licensees and permittees to submit the adverse event reports described in 9 CFR 116.9. This does not, however, preclude the existing requirement for mandatory reporting under 9 CFR 116.5(b). During the implementation period, the CVB will work with industry to develop guidance documents explaining what actions CVB expects licensees and permittees to take in order to be in compliance with the new regulation.

IV. IMPLEMENTATION/ APPLICABILITY

The phase-in period for implementation of the new regulations is effective immediately.