Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 18-05

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

FROM: Byron Rippke
Director

BYRON RIPPKE
Digitally signed by BYRON RIPPKE
DN: c=US, o=U.S. Government, ou=Department of Agriculture, cn=BYRON RIPPKE, 0.9.2342.19200300.100.1.1=12001000004093
Date: 2018.03.30 07:29:34 -05'00'

SUBJECT: Detection of Senecavirus A in Veterinary Biological Products

I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is aware that certain veterinary biological products may contain a contaminating virus not easily detected by current routine test methods and to describe actions to address this issue.

II. BACKGROUND

Senecavirus A (SVA) is a single-stranded RNA virus belonging to the family *Picornaviridae* that causes blister-like lesions on the mouth, snout, and hooves in susceptible swine. These lesions are clinically indistinguishable from lesions caused by exotic agents including foot-and-mouth disease, swine vesicular disease, vesicular stomatitis, and swine vesicular exanthema. This virus was uncommon in the U.S. prior to 2015, but has become more prevalent since that time. SVA has been found as a contaminant in porcine trypsin and serum.

Under the authority of the Virus-Serum-Toxin Act and title 9, *Code of Federal Regulations* (9 CFR), the CVB requires that all veterinary biological products be tested for purity. The tests described in 9 CFR 113.53 (Requirements for ingredients of animal origin used for production of biologics) are not able to detect the presence of SVA.

III. ACTION (or POLICY)

The CVB is issuing this notice to ensure that veterinary biological product manufacturers who use ingredients of animal origin derived from swine in their production processes are aware of this issue and can prevent the use of material that does not meet acceptable standards for purity and quality in the manufacturing process.

Results of of all testing for extraneous agents conducted on ingredients of animal origin, including tests required by 9 CFR 113.53 shall be recorded by the testing laboratory and made a part of the licensee's records. If requested, these data would be made available to the CVB for review.

To address the issue the CVB has developed assays for the detection of SVA nucleic acid as well as for the detection of viable SVA. These protocols are available on the CVB website.

IV. IMPLEMENTATION/ APPLICABILITY

The CVB is now testing all Master Seeds and Master Cell Stocks that have been produced using ingredients derived from swine for the presence of SVA.