



CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 16-03

Animal and Plant
Health Inspection
Service

Veterinary Services
Center for Veterinary
Biologics

1920 Dayton Avenue
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Ames, IA 50010

(515) 337-6100

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

FROM: Byron Rippke
Director

SUBJECT: Veterinary Biologics Containing Senecavirus A

I. PURPOSE

The purpose of this notice is to inform interested parties that the Center for Veterinary Biologics (CVB) is accepting veterinary biologics product license and permit applications for veterinary biological products used in the prevention, diagnosis, and treatment of Senecavirus A (SVA) also known as Seneca Valley Virus (SVV).

II. BACKGROUND

SVA is a non-enveloped single-stranded RNA virus of the family *Picornaviridae* of which Foot and Mouth Disease Virus and Swine Vesicular Disease Virus are also members. SVA is an emerging pathogen causing blister-like lesions on the mouth, snout, or hooves in susceptible swine, indistinguishable from reportable vesicular Foreign Animal Diseases. Recent case reports in the U.S. and Brazil have identified SVA as the cause of high mortality in piglets less than seven days of age.

III. ACTION (or POLICY)

Interested parties should refer to Title 9, Code of Federal Regulations, Chapter I, Subchapter E; Veterinary Services (VS) Memorandum 800.50, Basic License Requirements and Guidelines for Submission of Materials in Support of Licensure; VS Memorandum 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale; and VS Memorandum 800.73, General Guidance for Test Kits Intended for the Diagnosis of Animal Diseases. This information is available on the CVB website:

www.aphis.usda.gov/animalhealth/cvb_regsandguidance

IV. IMPLEMENTATION/ APPLICABILITY

Applications and supporting materials should be submitted to the CVB-Policy, Evaluation, and Licensing for review. Licenses or permits for test kits that detect antigen will contain distribution restrictions.