



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE 23-11

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

FROM: David M. White
Acting Director

SUBJECT: Killed/Non-viable Veterinary Vaccines and Veterinary Diagnostic Products Targeting Egg Drop Syndrome in Chickens

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 killed/non-viable veterinary biological products used to vaccinate chickens against Egg Drop Syndrome (EDS) and veterinary diagnostic products for EDS.

II. BACKGROUND

EDS is caused by Duck Adenovirus A (DAdV-A) in the genus Atadenovirus under the *Adenoviridae* family. DAdV-A is a double-stranded non-enveloped DNA virus that causes infected chickens to lay soft/thin-shelled chicken eggs or chicken eggs without shells. The disease has been reported on chicken layer farms in several countries outside the United States. This virus was sporadic in the United States prior to 2019 and has become more prevalent since that time.

III. ACTION (or POLICY)

Parties interested in licensing or permitting an EDS vaccine or diagnostic product 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; and VS Memorandum 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale. This information is available on the CVB website:

www.aphis.usda.gov/animalhealth/cvb_regsandguidance

IV. IMPLEMENTATION/ APPLICABILITY

Applications and supporting materials may be submitted to the CVB-Policy, Evaluation, and Licensing for review effective immediately.