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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-17

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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

FROM: Richard E. Hill, Jr. /s/ Byron E. Rippke, for
Director
Center for Veterinary Biologics

SUBJECT: Accepting Product License Applications for Epizootic Hemorrhagic
Disease Vaccine

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 Epizootic Hemorrhagic Disease Vaccine.

II. BACKGROUND

Epizootic hemorrhagic disease virus (EHDV) serotypes 1 and 2 have been implicated in epizootics of white-tailed deer in the United States and Canada, with serotype 2 most often implicated. Serotype 6 has been identified from samples collected in several states of the United States. The EHDVs belong to the genus *Orbivirus*, family *Reoviridae*. EHDV is transmitted via a *Culicoides* biting fly or midge. Epizootic hemorrhagic disease (EHD) can have severe disease impacts in wild and captive white-tailed deer.

III. ACTION

The CVB will consider license, including conditional license, and permit applications for Epizootic Hemorrhagic Disease Vaccine. The Serotypes of the included acceptable fractions are limited to those isolated from animals naturally infected in the United States. Interested parties should refer to Title 9, Code of Federal Regulations, Subchapter E; Veterinary Services Memorandum (VS Memo) 800.50, Basic License Requirements for Applicants; and VS Memo 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale. This information is available on the CVB website: www.aphis.usda.gov/animal_health/vet_biologics/vb_regs_and_guidance.shtml

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



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