



October 5, 2005

United States  
Department of  
Agriculture

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-18**

Animal and Plant  
Health Inspection  
Service

Subject: Canine Influenza Virus Vaccine and Related Diagnostic Test Kits

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants  
Area Veterinarians in Charge, VS  
State Veterinarians

Center for Veterinary  
Biologics

Veterinary Services Management Team  
Directors, Center for Veterinary Biologics

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**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 Canine Influenza Virus Vaccine and related diagnostic test kits.

**II. BACKGROUND**

Recent outbreaks of respiratory disease in canines in the United States have been linked to canine influenza virus. Originally observed in greyhound dogs, the virus lately has spread to other canine populations. Serological and molecular evidence suggests that the causative agent is closely related to equine influenza A (H3N8) virus. Confirmed cases have been reported in several states.

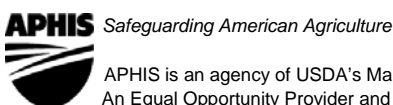
**III. ACTION**

The CVB will consider license and permit applications for Canine Influenza Virus Vaccine and related diagnostic test kits. Interested parties should refer to Title 9, Code of Federal Regulations, Subchapter E; Veterinary Services (VS) Memorandum 800.50, Basic License Requirements for Applicants; VS Memorandum 800.101, U.S. Veterinary Biological Product Permits for Distribution and Sale; and VS Memorandum 800.73, General Requirements for Immunodiagnostic Test Kits for the Detection of Antibody or Antigen, for guidance. This information is available on the CVB website: [www.aphis.usda.gov/vs/cvb/regsandguidance.htm](http://www.aphis.usda.gov/vs/cvb/regsandguidance.htm)

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

/s/ Byron E. Rippke for

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics



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