



June 23, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-12

**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
Area Veterinarians in Charge, VS
State Veterinarians

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

SUBJECT: Issuance of a Conditional License for Canine Influenza Vaccine, H3N8,
Killed Virus

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Schering-Plough Animal Health Corp., Establishment No. 165A, Elkhorn, Nebraska, for the manufacture and distribution of Canine Influenza Vaccine, H3N8, Killed Virus.

A veterinary biological product regulated under the Virus-Serum Toxin Act must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in Title 9, Code of Federal Regulations (9 CFR) Part 102, regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstances. The special circumstance addressed here is the absence of other licensed veterinary biological products for use in the control of respiratory disease associated with canine influenza virus infection in dogs.

This conditional license was issued following the acceptance of data supporting product purity, product safety under normal conditions of use in field safety trials, and demonstration that the product has a reasonable expectation of efficacy. The conditional license will expire one year from the date of the license. In accordance with 9 CFR 102, progress acceptable to APHIS toward regular licensure must be made in order for APHIS to consider reissuance of the conditional license.



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