



October 16, 2012

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-22

**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 Leadership Team

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

SUBJECT: Issuance of a Conditional License for Equine Rhinitis A Vaccine

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Boehringer Ingelheim Vetmedica, Inc, Establishment No. 124, St. Joseph, Missouri, for the manufacture and distribution of Equine Rhinitis A Vaccine, 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, Part 102, regarding the licensing of veterinary biological products provide that a conditional veterinary biological product license may be issued to meet an emergency condition, limited market, local situation, or special circumstance. The special circumstance addressed here is that there are no Equine Rhinitis Type A vaccines available for high risk/performance horses.

Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy. This conditional license was issued on the basis that the licensee demonstrated that the product has a reasonable expectation of efficacy. Safety of the product has been established through a safety study. APHIS will evaluate their progress throughout the next year. The conditional license will expire one year from the date of the license.



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