



November 18, 2011

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-23

**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 West Nile Virus Vaccine, Killed
Virus

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 West Nile Virus 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 the availability of a West Nile vaccine approved for use in alligators.

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 has demonstrated the product has a reasonable expectation of efficacy. Safety of the product has been established through a safety study. The conditional license will expire one year from the date of the license.



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