



November 4, 2013

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-15

**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: Steven A. Karli
Acting Director
Center for Veterinary Biologics

SUBJECT: Issuance of a Conditional License for Bronchitis Vaccine, Georgia Type,
Live Virus

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Zoetis, Inc., Establishment No. 190, Lincoln, Nebraska, for the manufacture and distribution of Bronchitis Vaccine, Georgia Type, Live Virus. The product is based on the Georgia 2008 strain of infectious bronchitis 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 currently licensed Bronchitis Vaccine, Georgia Type, Live Virus have not shown protection against the infectious bronchitis virus, Georgia 2008.

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 efficacy and safety of the product. 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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