



CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 15-11

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: Byron E. Rippke
Director

**BYRON
RIPPKE**

Digitally signed by BYRON RIPPKE
DN: c=US, o=U.S. Government,
ou=Department of Agriculture,
cn=BYRON RIPPKE,
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Date: 2015.09.15 12:26:49 -05'00'

SUBJECT: Issuance of a Conditional License for Canine Lymphoma Vaccine,
DNA

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Merial, Inc., Establishment No. 298, Athens, Georgia, for the manufacture and distribution of Canine Lymphoma Vaccine, DNA.

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 need for a product for the therapeutic immunization of dogs with large B-cell lymphoma after remission following chemotherapy.

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 Merial, Inc., has demonstrated that the product has a reasonable expectation of efficacy. Safety of the product has been established through safety studies and field safety trials. Merial has provided acceptable evidence of commitment to APHIS to complete studies to demonstrate the efficacy of this product and to conduct any other work required for full licensure. APHIS will evaluate their progress. The conditional license will expire two years from the date of the license.