



United States  
Department of  
Agriculture

March 26, 2007

Animal and Plant  
Health Inspection  
Service

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 07-03**

Veterinary Services

**Subject:** Issuance of a Conditional License for Canine Melanoma Vaccine, DNA

Center for Veterinary  
Biologics

**To:** Biologics Licensees, Permittees, and Applicants  
Veterinary Services Management Team  
Directors, Center for Veterinary Biologics  
Area Veterinarians in Charge, VS  
State Veterinarians

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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 Melanoma 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 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 special circumstance. The special circumstance addressed here is the need for a product to treat dogs with stage II or stage III oral melanoma in which local disease control has been achieved.

Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy. The 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 field safety trials. Merial, Inc., has provided a written 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 later this year. The conditional license will expire 1 year from the date of the license.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics



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