



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 23-15

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Geetha Srinivas, DVM, PhD
Director

SUBJECT: Issuance of a Conditional License for Rabbit Hemorrhagic Disease Virus

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Medgene Labs, Establishment No. 474, Brookings, South Dakota, for the manufacture and distribution of Rabbit Hemorrhagic Disease Vaccine, Serotype 2, Killed Baculovirus Vector.

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 disease in rabbits caused by Rabbit Hemorrhagic Disease Virus.

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 that the product has a reasonable expectation of efficacy. APHIS will evaluate their progress throughout the next year. The conditional license will expire one year from the date of the license.