



June 7, 2012

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-13**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

1920 Dayton Avenue  
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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 Foot and Mouth Disease Virus  
Vaccine, Live Adenovirus Vector

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional license to Antelope Valley Bios, Inc., Establishment No. 419, Lincoln, Nebraska, for the manufacture and distribution of Foot and Mouth Disease Virus Vaccine, Live Adenovirus 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 the need for the vaccine in the event of an emergency condition. Domestic distribution will be under APHIS control as part of an official animal disease control program.

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 several safety studies, including a field safety trial announced through a Federal Register Notice. The conditional license will expire 2 years from the date of the license.



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