



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS DRAFT NOTICE NO. 17-16

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

**FROM:** Byron E. Rippke,  
Director

**SUBJECT:** Issuance of a Conditional License for Canine Osteosarcoma Vaccine,  
Live *Listeria* Vector

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Antelope Valley Bios, Inc., Establishment No. 419, Lincoln, Nebraska, for the manufacture and distribution of Canine Osteosarcoma Vaccine, Live *Listeria* 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 a biological intervention for canine osteosarcoma in order to afford veterinarians another post-surgical treatment option beyond traditional chemotherapeutic intervention.

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 a reasonable expectation of efficacy was demonstrated during field trials conducted in dogs that had been clinically diagnosed with osteosarcoma and undergone surgical removal of the primary appendicular tumor. Dogs were then treated with carboplatin. Following radiographic confirmation of the absence of pulmonary metastasis, affected dogs received a 3-dose primary vaccination series with the canine osteosarcoma vaccine and then median survival time was compared to historical standards. The conditional license will expire one year from the date of the license. APHIS will evaluate the firm's progress throughout the next year toward regular licensure in order to consider reissuance of the conditional license.