



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 20-07

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

**FROM:** Byron Rippke  
Director

**SUBJECT:** Issuance of a Conditional License for Epizootic Bovine Abortion  
Agent Vaccine, Live Culture

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Hygieia Biological Laboratories, Establishment No. 407, Woodland, California, for the manufacture and distribution of Epizootic Bovine Abortion Agent Vaccine, Live Culture.

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 in this notice is abortion caused by *Pajaroellobacter abortibovis*.

Conditionally licensed products are required to be pure, 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. Safety of the product has been established through a safety study. APHIS will evaluate their progress throughout the next year. The conditional license will expire 2 years from the date of the license.