



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-02

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

**FROM:** Byron E. Rippke  
Director

**SUBJECT:** Issuance of a Conditional License for *Moraxella Bovoculi* Bacterin

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Addison Biological Laboratory, Inc., Establishment No. 355, Fayette, Missouri, for the manufacture and distribution of *Moraxella Bovoculi* Bacterin.

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 first availability of a *Moraxella bovoculi* vaccine against pinkeye or infectious bovine keratoconjunctivitis approved for use in cattle.

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. 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 1 year from the date of the license.