



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 23-02

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

**FROM:** David M. White  
Acting Director

**SUBJECT:** Issuance of a Conditional License for American Foulbrood

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Diamond Animal Health, Inc., Establishment No. 213, Des Moines, Iowa, for the manufacture and distribution of Paenibacillus Larvae 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 disease in honeybees caused by *Paenibacillus larvae* (American Foulbrood).

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 two years from the date of the license.