



December 11, 2012

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-24

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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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/ Byron E. Rippke, for
Director
Center for Veterinary Biologics

SUBJECT: Issuance of a Conditional License for Streptococcus Uberis Bacterin

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 Streptococcus Uberis 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 9 CFR Part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or special circumstance. The special circumstance addressed here is the need for a product to aid in the reduction of mastitis due to *Streptococcus uberis*.

Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy. The conditional license was issued on the basis that Hygieia Biological Laboratories has demonstrated that the product has a reasonable expectation of efficacy. Safety of the product has been established through field safety trials. Hygieia Biological Laboratories has provided a written commitment to APHIS to complete studies to demonstrate the efficacy of this product and to conduct any other work required for full licensure. APHIS will evaluate their progress later this year. The conditional license will expire one year from the date of the license.



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