



May 8, 2012

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-10

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

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 Corynebacterium
Pseudotuberculosis Bacterin

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Texas Vet Lab, Inc., Establishment No. 290, San Angelo, Texas, for the manufacture and distribution of Corynebacterium Pseudotuberculosis 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 need for a licensed product for use in goats.

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 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 one year from the date of the license.



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