

August 28, 2000

**CENTER FOR VETERINARY BIOLOGICS NOTICE 00-12**

Subject: Issuance of a Conditional License for Mycoplasma Bovis Bacterin

To: Area Veterinarians in Charge, VS  
State Veterinarians  
Veterinary Services Management Team  
Directors, Center for Veterinary Biologics

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 Mycoplasma Bovis 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 prevention of respiratory disease caused by Mycoplasma Bovis in stocker calves. 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 Texas Vet Lab, Inc., has demonstrated that the product has a reasonable expectation of efficacy. Texas Vet Lab 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 in one year.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.  
Director  
Center for Veterinary Biologics

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