



September 12, 2006

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-19

Subject: Issuance of a Conditional License for Mycobacterium Paratuberculosis
DNA Test Kit, Polymerase Chain Reaction

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

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Tetracore, Inc., Establishment No. 644, Rockville, Maryland, for the manufacture and distribution of Mycobacterium Paratuberculosis DNA Test Kit, Polymerase Chain Reaction.

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 may be issued. The regulations in Title 9, Code of Federal Regulations, 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 other special circumstances. There is no licensed real-time polymerase chain reaction diagnostic test kit currently available that provides a rapid *in vitro* assay for the detection of *Mycobacterium paratuberculosis* DNA in specimens derived from fecal origin.

This conditional license was issued following the acceptance of data demonstrating adequate kit performance for the detection of *M. paratuberculosis* DNA from archived fecal specimens and experimentally prepared specimens. The firm is required to collect additional field data and further validate the diagnostic specificity and sensitivity of this kit before APHIS will issue a regular product license. The conditional license will expire in one year.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director



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