



August 5, 2003

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-11

Marketing and
Regulatory
Programs

Subject: Issuance of a Conditional License for Mycobacterium Bovis Gamma Interferon Test Kit for Cervids

Animal and Plant
Health Inspection
Service

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

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The Animal and Plant Health Inspection Service (APHIS) has issued a conditional United States Veterinary Biological Product License to Biocor Animal Health, Inc., Establishment No. 462, Omaha, Nebraska, for the manufacture and distribution of Mycobacterium Bovis Gamma Interferon Test Kit for Cervids.

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 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 other special circumstances. There is no licensed diagnostic test kit currently available that provides a rapid *in vitro* assay for the detection and diagnosis of bovine tuberculosis in cervids.

This conditional license was issued following the acceptance of data demonstrating adequate kit performance for the detection of *M. bovis* infection in cervids. The firm is required to collect additional field data and further validate the potency test 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
Center for Veterinary Biologics



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