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United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-16

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

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Biologics
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Subject: Issuance of a Conditional License for Mycobacterium Tuberculosis
Gamma Interferon Test Kit for Non-Human Primates

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 Biocor Animal Health, Inc., Establishment 462, Omaha, Nebraska, for the manufacture and distribution of Mycobacterium Tuberculosis Gamma Interferon Test Kit For Non-Human Primates.

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 a biological product provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstance. There is no licensed diagnostic test kit currently available that provides a rapid *in vitro* assay for the detection and diagnosis of tuberculosis in primates.

The conditional product license was issued following the acceptance of data demonstrating adequate kit performance for the detection of *M. tuberculosis* complex infection in non-human primates. 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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