



February 26, 2004

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-06

Animal and Plant
Health Inspection
Service

Subject: Issuance of a Conditional License for Canine Gonadotropin Releasing Factor Immunotherapeutic

Veterinary Services

Center for Veterinary
Biologics

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
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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 Canine Gonadotropin Releasing Factor Immunotherapeutic.

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 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 veterinary biologic approved for the treatment of benign canine prostatic hyperplasia. Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy.

The conditional product license was issued on the basis that Biocor Animal Health has demonstrated that the product has a reasonable expectation of efficacy. Safety of the product has been established through field safety trials. Biocor Animal Health 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 one year from the date of the license.

/s/ Byron E. Rippke for

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



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