United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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April 20, 2005

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-10

Subject: Issuance of a Conditional License for Streptococcus Equi Antibody

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 Mg Biologics, Inc., Establishment No. 614, Ames, Iowa, for the manufacture and distribution of Streptococcus Equi Antibody, Equine Origin.

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 other special circumstances. The special circumstance addressed here is the absence of other licensed veterinary biological antibody products intended as an adjunct to other available therapy in the treatment of disease caused by *Streptococcus equi* in horses.

This conditional license was issued following the acceptance of data supporting purity, product safety under normal conditions of use (field safety), and demonstration that the product has a reasonable expectation of efficacy. This license will expire in 1 year. In accordance with 9 CFR Part 102, progress toward regular licensure must be pursued for reissuance of the conditional license.

/s/ Richard E. Hill, Jr.

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