



November 19, 2004

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-21

Animal and Plant
Health Inspection
Service

Subject: Issuance of a Conditional License for West Nile Virus Antibody,
Equine Origin

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 Colorado Serum Company, Establishment No. 188, Denver, Colorado, for the manufacture and distribution of West Nile Virus 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 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 availability of non-conditionally licensed veterinary biological antibody products intended as an adjunct to other available therapy in the treatment of disease caused by West Nile Virus in horses.

This conditional license was issued following the acceptance of data supporting product 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