

February 26, 2001

CENTER FOR VETERINARY BIOLOGICS NOTICE 01-03

Subject: Applications for Licensure of West Nile Virus Vaccine

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

The purpose of this notice is to inform interested parties of Animal and Plant Health Inspection Service (APHIS) policy regarding licensure of vaccines directed against West Nile Virus (WNV). Center for Veterinary Biologics Notice 00-02, issued January 11, 2000, indicated the availability of WNV isolates for research purposes and provided a procedure for obtaining isolates from the National Veterinary Services Laboratories. The reemergence and spread of WNV cases in the northeastern United States in the past year has resulted in reevaluation of APHIS policy regarding WNV; APHIS will now accept applications for licensure of vaccines directed against WNV.

There is direct evidence that WNV over-wintered between 1999 and 2000 in mosquitoes in the New York City area. Comparing WNV activity in 2000 to that in 1999, it is apparent that the geographic distribution of WNV expanded considerably, even after accounting for increased detection due to intensified surveillance efforts in 2000. In 1999, WNV activity was detected in only 4 states; in 2000, activity was detected in an additional 8 states and the District of Columbia. The number of cases in horses has also increased.

Given the potential for additional cases of WNV, APHIS has determined that development of an effective vaccine for WNV may aid in controlling the threat posed by this agent to the equine industry in the United States. Requests for an application package for licensure of proposed vaccines for WNV should be made to the Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, Iowa 50010.

/s/ Richard E. Hill, Jr.

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Director
Center for Veterinary Biologics