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Department of
Agriculture

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Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-06

Subject: Draft Standard Requirement for Equine Influenza Vaccine, Killed Virus

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

The purpose of this notice is to announce the availability of the first draft of a Standard Requirement (SR) for Equine Influenza Vaccine (EIV).

This draft SR reflects current APHIS thinking on the requirements for licensing EIV. It is being made available for information prior to the initiation of bilateral discussions with European Union (EU) regulatory officials concerning the compatibility of the respective U.S. and EU efficacy and potency requirements.

Center for Veterinary Biologics personnel have presented the concepts of efficacy and potency contained in this draft at equine influenza symposiums in Miami, Florida, and Budapest, Hungary.

We will announce the structure, topics, and date(s) of our discussions with the EU as such meetings are scheduled.

A copy of the draft SR is available as an Adobe Acrobat file on the world wide web at <http://www.aphis.usda.gov/vs/cvb/regsandguidance.htm>.

/s/ Richard E. Hill, Jr.

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

