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**United States  
Department of  
Agriculture**

Marketing and  
Regulatory  
Programs

Animal and Plant  
Health Inspection  
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Veterinary Services

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**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 02-01**

**Subject:** Critical Study Dates for Licensing and Reference Qualification Studies

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

**I. PURPOSE**

The purpose of this notice is to clarify the policy of the Center for Veterinary Biologics (CVB) regarding critical dates for host animal studies performed in support of licensure and/or reference qualification and maintenance.

**II. POLICY**

All licensees, permittees, and applicants, when submitting protocols for pivotal studies, should include the dates of critical study events. Critical events include, but are not limited to, date(s) of vaccination, challenge, post-challenge observation, and necropsy. This information should be supplied sufficiently in advance of the study so that CVB personnel may arrange to observe key portions of the study, if desired.

If the dates provided in the protocol subsequently change, an updated schedule should be provided to the CVB.

/s/ Richard E. Hill, Jr.

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

