CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-16

Subject: Posting of Selected Center for Veterinary Biologics Notices and Veterinary Services Memoranda on the Center for Veterinary Biologics Web Site for Comment

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

I. PURPOSE

This notice informs licensees, permittees, and applicants of the intent of the Center for Veterinary Biologics (CVB) to continue to post selected draft CVB Notices and Veterinary Services (VS) Memoranda on the CVB web site to solicit comments from the veterinary biologics industry and interested parties.

II. BACKGROUND

On December 10, 2004, the CVB published CVB Notice No. 04-23. This Notice described a 6-month pilot project during which selected draft guidance documents were to be posted on the CVB web site for a 3-week comment period. The pilot project was completed on June 13, 2005. The CVB has evaluated the value of the project and has determined that the practice of posting selected draft guidance documents will continue and will be re-evaluated annually.

III. POLICY

1. The CVB will determine which documents will be posted for comment. Selected draft documents will be posted at: http://www.aphis.usda.gov/vs/cvb/ under the “Programs Regulation and Guidance” link. Draft documents will be posted on this page under the heading “Draft Guidance Documents for Comment”.

2. Postings may occur at any time during the week. In order to minimize the number of times the web site must be checked, the 3-week time allotment for commenting will not begin until the first Monday at noon Central Time after the document was posted. The draft document will be removed from the web site soon after the comment period is completed.
3. Comments will be accepted only by email. The comments must be addressed to cvb@aphis.usda.gov. (This address can also be accessed via the “Contact Us” link on the web site homepage.) The subject line of the email must state, “Comments on Notice/Memorandum <Draft Identification Number>. For example, “Comments on VS Memorandum No. Draft-XXX” or “Comments on CVB Notice No. Draft-XXX.”

Comments submitted in the acceptable format will be acknowledged as received, but no response addressing any specific comment will be returned.

4. The CVB will consider all comments when formulating further guidance related to the draft document. CVB guidance documents may not incorporate all comments received.

5. Issues presented in draft documents will not be effective until final guidance documents are published. Some of the issues presented may never be adopted in final guidance documents.

/s/ Richard E. Hill, Jr.

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