



December 10, 2004

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 04-23

Animal and Plant
Health Inspection
Service

Subject: Posting of Selected Center for Veterinary Biologics Draft Notices and Veterinary Services Draft Memoranda on the Center for Veterinary Biologics Web site for a Comment Period

Veterinary Services

Center for Veterinary
Biologics

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

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I. PURPOSE

This notice informs licensees, permittees, and applicants of the intent of the Center for Veterinary Biologics (CVB) to post selected draft CVB Notices and Veterinary Services (VS) Memoranda on the CVB web site for a 3-week period prior to finalizing the documents in order to solicit comments from the veterinary biologics industry and interested parties.

II. BACKGROUND

From time to time, the CVB publishes guidance documents in the form of VS Memoranda or CVB Notices. Issues contained in these guidance documents can have an impact on companies manufacturing veterinary biologics. In an effort to obtain fair and balanced input from the veterinary biologics industry prior to finalizing guidance documents, CVB is initiating a 6-month pilot project during which selected draft guidance documents will be posted on the CVB web site for a 3-week comment period. If successful, the practice may be extended indefinitely.

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. The draft documents will be posted under the heading "Draft Guidance Documents for Comment".
2. Postings can occur at any time during the week. In order to decrease 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 Standard 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.) Only comments that contain a subject line formatted as indicated will be accepted: "Comments on draft" VS Memorandum/CVB Notice No. Draft-XXX (e.g., Comments on VS Memorandum No. Draft-XXX, Comments on CVB Notice No. Draft-XXX.)

Comments that are 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 that are received and acknowledged when formulating the final guidance related to the draft document. However, the final CVB document may not reflect the incorporation of all comments.

5. This pilot project will begin with the first web site posting on December 13, 2004, and will continue until June 13, 2005. After the 6-month trial period, the CVB will evaluate the value of the project and determine if the practice of posting draft documents will continue.

6. 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