Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

1920 Dayton Avenue PO Box 844 Ames, IA 50010

(515) 337-6100

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 24-04

TO: Biologics Licensees, Permittees, and Applicants

Directors, Center for Veterinary Biologics Veterinary Services Leadership Team

FROM: Geetha B. Srinivas

Director, Center for Veterinary Biologics

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

I. PURPOSE

This notice informs licensees, permittees, and applicants of the Center for Veterinary Biologics (CVB) policy on posting 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 August 22, 2005, the CVB published CVB Notice No. 05-16. This notice announced formalization of the practice of publicly posting selected draft guidance documents on the CVB web site for a 3-week comment period. That notice has become outdated, and program-wide changes to the APHIS website and e-mail domain naming have resulted in multiple non-functional hyperlinks within Notice No. 05-16. This notice is to provide updated guidance and improve stakeholder access to draft documents that are posted for public comment.

III. POLICY

- 1. The CVB determines which documents will be posted for comment. Selected draft documents are posted at: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics under the "Biologics Regulations & Guidance" link and in the Rulemaking and Policy Development subsection. Draft documents will be posted under the heading "Draft Guidance Documents for Comment".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 start the first Monday after a document was posted at 12:00 PM Central Standard Time (CST). The draft document will be removed from the web site soon after the comment period is completed.

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- 3. Comments will only be accepted by email. The comments must be addressed to cvb@usda.gov. (This address can also be accessed via the "Contact Us" link from the "About the Center for Veterinary Biologics (CVB)" link on the web site homepage.) The subject line of the email must state, "Comments on draft notice/memo <insert ID 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. Comments must be submitted by 12:00 PM CST on the due date indicated for a given document.
- 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. Final decisions or actions presented in draft documents will not be effective until final guidance documents are published. Some of the issues presented may not be adopted in final guidance documents.

IV. IMPLEMENTATION/ APPLICABILITY

This Notice is effective immediately and replaces CVB Notice No. 05-16 which is cancelled.