



February 2, 2011

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-02**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

1920 Dayton Avenue  
PO Box 844  
Ames, IA 50010  
(515) 337-6100

**TO:** Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics  
Veterinary Services Management Team

**FROM:** Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*  
Director  
Center for Veterinary Biologics

**SUBJECT:** Generation and Implementation of Draft Guidance

**I. PURPOSE**

The purpose of this Notice is to clarify how Draft Guidance documents are generated and implemented by the Center for Veterinary Biologics (CVB).

**II. BACKGROUND**

Draft Guidance refers to guidance documents (Title 9, Code of Federal Regulations, Part 101.2) related to matters that fall under the Virus-Serum-Toxin-Act that are in the form of draft Memoranda or draft Notices that have not been finalized.

**III. POLICY**

Draft Guidance is shared with the public in order to provide transparency regarding current thinking and to elicit comments to improve the document. Draft Guidance is not considered mandatory to industry and will not be implemented as such by the CVB. However, Draft Guidance should be regarded as conveying the direction in which the CVB is planning to move, and provide guidance about this.

To clarify the intent of Draft Guidance, draft documents will include information regarding the scope and implementation of the guidance document, and what products and/or processes will be affected.



*Safeguarding American Agriculture*

APHIS is an agency of USDA's Marketing and Regulatory Programs  
An Equal Opportunity Provider and Employer

Federal Relay Service  
(Voice/TTY/ASCII/Spanish)  
1-800-877-8339