CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-02

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

     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SUBJECT: Generation and Implementation of Draft Guidance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The purpose of this Notice is to clarify how Draft Guidance documents are generated and implemented by the Center for Veterinary Biologics (CVB).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Draft Guidance refers to guidance documents (Title 9, Code of Federal Regulations, Part 101.2) related to matters that fall under the Virus-Serum-Toxin-Act that are in the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Draft Guidance is shared with the public in order to provide transparency regarding current thinking and to elicit comments to improve the document. Draft Guidance is not considered mandatory to industry and will not be implemented as such by the CVB. However, Draft Guidance should be regarded as conveying the direction in which the CVB is planning to move, and provide guidance about this.

To clarify the intent of Draft Guidance, draft documents will include information regarding the scope and implementation of the guidance document, and what products and/or processes will be affected.