



March 17, 2011

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-06**

**United States  
Department of  
Agriculture**

Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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

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

**SUBJECT:** Cancellation of Veterinary Services Memorandum 800.96 and Notice of  
Example Data Files

**I. PURPOSE**

The purpose of this Notice is to notify Biologics Licensees, Permittees, and Applicants of the cancellation of Veterinary Services Memorandum (VSM) 800.96, Guidelines for Submitting Electronic Data Files for Statistical Analysis. The notice also serves to inform interested parties about example data formats on the Center for Veterinary Biologics (CVB) website.

**II. BACKGROUND**

In compliance with Title 9, Code of Federal Regulations, Part 102.3 (b)(2)(ii), applications for United States Veterinary Biological Product Licenses must be supported by data as outlined in VSM 800.50, Section IV.C., Supporting Data for a Product License Application. License applicants commonly use electronic files to submit such data. VSM 800.96 included guidance for data files. To clarify the guidance, data format examples and descriptions have been posted to the CVB website, making VSM 800.96 unnecessary.

**III. ACTION**

VSM 800.96, Guidelines for Submitting Electronic Data Files for Statistical Analysis, is cancelled. Examples and descriptions of electronic data formats that are suitable for submission to CVB can be found at [http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/vb\\_data\\_formats.shtml](http://www.aphis.usda.gov/animal_health/vet_biologics/vb_data_formats.shtml).



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**IV. IMPLEMENTATION / APPLICABILITY**

Example data formats are available immediately on the CVB website. VSM 800.96 will be removed from the website April 1, 2011.