Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 16-07

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

FROM: Byron E. Rippke
Director

BYRON RIPPKE

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Date: 2016.05.16 13:35:32 -05'00'

SUBJECT: In-depth Inspection Report Format

I. PURPOSE

The Center for Veterinary Biologics (CVB) evaluated the inspection report process for in-depth inspections as part of a business process improvement project. The proposed outcome was to reduce the CVB resources needed to write and finalize the inspection report while maintaining the current inspection process as outlined in Veterinary Services Memorandum 800.91.

II. BACKGROUND

Data were collected prior to the pilot project to provide benchmark measurements. The pilot project was conducted from March through August 2015. The evaluation of data collected during the pilot project demonstrated a reduction in CVB resources needed to prepare and finalize an inspection report, and a shorter reporting time between the end of the inspection and the sending of the inspection report. The scope of this project and policy change only applies to in-depth inspection reports for U.S. Veterinary Biologics Licensee facilities and Permittee quarantine sites.

III. POLICY

The in-depth inspection reports will focus on violations and the regulatory requirements expected to ensure compliance. The report will consist of a cover letter, providing background on the inspection and expectations, and an Attachment of Violations.

The Attachment of Violations will consist of up to four categories as follows:

- **SERIOUS violation** - May affect quality of product or be willful;
- **LESS SERIOUS violation -** By repetition or very nature, may affect quality of a product;
- **MINOR violation –** Is not apt to affect quality of product but indicate laxity or error that could become more serious if not corrected. If numerous minor exceptions are noted during the inspection, it is indicative of poor management and should be considered as having cumulative effect; and
- **ITEM(S) OF CONCERN** – No violation of the regulations was discovered, but indicates a lack of control or understanding for the intent of the regulations.

Violations or items of concern will be reported based on the level of seriousness as determined by the CVB. A brief description of the violation and the 9 CFR citation, the actual observation, and the action agreement by the regulated entity will be documented in the attachment.

IV. IMPLEMENTATION/ APPLICABILITY

This change will be effected upon publication of this Notice. At this time, the policy applies to in-depth inspections of U.S. Veterinary Biologics Licensee facilities and Permittee quarantine sites.

Veterinary Services Memorandum 800.91 will be reviewed and updated to reflect the change in reporting.