USDA
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

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 21-02

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

FROM: Byron Rippke
Director

BYRON RIPPKE

Digitally signed by BYRON RIPPKE
Date: 2021.01.05 11:42:47 -06'00'

SUBJECT: Record Audit Inspections

I. PURPOSE

This Notice informs regulated entities of a new process implemented to monitor controlled activities that would routinely be reviewed during an on-site inspection.

This is only to be implemented for existing establishments holding an unsuspended or unrevoked establishment license with the Center for Veterinary Biologics (CVB) and is not intended for prelicensing inspections of unlicensed establishments.

II. BACKGROUND

Inspections are mission critical, but during the COVID-19 pandemic, travel has not been recommended, therefore suspending the normal inspection process. An interim inspection process is being implemented in the form of a records audit. Records will be requested in accordance with title 9, *Code of Federal Regulations* (9CFR), part 116.5(a).

These audits can be used to confirm veterinary biologics manufacturers have the appropriate checks and balances built into their methods of operation that provide for a well-controlled production and testing environment. This is only a snapshot in time for a small sampling of the entirety of the processes that occur at the site. Documentation of all production and testing steps is required and used to measure compliance to the regulations cited in the 9 CFR and the outlines of production on file with CVB.

III. ACTION

A. CVB will send a letter to the licensee requesting specific serial(s) assembly records and process deviation summaries.

B. The licensee will submit the information in accordance with the instructions listed in the letter within 3 working days of receipt. No corrections, additions, or deletions to the original record should be made prior to submission.

C. CVB will review these documents for compliance against the regulations and filed outline of production.

D. CVB will request additional records related to specific facets of production via a Request Information from Submitter child loop in the NCAH Portal. Response to these requests should be received within 3 working days from the date of the request.

E. CVB may request video conferences to review questions or issues noted during the review of documents. This will provide an opportunity to share screens as part of the audit process.

F. Any violations noted or actions required will be communicated to the liaison through a conference call, similar to an on-site closing meeting.

G. A written inspection report will be provided to the entity.

IV. IMPLEMENTATION/ APPLICABILITY

This practice goes into effect immediately.