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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. 13-06

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

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

SUBJECT: Reporting Inactivation Test Results on APHIS Forms 2008 for Inactivated Veterinary Biological Products with the Restriction "For Further Manufacture (FFM)"

I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants that the Center for Veterinary Biologics (CVB) now requires the reporting of inactivation confirmation test results on APHIS Forms 2008. This Notice applies only to inactivated products that have the license restriction "For Further Manufacture" (FFM) and that have an Outline of Production requirement for inactivation, including autogenous products and prelicense products that will be given the FFM restriction upon licensure.

II. BACKGROUND

The CVB is committed to ensuring inactivated veterinary biological products are safe to ship. Currently there are FFM products prepared from animal pathogens, some of which are zoonotic. Previously, the CVB has not required the results of inactivation confirmation testing to be reported on the APHIS Form 2008. This reporting will aid in ensuring safe shipment of the product and is provided for under 9 CFR 114.3(d), 113.10, and 103.3(b).

III. ACTION

Manufacturers shall specify the inactivation confirmation test, the test validity criteria, the criteria for satisfactory results, and the date the inactivation validation report was accepted by the CVB in Section V of the Outline of Production. For products licensed prior to the date of this Notice, the acceptance date may be the date of the Outline in effect at the time of licensure. Manufacturers may contact their reviewer for guidance.

Requests for release of inactivated FFM product (licensed or in prelicense) to be shipped between licensed entities shall report the results of inactivation confirmation testing on APHIS Form 2008, as applicable.

IV. IMPLEMENTATION/ APPLICABILITY

For reporting inactivation test results on the APHIS Form 2008, this change is effective from the date of this Notice.

For Outlines of Production, the change is effective by the time of the next annual review or prior to licensure, as applicable.

For products still in prelicense status as of the date of this Notice, CVB acceptance of an inactivation validation report (or exemption therefrom) is required prior to licensure. Manufacturers should contact their reviewers for guidance.