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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. APHIS-2014-0033]

In Vitro Tests for Serial Release

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the "In vitro tests for serial release" regulations by removing a footnote that refers to one method to calculate the relative antigen content of inactivated veterinary biological products and relative potency calculation software available from Veterinary Services' Center for Veterinary Biologics (CVB). CVB will no longer provide or update the software and the written method for using the software will no longer be used. This action will update the regulations.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Section Leader, Operational Support, Center for Veterinary Biologics Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 851-3426.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR 113.8 provide criteria for acceptable in vitro potency tests for the serial release of live and inactivated veterinary biological products. As provided in the

regulations, the potency of inactivated products is evaluated by comparing the relative antigen content of the product to an unexpired reference using a parallel line immunoassay or another acceptable procedure. The footnote in paragraph (c) of this section refers to one method that can be used to evaluate the relative antigen content using Supplementary Assay Method (SAM) 318 and relative potency calculation software available from Veterinary Services' Center for Veterinary Biologics (CVB). CVB is no longer providing or updating the software, and the written method for using the software, described in SAM 318, will no longer be used. Therefore, we are removing that footnote.

This rule relates to internal agency management. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity to comment are not required, and this rule may be made effective less than 30 days after publication in the Federal Register. Further, since this rule relates to internal agency management, it is exempt from the provisions of Executive Orders 12866 and 12988. Finally, this action is not a rule as defined by the Regulatory Flexibility Act, and thus is exempt from the provisions of that Act.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects in 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 113 is amended as follows:

PART 113--STANDARD REQUIREMENTS

1. The authority citation for part 113 continues to read as follows:

Authority: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.4.

§ 113.8 [Amended]

2. In § 113.8, paragraph (c), footnote 1 is removed.

§ 113.100 [Amended]

3. In § 113.100, paragraph (f), footnote 2 is redesignated as footnote 1.

§ 113.200 [Amended]

4. In § 113.200, paragraph (f), footnote 3 is redesignated as footnote 2.

Done in Washington, DC, this 23rd day of May 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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