Rules and Regulations

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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* May 30, 2014.

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.

[FR Doc. 2014–12550 Filed 5–29–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2014–N–0429]

Medical Devices; Immunology and Microbiology Devices; Classification of Dengue Virus Serological Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying dengue virus serological reagents into class II (special controls). The special controls that will apply to the device are identified in this order, and the codified language for the dengue serological reagents classification will include the identification of the special controls that will apply to this device. The Agency is classifying the device into class II (special controls) because special controls, in addition to general controls, will provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective June 30, 2014. The classification was applicable April 8, 2011.

FOR FURTHER INFORMATION CONTACT: Beena Puri, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5553, Silver Spring, MD 20993–0002, 301–796–6202.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA