United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-25

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: New Policy on Biological Product Samples Submitted to the Center for Veterinary Biologics and the Concurrent Testing Selection Period

I. PURPOSE

This Notice informs licensees, permittees, and applicants of the current Center for Veterinary Biologics (CVB) policy concerning the submission of biological product samples prior to releasing a serial for marketing. The CVB has decided to reduce the number of samples submitted to a minimum of two containers or a sufficient quantity of one dose containers to conduct the potency test requiring multiple containers, e.g. rabies, for all product codes. In addition, the concurrent testing selection period will be reduced to seven calendar days. There will be no change to diagnostic test kit sample submission or the selection period.

II. BACKGROUND

Title 9, Code of Federal Regulations (9 CFR), Part 113.3 requires each licensee or permittee to submit representative samples of each serial or subserial of a biological product manufactured or imported into the U.S. prior to serial release. The current sample policy is found in Veterinary Services Memorandum 800.59. The annual cost of processing, storage, and disposal of biologic test samples has steadily increased. In response, the CVB has reviewed alternatives to current testing and sample submission processes. Decreasing the number of biologic samples will provide a benefit to the National Centers for Animal Health (NCAH) through reduced processing, maintenance, and disposal costs, will reduce the environmental impact of the NCAH by reducing the volume of hazardous and non-recyclable waste disposal, and will allow the licensee or permittee to market samples which would have previously been maintained at the CVB.

III. POLICY

1. The CVB will require prelicense products, Master Seeds and Master Cell sample submissions to remain the same as required in 9 CFR 113.3(c).

2. The licensee or permittee will continue to select all prerelease serial samples as required in 9 CFR 113.3(b).

    a. The licensee or permittee will submit a minimum of two containers or a sufficient quantity of one dose containers to conduct the potency test requiring multiple containers, e.g. rabies, at the CVB.
    b. When a serial of product is imported in more than one shipment, representative samples from each shipment must be selected by the permittee but only samples from the first shipment must be submitted to CVB as prerelease serial samples.
    c. The licensee or permittee will hold selected samples not initially submitted at the storage temperature recommended on the label while awaiting a request by the CVB to submit additional samples.
    d. If additional sample submission is not requested by the CVB, the additional samples may be returned to the inventory after the serial is released for marketing by the CVB.
    e. If additional sample submission is requested on a routine basis, the CVB will notify the firm to submit the recommended quantity.

3. To offset the time to submit additional samples, the concurrent testing selection period will be reduced to 7 calendar days after samples are received by the CVB.

    a. If additional samples are requested for testing, the licensee or permittee will be notified.

4. The licensee or permittee will continue to select APHIS reserve samples as required in 9 CFR 113.3(e).

The reduced sample submission and selection window are a privilege for the licensee or permittee. At any time, the CVB may notify licensees and permittees to submit the full complement of samples as required in 9 CFR 113.3(b). Included in this notification, the CVB will identify the basis for revoking the limited sample submission privilege. Inspection or investigation findings and regulatory/compliance concerns are examples of events which may trigger such a notification.

IV. IMPLEMENTATION/ APPLICABILITY

This change is effective January 1, 2013.