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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. 12-07

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

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

SUBJECT: Submission of Master Seeds, Master Cell Stocks, and Master Sequences to the Center for Veterinary Biologics for Confirmatory Testing

I. PURPOSE

This Notice describes procedures that are being implemented to streamline Master Seed, Master Cell Stock, and Master Sequence sample submission.

II. BACKGROUND

Confirmatory testing of Master Seeds, Master Cell Stocks, and Master Sequences (MS) is conducted at the Center for Veterinary Biologics (CVB) as part of the licensing/permitting process for veterinary biologic products. After review of the firm's MS report, the firm's Reviewer will issue a test authorization number, authorizing the firm to submit samples for confirmatory testing at the CVB. For biotechnology-derived MSs, a Summary Information Format (SIF) must be submitted by the firm for review and an Institutional Biosafety Committee (IBC) number assigned prior to issuance of the test authorization number.

III. POLICY

The following procedures are being implemented to facilitate the coordination of the test authorization, sample submission, and initiation of testing:

1. The firm's MS report and SIF (if applicable) must be complete and contain sufficient detail for procedures used in non-codified tests. The MS should be identified using the complete lot number (or other unique identifier), exactly as it appears on the label on the MS vials.

2. A CVB laboratory coordinator will be assigned to each test authorization. This person, along with the firm's reviewer, should serve as the primary contact for issues concerning sample submission. The CVB Laboratory Coordinator will provide the firm with a complete list of reagents needed for the testing.

3. In order to facilitate communication, the firm may wish to provide the CVB with the name and e-mail address, or phone number, of a laboratory contact person at the firm.

4. Samples should be sent within 30 days of the issuance of a test authorization. Samples submitted within 30 days will be given priority based on the date received at the CVB.

5. To facilitate the CVB's scheduling of confirmatory testing, firms should notify the Laboratory Coordinator with an anticipated ship date of samples upon receipt of the test authorization number.

6. Samples and reagents must be submitted with an APHIS Form 2020, with the following information included in the Remarks section:

   a. Test authorization number;
   b. IBC number, if applicable; and
   c. Submit to the attention of the CVB Laboratory Coordinator

7. The firm should provide the shipment tracking number to the CVB Laboratory Coordinator and the Reviewer at the time of shipment.

8. If the CVB laboratory encounters problems with confirmatory testing, the CVB will contact the firm to confirm the assay methodology and possible alignment needs. If/when these findings confirm that further trouble shooting is required by the firm, the test authorization may be canceled and reissued at a later date.

IV. IMPLEMENTATION/ APPLICABILITY

These procedures will be implemented immediately.