



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 23-10

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

FROM: David M. White
Acting Director

SUBJECT: Inclusion of Master Seed, and Master Cell Labels with Submissions to the Center of Veterinary Biologics (CVB) Laboratory

I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants of a change in CVB laboratory protocol for documentation of receipt and confirmation of required identification of Master Seed and Master Cell sample submissions. Implementation of the change in protocol will be facilitated by requesting that firms include additional detached copies of sample container labels with Master Seed and Master Cell submissions.

II. BACKGROUND

In accordance with Title 9, *Code of Federal Regulations* (9CFR sections 113.3 and 113.52), Master Seed and Master Cell Stock (MS/MCS) samples are required to be submitted to CVB prior to licensure of a veterinary biologic, to support approval of certain changes to the Outline of Production, or as otherwise requested. These samples must be labeled with a unique number or other identifier matching that of the MS/MCS stored at the establishment and the description found in the Outline of Production (additional guidance on sample identification may be found in Veterinary Services Memorandum 800.59). Identification on sample containers must also exactly match the item as it is listed on APHIS Form 2070, which is submitted prior to authorization of shipment, as well as APHIS Form 2020, which either accompanies the shipment or is submitted through the NCAH Portal. Upon receipt of the material, CVB personnel are required to verify that the sample container matches that of the submitted forms. Any discrepancies are resolved prior to testing of the sample. To confirm this process and further prevent the potential for misidentification, CVB is seeking to more permanently capture the verified correct identity of the submitted material upon receipt.

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III. ACTION (or POLICY)

CVB is requesting that firms submit at least two additional detached copies of container labels for any MS/MCS material submitted to the CVB Laboratory. These may be adhesive labels printed using the exact template of the labels on the sample vial or other container. If exact copies are unavailable, a reproduction of the label is acceptable, provided that the content is identical to that found on the sample container. Upon receipt by laboratory personnel, the sample container, additional label copies, submitted forms, and identifying information entered into CVB's electronic database will be compared to confirm correct identification of the samples received. The additional label copy will be attached to the signed APHIS Form 2020 and digitally retained.

IV. IMPLEMENTATION/ APPLICABILITY

This change will be effective 30 days from the date of this notice.