



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 14-16

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

FROM: Byron E. Rippke /s/ *Byron E. Rippke*
Acting Director

SUBJECT: Processing Special Outlines Describing Proposed Serial Release Assays

I. PURPOSE

The purpose of this Notice is to inform stakeholders of a change in how the Center for Veterinary Biologics (CVB) processes Special Outlines that describe proposed serial release assays.

II. BACKGROUND

When a company develops a new assay to use in serial release, the CVB requires a stepwise assay procedure, assay validation data to demonstrate suitability for purpose, and confirmatory testing by the CVB. Frequently the stepwise instructions are described in a Special Outline (SO). The SO is frequently submitted for review early in the approval process and often undergoes revision prior to final approval.

When the CVB returns comments and/or asks for revisions on draft SOs for serial release assays, each page of the document is stamped during processing with the same stamp used for all other Special Outlines and Outlines of Production. Typically this stamp signifies immediate acceptance. Having only one stamp worked historically because the assay still may not be used for serial release until the SO is cited in Section V of the relevant Outline(s) of Production (OP) of a licensed product. When looking solely at the Special Outline, however, it is often difficult to tell the approval status of the described assay.

III. ACTION

When processing SOs for serial release assays that have not yet met all requirements for final approval to use in serial release, a different restricted stamp will be used. The restricted stamp will state that the described assay is not allowed for use in serial release. This will provide an additional safeguard against premature implementation of an assay that has not yet been suitably validated and/or evaluated by the CVB laboratory.

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A final version of the SO must be stamped with the traditional non-restricted stamp, as well as be cited in the applicable OPs, before an assay may be used for serial release.

IV. IMPLEMENTATION/ APPLICABILITY

This change is effective as of the date of this Notice and pertains to all applicable Special Outlines processed hereafter.