USDA
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. 26-02

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

FROM: Geetha B. Srinivas, D.V.M., Ph.D.
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Date: 2026.01.29 15:49:45 -06'00'

SUBJECT: Option for Concurrent Confirmatory Testing of All Pre-license Serials

I. PURPOSE

The purpose of this notice is for the Center for Veterinary Biologics (CVB) to inform interested parties of the option for the CVB Laboratory to extend flexibility for concurrent confirmatory testing of pre-license serials (PLS), provided certain criteria are met, for all new veterinary biologics to help expedite licensure.

II. BACKGROUND

The CVB Laboratory conducts confirmatory testing of PLS under title 9, *Code of Federal Regulations* (9CFR), part 113.6 to ensure manufacturer's quality assurance processes for manufacturing consistency and product reliability through the lifecycle of production in the years post licensure. Confirmatory testing is conducted following manufacturer's satisfactory testing of PLS per 9 CFR 113.5 and the filed Outline of Production (OP) per 114.9, prior to approving the field safety study. Satisfactory PLS confirmatory testing and an approved field safety study are parts of the process to provide authorization for PLS to be sold and distributed, if not expired, upon licensure.

In response to industry feedback, CVB will extend flexibility to consider concurrent confirmatory testing of PLS when critical steps demonstrating adequate quality assurance and manufacturing controls are fully documented in the OP and related Special Outlines (SOs), if applicable.

III. ACTION

The concurrent confirmatory testing option cannot be used to address any unresolved issues with Section V testing (i.e. open issues with the CVB Laboratory), and is not meant to serve as a method to troubleshoot assays that are

not fully validated in the OP or SO. Firms requesting concurrent confirmatory testing of PLS must have the following steps completed prior to submitting the request:

- The pivotal efficacy study and label claim must be approved by CVB for each fraction in the veterinary biologic. The optimized manufacturing processes and controls for each fraction included in the efficacy serial must be fully described in the filed OP.
- Preliminary release and throughout dating specifications must be reviewed by CVB and stated in the filed OP. Release specifications must be finalized and included in the filed OP.
- The potency assay (Section V.C) and associated tests (Section V.E) must be validated and reviewed by CVB, and the methods (critical equipment, steps, and reagents) must be stated in the filed OP or SO. The assay method must be adequately documented such that a knowledgeable laboratory technician can replicate the firm's procedures without additional information.
- The remaining subsections of Section V of the Outline and any associated SOs must be approved, completed, reviewed, and filed with the CVB. This includes an approved dilution of preservative study.
- PLS have been manufactured according to the fully completed OP (as above) and are not expired.
- There are no relevant, open inspection or compliance concerns that require an OP or SO change to resolve the issue.

When the above criteria are met, the firm may submit a request for a pre-concurrent confirmatory testing meeting with CVB. The request should be submitted in a formal letter to the reviewer and include a narrative that addresses all the above criteria and includes reference to the mail log numbers demonstrating completion of all items listed. The reviewer will schedule a meeting with appropriate personnel. The firm should have operational staff available and be prepared to discuss the critical steps of the testing and when reagents will be available for CVB testing. Specific elements of new testing technology (equipment or reagents) should also be discussed. Testing requiring use of live animals may require additional time or resources to be completed, and CVB will make every effort in such cases to conduct concurrent testing. Bench records from test optimization may be requested for review prior to the meeting.

After the meeting, the CVB reviewer will work with CVB Laboratory personnel to confirm the firm has appropriately addressed any remaining clarifications or corrections discussed in the meeting. After any issues identified are resolved, the firm may submit a request for concurrent confirmatory testing of the PLS (APHIS Form 2072 or letter). The firm should be prepared to ship the PLS and requested reagents to the CVB Laboratory. CVB may conduct one retest upon an unsatisfactory or no-test result in the first round of testing. CVB will conduct concurrent confirmatory testing on a first-come, first-served basis per normal procedure. Testing order for all testing submissions will be determined when the CVB Laboratory receives all requested PLS and reagents shipped appropriately (e.g., no temperature deviations, arrived in a usable condition, labeled correctly).

Firms should submit their APHIS Form 2008 at the conclusion of their testing. Note in the comments section on the form that these products were submitted for concurrent confirmatory testing. CVB must be alerted immediately if the testing conducted by the firm results in any unsatisfactory result. CVB will halt concurrent confirmatory testing, the PLS in question will no longer be eligible for concurrent confirmatory testing as outlined in this Notice and must follow the existing confirmatory testing pathway.

This Notice should not imply CVB approval of all possible eventualities. Criteria for successful confirmation of the firm's testing procedures are unchanged. Firms may engage with other licensure requirements at their own risk per normal CVB evaluation procedures.

IV. IMPLEMENTATION/ APPLICABILITY

Firms may pursue this option effective immediately if all the criteria outlined above are met. CVB reserves the right to reject submissions if a firm does not follow the intent of this Notice or has repeated insufficient or incorrect submissions (i.e., more than three unsuccessful requests).

If a firm has three unsatisfactory results in concurrent testing of PLS of any or all product(s) by the firm or the CVB Laboratory, the option for concurrent confirmatory testing of PLS will be removed for all new products from that firm for a period of one year.