Serial Release – Rebottling/Reprocessing – Process

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Source Document: Title 9, *Code of Federal Regulations,* section114.17; Veterinary Services Memorandum No. 800.62; and CVB-SOP-0032, *Processing Serial Records*

Background:

These requests must be submitted on an APHIS Form 2008, not via a Mail Log Submission. Each request should have a Form 2008 for the product/serial being rebottled/reprocessed and a letter providing details concerning the reprocessing/rebottling process.

Rebottling of biological products is allowed for in accordance with title 9, *Code of Federal Regulations* (9 CFR), section114.17. This is part of the regulatory flexibility built into the 9 CFR regulations. Additional guidance is found in Veterinary Services Memorandum No. 800.62 (VSM 800.62), "Relabeling, Rebottling, and Reprocessing Veterinary Biological Products, Section V." The firm disposition on the Form 2008 request should be marked as Other - Rebottling.

Reprocessing of biological products is allowed for in accordance with 9 CFR 114.18. This is part of the regulatory flexibility built into the 9 CFR regulations. Additional guidance is found in VSM 800.62, "Relabeling, Rebottling, and Reprocessing Veterinary Biological Products, Section VI. A-C." The firm disposition on the Form 2008 request should be marked as "Reprocess & Retest."

VSM 800.62, Section VI.D, authorizes the reprocessing of product by adding two serials (both prepared in accordance with the filed Outline of Production (OP)) together to adjust antigen content. **This is not meant to include a serial of completed product already in final containers.** If this is requested, contact an Inspection and Compliance Section Leader.

Most steps follow the outline as listed in **CVB-SOP-0032**, **"**Processing Serial Records," with the following additions.

A. Biologics Compliance Assistant (BCA) Initial Review: Requests are shown in the Reprocess & Retest section in BCA initial review.

1. The BCA reviews the information on the incoming Form 2008 request (hardcopy or NCAH Portal submission) for accuracy and completeness. Important information to check is that the serial number(s) listed that need to be reprocessed are listed in both the firm's Form 2008 and/or letter, and the LSRTIS Entry screen.

2. The BCA may audit the submission back in accordance with the current version of **CVB-WI-0104**, "Serial Release – Audits and Reference Slips for IC Documents," if the information required is incomplete.

3. If the submission is not audited back, route it to the Specialist for review.

B. Specialist Review: The reason for review is listed as "R&R" under the Specialist Review

1. Review submission in accordance with the regulations listed in 9 CFR 114.17 or 114.18.

   a. Request should only be considered for product that has not left licensed premises. This is a regulatory requirement for rebottling and common sense for most reprocessing requests.

   b. A letter regarding the rebottling/reprocessing procedures should include all steps and locations where the rebottling/reprocessing will take place. Identity of materials to be used in the reprocessing event is also beneficial.

   c. The rebottled/reprocessed serial(s) must have a unique identification. This is entered when the request is logged into LSRTIS through the NCAH portal.

2. Review the supporting documents submitted.

   a. This may require reviewing the OP and/or the Facility Documents.

   b. Determine if the process described is detrimental to the purity of the product or would impact product stability.

3. Rebottling or Reprocessing IS NOT GRANTED for the following:

   a. Products containing a rabies fraction.

   b. In response to a contamination issue.

4. Determine if you will require a "Special Test" of the NEW/rebottled serial or NEW/reprocessed serial. See CVB-WI-0116**, "**Special Test Requests Initiated by Inspection and Compliance Staff," for complete directions.

Sterility tests would be appropriate for rebottled serials. Sterility and/or potency tests can be considered for reprocessed serials. If the potency test uses animals, requesting potency testing is discouraged but not prohibited.

5. Autogenous product - If the serial to be reprocessed is from an original first serial autogenous product, the reprocessed serial is no longer considered a first serial.

If the firm marks an autogenous serial with "Yes" for first serial and it is requesting to be reprocessed – this should be audited back to the firm with the comments that a reprocessed serial is not considered a first serial any longer.

6. Provide your conclusion in LSRTIS:
   Rebottling Approved
   Rebottling DENIED

   or

   Reprocessing & Retesting Approved
   Reprocessing & Retesting DENIED

7. Submit to BCA for finalizing by completing the review of the Form 2008.