Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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# Rebottling/Reprocessing - Process

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**Notes:**

# Rebottling/Reprocessing – Process

Source Document: Title 9, *Code of Federal Regulations,* part 114.17; Veterinary Services Memorandum No. 800.62; and CVB-SOP-0032, *Processing Serial Records*

**Background:**
Rebottling of biological products is allowed for in accordance with title 9, *Code of Federal Regulations* (9 CFR), part 114.17. 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.

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.

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) together to adjust antigen content. **This is not meant to include a serial of completed product already in final containers.**

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

**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 APHIS Form 2008 request (hardcopy or NCAH Portal submission) for accuracy and completeness. The **CVB-FRM-0086**, *Rebottling / Reprocessing Worksheet*, is used to document the review. The worksheet is attached to the serial record in LSRTIS, using Add Attachment to Aphis 2008, Type is General Attachment.

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

3. If the submission is not audited back, it can be submitted to the Specialist for review.

**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.

2. Review the information listed on **CVB-FRM-0086** and the supporting documents submitted.



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a. This may require reviewing the Outline of Production 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. **Note:** Rebottling or Reprocessing IS NOT GRANTED for products containing a rabies fraction.

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

   **or**

   **Reprocessing & Retesting Approved**
   **Reprocessing & Retesting DENIED**

6. Submit to BCA for finalization.



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