



**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

**1920 Dayton Avenue
PO Box 844
Ames, IA 50010**

(515) 337-6100

Serial Release - Rebottling/Reprocessing - Process

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Notes:

Serial Release – 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:

These requests must be submitted on an APHIS Form 2008, not via a Mail Log Submission. Each request should have an APHIS 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), 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. The firm disposition on the APHIS 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 APHIS 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) 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.

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](#), *Serial Release – Rebottling / Reprocessing Worksheet*, may be 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](#), *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.

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 information listed on [CVB-FRM-0086](#) and the supporting documents submitted.
 - 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. 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.
6. Provide your conclusion in LSRTIS:
Rebottling Approved
Rebottling DENIED

or

Reprocessing & Retesting Approved
Reprocessing & Retesting DENIED
6. Submit to BCA for finalization.