# United States Department of Agriculture
# Center for Veterinary Biologics

## Standard Operating Policy/Procedure

## Processing Requests for Rebottling/Reprocessing

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## 1. Purpose

The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) may authorize a manufacturer to rebottle or reprocess a biological product, in accordance with the Code of Federal Regulations, Title 9 (9 CFR) Sections 114.17 and 114.18. Reprocessing and rebottling requests are also described in Veterinary Services (VS) Memorandum 800.62. This document outlines the procedure for processing these requests.

## 2. Definitions

**2.1 BCA:** Biologics Compliance Assistant

**2.2 PC:** Program Coordinator

**2.3 IC:** Inspection and Compliance

**2.4 Specialist:** Biologics Specialist

**2.5 OAA:** Office Automation Assistant

**2.6 R&R:** Reprocessing and Rebottling

**2.7 Form 2008:** APHIS Form 2008

**2.8 VBIS:** Veterinary Biologics Information System

**2.9 Rebottling:** The process whereby all, or part, of a liquid serial that has not left the licensed establishment premise, is aseptically returned to the mixing tank, thoroughly mixed, and rebottled in new final containers.

**2.10 Reprocessing:** The process of modifying the product after all of the ingredients that make up a serial have been combined according to the applicable Outline of Production and the product is in its final form and composition.

**2.11 IC Document Tracking Database**: A relational database, which is located on the IC Intranet, used to track firm requests from the time they are received at CVB-IC, until a finalized response is mailed back to the requesting manufacturer. This database is located at: [redacted].

## 3. Responsibilities

**3.1 Licensee:** A licensee must submit its request for the authorization to rebottle or reprocess a serial to CVB-IC in writing. Such requests must describe the methods that will be used for the R&R and must state the proposed serial number that will be assigned to the new rebottled/reprocessed serial. The licensee must also submit a completed Form 2008 for the serial to be rebottled/reprocessed.

**3.2 IC-OAA:** The IC-OAA receives requests for rebottling or reprocessing from the licensed manufacturers as part of the daily incoming mail, and logs the request into the IC Document Tracking Database. The IC-OAA initials IC's copy of the Form 2008 as indication that the request has been received by CVB-IC for processing and has been logged into the database. The IC-OAA then places the request in the BCA pending drawers that contain the firm requests, filed by the date received, for preliminary review by the BCA.

**3.3 BCA:** The BCA performs the preliminary review for R&R requests. Once the secondary review is completed by the Specialist, the BCA processes any Form 2008s submitted in support of the request and finalizes any other documents to be returned to the manufacturer.

**3.4 Specialist:** The Specialist, or individual acting in his/her capacity (i.e. Section Leader or PC), performs a secondary review of requests for rebottling or reprocessing and authorizes or denies such requests. Except as provided by Section VI.D of VS Memorandum 800.62, firms must obtain authorization from CVB-IC prior to reprocessing a serial of product.

## 4. Procedures

### 4.1 The IC-OAA

- Stamps the date received on both copies of the Form 2008 and any other supporting documentation accompanying the request for rebottling or reprocessing submitted by the manufacturer and at this time enters the firm's request into the IC Doc Tracking database.

- Initials IC's copy of the Form 2008 in the "Remarks" section of the Form 2008 to indicate entry into the database.

- Places the request in the Pending Firm Request Files for documents waiting for the processing by the BCAs. These requests are organized in chronological order by date received.

### 4.2 The BCA

- Selects a request on a "first in-first out" basis according to date received.
- Completes the top portion, including Part A, of the current version of **ICFRM0006** or **ICFRM0007** (whichever is applicable for the type of request being made).
- For rebottling requests, the BCA verifies that the serial, or portion thereof, to be rebottled has not left licensed premises.
- If the preliminary review for rebottling or reprocessing is determined to be satisfactory, the BCA forwards the request to the Specialist who is assigned the firm along with the following documents: any copy of any previous Form 2008s on file; the new Form 2008s received that came in with the firms request; the applicable preliminary review worksheet (**ICFRM0006** or **ICFRM0007**) that has been completed by the BCA; and the Outline of Production and any other related documentation that is referenced by the Outline of Production.
- Returns requests failing preliminary review to the manufacturer, with an audit form (APHIS Form 2044) or, if necessary, a letter of explanation detailing the reason(s) for the return.

### 4.3 The Specialist

- Completes Part B of the applicable worksheet (**ICFRM0006** or **ICFRM0007**).
- Approves or denies the request.
- If the Specialist requests that a special test be conducted on the newly reprocessed serial, the Specialist includes a copy of the test request with the documentation that is returned to the BCA for processing (see **ICSOP0021**, Section 4).
- Signs both copies of the Form 2008s if approving the request.
- Returns the completed worksheet and all supporting materials back to the appropriate BCA for processing.

### 4.4 The BCA

- Completes Part C of the applicable worksheet and processes the Form 2008 in accordance with the disposition marked by the Specialist on the worksheet.

**Note: The completed Form 2008 is the firm's formal approval from IC to proceed. The Form 2008 must come back to the BCA signed by the Specialist if he/she is authorizing the firm's request.**

- If the serial status indicates that the serial **is not on test**, no samples were received for more than 15 days, and the Specialist authorizes the R&R:

  a. Enters the Form 2008 as R&R in VBIS.

  b. Add notes upon entry (R&R apprv per/specialist, new serial number will be _____ and the BCA's initials.)

  c. Immediately releases the serial in VBIS as "NRL" (Not to be Released).

  **Note: If the serial has previously been released to the marketplace, enter only the notes on the computer system. Do not go in and change the APHIS disposition on a previously released serial.**

  d. Stamps both copies of the Form 2008 with the R&R stamp, and writes in the new serial number as designated by the firm on both the IC copy and the firm's copy of the Form 2008.

  e. Stamps the title block on both Form 2008s with the "Specialist" stamp and stamps the date in the date field of both copies.

  f. Initials at the top of IC's copy of the Form 2008 indicating that the computer entry and the paperwork have both been completed for this request.

  g. Checks both the "incoming 2008s received report" and the "list of serials released report" for accuracy and initials off on both. The BCA also staples them together and files them in the "Released" notebook kept in the BCA area.

  h. Mails the firm's copy back to the firm.

  i. As a final step, the BCA completes the record for the rebottling/reprocessing request in the IC document tracking database. The record should already be in the database as logged in by the IC-OAA upon

receipt. The BCA searches for the existing R&R record. A general search of **all** requests is done in the database if the Form 2008 has the IC-OAA's initials in the "Remarks" section and the record does not come up in the serial specific search. It is possible that a data entry discrepancy may cause an individual serial record to not come up in the initial search.

The BCA completes all applicable fields in the database. Finalizing the routing completes the record in its entirety. If necessary, the BCA may add additional notes in the database for clarity.

j. The Lead BCA or designee may conduct random checks to ensure that the Form 2008 was processed correctly.

- If the serial to be reprocessed **is on test**:

  a. Files a copy of the request for special testing entered in VBIS by the Specialist in the BCA pending drawers according to the licensed establishment number and then the Product Code.

  b. Waits for test results from the lab, receipt of the newly reprocessed Form 2008 from the firm, and an action sheet to come off prior to processing the newly designated serial. The newly designated serial should reference the serial number it was reprocessed from in the remarks section. The BCA adds this as a note when entering the newly reprocessed serial.

  c. Confirms that the initial request for the reprocessing and the Form 2008 that accompanied the request was released in the computer system as "NRL."

- Initials at the top of the worksheet to indicate completion of the IC document tracking entry into the database.

- Files the completed **ICFRM0006** or **ICFRM0007** worksheet in the location designated for completed worksheets.

- Labels other supporting documents for filing in designated establishment files and the applicable Product Correspondence file.

- Places IC's copy of the Form 2008 and other supporting documentation for filing in the respective files by the File Clerk.

- If the rebottling/reprocessing Form 2008 has an original release as an addendum, the BCA staples it to the original Form 2008. The BCA files both

Form 2008s in test folder "A" which designates the current year. A history of 3 years is kept on file at Building 20 at the Combined Laboratory Facility.

### 4.5 The IC-OAA

- Performs a Quality Assurance (QA) review of the IC Document Tracking Database record by comparing the completed worksheet with the information entered in the database fields.

- If the database record is accurate, the IC-OAA selects "Locked" from the "QA Status" field on the IC Document Tracking Database. This selection locks the record from future changes.

- If errors are found in the database entries, the IC-OAA returns the worksheet to the BCA for correction of the database entry.

- Initials and dates the worksheet after the record is locked.

- Files the worksheet in the location designated for completed worksheets.

### 4.6 Resubmissions

If the firm resubmits a new/corrected request addressing previous deficiencies, the BCA or IC-OAA initiates a new record in the database and the review process begins again.

## 5. References

**5.1** Code of Federal Regulations, Title 9, Part 114, Section 17, Rebottling of biological products; and Section 18, Reprocessing of biological products

**5.2** Veterinary Services Memorandum No. 800.62, Relabeling, Rebottling, and Reprocessing Veterinary Biological Products

**5.3** ICFRM0006, *Rebottling Worksheet*, current version

**5.4** ICFRM0007, *Reprocessing Worksheet*, current version

**5.5** ICSOP0021, *Special Test Request Procedures*, current version

## 6. Summary of Revisions

- The Contact information has been updated.

- **4.4:** The reference to the Aspen Park location has been changed to Building. 20.