

United States Department of Agriculture  
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Processing Serial Records

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Processing Serial Records

Table of Contents

1. Purpose
2. Definitions
3. Responsibilities
4. Procedures
  - 4.1 Overview
  - 4.2 Receipt and Review of Incoming Form 2008s
  - 4.3 Log APHIS 2008
  - 4.4 BCA Initial Review
  - 4.5 2008 Review
  - 4.6 Specialist Reviews
  - 4.7 Lab Actions
  - 4.8 BCA Ready for Approval
  - 4.9 Specialist Ready for Signature
  - 4.10 QA Process
  - 4.11 Mailing and Filing Processed Form 2008s – Including Electronic Notification of Serial Release (ENSR)
  - 4.12 Phone and Verbal Releases
5. Audit Form 2008s
6. Hold Management
7. Processes for Firm Requests and Non-Typical Releases
  - 7.1 Inventory Transfers Requests
  - 7.2 Reprocess and Retesting and Rebottling Requests
  - 7.3 Extension of Dating Requests
  - 7.4 Short Dating
  - 7.5 Firm Mergers
  - 7.6 Challenged Test Results
8. System Functions/Releases to the NCAH Portal
  - 8.1 Daily Emails to the Firms
  - 8.2 Documents/Information Released to the NCAH Portal
  - 8.3 Status Changes for the Firms in the NCAH Portal
9. Delays in the Serial Release Processing
10. Retention of Documents
11. Summary of Revisions

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## Processing Serial Records

### 1. Purpose

Licensees and permittees of biological products shall submit to the Animal and Plant Health Inspection Service (APHIS) test summaries using the NCAH Portal or an APHIS Form 2008 (Form 2008) of testing performed on each serial or subserial of product, according to the *Code of Federal Regulations*, title 9 (9 CFR), part 116.7. The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) evaluates the firm's summaries and additional testing by CVB-Policy, Evaluation, and Licensing (PEL) and if found satisfactory, the serial or subserial is released by IC for sale and distribution. Guidelines for preparing and submitting Form 2008 are described in Veterinary Services (VS) Memorandum No. 800.53.

This document details the steps in the review process of the Form 2008, determining the appropriate disposition, and the process to release the serial in the Licensing, Serial Release, and Testing Information System (LSRTIS).

### 2. Definitions

#### 2.1 APHIS Form 2008

Form 2008, Veterinary Biologics Production and Test Report, or an equivalent approved by APHIS (see **ICWI0002**, *Approving Alternate Form 2008*), reports the entire testing summary for one serial or subserial submitted to CVB for serials eligible for marketing. APHIS Form 2008A is used as a continuation page for summaries requiring more than one page.

In this document the Form 2008 may also refer to the test summaries supplied by the manufacturers through the NCAH Portal.

#### 2.2 Program Coordinator (PC)

A Biologics Specialist (Specialist) assigned to perform certain unit-wide duties, including signing Form 2008s ready for final disposition and release.

#### 2.3 Licensing, Serial Release and Testing Information System (LSRTIS)

This database system is the information management system used by the CVB for serial information and processing.

#### 2.4 NCAH Portal

An external-facing application which enables web-based electronic submissions and responses between biologics firms and the CVB.

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## Processing Serial Records

### 3. Responsibilities

#### 3.1 Document Export Examiner and Biologic Compliance Assistant (BCA)

Processes incoming mail, reviews records, enters data, prepares serials for APHIS disposition, and mails a copy to firm.

#### 3.2 Lead BCA

Monitors the entry and release process, provides training, and performs quality assurance duties throughout the process.

#### 3.3 Specialist

Reviews selected test results from firm for compliance and determines acceptability, fields scientific questions and provides input, reviews and signs Form 2008s as the Authorized APHIS representative.

#### 3.4 Section Leaders

Provide guidance to overarching issues for the process, approve hold management requests, and make final decisions on issues of non-conformity.

#### 3.5 Product Specialist

Provides guidance regarding issues for the process and acts as liaison with PEL regarding prelicensing issues and test results.

### 4. Procedures

#### 4.1 Overview

Firms submit Veterinary Biologics Production and Test Summaries for serials prepared, either on a Form 2008 or through the NCAH Portal. This includes serials to be considered eligible for release, serials destroyed by the firm, filed for information, to correct data related to a specific serial, or requesting permission for a specific action related to a serial, such as a request to reprocess a serial or extend the dating of a serial.

There are two exceptions in which a summary format may be used in lieu of Form 2008:

- First Serial Autogenous Products – See VS Memorandum No. 800.69
- Allergenic Extracts – See VS Memorandum No. 800.53

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### Processing Serial Records

**4.2 Receipt and Review of Incoming Form 2008s** – See **ICWI0910**, *Mail Receipt, Process, and Distribution (BCA)* or **ICWI0915**, *Mail Receipt, Process, and Distribution (Student)*

Form 2008s are received via the NCAH Portal, a courier service, or the United States Postal Service. Hand-delivered Form 2008s are no longer accepted. Incoming Form 2008s must include the original signature of the Authorized Firm representative in Block 13 and an exact copy. Submission via the NCAH Portal is considered an authentic submission and does not require any additional electronic signatures.

**4.3 Log APHIS 2008** – See **ICWI1210**, *Log APHIS Form 2008*

All incoming Form 2008s that are received hard copy are entered into LSRTIS for processing. Form 2008s that are received via the NCAH Portal are received at the time the firm personnel submits them to the CVB, no data entry is required by CVB personnel.

**4.4 BCA Initial Review** – See **ICWI1310**, *BCA Initial Review*

The functions of the BCA initial review serve as a quality assurance check for data entry and the technical review of the Form 2008 for accuracy and completeness of submissions.

If internal data entry errors are noted, they are corrected during this review. If the Form 2008 does not contain adequate or complete information, it should be audited back to the firm. See **Section 5, Audit Form 2008s**.

If there are questions concerning scientific information or non-standard test results, the BCA submits the Form 2008, electronically and hard copy (if applicable), to the Specialist for review.

**4.5 2008 Review** – See **ICWI1510**, *Mock Checks in LSRTS Phase II*

The BCA compares the Form 2008 to the test system (serial spec sheet) from LSRTIS. A mandatory check may be requested by either a Specialist or Reviewer.

Criteria for a Mandatory 2008 Review include: program diseases, items with a long term review hold (items needing review longer than 3-6 months should be considered under Mandatory 2008 Review instead of Review Hold); also, products newly licensed should be entered for a period of one year post licensure.

**4.6 Specialist Reviews** – See **ICWI0048**, *Specialist Review Action within LSRTIS*

Specialists are required to review the information on many Form 2008s. Form 2008s with test results other than “S” (Satisfactory) are forwarded to the Specialist to determine the acceptability of the test outcome. In cases where the test information on the Form 2008

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### Processing Serial Records

does not match the test system in LSRTIS, the Specialist will research the issue and provide an action.

Firm requests submitted on Form 2008s should be sent to the Specialist for review. See **Section 7** for these types of requests.

In cases when the Specialist has deemed necessary, a Release Requirement may be applied when the information submitted or discovered by CVB-IC warrants additional information during the marketing of a specific serial or product.

A release requirement is an obligation placed on the establishment in conjunction with the marketing of a specific serial or product. Release requirements are at the discretion of the Biologics Specialist, Product Specialist, and/or Section Leader. See **ICWI0048**, *Specialist Review Action within LSRTIS*.

A Special Test Request may be considered by the Specialist as well. See **ICSOP0043**, *LSRTIS Special Test Request Procedures for Inspection and Compliance*, for guidance.

#### **4.7 Lab Actions –**

**4.7.1** Form 2008s that have completed the BCA Initial Review, mock check procedures, and if needed, Specialist Review, move to Lab Actions area. There are six sections under laboratory actions: waiting samples, waiting samples > 90 days, waiting testing, on test, pending licensure, and subserials. The system automatically determines the acceptability of a serial to move on to the next area, if the criterion is met.

**4.7.2** Conditional Release – See **ICWI0410**, *Conditional Serial Release*

Product samples still within the selection period or under test by the CVB may be conditionally released in documented emergency situations and on condition of immediate recall. (Use the current version of **ICFRM0010**, *Serials Ready for Conditional Action*.) A request for conditional release must be made in writing.

#### **4.8 BCA Ready for Approval – See ICWI1410, BCA Ready for Approval**

After the Form 2008 has been reviewed, the “at risk” date has passed and all testing by CVB has been completed, the Form 2008 can be prepared for signature and released to the marketplace.

**4.8.1** Guidance on APHIS Disposition and criteria for choosing specific dispositions may be found in **ICWI0130**, *APHIS Dispositions and Associated Information on Form 2008s*.

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### Processing Serial Records

**4.8.2** Serials listed under “Rejected” in LSRTIS have been placed there because of either an error in the system or a human error. Once the error has been remedied, the BCA can process this serial in accordance with the work instruction. BCAs or Product Specialist will monitor this list to ensure action is taken soon after the problem has been fixed.

**4.9 Specialist Ready for Signature** – See **ICWI0058**, *Ready for Signature Action in LSRTIS (Specialist and BCA Duties)*

The PC or Specialist is responsible for the final review of Form 2008s authorizing marketing disposition, prior to signing the electronic record and in Block 17 of the hard copy Form 2008 if applicable, as the Authorized APHIS representative.

The BCA may review and sign Form 2008s which acknowledge firm actions.

**4.10 QA Process** – See **ICWI1110**, *QA Process for Serial Release*

The Lead BCA or their designee does a final quality check of the hard copy signed Form 2008s prior to redistributing to the BCAs for mailing and filing. This is to ensure the Form 2008s are complete and meet the purpose intended.

**4.11 Mailing and Filing Processed Form 2008s – Including Electronic Notification of Serial Release** – See **ICWI0111**, *CVB-IC Mail/Filing*

The hard copy Form 2008s are returned to the firms one day per week (usually Wednesdays) to serve as written notification of the marketing status of each serial. However, the firms that have signed up for Email Notification of Serial Release (ENSR) are notified electronically by the LSRTIS notification process at 11 a.m. and 3 p.m., Central time, daily.

For Form 2008s received through the NCAH Portal, notification is submitted at 11 a.m. and 3 p.m., Central time, as well.

**4.12 Phone and Verbal Releases**

Phone releases may be authorized by CVB-IC management. This communication is captured in the LSRTIS IC Phone Log. This customer service is not utilized except in rare cases as the ENSR and NCAH Portal has replaced this service.

**5. Audit Form 2008s** – See **ICWI0075**, *Audits and Reference Slips for IC Documents*

If a discrepancy is observed at some point during the processing of the Form 2008, an APHIS Form 2044 (Form 2044) is generated documenting the issue. The Form 2044 and the Form 2008 are sent back to the firm for correction on a daily basis.

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### Processing Serial Records

#### 6. **Hold Management** – See **ICWI0810**, *Hold Management Process for APHIS Form 2008s*

There are two types of Hold Releases: Legal and Review. Both types of holds in the serial release process may be placed at the establishment level, product code level, or for a specific serial. A review hold can also have an agent level hold.

The hold may be requested by a Specialist for several reasons. Review holds do not need management approval. Legal holds must be submitted to a Section Leader, who has the responsibility to approve or deny the request.

Serial specific items, short term review, or those with specific release criteria (i.e., bench record review) should be considered for Review Holds. Legal Holds may have the criteria for anything that will delay or prohibit market release.

#### 7. **Processes for Firm Requests and Non-Typical Releases**

Circumstances in which a possible change in the release process noted above may not be followed include the following situations:

**7.1** Inventory Transfers: See **ICWI0310**, *Processing Inventory Transfers*

**7.2** Reprocessing and Retesting, and Rebottling Requests: See **ICSOP0006**, *Processing Requests for Reprocessing/Rebottling*

**7.3** Extensions of Dating: See **ICSOP0007**, *Extension of Dating – Biologics Compliance Assistant Procedures*, and **ICWI0107**, *Extension of Dating – Items for the Biologics Specialist to Consider*.

**7.4** Short Dating: A regulatory flexibility used if a serial meets the following criteria: Lyophilized or frozen product (Live Virus or Modified Live Virus), when the titration is below the release requirements, but above the end of dating requirements. Half-dating of the serial's expiration date may be given. This is NOT intended for use of killed viral or bacterial products.

NOTE: Short dating due to exportation of a serial is different. If this is the initial submission, it should be submitted as "Eligible for Release" by the firm. If the serial submission is changed due to the short dating for this purpose, this should be submitted by the firm as "Other – Expiration Date Correction."

**7.5** Firm Mergers. See **ICWI0042**, *Processing of APHIS Form 2008s for Prelicensing Serials related to Firm Mergers*. Inventory Transfers may also be related to mergers, see **Section 7.1**.

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### Processing Serial Records

**7.6** Challenged Test Results by the Firm. See **ICWI0061**, *Processing APHIS Form 2008s if Unsatisfactory Testing by the CVB and the Possible Challenge of the Test Results by the Manufacturer*

## 8. System Functions/Releases to NCAH Portal

See the System Administrators for LSRTIS for functionality in which the normal process needs to be halted or updated, specifically for ENSR or NCAH Portal releases.

### 8.1 Daily Emails to the Firms

Serial Release notifications are sent at 11 a.m. and 3 p.m., Central time, through the serial release inbox. Included in these notifications are the APHIS Disposition, CVB Laboratory Test Reports, Audit reports, and Reference Slips. These are sent to one email per firm and the email may be updated per instructions in **ICWI00239**, *Process for Email Address for Electronic Notification of Serial Release*.

### 8.2 Documents/Information Released to the NCAH Portal

The Liaison/Alternate Liaison, Quality Review role, and Serial Release role at the firm, who has level 2 eAuthentication through the USDA, may search on 2008 information. Updates to the NCAH Portal are sent at 11 a.m. and 3 p.m., Central time, also. Updates include a status change with the applicable CVB Response (APHIS Disposition, Audits, Reference Slips and Test Reports).

### 8.3 Status Changes for the Firm (within the NCAH Portal):

- **Submitted** – items have been received by the CVB. The item will not be updated until it is either complete, or the sample has been put on test.
- **Serial is on Test** – items have been received by the CVB and gone through the initial review. The firm may see the projected off-test date and the testing that is being performed. Updated off-test dates will be provided to the firm through the NCAH Portal as well.
- **Completed** – items have been signed by the CVB. If an APHIS Disposition shows, this will be the disposition assigned to the Form 2008. However, if a completed item does not have an APHIS Disposition showing, this Form 2008 was audited. The User must open the “Info” link to see the details of the release or audit.

*All “open” submissions will remain in the NCAH Portal until they are completed. Completed submissions are available to the firm for 60 days after their last action. Firms are expected to download the CVB response to their own system*

## Processing Serial Records

### 9. Delays in the Serial Release Processing

If for any reason the normal serial release process is interrupted (e.g., weather-related mail delays, issues with the computer system), releases may be granted verbally via telephone the next working day.

- Speak only to individuals authorized by the firm to receive serial release information. Read only the information on the Serial Status sheet.
- Mail the Form 2008s during the regular mailing process and add to customer service database.

### 10. Retention of Documents

**10.1** Form 2008s for the current year and the past two years are kept in the current files. Each product has 3 Test Report folders (A, B, and C) in the West file unit at CVB-2N. Form 2008s released during the current calendar year are filed in Folder A. Folders B and C contain Form 2008s from previous years. Form 2008s are retained for a total of seven years.

**10.2** The Action Sheets are retained in the Form 2008 Pending Files for at least 6 months. After this time, the Action Sheets are archived at the CVB record retention area located at 1920 Dayton Avenue, Ames, Iowa.

**10.3** The “List of Release Actions” is considered to be a checklist and not an activity report. These lists are maintained for six months.

### 11. Summary of Revisions

#### Section .03

- Incorporated changes related to the NCAH Portal.
- Included information related to work instructions not previously mentioned in the SOP.

#### Version .02

- The Contact information has been updated.
- This document has been rewritten to more accurately reflect the current practices in place.

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**Processing Serial Records**

- The information has been updated to reflect the LSRTIS rewrite in 2014.
- Information has been removed that relates to the HP3000/Reflections computer system.
- The information detailed specific job duties and time frames have been removed and incorporated into work instructions
- Information regarding electronic notification has been added.

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