



Animal and Plant
Health Inspection
Service

Veterinary Services

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Serial Release - Ready for Signature Action in LSRTIS (Specialist and BCA Duties)

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Notes:

Serial Release - Ready for Signature Action in LSRTIS (Specialist and BCA duties)

Source Document: CVB-SOP-0032, *Processing Serial Records*

LSRTIS - Ready for Signature Tab in the Serial Action Sheet is a listing of APHIS Form 2008s (Form 2008s) requiring signature. The signature is the final disposition for the specific Form 2008. It may be a marketing disposition, acknowledgement of receipt or completion of an audit.

This action should be the daily priority for the Specialist/Program Coordinator (PC) or the Biologics Compliance Assistants (BCA); usually completed prior to 10:30 a.m.

Market authorizations or prohibiting of marketing authorizations (see Section IV. c and d) may only be signed by Biologics Specialists, Managers (Export, Facilities, Investigation and Product Managers) Inspection and Compliance (IC) Section Leader, or IC Director.

Form 2008s submitted for reasons other than a market release may be signed by the BCA. The Specialist should review these Form 2008s prior to signature as one tool used to monitor controlled processes. Many “Other” 2008s may indicate a lack of control within the establishment. The Firm Dispositions that can be signed by the BCA:

- Other - File for Information
- Other - Inventory Corrections
- Other - Expiration Date Corrections
- Destroyed by Firm

Audited Serials (by the Specialist and the BCA) will also be on the list. REMINDER – the audited serial should be signed by the person who did the audit. If the auditor is not available, the audit may be signed by the PC or their Section Leader.

The list of serials under Ready for Signature is the “Action Sheet.” If it isn’t on that list, but you have a hard copy Form 2008 in front of you, you should not sign the 2008. Also, the disposition on the hard copy Form 2008 must match the disposition in LSRTIS under Ready for Signature, if applicable.

Reminder to review all test reports, mail logs and compliance actions that may be on the Serial Stat. The PC should also review any remarks from the Specialist in Specialist Review area.

Process:

I. Ready for Signature

- a. For hardcopy Form 2008s - Verify the Form 2008 matches the LSRTIS record.
- b. For All 2008s: Confirm the APHIS disposition is correct for the serial – or blank for an audited serial. Refer to CVB-WI-0129, Serial Release – APHIS Dispositions and Associated Information on 2008s).
- c. Review the Serial Stat to ensure all associated mail logs, holds, or previous 2008s have been reviewed and acted on appropriately.
 - i. Ensure I/NT or process deviations have been reviewed by the Specialist.
 - ii. If it is an “Other” 2008 submitted for correction, ensure the serial has been previously released for market.
 - iii. If the serial is part of a Review Hold, check to make sure release criteria (if applicable) has been included.
 - iv. Check to see if the laboratory had performed testing and if the APHIS Disposition matches the test results – See **CVB-WI-0091** for serials tested by CVB-L and marked as Test Completed UNSATISFACTORY
- d. The user can perform the following actions:
 - i. **Sign the 2008:** Click on the link “Sign” for that specific Serial #
 - ii. **Audit:** See Section II, Auditing a Serial
 - iii. **Reference Slip:** See Section III, Adding a Reference Slip
 - iv. **Reject:** Click on the “Reject” button. This action moves the 2008 back to the Ready for Approval, Rejected area to be held until ready to move on. This is not the same as an Audit action.
 - v. **Sign multiple 2008s:** Click on multiple toggle buttons for serials to make the “Sign” button appear, and allows the user to sign the 2008s.

II. Auditing a Serial

- a. See **CVB-WI-0104**, *Serial Release – Audits and Reference Slips for IC Documents*.
- b. **Once audited, the 2008 will move to BCA Ready for Approval and can be moved on for Signature.**
- c. All audits will be sent via ENSR. The hard copy forms will be sent back once per week to the firms but the firm can use the ENSR to resubmit prior to receiving back the hardcopy Form 2008. Portal submissions do not require a hard copy audit to be sent back.

III. Adding a Reference Slip

IF hard copy submission, the person who initiated the reference slip should be the one who prints out a reference slip and attaches to the 2008. Click on the “2008” link on the Action sheet for printing. See **CVB-WI-0104**.

IV. Electronic Notification of Serial Release (ENSR)

- a. The firms that have signed up for the ENSR will receive the notification of APHIS disposition for all 2008s processed (both those for the initial marketing authorization and for those providing additional data) and will occur at 11 a.m. or 3 p.m., central time, whichever comes following signing within the system.
- b. If the Form 2008 was received from the Portal, the Portal will also be updated for the firm at 11 a.m. and 3 p.m., with the APHIS Disposition, any test reports from the CVB, the ENSR Report, and a pdf file of the Form 2008 information that could be used in lieu of a hard copy Form 2008. In addition, any reference slips or audits will be sent to the Portal as well.
- c. APHIS Dispositions authorizing the market release of serials are as follows:
 - i. Not to be Tested
 - ii. Other – Extension of Dating Approved
 - iii. Other – Released for Further Manufacture
 - iv. Other – Serial Released for Market
 - v. Other – Subsequent Shipment Approved (for permitted product)
 - vi. Shortened Dating Approved
 - vii. Tests Completed Satisfactory
 - viii. Prelicense – Test Completed Satisfactory
 - ix. Prelicense Serial – Release for Market
 - x. Other – Conditional Release Granted
- d. APHIS Dispositions prohibiting shipment of the serial:
 - i. Other – UNSATISFACTORY Based on Firms Results
 - ii. Tests Completed UNSATISFACTORY
 - iii. Prelicense – EXPIRED
 - iv. Prelicense – Tests completed UNSATISFACTORY
 - v. Other – Serial NOT RELEASED FOR MARKET
 - vi. Shorten Dating DENIED
 - vii. Other – Subsequent Shipment DENIED
 - viii. Other – Extension of Dating DENIED