

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

The Ready for Signature action signs the final disposition to the APHIS Form 2008 (2008) or completes an audit record, ultimately completing a record for a specific 2008. This action should be the daily priority for the Specialist/Program Coordinator (PC) or the Biologics Compliance Assistants (BCA); usually completed prior to 11 a.m.

Only a Biologics Specialist, Senior Biologics Specialist, Product Specialist, Inspection and Compliance (IC) Section Leader, or IC Director sign 2008s for authorizing the market disposition.

However, other APHIS dispositions simply acknowledge the firm's action. The BCA can sign these 2008s. These include the following firm dispositions that may or may not need to be reviewed by the Specialist/PC prior:

No Specialist Review needed

- Destroyed by Firm

Specialist Review needed prior to signing

- File For Information
- Inventory Corrections
- Expiration Date Corrections

Just a reminder, that 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 2008 in front of you, you should not sign the 2008 or vice versa, unless the 2008 information was received from the NCAH Portal designated by a Y under the Portal column. Also, the disposition on the hard copy 2008 must match the disposition in LSRTIS under Ready for Signature, if applicable.

**Note: Audited serials will show here and should be signed by whoever signed the hard copy audit.

Process:

I. Ready for Signature

- a. Verify that the hard copy of the 2008 matches the record for which you are reviewing.
- b. Confirm the APHIS disposition is correct for the serial – or blank for an audited serial.
- c. 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

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- 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.
- v. **Sign multiple 2008s:** Click multiple toggle buttons for serials will make the “Sign” button appear, and allows the user to sign the 2008s.

II. Auditing a Serial

- a. See **ICWI0062**, *Auditing a Serial or Attaching a Reference Slip with LSRTIS*.
- b. **Once audited, the 2008 will move to BCA Ready for Approval and can be moved on for Signature.**
- c. The audits will be sent via ENSR as well as should be sent back hard copy once per week to the firms, if the APHIS Form 2008 is received hard copy. Portal submissions do not require a hard copy audit to be sent back.

III. Adding a Reference Slip

The person who initiated the reference slip should be the one who prints the hard copy and attaches to the 2008, if the 2008 is received hard copy. Click on the “2008” link on the Action sheet for printing. See **ICWI0062**, *Auditing a Serial or Attaching a Reference Slip with LSRTIS*.

IV. Electronic Notification of Serial Release (ESR)

- 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. For Further Manufacture 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

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- viii. Prelicense – Test Completed Satisfactory
- ix. Prelicense Serial – Release for Market

- 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