

Hold Management Process for APHIS Form 2008s

The Hold Management process is a way for Inspection and Compliance (IC) to perform extra review and ensure serials are not released to the market if there are substantiated reasons. They are maintained within the LSRTIS module, under the Serial Release heading.

Criteria for Legal Hold: Issues that are of regulatory in nature and have been communicated to the firm in writing that IC is withholding product from the market place.

Criteria for Review Hold: Serial specific items, short term review (< 3 months), or those with specific release criteria (i.e., bench record review) should be considered.

NOTE: Instead of a Hold, a user may also consider utilizing Mandatory 2008 Review. These may include: program diseases, items with a long term review hold (longer than 3-6 months), and newly licensed products (for 1 year post licensure).

A. Placing a Legal Hold

Specialist fills out a PINK Legal Hold Release, **ICFRM0020**, *Legal Hold Release Document*

1. **Specialist** enters data into LSRTIS through Hold Management, +Create Serial Hold
2. Add appropriate information for the hold. A hold can be placed at the Establishment level, Product Code, or Antigen Fraction level or for a specific serial.
 - a. Choose **Legal** from pull-down list
 - b. Establishment
 - c. Product Code
 - d. Serial #
 - **Leave blank** unless the serial number is specific
 - **DO NOT enter "ALL,"** as this will only look for serials identified as "ALL."
 - e. Hold Reason:
 - Inspection – On-site inspection observations or actions
 - Question about product quality
 - Outlines of Production have not been reviewed annually
 - Expired Reference – self explanatory
 - Investigation – related to Veterinary Biologics Investigations (VBIs)
 - Review – any hold that does not fit the reasons above
 - Expired Conditional License
 - Inactive Product License
 - Outline Review
 - *For multiple reasons, use CTRL + Shift and click on each applicable drop down.
 - f. Release Criteria – enter the criteria that must be met to release individual serials or the hold in general – BE SPECIFIC

This will move the request to **Product Manager Reviews**.

3. The **Section Leader** can either **Accept** or **Deny** the request in LSRTIS.
 - a. Review PINK – if agree, sign and date.
 - b. In LSRTIS go to Product Manager Review, Recommended Holds
 - c. Click OK if approve; this will activate the hold.

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- d. *Click Deny* if the request is denied; this will end the process.
- e. Submit finalized PINK to responsible Biologics Compliance Assistant (BCA)

The PINK is then submitted to the BCA responsible for the firm. They will file the document in the pending drawer.

B. Intermittent Removal of Legal Holds – when APHIS Form 2008 (Form 2008) is submitted for release. This is done mostly if a serial was made prior to the hold being into effect (i.e., expired reference).

1. BCA

- a. Pull PINK from the drawer
- b. Place a hold release sticker on the back of the pink and fill out the date and serial number
- c. Clip hardcopy Form 2008 to PINK and place in purple folder
- d. From BCA Initial Review Box, push Form 2008 to Specialist. List Reason as Legal Hold

2. Specialist

- a. Review Form 2008 against the release criteria listed
- b. In LSRTIS, *Click Review* link

Approve –

- If known, you may mark the appropriate APHIS Disposition, but this is not required.
- In comments type, “Meets release criteria,” or any other pertinent information.
- Document reason for hold release on sticker on back of PINK and sign the sticker.

Deny – allows you to maintain the electronic Form 2008 in the Specialist Review box while waiting for additional information. In most cases, the Specialist should Audit the serial (see **ICWI0062**, *Auditing a Serial or Attaching a Reference Slip within LSRTIS*, for Auditing procedures).

If you intend to UNSAT the serial based on firm’s test result, you must approve the hold release and mark the APHIS 2008 Disposition as “Other – Unsat based on Firm’s Test Results.”

Return Purple Folder to BCA

3. BCA

Moves the Form 2008 through system following the process in **ICSOP0010**, *Processing Serial Records*.

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C. Final Removal of a Legal Hold – when the firm has met all the criteria requested, the serial has already been processed, or the licensed has been terminated a hold can be removed.

1. Specialist

- a. Fill out PINK with reason to remove hold
- b. Go to **Hold Management** and search for the applicable hold
- c. *Click* on **Show**
- d. *Click* on the Recommend for Removal
- e. Submit PINK to Section Leader or designate

2. Section Leader or designate

- a. Review PINK – if agree, sign at Removal Authorized by and date.
- b. In LSRTIS go to Product Manager Review, Recommended Holds
- c. and *Click* OK
- d. Submit finalized PINK to responsible BCA

3. BCA – file PINK in product correspondence for the firm.

D. Placing a Review Hold

Specialist fills out a YELLOW Review Hold Release Document, **ICFRM0024**

Check – BCA Review if a Form 2008 that meets the release criteria documented does not need to go to the Specialist

Check – Specialist Review if the Form 2008 needs to go to the Specialist regardless of the situation

Specialist enters data into LSRTIS through Hold Management

1. Choose + Create Serial Hold

2. Choose Type as **Review** from drop-down list

Add appropriate information for the hold – a hold can be placed at the Establishment level, Product Code or Antigen Fraction level, or for a specific serial.

3. Establishment

4. Product

5. Serial

- a. **Leave blank** unless the serial number is specific
- b. **DO NOT enter “ALL,”** as this will only look for serials identified as “ALL.”

6. Hold Reason

- a. Limited Serials Produced – in cases in which few serials are prepared each year and there is reason to suspect testing issues – could also consider putting the Code on 100% mock check. Request through a Section Leader.
- b. Technology Transfer – used for mergers between firms
- c. Outline Review – waiting for a specific change in the outline of production to be approved
- d. Unsatisfactory testing – by the firm. Information as to which test was unsatisfactory at the firm should be included. Usually we are expecting a DBF 2008, but could also be request for reprocessing (in the case of an unsatisfactory potency test).

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- e. CVB Testing Performed – in some cases, CVB testing is set at 100% but testing on the bulk differs from testing on the final use product; therefore, must be walked through the system, example, Est. [REDACTED] Code [REDACTED].
 - f. Inspection – on-site inspection observations or actions
 - g. Investigation – related to VBIs
 - h. Review – any hold that does not fit the reasons above.
7. Release Criteria. Type any relevant information including how to release individual serials and when to remove the hold. BE SPECIFIC
 8. Based on the box you checked on **ICFRM0024**, INCLUDE one of the following review levels:
 - BCA Review or
 - Specialist Review

E. Intermittent Removal of Review Holds – when APHIS Form 2008 is submitted for release

1. BCA

- a. Pull YELLOW from the drawer
- b. Place a hold release sticker on the back of the pink and fill out the date and serial number
- c. If 2008 is BCA review, note outcome on the sticker and push OK.
- d. If 2008 requires Specialist review, clip hardcopy Form 2008 to YELLOW and place in purple folder.
- e. From BCA Initial Review Box, push Form 2008 to Specialist. List Reason as Review Hold

2. Specialist

Review Form 2008 either against the release criteria listed and/or the serial spec sheet/Outline.

In LSRTIS *Click Review* link

Approve –

- If known, you may mark the appropriate APHIS Disposition, but this is not required.
- In comments type, “Meets release criteria,” *click Save*
- Document reason for hold release on sticker on back of YELLOW and sign the sticker

Deny – allows you to maintain the electronic Form 2008 in the Specialist Review box while waiting for additional information. In most cases of denying the serial, the Specialist should Audit the serial (see **ICWI0062** for Auditing procedures).

F. Final Removal of Review Hold – the Specialist is responsible for determining when the Review Hold is no longer needed. They will remove the Review Hold in LSRTIS and also remove the YELLOW from the pending drawer. Provide the Yellow hold to the BCA for filing purposes.