



**Animal and Plant
Health Inspection
Service**

Hold Management Process for APHIS Form 2008s

Veterinary Services

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Hold Management Process for APHIS Form 2008s

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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).

Beginning in October 2019, duplicate entry of new Holds is not required. The official record will be within the LSRTIS System.

A. Placing a Legal Hold

1. **Specialist** enters data into LSRTIS through Serial Release - 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"**.
 - e. Hold Reason: (choose one)
 - Contamination
 - Unsatisfactory Testing
 - Limited Serials Produced
 - 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

- g. VBI Number: (enter one number if applicable. xx-xxx)
- h. Comments: enter any other information that provided background.
- i. Mail Item #(s): Enter all applicable Mail log numbers, including the outgoing letter to the firm. A letter to the firm must be included for all Legal Holds.
- j. Phone Logs #(s): Enter all applicable phone log records.

This will move the request to **Product Manager Reviews within the Serial Release Module, Recommended Holds**. However, you should still notify the Section Leader that a hold was initiated.

- 3. The **Section Leader** can either **Accept** or **Deny** the request in LSRTIS.
 - a. In LSRTIS go to the Serial Release Module, Product Manager Review, Recommended Holds
 - b. *Click OK* if approve; this will activate the hold.
 - c. *Click Deny* if the request is denied; this will end the process.

B. Intermittent Release 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), or if the serial meets the criteria.

1. BCA

- a. Pull PINK from the drawer, if the hold was issued prior to October 2019.
- 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 –
- Mark the appropriate APHIS Disposition
 - 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, if the hold was issued prior to October 2019.

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.

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.”

3. BCA

Moves the Form 2008 through system following the process in CVB-SOP-0032, *Processing Serial Records*.

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. A letter back to the firm, removing the hold is not needed.

1. Specialist

- a. Fill out PINK with reason to remove hold, if the hold was issued prior to October 2019.
- 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
- f. Notify the Section Leader if the Pink Hold sheet was not created.

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 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. *DO NOT enter “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).
 - 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. 188 Code 5302.00.
 - 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
Based on the box you checked on CVB-FRM-0094, INCLUDE one of the following review levels: BCA Review or Specialist Review
8. VBI Number: (enter one number if applicable. xx-xxx)
9. Comments: enter any other applicable comments, including if the BCA may review or if the Specialist is required.
10. Mail Item #(s): Enter all applicable ML #s, including the outgoing letter to the firm.
11. Phone Logs #(s): Enter all applicable phone log records.

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

1. BCA

- a. Pull YELLOW from the drawer, if the hold was issued prior to October 2019.
- b. Place a hold release sticker on the back of the yellow 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, list Reason as Review Hold and push the 2008 to Specialist Review.

2. Specialist

Review Form 2008 against the release criteria listed and the serial spec sheet and Outline. In LSRTIS *Click Review* link

Approve –

- Mark the appropriate APHIS Disposition
- In comments type, “Meets release criteria,” *click Save*
- Document reason for hold release on sticker on back of YELLOW and sign the sticker if the hold was issued prior to October 2019.

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 Form 2008.

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.