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## **Serial Release - Hold Management Process for APHIS Form 2008s**

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**Notes:**

## Serial Release – Hold Management Process for APHIS Form 2008s

Source Document: [CVB-SOP-0032](#), *Processing Serial Records*

The Hold Management process is one method for Inspection and Compliance (IC) to perform a review of specific serials or products prior to authorizing release of the serial to the marketplace. The reason for the Hold Action must be clearly documented. Hold Actions are maintained within the LSRTIS module, under the Serial Release heading. The paper based system was discontinued in Fall 2020.

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 Review 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 - this is a regulatory action and as such requires written notification to the firm. The notification is reviewed by the SL – Compliance prior to placing the Legal Hold information into LSRTIS. It is considered an informal license suspension.**

1. **Specialist** enters data into LSRTIS through Serial Release - Hold Management, +Create Serial Hold
2. Add appropriate information for the legal hold. A hold can be placed at the Establishment level, Product Code, Antigen Fraction level or for a specific serial. In addition, multiple holds are allowed, if the release criteria is the same.
  - a. Choose **Legal** from pull-down list
  - b. Establishment
  - c. Product(s)
  - d. Serial(s)
    - **Leave blank** unless the serial number is specific **DO NOT enter "ALL"**.
  - e. Hold Reason: (choose one)
    - Contamination – 9 CFR 113.26, 113.27, 113.28, 113.30, 113.31, 113.32, 113.36, 113.37, 113.42, 113.43, 113.46, 113.47, 113.50, 113.51, 113.52, 113.53, 113.55 or other applicable regulations related to purity of product
    - Unsatisfactory Testing – 9 CFR 113.5, 113.6
    - Inspection – On-site inspection observations or actions which resulted in a violation – cite regulation listed in inspection report
    - Expired Reference – 9 CFR 113.8(d)- use CVB-TEM-0015
    - Investigation – related to Veterinary Biologics Investigations (VBIs)
    - Inactive Product License – 9 CFR 105.4 - use CVB-TEM-5107

- Outline Review – 9 CFR 114.8(d) waiting for a specific change in the Outline of Production to be approved by PEL.  
\*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. This includes the ML for the Legal Hold letter sent to the firm.
- 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.
4. Holds for Expired References
  - a. Within the Product Manager – Recommended Hold, products that have references associated with them that are expired will automatically be sent to this queue. These will show as “Hold Initiated from Expired References” in the Action history.
  - b. These should be reviewed against the current reference module for any extensions, the Outline of Production for updates to the reference, or PEL Mail Logs.
  - c. Only updates in the Outline will allow official updates to the reference module though.
  - d. If no updates to the current expired reference, then a Legal Hold should be initiated. Go to Step A.2.i.

**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. 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.

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 the legal hold can be removed. A letter back to the firm, removing the hold is not needed.

#### 1. Specialist

- a. Go to **Hold Management** and search for the applicable hold
- b. *Click* on **Show**
- c. *Click* on the Recommend for Removal
- d. Notify the Section Leader.

#### 2. Section Leader or designate

- a. In LSRTIS go to Product Manager Review, Recommended Holds
- b. and *Click* OK if agree; if not Click Deny

**D. Placing a Review Hold– this is not regulatory in nature and the firm does not need to be notified prior to 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 Antigen Fraction level, or for a specific serial. In addition, multiple holds are allowed, if the release criteria is the same.
3. Establishment
4. Product(s)
5. Serial(s)
  - 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. 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).

- d. 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, [REDACTED]
- e. Inspection – on-site inspection observations or actions but no violations were noted. This could be related to an item of concern.
- f. Investigation – related to VBIs
- g. 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. If 2008 is BCA review, note outcome and push OK.
- b. 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*

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