



**Animal and Plant  
Health Inspection  
Service**

**Veterinary Services**

**Center for Veterinary  
Biologics**

**1920 Dayton Avenue  
PO Box 844  
Ames, IA 50010**

**(515) 337-6100**

## **Serial Release - BCA Initial Review**

**Document Number: CVB-WI-0164**

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**Effective Date: 12 Jul 2022**

**Notes:**

## Serial Release - BCA Initial Review

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

BCA Initial Review is a step for review of data entry of the record both for the NCAH Portal and internally entered documents received hard copy. This process is usually done between 10 a.m. and 2 p.m.

The Biologics Compliance Assistant (BCA) will select the **Serial Release** within the LSRTIS module and then select **Action Sheet** option. Use tab, “BCA Initial Review.”

A. View APHIS Form 2008 (Form 2008) entries by clicking on (Toggle Visibility) to open either **Primary Establishments**, firms assigned to the BCA or **Backup Establishments**, all other firms. The Form 2008s will be sorted based on the establishment disposition entered, then by Firm/Product/Serial Number. The user may sort on PRTL column and Entry time stamp also.

B. Review of Form 2008 – Locate Serial to Review under Serial Action Sheet

**Eligible for Release:**

Show 50 entries

	PRTL	Entry	Est	Product	Serial Number	Hold?					
<input type="checkbox"/>	Y	01/15/2016 15:21:01	999	205100	333						
<input type="checkbox"/>	Y	01/19/2016 06:55:51									
<input type="checkbox"/>	Y	01/19/2016 11:30:24									
<input type="checkbox"/>	N	01/19/2016 13:11:36									

to open record for data review

2008 / Serial Stat

2008 / Serial Stat

2008 / Serial Stat

2008 / Serial Stat

Info Audit Reference Slip Specialist Review 2008 / Serial Stat

Click on “2008” link.

1. Review Blocks 1-8 and 10-12 to ensure the submission is complete and correct; also review the data entry for correctness.
  - a. If a 2008 is a NCAH Portal Submission (marked as Y in the PRTL column), ensure the License Status is “Active.”
  - b. Ensure data entered matches the specifics for the product.
  - c. Ensure there is a Portal Test Data File received for those Form 2008s that need one. Mandatory for all Firm Dispositions except: File for Information, For Further Manufacture, Inventory Correction, and Expiration Date Correction.
  - d. Items required on the Test Data file: (Find the firm guidance within the 2008 portal user guide, # 5 [USDA APHIS | NCAH Portal User Guides](#))
    - Establishment #,
    - Product Code,
    - Serial #,
    - Test Reference identification,
    - date started and date concluded,
    - All test results, including validity and controls requirements, and the test conclusion.

- Also include any explanations for No Test and/or Inconclusive results.
  - Expiration date of the serial is also *requested*.
2. Note: any referenced serial in Block 11. If the 2008s are a Portal submission, these referenced serials may be added to the comments field in LSRTIS.
    - a. If no corrections are needed and the Form 2008 does not need to be sent to Specialist for Review, click on “OK BCA Initial Review” – this will move the record to 2008 Review or BCA Ready for Approval (DBF and FFM serials, for example).

**Attachments**

Add Attachment To Aphis 2008

Attachment	Type	
Test Attachment.docx	Portal Letter	FROM PORTAL

**Action History**

Action	Employee	Timestamp	Info
Aphis 2008 Logged In	NCAH-Portal, NCAH-Portal	2016-01-27 13:04:44.0	Aphis 2008 info received through NCAH Portal; submitted by Teslerfive, Ncah

- b. If the data entry needs to be corrected or comments added, click **Edit**, make corrections, and add comment, and then click **Update**. The record should remain in BCA Initial Review.
  - c. If the serial needs to be sent onto the Specialist but no edits are required, choose the “Specialist Review” option within the 2008 view.
- C. Determine if the Form 2008 should be sent for **Specialist Review**. **These are in order of importance** (if two or more options are relevant, use the first applicable, in the order below).
1. **Destroyed** –For serials that have been destroyed by the firm.
  2. **Legal Hold** – Mandatory that these go to the Specialist
  3. **Review Hold** that requires specialist review as noted on the worksheet.
  4. **VSM 800.62 IV.D.** – Any time a firm references this section of the memo for a reprocessing Form 2008, which did not need approval from CVB to perform the reprocessing.
  5. **I/NT** noted in Section 9E of Form 2008
- If the serial does not have an I/NT, but a related subserial has an I/NT, that would also be sent to the specialist for review under Release Action.

If from Portal – Open the Attachment type “Portal Test Data File” for review of Section 9 test data. Review for I/NT or comments that need Specialist Review.

6. **VBI** – Serials that reference a Veterinary Biologics Investigation (VBI) number should go to the Specialist assigned to the VBI.
7. **Prelicense** – Serials submitted to support licensure of a product  
Note: After Specialist Review, these serials will move to LSRTIS “Laboratory Actions - Pending Licensure” until the product license is signed by CVB-PEL.
8. **Process Deviation** – A regulatory flexibility request by the manufacturer. The serial was produced outside of the Outline or Standard Requirements; however, the firm has deemed the product to be eligible for release. The Biologics Specialist, or their Supervisor, should review the request.
9. **Release Action** – Some other notation or difference in the data submitted for review on a serial that has not been marketed yet. It may include one of the following reasons:
  - a. Animal test is satisfactory, but there was a death during the testing period
  - b. Reference to a Letter, usually regarding a process deviation
  - c. Received with a cover letter and/or bench records  
(If additional attachments are received from the Portal, the attachment type will be labeled as “Portal Letter.”)
  - d. Any unusual comments in Block 11  
(This will be labeled as “NCAH Portal Remarks” within the Info Section of the 2008 view.)
10. **Short-dating Request** – A request to market a modified live or avirulent live lyophilized product with dating shorter than allowed in the Outline because the potency is below release but above end-of-dating requirements. (Regulatory Flexibility) - See **CVB-WI-0130**, *Shortened Dating – Process*, for more information.
11. **Transfer Request** – A request to move part or all of a **released** serial inventory to another product code (and possibly another establishment in the case of mergers), also known as the “2<sup>nd</sup> leg” of a transfer. (Regulatory Flexibility)
12. **Inventory Correction** – If the number is significantly different or the fill/dose size has changed, this should be sent to the specialist for review.
13. **Expiration Date Correction** – any time the firm needs to correct the expiration date – not used for Extension of dating requests.
14. **R&R** – A request to reprocess and retest a serial in accordance with 9 CFR 114.18. These may be unreleased or released serials. If it is released serial, you may print serial stat for the Specialist. See **CVB-WI-0106**, *Rebottling/Reprocessing – Process*, for more information.

15. **Rebottling** – A request to rebottle a serial in accordance with 9 CFR 114.17. These may be unreleased or released serials. If it is released serial, you may print serial stat for the Specialist. See **CVB-WI-0106**, for more information.
16. **EOD** – A request to extend the dating of a serial in accordance with 9 CFR 114.14. See **CVB-WI-0117**, *Extension of Dating – Process*, for further information.
17. **Inactivation Testing** – used for Further Manufacture products that need inactivation testing reported to the CVB, usually killed products.
18. **File for Information** – used for when a disposition of FFI is entered, but needs to be reviewed by the Specialist, for example, stability testing.
19. **Other** – For items that do not fit under the other categories.

D. If the record should be sent to Specialist review:

1. LSRTIS - click **Specialist Review** on Serial Action Sheet screen (or within the 2008 link) and select the correct item from the list of values (LOV). Click  Send to Specialist.
2. Hardcopy – place in **PURPLE** folder for review (if applicable)  
If multiple firms have Forms 2008s needing Specialist review, use separate **PURPLE** folders for separate firms.

FOR HOLDS – For additional information, see Hold Management Process work instructions (**CVB-WI-0158**, *Hold Management Process for APHIS Form 2008s*).

NOTE – Electronic Holds were instituted November 2019; therefore, newer holds may not have a paper copy.

3. In general, Items C. 1-6 should go to the Specialist responsible for the firm or the Program Coordinator (PC) if the Specialist is out for more than 24 hours.
4. In general, Items C. 7-19 should wait for the Specialist responsible for the firm or investigation.

E. Auditing an APHIS Form 2008

If there is a technical error or the Form 2008 is incomplete and the information cannot be changed or added, the Form 2008 should be audited. This can be done at any time during the serial release process prior to signature of the Form 2008 (hard copy and LSRTIS). See **CVB-WI-0104**, *Audits and Reference Slips for IC Documents*, within LSRTIS for the auditing process.