

BCA Initial Review

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

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.
2. Note any referenced serial in Block 11 on Form 2008. Write the date received or APHIS release information in Block 11 and initial. If the 2008s is 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).

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The screenshot displays the 'Attachments' and 'Action History' sections of the BCA Initial Review interface. The 'Attachments' section includes a table with columns for Attachment, Type, and FROM PORTAL. The 'Action History' section includes a table with columns for Action, Employee, Timestamp, and Info. Below the tables are several action buttons: Edit, OK BCA Initial Review, Specialist Review, Audit, Reference Slip, Edit ENSR Data, and Delete.

Attachment	Type	FROM PORTAL
Test Attachment.docx	Portal Letter	FROM PORTAL

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 Testerfive, Ncah

Buttons: Edit, OK BCA Initial Review, Specialist Review, Audit, Reference Slip, Edit ENSR Data, Delete

- 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**

1. **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.

2. **Legal Hold**

3. **Review Hold** that requires specialist review as noted on the worksheet

4. **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.)

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5. **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)

NOTE: We should not be using the Short Dating APHIS disposition for when the firm wants to shorten the dating for exporting/marketing purposes. These are simply released as “Not to be Tested.”

6. **File for Information**

7. **Conditional Release** – A request by the manufacturer

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. **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 “2nd leg” of a transfer. (Regulatory Flexibility)

10. **Inventory Correction** – If the number is significantly different or the fill/dose size has changed, this should be sent to the specialist for review.

11. **Expiration Date Correction**

12. **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.

13. **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 **ICSOP0006**, *Processing Requests for Rebottling/Reprocessing*, for more information.

14. **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 **ICSOP0006** for more information.

15. **EOD** – A request to extend the dating of a serial in accordance with 9 CFR 114.14. See **ICSOP0007**, *Extension of Dating – Biologics Compliance Assistant Procedures*, for more information.

16. **Other** – For items that do not fit under the other categories.

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17. **VBI** – Serials that reference a Veterinary Biologics Investigation number should go to the Specialist assigned to the VBI.

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 2008s needing Specialist review, use separate **PURPLE** folders for separate firms.

FOR HOLDS – For additional information, see Hold Management Process work instructions (**ICWI0810**, *Hold Management Process for APHIS Form 2008s*).

Pull Pink or Yellow Hold from pending serials drawer

Place Hold sticker to the back of the Pink or Yellow Hold and add date/serial number

Clip Pink or Yellow Hold to 2008

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. 7-15 should wait for the Specialist responsible for the firm or investigation.
If the Specialist assigned to the firm or investigation is out and the serial/issue cannot wait for their return, give **PURPLE** folder(s) to the PC or their Supervisor.
If a Form 2008 is from the Portal, communication to those individuals may be needed.

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 (see **ICWI0610**, *APHIS Form 2008 Pen and Ink Guidance*, for guidance), 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).

1. Click on **Audit**
2. Chose Audit Reason that is most applicable. At this point in the process, Incomplete Form is the most likely choice.
3. Type a short explanation of issue in Comments – remember, this will be sent to the firm, so it should be professional; use complete sentences and grammar and spelling should be correct.
4. Click on ✓Audit – the signature line on the ENSR will reflect the person who initiated the audit.
5. The record will move to BCA Ready for Approval.