

# BCA Ready for Approval

All APHIS Form 2008s (Form 2008s) will be assembled by the Biologics Compliance Assistants (BCAs) at BCA Ready for Approval tab in the process (including Audits) for a final review and processing of the paperwork prior to signature. This includes printing out test reports, stamping the Form 2008s with the appropriate APHIS Disposition, the title of the signatory and the date, and performing a final quality check for completeness of the document, if received hard copy.

If the 2008 information is received from the NCAH Portal, the Ready for Approval Process is used for a quality check of the APHIS Disposition.

This process is usually done after BCA arrival through 9:30 a.m.

## A. Serial Release Process

The BCA will select the **Serial Release** within the LSRTIS module and then select **Action Sheet** option. Use the tab, "BCA Ready for Approval."

1. View Form 2008 entries by clicking on (Toggle Visibility) to open either **Primary Establishments** for firms assigned to the BCA or **Backup Establishments** for all other firms within the Initial group. The Form 2008s will be sorted on Initial or Rejected.

❖ Rejected is a parking lot for serials that have issues or questions to be answered but have moved through the rest of the process (see **Section D**).

2. The serial records listed under **Initial** are the serials that are eligible for release, completion of a firm request, or acknowledgment of information received.

BCA Initial Review | 2008 Review | Lab Actions | **BCA Ready For Approval** | Ready For Signature | Specialist Review | Product Manager Review | Misc

**Primary Establishments(0):**  
(Toggle Visibility)

**Backup Establishments(24):**  
(Toggle Visibility)

**Initial**

Show 50 entries Search: 99

	PRTL	Entry	Est	Product	Serial #	APHIS Disposition							
<input type="checkbox"/>	Y	04/20/2016	999	205100	16MAR2	Not to be Tested				Audit	Reference Slip	Specialist Review	2008 / Serial Stat
<input type="checkbox"/>	Y	04/20/2016	999A	740000	16MAR2	Not to be Tested				Audit	Reference Slip	Specialist Review	2008 / Serial Stat
<input type="checkbox"/>	N	03/25/2016	999	264853	25MAR2	Other - Serial Released for Market	Test Report			Audit	Reference Slip	Specialist Review	2008 / Serial Stat
<input type="checkbox"/>	N	03/25/2016	999	500400	25MAR1	Other - Serial Released for Market	Test Report			Audit	Reference Slip	Specialist Review	2008 / Serial Stat

0 total entries

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### B. Processing Form 2008s

Match the hard copy Form 2008 to the list under BCA Ready for Approval. (At the point the NCAH Portal is utilized, a hard copy Form 2008 may not be present.)

The BCA may click on Serial Stat link to verify no testing was done.

Process hard copy Form 2008 by doing the following:

1. Check APHIS Disposition box (Block 16) – see **ICWI0130** for dispositions
2. Stamp title (Block 18)
3. Stamp the date (Block 19)
4. Stamp/type any additional release info in Block 16 if applicable

Process electronic Form 2008 (from Portal) by:

1. Ensure the APHIS Disposition is correct
2. Determine the CVB Testing matches the APHIS Disposition
3. Check Audits and/or Reference slips are complete

Click on Serial to move it forward. This can be done in batches or within the 2008 view link. If

done in batches, click on  at the bottom of the page.

If the serial has been tested, click on Test Report link (which will show in the column between APHIS Disposition and Audit), print two copies if received hard copy, and staple one copy to the original and the other to the firm's copy of the Form 2008. No printing is needed if the information was received from the Portal.

If there is a No Test or Inconclusive on the Test Report, click on the serial stat, scroll down to the Testing area to see if there are any comments the lab has entered that gives you more information about the test results the lab determined. Make sure to check all the test results if there are more than one test result. If you have questions about the lab results, check with the Product Specialist or Specialist for that firm before moving that serial forward.

REMINDER – any serial received hardcopy that is unacceptable for marketing should be stamped and signed in **RED**. This includes:

1. Serials tested unsatisfactory by CVB
2. Serial unsatisfactory based on the firm's test results
3. Serials destroyed by the firm

Give all hard copy Form 2008s for Specialist Signature to the Program Coordinator. However, there are a few APHIS Dispositions that can be signed by the BCA. See **ICWI0058**, *Ready for Signature Action in LSRTIS (Specialists and BCA Duties)*, for Form 2008s for this list.

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## C. Rejected

If a serial should not be released for a variety of reasons, the Specialist can push the serial to Rejected.

The BCA needs to edit the serial in tab BCA Ready for Approval and add note as to why prior to pushing it to the Specialist to reject.

1. Click on 2008
2. Click on Edit
3. Add note in Comments

The Specialist should then click on Reject and the serial goes back to BCA Ready for Approval in the reject section.

## Serial Action Sheet

APHIS 2008 152,374 updated

BCA Initial Review | 2008 Review | Lab Actions | **BCA Ready For Approval** | Ready For Signature | Specialist Review | Product Manager Review | Misc

Show 50 entries Search: [ ]

Establishment	Product	Serial Number	APHIS Disposition	Firm Disposition					
			Not to be Tested	Eligible for Release	Audit	Reference Slip	<b>Reject</b>	Sign	2008 / Serial Stat

Showing 1 to 1 of 1 entries

First Previous Next Last

## D. Audits

If a Form 2008 has been audited by either the Specialist or the BCA, it will be directed to the BCA Ready for Approval. The Audit form should be printed off and signed both manually and electronically. Refer to **ICWI0062**, *Auditing a Serial or Attaching a Reference Slip within LSRITS*, for processes on auditing a serial. If received from the Portal, no printing is required.

1. Form 2008s that were audited in the Serial Release process will show “Audited” in the action sheet (shown below).

## Serial Action Sheet

APHIS 2008 153,362 updated

BCA Initial Review | 2008 Review | Lab Actions | **BCA Ready For Approval** | Ready For Signature | Specialist Review | Product Manager Review | Misc

**Primary Establishments(50):**  
(Toggle Visibility)

**Initial**

Show 50 entries

PRTL	Establishment	Product	Serial #	APHIS Disposition					
N				Not to be Tested			<b>Audited</b>		
N				Not to be Tested			<b>Audit</b>		

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2. Ensure the hardcopy Audit form is printed out, if needed. This can be found under the 2008 link, under the Attachments subheading, Aphis2044, or PDF link within Audit Actions subheading.

## Serial Action Sheet

APHIS 2008 153,302 updated

BCA Initial Review | 2008 Review | Lab Actions | **BCA Ready For Approval** | Ready F or Signature | Specialist Review | Product Manager Review | Misc

**Primary Establishments(50):**  
[Google Visibility](#)

Initial

Page 50 of 50 entries

PRTL	Establishment	Product	Serial #	APRES Disposition					
N				Not to be Tested	Audited	Reference Slip	Specialist Review	OK	2008 / Serial Stat
N				Not to be Tested	Audit	Reference Slip	Specialist Review	OK	2008 / Serial Stat

<b>Establishment Disposition</b>	Eligible for Release
<b>Received Date</b>	11/26/2014
<b>Expiration Date</b>	04/05/2016
<b>Serial Status</b>	Active
<b>Doses</b>	294225 Doses
<b>Autogenous?</b>	No
<b>First Serial?</b>	No
<b>Fifty Or Less Vials?</b>	No
<b>Comments</b>	

## Attachments

Add Attachment To Aphis 2008  
 Aphis2044

## Action History

Action	Employee	Timestamp	Info
Aphis 2008 Logged In	SCHILTZ, MATTHEW	2014-11-26 11:53:16.0	
Initially Reviewed By BCA	Santi, Sharon	2014-11-26 12:25:49.0	
2008 Review - Not Reviewed	Santi, Sharon	2014-11-26 12:41:55.0	
Aphis 2008 Updated	Watson, Jeanette	2015-07-01 13:35:13.0	

## Audit Actions

Action	Employee	Timestamp	Audit Reason	Audit Comments	
Aphis 2008 Audited	Watson, Jeanette	2015-07-13 12:58:43.0	Invalid Expiration Date	test	PDF EDIT

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## F. Stability Test Reports

The CVB-Laboratory may perform stability testing on a serial that is near the end of its expiration dating. In these instances, the CVB-Inspection and Compliance is responsible for sending these test results to the manufacturer. These should be printed out at the time when other Form 2008s are being processed in the Ready for Approval area. However, they are found in the “MISC” tab of the Serial Release action sheet.

LSRTIS Testing - Sample Processing - Serial Release - Reports & Searching - Licensing - IC - Admin - Mail Phone

BCA Initial Review 2008 Review Lab Actions **BCA Ready For Approval** Ready For Signature Specialist Review Product Manager Review Misc

**For Follow Up(42):**  
(Toggle Visibility)

**Stability Tests - Last 7 Days(1):**  
(Toggle Visibility)

Show 00 entries Search: [ ]

Establishment	Product	Serial Number	Has Unsat?
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Showing 1 to 1 of 1 entries Test Report Serial Stat

1. The Stability test reports should be checked at least one time per week as the test reports stay within this view for seven calendar days.
2. Test report with Inconclusives, No Tests, or Unsatisfactory test conclusions should be routed to the Specialist or Program Coordinator for review prior to being sent out to the manufacturer.
3. Satisfactory test reports or those initialed off may then be mailed to the manufacturer at the normal mail timelines.

\* If a serial should be at the BCA Ready for Approval step, but is stuck within the Lab Actions (will be in the Subserials subheading), contact a System Administrator – a person with this access can run the overnight job which moves these serials on if all criteria have been met.