NCAH PORTAL CVB QUICK REFERENCE GUIDE



Submission History (CVB) and Account Details

Where were changes made in the 2/8/2021 version?

1. Page 7 - The Reviewer's name column was added to the Search Results when using the Submission History to find APHIS 2049 submissions to PEL.

Where were changes made in the 3/11/2020 version?

1. Page 12 - CVB email addresses for contacting Serial Release and PIMS were updated

Where were changes made in the 8/29/2017 version?

1. Page 12 - Information regarding adding an optional email address for NCAH Portal Notifications emails was added

Where were changes made in the 8/14/2017 version?

- Page 12 The first bullet under Submissions Included was changed to this:
 Policy Evaluations & Licensing ALL
- 2. Page numbering throughout the document was corrected.

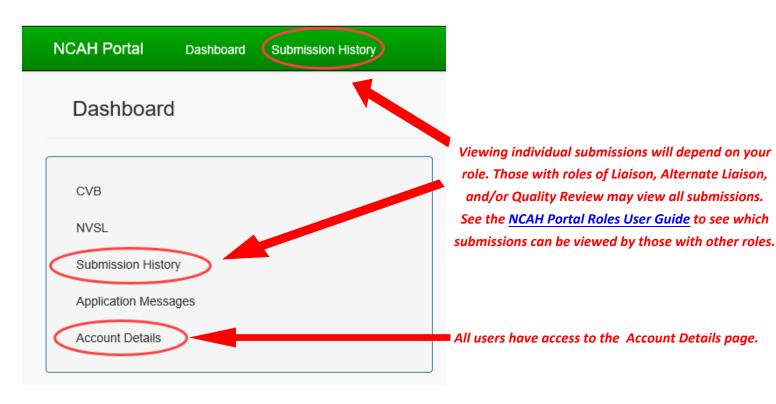
Where were changes made in the 6/23/2017 version?

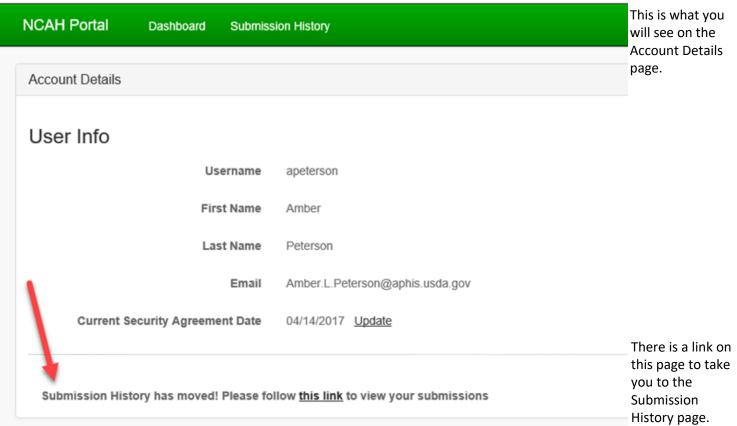
- 1. Page 2 Submission History and Account Details have been split into separate pages in the NCAH Portal.
- 2. <u>Page 13</u> "CVB Historical Search" has been renamed "CVB Search" to more accurately reflect items that can be found using this method.
- 3. Page 13 Three fields have been added to the CVB Search screen to enhance search capability; Product Code, Serial Number and Last Action Date.

Where were changes made in the 10/21/2016 version?

- 1. There were numerous additions and updates made in this latest version so it is recommended that a complete review of the document be done. Some of the most notable changes include:
 - Important Things to Remember on page 3
 - Information related to recently added submission types (APHIS 2048s and 2049s)
 - A new section on Rejected Samples
 - A new section on Daily Emails

This guide will show you how to find your user information in the **Account Details** and how to find information on electronic submissions and communications with the CVB in the **Submission History**. These are two separate areas.





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The Submission History page is broken down into three categories:

- 1. Recent Activity (2 weeks)
- 2. Submissions Not Yet Received
- 3. CVB Search

This user guide will show you how to keep track of all your submissions using the Submission History page.

Before you get started there are some important things to keep in mind:



All "open" submissions (Submitted or Awaiting Update from Submitter statuses) remain accessible in the NCAH portal until they are completed.



Completed submissions are only available for 60 days after their Last Action Date.



Firms are expected to download CVB responses to their own digital archives prior to the 60-day deadline.

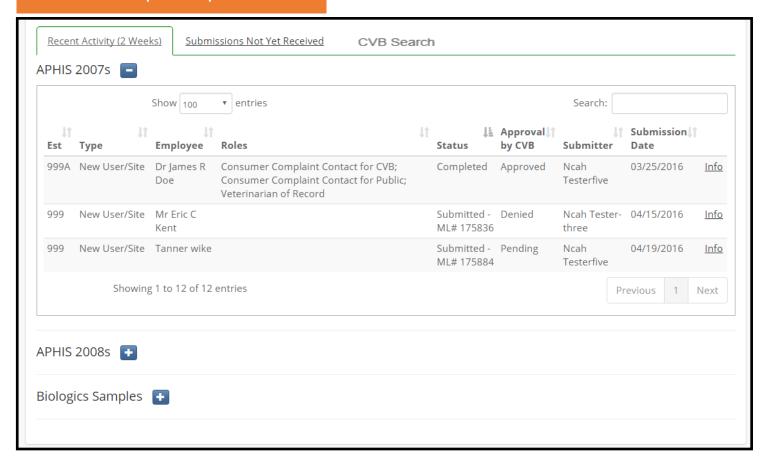


Please note that the integrity of a digital signature is lost once a document is printed. Therefore, if you wish to have a print copy for handy reference, also maintain the digital files downloaded from the portal to substantiate the integrity of any printed documents.

RECENT ACTIVITY (2 WEEKS)

This area captures submissions that have had any type of action (either within the NCAH Portal or at the CVB) that updates the NCAH Portal within the last 2 weeks. Items are broken down by submission type. Continue reading for details on information in this section by submission type.

RECENT ACTIVITY (2 WEEKS) - APHIS 2007s



APHIS 2007s – Items initially sort on the Approval by CVB Category, then by the Status of the submission. The Liaison, Alternate Liaison and Quality Review role may search on and view all 2007 information. The user who entered specified 2007 information may also search and view that particular 2007(s) only.

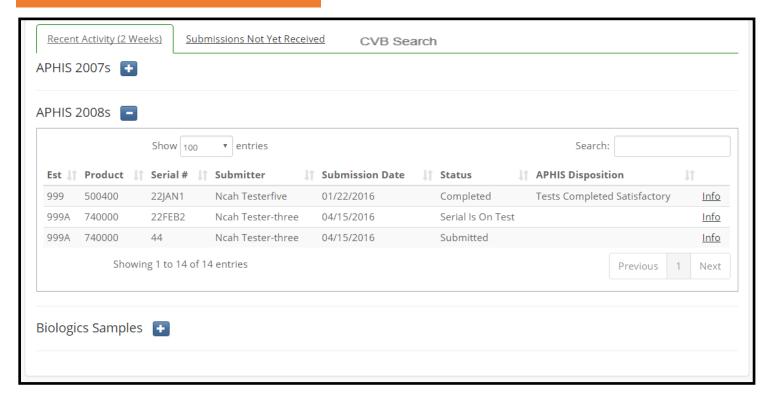
What are the different categories in "Approval by CVB"?

Approved items are submissions completed by the CVB and the submitted information was accepted.

<u>Denied</u> items are submissions completed by the CVB, however, the submission was not accepted. Additional information may be needed to complete the submission.

Pending items are submissions that are still in the process of being reviewed at the CVB.

RECENT ACTIVITY (2 WEEKS) - APHIS 2008s



APHIS 2008s - Items initially sort on Status of a 2008 Submission, then items are sorted by the Establishment number, then Product Code, Serial #.

The Serial Release role, Liaison/Alternate, and Quality Review role may search on 2008 information. In addition, the user who entered the specified 2008 information may also search.

Updates to the NCAH Portal for Status changes are sent at 11am and 3pm Central Time each business day.

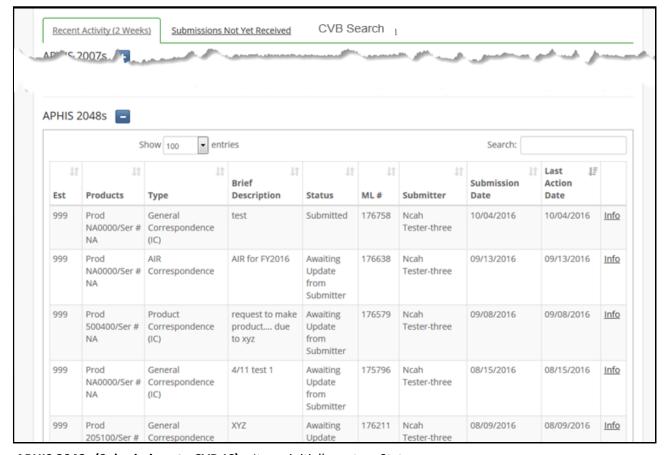
What are the different categories in "Status"?

<u>Completed</u> items have been signed by the CVB. If an APHIS Disposition shows, this will be the disposition assigned to the Form 2008. However, if a completed item does not have an APHIS Disposition showing, this Form 2008 was audited. The User must open the "Info" link to see the details of the release or audit.

<u>Serial is On Test</u> items have been received by the CVB and gone through the initial review. Within the "Info" link the user can see the projected off-test date and the testing that is being performed.

<u>Submitted</u> items have been received by the CVB. The item will not be updated until it is either complete, or the sample has been put on test.

RECENT ACTIVITY (2 WEEKS) - APHIS 2048s



APHIS 2048s (Submissions to CVB-IC) – Items initially sort on Status.

The Liaison/Alternate Liaison, Quality Review role may search on the 2048s (IC Correspondence).

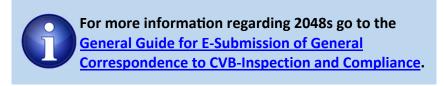
Updates to the portal are sent at 11:00 a.m. and 3:00 p.m. Central time. Updates include a status change with the applicable CVB Response, or CVB Initiated Correspondence.

What are the different categories in "Status"?

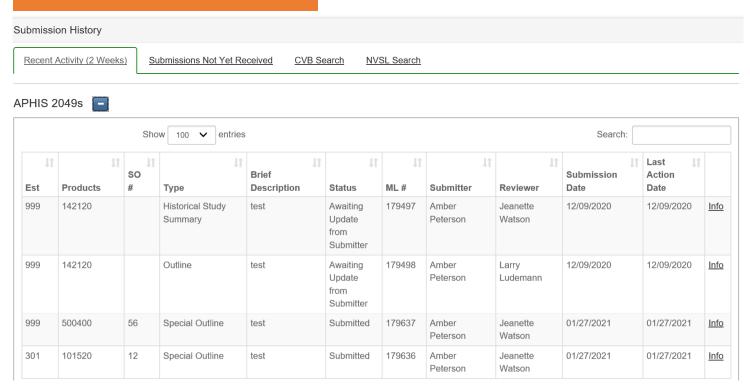
Submitted – Submission been sent from the NCAH portal to the CVB Mail Log and is an Active Mail log item.

<u>Awaiting Update from Submitter</u> – Upon request by the firm to CVB (either by email or phone call to the Biologics Specialist or other IC Employee). See Updating a Portal Submission within the IC e-Submission User Guide for details on submission.

<u>Complete</u> – The Mail activity has been completed for the Mail Log with one of the following outcomes: CVB Response, No Outgoing Correspondence, CVB Initiated Correspondence, Response is linked to a different Mail log Item.



RECENT ACTIVITY (2 WEEKS) - APHIS 2049s



APHIS 2049s (Submissions to CVB-PEL) – Items initially sort on Status.

The Liaison/Alternate Liaison, Quality Review role may search on the 2049s (PEL Correspondence).

Updates to the portal are sent at 11:00 a.m. and 3:00 p.m. Central time. Updates include a status change with the applicable CVB Response, or CVB Initiated Correspondence. It also includes status changes on Awaiting Updates from the Submitter (initiated/completed).

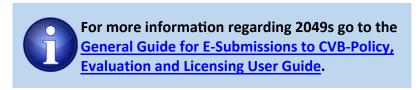
Items found here are those having some kind of status update (new submissions or CVB updates) in the portal in the past two weeks. This page also features items in the Awaiting Update from Submitter status regardless of the Last Action Date.

What are the different categories in "Status"?

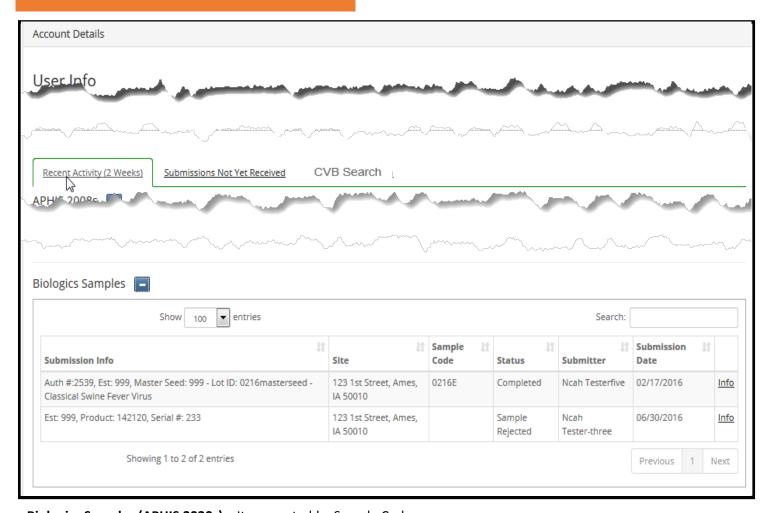
<u>Submitted</u> – Submission sent from the NCAH portal to the CVB Mail Log, or created manually by the CVB in the mail log, and is an Active Mail log item.

<u>Awaiting Update from Submitter</u> – The CVB has requested additional, or revised, information from the submitter. Status returns to Submitted when the requested information is acknowledged as acceptable by the CVB. There will be a short interval between submitting updates and having the CVB acknowledge acceptability.

Complete – The CVB response to the submission has been released to the portal.



RECENT ACTIVITY (2 WEEKS) - Biologics Samples



Biologics Samples (APHIS 2020s) – Items sorted by Sample Code.

The Sampler, Liaison/Alternate, and Quality Review role may search on samples.

Updates to the NCAH Portal that show the sample code for records are sent at 3pm Central Time each business day.

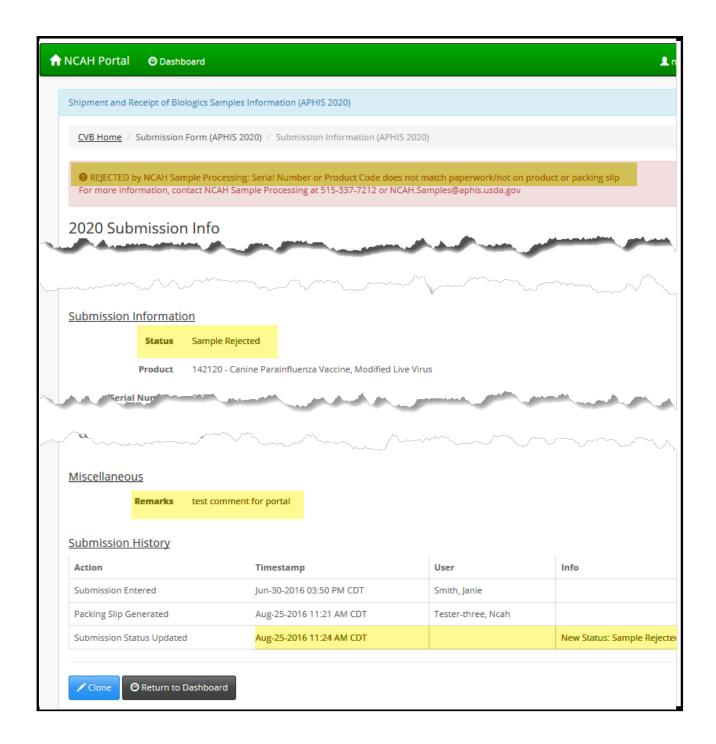
What are the different categories in "Status"?

<u>Completed</u> – Sample received by the CVB, and verified. The at-risk window for testing will begin on the subsequent day of receipt.

<u>Sample Rejected</u> – Sample received by the CVB. However, sample verification was not completed due to a problem with the sample or a discrepancy between the information on the sample and the packing slip received with the sample. The sample is being rejected for the reason stated. *Reasons will be specified within the Info link for the selected sample (see example on next page)*. No Sample Code will be assigned. The Firm MUST re-submit samples for release of the serial.

REJECTED Biologics Samples

If you have samples rejected by NCAH Sample Processing, you will see the information in the NCAH Portal as shown below.



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SUBMISSIONS NOT YET RECEIVED

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Recent Activity (2 Weeks)	Submissions Not Yet Received	CVB Search		
APHIS 2007s not yet sul	bmitted to CVB 🛨			
APHIS 2008s not yet sul	bmitted to CVB 🛨			
APHIS 2048s not yet sul	bmitted to CVB 🛨			
APHIS 2049s not yet sul	bmitted to CVB 🛨			
STR Samples for Serials	not yet received by CVB			
STR Samples for Master	r Seeds not yet received by 0	CVB +		
Routine Samples for Pro	oducts/Serials not yet receiv	red by CVB +		

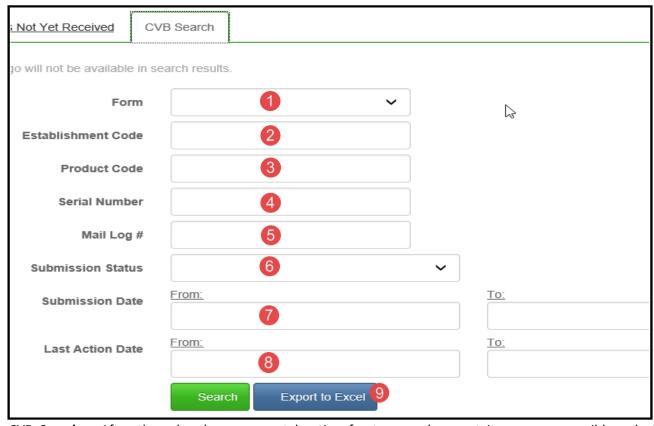
Submissions Not Yet Received – This area shows submissions that are still in the "Draft" stage that have not been submitted to the CVB yet *or have not yet had an action performed at the CVB*.

Editing is available for those submissions that allow it (all submissions except for Biologics Samples).

Roles for reading and/or editing are the same as those who can see items within the Recent Activity (2 weeks). However, the Liaison/Alternate and Serial Release for APHIS Form 2008 information can submit individual submissions through this module.

Account Details and Submission History - (CVB)

CVB SEARCH



CVB Search – After there has been no portal action for two weeks, most items are accessible only through the CVB Search page until they are eliminated from the portal altogether. Items on the Recent Activity page may also be queried through the CVB Search page.

IMPORTANT: Completed items only stay in the NCAH Portal for 60 days after the date of the last action.

- 1 Form Choose which type of information you are looking for (either the APHIS Form Number or Mail log # is mandatory)
- Establishment Code Enter the applicable Establishment Code
- 3 Product Code Enter the applicable Product Code
- iggle 4 Serial Number Enter the applicable Serial Number
- 6 Mail Log # this is applicable to APHIS Forms 2007, 2048, and 2049
- 6 Submission Status Choose one of the options for the drop-down list:
 - a. Awaiting Update from Submitter Applicable to APHIS Forms 2048 and 2049
 - b. Completed Applicable to all APHIS Forms including Sample Submissions
 - c. Serial Is On Test Only Applicable to the APHIS Form 2008 information
 - d. Submitted Applicable to all APHIS Forms except Sample Submissions
- Submission Date This field searches based on the date of submission by the firm; enter a date range in which you want to search
- 8 Last Action Date This field searches based on the date of the last action performed on the item by either the firm or CVB; enter a date range in which you want to search
- Seport to Excel Click here to export the search results to Excel and capture the data in an editable format

NCAH PORTAL CVB QUICK REFERENCE GUIDE [3]



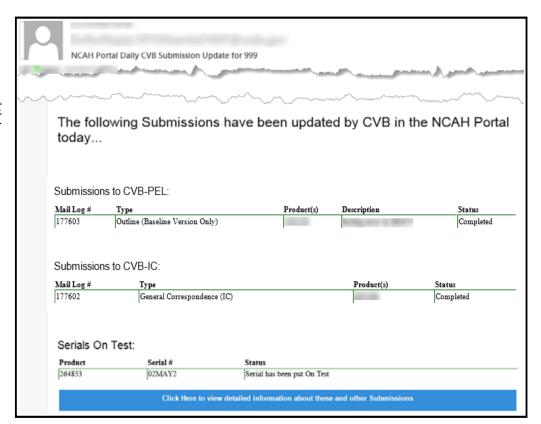
Submission History (CVB) and Account Details

DAILY EMAIL NOTIFICATION

A daily email, sent at 3:30 p.m. Central time, will be sent to the email address provided to CVB for Electronic Notification of Serial Release (ENSR) as well as the email address for NCAH Portal Notifications (if provided). This email will contain a summary of all submissions processed by CVB, through the NCAH Portal. A direct link to the NCAH Portal will be available at the end of the email.

Submissions Included:

- Policy Evaluations & Licensing ALL
- Inspection and Compliance Correspondence
 - *Serial release notifications are <u>not</u> included these will remain in their individual emails at 11:00 a.m. and 3:00 p.m. Central time.
- CVB Laboratory Information on Serials put on Test, once a Form 2008 has been received by the firm.
- Sample Processing Samples received, with the corresponding Sample Code assigned.





How to Update the ENSR email address:

Firms may request changes to the ENSR email address in writing to CVB-IC, or by requesting the change through the APHIS-CVB Serial Release – Inbox email address APHIS-CVB Serial Release **<cvb.serialrelease@usda.gov>**.

CVB-IC will respond requesting verification of a valid email address. The message will be similar to the following:

"We are responding to your letter (or email) dated [mm/dd/year] verifying the email address you supplied for notification of release of biological products as noted in VS Memorandum 800.53. Please reply to this email within 2 business days to serve as verification that your email address is viable."

Upon firm response, the email address will be updated in the CVB database, and subsequent emails will be sent to the new address.



How to Update the NCAH Portal Notifications email address:

Firms may provide a NCAH Portal Notifications email address, or request changes to it, by emailing **<CVB.PIMS@usda.gov>.** with the subject line, "ACTION REQUESTED: Email address for NCAH Portal notification emails".

If the email address requested is not the same as the one used to send the request, then CVB-PIMS may respond requesting verification of a valid email address. The message will be similar to the following:

"We are responding to your email dated [mm/dd/year] to verify the email address you supplied for NCAH Portal notifications, [insert email address here], is valid. Please reply from this email address within 2 business days to serve as verification that the email address is viable."

Upon firm response, the email address will be entered or updated in the CVB database.

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