General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Where were changes made in the 10/20/2016 version?

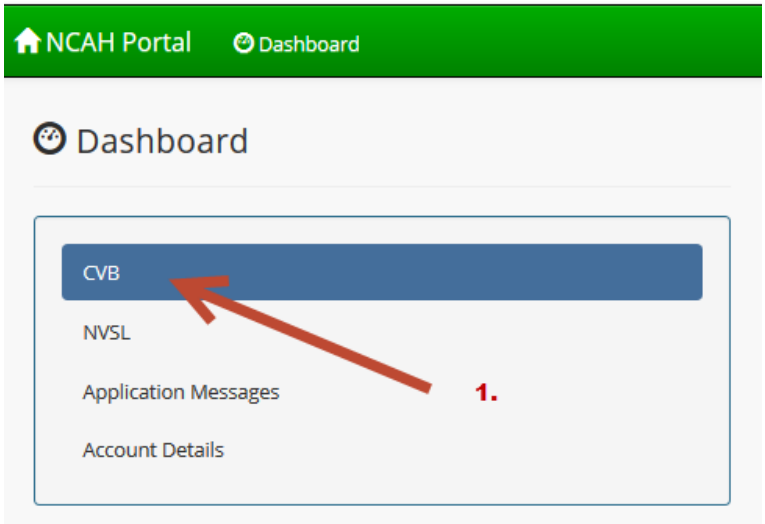
1. Pages 15-17 were added to provide explanation of the different Statuses users can see on the Account Details page as they relate to CVB-IC General Correspondence (2048) submissions.

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

For General Correspondence submissions to CVB Inspection & Compliance (APHIS Form 2048), start by entering the CVB section of the Portal and then navigating to the Create New Submission to IC.

Any user with Level 2 eAuth can enter the 2048 information. Quality Review Users have Read Only Access to All submission.

Only Liaisons and Alternate Liaisons may submit to the CVB.



You will be taken to the CVB Inspection and Compliance E-Submission Form.

Next - Entering information in the Inspection and Compliance E-Submission Form (2048)

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

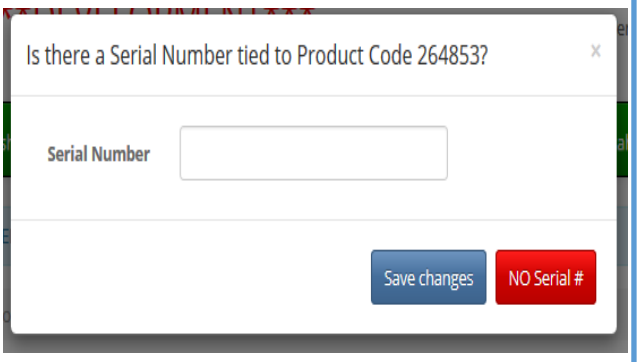
Entering Information

Establishment - Self-Explanatory.

Product Code(s) - Enter all applicable product codes directly related to the submission. **Choose the** + **to save the Code to the record and add multiple product codes.**

Enter **NA0000 for submissions that are not product related.*

Serial Number - Upon entering a Product Code, a new window will pop up asking *"Is there a Serial Number tied to Product Code xxxxxx?"*



Do Not Enter Symbols (i.e. hyphens (-) or slashes (/ \)).

- If there is a Serial Number tied to the Product Code, **enter it and then click** Save changes

  *Repeat the process for each serial number associated with the submission.

- If the submission is not directly related to a serial number, **leave the field blank, and click** NO Serial #

VBI # - Only enter if an investigation number (VBI #) has been provided by the CVB-Inspection and Compliance. This must be in the format noted (##-###).

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Submission Type - This is a mandatory field. Only one submission type may be chosen per submission. Choose from one of the following available types:

- **AER Correspondence -** Correspondence relating to Adverse Events, whether requested from the CVB or directly from the manufacturer regarding adverse events associated with a product or serial.
- **AIR Correspondence -** Correspondence or responses associated with Administrative Inspection Reviews
- **General Correspondence (IC)* -** Any correspondence including letters referencing more than one product code, or those that have no product associated.

  **Use as default if others do not apply.*
- **Inspection -** Correspondence relating to an inspection performed by CVB-IC. This may include action item responses or clarification requests.
- **Investigation -** Correspondence relating to an investigation initiated by the CVB-IC. Ensure to include the VBI number in the applicable field.
- **Product Correspondence (IC) -** Any correspondence associated with ONE product code. If more than one product code is associated with the correspondence, use General Correspondence (IC).

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

(Submission) Subtypes - This is a Non-Mandatory field. **If applicable, multiple subtypes may be chosen. Select an entry from the list and click the + button. Repeat for additional entries.**

- **Bench Records Relating to a 2008 -** If Bench Records are requested by the CVB for a 2008 that is already submitted to the CVB, create a new 2048 submission.

  *Include the Product Code and Serial number for the selected record, if applicable.

- **Immediate Notification -** The NCAH Portal may be utilized to submit immediate notifications to the CVB in accordance with 9 CFR 116.5(b) and VSM 800.57. Use this submission subtype for these types of notifications.

  If concise enough, the Brief Description may be utilized to provide the preliminary information without additional attachments—*remember this has a 200 character limit*.

- **Process Deviation -** Include this subtype if a submission is related to a process deviation - any step of production that is outside of the standard requirement or outline of production

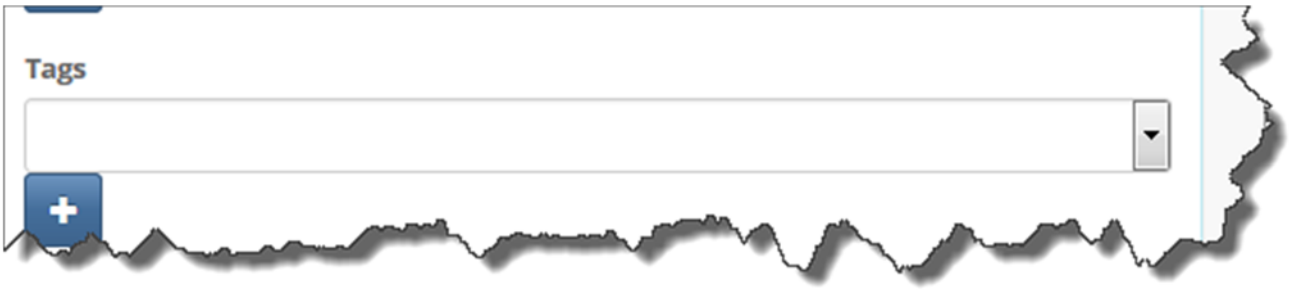
  *If the deviation is related to specific serials, include the Product Code(s) and Serials Number(s).

  *If the deviation is related to a production lot, include the Antigen name(s) and lot number(s) in the Brief Description.

- **Voluntary Stop Sale -** Include this subtype if a submission is notifying the CVB of a Voluntary Stop Distribution and Sale in accordance with VSM 800.57, *Market Suspension*, ensure to chose this subtype. This may be used in conjunction with the **Immediate Notification** subtype.

Submission of Form 2007 information should be submitted through the NCAH Portal Qualification of Veterinary Biologics Personnel (APHIS 2007) module.

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)



Tags - This is a Non-Mandatory field, in which more than one tag may be chosen. Tags are primarily additional information not specifically related to the submission information.

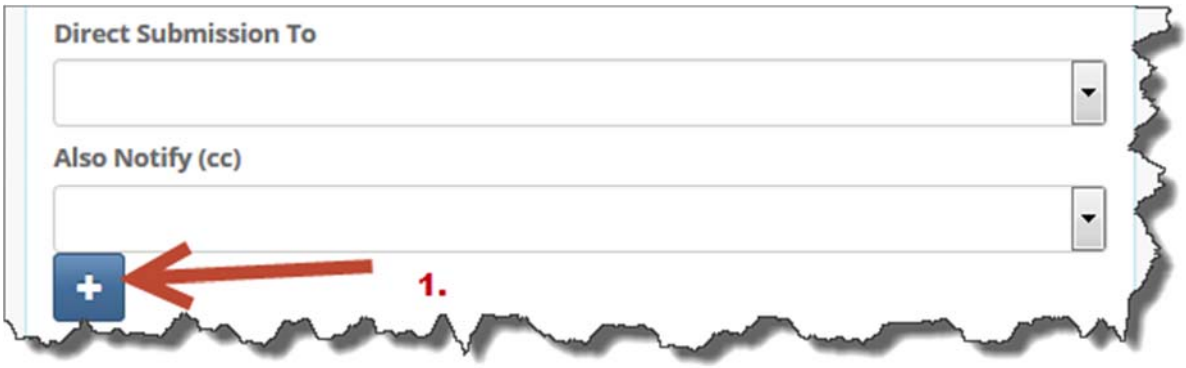
Product Distributed - Utilize this tag if any portion of the product/serial was distributed off licensed premises, for **Voluntary Stop Sale** and **Immediate Notification** submissions.

Firm Priority - Use with discretion. Using this tag, will delay other submissions for the firm. Use this tag if the submission is a high priority for the firm for processing.

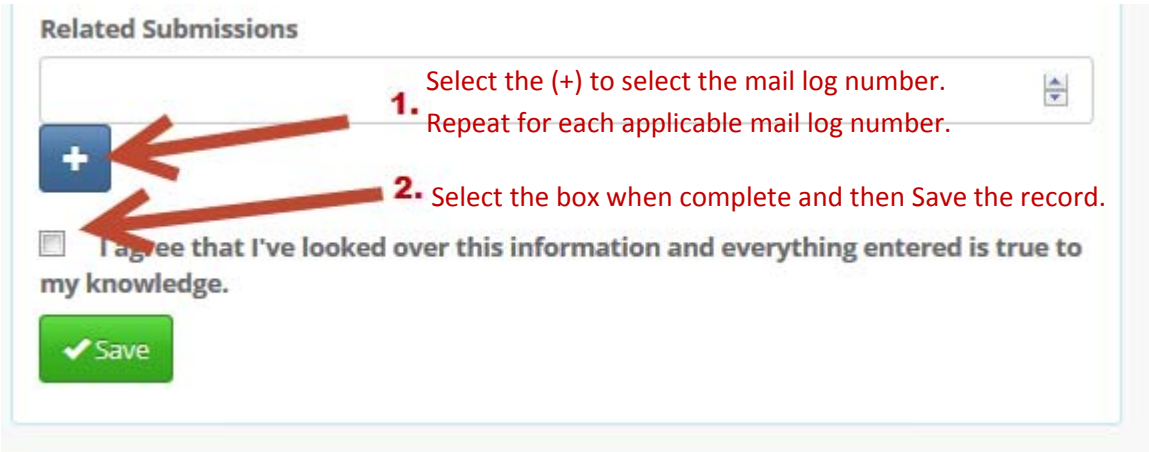
Brief Description - This is a Mandatory field that should provide the purpose / subject of the submission. If the submission is related to production lots, include any lot numbers (if possible). Maximum character limit is 200 (with spaces).

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Direct Submission To - This lists any Biologics Specialist within the CVB-Inspection and Compliance Unit. This will not route the submission directly to the recipient; it's used as a tool to help determine who the submission can be manually routed to. Select one name from the list.



Also Notify (cc) - This provides the firms the ability to "carbon copy" any individual(s) within the CVB. Select a name from the list and then click the + to add that person. Repeat to add additional CVB Employees.



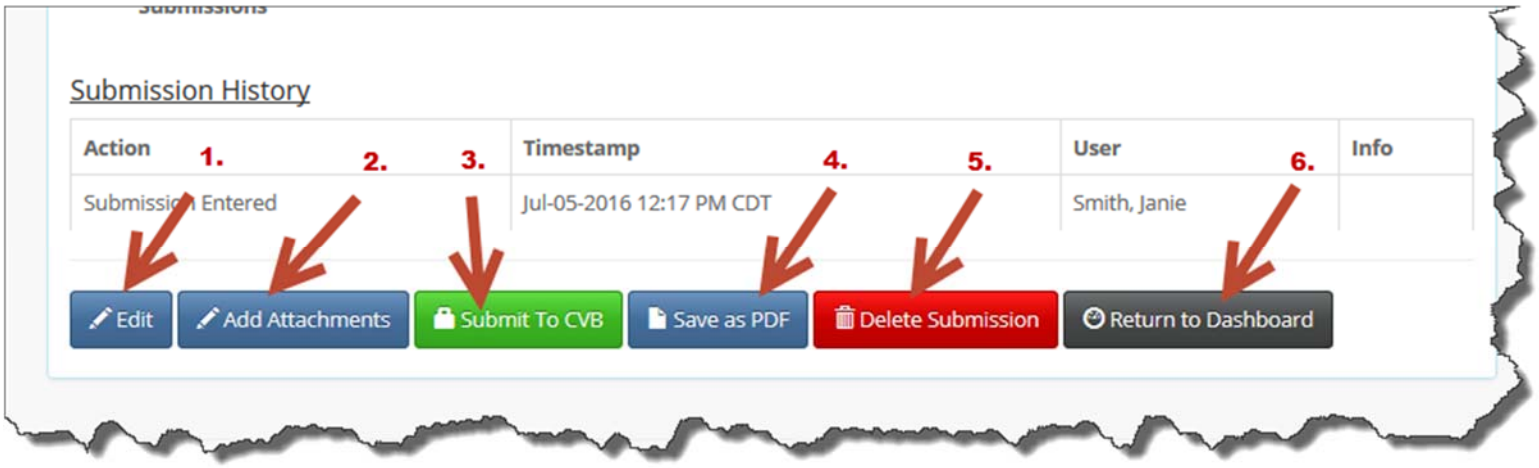
Related Submissions - If applicable, the mail log number of any directly related submissions may be entered. Include the mail log number if the submissions is a follow-up to a CVB Response or if there are other items to consider. Multiple mail log numbers may be entered.

At this point **the submission is not yet complete.**

Attachments (Letter, bench records, etc.) may still need to be added to the record before submission to the CVB.

All 2048 submissions should have either an attached document or occasionally, a detailed explanation in the Brief Description will be sufficient.

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)



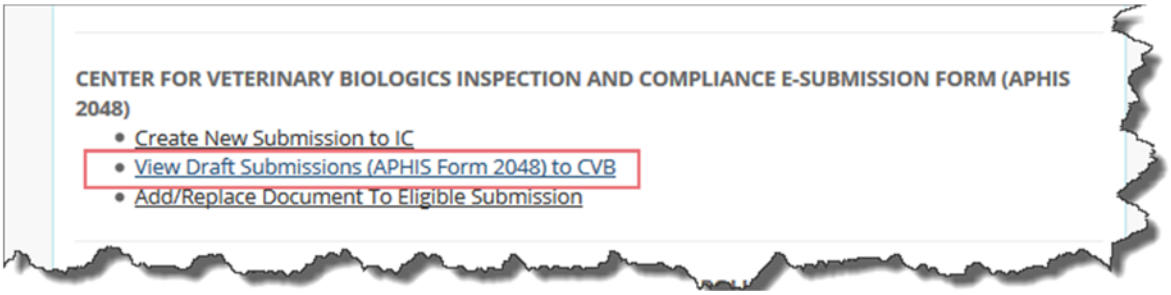
Allows the user to edit any field entered in the 2048 Information. NOTE: No submission that has been submitted to the CVB can be edited (with the exception of the attachment). See **Updating a Portal Submission that is with the CVB** section in this documents for guidance on updating attachments.

In cases of duplicate entries, or other mistakes, the user may delete an entire submission. No record of that submission will be able to be obtained upon deletion. 2048 Information.
NOTE: No submission that has been submitted to the CVB can be deleted.

Allows the user to get a printer-friendly PDF document with the 2048 submission information, along with the submitted file information (no direct links), CVB Response file information (no direct links), and the submission history.

This takes the user back to the CVB Dashboard.

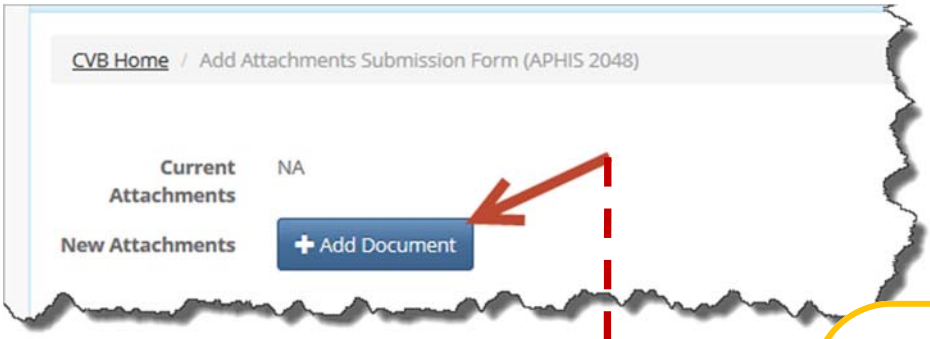
The draft submission can be found in the "View Draft Submissions (APHIS Form 2048) to CVB" link in the CVB Dashboard.



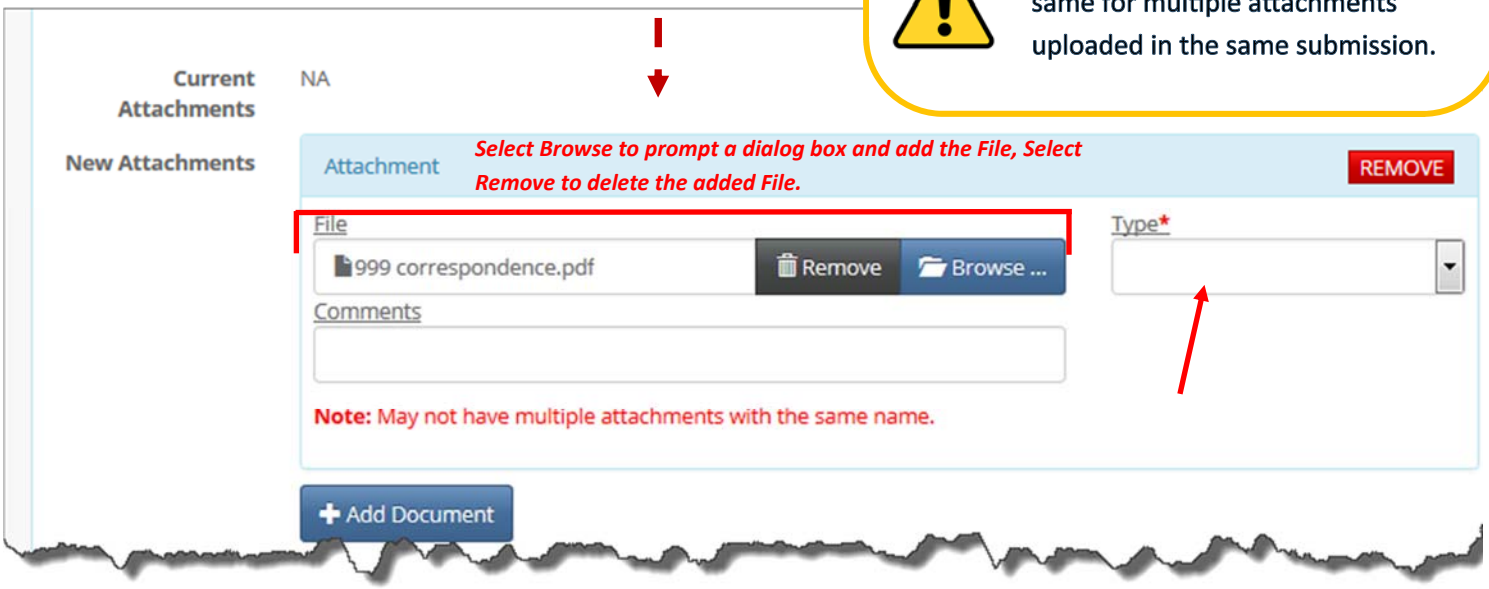
Next - Adding Attachments

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Select Add Document to be able to add attachment(s) to the record. Multiple attachments may be added for a single submission.



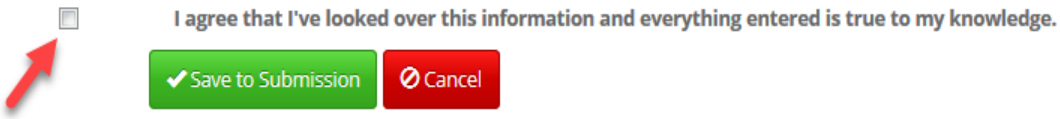
The file name SHOULD NOT be the same for multiple attachments uploaded in the same submission.



File - The CVB-IC requests that the majority of the incoming documents be uploaded as a .pdf file.

Type - All files, including letters, bench records, or other requests for CVB-IC will be entered as "Incoming Submission (Core)".

Comments - This is a Non-Mandatory field limited to 150 characters. Comments pertaining specifically to the individual document may be entered here.



Click on the checkbox, then the Save to Submission button

Next - Submitting to the CVB

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

There are 2 ways to Submit To CVB:
1-From the Submission
2-From the CVB Dashboard

#1 - From the Submission: When the submission is complete and ready to send to the CVB, click on Submit To CVB (available to liaisons and alternate liaisons only).

Submission History

Action	Timestamp	User	Info
Submission Entered	Jul-05-2016 12:17 PM CDT	Smith, Janie	
Submission Updated	Jul-05-2016 12:34 PM CDT	Smith, Janie	
Submission Updated	Jul-05-2016 01:51 PM CDT	Smith, Janie	Attachments added
Submitted To CVB	Jul-05-2016 01:57 PM CDT	Smith, Janie	ML# 176226

Save as PDF | Return to Dashboard

Note the mail log (ML) ID that is returned to the portal user immediately. This identifier is the most direct way of identifying a particular submission when communicating with the CVB.

#2 - From the CVB Dashboard: Click on "View Draft Submissions (APHIS Form 2048) to CVB."

Or choose the More info... link to review the individual submission and submit.

CVB Home / Open Submissions (APHIS 2048)

Select Draft Submissions (APHIS 2048) Not Yet Submitted To CVB

☐	999	Prod 142120/Ser # NA	Personnel	test	More Info...
☐	999	Prod NA0000/Ser # NA	Personnel	providing documentation of sampler training	More Info...

Submit To CVB

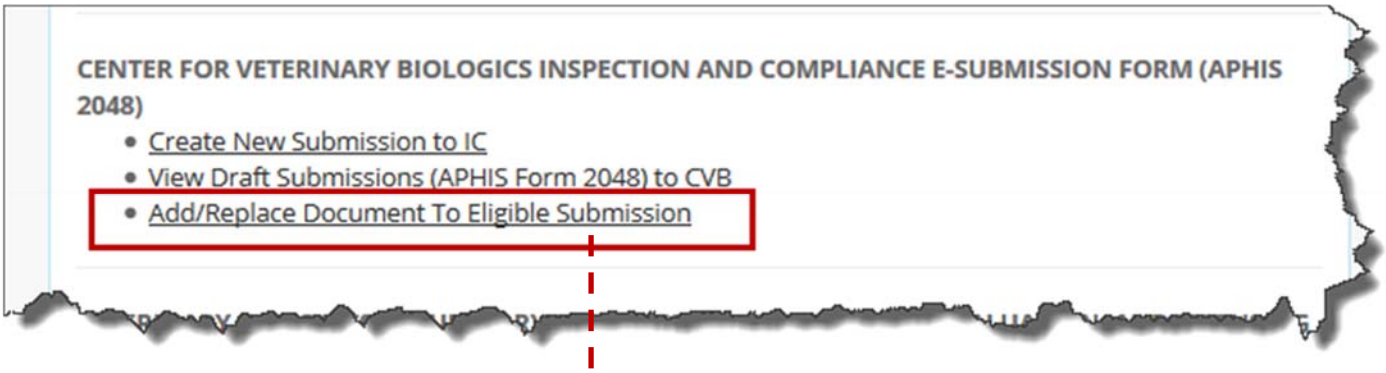
Next - Updating a Portal Submission

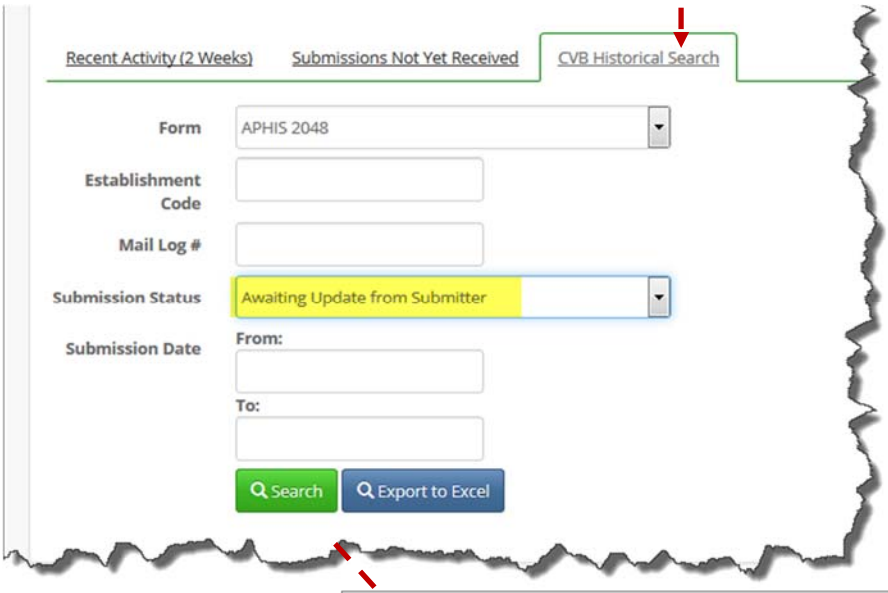
General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Updating a Portal Submission that is with the CVB

In instances that a **corrected letter**, or **additional information** needs to be added to a submission prior to CVB review of the original submission, the firm may add or replace a document within that submission.

However, the firm must first contact the CVB-IC (either the Biologics Specialist or the BCA) and request a "*Request Info From Submitter*" action. This will move the submission into an Eligible Submission for the firm.

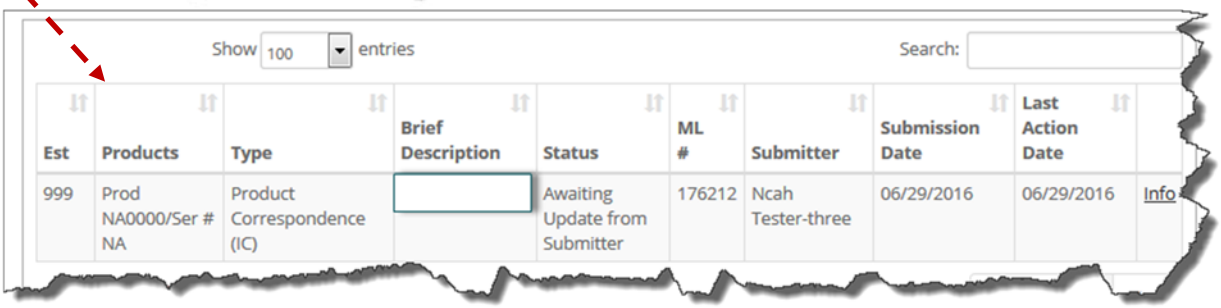




Any known search criteria may be entered, such as Form type (APHIS 2048), Mail Log #, or Submission Status (Awaiting Update from Submitter will default from the dashboard link).

Upon entering the info, the Results will populate, and you can choose the "Info" link to open the record. If the Status is "Awaiting Update from Submitter", you may append any attachment.

See Account Details User Guide for further guidance.

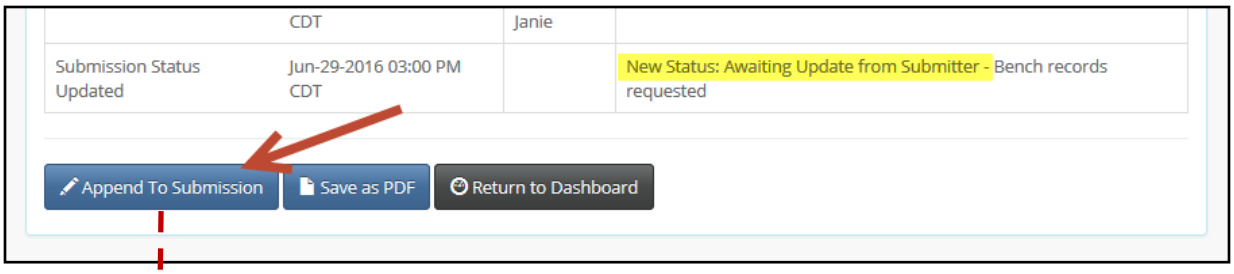


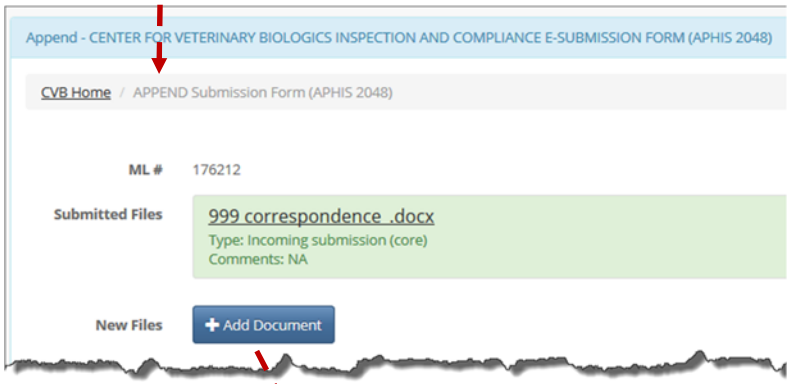
General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Updating a Portal Submission that is with the CVB (continued)

Only Liaisons and Alternate Liaisons may append a document to a submission. The documents are transferred immediately to the CVB without a separate Submit to CVB action.

The Liaison or Alternate Liaison may append only one document at a time.

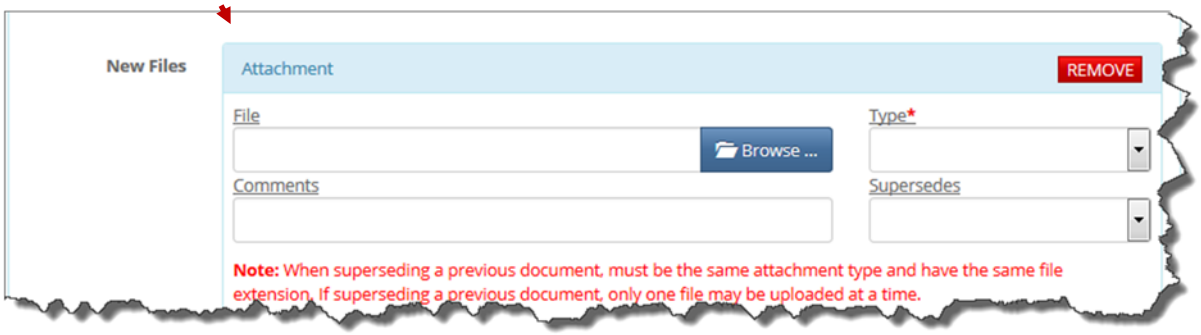




Users may indicate that the new document supersedes/replaces a previously uploaded document, provided that the document type and file extension (e.g., pdf) for both are the same.

This will cause versioning in the CVB Mail Log, to ensure that CVB personnel are working with the most current version. Superseded versions are retained by the CVB for historical purposes.

Once the appended document is submitted, an email is sent to all CVB employees currently working with the submission so they are aware of the update.



Comments - Specify the nature of the document, whether it is a new file or supersedes another file, and reason for the attachment.

Next - Responses from the CVB

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Responses from the CVB

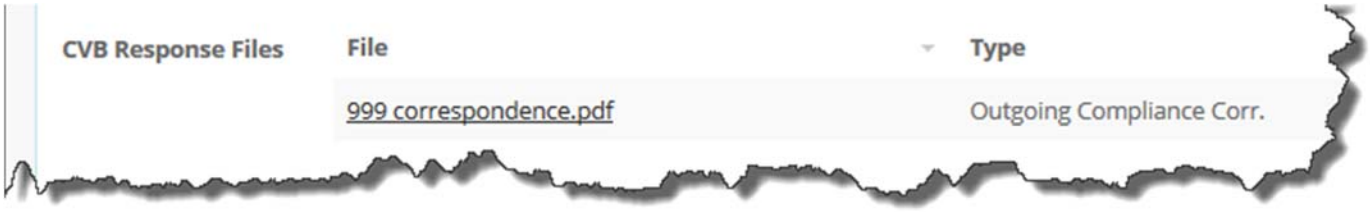
2048 submissions transferred to the CVB are updated at defined times in the course of CVB review/processing:

- When the CVB needs additional input from the submitter: The status of the submission changes from Submitted to **Awaiting Update from the Submitter**.
- When the CVB acknowledges receipt of the requested additional input: The status of the submission changes back to **Submitted** after being in Awaiting Update from the Submitter status.
- Upon completion of regulatory review: The status of the submission changes to **Completed**. The term "completed" refers only to the status of regulatory review and has no bearing on whether the submitted information was acceptable for the purpose intended. The CVB Response letter will detail this response, if applicable.

CVB Response Types

If a response is not needed by the CVB-IC, a mail log tag of "No Outgoing Correspondence" will be added. This will display in the NCAH Portal as the CVB Response.

If a response from the CVB is sent, the File (response letter) will be attached to the Submission Info page, along with the Attachment Type.

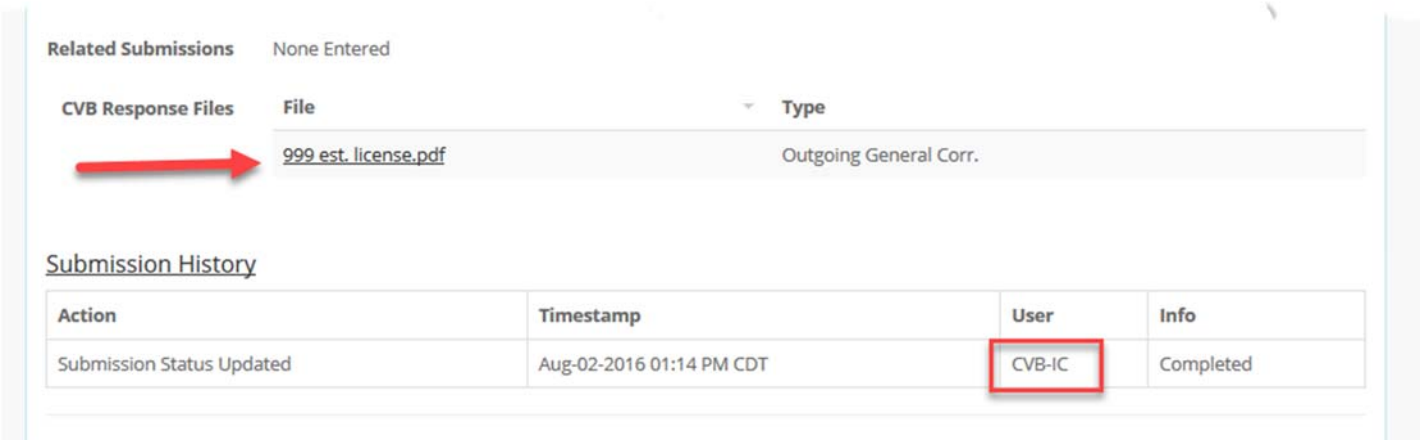


To see status update information of the 2048, including response letters from the CVB, and Attachment Type information see your Account Details page in the NCAH Portal.
Click here to see the Account Details User Guide.

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

CVB Initiated Correspondence

Occasionally the CVB will release to portal formal CVB correspondence that did not arise as a direct response to something a portal user submitted. When this occurs, the Submission History will show the item was created by CVB.



Related Submissions None Entered

CVB Response Files

File	Type
999 est. license.pdf	Outgoing General Corr.

Submission History

Action	Timestamp	User	Info
Submission Status Updated	Aug-02-2016 01:14 PM CDT	CVB-IC	Completed

Retention of 2048 items in the NCAH Portal

All "open" submissions remain in the NCAH Portal until they are completed.

Completed submissions are available for 60 days after their last action date.

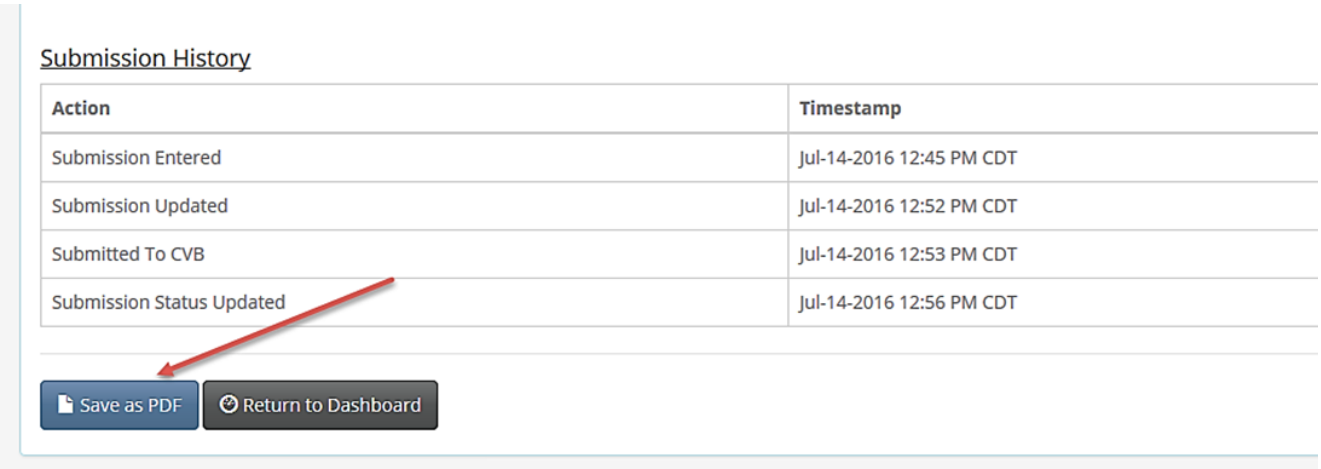
Firms are expected to download CVB responses to their own system.

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

To see status information of 2048s see your Account Details page in the NCAH Portal.
Click here to see the Account Details User Guide.

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Submitters may generate a pdf report of the information on the completed 2048 entry screen at any time. Click on the "Save as PDF" button at the bottom of the detail page for any submission.



Submission History

Action	Timestamp
Submission Entered	Jul-14-2016 12:45 PM CDT
Submission Updated	Jul-14-2016 12:52 PM CDT
Submitted To CVB	Jul-14-2016 12:53 PM CDT
Submission Status Updated	Jul-14-2016 12:56 PM CDT

Save as PDF | Return to Dashboard

Explanation of Statuses on the Account Details Page

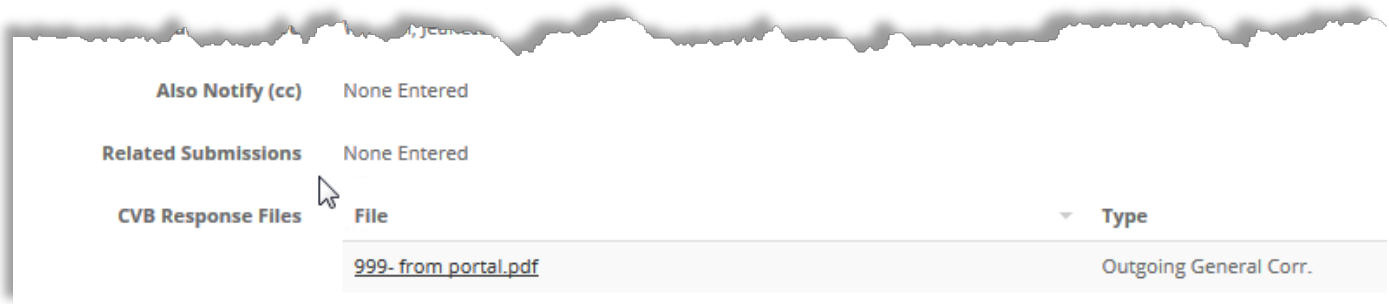
What are the different categories in "Status" on the Account Details page?

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

Awaiting Update from Submitter – 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.

Complete – 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.

- ***CVB Response*** – The Outgoing Correspondence Files (Outgoing General Correspondence, Outgoing Compliance Correspondence, Outgoing Enclosure document types) will be displayed within the CVB Response Files area.



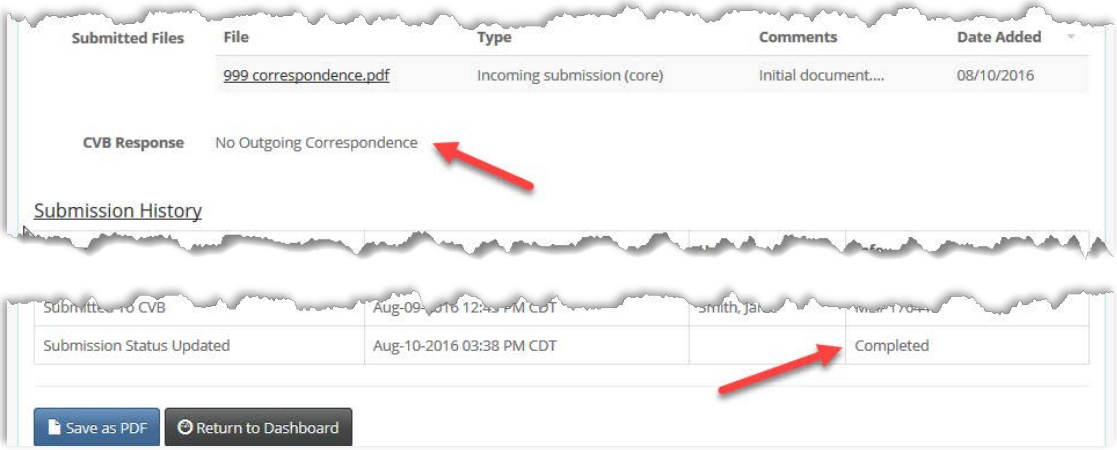
Also Notify (cc)	None Entered	
Related Submissions	None Entered	
CVB Response Files	File	Type
	999- from portal.pdf	Outgoing General Corr.

continued on next page...

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

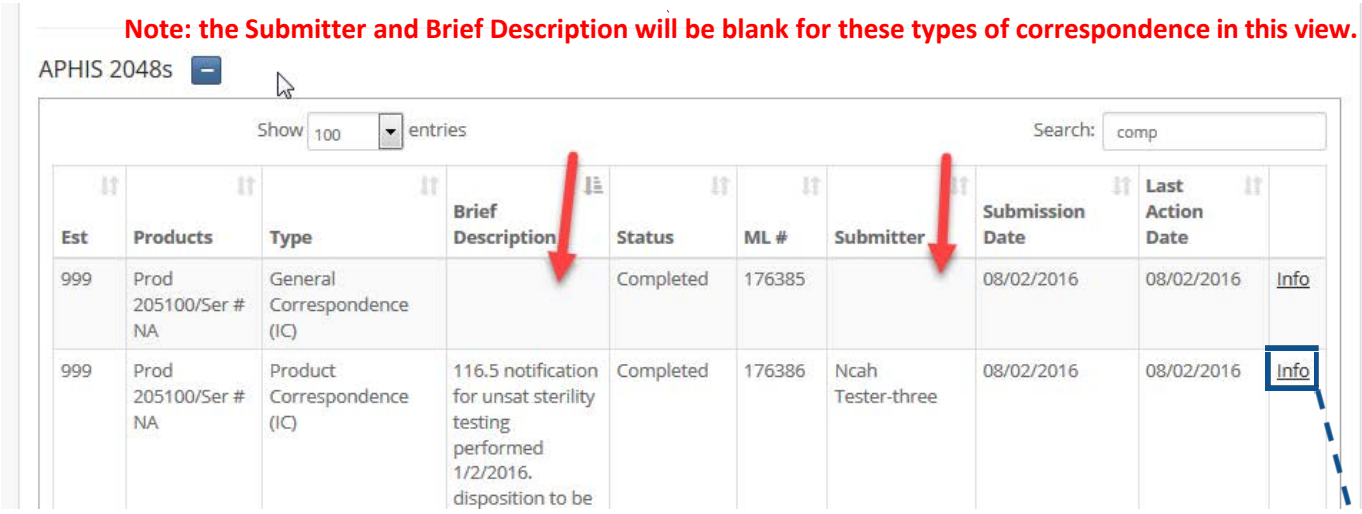
Further explanation of "Complete" status...*continued from previous page*

- ***No Outgoing Correspondence*** – The submission does not require an immediate response from the CVB-IC. The incoming document has been received and filed.

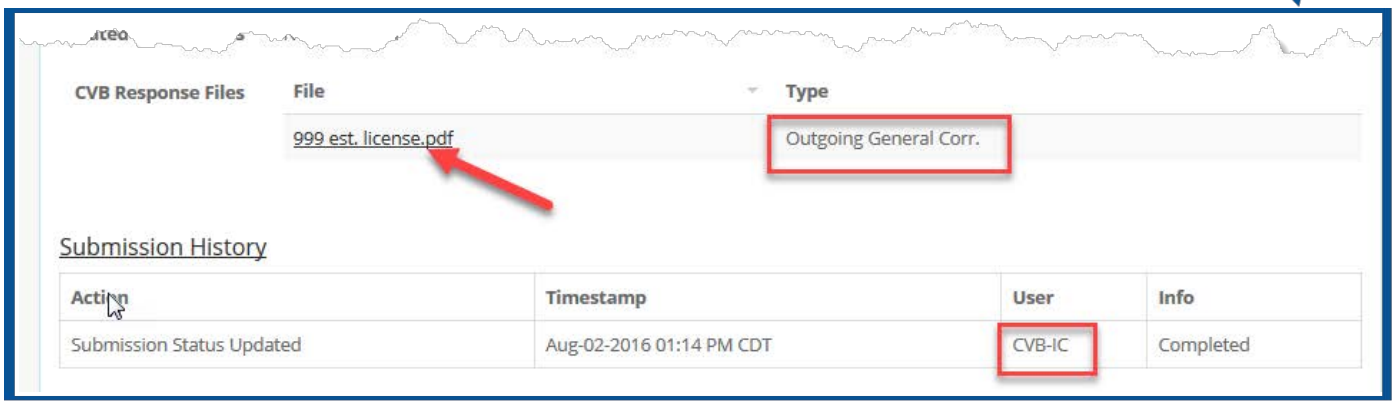


- ***CVB Initiated Correspondence*** – Any correspondence that initiated at the CVB.

Note: the Submitter and Brief Description will be blank for these types of correspondence in this view.



The Portal item info screen will indicate the submission is from CVB-IC, date submitted to the firm, and the response file(s).



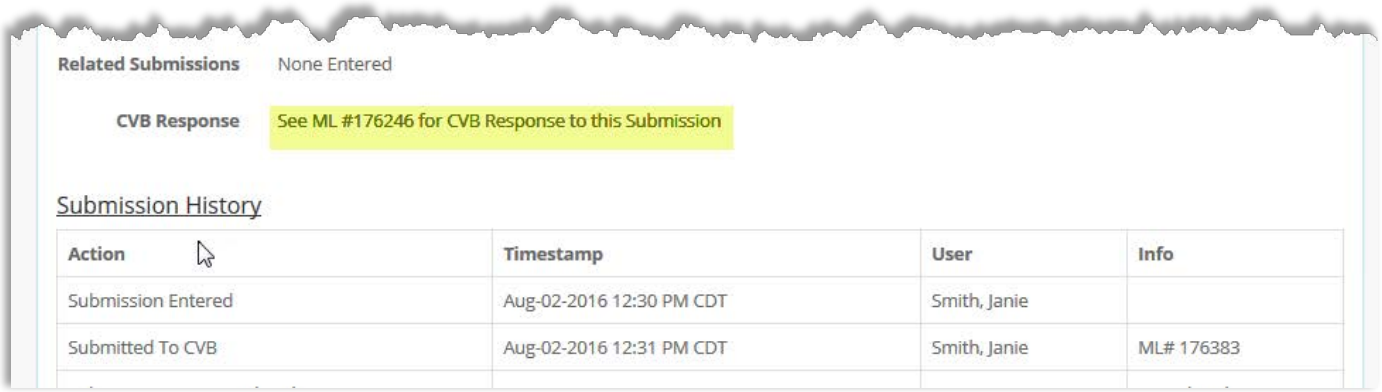
continued on next page...

General Guide for CVB Inspection & Compliance E-Submission Correspondence (APHIS 2048)

Explanation of Statuses on the Account Details Page

Further explanation of "Complete" status…*continued from previous page*

- ***Response is linked to a different Mail log Item*** – CVB may link multiple mail logs together, where only one submission will contain the CVB Response (Functionally linked Mail log items). The mail log item, that does not have the outgoing correspondence, will have a CVB Response of "See ML xxxxxx for CVB Response to this Submission".



Related Submissions None Entered

CVB Response See ML #176246 for CVB Response to this Submission

Submission History

Action	Timestamp	User	Info
Submission Entered	Aug-02-2016 12:30 PM CDT	Smith, Janie	
Submitted To CVB	Aug-02-2016 12:31 PM CDT	Smith, Janie	ML# 176383