

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

Where were changes made in the July 15, 2025, version?

1. Updated links and screenshots throughout document.

Where were changes made in the 1/17/2020 version?

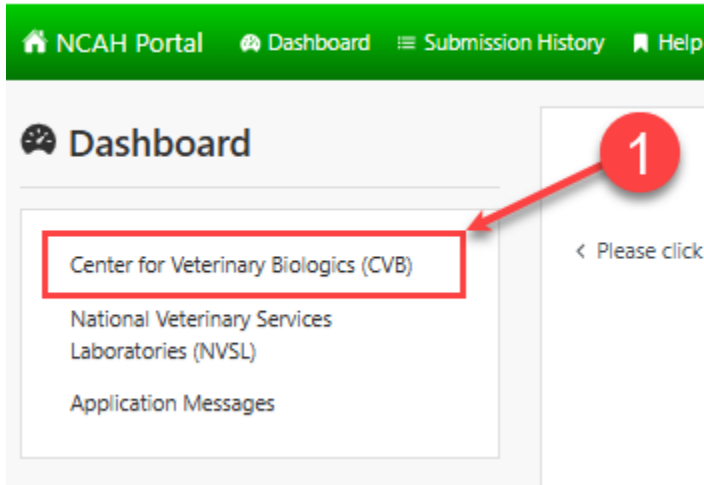
1. Updates were made to eAuthentication account references
2. Page 4, Submission Type options were updated.
3. Page 5, Submission Subtype options were updated.
4. Page 13, CVB Response Types were updated.

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

1. Pages 15-17, 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 Center for Veterinary Biologics (CVB) section of the NCAH Portal. Navigate to the CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048) and select Create New Submission to IC.



Any user with a verified identity eAuth account can enter the 2048 information. Quality Review Users have Read Only Access to All submissions.

Only Liaisons and Alternate Liaisons may submit to the CVB.

CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)

- Create New Submission to IC
- View Draft Submissions (APHIS Form 2048) to CVB
- Add/Replace Document To Eligible Submission

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)

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Entering Information

Fields with a red asterisk (*) are required.

Create - CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)

CVB Home / Submission Form (APHIS 2048)

Information

Establishment* 999 - Your Firm, Inc. ▼

Primary Site ▼

Additional Sites ▼ +

Product Code(s)* 500400 +

Establishment - Self-Explanatory.

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

* Enter NA0000 for submissions that are not product related.

Serial Number

Save changes NO Serial #

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 #

Note: Format must be ##-###

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

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The screenshot shows a web form with a 'Submission Type*' dropdown menu. The dropdown is open, showing a list of options. A blue button with a right-pointing arrow is visible to the right of the dropdown. The form is overlaid on a background image of a torn piece of paper.

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
- **Facility Documents** - Refer to [NCAH Portal User Guide #26, Submitting Facility Documents to Inspection and Compliance \(IC\)](#).
- **General Correspondence (IC)*** - Any correspondence including letters referencing more than one product code, or those that have no product associated. Also use this when submitting preliminary facility drawings for CVB comment.
**NOTE: Use "General Correspondence (IC)" as default if other options 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. Be sure to include the VBI number in the applicable field.
- **Pharmacovigilance** - Correspondence related to pharmacovigilance.
- **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).

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(Submission) Subtypes - This is a Non-Mandatory field. If applicable, multiple subtypes may be chosen. Select an entry from the list and click the add 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 choose this subtype. This may be used in conjunction with the **Immediate Notification** subtype.
- **Pharmacovigilance Onboarding** - Apart of the on-boarding process for licensees/permittees to be in compliance with 9 CFR 116.9. To receive the guidance documents to use the Gateway for adverse event reporting (AERs), licensees/permittees should send this request to the CVB using this subtype.
- **Preliminary Facility Documents** - This is intended to only be used with General Correspondence submission type. Drawings submitted for comment prior to construction or anticipation of renovations. See VSM 800.78.

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

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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).

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 add button. Repeat to add additional CVB Employees.

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Related Submissions

+

Select the (+) button to add the mail log number. Repeat for each applicable mail log number.

☐ I agree that I've looked over this information and everything entered is true to my knowledge.

Save

Select the box when complete and then Save the record.

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.

Check the box acknowledging you've looked over the information and everything entered is true to your knowledge, then click Save.



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.

Action	Timestamp	User	Info
Submission Entered	May-28-2025 12:40 PM CDT	Herr, Crosley	

Edit

Add Attachments

Submit To CVB

Save as PDF

Delete Submission

Return to Dashboard

Edit - 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 below in this document for guidance on updating attachments.

Delete Submission - 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.

Save as PDF - 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.

Return to Dashboard - This takes the user back to the CVB Dashboard.

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

CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)

- [Create New Submission to IC](#)
- [View Draft Submissions \(APHIS Form 2048\) to CVB](#)
- [Add/Replace Document To Eligible Submission](#)

Adding Attachments

Select **Add Attachments** to add attachment(s) to the record. Multiple attachments may be added for a single submission by selecting **Add Document** or **Add Facility Document**.

Action	Timestamp	User	Info
Submission Entered	May-28-2025 12:40 PM CDT	Herr, Crosley	

[Edit](#)
[Add Attachments](#)
[Submit To CVB](#)
[Save as PDF](#)
[Delete Submission](#)
[Return to Dashboard](#)



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

Add Attachments - CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)

[CVB Home](#) / Add Attachments Submission Form (APHIS 2048)

Current Attachments

NA

New Attachments

[Add Document](#)

[Add Facility Document](#)

☐ I agree that I've looked over this information and everything entered is true to my knowledge.

[Save to Submission](#)

[Cancel](#)

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Add Attachments - CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)

[CVB Home](#) / Add Attachments Submission Form (APHIS 2048)

Current Attachments: NA

New Attachments:

Attachment REMOVE

File: PDF Testing.pdf Remove Browse ...

Type*:

Comments:

Note: May not have multiple attachments with the same name.

+ Add Document + Add Facility Document

Annotations:

- Select Browse to prompt a dialog box and add the File.
- Select Remove to delete the added File.

File - The CVB-IC requests 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.

☒ I agree that I've looked over this information and everything entered is true to my knowledge.

✓ Save to Submission ⏪ Cancel

Check the box acknowledging you've looked over the information and everything entered is true to your knowledge, then click the Save to Submission button.

Next: Submit to CVB

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There are two ways to Submit To CVB:

1. From the Submission
2. From the CVB Dashboard

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

Action	Timestamp	User	Info
Submission Entered	May-28-2025 12:40 PM CDT	Herr, Crosley	
Submission Updated	May-28-2025 02:34 PM CDT	Herr, Crosley	Attachments added

[Edit](#)
[Add Attachment](#)
[Submit To CVB](#)
[Save as PDF](#)
[Delete Submission](#)
[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.

Submission Updated	May-28-2025 02:34 PM CDT	Herr, Crosley	Attachments added
Submitted To CVB	May-28-2025 02:36 PM CDT	Herr, Crosley	ML# 290612

[Save as PDF](#)
[Return to Dashboard](#)

From the CVB Dashboard - Click on “View Draft Submissions (APHIS Form 2048) to CVB.” Check the boxes for the items you are wanting to submit, then click the Submit To CVB button. Or, select the More info... link to review the individual submission and submit.

CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048) Open Submissions

CVB Home / Open Submissions (APHIS 2048)

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

☐	999 Prod 264853/Ser # NA; Prod 500400/Ser # FUN1234	AIR Correspondence	For testing purposes only	More Info...
☐	999 Prod 500400/Ser # FUN9999	General Correspondence (IC)	For training purposes only	More Info...

[Submit To CVB](#)

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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 CVB-IC (either the Biologics Specialist or the BCA) and request a “*Request Info from Submitter*” action. This request may be done by email or phone call to the CVB-IC representative. This will move the submission into an Eligible Submission for the firm.

CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)

- [Create New Submission to IC](#)
- [View Draft Submissions \(APHIS Form 2048\) to CVB](#)
- [Add/Replace Document To Eligible Submission](#)

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).

Submission History

Recent Activity (2 Weeks)
Submissions Not Yet Received
CVB Search

Note: Submissions completed over 60 days ago will not be available in search results.

Form*	APHIS 2048		
Submission Type			
Establishment Code			
Product Code			
Serial Number			
Mail Log #			
Submission Status	Awaiting Update from Submitter		
APHIS 2005 Application #			
Submission Date	From:	To:	
Last Action Date	From:	To:	

Search
Export to Excel

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”, the Liaison or Alternate Liaison may append any attachment one document at a time.

See [Submission History and Account Details User Guide](#) for further guidance.

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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.*

Select Append To Submission, then select Add Document.

The screenshot shows the NCAH Portal interface. At the top, there's a submission status area with a table showing 'Submission Status' as 'Updated' and a timestamp 'May-28-2025 03:23 PM CDT'. A red circle with the number '1' is next to the 'Append To Submission' button. Below this, there's a section titled 'Append - CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE E-SUBMISSION FORM (APHIS 2048)'. This section has a breadcrumb trail 'CVB Home / APPEND Submission Form (APHIS 2048)'. It shows 'ML #' as '290593' and 'Submitted Files' with a file named 'For Training Purposes Only.pdf'. Below this, there's a 'New Files' section with a red circle with the number '2' next to the 'Add Document' button. A red arrow points from the 'Append To Submission' button to the 'Add Document' button.

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.

File - Select Browse to prompt a dialog box and add the File.

Type – Select the same document type as the file you are superseding.

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

Supersedes – Select the file you are superseding.

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.

Next - Responses from the CVB

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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.



- "**Return Action Required by the Firm**" - used in instances when the CVB Expects a response from the firm, usually in a given time frame.
- "**Voluntary Stop Distribution and Sale Acknowledged**" - The CVB response for voluntary stop distribution and sale action based on a temperature excursion which is outside the Outline of Production or 9 CFR 114.11 requirements and the firm decides to reject (Destroy) the product that was involved will be tagged as “No Outgoing Correspondence” and “Voluntary Stop Distribution and Sale Acknowledged”.

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.

CVB Response Files	
File	Type
PDF Testing.pdf	Outgoing Compliance Correspondence



To see status update information of the 2048, including response letters from the CVB, and Attachment Type information see your Submission History (CVB) page in the NCAH Portal.

[View the Submission History \(CVB\) and 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.

CVB Response Files

File	Type
PDF Testing.pdf	Outgoing Compliance Correspondence

Action	Timestamp	User	Info
Submission Status Updated	May-30-2025 10:53 AM CDT	CVB-IC	Completed

[Save as PDF](#)
[Return to Dashboard](#)

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 Submission History (CVB) page in the NCAH Portal.

[View the Submission History \(CVB\) and Account Details User Guide.](#)

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 Status Updated

May-30-2025 10:53 AM CDT

[Save as PDF](#)
[Return to Dashboard](#)

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

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	<table border="1"> <thead> <tr> <th>File</th> <th>Type</th> </tr> </thead> <tbody> <tr> <td>PDF Testing.pdf</td> <td>Outgoing Compliance Correspondence</td> </tr> </tbody> </table>	File	Type	PDF Testing.pdf	Outgoing Compliance Correspondence
File	Type				
PDF Testing.pdf	Outgoing Compliance Correspondence				

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

CVB Response

- No Outgoing Correspondence

Action	Timestamp	User	Info
Submitted to CVB	May-30-2025 10:51 AM CDT	Henry Osley	ML 202514
Submission Status Updated	May-30-2025 10:53 AM CDT		Completed

Save as PDF Return to Dashboard

Further explanation of "Complete" status...continued on next page

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

- **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).

APHIS 2048s 

Show entries

Search:

Est	Products	Type	Brief Description	Status	ML #	Submitter	Submission Date	Last Action Date	
999	Prod 500400/Ser # FUN9999	General Correspondence (IC)		Completed	290613		05/28/2025	05/30/2025	Info

CVB Response Files

File	Type
PDF Testing.pdf	Outgoing Compliance Correspondence

Action	Timestamp	User	Info
Submission Status Updated	May-30-2025 10:53 AM CDT	CVB-IC	Completed

[Save as PDF](#) [Return to Dashboard](#)

- **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**”.

CVB Response	See ML #290593 for CVB Response to this Submission		
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Action	Timestamp	User	Info
Submission Entered	May-28-2025 02:44 PM CDT	Herr, Crosley	
Submitted To CVB	May-30-2025 10:51 AM CDT	Herr, Crosley	ML# 290614