

2049s - Submitting Items to Policy, Evaluation and Licensing (PEL)

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

1. [Page 9](#) - 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 10/14/2020 version?

1. [Page 8 - 10, the process and rules associated with appending documents to submissions AFTER they have been submitted to the CVB has changed.](#) *Firms may no longer append documents after submission unless they contact the CVB first and a "Request Info from Submitter" loop is opened.*
2. [Page 13, Organization of the Submission History Page section](#) was updated to reflect the move of this information from the Account Details page to the Submission History Page

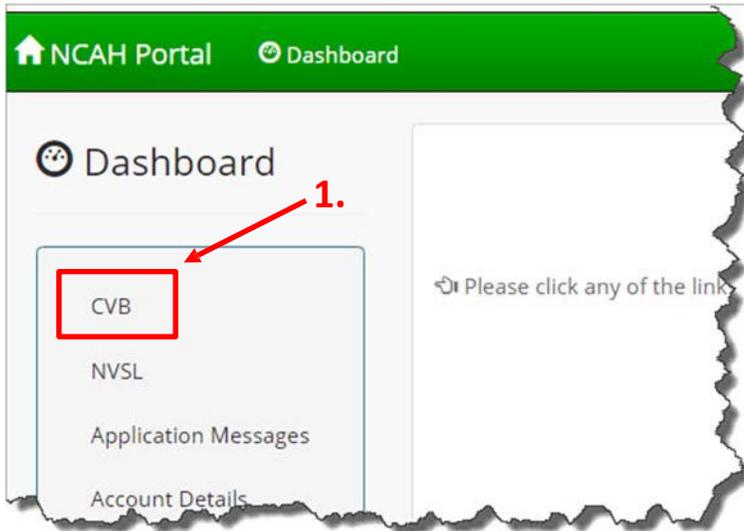
Where were changes made in the 10/18/2019 version?

1. [Page 3, "APHIS 2005" was removed from the list of Submission Types.](#) *APHIS 2005s have a different method of submission in the NCAH Portal now - refer to user guides 27, 28 or 29 based on the reason for submission.*

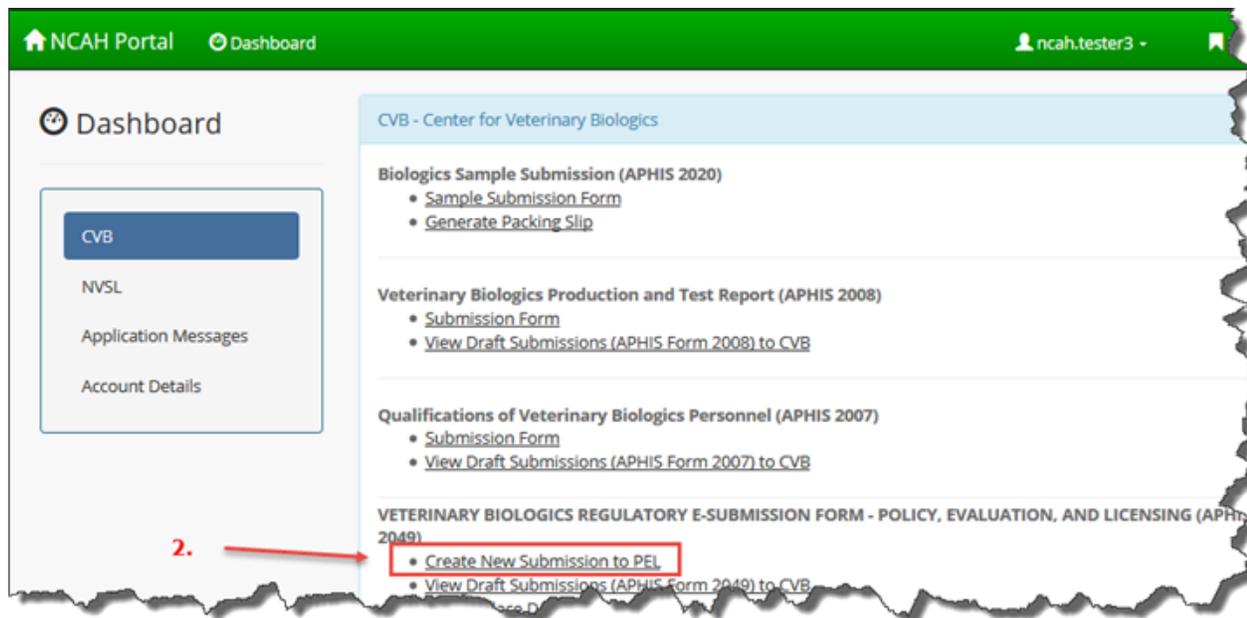
Where were changes made in the 9/13/2019 version?

1. [Page 3, clarifying language was added regarding entry of data in the Product Code field](#)

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For APHIS Form 2049 submissions, start by entering the CVB section of the Portal and then navigating to the 2049 Submission Form.



You will be taken to the Veterinary Biologics Regulatory E-Submission Form for Policy, Evaluation, and Licensing.

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Definition of a “submission”—Portal entries will be transferred directly to the CVB Mail Log upon submission. When multiple documents or requests are to be submitted on the same day, it is important for submitters to align, to the extent possible, with CVB thinking on what constitutes separate submissions, with separate 2049 forms. Click the button below to learn more.

Business rules for separating items into distinct submissions

Completing Submission Data

Information

Fields with a red asterisk (*) are required.

Establishment*	999 - Your Firm, Inc.
Product Code(s)*	<input type="text"/> +
Special Outline No.	<input type="text"/>
Submission Type*	<input type="text"/>
Subtypes*	<input type="text"/> +
Tags	<input type="text"/> +
Brief Description*	<input style="height: 40px;" type="text"/>
Direct Submission To*	<input type="text"/>
Also Notify (cc)	<input type="text"/> +
Related Prior Completed (Reviewed) Submissions	<input type="text"/> +

Fields with + buttons: Type desired value or select from a list of values associated with your establishment(s). Click + button to add to your record. May add multiple values.

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

Save

Establishment—Only those establishments for which the user has a current APHIS Form 2007 on file will be available in the drop-down menu.

Product Code—User may select codes assigned to the selected Establishment. If the submission does not apply to a particular product, select NA0000. If the submission applies to a product that has not yet been assigned a USDA Product Code, enter UNASGN. NOTE: enter only alphanumeric. Do NOT include the decimal point.

Special Outline No.—Enter only if the submission pertains to a Special Outline

Submission Type—Use the following business rules to determine the appropriate submission type:

- Protocol is for pre-study review.
- Report is for data of any kind, whether formatted as a formal report or simply a summary appended to a letter.
- Historical Study Summary is for submissions containing *only* a study summary, for a study previously reviewed by the CVB, to be posted at productdata.aphis.usda.gov. (Select “Report” for study summaries co-submitted with new reports to be reviewed.) --APHIS Forms 2001, 2003, 2070, 2071, and 2072: self-explanatory
- Labels, post-license: For labels *to be used on* postlicense product, regardless whether the labels are submitted before or after licensure. Do NOT use this submission type for experimental labels or labels for product exported under FDA-EREA. ***See separate [“2049 Guide to Submitting Labels”](#) and [“Using CVB Template for a Label Mounting Sheet”](#) ***
- Outline: for Outlines of Production
- Special Outline: for Special Outlines
- Use Correspondence only if other values do not apply.

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Submission Subtype—Use the following business rules to determine the appropriate subtype(s). More than one subtype may be selected. *Outlines and labels do not have an applicable subtype.*

Submission Subtype Value	Description
103.3/other movements	For authorizations to move product under 9CFR 103.3 or to move items into production facilities or other locations
Administrative/license maintenance	For routine letters about license application/termination/inactivation or special outline inactivation.
Assay validation - potency	For initial assay validation or to support changes in potency assay architecture/format (other than diagnostic kits)
Assay validation - RelPot Transition	For submissions to support changes in analysis packages away from RelPot, per CVB Notice 13-18
Assay validation - other	For initial validation, or to support changes in architecture/format, of assays other than potency assays, RelPot transitions, or diagnostic kits.
Assay reagent change	For submissions supporting the change to new reagent lots in a previously validated assay (other than diagnostic panels)
Cell	Submissions pertaining to Master Cells
Confirmatory Test Request	For submissions where confirmatory testing by the CVB is being requested (Seeds, Cells, Preliminary Serials, Outline Changes)
Diagnostic field study	Ruggedness studies for kits
Diagnostic Panel Validation	For submissions supporting the samples (initial and replacement) used in serial release testing for diagnostic test kits
Diagnostic spec-sens	Specificity/sensitivity studies for kits
Dilution of Preservative	Studies to support media volumes used for serial release sterility/purity testing
Efficacy-component compatibility	Lack of interference studies
Efficacy-pivotal or DOI	Both short- and long-term pivotal efficacy studies
Efficacy-proof of concept/other	For exploratory studies, challenge model development, and other miscellaneous studies
Efficacy-reference qualification	Qualification or requalification studies (<u>not</u> stability monitoring data)
Establishment issue	Submissions pertaining to an establishment license, including corporate acquisitions and mergers
Exemption	Exemption requests
FDA-EREA	Submissions regarding products to be exported under the Food and Drug Administration's Export Reform and Enhancement Act of 1996
Inactivation kinetics	For submissions demonstrating inactivation or detoxification kinetics
Jurisdiction/Licensability	Issues regarding regulatory jurisdiction or other concerns regarding whether something is licensable.
Labeling Issues	Correspondence dealing with labeling issues. Do NOT use on routine label submissions.
Manufacturing Process (Mfr Proc)	Proposals to change manufacturing methods. Equivalency studies (not efficacy) when changing formulations or processes
Personnel	Consent to share CBI (for liaisons etc, use 2007 entry in portal)
Residue clearance	Slaughter withdrawal, adjuvant clearance
SIF/Risk Analysis	SIFs and other risk-related documents
Safety-backpassage	Reversion to virulence studies
Safety-field	Typical field safety, per VSM 800.204
Safety-overdose	Overdose studies
Safety-shed/spread/tropism	Shed/spread studies and non-target safety
Safety-special claims	Such as safe in pregnant cows or some other special condition not adequately addressed in a normal field safety study
Seed	Submission pertaining to Master Seeds
Stability-confirm dating	Confirming product dating, per 9CFR 114.13
Stability-reference monitoring	Periodic potency reference monitoring reports, per VSM 800.211

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Tags—Use the following business rules to select tags, as appropriate.

Tag Value	Description
Firm’s Licensing Plan	For submissions where you are sending us your anticipated list of submissions needed for licensure, for CVB concurrence. See CVB Notice 11-12 for details.
Firm’s Priority	Use this tag if the submission is high priority for processing. Use with discretion!
Single Tier Labeling	Use this tag if you are submitting labels for post-license use that have claims formatted according to the single tier rule and are in compliance with other single-tier guidance in VSM 800.54 .

Brief Description—Explain the purpose of the submission. Include study numbers, but be succinct. Maximum 200 characters.

Direct Submission To—Select the name of the CVB reviewer for your establishment. In most cases, the CVB mail log item that is created from this submission will be routed directly to this person. Exception: Historical Study Summary submissions will be routed to the Single Tier Implementation Team, regardless of the reviewer specified on the 2049 form.

Also notify (cc)—Optionally select the name(s) of additional CVB employees that you wish to be notified when this submission is transferred (submitted) to the CVB mail log. It is not necessary to list the assigned IC specialist or BCA for your establishment, as they are automatically notified at the time that PEL processes the submission.

Related Prior Completed (Reviewed) Submissions—List the Mail Log ID numbers of any directly related, prior reviewed/completed submissions if this submission is a follow-up to a CVB response or if there are precedents that need to be considered while reviewing this submission.



Once the form is completed, click on  to create a draft portal item. You may proceed preparing your item for submission at this time, or you may access it again later. If you elect to resume your preparation later, the draft may be found at by clicking the following menu item on the Dashboard:



Locate your draft item from the list and click on More info... to open the item.

Once the item is opened, you have the following choices:

NOTE: The "Submit to CVB" button is only visible to liaisons and alternate liaisons.

VETERINARY BIOLOGICS REGULATORY E-SUBMISSION FORM - POLICY, EVALUATION, AND LICENSING (APHIS 2049) Information

CVB Home / Submission Form (APHIS 2049) / Submission Information (APHIS 2049)

2049 Submission Info

Status Submission Entered

Establishment 999 - Your Firm, Inc.

Product(s) • 264853

Submission History

Action	Timestamp	User	Info
Submission Entered	Apr-28-2016 10:26 AM CDT	Smith, Jane	
Submission Updated	Apr-28-2016 10:41 AM CDT	Smith, Jane	

Edit data fields in the 2049 form (points to Edit button)

Add supporting documents to my 2049 submission (points to Add Attachments button)

Buttons: Edit, Add Attachments, Submit To CVB, Delete Submission, Return to Dashboard

Adding documents to the draft 2049 item

With exceedingly rare exceptions, you must attach supporting documents to a 2049 submission before it is submitted.

[Details on file formats](#)

Click the button to read more about preferred file formats, size restrictions, and other important information to help the CVB review your submission.

Click on the Add Attachments button, then click on Add Document, to upload a file.

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[CVB Home](#) / Add Attachments Submission Form (APHIS 2049)

Current Attachments NA

New Attachments

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

There will be additional document choices for label and outline submissions.

Current Attachments NA

New Attachments

Attachment

File

Type*

Comments

Submitter's Study ID

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

File — The interface to search for a document is similar to many Windows-based applications. Click the Browse button and navigate to the location on your computer where the desired document is located. With the exception of hyphens (-) and underscores (_), **do not include special characters in your file names**. If filenames have prohibited special characters, the characters will be stripped out of the filename upon upload.

Type—Select a document type according to the following business rules:

Document Type	Description
Incoming submission (Core)	all letters, reports, protocols or other text documentation <i>except for</i> a draft individual study summary to be posted at productdata.aphis.usda.gov.
Incoming statistical data files	See the Data Guidance on the CVB website for technical details.
Incoming sequence data	genetic sequence data for Master Seeds (mainly recombinants)
Draft Individual Summary	A study summary intended for publication on productdata.aphis.usda.gov, in accordance with 9CFR 112.2(a)(9)(v)
Incoming post-license labels	This choice is only available for Label submissions. Post-license labeling, one label per document. ***See User Guide 11 - "Submitting Labels to CVB-Policy, Evaluation and Licensing" for more details on NCAH Portal procedures and "User Guide 13 - "Using the CVB Template for a Label Mounting Sheet" for details on preparing your submission***
Incoming Outline	This choice only available for Outline and Special Outline submission. ***See User Guide 20 - "Submitting Outlines to Policy, Evaluation and Licensing (PEL)" for more details***

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Submitter’s Study ID: Firms are strongly encouraged to assign unique identifiers to each study they submit to the CVB, to allow for easy differentiation of similar studies. Please add the unique study identifier if the document being uploaded has one. (This field is not available for statistical data files because of how they are handled at the CVB. The study ID should be noted within the statistical files.)

Comments—Enter any comments pertaining specifically to the individual document. (This field not available for statistical data files because of how such files are handled at the CVB. If you have comments specific to statistical files, mention them in a cover letter.)

Repeat this procedure for each document you wish to upload to the submission.

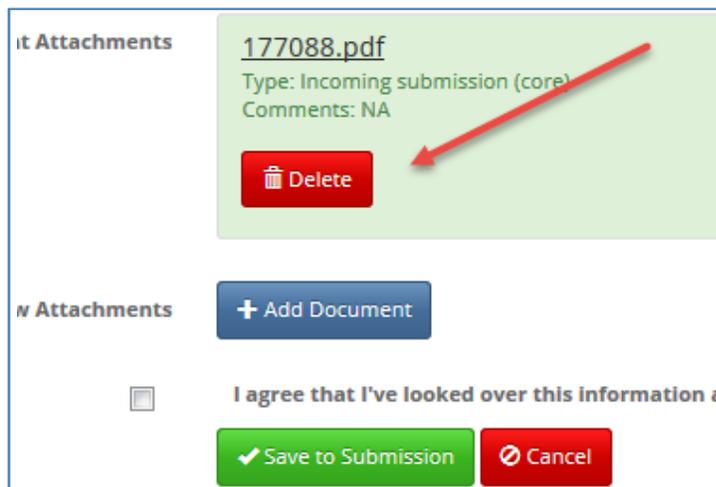
Uploading multiple documents at once

Multiple Incoming documents (except outlines/special outlines/post-license labels) may be selected at once, for uploading in a single action, *provided that* they all are of the same document type and have unique file names.

To select more than one file in the File field, highlight the first file, then hold the Control key down while selecting additional files. If the desired files are all in a continuous sequence in the listing from which you are selecting, you can highlight the first file, then hold down the Shift key while clicking on the final file to select the entire group at once.

Removing a document prior to submitting to the CVB

An uploaded document may be removed from a 2049 item, *provided that* the item has not yet been submitted to the CVB. To remove an uploaded document, first click on the Add Attachment button at the bottom of the 2049 Submission Info page. In the pop-up box that appears, there is an option to remove previously uploaded documents. This functionality is only available before the item is submitted.



Submitting to CVB

When the portal item is completely ready to send to the CVB, click on the Submit to CVB button (available to liaisons and alternate liaisons only). 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.

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Updating a Portal Submission that is with the CVB

Do not create a new 2049 submission to amend/update documents in an open submission. In instances that additional or replacement documents need to be added to a 2049 submission after it has been submitted to the CVB (i.e. appending a document) **the firm must contact the CVB Reviewer and request a "Request Info From Submitter" action.** This request may be done by email or phone call to the CVB Reviewer. Once the "Request Info From Submitter" action has been initiated by the Reviewer, the submission will be eligible for appending documents in the NCAH Portal. Follow the steps below to append a document.

Click on the hyperlink on the CVB page of the Dashboard that allows you to search for the desired 2049 submission:

VETERINARY BIOLOGICS REGULATORY E-SUBMISSION FORM - POLICY, EVALUATION, AND LICENSING (APHIS 2049)

- [Create New Submission to PEL](#)
- [View Draft Submissions \(APHIS Form 2049\) to CVB](#)
- [Add/Replace Document To Eligible Submission](#)



Enter the Mail Log # of the submission you need to append documents to on the CVB Search screen and click the Search button.

Your item will be shown in the table below the search fields.

Click on the Info link in the far right column to open the item.

NCAH Portal Dashboard Submission History apetersor Help

Submission History

[Recent Activity \(2 Weeks\)](#)
[Submissions Not Yet Received](#)
[CVB Search](#)
[NVSL Search](#)

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

Form* APHIS 2049

Submission Type

Establishment Code

Product Code

Serial Number

Mail Log # 179636

Submission Status

APHIS 2005 Application #

Submission Date From:

To:

Last Action Date From:

To:

Search
Export to Excel

Show 100 entries

Est	Products	SO #	Type	Brief Description	Status	ML #	Submitter	Reviewer	Submission Date	Last Action Date	
301	101520	12	Special Outline	test	Submitted	179636	Amber Peterson	Jeanette Watson	01/27/2021	01/27/2021	Info

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An item is open for document additions as long as the Append Submission button is available at the bottom of the Submission Info page for the item. **Click on the Append to Submission button** to start the process.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-09-2016 11:26 AM CST	ncah.tester1	
Submitted To CVB	Mar-09-2016 11:29 AM CST	ncah.tester3	ML# 175564
Submission Updated	Mar-23-2016 01:40 PM CDT	Smith, Jane	Attachments altered - APPENDED
Submission Status Updated	Apr-18-2016 11:18 AM CDT		New Status: Awaiting Update from Subm

The procedure to Append a document is largely the same as used to Attach documents prior to submitting to the CVB, with the following differences:

- Only users with the liaison or alternate liaison role can Append documents, as they are transferred immediately to the CVB without a separate Submit to CVB action. Other users may see the Append Submission button for awareness, but will not be able to complete an Append action.
- Users 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.

ML # 175940

Submitted Files

- [CoverLetter.docx](#)
Type: Incoming submission (core)
Comments: NA
- [EfficacyReportABCwithRequestedCorrections.docx](#)
Type: Incoming submission (core)
Comments: NA

Superseded Files

- [EfficacyReportABC.docx](#)

New Files

Attachment REMOVE

File: Remove Browse ...

Type*:

Comments:

Submitter's Study ID:

Supersedes:

<---Picklist contains only documents that have not yet been superseded. Leave blank if document does not supersede another.

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

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When to expect portal updates from the CVB

2049 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.

Status changes are noted in the Account Details section of the portal twice daily, at 11 AM and 3 PM Central US Time, which can be viewed by anyone having portal access. Additionally, a daily email, listing all of the portal items that have had a status change during the past 24 hours, will be sent at approximately 3:30 pm to the email address on file with the CVB for delivery of Electronic Notification of Serial Release (ENSR).

What you will receive from CVB at a status change

When the CVB requests an update from the submitter—A brief description of the request will appear in the Submission History. The reviewer may provide further detail via email or telephone.

<u>Submission History</u>			
Action	Timestamp	User	Info
Submission Entered	Apr-18-2016 02:55 PM CDT	Smith, Jane	
Submission Updated	Apr-18-2016 02:55 PM CDT	Smith, Jane	Attachments added
Submitted To CVB	Apr-18-2016 02:55 PM CDT	Smith, Jane	ML# 175865
Submission Status Updated	Apr-18-2016 02:58 PM CDT		New Status: Awaiting Update from Submitter - I'm missing a doc. Pls send.

When the CVB releases a formal response (status goes to completed)—Outgoing documents, if any, will be attached to the Submission Info page

Submissions

Submitted Files	File	Type	Submitter's Study ID	Comments	Date Added
	[REDACTED]	Incoming submission (core)			04/29/2016

CVB Response Files

File	Type
CVBResponseLetter.docx	Outgoing Correspondence
EnclosureCitedInCVBResponseLetter.docx	Outgoing Enclosures

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-22-2016 02:54 PM CDT	Smith, Jane	
Submission Updated	Mar-22-2016 02:55 PM CDT	Smith, Jane	Attachments altered
Submitted To CVB	Mar-22-2016 02:55 PM CDT	Smith, Jane	ML# 175638
Submission Status Updated	Apr-29-2016 01:49 PM CDT		Completed

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Occasionally the CVB will close out a submission without a formal letter, typically for simple transactions where an acknowledgment of receipt is sufficient. In those instances, that acknowledgment statement will be in the Remarks section.

Also Notify (cc)	None Entered
Related Prior Completed (Reviewed) Submissions	None Entered
CVB Response	Filed for information only 

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-22-2016 02:58 PM CDT	Smith, Jane	
Submitted To CVB	Mar-22-2016 02:58 PM CDT	Smith, Jane	ML# 175640
Submission Status Updated	Apr-29-2016 01:49 PM CDT		Completed

All 2049 submissions changing to Completed status should have either an outgoing document attached or an explanatory Remark.

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.

Submission History

Action	Timestamp	User	Info
Submission Entered	Aug-02-2016 10:59 AM CDT	CVB-PEL	Created By CVB-PEL

Retention of 2049 items in the NCAH Portal

All “open” submissions (Submitted or Awaiting Update from Submitter statuses) remain accessible 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 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, even 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.**

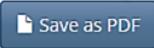
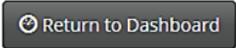
 **To see status information of 2049s see your Submission History (CVB) page in the NCAH Portal.**
[Click here to see the Submission History \(CVB\) and Account Details User Guide.](#)

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Submitters may generate a pdf report of the information on the completed 2049 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

Organization of Items on the Submission History Page

 **Dashboard**

- Center for Veterinary Biologics (CVB)
- National Veterinary Services Laboratories (NVSL)
- Submission History 
- Application Messages
- Account Details



[Recent Activity \(2 Weeks\)](#)
[Submissions Not Yet Received](#)
[CVB Historical Search](#)

Recent Activity

Items having some kind of status update (new submissions or CVB updates) in the portal in the past two weeks are featured in the Recent Activity tab of the Account Details page. This page also features items in the Awaiting Update from Submitter status regardless of the Last Action Date.

Submissions Not Yet Received

This tab lists 2049 items still in draft status that have not been submitted to the CVB.

CVB Historical Search

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

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Submission History

[Recent Activity \(2 Weeks\)](#)
[Submissions Not Yet Received](#)
[CVB Search](#)
[NVSL Search](#)

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

Form*

Submission Type

Establishment Code

Product Code

Serial Number

Mail Log #

Submission Status

APHIS 2005 Application #

Submission Date From: To:

Last Action Date From: To:

🔍 Search
📄 Export to Excel

Show entries

Search:

Est	Products	SO #	Type	Brief Description	Status	ML #	Submitter	Reviewer	Submission Date	Last Action Date	
301	101520	12	Special Outline	test	Submitted	179636	Amber Peterson	Jeanette Watson	01/27/2021	01/27/2021	Info

- Users may enter any combination of search parameters, and the system returns submissions meeting all criteria.
- Clicking on the Search button returns an online listing of applicable submissions, with a hyperlink to the full submission record. Only a single Form type may be queried at one time when using the Search button.
- Clicking on the Export to Excel button returns listings in a downloadable spreadsheet format that then can be further manipulated to meet the user's needs. Use this option if you wish to return listings for more than one Form type.