

APHIS Form 2005 - Application for United States Veterinary Biological Product Permit
RESEARCH AND EVALUATION

Version History

Action	Date	By	Changes Made
Version 1	09/11/2019	Amber Peterson	New
Version 2	03/22/2021	Amber Peterson	<ol style="list-style-type: none"> Page 9 - Users can generate a PDF of their submission data Page 12 - The email address used for communications to NCAH Portal users for the APHIS 2005 submissions was changed from DoNotReplyLSRTIS@usda.gov to CVBpermits@usda.gov Page 12 - Language was added to the email regarding the need to save the permit from the NCAH Portal as it is only available there for 60 days past completion

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TABLE OF CONTENTS

This guide is intended for use by those individuals using the NCAH Portal for submission of APHIS Form 2005 for issuance of a United States Veterinary Biological Product Permit for RESEARCH & EVALUATION. Submit an application for each product. Attach supporting materials.

Section 1 - [Access Information](#)

Section 2 - [Entering Information to be Submitted](#)

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If you are looking for instructions on how to submit an APHIS Form 2005 for issuance of a United States Veterinary Biological Product Permit for the purpose of Transit Shipment or General Sales & Distribution, refer to the following user guides:

- [User Guide 28](#) - APHIS Form 2005 - Application for United States Veterinary Biological Product Permit: Transit Shipment Only
- [User Guide 29](#) - APHIS Form 2005 - Application for United States Veterinary Biological Product Permit: Sales & Distribution



Some fields may look differently than the screenshots in this user guide depending on the browser you are using. Basic functionality should not be affected.

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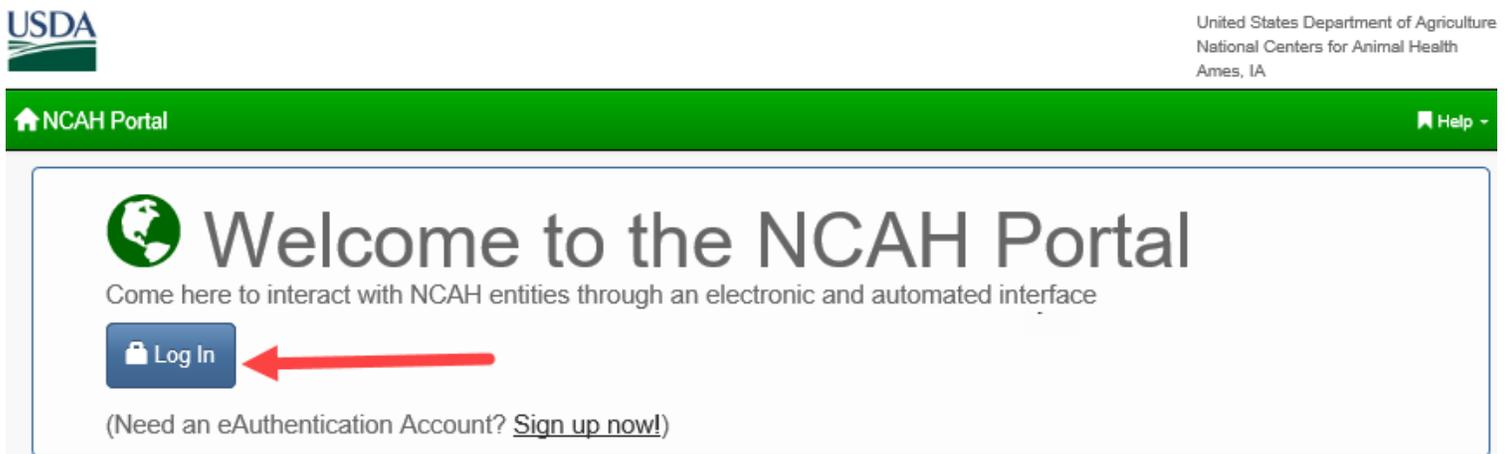
ACCESS INFORMATION

The NCAH Portal can be accessed using this URL: <https://ncahappspub.aphis.usda.gov/NCAHPortal/public/>

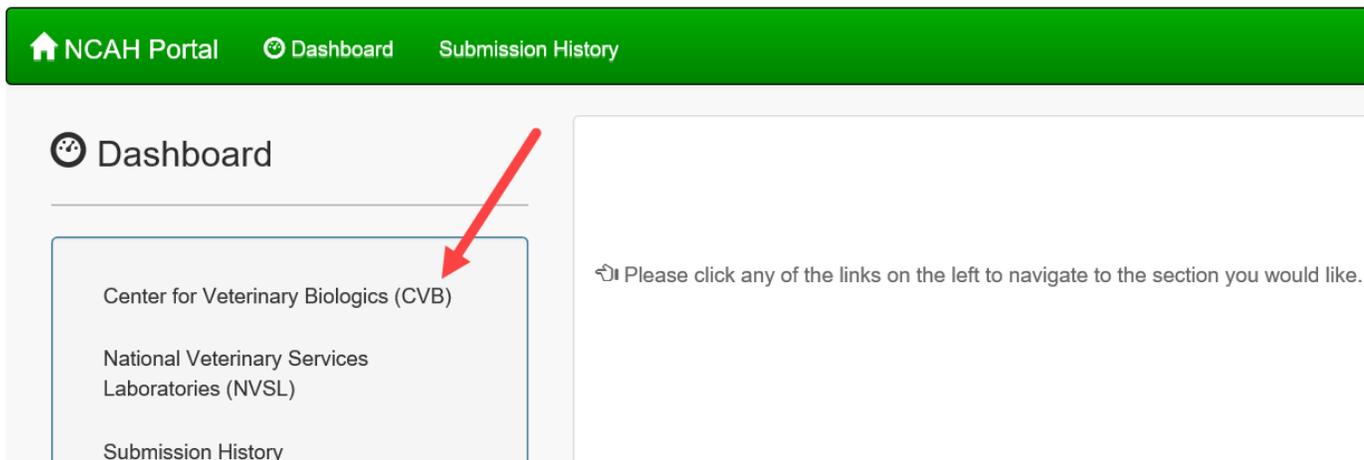
There is also a link available on the [NCAH Portal Guidance page](#) of the CVB website.

 **Users are required to have an eAuthentication account for access.** There is a link on the home page if you need an eAuthentication account. For more information on eAuthentication accounts go to <https://www.eauth.usda.gov/home>.

Click on the Log In button to enter the NCAH Portal.



Click on *Center for Veterinary Biologics (CVB)* in the Dashboard.



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ENTERING INFORMATION TO BE SUBMITTED

There are two options in the **Biological Product Permits (APHIS 2005)** section.

- **Submission Form** - used to enter information to submit a new application
- **View Draft Submissions (Biological Product Permits) to CVB** - used to view submissions for which information has been entered BUT have not yet been submitted to the CVB. You may choose to submit a draft submission from here.

Click on **Submission Form** to begin a new application.

Dashboard

Center for Veterinary
Biologics (CVB)

National Veterinary
Services
Laboratories (NVSL)

Submission History

Account Details

CVB - Center for Veterinary Biologics

Biological Product Permits (APHIS 2005)

- [Submission Form](#)
- [View Draft Submissions \(Biological Product Permits\) to CVB](#)

Note: Veterinary biologic products specifically include final form vaccines, bacterins, antitoxins, immunomodulators and diagnostic kits for the prevention, diagnosis, management or treatment of animal diseases. The CVB does not issue permits for human products, animal tissues, antisera, cell lines, reagents, proficiency panels, bacterial isolates, virus isolates, or other materials that do not fit the veterinary biologic description above. For these materials please visit [Animal Products](#) or [Organisms and Vectors](#) for appropriate permit information.

Complete the fields on the screen. Red asterisks (*) next to a field indicate that it is required to be completed. Helpful information may be shown under a field in to aid you in completion.

Create - VETERINARY BIOLOGICAL PRODUCT PERMITS E-SUBMISSION FORM

[CVB Home](#) / Submission Form

Submission Information

Submission Type* Research & Evaluation Transit Shipment Only

Previous Permit
Number(s)
(If Applicable)

Note: Separate by semicolons if more than one.

**Make sure that Research & Evaluation is marked.
Click in the circle to select if it isn't.**

**If you have received a permit for the
same product previously, enter the
permit number here.**

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ENTERING INFORMATION TO BE SUBMITTED (continued)

Applicant Information

Applicant Name First* Last*

Position Title

Organization*

Address* Street*

Country* United States State* City* Postal Code*

Producer Information

Producer Organization*

Point Of Contact

Address* Street*

Producer City* Producer Country*

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ENTERING INFORMATION TO BE SUBMITTED (continued)

Product Shipment Information

Product Name*

Product Type*

Diagnostic Test Kit Vaccine Other **Click in circle to select an option.**

Product Description*

Note: Enclose brief description of product; methods of propagation including composition of medium; species of animals or cell cultures used; method of inactivation or attenuation. Maximum number of characters for this field is 1000.

In Vitro/In Vivo?*

In Vitro Only In Vivo Only Both In Vitro and In Vivo

Product Use or Evaluation*

Note: Recommendation for use; and proposed plan of evaluation pursuant to 9 CFR 104.4(a). Attach additional documents to this submission, if needed. Maximum number of characters for this field is 1000.

Estimated Arrival Date*

Quantity*

Estimated Quantity*

Type*

Click on down arrow to see more options, click on the one you want to select.

Port of Entry*

This is the only option for Port of Entry.

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ENTERING INFORMATION TO BE SUBMITTED (continued)

Institution Performing Research

Same As Applicant?

Click in this checkbox if the information is the same as what you entered above for the Applicant. When checked, the fields directly below will not be shown.

Name

First*

Last*

Organization*

Address*

Street*

Country*

United States

State*

City*

Postal Code*

Misc

Remarks

Enter any additional information, clarification or comments in this field.

Clicking in this checkbox indicates your agreement with the statement.

In accordance with the Act of Congress approved March 4, 1913 (37 Stat. 832-833; 21 U.S.C. 151-158), application is hereby made for a permit to import the herein named biological product for the purpose specified as the Submission Type. If a permit is issued under this application, the recipient expressly agrees to conform strictly to all rules, regulations and orders of the Department governing the importation of veterinary biological products and that the product will not be labeled or advertised so as to mislead or deceive in any particular.

Attachments may be added after clicking on the Save button.

If you need to attach documents, it will be done in the next step.

Click on the Save button when you are done. This saves a DRAFT of the submission, but does not submit it.

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ENTERING INFORMATION TO BE SUBMITTED (continued)

After clicking on the SAVE button, you will see this message at the top of the screen.

i APHIS 2005 Submission has been saved. Until the point the submission has been received this information may be altered by you. Once this submission is received by CVB, this information will no longer be editable. **x**

You will also see a preview of the DRAFT submission you just created.

VETERINARY BIOLOGICAL PRODUCT PERMITS E-SUBMISSION Information

[CVB Home](#) / [Submission Form \(APHIS 2005\)](#) / [Submission Information \(APHIS 2005\)](#)

Submission Info

Status	Submission Entered
Submission Type	Research & Evaluation
Previous Permit Number(s)	12359

Applicant Information

Applicant Name	Red Chocolate
Position Title	
Organization	M&M
Address	789 Sweet St Hershey, PA 45678 United States

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ENTERING INFORMATION TO BE SUBMITTED (continued)

At the bottom of the preview you will see the Submission History for this DRAFT submission. You can save a PDF of your submission data at this point by clicking on the "Save as PDF" button.

"Submission Entered" means that data has been entered for the submission and it has been saved, but it has not been submitted to the CVB yet.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-16-2021 04:41 PM CDT	apeterson	

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

At this point, you have a number of options that you can use depending on how you want to proceed.

Edit - Use this button to go back and make changes to the information entered.

Add Attachments - Use this button to add documents to support your application. Example: Summary Information Format (SIF)

Submit To CVB - Use this button to submit the application to the CVB.

Delete Submission - Use this button to delete the submission completely.

Save as PDF - User this button to save a PDF copy of the submission data.

Return to Dashboard - Use this button to go back to the CVB Dashboard.

 If changes are made to a submission, that action is captured in the Submission History.

Submission History

Example of what you see after editing a submission

Action	Timestamp	User	Info
Submission Entered	Mar-16-2021 04:41 PM CDT	apeterson	
Submission Updated	Mar-16-2021 04:46 PM CDT	apeterson	

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

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ATTACHING DOCUMENTS TO THE SUBMISSION

Click on the **Add Attachments** button at the bottom of the draft.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-16-2021 04:41 PM CDT	apeterson	

Click on the **Add Document** button. Fields for attaching a document will become visible.

Click on the **Browse...** button and select the file you want to upload.

New Attachments

Attachment	REMOVE
<p>File</p> <input type="text"/> <input type="button" value="Browse ..."/>	
Comments	

Click on the **checkbox** and then the **Save to Submission** button to complete the attachment process.

New Attachments

Attachment	REMOVE
<p>File</p> <input type="text" value="PDF for testing purposes.pdf"/> <input type="button" value="Remove"/> <input type="button" value="Browse ..."/>	
Comments	
<p>Note: May not have multiple attachments with the same name.</p>	

Use this button if you want to attach another document to this submission.

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

Click the Save to Submission button when you're done.

You will see this flag at the top of the screen and be returned to the DRAFT submission preview.

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SUBMITTING TO THE CVB

Click on the *Submit to CVB* button at the bottom of the draft.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-16-2021 04:41 PM CDT	apeterson	

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

You will see this message at the top of the screen, as well as a view of the data that was submitted.

ⓘ APHIS 2005 Submission has been Submitted To CVB. The information on this Submission is no longer available for editing. ✕

At the bottom of the screen you will see the Submission History now has a line with an action of "Submitted to CVB" with the timestamp and user ID of the submitter. You can still Save a PDF copy of the submitted data at this point.

Submission History

Action	Timestamp	User	Info
Submission Entered	Mar-16-2021 04:41 PM CDT	apeterson	
Submission Updated	Mar-16-2021 04:46 PM CDT	apeterson	
Submitted To CVB	Mar-16-2021 04:53 PM CDT	apeterson	

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

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WHAT TO EXPECT AFTER SUBMISSION

When the APHIS 2005 is received by the CVB, it is processed and if approved, a permit is returned to the applicant. Notification of status changes for the submission will be shown on a NCAH Portal Update email that is sent to the submitter at 3:30pm CST on the day of the status change.

Below is an example email. You will see the application number, product name and status of the submission. **Click on the link in the blue bar at the bottom of the email to see the complete submission in the NCAH Portal and access the official permit.**

NCAH Portal Daily CVB Submission Update for APHIS 2005 - APHIS Form 2005 (Research & Evaluation) Application # [REDACTED]

CP CVB Permits <CVBpermits@usda.gov>
To [REDACTED]
Cc ○ APHIS-CVB Program Information Management and Security

This email is sent from an account that is not monitored and is used for sending email messages only. If you have any questions, please contact us at CVB.PIMS@usda.gov

 **NCAH Portal Updates!**

The following APHIS 2005 Submissions have been updated by CVB in the NCAH Portal today:

Application #	Type	Product Name	Status
179812	APHIS Form 2005 (Research & Evaluation)	Product X	Approved

This permit will only be available in the NCAH Portal for 60 days from the date of completion. You must save the permit to a location outside of the NCAH Portal prior to that time.

[Click HERE to download the PERMIT and view other information about this submission.](#)

This message may contain Confidential Business Information, which includes trade secrets, commercial and financial information, including marketing information. Release of Confidential Business Information concerning the Veterinary Biologics Program is prohibited under the Trade Secrets Act, 18 U.S.C. 1905.

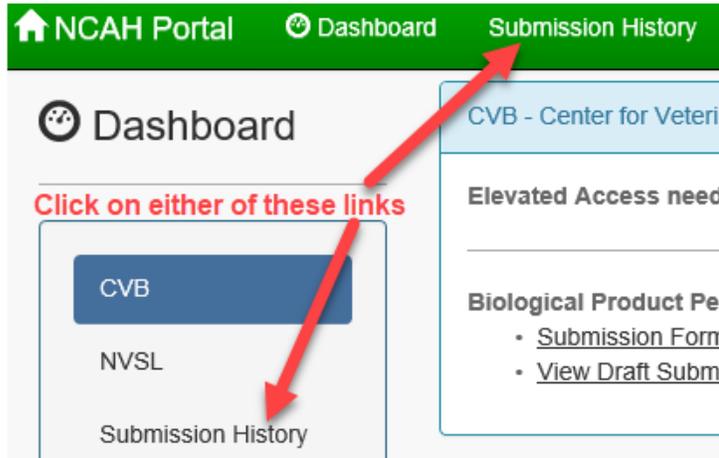


NOTE: *The records will only be available in the NCAH Portal for 60 days after completion. You must SAVE your permit so that you have it after 60 days.*

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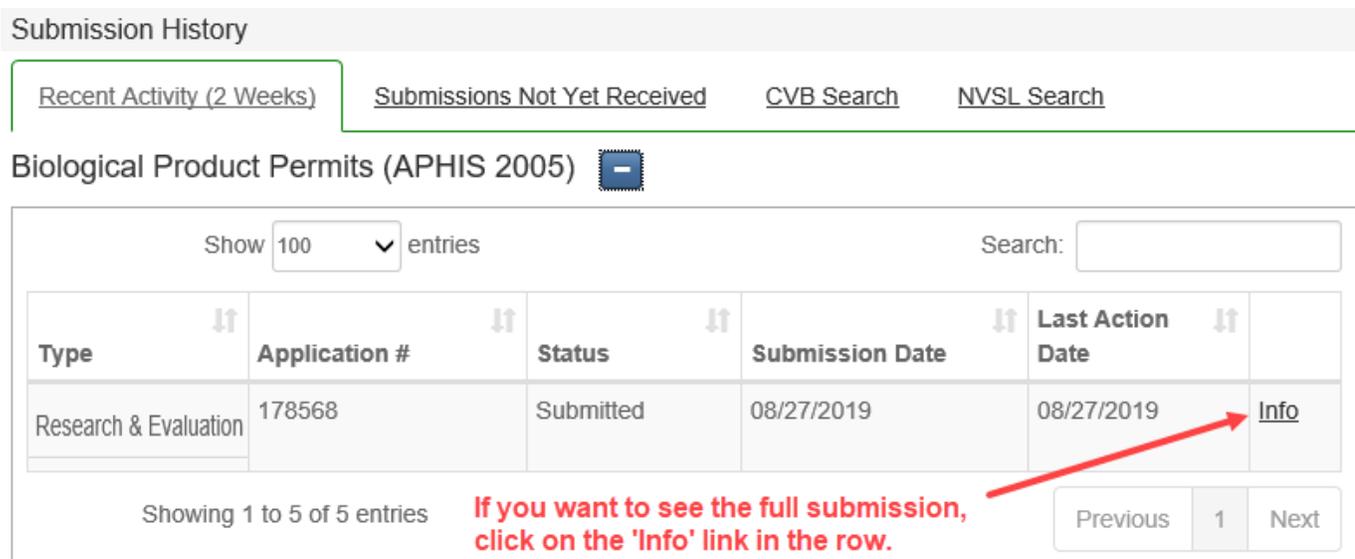
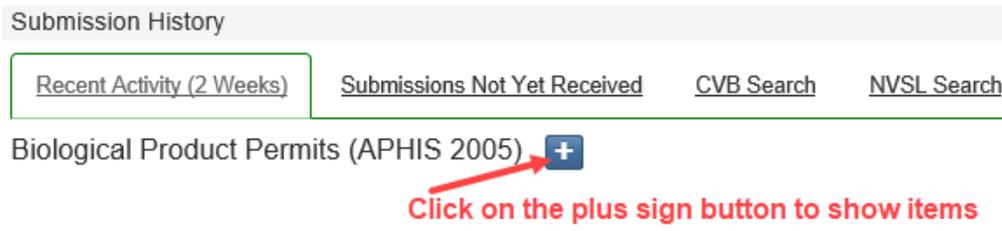
CHECKING YOUR SUBMISSION STATUS

After you've submitted you can check the status of any of your submissions in the 'Submission History' section of the CVB Dashboard.



Pay attention to the tabs at the top of the Submission History screen.

- Recent Activity (2 weeks)** - shows items that have had actions on them by you or the CVB in the last 2 weeks
- Submissions Not Yet Received** - shows items that you have not yet submitted to the CVB
- CVB Search** - use this to search for all items by type, select "Biologics Permits (APHIS 2005)" in the 'Form' field
- NVSL Search** - Not Applicable to Biologics Product Permits



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YOUR OFFICIAL PERMIT

An electronic copy of the permit will be returned to the submitter via the NCAH Portal.

To access the electronic copy of the permit, follow these steps:

1. Access the item within the NCAH Portal using either Submission History or the link in the email
2. Within the record, scroll down to the Miscellaneous (Misc) section
3. Find the "Response Files from CVB" - an electronic copy of the permit will be a file attached there

Misc

Comments

Submitted Files **File** ▼ **Comments**

[PDF for testing purposes.pdf](#)

Response Files from CVB **File** ▼ **Comments**

[permitfordemo.pdf](#) ← Click here to open your permit and view, save and/or print it.

Submission History

Action	Timestamp	User	Info
Submission Entered	Aug-23-2019 03:50 PM CDT	apeterson	
Submission Updated	Aug-26-2019 11:05 AM CDT	apeterson	Attachments added
Submitted To CVB	Aug-26-2019 11:32 AM CDT	apeterson	
Submission Status Updated	Aug-26-2019 03:57 PM CDT		Completed

Return to Dashboard



NOTE: The records will only be available in the NCAH Portal for 60 days after completion. You must **SAVE** your permit so that you have it after 60 days.