Version History

Action	Date	Ву	Changes Made
Version 1	09/11/2019	Amber Peterson	New
Version 2	03/22/2021	Amber Peterson	 Page 6 - A checkbox has been added to the Transit Information section for "Product is used in animals shipped from the US?". If checked then the Street and Destination City fields are not required. Destination Country is still required. Page 8 - Users can generate a PDF of their submission data Page 11 - 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 11 - 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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APHIS Form 2005 - Application for United States Veterinary Biological Product Permit TRANSIT SHIPMENT ONLY

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 TRANSIT SHIPMENT ONLY. Submit an application for each product. Attach supporting materials.

- Section 1 Access Information
- Section 2 Entering Information to be Submitted
- Section 3 Attaching Documents to the Submission
- Section 4 Submitting to the CVB
- Section 5 What to Expect After Submission
- Section 6 Checking Your Submission Status
- **Section 7 Your Official Permit**



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 Research & Evaluation or General Sales & Distribution, refer to the following user guides:

• User Guide 27 - APHIS Form 2005 - Application for United States Veterinary Biological Product Permit: Research and Evaluation

• 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.

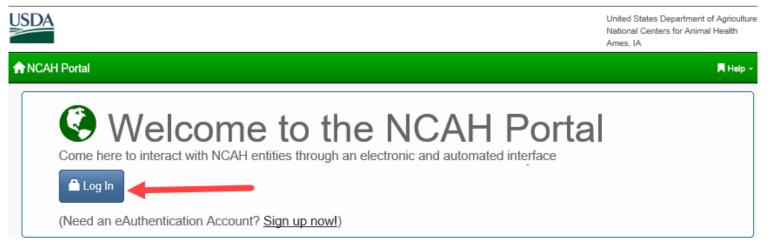
ACCESS INFORMATION

The NCAH Portal can be accessed using this URL: <u>https://ncahappspub.aphis.usda.gov/NCAHPortal/public/</u> There is also a link available on the NCAH Portal Guidance page of the CVB website.

<u>^</u>

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 CVB in the Dashboard.

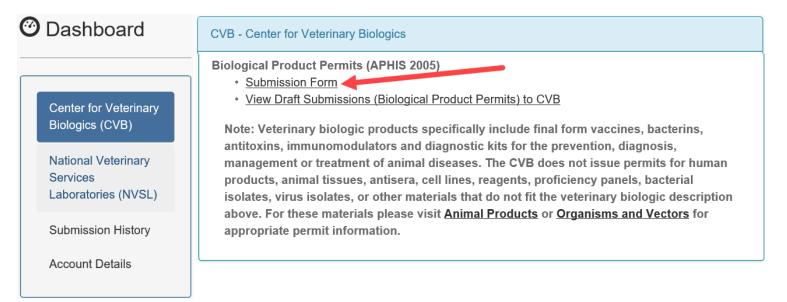
♠ NCAH Portal	𝕲 Dashboard	Submission Hist	огу
Center for Veter National Veterin Laboratories (N Submission His	erinary Biologics (C\ nary Services IVSL)	/B)	ণ্টা Please click any of the links on the left to navigate to the section you would like.

ENTERING INFORMATION TO BE SUBMITTED

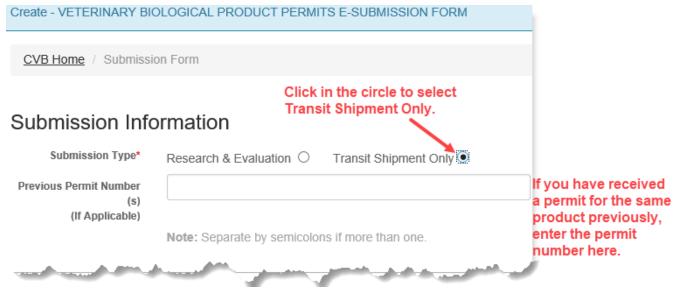
There are two options in the Biological Product Permits (APHIS 2005) section.

- 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.



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 gray text to aid you in completion.



ENTERING INFORMATION TO BE SUBMITTED (continued)

Applicant Name	First*		Last*		
Position Title					
Organization*					
Address*	Street*				
	<u>Country*</u> United States	State*		<u>City*</u>	Postal Code*
	United States		~		
Producer Inform			~		
Producer Inform			~		
Producer Inform Producer Organization* Point Of Contact			~		
Producer Organization*					

ENTERING INFORMATION TO BE SUBMITTED (continued)

Product Shipment Information

Product Nan	ne*					
Estimated Arrival Da	te*					
Quantity*		ated Quantity*		Type*		Click on the down arrow
				ML	~	to see more options then
Port of Ent	rv* Any	/ US Port	~			click on the one you want to select.
	-	s the only option for	r Port of E	ntry		
Transit Info						
	Carrier(s)					
Dates i	n Transit	Arrival			Departure	
Product is used ir	n animals				If this b	ox is checked then the Street
shipped from	n the US?					stination City fields will no
Destination	Address*	Street*			longer l	be required.
					D 4' 4'	
		Destination City*			Destinatio	n Country*
						\checkmark
Misc						
Remarks		any additional infor	mation, c	larification or	commer	its
	in this	neid.				
Clicking in						
this 📥 🗌	In accord	ance with the Act of C	ongress a	pproved March	4, 1913 (3	7 Stat. 832-833; 21 U.S.C. 151-
checkbox indicates		-	-	-		amed biological product for the
your		specified as the Subm expressly agrees to c		-		der this application, the
agreement	-			-	_	ducts and that the product will
with the		be labeled or advertised so as to mislead or deceive in any particul				ticular.
statement.	Attachme	ents may be added aft	er clickina	on the Save bu	itton	If you need to attach
			er enering			documents, it
	🗸 🗸 Save	Click on the Sav	ve button	when		will be done in
		you are done. T	his saves	a		the next step.
		DRAFT of the si				
		does not submi		-	Publica	ation Date: 03/22/2021 Page 6 of 13

ENTERING INFORMATION TO BE SUBMITTED (continued)

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

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.

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	Transit Shipment Only						
Applicant Inform	ation						
Applicant Name	Testing Demo						
Position Title							
Organization	Demos R Us						
Address	123 Street Ames, IA 55555 United States						
Producer Information	ation						
Producer	Products 4 Testing						

ENTERING INFORMATION TO BE SUBMITTED (continued)

At the bottom of the preview you will see the Submission History for this DRAFT submission. "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	User	Info				
Submission Entered	Mar-16-2021 04:41 PM CDT	apeterson				
Fedit Add Attachments	Submit To CVB	Save as PDF OREturn to Dasht	board			

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.

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.

ction	Timestamp	Timestamp		Info
ubmission Entered	Mar-16-2021 04:41 PM CDT	Mar-16-2021 04:41 PM CDT		
ubmission Updated	Mar-16-2021 04:46 PM CDT	Mar-16-2021 04:46 PM CDT		
Edit 🖍 Add Attachments	Submit To CVB	ssion Save as	s PDF	@ Return

ATTACHING DOCUMENTS TO THE SUBMISSION

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

Action	Timestamp	Timestamp			Info
Submission Entered	Mar-16-2021	Mar-16-2021 04:41 PM CDT			
🖍 Edit 📝 Add Attachments	Submit To CVB	Delete Submission	Save as PD	F Ø Return to	Dashboard

Click on the Add Document button.

+ Add Document

Fields for attaching a document will become visible.

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



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

New Attachments	Attachment REMOVE						
	File						
	PDF for testing purposes.pdf 🛱 Remove 🖆 Browse						
	Comments						
	Note: May not have multiple attachments with the same name.						
You must click in the checkbox to	+ Add Document						
move on.	agree that I've looked over this information and everything entered is true to my knowledge.						
	✓ Save to Submission Ø Cancel						
	Click the Save to Submission button when you're done.						
You will see this fla	ag at the top of the screen and be returned to the DRAFT submission preview.						
Ocuments hat the second sec	ve been successfully added 🛛 🗙						

SUBMITTING TO THE CVB

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

Submission History	1				
Action	Timestamp			User	Info
Submission Entered	Mar-16-2021 04:4	1 PM CDT		apeterson	
🖍 Edit 🖍 Add Attachments	L Submit To CVB	Delete Submission	Save as PDF	Return to Das	hboard
APHIS 2005 Submission has bee for editing.	en Submitted To CVB. T	he information on this	Submission is no	longer available 🛛 🗙	

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.

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 OR Return to Dashboard						



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.

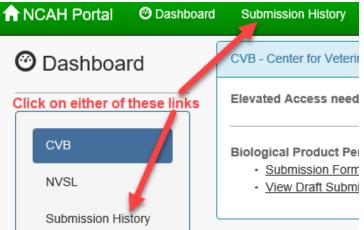
Below is an example email. You will see the application number, product name and status of the submission. Click on the link in the blue bar at the bottom of the email to see the complete submission in the NCAH Portal and access the official permit.

ICAH Portal Daily CVB Submission Update for APHIS 2005 - APHIS Form 2005 () Application #	
CVB Permits <cvbpermits@usda.gov> To Cc OAPHIS-CVB Program Information Management and Security</cvbpermits@usda.gov>	
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	
USDA 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 (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.	
his 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 Secr Act, 18 U.S.C. 1905.	ets

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.

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

Submission History									
Recent Activity (2 Weeks)	Submissions Not Yet Received	CVB Search	NVSL Search						
Biological Product Permits (APHIS 2005)									
Click on the plus sign button to show items									

Submission History									
Recent Activity (2 V	leeks) Submissions I	NVSL	Search						
Biological Product Permits (APHIS 2005)									
Show 100 v entries Search:									
.↓↑ Type	L1 Application #	L1 Status	Submission Date	11	Last Action Date	11			
Transit Shipment Only	178568	Submitted	08/27/2019		08/27/2019	-	<u>Info</u>		
Showing 1 to 5 of 5 entries If you want to see the full submission , click on the 'Info' link in the row.			n, 🦯	Previous	1	Next			



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** File Comments from CVB permitfordemo.pdf Click here to open your permit and view, save and/or print it. Submission History Action Timestamp User Info apeterson Submission Entered Aug-23-2019 03:50 PM CDT 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.