# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

### **Version History**

Action	Date	Ву	Changes Made
Version 1	09/11/2019	Amber Peterson	New
Version 2	03/22/2021	7	<ol> <li>Page 5 - In the Submission Information section, a Quarantine Site field was added</li> <li>Page 9 - Users can generate a PDF of their submission data</li> </ol>

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# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **TABLE OF CONTENTS**

This guide is intended for use only by **active permittees** using the NCAH Portal for submission of APHIS Form 2005 for issuance of a United States Veterinary Biological Product Permit for the purpose of GENERAL SALES & DISTRIBUTION. 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 Transit Shipment, refer to the following user guides:

- <u>User Guide 27</u> APHIS Form 2005 Application for United States Veterinary Biological Product Permit: Research and Evaluation
- <u>User Guide 28</u> APHIS Form 2005 Application for United States Veterinary Biological Product Permit: Transit Shipment Only



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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# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **ACCESS INFORMATION**

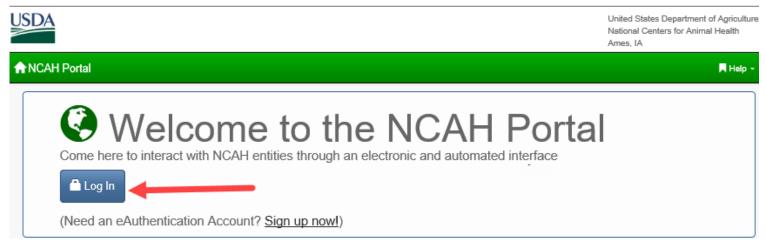
Submission of APHIS Form 2005 for the purpose of Sales and Distribution can be done via the NCAH Portal **only** if the following conditions are met for the submitter.

- 1. The submitter has an eAuthentication account with a verified identity. For more information on eAuthentication accounts go to <a href="https://www.eauth.usda.gov/home">https://www.eauth.usda.gov/home</a>. There is a link on the NCAH Portal home page if you need an eAuthentication account.
- 2. The submitter is an active employee and liaison or alternate liaison at the permittee Quarantine site.
- 3. The permittee is enabled for use of the NCAH Portal.
- 4. The submitter's eAuthentication username has been entered into CVB's internal processing service (LSRTIS). This is done by submitting a APHIS Form 2007 for the submitter (NCAH Portal User Guide #4).

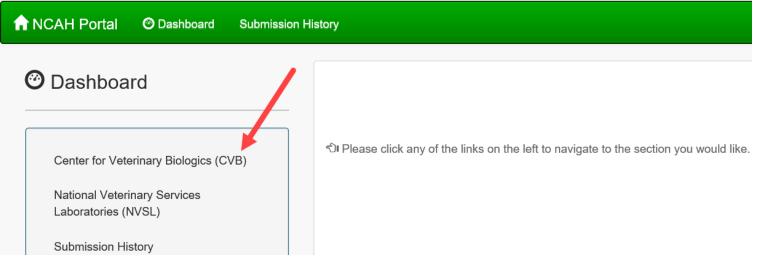
The NCAH Portal can be accessed using this URL: https://ncahappspub.aphis.usda.gov/NCAHPortal/public/

There is also a link available on the NCAH Portal Guidance page of the CVB website.

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



#### Click on CVB in the Dashboard.



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# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **ENTERING INFORMATION TO BE SUBMITTED**

Find the Biological Product Permits (APHIS 2005) section and click on Submission Form.



### CVB - Center for Veterinary Biologics

### Biologics Sample Submission (APHIS 2020)

- Generate Packing Slip
- · Processed Samples

#### CVB

NVSL

Submission History

Application Messages

Account Details

#### Veterinary Biologics Production and Test Report (APHIS 2008)

- · Submission Form
- View Draft Submissions (APHIS Form 2008) to CVB

#### Qualifications of Veterinary Biologics Personnel (APHIS 2007)

- Submission Form
- · View Draft Submissions (APHIS Form 2007) to 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

## 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

#### **Biologics Export Certification**

- Submission Form
- · View Draft Submissions (Biologics Export Certification) to CVB

#### **Biological Product Permits (APHIS 2005)**

- · Submission Form ·
- View Draft Submissions (Biological Product Permits) to CVB



View Draft Submissions (Biological Product Permits) to CVB option is 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.

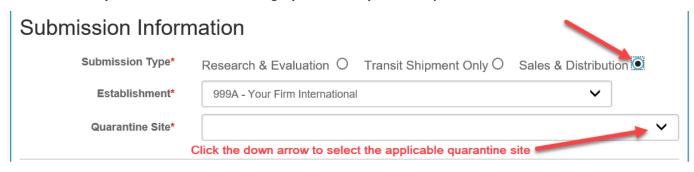
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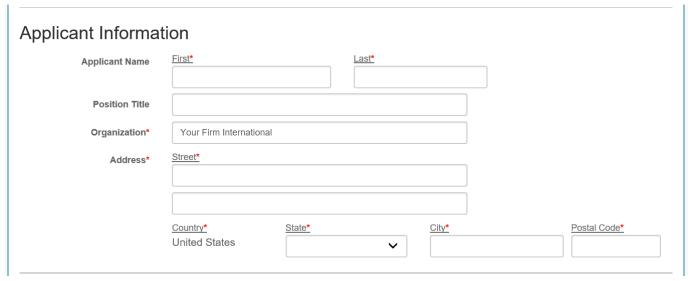
# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **ENTERING INFORMATION TO BE SUBMITTED (continued)**

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.



In the **Establishment** and **Quarantine Site** fields, data associated with your Establishment will be autopopulated from LSRTIS. If you are an approved active user with the appropriate roles at multiple establishments and/or sites, use the down arrows in the fields to open a picklist and then select appropriately from there.



Producer Informat	tion	
Producer Organization*		
Point Of Contact		
Address*	Street*	
	Producer City*  Producer Country*	



# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

### **ENTERING INFORMATION TO BE SUBMITTED (continued)**

Product Name*	ipment Infor					
Sales & Dis	stribution Inf	ormation		Click on the down		
Direct Submission To*	~			show options, click to select the person to whom you want your submission to go to.		
Storage Address Same As Applicant?	<b>4</b>					
Address*	Street*			storage ( address applican	his box if the [Quarantine) is the same as the t so you don't hav the information	
	Country* United States	State*	City*	twice.	Postal Code*	
	Corporation O	Partnership O	Individual C	)		
Organization Type*						

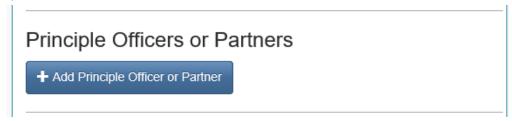
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# APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION

#### **ENTERING INFORMATION TO BE SUBMITTED (continued)**

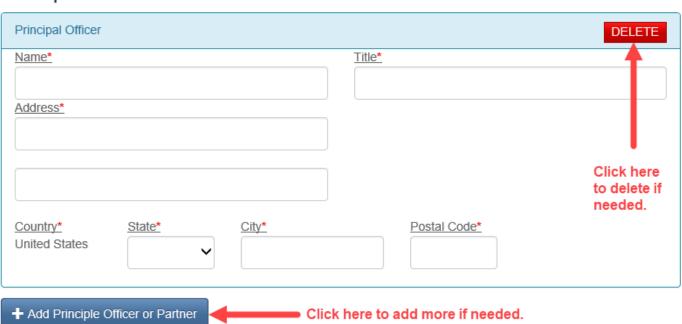
When you click on the *Add Principle Officer or Partner* button, a new window will open with a field asking how many you would like to add. *You must have at least one.* 



**Enter the number you want to add and click on the** *Create* **button.** Fields will then be shown on the screen to enter information for Principle Officer(s) or Partners.



### Principle Officers or Partners





# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **ENTERING INFORMATION TO BE SUBMITTED (continued)**



Remarks

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

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.

✓ Save

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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# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **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	Sales & Distribution					
Establishment	999A - Your Firm International					
Direct Submission To	Ludemann, Larry					
Applicant Information						
Applicant Name	John Doe					

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# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **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	Timestamp	User	Info		
Submission Entered	Mar-16-2021 04:41 PM CDT		apeterson		
✓ Edit ✓ Add Attachments 🚨 St	ubmit To CVB	Save as PDI	Return to Da	shboard	

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.

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

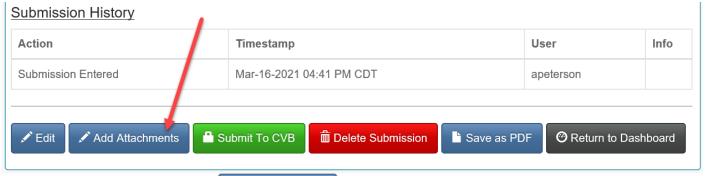


# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### ATTACHING DOCUMENTS TO THE SUBMISSION

\*If Articles of Incorporation are required, this is how you would attach them.

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



Click on the Add Document button.

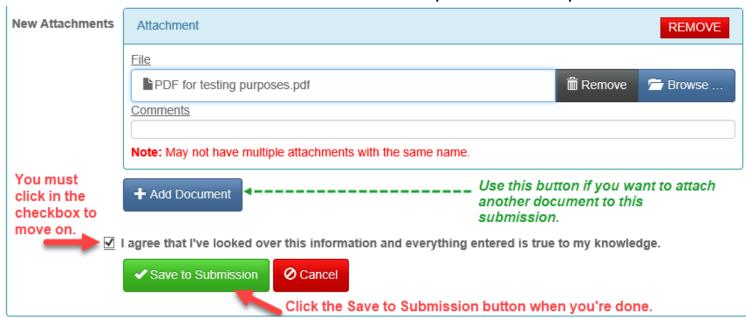
+ Add Document

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.



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

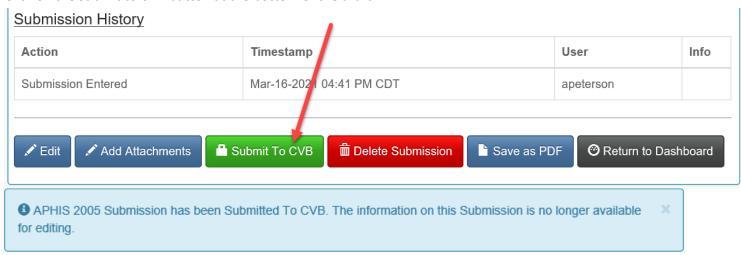
Documents have been successfully added
 X



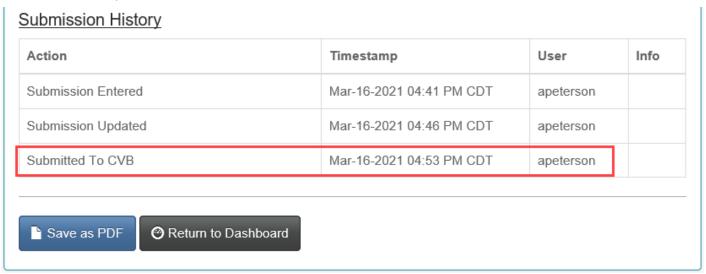
# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **SUBMITTING TO THE CVB**

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



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.





# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### WHAT TO EXPECT AFTER SUBMISSION

When the APHIS 2005 is received by the CVB, it is processed and if approved, a permit is returned in the NCAH Portal. Notification of status changes for the submission will be shown on a NCAH Portal Update email that is sent 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 999A



APHIS-NCAH Application Support

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 <a href="mailto:CVB.PIMS@usda.gov">CVB.PIMS@usda.gov</a>



### **NCAH Portal Updates!**

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

#### Submissions to CVB-PEL:

Mail Log #	Туре	Product(s)	Description	Status	CVB Response
179833	APHIS Form 2005 (Sales & Dist Permit Application)			Completed	

Click Here to view detailed information about these and other Submissions



**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.

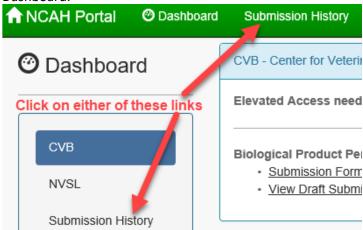
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# APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION

#### **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.

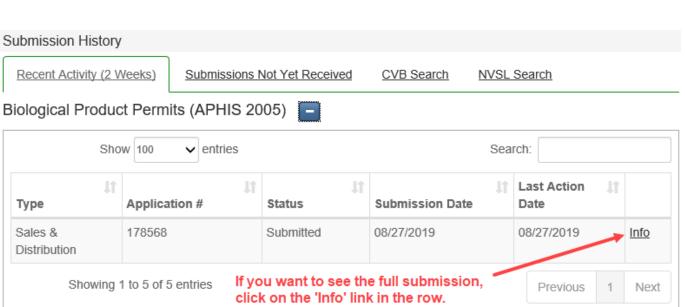


Pay attention to the tabs at the top of the Submission History screen.

**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







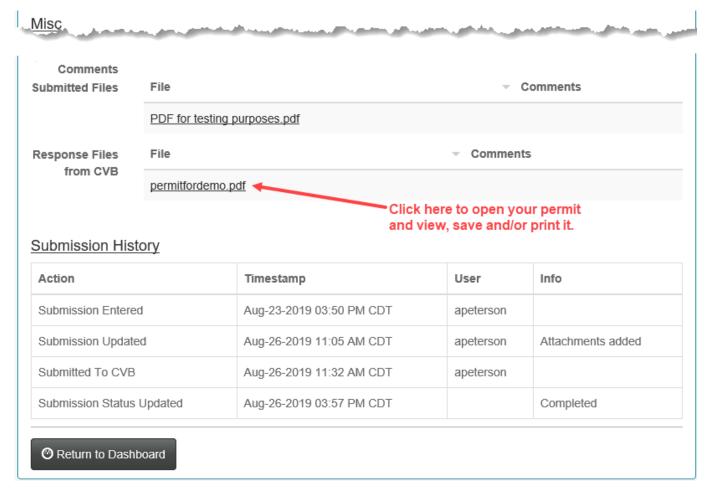
# **APHIS Form 2005 - Application for United States Veterinary Biological Product Permit SALES & DISTRIBUTION**

#### **YOUR OFFICIAL PERMIT**

A hard copy permit will be sent to the submitter. An electronic copy of the permit will also be returned in 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





**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.