

NCAH PORTAL CVB PRINTABLE USER GUIDE

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NCAH PORTAL CVB QUICK REFERENCE GUIDE

Logging In

On the Portal Home Page you can Log In and find features that will help you navigate the application.



United States Department of Agriculture
National Centers for Animal Health
Ames, IA

Home icon NCAH Portal Help icon



Welcome to the NCAH Portal

Come here to interact with NCAH entities through an electronic and automated interface



Click here to Log In if you already have an eAuth account

Click here if you need an eAuth account

(Need an eAuthentication Account? [Sign up now!](#))

Important Messages

- **Oct 01, 2014:** The NCAH Portal is now ready for use. Feel free to look around and give feedback.

About

Use of this application will allow external users to submit forms and samples through a portal atmosphere.

Included NCAH Entities

- CVB
- [Go here](#) for Contact Information

Warnings

Some portions of this application may require elevated security levels in e-Authentication - Level 2.

- [USDA.gov](#)
- [FOIA](#)
- [USA.gov](#)

- [Contact Us](#)
- [FAQs](#)
- [User Guide](#)

Find resources to help you use the Portal here

[Back to top](#)

Next: Logging In

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Logging In

There are two ways to log in; with a User ID/Password combination or with a Lincpass.

User ID + Password

Enter eAuthentication User ID & Password

Select "Login"

LincPass

Select the picture hyperlink under "LincPass (PIV)"

An on screen dialog box will appear asking for confirmation of your certificate. Confirm the Certificate and select "OK"

Enter LincPass Pin.

Select "OK"

No matter which way you log in, you will be taken to the NCAH Portal Dashboard.

Portal Roles

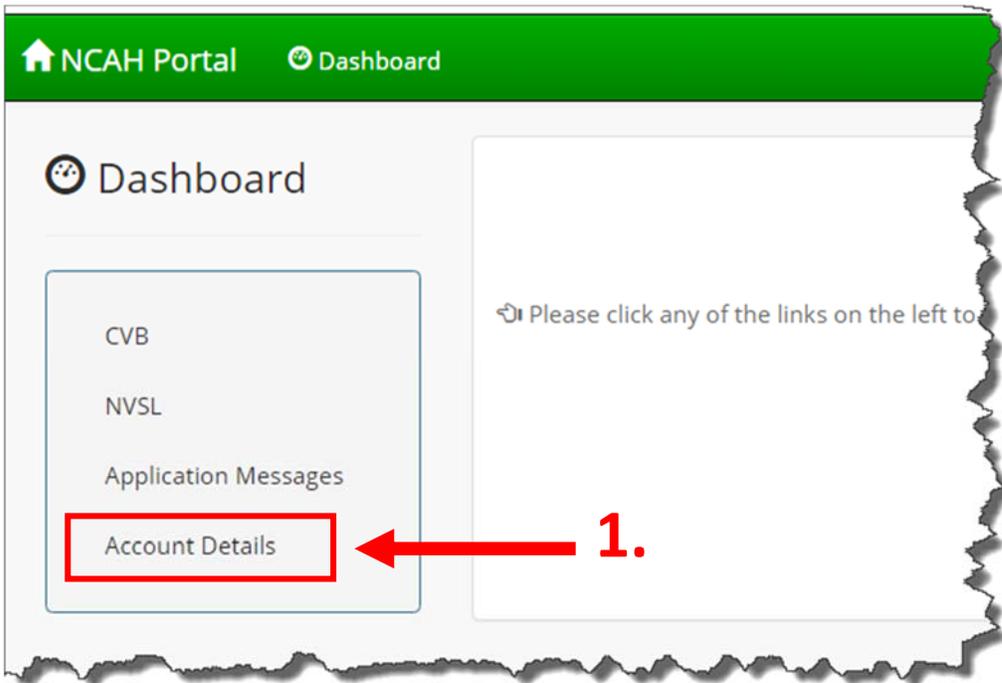
NCAH PORTAL CVB QUICK REFERENCE GUIDE

LSRTIS Designated Role	Description	2020	2008	2007
Liaison	Point of contact for all official correspondence submitted to & received from the CVB. Firm designated role that is confirmed by the CVB	No entry allowed No submission to CVB Can View All	Entry allowed Can Edit All Can Submit to CVB Can View All	Entry allowed Can Edit All Can Submit to CVB Can View all
Alternate Liaison	Secondary point of contact for all official correspondence. Firm designated role that is confirmed by the CVB	No entry allowed No submission to CVB Can View All	Entry allowed Can Edit All Can submit to CVB Can View All	Entry allowed Can Edit All Can submit to CVB Can View all
Serial Release	Point of contact for Serial Release, preparation and submission of biological production and test reports. Firm Designated Role	No entry allowed No submission to CVB	Entry allowed Can Edit All Can submit to CVB Can View All	Can Enter own Can Edit own Can View own No submission to CVB
Sampler	Firm designated role for the selection and submission of government retention samples & master seeds and cells. Role is confirmed by the CVB	Entry allowed Can Print packing slips and Submit to CVB Can View All	Entry allowed Can View only those they've done No submission to CVB	Can Enter own Can Edit own Can View own No submission to CVB
Quality Review	Firm designated role that allows for quality checks on all submissions prior to being submitted to the CVB.	No entry allowed No submission to CVB Can View All	Entry allowed Can Edit All Can View All No submission to CVB	Can Enter All Can Edit All Can View All No submission to CVB
No Specific Role designated in LSRTIS (see Description for details)	An employee that has an active 2007 <u>and</u> USDA Level 2 eAuthentication, but none of the roles above assigned in LSRTIS.	No entry allowed No submission to CVB No View	Entry allowed Can View only those they've done No submission to CVB	Can Enter own Can Edit own Can View own No submission to CVB

**Note: Employees may have more than one role. Not all roles are required to be filled to use the Portal. For example, a firm may have one employee designated as both Liaison and Sampler.*

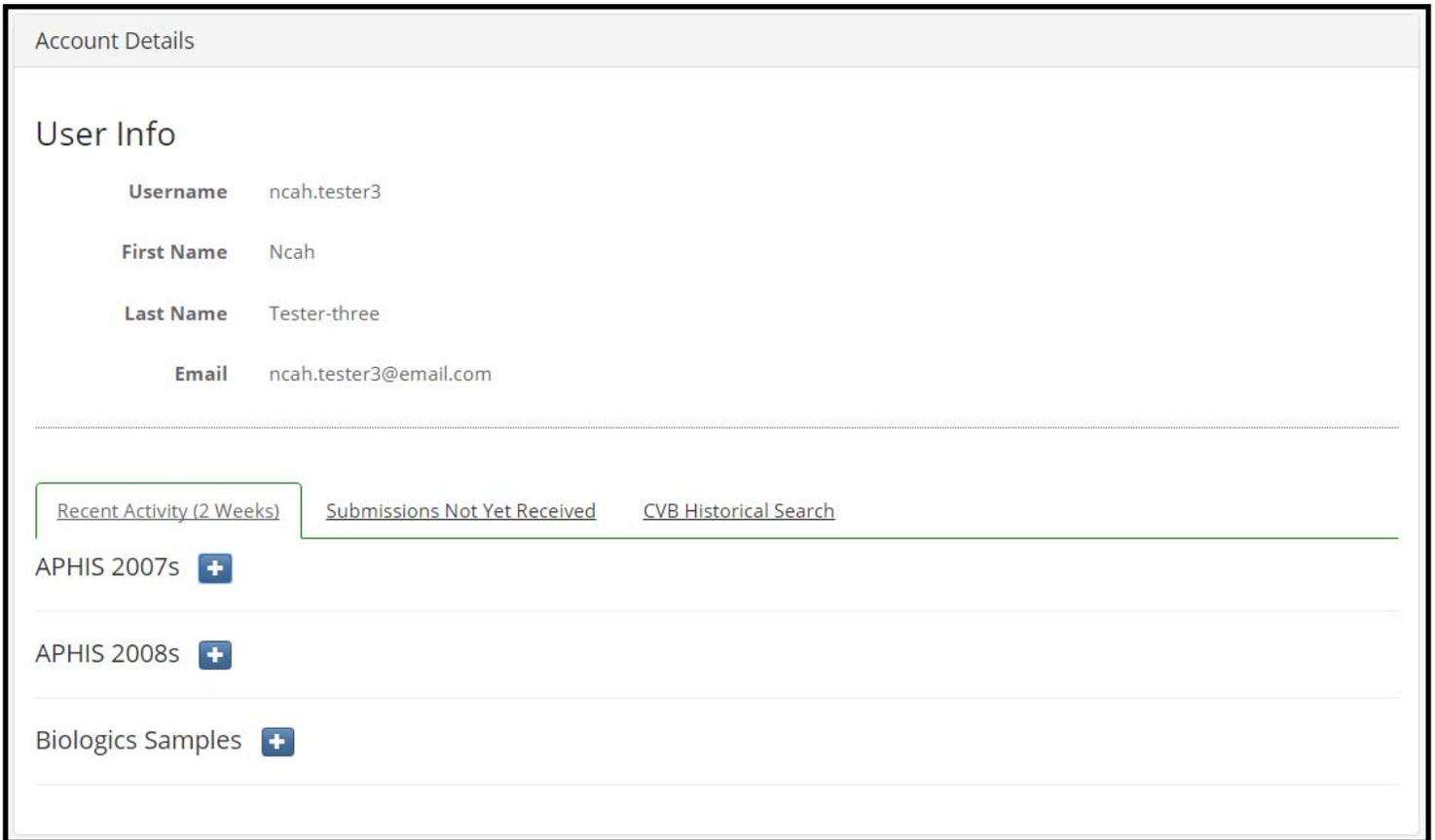
NCAH PORTAL CVB QUICK REFERENCE GUIDE

Account Details - (CVB)



All users have access to the Account Details page. Users can view details on Recent Activity, Submissions Not Yet Received, and perform Historical Searches.

You will be taken to the Account Details page. (See Picture Below)



NCAH PORTAL CVB QUICK REFERENCE GUIDE

Account Details - (CVB)

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

APHIS 2007s -

Show entries
Search:

⇕ Est	⇕ Type	⇕ Employee	⇕ Roles	⇕ Status	⇕ Approval by CVB	⇕ Submitter	⇕ Submission Date	⇕ Info
999A	New User/Site	Dr James R Doe	Consumer Complaint Contact for CVB; Consumer Complaint Contact for Public; Veterinarian of Record	Completed	Approved	Ncah Testerfive	03/25/2016	Info
999	New User/Site	Mr Eric C Kent		Submitted - ML# 175836	Denied	Ncah Tester- three	04/15/2016	Info
999	New User/Site	Tanner wike		Submitted - ML# 175884	Pending	Ncah Testerfive	04/19/2016	Info

Showing 1 to 12 of 12 entries

Previous
1
Next

APHIS 2008s +

Biologics Samples +

RECENT ACTIVITY (2WEEKS)

Recent Activity (2 weeks) – This area captures submissions that have had any type of action either within the NCAH Portal, or at the CVB that updates the Portal.

APHIS 2007s – Items initially sort on the Approval by CVB Category, then by the Status of the submission. The Liaison/Alternate, and Quality Review role may search on 2007 information. In addition, the user who entered the specified 2007 information may also search.

Updates to the portal, which capture an action for the 2 week, include completion of the Mail log item.

Approval by CVB:

Approved items are submissions complete by the CVB and the submitted information was accepted

Denied items are submissions complete by the CVB, however, the submission was not accepted. Additional information may be needed to complete the submission.

Pending items are submission that are still in the process of being reviewed at the CVB.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Account Details - (CVB)

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

APHIS 2007s +

APHIS 2008s -

Show entries
Search:

Est	Product	Serial #	Submitter	Submission Date	Status	APHIS Disposition	Info
999	500400	22JAN1	Ncah Testerfive	01/22/2016	Completed	Tests Completed Satisfactory	Info
999A	740000	22FEB2	Ncah Tester-three	04/15/2016	Serial Is On Test		Info
999A	740000	44	Ncah Tester-three	04/15/2016	Submitted		Info

Showing 1 to 14 of 14 entries

Previous
1
Next

Biologics Samples +

APHIS 2008s - Items initially sort on Status of a 2008 Submission, then items are sorted by the Establishment number, then Product Code, Serial #.

The Serial Release role, Liaison/Alternate, and Quality Review role may search on 2008 information. In addition, the user who entered the specified 2008 information may also search.

Updates to the portal are at 11:00 a.m. and 3:00 p.m. CST that will include a Status change:

Completed items have been signed by the CVB. If an APHIS Disposition shows, this will be the disposition assigned to the Form 2008. However, if a completed item does not have an APHIS Disposition showing, this Form 2008 was audited. The User must open the "Info" link to see the details of the release or audit.

Serial is On Test items have been received by the CVB, and gone through the initial review. Within the Info link the user can see the projected off-test date and the testing that is being performed.

Submitted items have been received by the CVB. The item will not be updated until it is either complete, or the sample has been put on test.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Account Details - (CVB)

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

APHIS 2007s +

APHIS 2008s +

Biologics Samples -

Show entries
Search:

Submission Info	⇅ Sample Code	⇅ Status	⇅ Submitter	⇅ Submission Date	⇅
Est: 999, Product: 264853, Serial #: 04150016	0413B	Sample Received	Ncah Tester-three	04/13/2016	Info
Est: 999, Product: 264853, Serial #: 18FEB2	0420C	Sample Received	Ncah Tester-three	04/20/2016	Info
Est: 999A, Product: 740000, Serial #: 08MAR1	0420D	Sample Received	Ncah Tester-three	04/20/2016	Info

Showing 1 to 3 of 3 entries

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Next

Biologics Samples (2020s) – Items sorted by Sample Code.

The Sampler, Liaison/Alternate, and Quality Review role may search on samples. Updates to portal are sent at 3:00pm CST that will update the record with the sample code.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Account Details - (CVB)

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

APHIS 2007s not yet submitted to CVB +

APHIS 2008s not yet submitted to CVB -

Show entries
Search:

Establishment	Product	Serial Number	Disposition	Info
999 - Your Firm, Inc.	500400 - Avian Influenza Virus Antibody Test Kit	16MAR5	Other - Transfer Request	Info
999 - Your Firm, Inc.	205100 - Autogenous Bacterin	123PMASON2	Eligible for Release	Info
999 - Your Firm, Inc.	264853 - Escherichia Coli Bacterin	24MAR1	Reprocess & Retest	Info
999 - Your Firm, Inc.	205100 - Autogenous Bacterin	1A	Other - Extension of Dating	Info
999 - Your Firm, Inc.	205100 - Autogenous Bacterin	524	Other - Rebottling	Info
999 - Your Firm, Inc.	264853 - Escherichia Coli Bacterin	16MAR3	Destroyed by Firm	Info

Showing 1 to 26 of 26 entries

Previous
1
Next

STR Samples for Serials not yet received by CVB +

STR Samples for Master Seeds not yet received by CVB +

Routine Samples for Products/Serials not yet received by CVB +

SUBMISSIONS NOT YET RECEIVED

Submissions Not Yet Received – This area captures submissions that are within the “Draft” Stage in the CVB Dashboard or yet to have an action performed at the CVB.

Editing is available for those submission that allow it (all submissions except for Biologics Samples).

Roles are the same as those who can see items within the Recent Activity (2 weeks). However, the Liaison/Alternate and Serial Release for APHIS Form 2008 information can submit individual submissions through this module.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Account Details - (CVB)

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

Submission Type

Establishment Code

Mail Log #

Submission Date

From:

To:

-----> *Select Submission Type to include in search.*

-----> *Enter Establishment Code to include in search if desired.*

-----> *Enter Mail Log # to include in search if desired.*

-----> *Enter Submission Date to include in search if desired. Date range search available utilizing the "From" and "To" fields.*

-----> *Select to perform a search based on the entered criteria.*

Show entries
Search:

Est	Type	Employee	Roles	Status	Approval by CVB	Submitter	Submission Date	
999A	Modify Employee Information	Dr James R Doe	Consumer Complaint Contact for CVB; Site Contact; Veterinarian of Record	Submitted - ML# 175860	Pending	Ncah Tester-three	04/18/2016	Info

Showing 1 to 5 of 5 entries

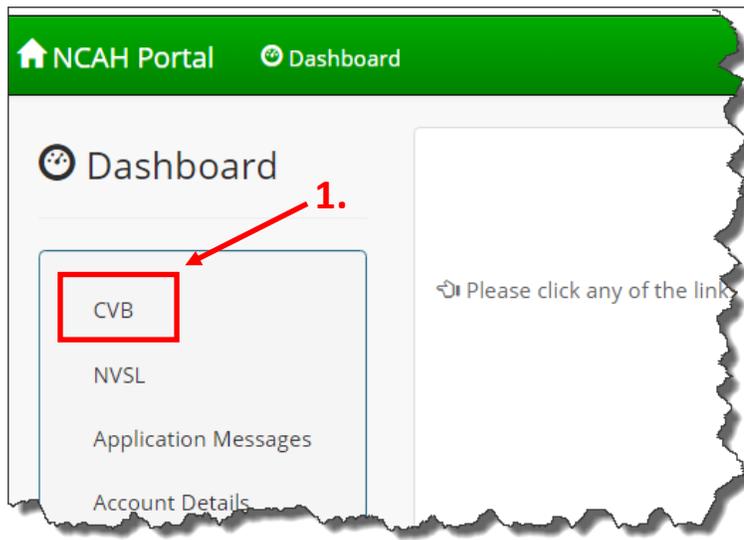
Previous 1 Next

CVB HISTORICAL SEARCH

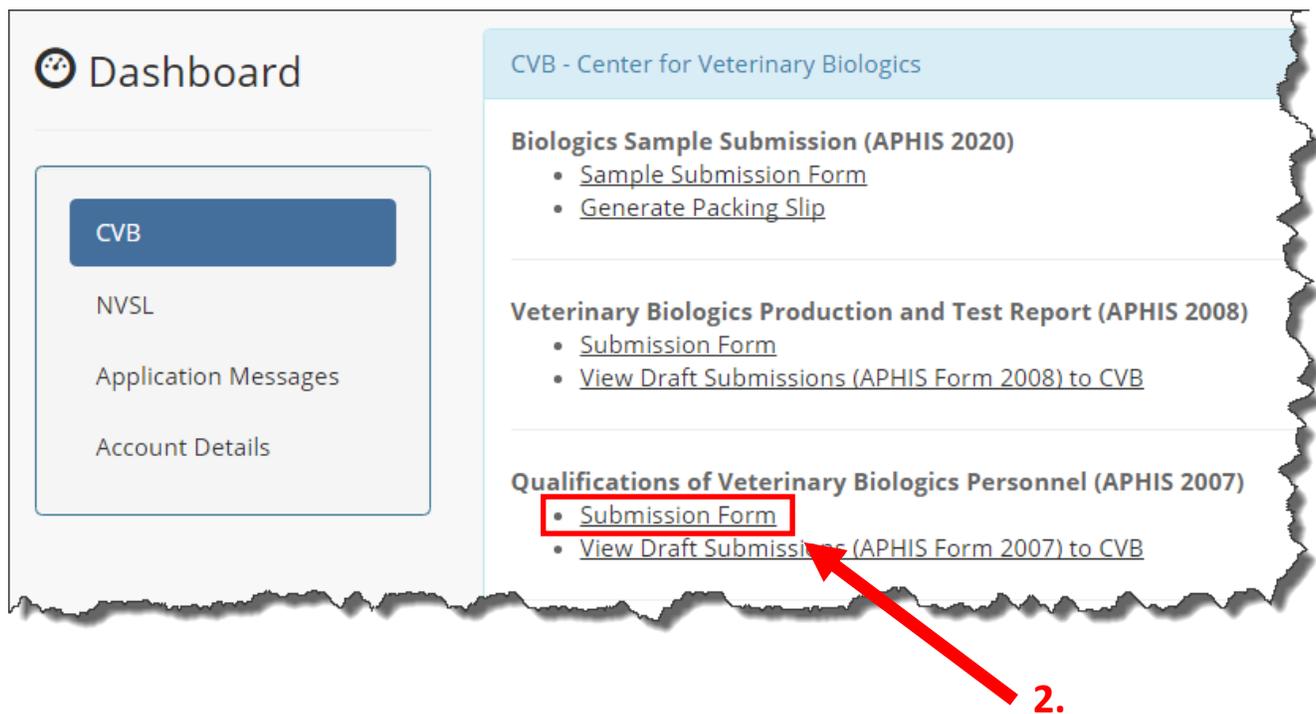
CVB Historical Search – This area is a search of items within the NCAH Portal that are either still pending within the CVB, or completed submissions - up to 60 days of the last action.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Qualifications of Veterinary Biologics Personnel - (APHIS 2007)



For APHIS Form 2007 submissions, start by entering the CVB section of the Portal and then navigating to the 2007 Submission Form.



You will be taken to the Qualifications of Veterinary Biologics Personnel Form.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Qualifications of Veterinary Biologics Personnel - (APHIS 2007)

Create - Qualifications of Veterinary Biologics Personnel (APHIS 2007)

Fields with a red asterisk (*) are required.

[CVB Home](#) / Submission Form (APHIS 2007)

Establishment Information

Submission Type*	New User/Site ▼	-----> <i>Select from drop-down menu.</i>
Establishment*	999 - Your Firm, Inc. ▼	-----> <i>Select from drop-down menu.</i>
Site Address*	123 1st Street, Ames, IA 50010 ▼	-----> <i>Select from drop-down menu.</i>

ESTABLISHMENT INFORMATION

Submission Type

New User/Site - For an employee who has never had an APHIS Form 2007 submitted to the CVB for the selected Establishment Site.

Modify Employee Information - For an employee who already has information existing under the selected Establishment Site and the information needs to be updated. This option will pull the existing information for modifications.

Inactivate User - For an employee who is no longer employed or no longer needs access to the NCAH Portal. This option will also pull the existing information from the CVB database and will automatically terminate access to the NCAH Portal upon submission to the CVB.

Establishment - Select from the list of manufacturers. This list is populated by the active manufacturers the current portal user is assigned to within the CVB database.

Site Address - Provide the physical address of the applicant's main work duty station. All licensed sites will appear in the drop down list.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Qualifications of Veterinary Biologics Personnel - (APHIS 2007)

Employee Information

Select "Prefix" from drop-down menu, and enter Employee's Name Information.

Name*	<u>Prefix</u> Mr ▾	<u>Last*</u> Doe	<u>First*</u> James	<u>Middle</u> R
--------------	-----------------------	---------------------	------------------------	--------------------

Enter Employee's Work Contact Information.

Contact Info	<u>Phone Number</u> 155-255-5555	<u>Fax Number</u> 	<u>E-Mail Address</u> james.r.doe@me.com
	<u>eAuthentication Username</u> jrdoe		

EMPLOYEE INFORMATION

Name

Prefix - Select Prefix for employee. This is a non-mandatory field

Last - Enter employee's last name.

First - Enter employee's first name.

Middle - If available enter employee's middle name, this is a non-mandatory field.

Contact Info

Phone Number - Although not mandatory, applicants are strongly encouraged to provide their work phone number. Provide the country code if the primary work site is outside of the United States.

Fax Number - This is a non-mandatory field for the employee's work fax number.

E-mail Address - This is a non-mandatory field for the employee's work email address; however, is strongly encouraged for roles receiving written communication from APHIS such as Liaison, Alternate Liaison, and Serial Release.

eAuthentication Username - This is a non-mandatory field for the employee's eAuth user name. However, this is needed for an employee to obtain access to the NCAH Portal. Specific portal access roles will be based upon duties/roles, as show in the Employment Information Section of this document.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Qualifications of Veterinary Biologics Personnel - (APHIS 2007)

Employment Information

Job Title* -----> *Enter employee's Job Title at establishment*

Year Employed -----> *Enter year started at employment site. Format (YYYY)*

Duties/Roles

Not Selected	Selected
Showing all 10	Showing all 2
Filter -> <i>Enter text to search "Not Selected" list.</i>	Filter --> <i>Enter text to search "Selected" list.</i>
<i>Select single arrow to move one selected item, and double arrows to move all items in search box.</i>	
<div style="background-color: #333; color: white; padding: 2px; text-align: center;"> →→ → </div> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 2px;"> Animal Care Supervisor Chair Institutional Biosafety Committee Chair, Animal Care/Use Committee (IACUC) Export Contact Liaison </div>	<div style="background-color: #333; color: white; padding: 2px; text-align: center;"> ← ←← </div> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 2px;"> Consumer Complaint Contact for CVB Veterinarian of Record </div>

EMPLOYMENT INFORMATION

Duties/Roles - Select any role(s) that are assigned to the employee. These roles are usually in relation to a government assigned role or contact. Not all applicants will have assigned roles.

Note: Please see Portal Roles User Guide for designated roles within the NCAH Portal. Starred(*) items below are roles that enable elevated levels of portal access.

Supervisor, Animal Care – Firm designated role.

Chair, Animal Care/Use Committee (IACUC) – Firm designated role.

Consumer Complaint Contact – Firm designated role.

Export Contact – Firm designated role. The primary contact for export documents.

Liaison* – Confirmed by the CVB. Primary point of contact for all official correspondence submitted.

Liaison, Alternate* – Confirmed by the CVB. Secondary point of contact for all official correspondence.

Quality Review * - Firm designated role. Role that has access for quality checks on all NCAH Portal submissions prior to being submitted to the CVB.

Sampler, Authorized * – Confirmed by the CVB. Designated role for the selection and submission of government routine/retention samples & master seeds and cells.

Serial Release * - Firm designated role. Point of contact for the preparation and submission of biological summaries (APHIS Form 2008s).

Site Contact – Firm designated role. Contact for CVB for sites that may not have liaisons or alternate liaisons, such as foreign manufacturing sites.

Veterinarian of Record – Firm designated role.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Qualifications of Veterinary Biologics Personnel - (APHIS 2007)

Educational History

Use text fields and drop-down menus to enter employee education history.

Education
Select to delete education dialog box. -----> DELETE

<u>Name of Institution*</u>	<u>Degree Type*</u>	<u>Year Obtained*</u>
<input type="text" value="ISU"/>	<input type="text" value="DVM"/>	<input type="text" value="2013"/>

+ Add Education History
-----> Select to add additional education history.

Misc

Data File Browse ... -----> Select browse to prompt a dialog box to add a data file.

Note: You may add an optional attachment if you would like to add more data.

Remarks

-----> Enter any remarks.

I agree that I've looked over this information and everything entered is true to my knowledge. -----> Check box once complete.

✔ Save
-----> Select button to save form.

EDUCATION HISTORY

Education – Only list education relevant to working in the biologics industry or with biological products. Although this is not a mandatory entry, education should be included for applicants seeking to be acknowledged by the CVB as liaisons or alternate liaisons.

Name of Institution – Provide the name of school, university, or institution accredited to issue degree or certificate.

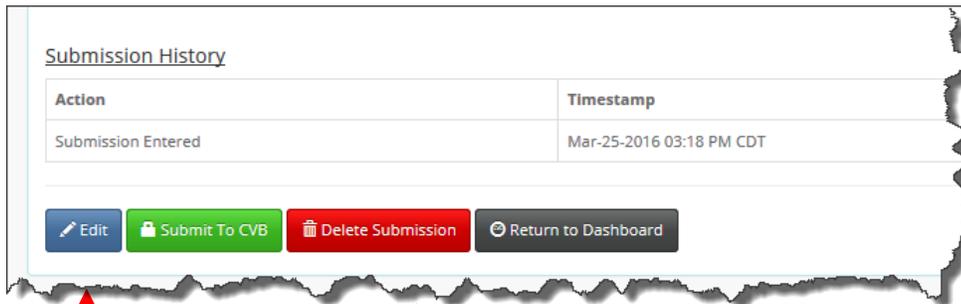
MISC.

Data File – Optional attachment for any relevant information for the applicant that elects to provide. Examples may include evidence of trainings (such as sampler training), or requests for CVB confirmed roles (Liaison).

Remarks – Optional field for any additional comments, up to 150 characters.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Qualifications of Veterinary Biologics Personnel - (APHIS 2007)



Select to Edit the submitted form.

Note: *Once CVB has received the form you can no longer edit or delete the form.*

Select to Delete the submitted form.

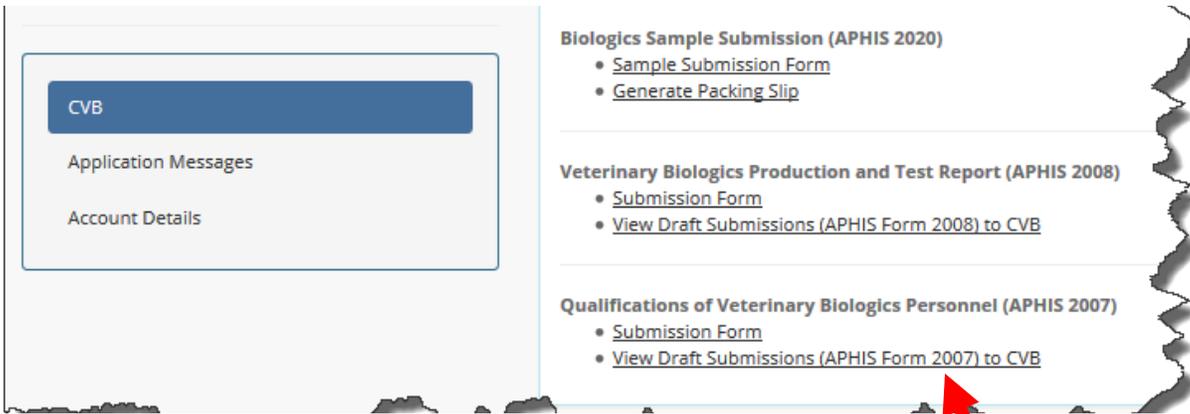
SUBMIT ONE 2007 TO CVB

Submit – Only liaisons or alternate liaisons may submit APHIS Form 2007s to the CVB. Upon submission, the user will receive the Mail

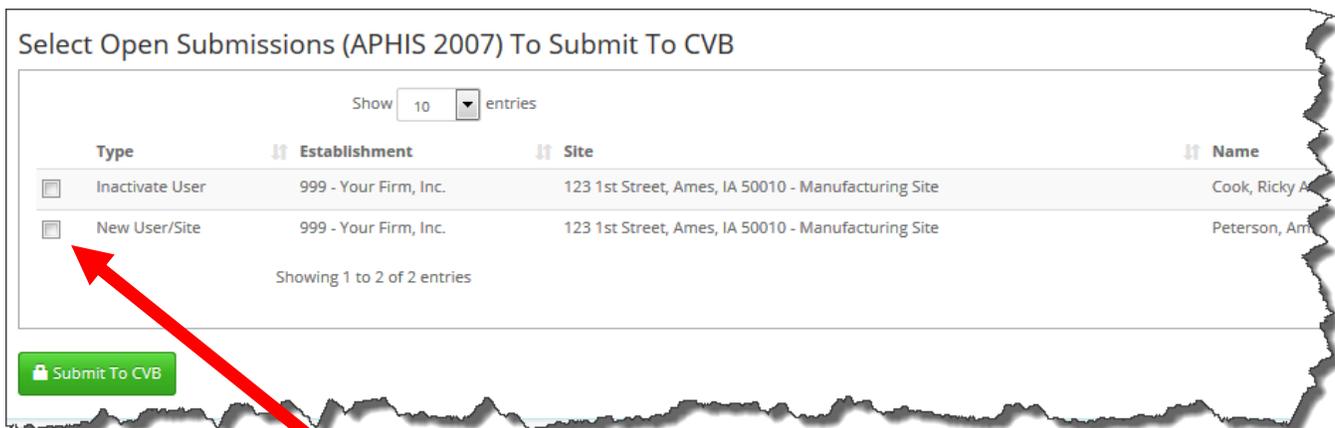
NCAH PORTAL CVB QUICK REFERENCE GUIDE

Qualifications of Veterinary Biologics Personnel - (APHIS 2007)

SUBMIT MULTIPLE 2007s TO CVB



To submit multiple 2007s in one submission to the CVB, choose the View Draft Submissions to the CVB.

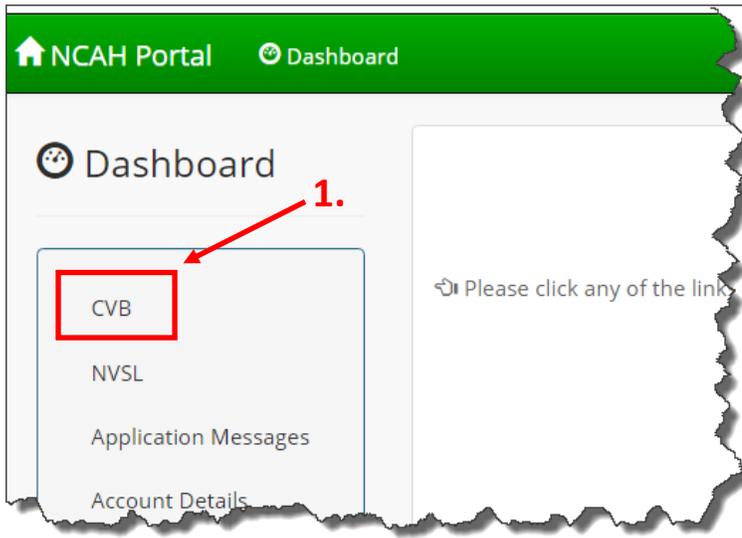


To submit multiple 2007s in one submission to the CVB, click in the check boxes for items to be submitted

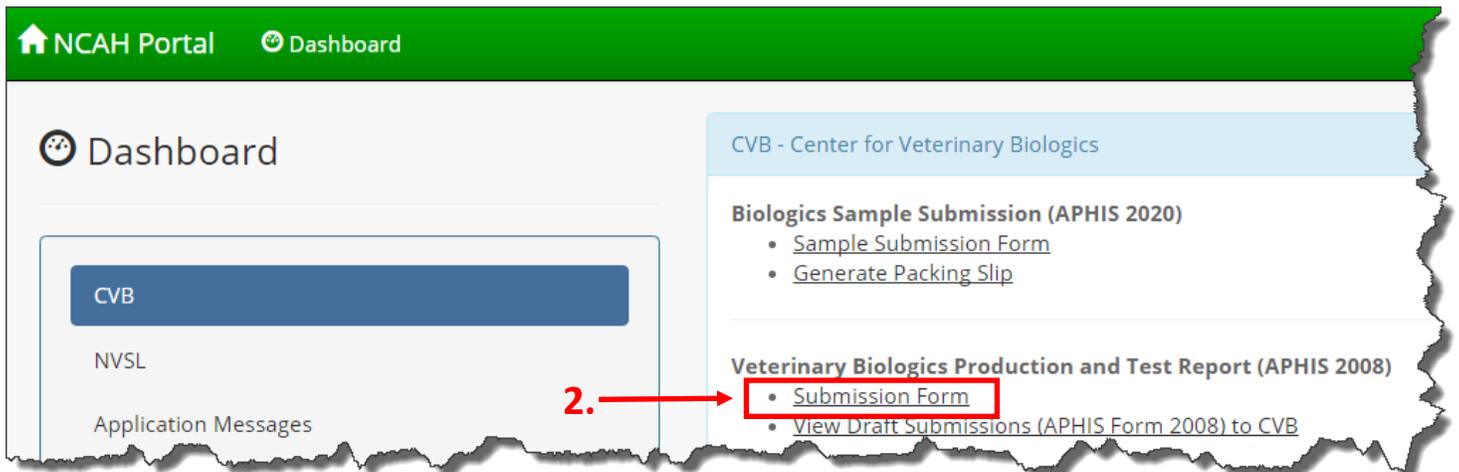
Note: *Once CVB has received the form you can no longer edit or delete the form.*

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Veterinary Biologics Production and Test Report - (APHIS 2008)



For APHIS Form 2008 submissions, start by entering the CVB section of the Portal and then navigating to the 2008 Submission Form.



You will be taken to the Veterinary Biologics Production and Test Report Form.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Veterinary Biologics Production and Test Report - (APHIS 2008)

Create - Veterinary Biologics Production and Test Report (APHIS 2008)

Fields with a red asterisk (*) are required.

[CVB Home](#) / Submission Form (APHIS 2008)

Establishment*	999 - Your Firm, Inc. ▾	-----> <i>Select from drop-down menu.</i>
Site Address*	123 1st Street, Ames, IA 50010 ▾	-----> <i>Select from drop-down menu.</i>
Product Code*	205100 ▾	-----> <i>Select from drop-down menu. Type ahead feature is available.</i>
Product Name	Autogenous Bacterin	-----> <i>Auto-populated, based on Product Code.</i>
Serial Number*	16mar2	-----> <i>Enter Serial Number, 20 alphanumeric characters only.</i>

SERIAL INFORMATION

Establishment – Only those establishments for which the submitting employee has an APHIS Form 2007 on file will be available in the drop-down menu.

Site Address – The mailing address of the selected establishment will default in this box. All licensed or permitted sites are available in the drop-down menu. The user may select either the mailing address or the site from which the 2008 was generated.

Product Code – A list of product codes for the selected licensee or permittee will appear.

Product Name – Will auto-populate based on the product code.

Serial Number – Enter serial or subserial number assigned by the manufacturer.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Veterinary Biologics Production and Test Report - (APHIS 2008)

Autogenous or Prescription Product (platform)? -----> *Check the box if applicable. See VSM 800.69 or 800.213 for guidance.*

Agents for Autogenous or Prescription Product (platform)

Not Selected

Showing all 2

Filter ---> *Enter text to search "Not Selected" list.*

<--> >

Bovine Virus Diarrhea Virus, Type 1
Bovine Virus Diarrhea Virus, Type 2

Selected

Showing all 2

Filter -----> *Enter text to search "Selected" list.*

< <--<

Influenza Virus, Swine, H1N1
Influenza Virus, Swine, H3N2

Select single arrow to move one selected item, and double arrows to move all items in search box.

First Serial Y N -----> *Select "Y" if First Serial.*

≤ 50 Containers Y N -----> *Select "Y" if ≤ 50 Containers.*

Fill Date -----> *Enter Fill Date.*

Expiration Date -----> *Enter Expiration Date.*

Autogenous or Prescription Product? - Optional field if a serial or subserial is considered an autogenous product or prescription product. Checking this box will provide the ability to enter agents for the Autogenous/Prescription product. It will also provide the ability to enter if the serial is the first serial or if it contains less than or equal to 50 containers/vials.

Agents for Autogenous or Prescription Product - Select any agents used to make the product. Multiple agents can be selected. Agents not available in the list may be entered in the Remarks Section.

First Serial - Select the check-box if the serial is a first serial made from the isolate. Autogenous first serials do not require test data to be submitted (still follow policy in VS Memorandum 800.69, 1st serial summaries).

Fill Date - Enter the date the final containers were filled. If not applicable (i.e. bulk containers), leave blank.

Expiration Date - Enter the expiration date assigned to the final container. This field is mandatory for all Establishment Dispositions except: Destroyed By Firm, File for Information, To be Reprocessed and Retested, or For Further Manufacture.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Veterinary Biologics Production and Test Report - (APHIS 2008)

Establishment Disposition

Disposition by Firm* -----> *Select from drop-down menu.*

ESTABLISHMENT DISPOSITION

Disposition by Firm – Select the applicable disposition assigned by the licensee or permittee. With many of the dispositions noted below, additional information is required.

Note: Any disposition that is selected by the manufacturer may be changed by the CVB. Changes will be communicated back to the firm.

Eligible for Release - This is the default Firm Disposition for serials that have not yet been released to the market, but meet requirements for marketing.

Destroyed by Firm - For any serial not released to the market and destroyed by the manufacturer.

Destruction Reason - Select from the available list of reasons for destruction of the serial (i.e. unsatisfactory potency testing, unsatisfactory purity testing and other.)

Destruction Date - Enter the actual date the destruction of the serial occurred. The date should not be in the future.

Destruction Comments - Optional field for any other pertinent information.

To be Reprocessed & Retested - This is used to request permission to reprocess a serial. Enter the Product Code and Serial Number(s) to identify the reprocessed serial(s), as specified in VSM 800.62.

Other - Expiration Date Correction

Other - Extension of Dating- This is used to request additional dating on remaining inventory nearing expiration, provided that assurances of continued potency are provided

On Licensed Premises? - When selected the field “On Licensed Premises?” will appear within the Inventory for Release section. Select the check-box if the remaining inventory of the serial is on licensed premise.

Other - File For Information - Used for a variety of reasons to provide additional information to the CVB.

Other - Inventory Correction

Other - Rebottling - This is used to request permission to rebottle a serial. Enter the Product Code and the Serial Number(s) to identify the rebottled serial(s) as specified in VSM 800.62.

Other - Subsequent Shipment - Permittees utilize this disposition when a serial is brought into the United States in more than one shipment. Use this reason for the second or subsequent shipment when the first shipment of the serial has already been released. See VSM 800.101 for guidance.

Other - Transfer Request - This is used to notify the CVB of a transfer of inventory from one product code to another code, as allowed in the Outline of Production. Enter the Establishment Code, Product Code and the Serial Number(s) to identify the new Transfer Serial(s). Processing procedures should follow ICWI0310.

Other - Shorten Dating - Shorten Dating requests are used in instances when the virus titration result is below release; but above through-dating. CVB may consider release based on regulatory flexibility.

Other - For Further Manufacture - Bulk lots that are not for release to the market, but may be sent to another manufacturer for further processing.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Veterinary Biologics Production and Test Report - (APHIS 2008)

For Further Manufactured (FFM) Serials - If a serial was produced with manufacturing intermediates produced by another licensed manufacturer, enter the FFM Establishment Code, Product Code and Serial Number used in the production of the serial. The license or permittee number and the serial number fields will appear if the Outline of Production allows the option to use FFM material. If more than one FFM is used for a Serial, choose the “+” button to enter further information. If an option does not appear in the drop-down, enter this information in the Remarks section.

The screenshot shows two sections of the APHIS 2008 form. The 'Test Data' section has a title 'Test Data' and a red instruction: 'Select Browse to prompt a dialog box and add a Test Data file, and Remove to delete the added file.' Below this is a 'Test Data File' field containing 'Test PDF.pdf' with 'Remove' and 'Browse ...' buttons. A note below the field states: 'Note: This file should contain a list of all testing data/results.' The 'Inventory for Release' section has two fields: 'Number of Total Doses*' with the value '2000' and a red dashed arrow pointing to the instruction 'Enter Number of Total Doses.'; and 'Container Units*' with the value 'Doses' and a red dashed arrow pointing to the instruction 'Select from drop-down menu.'

TEST DATA

Test Data File - This must be a .pdf file that contains all tests conducted by the licensee or permittee to support release of the serial or subserial as defined in Section V of the Outline of Production. All details required on the APHIS Form 2008 should be provided: Test Reference identification, date started and date concluded, all test results, including validity and controls requirements, and the test conclusion. Also include any explanations for a No Test and Inconclusive results. See VS Memorandum 800.53.

The test data file is mandatory for all Firm Dispositions, except File for Information, For Further Manufacture, Inventory Corrections, and Expiration Date Corrections.

Inventory For Release - Depending on form field selections you may have some of the following options available.

INVENTORY FOR RELEASE

Container Units - Select the unit of measure used for each serial; choose if the serial is final containers (doses), bulk (mL), or diagnostic test kit (units).

Containers - Enter the number of containers eligible for release.

Container Size - Enter the quantity in each container or tests that can be performed with each kit. For those with more than one dose size, select the “+” button to add additional lines

Total Doses Manufactured - When a permittee manufactures a serial internationally, the total doses manufactured should be reported to the CVB, regardless of how much is imported into the United States in a single shipment. Those doses imported should be reported in the # Containers and Container Size fields in this section.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Veterinary Biologics Production and Test Report - (APHIS 2008)

Misc Select Browse to prompt a dialog box and add a Letter, and Remove to delete the added Letter.

Letter Test PDF.pdf Remove Browse ...

Note: You may add an optional attachment if you would like to add more data.

Remarks Harvest date = 3/3/2016 -----> Enter Remarks.

I agree that I've looked over this information and everything entered is true to my knowledge. ----> Check box once complete.

✔ Save -----> Select button to Save form.

MISC.

Letter - If any supplemental information is needed to support consideration of release, attach a single file. This information may include bench records, or referenced letters. **DO NOT ATTACH** correspondence that needs response by the CVB other than release of serial.

Remarks - Include any pertinent information in this area, not already captured elsewhere in the submission.

Select to Edit the submitted form.

Can only Edit if CVB has not received the form.

Select to Submit the form to CVB.

Submission History

Action	Time stamp
Submission Entered	Apr-11-2016 09:37 AM CDT

✎ Edit
✎ Clone
🔒 Submit To CVB
🗑 Delete Submission
🏠 Return to Dashboard

Select to Clone the submitted form.

Select to Delete the submitted form.

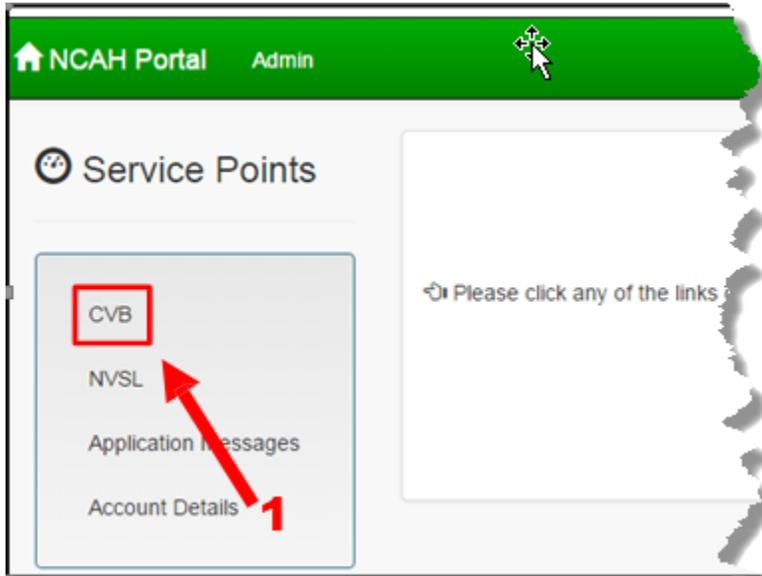
CLONING

Cloning - Cloning allows the user to copy fields from the submission form. Fields that are copied include: Product Code, Fill Date, Expiration Date, Disposition by Firm, and Remarks.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

For all types of sample submissions, start by entering the CVB section of the Portal and then navigating to the Sample Submission Form.



*Only users with the **Sampler Role** can enter sample information and generate Packing Slips to be shipped with samples.*



You will be taken to the Biologics Sample Submission Form.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

Create - Shipment and Receipt of Biologics Samples (APHIS 2020)

[CVB Home](#) / Submission Form (APHIS 2020)

Fields with a red asterisk (*) are required.

Serial Information

Auth Number -----> *Not needed for Routine Samples.*

Establishment* -----> *Select from drop-down menu, if different from default.*

Site Address* -----> *Select from drop-down menu, if different from default.*

Product Code* -----> *Select from drop-down menu.*

Product Name -----> *This field will be auto-populated based on the selected Product Code.*

Serial Number* -----> *Enter Serial Number, 20 alphanumeric characters only—NO SYMBOLS.*

Serial Information

Establishment – This list is populated by the active manufacturers the user is assigned to within the CVB database.

Site Address – Defaulted to manufacturer’s mailing address; however, this can be the address from where the samples are being shipped. All licensed sites will appear in the drop down list, for domestic manufacturers.

Product Code – Select from the list of all available product codes for the manufacturer if not auto-populated.

Product Name – This field will auto-populate based upon the selected product code.

Serial Number – This field is free text, however, the serial number listed here must match the Form 2008 submission exactly, or the records will not match up. Do not enter symbols.

Auth Number – This field is for the STR (Special Request authorization number) assigned by the CVB. For entry of samples for STR Auth Numbers, see the User Manual for [Sample Entry for a Special Test Request](#).

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

Sample Information

Purpose* Type*
 → *Select "Routine" from drop-down menu.*

Subserial? → *Check the box if applicable.*

Package Shipped With* Type*
 → *Select from drop-down menu.*

Size*

<u>Number of Containers*</u>	<u>Amount Per Container*</u>	<u>Type*</u>
<input type="text" value="5"/>	<input type="text" value="4"/>	<input type="text" value="Doses"/>

Enter Number of Containers and Amount Per Container. Select from drop-down menu.

Sample Type* → *Enter if the sample is either Bulk or Final.*

Contains Thimerosal? → *Check the box if the sample has Thimerosal or Merthiolate.*

Sample Information - Routine

Purpose (Routine) – Submission of routine post-license sample to the CVB that will be eligible to be selected for confirmatory (check) testing. Other options include (Pre-license and Resubmission)

Subserial – Indicate if the serial is considered a subserial by the manufacturer.

Packaged Shipped With – Samples shall be kept under refrigeration at 35°- 45°F (2°-7°C) unless otherwise specified in the approved Outline of Production (9 CFR 114.11).

Size: Number of Containers—See VSM 800.59 for guidance (9 CFR 113.3)

Amount Per Container—The number of doses/mLs/Units per container. If more than one sample size is submitted, use the smallest volume for entry. If the volume is less than 1 *unit*, round the number up to 1. If the volume is not a whole number, but is greater than 1 (i.e. 10.5 mL), round down to the nearest whole number.

Type—Doses, mL, Units, Kits.

Sample Type—Final samples should be submitted in most cases, unless directed by the CVB.

Contains Thimerosal?—Utilize this check box if the product contains Thimerosal.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

Sample Information—Resubmission

Sample Information

Purpose* Type*
Resubmission

Sample Code

Subserial?

Package Shipped With* Type*
Ice Pack

Purpose (Resubmission) – Submission of resubmission samples to the CVB that will had been requested for either routine testing or special request testing.

Sample Code —If testing was initiated by the CVB on routine testing, but more samples are needed to finish the testing, the CVB will contact the firm to request more samples to be resubmitted. In most cases, a sample code is known and should be filled in here.

Misc.

Remarks – Enter any applicable informa on not contained in the above elds. (i.e. who requested the resubmission of samples)

Save—Upon saving, the record must be printed as a Packing Slip and submitted to the CVB with the sample packaging.

Misc

Remarks Enter Remarks if any. ----->Enter Remarks.

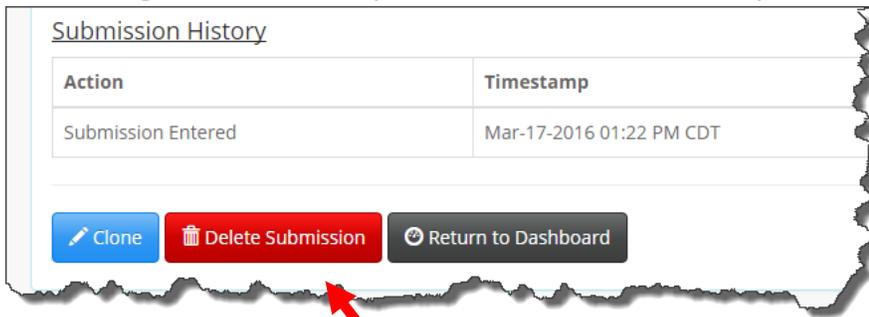
I agree that I've looked over this information and everything entered is true to my knowledge. --> Check box once complete.

✔ Save -----> Select button to Save form.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Routine Samples"

After saving the submission, you will be directed to the Shipment and Receipt Page.



Select to Clone the submitted form.

Select to Delete the submitted form. The record may be deleted until it has been received by the CVB.

If a record needs any corrections, it must be deleted and re-entered completely.

CLONING

Cloning - Cloning allows the user to copy fields from the submission form. Fields that are copied include: Product Code, Purpose, Shipment with Type, Number of Containers, Amount Per Container, Dose Type, Sample Type, Containing Thimerosal, and Remarks.

Entry of Information for Submission of Routine Samples Complete

For guidance on submitting the sample to CVB, see the User Manual for [Generating a Packing Slip for Shipment of Samples](#).

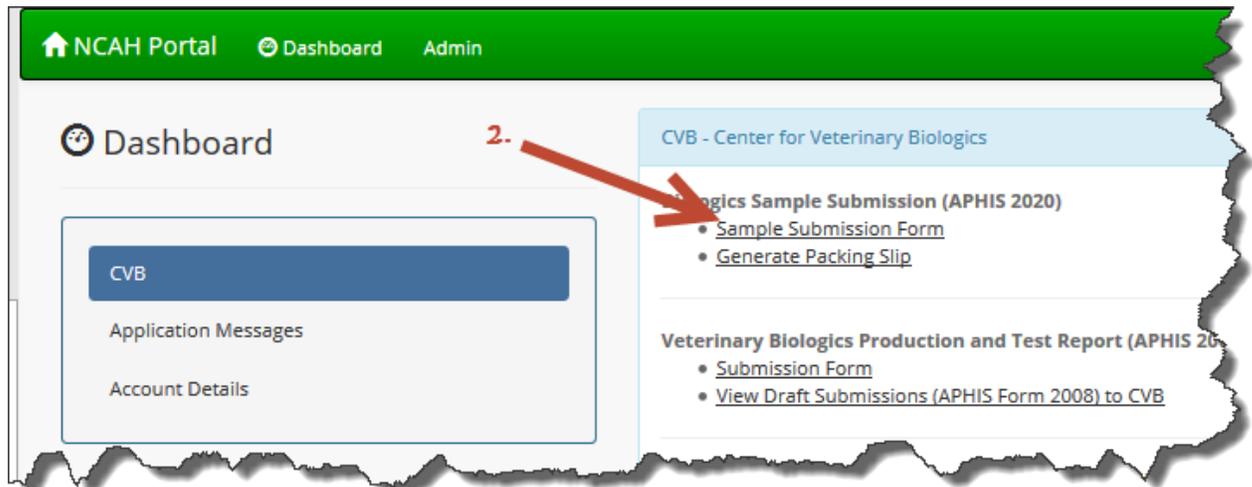
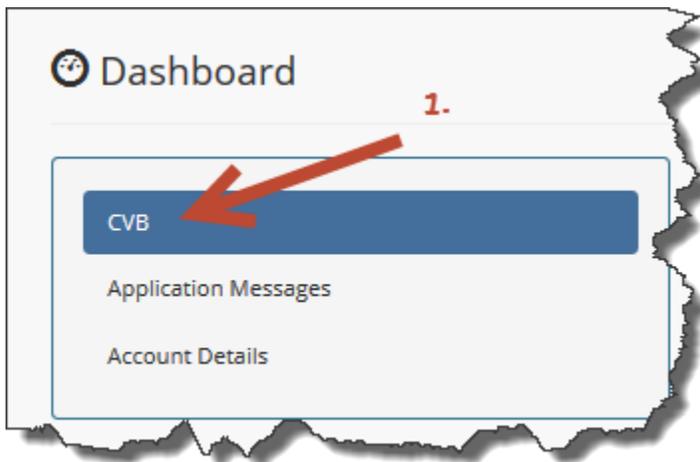
NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Special Request"

- * **Special Test Request (STR)** applies to samples pre-authorized by the CVB, such as those for prelicense testing, or testing of Master Seeds or Master Cells.

Only users with the **Sampler Role** can enter sample information and generate Packing Slips to be shipped with samples.

For all types of sample submissions, start by entering the CVB section of the Portal and then navigating to the Sample Submission Form.



You will be taken to the Biologics Sample Submission Form.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Special Request"

Create - Shipment and Receipt of Biologics Samples (APHIS 2020)

Fields with a red asterisk (*) are required.

[CVB Home](#) / [Submission Form \(APHIS 2020\)](#)

Serial Information

Auth Number	2538	<input type="button" value="✕ Reset"/>	<i>-----> Enter Authorization Number/Special Request (STR Number) provided by the CVB.</i>
Establishment*	999 - Your Firm, Inc.		
Site Address*	<input type="text" value="123 1st Street, Ames, IA 50010"/>		<i>-----> Select from drop-down menu.</i>
Product Code*	264853		
Product Name	Escherichia Coli Bacterin		
Serial Number*	16FEB4		
Purpose*	Resubmission		
Sample Code	<input type="text" value="1234ABC"/>		<i>-----> Enter Sample Code, if provided by the CVB only.</i>

SERIAL INFORMATION

Authorization Number - Upon entry of the authorization number the following will auto-populate for each type of sample:

Serial or Subserial - The Establishment number and Establishment name, Product Code, Product name, Serial Number, and Purpose designated by the CVB.

Master Seed - The Establishment number and Establishment name, Master Seed identification, and Purpose.

Master Cell - The Establishment number and Establishment name, Master Cell identification, and Purpose.

Site Address - Default is the manufacturer's mailing address. All licensed sites will appear in the drop down list.

Product Code - Select from the list of all available product codes for the manufacturer if not auto-populated.

Product Name - This field will auto-populate based upon the selected product code.

Sample Code - Non-mandatory field that appears when Sample Purpose is Resubmission. Only valid Sample Codes assigned by CVB for the specified Product Code and Serial Number can be entered.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Special Request"

Sample Information

Subserial? -----> *Check the box if serial is considered subserial by the manufacturer.*

Package Shipped With* Type*
Ice Pack -----> *Select from drop-down menu.*

Size* Number of Containers* Amount Per Container* Type*

5

6

ML

Enter Number of Containers and Amount Per Container. *Select from drop-down menu.*

Sample Type* Final -----> *Select from drop-down menu Bulk or Final.*

Contains Thimerosal? -----> *Check the box if sample has Thimerosal (Merthiolate).*



Packaged Shipped With - Samples shall be kept under refrigeration at 35° - 45°F (2° - 7°C) unless otherwise specified in the approved Outline of Production (9 CFR 114.11).

Misc

Remarks Enter Remarks if any. -----> *Enter Remarks.*

I agree that I've looked over this information and everything entered is true to my knowledge. -----> *Check box once complete.*

✔ Save -----> *Select button to Save form.*



Remarks - Enter any applicable information not contained in the above fields.

Save - Upon saving, the record must be printed and submitted to the CVB with the sample packaging to be submitted to the CVB.

Submission History

Action	Timestamp
Submission Entered	Mar-18-2016 09:48 AM CDT

🗑 Delete Submission
🏠 Return to Dashboard

Select to Delete the submitted form. The record may be deleted until it has been received by the CVB. If a record needs any corrections, it must be deleted and re-entered completely.

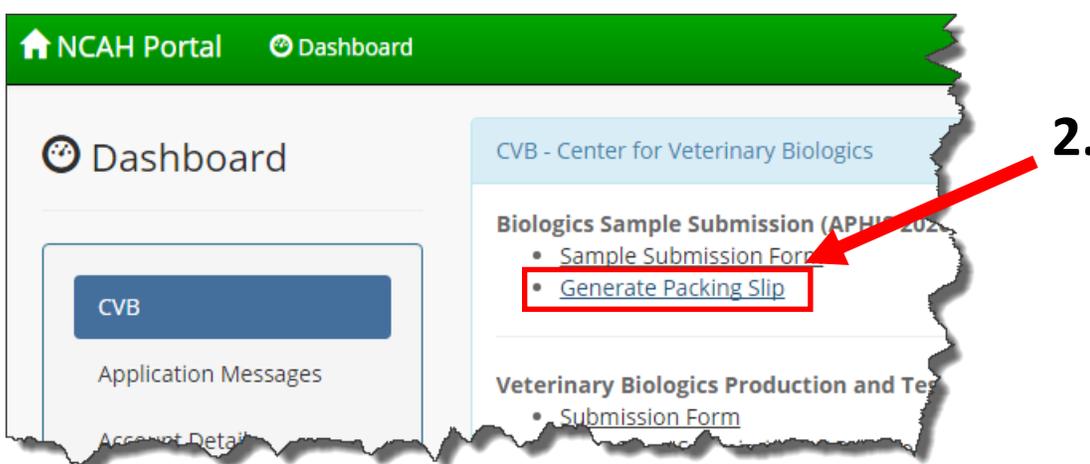
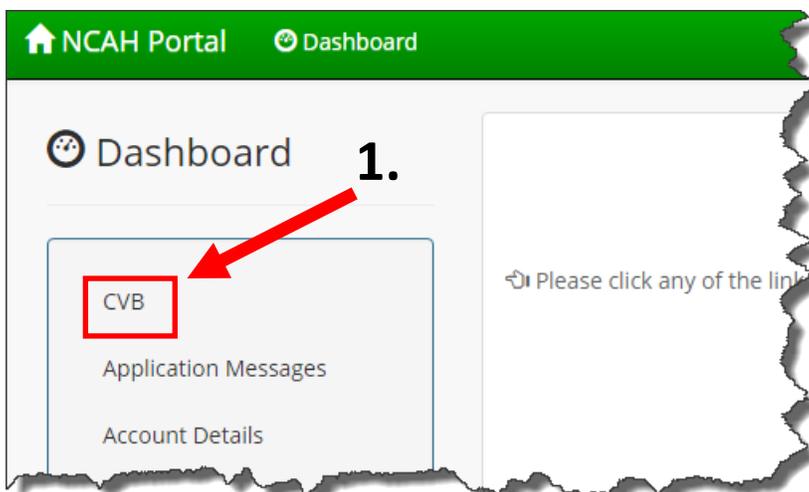
NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Generate Packing Slip"

- * Before generating a packing slip, the sample details must be entered in for the APHIS Form 2020 information.
- * APHIS 2020 records will be held in the portal for 60 days, after which they are purged.

Only users with the *Sampler Role* can enter sample information and generate Packing Slips to be shipped with samples.

For all types of sample submissions, start by entering the CVB section of the Portal and then navigating to the Generate Packing Slip hyperlink.



You will be taken to the APHIS 2020 Packing Slip Page.

Next: Generating Packing Slips.

NCAH PORTAL CVB QUICK REFERENCE GUIDE

Biologics Sample Submissions - (APHIS 2020) "Generate Packing Slip"

3. Select the check-boxes next to desired submissions to generate a packing slip for samples to be shipped.

Resubmission Samples for Products/Serials not yet received by CVB

Search:

Show 10 entries

Establishment	Product	Serial Number	Type	Submission Date
<input checked="" type="checkbox"/> 999 - Your Firm, Inc.	500400 - Avian Influenza Virus Antibody Test Kit	31DEC3	Final	02/18/2016 Info
<input type="checkbox"/> 999 - Your Firm, Inc.	205100 - Autogenous Bacterin	17FEB4	Final	02/22/2016 Info

Showing 1 to 5 of 5 entries

1

4.

03/18/2016 - FOR OFFICIAL USE ONLY

Center for Veterinary Biologics
Biologics Sample Submission - Packing Slip
Establishment: 999A - Your Firm International
Site: 123 1st Street, Ames, IA 50010

Special Request Auth Num: 2558
Product: 740000 - Clostridium Chauvoei-Septicum-Novyi-Sordellii-Haemophilus Somnus Bacterin-Toxoid
Serial Number: 02MAR3 - Submission Date: March 02, 2016

Purpose: Resubmission **Is Subserial: No** **Shipped With: Ice Pack** **Sample Type: Final**
Number Of Containers: 2 **Amount Per Container: 25 Doses**

Comments: str submission (initial)
Submitter: Testerfive, Neah


11799-0

5. Print packing slip.

6. Include packing slip with sample shipment.

The Sample Code is not provided until the sample has been received and verified by the CVB.