

Where were changes made in the 6/22/2016 version?

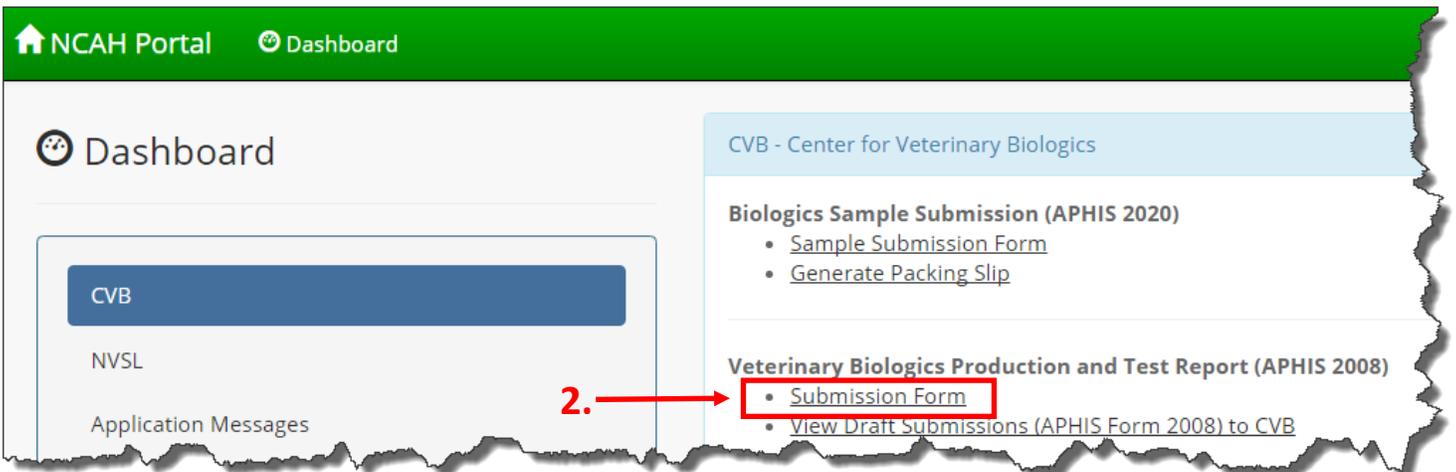
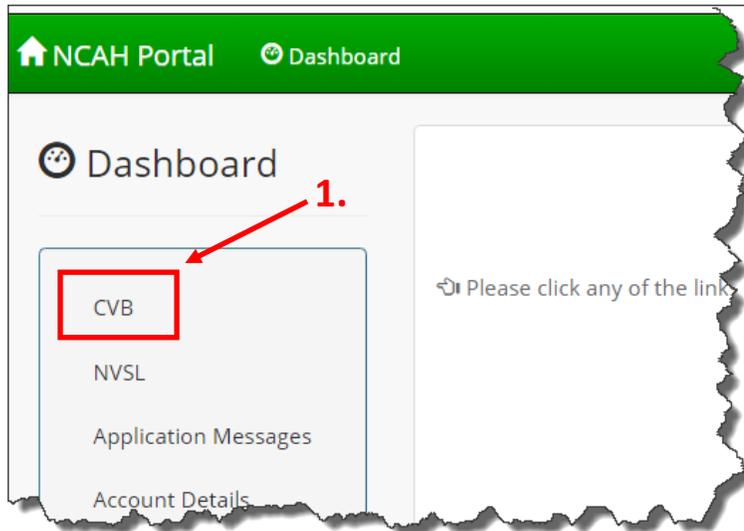
1. [The publication date was moved to the lower right of each page so it is within printable margins](#)
2. [Page 3, Product Code](#)
3. [Page 4, First Serial and ≤50 Containers](#)
4. [Page 6, Test Data File](#)
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6. [Page 7, Reviewing Your Entry](#)

NCAH PORTAL CVB QUICK REFERENCE

General Guide for 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.

Any user with Level 2 eAuth can enter 2008 information. Only users with the **Liaison, Alternate Liaison, or Serial Release Role** may submit to the CVB.



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

Next: Entering information in the Veterinary Biologics Production and Test Report (APHIS 2008)

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General Guide for Veterinary Biologics Production and Test Report (APHIS 2008)

SERIAL INFORMATION

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

Fields with a red asterisk (*) are required.

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

Establishment*	<input type="text" value="999 - Your Firm, Inc."/>	- - - - -> <i>Select from drop-down menu.</i>
Site Address*	<input type="text" value="123 1st Street, Ames, IA 50010"/>	- - - - -> <i>Select from drop-down menu.</i>
Product Code*	<input type="text" value="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*	<input type="text" value="16mar2"/>	- - - - -> <i>Enter Serial Number, 20 alphanumeric characters only. NO SYMBOLS.</i>

Establishment – Only those establishments for which the employee entering the information has an APHIS Form 2007 on file for, 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.

NOTE: Any product code, ever assigned to your firm will be listed here in an effort to make the system flexible to users' needs and situations (like information needed on a Destroyed serial for one that was recently terminated, or if there was a firm merger).

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

Serial Number – Enter serial or subserial number assigned by the manufacturer. Do not include symbols.

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ESTABLISHMENT DISPOSITION

Establishment Disposition

Disposition by Firm*

Eligible for Release ▾

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

- ❖ **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 the "Extension of Dating" field is 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 filed 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.

- ❖ **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 licensee 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.

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TEST DATA

Test Data

Select Browse to prompt a dialog box and add a Test Data file, and Remove to delete the added file.

Test Data File

Test PDF.pdf

Remove

Browse ...

Note: This file should contain a list of all testing data/results.

Inventory for Release

Number of Total Doses*

2000

→ Enter Number of Total Doses.

Container Units*

Doses

→ Select from drop-down menu.

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. Details required on the APHIS Form 2008 should be included: Establishment #, Product Code, Serial #, 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 No Test and/or Inconclusive results. See VS Memorandum 800.53. Expiration date of the serial is also requested.

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

*The information in the test data file must be legible on the screen.

NOTICE: If using a PDF fillable form, such as the fillable APHIS 2008, the user must lock or "flatten" the PDF document after completing the form fields to ensure that the 2008 Report generated in the NCAH Portal accurately displays the data entered, the document can be viewed on all devices, and to prevent other users from manipulating or editing the information. The document uploaded to the NCAH Portal cannot be altered once it has been uploaded; however, flattening the form prior to uploading will prevent any user from saving the document and editing the form fields. Follow the steps below to "flatten" a completed PDF fillable form:

1. Open fillable form.
2. Add appropriate data.
3. Select File.
4. Select Print.
5. Select the PDF printer. (e.g. the Adobe PDF printer is installed automatically with Adobe Acrobat)
6. Select OK.
7. Specify location on your computer/network to save the printed, "flattened" version of the form.
8. Select Save.
9. Upload the printed, "flattened" version of the form to the NCAH Portal.

INVENTORY FOR RELEASE

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

- **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

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MISC

Misc

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

Letter Remove Browse ...

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

Remarks 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.

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. ***NOTE:** Serials previously audited by the CVB that are being resubmitted by the licensee or permittee should have the audit, with signature, as well as any applicable comments attached here.

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

REVIEWING YOUR ENTRY

Select this button to Edit the submitted form.

****You can only Edit if CVB has not received the form.**

Select this button to Submit the form to CVB. ****Only those with the Liaison, Alternate Liaison or Serial Release role will see this button.**

The screenshot shows a table with the following content:

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

Below the table are five buttons: Edit (blue), Clone (blue), Submit To CVB (green), Delete Submission (red), and Return to Dashboard (grey). Red arrows point from text annotations to the Edit, Clone, Submit To CVB, and Delete Submission buttons.

Select this button to Clone the submitted form.

Select this button 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.

To see status updates of the 2008, including the assigned APHIS Disposition see the Account Details page in the NCAH Portal.

[Click here to go to the Account Details user guide.](#)

NCAH PORTAL CVB QUICK REFERENCE

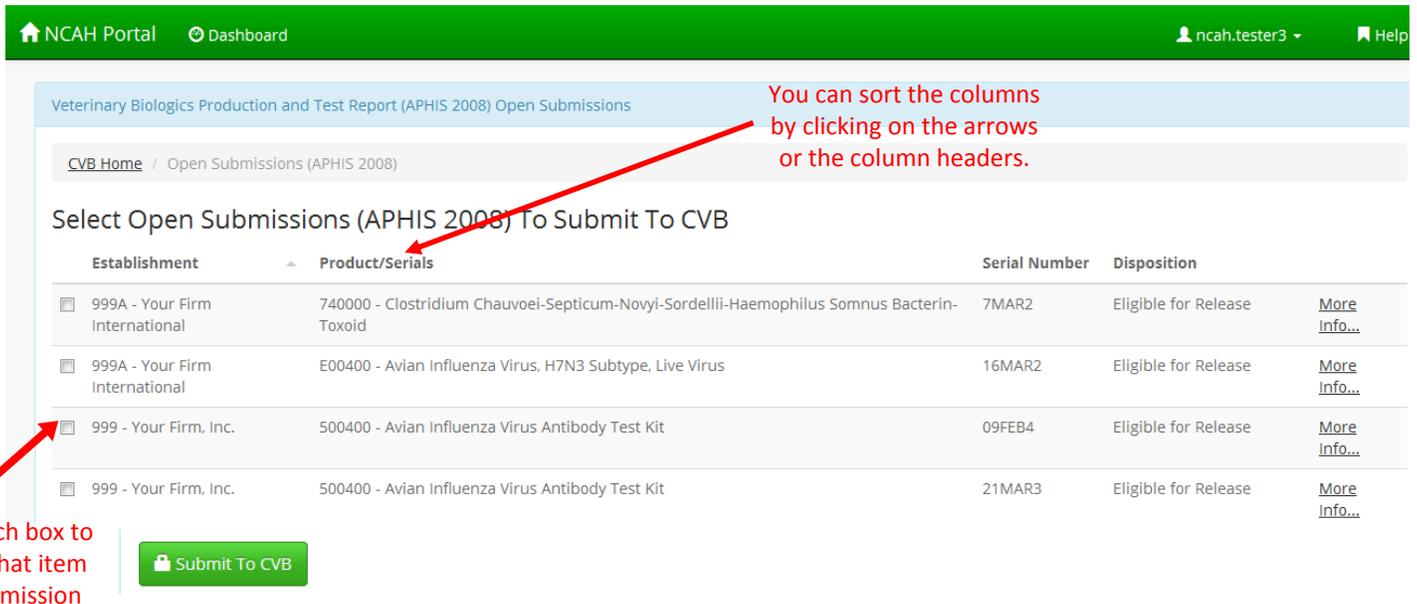
General Guide for Veterinary Biologics Production and Test Report (APHIS 2008)

Submitting Multiple 2008s to the CVB

To submit 2008s directly to the CVB, click 'View Draft Submissions (APHIS Form 2008 to CVB)' on the Dashboard.



Any 2008 records may be submitted together. Each record will be reviewed and processed individually at the CVB. Select any record's check box, and then click Submit to CVB. At this point a record cannot be edited or deleted. If there are discrepancies found, contact the CVB for the record to be audited (if not processed already).



To view status updates including when a 2008 is on Test or if the 2008 has been completed, see the Account Details page in the NCAH Portal. [Click here to go to the Account Details user guide.](#)