

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

Where were changes made in the 1/7/2025 version?

1. Page 8, clarification added to the steps on how to flatten the 2008 form prior to uploading.
2. Updated screenshots and links throughout the document.

Where were changes made in the 10/8/2020 version?

1. Page 6, clarifying language and a screenshot were added for a new requirement for three Dispositions by Firm. If the Disposition of "Other-Prelicense", "Other-Outline of Production Change" or "Other-Technology Transfer" is selected it is now required to select a Reviewer's name. A new field with a drop-down menu to select the Reviewer's name will now appear when one of those Dispositions is chosen.

Where were changes made in the 1/17/2020 version?

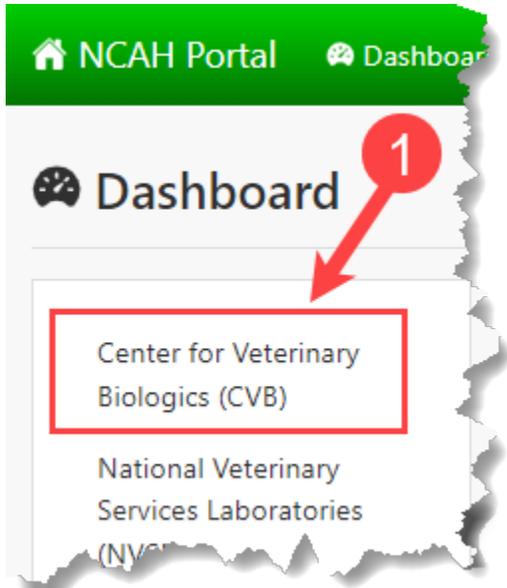
1. Updates were made to eAuthentication account references

Where were changes made in the 9/13/2019 version?

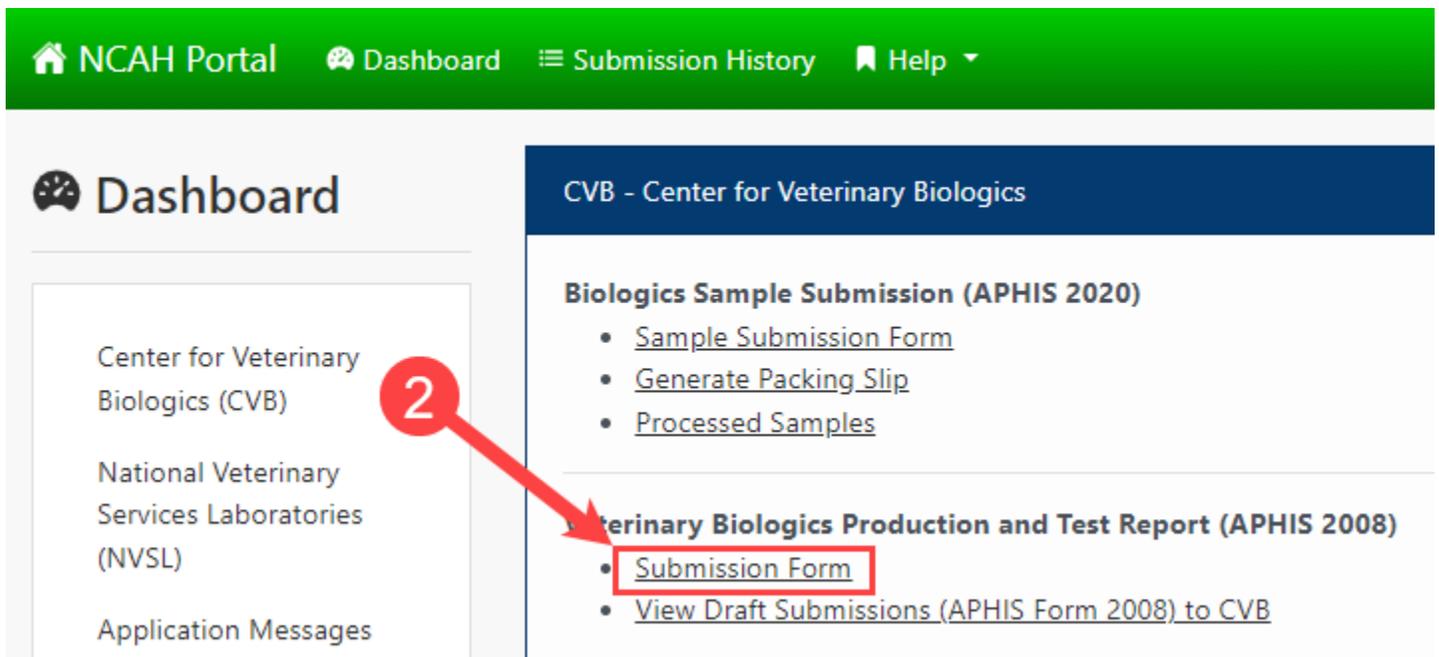
1. Page 3, clarifying language was added regarding entry of data in the Product Code field

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For APHIS Form 2008 submissions, start by entering the Center for Veterinary Biologics (CVB) section of the NCAH Portal and then navigating to the Veterinary Biologics Production and Test Report (APHIS 2008) Submission Form.



Any user with a verified identity account can enter 2008 information. Only users with the *Liaison, Alternate Liaison, or Serial Release Role* may submit to the CVB. [Click this link to see a chart of all roles and privileges.](#)



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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SERIAL INFORMATION

Fields with a red asterisk (*) are required.

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

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

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information is 0579-0013. The time required to complete this information collection is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0013

Serial Information

Establishment*	<input type="text" value="999 - Your Firm, Inc."/> ▼	Select from drop-down menu
Site Address*	<input type="text" value="123 1st Street, Ames, IA 50010"/> ▼	Select from drop-down menu
Product Code*	<input type="text" value="190520"/> ▼	Select from drop-down menu. Type ahead feature is available. Note: enter only alphanumeric. Do NOT include the decimal point.
Product Name	Rabies Vaccine, Killed Virus, recombinant Auto-populated, based on Product Code	
Serial Number*	<input type="text" value="test1"/>	Enter Serial Number, 20 alphanumeric characters only. NO SYMBOLS.

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. If using the type ahead feature, do NOT include the decimal point.

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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Autogenous or Prescription Product? Check the box if applicable. See VSM 800.69 or 800.213 for guidance

Agents for Autogenous or Prescription Product

Not Selected
Showing all 472

Selected
Empty list

Enter text to search "Not Selected" list

Enter text to search "Selected" list

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

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 select 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 should be entered in the Remarks Section. Identification of the organisms/agents should be sufficient for determination of causative agent for first serials, or genus and species for bacteria, fungus, and mycoplasmas; family for Virus for all subsequent serials.

First Serial - Select Y [yes] 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).

≤ 50 Containers - Select Y [yes] if the serial has less than or equal to 50 containers/vials produced for manufacturing purposes.

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.

Is this a subserial?

Related Subserials*

+ ADD Subserial

Is this a Subserial? – Optional field to denote a serial as one of multiple subserials produced (9 CFR 101.3(i)).

Upon this selection the “**Related Subserials**” field will appear. Enter each subserial that make up the total quantity of the completed product. This only needs to be filled out on one record (usually on the 1st or parent record).

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ESTABLISHMENT DISPOSITION

Establishment Disposition

Disposition by Firm*

Eligible for Release

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.*

Establishment Disposition	Criteria for Selecting Firm disposition
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	Acknowledgement of an <u>unreleased</u> serial that has been destroyed by the firm. <i>NOTE: It is not an intent to destroy.</i>
	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.
Reprocess & Retest	This is used to request permission to reprocess a serial.
	Enter the new Product Code and Serial Number(s) to identify the reprocessed serial(s), as specified in VSM 800.62.
Other - Expiration Date Correction	Acknowledges the Firm's expiration date correction. <i>NOTE: this is not an extension of dating</i>
Other - Extension of Dating	This is used to request additional dating on remaining inventory nearing expiration, provided that assurances of continued potency are provided and in accordance with 9 CFR 114.14.
	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	Information submitted to CVB on a serial or bulk material that already has an APHIS disposition. It may be at the request of CVB, or additional information provided by the firm. May or may not impact marketability of the serial.
Other - Inventory Correction	Acknowledges the Firm's inventory correction.
Other - Rebottling	This is used to request permission to rebottle a serial.
	Enter the new Product Code and the Serial Number(s) to identify the rebottled serial(s) as specified in VSM 800.62 and 9 CFR 114.17.

List continued on next page

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ESTABLISHMENT DISPOSITION (continued)

Disposition by Firm – continued from previous page

Establishment Disposition	Criteria for Selecting Firm disposition
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 CVB-WI-0147.
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.
Other - Prelicense	APHIS Form 2008s for prelicense serials should be submitted prior to requesting authorization from CVB Policy, Evaluation, and Licensing (PEL) to submit samples. Submitting the prelicense 2008s does not give authorization to submit prelicense serials for testing. You should have an authorization number from the CVB-PEL to submit prelicense samples. Refer to User Guide 21 .
	**Select the Reviewer’s name that you are working with on the licensing of the product from the drop-down list in the Reviewer field that appears when you select "Other-Prelicense"
Other - Outline of Production Change	When a licensee or permittee is directed by their licensing reviewer to provide a serial(s) for confirmatory testing to support a proposed Outline of Production change, this should be chosen. Refer to User Guide 21 .
	**Select the Reviewer’s name that you are working with on the outline change from the drop-down list in the Reviewer field that appears when you select "Other-Outline of Production Change"
Other – Technology Transfer	When a licensee or permittee is directed by their licensing reviewer to provide a serial(s) for confirmatory testing to support a technology transfer request, this should be chosen. Refer to User Guide 21 .
	**Select the Reviewer’s name that you are working with on the outline change from the drop-down list in the Reviewer field that appears when you select "Other-Outline of Production Change"

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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**This is what the field will look like if a Reviewer's name is required based on your selection for Disposition by Firm.

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. 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.

NOTICE: 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 using Adobe Acrobat:

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

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- In order to complete a submission, the test data file is mandatory for all Firm Dispositions, except: File for Information, For Further Manufacture, Inventory Corrections and Expiration Date Corrections. *NOTE: In some instances, with these dispositions, a test data file may be required by regulations. Always follow all applicable regulations.*
- The information in the test data file must be legible on the screen.
- Do NOT attach anything other than Test Data. The information you attach here will be shown on Page 2 of the 2008 Report generated by the NCAH Portal after market authorization. [Click here to see an example.](#)

INVENTORY FOR RELEASE

Inventory for Release

Note: Use a separate line for each size container.

# Containers*	Container Size*	Total	
5000	1	5,000.00	<input type="button" value="+"/>

Container Units* Doses ▼

	<u>Total Containers</u>	<u>Total Doses</u>
Totals	5,000	5,000.00

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.

If the user selects "Autogenous, 1st Serial" in the Serial Information section, then the Inventory break down changes to only entering "Number of Total Doses".

Inventory for Release

Number of Total Doses*

Container Units* Doses ▼

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MISC

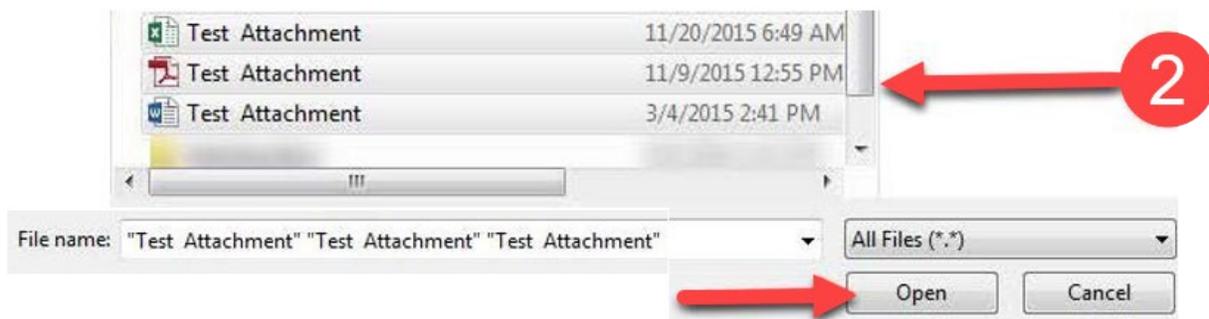
Misc

Letter(s)

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

VBI #

Note: Format must be ##-###



Misc

Letter(s)

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

Letter(s) - If any supplemental information is needed to support consideration of release, attach one or more files. This information may include bench records or referenced letters. DO NOT ATTACH correspondence that needs response by the CVB other than release of serial. Multiple attachments may be uploaded in a single action.

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.*

VBI # - when testing has been conducted in response to a CVB investigation (VBI), CVB-IC will provide the VBI number (in the format of XX-XXX).

Related Submissions (Mail Log #) – when applicable, a mail log number (either initiated by the establishment through the NCAH Portal, or by the CVB- PEL or IC) may be entered here in lieu of attaching letters to the submission. Multiple mail log numbers may be entered.

Remarks - Include any pertinent information not captured elsewhere in the submission. However, please note special characters, such as the apostrophes or quotes as copied from Microsoft Word should be removed from this section (examples include “”, ‘, °, μ).

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REVIEWING YOUR ENTRY

Action	Timestamp
Submission Entered	Aug-14-2024 02:00 PM CDT

Edit
Clone
Submit To CVB
Delete Submission
Return to Dashboard

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

Select this button to Edit **** You can only Edit if CVB has not received the form****

Select this button to Clone the submission form

Select this button to Delete the submitted

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.

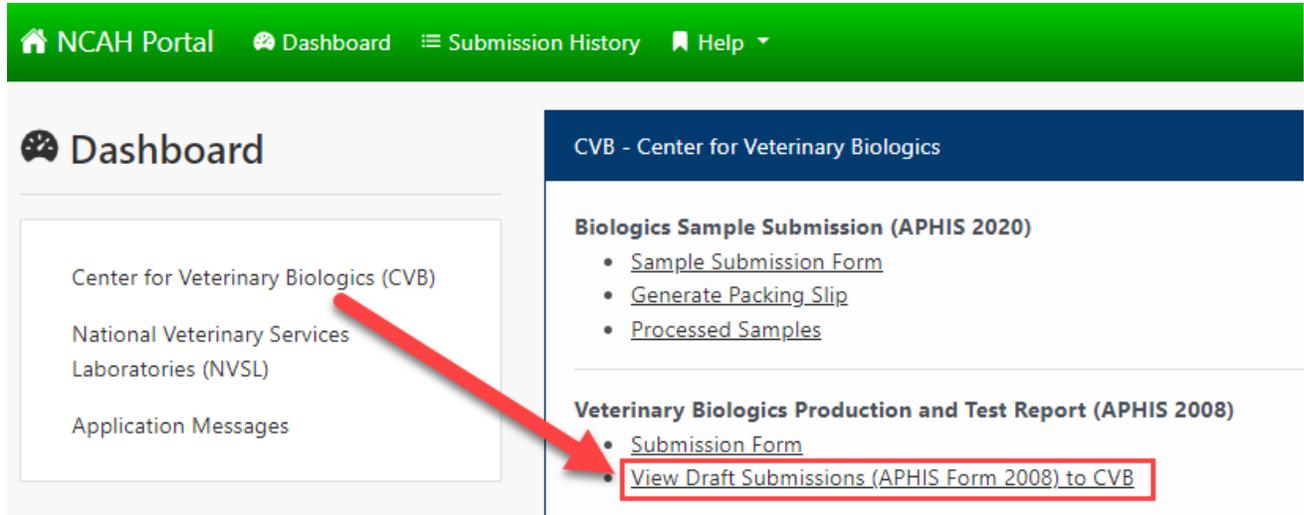
Go to the next page to see how to submit multiple 2008s to the CVB.



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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).

Veterinary Biologics Production and Test Report (APHIS 2008) Open Submissions

[CVB Home](#) / [Open Submissions \(APHIS 2008\)](#)

You can sort the columns by clicking on the arrows or the column headers

Select Open Submissions (APHIS 2008) To Submit To CVB

Establishment	Product/Serials	Serial Number	Disposition
<input type="checkbox"/> 999A - Your Firm International	740000 - Clostridium Chauvoel-Septicum-Novyi-Sordellii-Haemophilus Somnus Bacterin-Toxoid	7MAR2	Eligible for Release More Info...
<input type="checkbox"/> 999A - Your Firm International	E00400 - Avian Influenza Virus, H7N3 Subtype, Live Virus	16MAR2	Eligible for Release More Info...
<input type="checkbox"/> 999 - Your Firm, Inc.	500400 - Avian Influenza Virus Antibody Test Kit	09FEB4	Eligible for Release More Info...
<input type="checkbox"/> 999 - Your Firm, Inc.	500400 - Avian Influenza Virus Antibody Test Kit	21MAR3	Eligible for Release More Info...

Click each box to select that item for submission

To view status updates including the assigned APHIS Disposition, when a 2008 is on Test or if the 2008 has been completed, see your Submission History (CVB) page in the NCAH Portal.
[Click here to see the Submission History \(CVB\) and Account Details User Guide.](#)