U.S. Food and Drug Administration

Accredited Third-Party Certification Program Portal

Instructions for a Certification Body to Manage Accreditation Status in the Program

Table of Contents

1 Introduction

This document is intended for use by Accredited Third-Party Certification Bodies (CBs) – accredited by recognized Accreditation Bodies (ABs) – participating in FDA's Accredited Third-Party Certification Program.

This document provides detailed instructions on how a CB can use FDA's electronic portal for the following:

- Create an FDA online account
- Access the CB portal
- Submit supplemental documentation
- Add/Edit/View regulatory audit reports (RAR)
- Add/view certifications
- Manage agents and officers
- Submit reports and notifications

2 Overview of FDA Portals for Electronic Accredited Third-Party Certification Program Submissions

FDA Industry Systems (FIS)

FIS is an electronic portal which facilitates submissions to FDA; it includes registration, listing, and other notifications. FIS is available 24 hours a day, seven days a week. It provides general entry to a series of systems which allow electronic submissions to FDA.

FDA's Unified Registration and Listing System (FURLS)

FURLS is a specific component of FIS. Persons with an FDA account ID and password for the FIS electronic portal can use the FURLS systems to exchange information with the Agency.

Adding Attachments

Users of the FURLS system may need to provide supporting documentation to the Agency while working in the portal. This documentation can be provided by attaching an electronic file (e.g., reports, schematics, or other supporting information).

The electronic Accredited Third-Party Certification Program system supports the following document attachment types:

- .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

The maximum file size allowed is 50 MB. Relevant sections of this document will identify opportunities for adding attachments.

Supported Browsers

FURLS may be accessed using browsers (i.e., Firefox, Chrome, and Internet Explorer). Please visit the "Systems Requirements" section of the FURLS page for a list of approved browsers and browser versions. The "Systems Requirements" section can be found by navigating to https://www.access.fda.gov/.

Note: When navigating the CB portal, use the system-provided buttons (i.e., "Previous" or "Next") which can be found throughout the system.

Obtain an FDA Account through FDA FIS Electronic Portal

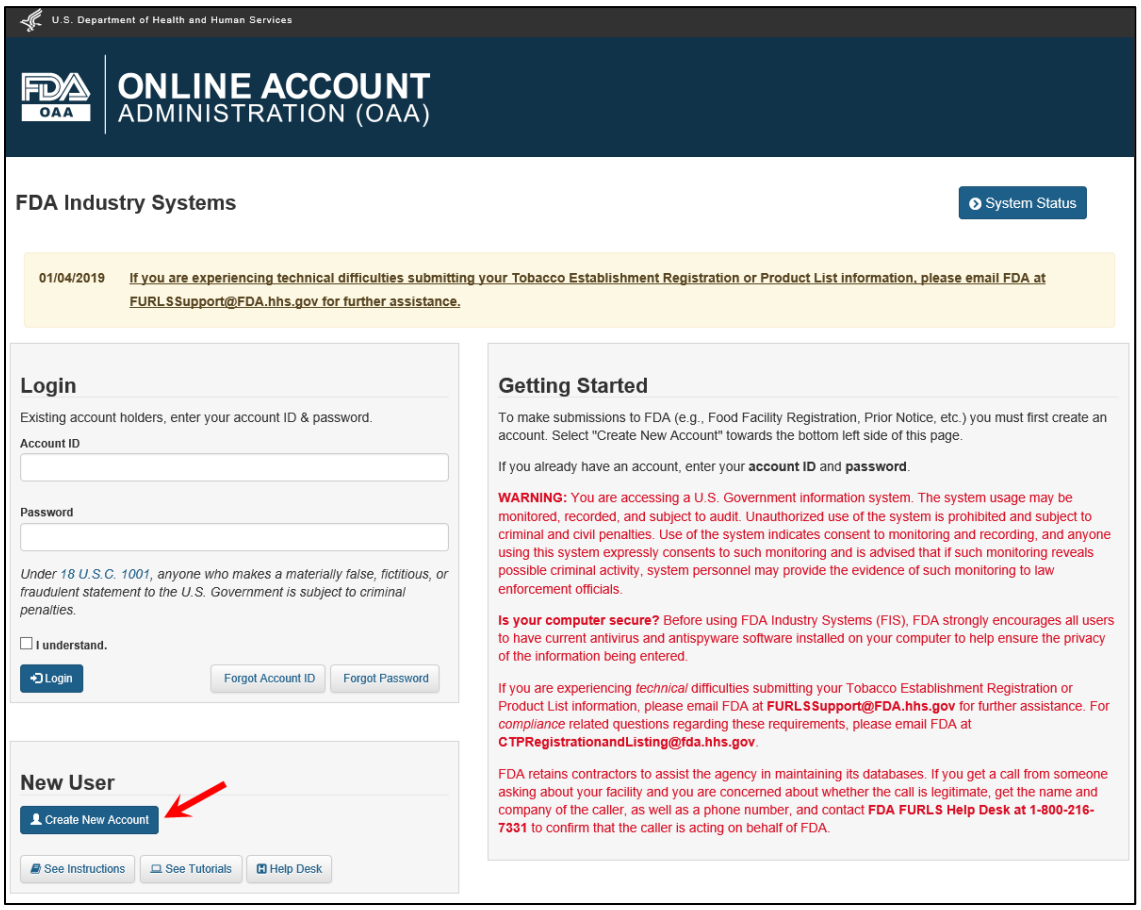
Each person who uses FURLS needs a personal FDA account ID and password, which can be obtained through the FDA FIS portal. To access the FIS electronic portal, go to https://www.access.fda.gov/oaa/. Follow the instructions for obtaining an FDA account ID and password below. Once the account has been created you will be able to log into the “Online Account Administration” (OAA) system and gain access to FURLS.

3 Create an FDA Online Account

To log into the “Online Account Administration” (OAA) system and gain access to FURLS, you will need to create an FDA online account.

To create an FDA online account, go to https://www.access.fda.gov/oaa/. Click on the “Create New Account” button on the “Online Account Administration (OAA) FDA Industry Systems” page (Figure 3.1). You will be directed to the “Create New Account” page.

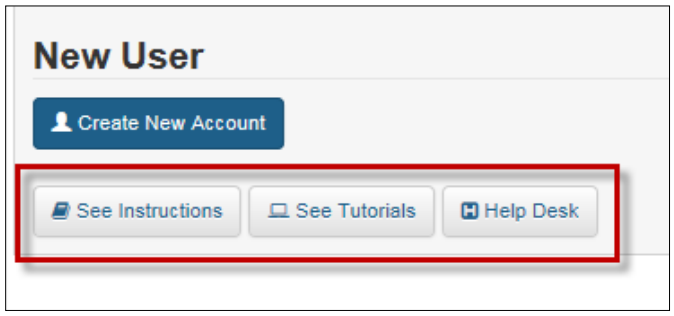
Figure 3.1 – FDA OAA Page



Note: The following buttons are displayed on the “OAA” landing page and direct you to informational pages on fda.gov, as indicated. You are not required to select any of these buttons to complete the application. These buttons are for your reference (Figure 3.2).

- **System Status –** Directs you to the “FDA Industry Systems – System Status” page which displays the current system status, system status explanations, and the system status history
- **See Instructions and See Tutorials –** Directs you to the “FDA Industry Systems User Guide: Account Management” page, which includes general information (i.e., step-by-step help guides and account management Q&A)
- **Help Desk –** Directs you to the “FDA Industry Systems” page, where FDA Help Desk contact information can be found

Figure 3.2 – Additional Buttons

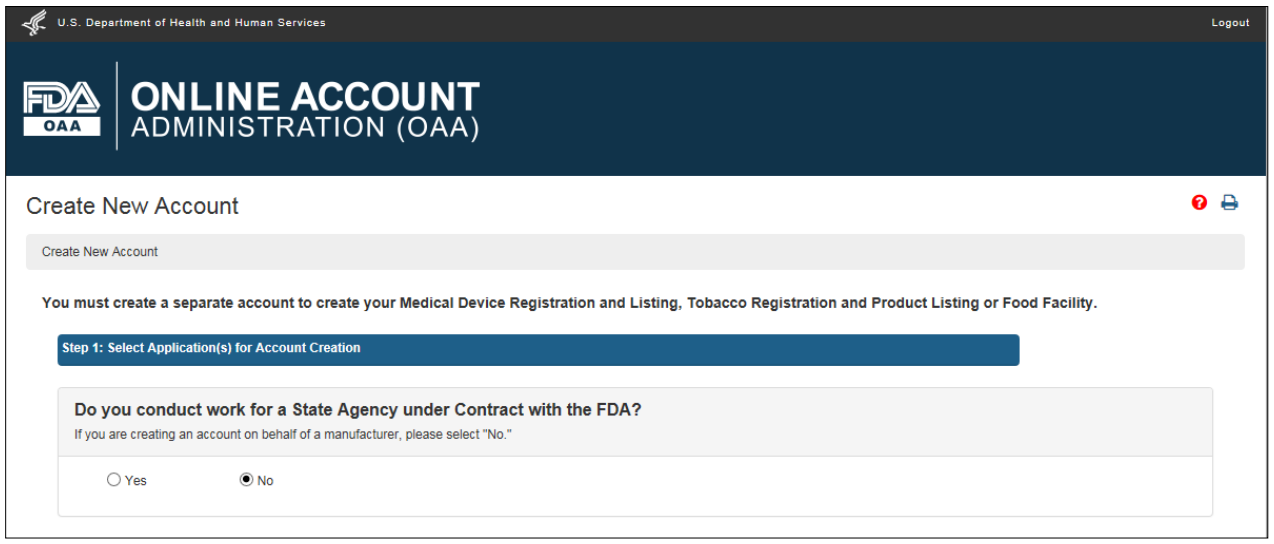


Click the “Create New Account” button:

The system displays the “Create New Account” page (Figure 3.3). You will see “Step 1: Select Application(s) for Account Creation.” Two radio buttons are displayed: “Yes” and “No.” Note that “No” is selected by default.

Note: Leave the default value of the selected radio button as “No.” The workflow created by selecting “Yes” directs you to a program that is not within the scope of this document.

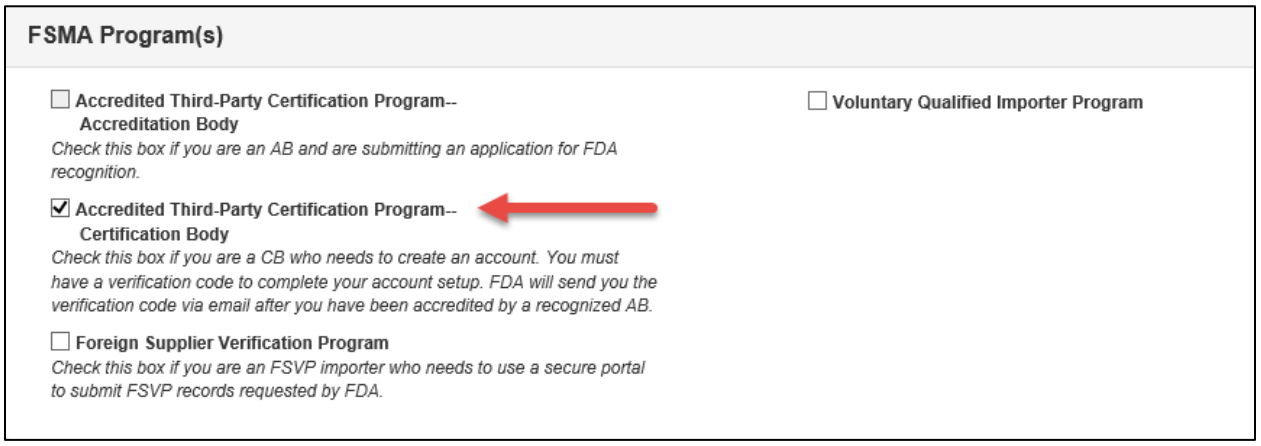
Figure 3.3 – Create New Account – Step 1: Select Application(s) for Account Creation



The system will display various FDA programs available in OAA.

Click the “Accredited Third-Party Certification Program – Certification Body" checkbox under the “FSMA Program(s)” section (Figure 3.4) and continue to the next step by clicking the “Continue” button at the bottom of the page.

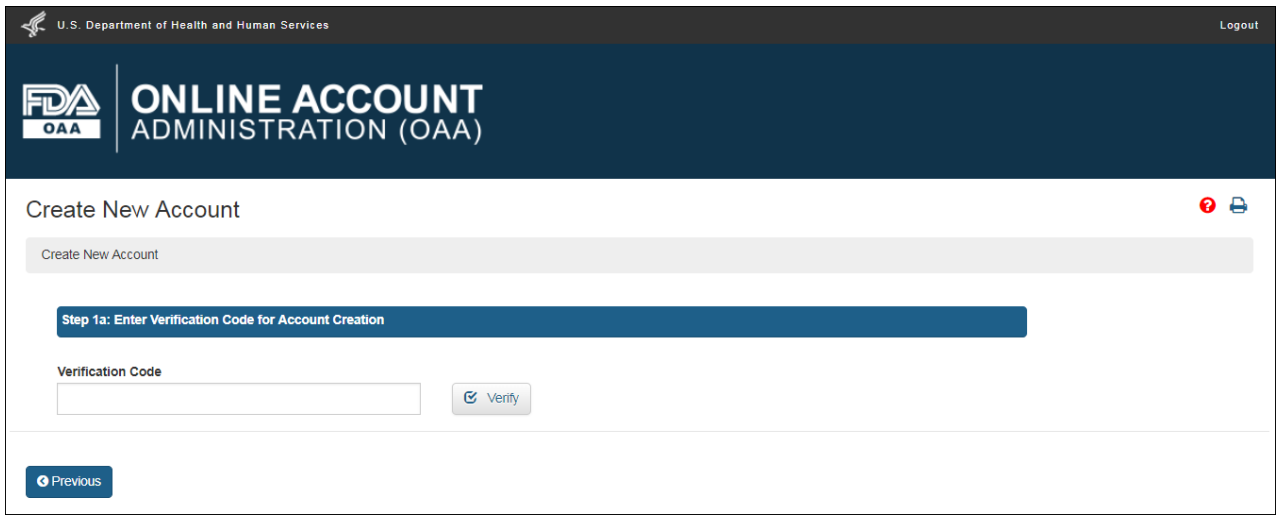
Figure 3.4 – Create New Account – FSMA Program(s)



The system will display the “Step 1a: Enter Verification Code for Account Creation” screen. You will receive a system-generated e-mail containing the verification code once the AB submits the CB accreditation via FURLS.

Enter the verification code in the box and click the “Verify” button. After the code is verified you will be able to create an account for accessing the CB portal (Figure 3.5).

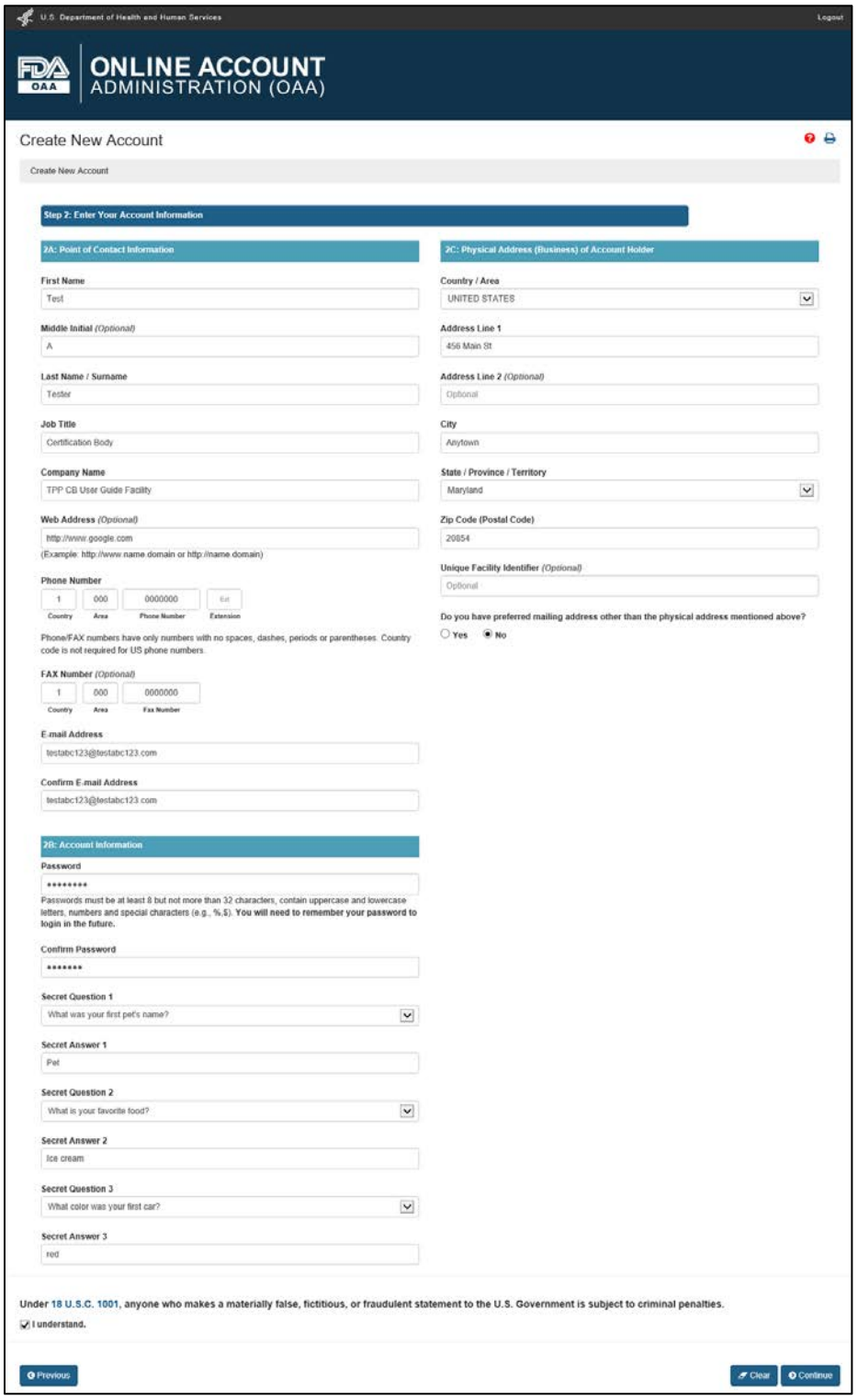
Figure 3.5 – Step 1a: Enter Verification Code for Account Creation



The system displays the “Step 2: Enter Your Account Information” screen. The CB applicant needs to complete the data entry fields in the “Point of Contact Information,” “Account Information,” and “Physical Address (Business) of Account Holder” sections (Figure 3.6).

Note: Some information in this section will be pre-filled based on the information provided by your recognized AB during the accreditation process.

Figure 3.6 – Create New Account – Step 2: Enter Your Account Information

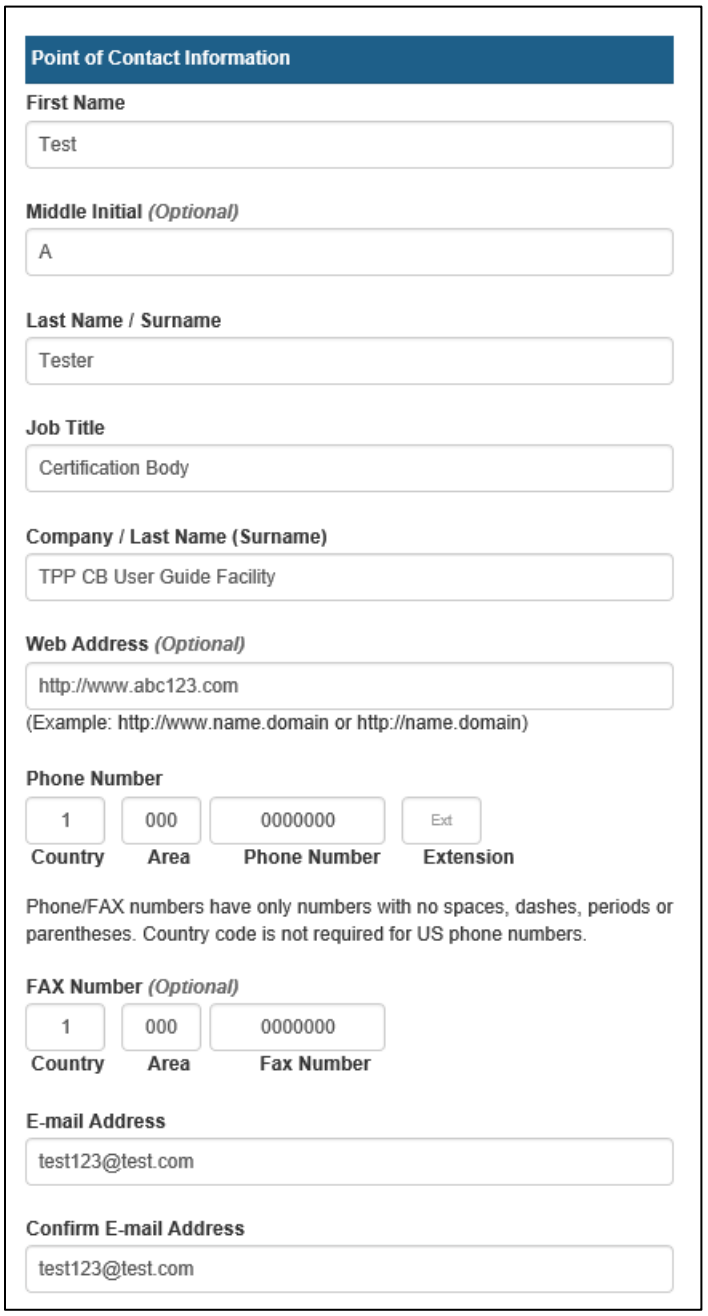


The following navigation buttons can be found throughout the system:

- **Previous –** Returns to the previous screen
- **Clear –** Clears all input entered on the specific page/section
- **Continue –** Proceeds to the next screen/step in the account creation process

Note: All fields are required, unless indicated as “Optional.” Complete each of the data fields in “Step 2A: Point of Contact Information” (Figure 3.7).

Figure 3.7 – Step 2A: Point of Contact Information



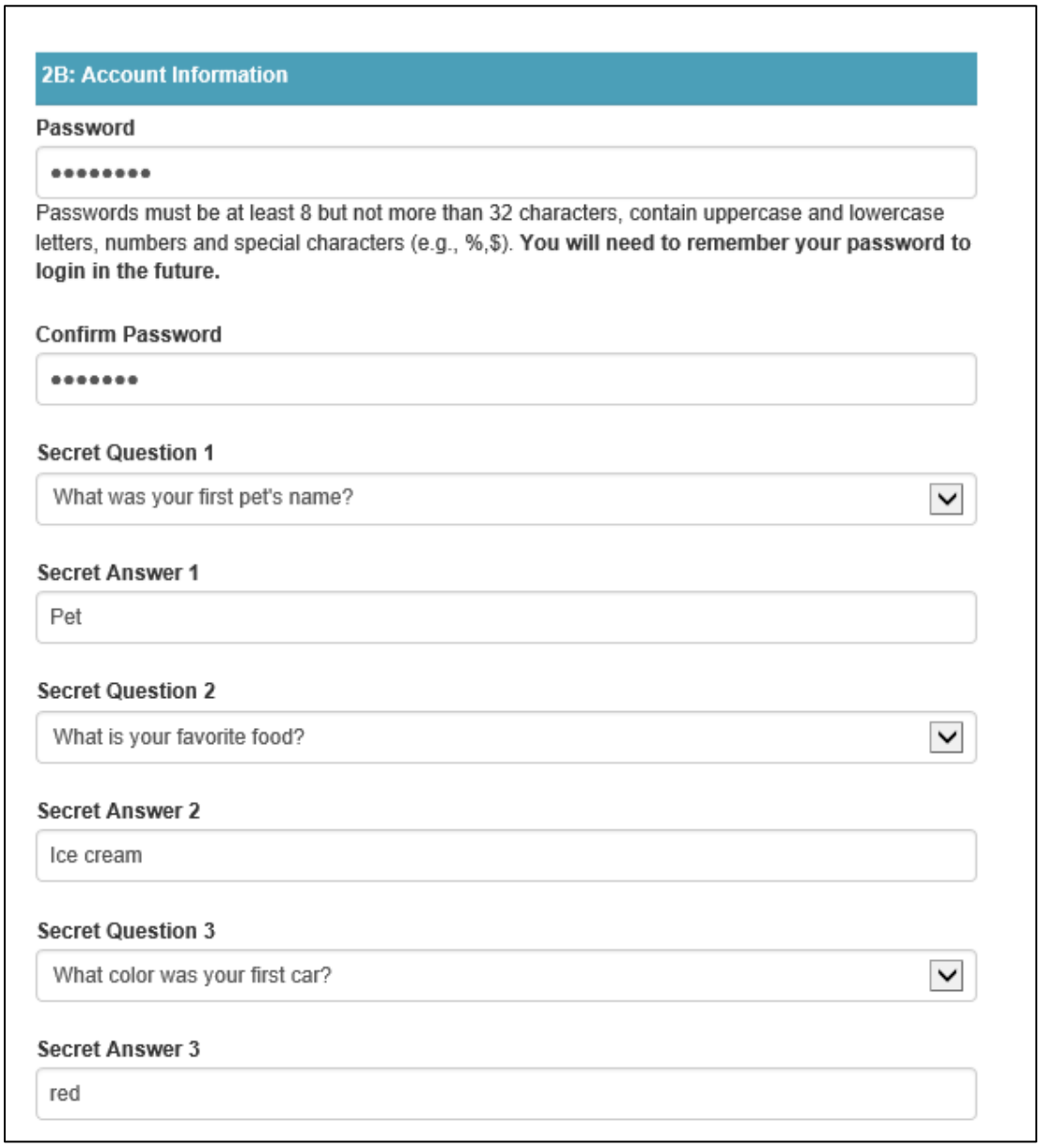
The data fields in the “Step 2A: Point of Contact Information” section include:

- **First Name –** The first name of the Point of Contact
- **Middle Initial (Optional field) –** The first letter of the Point of Contact’s middle name
- **Last Name/Surname –** The last name of the Point of Contact
- **Job Title –** The job title of the Point of Contact
- **Company Name –** The name of the company the Point of Contact represents
- **Web Address (Optional field) –** The URL of the company

- **Phone Number (Country/Area/Phone Number/Extension) –** The telephone number of the Point of Contact
  - "Country" is the country code.
  - "Area" is the area code.
  - "Phone Number" is the phone number.
  - "Extension" is the local phone extension to dial the Point of Contact, if applicable.
- **Fax Number (Country/Area/Fax Number) –** The fax number of the Point of Contact
  - "Country" is the country code.
  - "Area" is the area code.
  - "Fax Number" is the phone number.
- **E-mail Address –** The e-mail address of the Point of Contact
- **Confirm E-mail Address –** The re-entry of the Point of Contact's e-mail address
  Note: The entry must match the "E-mail Address" field.

Once you have completed "Step 2A," proceed to "Step 2B: Account Information" (Figure 3.8).

Figure 3.8 – Step 2B: Account Information



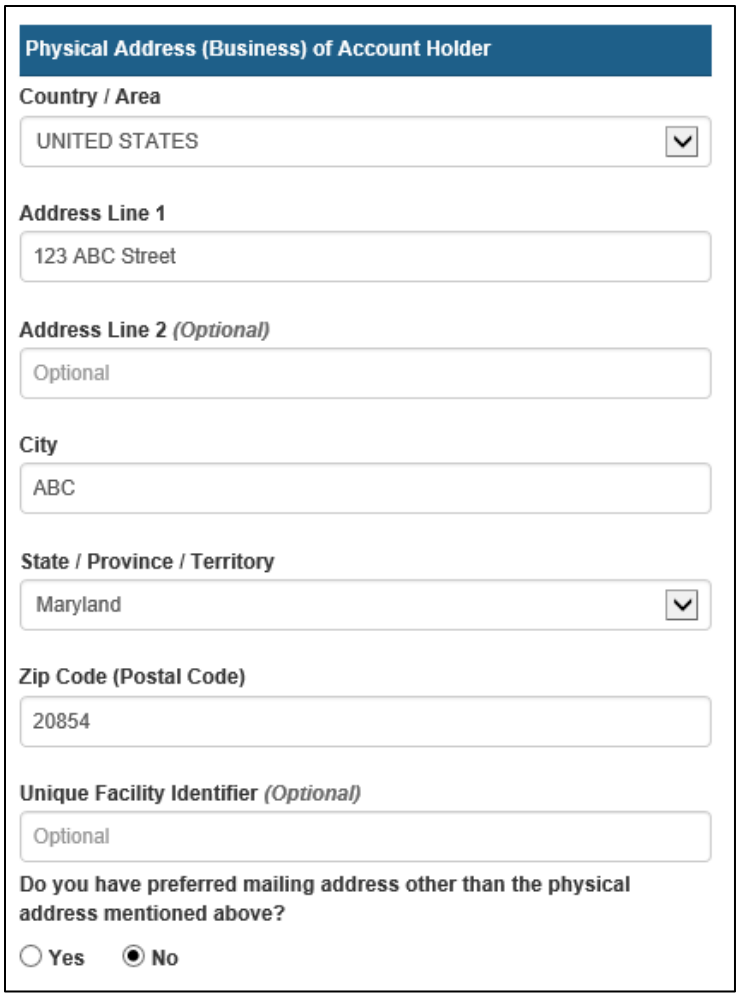
The data fields in “Step 2B: Account Information” include:

- **Password –** Use this field to create the password for your account. Use this password each time you log into the system.
- **Confirm Password –** Re-enter the password in the “Password” field. The entry must match the “Password” field.
- **Secret Question 1 –** This is the first secret question used to protect the account. Select a question from the dropdown list.
- **Secret Answer 1 –** This is the answer to the first secret question. Enter your response to the question selected in “Secret Question 1.”
- **Secret Question 2 –** This is the second secret question used to protect the account. Select a question from the dropdown list.
- **Secret Answer 2 –** This is the answer to the second secret question. Enter your response to the question selected in “Secret Question 2.”

- **Secret Question 3 –** This is the third secret question used to protect the account. Select a question from the dropdown list.
- **Secret Answer 3 –** This is the answer to the third secret question. Enter your response to the question selected in "Secret Question 3."

Once you have completed "Step 2B," proceed to "Step 2C: Physical Address (Business) of Account Holder" (Figure 3.9).

Figure 3.9 – Step 2C: Physical Address (Business) of Account Holder

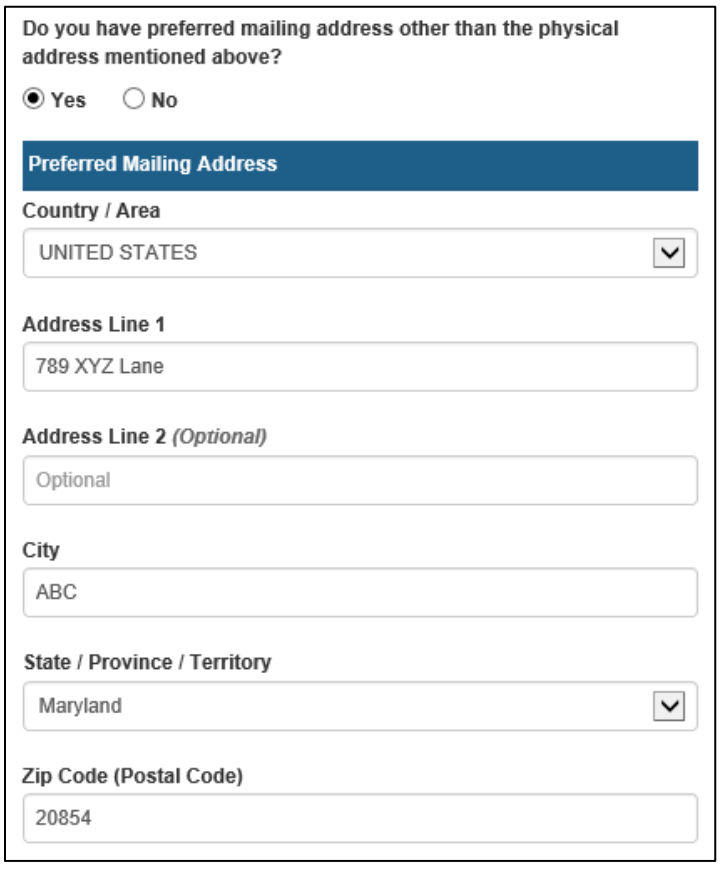


The data fields in "Step 2C: Physical Address (Business) of Account Holder" include:

- **Country/Area –** The country/area where the business is located
  Select a country/area from the dropdown list
- **Address Line 1 –** The address where the business is physically located
  This includes the number, street, quadrant, etc.
- **Address Line 2 (Optional field) –** The field to enter additional information about the physical location of the business
  This may include a suite or apartment number, if applicable.
- **City –** The city where the business is physically located
- **State/Province/Territory –** The state/province/territory where the business is physically located
- **Zip Code (Postal Code) –** The zip code (domestic) or postal code (foreign) where the business is physically located

- **Unique Facility Identifier (Optional field) –** This may be a DUNS number or FDA Establishment Identifier (FEI).
- **Do you have preferred mailing address other than the physical address mentioned above? –** Click the "Yes" or "No" radio button to answer this question.
    - If you select "No," click the checkbox for "I understand" at the bottom of the page (Figure 3.11). The physical address will be used as the mailing address.
    - If you select "Yes," "Section 2D: Preferred Mailing Address" will display. Complete the required information for the Preferred Mailing Address to proceed to the next step (Figure 3.10). The address entered in Section 2D will be used as the mailing address.

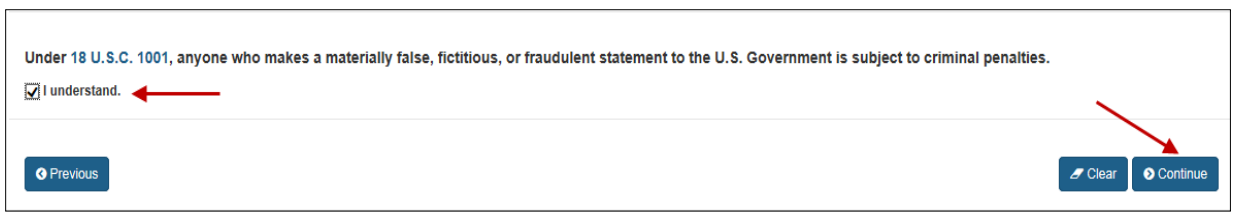
Figure 3.10 – Step 2D: Preferred Mailing Address



Click the checkbox for "I understand" at the bottom of the page (Figure 3.11).

Click the "Continue" button after you enter the required account information.

Figure 3.11 – Checkbox

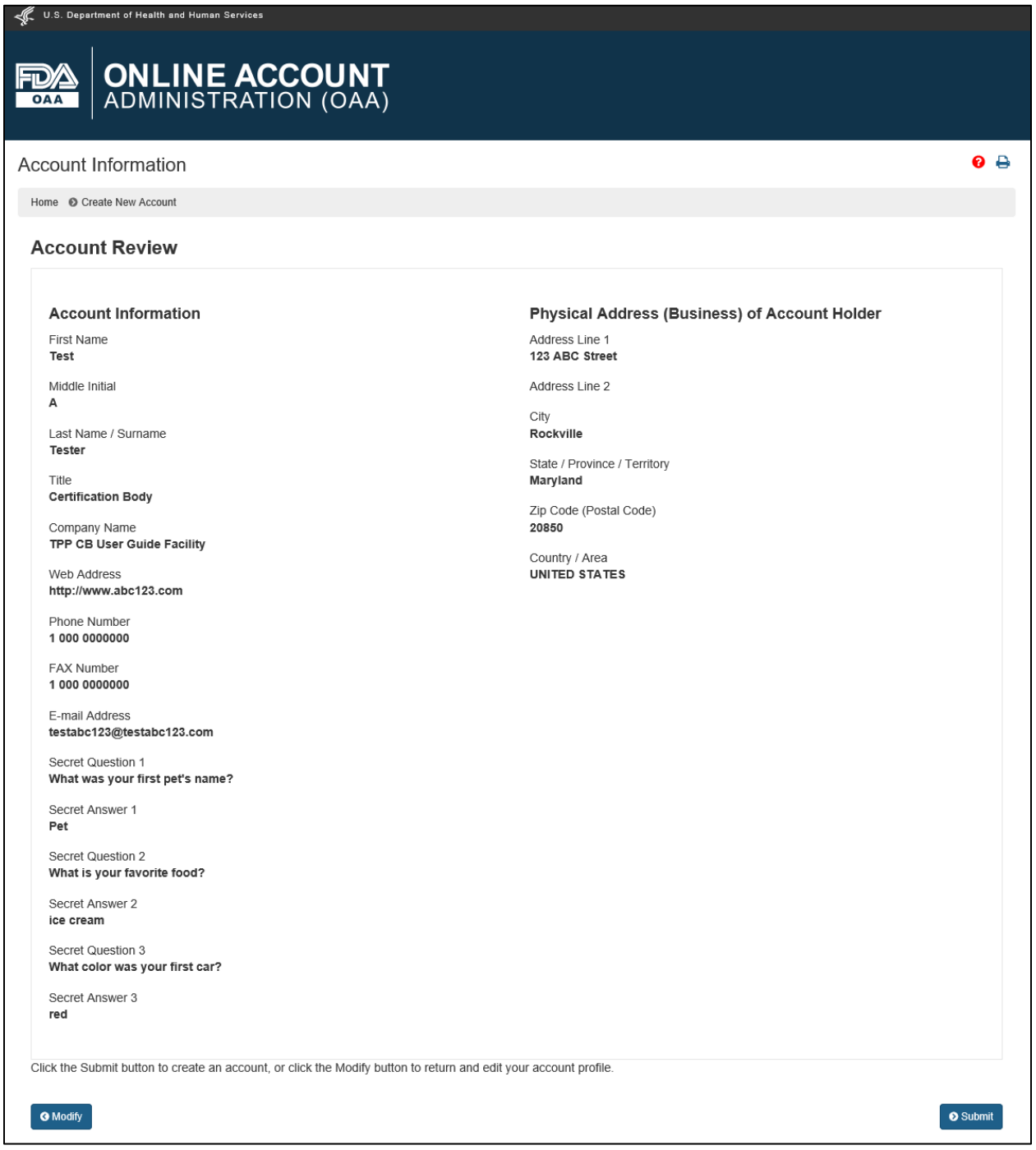


The "Account Review" page will display (Figure 3.12). Review the data entered to ensure it is correct.

Click the "Modify" button to edit the profile information on the previous page.

Click the “Submit” button to complete the process.

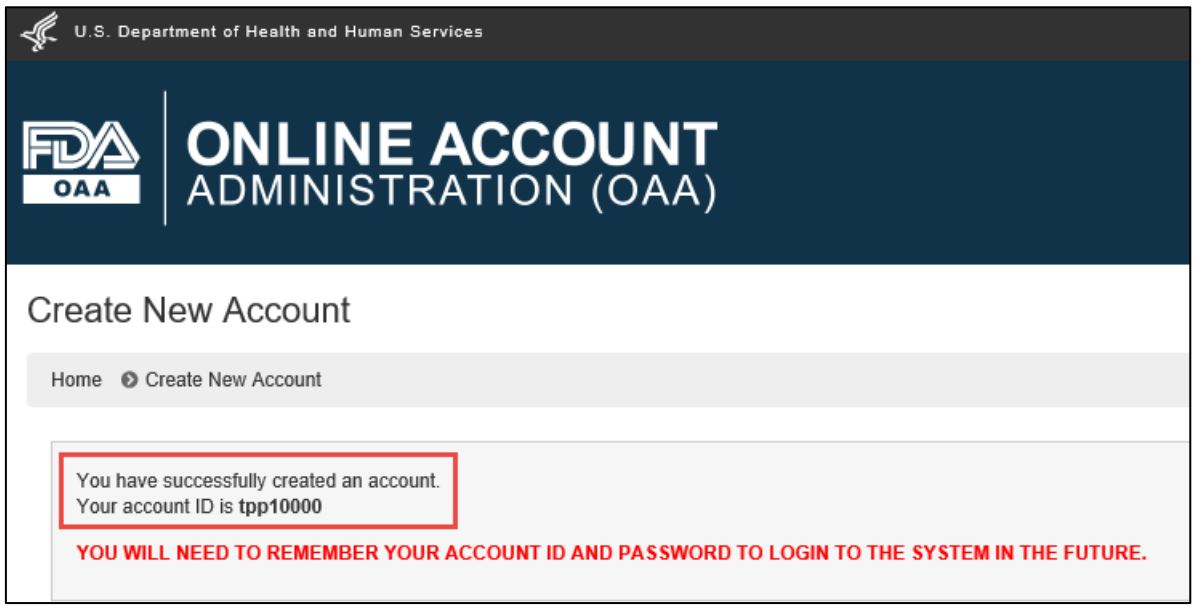
Figure 3.12 – Account Review Page



When you click the “Submit” button, the system will display a message indicating the account was created successfully. The message displays your account ID (Figure 3.13).

You must retain your account ID and password to log into the system in the future.

Figure 3.13 – Successful Account Creation Message Page



Once you create an account, you will receive an e-mail notification sent to the e-mail address entered in the "Account Information" page which contains the account ID (Figure 3.14).

Figure 3.14 – Account Creation Confirmation E-mail

Dear FDA Industry Systems Account User,

Please do not reply to this notification/e-mail.

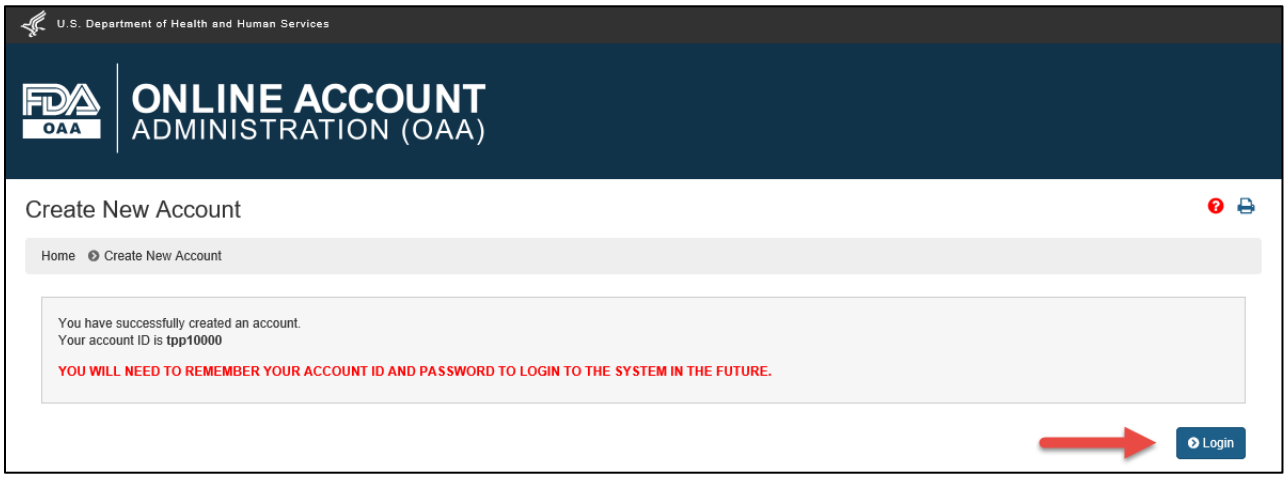
You have created a new account. The Account ID is **tpp10000**.

Thank you for using the FDA Industry Systems website.

If you need further assistance, please go to https://www.access.fda.gov/

Click the "Login" button to access the CB portal (Figure 3.15). Select "Accredited Third-Party Certification Program – Certification Body" under "FSMA Program(s)." Log into the CB portal to ensure the information was successfully submitted to FDA. Subsequent steps for accessing the portal are covered in Chapter 4, "Accessing the CB Portal as an Accredited Certification Body (CB)."

Figure 3.15 – Login



4 Accessing the CB Portal as an Accredited Certification Body (CB)

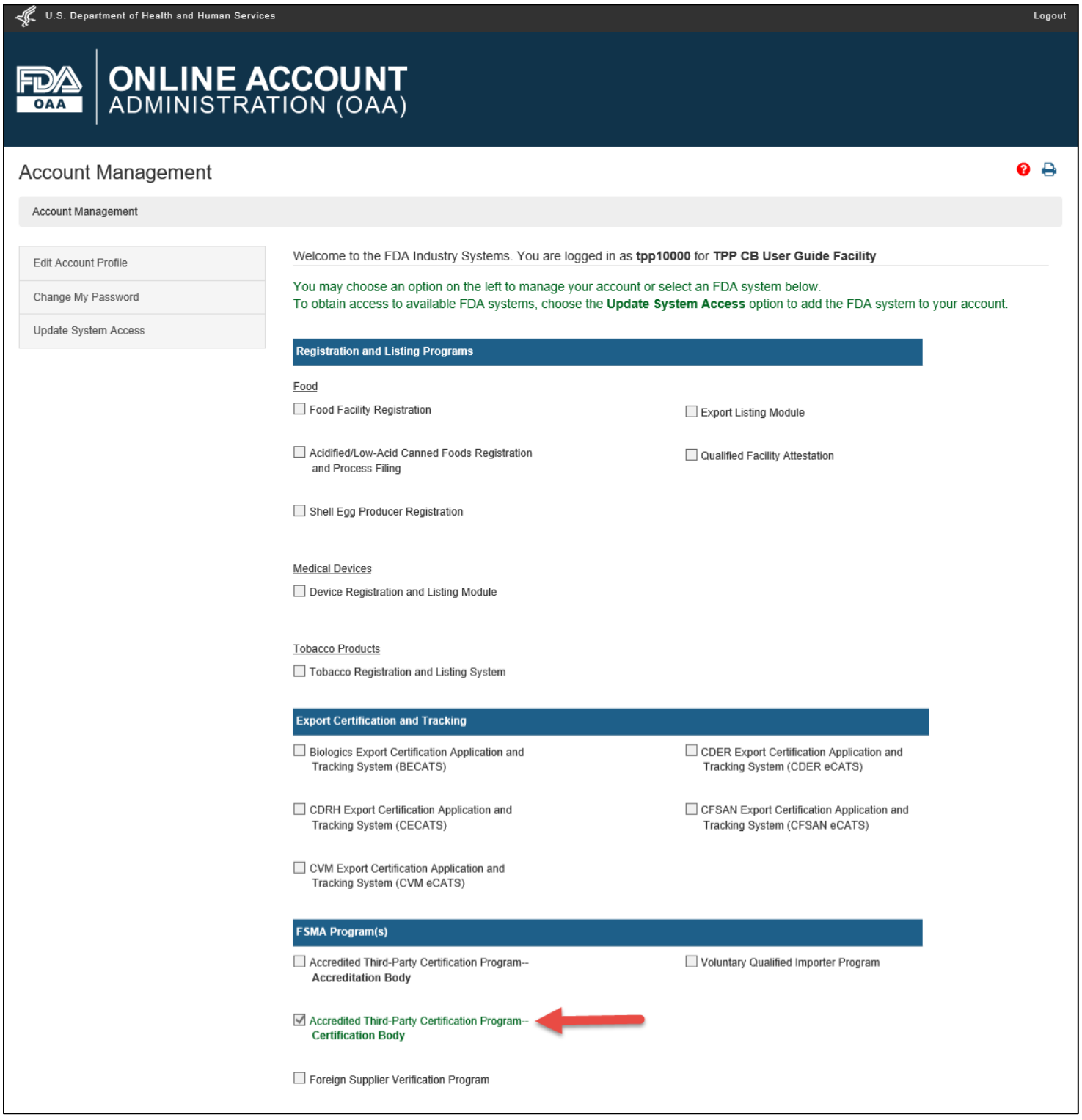
Log into the FDA “OAA” page (https://www.access.fda.gov/oaa/). This is the same page used to begin the process of creating a new OAA account (Figure 4.1).

Figure 4.1 – OAA Login

When you log into the FDA “OAA” page, the FURLS “Account Management” page will display (Figure 4.2).

Go to the “FSMA Program(s)” section and click the hyperlink for “Accredited Third-Party Certification Program – Certification Body.”

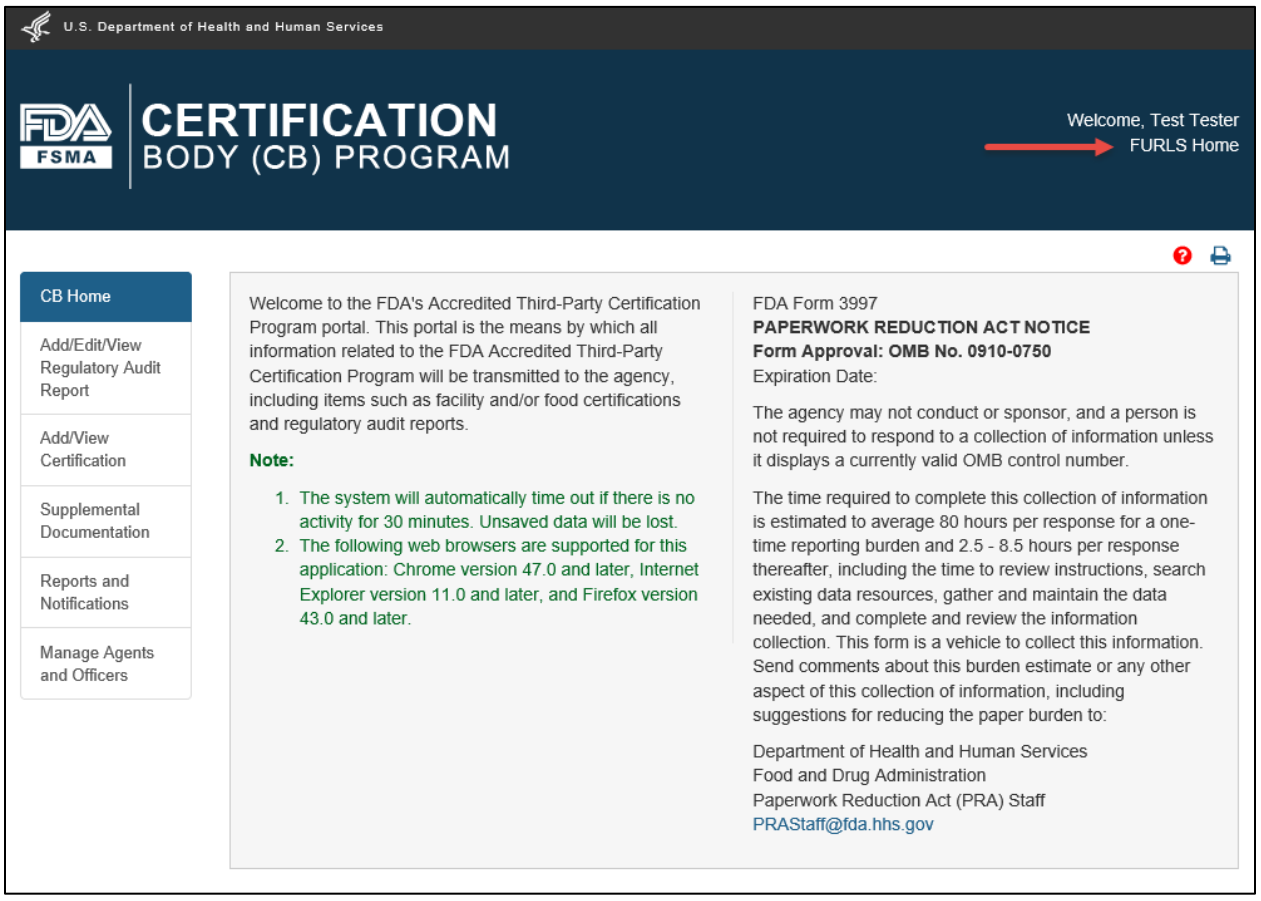
Figure 4.2 – OAA – FURLS Account Management Page



Select the hyperlink for “Accredited Third-Party Certification Program – Certification Body” to navigate to the “CB Home” page. The banner for this page is titled “Certification Body (CB) Program” (Figure 4.3). Each screen in the CB portal has this banner.

The “FURLS Home” link on the right side of the banner will direct you to the FURLS “Home” page, where you may log out.

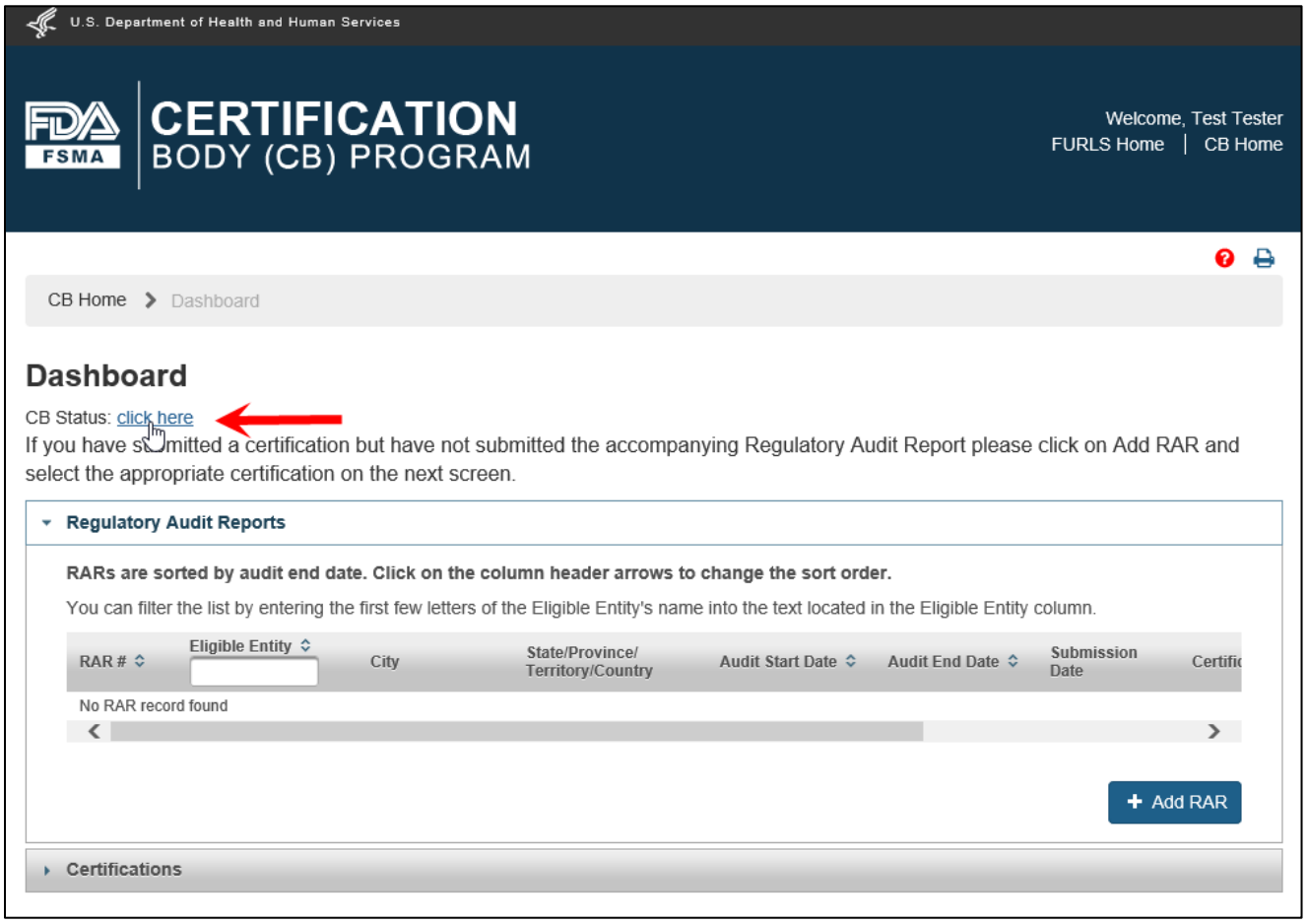
Figure 4.3 – CB Home Page



Note: You may view your accreditation status at any time by navigating to the “Dashboard” page (Figure 4.4). You can navigate to the “Dashboard” page by selecting either of the following links from the “CB Home” page:

- Add/Edit/View Regulatory Audit Report
- Add/View Certification

Figure 4.4 – Dashboard Page

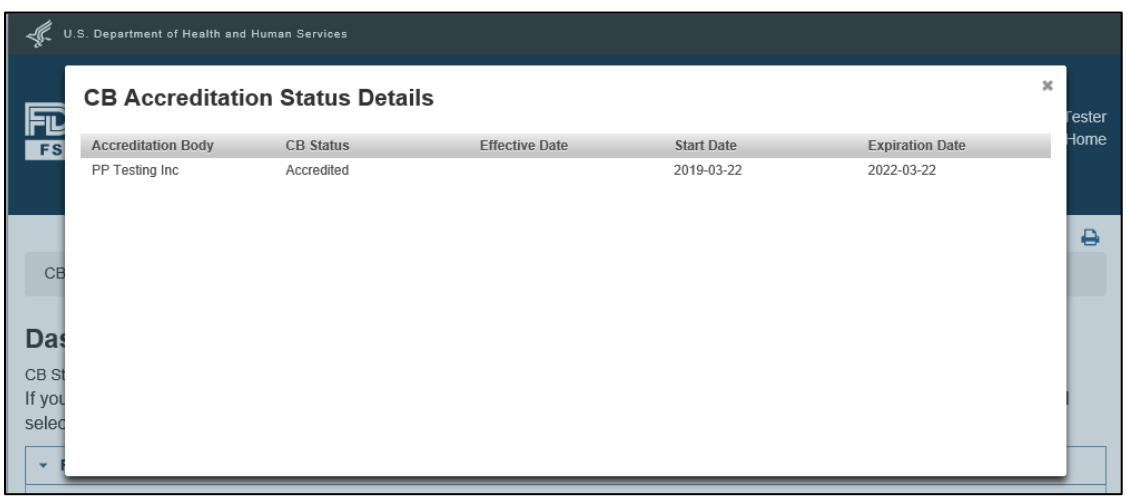


Click the “click here” link to display the “CB Accreditation Status Details” pop-up window (Figure 4.5).

The contents of the pop-up window include the “Accreditation Body,” “CB Status,” “Effective Date,” “Start Date,” and “Expiration Date”. Click the “x” icon in the right corner of the pop-up window to close it.

Click the "CB Home" link on the top of the banner (or from the breadcrumb) to return to the “CB Home” page.

Figure 4.5 – CB Accreditation Status Details Pop-up Window



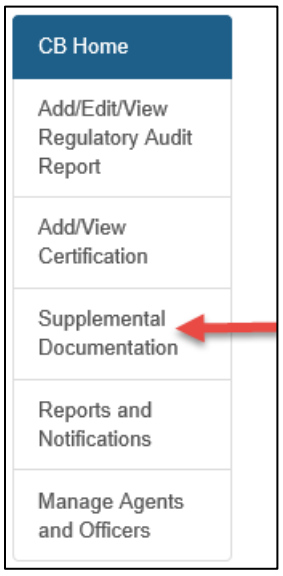
5 Supplemental Documentation

The Supplemental Documentation feature may be used to perform two main functions related to supplemental documents:

- Uploading and submitting documents to FDA
- Viewing the documents that have been submitted to FDA

To upload documents to the CB portal or view documents you have submitted to FDA, click the “Supplemental Documentation” link from the navigation menu on the “CB Home” page (Figure 5.1).

Figure 5.1 – Navigation Menu

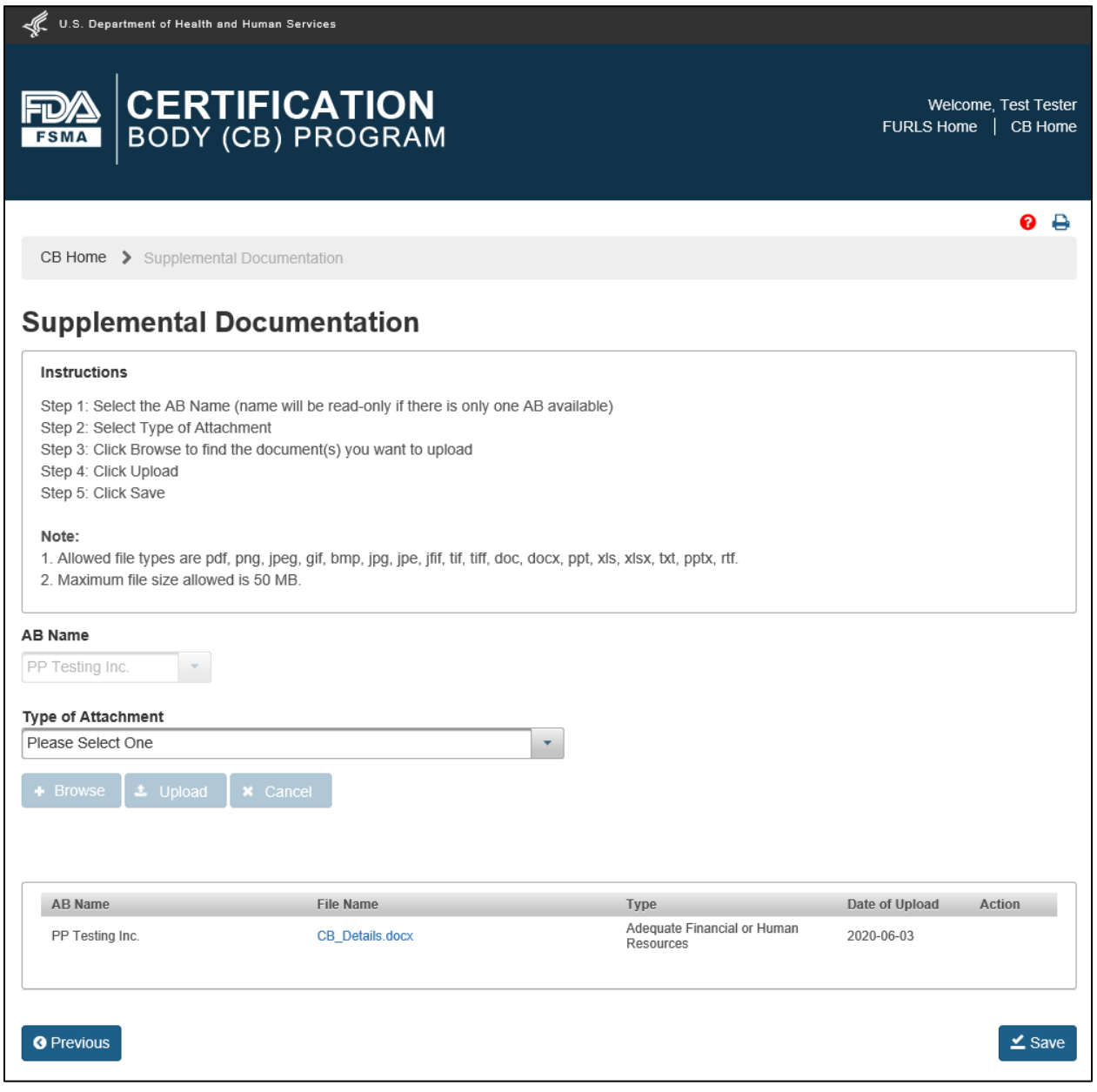


The system will display the “Supplemental Documentation” page (Figure 5.2). Any document(s) you previously submitted to FDA will display in a table at the bottom of the page. Click on the hyperlinked document name in the “File Name” column if you wish to view the document.

Follow Steps 1 - 5 from the “Instructions” section of the page to upload attachments.

Note: Click the “Previous” button at the bottom of the “Supplemental Documentation” page if you wish to return to the “CB Home” page.

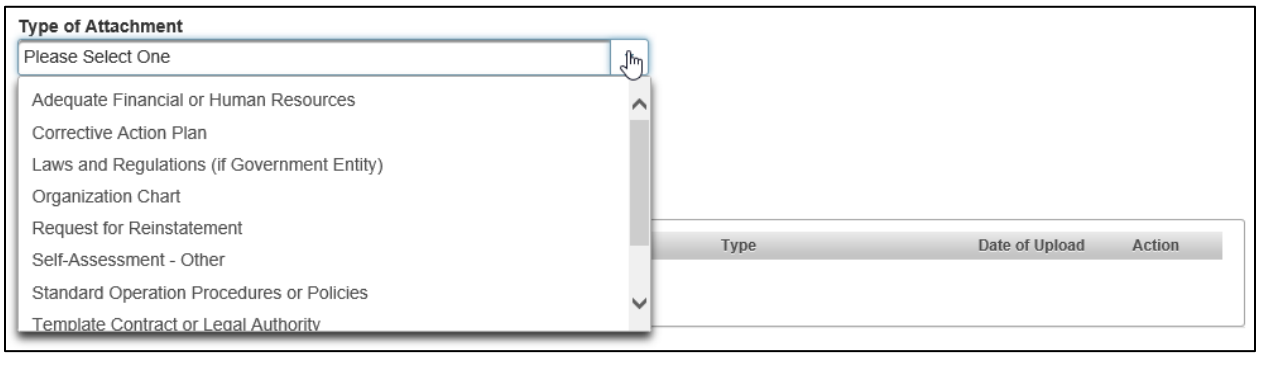
Figure 5.2 – Supplemental Documentation Page



Select the AB from the “AB Name” dropdown menu. If you are only accredited by one AB, the field will be pre-filled with the AB Name. If you are accredited by multiple ABs, select the appropriate AB from the dropdown menu.

Select a document description from the list in the “Type of Attachment” dropdown menu (Figure 5.3).

Figure 5.3 – Type of Attachment Menu

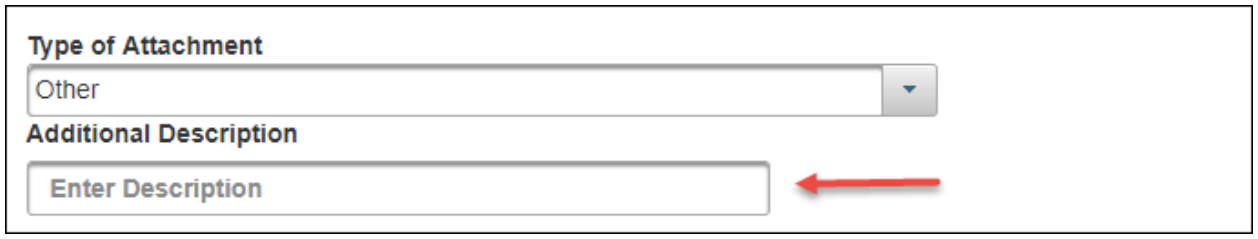


A text box labeled “Additional Description” will display if you select “Other” from the list (Figure 5.4).

Enter a detailed description of the document type in the “Additional Description” field, which allows a maximum of 200 characters.

You must enter a description in the “Additional Description” field to proceed to the next step.

Figure 5.4 – “Other” Attachment Type



Once you have selected from the “Type of Attachment” menu, the “Browse” button is enabled. Click the “Browse” button.

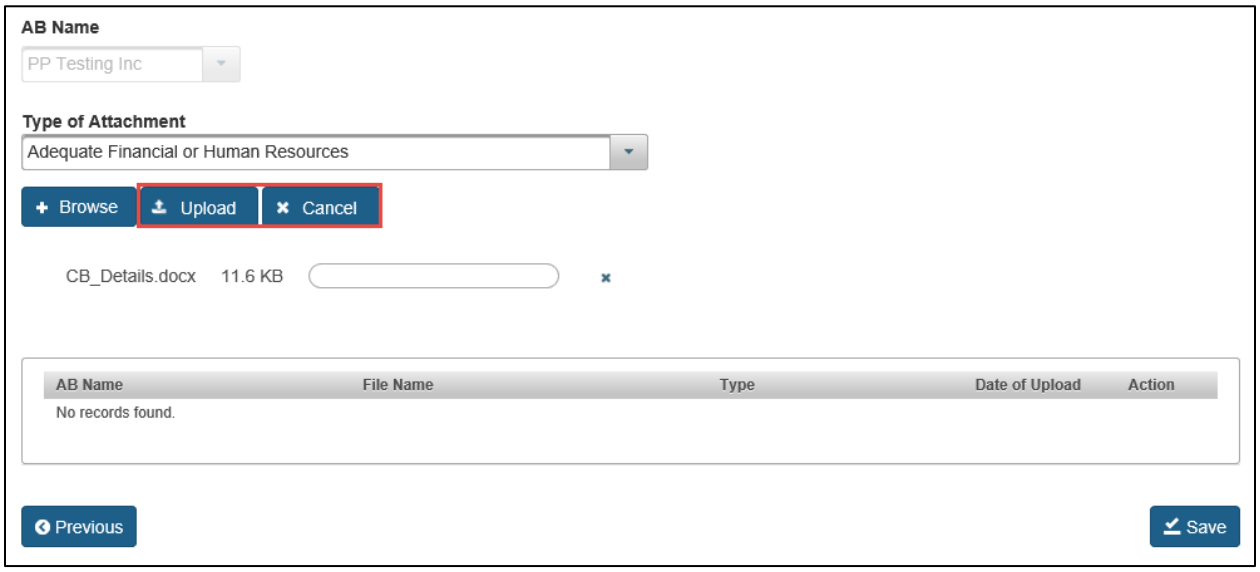
A pop-up window will appear, prompting you to access your file system.

Select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after you choose a file. The browsing window will close (Figure 5.5).

Click the “Cancel” button to discard the attachment upload.

Click the “Upload” button to complete the attachment upload.

Figure 5.5 – Upload and Cancel Buttons



Attachments must be configured as a document type supported by the system.

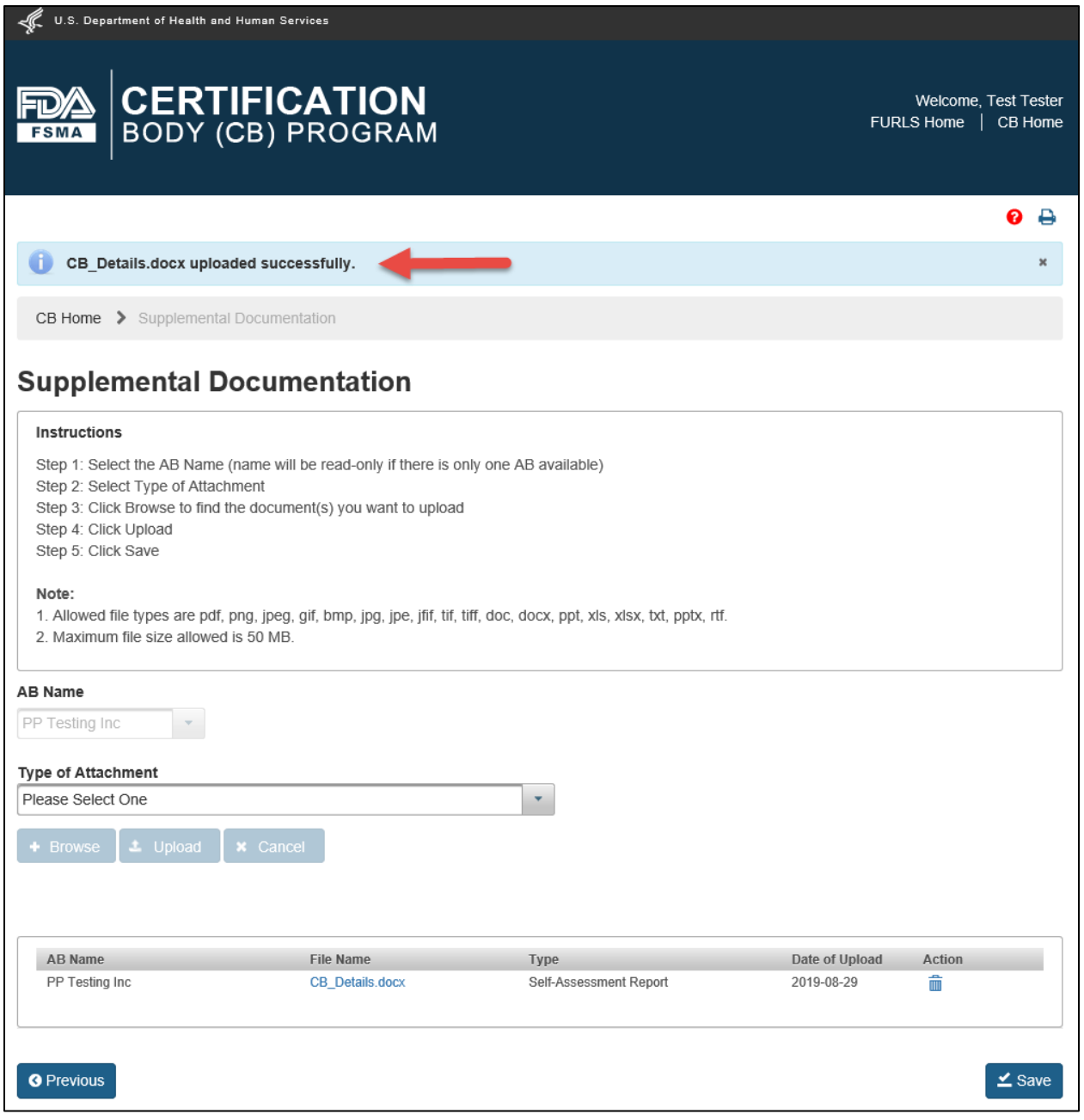
Note: The system supports the following document types: .pdf; .png; .jpeg; .gif; .bmp; .jpg; .jpe; .jfif; .tif; .tiff; .doc; .docx; .ppt; .xls; .xlsx; .txt; .pptx; or .rtf.

The maximum file size allowed is 50 MB.

Once the upload is complete, a confirmation message indicating a successful upload (along with the file name) will display at the top of the page (Figure 5.6).

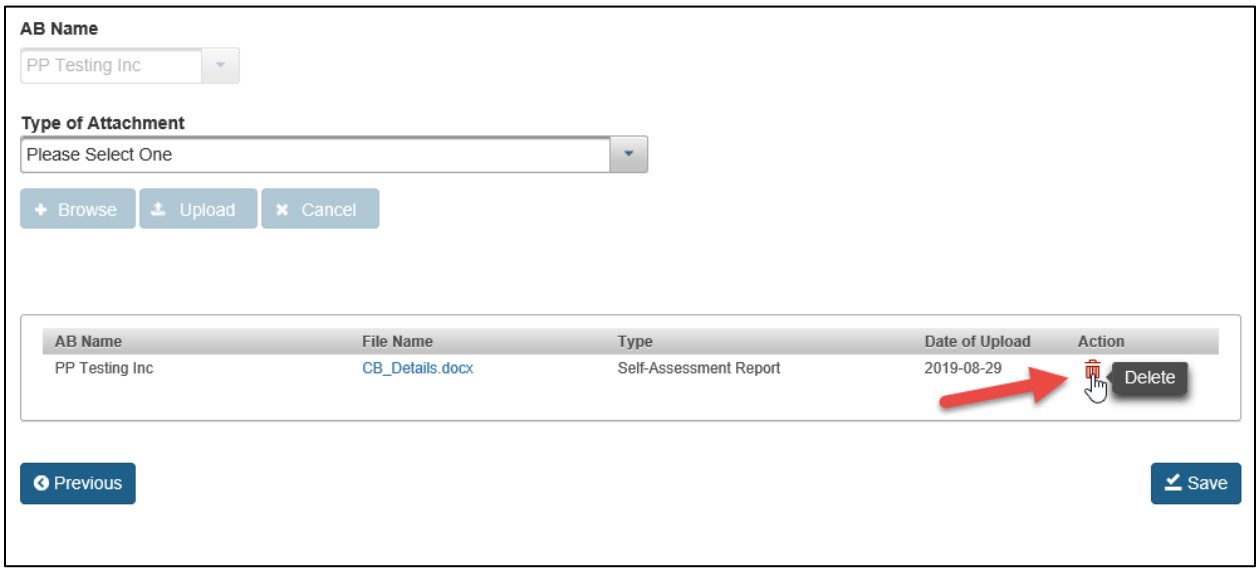
The system will display uploaded files in the table at the bottom of the page.

Figure 5.6 – Successful Upload Message



To remove the attachment from the table at the bottom of the page, click the trash/delete icon in the “Action” column (Figure 5.7).

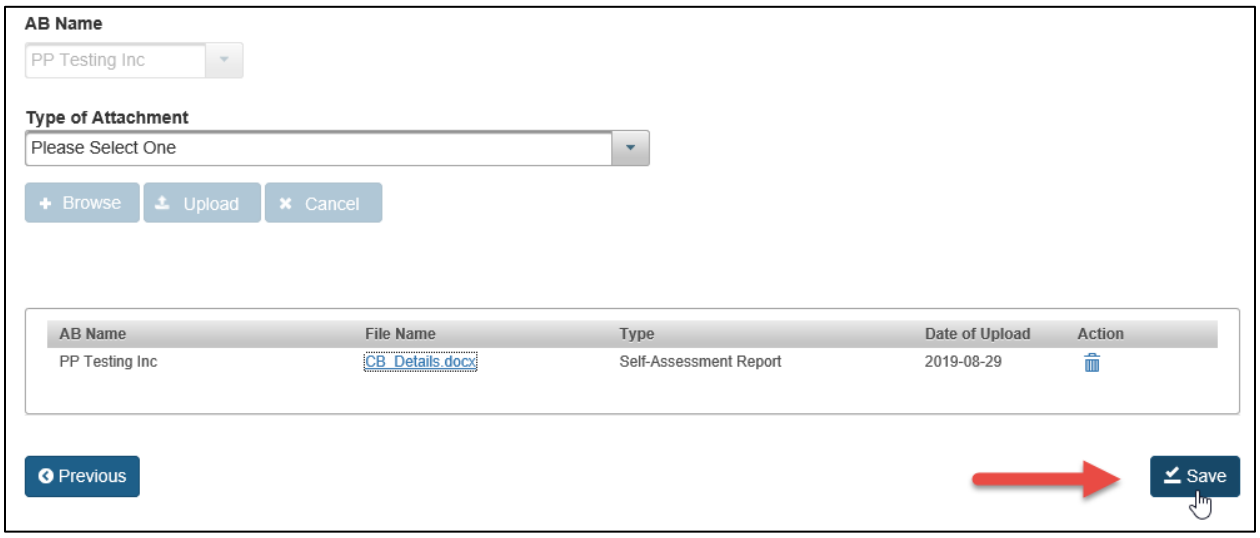
Figure 5.7 – Delete Attachment



After the additional files have been uploaded, click the “Save” button (Figure 5.8).

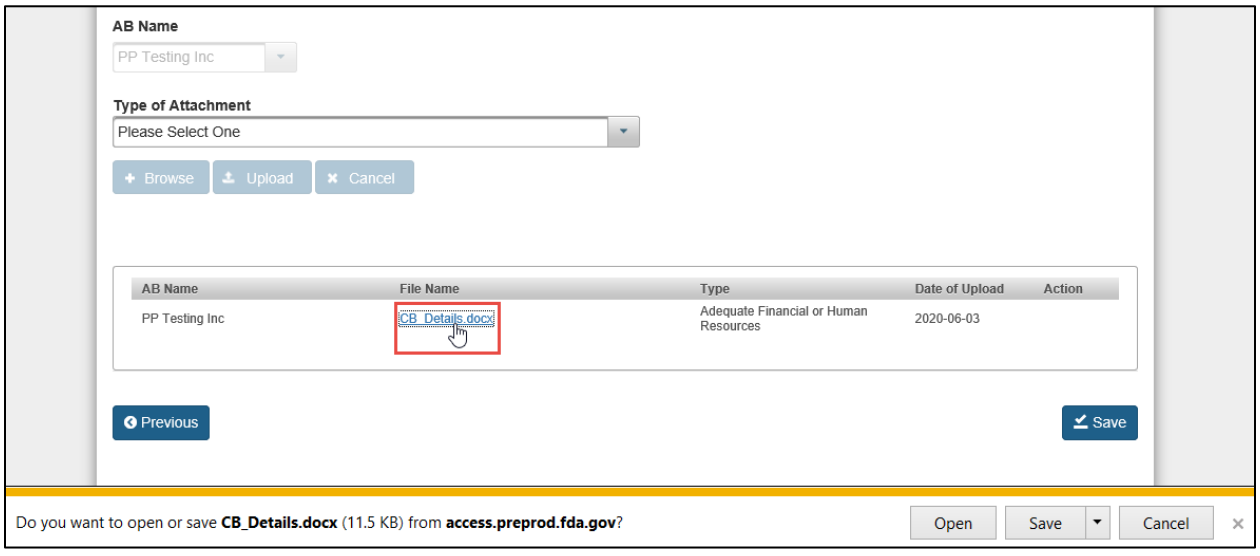
Note: You will not be able to delete an uploaded file once you click “Save.”

Figure 5.8 – Save Attachment



Once a file has been uploaded and added to the attachments table, the file name will become hyperlinked. If you click on the hyperlinked file name, you will be prompted to open or save the file (Figure 5.9).

Figure 5.9 – Hyperlinked file name



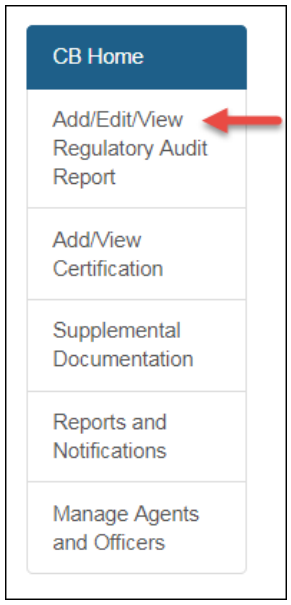
6 Add/Edit/View Regulatory Audit Report (RAR)

The Add/Edit/View Regulatory Audit Report feature may be used to perform three main functions related to regulatory audit reports:

- Creating and submitting a new regulatory audit report to FDA
- Editing or deleting draft regulatory audit reports that have not been submitted to FDA
- Viewing existing regulatory audit reports that have been submitted to FDA

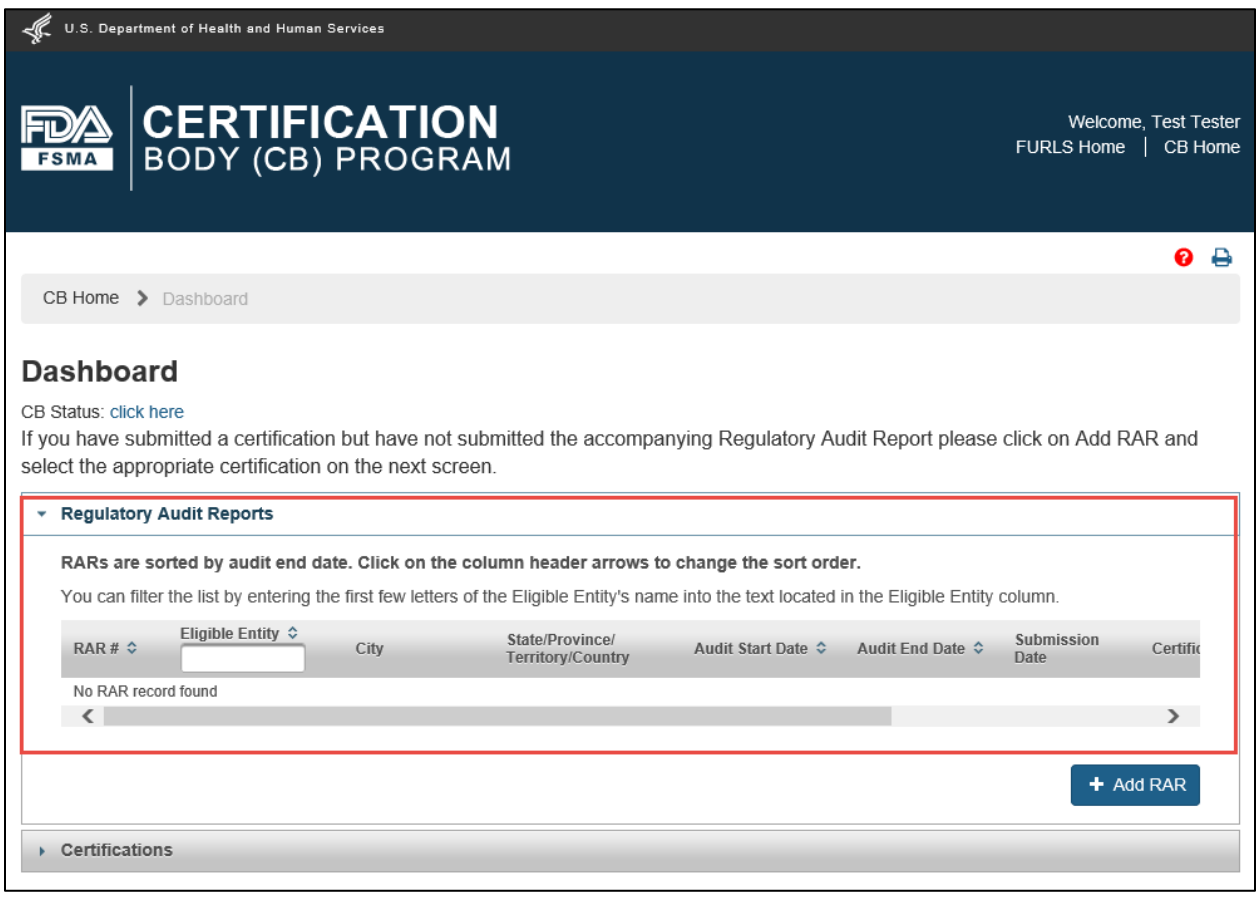
To access the regulatory audit report functionality, click the “Add/Edit/View Regulatory Audit Report” link from the navigation menu on the “CB Home” page (Figure 6.1).

Figure 6.1 – Navigation Menu



You will be navigated to the “Dashboard” page. The “Regulatory Audit Reports” accordion section will be expanded (Figure 6.2).

Figure 6.2 – Dashboard Page



There are three different scenarios associated with the creation and submission of a regulatory audit report:

- **Do you want to create and submit a new regulatory audit report and have not submitted the corresponding certification?**
  If yes, proceed to Section 6.1 of this chapter.

- **Do you want to submit the regulatory audit report for an existing certification?**
  If yes, proceed to Section 6.2 of this chapter.

- **Do you want to edit and submit a draft regulatory audit report that has already been started?**
  If yes, proceed to Section 6.3 of this chapter.

Note: You will see the following buttons while navigating the tabs during the course of the “Add RAR” process (Figure 6.3):

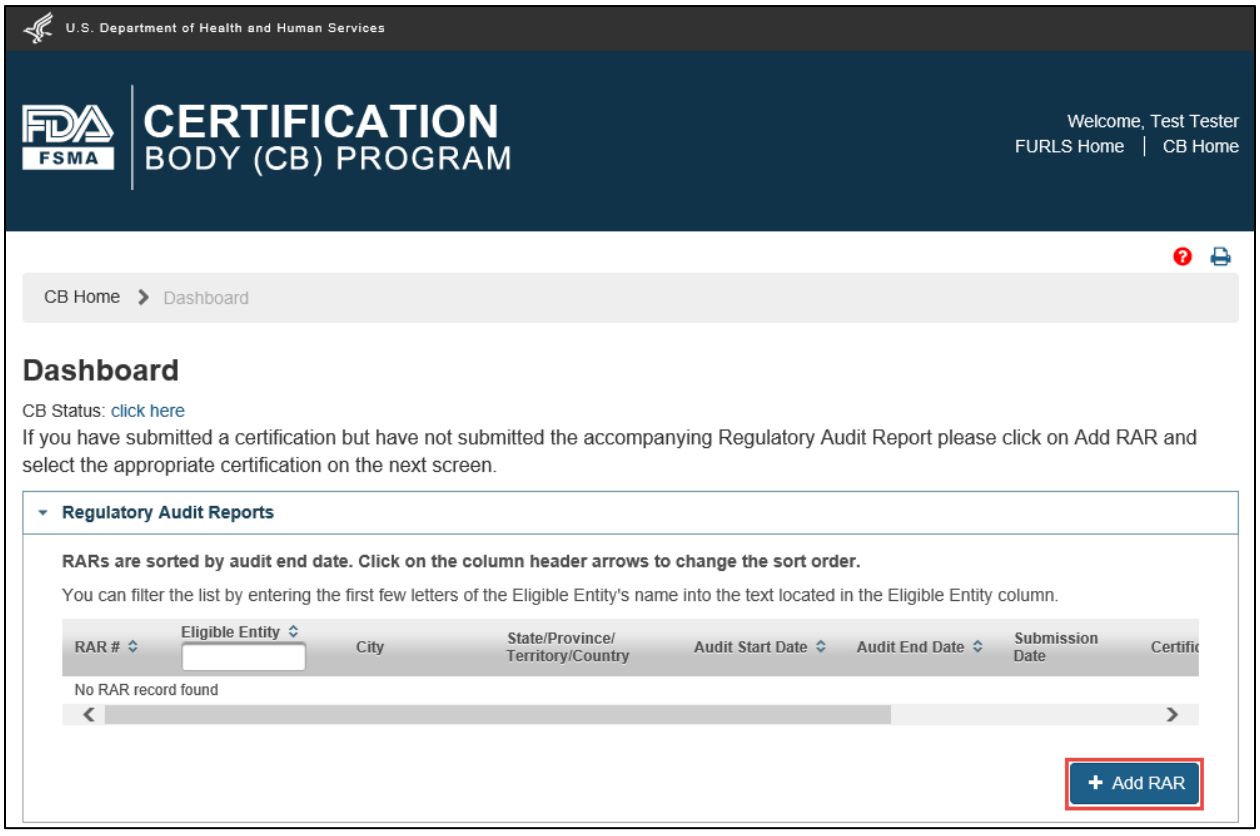
- **Previous –** Directs you to the previous page
- **Save –** Saves any input from the current page
  You must click the “Save” button to save your information.
- **Next –** Directs you to the next page

Figure 6.3 – Previous, Save, and Next Buttons

6.1 Create and Submit a New Regulatory Audit Report

To create and submit a new regulatory audit report, click the “Add RAR” button from the “Dashboard” page (Figure 6.4).

Figure 6.4 – Add RAR Button

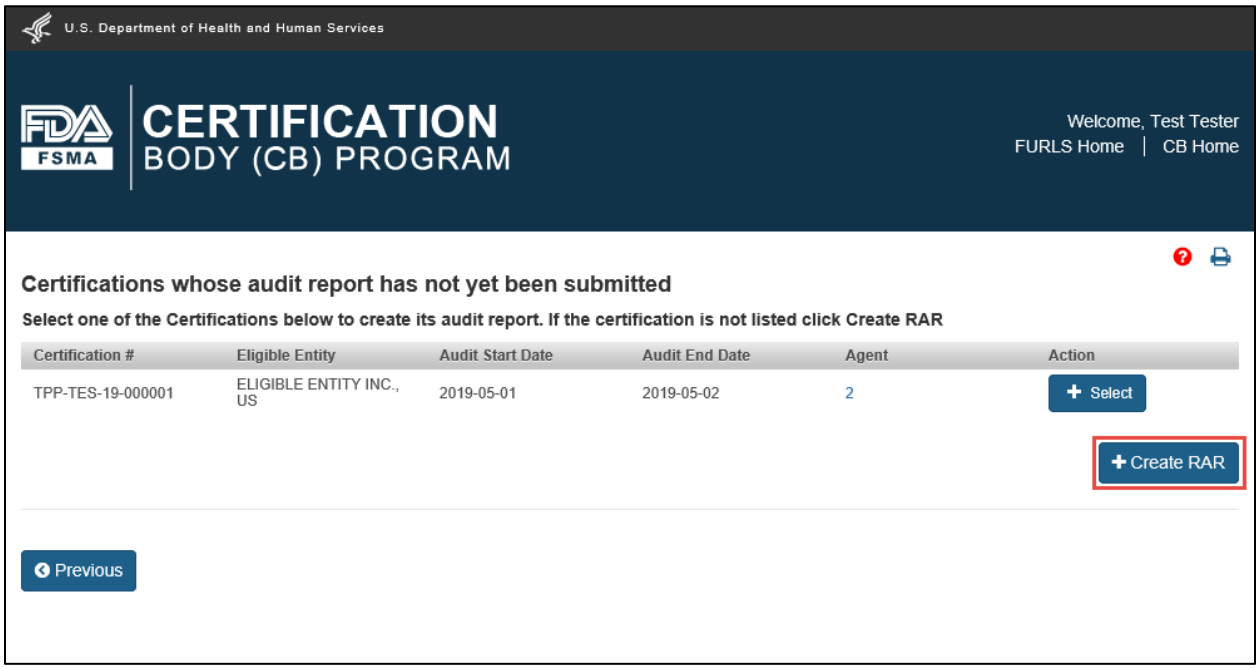


Note: If you submitted a regulatory audit report to FDA and have not submitted its corresponding certification, the system will display the “Certifications whose audit report has not yet been submitted” page with a list of regulatory audit report(s) (Figure 6.5).

If the regulatory audit report you are creating is not for one of the certifications in the list, click the “Create RAR” button to proceed to the “Audit Information” tab and create a new certification.

If you want to create the regulatory audit report for one of the certifications in the list, proceed to Section 6.2 of this chapter.

Figure 6.5 – Create RAR Button



6.1.1 Audit Information Tab

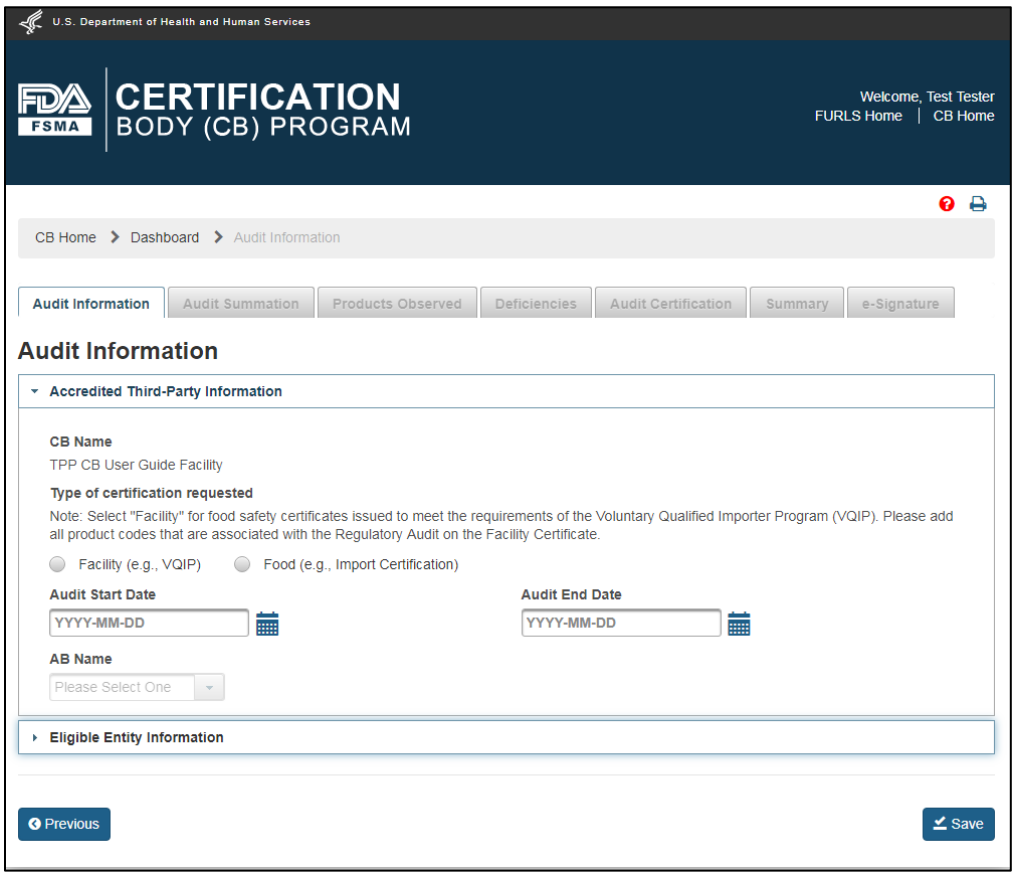
The “Audit Information” tab contains two main sections: The “Accredited Third-Party Information” section and the “Eligible Entity Information” section.

The “Accredited Third-Party Information” section of “Audit Information” tab is displayed after you click the “Add RAR” or “Create RAR” button (Figure 6.6).

You must complete the following data entry fields in the “Accredited Third-Party Information” section:

- **Type of certification requested –** Select “Facility (e.g., VQIP)” or “Food (e.g., Import Certification)” by its radio button.
  Note: If the purpose of the certification is to be used in the Voluntary Qualified Importer Program (VQIP), you must select "Facility."
- **Audit Start Date –** Select the start date of the regulatory audit from the calendar icon or enter the regulatory audit start date in “YYYY-MM-DD” format.
- **Audit End Date –** Select the end date of the regulatory audit from the calendar icon or enter the regulatory audit end date in “YYYY-MM-DD” format.
- **AB Name –** Select the name of the AB from the dropdown list. If you are accredited by more than one AB, select the AB who accredited you for the scope(s) covered in the regulatory audit.
  Note: The “AB Name” field will be enabled and list all the ABs, once the “Audit Start Date” has been selected or entered. The “AB Name” field will be pre-filled if you have only been accredited by one AB.

Figure 6.6 – Audit Information Tab



Two additional sections will display once the “Audit Start Date” and “AB Name” fields are completed – “Scope(s)” and “Audit Agent(s)” (Figure 6.7).

The “Scope(s)” table lists the scopes you have been accredited by the AB selected in the “AB Name” field.

Select the scope(s) covered during the regulatory audit by clicking the appropriate checkbox(es). You must choose at least one scope. The scope(s) relate to the specific type of facility, process(es), or food(s) covered during the regulatory audit.

The “Audit Agent(s)” section lists the active audit agents as of the audit start date. These agents are managed by the CB. If the active audit agent(s) is not listed in the in the “Select Agent(s)” table, add the audit agent using the “Manage Agents and Officers” section. Refer to Chapter 8 “Manage Agents and Officers” for additional instructions on how to add or manage audit agents.

Select the audit agent(s) who conducted the regulatory audit by clicking on an agent name from the “Select Agent(s)” window; the agent’s name will be highlighted.

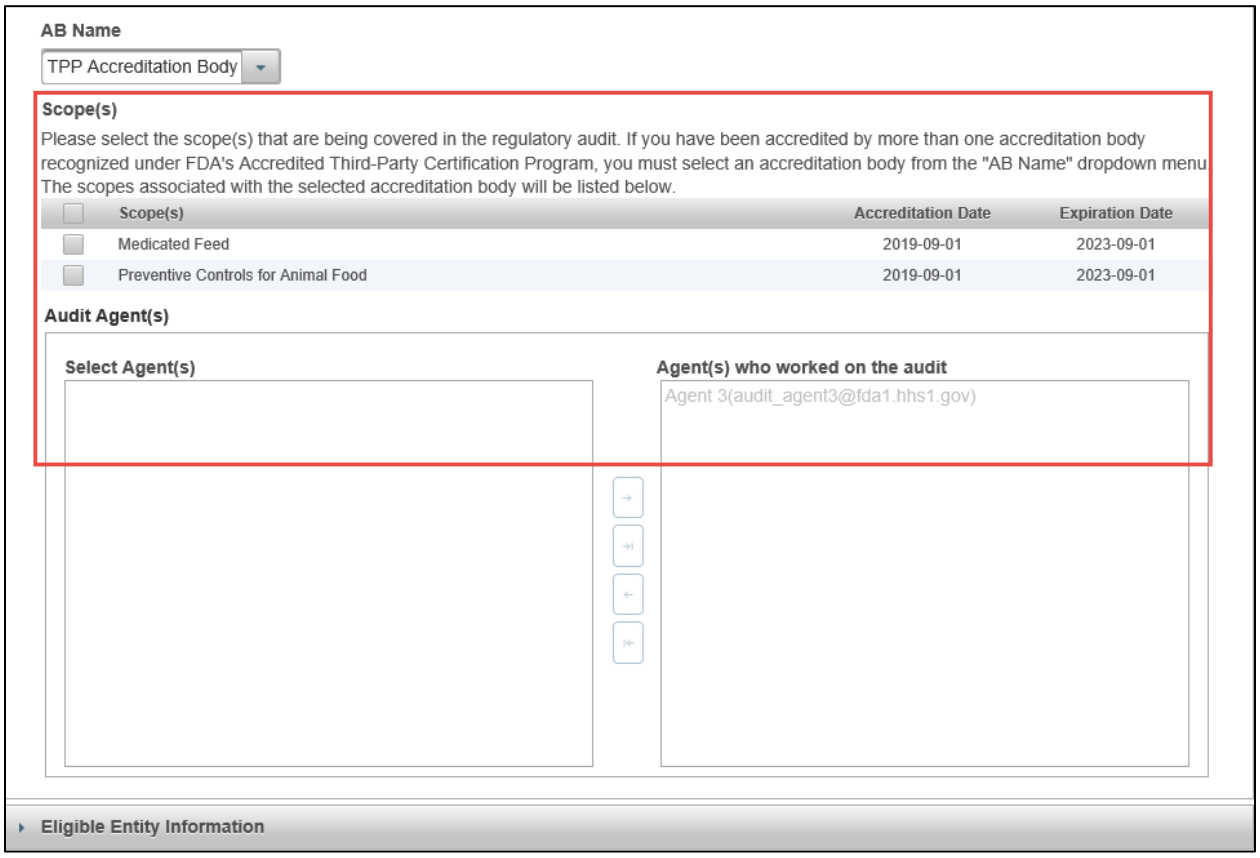
The following buttons may be used to add or remove the selected agent(s):

- **“Add” –** Moves the selected agent(s) to the “Agents who worked on the audit” column
- **“Add All” –** Selects and moves all agents to the “Agents who worked on the audit” column
- **“Remove” –** Removes the selected agent(s) from the “Agents who worked on the audit” column

- **“Remove All” –** Removes all agents from the “Agents who worked on the audit” column

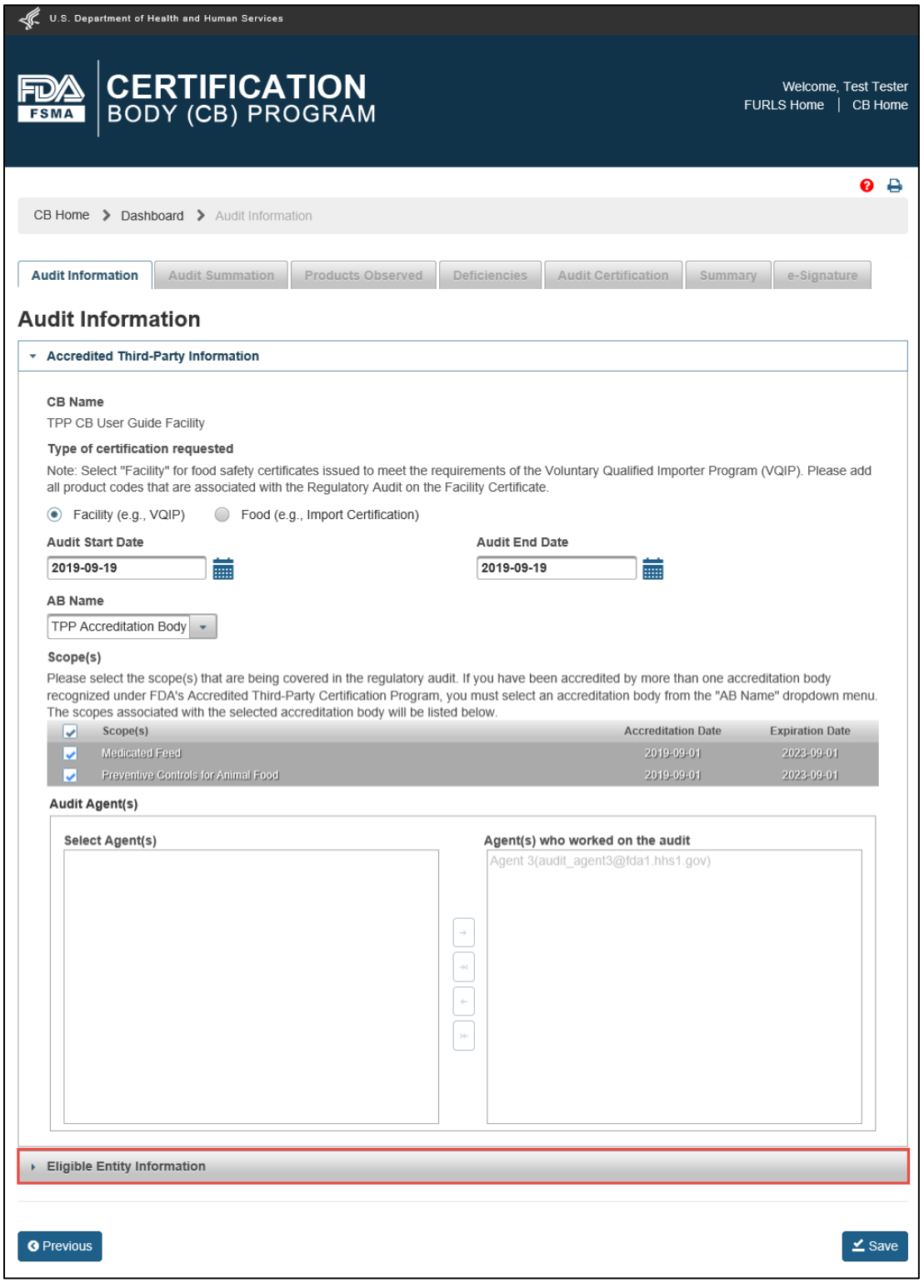
Note: The audit agent will be pre-selected and the field will be read-only if there is only one active audit agent available. If the audit agent displayed by the system did not conduct the audit, add the audit agent as described in the “Manage Agents and Officers” section. See Chapter 8 “Manage Agents and Officers” for additional instructions on how to manage audit agents.

Figure 6.7 – Audit Information Tab – Scope(s) and Audit Agent(s) Sections



Click on the “Eligible Entity Information” accordion section’s title bar to display its content (Figure 6.8).

Figure 6.8 – Audit Information Tab – Eligible Entity Information

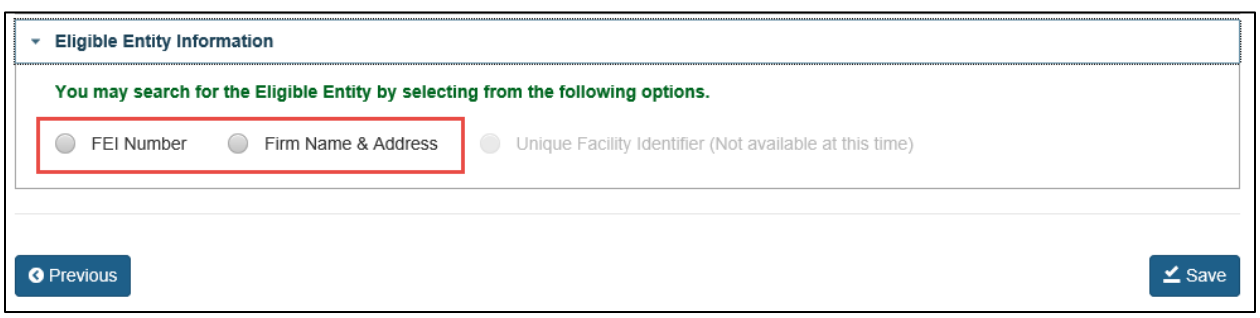


You must enter the firm information associated with the regulatory audit in the “Eligible Entity Information” section. There are two firm search options (Figure 6.9). You must select a radio button to display the search field. The two firm search options are:

- FEI Number
- Firm Name & Address

Note: If the regulatory audit was performed at a location that was different than the eligible entity, you will need to provide the audited facility information in the regulatory audit report as well. The steps for adding the audited facility information are described in Section 6.1.1.3 of this chapter.

Figure 6.9 – Eligible Entity Information – Search Options



For instructions on how to search by the FEI number, proceed to Section 6.1.1.1 of this chapter.

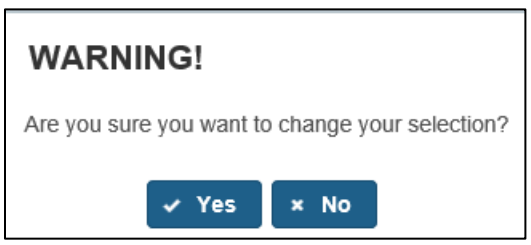
For instructions on how to search by the firm name and address, proceed to Section 6.1.1.2 of this chapter.

Note: You may change your search method selection (e.g., “FEI Number” vs. “Firm Name & Address”) at any time by clicking on the corresponding radio button.

The system will display a warning message if you change your selection (Figure 6.10).

Click “Yes” to change your selection. Click “No” to keep the current selection and dismiss the warning message.

Figure 6.10 – Eligible Entity Information – Warning Message

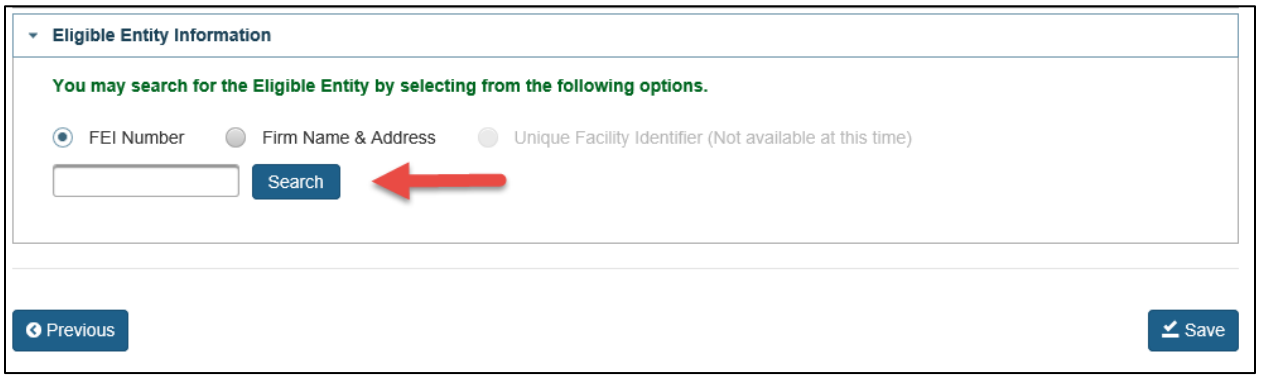


6.1.1.1 Eligible Entity Information – Search by FEI Number

If you have the firm’s FEI number, select the radio button to the left of “FEI Number.” An input field and the “Search” button will display (Figure 6.11).

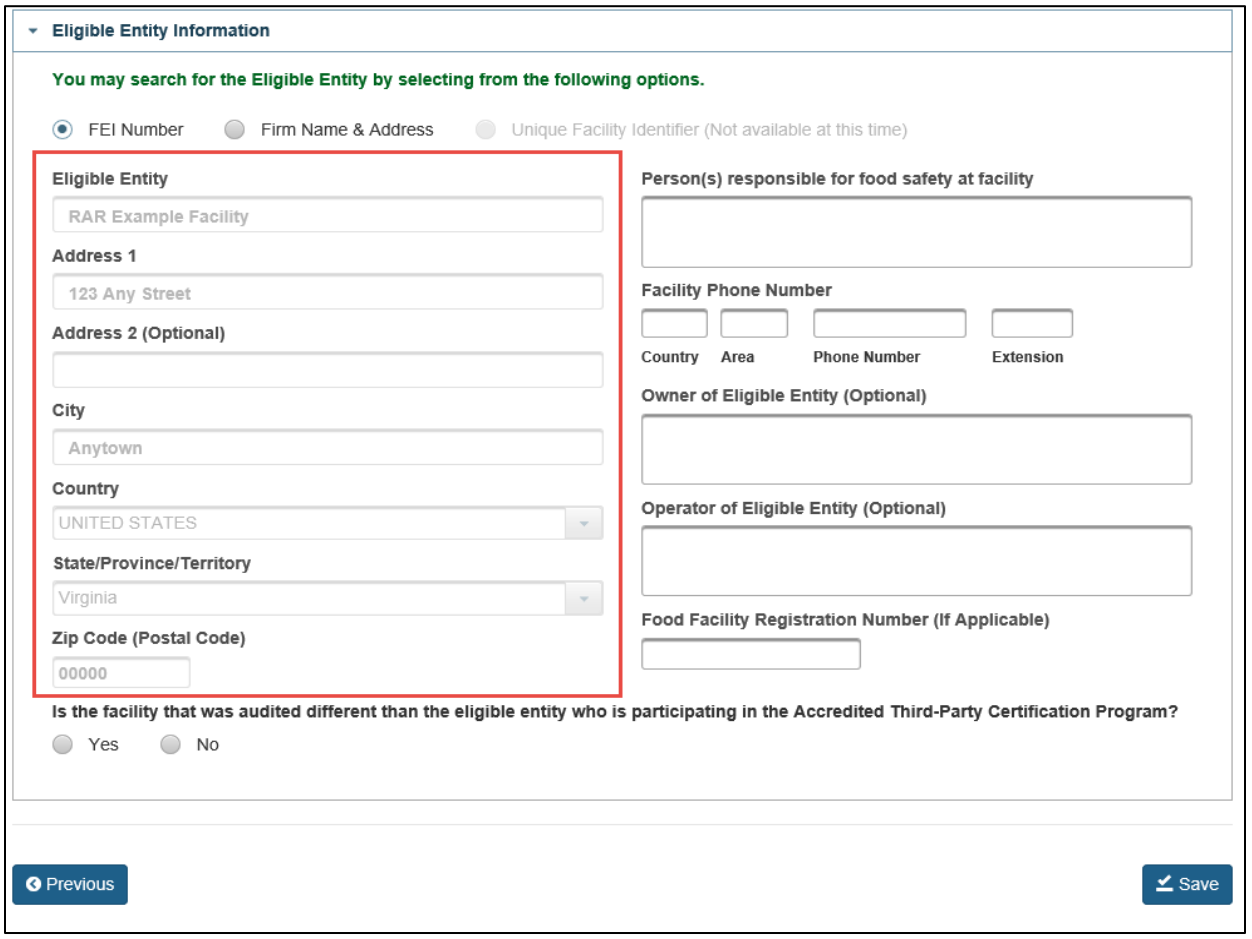
Enter the FEI number and click the “Search” button.

Figure 6.11 – Eligible Entity Information – Search by FEI Number



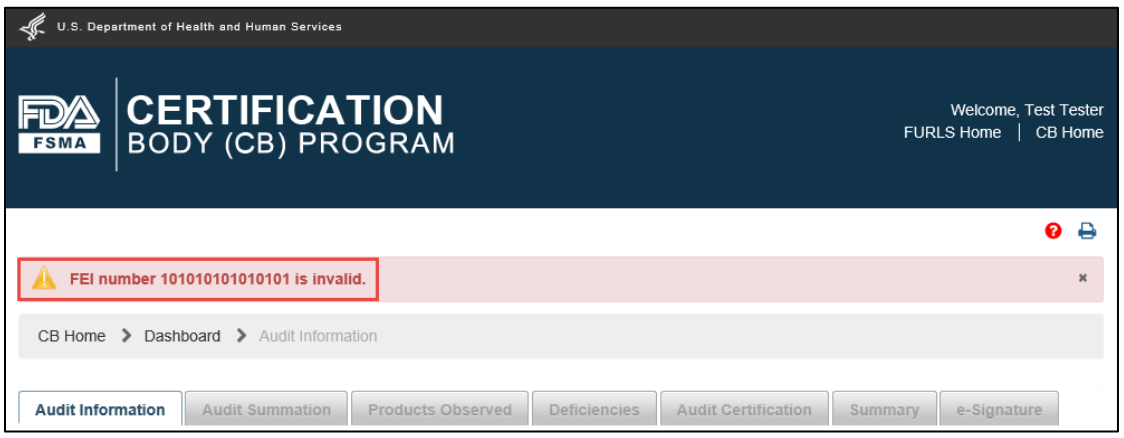
The system will display the corresponding Eligible Entity information from the FDA Firm Inventory if there is a match (Figure 6.12). Review the Eligible Entity information to confirm the firm information displayed is correct. If the firm information is incorrect, verify the FEI number you entered is correct and use the search function again. If the firm information displayed is still incorrect, proceed to Section 6.1.1.2 of this chapter to search for the eligible entity by Firm Name and Address.

Figure 6.12 – Eligible Entity Information – FEI Number Search Results



If you enter an invalid FEI number, the system will display an error message at the top of the page (Figure 6.13).

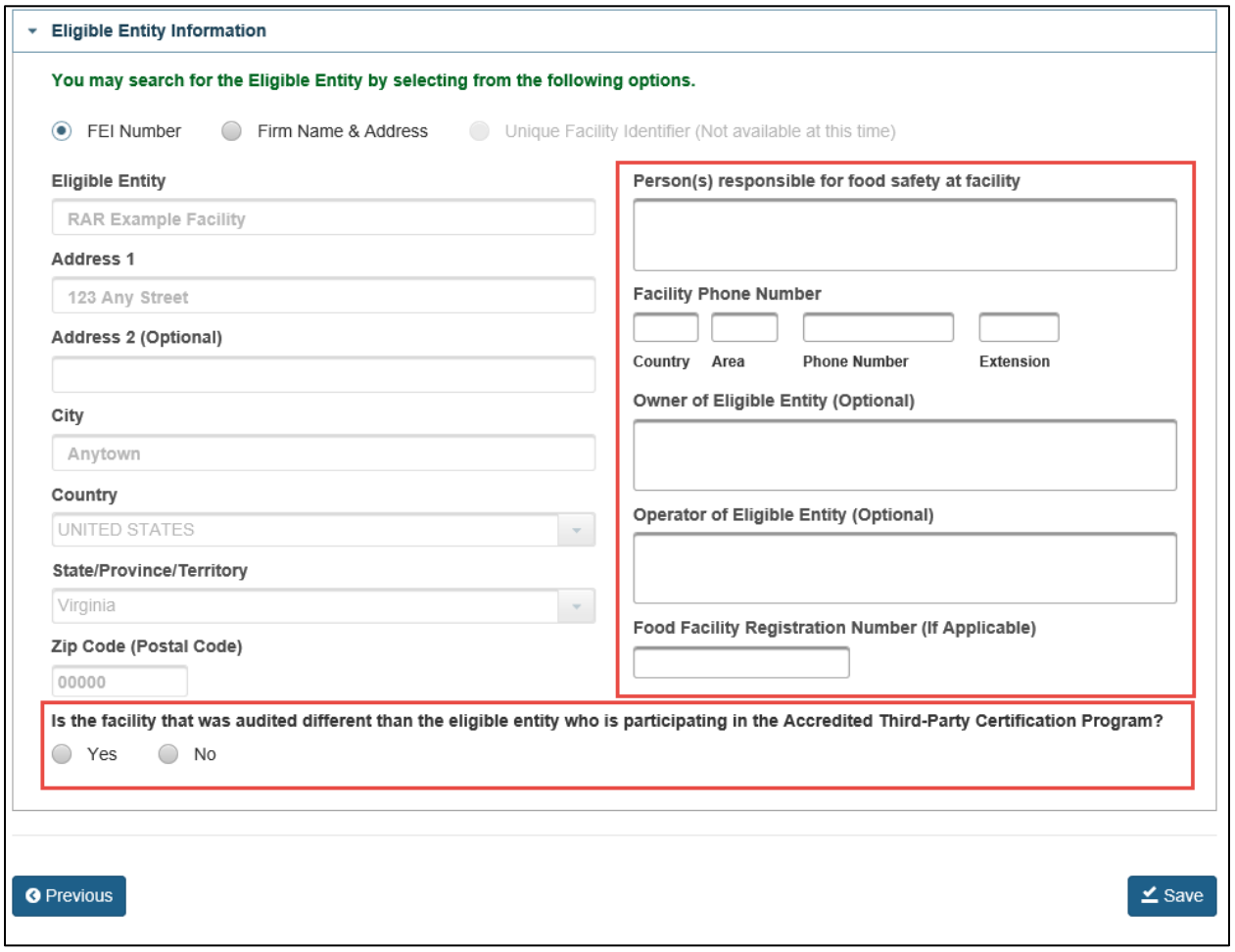
Figure 6.13 – Invalid FEI Number Error Message



Once the system displays the search results for the FEI number, complete the following fields (Figure 6.14):

- **Person(s) responsible for food safety at the facility –** Enter the name of the person(s) who has responsibility for the food safety program (i.e., the facility's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations) at the audited facility. The text field allows the entry of multiple names.
- **Facility Phone Number (Country/Area/Phone Number/Extension) –** The telephone number of the facility
  - "Country" is the country code.
  - "Area" is the area code.
  - "Phone Number" is the phone number.
  - "Extension" is the local phone extension, if applicable.
- **Owner of the Eligible Entity –** This is an optional text entry field to enter the name(s) of the owner(s) of the eligible entity, which allows a maximum of 200 characters.
- **Operator of the Eligible Entity –** This is an optional text entry field to enter the name(s) of the operator(s) of the eligible entity, which allows a maximum of 200 characters.
- **Food Facility Registration Number –** Submission of the 11-digit Food Facility Registration Number (FFRN) is required for facilities subject to the FDA's Registration Requirements under 21 CFR Part 1, Subpart H. The system will display an error message if the FFRN does not correspond to the provided FEI number: "FFR Number entered does not match with the Eligible Entity Information. Please try again."
  Note: For additional information on FFRN, please visit the "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)."
- **Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program? –** Select "Yes" or "No."
  - If you select "Yes," the system will display the search options for the audited facility. Proceed to Section 6.1.1.3 of this chapter for instructions on how to complete the "Audited Facility" portion of the "Eligible Entity Information" section. You must complete this section before proceeding to the "Audit Summation" tab.
  - If you select "No," click "Save". Once all the required fields on "Audit Information" tab have been completed, proceed to the "Audit Summation" tab of the regulatory audit report (Section 6.1.2 of this chapter).

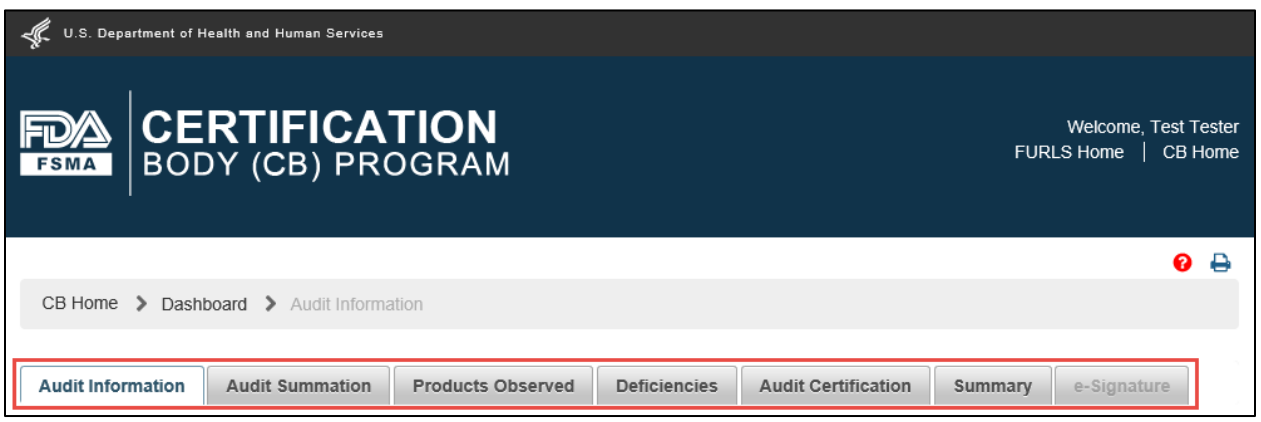
Figure 6.14 – Search by FEI Number – Additional Fields



Once you save your changes in the “Audit Information” tab, all the tabs (except “e-Signature”) will become enabled (Figure 6.15). The “Next” button will display at the bottom of the tab.

Proceed to the “Audit Summation” tab and Section 6.1.2 of this chapter.

Figure 6.15 – Additional Tabs of Regulatory Audit Report are Enabled



6.1.1.2 Eligible Entity Information – Search by Firm Name & Address

Select the radio button to the left of “Firm Name & Address” if you do not have the firm’s FEI number. The system will display additional data fields (Figure 6.16). The data fields are not case-sensitive.

Enter the firm information in the search fields displayed:

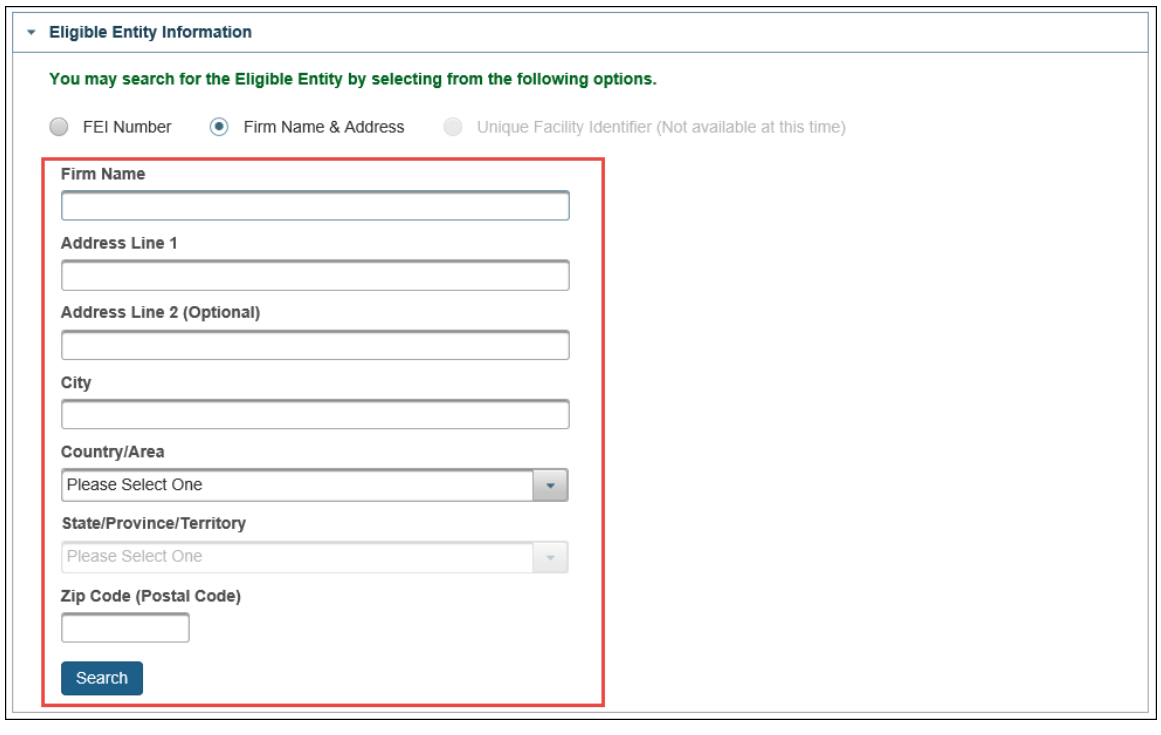
- **Firm Name –** The name of the firm
- **Address Line 1 –** The address where the firm is physically located – this includes the number, street, quadrant, etc.
- **Address Line 2 –** The field to enter additional information about the physical location of the firm – this may include a suite or apartment number, if applicable. This field is optional.
- **City –** The city where the firm is physically located
- **State/Province/Territory –** The state/province/territory where the firm is physically located
- **Zip Code (Postal Code) –** The zip code (domestic) or postal code (foreign) where the firm is physically located

  Note: Zip Code is only required for U.S. addresses; however, including the Postal Code may help refine your search results.

Once you enter the information in the search fields, click the “Search” button.

Note: If the regulatory audit was performed at a location that was different than the eligible entity, you will need to provide the audited facility information in the regulatory audit report as well. The steps for adding the audited facility information are described in Section 6.1.1.3 of this chapter.

Figure 6.16 – Eligible Entity Information – Search by Firm Name & Address



After you click “Search” the system will search for a match in the FDA Firm Inventory and display the corresponding eligible entity information, if it exists.

The system will display the search results(s) depending on the number of matches found for the firm information entered.

If one search result is returned, proceed to Section 6.1.1.2.1 of this chapter.

If more than one search result is returned, proceed to Section 6.1.1.2.2 of this chapter.

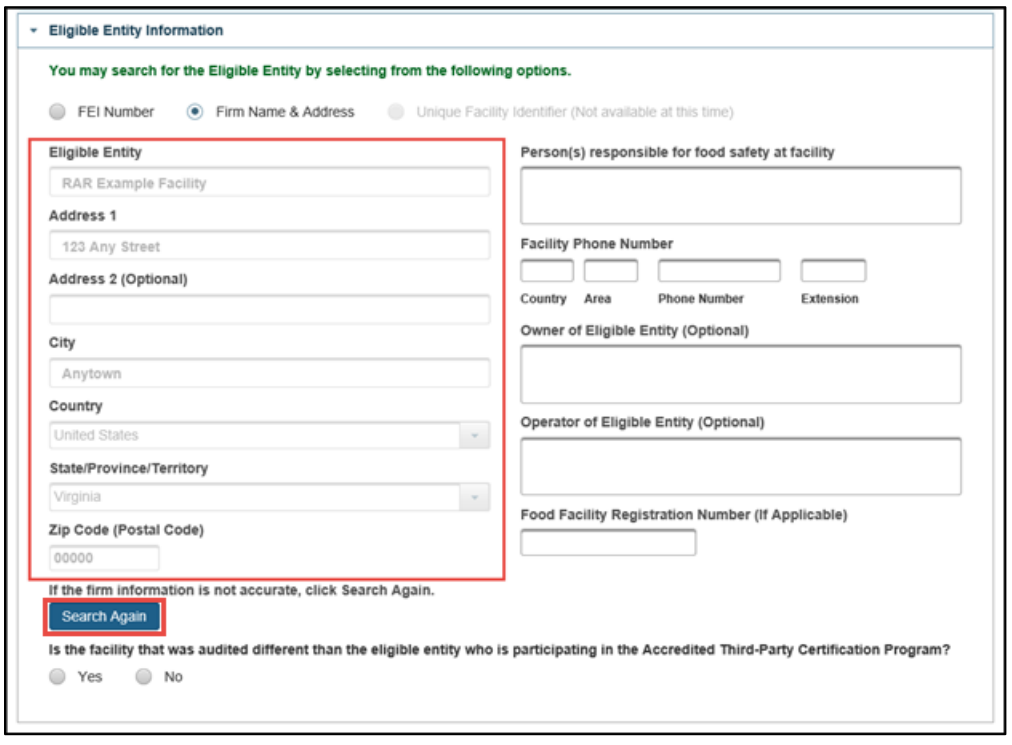
If no results are returned, proceed to Section 6.1.1.2.3 of this chapter.

6.1.1.2.1 Search by Firm Name & Address – Single Match

If the system returns one match, the firm name and address fields will be pre-filled and read-only after executing your search (Figure 6.17). If the pre-filled result does not contain the desired firm information, click the “Search Again” button to clear the pre-filled firm information and perform a new search.

Once you are ready to proceed with the listed firm, proceed to Section 6.1.1.2.4 of this chapter.

Figure 6.17 – Search by Firm Name & Address – Single Match



6.1.1.2.2 Search by Firm Name & Address – Multiple Match

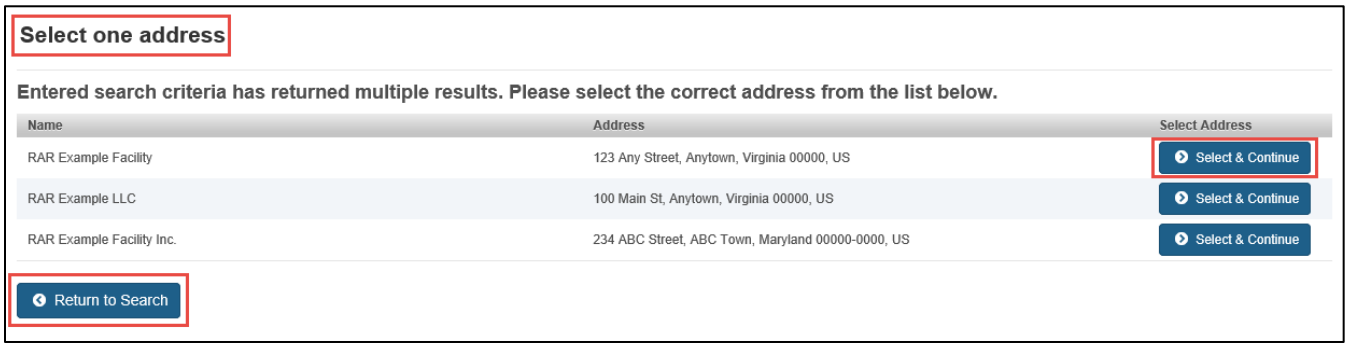
If more than one search result is returned, the system will display a “Select one address” pop-up window with a list of addresses found by the system (Figure 6.18).

Choose the desired address from the list and click “Select & Continue” on the right side of the row.

Otherwise, click “Return to Search” to return to the search fields.

Once you are ready to proceed with the listed firm, proceed to Section 6.1.1.2.4 of this chapter.

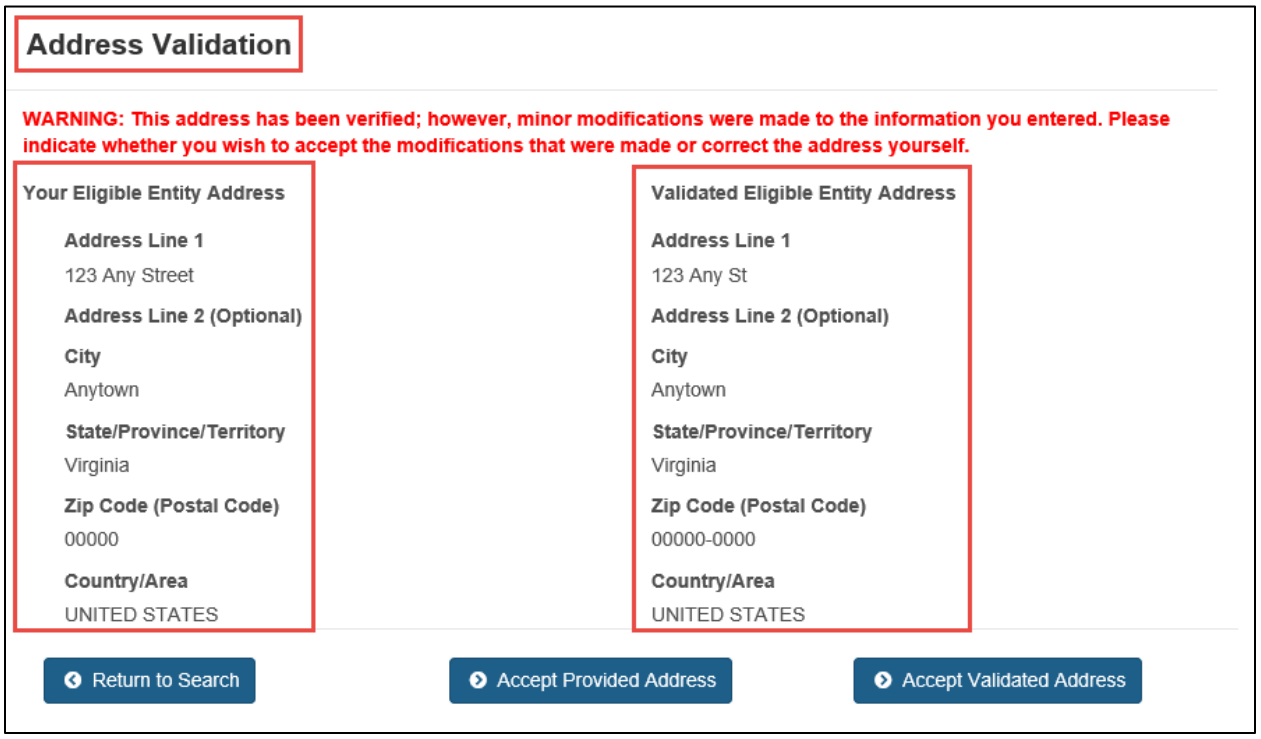
Figure 6.18 – Search by Firm Name & Address – Multiple Match



6.1.1.2.3 Search by Firm Name & Address – No Match

If no match was found for the Firm Name & Address search, the system will display the “Address Validation” pop-up window showing both the provided and validated addresses (Figure 6.19).

Figure 6.19 – Search by Firm Name & Address – No Match – Address Validation Pop-up Window

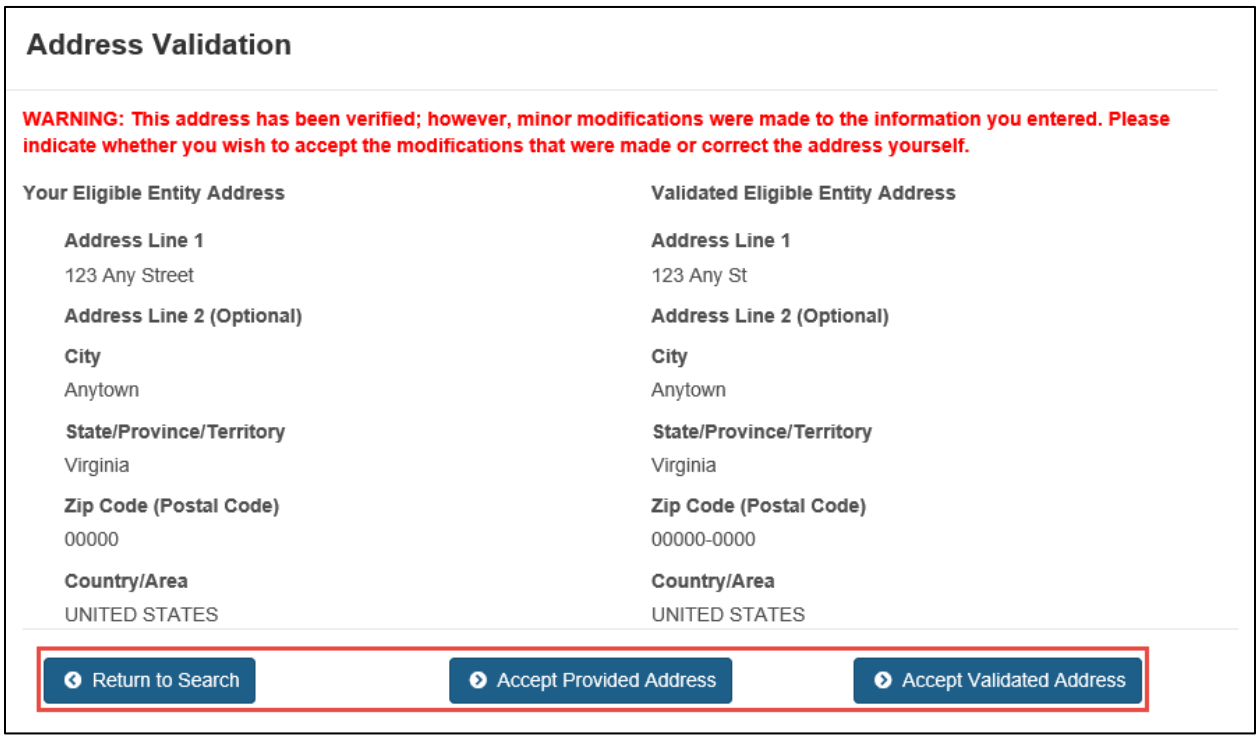


Click “Accept Provided Address” if you wish to keep the information in the “Your Eligible Entity Address” as-entered (Figure 6.20).

Click “Accept Validated Address” if the “Validated Eligible Entity Address” is accurate.

To edit the address you entered or begin a new search, click the “Return to Search” button to close the pop-up window and return to the “Audit Information” tab.

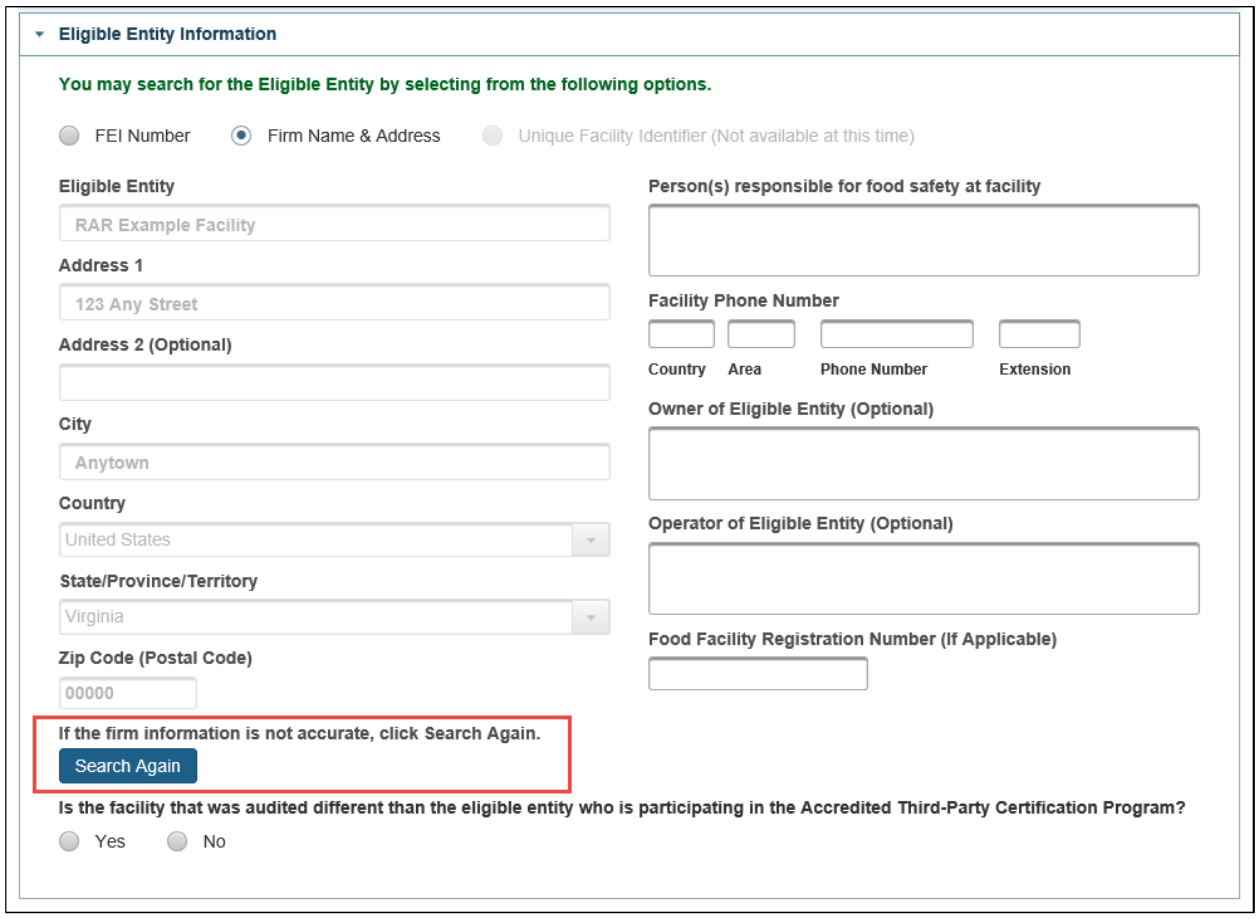
Figure 6.20 – Search by Firm Name & Address – Address Validation Pop-up Window Options



Once you have edited the firm information, click “Search Again” (Figure 6.21).

Once you are ready to proceed with the listed firm, proceed to Section 6.1.1.2.4 of this chapter.

Figure 6.21 – Search by Firm Name & Address – Search Again

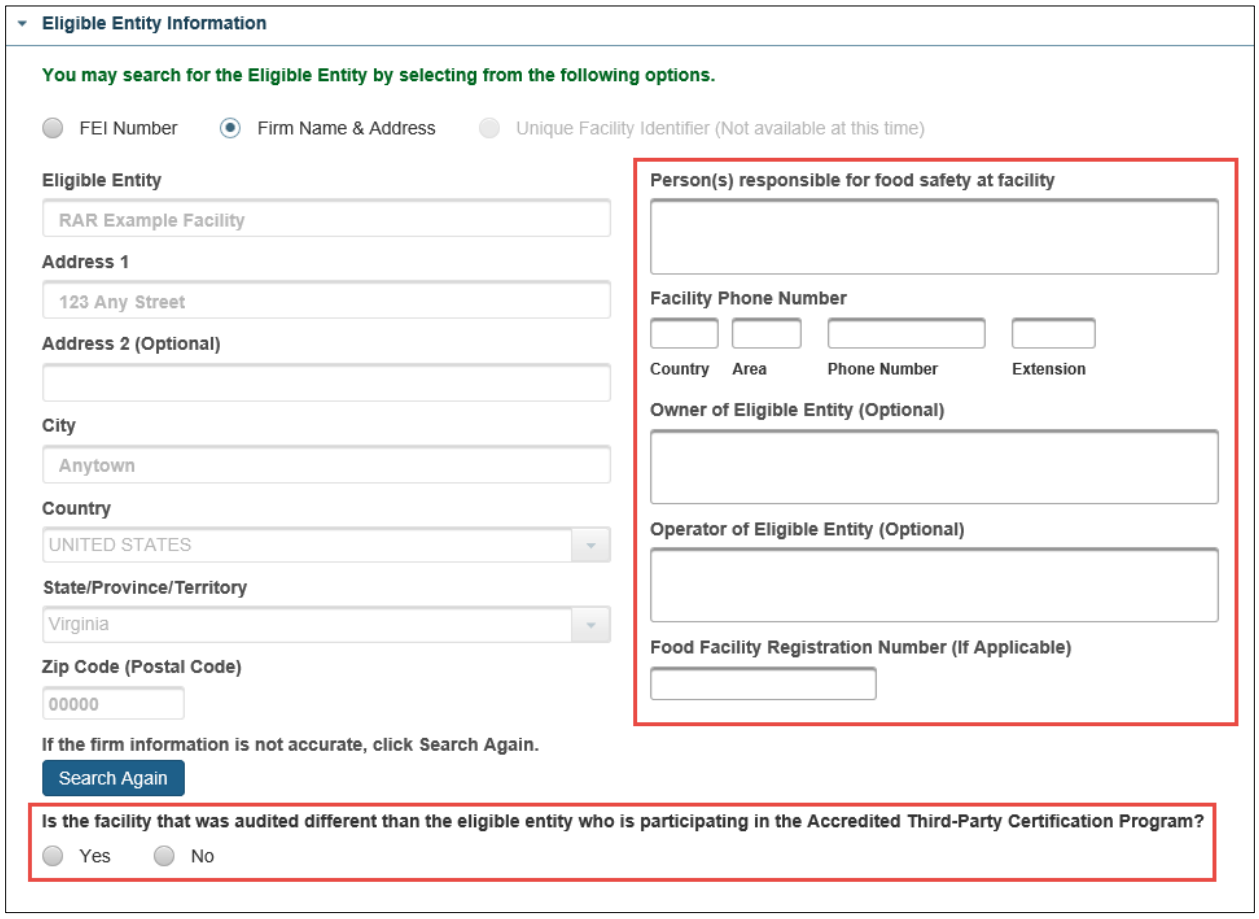


6.1.1.2.4 Completion of Additional Fields After Selecting Firm from Search Results

Once you have accepted the system search results for the Firm Name & Address of the Eligible Entity, complete the following additional fields (Figure 6.22):

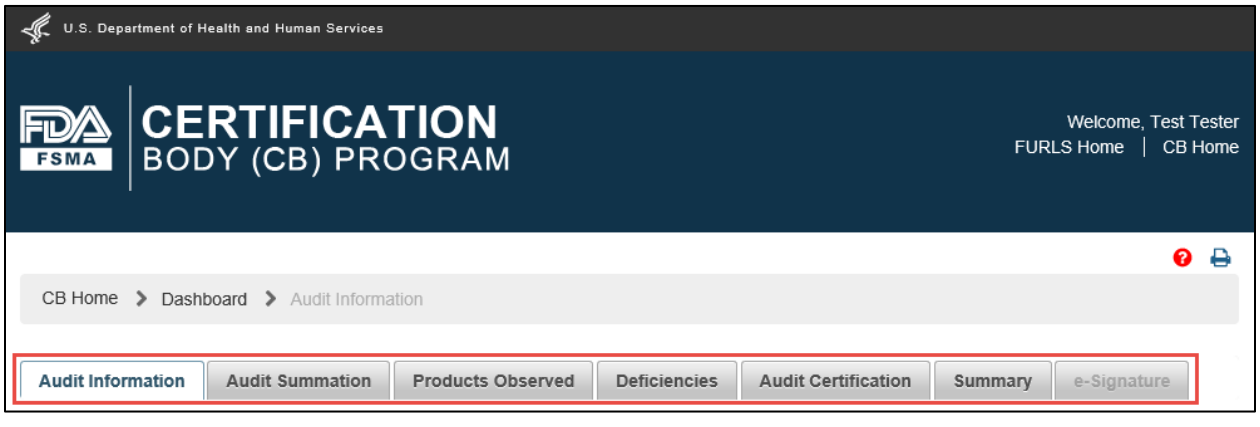
- **Person(s) responsible for food safety at the facility –** Text field which allows entry of multiple names
- **Facility Phone Number (Country/Area/Phone Number/Extension) –** The telephone number of the facility
  - "Country" is the country code.
  - "Area" is the area code.
  - "Phone Number" is the phone number.
  - "Extension" is the local phone extension, if applicable.
- **Owner of the Eligible Entity –** This is an optional text entry field to enter the name(s) of the owner(s) of the eligible entity, which allows a maximum of 200 characters.
- **Operator of the Eligible Entity –** This is an optional text entry field to enter the name(s) of the operator(s) of the eligible entity, which allows a maximum of 200 characters.
- **Food Facility Registration Number –** Submission of the 11-digit Food Facility Registration Number (FFRN) is required for facilities subject to the FDA's Registration Requirements under 21 CFR Part 1, Subpart H. The system will display an error message if the FFRN does not correspond to the provided FEI number: "FFR Number entered does not match with the Eligible Entity Information. Please try again."
- **Note:** For additional information on FFRN, please visit the "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)."
- **Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program? –** Select "Yes" or "No" to answer this question.
  - If you select "Yes," the system will display the search options for the audited facility. Proceed to Section 6.1.1.3 for instructions on how to complete the "Audited Facility" portion of the "Eligible Entity Information" section.
  - If you select "No," click "Save." Once all the required fields in the "Audit Information" tab have been completed, proceed to the "Audit Summation" tab of the regulatory audit report (Section 6.1.2 of this chapter).

Figure 6.22 – Eligible Entity Information – Firm Name & Address – Additional Fields



Click the “Save” button to save your changes. Once you save your changes in the “Audit Information” tab, all tabs except “e-Signature” will become enabled. The “Next” button will display at the bottom of the tab (Figure 6.23).

Figure 6.23 – Additional Tabs of Regulatory Audit Report are Enabled



Proceed to the “Audit Summation” tab by clicking the “Next” button or by clicking on the “Audit Summation” tab directly.

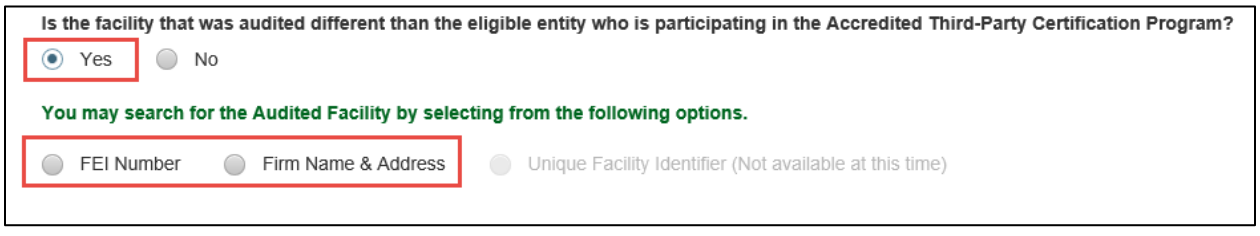
Proceed to Section 6.1.2 of this chapter.

6.1.1.3 Eligible Entity Information – Audited Facility

If you selected “Yes” in response to the question “Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?” the system will display the search options for the audited facility (Figure 6.24).

The system displays the same options in the “Audited Facility” section for searching the facility’s data in the “Eligible Entity Information” section: “FEI Number” and “Firm Name & Address.”

Figure 6.24 – Audited Facility – Search Options

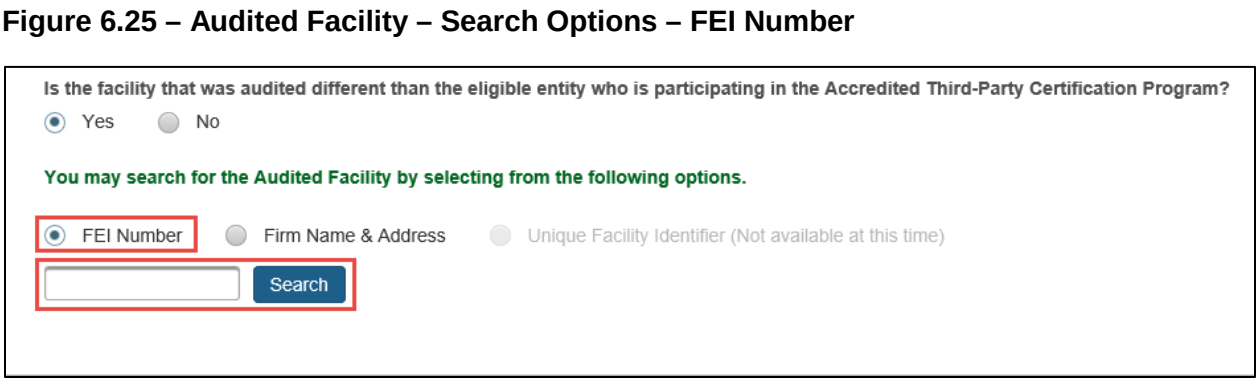


Select the radio button to the left of “FEI Number” if you have the firm’s FEI Number. An input field and the “Search” button will display (Figure 6.25).

Enter the FEI Number and click the “Search” button.

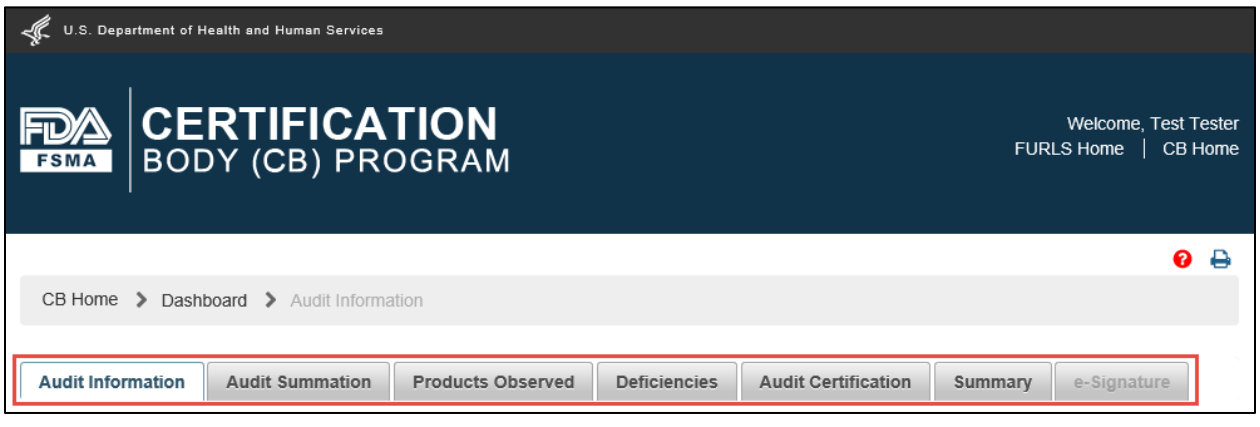
Repeat the steps to search by FEI Number (as described in Section 6.1.1.1 of this chapter for “Eligible Entity”).

Figure 6.25 – Audited Facility – Search Options – FEI Number



Click the “Save” button to save your changes. Once you save your changes in the “Audit Information” tab, all tabs except “e-Signature” will become enabled (Figure 6.26). The “Next” button will display at the bottom of the tab.

Figure 6.26 – Additional Tabs of Regulatory Audit Report are Enabled

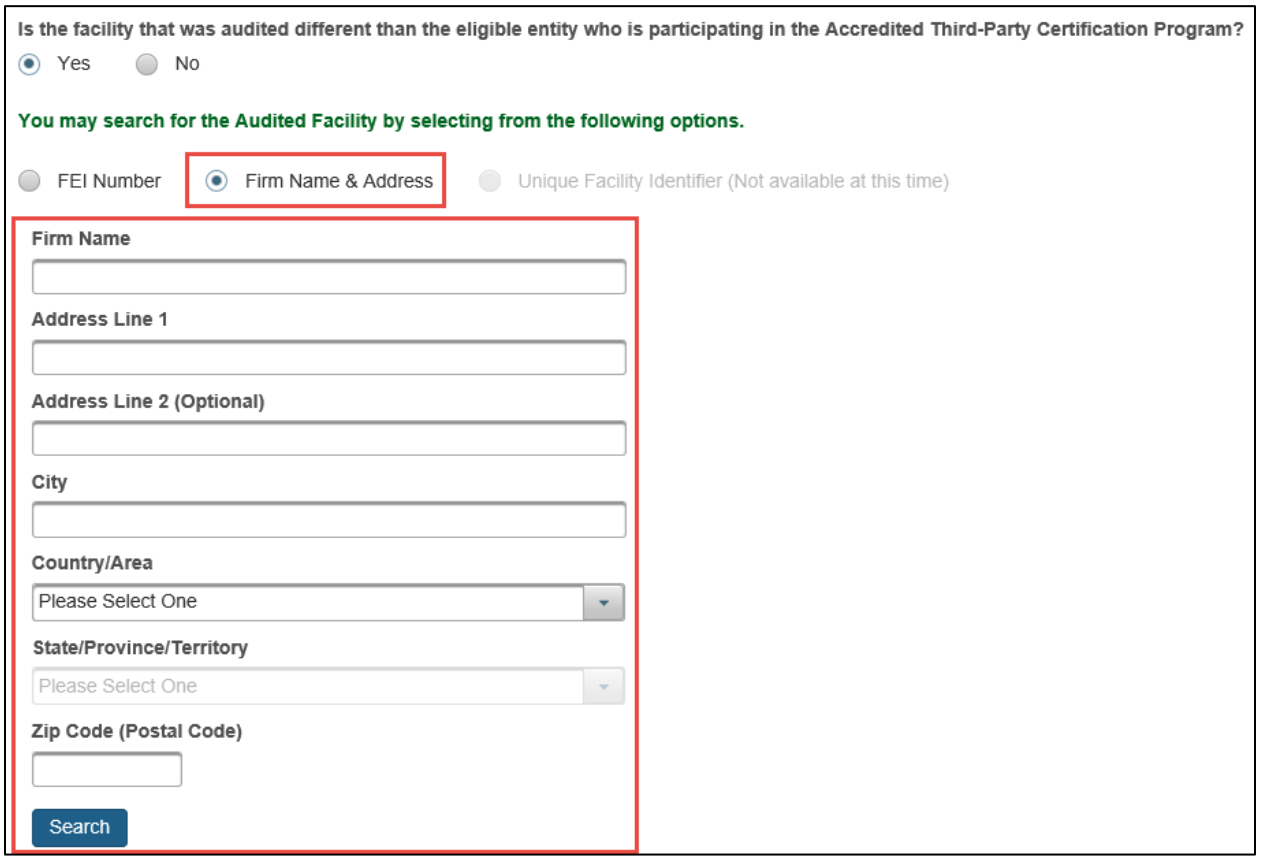


Once you are ready to proceed with the listed firm, proceed to the “Audit Summation” tab by clicking the “Next” button or by clicking on the “Audit Summation” tab directly.

Proceed to Section 6.1.2 of this chapter. If you do not have the firm’s FEI Number, select the radio button to the left of “Firm Name & Address” to search by the firm’s name and address. The input fields and “Search” button will display after the radio button is selected (Figure 6.27).

Enter the firm information and click the “Search” button.

Figure 6.27 – Audited Facility – Search Options – Firm Name & Address

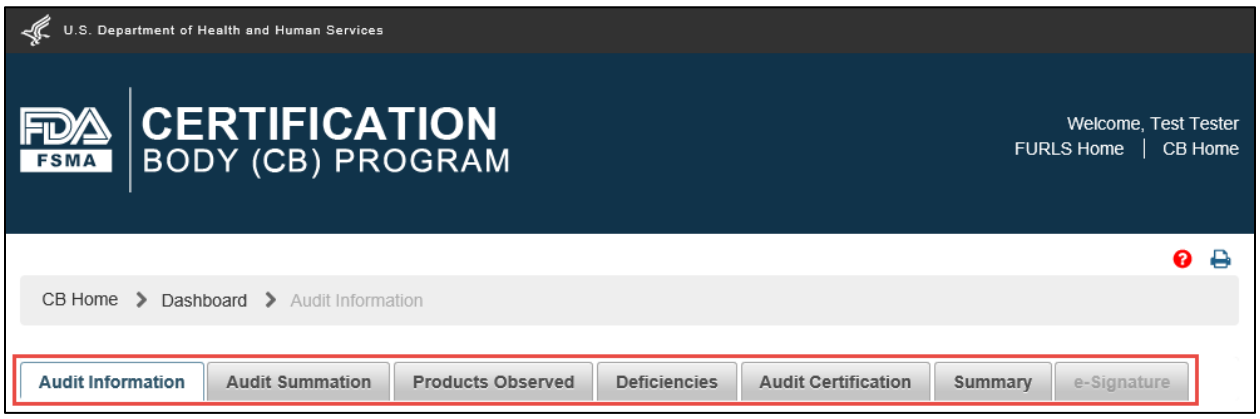


Repeat the steps to search by Firm Name & Address (as referenced in Section 6.1.1.2 of this chapter for “Eligible Entity”).

Click the “Save” button to save your changes. Once you save your changes in the “Audit Information” tab, all tabs except “e-Signature” will become enabled (Figure 6.28). The “Next” button will display at the bottom of the tab.

Once you save your changes, the system will save a draft of your regulatory audit report. You may need to correct any errors on the tab before the system will allow you to save the draft. You can edit and submit the report at a later date by selecting the draft from the “Dashboard” page. Refer to Section 6.3 of this chapter.

Figure 6.28 – Additional Tabs of Regulatory Audit Report are Enabled



Once you are ready to proceed with the listed firm, proceed to the “Audit Summation” tab by clicking the “Next” button (Figure 6.29) or by clicking the “Audit Summation” tab directly.

Proceed to Section 6.1.2 of this chapter.

Figure 6.29 – Audit Information Tab – Next Button

6.1.2 Audit Summation Tab

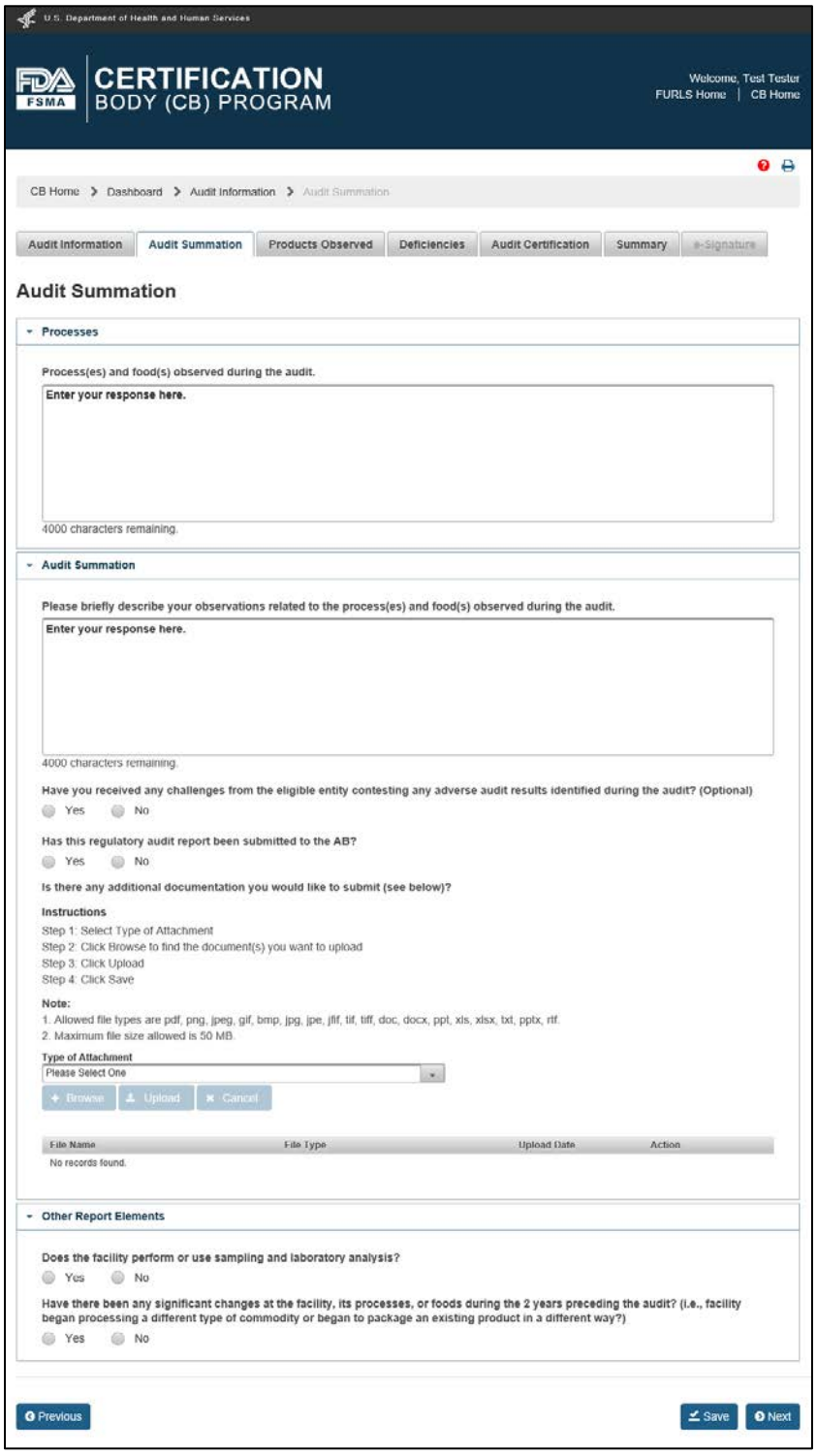
The “Audit Summation” tab allows you to summarize the results of the regulatory audit (e.g., the process(es) and food(s) observed during the regulatory audit and your observations related to the process(es) and food(s) observed during the audit).

Complete the following fields in the “Audit Summation” tab (Figure 6.30):

- **“Processes” Section:**
  - **Process(es) and food(s) observed during the audit –** Describe the processes and foods observed during the regulatory audit. This field allows up to 4,000 characters.
- **“Audit Summation” Section:**
  - **Please briefly describe your observations related to the process(es) and food(s) observed during the audit –** Describe your general audit observations related to compliance with the food safety requirements of the FD&C Act and FDA regulations. This field allows up to 4,000 characters.

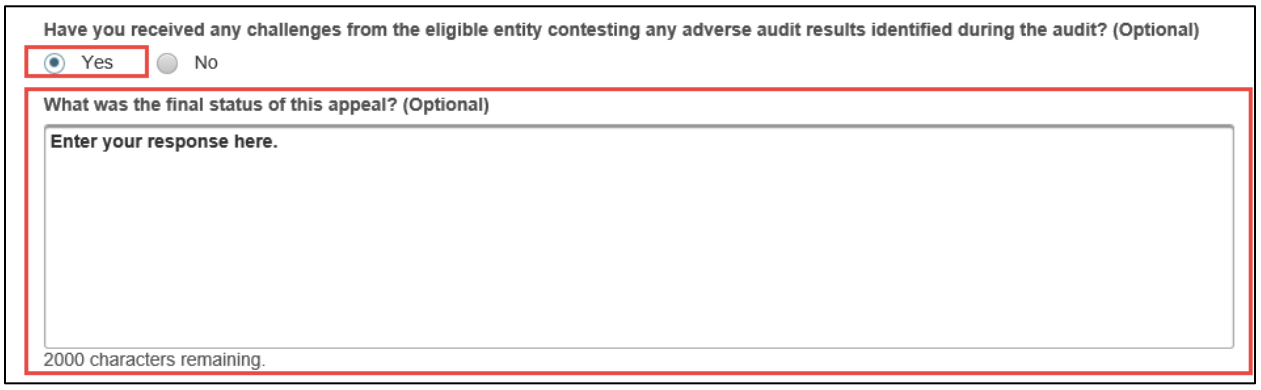
Note: Observations which present a reasonable probability that use of or exposure to food from the facility will cause Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA), or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, should be entered in the “Deficiencies” tab – not in this section.

Figure 6.30 – Audit Summation Tab



- **Have you received any challenges from the eligible entity contesting any adverse audit results identified during the audit? –** This question is optional. Select “Yes” or “No.”
  - If you select “Yes,” another field will display (Figure 6.31):
    - **What was the final status of this appeal? (Optional) –** Describe the final status of the appeal. This is an optional text field which allows a maximum of 2,000 characters.
  - If you select “No,” proceed to the next question.

Figure 6.31 – Additional Field for Appeal Status

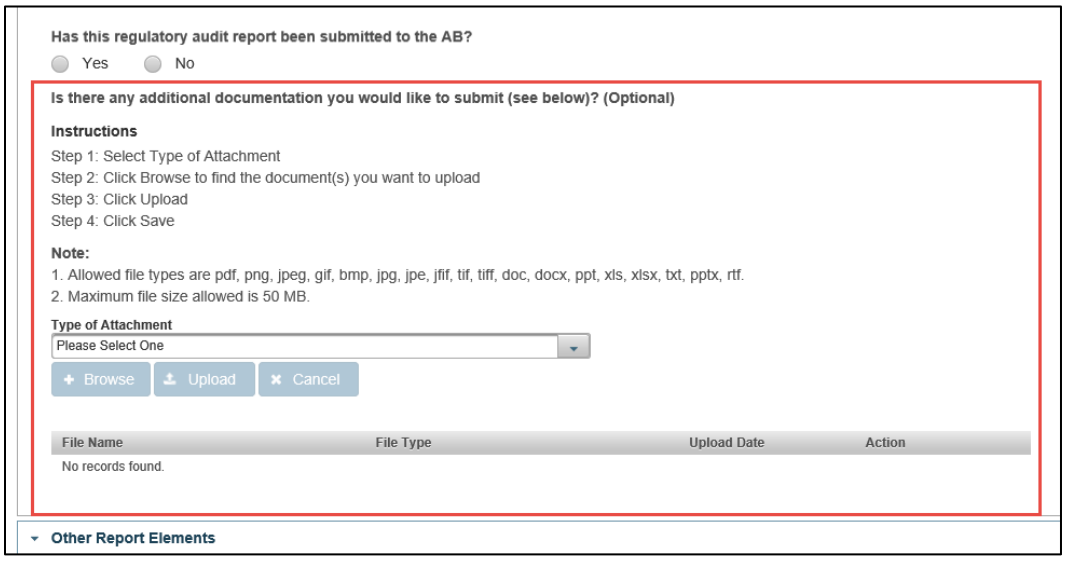


- **Has this regulatory audit report been submitted to the AB?** – Select "Yes" or "No."
- **Is there any additional documentation you would like to submit? (Optional)** – You may upload additional documents to support the regulatory audit report. Follow the instructions listed within the "Audit Summation" tab for uploading documents (Figure 6.32).

Note: The system supports the following document types: .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

The maximum file size allowed is 50 MB.

Figure 6.32 – Additional Documentation



Click the “Type of Attachment” dropdown menu and select one of the following options (Figure 6.33):

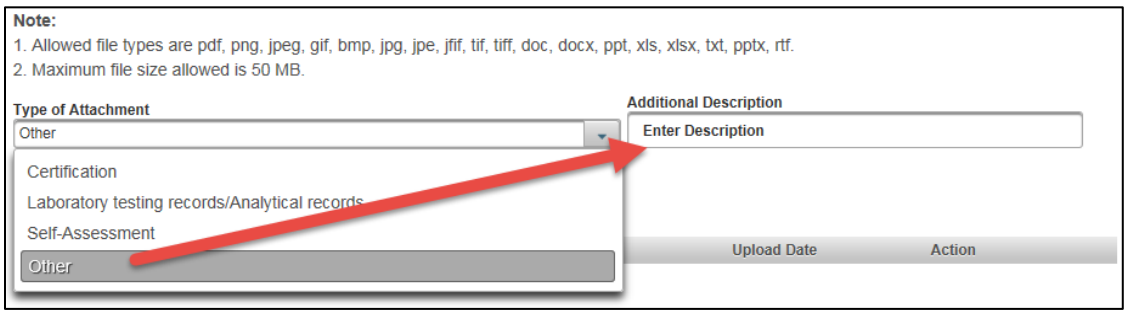
- “Certifications”
- “Laboratory testing records/Analytical records”
- “Self-Assessment”
- “Other”

Figure 6.33 – Type of Attachment Dropdown Menu

The text entry field “Additional Description” will display if you select “Other” from the list, which allows a maximum of 200 characters (Figure 6.34).

You must enter a description in the “Additional Description” field to proceed to the next step.

Figure 6.34 – Audit Summation Tab – Additional Description Field



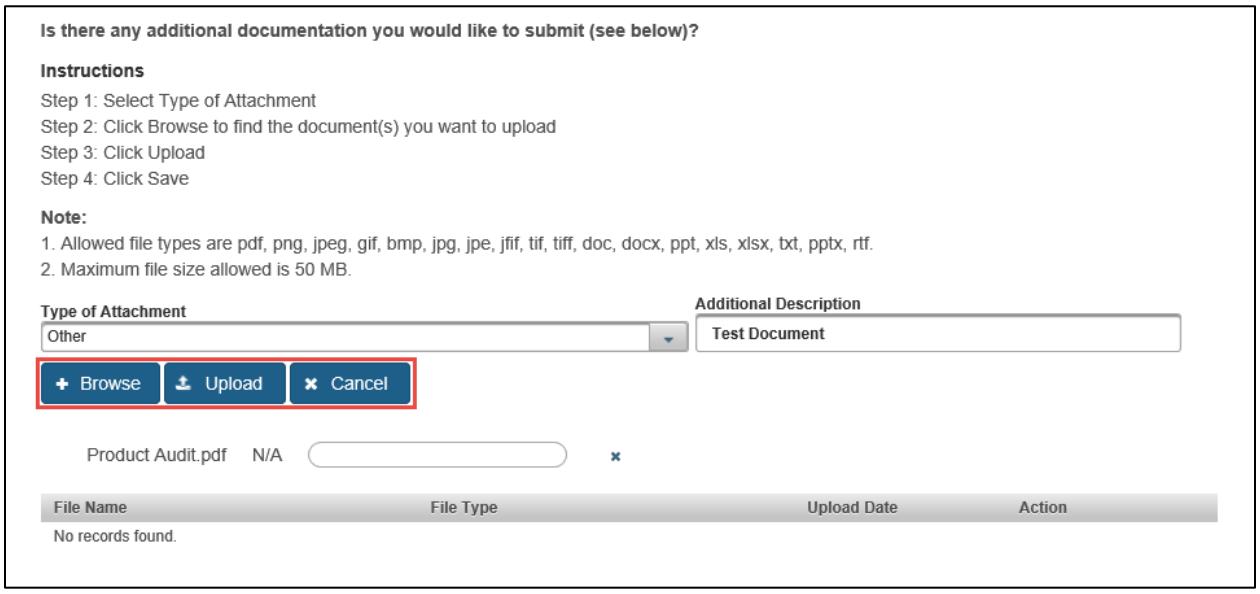
Click the “Browse” button. A pop-up window will appear, prompting you to access your file system.

Select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after you choose a file (Figure 6.35).

Click the “Cancel” button to discard the upload of the attachment.

Click the “Upload” button to complete the upload of the attachment.

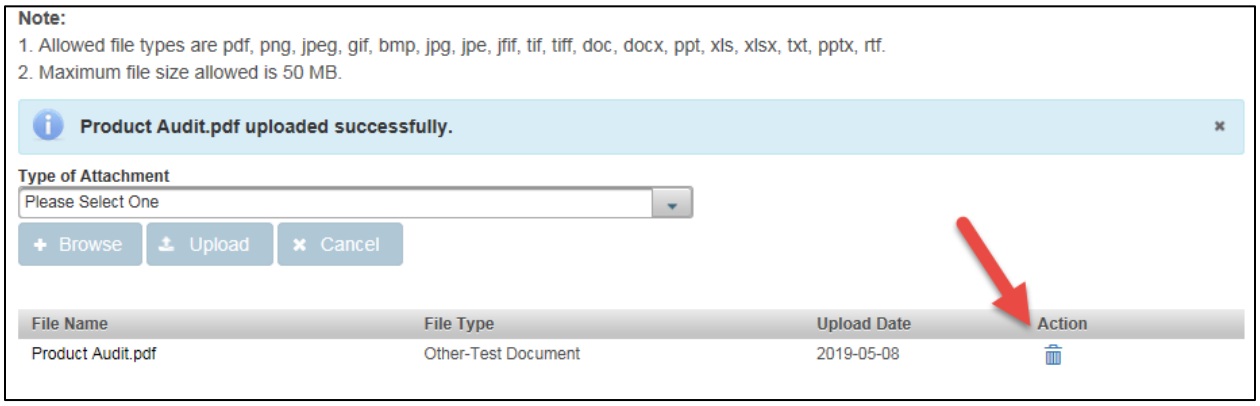
Figure 6.35 – Audit Summation Tab – Browse, Upload, and Cancel Buttons



Once the upload is complete, a confirmation message "<filename.filetype> uploaded successfully" will display above the "Type of Attachment" dropdown menu. The file name will be listed in the attachments table (Figure 6.36).

To remove the attachment, click the trash/delete icon in the "Action" column of the attachments table.

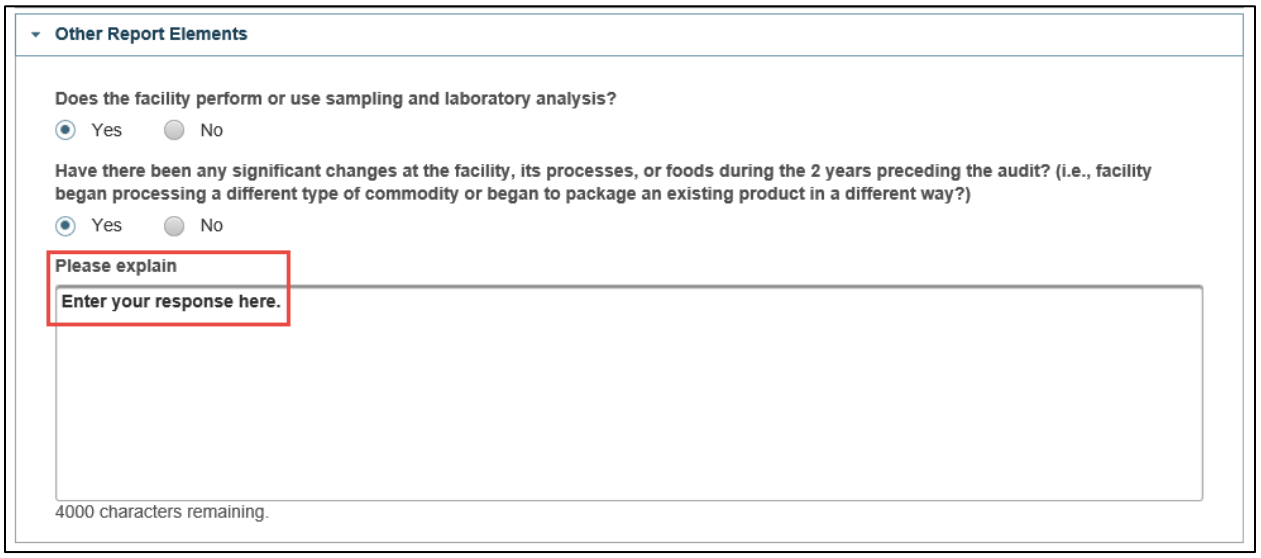
Figure 6.36 – Audit Summation Tab – Attachments Table



Complete the "Other Report Elements" section (Figure 6.37):

- **Does the facility perform or use sampling and laboratory analysis? –** Select **"**Yes" or "No."
- **Have there been any significant changes at the facility, its processes, or foods during the 2 years preceding the audit? (i.e., facility began processing a different type of commodity or began to package an existing product in a different way?) –** Select "Yes" or "No."
    - If you select "Yes," another field will display:
        - **Please explain –** This is a text field which allows up to 4,000 characters. Use this field to describe any significant changes at the facility, its processes, or foods during the two years preceding the regulatory audit.
    - If you select "No," no additional fields will display.

Figure 6.37 – Audit Summation Tab – Other Report Elements Section



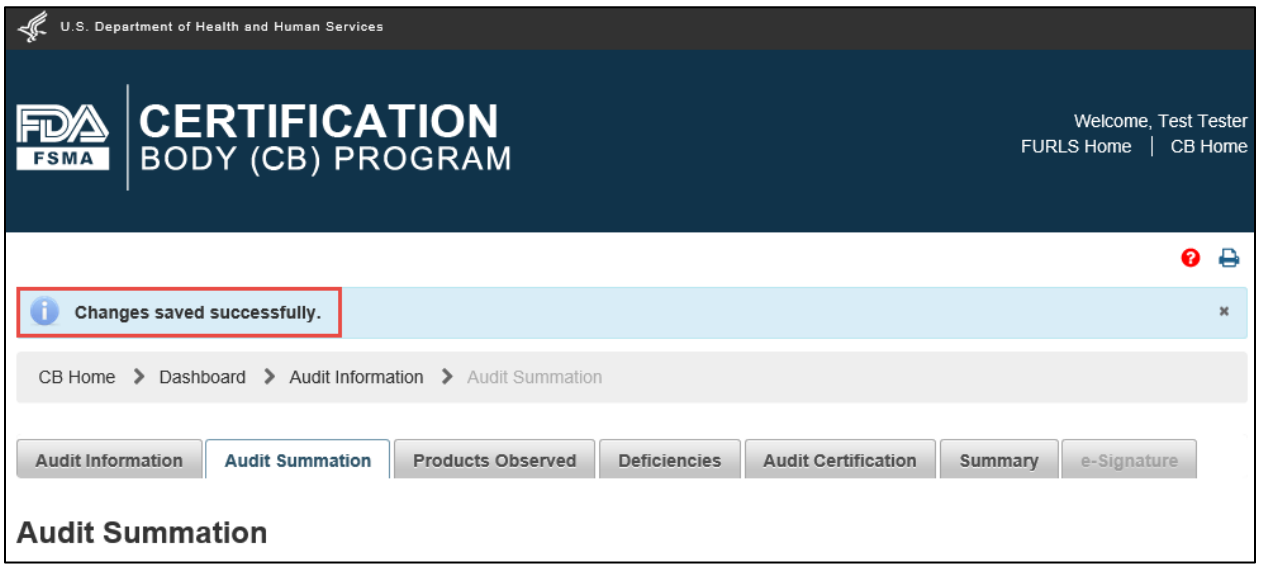
Once you have completed the information for this tab, click the “Save” button.

Once the “Changes saved successfully” message (Figure 6.38) appears at the top of the screen, proceed to the “Products Observed” tab.

Click the “Next” button or click on the “Products Observed” tab directly.

Proceed to Section 6.1.3 of this chapter.

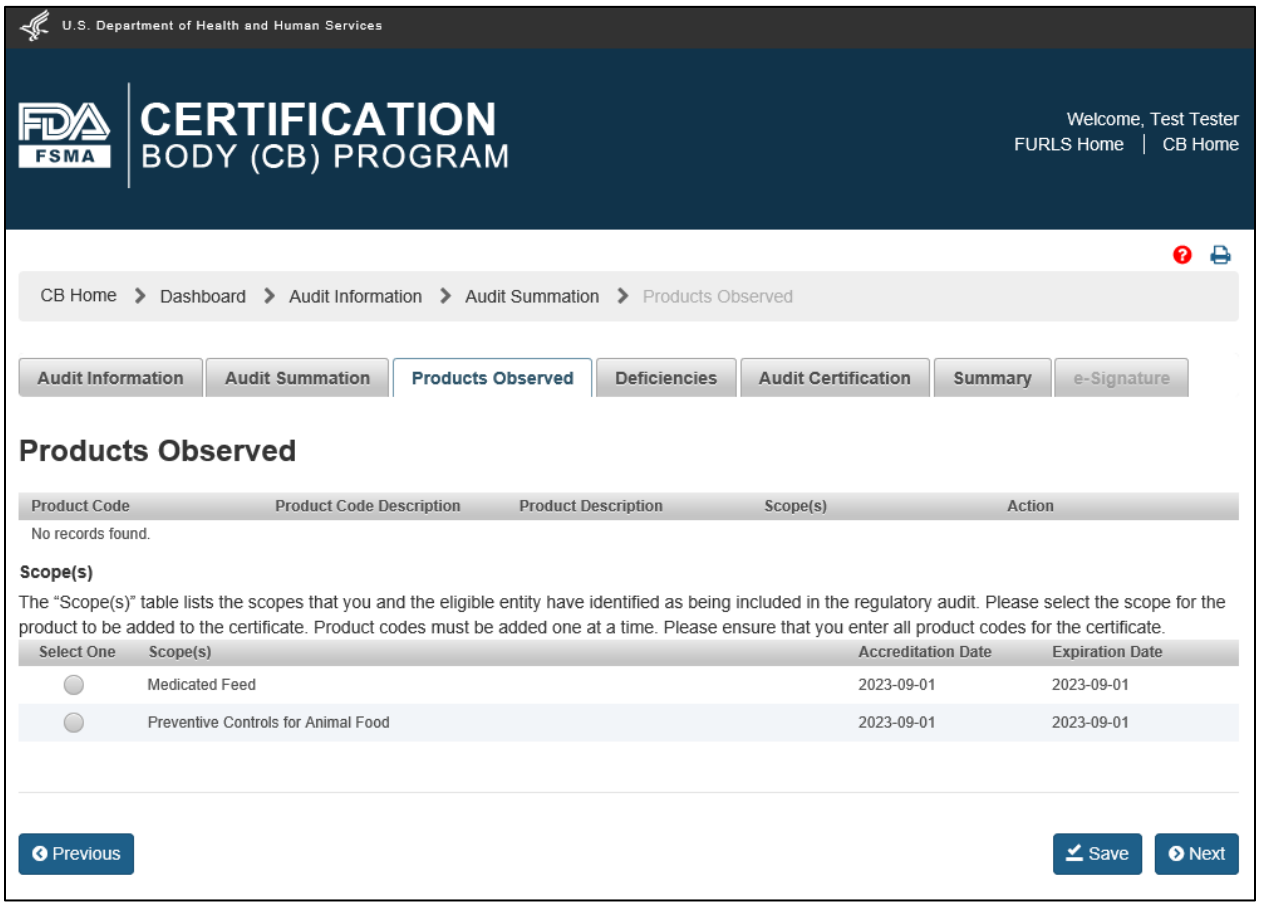
Figure 6.38 – Changes Saved Successfully Message



6.1.3 Products Observed Tab

The “Products Observed” tab allows you to enter the product codes of FDA regulated products that will be included in the certification (Figure 6.39).

Figure 6.39 – Products Observed Tab



The system will display the scope(s) you selected in the “Audit Information” tab. You may edit the scope(s) by clicking on the “Audit Information” tab.

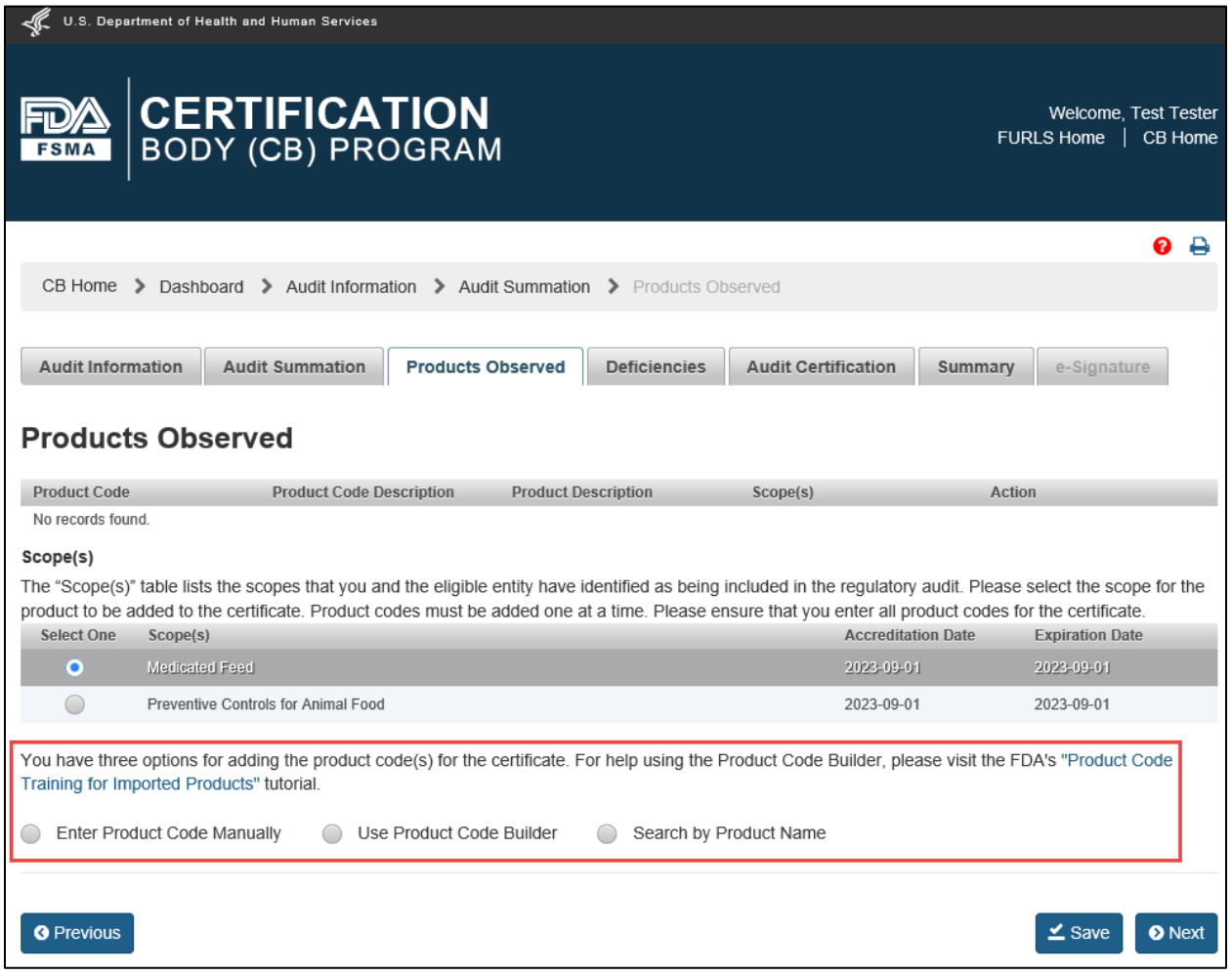
Select the scope of the product you wish to enter by clicking the radio button in the “Select One” column of the “Scope(s)” table. After you select a scope, the system will display three options for adding the corresponding product code(s) to the regulatory audit report (Figure 6.40).

You may use any of the following three options listed to add the product code(s) to the regulatory audit report. You may enter multiple product codes. Each product code must be added individually. Refer to the applicable section for instructions for each of the product code selection options:

- **Enter Product Code Manually –** You may use this option if you know the complete product code. Proceed to Section 6.1.3.1 of this chapter.
- **Use Product Code Builder –** You may use this option if you do not know the product code. Proceed to Section 6.1.3.2 of this chapter.
- **Search by Product Name –** You may use this option if you do not know the product code or do not want to use the Product Code Builder. Proceed to Section 6.1.3.3 of this chapter.

For information about Product Codes and the Product Code Builder, visit FDA's website on Product Codes and the Product Code Builder.

Figure 6.40 – Product Code Selection Options



6.1.3.1 Product Code Selection – Enter Product Code Manually

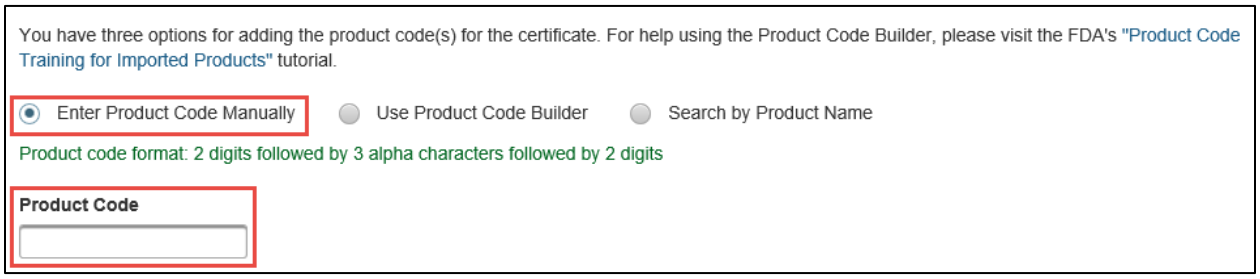
You may use the “Enter Product Code Manually” option if you know the complete product code. Select the radio button to the left of “Enter Product Code Manually.”

The “Product Code” field will display (Figure 6.41). Enter the product code in this field using the FDA product code format: Two digits followed by three alpha characters followed by two digits.

Note: There are some instances in which “SubClass” and/or “Process Indicator” for a selected industry/scope combination is not required. Therefore, the system may automatically display a dash (“-”) in place of one or both fields of the Product Code.

For help determining the Product Code, visit the FDA's website on Product Codes and the Product Code Builder.

Figure 6.41 – Product Code Selection – Enter Product Code Manually



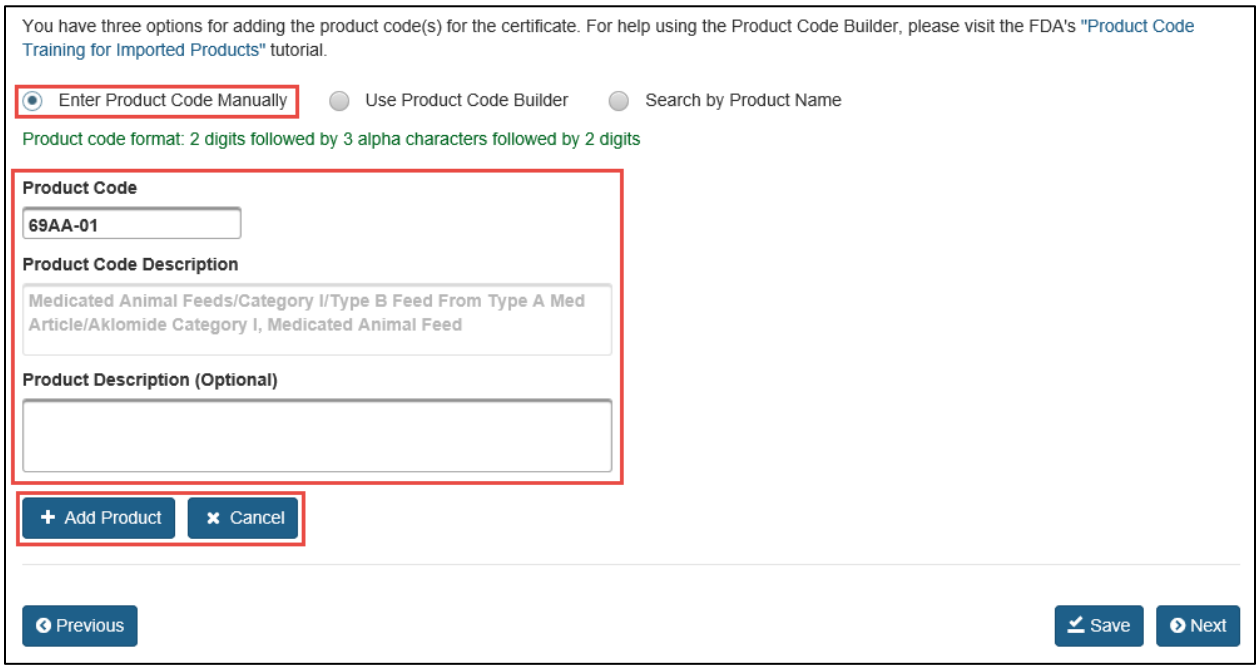
Once the system recognizes the product code, the following fields will display (Figure 6.42):

- **Product Code Description –** This is a read-only FDA Product Code Description that corresponds to the product code that was manually entered.
- **Product Description (Optional) –** This is an optional field in which you may provide your own product description.

Click the “Cancel” button to clear your entry for that product code and start over.

Click the “Add Product” button to add the product to the regulatory audit report.

Figure 6.42 – Enter Product Code Manually – Additional Fields



Once you click “Add Product,” the product will display in a table in the “Products Observed” tab (Figure 6.43).

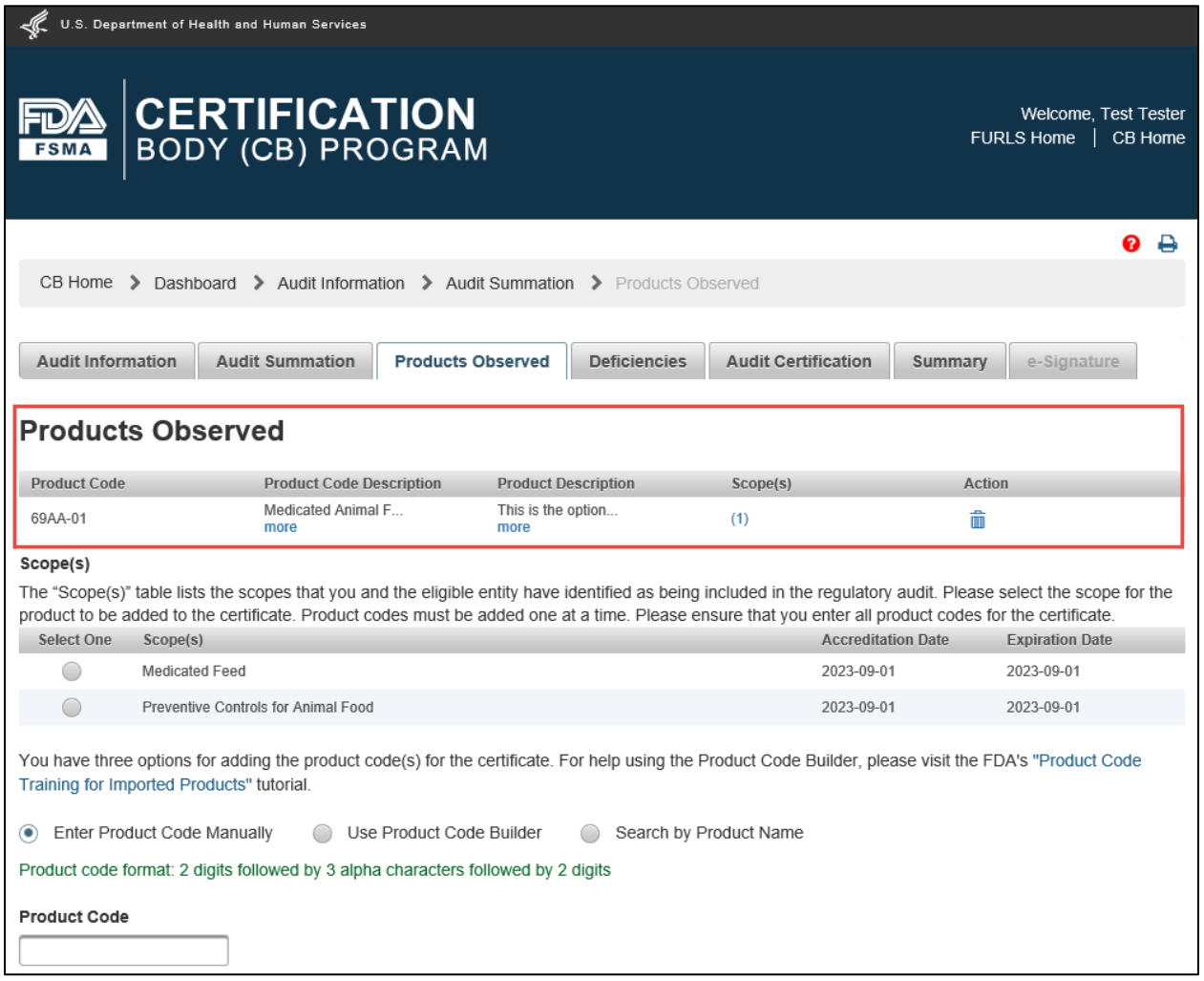
Repeat the previous steps to add more products.

If you have completed adding products to the regulatory audit report or would like instruction for adding products under a different scope, proceed to Section 6.1.3.4 of this chapter.

Click the trash/delete icon in the “Action” column of the table if you wish to remove the product.

Note: If any products intended to be certified are not listed, they will not be considered by FDA as covered under the regulatory audit report. Contact FDA if you submit a regulatory audit report and inadvertently leave out any product codes.

Figure 6.43 – Enter Product Code Manually – Product Added



6.1.3.2 Product Code Selection – Use Product Code Builder

You may use the "Use Product Code Builder" option if you do not know the product code. This option will create the seven character product code based on selections from five dropdown menus. Click the radio button to the left of "Use Product Code Builder" to build the product code (Figure 6.44).

Five dropdown menus will display after selecting the radio button. Click on the applicable menu to view and select an option from each:

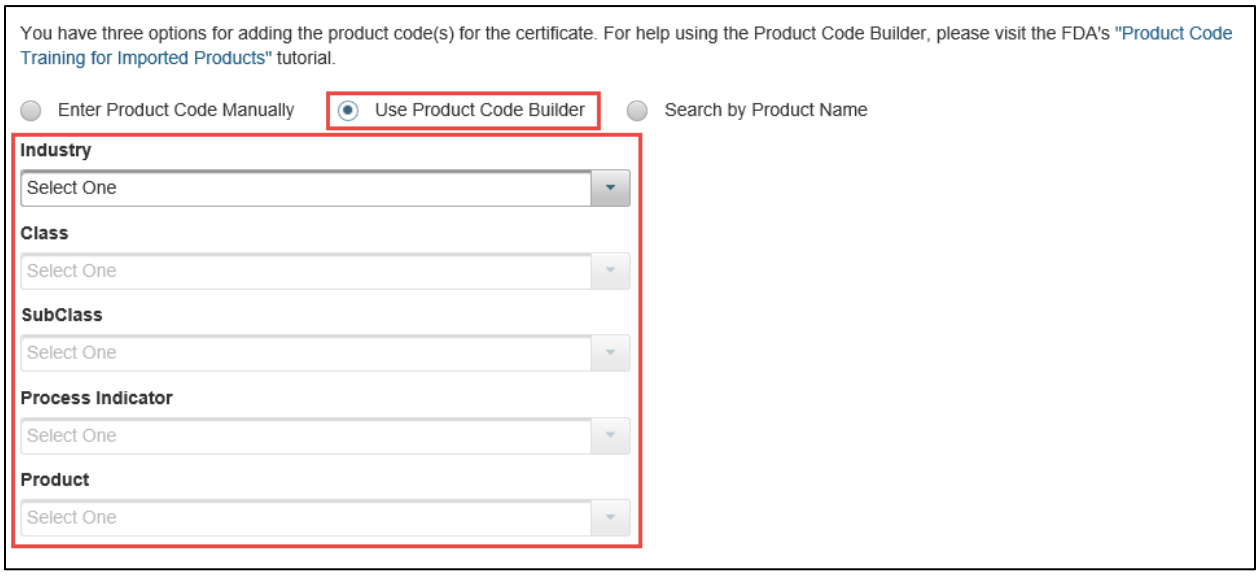
- **Industry –** The industry applicable to the product
  You must make a selection from the "Industry" menu before the system will allow you to select from the other menus.
- **Class –** The class applicable to the product
- **SubClass** – The subclass applicable to the product
- **Process Indicator –** The process indicator applicable to the product
- **Product –** The products available based on the selections from the previous four menus

Select the relevant value from each dropdown list by clicking directly on the menu, as applicable. Selections from the dropdown menus will enable the applicable subsequent menus.

Note: “SubClass” or “Process Indicator” menus may either be disabled or read-only, depending on whether they apply to the selected industry.

For help using the Product Code Builder, visit FDA's website on Product Codes and the Product Code Builder..

Figure 6.44 – Product Code Selection – Use Product Code Builder



After you select the values from all applicable dropdown menus, the following fields display (Figure 6.45):

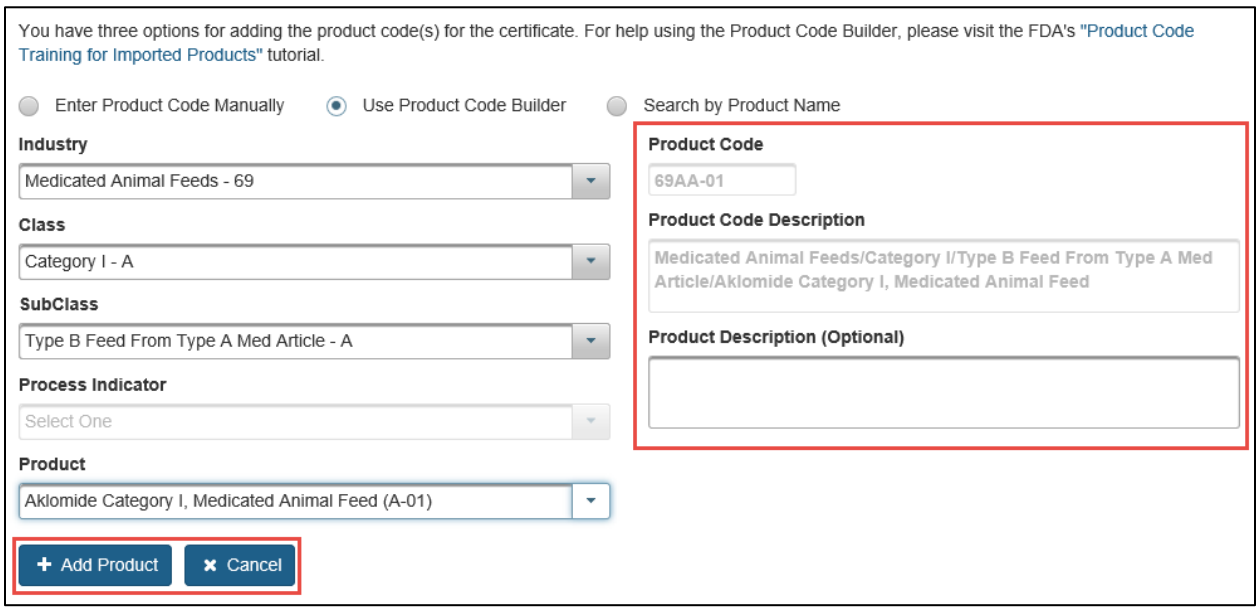
- **Product Code –** This is a read-only field that displays the seven character Product Code created from the dropdown menu selections.
- **Product Code Description –** This is a read-only field that displays the FDA Product Code Description that corresponds to the product code created from the dropdown menu selections.
- **Product Description (Optional) –** This is an optional field for you to provide your own product description.

Note: There are some instances in which “SubClass” and/or “Process Indicator” for a selected industry/scope combination is not required. Therefore, the system may automatically display a dash (“-”) in place of one or both fields of the Product Code in those instances.

Click the “Cancel” button to clear your selections made from the dropdown menus and choose the desired values.

Click the “Add Product” button to add the product to the regulatory audit report.

Figure 6.45 – Use Product Code Builder – Additional Fields



Once you click “Add Product,” the product will display in a table in the “Products Observed” tab (Figure 6.46).

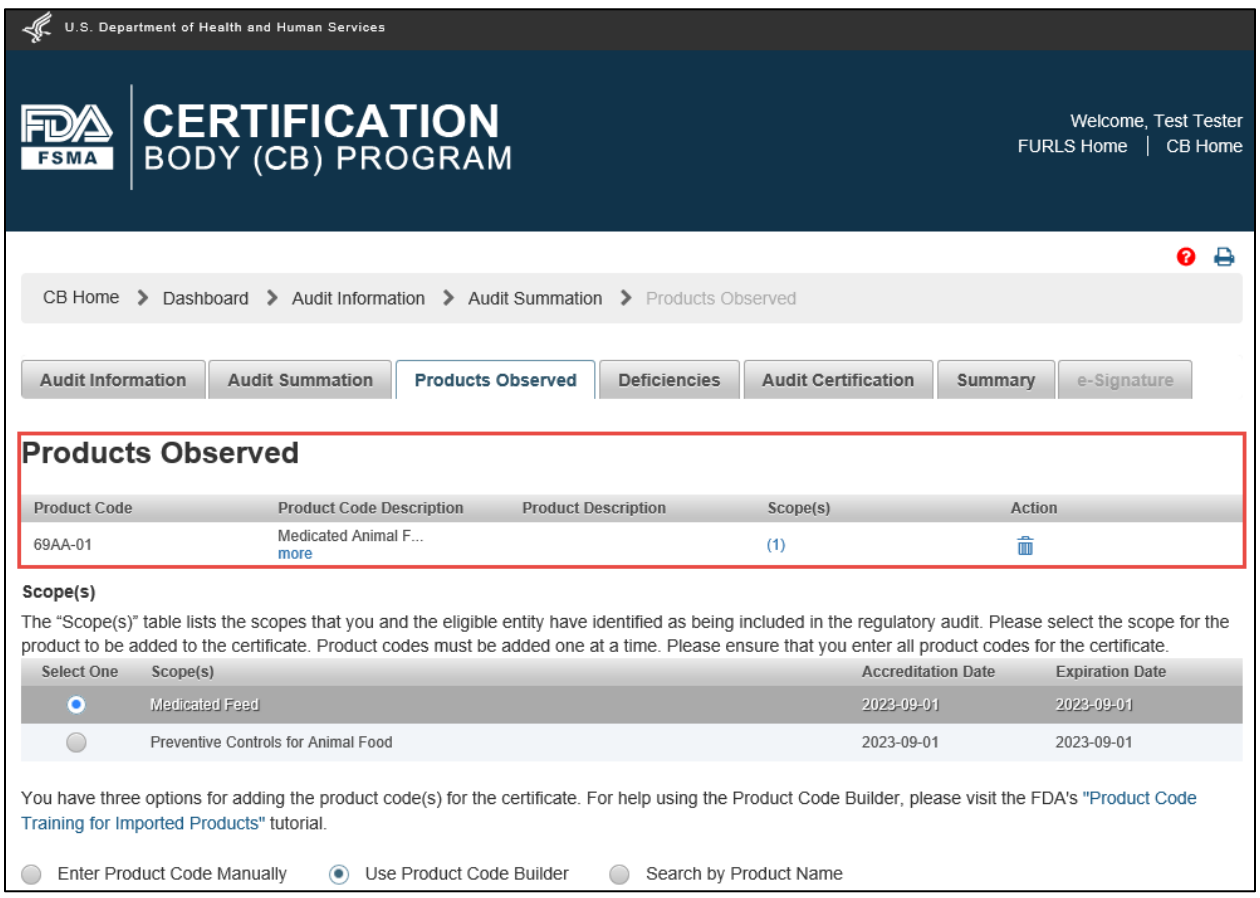
Repeat the previous steps to add more products.

If you have completed adding products to the regulatory audit report or would like instructions for adding products under a different scope, proceed to Section 6.1.3.4 of this chapter.

Click the trash/delete icon in the “Action” column of the table if you wish to remove the product.

Note: If any products intended to be certified are not listed, they will not be considered by FDA as covered under the regulatory audit report. Contact FDA if you submit a regulatory audit report and inadvertently leave out any product codes.

Figure 6.46 – Use Product Code Builder – Product Added



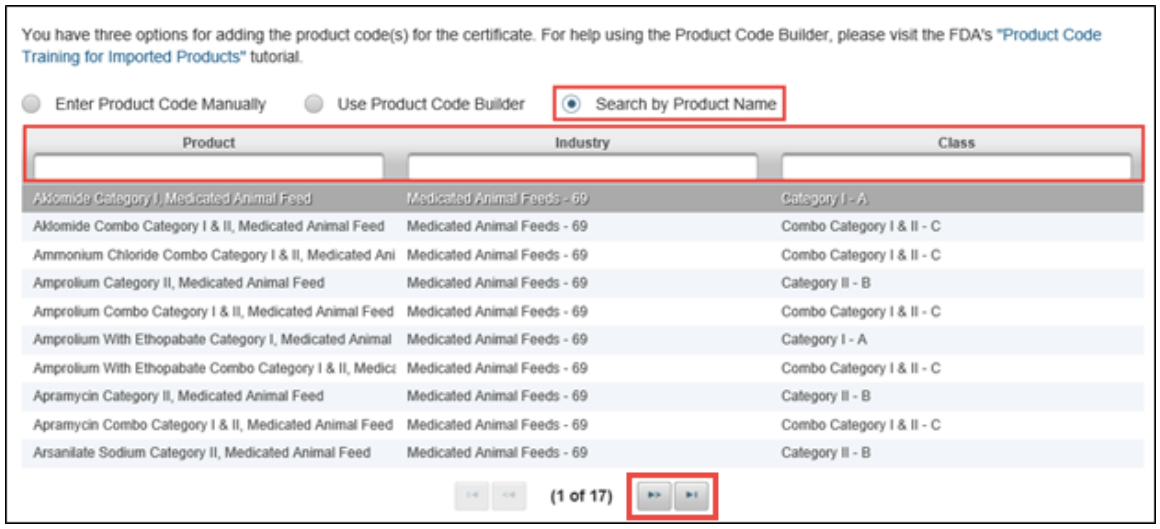
6.1.3.3 Product Code Selection – Search by Product Name

You may use the "Search by Product Name" option if you do not know the Product Code or do not want to use the Product Code Builder. Select the radio button to the left of "Search by Product Name." A table will display the following columns (Figure 6.47):

- **Product –** The available FDA regulated products associated to the scope selected from the "Scope(s)" section of the "Products Observed" tab
- **Industry –** The FDA product industry code applicable to the product
- **Class –** The class applicable to the product

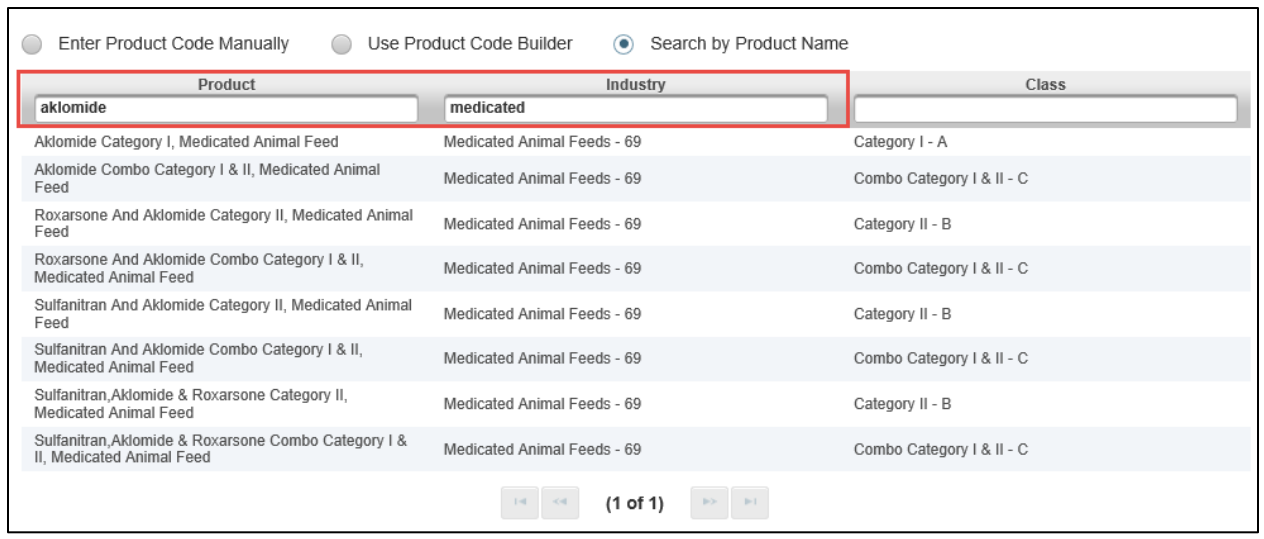
To filter the list, you may enter a keyword in any of the text fields at the top of the "Product," "Industry," or "Class" column. Alternatively, you may use the arrows at the bottom of the list to navigate through the pages [of the list] and identify the desired product.

Figure 6.47 – Product Code Selection – Search by Product Name



Type the keyword into the applicable search field(s). The system will refine the list based on your entry (Figure 6.48):

Figure 6.48 – Search by Product Name – List Filtered by Keyword



Select the desired value from the table by clicking on the applicable row. Once selected, additional fields will display (Figure 6.49):

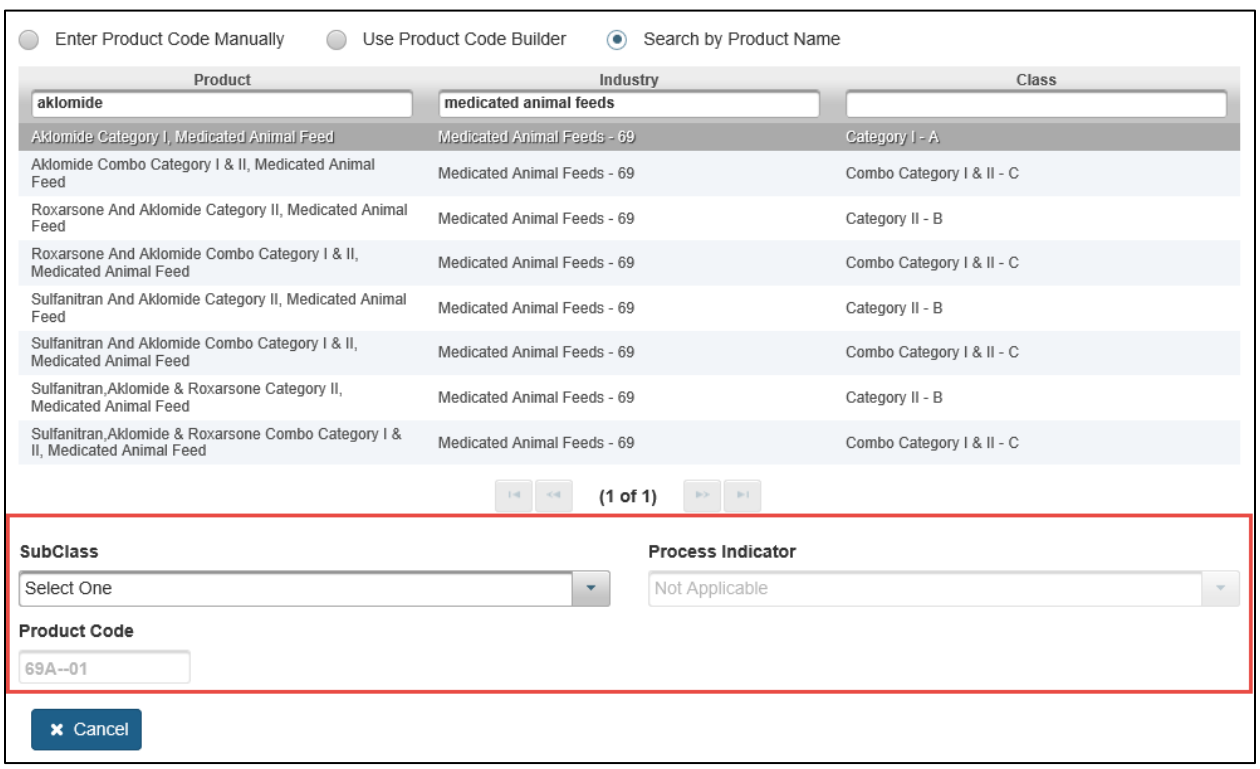
- **SubClass –** The subclass applicable to the product
- **Process Indicator –** The process indicator applicable to the product
- **Product Code –** The applicable product code – this field will be pre-filled and read-only once you have selected from the product list.

Select the relevant value from each dropdown list by clicking directly on the menu, as applicable. “SubClass” or “Process Indicator” menus may be disabled or read-only, depending on whether they apply to the selected industry.

Note: There are some instances in which “SubClass” and/or “Process Indicator” for a selected code combination are not required. Therefore, the system may automatically display a dash (“-”) in place of one or both fields of the Product Code in those instances.

For information on Product Codes and the Product Code Builder, visit the FDA's website on Product Codes and the Product Code Builder.

Figure 6.49 – Search by Product Name – Select Result and Additional Fields



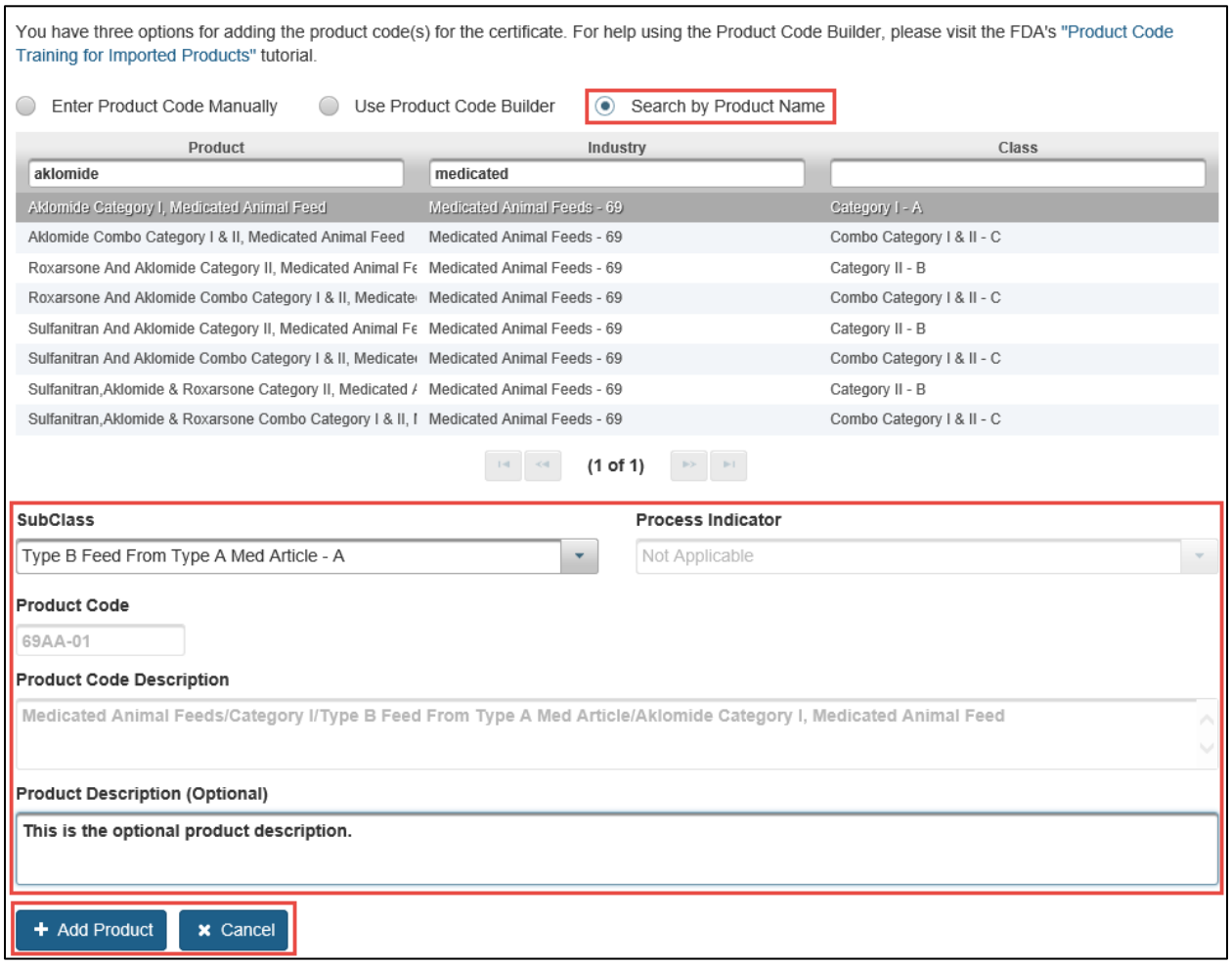
The following fields will display after you select from the “SubClass” and “Process Indicator” menus (Figure 6.50):

- **Product Code Description –** The read-only FDA product code description
  This field is displayed when the values for “SubClass” and “Process Indicator” are selected.
- **Product Description (Optional) –** An optional field to provide your own product code description
  This field is displayed when the value for “Process Indicator” is selected.

Click the “Cancel” button to clear selections made from the dropdown menus and choose the desired values.

Click the “Add Product” button to add the product to the regulatory audit report.

Figure 6.50 – Search by Product Name – Additional Fields, Add Product, and Cancel Buttons



Once you click “Add Product,” the product will display in a table in the “Products Observed” tab (Figure 6.51).

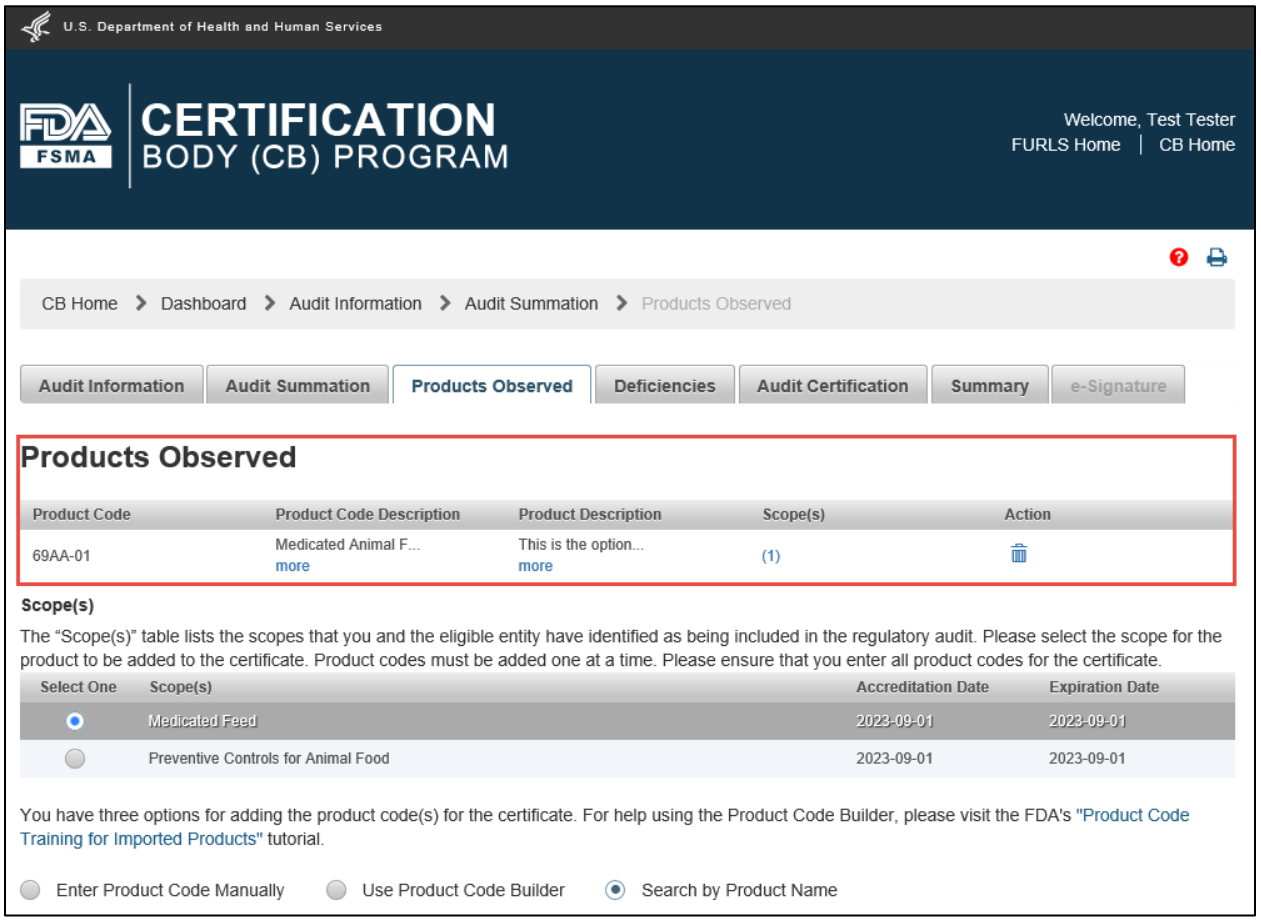
Repeat the previous steps to add more products.

If you have completed adding products to the regulatory audit report or would like instructions for adding products under a different scope, proceed to Section 6.1.3.4 of this chapter.

Click the trash/delete icon in the “Action” column of the table if you wish to remove the product.

Note: If any products intended to be certified are not listed, they will not be considered by FDA as covered under the regulatory audit report. Contact FDA if you submit a regulatory audit report and inadvertently leave out product codes.

Figure 6.51 – Search by Product Name – Product Added



6.1.3.4 Additional Product Code Selection Information

If you need to add a product code under a different scope, return to the "Scope(s)" section of the "Products Observed" tab. Click on the radio button of the scope that corresponds to the product code(s) you wish to enter. Add the product code(s) using one of the three options described in the preceding sections of this chapter.

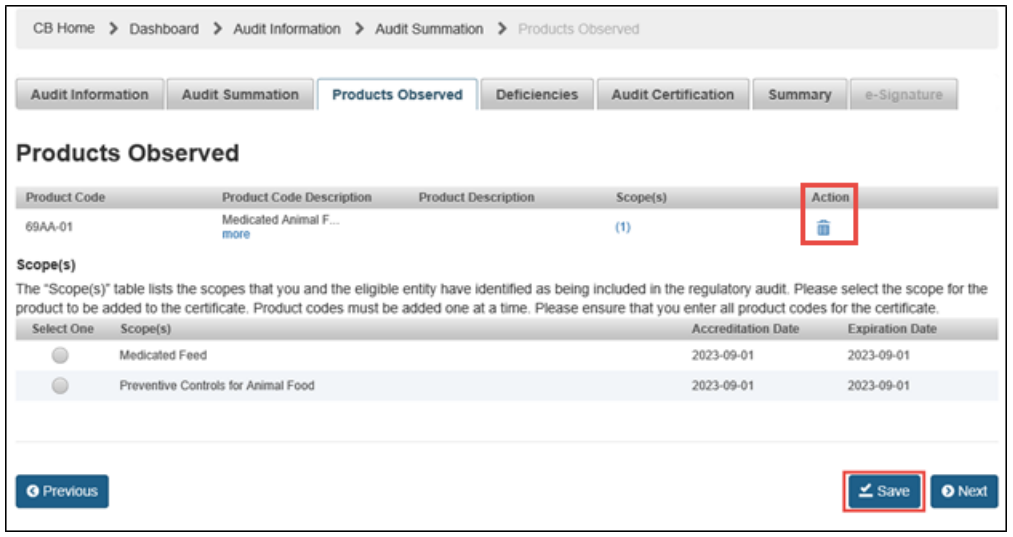
After you enter the product codes for each scope option (using any of the three available options), review the "Products Observed" table for accuracy.

After you add all the products, click the "Save" button (Figure 6.52).

You may delete any product by selecting the associated trash/delete icon in the "Action" column of the table.

****Important:** Once you submit the regulatory audit report to FDA you cannot add or delete product code(s).

Figure 6.52 – Products Observed – Trash Icon and Save Button

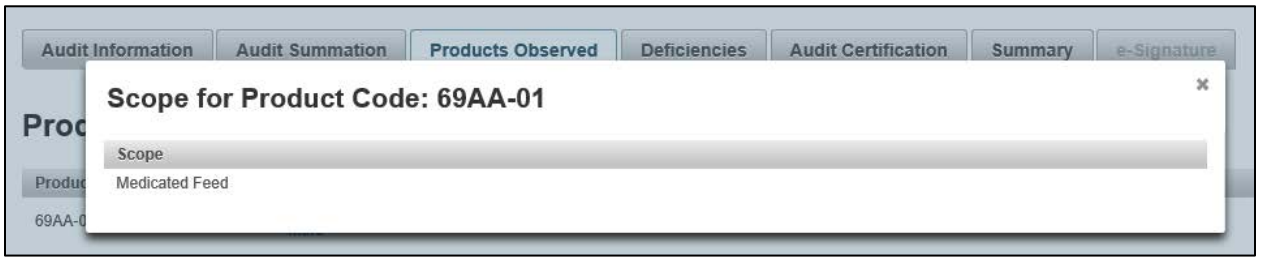


Once you have added a product to the regulatory audit report, the "Scope(s)" column of the table of product(s) will display the number of scopes to which the product is associated (Figure 6.53).

Figure 6.53 – Scope Hyperlink

Select the hyperlinked number from the "Scope(s)" column of the table to display a pop-up window. The pop-up window displays the name of the scope that was selected for the product and was added to the table of products (Figure 6.54).

Figure 6.54 – Scope for Product Code Pop-up Window

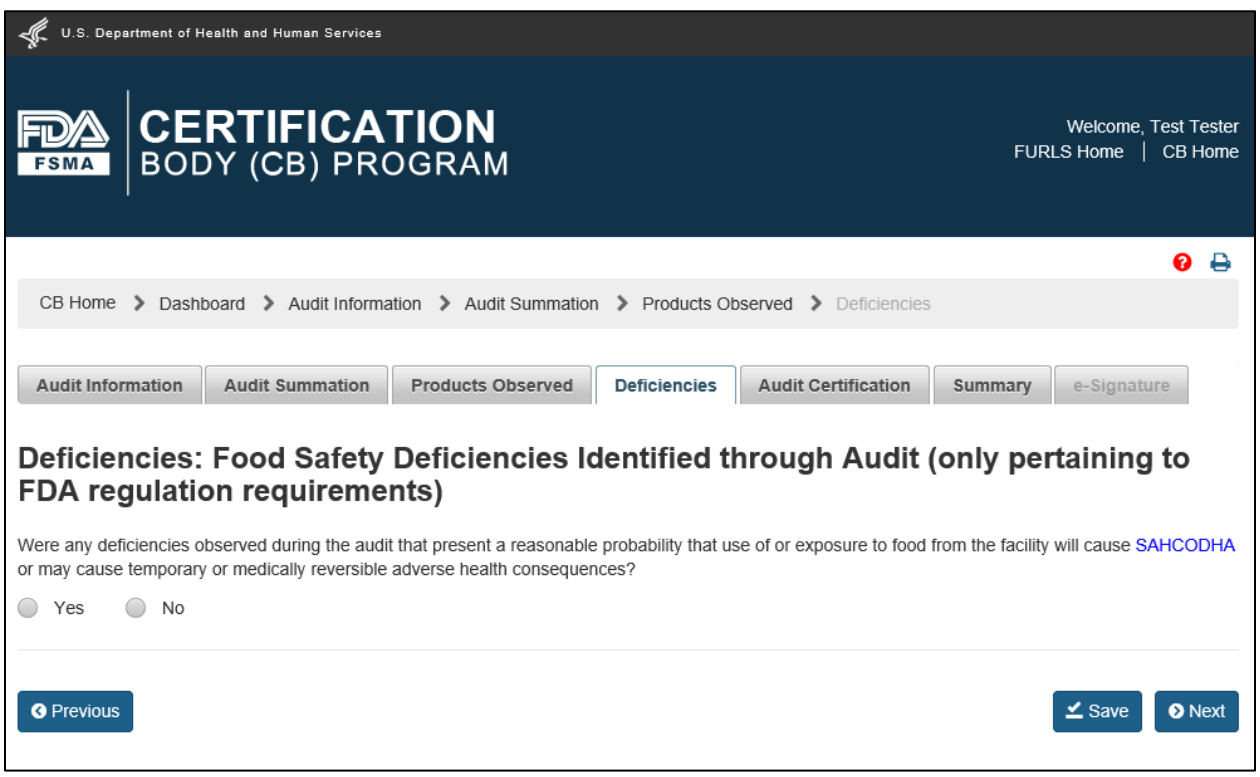


Click the "Next" button to proceed to the "Deficiencies" tab or click on the "Deficiencies" tab directly.

6.1.4 Deficiencies Tab

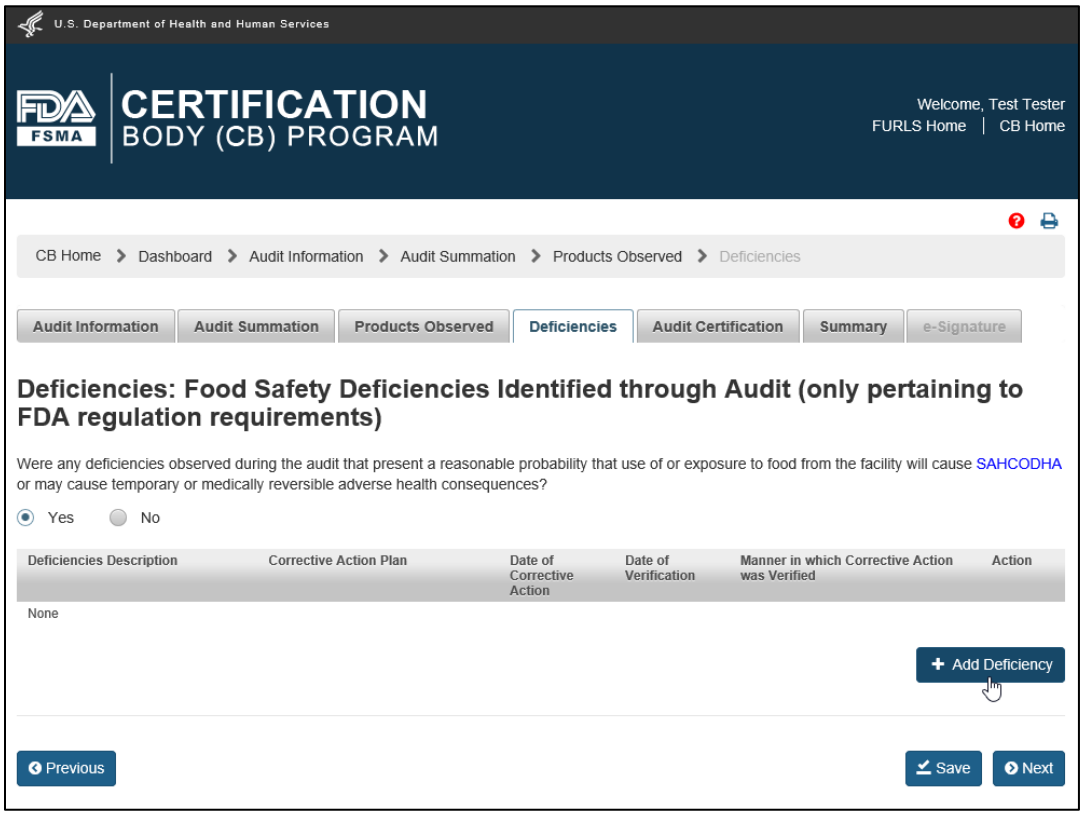
The "Deficiencies" tab allows you to summarize any deficiencies observed during the regulatory audit (Figure 6.55).

Figure 6.55 – Deficiencies Tab



- **Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause SAHCODHA, or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote?** – Select “Yes” or “No.”
    - If you select “Yes,” the “Add Deficiency” button will display and additional information will need to be submitted, as described in the next section (Figure 6.56).
    - If you select “No,” click the “Save” button and proceed to the “Audit Certification” tab by clicking the “Next” button – or on the “Audit Certification” tab directly. Proceed to Section 6.1.5 of this chapter.

Figure 6.56 – Deficiencies Tab – Add Deficiency Button



After you click the “Add Deficiency” button, the system will display additional required fields (Figure 6.57).

Complete the following required information for each deficiency identified through the regulatory audit:

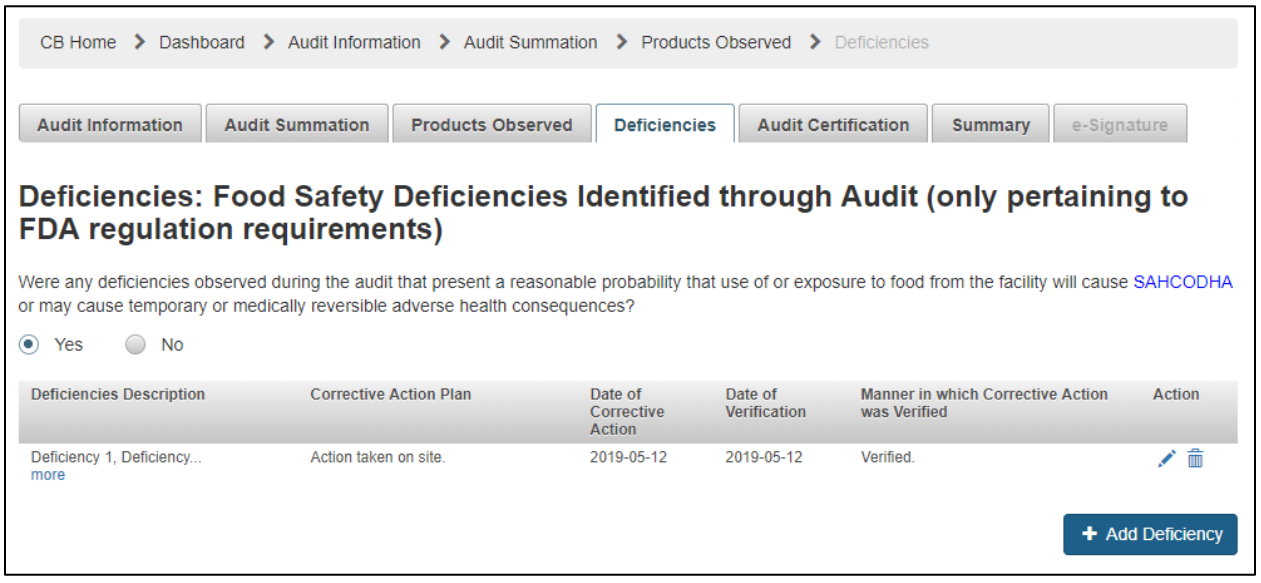
- **Please describe any deficiencies that present a reasonable probability that use of or exposure to food from the facility will cause SAHCODHA, or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. –** This is a text entry field and allows up to 4,000 characters.
- **Was corrective action implemented immediately and verified on site? –** Select “Yes” or “No.”
    - If you select “Yes,” the “Date of Corrective Action” field will be pre-populated with the regulatory audit end date.
    - If you select “No,” enter the date of the corrective action.
- **Please describe the corrective action plan for each such deficiency. –** This is a text entry field and allows up to 4,000 characters.
- **Date of Corrective Action –** Select the date on which the corrective action was taken with the calendar icon or enter it in “YYYY-MM-DD” format.
- **Describe the manner in which corrective action was verified –** This is a text field, which allows up to 4,000 characters.
- **Date of Verification of Corrective Action –** Select the date on which the corrective action was verified with the calendar icon or enter it in “YYYY-MM-DD” format.

Figure 6.57 – Deficiencies Tab – Additional Required Fields

After you have completed the applicable fields, click the “Add Deficiency” button or the “Cancel” button.

If you click “Add Deficiency,” the deficiency will appear in the table at the top of the tab (Figure 6.58). If you click “Cancel,” your deficiency information will be removed.

Figure 6.58 – Deficiencies Tab – Add Deficiency



Review the data you entered from the “Deficiency” table. You can delete data by selecting the trash/delete icon or edit the data by selecting the pencil/edit icon.

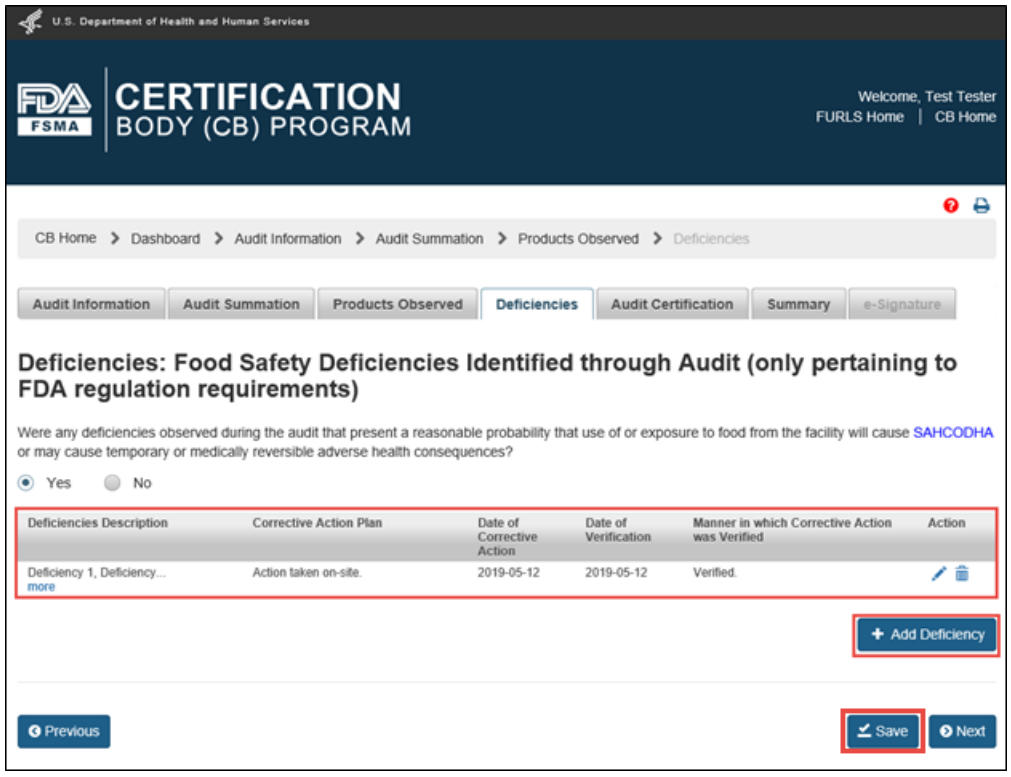
Enter any additional deficiencies by clicking the “Add Deficiency” button and repeating the steps.

Review your data in the “Deficiency” table and click the “Save” button (Figure 6.59). Once the “Changes saved successfully” message appears at the top of the screen, proceed to the “Audit Certification” tab.

Click the “Next” button to proceed to the “Audit Certification” tab or click on the “Audit Certification” tab directly.

Proceed to Section 6.1.5 of this chapter.

Figure 6.59 – Deficiency Table



6.1.5 Audit Certification Tab

The “Audit Certification” tab allows you to provide details regarding any certification you issue related to the regulatory audit report.

There are multiple scenarios which might occur in the “Audit Certification” tab, depending on whether you submit a certification with the regulatory audit report.

Proceed to the applicable section for instructions to complete the “Audit Certification” tab, as indicated below:

- If you are submitting both a new regulatory audit report and a new certification together (i.e., the certification does not exist yet) proceed to Section 6.1.5.1 of this chapter.
- If you plan to submit a certification for the regulatory audit report at a later date (i.e., submit only the regulatory audit report at this time) proceed to Section 6.1.5.2 of this chapter.
- If you will not submit a certification for the regulatory audit report, proceed to Section 6.1.5.3 of this chapter.

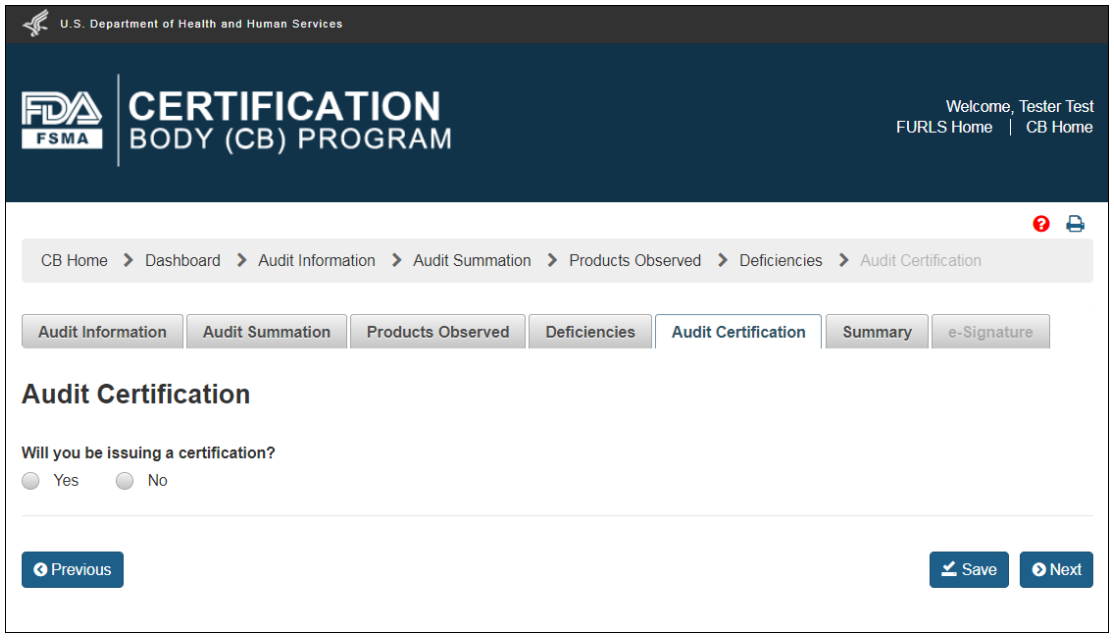
6.1.5.1 Submit a New Regulatory Audit Report and Submit the Issued Certification Information

To submit a new certification with the new regulatory audit report (i.e., the certification information has not been previously added in FURLS), follow the steps in this section.

Complete the following fields on the “Audit Certification” tab (Figure 6.60):

- **Will you be issuing a certification?** – Select “Yes.”

Figure 6.60 – Audit Certification Tab – "Will you be issuing a certification?"



Once you answer "Yes" to the question "Will you be issuing a certification?" another question will display (Figure 6.61):

- **Do you want to submit the certification with this audit report? –** Select "Yes."
  Additional fields will display:
- **Please provide the certification number –** Enter the certificate number using the required format. The format of the certification number must be "AAA-BBB-YY-xxxxxx."
  - **AAA –** The first three letters of the AB's name
  - **BBB –** The first three letters of the CB's name
  - **YY –** The year the certification was issued
  - **xxxxxx –** Enter six digits. It is recommended that you maintain sequential numbering. For example, your first certification for the specific AB/CB combination for that certification year could end '-000001,' followed by '000002,' and so on.
- **Date of Issuance –** Select the date the certification was issued with the calendar icon or enter it in "YYYY-MM-DD" format.
- **Expiration Date of Certification –** Select the certification's expiration date with the calendar icon or enter the date in "YYYY-MM-DD" format. The expiration date of the Certification cannot be more than one year from the date of issuance.
- **Was this certification issued to meet an import certification requirement under Section 801(q) of the FD&C Act [21 U.S.C. 381(q)]** – Select "Yes" or "No."

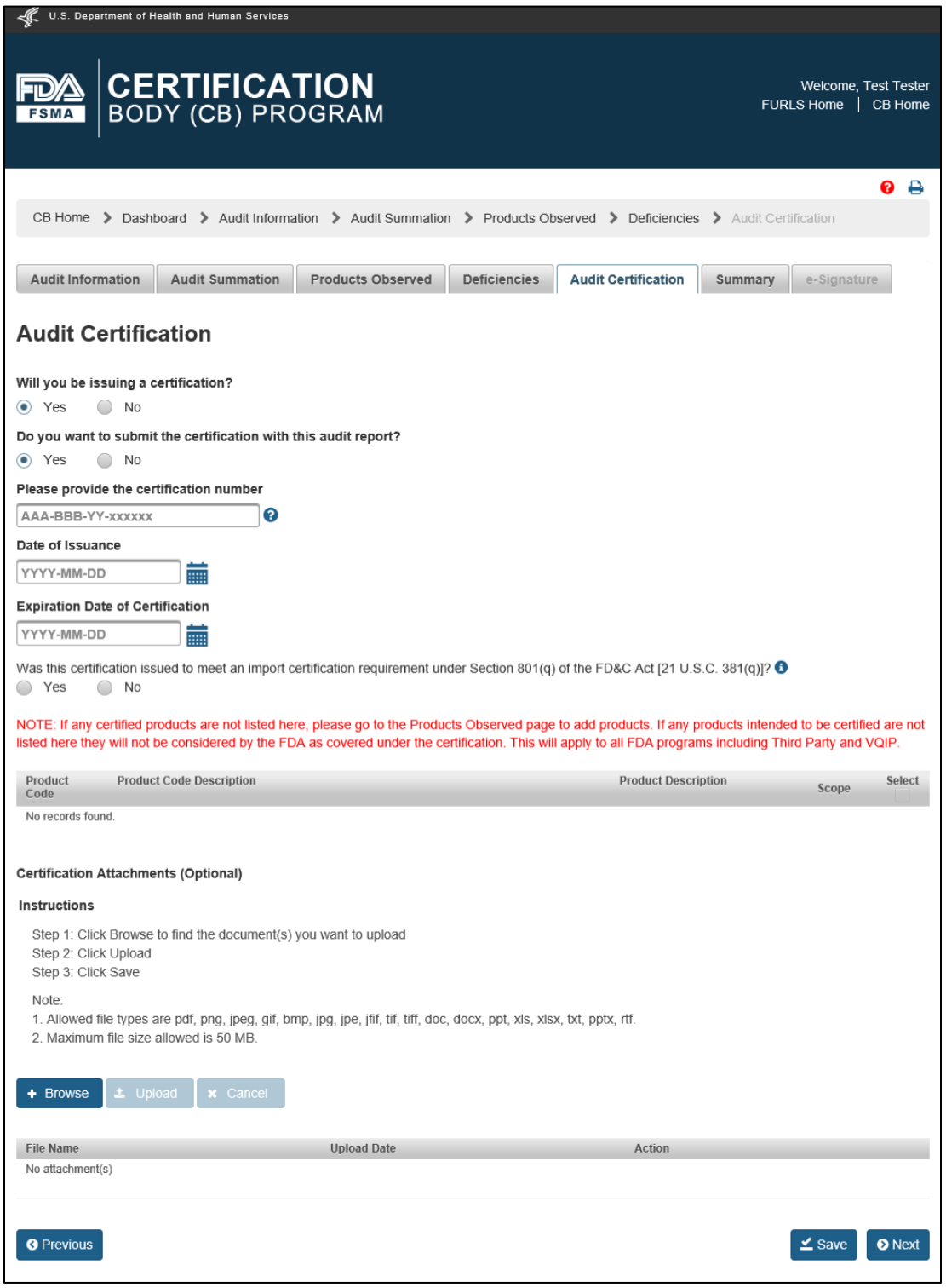
  Note: If you click the "Information" icon at the end of the question above, the following content will display in a pop-up:

  In certain circumstances, FDA may require certification of an imported food product to help prevent a potentially harmful food from entering the U.S.

  For more information on this authority, please see Section 801(q) of the FD&C Act and Section 303 of FSMA,

Authority to Require Import Certifications for Food." "Section 303" of the text is hyperlinked: https://www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma#SEC303

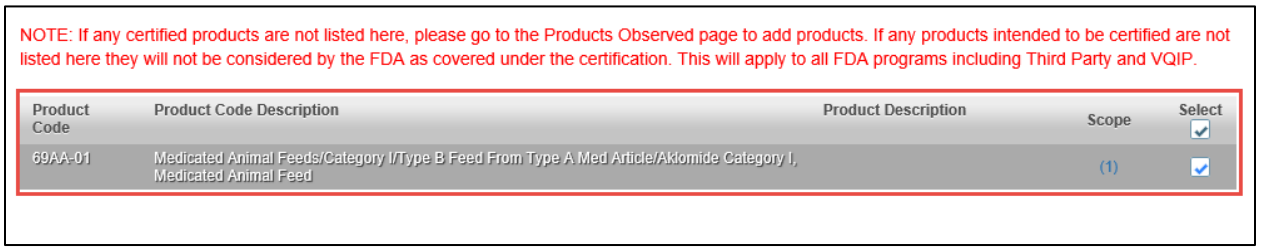
Figure 6.61 – Audit Certification Tab – Certification Will Be Submitted – Additional Fields



- **Product Table –** Select the checkbox(es) of the product code(s) listed in the product table that should be listed on the certificate resulting from the regulatory audit (Figure 6.62). At least one checkbox must be selected.

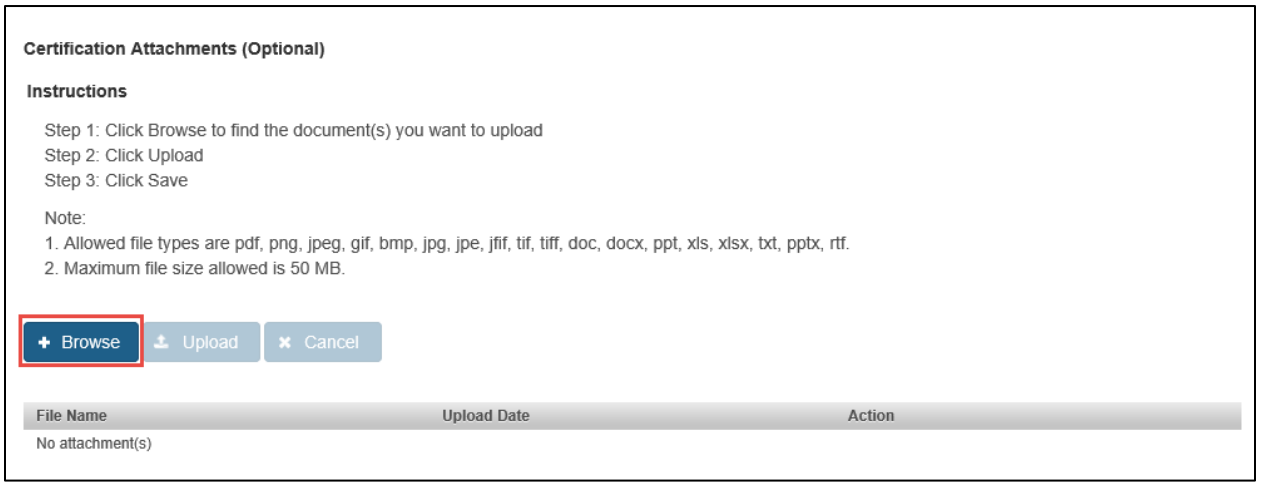
  Note: If any needed product codes are not listed here, go to the “Products Observed” tab to add the product codes. If any products intended to be certified are not listed, they will not be considered by FDA as covered under the certification. Contact FDA if you submit a regulatory audit report or certification and inadvertently leave out any product codes.

Figure 6.62 – Product Table



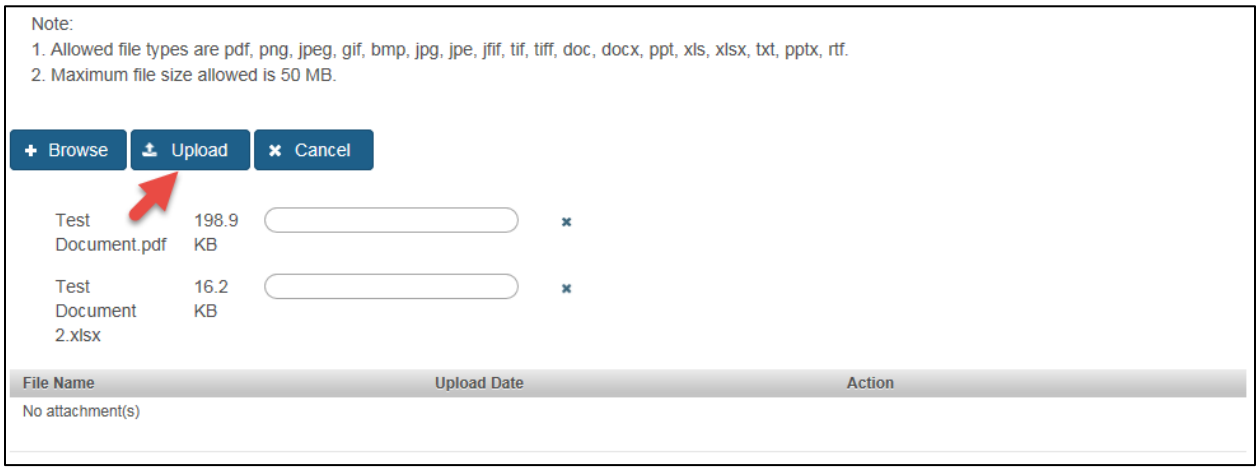
- **Certification Attachments (Optional) –** Upload any additional attachments applicable to the certification. Attachments must be a document type supported by the system (Figure 6.63).

Figure 6.63 – Certification Attachments (Optional)



Click the “Browse” button. A pop-up window will display. Select one or more file attachments. The “Upload” button will be enabled after a file is chosen as an attachment (Figure 6.64).

Figure 6.64 – Audit Certification Tab – Upload Button



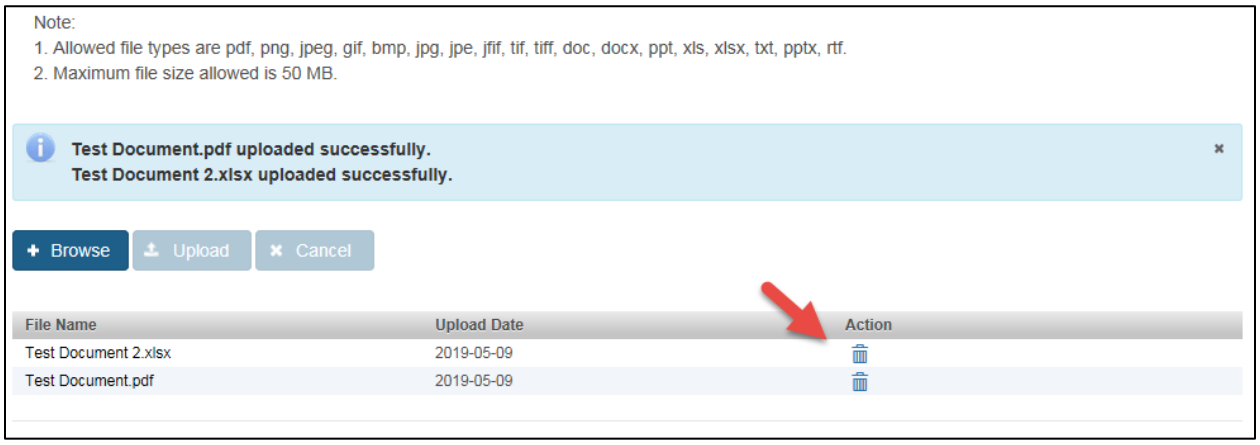
Click the “Cancel” button to discard the upload of the attachment.

Click the “Upload” button to complete the upload of the attachment.

Once the upload is complete, a confirmation message: “<filename.filetype> uploaded successfully” will display in the table of attachments (Figure 6.65).

To remove an uploaded attachment, click the trash/delete icon in the “Action” column of the attachment table.

Figure 6.65 – Audit Certification Tab – Attachments Table



Click the “Save” button to save your changes.

Click the “Next” button or click on the “Summary” tab directly to proceed to the “Summary” tab.

Proceed to Section 6.1.6 of this chapter.

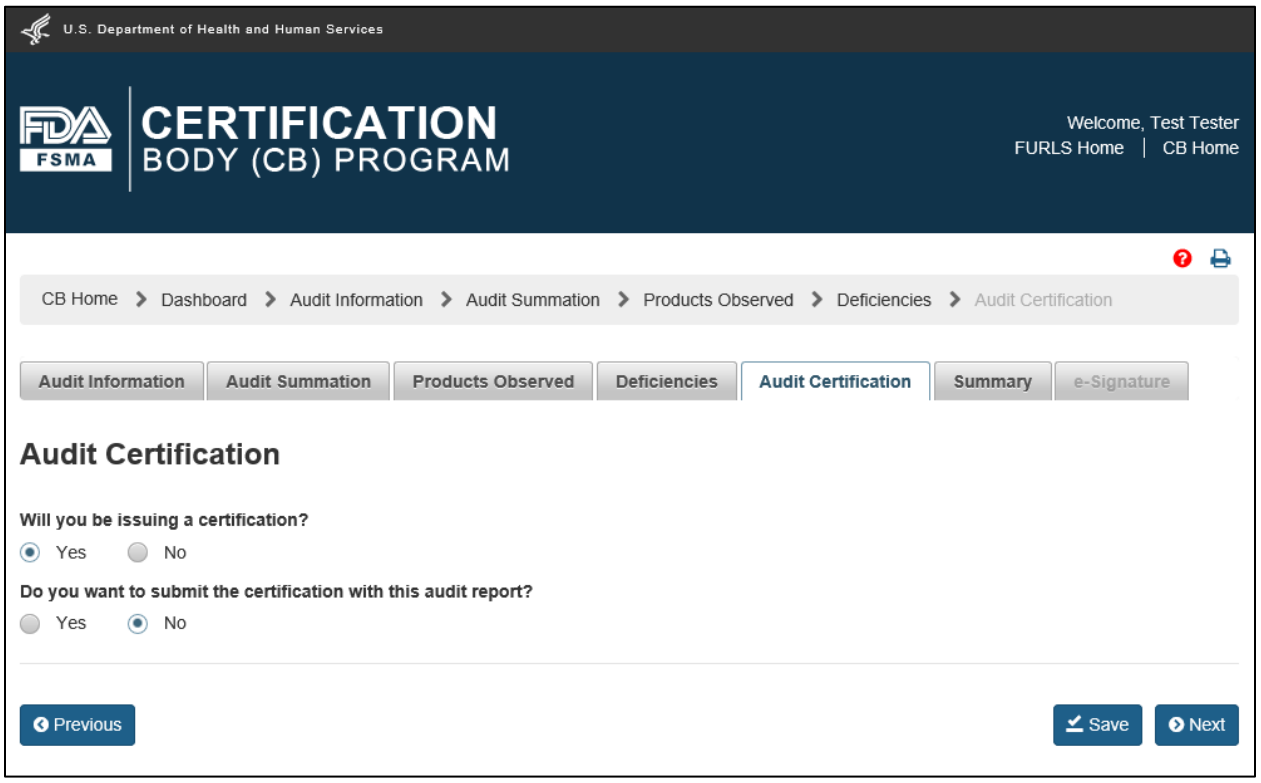
6.1.5.2 Submit a New Regulatory Audit Report and Submit the Issued Certification Information at Another Time

If you wish to submit the certification information for the regulatory audit report at a later date, you may only submit the regulatory audit report at this time. You may return to the system to submit its certification another time.

Complete the following fields on the “Audit Certification” tab (Figure 6.66):

- **Will you be issuing a certification? –** Select “Yes.”
  If you answer “Yes” to the question “Will you be issuing a certification?” another question will display:
- **Do you want to submit the certification with this audit report? –** Select “No.” No additional fields will display.

Figure 6.66 – Audit Certification Tab – “Do you want to submit the certification with this audit report?”



Click the “Save” button to save your changes.

Click the “Next” button or click on the “Summary” tab directly.

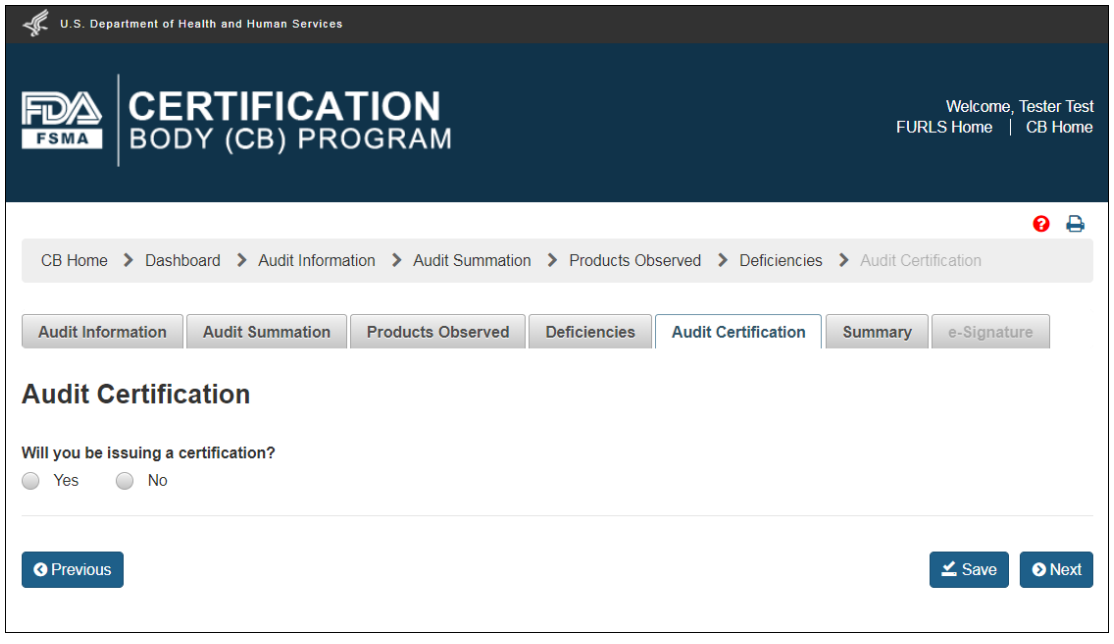
Proceed to Section 6.1.6 of this chapter.

6.1.5.3 Submit a New Regulatory Audit Report When No Certification Will be Issued

A regulatory audit report must be submitted for all regulatory audits (21 CFR 1.652(c)). If a certificate will not be issued based upon the results of the regulatory audit, complete the following fields on the “Audit Certification” tab (Figure 6.67):

- **Will you be issuing a certification? –** Select “No.”

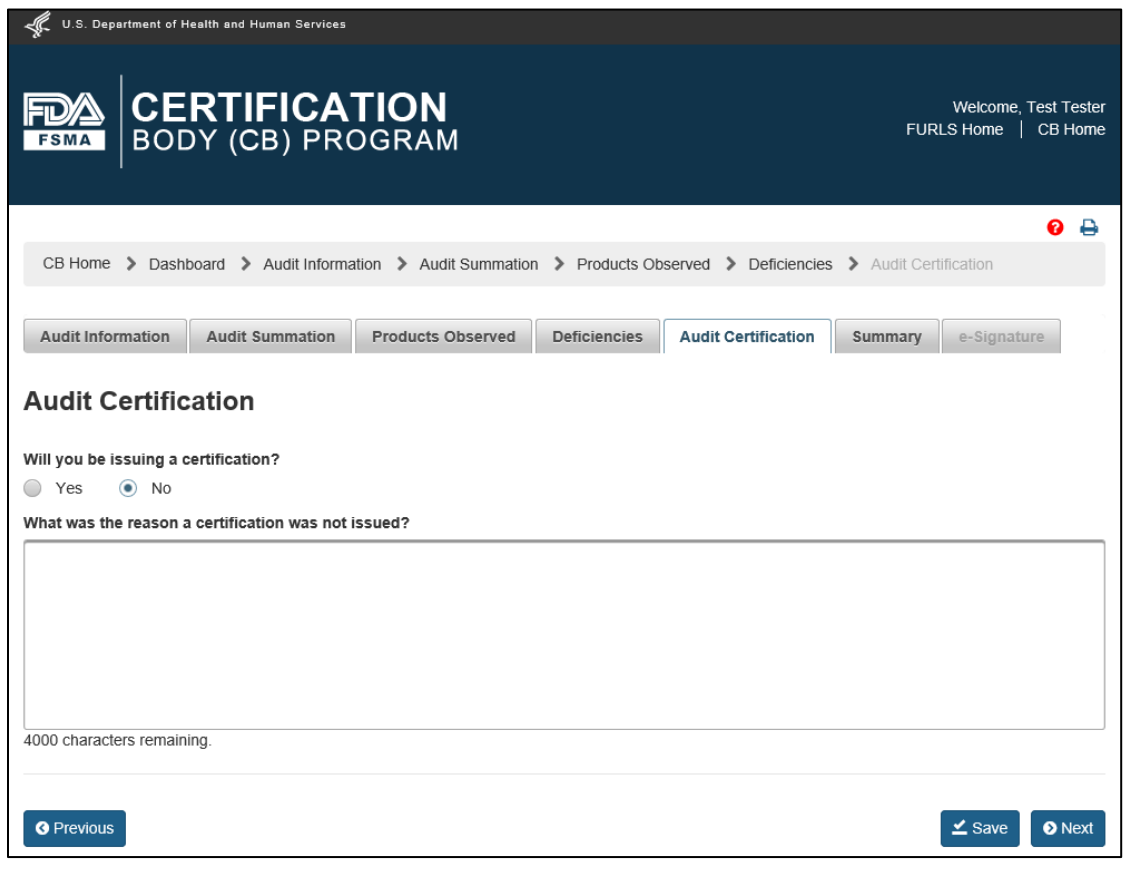
Figure 6.67 – Audit Certification Tab – Default View



A text entry field will display (Figure 6.68):

- **What was the reason a certification was not issued? –** This is a text entry field to enter the reason the certification was not issued, which allows a maximum of 4,000 characters.

Figure 6.68 – Audit Certification Tab – Certification Not Issued Selection



Click the “Save” button to save your changes.

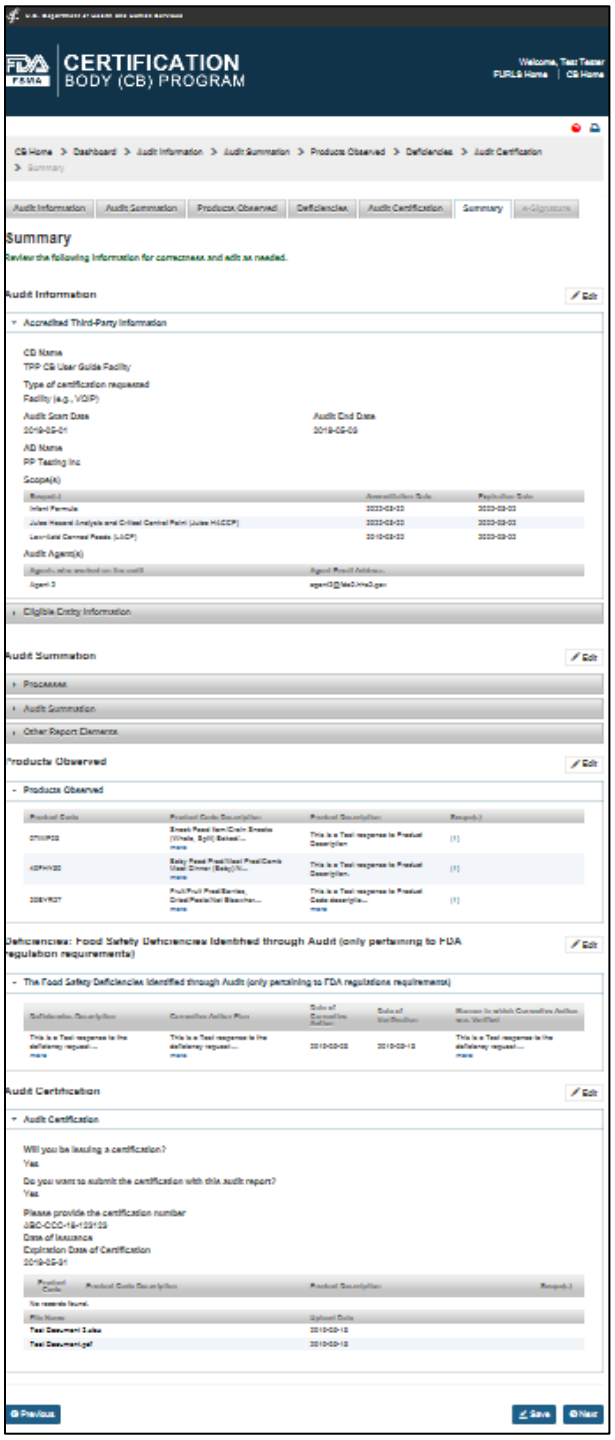
Click the “Next” button or click on the “Summary” tab directly to proceed to the “Summary” tab.

Proceed to Section 6.1.6 of this chapter.

6.1.6 Summary Tab

The “Summary” tab (Figure 6.69) allows you to review the details of your regulatory audit report prior to submission to FDA.

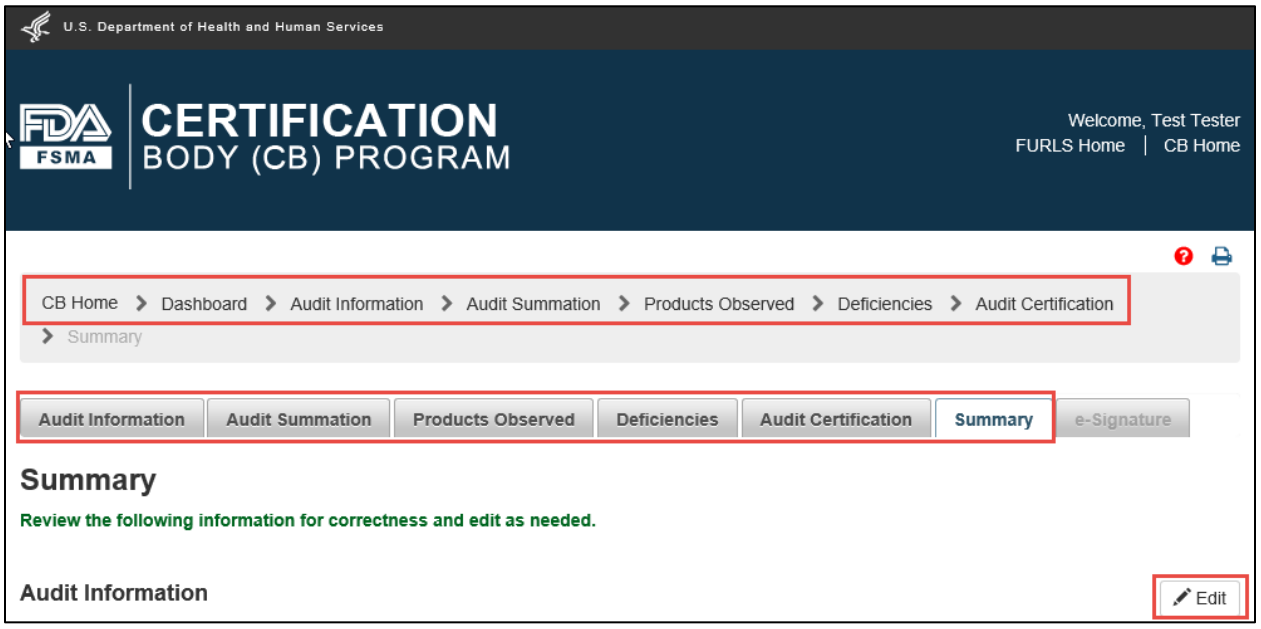
Figure 6.69 – Summary Tab



Review each of the sections in the “Summary” tab. You may need to click the accordion section’s title bar to view the section’s content.

You can edit a section by using its designated “Edit” button (Figure 6.70), clicking on its tab name directly, or clicking on its breadcrumb link at the top of the page. Click the “Save” button on any tabs where edits are added.

Figure 6.70 – Summary Tab – Section Review



Note: You will not be able to access “e-Signature” by clicking directly on the tab itself. The “e-Signature” tab can only be accessed once all required information from the previous tabs has been entered. Click the “Next” button.

****Important:** Once you submit the regulatory audit report to FDA it cannot be modified.

Proceed to Section 6.1.7 of this chapter.

6.1.7 e-Signature Tab

Once you have reviewed and completed the draft of your regulatory audit report, proceed to the “e-Signature” tab by clicking the “Next” button from the “Summary” tab.

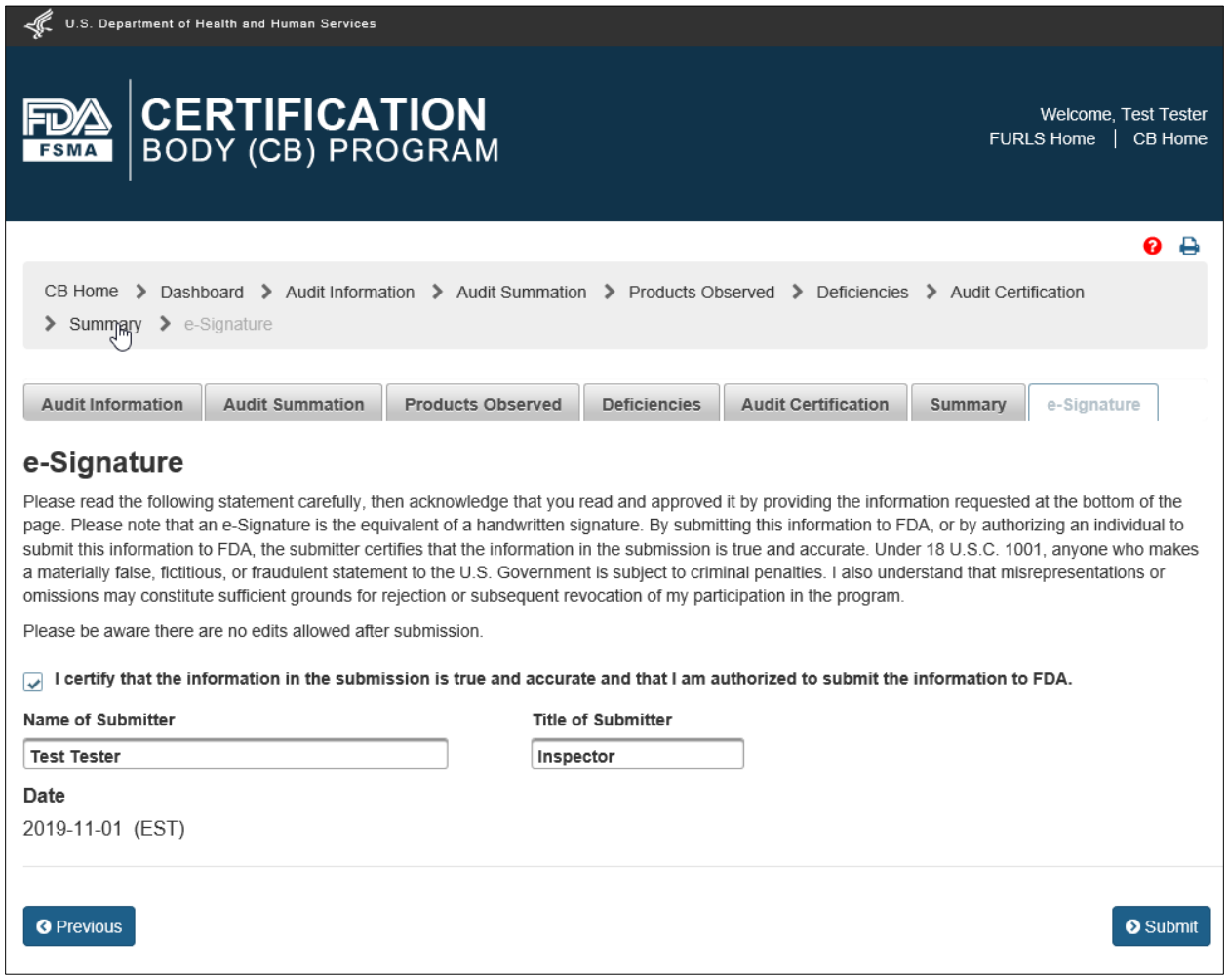
Follow the directions provided on the “e-Signature” tab (Figure 6.71).

Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

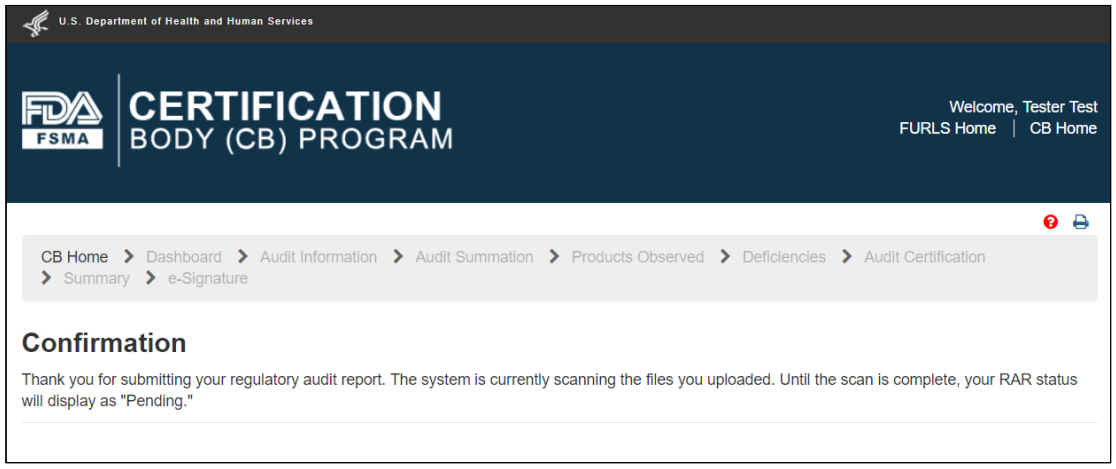
Click the “Submit” button to submit the regulatory audit report.

Figure 6.71 – e-Signature Tab



After you click the “Submit” button a “Confirmation” page will display for your review (Figure 6.72).

Figure 6.72 – Confirmation Page after Submission

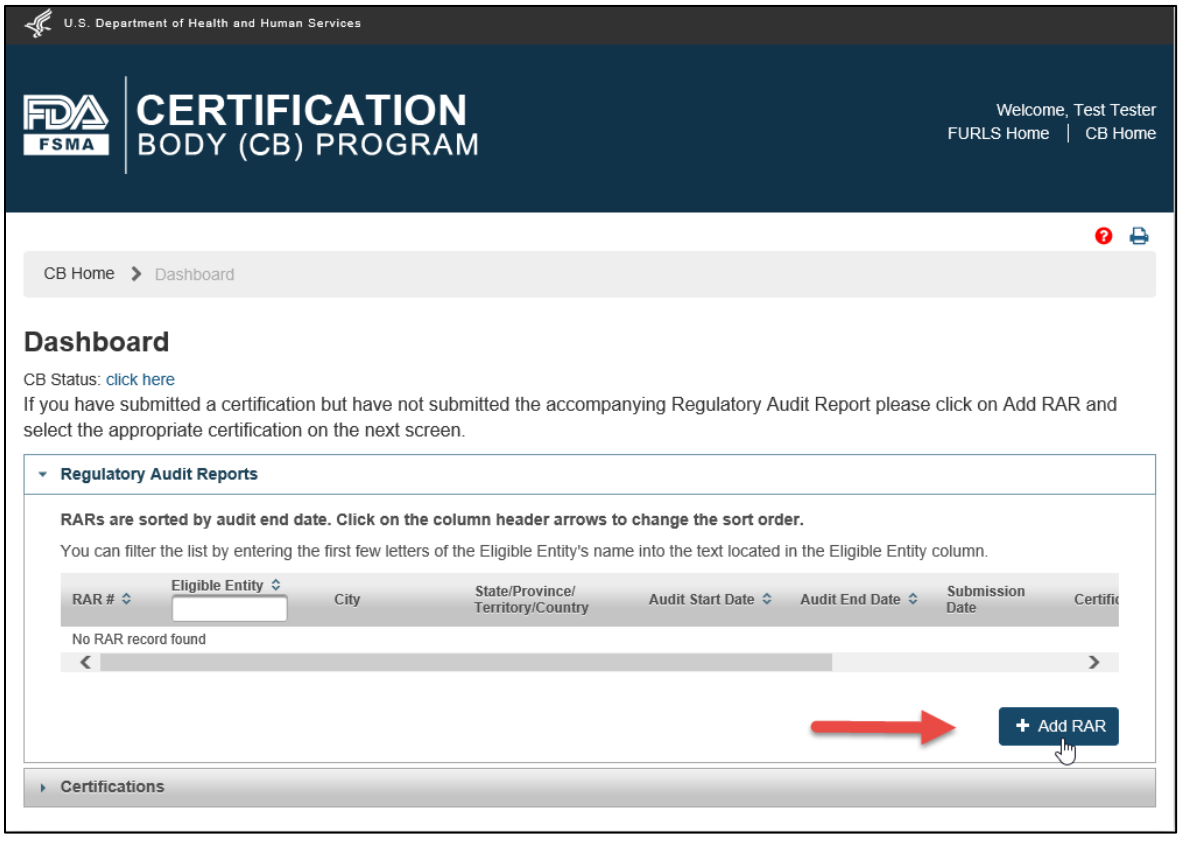


To view the status of your regulatory audit report, or to view and print the report details, proceed to Section 6.3 of this chapter.

6.2 Create a New Regulatory Audit Report for a Previously Submitted Certification

To create a new regulatory audit report when you have already submitted the corresponding certification, click the “Add RAR” button on the “Dashboard” page (Figure 6.73).

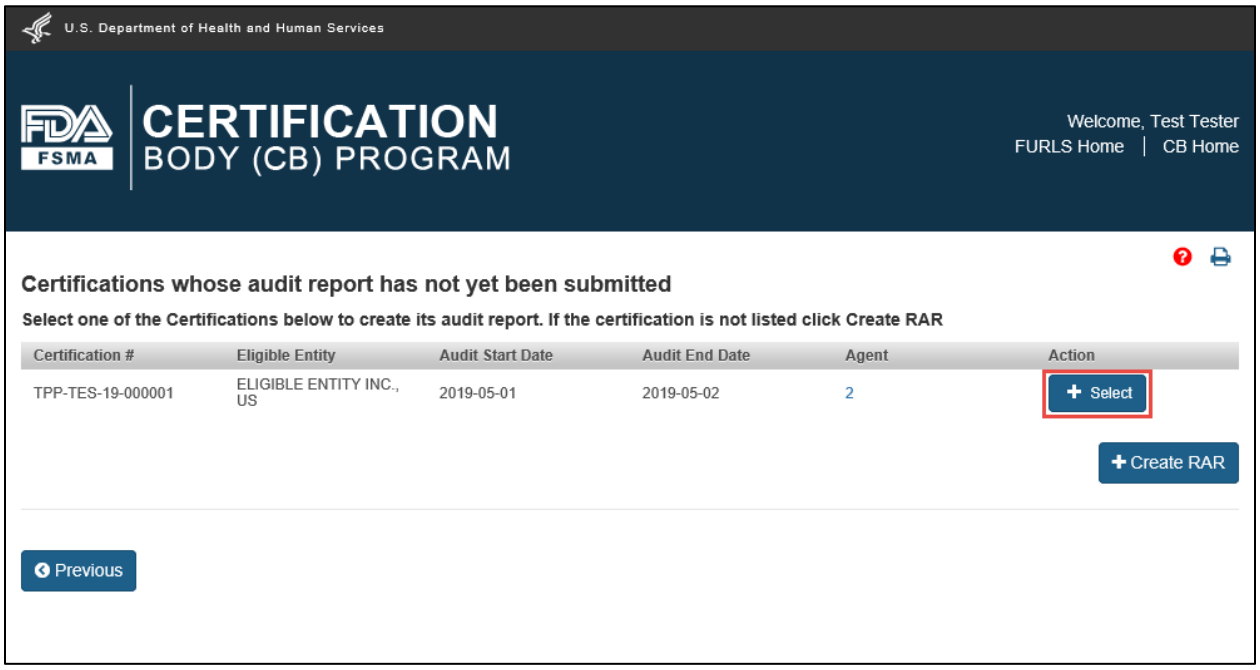
Figure 6.73 – Add RAR



If you have submitted at least one certification to FDA, but not its corresponding regulatory audit report, the system will display the page: “Certifications whose audit report has not yet been submitted,” with a list of certifications (Figure 6.74).

Choose the desired certification from the list to create the corresponding regulatory audit report. Click the “Select” button (in the “Action” column) on the right-hand side of the row.

Figure 6.74 – Certifications Whose Audit Report Has Not Yet Been Submitted

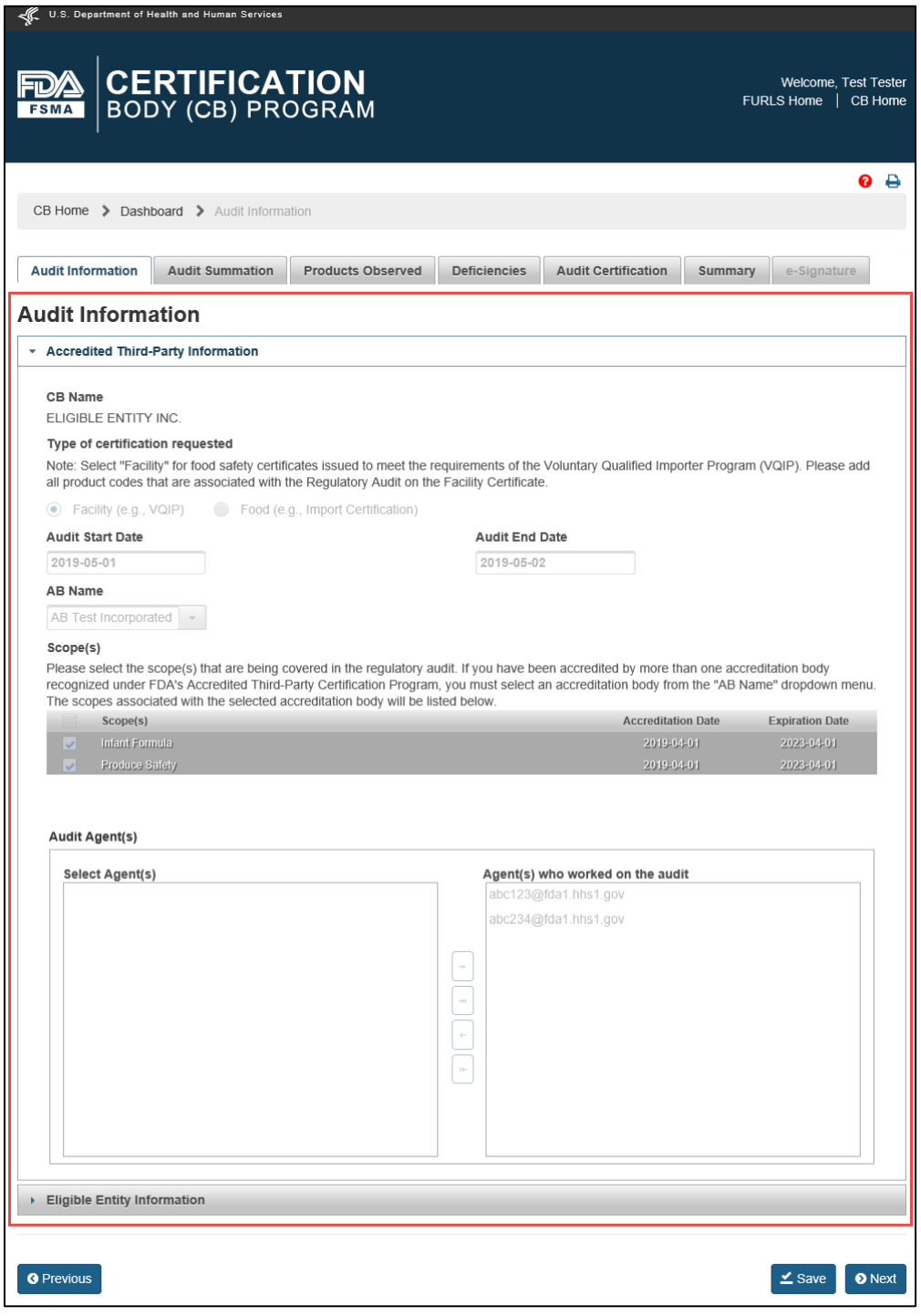


When you create a regulatory audit report from an existing certification, fields in the “Audit Information,” “Products Observed,” and “Audit Certification” tabs will be pre-filled and read-only with the information submitted in the certification.

6.2.1 Audit Information Tab

After you select the desired certification from the list, the system will display the “Audit Information” tab of the regulatory audit report (Figure 6.75). The “Audit Information” tab is the first tab of the regulatory audit report where information regarding the eligible entity covered in the audit is entered (as well as the audited facility, if it is different from the eligible entity).

Figure 6.75 – Accredited Third-Party Information Section Pre-filled with Certification Information



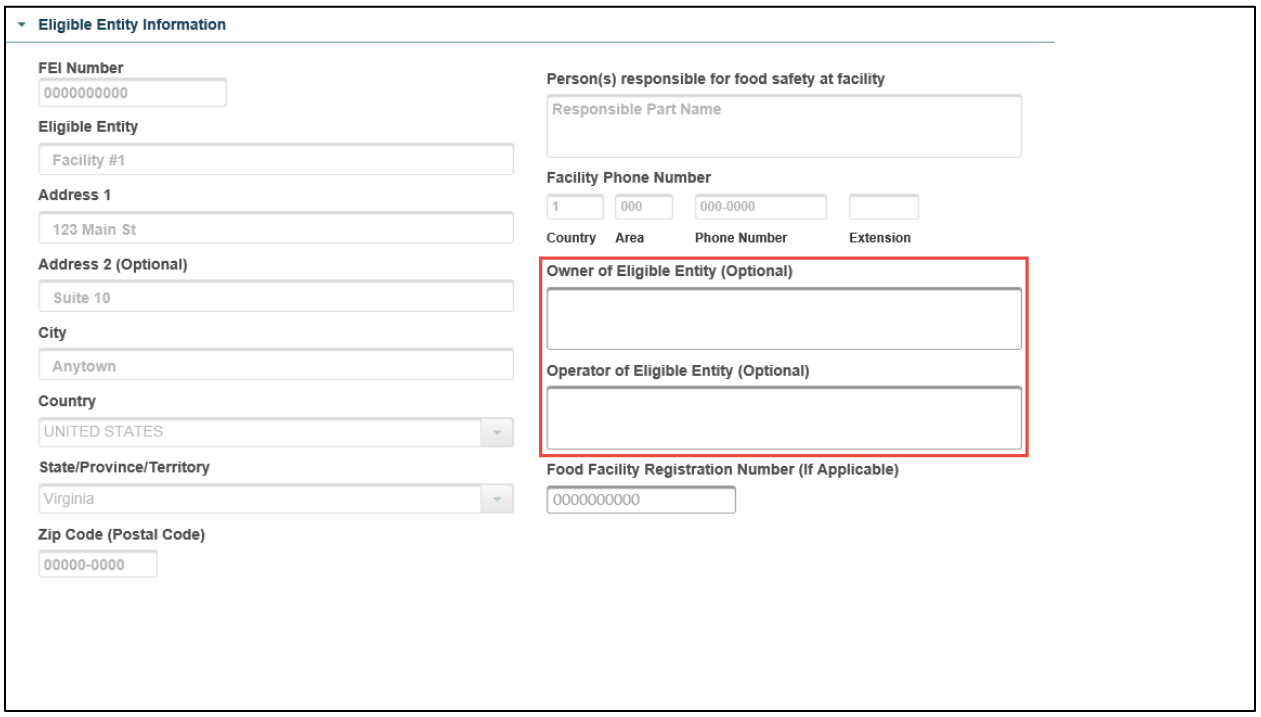
The “Eligible Entity Information” section of the “Audit Information” tab will be pre-filled with the information submitted with the certification. Click on the accordion section’s title bar to display its content (Figure 6.76).

Figure 6.76 – Eligible Entity Information Section

There are two additional fields in the “Eligible Entity Information” section which do not exist in the certification. They will not be pre-filled (Figure 6.77):

- **Owner of Eligible Entity (Optional) –** This is an optional text entry field to enter the name(s) of the owner(s) of the eligible entity, which allows a maximum of 200 characters.
- **Operator of Eligible Entity (Optional) –** This is an optional text entry field to enter the name(s) of the operator(s) of the eligible entity, which allows a maximum of 200 characters.

Figure 6.77 – Eligible Entity Information Section Optional Fields



Note: If you wish to save a draft of your regulatory audit report, click the “Save” button. You may need to correct any errors on the tab before the system will allow you to save the draft. You can edit and submit the report at a later date by selecting the draft from the “Dashboard” page. Refer to Section 6.3 of this chapter.

Click the “Next” button to proceed to the “Audit Summation” tab or click the “Audit Summation” tab directly.

Proceed to Section 6.2.2 of this chapter.

6.2.2 Audit Summation Tab

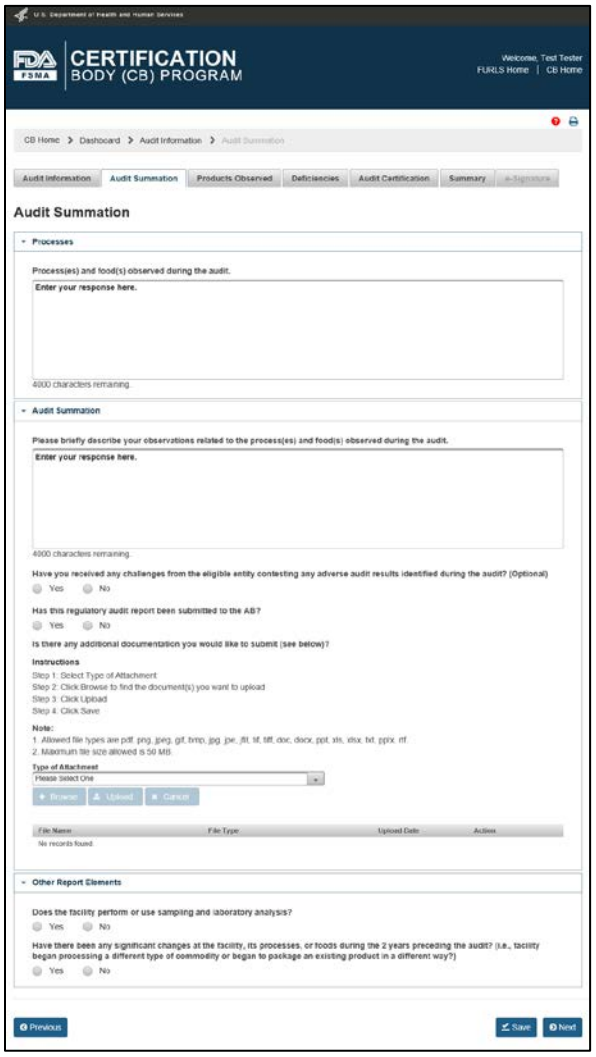
The “Audit Summation” tab allows you to summarize the results of the regulatory audit (e.g., the process(es) and food(s) observed during the regulatory audit and your observations related to the process(es) and food(s) observed during the audit).

Complete the following fields in the “Audit Summation” tab (Figure 6.78):

- **“Processes” Section:**
  - **Process(es) and food(s) observed during the audit –** Describe the processes and foods observed during the regulatory audit. This field allows a maximum of 4,000 characters.
- **“Audit Summation” Section:**
  - **Please briefly describe your observations related to the process(es) and food(s) observed during the audit –** Describe your general audit observations related to compliance with the food safety requirements of the FD&C Act and FDA regulations. This field allows a maximum of 4,000 characters.

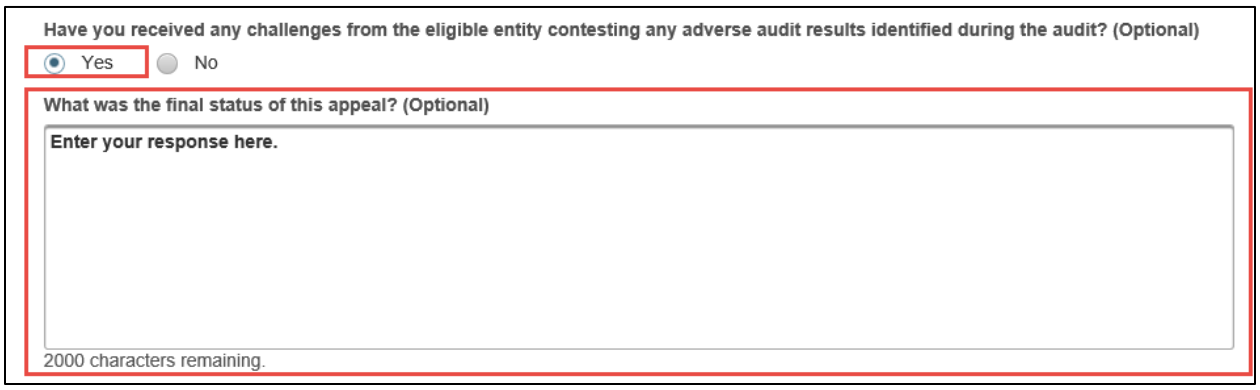
Note: Observations which present a reasonable probability that use of or exposure to food from the facility will cause Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA), or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, should be entered in the “Deficiencies” tab – not in this section.

Figure 6.78 – Audit Summation Tab



- **Have you received any challenges from the eligible entity contesting any adverse audit results identified during the audit? –** This question is optional. Select “Yes” or “No.”
  - If you select “Yes,” another field will display (Figure 6.79):
    - **What was the final status of this appeal? (Optional) –** Describe the final status of the appeal. This is an optional text field which allows a maximum of 2,000 characters.
  - If you select “No,” proceed to the next question.

Figure 6.79 – Additional Field for Appeal Status

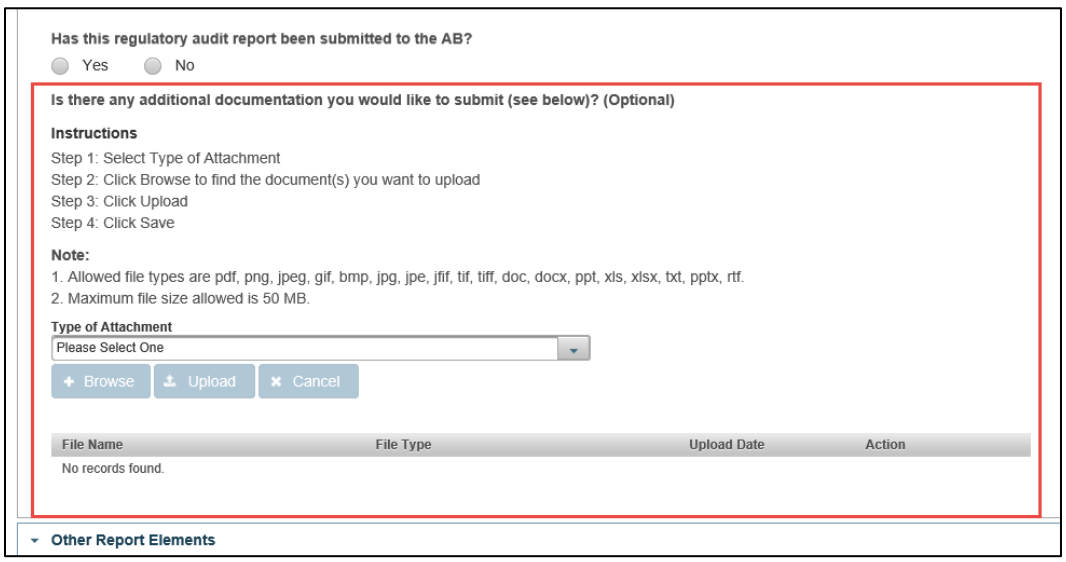


- **Has this regulatory audit report been submitted to the AB?** – Select “Yes” or “No.”
- **Is there any additional documentation you would like to submit? (Optional)** – You may upload additional documents to support the regulatory audit report. Follow the instructions listed within the “Audit Summation” tab for uploading documents (Figure 6.80).

Note: The system supports the following document types: .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

The maximum file size allowed is 50 MB.

Figure 6.80 – Additional Documentation



Click the “Type of Attachment” dropdown menu and select one of the following options (Figure 6.81):

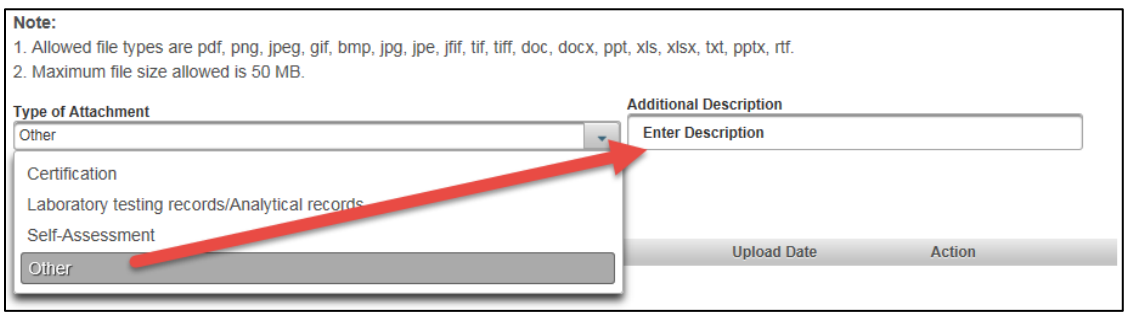
- “Certifications”
- “Laboratory testing records/Analytical records”
- “Self-Assessment”
- “Other”

Figure 6.81 – Type of Attachment Dropdown Menu

The text entry field “Additional Description” will display if you select “Other” from the list, which allows a maximum of 200 characters (Figure 6.82).

You must enter a description in the “Additional Description” field to proceed to the next step.

Figure 6.82 – Audit Summation Tab – Additional Description Field



Click the “Browse” button. A pop-up window will appear, prompting you to access your file system.

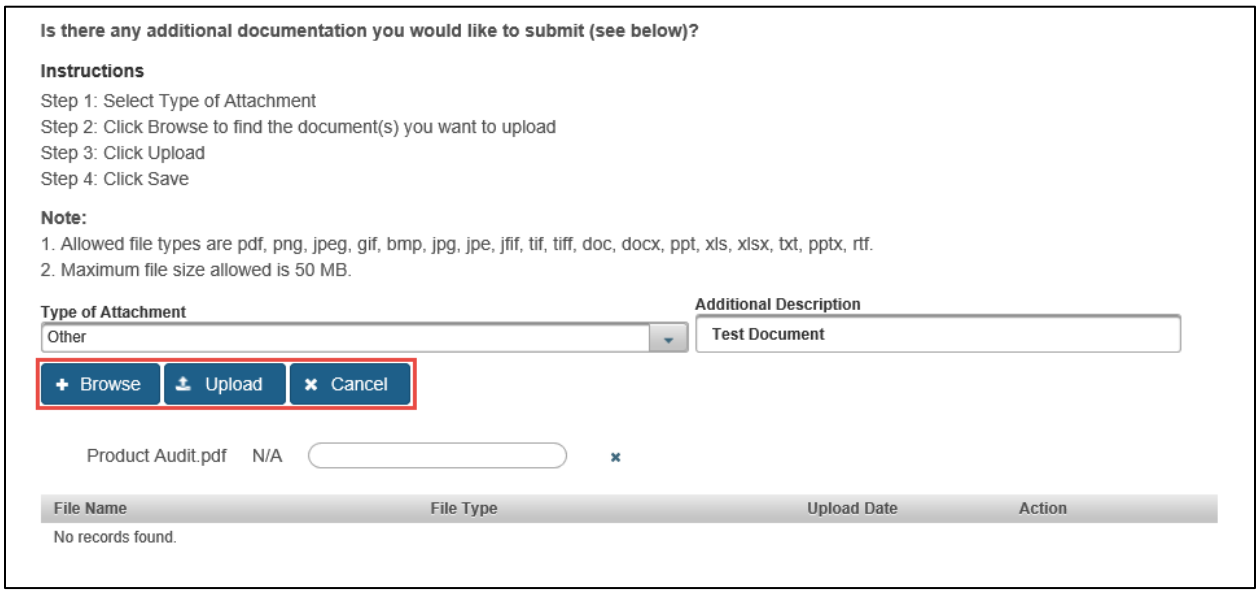
Select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after you choose a file (Figure 6.83).

Click the “Cancel” button to discard the upload of the attachment.

Click the “Upload” button to complete the upload of the attachment.

Click the “Browse” button. A pop-up window will appear, prompting you to access your file system.

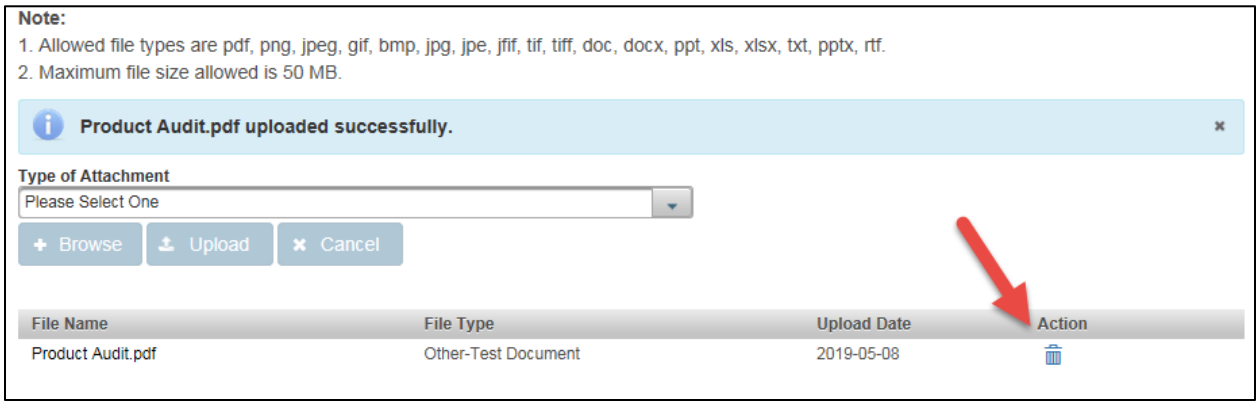
Figure 6.83 – Audit Summation Tab – Browse, Upload, and Cancel Buttons



Once the upload is complete, a confirmation message “<filename.filetype> uploaded successfully” will display above the “Type of Attachment” dropdown menu. The file name will be listed in the attachments table (Figure 6.84).

To remove the attachment, click the trash/delete icon (in the “Action” column) of the attachments table.

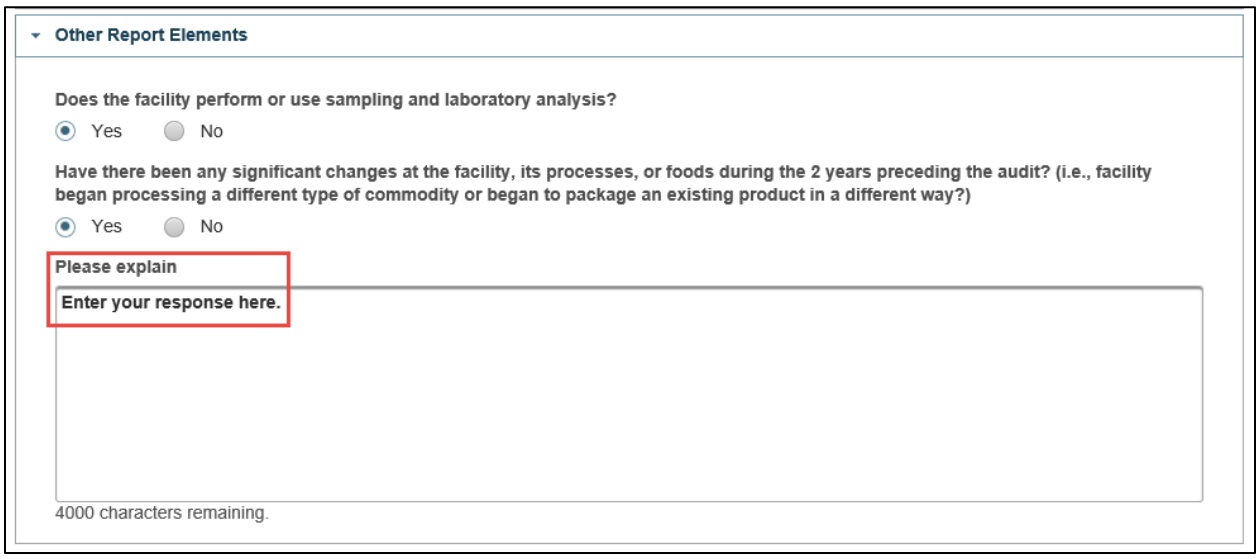
Figure 6.84 – Audit Summation Tab – Attachments Table



Complete the "Other Report Elements" section (Figure 6.85):

- **Does the facility perform or use sampling and laboratory analysis? –** Select **"**Yes" or "No."
- **Have there been any significant changes at the facility, its processes, or foods during the 2 years preceding the audit? (i.e., facility began processing a different type of commodity or began to package an existing product in a different way?) –** Select "Yes" or "No."
    - If you select "Yes," another field will display:
        - **Please explain –** This is a text entry field which allows up to 4,000 characters. Use this field to describe any significant changes at the facility, its processes, or foods during the two years preceding the regulatory audit.
    - If you select "No," no additional fields will display.

Figure 6.85 – Audit Summation Tab – Other Report Elements Section



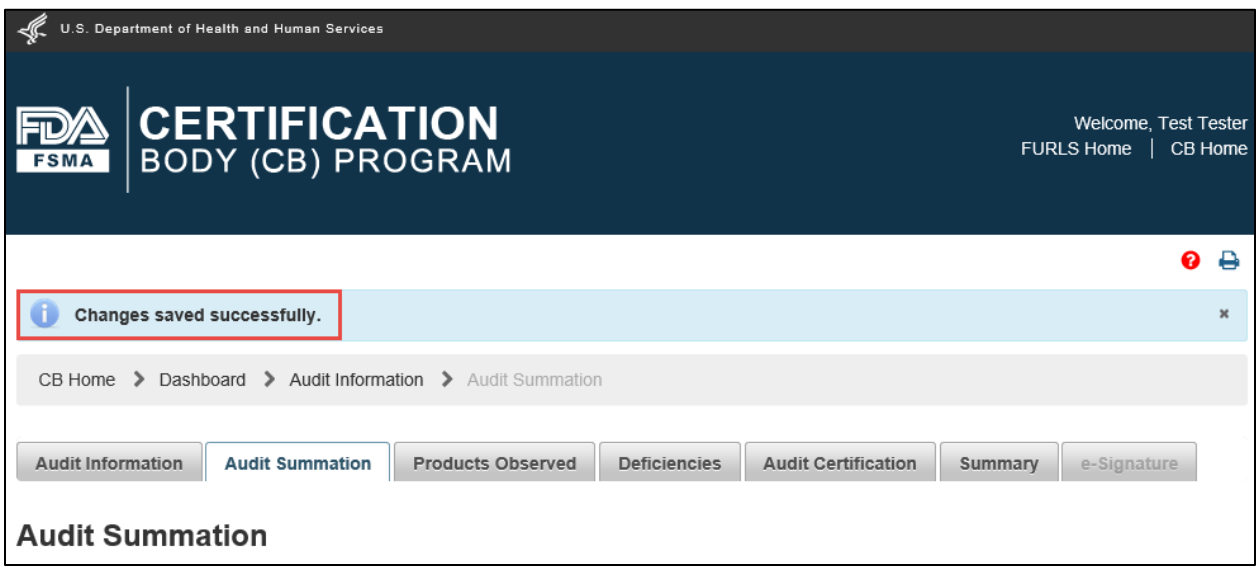
Once you have completed the information for this tab, click the "Save" button.

Once the "Changes saved successfully" message (Figure 6.86) appears at the top of the screen, proceed to the "Products Observed" tab.

Click the "Next" button or click on the "Products Observed" tab directly.

Proceed to Section 6.2.3 of this chapter.

Figure 6.86 – "Changes saved successfully" Message



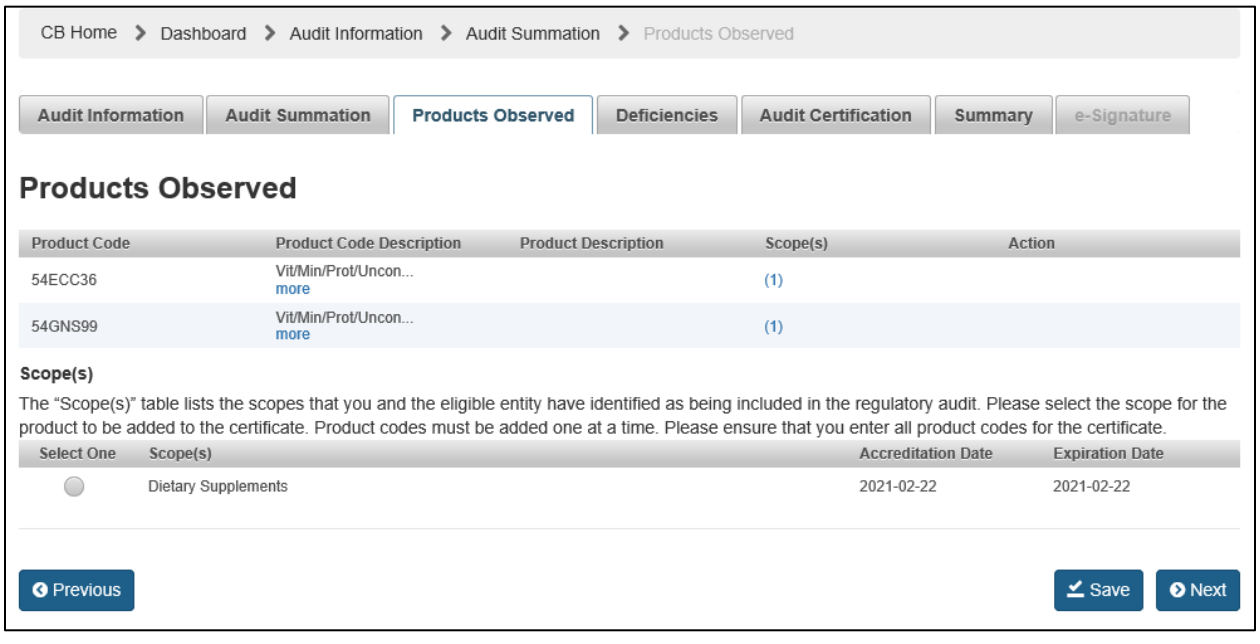
6.2.3 Products Observed Tab

The “Products Observed” tab allows you to enter the product codes of FDA regulated products that will be included in the regulatory audit report (Figure 6.87).

The product(s) entered in the corresponding certification will be pre-filled and read-only on the “Products Observed” tab. You cannot edit the products that were submitted as part of the certification, but you may add more products in the regulatory audit report.

Refer to Section 6.1.3 of this chapter for instructions on adding products to the regulatory audit report on the “Products Observed” tab.

Figure 6.87 – Products Observed Tab Pre-filled with Certification Information



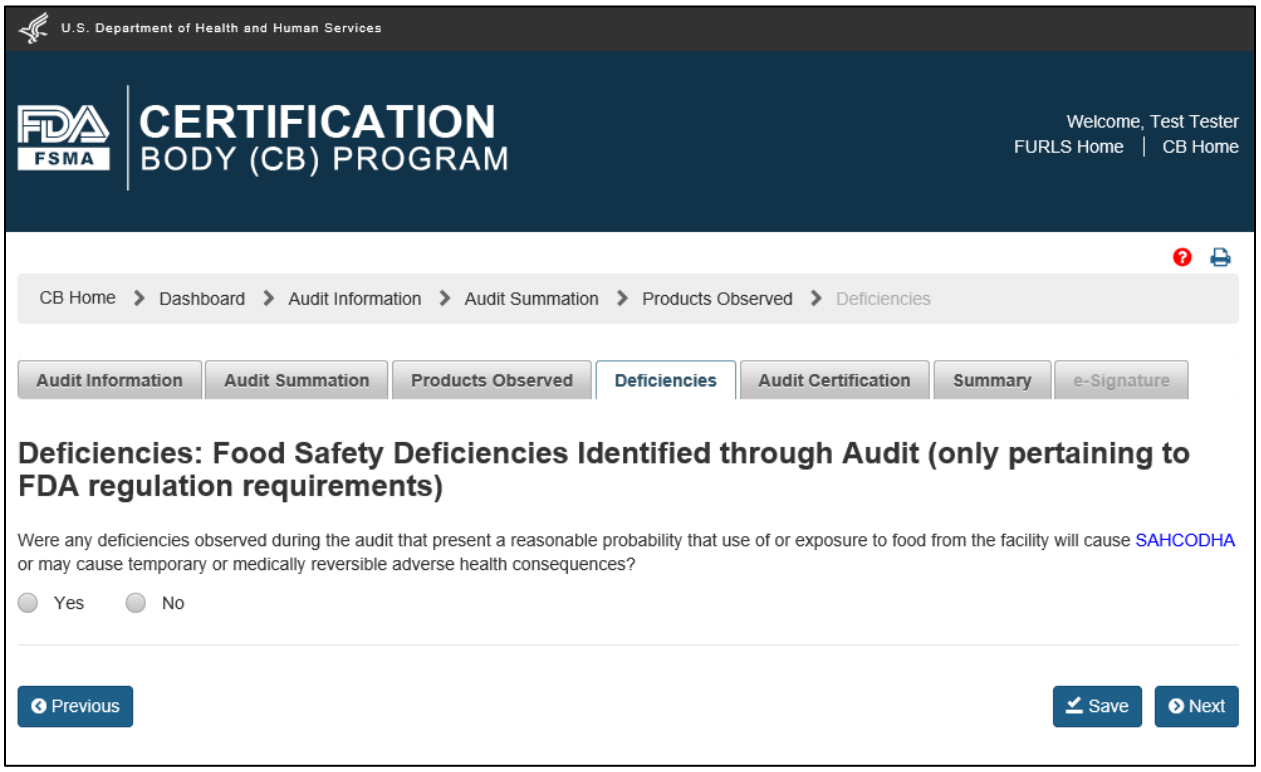
If you do not wish to add more products, proceed to the “Deficiencies” tab by clicking on the “Next” button or click on the “Deficiencies” tab directly.

Proceed to Section 6.2.4 of this chapter.

6.2.4 Deficiencies Tab

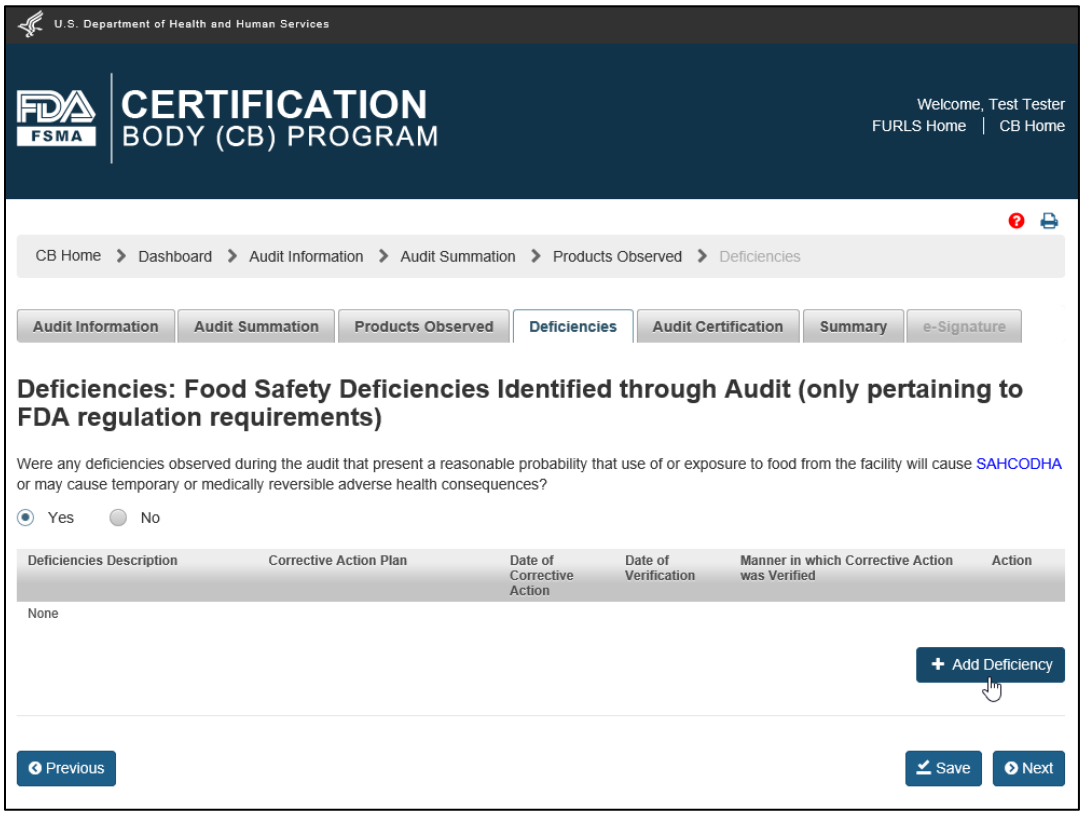
The “Deficiencies” tab allows you to summarize any deficiencies observed during the regulatory audit (Figure 6.88).

Figure 6.88 – Deficiencies Tab



- **Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause SAHCODHA, or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote?**
  – Select “Yes” or “No.”
    - If you select “Yes,” the “Add Deficiency” button will display and additional information will need to be submitted, as described below in this section (Figure 6.89).
    - If you select “No,” click the “Save” button and proceed to the “Audit Certification” tab by clicking the “Next” button – or on the “Audit Certification” tab directly. Proceed to Section 6.2.5 of this chapter.

Figure 6.89 – Deficiencies Tab – Add Deficiency Button



After you click the “Add Deficiency” button, the system will display additional required fields (Figure 6.90).

Complete the following required information for each deficiency identified through the regulatory audit:

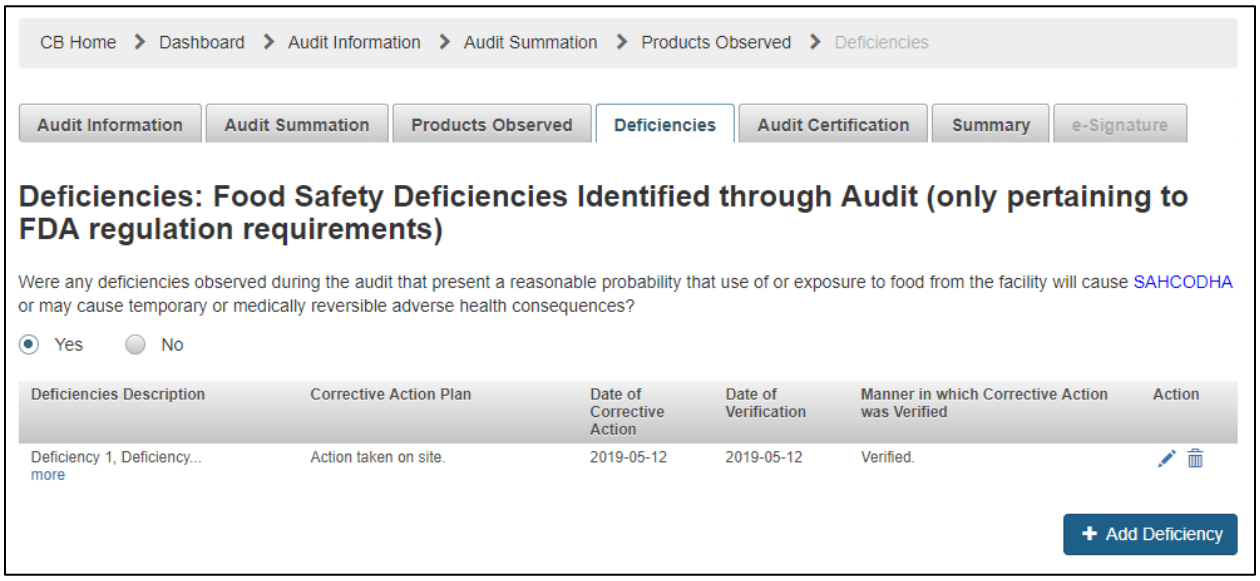
- **Please describe any deficiencies that present a reasonable probability that use of or exposure to food from the facility will cause SAHCODHA, or may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. –** This is a text entry field, which allows up to 4,000 characters.
- **Was corrective action implemented immediately and verified on site? –** Select “Yes” or “No.”
    - If you select “Yes,” the “Date of Corrective Action” field will be pre-populated with the regulatory audit end date.
    - If you select “No,” enter the date of the corrective action.
- **Please describe the corrective action plan for each such deficiency. –** This is a text entry field, which allows up to 4,000 characters.
- **Date of Corrective Action –** Select the date on which the corrective action was taken with the calendar icon or enter it in “YYYY-MM-DD” format.
- **Describe the manner in which corrective action was verified –** This text entry field, which allows up to 4,000 characters.
- **Date of Verification of Corrective Action –** Select the date on which the corrective action was verified with the calendar icon or enter it in “YYYY-MM-DD” format.

Figure 6.90 – Deficiencies Tab – Additional Required Fields

After you complete the applicable fields, click the “Add Deficiency” button or the “Cancel” button.

If you click “Add Deficiency,” the deficiency will appear in the table at the top of the tab (Figure 6.91). If you click “Cancel,” your deficiency information will be removed.

Figure 6.91 – Deficiencies Tab – Add Deficiency



Review the data you entered from the “Deficiency” table. You can delete data by selecting the trash/delete icon or edit the data by selecting the pencil/edit icon.

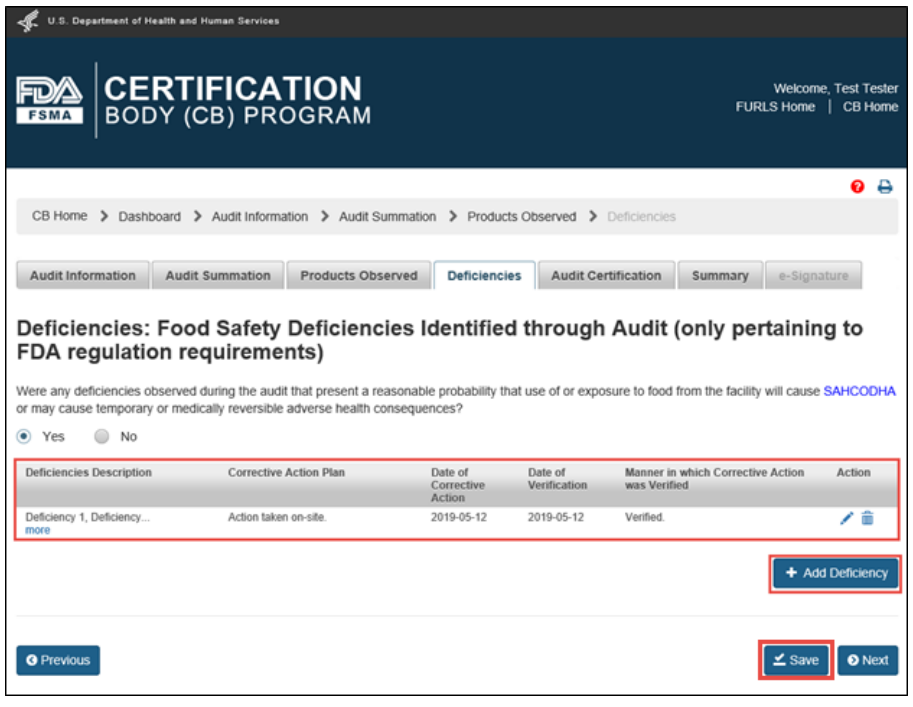
Enter any additional deficiencies by selecting the “Add Deficiency” button and repeating the steps.

Review your data in the “Deficiency” table and click the “Save” button (Figure 6.92). Once the “Changes saved successfully” message appears at the top of the screen, proceed to the “Audit Certification” tab.

Click the “Next” button to proceed to the “Audit Certification” tab or click on the “Audit Certification” tab directly.

Proceed to Section 6.2.5 of this chapter.

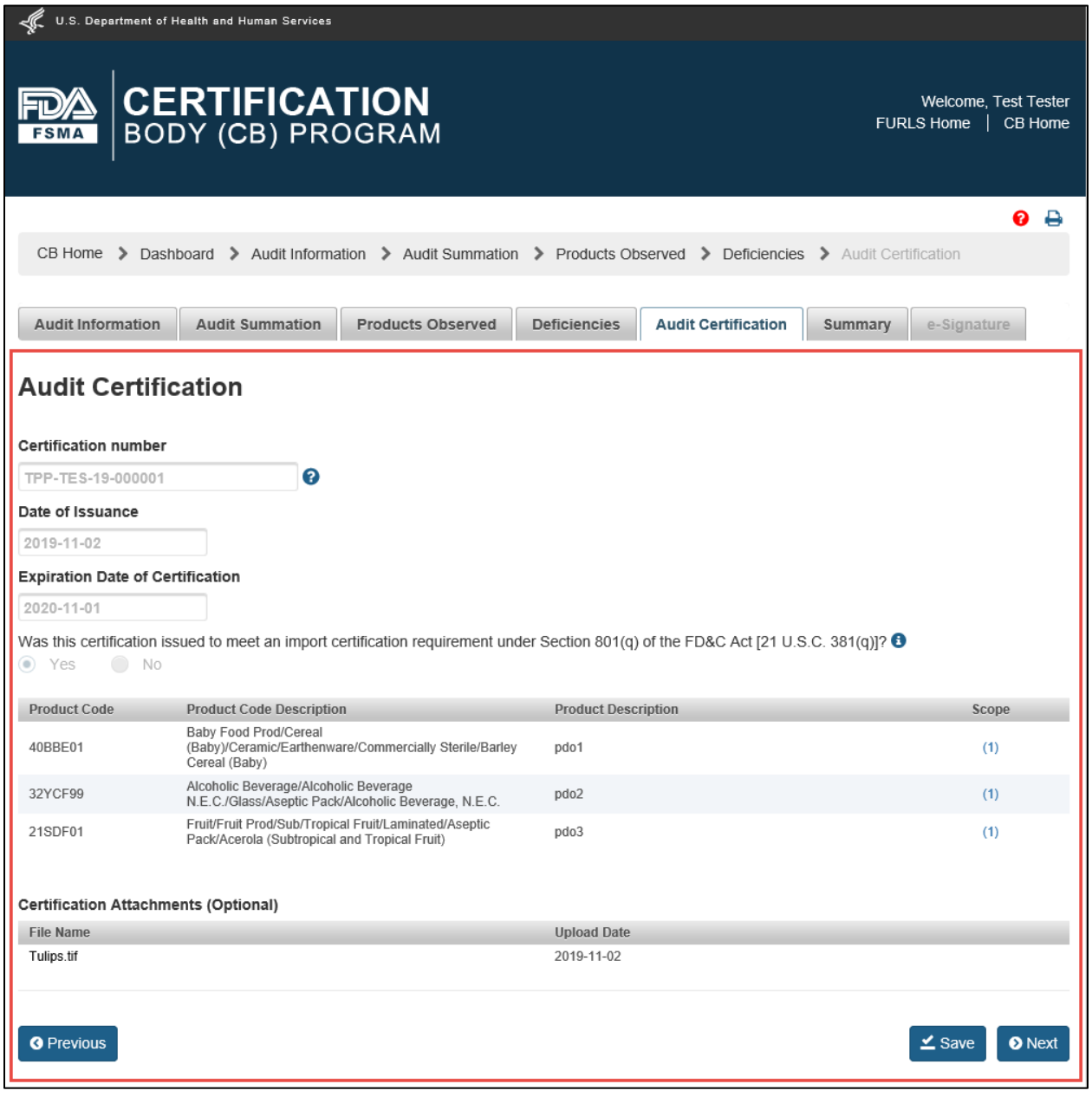
Figure 6.92 – Deficiency Table



6.2.5 Audit Certification Tab

The “Audit Certification” tab will be pre-filled and read-only with the information you submitted in the corresponding certification (Figure 6.93).

Figure 6.93 – Audit Certification Tab – Pre-filled with Certification Information



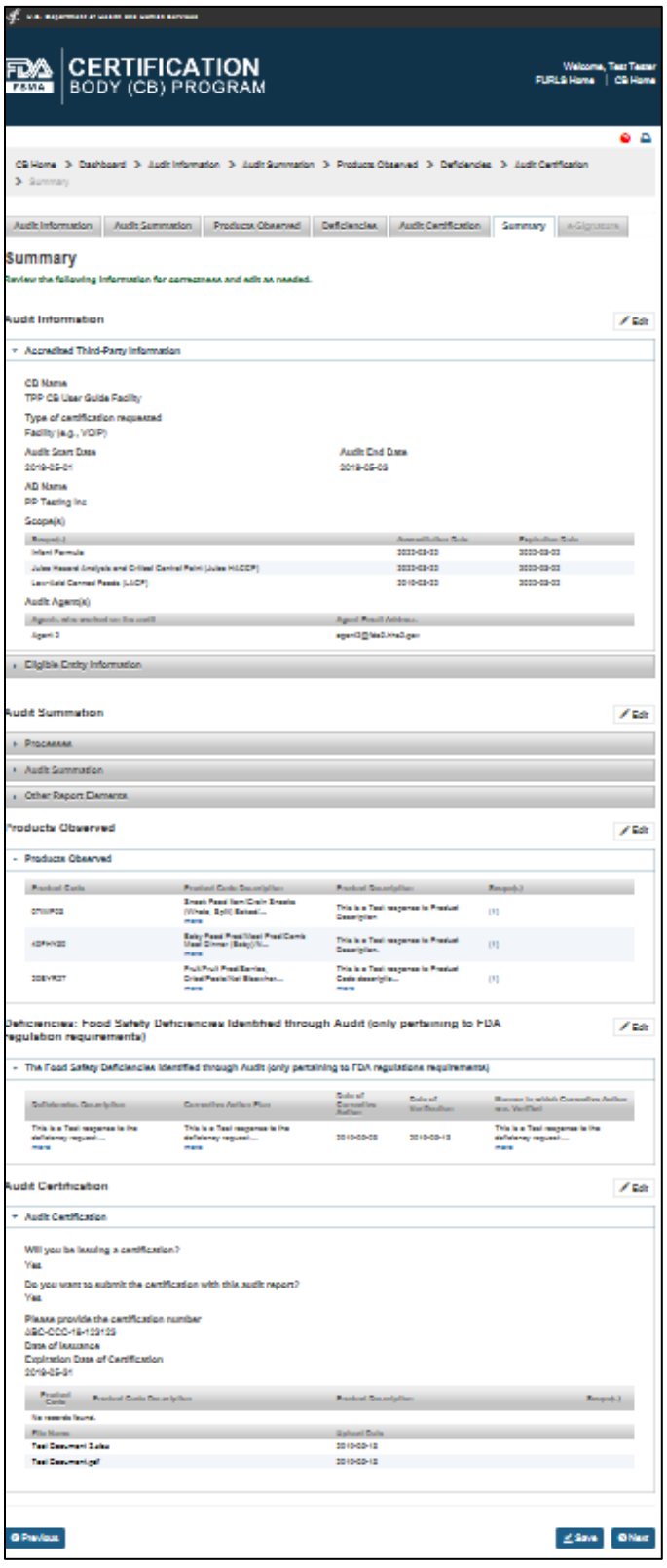
Click the “Next” button to proceed to the “Summary” tab or click on the “Summary” tab directly.

Proceed to Section 6.2.6.

6.2.6 Summary Tab

The “Summary” tab allows you to review the details of your regulatory audit report prior to submitting the report to FDA (Figure 6.94).

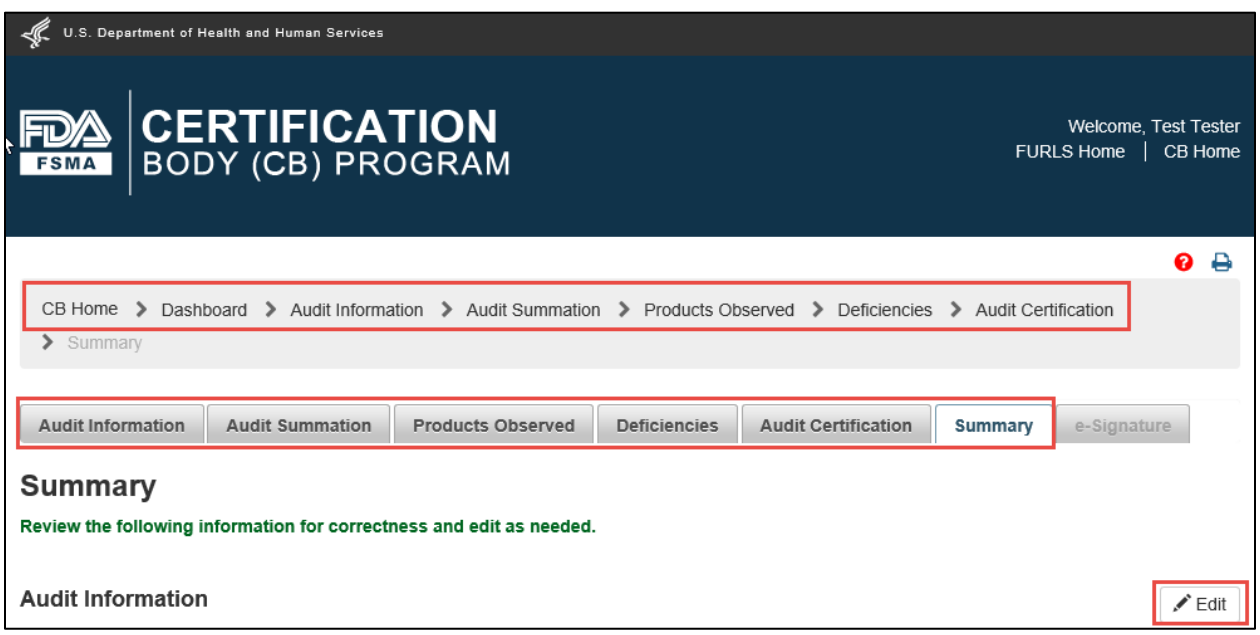
Figure 6.94 – Summary Tab



Review each of the sections in the “Summary” tab. You may need to click the accordion section’s title bar to view the section’s content.

You can edit a section by using its designated “Edit” button (Figure 6.95), clicking on its tab name directly, or clicking on its breadcrumb link at the top of the page. The pre-filled and read-only information from the submitted corresponding certification cannot be edited.

Figure 6.95 – Summary Tab – Section Review



Note: You will not be able to access “e-Signature” by clicking directly on the tab itself. The “e-Signature” tab can only be accessed once all required information from the previous tabs has been entered.

Click the “Next” button.

****Important:** Once you submit the regulatory audit report to FDA, it cannot be modified.

Proceed to Section 6.2.7 of this chapter.

6.2.7 e-Signature Tab

Once you have reviewed and completed the draft of your regulatory audit report, proceed to the “e-Signature” tab by clicking the “Next” button from the “Summary” tab.

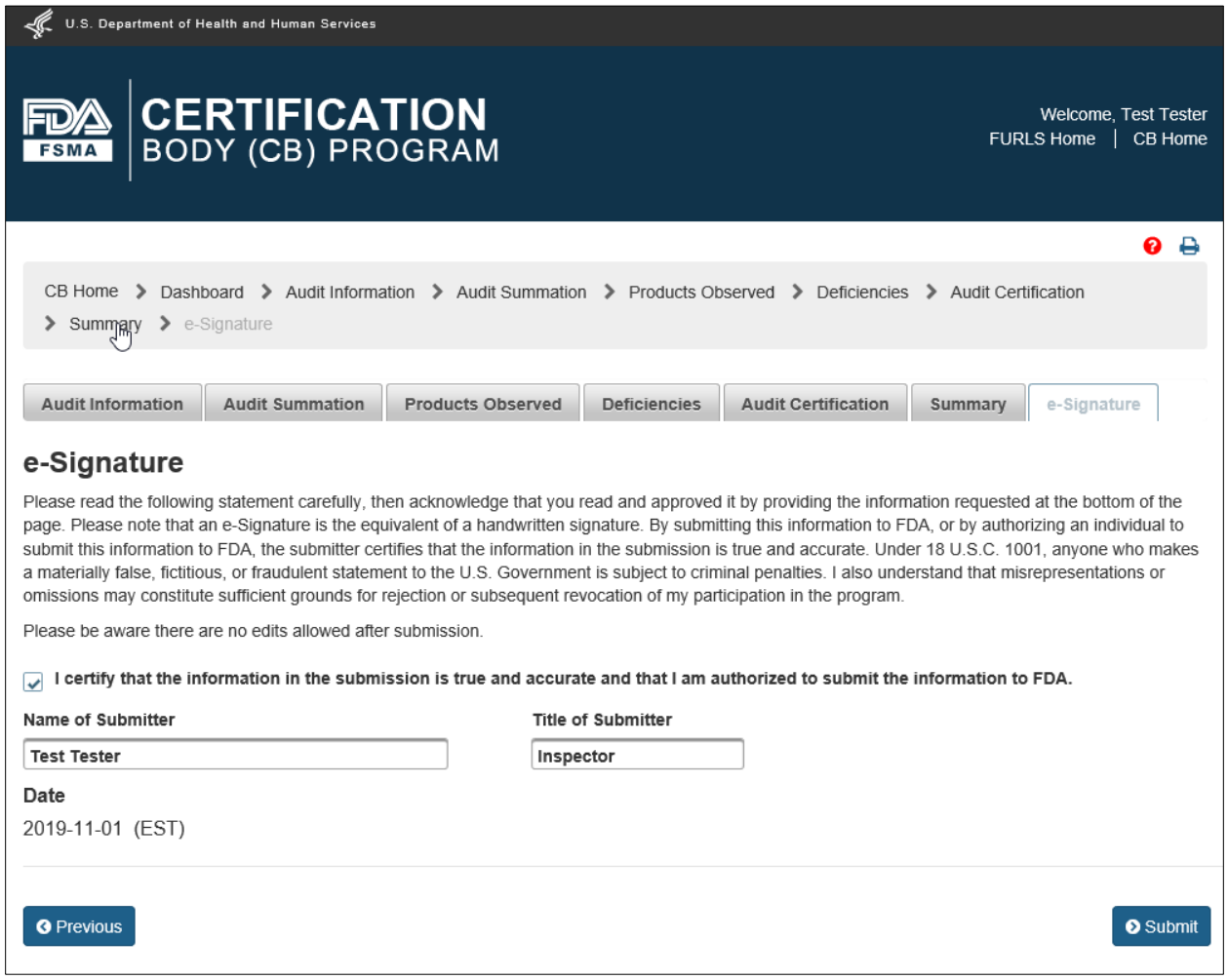
Follow the directions provided on the “e-Signature” tab (Figure 6.96).

Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

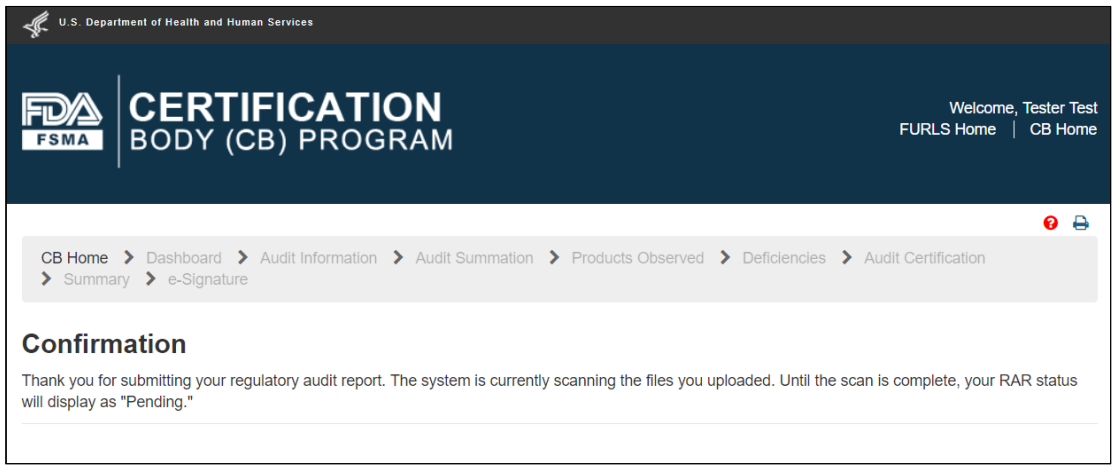
Click the “Submit” button to submit the regulatory audit report.

Figure 6.96 – e-Signature Tab



After clicking the “Submit” button, a “Confirmation” page will display for your review (Figure 6.97).

Figure 6.97 – Confirmation Page after Submission



To view the status of or to view /print your regulatory audit report, proceed to Section 6.3 of this chapter.

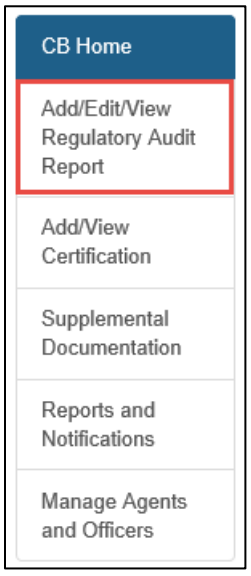
6.3 Edit, Delete, View or Print a Regulatory Audit Report

In addition to creating a regulatory audit report, the following actions can be performed from the Add/Edit/View Regulatory Audit Report feature:

- Editing or deleting a draft regulatory audit report that has not been submitted to FDA
- Viewing or printing the details of a regulatory audit report
- Viewing the status of a regulatory audit report

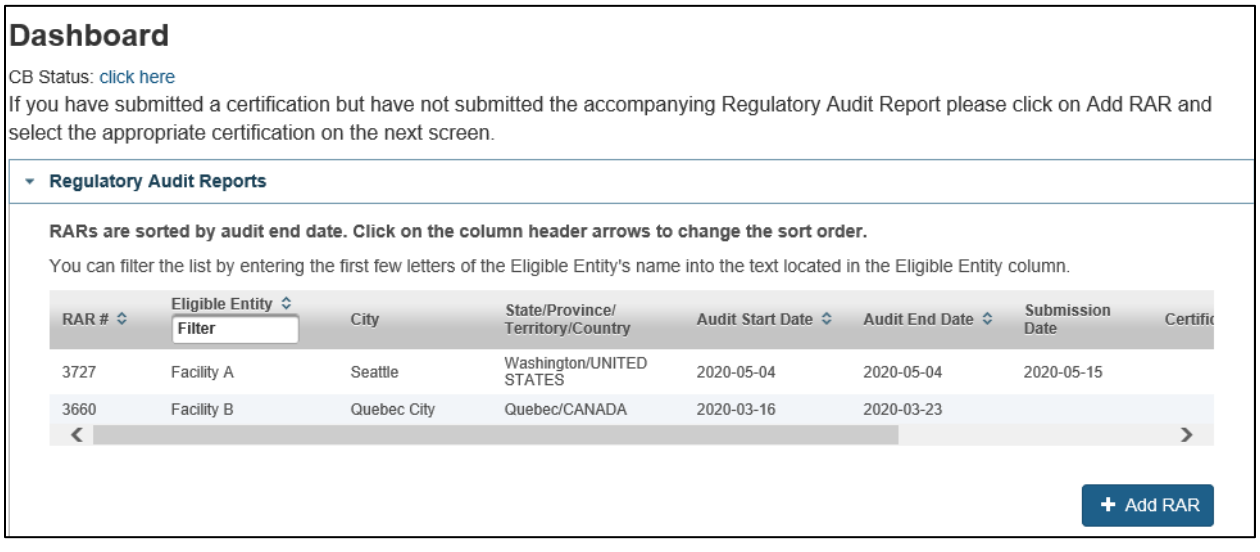
To access the regulatory audit report functionality, click the “Add/Edit/View Regulatory Audit Report” link from the navigation menu on the “CB Home” page (Figure 6.98).

Figure 6.98 – Navigation Menu



The system will display the “Dashboard” page. The “Regulatory Audit Reports” section will be expanded by default (Figure 6.99).

Figure 6.99 – Dashboard Page



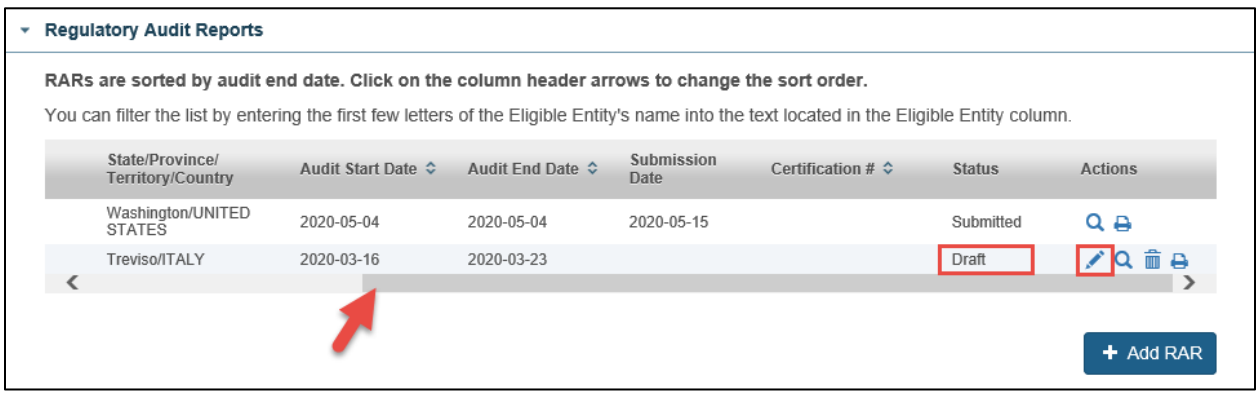
6.3.1 Edit or Delete a Draft Regulatory Audit Report

You may edit or delete a regulatory audit report while it is in “Draft” status. The edit and delete functions are not available for submitted regulatory audit reports.

Click and drag the horizontal scroll bar to scroll to the right in the “Regulatory Audit Reports” section and see the available icons in the “Actions” column.

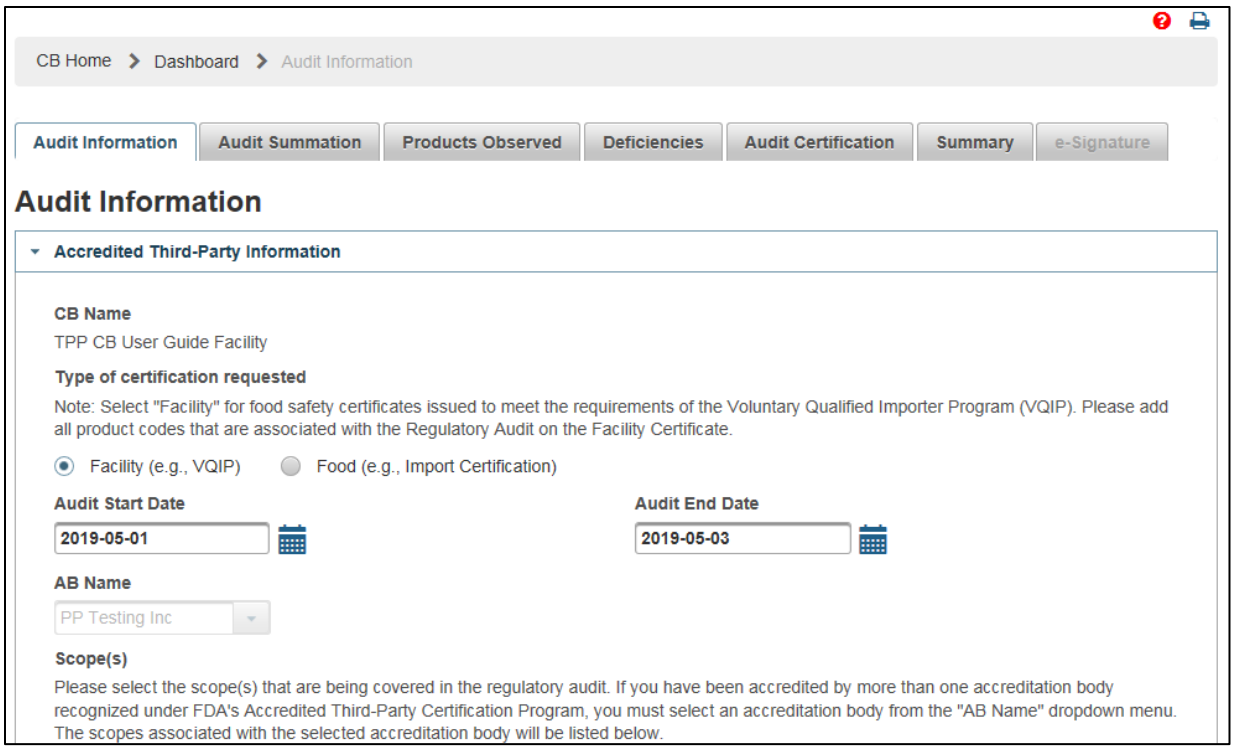
Click the edit/pencil icon from the “Actions” column to edit a regulatory audit report (Figure 6.100).

Figure 6.100 – Edit Icon for Draft Regulatory Audit Report



The system will navigate to the “Audit Information” tab and display the previously saved information (Figure 6.101).

Figure 6.101 – Edit the Draft Regulatory Audit Report



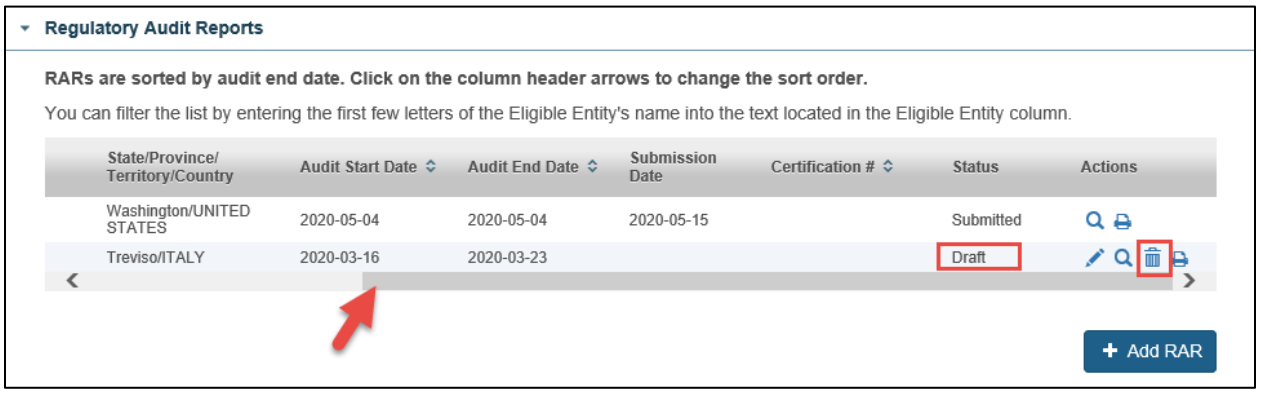
Navigate through the tabs of the draft regulatory audit report to make modifications or complete missing information, where applicable.

Note: The “Audit Information” tab cannot be edited once it has been saved. You may edit other tabs while the regulatory audit report is in “Draft” status. If you wish to edit information on the “Audit Information” tab, you must delete the regulatory audit report and start over.

Refer to the applicable section of this chapter for instructions on how to edit information in a specific tab of the regulatory audit report. Refer to Section 6.1 of this chapter if you are submitting a new regulatory audit report and have not submitted the corresponding certification. Refer to Section 6.2 of this chapter if you are submitting a regulatory audit report and have already submitted the corresponding certification.

Click the trash/delete icon from the “Actions” column of the “Regulatory Audit Reports” section to delete a regulatory audit report in “Draft” status (Figure 6.102).

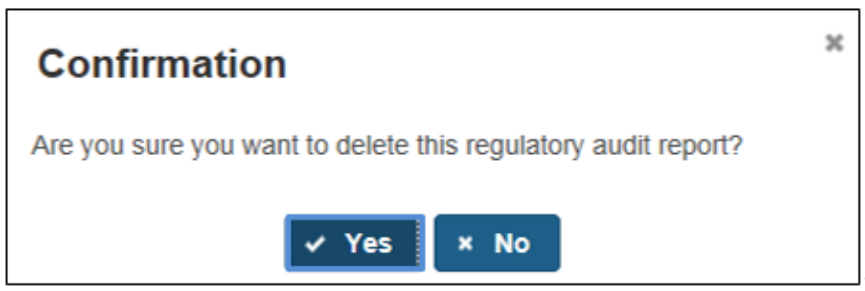
Figure 6.102 – Trash Icon for Draft Regulatory Audit Report



A prompt will appear to confirm that you want to delete the report (Figure 6.103).

Click the “Yes” button to proceed with the report deletion or click the “No” button to cancel the deletion and retain the draft report.

Figure 6.103 – Confirmation Pop-up Window



****Important:** Once you submit the regulatory audit report to FDA, it cannot be modified. Save the report again by clicking any of the “Save” buttons within a tab.

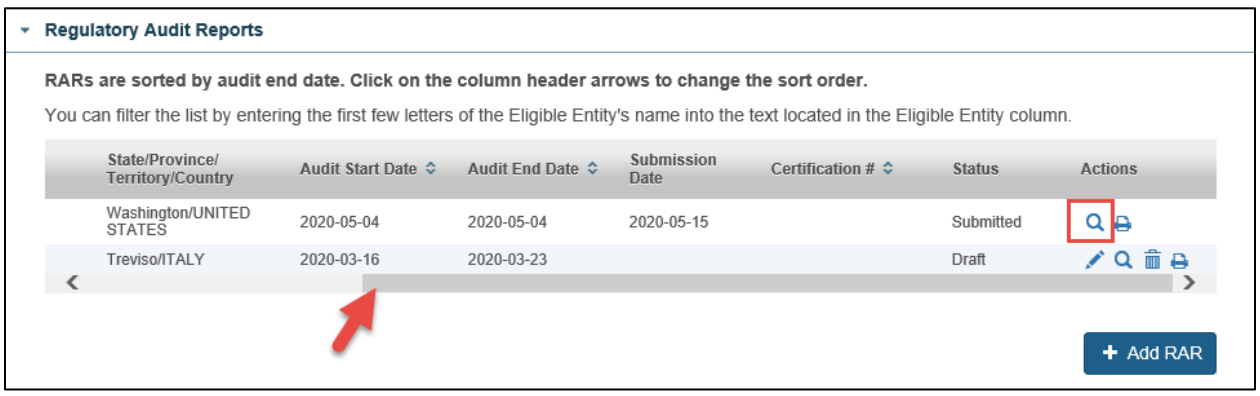
6.3.2 View the Details of a Regulatory Audit Report

You may view the details of a regulatory audit report in any status.

Click and drag the horizontal scroll bar to scroll to the right in the “Regulatory Audit Reports” section. You will see the available icons in the “Actions” column.

Click the view/magnifying glass icon in the “Actions” column to view the details of a regulatory audit report (in any status) (Figure 6.104).

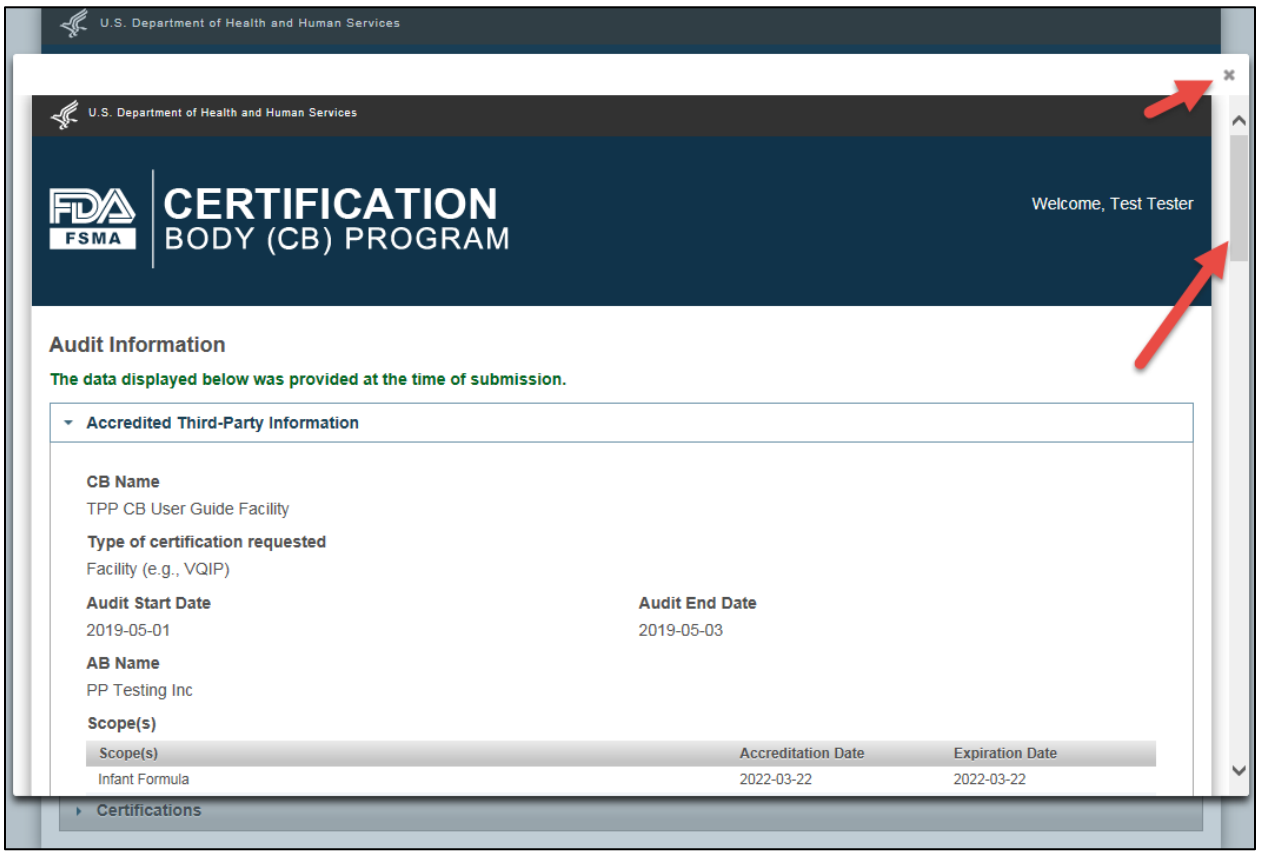
Figure 6.104 – View Icon



A pop-up window with the details of the regulatory audit report will open. You can select the vertical scroll bar on the right side of the window to view all of the information (Figure 6.105).

Click the “x” button at the top-right corner of the window to close the pop-up window and display the “Dashboard” page.

Figure 6.105 – Vertical Scrollbar and X Icon



6.3.3 Print the Details of a Regulatory Audit Report

You may print the details of a regulatory audit report in any status.

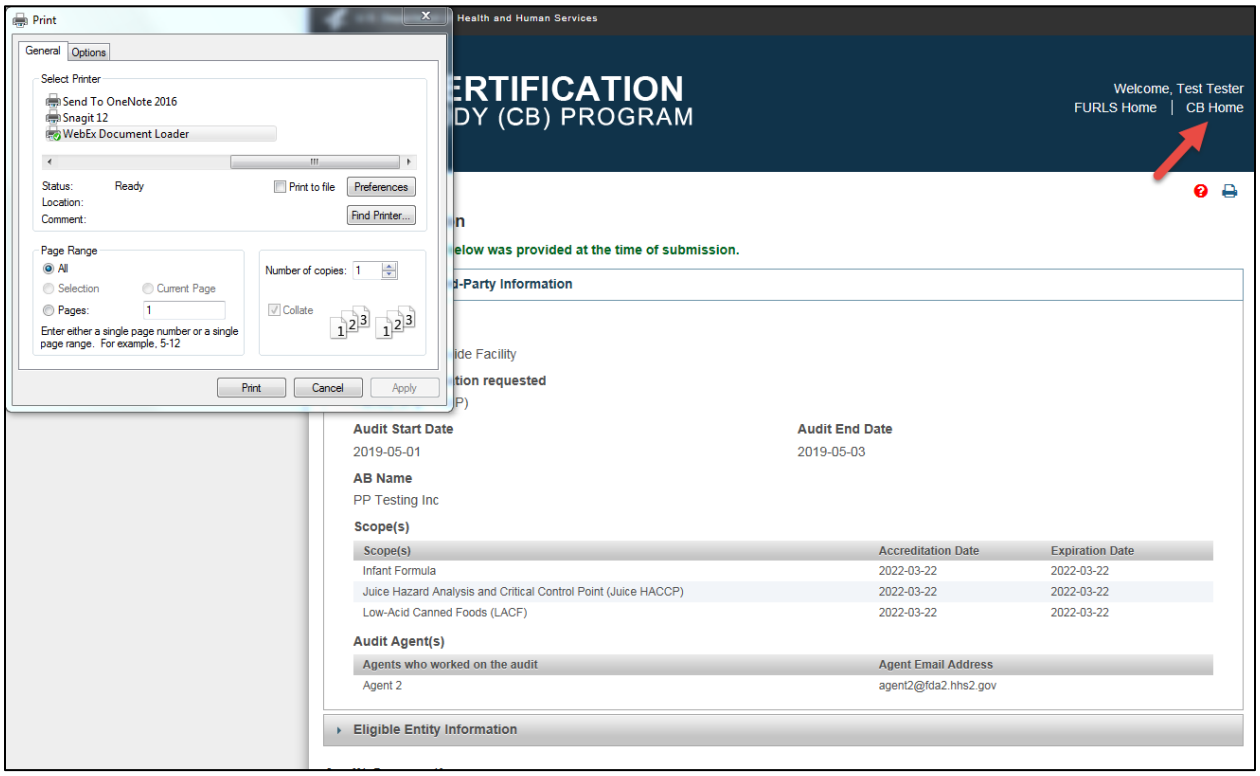
Click and drag the horizontal scroll bar to scroll to the right in the “Regulatory Audit Reports” section and view the available icons in the “Actions” column.

Click the print icon to print the details of a regulatory audit report. A printable page and dialog box from your operating system will display, allowing you to print the regulatory audit report (Figure 6.106).

After you finish printing the regulatory audit report, you can return to the “CB Home” page by clicking the “CB Home” link from the banner in the upper right corner of the page.

Click the “Yes” button in the “Confirmation” pop-up to navigate to the “CB Home” page.

Figure 6.106 – Dashboard – Print Button and CB Home Link



6.3.4 View the Status of a Regulatory Audit Report

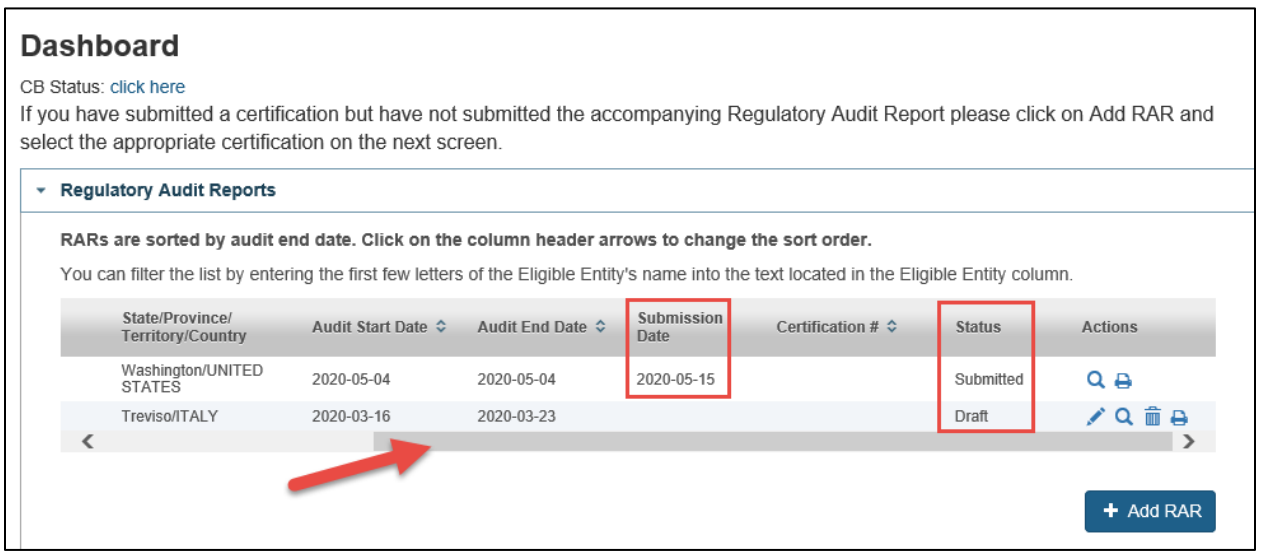
You may view the status of a regulatory audit report.

Click and drag the horizontal scroll bar to see the “Status” column by scrolling to the right within the “Regulatory Audit Reports” section (Figure 6.107).

The possible statuses are:

- **Draft –** The regulatory audit report has been saved but not yet submitted to FDA.
- **Pending –** The regulatory audit report has been submitted to FDA and is undergoing a scan of attachment(s) included with the submission. Once the attachment(s) passes the scan, it will update to “Transmitting.”
- **Transmitting –** The regulatory audit report has been submitted and is in the process of being downloaded by FDA. This status may only appear briefly before it is updated to the next status. Once it has been downloaded by FDA, the status will update to “Submitted.”
- **Submitted –** The regulatory audit report has been successfully received by FDA. The “Submission Date” column will display the applicable date.

Figure 6.107 – Regulatory Audit Report Statuses



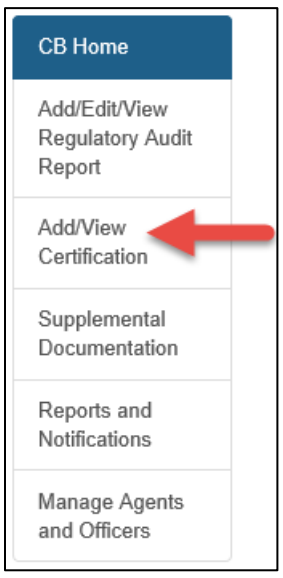
7 Add/View Certification

The Add/View Certification feature may be used to perform two main functions related to certifications:

- Creating and submitting a new certification to FDA
- Viewing existing certifications submitted to FDA

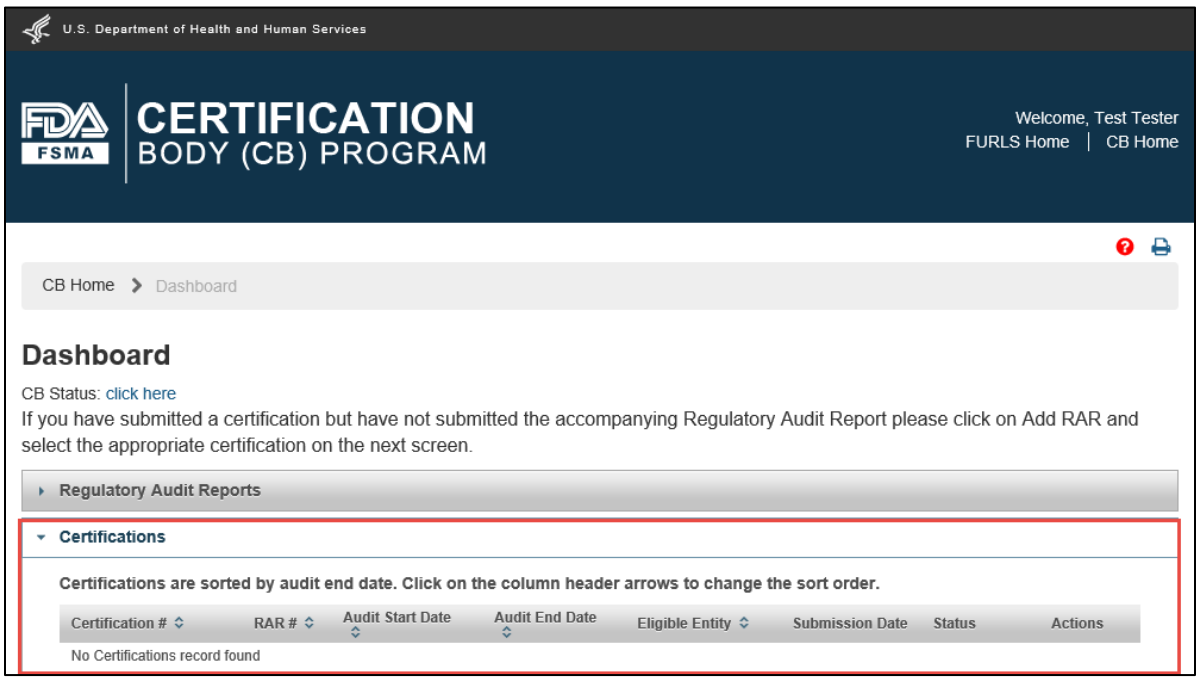
To access the certification functionality, click the “Add/View Certification” link from the navigation menu on the “CB Home” page (Figure 7.1).

Figure 7.1 – Navigation Menu



You will be navigated to the “Dashboard” page. The “Certifications” accordion section will expand (Figure 7.2).

Figure 7.2 – Dashboard



There are two scenarios associated with the creation and submission of a certification. The scenarios are based on whether the regulatory audit report has been submitted.

- **Do you want to submit a new certification when the corresponding regulatory audit report was not previously submitted?**
  If yes, proceed to Section 7.1 of this chapter.

- **Do you want to submit a new certification for an existing regulatory audit report that was previously submitted?**
  If yes, proceed to Section 7.2 of this chapter.

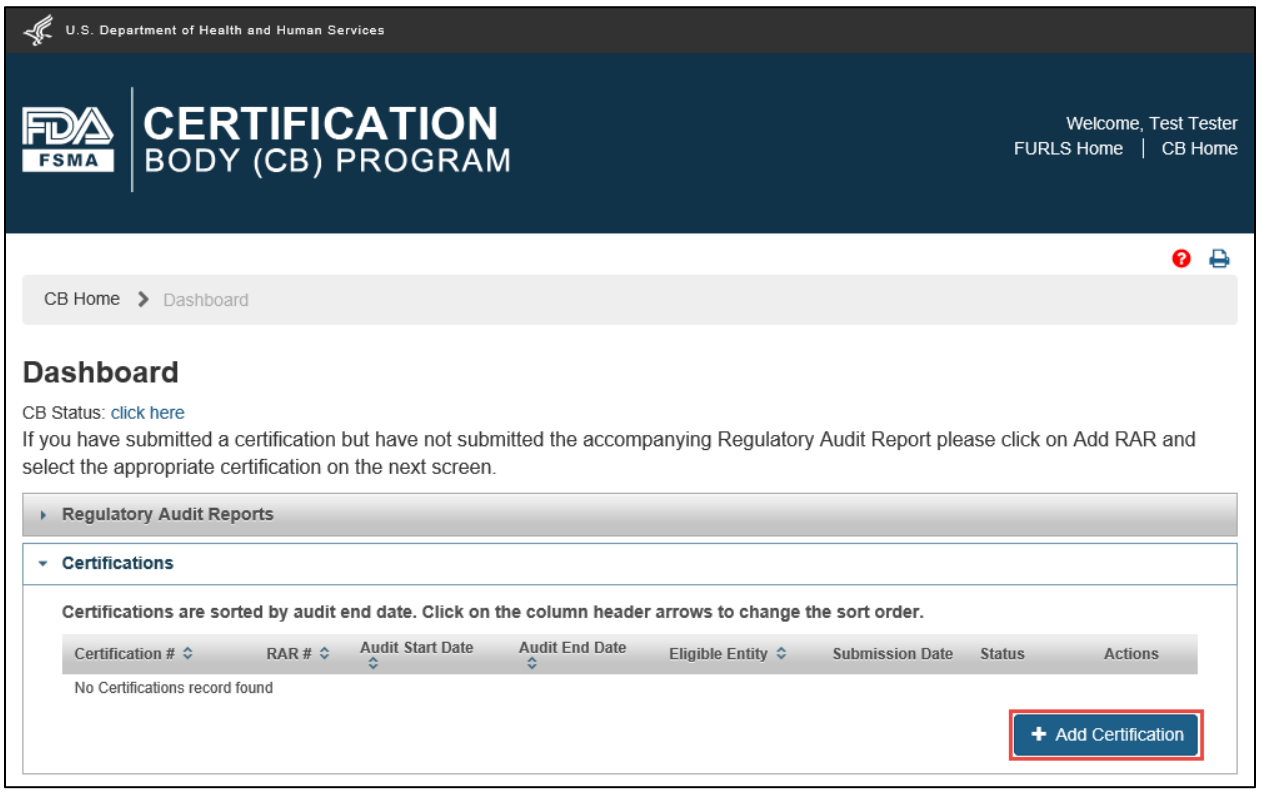
Note: Certifications cannot be saved as a draft version. All sections must be completed and submitted at the same time.

7.1 Create and Submit a New Certification When the Corresponding Regulatory Audit Report Has Not Been Submitted

To create and submit a new certification, click the “Add Certification” button on the “Dashboard” page (Figure 7.3). The system will display the “Accredited Third-Party Information” section of the “Certification Issued by Accredited Third-Party CB” page.

If you have not previously submitted a regulatory audit report to FDA, the system will display the “Accredited Third-Party Information” section of “Certification Issued by Accredited Third-Party CB” page. Proceed to Section 7.1.1 of this chapter.

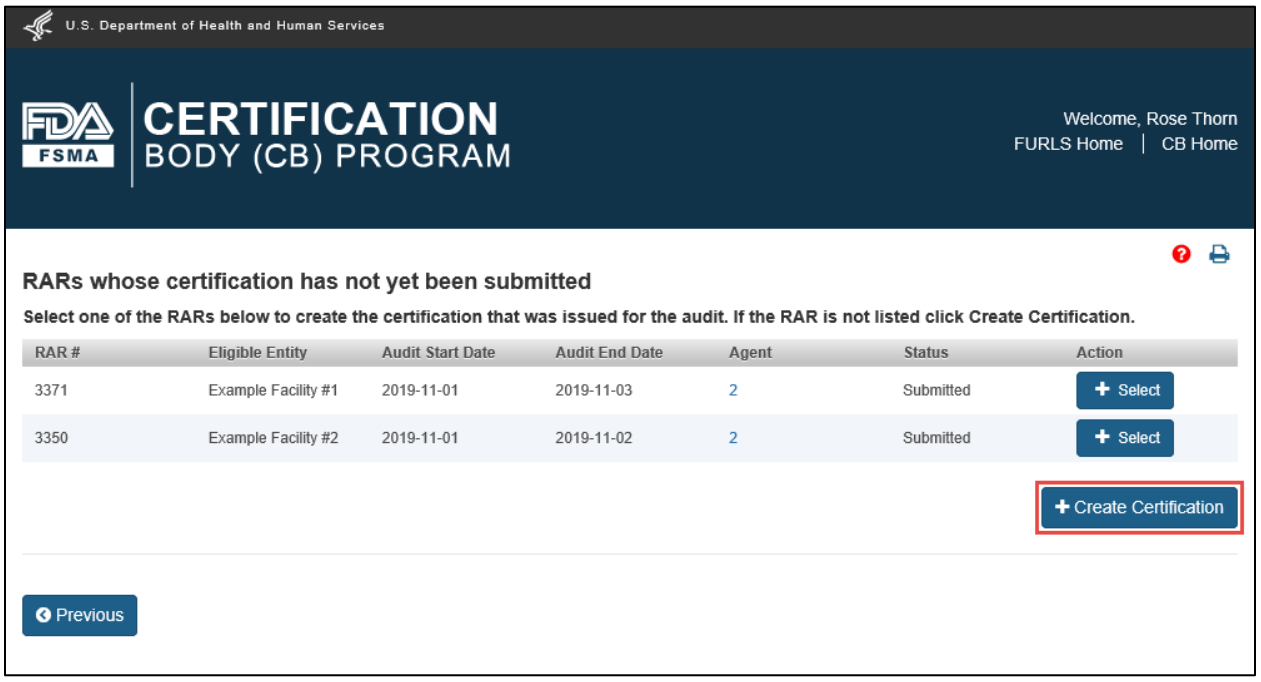
Figure 7.3 – Add Certification Button



If you have submitted at least one regulatory audit report to FDA, but not its corresponding certification, the system will display the “RARs whose certification has not yet been submitted” page with a list of the regulatory audit report(s) (Figure 7.4).

Click the “Create Certification” button to proceed to the “Certification Issued by Accredited Third-Party CB” page to create a new certification that does not correspond to the previously submitted regulatory audit report(s).

Figure 7.4 – Create Certification Button



7.1.1 Accredited Third-Party Information Section

The “Accredited Third-Party Information” section of “Certification Issued by Accredited Third-Party CB” page is displayed after you click the “Add Certification” or “Create Certification” button.

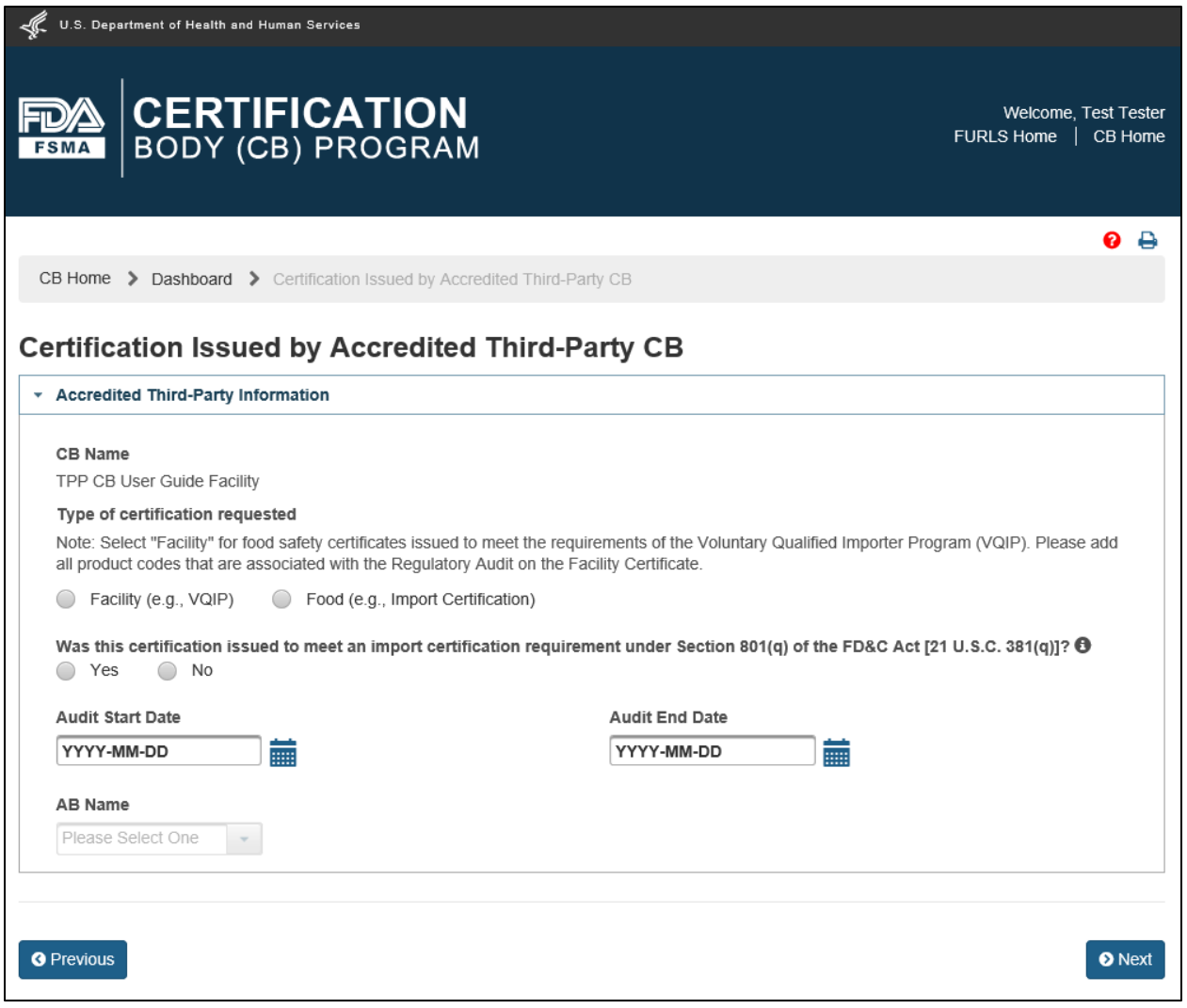
You must complete the following data entry fields in the “Accredited Third-Party Information” section (Figure 7.5):

- **CB Name –** This field is pre-filled with the CB’s name.
- **Type of certification requested –** Select “Facility (e.g., VQIP)” or “Food (e.g., Import Certification)” by clicking its radio button.
  Note: If the purpose of the certification is to be used in the Voluntary Qualified Importer Program (VQIP,) you must select "Facility."
- **Was this certification issued to meet an import certification requirement under Section 801(q) of the FD&C Act [21 U.S.C. 381(q)]? –** Select “Yes” or “No.”
- **Audit Start Date –** Select the start date of the regulatory audit from the calendar icon or enter the audit start date in “YYYY-MM-DD” format.
- **Audit End Date –** Select the end date of the regulatory audit from the calendar icon or enter the audit end date in “YYYY-MM-DD” format.
- **AB Name –** Select the name of the AB from the dropdown list. If you are accredited by more than one AB, select the AB who accredited you for the scope(s) covered in the regulatory audit.

Note: The “AB Name” field will be pre-filled if you have only been accredited by one AB.

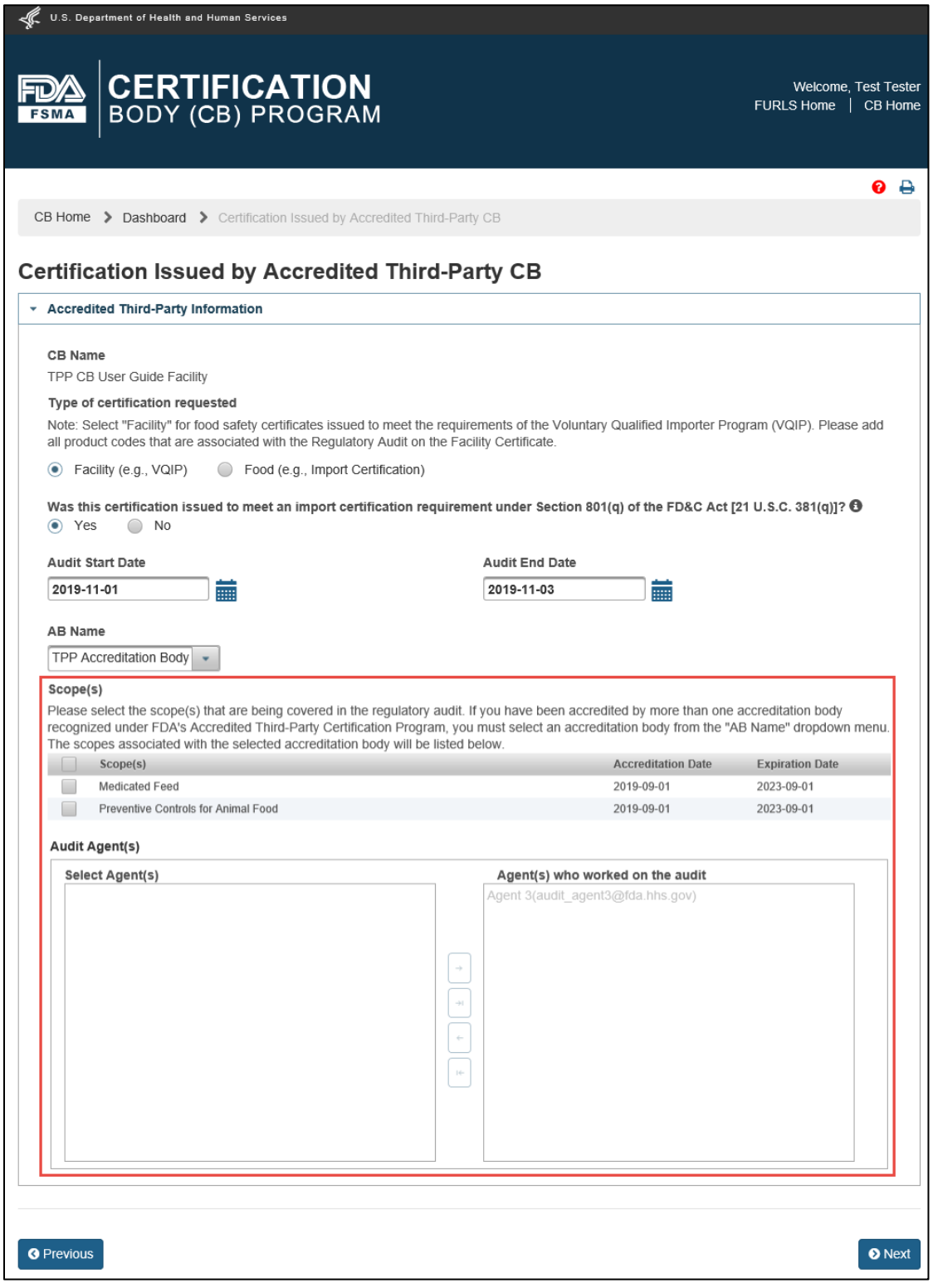
The “AB Name” field will auto-populate (or become enabled if there is more than one AB) once the “Audit Start Date” has been selected or entered.

Figure 7.5 – Accredited Third-Party Information Section



Two additional sections will display once the “Audit Start Date” and “AB Name” fields are completed – “Scope(s)” and “Audit Agent(s)” (Figure 7.6).

Figure 7.6 – Scope(s) and Audit Agent(s) Sections



The Scope(s) table lists the scopes you have been accredited by the selected AB in the “AB Name” field.

Select the scope(s) covered in the regulatory audit by clicking the appropriate checkbox(es). You must select at least one scope. The selected scopes must be related to the specific type of facility, process(es), or food(s) covered in the regulatory audit.

The “Audit Agent(s)” section lists the active audit agent(s) as of the selected audit start date. The active audit agents are managed by the CB. If the active audit agent(s) is not listed in the in the “Select Agent(s)” table, add the audit agent using the “Manage Agents and Officers” section. See Chapter 8 “Manage Agents and Officers,” for additional instructions on how to manage audit agents.

Select the audit agent(s) associated with the audit by clicking on an agent name from the “Select Agent(s)” window; the agent name will be highlighted. Use the following buttons to add or remove the selected audit agent(s):

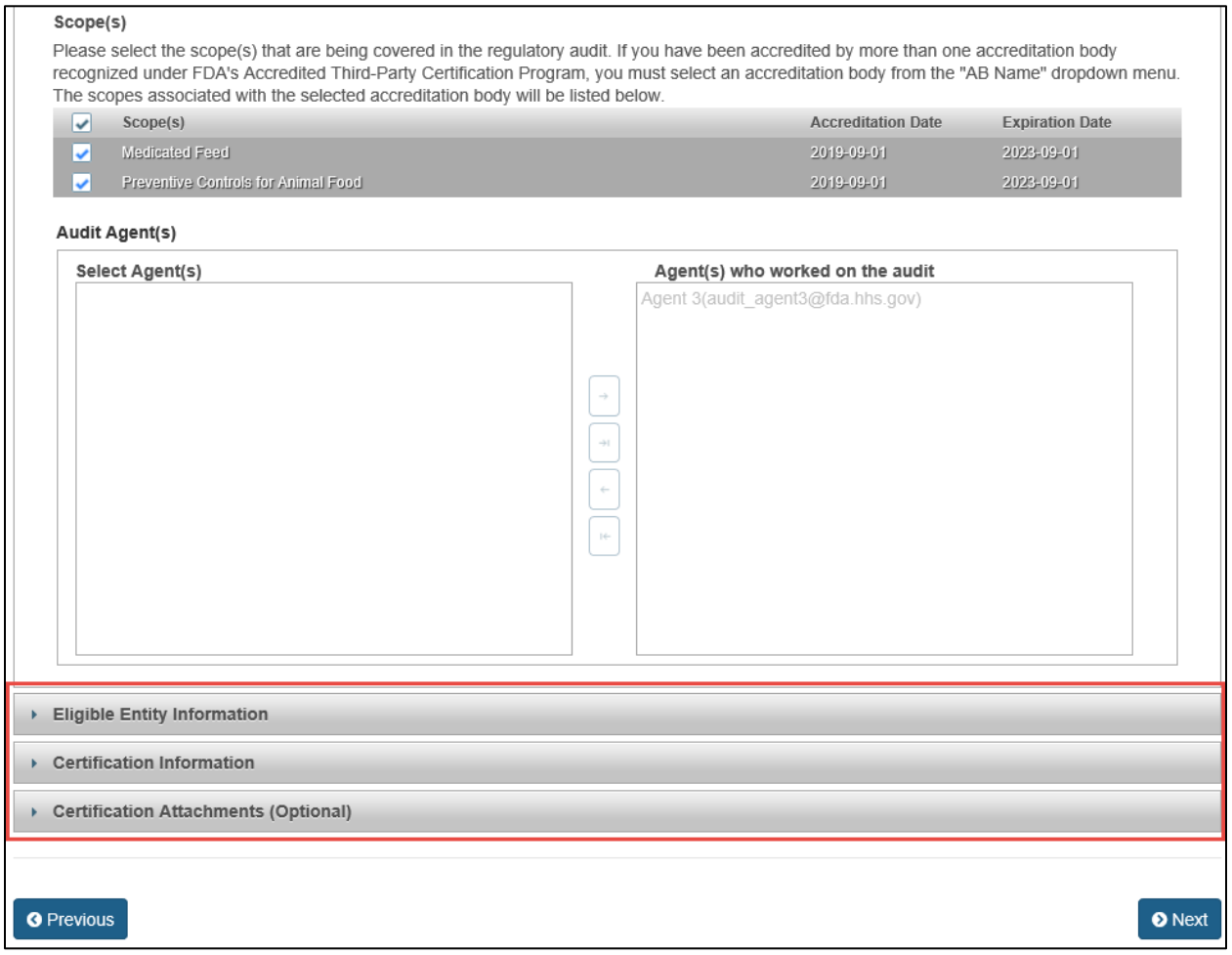
- **“Add” –** Moves the selected agent(s) to the “Agent(s) who worked on the audit” column
- **“Add All” –** Selects and moves all agents to the “Agent(s) who worked on the audit” column
- **“Remove” –** Removes the selected agent(s) from the “Agent(s) who worked on the audit” column
- **“Remove All” –** Removes all agents from the “Agent(s) who worked on the audit” column

Note: The agent will be pre-selected and added to the “Agent(s) who worked on the audit” section if there is only one audit agent available.

Once you have selected the scope(s), additional sections of the certification will display (Figure 7.7):

- Eligible Entity Information
- Certification Information
- Certification Attachments (Optional)

Figure 7.7 – Additional Sections Displayed After Scope(s) Selection



Note: Click the “Previous” button at the bottom of the “Certification Issued by Accredited Third-Party CB” page if you wish to return to the “Dashboard” page and start over.

Proceed to Section 7.1.2 of this chapter.

7.1.2 Eligible Entity Information Section

Click the “Eligible Entity Information” accordion section’s title bar to display the content of the section (Figure 7.8).

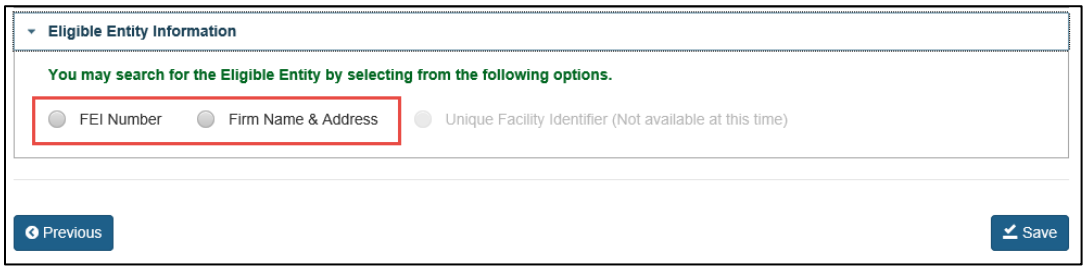
Figure 7.8 – Eligible Entity Information Section

You must enter the firm information associated with the regulatory audit in the “Eligible Entity Information” section. The “Eligible Entity” tab is where information regarding the eligible entity covered in the audit is entered (as well as the audited facility, if it is different from the eligible entity). There are two firm search options (Figure 7.9). You must select a radio button to display the search fields. The two firm search options are:

- FEI Number
- Firm Name & Address

Note: If the regulatory audit was performed at a different location than the eligible entity, you will need to provide the audited facility information in the certification as well. The steps for adding the audited facility information are described in Section 7.1.2.4 of this chapter.

Figure 7.9 – Eligible Entity Information – Search Options



For instructions on how to search by the FEI number, proceed to Section 7.1.2.1 of this chapter.

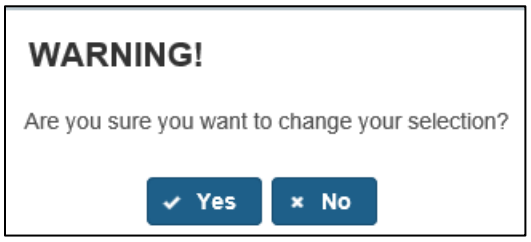
For instructions on how to search by the firm name and address, proceed to Section 7.1.2.2 of this chapter.

Note: You may change your search method selection (e.g., “FEI Number” vs. “Firm Name & Address”) at any time by clicking on the corresponding radio button.

The system will display a warning message if you change your selection (Figure 7.10).

Click “Yes” to change your selection. Click “No” to keep the current selection and dismiss the warning message.

Figure 7.10 – Eligible Entity Information – Warning Message

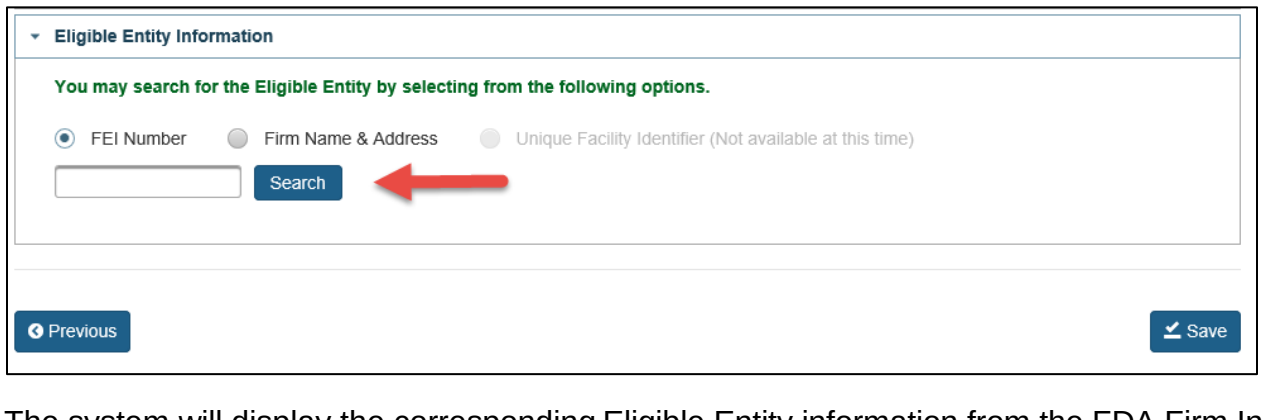


7.1.2.1 Eligible Entity Information Section - Search by FEI Number

If you have the firm's FEI number, select the radio button to the left of "FEI Number." An input field and the "Search" button will display (Figure 7.11).

Enter the FEI number and click the "Search" button.

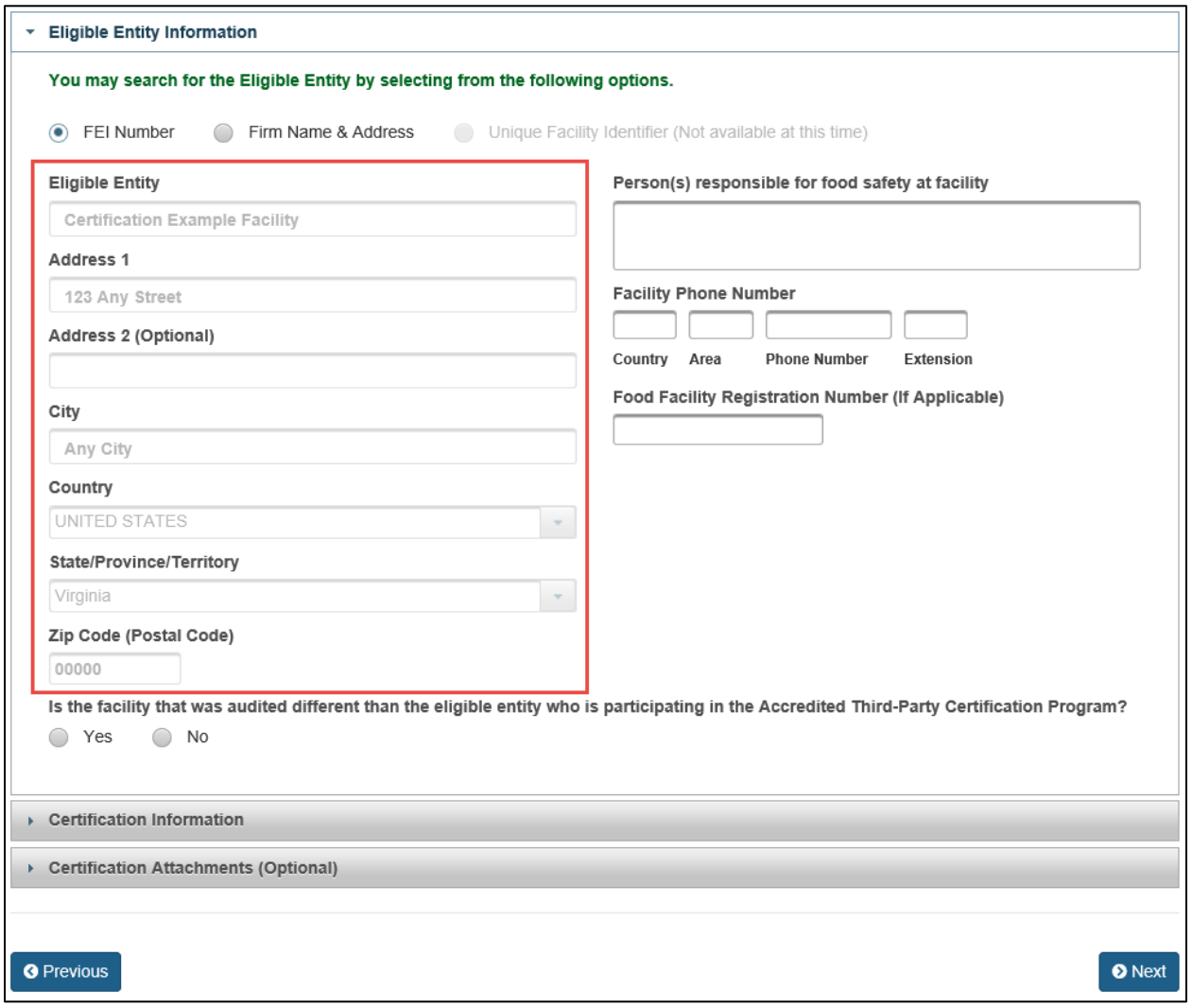
Figure 7.11 – Search by FEI Number



The system will display the corresponding Eligible Entity information from the FDA Firm Inventory if there is a match (Figure 7.12).

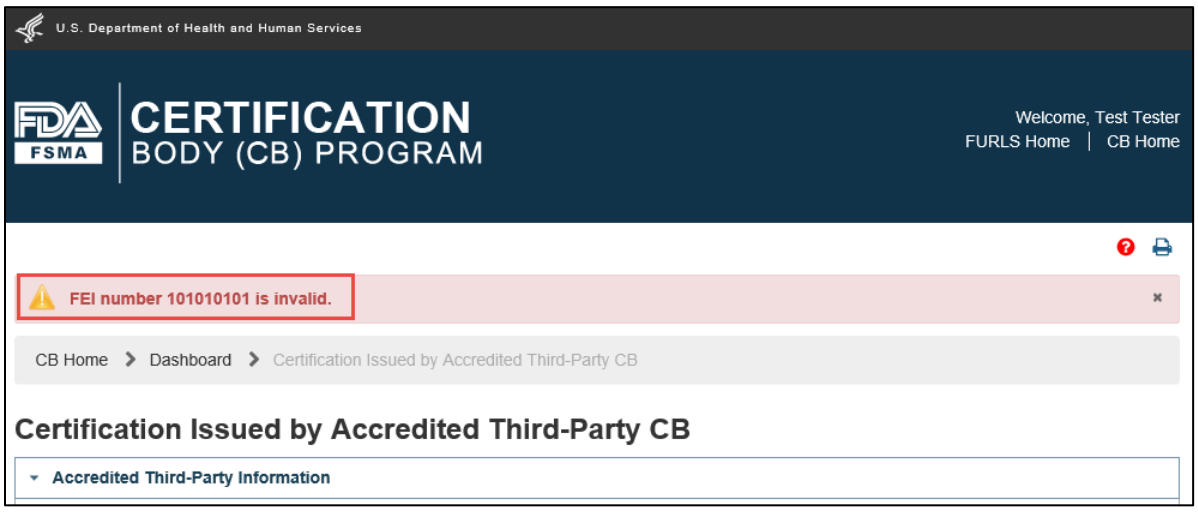
Review the Eligible Entity information to confirm that the firm information that is displayed is correct. If the firm information is incorrect, verify that the FEI number you entered is correct and use the search function again. If the firm information displayed is still incorrect, please proceed to Section 7.1.2.2 of this chapter to search for the eligible entity by Firm Name and Address.

Figure 7.12 – Eligible Entity Information – FEI Number Search Results



If you enter an invalid FEI number, the system will display an error message at the top of the page (Figure 7.13).

Figure 7.13 – Invalid FEI Number Error Message

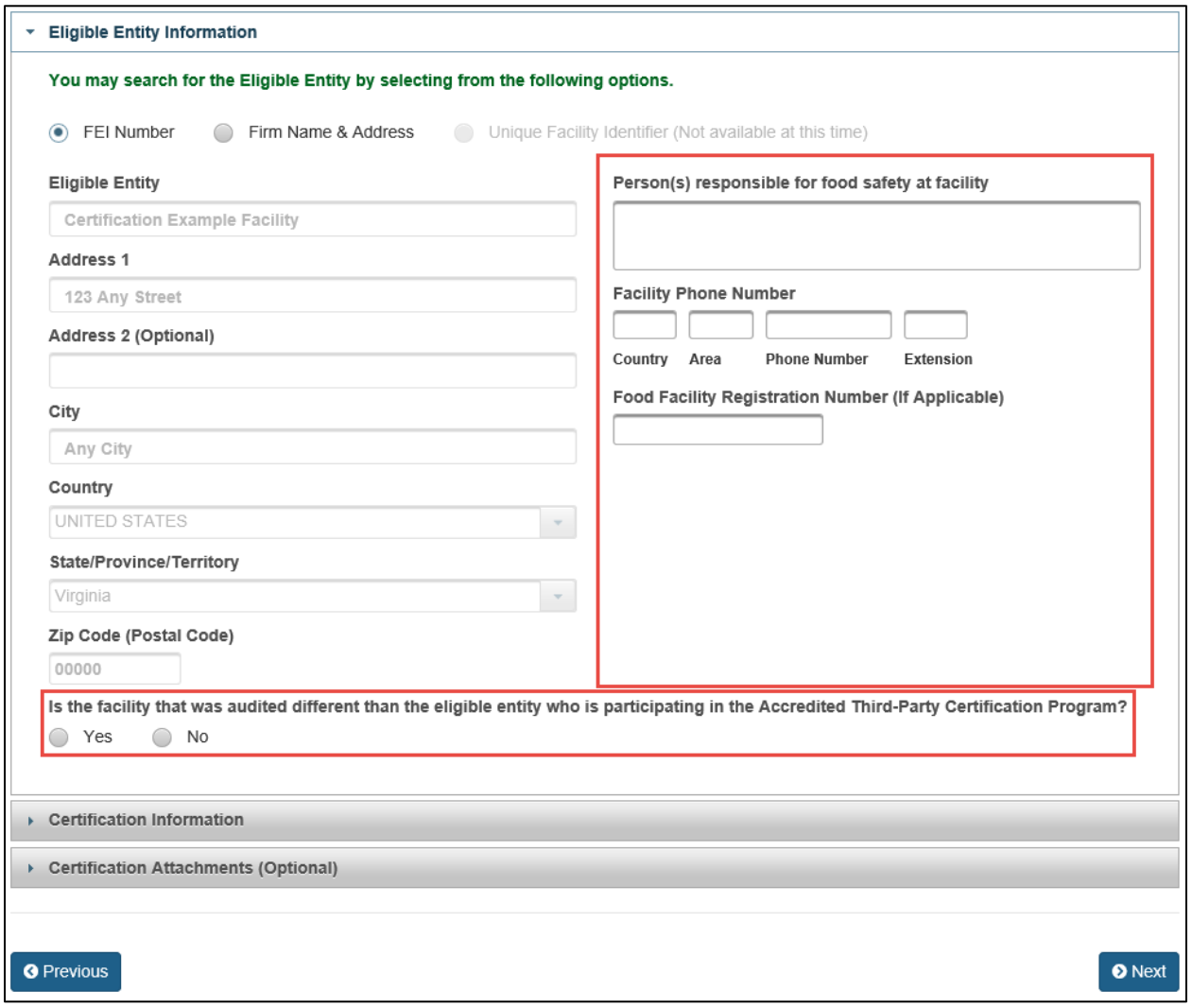


To correct any errors in the FEI number, re-enter the FEI number and click the “Search” button again.

Once the system displays the search results for the FEI Number, review the pre-filled information to make sure it is correct and complete the following fields (Figure 7.14):

- **Person(s) responsible for food safety at the facility –** Enter the name of the person(s) responsible for the food safety program (i.e., the facility’s compliance with the applicable food safety requirements of the FD&C Act and FDA regulations) at the audited facility. The field allows the entry of multiple names.
- **Facility Phone Number (Country/Area/Phone Number/Extension) –** The telephone number of the facility
  - “Country” is the country code.
  - “Area” is the area code.
  - “Phone Number” is the phone number.
  - “Extension” is the local phone extension, if applicable.
- **Food Facility Registration Number –** Submission of the 11-digit Food Facility Registration Number (FFRN) is required for facilities subject to the FDA’s Registration Requirements under 21 CFR Part 1, Subpart H. The system will display an error message if the FFRN does not correspond to the provided FEI number: “FFR Number entered does not match with the Eligible Entity Information. Please try again.”
  Note: For additional information on FFRN, please visit the “Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition).”
- **Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program? –** Select “Yes” or “No.”
  - If you select “Yes,” the system will display the search options for the audited facility (Figure 7.14). Proceed to Section 7.1.2.4 for instructions on how to complete the “Audited Facility” portion of the “Eligible Entity Information” section.
  - If you select “No,” proceed to the next section of the certification page, “Certification Information” and Section 7.1.3 of this chapter.

Figure 7.14 – Eligible Entity Information – Search by FEI Number – Additional Fields



7.1.2.2 Eligible Entity Information Section - Search by Firm Name & Address

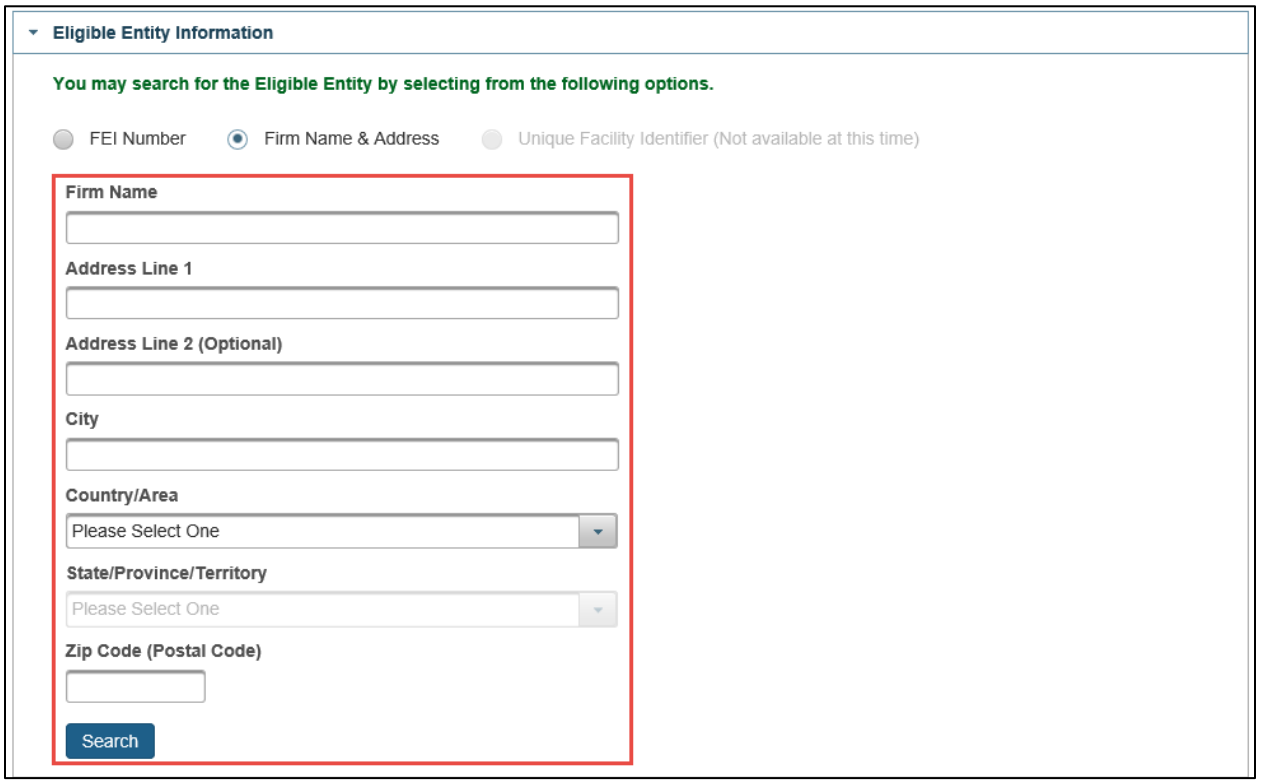
Select the radio button to the left of “Firm Name & Address” if you do not have the firm’s FEI number. The system will display additional data fields once you select the radio button (Figure 7.15). The text entry fields are not case-sensitive.

Enter the firm information in the search fields displayed:

- **Firm Name –** The name of the firm
- **Address Line 1 –** The address where the firm is physically located – this includes the number, street, quadrant, etc.
- **Address Line 2 –** The field to enter additional information about the physical location of the firm. This may include a suite or apartment number, if applicable. This field is optional.
- **City –** The city where the firm is physically located
- **State/Province/Territory –** The state/province/territory where the firm is physically located
- **Zip Code (Postal Code) –** The zip code (domestic) or postal code (foreign) where the firm is physically located
  Note: Zip Code is required only for U.S. addresses; however, including the Postal Code may help to refine your search results.

Once you have entered the information in the search fields, click the “Search” button.

Figure 7.15 – Eligible Entity Information – Search by Firm Name & Address



After you click the “Search” button the system will search for a match in the FDA Firm Inventory and display the corresponding eligible entity information, if it exists.

The system will display the search results(s) depending on the number of matches found for the firm information entered:

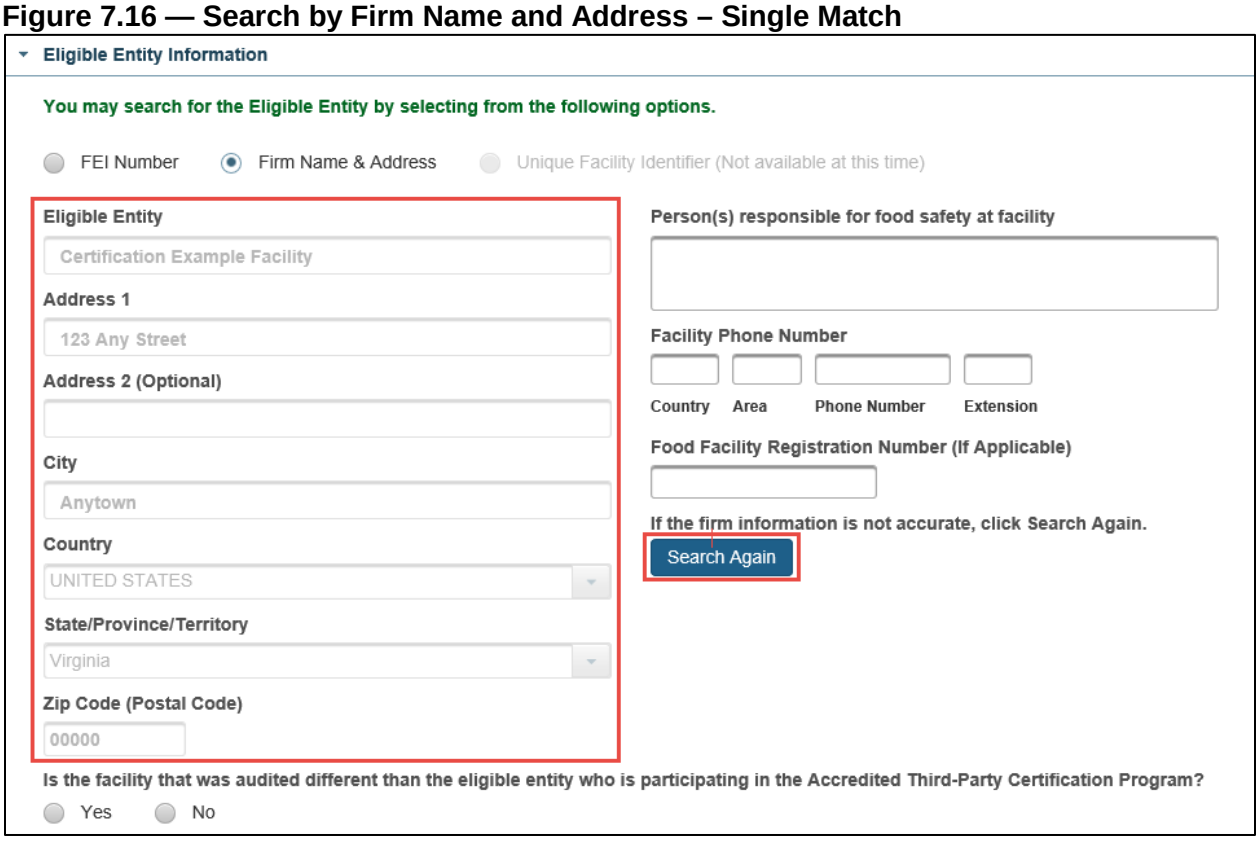
- If one search result is returned, proceed to Section 7.1.2.2.1 of this chapter.
- If more than one search result is returned, proceed to Section 7.1.2.2.2 of this chapter.
- If no results are returned, proceed to Section 7.1.2.2.3 of this chapter.

7.1.2.2.1 Eligible Entity Information – Search by Firm Name & Address – Single Match

If the system returns one match, the firm fields will be pre-filled after executing your search (Figure 7.16). Click the "Search Again" button if you wish to edit the firm information.

Once you are ready to proceed with the listed firm, proceed to Section 7.1.2.3 of this chapter.

Figure 7.16 — Search by Firm Name and Address – Single Match



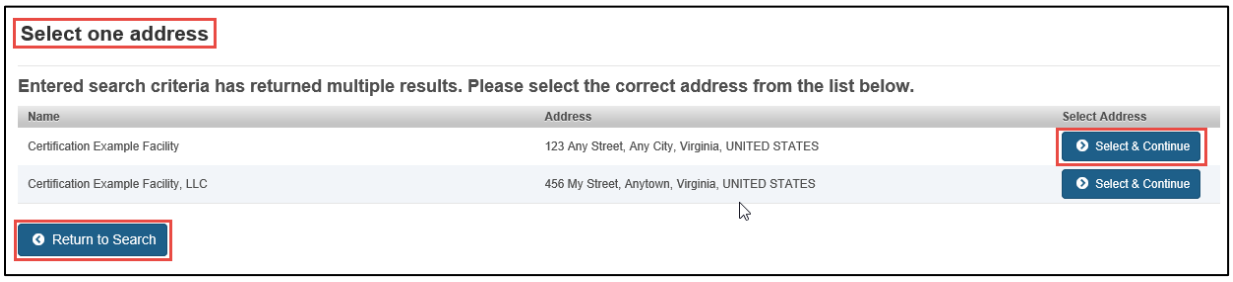
7.1.2.2.2 Eligible Entity Information – Search by Firm Name & Address – Multiple Match

If more than one search result is returned, the system will display a pop-up window which prompts you to "Select one address" on the right side of the row (Figure 7.17).

Choose the desired address from the list and click "Select & Continue" on the right side of the row. Otherwise, click "Return to Search" to return to the search fields.

Once you are ready to proceed with the listed firm, proceed to Section 7.1.2.3 of this chapter.

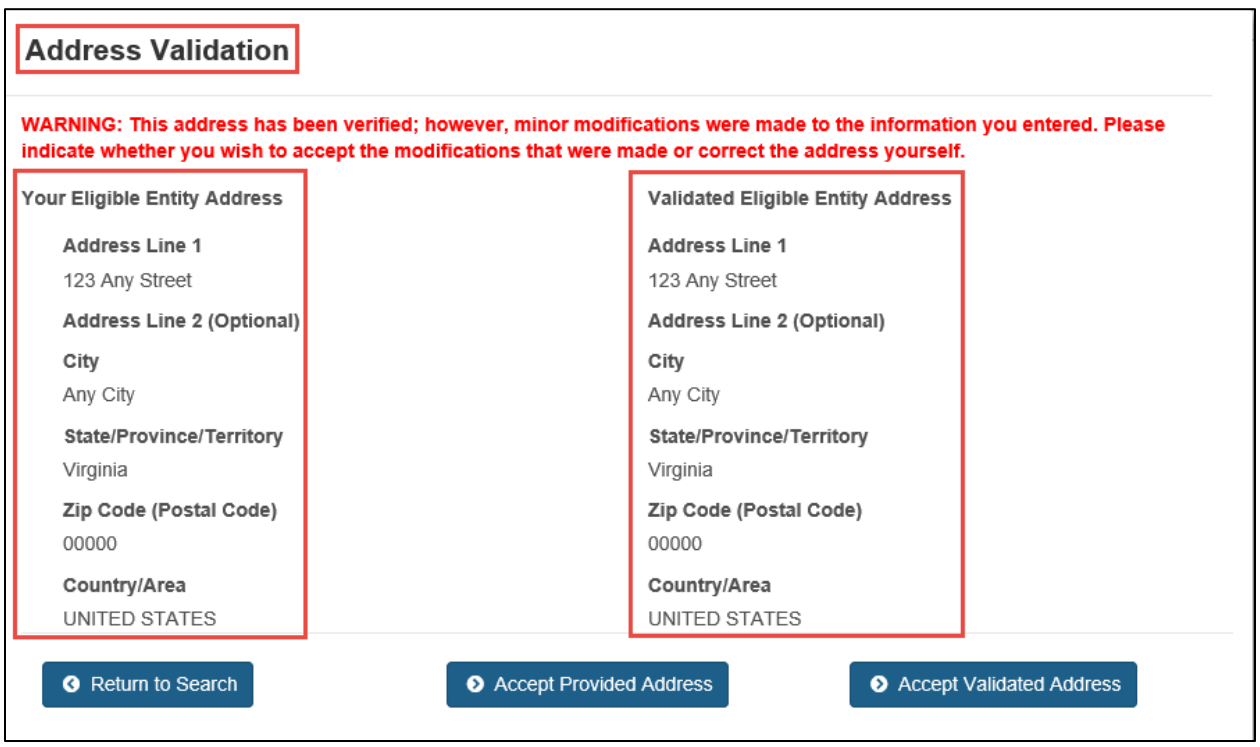
Figure 7.17 – Search by Firm Name & Address – Select One Address Pop-up Window



7.1.2.2.3 Eligible Entity Information – Search by Firm Name & Address – No Match

If no match was found for the Firm Name & Address search, the system will perform an address validation and display a pop-up window showing both the provided and validated addresses (Figure 7.18).

Figure 7.18 – Search by Firm Name & Address – Address Validation Pop-up Window



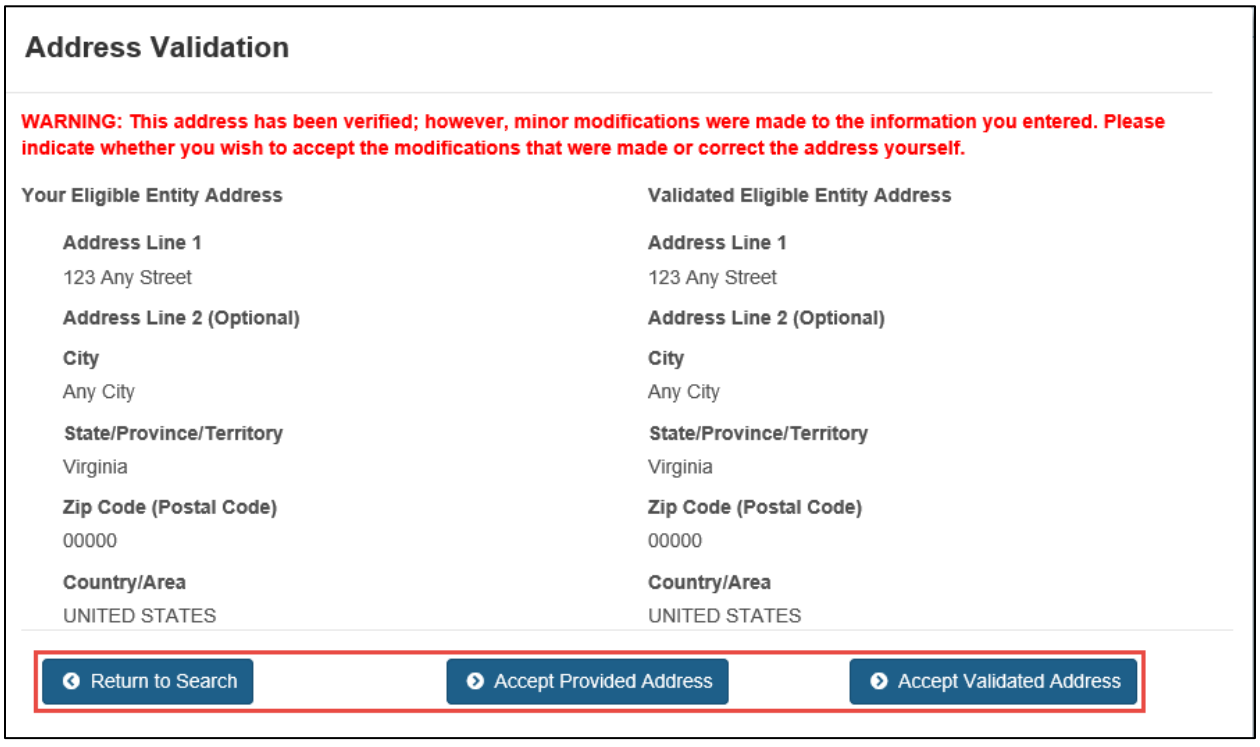
Click “Accept Provided Address” if you wish to keep “Your Eligible Entity Address” as-entered (Figure 7.19).

Click “Accept Validated Address” if the “Validated Eligible Entity Address” is accurate.

Click “Return to Search” to return to the main page and edit the entered address.

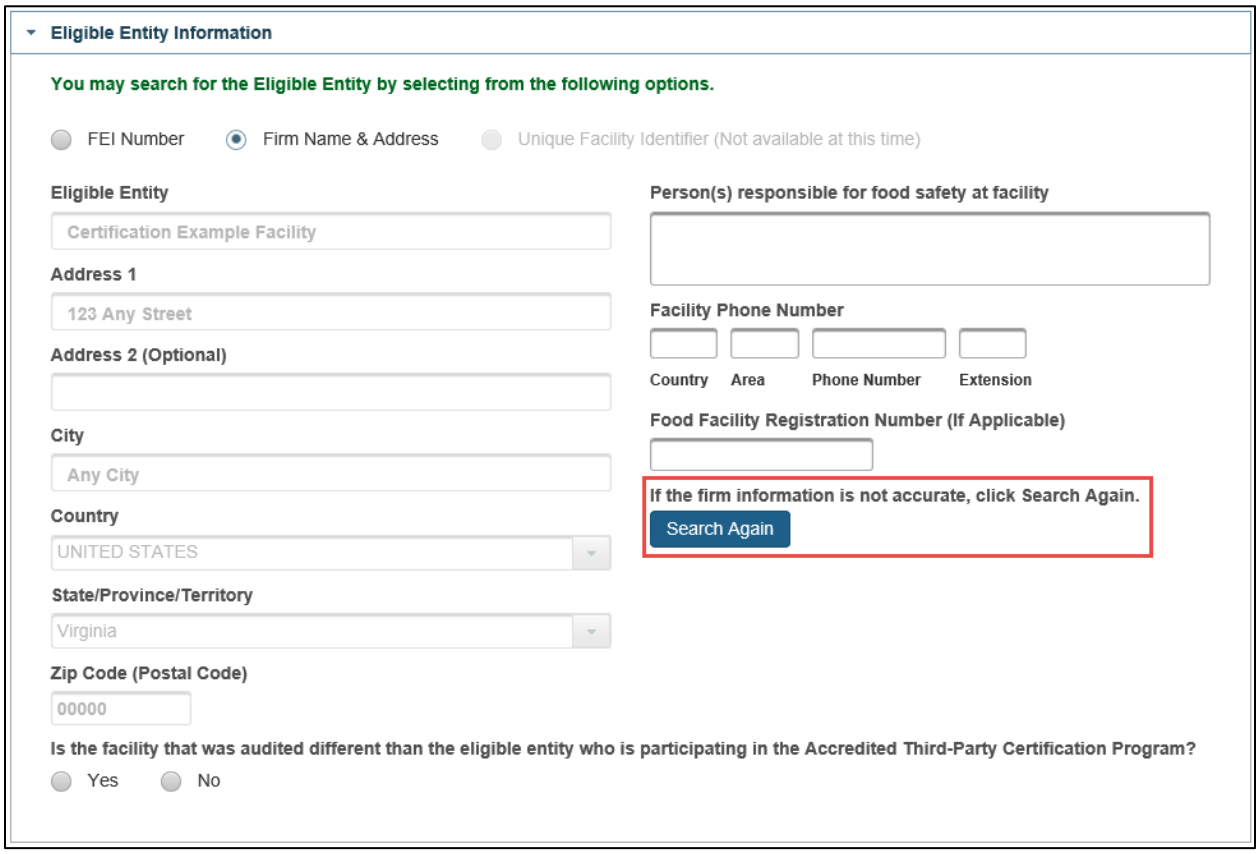
Once you are ready to proceed with the listed firm, proceed to Section 7.1.2.3 of this chapter.

Figure 7.19 – Search by Firm Name & Address – Address Validation Pop-up Window Options



To begin a new search, click the “Search Again” button and repeat the steps in Section 7.1.2.2 in this chapter (Figure 7.20).

Figure 7.20 – Search by Firm Name & Address – Search Again

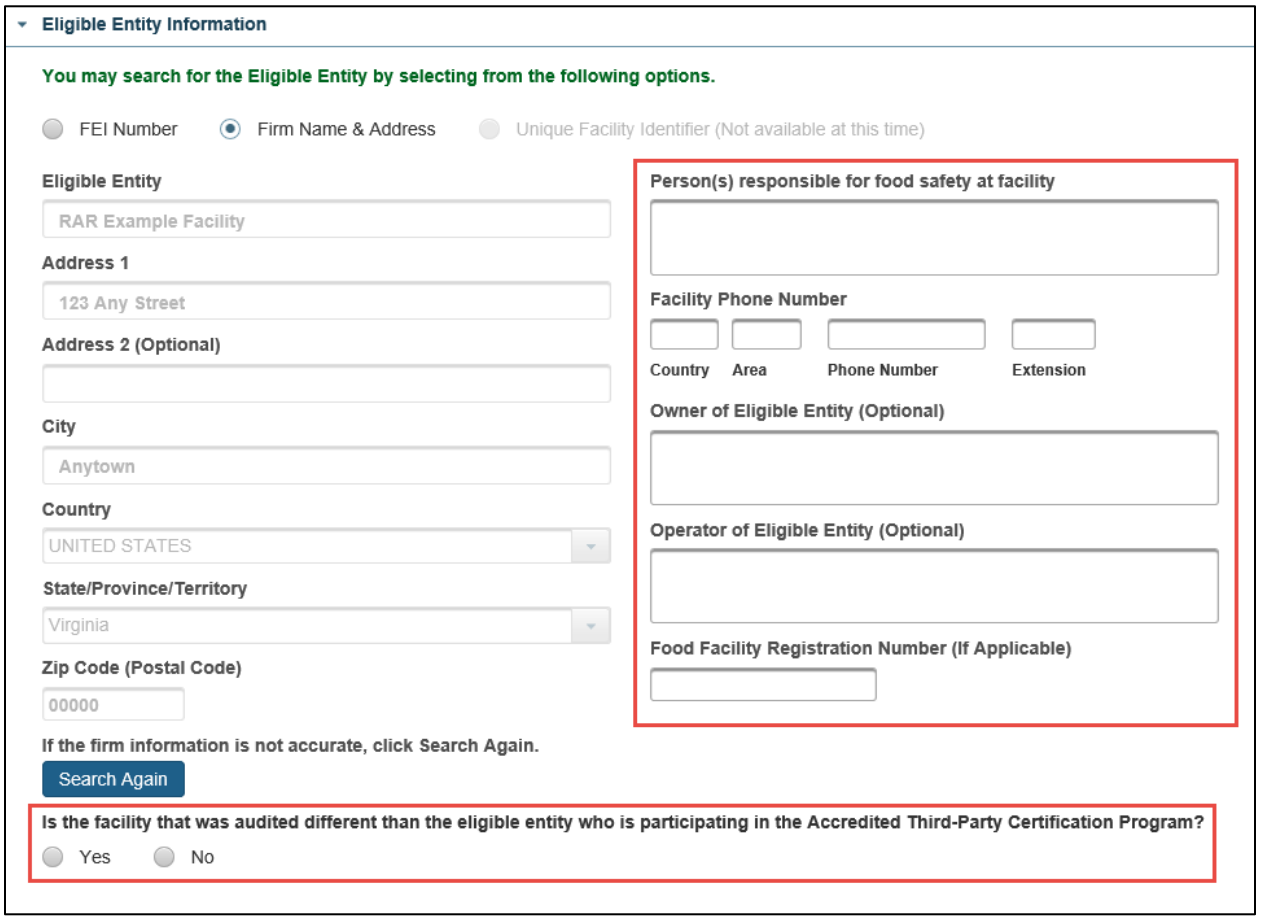


7.1.2.3 Eligible Entity Information Section – Completion of Additional Fields After Selecting Firm from Search Results

Once you are ready to proceed with the desired firm information obtained through the "Firm Name & Address" search, complete the following fields (Figure 7.21):

- **Person(s) responsible for food safety at the facility –** Enter the name of the person(s) responsible for the food safety program (i.e., the facility's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations) at the audited facility. The field allows for entry of multiple names.
- **Facility Phone Number (Country/Area/Phone Number/Extension) –** The telephone number of the facility
  - "Country" is the country code.
  - "Area" is the area code.
  - "Phone Number" is the phone number.
  - "Extension" is the local phone extension, if applicable.
- **Food Facility Registration Number –** Submission of the 11-digit Food Facility Registration Number (FFRN) is required to be submitted for facilities subject to the FDA's Registration Requirements under 21 CFR Part 1, Subpart H. The system will display an error message if the FFRN does not correspond to the provided FEI number: "FFR Number entered does not match with the Eligible Entity Information. Please try again."
  Note: For additional information on FFRN, please visit the "Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)."
- **Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program? –** Select "Yes" or "No."
  - If you select "Yes," the system will display the search options for the audited facility (Figure 7.21). Proceed to Section 7.1.2.4 for instructions on how to complete the "Audited Facility" portion of the "Eligible Entity Information" section.
  - If you select "No," proceed to the next section of the certification page "Certification Information" and Section 7.1.3 of this chapter.

Figure 7.21 – Eligible Entity Information – Search by Firm Name and Address – Additional Fields

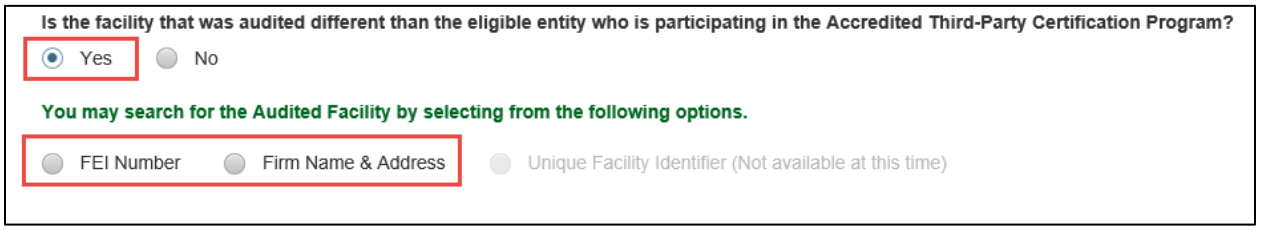


7.1.2.4 Eligible Entity Information Section – Audited Facility

If you selected "Yes" in response to the question "Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?" the system will display the search options for the audited facility (Figure 7.22).

The system displays the same options in the "Audited Facility" section when searching for the facility's information as in the "Eligible Entity Information" section: "FEI Number" and "Firm Name & Address."

Figure 7.22 – Audited Facility – Search Options

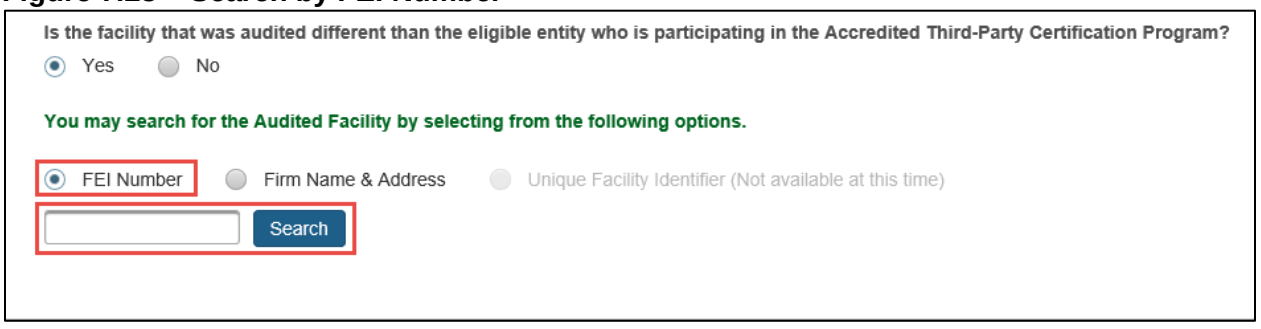


Select the radio button to the left of “FEI Number” if you have the firm’s FEI number. An input field and the “Search” button will display (Figure 7.23).

Enter the FEI Number and click the “Search” button.

Repeat the steps to search by FEI Number (as referenced in Section 7.1.2.1) for “Eligible Entity Information Section – Search by FEI Number.”

Figure 7.23 – Search by FEI Number



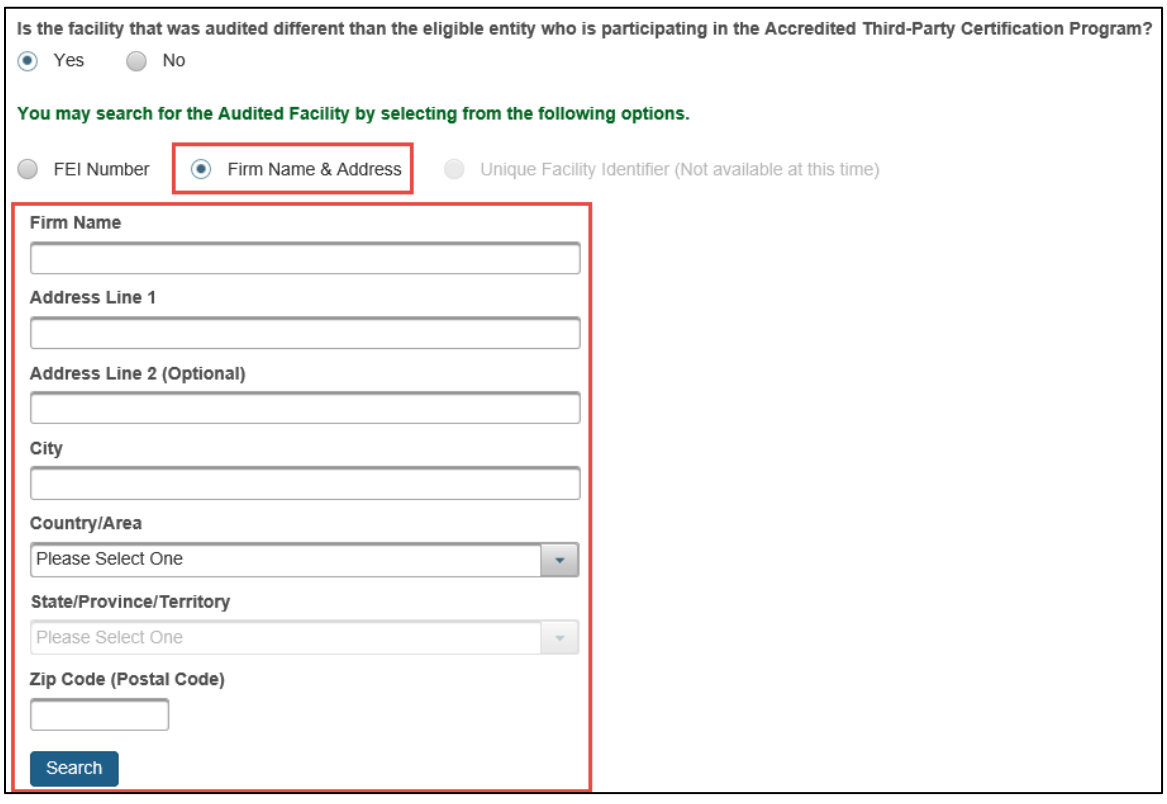
If you do not have the firm’s FEI Number, select the radio button to the left of “Firm Name & Address” to search by the firm’s name and address. An input field and the “Search” button will display (Figure 7.24).

Enter the firm information and click the “Search” button.

Repeat the steps to search by the firm’s name and address (as referenced in Section 7.1.2.2) for “Eligible Entity Information Section – Search by Firm Name & Address.”

Once you are ready to proceed with the audited facility information, proceed to Section 7.1.3 of this chapter.

Figure 7.24 – Search by Firm Name & Address



7.1.3 Certification Information Section

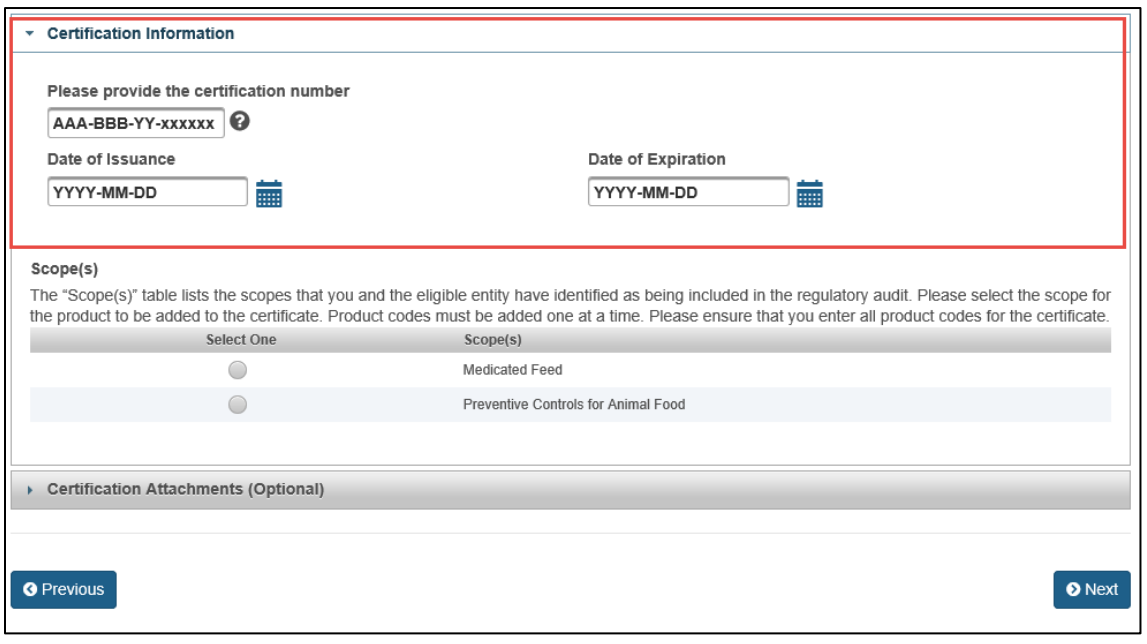
Click the “Certification Information” accordion section’s title bar to display the contents of the section (Figure 7.25).

Figure 7.25 - Certification Information Section

Complete the following data entry fields (Figure 7.26):

- **Please provide the certification number –** Enter the certificate number using the required format. The format of the certification number must be “AAA-BBB-YY-xxxxxx.”
  - **AAA –** Enter the first three letters of the AB's name.
  - **BBB –** Enter the first three letters of the CB's name.
  - **YY –** Enter the year the certification was issued.
  - **xxxxxx –** Enter six digits. It is recommended that you maintain sequential numbering. For example, your first certification for the specific AB/CB combination for that certification year could end ‘-000001,’ followed by ‘000002,’ and so on.
- **Date of Issuance –** Select the date the certification was issued from the calendar icon or enter it in “YYYY-MM-DD” format.
- **Date of Expiration –** Select the expiration date of the certification from the calendar icon or enter it in “YYYY-MM-DD” format. The date of expiration cannot be more than one year from the date of issuance.

Figure 7.26 – Certification Information Section Fields

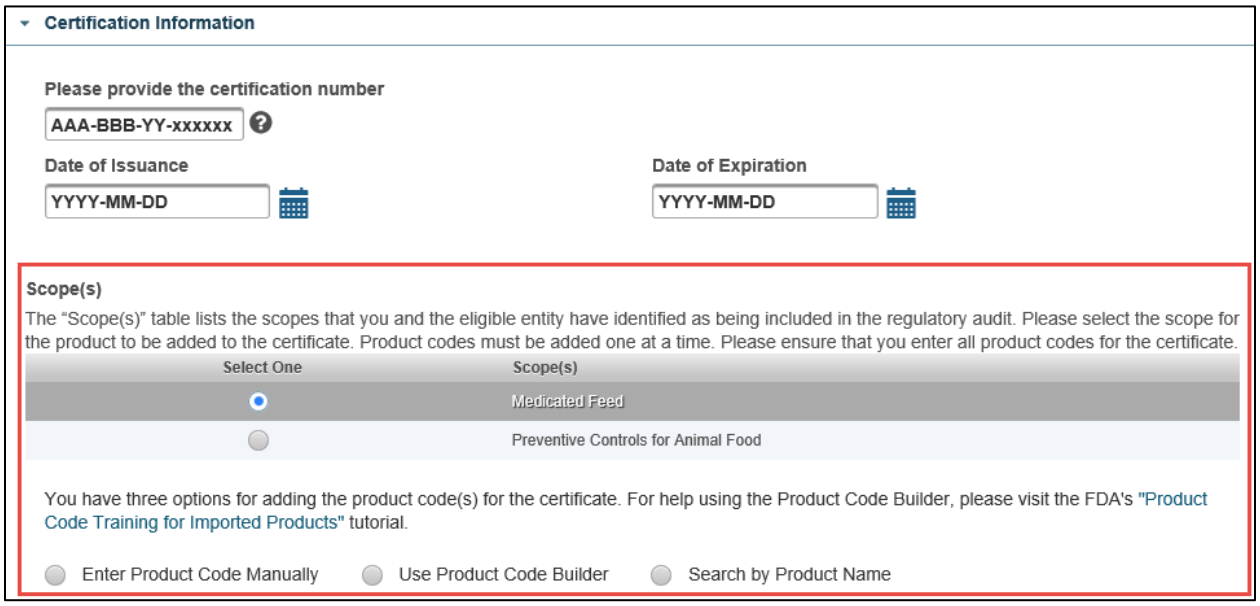


The “Scope(s)” section allows you to select the scope(s) and enter the product code(s) of the FDA regulated product(s) that will be included in the certification.

The scope(s) listed in the “Scope(s)” section is populated from the scope(s) that were previously selected in the “Accredited Third-Party Information” section of the certification.

Select the associated scope of the product you wish to enter by clicking on the radio button in the “Select One” column of the “Scope(s)” table. After you select a scope, the system will display three options for adding the corresponding product code(s) to the certificate (Figure 7.27). For information about Product Codes and the Product Code Builder, visit FDA's website on Product Codes and the Product Code Builder.

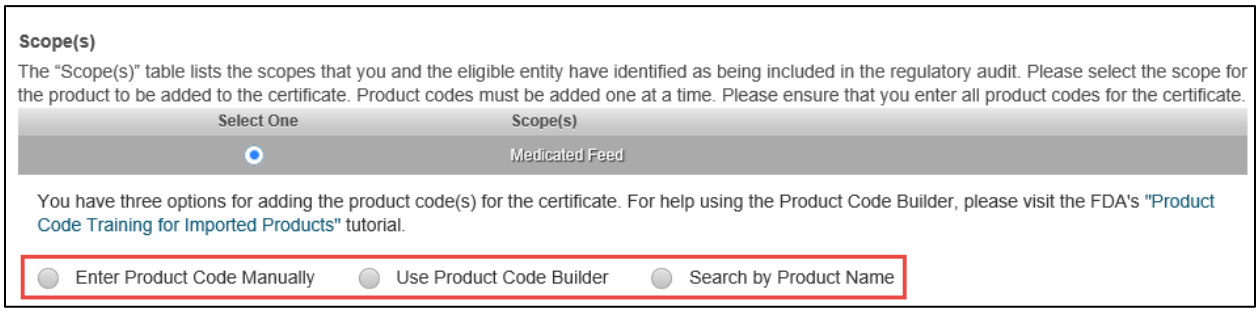
Figure 7.27 – Product Code Selection Options



You may use any of the three options to add a product code(s) to the certificate (Figure 7.28). You may enter multiple product codes. Each product code must be added individually. The instructions for each product code option are below.

- **Enter Product Code Manually –** You may use this option if you know the complete Product Code. Proceed to Section 7.1.3.1 of this chapter.
- **Use Product Code Builder –** You may use this option if you do not know the product code. Proceed to Section 7.1.3.2 of this chapter.
- **Search by Product Name –** You may use this option if you do not know the Product Code or do not want to use the Product Code Builder. Proceed to Section 7.1.3.3 of this chapter.

Figure 7.28 – Product Code Selection Options



7.1.3.1 Product Code Selection – Enter Product Code Manually

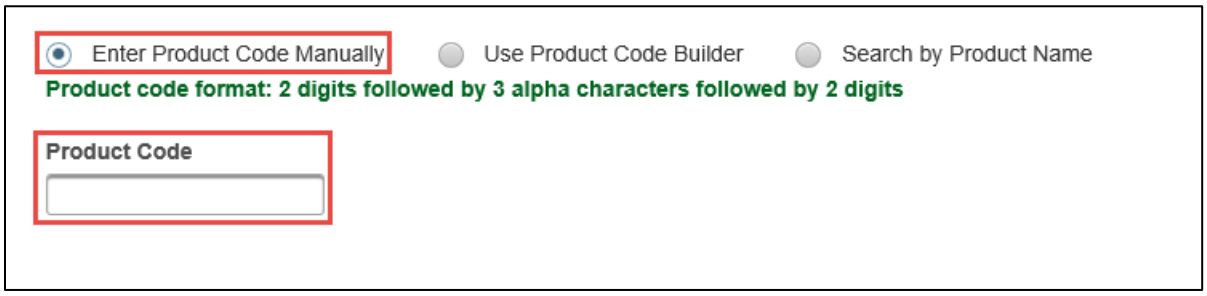
You may use the “Enter Product Code Manually” option if you know the complete product code. Select the radio button to the left of “Enter Product Code Manually” (Figure 7.29).

The “Product Code” field will display. Enter the product code in this field using the FDA product code format: two digits followed by three alpha characters followed by two digits.

Note: There are some instances in which “SubClass” and/or “Process Indicator” for a selected industry/scope combination is not required. Therefore, the system may automatically display a dash (“-”) in place of one or both fields of the Product Code in those instances.

For help determining the Product Code, visit the FDA's website on Product Codes and the Product Code Builder.

Figure 7.29 – Product Code Selection – Enter Product Code Manually



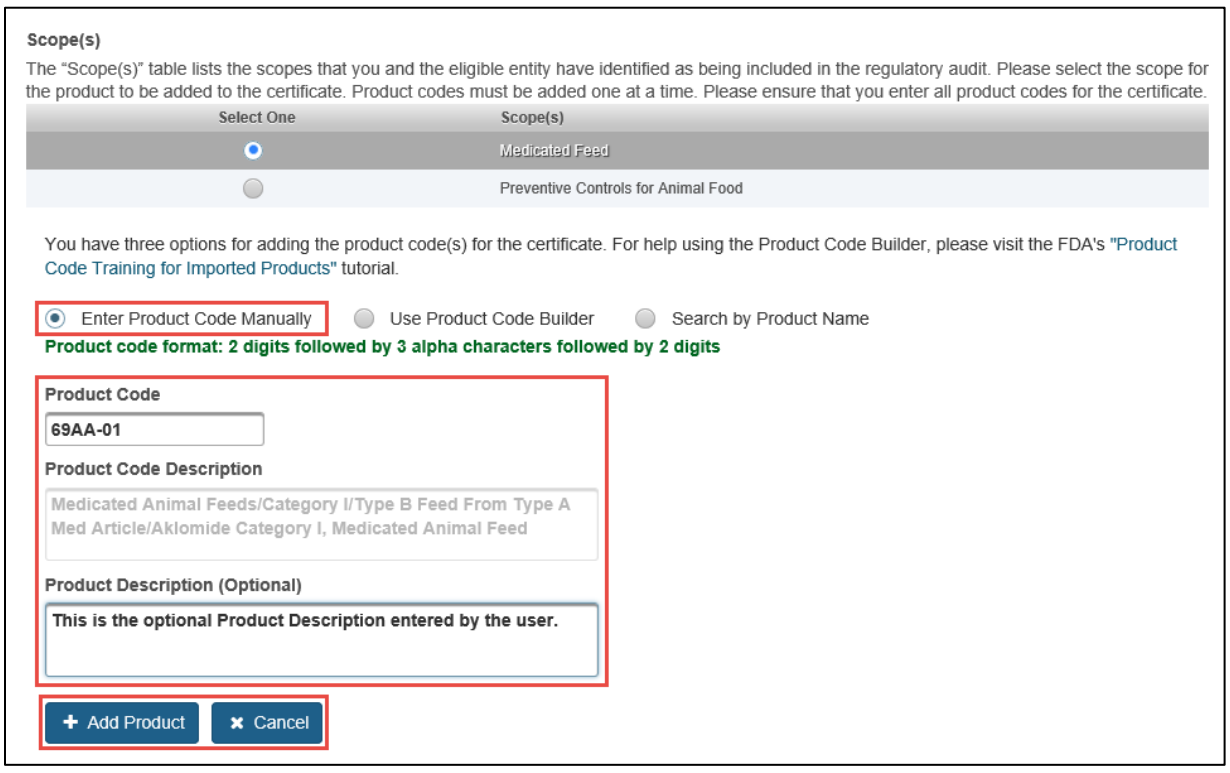
Once the system recognizes the product code, the following fields will display (Figure 7.30):

- **Product Code Description –** This is a read-only field that displays the FDA Product Code Description that corresponds to the product code that was manually entered.
- **Product Description (Optional) –** This is an optional field in which you may provide your own product description.

Click the “Cancel” button to clear your entry for that product code and start over.

Click the “Add Product” button to add the product to the certificate.

Figure 7.30 – Enter Product Code Manually – Additional Fields



Once you click “Add Product,” the product will display in a table in the “Certification Information” section (Figure 7.31).

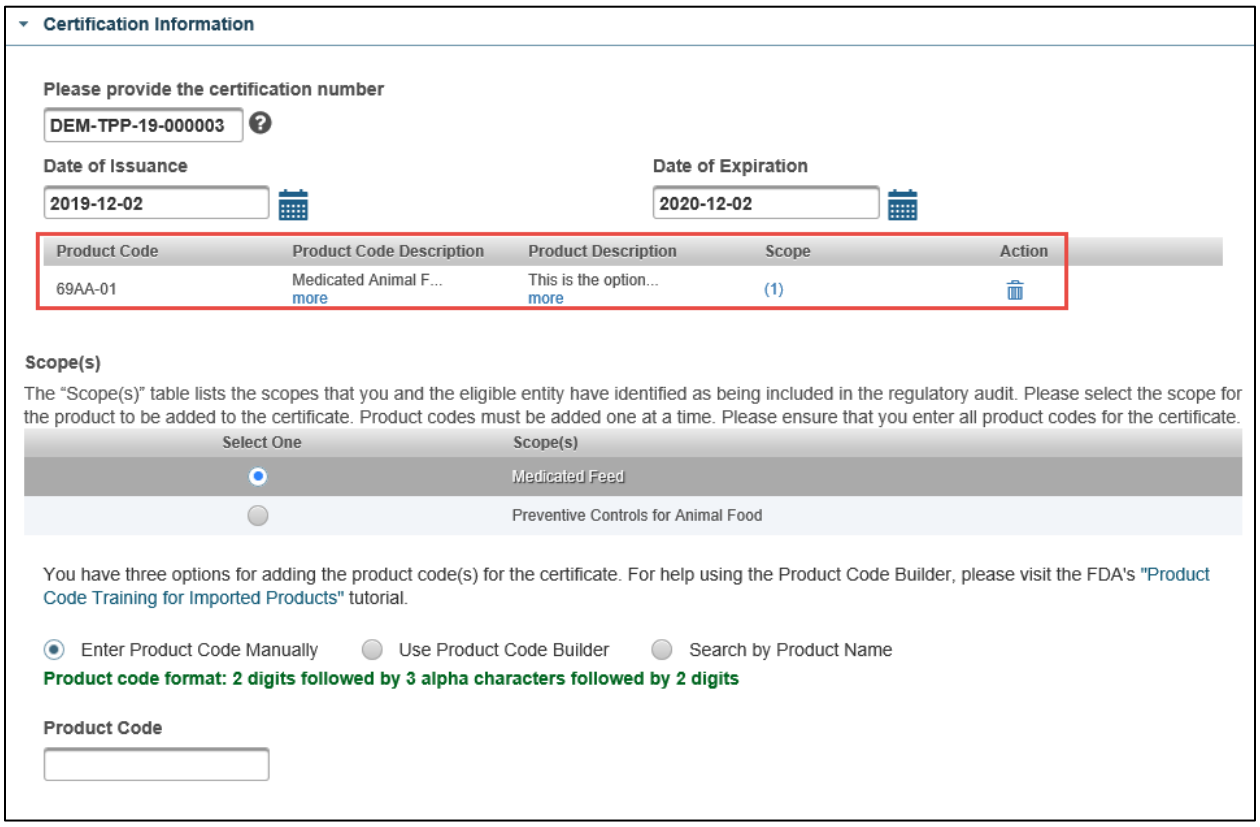
Repeat the previous steps to add more products.

If you have completed adding products to the certificate or would like instruction for adding products under a different scope, proceed to Section 7.1.3.4 of this chapter.

Click the trash/delete icon in the “Action” column of the table if you wish to remove a product.

Note: Once you submit the certification to FDA, you cannot add or delete product code(s). If any products intended to be certified are not listed, they will not be considered by FDA as covered under the certification. Contact FDA if you submit a certification and inadvertently leave out product codes that were certified.

Figure 7.31 – Enter Product Code Manually – Product Added



7.1.3.2 Product Code Selection – Use Product Code Builder

You may use the “Use Product Code Builder” option if you do not know the product code. The “Use Product Code Builder” will create the seven character product code based upon selections from five dropdown menus. Select the radio button to the left of “Use Product Code Builder” to build the product code (Figure 7.32).

Five dropdown menus will display after selecting the radio button. Click the applicable menu to view and select the choice from each menu:

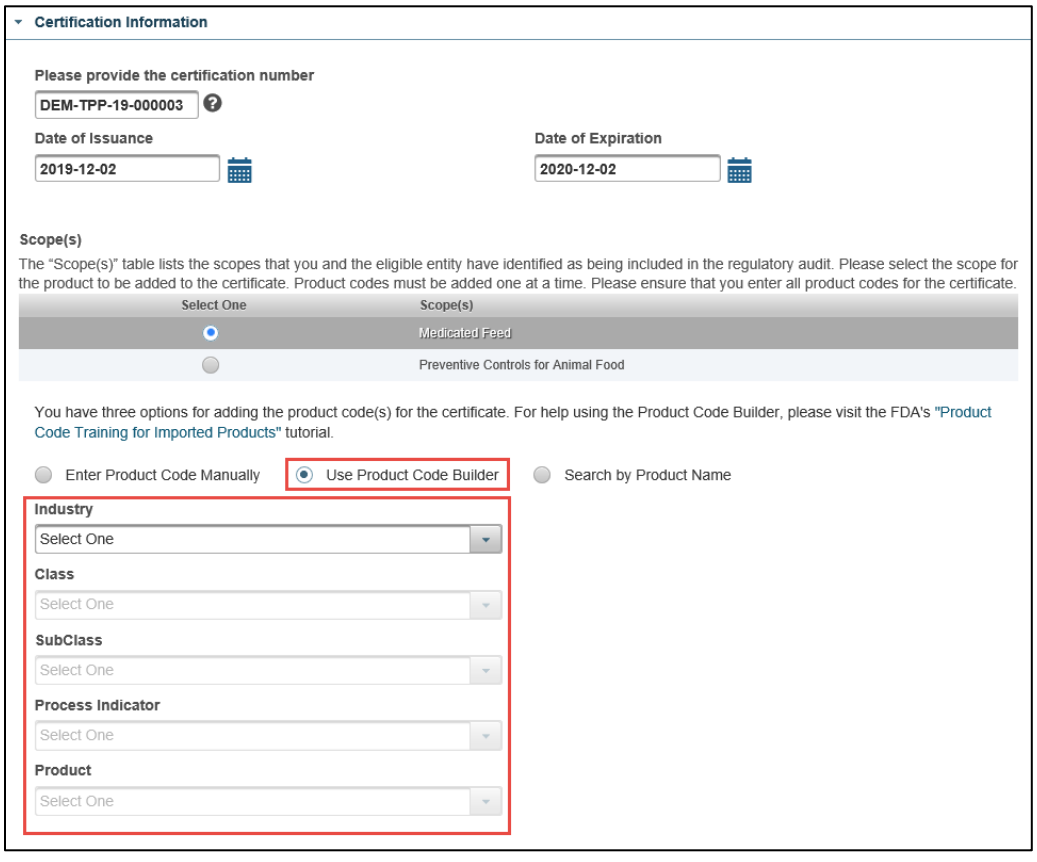
- **Industry –** The industry applicable to the product
  You must make a selection from the “Industry” menu before the system will allow you to select from the other menus.
- **Class –** The class applicable to the product
- **SubClass –** The subclass applicable to the product
- **Process Indicator –** The process indicator applicable to the product
- **Product –** The products available based on the selections from the previous four menus

Select the relevant value from each dropdown list by clicking directly on the menu, as applicable. Selections in the dropdown menus will enable the applicable subsequent menus.

Note: “SubClass” or “Process Indicator” menus may become disabled or read-only, depending on whether they apply to the selected industry.

For help using the Product Code Builder, visit FDA's website on Product Codes and the Product Code Builder.

Figure 7.32 – Product Code Selection – Use Product Code Builder



After you select the values for all applicable dropdown menus, the following fields will display (Figure 7.33):

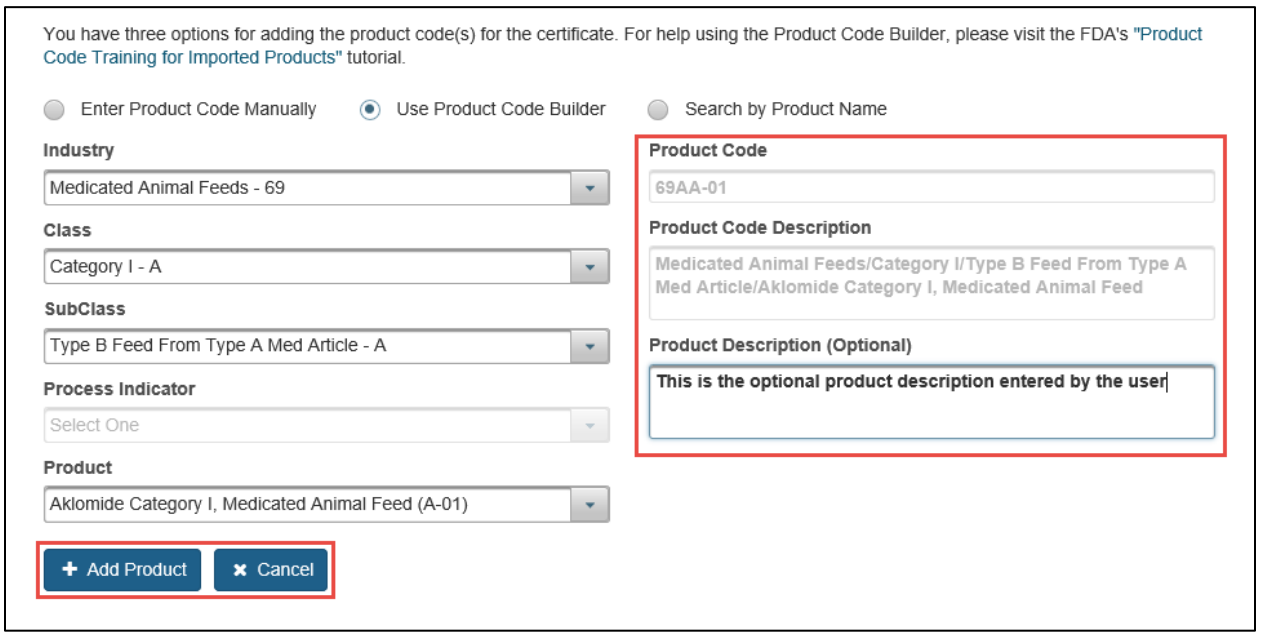
- **Product Code –** This is a read-only field that displays the seven character Product Code created from the dropdown menu selections.
- **Product Code Description –** This is a read-only field that displays the FDA Product Code Description that corresponds to the product code created from the dropdown menu selections.
- **Product Description (Optional) –** This is an optional field to enter your own product description.

Note: There are some instances in which “SubClass” and/or “Process Indicator” for a selected code combination are not required. Therefore, the system may automatically display a dash (“-”) in place of one or both fields of the Product Code in those instances.

Click the “Cancel” button to clear your selections made from the dropdown menus and choose the desired values.

Click the “Add Product” button to add the product to the certificate.

Figure 7.33 – Use Product Code Builder – Additional Fields



Once you click “Add Product,” the product will display in a table in the “Certification Information” section (Figure 7.34).

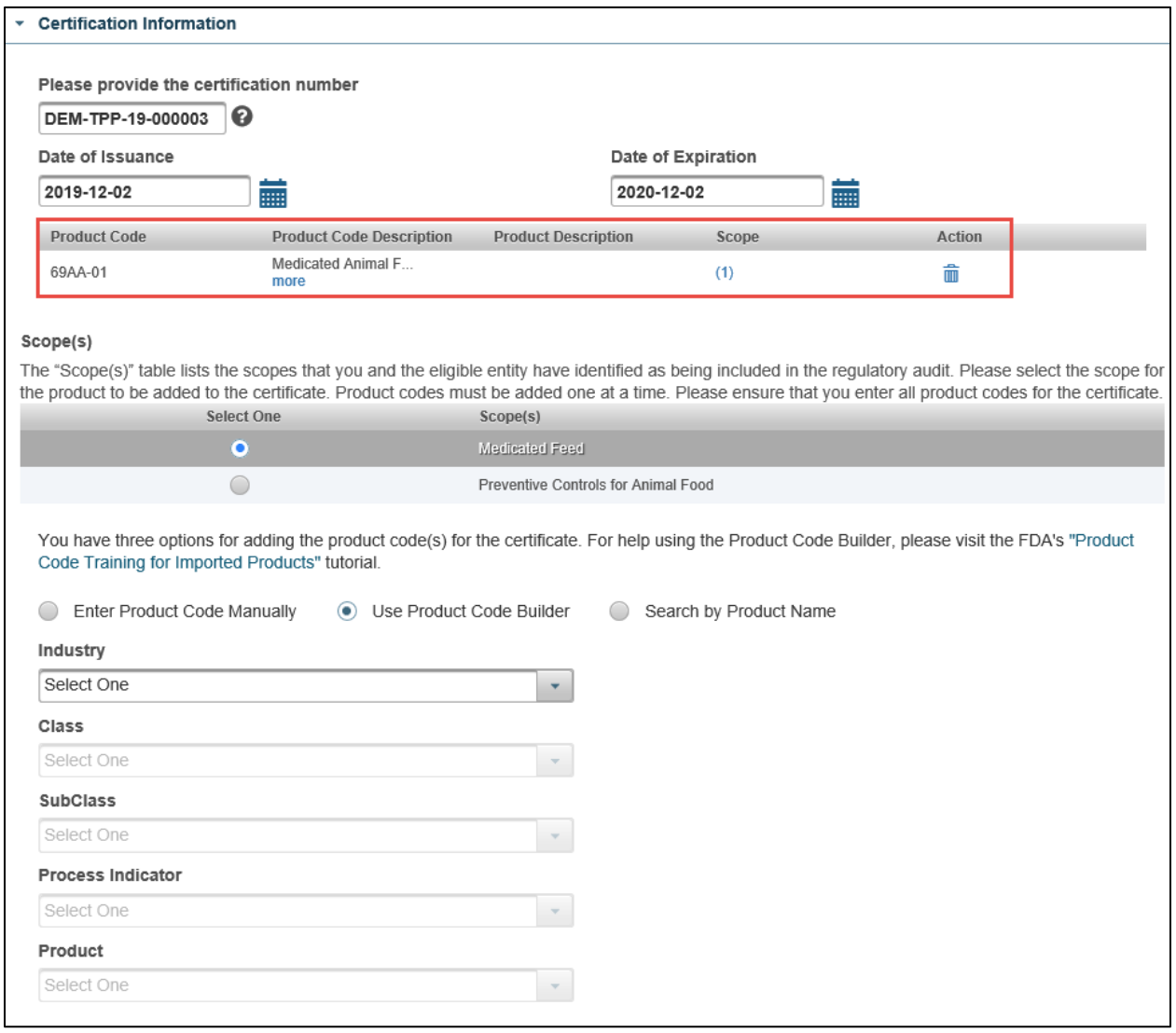
Repeat the previous steps to add more products.

If you have completed adding products to the certificate or would like instruction for adding products under a different scope, proceed to Section 7.1.3.4 of this chapter.

Click the trash/delete icon in the “Action” column of the table if you wish to remove the product.

Note: Once you submit the certification to FDA, you cannot add or delete product code(s). If any products intended to be certified are not listed, they will not be considered by FDA as covered under the certification. Contact FDA if you submit a certification and inadvertently leave out product codes that were certified.

Figure 7.34 – Use Product Code Builder – Product Added



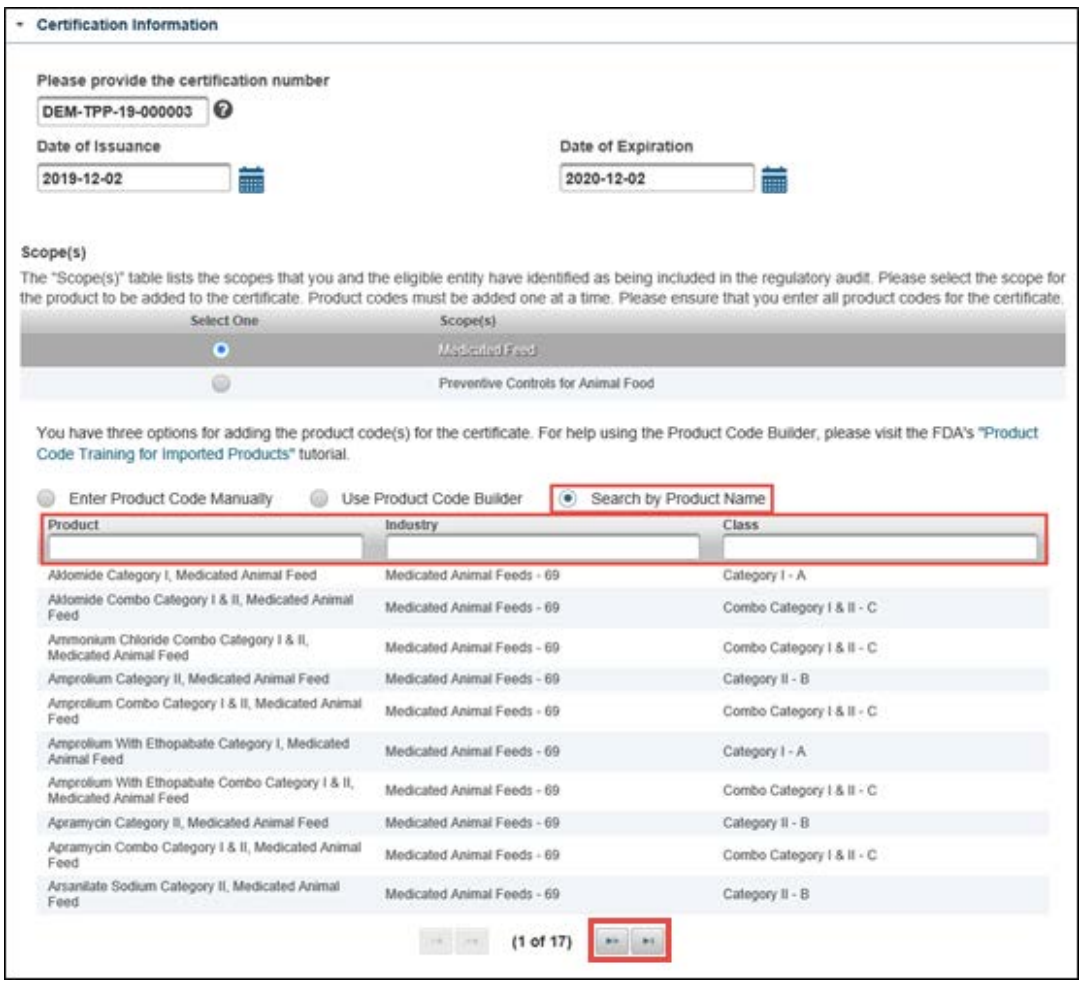
7.1.3.3 Product Code Selection – Search by Product Name

You may use the “Search by Product Name” option if you do not know the Product Code or do not want to use the Product Code Builder. Select the radio button to the left of “Search by Product Name.” A table will display the following columns, with keyword search fields at the top of each (Figure 7.35):

- **Product –** The available FDA regulated products associated to the scope selected from the “Scope(s)” section of the “Certification Information” section
- **Industry –** The FDA product industry code applicable to the product
- **Class –** The class applicable to the product

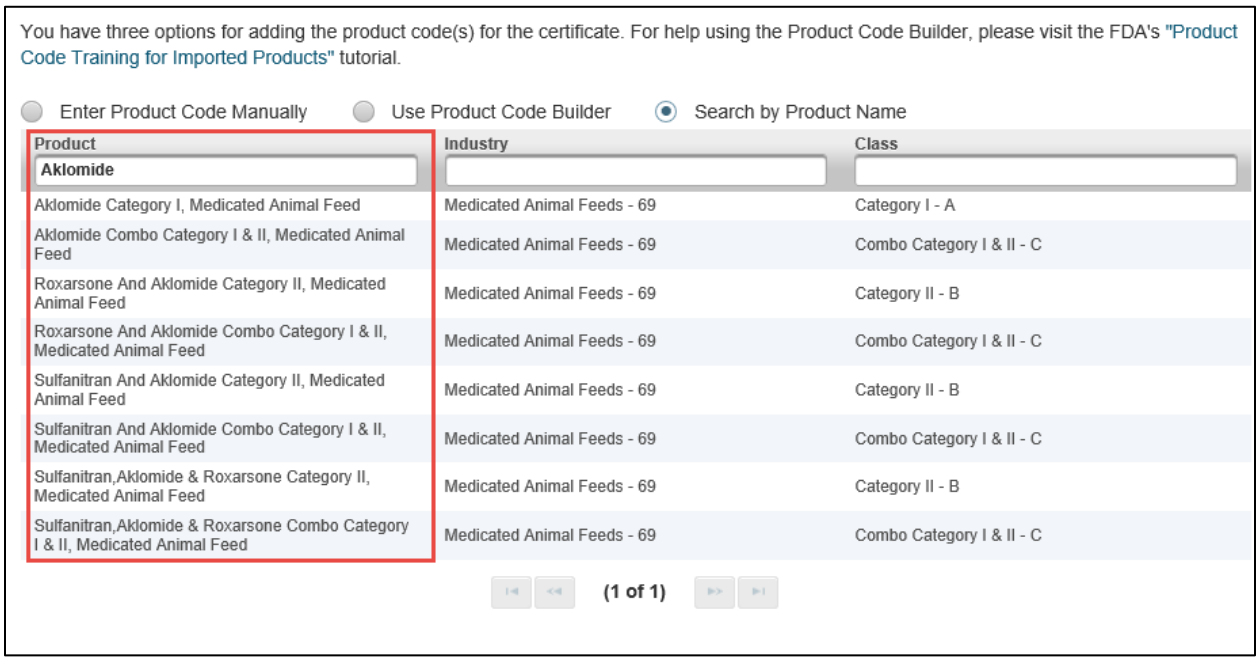
To filter the list, enter a keyword in any of the text fields at the top of the “Product,” “Industry,” or “Class” columns. Alternatively, you may use the arrows at the bottom of the list to navigate through the pages [of the list] to identify the desired product.

Figure 7.35 – Product Code Selection – Search by Product Name



Type the keyword into the applicable search field(s) and the system will refine the list based on your entry (Figure 7.36).

Figure 7.36 – Search by Product Name – List Filtered by Keyword



Select the desired value from the table by clicking on the applicable row. Once selected, additional fields will display (Figure 7.37).

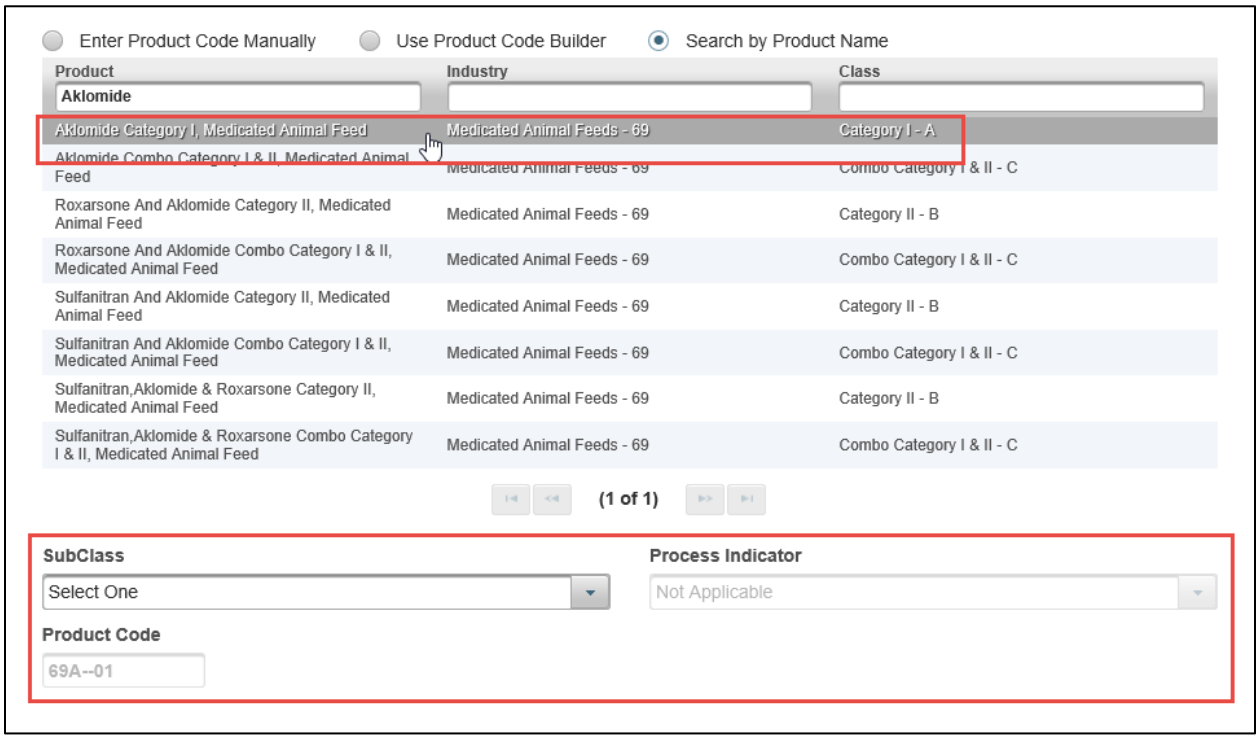
- **SubClass –** The subclass applicable to the product
- **Process Indicator –** The process indicator applicable to the product
- **Product Code –** The applicable product code

Select the relevant value from each dropdown list by clicking directly on the menu, as applicable. “SubClass” or “Process Indicator” menus may be disabled or read-only, depending on whether they apply to the selected industry.

Note: There are some instances in which “SubClass” and/or “Process Indicator” for a selected industry/scope combination is not required. Therefore, the system may automatically display a dash (“-”) in place of one or both fields of the Product Code in those instances.

For information on Product Codes and the Product Code Builder, visit the FDA's website on Product Codes and the Product Codes Builder.

Figure 7.37 – Search by Product Name – Select Result and Additional Fields



The following fields will display after you select the desired value from the “SubClass” and “Process Indicator” menus (Figure 7.38).

- **Product Code Description –** The read-only FDA product code description
  This field is displayed when the values for “SubClass” and “Process Indicator” are selected.
- **Product Description (Optional) –** An optional field to provide your own product code description
  This field is displayed when value for “Process Indicator” is selected.

Click the “Cancel” button to clear your selections from the dropdown menus and choose the desired values.

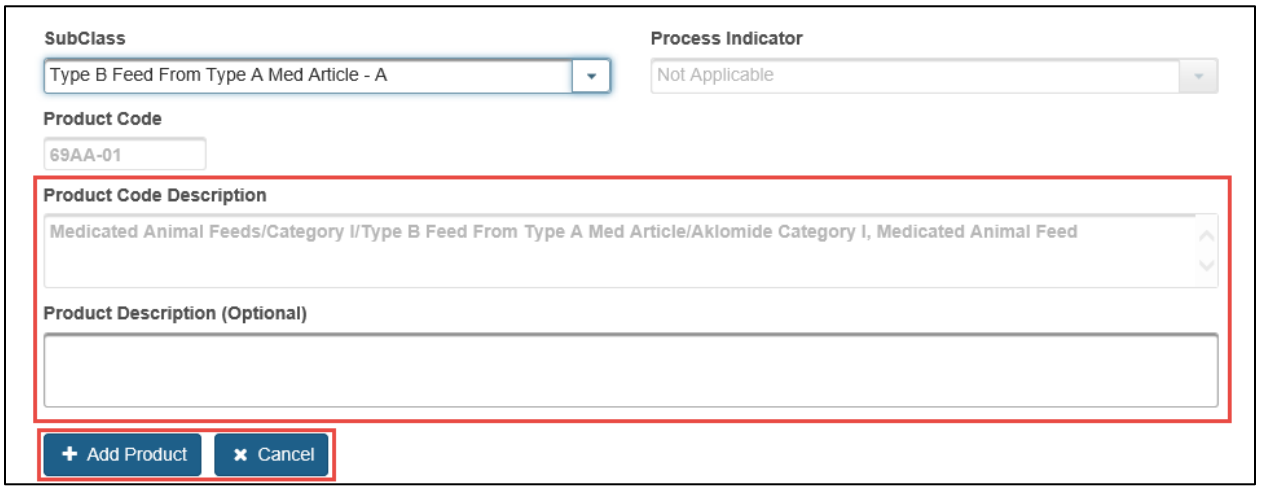
Click the “Add Product” button to add the product to the certificate.

Repeat the previous steps to add more products.

If you have completed adding products to the certification or would like instruction for adding products under a different scope, proceed to Section 7.1.3.4 of this chapter.

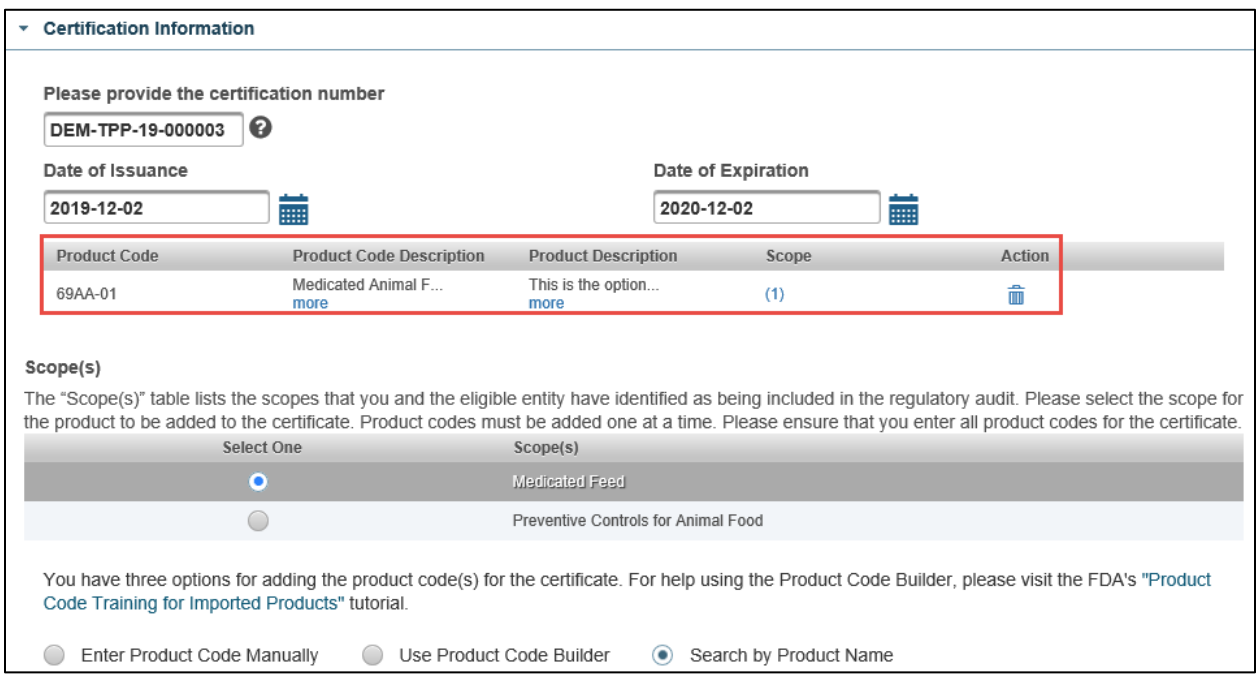
Note: Once you submit the certification to FDA, you cannot add or delete product code(s). If any products intended to be certified are not listed, they will not be considered by FDA as covered under the certification. Contact FDA if you submit a certification to FDA and inadvertently leave out product codes that were certified.

Figure 7.38 –Search by Product Name – Additional Fields, Add Product, and Cancel Buttons



Once you click “Add Product,” the product will display in a table in the “Certification Information” section (Figure 7.39).

Figure 7.39 – Search by Product Name – Product Added



7.1.3.4 Additional Product Code Selection Information

If you need to add a product code under a different scope, go back to the “Scope(s)” table of the “Certification Information” section. Click on the radio button of the scope that corresponds to the product code(s) you wish to enter. Add the product code(s) using one of the three options described above.

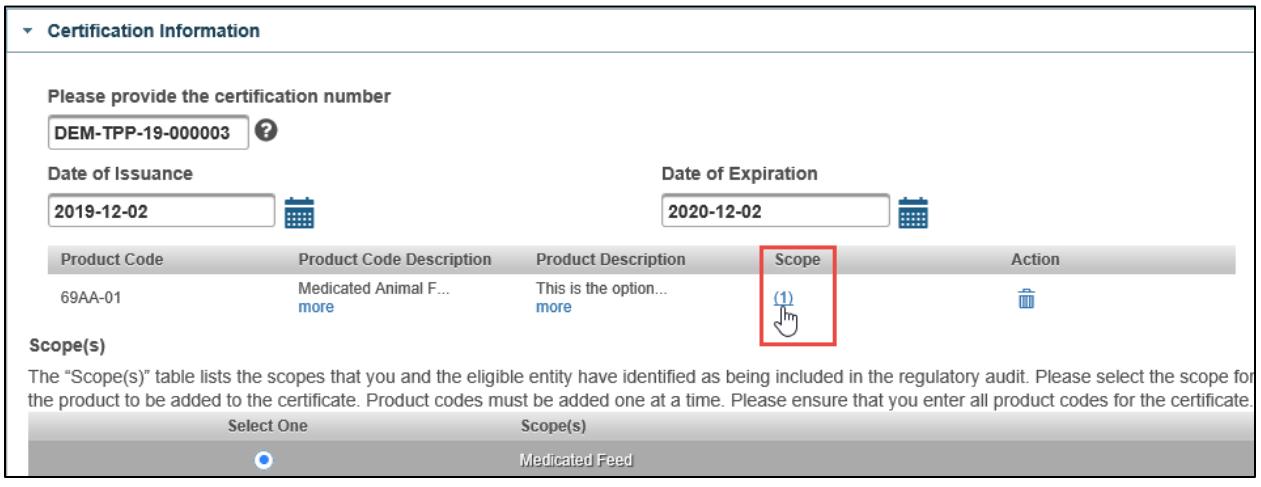
After you have entered the product code(s) for the certificate (using one of the three available options,) review the list of products added to the “Certification Information” section for accuracy. You may delete any product code by selecting the associated trash/delete icon (Figure 7.40).

****Important:** Once you submit the certification to FDA, you cannot add or delete product code(s). If any products intended to be certified are not listed, they will not be considered by FDA as covered under the certification. Contact FDA if you submit a certification and inadvertently leave out product codes that were certified.

Figure 7.40 – Product Added – Trash/Delete Icon

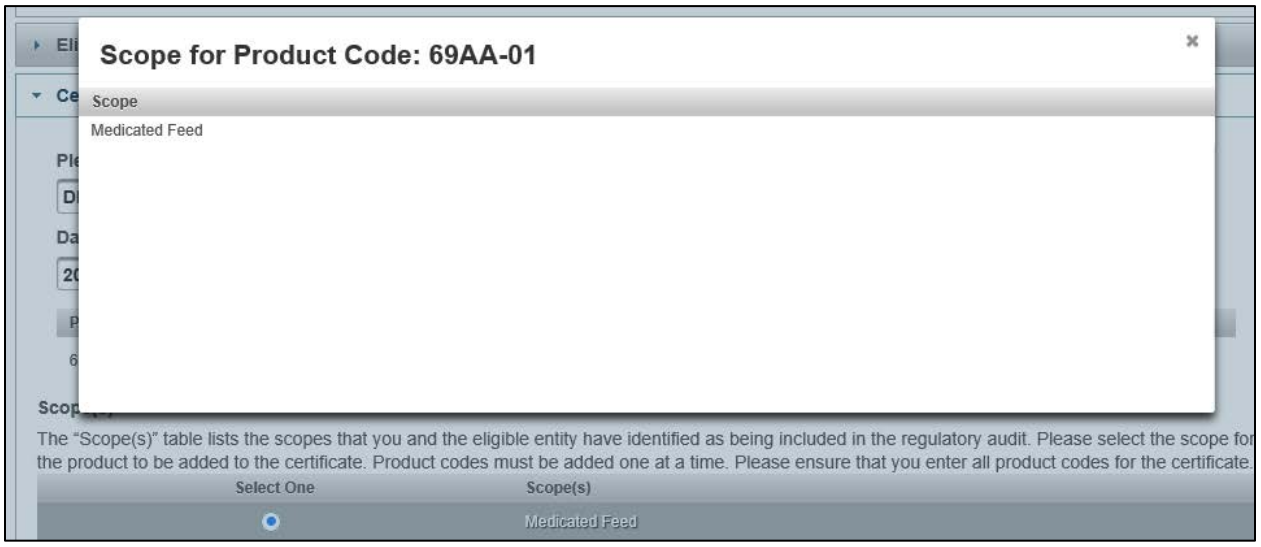
Once you have added a product to the certificate, the “Scope” column of the table of product(s) will display the number of scopes to which the product is associated (Figure 7.41).

Figure 7.41 – Scope Hyperlink



Select the hyperlinked number from the “Scope” column of the table to display a pop-up window. The pop-up window displays the name of the scope that was selected for the product added to the table of products (Figure 7.42).

Figure 7.42 – Scope for Product Code Pop-up Window



Proceed to Section 7.1.4 of this chapter.

7.1.4 Certification Attachments (Optional) Section

Click the “Certification Attachments (Optional)” accordion section’s title bar to display the section contents (Figure 7.43). You may upload any attachments associated with the certification in this section; this is optional.

Figure 7.43 – Certification Attachments (Optional) Section

Click the “Browse” button (Figure 7.44). A pop-up window will appear, prompting you to access your file system. Select the desired file to include with the certification.

The “Upload” and “Cancel” buttons will be enabled after you choose a file.

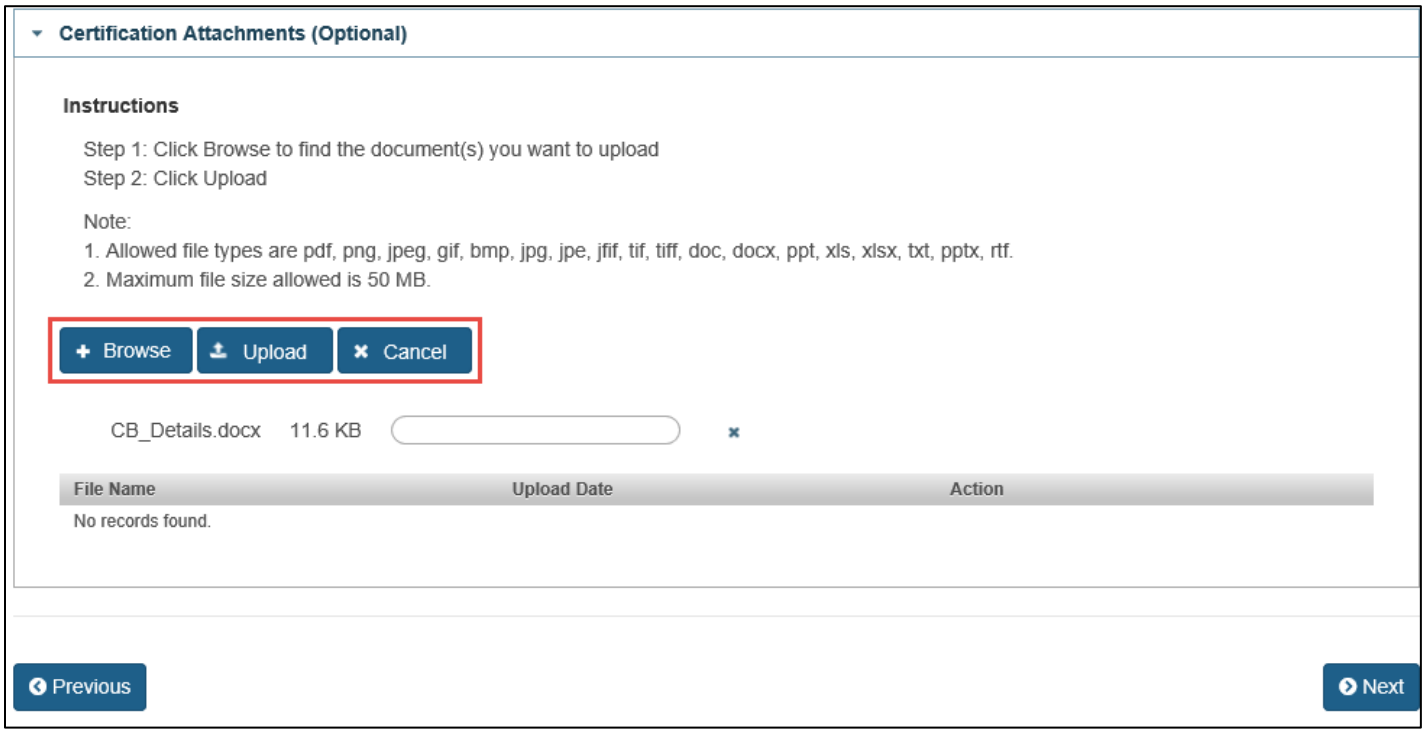
Click the “Cancel” button to discard the upload of the attachment.

Click “Upload” to complete the upload of the attachment.

Note: The system supports the following document types: .pdf; .png; .jpeg; .gif; .bmp; .jpg; .jpe; jfif; .tif; .tiff; .doc; .docx; .ppt; .xls; .xlsx; .txt; .pptx; or .rtf.

The maximum file size allowed is 50 MB.

Figure 7.44 – Certification Attachments (Optional) Buttons



Once the upload is complete, a confirmation message “<filename.filetype> uploaded successfully” will display within the “Certification Attachments (Optional)” section. The file name will be listed in the table of attachments (Figure 7.45).

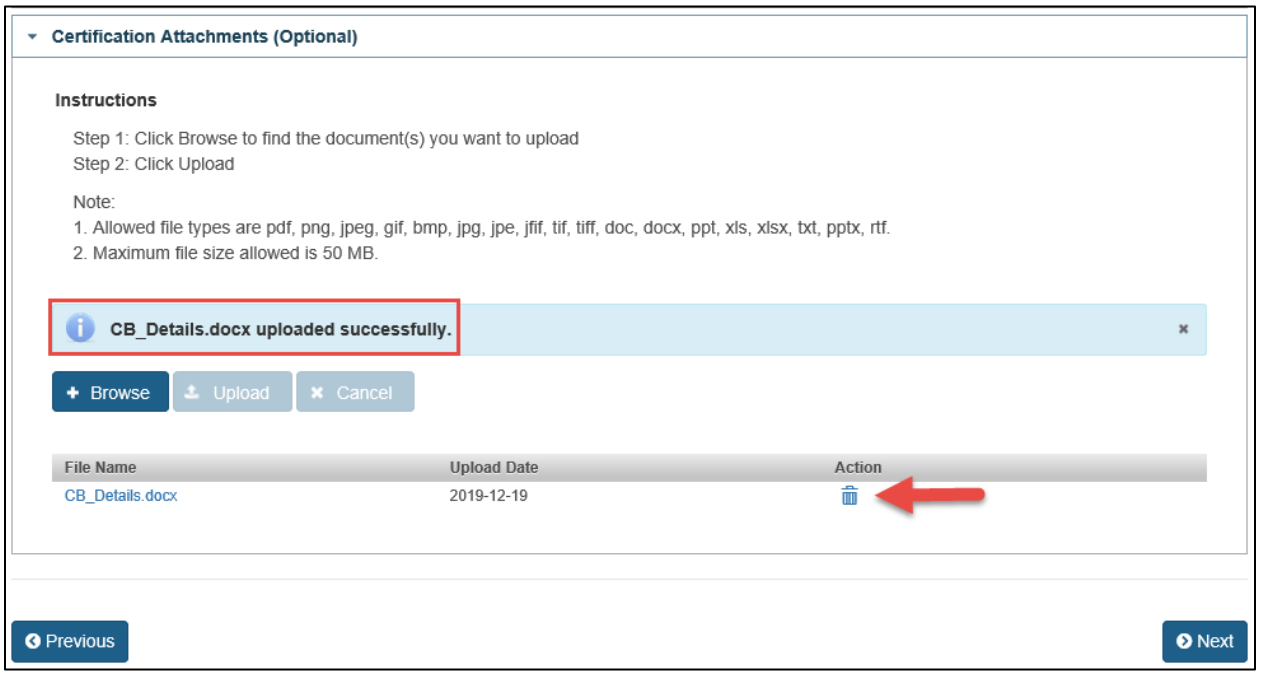
Repeat the previous steps to upload additional files.

To remove an attachment, click the trash/delete icon in the “Action” column of the attachments table.

Click the “Next” button to proceed to the “e-Signature” page.

Proceed to Section 7.1.5 of this chapter.

Figure 7.45 – Attachments – Upload Confirmation and Trash Icon



7.1.5 e-Signature Page

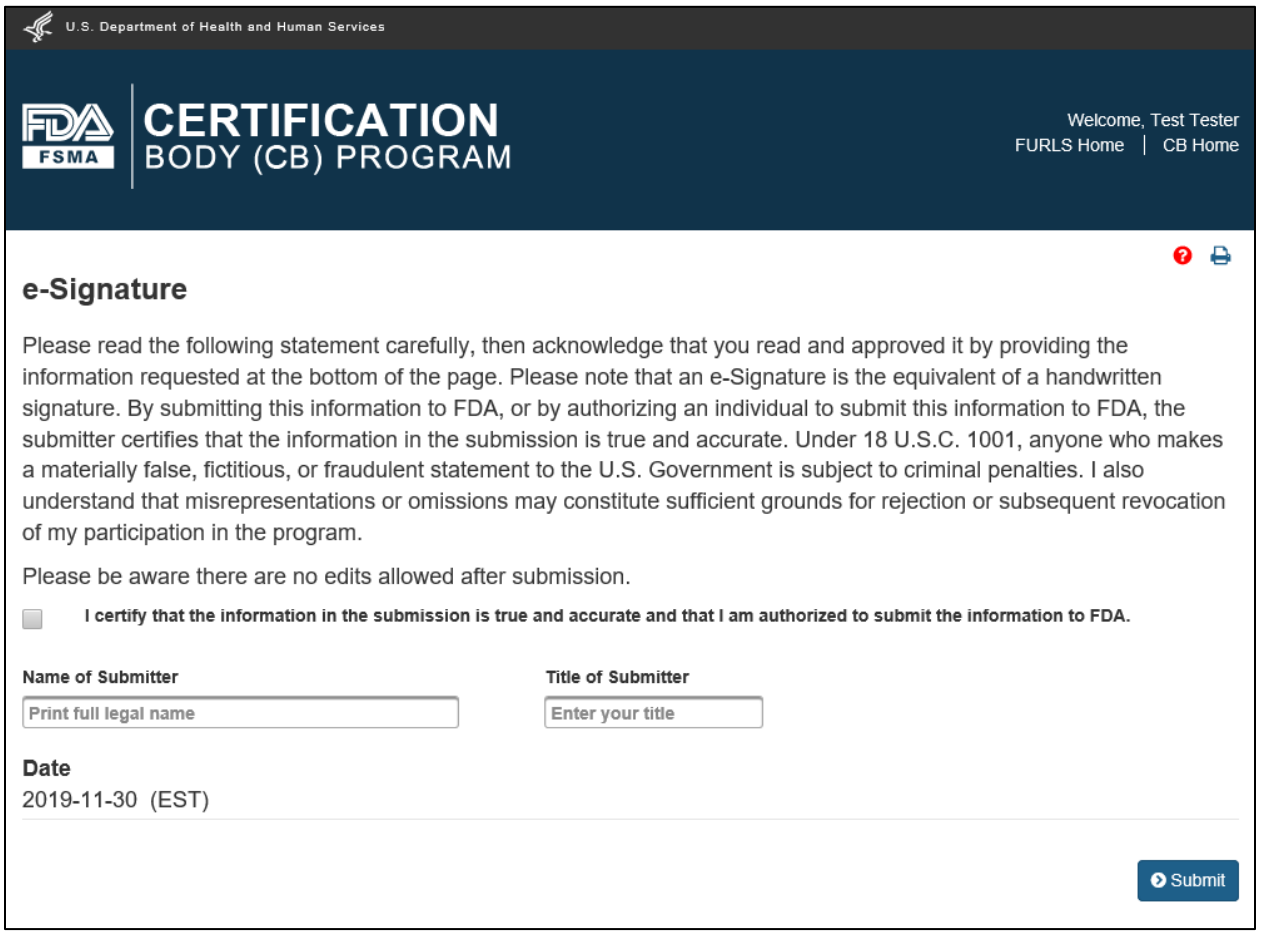
Follow the directions provided on the “e-Signature” page (Figure 7.46).

Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

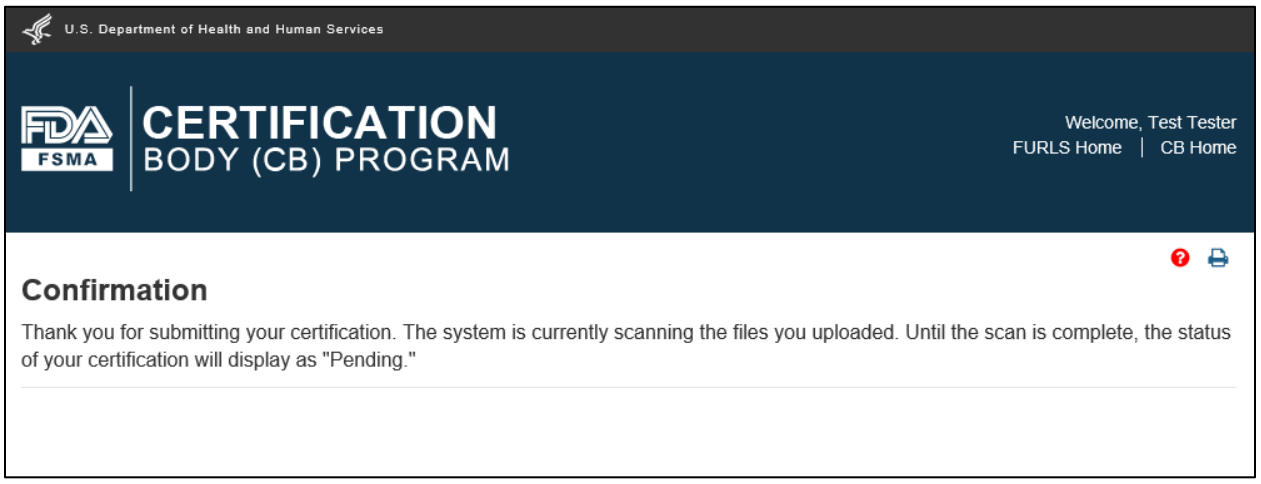
Click the “Submit” button to submit the certification.

Figure 7.46 – e-Signature Page



After you click the “Submit” button a “Confirmation” page will display for your review (Figure 7.47).

Figure 7.47 – Confirmation Page



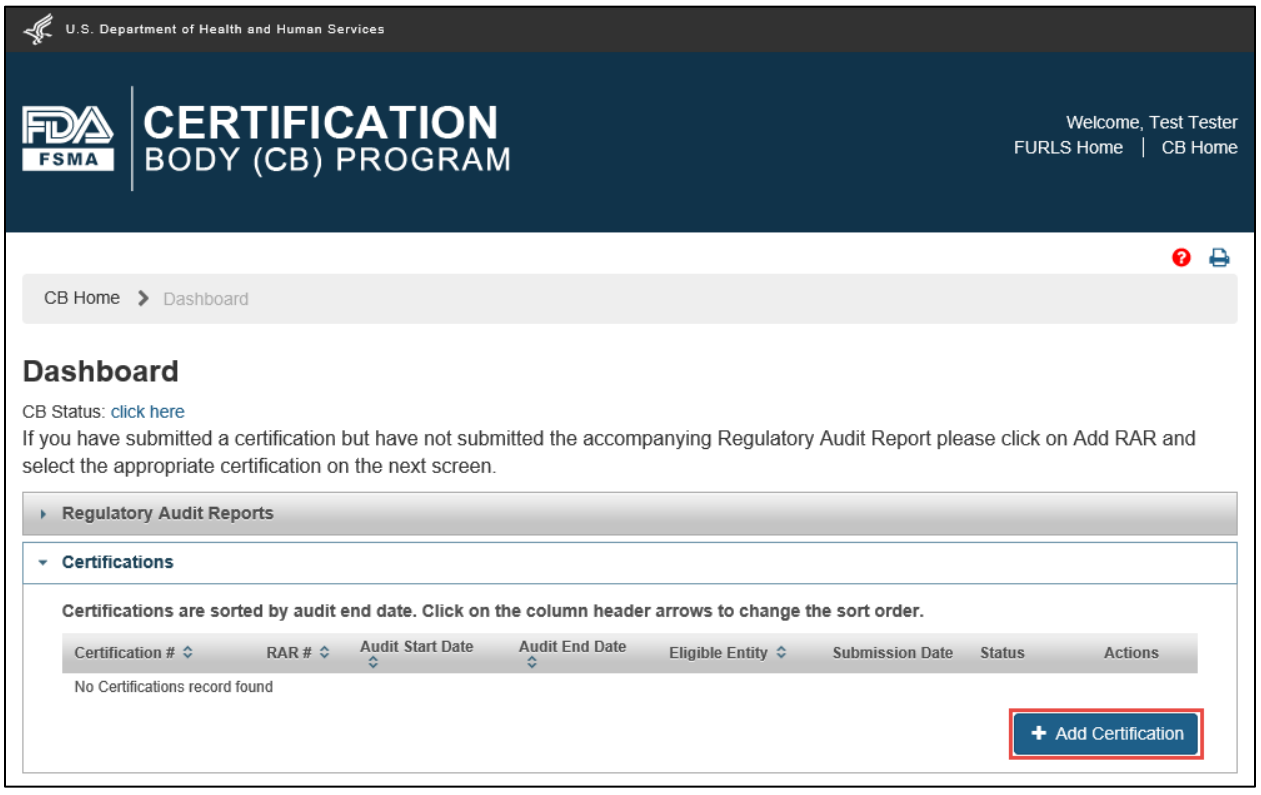
To view the status of your certification, or to view and print the certification details, proceed to Section 7.3 of this chapter.

7.2 Create and Submit a Certification to Add to an Existing Regulatory Audit Report

You may create a certification to add to an existing regulatory audit report. You may use this option only if the regulatory audit report does not have an associated certification.

To begin, click the “Add Certification” button from the Dashboard (Figure 7.48).

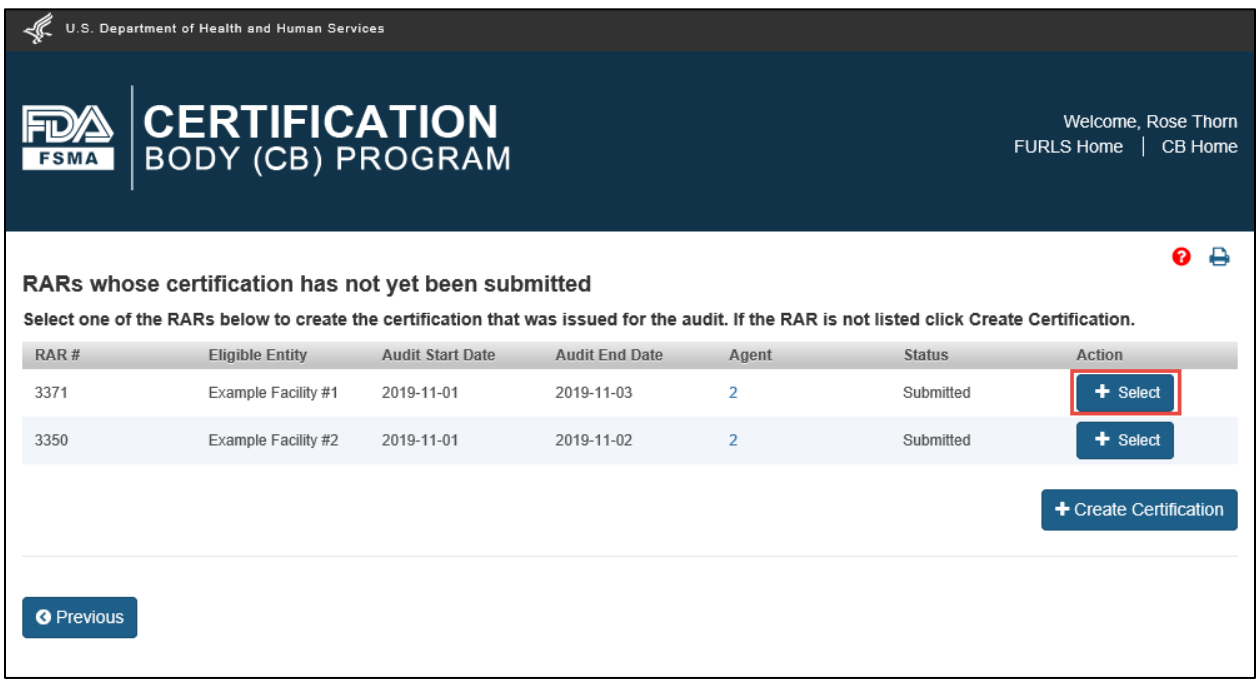
Figure 7.48 – Add Certification Button



If you submitted at least one regulatory audit report to FDA but not its corresponding certification, the system will display the page, “RARs whose certification has not yet been submitted,” with a list of the applicable regulatory audit report(s) (Figure 7.49).

Choose the desired regulatory audit report from the list to add a certificate. Click the “Select” button (in the “Action” column) on the right side of the row.

Figure 7.49 – Regulatory Audit Reports Whose Certification Has Not Yet Been Submitted



The system will display the “Certification Issued by Accredited Third-Party CB” page, with “Accredited Third-Party Information” section displayed (Figure 7.50).

The sub-section fields will be pre-filled and read-only with information submitted in the selected regulatory audit report, wherever applicable. Pre-filled fields are read-only.

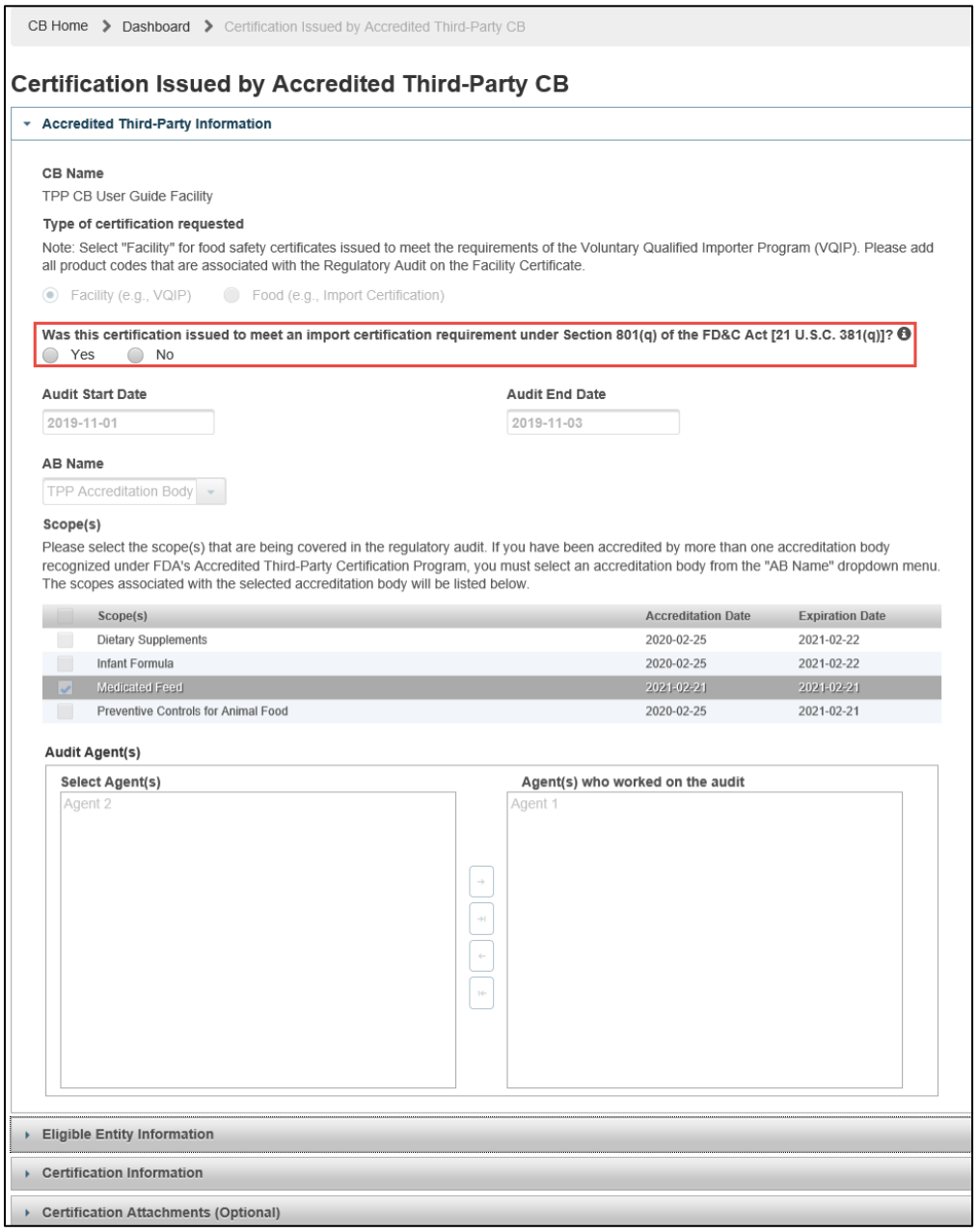
Proceed to Section 7.2.1 of this chapter.

7.2.1 Accredited Third-Party Information Section

The following field must be completed by the user to submit the certification:

- **Was this certification issued to meet an import certification requirement under Section 801(q) of the FD&C Act [21 U.S.C. 381(q)]? –** Select “Yes” or “No.” This is a required field.

Figure 7.50 – Accredited Third-Party Information Section – Pre-filled from Regulatory Audit Report



Note: Click the “Previous” button at the bottom of the “Certification Issued by Accredited Third-Party CB” page if you wish to return to the “Dashboard” page and start over.

Proceed to Section 7.2.2 of this chapter.

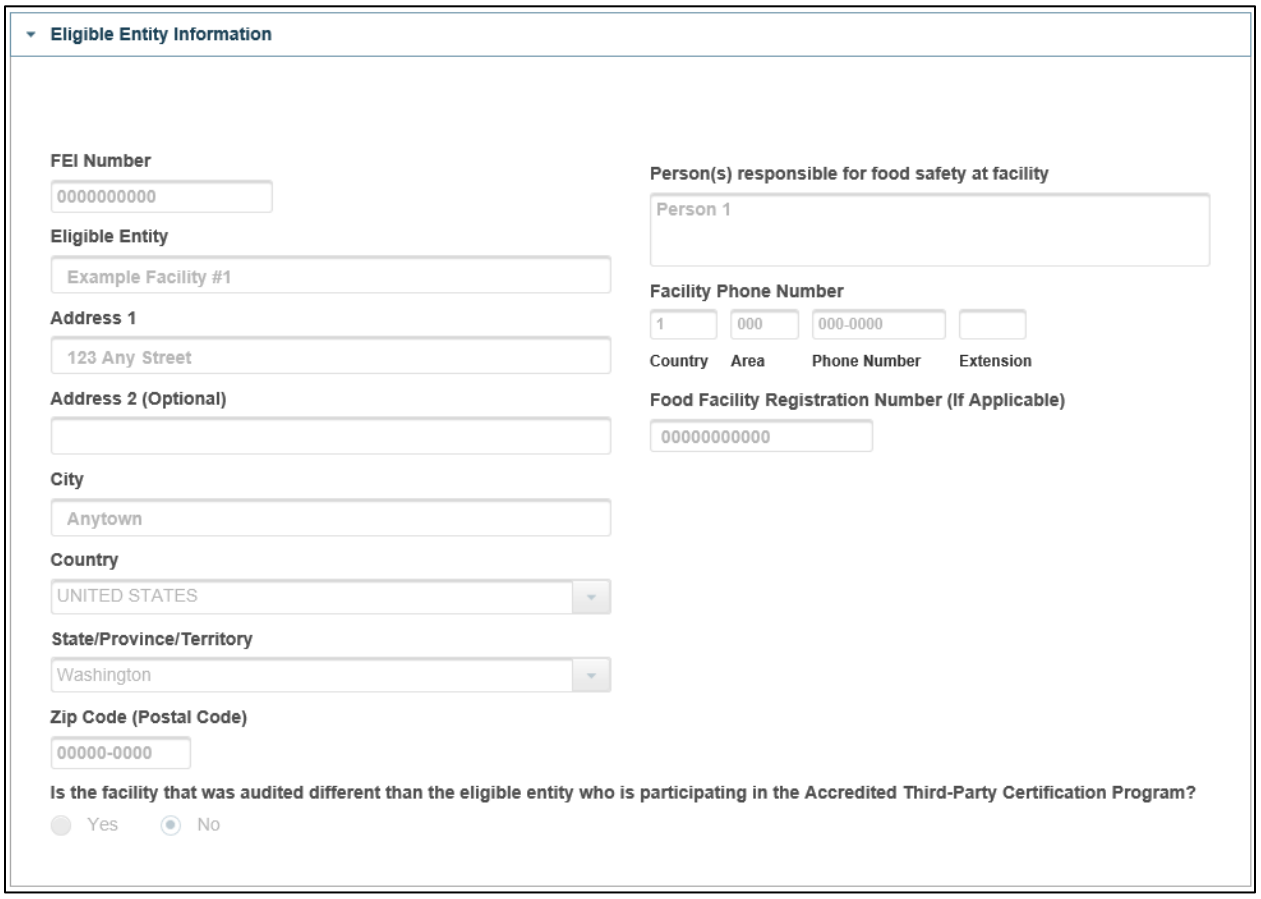
7.2.2 Eligible Entity Information Section

Click on the accordion section’s title bar to display its content (Figure 7.51).

Figure 7.51 – Eligible Entity Information Section

The “Eligible Entity Information” section of the certification will be pre-filled with the information submitted in the regulatory audit report (Figure 7.52).

Figure 7.52 – Eligible Entity Information Section – Pre-filled from Regulatory Audit Report



Proceed to Section 7.2.3 of this chapter.

7.2.3 Certification Information Section

Click the “Certification Information” accordion section’s title bar to display its content (Figure 7.53).

Figure 7.53 – Certification Information Section

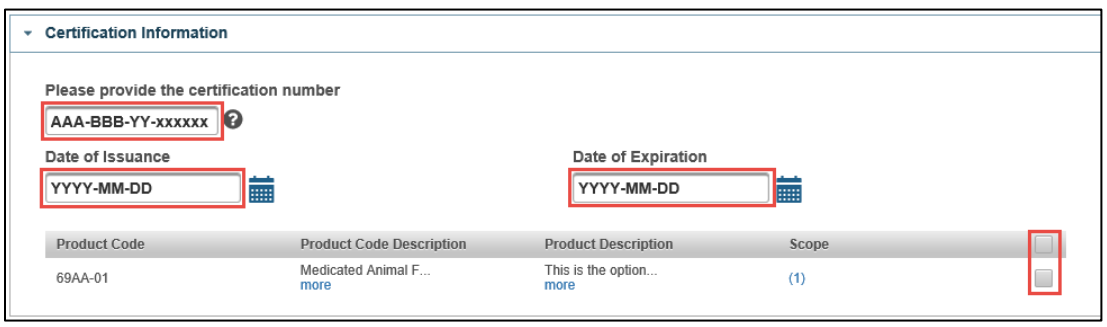
The fields in this section are pre-filled from the information submitted in the regulatory audit report, but they are editable (Figure 7.54):

- **Please provide the certification number –** Enter the certificate number using the required format. The format of the certification number must be “AAA-BBB-YY-xxxxxx.”
  - **AAA –** Enter the first three letters of the AB's name.
  - **BBB –** Enter the first three letters of the CB's name.
  - **YY –** Enter the year the certification was issued.
  - **xxxxxx –** Enter six digits. It is recommended that you maintain sequential numbering. For example, your first certification for the specific AB/CB combination for that certification year could end ‘-000001,’ followed by ‘000002,’ and so on.
- **Date of Issuance –** Select the date the certification was issued with the calendar icon or enter the date in “YYYY-MM-DD” format.
- **Date of Expiration –** Select the certification’s expiration date with the calendar icon or enter the date in “YYYY-MM-DD” format. The expiration date cannot be more than one year from the date of issuance.

The product(s) submitted under “Products Observed” tab in the regulatory audit report will be listed here. Any of the product(s) listed can be selected by clicking inside its checkbox. You can select the checkbox at the top of the checkbox column to select all the checkboxes.

Note: Once you submit the certification to FDA, you cannot add or delete product code(s). If any products intended to be certified are not listed, they will not be considered by FDA as covered under the certification. Contact FDA if you submit a certification and inadvertently leave out product codes that were certified.

Figure 7.54 – Certification Information Section



Proceed to Section 7.2.4 of this chapter.

7.2.4 Certification Attachments (Optional) Section

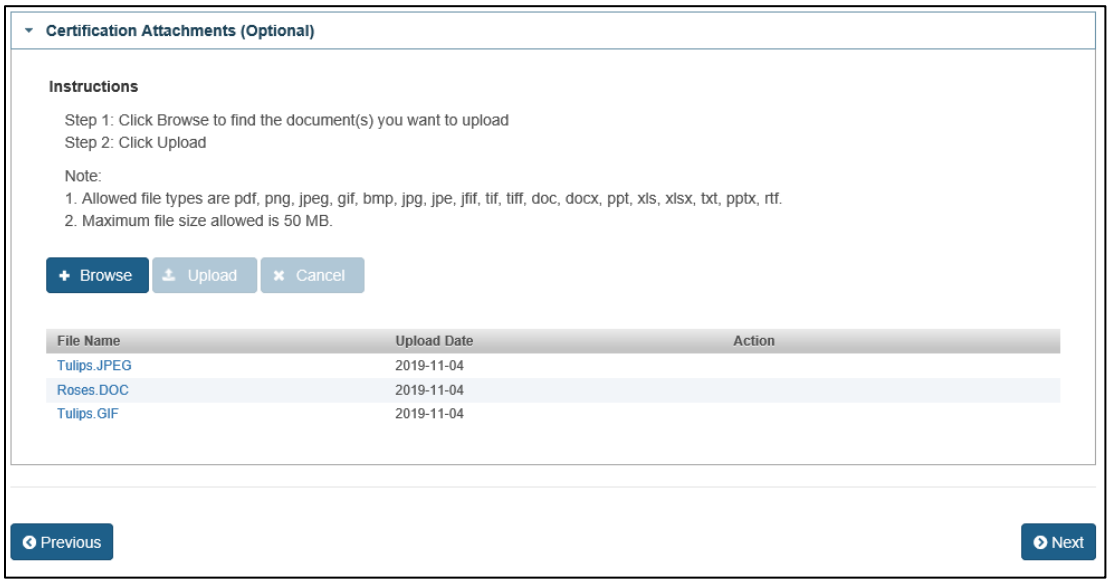
Click the “Certification Attachments (Optional)” accordion section’s title bar to display its contents (Figure 7.55).

Figure 7.55 – Certification Attachments (Optional) Section

This section will be pre-filled with the attachments submitted with the regulatory audit report and cannot be deleted. You can upload additional attachments for the certification, if desired.

Click the “Browse” button. A pop-up window will appear prompting you to access your file system (Figure 7.56).

Figure 7.56 – Attachments Submitted with the Regulatory Audit Report

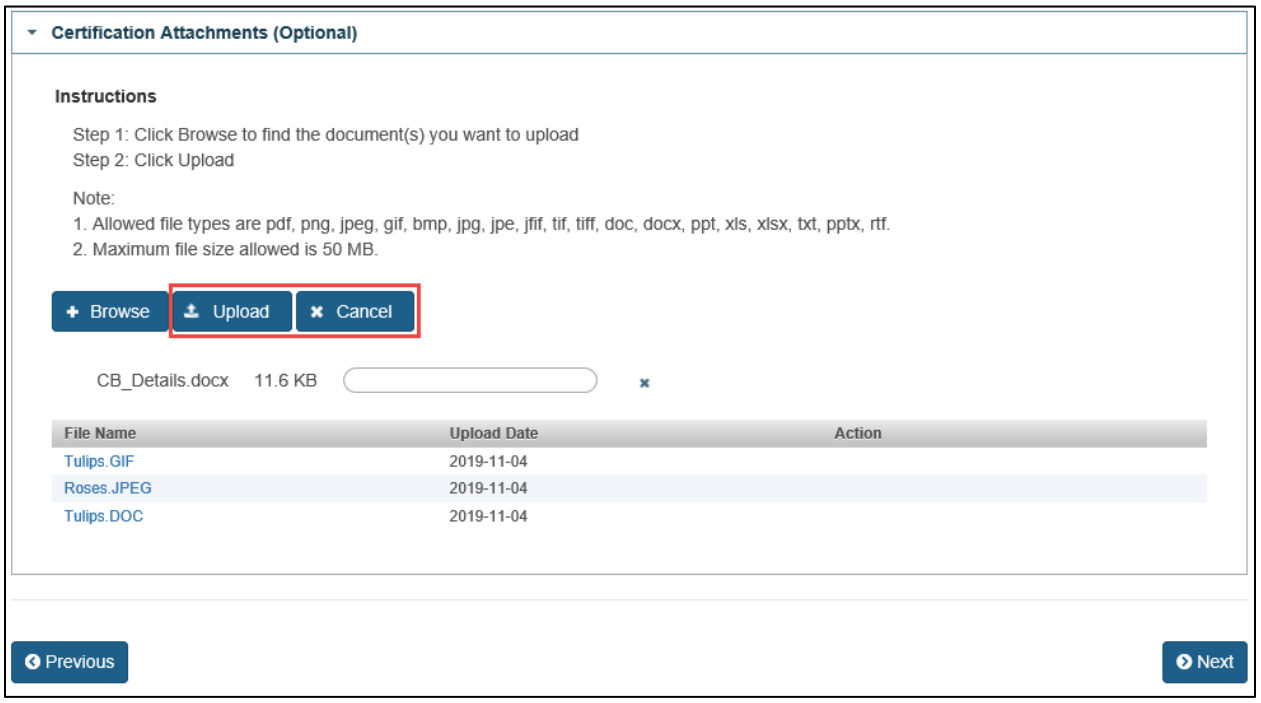


Select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after you select a file (Figure 7.57).

Click the “Upload” button to complete upload of the attachment.

Click “Cancel” to discard the upload of an attachment.

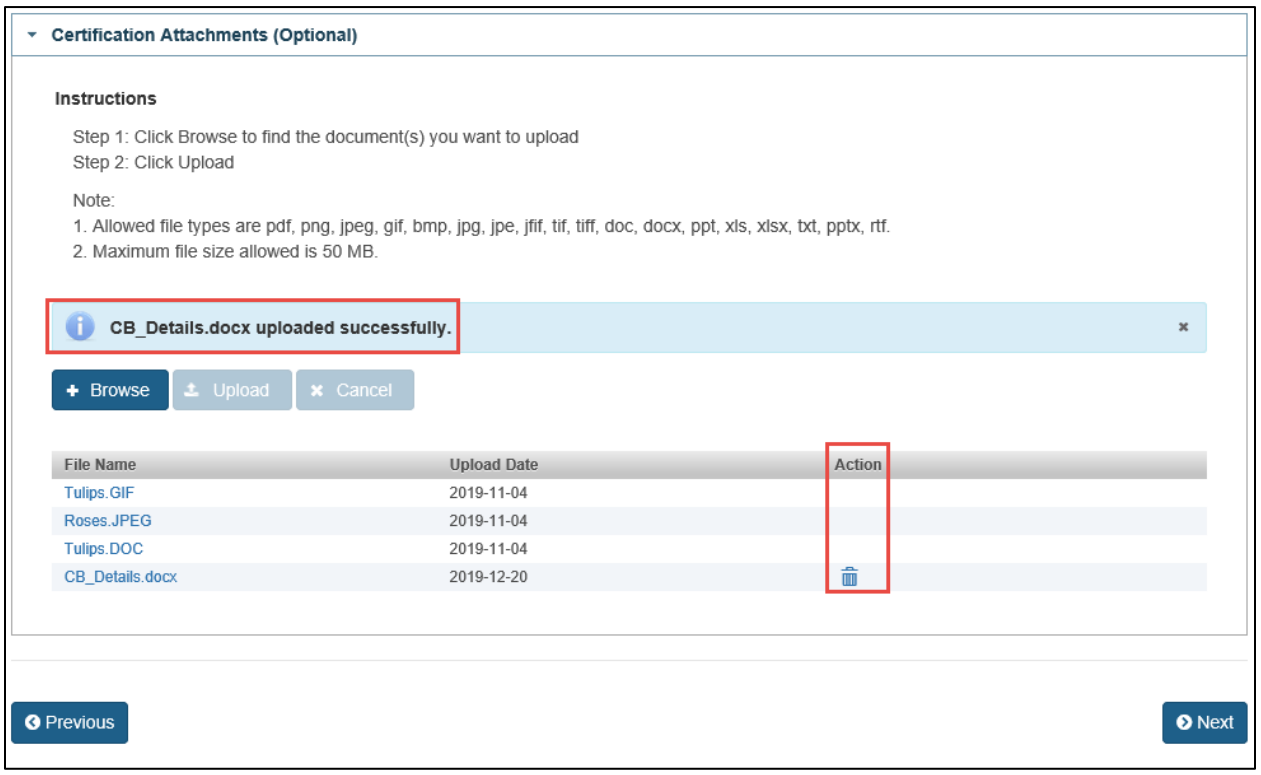
Figure 7.57 – Upload and Cancel Buttons



Once the upload is complete, a confirmation message “<filename.filetype> uploaded successfully” will display within the section. The file name will be listed in the attachments table (Figure 7.58).

To remove the attachment, click the trash/delete icon in the “Action” column of the attachments table.

Figure 7.58 – Successful Upload Confirmation and Trash Icon



Once you have completed all applicable changes, click the “Next” button to proceed to the “e-Signature” page.

Proceed to Section 7.2.5 of this chapter.

7.2.5 e-Signature Page

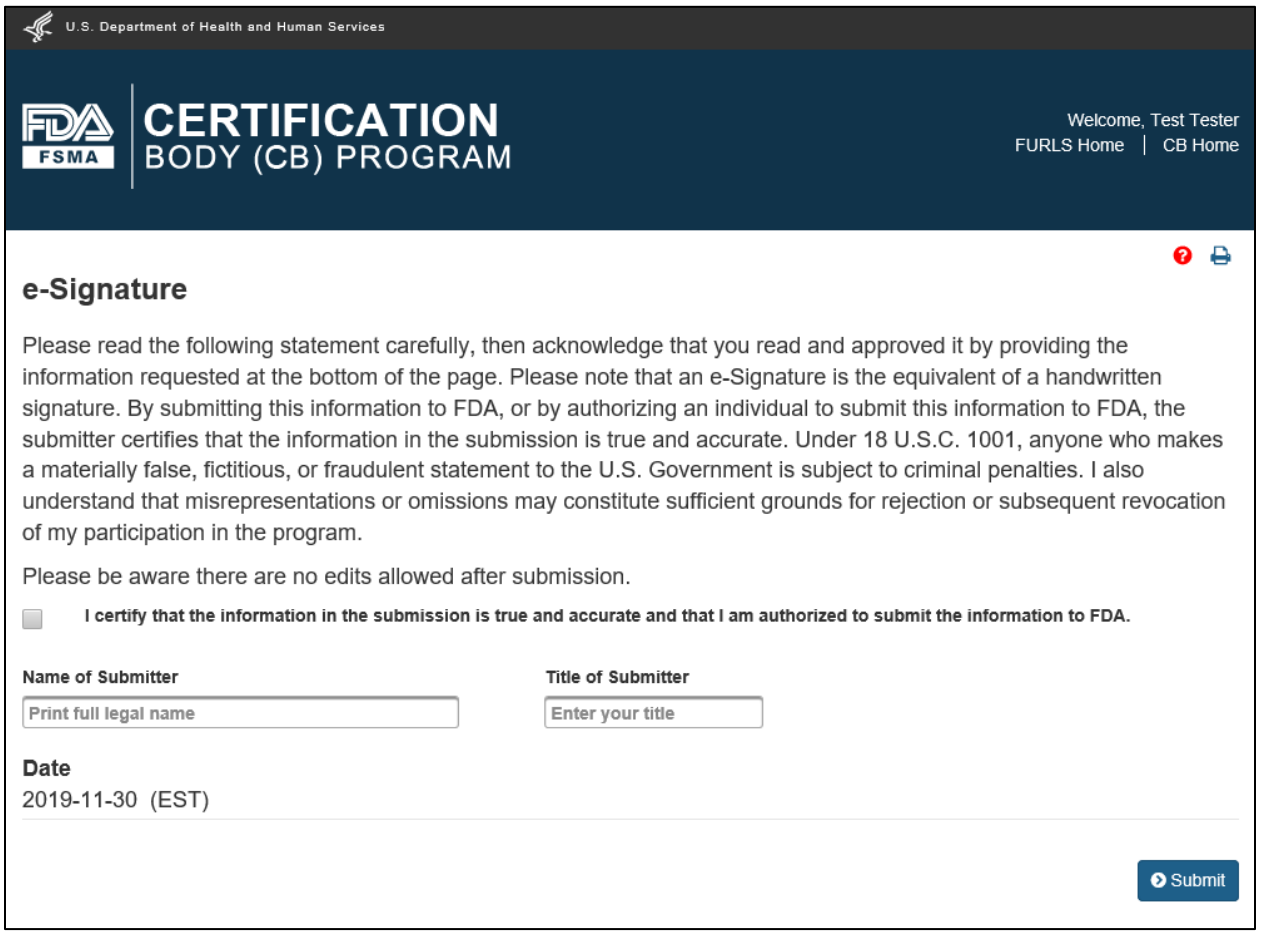
Follow the directions provided on the “e-Signature” page (Figure 7.59).

Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

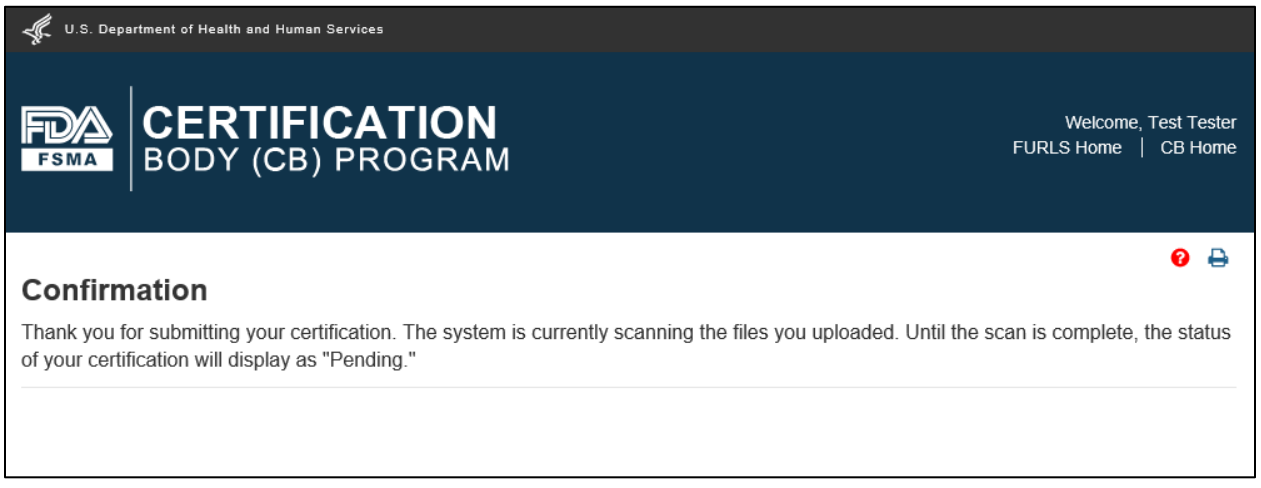
Click the “Submit” button to submit the certification.

Figure 7.59 – e-Signature Page



After clicking the “Submit” button, a “Confirmation” page will display for your review (Figure 7.60).

Figure 7.60 – Confirmation Page



To view the status of your certification, or to view and print the certification details, proceed to Section 7.3 of this chapter.

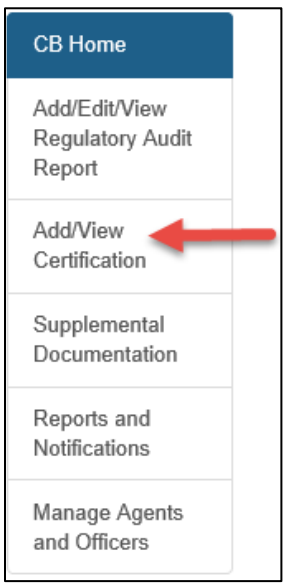
7.3 View or Print a Certification

In addition to creating a certification, the following actions can be performed from the Add/View Certification feature:

- Viewing or printing the details of a certification
- Viewing the status of a certification

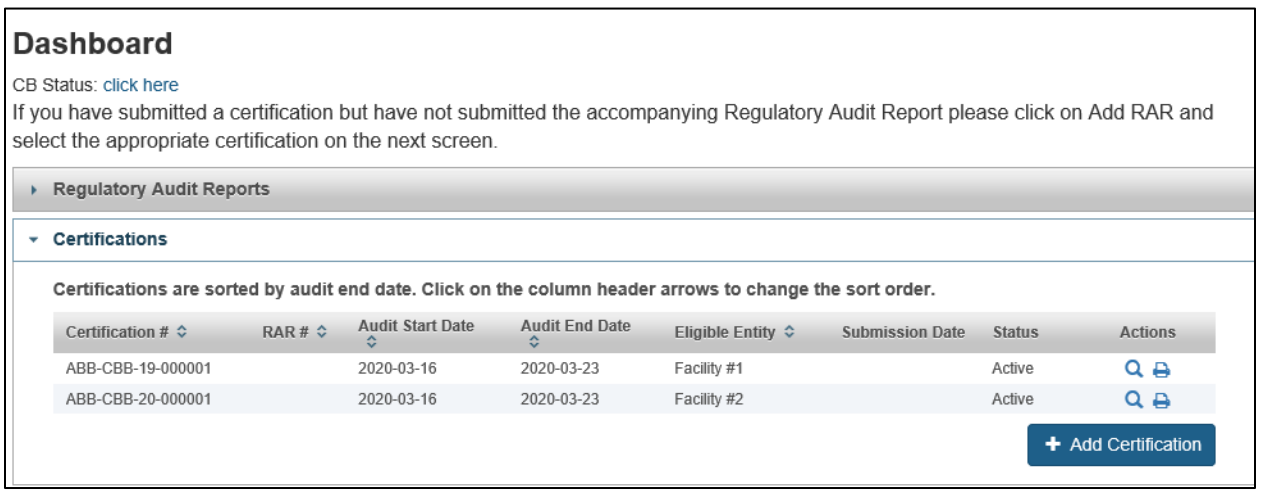
To access the certification functionality, click the “Add/View Certification” link from the navigation menu on the “CB Home” page (Figure 7.61).

Figure 7.61 — Navigation Menu



The system will display the “Dashboard” page, and “Certifications” section will be expanded by default (Figure 7.62).

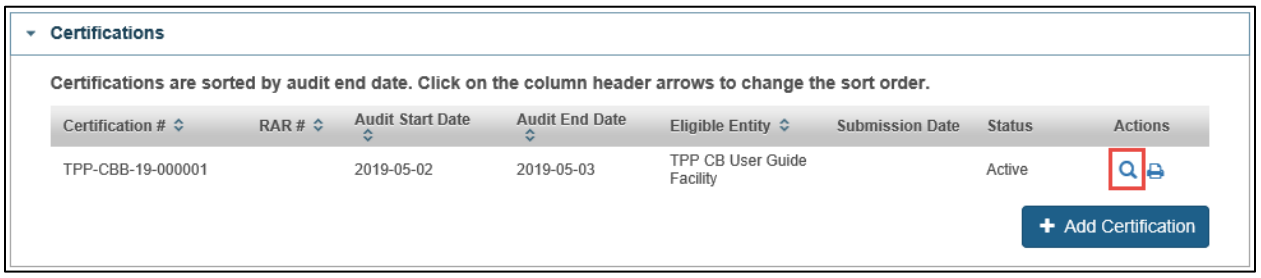
Figure 7.62 – Dashboard Page



7.3.1 View the Details of a Certification

Click the view/magnifying glass icon from the “Actions” column to view the details of a certification (Figure 7.63).

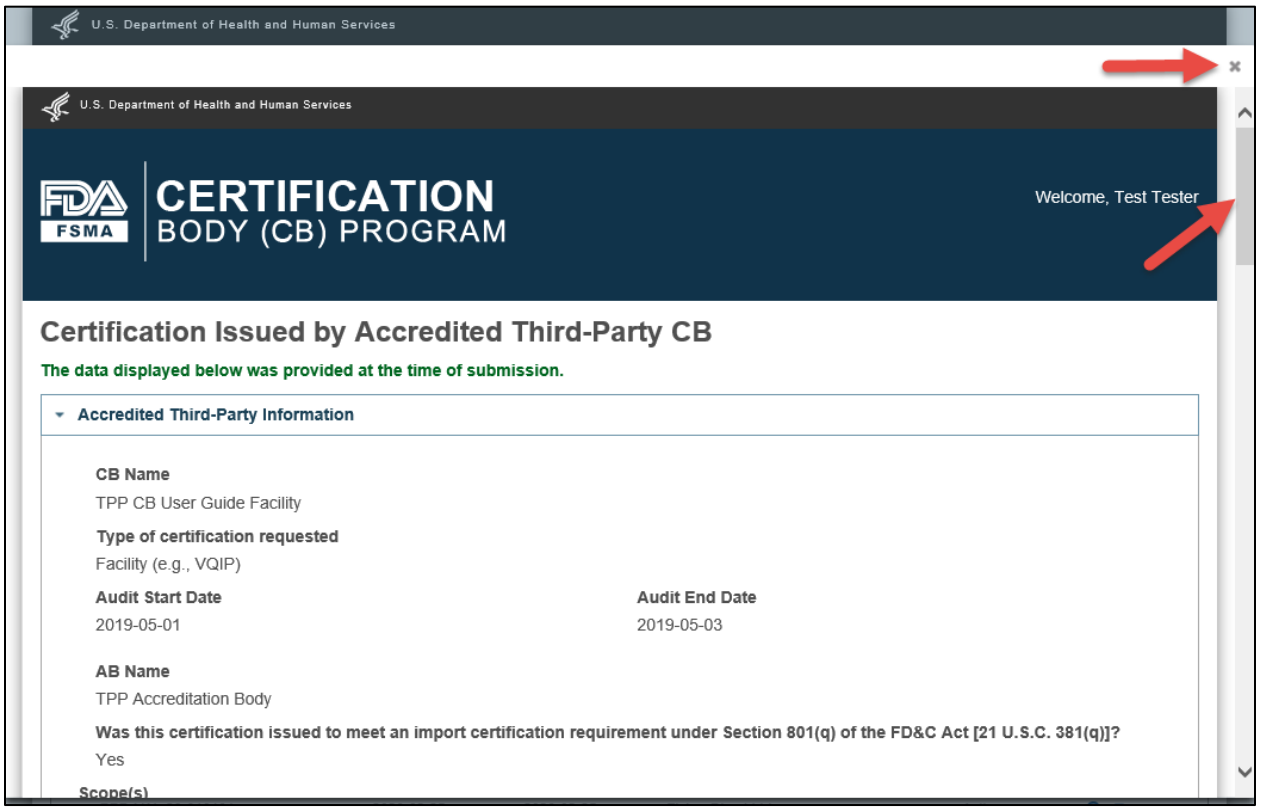
Figure 7.63 – View Icon



A pop-up window with the details of the certification will open. Click and drag the vertical scroll bar on the right side of the window to view all of the information (Figure 7.64).

Click the “x” button at the top-right corner of the window to close the pop-up window and display the “Dashboard” page.

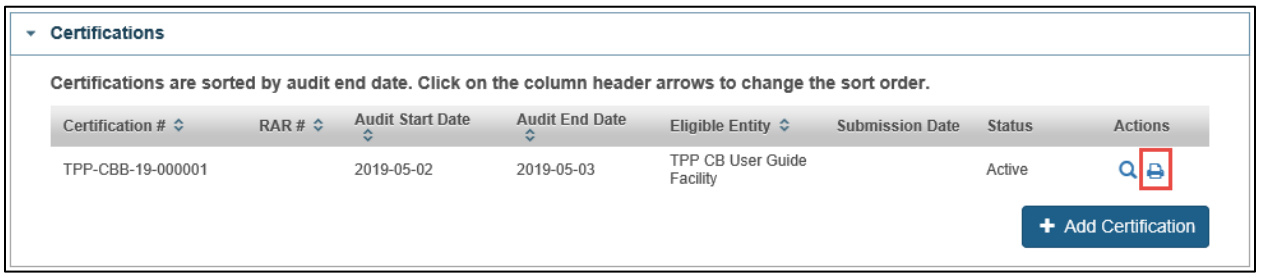
Figure 7.64 – View Pop-Up Window



7.3.2 Print the Details of a Certification

Click the print icon from the “Actions” column to print the details of a certification (Figure 7.65).

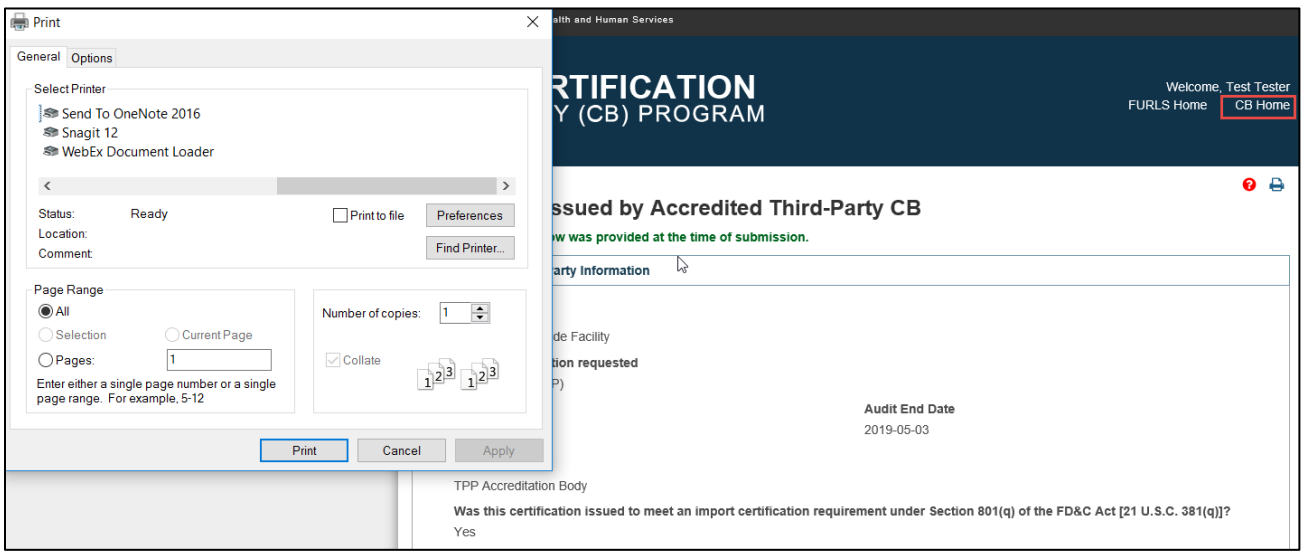
Figure 7.65 – Print Icon



A printable page and the print dialog box from your operating system will display, allowing you to print the certification (Figure 7.66).

After you finish printing the certification you can return to the “CB Home” page by clicking the “CB Home” link from the banner in the upper right corner of the page.

Figure 7.66 – Printable Page, Print Dialog Box, and CB Home Link



Click the “Yes” button in the “Confirmation” pop-up to navigate to the “CB Home” page.

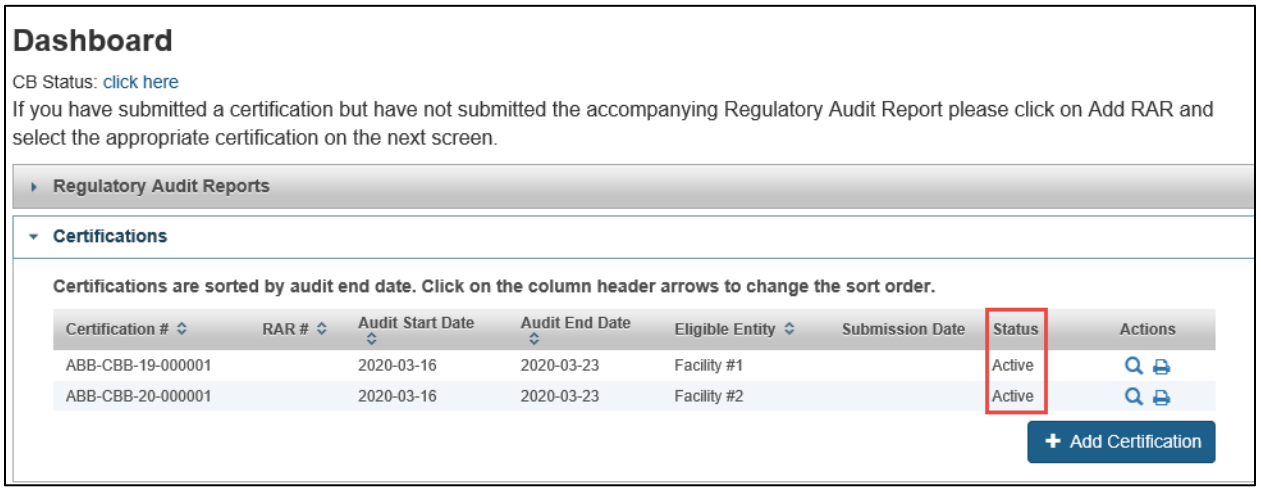
7.3.3 View the Status of a Certification

The status of a certification will display in the “Status” column of the “Certifications” section (Figure 7.67).

The possible statuses are:

- **Pending –** The certification has been submitted to FDA and is undergoing a scan of attachment(s) included with the submission. Once the attachment(s) passes the scan, it will update to “Transmitting.”
- **Transmitting –** The certification has been submitted and is in the process of being downloaded by FDA. This status may only appear briefly before it is updated to the next status. Once it has been downloaded by FDA, the status will update to “Active.”
- **Active –** The certification has been successfully received by FDA.
- **Expired –** The certification has expired and is no longer valid.

Figure 7.67 – Certification Status



8 Manage Agents and Officers

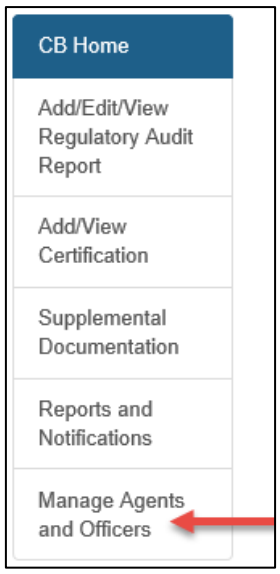
The “Manage Agents and Officers” feature may be used to perform the following two main functions related to audit agents and officers:

- Updating the status of an existing audit agent or officer
- Adding a new audit agent or officer

At least one audit agent and one officer will be added to the CB profile by the recognized AB when the CB is accredited.

To access the audit agent and officer management functionality, click the “Manage Agents and Officers” link from the navigation menu on the “CB Home” page (Figure 8.1).

Figure 8.1 – Navigation Menu

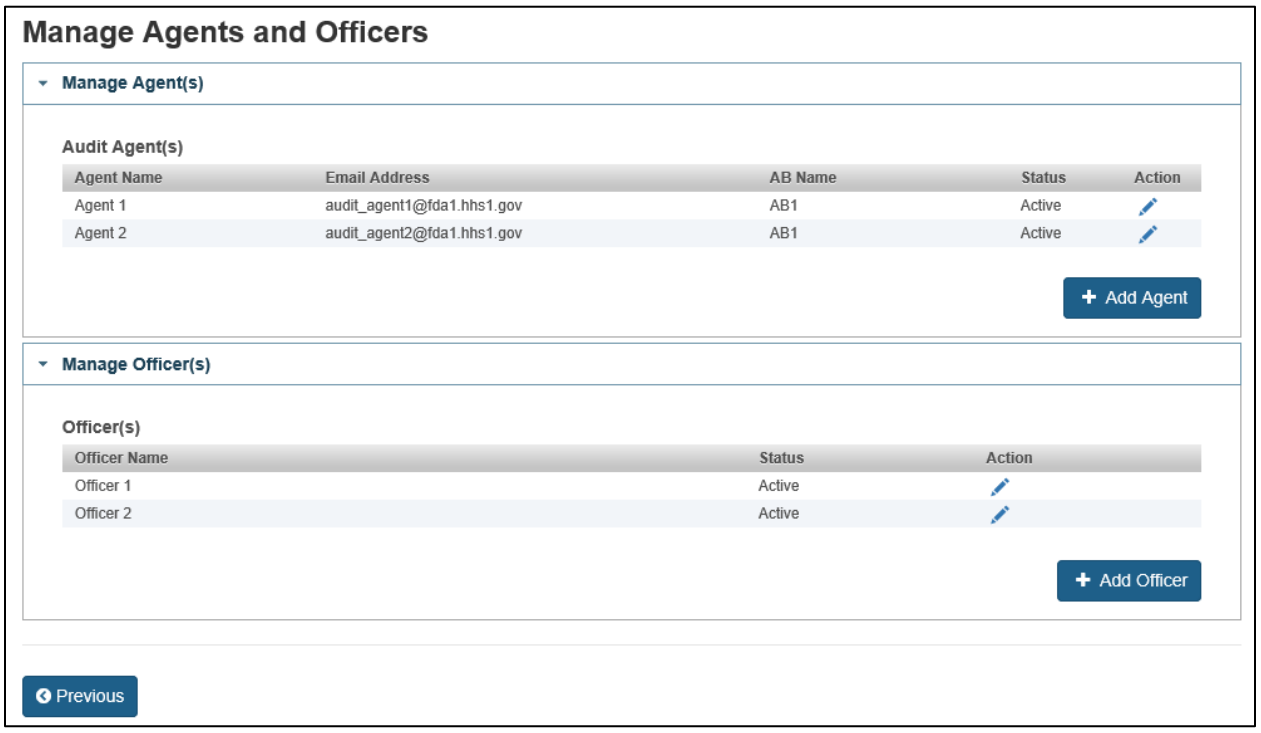


The “Manage Agents and Officers” page contains the following sections, which are expanded by default (Figure 8.2):

- Manage Agent(s)
- Manage Officer(s)

Any audit agent(s) and/or officer(s) initially entered into the system by the recognized AB will be listed in the applicable section.

Figure 8.2 – Manage Agents and Officers Page



To edit an existing audit agent, proceed to Section 8.1 of this chapter.

To add a new audit agent, proceed to Section 8.2 of this chapter.

To edit an existing officer, proceed to Section 8.3 of this chapter.

To add a new officer, proceed to Section 8.4 of this chapter.

Note: Click the “Previous” button at the bottom of the “Manage Agents and Officers” page if you wish to return to the “CB Home” page.

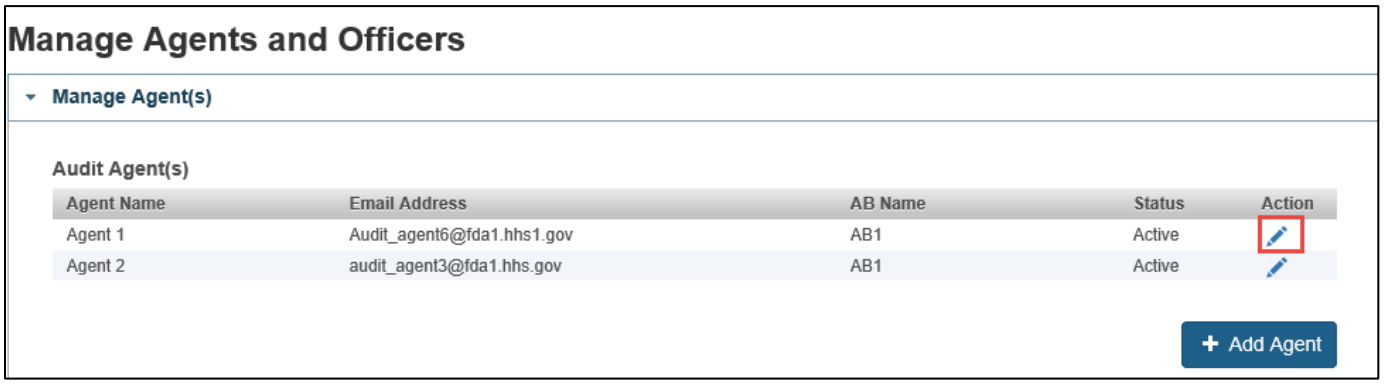
8.1 Edit an Existing Agent

To update the name, status, or effective date of an existing audit agent(s), click the pencil/edit icon in the “Action” column in the “Audit Agent(s)” table under the “Manage Agent(s)” section (Figure 8.3).

Please ensure there is one active audit agent listed at all times. If you only have one audit agent, add a new, active audit agent before updating the status of the existing audit agent to “Inactive.” A new audit agent will be “Active” by default.

Note: The system identifies audit agents by their unique e-mail address. An audit agent’s e-mail address cannot be edited once saved. Contact FDA if an existing audit agent’s e-mail address has changed.

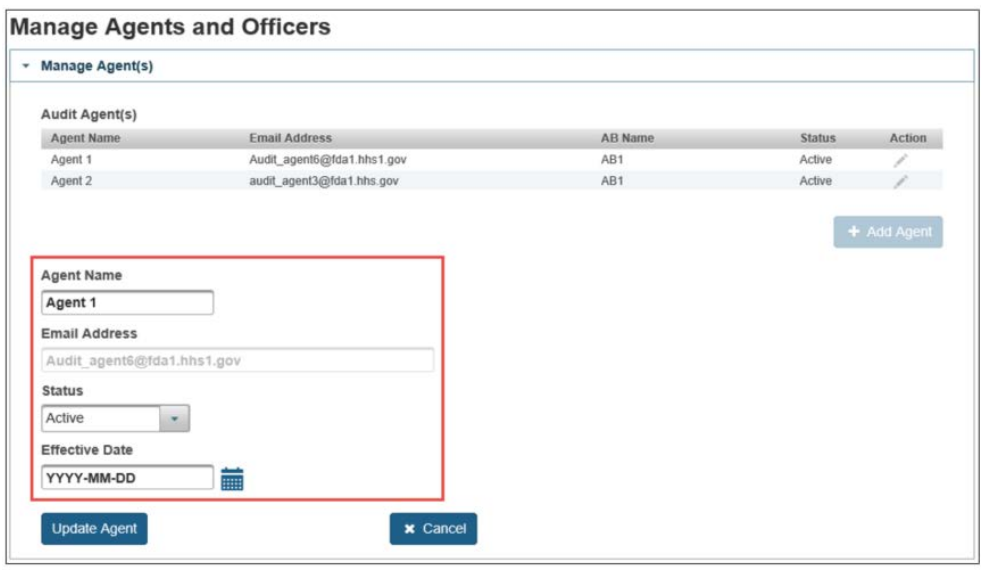
Figure 8.3 – Edit Icon



After you click the pencil/edit icon, the following fields will display below the “Audit Agent(s)” table (Figure 8.4):

- **Agent Name –** This is the text entry field to enter the full name of the audit agent.
- **Email Address –** This is the text entry field to enter the e-mail address of the audit agent.
- **Status –** This is the menu to select the status of the audit agent (“Active” or “Inactive”).
- **Effective Date –** This is the field to enter the effective date of the status change of the audit agent. Select the date with the calendar icon or enter it in “YYYY-MM-DD” format.

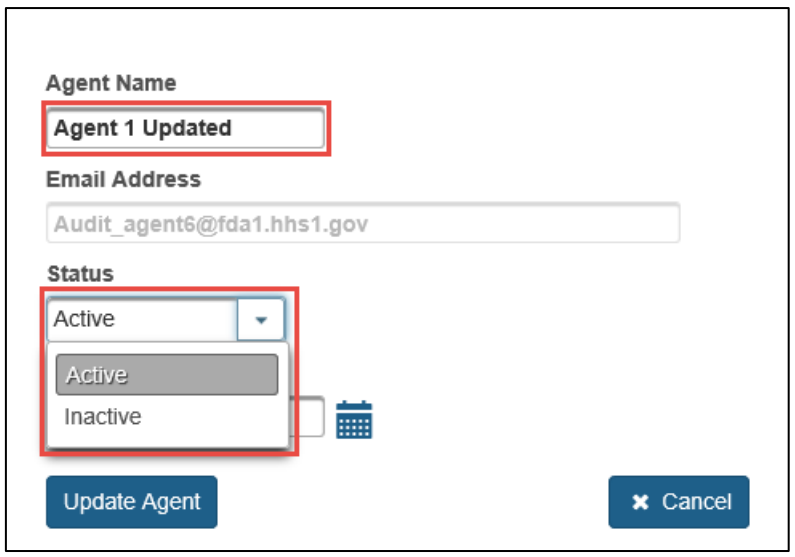
Figure 8.4 – Agent Fields



To edit the audit agent's name, click inside the "Agent Name" field and enter their first and last name (Figure 8.5).

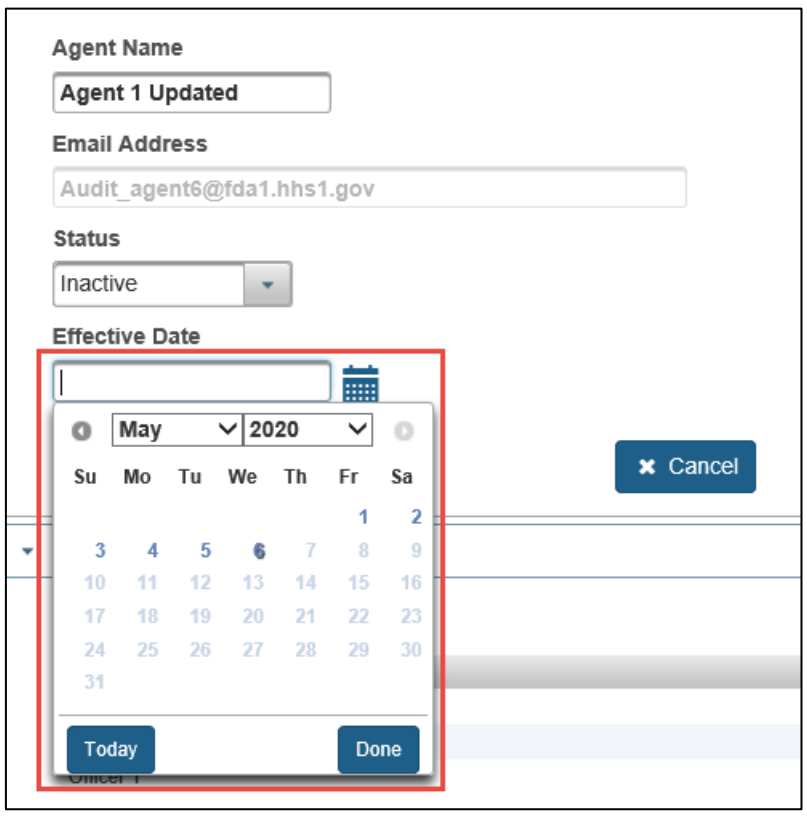
To update the audit agent's status, select the desired status from the "Status" dropdown menu ("Active or "Inactive," as applicable).

Figure 8.5 – Agent Name Field and Status Menu



Once you have updated the audit agent's information, select the effective date of the change in the "Effective Date" field (Figure 8.6).

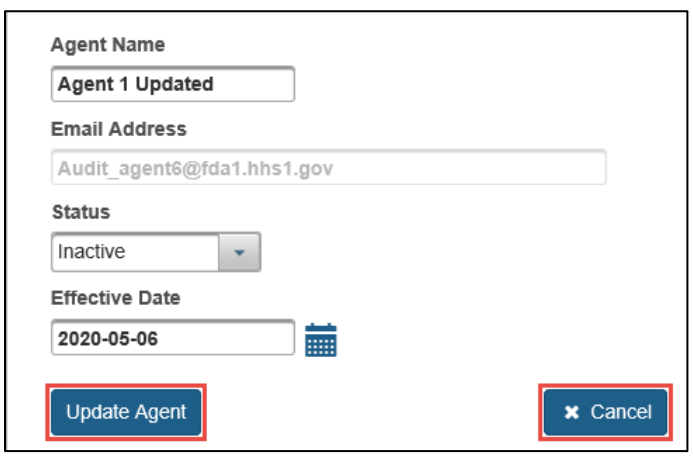
Figure 8.6 – Effective Date



Click the “Cancel” button to remove your changes (Figure 8.7).

Click the “Update Agent” button once you have completed your changes.

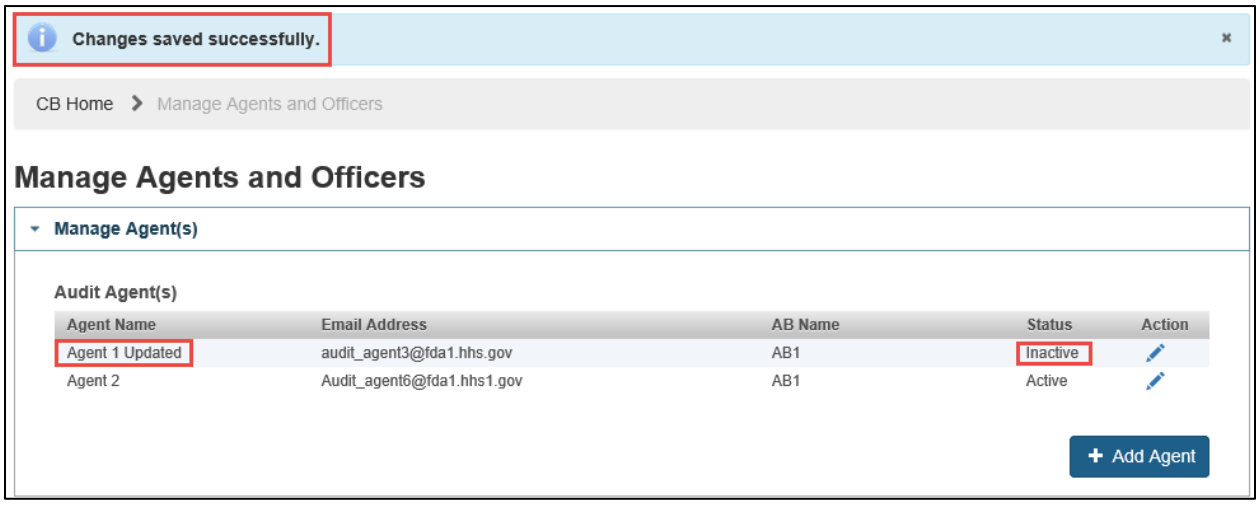
Figure 8.7 – Update Agent and Cancel Buttons



After you click the “Update Agent” button, the system will display the “Changes saved successfully” message at the top of the page (Figure 8.8).

The updated audit agent’s name and/or status will display in the “Agent Name” and/or “Status” column(s) of the “Audit Agent(s)” table on the “Manage Agents and Officers” page.

Figure 8.8 – Updated Agent Fields and Changes Saved Successfully Message

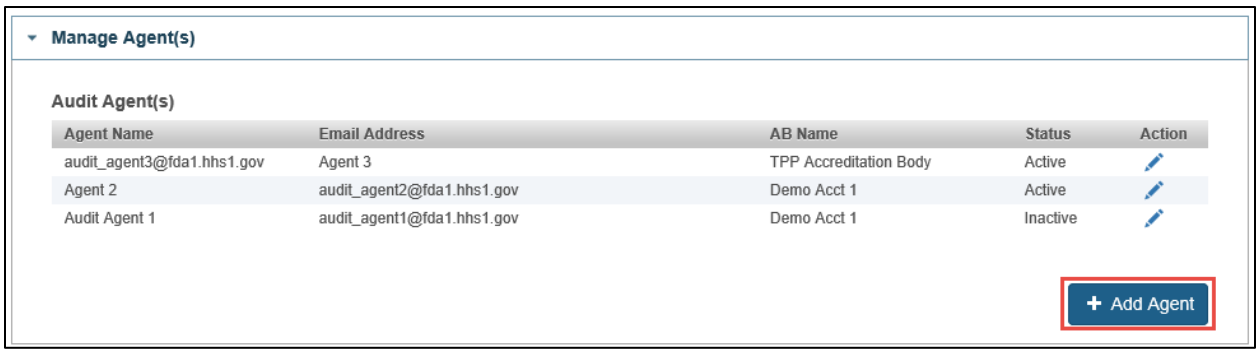


8.2 Add a New Agent

To add a new audit agent, click the “Add Agent” button below the “Audit Agent(s)” table (Figure 8.9).

Note: The system identifies audit agents by their unique e-mail address. Enter the correct e-mail address for a new audit agent, as it cannot be changed once saved.

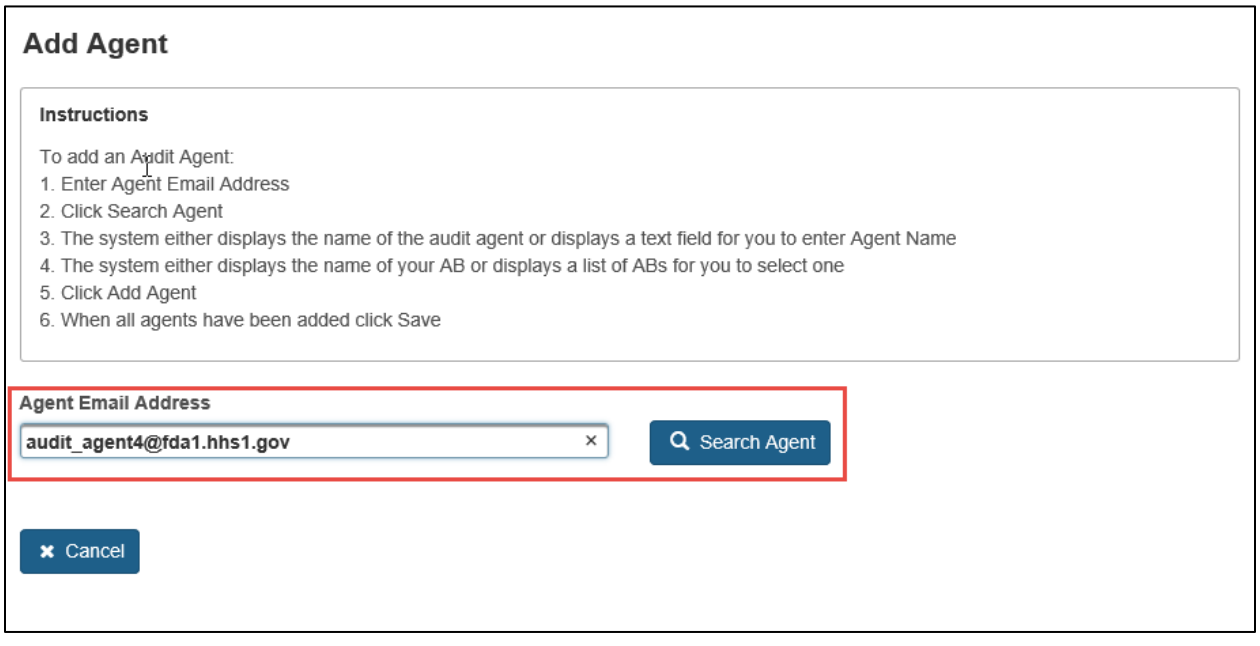
Figure 8.9 – Add Agent Button



Once you click the “Add Agent” button, the system will display the “Add Agent” pop-up window (Figure 8.10).

Enter a valid e-mail address in the “Agent Email Address” text entry field and click the “Search Agent” button.

Figure 8.10 – Add Agent Pop-up Window

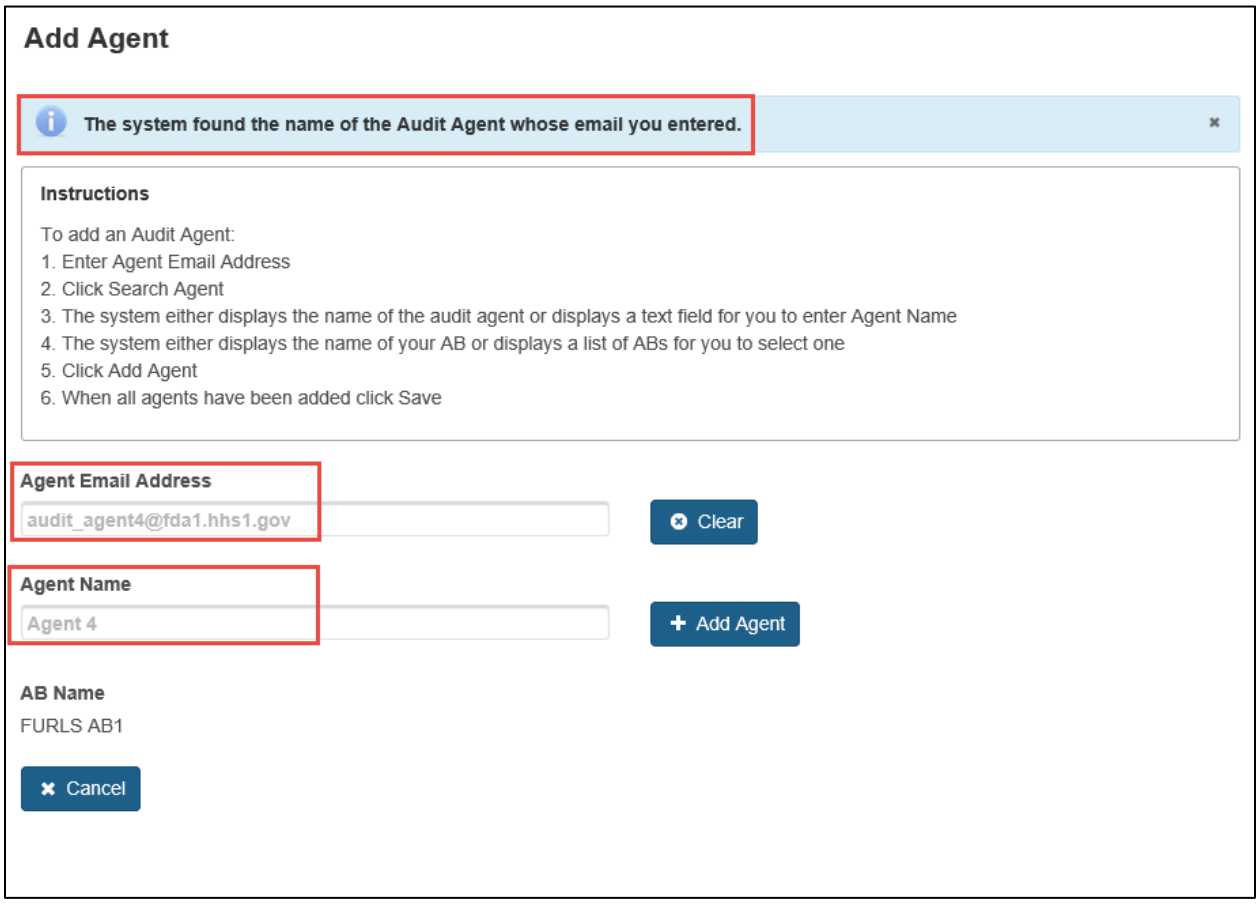


The system will display the “Agent Name” field.

If the system returns a match (i.e., the agent's e-mail address already exists in the system), the field will be pre-filled with the associated audit agent name (Figure 8.11).

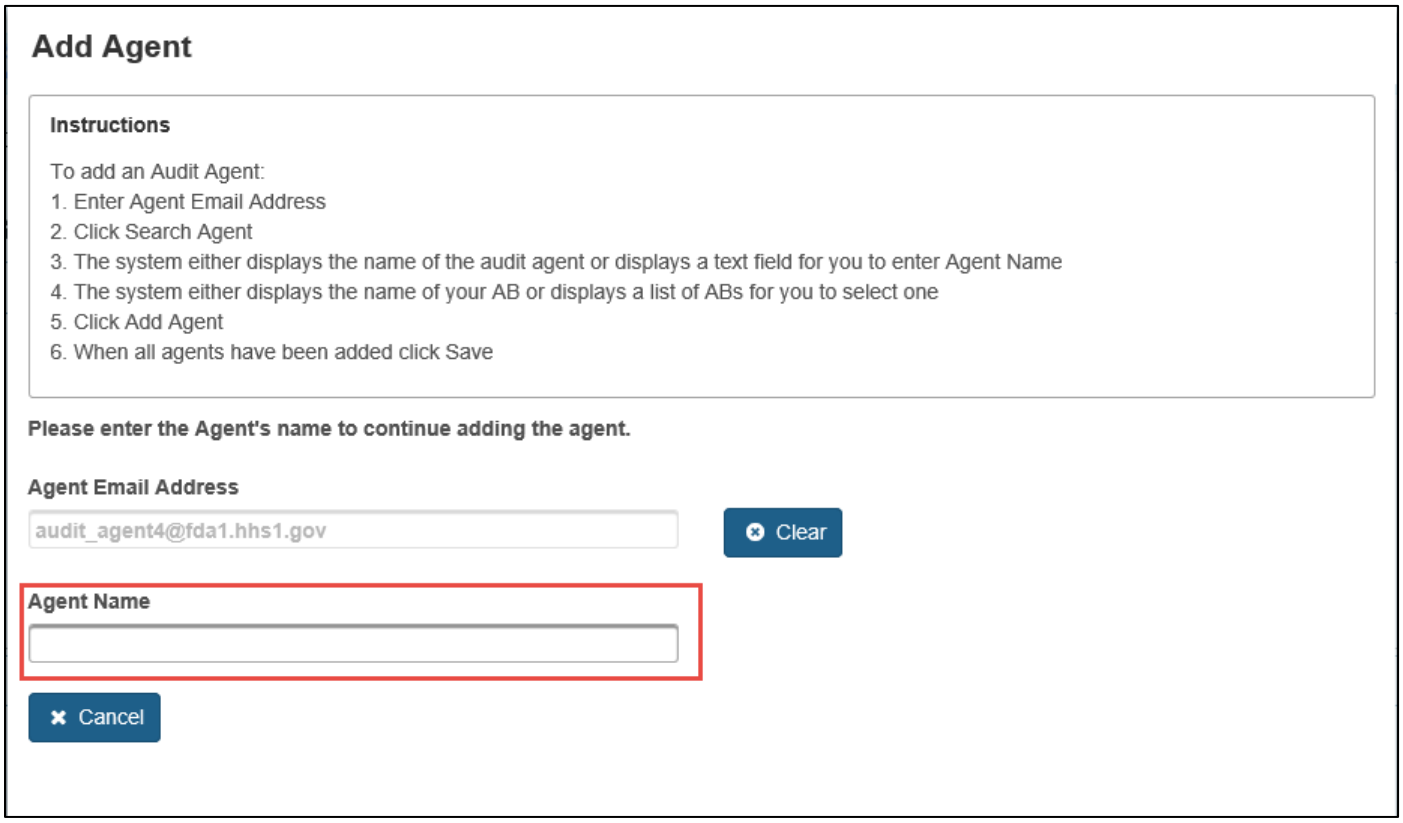
The system will display a confirmation message.

Figure 8.11 – Agent Name Field Is Pre-filled and Confirmation Message



If the system does not return a match for the e-mail address, the “Agent Name” field will be blank (Figure 8.12). Enter the audit agent’s first and last name in the “Agent Name” field.

Figure 8.12 – Agent Name Field is Blank



Once you enter the audit agent's name in the "Agent Name" field (or the system pre-fills the "Agent Name" field), the system will display the "AB Name" table. The table will list any ABs that have issued you accreditation under the Accredited Third-Party Certification Program (Figure 8.13).

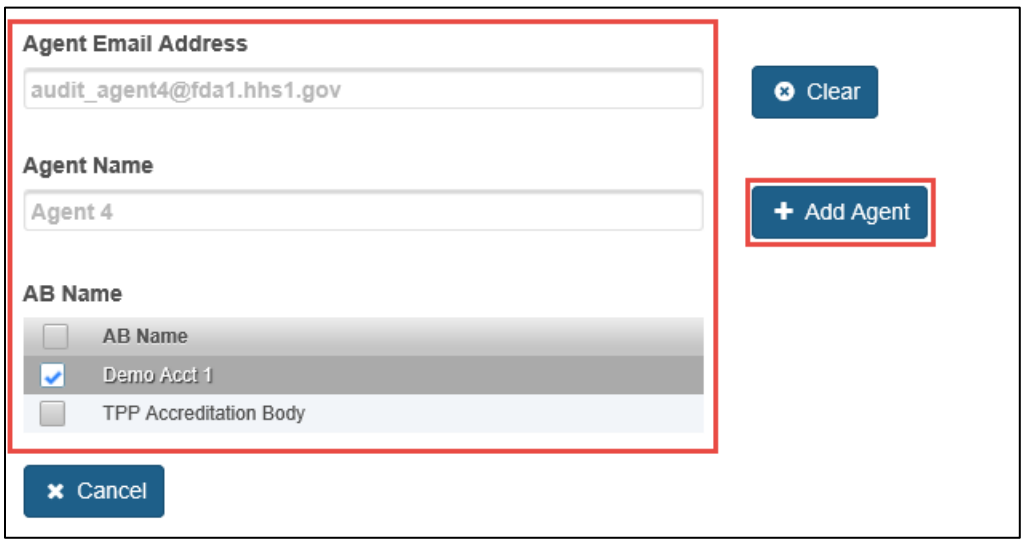
The "AB Name" field will be pre-filled if you have only been accredited by one AB.

Select one or more AB(s) by clicking inside the checkbox(es). If you are accredited by more than one AB, select the AB(s) associated with the scope(s) the audit agent will assess.

You may click the individual checkbox to the left of each AB Name or click the checkbox at the top of the column to select all ABs listed.

The "Add Agent" button will display once the required information has been populated (i.e., the "Agent Email," "Agent Name," and "AB Name" fields).

Figure 8.13 – AB Name Table and Add Agent Button



Click the “Clear” button to remove the audit agent information you entered. The “Add Agent” window will remain open for you to search by a different e-mail address (Figure 8.14).

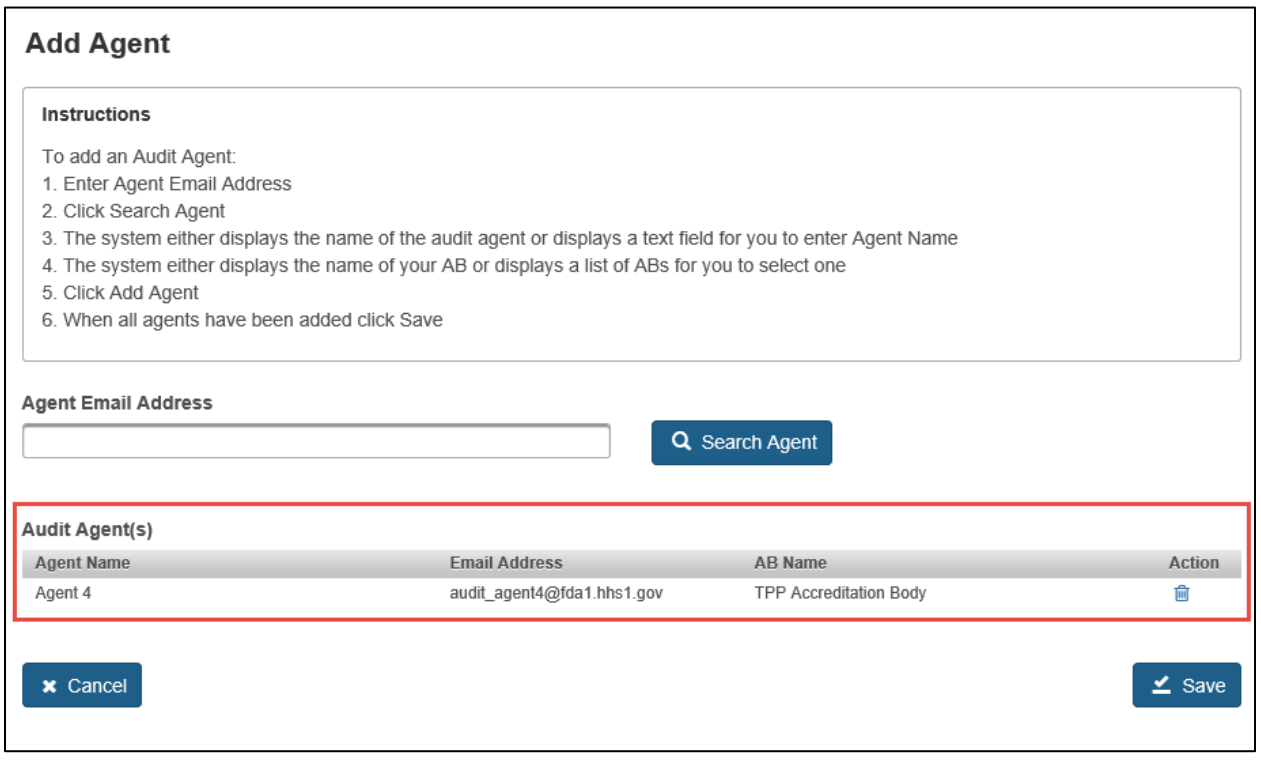
Click the “Cancel” button to discard your changes and close the “Add Agent” window.

Click the “Add Agent” button to complete adding the new audit agent.

Figure 8.14 – Clear, Cancel, and Add Agent Buttons

The audit agent will be added to the “Audit Agent(s)” table in the “Add Agent” window and the “Save” button will display (Figure 8.15).

Figure 8.15 – New Agent Added to Audit Agent(s) Table



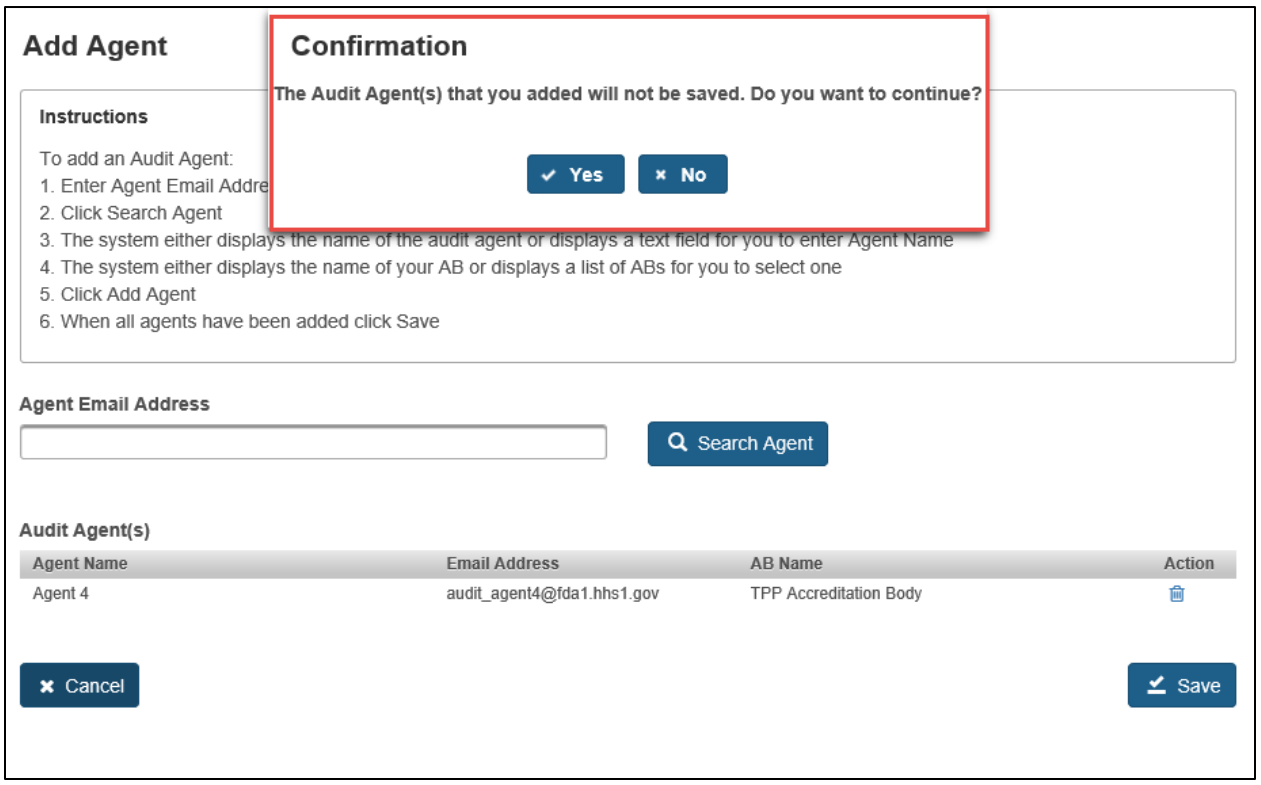
If you want to discard the changes and exit the “Add Agent” screen you can click the “Cancel” button.

If you click the “Cancel” button after you have added the audit agent, the system will display a confirmation pop-up (Figure 8.16). Select “Yes” or “No” from the pop-up before proceeding.

If you select “Yes” from the “Confirmation” pop-up, the “Add Agent” window will close and the changes will not be saved.

If you select “No,” the “Confirmation” pop-up will close. The “Add Agent” window will remain open and unchanged.

Figure 8.16 – Add Agent – Confirmation Pop-up



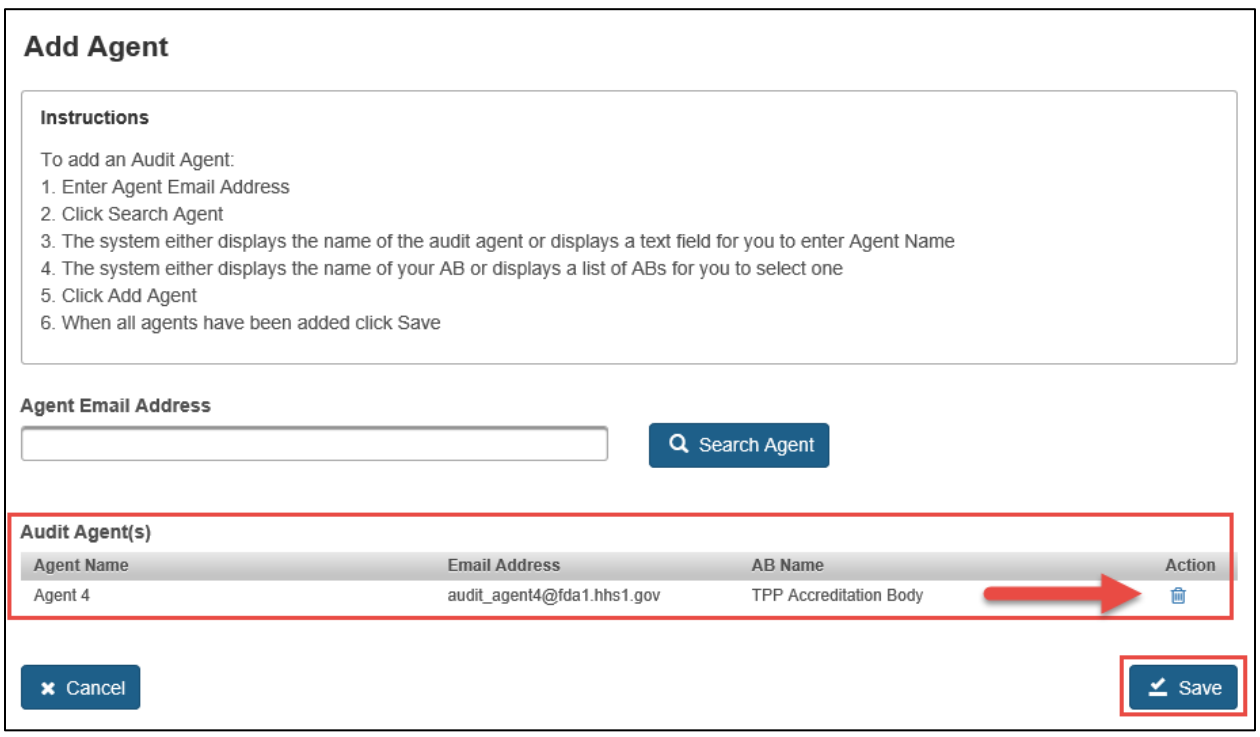
After the new audit agent is added to the “Audit Agent(s)” (Figure 8.15), the “Add Agent” window will remain open for you to search for additional e-mail addresses and add more audit agents.

Repeat the previous steps to add more audit agents.

You can delete the new audit agent(s) by clicking the trash/delete icon in the “Action” column of the “Audit Agent(s)” table (Figure 8.17). You will not be able to delete an audit agent after you click the “Save” button.

Once you have added all of the appropriate audit agents, click the “Save” button.

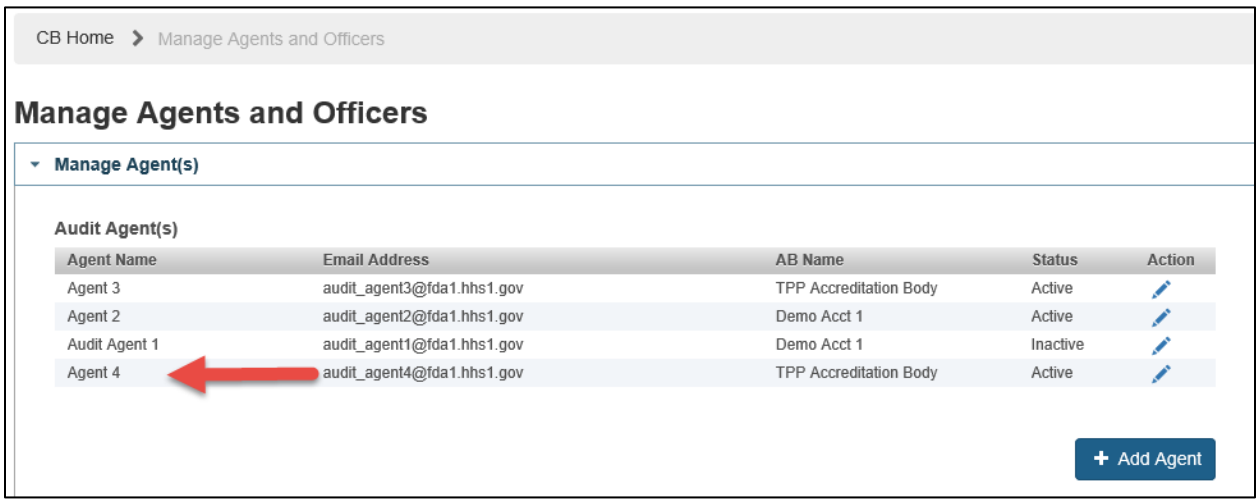
Figure 8.17 – Audit Agent(s) Table, Trash Icon, and Save Button



Once you click the “Save” button, the “Add Agent” window will close and the system will display the “Manage Agents and Officers” page.

The audit agent(s) you added will display in the “Audit Agent(s)” table, and the audit agent’s status will be “Active” by default (Figure 8.18).

Figure 8.18 – Audit Agent(s) Table with New Agent Added

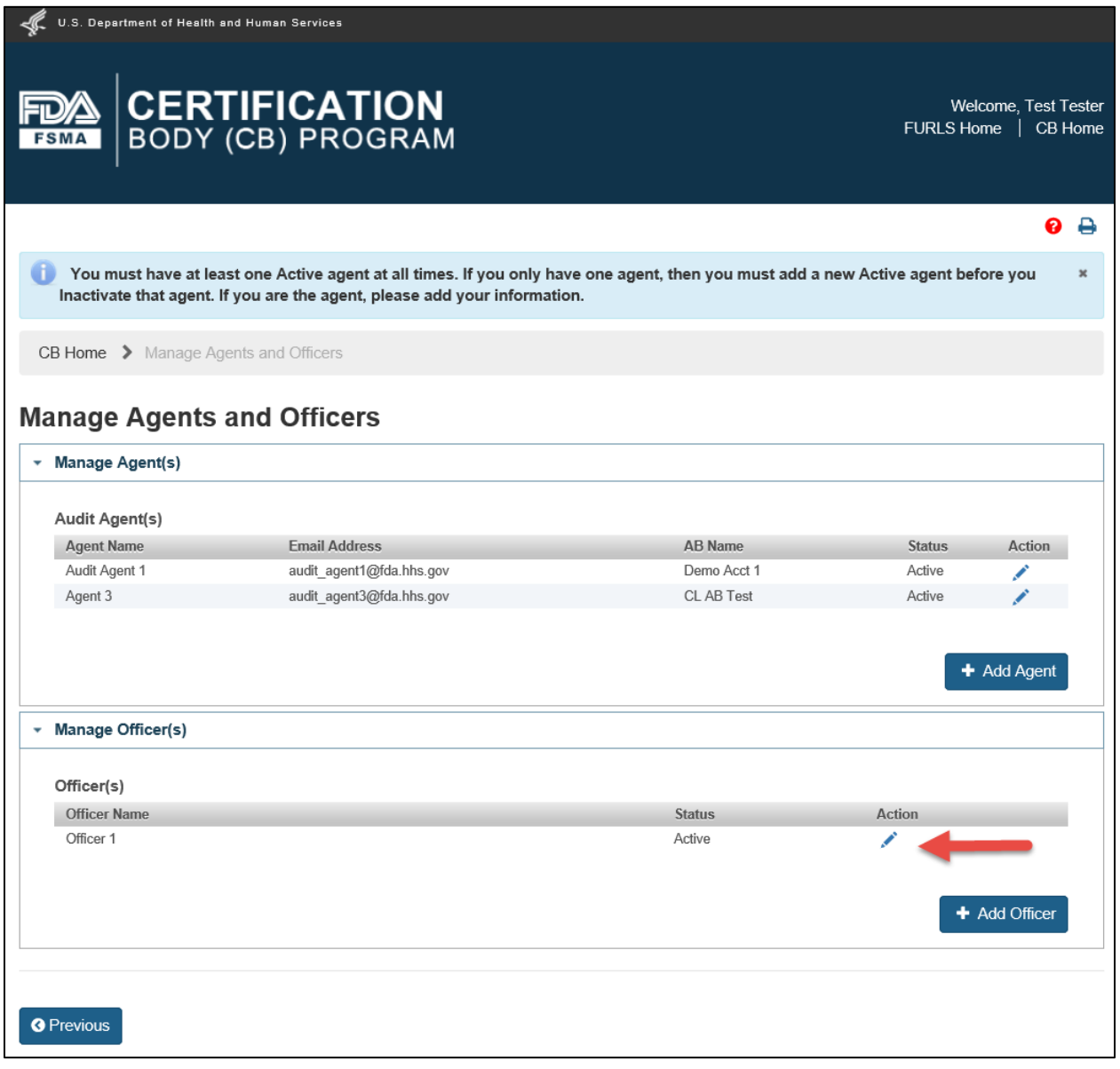


8.3 Edit an Existing Officer

To update the status of the existing officer(s), click the pencil/edit icon in the “Action” column of the “Manage Officer(s)” table (Figure 8.19).

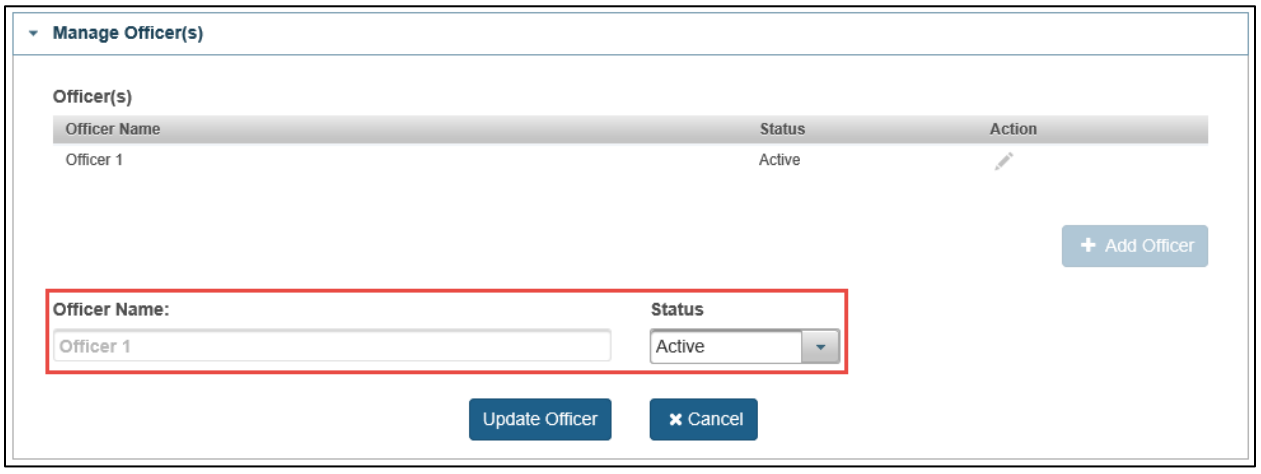
Please ensure that there is one active officer at all times. If you only have one officer, add a new, active officer before updating the status of the existing officer to “Inactive.” A new officer will be “Active” by default.

Figure 8.19 – Edit Icon



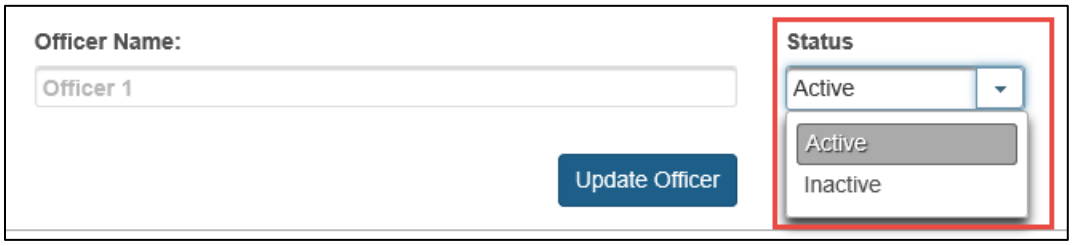
Once you click the pencil/edit icon, the officer's details will display below the "Officer(s)" table (Figure 8.20).

Figure 8.20 – Officer Details



You may update the status (i.e., "Active" or "Inactive") of the officer by selecting the "Status" dropdown menu (Figure 8.21).

Figure 8.21 – Status Menu

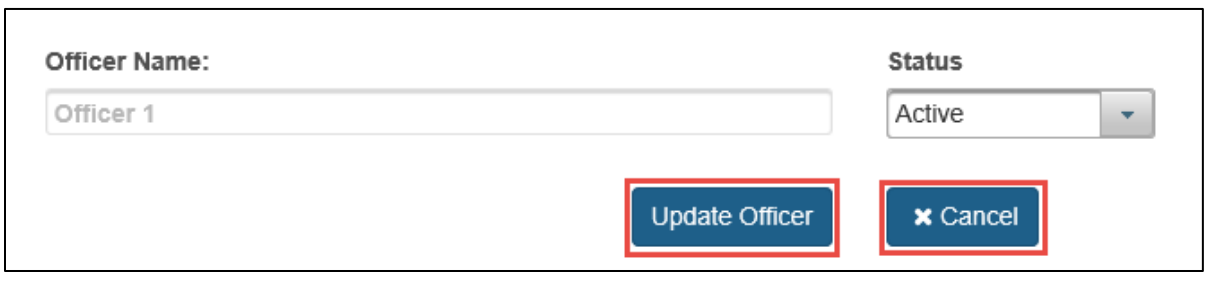


After you select the desired status, click the "Update Officer" button.

Click the "Cancel" button to remove your changes (Figure 8.22).

Click the "Update Officer" button to confirm your changes.

Figure 8.22 – Cancel and Update Officer Buttons

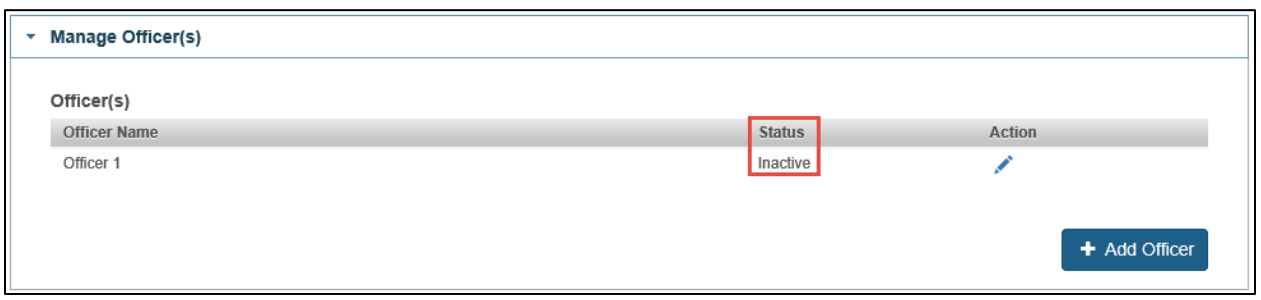


The system will display the “Changes saved successfully” message at the top of the page (Figure 8.23).

Figure 8.23 – Changes Saved Successfully Message

The officer’s status will be updated in the “Status” column of the “Officer(s)” table on the “Manage Agents and Officers” page (Figure 8.24).

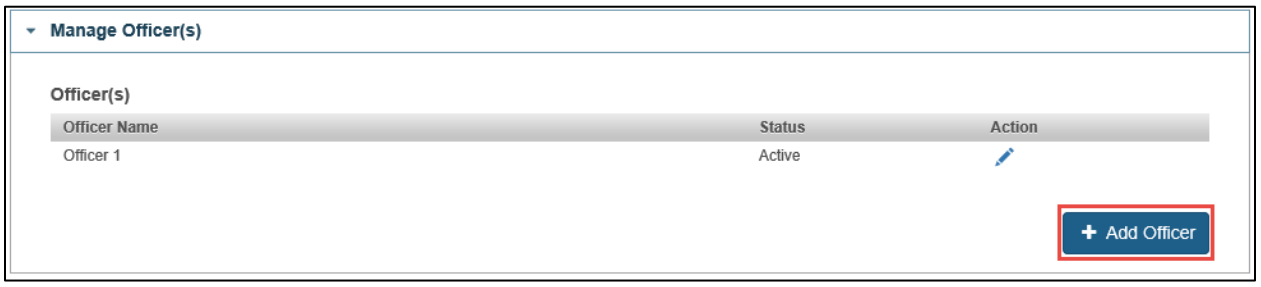
Figure 8.24 – Updated Officer Status



8.4 Add a New Officer

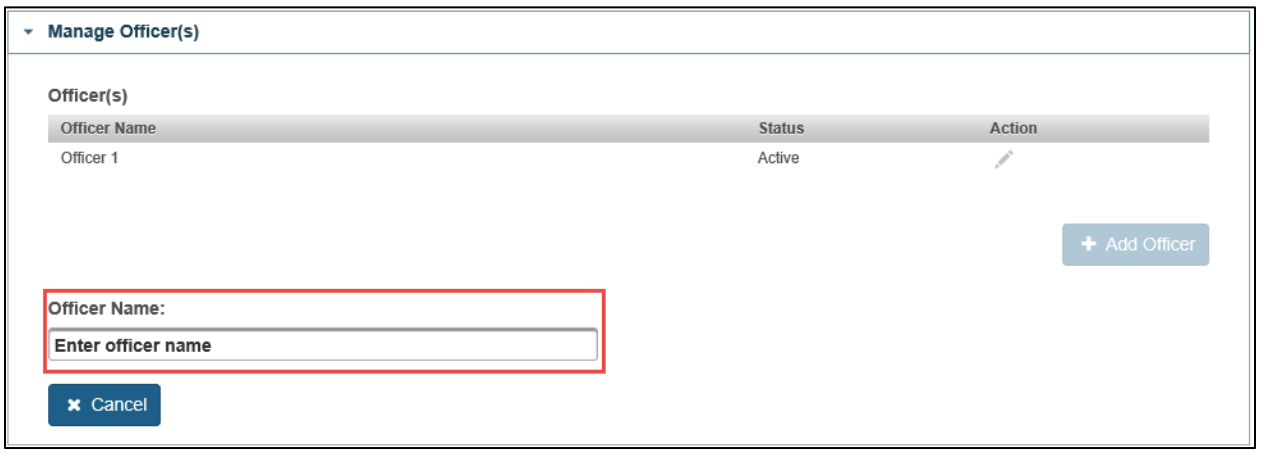
To add a new officer, click the “Add Officer” button below the “Officer(s)” table (Figure 8.25).

Figure 8.25 – Add Officer Button



The “Officer Name” text entry field will display (Figure 8.26).

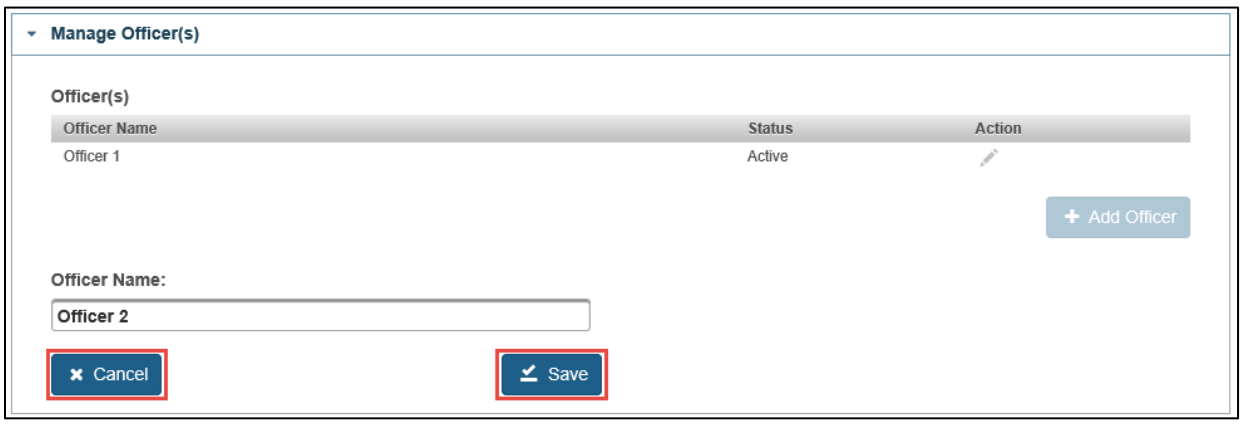
Figure 8.26 – Officer Name



Enter the officer’s first and last name in the “Officer Name” field.

Click the “Save” button to add the officer or click “Cancel” to remove your changes (Figure 8.27).

Figure 8.27 – Cancel and Save Buttons

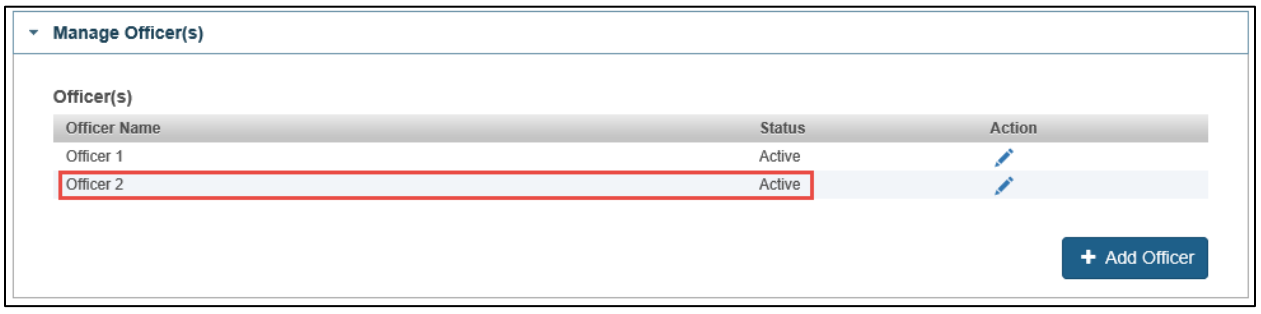


Once you click the “Save” button, the system will display a confirmation message at the top of the page (Figure 8.28).

Figure 8.28 – Officer Saved Successfully Message

The new officer will be added to the “Officer(s)” table on the “Manage Agents and Officers” page. The officer’s status will be “Active” by default (Figure 8.29).

Figure 8.29 – Officer(s) Table with New Officer Added



Repeat the previous steps to add more officers.

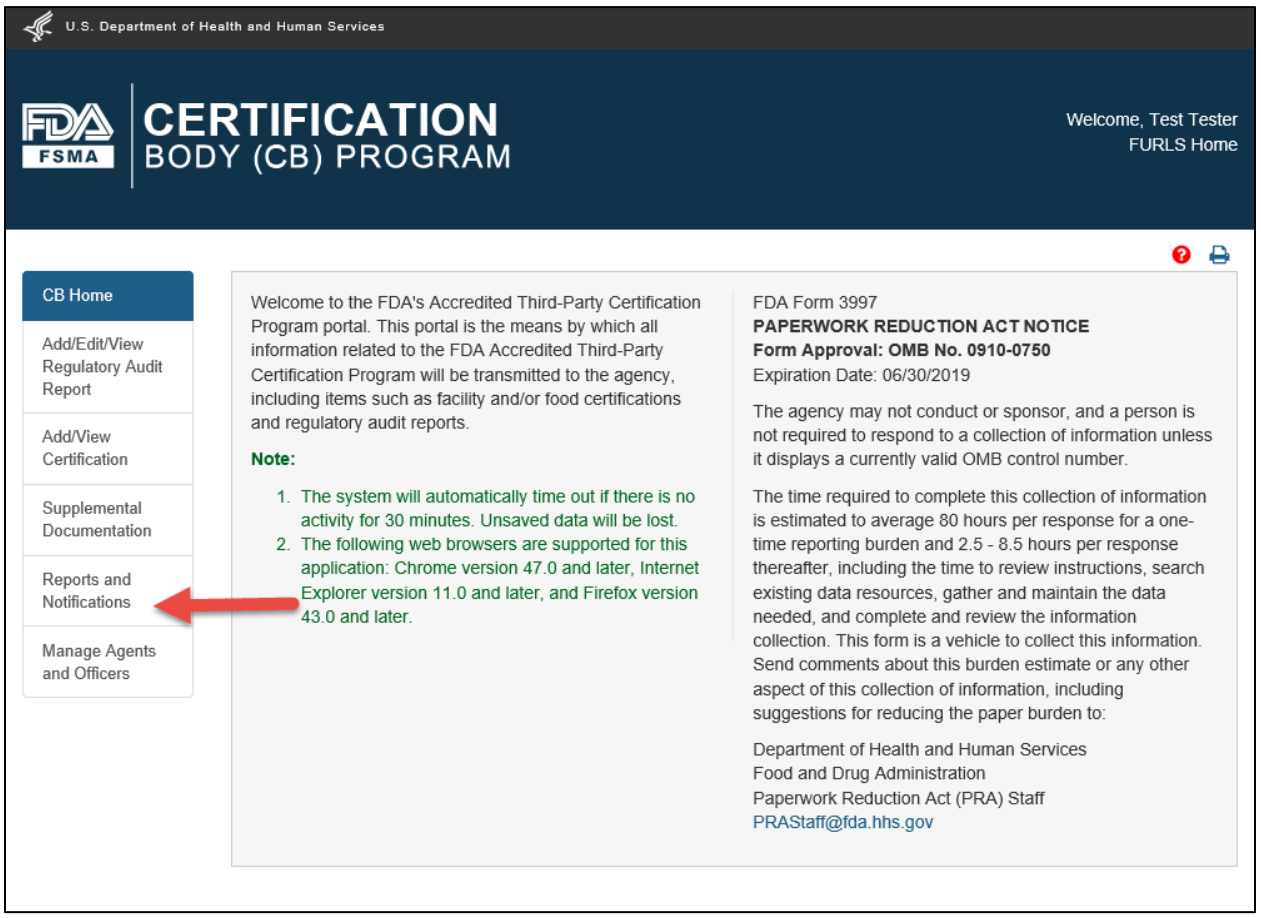
9 Reports and Notifications

The “Reports and Notifications” feature may be used to (electronically) notify FDA of events or updates regarding the following conditions or scenarios:

- Any issued food or facility certification that has been withdrawn, suspended, or reinstated by a CB
- A condition that could cause or contribute to a serious risk to the public health
- Relinquishment or non-renewal of accreditation status

To access the reports and notifications functionality, click the “Reports and Notifications” link from the navigation menu on the “CB Home” page (Figure 9.1).

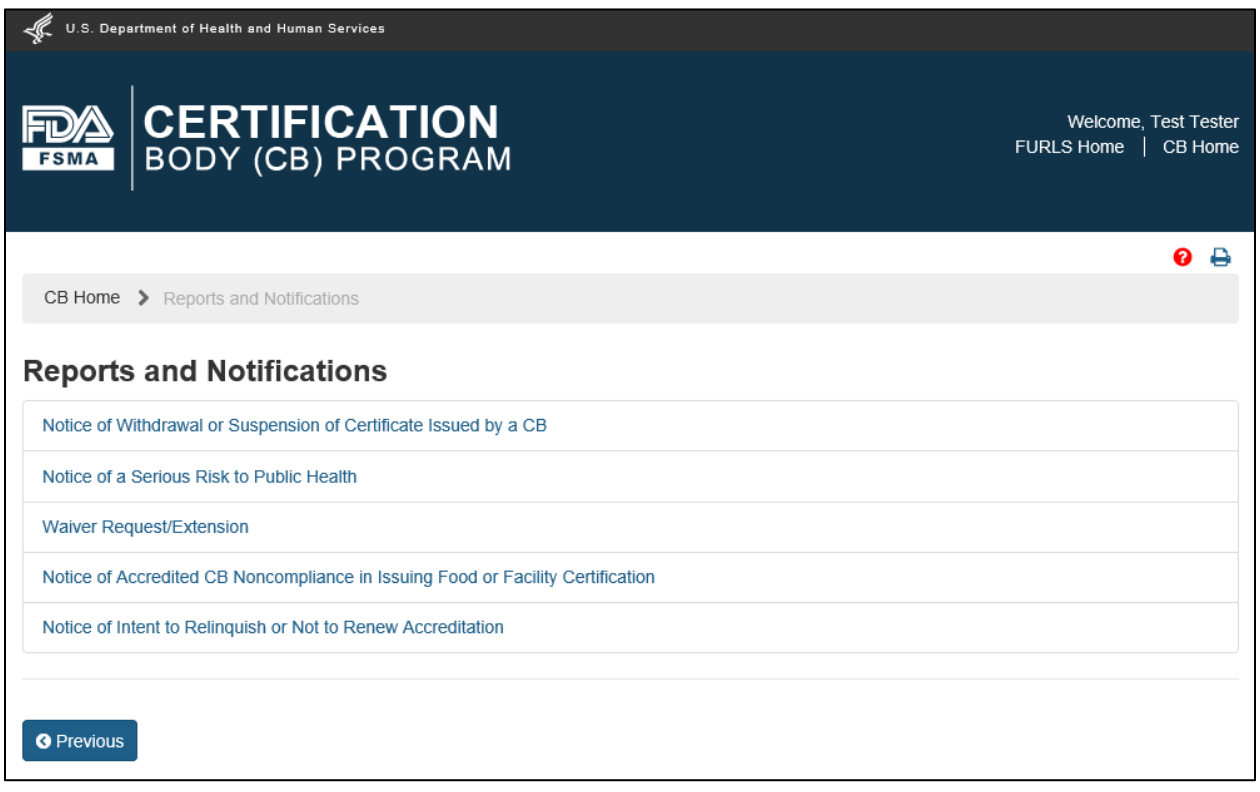
Figure 9.1 – Navigation Menu



The system will display the “Reports and Notifications” page (Figure 9.2) with the following reports and notifications available:

- **Notice of Withdrawal or Suspension of Certificate Issued by a CB –** Generates a notice to FDA when a CB reports the withdrawal or suspension of any food or facility certification of an eligible entity and the basis for such action
- **Notice of a Serious Risk to Public Health –** Generates a notice to FDA when a CB reports a condition discovered during a consultative or regulatory audit that could cause or contribute to a serious risk to public health
- **Waiver Request/Extension –** Generates a notice to FDA when a CB requests that FDA waive the requirement that limits an audit agent from conducting a regulatory audit of an eligible entity, if the audit agent has conducted a consultative or regulatory audit for the same eligible entity in the preceding 13 months
- **Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification –** Generates a notice to FDA when a CB reports failure to comply with the regulation in issuing a food or facility certification
- **Reinstatement of a Suspended Certification –** Generates a notice to FDA when a CB reports the reinstatement of a suspended certification
  This notice is only displayed in the “Reports and Notifications” page if the CB has suspended at least one food or facility certification of an eligible entity.
- **Notice of Intent to Relinquish or Not to Renew Accreditation –** Generates a notice to FDA when a CB reports their intent to relinquish or to not renew accreditation

Figure 9.2 – Reports and Notifications Page

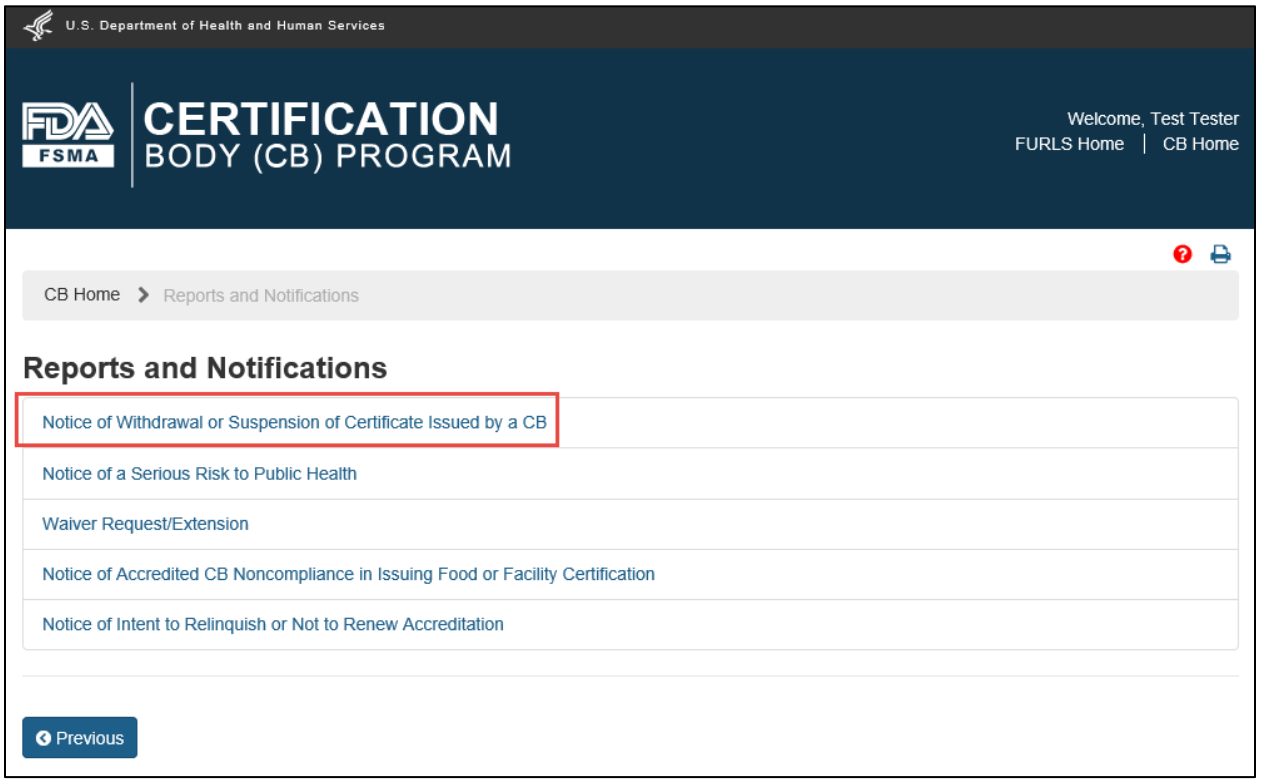


Note: “Reinstatement of a Suspended Certification” will also display in the list of “Reports and Notifications” if you currently have suspended at least one food or facility certification of an eligible entity (i.e., you submitted a “Notice of Withdrawal or Suspension of Certificate Issued by a CB”). Refer to Section 9.5 of this chapter for additional information.

9.1 Notice of Withdrawal or Suspension of Certificate Issued by a CB

To notify FDA of withdrawal or suspension of any food or facility certification for an eligible entity (and the basis for such action), click the “Notice of Withdrawal or Suspension of Certificate Issued by a CB” link on the “Reports and Notifications” page (Figure 9.3).

Figure 9.3 – Reports and Notifications Page



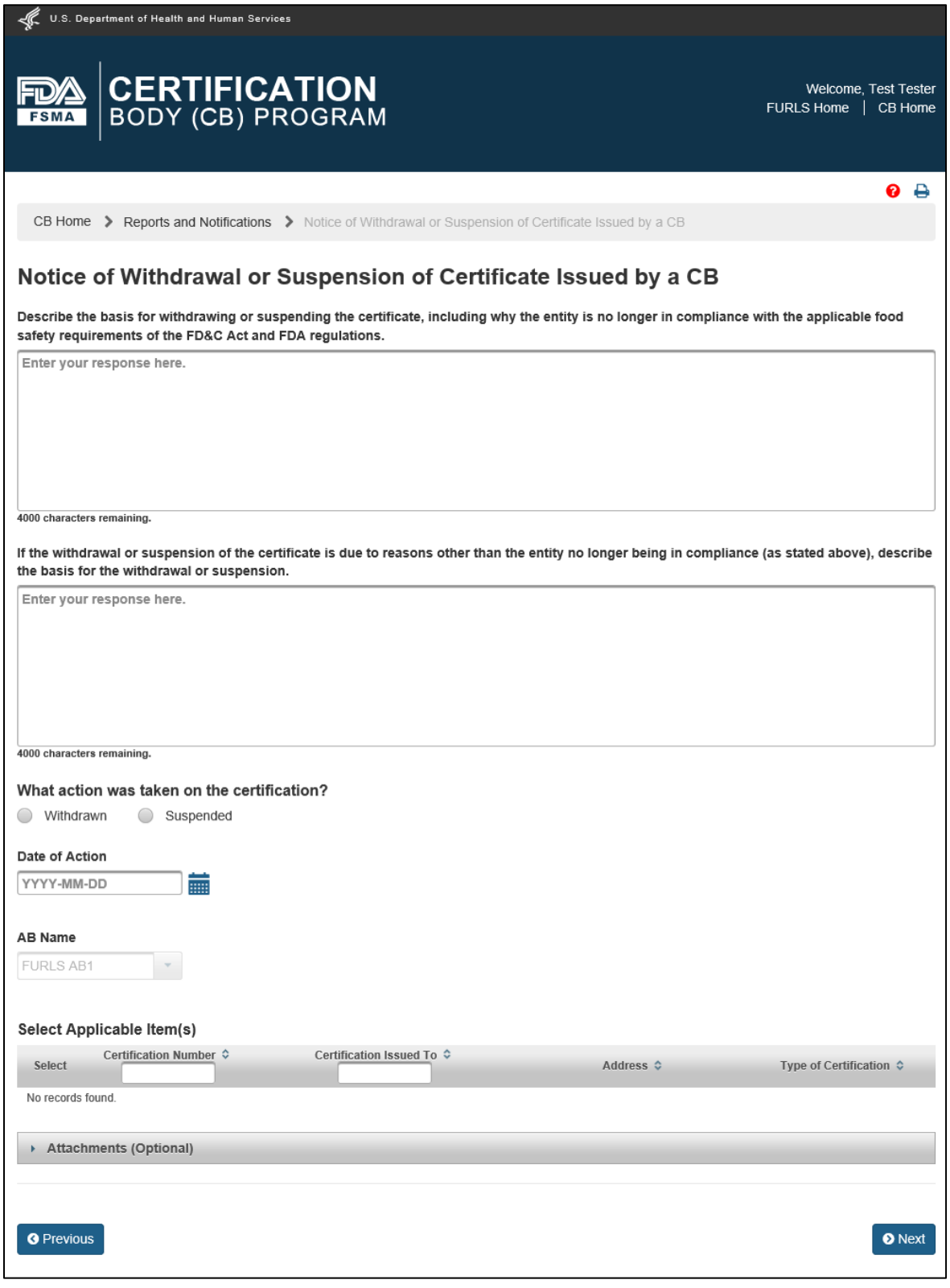
The system will display the “Notice of Withdrawal or Suspension of Certificate Issued by a CB” page (Figure 9.4).

Complete the following fields:

- **Describe the basis for withdrawing or suspending the certificate, including why the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. –** This is a text entry field, which allows a maximum of 4,000 characters.
- **If the withdrawal or suspension of the certificate is due to reasons other than the entity no longer being in compliance (as stated above), describe the basis for the withdrawal or suspension. –** This is a text entry field, which allows a maximum of 4,000 characters.
- **What action was taken on the certification? –** Select “Withdrawn” or “Suspended” by clicking its radio button.
- **Date of Action –** Select the date of action from the calendar icon or enter the date in “YYYY-MM-DD” format.
- **AB Name –** Select the name of the AB from the dropdown menu. If you are accredited by more than one AB, select the AB who accredited you for the scope(s) covered in the certification that is being withdrawn or suspended.

  Note: The “AB Name” field will be enabled and list all the ABs once “Audit Start Date” has been selected or entered. The “AB Name” field will be pre-filled if you have only been accredited by one AB.

Figure 9.4 – Notice of Withdrawal or Suspension of Certificate Issued by a CB Page

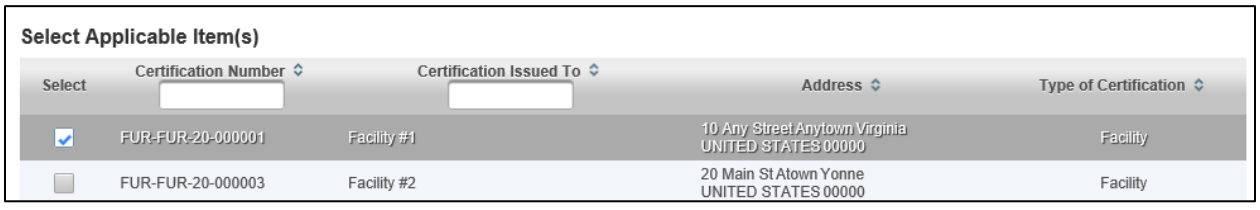


Once you have made a selection from **“What action was taken on the certification?”** and **“AB Name”** (as described above,) the system will display a list of available certifications in the “Select Applicable Item(s)” table (Figure 9.5).

Select the certification(s) you wish to include in the notification by clicking the corresponding checkbox(es). At least one certification must be selected.

Note: The system will allow you to add more than one certification in a single notice, but only allows for one action per notice (i.e., withdrawal or suspension).

Figure 9.5 – Select Applicable Items Table – Certifications Available



To upload documents to your notice, proceed to the “Attachments (Optional)” section (Figure 9.6).

Click the accordion section’s title bar to display the content of the section. This section is optional.

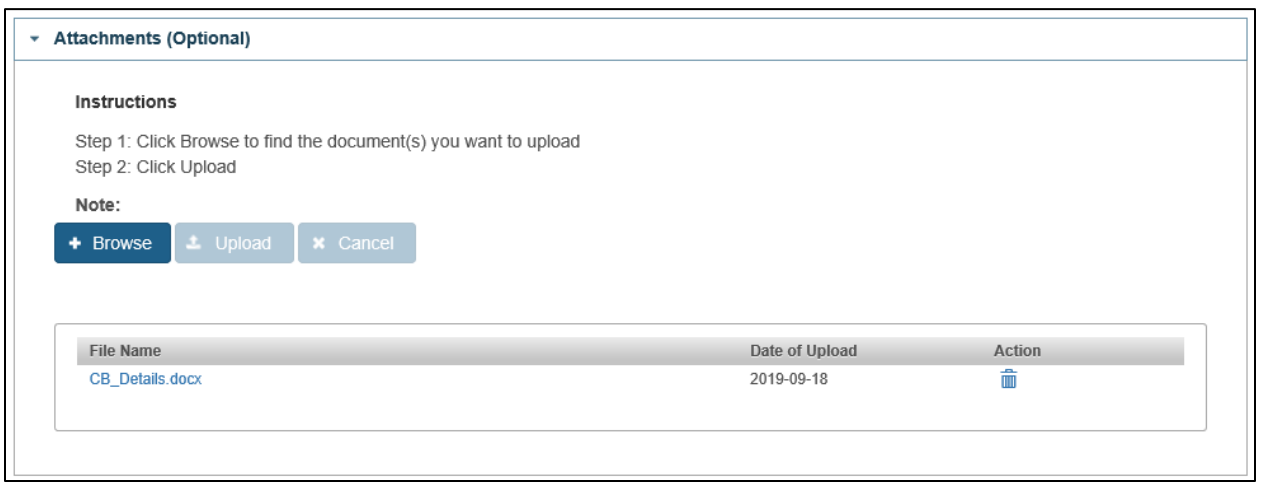
Follow Steps 1 - 4 (listed below) to upload attachments.

1. Click the “Browse” button and choose the file to upload.
2. The “Upload” and “Cancel” buttons will be enabled after a file has been chosen.
    - Click the “Cancel” button to discard the upload of the attachment.
    - Click the “Upload” button to complete the upload of the attachment.
3. Once the upload is complete a confirmation message with the file name will display at the top of the page. The attachment details will display in a table.
4. To remove the attachment, click the trash/delete icon in the “Action” column.

Note: The system supports the following document types: .pdf; .png; .jpeg; .gif; .bmp; .jpg; .jpe; jfif; .tif; .tiff; .doc; .docx; .ppt; .xls; .xlsx; .txt; .pptx; or .rtf.

The maximum file size allowed is 50 MB.

Figure 9.6 – Attachments (Optional) Section



Repeat the previous steps to upload additional files.

Click the “Previous” button at the bottom of the page if you wish to return to the “Reports and Notifications” page and start over.

Click the “Next” button at the bottom of the page to proceed to the “e-Signature” page.

Follow the directions provided on the “e-Signature” page (Figure 9.7).

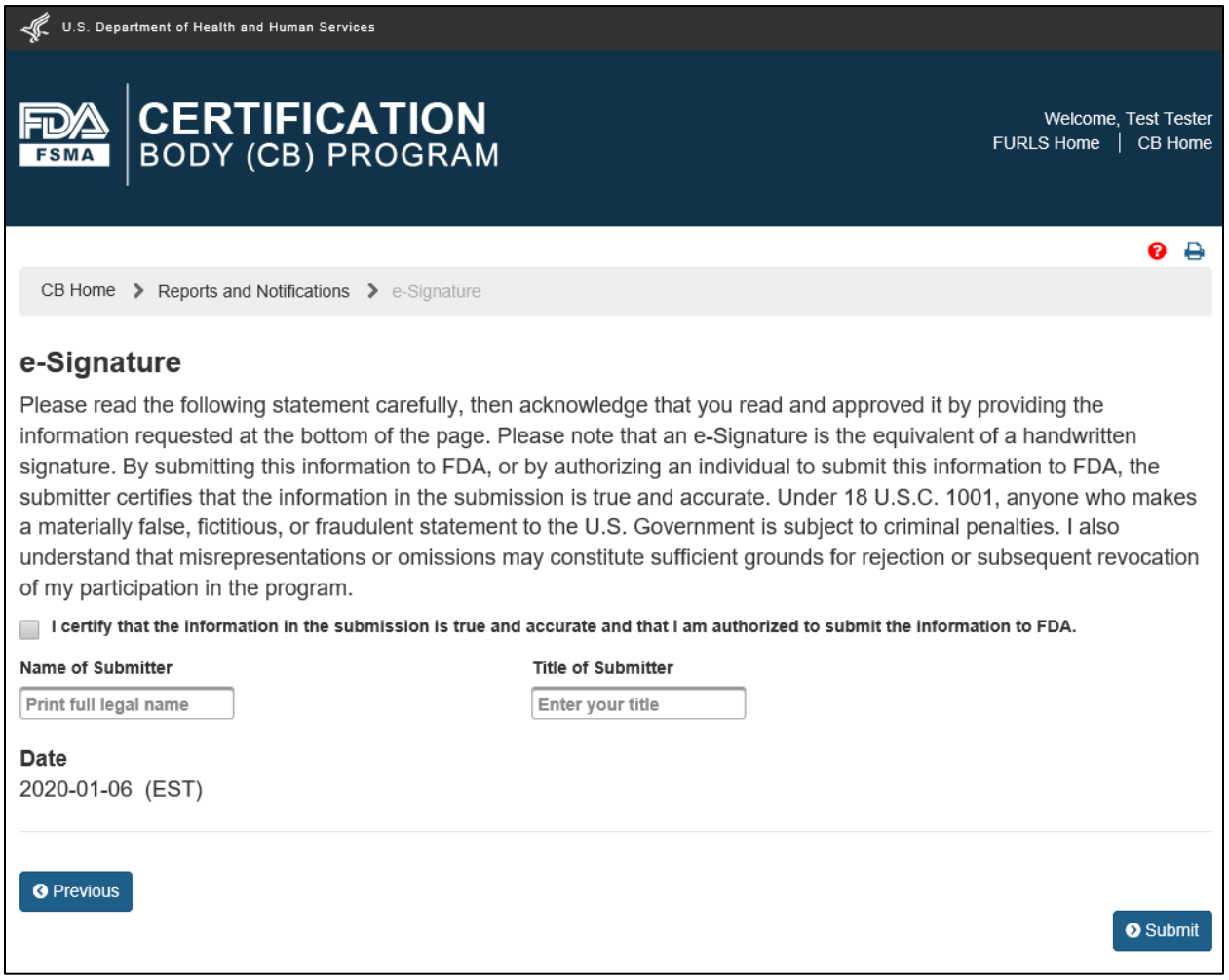
Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

Click the “Previous” button if you wish to return to the “Notice of Withdrawal or Suspension of Certificate issued by a CB” page.

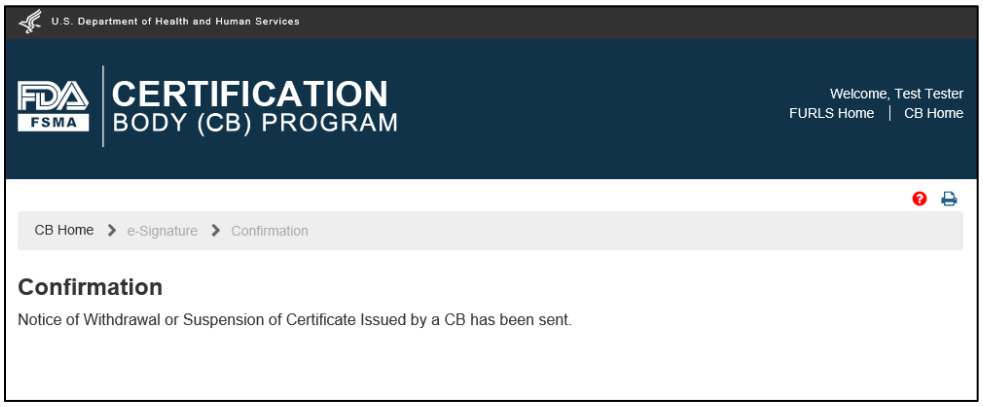
Click the “Submit” button to complete submission of the notice.

Figure 9.7 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page indicating the notification has been sent to FDA (Figure 9.8).

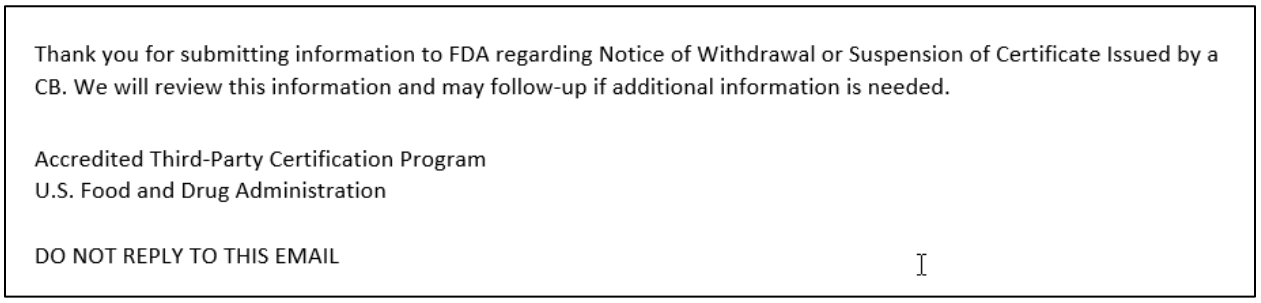
Figure 9.8 – Confirmation Page



The system will send you an e-mail indicating the notice was received by FDA (Figure 9.9). The AB you selected in the notice will receive a copy of the e-mail.

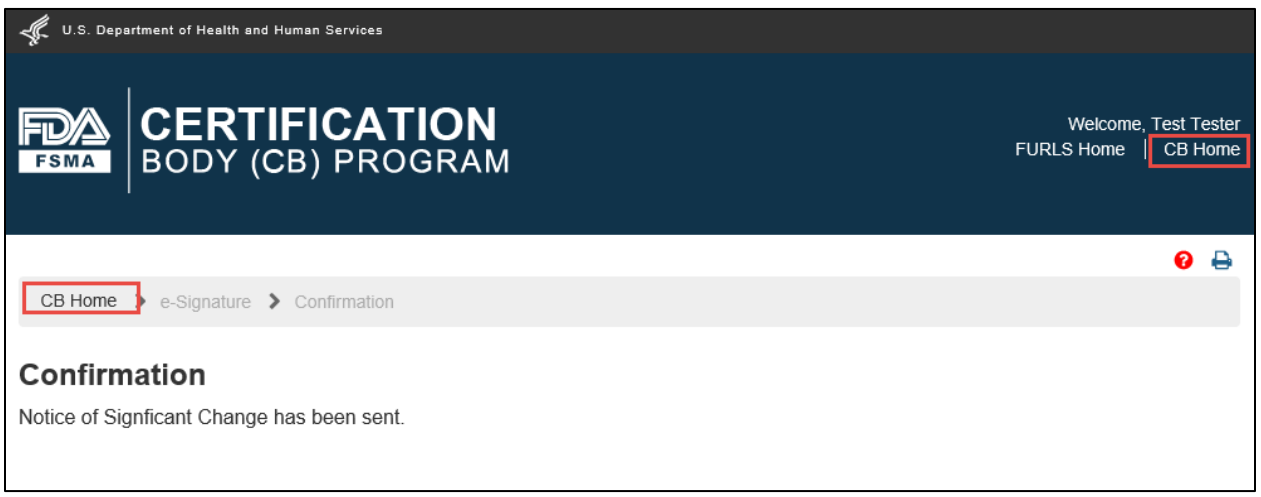
Note: The image (below) only depicts the e-mail notification text.

Figure 9.9 – E-mail Confirmation



Click the “CB Home” link on the top of the banner (or from the breadcrumb) to return to “CB Home” page (Figure 9.10).

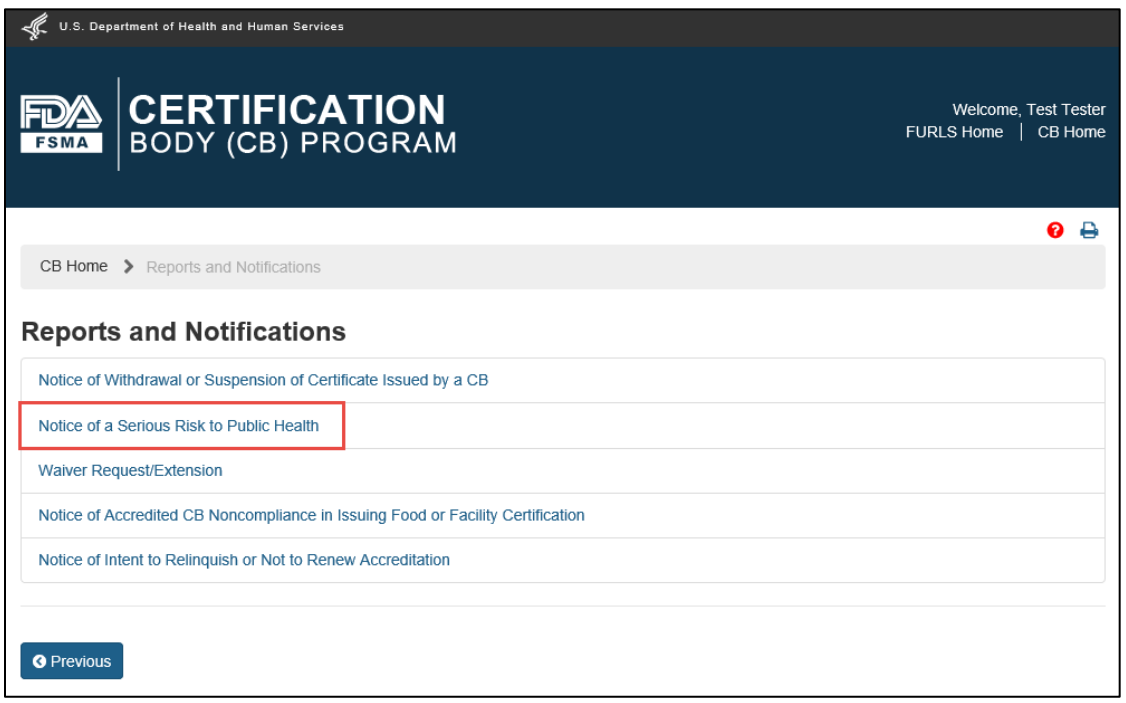
Figure 9.10 – Links to CB Home Page



9.2 Notice of Serious Risk to Public Health

To notify FDA of a condition discovered during a consultative or regulatory audit that could cause or contribute to a serious risk to public health, click the “Notice of a Serious Risk to Public Health” link on the “Reports and Notifications” page (Figure 9.11).

Figure 9.11 – Reports and Notifications Page



The system will display the “Notice of Serious Risk to Public Health” page (Figure 9.12).

Figure 9.12 – Notice of Serious Risk to Public Health Page

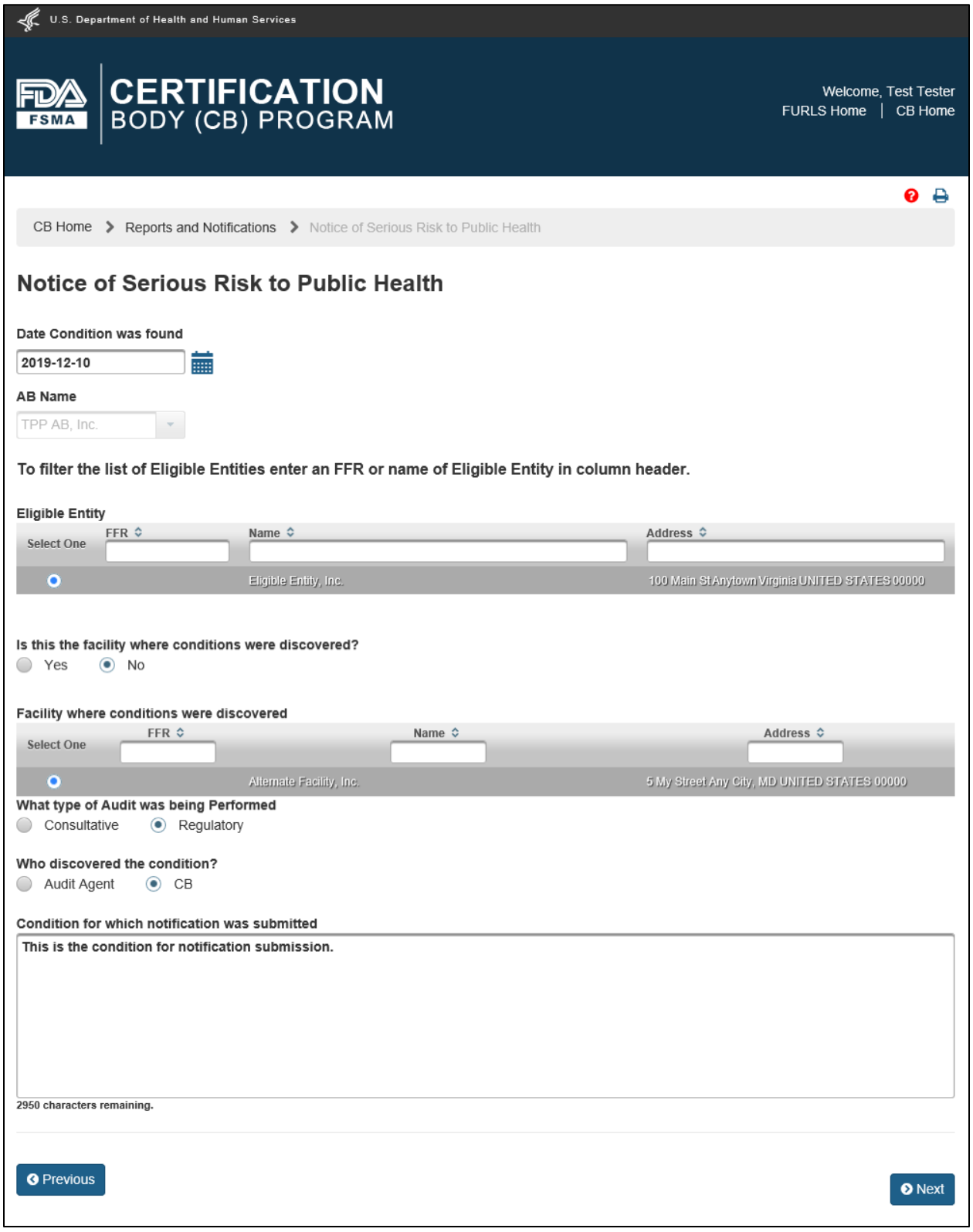
Complete the following data fields (Figure 9.13):

- **Date Condition was found –** Select the date the condition that could cause or contribute to a serious risk to public health was discovered during a consultative or regulatory audit from the calendar icon or enter the date in "YYYY-MM-DD" format.
- **AB Name –** Select the name of the AB from the dropdown menu. If you are accredited by more than one AB, select the AB who accredited you for the scope(s) covered in the consultative or regulatory audit.
  Note: If you have only been accredited by one AB, the "AB Name" field will be pre-filled once the "Audit Start Date" has been selected or entered.
- **To filter the list of Eligible Entities, enter an FFR Number or name of Eligible Entity in column header –** In the "Eligible Entity" table, select the eligible entity by clicking its radio button in the "Select One" column. The system will display the list of facilities which have a submitted certification; you may select from that list to indicate at which facility the conditions were discovered.
- **Is this the facility where the condition was discovered? –** The system will display this question once you have selected the Eligible Entity, "Yes" or "No."
  - If you select "Yes," proceed to **"What type of audit was being performed?"**
  - If you select "No," the **"Facility where conditions were discovered"** table appears (Figure 9.13). Select the facility by clicking its radio button.
    Note: You may filter the list of facilities by entering an FFR or name of facility in column header.
- **What type of audit was being performed –** Select "Consultative" or "Regulatory" by clicking the radio button to the left of the text.
- **Who discovered the condition? –** Select "Audit Agent" or "CB" by clicking the radio button to the left of the text.
- **Condition for which notification was submitted –** Describe the condition(s) in the text entry field, which allows a maximum of 3,000 characters.

Click the "Previous" button at the bottom of the page if you wish to return to the "Reports and Notifications" page and start over.

Click the "Next" button at the bottom of the page to proceed to the "e-Signature" page.

Figure 9.13 – Notice of Serious Risk to Public Health Page



Follow the directions provided on the “e-Signature” page (Figure 9.14).

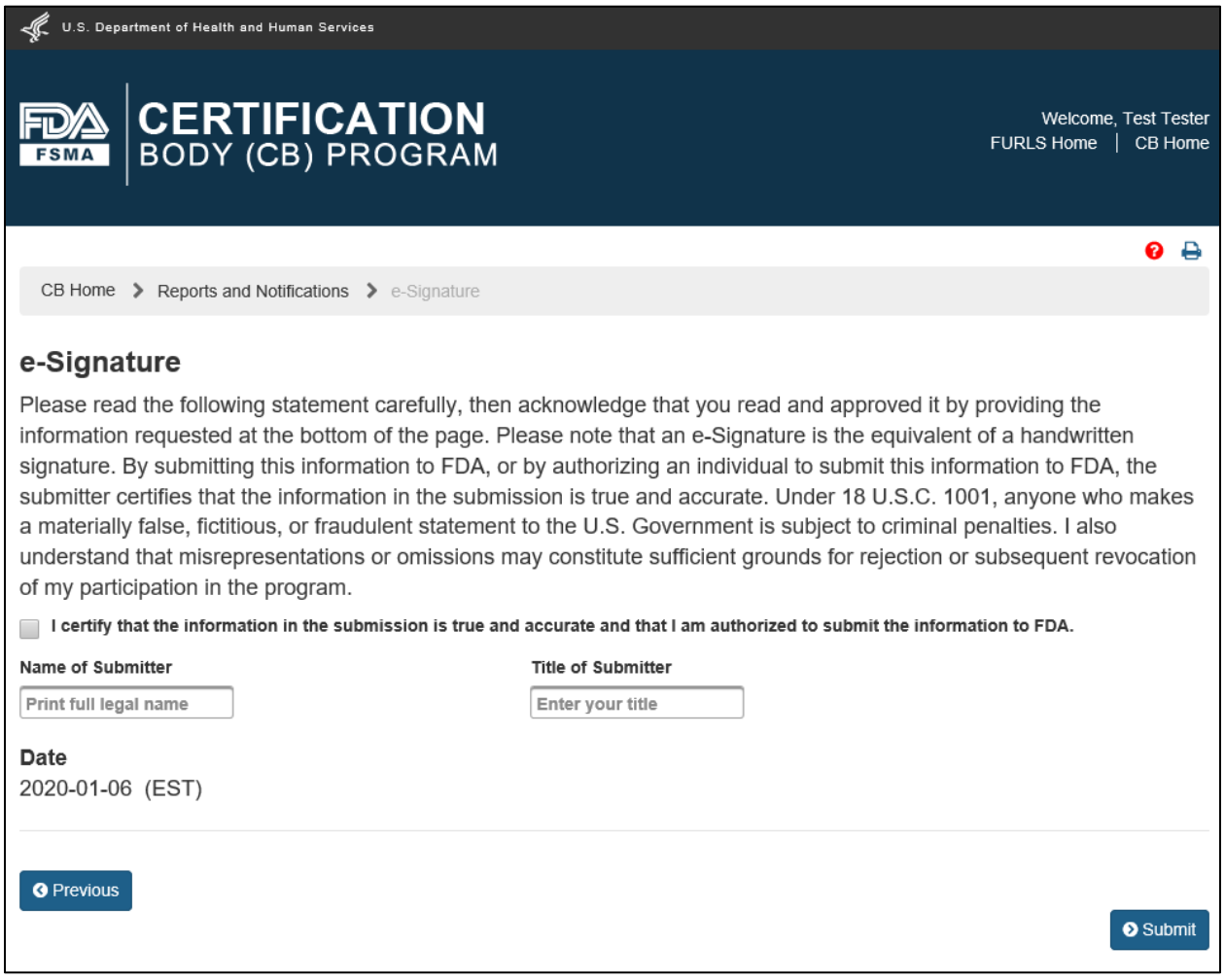
Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

Click the “Previous” button if you wish to return to the “Notice of Serious Risk to Public Health” page.

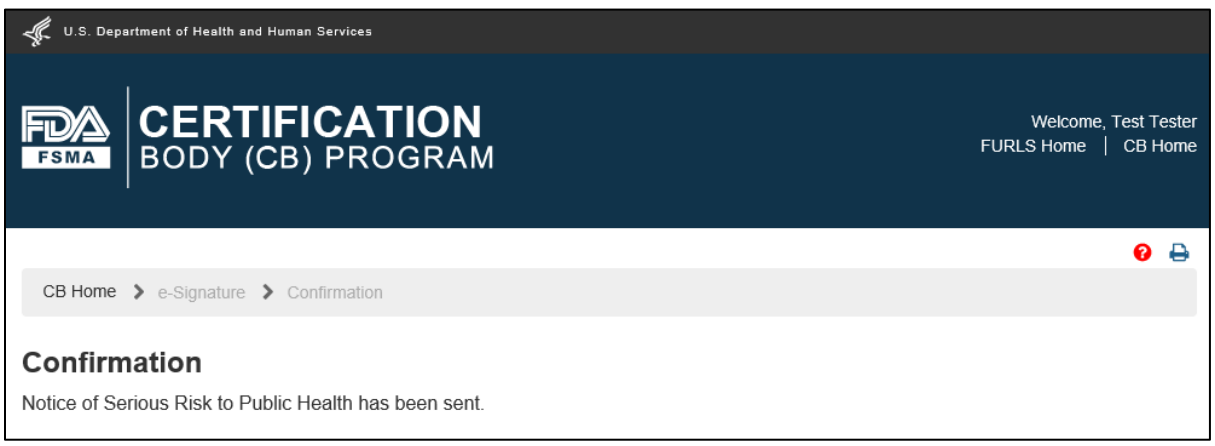
Click the “Submit” button to complete submission of the notice.

Figure 9.14 – e-Signature Page



After you click the “Submit” button the system will display the “Confirmation” page, indicating the notification has been sent to FDA (Figure 9.15).

Figure 9.15 – Confirmation Page



The system will send you an e-mail indicating the notice was received by FDA (Figure 9.16). The AB you selected in the notice will receive a copy of the e-mail.

Note: The image (below) only depicts the e-mail notification text.

Figure 9.16 – E-mail Confirmation

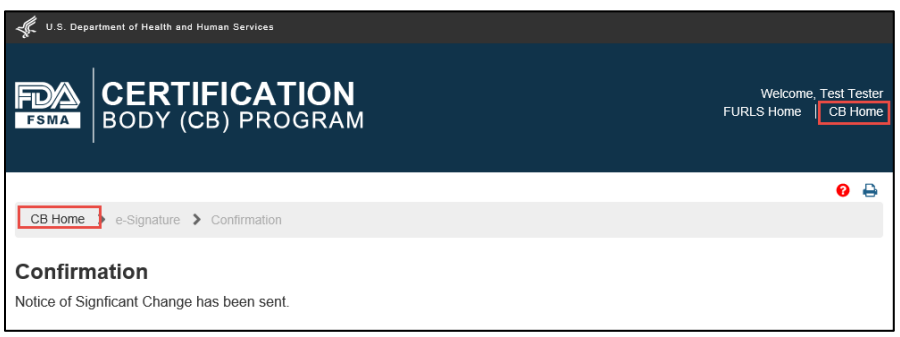
Thank you for submitting information to FDA regarding Notice of Serious Risk to Public Health. We will review this information and may follow-up if additional information is needed.

Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

Click the “CB Home” link on the top of the banner (or from the breadcrumb) to return to “CB Home” page (Figure 9.17).

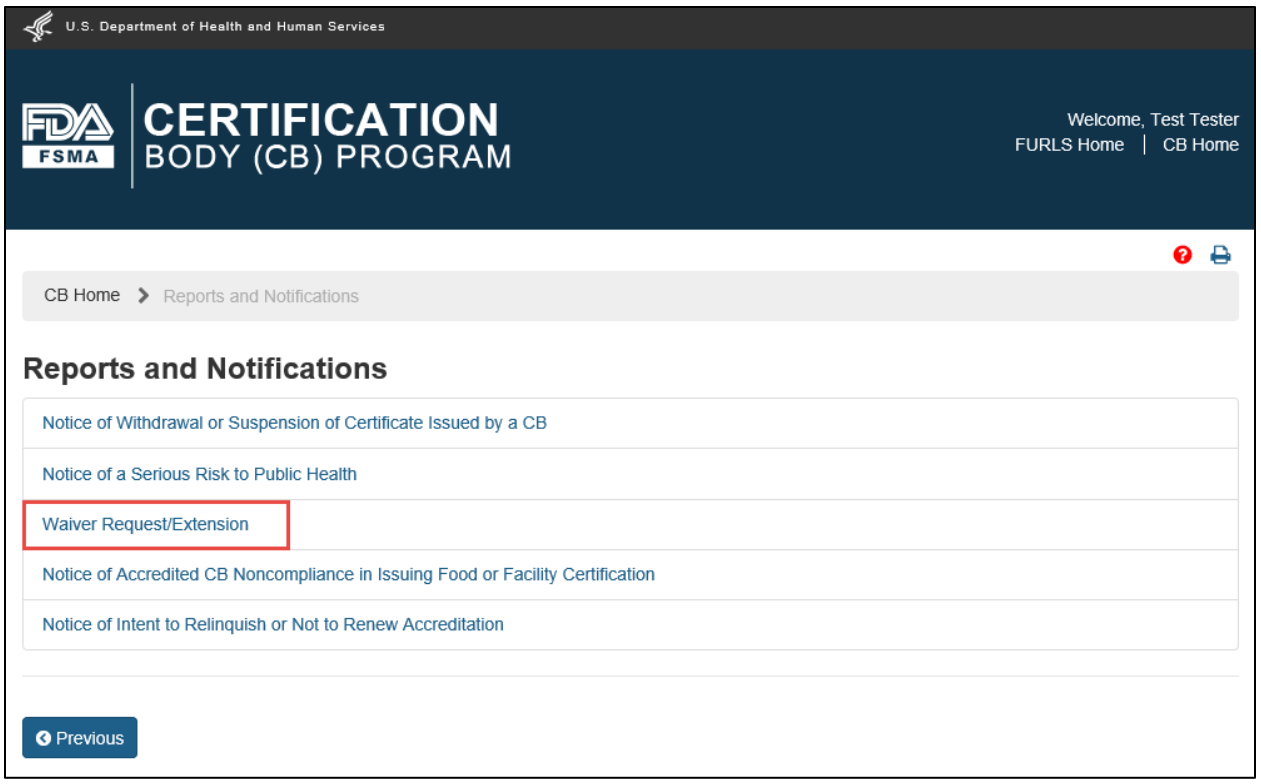
Figure 9.17 – Links to CB Home Page



9.3 Waiver Request/Extension

To request that FDA waive the requirement that limits an audit agent from conducting a regulatory audit of an eligible entity if the audit agent has conducted a consultative or regulatory audit of the same eligible entity during the preceding 13 months, click the “Waiver Request/Extension” link on the “Reports and Notifications” page (Figure 9.18).

Figure 9.18 – Reports and Notifications Page

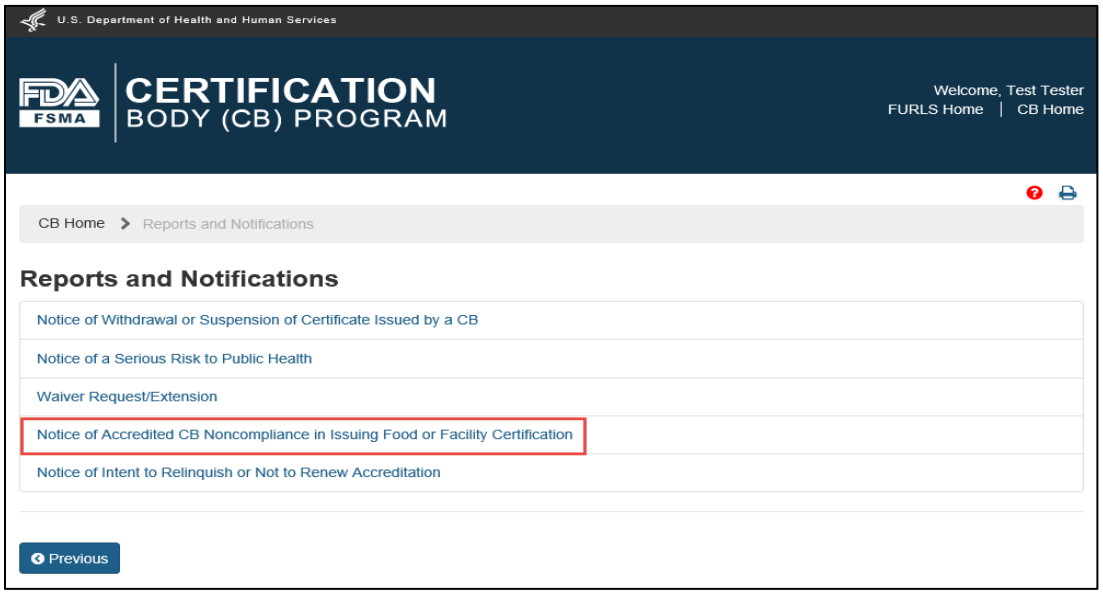


If you have questions about completing the data entry fields or the process for submitting this information, please contact us at FDAthirdpartyprogram@fda.hhs.gov.

9.4 Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

To notify FDA of a failure to comply with the regulation in issuing a food or facility certification, click the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” link on the “Reports and Notifications” page (Figure 9.19).

Figure 9.19 – Reports and Notifications Page

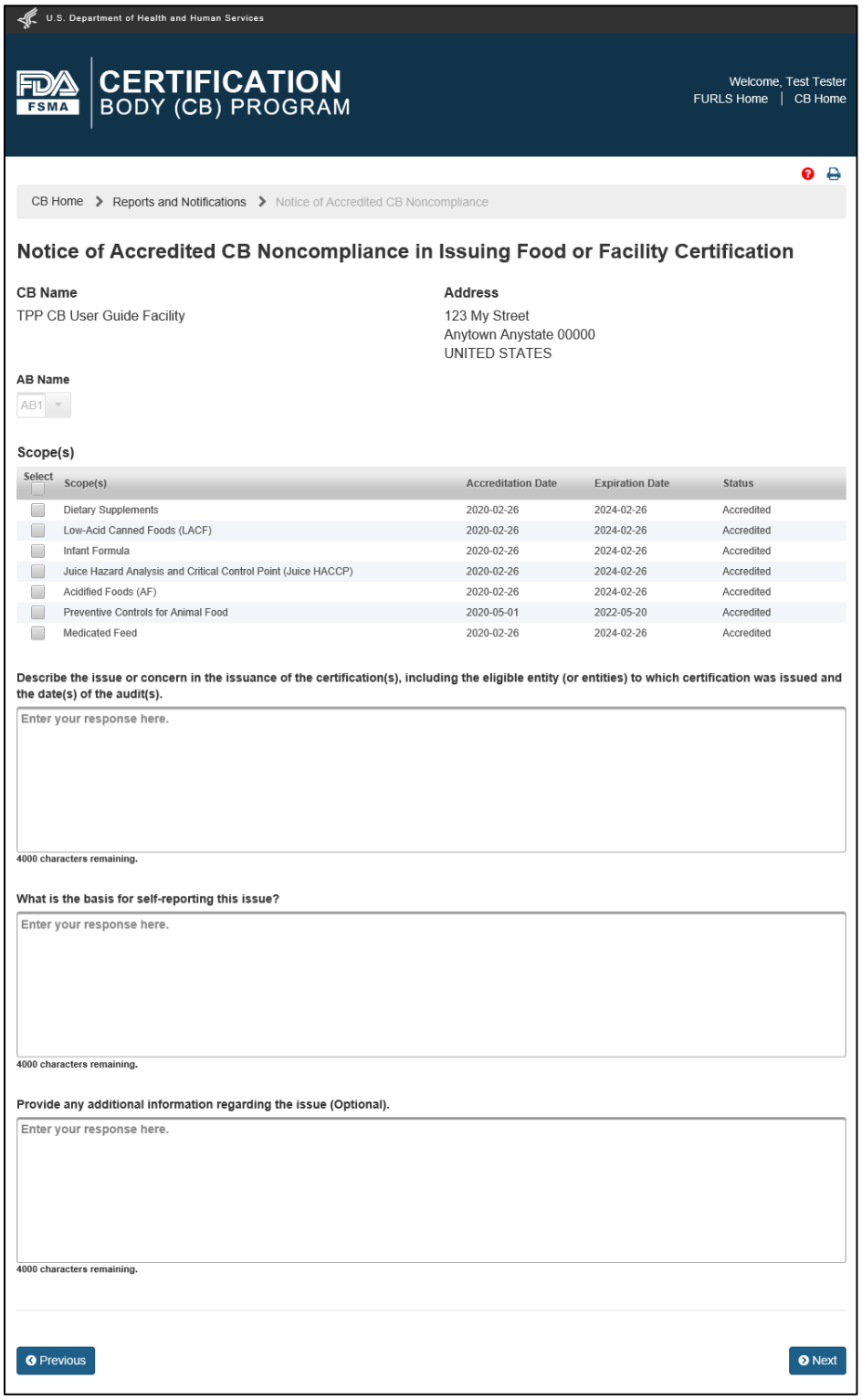


The system will display the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” page with the “CB Name” and “Address” information as read-only (Figure 9.20).

Complete the following data fields:

- **AB Name –** Select the name of the AB from the dropdown menu. If you are accredited by more than one AB, select the AB who accredited you for the scope(s) covered in the certification pertaining to the notice.
  Note: The “AB Name” field will be pre-filled if you have only been accredited by one AB.
- **Scope(s) –** Click the checkbox of the applicable scope(s).
- **Describe the issue or concern in the issuance of the certification(s), including the eligible entity (or entities) to which certification was issued and the date(s) of the audit(s). –** Enter the response in the text entry field, which allows a maximum of 4,000 characters.
- **What is the basis for self-reporting this issue? –** Enter the response in the text entry field, which allows a maximum of 4,000 characters.
- **Provide any additional information regarding the issue (Optional).** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.

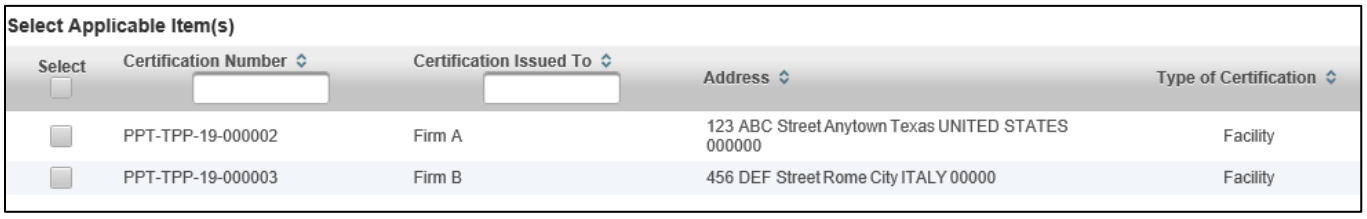
Figure 9.20 – Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification Page



Once you have selected the applicable scope(s), the system will display the “Select Applicable Item(s)” table at the bottom of the page (Figure 9.21).

Select the certificate(s) you would like to include in the notice to FDA by clicking the checkbox in the “Select” column in the table.

Figure 9.21 – Select Applicable Item(s) Table


Select Applicable Item(s)

Select	Certification Number	Certification Issued To	Address	Type of Certification
☐	PPT-TPP-19-000002	Firm A	123 ABC Street Anytown Texas UNITED STATES 000000	Facility
☐	PPT-TPP-19-000003	Firm B	456 DEF Street Rome City ITALY 00000	Facility

Click the “Previous” button at the bottom of the page if you wish to return to the “Reports and Notifications” page and start over.

Click the “Next” button at the bottom of the page to proceed to the “e-Signature” page.

Follow the directions provided on the “e-Signature” page (Figure 9.22).

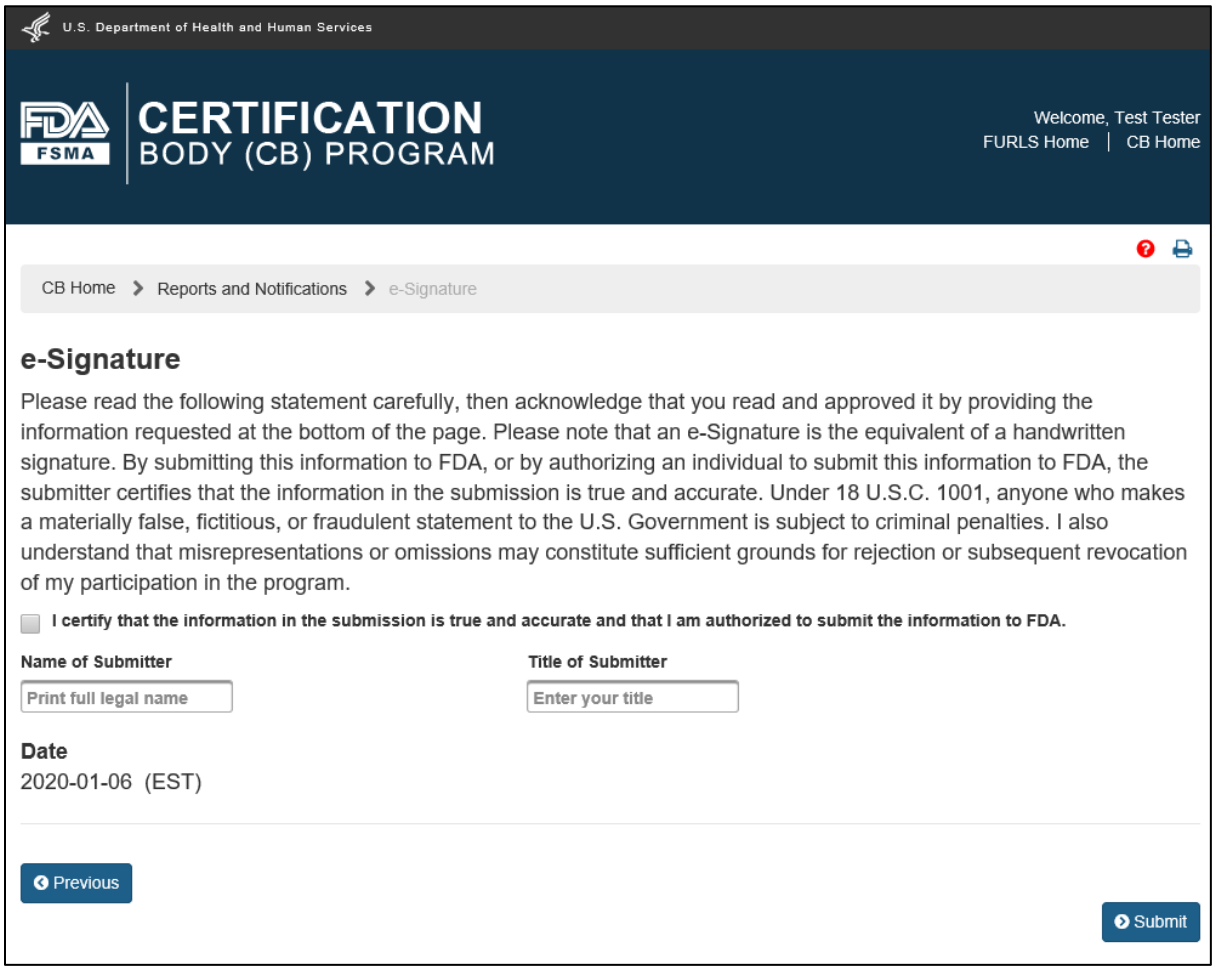
Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

Click the “Previous” button if you wish to return to the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” page.

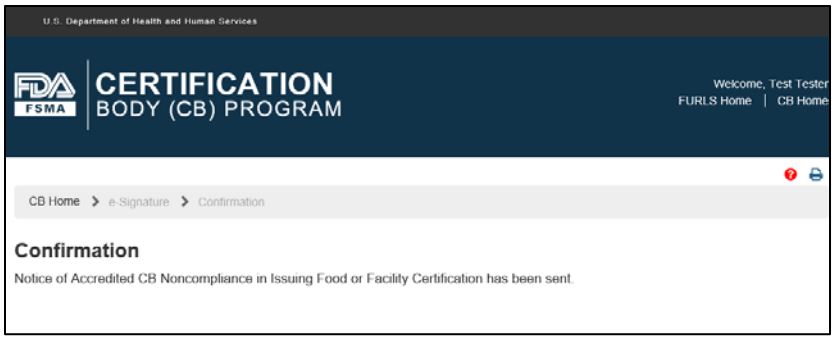
Click the “Submit” button to complete submission of the notice.

Figure 9.22 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page, indicating the notification has been sent to FDA (Figure 9.23).

Figure 9.23 – Confirmation Page



The system will send you an e-mail indicating the notice was received by FDA (Figure 9.24). The AB you selected in the notice will receive a copy of the e-mail.

Note: The image (below) only depicts the e-mail notification text.

Figure 9.24 – E-mail Confirmation

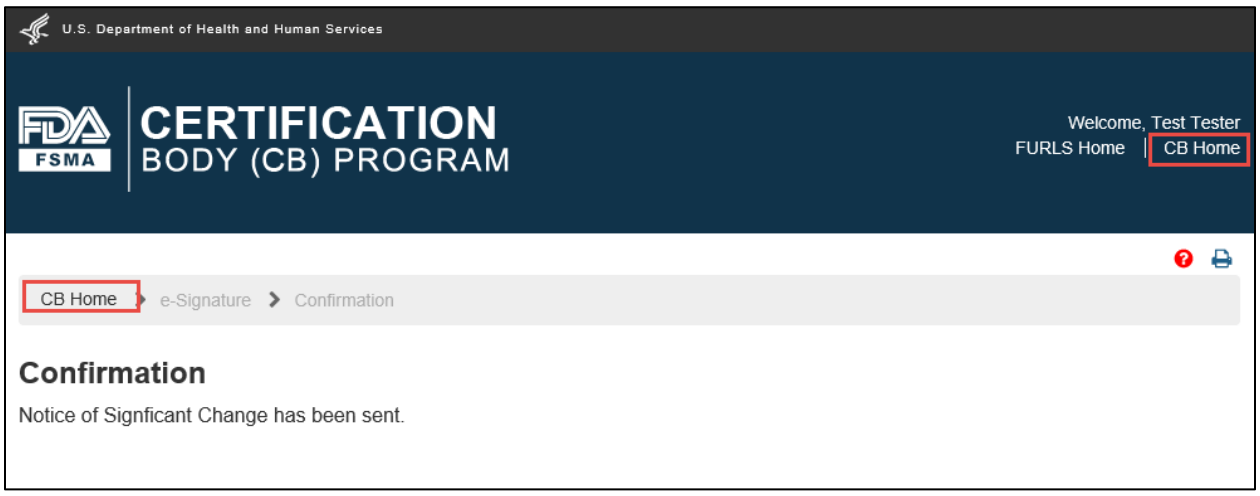
Thank you for submitting information to FDA regarding Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification. We will review this information and may follow-up if additional information is needed.

Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

Click the “CB Home” link on the top of the banner (or from the breadcrumb) to return to “CB Home” page (Figure 9.25).

Figure 9.25 – Links to CB Home Page

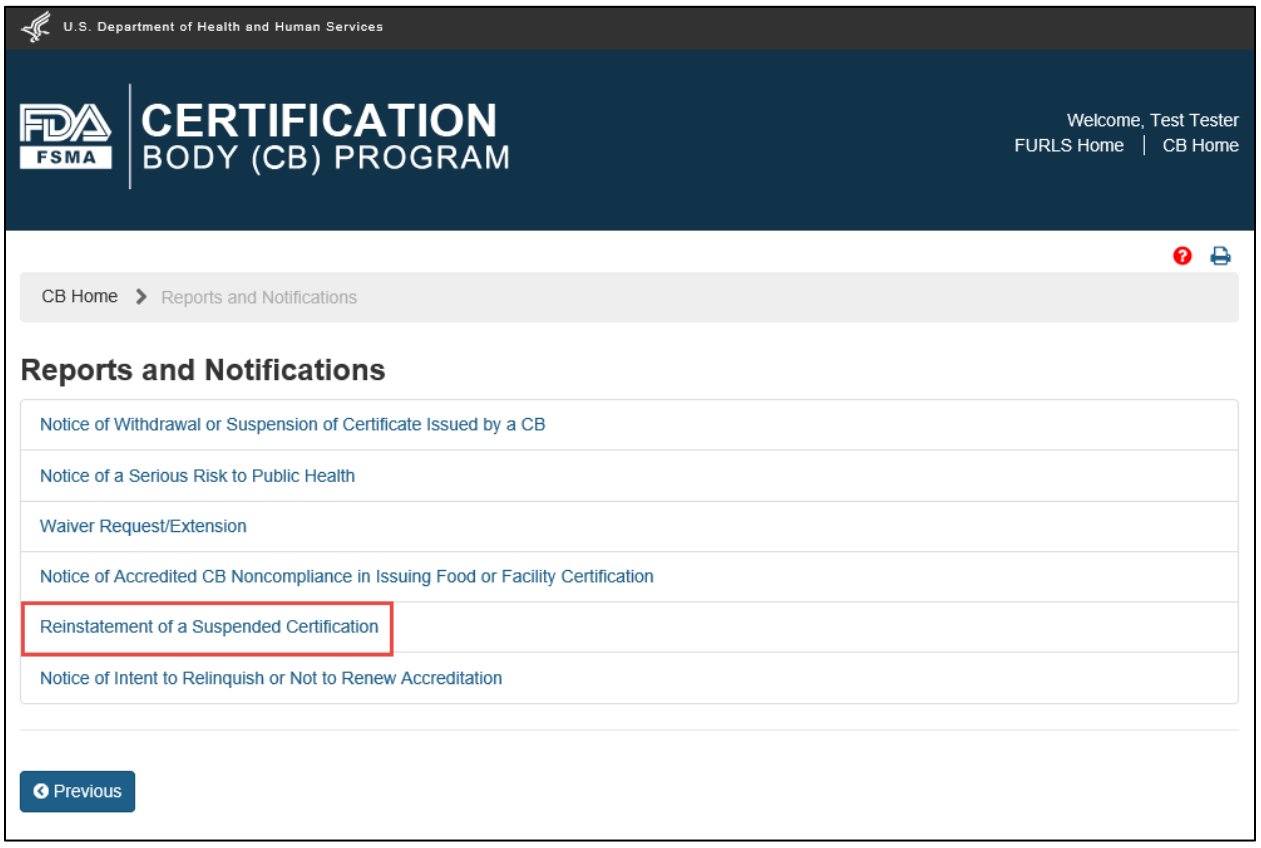


9.5 Reinstatement of a Suspended Certification

To notify FDA of the reinstatement of a suspended certification, click the “Reinstatement of a Suspended Certification” link on the “Reports and Notifications” page (Figure 9.26).

Note: This notice is only displayed on the “Reports and Notifications” page if you have suspended at least one food or facility certification of an eligible entity.

Figure 9.26 – Reports and Notifications Page

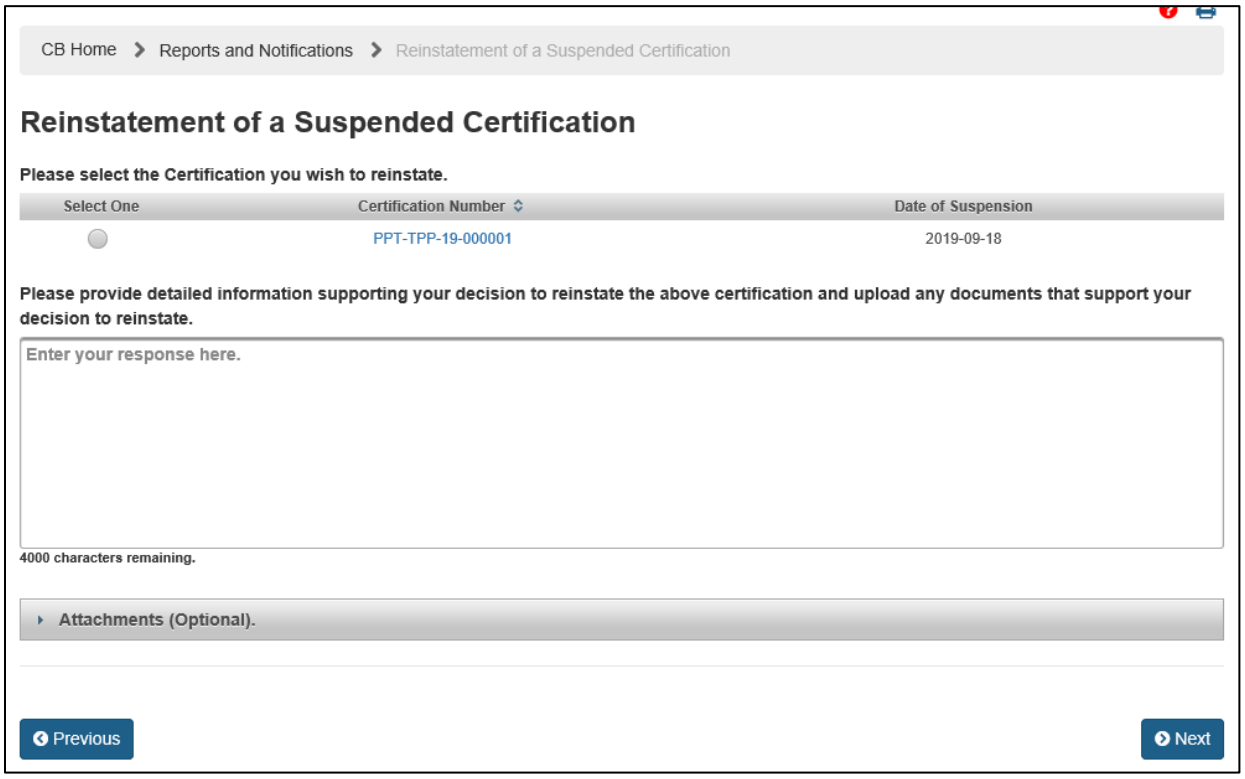


The system will display the “Reinstatement of a Suspended Certification” page (Figure 9.27).

Complete the following data fields:

- **Please select the Certification you wish to reinstate. –** Select the suspended certification by clicking its radio button in the “Select One” column.
- **Please provide detailed information supporting your decision to reinstate the above certification and upload any documents that support your decision to reinstate. –** Enter a response in the text entry field, which allows a maximum of 4,000 characters.

Figure 9.27 – Reinstatement of a Suspended Certification Page

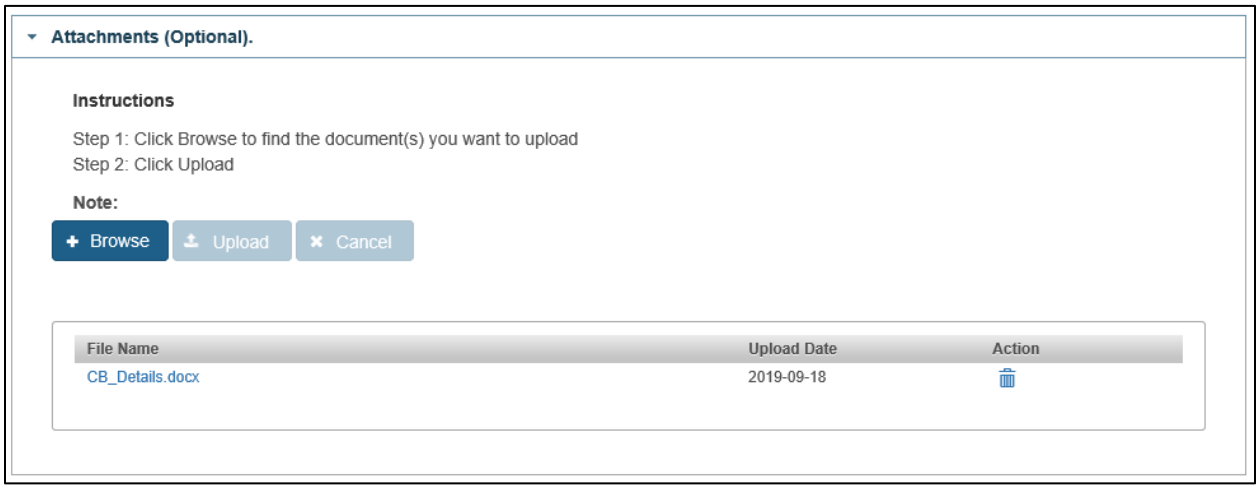


To upload documents to your notice, use the “Attachments (Optional)” section (Figure 9.28).

Follow Steps 1 - 4 (listed below) to upload attachments.

1. Click the “Browse” button and choose the file to upload.
2. The “Upload” and “Cancel” buttons will be enabled after a file has been chosen.
    - Click the “Cancel” button to discard the upload of the attachment.
    - Click the “Upload” button to complete the upload of the attachment.
3. Once the upload is complete a confirmation message with the file name will display at the top of the page. The attachment details will display in a table.
4. To remove the attachment, click the trash/delete icon in the “Action” column.

Figure 9.28 – Attachments (Optional) Section



Repeat the previous steps to upload additional attachments.

Click the “Previous” button at the bottom of the page if you wish to return to the “Reports and Notifications” page and start over.

Click the “Next” button at the bottom of the page to proceed to the “e-Signature” page.

Follow the directions provided on the “e-Signature” page (Figure 9.29).

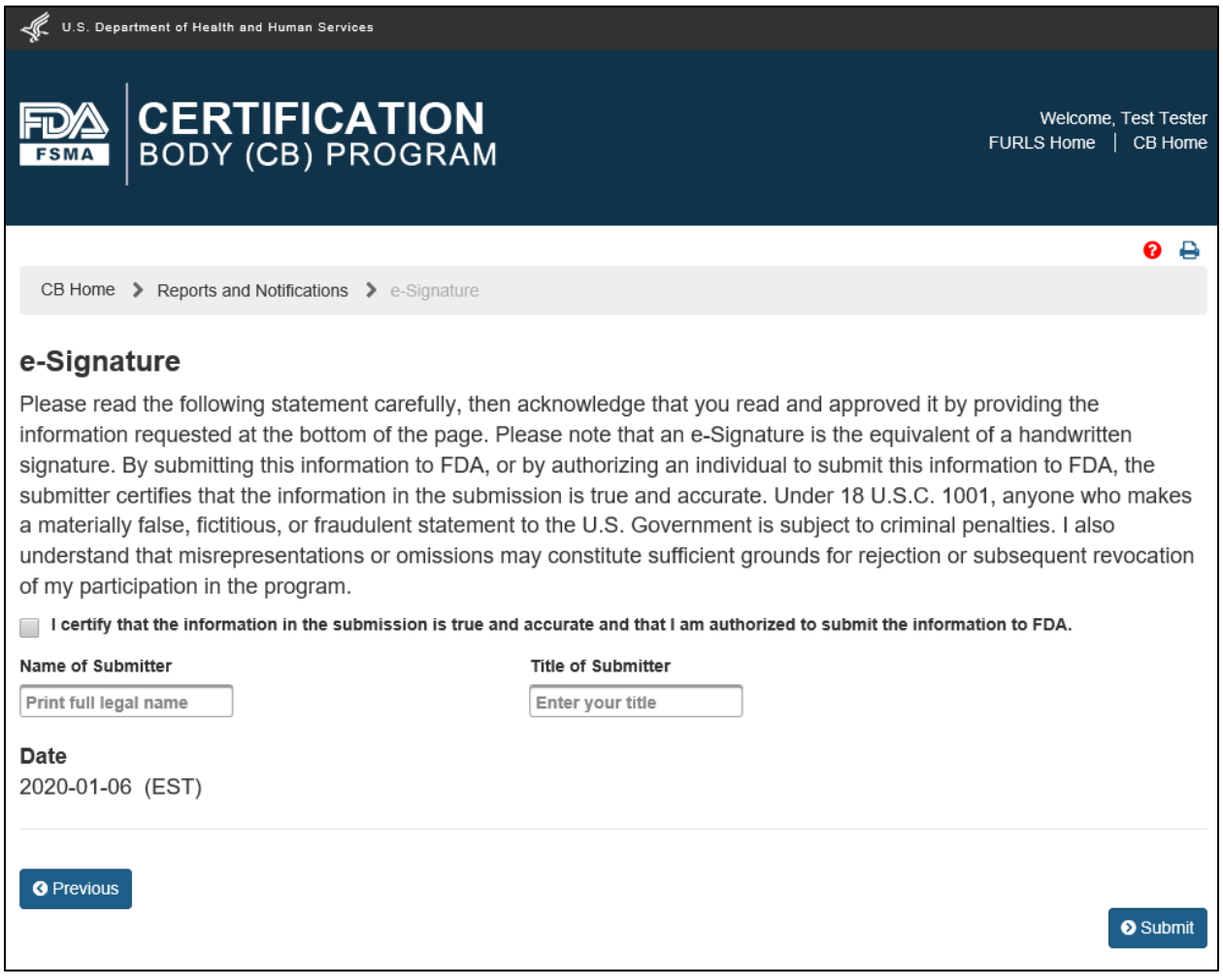
Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

Click the “Previous” button if you wish to return to the “Reinstatement of a Suspended Certification” page.

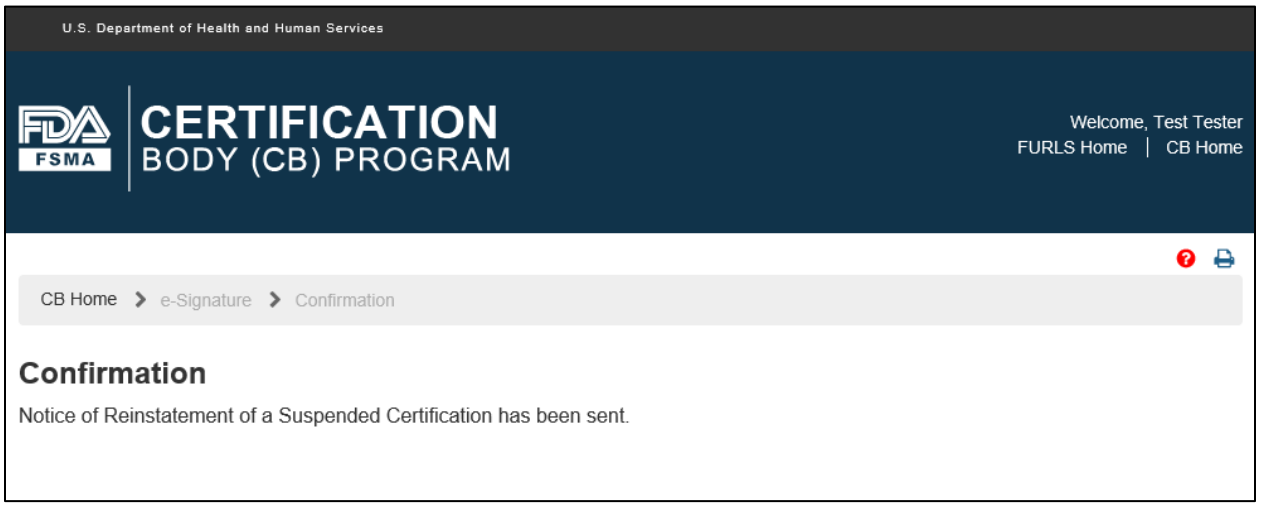
Click the “Submit” button to complete submission of the notice.

Figure 9.29 – e-Signature Page



After you click the “Submit” button the system will display the “Confirmation” page, indicating the notification has been sent to FDA (Figure 9.30).

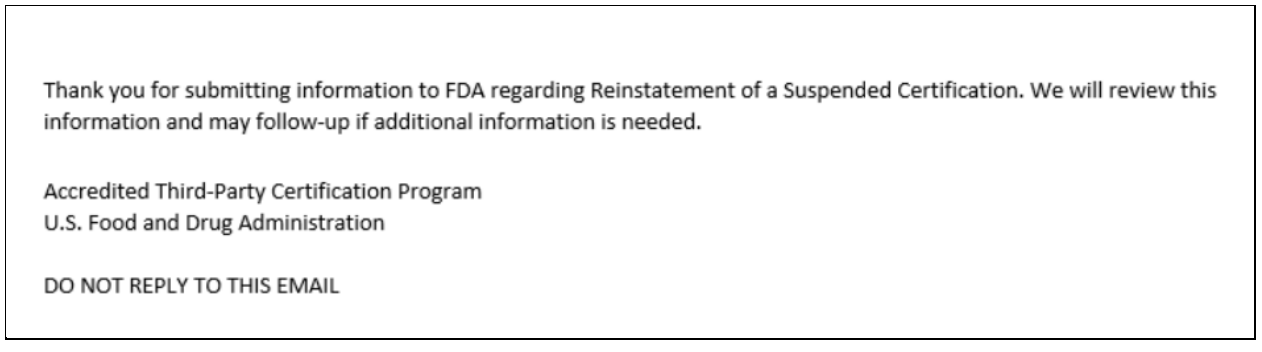
Figure 9.30 – Confirmation Page



The system will send you an e-mail indicating the notice was received by FDA (Figure 9.31). The AB you selected in the corresponding “Notice of Withdrawal or Suspension of Certificate Issued by a CB” will receive a copy of the e-mail.

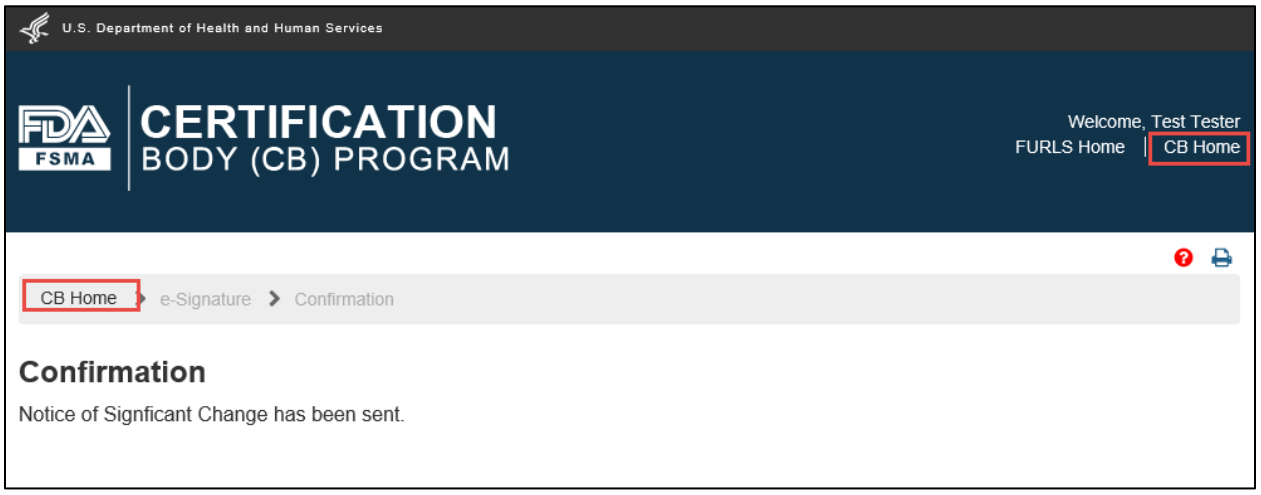
Note: The image (below) only depicts the e-mail notification text.

Figure 9.31 – E-mail Confirmation



Click the “CB Home” link on the top of the banner (or from the breadcrumb) to return to “CB Home” page (Figure 9.32).

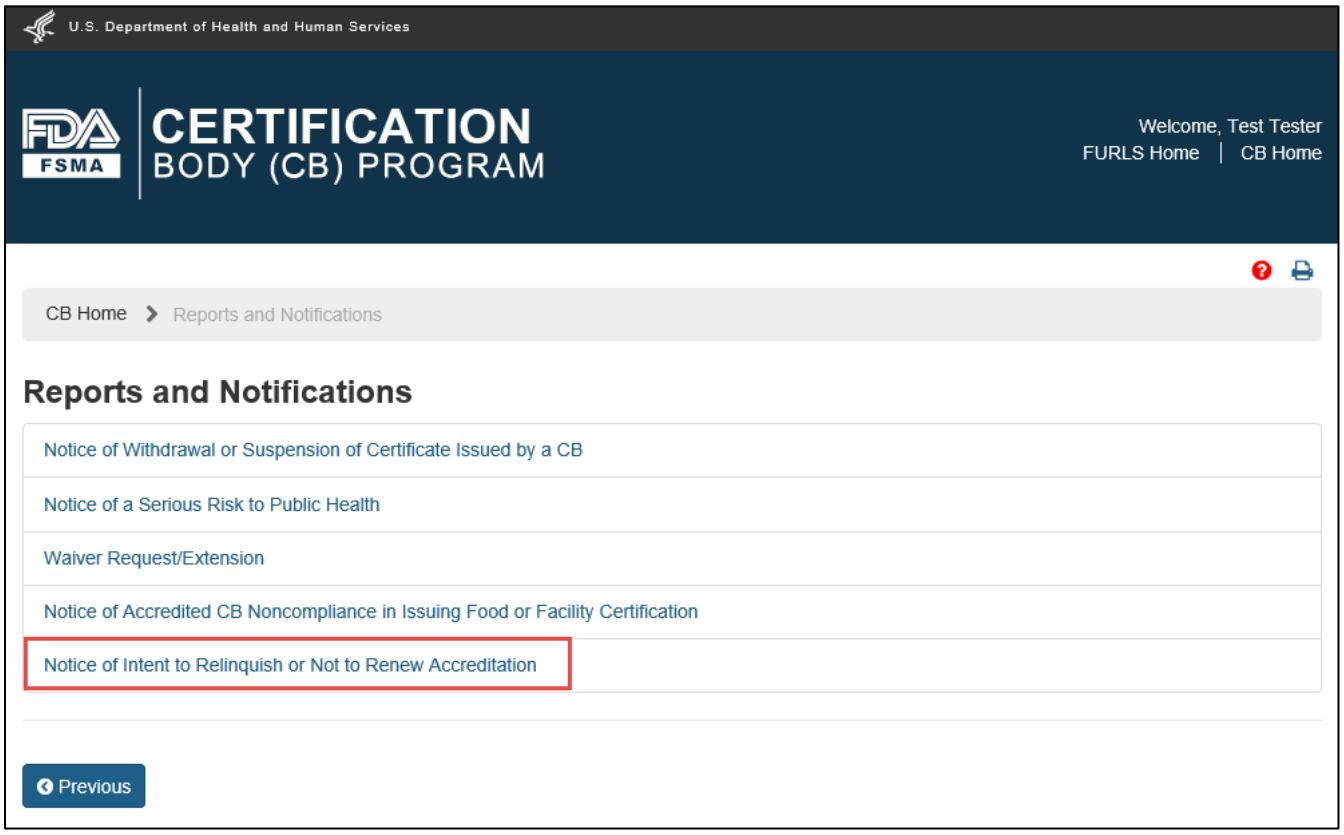
Figure 9.32 – Links to CB Home Page



9.6 Notice of Intent to Relinquish or Not to Renew Accreditation

To notify FDA at least 60 days before voluntarily relinquishing accreditation or before allowing accreditation to expire without seeking renewal, click the “Notice of Intent to Relinquish or Not to Renew Accreditation” link on the “Reports and Notifications” page (Figure 9.33).

Figure 9.33 – Reports and Notifications Page



The system will display the “Notice of Intent to Relinquish or Not to Renew Accreditation” page (Figure 9.34).

The system will display the following data fields:

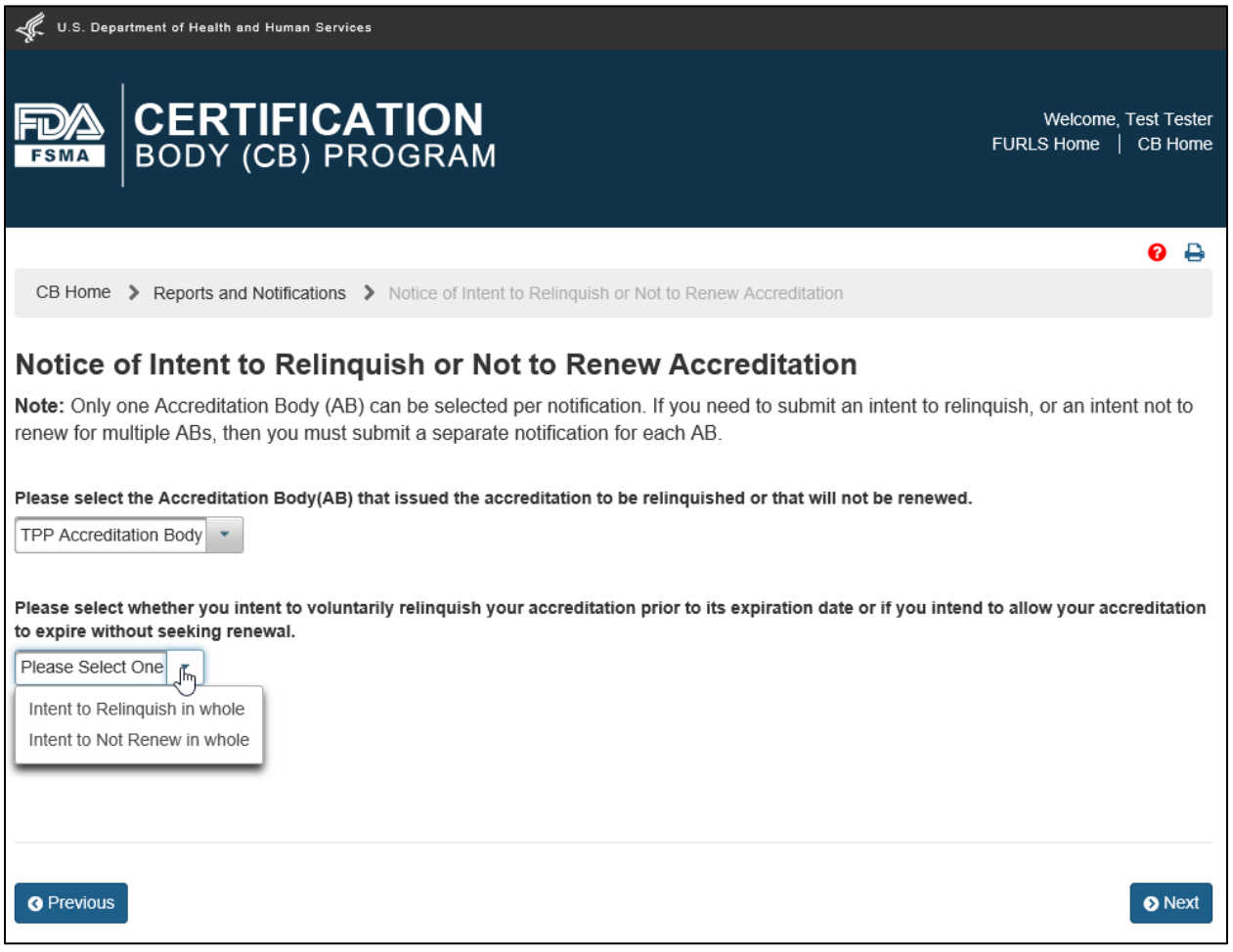
- **Please select the Accreditation Body (AB) that issued the accreditation to be relinquished or that will not be renewed. –** Select the name of the AB from the dropdown menu.

  Note: The AB selection will be pre-filled if you are only accredited by one AB.

The following question will display after you have selected the AB (or after the system has pre-filled the AB):

- **Please select whether you intend to voluntarily relinquish your accreditation prior to its expiration date or if you intend to allow your accreditation to expire without seeking renewal. –** The system displays a dropdown menu with the choices to “Intent to Relinquish in whole” or “Intent to Not Renew in whole.”

Figure 9.34 – Notice of Intent to Relinquish or Not to Renew Accreditation Page



If you select “Intent to Relinquish in whole” proceed to Section 9.6.1 of this chapter.

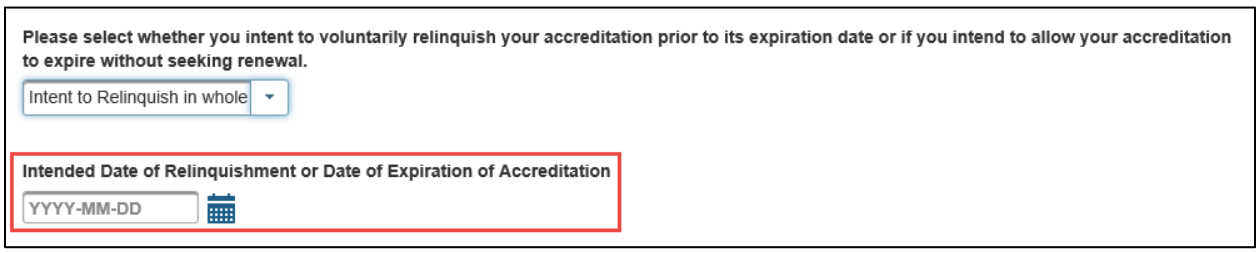
If you select “Intent to Not Renew in whole” proceed to Section 9.6.2 of this chapter.

9.6.1 Intent to Relinquish in Whole

Once you have selected “Intent to Relinquish in whole” the system will display additional data fields (Figure 9.35):

- **Intended Date of Relinquishment or Date of Expiration of Accreditation –** Select the date of relinquishment with the calendar icon or enter it in “YYYY-MM-DD” format. The date of relinquishment must be a future date and cannot be greater than the maximum expiration date of the scope(s) for which you are accredited.

Figure 9.35 – Intent to Relinquish in Whole



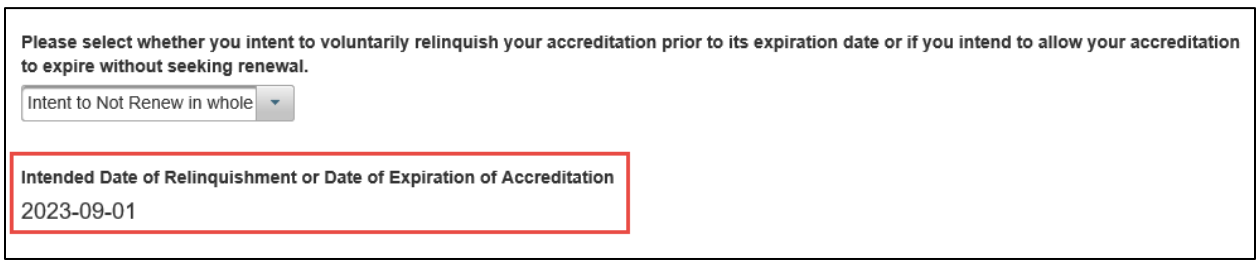
Proceed to Section 9.6.3 of this chapter.

9.6.2 Intent to Not Renew in Whole

Once you have selected “Intent to Not Renew in Whole,” the system will display additional data fields (Figure 9.36):

- **Intended Date of Relinquishment or Date of Expiration of Accreditation –** The date will be pre-filled and read-only, based on the maximum expiration date of the scope(s) for which you are accredited by the selected AB.

Figure 9.36 – Intent to Not Renew in Whole



Proceed to Section 9.6.3 of this chapter.

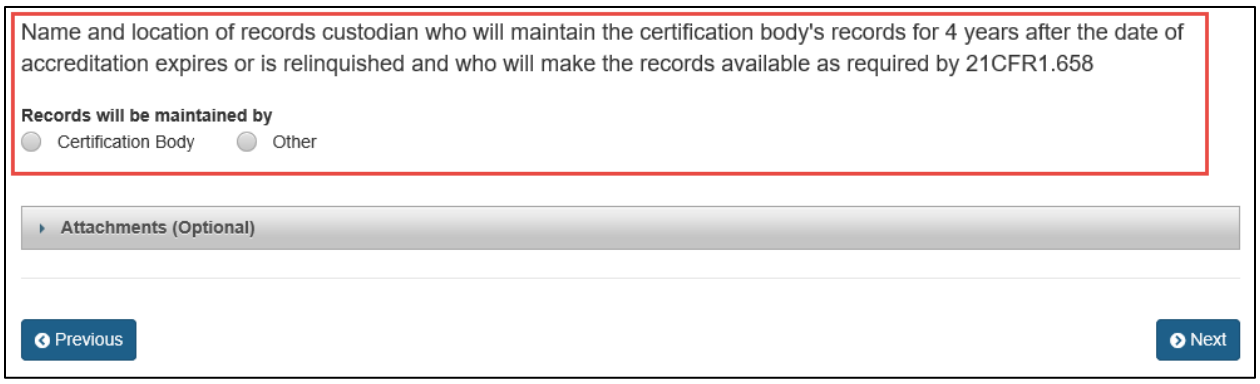
9.6.3 Records Custodian and Attachments

Once you select “Intent to Not Renew in whole” or “Intent to Relinquish in whole” from the list, the system will display the “Records maintained by” field with the following two options (Figure 9.37):

- **Certification Body –** Select this option if you will maintain your records for four years following the date of expiration of accreditation or effective date of relinquishment. Select “Certification Body” by clicking its radio button to display your read-only contact information.
- **Other –** Select this option if someone other than you will maintain your records for four years following the date of expiration of accreditation or effective date of relinquishment. Select “Other” by clicking its radio button to display fields to enter the contact information for the designated records custodian.

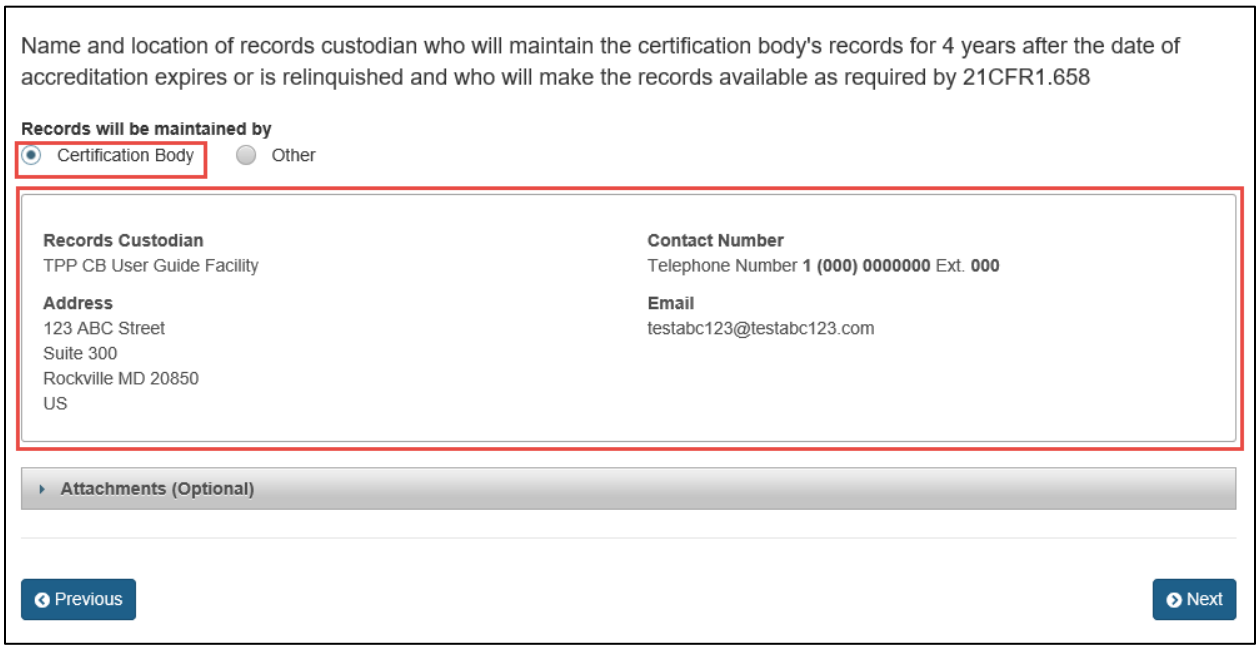
Click the radio button to the left of your selection for “Records will be maintained by.”

Figure 9.37 – “Records Will Be Maintained By” Options



If you select “Certification Body” the system will display your read-only contact information (Figure 9.38).

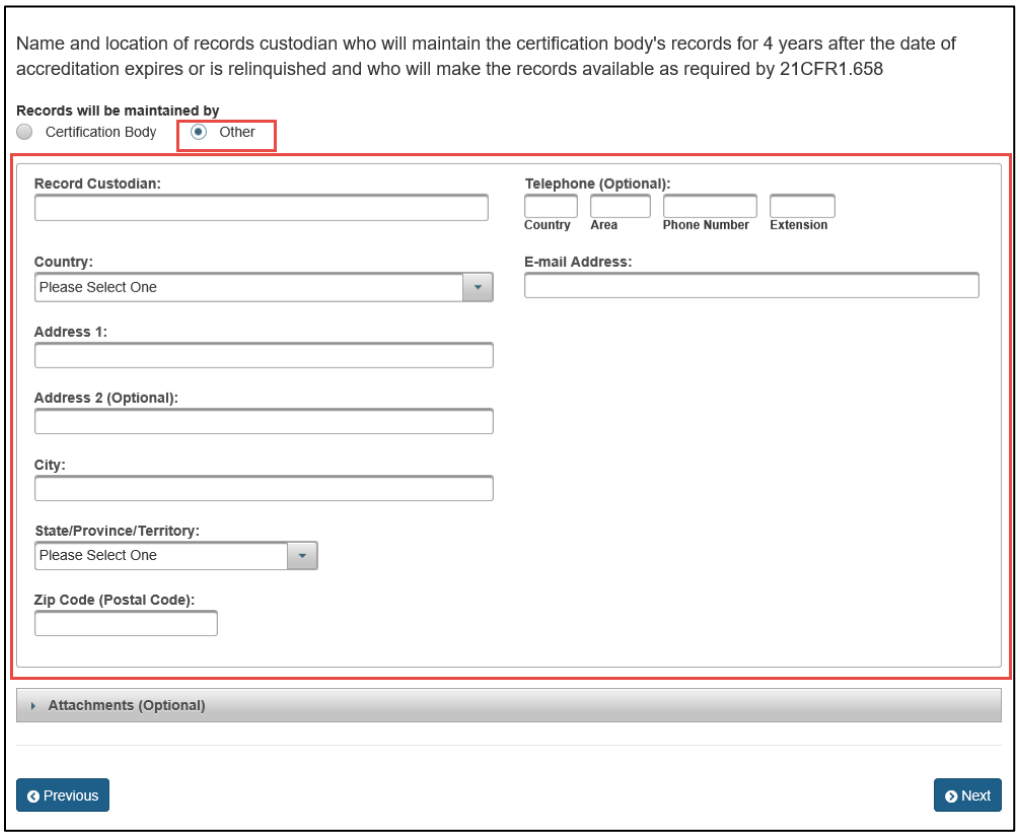
Figure 9.38 – Records Will Be Maintained by Certification Body



If you select “Other,” the system will display the following data fields that you must complete (Figure 9.39):

- **Records Custodian –** The name of the person responsible for maintaining the records
- **Country –** The country where the records will be physically located
- **Address 1 –** The street address where the records will be physically located
- **Address 2 (Optional) –** The additional information about the physical location of the records (this may include a suite or apartment number, if applicable)
- **City –** The city where the records will be physically located
- **State/Province/Territory –** The state/province/territory where the records will be physically located
- **Zip Code (Postal Code) –** The postal code where the records will be physically located
- **Telephone (Optional)**
    - **Country –** The country code of the Records Custodian
    - **Area –** The area code of the Records Custodian
    - **Phone Number –** The phone number of the Records Custodian
    - **Extension –** The extension number of the Records Custodian
- **E-mail Address –** The e-mail address of the Records Custodian

Figure 9.39 – Records will be Maintained by Other



To upload documents to your notice, use the “Attachments (Optional)” section (Figure 9.40).

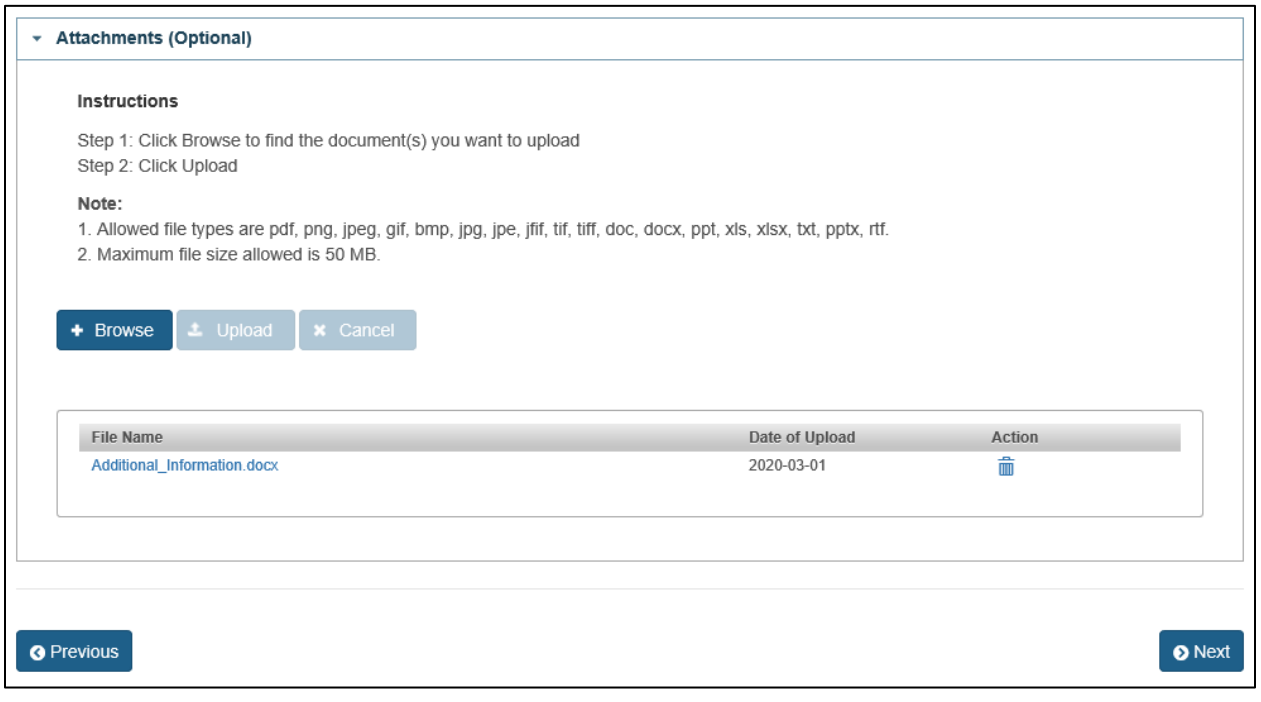
Follow Steps 1 - 4 (listed below) to upload attachments.

1. Click the “Browse” button and choose the file to upload.
2. The “Upload” and “Cancel” buttons will be enabled after a file has been chosen.
    - Click the “Cancel” button to discard the upload of the attachment.
    - Click the “Upload” button to complete the upload of the attachment.
3. Once the upload is complete, a confirmation message with the file name will display at the top of the page. The attachment details will display in a table.
4. To remove the attachment, click the trash/delete icon in the “Action” column.

Note: The system supports the following document types: .pdf; .png; .jpeg; .gif; .bmp; .jpg; .jpe; jfif; .tif; .tiff; .doc; .docx; .ppt; .xls; .xlsx; .txt; .pptx; or .rtf.

The maximum file size allowed is 50 MB.

Figure 9.40 – Attachments (Optional) Section



Repeat the previous steps to upload additional attachments.

Click the “Previous” button if you wish to return to the “Reports and Notifications” page and start over.

Click the “Next” button at the bottom of the page to proceed to the “e-Signature” page.

Follow the directions provided on the “e-Signature” page (Figure 9.41).

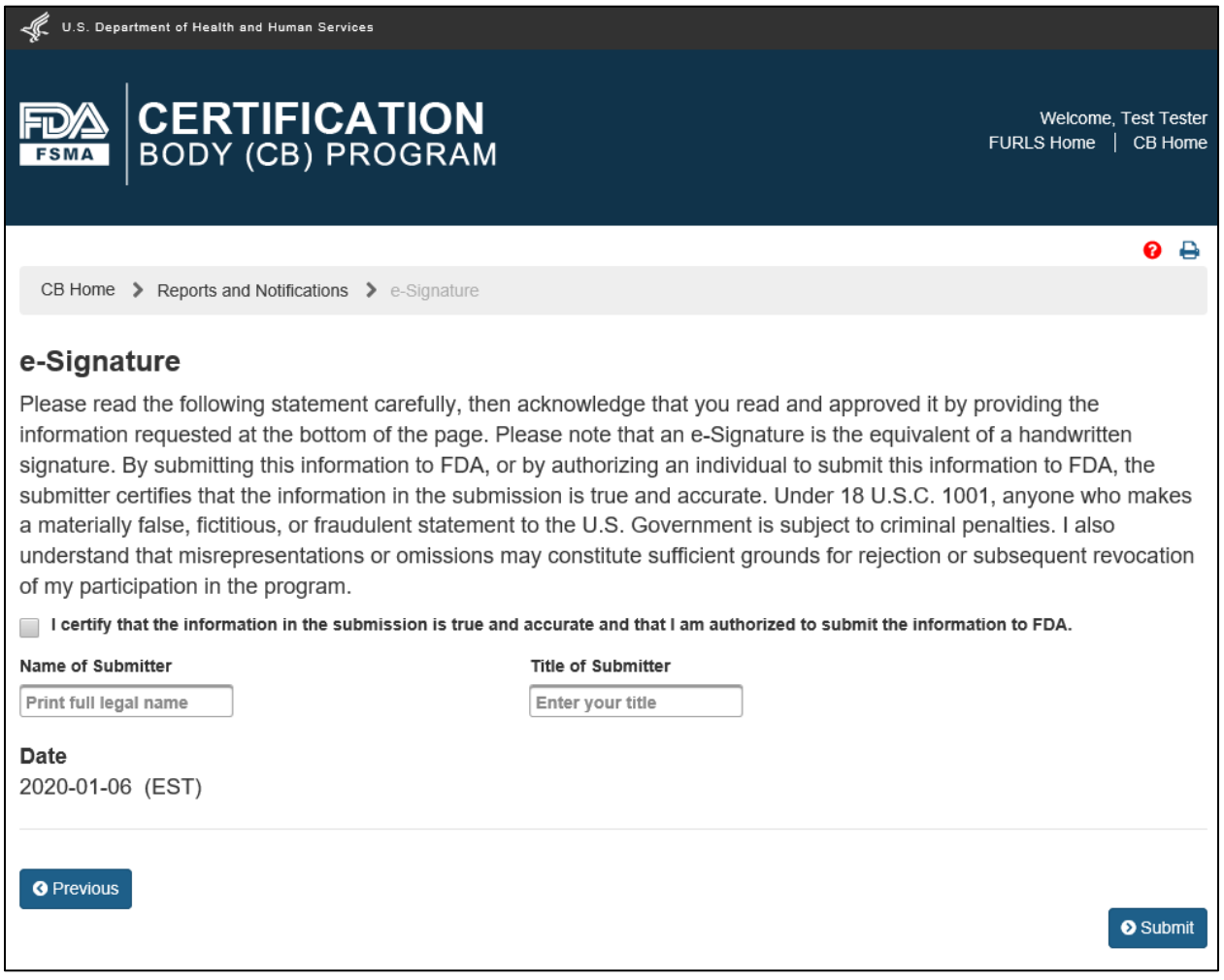
Complete the following fields:

- **I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA**. **–** Click inside the checkbox.
- **Name of Submitter –** Enter the first and last name of the submitter.
- **Title of Submitter –** Enter the title of the submitter.

Click the “Previous” button if you wish to return to the “Notice of Intent to Relinquish or Not to Renew Accreditation” page.

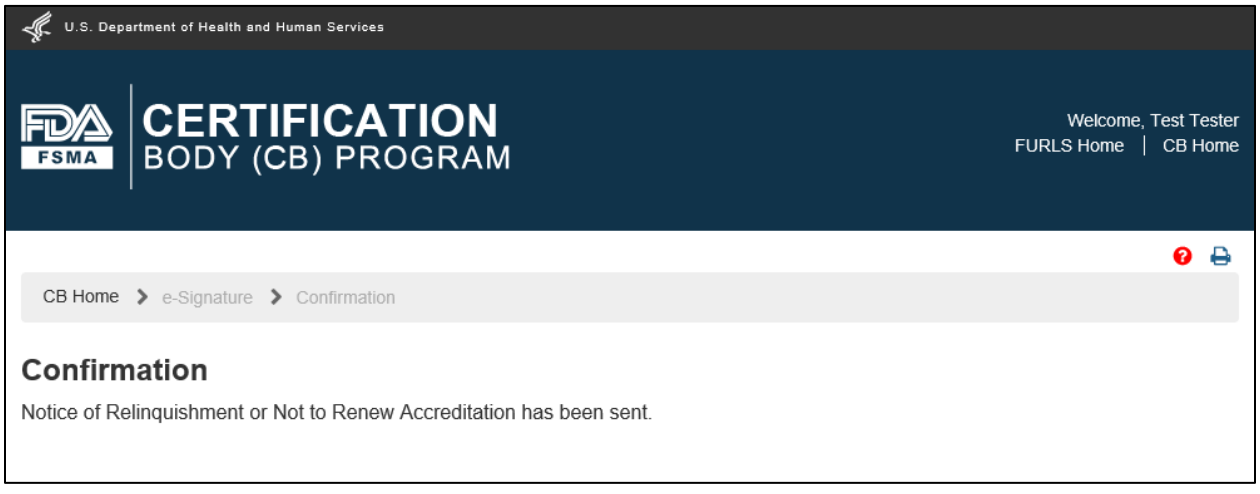
Click the “Submit” button to complete submission of the notice.

Figure 9.41 – **e-Signature Page**



After you click the “Submit” button the system will display the “Confirmation” page, indicating the notification has been sent to FDA (Figure 9.42).

Figure 9.42 – Confirmation Page



The system will send you an e-mail indicating the notice was received by FDA (Figure 9.43). The AB you selected in the notice will receive a copy of the e-mail.

Note: The image (below) only depicts the e-mail notification text.

Figure 9.43 – E-mail Confirmation

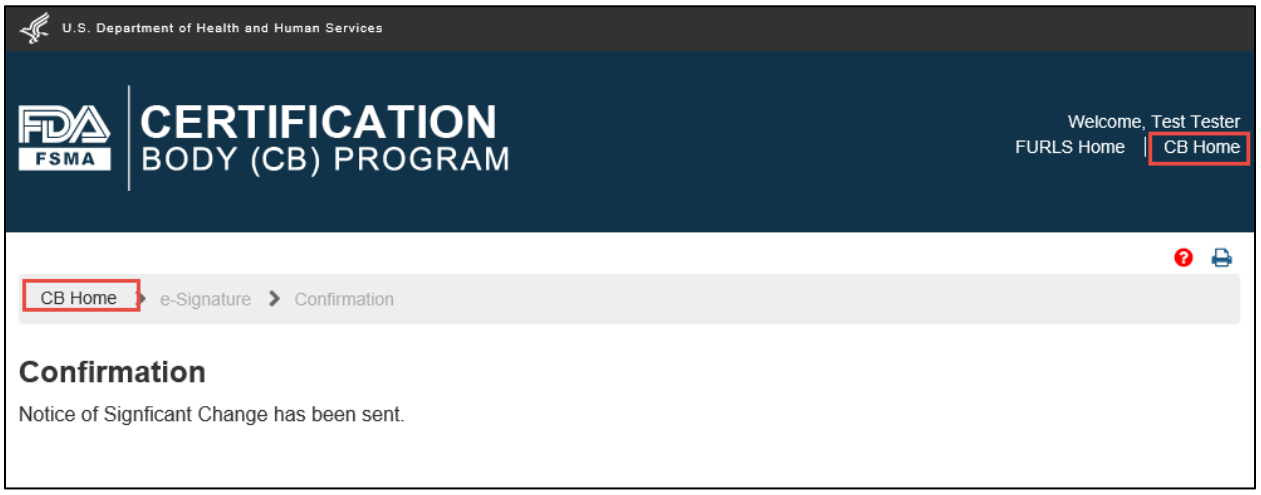
Thank you for submitting information to FDA regarding Notice of Intent to Relinquish or Not to Renew Accreditation. We will review this information and may follow-up if additional information is needed.

Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

Click the “CB Home” link on the top of the banner (or from the breadcrumb) to return to “CB Home” page (Figure 9.44).

Figure 9.44 – Links to CB Home Page



APPENDIX A: Abbreviations

AB	Accreditation Body
CB	Certification Body
CFSAN	Center for Food Safety and Applied Nutrition
FDA	U.S. Food and Drug Administration
OAA	Online Account Administration
ORA	Office of Regulatory Affairs
RAR	Regulatory Audit Report
FFRN	Food Facility Registration Number

Icon Behavior

Standardized icons are used throughout the system. Each icon performs a specific system function. The icon description and system function are described below:

Icon Description	Icon	System Function
Magnifying Glass		View the associated item.
Pencil		Edit the associated item.
Numbers within parenthesis		Lists the total number of records associated with the item. The number within parenthesis is a clickable link. • Example, “(1)” indicates that there is one scope associated to a product in regulatory audit report or certification. The CB may click the link to view a list of scopes.
Trash Can		Delete the associated item.
Printer		Print the associated item.