



U.S. Food and Drug Administration

Accredited Third-Party Certification Program Portal

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

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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

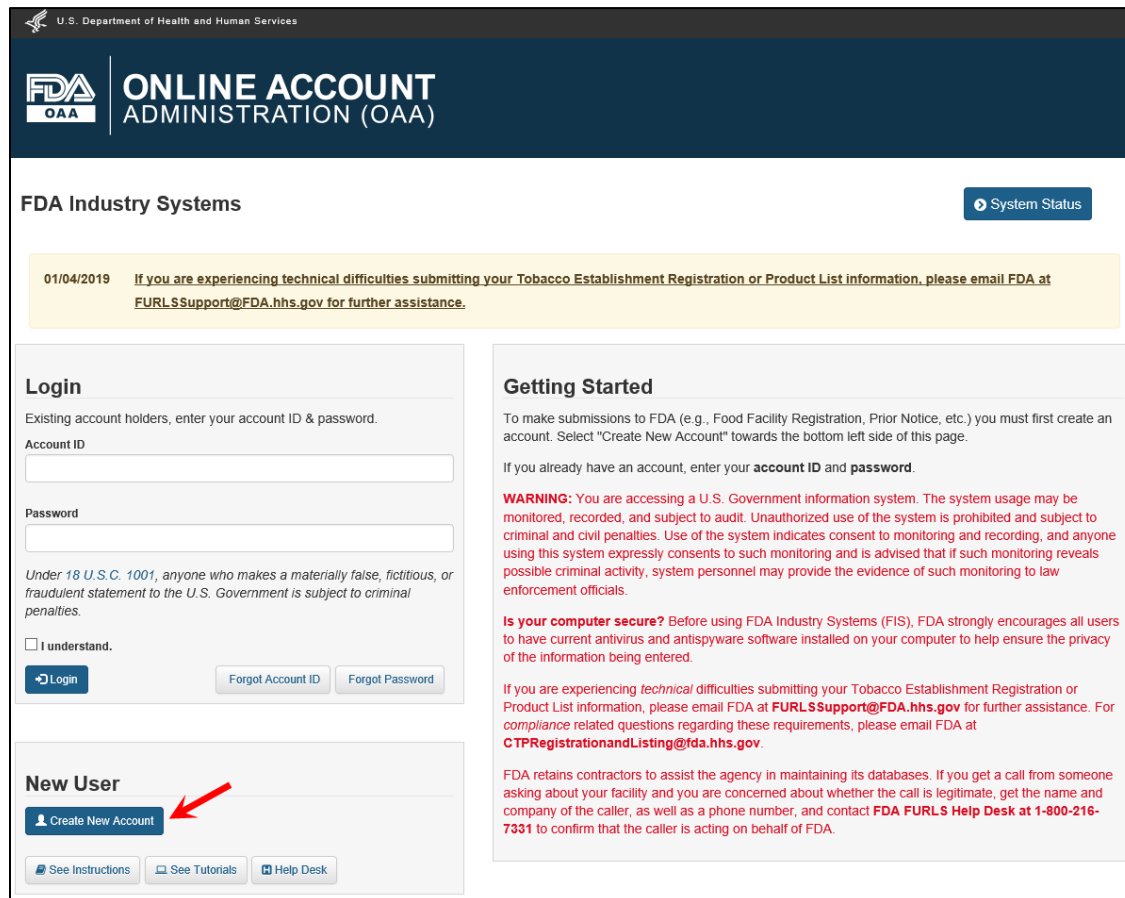
Each person who uses FURLS needs a personal FDA account ID and password, which can be obtained through the FDA FIS portal. To access the FIS electronic portal, go to <https://www.access.fda.gov/oa/>. Follow the instructions for obtaining an FDA account ID and password below. Once the account has been 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/oa/>. 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.

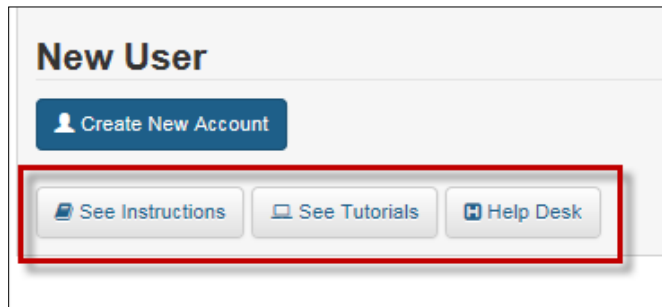
Figure 3.1 – FDA OAA Page



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

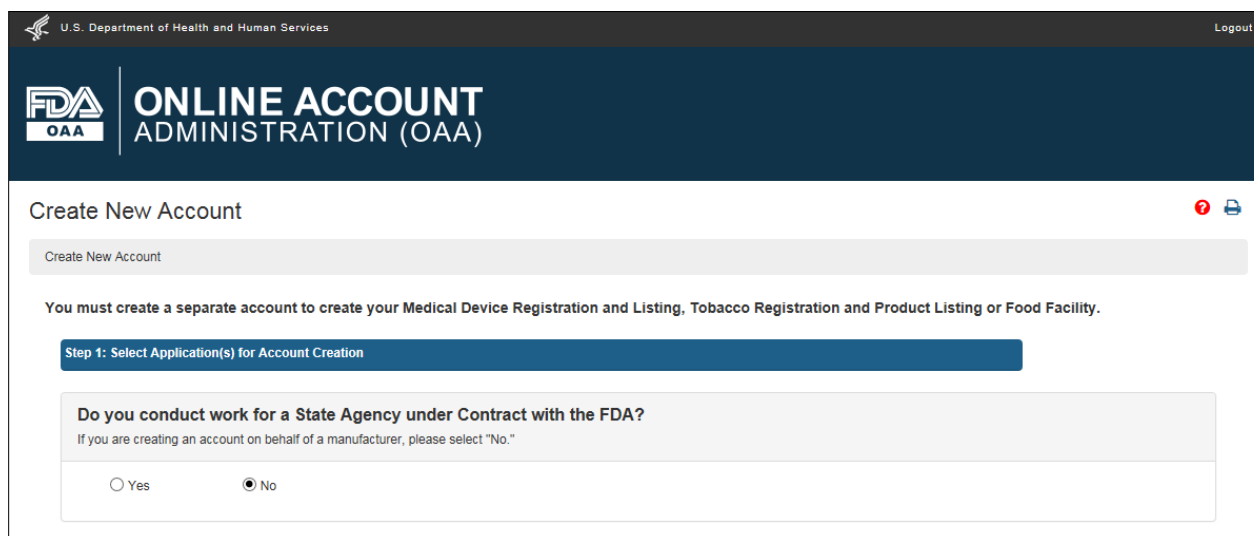


Click the “Create New Account” button:

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)

FSMA Program(s)

Accredited Third-Party Certification Program-- Accreditation Body
Check this box if you are an AB and are submitting an application for FDA recognition.

Accredited Third-Party Certification Program-- Certification Body 
Check this box if you are a CB who needs to create an account. You must have a verification code to complete your account setup. FDA will send you the verification code via email after you have been accredited by a recognized AB.

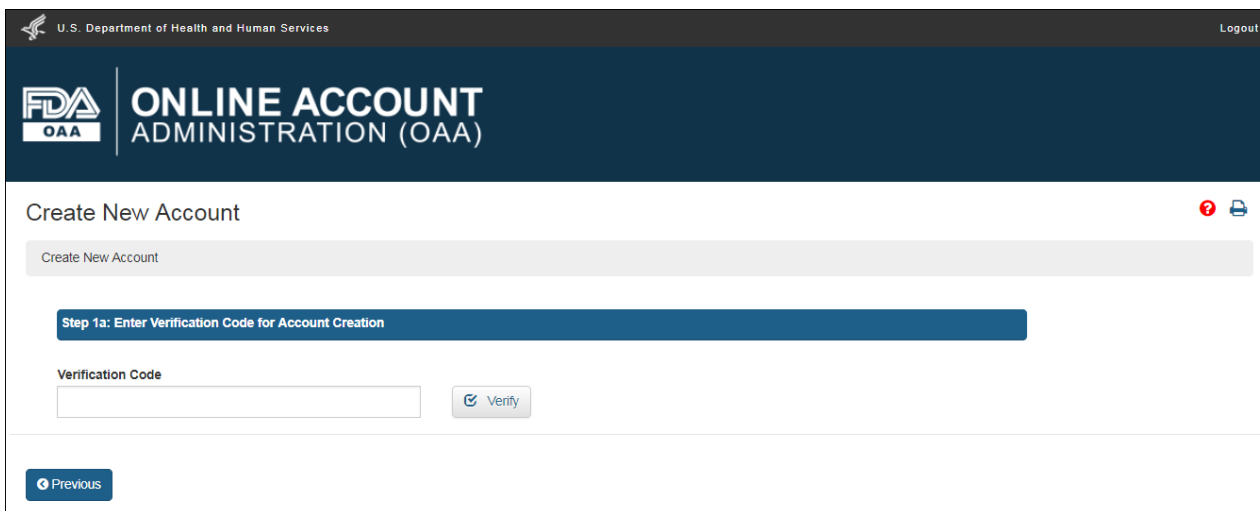
Foreign Supplier Verification Program
Check this box if you are an FSVP importer who needs to use a secure portal to submit FSVP records requested by FDA.

Voluntary Qualified Importer Program

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).

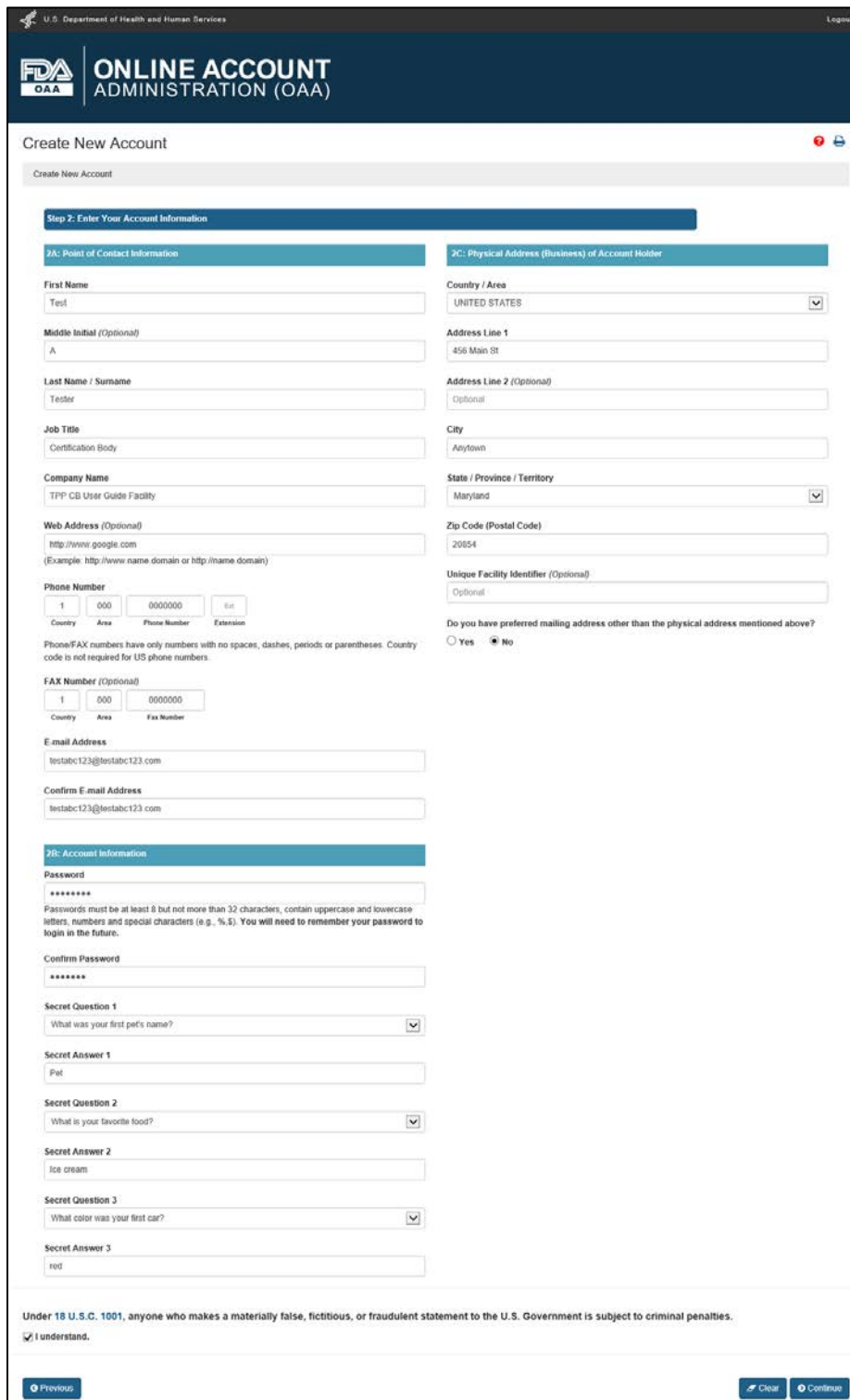
Figure 3.5 – Step 1a: Enter Verification Code for Account Creation



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



U.S. Department of Health and Human Services

FDA ONLINE ACCOUNT ADMINISTRATION (OAA)

Create New Account

Step 2: Enter Your Account Information

1A: Point of Contact Information

First Name: Test

Middle Initial (Optional): A

Last Name / Surname: Tester

Job Title: Certification Body

Company Name: TPP CB User Guide Facility

Web Address (Optional): http://www.google.com
(Example: http://www.name.domain or http://name.domain)

Phone Number: 1 000 0000000 54

FAX Number (Optional): 1 000 0000000

E-mail Address: testabc123@testabc123.com

Confirm E-mail Address: testabc123@testabc123.com

2C: Physical Address (Business) of Account Holder

Country / Area: UNITED STATES

Address Line 1: 456 Main St

Address Line 2 (Optional): Optional

City: Anytown

State / Province / Territory: Maryland

Zip Code (Postal Code): 20054

Unique Facility Identifier (Optional): Optional

Do you have preferred mailing address other than the physical address mentioned above?
 Yes No

2B: Account Information

Password: *****
Passwords must be at least 8 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., % \$). You will need to remember your password to login in the future.

Confirm Password: *****

Secret Question 1: What was your first pet's name?
 Secret Answer 1: Pet

Secret Question 2: What is your favorite food?
 Secret Answer 2: Ice cream

Secret Question 3: What color was your first car?
 Secret Answer 3: red

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand.

Previous Clear Continue

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

Point of Contact Information

First Name

Middle Initial (Optional)

Last Name / Surname

Job Title

Company / Last Name (Surname)

Web Address (Optional)

(Example: http://www.name.domain or http://name.domain)

Phone Number

1	000	0000000	Ext
<small>Country</small>	<small>Area</small>	<small>Phone Number</small>	<small>Extension</small>

Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.

FAX Number (Optional)

1	000	0000000
<small>Country</small>	<small>Area</small>	<small>Fax Number</small>

E-mail Address

Confirm E-mail Address

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

2B: Account Information

Password

Passwords must be at least 8 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., %,\$). **You will need to remember your password to login in the future.**

Confirm Password

Secret Question 1

What was your first pet's name?
▼

Secret Answer 1

Secret Question 2

What is your favorite food?
▼

Secret Answer 2

Secret Question 3

What color was your first car?
▼

Secret Answer 3

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

Physical Address (Business) of Account Holder

Country / Area
 ▼

Address Line 1

Address Line 2 (Optional)

City

State / Province / Territory
 ▼

Zip Code (Postal Code)

Unique Facility Identifier (Optional)

Do you have preferred mailing address other than the physical address mentioned above?
 Yes No

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

Do you have preferred mailing address other than the physical address mentioned above?

Yes No

Preferred Mailing Address

Country / Area

UNITED STATES ▼

Address Line 1

789 XYZ Lane

Address Line 2 (Optional)

Optional

City

ABC

State / Province / Territory

Maryland ▼

Zip Code (Postal Code)

20854

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

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand. ←

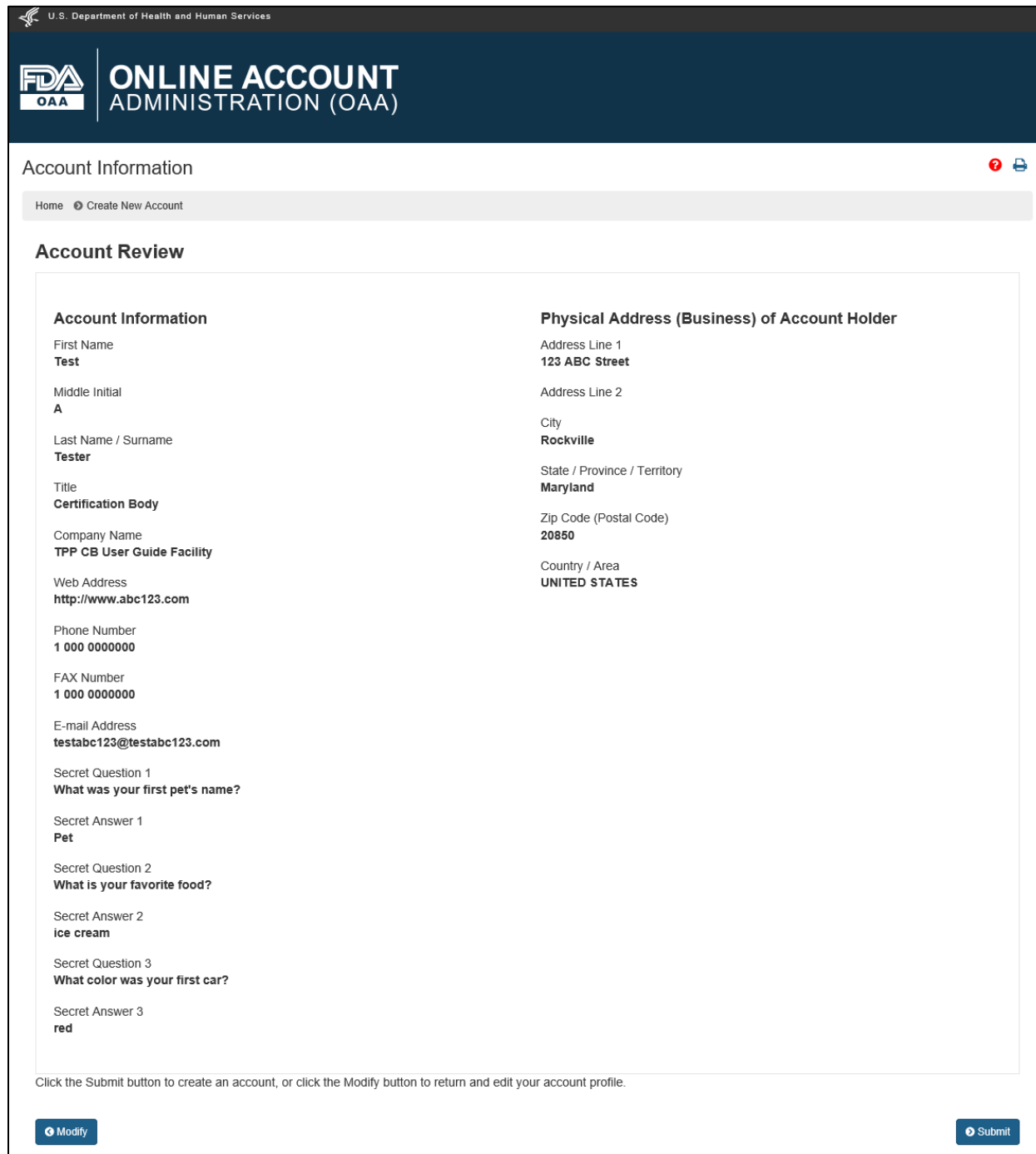
⏪ Previous
Clear ⏩ Continue

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



U.S. Department of Health and Human Services

FDA OAA ONLINE ACCOUNT ADMINISTRATION (OAA)

Account Information ? 🖨️

Home [Create New Account](#)

Account Review

Account Information	Physical Address (Business) of Account Holder
First Name Test	Address Line 1 123 ABC Street
Middle Initial A	Address Line 2
Last Name / Surname Tester	City Rockville
Title Certification Body	State / Province / Territory Maryland
Company Name TPP CB User Guide Facility	Zip Code (Postal Code) 20850
Web Address http://www.abc123.com	Country / Area UNITED STATES
Phone Number 1 000 0000000	
FAX Number 1 000 0000000	
E-mail Address testabc123@testabc123.com	
Secret Question 1 What was your first pet's name?	
Secret Answer 1 Pet	
Secret Question 2 What is your favorite food?	
Secret Answer 2 ice cream	
Secret Question 3 What color was your first car?	
Secret Answer 3 red	

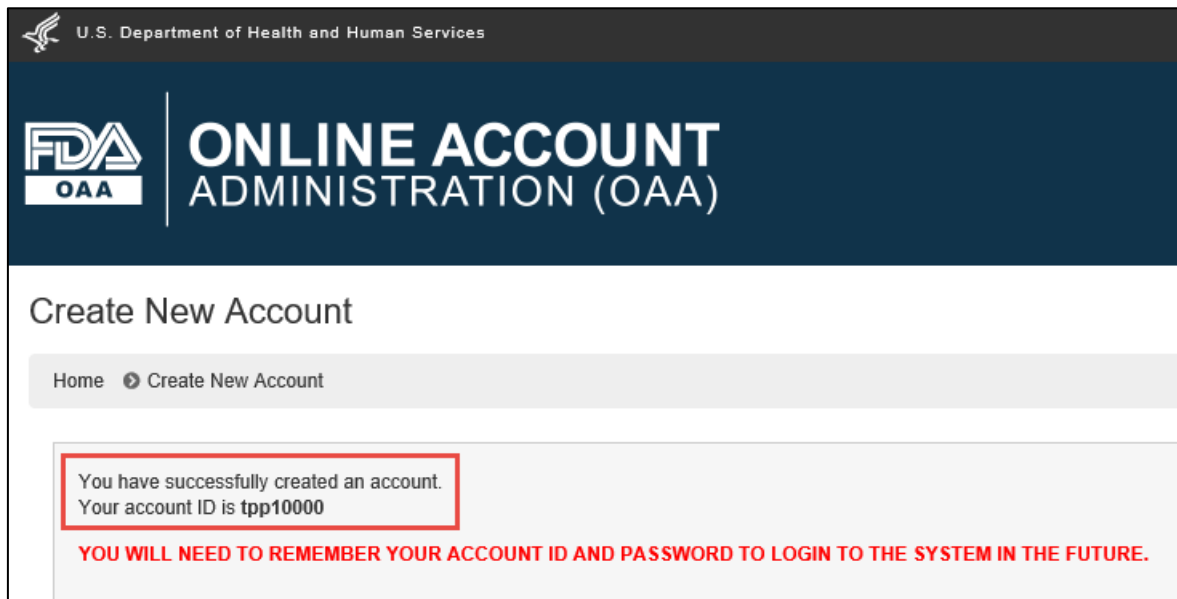
Click the Submit button to create an account, or click the Modify button to return and edit your account profile.

[Modify](#) [Submit](#)

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).

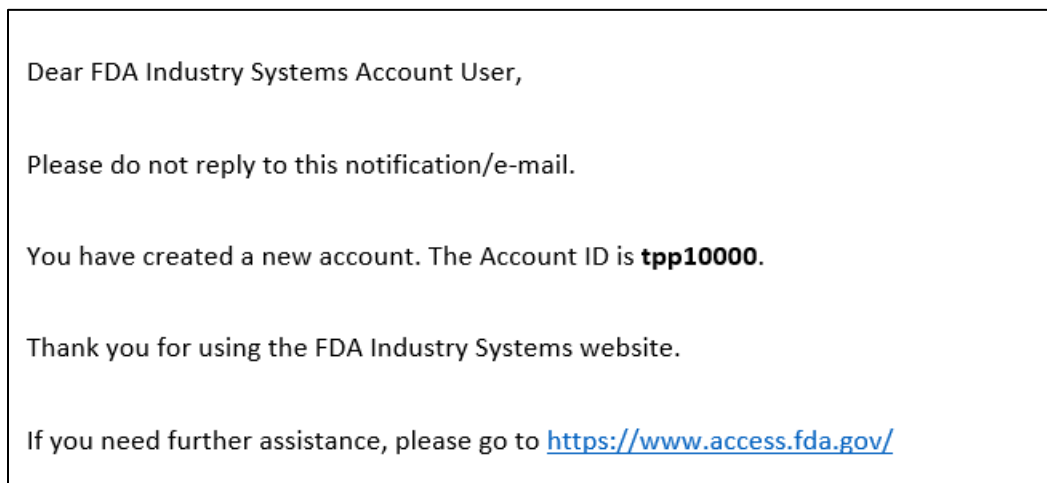
You must retain your account ID and password to log into the system in the future.

Figure 3.13 – Successful Account Creation Message Page



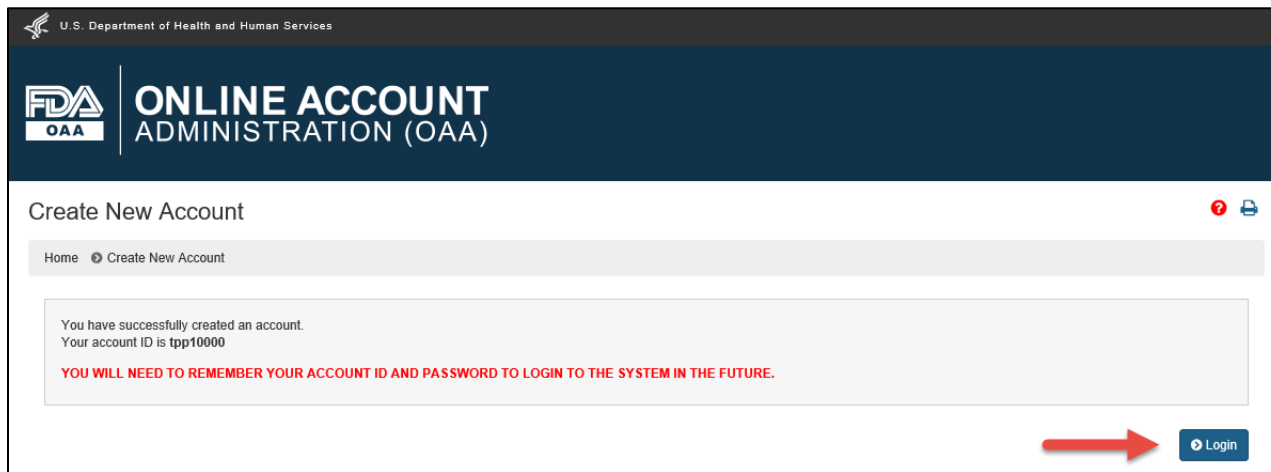
Once you create an account, you will receive an e-mail notification sent to the e-mail address entered in the “Account Information” page which contains the account ID (Figure 3.14).

Figure 3.14 – Account Creation Confirmation E-mail



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/oa>). This is the same page used to begin the process of creating a new OAA account (Figure 4.1).

Figure 4.1 – OAA Login



U.S. Department of Health and Human Services

FDA | **ONLINE ACCOUNT ADMINISTRATION (OAA)**

FDA Industry Systems

Login

Existing account holders, enter your account ID & password.

Account ID

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand.

[Login](#) [Forgot Account ID](#) [Forgot Password](#)

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

U.S. Department of Health and Human Services Logout

FDA | **ONLINE ACCOUNT ADMINISTRATION (OAA)**

Account Management ? 🖨

Account Management

Edit Account Profile

Change My Password

Update System Access

Welcome to the FDA Industry Systems. You are logged in as **tpp10000** for **TPP CB User Guide Facility**

You may choose an option on the left to manage your account or select an FDA system below.
To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

Registration and Listing Programs

Food

Food Facility Registration Export Listing Module

Acidified/Low-Acid Canned Foods Registration and Process Filing Qualified Facility Attestation

Shell Egg Producer Registration

Medical Devices

Device Registration and Listing Module

Tobacco Products

Tobacco Registration and Listing System

Export Certification and Tracking


Biologics Export Certification Application and Tracking System (BECATS) CDER Export Certification Application and Tracking System (CDER eCATS)

CDRH Export Certification Application and Tracking System (CECATS) CFSAN Export Certification Application and Tracking System (CFSAN eCATS)

CVM Export Certification Application and Tracking System (CVM eCATS)

FSMA Program(s)

Accredited Third-Party Certification Program-- Accreditation Body Voluntary Qualified Importer Program

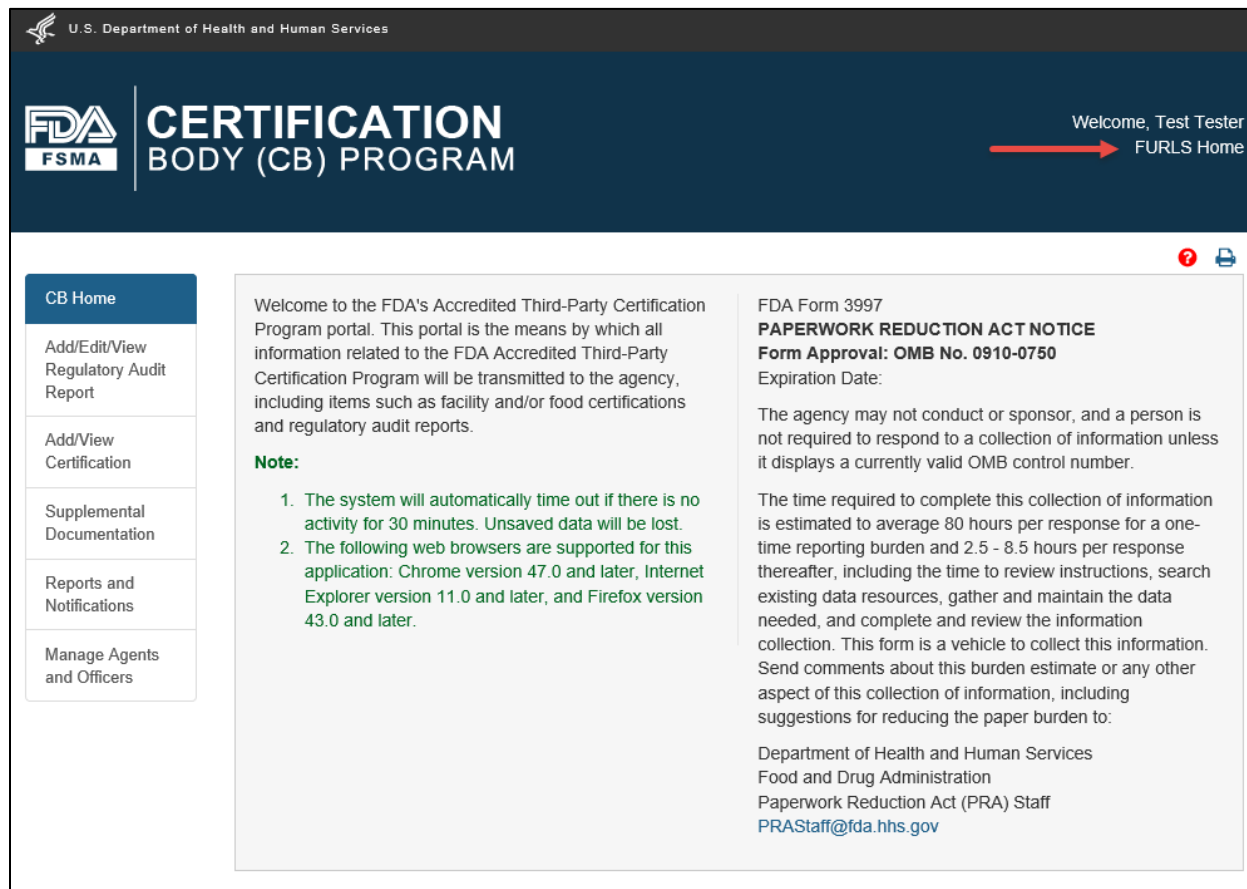
Accredited Third-Party Certification Program-- Certification Body 

Foreign Supplier Verification Program

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.

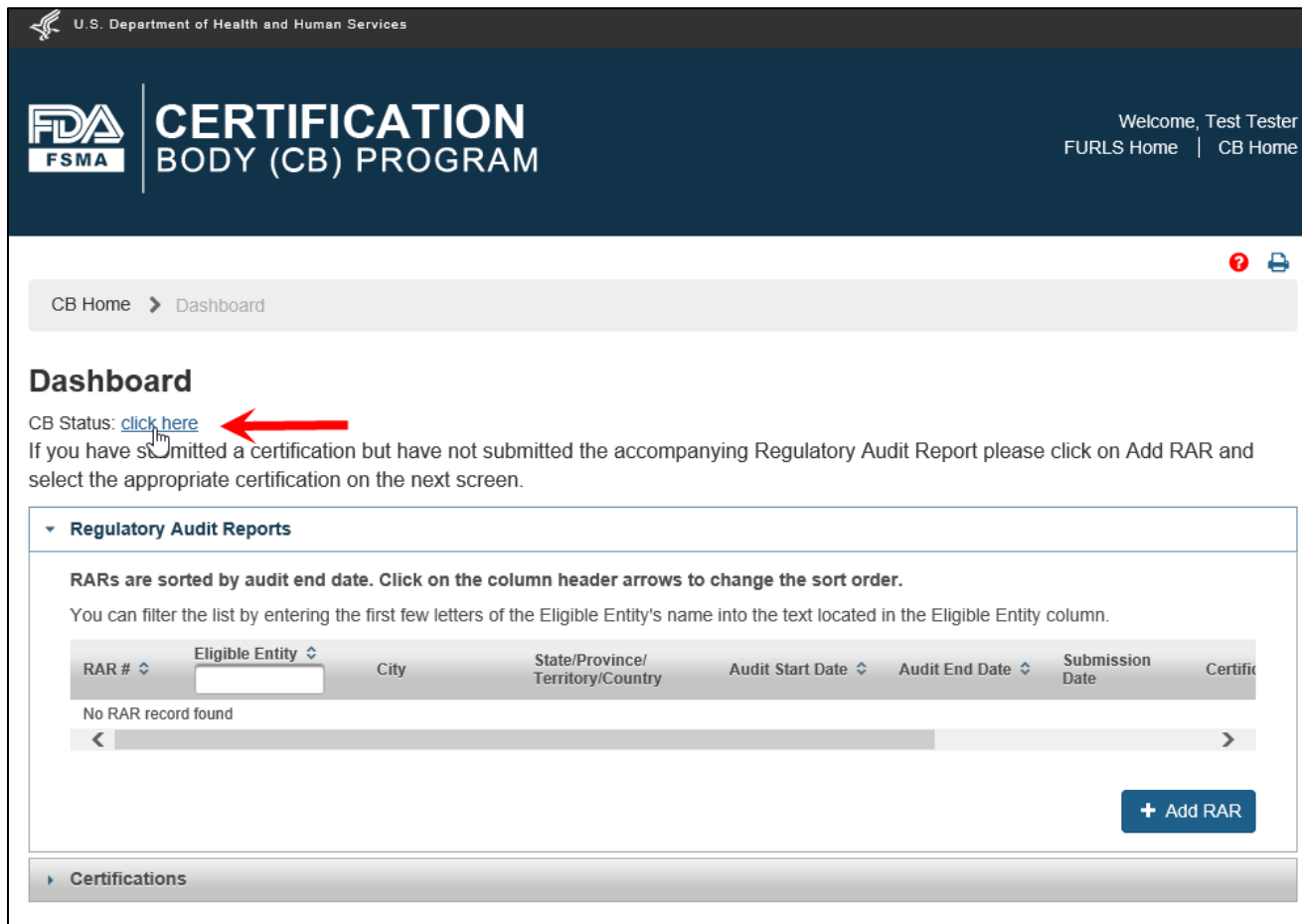
Figure 4.3 – CB Home Page



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

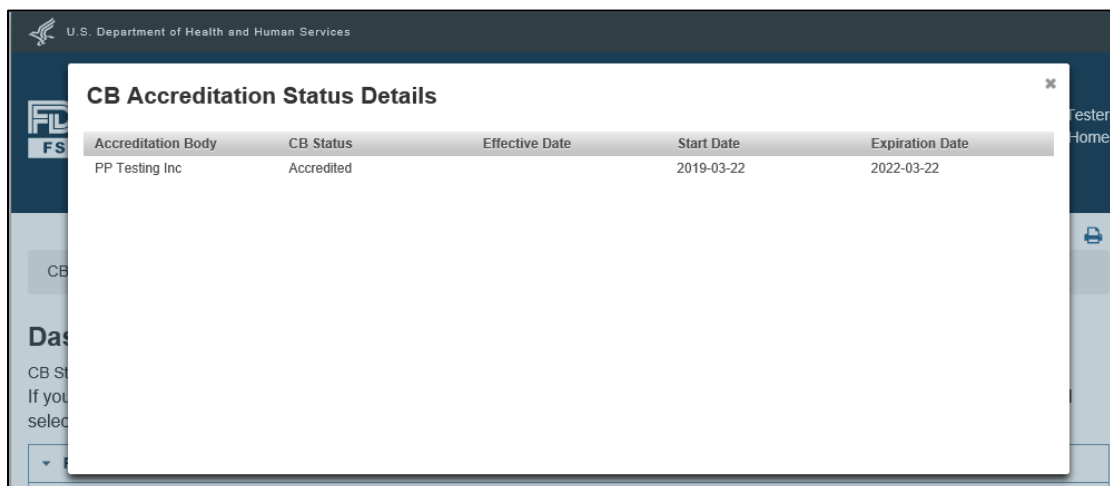


Click the “click here” link to display the “CB Accreditation Status Details” pop-up window (Figure 4.5).

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



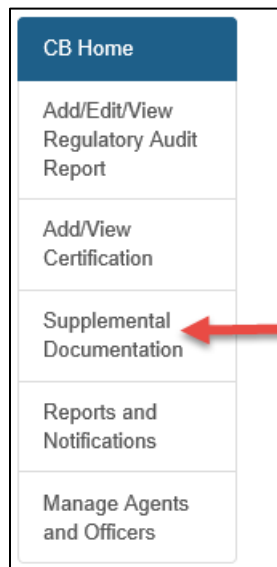
5 Supplemental Documentation

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

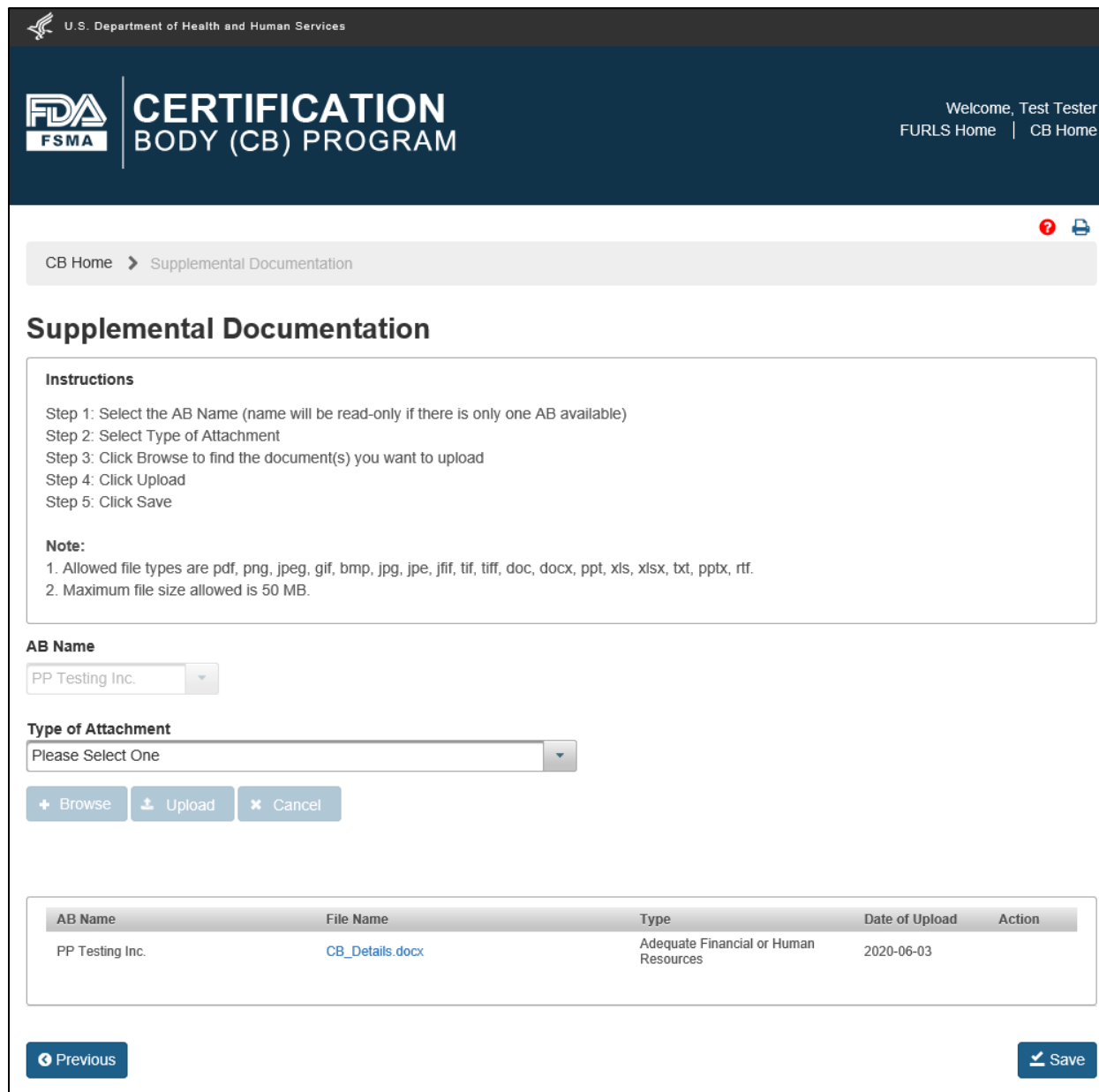


The system will display the “Supplemental Documentation” page (Figure 5.2). Any document(s) you previously submitted to FDA will display in a table at the bottom of the page. Click on the hyperlinked document name in the “File Name” column if you wish to view the document.

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



U.S. Department of Health and Human Services

FDA **CERTIFICATION**
FSMA **BODY (CB) PROGRAM**

Welcome, Test Tester
FURLS Home | CB Home

CB Home > Supplemental Documentation

Supplemental Documentation

Instructions

Step 1: Select the AB Name (name will be read-only if there is only one AB available)
 Step 2: Select Type of Attachment
 Step 3: Click Browse to find the document(s) you want to upload
 Step 4: Click Upload
 Step 5: Click Save

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

AB Name

PP Testing Inc.

Type of Attachment

Please Select One

+ Browse Upload Cancel

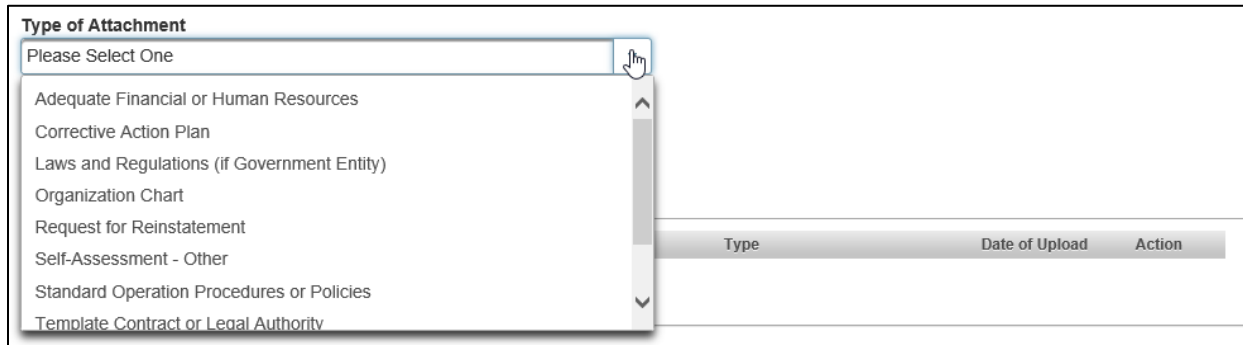
AB Name	File Name	Type	Date of Upload	Action
PP Testing Inc.	CB_Details.docx	Adequate Financial or Human Resources	2020-06-03	

Previous Save

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

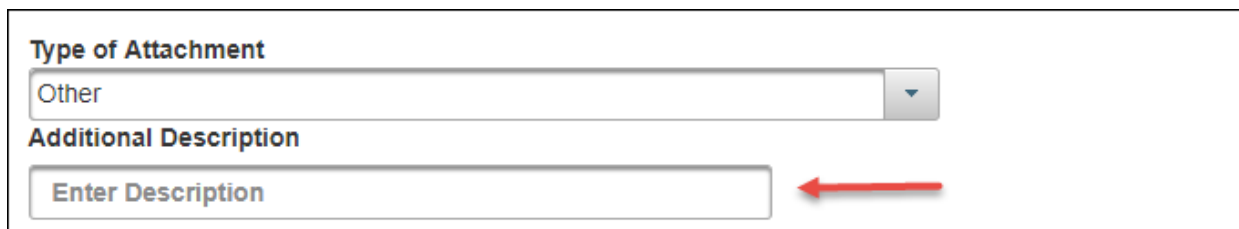


A text box labeled “Additional Description” will display if you select “Other” from the list (Figure 5.4).

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

AB Name

Type of Attachment

11.6 KB

AB Name	File Name	Type	Date of Upload	Action
No records found.				

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

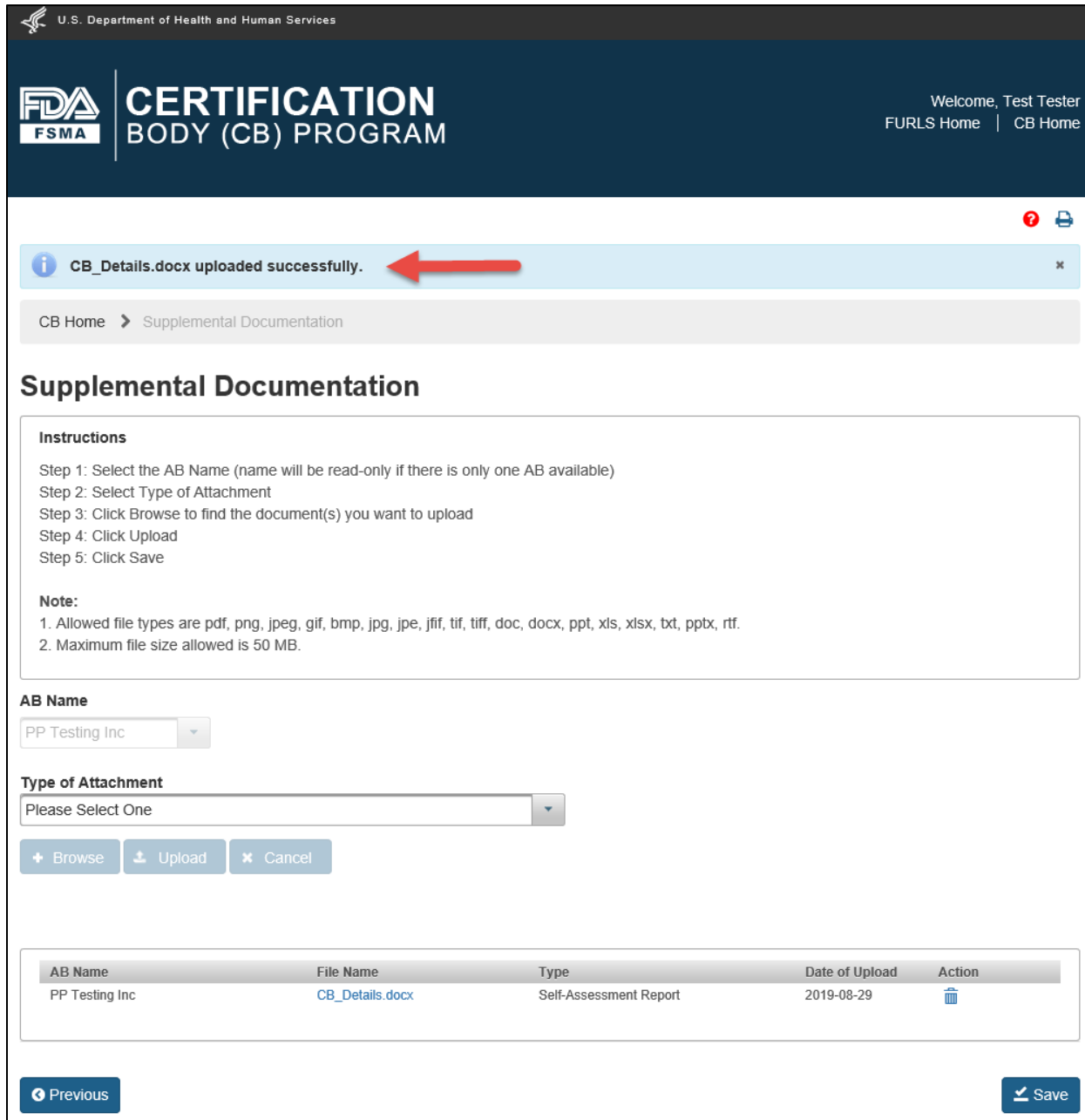
Note: The system supports the following document types: .pdf; .png; .jpeg; .gif; .bmp; .jpg; .jpe; .jfif; .tif; .tiff; .doc; .docx; .ppt; .xls; .xlsx; .txt; .ptx; or .rtf.

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



The screenshot shows the FDA FSMA Certification Body (CB) Program interface. At the top, there is a navigation bar with the FDA logo, the text "CERTIFICATION BODY (CB) PROGRAM", and a user greeting "Welcome, Test Tester" with links for "FURLS Home" and "CB Home".

A light blue notification banner at the top of the main content area displays the message: "CB_Details.docx uploaded successfully." A red arrow points to this message. The banner includes an information icon on the left and a close icon on the right.

Below the notification, a breadcrumb trail shows "CB Home > Supplemental Documentation". The main heading is "Supplemental Documentation".

The "Instructions" section lists the following steps:

- Step 1: Select the AB Name (name will be read-only if there is only one AB available)
- Step 2: Select Type of Attachment
- Step 3: Click Browse to find the document(s) you want to upload
- Step 4: Click Upload
- Step 5: Click Save

A "Note" section provides additional information:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

The "AB Name" field is a dropdown menu currently showing "PP Testing Inc". The "Type of Attachment" field is a dropdown menu currently showing "Please Select One". Below these fields are three buttons: "+ Browse", "Upload", and "Cancel".

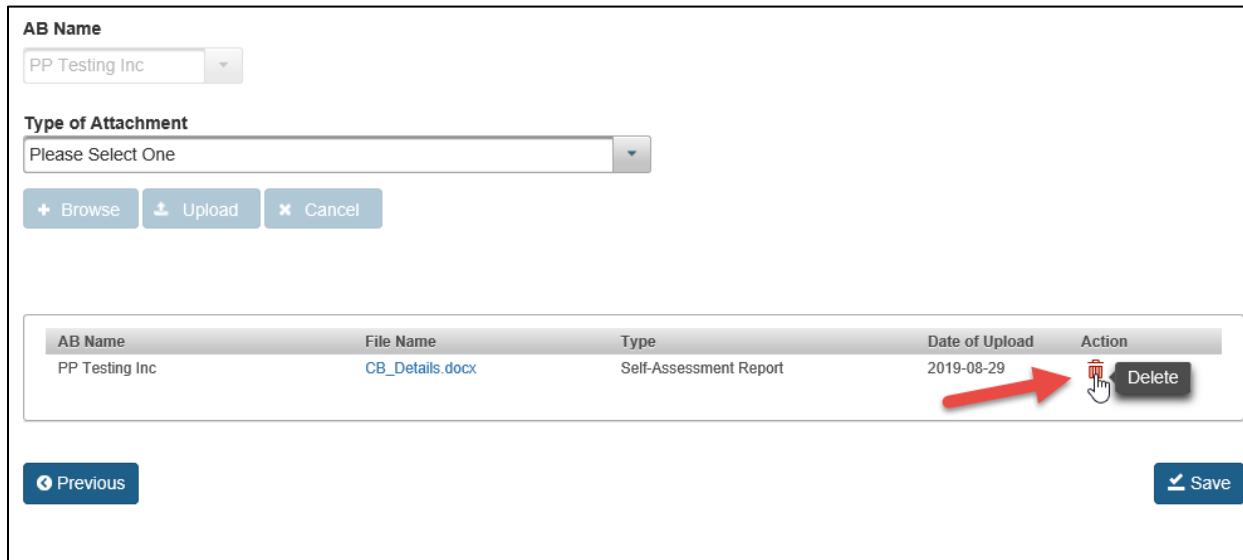
At the bottom, there is a table with the following data:

AB Name	File Name	Type	Date of Upload	Action
PP Testing Inc	CB_Details.docx	Self-Assessment Report	2019-08-29	

At the bottom left, there is a "Previous" button with a left arrow icon. At the bottom right, there is a "Save" button with a checkmark icon.

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



AB Name
PP Testing Inc

Type of Attachment
Please Select One

+ Browse Upload × Cancel

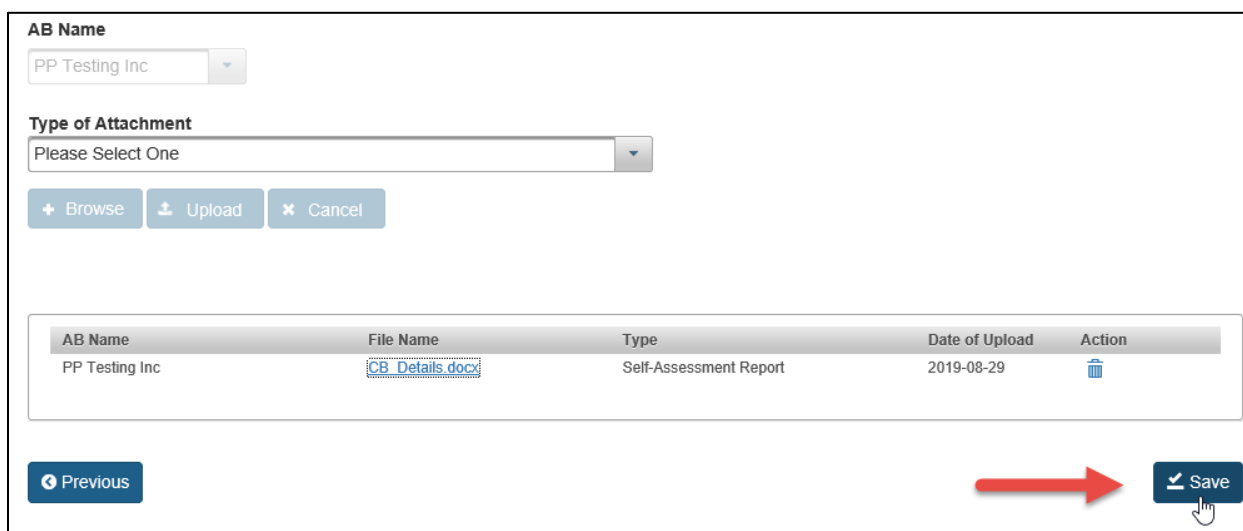
AB Name	File Name	Type	Date of Upload	Action
PP Testing Inc	CB_Details.docx	Self-Assessment Report	2019-08-29	 Delete

Previous Save

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



AB Name
PP Testing Inc

Type of Attachment
Please Select One

+ Browse Upload × Cancel

AB Name	File Name	Type	Date of Upload	Action
PP Testing Inc	CB_Details.docx	Self-Assessment Report	2019-08-29	

Previous Save

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

AB Name
PP Testing Inc

Type of Attachment
Please Select One

+ Browse Upload * Cancel

AB Name	File Name	Type	Date of Upload	Action
PP Testing Inc	CB_Details.docx	Adequate Financial or Human Resources	2020-06-03	

Previous Save

Do you want to open or save **CB_Details.docx** (11.5 KB) from access.preprod.fda.gov? Open Save Cancel x

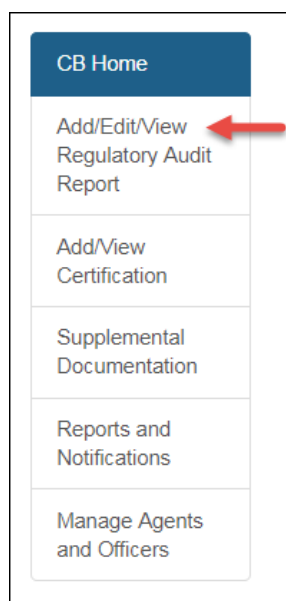
6 Add/Edit/View Regulatory Audit Report (RAR)

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

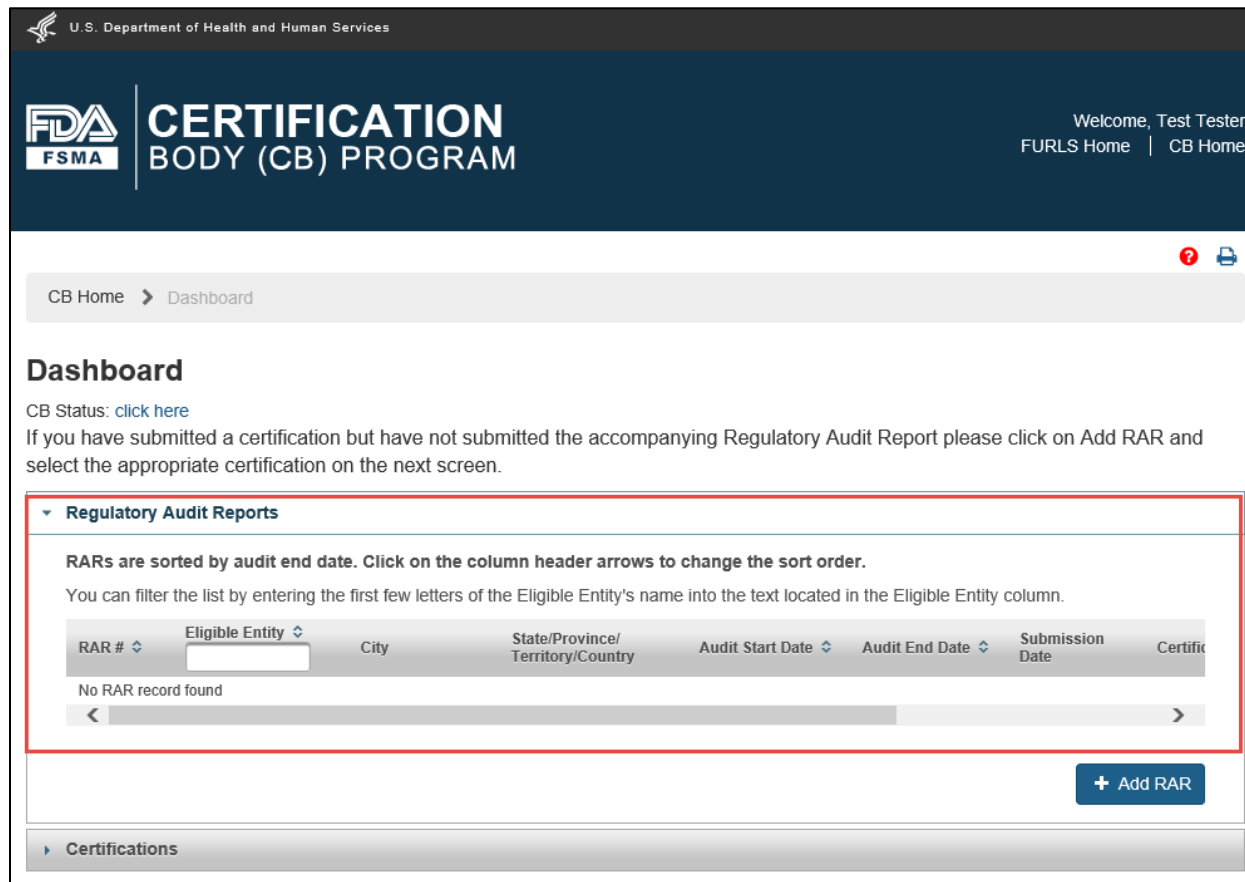
To access the regulatory audit report functionality, click the “Add/Edit/View Regulatory Audit Report” link from the navigation menu on the “CB Home” page (Figure 6.1).

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

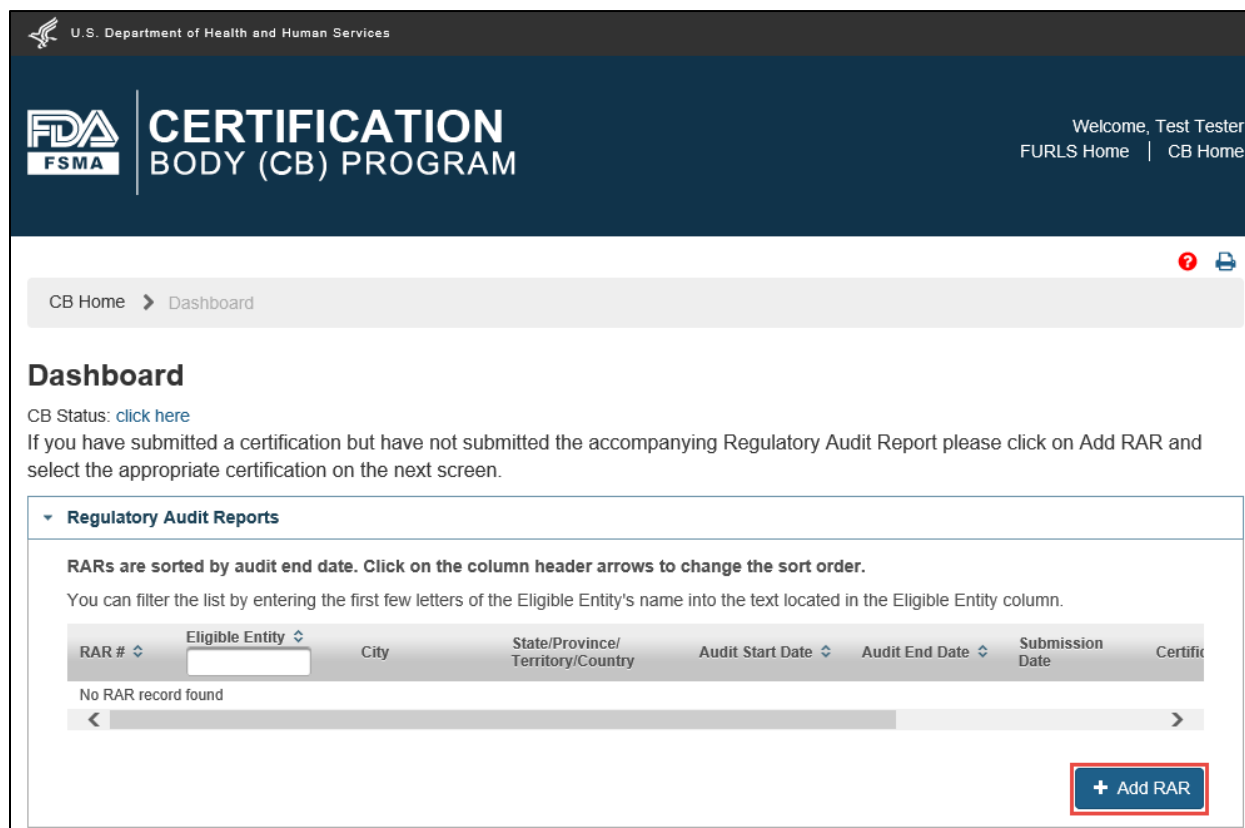
Figure 6.3 – Previous, Save, and Next Buttons



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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

[CB Home](#) > [Dashboard](#)

Dashboard

CB Status: [click here](#)

If you have submitted a certification but have not submitted the accompanying Regulatory Audit Report please click on Add RAR and select the appropriate certification on the next screen.

Regulatory Audit Reports

RARs are sorted by audit end date. Click on the column header arrows to change the sort order.

You can filter the list by entering the first few letters of the Eligible Entity's name into the text located in the Eligible Entity column.

RAR #	Eligible Entity	City	State/Province/Territory/Country	Audit Start Date	Audit End Date	Submission Date	Certification
No RAR record found							

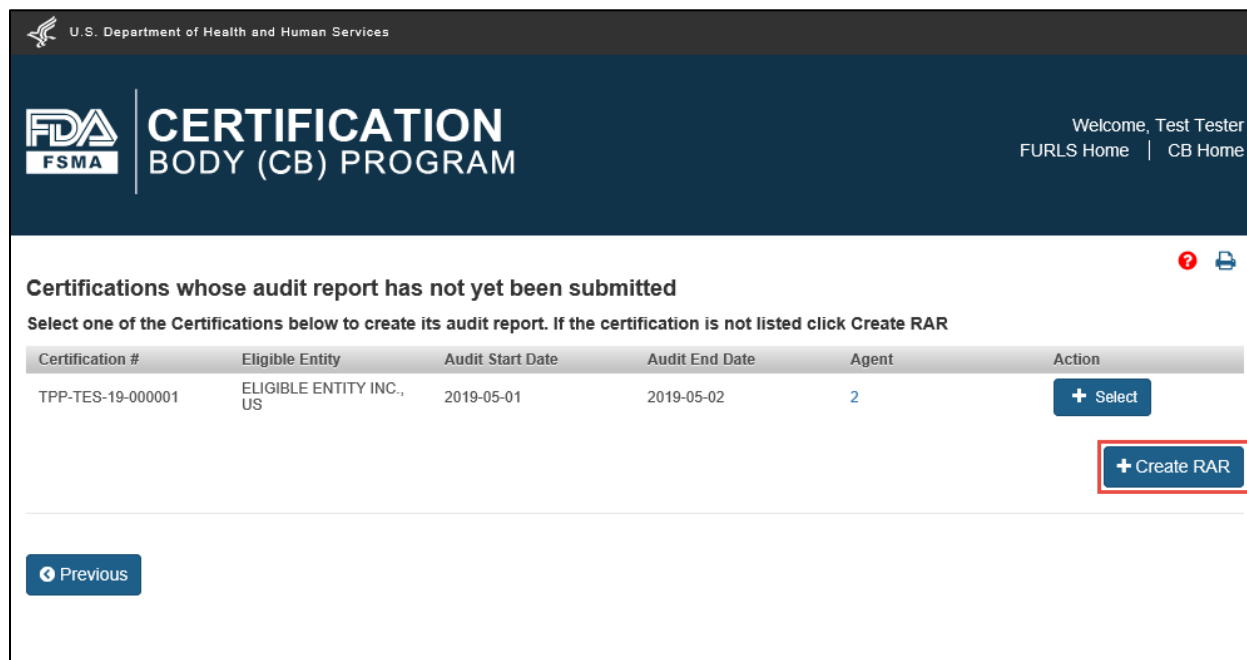
[+ Add RAR](#)

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

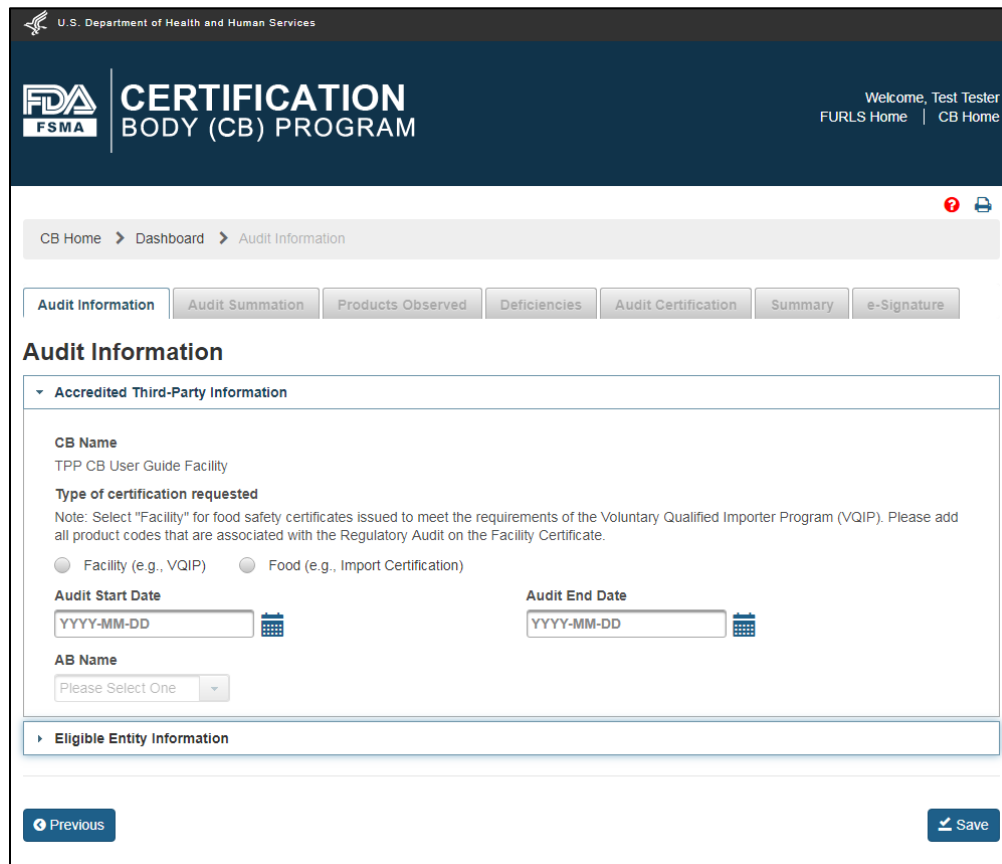
The “Audit Information” tab contains two main sections: The “Accredited Third-Party Information” section and the “Eligible Entity Information” section.

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.

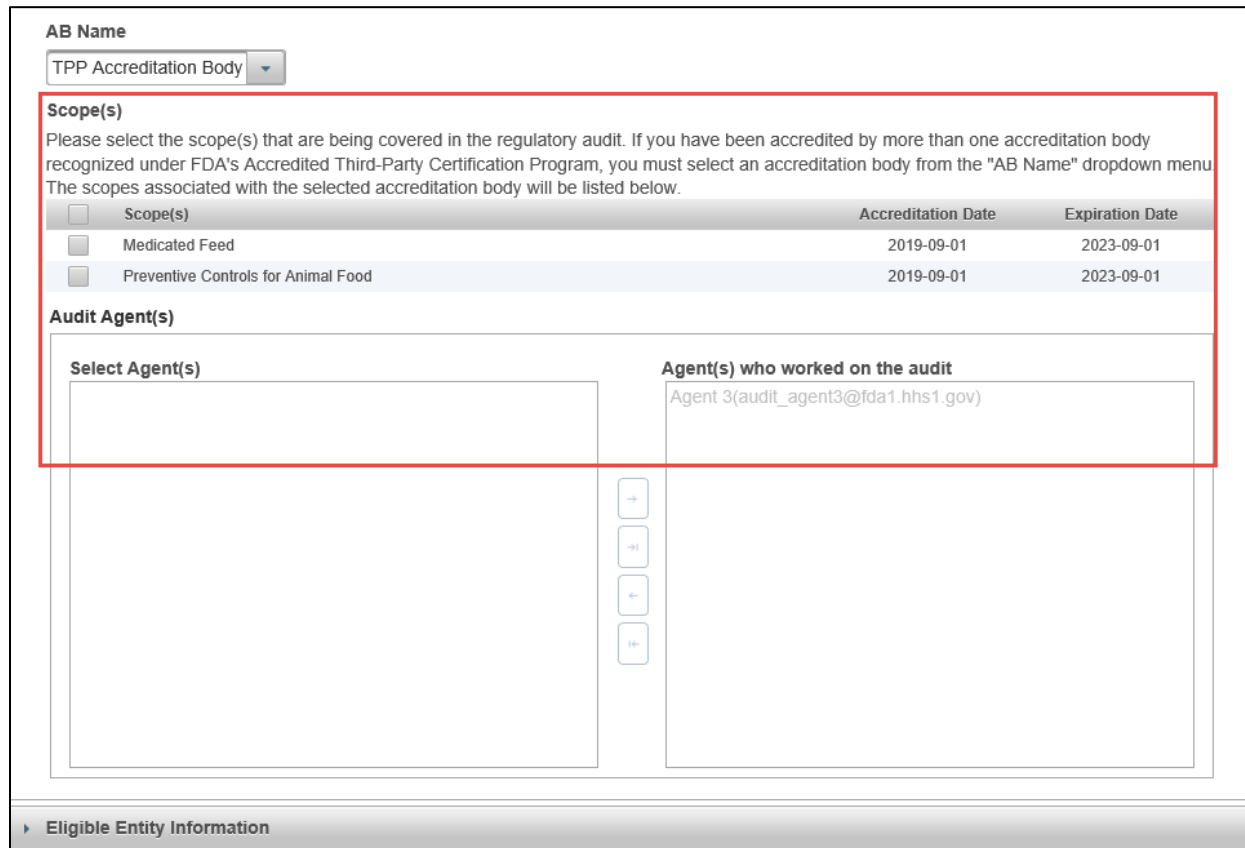
The following buttons may be used to add or remove the selected agent(s):

-  **“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



AB Name
 TPP Accreditation Body

Scope(s)
 Please select the scope(s) that are being covered in the regulatory audit. If you have been accredited by more than one accreditation body recognized under FDA's Accredited Third-Party Certification Program, you must select an accreditation body from the "AB Name" dropdown menu. The scopes associated with the selected accreditation body will be listed below.

Scope(s)	Accreditation Date	Expiration Date
<input type="checkbox"/> Medicated Feed	2019-09-01	2023-09-01
<input type="checkbox"/> Preventive Controls for Animal Food	2019-09-01	2023-09-01

Audit Agent(s)

Select Agent(s)


Agent(s) who worked on the audit
 Agent 3(audit_agent3@fda1.hhs1.gov)

Eligible Entity Information

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

U.S. Department of Health and Human Services



**CERTIFICATION
BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

[CB Home](#) > [Dashboard](#) > [Audit Information](#)

Audit Information
Audit Summation
Products Observed
Deficiencies
Audit Certification
Summary
e-Signature

Audit Information

▼ **Accredited Third-Party Information**

CB Name
TPP CB User Guide Facility

Type of certification requested
Note: Select "Facility" for food safety certificates issued to meet the requirements of the Voluntary Qualified Importer Program (VQIP). Please add all product codes that are associated with the Regulatory Audit on the Facility Certificate.

Facility (e.g., VQIP)
 Food (e.g., Import Certification)

Audit Start Date
Audit End Date

AB Name

Scope(s)
Please select the scope(s) that are being covered in the regulatory audit. If you have been accredited by more than one accreditation body recognized under FDA's Accredited Third-Party Certification Program, you must select an accreditation body from the "AB Name" dropdown menu. The scopes associated with the selected accreditation body will be listed below.

<input checked="" type="checkbox"/> Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="checkbox"/> Medicated Feed	2019-09-01	2023-09-01
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	2019-09-01	2023-09-01

Audit Agent(s)

Select Agent(s)

Agent(s) who worked on the audit

Agent 3(audit_agent3@fda1.hhs1.gov)

→

⇌

←

⇌

▶ **Eligible Entity Information**

↶ Previous

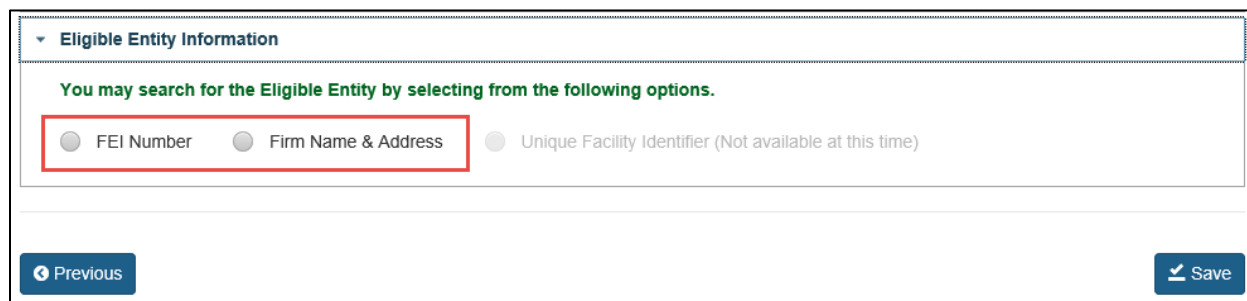
✓ Save

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



Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

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

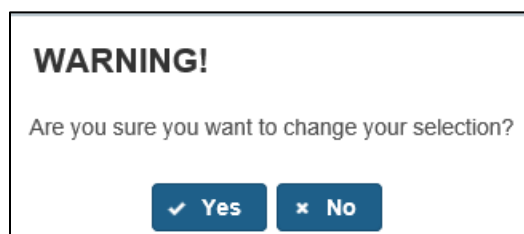
For instructions on how to search by the firm name and address, proceed to Section 6.1.1.2 of this chapter.

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



WARNING!

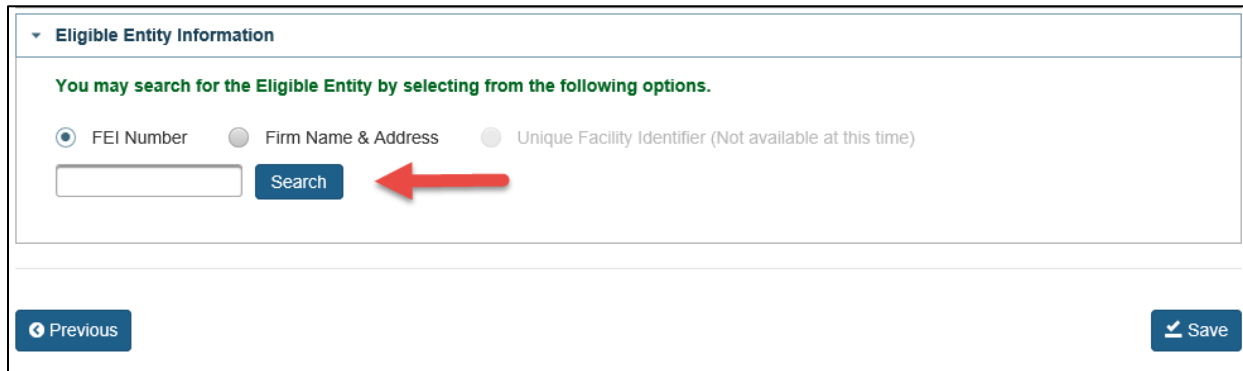
Are you sure you want to change your selection?

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



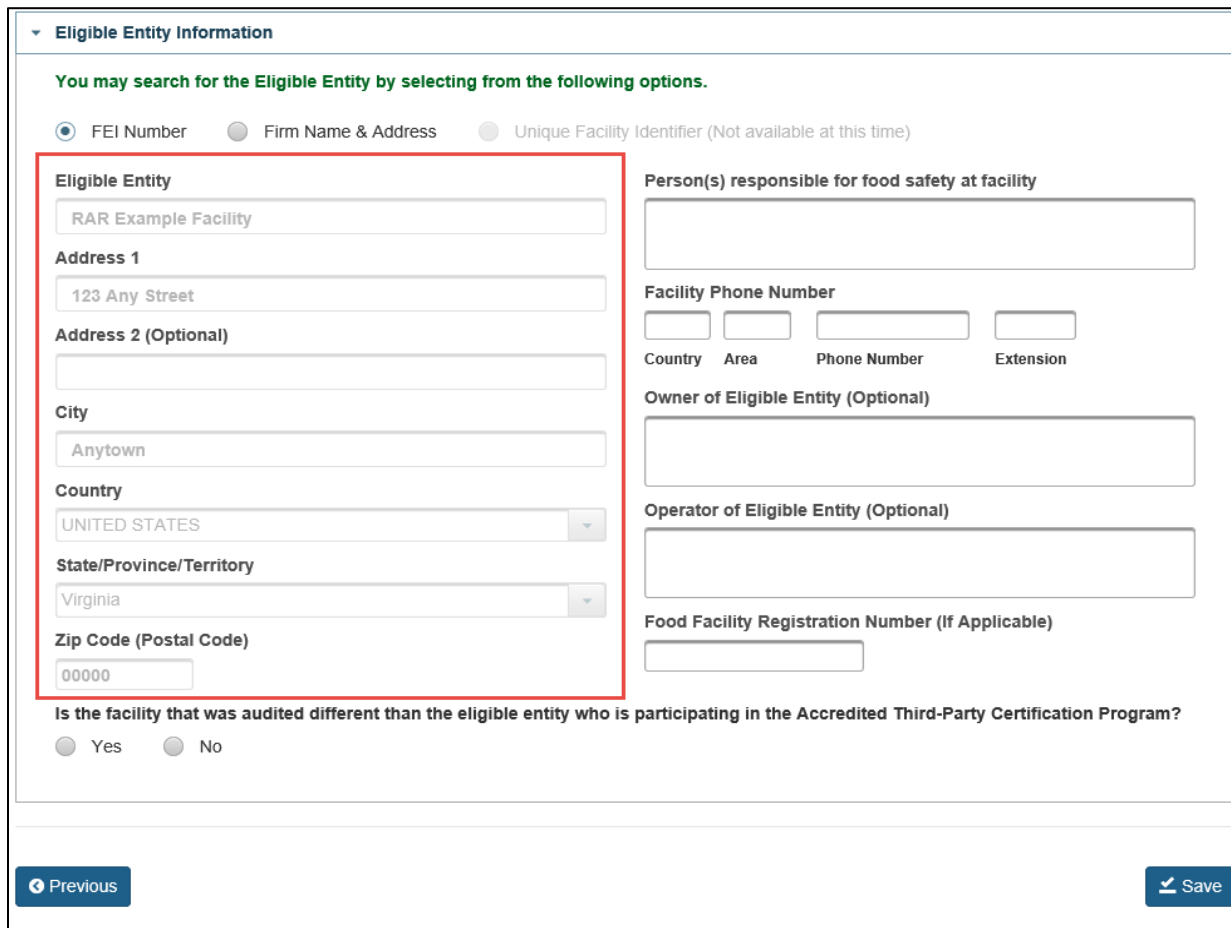
Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

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



Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

Eligible Entity

Address 1

Address 2 (Optional)

City

Country

State/Province/Territory

Zip Code (Postal Code)

Person(s) responsible for food safety at facility

Facility Phone Number

 Country Area Phone Number Extension

Owner of Eligible Entity (Optional)

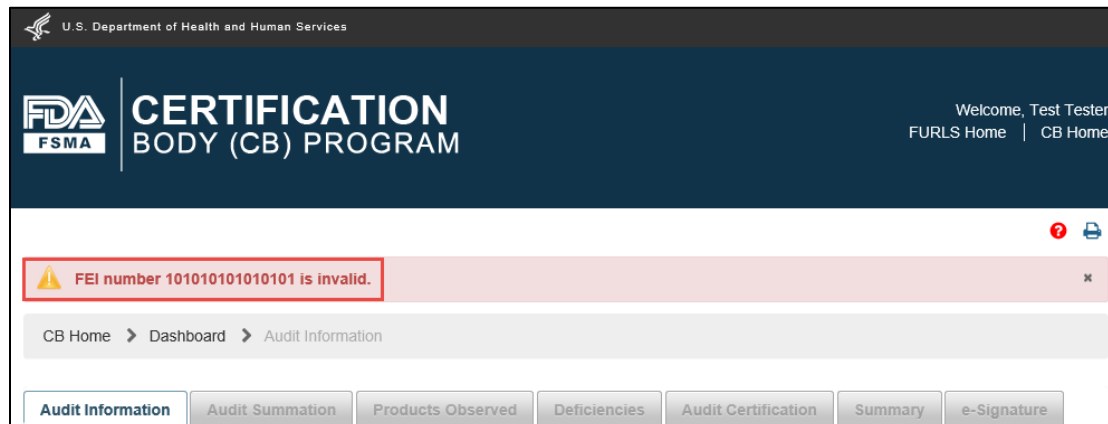
Operator of Eligible Entity (Optional)

Food Facility Registration Number (If Applicable)

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?
 Yes No

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

Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

Eligible Entity

Address 1

Address 2 (Optional)

City

Country

State/Province/Territory

Zip Code (Postal Code)

Person(s) responsible for food safety at facility

Facility Phone Number

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Country	Area	Phone Number	Extension

Owner of Eligible Entity (Optional)

Operator of Eligible Entity (Optional)

Food Facility Registration Number (If Applicable)

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes
 No


[Previous](#)
[Save](#)

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

U.S. Department of Health and Human Services



CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard > Audit Information

Audit Information	Audit Summation	Products Observed	Deficiencies	Audit Certification	Summary	e-Signature
--------------------------	-----------------	-------------------	--------------	---------------------	---------	-------------

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:

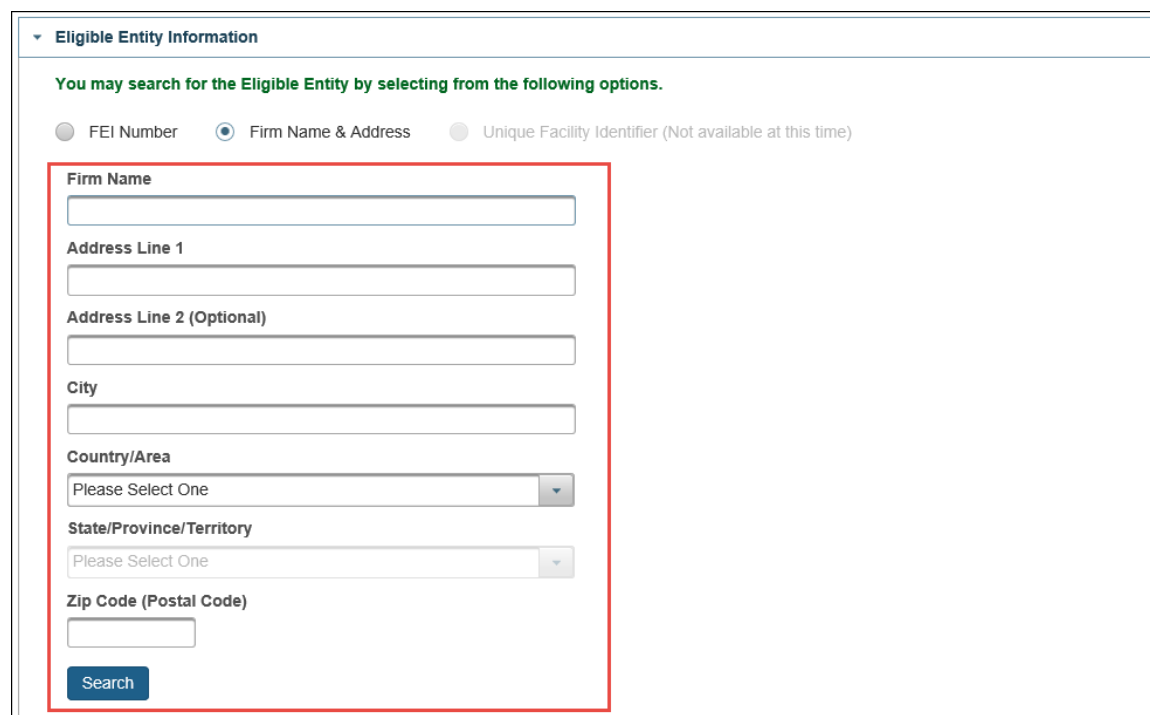
- **Firm Name** – The name of the firm
- **Address Line 1** – The address where the firm is physically located – this includes the number, street, quadrant, etc.
- **Address Line 2** – The field to enter additional information about the physical location of the firm – this may include a suite or apartment 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.

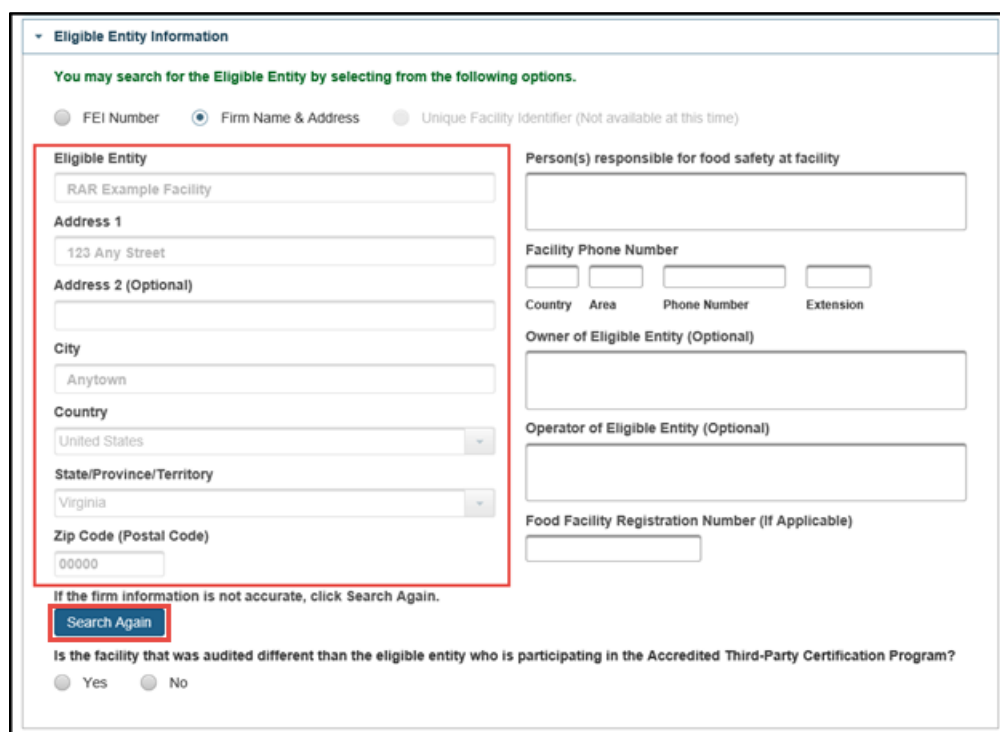
If no results are returned, proceed to Section 6.1.1.2.3 of this chapter.

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



The screenshot shows a web form titled "Eligible Entity Information". At the top, it says "You may search for the Eligible Entity by selecting from the following options." with three radio buttons: "FEI Number", "Firm Name & Address" (which is selected), and "Unique Facility Identifier (Not available at this time)".

The form is divided into two columns. The left column contains the following fields, all of which are pre-filled with example data and enclosed in a red box:

- Eligible Entity:** RAR Example Facility
- Address 1:** 123 Any Street
- Address 2 (Optional):** (empty)
- City:** Anytown
- Country:** United States
- State/Province/Territory:** Virginia
- Zip Code (Postal Code):** 00000

The right column contains the following fields:

- Person(s) responsible for food safety at facility:** (empty)
- Facility Phone Number:** Four input boxes for Country, Area, Phone Number, and Extension.
- Owner of Eligible Entity (Optional):** (empty)
- Operator of Eligible Entity (Optional):** (empty)
- Food Facility Registration Number (If Applicable):** (empty)

At the bottom of the form, there is a red box around a "Search Again" button and a question: "If the firm information is not accurate, click Search Again." Below this is a question: "Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?" with "Yes" and "No" radio buttons.

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

Select one address

Entered search criteria has returned multiple results. Please select the correct address from the list below.

Name	Address	Select Address
RAR Example Facility	123 Any Street, Anytown, Virginia 00000, US	Select & Continue
RAR Example LLC	100 Main St, Anytown, Virginia 00000, US	Select & Continue
RAR Example Facility Inc.	234 ABC Street, ABC Town, Maryland 00000-0000, US	Select & Continue

[Return to Search](#)

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

Address Validation

WARNING: This address has been verified; however, minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications that were made or correct the address yourself.

<p>Your Eligible Entity Address</p> <p>Address Line 1 123 Any Street</p> <p>Address Line 2 (Optional)</p> <p>City Anytown</p> <p>State/Province/Territory Virginia</p> <p>Zip Code (Postal Code) 00000</p> <p>Country/Area UNITED STATES</p>	<p>Validated Eligible Entity Address</p> <p>Address Line 1 123 Any St</p> <p>Address Line 2 (Optional)</p> <p>City Anytown</p> <p>State/Province/Territory Virginia</p> <p>Zip Code (Postal Code) 00000-0000</p> <p>Country/Area UNITED STATES</p>
---	---

[Return to Search](#)

[Accept Provided Address](#)

[Accept Validated Address](#)

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

Address Validation

WARNING: This address has been verified; however, minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications that were made or correct the address yourself.

Your Eligible Entity Address	Validated Eligible Entity Address
Address Line 1 123 Any Street	Address Line 1 123 Any St
Address Line 2 (Optional)	Address Line 2 (Optional)
City Anytown	City Anytown
State/Province/Territory Virginia	State/Province/Territory Virginia
Zip Code (Postal Code) 00000	Zip Code (Postal Code) 00000-0000
Country/Area UNITED STATES	Country/Area UNITED STATES

← Return to Search
→ Accept Provided Address
→ Accept Validated Address

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

▼ **Eligible Entity Information**

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

<p>Eligible Entity</p> <input type="text" value="RAR Example Facility"/> <p>Address 1</p> <input type="text" value="123 Any Street"/> <p>Address 2 (Optional)</p> <input type="text"/> <p>City</p> <input type="text" value="Anytown"/> <p>Country</p> <input type="text" value="United States"/> <p>State/Province/Territory</p> <input type="text" value="Virginia"/> <p>Zip Code (Postal Code)</p> <input type="text" value="00000"/>	<p>Person(s) responsible for food safety at facility</p> <input type="text"/> <p>Facility Phone Number</p> <table border="0"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td>Country</td> <td>Area</td> <td>Phone Number</td> <td>Extension</td> </tr> </table> <p>Owner of Eligible Entity (Optional)</p> <input type="text"/> <p>Operator of Eligible Entity (Optional)</p> <input type="text"/> <p>Food Facility Registration Number (If Applicable)</p> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Country	Area	Phone Number	Extension
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>						
Country	Area	Phone Number	Extension						

If the firm information is not accurate, click Search Again.

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes
 No

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

Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

Eligible Entity

Address 1

Address 2 (Optional)

City

Country

State/Province/Territory

Zip Code (Postal Code)

If the firm information is not accurate, click Search Again.

Person(s) responsible for food safety at facility

Facility Phone Number

Country Area Phone Number Extension

Owner of Eligible Entity (Optional)

Operator of Eligible Entity (Optional)

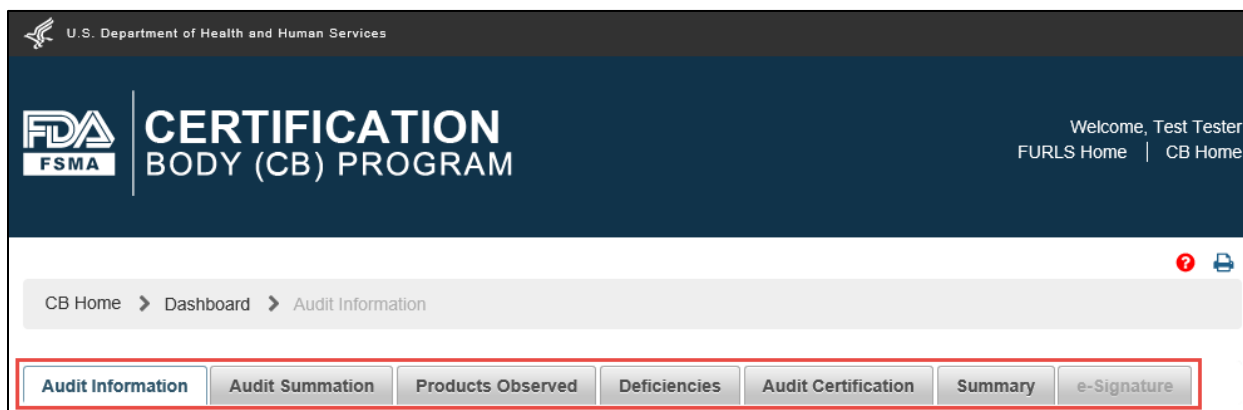
Food Facility Registration Number (If Applicable)

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes
 No

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



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CB Home > Dashboard > Audit Information

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

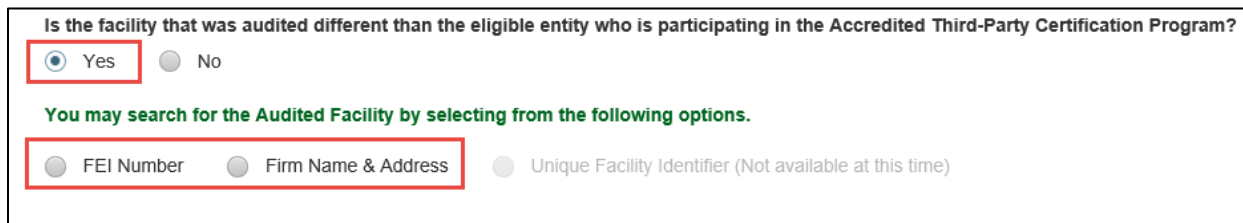
Proceed to Section 6.1.2 of this chapter.

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



Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes No

You may search for the Audited Facility by selecting from the following options.

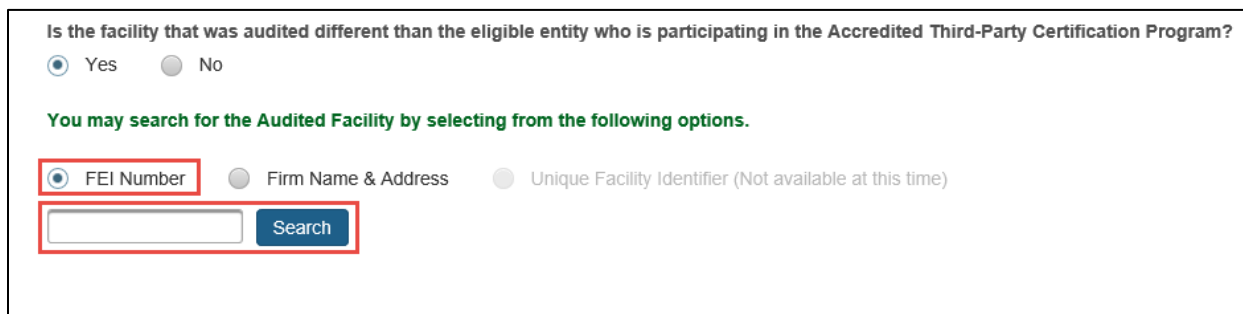
FEI Number Firm Name & Address Unique Facility Identifier (Not available at this time)

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



Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

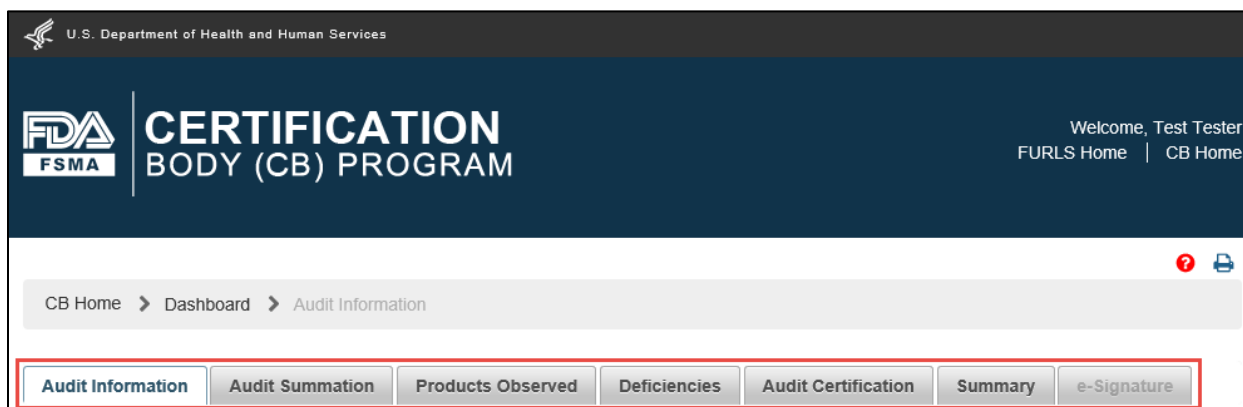
Yes No

You may search for the Audited Facility by selecting from the following options.

FEI Number Firm Name & Address Unique Facility Identifier (Not available at this time)

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



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CB Home > Dashboard > Audit Information

Audit Information | Audit Summation | Products Observed | Deficiencies | Audit Certification | Summary | e-Signature

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

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes No

You may search for the Audited Facility by selecting from the following options.

FEI Number Firm Name & Address Unique Facility Identifier (Not available at this time)

Firm Name

Address Line 1

Address Line 2 (Optional)

City

Country/Area
Please Select One

State/Province/Territory
Please Select One

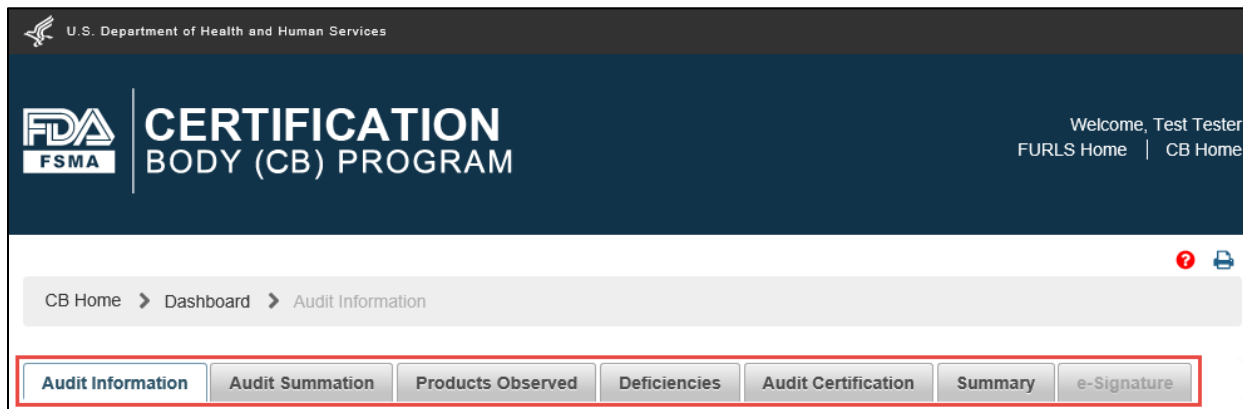
Zip Code (Postal Code)

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

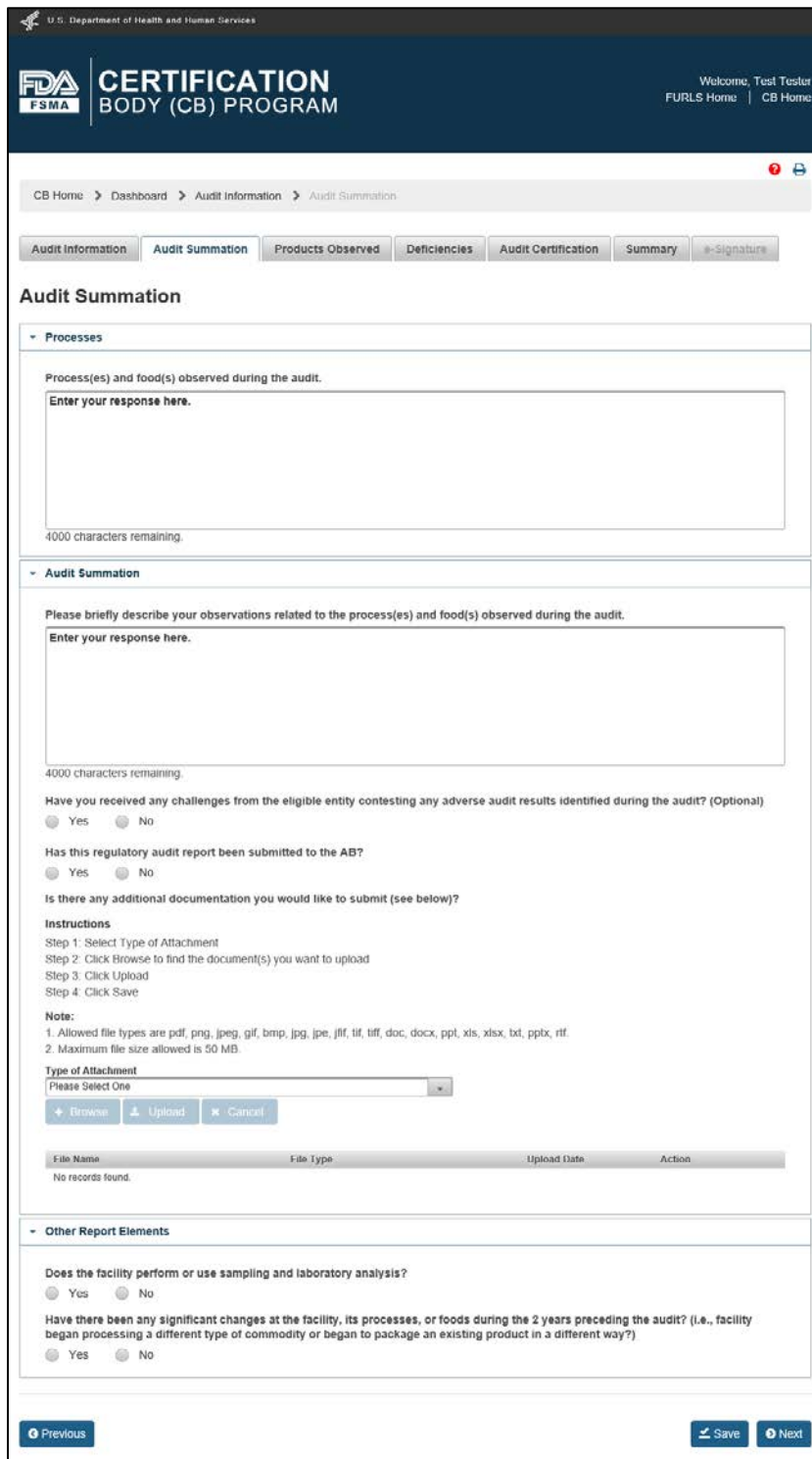
The “Audit Summation” tab allows you to summarize the results of the regulatory audit (e.g., the process(es) and food(s) observed during the regulatory audit and your observations related to the process(es) and food(s) observed during the audit).

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



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CB Home > Dashboard > Audit Information > Audit Summation

Audit Information | **Audit Summation** | Products Observed | Deficiencies | Audit Certification | Summary | Signature

Audit Summation

Processes

Process(es) and food(s) observed during the audit.

Enter your response here.

4000 characters remaining.

Audit Summation

Please briefly describe your observations related to the process(es) and food(s) observed during the audit.

Enter your response here.

4000 characters remaining.

Have you received any challenges from the eligible entity contesting any adverse audit results identified during the audit? (Optional)

Yes No

Has this regulatory audit report been submitted to the AB?

Yes No

Is there any additional documentation you would like to submit (see below)?

Instructions

Step 1: Select Type of Attachment
 Step 2: Click Browse to find the document(s) you want to upload
 Step 3: Click Upload
 Step 4: Click Save

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

Type of Attachment
 Please Select One

File Name	File Type	Upload Date	Action
No records found.			

Other Report Elements

Does the facility perform or use sampling and laboratory analysis?

Yes 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?)

Yes No

- **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

Have you received any challenges from the eligible entity contesting any adverse audit results identified during the audit? (Optional)

Yes No

What was the final status of this appeal? (Optional)

Enter your response here.

2000 characters remaining.

- **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

Has this regulatory audit report been submitted to the AB?

Yes No

Is there any additional documentation you would like to submit (see below)? (Optional)

Instructions

Step 1: Select Type of Attachment
 Step 2: Click Browse to find the document(s) you want to upload
 Step 3: Click Upload
 Step 4: Click Save

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

Type of Attachment

Please Select One

+ Browse Upload * Cancel

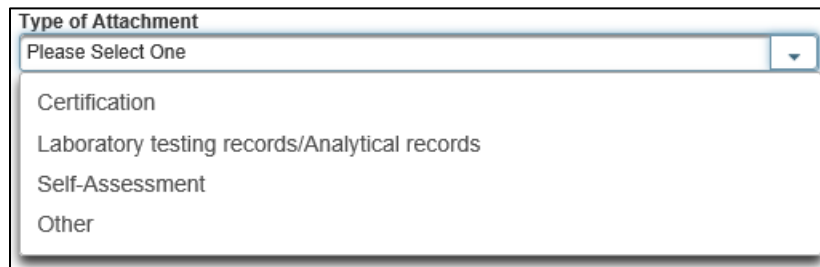
File Name	File Type	Upload Date	Action
No records found.			

Other Report Elements

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”

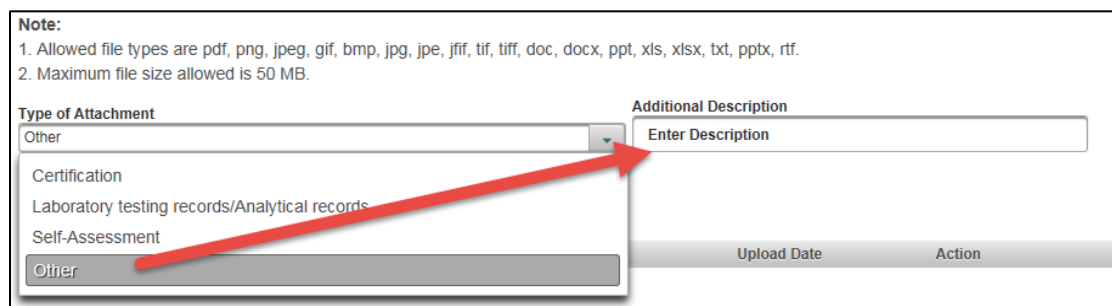
Figure 6.33 – Type of Attachment Dropdown Menu



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

Is there any additional documentation you would like to submit (see below)?

Instructions
 Step 1: Select Type of Attachment
 Step 2: Click Browse to find the document(s) you want to upload
 Step 3: Click Upload
 Step 4: Click Save

Note:
 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

Type of Attachment: Other
 Additional Description: Test Document

+ Browse Upload × Cancel

Product Audit.pdf N/A [] ×

File Name	File Type	Upload Date	Action
No records found.			

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

Note:
 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

Product Audit.pdf uploaded successfully.

Type of Attachment: Please Select One

+ Browse Upload × Cancel

File Name	File Type	Upload Date	Action
Product Audit.pdf	Other-Test Document	2019-05-08	

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

Other Report Elements

Does the facility perform or use sampling and laboratory analysis?
 Yes 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?)
 Yes No

Please explain

Enter your response here.

4000 characters remaining.

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

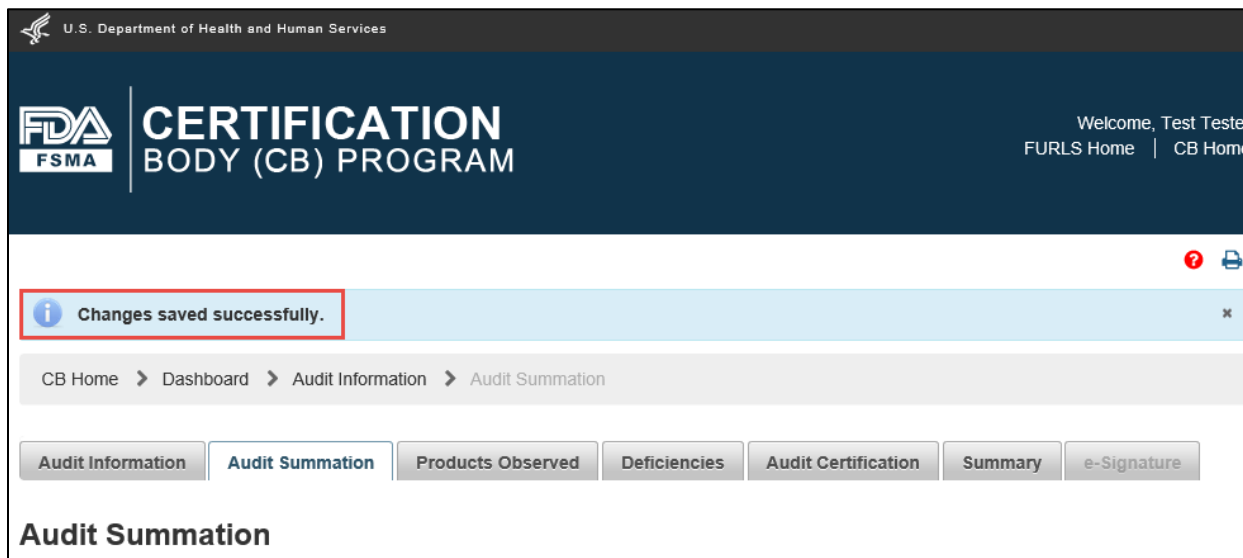
Once the “Changes saved successfully” message (Figure 6.38) appears at the top of the screen, proceed to the “Products Observed” tab.

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

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?
🖨️

i **Changes saved successfully.**
×

CB Home > Dashboard > Audit Information > Audit Summation

Audit Information

Audit Summation

Products Observed

Deficiencies

Audit Certification

Summary

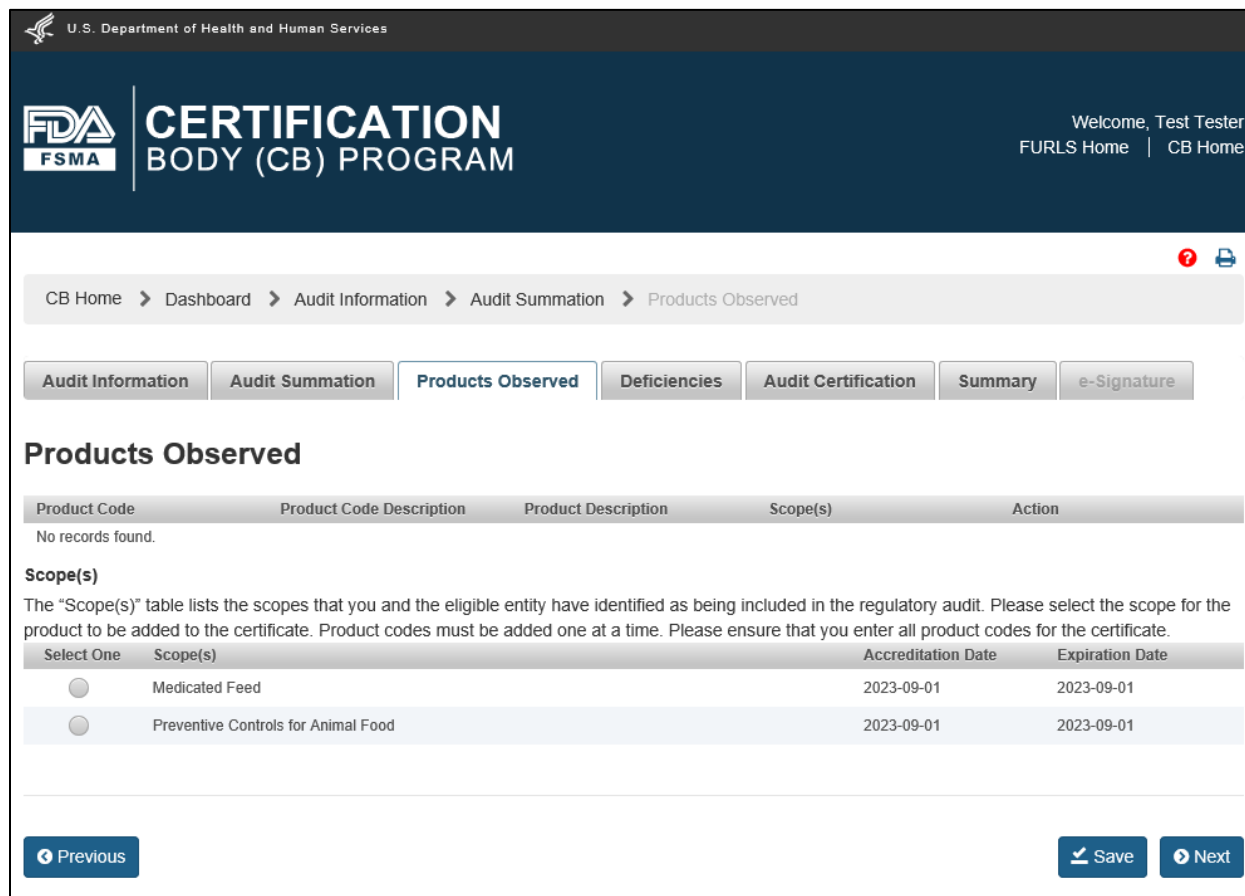
e-Signature

Audit Summation

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



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CB Home > Dashboard > Audit Information > Audit Summation > Products Observed

Audit Information | Audit Summation | **Products Observed** | Deficiencies | Audit Certification | Summary | e-Signature

Products Observed

Product Code	Product Code Description	Product Description	Scope(s)	Action
No records found.				

Scope(s)

The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="radio"/>	Medicated Feed	2023-09-01	2023-09-01
<input type="radio"/>	Preventive Controls for Animal Food	2023-09-01	2023-09-01

[Previous](#) [Save](#) [Next](#)

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.

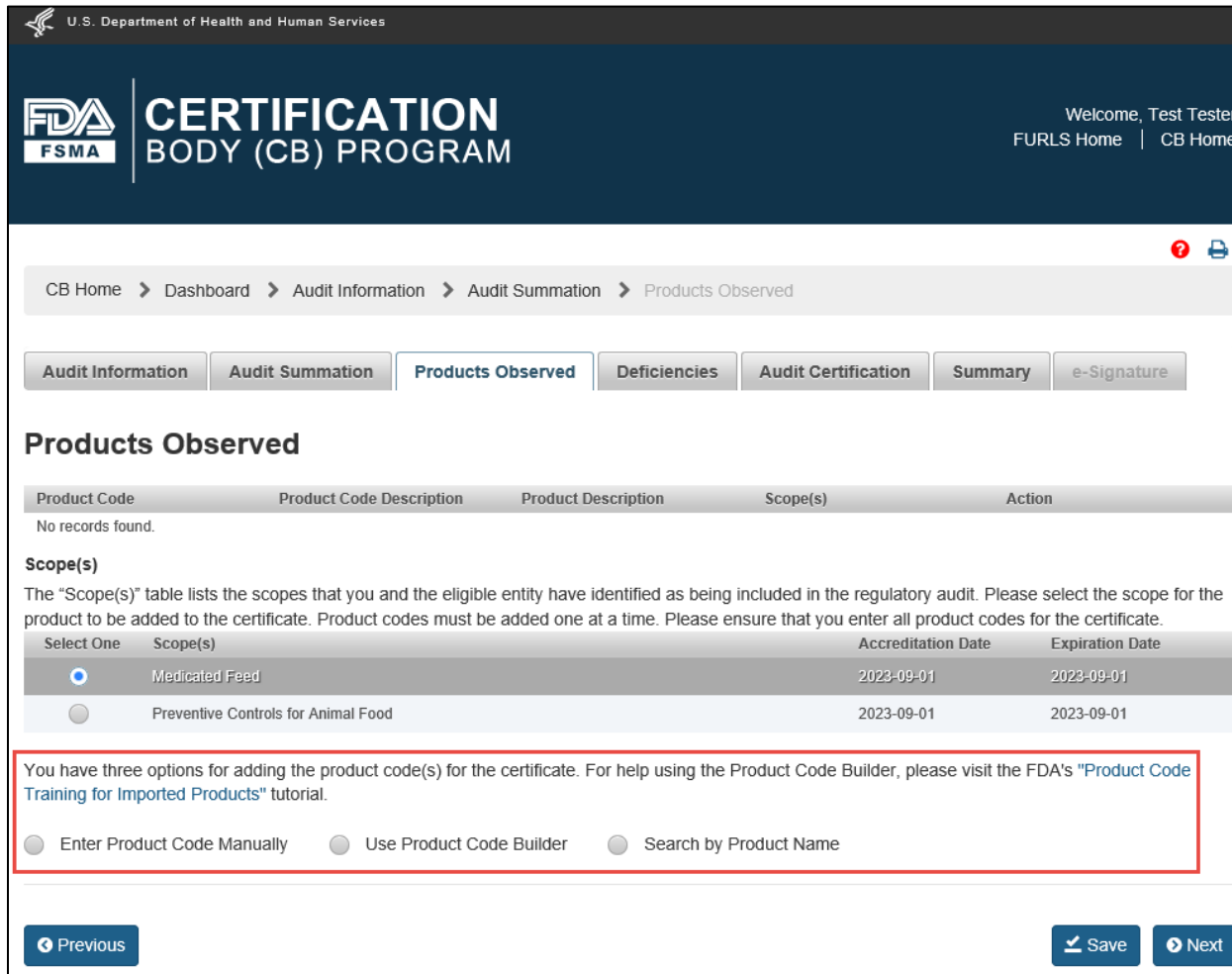
Select the scope of the product you wish to enter by clicking the radio button in the “Select One” column of the “Scope(s)” table. After you select a scope, the system will display three options for adding the corresponding product code(s) to the regulatory audit report (Figure 6.40).

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



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Products Observed

Product Code	Product Code Description	Product Description	Scope(s)	Action
No records found.				

Scope(s)

The "Scope(s)" table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="radio"/>	Medicated Feed	2023-09-01	2023-09-01
<input type="radio"/>	Preventive Controls for Animal Food	2023-09-01	2023-09-01

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually Use Product Code Builder Search by Product Name

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6.1.3.1 Product Code Selection – Enter Product Code Manually

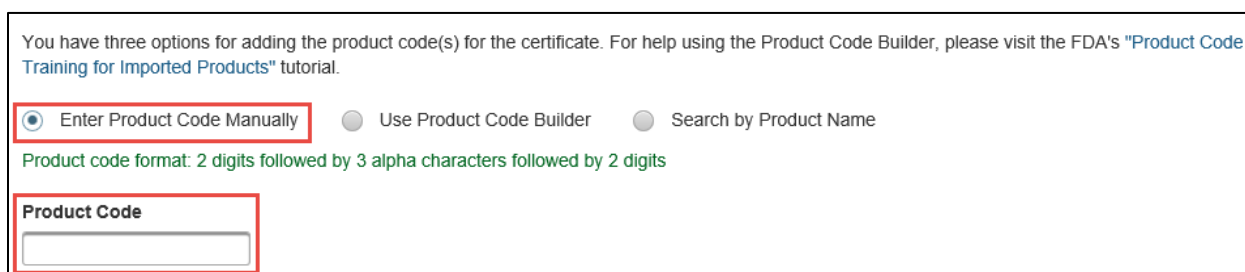
You may use the “Enter Product Code Manually” option if you know the complete product code. Select the radio button to the left of “Enter Product Code Manually.”

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



You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "Product Code Training for Imported Products" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product code format: 2 digits followed by 3 alpha characters followed by 2 digits

Product Code

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

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product code format: 2 digits followed by 3 alpha characters followed by 2 digits

Product Code

Product Code Description

Product Description (Optional)

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

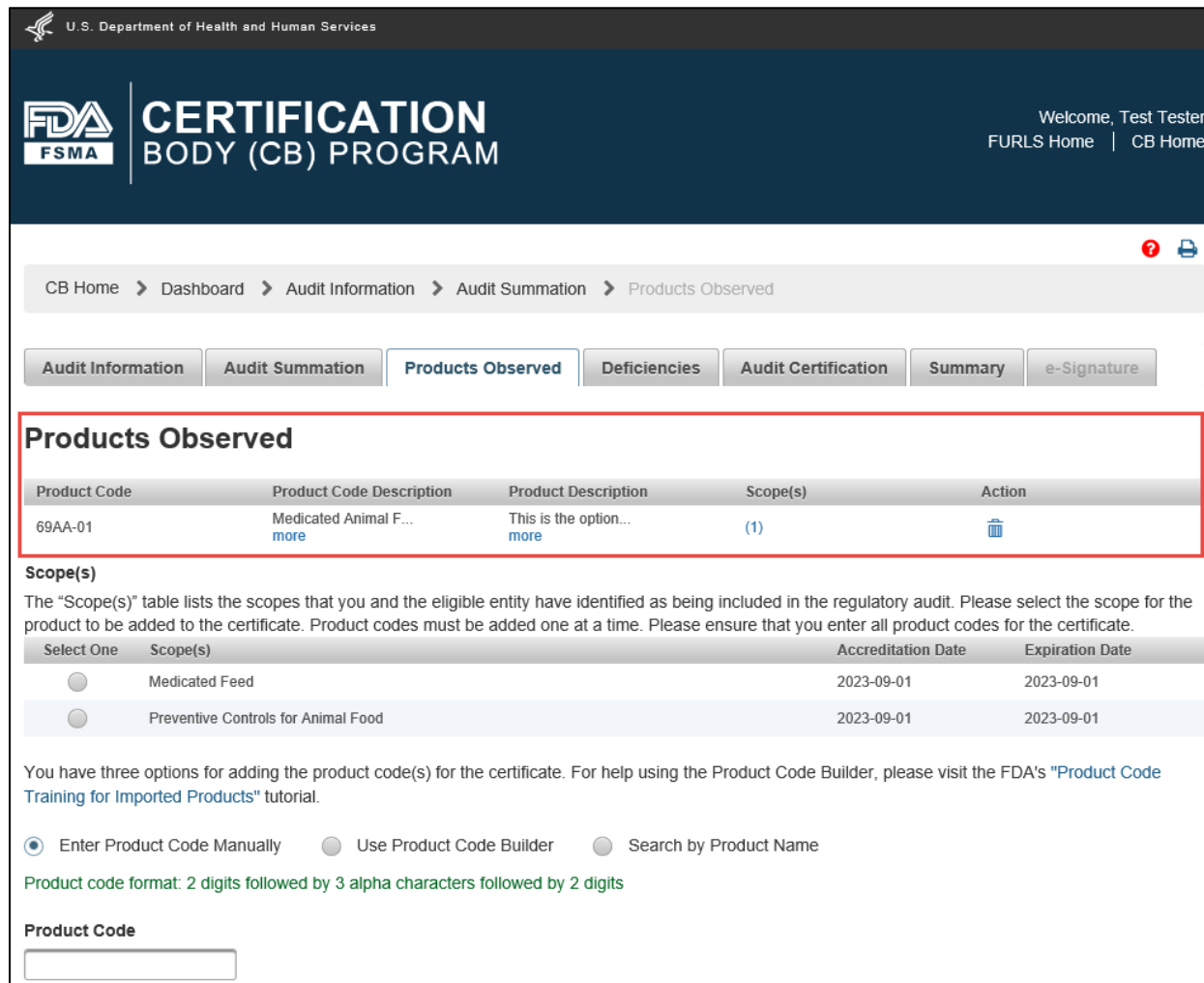
Repeat the previous steps to add more products.

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



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Products Observed

Product Code	Product Code Description	Product Description	Scope(s)	Action
69AA-01	Medicated Animal F... more	This is the option... more	(1)	

Scope(s)

The "Scope(s)" table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)	Accreditation Date	Expiration Date
<input type="radio"/>	Medicated Feed	2023-09-01	2023-09-01
<input type="radio"/>	Preventive Controls for Animal Food	2023-09-01	2023-09-01

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually Use Product Code Builder Search by Product Name

Product code format: 2 digits followed by 3 alpha characters followed by 2 digits

Product Code

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

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "Product Code Training for Imported Products" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Industry

Select One

Class

Select One

SubClass

Select One

Process Indicator

Select One

Product

Select One

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

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Industry
 Medicated Animal Feeds - 69

Class
 Category I - A

SubClass
 Type B Feed From Type A Med Article - A

Process Indicator
 Select One

Product
 Aklomide Category I, Medicated Animal Feed (A-01)

Product Code
 69AA-01

Product Code Description
 Medicated Animal Feeds/Category I/Type B Feed From Type A Med Article/Aklomide Category I, Medicated Animal Feed

Product Description (Optional)
 [Empty text area]

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

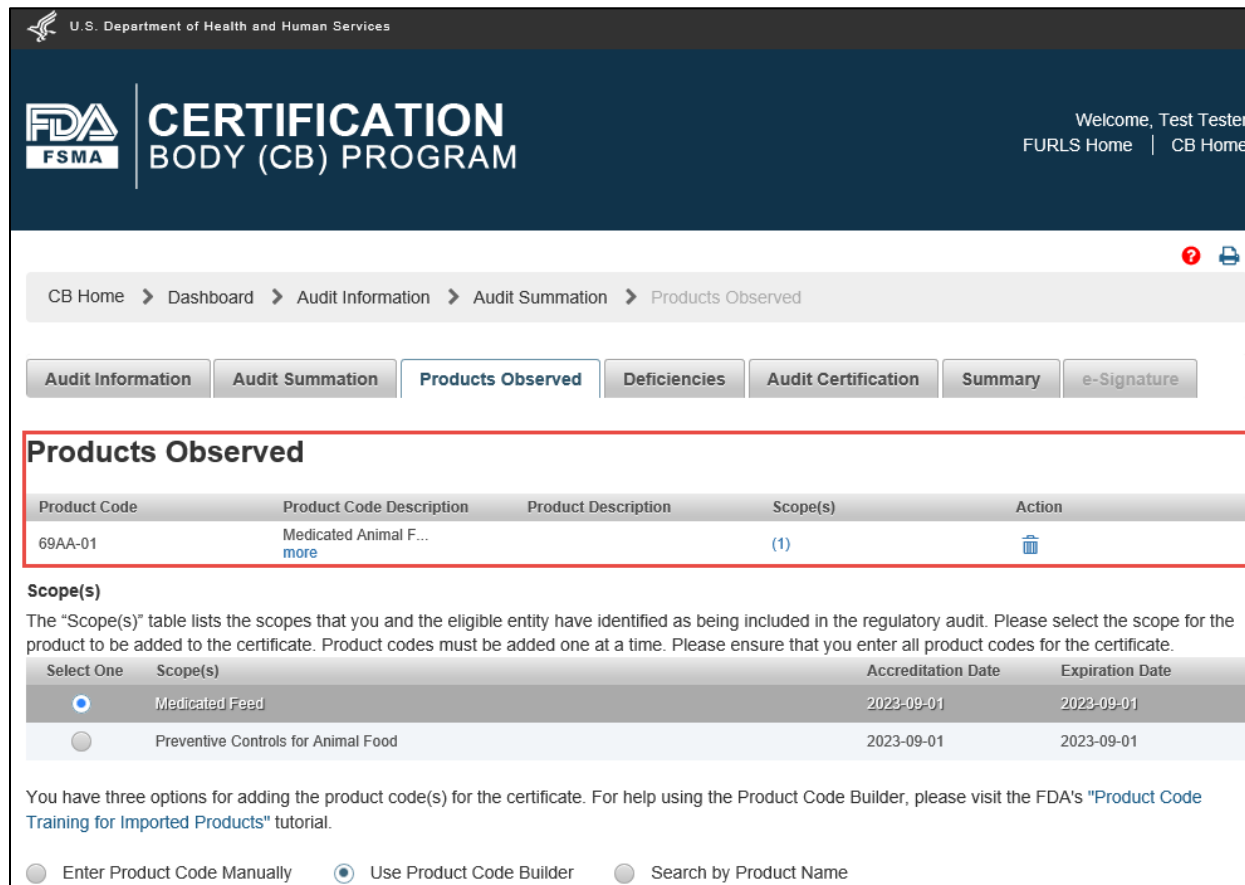
Repeat the previous steps to add more products.

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



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Products Observed

Product Code	Product Code Description	Product Description	Scope(s)	Action
69AA-01	Medicated Animal F... more		(1)	

Scope(s)

The "Scope(s)" table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="radio"/>	Medicated Feed	2023-09-01	2023-09-01
<input type="radio"/>	Preventive Controls for Animal Food	2023-09-01	2023-09-01

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually Use Product Code Builder Search by Product Name

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

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "Product Code Training for Imported Products" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product	Industry	Class
Aklomide Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Ammonium Chloride Combo Category I & II, Medicated Ani	Medicated Animal Feeds - 69	Combo Category I & II - C
Amprolium Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Amprolium Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Amprolium With Ethopabate Category I, Medicated Animal	Medicated Animal Feeds - 69	Category I - A
Amprolium With Ethopabate Combo Category I & II, Medic	Medicated Animal Feeds - 69	Combo Category I & II - C
Apramycin Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Apramycin Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Arsanilate Sodium Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B

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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

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product	Industry	Class
aklomide	medicated	
Aklomide Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Roxarsone And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Roxarsone And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran, Aklomide & Roxarsone Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran, Aklomide & Roxarsone Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C

(1 of 1)

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

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product	Industry	Class
aklomite	medicated animal feeds	
Aklomide Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Roxarsone And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Roxarsone And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran, Aklomide & Roxarsone Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran, Aklomide & Roxarsone Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C

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SubClass
 Select One

Process Indicator
 Not Applicable

Product Code
 69A--01

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

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product	Industry	Class
aklomite	medicated	
Aklomite Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Aklomite Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Roxarsone And Aklomite Category II, Medicated Animal Fe	Medicated Animal Feeds - 69	Category II - B
Roxarsone And Aklomite Combo Category I & II, Medicate	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran And Aklomite Category II, Medicated Animal Fe	Medicated Animal Feeds - 69	Category II - B
Sulfanitran And Aklomite Combo Category I & II, Medicate	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran,Aklomite & Roxarsone Category II, Medicated /	Medicated Animal Feeds - 69	Category II - B
Sulfanitran,Aklomite & Roxarsone Combo Category I & II, I	Medicated Animal Feeds - 69	Combo Category I & II - C

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SubClass: Type B Feed From Type A Med Article - A
Process Indicator: Not Applicable

Product Code: 69AA-01
Product Code Description: Medicated Animal Feeds/Category II/Type B Feed From Type A Med Article/Aklomite Category I, Medicated Animal Feed
Product Description (Optional): This is the optional product description.

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

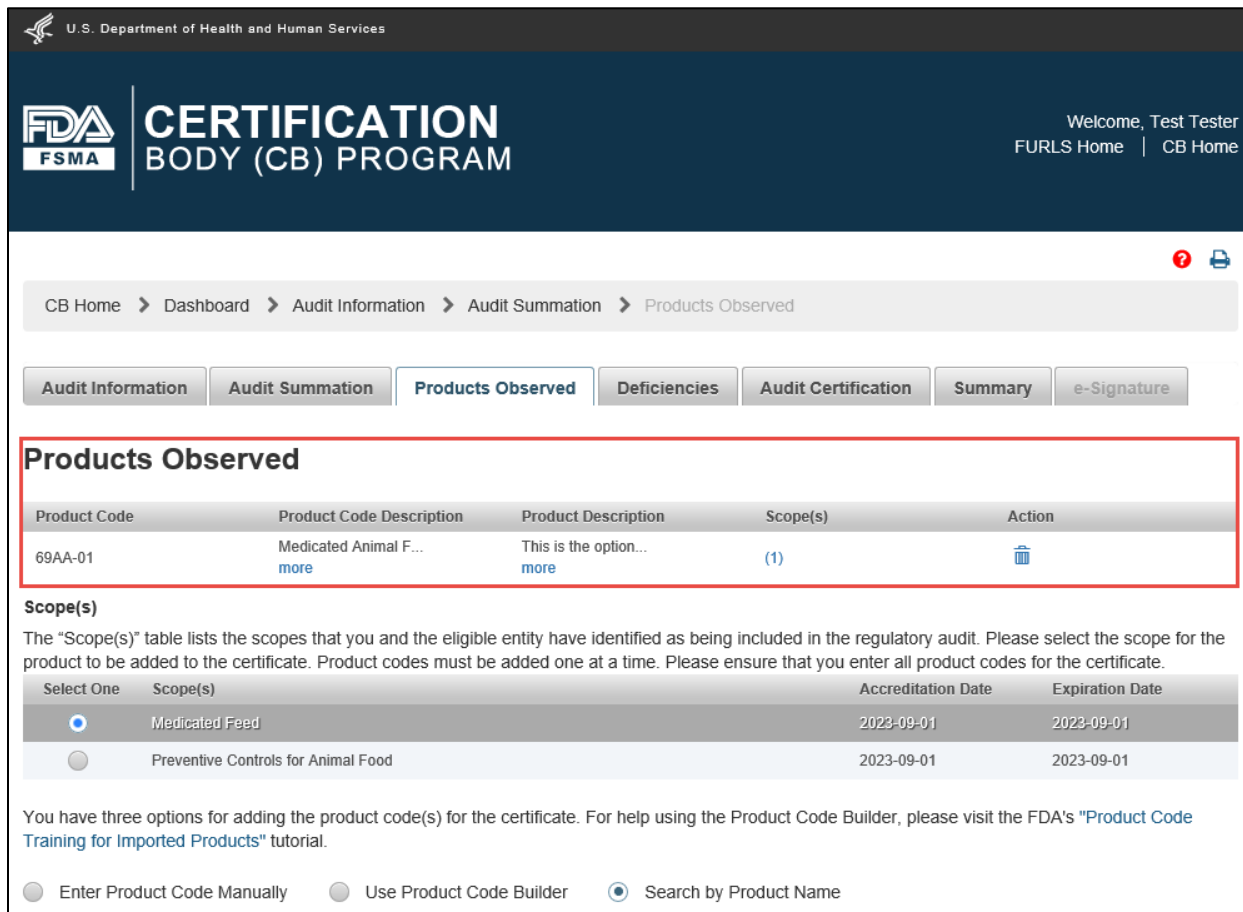
Repeat the previous steps to add more products.

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



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Products Observed

Product Code	Product Code Description	Product Description	Scope(s)	Action
69AA-01	Medicated Animal F... more	This is the option... more	(1)	

Scope(s)

The "Scope(s)" table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="radio"/>	Medicated Feed	2023-09-01	2023-09-01
<input type="radio"/>	Preventive Controls for Animal Food	2023-09-01	2023-09-01

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "[Product Code Training for Imported Products](#)" tutorial.

Enter Product Code Manually Use Product Code Builder Search by Product Name

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.

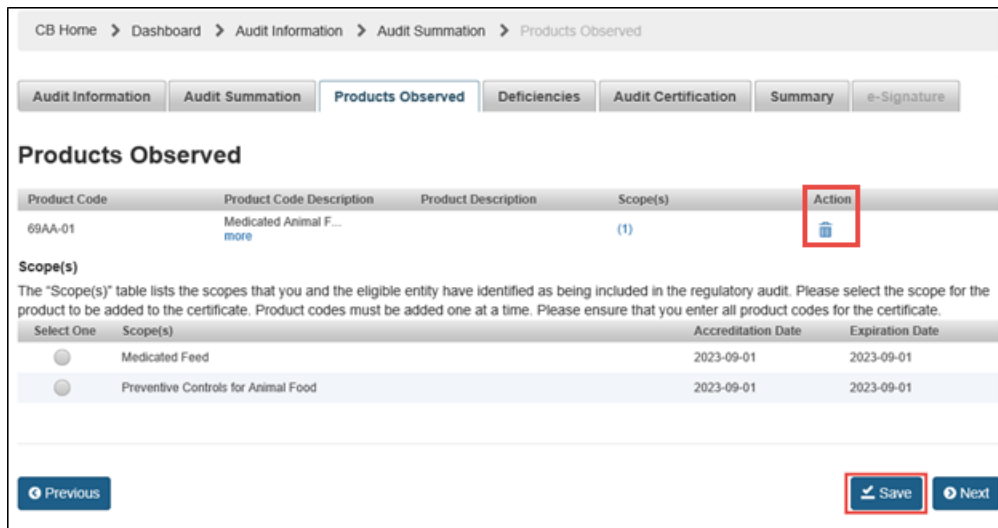
After you enter the product codes for each scope option (using any of the three available options), review the "Products Observed" table for accuracy.

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.

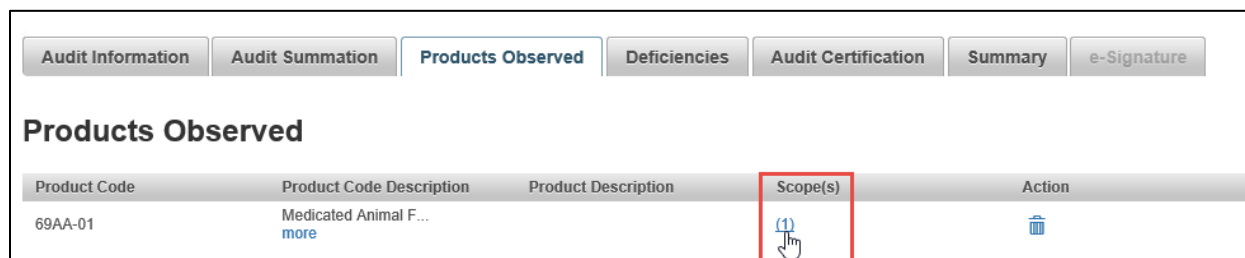
****Important:** Once you submit the regulatory audit report to FDA you cannot add or delete product code(s).

Figure 6.52 – Products Observed – Trash Icon and Save Button



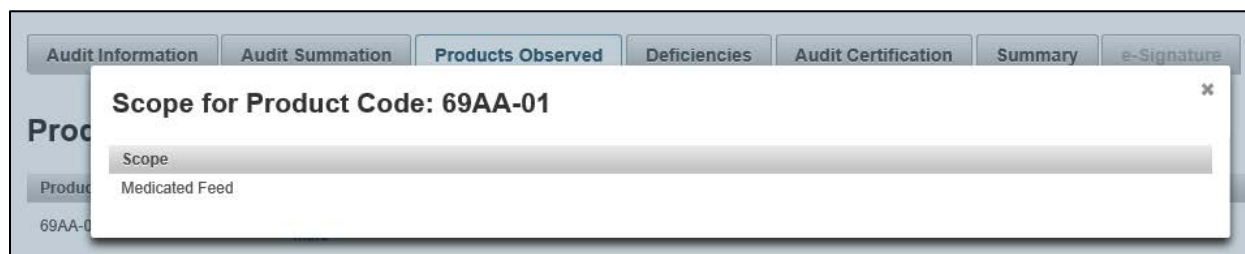
Once you have added a product to the regulatory audit report, the “Scope(s)” column of the table of product(s) will display the number of scopes to which the product is associated (Figure 6.53).

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

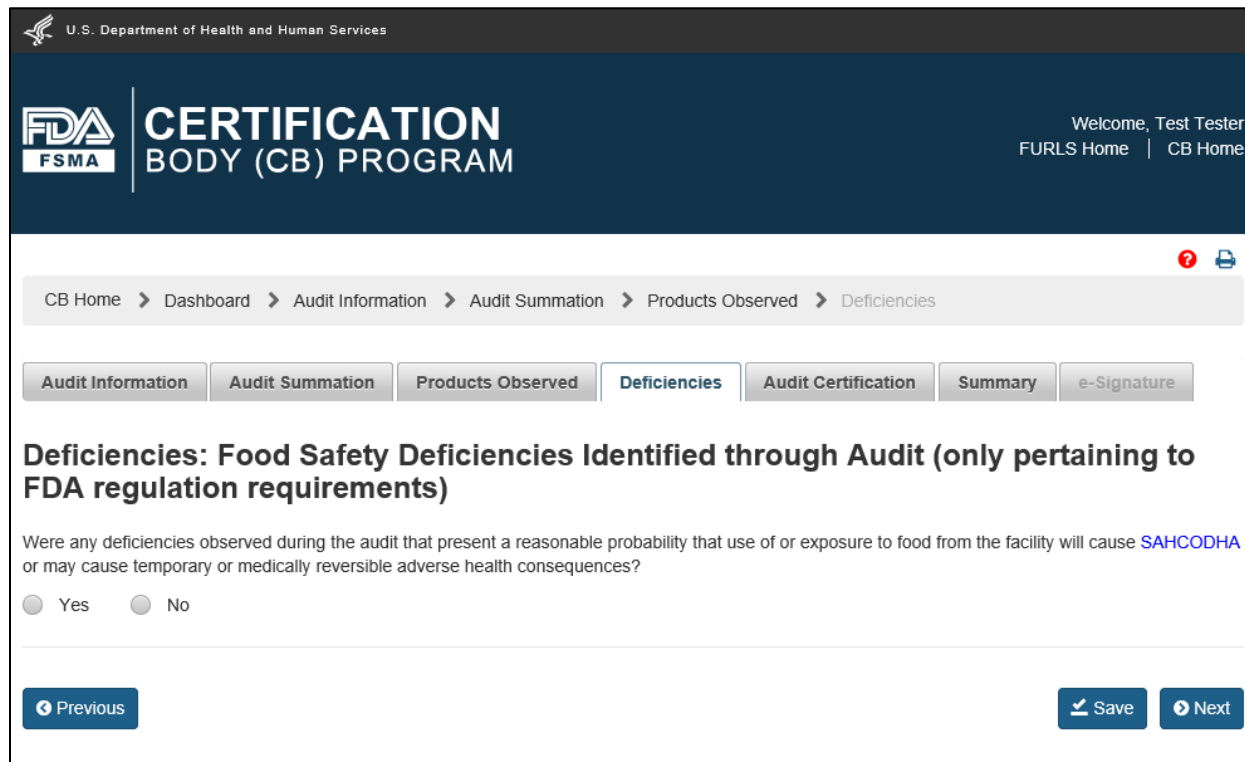


Click the “Next” button to proceed to the “Deficiencies” tab or click on the “Deficiencies” tab directly.

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



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Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

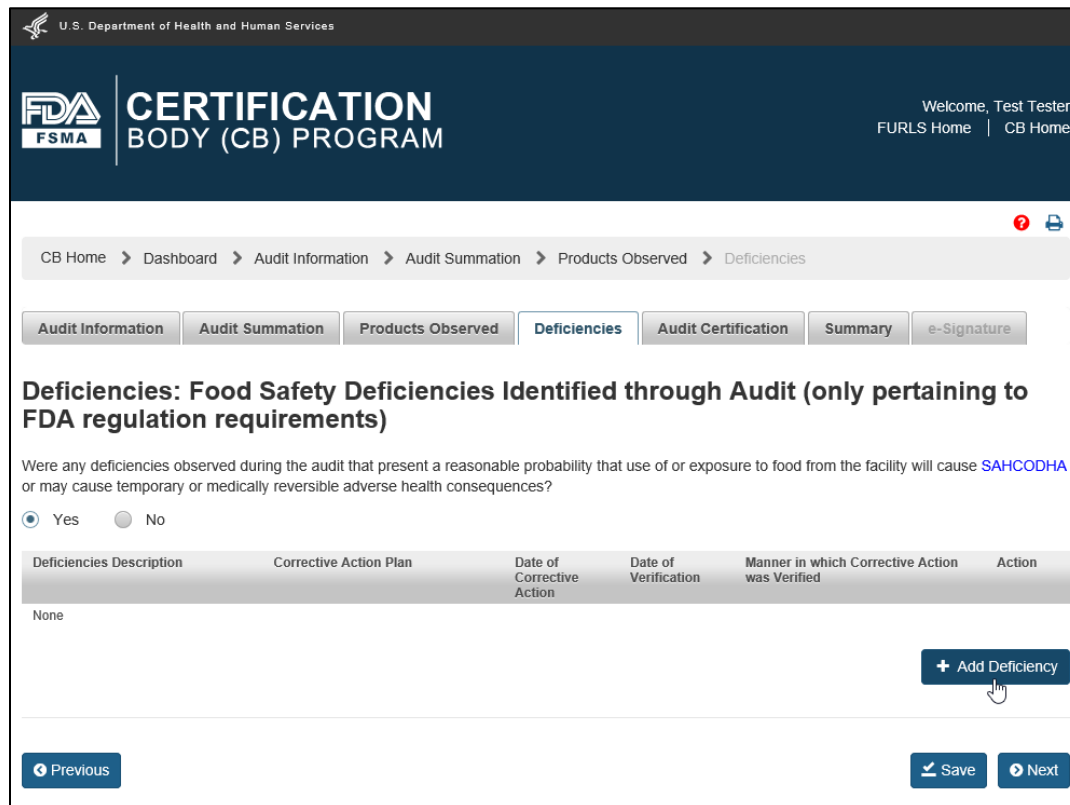
Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause [SAHCODHA](#) or may cause temporary or medically reversible adverse health consequences?

Yes No

[Previous](#) [Save](#) [Next](#)

- **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



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Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause SAH/CODHA or may cause temporary or medically reversible adverse health consequences?

Yes No

Deficiencies Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Manner in which Corrective Action was Verified	Action
None					

Please describe any deficiencies that present a reasonable probability that use of or exposure to food from the facility will cause SAH/CODHA or may cause temporary or medically reversible adverse health consequences.

Enter your response here.

4000 characters remaining.

Was corrective action implemented immediately and verified on site?

Yes No

Please describe the corrective action plan for each such deficiency.

Enter your response here.

4000 characters remaining.

Date of Corrective Action

YYYY-MM-DD

Describe the manner in which the corrective action was verified.

Enter your response here.

4000 characters remaining.

Date of Verification of Corrective Action

YYYY-MM-DD

Cancel + Add Deficiency

Previous Save Next

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



CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies

Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause SAH/CODHA or may cause temporary or medically reversible adverse health consequences?

Yes No

Deficiencies Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Manner in which Corrective Action was Verified	Action
Deficiency 1, Deficiency... more	Action taken on site.	2019-05-12	2019-05-12	Verified.	 

[+ 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.

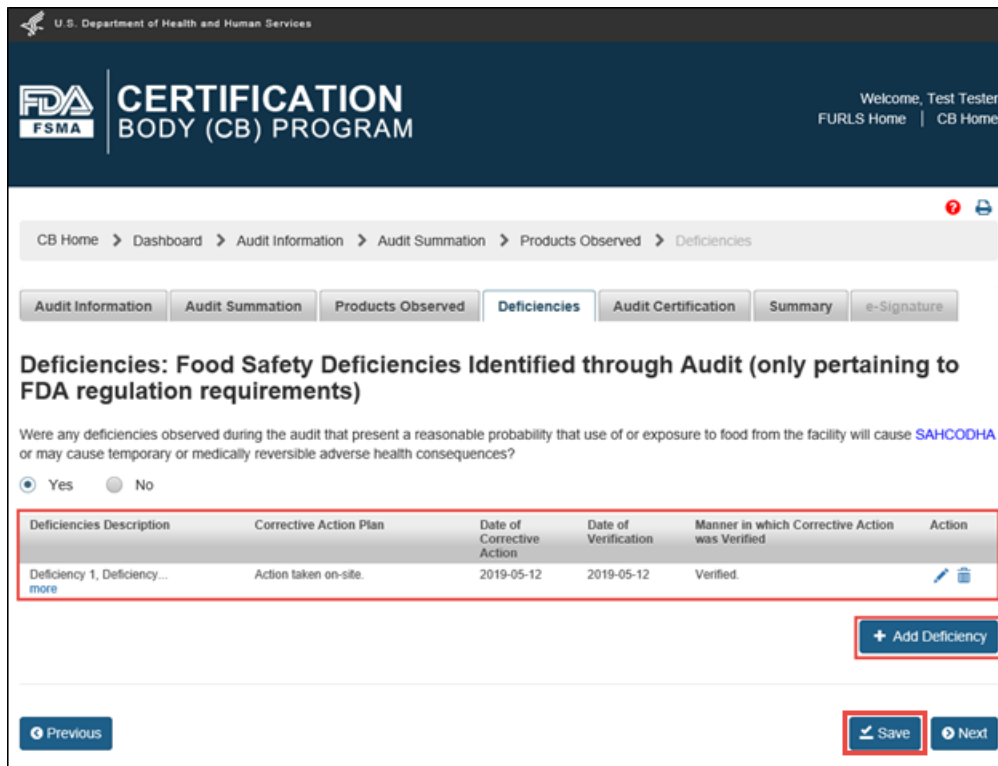
Enter any additional deficiencies by clicking the “Add Deficiency” button and repeating the steps.

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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
FURLS Home | CB Home


CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies

Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause SAH/CODHA or may cause temporary or medically reversible adverse health consequences?

Yes No

Deficiencies Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Manner in which Corrective Action was Verified	Action
Deficiency 1, Deficiency... more	Action taken on-site.	2019-05-12	2019-05-12	Verified.	

[+ Add Deficiency](#)

[Previous](#) [Save](#) [Next](#)

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.

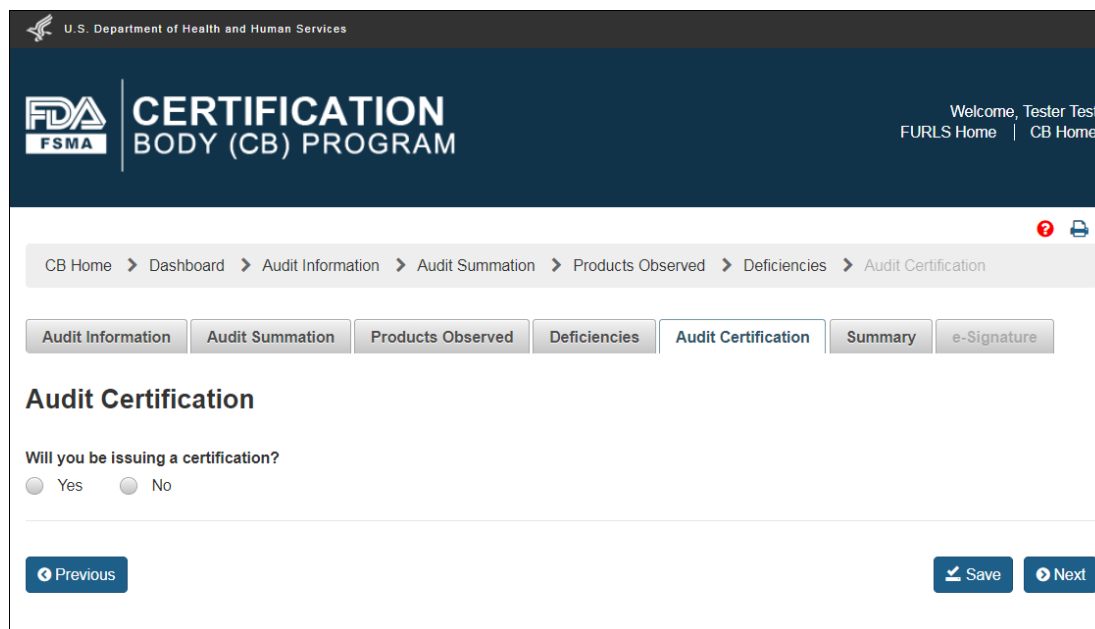
6.1.5.1 Submit a New Regulatory Audit Report and Submit the Issued Certification Information

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:

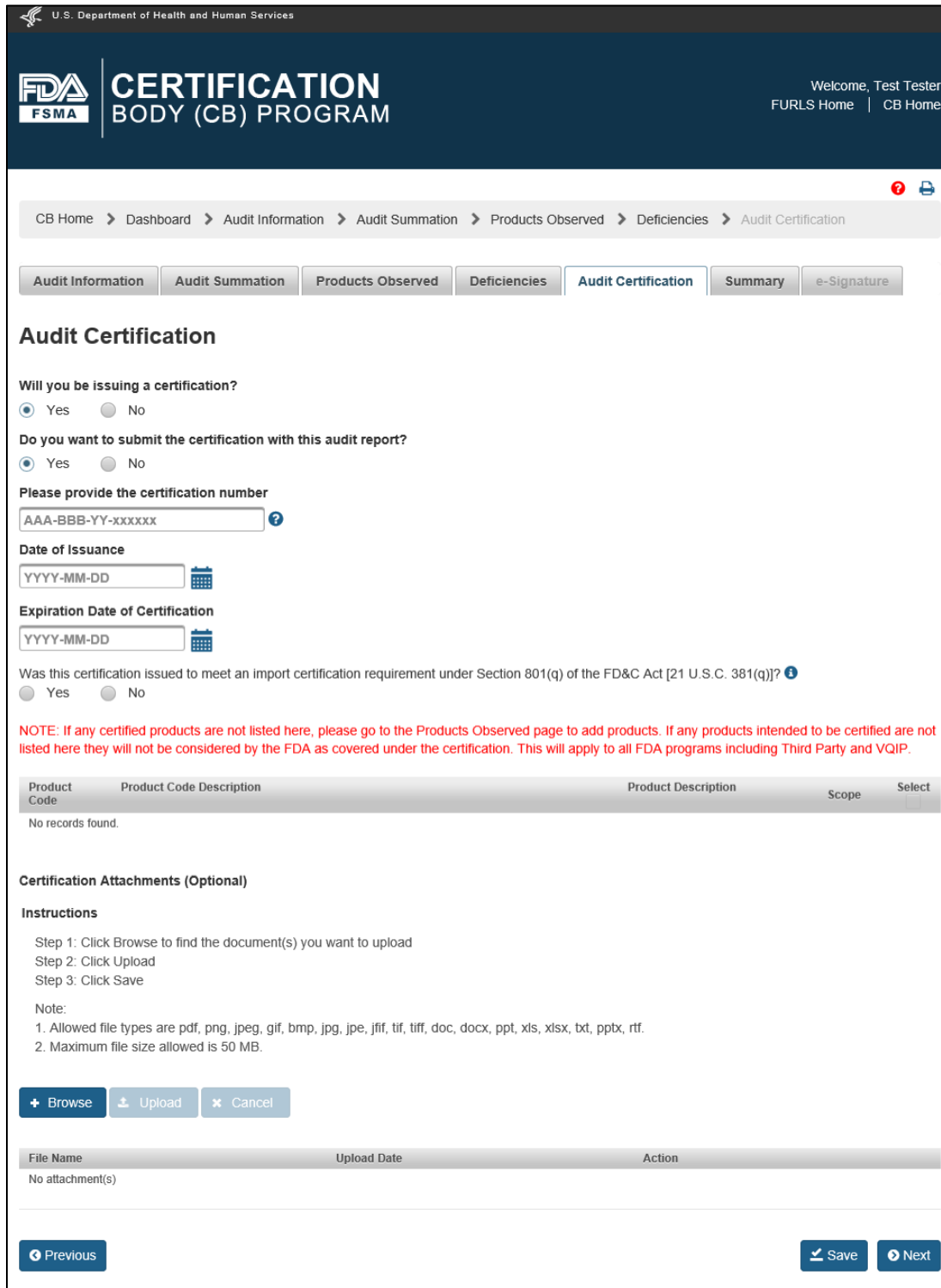
In certain circumstances, FDA may require certification of an imported food product to help prevent a potentially harmful food from entering the U.S.

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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies > Audit Certification

Audit Information | Audit Summation | Products Observed | Deficiencies | **Audit Certification** | Summary | e-Signature

Audit Certification

Will you be issuing a certification?
 Yes No

Do you want to submit the certification with this audit report?
 Yes No

Please provide the certification number
 ?

Date of Issuance

Expiration Date of 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)]?
 Yes No

NOTE: If any certified products are not listed here, please go to the Products Observed page to add products. If any products intended to be certified are not listed here they will not be considered by the FDA as covered under the certification. This will apply to all FDA programs including Third Party and VQIP.

Product Code	Product Code Description	Product Description	Scope	Select
No records found.				

Certification Attachments (Optional)

Instructions

Step 1: Click Browse to find the document(s) you want to upload
 Step 2: Click Upload
 Step 3: Click Save

Note:

- Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
- Maximum file size allowed is 50 MB.

+ Browse | Upload | Cancel

File Name	Upload Date	Action
No attachment(s)		

Previous | Save | Next

- **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

NOTE: If any certified products are not listed here, please go to the Products Observed page to add products. If any products intended to be certified are not listed here they will not be considered by the FDA as covered under the certification. This will apply to all FDA programs including Third Party and VQIP.

Product Code	Product Code Description	Product Description	Scope	Select
69AA-01	Medicated Animal Feeds/Category I/Type B Feed From Type A Med Article/AKlomid Category I, Medicated Animal Feed		(1)	<input checked="" type="checkbox"/>

- **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)

Certification Attachments (Optional)

Instructions

Step 1: Click Browse to find the document(s) you want to upload
 Step 2: Click Upload
 Step 3: Click Save

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

File Name	Upload Date	Action
No attachment(s)		

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

Note:
 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

+ Browse **Upload** × Cancel

Test Document.pdf	198.9 KB	<input type="text"/>	×
Test Document 2.xlsx	16.2 KB	<input type="text"/>	×

File Name	Upload Date	Action
No attachment(s)		

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

Note:
 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

Test Document.pdf uploaded successfully.
Test Document 2.xlsx uploaded successfully.

+ Browse Upload × Cancel

File Name	Upload Date	Action
Test Document 2.xlsx	2019-05-09	
Test Document.pdf	2019-05-09	

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.

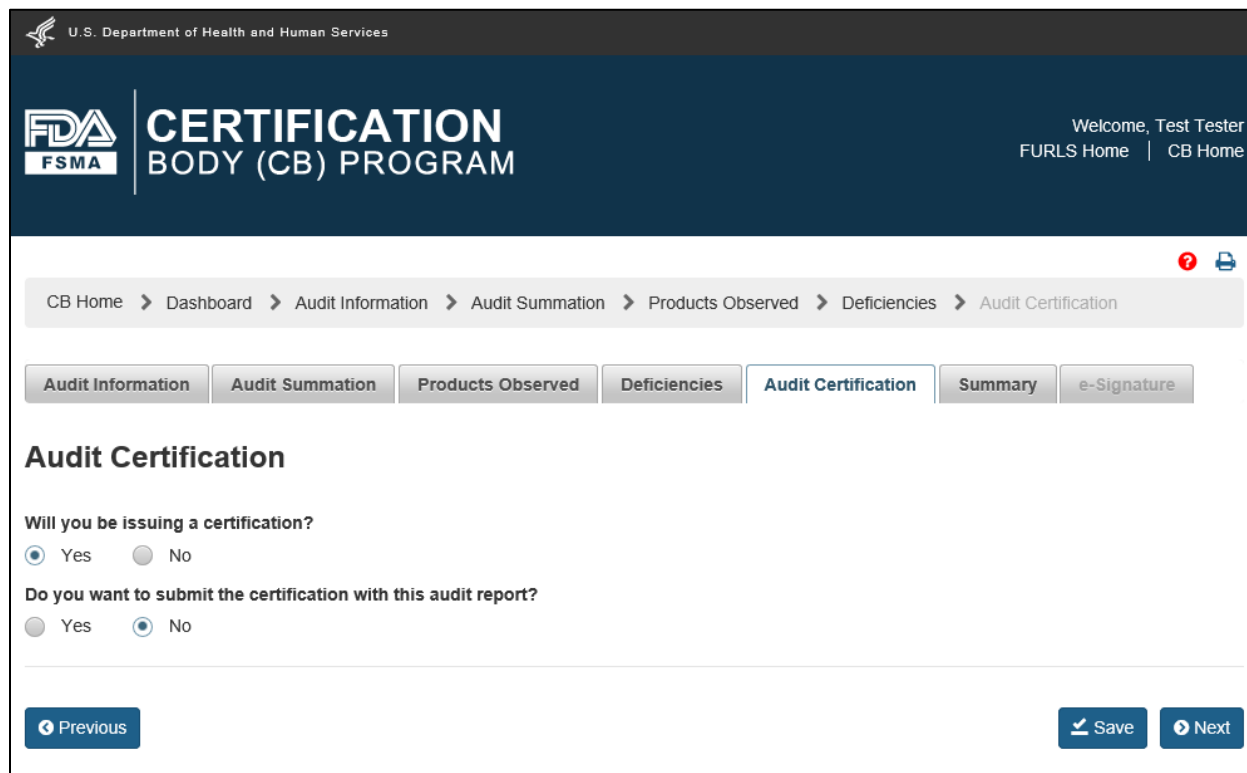
6.1.5.2 Submit a New Regulatory Audit Report and Submit the Issued Certification Information at Another Time

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?”



U.S. Department of Health and Human Services

FDA FSMA | **CERTIFICATION BODY (CB) PROGRAM**

Welcome, Test Tester
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CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies > Audit Certification

Audit Information | Audit Summation | Products Observed | Deficiencies | **Audit Certification** | Summary | e-Signature

Audit Certification

Will you be issuing a certification?

Yes No

Do you want to submit the certification with this audit report?

Yes No

[Previous](#) [Save](#) [Next](#)

Click the “Save” button to save your changes.

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

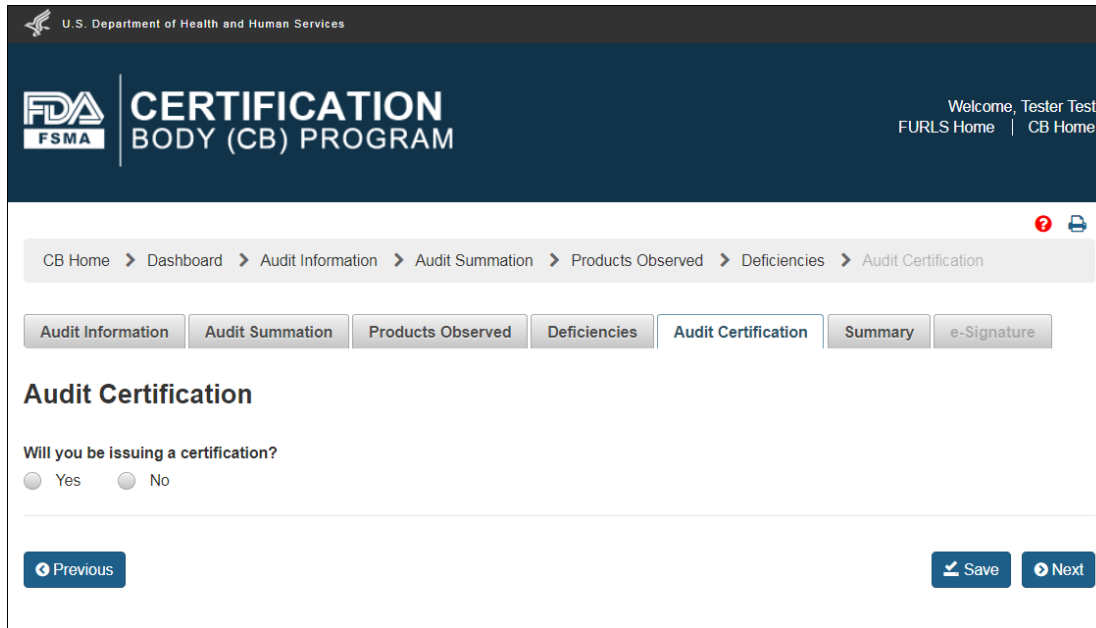
Proceed to Section 6.1.6 of this chapter.

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.”

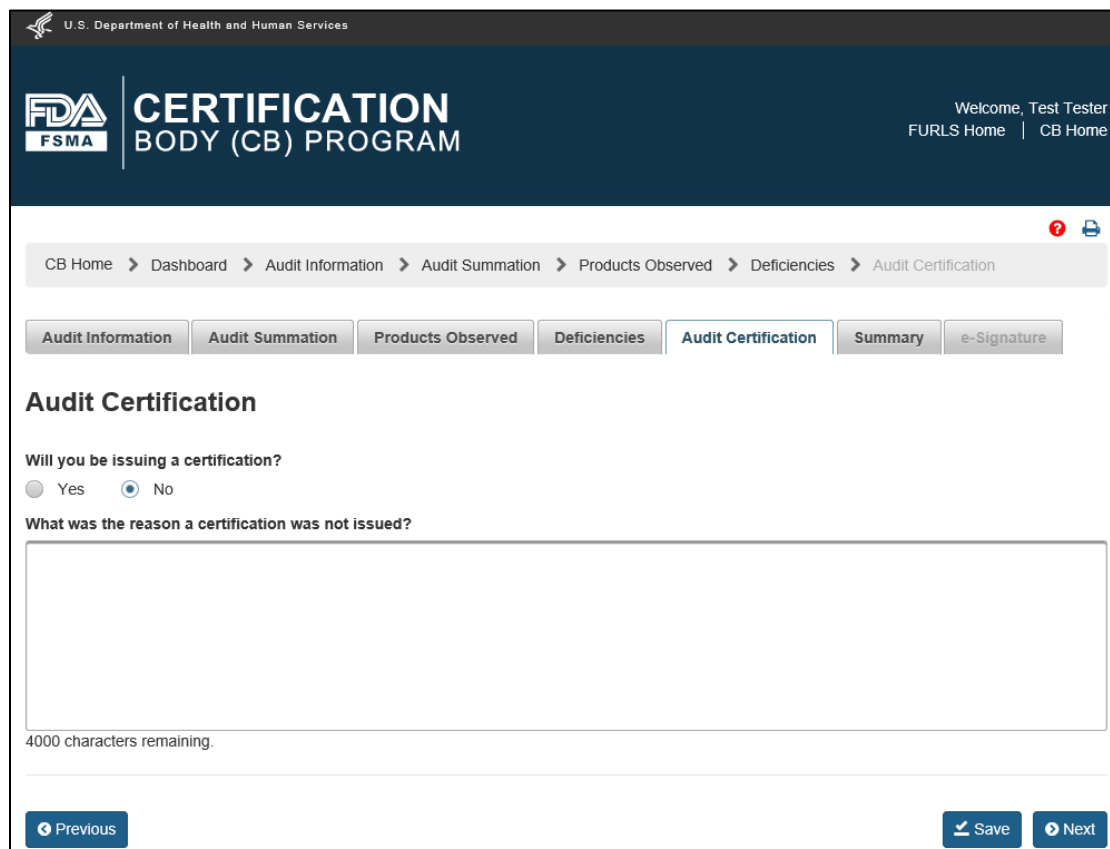
Figure 6.67 – Audit Certification Tab – Default View



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



Summary
Review the following information for correctness, and edit as needed.

Audit Information [Edit](#)

Accredited Third-Party Information

CB Name
 TPP CB User Guide Facility
 Type of certification requested
 Facility (e.g., VOP)
 Audit Start Date
 2019-02-01
 Audit End Date
 2019-02-03
 AD Name
 PP Testing Inc.
 Scope(s)

Product(s)	Approval Date	Expiration Date
Wheat Flour	2019-02-03	2020-02-03
Whole Wheat Flour and Other Cereal Flour (Wheat, Rye, Barley, etc.)	2019-02-03	2020-02-03
Low-Moisture Cereal Flours (LMCF)	2019-02-03	2020-02-03

Audit Agent(s)

Agents who worked on the audit	Agent Email Address
Agent 3	agent3@pp1.com

Eligible Entity Information

Audit Summation [Edit](#)

PROCXMR

Audit Summation

Other Report Elements

Products Observed [Edit](#)

Products Observed

Product Code	Product Code Description	Product Description	Remarks
020102	Wheat Flour (Soft White) (100% Hard Enduro)	This is a Test response to Product Description.	(1)
020103	Wheat Flour (Soft White) (100% Hard Enduro) (Wheat)	This is a Test response to Product Description.	(1)
020104	Wheat Flour (Soft White) (100% Hard Enduro) (Wheat) (Wheat)	This is a Test response to Product Description.	(1)

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements) [Edit](#)

The Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

Deficiency Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Reason for which Corrective Action was Verified
This is a Test response to the deficiency request...	This is a Test response to the deficiency request...	2019-02-03	2019-02-03	This is a Test response to the deficiency request...

Audit Certification [Edit](#)

Audit Certification

Will you be issuing a certification?
 Yes

Do you want to submit the certification with this audit report?
 Yes

Please provide the certification number
 12345678901234567890

Date of Issuance
 2019-02-01

Expiration Date of Certification
 2019-02-01

Product Code	Product Code Description	Product Description	Remarks
No records found.			

File Name
 Test Document 1.xlsx
 Upload Date
 2019-02-03

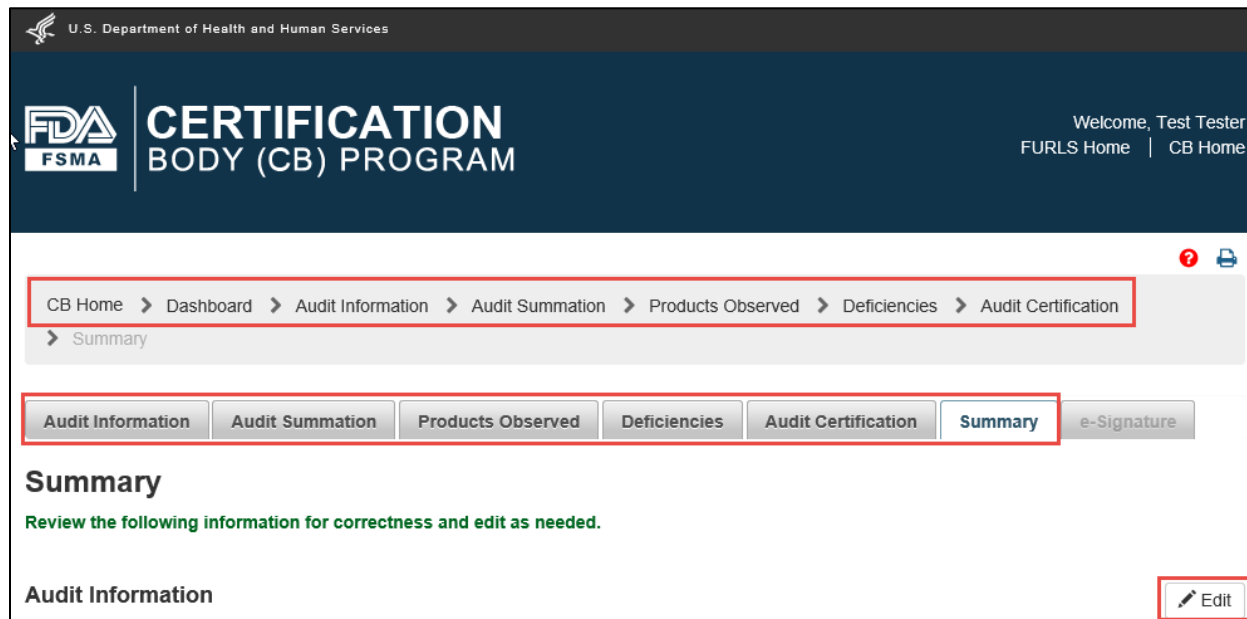
File Name
 Test Document 2.pdf
 Upload Date
 2019-02-03

[Previous](#) [Save](#) [Next](#)

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.

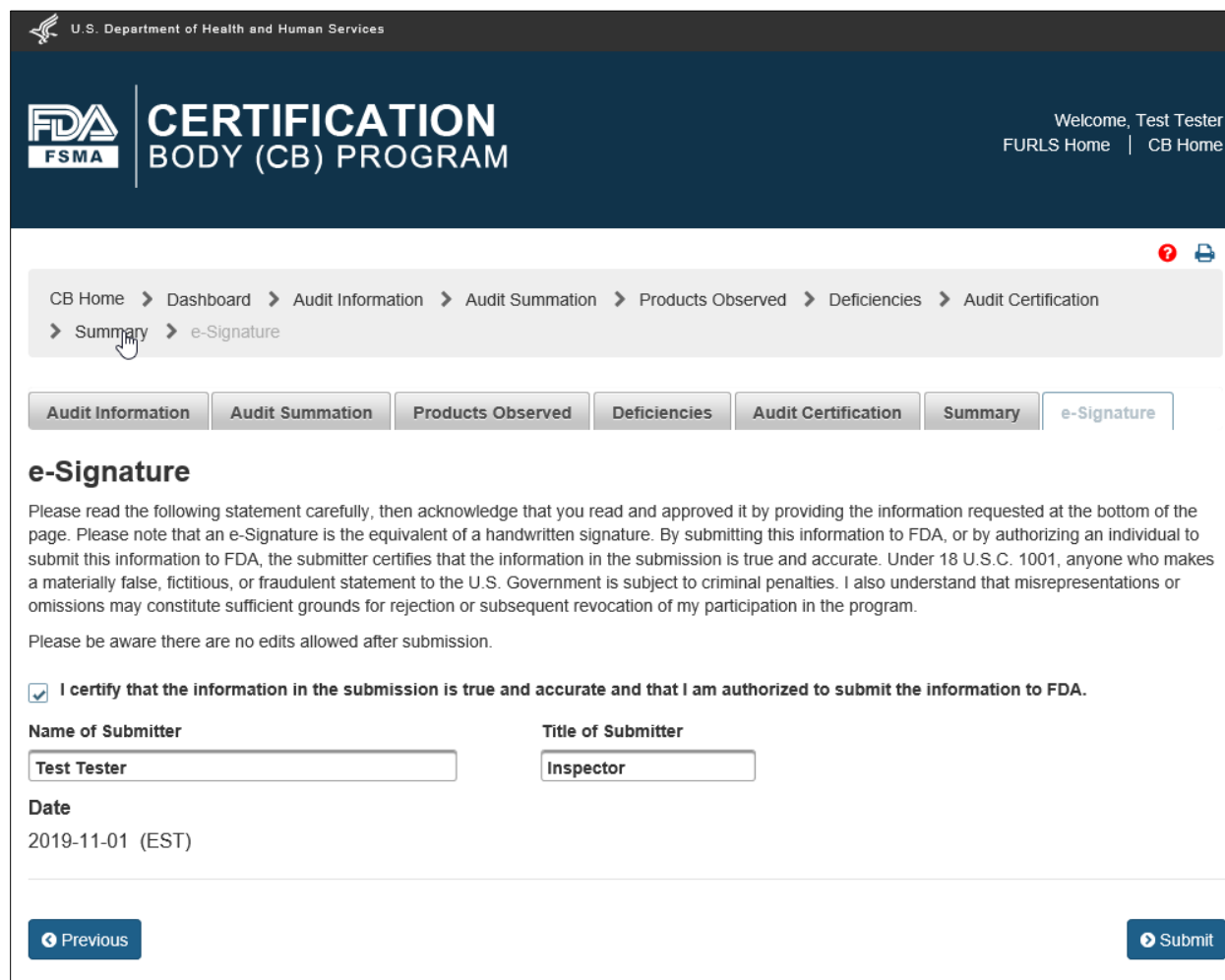
Follow the directions provided on the “e-Signature” tab (Figure 6.71).

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.

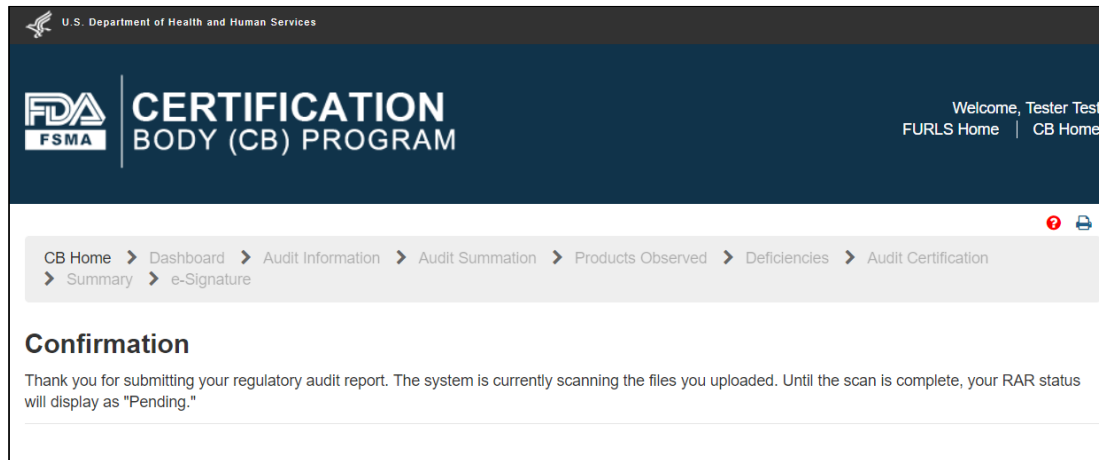
Figure 6.71 – e-Signature Tab



The screenshot shows the 'e-Signature' tab in the FDA Certification Body (CB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'CERTIFICATION BODY (CB) PROGRAM'. A user greeting 'Welcome, Test Tester' and links for 'FURLS Home' and 'CB Home' are visible. A breadcrumb trail shows the navigation path: 'CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies > Audit Certification > Summary > e-Signature'. A series of tabs at the bottom of the breadcrumb area includes 'Audit Information', 'Audit Summation', 'Products Observed', 'Deficiencies', 'Audit Certification', 'Summary', and 'e-Signature', with 'e-Signature' being the active tab. The main content area is titled 'e-Signature' and contains a disclaimer: 'Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program. Please be aware there are no edits allowed after submission.' Below the disclaimer is a checked checkbox with the text 'I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.' There are two input fields: 'Name of Submitter' with the value 'Test Tester' and 'Title of Submitter' with the value 'Inspector'. The 'Date' is displayed as '2019-11-01 (EST)'. At the bottom of the form, there are two buttons: 'Previous' and 'Submit'.

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

Figure 6.72 – Confirmation Page after Submission

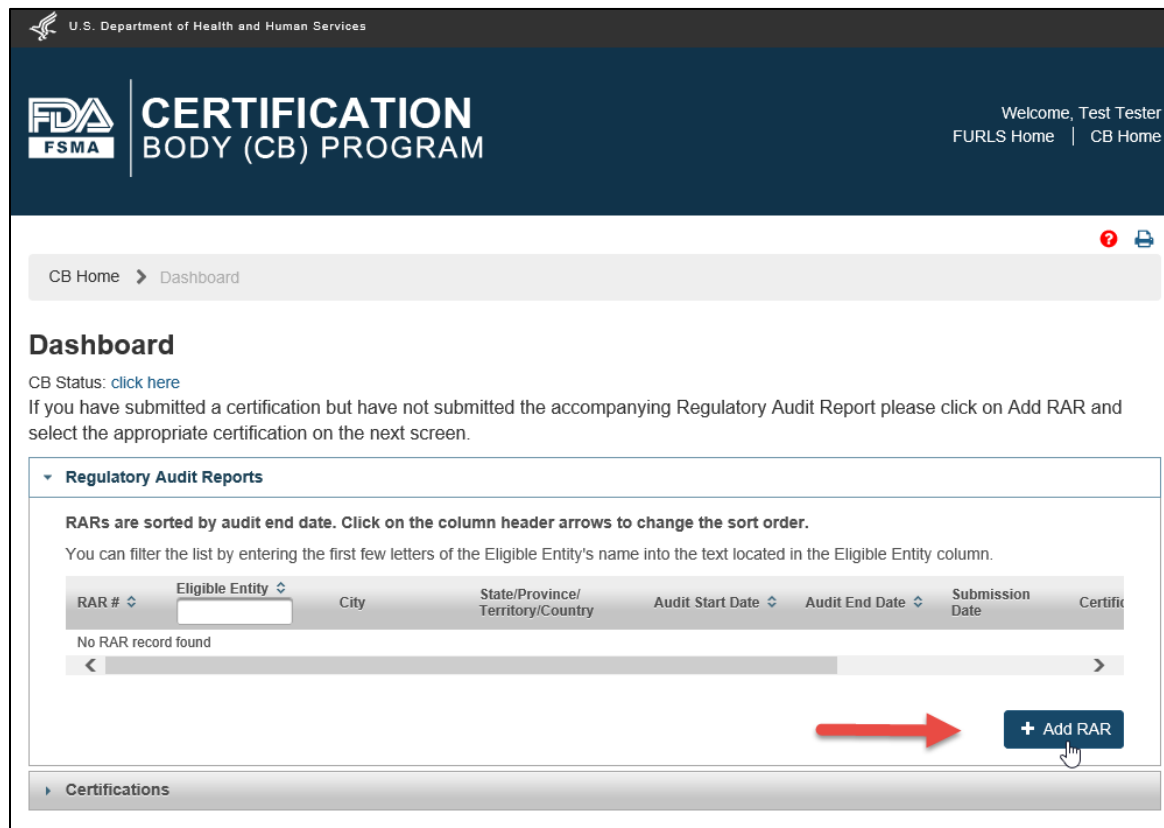


To view the status of your regulatory audit report, or to view and print the report details, proceed to Section 6.3 of this chapter.

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

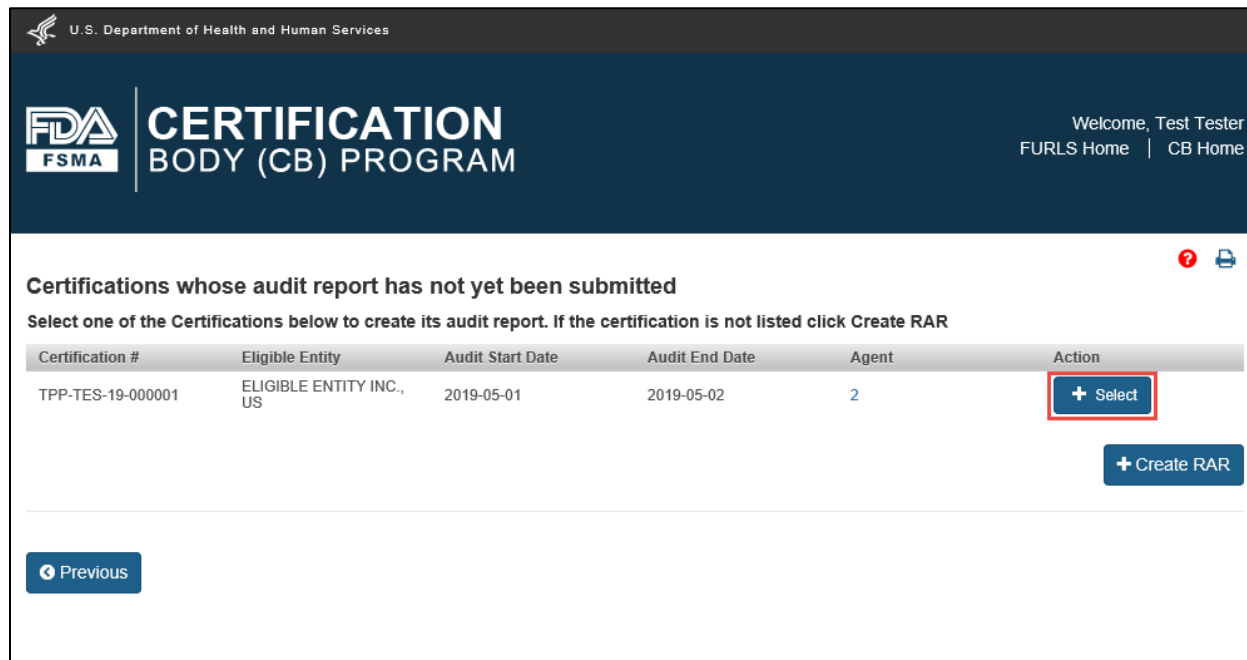


The screenshot shows the 'Dashboard' page of the FDA Certification Body (CB) Program. The page header includes the FDA logo and 'CERTIFICATION BODY (CB) PROGRAM'. A navigation breadcrumb shows 'CB Home > Dashboard'. The main content area is titled 'Dashboard' and includes a 'CB Status: [click here](#)' link. Below this, a message states: 'If you have submitted a certification but have not submitted the accompanying Regulatory Audit Report please click on Add RAR and select the appropriate certification on the next screen.' A section titled 'Regulatory Audit Reports' contains instructions: 'RARs are sorted by audit end date. Click on the column header arrows to change the sort order.' and 'You can filter the list by entering the first few letters of the Eligible Entity's name into the text located in the Eligible Entity column.' Below these instructions is a table with columns: 'RAR #', 'Eligible Entity', 'City', 'State/Province/Territory/Country', 'Audit Start Date', 'Audit End Date', 'Submission Date', and 'Certification'. The table currently displays 'No RAR record found' and a pagination bar. A red arrow points to a blue '+ Add RAR' button located at the bottom right of the table area.

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



U.S. Department of Health and Human Services

FDA FSMA | **CERTIFICATION BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

Certifications whose audit report has not yet been submitted

Select one of the Certifications below to create its audit report. If the certification is not listed click **Create RAR**

Certification #	Eligible Entity	Audit Start Date	Audit End Date	Agent	Action
TPP-TES-19-000001	ELIGIBLE ENTITY INC., US	2019-05-01	2019-05-02	2	+ Select

+ Create RAR

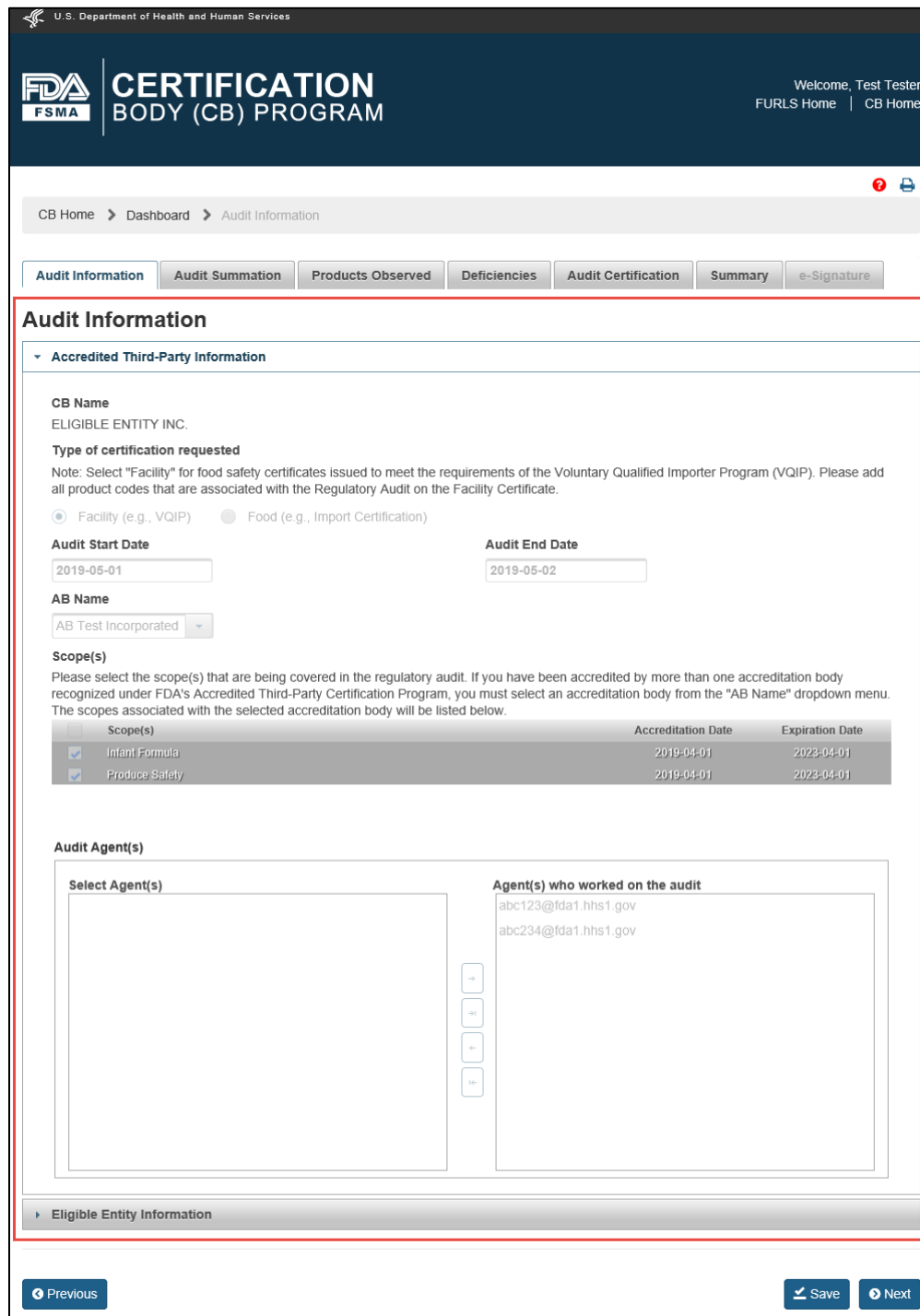
Previous

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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard > Audit Information

Audit Information | Audit Summation | Products Observed | Deficiencies | Audit Certification | Summary | e-Signature

Audit Information

▼ Accredited Third-Party Information

CB Name
 ELIGIBLE ENTITY INC.

Type of certification requested
 Note: Select "Facility" for food safety certificates issued to meet the requirements of the Voluntary Qualified Importer Program (VQIP). Please add all product codes that are associated with the Regulatory Audit on the Facility Certificate.

Facility (e.g., VQIP) Food (e.g., Import Certification)

Audit Start Date 2019-05-01 **Audit End Date** 2019-05-02

AB Name
 AB Test Incorporated

Scope(s)
 Please select the scope(s) that are being covered in the regulatory audit. If you have been accredited by more than one accreditation body recognized under FDA's Accredited Third-Party Certification Program, you must select an accreditation body from the "AB Name" dropdown menu. The scopes associated with the selected accreditation body will be listed below.

Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="checkbox"/> Infant Formula	2019-04-01	2023-04-01
<input checked="" type="checkbox"/> Produce Safety	2019-04-01	2023-04-01

Audit Agent(s)

Select Agent(s)

Agent(s) who worked on the audit
 abc123@fda1.hhs1.gov
 abc234@fda1.hhs1.gov

▶ Eligible Entity Information

Previous Save Next

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).

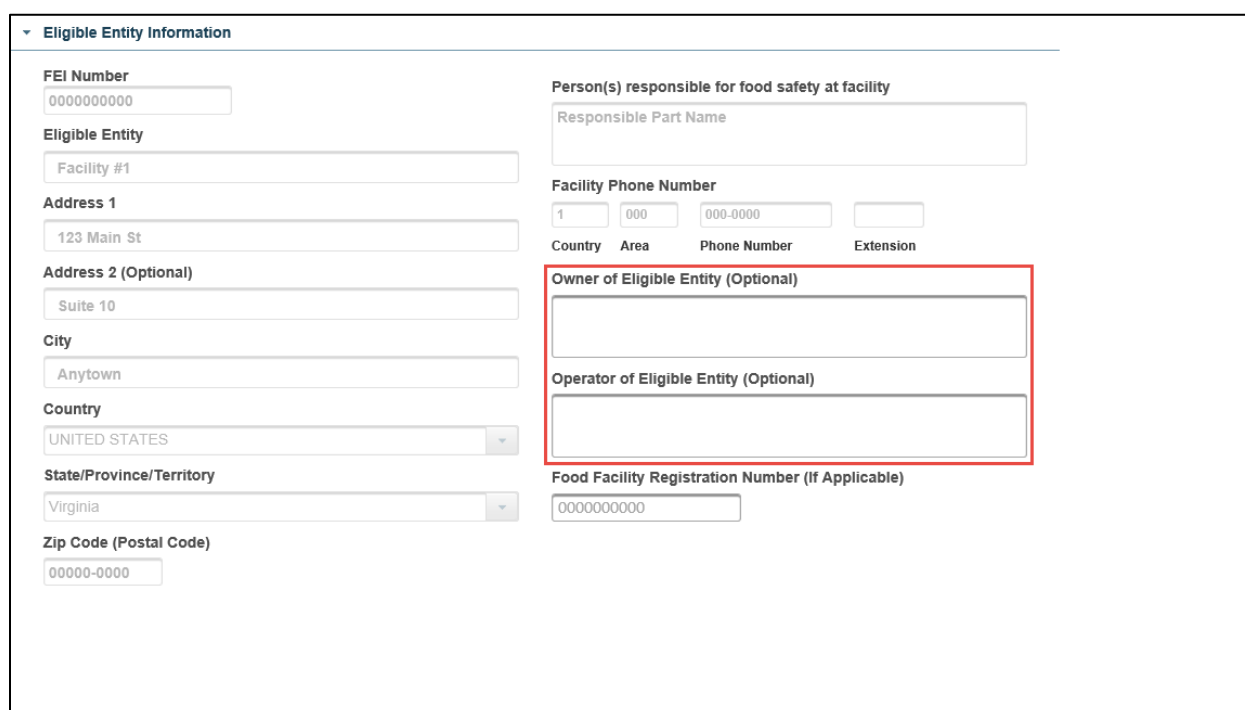
Figure 6.76 – Eligible Entity Information Section



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

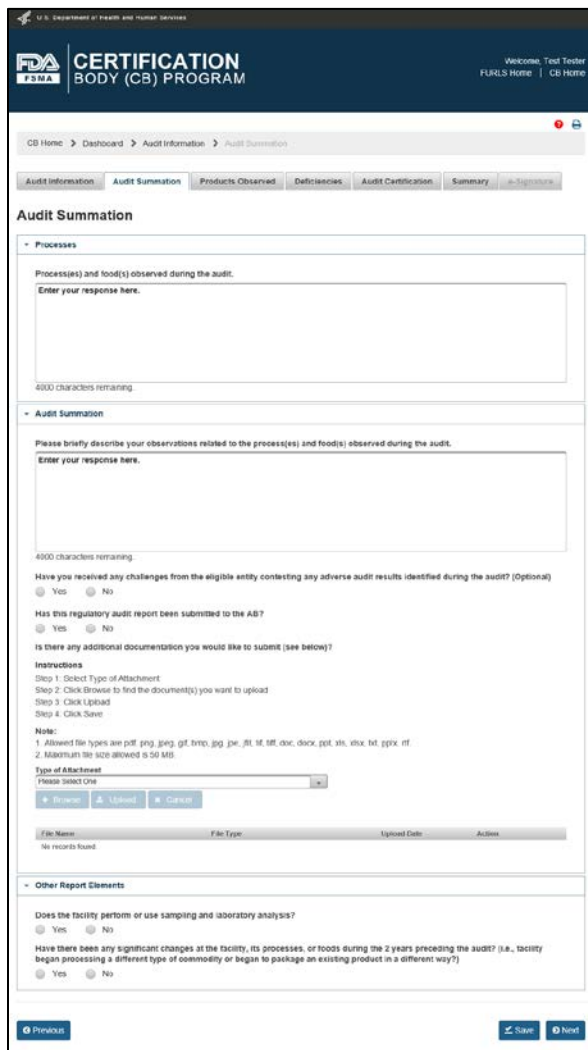
The “Audit Summation” tab allows you to summarize the results of the regulatory audit (e.g., the process(es) and food(s) observed during the regulatory audit and your observations related to the process(es) and food(s) observed during the audit).

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.

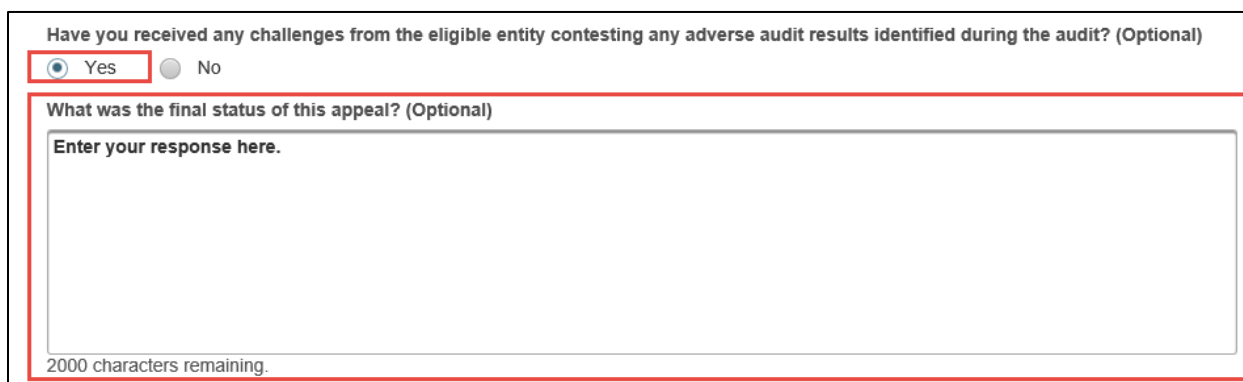
Note: Observations which present a reasonable probability that use of or exposure to food from the facility will cause Serious Adverse Health Consequences or Death to Humans or Animals (SAHCODHA), or may cause temporary or medically reversible adverse health consequences or where the probability of serious 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

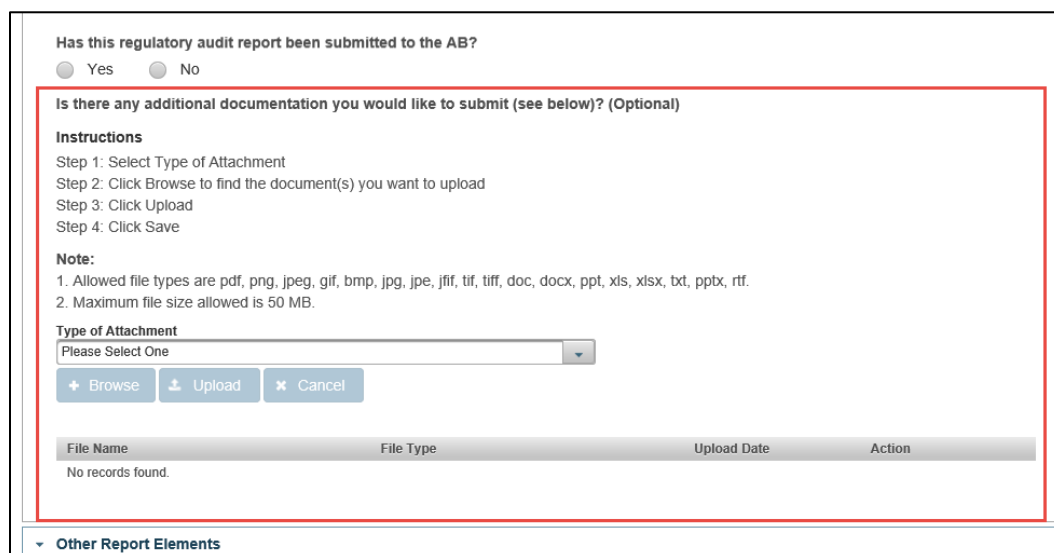


- **Has this regulatory audit report been submitted to the AB?** – Select “Yes” or “No.”
- **Is there any additional documentation you would like to submit? (Optional)** – You may upload additional documents to support the regulatory audit report. Follow the instructions listed within the “Audit Summation”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

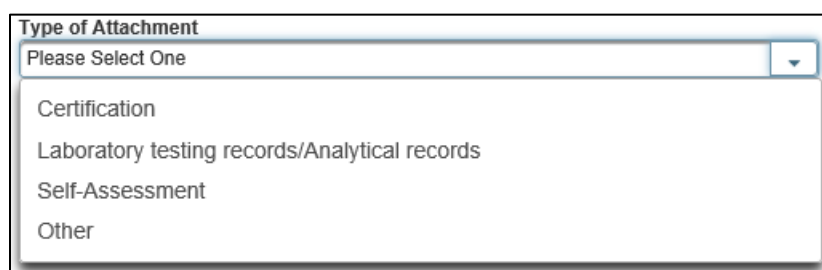
Figure 6.80 – Additional Documentation



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.

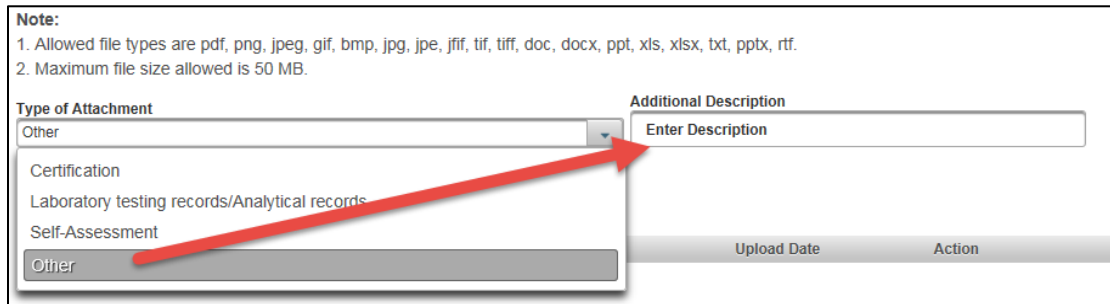
Figure 6.82 – Audit Summation Tab – Additional Description Field

Note:
 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

Type of Attachment: Other
 Certification
 Laboratory testing records/Analytical records
 Self-Assessment
 Other

Additional Description: Enter Description

Upload Date Action



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

Is there any additional documentation you would like to submit (see below)?

Instructions
 Step 1: Select Type of Attachment
 Step 2: Click Browse to find the document(s) you want to upload
 Step 3: Click Upload
 Step 4: Click Save

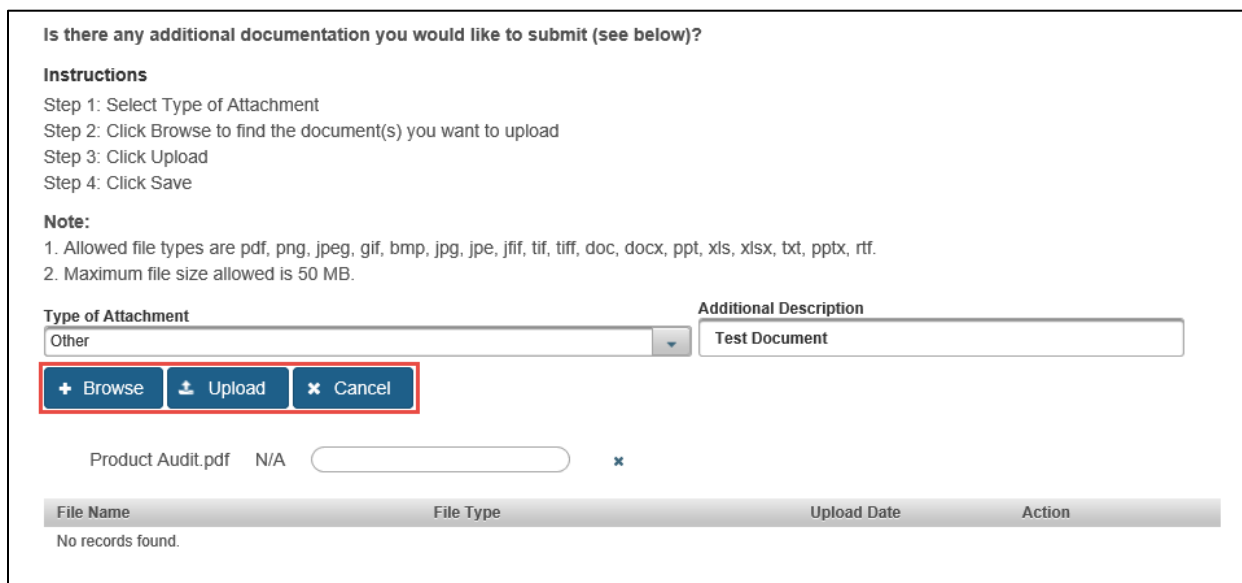
Note:
 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

Type of Attachment: Other
 Additional Description: Test Document

+ Browse Upload Cancel

Product Audit.pdf N/A ×

File Name	File Type	Upload Date	Action
No records found.			



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

Note:
 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 2. Maximum file size allowed is 50 MB.

Product Audit.pdf uploaded successfully.

Type of Attachment
 Please Select One

+ Browse Upload Cancel

File Name	File Type	Upload Date	Action
Product Audit.pdf	Other-Test Document	2019-05-08	

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

Other Report Elements

Does the facility perform or use sampling and laboratory analysis?
 Yes 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?)
 Yes No

Please explain
 Enter your response here.

4000 characters remaining.

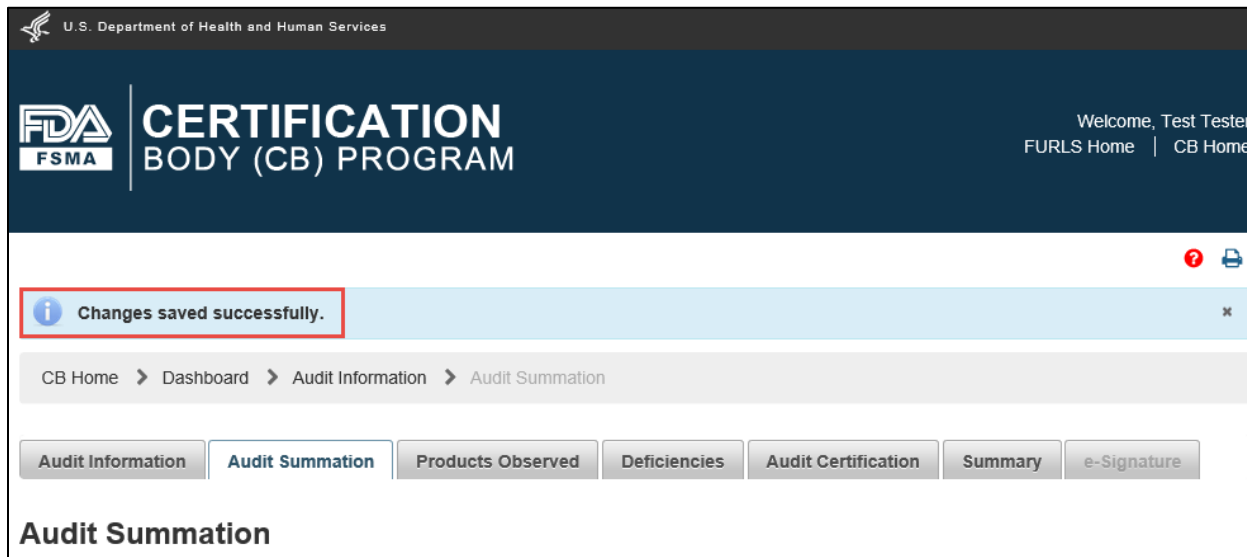
Once you have completed the information for this tab, click the “Save” button.

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



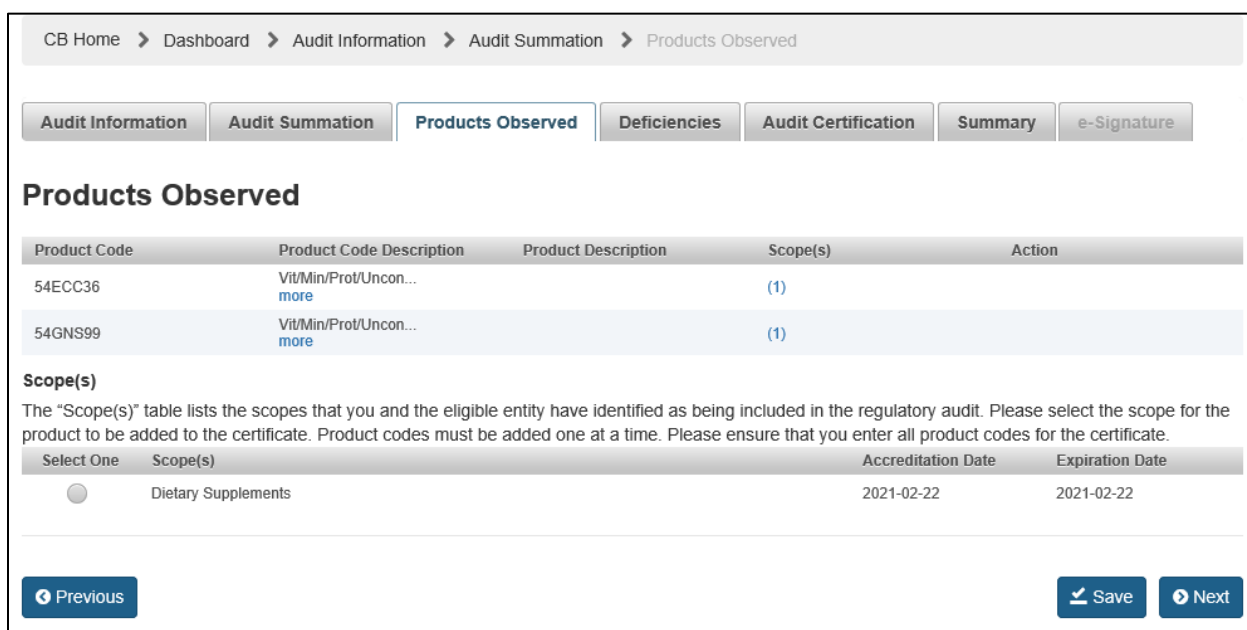
6.2.3 Products Observed Tab

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



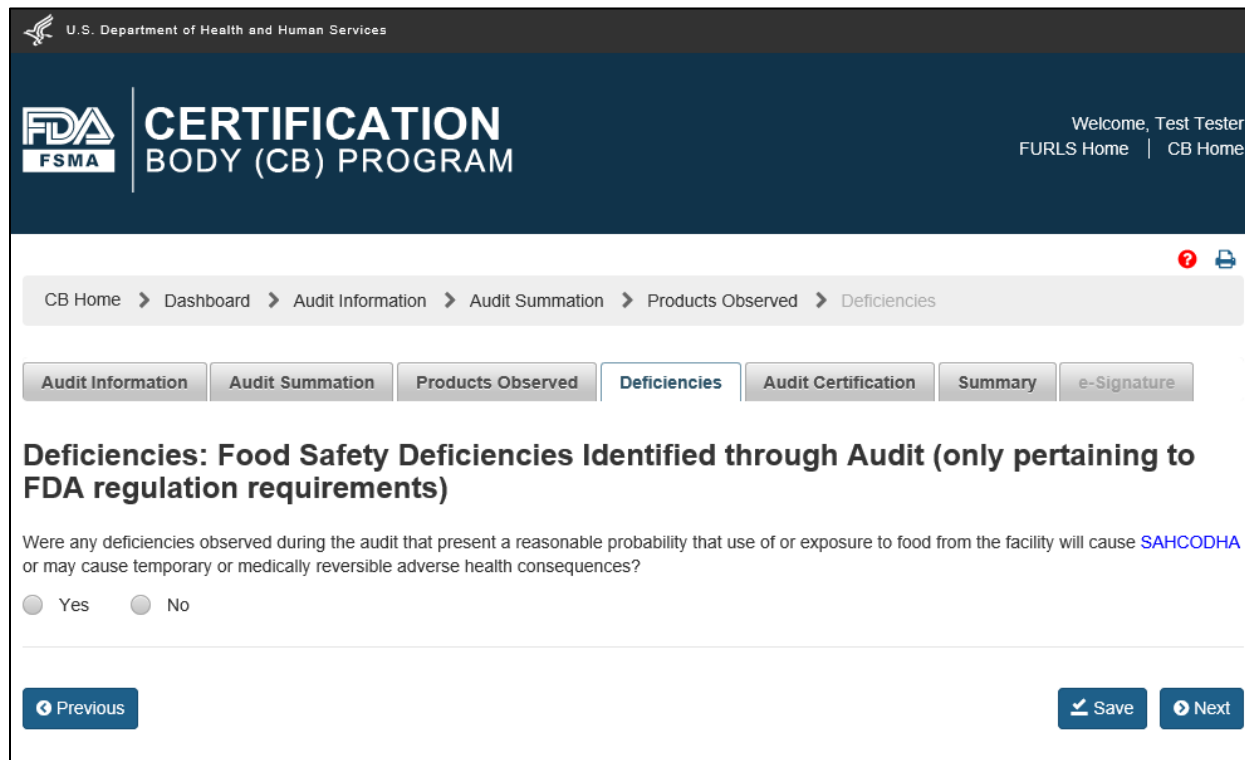
If you do not wish to add more products, proceed to the “Deficiencies” tab by clicking on the “Next” button or click on the “Deficiencies” tab directly.

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



U.S. Department of Health and Human Services

FDA **CERTIFICATION**
FSMA **BODY (CB) PROGRAM**

Welcome, Test Tester
FURLS Home | CB Home

CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies

Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

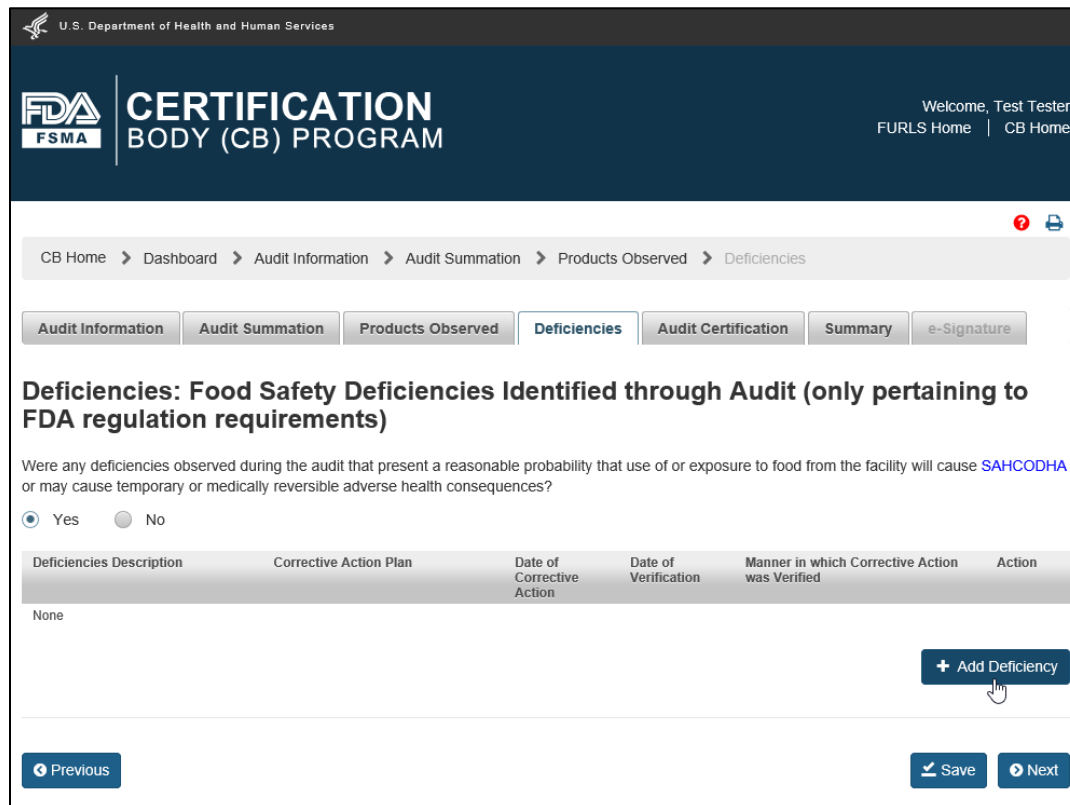
Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause [SAHCODHA](#) or may cause temporary or medically reversible adverse health consequences?

Yes No

Previous Save Next

- **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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
FURLS Home | CB Home

CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies

Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

Were any deficiencies observed during the audit that present a reasonable probability that use of or exposure to food from the facility will cause SAH/CODHA or may cause temporary or medically reversible adverse health consequences?

Yes No

Deficiencies Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Manner in which Corrective Action was Verified	Action
None					

Please describe any deficiencies that present a reasonable probability that use of or exposure to food from the facility will cause SAH/CODHA or may cause temporary or medically reversible adverse health consequences.

Enter your response here.

4000 characters remaining.

Was corrective action implemented immediately and verified on site?

Yes No

Please describe the corrective action plan for each such deficiency.

Enter your response here.

4000 characters remaining.

Date of Corrective Action

YYYY-MM-DD

Describe the manner in which the corrective action was verified.

Enter your response here.

4000 characters remaining.

Date of Verification of Corrective Action

YYYY-MM-DD

Cancel + Add Deficiency

Previous Save Next

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



CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies

Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

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?

Yes No

Deficiencies Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Manner in which Corrective Action was Verified	Action
Deficiency 1, Deficiency... more	Action taken on site.	2019-05-12	2019-05-12	Verified.	 

[+ 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

U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM Welcome, Test Tester
FURLS Home | CB Home



CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies

Audit Information | Audit Summation | Products Observed | **Deficiencies** | Audit Certification | Summary | e-Signature

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

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?

Yes No

Deficiencies Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Manner in which Corrective Action was Verified	Action
Deficiency 1, Deficiency... more	Action taken on-site.	2019-05-12	2019-05-12	Verified.	 

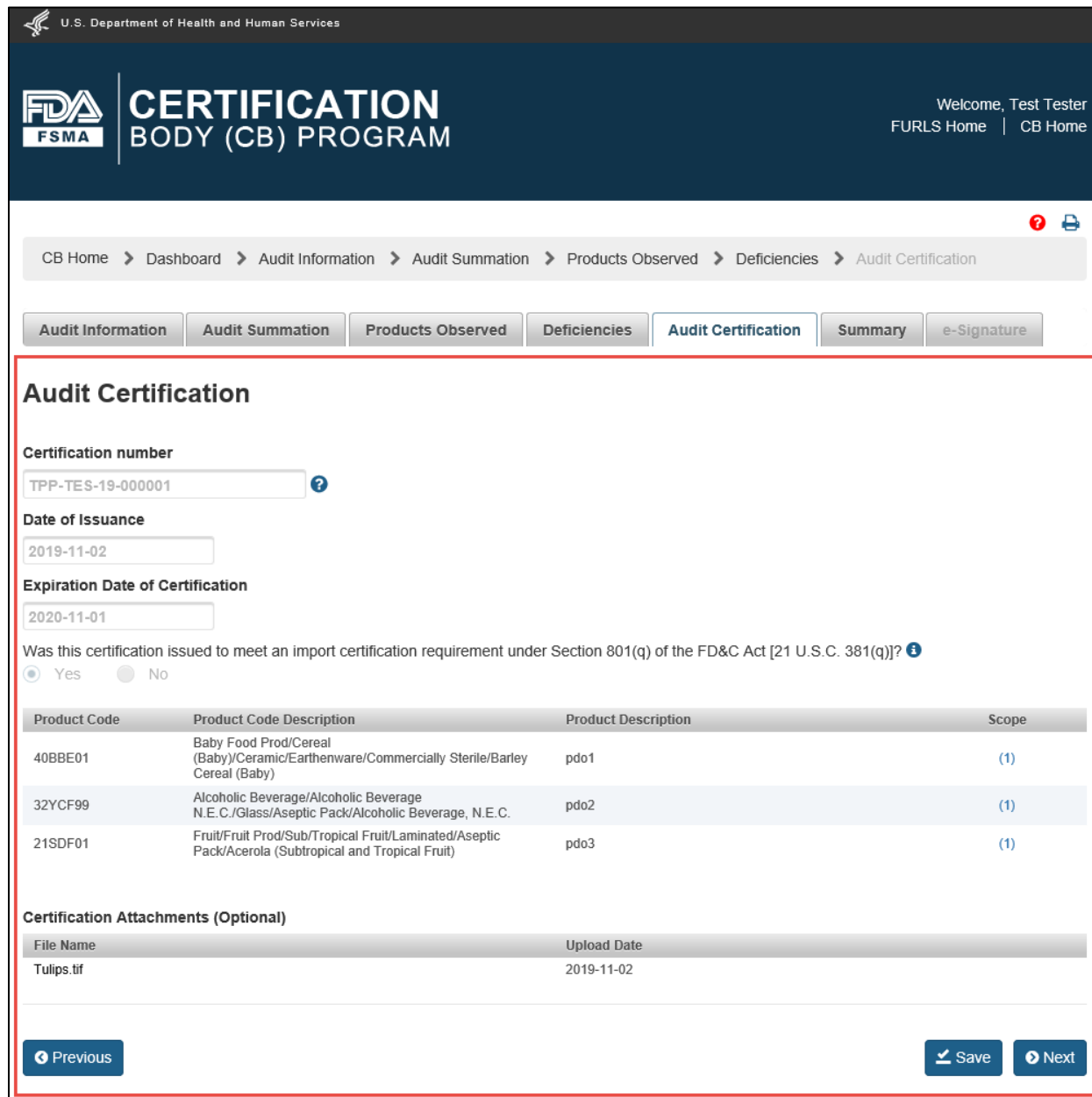
[+ Add Deficiency](#)

[Previous](#) [Save](#) [Next](#)

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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies > Audit Certification

Audit Information | Audit Summation | Products Observed | Deficiencies | **Audit Certification** | Summary | e-Signature

Audit Certification

Certification number

Date of Issuance

Expiration Date of 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)]?
 Yes No

Product Code	Product Code Description	Product Description	Scope
40BBE01	Baby Food Prod/Cereal (Baby)/Ceramic/Earthenware/Commercially Sterile/Barley Cereal (Baby)	pdo1	(1)
32YCF99	Alcoholic Beverage/Alcoholic Beverage N.E.C./Glass/Aseptic Pack/Alcoholic Beverage, N.E.C.	pdo2	(1)
21SDF01	Fruit/Fruit Prod/Sub/Tropical Fruit/Laminated/Aseptic Pack/Acerola (Subtropical and Tropical Fruit)	pdo3	(1)

Certification Attachments (Optional)

File Name	Upload Date
Tulips.tif	2019-11-02

[Previous](#) [Save](#) [Next](#)

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



The screenshot shows the 'Summary' tab of the FDA Certification Body (CB) Program. The breadcrumb trail is: CB Home > Dashboard > Audit Information > Audit Summaries > Products Observed > Deficiencies > Audit Certification > Summary. The 'Summary' tab is selected in the navigation bar.

Summary
Review the following information for correctness and edit as needed.

Audit Information [Edit]

Accredited Third-Party Information

CD Name
TRP CB User Guide Facility
Type of certification requested
Facility (e.g., VQP)
Audit Start Date: 2019-05-01 Audit End Date: 2019-05-03
AD Name: PP Testing Inc.
Scope(s)

Scope(s)	Accreditation Date	Expiration Date
Infectious Agents	2019-03-01	2020-03-01
Water Hazard Analysis and Critical Control Point (Water HACCP)	2019-03-01	2020-03-01
Low-Acid Canned Foods (LACF)	2019-03-01	2020-03-01

Audit Agent(s)
Agent(s) who worked on the audit: Agent 2 Agent Email Address: agent2@us2.mad.gov

Eligible Entity Information

Audit Summaries [Edit]

Process(es)
Audit Summaries
Other Report Elements

Products Observed [Edit]

Products Observed

Product Code	Product Code Description	Product Description	Response
010P02	Bread/Past Item/Crout/Bread (Whole, Split) Baked... more	This is a Test response to Product Description.	(1)
020V02	Bakery Past/Past/Past/Past/Past (Bakery) Baked... more	This is a Test response to Product Description.	(1)
200V02	Pastry/Past/Past/Past/Past/Past (Pastry) Baked... more	This is a Test response to Product Description.	(1)

Deficiencies: Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements) [Edit]

The Food Safety Deficiencies Identified through Audit (only pertaining to FDA regulation requirements)

Deficiency Description	Corrective Action Plan	Date of Corrective Action	Date of Verification	Whether to which Corrective Action was Verified
This is a Test response to the deficiency request... more	This is a Test response to the deficiency request... more	2019-05-01	2019-05-03	This is a Test response to the deficiency request... more

Audit Certification [Edit]

Audit Certification

Will you be issuing a certification?
Yes

Do you want to submit the certification with this audit report?
Yes

Please provide the certification number
JSC-CCC-19-122123
Date of Issuance
Expiration Date of Certification
2019-05-01

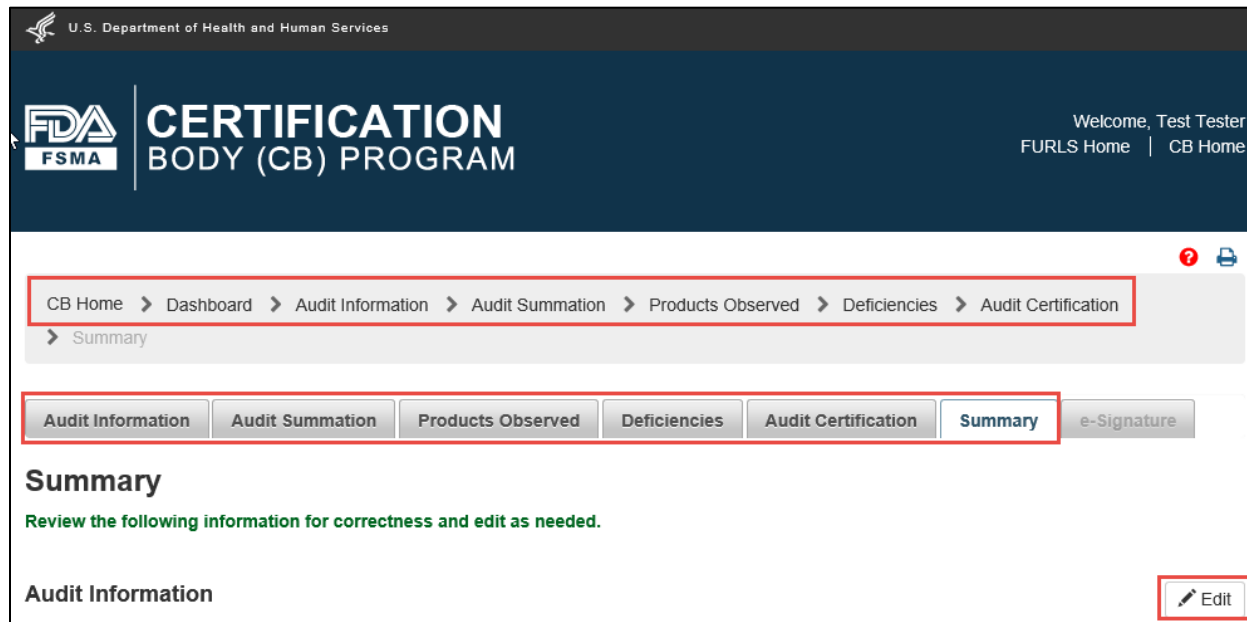
Product Code	Product Code Description	Product Description	Response
No records found.			
File Name		Upload Date	
Test Document 1.xlsx		2019-05-01	
Test Document 2.pdf		2019-05-01	

Navigation: [Previous] [Save] [Next]

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.

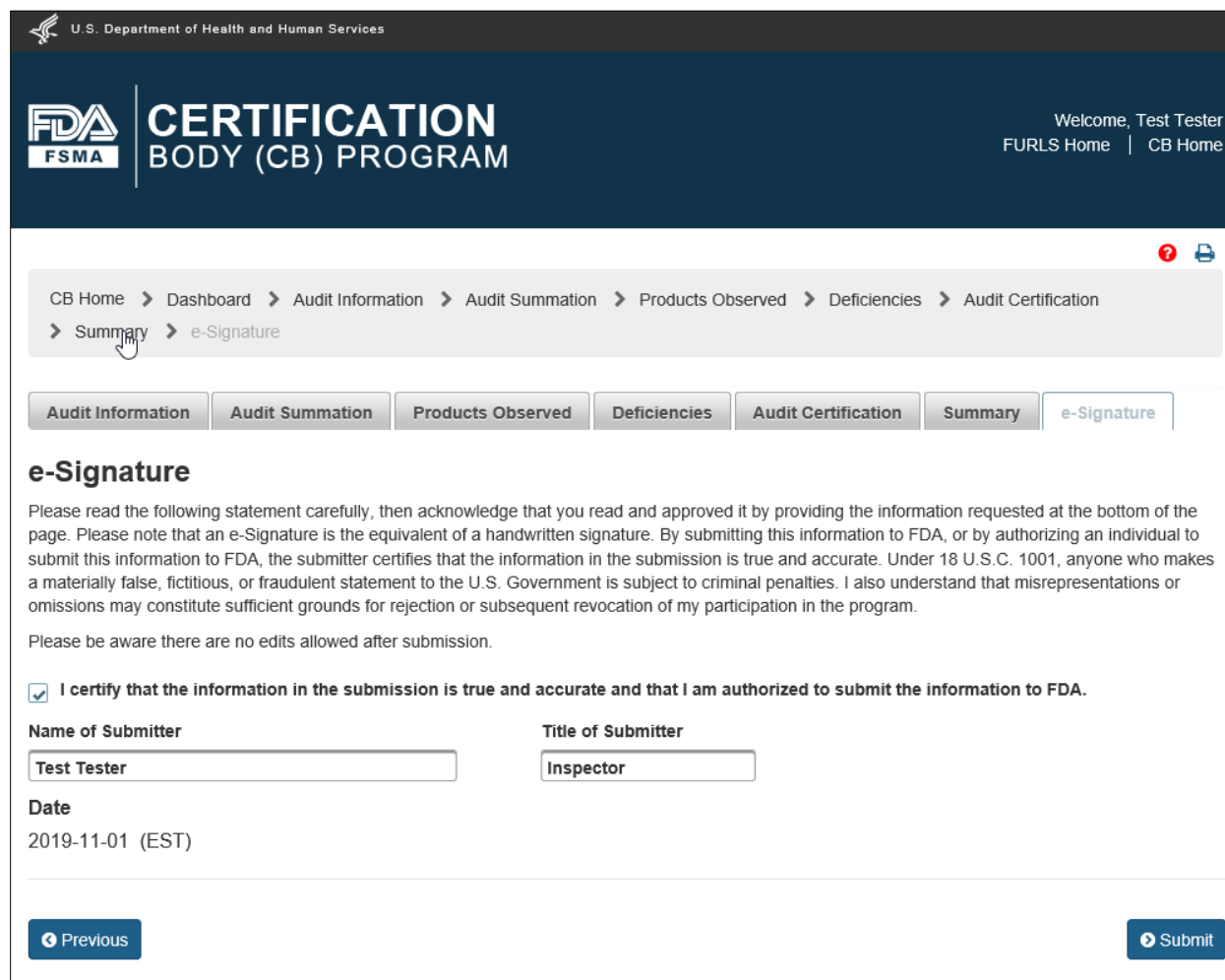
Follow the directions provided on the “e-Signature” tab (Figure 6.96).

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



U.S. Department of Health and Human Services

FDA FSMA | **CERTIFICATION BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard > Audit Information > Audit Summation > Products Observed > Deficiencies > Audit Certification
 > Summary > e-Signature

Audit Information | Audit Summation | Products Observed | Deficiencies | Audit Certification | Summary | **e-Signature**

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program.

Please be aware there are no edits allowed after submission.

I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.

Name of Submitter

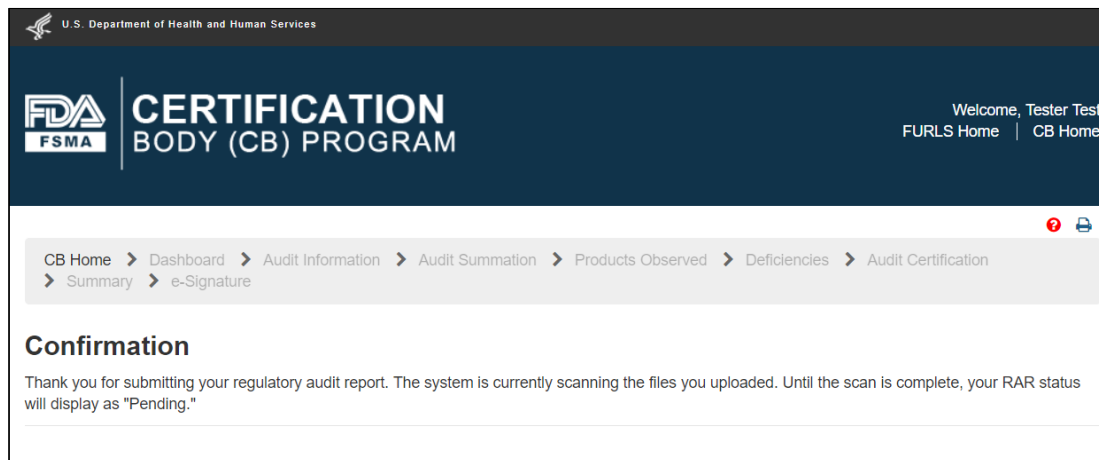
Title of Submitter

Date
 2019-11-01 (EST)

[Previous](#) [Submit](#)

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.

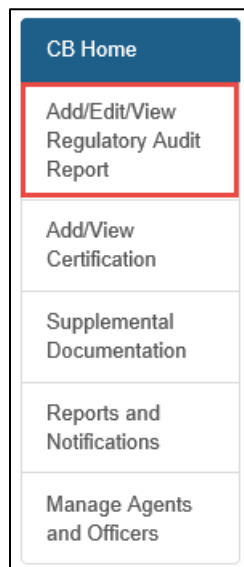
6.3 Edit, Delete, View or Print a Regulatory Audit Report

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

Dashboard

CB Status: [click here](#)

If you have submitted a certification but have not submitted the accompanying Regulatory Audit Report please click on Add RAR and select the appropriate certification on the next screen.

▼ **Regulatory Audit Reports**

RARs are sorted by audit end date. Click on the column header arrows to change the sort order.

You can filter the list by entering the first few letters of the Eligible Entity's name into the text located in the Eligible Entity column.

RAR #	Eligible Entity	City	State/Province/Territory/Country	Audit Start Date	Audit End Date	Submission Date	Certific
3727	Facility A	Seattle	Washington/UNITED STATES	2020-05-04	2020-05-04	2020-05-15	
3660	Facility B	Quebec City	Quebec/CANADA	2020-03-16	2020-03-23		

[+ Add RAR](#)

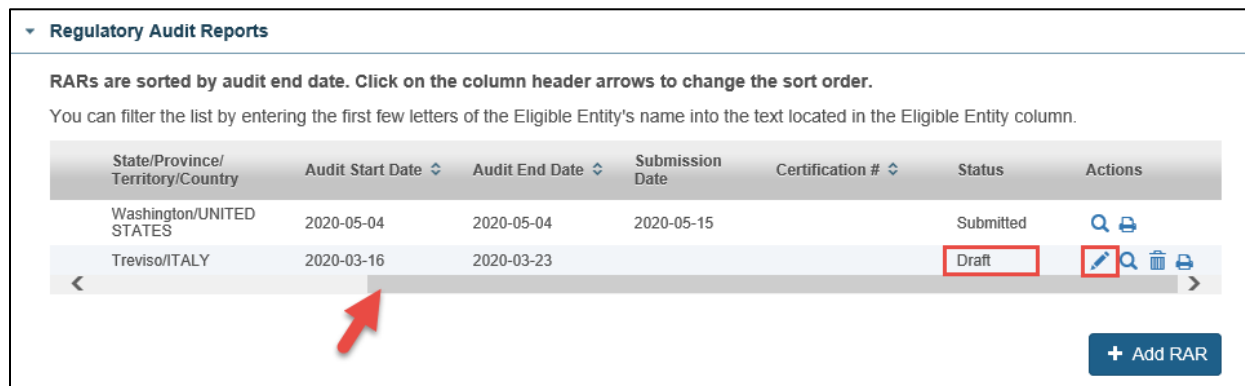
6.3.1 Edit or Delete a Draft Regulatory Audit Report

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.

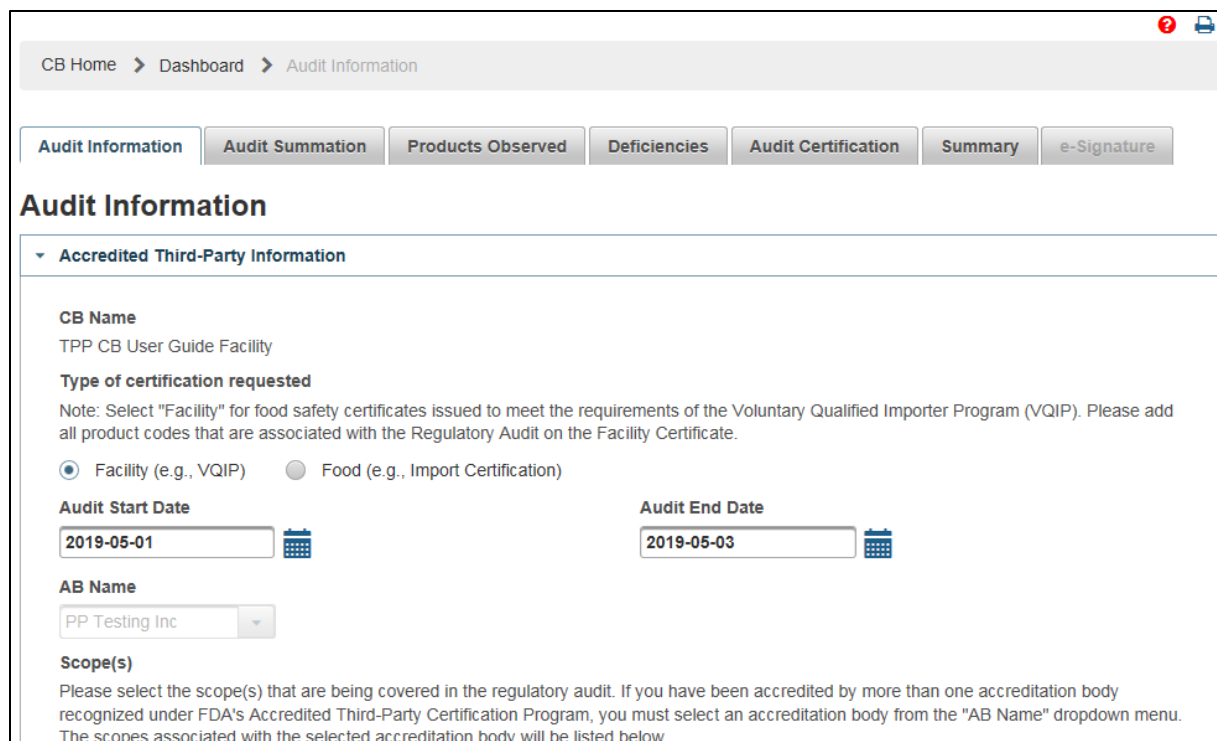
Click the edit/pencil icon from the “Actions” column to edit a regulatory audit report (Figure 6.100).

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



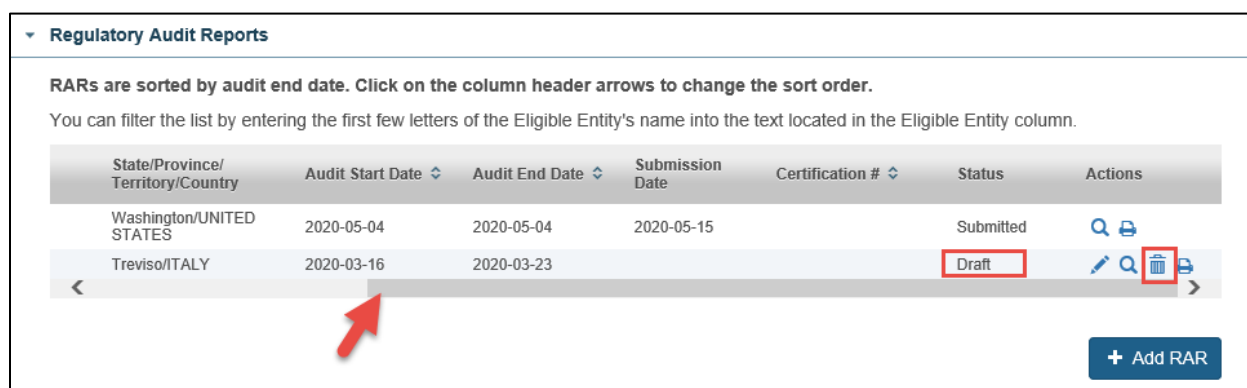
Navigate through the tabs of the draft regulatory audit report to make modifications or complete missing information, where applicable.

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).

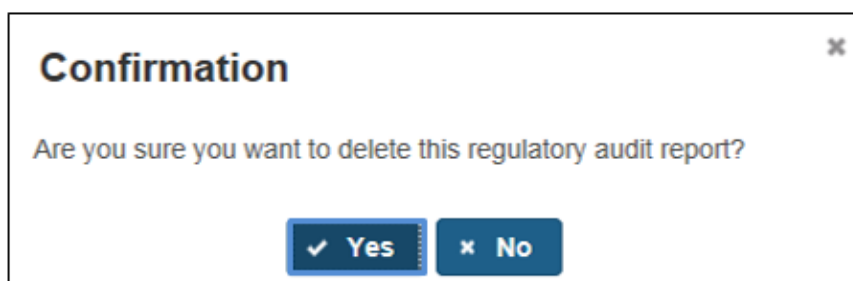
Figure 6.102 – Trash Icon for Draft Regulatory Audit Report



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.

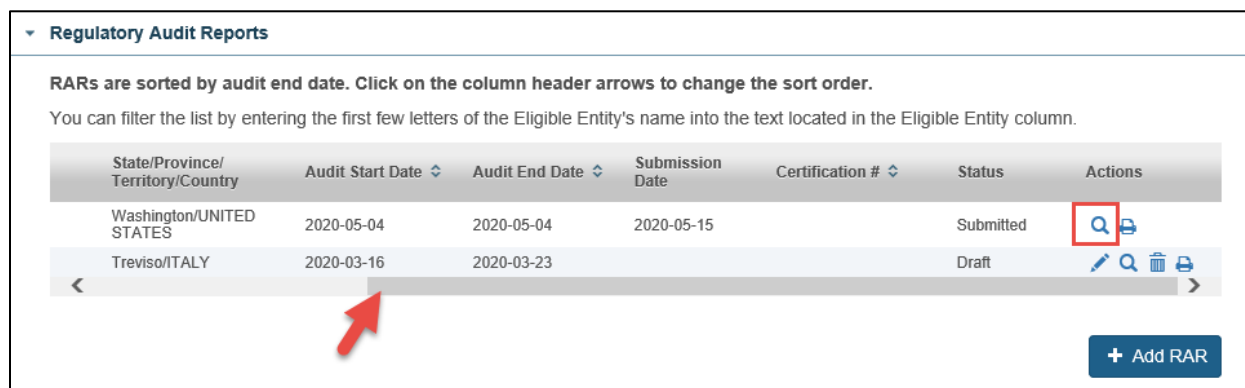
6.3.2 View the Details of a Regulatory Audit Report

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



▼ Regulatory Audit Reports

RARs are sorted by audit end date. Click on the column header arrows to change the sort order.

You can filter the list by entering the first few letters of the Eligible Entity's name into the text located in the Eligible Entity column.

State/Province/Territory/Country	Audit Start Date ↕	Audit End Date ↕	Submission Date	Certification # ↕	Status	Actions
Washington/UNITED STATES	2020-05-04	2020-05-04	2020-05-15		Submitted	 
Treviso/ITALY	2020-03-16	2020-03-23			Draft	   

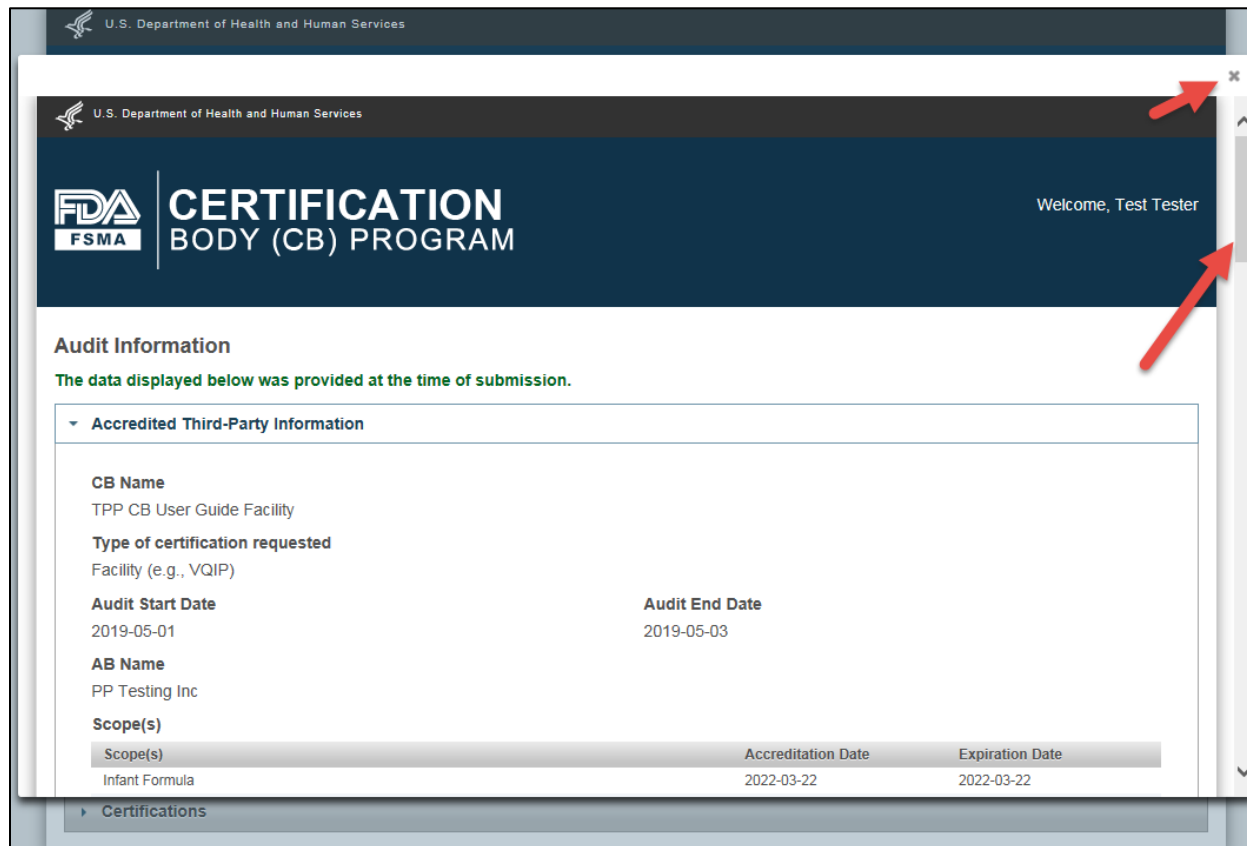
< [Horizontal Scroll Bar] >

[+ Add RAR](#)

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.

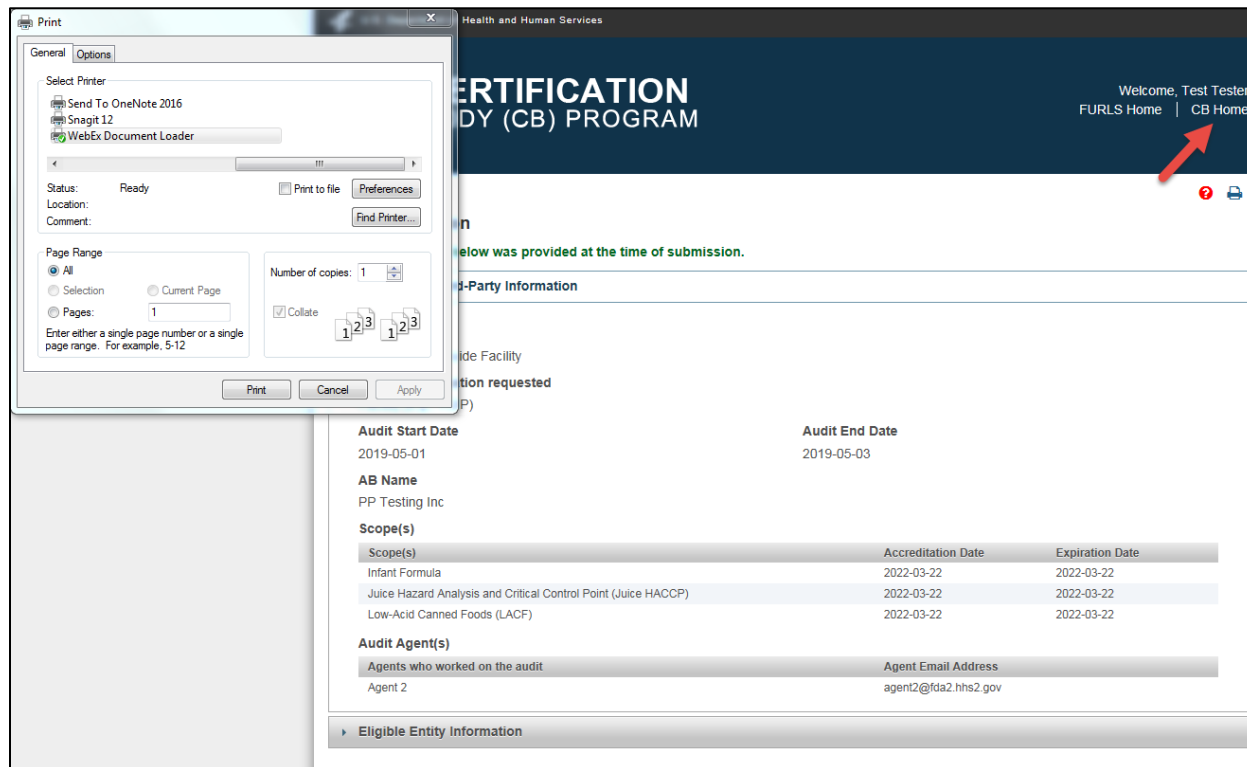
Click and drag the horizontal scroll bar to scroll to the right in the “Regulatory Audit Reports” section and view the available icons in the “Actions” column.

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



The screenshot displays a web application interface for the 'CERTIFICATION BODY (CB) PROGRAM'. The top navigation bar includes a user greeting 'Welcome, Test Tester' and two links: 'FURLS Home' and 'CB Home'. A red arrow points to the 'CB Home' link. A print dialog box is open in the foreground, showing printer selection options (Send To OneNote 2016, Snagit 12, WebEx Document Loader) and page range settings (All, Selection, Current Page, Pages: 1). The main content area shows a message: 'Information below was provided at the time of submission.' followed by a section for 'Third-Party Information'. Below this, there is a table for 'Audit Start Date' and 'Audit End Date' (2019-05-01 to 2019-05-03), an 'AB Name' (PP Testing Inc), and a 'Scope(s)' table with columns for 'Scope(s)', 'Accreditation Date', and 'Expiration Date'. The 'Scope(s)' table lists 'Infant Formula', 'Juice Hazard Analysis and Critical Control Point (Juice HACCP)', and 'Low-Acid Canned Foods (LACF)', all with accreditation and expiration dates of 2022-03-22. Below the scope table is an 'Audit Agent(s)' section with columns for 'Agents who worked on the audit' and 'Agent Email Address', listing 'Agent 2' with email 'agent2@fda2.hhs2.gov'. At the bottom, there is a section for 'Eligible Entity Information'.

Audit Start Date	Audit End Date
2019-05-01	2019-05-03

AB Name
PP Testing Inc

Scope(s)	Accreditation Date	Expiration Date
Infant Formula	2022-03-22	2022-03-22
Juice Hazard Analysis and Critical Control Point (Juice HACCP)	2022-03-22	2022-03-22
Low-Acid Canned Foods (LACF)	2022-03-22	2022-03-22

Agents who worked on the audit	Agent Email Address
Agent 2	agent2@fda2.hhs2.gov

Eligible Entity Information

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

Dashboard







CB Status: [click here](#)

If you have submitted a certification but have not submitted the accompanying Regulatory Audit Report please click on Add RAR and select the appropriate certification on the next screen.

Regulatory Audit Reports

RARs are sorted by audit end date. Click on the column header arrows to change the sort order.

You can filter the list by entering the first few letters of the Eligible Entity's name into the text located in the Eligible Entity column.

State/Province/Territory/Country	Audit Start Date ↕	Audit End Date ↕	Submission Date	Certification # ↕	Status	Actions
Washington/UNITED STATES	2020-05-04	2020-05-04	2020-05-15		Submitted	 
Treviso/ITALY	2020-03-16	2020-03-23			Draft	   

[+ Add RAR](#)

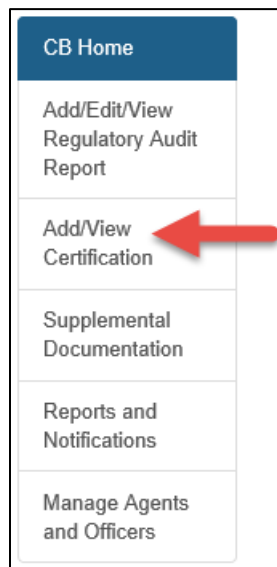
7 Add/View Certification

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

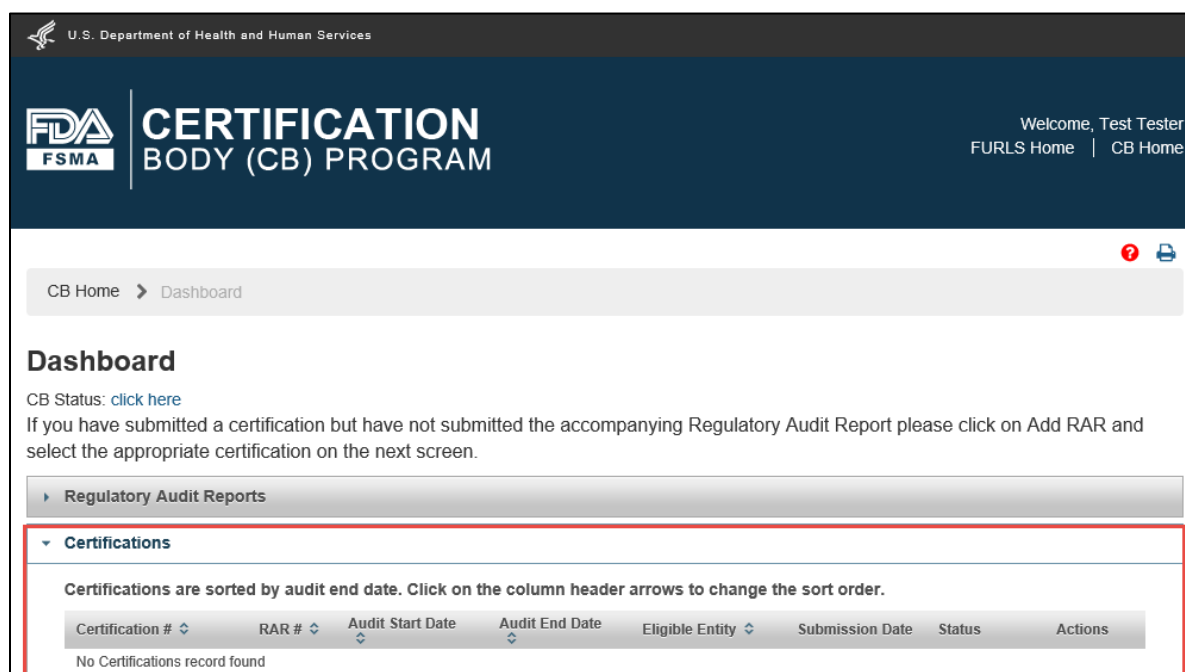
To access the certification functionality, click the “Add/View Certification” link from the navigation menu on the “CB Home” page (Figure 7.1).

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.

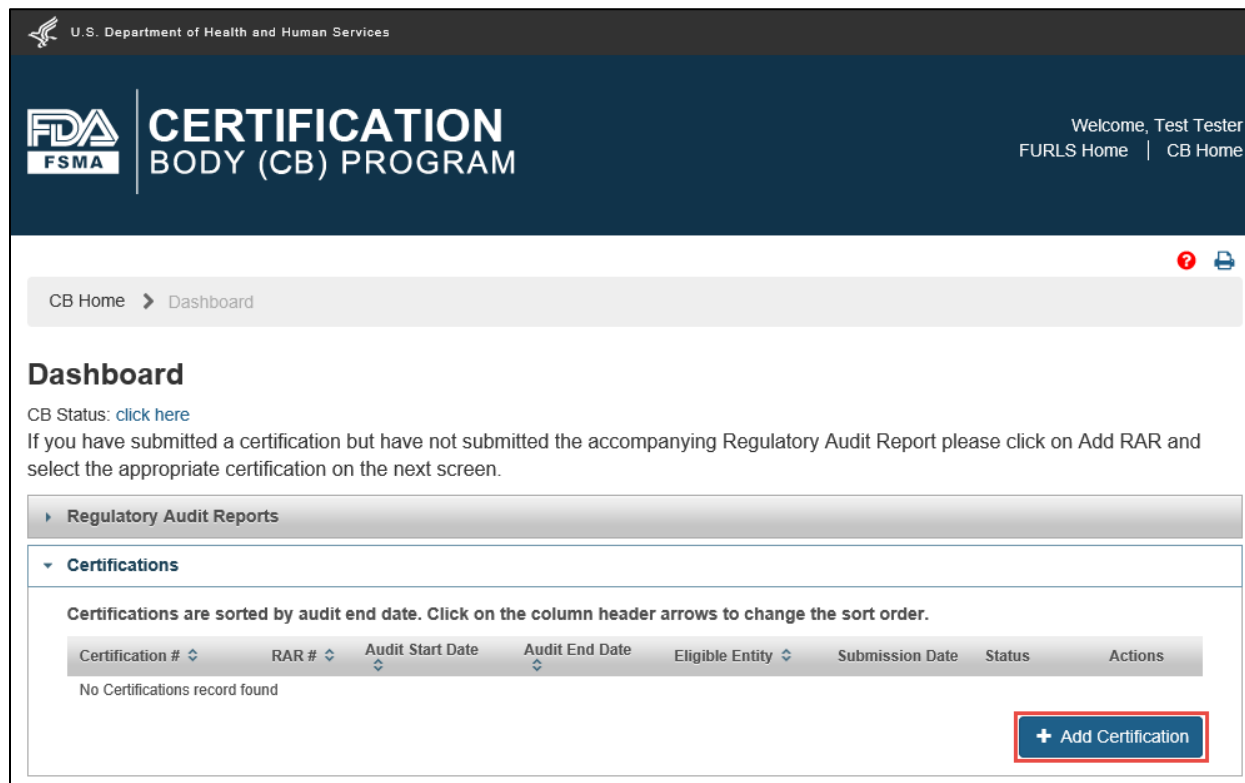
Note: Certifications cannot be saved as a draft version. All sections must be completed and submitted at the same time.

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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard

Dashboard

CB Status: [click here](#)

If you have submitted a certification but have not submitted the accompanying Regulatory Audit Report please click on Add RAR and select the appropriate certification on the next screen.

▶ Regulatory Audit Reports

▼ Certifications

Certifications are sorted by audit end date. Click on the column header arrows to change the sort order.

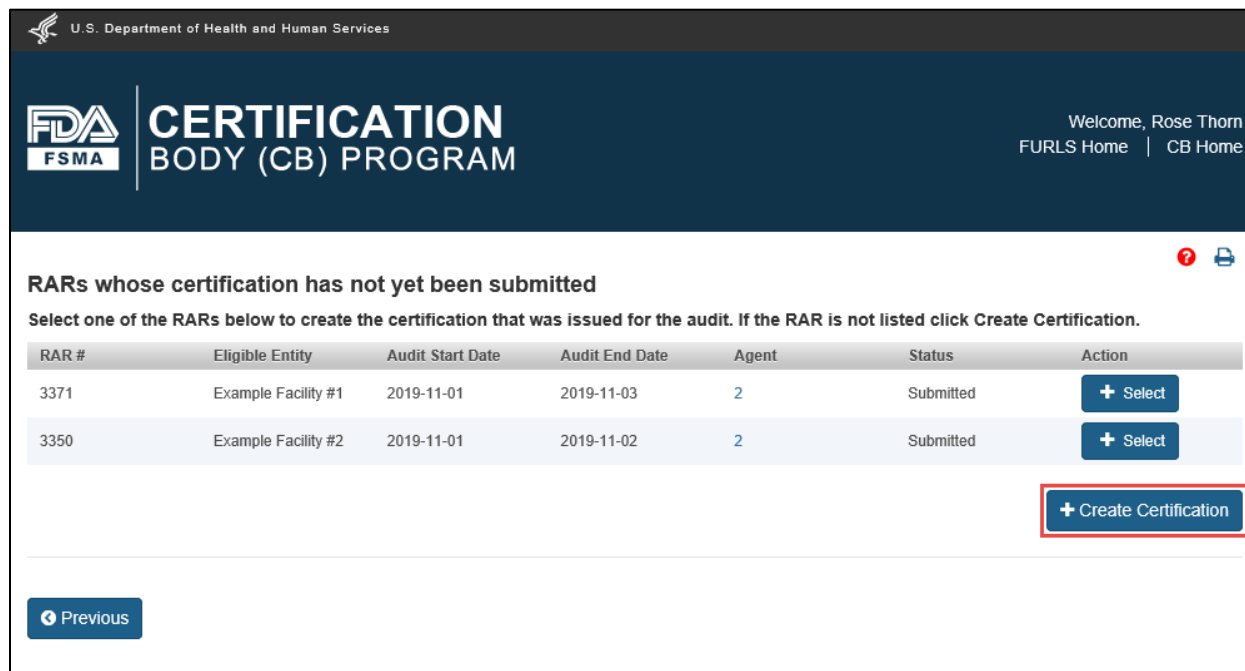
Certification #	RAR #	Audit Start Date	Audit End Date	Eligible Entity	Submission Date	Status	Actions
No Certifications record found							

[+ Add Certification](#)

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.

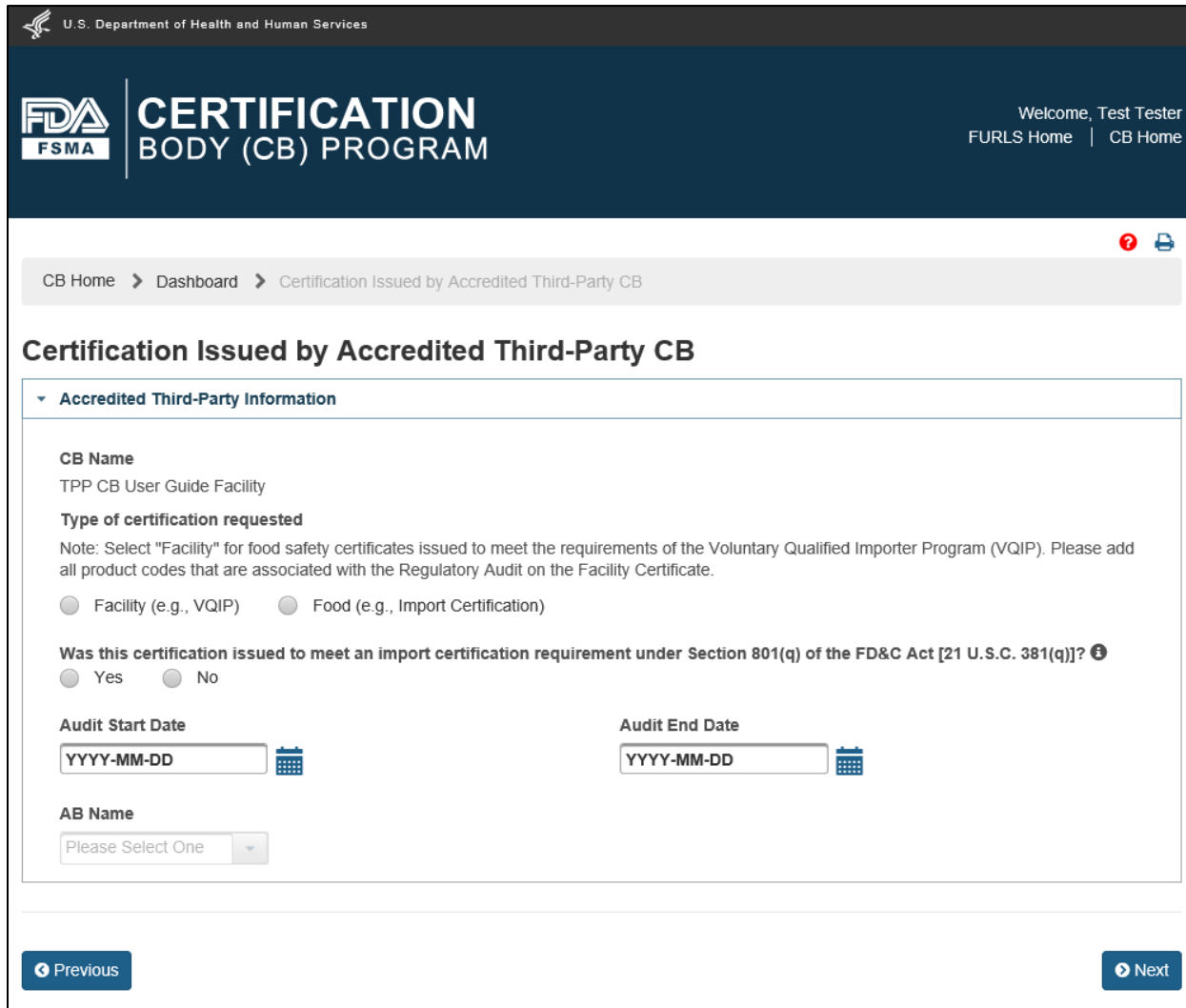
You must complete the following data entry fields in the “Accredited Third-Party Information” section (Figure 7.5):

- **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.

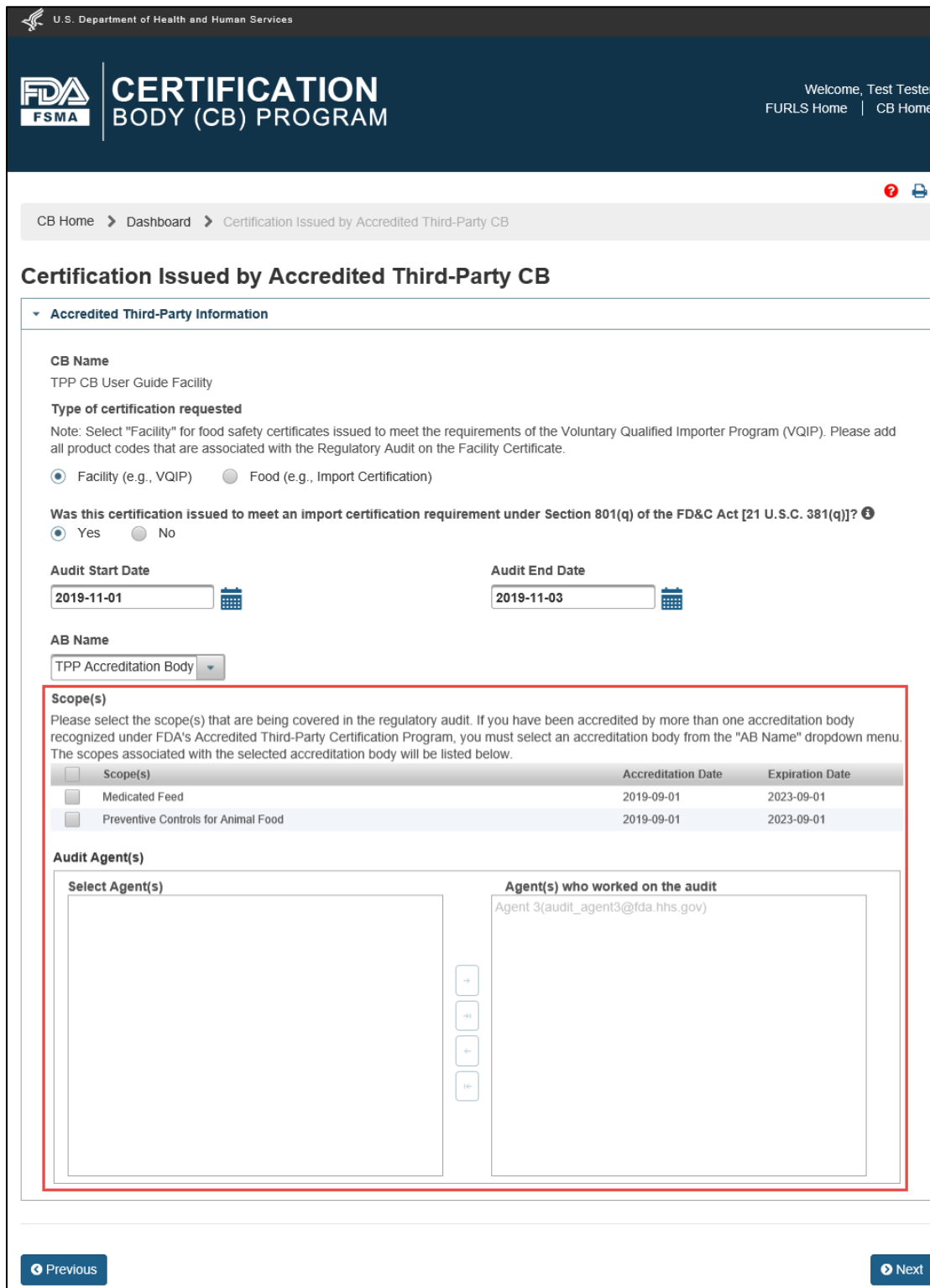
Figure 7.5 – Accredited Third-Party Information Section



The screenshot shows the 'Certification Issued by Accredited Third-Party CB' page. The header includes the FDA logo and 'CERTIFICATION BODY (CB) PROGRAM'. The breadcrumb trail is 'CB Home > Dashboard > Certification Issued by Accredited Third-Party CB'. The main section is titled 'Certification Issued by Accredited Third-Party CB' and contains a form for 'Accredited Third-Party Information'. The form fields are: 'CB Name' (pre-filled with 'TPP CB User Guide Facility'), 'Type of certification requested' (radio buttons for 'Facility (e.g., VQIP)' and 'Food (e.g., Import 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)]?' (radio buttons for 'Yes' and 'No'), 'Audit Start Date' (calendar icon and 'YYYY-MM-DD' input), 'Audit End Date' (calendar icon and 'YYYY-MM-DD' input), and 'AB Name' (dropdown menu with 'Please Select One'). Navigation buttons for 'Previous' and 'Next' are at the bottom.

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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard > Certification Issued by Accredited Third-Party CB

Certification Issued by Accredited Third-Party CB

▼ Accredited Third-Party Information

CB Name
 TPP CB User Guide Facility

Type of certification requested
 Note: Select "Facility" for food safety certificates issued to meet the requirements of the Voluntary Qualified Importer Program (VQIP). Please add all product codes that are associated with the Regulatory Audit on the Facility Certificate.

Facility (e.g., VQIP) Food (e.g., Import 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)]?
 Yes No

Audit Start Date

Audit End Date

AB Name

Scope(s)
 Please select the scope(s) that are being covered in the regulatory audit. If you have been accredited by more than one accreditation body recognized under FDA's Accredited Third-Party Certification Program, you must select an accreditation body from the "AB Name" dropdown menu. The scopes associated with the selected accreditation body will be listed below.

Scope(s)	Accreditation Date	Expiration Date
<input type="checkbox"/> Medicated Feed	2019-09-01	2023-09-01
<input type="checkbox"/> Preventive Controls for Animal Food	2019-09-01	2023-09-01

Audit Agent(s)

Select Agent(s)

Agent(s) who worked on the audit





Agent 3(audit_agent3@fda.hhs.gov)

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

Scope(s)
Please select the scope(s) that are being covered in the regulatory audit. If you have been accredited by more than one accreditation body recognized under FDA's Accredited Third-Party Certification Program, you must select an accreditation body from the "AB Name" dropdown menu. The scopes associated with the selected accreditation body will be listed below.

<input checked="" type="checkbox"/> Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="checkbox"/> Medicated Feed	2019-09-01	2023-09-01
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	2019-09-01	2023-09-01

Audit Agent(s)

Select Agent(s)

Agent(s) who worked on the audit

Agent 3(audit_agent3@fda.hhs.gov)

→

⇌

←

⇐

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

← Previous

Next →

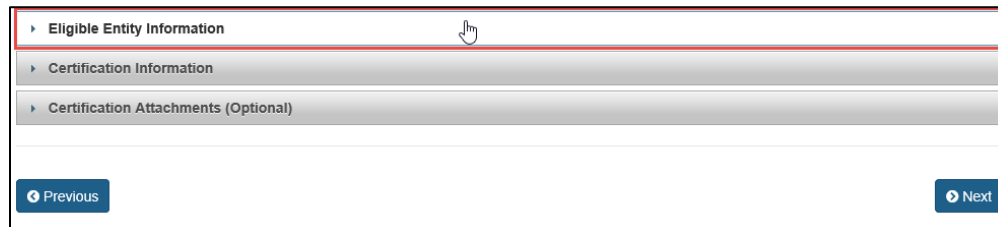
Note: Click the “Previous” button at the bottom of the “Certification Issued by Accredited Third-Party CB” page if you wish to return to the “Dashboard” page and start over.

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

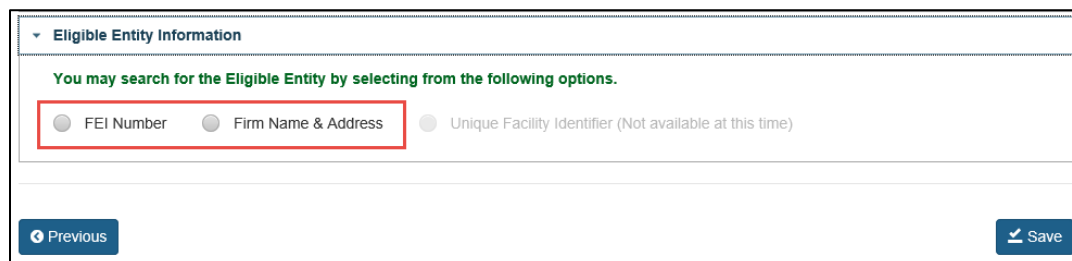


You must enter the firm information associated with the regulatory audit in the “Eligible Entity Information” section. The “Eligible Entity” tab is where information regarding the eligible entity covered in the audit is entered (as well as the audited facility, if it is different from the eligible entity). 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

WARNING!

Are you sure you want to change your selection?

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

Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number Firm Name & Address Unique Facility Identifier (Not available at this time)



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

Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

Eligible Entity

Certification Example Facility

Address 1

123 Any Street

Address 2 (Optional)

City

Any City

Country

UNITED STATES

State/Province/Territory

Virginia

Zip Code (Postal Code)

00000

Person(s) responsible for food safety at facility

Facility Phone Number

Country Area Phone Number Extension

Food Facility Registration Number (If Applicable)

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?


Yes
 No

[Previous](#)
[Next](#)

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

U.S. Department of Health and Human Services



CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

⚠ FEI number 101010101 is invalid. ✕

[CB Home](#) > [Dashboard](#) > [Certification Issued by Accredited Third-Party CB](#)

Certification Issued by Accredited Third-Party CB

▾ Accredited Third-Party Information

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

Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

<p>Eligible Entity</p> <input type="text" value="Certification Example Facility"/>	<p>Person(s) responsible for food safety at facility</p> <input type="text"/>								
<p>Address 1</p> <input type="text" value="123 Any Street"/>	<p>Facility Phone Number</p> <table border="0"> <tr> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td style="font-size: small;">Country</td> <td style="font-size: small;">Area</td> <td style="font-size: small;">Phone Number</td> <td style="font-size: small;">Extension</td> </tr> </table>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Country	Area	Phone Number	Extension
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>						
Country	Area	Phone Number	Extension						
<p>Address 2 (Optional)</p> <input type="text"/>	<p>Food Facility Registration Number (If Applicable)</p> <input type="text"/>								
<p>City</p> <input type="text" value="Any City"/>									
<p>Country</p> <input type="text" value="UNITED STATES"/>									
<p>State/Province/Territory</p> <input type="text" value="Virginia"/>									
<p>Zip Code (Postal Code)</p> <input type="text" value="00000"/>									

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes
 No

[Previous](#)
[Next](#)

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

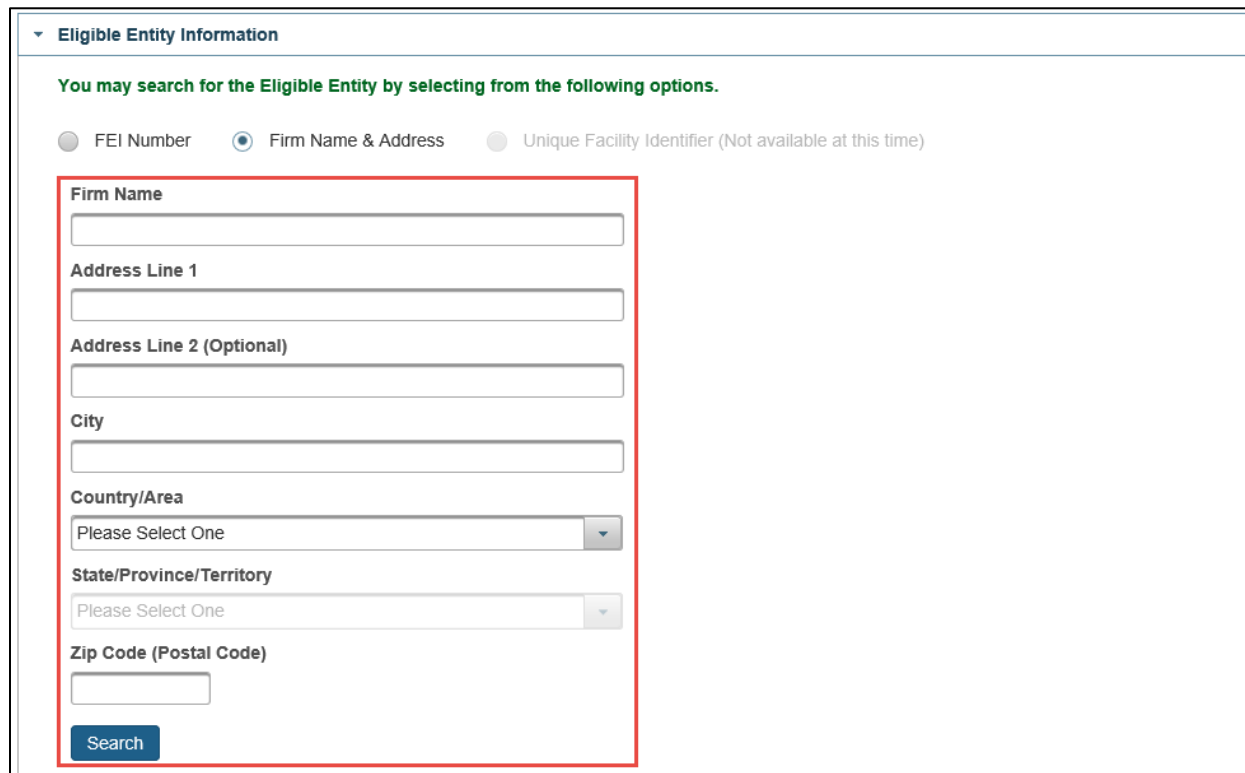
Select the radio button to the left of “Firm Name & Address” if you do not have the firm’s FEI number. The system will display additional data fields once you select the radio button (Figure 7.15). The text entry fields are not case-sensitive.

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

Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

Eligible Entity
 Certification Example Facility

Address 1
 123 Any Street

Address 2 (Optional)

City
 Anytown

Country
 UNITED STATES

State/Province/Territory
 Virginia

Zip Code (Postal Code)
 00000

Person(s) responsible for food safety at facility

Facility Phone Number
 Country Area Phone Number Extension

Food Facility Registration Number (If Applicable)

If the firm information is not accurate, click Search Again.

Search Again

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?
 Yes No

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

Select one address

Entered search criteria has returned multiple results. Please select the correct address from the list below.

Name	Address	Select Address
Certification Example Facility	123 Any Street, Any City, Virginia, UNITED STATES	Select & Continue
Certification Example Facility, LLC	456 My Street, Anytown, Virginia, UNITED STATES	Select & Continue

Return to Search

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

Address Validation

WARNING: This address has been verified; however, minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications that were made or correct the address yourself.

<p>Your Eligible Entity Address</p> <p>Address Line 1 123 Any Street</p> <p>Address Line 2 (Optional)</p> <p>City Any City</p> <p>State/Province/Territory Virginia</p> <p>Zip Code (Postal Code) 00000</p> <p>Country/Area UNITED STATES</p>	<p>Validated Eligible Entity Address</p> <p>Address Line 1 123 Any Street</p> <p>Address Line 2 (Optional)</p> <p>City Any City</p> <p>State/Province/Territory Virginia</p> <p>Zip Code (Postal Code) 00000</p> <p>Country/Area UNITED STATES</p>
--	---

← Return to Search

→ Accept Provided Address

→ Accept Validated Address

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

Address Validation

WARNING: This address has been verified; however, minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications that were made or correct the address yourself.

Your Eligible Entity Address	Validated Eligible Entity Address
<p>Address Line 1 123 Any Street</p> <p>Address Line 2 (Optional)</p> <p>City Any City</p> <p>State/Province/Territory Virginia</p> <p>Zip Code (Postal Code) 00000</p> <p>Country/Area UNITED STATES</p>	<p>Address Line 1 123 Any Street</p> <p>Address Line 2 (Optional)</p> <p>City Any City</p> <p>State/Province/Territory Virginia</p> <p>Zip Code (Postal Code) 00000</p> <p>Country/Area UNITED STATES</p>

← Return to Search
→ Accept Provided Address
→ Accept Validated Address

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

▼ **Eligible Entity Information**

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

<p>Eligible Entity</p> <input type="text" value="Certification Example Facility"/>	<p>Person(s) responsible for food safety at facility</p> <input type="text"/>
<p>Address 1</p> <input type="text" value="123 Any Street"/>	<p>Facility Phone Number</p> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
<p>Address 2 (Optional)</p> <input type="text"/>	<p>Country Area Phone Number Extension</p>
<p>City</p> <input type="text" value="Any City"/>	<p>Food Facility Registration Number (If Applicable)</p> <input type="text"/>
<p>Country</p> <input type="text" value="UNITED STATES"/>	<div style="border: 2px solid red; padding: 5px;"> <p>If the firm information is not accurate, click Search Again.</p> <input type="button" value="Search Again"/> </div>
<p>State/Province/Territory</p> <input type="text" value="Virginia"/>	
<p>Zip Code (Postal Code)</p> <input type="text" value="00000"/>	

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes
 No

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

Eligible Entity Information

You may search for the Eligible Entity by selecting from the following options.

FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

Eligible Entity

Address 1

Address 2 (Optional)

City

Country

State/Province/Territory

Zip Code (Postal Code)

If the firm information is not accurate, click Search Again.

Person(s) responsible for food safety at facility

Facility Phone Number

Country Area Phone Number Extension

Owner of Eligible Entity (Optional)

Operator of Eligible Entity (Optional)

Food Facility Registration Number (If Applicable)

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes
 No

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

Is the facility that was audited different than the eligible entity who is participating in the Accredited Third-Party Certification Program?

Yes
 No

You may search for the Audited Facility by selecting from the following options.

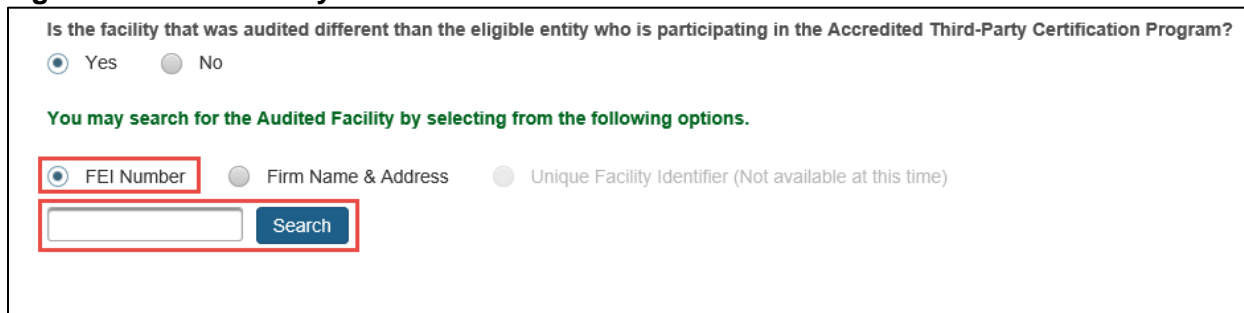
FEI Number
 Firm Name & Address
 Unique Facility Identifier (Not available at this time)

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



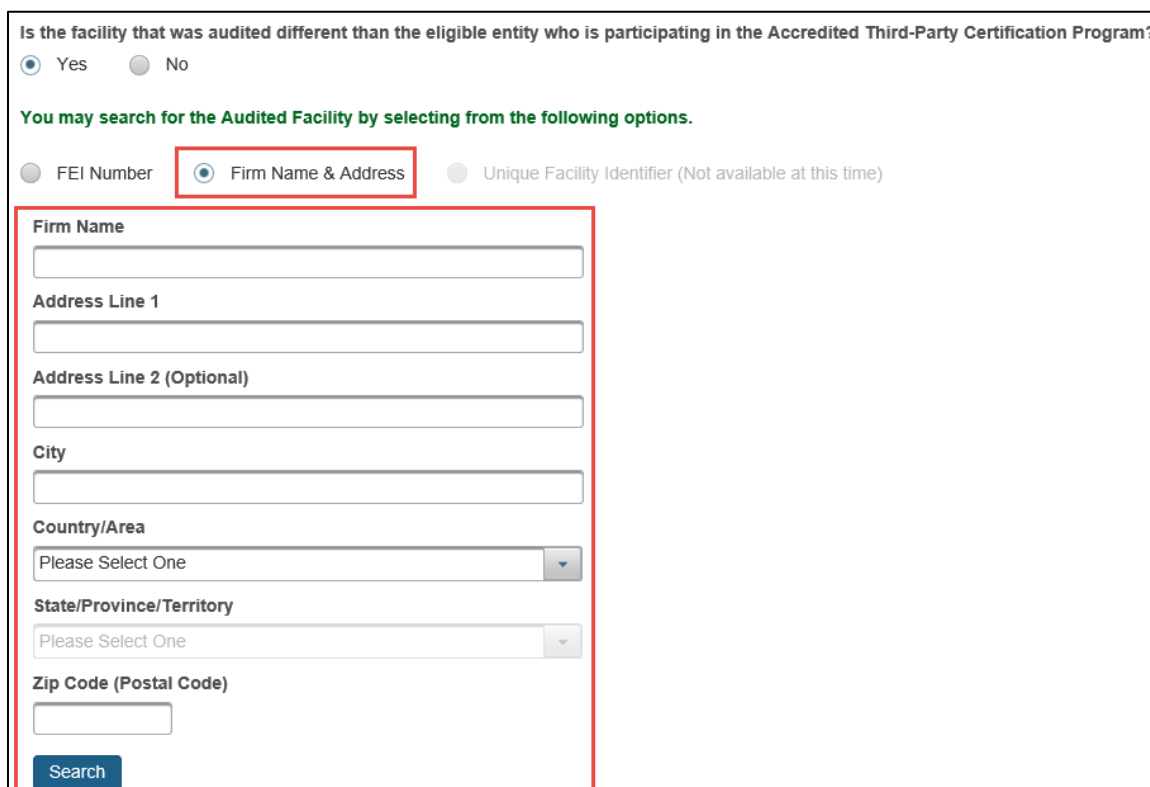
If you do not have the firm’s FEI Number, select the radio button to the left of “Firm Name & Address” to search by the firm’s name and address. An input field and the “Search” button will display (Figure 7.24).

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).

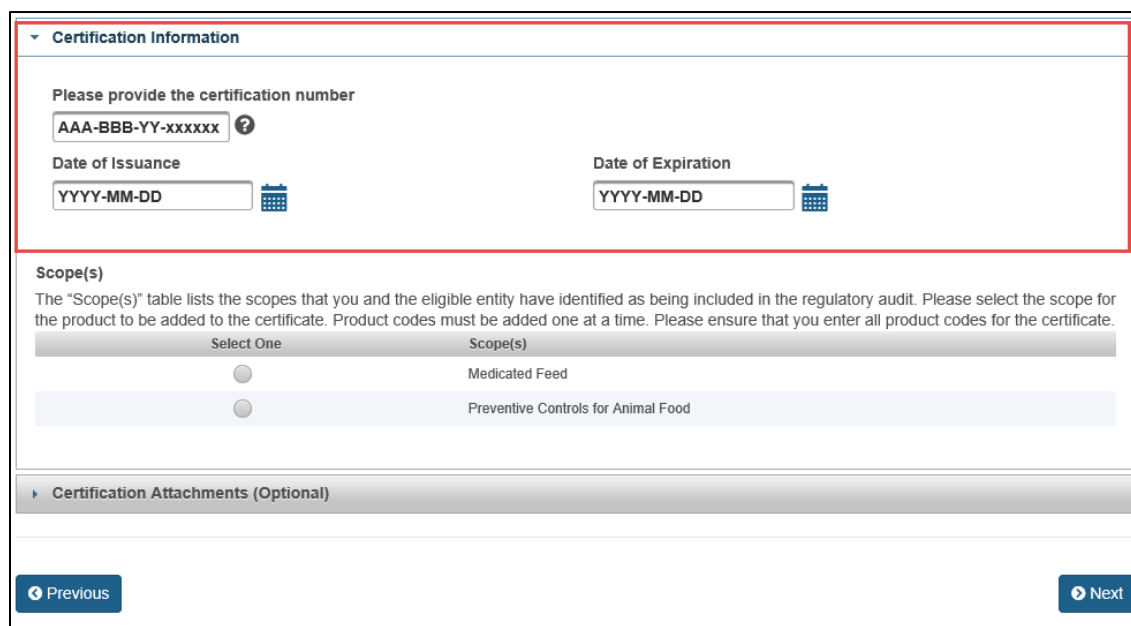
Figure 7.25 - Certification Information Section



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

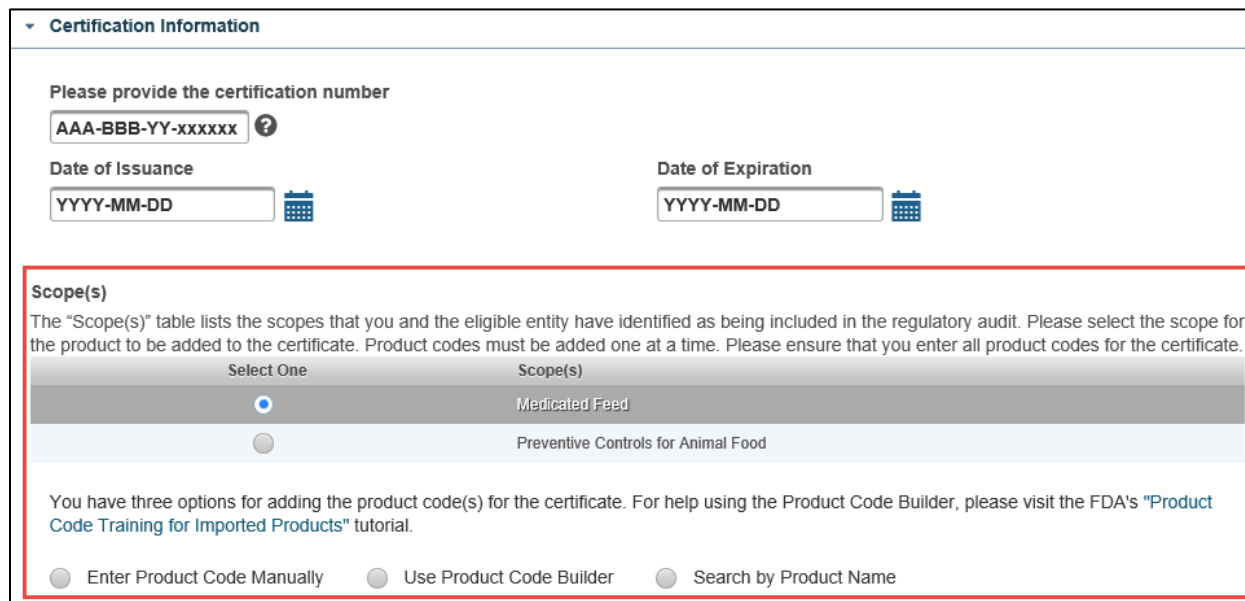


The “Scope(s)” section allows you to select the scope(s) and enter the product code(s) of the FDA regulated product(s) that will be included in the certification.

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



▼ Certification Information

Please provide the certification number
 ?

Date of Issuance  Date of Expiration 

Scope(s)
 The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

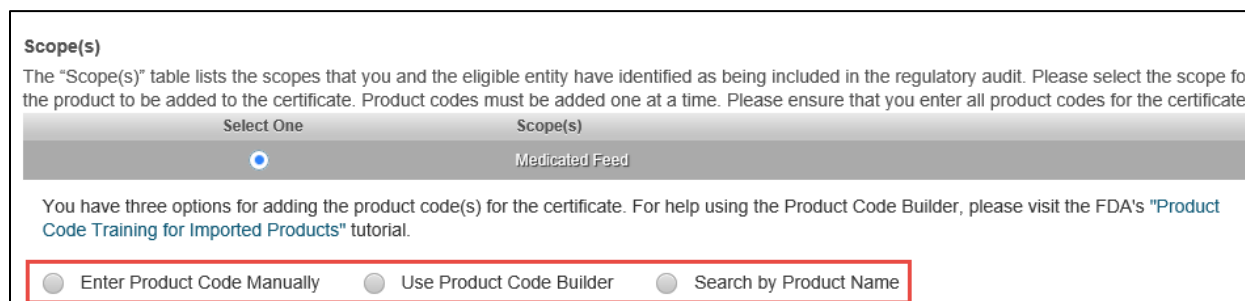
You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "[Product Code Training for Imported Products](#)" tutorial.

Enter Product Code Manually Use Product Code Builder Search by Product Name

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



Scope(s)
 The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "[Product Code Training for Imported Products](#)" tutorial.

Enter Product Code Manually Use Product Code Builder Search by Product Name

7.1.3.1 Product Code Selection – Enter Product Code Manually

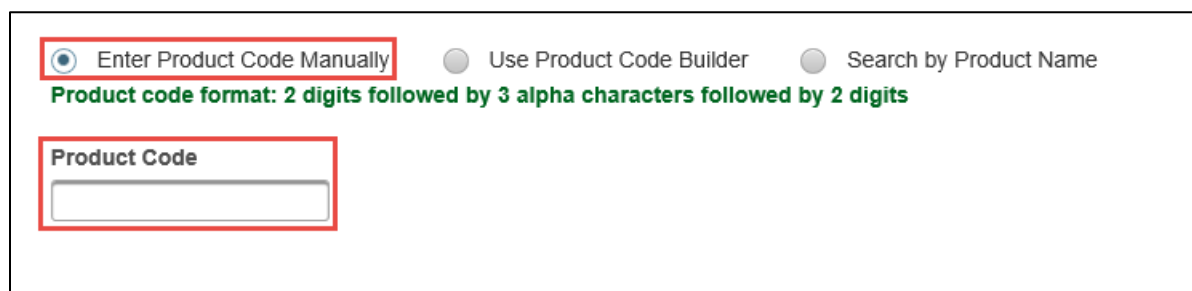
You may use the “Enter Product Code Manually” option if you know the complete product code. Select the radio button to the left of “Enter Product Code Manually” (Figure 7.29).

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



The screenshot shows a web interface for selecting a product code. At the top, there are three radio button options: "Enter Product Code Manually" (which is selected and highlighted with a red box), "Use Product Code Builder", and "Search by Product Name". Below these options, a green text instruction reads: "Product code format: 2 digits followed by 3 alpha characters followed by 2 digits". Underneath this instruction is a text input field labeled "Product Code", which is also highlighted with a red box.

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

Scope(s)
 The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product code format: 2 digits followed by 3 alpha characters followed by 2 digits

Product Code

Product Code Description
 Medicated Animal Feeds/Category I/Type B Feed From Type A Med Article/Aklomide Category I, Medicated Animal Feed

Product Description (Optional)

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


▼ Certification Information

Please provide the certification number

DEM-TPP-19-000003 ?

Date of Issuance: 2019-12-02 

Date of Expiration: 2020-12-02 

Product Code	Product Code Description	Product Description	Scope	Action
69AA-01	Medicated Animal F... more	This is the option... more	(1)	

Scope(s)

The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "Product Code Training for Imported Products" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product code format: 2 digits followed by 3 alpha characters followed by 2 digits

Product Code

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:

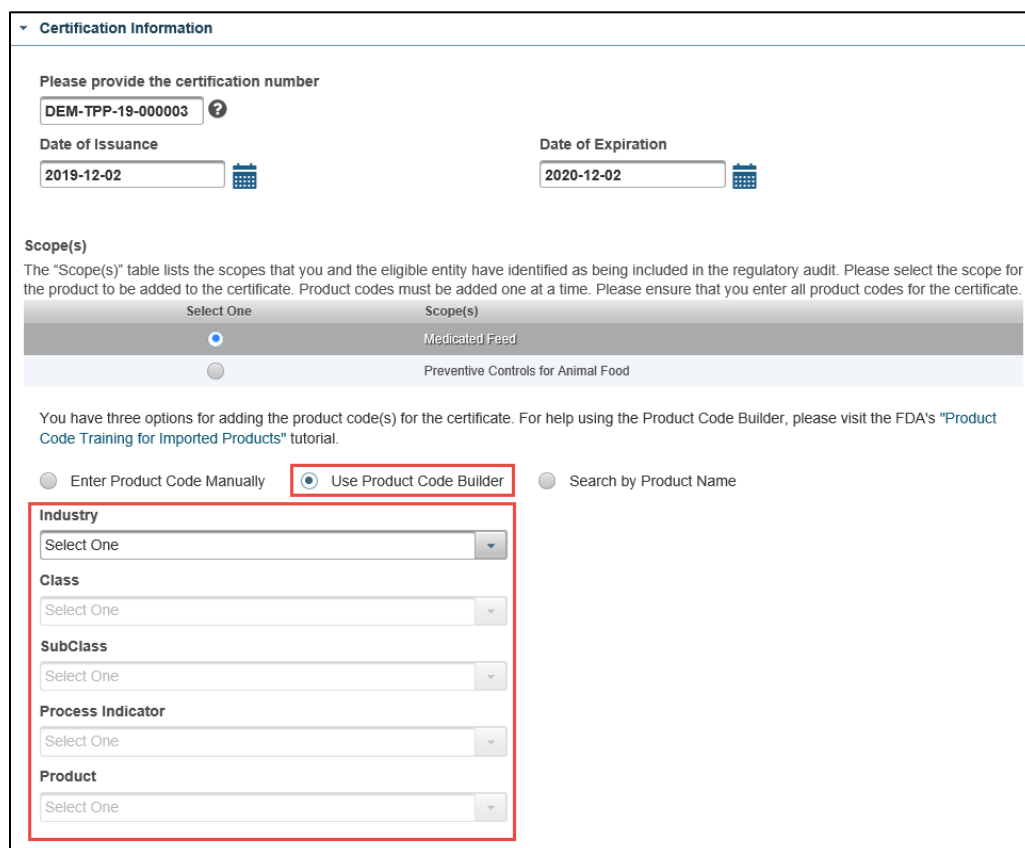
- **Industry** – The industry applicable to the product
You must make a selection from the “Industry” menu before the system will allow you to select from the other menus.
- **Class** – The class applicable to the product
- **SubClass** – The subclass applicable to the product
- **Process Indicator** – 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



▼ Certification Information

Please provide the certification number

Date of Issuance  Date of Expiration 

Scope(s)
 The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "Product Code Training for Imported Products" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Industry

Class

SubClass

Process Indicator

Product

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

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "[Product Code Training for Imported Products](#)" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Industry
 Medicated Animal Feeds - 69

Class
 Category I - A

SubClass
 Type B Feed From Type A Med Article - A

Process Indicator
 Select One

Product
 Aklomide Category I, Medicated Animal Feed (A-01)

Product Code
69AA-01

Product Code Description
Medicated Animal Feeds/Category I/Type B Feed From Type A Med Article/Aklomide Category I, Medicated Animal Feed

Product Description (Optional)
This is the optional product description entered by the user

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

▼ Certification Information

Please provide the certification number
 ?

Date of Issuance  Date of Expiration 

Product Code	Product Code Description	Product Description	Scope	Action
69AA-01	Medicated Animal F... more		(1)	

Scope(s)

The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "[Product Code Training for Imported Products](#)" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Industry
 ▼

Class
 ▼

SubClass
 ▼

Process Indicator
 ▼

Product
 ▼

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

Certification Information

Please provide the certification number

Date of Issuance: Date of Expiration:

Scope(s)
 The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA’s “Product Code Training for Imported Products” tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product	Industry	Class
Atkometide Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Atkometide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Ammonium Chloride Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Amprolium Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Amprolium Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Amprolium With Ethopabate Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Amprolium With Ethopabate Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Apramycin Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Apramycin Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Arsanilate Sodium Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B

(1 of 17)

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

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's ["Product Code Training for Imported Products"](#) tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product	Industry	Class
Aklomide		
Aklomide Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Roxarsone And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Roxarsone And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran, Aklomide & Roxarsone Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran, Aklomide & Roxarsone Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C

(1 of 1)

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

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

Product	Industry	Class
Aklomide		
Aklomide Category I, Medicated Animal Feed	Medicated Animal Feeds - 69	Category I - A
Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Roxarsone And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Roxarsone And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran And Aklomide Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran And Aklomide Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C
Sulfanitran, Aklomide & Roxarsone Category II, Medicated Animal Feed	Medicated Animal Feeds - 69	Category II - B
Sulfanitran, Aklomide & Roxarsone Combo Category I & II, Medicated Animal Feed	Medicated Animal Feeds - 69	Combo Category I & II - C

(1 of 1)

SubClass

Process Indicator

Product Code

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.

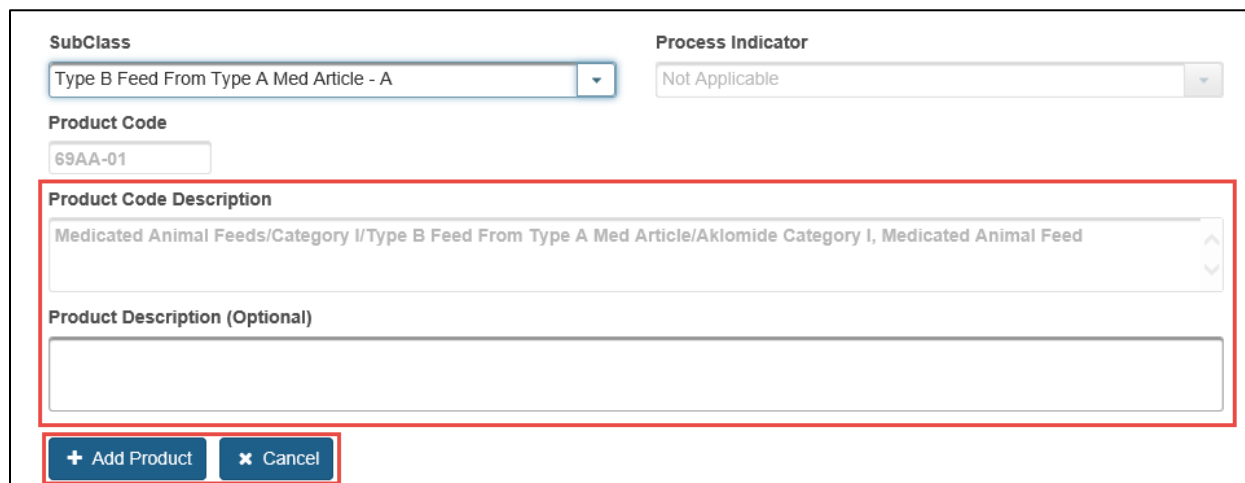
Click the “Add Product” button to add the product to the certificate.

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




The screenshot shows a web form with the following elements:



- SubClass:** A dropdown menu with the selected value "Type B Feed From Type A Med Article - A".
- Process Indicator:** A dropdown menu with the selected value "Not Applicable".
- Product Code:** A text input field containing "69AA-01".
- Product Code Description:** A read-only text area containing "Medicated Animal Feeds/Category II/Type B Feed From Type A Med Article/Aklomide Category I, Medicated Animal Feed".
- Product Description (Optional):** An empty text input field.
- Buttons:** Two buttons at the bottom: "+ Add Product" and "x Cancel".


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

▼ Certification Information

Please provide the certification number
 

Date of Issuance  Date of Expiration 

Product Code	Product Code Description	Product Description	Scope	Action
69AA-01	Medicated Animal F... more	This is the option... more	(1)	

Scope(s)
 The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed
<input type="radio"/>	Preventive Controls for Animal Food

You have three options for adding the product code(s) for the certificate. For help using the Product Code Builder, please visit the FDA's "[Product Code Training for Imported Products](#)" tutorial.

Enter Product Code Manually
 Use Product Code Builder
 Search by Product Name

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).

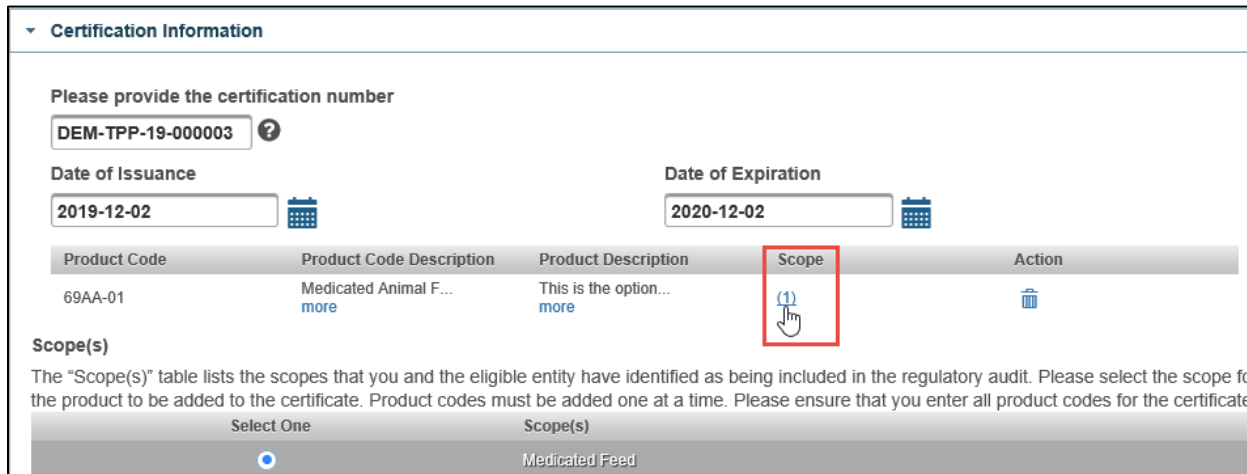
****Important:** Once you submit the certification to FDA, you cannot add or delete product code(s). If any products intended to be certified are not listed, they will not be considered by FDA as covered under the certification. Contact FDA if you submit a certification and inadvertently leave out product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

Figure 7.40 – Product Added – Trash/Delete Icon

Product Code	Product Code Description	Product Description	Scope	Action
69AA-01	Medicated Animal F... more	This is the option... more	(1)	

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



Certification Information
 Please provide the certification number
 DEM-TPP-19-000003 ?
 Date of Issuance: 2019-12-02
 Date of Expiration: 2020-12-02

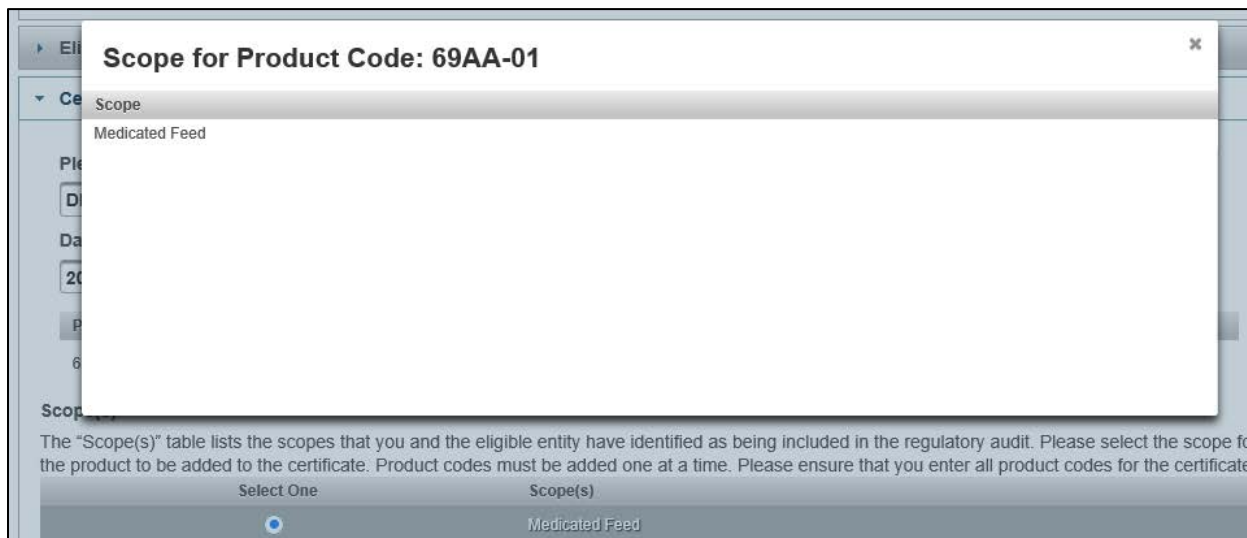
Product Code	Product Code Description	Product Description	Scope	Action
69AA-01	Medicated Animal F... more	This is the option... more	(1)	

Scope(s)
 The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed

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



Scope for Product Code: 69AA-01

Scope
Medicated Feed

The “Scope(s)” table lists the scopes that you and the eligible entity have identified as being included in the regulatory audit. Please select the scope for the product to be added to the certificate. Product codes must be added one at a time. Please ensure that you enter all product codes for the certificate.

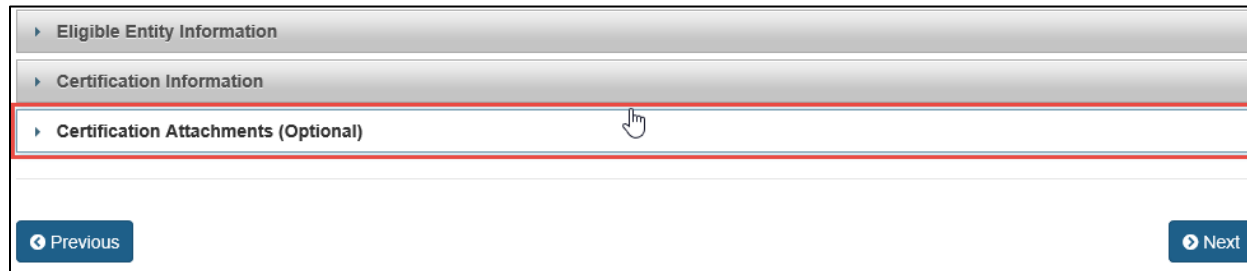
Select One	Scope(s)
<input checked="" type="radio"/>	Medicated Feed

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.

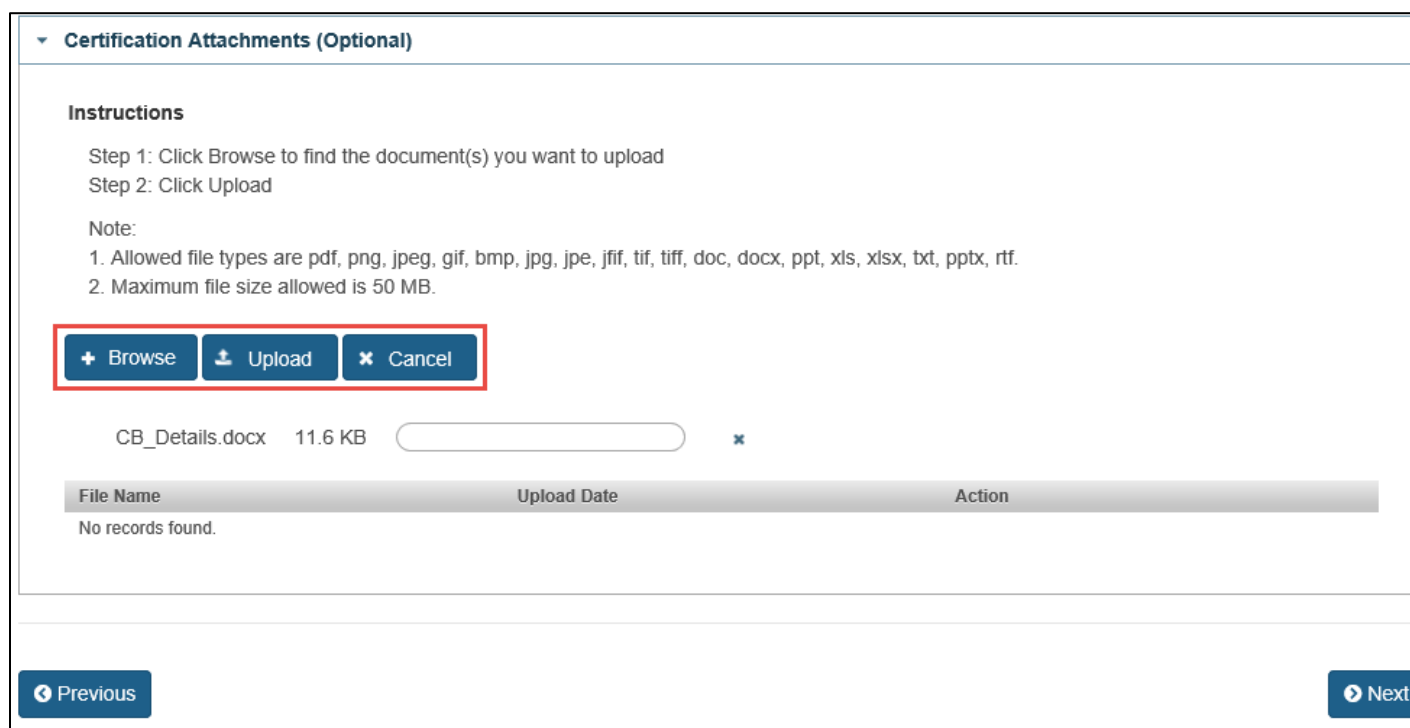
Click the “Cancel” button to discard the upload of the attachment.

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

▼ Certification Attachments (Optional)

Instructions


Step 1: Click Browse to find the document(s) you want to upload
 Step 2: Click Upload

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

i **CB_Details.docx uploaded successfully.** ×

+ Browse
↓ Upload
✕ Cancel

File Name	Upload Date	Action
CB_Details.docx	2019-12-19	 ←

◀ Previous
Next ▶

7.1.5 e-Signature Page

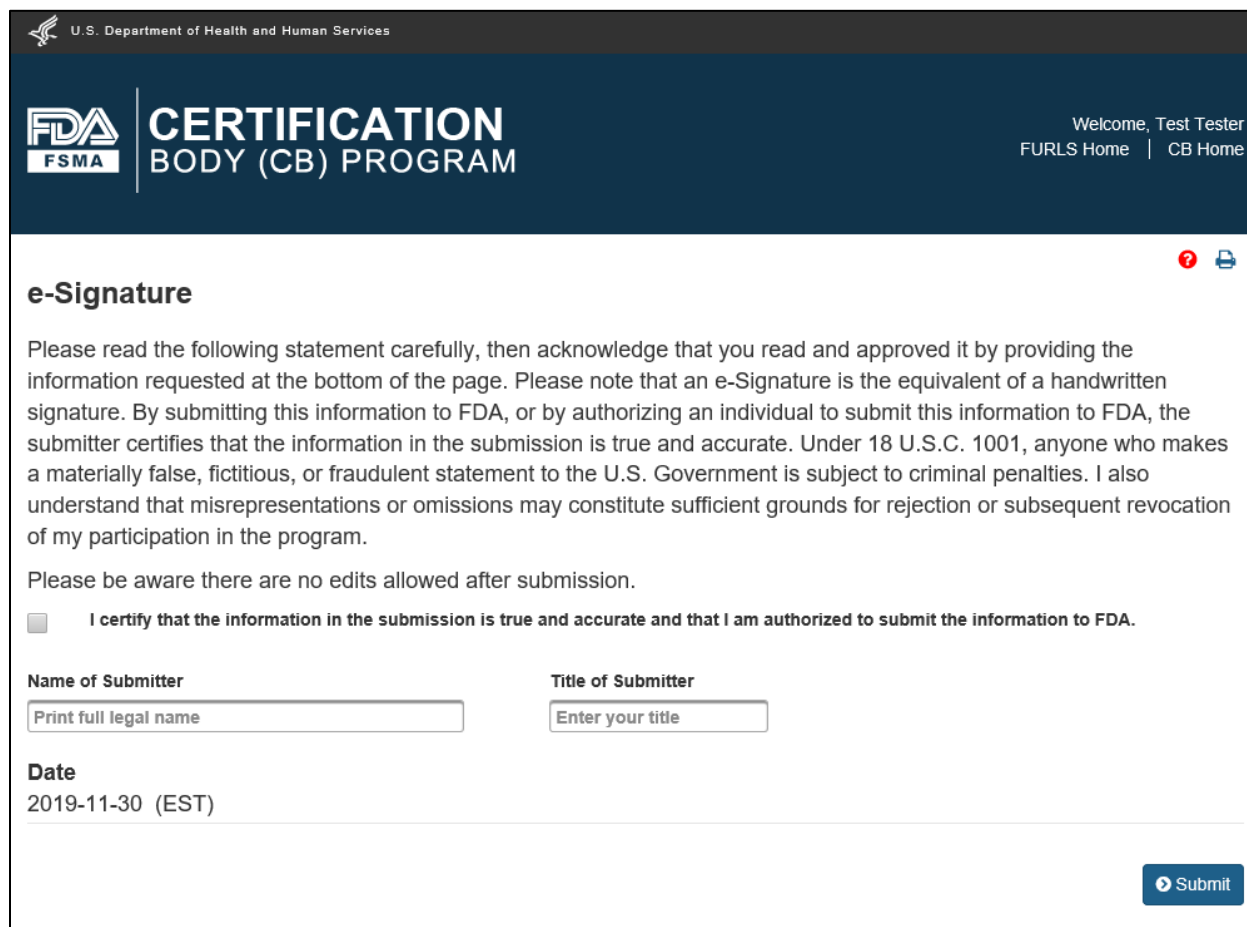
Follow the directions provided on the “e-Signature” page (Figure 7.46).

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



U.S. Department of Health and Human Services

FDA **CERTIFICATION**
FSMA **BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program.

Please be aware there are no edits allowed after submission.

I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.

Name of Submitter

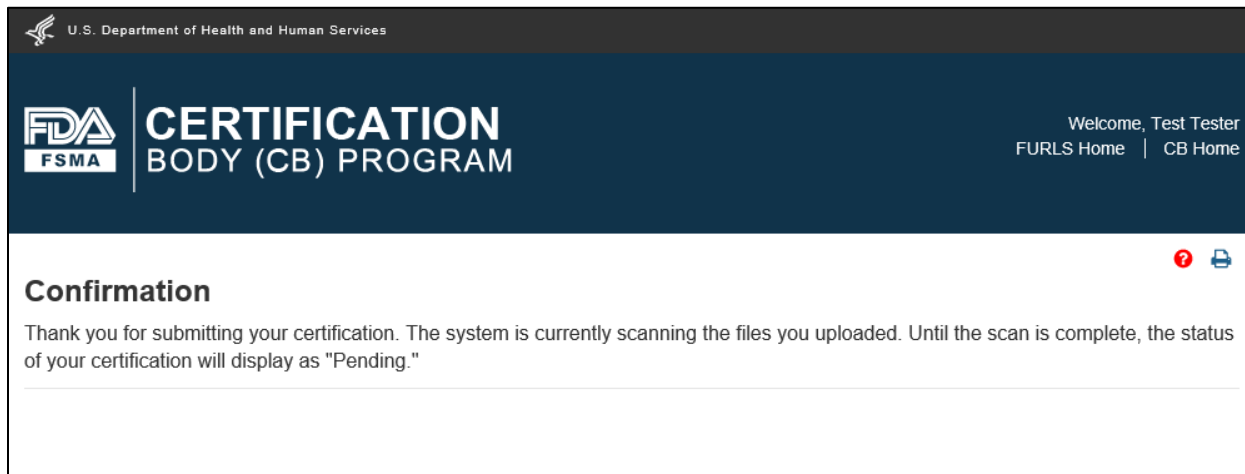
Title of Submitter

Date
2019-11-30 (EST)

[Submit](#)

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

Figure 7.47 – Confirmation Page



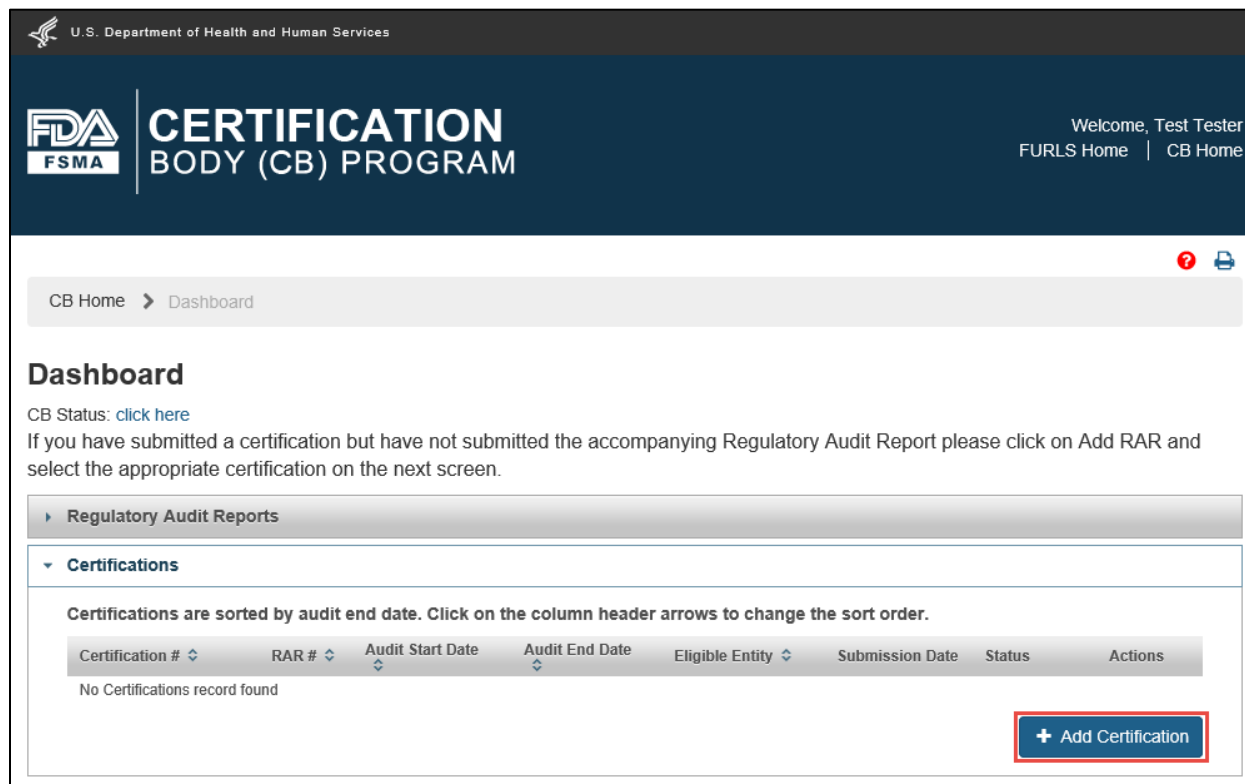
To view the status of your certification, or to view and print the certification details, proceed to Section 7.3 of this chapter.

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



U.S. Department of Health and Human Services

FDA FSMA | **CERTIFICATION BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Dashboard

Dashboard

CB Status: [click here](#)

If you have submitted a certification but have not submitted the accompanying Regulatory Audit Report please click on Add RAR and select the appropriate certification on the next screen.

Regulatory Audit Reports

Certifications

Certifications are sorted by audit end date. Click on the column header arrows to change the sort order.

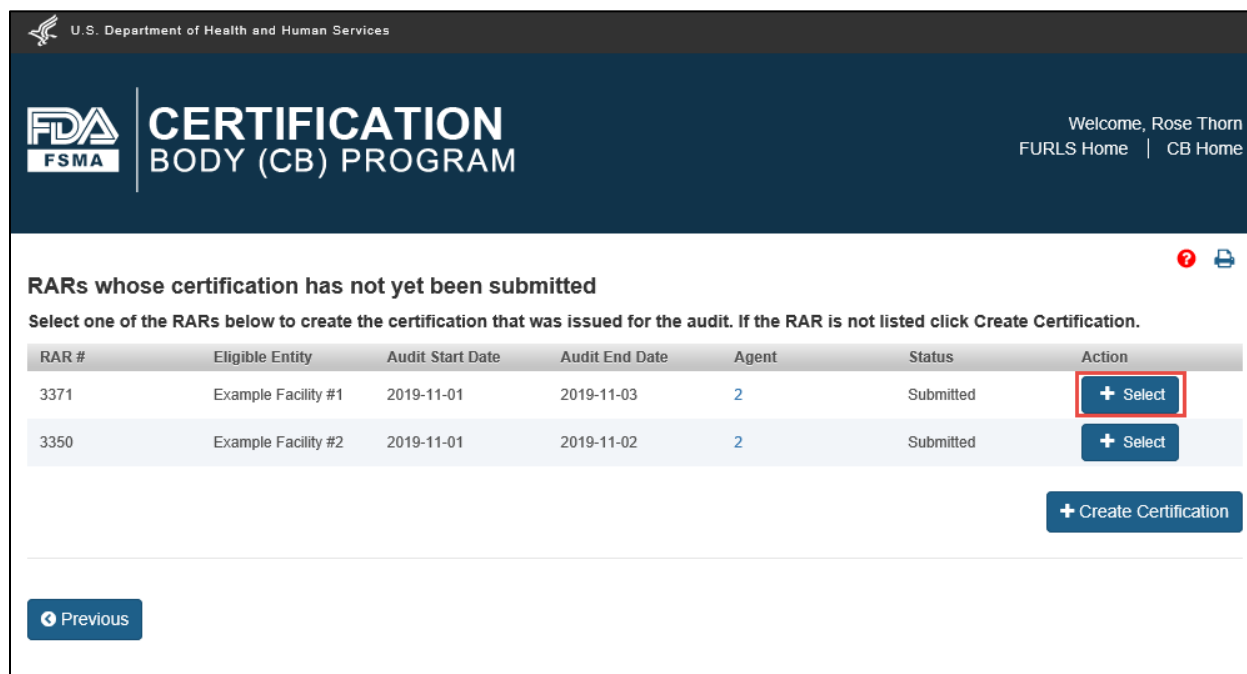
Certification #	RAR #	Audit Start Date	Audit End Date	Eligible Entity	Submission Date	Status	Actions
No Certifications record found							

+ Add Certification

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



U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Rose Thorn
[FURLS Home](#) | [CB Home](#)

RARs whose certification has not yet been submitted

Select one of the RARs below to create the certification that was issued for the audit. If the RAR is not listed click **Create Certification**.

RAR #	Eligible Entity	Audit Start Date	Audit End Date	Agent	Status	Action
3371	Example Facility #1	2019-11-01	2019-11-03	2	Submitted	+ Select
3350	Example Facility #2	2019-11-01	2019-11-02	2	Submitted	+ Select

+ Create Certification

Previous

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

CB Home > Dashboard > Certification Issued by Accredited Third-Party CB

Certification Issued by Accredited Third-Party CB

▼ Accredited Third-Party Information

CB Name
 TPP CB User Guide Facility

Type of certification requested
 Note: Select "Facility" for food safety certificates issued to meet the requirements of the Voluntary Qualified Importer Program (VQIP). Please add all product codes that are associated with the Regulatory Audit on the Facility Certificate.

Facility (e.g., VQIP) Food (e.g., Import 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)]? ⓘ

Yes No

Audit Start Date **Audit End Date**
 2019-11-01 2019-11-03

AB Name
 TPP Accreditation Body

Scope(s)
 Please select the scope(s) that are being covered in the regulatory audit. If you have been accredited by more than one accreditation body recognized under FDA's Accredited Third-Party Certification Program, you must select an accreditation body from the "AB Name" dropdown menu. The scopes associated with the selected accreditation body will be listed below.

Scope(s)	Accreditation Date	Expiration Date
<input type="checkbox"/> Dietary Supplements	2020-02-25	2021-02-22
<input type="checkbox"/> Infant Formula	2020-02-25	2021-02-22
<input checked="" type="checkbox"/> Medicated Feed	2021-02-21	2021-02-21
<input type="checkbox"/> Preventive Controls for Animal Food	2020-02-25	2021-02-21

Audit Agent(s)

Select Agent(s)

Agent 2

Agent(s) who worked on the audit

Agent 1

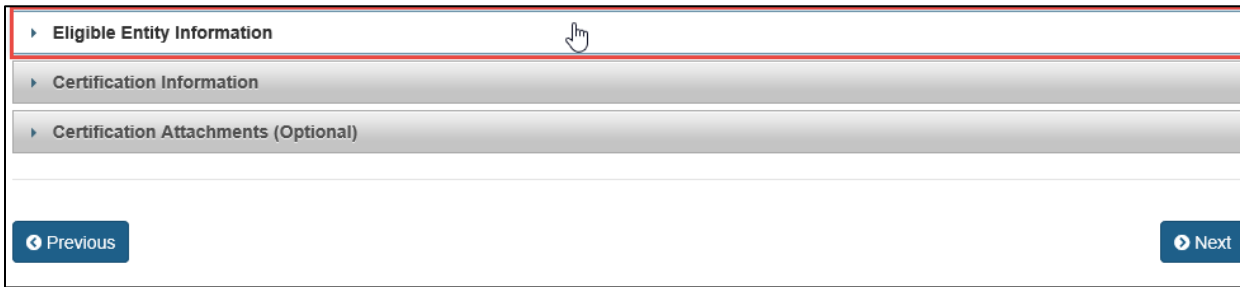
Note: Click the “Previous” button at the bottom of the “Certification Issued by Accredited Third-Party CB” page if you wish to return to the “Dashboard” page and start over.

Proceed to Section 7.2.2 of this chapter.

7.2.2 Eligible Entity Information Section

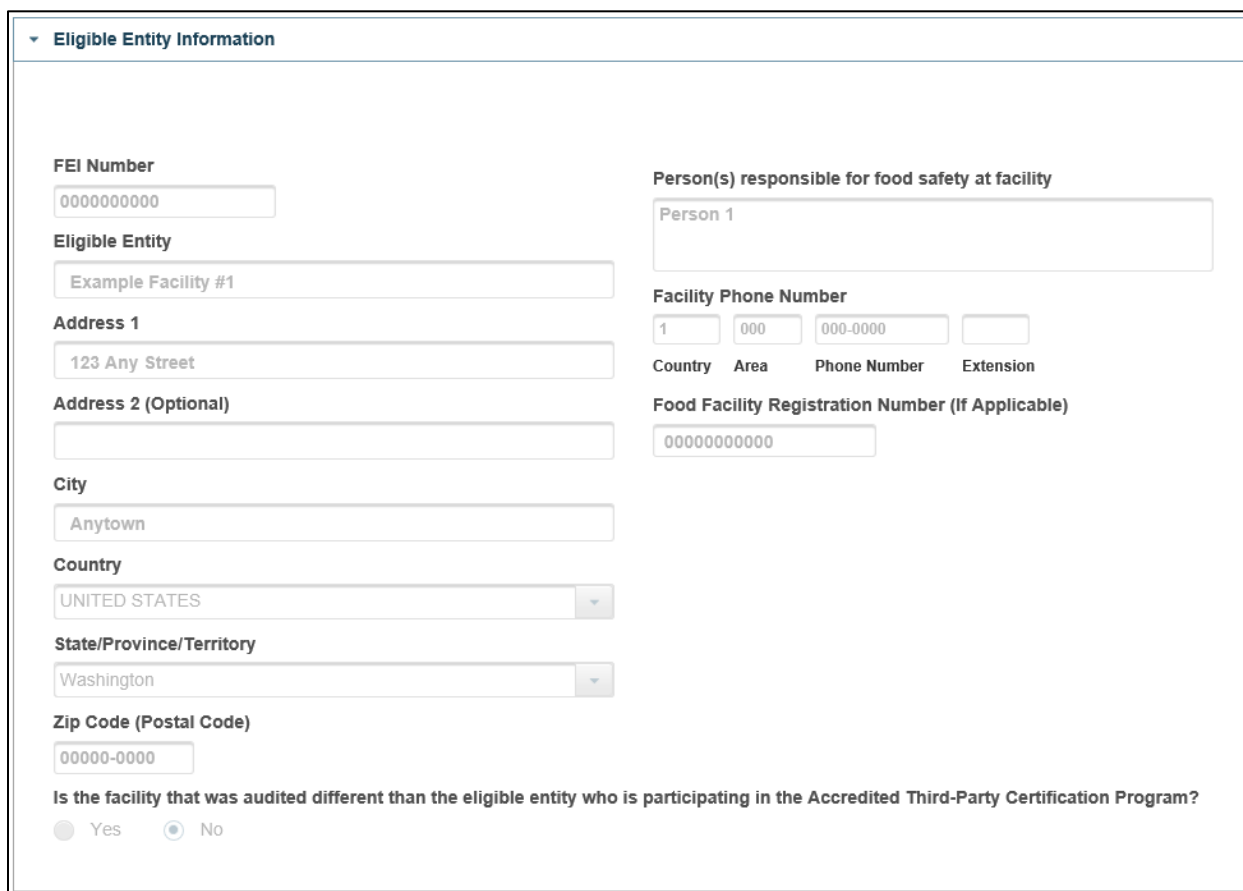
Click on the accordion section’s title bar to display its content (Figure 7.51).

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



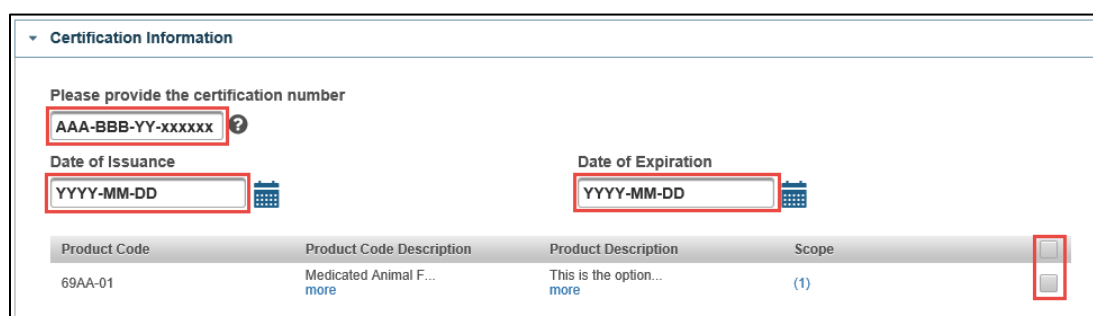
The fields in this section are pre-filled from the information submitted in the regulatory audit report, but they are editable (Figure 7.54):

- **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

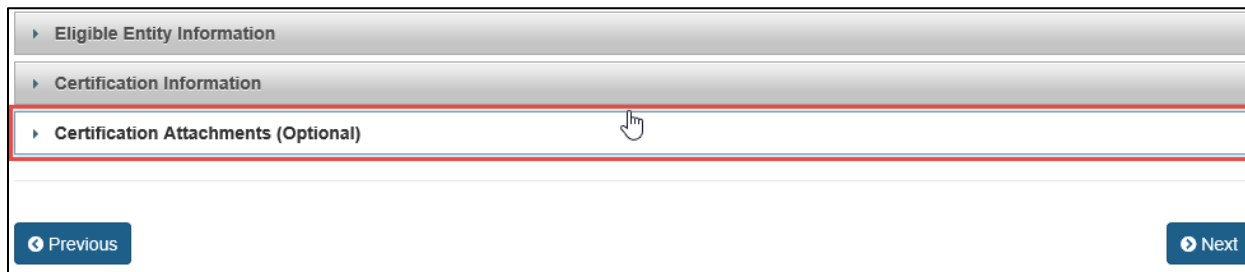


Proceed to Section 7.2.4 of this chapter.

7.2.4 Certification Attachments (Optional) Section

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

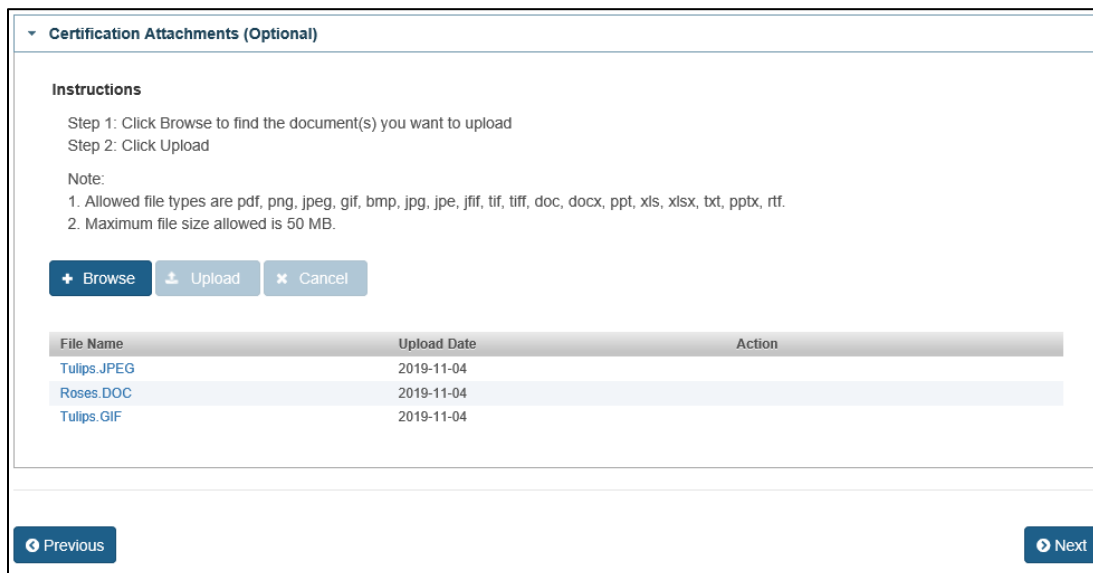
Figure 7.55 – Certification Attachments (Optional) Section



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

▼ **Certification Attachments (Optional)**

Instructions

Step 1: Click Browse to find the document(s) you want to upload
 Step 2: Click Upload

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

+ Browse
⬇️ Upload
✖️ Cancel

CB_Details.docx 11.6 KB ✖️

File Name	Upload Date	Action
Tulips.GIF	2019-11-04	
Roses.JPEG	2019-11-04	
Tulips.DOC	2019-11-04	

⬅️ Previous
Next ➡️

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

▼ Certification Attachments (Optional)

Instructions

Step 1: Click Browse to find the document(s) you want to upload
 Step 2: Click Upload

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

i **CB_Details.docx uploaded successfully.** ✕

+ Browse
⬇ Upload
✕ Cancel

File Name	Upload Date	Action
Tulips.GIF	2019-11-04	
Roses.JPEG	2019-11-04	
Tulips.DOC	2019-11-04	
CB_Details.docx	2019-12-20	🗑

⬅ Previous
➡ Next

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

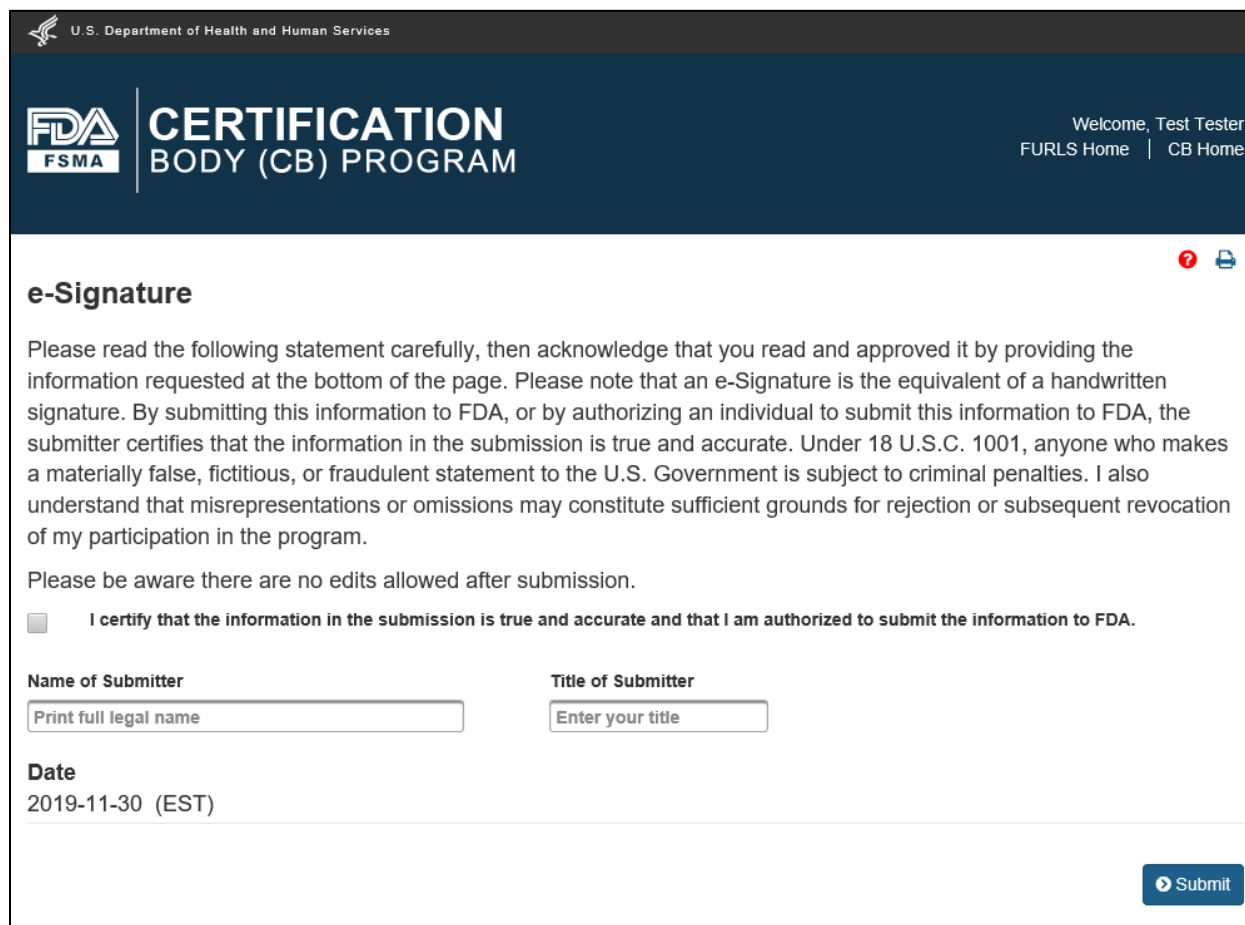
Follow the directions provided on the “e-Signature” page (Figure 7.59).

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



The screenshot shows the "e-Signature" page for the FDA FSMA Certification Body (CB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "CERTIFICATION BODY (CB) PROGRAM". There are also links for "Welcome, Test Tester", "FURLS Home", and "CB Home".

The main content area is titled "e-Signature" and contains the following text:

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program.

Please be aware there are no edits allowed after submission.

I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.

Below the certification statement, there are two input fields:

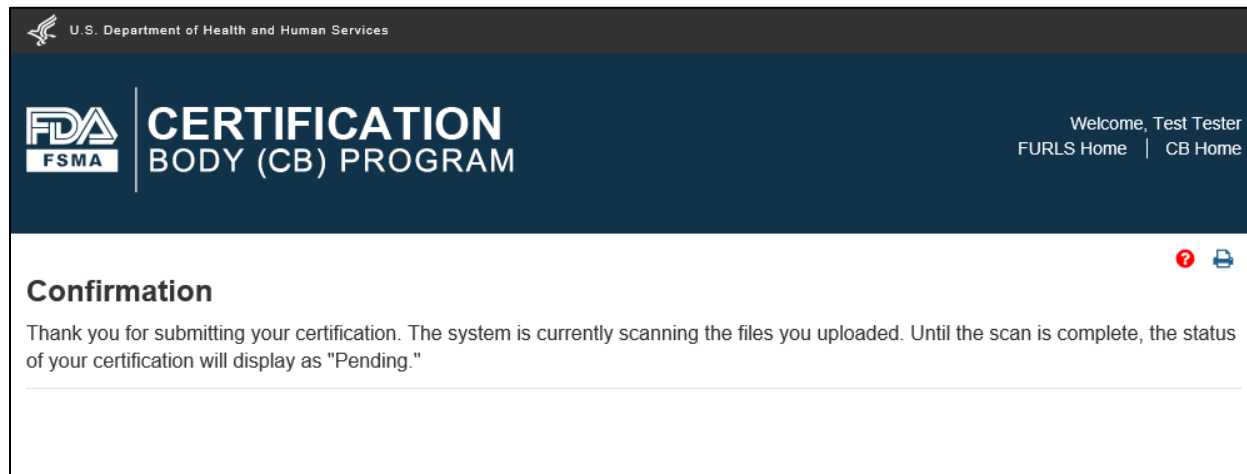
- Name of Submitter**: A text box with the placeholder "Print full legal name".
- Title of Submitter**: A text box with the placeholder "Enter your title".

Below the input fields, there is a "Date" field showing "2019-11-30 (EST)".

At the bottom right of the page, there is a blue "Submit" button.

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.

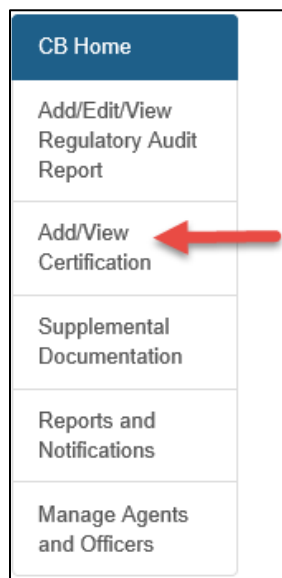
7.3 View or Print a Certification

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

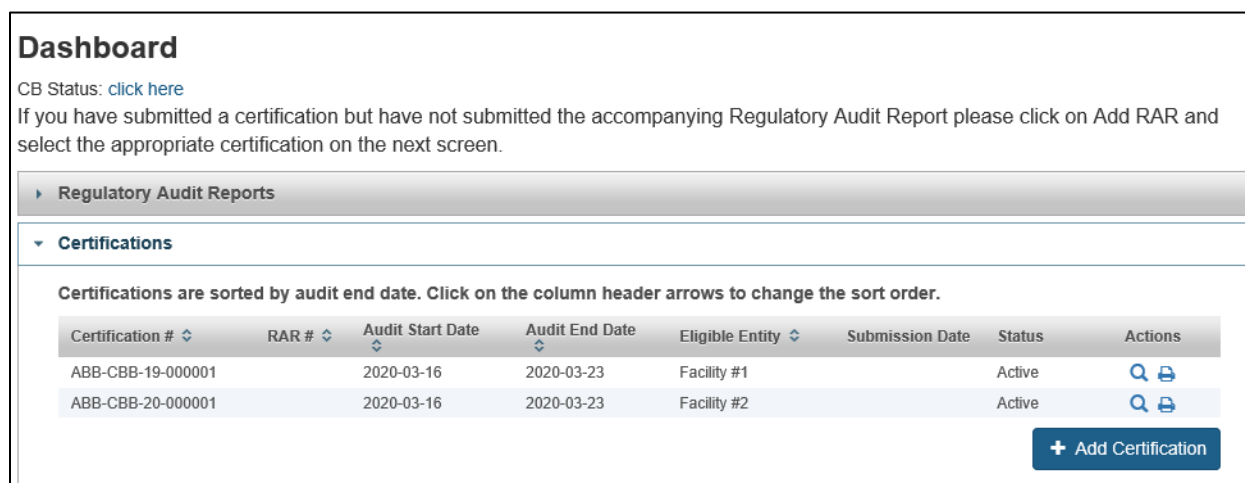
To access the certification functionality, click the “Add/View Certification” link from the navigation menu on the “CB Home” page (Figure 7.61).

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



7.3.2 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

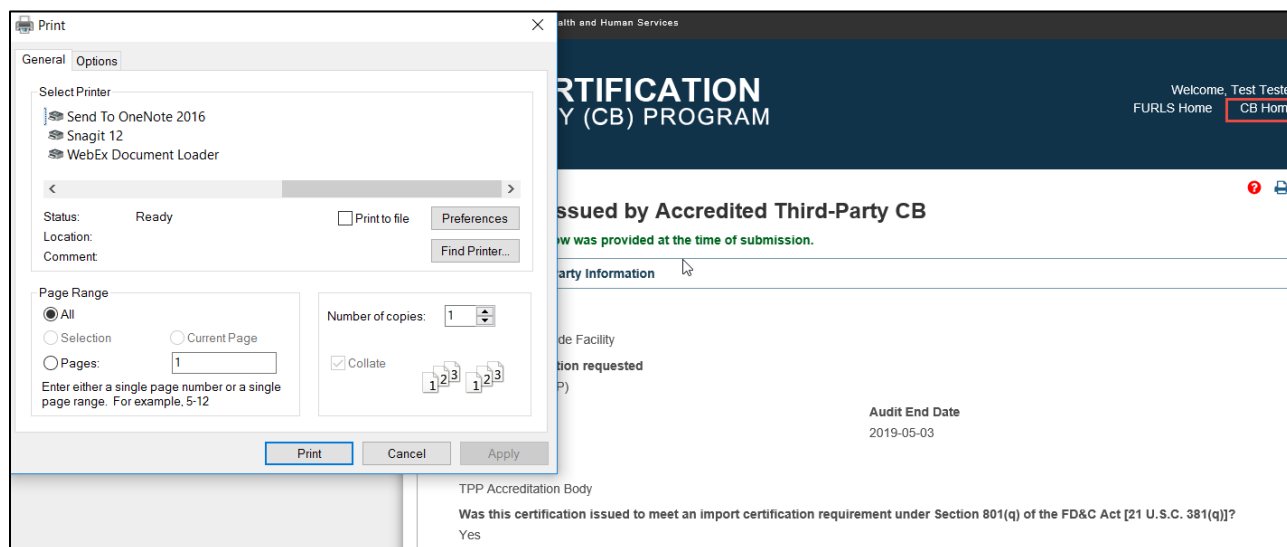
Certification #	RAR #	Audit Start Date	Audit End Date	Eligible Entity	Submission Date	Status	Actions
TPP-CBB-19-000001		2019-05-02	2019-05-03	TPP CB User Guide Facility		Active	

[+ Add Certification](#)

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

Dashboard





CB Status: [click here](#)

If you have submitted a certification but have not submitted the accompanying Regulatory Audit Report please click on Add RAR and select the appropriate certification on the next screen.

▶ Regulatory Audit Reports

▼ Certifications

Certifications are sorted by audit end date. Click on the column header arrows to change the sort order.

Certification # ↕	RAR # ↕	Audit Start Date ↕	Audit End Date ↕	Eligible Entity ↕	Submission Date	Status	Actions
ABB-CBB-19-000001		2020-03-16	2020-03-23	Facility #1		Active	 
ABB-CBB-20-000001		2020-03-16	2020-03-23	Facility #2		Active	 

[+ Add Certification](#)

8 Manage Agents and Officers

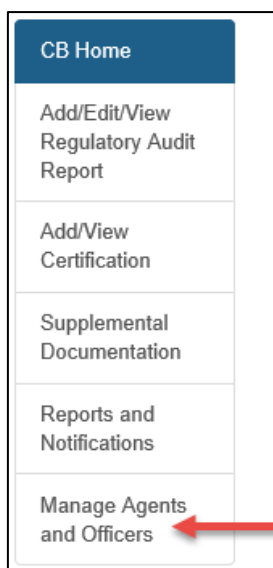
The “Manage Agents and Officers” feature may be used to perform the following two main functions related to audit agents and officers:

- 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

Manage Agents and Officers

▼ **Manage Agent(s)**



Audit Agent(s)

Agent Name	Email Address	AB Name	Status	Action
Agent 1	audit_agent1@fda1.hhs1.gov	AB1	Active	
Agent 2	audit_agent2@fda1.hhs1.gov	AB1	Active	

+ Add Agent

▼ **Manage Officer(s)**

Officer(s)

Officer Name	Status	Action
Officer 1	Active	
Officer 2	Active	

+ Add Officer

← Previous

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



Manage Agents and Officers				
▼ Manage Agent(s)				
Audit Agent(s)				
Agent Name	Email Address	AB Name	Status	Action
Agent 1	Audit_agent6@fda1.hhs1.gov	AB1	Active	
Agent 2	audit_agent3@fda1.hhs.gov	AB1	Active	

[+ Add Agent](#)

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


Manage Agents and Officers				
▼ Manage Agent(s)				
Audit Agent(s)				
Agent Name	Email Address	AB Name	Status	Action
Agent 1	Audit_agent6@fda1.hhs1.gov	AB1	Active	
Agent 2	audit_agent3@fda1.hhs.gov	AB1	Active	

[+ Add Agent](#)

Agent Name
Agent 1

Email Address
Audit_agent6@fda1.hhs1.gov

Status
Active

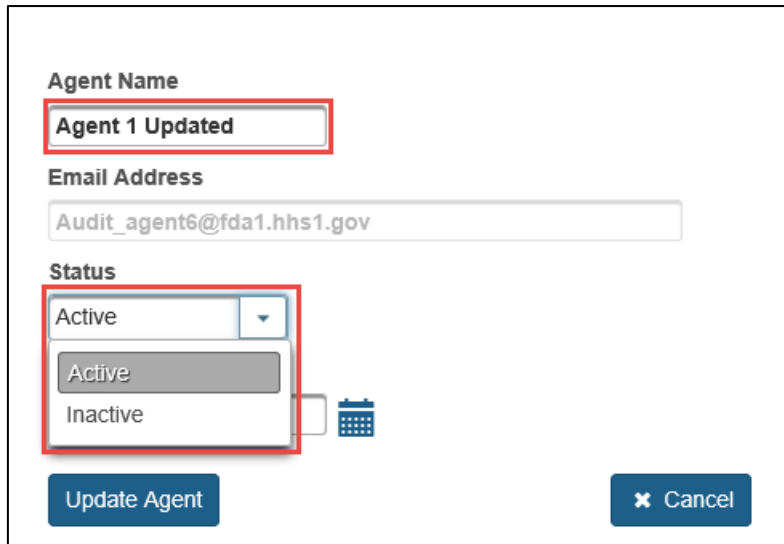
Effective Date
YYYY-MM-DD 

[Update Agent](#) [Cancel](#)

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



Agent Name
Agent 1 Updated

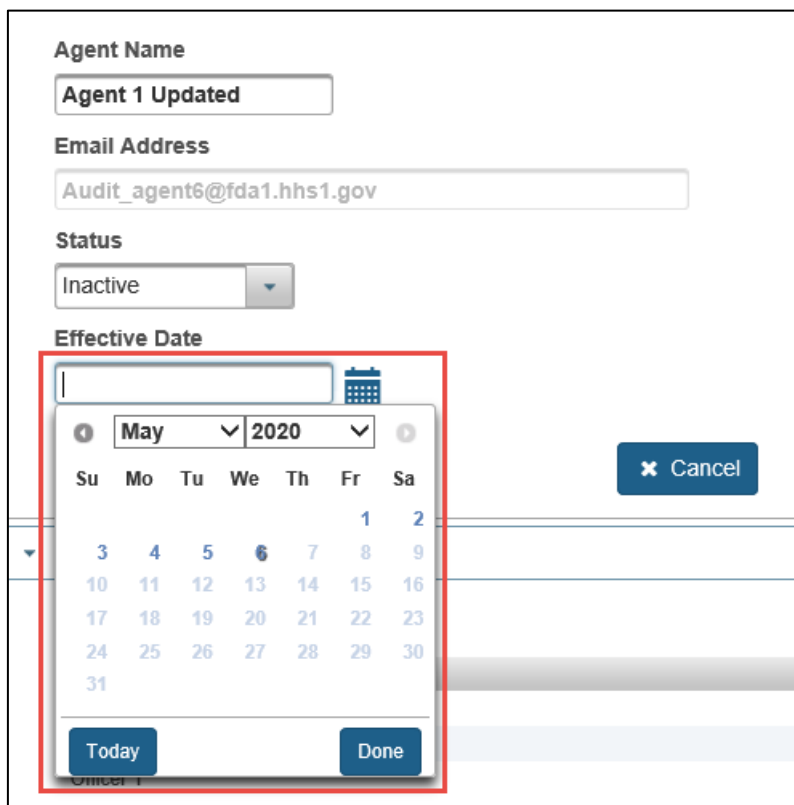
Email Address
Audit_agent6@fda1.hhs1.gov

Status
Active
Inactive

Update Agent × Cancel

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



Agent Name
Agent 1 Updated

Email Address
Audit_agent6@fda1.hhs1.gov

Status
Inactive

Effective Date

× Cancel

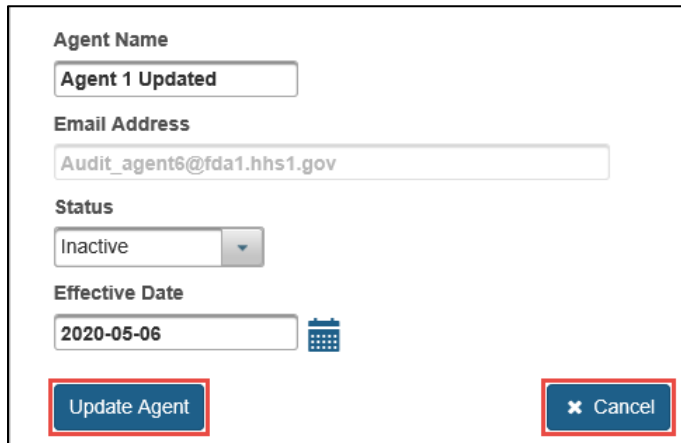
Su	Mo	Tu	We	Th	Fr	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Today Done

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



Agent Name
Agent 1 Updated

Email Address
Audit_agent6@fda1.hhs1.gov

Status
Inactive

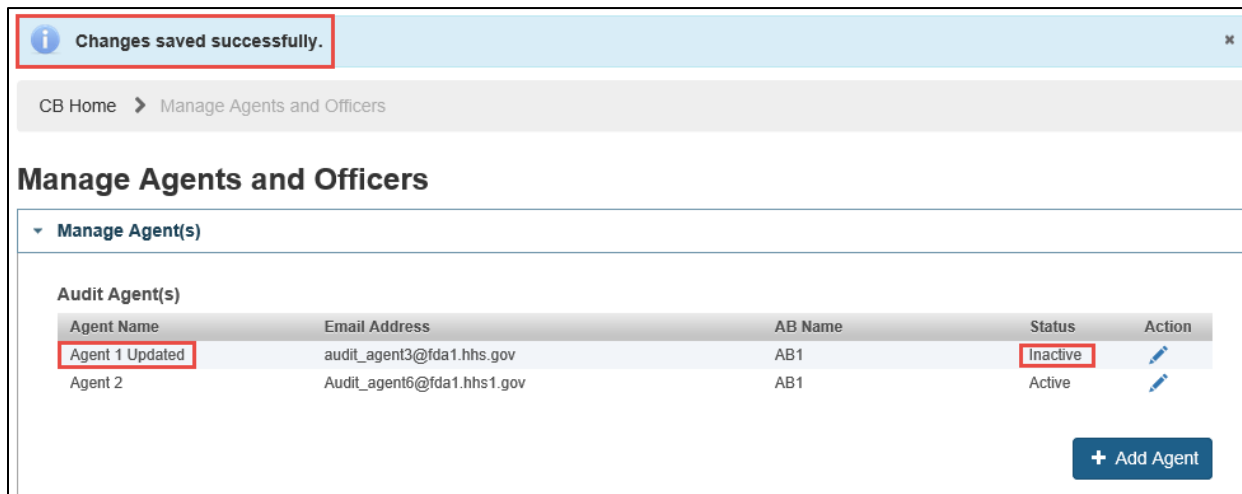
Effective Date
2020-05-06

Update Agent × Cancel

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



Changes saved successfully.

CB Home > Manage Agents and Officers

Manage Agents and Officers

Manage Agent(s)

Audit Agent(s)

Agent Name	Email Address	AB Name	Status	Action
Agent 1 Updated	audit_agent3@fda1.hhs.gov	AB1	Inactive	
Agent 2	Audit_agent6@fda1.hhs1.gov	AB1	Active	

+ Add Agent

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

▼ Manage Agent(s)

Audit Agent(s)

Agent Name	Email Address	AB Name	Status	Action
audit_agent3@fda1.hhs1.gov	Agent 3	TPP Accreditation Body	Active	
Agent 2	audit_agent2@fda1.hhs1.gov	Demo Acct 1	Active	
Audit Agent 1	audit_agent1@fda1.hhs1.gov	Demo Acct 1	Inactive	

[+ Add Agent](#)

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

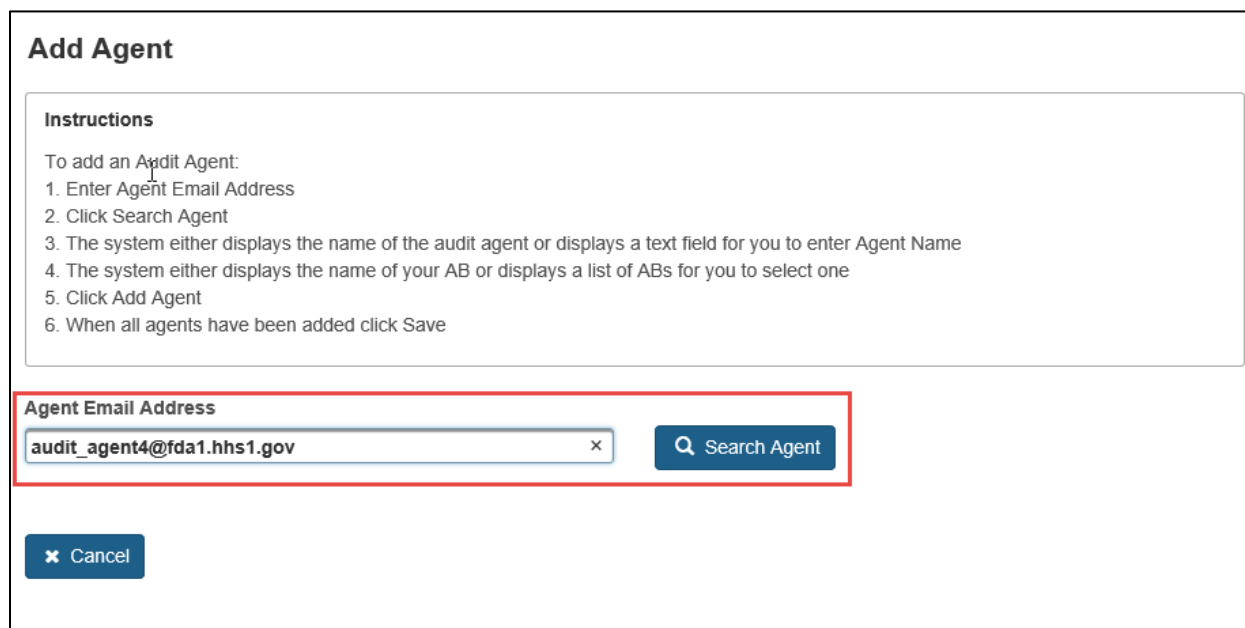

Add Agent


Instructions

To add an Audit Agent:

1. Enter Agent Email Address
2. Click Search Agent
3. The system either displays the name of the audit agent or displays a text field for you to enter Agent Name
4. The system either displays the name of your AB or displays a list of ABs for you to select one
5. Click Add Agent
6. When all agents have been added click Save

Agent Email Address


 Search Agent

 Cancel

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

Add Agent

i The system found the name of the Audit Agent whose email you entered. ✕

Instructions

To add an Audit Agent:

1. Enter Agent Email Address
2. Click Search Agent
3. The system either displays the name of the audit agent or displays a text field for you to enter Agent Name
4. The system either displays the name of your AB or displays a list of ABs for you to select one
5. Click Add Agent
6. When all agents have been added click Save

Agent Email Address

 ✕ Clear

Agent Name

 + Add Agent

AB Name

FURLS AB1

✕ Cancel

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

Add Agent

Instructions

To add an Audit Agent:

1. Enter Agent Email Address
2. Click Search Agent
3. The system either displays the name of the audit agent or displays a text field for you to enter Agent Name
4. The system either displays the name of your AB or displays a list of ABs for you to select one
5. Click Add Agent
6. When all agents have been added click Save

Please enter the Agent's name to continue adding the agent.

Agent Email Address

Agent Name

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).

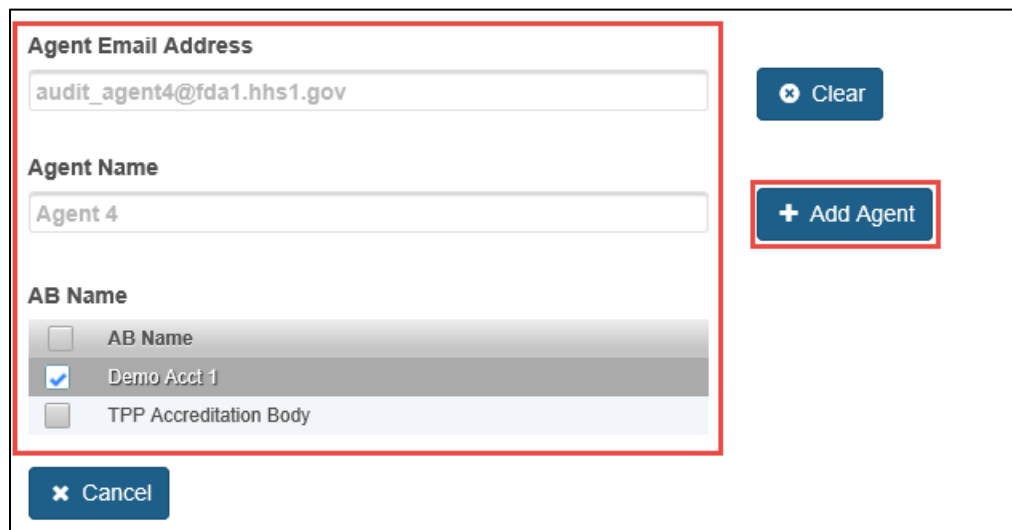
The "AB Name" field will be pre-filled if you have only been accredited by one AB.

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



The screenshot shows a form with the following elements:

- Agent Email Address:** A text input field containing "audit_agent4@fda1.hhs1.gov". To its right is a blue "Clear" button with a trash icon.
- Agent Name:** A text input field containing "Agent 4". To its right is a blue "+ Add Agent" button.
- AB Name Table:** A table with three rows, each with a checkbox on the left and text on the right.

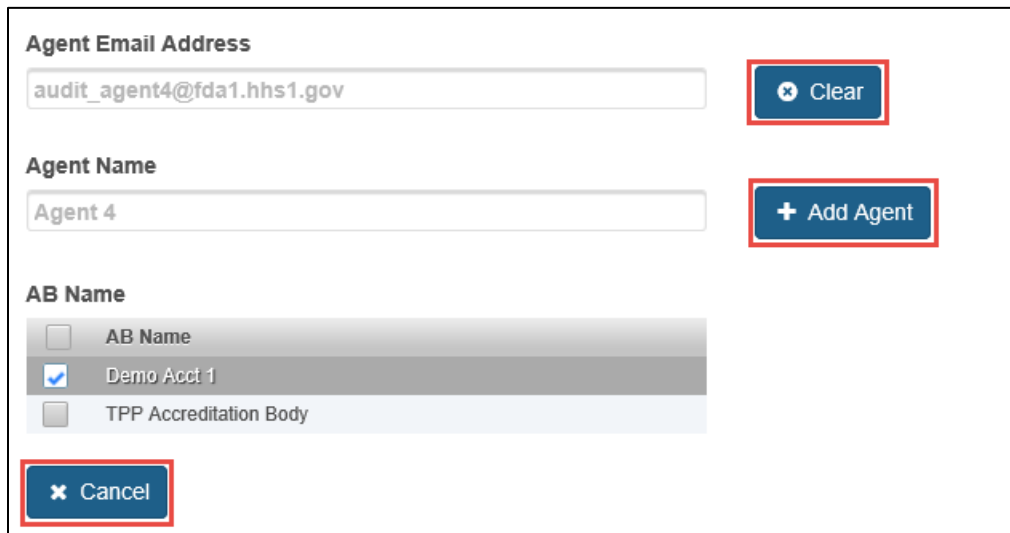
<input type="checkbox"/>	AB Name
<input checked="" type="checkbox"/>	Demo Acct 1
<input type="checkbox"/>	TPP Accreditation Body
- Cancel:** A blue "x Cancel" button at the bottom left.

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



Agent Email Address
 Clear

Agent Name
 + Add Agent

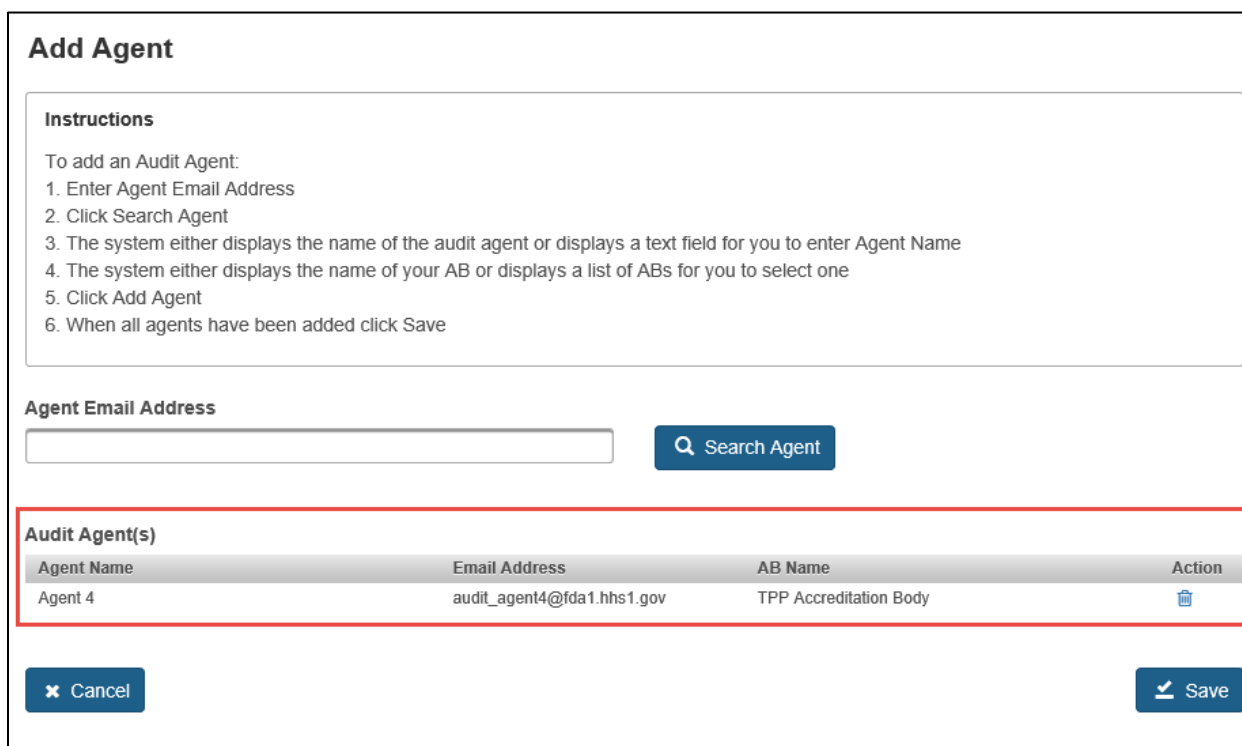
AB Name

- AB Name
- Demo Acct 1
- TPP Accreditation Body

× Cancel

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



Add Agent

Instructions

To add an Audit Agent:

1. Enter Agent Email Address
2. Click Search Agent
3. The system either displays the name of the audit agent or displays a text field for you to enter Agent Name
4. The system either displays the name of your AB or displays a list of ABs for you to select one
5. Click Add Agent
6. When all agents have been added click Save

Agent Email Address
 Search Agent

Audit Agent(s)

Agent Name	Email Address	AB Name	Action
Agent 4	audit_agent4@fda1.hhs1.gov	TPP Accreditation Body	

× Cancel Save

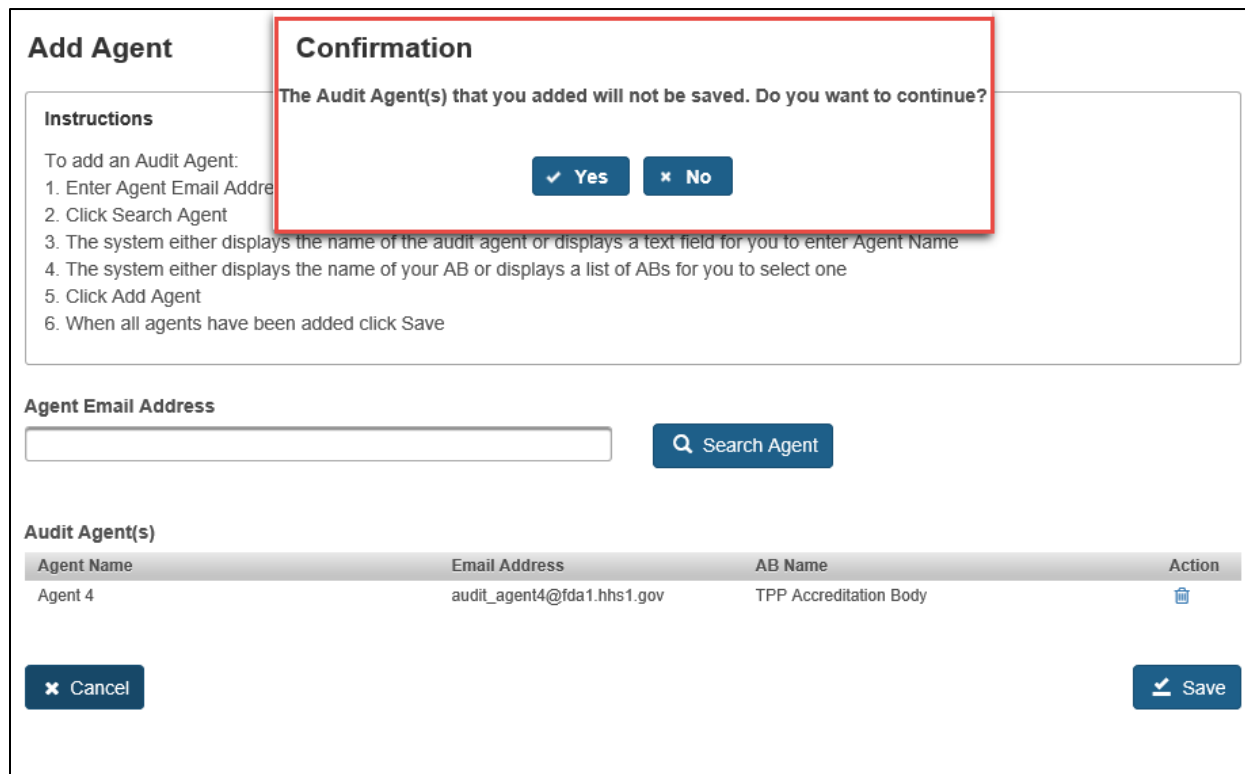
If you want to discard the changes and exit the “Add Agent” screen you can click the “Cancel” button.

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



Add Agent

Confirmation
The Audit Agent(s) that you added will not be saved. Do you want to continue?

✓ Yes ✗ No

Instructions

To add an Audit Agent:

1. Enter Agent Email Address
2. Click Search Agent
3. The system either displays the name of the audit agent or displays a text field for you to enter Agent Name
4. The system either displays the name of your AB or displays a list of ABs for you to select one
5. Click Add Agent
6. When all agents have been added click Save

Agent Email Address

Audit Agent(s)

Agent Name	Email Address	AB Name	Action
Agent 4	audit_agent4@fda1.hhs1.gov	TPP Accreditation Body	<input type="button" value="Delete"/>

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

Add Agent

Instructions

To add an Audit Agent:

1. Enter Agent Email Address
2. Click Search Agent
3. The system either displays the name of the audit agent or displays a text field for you to enter Agent Name
4. The system either displays the name of your AB or displays a list of ABs for you to select one
5. Click Add Agent
6. When all agents have been added click Save

Agent Email Address

 🔍 Search Agent

Audit Agent(s)

Agent Name	Email Address	AB Name	Action
Agent 4	audit_agent4@fda1.hhs1.gov	TPP Accreditation Body	🗑️

✖ Cancel
✔ Save

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

CB Home > Manage Agents and Officers

Manage Agents and Officers

▼ Manage Agent(s)

Audit Agent(s)

Agent Name	Email Address	AB Name	Status	Action
Agent 3	audit_agent3@fda1.hhs1.gov	TPP Accreditation Body	Active	✎
Agent 2	audit_agent2@fda1.hhs1.gov	Demo Acct 1	Active	✎
Audit Agent 1	audit_agent1@fda1.hhs1.gov	Demo Acct 1	Inactive	✎
Agent 4	audit_agent4@fda1.hhs1.gov	TPP Accreditation Body	Active	✎

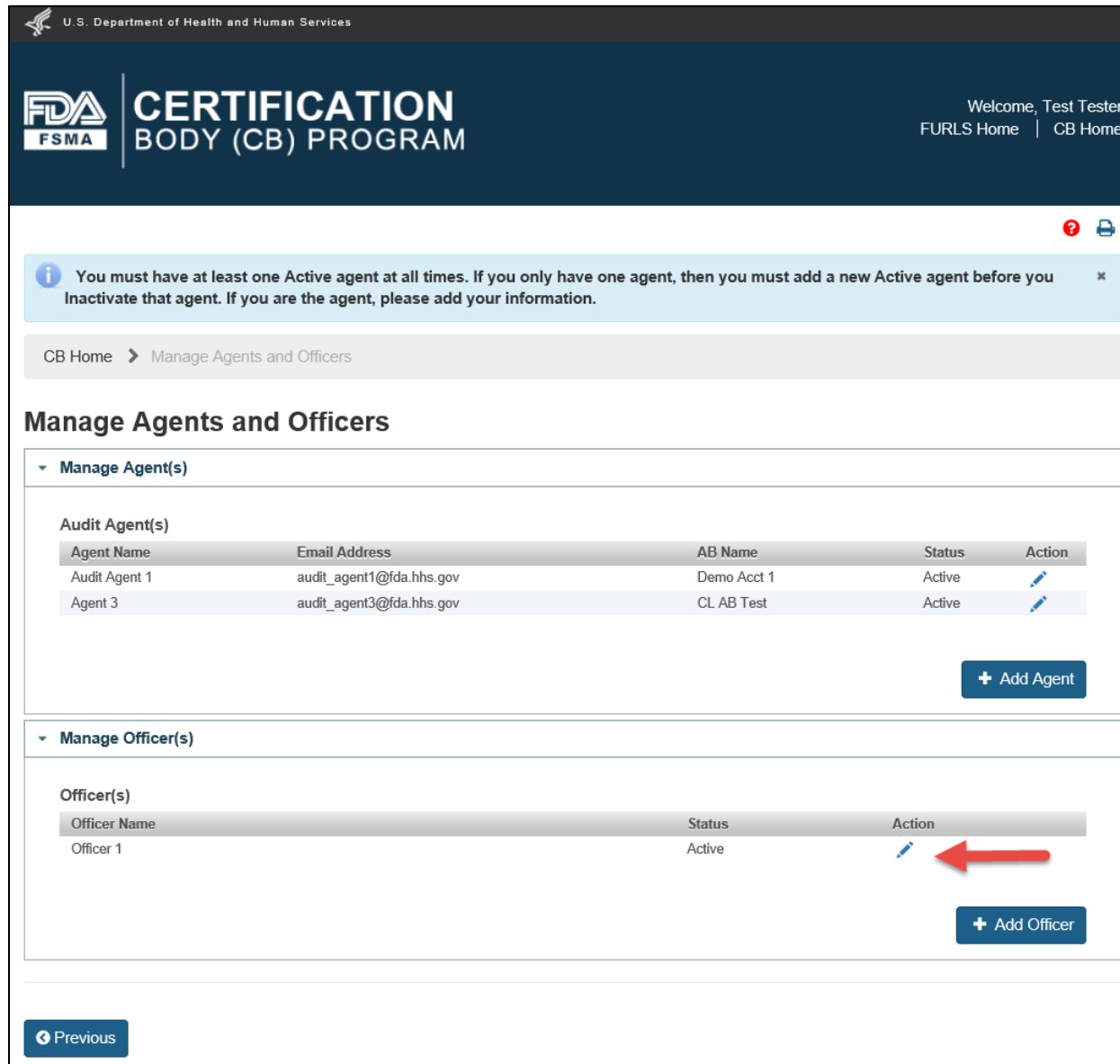
+ Add Agent

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.

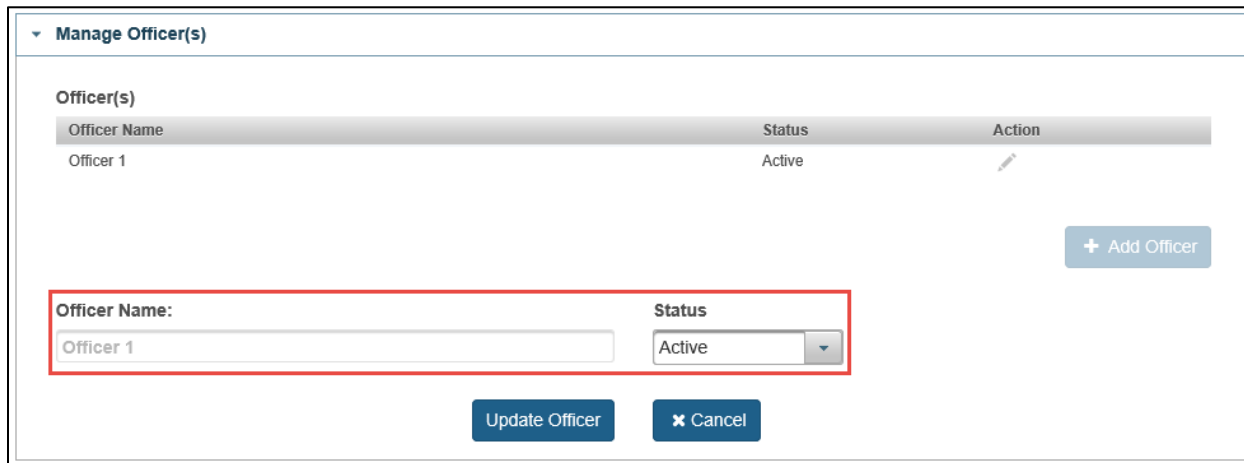
Figure 8.19 – Edit Icon



The screenshot shows the 'Manage Agents and Officers' page. At the top, there is a navigation bar with the FDA logo and 'CERTIFICATION BODY (CB) PROGRAM'. A welcome message for 'Test Tester' is visible. Below the navigation bar, a blue information banner states: 'You must have at least one Active agent at all times. If you only have one agent, then you must add a new Active agent before you Inactivate that agent. If you are the agent, please add your information.' Below this is a breadcrumb trail: 'CB Home > Manage Agents and Officers'. The main content area is titled 'Manage Agents and Officers' and contains two sections: 'Manage Agent(s)' and 'Manage Officer(s)'. The 'Manage Agent(s)' section has a table with columns: Agent Name, Email Address, AB Name, Status, and Action. It lists 'Audit Agent 1' and 'Agent 3', both with 'Active' status and edit icons. An '+ Add Agent' button is at the bottom right. The 'Manage Officer(s)' section has a table with columns: Officer Name, Status, and Action. It lists 'Officer 1' with 'Active' status and an edit icon. A red arrow points to this edit icon. An '+ Add Officer' button is at the bottom right. A 'Previous' button is located at the bottom left of the page.

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



The screenshot shows a web interface titled "Manage Officer(s)". At the top, there is a table with the following structure:

Officer Name	Status	Action
Officer 1	Active	

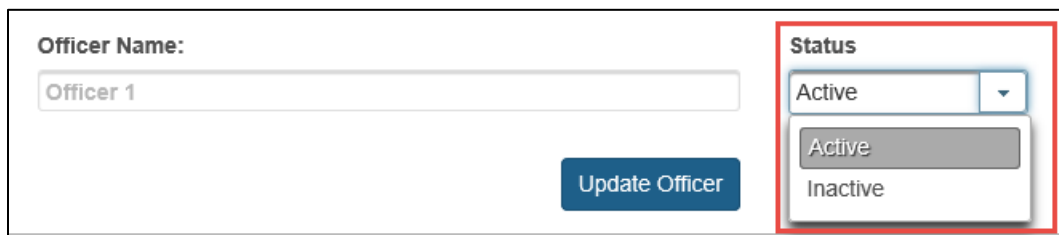
Below the table, there is a form for editing the officer's details. The form includes:

- An "Officer Name" input field containing "Officer 1".
- A "Status" dropdown menu currently set to "Active".
- Buttons for "Update Officer" and "Cancel".

A red box highlights the "Officer Name" and "Status" fields in the form.

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



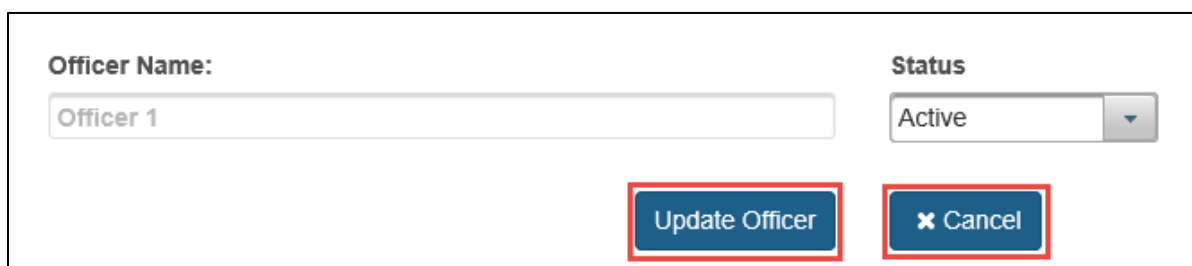
This close-up shows the "Status" dropdown menu. The menu is open, displaying two options: "Active" and "Inactive". The "Active" option is currently selected. A red box highlights the dropdown menu.

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.

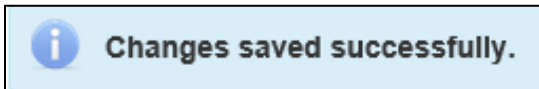
Figure 8.22 – Cancel and Update Officer Buttons



This close-up shows the "Update Officer" and "Cancel" buttons. Both buttons are highlighted with a red box.

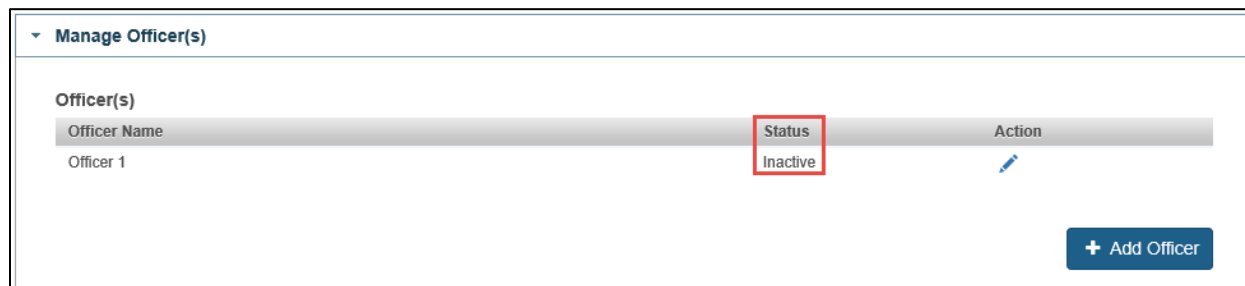
The system will display the “Changes saved successfully” message at the top of the page (Figure 8.23).

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



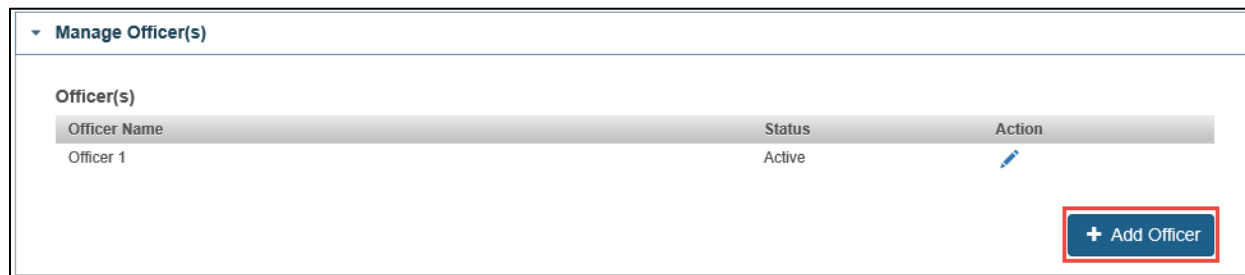
The screenshot shows a web interface for managing officers. At the top left, there is a dropdown menu labeled "Manage Officer(s)". Below it, the heading "Officer(s)" is followed by a table. The table has three columns: "Officer Name", "Status", and "Action". The first row of data shows "Officer 1" in the "Officer Name" column, "Inactive" in the "Status" column (which is highlighted with a red rectangular box), and a blue pencil icon in the "Action" column. At the bottom right of the table area, there is a blue button with a white plus sign and the text "+ Add Officer".

Officer Name	Status	Action
Officer 1	Inactive	

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



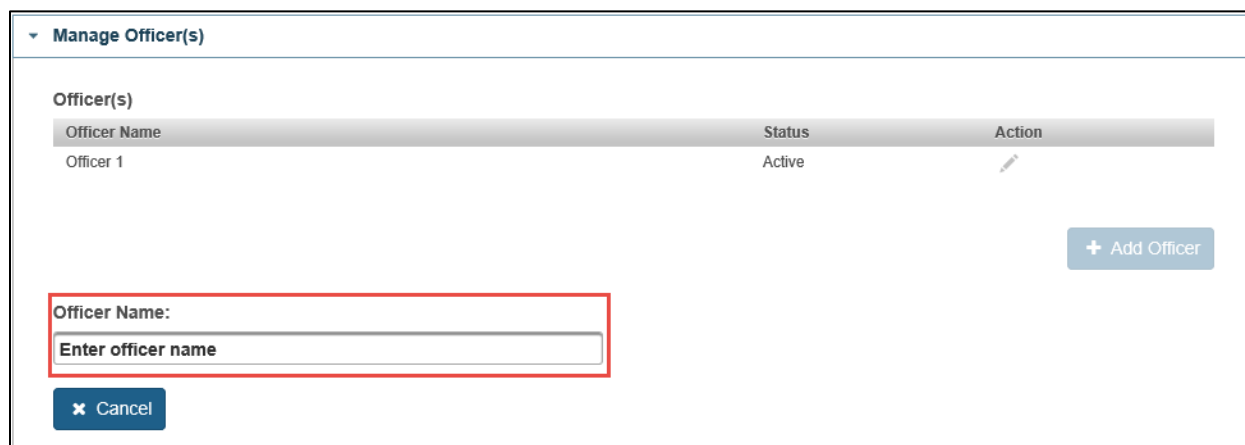
The screenshot shows a web interface titled "Manage Officer(s)". Below the title is a table with the following structure:

Officer Name	Status	Action
Officer 1	Active	

Below the table, there is a blue button with a plus sign and the text "+ Add Officer", which is highlighted with a red rectangular box.

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

Figure 8.26 – Officer Name



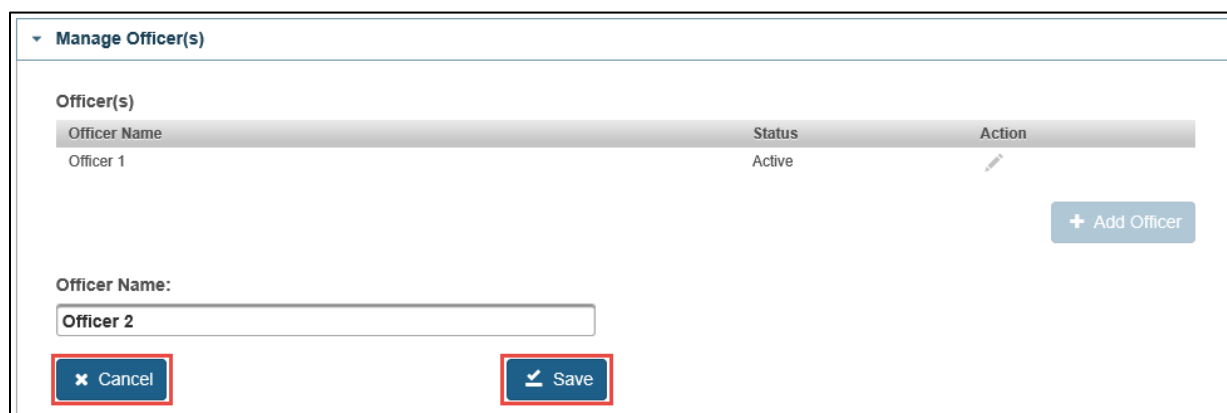
The screenshot shows the same "Manage Officer(s)" interface as Figure 8.25, but with a modal form open. The modal form contains the following elements:

- A label "Officer Name:" followed by a text input field containing the placeholder text "Enter officer name". This input field is highlighted with a red rectangular box.
- A blue button with a plus sign and the text "+ Add Officer" located to the right of the input field.
- A blue button with a close icon and the text "Cancel" located below the input field.

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).

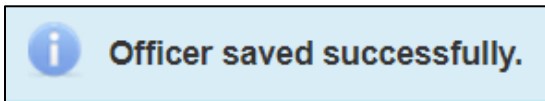
Figure 8.27 – Cancel and Save Buttons



The screenshot shows the "Manage Officer(s)" interface with the modal form open. The "Officer Name" input field now contains the text "Officer 2". Below the input field, there are two buttons: a blue button with a close icon and the text "Cancel" (highlighted with a red box) and a blue button with a checkmark icon and the text "Save" (also highlighted with a red box).



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

Manage Officer(s)		
Officer(s)		
Officer Name	Status	Action
Officer 1	Active	
Officer 2	Active	

[+ Add Officer](#)

Repeat the previous steps to add more officers.

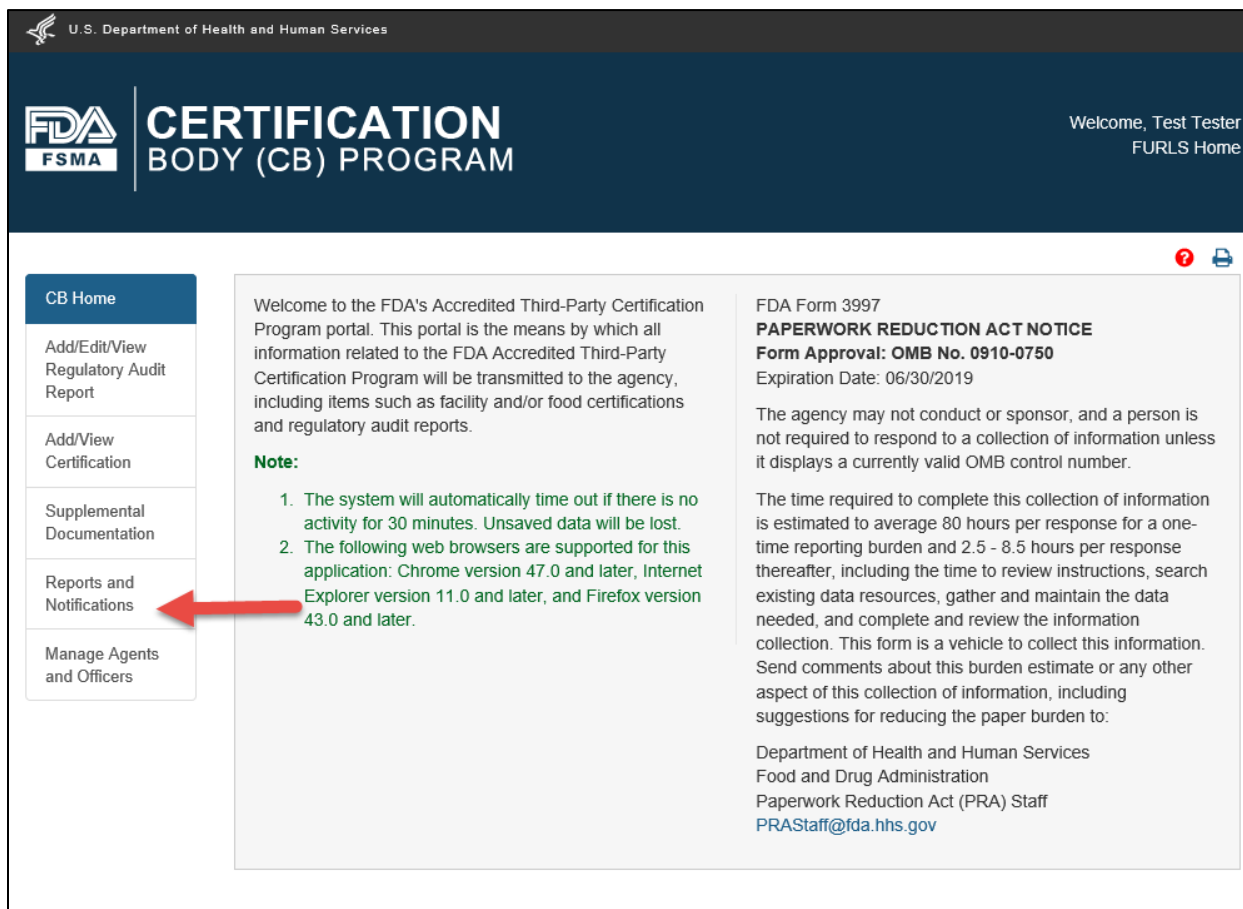
9 Reports and Notifications

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

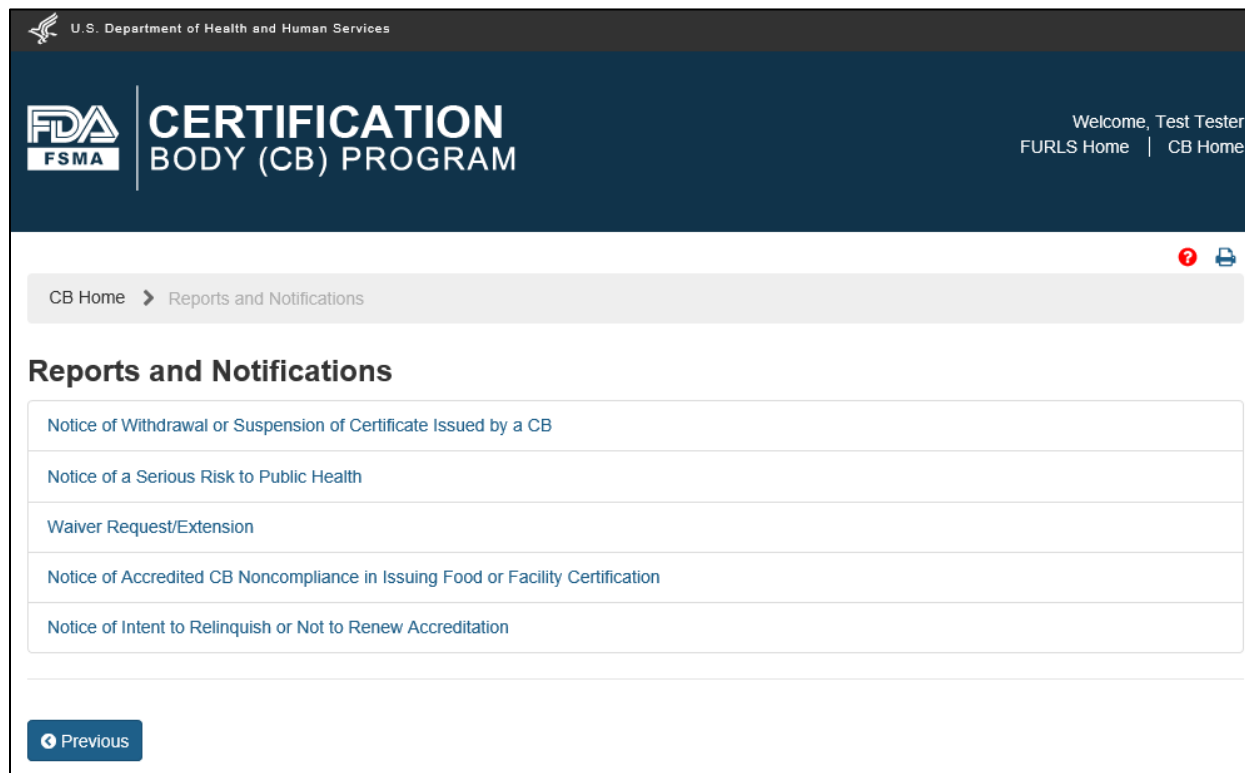


The screenshot shows the FDA Certification Body (CB) Program portal. At the top, it says "U.S. Department of Health and Human Services" and "Welcome, Test Tester" with a "FURLS Home" link. The main header includes the FDA FSMA logo and "CERTIFICATION BODY (CB) PROGRAM". A navigation menu on the left lists several options: "CB Home", "Add/Edit/View Regulatory Audit Report", "Add/View Certification", "Supplemental Documentation", "Reports and Notifications" (highlighted with a red arrow), and "Manage Agents and Officers". The main content area contains a welcome message, a "Note" with two points about system timeouts and supported browsers, and a "PAPERWORK REDUCTION ACT NOTICE" regarding Form 3997, including an expiration date and contact information for the PRA Staff.

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

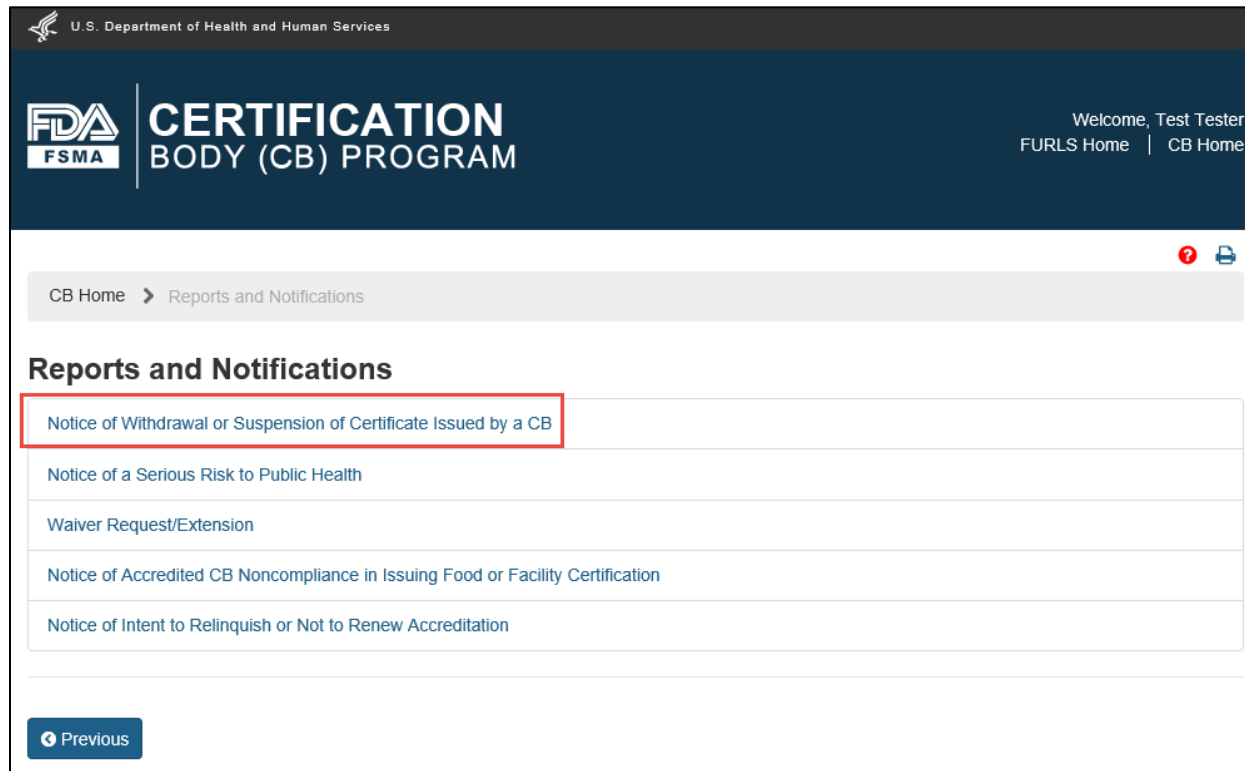


Note: “Reinstatement of a Suspended Certification” will also display in the list of “Reports and Notifications” if you currently have suspended at least one food or facility certification of an eligible entity (i.e., you submitted a “Notice of Withdrawal or Suspension of Certificate Issued by a CB”).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

U.S. Department of Health and Human Services



**CERTIFICATION
BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Reports and Notifications > Notice of Withdrawal or Suspension of Certificate Issued by a CB

Notice of Withdrawal or Suspension of Certificate Issued by a CB

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.

Enter your response here.

4000 characters remaining.

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.

Enter your response here.

4000 characters remaining.

What action was taken on the certification?

Withdrawn Suspended

Date of Action

YYYY-MM-DD

AB Name

FURLS AB1

Select Applicable Item(s)

Select	Certification Number	Certification Issued To	Address	Type of Certification
No records found.				

▶ Attachments (Optional)

◀ Previous

Next ▶

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

Select Applicable Item(s)				
Select	Certification Number	Certification Issued To	Address	Type of Certification
<input checked="" type="checkbox"/>	FUR-FUR-20-000001	Facility #1	10 Any Street Anytown Virginia UNITED STATES 00000	Facility
<input type="checkbox"/>	FUR-FUR-20-000003	Facility #2	20 Main St Atown Yonne UNITED STATES 00000	Facility

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.

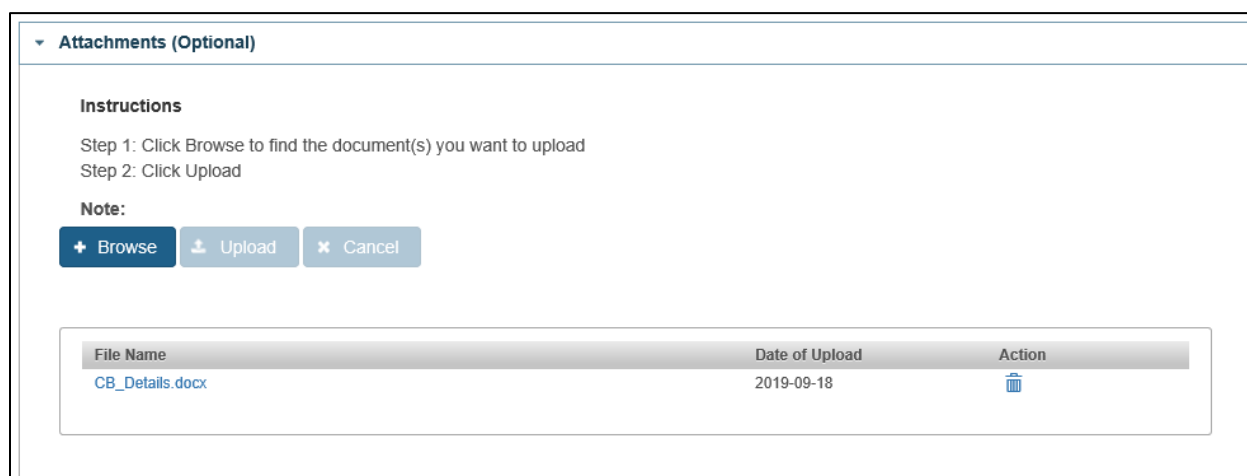
Follow Steps 1 - 4 (listed below) to upload attachments.

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




▼ Attachments (Optional)

Instructions

Step 1: Click Browse to find the document(s) you want to upload
Step 2: Click Upload

Note:

+ Browse Upload Cancel

File Name	Date of Upload	Action
CB_Details.docx	2019-09-18	

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).

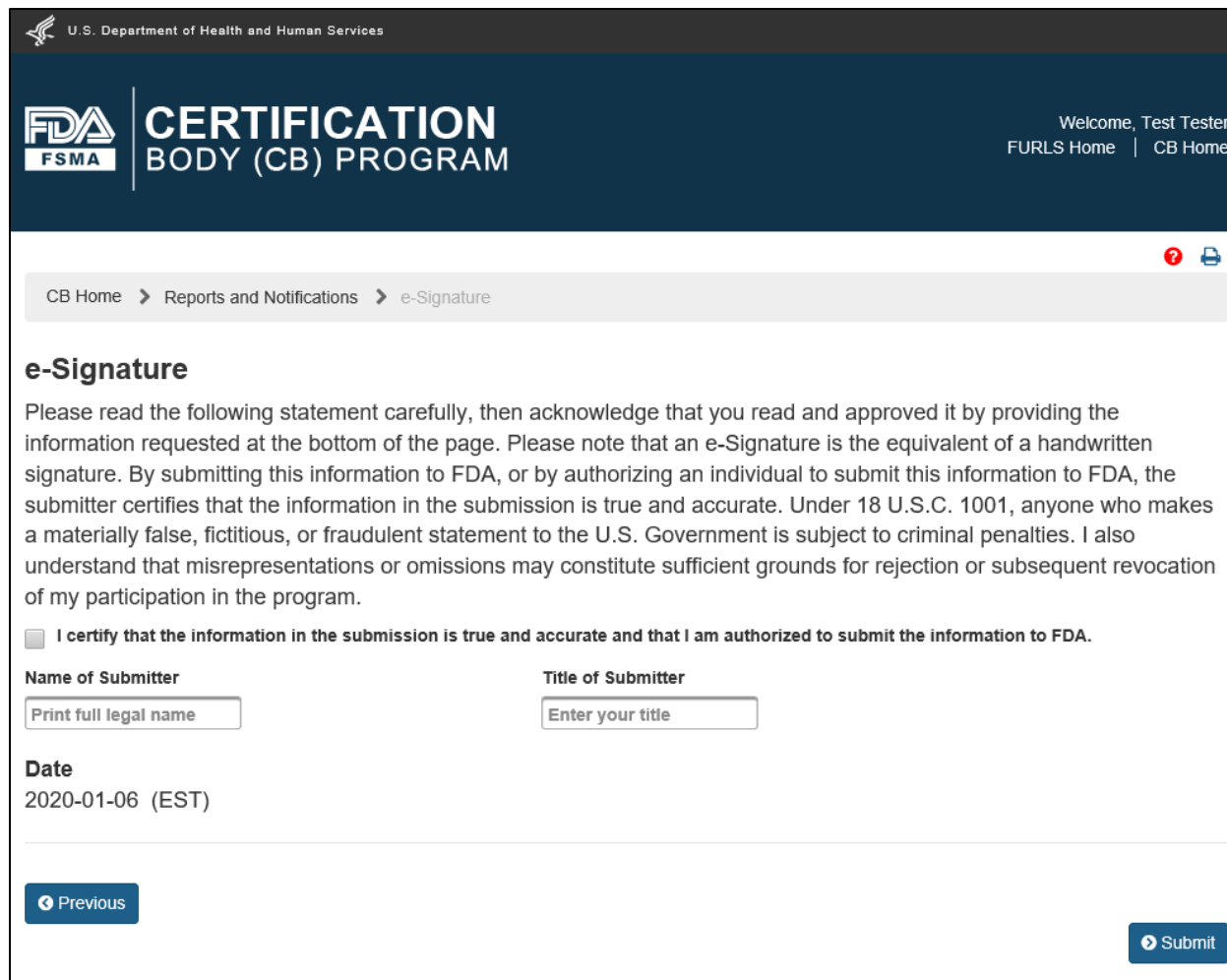
Complete the following fields:

- **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



U.S. Department of Health and Human Services

FDA | **CERTIFICATION**
FSMA | **BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

[CB Home](#) > [Reports and Notifications](#) > [e-Signature](#)

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program.

I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.

Name of Submitter

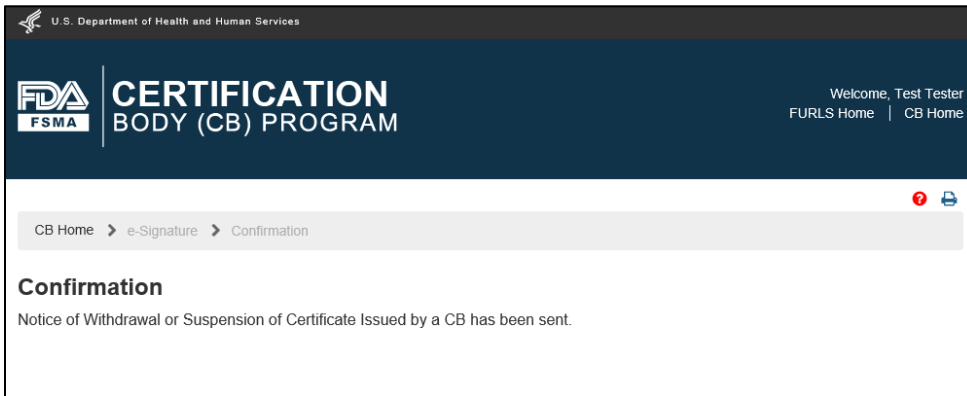
Title of Submitter

Date
2020-01-06 (EST)

[Previous](#) [Submit](#)

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

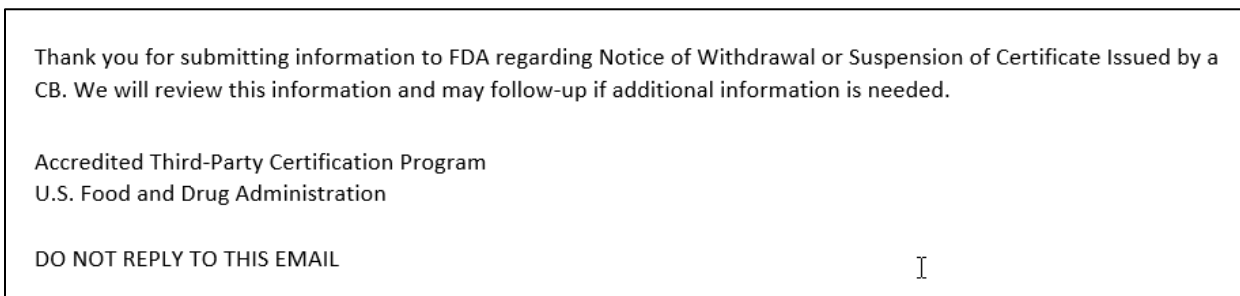
Figure 9.8 – Confirmation Page



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.

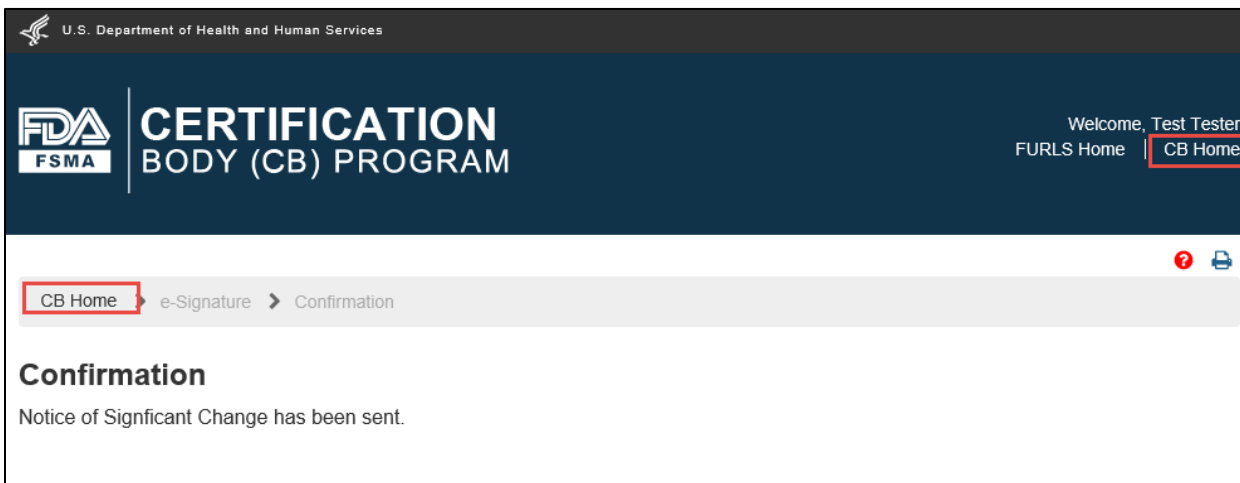
Note: The image (below) only depicts the e-mail notification text.

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).

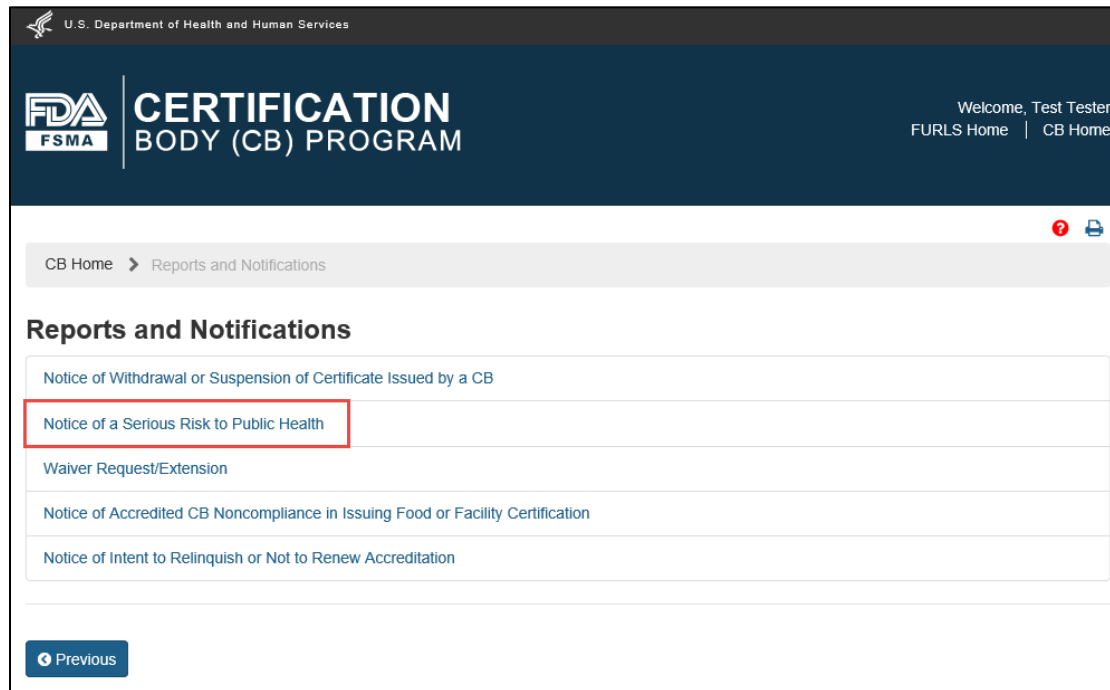
Figure 9.10 – Links to CB Home Page



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

U.S. Department of Health and Human Services



CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Reports and Notifications > Notice of Serious Risk to Public Health

Notice of Serious Risk to Public Health

Date Condition was found

AB Name

To filter the list of Eligible Entities enter an FFR or name of Eligible Entity in column header.

Eligible Entity

Select One	FFR	Name	Address
<input type="radio"/>		Eligible Entity Company	100 Main Street Anytown Virginia UNITED STATES

What type of Audit was being Performed
 Consultative Regulatory

Who discovered the condition?
 Audit Agent CB

Condition for which notification was submitted

3000 characters remaining.

⏪ Previous
Next ⏩

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

U.S. Department of Health and Human Services



CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Reports and Notifications > Notice of Serious Risk to Public Health

Notice of Serious Risk to Public Health

Date Condition was found

AB Name

To filter the list of Eligible Entities enter an FFR or name of Eligible Entity in column header.

Eligible Entity	FFR	Name	Address
<input type="radio"/> Select One	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="radio"/> Eligible Entity, Inc.			100 Main St Anytown Virginia UNITED STATES 00000

Is this the facility where conditions were discovered?
 Yes No

Facility where conditions were discovered	FFR	Name	Address
<input type="radio"/> Select One	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="radio"/>		Alternate Facility, Inc.	5 My Street Any City, MD UNITED STATES 00000

What type of Audit was being Performed
 Consultative Regulatory

Who discovered the condition?
 Audit Agent CB

Condition for which notification was submitted

This is the condition for notification submission.

2950 characters remaining.

Previous
Next

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

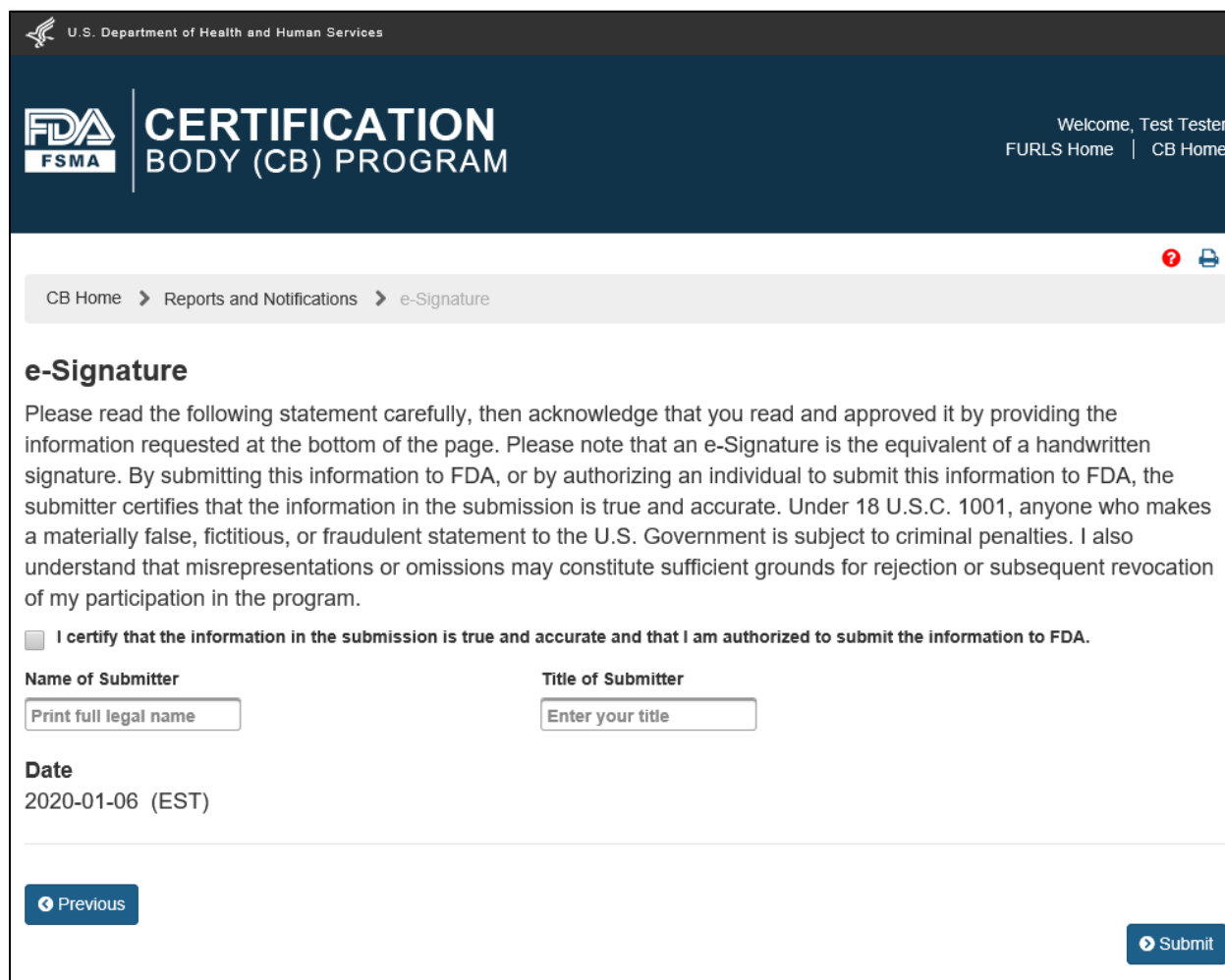
Complete the following fields:

- **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



U.S. Department of Health and Human Services

FDA | **CERTIFICATION**
FSMA | **BODY (CB) PROGRAM**

Welcome, Test Tester
FURLS Home | CB Home

CB Home > Reports and Notifications > e-Signature

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program.

I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.

Name of Submitter
Print full legal name

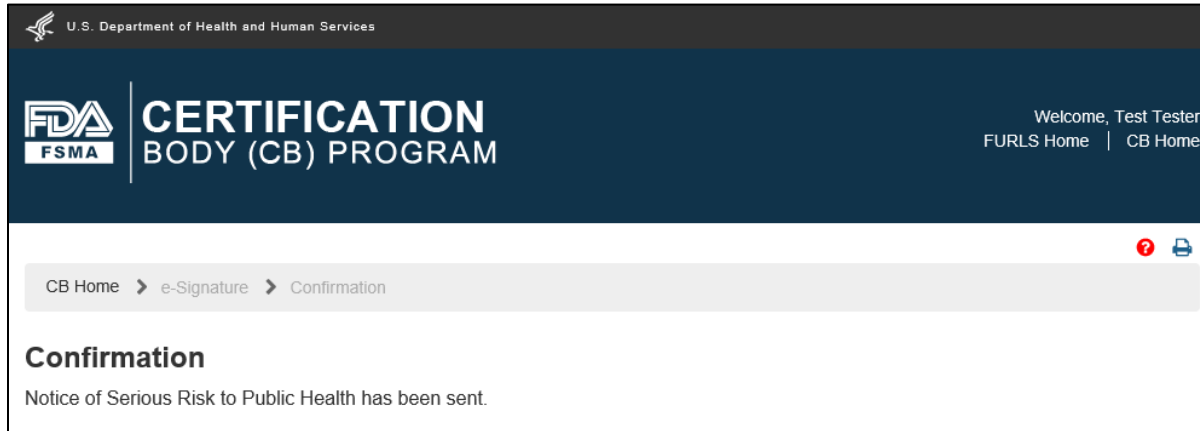
Title of Submitter
Enter your title

Date
2020-01-06 (EST)

Previous Submit

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

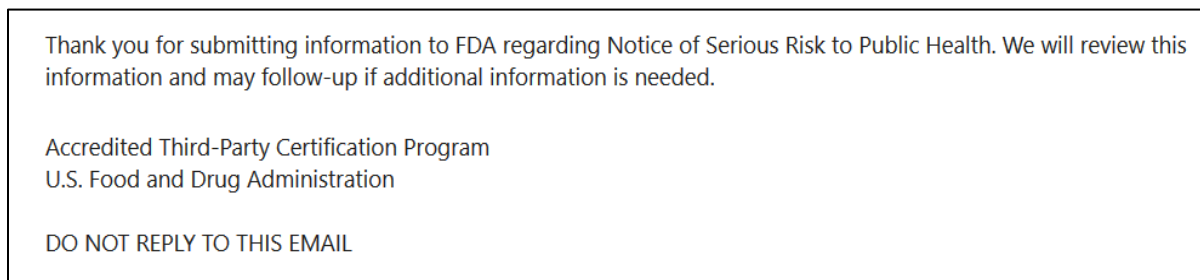
Figure 9.15 – Confirmation Page



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.

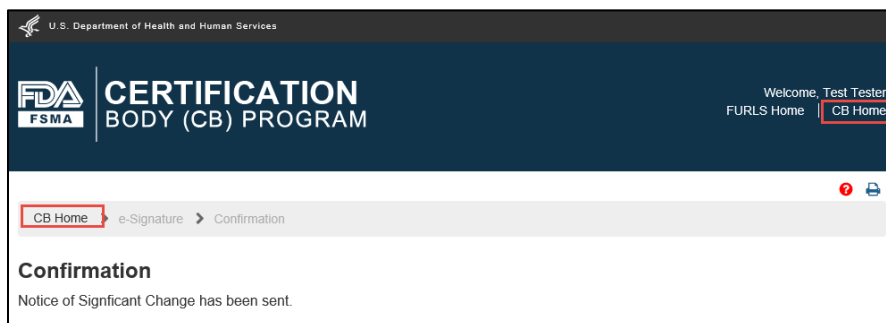
Note: The image (below) only depicts the e-mail notification text.

Figure 9.16 – E-mail Confirmation



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

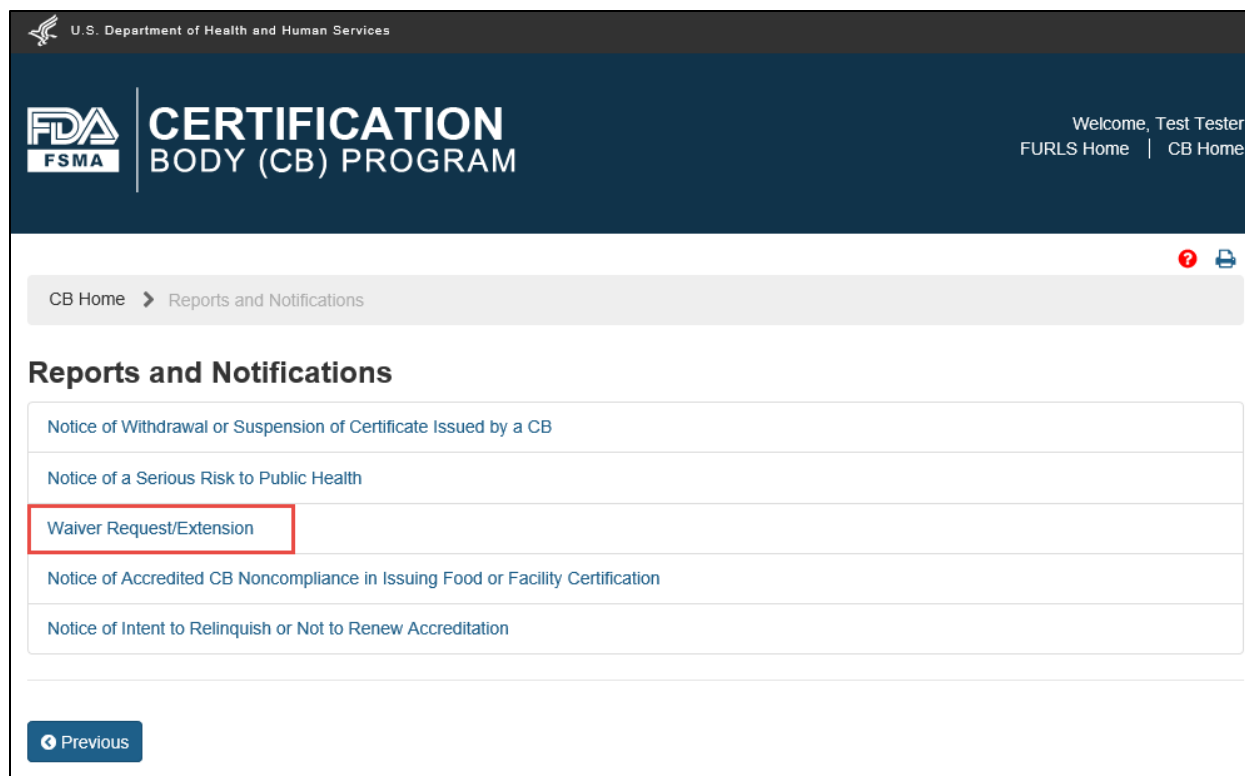
Figure 9.17 – Links to CB Home Page



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

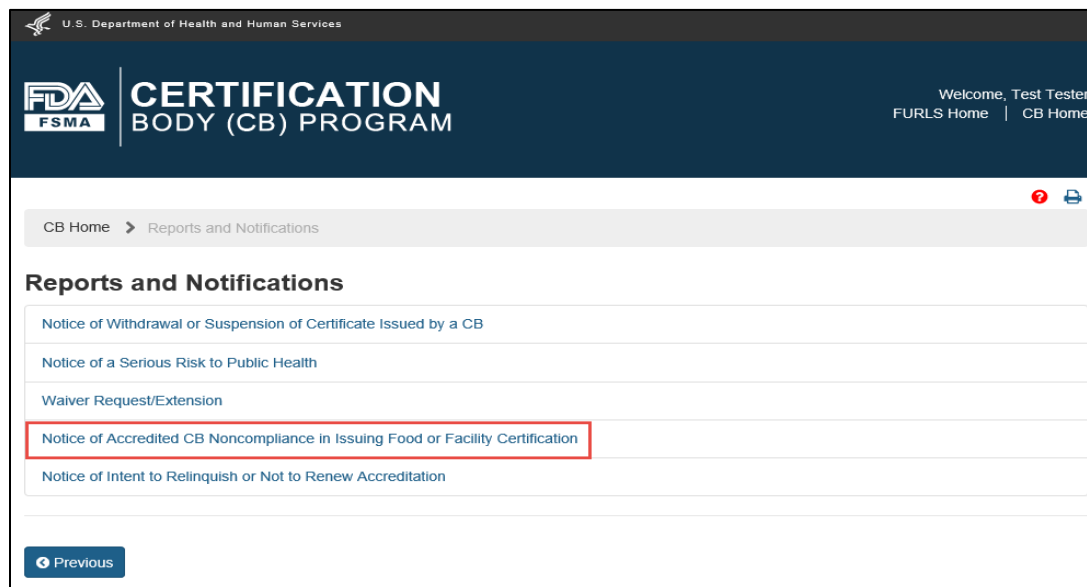


If you have questions about completing the data entry fields or the process for submitting this information, please contact us at FDAt hirdpartyprogram@fda.hhs.gov.

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

U.S. Department of Health and Human Services

FDA FSMA CERTIFICATION BODY (CB) PROGRAM

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

[CB Home](#) > [Reports and Notifications](#) > [Notice of Accredited CB Noncompliance](#)

Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

CB Name
 TPP CB User Guide Facility

Address
 123 My Street
 Anytown Anystate 00000
 UNITED STATES

AB Name
 AB1

Scope(s)

Select	Scope(s)	Accreditation Date	Expiration Date	Status
<input type="checkbox"/>	Dietary Supplements	2020-02-26	2024-02-26	Accredited
<input type="checkbox"/>	Low-Acid Canned Foods (LACF)	2020-02-26	2024-02-26	Accredited
<input type="checkbox"/>	Infant Formula	2020-02-26	2024-02-26	Accredited
<input type="checkbox"/>	Juice Hazard Analysis and Critical Control Point (Juice HACCP)	2020-02-26	2024-02-26	Accredited
<input type="checkbox"/>	Acidified Foods (AF)	2020-02-26	2024-02-26	Accredited
<input type="checkbox"/>	Preventive Controls for Animal Food	2020-05-01	2022-05-20	Accredited
<input type="checkbox"/>	Medicated Feed	2020-02-26	2024-02-26	Accredited

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 your response here.

4000 characters remaining.

What is the basis for self-reporting this issue?

Enter your response here.

4000 characters remaining.

Provide any additional information regarding the issue (Optional).

Enter your response here.

4000 characters remaining.

[Previous](#) [Next](#)

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
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>		
<input type="checkbox"/>	PPT-TPP-19-000002	Firm A	123 ABC Street Anytown Texas UNITED STATES 000000	Facility
<input type="checkbox"/>	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).

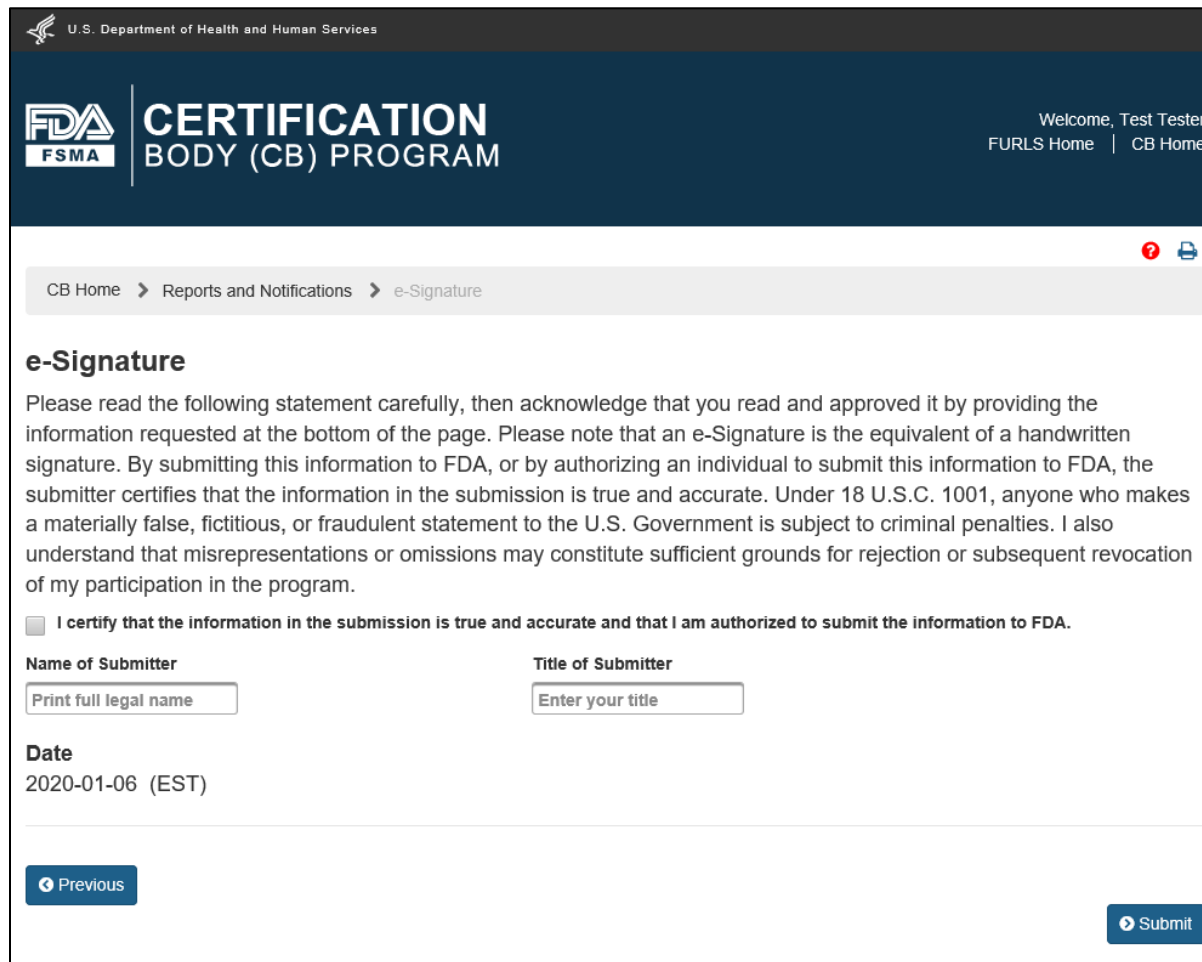
Complete the following fields:

- **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



U.S. Department of Health and Human Services

FDA **CERTIFICATION**
FSMA **BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > Reports and Notifications > e-Signature

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program.

I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.

Name of Submitter

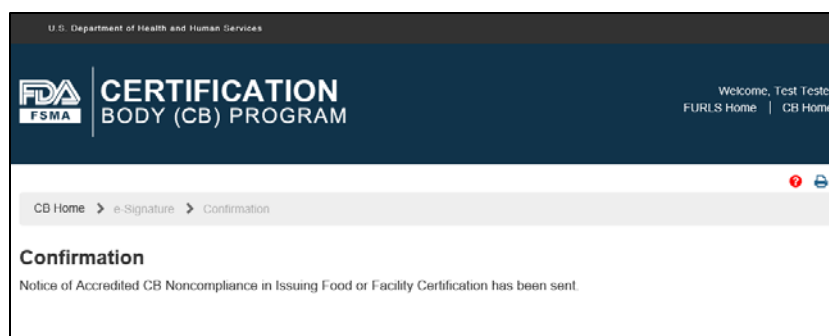
Title of Submitter

Date
 2020-01-06 (EST)

[Previous](#) [Submit](#)

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



U.S. Department of Health and Human Services

FDA **CERTIFICATION**
FSMA **BODY (CB) PROGRAM**

Welcome, Test Tester
[FURLS Home](#) | [CB Home](#)

CB Home > e-Signature > Confirmation

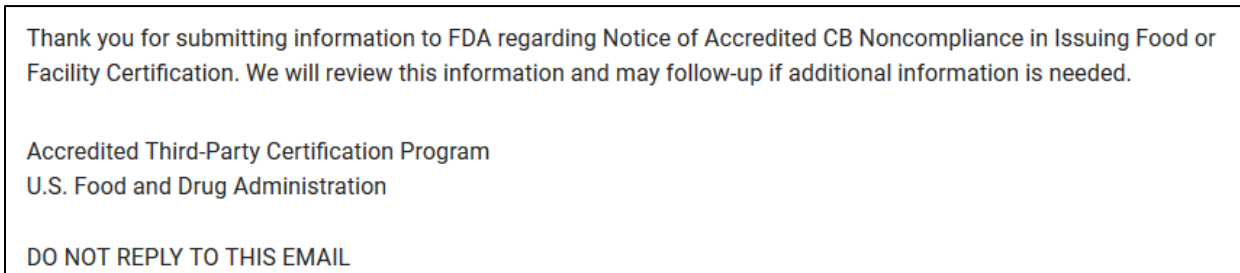
Confirmation

Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification has been sent.

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.

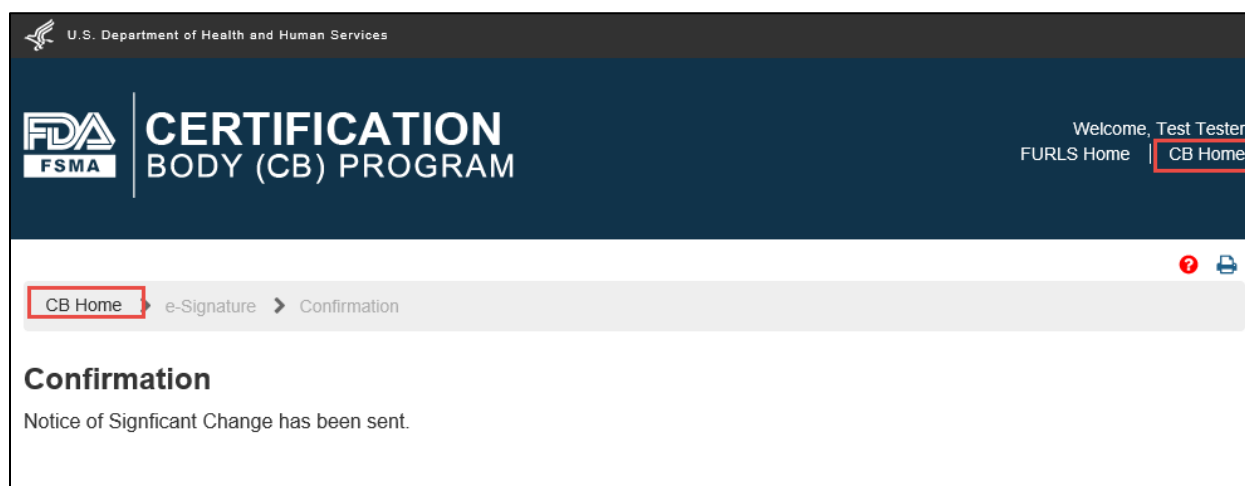
Note: The image (below) only depicts the e-mail notification text.

Figure 9.24 – E-mail Confirmation



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

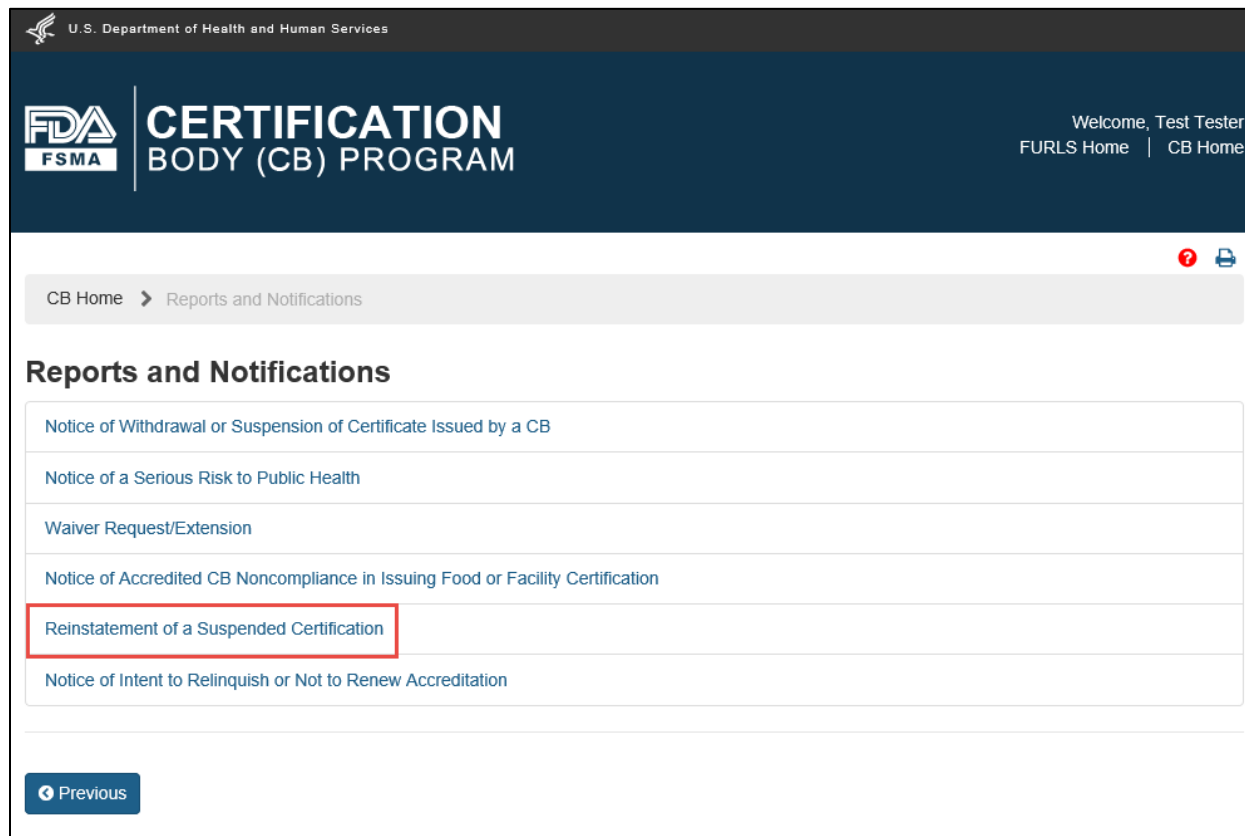


9.5 Reinstatement of a Suspended Certification

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



U.S. Department of Health and Human Services

FDA FSMA | **CERTIFICATION BODY (CB) PROGRAM**

Welcome, Test Tester
FURLS Home | CB Home

CB Home > Reports and Notifications

Reports and Notifications

- Notice of Withdrawal or Suspension of Certificate Issued by a CB
- Notice of a Serious Risk to Public Health
- Waiver Request/Extension
- Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
- Reinstatement of a Suspended Certification**
- Notice of Intent to Relinquish or Not to Renew Accreditation

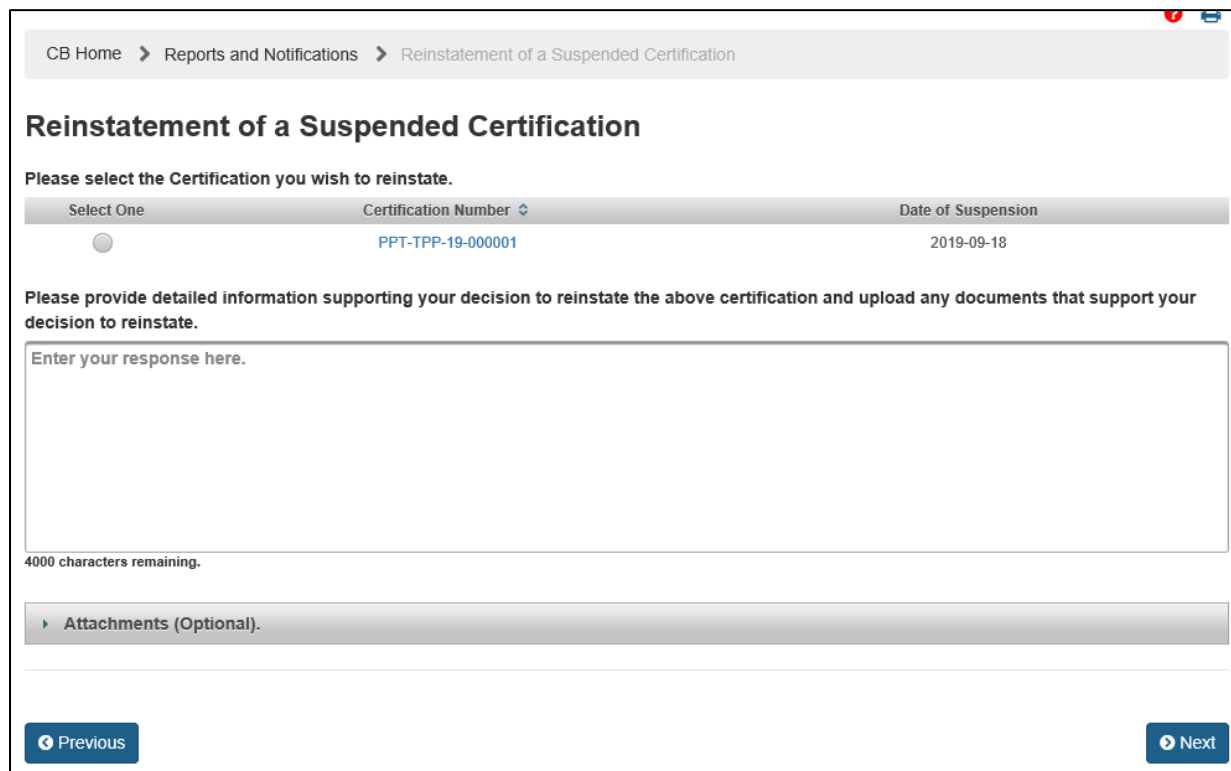
Previous

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



CB Home > Reports and Notifications > Reinstatement of a Suspended Certification

Reinstatement of a Suspended Certification

Please select the Certification you wish to reinstate.

Select One	Certification Number	Date of Suspension
<input type="radio"/>	PPT-TPP-19-000001	2019-09-18

Please provide detailed information supporting your decision to reinstate the above certification and upload any documents that support your decision to reinstate.

Enter your response here.

4000 characters remaining.

▶ Attachments (Optional).

[Previous](#) [Next](#)

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

▼ Attachments (Optional).

Instructions

Step 1: Click Browse to find the document(s) you want to upload
 Step 2: Click Upload

Note:

File Name	Upload Date	Action
CB_Details.docx	2019-09-18	

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).

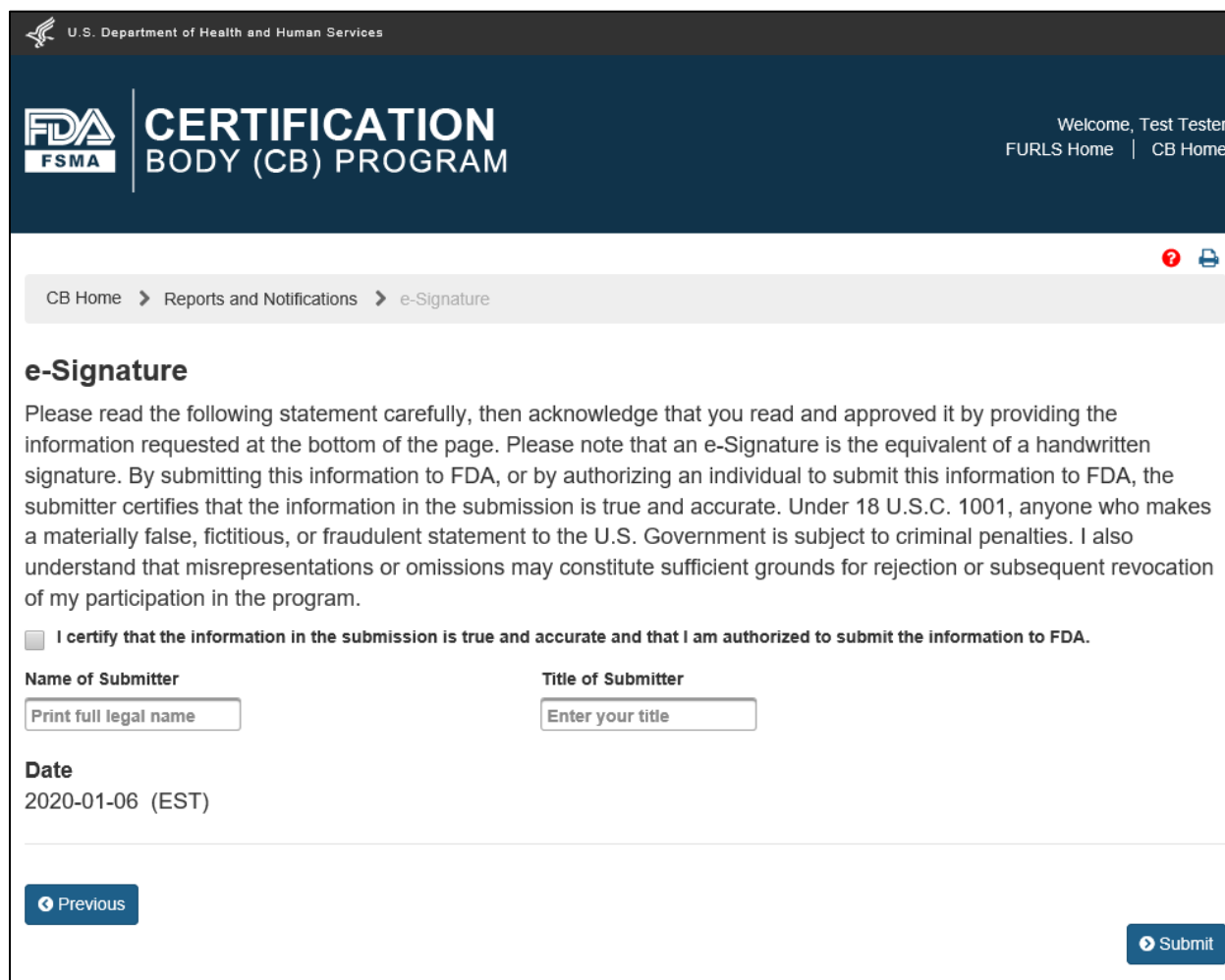
Complete the following fields:

- **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.

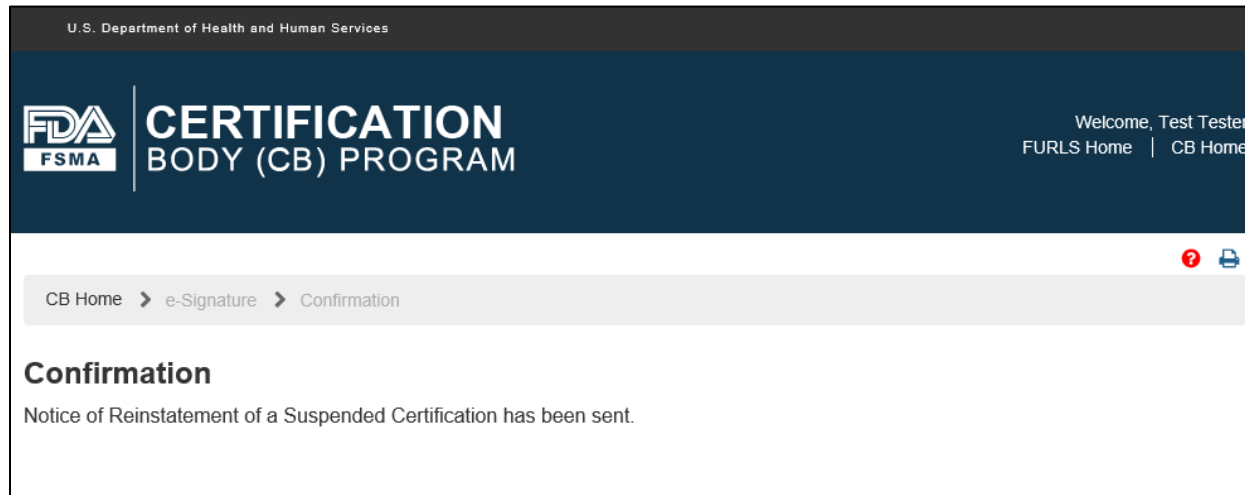
Figure 9.29 – e-Signature Page



The screenshot shows the FDA e-Signature page for the Certification Body (CB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "CERTIFICATION BODY (CB) PROGRAM". A user greeting "Welcome, Test Tester" and links for "FURLS Home" and "CB Home" are visible in the top right. A breadcrumb trail shows "CB Home > Reports and Notifications > e-Signature". The main heading is "e-Signature". Below this is a paragraph of text explaining the e-signature process and the legal consequences of providing false information. A checkbox is present with the text "I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA." Below the checkbox are two input fields: "Name of Submitter" with a placeholder "Print full legal name" and "Title of Submitter" with a placeholder "Enter your title". The "Date" is displayed as "2020-01-06 (EST)". At the bottom left is a "Previous" button and at the bottom right is a "Submit" button.

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

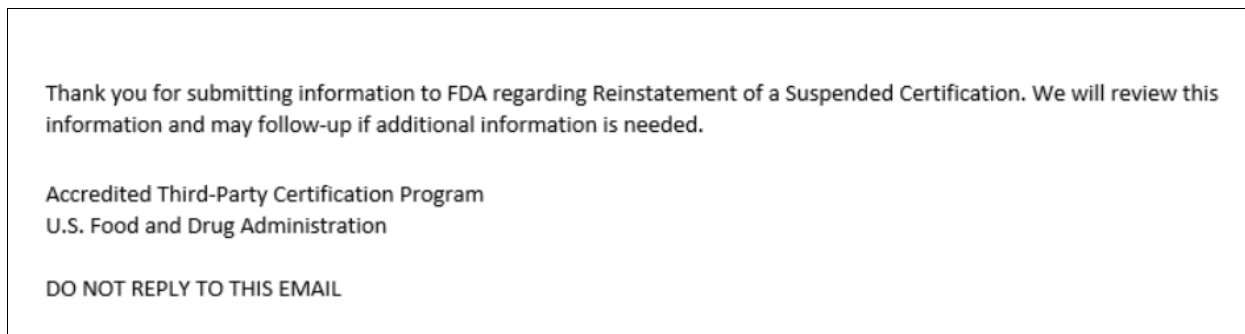
Figure 9.30 – Confirmation Page



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.

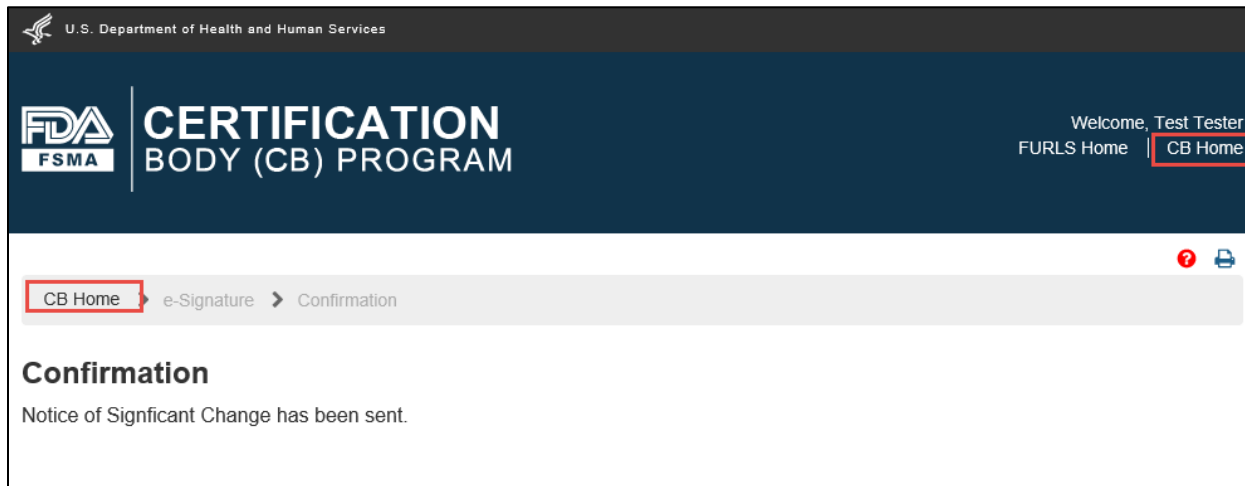
Note: The image (below) only depicts the e-mail notification text.

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).

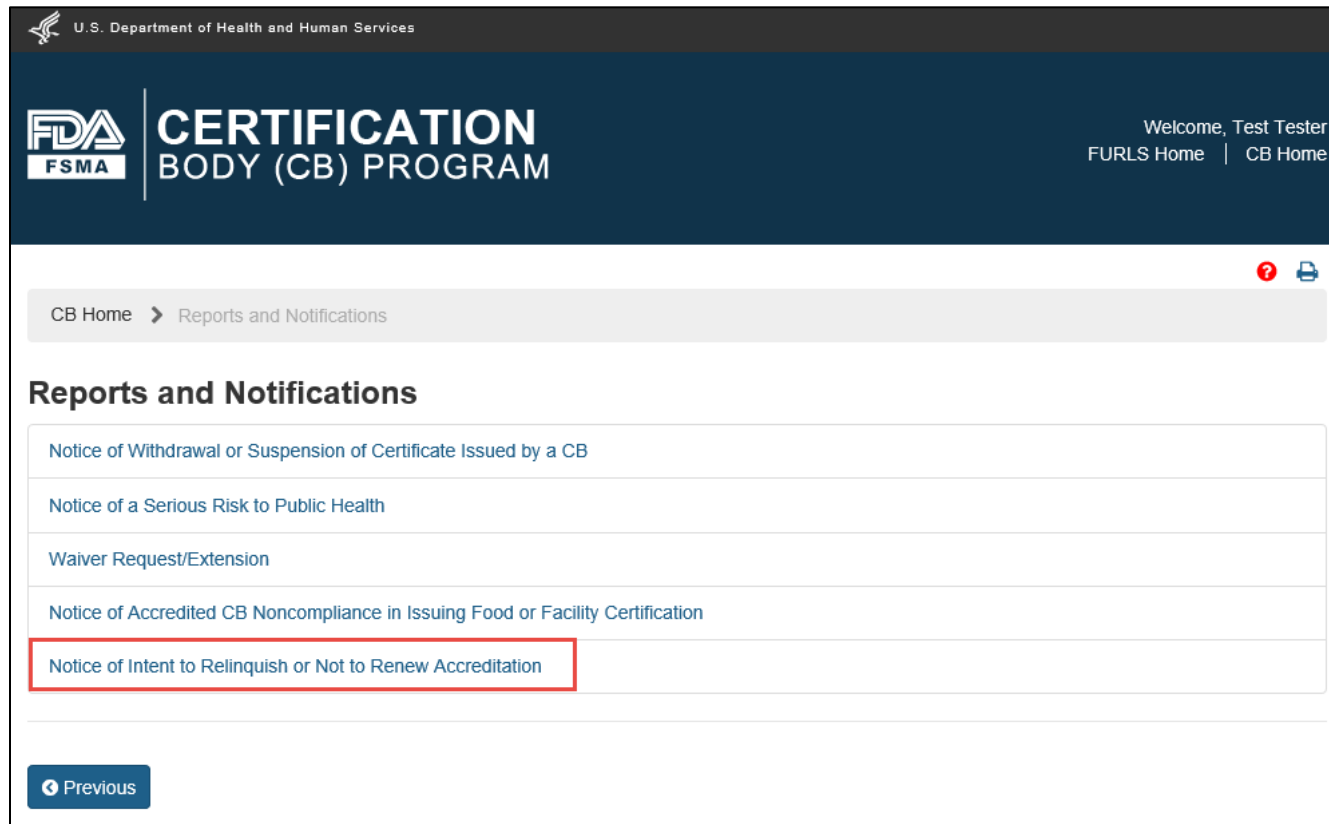
Figure 9.32 – Links to CB Home Page



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



U.S. Department of Health and Human Services

FDA **CERTIFICATION**
FSMA **BODY (CB) PROGRAM**

Welcome, Test Tester
FURLS Home | CB Home

CB Home > Reports and Notifications

Reports and Notifications

- Notice of Withdrawal or Suspension of Certificate Issued by a CB
- Notice of a Serious Risk to Public Health
- Waiver Request/Extension
- Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
- Notice of Intent to Relinquish or Not to Renew Accreditation**

Previous

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:

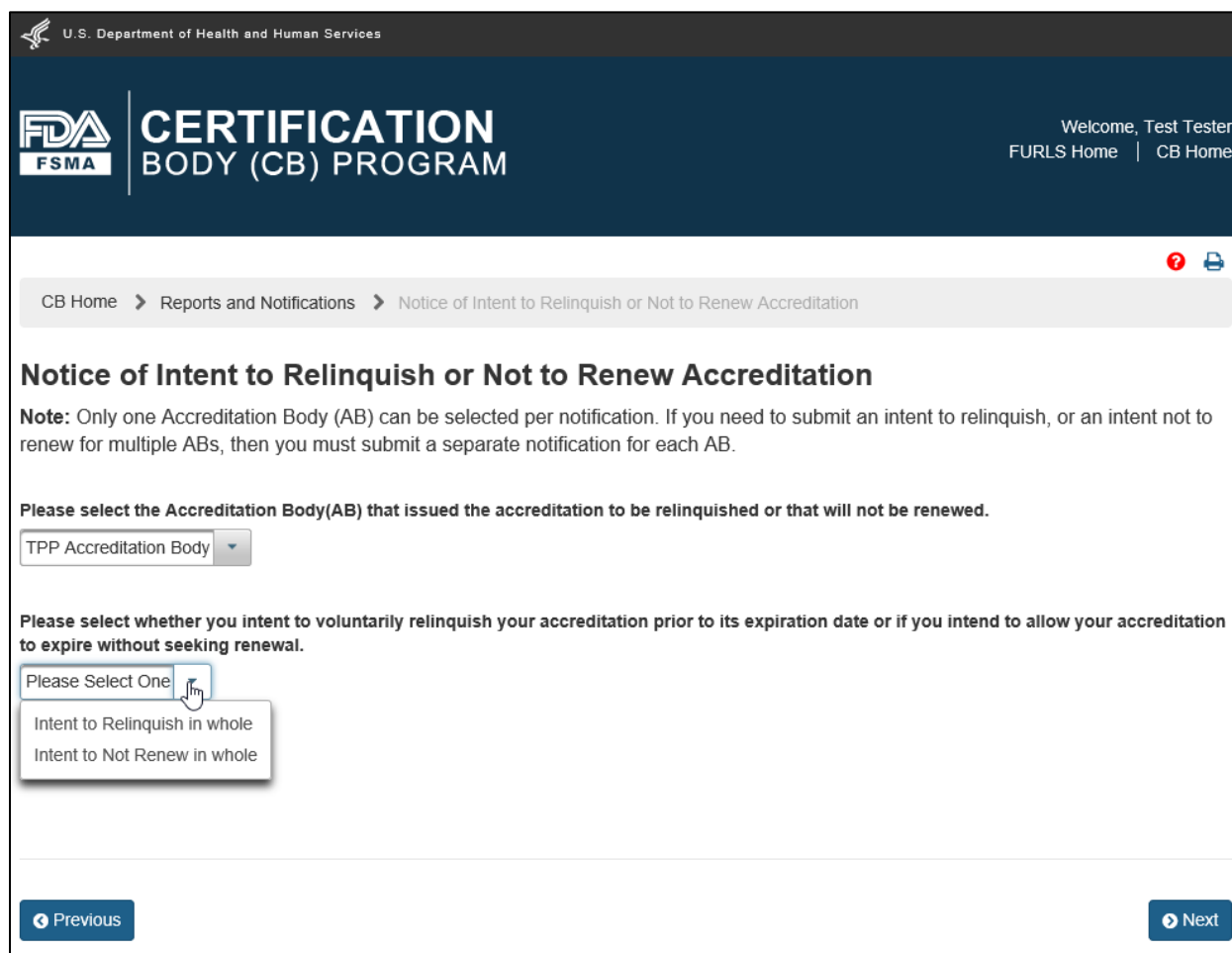
- **Please select the Accreditation Body (AB) that issued the accreditation to be relinquished or that will not be renewed.** – Select the name of the AB from the dropdown menu.

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

Please select whether you intent to voluntarily relinquish your accreditation prior to its expiration date or if you intend to allow your accreditation to expire without seeking renewal.

Intent to Relinquish in whole ▾

Intended Date of Relinquishment or Date of Expiration of Accreditation

YYYY-MM-DD 

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

Please select whether you intent to voluntarily relinquish your accreditation prior to its expiration date or if you intend to allow your accreditation to expire without seeking renewal.

Intent to Not Renew in whole ▾

Intended Date of Relinquishment or Date of Expiration of Accreditation

2023-09-01

Proceed to Section 9.6.3 of this chapter.

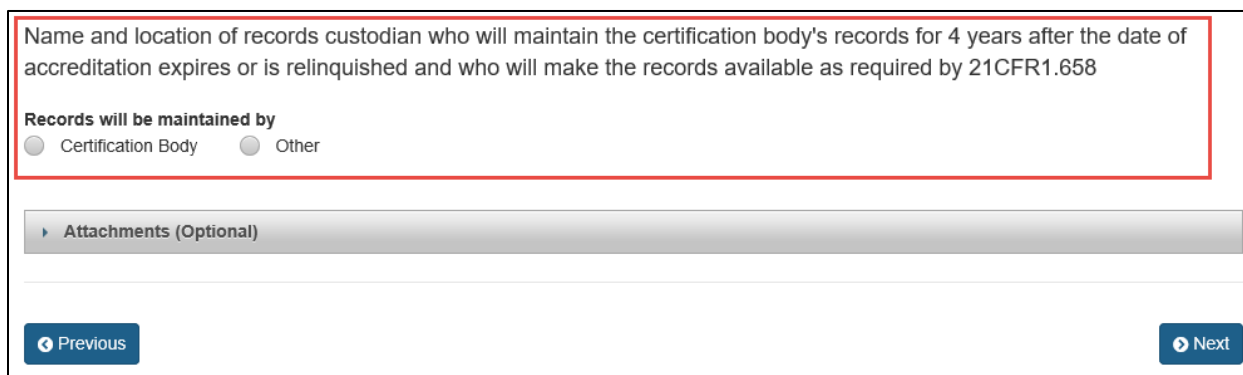
9.6.3 Records Custodian and Attachments

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



Name and location of records custodian who will maintain the certification body's records for 4 years after the date of accreditation expires or is relinquished and who will make the records available as required by 21CFR1.658

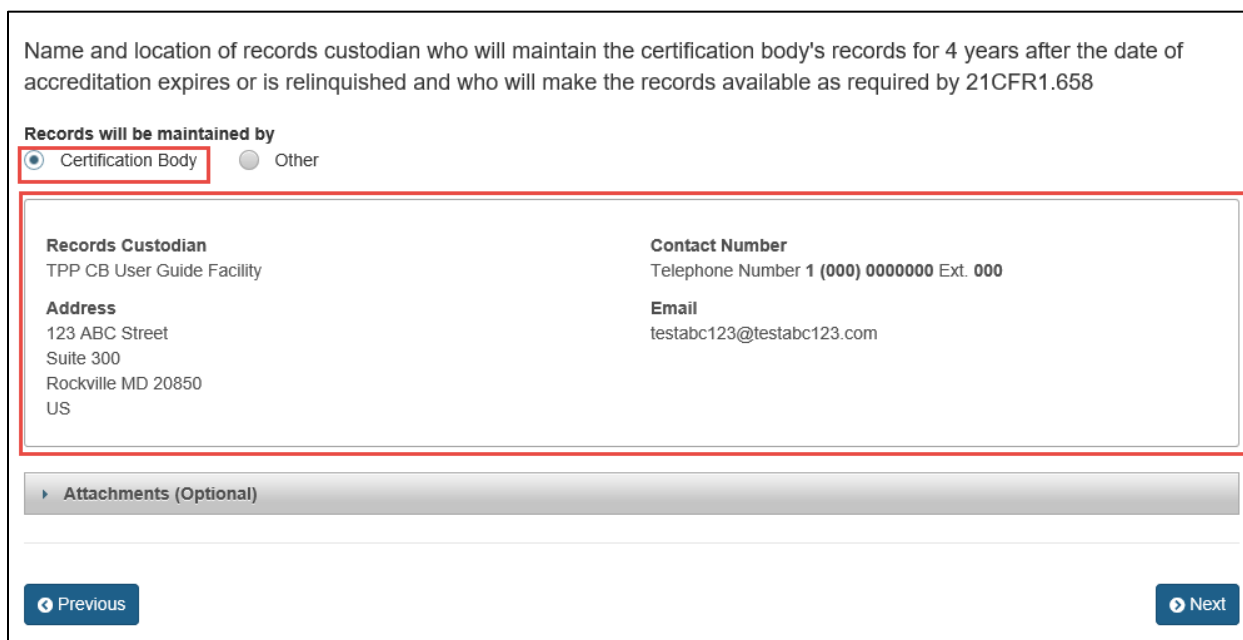
Records will be maintained by
 Certification Body Other

▶ Attachments (Optional)

◀ Previous ▶ Next

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



Name and location of records custodian who will maintain the certification body's records for 4 years after the date of accreditation expires or is relinquished and who will make the records available as required by 21CFR1.658

Records will be maintained by
 Certification Body Other

Records Custodian TPP CB User Guide Facility	Contact Number Telephone Number 1 (000) 0000000 Ext. 000
Address 123 ABC Street Suite 300 Rockville MD 20850 US	Email testabc123@testabc123.com

▶ Attachments (Optional)

◀ Previous ▶ Next

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

Name and location of records custodian who will maintain the certification body's records for 4 years after the date of accreditation expires or is relinquished and who will make the records available as required by 21CFR1.658

Records will be maintained by

Certification Body Other

Record Custodian:

Telephone (Optional):
Country Area Phone Number Extension

Country:

E-mail Address:

Address 1:

Address 2 (Optional):

City:

State/Province/Territory:

Zip Code (Postal Code):

▸ Attachments (Optional)

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

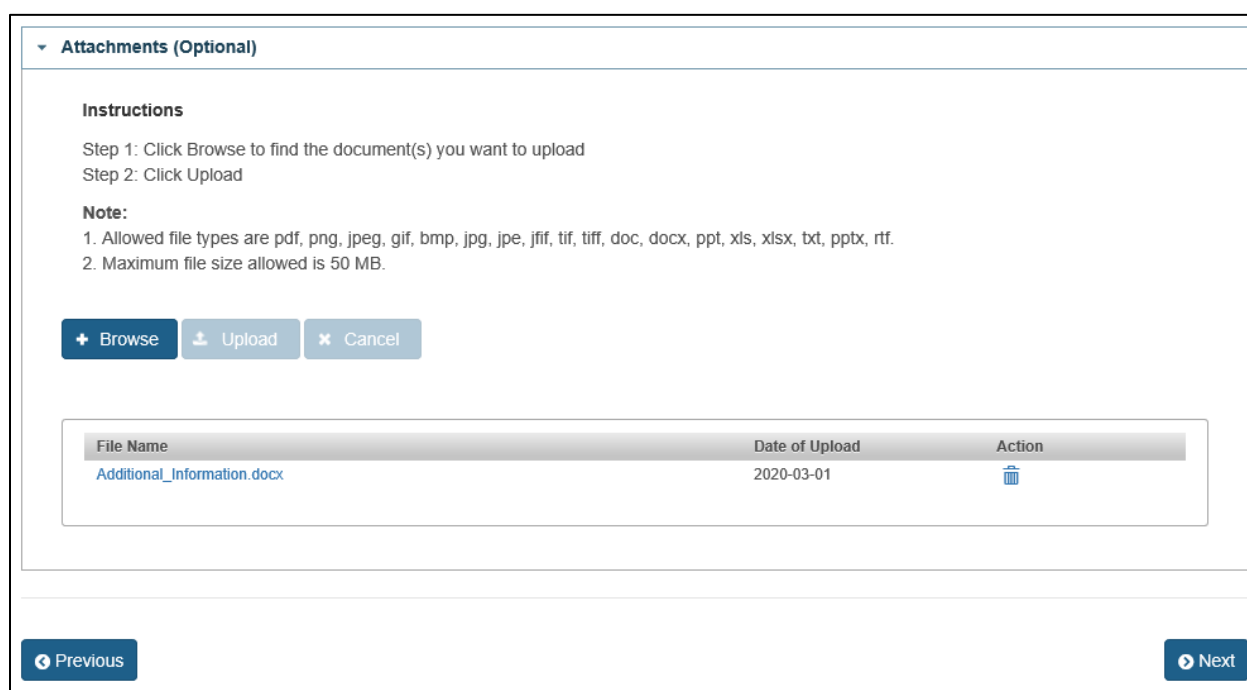
Follow Steps 1 - 4 (listed below) to upload attachments.

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



▼ Attachments (Optional)


Instructions

Step 1: Click Browse to find the document(s) you want to upload
 Step 2: Click Upload

Note:

1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

+ Browse Upload Cancel

File Name	Date of Upload	Action
Additional_Information.docx	2020-03-01	

◀ Previous Next ▶

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).

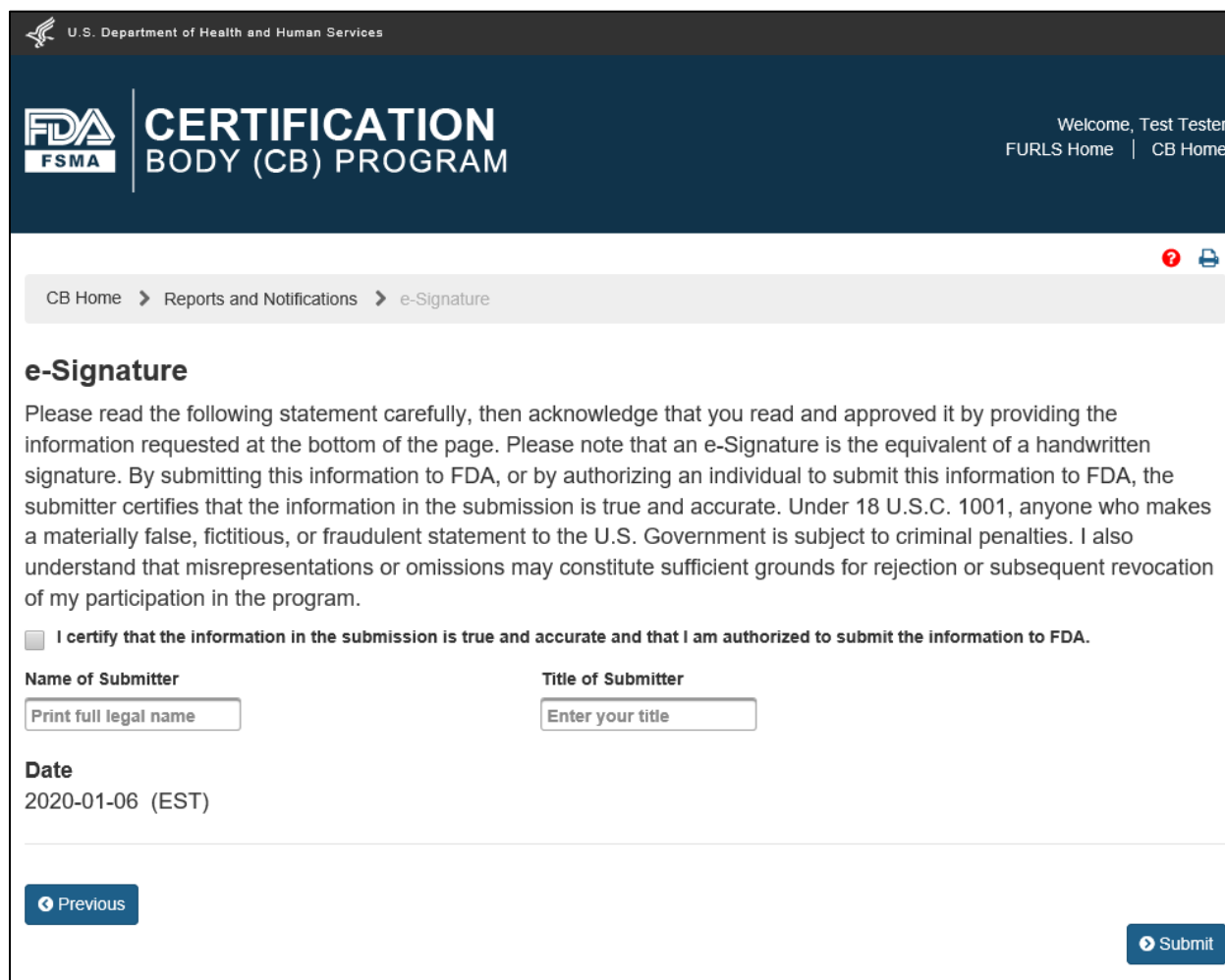
Complete the following fields:

- **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



U.S. Department of Health and Human Services

FDA | **CERTIFICATION**
FSMA | **BODY (CB) PROGRAM**

Welcome, Test Tester
FURLS Home | CB Home

CB Home > Reports and Notifications > e-Signature

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions may constitute sufficient grounds for rejection or subsequent revocation of my participation in the program.

I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA.

Name of Submitter
Print full legal name

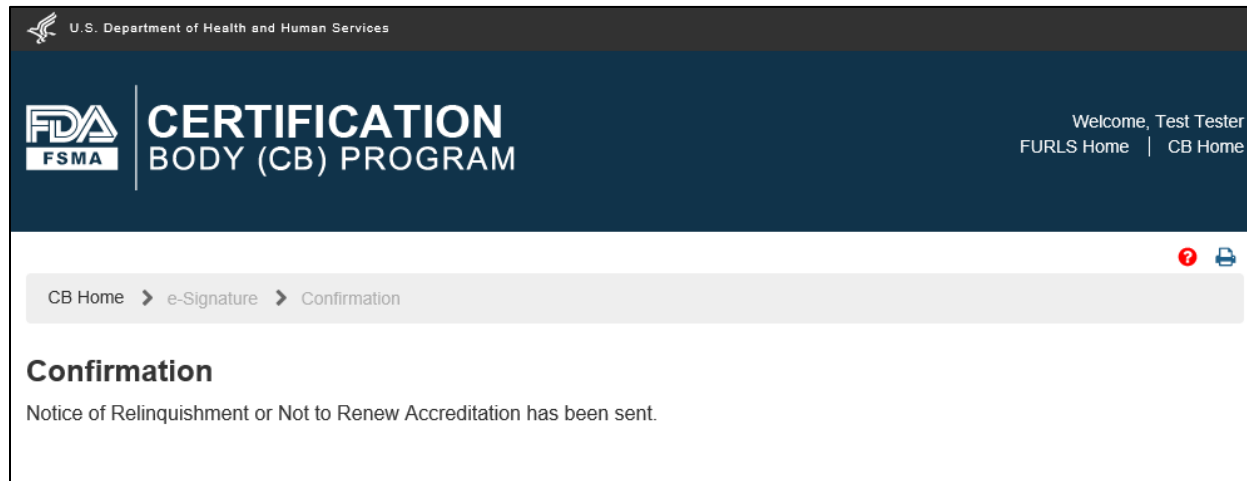
Title of Submitter
Enter your title

Date
2020-01-06 (EST)

Previous Submit

After you click the “Submit” button the system will display the “Confirmation” page, indicating the notification has been sent to FDA (Figure 9.42).

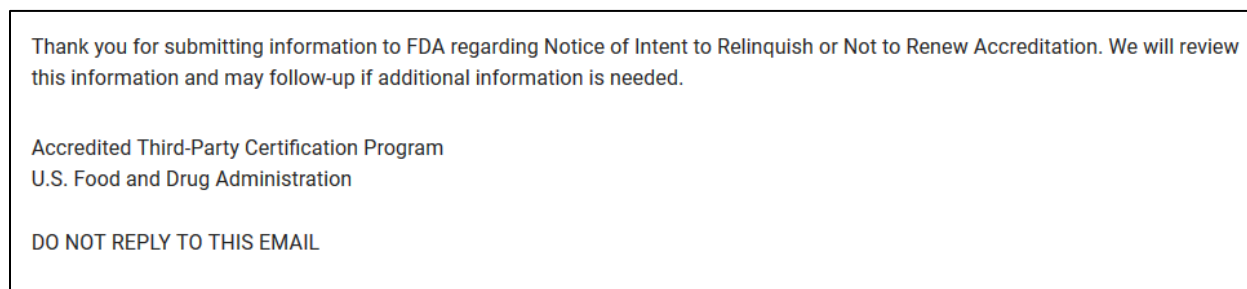
Figure 9.42 – Confirmation Page



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.

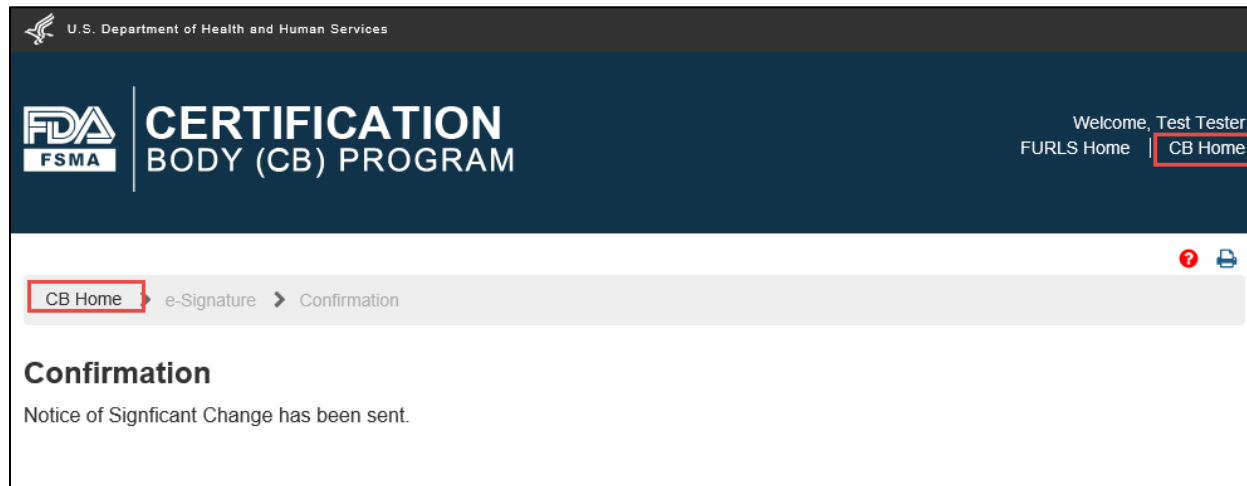
Note: The image (below) only depicts the e-mail notification text.

Figure 9.43 – E-mail Confirmation



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



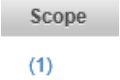




APPENDIX A: Abbreviations

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. <ul style="list-style-type: none"> 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.