U.S. Food and Drug Administration

Accredited Third-Party Certification Program Portal

Instructions for an Accreditation Body to Apply for and Manage Recognition Status in the Program

Table of Contents

1 Introduction

This document is intended for Accreditation Bodies (ABs), or persons authorized to act on their behalf, who are applying for recognition or participating in the U.S. Food and Drug Administration's (FDA's) Accredited Third-Party Certification Program. Recognized ABs may manage their profiles and the status of the Third-Party Certification Bodies (CBs) they have accredited.

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

- Create an AB account
- Submit an application
- Submit an application for renewal
- Add and view accredited CBs
- Renew the accreditation of CBs
- Submit supplemental documentation
- 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 making 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)

FDA's Unified Registration and Listing System (FURLS) is a specific component of FIS. Persons with an FDA account ID and password for the FIS electronic portal can use systems within the FURLS components to exchange information with the Agency. The FURLS system described in this document is for the Accredited Third-Party Certification Program.

Adding Attachments

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

The electronic Accredited Third-Party Certification Program system supports attachments of 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.

Relevant sections of this document will identify opportunities for adding attachments.

Supported Browsers

FURLS may be accessed using Microsoft Edge, Chrome, or Firefox. 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 Access.fda.gov.

Note: To navigate within the AB portal, use the system's navigation buttons (i.e., "Previous," or "Next") rather than the browser's "forward" or "back" buttons.

Obtain an FDA Account through the FDA FIS Electronic Portal

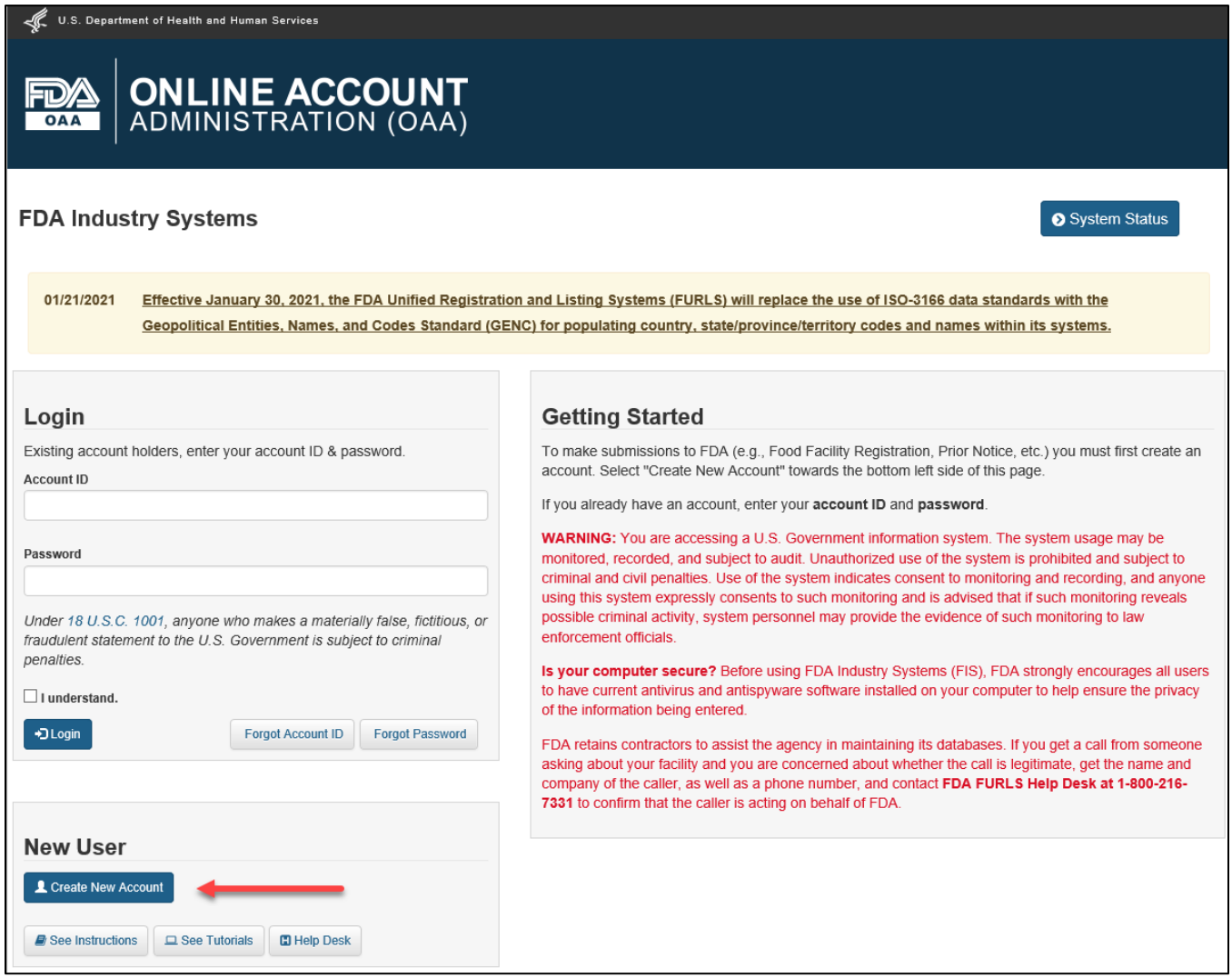
Each person who uses this system needs a personal FDA Account ID and password. To access the FIS electronic portal, navigate to the Access.fda.gov OAA site. Click the "Create New Account" button (near the bottom of the page) in the "New User" section. Follow the instructions for obtaining an FDA Account ID and password below. Once the account has been created, you will be able to log into the "Online Account Administration" (OAA) system.

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.

Create an FDA online account by clicking on the "Create New Account" button on the FIS OAA page (Figure 3.1). You will be directed to the "Create New Account" page.

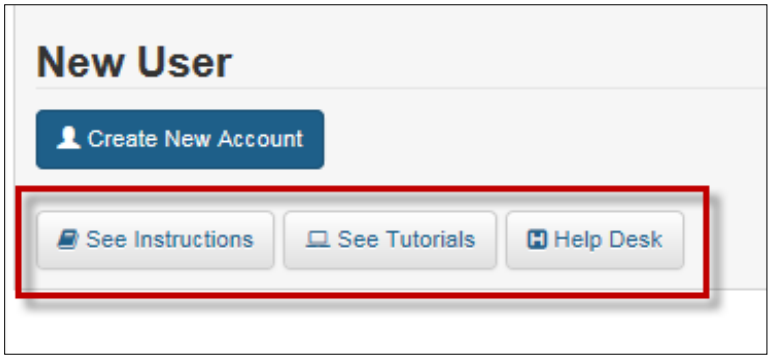
Figure 3.1 – FIS Online Account Administration (OAA) Page



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

Note: The following buttons are displayed on the "OAA" landing page and direct users to informational pages on fda.gov, as indicated. Users will not be required to select any of these buttons in order to complete applications; they are there for users' reference, if needed (Figure 3.2).

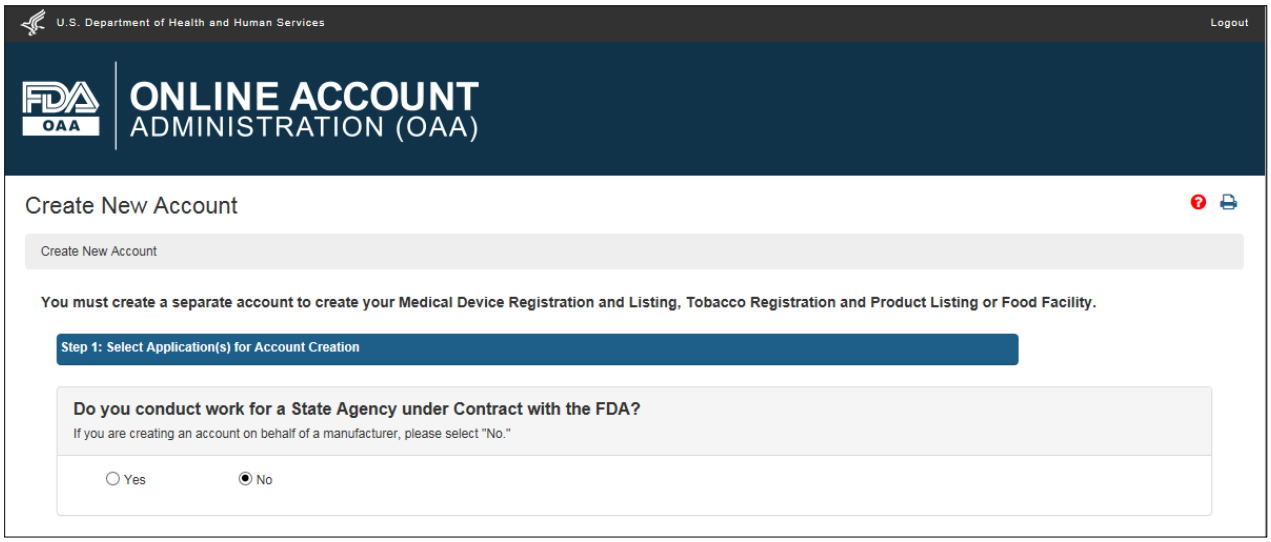
Figure 3.2 – Additional Buttons



Click the “Create New Account” button. The system will display the “Create New Account” page. “Step 1: Select Application(s) for Account Creation” will appear. Two radio buttons will be displayed, “Yes” and “No.” Note that “No” is selected by default (Figure 3.3).

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

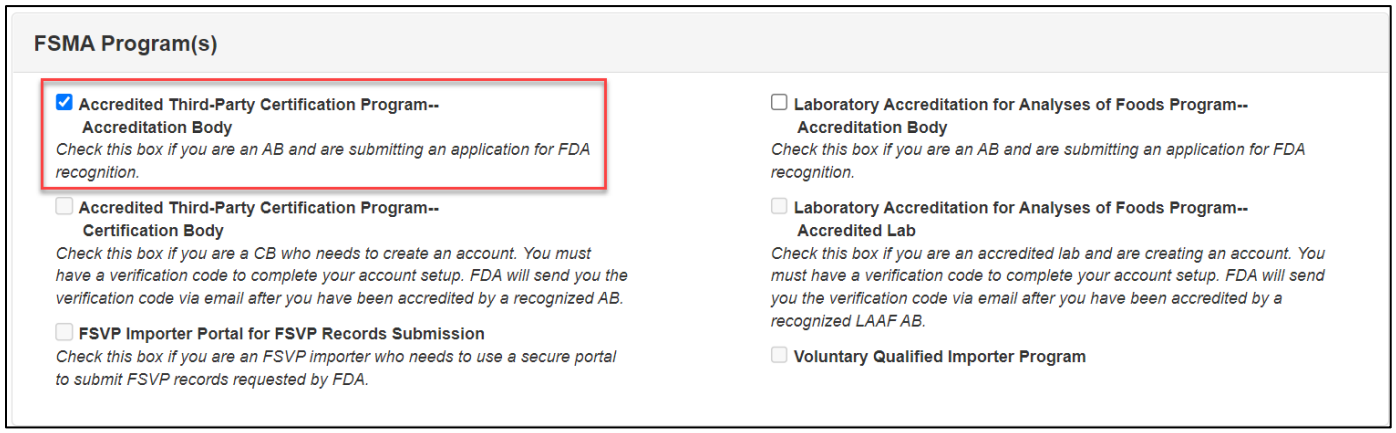
Figure 3.3 – Step 1: Select Application(s) for Account



The system will display the various programs available in OAA.

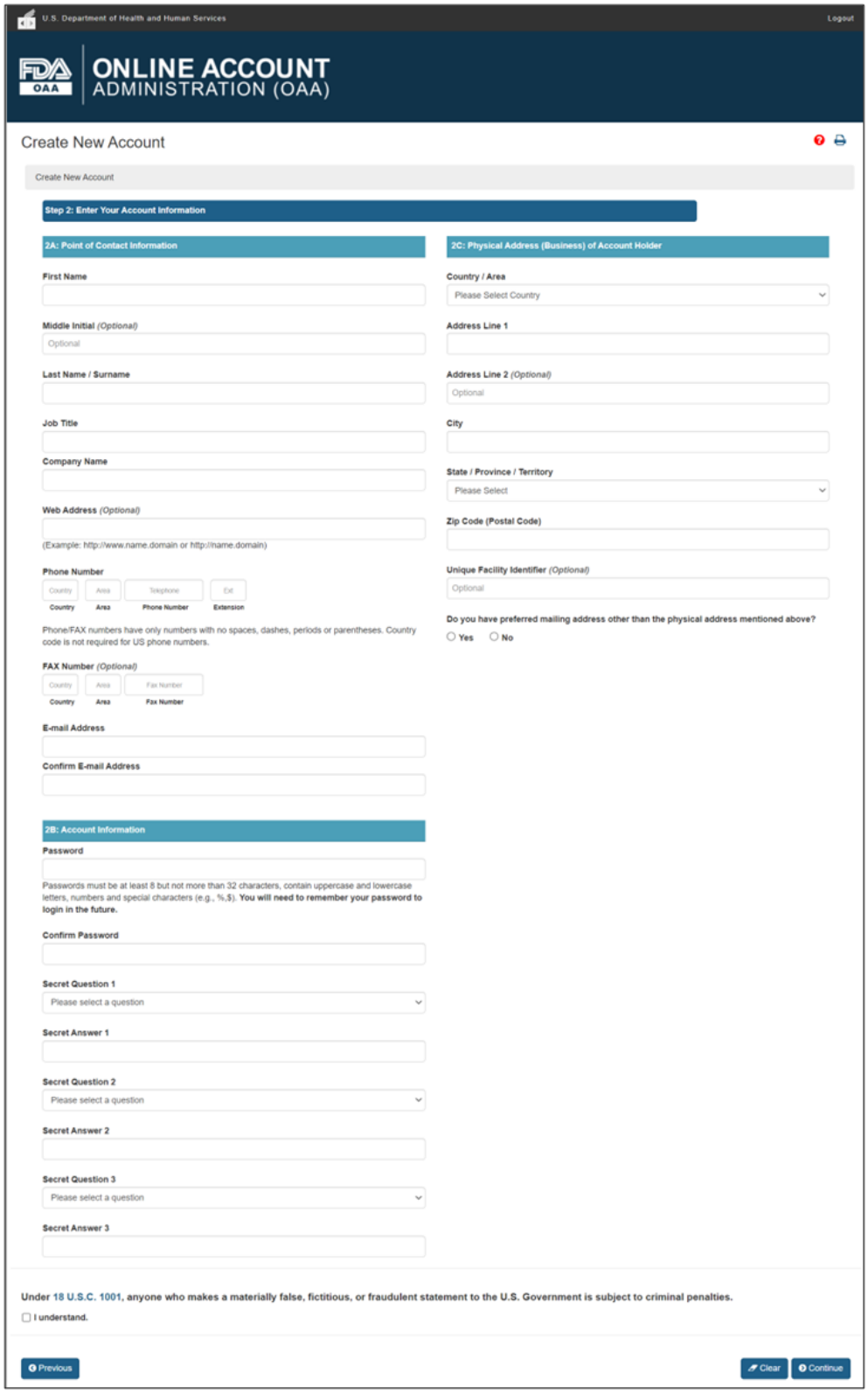
Select the “Accredited Third-Party Certification Program - Accreditation Body" checkbox under the “FSMA Program(s)” section and click the “Continue” button to proceed (Figure 3.4).

Figure 3.4 – Accredited Third-Party Certification Program – Accreditation Body



The next section is “Step 2: Enter Your Account Information” where you will provide “Point of Contact” information, unique account information, and the account holder’s physical address (Figure 3.5).

Figure 3.5 – Create New Account – Step 2: Enter Your Account Information



The following navigation buttons can be found throughout the system:

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

Note: All application fields are required, unless indicated as "Optional."

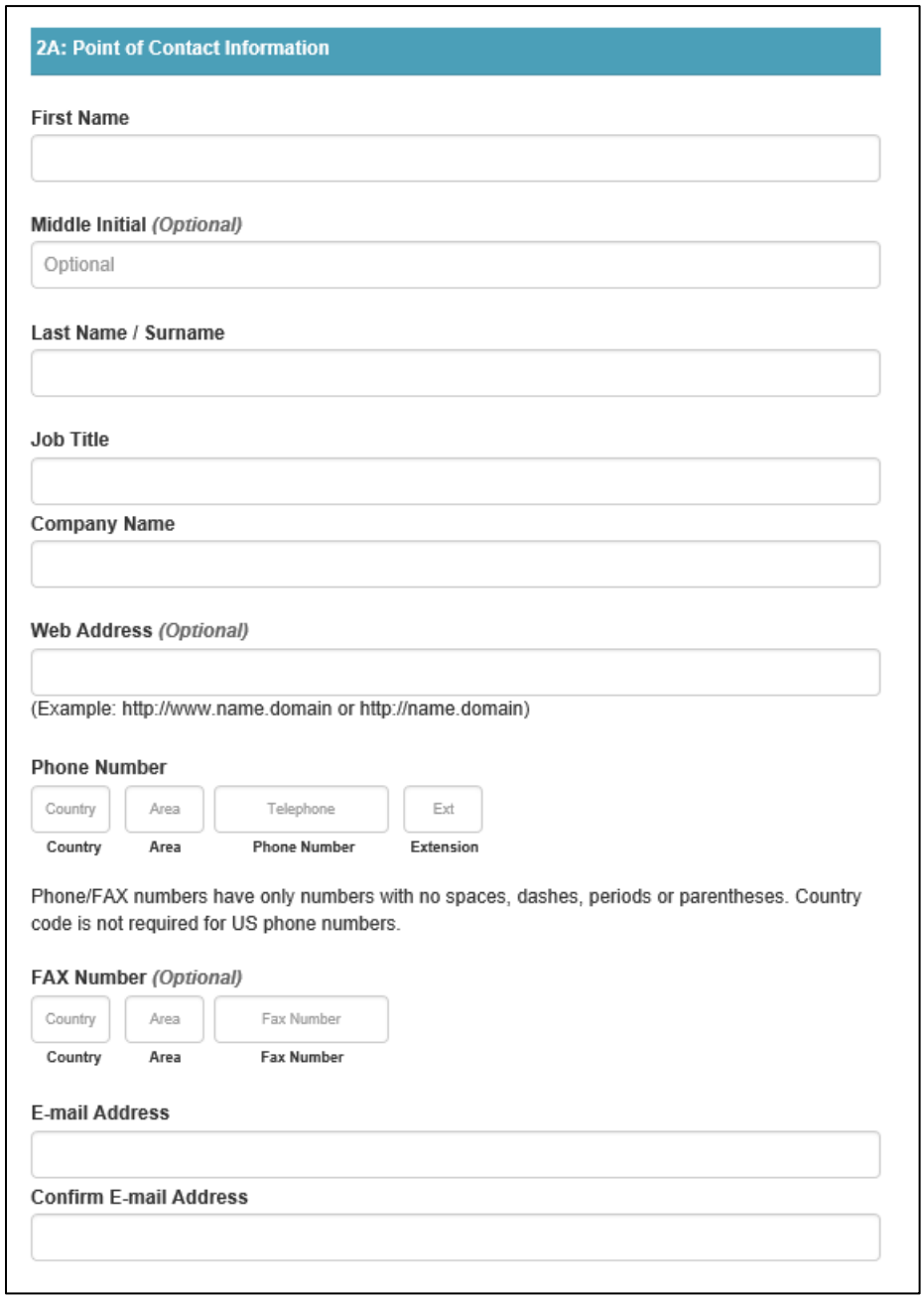
Enter "N/A" in any required field that does not apply.

Complete each of the data fields in Step 2A (Figure 3.6).

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/surname 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 fax 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.

Figure 3.6 – Step 2A: Point of Contact Information

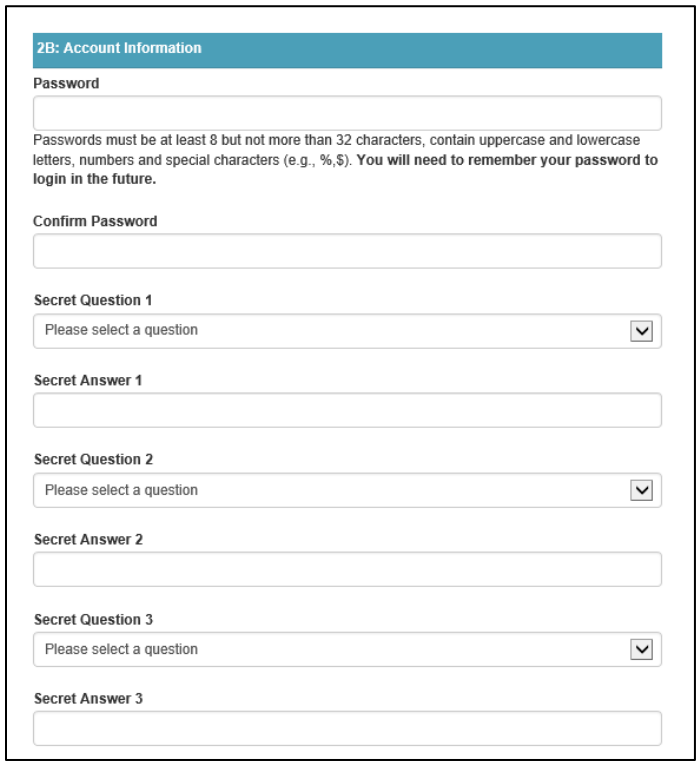


Once Step 2A is completed, proceed to “Step 2B: Account Information” (Figure 3.7).

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

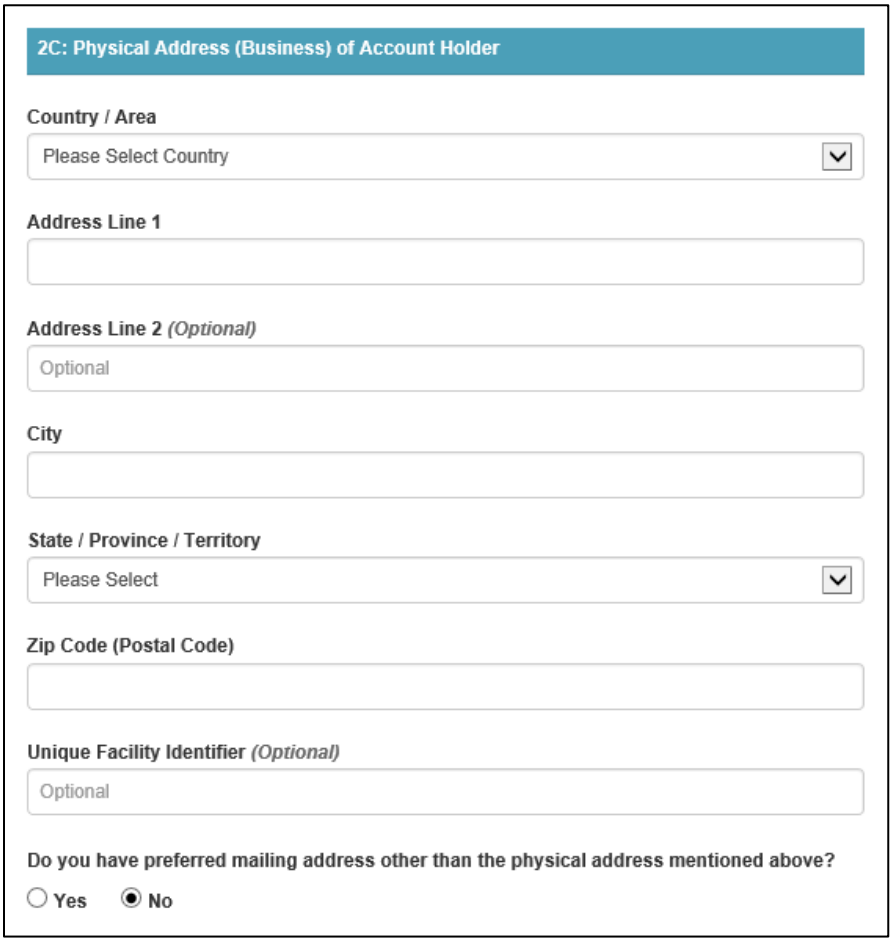
- **Password** – Use this field to create the password for the AB account. Use this password for each system login.
- **Confirm Password** – Re-enter the password in the “Password” field. The entry must match the “Password” field.
- **Secret Question 1** – This is the first secret question used to protect 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.”

Figure 3.7 – Step 2B: Account Information



Once Step 2B is completed, proceed to “Step 2C: Physical Address (Business) of Account Holder” (Figure 3.8).

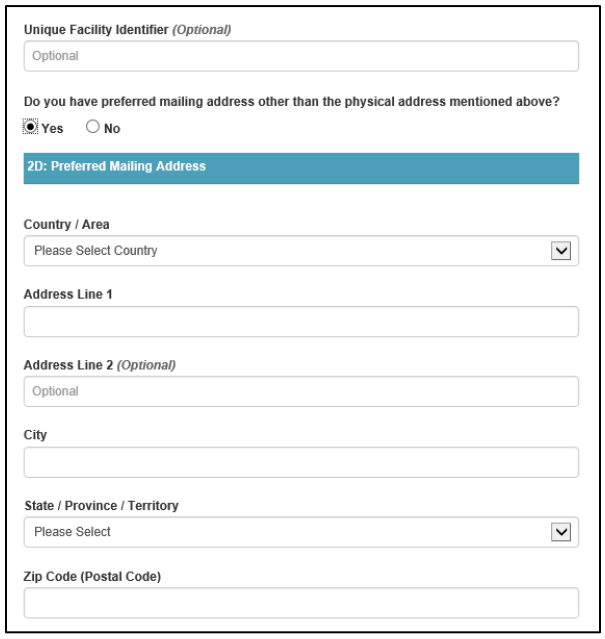
Figure 3.8 – Step 2C: Physical Address (Business) of Account Holder



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

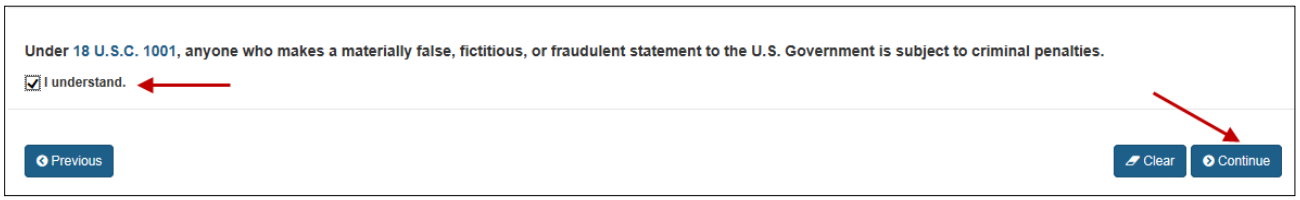
- **Country/Area** – The country/area where the business is located
  Select a country/area from the dropdown list.
- **Address Line 1** – The address where the business is physically located
  This includes the number, street, quadrant, etc.
- **Address Line 2 (Optional field)** – The field to enter additional information about the physical location of the company
  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?** – Select the “Yes” or “No” radio buttons to answer this question.
  - If you select “No,” click the checkbox for “I understand” at the bottom of the page (Figure 3.9). 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. Select the checkbox for “I understand” at the bottom of the page (Figure 3.10). The address entered in Section 2D will be used as the mailing address.

Figure 3.9 – Step 2D: Preferred Mailing Address



Click the “Continue” button after entering the required account information (Figure 3.10).

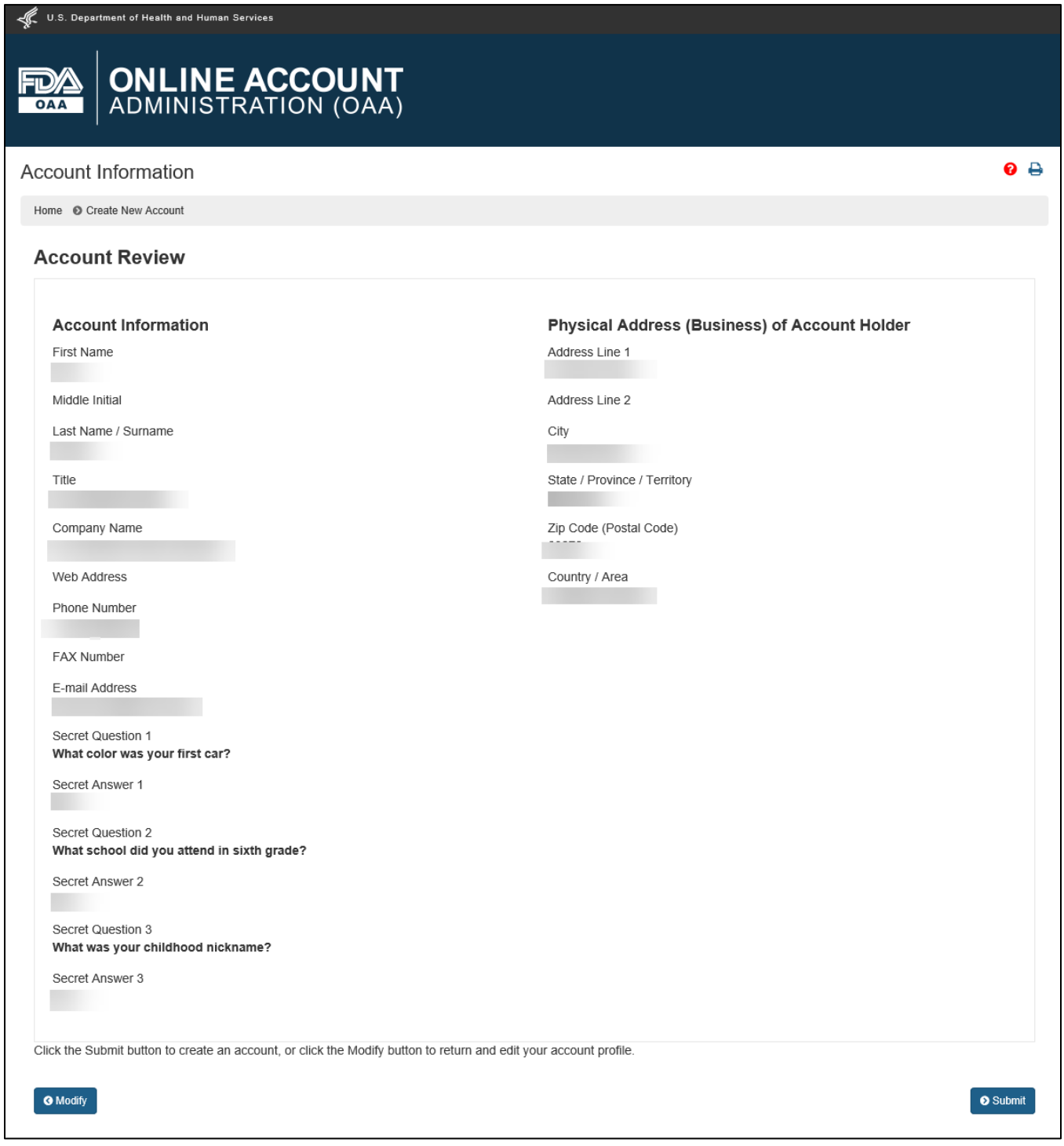
Figure 3.10 – Checkbox



The “Account Review” page will be displayed (Figure 3.11). Review the data to ensure it is correct.

Click the “Submit” button to complete the process. Click the “Modify” button to edit the profile information on the previous page.

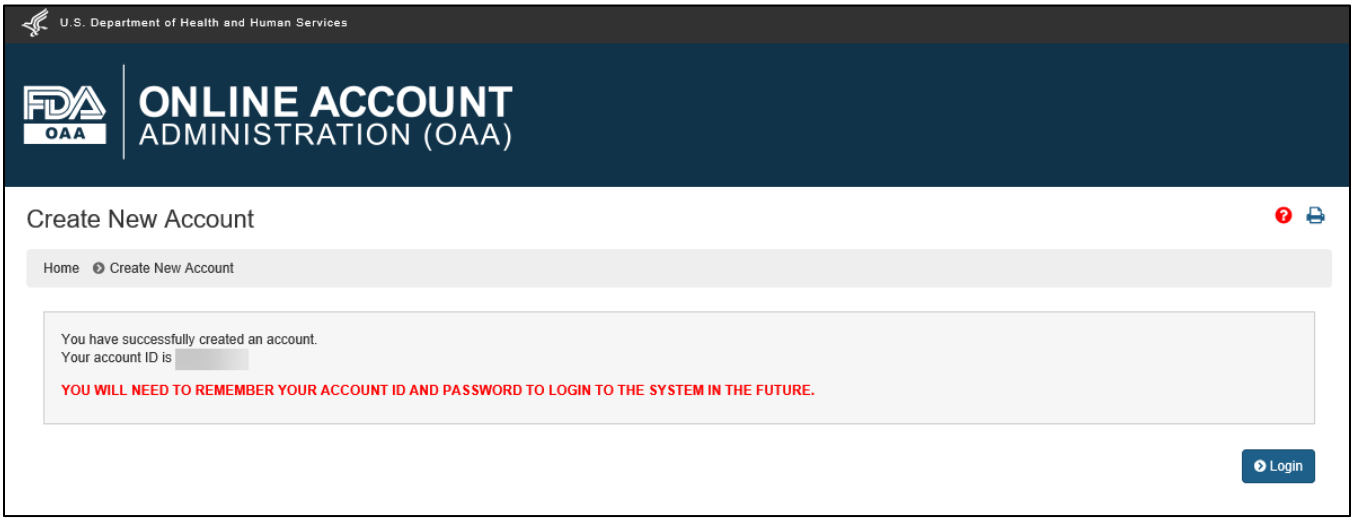
Figure 3.11 – Account Review Page



After you click “Submit,” the system will display a message confirming the account was created successfully. The message will display the “Account ID” (Figure 3.12).

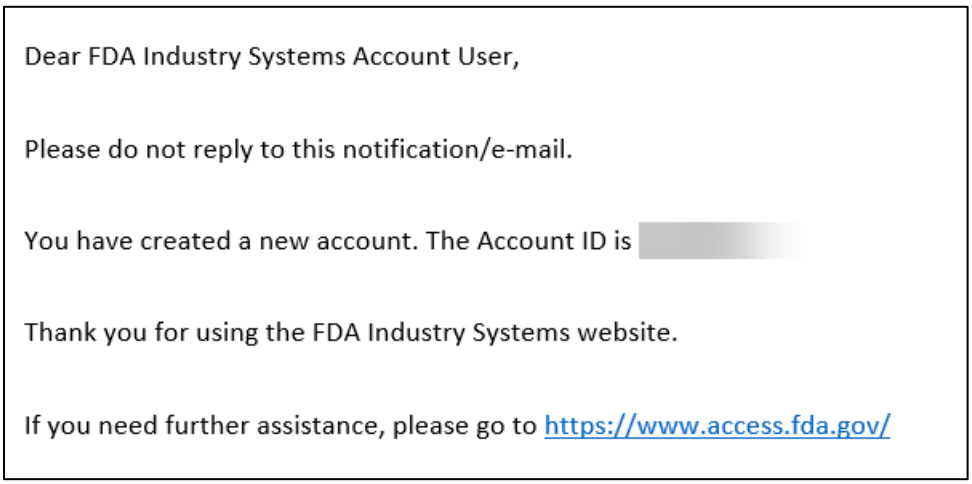
You will need to retain the account ID and password to log into the system in the future.

Figure 3.12 – Successful Account Creation Message



After creating an account, the system will send an e-mail to the address entered on the "Account Information" page (Figure 3.13).

Figure 3.13 – User Account Information E-mail Notification



4 Log into the AB Portal

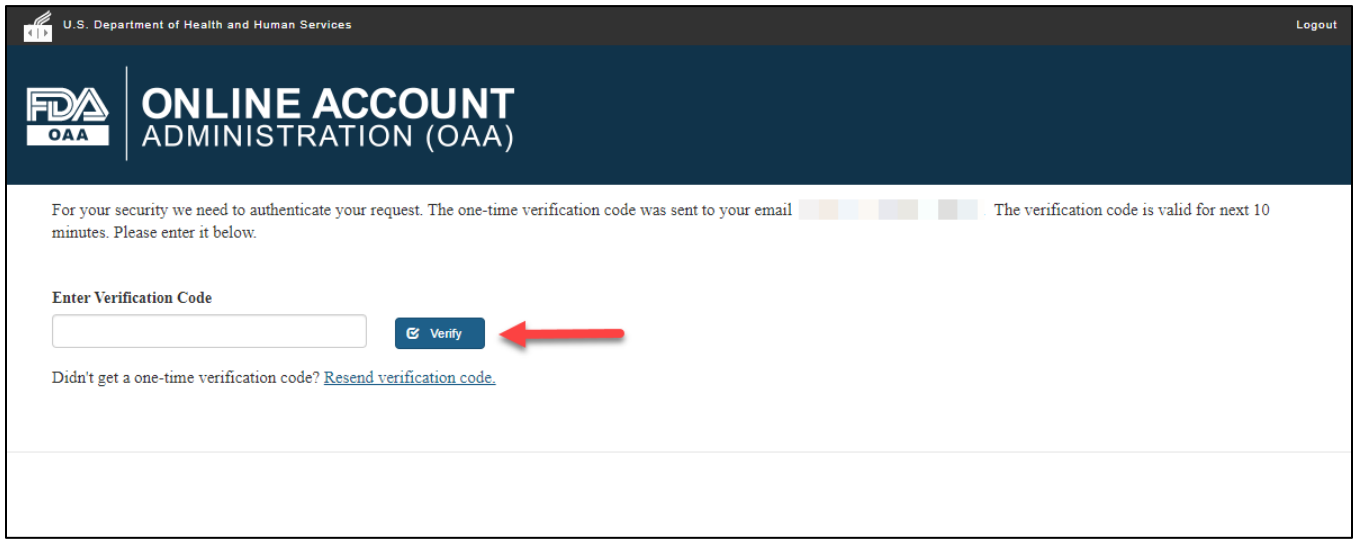
Log into the FDA "OAA" page. This is the same page used to begin the process of creating a new OAA account (Figure 4.1).

Figure 4.1 – OAA Login

Once logged into the FDA "OAA" page, you will be prompted to enter a verification code (Figure 4.2). The verification code will be sent to the e-mail to the address entered on the "Account Information" page. If you have not received the verification code within ten minutes, click "Resend verification code" on the page. Once you have received the code, enter it in the box labeled "Enter Verification Code," then click the "Verify" button.

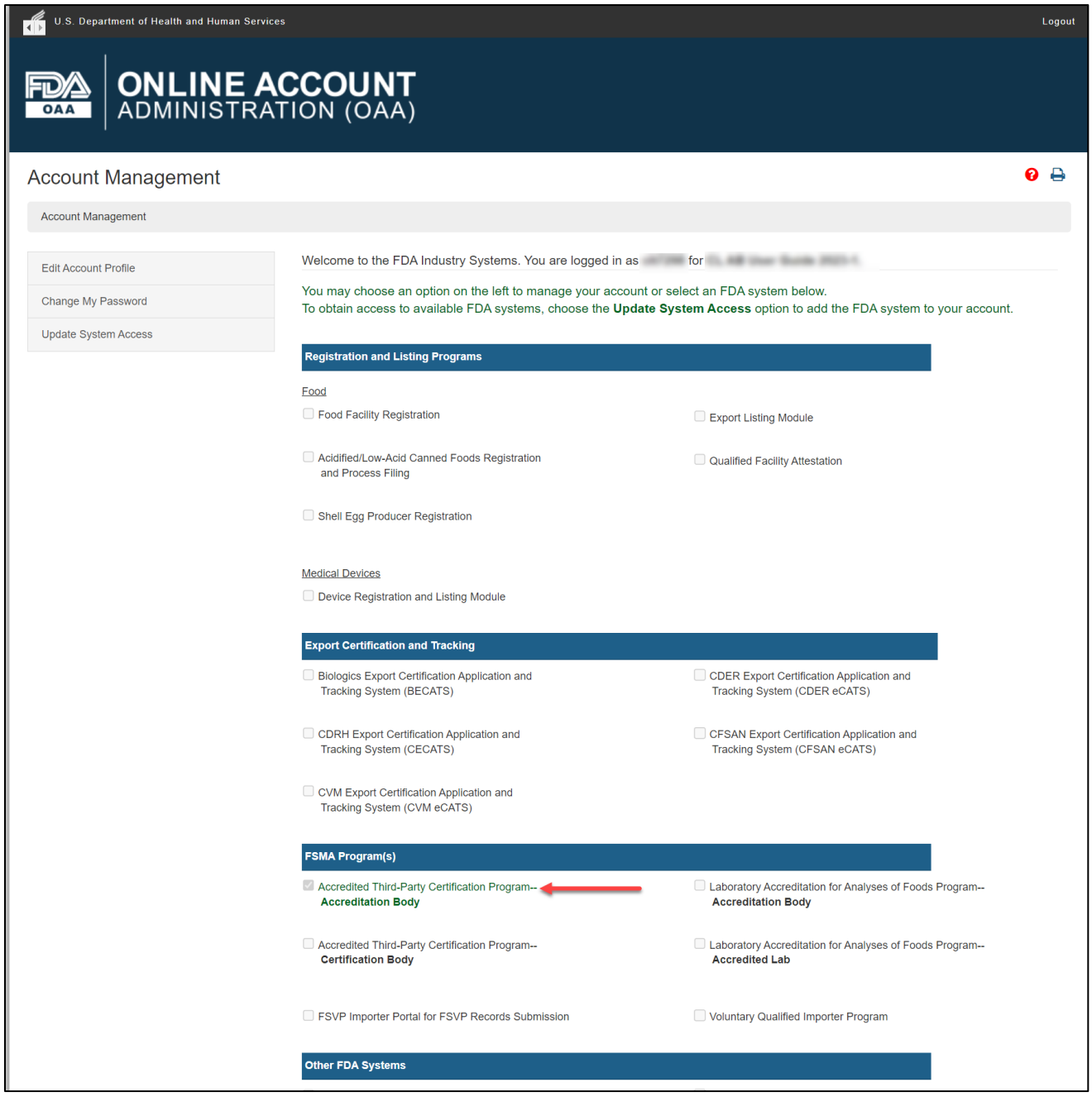
Note: You will be prompted to enter a verification code each time you login.

Figure 4.2 – Enter Verification Code



You will then be directed to the FURLS “Account Management” home page (Figure 4.3). Navigate to the “FSMA Program(s)” section and select the hyperlink for "Accredited Third-Party Certification Program – Accreditation Body.”

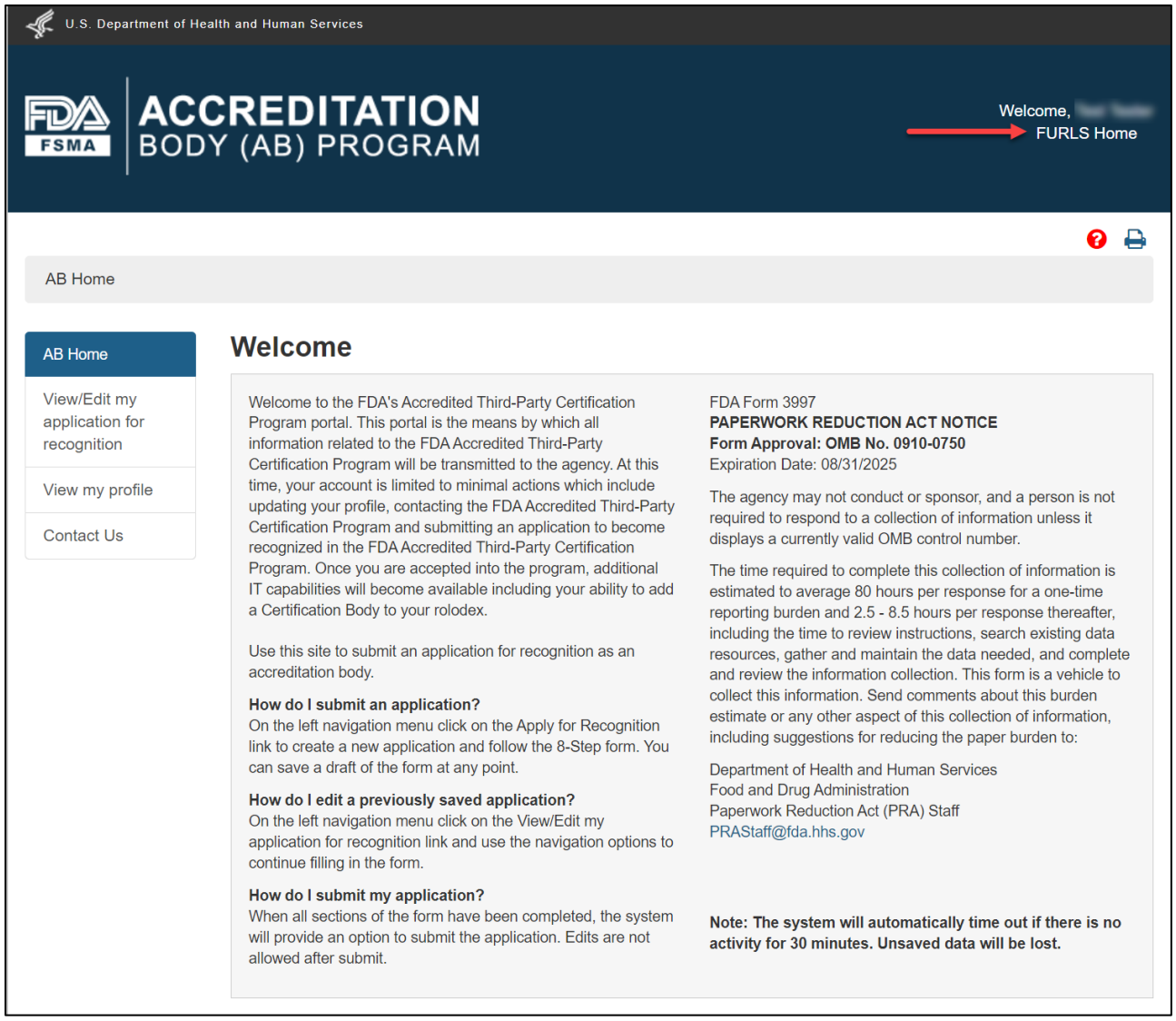
Figure 4.3 – OAA – FURLS Account Management Home Page



Click the hyperlink for “Accredited Third-Party Certification Program – Accreditation Body” to navigate to the “AB Home” page; the banner is titled “Accreditation Body (AB) Program” (Figure 4.4).

Note: Each screen in the AB portal has the banner “Accreditation Body (AB) Program.” The “FURLS Home” link on the right side of the banner will navigate you back to the “FURLS Home” page, where you may log out.

Figure 4.4 – AB Home Page

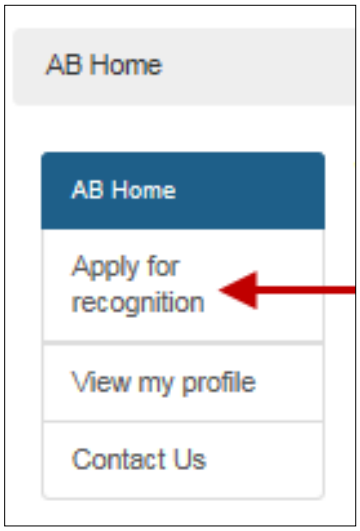


5 Apply for Recognition

The “Apply for Recognition” feature may be used to (electronically) apply for approval from FDA to participate in the program as a recognized AB. See 21 CFR 1.610 for information on eligibility for seeking recognition and 21 CFR 1.611-1.615 for information on the TPP requirements to qualify for recognition.

Click the “Apply for Recognition” link on the navigation menu on the “AB Home” page to create a new application for recognition as an AB (Figure 5.1).

Figure 5.1 – Navigation Menu



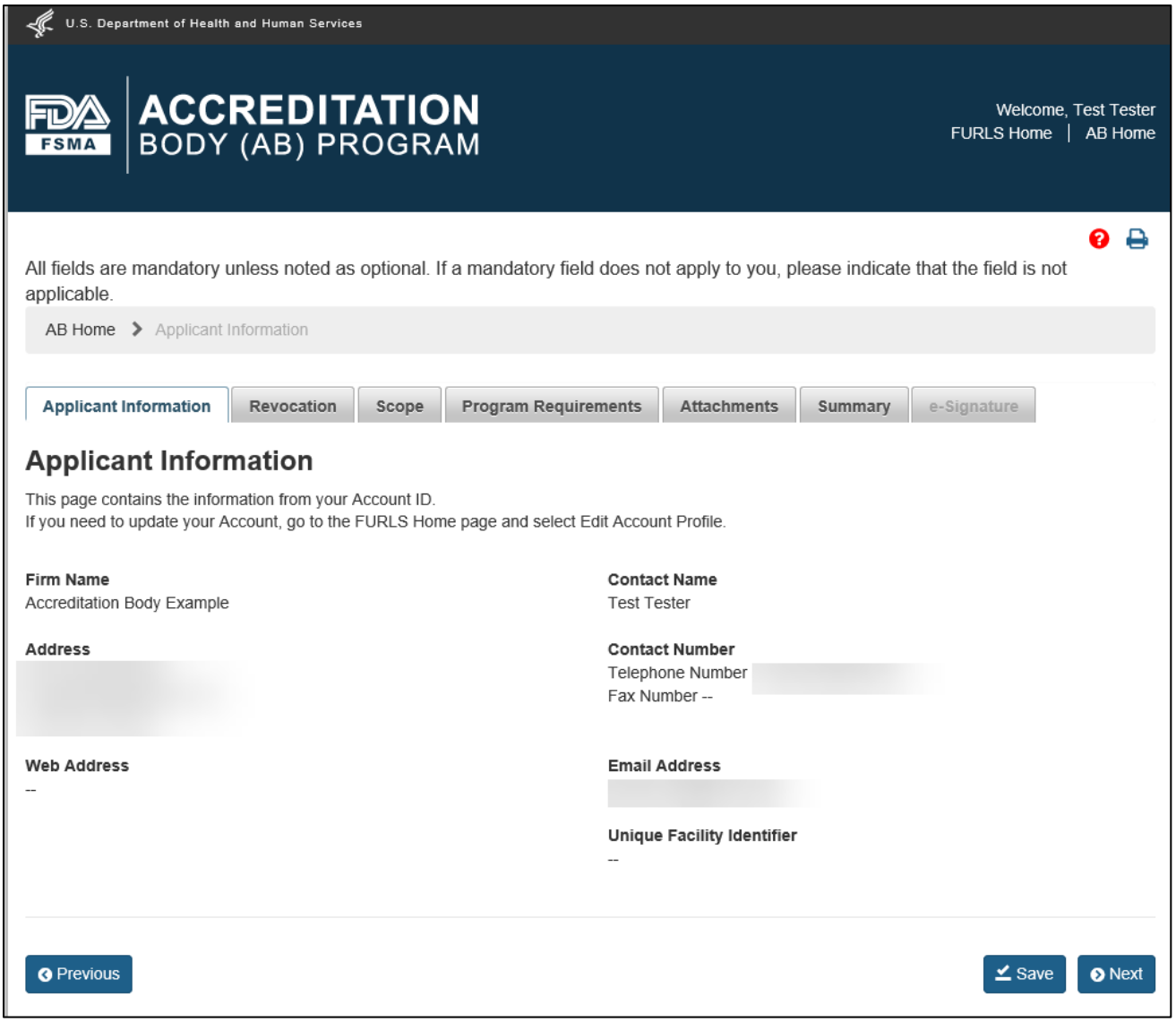
The “Applicant Information” page will open (Figure 5.2).

5.1 Applicant Information Page

The “Applicant Information” page displays read-only information from your user profile. Verify that the information listed in the “Applicant Information” page is accurate.

Note: To navigate to the main menu on the “AB Home” page, click the "AB Home" link from the top of the banner (or from the breadcrumb) displayed on each page.

Figure 5.2 – Applicant Information Page



Note: You will see the following buttons while navigating the pages during the course of the application process (Figure 5.3):

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

Figure 5.3 – Previous, Save, and Next Buttons

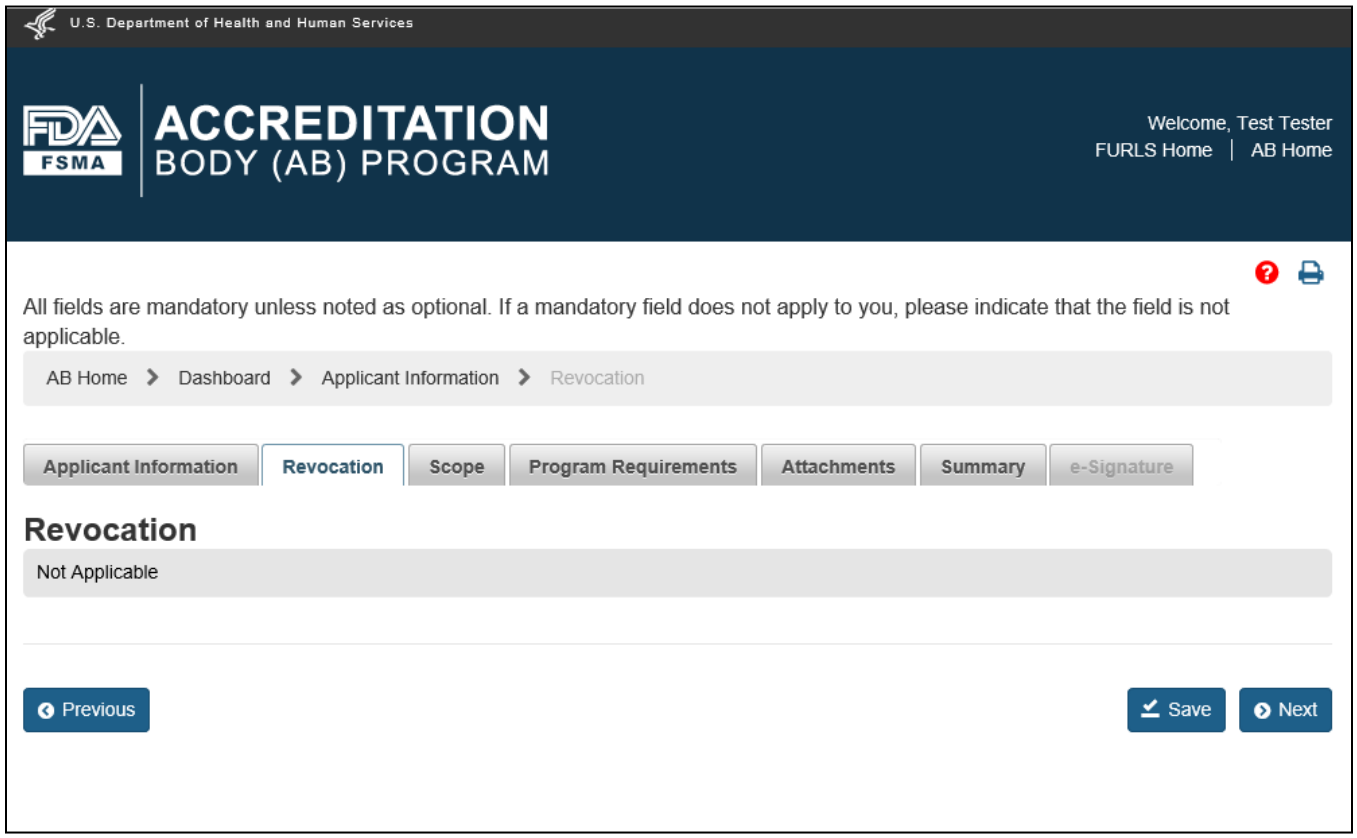
Click the “Next” button to proceed to the next page or, click on the “Revocation” tab.

The system will display the “Revocation” page (Figure 5.4).

5.2 Revocation Page

The system will indicate “Not Applicable” on the “Revocation” page. No action is required on this page.

Figure 5.4 – Revocation Page



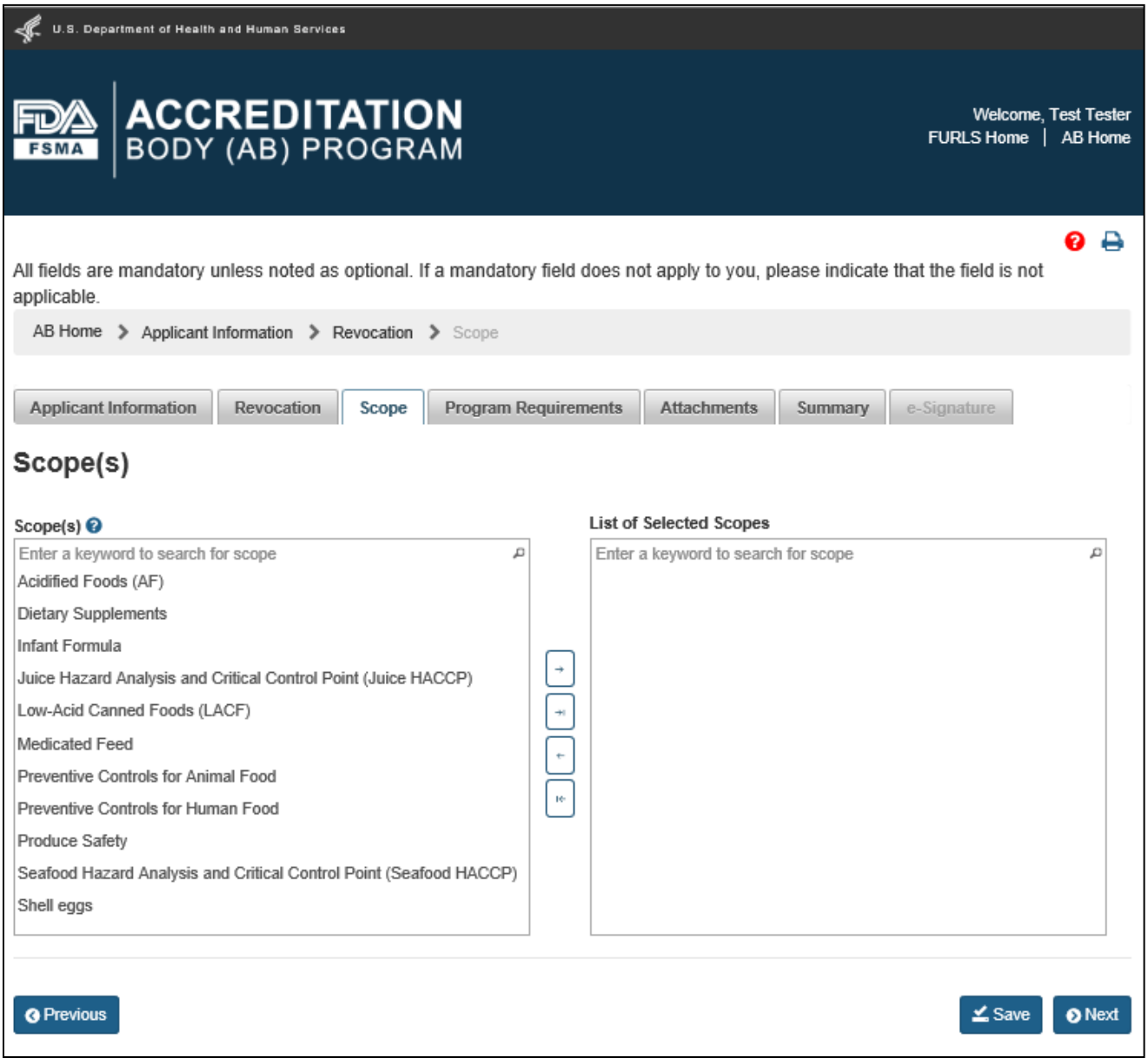
Click the “Next” button to proceed to the next page or, click on the “Scope” tab.

The system will display the “Scope” page (Figure 5.5).

5.3 Scope(s) Page

The “Scope(s)” page lists the scopes of recognition which you may select for your application.

Figure 5.5 – Scope Page



This page contains a list of the scopes of recognition (Figure 5.6). You may add any scopes for consideration in the application by selecting them from the “Scope(s)” section (on the left-hand side of the page) and adding them to the “List of Selected Scopes” (on the right-hand side of the page). Alternatively, scopes may be removed from the “List of Selected Scopes” section by

selecting them from the “List of Selected Scopes” section and adding them to the “Scope(s)” section.

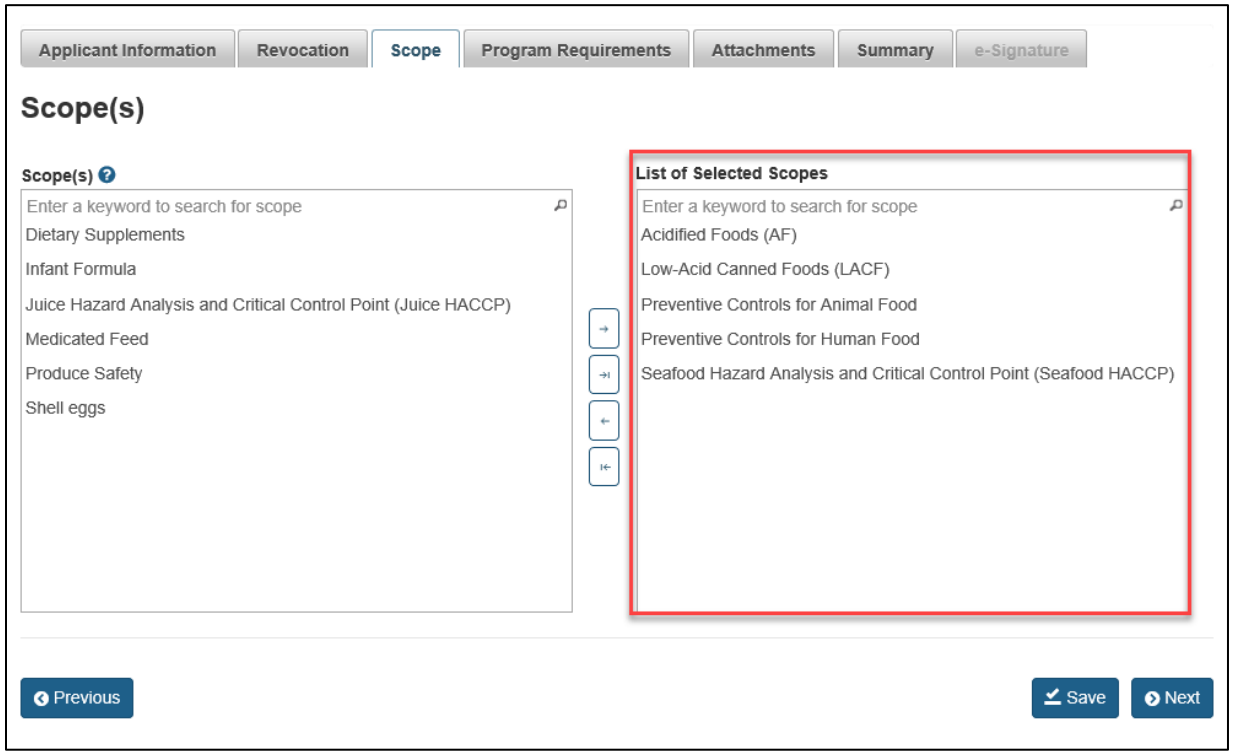
To select a scope, double click on the scope name to move it between sections. You may also left click on the scope name and it will appear highlighted. Select at least one scope and add it to the “List of Selected Scopes” section (on the right-hand side of the page) to complete the application.

Use one of the following buttons to add or remove the selected scope(s):

- “Add”– Moves the selected scope to the “List of Selected Scopes”
- “Add All” – Selects and moves all scopes to the “List of Selected Scopes”
- “Remove” – Removes one selected scope from the “List of Selected Scopes”
- “Remove All” – Removes all scopes from the “List of Selected Scopes”

Click the “Save” button when all scopes you are applying for have been selected.

Figure 5.6 – List of Selected Scopes



Click the “Next” button to proceed to the next page or, click on the “Program Requirements” tab.

The system will display the “Program Requirements” page.

5.4 Program Requirements Page

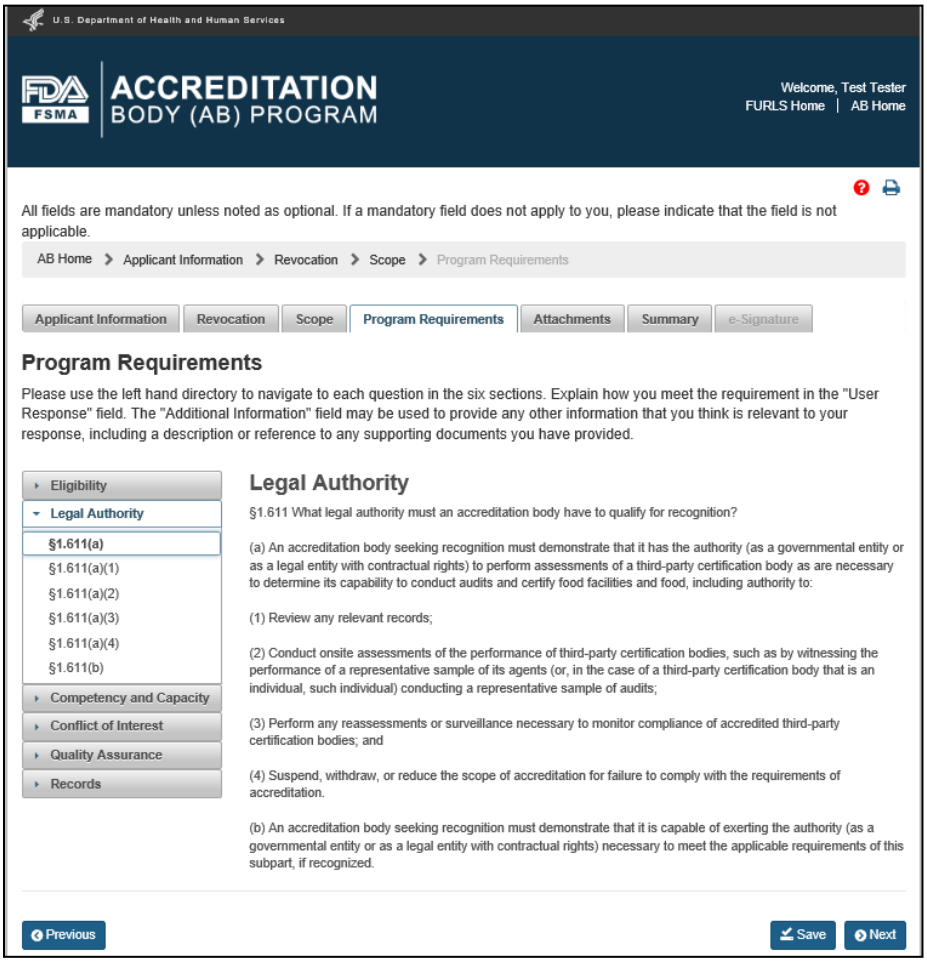
The “Program Requirements” page is where you will answer questions and attach files in accordance with the following requirement sections:

- Legal Authority
- Competency and Capacity
- Conflict of Interest
- Quality Assurance
- Records

The section names are listed on the left-hand side of the page. The “Legal Authority” section is expanded by default upon navigating to the page (Figure 5.7).

Note: The “Eligibility” section is informational only.

Figure 5.7 – Program Requirements Page Default View



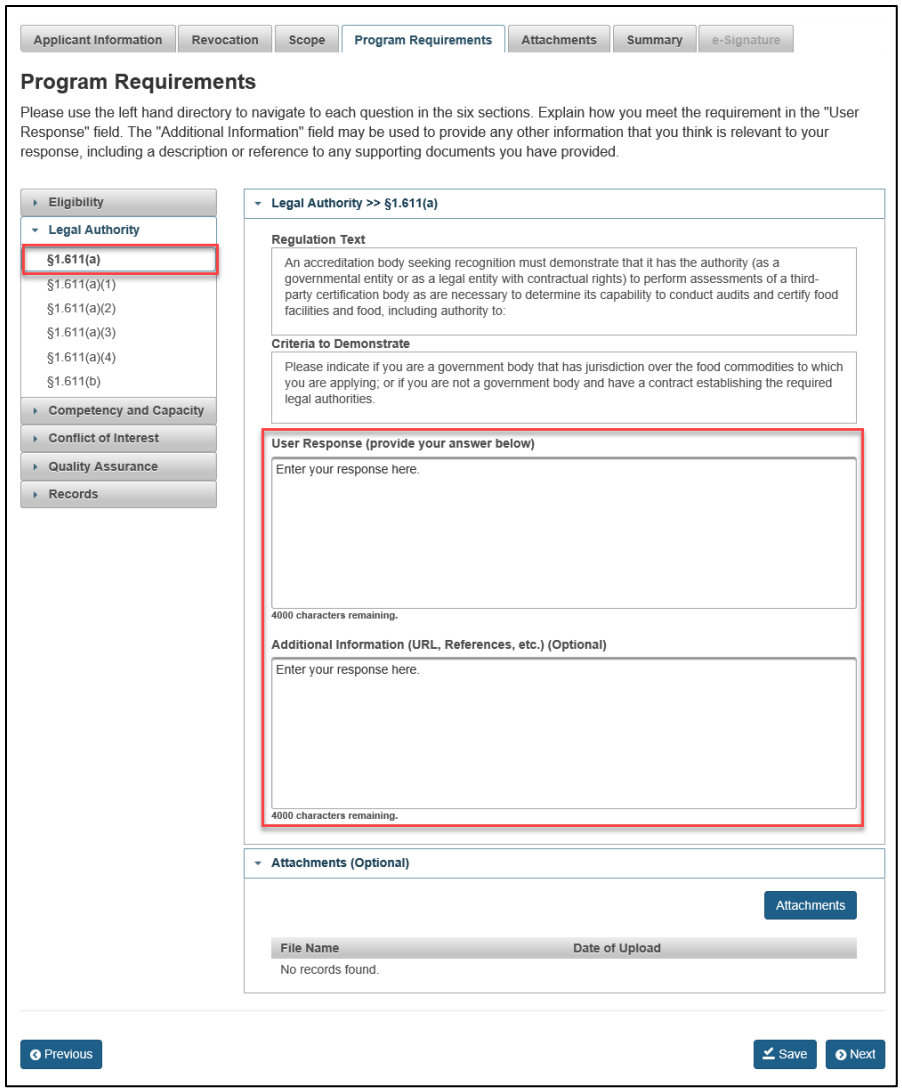
Each section has a definition and associated questions. Click the section heading to display the question links. Click on each requirement to display the user input fields (Figure 5.8).

The system will display the following user input fields for each question:

- **User Response (provide your answer below)** – This is a text entry field to respond to the "Regulation Text" and "Criteria to Demonstrate" read-only information displayed above each question. The text entry field allows for a maximum of 4,000 characters.
- **Additional Information (URL, References, etc.) (Optional)** – This is an optional text entry field to include any additional information. The text entry field allows for a maximum of 4,000 characters.

Note: All questions must be answered to complete the application process in the system.

Figure 5.8 – Program Requirements User Input Fields



Attachments may be uploaded with each response in the “Attachments (Optional)” section of the “Program Requirements” page.

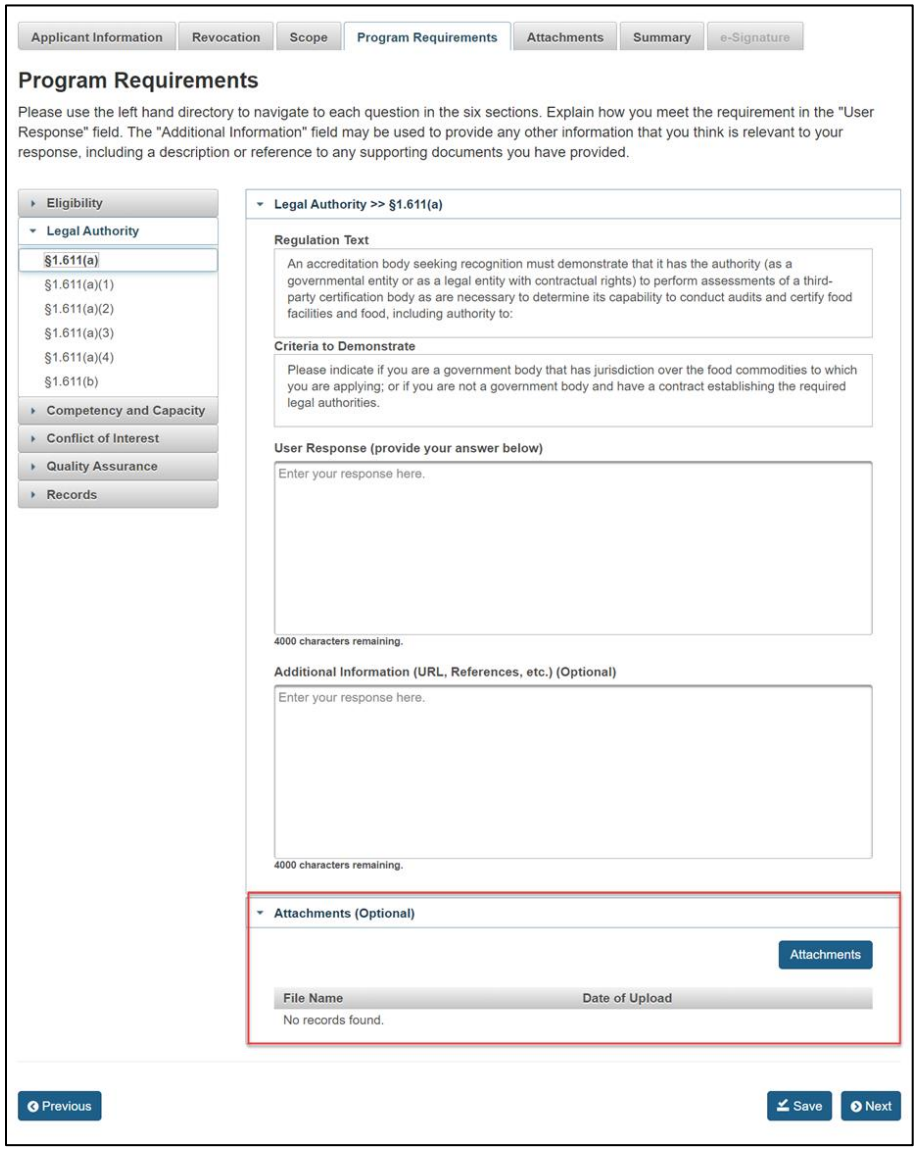
Attachments must be a document type supported by the system.

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.

Click the “Attachments” button in the “Attachments (Optional)” section to open the attachment window (Figure 5.9).

Figure 5.9 – Attachments Section



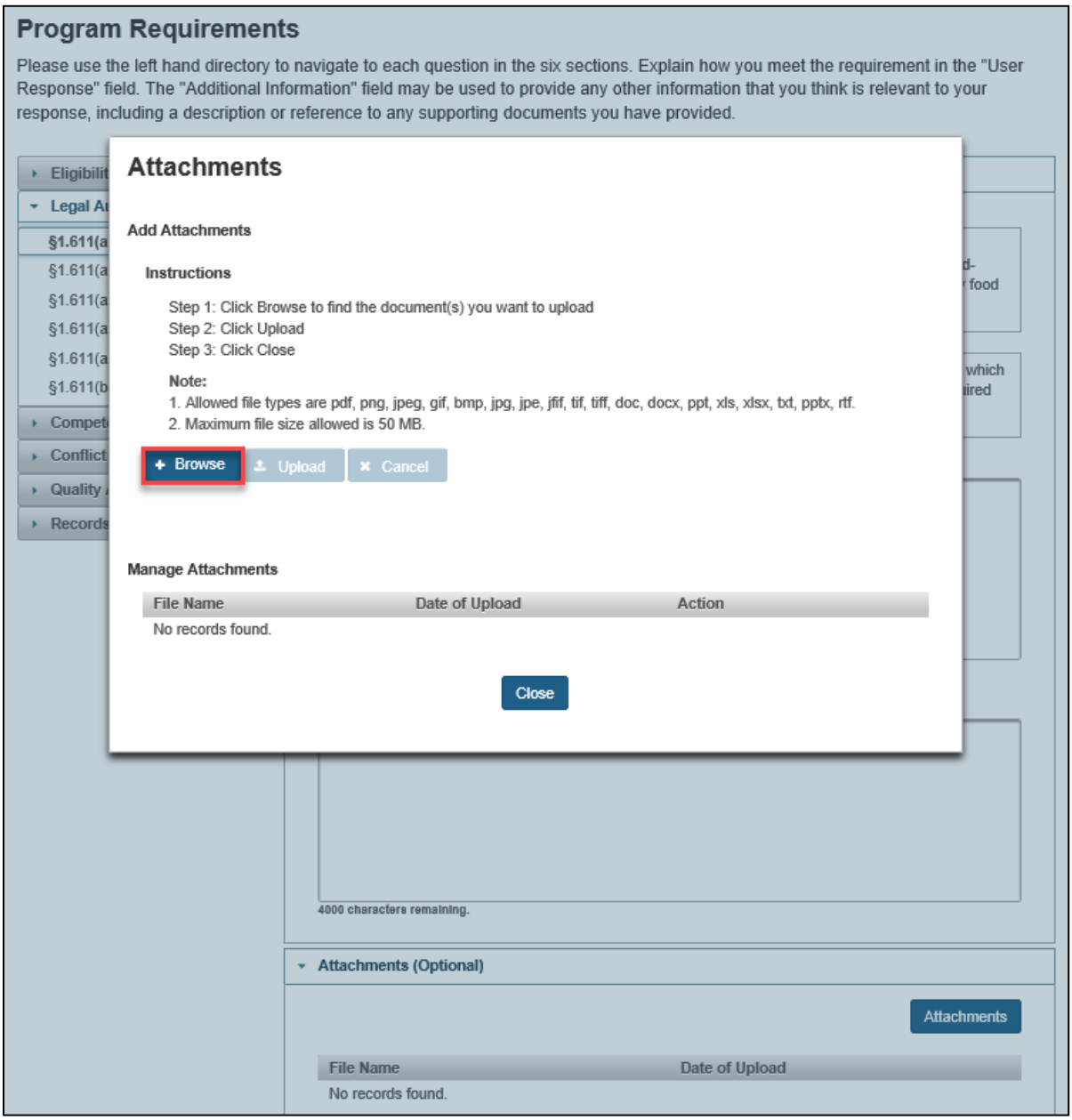
The system will display the “Attachments” pop-up window (Figure 5.10).

Click the “Browse” button in the “Attachments” window to select a file.

The “Upload” button will become enabled after a file has been chosen as an attachment.

Click the “Upload” button to complete the upload.

Figure 5.10 – Attachments Window

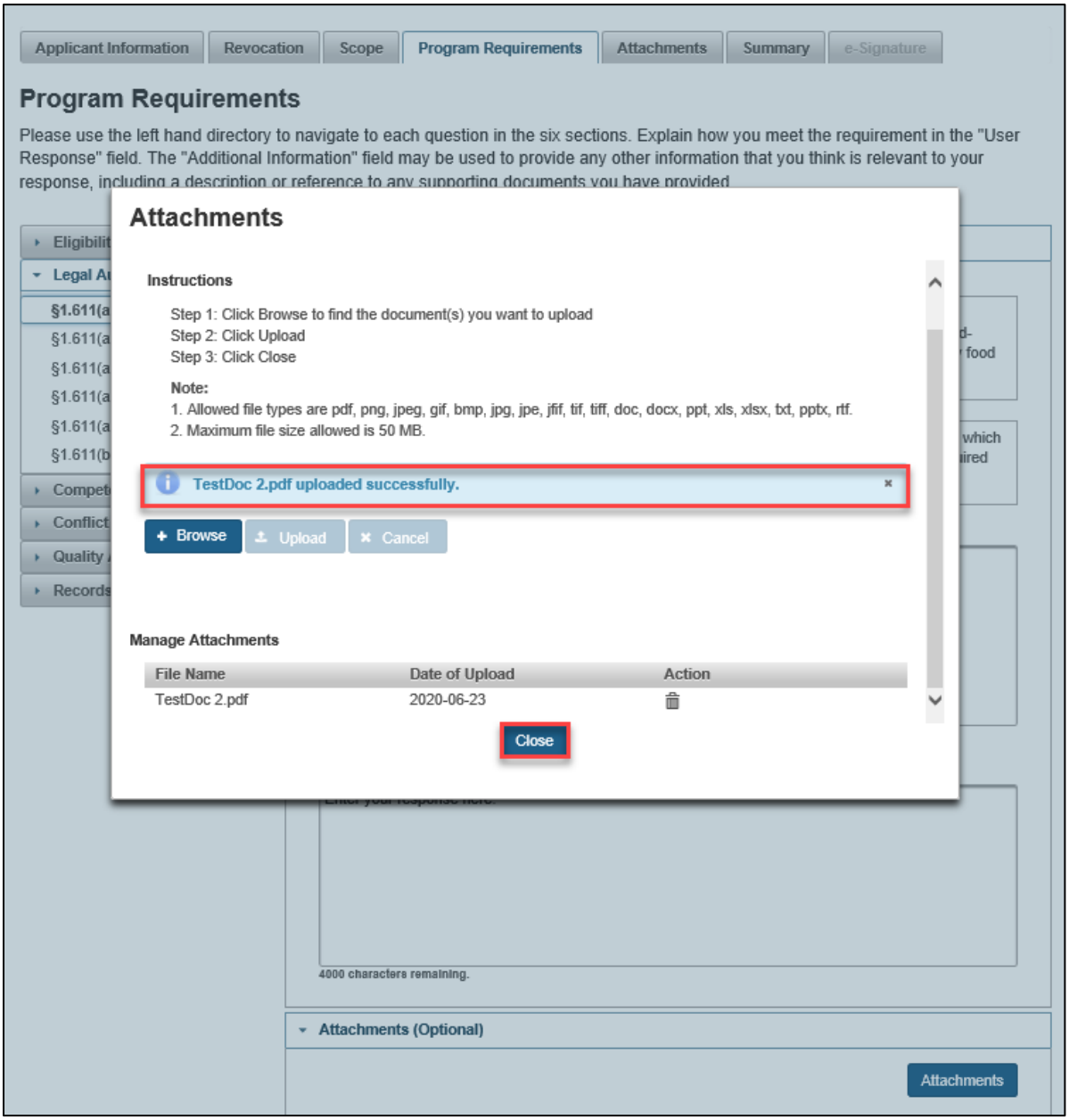


Once the upload is complete, a confirmation message with the file name will display in the "Attachments" window (Figure 5.11).

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

Click the "Close" button to close the "Attachments" window after the file has been uploaded.

Figure 5.11 – Attachments to Program Requirements Questions



Important: Click the "Save" button upon completion.

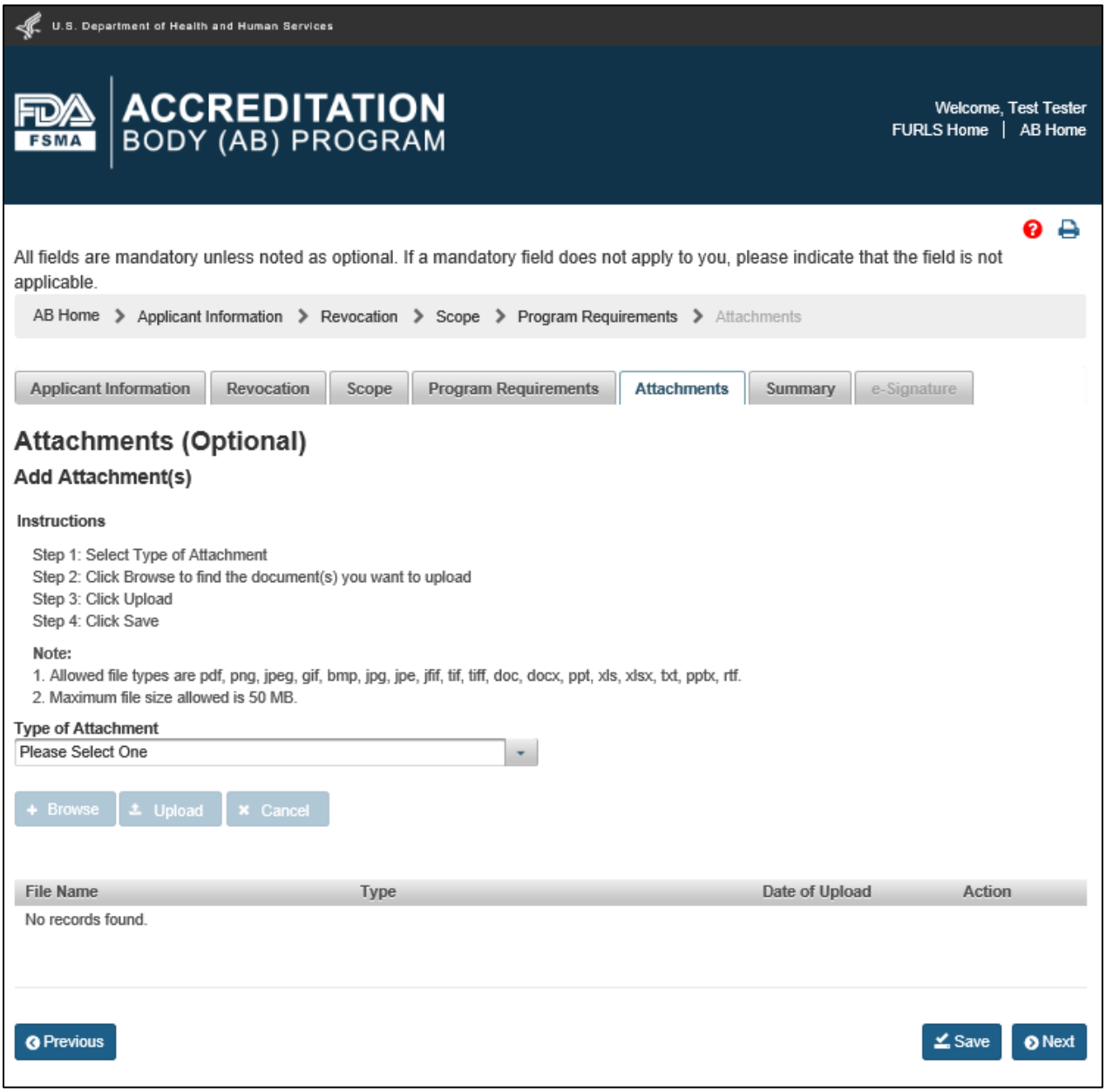
Proceed to the next page by clicking the “Next” button or by clicking on the “Attachments” tab.

The system will display the “Attachments” page.

5.5 Attachments Page

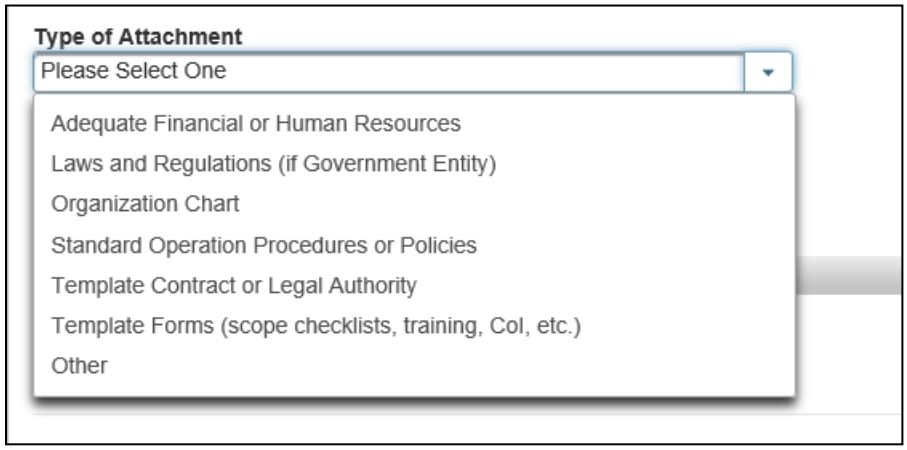
To upload additional documents to the application, follow the four-step process outlined on the “Attachments” page. The system will display uploaded files in the table at the bottom of the page (Figure 5.12). This page is optional.

Figure 5.12 – Attachment Instructions



Select the type of attachment from the list (Figure 5.13).

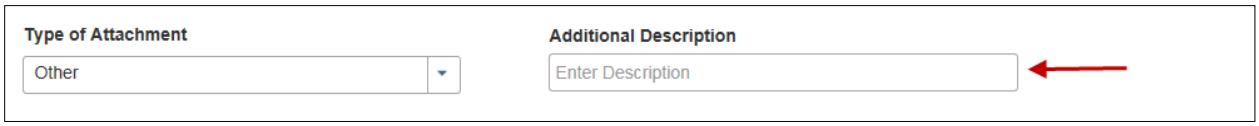
Figure 5.13 – Type of Attachment



If “Other” is selected from the list, a text entry field labeled “Additional Description” will display (Figure 5.14).

Enter a description of the document type in the “Additional Description” field (maximum of 45 characters).

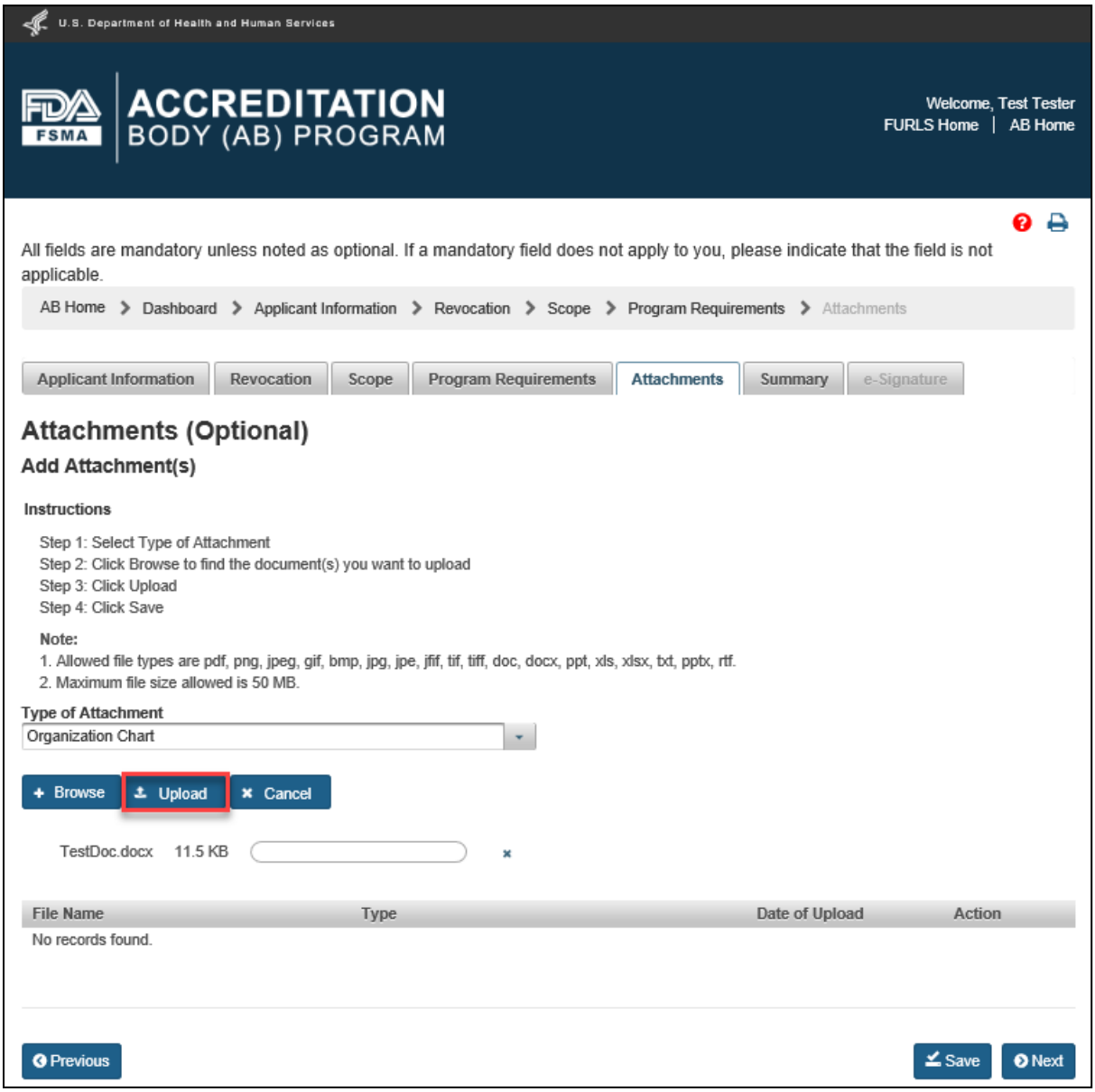
Figure 5.14 – Other Attachments



Once the “Type of Attachment” is selected, the “Browse” button will be enabled. Click the “Browse” button to search for and select the desired file for upload.

The browsing window will close once a file is selected. The “Upload” and “Cancel” buttons will be enabled once the browsing window closes (Figure 5.15).

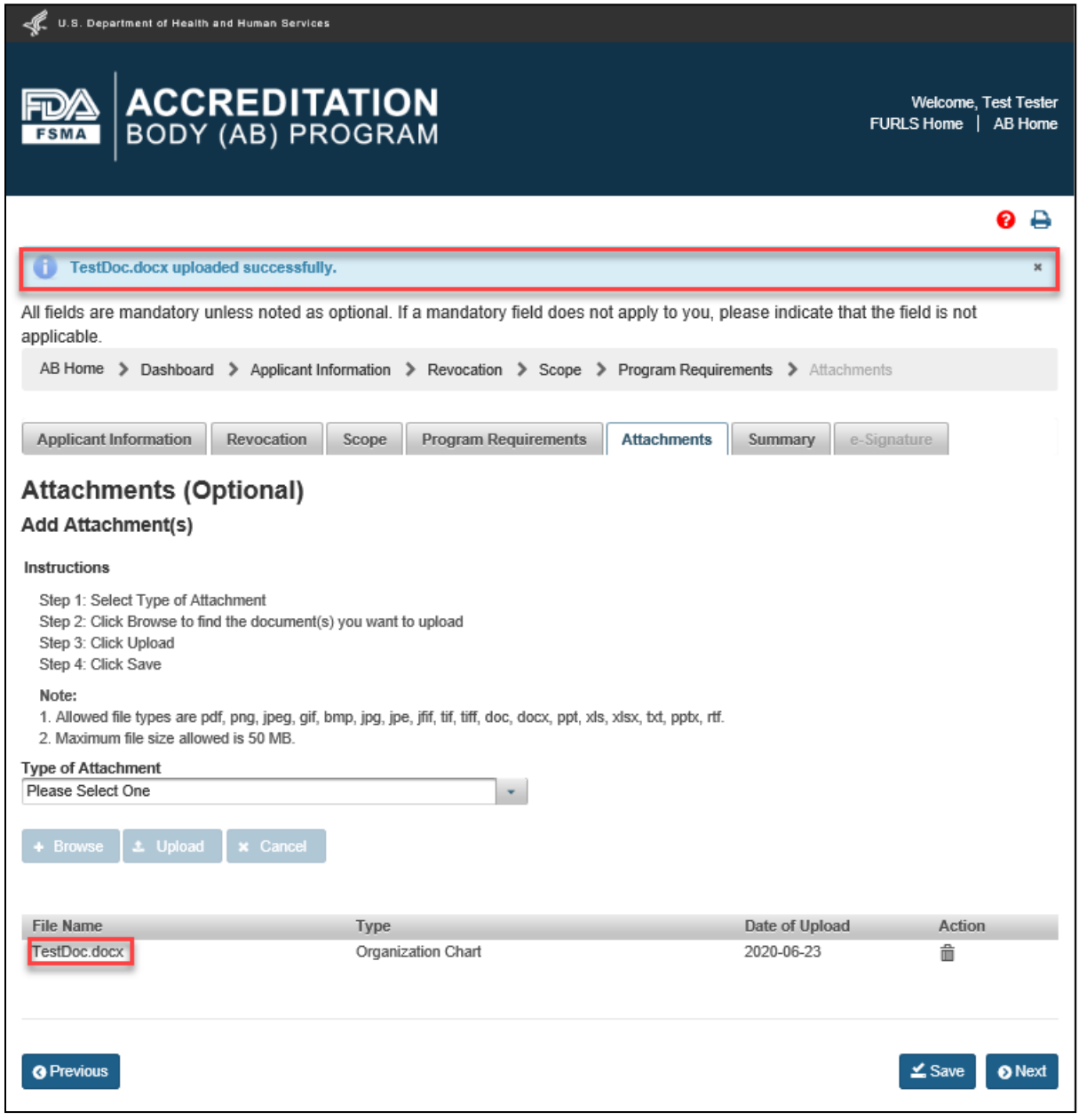
Figure 5.15 – Upload and Cancel Buttons



Click the “Upload” button to attach the file. Click the “Cancel” button to remove the file from the menu.

Confirmation of a successful upload will be displayed at the top of the page upon completion (Figure 5.16).

Figure 5.16 – Successful Upload Message



Follow the four-step process outlined on the page to upload any additional files.

After the files have been uploaded, click the “Save” button.

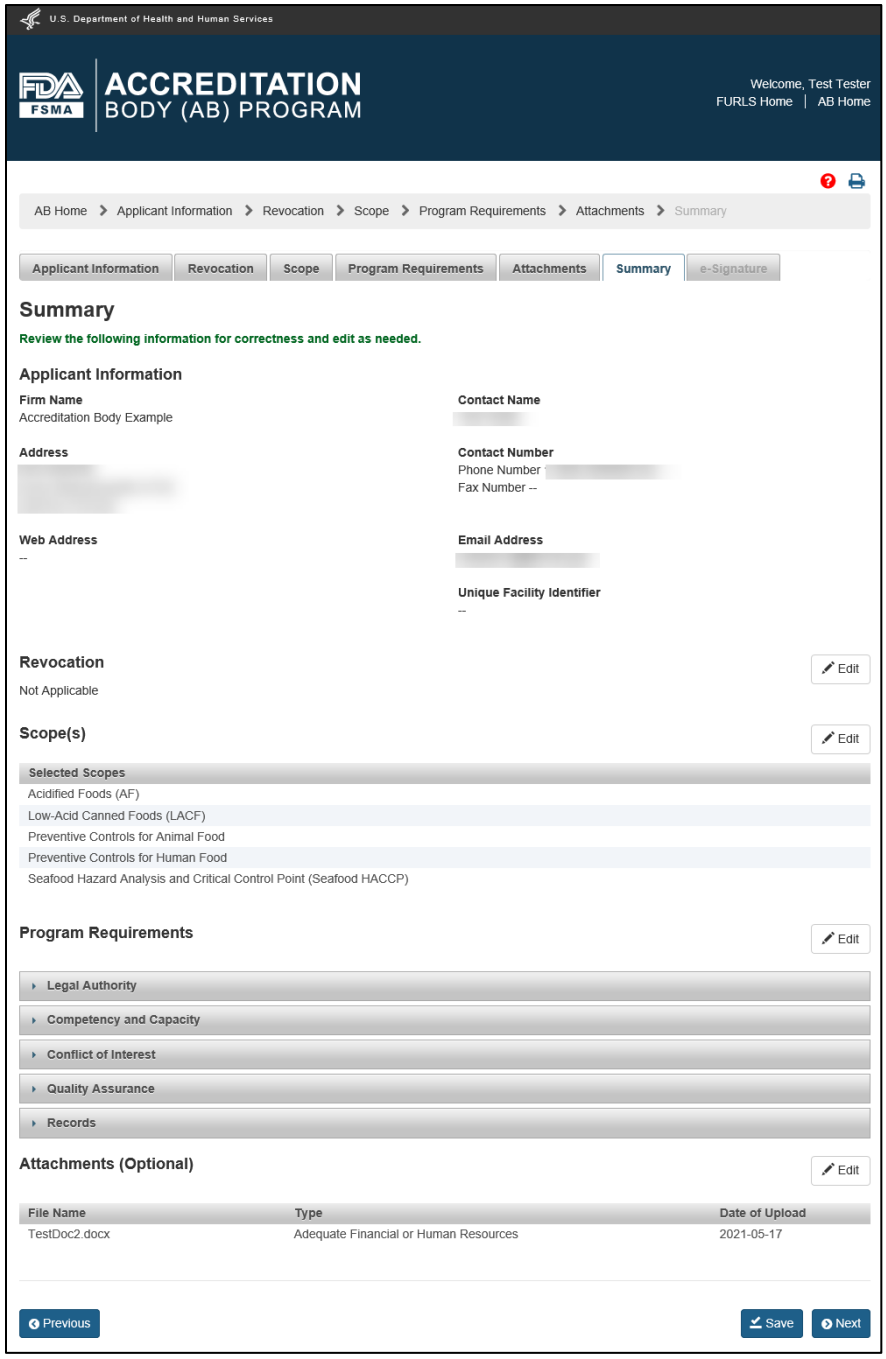
Click the “Next” button to proceed to the next page or, click on the “Summary” tab.

The system will display the “Summary” page.

5.6 Summary Page

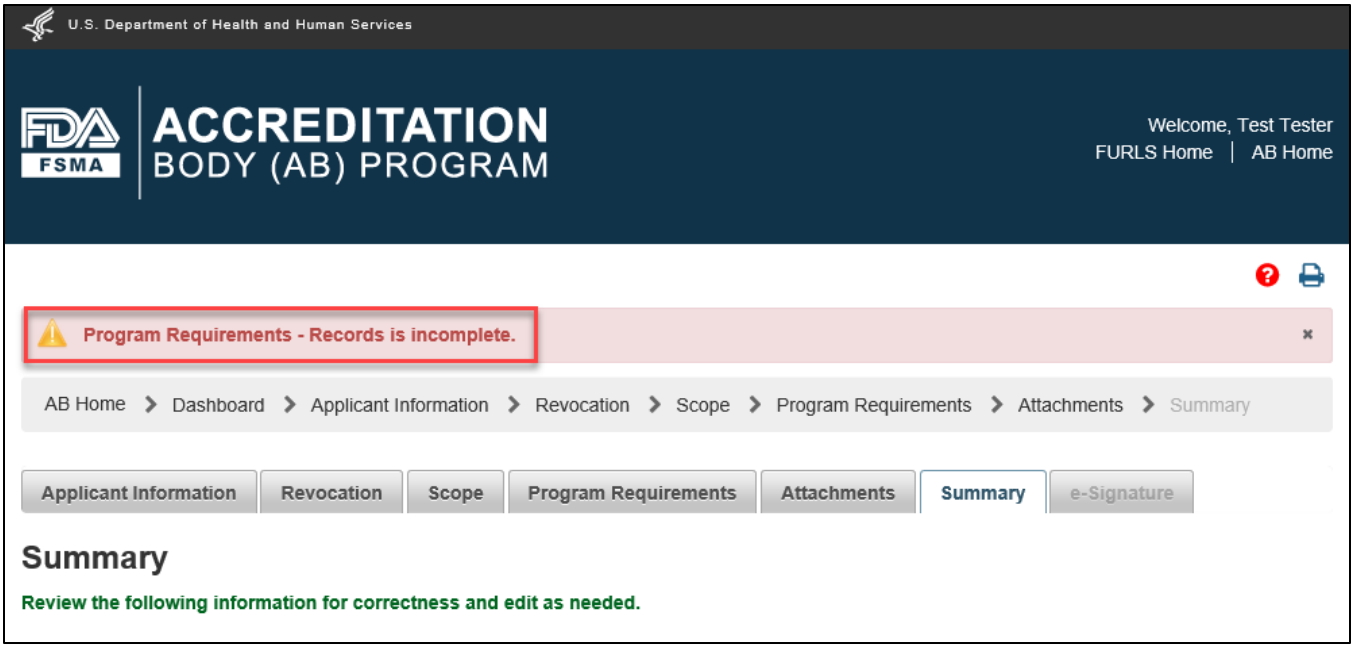
The “Summary” page allows you to review the information on the page for accuracy (Figure 5.17).

Figure 5.17 – Summary Page



After reviewing the information, click the “Next” button. The system will validate that all required fields have been completed. If an error is found, the system will post the relevant error message (Figure 5.18).

Figure 5.18 – Summary Page Error Message

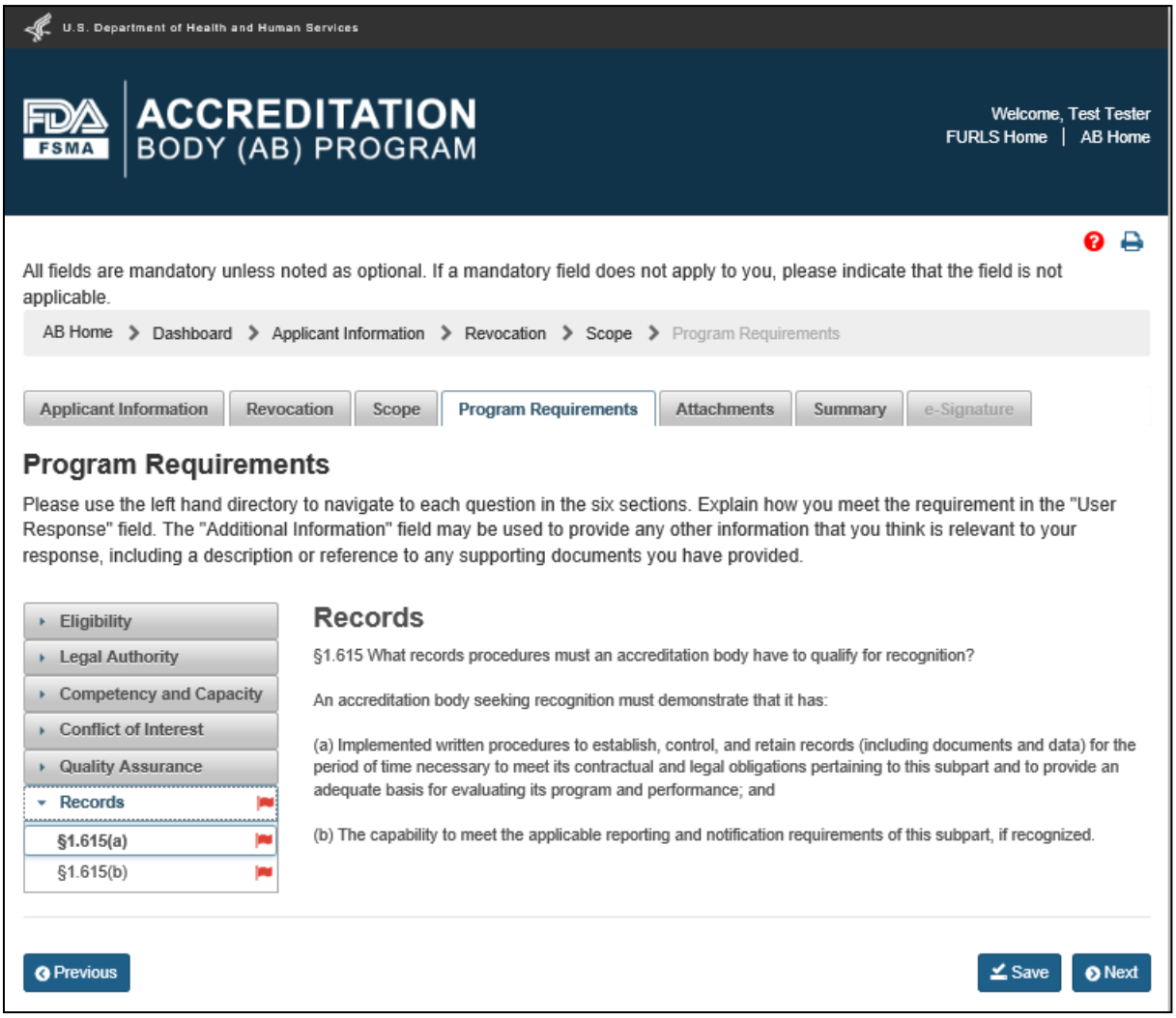


To be able to submit the application, correct any issues that were found and flagged by the system.

The system will mark errors on the “Program Requirements” page with a red flag icon if the response is incomplete (Figure 5.19). Any program requirement section that contains an error will display a red flag next to it in the dropdown menu.

Click the flagged section to expand the dropdown menu to view which specific questions have an error and complete the field.

Figure 5.19 – Flagged Program Requirements



If there are no errors, the system will display the “e-Signature” page.

5.7 e-Signature and Confirmation Page

Follow the directions provided on the “e-Signature” page (Figure 5.20).

Note: The “e-Signature” page does not become enabled until all errors indicated on the “Summary” page have been corrected and saved.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

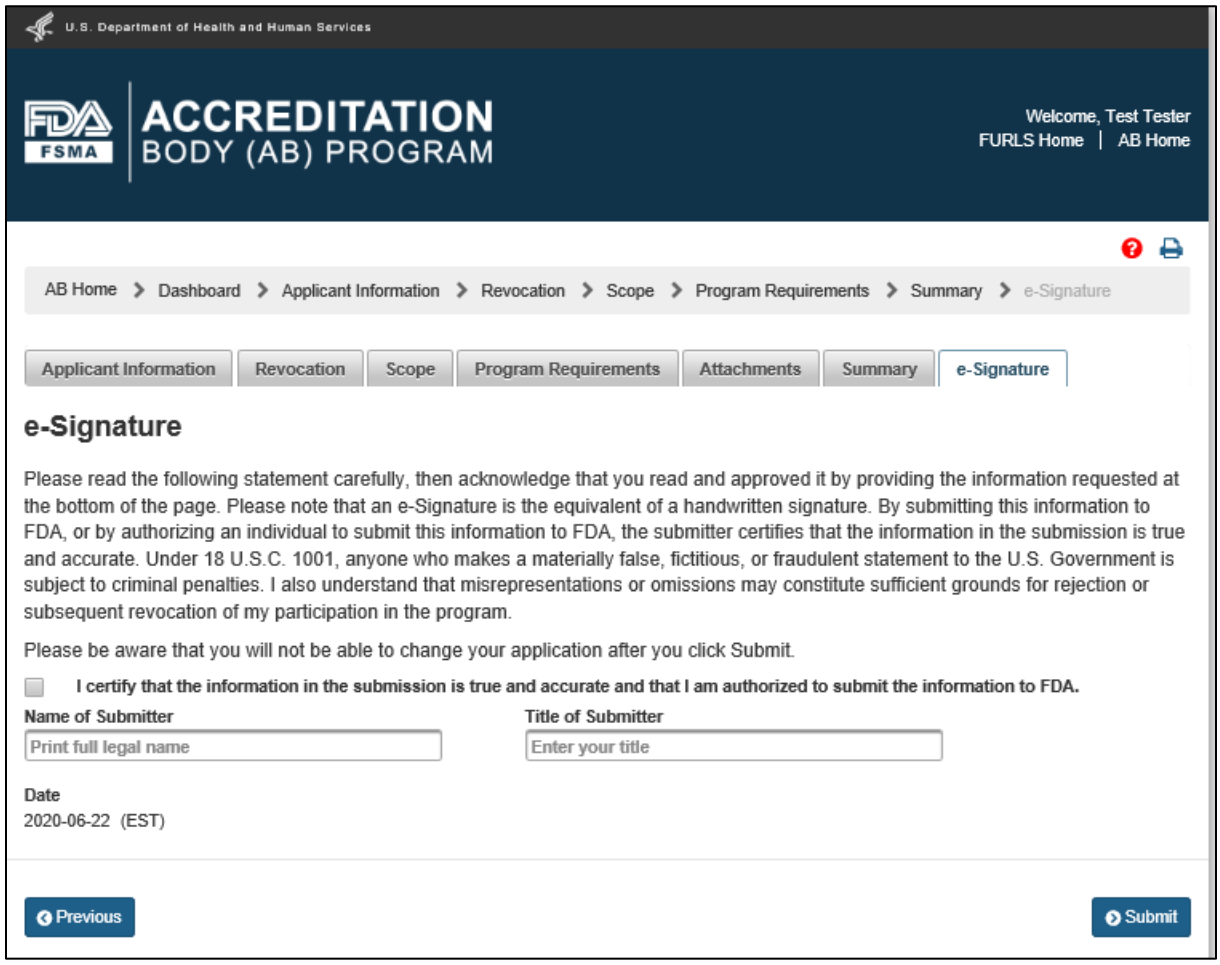
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Summary” page.

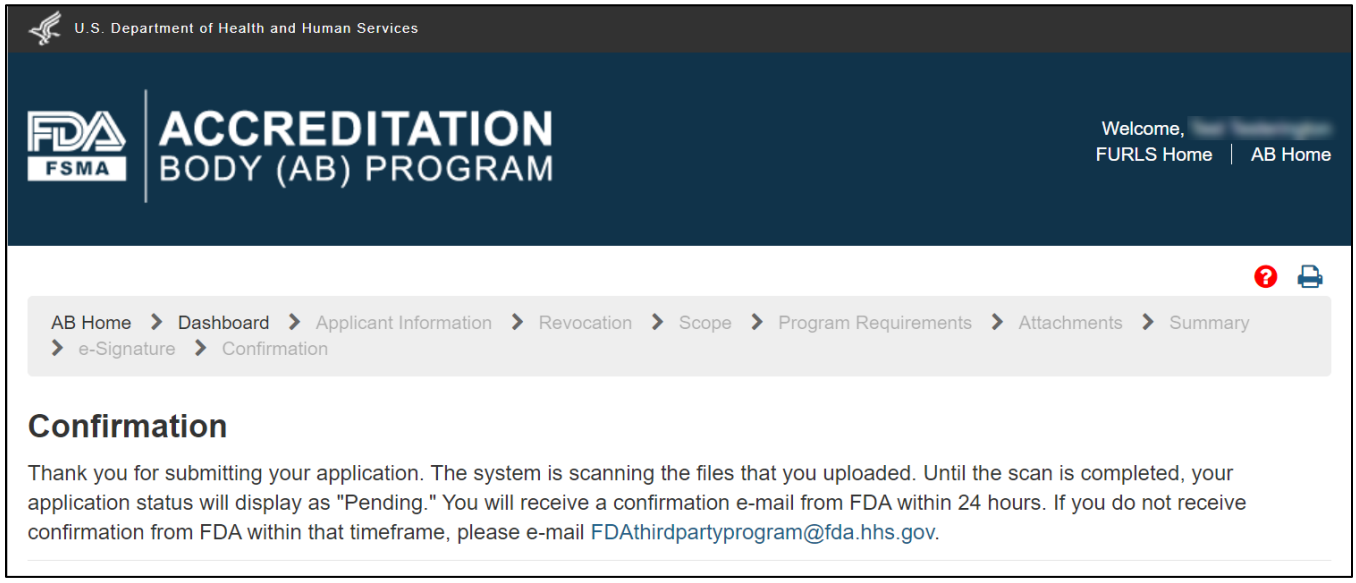
Click the “Submit” button to complete submission to FDA.

Figure 5.20 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 5.21).

Figure 5.21 – Confirmation Page

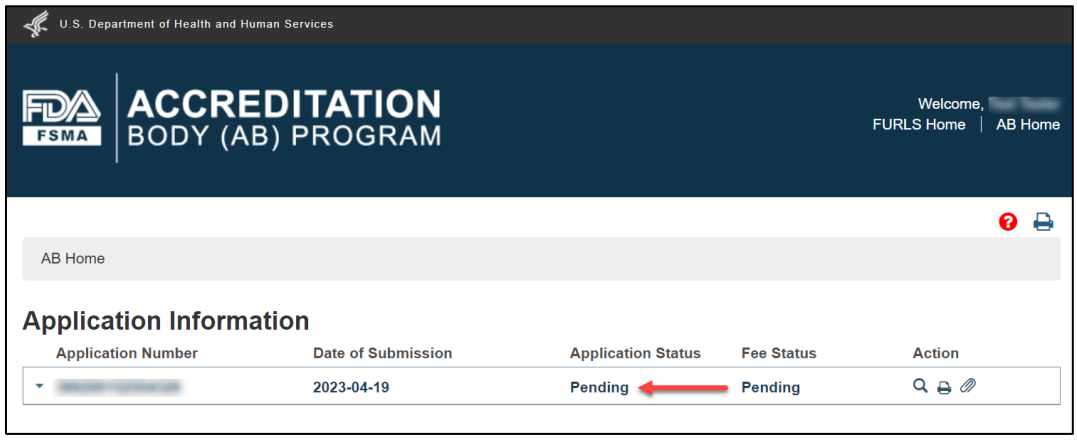


5.8 Application Status

To check the status of the application, refer to the “Application Information” page. To navigate to this page from the “Confirmation” page, click on the “Dashboard” breadcrumb at the top of the screen. To navigate to the ”Application Information” page from the “AB Home” page, select the “View/Edit my application for recognition” option from the left-hand navigation menu.

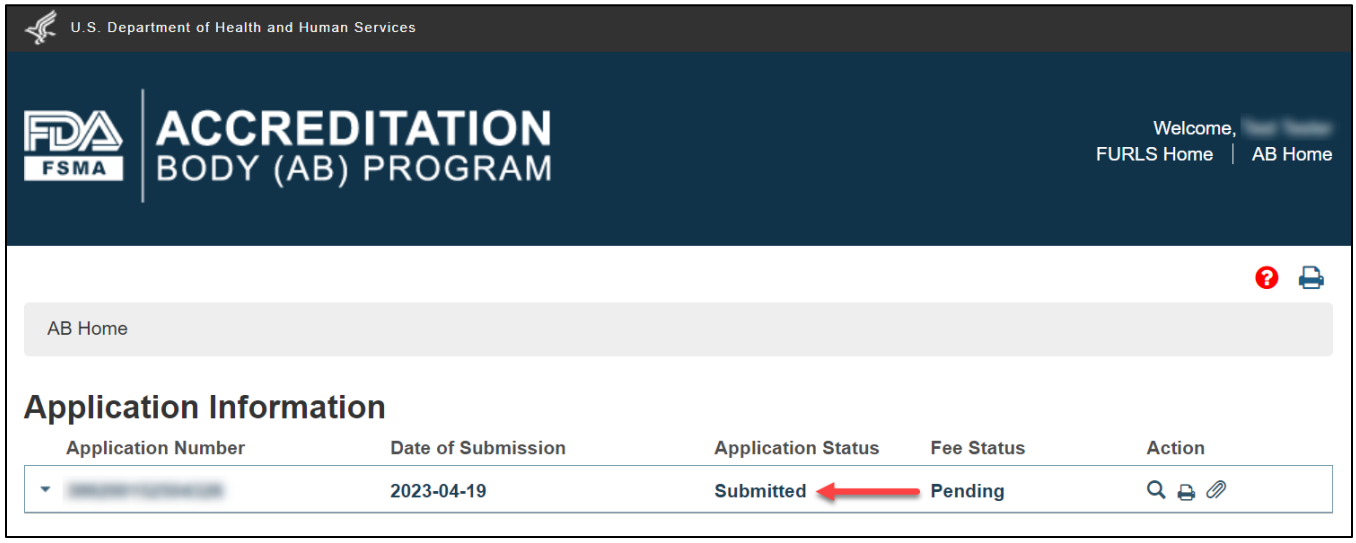
After the application has been submitted, it will be assigned an application number and the application status will be displayed as “Pending” on the “Application Information” page (Figure 5.22).

Figure 5.22 – Pending Application Status



When FDA receives the completed application, the status on the “Application Information” page will change to “Submitted” (Figure 5.23).

Figure 5.23 – Submitted Application Status



The system will send an e-mail to the address entered on the “Account Management” page indicating the application was received by FDA (Figure 5.24). Note that the image below only depicts the e-mail notification text.

FDA will begin review of your application once you have paid your user fee. As indicated in the email notification text, you will receive an invoice from the User Fee System with guidance on how to submit your payment.

Figure 5.24 – E-mail Notification

Thank you for applying to FDA's Accredited Third-Party Certification Program, your electronic submission has been received by the Agency. To process your application and to ensure all required data elements have been submitted, you must first pay the associated user fee. You will receive an invoice from the User Fee System with guidance on how to submit your payment. Once your payment has been received by the Agency, we will begin reviewing your application for participation in the program.

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U.S. Food and Drug Administration

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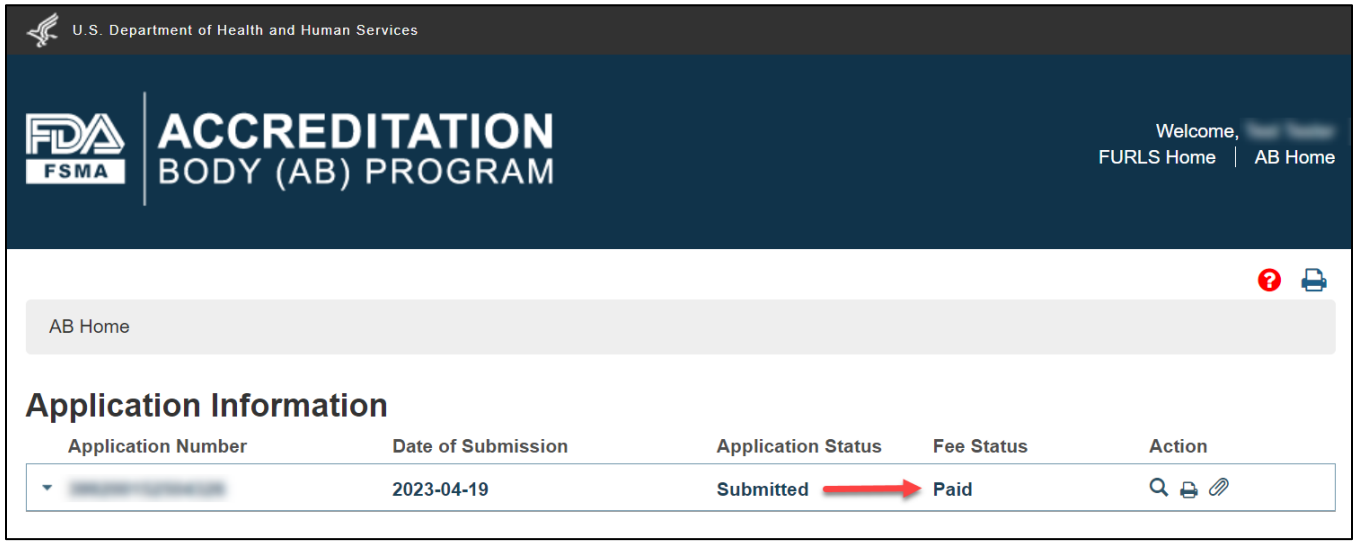
After the user fee has been received and processed, the “Fee Status” on the “Application Information” page will update from “Pending” to “Paid” (Figure 5.25).

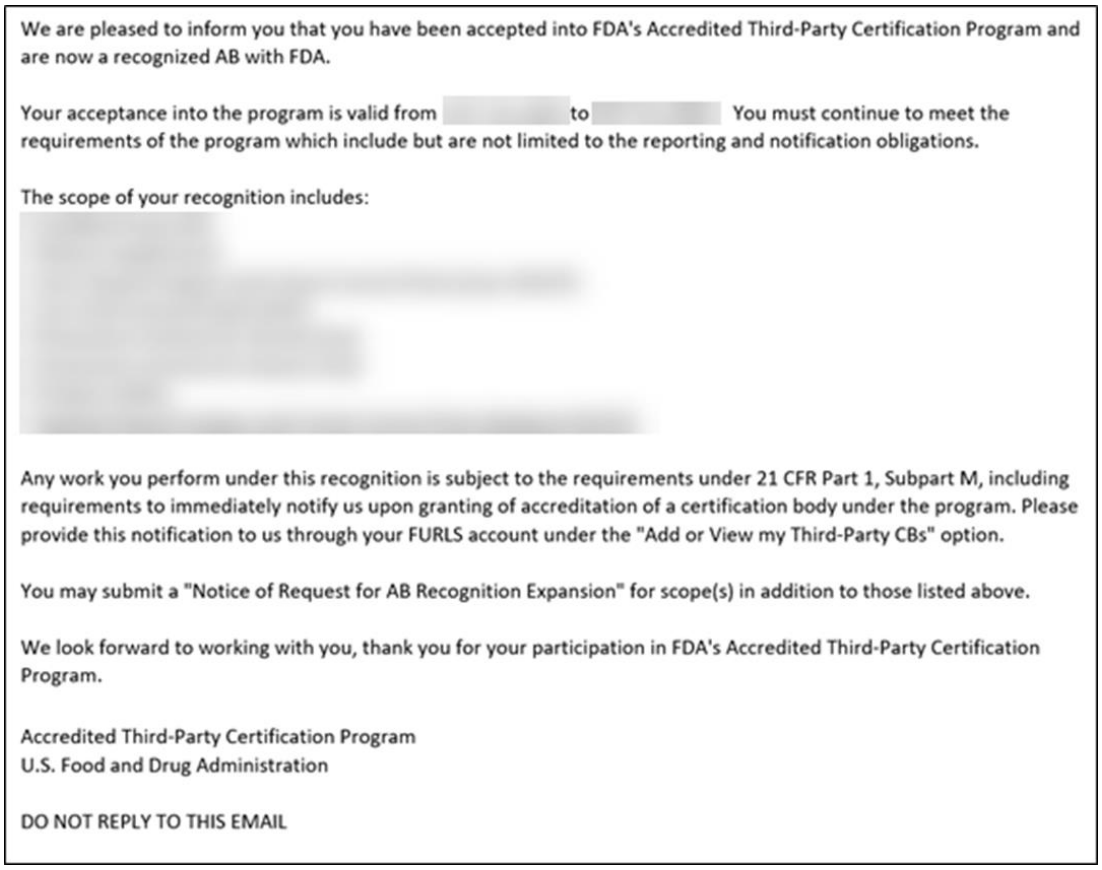
Figure 5.25 – Paid Fee Status



When FDA has made a decision on your application, you will receive an e-mail notification.

If your application has been approved, the system will send an e-mail to the address entered on the “Account Management” page (Figure 5.26). Note that the image below only depicts an example of the e-mail notification text.

Figure 5.26 – E-mail Notification



We are pleased to inform you that you have been accepted into FDA's Accredited Third-Party Certification Program and are now a recognized AB with FDA.

Your acceptance into the program is valid from [redacted] to [redacted] You must continue to meet the requirements of the program which include but are not limited to the reporting and notification obligations.

The scope of your recognition includes:

[redacted]

Any work you perform under this recognition is subject to the requirements under 21 CFR Part 1, Subpart M, including requirements to immediately notify us upon granting of accreditation of a certification body under the program. Please provide this notification to us through your FURLS account under the "Add or View my Third-Party CBs" option.

You may submit a "Notice of Request for AB Recognition Expansion" for scope(s) in addition to those listed above.

We look forward to working with you, thank you for your participation in FDA's Accredited Third-Party Certification Program.

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U.S. Food and Drug Administration

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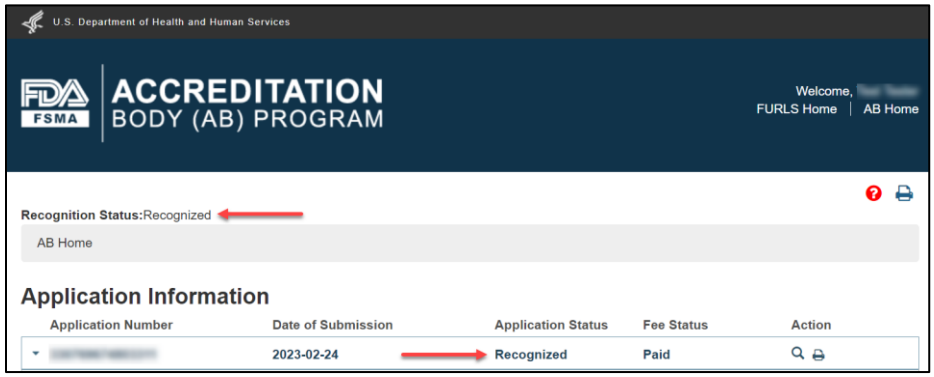
The “Application Status” and “Recognition Status” will display as “Recognized” on the “Application Information” page (Figure 5.27).

Figure 5.27 – Recognized Status



Each of the approved scopes will display as “Approved,” along with the start and expiration dates for the recognition of each approved scope.

As a Recognized AB, you will now have access to perform the following functions in the FURLS system:

- Add and view accredited CBs – Refer to Chapter 9 “Add or View Third-Party Certification Bodies (CBs)”
- Renew and expand the accreditation of CBs – Refer to Chapter 11, Section 11.6 “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB”
- Upload and submit documents – Refer to Chapter 10 “Supplemental Documentation”
- Submit reports and notifications – Refer to Chapter 11 “Reports and Notifications”
- Submit your application for renewal of recognition – Refer to Chapter 8 “Apply for Renewal of Recognition”

If your application has been returned for additional information, refer to Chapter 6, “Application Returned for Action.”

If your application has been denied, refer to Chapter 7, “Submit Reconsideration Request.”

6 Application Returned for Action

The “Returned for Action” functionality may be used when FDA determines that additional information is needed in an application.

If the application has been returned for additional information, the system will send an e-mail to the address entered on the “Account Management” page indicating the program requirement(s) where additional information is being requested (Figure 6.1). Note that the image below only depicts an example of the e-mail notification text.

Figure 6.1 – E-mail Notification

Thank you for your interest in participating in FDA's Accredited Third-Party Certification Program. Upon review of your application, the Agency has determined the need for additional information and/or clarification. In order for the Agency to continue its review of your application, you must address the following issues:

§1.611 - Legal Authority.

Until the Agency receives the information identified above, your application package will be held in abeyance. Please note, if the requested information is not received in a timely manner it may result in a need for re-application on your part.

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U.S. Food and Drug Administration

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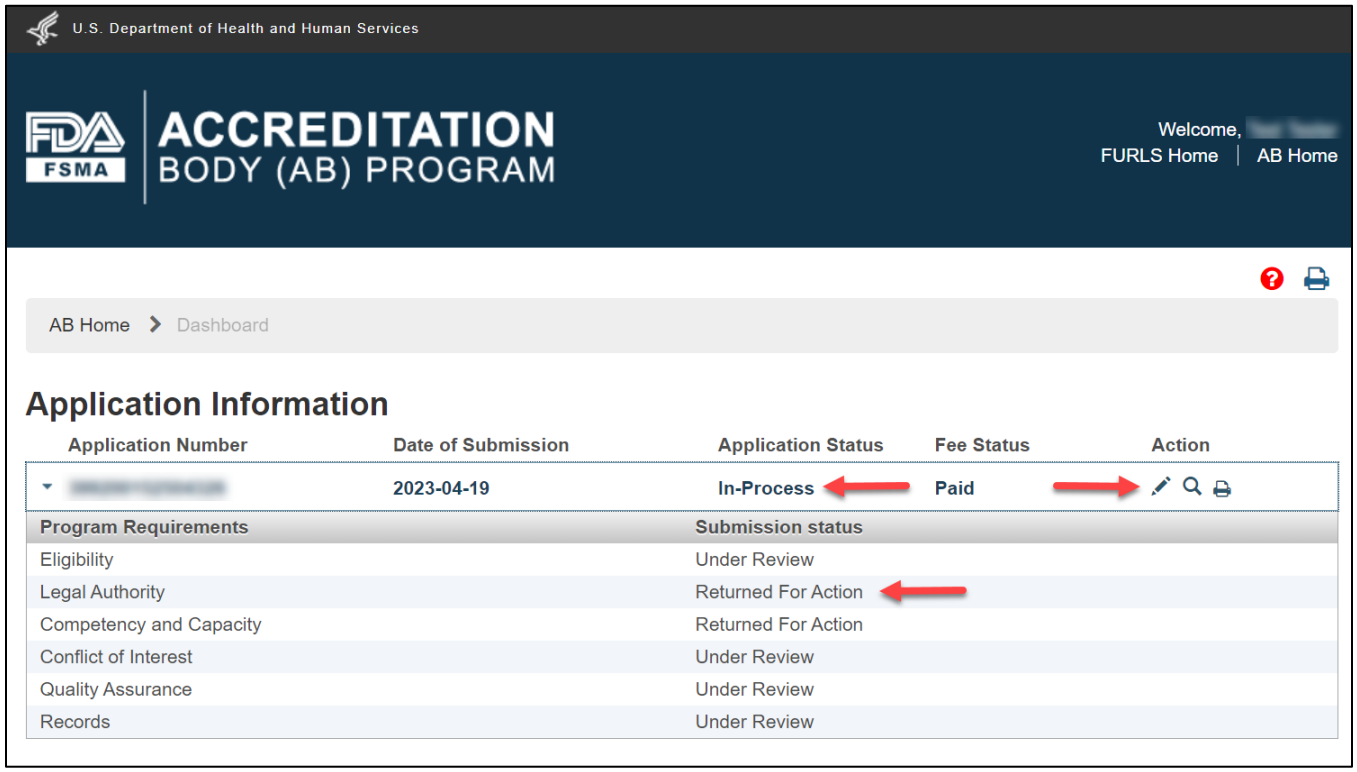
FDA will continue the application review process after the requested information is submitted.

The application status will display as “In-Process” on the “Application Information” page (Figure 6.2).

The submission status will be displayed as “Returned for Action” for the program requirement(s) where additional information was requested. The status of all other program requirements criteria will display as “Under Review.” To address the information request from FDA, click the pencil/edit icon in the “Action” column on the “Application Information” page.

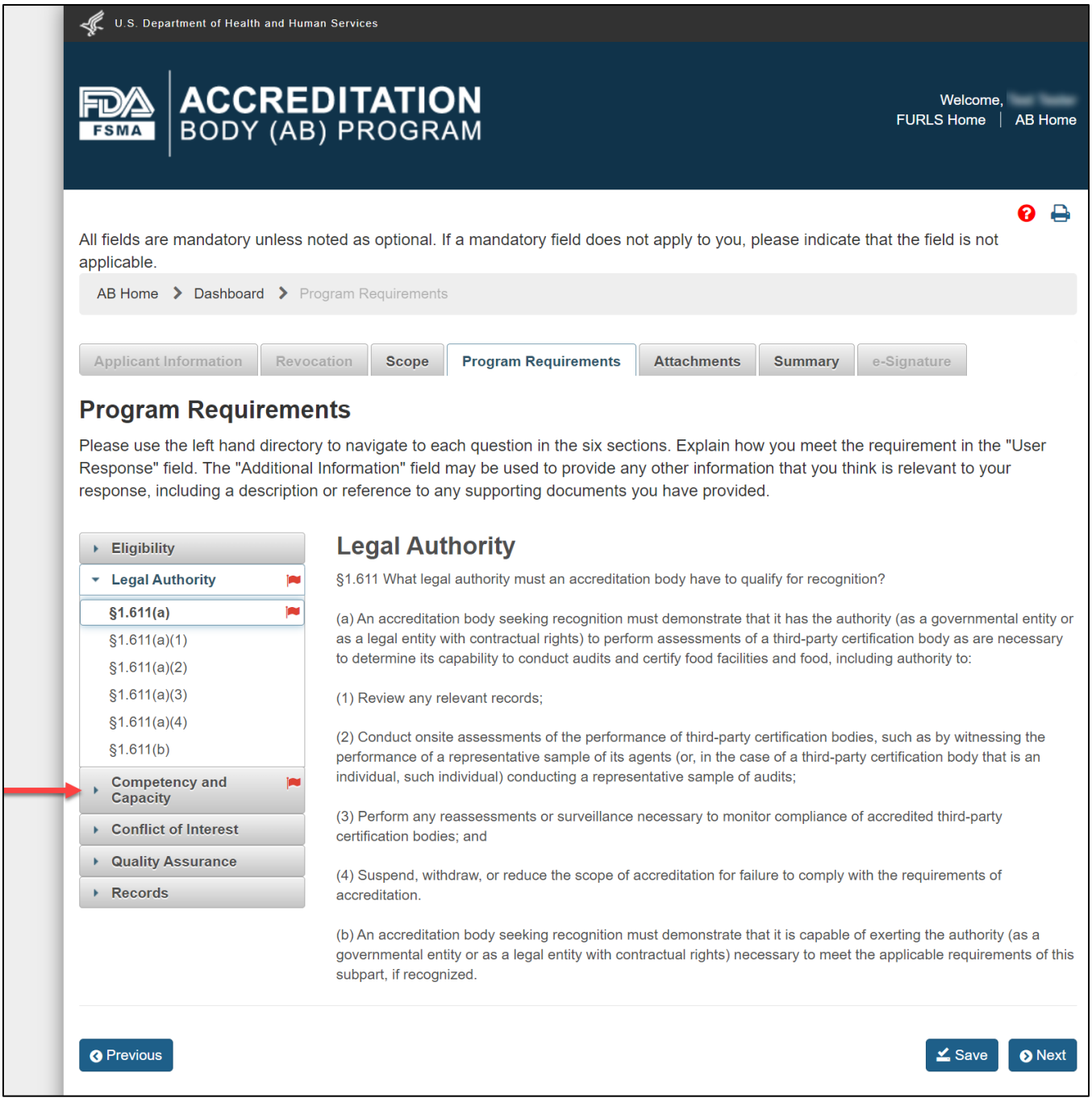
Figure 6.2 – In-Process Application Status and Edit Icon



After the pencil/edit icon in the “Action” column is clicked, the system will open the “Program Requirements” page (Figure 6.3). Program requirements criteria that display red flags indicate a response is needed. Navigate to the red-flagged section to provide the answers, information, and/or attachments.

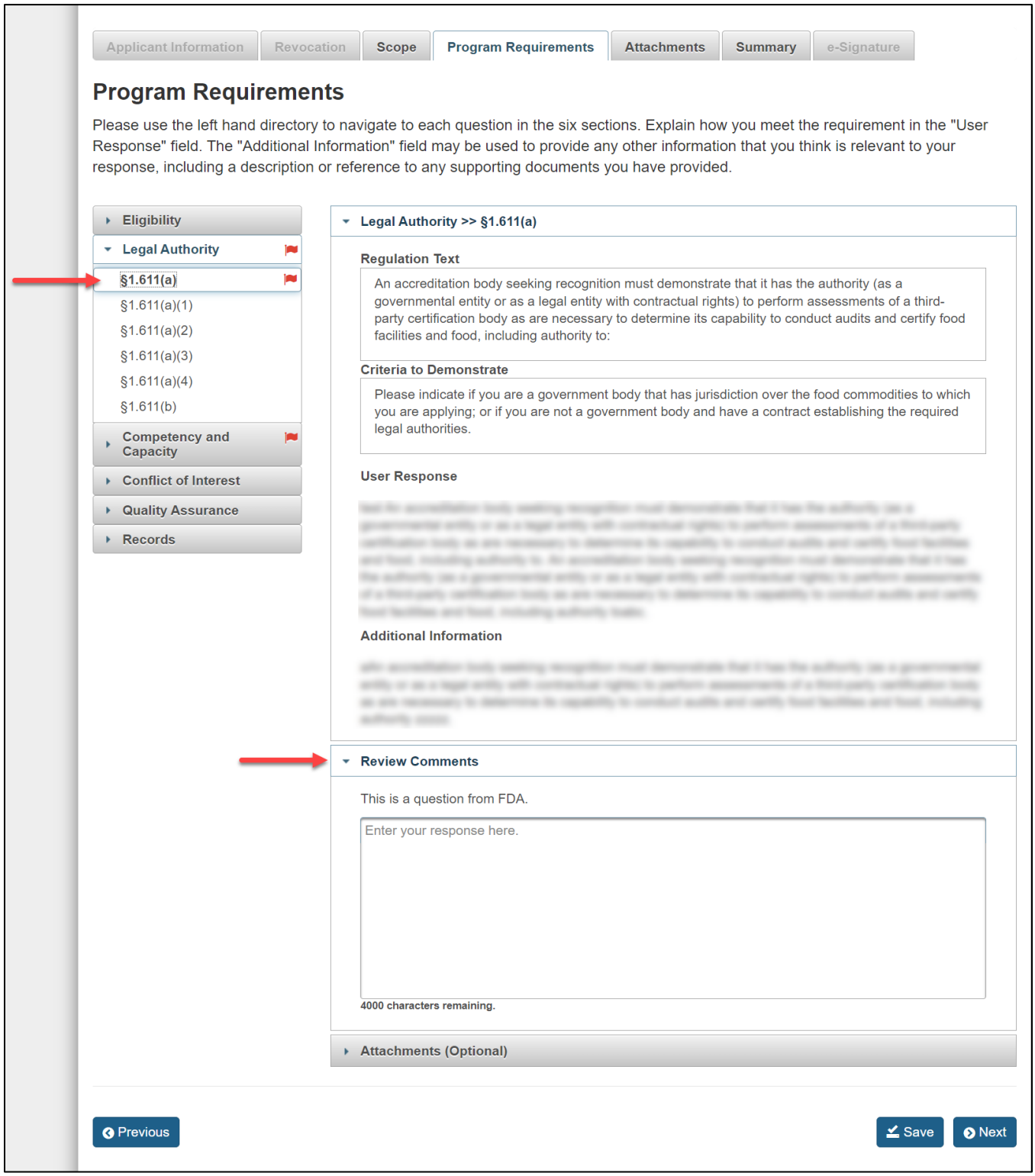
Click on the arrow next to the program requirement section name to expand the section.

Figure 6.3 – Program Requirements Page with Red Flags



Click on the red-flagged question link to view the question from FDA in the “Review Comments” section (Figure 6.4).

Figure 6.4 – Review Comments Section



Enter your response in the text entry box, which allows up to 4,000 characters. Attachments may be uploaded with each response in the “Attachments (Optional)” section of the “Program Requirements” page.

Attachments must be a document type supported by the system.

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.

Click the “Attachments” button in the “Attachments (Optional)” section to open the attachment window.

Note: If FDA has sent questions for more than one program requirement section, you may submit your responses for each section separately, if desired. However, if there are multiple questions for a single program requirement section, you need to respond to all questions for that section in order to submit your responses.

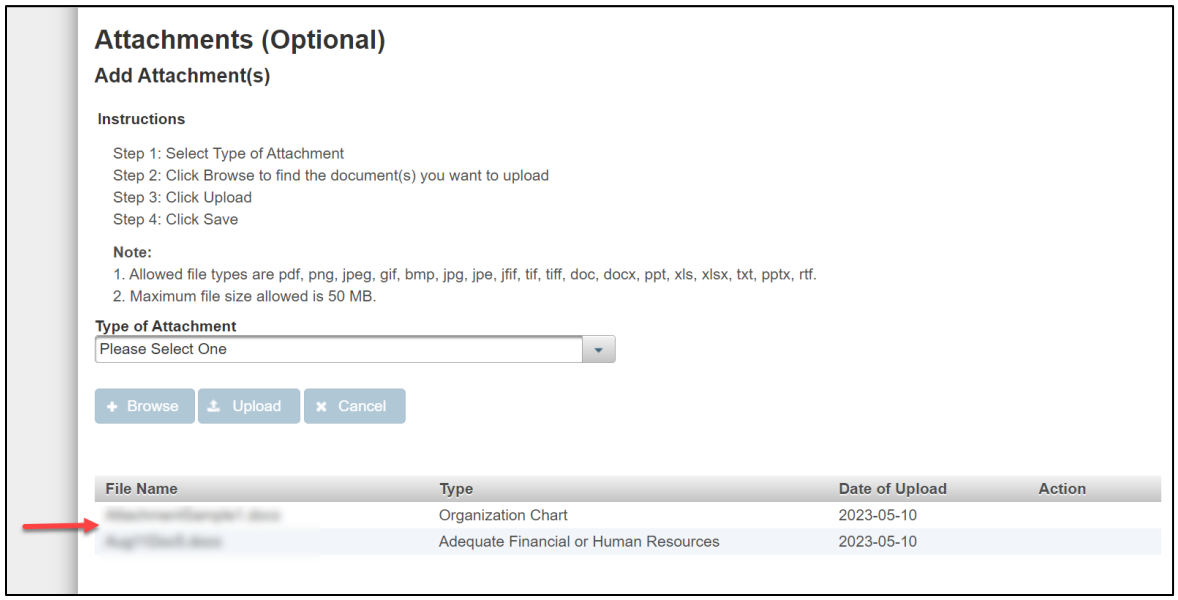
Refer to Section 5.4 of this document for instructions on completing the “Program Requirements” section, if needed.

Additional Revisions

In addition to the “Program Requirements” page, the “Scope” and “Attachments” page also will be enabled when the application is returned for action. If you choose to do so, the system will allow you to upload more documents and modify the scope selection at this time.

- **Attachments** – You may upload any additional documents in the “Attachments” page of the application to include with the response to FDA. Documents you included with your initial application submission will be listed in the table at the bottom of the page (Figure 6.5). Refer to Section 5.5 of this document for instructions on uploading additional documents in the “Attachments” page, if needed.

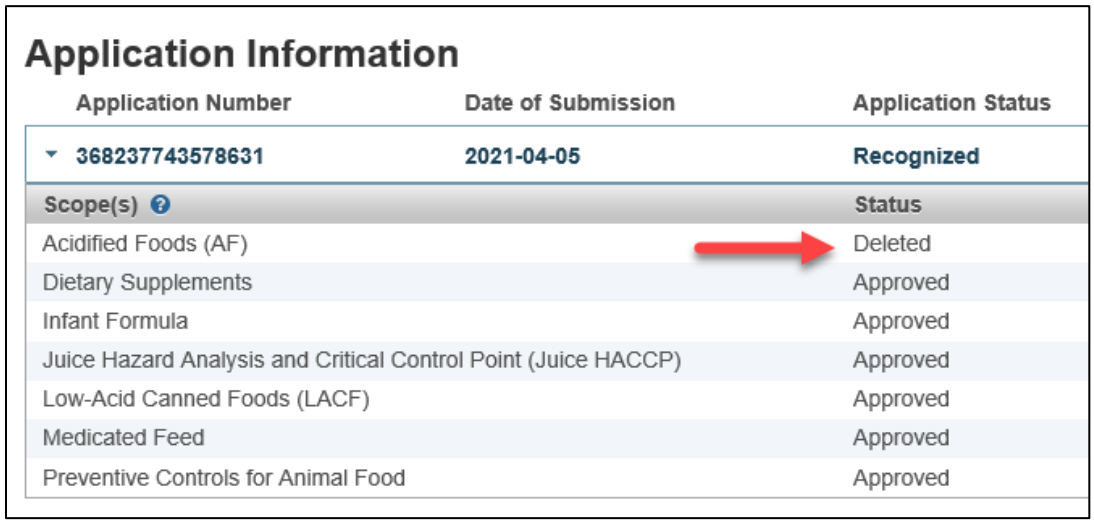
Figure 6.5 – Attachments from Initial Application Submission



- **Scopes** – The "List of Selected Scopes" section of the "Scope" page will be pre-filled with the scopes that were submitted with your initial application. You may add any scope(s) not included in the initial submission to FDA, if desired. You can also delete any scope(s) you no longer want to include as part of the recognition application. Refer to Section 5.3 of this document for instructions on adding or removing scopes, if needed.

  Note: Any scope included in the initial application that you deleted when the application was returned for action (and remain deleted at the time of approval) will display as "Deleted" on the "Application Information" page (Figure 6.6).

Figure 6.6 – Deleted Scope

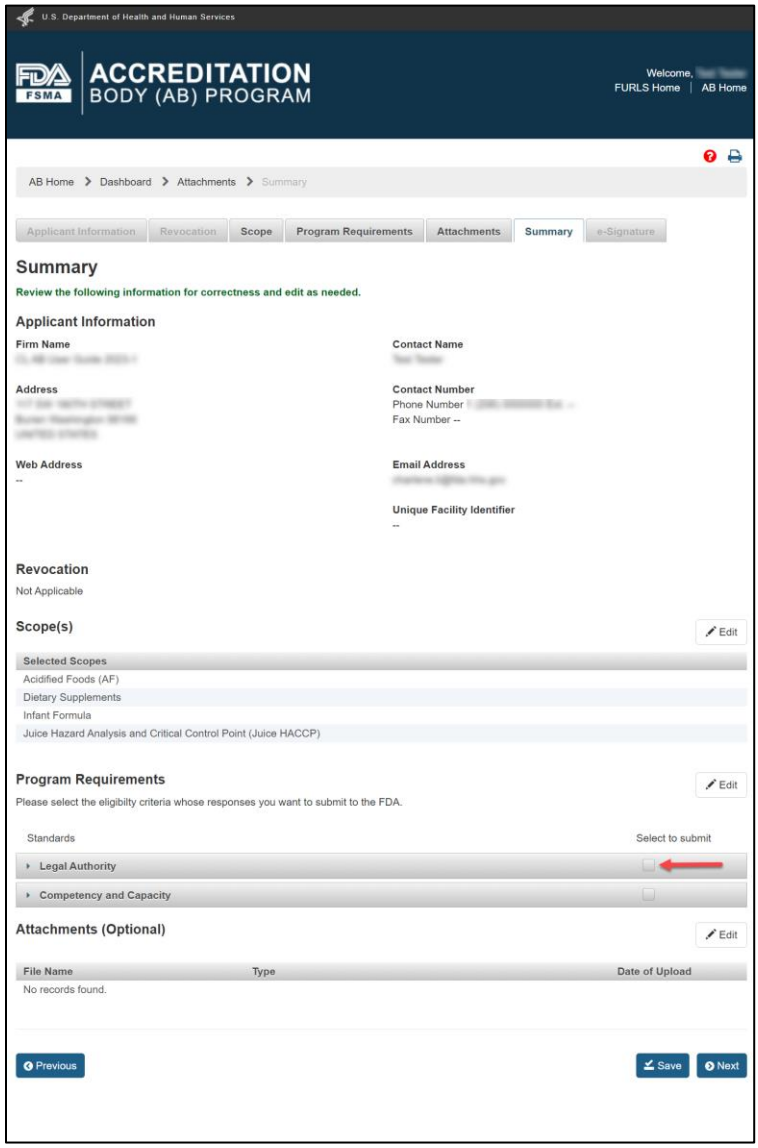


Once all outstanding items have been addressed and any revisions that have been made, navigate to the “Summary” page by clicking the “Save” and “Next” buttons from the “Program Requirements” page or, by clicking the “Summary” tab.

Review the information for accuracy and select the checkbox next to the applicable “Program Requirements” section(s) being submitted (Figure 6.7). Click the “Save” and “Next” buttons.

Note: If FDA has sent questions for more than one program requirement section, you may submit your responses separately, if desired. However, if there are multiple questions for a single program requirement section, you need to respond to all questions for that section in order to select that program requirement section for submission to FDA (i.e., checkbox will not appear).

Figure 6.7 – Summary Page



The system will validate that all required fields have been completed. If no errors are found, the “e-Signature” page will display (Figure 6.8).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

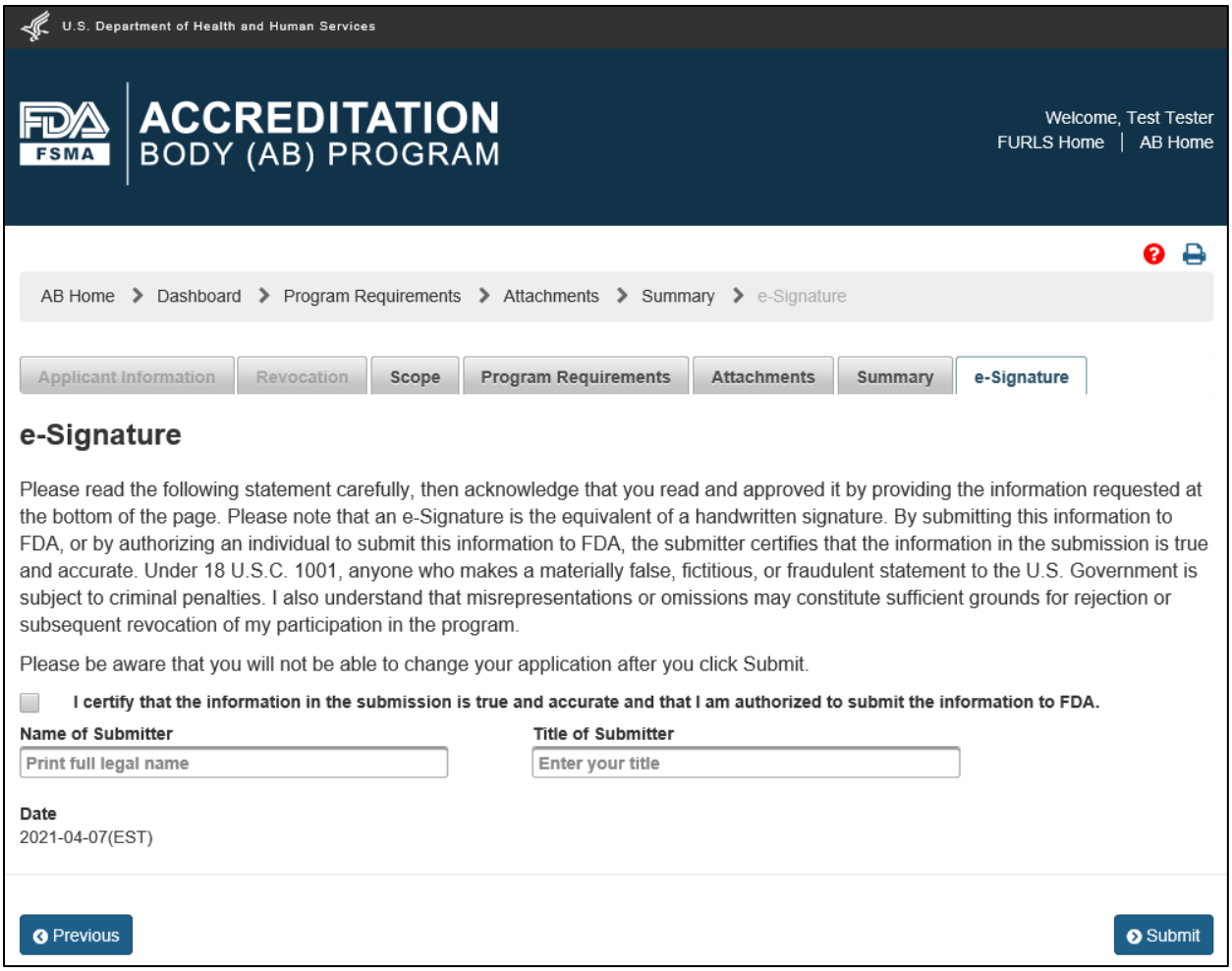
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Summary” page.

Click the “Submit” button to complete submission to FDA.

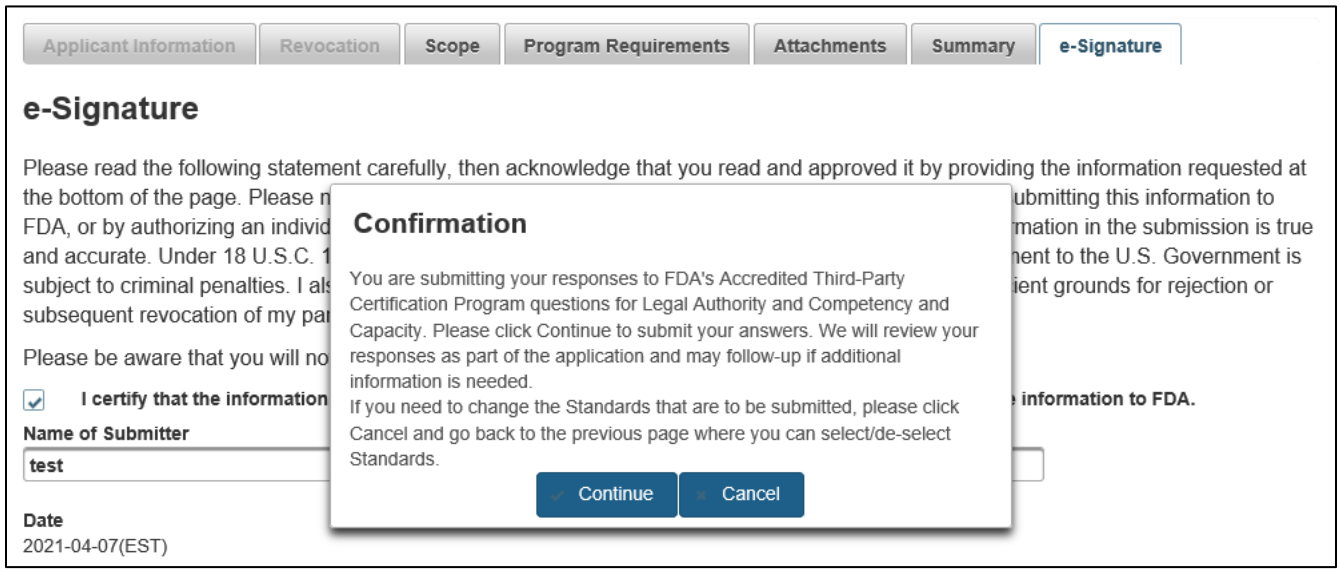
Figure 6.8 – e-Signature Page



After clicking the “Submit” button from the e-Signature page, the system will display a confirmation pop-up message (Figure 6.9). Follow the instructions in the pop-up.

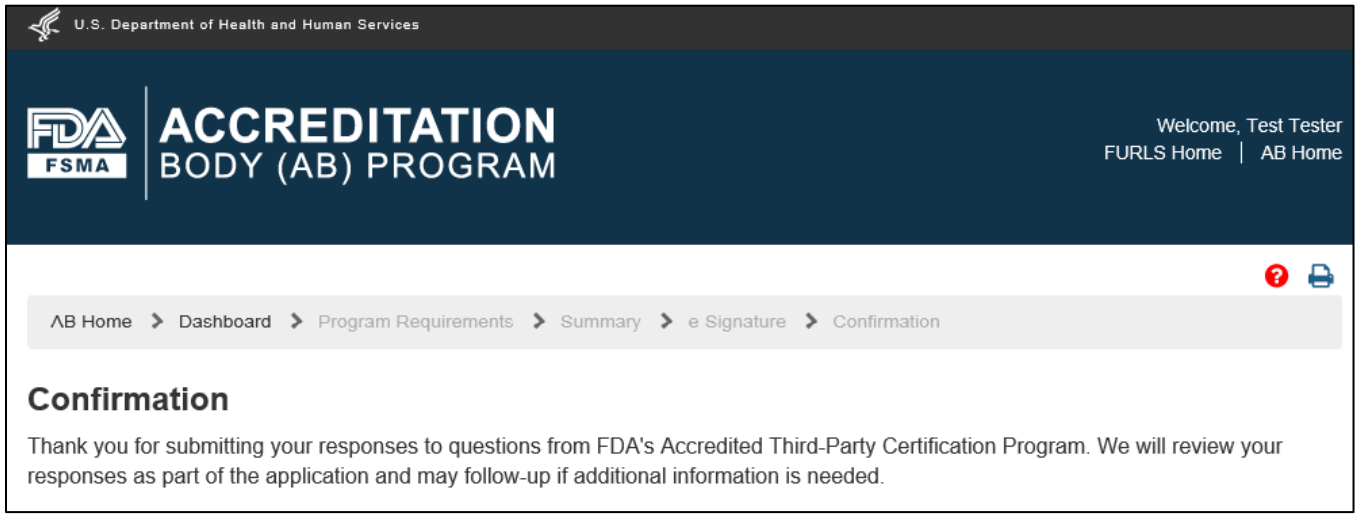
Click the “Continue” button to proceed with the submission and continue to the “Confirmation” page. Click the “Cancel” button to resume editing the application.

Figure 6.9 – Confirmation Pop-up



After clicking the “Continue” button in the pop-up message, the system will display the “Confirmation” page (Figure 6.10).

Figure 6.10 – Confirmation Page



Upon submission of the responses to FDA, the system will send an e-mail confirmation to the address entered on the “Account Management” page (Figure 6.11). Note that the image below only depicts the e-mail notification text.

Figure 6.11 – E-mail Notification

Thank you for submitting your responses to questions from FDA's Accredited Third-Party Certification Program. We will review your responses as part of your application and may follow-up if additional information is needed.

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

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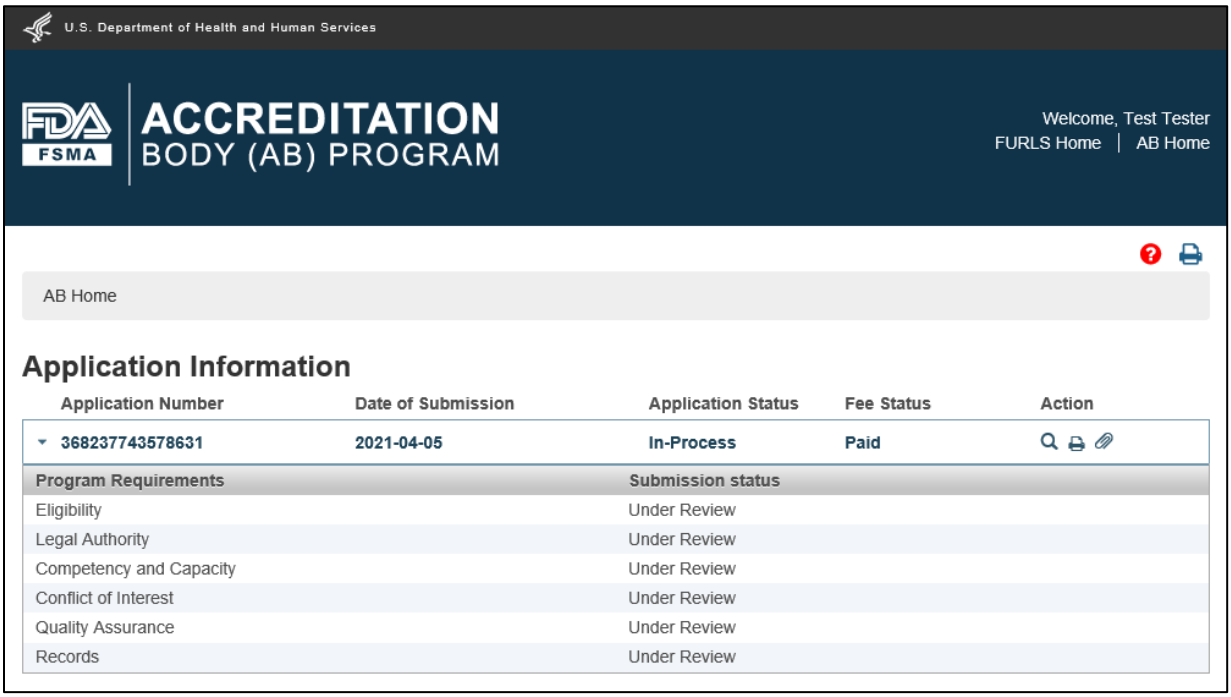
After the application that was returned for action has been submitted, the “Application Status” will remain as “In-Process” until FDA approves or denies it (Figure 6.12).

Figure 6.12 – In-Process Application Status



When FDA has made a decision on your application, the system will send an e-mail to the address entered on the “Account Management” page.

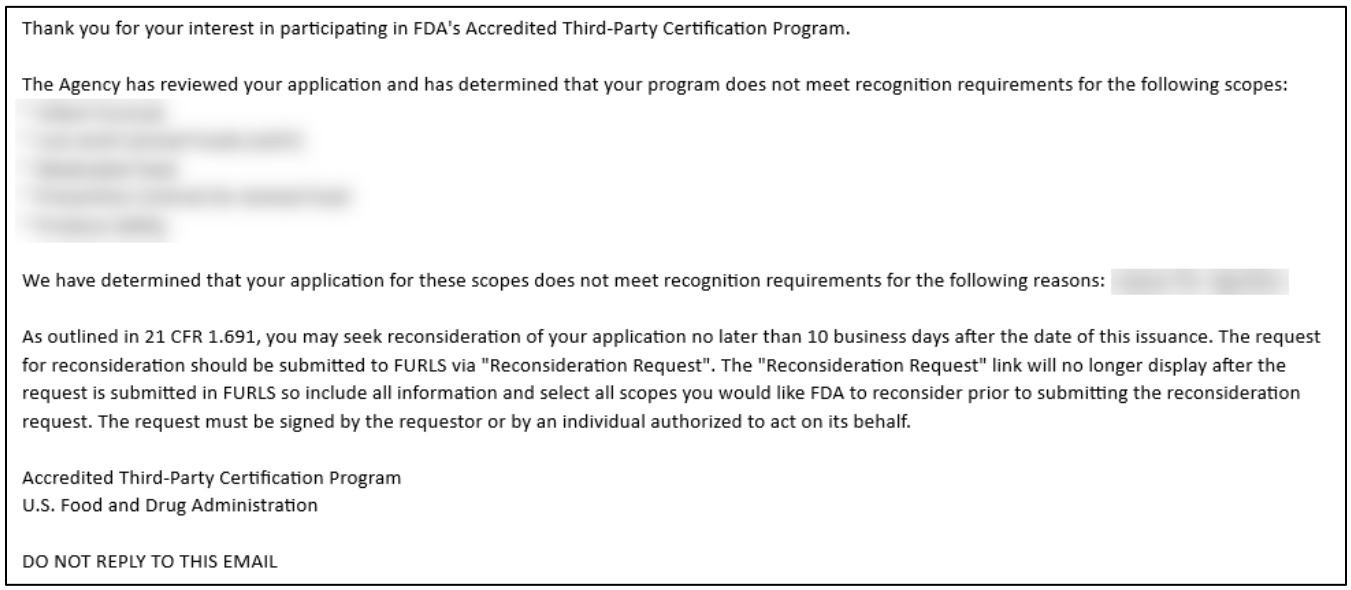
Refer to Section 5.8 of this document for information relating to FDA decisions and application statuses.

7 Submit Reconsideration Request

The “Reconsideration Request” feature may be used to request reconsideration of your application if it was denied by FDA. See 21 CFR 1.691 for additional information on requesting reconsideration of a denial by FDA.

If FDA denies your application, you will receive the following e-mail notification (Figure 7.1). Note that the image below only depicts an example of the e-mail notification text.

Figure 7.1 – E-mail Notification



Thank you for your interest in participating in FDA's Accredited Third-Party Certification Program.

The Agency has reviewed your application and has determined that your program does not meet recognition requirements for the following scopes:

We have determined that your application for these scopes does not meet recognition requirements for the following reasons:

As outlined in 21 CFR 1.691, you may seek reconsideration of your application no later than 10 business days after the date of this issuance. The request for reconsideration should be submitted to FURLS via "Reconsideration Request". The "Reconsideration Request" link will no longer display after the request is submitted in FURLS so include all information and select all scopes you would like FDA to reconsider prior to submitting the reconsideration request. The request must be signed by the requestor or by an individual authorized to act on its behalf.

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

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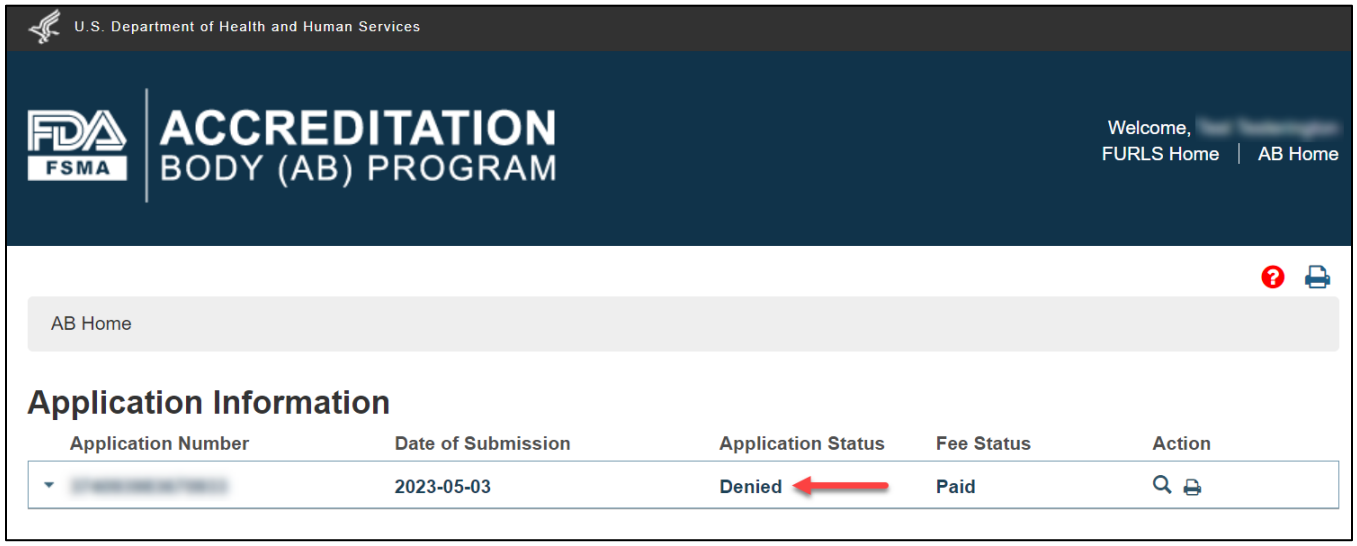
You may submit an application reconsideration request for any scopes that have been denied on the initial application to be reconsidered by FDA. Navigate to the “Application Information” page to check the status of an application.

The “Application Status” field will display as “Denied” if an application is not approved (Figure 7.2).

****Important: You will have 10 business days from the date of notification of the denial from FDA to submit a reconsideration request. The “Reconsideration Request” link will no longer display after the request is submitted so include all information and select all scopes you would like FDA to reconsider prior to submitting the reconsideration request.**

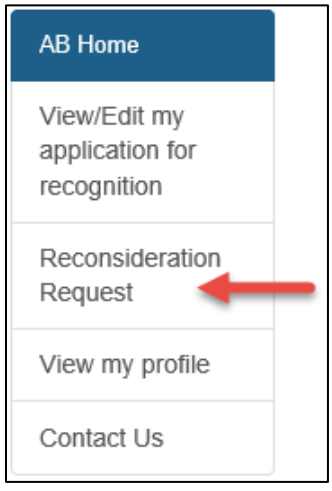
Figure 7.2 – Denied Application Status



The “Reconsideration Request” link will display on the navigation menu on the “AB Home” page if FDA has denied at least one scope in the application for recognition (Figure 7.3).

Click on the “Reconsideration Request” link on the navigation menu.

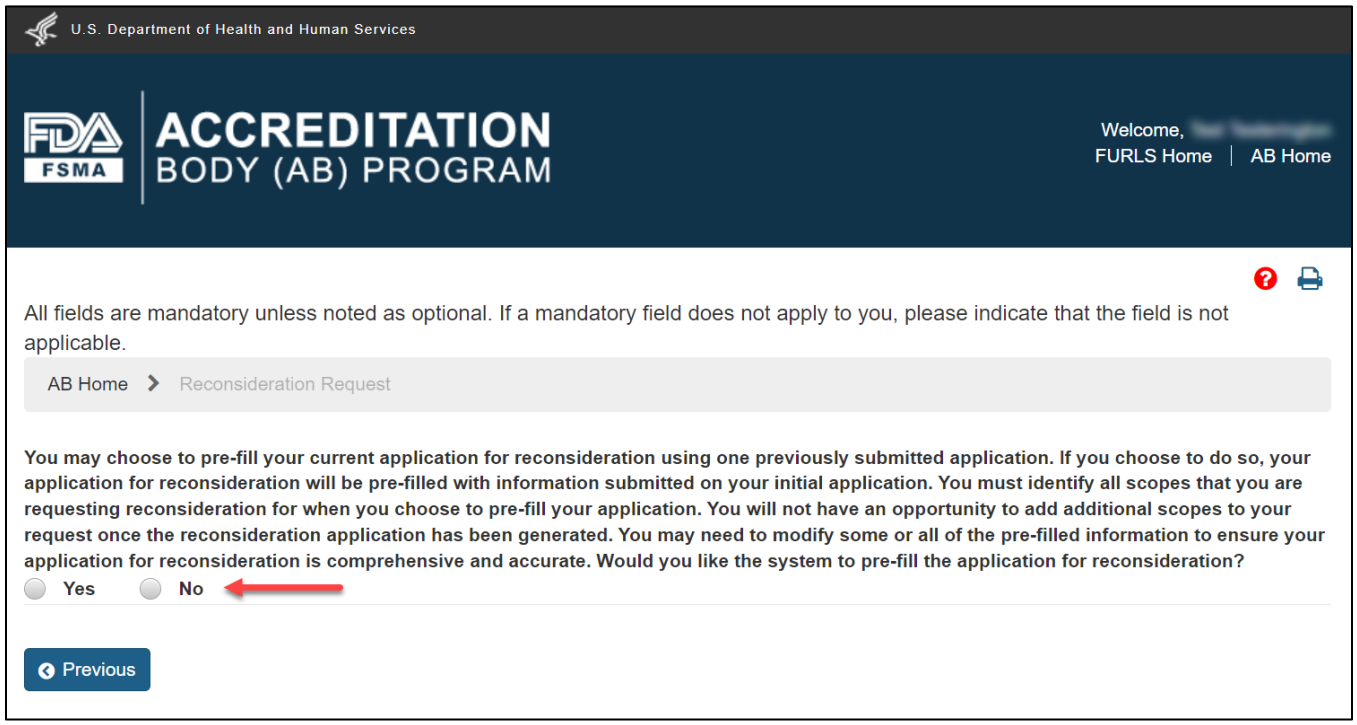
Figure 7.3 – Navigation Menu



The system will display the “Reconsideration Request” page (Figure 7.4).

The system will display the question about whether you would like the system to pre-fill the application for reconsideration. Select “Yes” or “No” by clicking one of the radio buttons below the question.

Figure 7.4 – Reconsideration Request Page



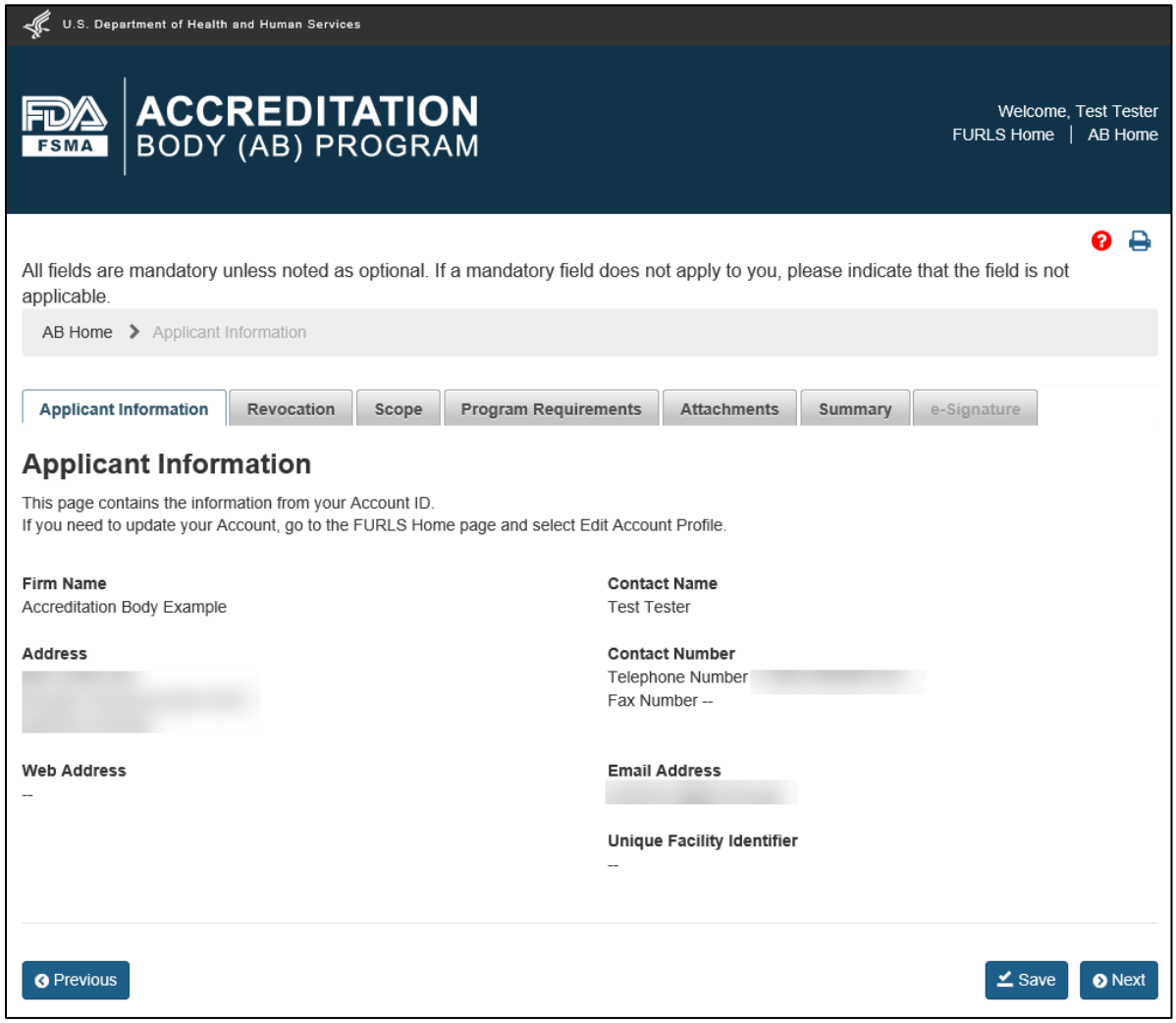
- If you select “Yes,” the system will display the “Applicant Information” page of the application, pre-filled with the read-only profile information (Figure 7.5). The remainder of the application will be pre-filled with the information submitted in the original application and is editable.

  Note: You will need to select the scopes in the Reconsideration Request, as they will not be pre-filled even if “Yes” is selected.

- If you select “No,” the system will display the “Next” button on the “Reconsideration Request” page. Click the “Next” button to proceed to the “Applicant Information” page. The “Applicant Information” page of the application will be pre-filled with the read-only profile information (Figure 7.5). All other application information will not be pre-filled and will be entered manually.

Note: If you need to edit your profile information, you may do so on the "Online Account Administration (OAA)" page. Navigate to the "AB Home" page, select "View my profile" from the left navigation menu, and click the "Edit Profile" button. Edit the information as desired.

Figure 7.5 – Applicant Information Page



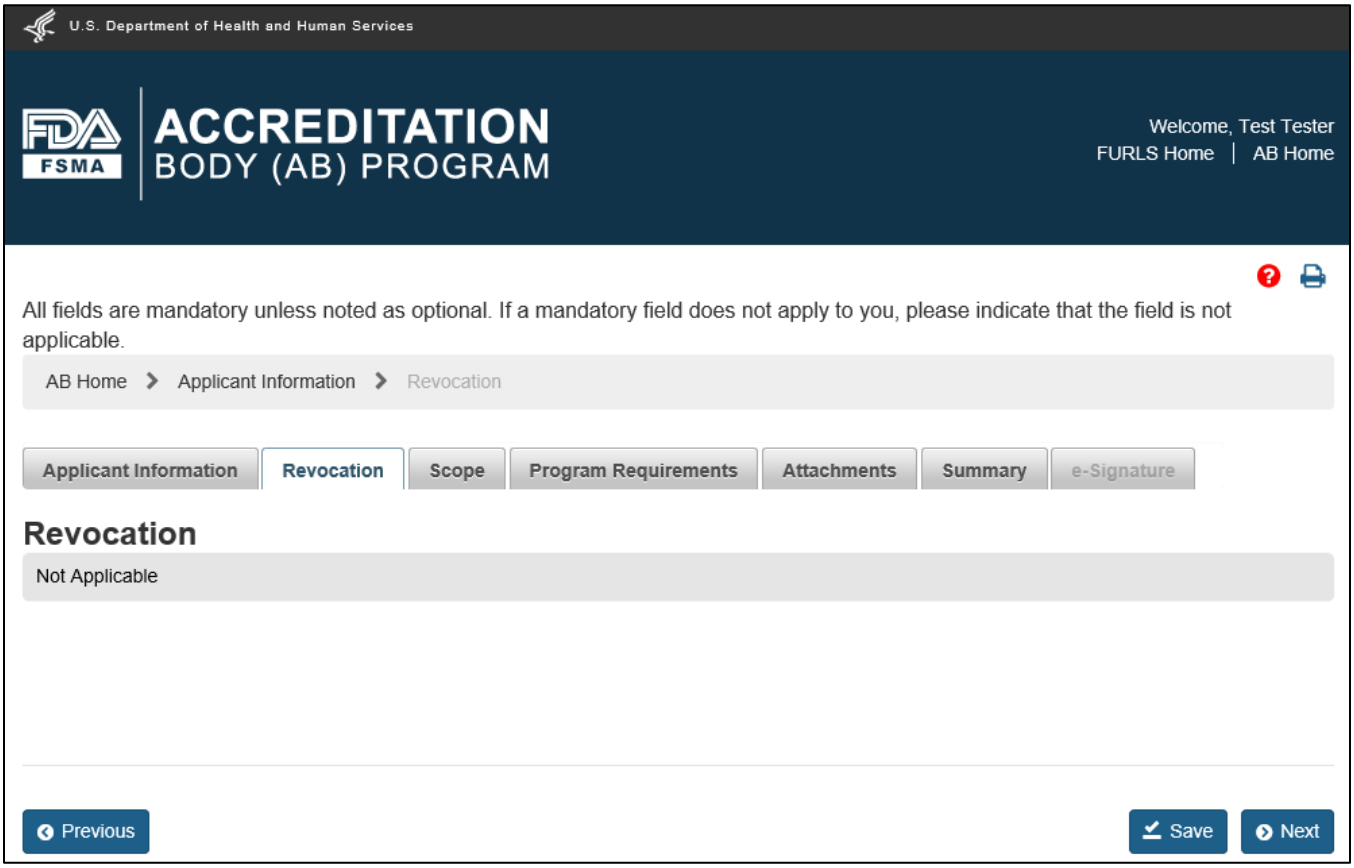
The following navigation buttons are available:

- **Previous** – Directs users to the previous page
- **Save** – Saves any input from the current page
  Click the "Save" button to save your information.
- **Next** – Directs users to the next page

Click the "Next" button to proceed to the next page or, click on the "Revocation" tab.

The system will display the “Revocation” page (Figure 7.6). The system will indicate “Not Applicable” on this page. No action is required on this page.

Figure 7.6 – Revocation Page



Click the “Next” button to proceed to the next page or, click on the “Scope” tab.

The system will display the “Scope(s)” page (Figure 7.7).

The “Scope(s)” section (on the left-hand side of the page) will show all the scopes which were not approved in the original application.

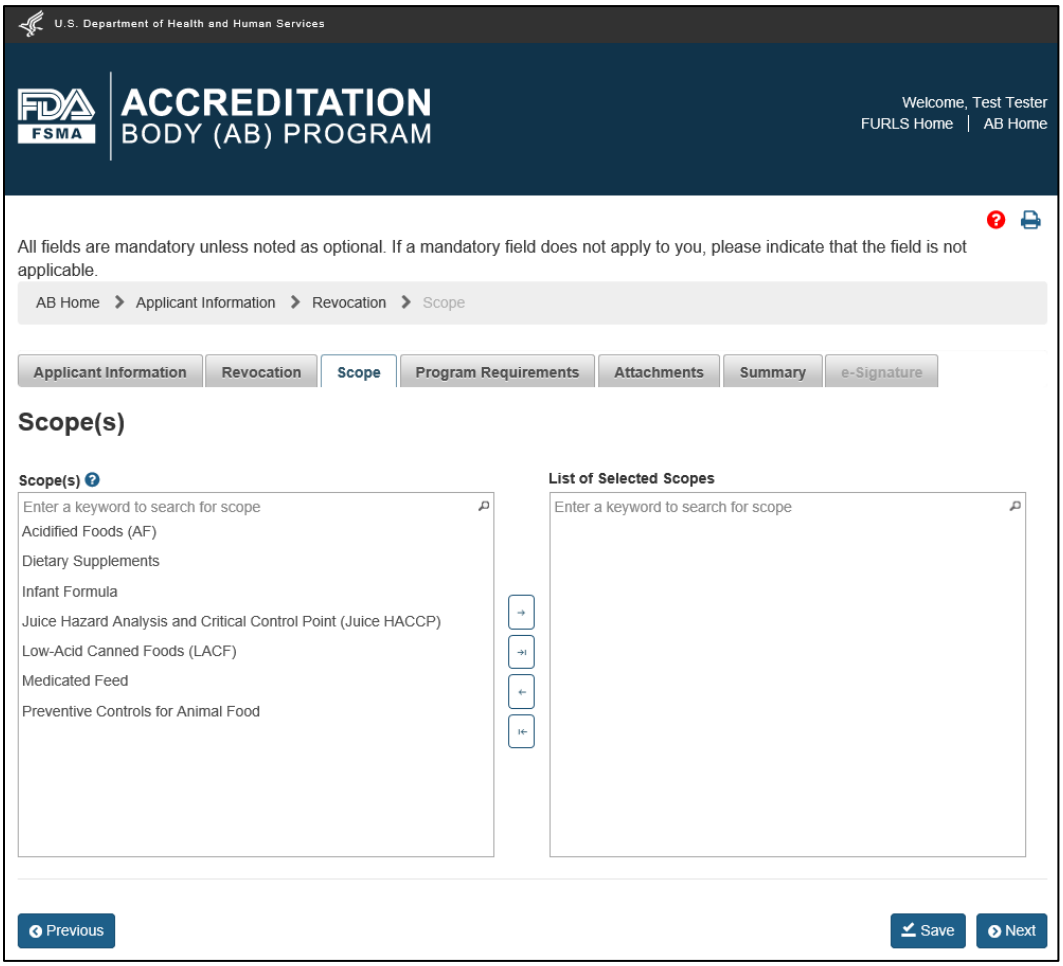
Select the scope(s) for which you are applying for reconsideration.

Refer to Section 5.3 of this document for instructions on adding or removing scopes, if needed.

Note: If the application for recognition was denied in whole (i.e., all of the scopes were denied), all of the scopes submitted in the original application will be listed in the “Scope” section of the “Scope(s)” page. Otherwise, only the scope(s) that were not approved will be listed.

Click the “Save” button when all scopes you want to include for the reconsideration request have been selected.

Figure 7.7 – Scopes Page



Click the “Next” button to proceed to the next page or, click on the “Program Requirements” tab.

The system will display the “Program Requirements” page (Figure 7.8).

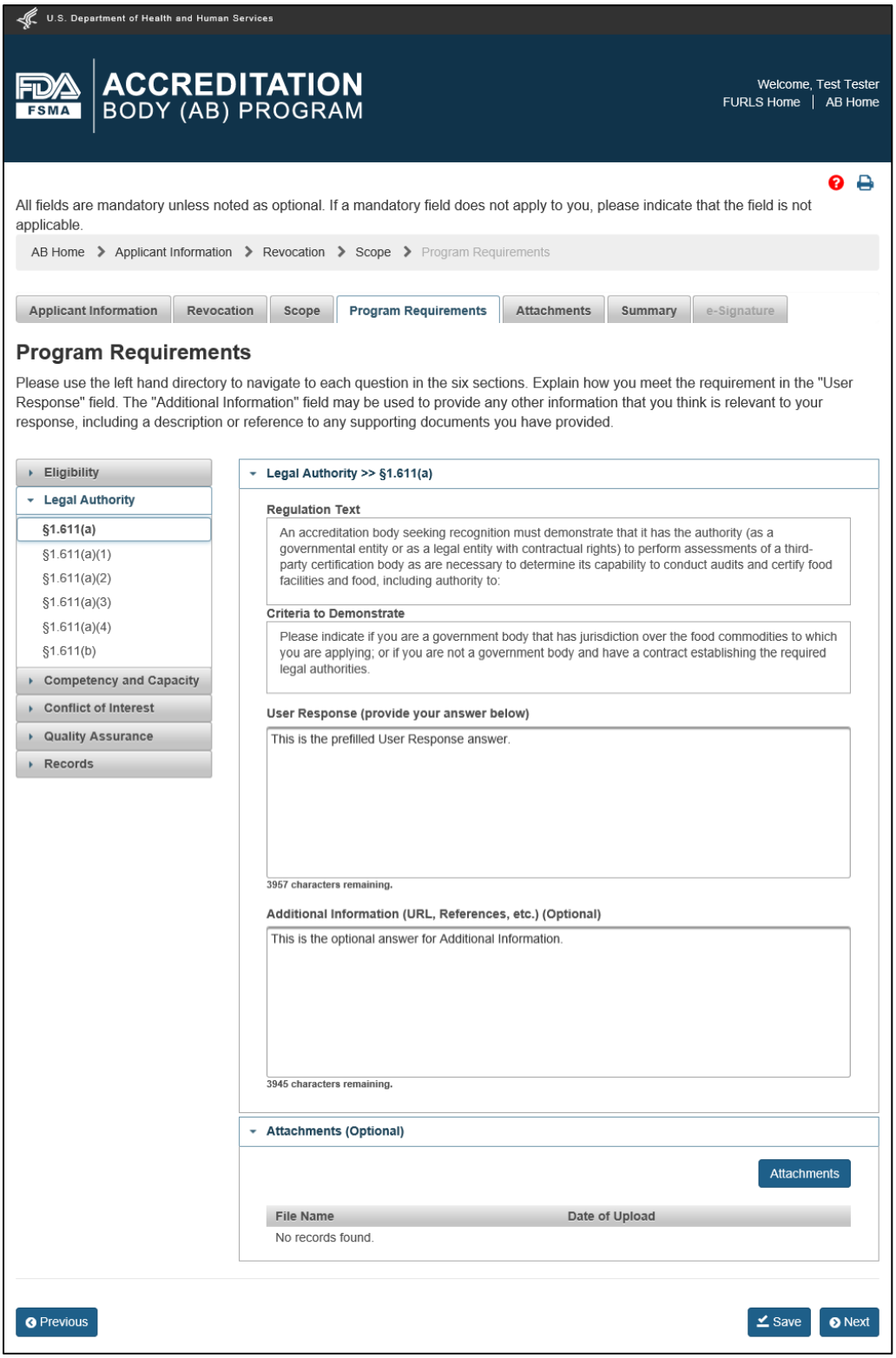
- If you selected “Yes” at the beginning of the reconsideration request, this page will be pre-filled with the information provided in the initial application.

  You may edit responses submitted on the original application in the “Program Requirements” page (as needed) to support the reconsideration request. You also may add attachments, if desired.

- If you selected “No” at the beginning of the reconsideration request, the “Applicant Information” page will be pre-filled with the read-only profile information. All other application information will not be pre-filled and will need to be entered manually.

Refer to Section 5.4 of this document for instructions on completing the “Program Requirements” page, if needed.

Figure 7.8 – Program Requirements Page



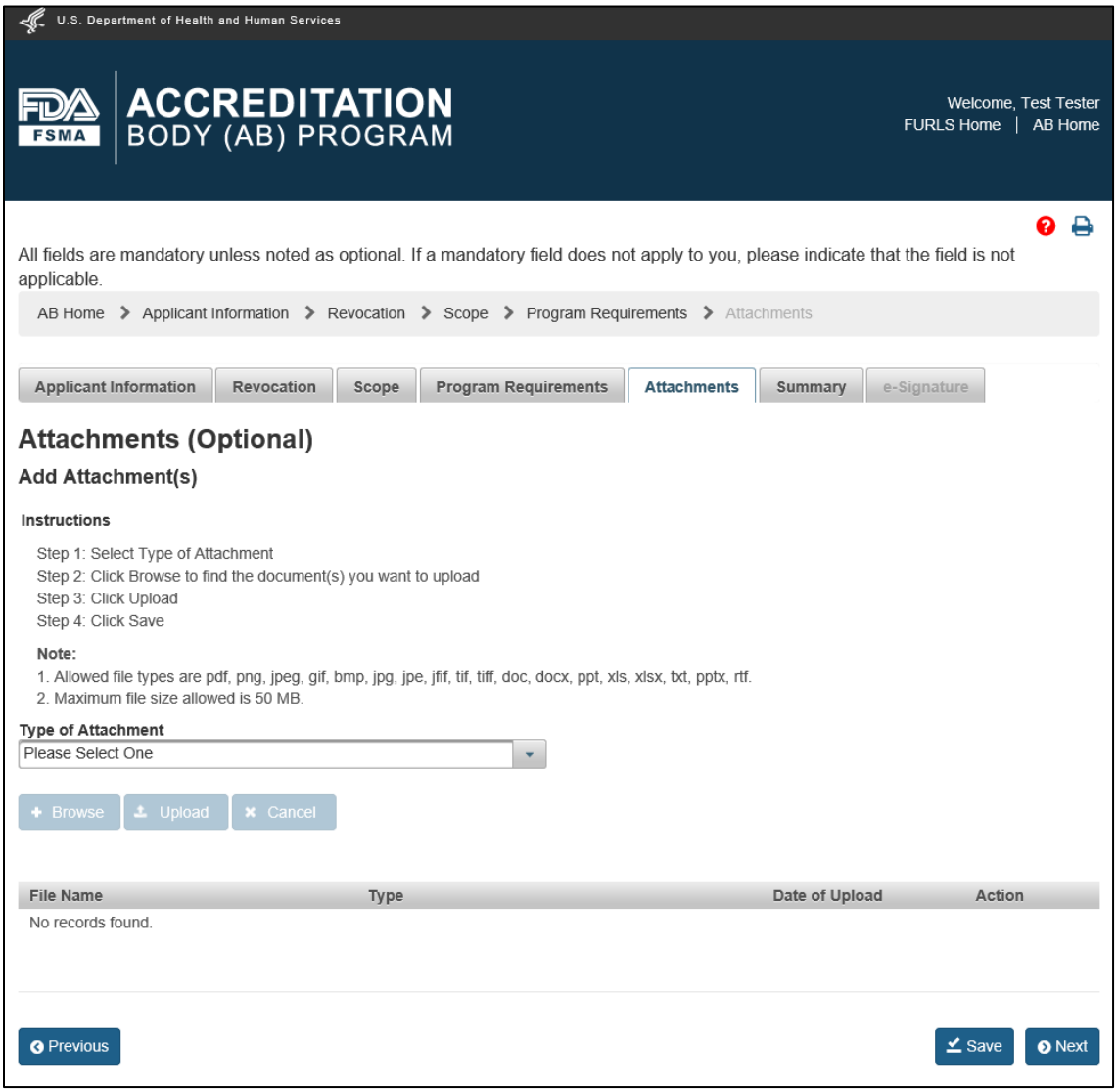
Click the “Save” button to save any changes. Click the “Next” button to proceed to the next page or, click on the “Attachments” tab. The system will display the “Attachments” page (Figure 7.9).

Note: Uploading a file in the “Attachments” page is optional.

Upload additional files in the “Attachments” page by following the four-step process outlined on the page. Documents you included with your initial application submission will be listed in the table at the bottom of the page.

Refer to Section 5.5 of this document for instructions on uploading documents in the “Attachments” page, if needed.

Figure 7.9 – Attachments Page



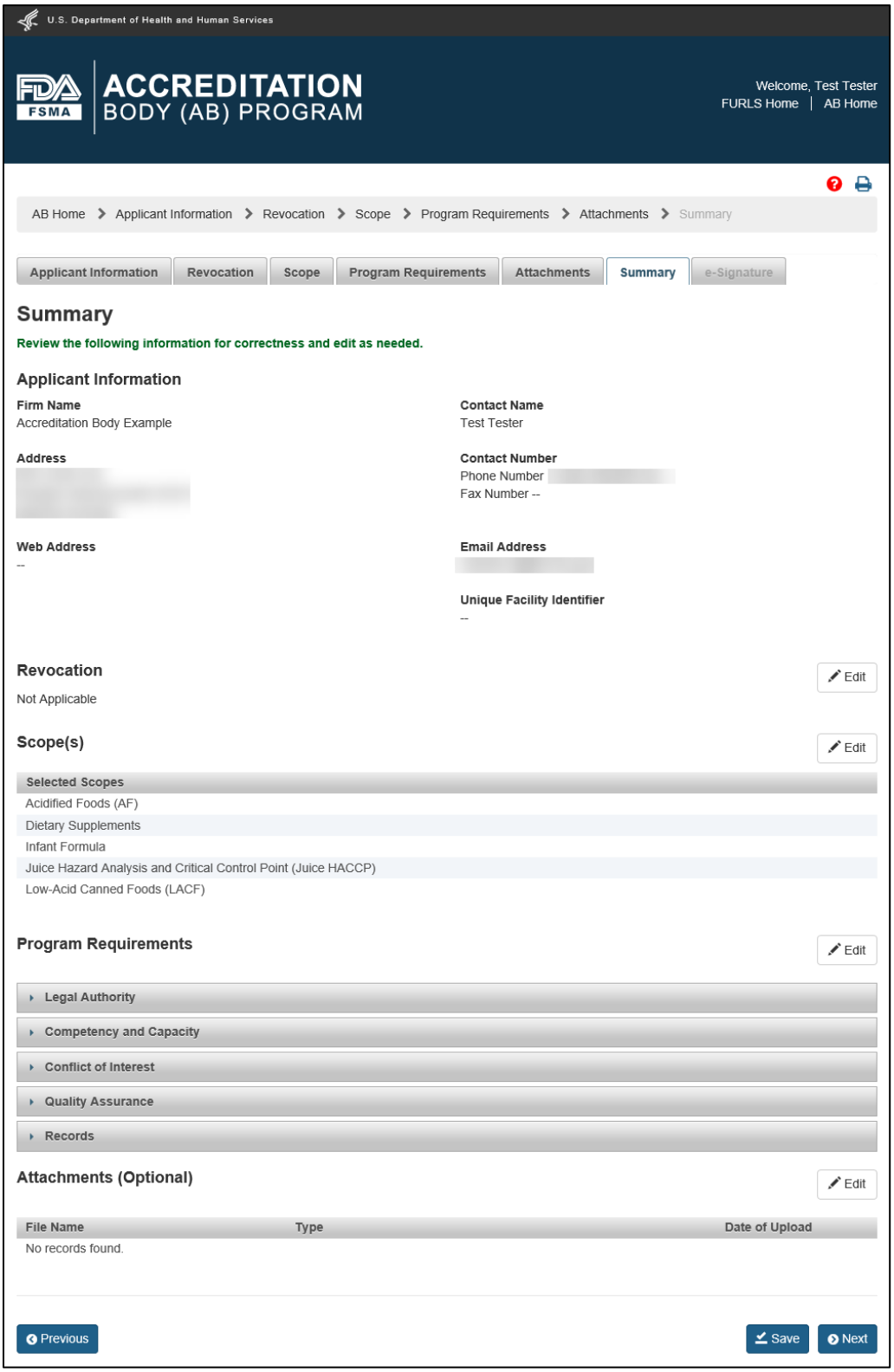
Click the “Next” button to proceed to the next page or, click on the “Summary” tab.

The system will display the “Summary” page for you to review the information for accuracy (Figure 7.10). After reviewing the “Summary” page, click the “Save” button.

The system will display the “Edit” button for each section of the application on the “Summary” page. Click the “Edit” button to return to the page and edit any section before submitting the reconsideration request.

Refer to Section 5.6 of this document for additional instructions on completing the “Summary” page, if needed.

Figure 7.10 – Summary Page



After reviewing the “Summary” page and applying any applicable edits to the reconsideration request, click the “Next” button to proceed to the “e-Signature” page.

The system will validate that all required fields have been completed.

If no errors are found, the system will display the “e-Signature” page (Figure 7.11).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

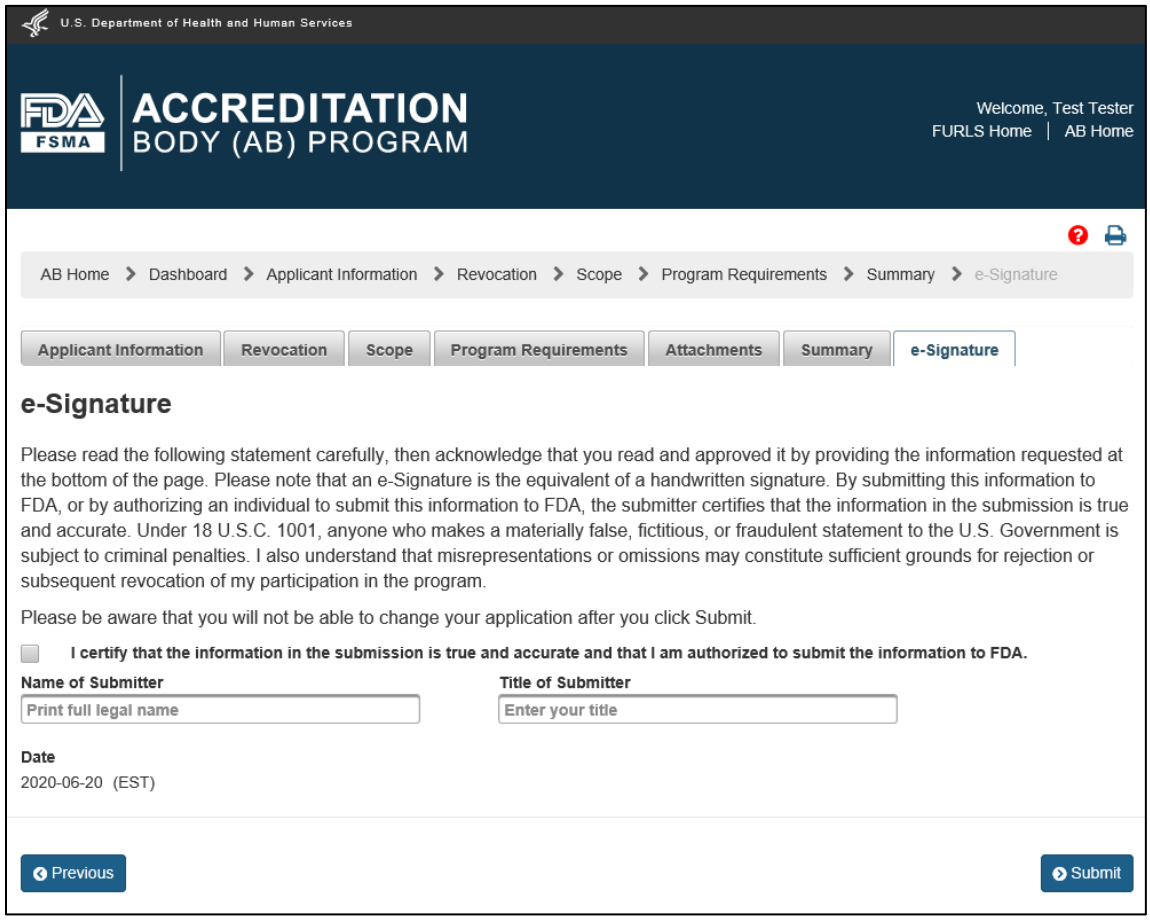
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Summary” page.

Click the “Submit” button to complete submission to FDA.

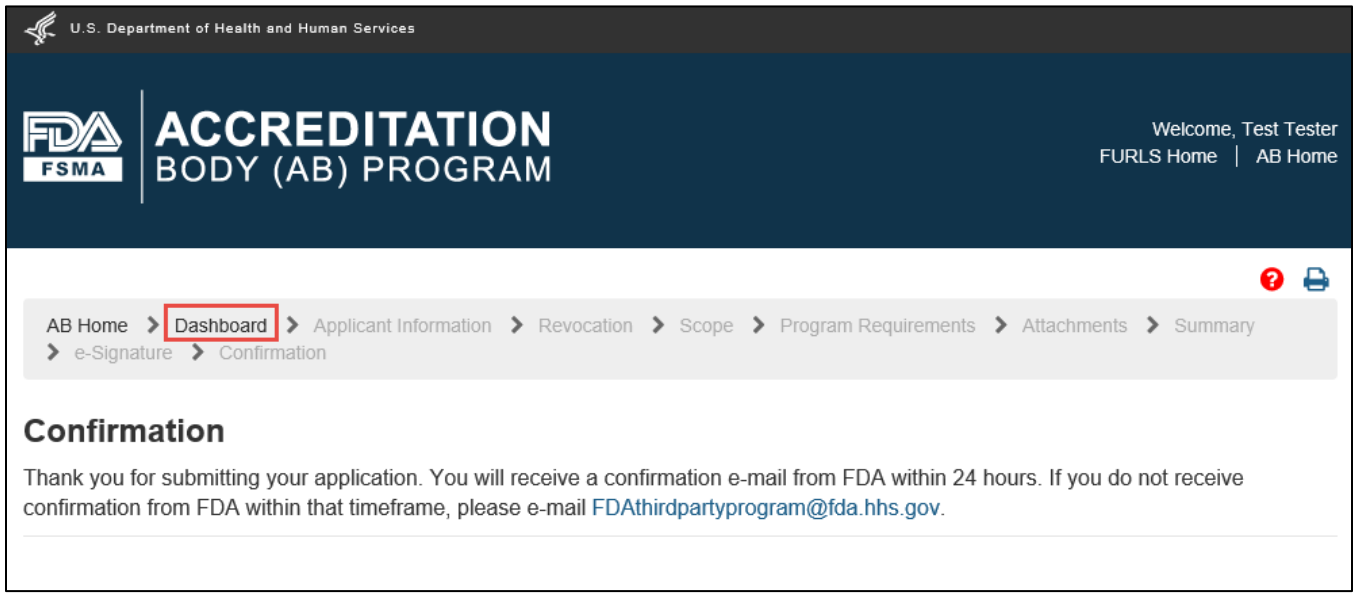
Figure 7.11 – e-Signature Page



Once the reconsideration request has been submitted, the system will display the "Confirmation" page (Figure 7.12).

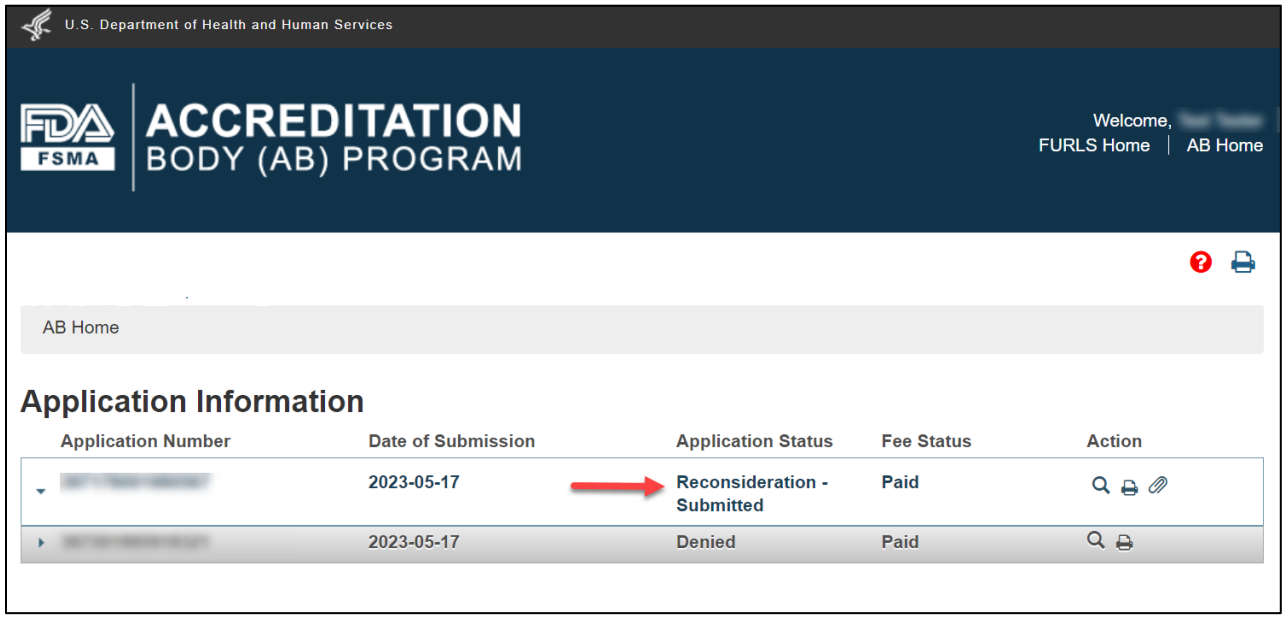
Click the "Dashboard" link from the breadcrumb on the "Confirmation" page to navigate to the "Application Information" page and view the status of the reconsideration request.

Figure 7.12 – Confirmation Page



When FDA receives the reconsideration request, the status will display as "Reconsideration – Submitted" (Figure 7.13).

Figure 7.13 – Reconsideration Request – Submitted Status



The system will send an e-mail to the address entered on the “Account Management” page indicating the reconsideration request was received by FDA (Figure 7.14). Note that the image below only depicts the e-mail notification text.

Figure 7.14 – E-mail Notification

Thank you for applying to FDA's Accredited Third-Party Certification Program. We appreciate your interest in participating in the program. Your electronic submission has been received by the Agency. The Agency is currently processing your request for reconsideration to ensure all required data elements have been submitted in order for the Agency to complete a comprehensive review of your application. During the Agency's review you may be contacted for additional information that may be needed to allow the Agency to complete the review.

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

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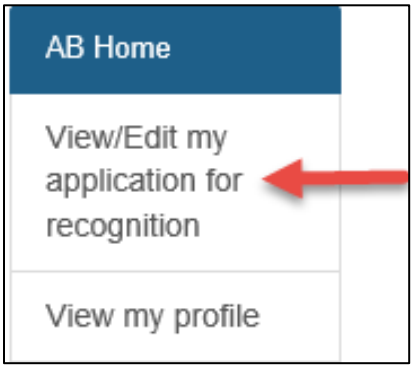
To check the status of the reconsideration request after submission, click the “View/Edit my application for recognition” link on the navigation menu on the “AB Home” page (Figure 7.15).

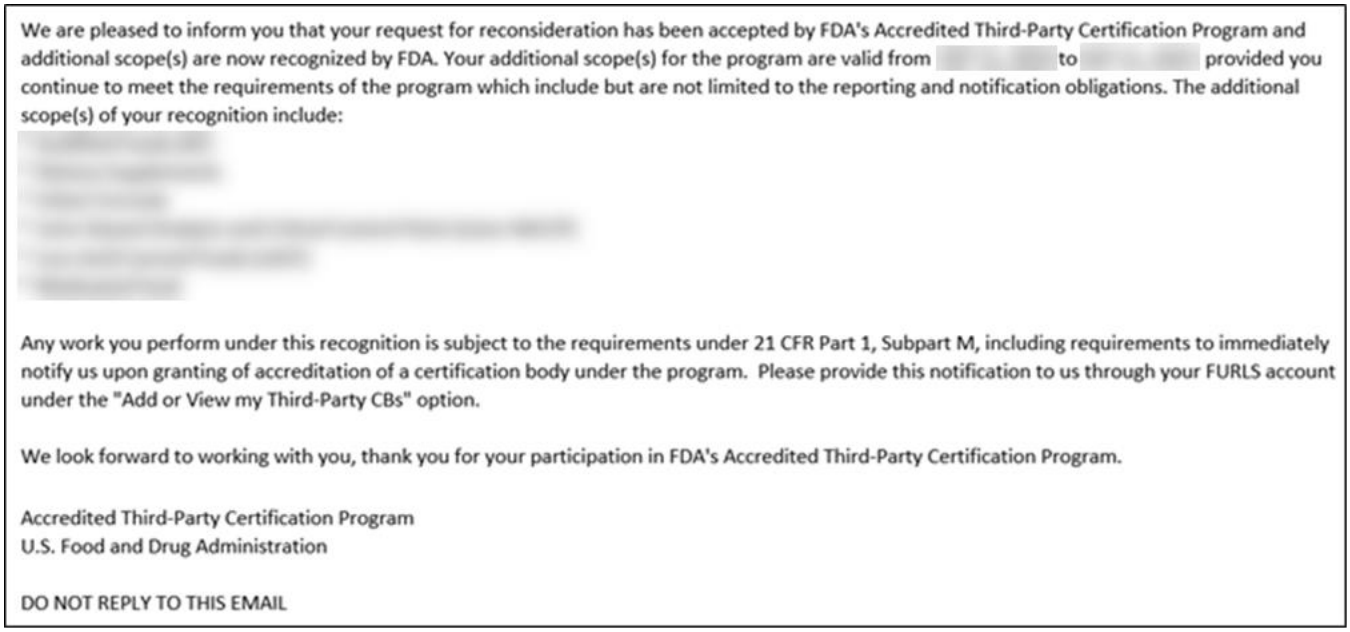
Figure 7.15 – Navigation Menu



7.1 Reconsideration – Recognized

If your reconsideration request has been approved for any scope(s), the system will send an e-mail to the address entered on the "Account Management" page (Figure 7.16). Note that the image below only depicts an example of the e-mail notification text.

Figure 7.16 – E-mail Notification



We are pleased to inform you that your request for reconsideration has been accepted by FDA's Accredited Third-Party Certification Program and additional scope(s) are now recognized by FDA. Your additional scope(s) for the program are valid from [redacted] to [redacted] provided you continue to meet the requirements of the program which include but are not limited to the reporting and notification obligations. The additional scope(s) of your recognition include:

[redacted]

Any work you perform under this recognition is subject to the requirements under 21 CFR Part 1, Subpart M, including requirements to immediately notify us upon granting of accreditation of a certification body under the program. Please provide this notification to us through your FURLS account under the "Add or View my Third-Party CBs" option.

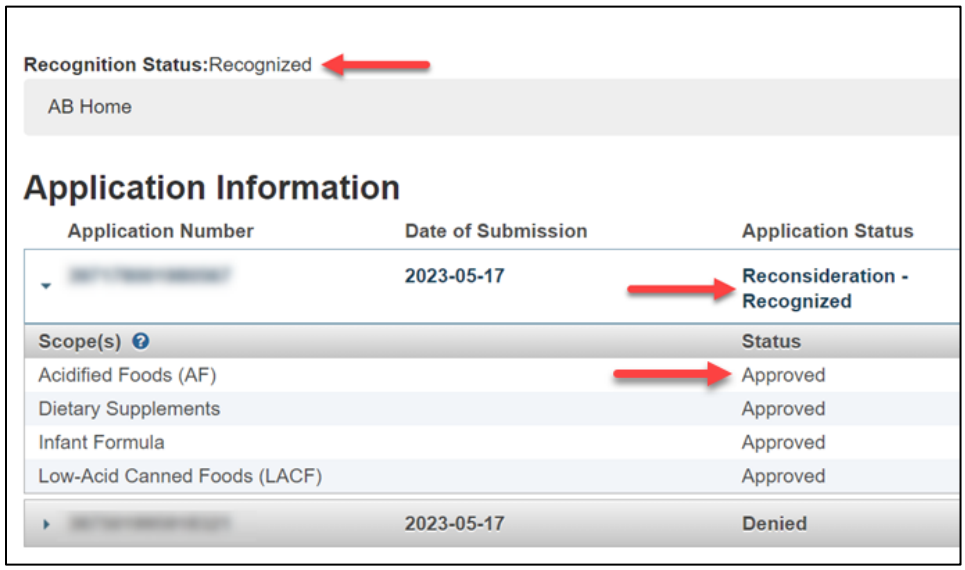
We look forward to working with you, thank you for your participation in FDA's Accredited Third-Party Certification Program.

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

DO NOT REPLY TO THIS EMAIL

The "Application Status" will display as "Reconsideration – Recognized," and "Recognition Status" will display as "Recognized" on the "Application Information" page (Figure 7.17).

Figure 7.17 – Reconsideration – Recognized Status and Approved Scopes



Recognition Status: Recognized

AB Home

Application Information

Application Number	Date of Submission	Application Status
[redacted]	2023-05-17	Reconsideration - Recognized

Scope(s)	Status
Acidified Foods (AF)	Approved
Dietary Supplements	Approved
Infant Formula	Approved
Low-Acid Canned Foods (LACF)	Approved

[redacted]	2023-05-17	Denied

Each of the scopes will display as “Approved,” along with the start and expiration dates for the recognition of each approved scope.

As a Recognized AB, you will now have full access to perform the following functions in the FURLS system:

- Add and view accredited CBs – Refer to Chapter 9 “Add or View Third-Party Certification Bodies (CBs)”
- Renew the accreditation of CBs – Refer to Chapter 11, Section 11.6 “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB”
- Upload and submit documents – Refer to Chapter 10 “Supplemental Documentation”
- Submit reports and notifications – Refer to Chapter 11 “Reports and Notifications”
- Submit your application for renewal of recognition – Refer to Chapter 8 “Apply for Renewal of Recognition”

If your reconsideration request has been returned for additional information, refer to Chapter 6 “Application Returned for Action.”

If your reconsideration request has been denied, refer to Section 7.2 of this chapter, “Reconsideration – Denied.”

7.2 Reconsideration – Denied

If your reconsideration request has been denied for all the scopes that were submitted, the system will send an e-mail to the address entered on the “Account Management” page (Figure 7.18). Note that the image below only depicts the e-mail notification text.

Figure 7.18 – E-mail Notification

Thank you for your interest in participating in FDA's Accredited Third-Party Certification Program. The Agency has reviewed your request for reconsideration and has determined that your application does not meet recognition requirements at this time for the following reasons: [redacted]

As outlined in 21 CFR 1.692, you may seek internal agency review of the denied reconsideration no later than 10 business days after the date of this issuance. The request for internal agency review should be submitted to FURLS via an application attachment and note that you are seeking internal agency review. The request must be signed by the requestor or by an individual authorized to act on its behalf.

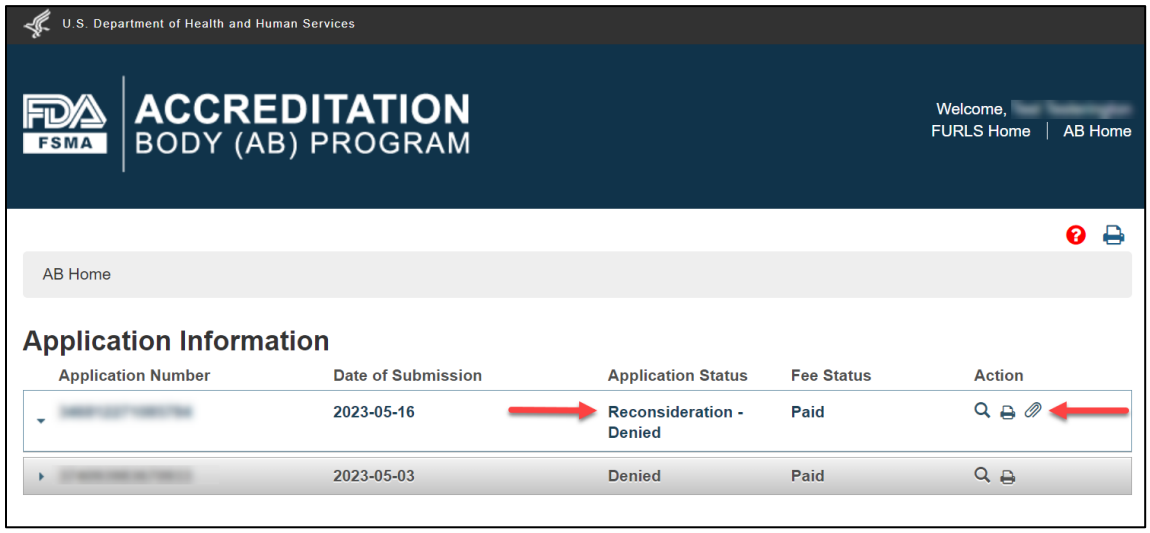
If you would still like to seek recognition, you must submit a new application.

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

DO NOT REPLY TO THIS EMAIL

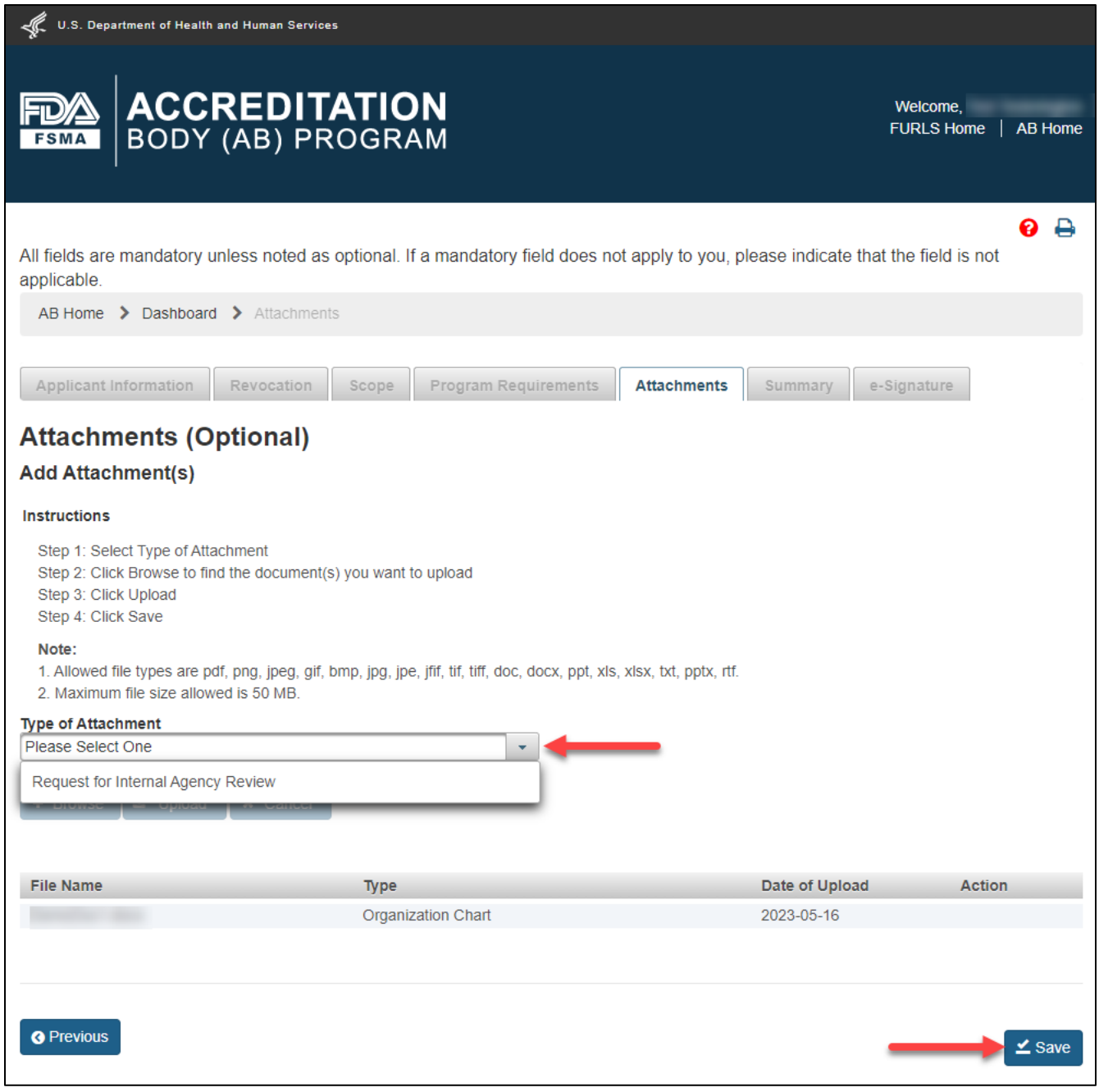
The application status will display as “Reconsideration - Denied” (Figure 7.19). Click the paper clip/attachment icon in the “Action” column of the page to submit a request for internal agency review. See 21 CFR 1.692 for additional information on requesting internal agency review of a denial by FDA.

Figure 7.19 – Reconsideration – Denied Status



The system will display the “Attachments” page (Figure 7.20). All other tabs of the application will be disabled. Select “Request for Internal Agency Review” from the “Type of Attachment” dropdown menu. Upload the desired file(s) and click the “Save” button to transmit your request to FDA.

Figure 7.20 – Attachments Page



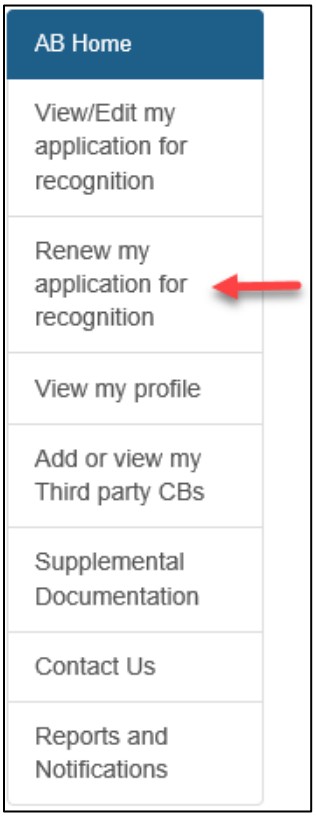
8 Apply for Renewal of Recognition

The “Renew my application for recognition” feature may be used to (electronically) apply for renewal of recognition from FDA to continue participation in the program as a recognized AB.

Note: The system will open up the option for renewal of recognition one year prior to the expiration of your current recognition.

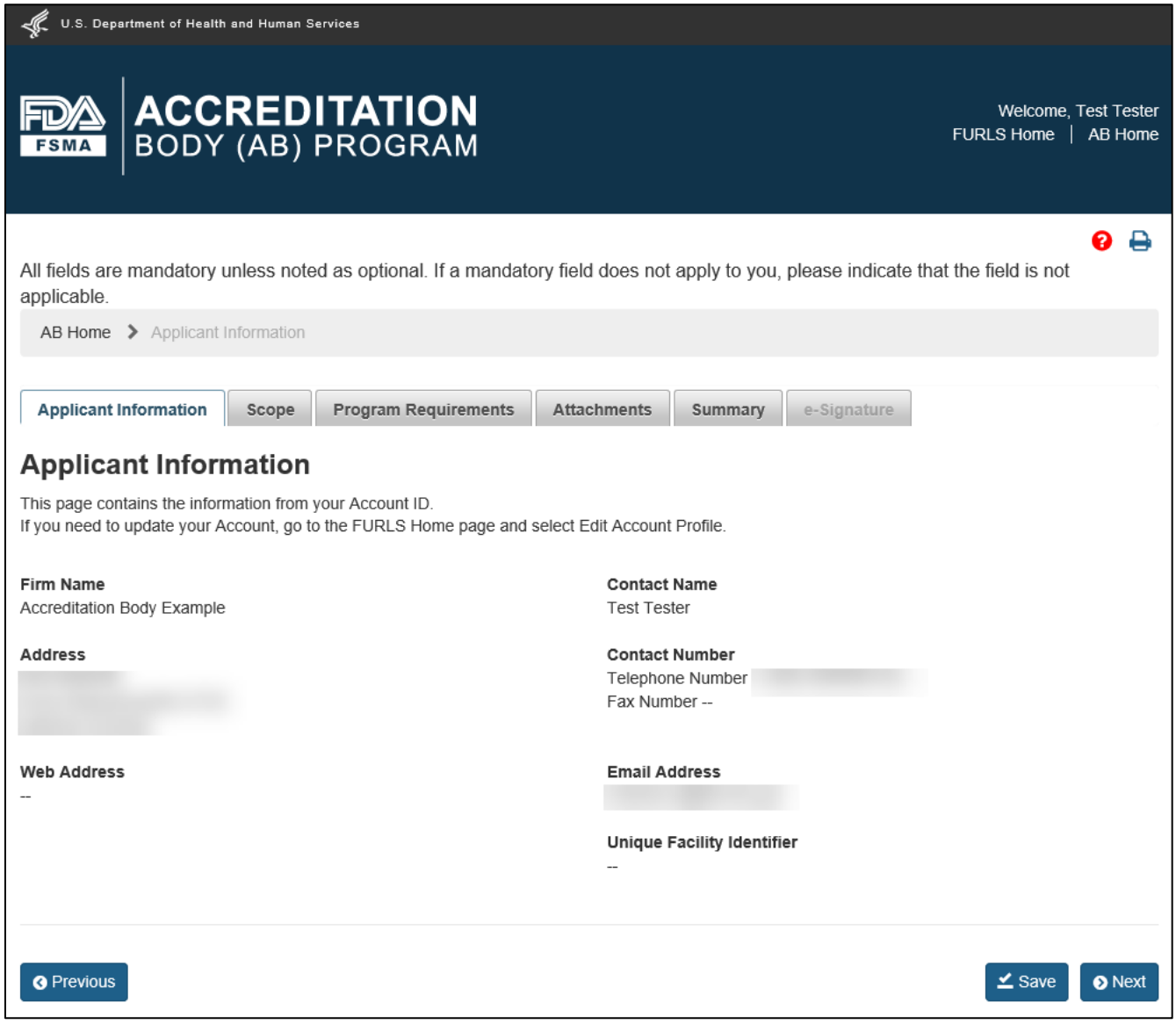
Click the “Renew my application for recognition” link on the navigation menu (Figure 8.1).

Figure 8.1 – Navigation Menu



The system will display the “Applicant Information” page of the renewal application (Figure 8.2).

Figure 8.2 – Applicant Information Page



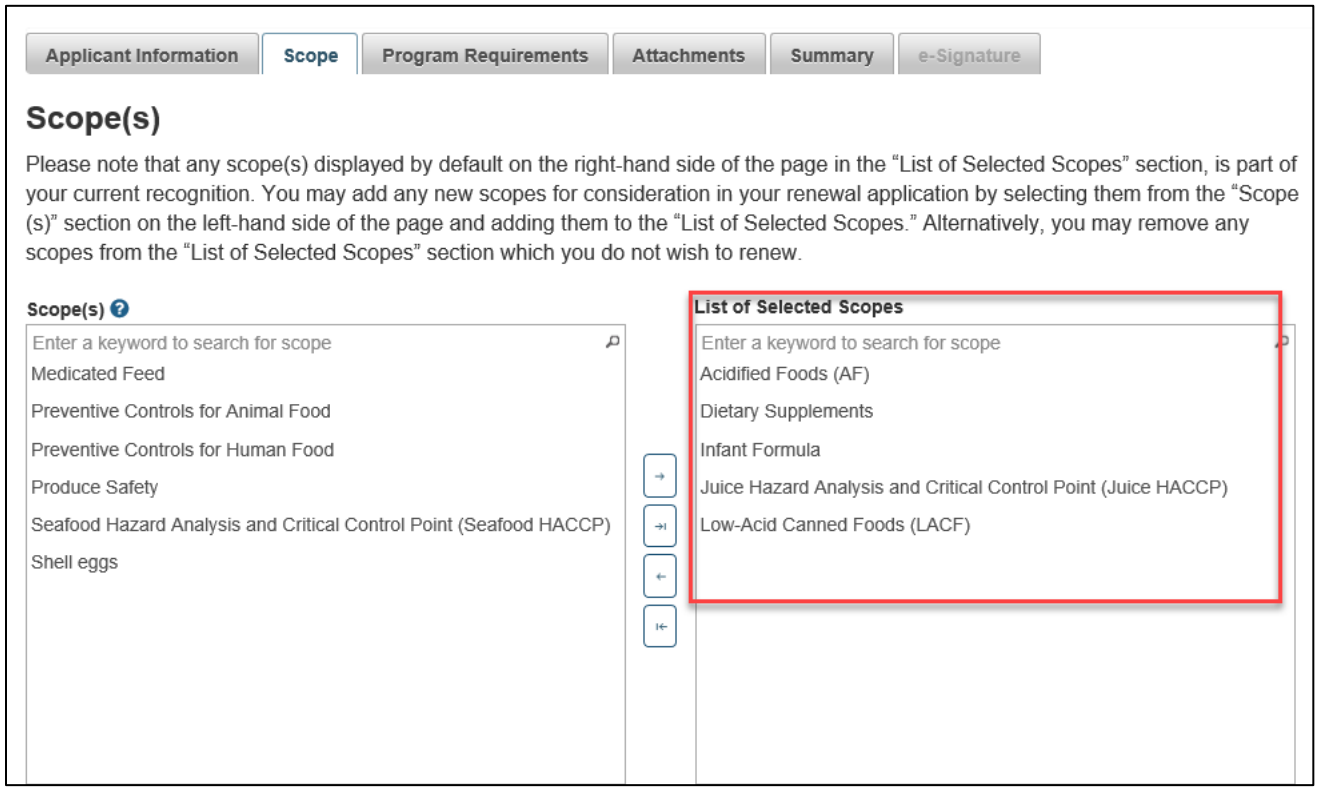
Refer to Chapter 5 “Apply for Recognition” for instructions to complete each of the pages of the application, with the following considerations for renewal:

- **Scope Page** – Any scopes displayed by default in the “List of Selected Scopes” section (on the right-hand side of the page) are part of the current recognition (Figure 8.3).

  You may add any new scopes for consideration in the renewal application by selecting them from the “Scope(s)” section (on the left-hand side of the page) and adding them to the “List of Selected Scopes.” Alternatively, scopes may be removed from the “List of Selected Scopes” section by selecting them from the “List of Selected Scopes” section (on the right-hand side of the page) and adding them to the “Scope(s)” section if you do not want to these scopes to be considered as part of the renewal application.

  Refer to Section 5.3 of this document for instructions on adding or removing scopes, if needed.

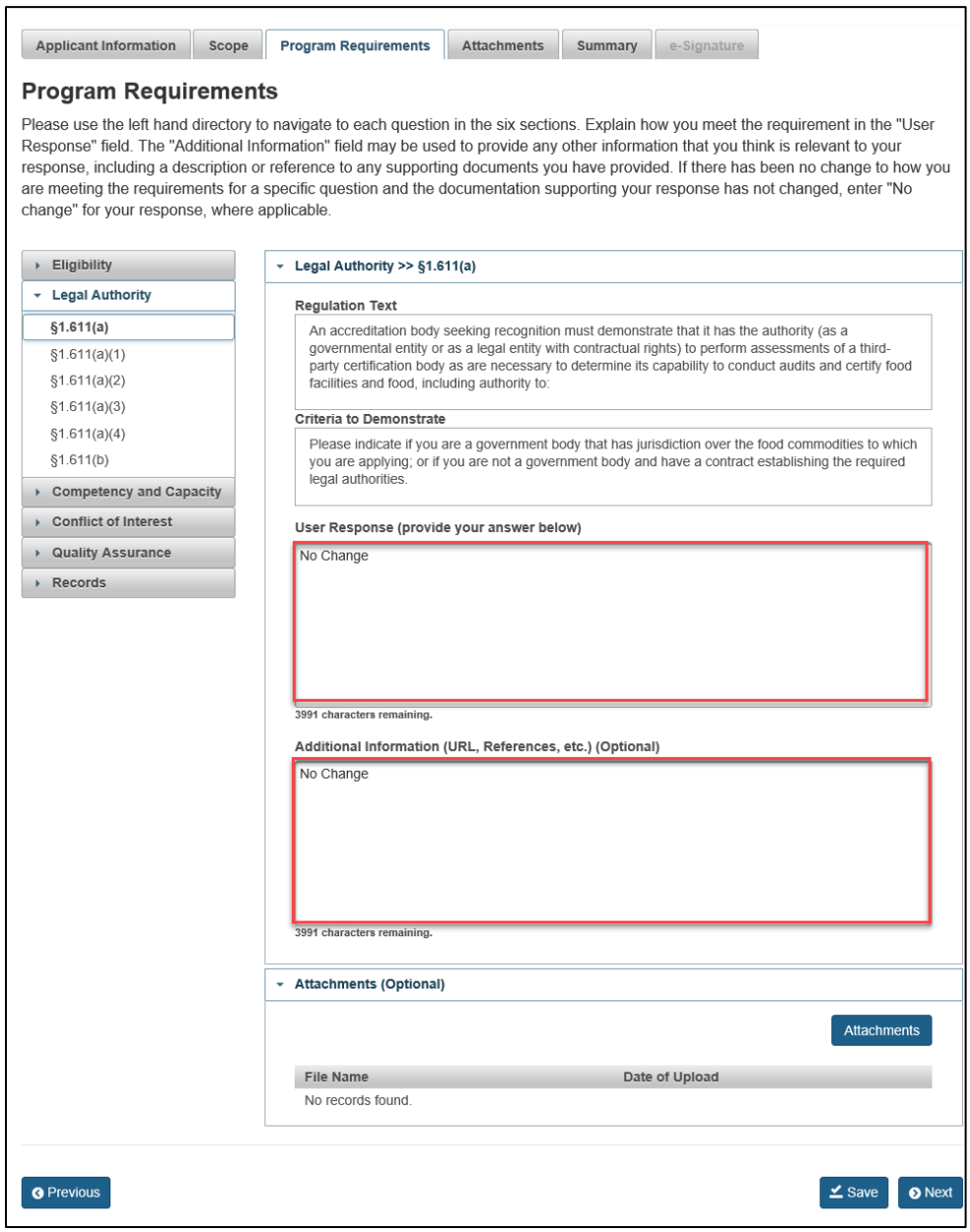
Figure 8.3 – Scope Page



Note: It is recommended to submit the “Notice of Request for AB Recognition Expansion” if you wish to add scopes to your recognition but are not applying for renewal of recognition yet. Refer to Section 11.8 of this document, “Notice of Request for AB Recognition Expansion” for instructions.

- **Program Requirements Page** – Complete each of the fields, as applicable.
    - If there have been no changes as to how the requirements for a specific question are being met since your previous application for recognition was submitted and the documentation supporting the response has not changed, enter “No change” (Figure 8.4). Refer to Section 5.4 of this document for instructions on completing the “Program Requirements” page, if needed.

Figure 8.4 – No Change Response



Complete all of the sections and proceed to the “Summary” page. After reviewing the “Summary” page, click the “Save” button. To proceed, click the “Next” button. The system will validate that all required fields have been completed. If an error is found, the system will post the relevant error message. Refer to Section 5.6 of this document for additional instructions on completing the “Summary” page, if needed.

If there are no errors, the system will display the “e-Signature” page (Figure 8.5).

Note: The “e-Signature” page does not become enabled until all errors indicated on the “Summary” page have been corrected and the corrections have been saved.

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

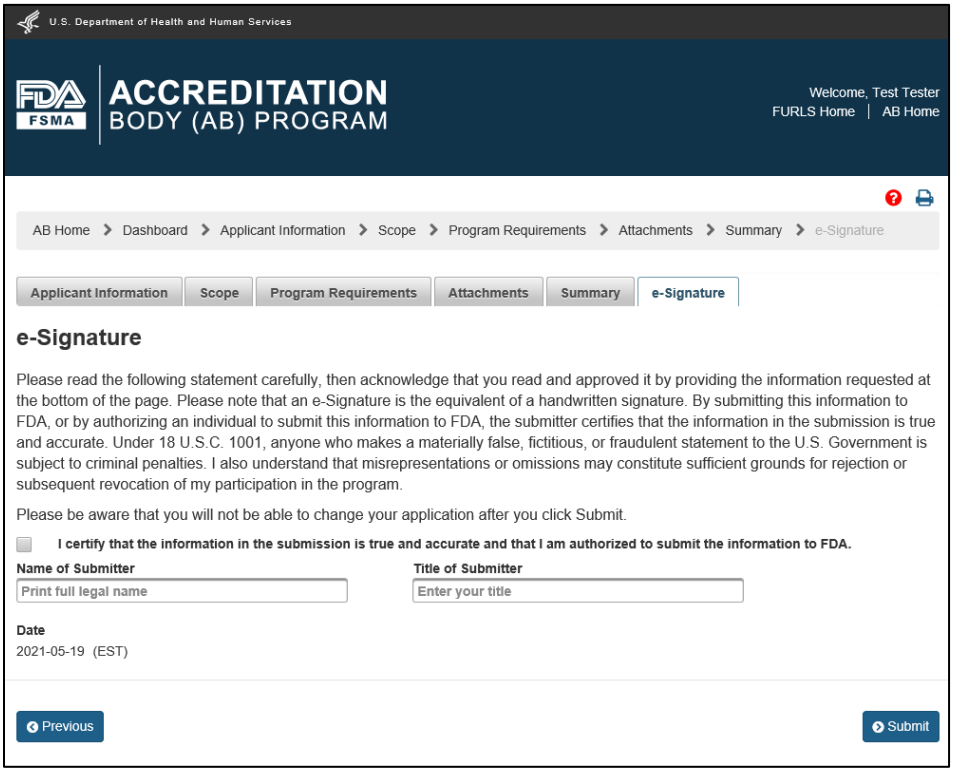
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Summary” page.

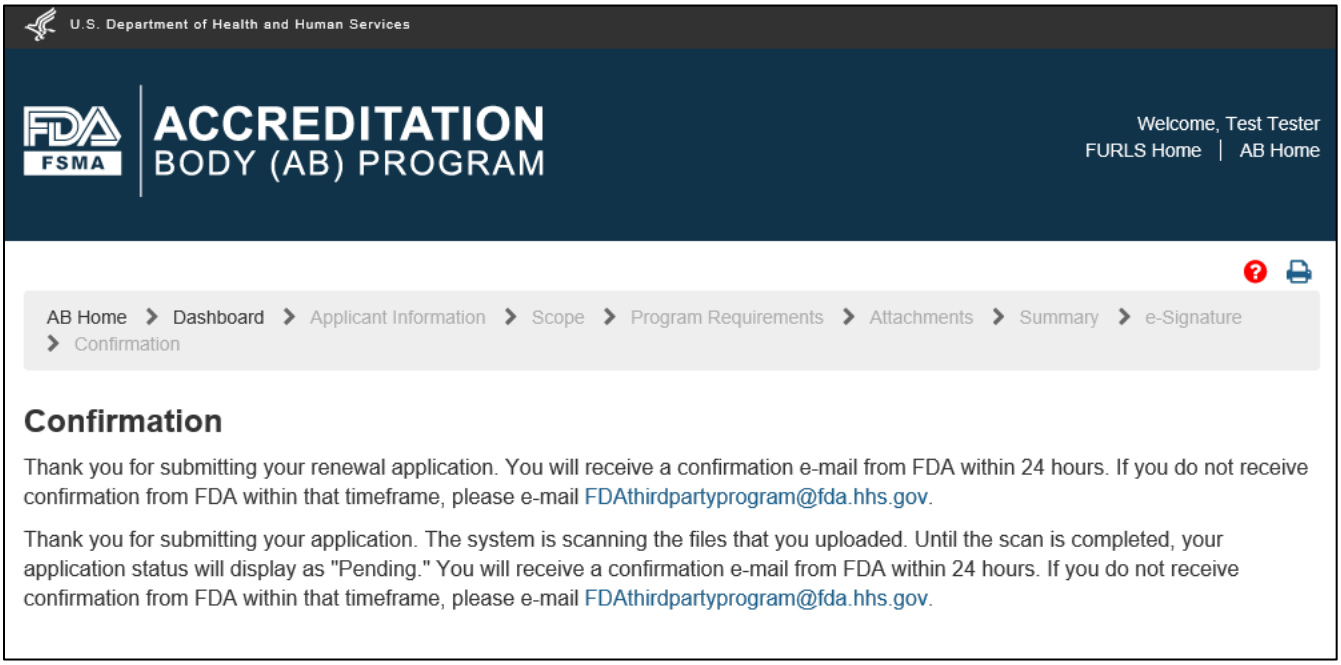
Click the “Submit” button to complete submission to FDA.

Figure 8.5 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 8.6).

Figure 8.6 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating that the renewal application was received by FDA (Figure 8.7). Note that the image below only depicts the e-mail notification text.

Figure 8.7 – E-mail Notification

Thank you for applying for renewal to FDA's Accredited Third-Party Certification Program. We appreciate your interest in renewing your participation in the program. Your electronic submission has been received by the Agency. The Agency is currently processing your request for renewal to ensure all required data elements have been submitted in order for the Agency to complete a comprehensive review of your application. During the Agency's review you may be contacted for additional information that may be needed to allow the Agency to complete the review.

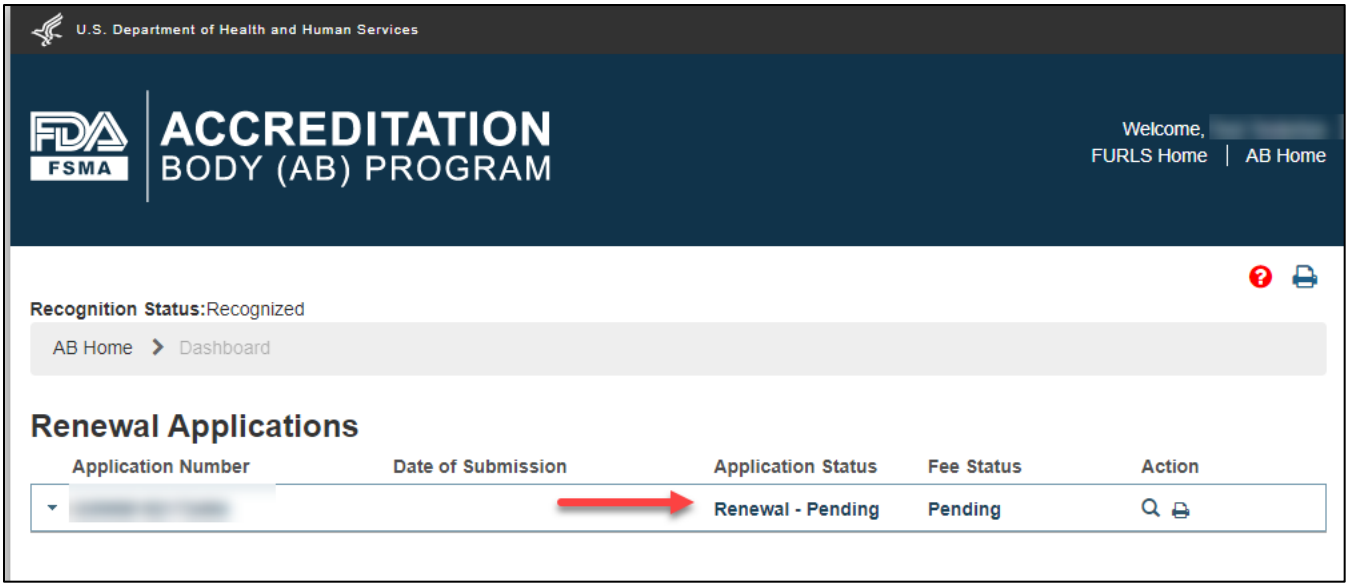
Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

To check the status of the application, refer to the “Renewal Applications” page (Figure 8.8). To navigate to the page from the “AB Home” page, select the “View/Edit my renewal application” option from the left-hand navigation menu.

After the application has been submitted, it will be assigned an application number and the application status will be displayed as “Renewal - Pending” on the “Renewal Applications” page.

Figure 8.8 – Renewal - Pending Application Status

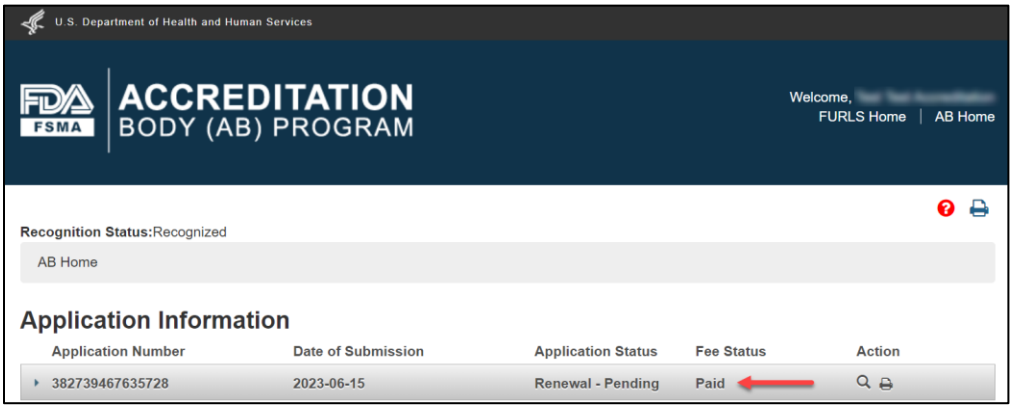


When FDA receives the completed application, the status on the “Application Information” page will change to “Renewal - Submitted”.

FDA will begin review of your application once you have paid your user fee. You will receive an invoice from the User Fee System with guidance on how to submit your payment.

After the user fee has been received and processed, the “Fee Status” on the “Application Information” page will update from “Pending” to “Paid” (Figure 8.9).

Figure 8.9 – Paid Fee Status



When FDA has made a decision on your renewal application, you will receive an e-mail notification.

If your renewal application has been approved, the system will send an e-mail to the address entered on the “Account Management” page (Figure 8.10). Note that the image below only depicts an example of the e-mail notification text.

Figure 8.10 – E-mail Notification

We are pleased to inform you that your participation in FDA's Accredited Third-Party Certification Program has been renewed and remains valid until [redacted]

You must continue to meet the requirements of the program which include but are not limited to the reporting and notification obligations. You are recognized for the following scopes:

[redacted]

Any work you perform under this recognition renewal continues to be subject to the requirements under 21 CFR Part 1, Subpart M, including requirements to immediately notify us upon granting of accreditation of a certification body under the program. Please provide this notification to us through your FURLS account under the "Add or View my Third-Party CBs" option.

You may submit a "Notice of Request for AB Recognition Expansion" for scope(s) in addition to those listed above.

We look forward to working with you, thank you for your continued participation in FDA's Accredited Third-Party Certification Program.

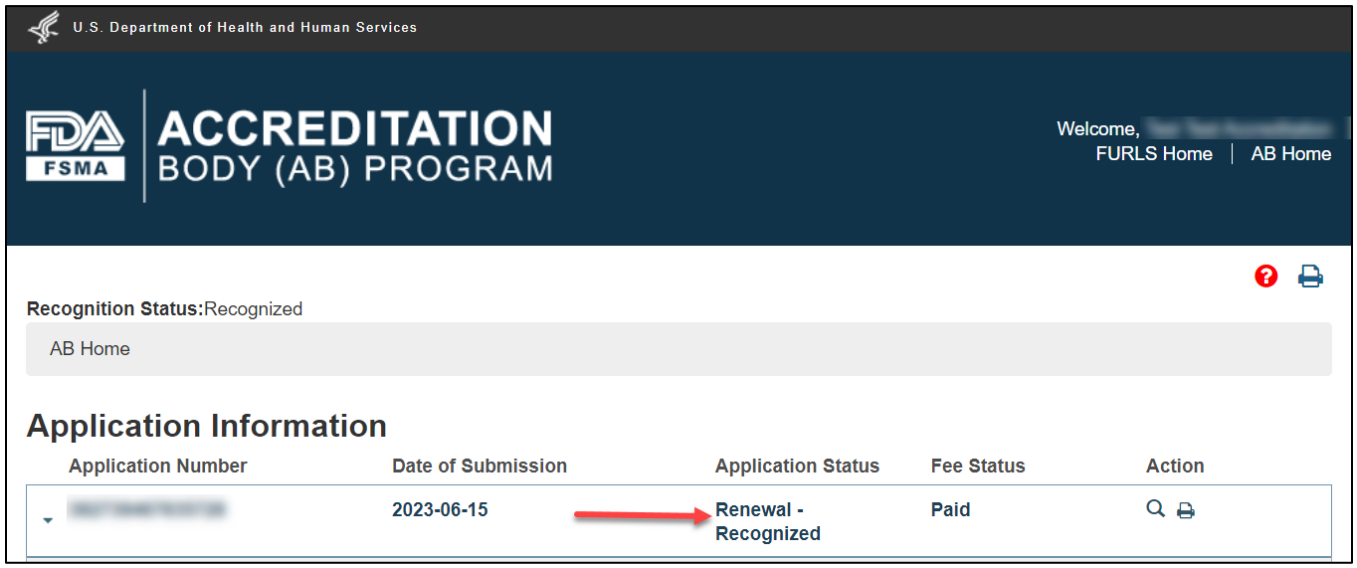
Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

The “Application Status” will display as “Renewal – Recognized” on the “Application Information” page (Figure 8.11). Additionally, the scope(s) “Expiration Date” fields will be updated to reflect the updates.

Once your renewal application has been approved, you will be able to continue to access the full privileges as a Recognized AB in the FURLS system, through the new program expiration date.

Figure 8.11 – Renewal - Recognized Status



If your renewal application has been returned for additional information, the system will send an e-mail to the address entered on the "Account Management" page indicating the program requirement(s) where additional information is being requested (Figure 8.12). Note that the image below only depicts an example of the e-mail notification text.

To address the information request from FDA, click the pencil/edit icon in the "Action" column on the "Renewal Applications" page.

Refer to Chapter 6, "Application Returned for Action" for additional information.

Figure 8.12 – E-mail Notification

Thank you for your interest in renewing participation in FDA's Accredited Third-Party Certification Program. Upon review of your application, the Agency has determined the need for additional information and/or clarification. In order for the Agency to continue its review of your application, you must address the following issues:

§1.611 - Legal Authority.

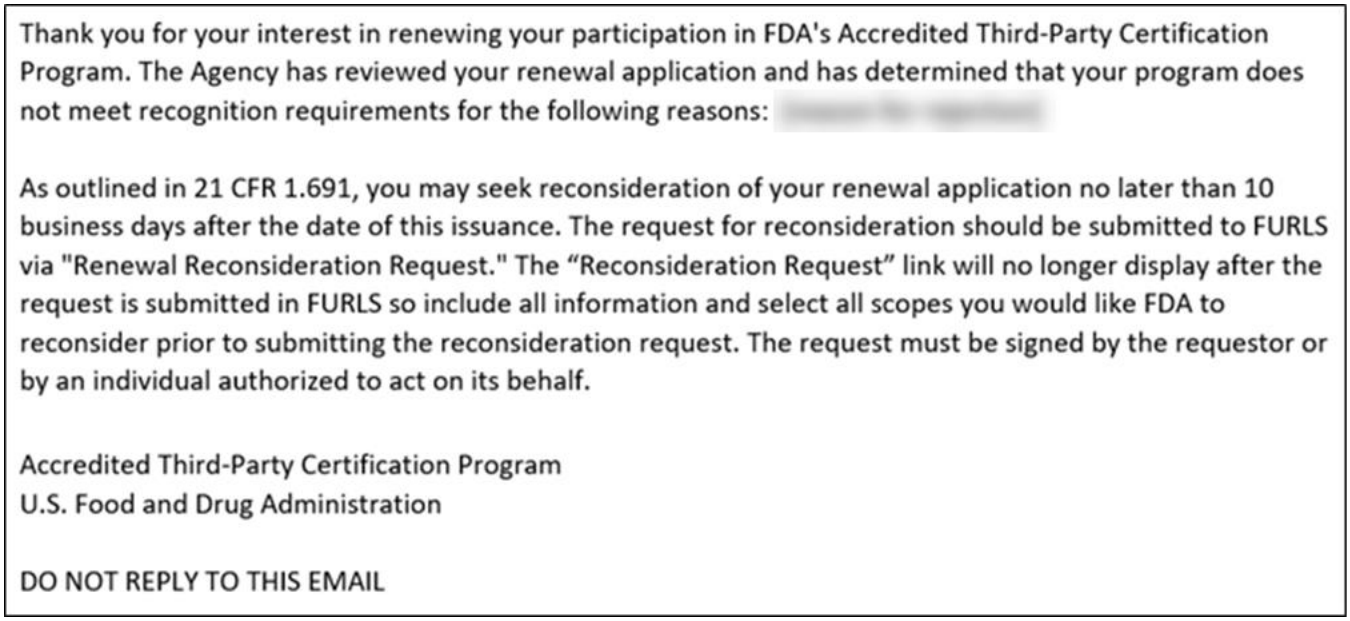
Until the Agency receives the information identified above, your application package will be held in abeyance. Please note, if the requested information is not received in a timely manner it may result in the expiration of your program participation.

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

DO NOT REPLY TO THIS EMAIL

If your renewal application has been denied for all scopes, the system will send an e-mail to the address entered on the “Account Management” page (Figure 8.13). Note that the image below only depicts the e-mail notification text.

Figure 8.13 – E-mail Notification



Thank you for your interest in renewing your participation in FDA's Accredited Third-Party Certification Program. The Agency has reviewed your renewal application and has determined that your program does not meet recognition requirements for the following reasons:

As outlined in 21 CFR 1.691, you may seek reconsideration of your renewal application no later than 10 business days after the date of this issuance. The request for reconsideration should be submitted to FURLS via "Renewal Reconsideration Request." The “Reconsideration Request” link will no longer display after the request is submitted in FURLS so include all information and select all scopes you would like FDA to reconsider prior to submitting the reconsideration request. The request must be signed by the requestor or by an individual authorized to act on its behalf.

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

DO NOT REPLY TO THIS EMAIL

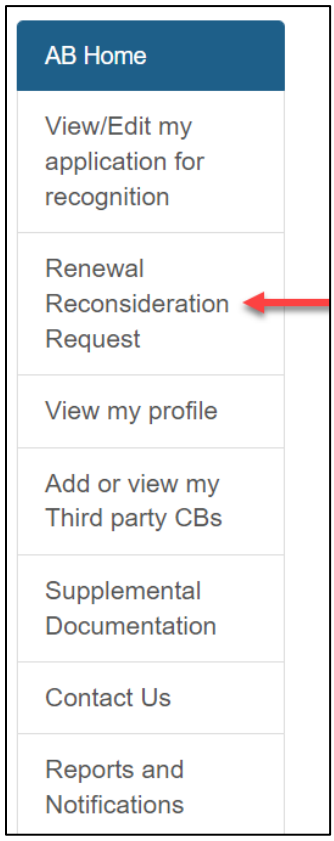
You may submit a renewal application reconsideration request for any scopes that have been denied on the initial application to be reconsidered by FDA.

The “Renewal Reconsideration Request” link will display on the navigation menu on the “AB Home” page if FDA has denied at least one scope in the renewal application (Figure 8.14). The link will no longer display once the “Renewal Reconsideration Request” is submitted to FDA.

****Important**: You will have 10 business days from the date of notification of the denial from FDA to submit a renewal reconsideration request. The “Renewal Reconsideration Request” link will no longer display after the request is submitted so include all information and select all scopes you would like FDA to reconsider prior to submitting the renewal reconsideration request.

Click on the “Renewal Reconsideration Request” link on the navigation menu. Refer to Chapter 7 “Reconsideration Request” for information on submitting a reconsideration request, if needed.

Figure 8.14 – Navigation Menu



9 Add or View Third-Party Certification Bodies (CBs)

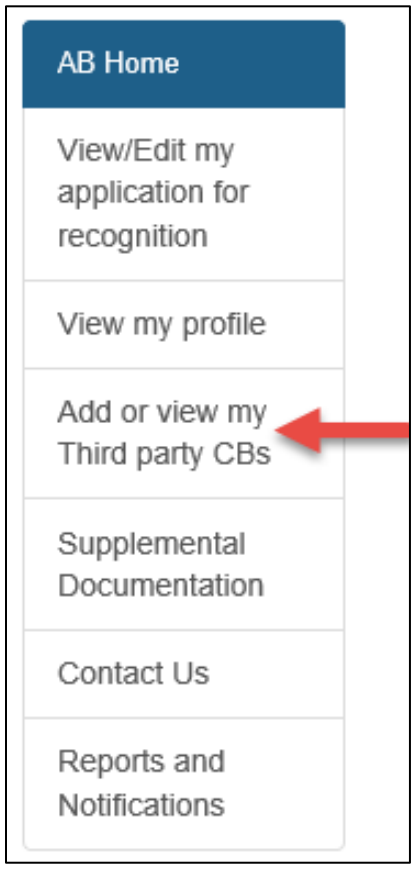
The “Add or view my Third-Party CBs” feature may be used to perform the following two functions:

- Add a new accredited CB to the system
- View the details for an accredited CB

To add a new accredited CB to the system or view the details for an accredited CB, click the “Add or view my Third-Party CBs” link from the navigation menu on the “AB Home” page (Figure 9.1).

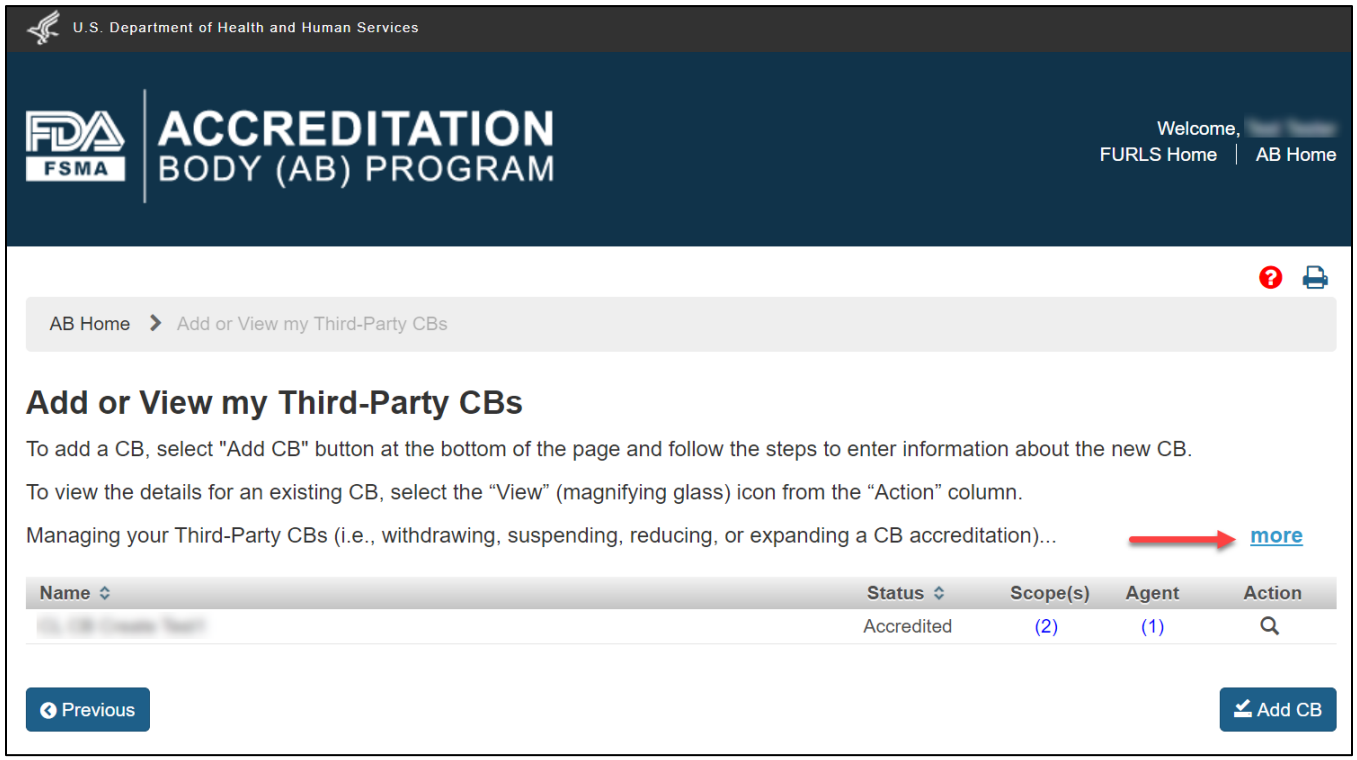
Note: To renew the accreditation of a CB refer to Section 11.6 of this document, “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB.”

Figure 9.1 – Navigation Menu



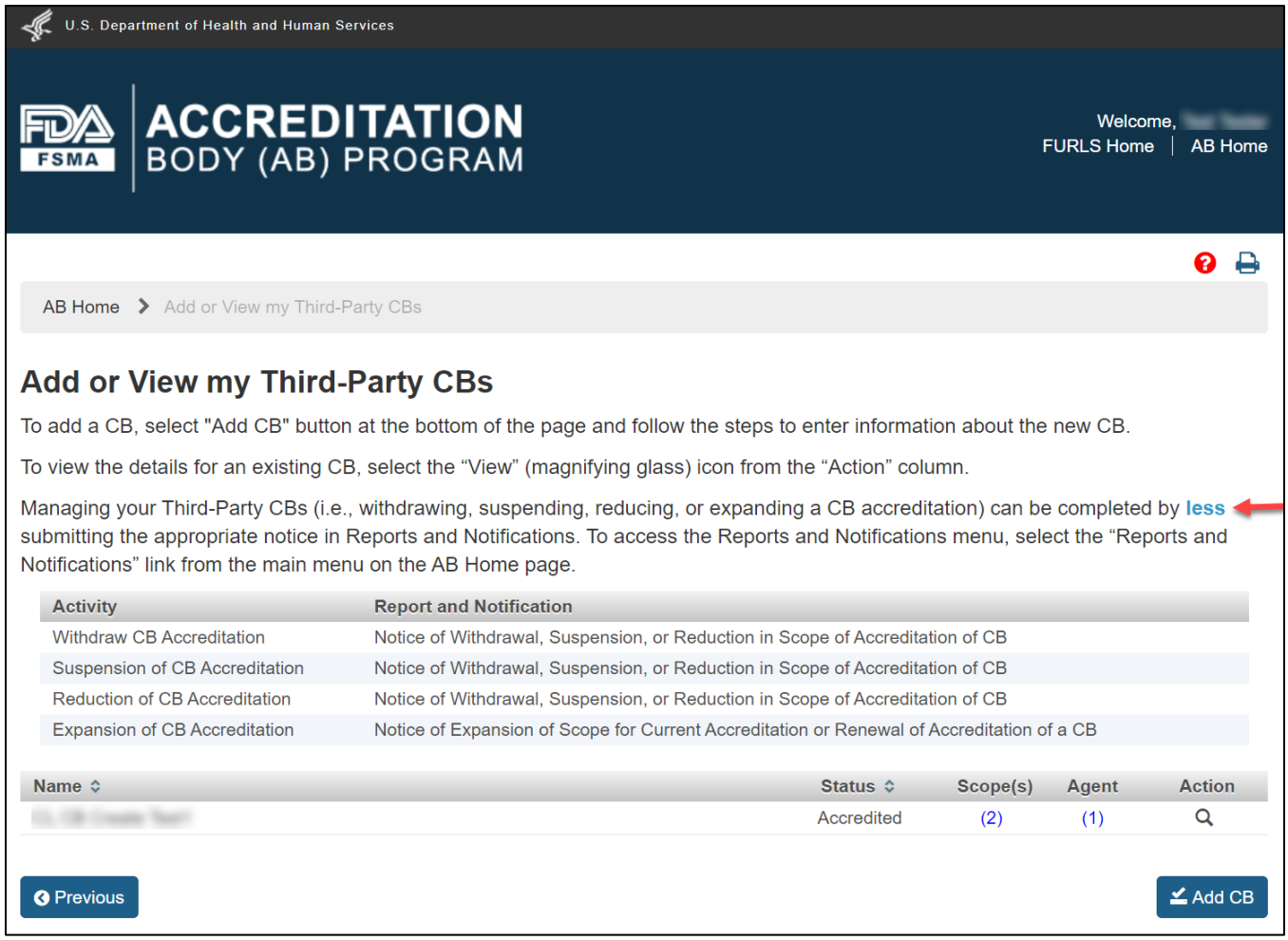
The system will display the “Add or View my Third-Party CBs” page (Figure 9.2). Click the “more” link to display all of the instructional text at the top of the page.

Figure 9.2 – Add or View my Third-Party CBs Page – Default View



The "more" link will change to the "less" link. Click the "less" link to collapse the text (Figure 9.3).

Figure 9.3 – Add or View my Third-Party CBs Page – Instructional Text



To add a new accredited CB, proceed to Section 9.1 of this chapter.

To view the details of the accredited CB(s) that have already been added to the system, proceed to Section 9.2 of this chapter.

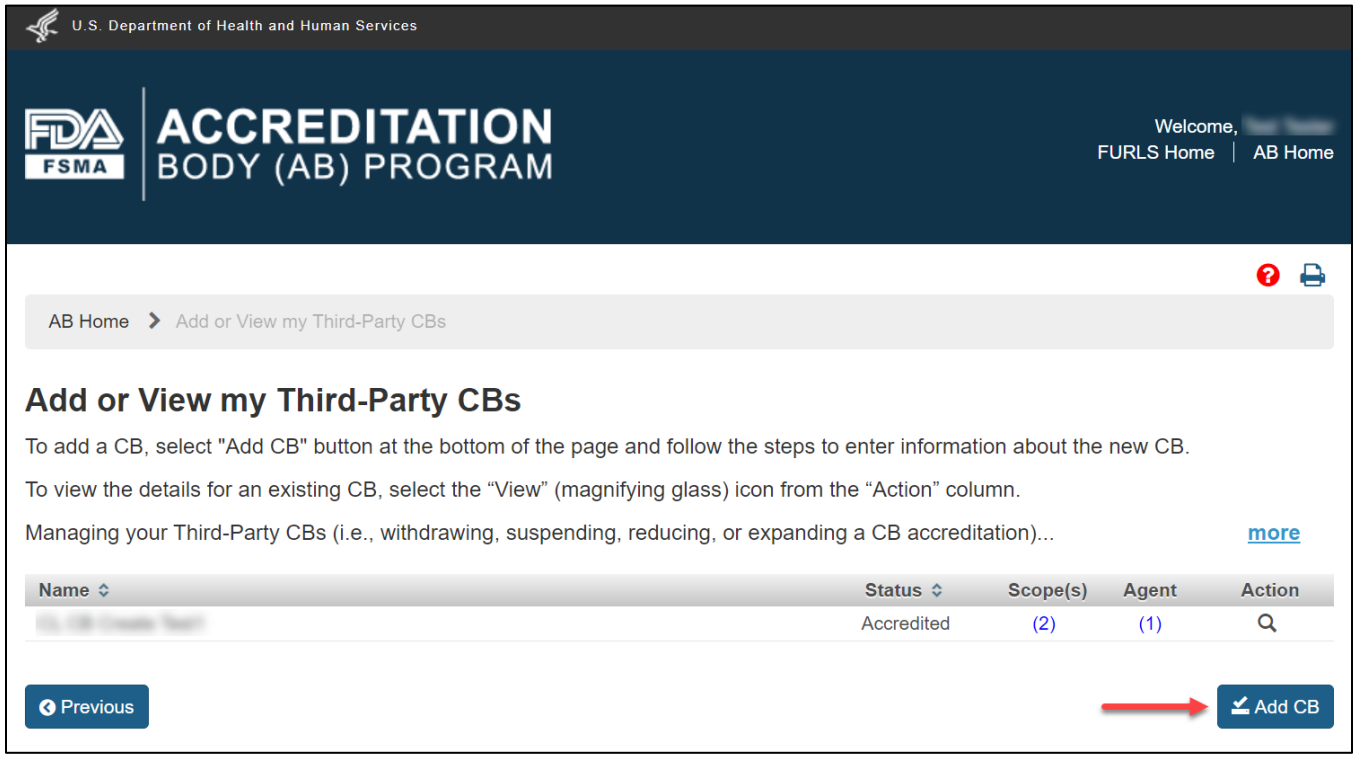
Note: To manage CB(s) (i.e., withdraw, suspend, reduce, expand or, renew a CB accreditation), identify the activity from the "Activity" column of the table on the "Add or View my Third-Party CBs" page and find the corresponding notice listed in the "Reports and Notifications" column of the same table.

Refer to Chapter 11 "Reports and Notifications" for instructions and additional information regarding reports and notifications.

9.1 Add a New Accredited Third-Party Certification Body (CB)

To notify FDA upon granting accreditation to a CB and to add the accredited CB to the AB portal, click the “Add CB” button at the bottom of the page (Figure 9.4).

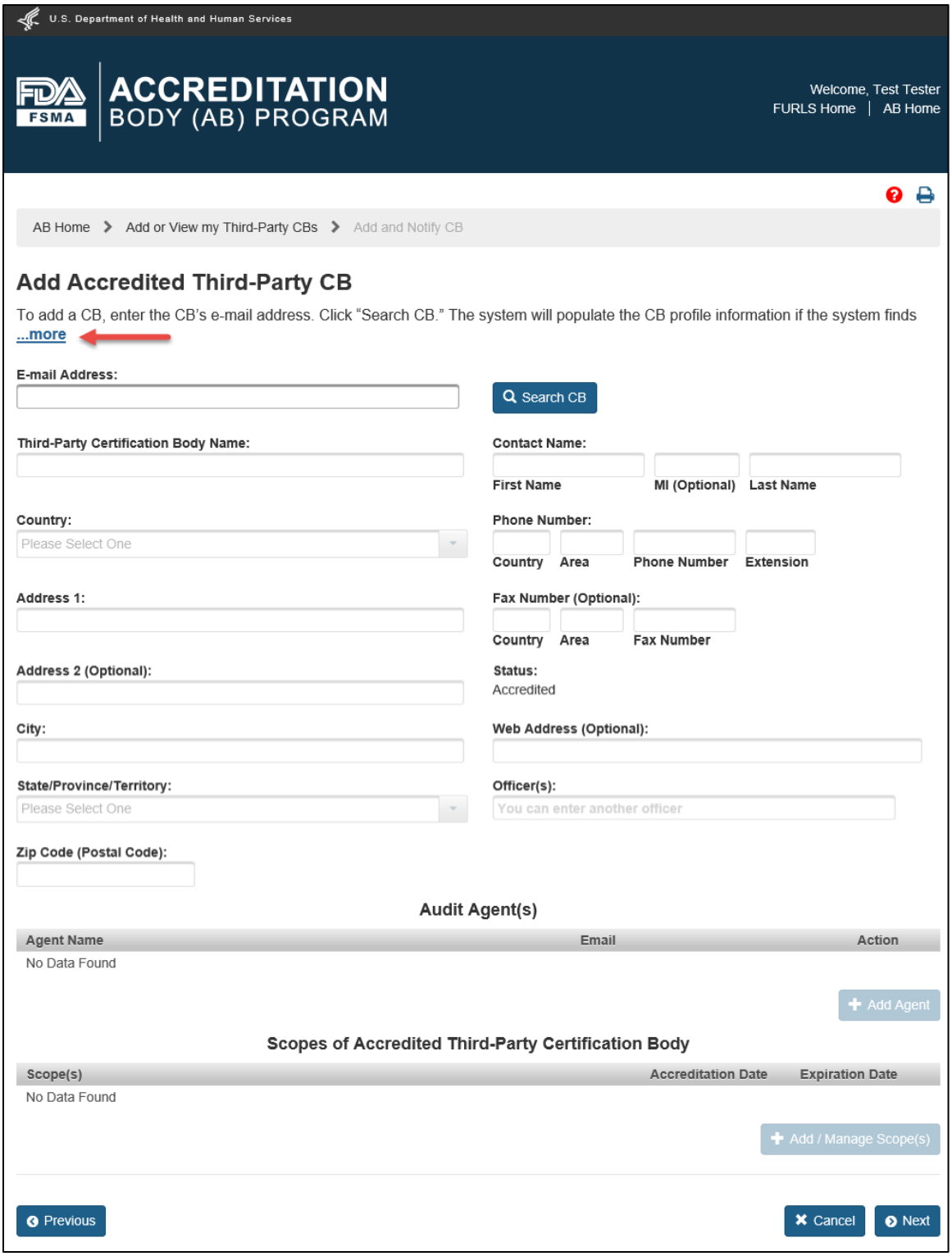
Figure 9.4 – Add CB Button



The system will display the “Add Accredited Third-Party CB” page.

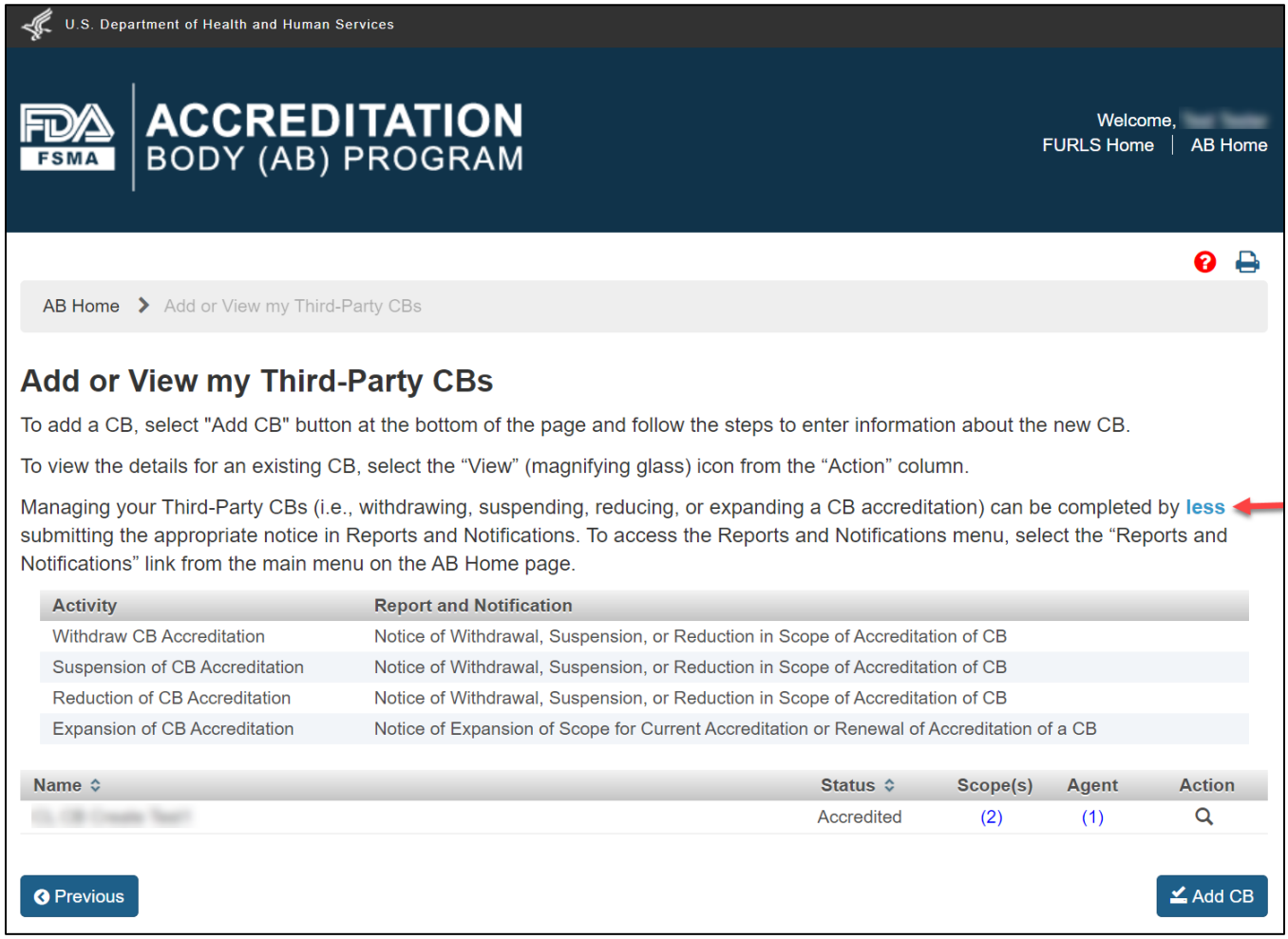
Click the “…more” link to display all of the instructional text at the top of the page (Figure 9.5).

Figure 9.5 – Add Accredited Third-Party CB Page – More Link



The "…more" link will change to the "less" link. Click the "less" link to collapse the text (Figure 9.6).

Figure 9.6 – Add Accredited Third-Party CB Page – Instructional Text

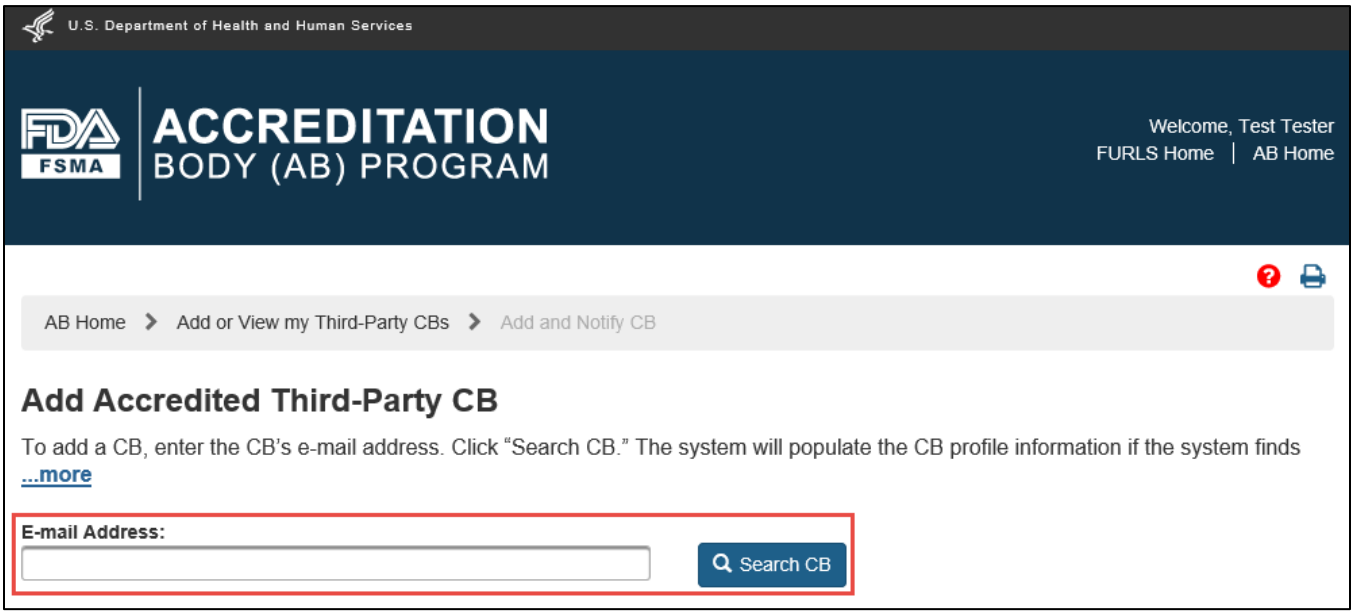


Enter the e-mail address of the new CB in the "E-mail Address" field and click the "Search CB" button (Figure 9.7). If the system returns a match (i.e., the CB's e-mail address already exists in the system), the field will be pre-filled with the CB's information.

If a match is not found for the searched e-mail address, enter the information for the CB.

Note: The CB data fields will not become enabled until an e-mail address is entered, and the "Search CB" button is clicked.

Figure 9.7 – E-mail Address Field and Search CB Button



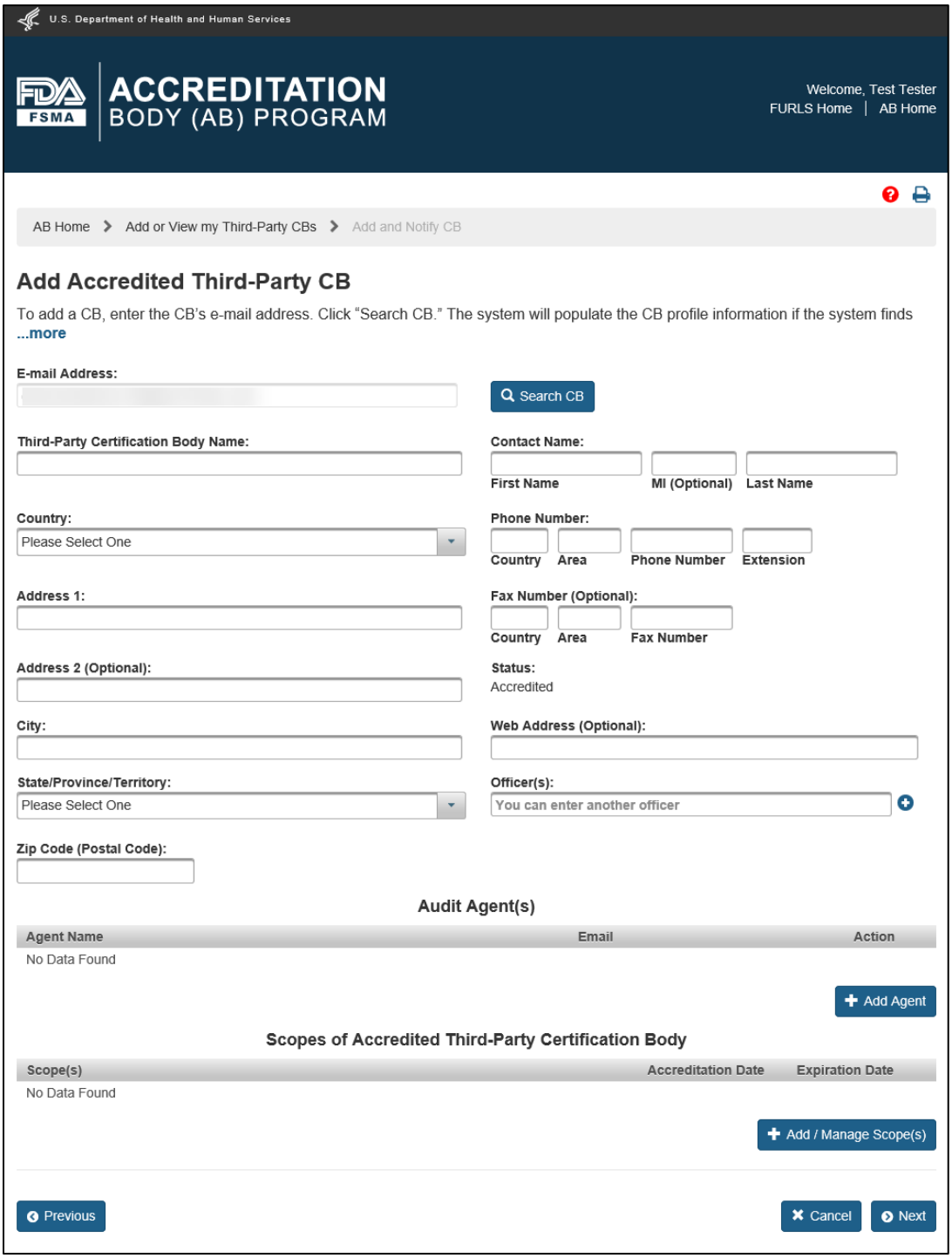
The data fields on the "Add Accredited Third-Party CB" page include (Figure 9.8):

- **E-mail Address** – The e-mail address for the Point of Contact
- **Third-Party Certification Body Name** – The name of the CB the Point of Contact represents
- **Country** – The country where the CB is physically located
- **Address 1** – The address where the CB is physically located (includes the number, street, quadrant, etc.)
- **Address 2 (Optional)** – The additional information about the physical location of the CB (may include a suite or apartment number, if applicable)
- **City** – The city where the CB is physically located
- **State/Province/Territory** – The state/province/territory of the CB
- **Zip Code (Postal Code)** – The zip code or postal code of the CB
- **Contact Name**
    - **First Name** – The first name of the Point of Contact
    - **MI (Optional)** – The first letter of the Point of Contact's middle name
    - **Last Name** – The last name of the Point of Contact
- **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 of 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 fax number.
- **Web Address (Optional field)** – The URL of the company
- **Officer(s)** – The Officer(s) of the company

Complete the data fields.

Figure 9.8 – Add Accredited Third-Party CB Page – Data Fields

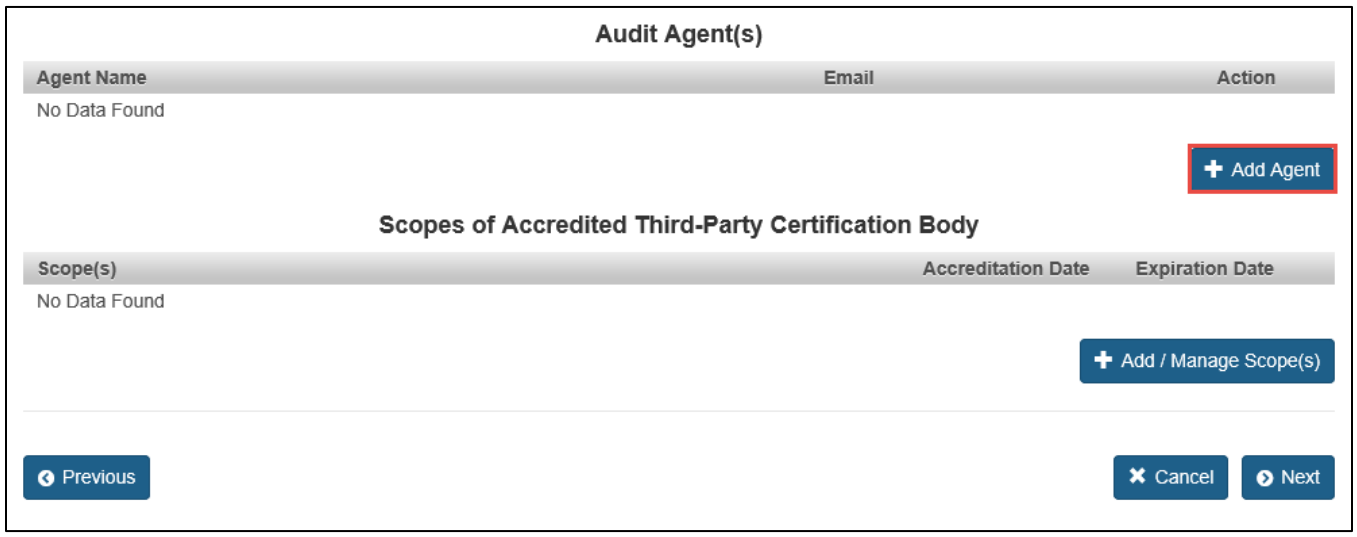


The "Add Agent" and "Add/Manage Scope(s)" buttons become enabled once the data is entered.

Click the “Add Agent” button to add the accredited CB’s audit agents (Figure 9.9).

Note: Please ensure that there is one active audit agent listed at all times.

Figure 9.9 – Add Agent Button

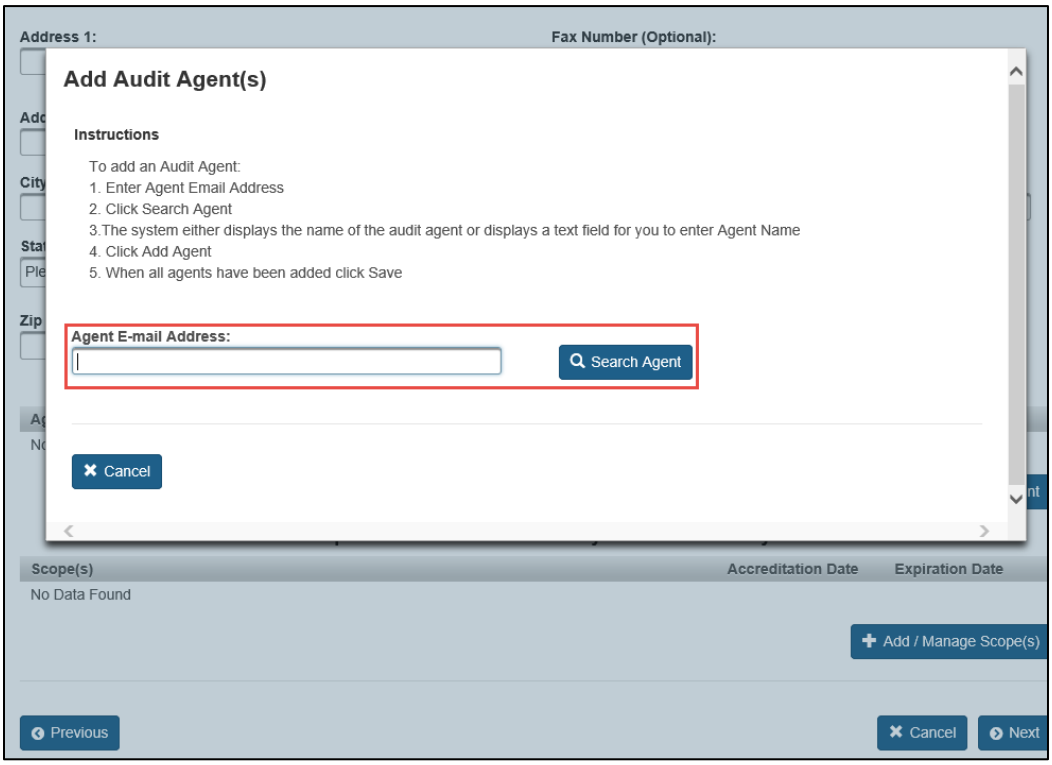


The system will display the “Add Audit Agent(s)” pop-up window (Figure 9.10).

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

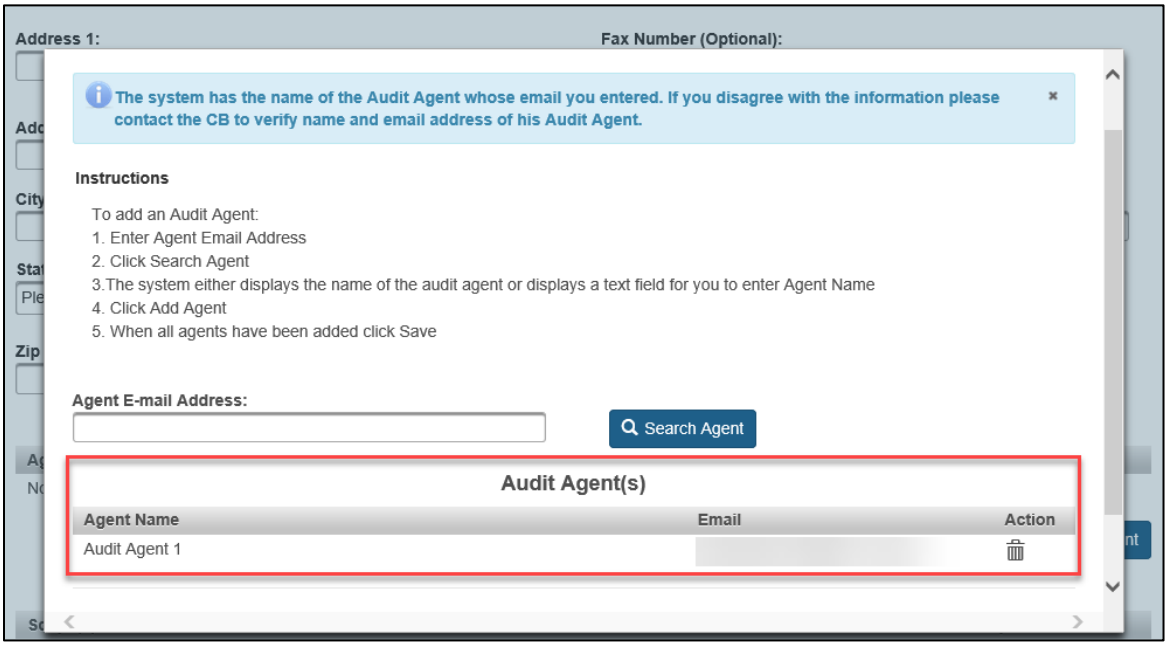
Note: The system identifies an audit agent by their unique e-mail address. An audit agent’s e-mail address cannot be edited once saved.

Figure 9.10 – Add Audit Agent(s) Pop-up Window



If a match is found for the searched e-mail address, the audit agent's information will be displayed in the "Audit Agent(s)" table in the window (Figure 9.11).

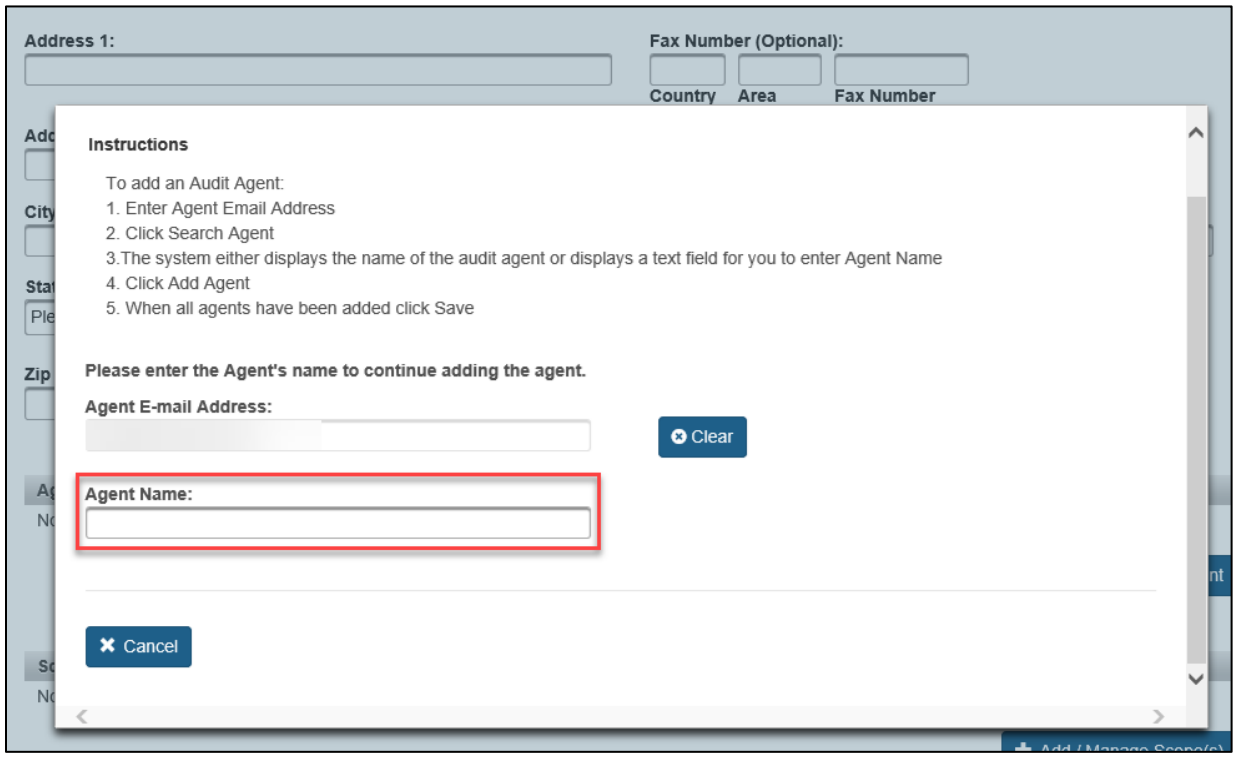
Figure 9.11 – Audit Agent(s) Table



If the system does not return a match for the e-mail address, the “Agent Name” field will be blank (Figure 9.12).

Enter the audit agent’s first and last name in the “Agent Name” field and click the “Add Agent” button to add it to the “Audit Agent(s)” table.

Figure 9.12 – Agent Name Field

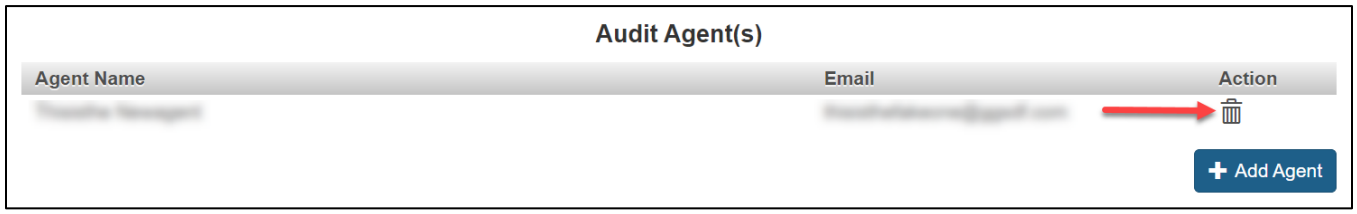


Once all of the desired audit agents have been entered, click the “Save” button to return to the “Add Accredited Third-Party CB” page. The audit agent(s) will be displayed in the “Audit Agent(s)” table on the main page (Figure 9.13).

You can delete an audit agent from the “Audit Agent(s)” table by clicking the trash/delete icon in the “Action” column of the table (Figure 9.13).

Note: Once you submit the CB’s information and the accredited CB has been added to the system, only the CB will have the ability to add new agents and edit the information for existing agents.

Figure 9.13 – Audit Agent(s) Table



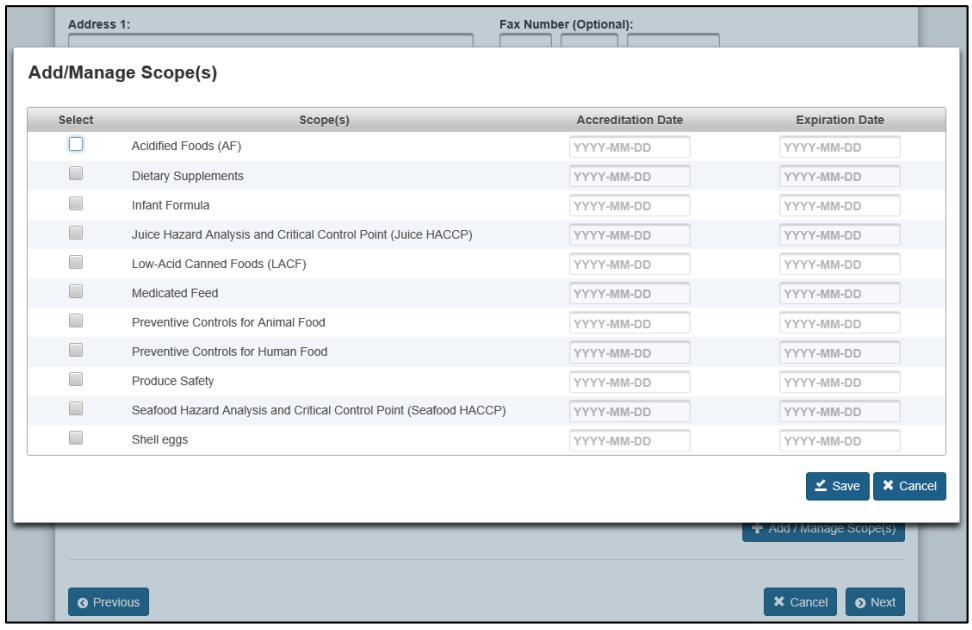
After completing the "Audit Agent(s)" section, click the "Add/Manage Scope(s)" button to select the scopes for which the CB was accredited (Figure 9.14).

Figure 9.14 – Add/Manage Scope(s) Button

The system will display the "Add/Manage Scope(s)" pop-up window (Figure 9.15).

The system will also display the list of scope(s) for which the AB is recognized. Select the scope(s) for which the CB has been accredited for by checking the box in the "Select" field. Select at least one scope.

Figure 9.15 – Add/Manage Scope(s) Pop-up Window

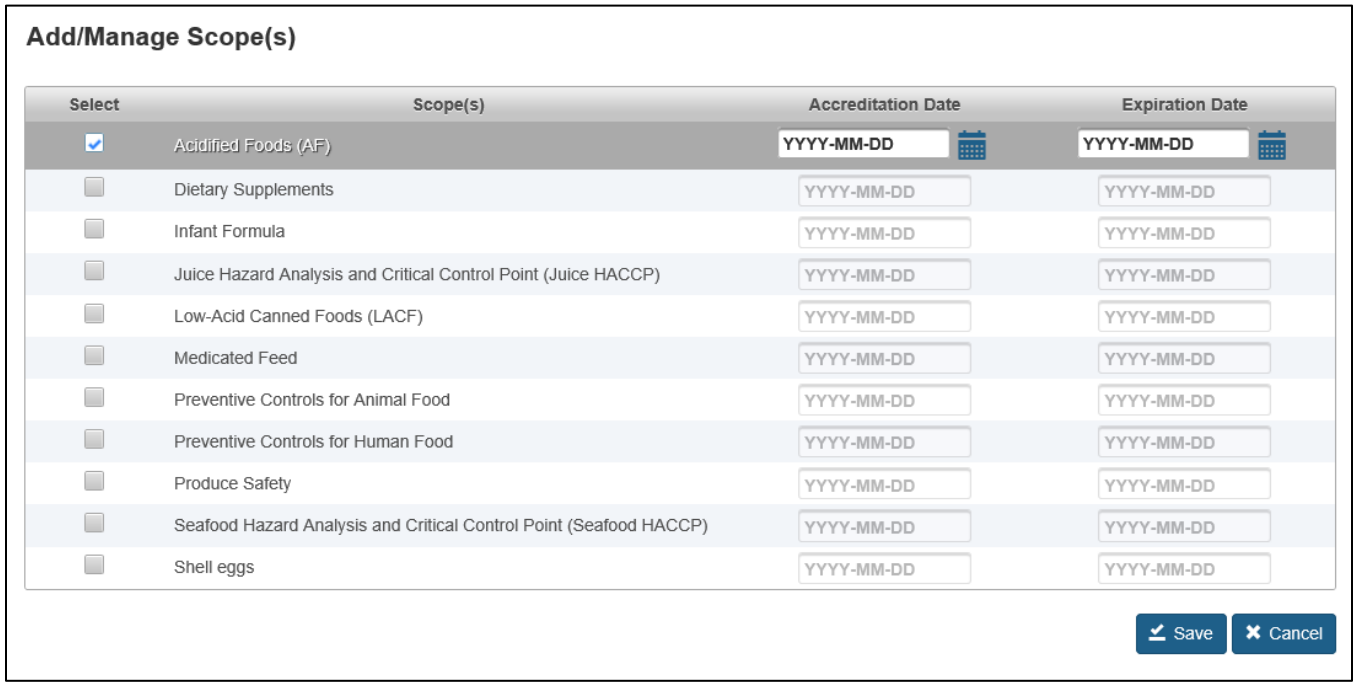


The “Accreditation Date” and “Expiration Date” fields for a scope are enabled once the scope is selected (Figure 9.16).

Select the dates for the “Accreditation Date” and “Expiration Date” fields using the calendar feature or enter the date in “YYYY-MM-DD” format.

Click the “Save” button when all of the scope(s) that a CB has been accredited for have been selected and the dates have been entered.

Figure 9.16 – Add/Manage Scope(s) Pop-up Window – Date Fields Enabled



The system will close the “Add/Manage Scope(s)” pop-up window after the “Save” button is clicked. The newly added scopes and dates will display in the “Scopes of Accredited Third-Party Certification Body” table on the “Add Accredited Third-Party CB” page (Figure 9.17).

Figure 9.17 – Scopes of Accredited Third-Party Certification Body Table

After you have entered all of the information, click the “Next” button.

The system will display the “e-Signature” page (Figure 9.18).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

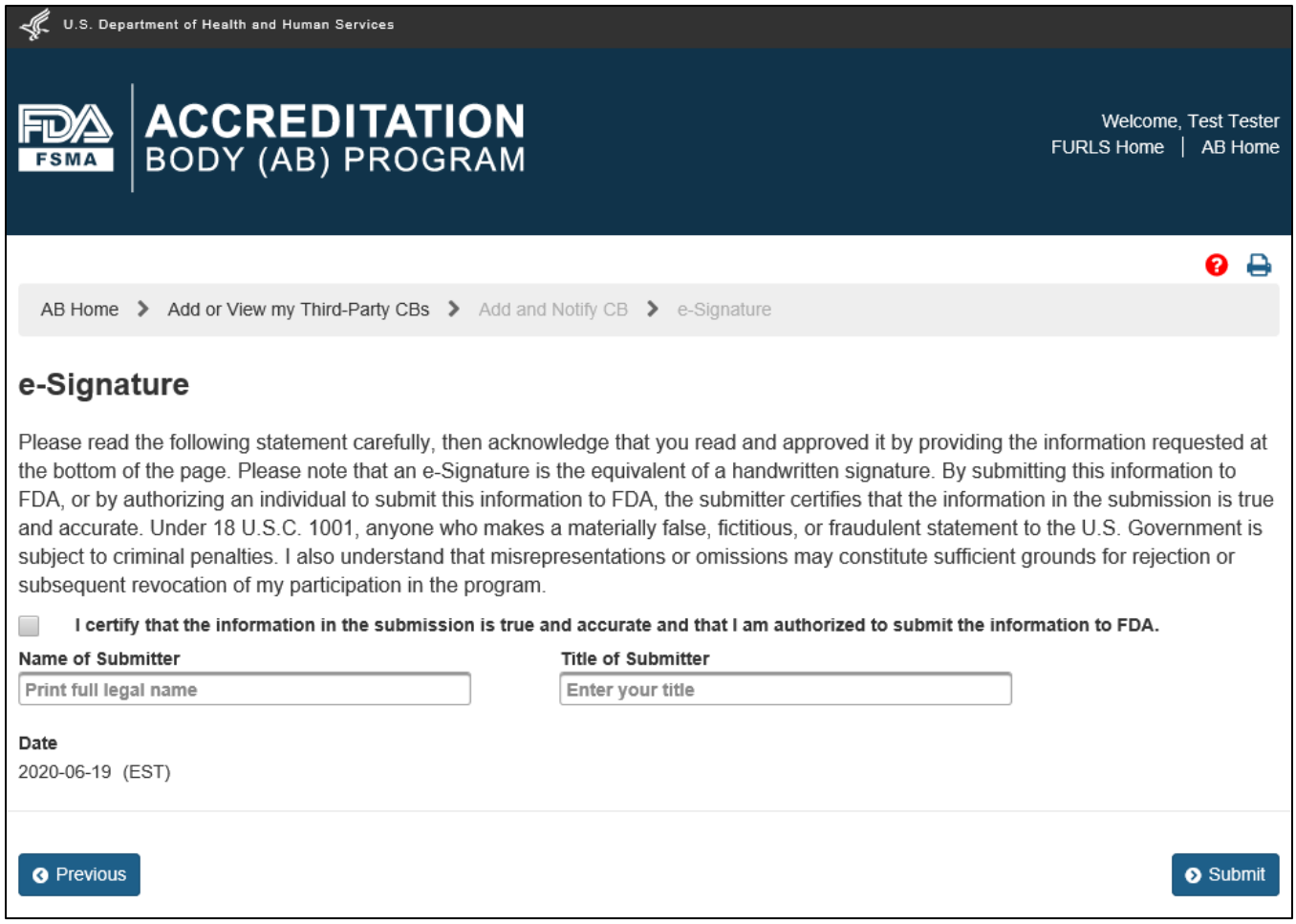
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Add or View my Third-Party CBs” page.

Click the “Submit” button to complete submission to FDA.

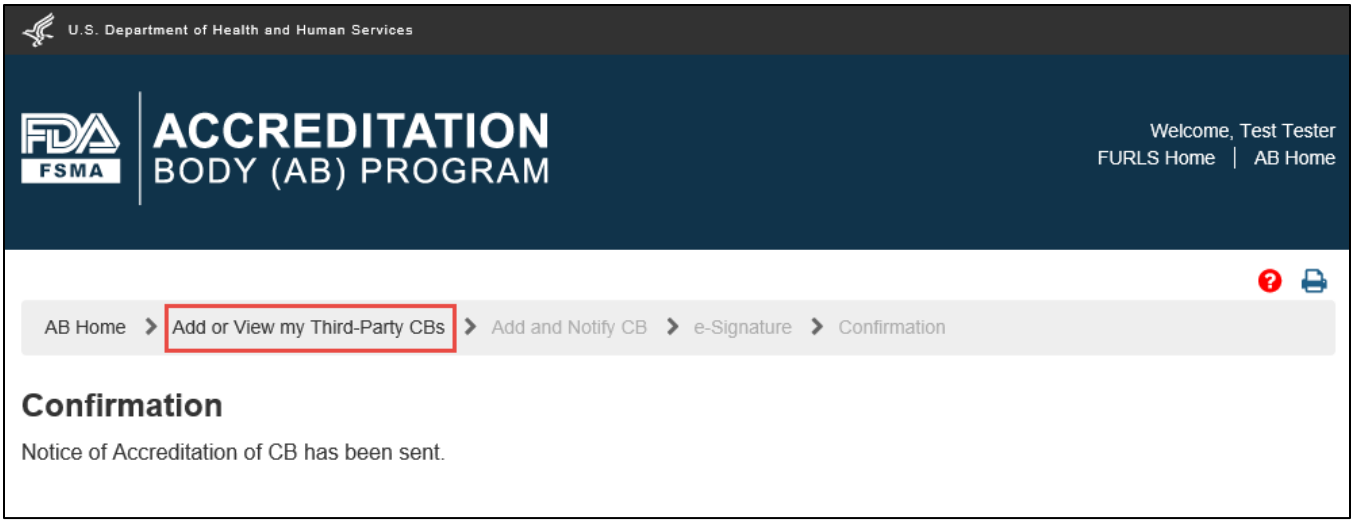
Figure 9.18 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 9.19).

Once you submit the CB’s information, FDA will receive a Notice of Accreditation of the CB.

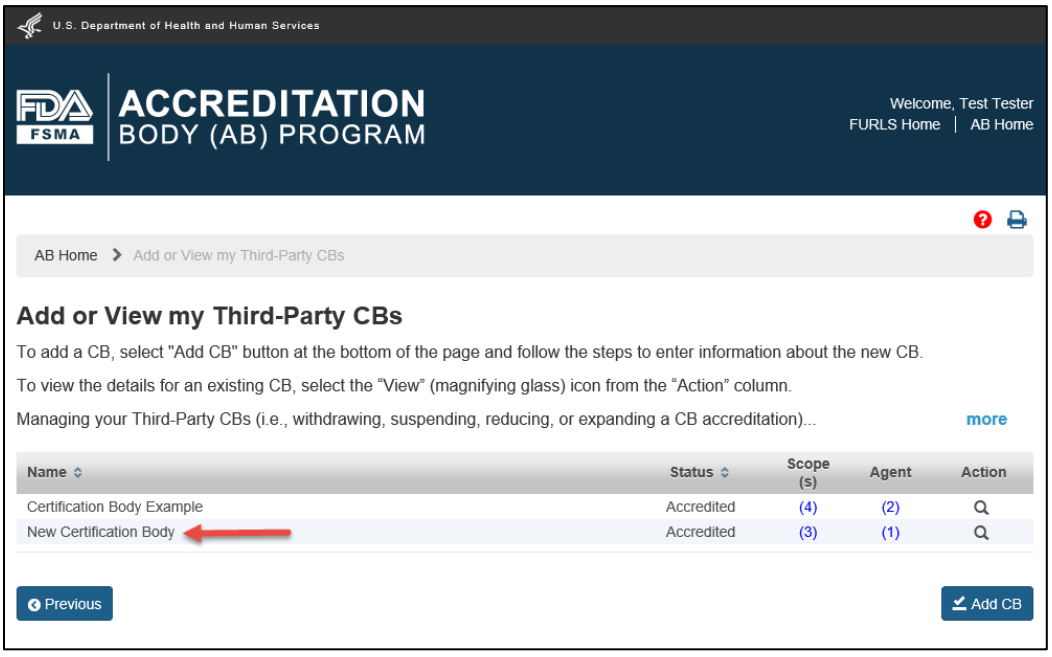
Figure 9.19 – Confirmation Page



Click the “Add or View my Third-Party CBs” link from the breadcrumb at the top of the “Confirmation” page to return to the “Add or View my Third-Party CBs” page or, click the “AB Home” link from the breadcrumb (or banner) and select the link from the main menu.

The new CB will be listed in the CB table on the page (Figure 9.20).

Figure 9.20 – New CB Added



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 9.21). Note that the image below only depicts the e-mail notification text.

Note: The AB and accredited CB will receive a separate e-mail notification of the accreditation. The e-mail to the accredited CB includes steps to complete their account setup.

Figure 9.21 – E-mail Notification

Thank you for submitting information to FDA regarding the Notice of Accreditation of CB. We will review this information and may follow-up if additional information is needed.

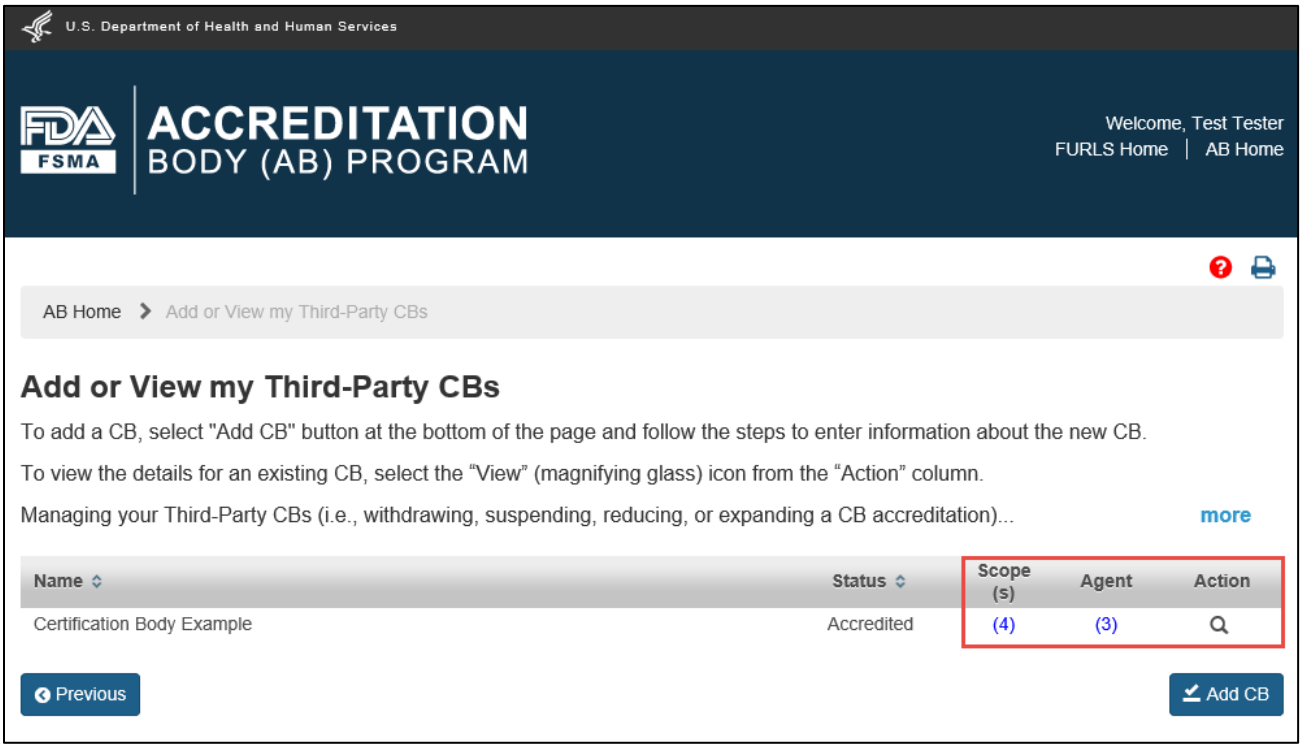
Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

9.2 View the Details of Accredited CBs

To view the details of your accredited CBs in the AB portal (including scopes, audit agents, officers, and profile information), select the links displayed in the CB table on the “Add or View my Third-Party CBs” page (Figure 9.22).

Figure 9.22 – Links to View CB Details



To view the scopes for which the CB is accredited, click the hyperlinked number in the "Scope(s)" column of the CB table (Figure 9.23).

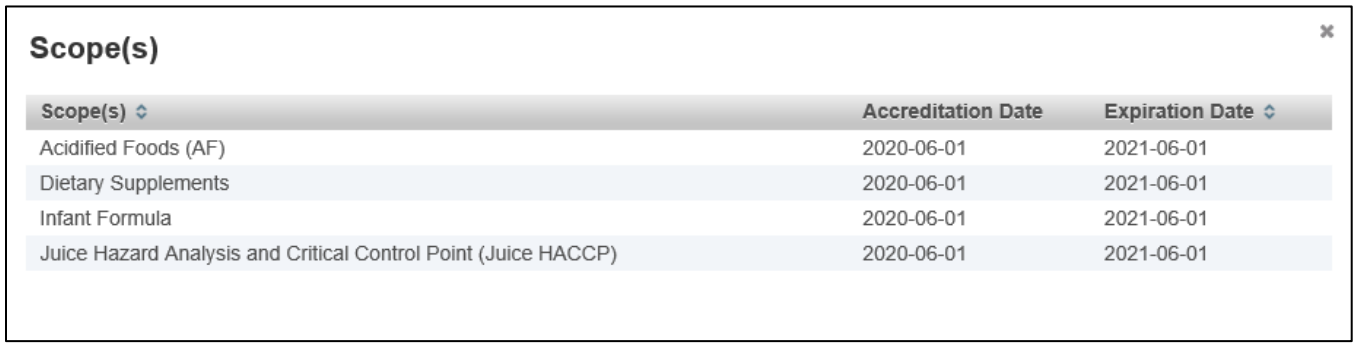
Figure 9.23 – Scope(s) Hyperlink

The system will display the "Scope(s)" pop-up window (Figure 9.24).

The scope(s) for which the CB has been accredited, as well as the accompanying accreditation and expiration dates, will be displayed.

Click the "x" icon in the upper right corner of the window to close the window and return to the "Add or View my Third-Party CBs" page.

Figure 9.24 – Scope(s) Pop-up Window



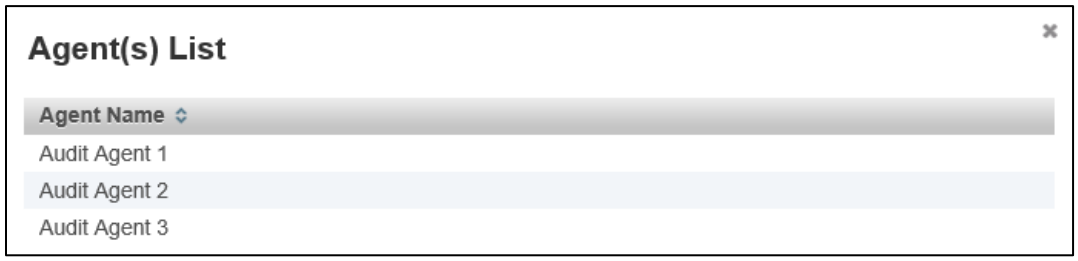
To view the list of active audit agents for the accredited CB, click the hyperlinked number in the "Agent" column of the CB table (Figure 9.25).

Figure 9.25 – Agent Hyperlink

The system will display the "Agent(s) List" pop-up window and list the accredited CB's agent(s) by "Agent Name" (Figure 9.26). Any audit agents that were added by the CB (following accreditation) and are in "Active" status will also be displayed in the list of agents.

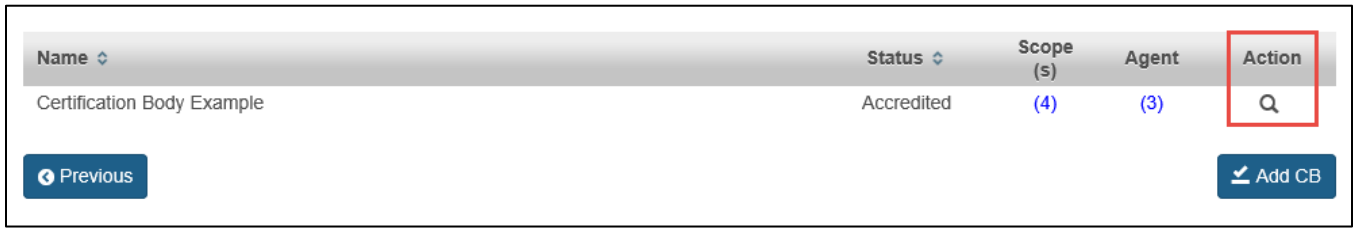
Click the "x" icon in the upper right corner of the window to return to the "Add or View my Third-Party CBs" page.

Figure 9.26 – Agent(s) List Pop-up Window



To view the accreditation details of an accredited CB, click the view/magnifying glass icon in the “Action” column of the CB table (Figure 9.27).

Figure 9.27 – View Icon



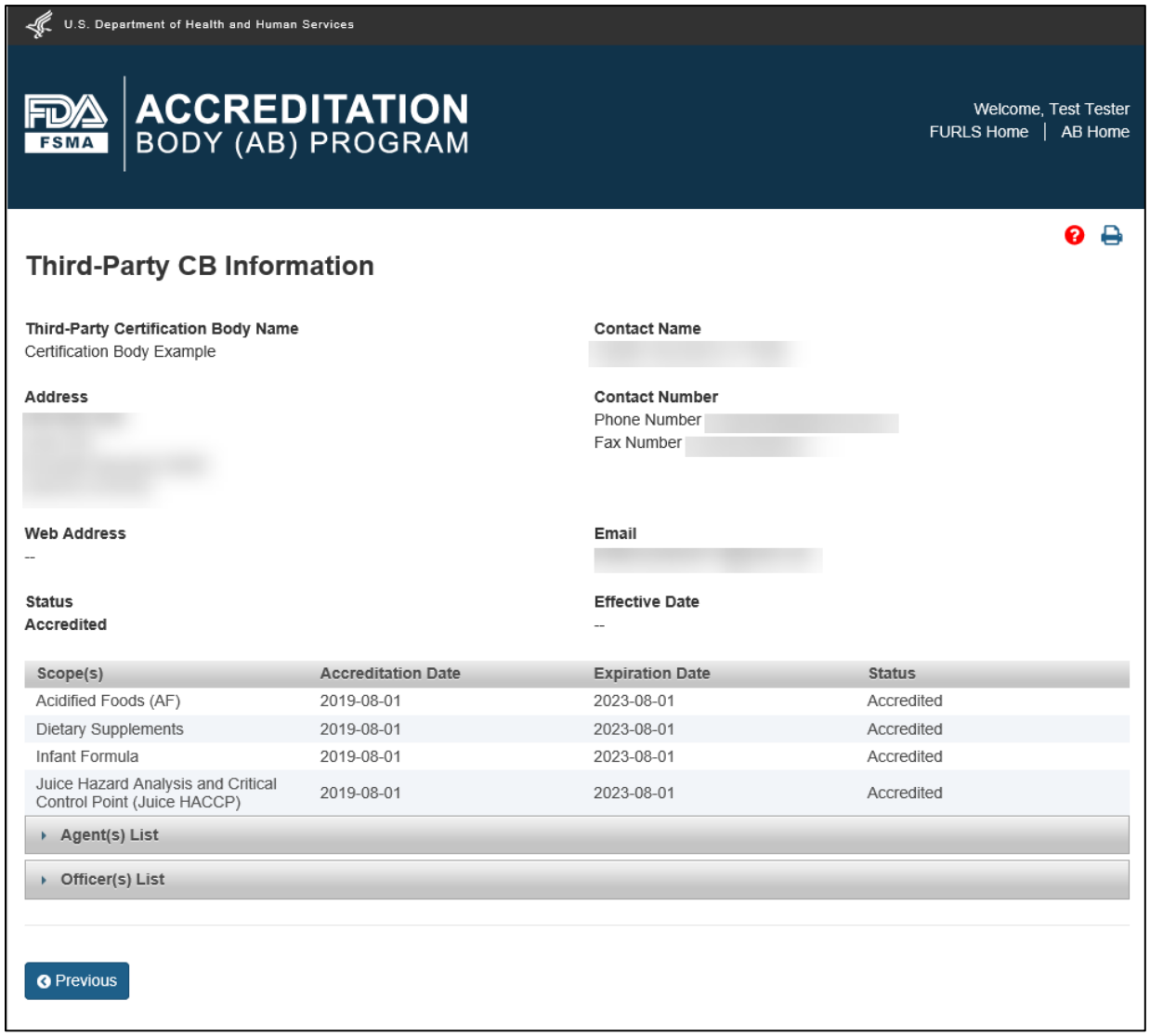
The system will display the “Third-Party CB Information” page with read-only details for the selected CB (Figure 9.28). The CB’s profile information and scopes will display by default.

Click the accordion section title bars for “Agent(s) List” to view the CB’s audit agent(s); click “Officer(s)” to view the CB’s officer(s) information that the accredited CB would add to the system.

Note: If the status of a CB’s scope(s) or accreditation has been changed via one of the notices in the “Reports and Notifications” menu, the updated status and effective date of the change will be displayed in the “Status” and “Effective Date of Change” columns of the scopes table.

Click the “Previous” button at the bottom of the page to return to the “Add or View my Third-Party CBs” page.

Figure 9.28 – Third-Party CB Information Page



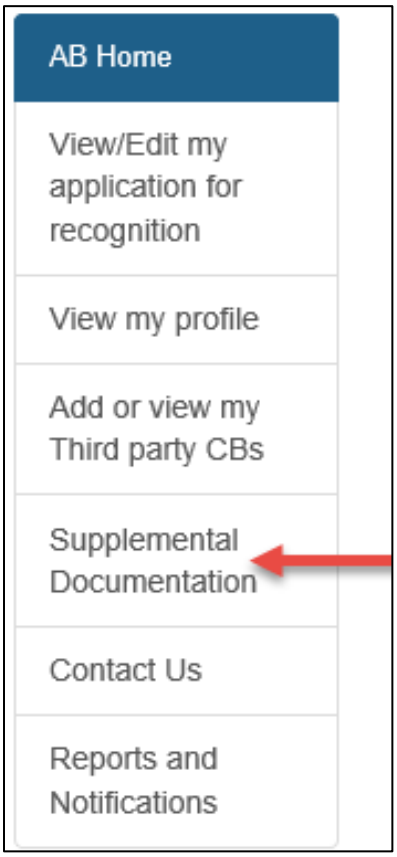
10 Supplemental Documentation

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

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

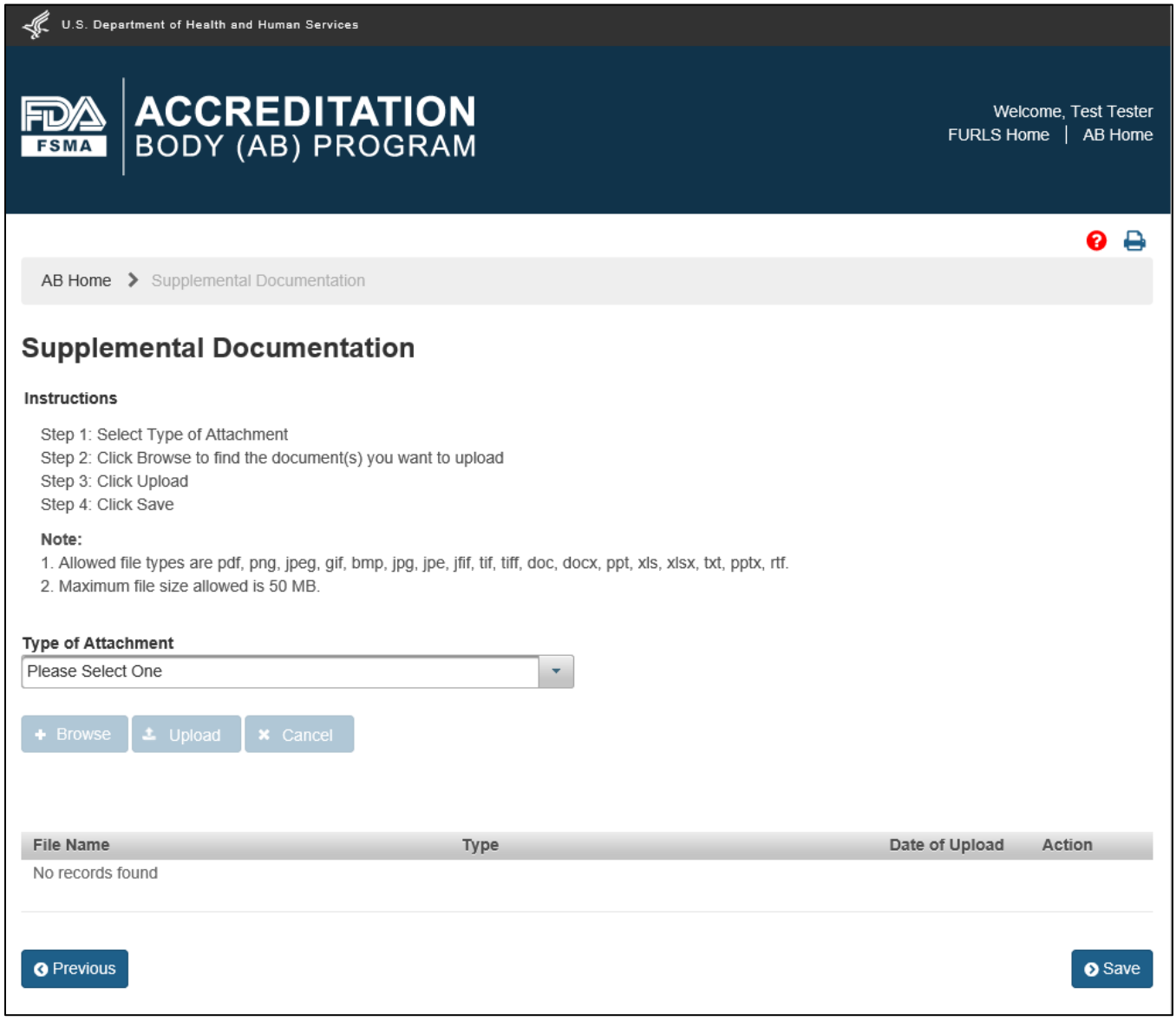
To upload documents to the AB portal or view documents you have submitted to FDA, click the “Supplemental Documentation” link from the navigation menu on the “AB Home” page (Figure 10.1).

Figure 10.1 – Navigation Menu



The system will display the “Supplemental Documentation” page (Figure 10.2). 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 – 4 from the “Instructions” section of the page to upload attachments.

Figure 10.2 – Supplemental Documentation Page

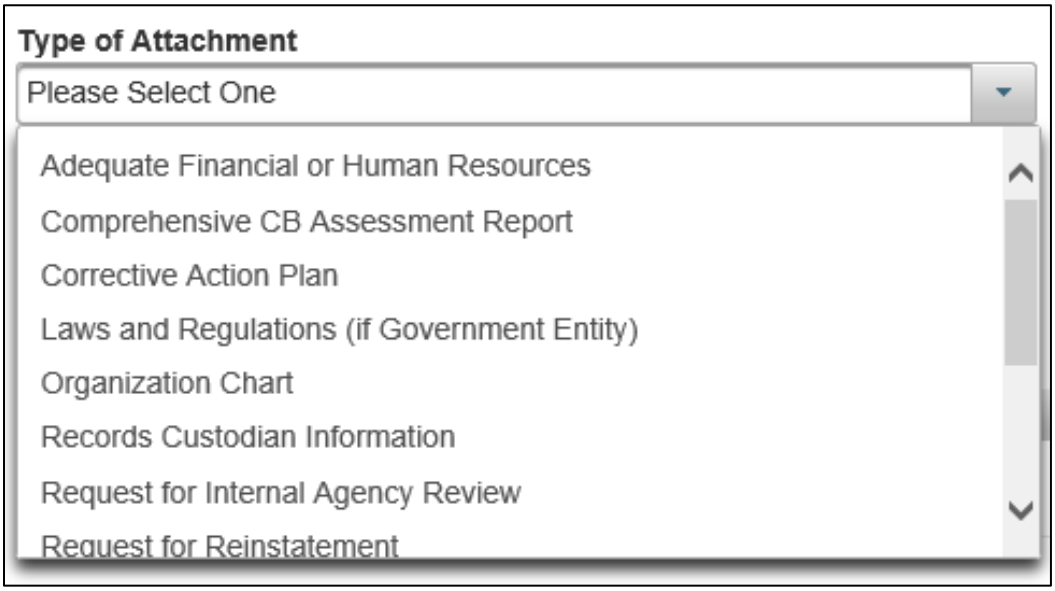


Note: Click the “Previous” button at the bottom of the “Supplemental Documentation” page if you wish to return to the “AB Home” page.

Select a document description from the list in the “Type of Attachment” dropdown menu (Figure 10.3). The complete list of available document types is as follows:

- Adequate Financial or Human Resources
- Comprehensive CB Assessment Report
- Corrective Action Plan
- Laws and Regulations (if Government Entity)
- Organization Chart
- Records Custodian Information
- Request for Internal Agency Review
- Request for Regulatory Hearing
- Request for Reinstatement
- Self-Assessment – Other
- Standard Operation Procedures or Policies
- Template Contract or Legal Authority
- Template Forms (scope checklists, training, CoI, etc.)
- Other

Figure 10.3 – Type of Attachment Dropdown Menu



Note: There are specific scenarios in which some of the options from the “Type of Attachment” menu should be used:

- **Request for Regulatory Hearing** – Select this list value when requesting a regulatory hearing after FDA has revoked recognition. This list value will only display in the “Type of Attachment” list if the current program status is “Revoked.”
- **Request for Internal Agency Review** – Select this list value when requesting internal agency review after FDA has denied renewal reconsideration.

A text box labeled “Additional Description” will display if “Other” has been selected from the list (Figure 10.4).

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

Note: A description must be entered in the “Additional Description” field if “Other” has been selected as the “Type of Attachment” to proceed to the next step in the system.

Figure 10.4 – Other Attachment Type and Additional Description Field

Once a selection has been made from the “Type of Attachment” menu, the “Browse” button will be enabled. Click the “Browse” button.

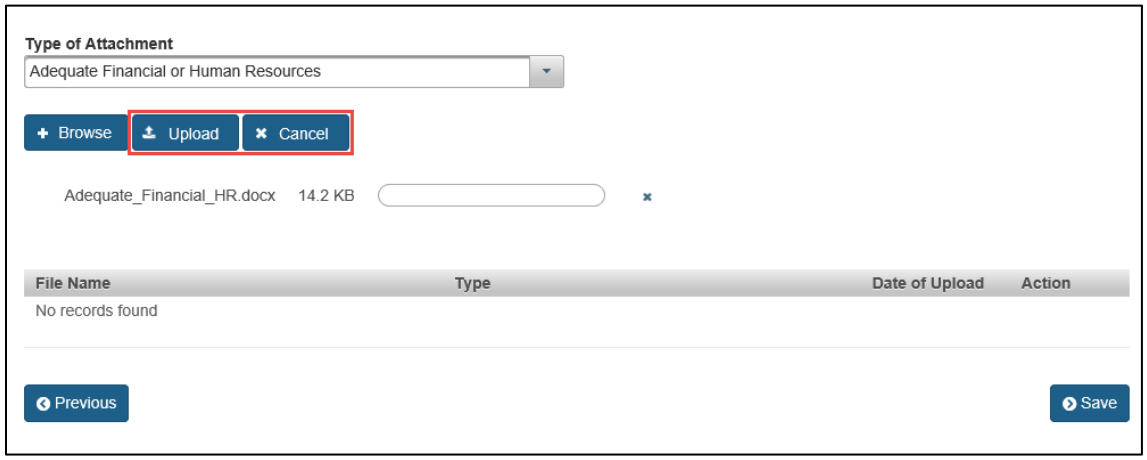
A pop-up window will appear, prompting you to access the file system.

Select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after a file is chosen. The browsing window will close once you select either option (Figure 10.5).

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

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

Figure 10.5 – Upload and Cancel Buttons



Attachments must be a document type supported by the system.

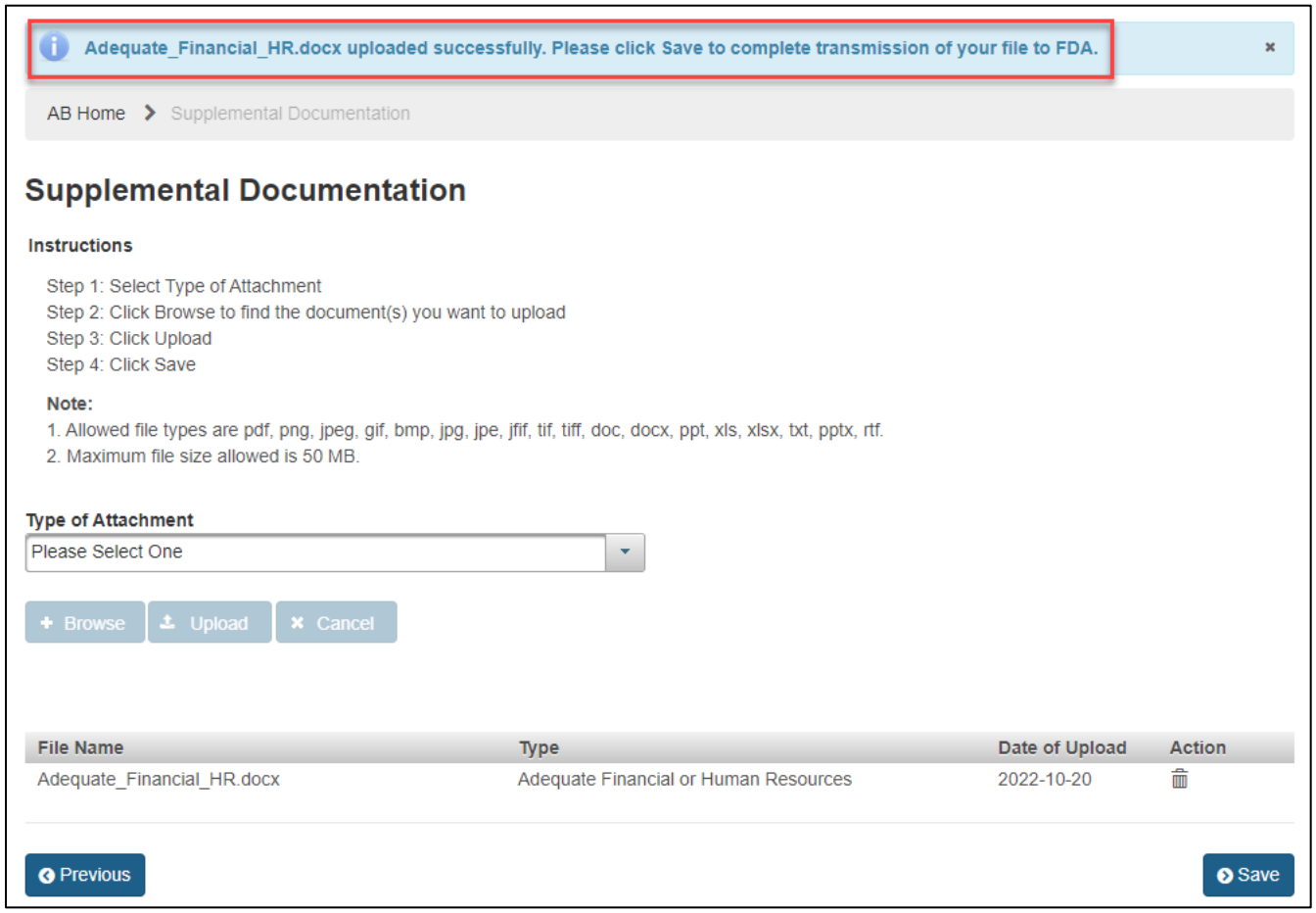
Note: The system supports the following document types: .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

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 be displayed at the top of the page (Figure 10.6).

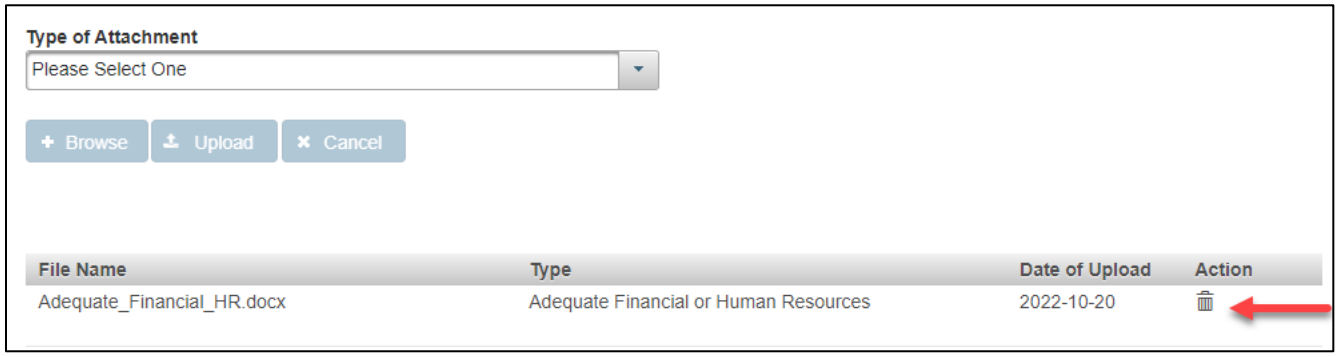
The system will display the uploaded files in a table at the bottom of the page.

Figure 10.6 – Successful Upload Message



To remove the attachment from the table at the bottom of the page, click the trash/delete icon in the “Action” column (Figure 10.7).

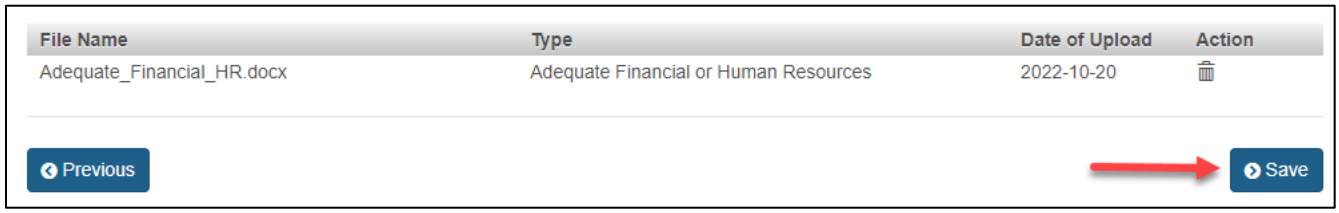
Figure 10.7 – Delete Attachment



After the additional files have been uploaded, click the “Save” button (Figure 10.8).

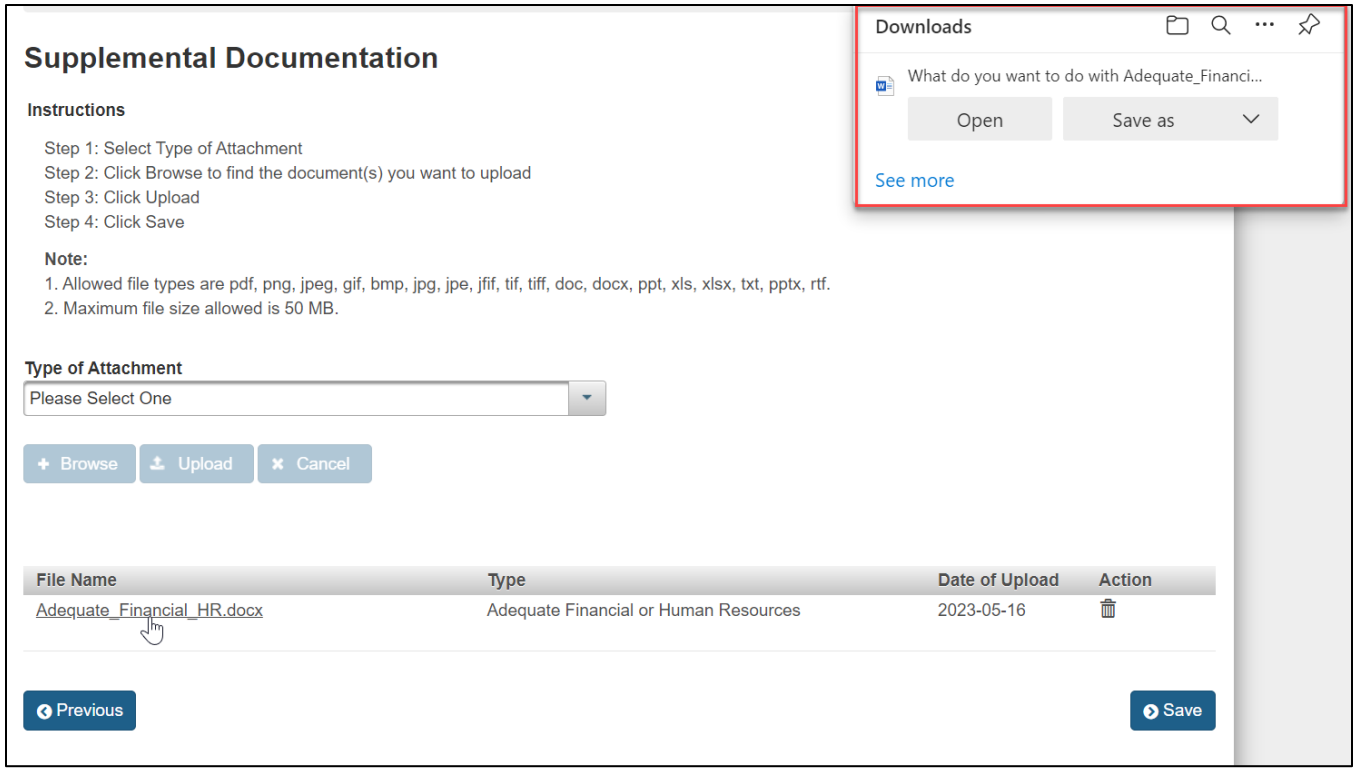
****Important:** Uploaded files cannot be deleted once “Save” has been clicked. You must click “Save” to complete file transmission to FDA. Please contact FDA by e-mail at FDAthirdpartyprogram@fda.hhs.gov if you have uploaded an incorrect file.

Figure 10.8 – Save Attachment



Once a file has been uploaded and added to the “Attachments” table, the file name will become hyperlinked. If the hyperlinked file name is clicked, you will be prompted to open or save the file (Figure 10.9).

Figure 10.9 – Hyperlinked File Name



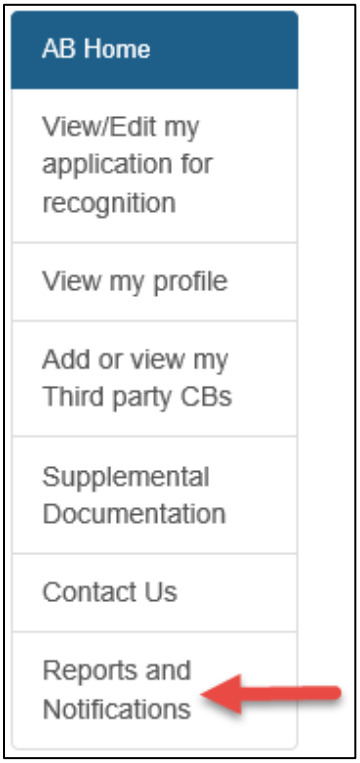
11 Reports and Notifications

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

- Determination that an accredited CB failed to comply with the requirements in issuing a food or facility certification
- Withdrawal, suspension, or reduction in scope of a CB’s accreditation
- Denial of accreditation of a CB
- A significant change which would affect the manner in which the AB complies with the requirements for this program
- Intention to relinquish or not to renew recognition
- Expansion of scope of an accredited CB
- Renewal of current accreditation of a CB
- Reinstatement of a suspended CB
- Expansion of scope of your current recognition
- Report results of annual self-assessment

To access the reports and notifications feature, click the “Reports and Notifications” link from the navigation menu on the “AB Home” page (Figure 11.1).

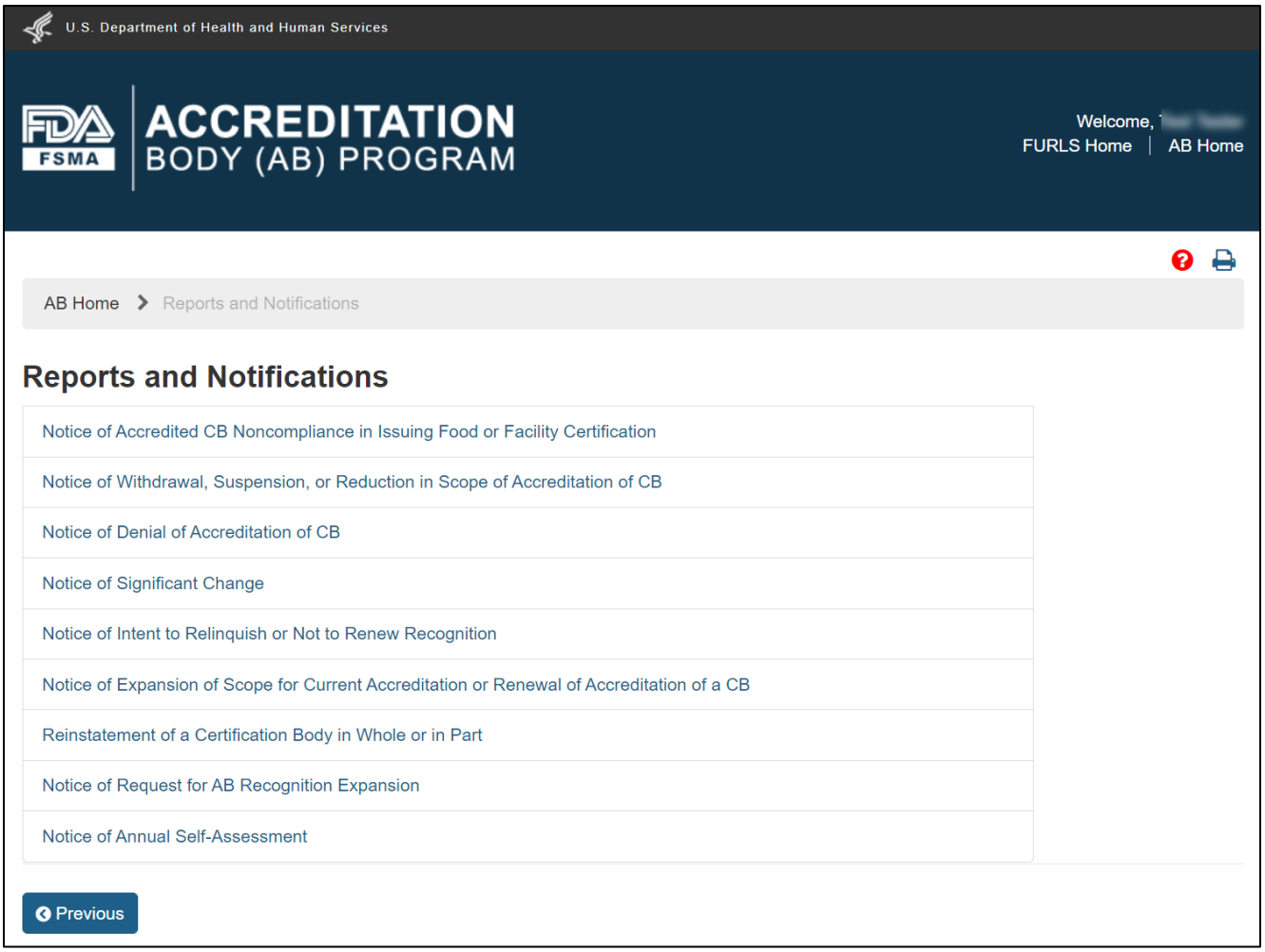
Figure 11.1 – Navigation Menu



The system will display the “Reports and Notifications” page with the following reports and notifications available (Figure 11.2):

- **Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification** – Generates a notice to FDA when the AB reports their determination that a CB the AB accredited failed to comply with the requirements in issuing a food or facility certification.
- **Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB** – Generates a notice to FDA when the AB reports the withdrawal, suspension, or reduction of scope of a CB’s accreditation.
- **Notice of Denial of Accreditation of CB** – Generates a notice to FDA when the AB reports the denial of accreditation of a CB.
- **Notice of Significant Change** – Generates a notice to FDA when the AB reports a significant change which would affect the manner in which it complies with the requirements for this program.
- **Notice of Intent to Relinquish or Not to Renew Recognition** – Generates a notice to FDA when the AB reports their intent to relinquish or not to renew recognition.
- **Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB** – Generates a notice to FDA when the AB reports the expansion of an accredited CB’s scopes or renewal of a CBs accreditation.
- **Reinstatement of a Certification Body in Whole or in Part** – Generates a notice to FDA when the AB reports the reinstatement of a CB’s accreditation.
  Note: This notification is only available in the system if the recognized AB previously notified FDA of their determination to suspend the CB’s accreditation of the specific scope(s) or the CB’s accreditation in whole.
- **Notice of Request for AB Recognition Expansion** – Generates a notice to FDA when the AB requests to be recognized for additional scope(s) in the program.
- **Notice of Annual Self-Assessment** – Generates a notice to FDA when the AB reports the results of their annual self-assessment.

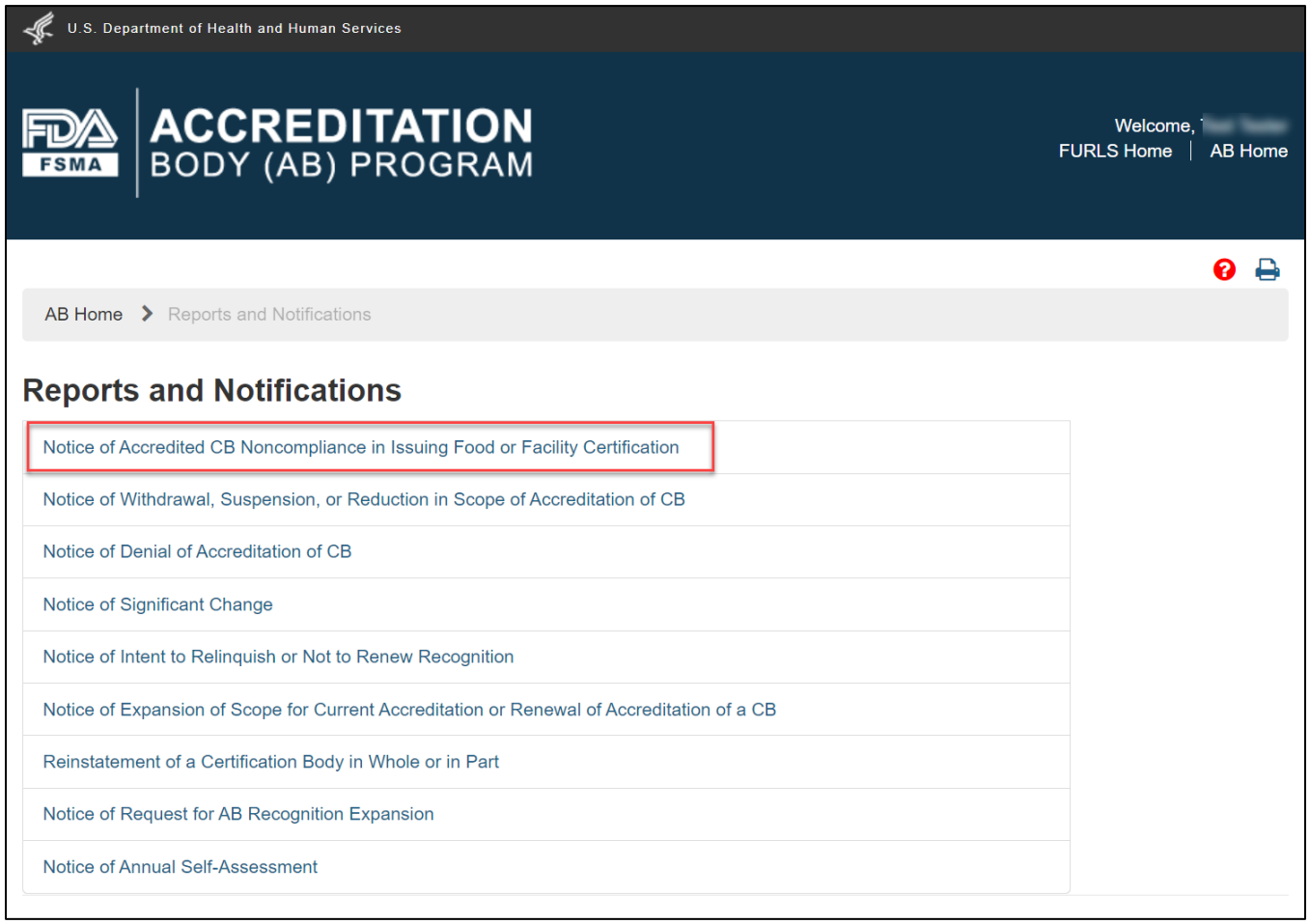
Figure 11.2 – Reports and Notifications Page



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

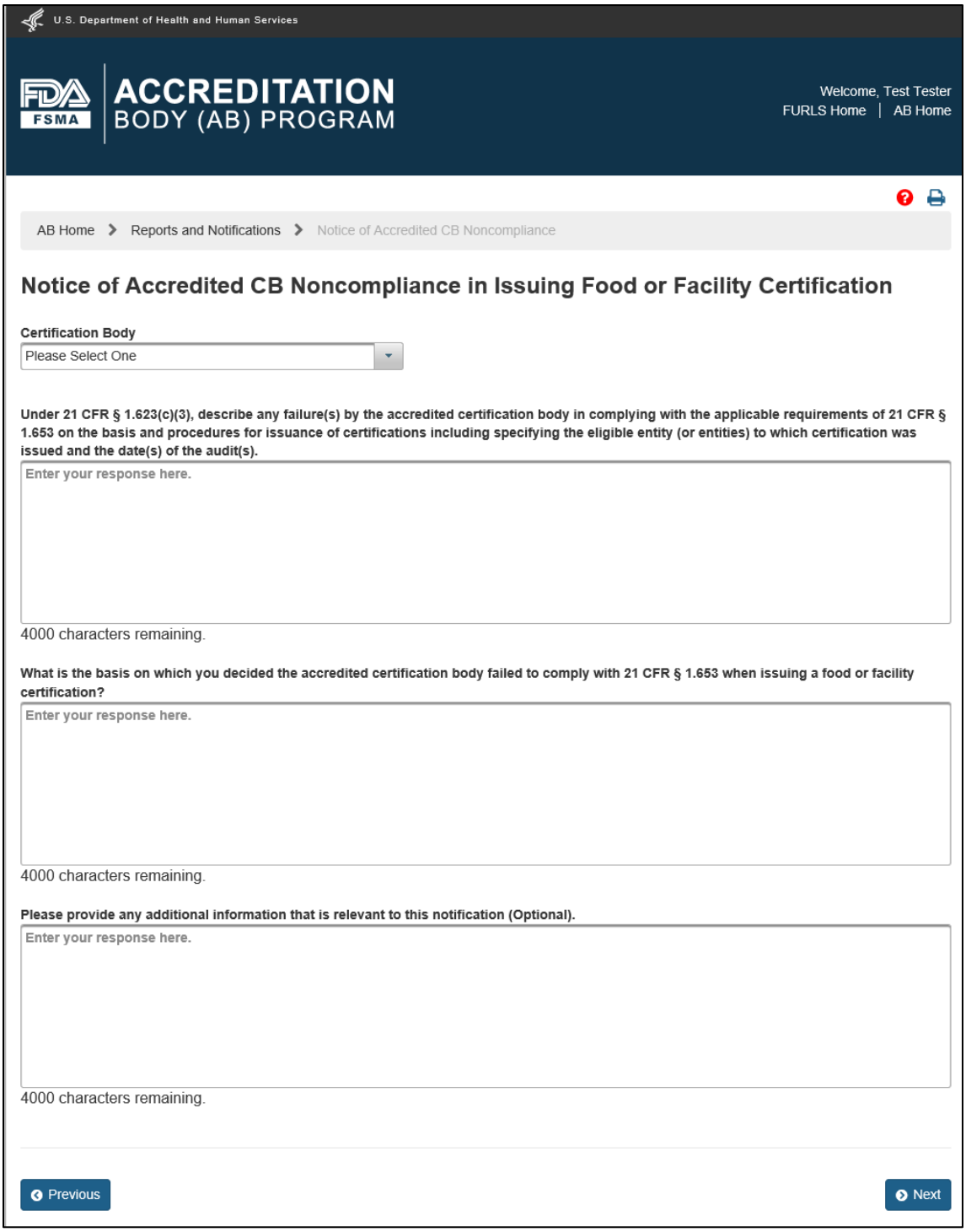
To notify FDA of a determination that a CB that you accredited failed to comply with the requirements in issuing a food or facility certification, click the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” link on the “Reports and Notifications” page (Figure 11.3).

Figure 11.3 – Reports and Notifications Page



The system will display the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” page (Figure 11.4).

Figure 11.4 – Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification



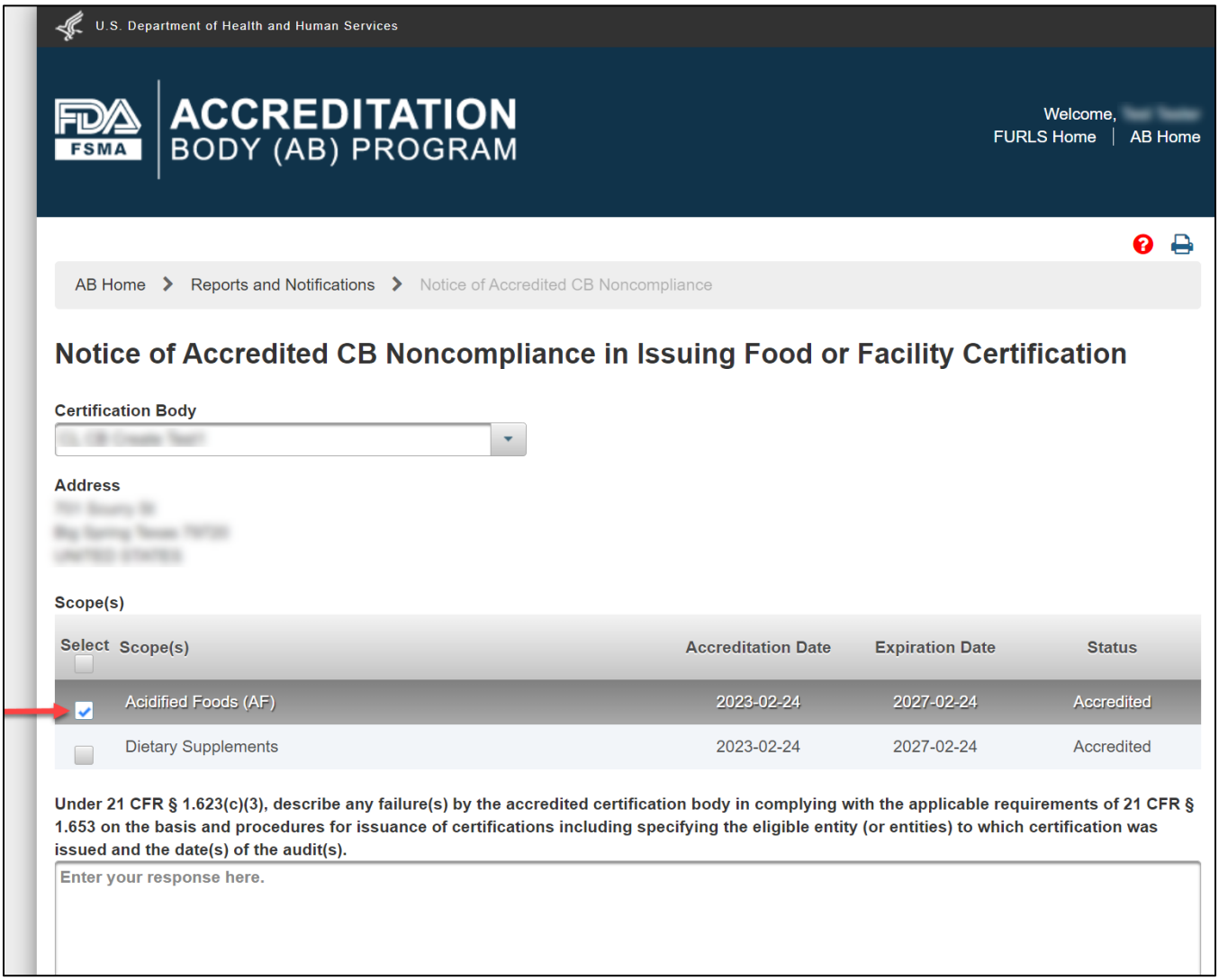
Select the CB name from the “Certification Body” dropdown menu.

The system will then display the CB’s read-only address and a table of accredited scopes

above the first question in the notice (Figure 11.5). Select the checkbox next to the applicable scope(s) to be submitted with the notice. You may select more than one scope.

To select all of the scopes, select the checkbox in the “Select” column heading.

Figure 11.5 – CB Address and Scope Information

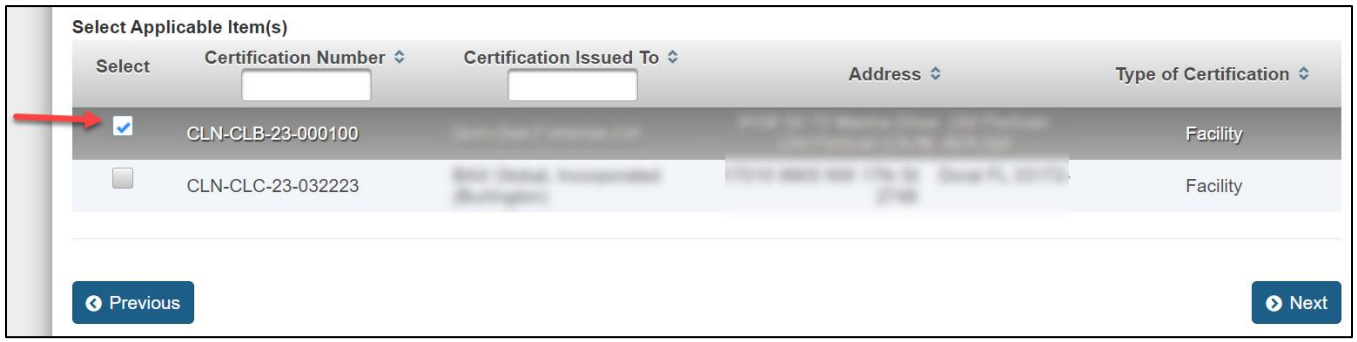


Provide answers to the questions in the text box fields. Each textbox allows for a maximum of 4,000 characters.

Once you have selected the applicable scope(s), the system will display a table of certifications at the bottom of the page.

Select the certification(s) to be included in the notice to FDA by clicking the checkbox in the “Select” column in the table (Figure 11.6). You may select more than one certification.

Figure 11.6 – Notice with Certification Selected



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.

The system will display the “e-Signature” page (Figure 11.7).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

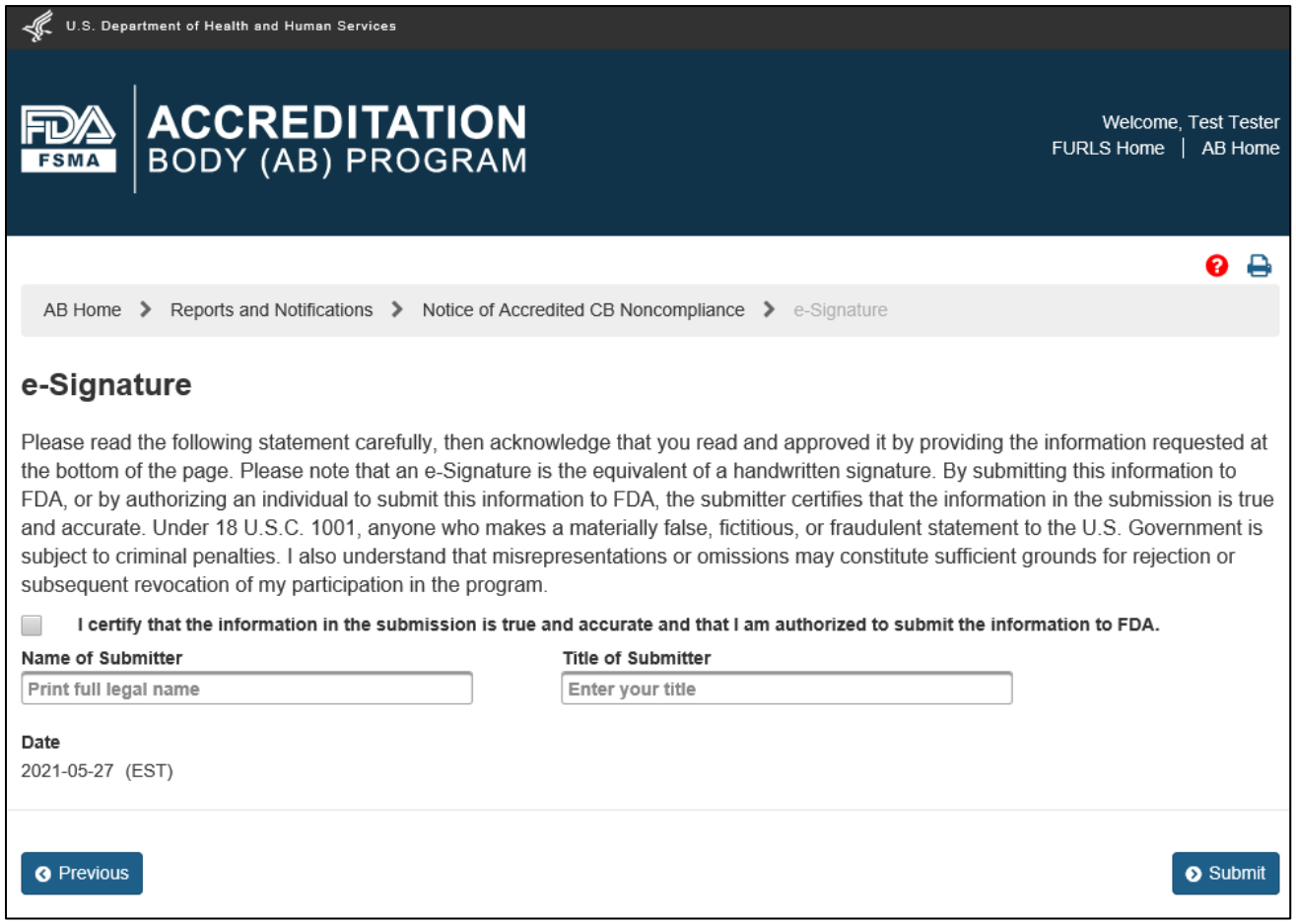
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – 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.

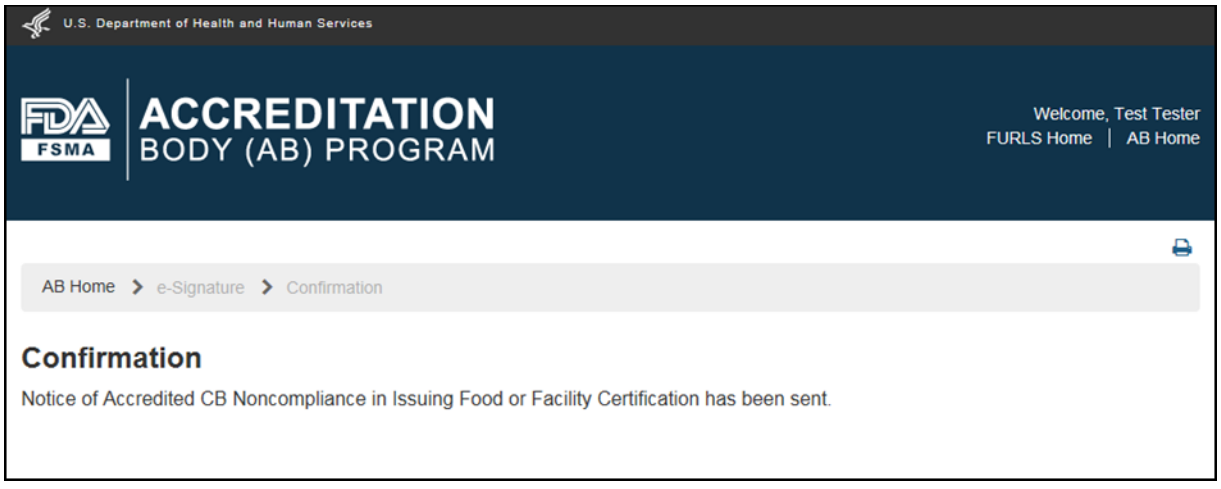
Click the “Submit” button to complete submission of the notice to FDA.

Figure 11.7 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.8).

Figure 11.8 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.9). Note that the image below only depicts the e-mail notification text.

Figure 11.9 – E-mail Notification

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

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

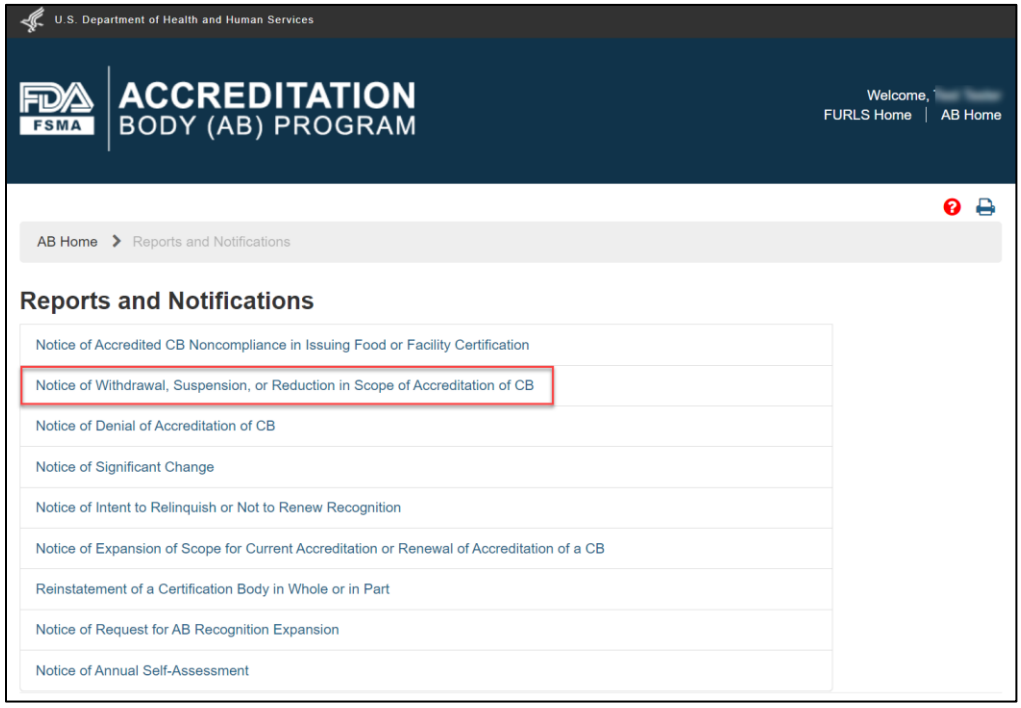
DO NOT REPLY TO THIS EMAIL

Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.2 Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB

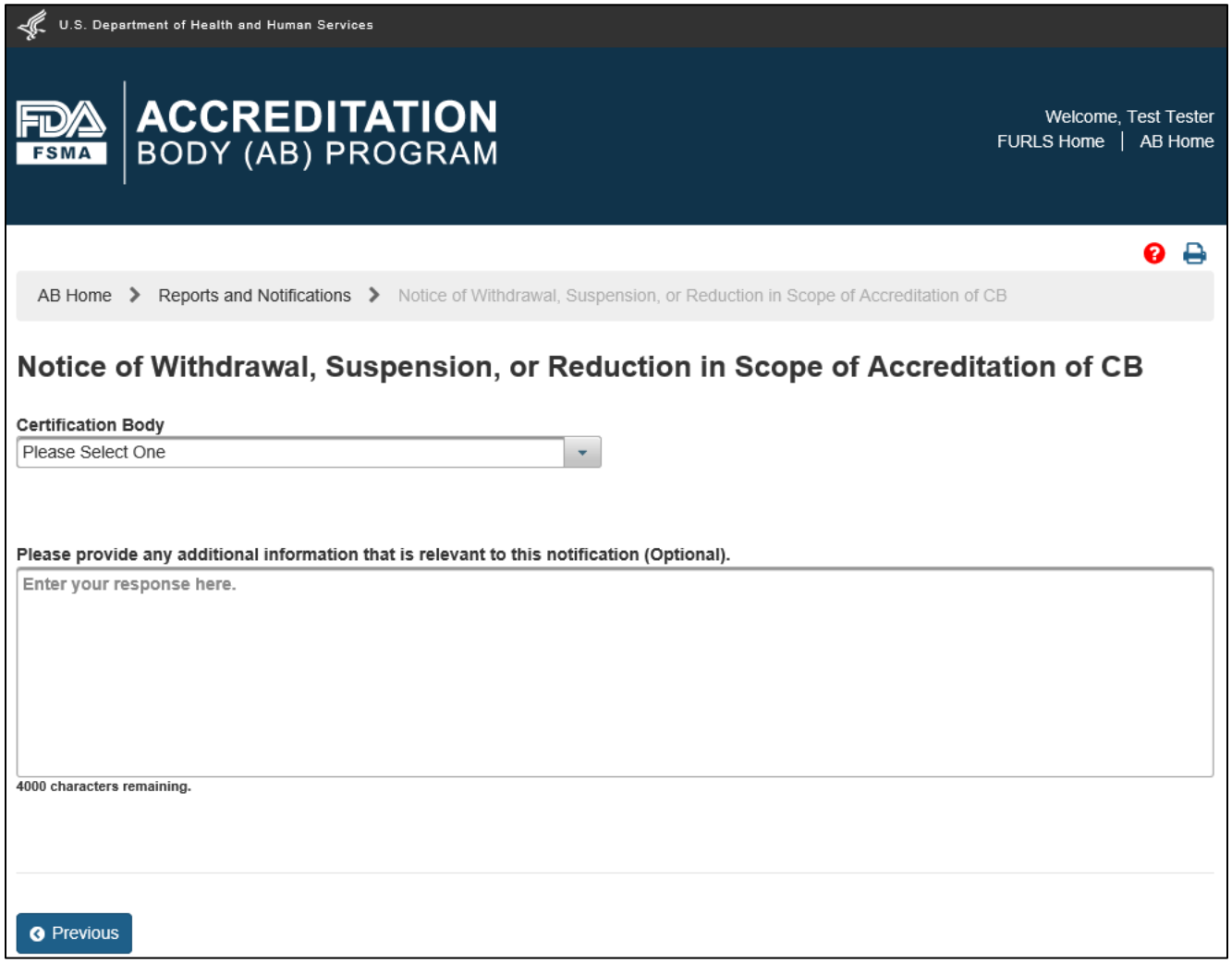
To notify FDA of the withdrawal, suspension, or reduction of scope of a CB’s accreditation, click the “Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB” link on the “Reports and Notifications” page (Figure 11.10).

Figure 11.10 – Reports and Notifications Page



The system will display the “Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB” page (Figure 11.11).

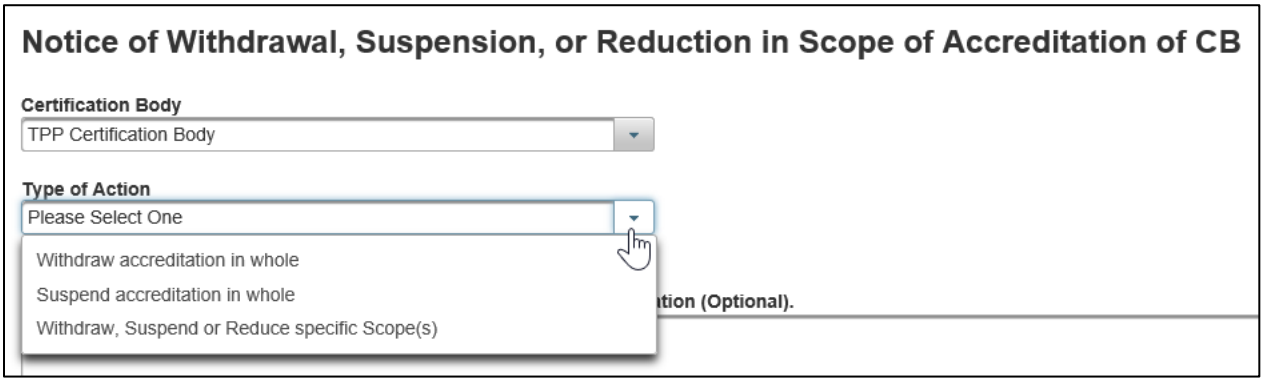
Figure 11.11 – Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB



Select the CB from the “Certification Body” dropdown menu and then select the “Type of Action” from the dropdown menu (Figure 11.12). The “Type of Action” options include:

- Withdraw accreditation in whole – Proceed to Section 11.2.1 of this chapter
- Suspend accreditation in whole – Proceed to Section 11.2.2 of this chapter
- Withdraw, suspend, or reduce specific scope(s) – Proceed to Section 11.2.3 of this chapter

Figure 11.12 – Certification Body and Type of Action

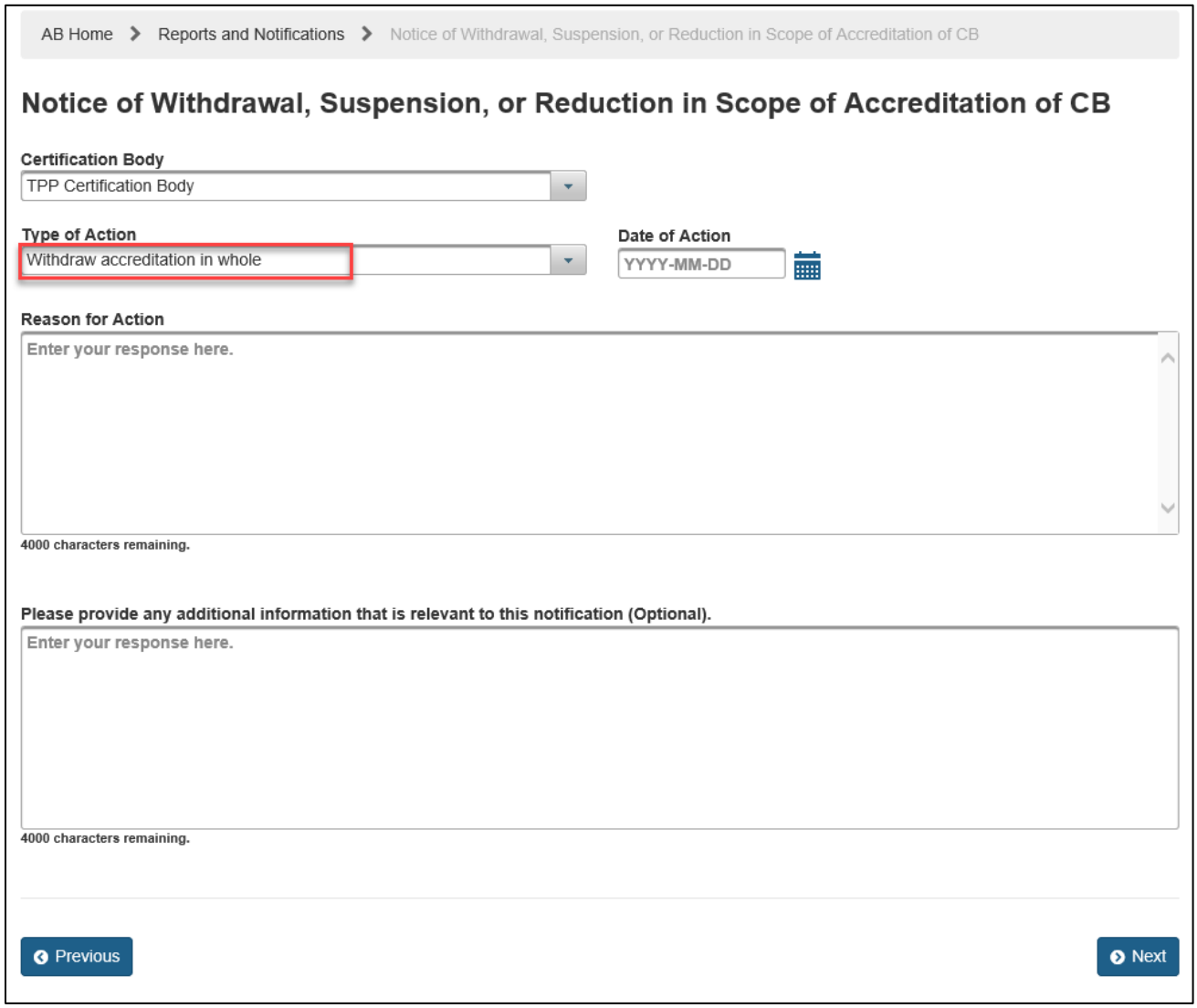


11.2.1 Withdraw Accreditation in Whole

The following data entry fields will appear if “Withdraw accreditation in whole” is selected as the “Type of Action” (Figure 11.13):

- **Date of Action** – Select the date from the calendar icon or enter the date in “YYYY-MM-DD” format.
- **Reason for Action** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.
- **Please provide any additional information that is relevant to this notification (Optional).** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.

Figure 11.13 – Withdraw Accreditation in Whole



Complete the data entry fields.

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

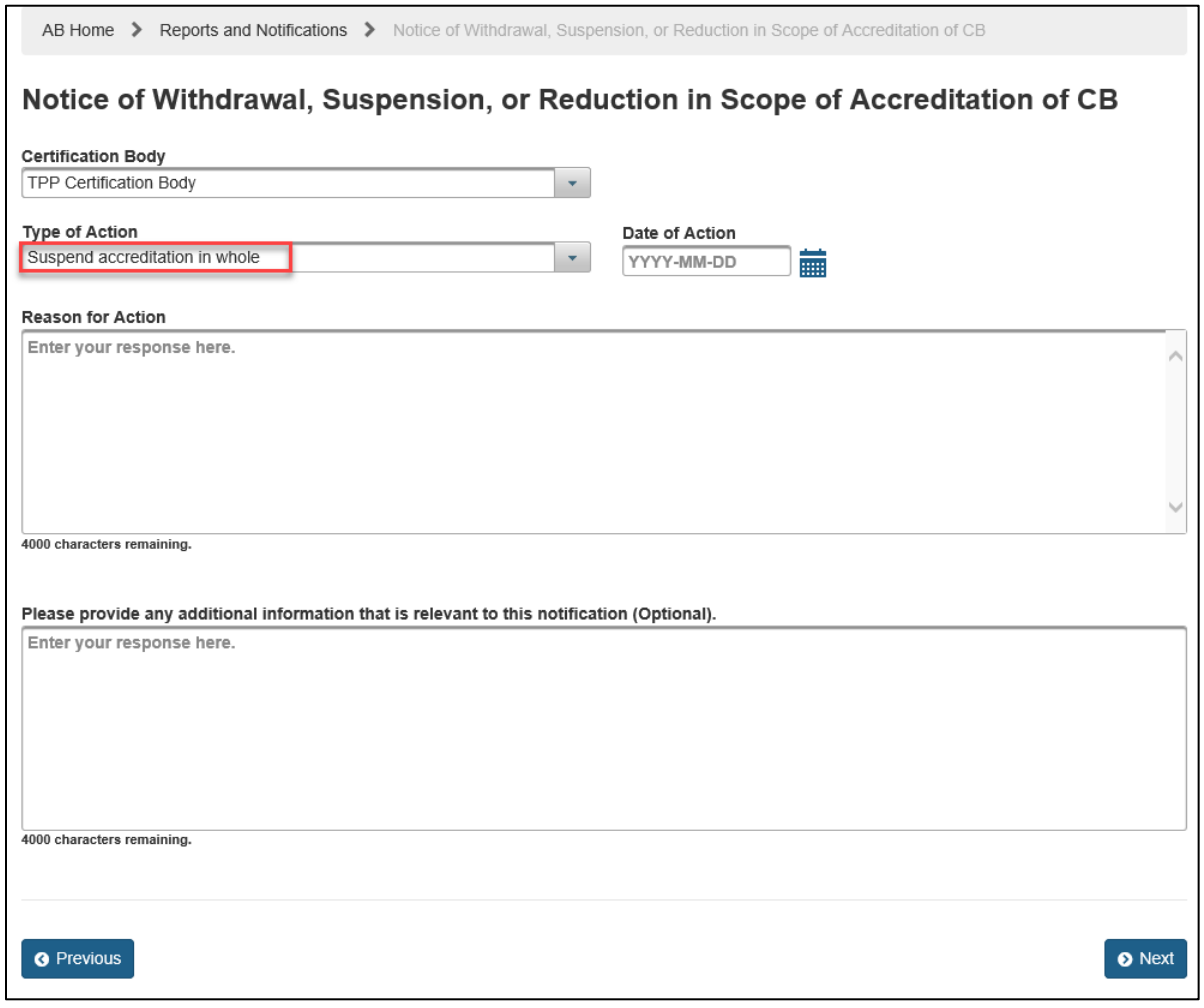
Proceed to Section 11.2.4 of this chapter for instructions to submit the notice.

11.2.2 Suspend Accreditation in Whole

The following data entry fields will appear if “Suspend accreditation in whole” is selected as the “Type of Action” (Figure 11.14):

- **Date of Action** – Select the date from the calendar icon or enter the date in “YYYY-MM-DD” format.
- **Reason for Action** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.
- **Please provide any additional information that is relevant to this notification (Optional).** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.

Figure 11.14 – Suspend Accreditation in Whole



Complete the data entry fields.

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

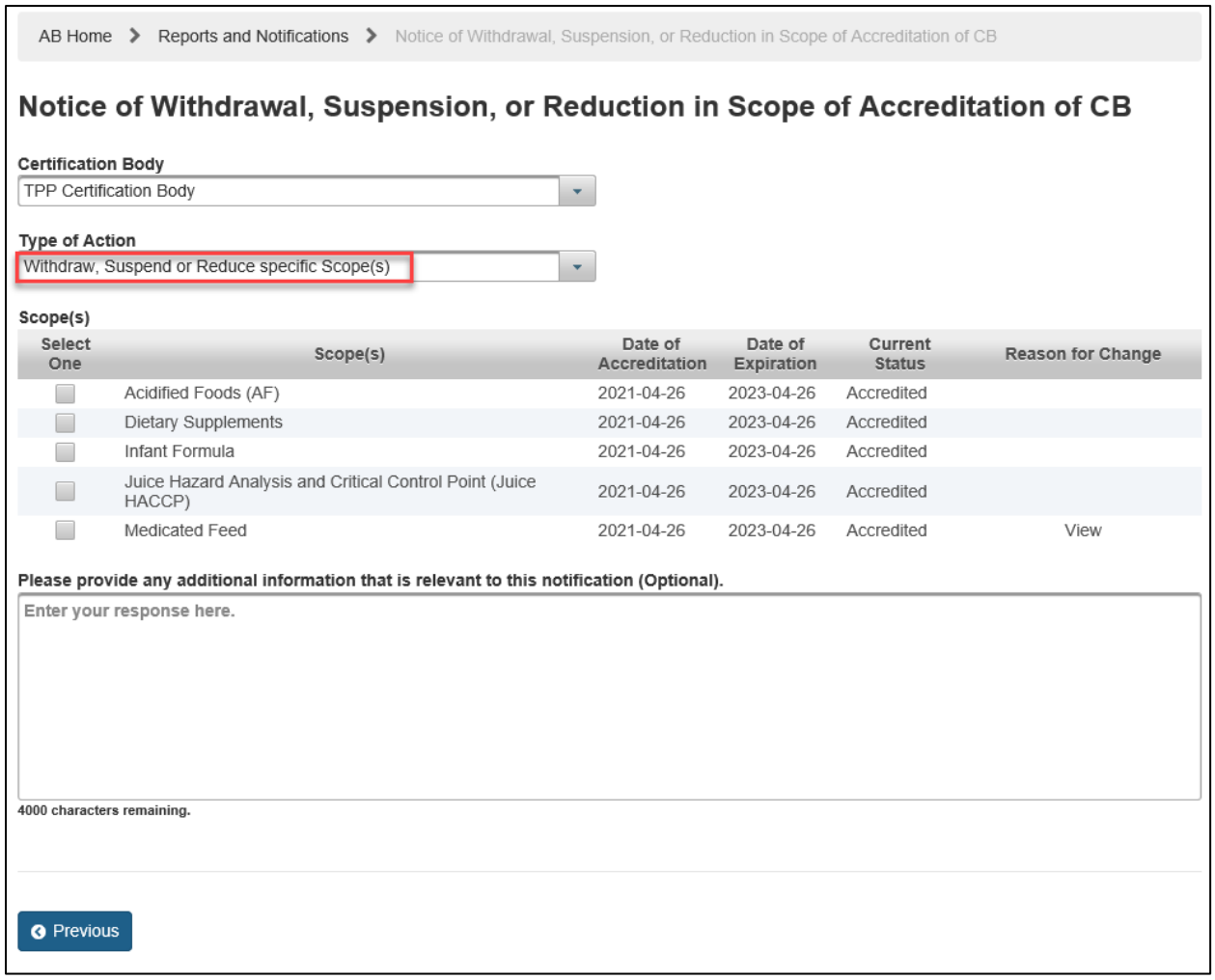
Proceed to Section 11.2.4 of this chapter for instructions to submit the notice.

11.2.3 Withdraw, Suspend, or Reduce Specific Scope(s)

The following data entry fields will appear if “Withdraw, Suspend, or Reduce specific Scope(s)” is selected as the “Type of Action” (Figure 11.15):

- **Scope(s)** – Click the checkbox of the applicable scope(s). (Additional data entry fields will appear after a scope is selected.)
- **Please provide any additional information that is relevant to this notification (Optional).** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.

Figure 11.15 – Withdraw, Suspend, or Reduce Specific Scope(s)

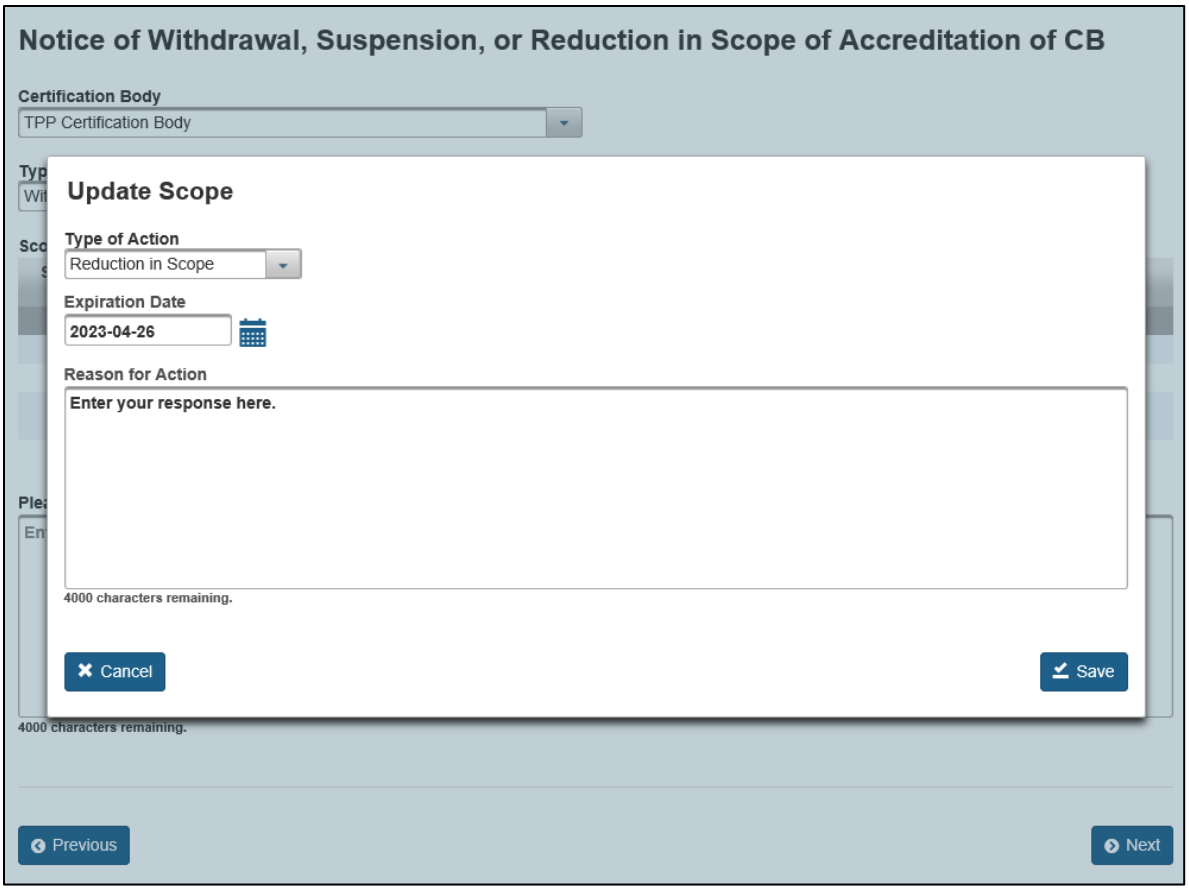


Select a scope you wish to include in the notice by clicking checkbox in the “Select One” column of the “Scope(s)” table. Once a scope is selected, the “Update Scope” pop-up window will display with the following data entry fields (Figure 11.16):

- **Type of Action** – Select the action from the dropdown menu. The “Type of Action” options include “Suspended,” “Withdrawn,” or “Reduction in Scope.”
- **Date of Action** (or the “**Expiration Date**” if “Reduction in Scope” is selected) – Select the date from the calendar icon or enter the date in “YYYY-MM-DD” format.
- **Reason for Action** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.
- **Please provide any additional information that is relevant to this notification (Optional).** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.

Click the “Save” button in the pop-up window.

Figure 11.16 – Update Scope Pop-up Window



Select any additional scope(s) by clicking checkbox in the “Select One” column of the “Scope(s)” table on the “Notice of Withdrawal, Suspension, or Reduction in Scope of

Accreditation of CB" page. Repeat the steps to complete the data entry fields in the "Update Scope" pop-up window.

Click the "Next" button once the selection of all applicable scopes is completed.

Click the "Save" button in the pop-up window to save the information and close the pop-up window.

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

Proceed to Section 11.2.4 of this chapter for instructions to submit the notice.

11.2.4 Notice Submission

Once you have completed your changes to the CB's accreditation, click the "Next" button on the "Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB" page to proceed to the "e-Signature" page (Figure 11.17).

Follow the directions provided on the "e-Signature" page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

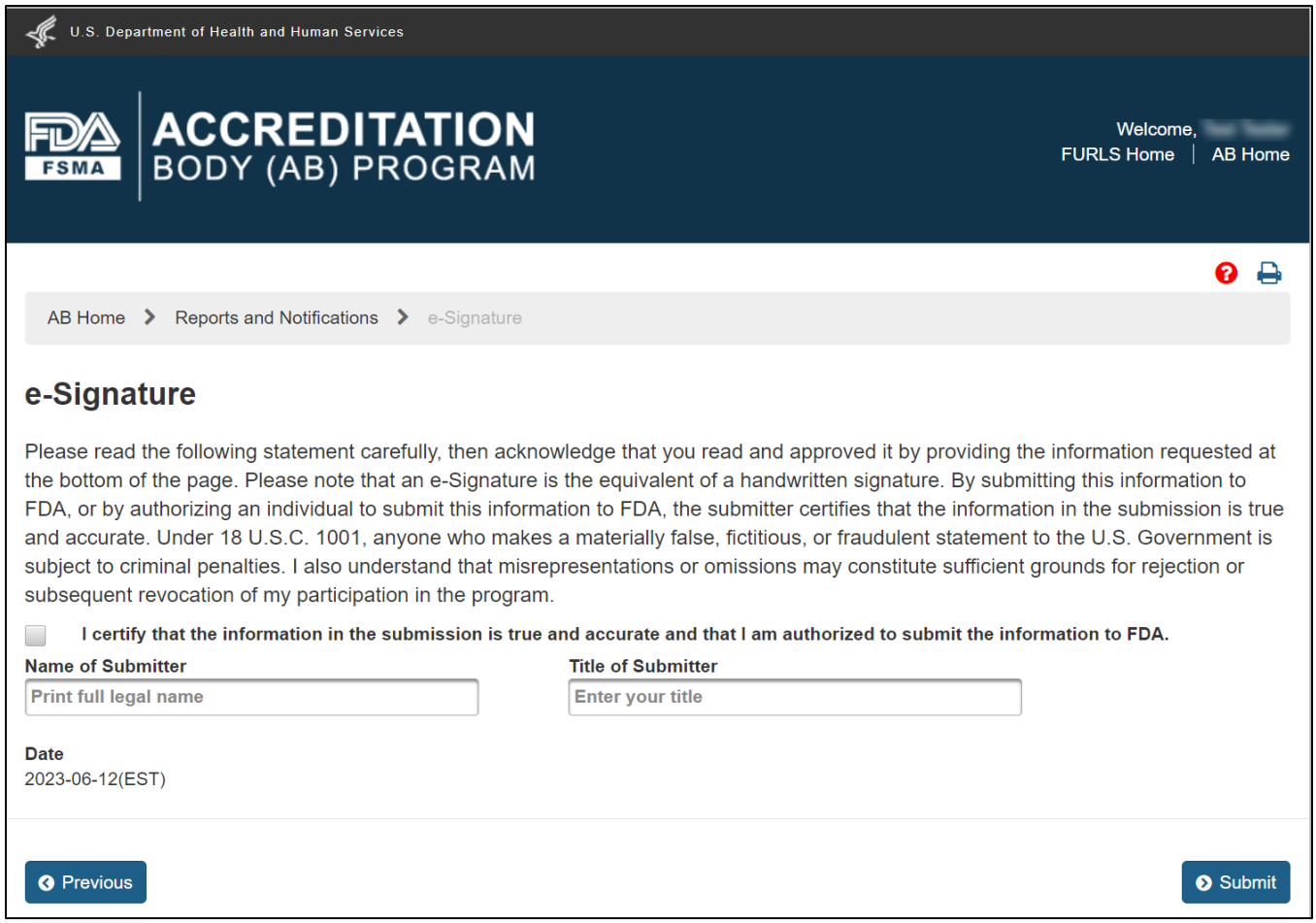
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the "Previous" button if you wish to return to the "Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB" page.

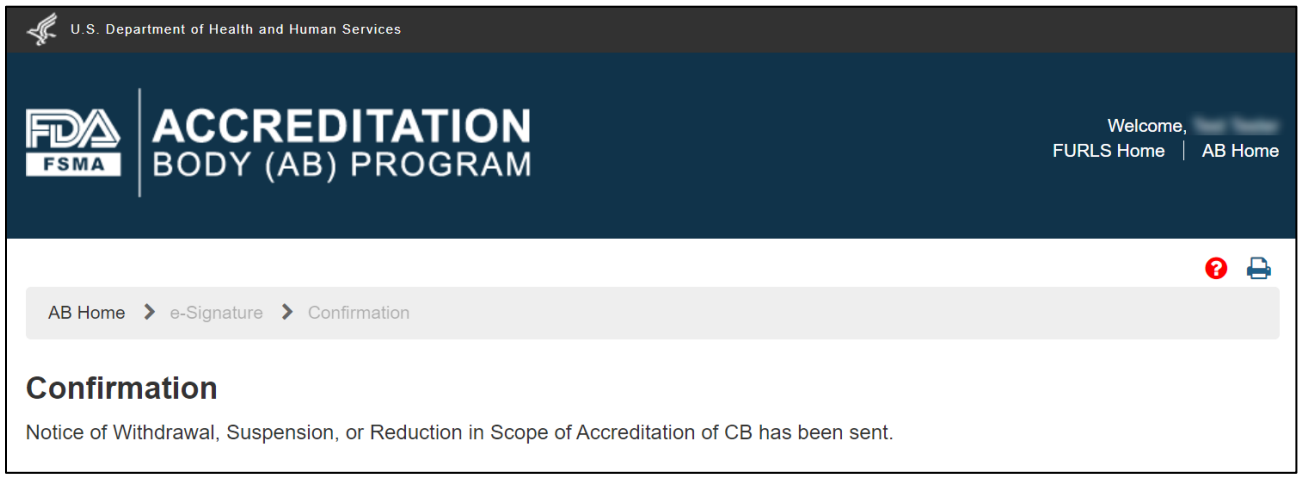
Click the "Submit" button to complete submission of the notice to FDA.

Figure 11.17 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.18).

Figure 11.18 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.19). Note that the image below only depicts the e-mail notification text.

Figure 11.19 – E-mail Notification

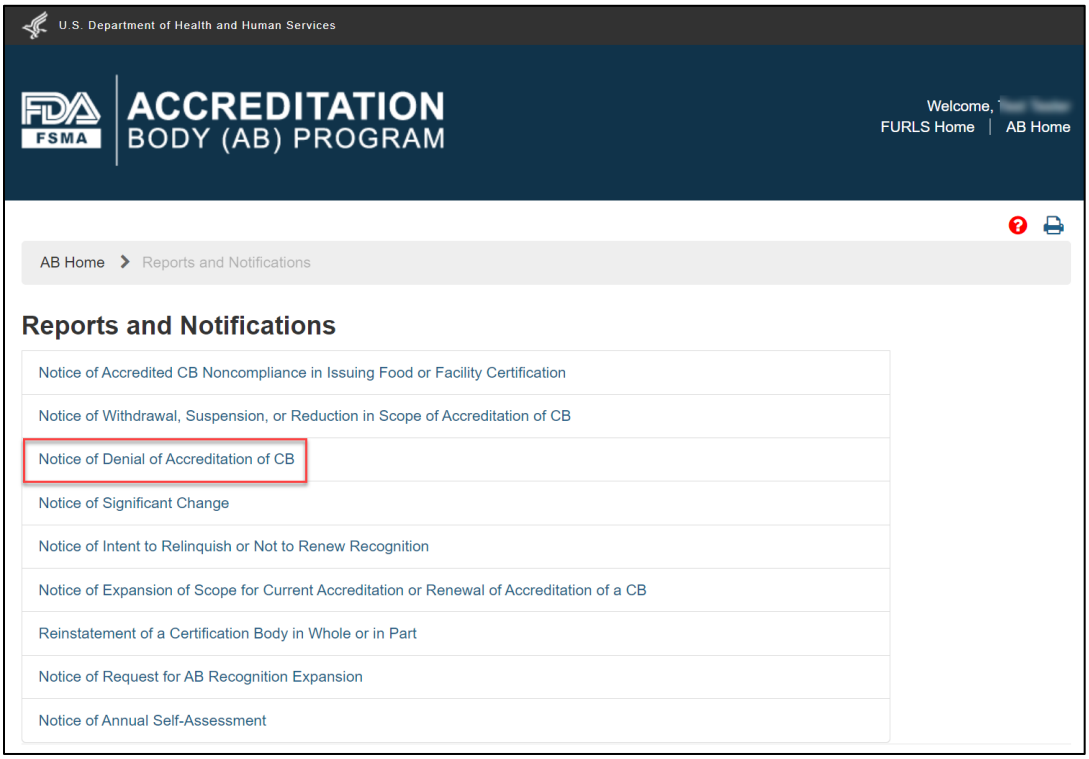
> Thank you for submitting information to FDA regarding the Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB. We will review this information and may follow-up if additional information is needed.
>
> Accredited Third-Party Certification Program
> U.S. Food and Drug Administration
>
> DO NOT REPLY TO THIS EMAIL

Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.3 Notice of Denial of Accreditation of CB

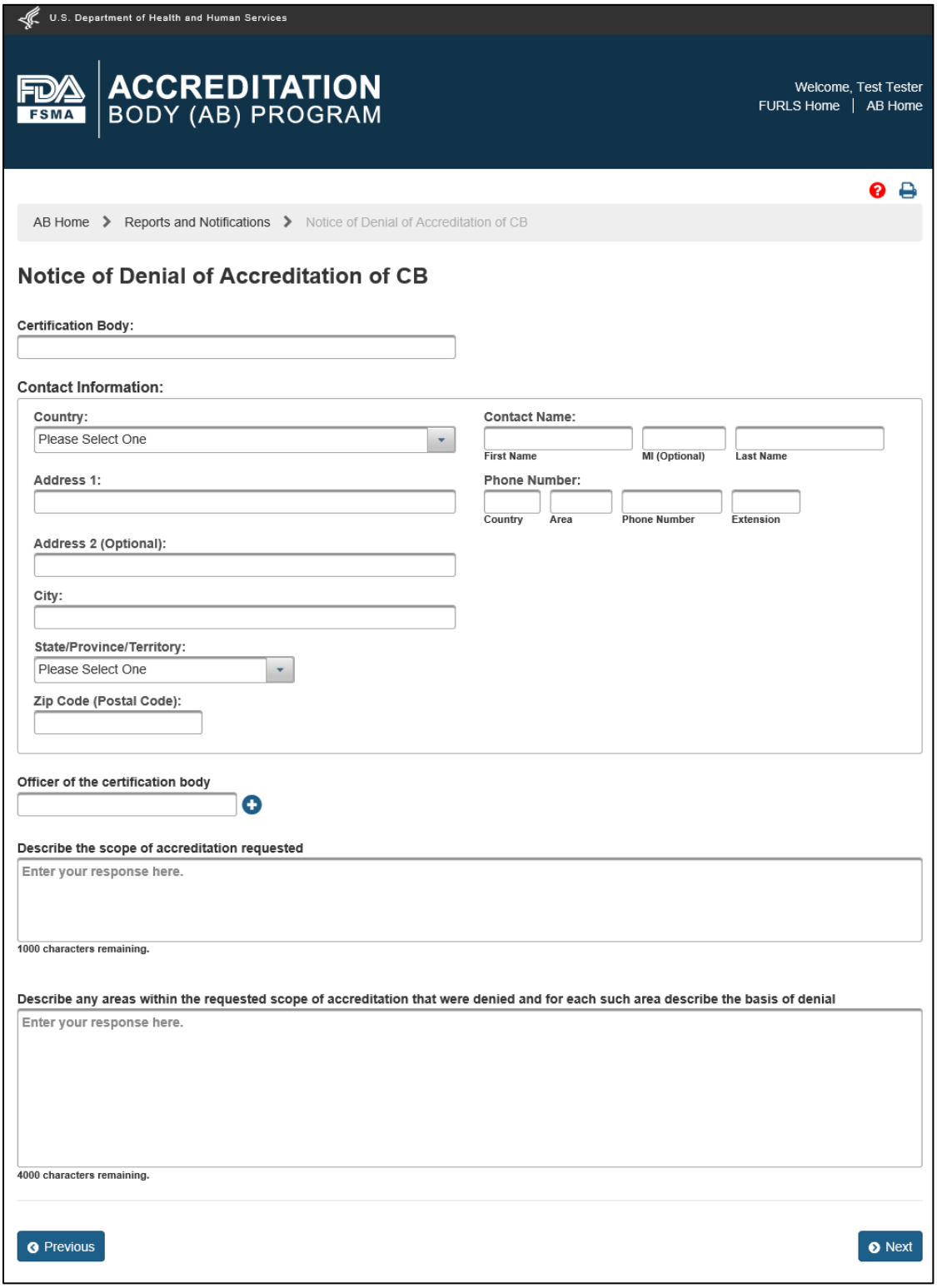
To notify FDA of the denial of accreditation of a CB, click the “Notice of Denial of Accreditation of CB” link in the “Reports and Notifications” page (Figure 11.20).

Figure 11.20 – Reports and Notifications Page



The system will display the “Notice of Denial of Accreditation of CB” page (Figure 11.21).

Figure 11.21 – Notice of Denial of Accreditation of CB



Complete the following data fields:

- **Certification Body** – The name of the CB that was denied accreditation
- **Contact Information**
  - **Country** – The country where the CB is physically located
  - **Address 1** – The address where the CB is physically located (includes the number, street, quadrant, etc.)
  - **Address 2 (Optional)** – The additional information about the physical location of the CB (may include a suite or apartment number, if applicable)
  - **City** – The city where the CB is physically located
  - **State/Province/Territory** – The state/province/territory of the CB
  - **Zip Code (Postal Code)** – The zip code or postal code of the CB
- **Contact Name**
  - **First name** – The first name of the Point of Contact
  - **MI (Optional)** – The first letter of the Point of Contact's middle name
  - **Last Name** – The last name or surname of the Point of Contact
- **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 of the Point of Contact, if applicable.
- **Officer of the Certification Body** – The Officer(s) of the CB
- **Describe the scope of accreditation requested** – The scopes that were denied accreditation
- **Describe any areas within the requested scope of accreditation that were denied and for each such area describe the basis of denial** – The areas of denial and the reason(s) why the action was taken

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 on the bottom of the page to proceed to the "e-Signature" page.

The system will display the "e-Signature" page (Figure 11.22).

Follow the directions provided on the "e-Signature" page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

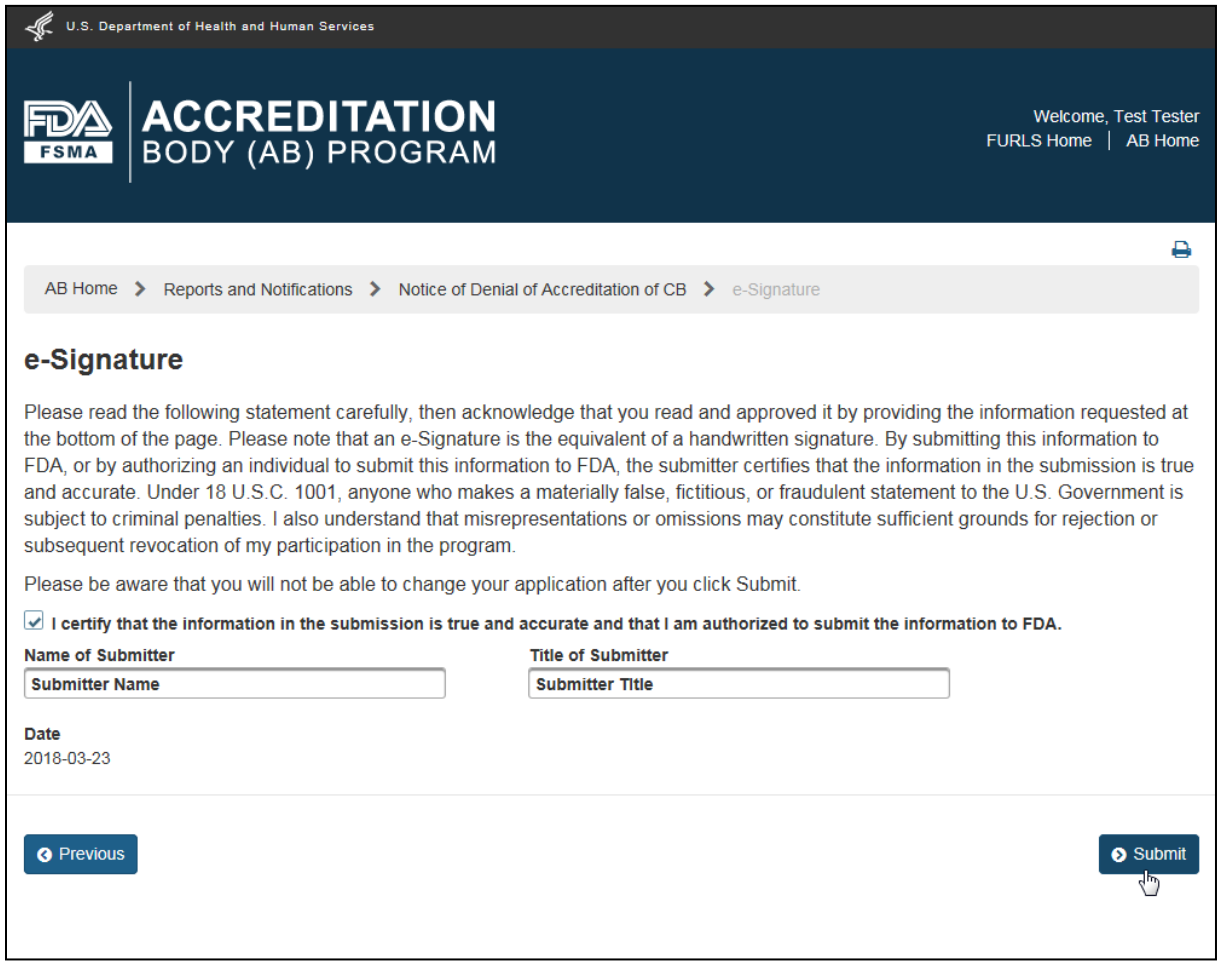
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the "Previous" button if you wish to return to the "Notice of Denial of Accreditation of CB" page.

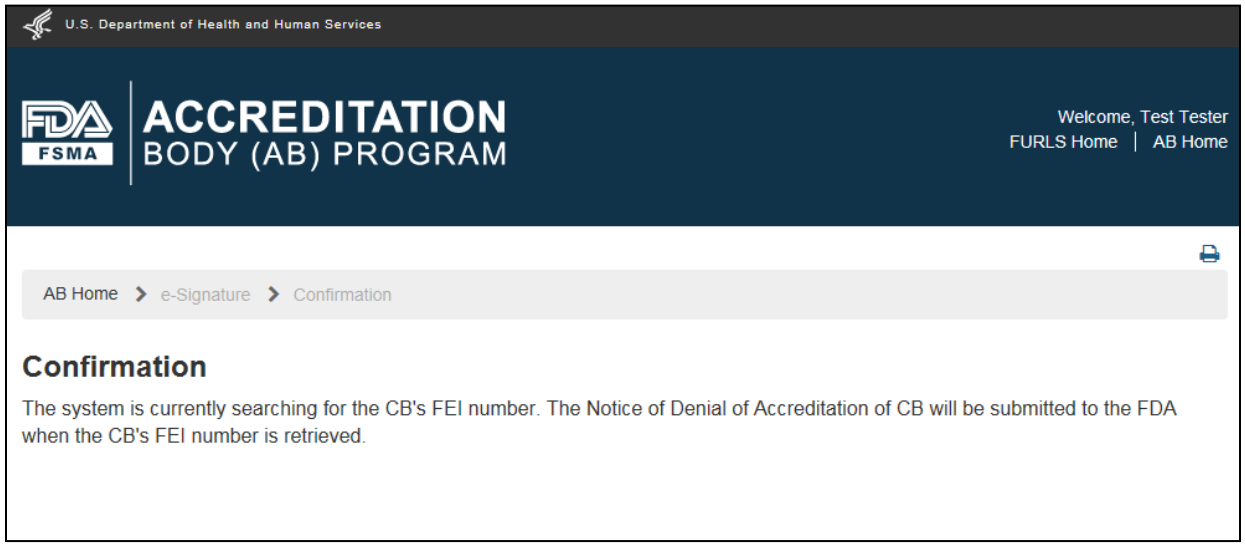
Click the “Submit” button to complete submission of the notice to FDA.

Figure 11.22 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.23).

Figure 11.23 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.24). Note that the image below only depicts the e-mail notification text.

Figure 11.24 – E-mail Notification

Thank you for submitting information to FDA regarding the Notice of Denial of Accreditation of CB. We will review this information and may follow-up if additional information is needed.

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

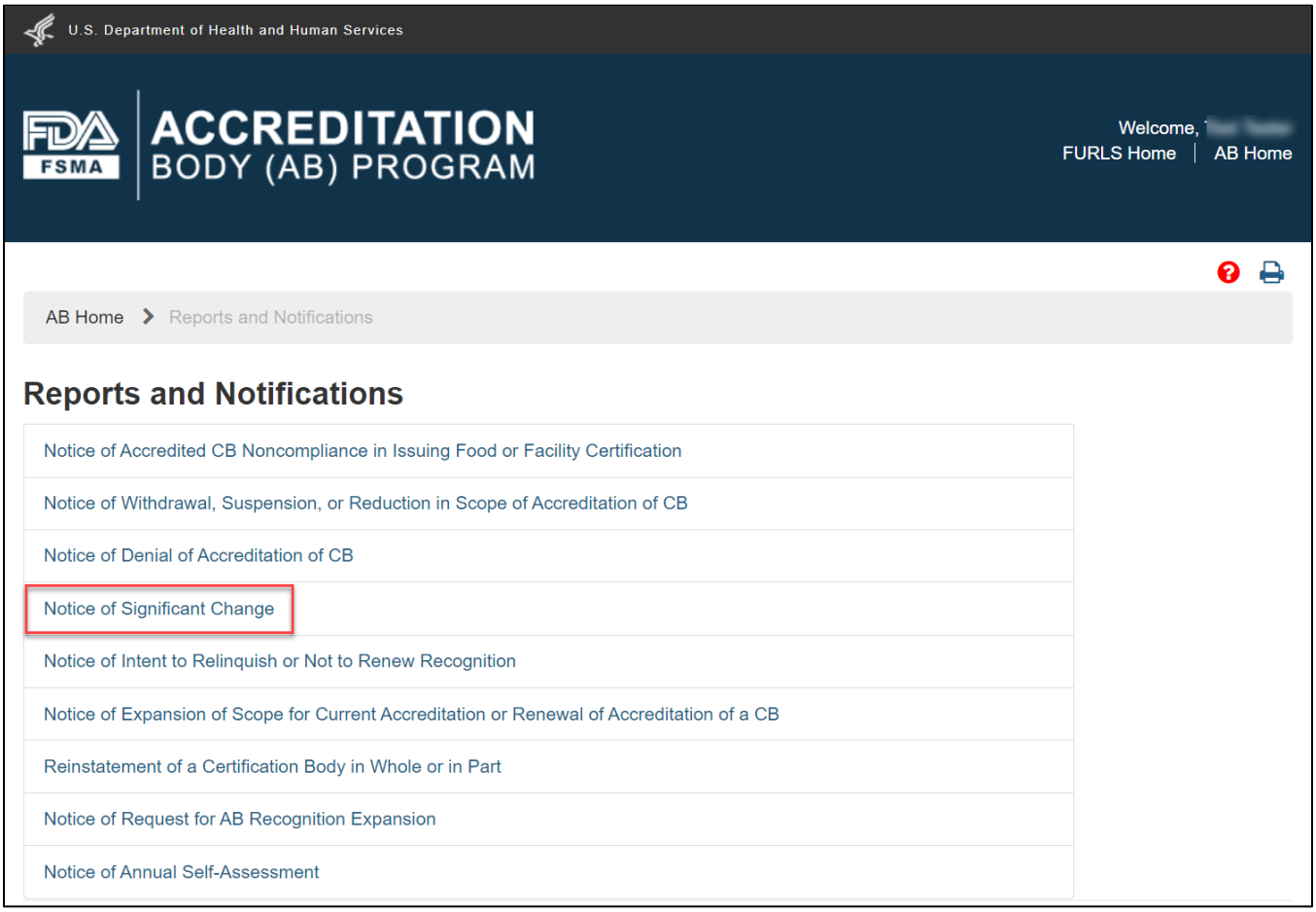
DO NOT REPLY TO THIS EMAIL

Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.4 Notice of Significant Change

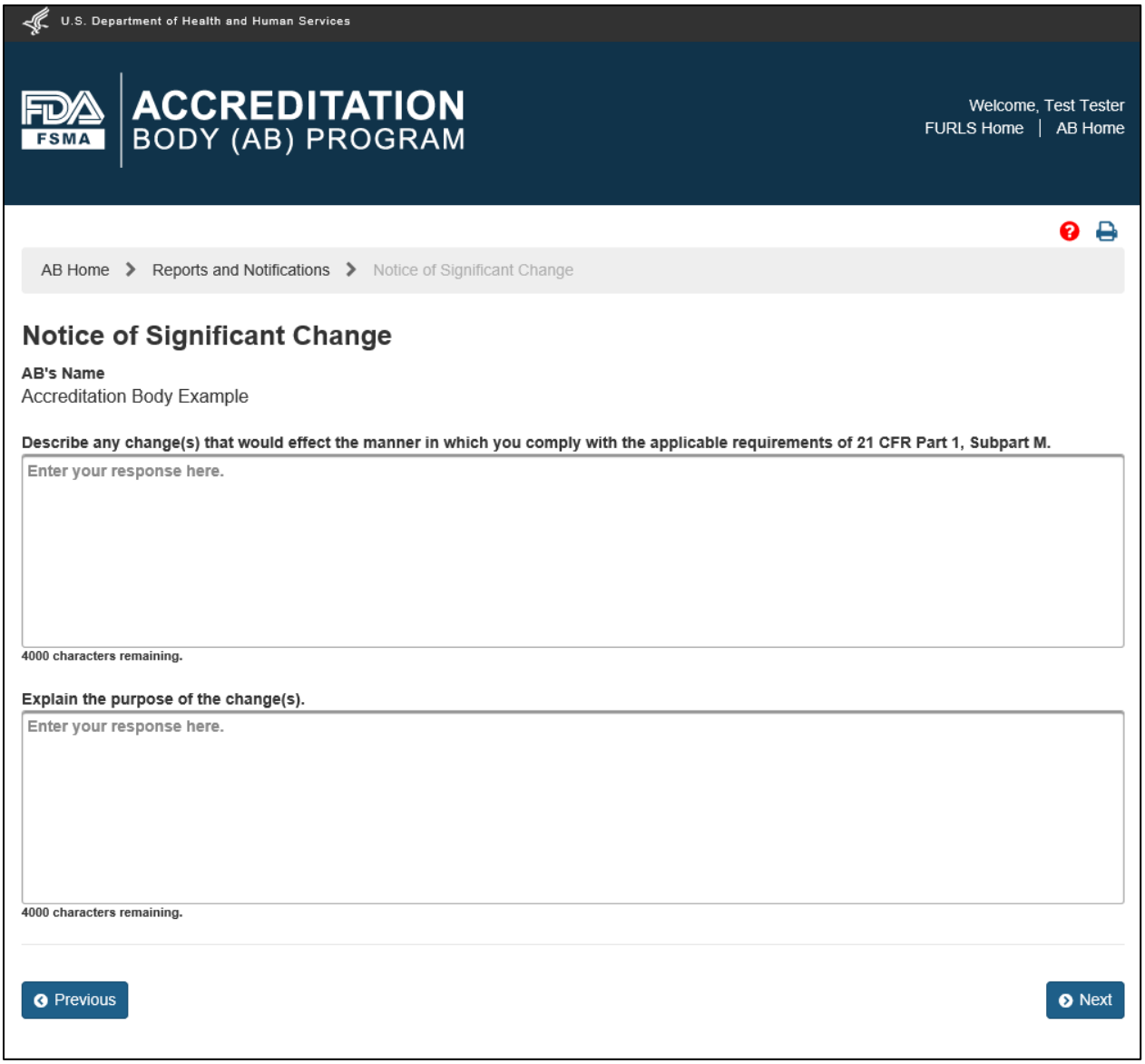
To notify FDA of a significant change that would affect the manner in which the AB complies with the requirements for this program, click the “Notice of Significant Change” link in the “Reports and Notifications” page (Figure 11.25).

Figure 11.25 – Reports and Notifications Page



The system will display the “Notice of Significant Change” page (Figure 11.26).

Figure 11.26 – Notice of Significant Change



Complete the following text entry fields:

- **Describe any change(s) that would affect the manner in which you comply with the applicable requirements of 21 CFR Part 1, Subpart M –** Enter the response in the text entry field, which allows a maximum of 4,000 characters.
- **Explain the purpose of the change(s) –** Enter the response in the text entry field, which allows a maximum of 4,000 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.

The system will display the “e-Signature” page (Figure 11.27).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

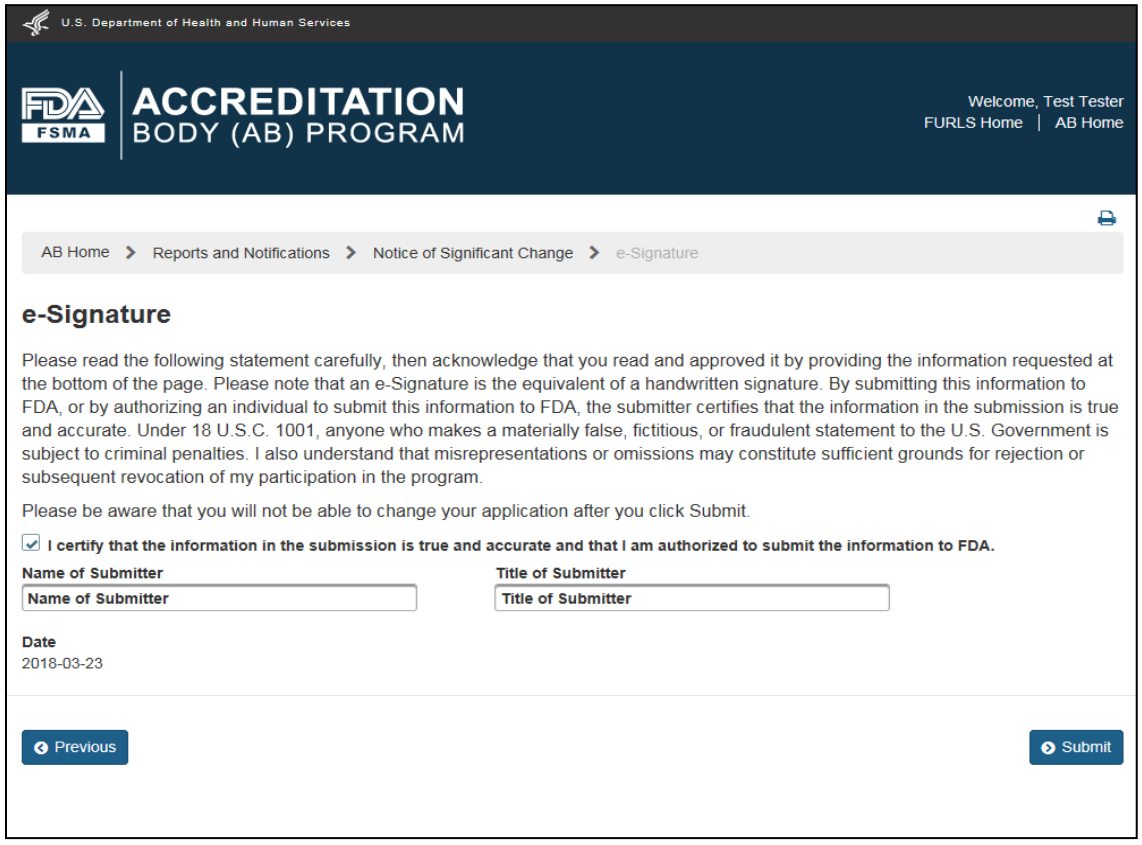
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Notice of Significant Change” page.

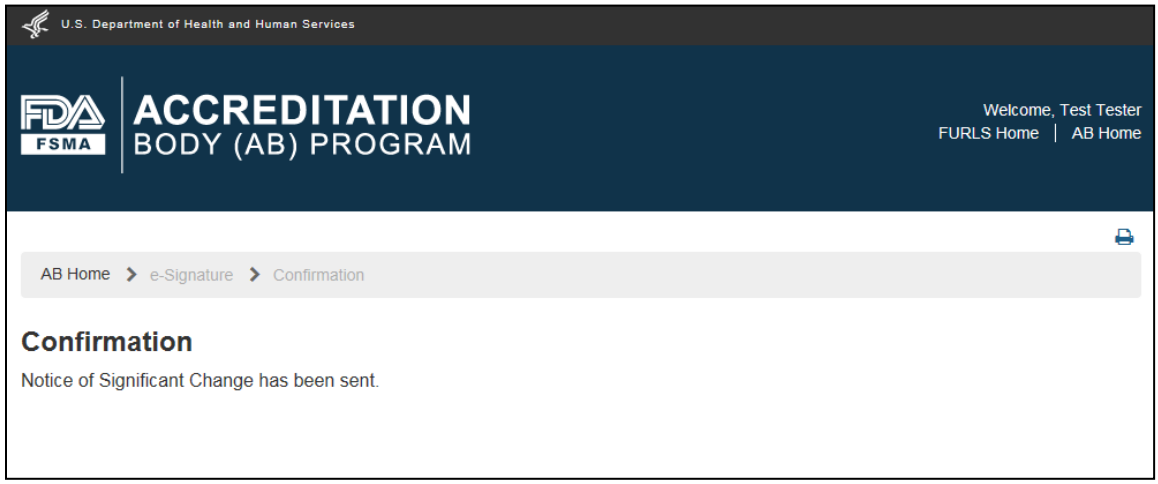
Click the “Submit” button to complete submission of the notice to FDA.

Figure 11.27 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.28).

Figure 11.28 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.29). Note that the image below only depicts the e-mail notification text.

Figure 11.29 – E-mail Notification

Thank you for submitting information to FDA regarding the Notice of Significant Change. We will review this information and may follow-up if additional information is needed.

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

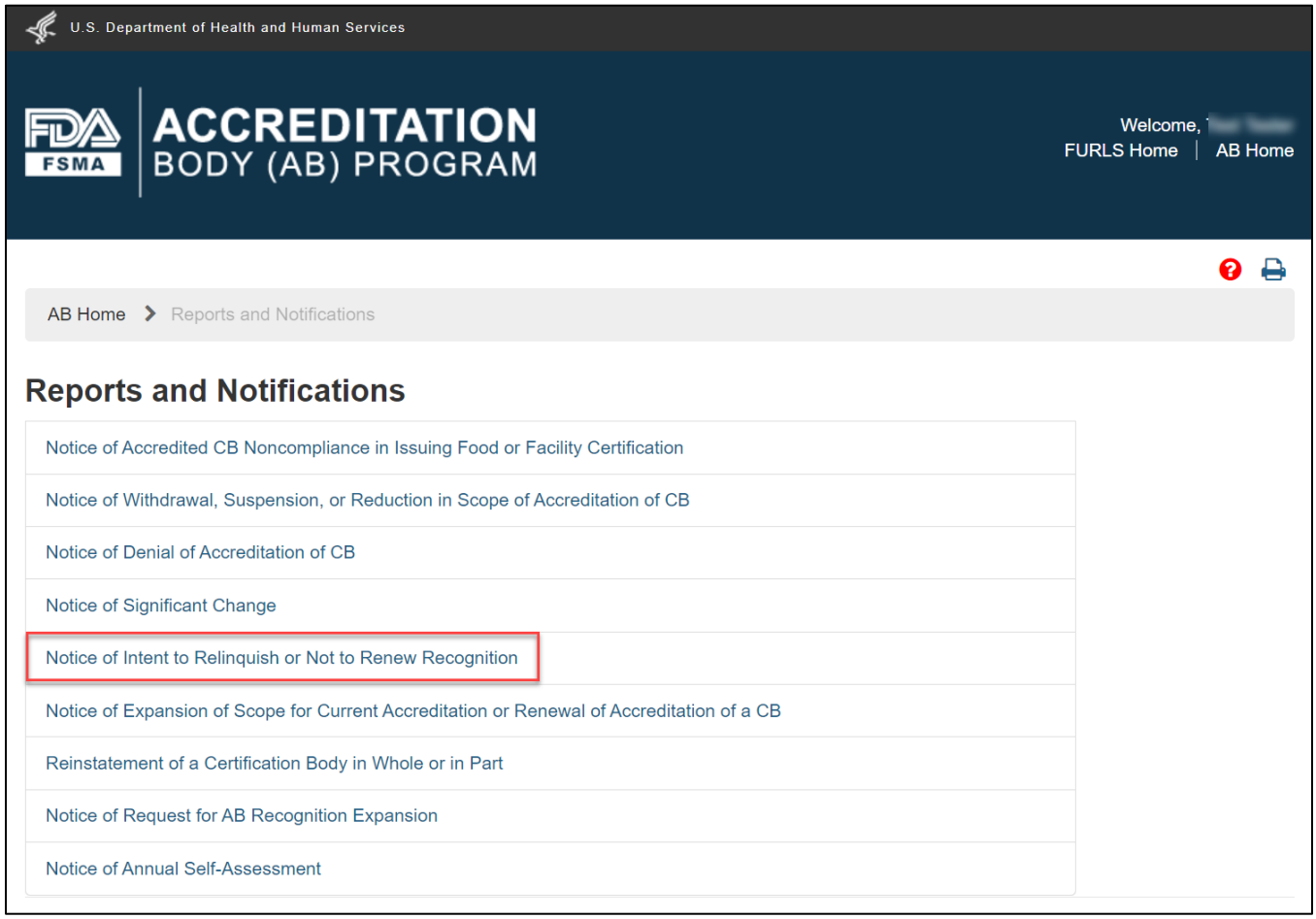
DO NOT REPLY TO THIS EMAIL

Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.5 Notice of Intent to Relinquish or Not to Renew Recognition

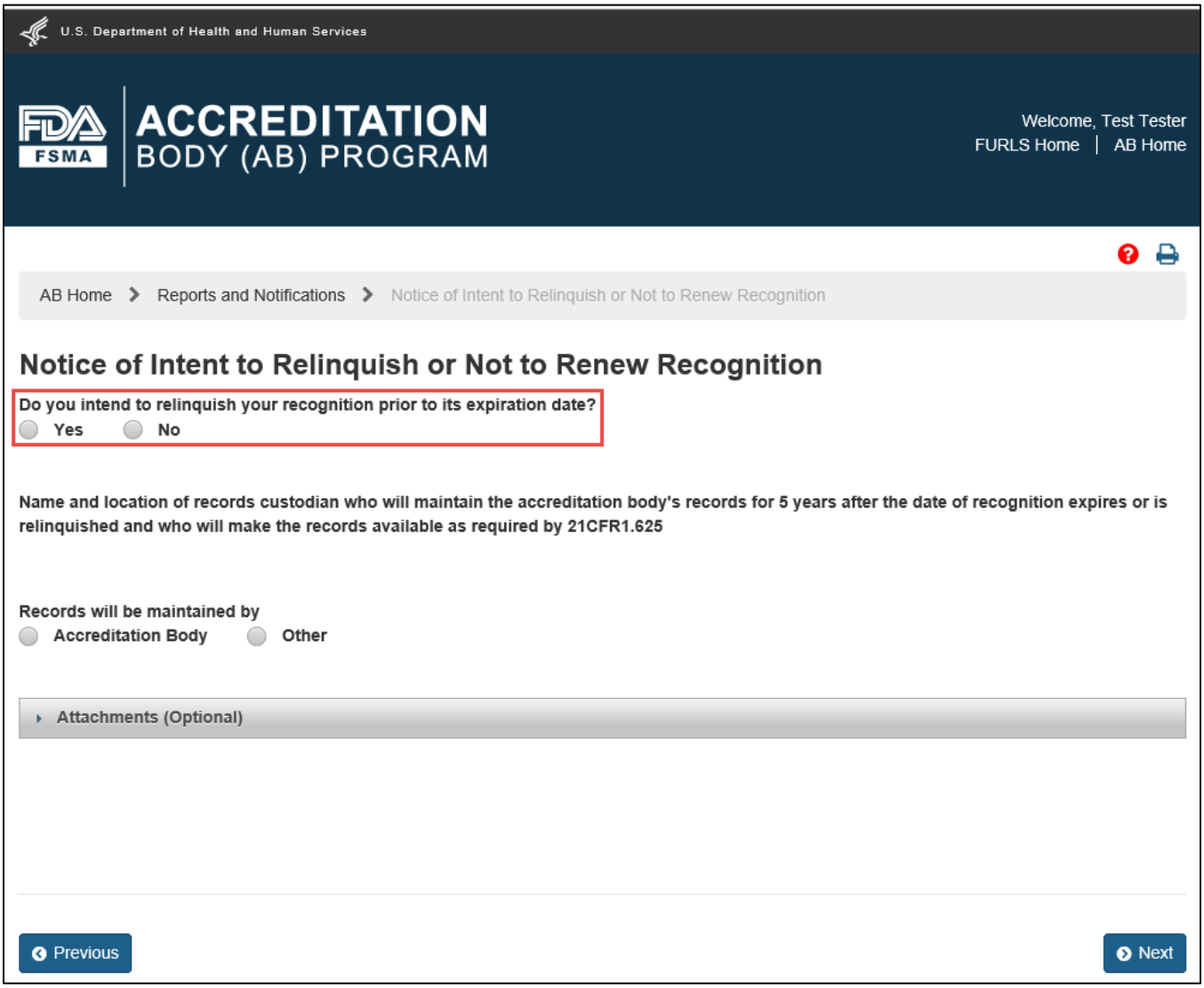
To notify FDA before voluntarily relinquishing recognition or before allowing your recognition to expire without seeking renewal, click the “Notice of Intent to Relinquish or Not to Renew Recognition” link on the “Reports and Notifications” page (Figure 11.30).

Figure 11.30 – Reports and Notifications Page



The system will display the “Notice of Intent to Relinquish or Not to Renew Recognition” page (Figure 11.31).

Figure 11.31 – Notice of Intent to Relinquish or Not to Renew Recognition



The system will display the following data field:

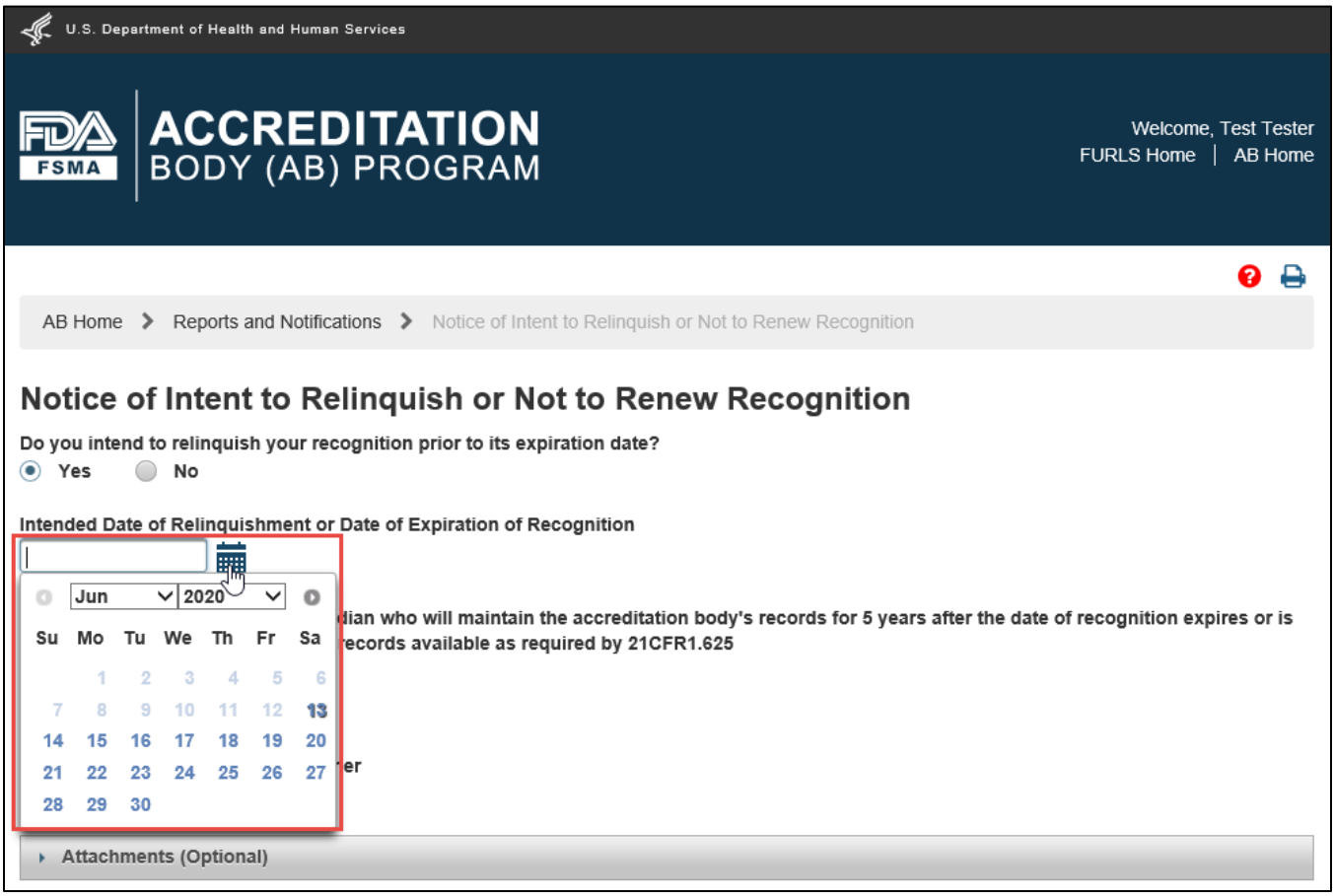
- **Do you intend to relinquish your recognition prior to its expiration date?** – Select “Yes” or “No” by clicking its radio button.
    - Click the radio button next to “Yes” to report your intent to relinquish recognition prior to your expiration date. If “Yes” is selected, proceed to Section 11.5.1 of this chapter.
    - Click the radio button next to “No” to report your intent to not renew recognition. If “No” is selected, proceed to Section 11.5.2 of this chapter.

11.5.1 Intent to Relinquish Recognition

After selecting “Yes” to report your intent to relinquish recognition prior to your expiration date, the system will display the following data field (Figure 11.32):

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

Figure 11.32 – Intended Date of Relinquishment or Date of Expiration of Recognition – Date Selection



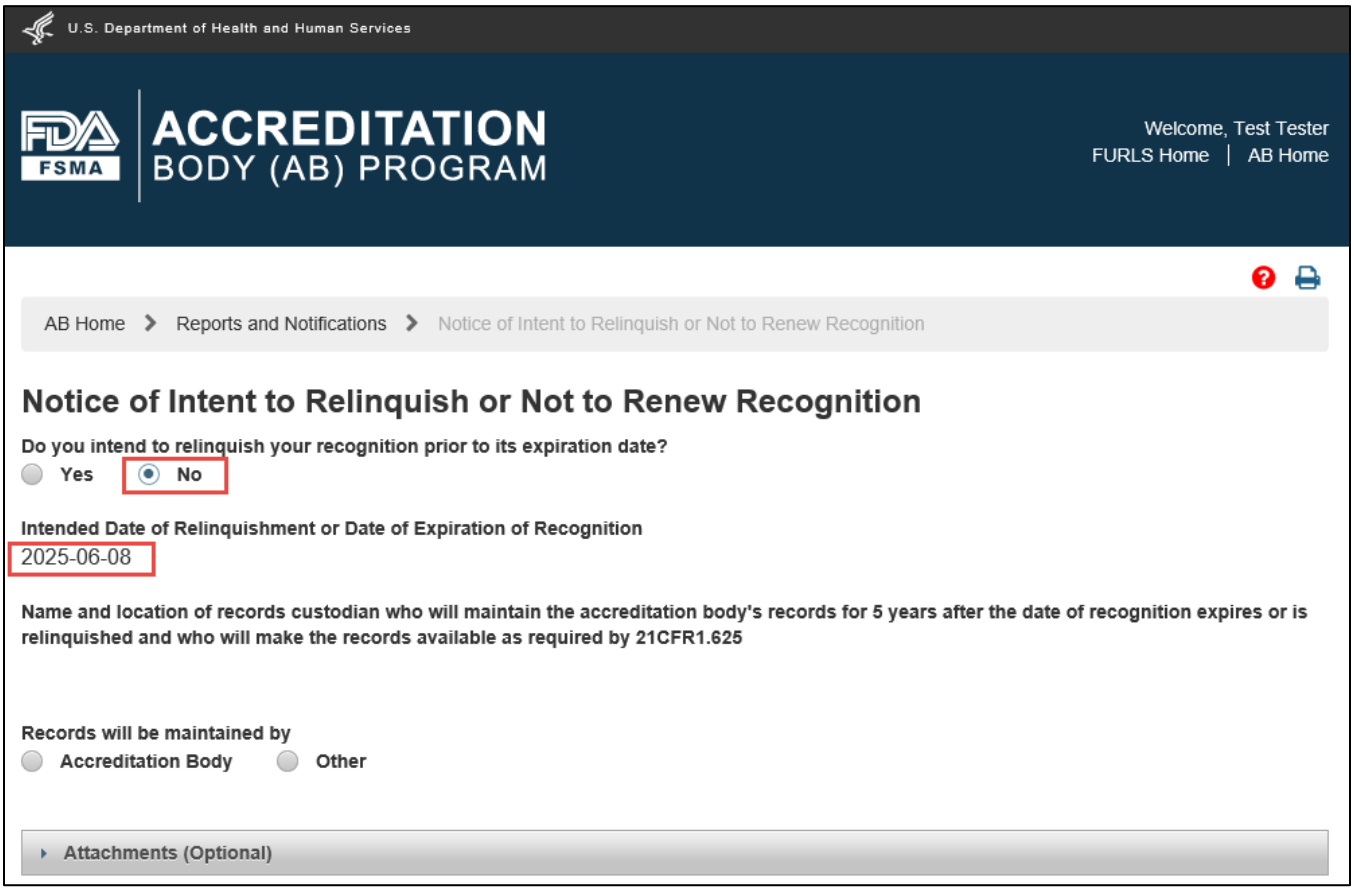
Select or enter the date of relinquishment and proceed to Section 11.5.3 of this chapter for the next steps.

11.5.2 Intent Not to Renew Recognition

After selecting “No” to report your intent to not renew recognition, the system will display the following read-only information (Figure 11.33):

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

Figure 11.33 – Intended Date of Relinquishment or Date of Expiration of Recognition – Pre-filled Date



Review the pre-filled date and proceed to Section 11.5.3 of this chapter for the next steps.

11.5.3 Records Custodian and Attachments

Once you have selected the intended date of relinquishment or date of expiration of recognition, the system will display the “Records maintained by” field with the following two options (Figure 11.34):

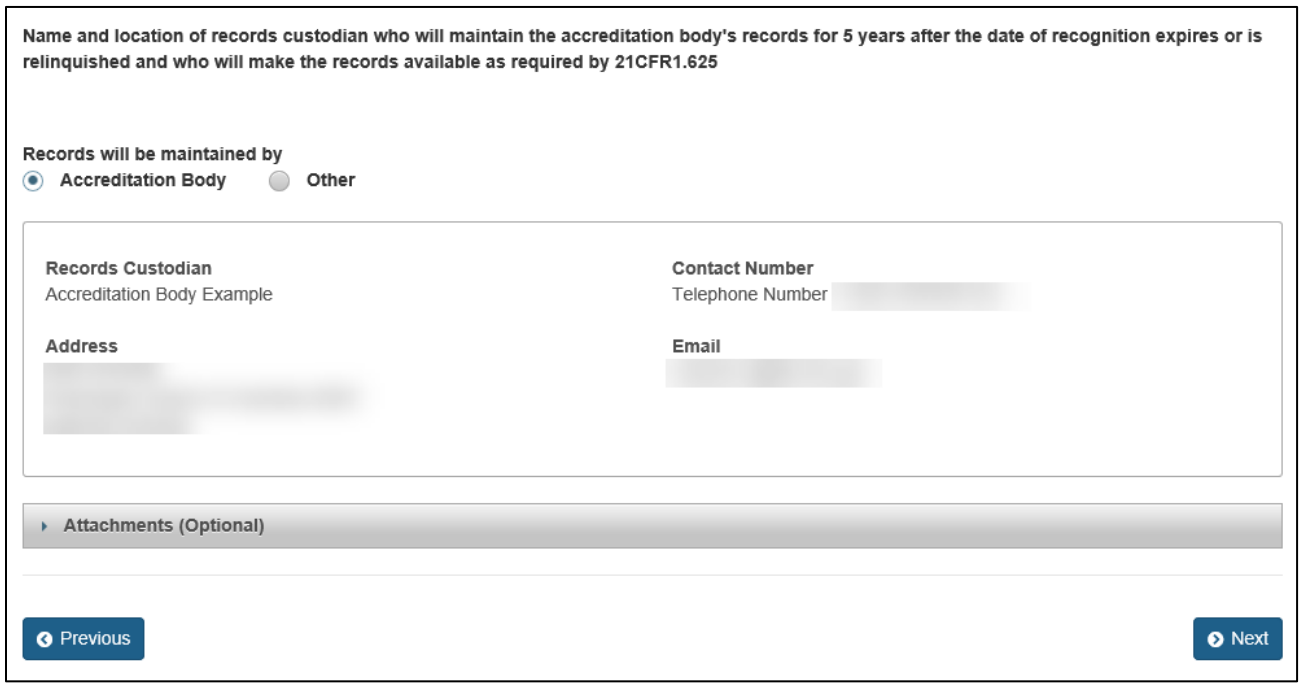
- Accreditation Body – Select this option if you will be maintaining your records. Select “Accreditation Body” by clicking its radio button to display your read-only contact information.
- Other – Select this option if someone other than you will be maintaining your records. Select “Other” by clicking 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 11.34 – Records Will Be Maintained By

If you select “Accreditation Body” by clicking the radio button, the system will display the read-only contact information (Figure 11.35).

Figure 11.35 – Records Will Be Maintained by Accreditation Body

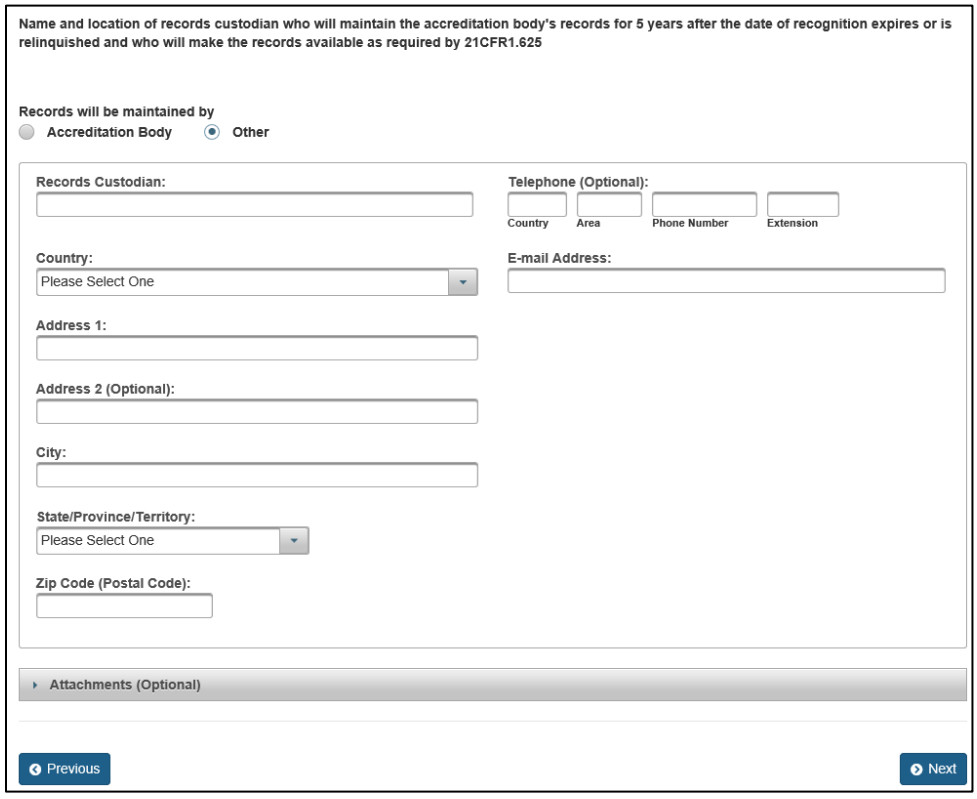


If you select “Other” by clicking the radio button, the system will display the following data fields (Figure 11.36):

- **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 address where the records will be physically located (includes the number, street, quadrant, etc.)
- **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 zip code or postal code where the records will be physically located
- **Telephone (Optional field)** – The telephone number of the records custodian
    - “Country” is the country code.
    - “Area” is the area code.
    - “Phone Number” is the phone number.
    - “Extension” is the local phone extension, if applicable.
- **E-mail Address –** The e-mail address of the records custodian

Complete the data fields to enter the contact information for the designated records custodian.

Figure 11.36 – Records Maintained by Other



To upload documents to the notice, use the “Attachments (Optional)” section (Figure 11.37). Attachments are not required to submit the notice.

Click the accordion section title bar for “Attachments (Optional)” to proceed with adding attachments.

Follow the four-step process to upload attachments.

Click the “Browse” button to search for and select the desired file for upload.

The browsing window will close once a file is selected. The “Upload” and “Cancel” buttons will be enabled once the browsing window closes.

Click the “Upload” button to attach the file. Click the “Cancel” button to remove the file from the menu.

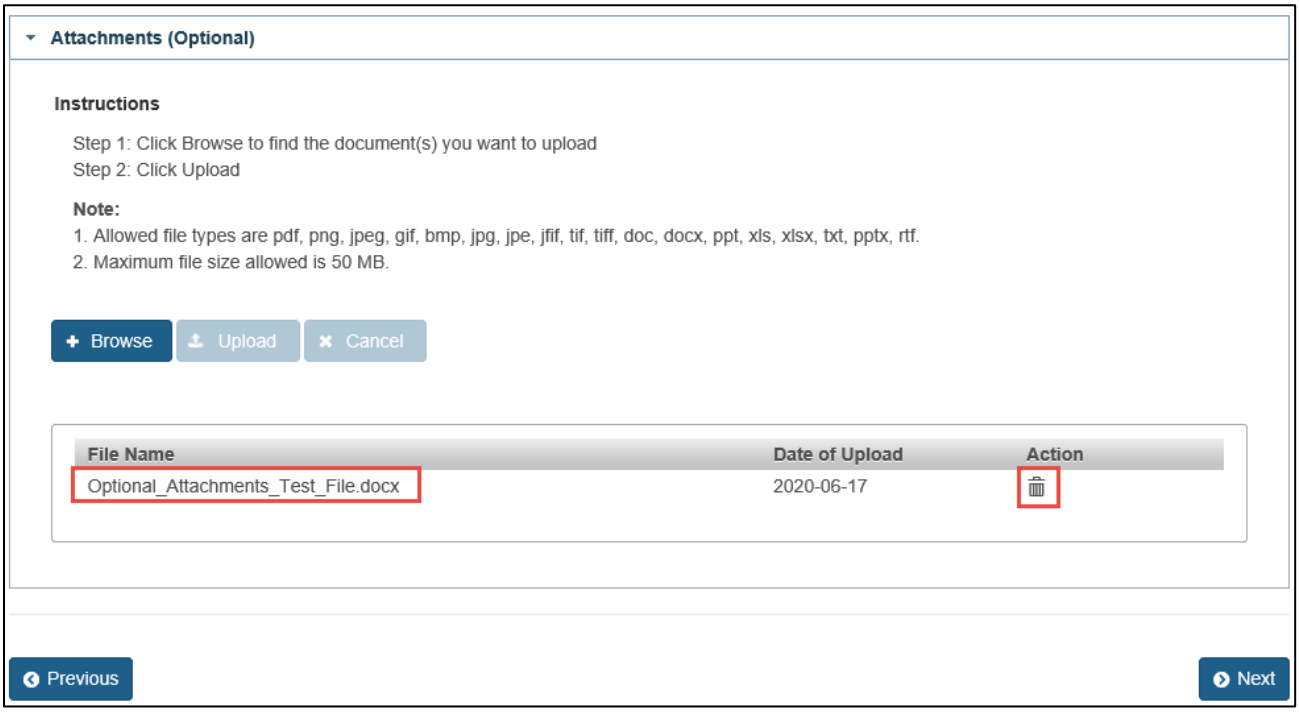
Note: The system supports the following document types: .pdf; .png; .jpeg; .gif; .bmp; .jpg; .jpe; jfif; .tif; .tiff; .doc; .docx; .ppt; .xls; .xlsx; .txt; .pptx; or .rtf.

The maximum file size allowed is 50 MB.

Once the upload is complete, a confirmation message with the file name will display at the top of the page. The attachment details will display in a table.

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

Figure 11.37 – Attachments (Optional) Section



Repeat the previous steps to upload additional attachments.

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

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

The system will display the “e-Signature” page (Figure 11.38).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

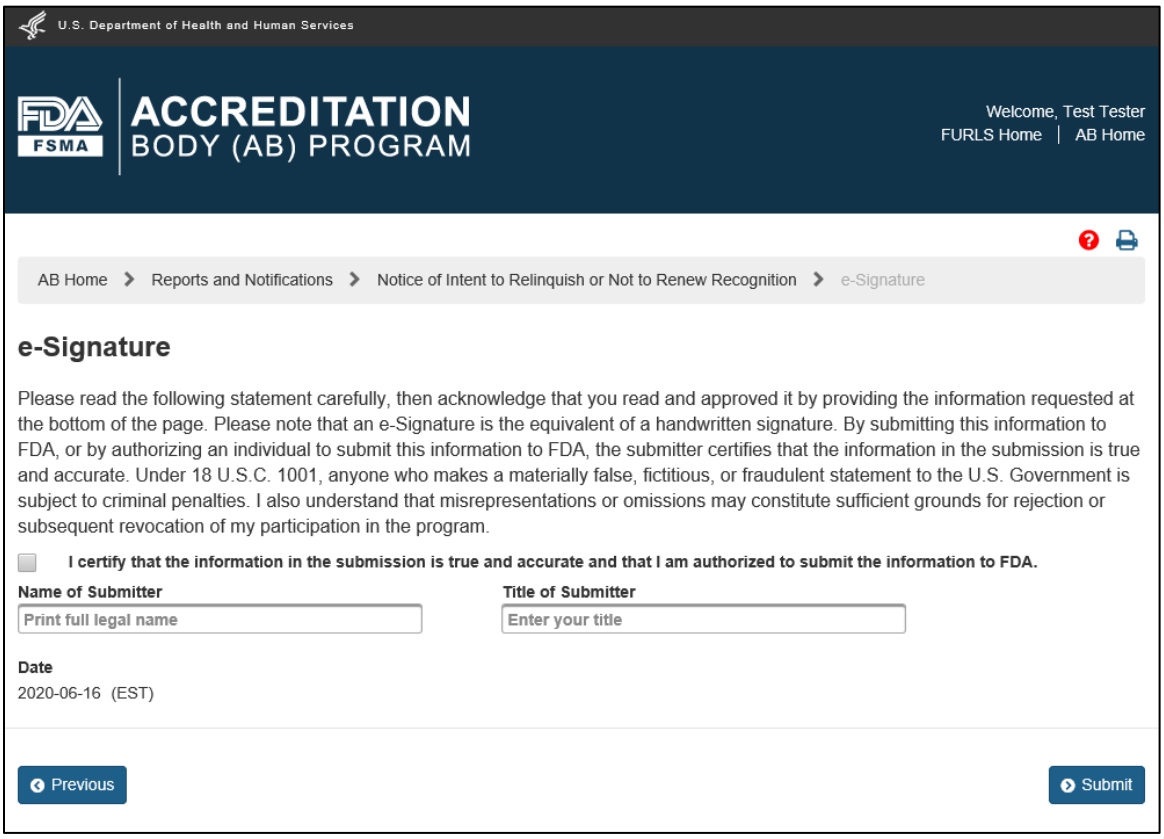
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – 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 Recognition” page.

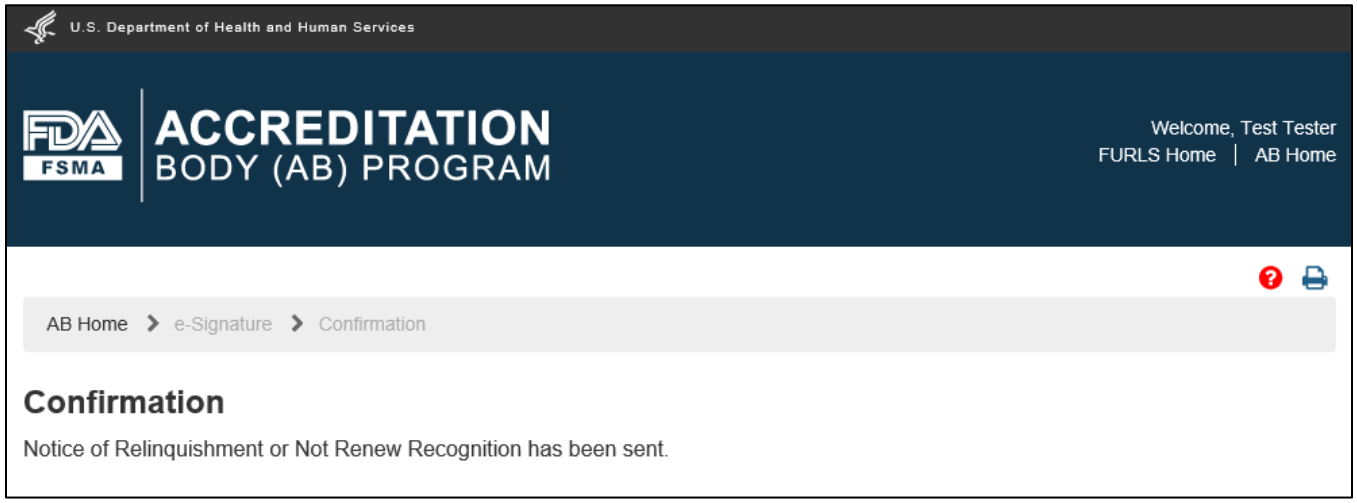
Click the “Submit” button to complete submission of the notice to FDA.

Figure 11.38 – e-Signature Page



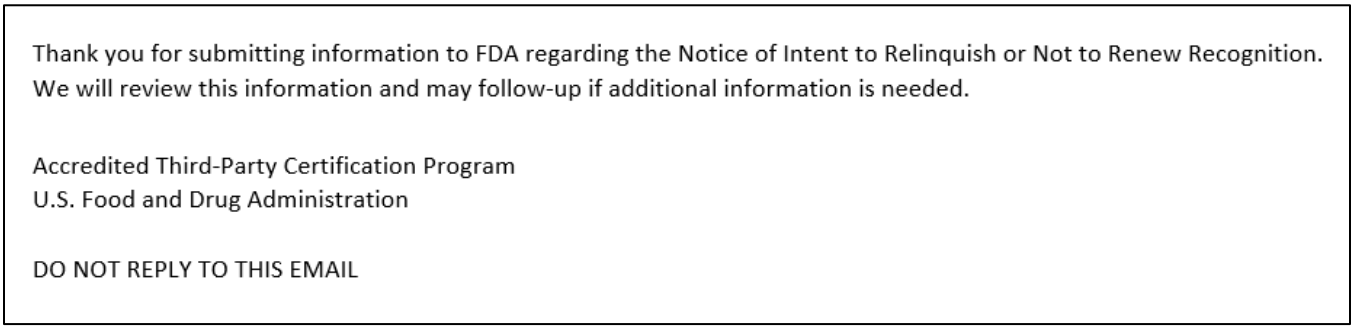
After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.39).

Figure 11.39 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.40). Note that the image below only depicts the e-mail notification text.

Figure 11.40 – E-mail Notification

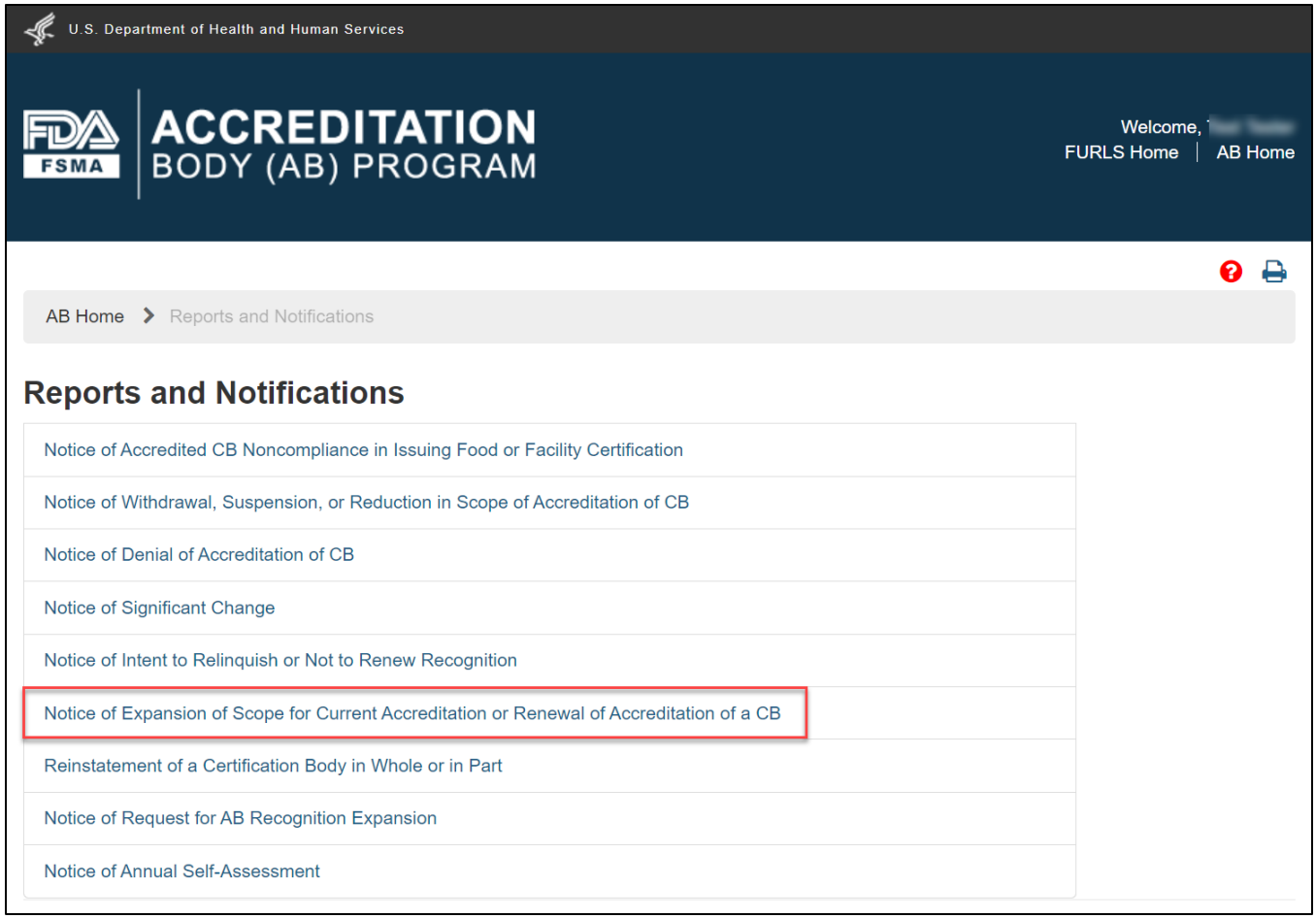


Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.6 Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB

To notify FDA of the expansion of an accredited CB's scope(s) or renewal of a CB's accreditation, click the "Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB" link on the "Reports and Notifications" page (Figure 11.41).

Figure 11.41 – Reports and Notifications Page

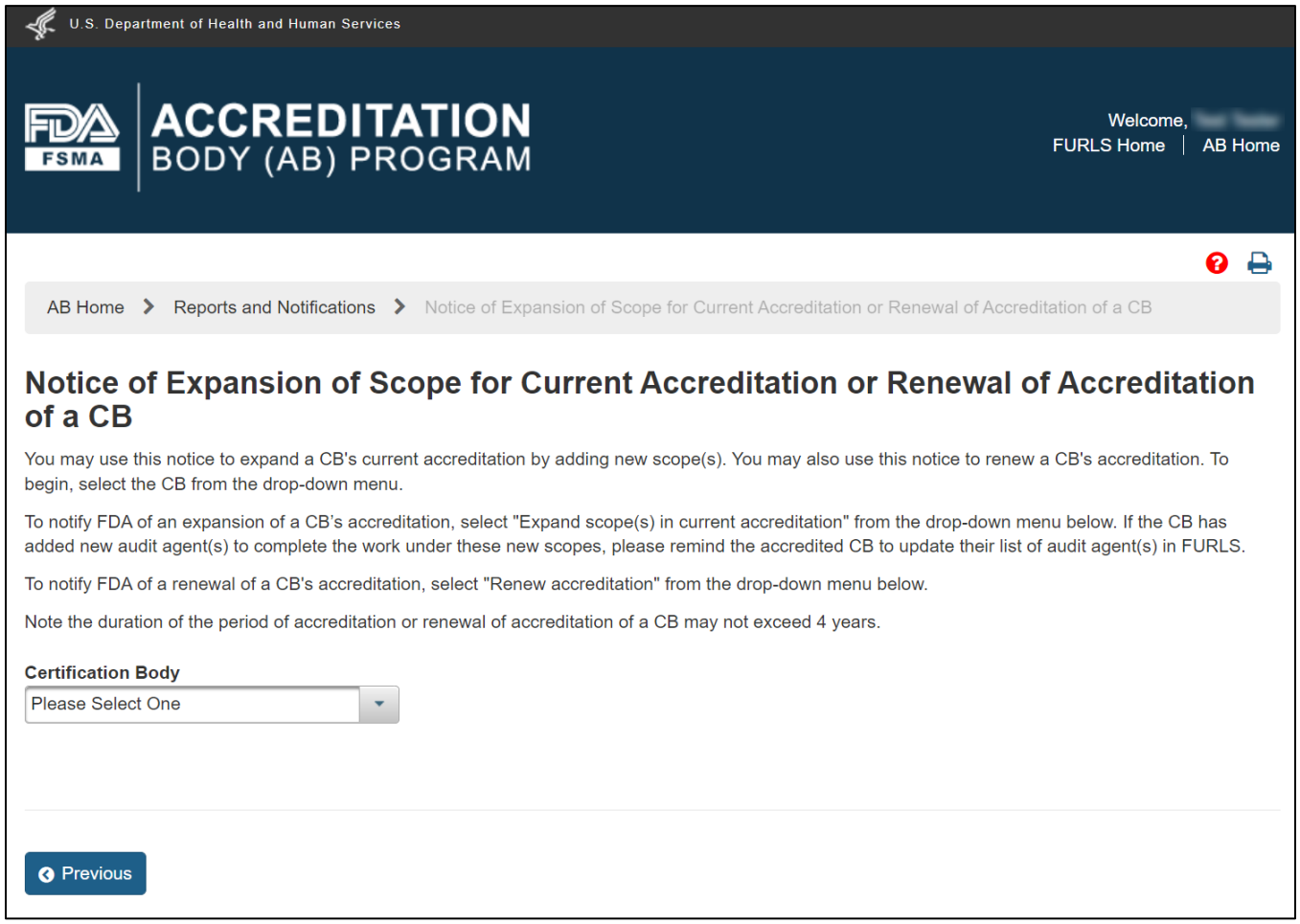


The system will display the “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB” page (Figure 11.42).

Select the name of the accredited CB from the “Certification Body” dropdown menu.

Note: A CB will no longer be available for selection from the “Certification Body” dropdown menu once its accreditation has expired. The “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB” should be submitted to FDA informing them of the CB’s renewal of accreditation prior to the CB’s expiration.

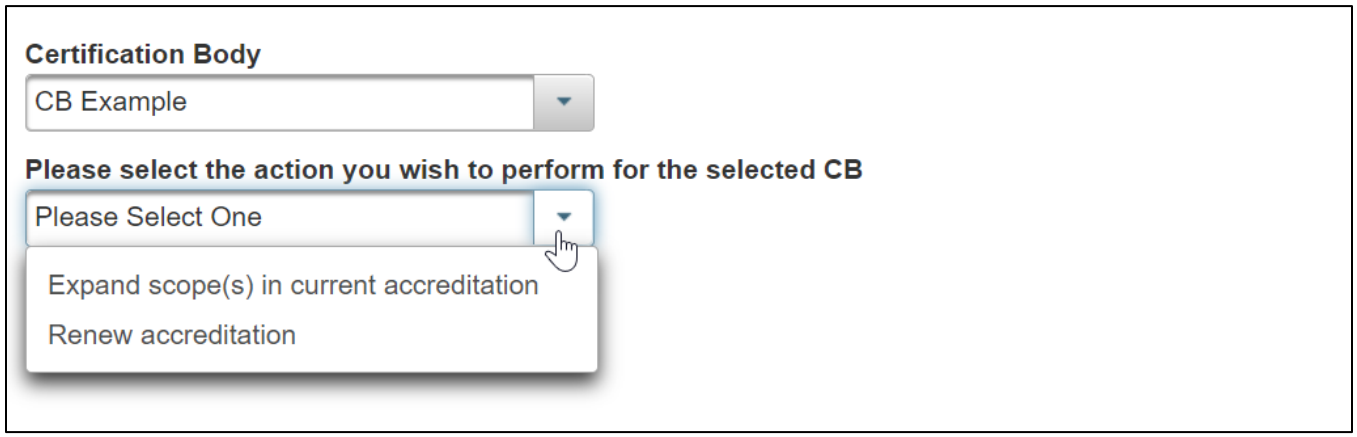
Figure 11.42 – Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB



The following will display after you have selected the accredited CB:

- **“Please select the action you wish to perform for the selected CB”** (Figure 11.43). The system displays a dropdown menu with the choices to “Expand scope(s) in current accreditation” or “Renew Accreditation.”

Figure 11.43 – Please Select the Action You Wish to Perform for the Selected CB Menu



To expand the scope(s) of accreditation for an accredited CB, proceed to Section 11.6.1 of this chapter.

To renew the accreditation of an accredited CB, proceed to Section 11.6.2 of this chapter.

Note: You will be able to add new scopes to a CB's accreditation during submission of either notice (expansion or renewal).

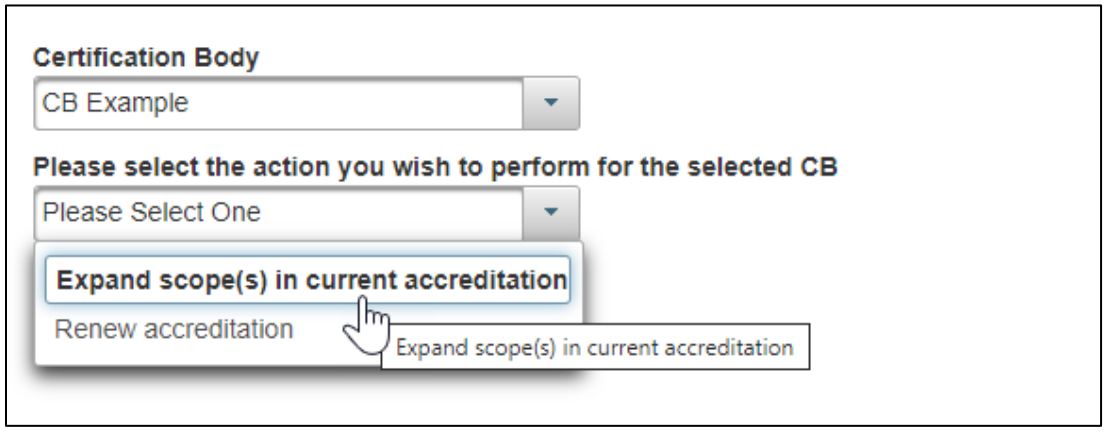
11.6.1 Expand Scope(s) for an Accredited CB

To notify FDA of the expansion of scope(s) as part of the CB's current accreditation, select the "Expand scope(s) in current accreditation" option from the dropdown menu (Figure 11.44).

This notice may be used to inform FDA of the following updates:

- Changes to the expiration date for the CB's currently accredited scope(s)
- Addition of new scope(s) to the CB's current accreditation

Figure 11.44 – Expand Scope(s) in Current Accreditation Menu

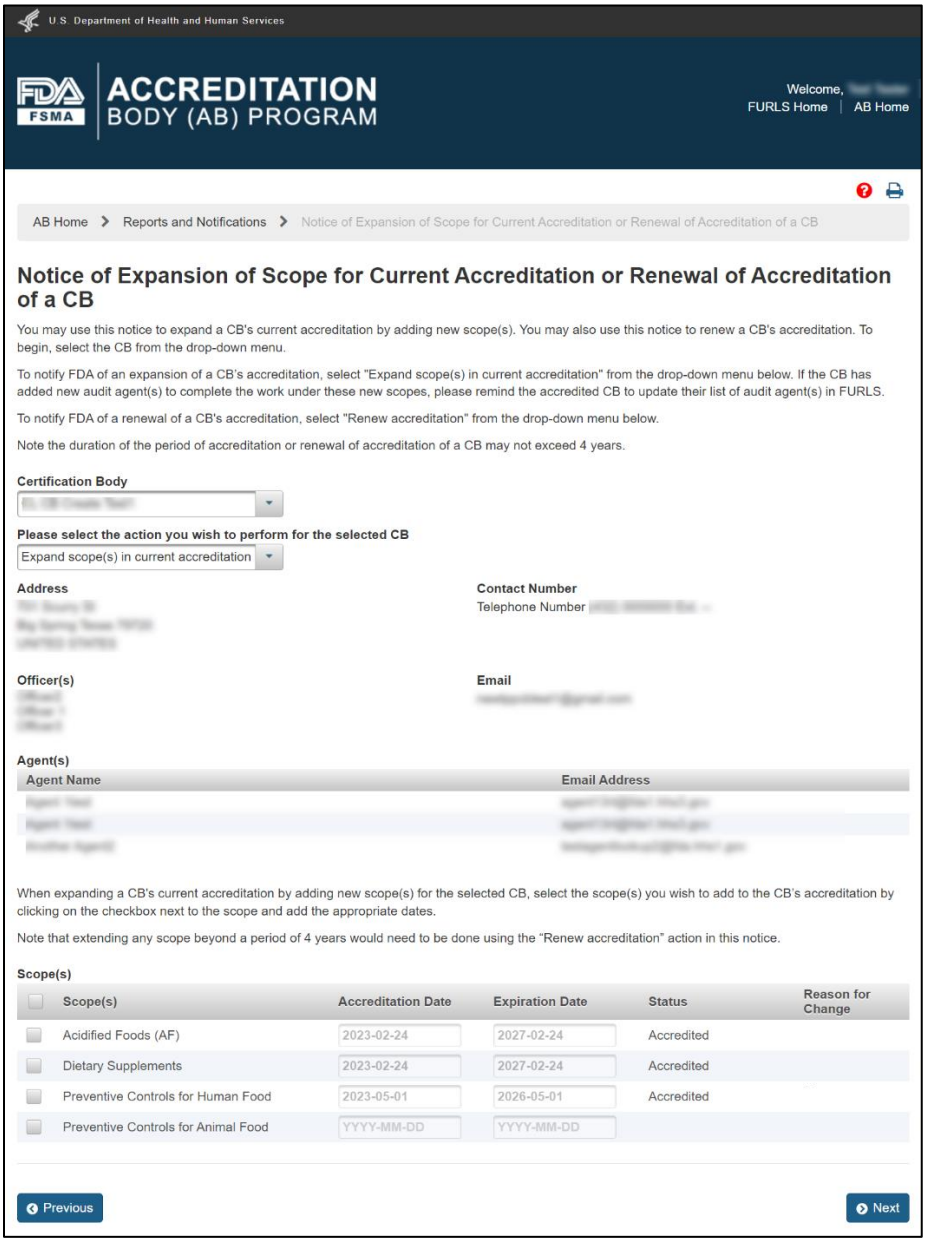


Once you have selected the “Expand scope(s) in current accreditation” option from the dropdown menu, the system will display the following (Figure 11.45):

- **Accredited CB’s Information** – The read-only profile information for the selected CB
- **Scope(s)** – Click the checkbox of the applicable scope to expand the accreditation period for a currently accredited scope or, to add a new scope to the CB’s current accreditation. (Additional data entry fields will appear after a scope is selected.)

  Note: Each scope is updated individually in this notice so only one checkbox can be selected at a time.

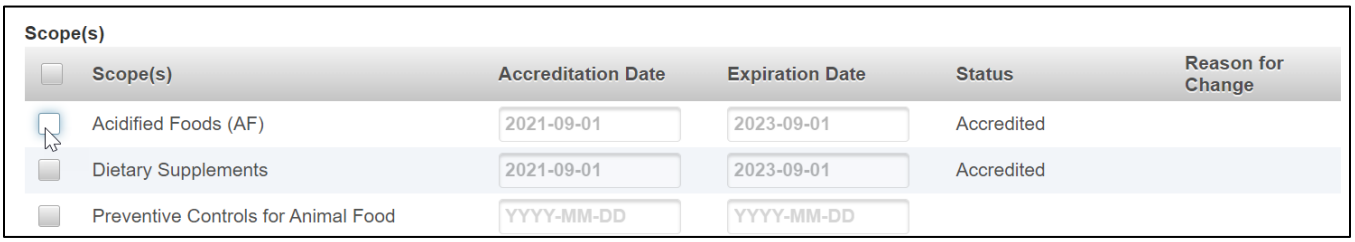
Figure 11.45 – Additional Notice Information Displayed After Expansion Selection



The “Scope(s)” table will list the scope(s) which are either in “Accredited” or “Reinstated" status for the selected CB, as well as any other scope(s) that you are recognized for but which you have not yet accredited the CB.

To expand the accreditation period for a scope for which the CB is currently accredited, click the checkbox next to the scope in the “Scope(s)” table (Figure 11.46).

Figure 11.46 – Checkbox for Scope Selection



Once you have selected a scope, the system will display the “Update Scope” pop-up window with the following fields (Figure 11.47):

- **Expiration Date** – Select the expiration date of the accreditation for the selected scope from the calendar icon or enter the expiration date in “YYYY-MM-DD” format.
- **Reason for Change** – Enter the reason for the update to the scope’s expiration date in the text entry field, which allows a maximum of 1,000 characters.

Figure 11.47 – Update Scope Pop-up Window

Click the “Cancel” button in the “Update Scope” window to dismiss the changes.

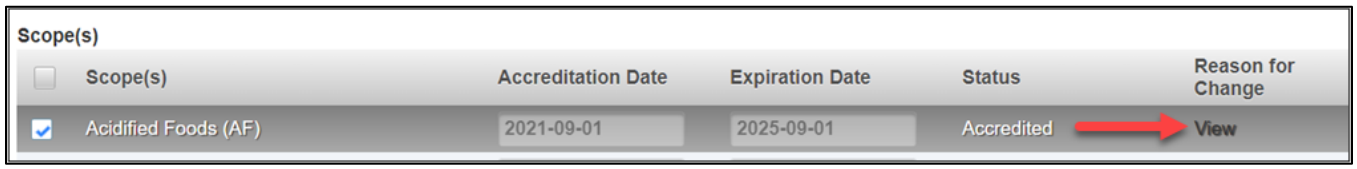
Complete the data fields and click the “Save” button in the “Update Scope” window.

The system will close the window and return to the “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB” page.

The scope will reflect the updated expiration date in the “Scope(s)” table after saving the changes entered in the “Update Scope” window (Figure 11.48).

The “Reason for Change” column in the “Scope(s)” table will be populated with a “View” hyperlink. Click “View” to see the submitted reason for the change.

Figure 11.48 – Updated Scope with View Link



Repeat the previous steps to update the expiration dates of any additional scopes. Each scope is updated individually.

Note: Deselecting the checkbox of an updated scope before submitting the notice will act as a “cancel” feature and will remove the changes.

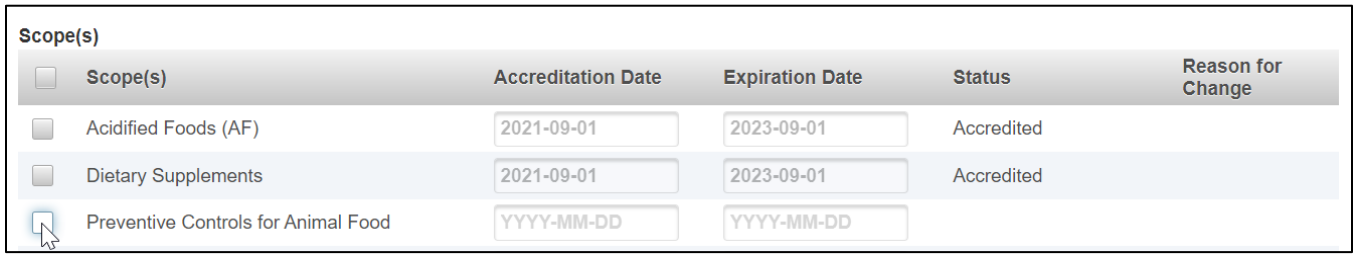
****Important:** Once changes are saved, the system will reflect the changes in the CB’s details however, they will not be sent to FDA until the notice has been submitted.

Proceed with this section to add a new scope to the CB’s current accreditation.

Proceed to Section 11.6.3 of this chapter for instructions to submit the notice.

To add a new scope for which the CB is not yet accredited, select a scope by clicking its checkbox in the “Scope(s)” table (Figure 11.49).

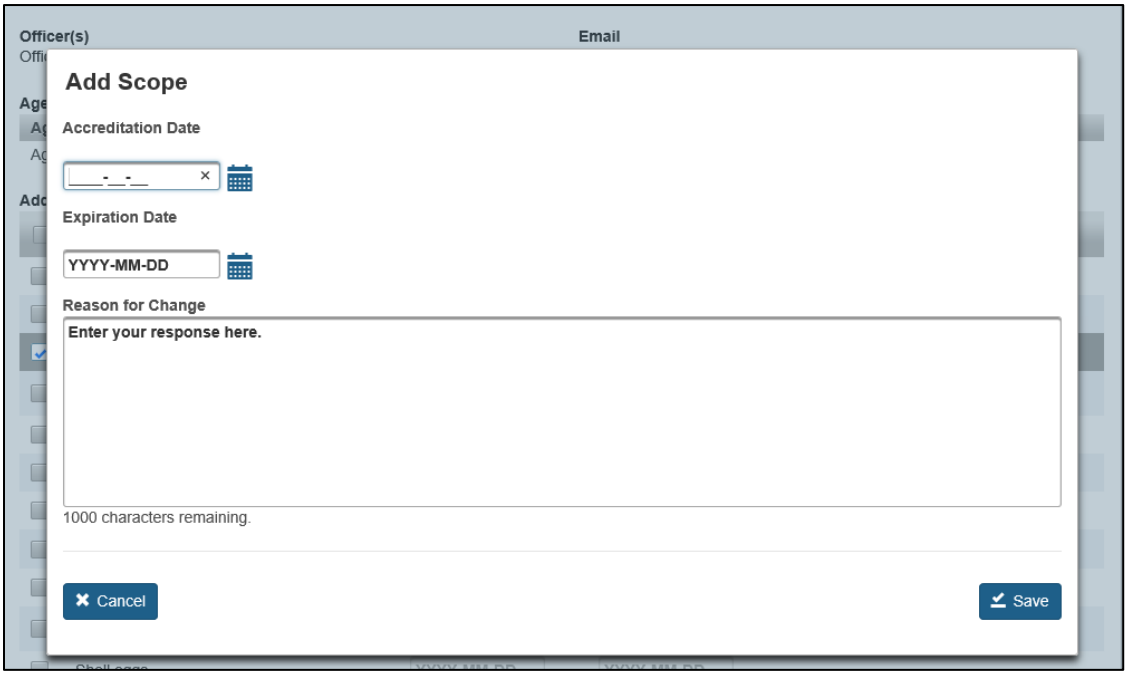
Figure 11.49 – Checkbox for Scope Selection



Once you have selected a scope, the system will display an “Add Scope” pop-up window with the following fields (Figure 11.50):

- **Accreditation Date** – Select the start date of the accreditation for the selected scope from the calendar icon or enter the accreditation date in “YYYY-MM-DD” format.
- **Expiration Date** – Select the expiration date of the accreditation for the selected scope from the calendar icon or enter the expiration date in “YYYY-MM-DD” format.
- **Reason for Change** – Enter the reason the scope was added to the CB’s accreditation in the text entry field, which allows a maximum of 1,000 characters.

Figure 11.50 – Add Scope Pop-up Window (Expand scope)

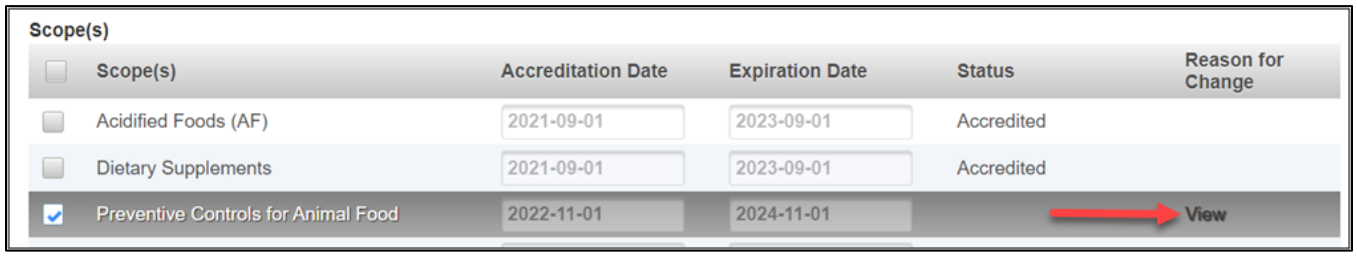


Click the “Cancel” button in the “Add Scope” window to discard the changes and close the window.

Click the “Save” button to save the changes. The system will close the “Add Scope” window and return to the main “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB” page.

The scope will reflect the update in the “Scope(s)” table after saving changes in the “Add Scope” window (Figure 11.51). After updating a scope, the “Reason for Change” column in the “Scope(s)” table will be populated with the “View” hyperlink. Click the “View” button to see the submitted reason for the change.

Figure 11.51 – Added Scope



Repeat the previous steps to add more scopes to the CB's current accreditation. Each scope is added individually in this notice.

Note: Deselecting the checkbox of an updated scope before submitting the notice will act as a "cancel" feature and will remove the changes.

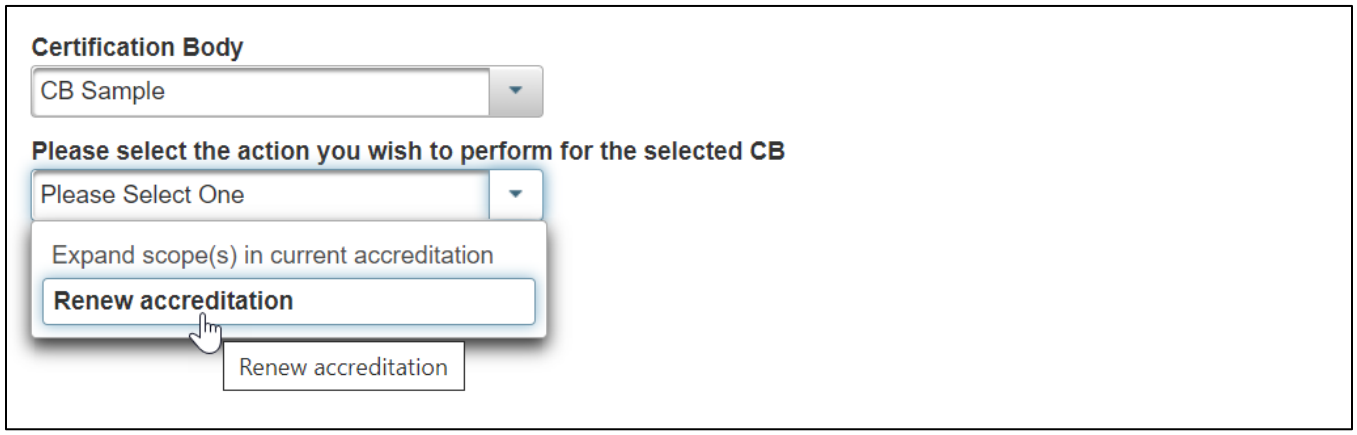
****Important:** Once changes are saved, the system will reflect the changes in the CB's details however, they will not be sent to FDA until the notice has been submitted.

Proceed to Section 11.6.3 of this chapter for instructions to submit the notice.

11.6.2 Renew the CB's Current Accreditation

To notify FDA of the renewal of a CB's accreditation, select the "Renew accreditation" option from the dropdown menu (Figure 11.52).

Figure 11.52 – Renew Accreditation Menu Option

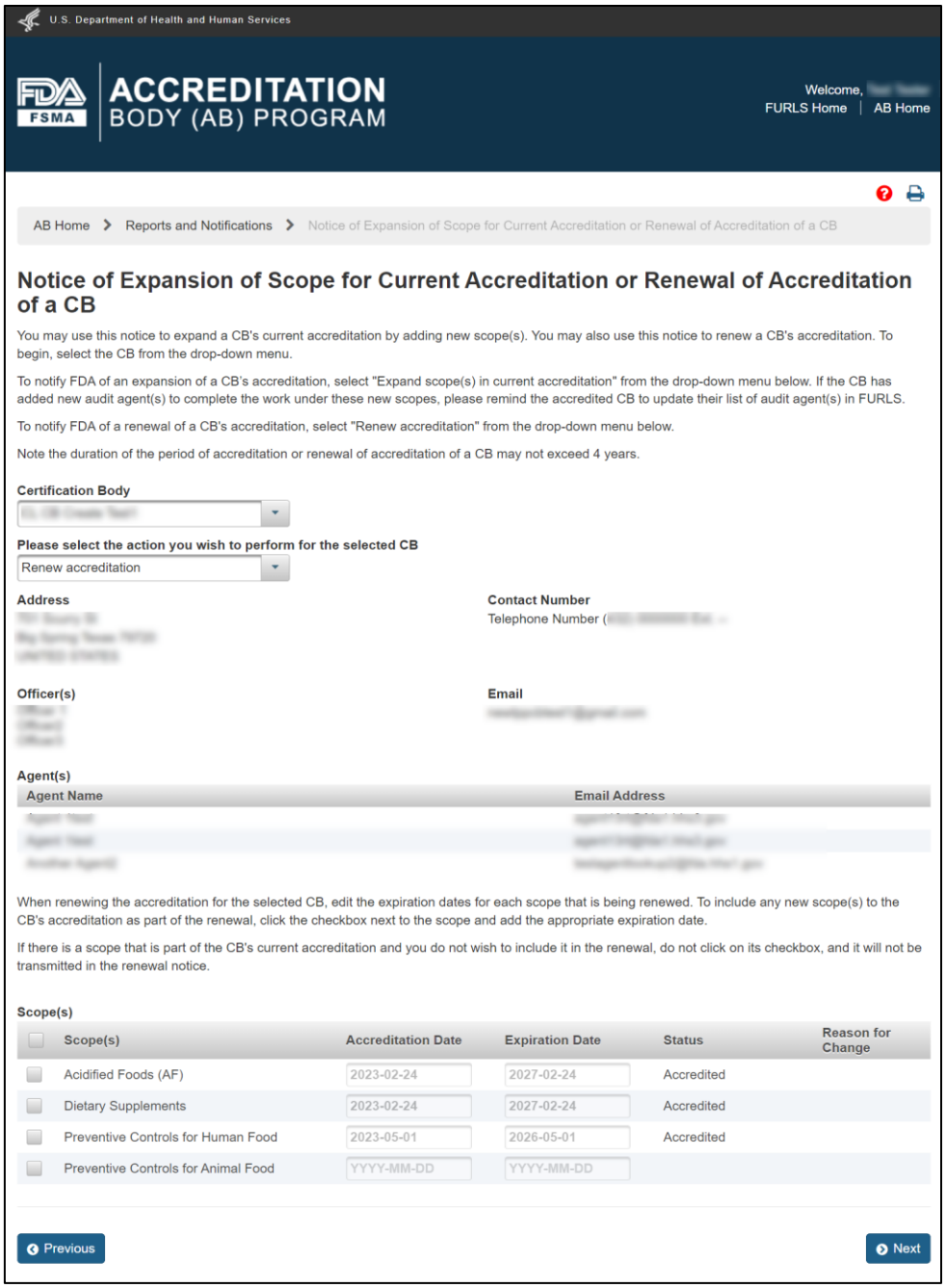


Once you have selected the "Renew accreditation" option from the dropdown menu, the system will display the following (Figure 11.53):

- **Accredited CB's Information** – The read-only profile information for the selected CB
- **Scope(s)** – A table listing the scope(s) which are in "Accredited" or "Reinstated" status for the selected CB, as well as any other scope(s) that you are recognized for but which you have not yet accredited the selected CB.

  Note: Each scope is updated individually in this notice so only one checkbox can be selected at a time.

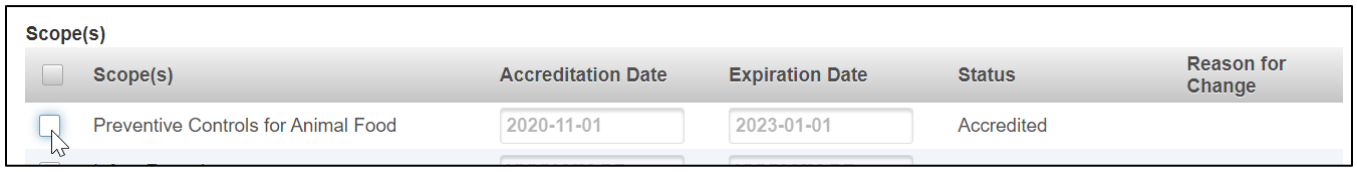
Figure 11.53 – Additional Notice information Displayed After Renew Selection



To renew the CB's accreditation for a scope for which the CB is currently accredited, click the checkbox next to the scope in the "Scope(s)" table (Figure 11.54).

Note: The system will open up the option for renewal of an active scope when the scope is within six months of its expiration.

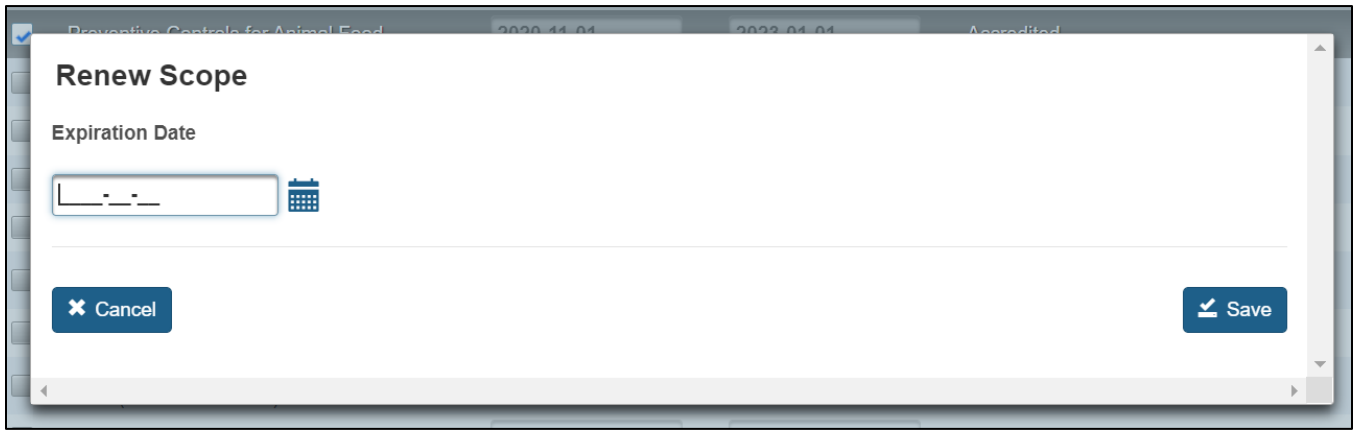
Figure 11.54 – Checkbox for Scope Selection



Once you have selected a scope, the system will display the "Renew Scope" pop-up window with the following field (Figure 11.55):

- **Expiration Date** – Select the new expiration date of the accreditation for the selected scope from the calendar icon or enter the expiration date in "YYY-MM-DD" format.

Figure 11.55 – Renew Scope Pop-up Window



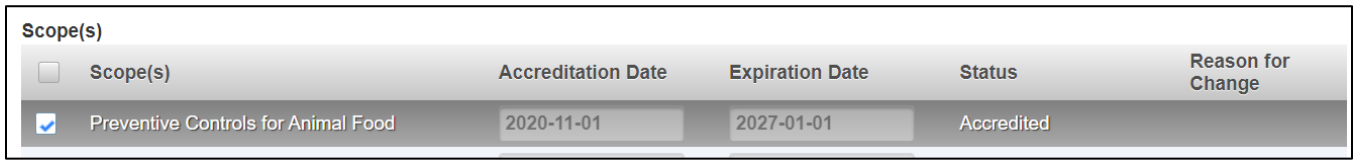
Click the "Cancel" button in the "Renew Scope" window to dismiss the changes and close the window.

Complete the data field and click the "Save" button in the "Renew Scope" window.

The system will close the window and return to the "Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB" page.

The scope will reflect the updated expiration date in the “Scope(s)” table after saving the changes entered in the “Renew Scope” window (Figure 11.56).

Figure 11.56 – Renewed Scope



Repeat the previous steps to renew the CB’s accreditation for additional scopes. Each scope is renewed individually within this notice.

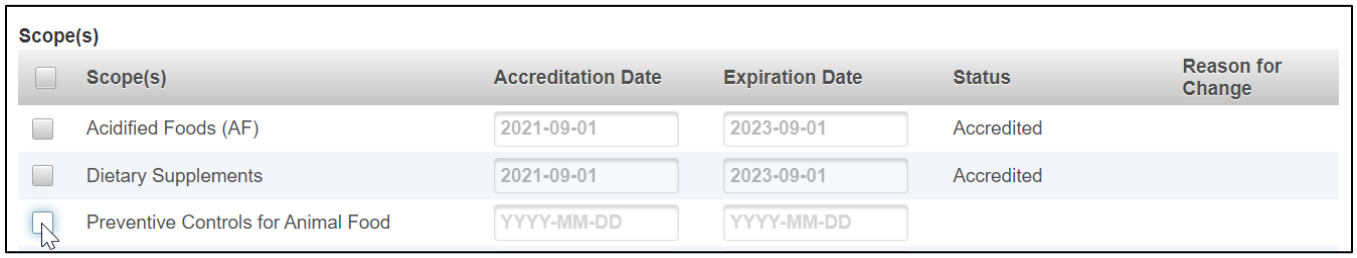
If there is a scope that is part of the CB's current accreditation and you do not wish to include it in the renewal, do not click on its checkbox, and it will not be transmitted in the renewal notice.

Note: Deselecting the checkbox of a renewed scope before submitting the notice will act as a “cancel” feature and will remove the changes.

****Important:** Once changes are saved, the system will reflect the changes in the CB’s details however, they will not be sent to FDA until the notice has been submitted.

To add a new scope to the CB’s accreditation as part of its renewal, select a scope by clicking its checkbox in the “Scope(s)” table (Figure 11.57).

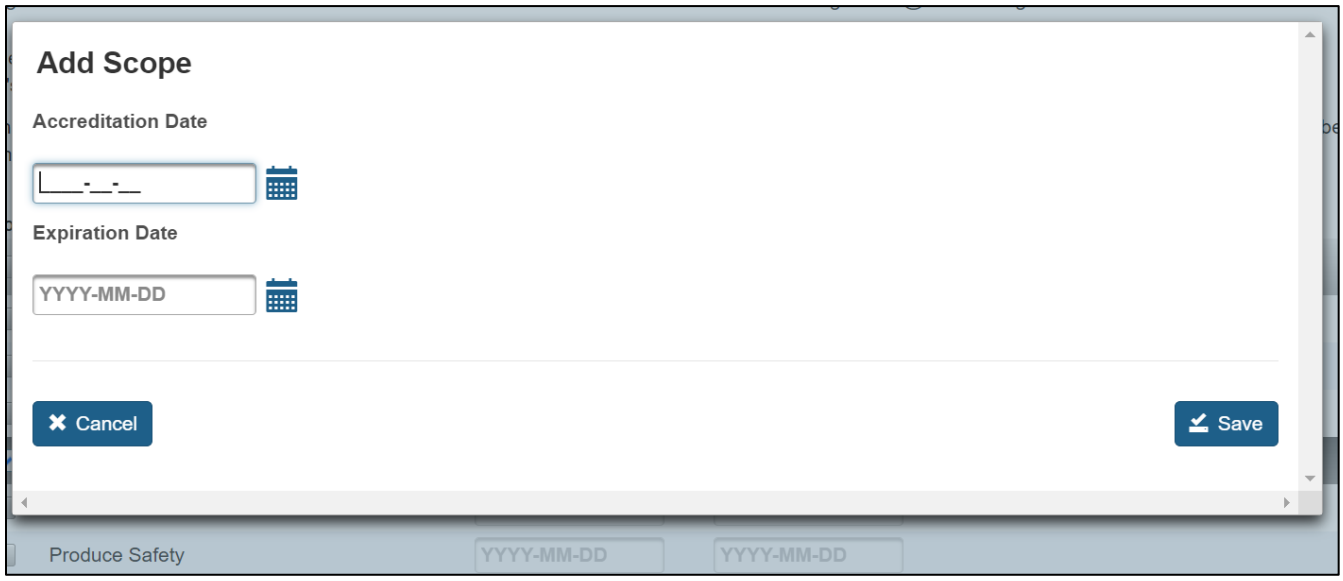
Figure 11.57 – Checkbox for Scope Selection



Once you have selected a scope, the system will display an “Add Scope” pop-up window with the following fields (Figure 11.58):

- **Accreditation Date** – Select the start date of the accreditation for the selected scope from the calendar icon or enter the accreditation date in “YYYY-MM-DD” format.
- **Expiration Date** – Select the expiration date of the accreditation for the selected scope from the calendar icon or enter the expiration date in “YYYY-MM-DD” format.

Figure 11.58 – Add Scope Pop-up Window (Expand Scope)

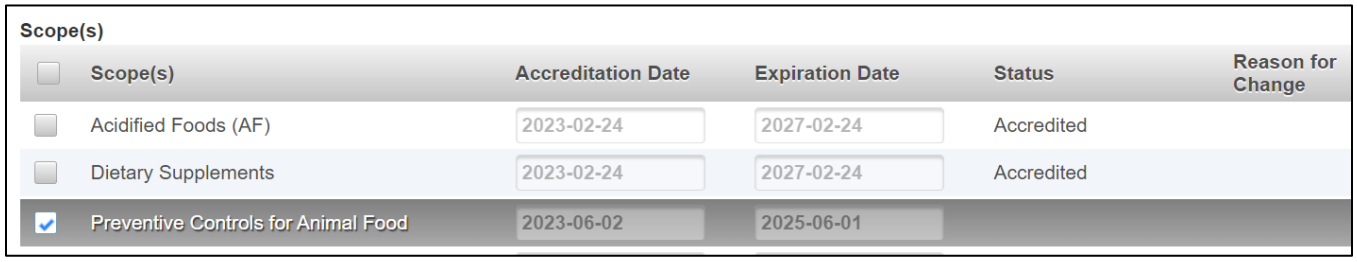


Click the “Cancel” button in the “Add Scope” window to discard the changes and close the window.

Click the “Save” button to save the changes. The system will close the “Add Scope” window and return to the main “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB” page.

The scope will reflect the update in the “Scope(s)” table after saving changes in the “Add Scope” window (Figure 11.59).

Figure 11.59 – Added Scope



Repeat the previous steps to add more scopes to the CB’s renewal of accreditation. Each scope is added individually in this notice.

Note: Deselecting the checkbox of an updated scope before submitting the notice will act as a “cancel” feature and will remove the changes.

****Important:** Once changes are saved, the system will reflect the changes in the CB’s details however, they will not be sent to FDA until the notice has been submitted.

Proceed to Section 11.6.3 of this chapter for instructions to submit the notice.

11.6.3 Notice Submission

Once you have completed your changes to each scope that is being updated for the selected accredited CB, click the “Next” button on the “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB” page to proceed to the “e-Signature” page.

The system will display the “e-Signature” page (Figure 11.60).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

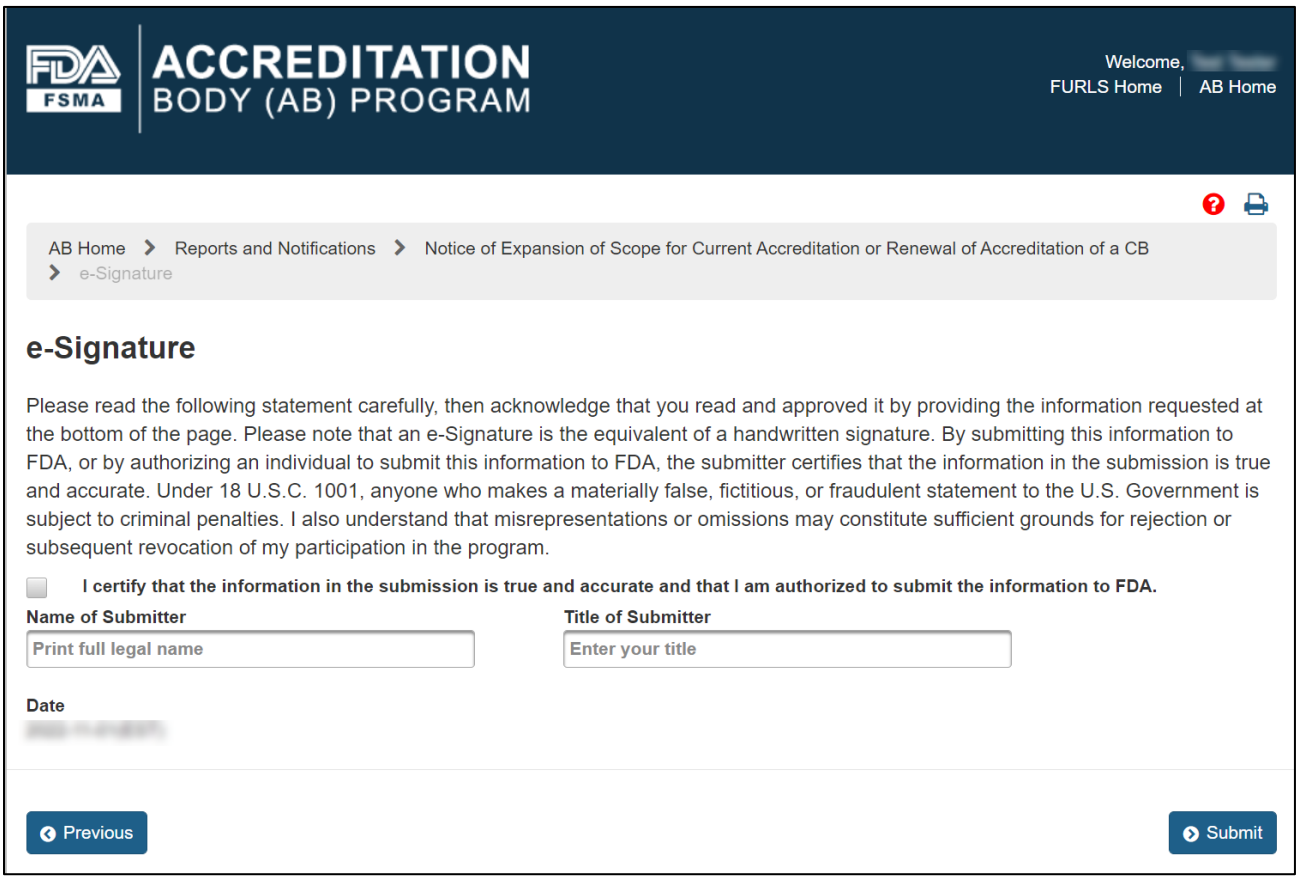
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Notice of Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB” page.

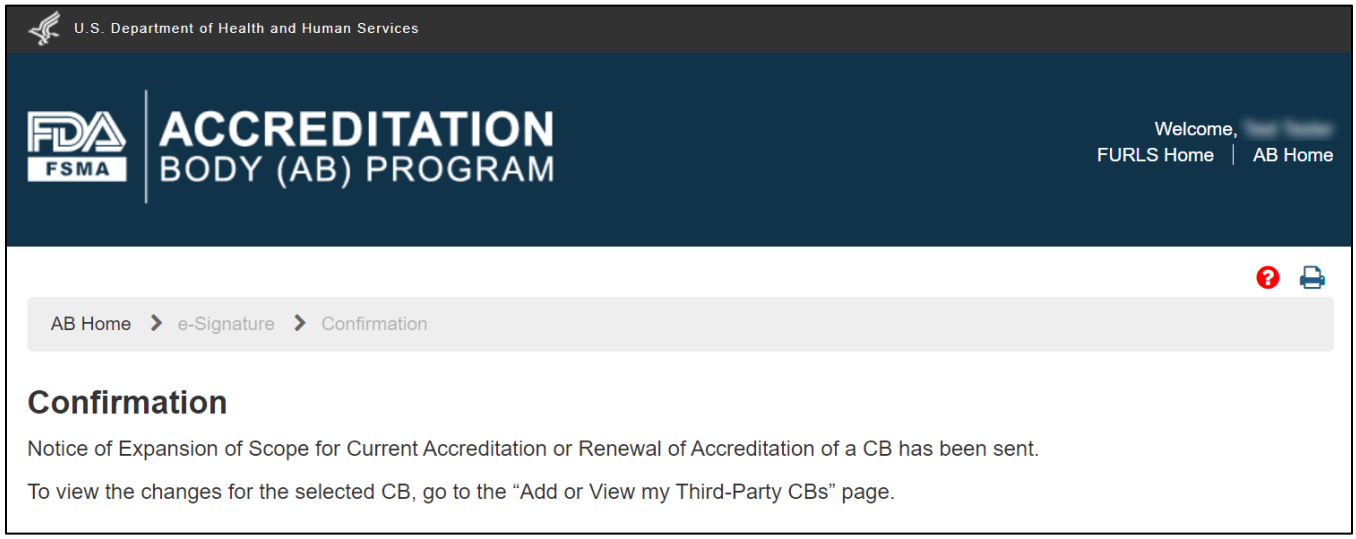
Click the “Submit” button to complete submission of the notice to FDA.

Figure 11.60 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.61).

Figure 11.61 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.62). Note that the image below only depicts the e-mail notification text.

Figure 11.62 – E-mail Notification

Thank you for submitting information to FDA regarding the Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB. We will review this information and may follow-up if additional information is needed.

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

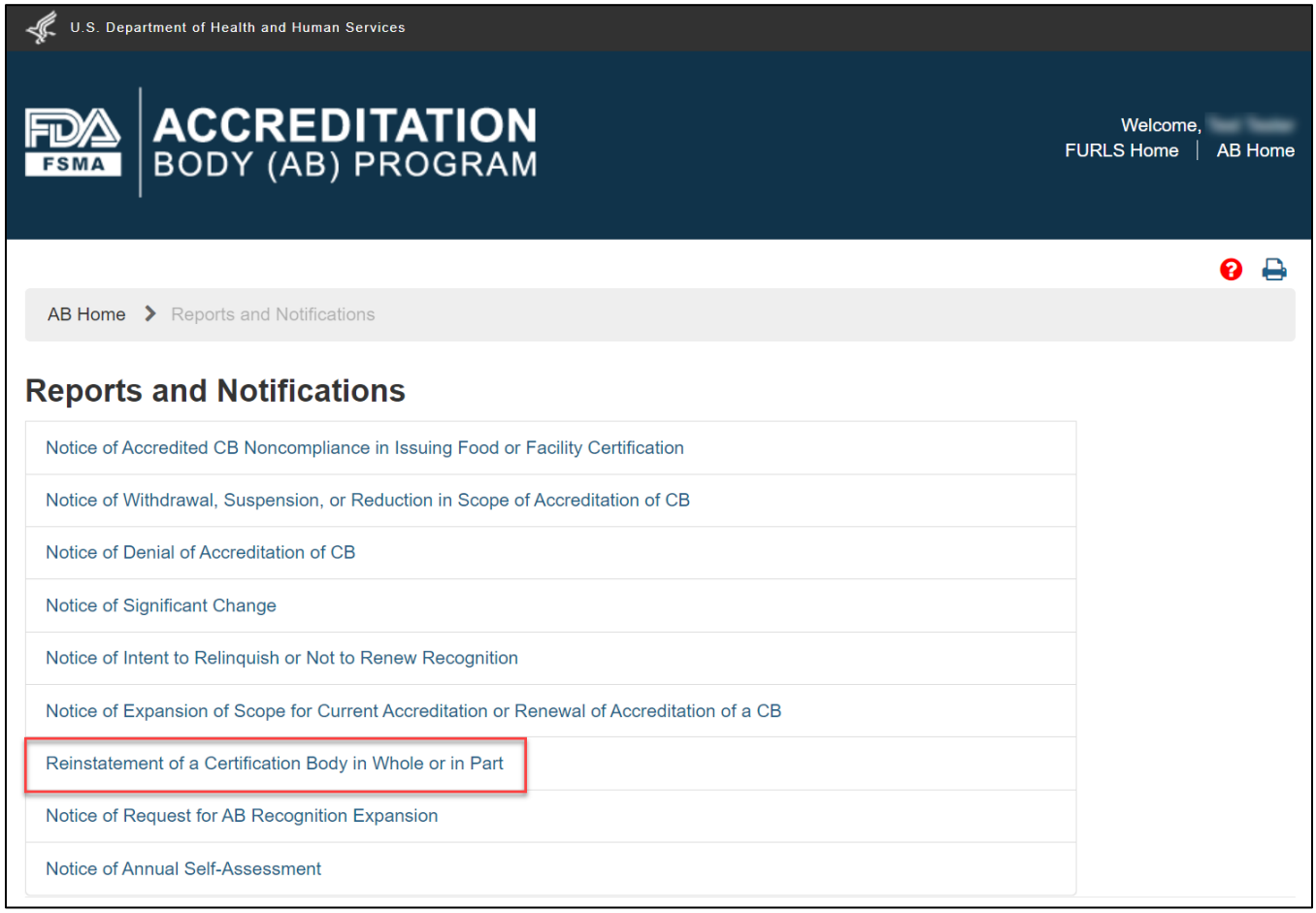
DO NOT REPLY TO THIS EMAIL

Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.7 Reinstatement of a Certification Body in Whole or in Part

FDA would be notified of the suspension of a CB's accreditation through the "Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB." If you make the determination to reinstate the CB's accreditation, notify FDA of the reinstatement by clicking the "Reinstatement of a Certification Body in Whole or in Part" link in the "Reports and Notifications" page (Figure 11.63).

Figure 11.63 – Reports and Notifications Page

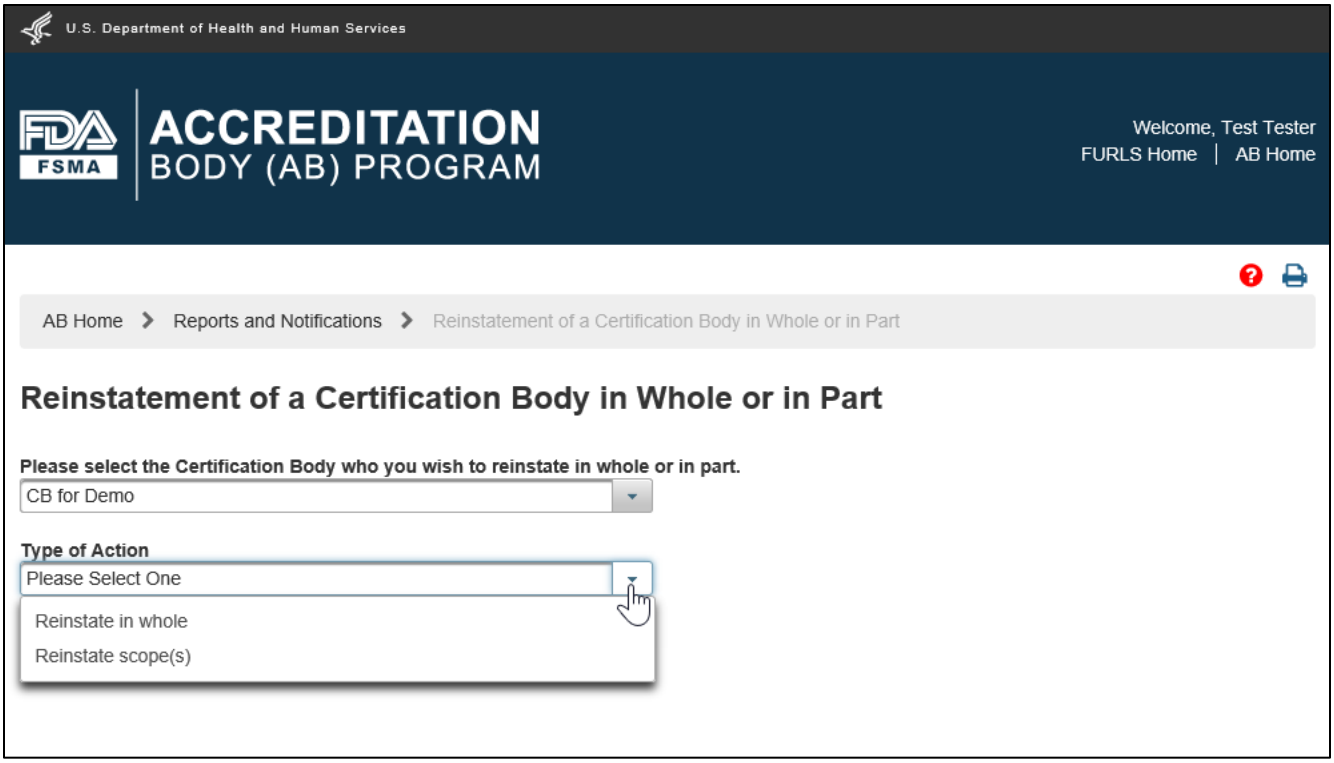


The system will display the “Reinstatement of a Certification Body in Whole or in Part” page.

Complete the following data fields:

- **Please select the Certification Body who you wish to reinstate in whole or in part.** – Select the CB to be reinstated from the dropdown menu.
- **Type of Action** – Select the “Type of Action” from the dropdown menu (Figure 11.64). The “Type of Action” options include “Reinstate in whole” and “Reinstate scope(s).”

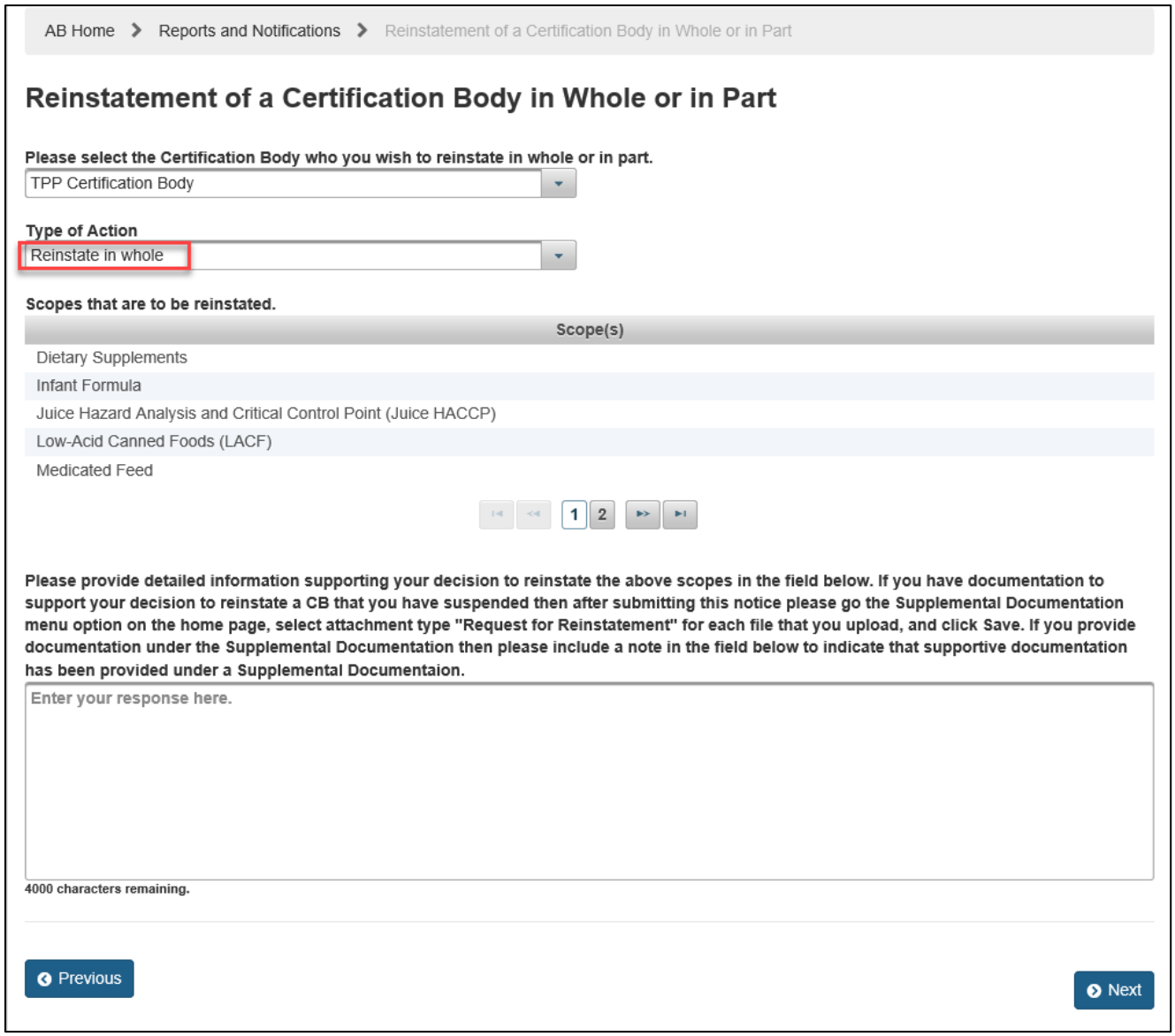
Figure 11.64 – Reinstatement of a Certification Body in Whole or in Part



The system will display the following when “Reinstate in whole” is selected as the “Type of Action” (Figure 11.65):

- **Scope(s) that are to be reinstated** – The pre-filled and read-only list of the CB’s scopes that had been accredited prior to the changes submitted through the “Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB.”
- **Please provide detailed information supporting your decision to reinstate the above scopes in the field below.** – Enter a response in the text entry field, which allows a maximum of 4,000 characters.

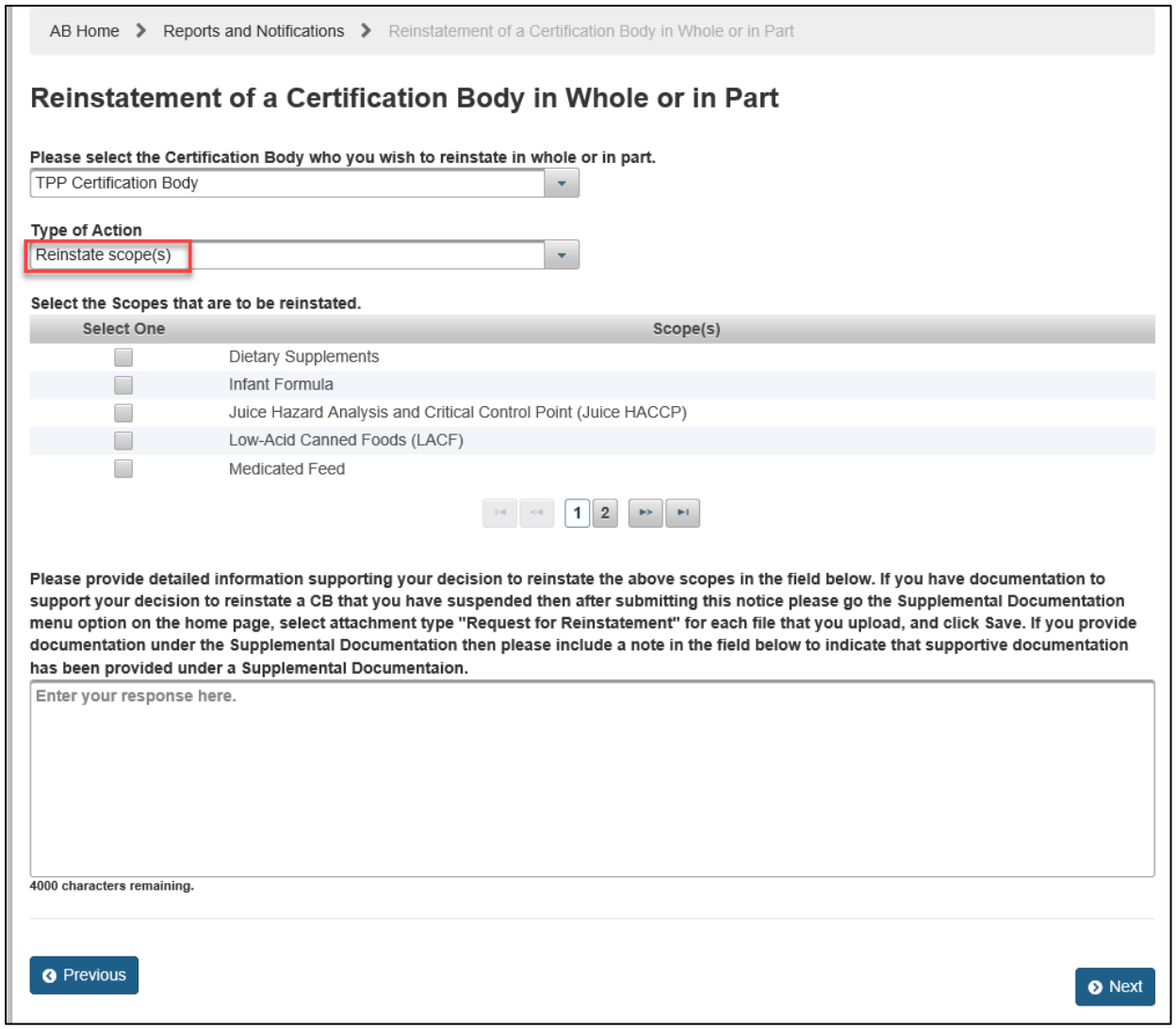
Figure 11.65 – Reinstate in Whole



The system will display the following when “Reinstate scope(s)” is selected as the “Type of Action (Figure 11.66).

- **Select the Scope(s) that are to be reinstated** – Select the applicable scope(s) for reinstatement by clicking the checkbox to the left of the scope name.
- **Please provide detailed information supporting your decision to reinstate the above scopes in the field below.** – Enter a response in the text entry field, which allows a maximum of 4,000 characters.

Figure 11.66 – Reinstate Scope(s)



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.

The system will display the “e-Signature” page (Figure 11.67).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

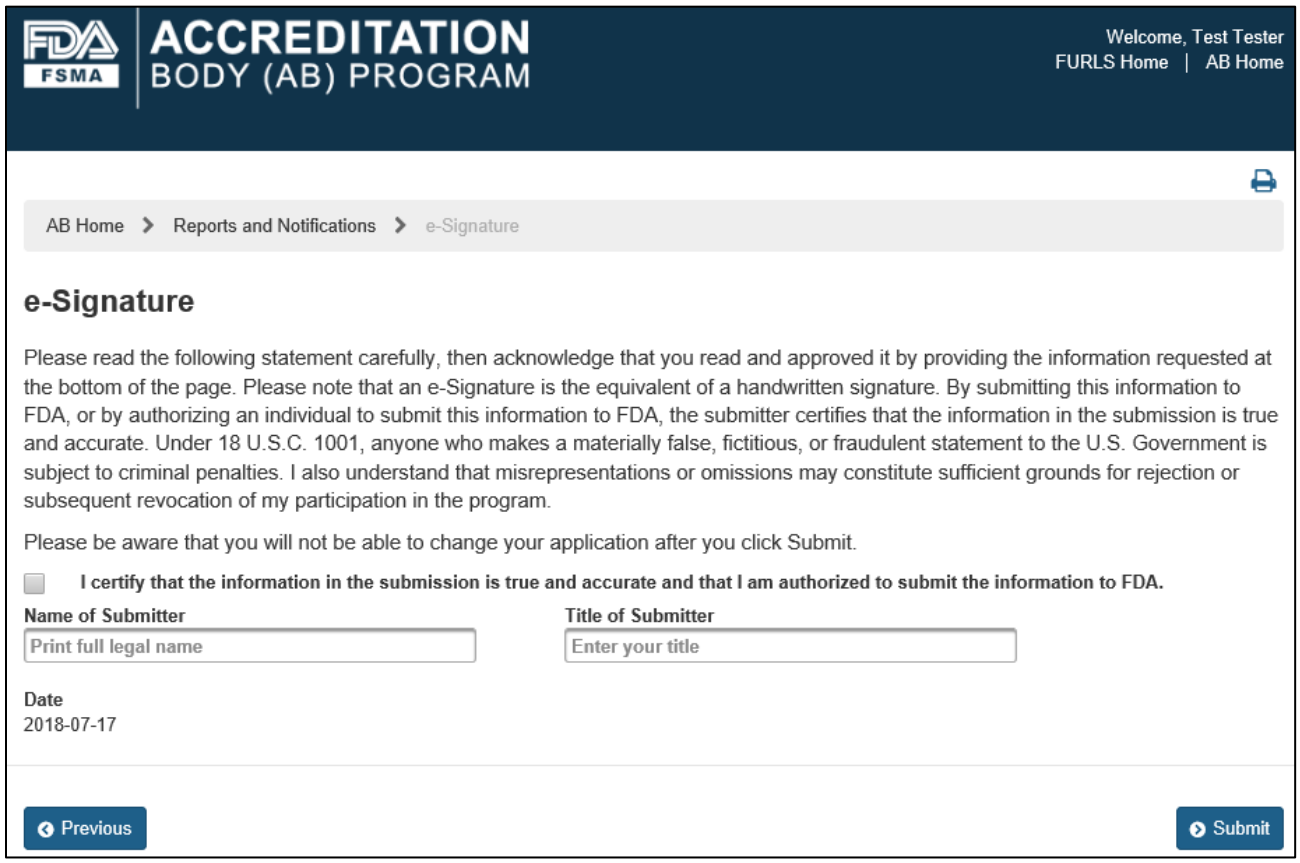
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Notice Reinstatement of a Certification Body in Whole or in Part” page.

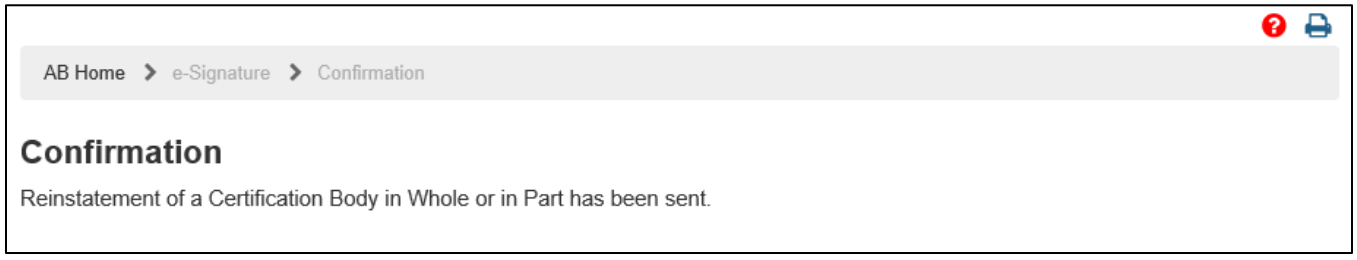
Click the “Submit” button to complete submission of the notice to FDA.

Figure 11.67 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.68).

Figure 11.68 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.69). Note that the image below only depicts the e-mail notification text.

Figure 11.69 – E-mail Notification

Thank you for submitting information to FDA regarding the Reinstatement of a Certification Body in Whole or in Part. We will review this information and may follow-up if additional information is needed.

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

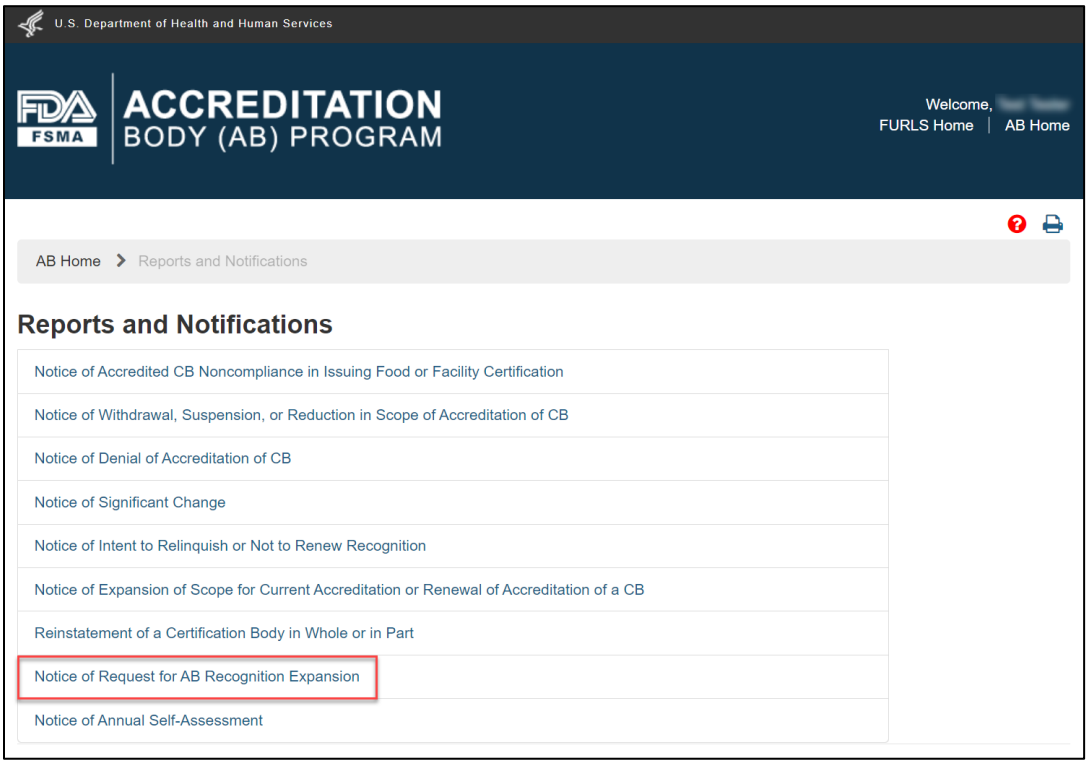
DO NOT REPLY TO THIS EMAIL

Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.8 Notice of Request for AB Recognition Expansion

To notify FDA of your request for recognition of additional scope(s), click the “Notice of Request for AB Recognition Expansion” link on the “Reports and Notifications” page (Figure 11.70).

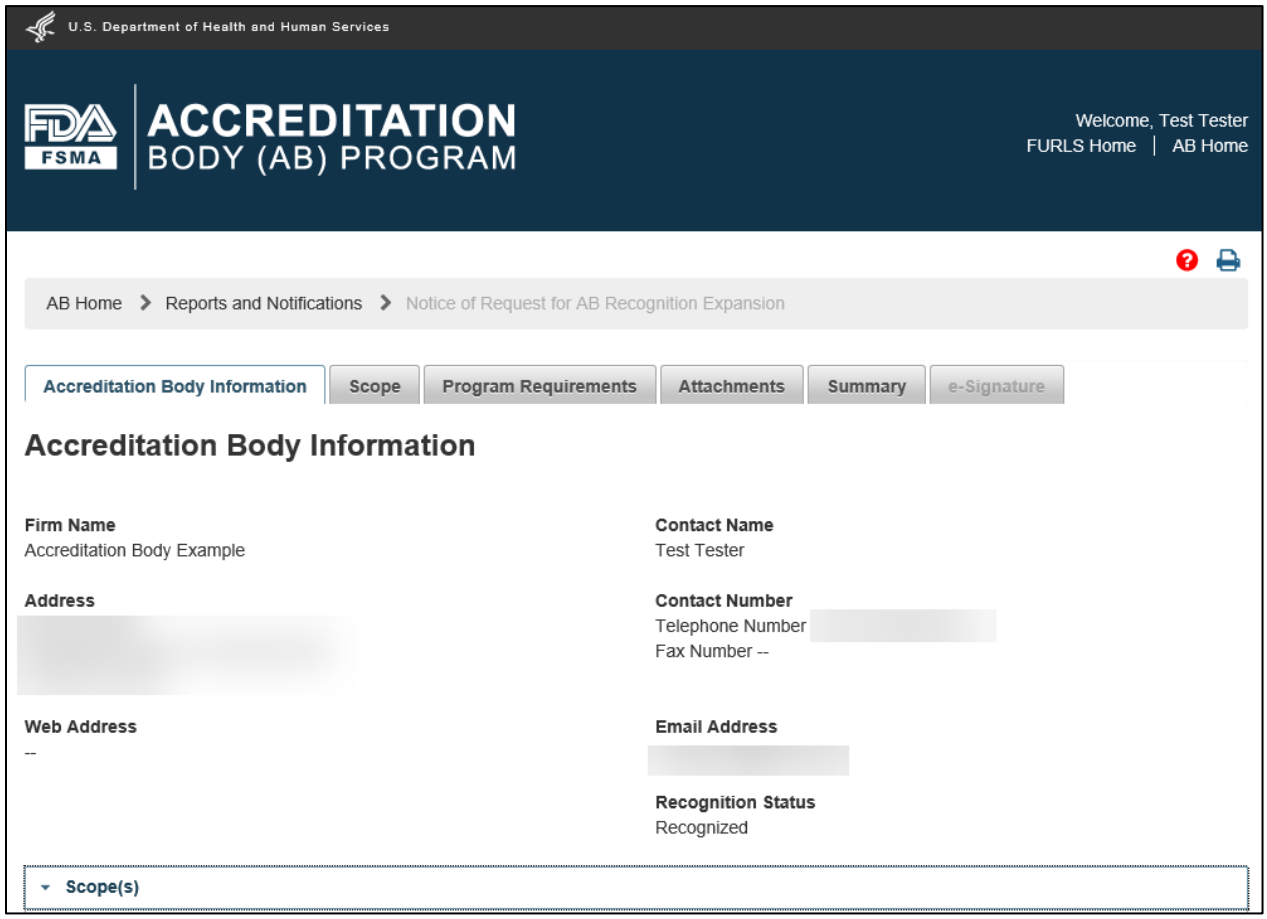
Figure 11.70 – Reports and Notifications Page



The system will display the “Accreditation Body Information” page as the first page of the Notice of Request for AB Recognition Expansion, with the read-only information from the user profile (Figure 11.71).

Click the “Scopes” accordion section’s title bar to display the currently recognized scope(s).

Figure 11.71 – Notice of Request for AB Recognition Expansion



Note: You will see the following buttons while navigating the pages during the course of this notice:

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

Click the “Next” button to proceed to the next page or, click on the “Scope” tab.

The system will display the “Scope” page (Figure 11.72).

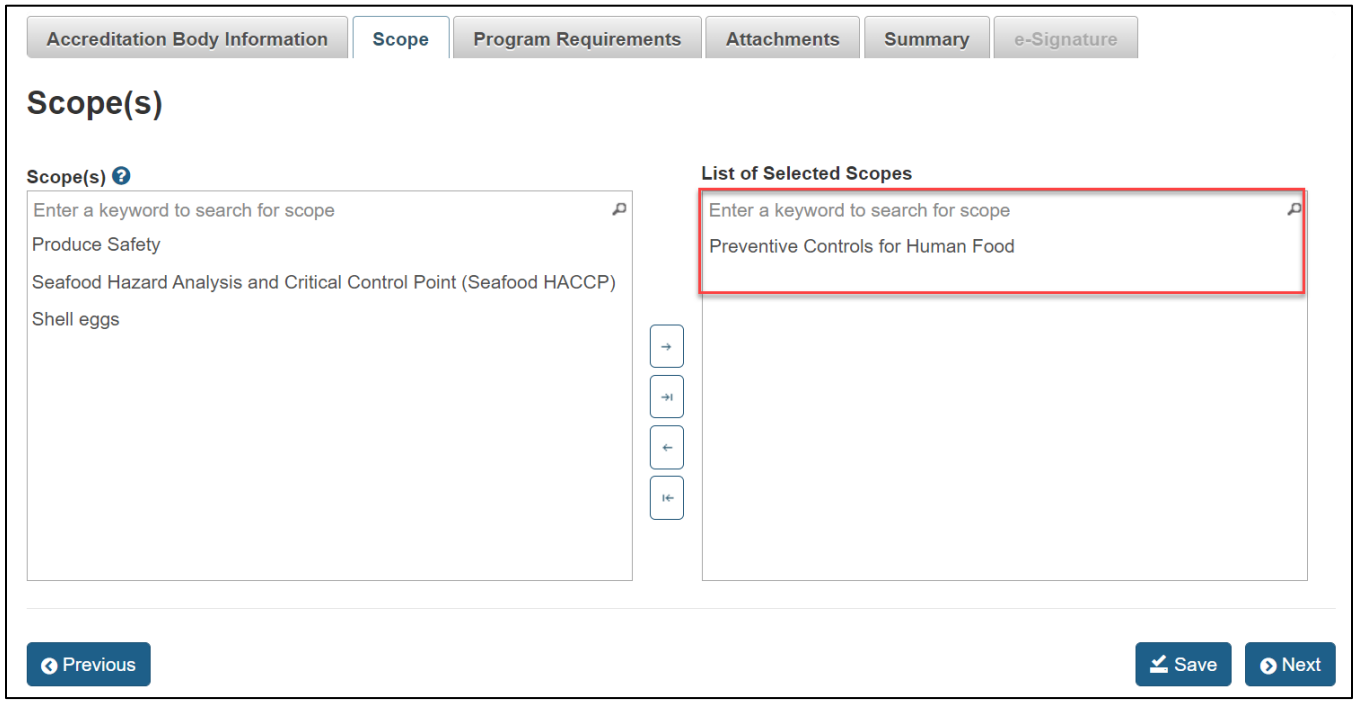
The “Scope” section (on the left-hand side of the page) contains a list of available scopes (i.e., scopes that are not currently part of your recognition).

Select the scope(s) for which you are requesting to add to your recognition.

Refer to Section 5.3 of this document for instructions on adding or removing scopes, if needed.

Click the “Save” button when all applicable scopes have been selected.

Figure 11.72 – Scope Page



Note: If you wish to save your work and complete the notice later, you may save a draft of the notice by clicking the “Save” button from any page of the notice. Refer to Section 11.8.1 “Notice Dashboard” of this chapter for instructions to access and resume work on the notice draft.

Click the “Next” button to proceed to the next page or, click on the “Program Requirements” tab.

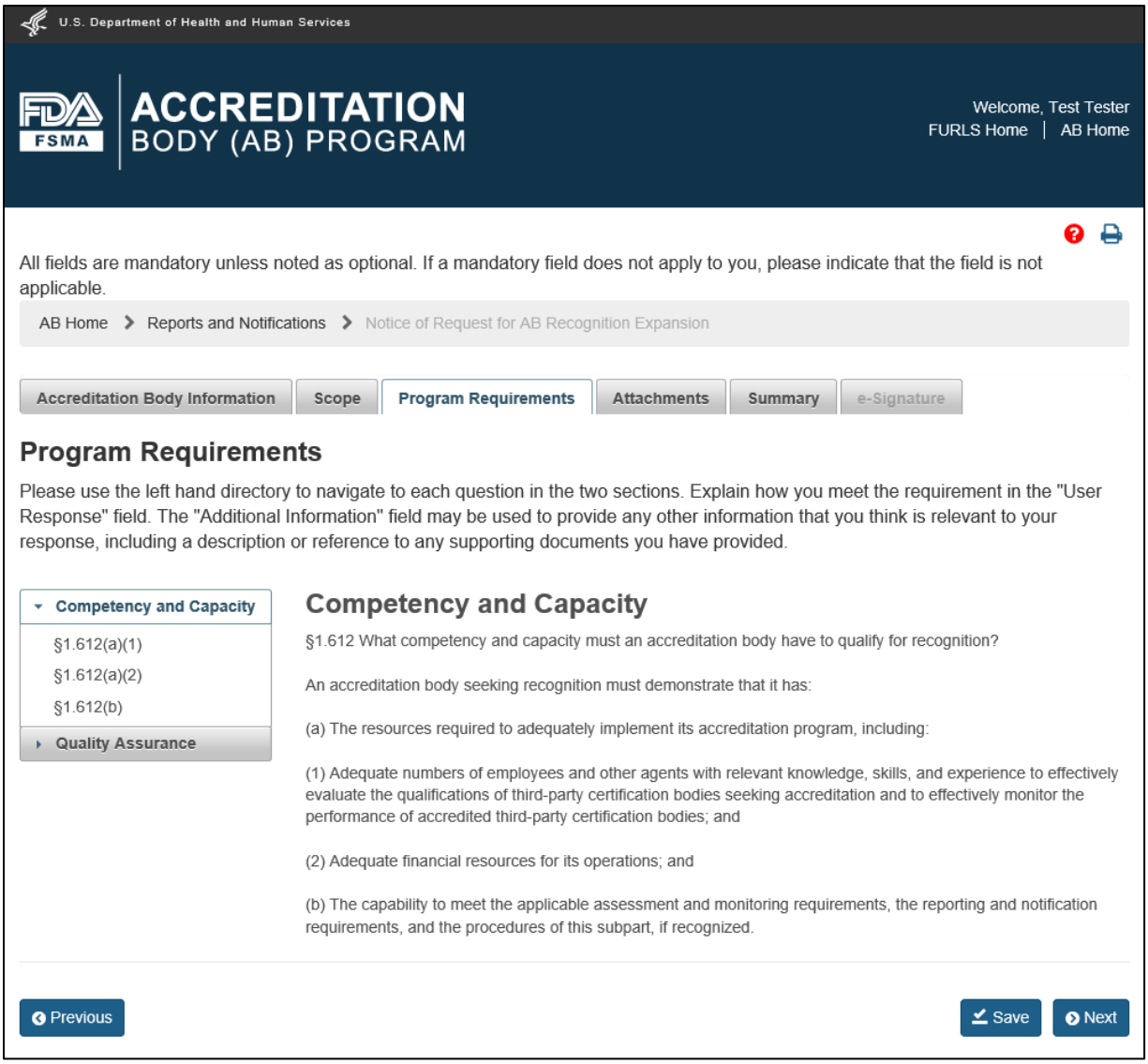
The system will display the “Program Requirements” page, where you will answer questions and attach files in accordance with the following requirement sections (Figure 11.73):

- Competency and Capacity
- Quality Assurance

The section names are listed on the left-hand side of the page. The first section, “Competency and Capacity,” is expanded by default upon navigating to the page.

Refer to Section 5.4 of this document for instructions on completing the “Program Requirements” page, if needed.

Figure 11.73 – Program Requirements Page

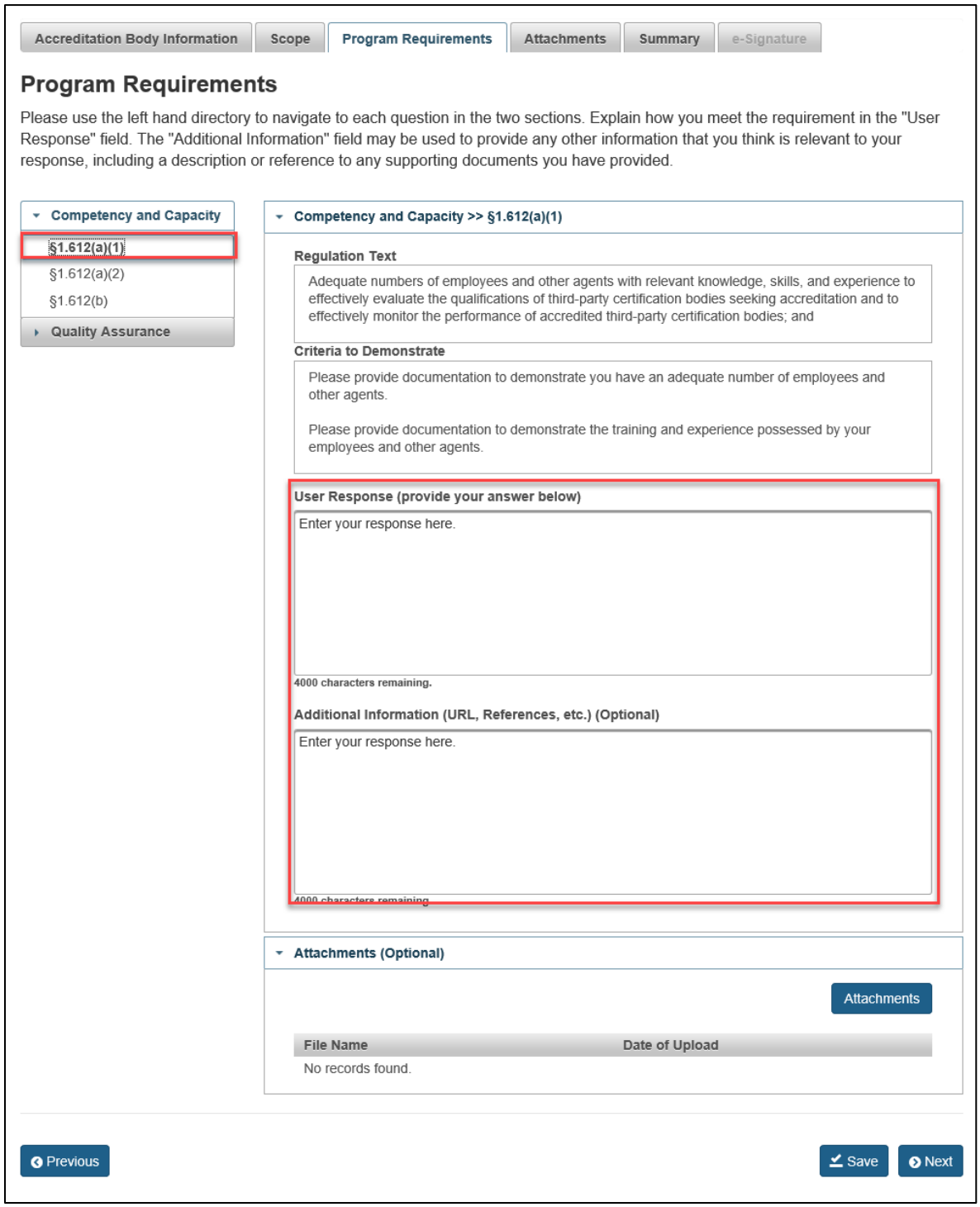


Each section has a definition and associated questions. Click the section heading to display the associated question links. Click on each requirement to display the user input fields (Figure 11.74).

The system will display the following user input fields for each question:

- **User Response (provide your answer below)** – This is a text entry field to respond to the “Regulation Text” and “Criteria to Demonstrate” textboxes displayed above each question. The text entry field allows for a maximum of 4,000 characters.
- **Additional Information (URL, References, etc.) (Optional)** – This is an optional text entry field to include any additional information. The text entry field allows for a maximum of 4,000 characters.

Figure 11.74 – Program Requirements User Input Fields



Attachments may be uploaded with each response in the “Attachments (Optional)” section of the “Program Requirements” page.

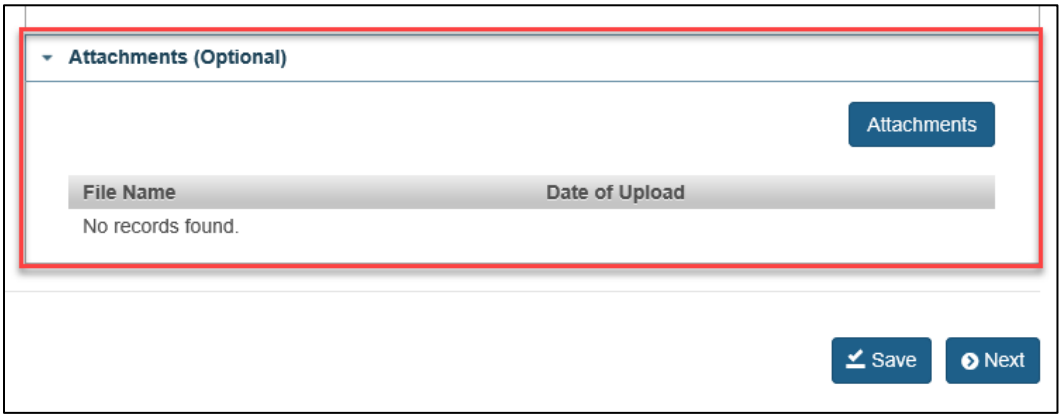
Attachments must be a document type supported by the system.

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.

Click the “Attachments” button in the “Attachments (Optional)” section to open the attachment window (Figure 11.75).

Figure 11.75 – Attachments Section



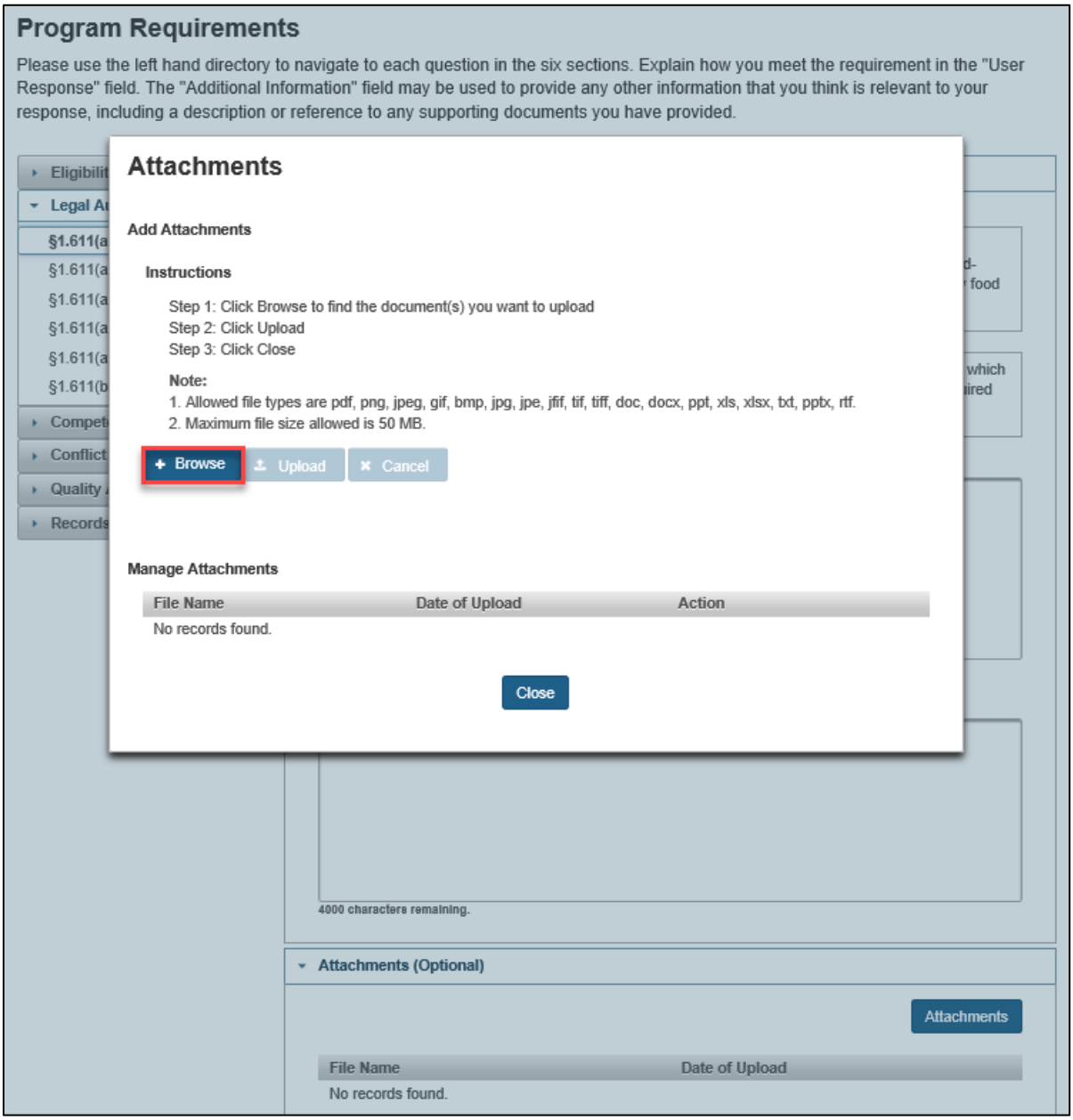
The system will display the “Attachments” pop-up window (Figure 11.76).

Click the “Browse” button in the “Attachments” window to select a file.

The “Upload” button will become enabled after a file has been chosen as an attachment.

Click the “Upload” button to complete the upload.

Figure 11.76 – Attachments Window

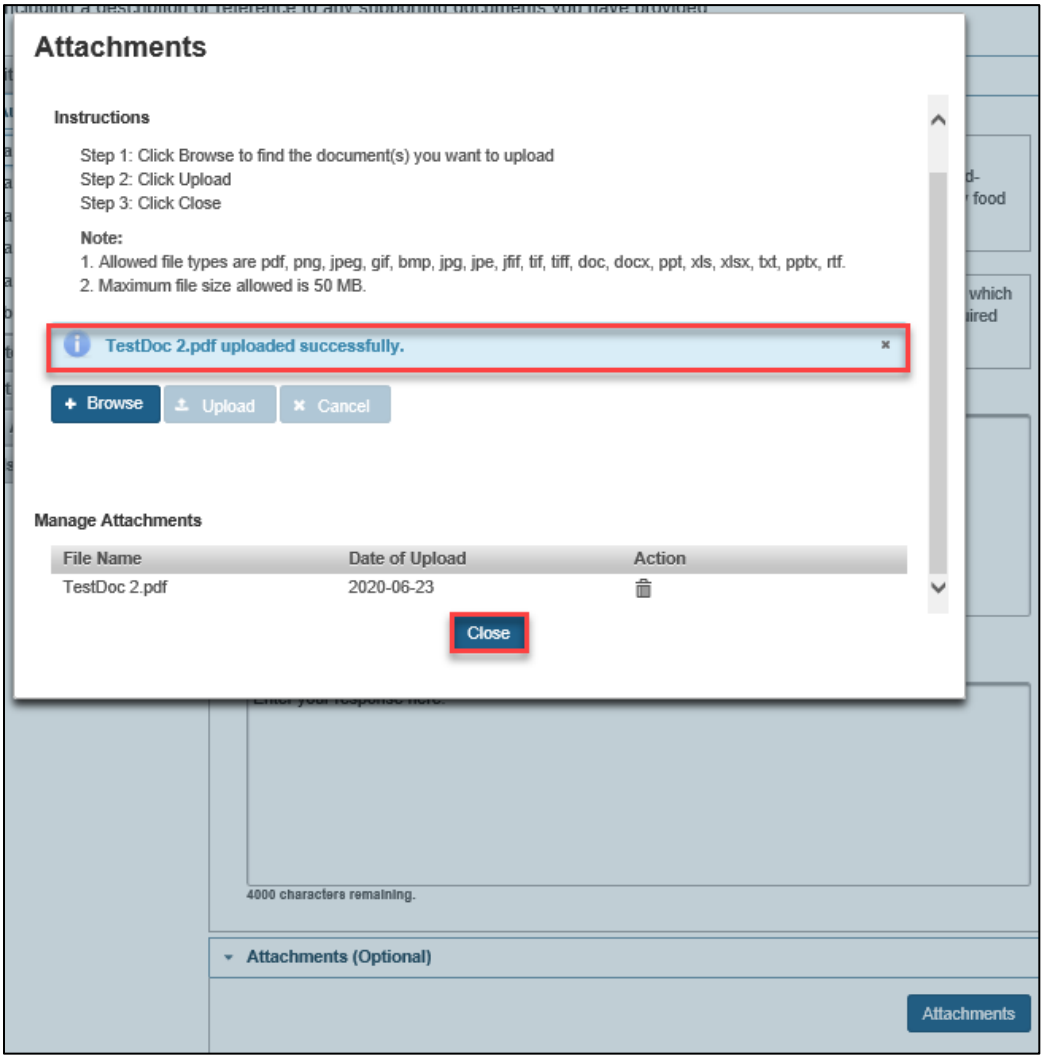


Once the upload is complete, a confirmation message with the file name will display in the “Attachments” window (Figure 11.77).

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

Click the “Close” button to close the “Attachments” window after the file has been uploaded.

Figure 11.77 – Attachments to Program Requirements Questions



Important: Click the “Save” button upon completion.

Click the “Next” button to proceed to the next page or, click on the “Attachments” tab.

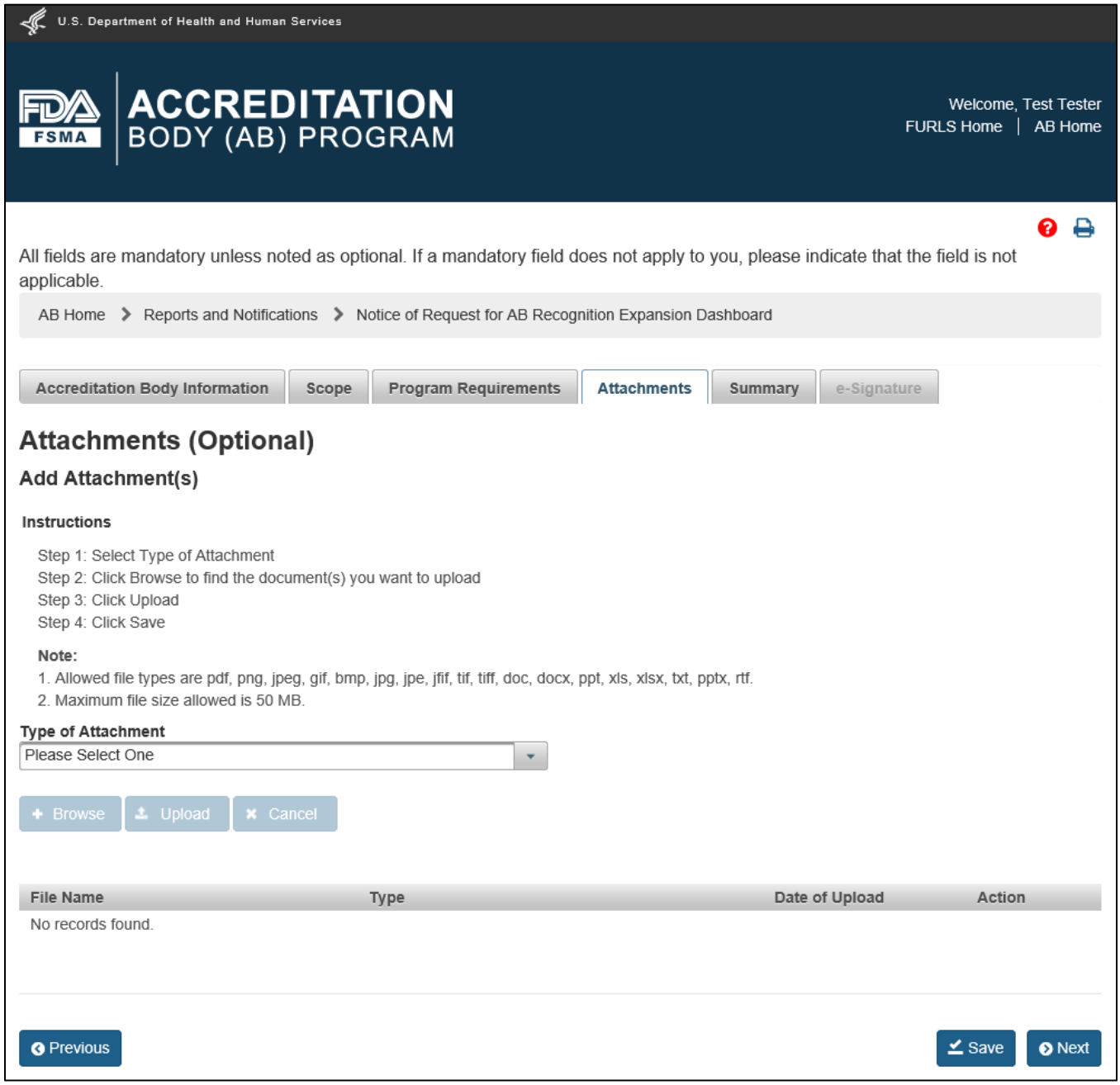
The system will display the “Attachments” page (Figure 11.78).

To upload additional documents to the notice, follow the four-step process outlined on the page. The system will display uploaded files in the table at the bottom of the page.

This page is optional.

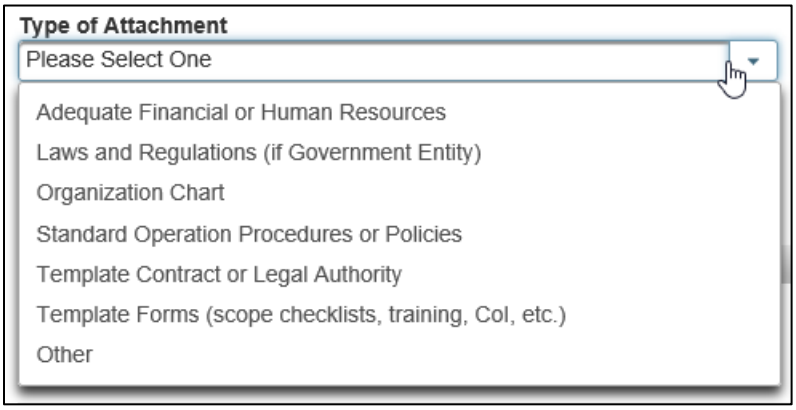
Refer to Section 5.5 of this document for instructions on uploading documents to the "Attachments" page, if needed.

Figure 11.78 – Attachments Page



Select the type of attachment from the list (Figure 11.79).

Figure 11.79 – Type of Attachment



A text box labeled “Additional Description” will display if “Other” is selected from the list (Figure 11.80).

Enter a description of the document type in the “Additional Description” field (maximum 45 characters).

Figure 11.80 – Other Attachments

Once the “Type of Attachment” is selected, the “Browse” button will become enabled (Figure 11.81). Click the “Browse” button to search for and select the desired file for upload.

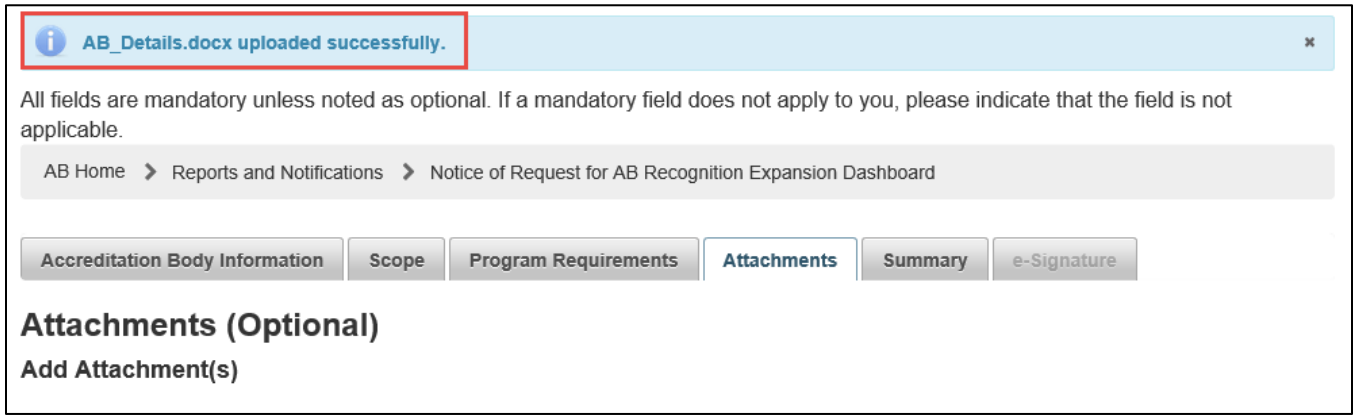
The browsing window will close once a file is selected. The “Upload” and “Cancel” buttons will be enabled once the browsing window closes.

Figure 11.81 – Browse, Upload, and Cancel Buttons

Click the “Upload” button to attach the file. Click the “Cancel” button to remove the file from the menu.

Confirmation of a successful upload will be displayed at the top of the page upon completion (Figure 11.82).

Figure 11.82 – Successful Upload Message



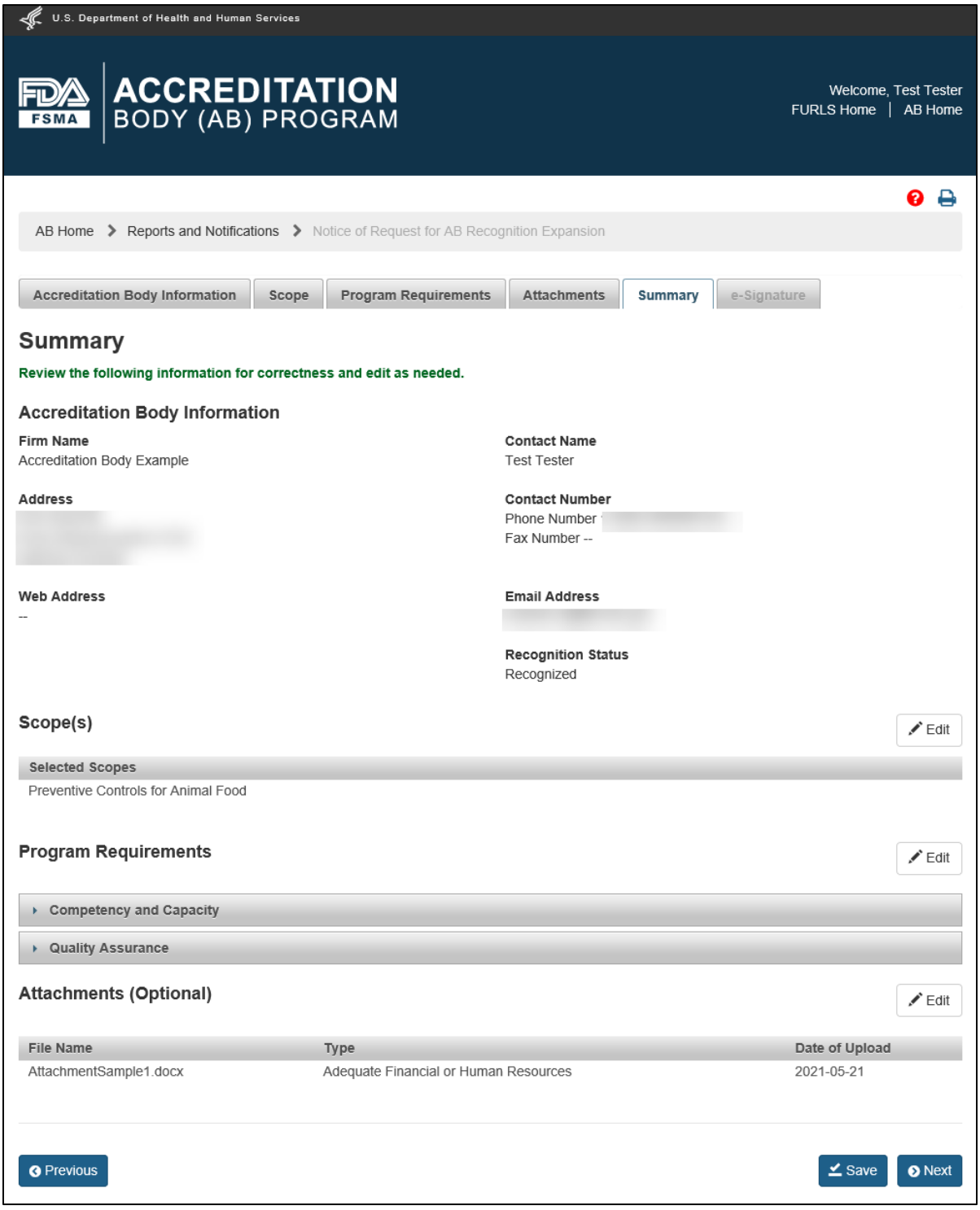
Follow the four-step process outlined on the page to upload any additional files.

After the files have been uploaded, click the “Save” button.

Click the “Next” button to proceed to the next page or, click on the “Summary” tab.

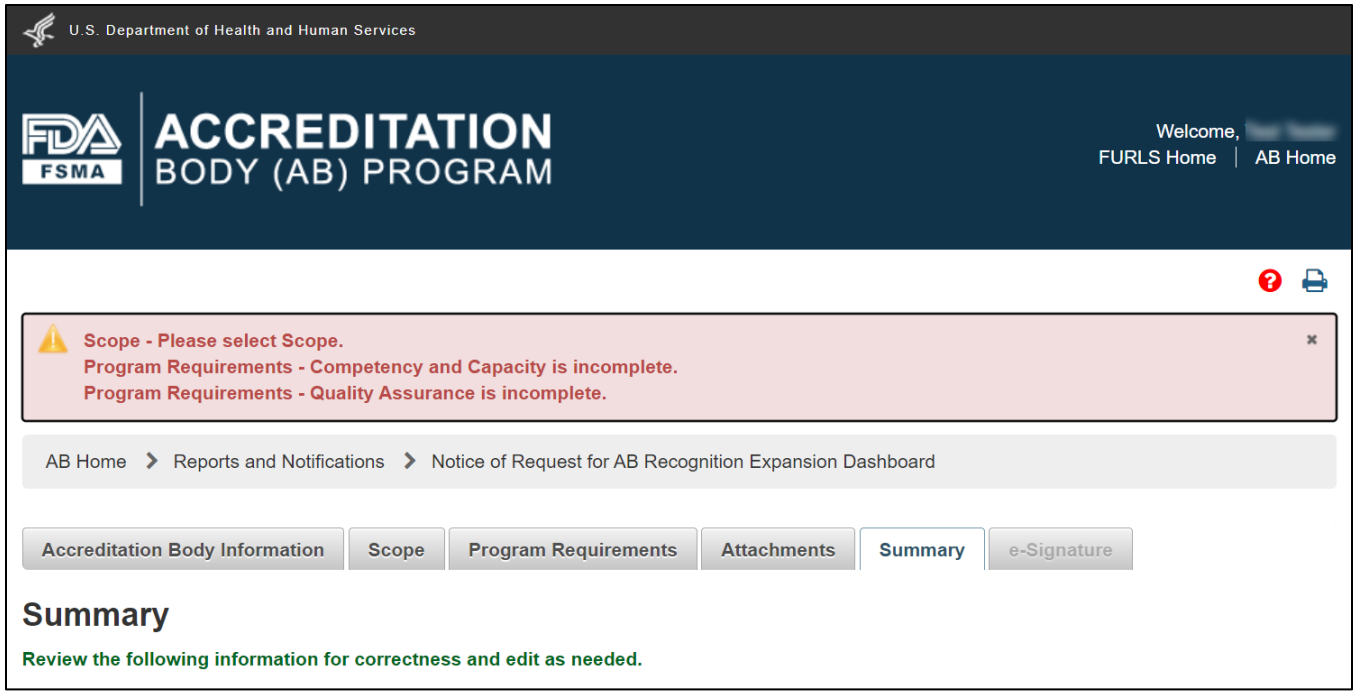
The system will display the “Summary” page for you to review the information on the page for accuracy (Figure 11.83).

Figure 11.83 – Summary Page



After reviewing the information, click the “Next” button. The system will validate that all required fields have been completed. If an error is found, the system will post the relevant error message at the top of the page (Figure 11.84).

Figure 11.84 – Summary Page Error Messages



If there are no errors, the system will display the “e-Signature” page (Figure 11.85).

Note: The “e-Signature” page does not become accessible until all errors indicated on the “Summary” page have been corrected and saved.

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

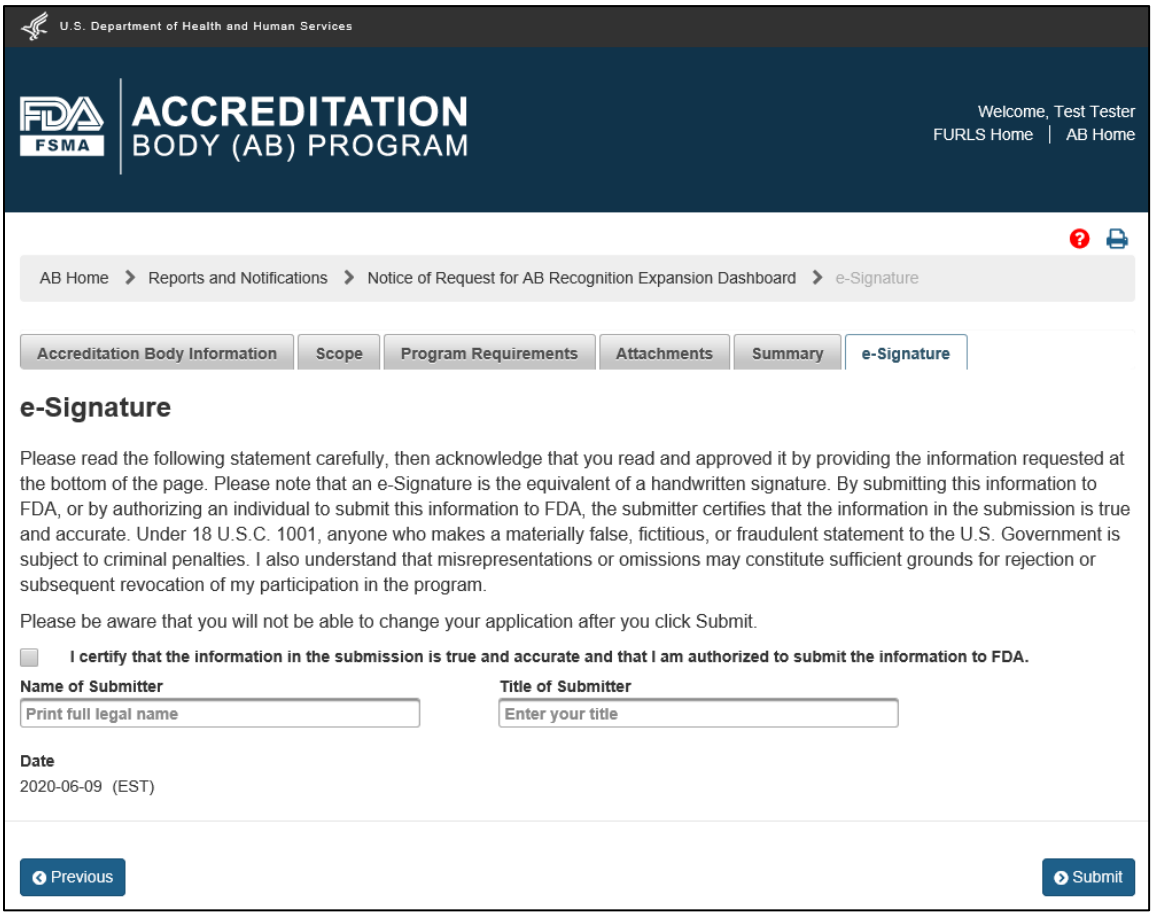
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Summary” page.

Click the “Submit” button to complete submission to FDA.

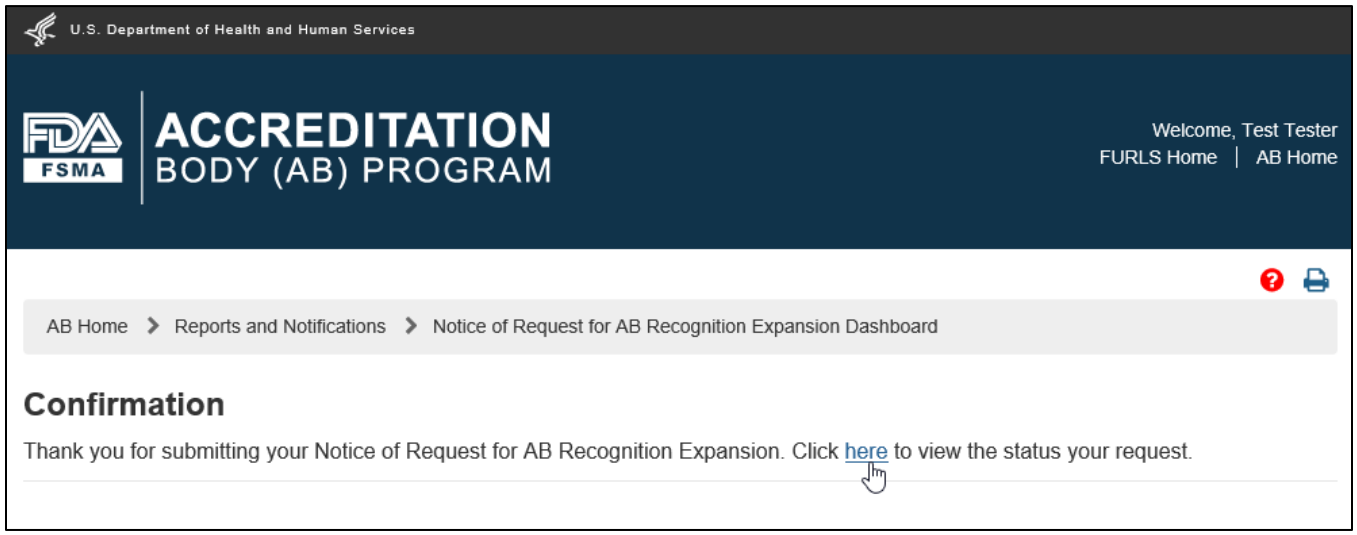
Figure 11.85 – e-Signature Page



After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.86).

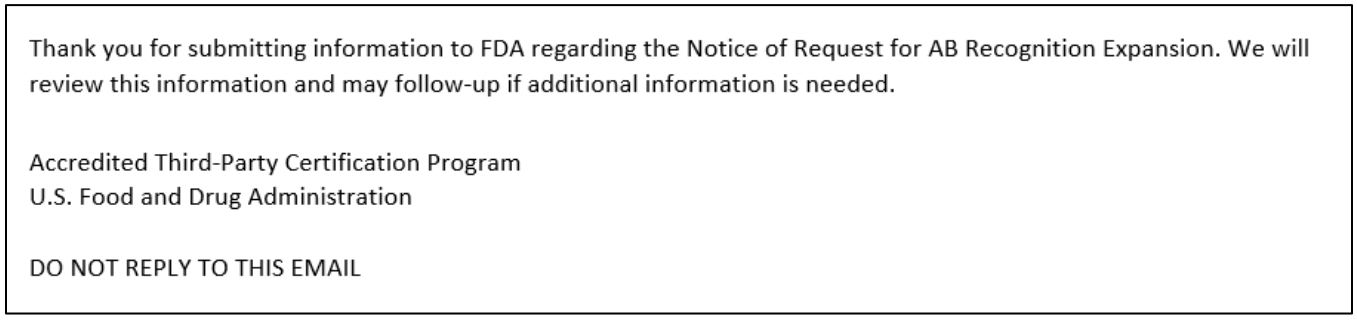
On the confirmation page, click the “here” link from the confirmation message to navigate to the notice “Dashboard” page.

Figure 11.86 – Confirmation Page



The system will send an e-mail to the address entered on the "Account Management" page indicating the notice was received by FDA (Figure 11.87). Note that the image below only depicts the e-mail notification text.

Figure 11.87 – E-mail Notification



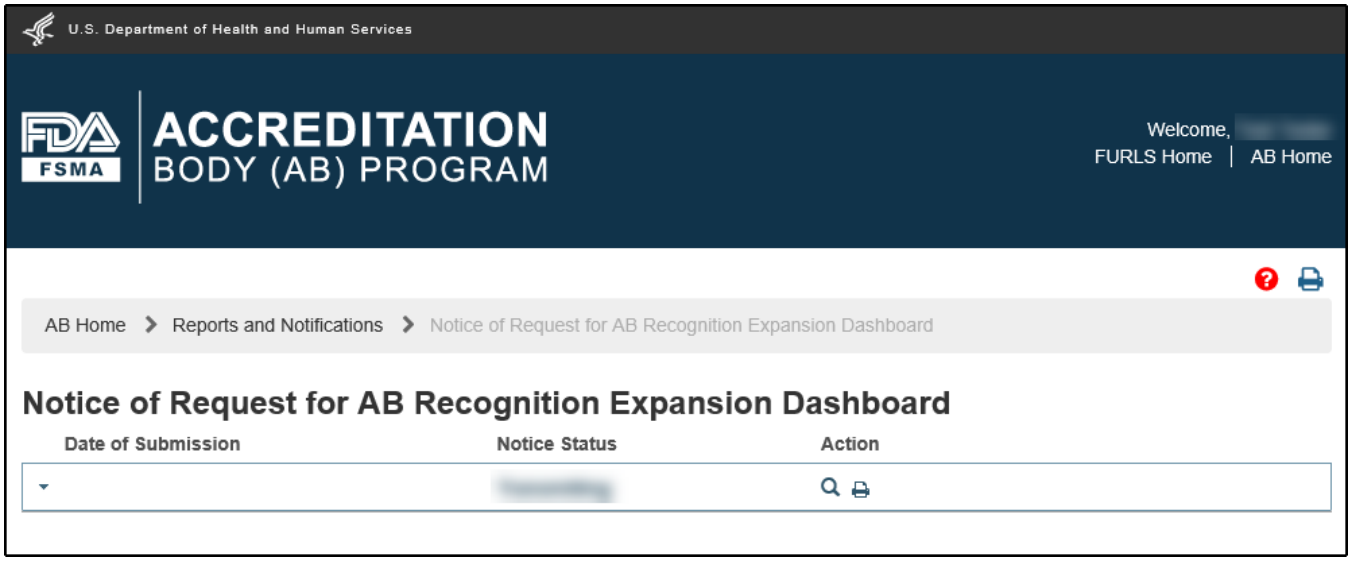
11.8.1 Notice Dashboard

The "Notice of Request for AB Recognition Expansion Dashboard" page may be used to perform the following two functions related to the notice:

- View the status of the notice
- Delete or edit a draft of the previously saved notice

To navigate to the notice “Dashboard” page, navigate to the “Reports and Notifications” page, then select the link for “Notice of Request for AB Recognition Expansion.” The notice “Dashboard” page will display (Figure 11.88).

Figure 11.88 – Notice of Request for AB Recognition Expansion Dashboard



If you wish to view the status of the notice, proceed to Section 11.8.2 of this chapter.

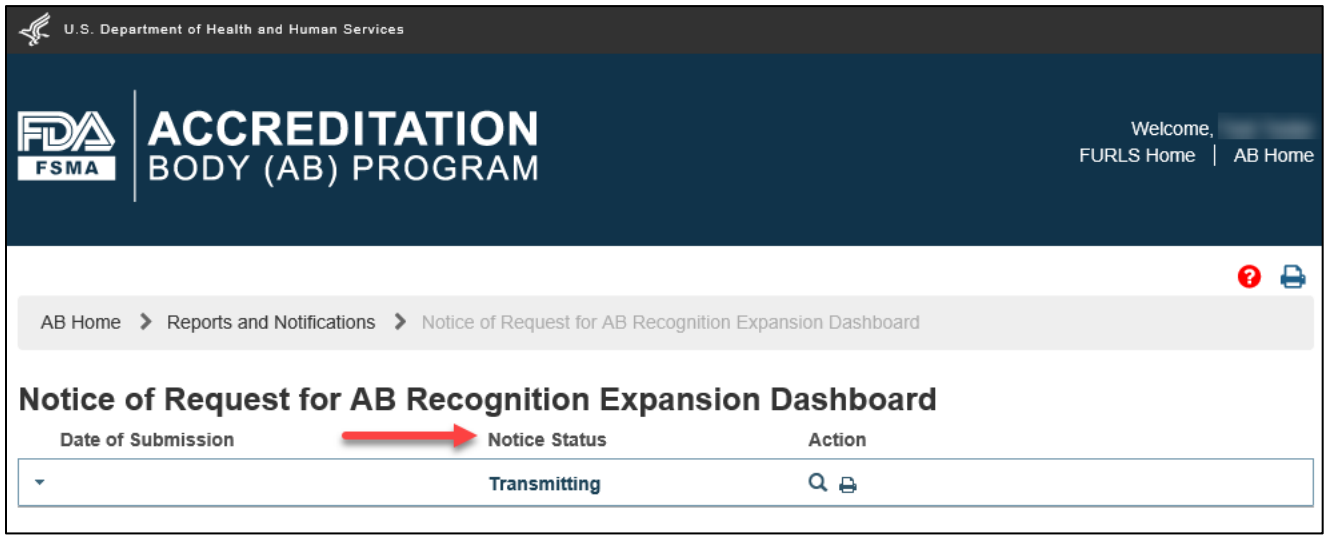
If you wish to delete or edit a draft of the previously saved notice, refer to Section 11.8.3 of this chapter.

11.8.2 View the Status of the Notice

The system will display the status of the notice in the “Notice Status” column of the notice “Dashboard” page (Figure 11.89). The possible notice statuses are as follows:

- **Draft** – The notice has been saved but not yet submitted to FDA.
- **Pending** – The notice 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 notice 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 notice has been successfully received by FDA.
- **Denied** – FDA has completed the review of the notice request and denied the request for additional scope(s) to be added to your recognition. You may submit a new notice if you wish FDA to reconsider the decision.
- **Approved** – FDA has completed the review of the notice request and approved the request for additional scope(s) to be added to your recognition.

Figure 11.89 – Notice Status



When FDA has made a decision on your request, you will receive an e-mail notification.

If your request has been approved, the system will send an e-mail to the address entered on the “Account Management” page (Figure 11.90).

Note that the image below only depicts an example of the e-mail notification text.

Figure 11.90 – E-mail Notification

We are pleased to inform you that your request for recognition expansion has been approved by FDA's Accredited Third-Party Certification Program.

The recognition period of the approved scope(s) is from [redacted] to [redacted] . You must continue to meet the requirements of the program, which include but are not limited to, the reporting and notification obligations. The additional scope(s) of your recognition include:

[redacted]

Any work you perform under this recognition is subject to the requirements under 21 CFR Part 1, Subpart M, including requirements to immediately notify us upon granting of accreditation of a certification body under the program. Please provide this notification to us through your FURLS account under the "Add or View my Third-Party CBs" option.

We look forward to working with you. Thank you for your participation in FDA's Accredited Third-Party Certification Program

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

DO NOT REPLY TO THIS EMAIL

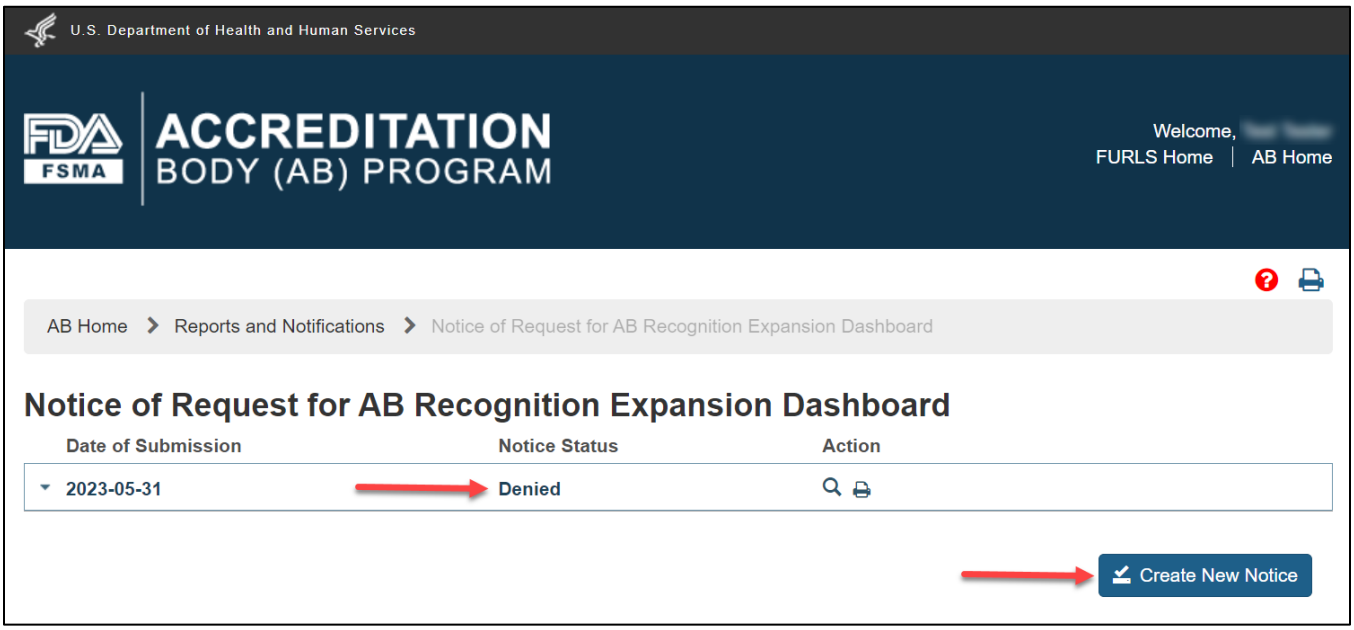
The “Notice Status” will display as “Approved” on the “Dashboard” page and the approved scope(s) will be listed.

If your request has been denied, the system will send an e-mail to the address entered on the “Account Management” page.

The “Notice Status” will display as “Denied” on the “Dashboard” page (Figure 11.91).

Additional notices can be submitted (i.e., for a scope that has not been previously requested or, a scope from a previous request that was denied). To submit a new notice, click the “Create New Notice” button.

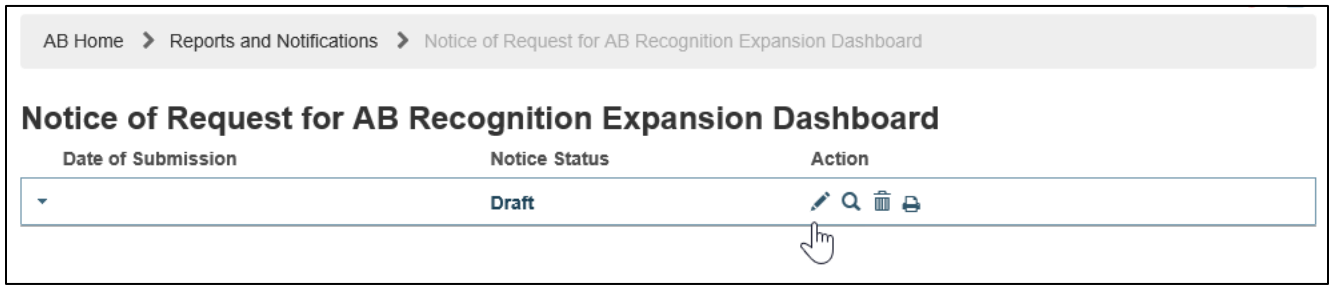
Figure 11.91 – Denied Notice Status and Create New Notice Button



11.8.3 Delete or Edit the Notice in Draft Status

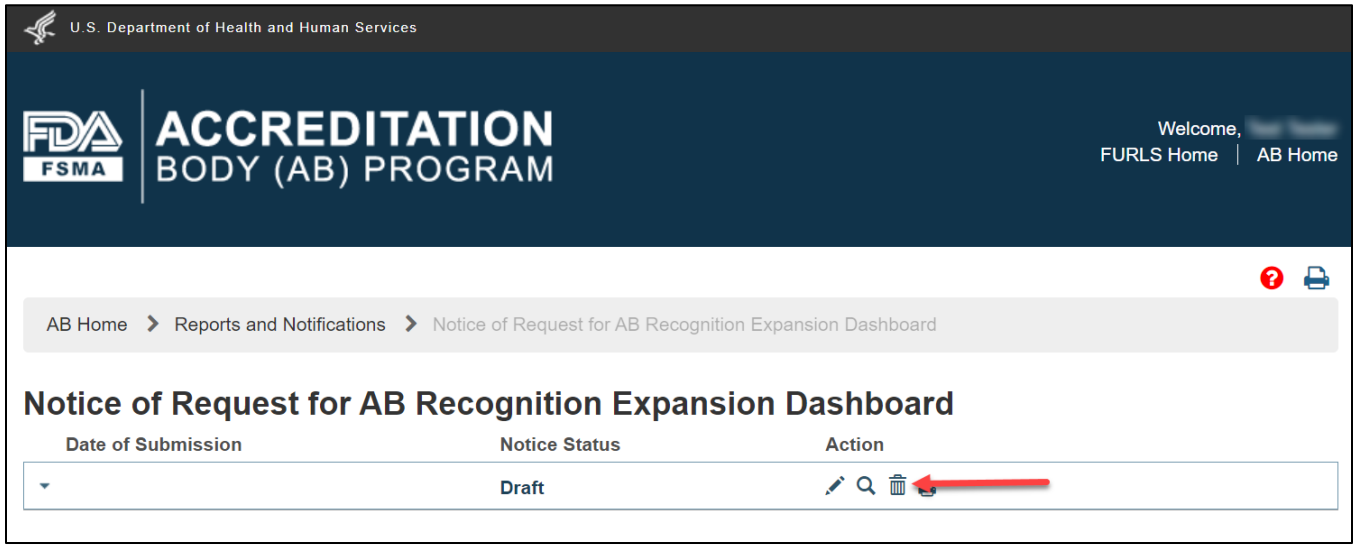
The system will display icons in the “Action” column of the “Dashboard” page (Figure 11.92).

Figure 11.92 – Notice Dashboard



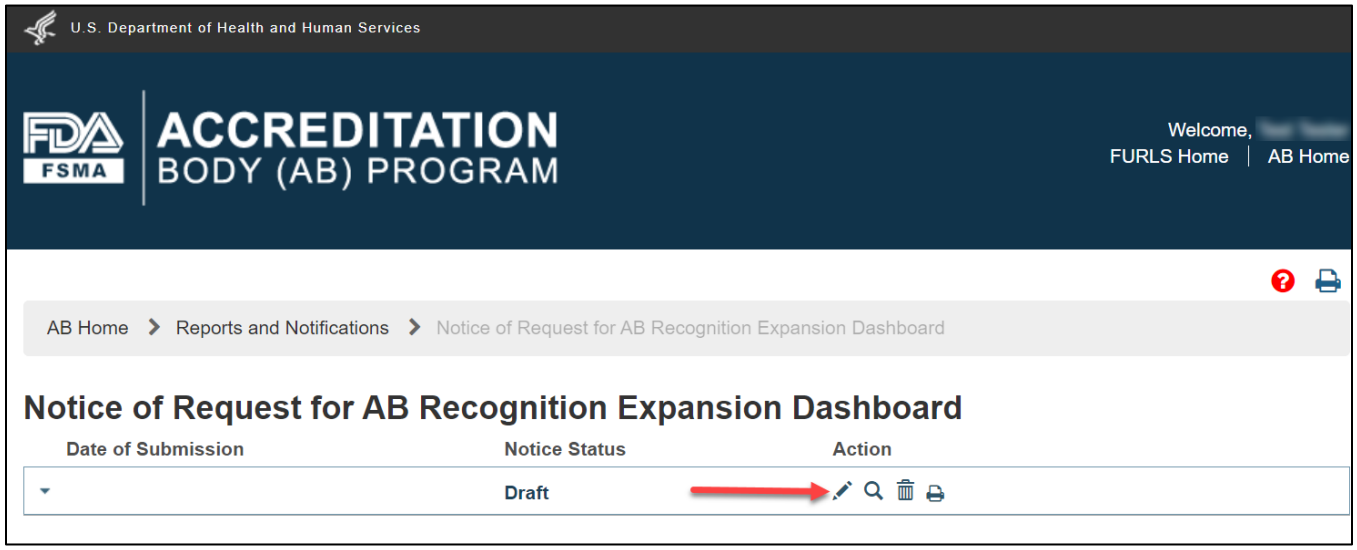
Click the trash/delete icon from the “Action” column of the “Dashboard” page to delete the notice in “Draft” status and start over, if desired (Figure 11.93).

Figure 11.93 – Trash Icon



Click the edit/pencil icon from the “Action” column of the “Dashboard” page to edit a notice in “Draft” status (Figure 11.94).

Figure 11.94 – Edit Icon

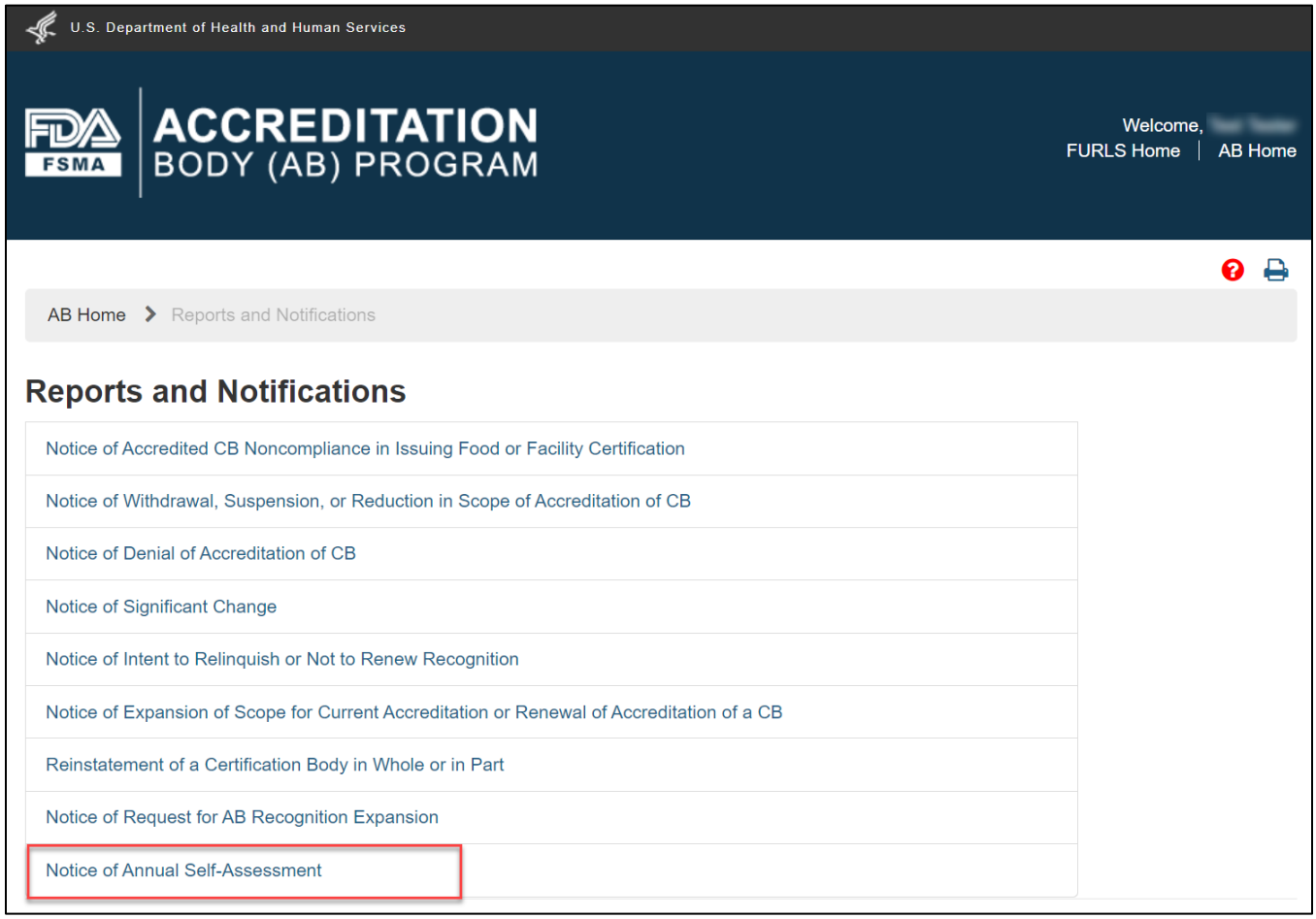


The system will display the read-only “Accreditation Body Information” page as the first page of the Notice of Request for AB Recognition Expansion. Navigate through the tabs of the draft notice to make modifications or complete missing information, where applicable. Follow the instructions provided in section 11.8 of this chapter to complete each page of the notice, as needed.

11.9 Notice of Annual Self-Assessment

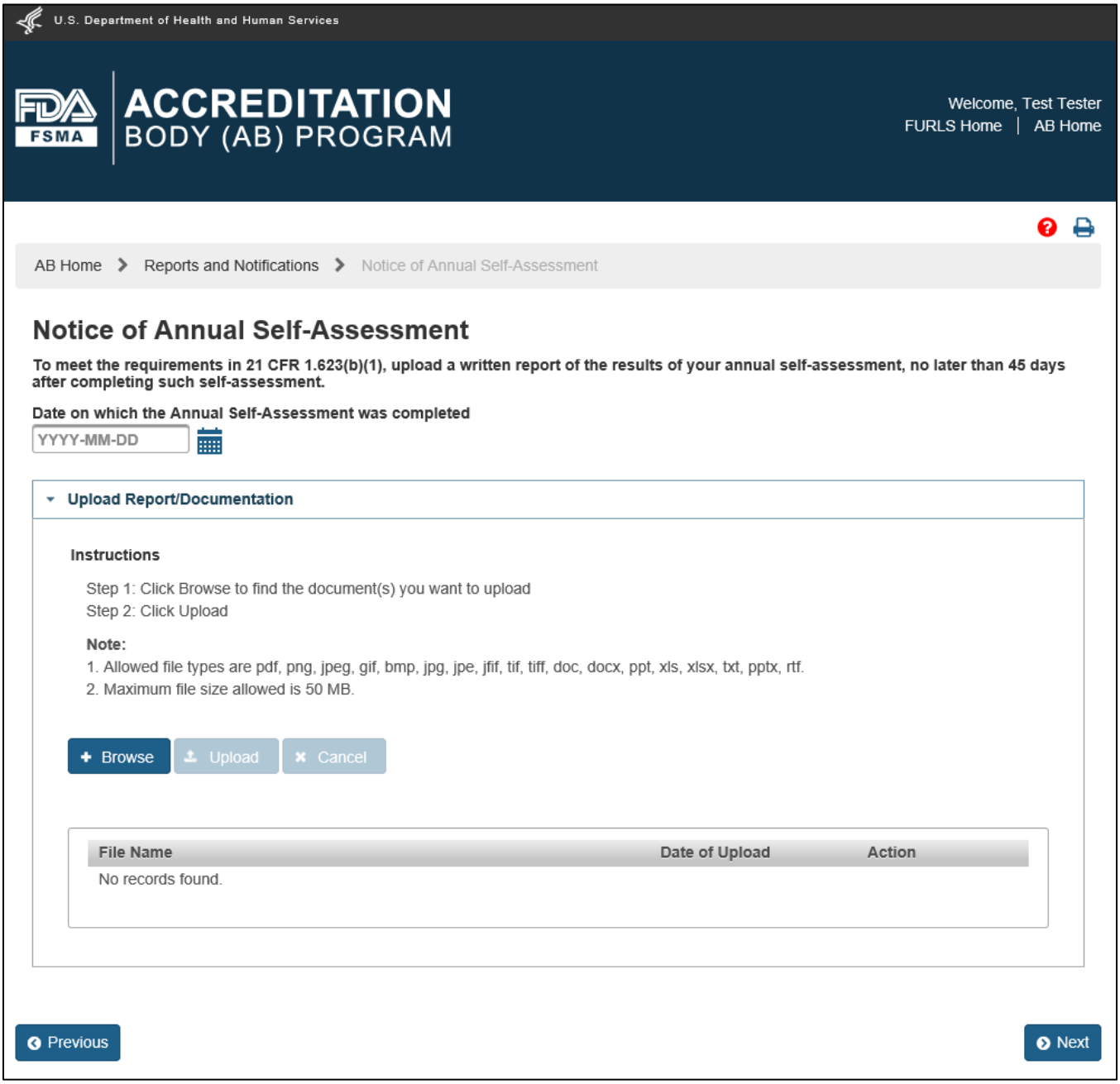
To notify FDA of the results of your annual self-assessment, click the “Notice of Annual Self-Assessment” link on the “Reports and Notifications” page (Figure 11.95).

Figure 11.95 – Reports and Notifications Page



The system will display the “Notice of Annual Self-Assessment” page (Figure 11.96).

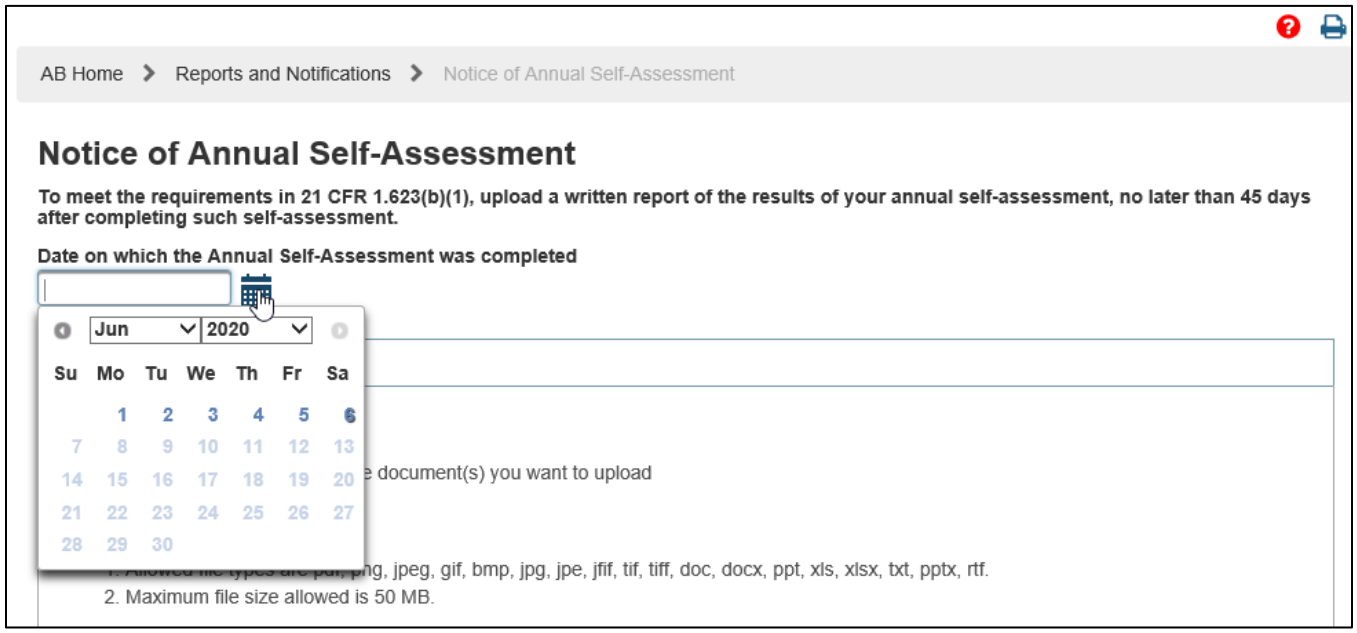
Figure 11.96 – Notice of Annual Self-Assessment



Complete the following data field:

- **Date on which the Annual Self-Assessment was completed** – Select the date with the calendar icon or enter it in “YYYY-MM-DD” format (Figure 11.97).

Figure 11.97 – Date on which the Annual Self-Assessment was completed



Once the data field is complete, use the “Upload Report/Documentation” section to upload the document(s) to report the results of your annual self-assessment (Figure 11.98).

Follow the four-step process outlined on the page to upload attachments.

Click the “Browse” button to search for and select the desired file for upload.

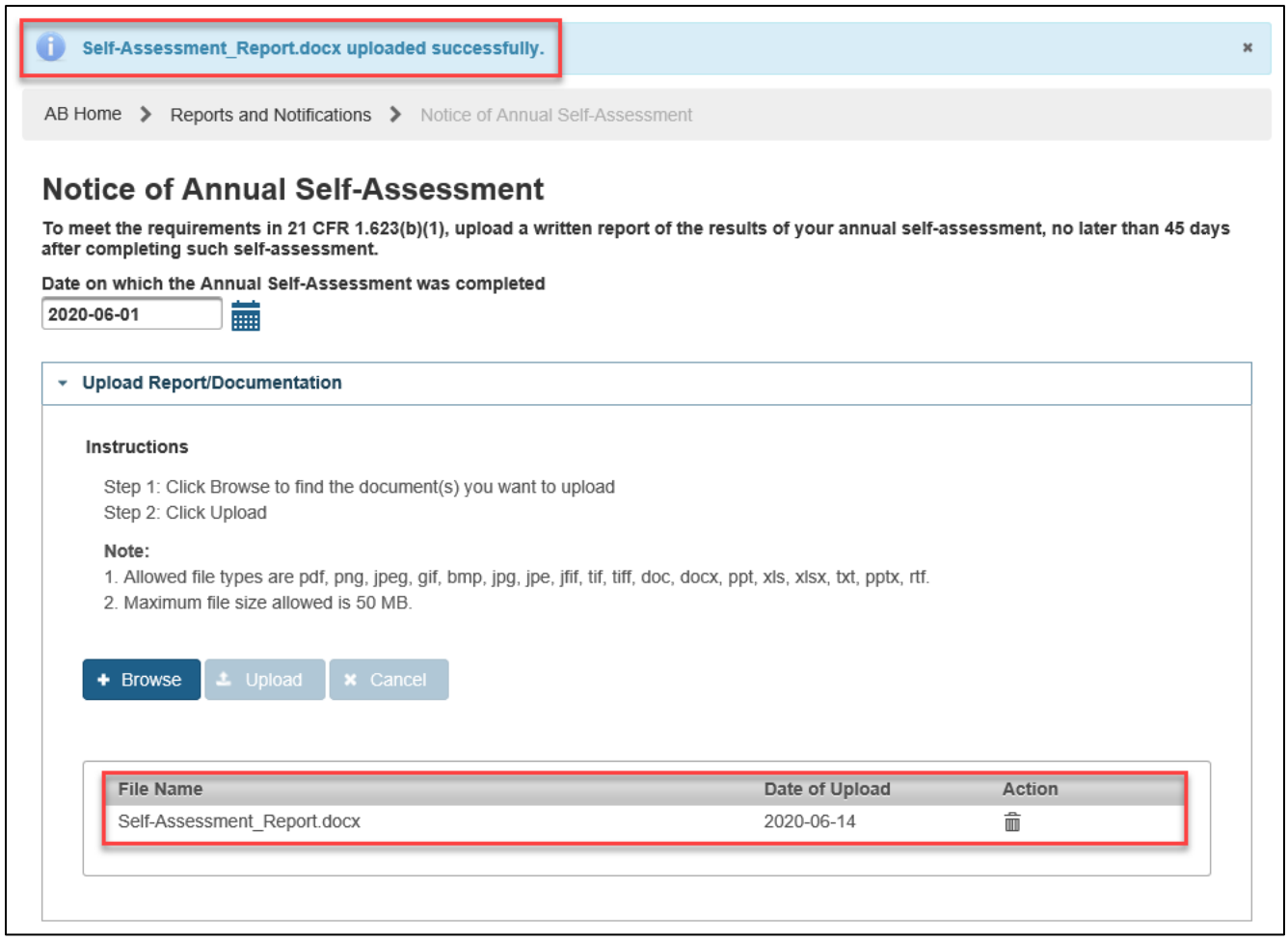
The browsing window will close once a file is selected. The “Upload” and “Cancel” buttons will be enabled once the browsing window closes.

Click the “Upload” button to attach the file. Click the “Cancel” button to remove the file from the menu.

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.

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

Figure 11.98 – Upload Report/Documentation Section



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

The system will display the “e-Signature” page (Figure 11.99).

Follow the directions provided on the “e-Signature” page.

Click the checkbox to certify the information in the submission is true and accurate and, that you are authorized to submit the information to FDA.

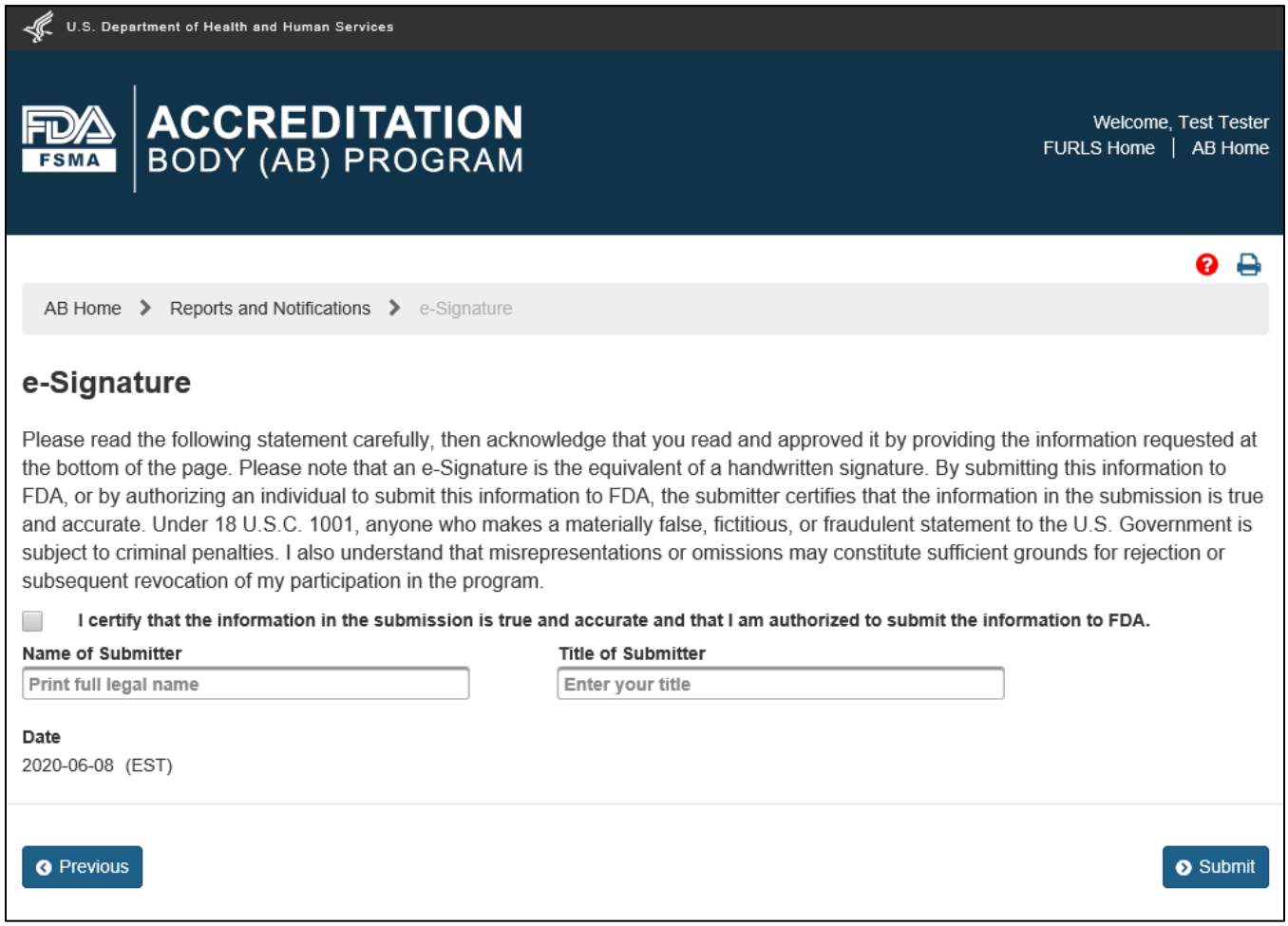
Complete the following data fields:

- **Name of Submitter** – The first and last name of the submitter
- **Title of Submitter** – The title of the submitter

Click the “Previous” button if you wish to return to the “Notice of Annual Self-Assessment” page.

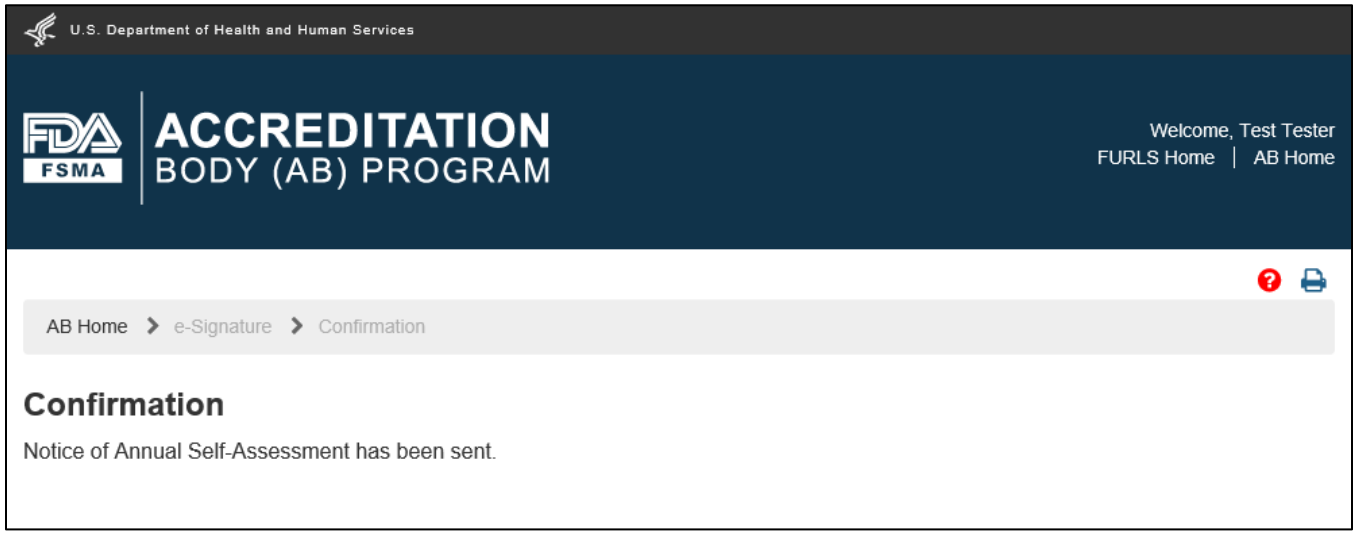
Click the “Submit” button to complete submission to FDA.

Figure 11.99 – e-Signature Page



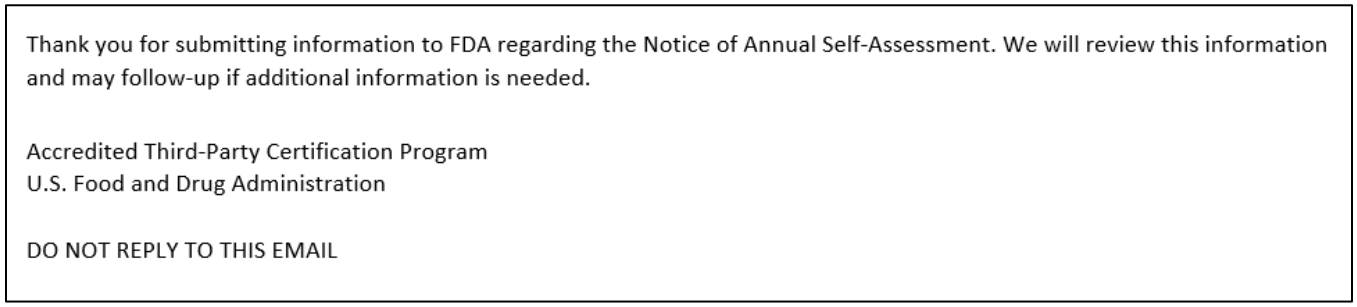
After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.100).

Figure 11.100 – Confirmation Page



The system will send an e-mail to the address entered on the “Account Management” page indicating the notice was received by FDA (Figure 11.101). Note that the image below only depicts the e-mail notification text.

Figure 11.101 – E-mail Notification



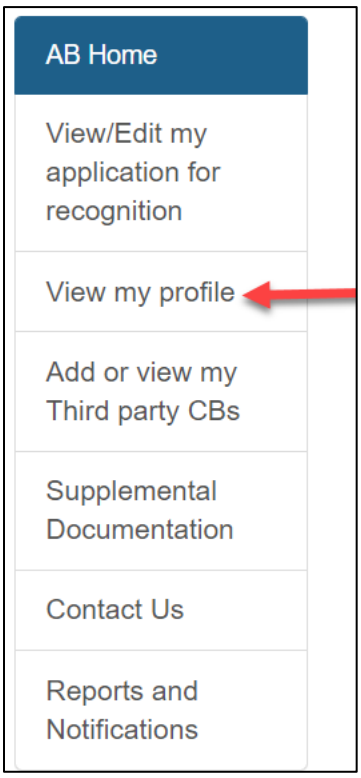
Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

12 View My Profile

The “View My Profile” feature may be used to view and edit the account information submitted during the OAA account creation.

To access the “View My Profile” feature, click the “View my profile” link from the navigation menu on the “AB Home” page (Figure 12.1).

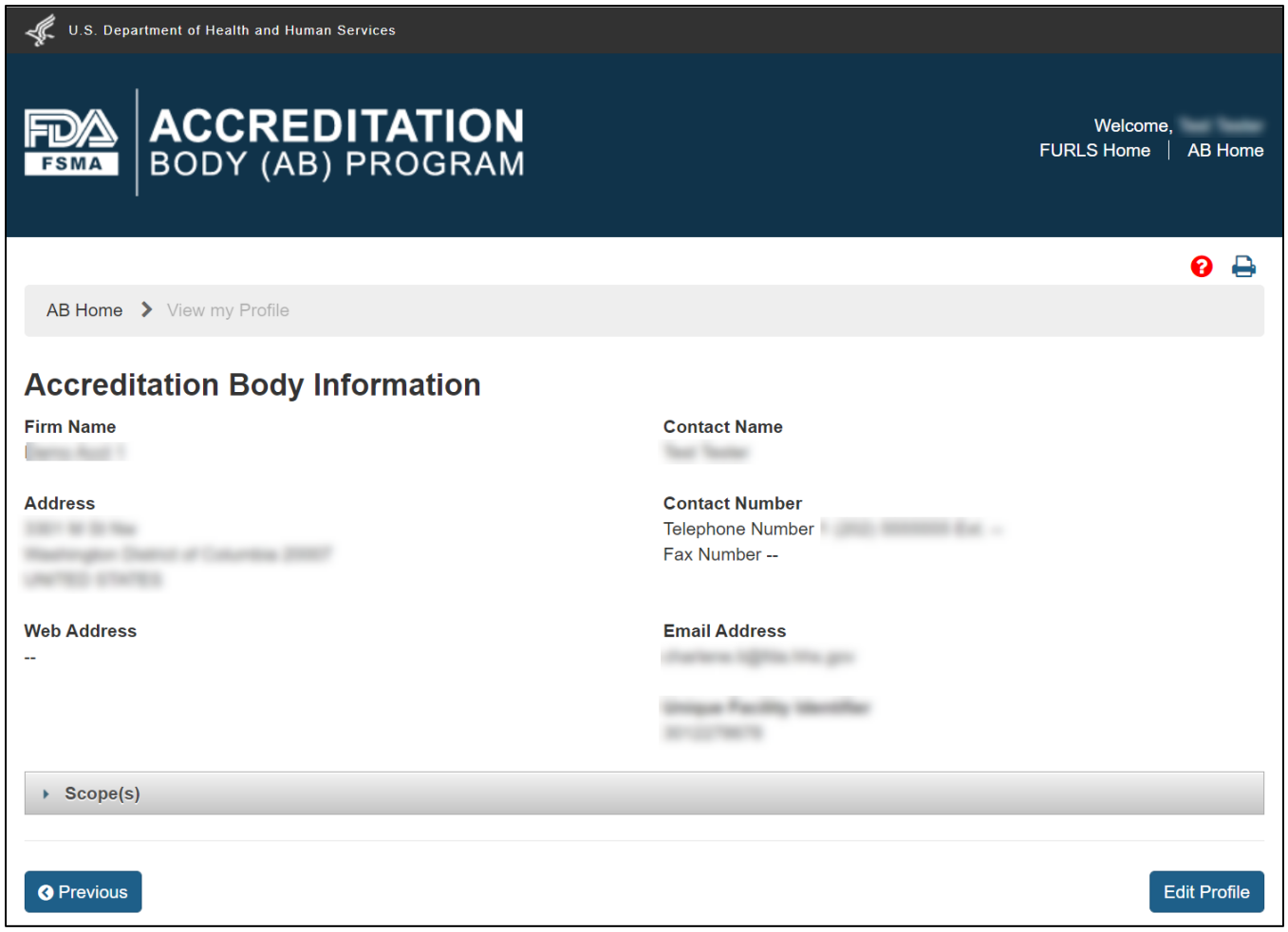
Figure 12.1 – Navigation Menu



The system will display the “Accreditation Body Information” page, which contains your read-only profile information from OAA (Figure 12.2).

The page also will display the “Scope(s)” accordion panel, which contains each scope in your recognition, as well as their status, accreditation, and expiration dates.

Figure 12.2 – Accreditation Body Information



Click the accordion section's title bar to view the scope details (Figure 12.3).

Figure 12.3 – Scope(s) Accordion Section

To edit your account profile information in OAA, click the "Edit Profile" button from the bottom of the "View my Profile page" (Figure 12.4).

Click the "Previous" button to return to the "AB Home" page.

Figure 12.4 – Edit Profile and Previous Buttons

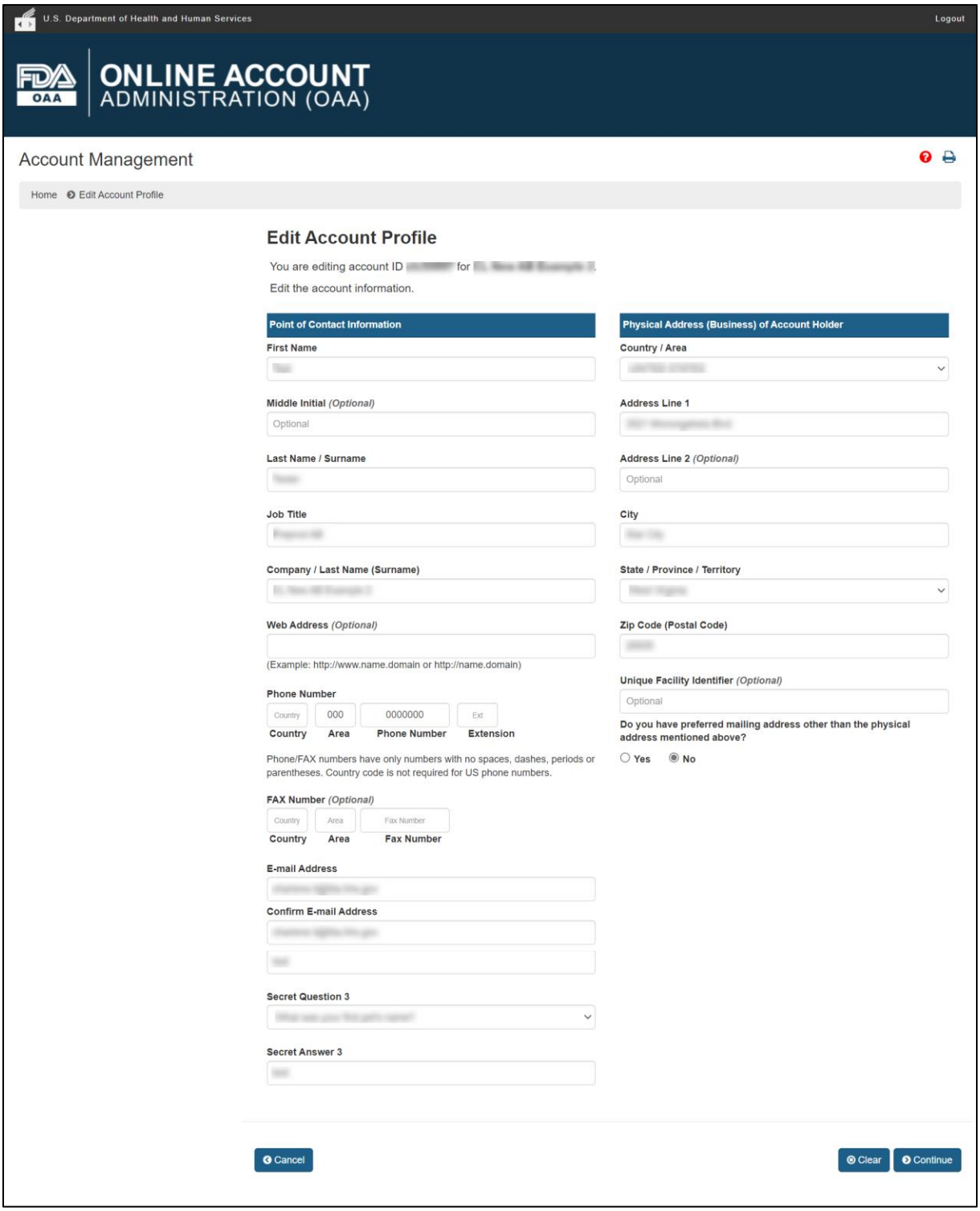
The system will display the “Edit Account Profile” page of Account Management (Figure 12.5).

Note: All of the fields will be editable.

The following buttons will display:

- **Clear** – Removes all of the account information on the page
- **Note:** If you clicked “Clear” and wish to restore your account information, click the “Cancel” button and navigate back to the “View my Profile” page.
- **Cancel** – Discards any changes and returns to the main OAA page
- **Continue** – Navigates users to the review page where you may confirm your changes before submitting

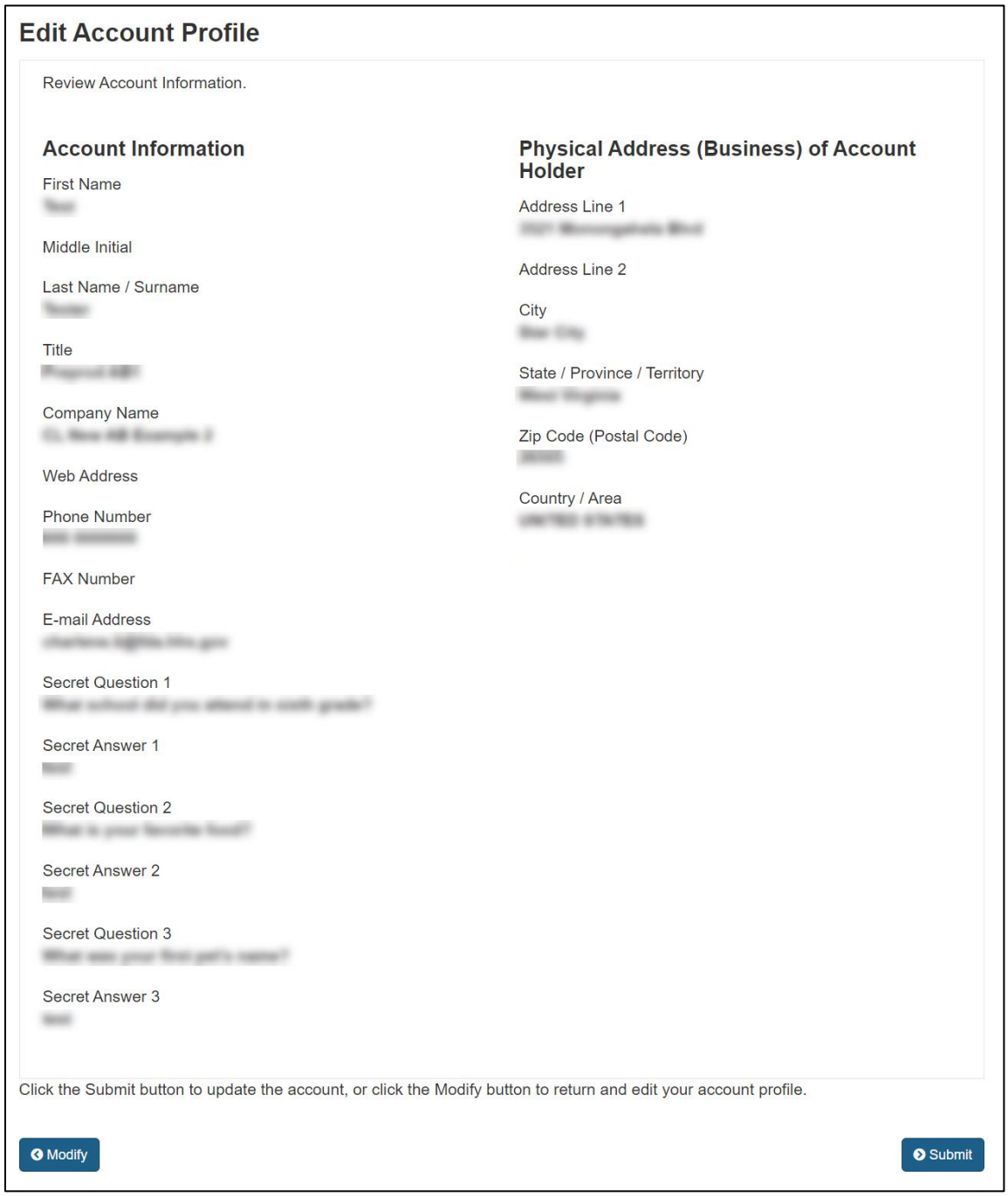
Figure 12.5 – Edit Account Profile Page



After you click “Continue,” the system will display the “Edit Account Profile” page as read-only for you to review.

Click the “Modify” button if you wish to make additional changes before submitting. Click the “Submit” button once you have verified the changes (Figure 12.6).

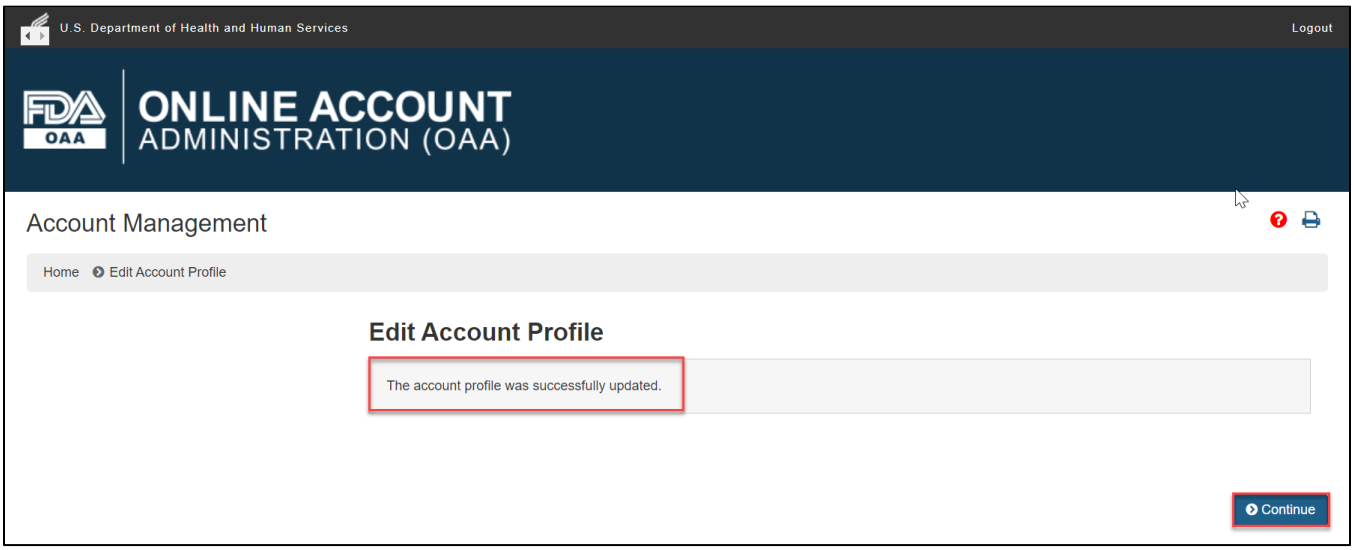
Figure 12.6 – Edit Account Profile – Read-Only View with Submit and Modify Buttons



Once you click the “Submit” button, the system will display a confirmation message stating the update was successful (Figure 12.7).

Click the “Continue” button to navigate back to the “View my Profile” page.

Figure 12.7 – Successful Update Message

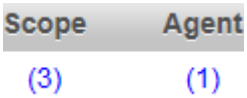


APPENDIX A: Abbreviations

AB	Accreditation Body
CB	Certification Body
FDA	U.S. Food and Drug Administration
OAA	Online Account Administration

APPENDIX B: Icon Behavior

Standardized icons are used throughout the system. Each icon performs a specific system function. The icon description and system function are described below:

Icon Description	Icon	System Function
Magnifying Glass		View the associated item.
Pencil		Edit the associated item.
Numbers within parenthesis		Lists the total number of records associated with the item. The number within parenthesis is a clickable link. • Example, “(3)” indicates that there are three scopes associated with the accredited CB. The AB may click the link to view the three scopes records. • Example, “(1)” indicates that there is one audit agent associated to the accredited CB. The AB may click the link to view a list of active audit agent(s).
Trash Can		Delete the associated item.
Printer		Print the associated item.