U.S. Food and Drug Administration

Accredited Third-Party Certification Program Portal

Electronic User Guide

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

Table of Contents

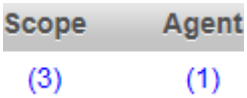
November 2018

Abbreviations

AB	Accreditation Body
CB	Certification Body
CFSAN	Center for Food Safety and Applied Nutrition
FDA	U.S. Food and Drug Administration
OAA	Online Account Administration
ORA	Office of Regulatory Affairs

Icon Behavior

Standardized icons are used throughout the system. Each icon performs a specific system function. The icon description and system function is 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 certification body. The AB may click the link to view the three scopes records. • Example, “(1)” indicates that there is one audit agent associated to the certification body. 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.

1 Introduction

This document is intended for Accreditation Bodies (ABs) or persons who are authorized to act on their behalf, who are applying or seeking renewal for recognition in FDA's Accredited Third-Party Certification Program. If approved by FDA, ABs may manage their profiles, including the Certification Bodies (CBs) they have accredited.

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

- Submit an application
- Manage an AB profile
- Add and manage CBs
- Communicate with FDA

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

FDA Industry Systems (FIS)

FDA Industry Systems (FIS) is an electronic portal which facilitates making submissions to the 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 the 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 an electronic file (e.g., reports, schematics, or other supporting information).

The electronic Accredited Third-Party Certification Program system supports attachments of the following document types: 1) .pdf; 2) .png; 3) .jpeg; 4) .gif; 5) .bmp; 6) .jpg; 7) .jpe; 8). jfif; 9) .tif; 10) .tiff; 11) .doc; 12) .docx; 13) .ppt; 14) .xls; 15) .xlsx; 16) .txt; 17) .pptx; and 18) .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 Firefox, Chrome, or Internet Explorer. Please visit the "Systems Requirements" section of the FURLS page for a list of approved browsers and browser versions. The "Systems Requirements" section can be found by navigating to https://www.access.fda.gov/.

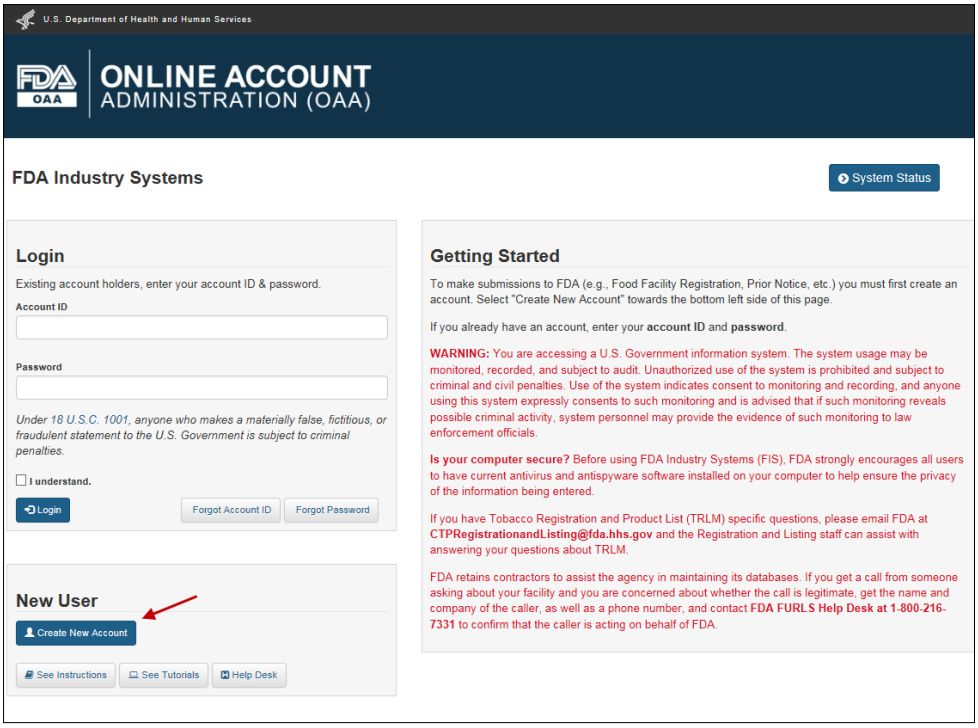
Obtain an FDA Account through the FDA FIS Electronic Portal

Each person who uses this system needs a personal FDA Account ID and password. To access the FIS electronic portal, go to https://www.access.fda.gov/oaa/. Click the "Create New Account" button near the bottom of the page, in the New User section. Then 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

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

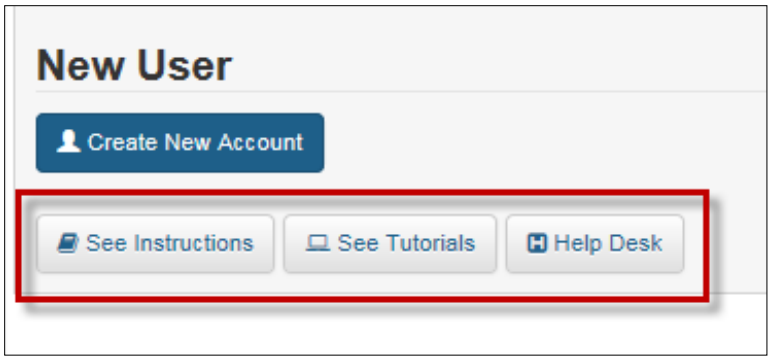
Figure 3.1 – FDA OAA Page



- **System Status –** Directs users to the “FDA Industry Systems – System Status” page which displays the current system status, system status explanations, and the system status history.
- **See Instructions and See Tutorials –** Directs 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 you to informational pages on fda.gov as indicated. You will not be required to select any of these buttons in order to complete your application, but are there for your reference if needed (Figure 3.2):

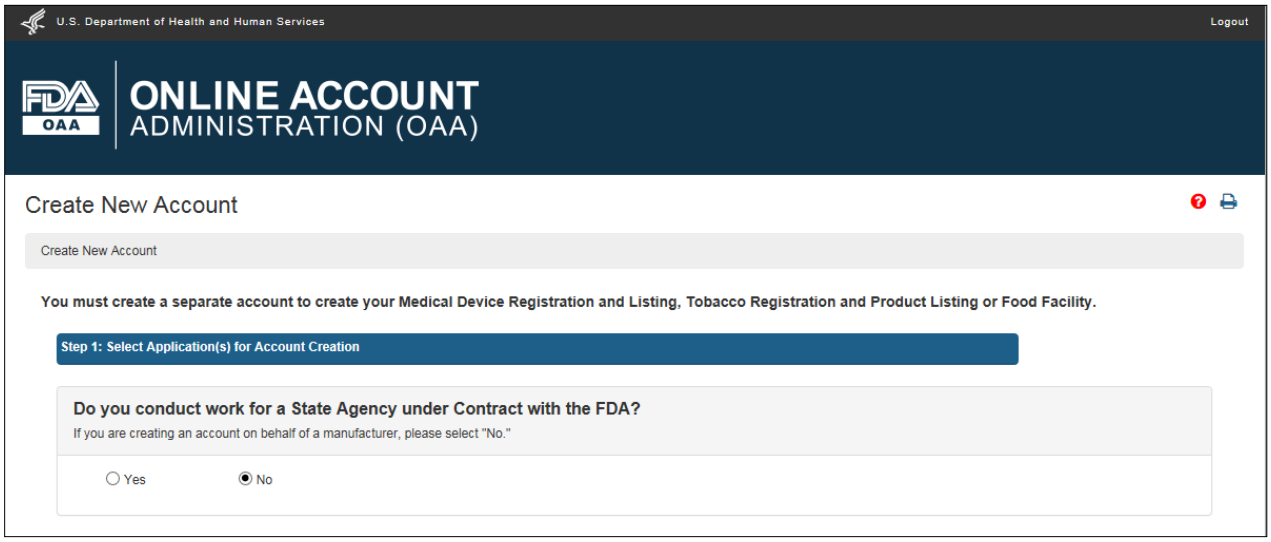
Figure 3.2 – Additional Buttons



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

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

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



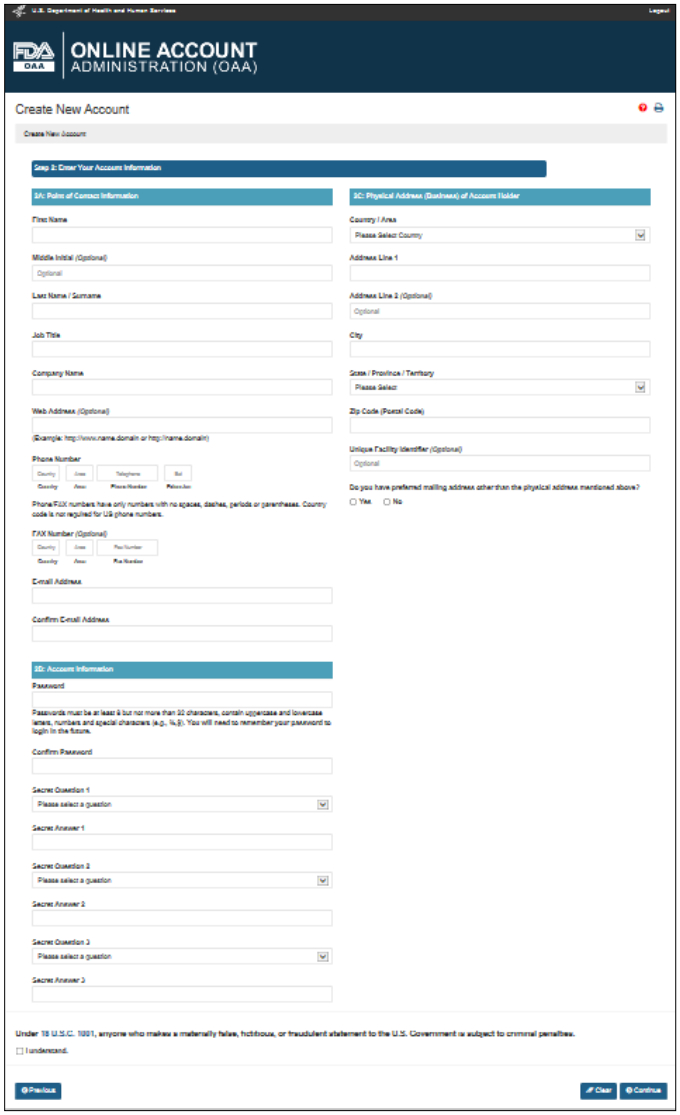
The system displays the various programs available in OAA.

Select the “Third-Party Program - Accreditation Body" checkbox under the “FSMA Program(s)” section (Figure 3.4) and continue to the next step.

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

The next section is “Step 2: Enter Your Account Information” where AB applicants provide their Point of Contact information, unique account information, and the account holders 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:

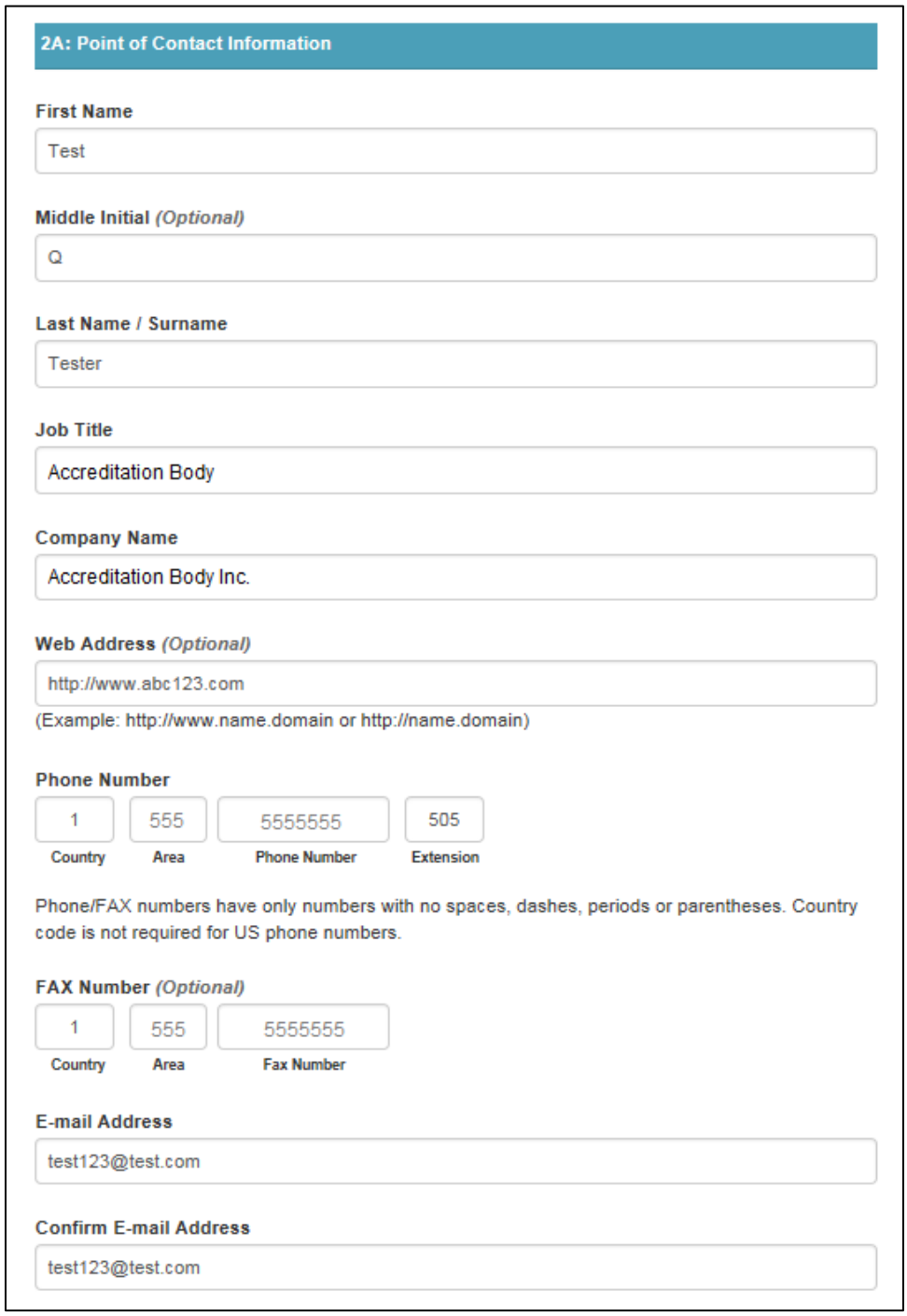
- **Previous –** Returns to the previous screen
- **Clear –** Clears all input entered on the specific page/section
- **Continue –** Proceeds to the next screen/step in the account creation process

Note: All application fields are required, unless indicated as “Optional.” Non-required fields will be marked as “Optional.”

Enter “N/A” in any required field that does not apply to you.

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

Figure 3.6 – Step 2A: Point of Contact Information

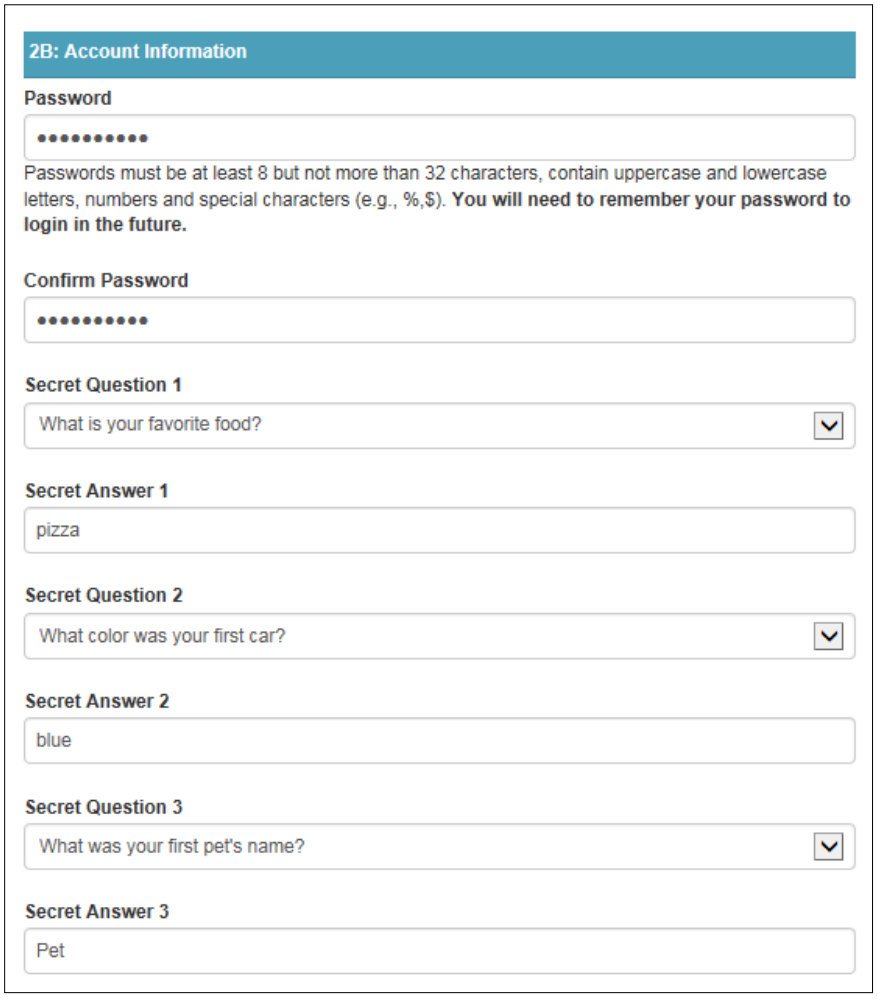


The data fields in the “Step 2A: Point of Contact Information” section include:

- **First Name –** The first name of the Point of Contact.
- **Middle Initial (Optional field) –** The first letter of the Point of Contact’s middle name.
- **Last Name/Surname –** The last name of the Point of Contact.
- **Job Title –** The job title of the Point of Contact.
- **Company Name –** The name of the company the Point of Contact represents.
- **Web Address (Optional field) –** The URL of the company.
- **Phone Number (Country/Area/Phone Number/Extension) –** The telephone number of the Point of Contact.
    - “Country” is the country code.
    - “Area” is the three-digit area code.
    - “Phone Number” is the seven-digit 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 three-digit area code. “Fax Number” is the seven-digit phone number.
- **E-mail Address –** The e-mail address of the Point of Contact.
- **Confirm E-mail Address –** The re-entry of the Point of Contact’s e-mail address (the entry must match the “E-mail Address” field).

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

Figure 3.7 – Step 2B: Account Information



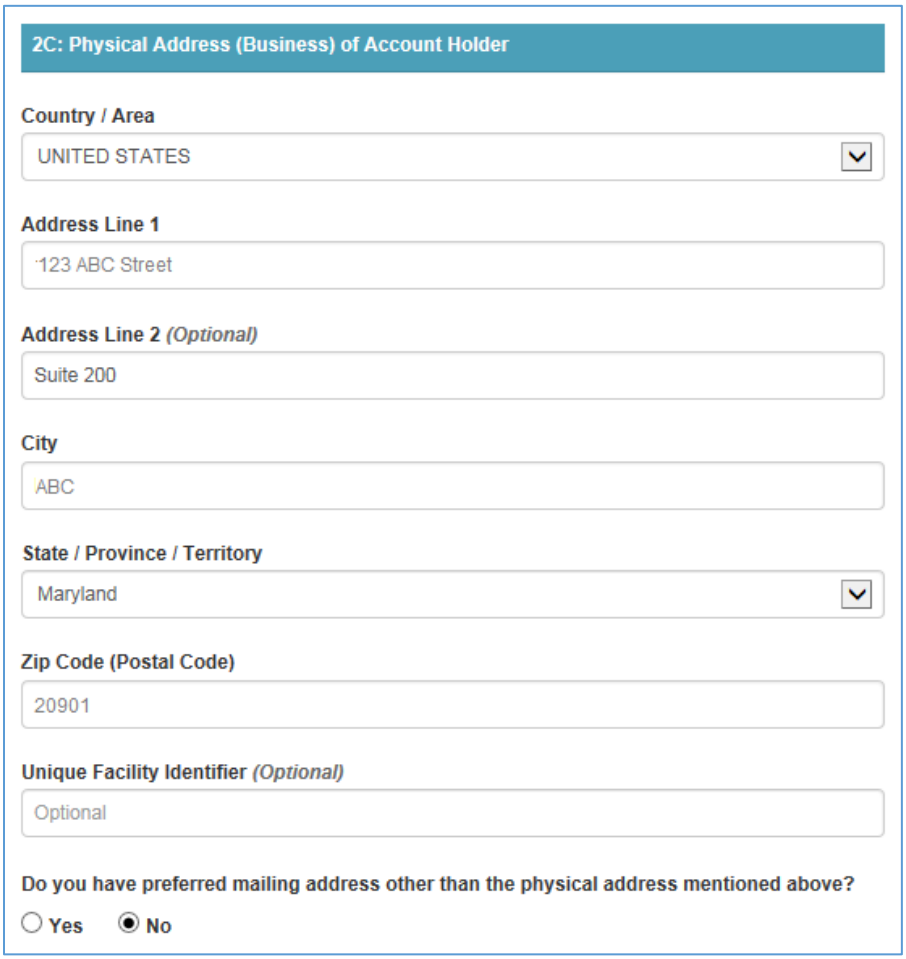
The data fields in Section 2B - Account Information include:

- **Password –** Use this field to create the password for the AB’s account. Use this password each time you log into the system.
- **Confirm Password –** Re-enter the password in the “Password” field. The entry must match the “Password” field.
- **Secret Question 1 –** This is the first secret question used to protect the account. Select a question from the drop-down 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 –** The second secret question used to protect the account. Select a question from the drop-down 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 drop-down list.
- **Secret Answer 3 –** This is the answer to the third secret question. Enter your response to the question selected in “Secret Question 3.”

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

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 drop-down 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 “No” - Select the checkbox for “I understand” at the bottom of the page (Figure 3.10). The physical address will be used as the mailing address.
    - If “Yes” - “Section 2D: Preferred Mailing Address” displays. Section 2D must be completed to proceed to the next step (Figure 3.9). Next, 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

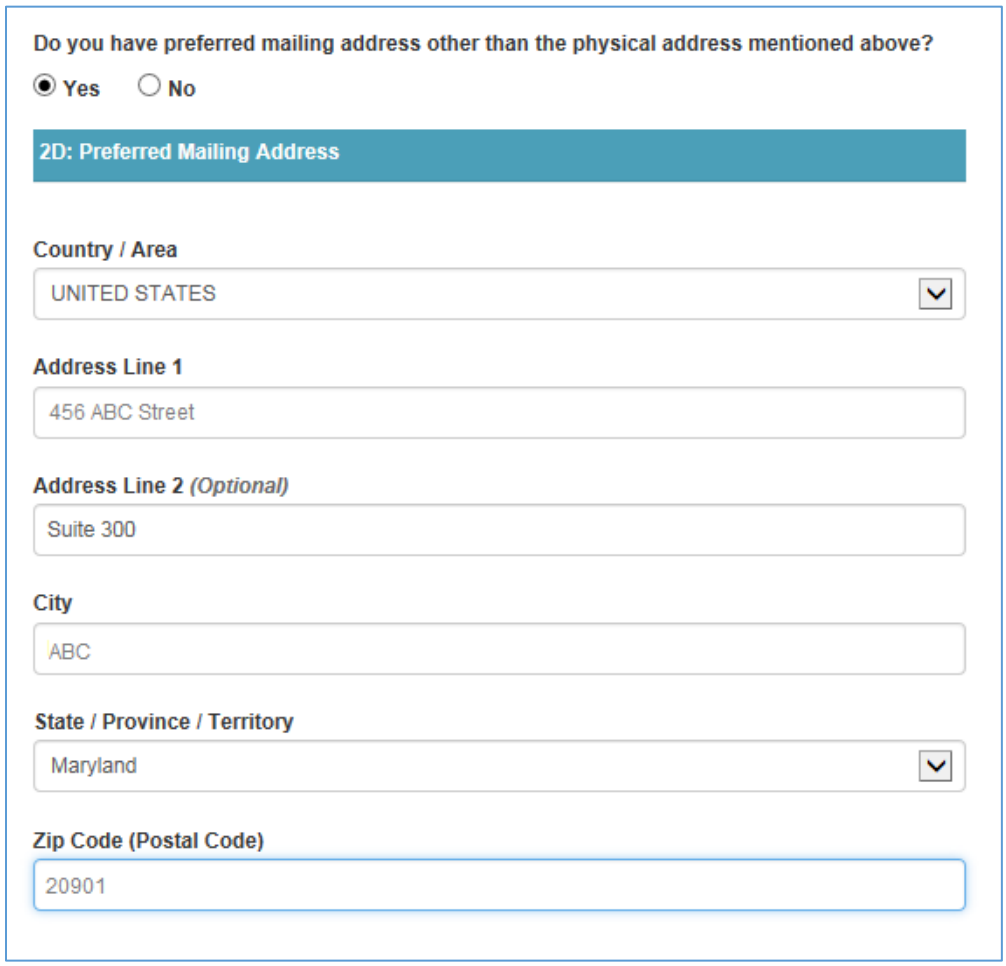
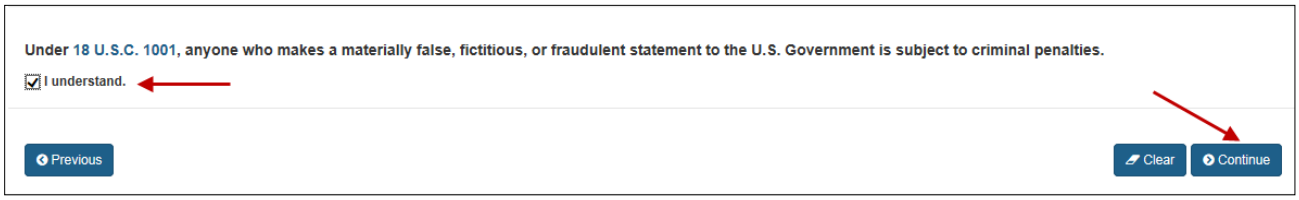


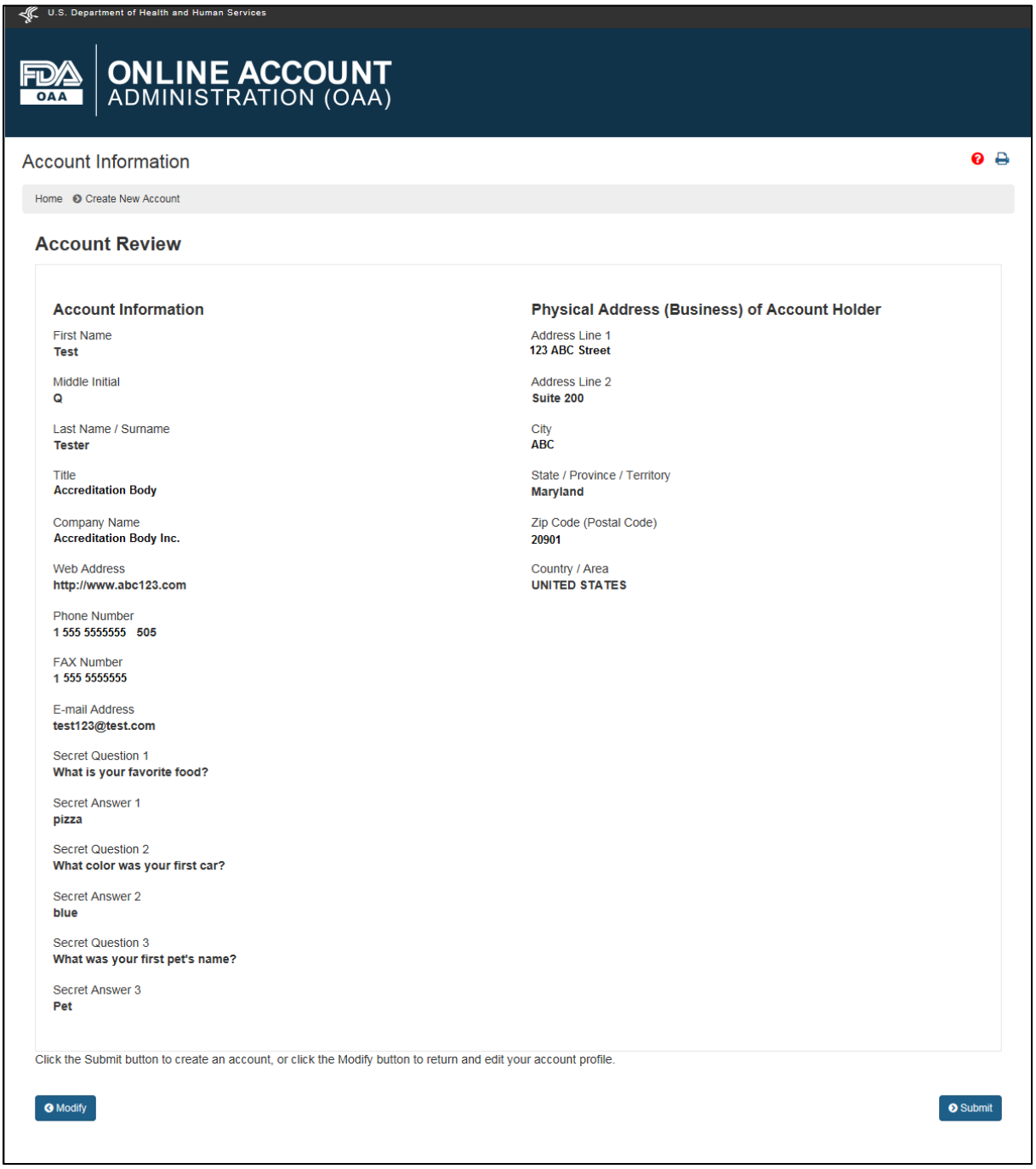
Figure 3.10 – Checkbox



"Continue" after you have entered the required account information (Figure 3.10). The "Account Review" page will be displayed (Figure 3.11). Review the data entered to ensure it is correct.

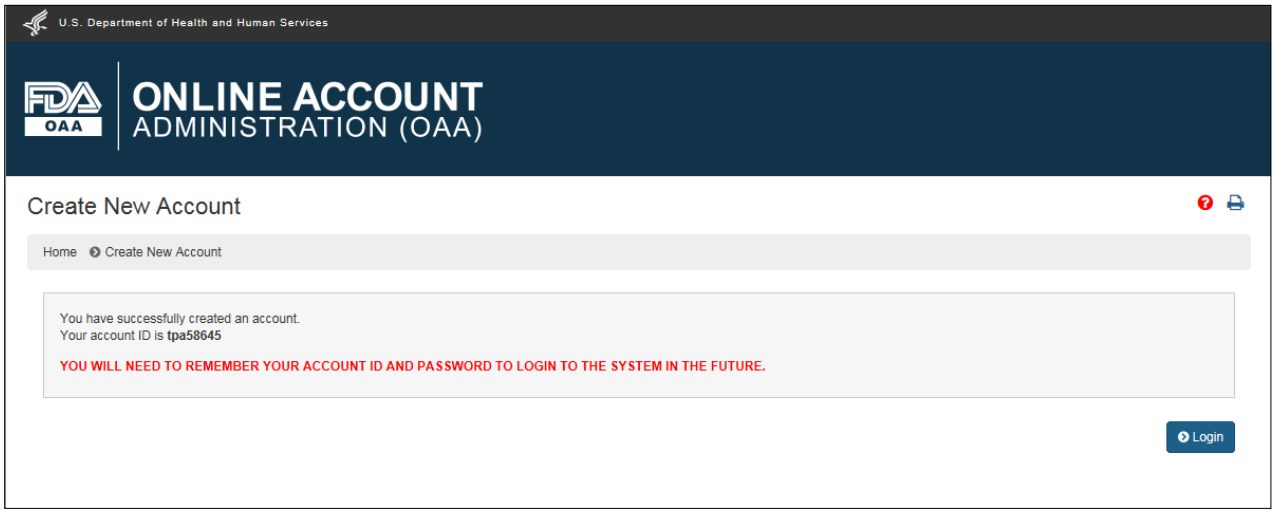
Click "Submit" to complete the process. Click "Modify" to edit the profile information in the previous page.

Figure 3.11 – Account Review Page



When you click “Submit,” the system displays a message that the account was created successfully. The message displays your Account ID (Figure 3.12). You will need to retain your account ID and password to login to the system in the future.

Figure 3.12 – Successful Account Creation Message Page



Once you create an account, you will receive an e-mail notification to the e-mail address entered in “Account Information” page (Figure 3.13).

Figure 3.13 – Account Creation Confirmation e-mail

Dear FDA Industry Systems Account User,

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

You have created a new account. The Account ID is **tpa58645**.

Thank you for using the FDA Industry Systems website.

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

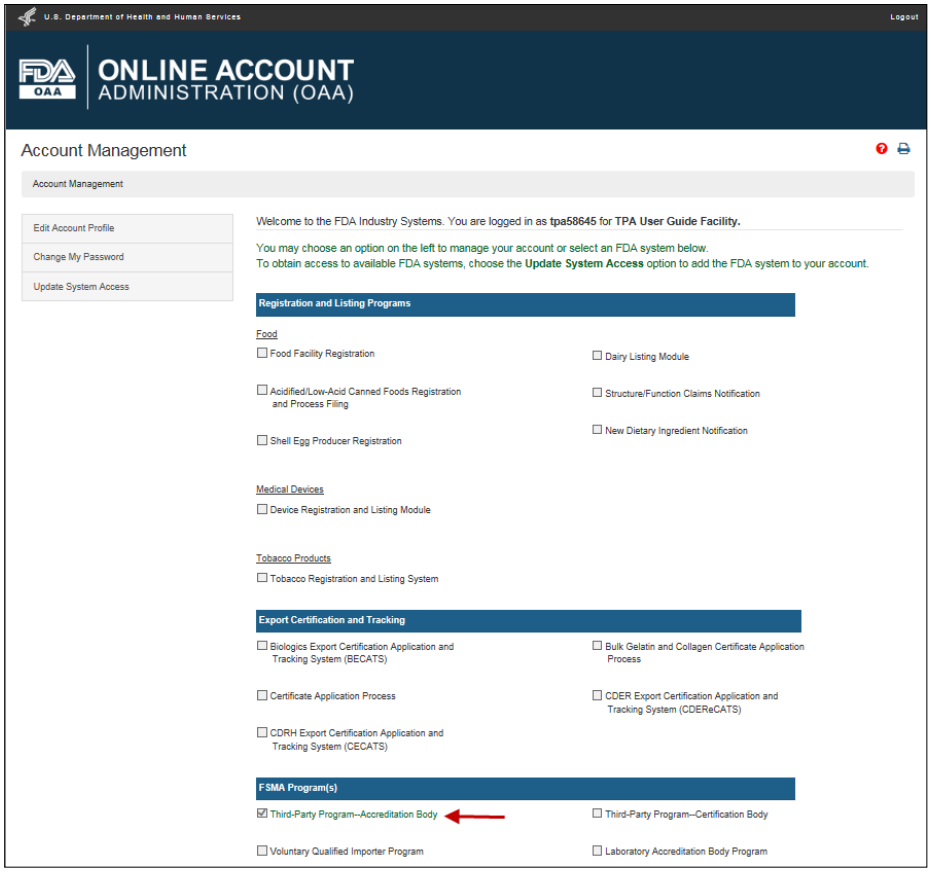
4 Submit an Application for Recognition as an Accreditation Body (AB)

As an AB, log into the FDA “OAA” page (https://www.access.fda.gov/oaa/), which is the same page used to begin the process of creating a new OAA account (Figure 4.1).

Figure 4.1 – OAA Login

Once the AB has logged into the FDA “OAA” page, the FURLS “Account Management” homepage (Figure 4.2) is displayed. Go to the “FSMA Program(s)” section and select the hyperlink for "Third-Party Program—Accreditation Body.”

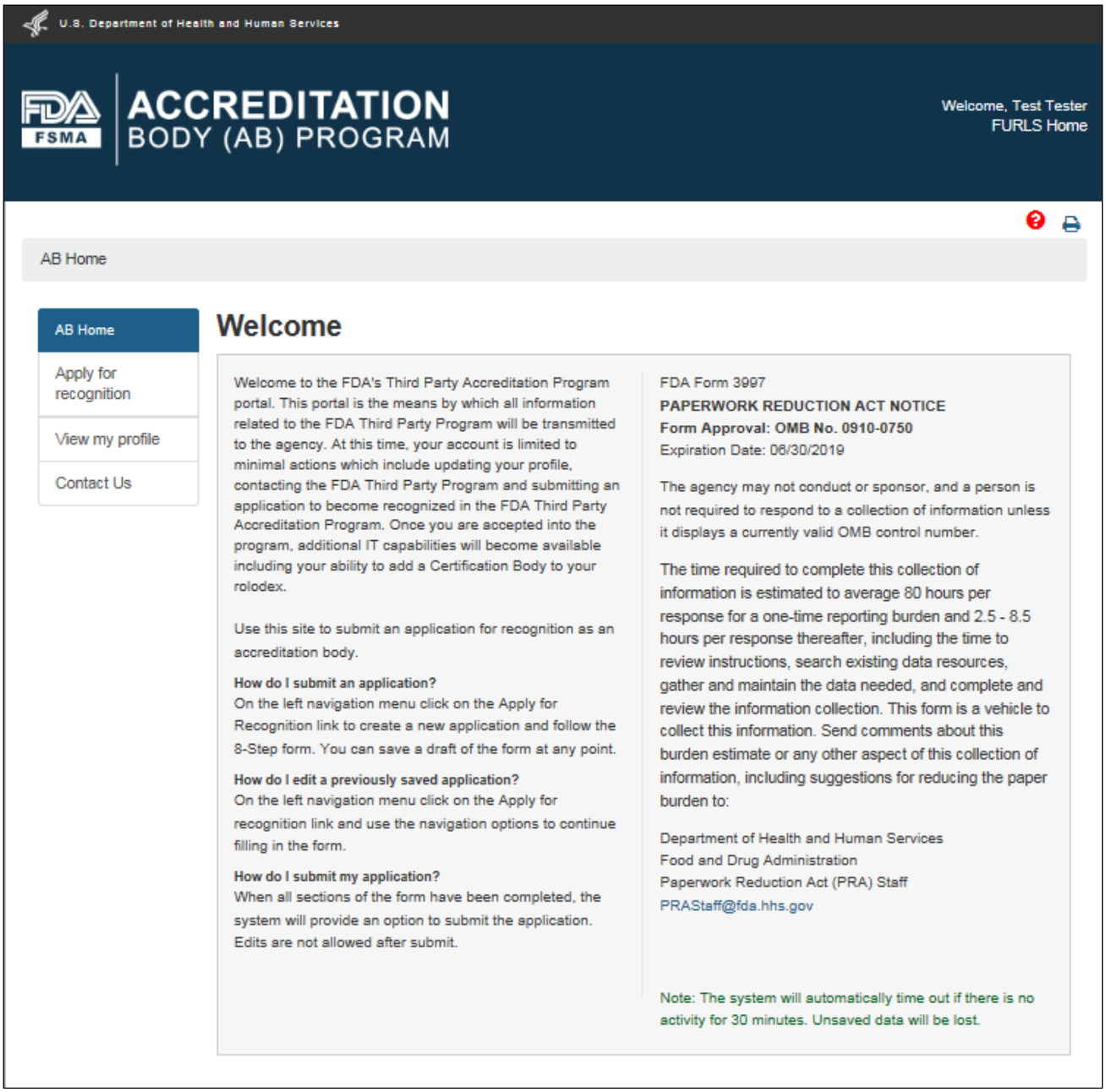
Figure 4.2 – OAA - FURLS Account Management Home Page



Select the hyperlink for “Third-Party Program—Accreditation Body” to navigate to the “AB Home” page; the banner for this page is titled “Accreditation Body (AB) Program” (Figure 4.3).

Note that each screen in the AB electronic submission process has the banner “Accreditation Body (AB) Program.” The “FURLS Home” link on the right side of the banner will take you back to the FURLS “Home” page, where you may log out.

Figure 4.3 – AB “Home” Page

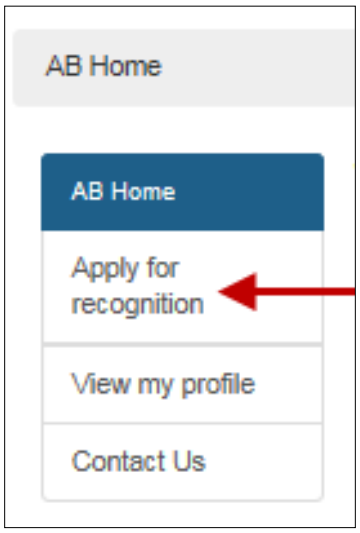


5 Apply for Recognition and Implementing FDA Regulations

Select the “Apply for Recognition” link in the left navigation menu (Figure 5.1) to create a new application for recognition as an AB. The “Applicant Information” page (Figure 5.2) will open.

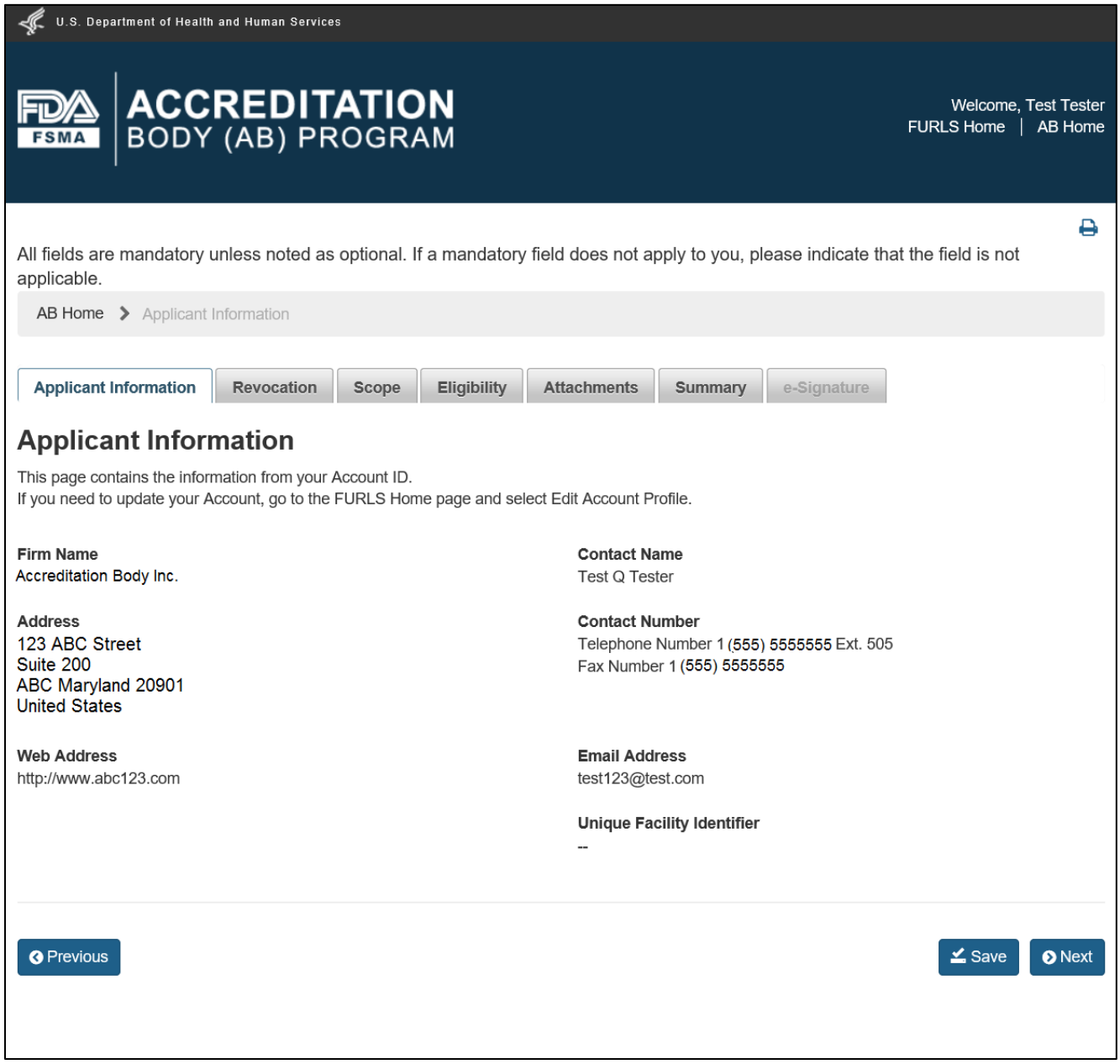
"AB Home" will take you to the Main Menu on the “AB Home” page.

Figure 5.1 – Apply for Recognition



Verify that the information listed in “Applicant Information” tab (Figure 5.2) is correct and click the “Next” button or click the “Revocation” tab directly. This page displays read-only information from your user profile.

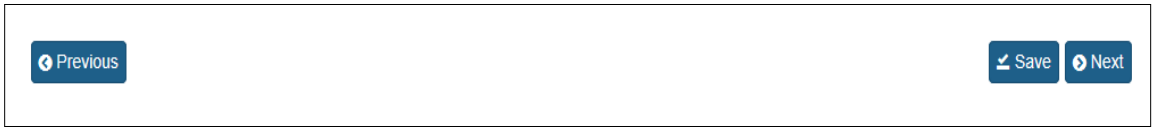
Figure 5.2 – Applicant Information



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

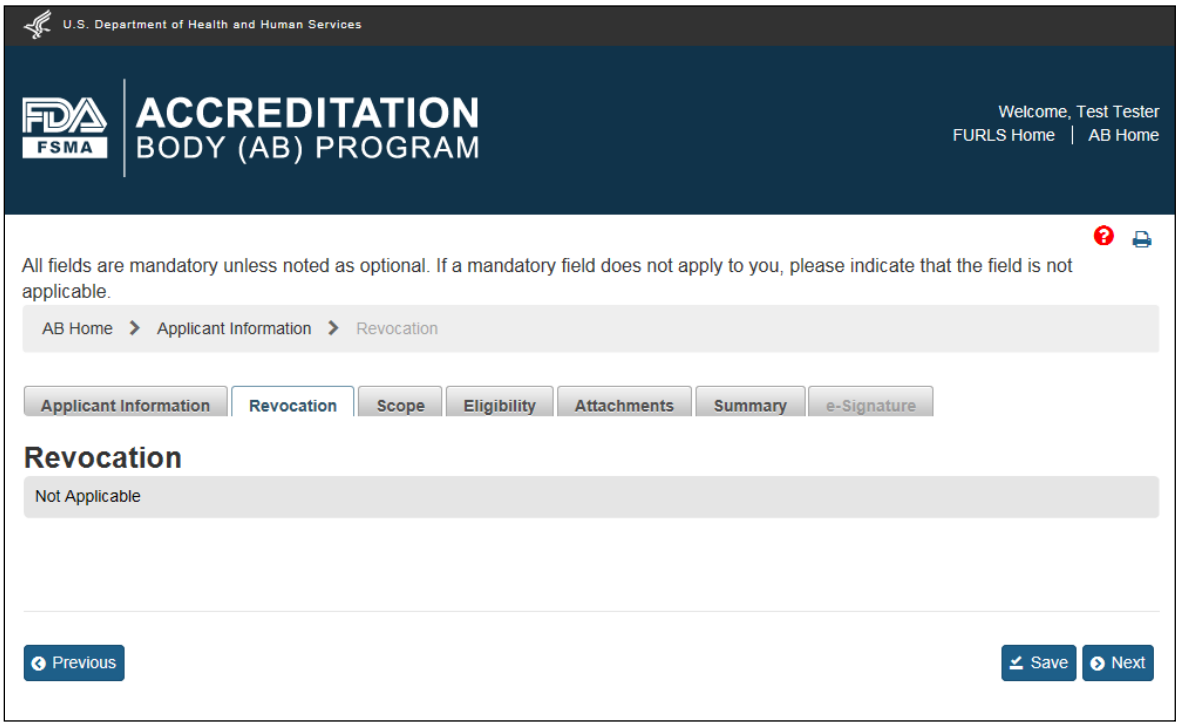
- **Previous –** Directs you to the previous page; this saves any user input from other pages, **only during the current session**.
- **Save –** Saves any input from the current page (from session to session), even if the application has not been completed.
- **Next –** Directs you to the next page; will save any user input from other pages **only during the current session**.

Figure 5.3 – Previous, Save and Next Buttons



The default value stated on the “Revocation” tab is “Not Applicable” (Figure 5.4).

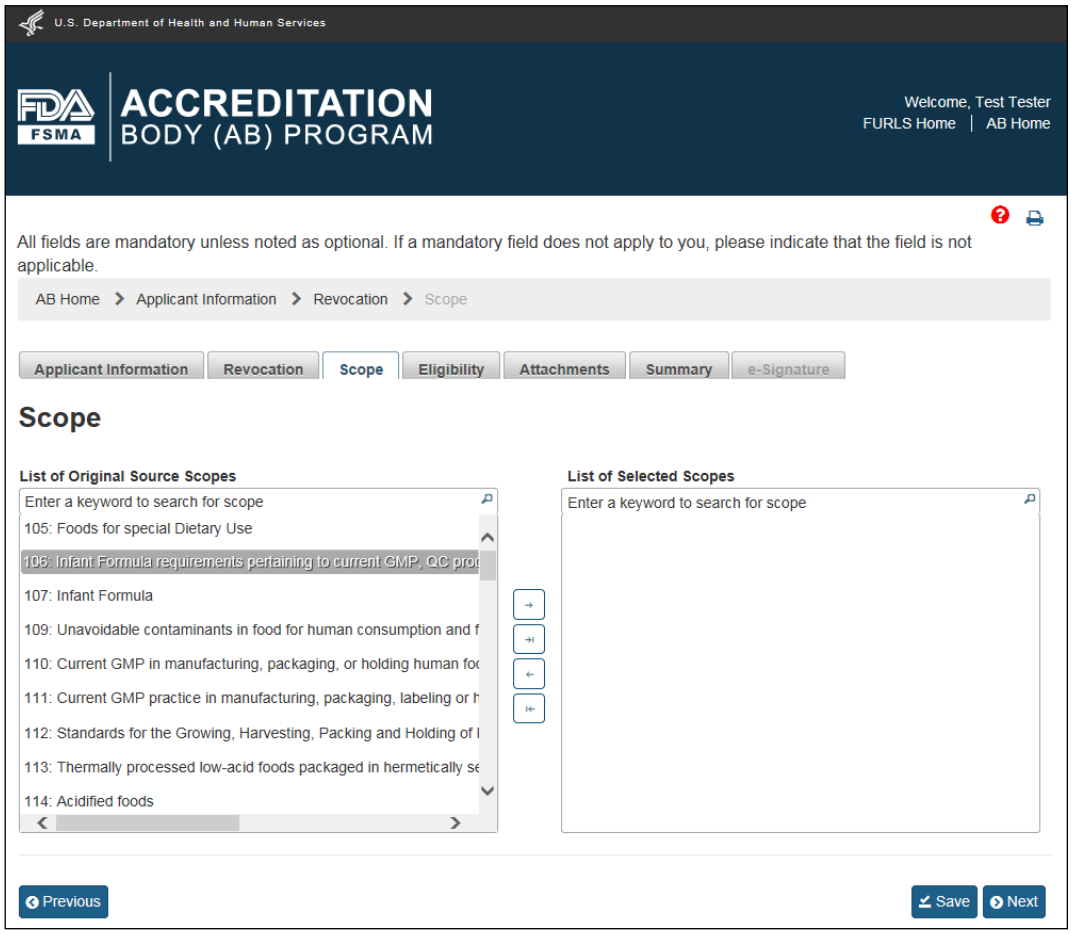
Figure 5.4 – Revocation



Proceed to the next tab by clicking the “Next” button or click directly on the “Scope” tab (Figure 5.5).

The “Scope” tab lists the 21 CFR regulations for which you may apply. The 21 CFR regulations will henceforth be referred to as scopes.

Figure 5.5 – Scope



This page contains a list of all possible scopes. You must select at least one scope from the “List of Original Source Scopes” to complete your application.

To select a scope, left click the text; the text will appear highlighted. The following buttons are used to add or remove selected scopes:

- → “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.”

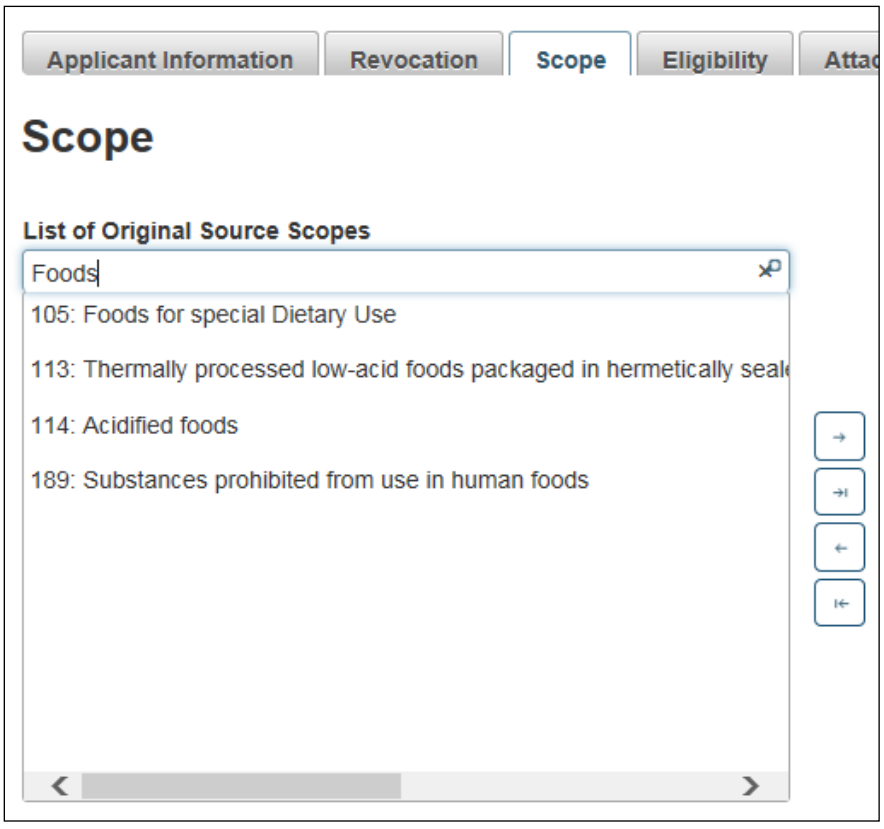
Use the scroll bar at the bottom of the “List of Original Source Scopes” to see full titles of scopes.

A keyword(s) search can be performed in either the “List of Original Source Scopes” or “List of Selected Scopes.

Type the keyword(s) in the Search bar (Figure 5.6). The search results can be added or deleted from the respective lists.

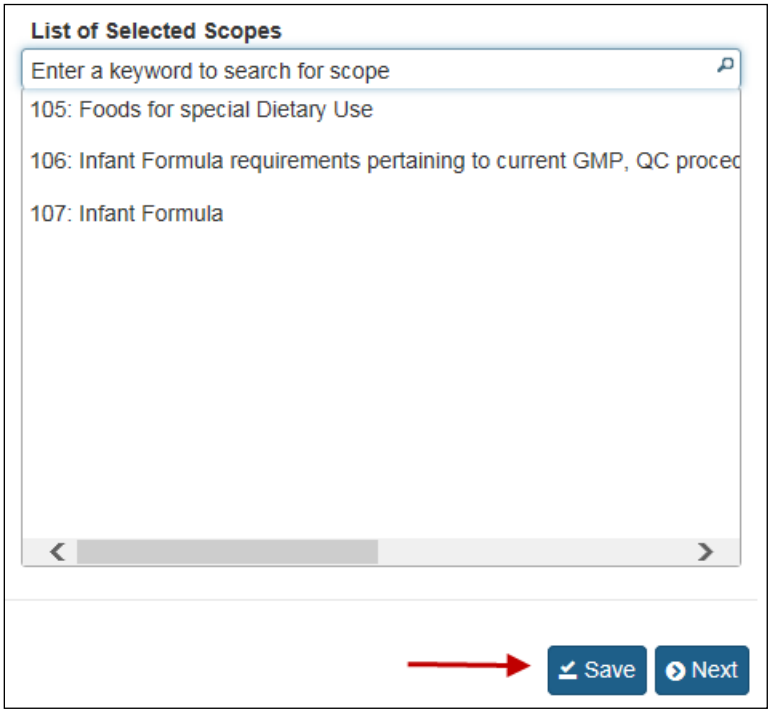
Clear the “Search” box by using the “Backspace” key or highlighting the text and pressing the “Delete” key.

Figure 5.6 – Searching by Scope



Click the “Save” button when all applicable scopes have been selected (Figure 5.7).

Figure 5.7 – Save and Next

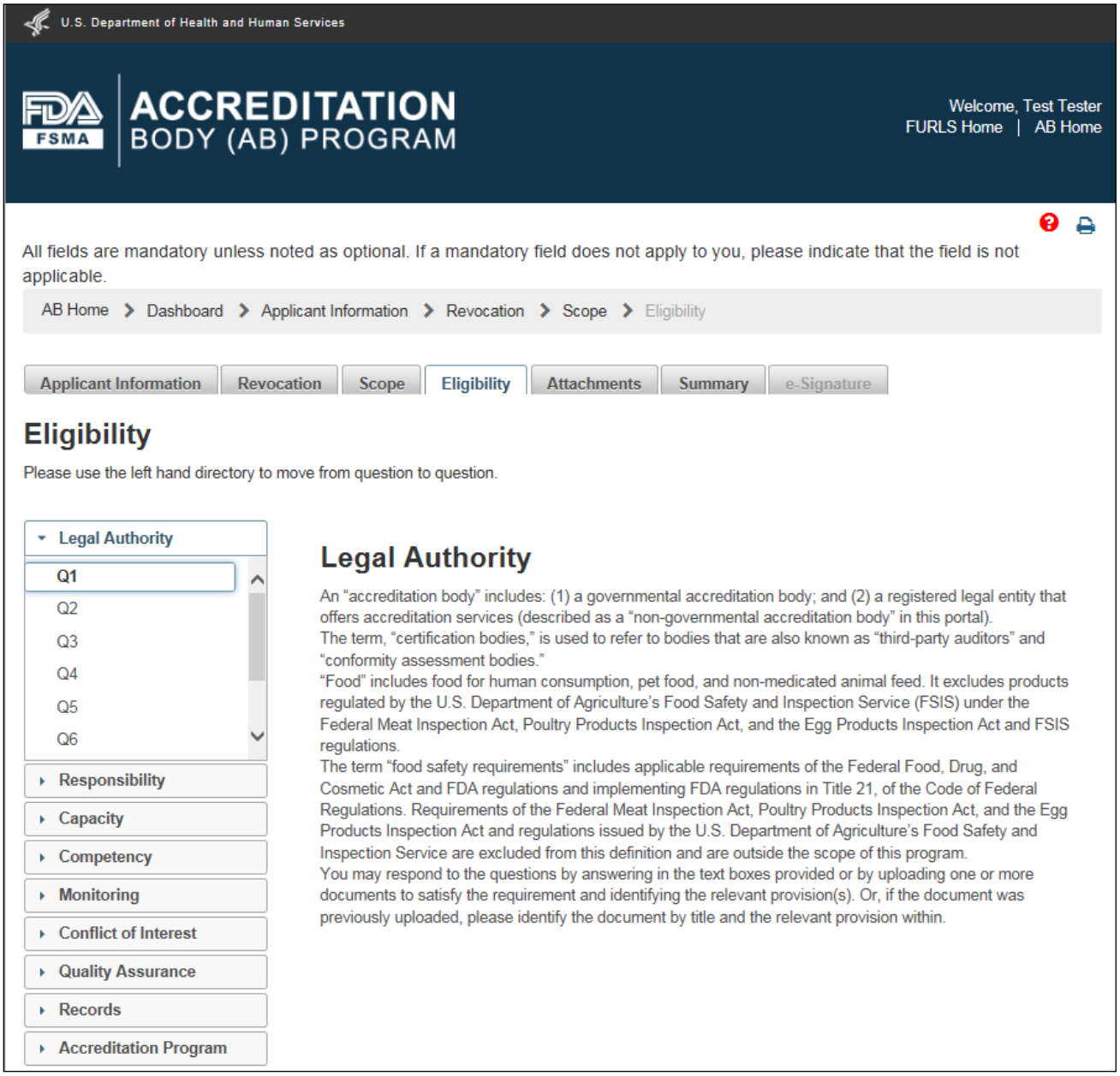


Click the “Next” button to proceed to the “Eligibility” page. You may also click the “Eligibility” tab directly. The “Eligibility” page allows you to answer questions and attach files for the following standards:

- Legal Authority
- Responsibility
- Capacity
- Competency
- Monitoring
- Conflict of Interest
- Quality Assurance
- Records
- Accreditation Program

The standards are listed on the left-hand side of the page. The first standard, “Legal Authority,” is expanded by default upon navigating to the page (Figure 5.8).

Figure 5.8 – Eligibility Default View

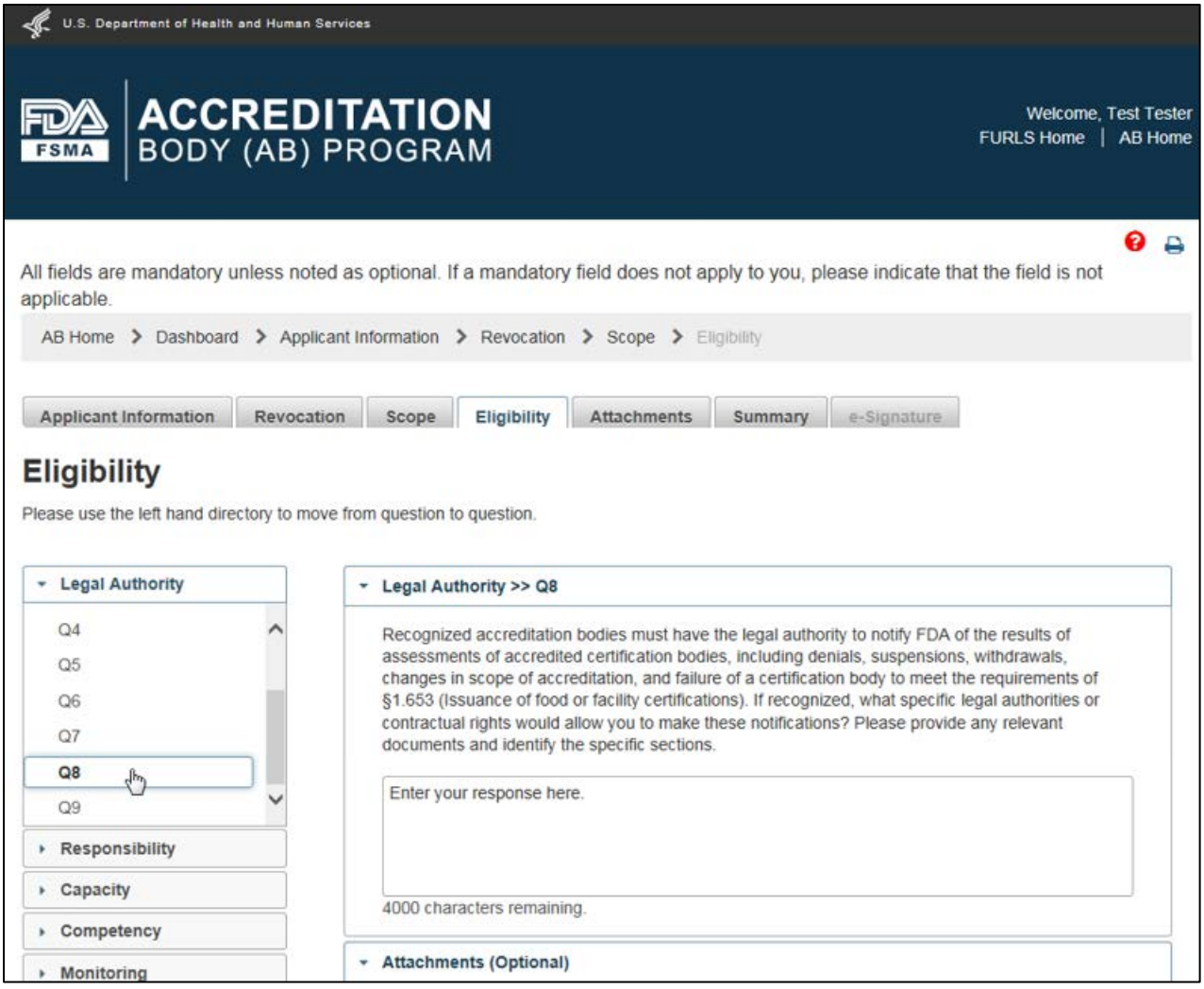


Each standard tab has a definition and associated questions. Click the standard drop-down to display the question links.

Select the question link to display the “Question and Response” text box (Figure 5.9).

Note: You must answer all the questions to complete the application process.

Figure 5.9 – Completing Eligibility Standards Questions



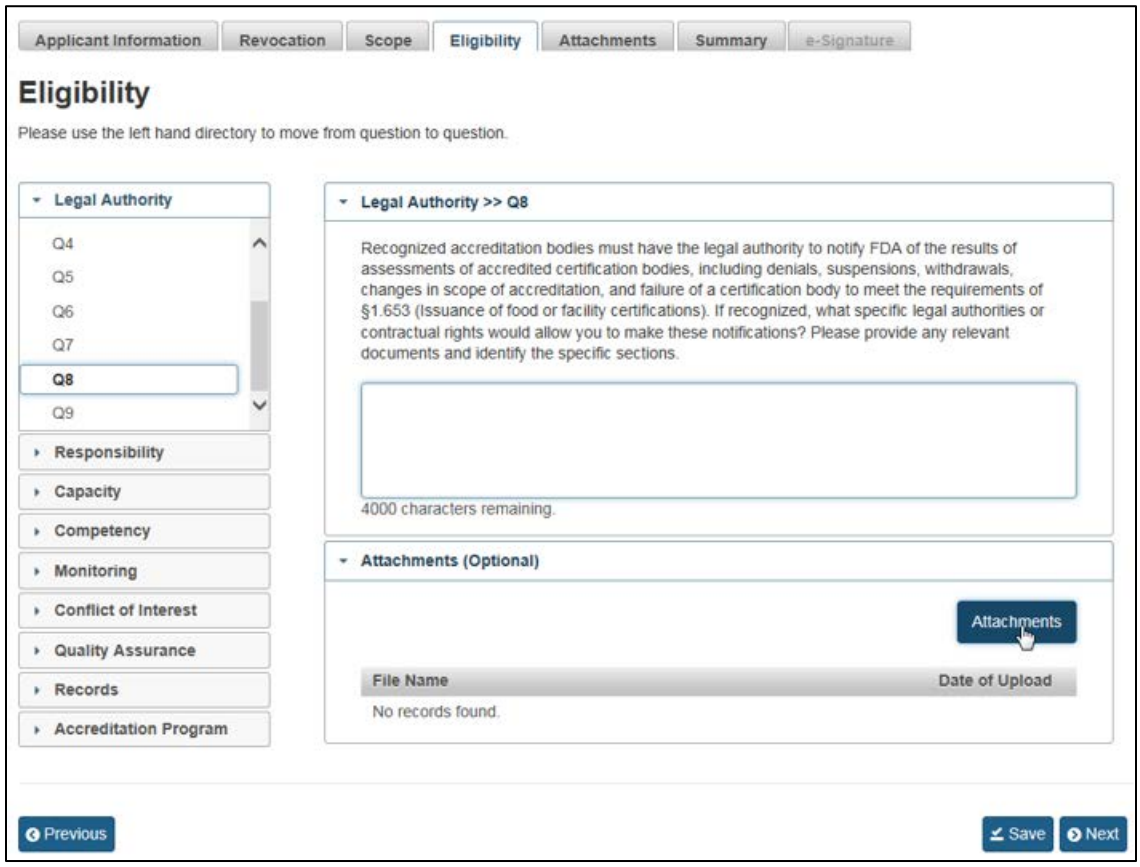
Attachments may be uploaded with each response. Attachments must be a document type supported by the system.

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

The maximum file size allowed is 50 MB.

Click the “Attachments” button to open the attachment screen (Figure 5.10).

Figure 5.10 – Opening Attachments Window



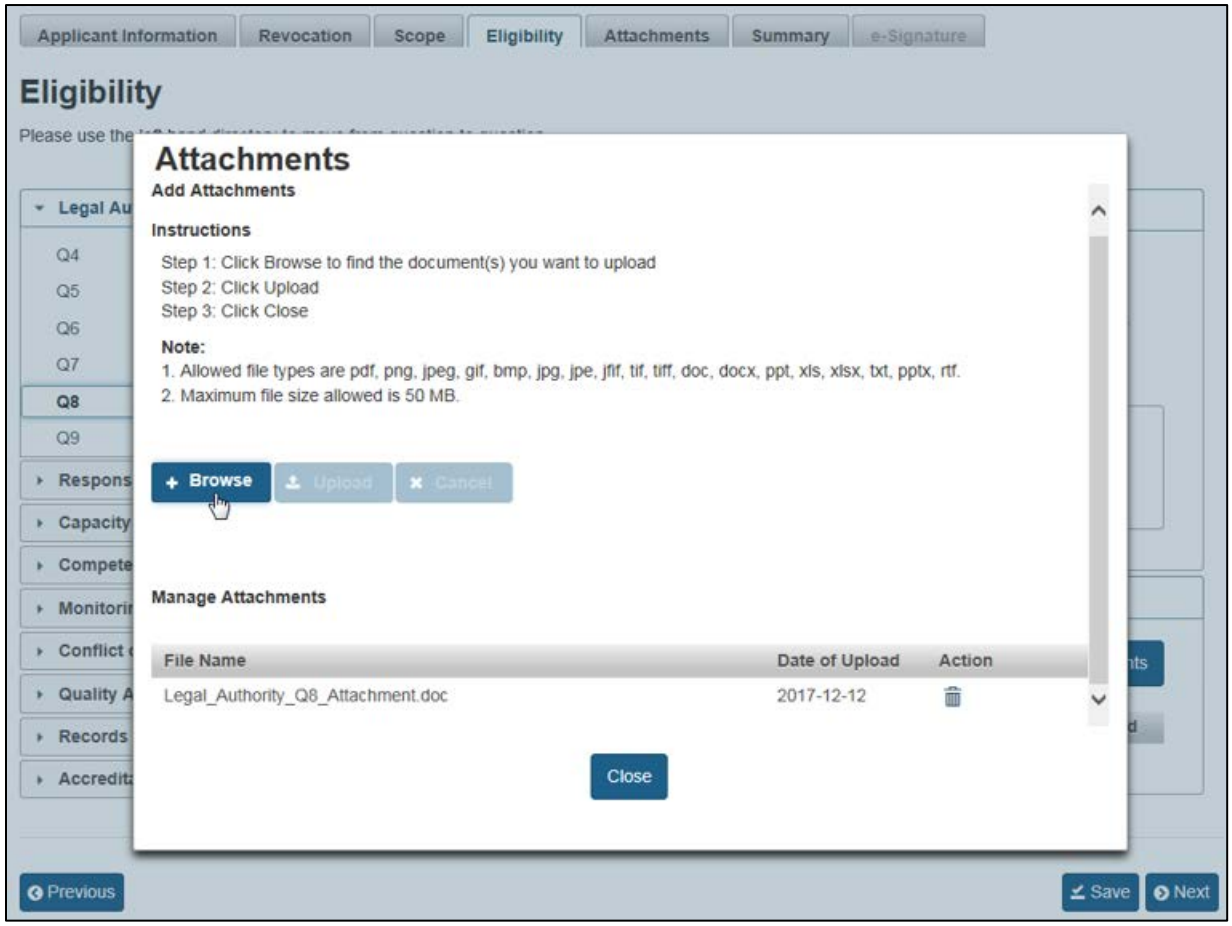
The system will display a pop-up window (Figure 5.11).

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 upload (Figure 5.11).

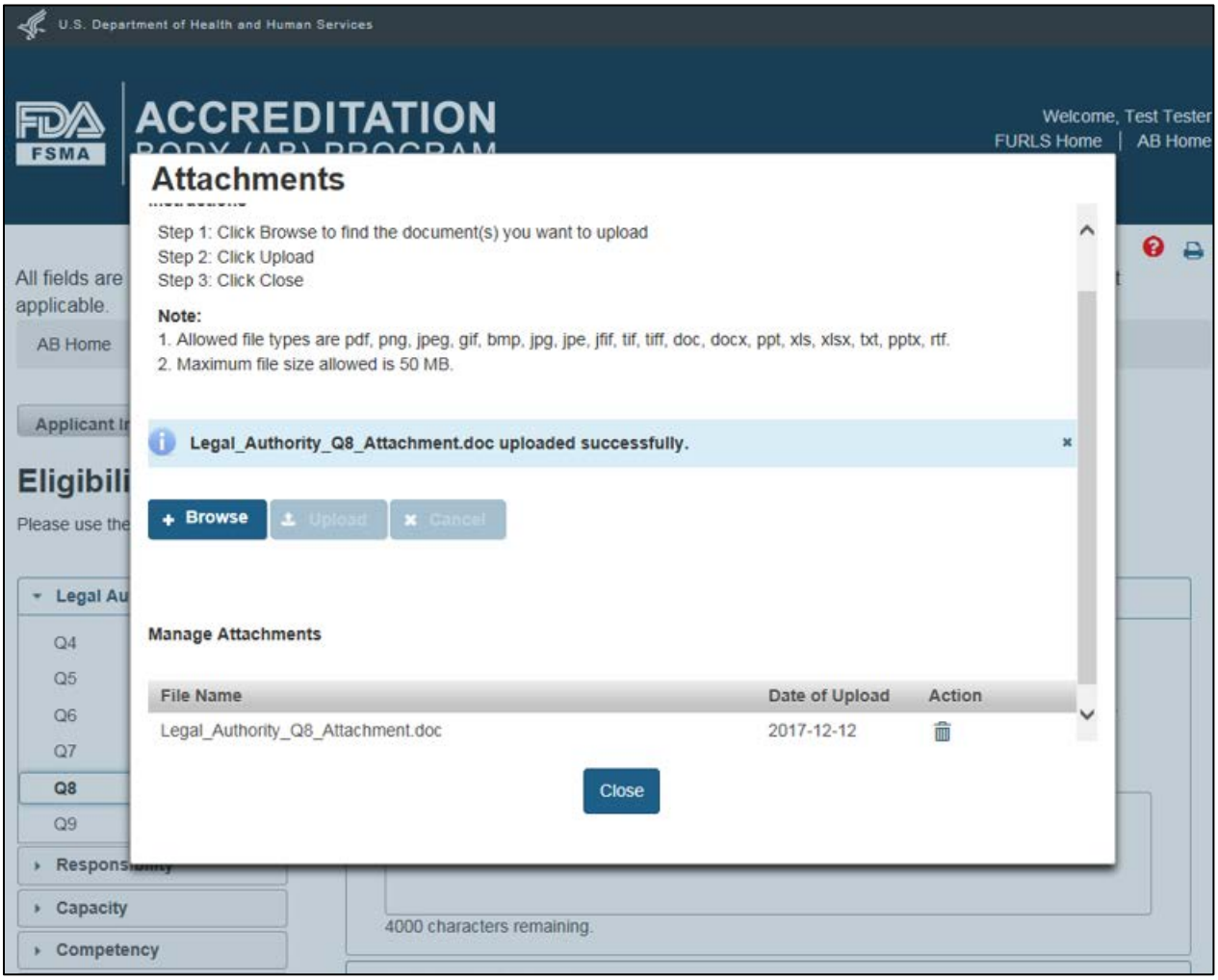
Figure 5.11 – Attachments Window



Once the upload is complete, a confirmation message with the file name will display in the "Attachments" window (Figure 5.12).

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

Figure 5.12 – Attachments to Eligibility Questions



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

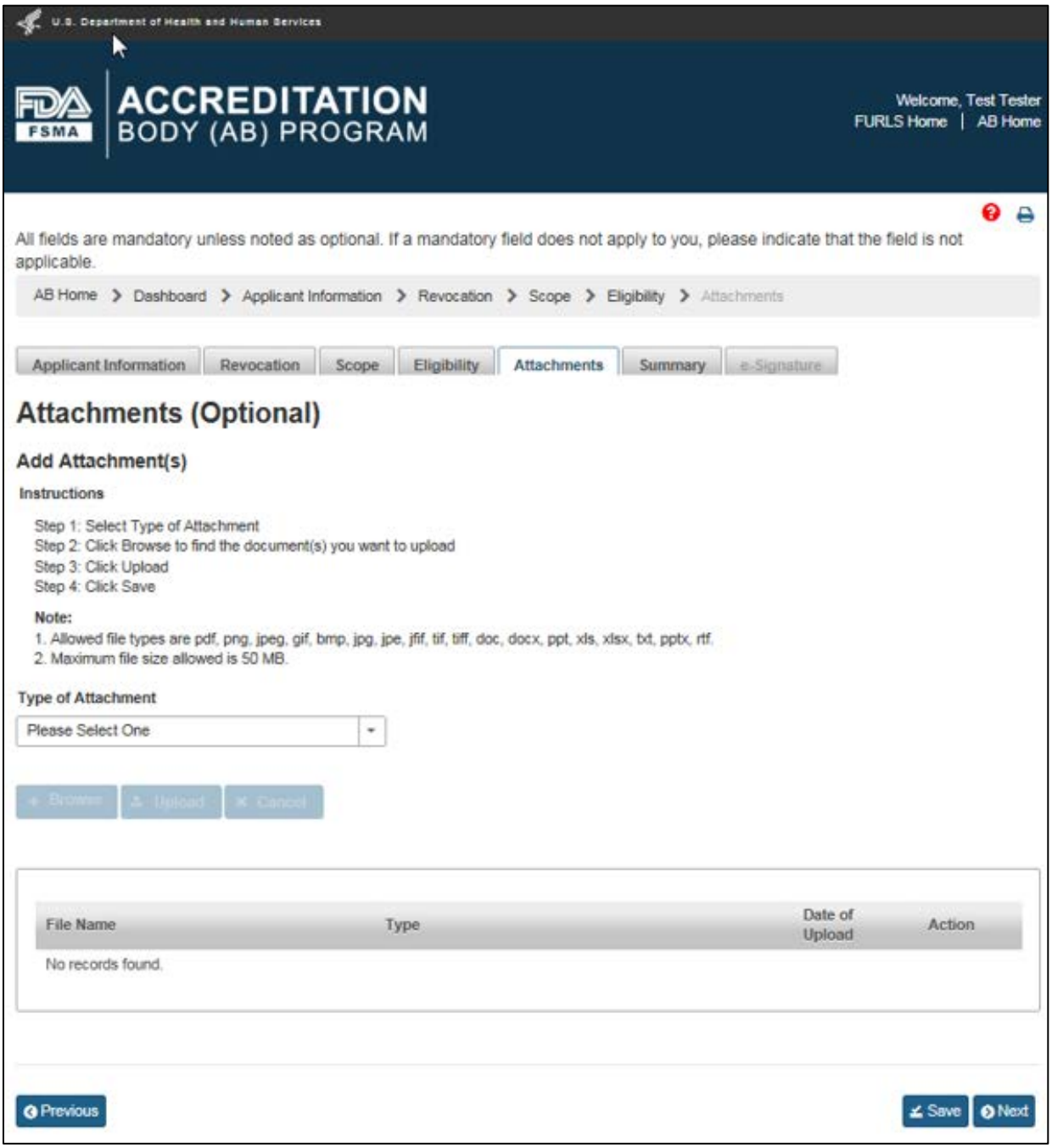
You must answer all of the Eligibility questions in order to complete the application. **Important:** Click "Save" upon completion.

Proceed to the next tab by clicking "Next" button or click directly on the "Attachments" tab.

To upload documents to your application, use the "Attachments" tab. This tab is optional.

Follow steps 1 - 4 in the instructions to upload attachments (Figure 5.13).

Figure 5.13 – Attachments



Select the type of attachment from the list (Figure 5.14).

Figure 5.14 - Type of Attachment

A text box labeled “Additional Description” will display if you select “Other” from the list (Figure 5.15).

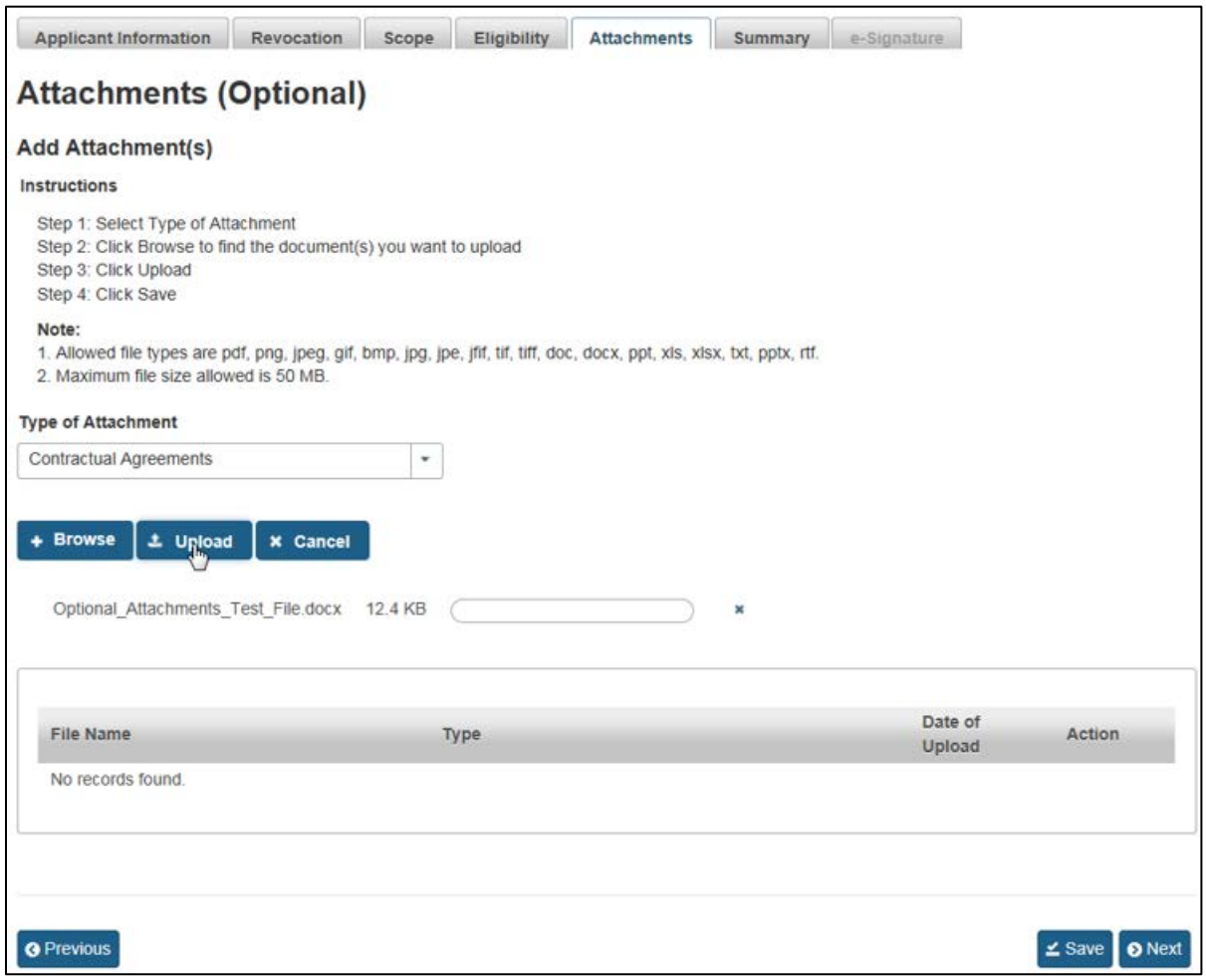
Enter a detailed description of the document type in the “Additional Description” field (maximum 45 characters).

Figure 5.15 – Other Attachments

Once you have selected a Type of Attachment, the “Browse” button becomes 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 5.16).

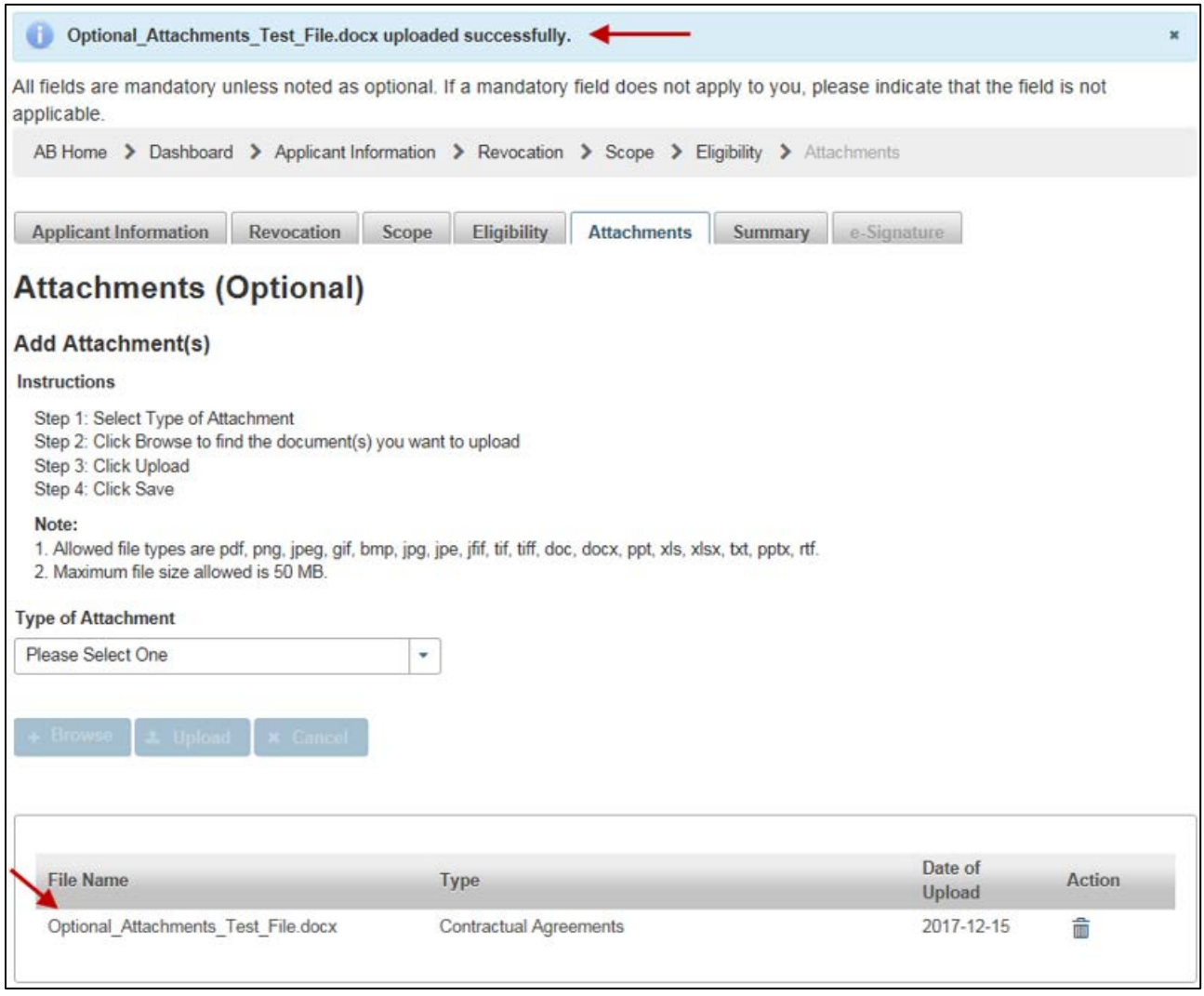
Figure 5.16 – Upload and Cancel Buttons



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

Confirmation of successful upload will be displayed at the top of the page upon completion (Figure 5.17).

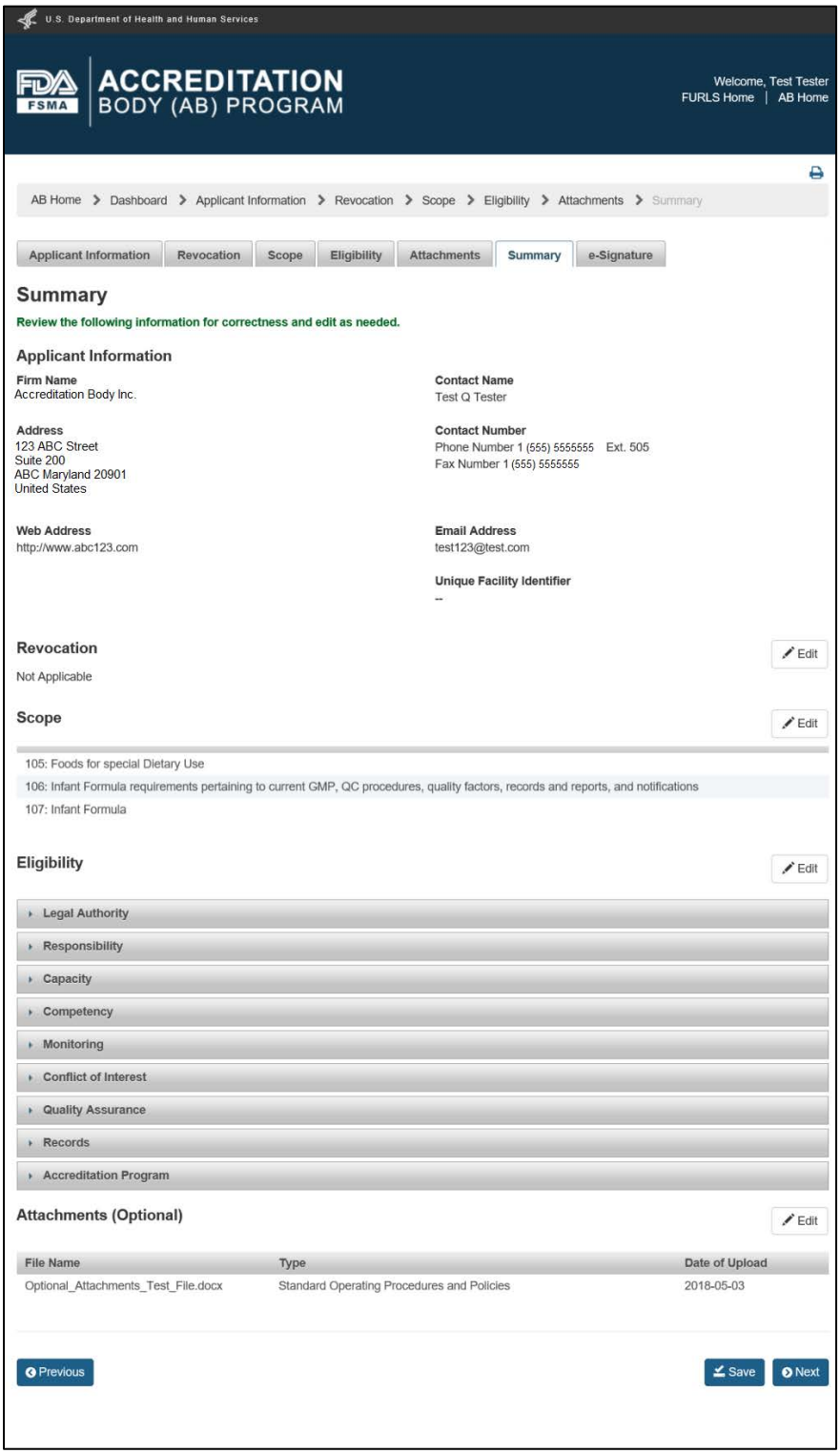
Figure 5.17 – Successful Upload Message



After the additional files have been uploaded, click the “Save” and “Next” buttons or, click the “Summary” tab.

The system will display the “Summary” page (Figure 5.18). Review the data for accuracy.

Figure 5.18 – Summary Page

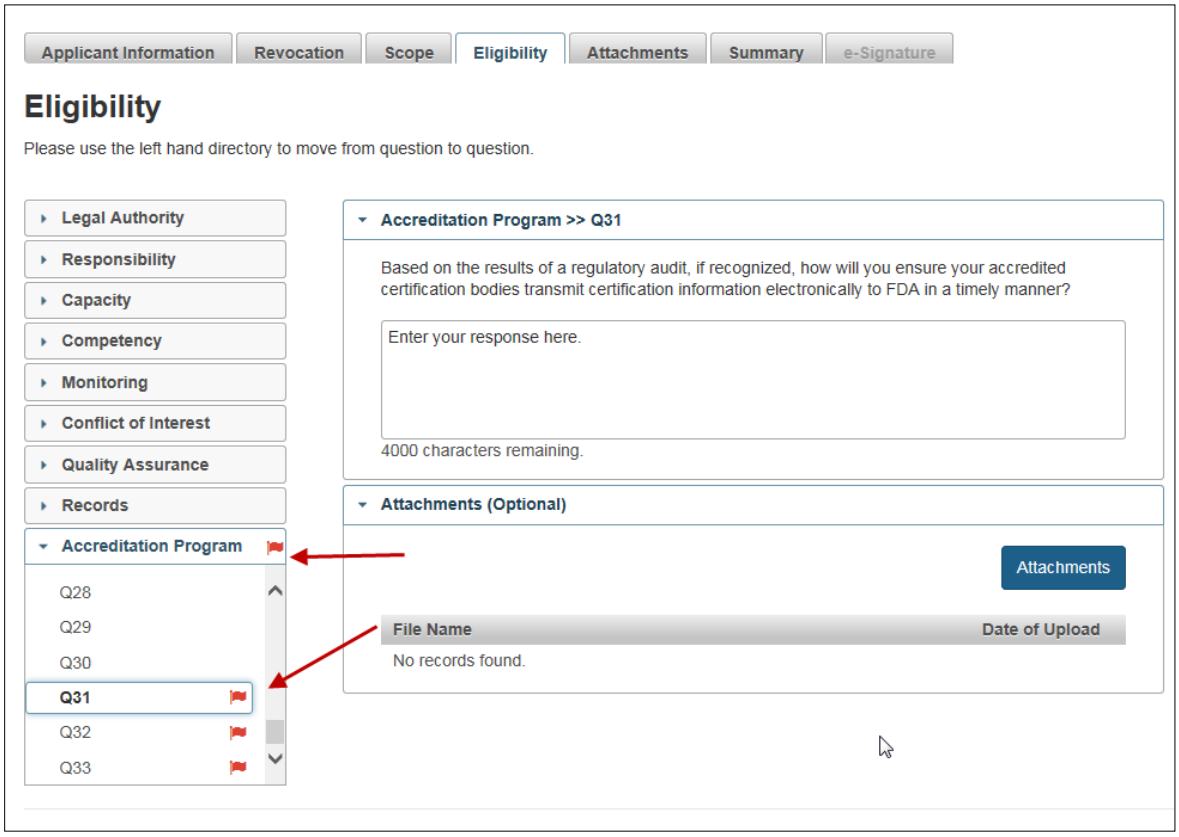


After reviewing the “Summary” page click the “Save” and then the “Next” button(s). The system validates all the information you entered. If an error is found, the system will post a relevant error message.

To be able to submit the application, correct any issues that were found and flagged by the system. The system marks errors with a red flag icon (Figure 5.19). Any eligibility area that contains an error will show a red flag in the drop-down menu.

Click the flag(s) to expand the drop-down menu to see which specific questions have an error.

Figure 5.19 – Submission Errors



If there are no errors, the system will display the “e-Signature” page (Figure 5.20).

Note: The “e-Signature” tab 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.

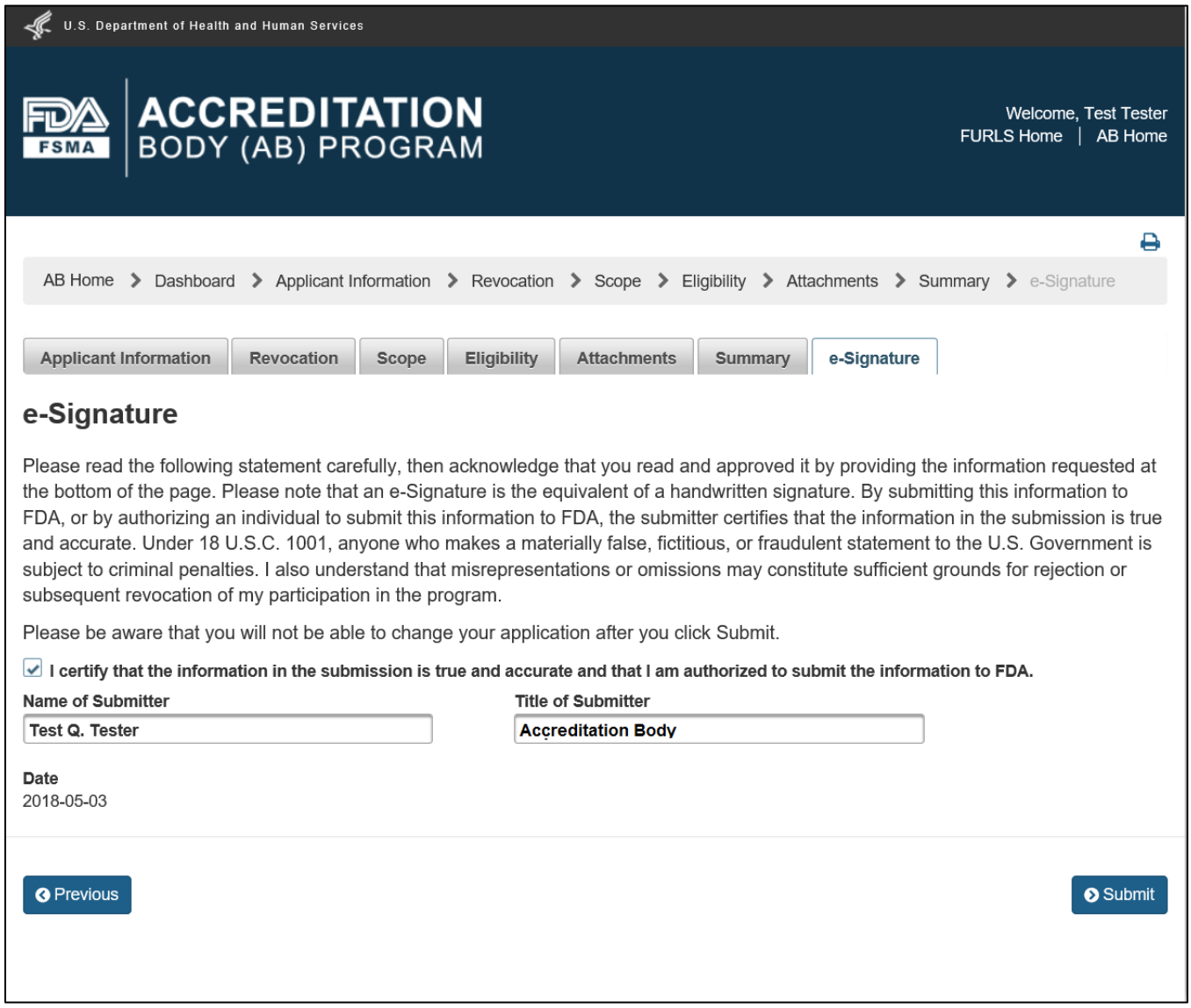
Click the check mark to indicate you certify the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA.

The following data fields are present:

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

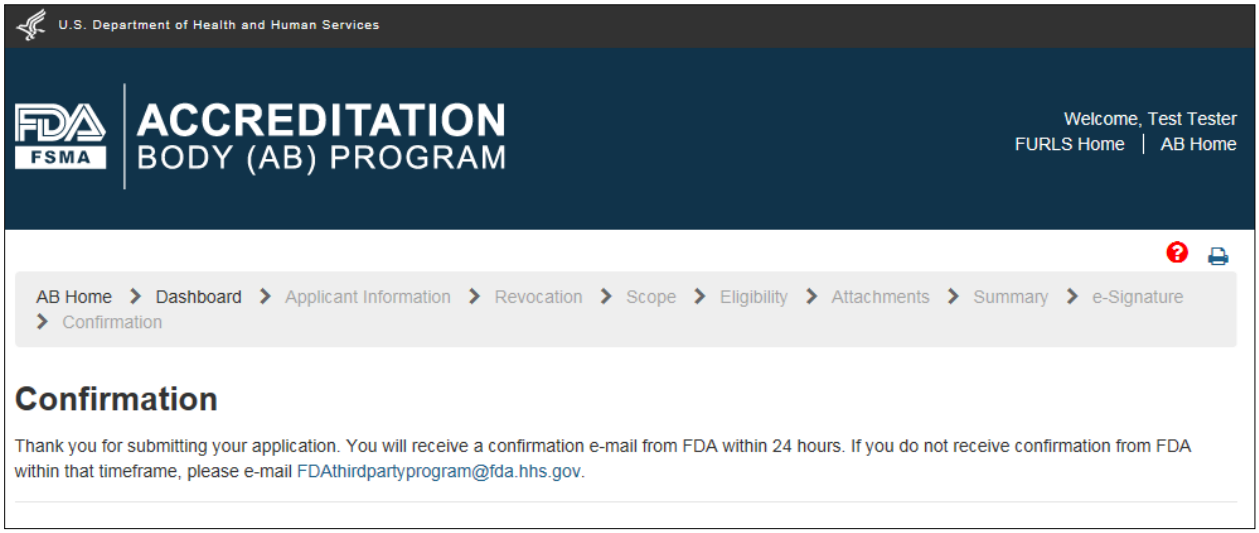
Fill in the required data fields, and click the “Submit” button.

Figures 5.20 – e-Signature Page



The system will post a confirmation message on the page (Figure 5.21).

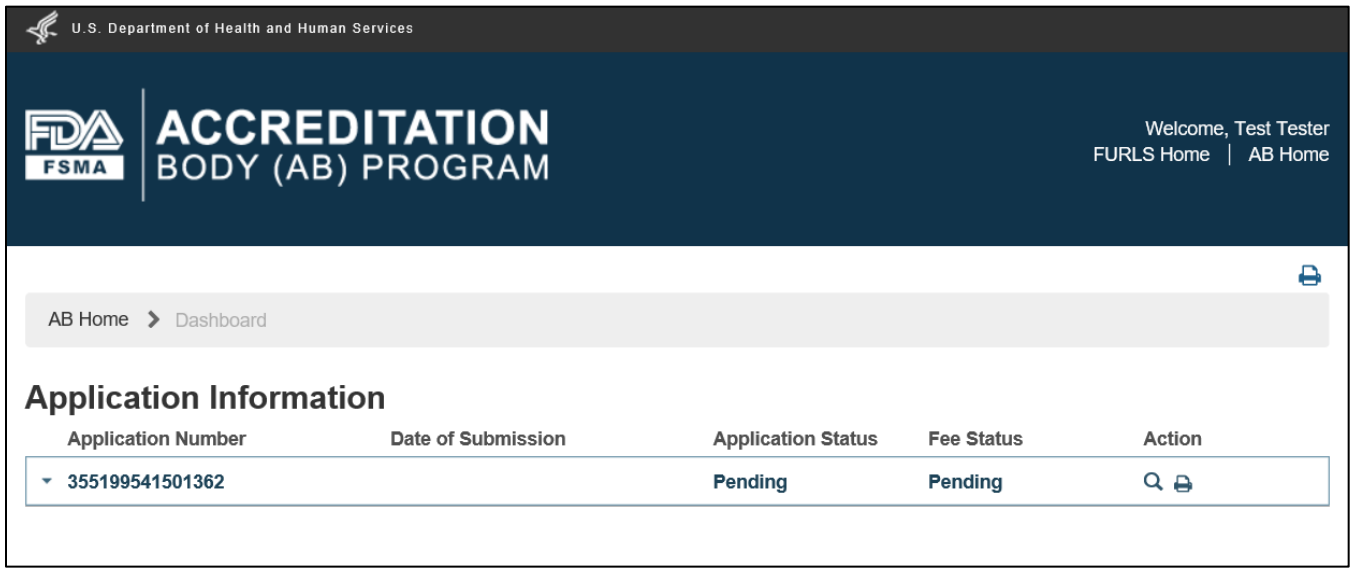
Figure 5.21 – Confirmation Message



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

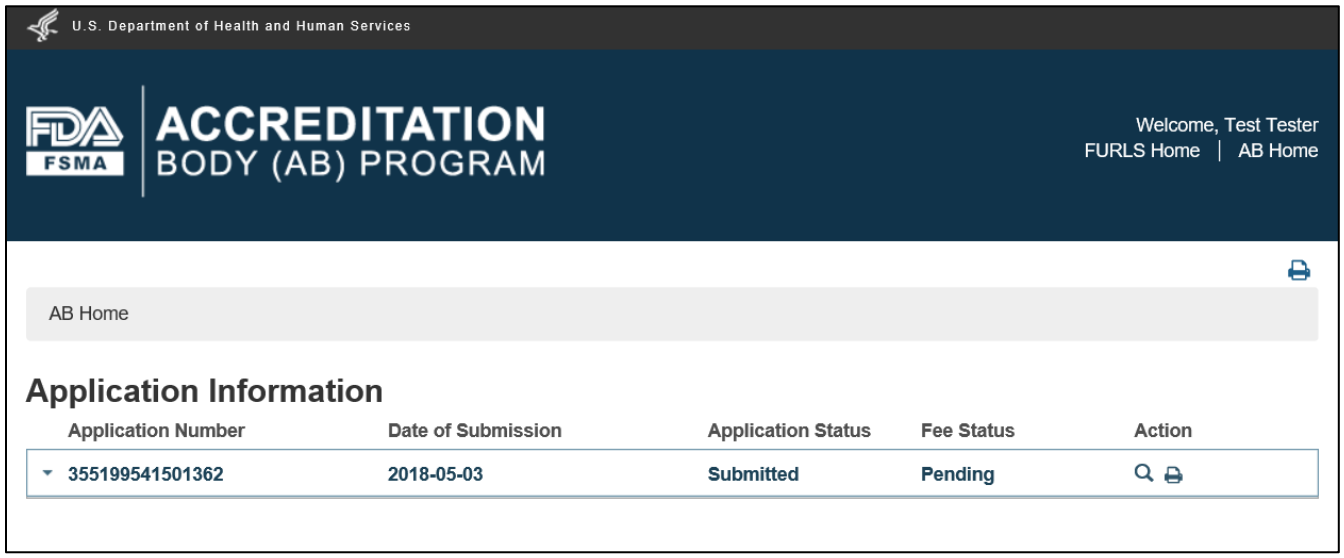
After the application has been submitted, it is assigned an Application Number and the Application Status will be displayed as “Pending” on the Dashboard (Figure 5.22).

Figure 5.22 – Application "Pending" Status



When FDA receives the completed application, the status on the dashboard will change to "Submitted" (Figure 5.23).

Figure 5.23 – Application "Submitted" Status



6 Application Returned for Further Action

The FDA may return an application if it determines that additional information is needed. The FDA will provide guidance to the applicant on what information is needed to address any concerns.

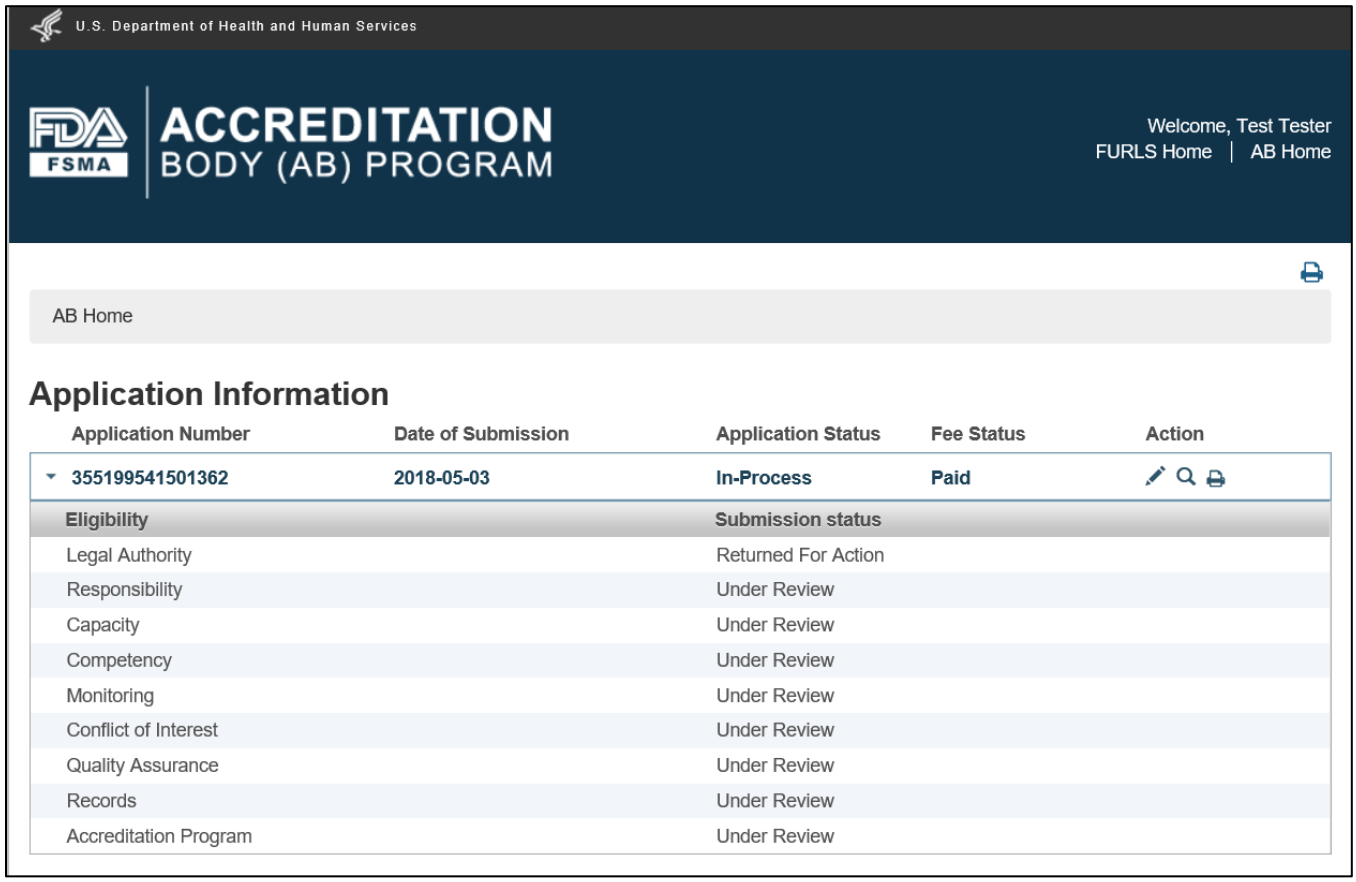
The applicant must submit the requested information before the FDA will continue the application review process.

When the application has been returned with additional information, the application status will display as “In-Process.”

The Eligibility criteria in question will display as “Returned for Action.”

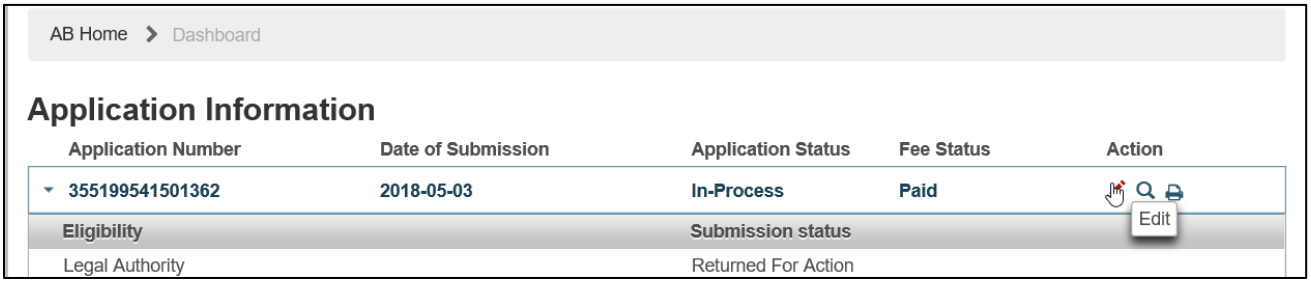
The status of all other Eligibility criteria will display as “Under Review” (Figure 6.1).

Figure 6.1 – Application “In-Process” Status



To address the information request from FDA, click the “Edit” (pencil) icon in the “Action” column on the “Application Information” page (Figure 6.2).

Figure 6.2 – Edit icon

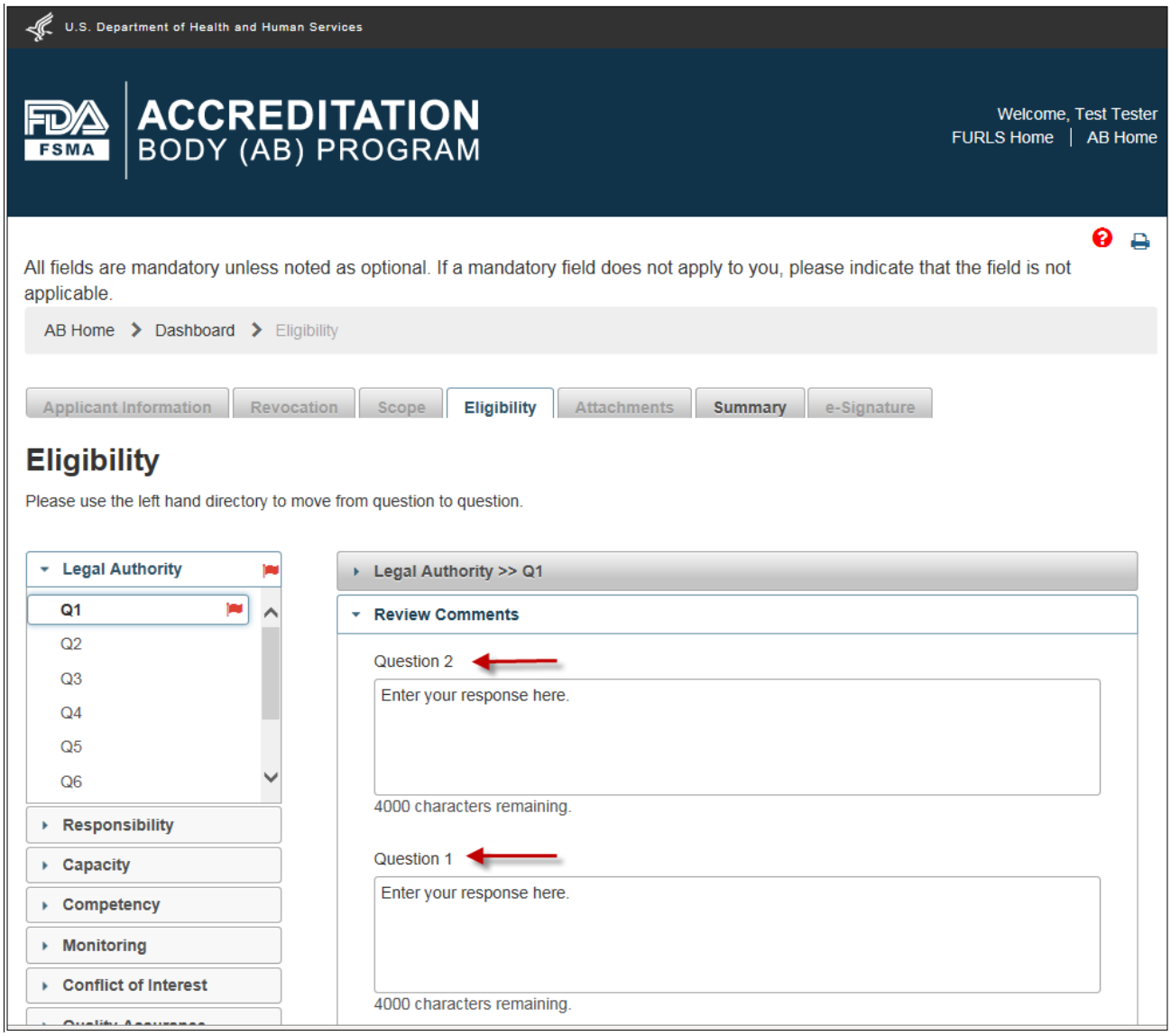


The system will open the “Eligibility” page (Figure 6.3). Eligibility criteria that display red flags indicate a response is needed. Click on the standard drop-down to expand the section.

Click on the questions marked with red flags to provide your response. Questions may have one or more requests (Figure 6.3).

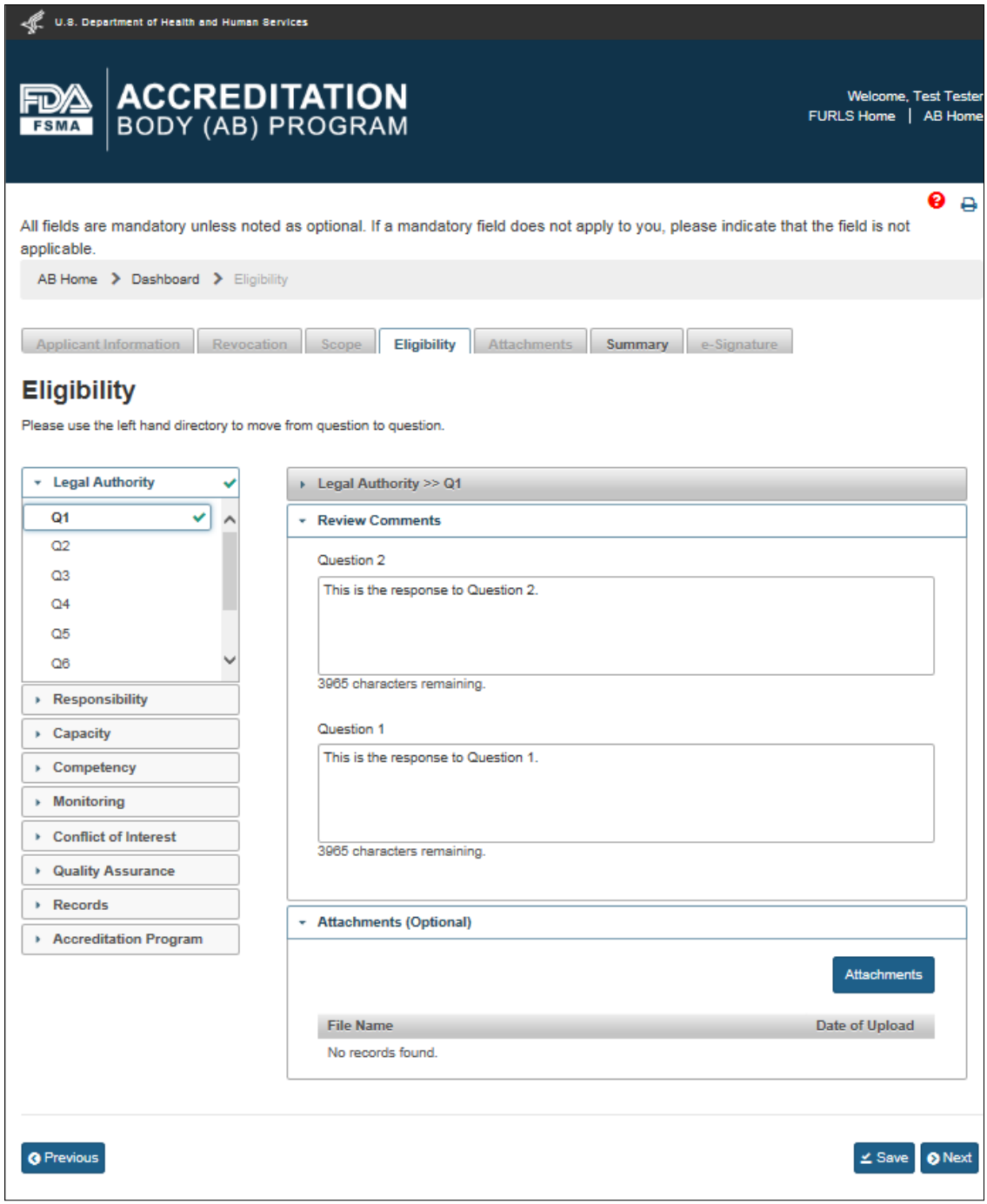
Go directly to the red-flagged standard(s) to provide the required answers, information and/or attachments.

Figure 6.3 – Eligibility Criteria Page with Red Flags



After you have addressed any outstanding items, the red flag will change to a green checkmark (Figure 6.4).

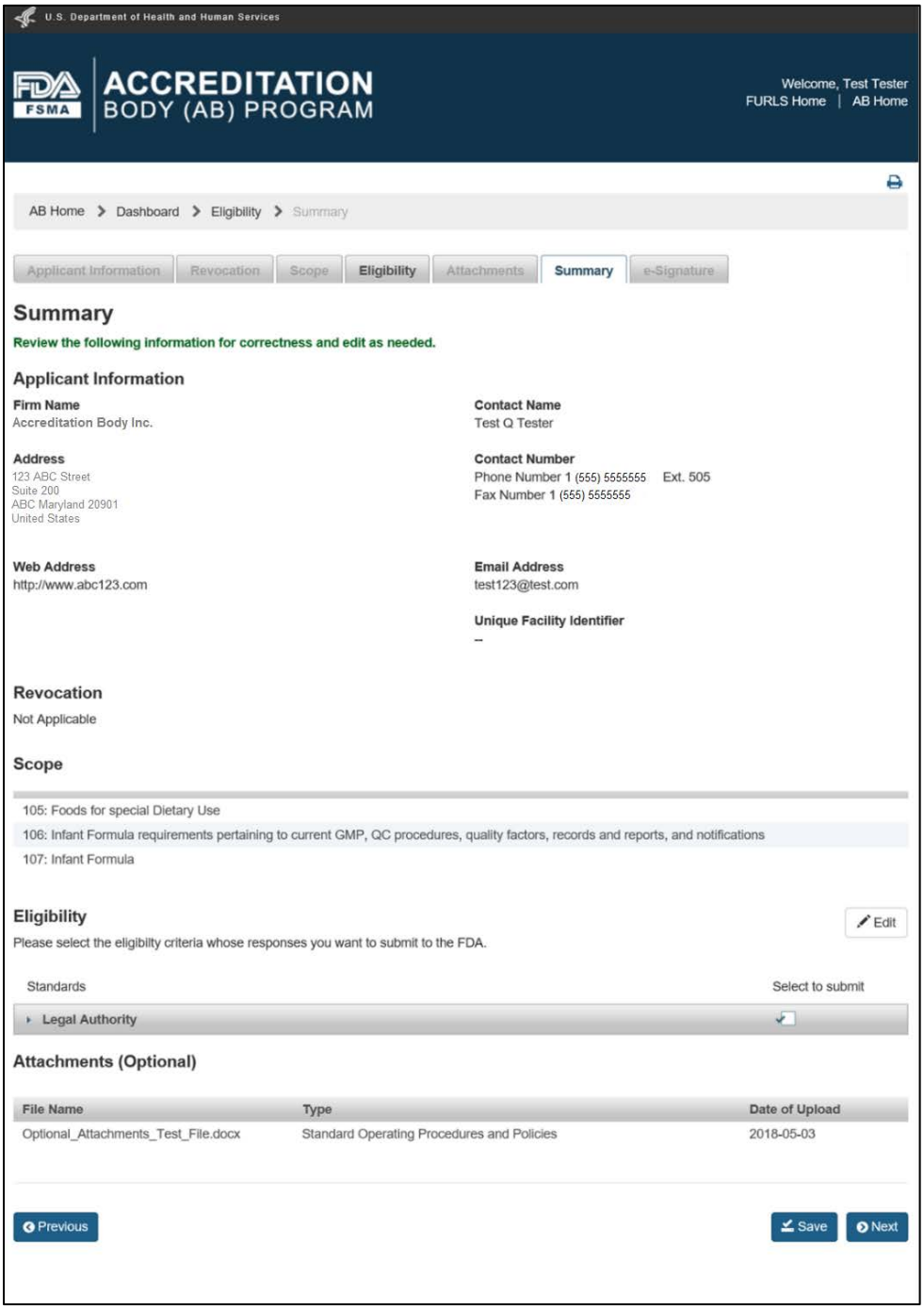
Figure 6.4 – Eligibility Criteria Page with Green Checkmarks



Once you have addressed all outstanding items, go to the “Summary” page by clicking the

"Save" and "Next" buttons from the "Eligibility" page, or clicking the "Summary" tab directly. Verify the information and select the checkbox next to the applicable standard being resubmitted (Figure 6.5). Click the "Save" and "Next" buttons.

Figure 6.5 – Summary Page



The system validates all the information and if no errors are found, the “e-Signature” page is displayed (Figure 6.6). If an error is found, the system will post an error message.

After you correct the error, re-submit the application.

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

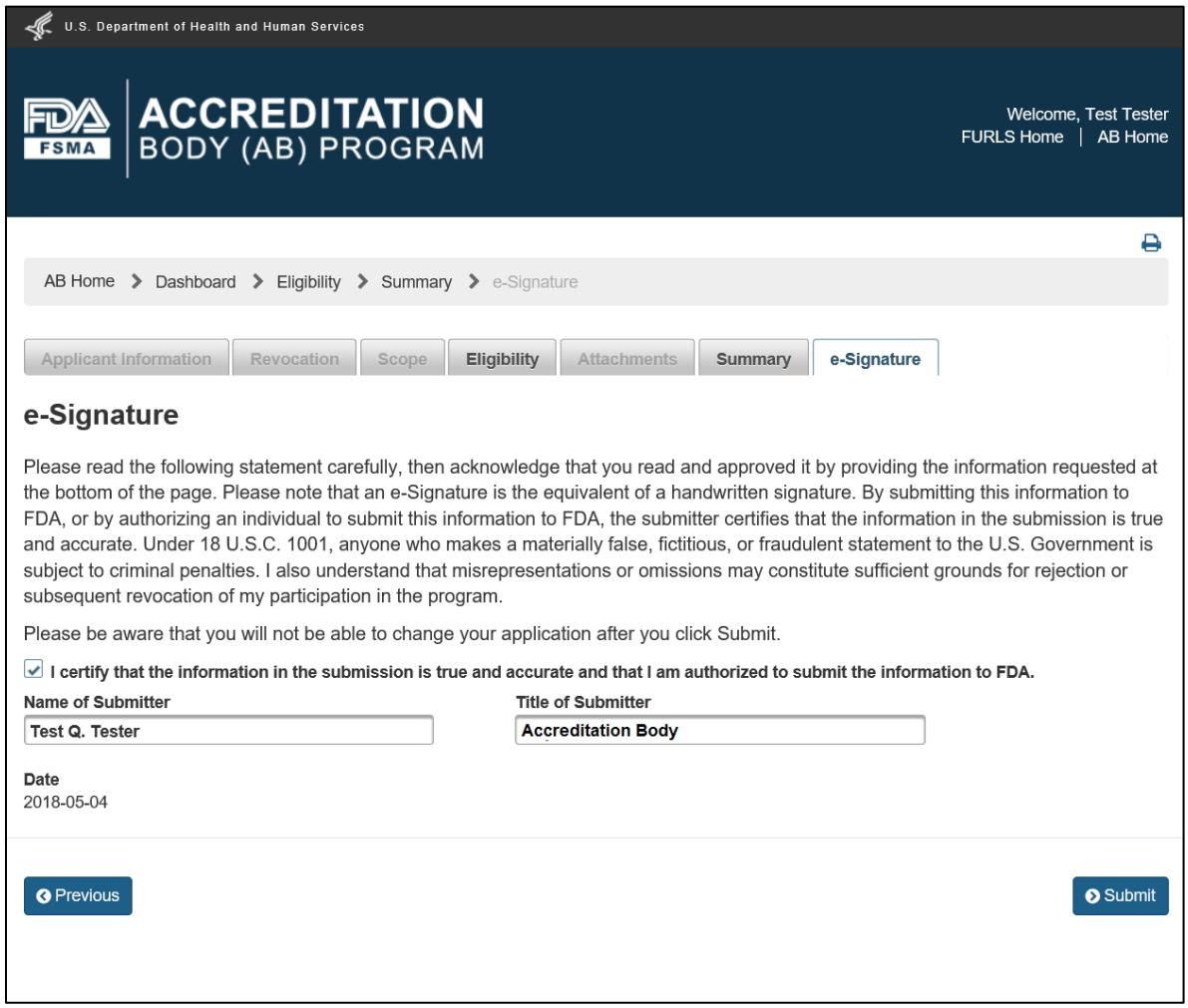
Click the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

The following data fields are present:

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

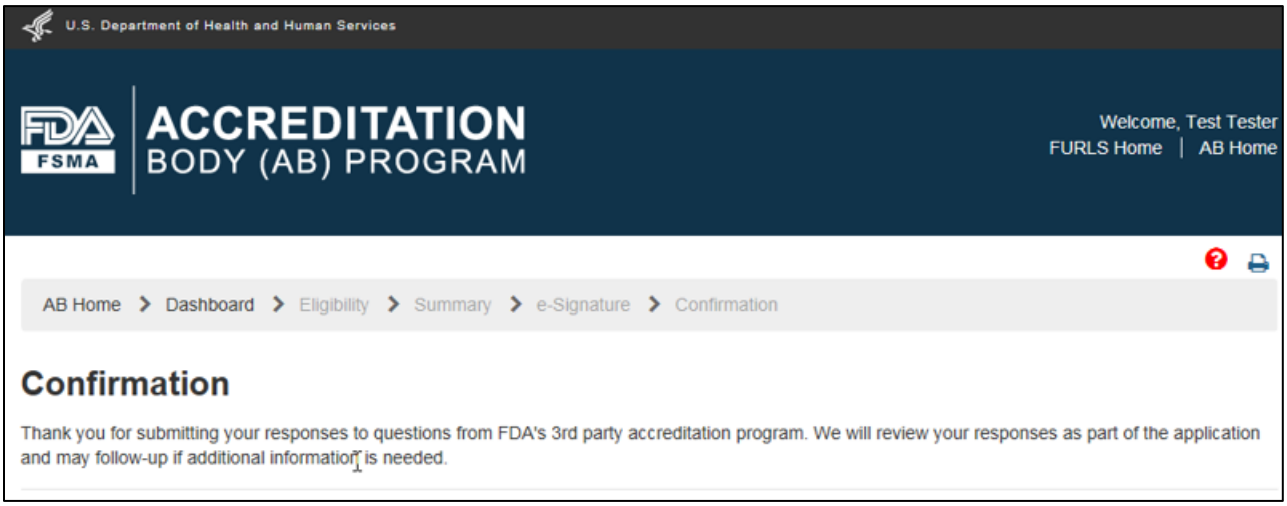
Fill in the required data fields and click the “Submit” button.

Figure 6.6 – e-Signature Page



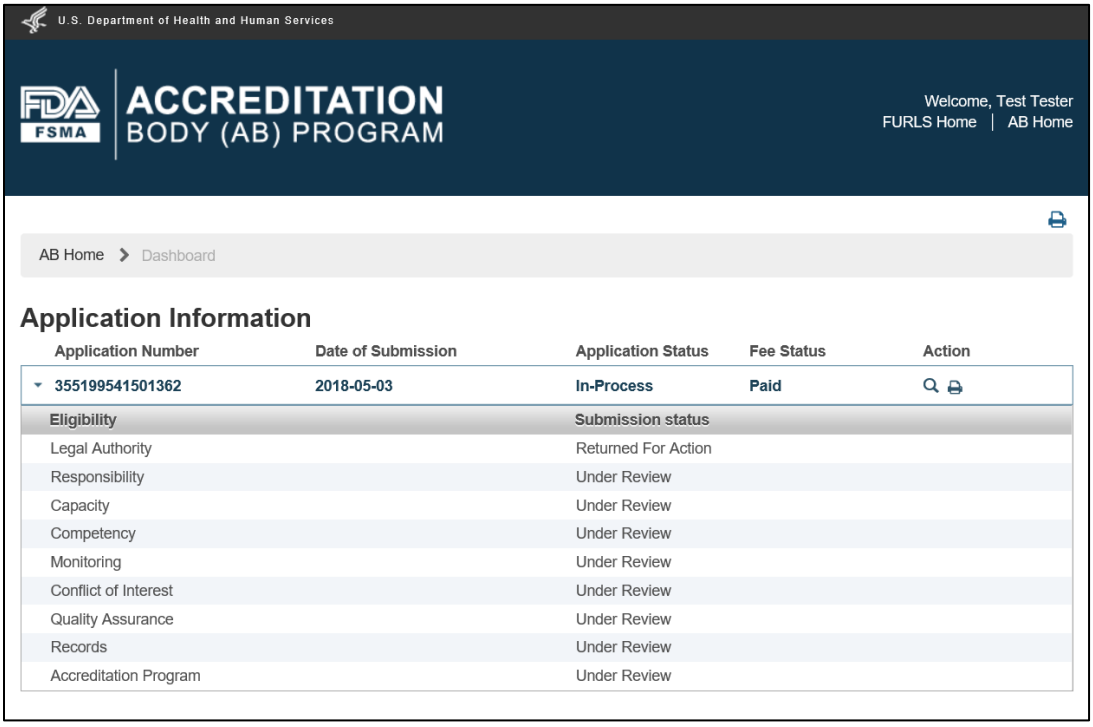
The system will post a confirmation message on the page (Figure 6.7).

Figure 6.7 – Confirmation Message



After the application has been re-submitted, the “Application Status” will become “In-Process.”

Figure 6.8 – Application “In-Process” Status

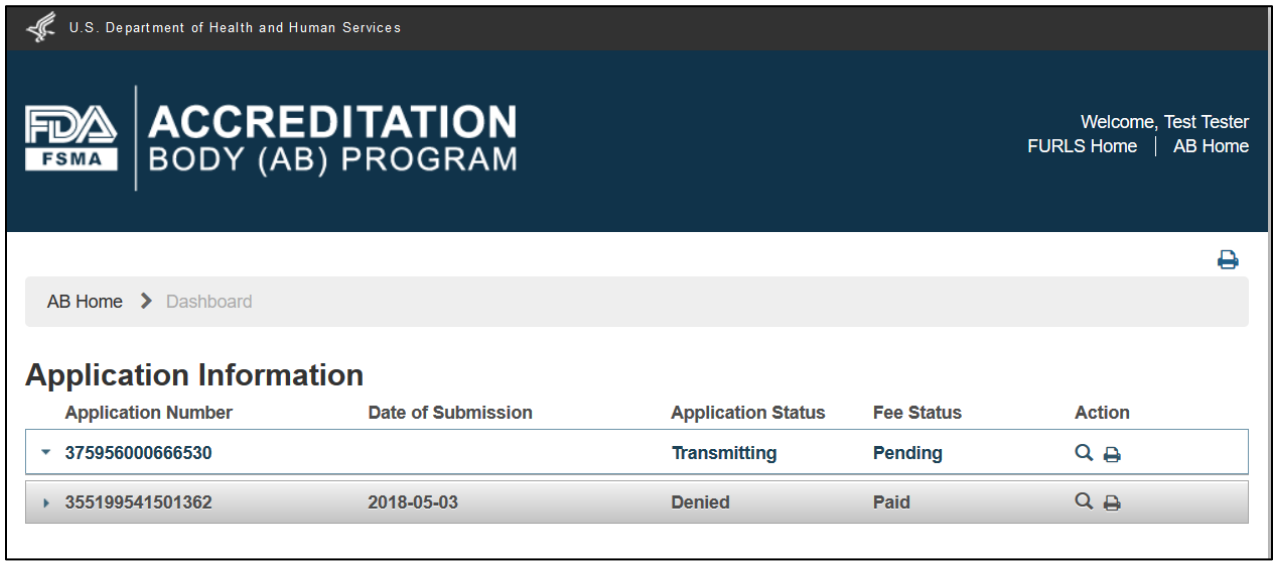


7 Reconsideration Request

You may submit a “Reconsideration Request” if any scopes have been denied. Navigate to the “Dashboard” to check the status of your application.

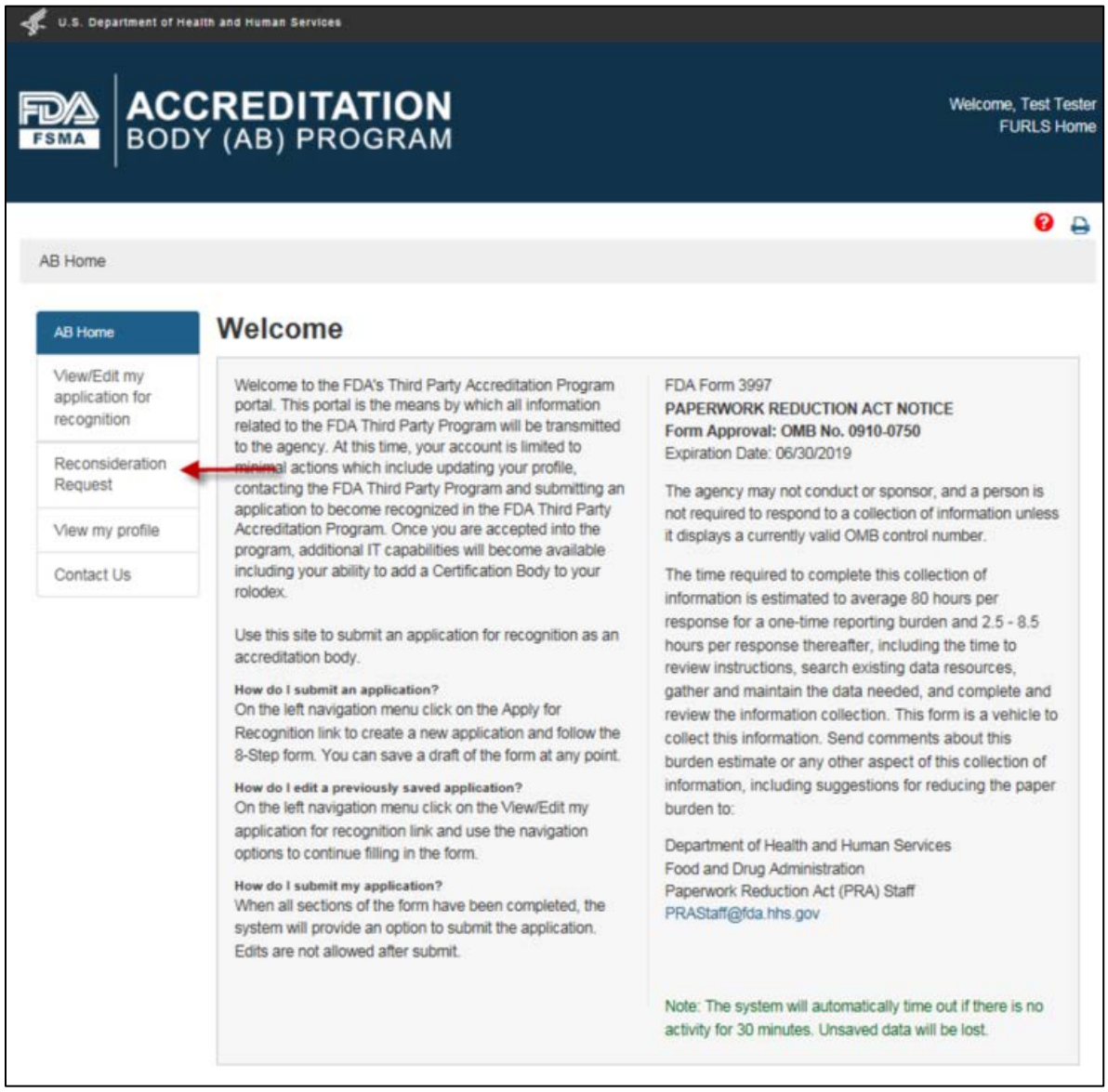
The “Application Status” field will display “Denied” if an application is not approved (Figure 7.1).

Figure 7.1 – Application “Denied” Status



You can access the reconsideration request from the “AB Home” screen. Click on the “Reconsideration Request” option on the left navigation menu (Figure 7.2).

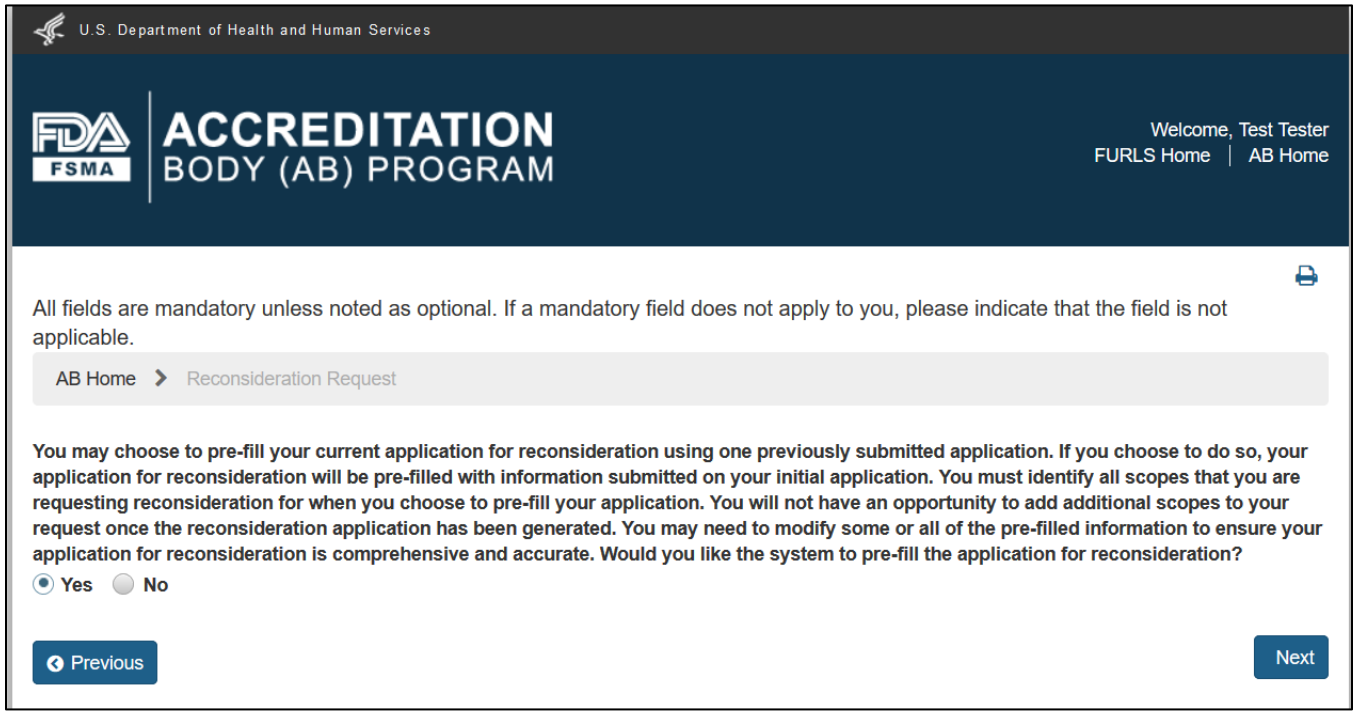
Figure 7.2 – AB Home – Reconsideration Request Menu Option



Select the link to “Reconsideration Request”; the system will open the “Reconsideration” page.

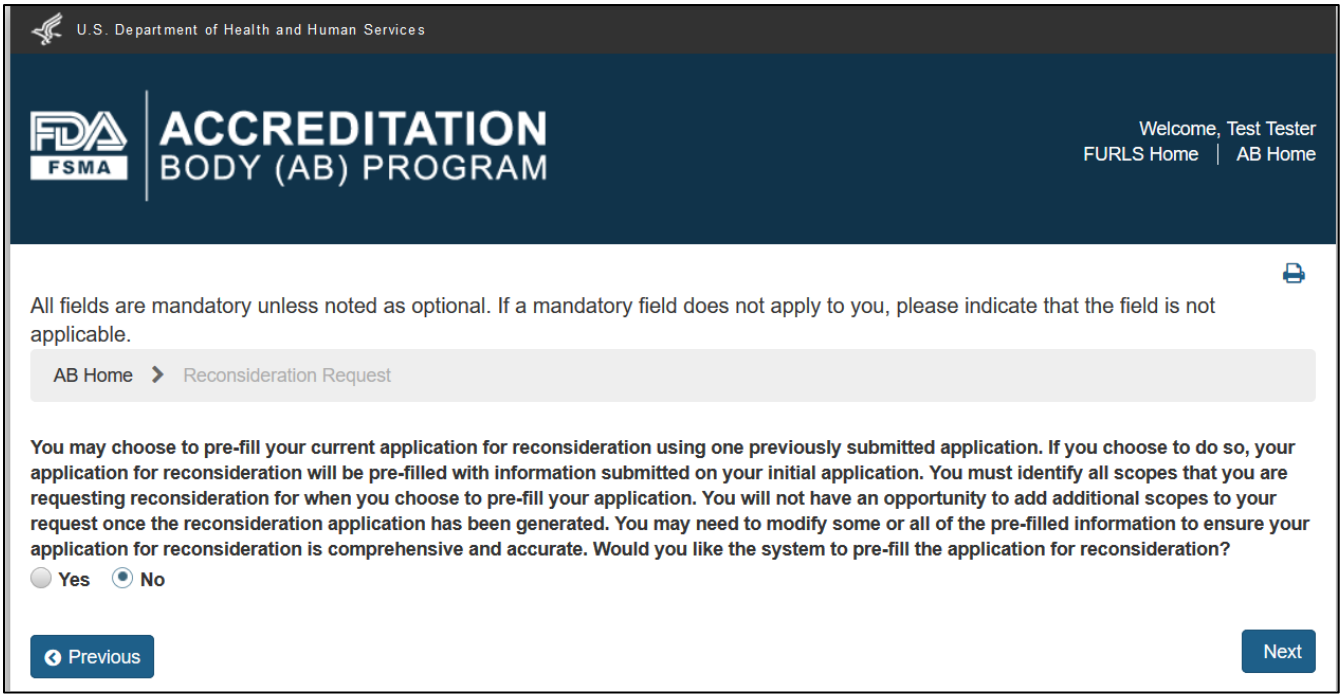
If you choose “Yes” (Figure 7.3), then the application will be prefilled with your previously-entered profile information; however, if you need to edit any information, you will need to do so in OAA.

Figure 7.3 – Reconsideration Page (“Yes”)



If you choose “No” (Figure 7.4), the applicant information will not be prefilled and all application information must be entered.

Figure 7.4 – Reconsideration Page (“No”)



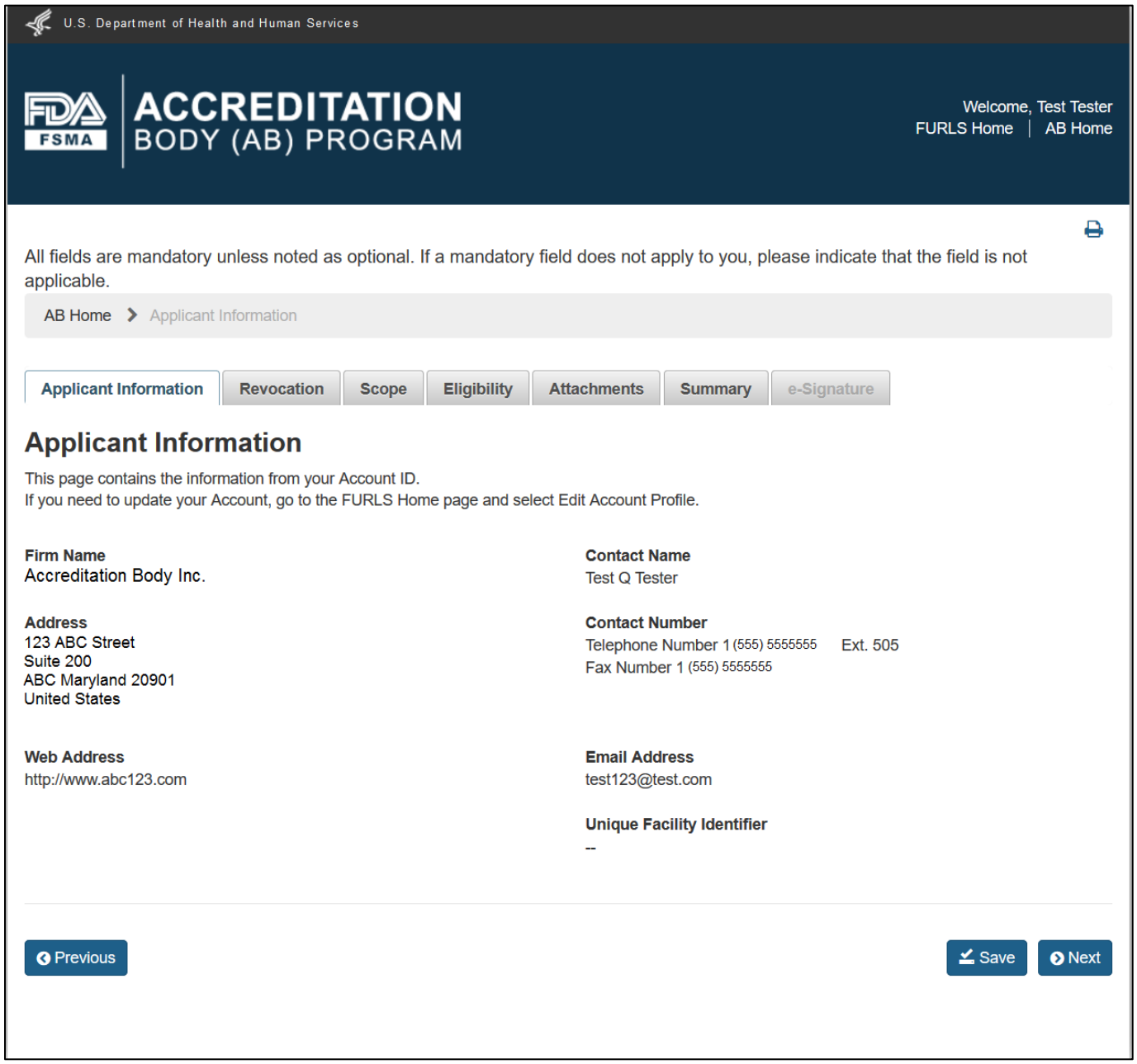
The “Next” button will appear at the bottom of the screen once a radio button is selected.

Click the “Next” button to go to the next page, “Applicant Information” (Figure 7.5). The information on this page is read-only.

The following navigation buttons are available:

- **Previous** – Directs to the previous page.
- **Save** – Saves any user input from the current page from session to session even if the application has not been completed.
- **Next** – Directs to the next page; will save any user input from other pages **only during the current session.**

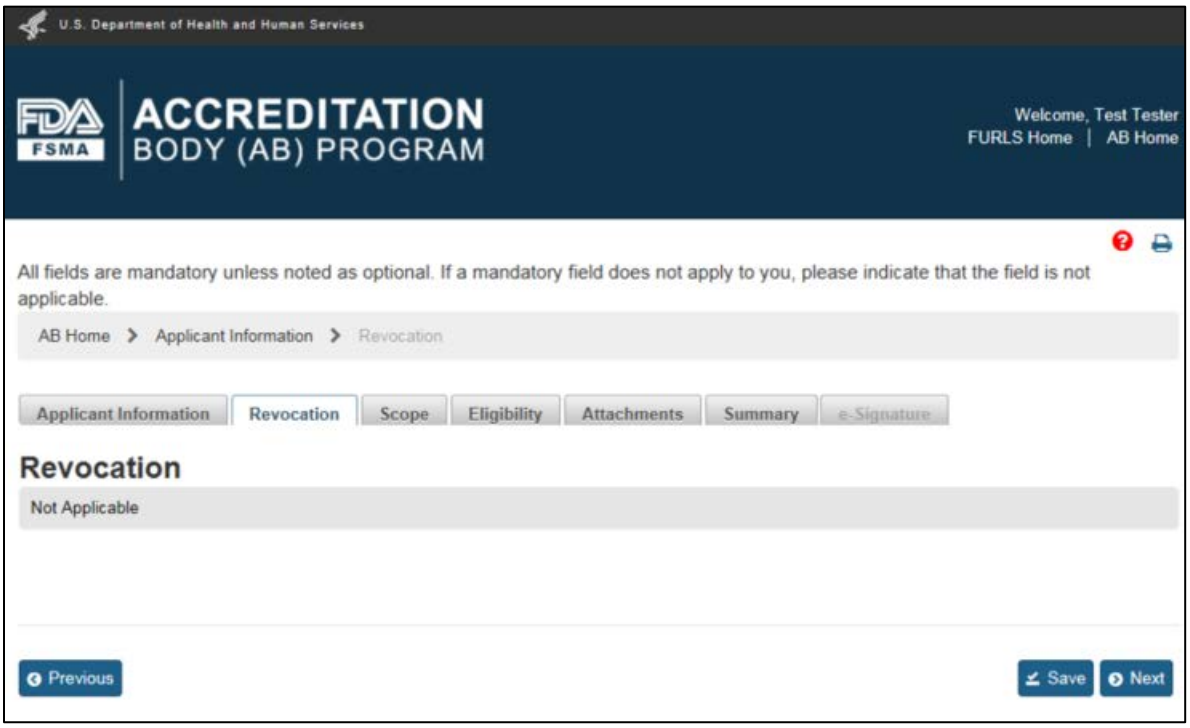
Figure 7.5 – Applicant Information Page



Click the “Next” button to go to the “Revocation” page (Figure 7.6).

The system will check for a record of previous FDA revocation of this AB. If none are found “Not Applicable” is displayed.

Figure 7.6 – Revocation Page



Click the “Next” button to open the “Scope” page (Figure 7.7). The “List of Original Scopes” shows all the scopes which were not approved in the original application.

Select the scopes you are applying for reconsideration.

Select at one (or more) scopes from the “List of Original Source Scopes” to complete your application.

To select a scope, left-click on the text. The text will appear highlighted. The following buttons may be used to add or remove selected scopes:

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

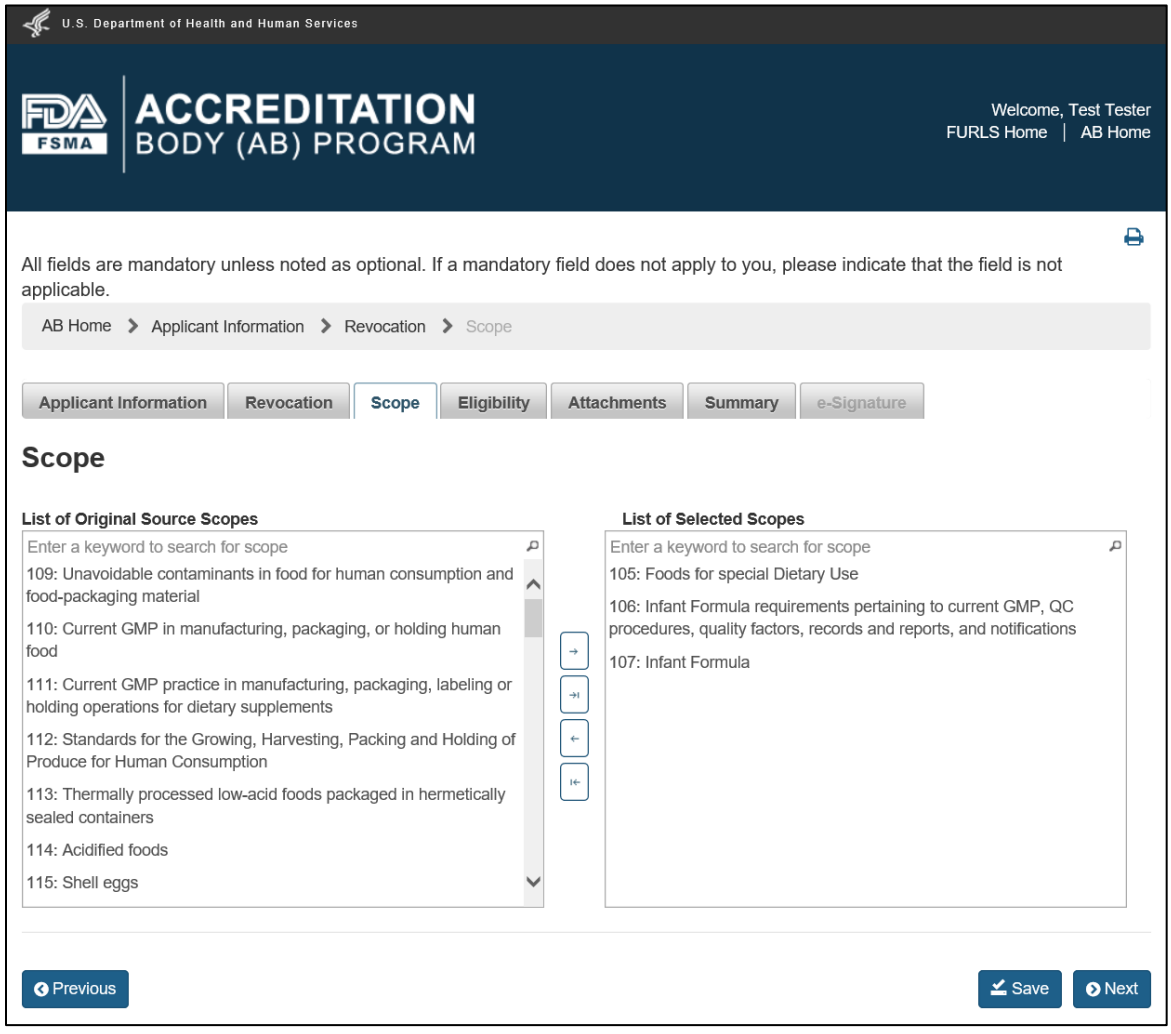
Use the scroll bar at the bottom of the “List of Original Source Scopes” to see the full titles of scopes.

A keyword(s) search can be performed in either the “List of Original Source Scopes” or “List of Selected Scopes. Type the keyword(s) in the Search bar (as was shown in Figure 5.7). The search results can be added or deleted from the respective lists.

Clear the Search box by using the “Backspace” key or highlighting the text and pressing the “Delete” key.

Note: Even if you select “Yes” on the “Reconsideration” page the system will not prefill the scopes.

Figure 7.7 – Scope Page

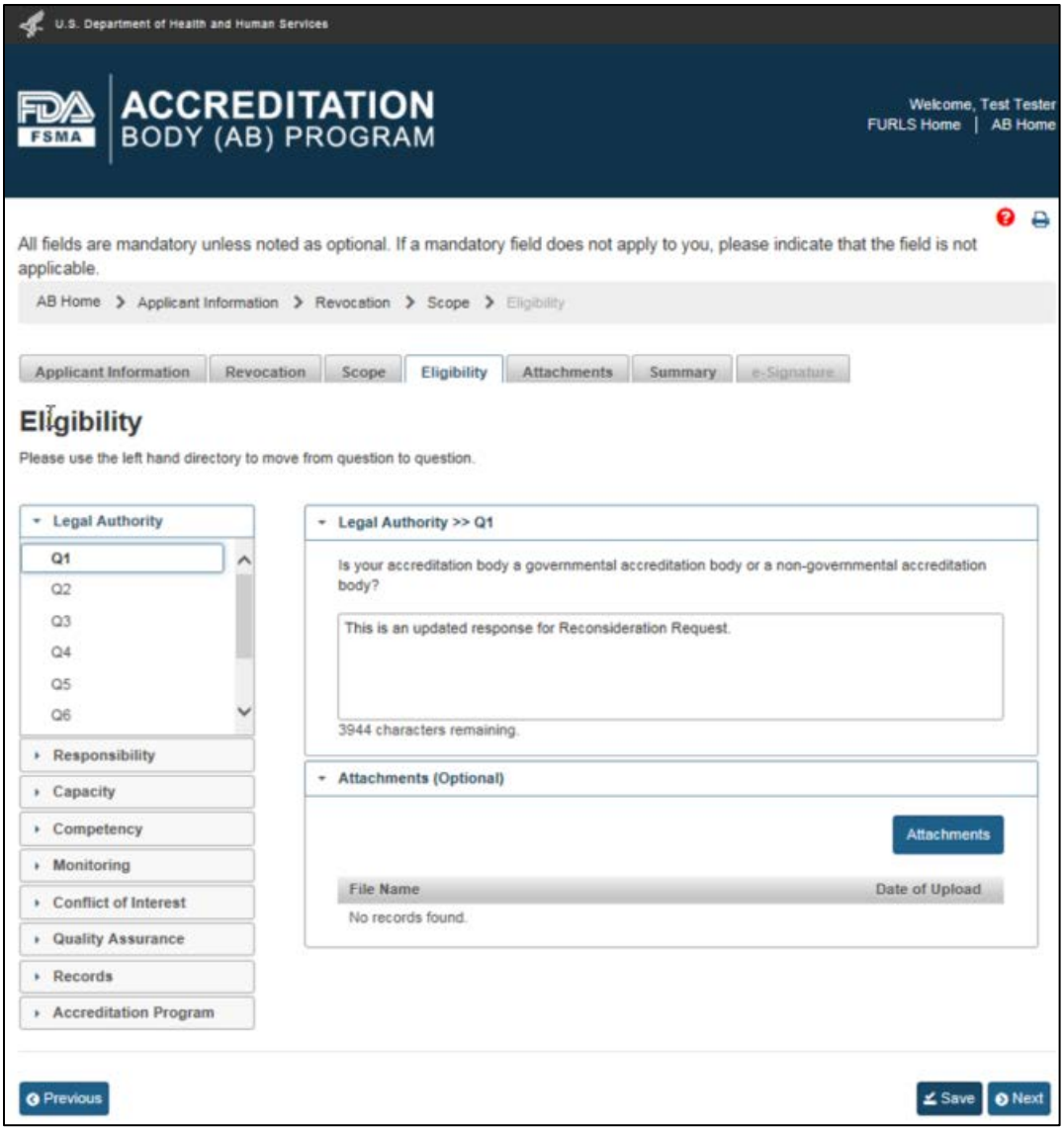


Click the “Next” button and go to the “Eligibility Criteria” page (Figure 7.8). This page will be prefilled with the information you provided in the initial application if you selected “yes” on the initial Reconsideration page (See Figure 7.3).

Update the page, as needed, to support your reconsideration request.

Click the “Save” button to save any changes.

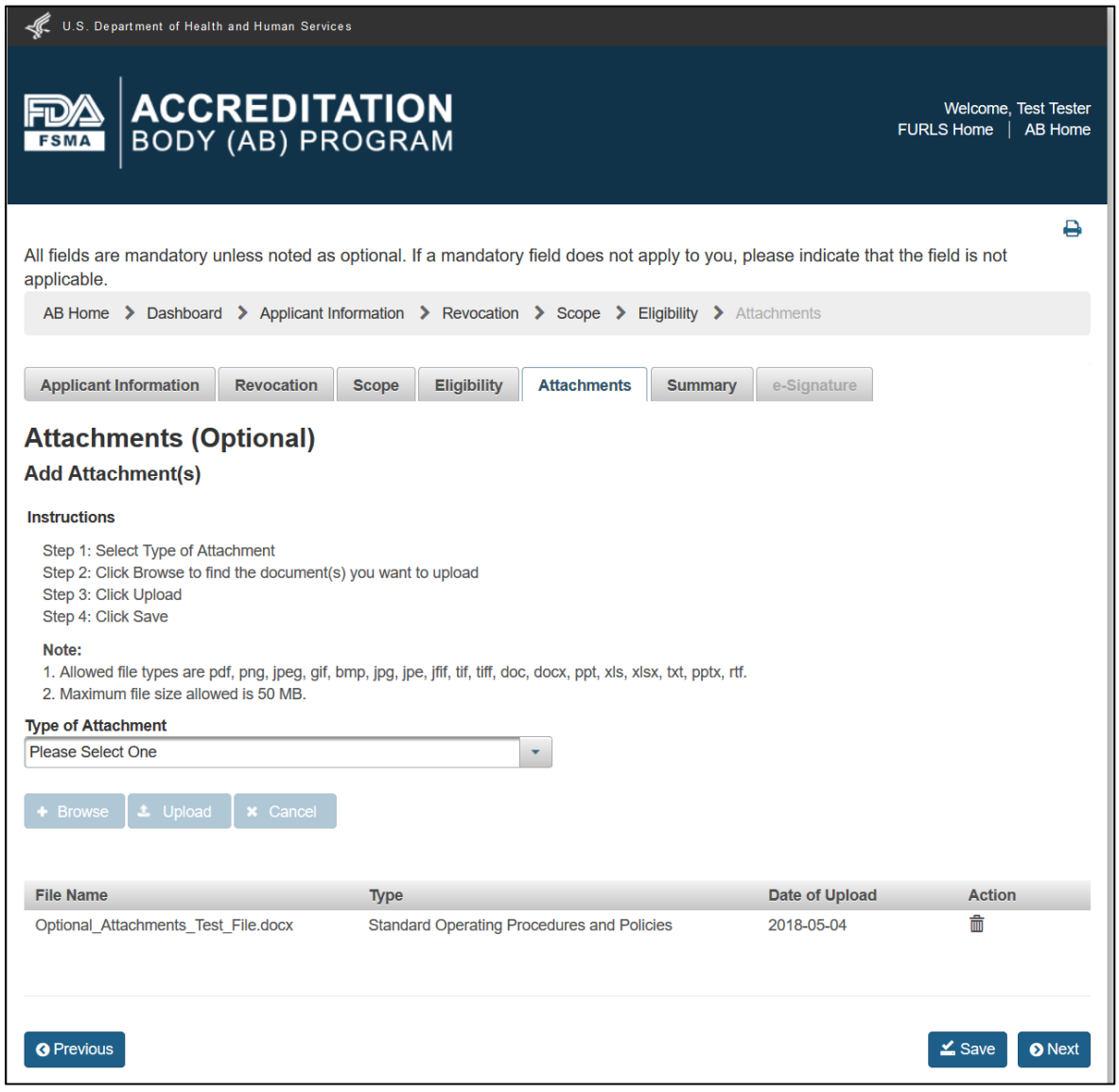
Figure 7.8 – Eligibility Criteria Page



Click the “Next” button to go to the “Attachments” page (Figure 7.9).

Upload files in the “Attachments” page by following the four-step process outlined on the page. The system displays uploaded files in the table at the bottom of the page.

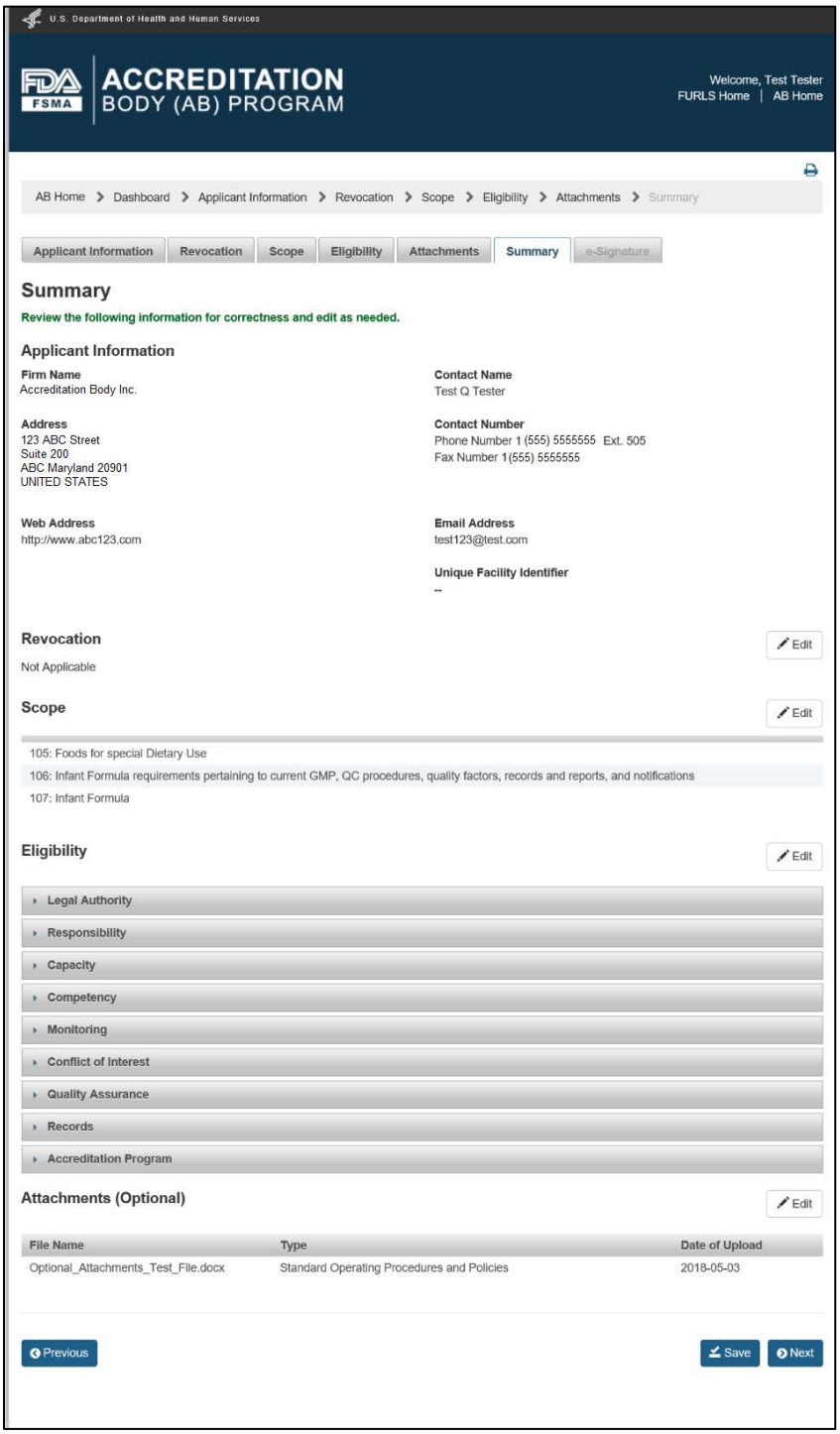
Figure 7.9 – Attachments Page



Note: The “Attachments” page is optional. You may choose to click the “Save” button on the “Eligibility Criteria” page, and then select the “Summary” tab, which will open the “Summary” page (Figure 7.10) to bypass the “Attachments” page.

Within the “Summary” page, review the application information and make any edits, if needed.

Figure 7.10 – Summary Page



After completing the “Summary” page, click the “Next” button to move to the “e-Signature” page.

The system will validate that all required fields have been completed. If no errors are found, the system opens the “e-Signature” page (Figure 7.11). If an error is found, the system will post an error message.

To be able to submit the application, correct any issues that were found.

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

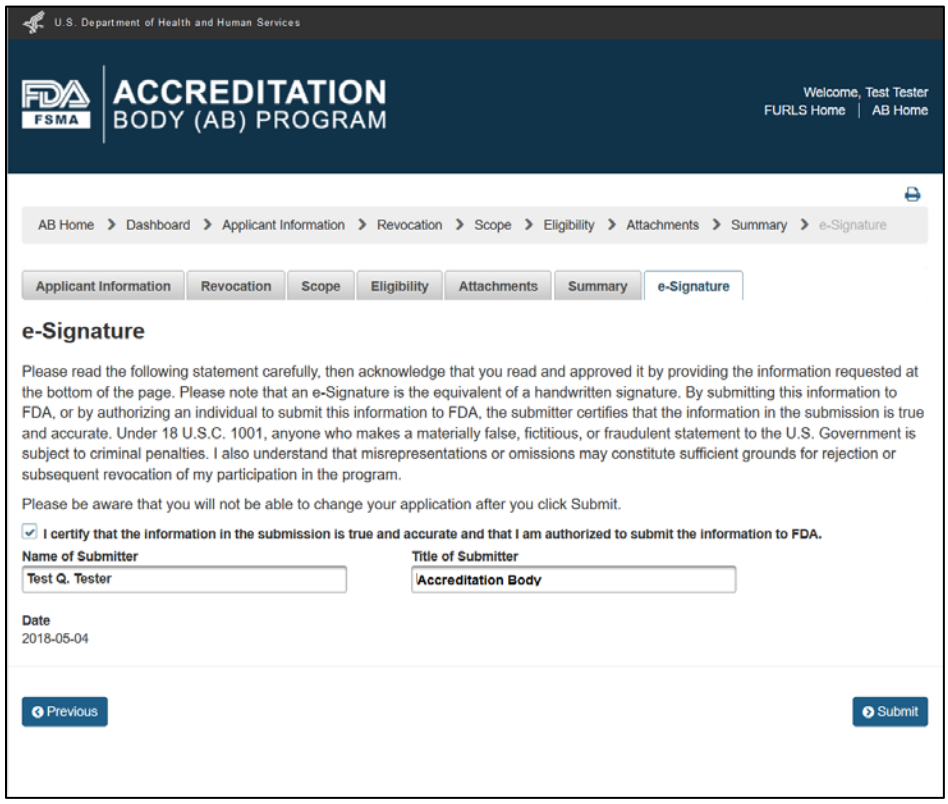
Click the check mark to certify that the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA.

The following data fields are present:

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

Fill in the required data fields and click the “Submit” button.

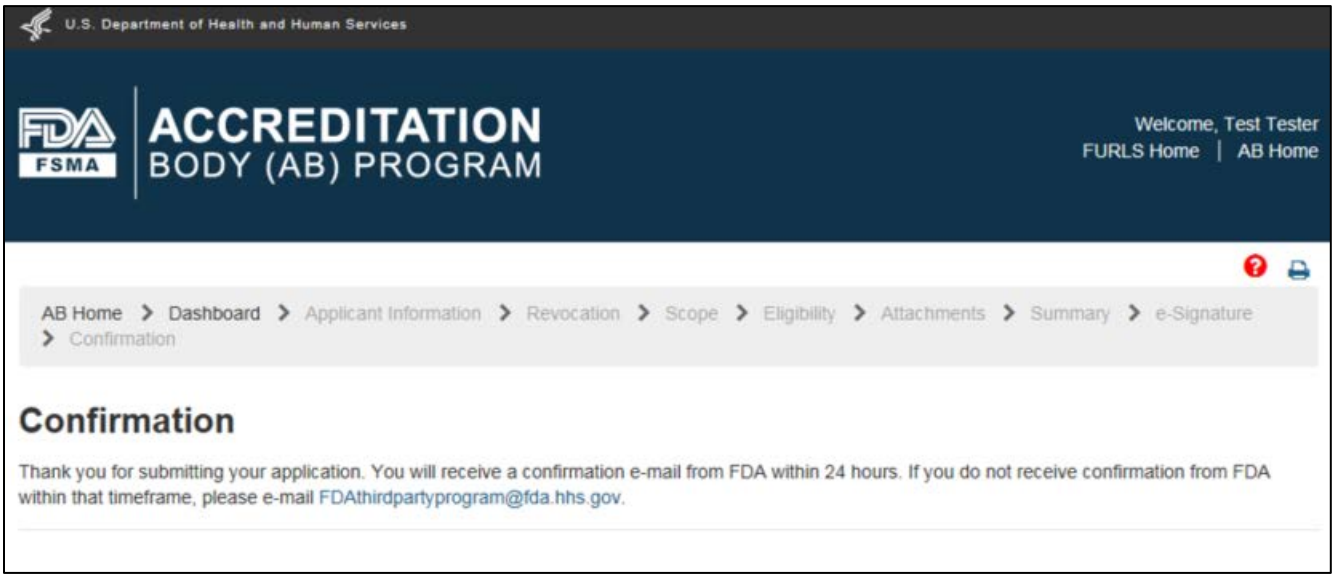
Figure 7.11 – e-Signature Page



Once your reconsideration request has been transmitted, the system will display a confirmation

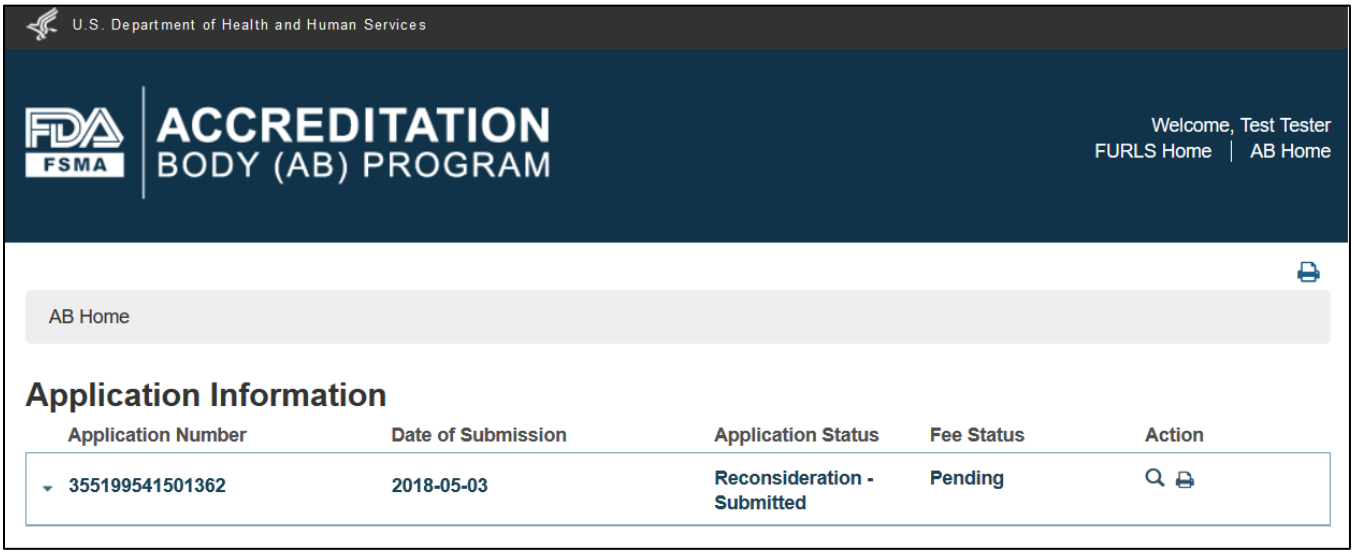
message on the page (Figure 7.12).

Figure 7.12 – Confirmation Message



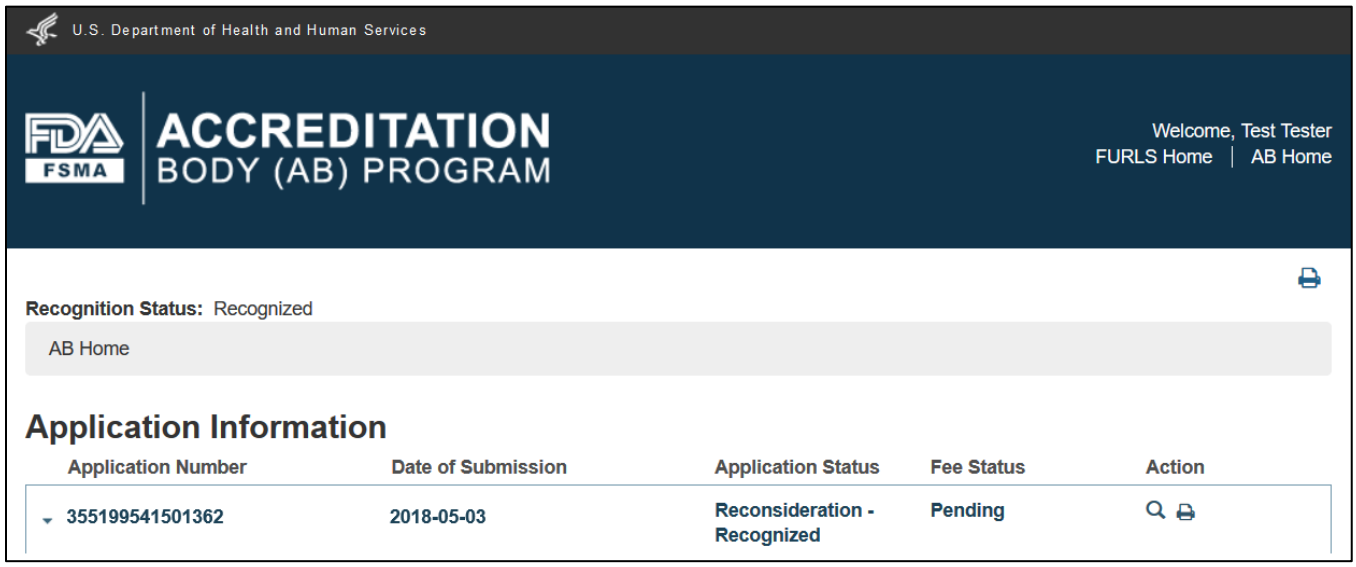
Once FDA receives the reconsideration application transmission, the application status will display as “Reconsideration - Submitted” (Figure 7.13).

Figure 7.13 – Application “Submitted” Status



If FDA approves the reconsideration application for any scopes, the application status will display as “Reconsideration - Recognized” (Figure 7.14).

Figure 7.14 – Application "Recognized" Status

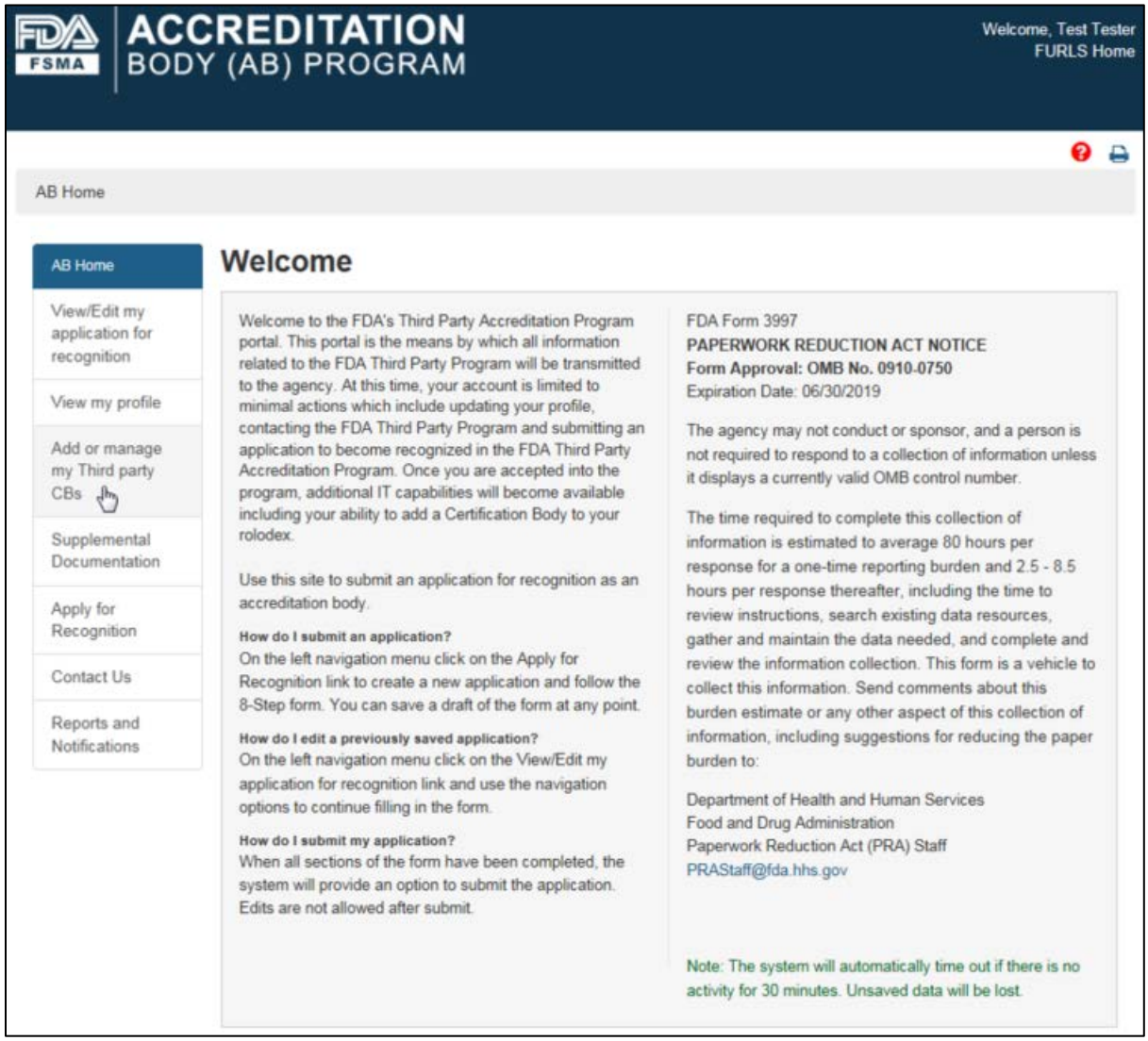


8 Add or Manage Third-Party Certification Bodies (CBs)

Once recognized by the FDA, you will need to supply information related to the Certification Bodies (CB) you accredit under the Accredited Third-Party Certification program.

Select the “Add or Manage my Third-Party CBs” option from the left navigation menu on the “AB Home” page (Figure 8.1) to add a new CB, or modify information for an existing CB.

Figure 8.1 – AB Homepage with Add or Manage My Third-Party CBs Menu Option

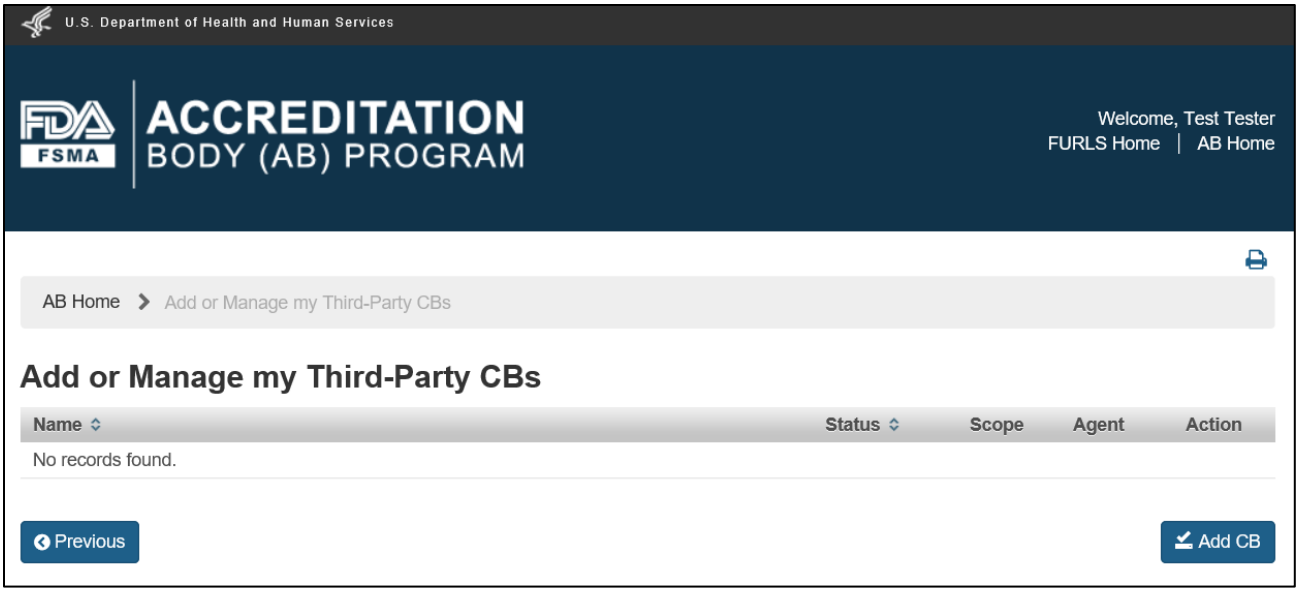


8.1 Add Accredited Third-Party CB

Click on the “Add or manage my Third-party CBs” button. The system will display the “Add or Manage my Third-Party CBs” page (Figure 8.1.1).

Click the “Add CB” button to add a new CB.

Figure 8.1.1 – Add or Manage my Third-Party CBs Page

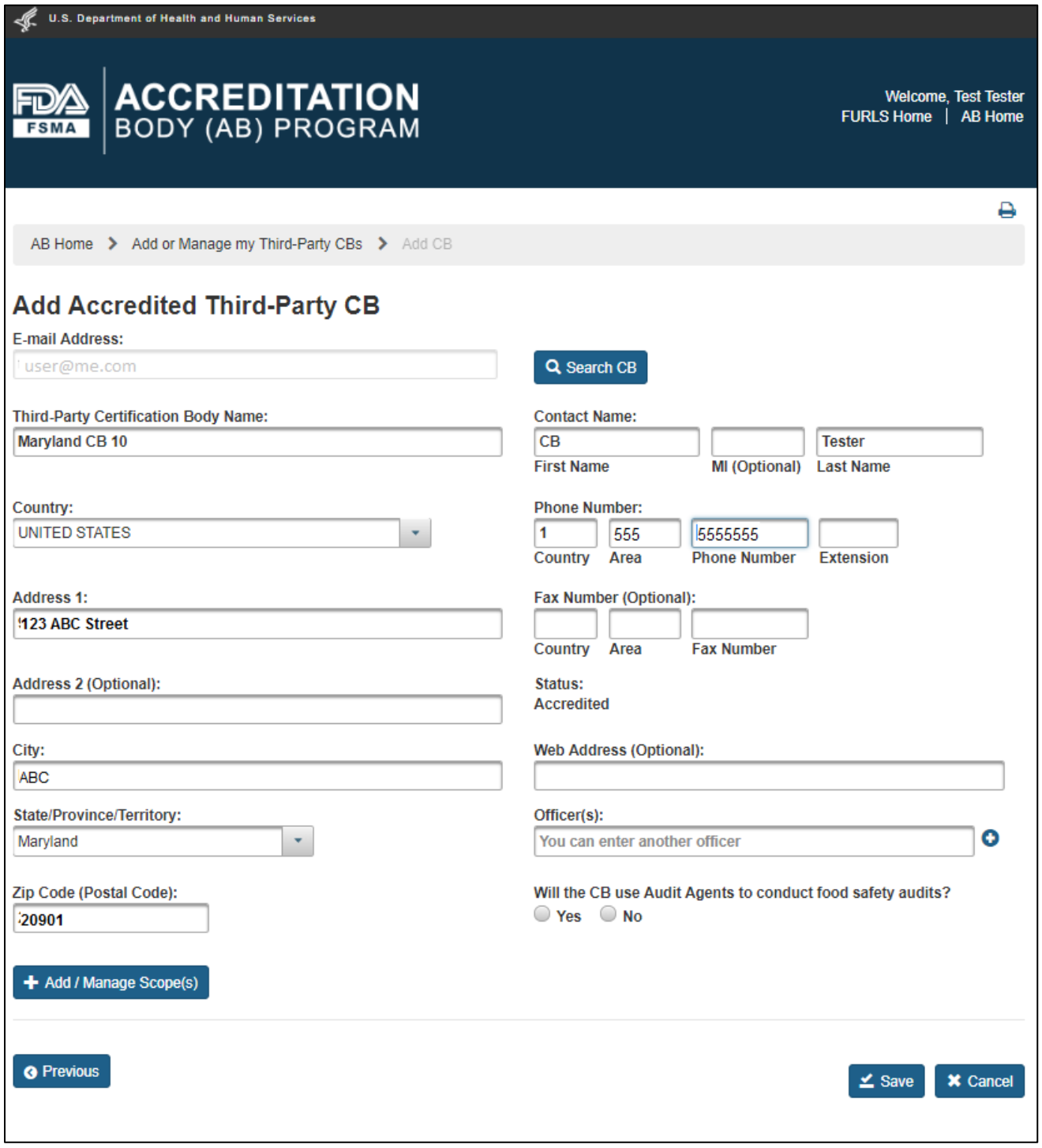


The system will display the “Add Accredited Third-Party CB” page (Figure 8.1.2). Enter the e-mail address of the new CB and click the “Search” button. If the system finds the mail address in the database it populates the relevant fields with the CB’s information.

If the search does not find an existing CB, enter the required information.

Note: The CB data fields will not become enabled until you enter an e-mail address and click the “Search CB” button.

Figure 8.1.2 – Add Accredited Third-Party CB Page

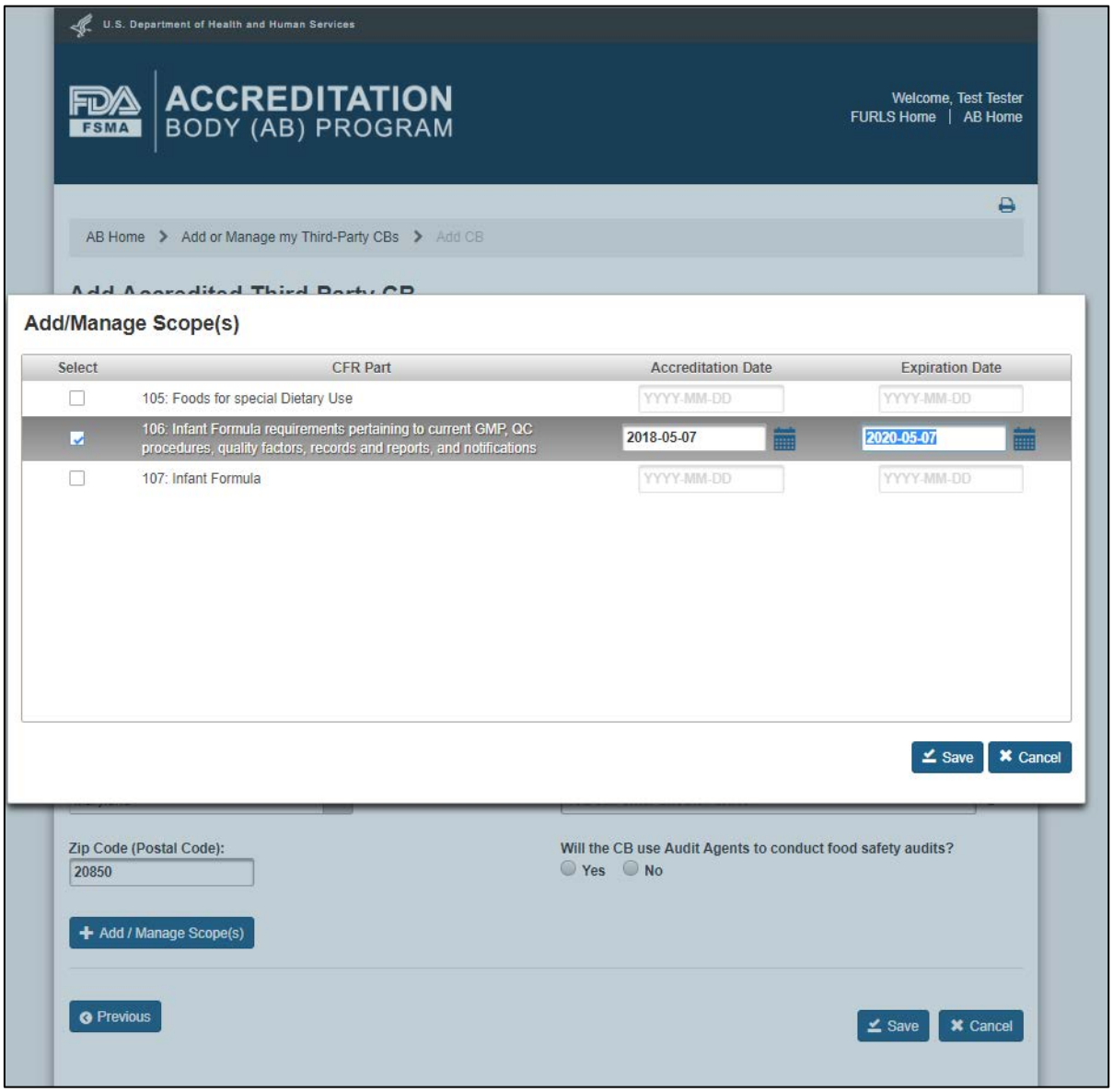


The data fields for completion in the “Add Accredited Third-Party CB” page are:

- **E-mail Address –** The e-mail address for the CB you want to add.
- **Third-Party Certification Body Name –** The name of the CB that you want to add.
- **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 field) – The additional information about the physical location of the company (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 field) –** The first letter of the Point of Contact’s middle name.
  - **Last Name –** The last name of the Point of Contact.
- **Phone Number**
  - **Country –** The country code of the Point of Contact.
  - **Area –** The area code of the Point of Contact.
  - **Phone Number –** The phone number of the Point of Contact.
  - **Extension –** The extension number of the Point of Contact.
- **Fax Number**
  - **Country (Optional field) –** The country code for the fax number.
  - **Area (Optional field) –** The area code for the fax number.
  - **Fax Number (Optional field) –** The fax number for the Point of Contact.
- **Web Address (Optional field) –** The URL of the CB.
- **Officer(s) –** The Officer(s) of the CB.

The “Add/Manage Scope(s)” button becomes enabled once you have entered all the required data. Click the “Add/Manage Scope(s)” button to associate scopes to the CB. The system will open the “Add/Manage Scope(s)” display in a new window (Figure 8.1.3).

Figure 8.1.3 – Add/Manage Scope(s) Window

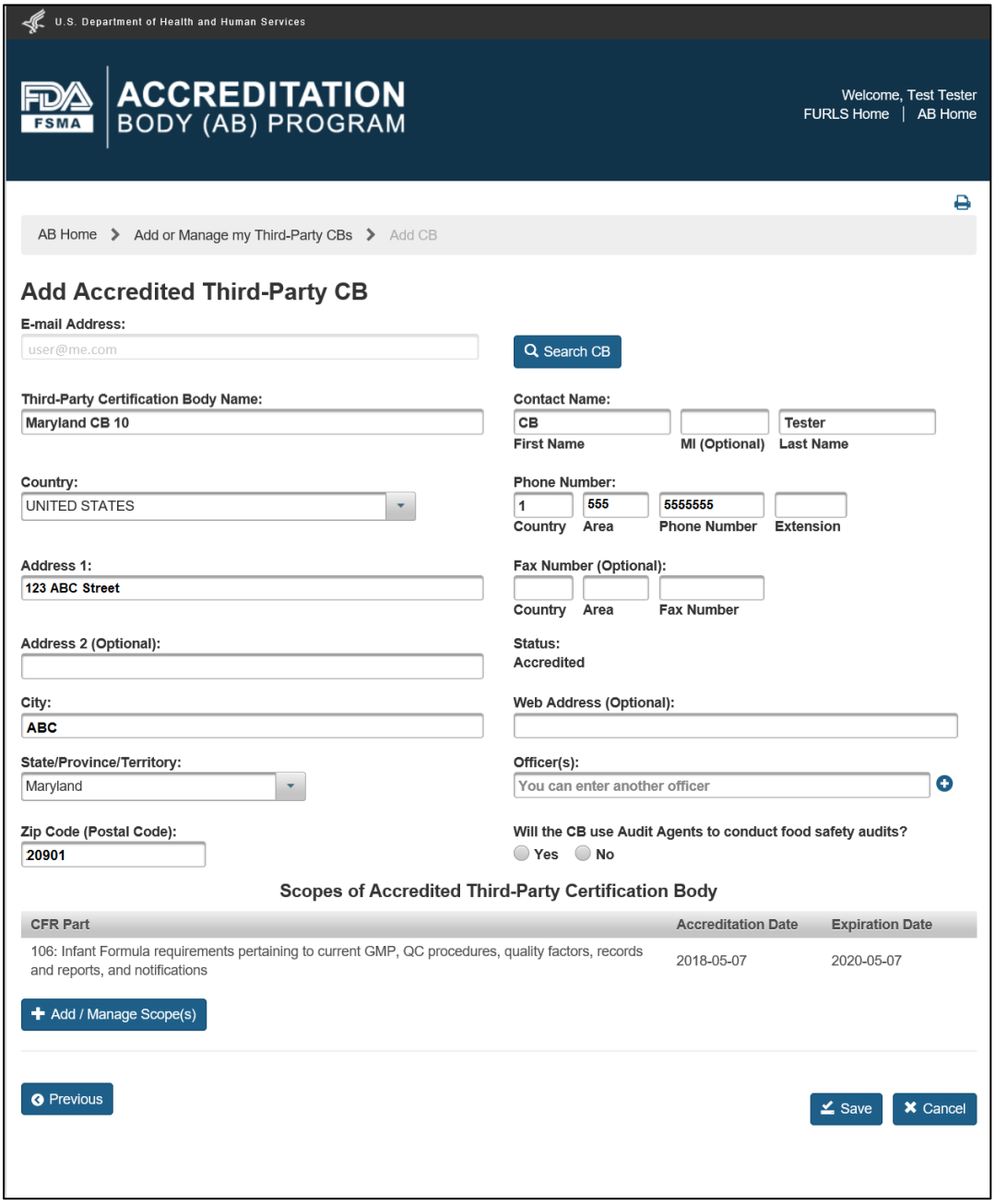


The system displays your recognized scope(s). Select the scopes you will associate to the CB by checking the box in the “Select” field. You must select at least one scope.

The “Accreditation Date” and “Expiration Date” fields are enabled once the scope is selected. Enter the dates for each selected scope in “YYYY-MM-DD” format.

Click the “Save” button when all the data is entered. The system will close the “Add/Manage Scope(s)” window and returns to the main page. The newly added scopes will be displayed in the “Scopes of Accredited Third-Party Certification Body” table (Figure 8.1.4).

Figure 8.1.4 – Scopes of Accredited Third-Party Certification Body Page



Once a scope has been added the “Will the CB use Audit Agents to conduct food safety audits?” question becomes enabled. Select “Yes” or “No.”

If you select “No” the system displays the “Audit Agent(s)” table and pre-populates it with the CB’s name.

If you select “Yes” the “Add Audit Agent(s)” window displays over the page. Enter an e-mail address and click the “Search Agent” button (Figure 8.1.5).

If the search finds an existing e-mail address in the system, then the Audit Agent’s name will be displayed. If the search does not find a match a text field will be displayed.

Enter the Audit Agent’s name in the text field and click the “Add Agent” button (Figure 8.1.6).

The agent is added to the “Audit Agent(s)” table (Figure 8.1.7). Once you have provided the Audit Agent information, click the “Save” button to return to the “Add Accredited Third-Party CB” page.

Figure 8.1.5. – Add Audit Agent(s) Window Part 1

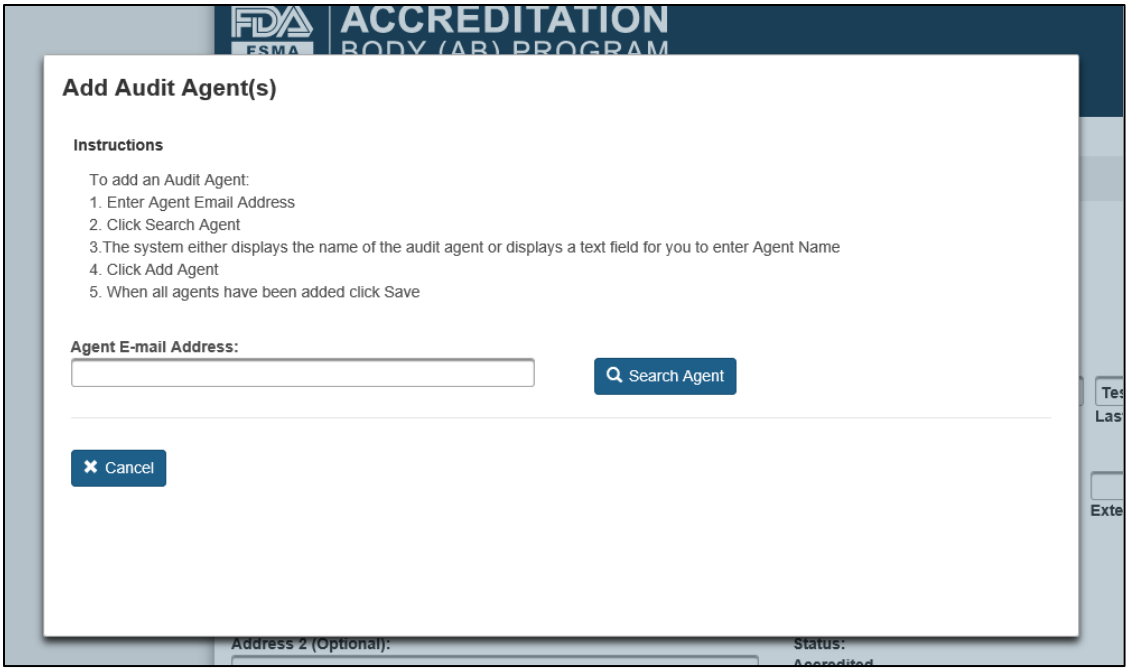


Figure 8.1.6 – Add Audit Agent(s) Window Part 2

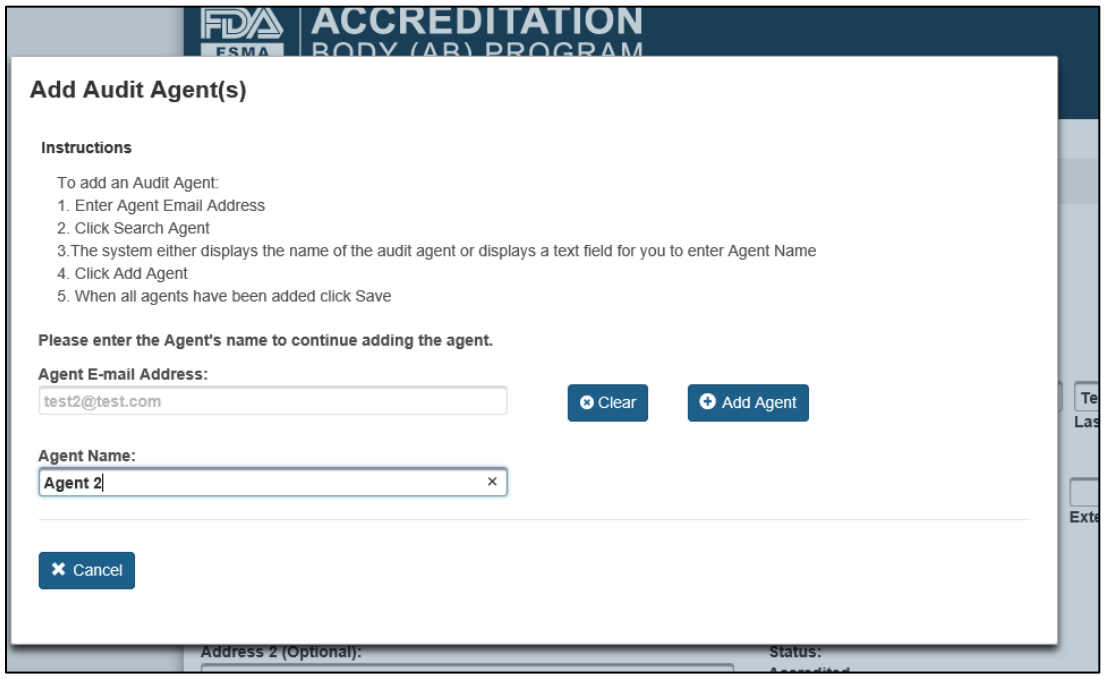
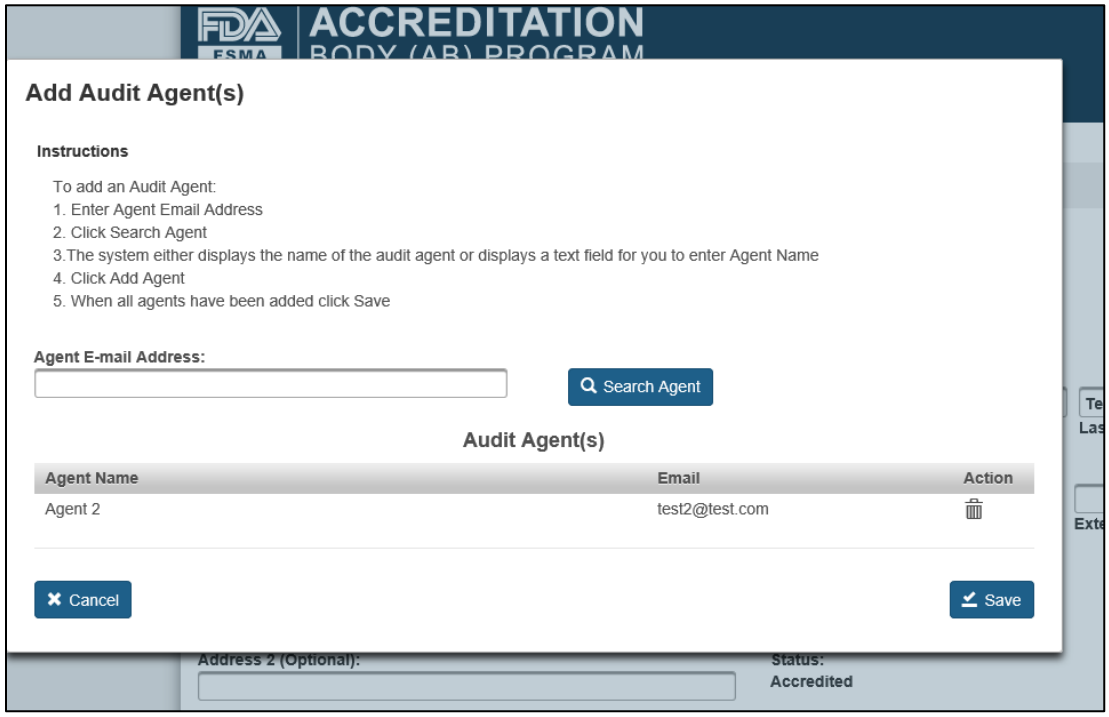
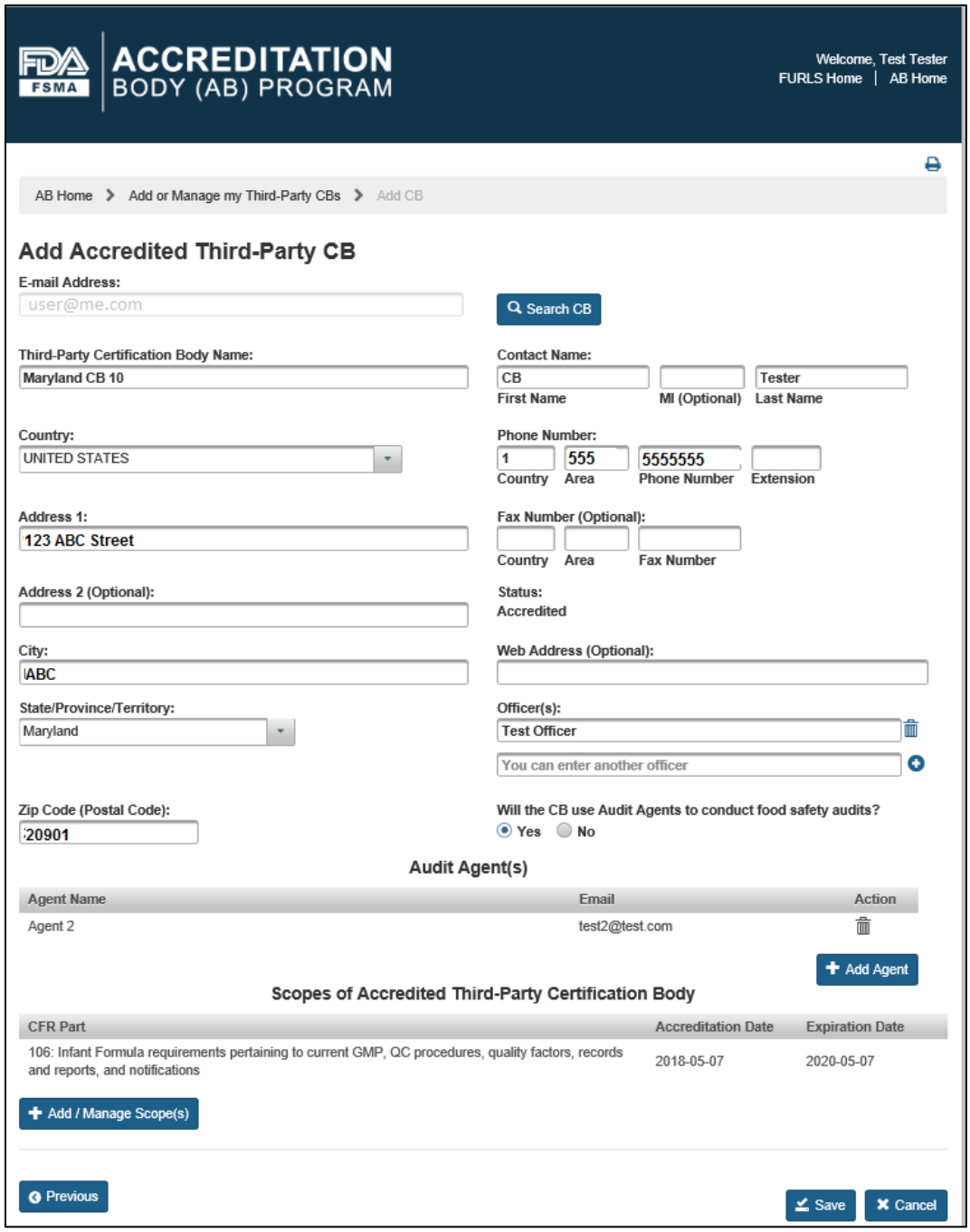


Figure 8.1.7 – Add Audit Agent(s) Window Part 3



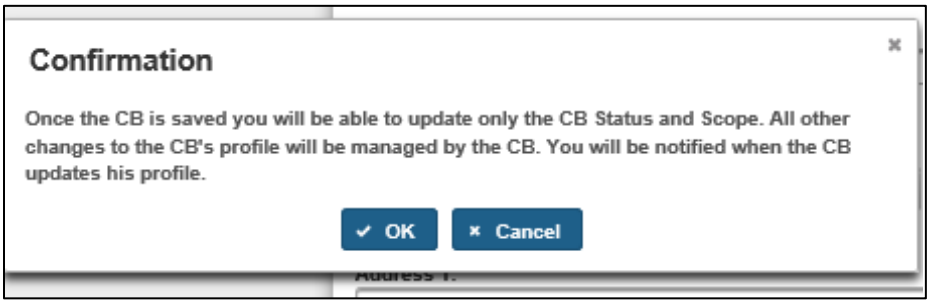
After saving the information, an “Audit Agent(s)” section will appear on the “Add Accredited Third-Party CB” page (Figure 8.1.8). A list of saved Audit Agent(s) will be displayed in the Audit Agent(s) table.

Figure 8.1.8 – Audit Agent(s) Table



After entering all mandatory information, click the “Save” button on the “Add Accredited Third-Party CB” page. If there are no errors, the system will display a confirmation message over the page (Figure 8.1.9).

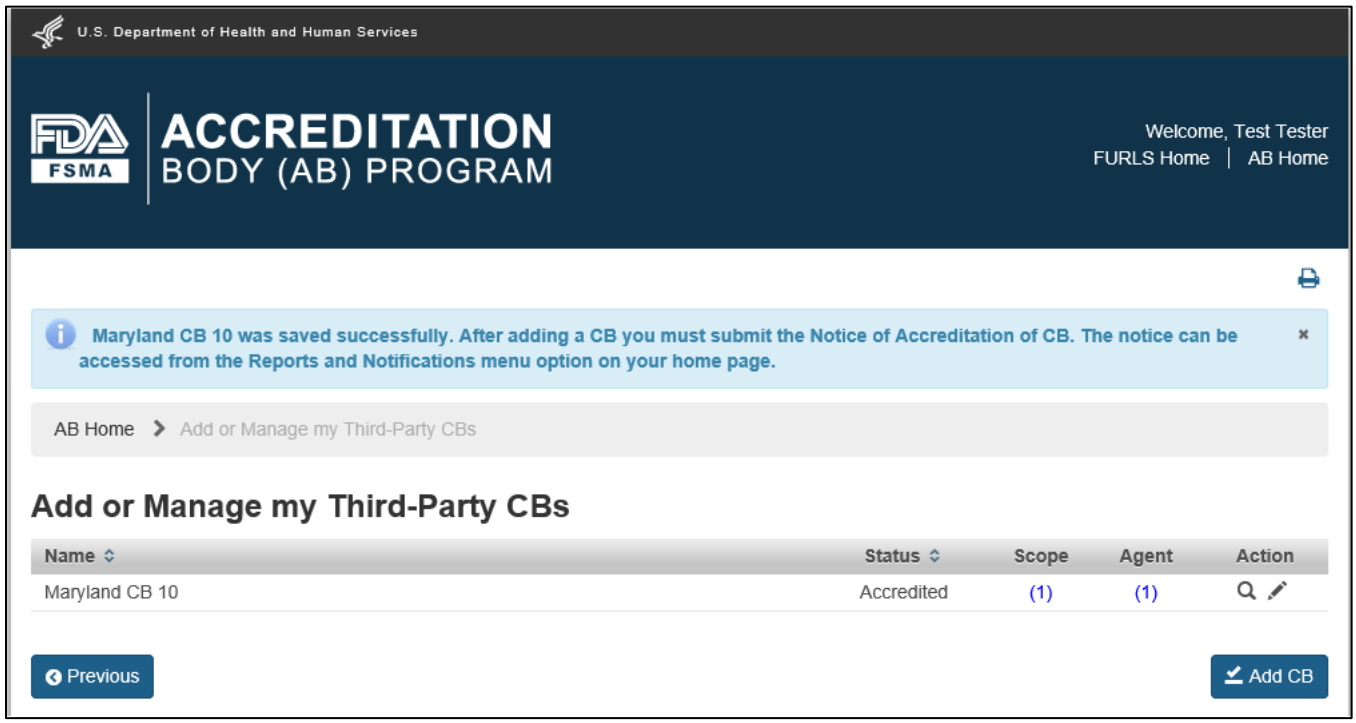
Figure 8.1.9 – Confirmation Message



Click the “OK” button to close the confirmation message. The system will navigate to the “Add or Manage my Third-Party CBs” page. The system will display the newly added CB in the table (Figure 8.1.10).

Note: A CB accreditation will not be reported to the FDA until you complete the “Notice of Accreditation of CB” from the “Reports and Notifications” tab. You will receive a confirmation message instructing you to complete the notification after you enter the accreditation information (Figure 8.1.10). Section 9.1 of this user guide provides instructions on how to complete and submit the notification.

Figure 8.1.10 – Add or Manage my Third-Party CBs Page

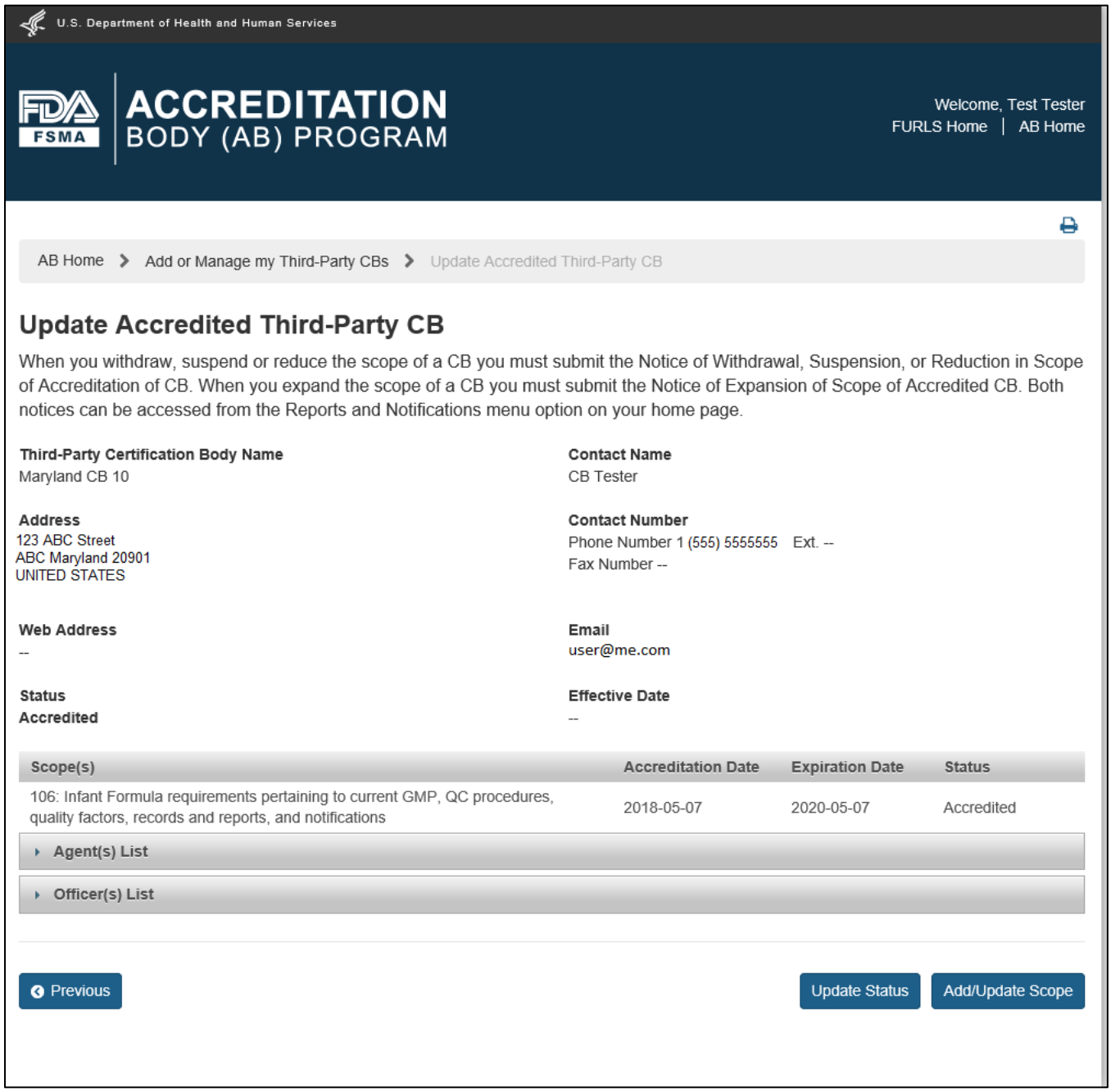


8.2 Update Accredited Third-Party CB

Update an Accredited Third-Party CB by clicking the pencil icon in the “Action” column on the “Add or Manage my Third-Party CBs” page (Figure 8.2.1).

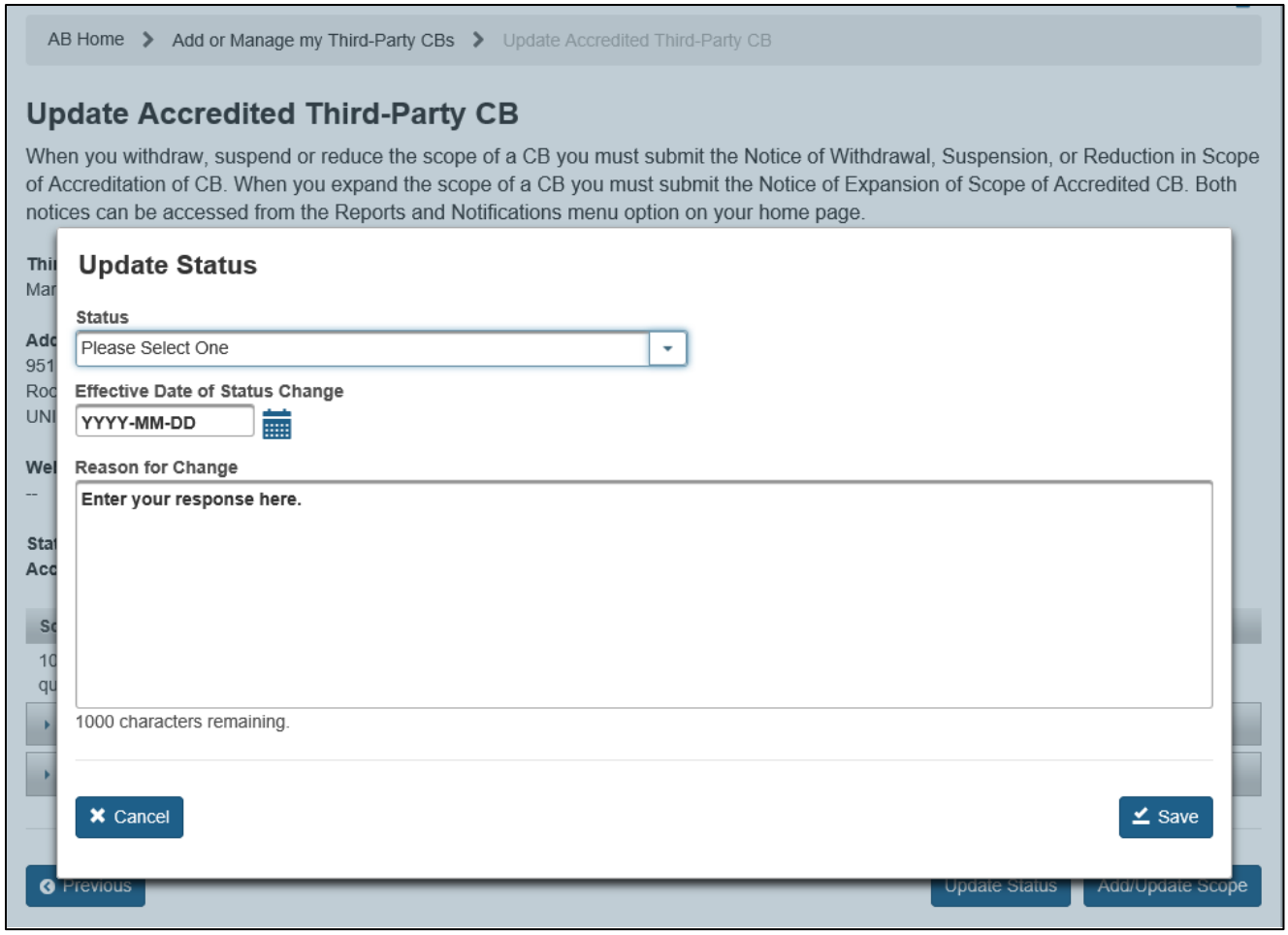
Figure 8.2.1 – Add or Manage my Third-Party CBs Page

Figure 8.2.2 – Update Accredited Third-Party CB Page



Update the CB(s) status by clicking the “Update Status” button. The system displays an “Update Status” window (Figure 8.2.3).

Figure 8.2.3 – Update Status Window



The options available in the “Status” drop-down field are dependent on the current status of the CB (Figure 8.2.4). For example:

- If the CB is “Accredited,” then the status can be updated to “Suspended” or “Withdrawn.”
- If the CB is “Suspended,” then the status can be updated to “Accredited” or “Withdrawn.”
- If the CB is “Reinstated,” then the status can be updated to “Withdrawn” or “Suspended.”
- If the CB is “Withdrawn,” then the status cannot be updated until it has first been “Reinstated” via the “Reinstatement of a Certification Body in Whole or in Part” notification (see Section 9.8 for details).

An AB cannot update CB statuses that were updated by the FDA.

The following data fields are present:

- **Status -** The drop-down options are “Suspended” or “Withdrawn.”
- **Effective Date of Status Change –** The effective date of the status change.
- **Reason for change -** The reason for status change.

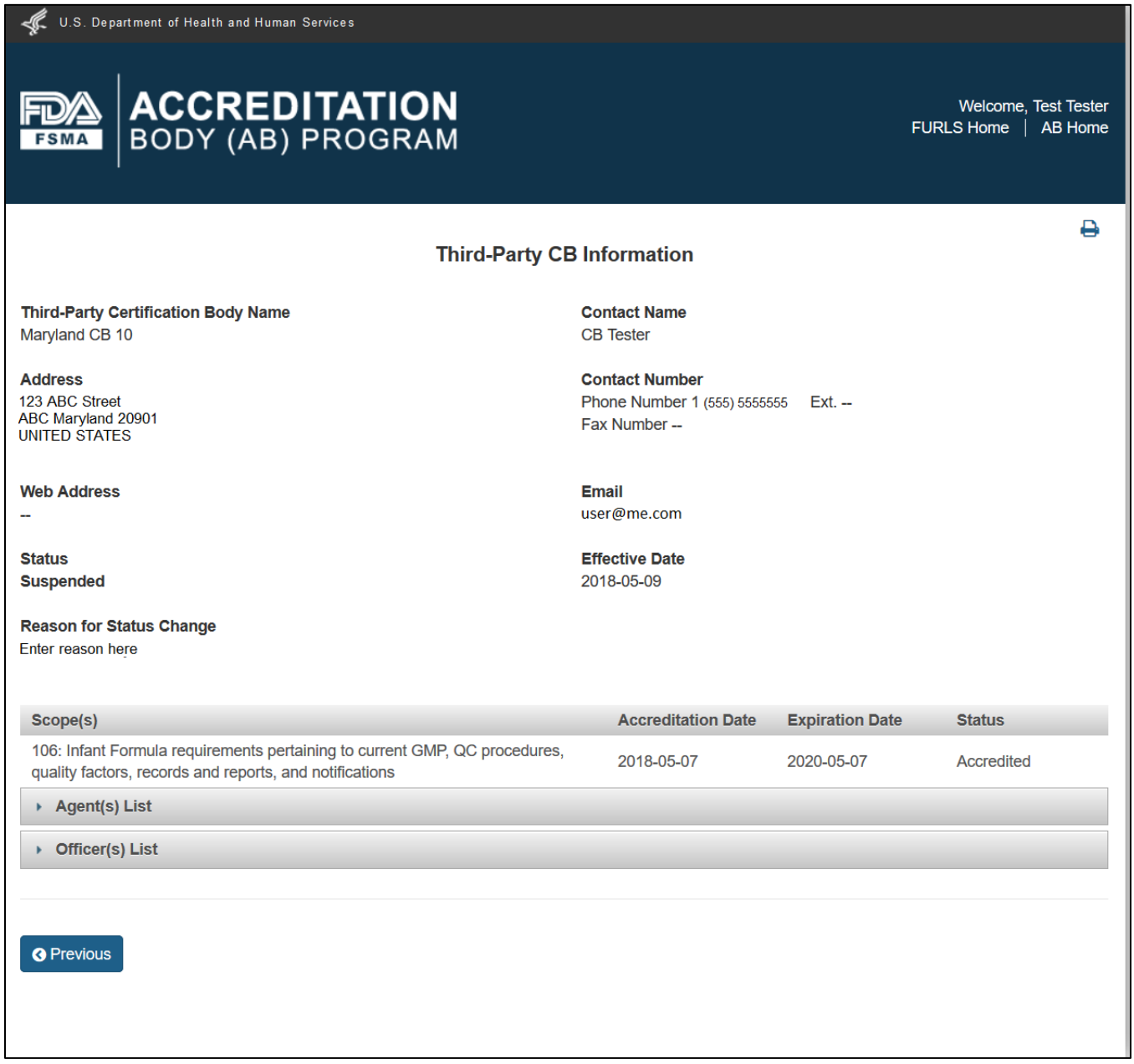
Fill in the required data fields, and click the “Save” button.

Figure 8.2.4 – Update Status window selections

The system closes the “Update Status” window and returns to the “Update Accredited Third-Party CB” page.

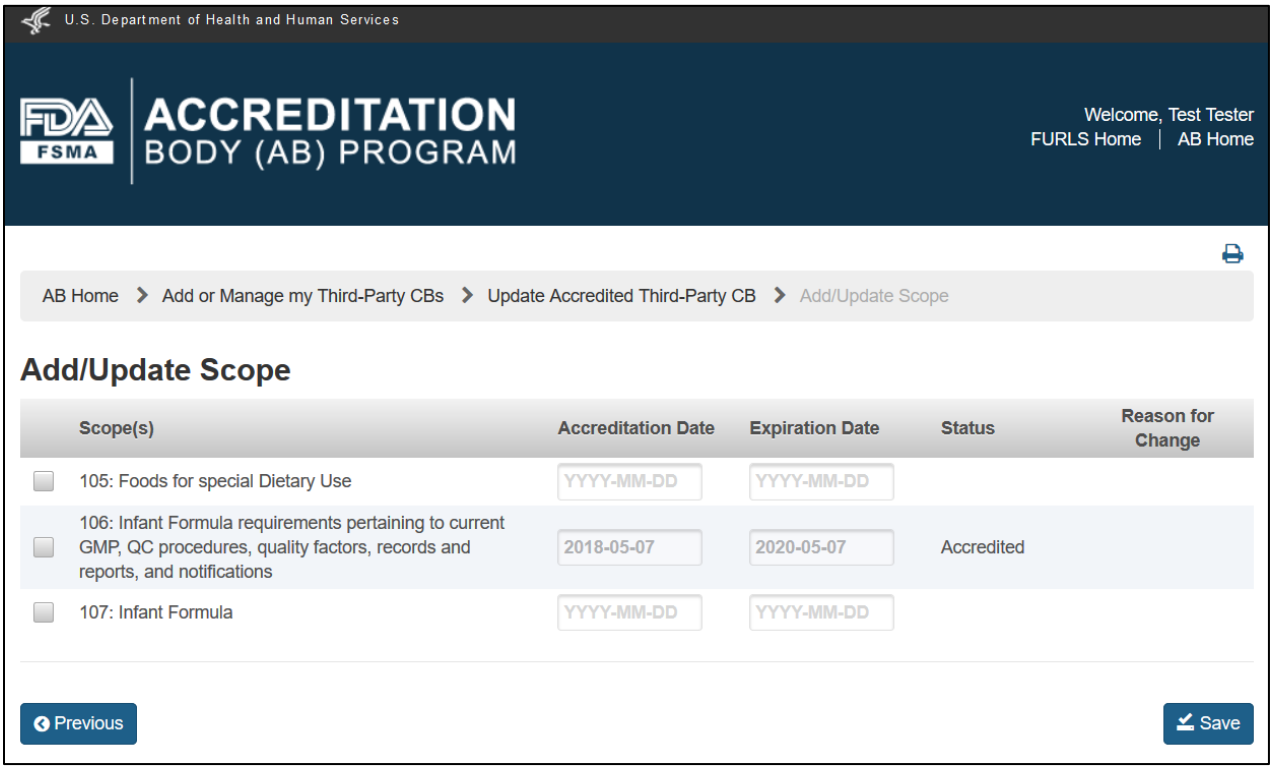
The updated status displays in the “Status” field on the central portion of the page (Figure 8.2.5).

Figure 8.2.5 – Update Accredited Third Party CB Page with updated CB Status



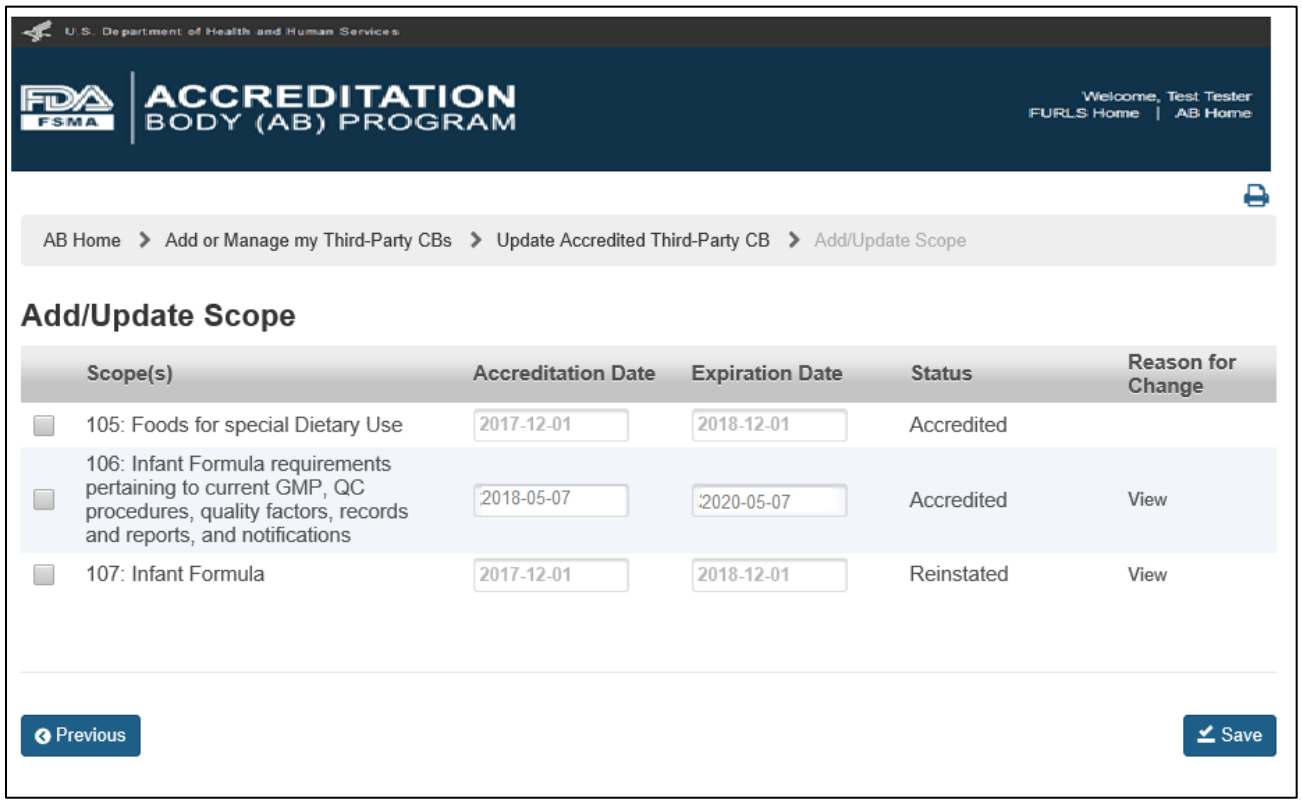
Add and/or update the CB's scopes by clicking the "Add/Update Scope" button from the "Update Accredited Third-Party CB" page. The system displays the "Add/Update Scope" page (Figure 8.2.6).

Figure 8.2.6 – Add/Update Scope Page Part 1



Only scopes that have an Accreditation and Expiration date can be selected (Figure 8.2.7).

Figure 8.2.7 – Add/Update Scope Page Part 2



Select the checkbox for the scope that you would like to update on the "Add/Update Scope" page. The system displays the "Update Scope" window (Figure 8.2.8).

When updating scopes, the options available in the "Status" drop-down field are dependent on the current status of the specific scope (Figure 8.2.8). For example:

- If the scope is "Accredited," then the status can be updated to "Suspended" or "Withdrawn."
- If the scope is "Suspended," then the status can be updated to "Accredited" or "Withdrawn."
- If the scope is "Withdrawn," then the status can be updated to "Accredited."
- If the scope is "Reinstated," then the status can be updated to "Suspended" or "Withdrawn."

An AB cannot update scopes that are "Failed to Renew. "An AB cannot update CB scopes that were changed by FDA. An AB cannot add a scope to a CB if that particular scope is in the "Suspended" status.

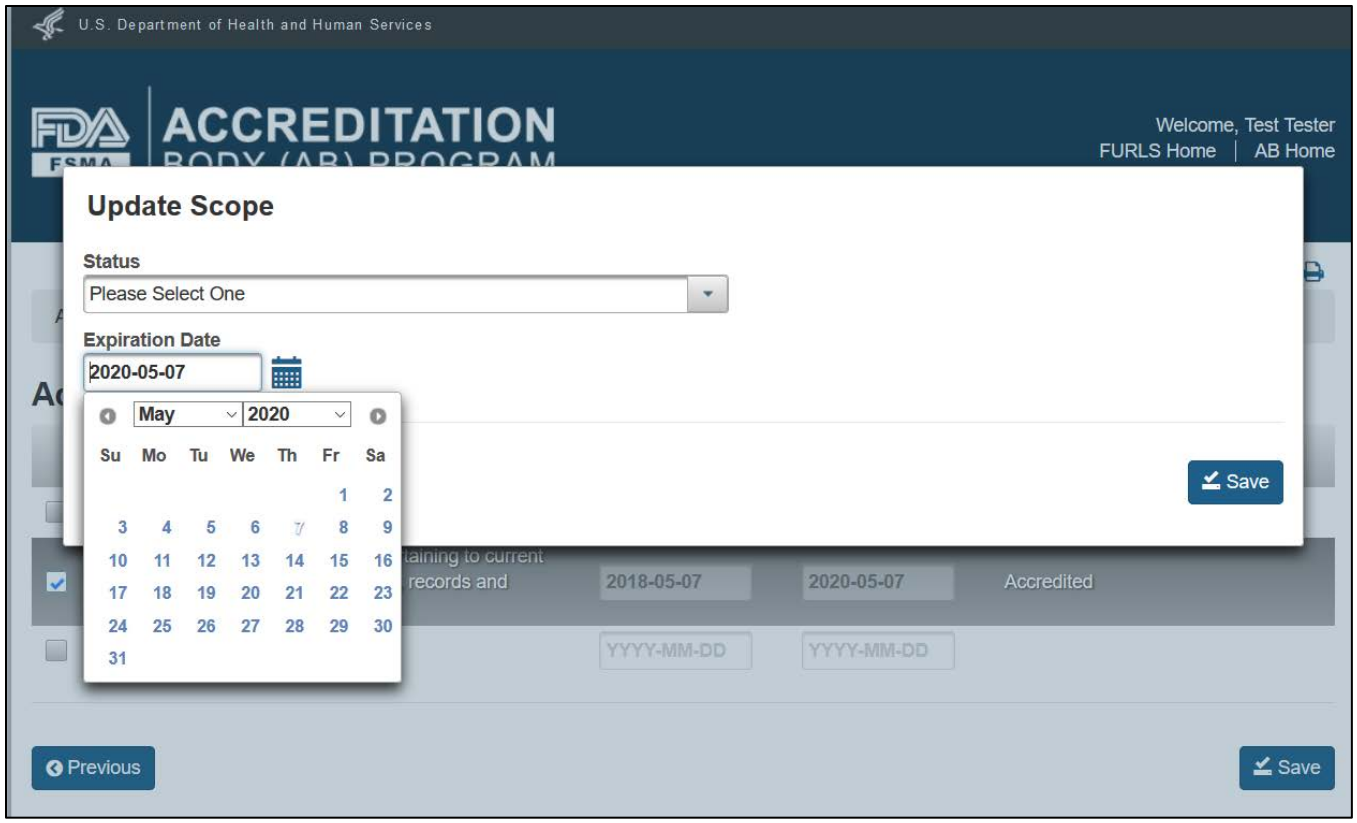
The following data fields are present:

- **Status –** The drop-down menu option of "Reinstated," "Suspended," or "Withdrawn."

- **Expiration Date –** The expiration date of the added or updated scope.

Note: Do not select a status from the “Status” menu when only extending the Expiration Date.

Figure 8.2.8 – Update Scope Window

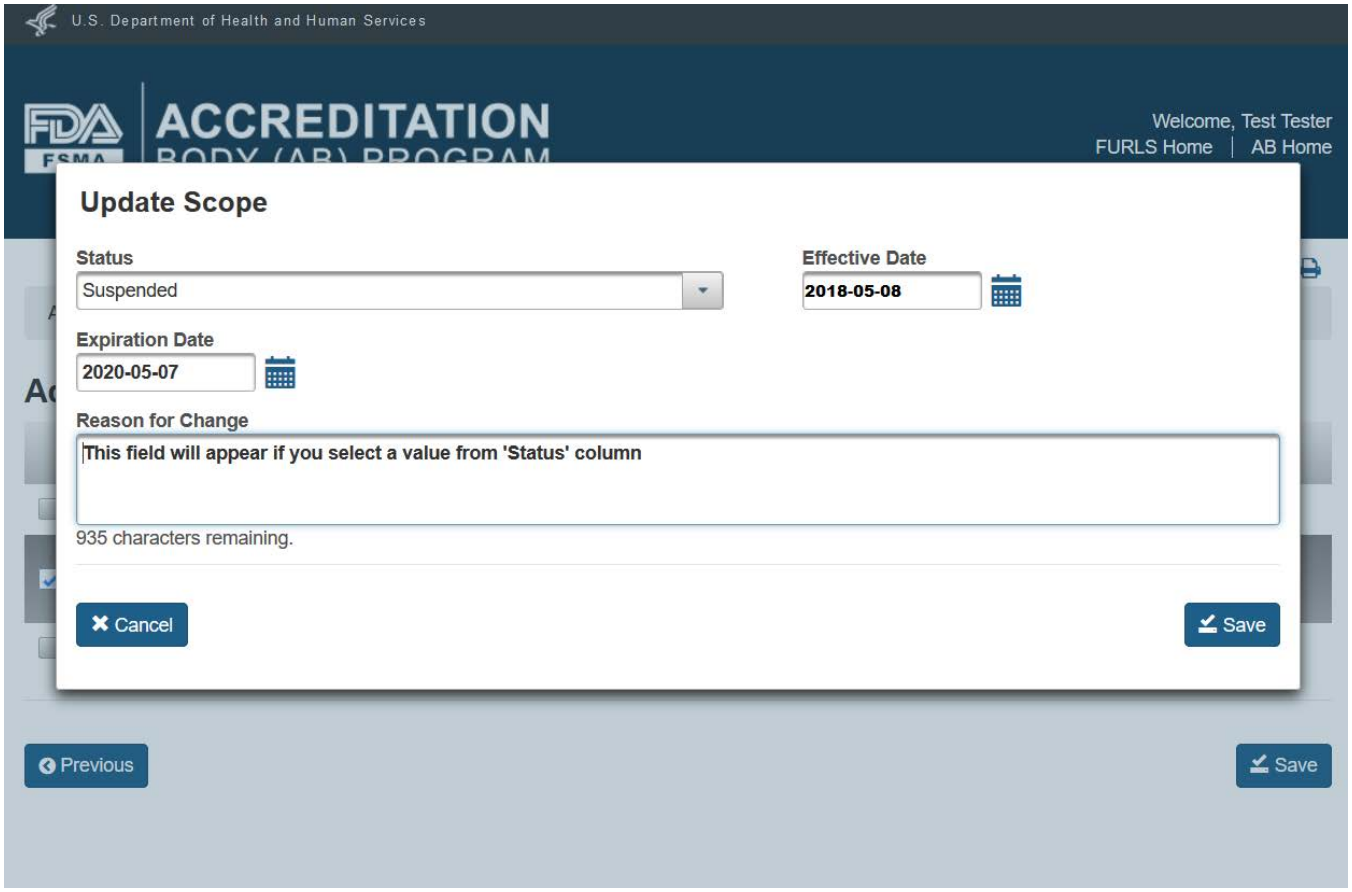


If you select a status from the drop-down list the system will display the following data fields (Figure 8.2.9):

- **Status –** The drop-down menu option of “Suspended” or “Withdrawn.”
- **Expiration Date -** The updated expiration date of the scope.
- **Reason for Change -** The reason the scope expiration date was changed.
- **Effective Date –** The date the status change became effective.

Note: The scope effective date cannot precede the start date, or exceed the expiration date of the CB accreditation.

Figure 8.2.9 – Update Scope Window – Suspended Status

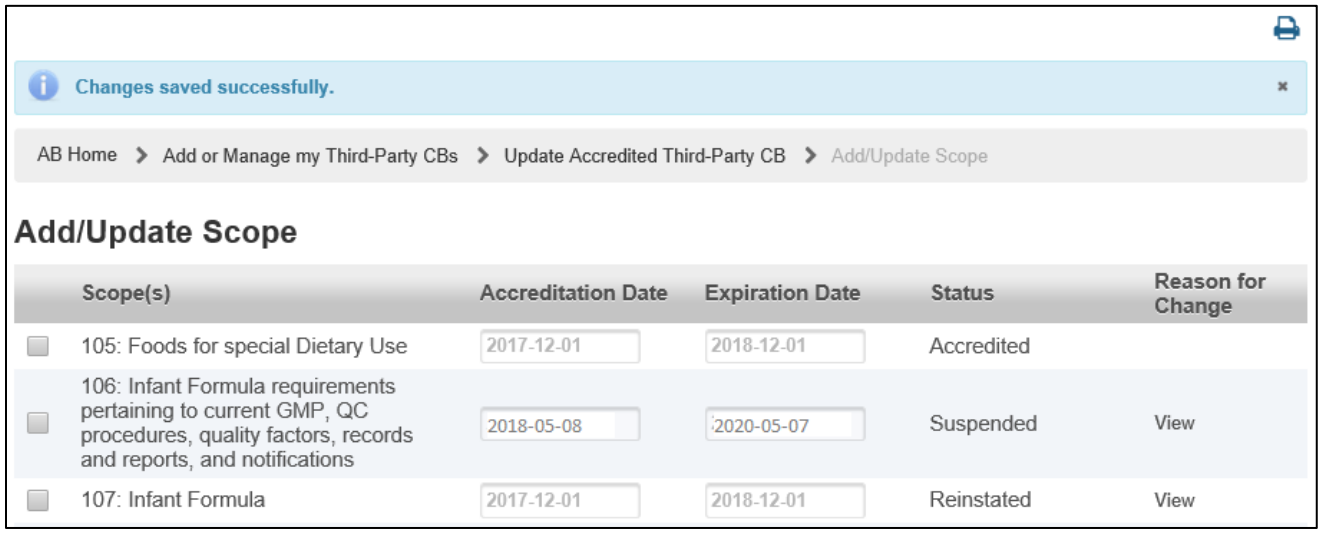


Fill in the required data fields, and click the “Save” button from the “Update Scope” window; the system will close the window. Then click the “Save” button from the “Update Scope” page.

Note: The changes will not be saved if the “Save” button is not clicked in both places.

View the scope update(s) in the “Add/Update Scope” page (Figure 8.2.10).

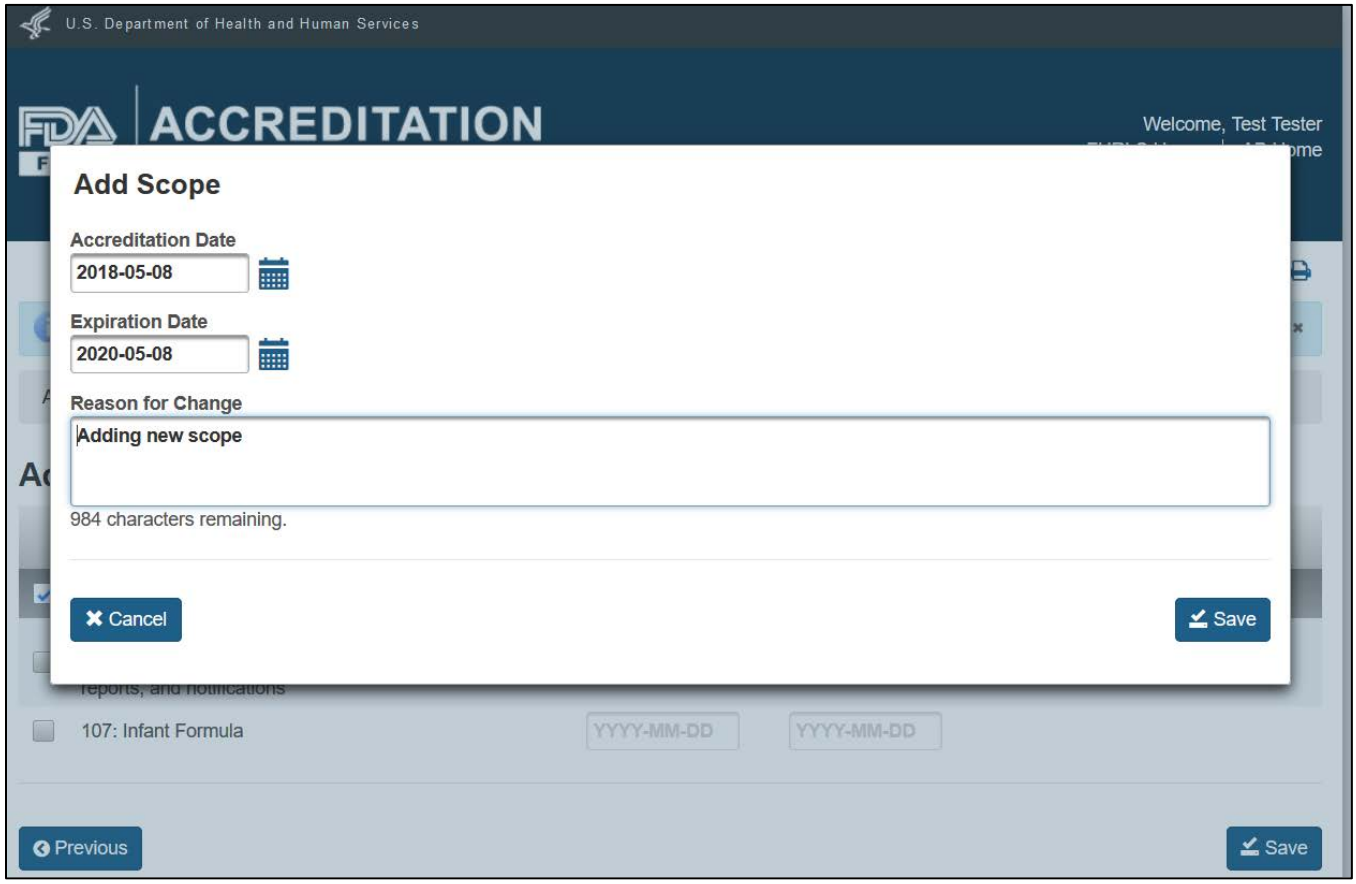
Figure 8.2.10 - Updated Scope



To add a scope, return to the “Update Accredited Third-Party CB” page. Click the “Add/Update Scope” button (Figure 8.2.2).

Select a scope that does not have a value in the “Status” column (See Figure 8.2.6). The system displays an “Add Scope” window (Figure 8.2.11).

Figure 8.2.11 – Add Scope Window



Fill in the required data fields:

- **Accreditation Date –** The start date for the scope accreditation.
- **Expiration Date –** The expiration date for the scope accreditation (the scope expiration date cannot exceed the accreditation expiration date).
- **Reason for Change –** The reason the scope was added to the accreditation.

Click the “Save” button. The system closes the “Add Scope” window and returns to the main “Add/Update Scope” page.

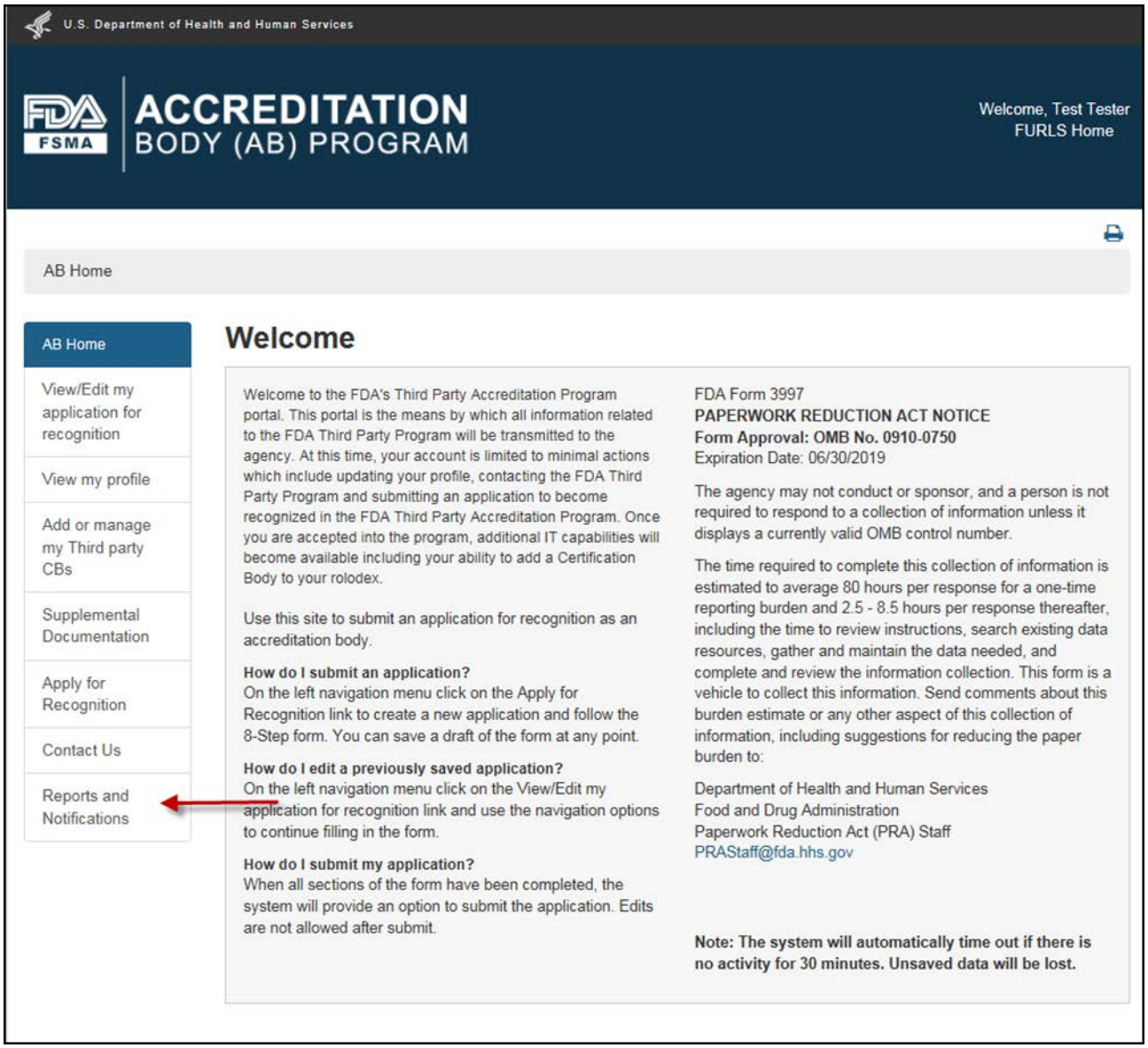
Click “Save.”

9 Reports and Notifications

Several options exist within the Reports and Notifications directory.

To access the available functionality, click the “Reports and Notifications” option from the left navigation menu on the “AB Home” page (Figure 9.1).

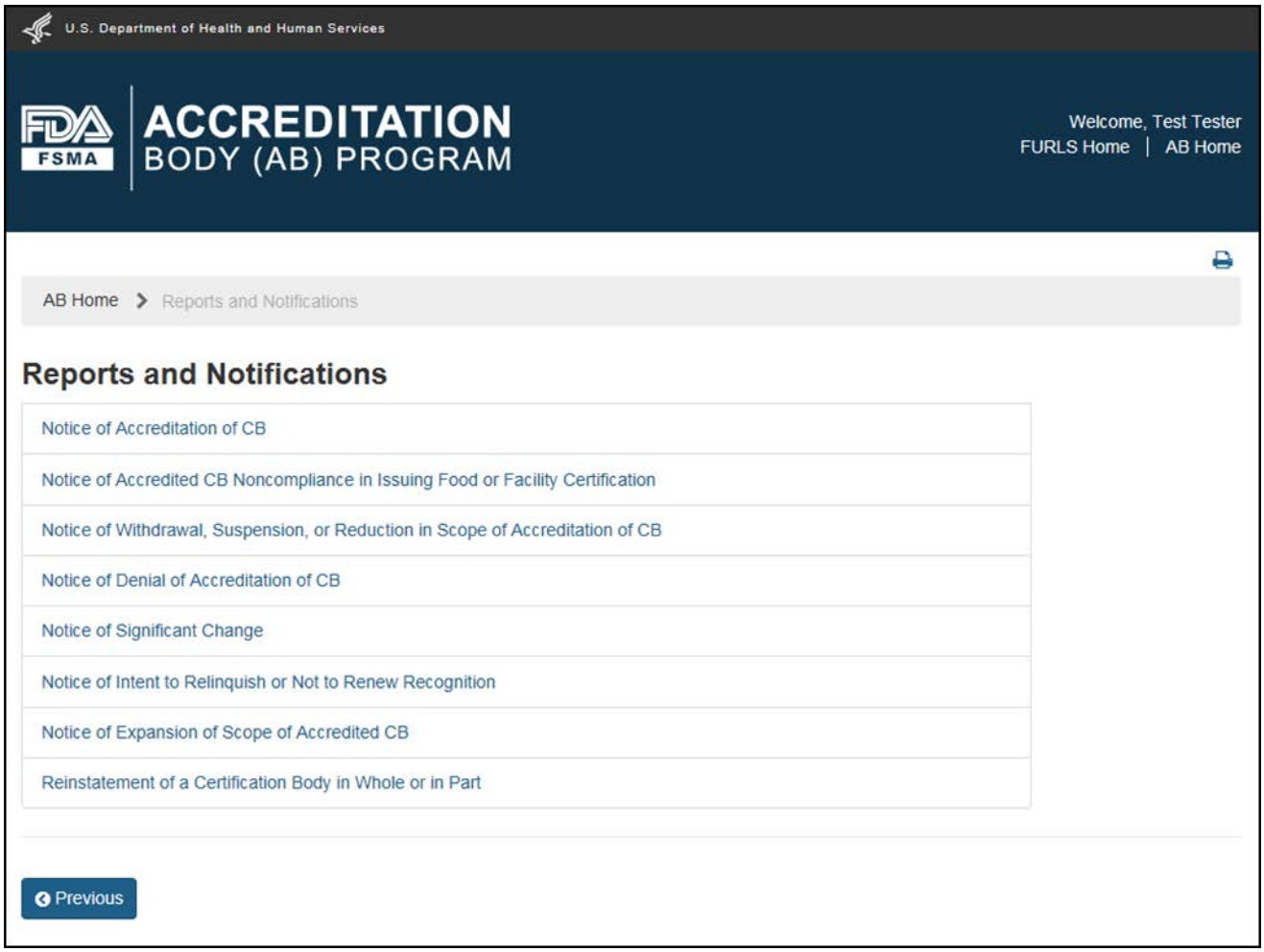
Figure 9.1 – AB Home Page with Reports and Notifications Menu Option



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

- **Notice of Accreditation of CB –** Generates a notice to FDA when the AB accredits a CB.
- **Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification –** Generates a notice to FDA when the CB has a noncompliance with the requirements of 21 CFR Part 1, Subpart M.
- **Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB –** Generates a notice to FDA when the AB takes the following actions with CB; withdrawal, suspension, or reduction in scope.
- **Notice of Denial of Accreditation of CB –** Generates a notice to FDA when the AB denies accreditation to a CB.
- **Notice of Significant Change –** Generates a notice to FDA when the AB makes any significant change which would affect the way it complies with the requirements of 21 CFR Part 1, Subpart M.
- **Notice of Intent to Relinquish or Not to Renew Recognition –** Generates a notice to FDA when the AB intends to relinquish recognition or does not plan to renew recognition.
- **Notice of Expansion of Scope of Accredited CB –** Generates a notice to FDA when the AB issues an expansion of the CBs accreditation.
- **Reinstatement of a Certification Body in Whole or in Part –** Generates a notice to FDA when the AB reinstates an accreditation to the CB (the notification is only available if an AB-CB relationship is suspended - or if scopes within an AB-CB relationship have been suspended).

Figure 9.2 – Reports and Notifications Page



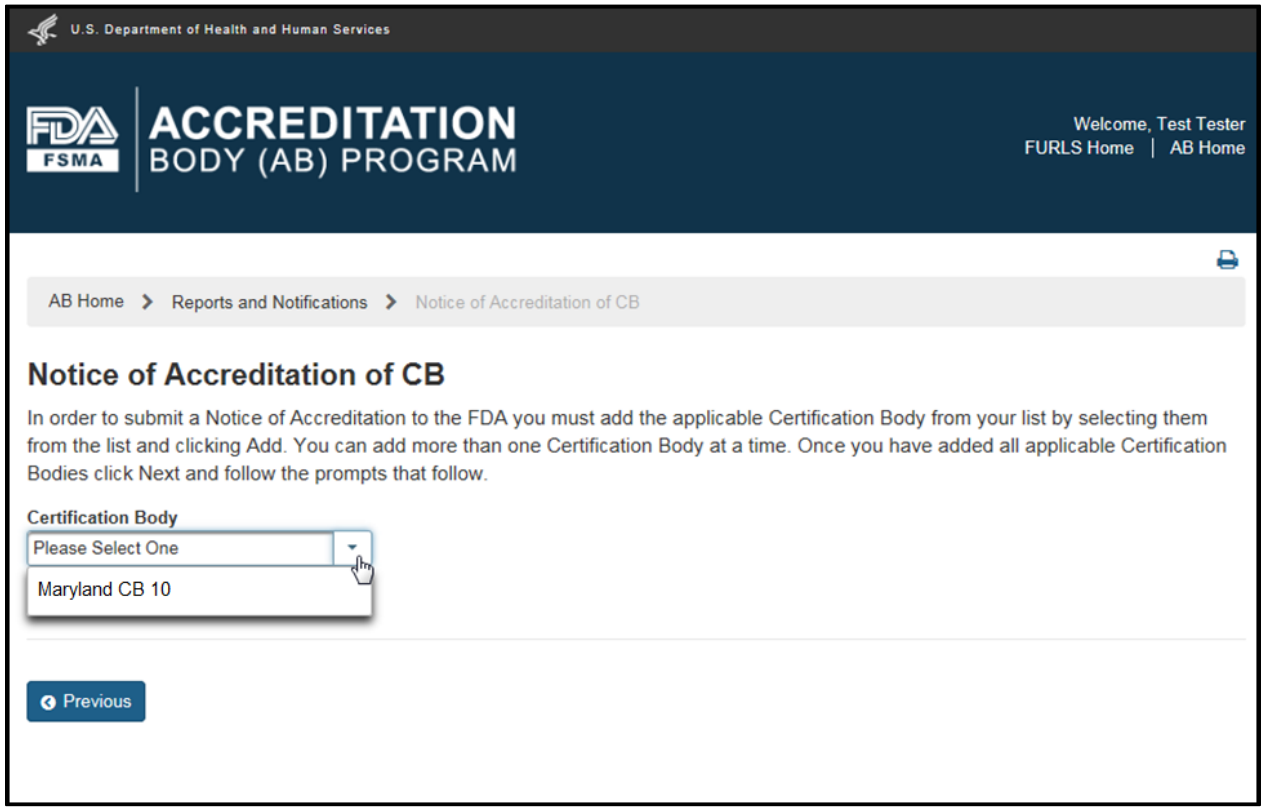
9.1 Notice of Accreditation of CB

To add an accredited CB to your account, submit a “Notice of Accreditation of CB.”

Select “Notice of Accreditation of CB” from the “Reports and Notifications” page. The system displays the “Notice of Accreditation of CB” page (Figure 9.1.1).

Select the CB from the “Certification Body” drop-down to notify the FDA of their accreditation.

Figure 9.1.1 – Notice of Accreditation of CB Page



Select a CB from the “Certification Body” drop-down menu. The drop-down menu will display CB names that have been added in the “Add or manage Third party CBs” menu. The drop-down menu will not display CBs that were included in a previous notification.

Note: The “Certification Body” drop-down list will not appear if there are no CB accounts pending notification, and the system will display a message to that effect.

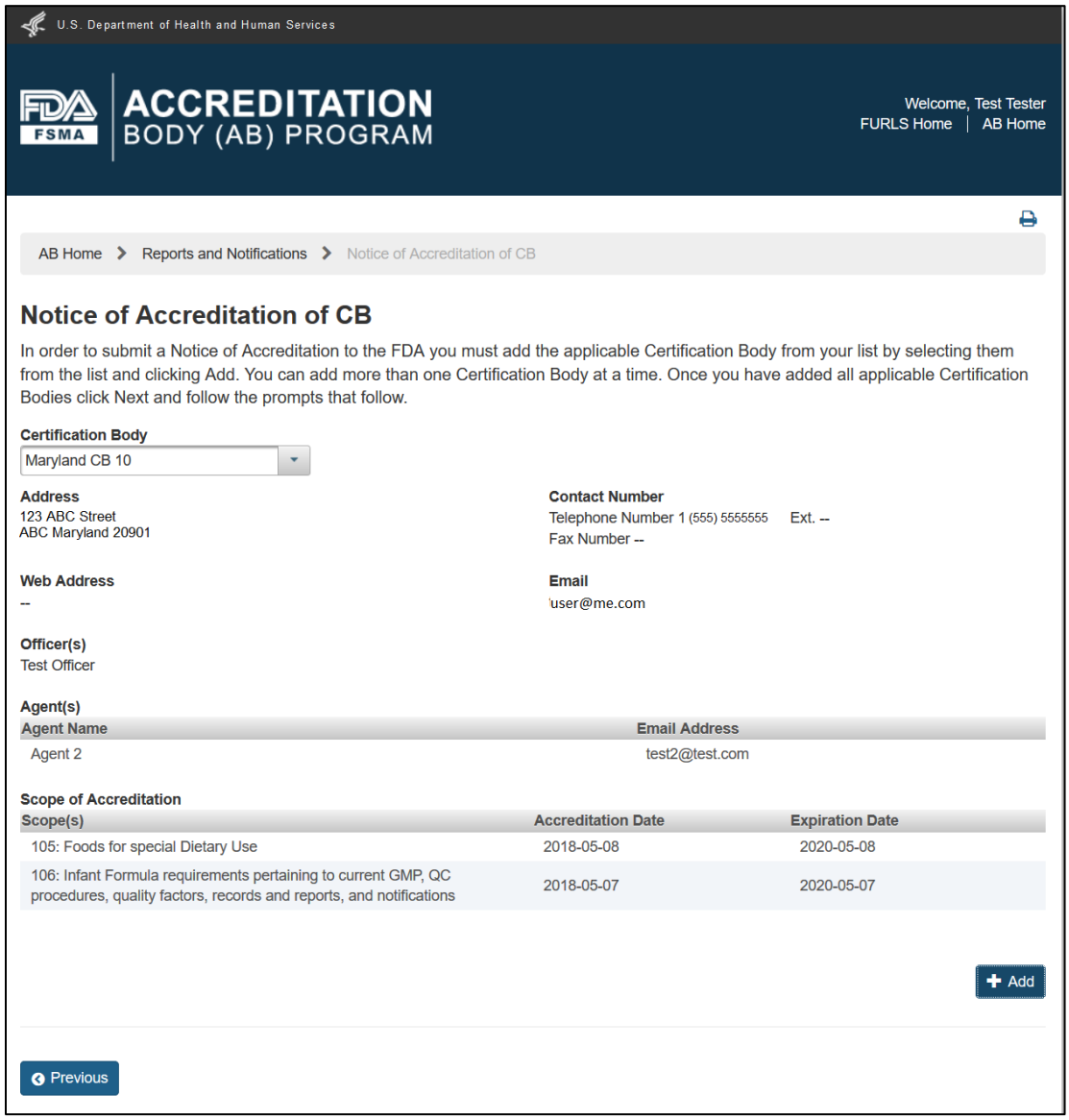
Upon selecting a CB from the drop-down menu, the system expands the page to display all the CB’s information, including accredited scopes (Figure 9.1.2).

Click “Add” to navigate to the “Notice of Accreditation of CB” page. You will see a confirmation

message at the top of the page that the selected CB was added to the Notice of Accreditation (Figure 9.1.3).

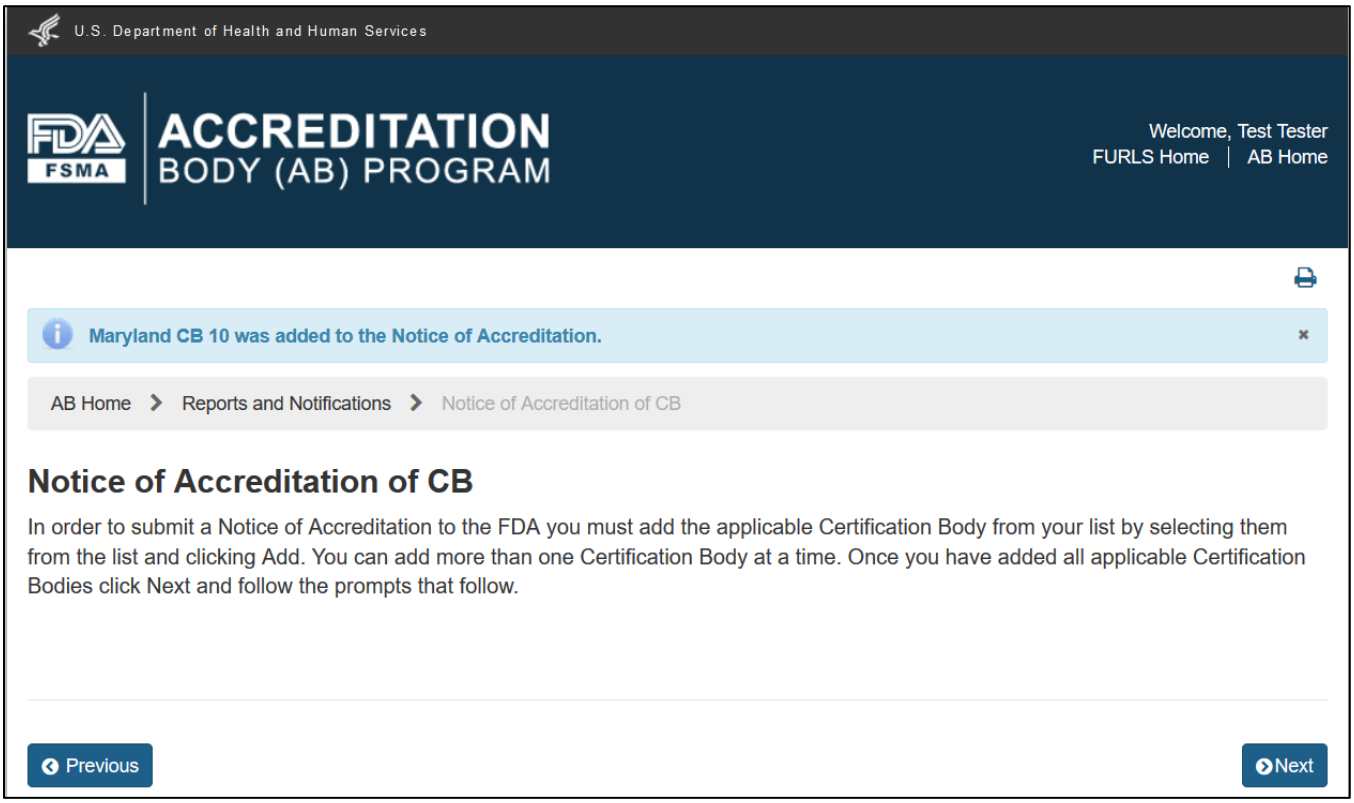
Select additional CBs from the drop-down menu to add multiple CBs to the same Notice of Accreditation. Once you have added all applicable CBs click “Next.”

Figure 9.1.2 – Notice of Accreditation of CB Page with CB and Scope Information



The system then displays the next page of instructional text (Figure 9.1.3).

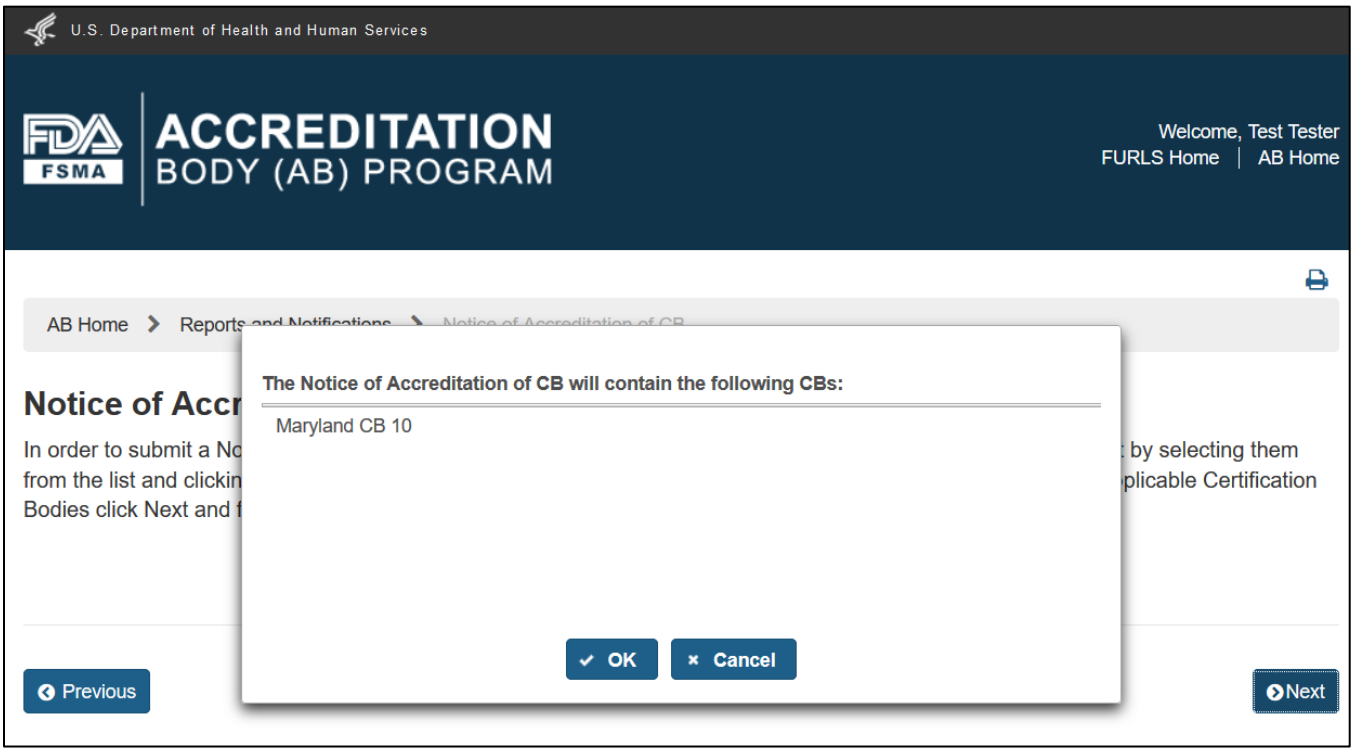
Figure 9.1.3 –Notice of Accreditation of CB Before Submission



Click the “Next” button and the system will display a pop-up window containing the confirmation message (Figure 9.1.4).

To cancel the action, click the “Cancel” button and return to the “Notice of Accreditation of CB” page or, proceed with the notice by clicking the “OK” button.

Figure 9.1.4 – Confirmation Message



Once you have clicked the “OK” button to confirm the addition of the CB to the Notice of Accreditation, the system will display the “e-Signature” page (Figure 9.1.5).

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

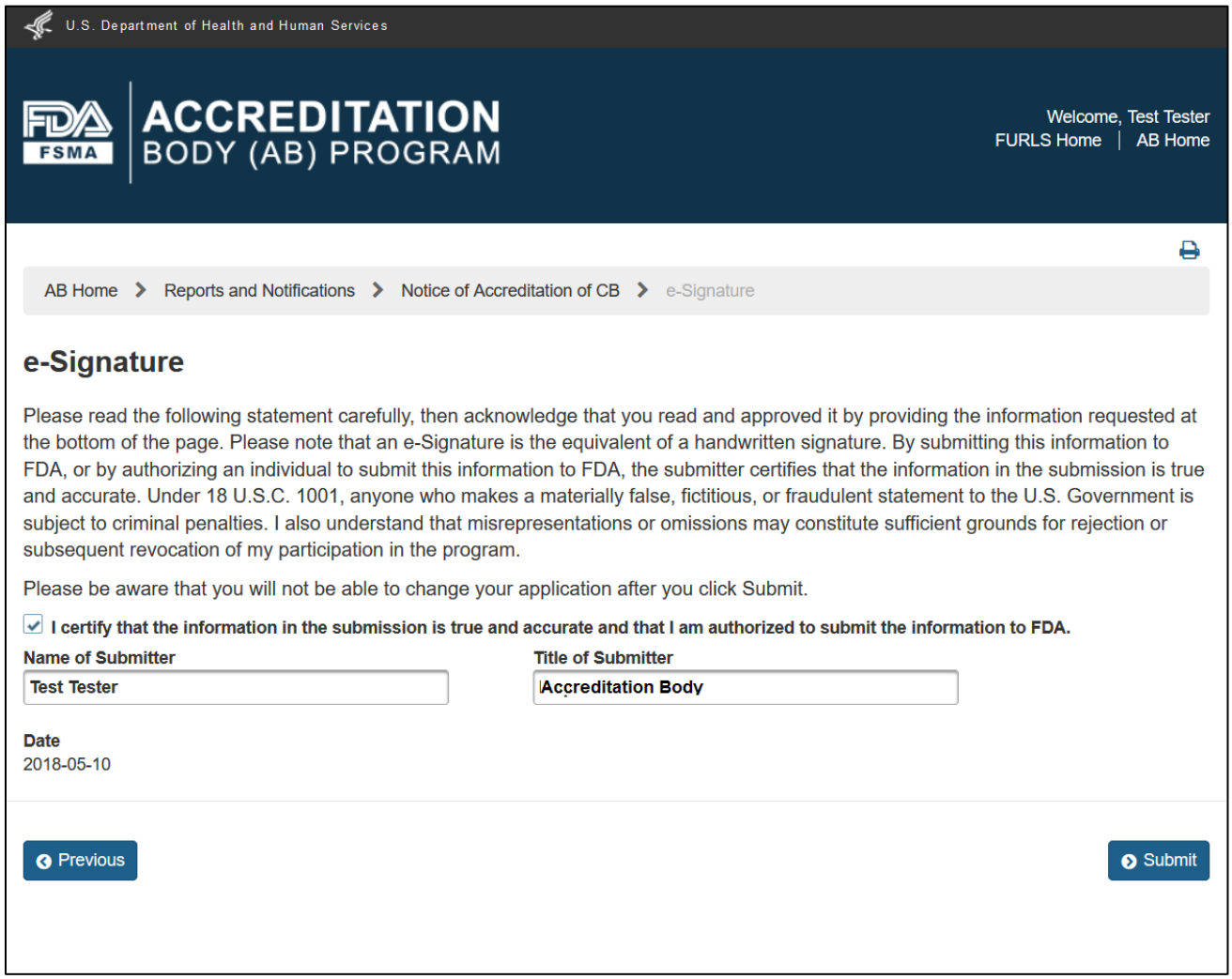
Click the check mark to indicate you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

The following data fields are present:

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

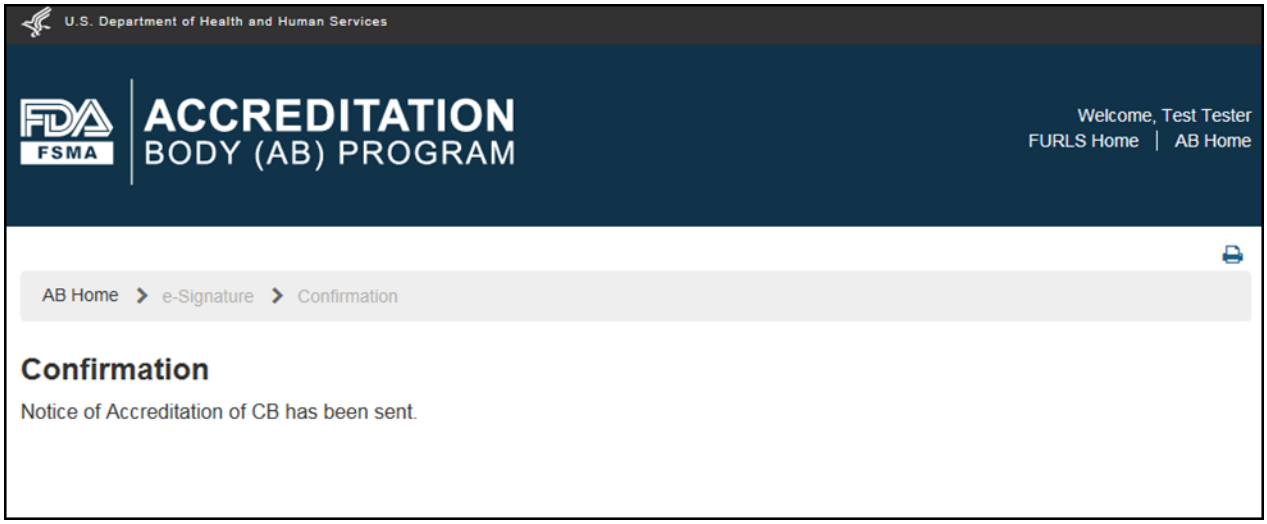
Fill in the required data fields and click the “Submit” button.

Figure 9.1.5 – e-Signature Page



After you click the “Submit” button the system will display the confirmation message that the notification has been sent to FDA (Figure 9.1.6).

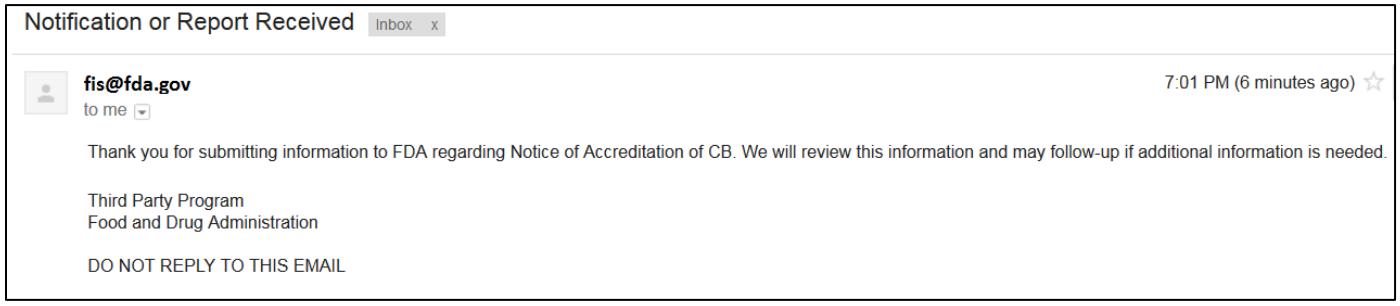
Figure 9.1.6 – Confirmation Message Page



A confirmation e-mail is sent to the AB Point of Contact indicating that the Notice of Accreditation was received (Figure 9.1.7).

Please note that all emails will be sent from the fis@fda.gov email address (see example in Figure 9.1.7 below).

Figure 9.1.7 – E-mail Notification Sent to AB User



Note: The CB must complete the account verification procedure and log into the FURLS Certification Body Portal to complete the accreditation process.

The CB will receive an email containing the verification code. This verification code must be entered in the FURLS OAA account screen. Once the verification is complete, the CB must navigate to the FSMA section of the FURLS landing page and click on the “Third-Party Program Certification Body” link. The CB will be navigated to the Third-Party Certification Body

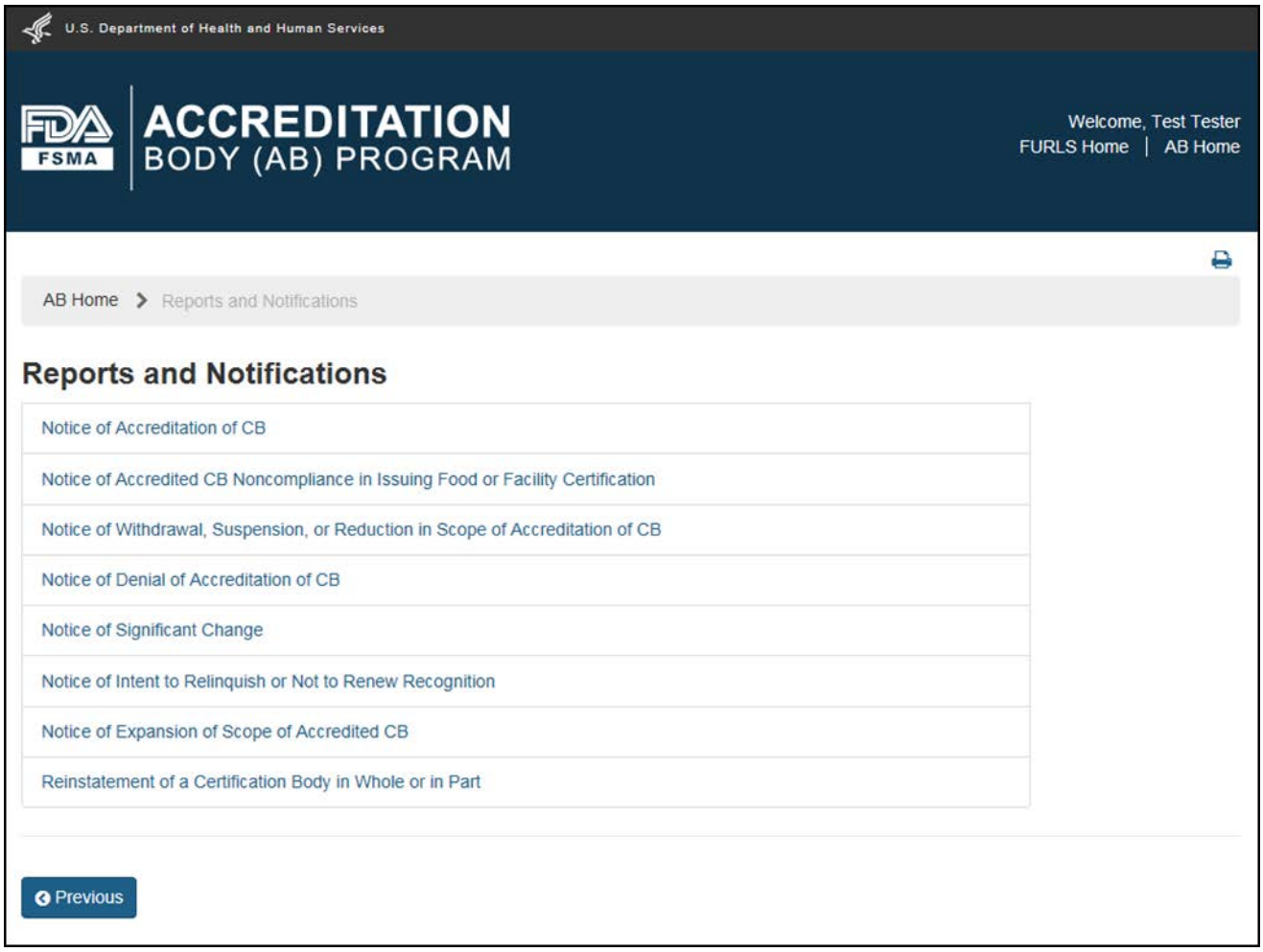
home page. This will complete the accreditation notification to the FDA.

Please visit the FURLS Certification Body User Guide for more information. Section 1.0 provides instructions for creating a CB account and the verification procedures. Section 2.0 provides instructions for logging in to the Third-Party Certification Body home page.

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

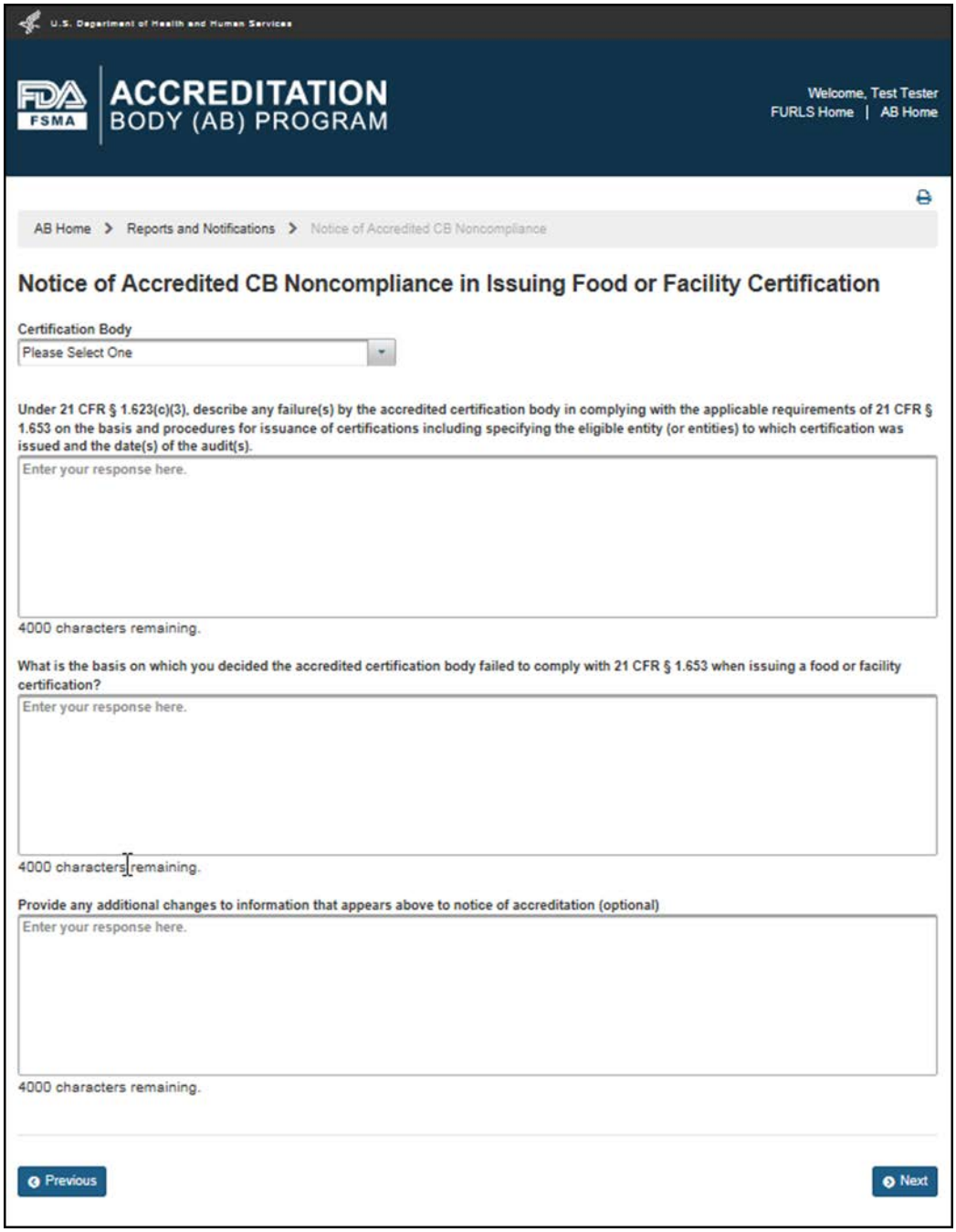
Select the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” link in the “Reports and Notifications” page (Figure 9.2.1).

Figure 9.2.1 – Reports and Notifications Page



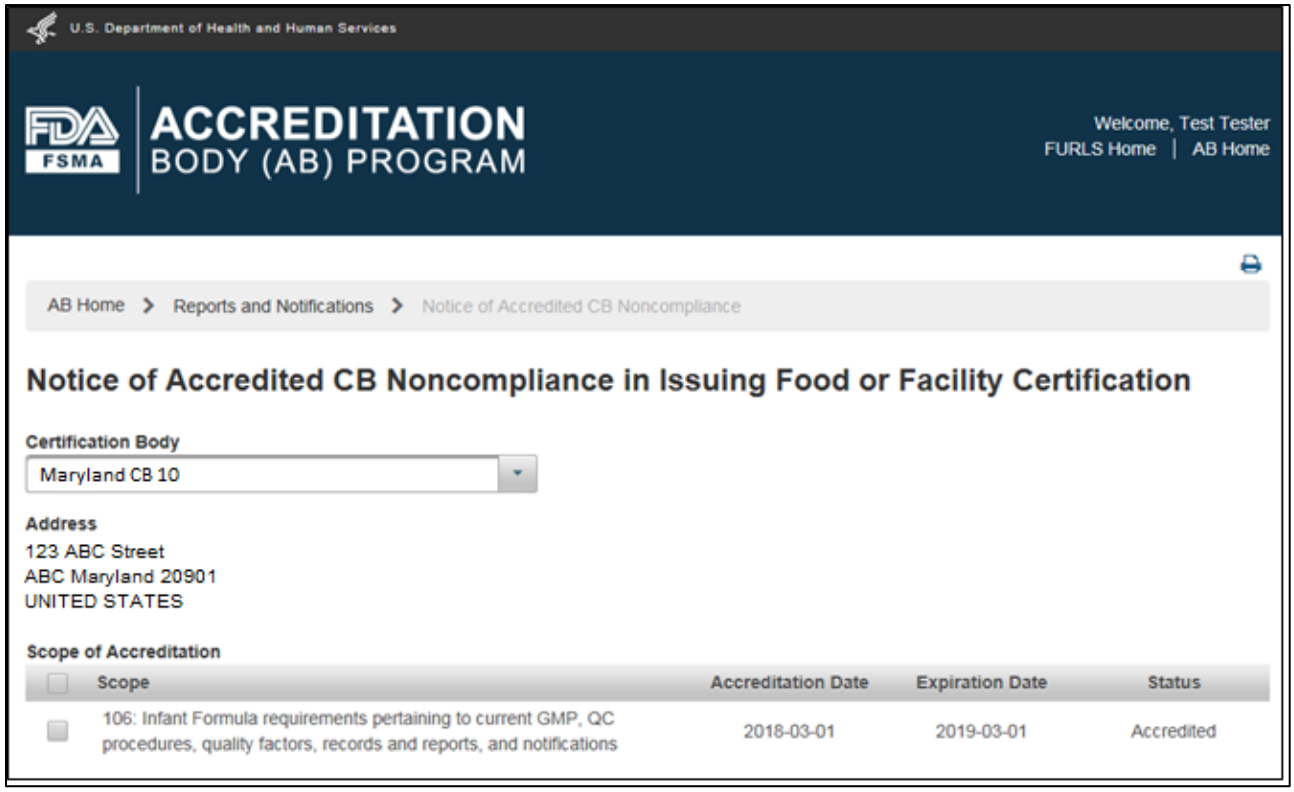
The system displays the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” page (Figure 9.2.2).

Figure 9.2.2 – Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification Page



Select the CB from the “Certification Body” drop-down menu. The system will display the CB’s address and accredited scopes (Figure 9.2.3).

Figure 9.2.3 – CB Address and Scope Information



Select the checkbox next to the scope(s) to be submitted with the notice.

To select all of the scopes check the box in the column heading. Provide answers to the following questions regarding the non-compliance in the text box fields:

- **Under 21 CFR § 1.623(c)(3), describe any failure(s) by the accredited certification body in complying with the applicable requirements of 21 CFR § 1.653 on the basis and procedures for issuance of certifications including specifying the eligible entity (or entities) to which certification was issued and the date(s) of the audit(s).**

- **Under 21 CFR § 1.623(c)(3), describe any failure(s) by the accredited certification body in complying with the applicable requirements of 21 CFR § 1.653 on the basis and procedures for issuance of certifications including specifying the eligible entity (or entities) to which certification was issued and the date(s) of the audit(s).**

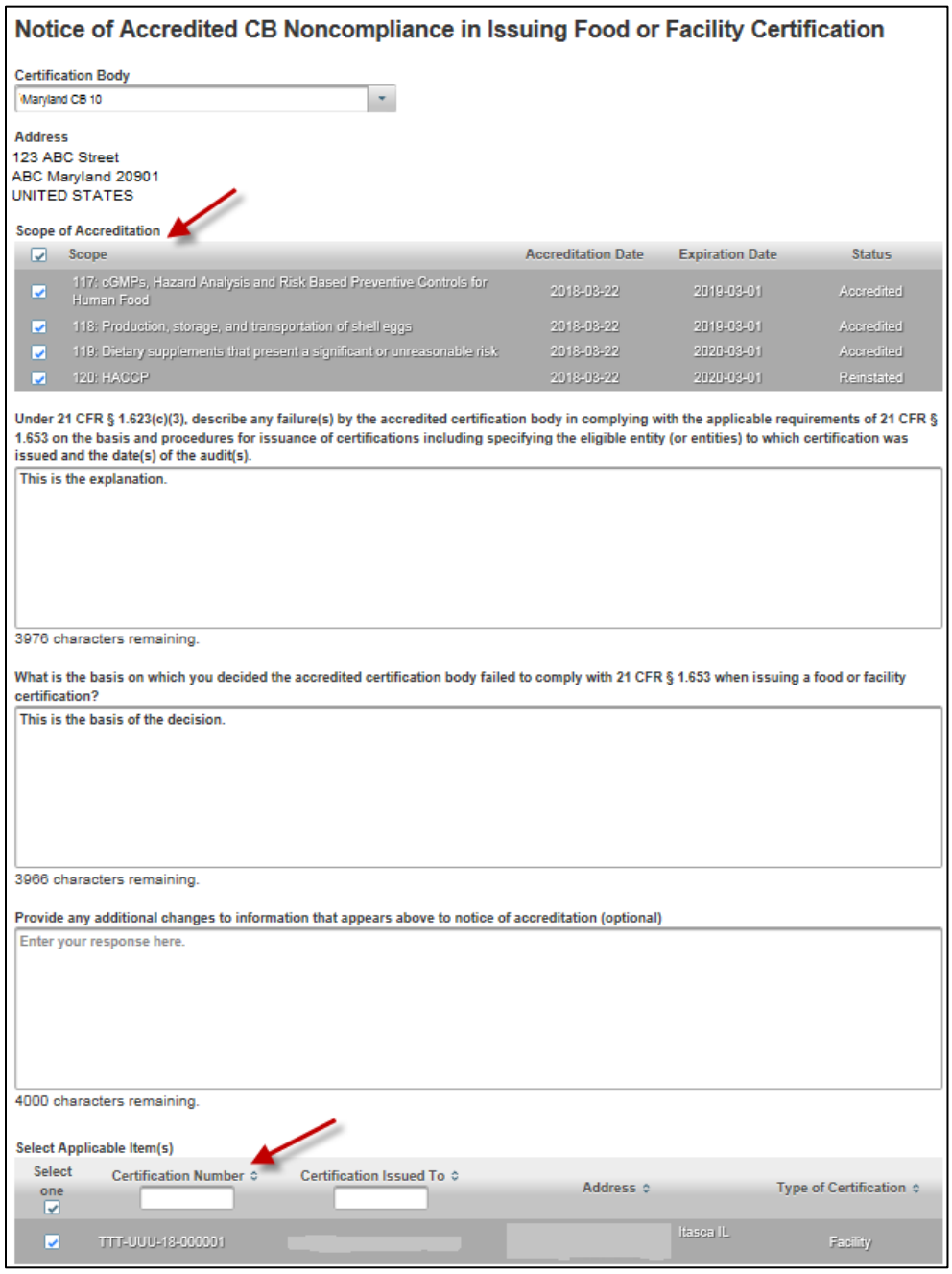
- **Provide any additional changes to information that appears above to notice of accreditation (optional).**

The system will display a table of certificates at the bottom of the screen after one or more scopes are selected (Figure 9.2.4).

Select the certificate(s) to be included in the notice of non-compliance. Select the checkbox in the “Select one” column (Figure 9.2.4).

To select all of the certificates select the checkbox in the column header.

Figure 9.2.4 – Notice with Selected Scopes and Certification



Click the “Next” button. The system will display the “e-Signature” page (Figure 9.2.5).

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

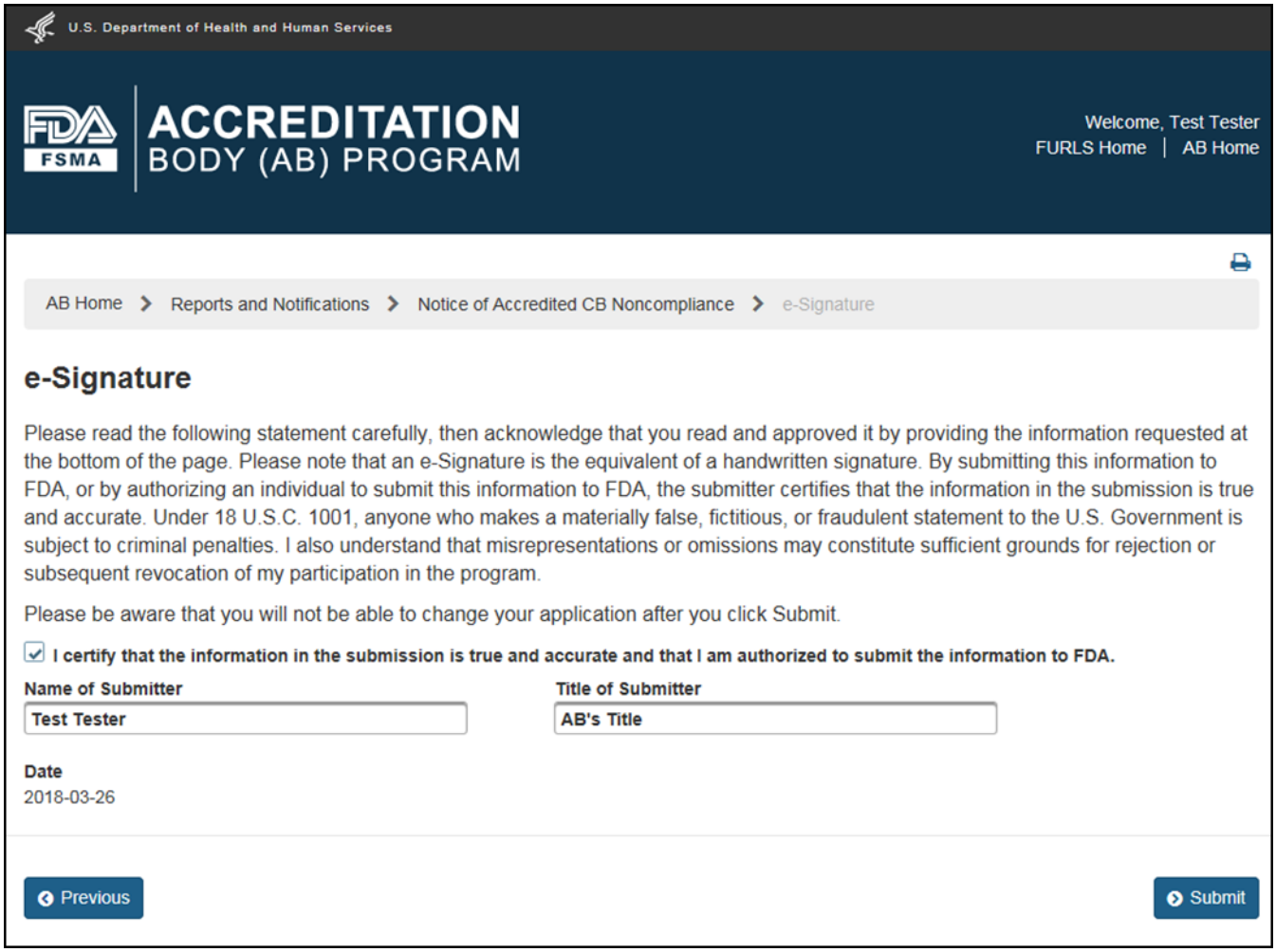
Click the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

The following data fields are present:

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

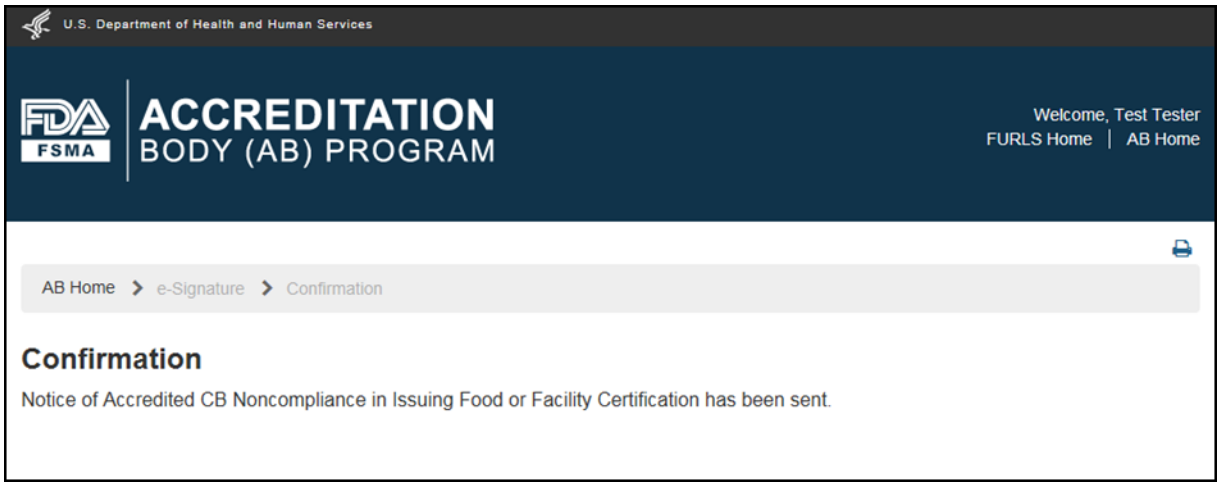
Fill in the required data fields, and click the “Submit” button.

Figure 9.2.5 – e-Signature Page



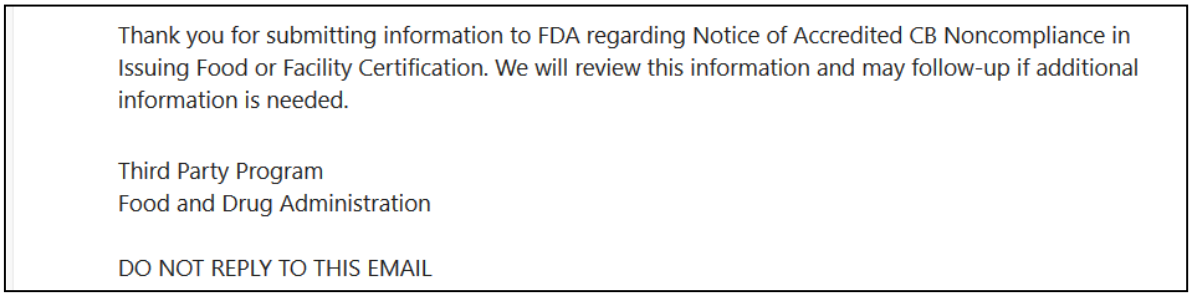
After you click the “Submit” button the system will display the confirmation message (Figure 9.2.6).

Figure 9.2.6 – Confirmation Message



An e-mail is sent to the AB indicating that the notice was received by the FDA (Figure 9.2.7 – Image depicts the email notification text only).

Figure 9.2.7 – E-mail to AB User

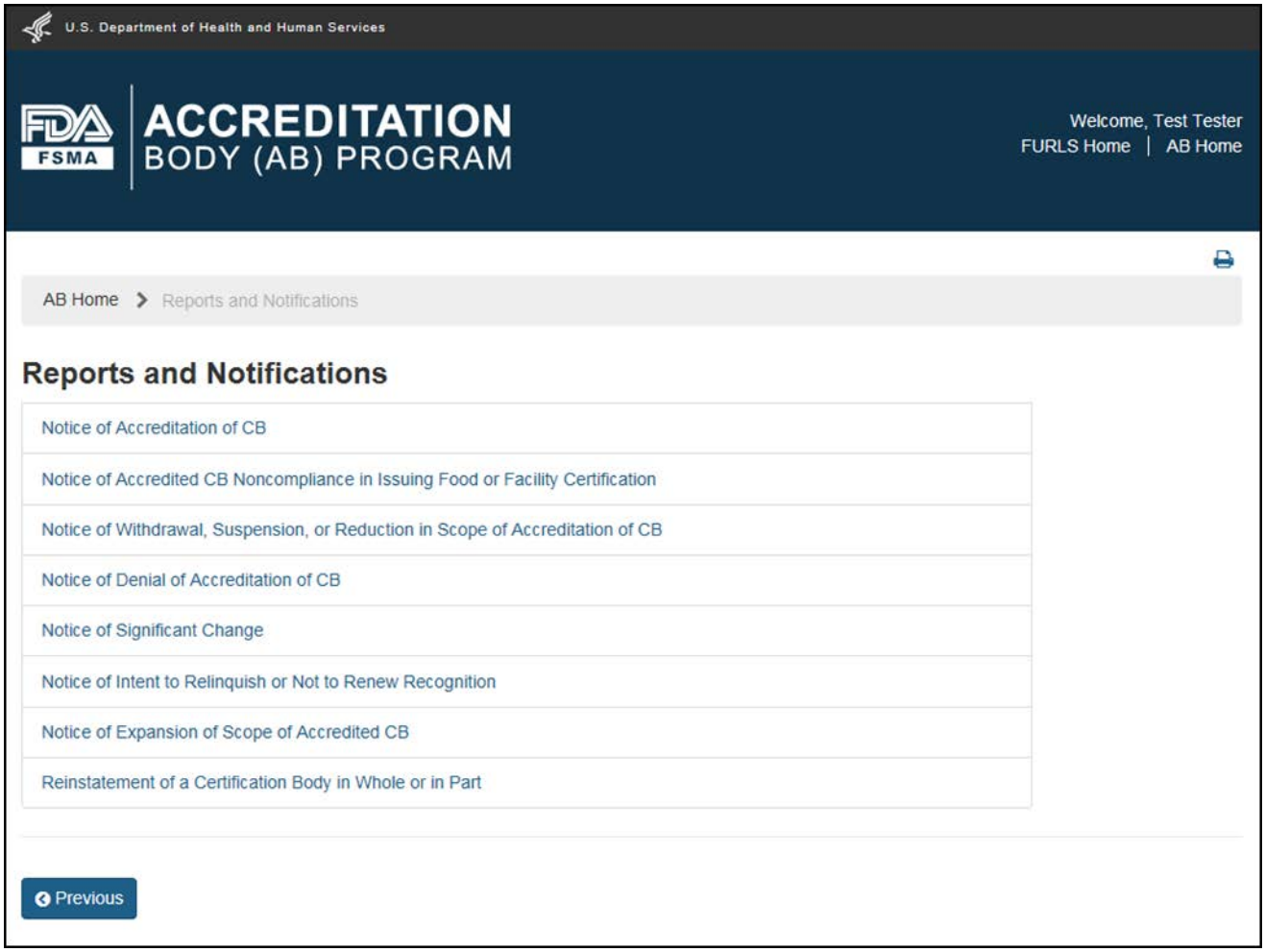


Return to the “Reports and Notifications” page by clicking on the “AB Home” link on the top of the banner.

9.3 Notice of Denial of Accreditation of CB

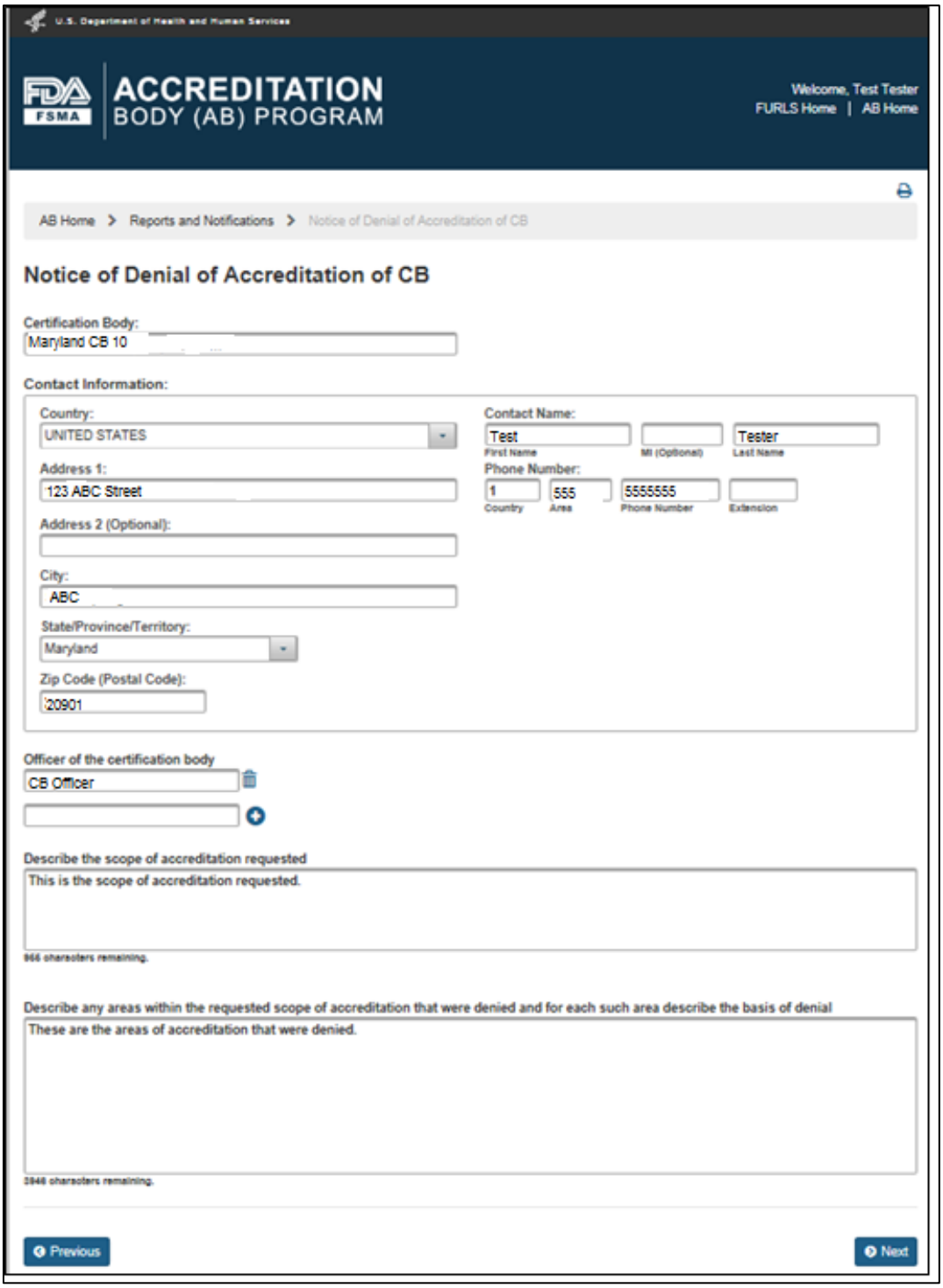
Select the “Notice of Denial of Accreditation of CB” link in the “Reports and Notifications” page (Figure 9.3.1).

Figure 9.3.1 – Reports and Notifications Page



The system displays the “Notice of Denial of Accreditation of CB” page (Figure 9.3.2).

Figure 9.3.2 – Notice of Denial of Accreditation of CB Page



Complete the following data fields:

- **Certification Body –** The name of the CB that the AB would like to add to the notice of denial of accreditation.
- **Contact Information**
    - **Country –** The country where the CB is physically located.
    - **Address 1 –** The street address where the CB is physically located.
    - **Address 2 (Optional) –** Use this 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 of the CB.
    - **Zip Code (Postal Code) –** The 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 –** The country code of the Point of Contact.
    - **Area –** The area code of the Point of Contact.
    - **Phone Number –** The phone number of the Point of Contact.
    - **Extension – T**he extension number of the Point of Contact.
- **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 "Next" button.

The system displays the “e-Signature” page (Figure 9.3.3).

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

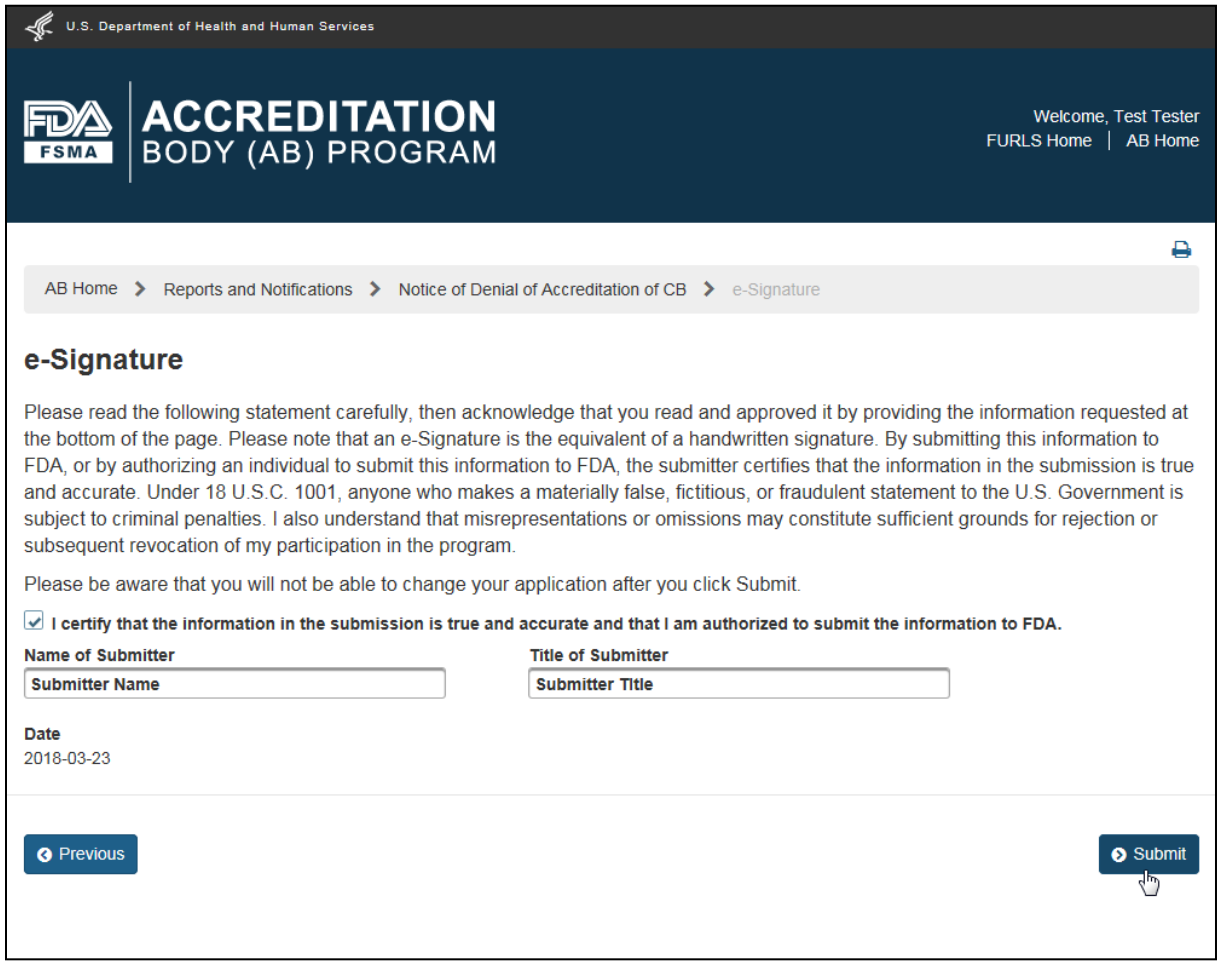
Click the check mark to certify that the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA.

The following data fields are present:

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

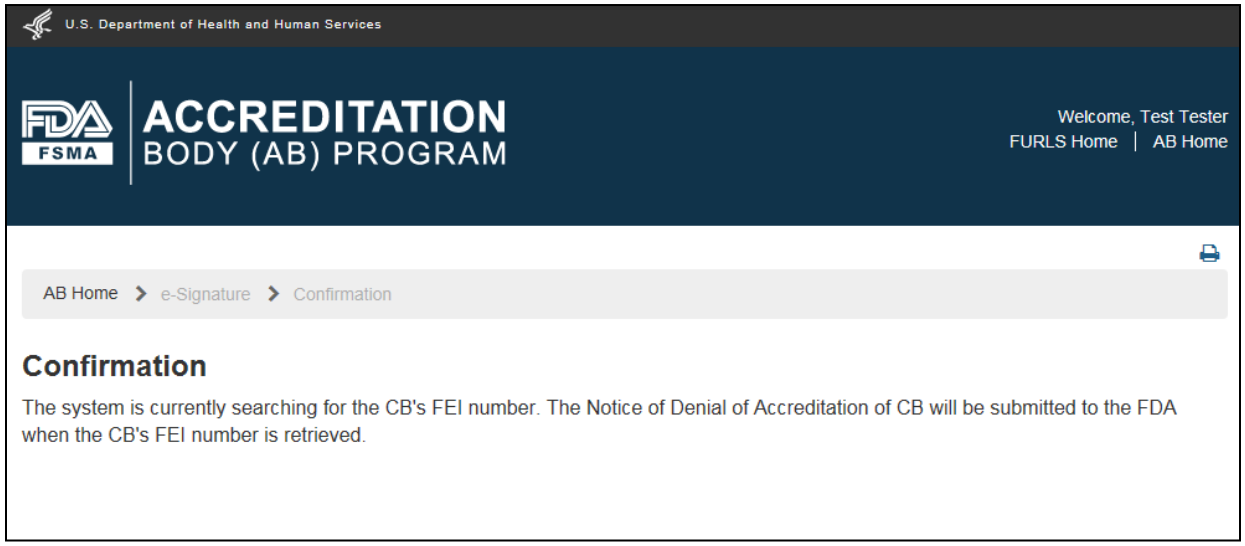
Fill in the required data fields, and click the “Submit” button.

Figure 9.3.3 – e-Signature Page



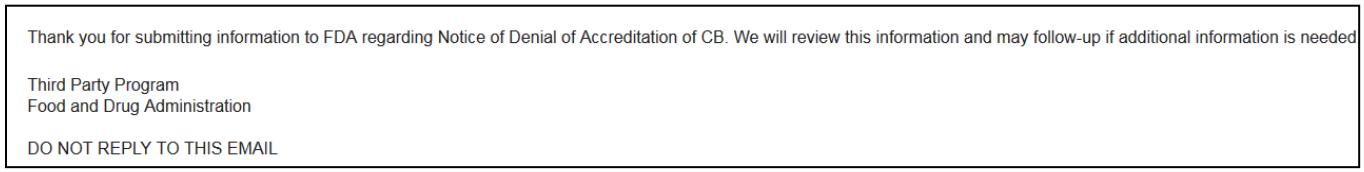
After you click the “Submit” button the system will display the confirmation message (Figure 9.3.4).

Figure 9.3.4 – Confirmation Message Page



An e-mail is sent to the AB indicating that the notice was received by the FDA (Figure 9.3.5 – Image depicts the email notification text only).

Figure 9.3.5 – E-mail Sent to AB User

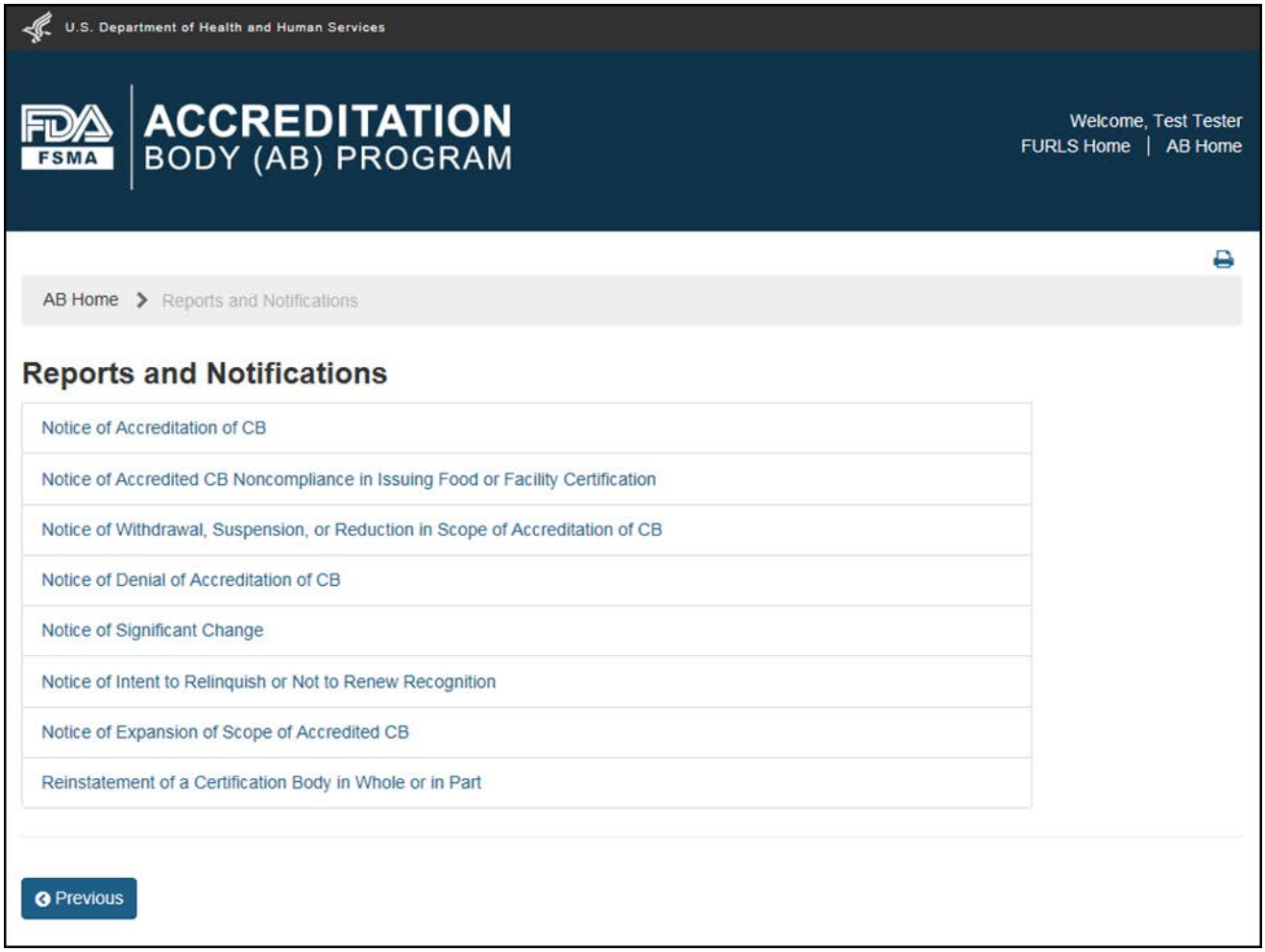


Return to the “Reports and Notifications” page by clicking on the “AB Home” link on the top of the banner.

9.4 Notice of Significant Change

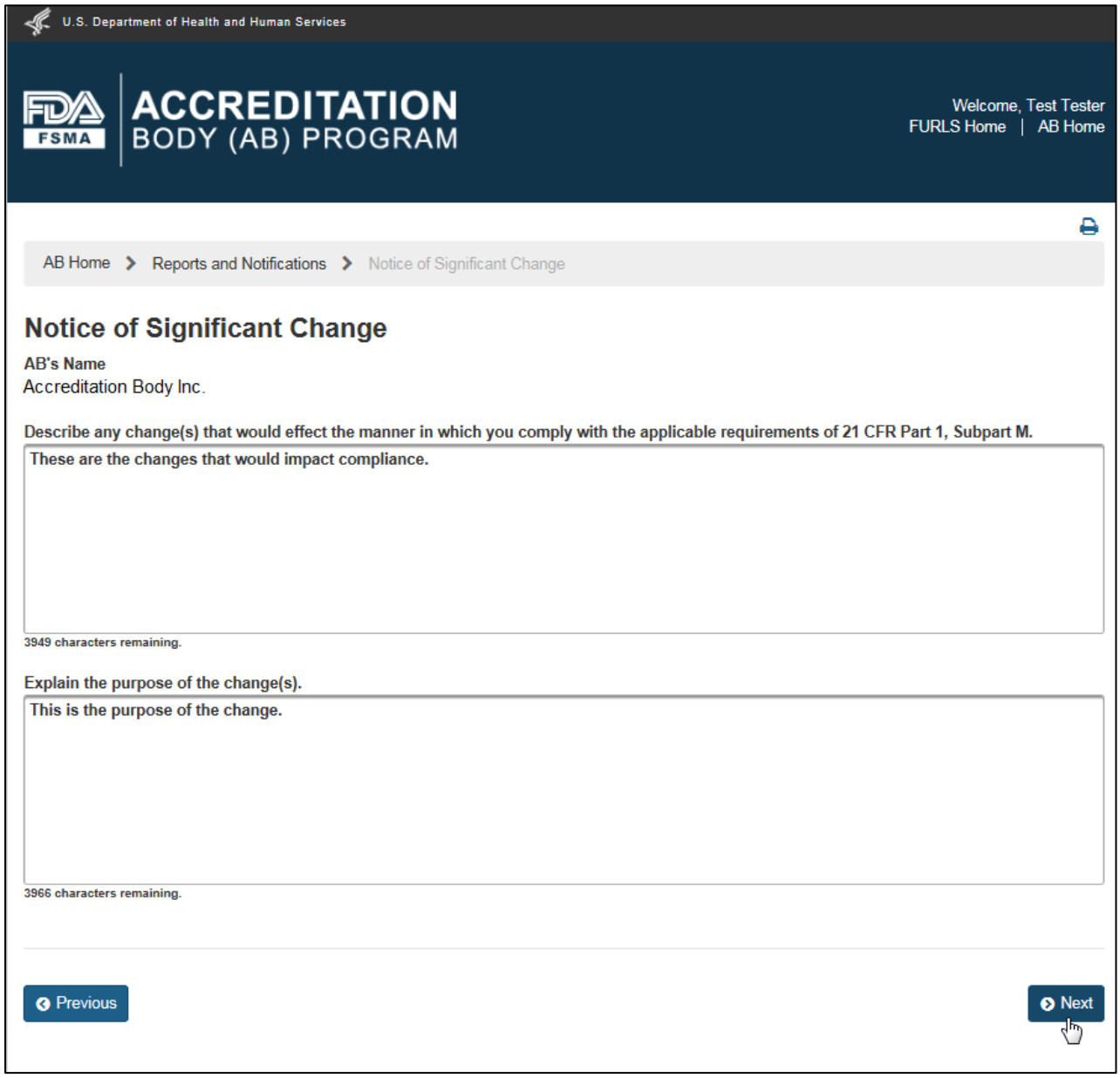
Select the “Notice of Significant Change” link in the “Reports and Notifications” page (Figure 9.4.1).

Figure 9.4.1 – Reports and Notifications Page



The system displays the “Notice of Significant Change” page (Figure 9.4.2).

Figure 9.4.2 – Notice of Significant Change Page



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 –** The changes observed with the CB that led to the notice of significant change.

- **Explain the purpose of the change(s) –**The purpose of the change (this could be a withdrawal, suspension, reduction in scope, etc.).

Click the “Next” button.

The system displays the “e-Signature” page (Figure 9.4.3).

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

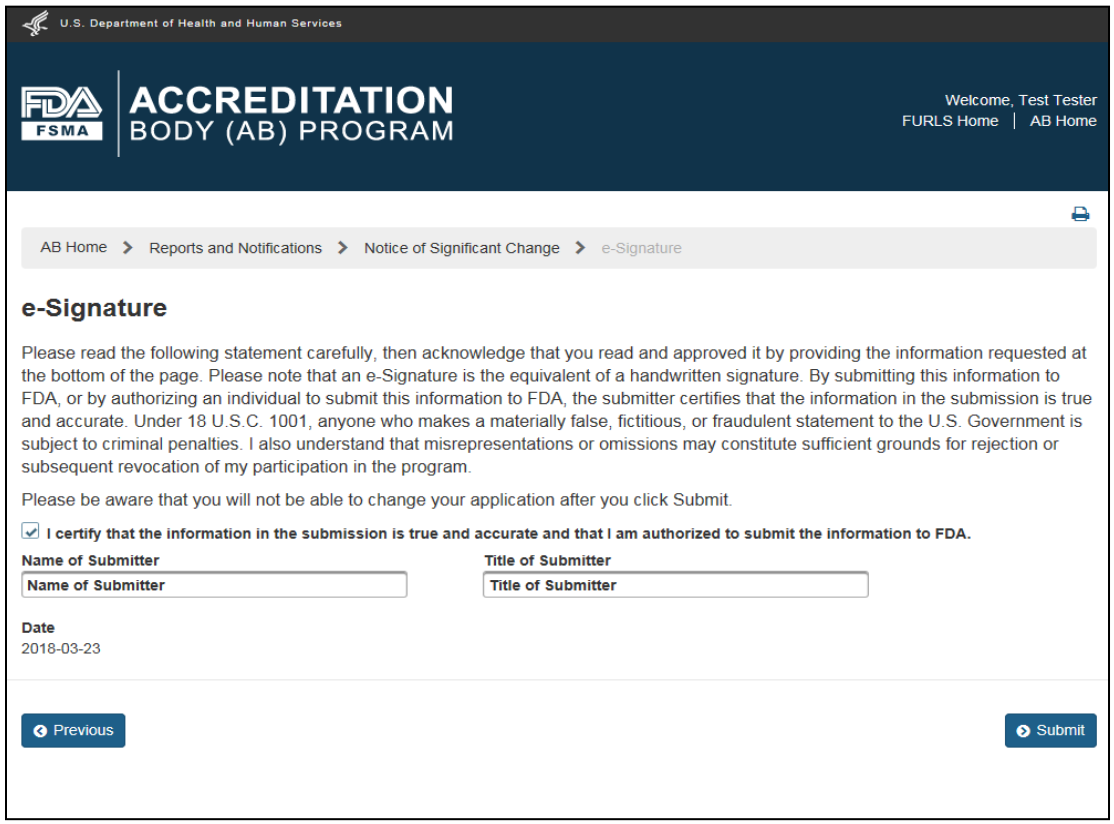
Click the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

The following data fields are present:

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

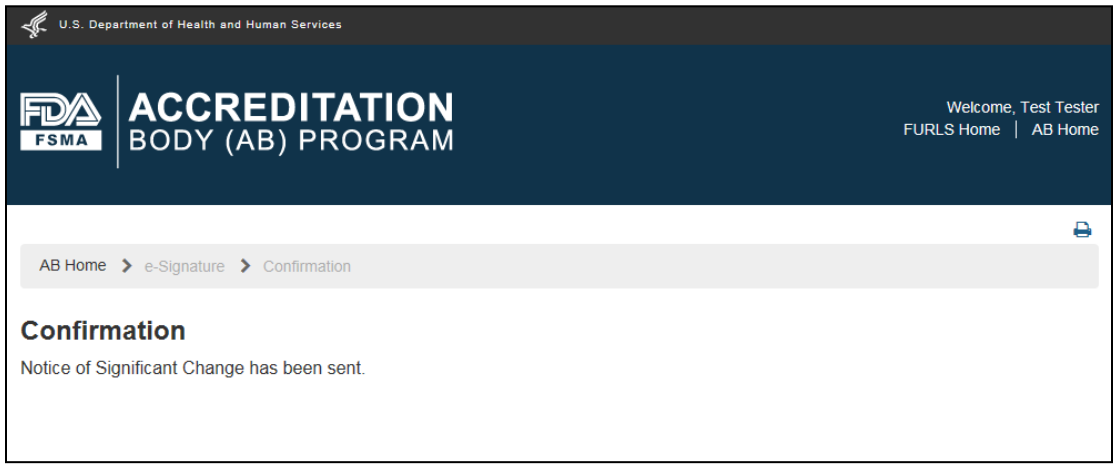
Fill in the required data fields, and click the “Submit” button.

Figure 9.4.3 – e-Signature Page



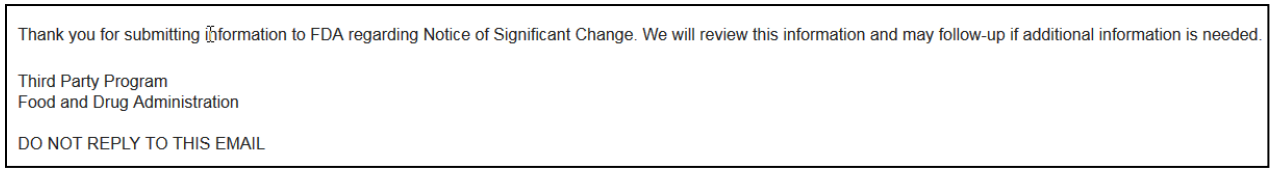
After you click the “Submit” button the system will display the confirmation message (Figure 9.4.4).

Figure 9.4.4 – Confirmation Message Page



An e-mail is sent to the AB indicating that the notice was received by the FDA (Figure 9.4.5 – Image depicts the email notification text only).

Figure 9.4.5 – E-mail sent to AB User


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

Third Party Program
Food and Drug Administration

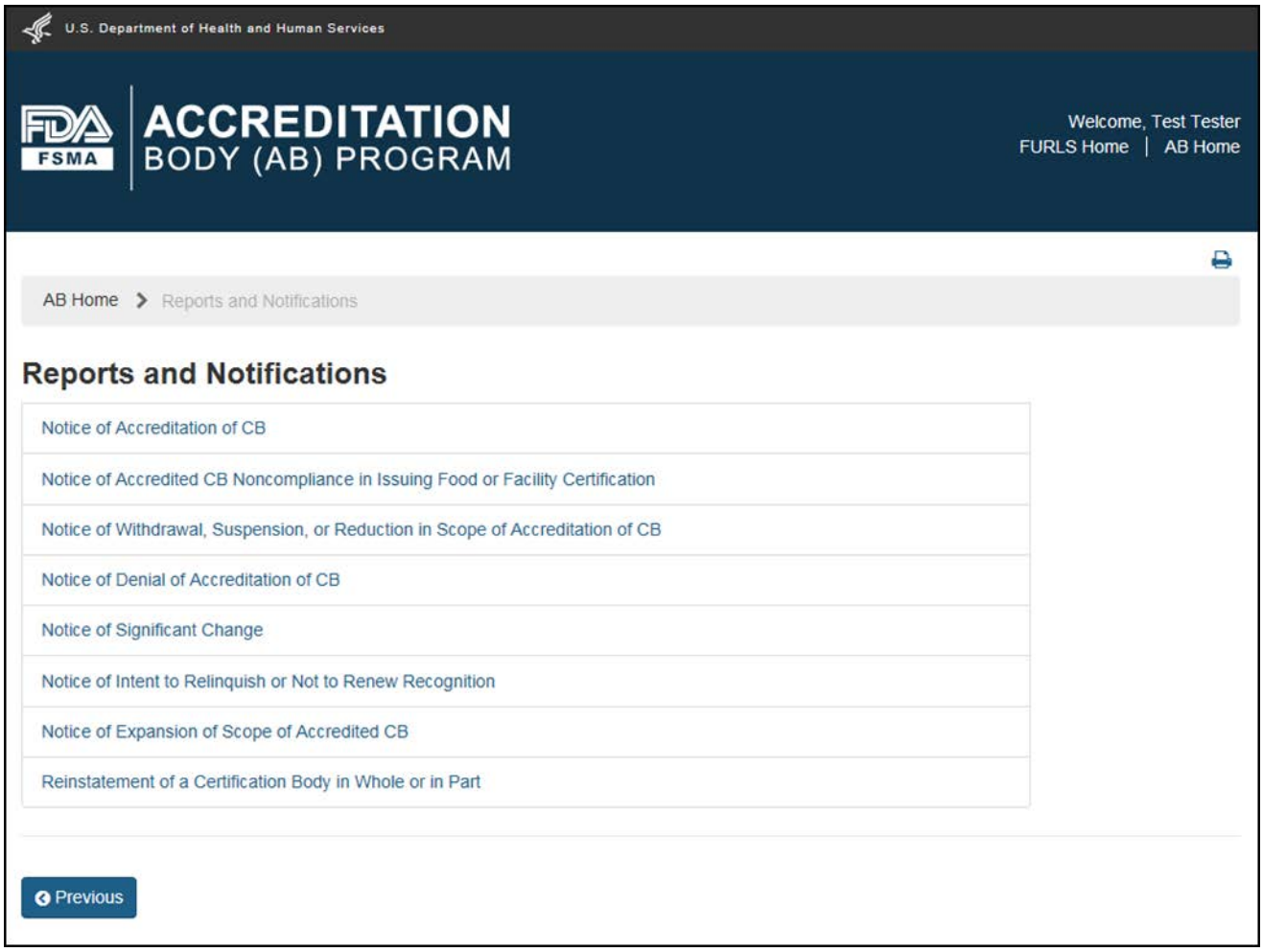
DO NOT REPLY TO THIS EMAIL

Return to the “Reports and Notifications” page by clicking on the “AB Home” link on the top of the banner.

9.5 Notice of Expansion of Scope of Accredited CB

Select the “Notice of Expansion of Scope of Accredited CB” link in the “Reports and Notifications” page (Figure 9.5.1).

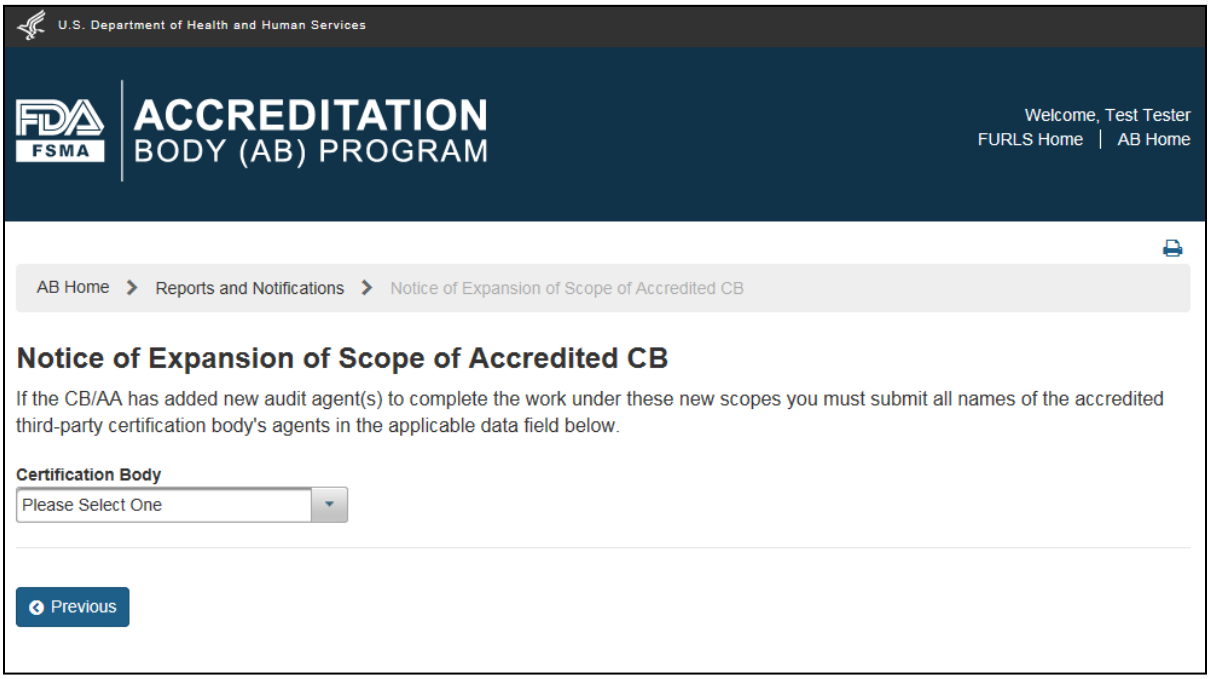
Figure 9.5.1 – Reports and Notifications Page



The system displays the “Notice of Expansion of Scope of Accredited CB” page (Figure 9.5.2).

Select a name from the “Certification Body” drop-down menu.

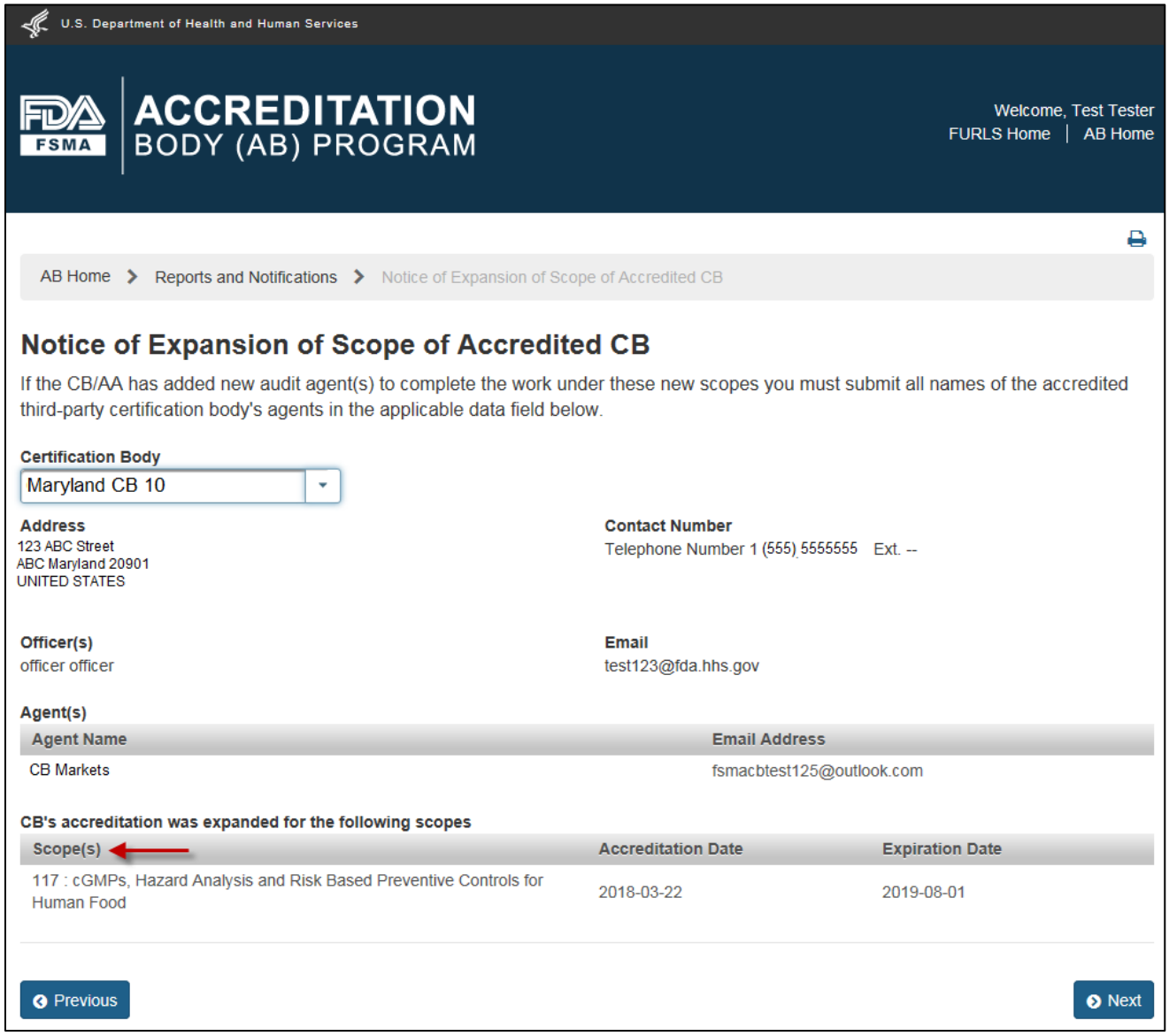
Figure 9.5.2 – Notice of Expansion of Scope of Accredited CB Page



The system displays the CB's information along with the list of expanded scope(s) (Figure 9.5.3).

Note: The expanded scopes that appear in the Notice of Expansion were those that were modified in "Add or Manage my Third-Party CBs" page.

Figure 9.5.3 – CB and Scope Information



Click the “Next” button.

The system displays the “e-Signature” page (Figure 9.5.4).

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

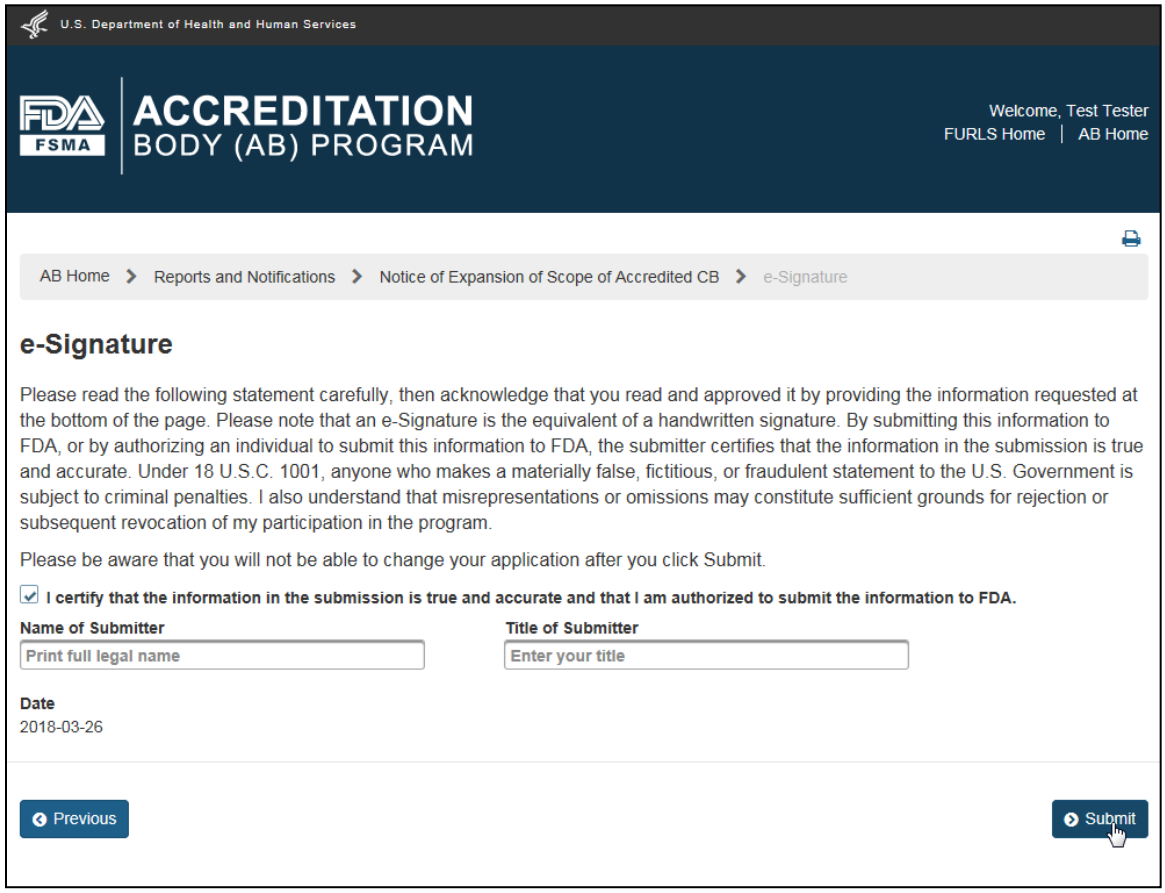
Click on the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

The following data fields are present:

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

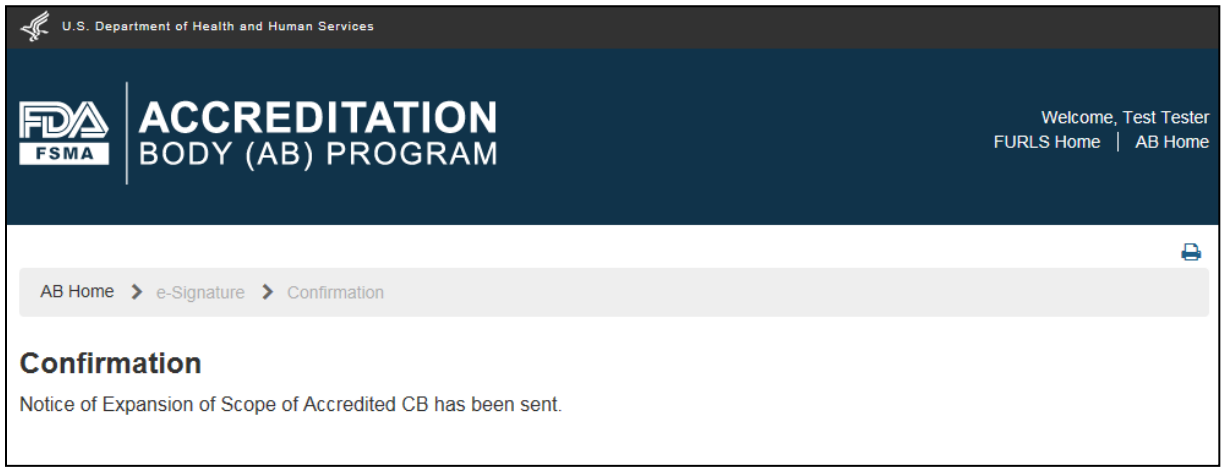
Fill in the required data fields, and click the “Submit” button.

Figure 9.5.4 – e-Signature Page



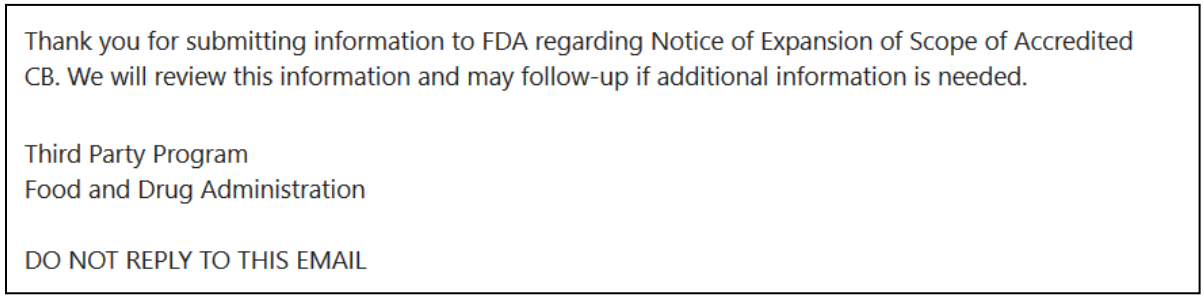
The system will display the confirmation message (Figure 9.5.5).

Figure 9.5.5 – Confirmation Message Page



An e-mail is sent to the AB indicating that the notice was received by the FDA (Figure 9.5.6 – Image depicts the email notification text only).

Figure 9.5.6 – E-mail sent to AB User

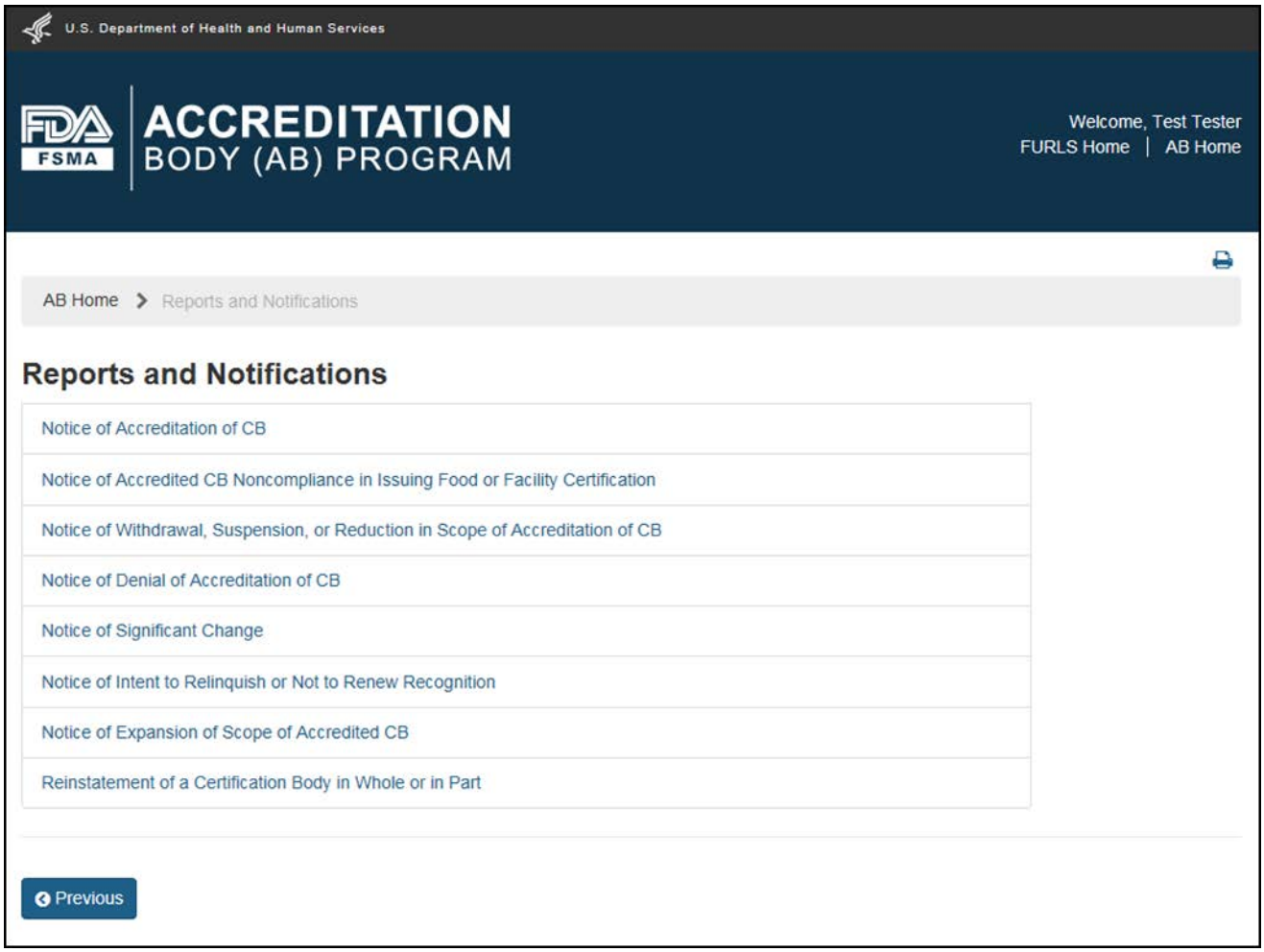


Return to the “Reports and Notifications” page by clicking on the “AB Home” link on the top of the banner.

9.6 Notice of Intent to Relinquish or Not to Renew

Select the “Notice of Intent to Relinquish or Not to Renew Recognition” link in the “Reports and Notifications” page (Figure 9.6.1).

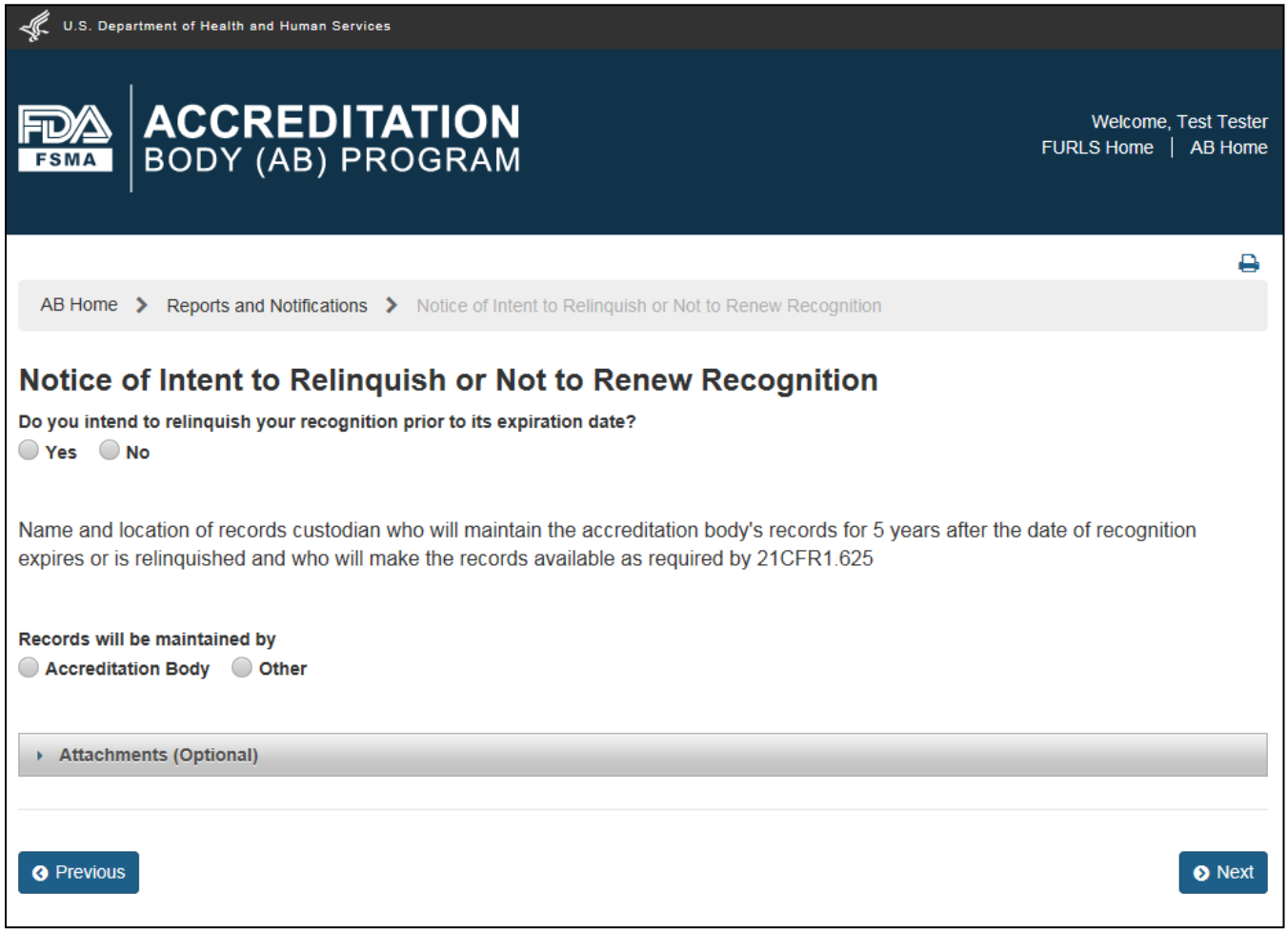
Figure 9.6.1 – Reports and Notifications Page



The system displays the “Notice of Intent to Relinquish or Not to Renew Recognition” page (Figure 9.6.2).

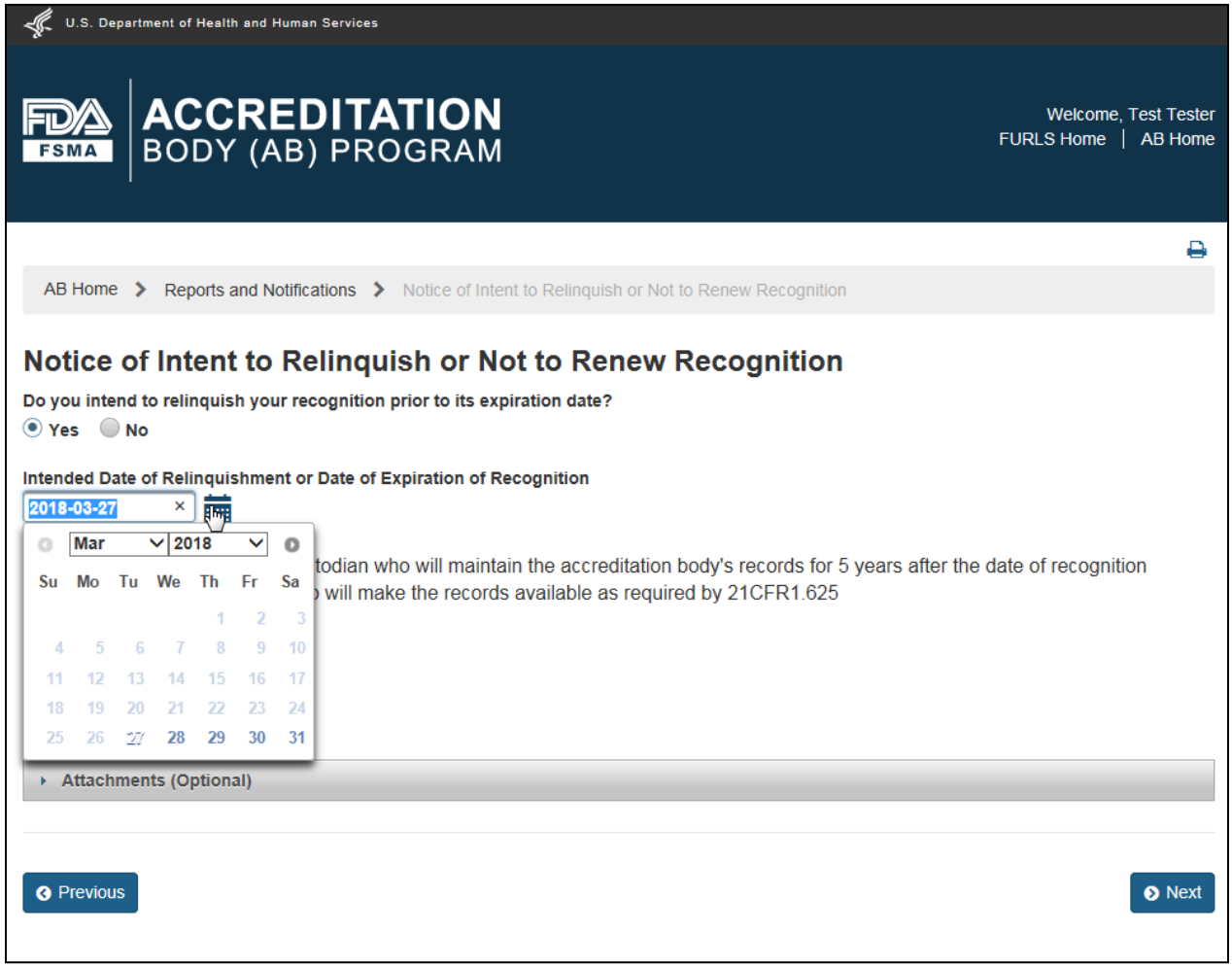
Answer the question, “Do you intend to relinquish your recognition prior to its expiration date?” by selecting one of the two options: “Yes” or “No.”

Figure 9.6.2 – Notice of Intent to Relinquish or Not to Renew Recognition Page



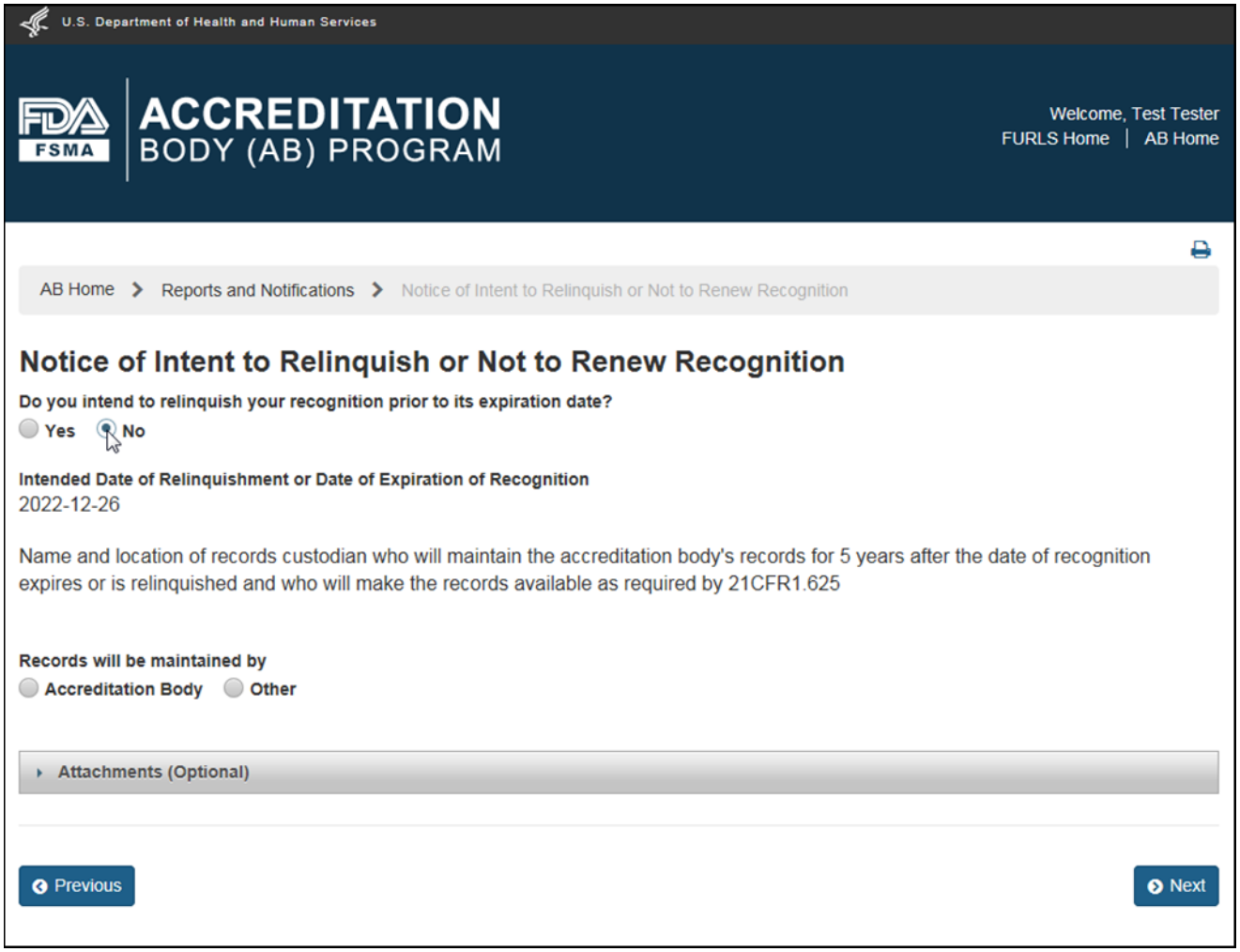
If you select “Yes,” the system displays the calendar feature and pick (or enter) the “Intended Date of Relinquishment” (Figure 9.6.3).

Figure 9.6.3 – Intended Date of Relinquishment or Date of Expiration of Recognition



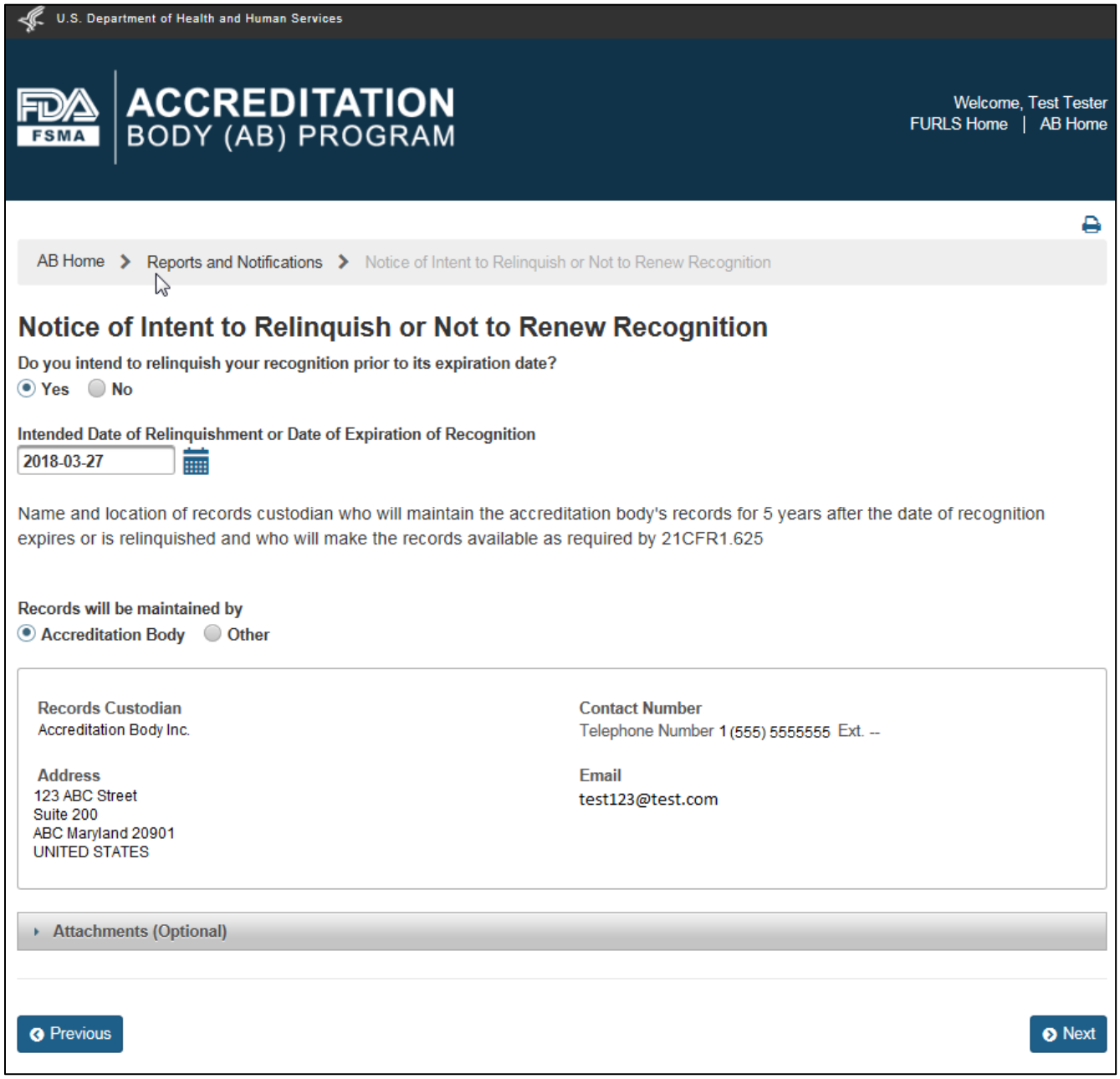
If you select “No” the system will display the AB’s date of expiration of recognition as Read-Only (Figure 9.6.4).

Figure 9.6.4 – Read-Only Date of Intended Date of Relinquishment or Date of Expiration of Recognition



Identify who will maintain your records upon relinquishment/non-renewal of your accreditation (Figure 9.6.5). If you select that the “Accreditation Body” will maintain the records, then the system will populate the AB’s information.

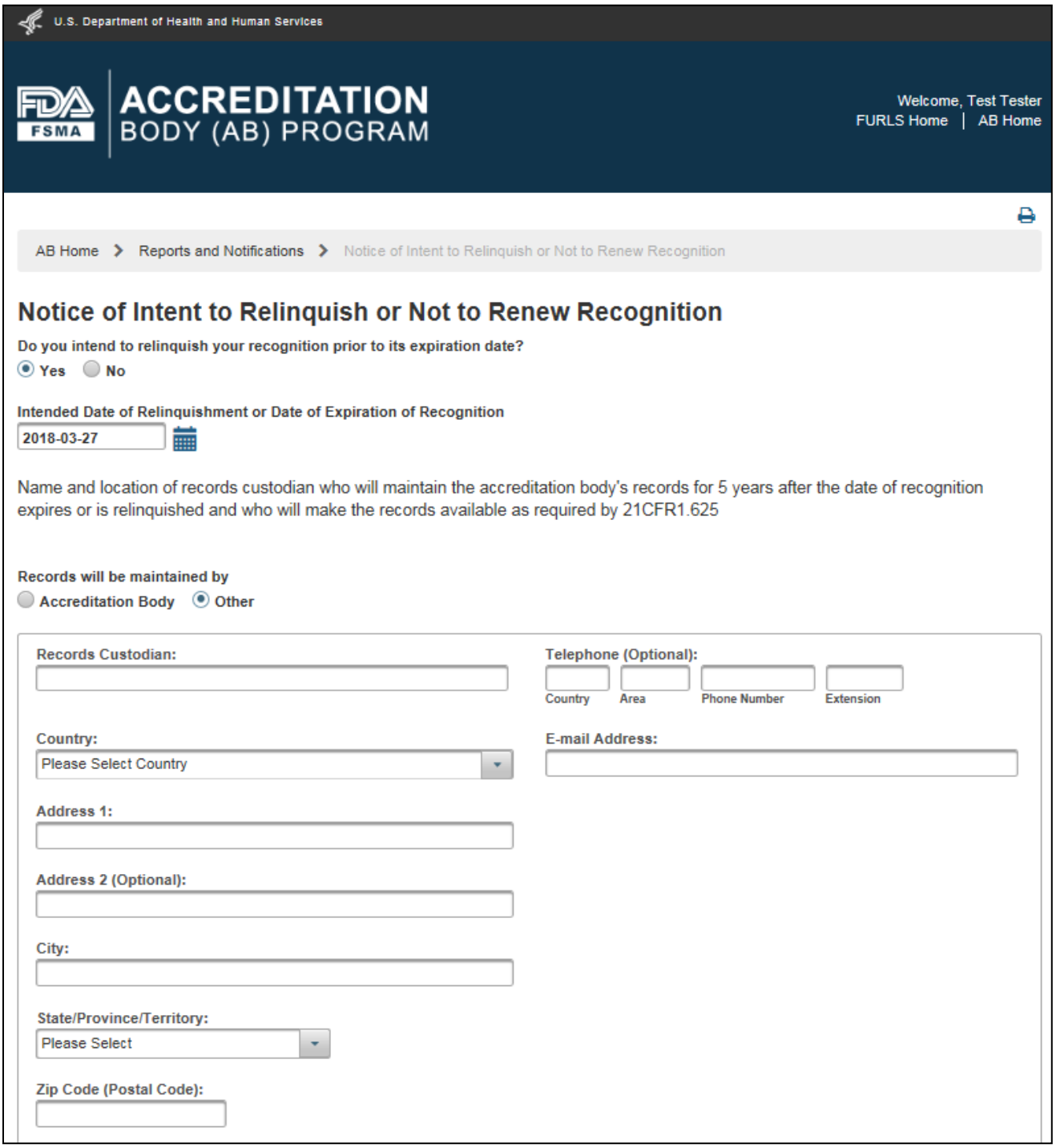
Figure 9.6.5 – Records Maintained By AB



If you select “Other”, the system displays the following data fields (Figure 9.6.6) that you must complete:

- **Records Custodian –** The name of the AB’s Records Custodian.
- **Country –** The country where AB’s Records Custodian is physically located.
- **Address 1 –** The street address where the AB’s Records Custodian is physically located.
- **Address 2 (Optional) –** The additional information about the physical location of the company (this may include a suite or apartment number, if applicable).
- **City –** The city where the AB’s record custodian is physically located.
- **State/Province/Territory –** The state/province/territory where the AB’s Records Custodian is physically located.
- **Zip Code (Postal Code) –** The postal code where the AB’s Records Custodian is physically located.
- **Telephone (Optional field)**
    - **Country –** The country code of the Point of Contact.
    - **Area –** The area code of the Point of Contact.
    - **Phone Number –** The phone number of the Point of Contact.
    - **Extension –** The extension number of the Point of Contact.
- **E-mail Address –** The e-mail address of the AB’s Records Custodian.

Figure 9.6.6 – Records Maintained by Other



Upload files to the notice using the “Attachments (Optional)” feature (Figure 9.6.5). Attachments are not required to submit the notice.

Click the “Next” button.

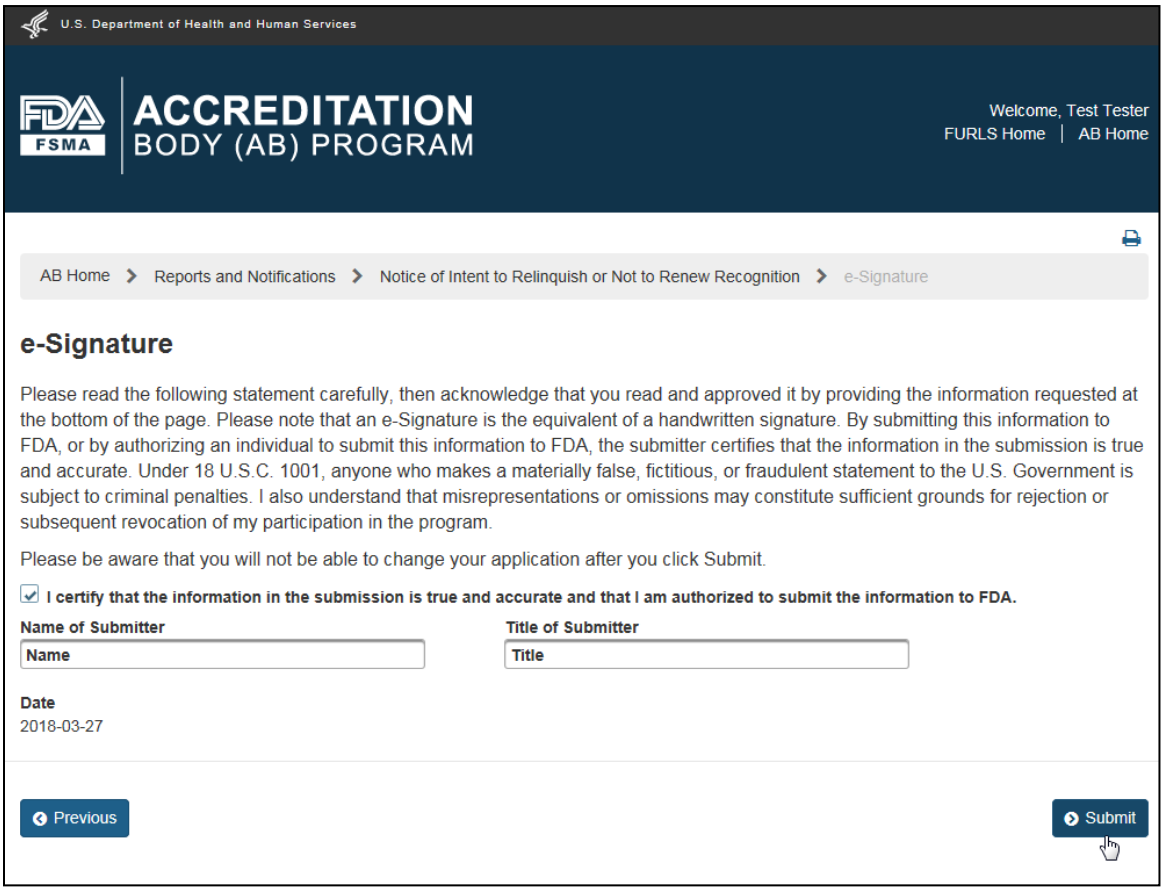
The system displays the “e-Signature” page (Figure 9.6.7).

Follow the directions provided on the “e-Signature” page. You must click on the check mark to certify that the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA. The following data fields are present:

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

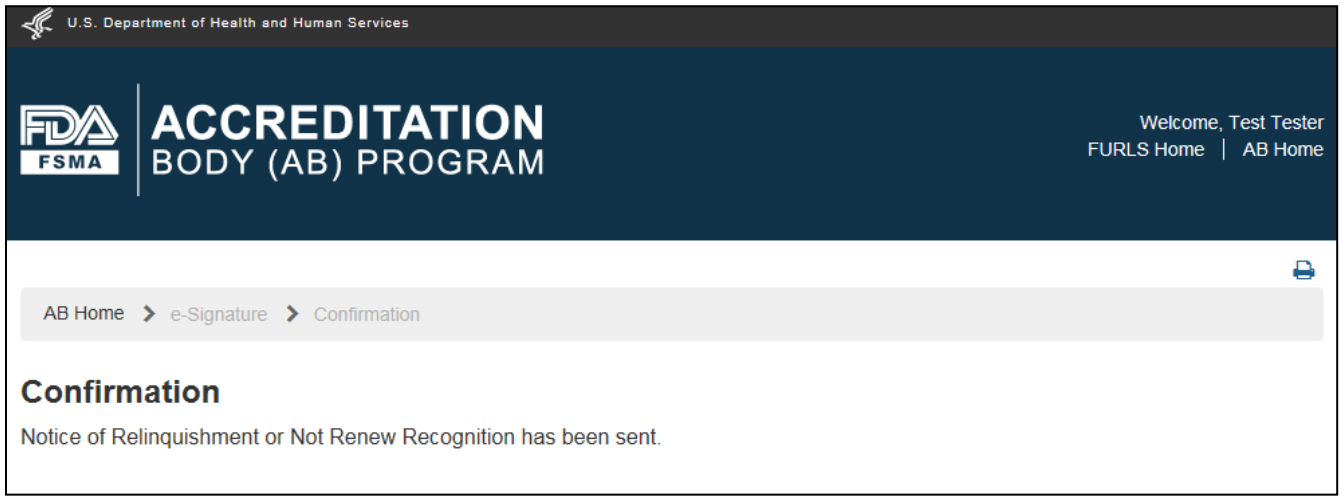
Fill in the required data fields, and click the “Submit” button.

Figure 9.6.7 – e-Signature Page



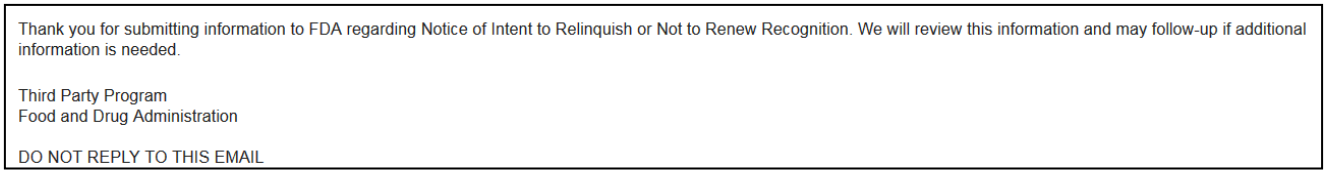
The system will display the confirmation message (Figure 9.6.8).

Figure 9.6.8 – Confirmation Message Page



An e-mail is sent to the AB indicating that the notice was received by the FDA (Figure 9.6.9 – Image depicts the email notification text only).

Figure 9.6.9 – E-mail Sent to AB User

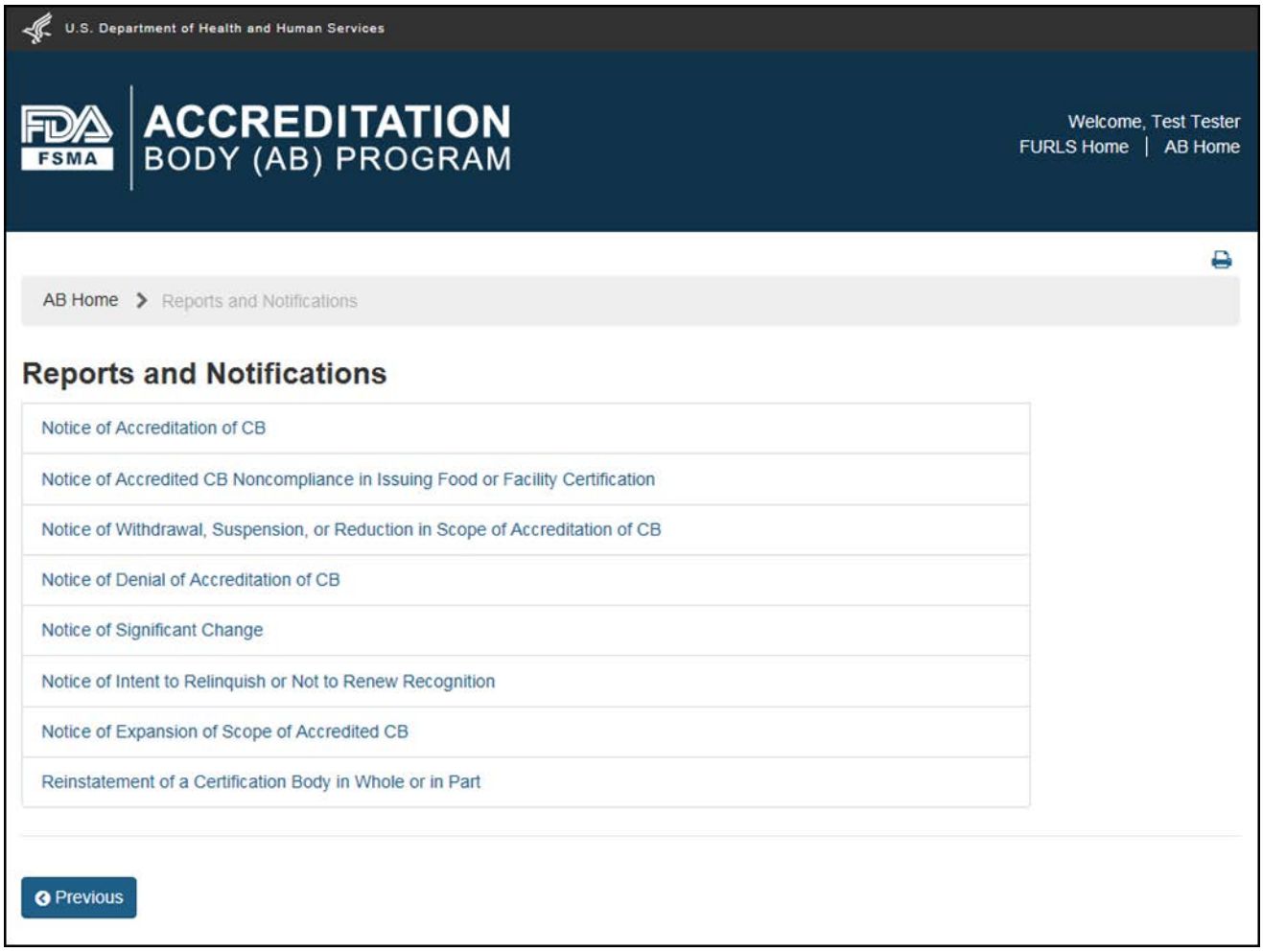


You can return to the “Reports and Notifications” page by clicking the “AB Home” link in the top of the banner.

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

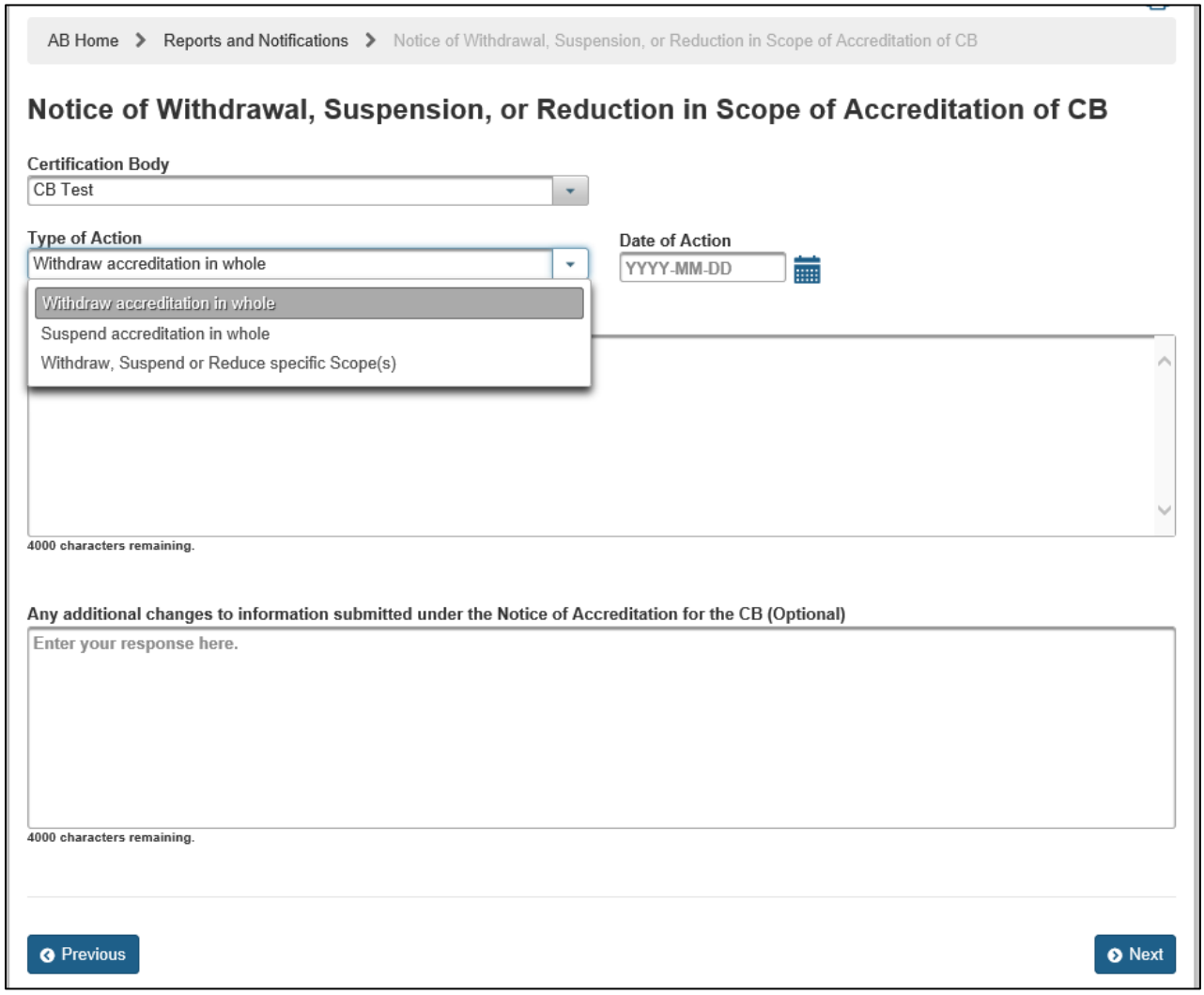
Select the “Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB” link in the “Reports and Notifications” page (Figure 9.7.1).

Figure 9.7.1 – Reports and Notifications Page



The system displays the “Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB” page. Select the “Certification Body” and the “Type of Action” (Figure 9.7.2).

Figure 9.7.2 – Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB Page



The following must be completed based on the "Type of Action" selected:

- **Withdraw accreditation in whole:**
  - Provide the "Date of Action" and the "Reason for Action" (Figure 9.7.2). You may also provide any additional changes to information submitted under the Notice of Accreditation for the CB (this section is optional).
- **Suspend accreditation in whole:**
  - Provide the "Date of Action" and the "Reason for Action" (Figure 9.7.2). You may also provide any additional changes to information submitted under the Notice of Accreditation for the CB (this section is optional).

- **Withdraw, Suspend, or Reduce specific Scope(s):**
  - The system displays the CB's scopes (Figure 9.7.3).
  - Select a scope and the "Update Scope" box displays (Figure 9.7.4). Select the "Type of Action" (Suspended, Withdrawn, or Reduction in Scope), and provide the "Date of Action" (or the "Expiration Date" if "Reduction in Scope" is selected) and the "Reason for Action." Click "Save" then click "Next" once selection of all applicable scopes are completed (optional section - you may also provide any additional changes to information submitted under the Notice of Accreditation for the CB.

Figure 9.7.3 – Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB Page

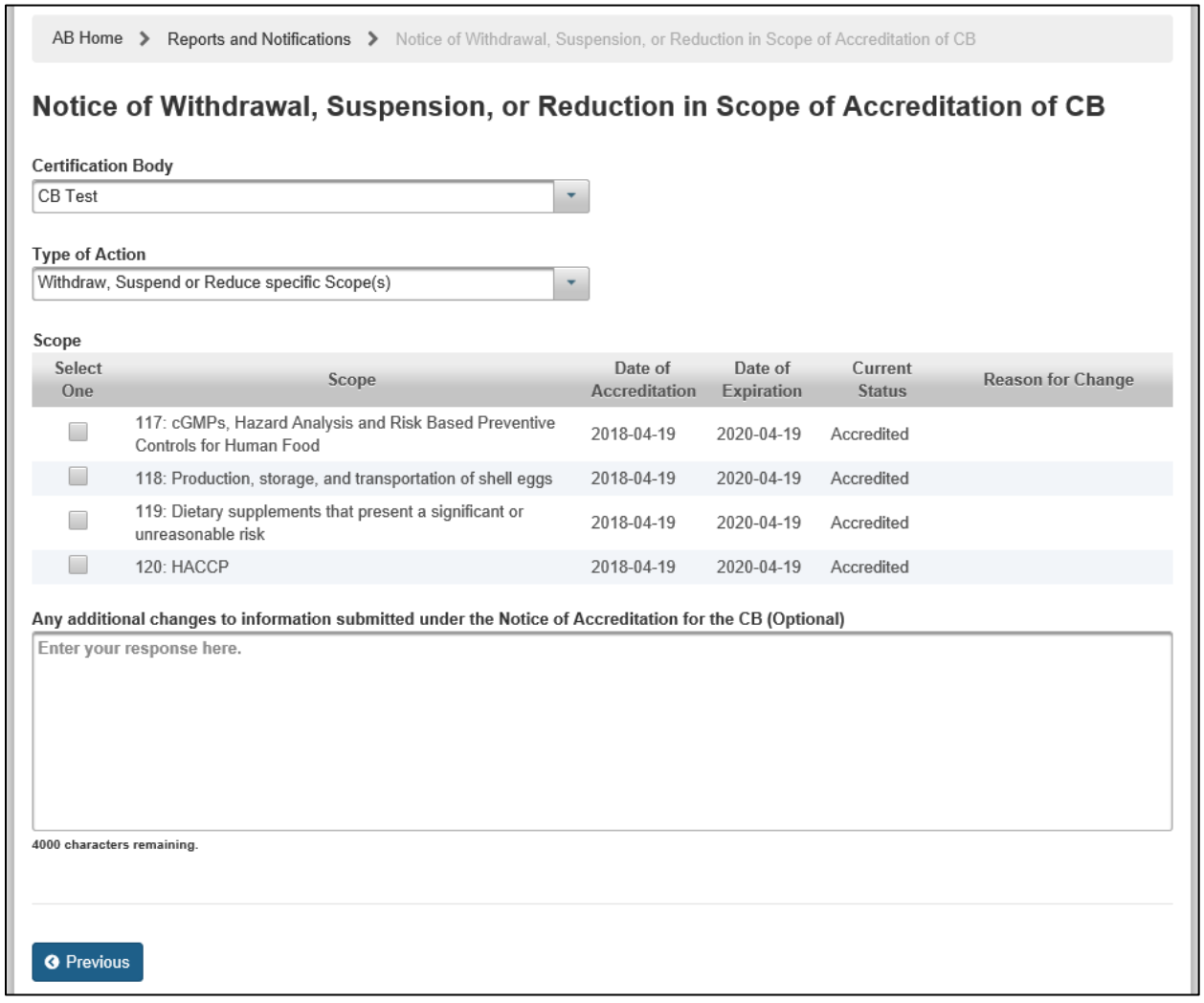
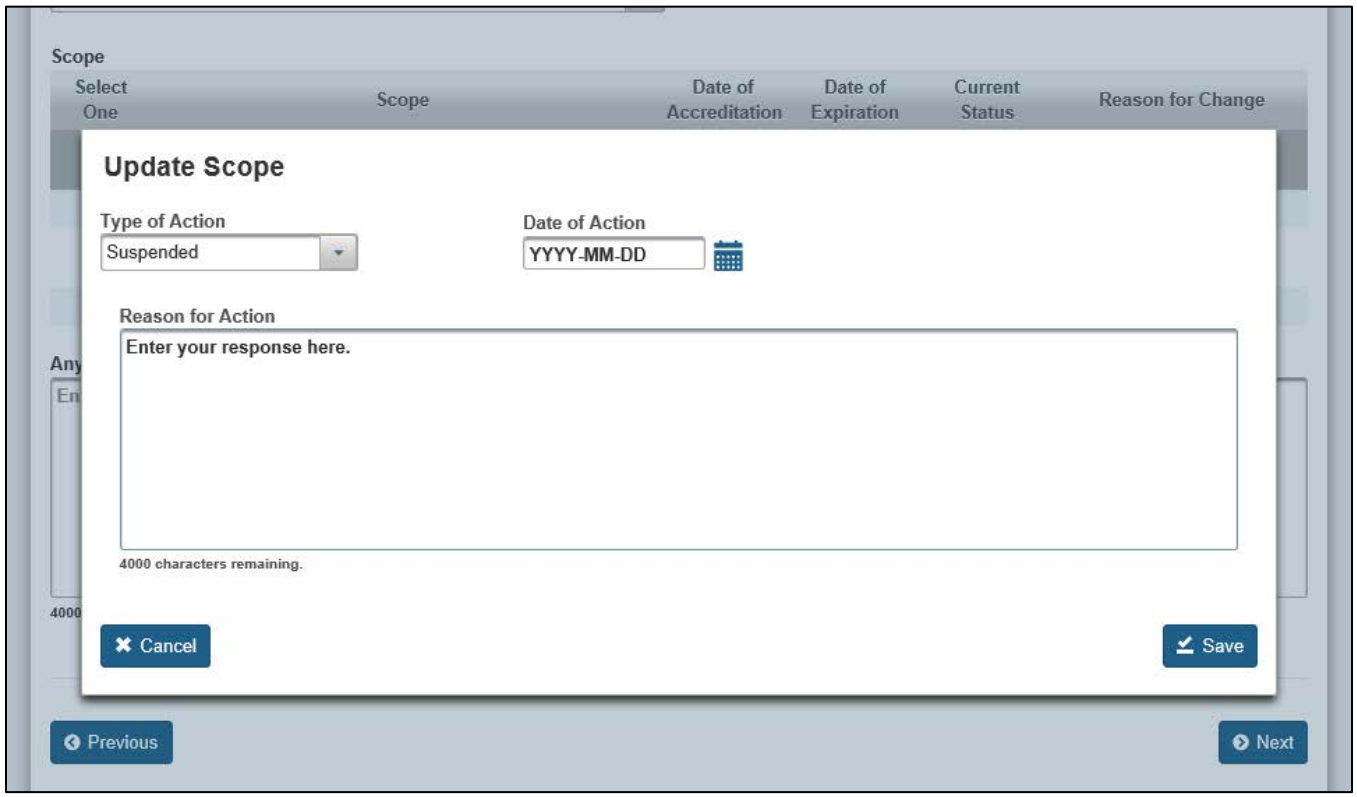


Figure 9.7.4 – Update Scope



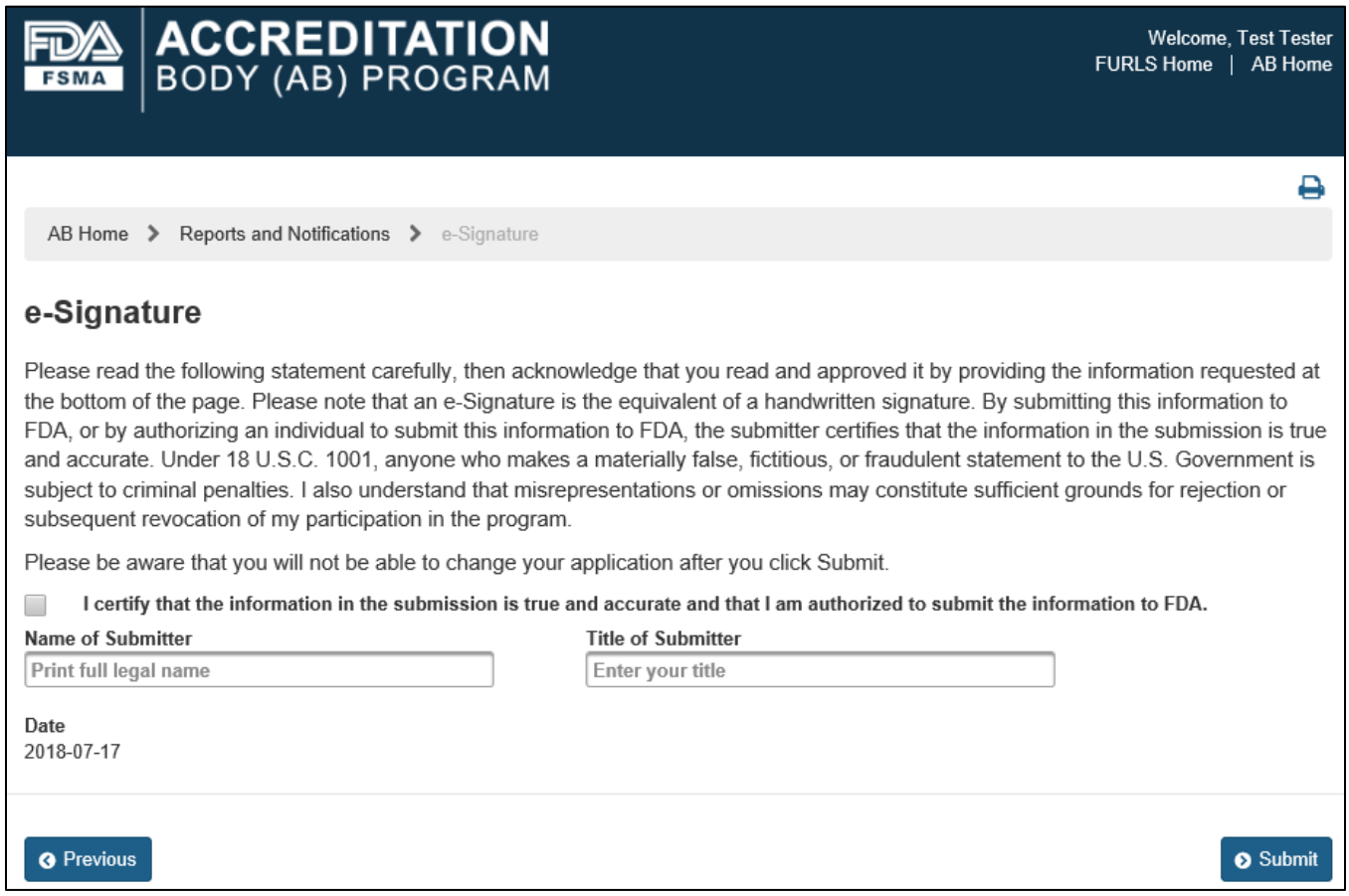
The system displays the “e-Signature” page (Figure 9.7.5).

Follow the directions provided on the “e-Signature” page. You must click on the check mark to certify that the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA. The following data fields are present:

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

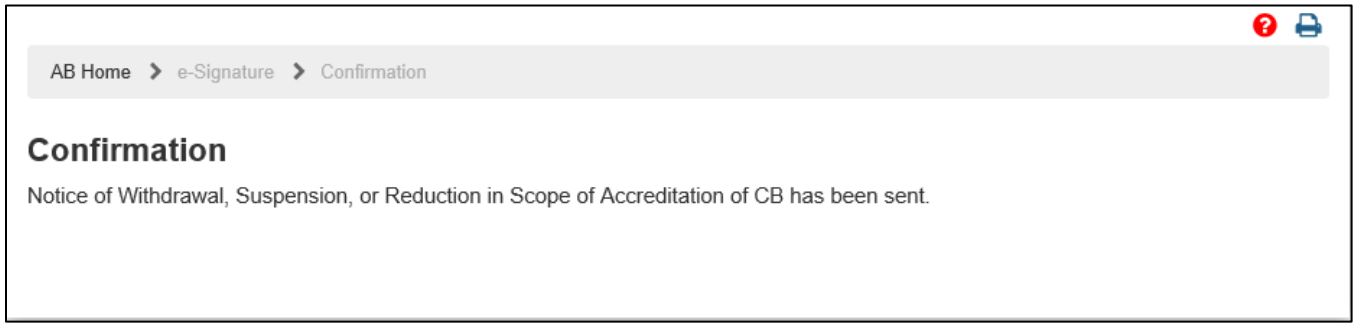
Fill in the required data fields, and click the “Submit” button.

Figure 9.7.5 – e-Signature Page



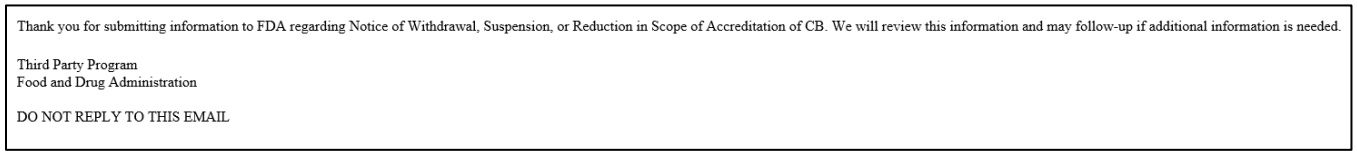
The system will display the confirmation message (Figure 9.7.6).

Figure 9.7.6 – Confirmation Message Page



An e-mail is sent to the AB indicating that the notice was received by the FDA (Figure 9.7.7 – Image depicts the email notification text only).

Figure 9.7.7 – E-mail Sent to AB User



Thank you for submitting information to FDA regarding 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.

Third Party Program
Food and Drug Administration

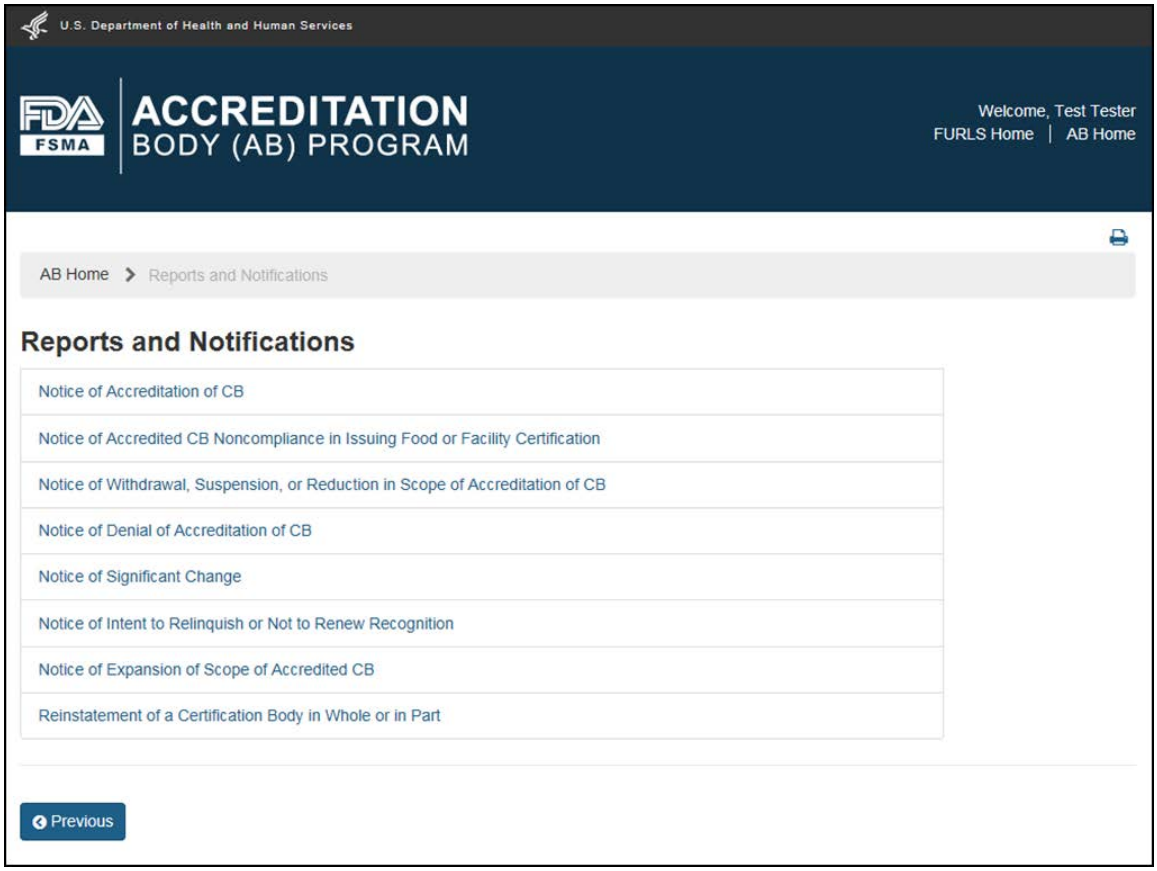
DO NOT REPLY TO THIS EMAIL

You can return to the “Reports and Notifications” page by clicking the “AB Home” link in the top of the banner.

9.8 Reinstatement of a Certification Body in Whole or in Part

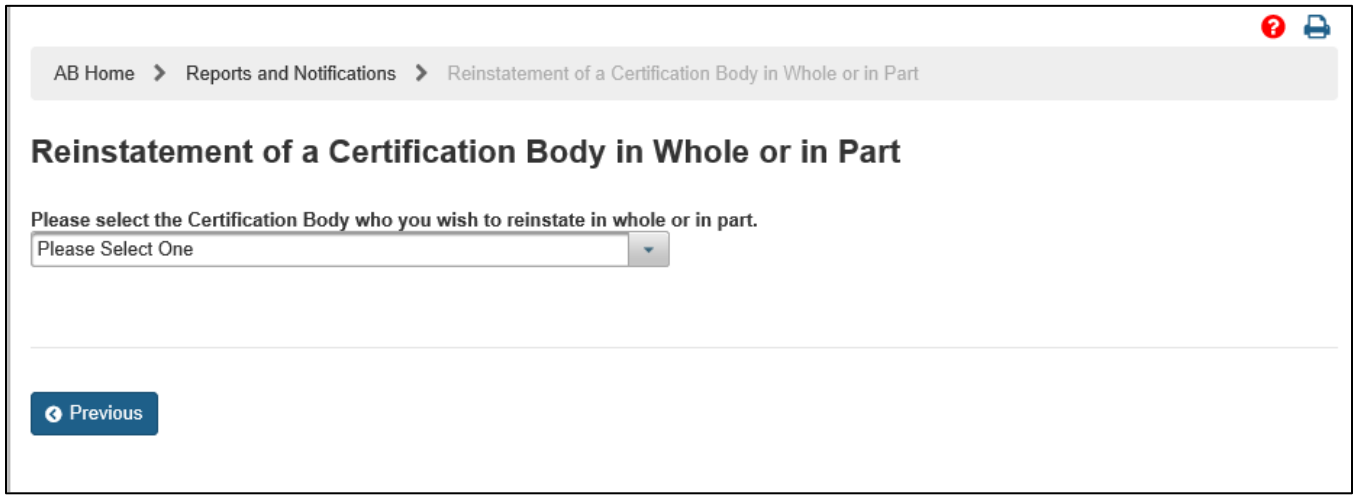
Select the “Reinstatement of a Certification Body in Whole or in Part” link in the “Reports and Notifications” page (Figure 9.8.1).

Figure 9.8.1 – Reinstatement of a Certification Body in Whole or in Part



The system displays the “Reinstatement of a Certification Body in Whole or in Part” page. Select the Certification Body who you wish to reinstate in whole or in part, then select the “Type of Action” (Figure 9.8.2).

Figure 9.8.2 – Reinstatement of a Certification Body in Whole or in Part Page



The following occurs based on the “Type of Action” selected:

- **Reinstate in whole:**
  - The system displays the CB’s scopes and you must provide detailed information supporting your decision to reinstate in whole (Figure 9.8.3).
- **Reinstate scope(s):**
  - The system displays the CB’s scopes and you must select the scopes that are to be reinstated. Then provide detailed information supporting your decision to reinstate the selected scopes (Figure 9.8.4).

Figure 9.8.3 – Reinstate in whole

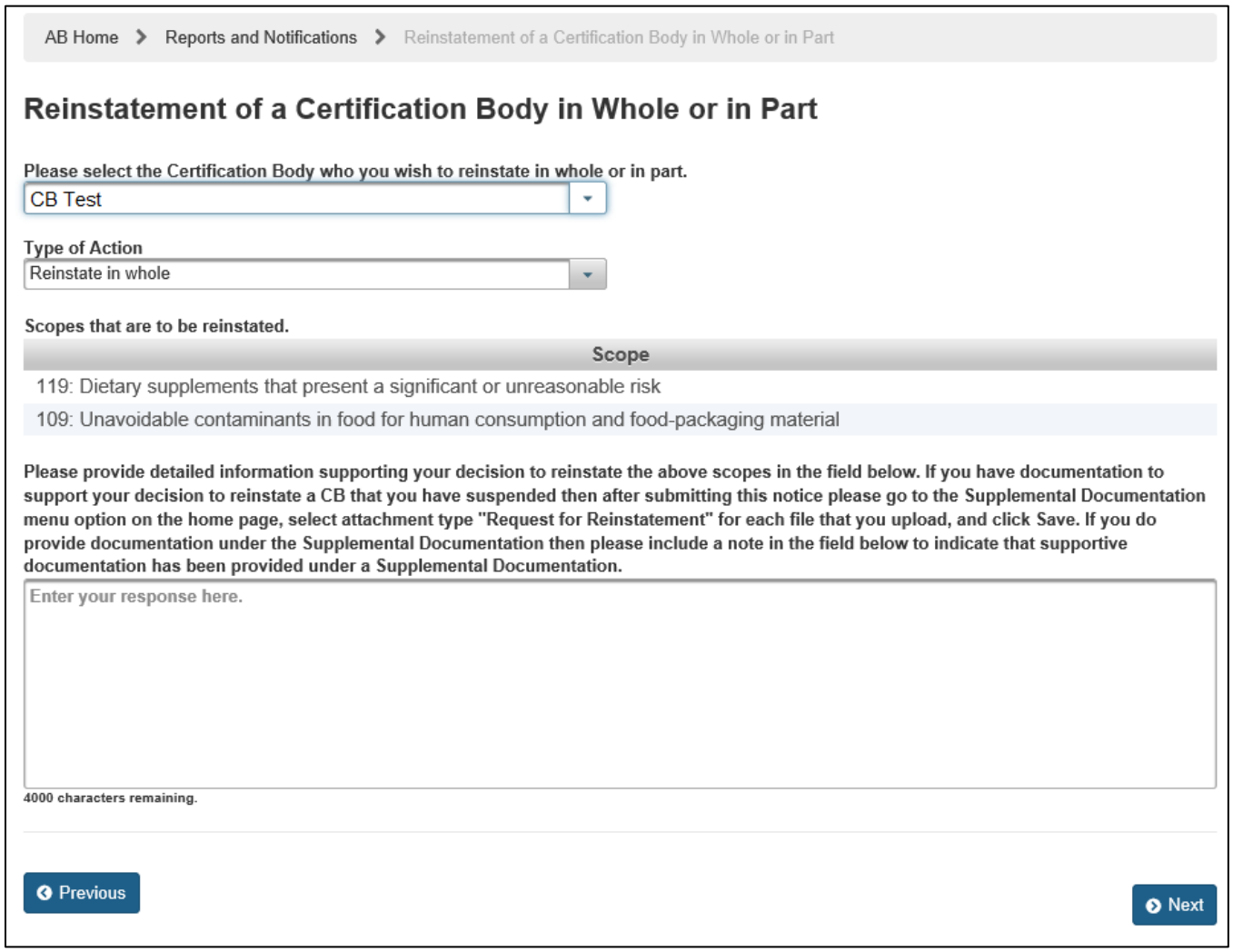
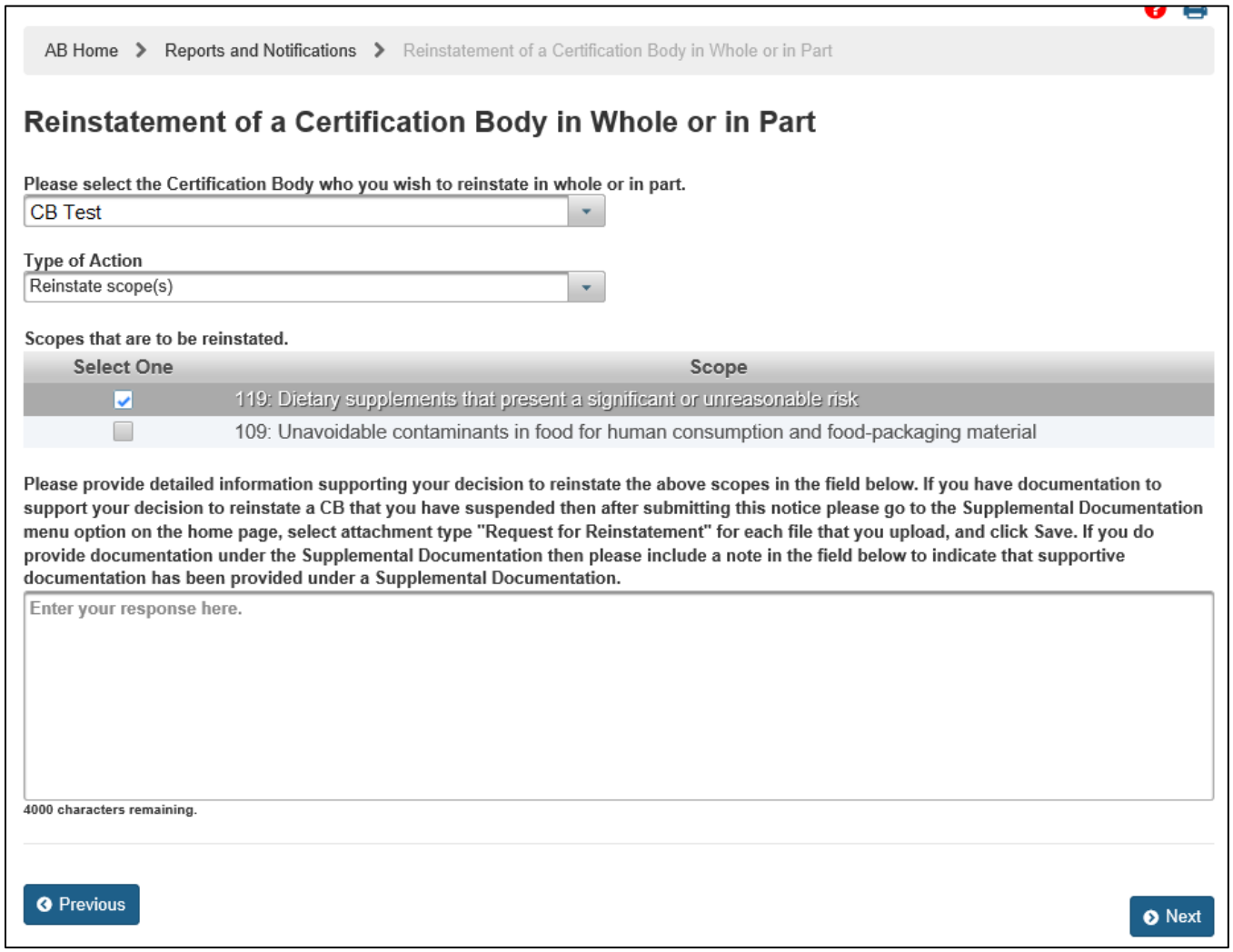


Figure 9.8.4 – Reinstate scope(s)



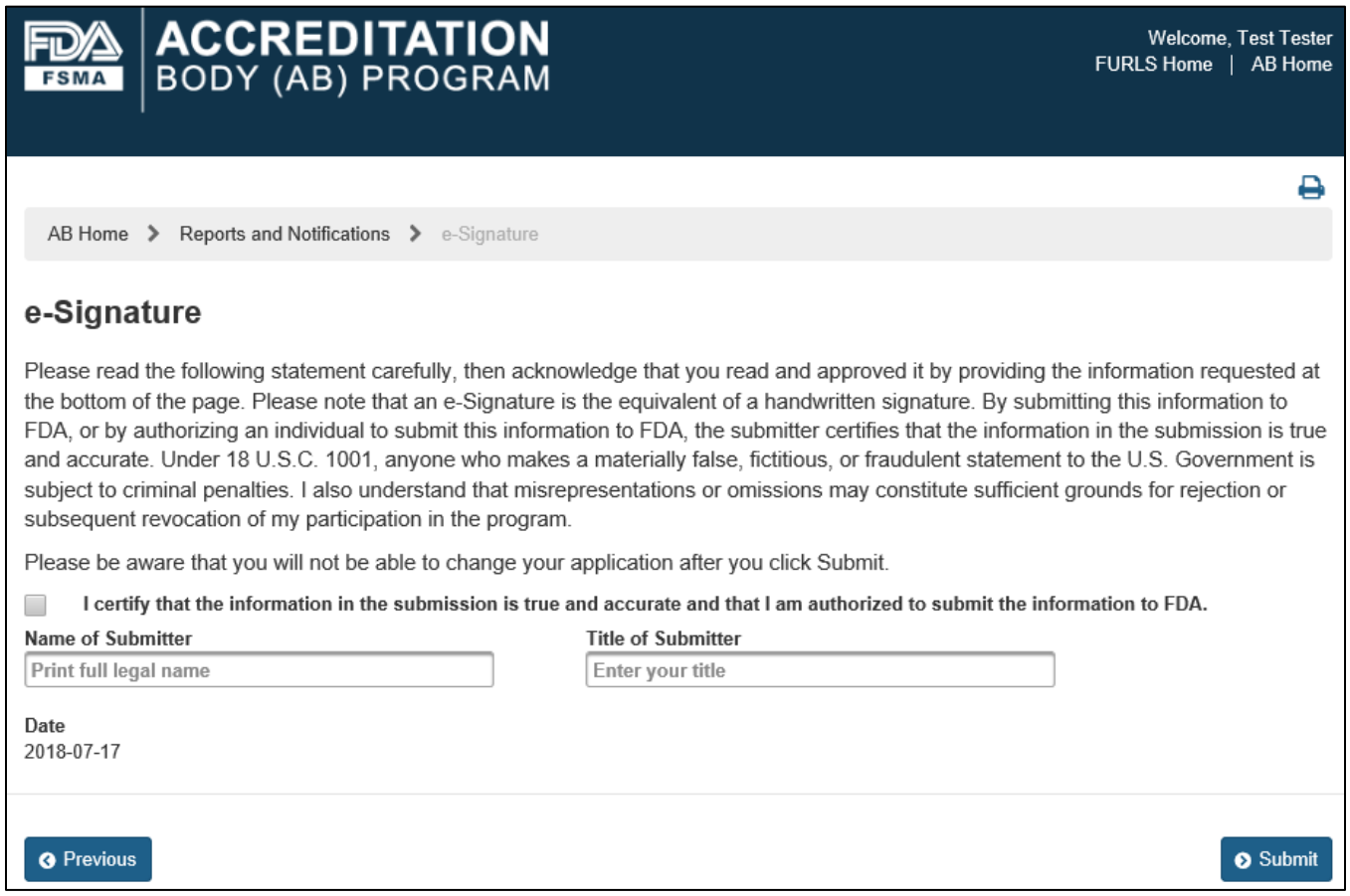
The system displays the “e-Signature” page (Figure 9.8.5).

Follow the directions provided on the “e-Signature” page. You must click on the check mark to certify that the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA. The following data fields are present:

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

Fill in the required data fields, and click the “Submit” button.

Figure 9.8.5 – e-Signature Page

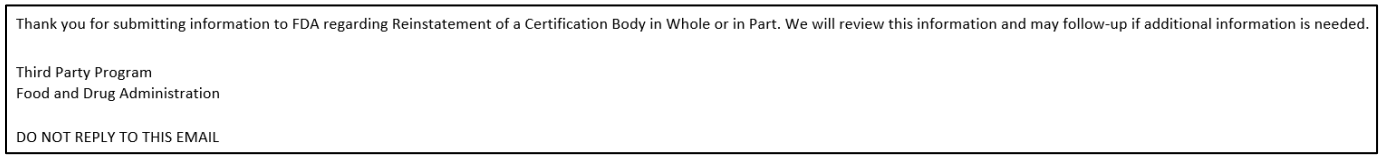


The system will display the confirmation message (Figure 9.8.6).

Figure 9.8.6 – Confirmation Message Page

An e-mail is sent to the AB indicating that the notice was received by the FDA (Figure 9.8.7 – Image depicts the email notification text only).

Figure 9.8.7 – E-mail Sent to AB User


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

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DO NOT REPLY TO THIS EMAIL

You can return to the “Reports and Notifications” page by clicking the “AB Home” link in the top of the banner.