



**U.S. FOOD & DRUG
ADMINISTRATION**

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**

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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	<table border="1"> <thead> <tr> <th>Scope</th> <th>Agent</th> </tr> </thead> <tbody> <tr> <td>(3)</td> <td>(1)</td> </tr> </tbody> </table>	Scope	Agent	(3)	(1)	<p>Lists the total number of records associated with the item. The number within parenthesis is a clickable link.</p> <ul style="list-style-type: none"> • 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).
Scope	Agent					
(3)	(1)					
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/>.

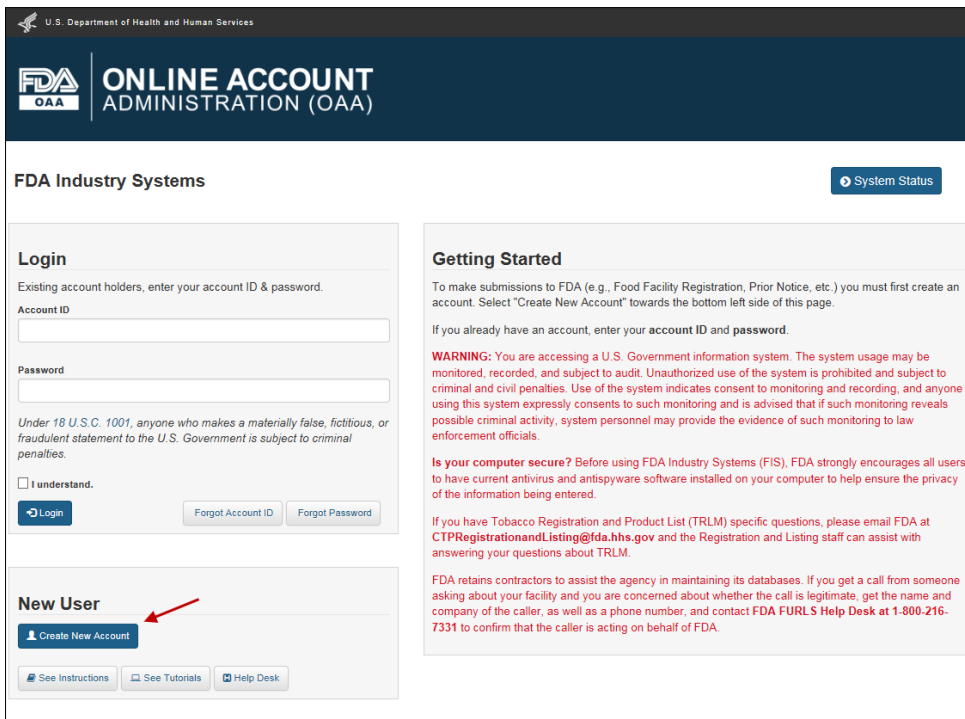
Obtain an FDA Account through the FDA FIS Electronic Portal

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/oa/>. 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.

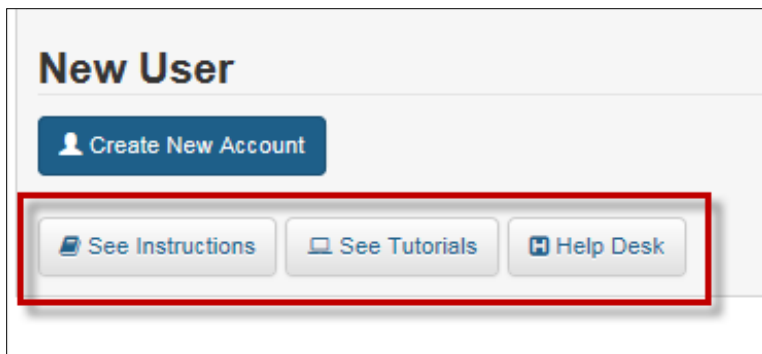
Figure 3.1 – FDA OAA Page



- **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

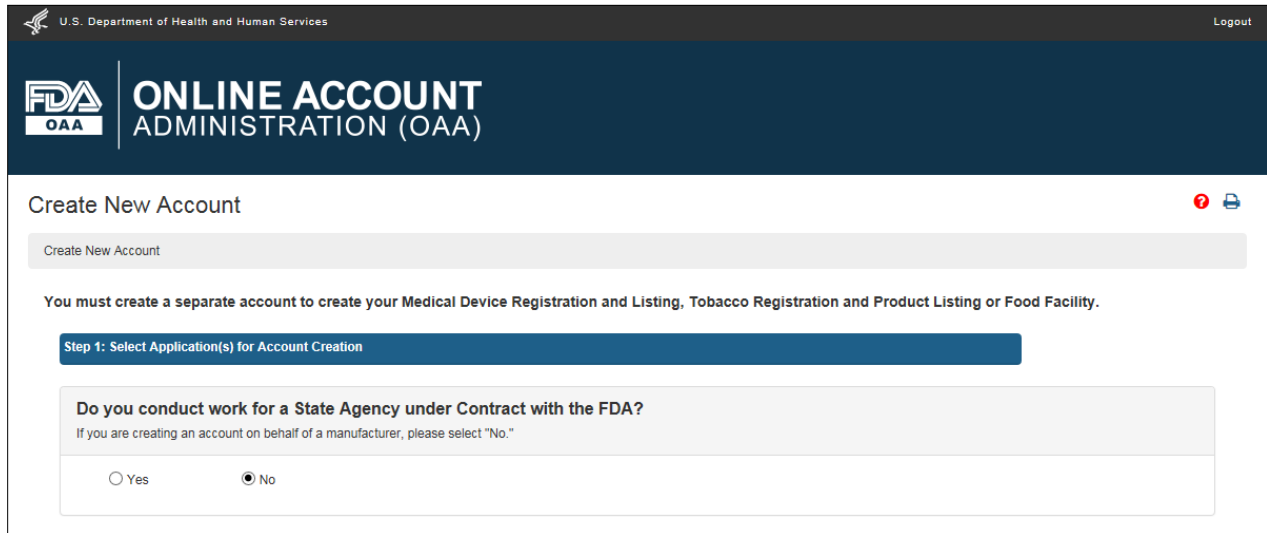


Click the “Create New Account” button:

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



U.S. Department of Health and Human Services Logout

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

Create New Account ? 🖨

Create New Account

You must create a separate account to create your Medical Device Registration and Listing, Tobacco Registration and Product Listing or Food Facility.

Step 1: Select Application(s) for Account Creation

Do you conduct work for a State Agency under Contract with the FDA?
If you are creating an account on behalf of a manufacturer, please select "No."

Yes No

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)



FSMA Program(s)

Laboratory Accreditation Body Program

Third-Party Program--Accreditation Body

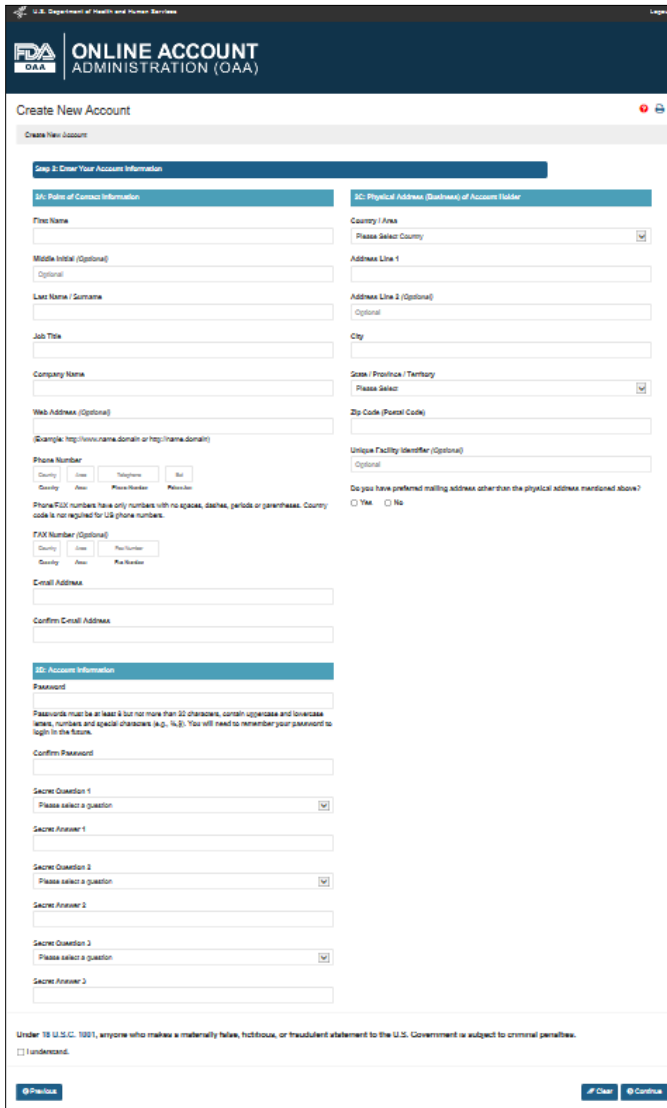
Third-Party Program--Certification Body

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

Voluntary Qualified Importer Program

The 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

2A: Point of Contact Information

First Name

Middle Initial (Optional)

Last Name / Surname

Job Title

Company Name

Web Address (Optional)

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

Phone Number

<input type="text" value="1"/>	<input type="text" value="555"/>	<input type="text" value="5555555"/>	<input type="text" value="505"/>
Country	Area	Phone Number	Extension

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

FAX Number (Optional)

<input type="text" value="1"/>	<input type="text" value="555"/>	<input type="text" value="5555555"/>
Country	Area	Fax Number

E-mail Address

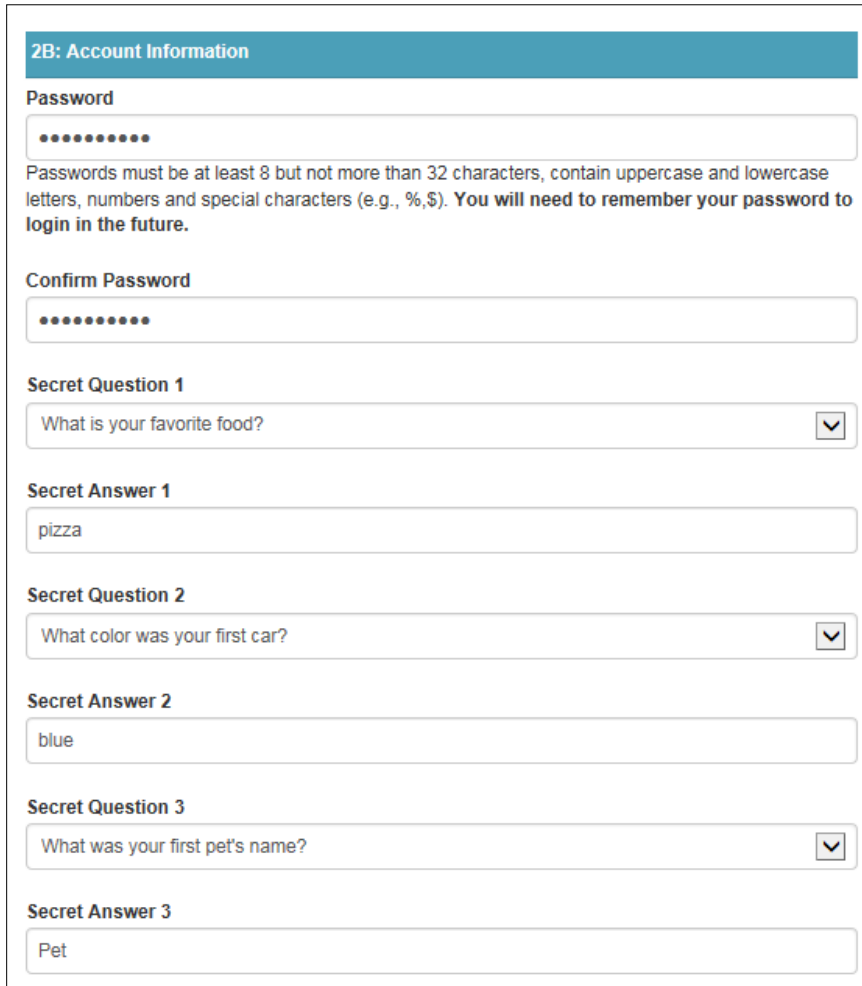
Confirm E-mail Address

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

- **First Name** – The first name of the Point of Contact.
- **Middle Initial (Optional field)** – The first letter of the Point of Contact’s middle name.
- **Last Name/Surname** – The last name of the Point of Contact.
- **Job Title** – The job title of the Point of Contact.
- **Company Name** – The name of the company the Point of Contact represents.
- **Web Address (Optional field)** – The URL of the company.
- **Phone Number (Country/Area/Phone Number/Extension)** – The telephone number of the Point of Contact.
 - “Country” is the country code.
 - “Area” is the 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



2B: Account Information

Password
••••••••

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

Confirm Password
••••••••

Secret Question 1
What is your favorite food? ▼

Secret Answer 1
pizza

Secret Question 2
What color was your first car? ▼

Secret Answer 2
blue

Secret Question 3
What was your first pet's name? ▼

Secret Answer 3
Pet

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

2C: Physical Address (Business) of Account Holder

Country / Area
UNITED STATES

Address Line 1
123 ABC Street

Address Line 2 (Optional)
Suite 200

City
ABC

State / Province / Territory
Maryland

Zip Code (Postal Code)
20901

Unique Facility Identifier (Optional)
Optional

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

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

- **Country/Area** – The country/area where the business is located. Select a country/area from the 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

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

2D: Preferred Mailing Address

Country / Area
UNITED STATES

Address Line 1
456 ABC Street

Address Line 2 (Optional)
Suite 300

City
ABC

State / Province / Territory
Maryland

Zip Code (Postal Code)
20901

Figure 3.10 – Checkbox

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

I understand.

Previous Clear Continue

“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

U.S. Department of Health and Human Services

ONLINE ACCOUNT ADMINISTRATION (OAA)

Account Information ?

[Home](#) [Create New Account](#)

Account Review

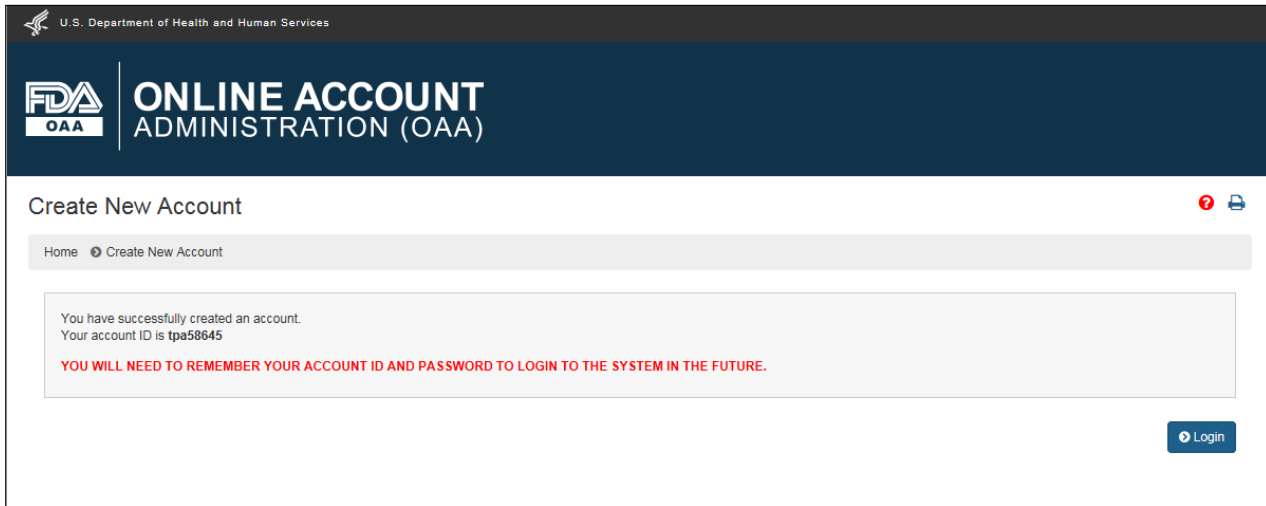
Account Information	Physical Address (Business) of Account Holder
<p>First Name Test</p> <p>Middle Initial Q</p> <p>Last Name / Surname Tester</p> <p>Title Accreditation Body</p> <p>Company Name Accreditation Body Inc.</p> <p>Web Address http://www.abc123.com</p> <p>Phone Number 1 555 5555555 505</p> <p>FAX Number 1 555 5555555</p> <p>E-mail Address test123@test.com</p> <p>Secret Question 1 What is your favorite food?</p> <p>Secret Answer 1 pizza</p> <p>Secret Question 2 What color was your first car?</p> <p>Secret Answer 2 blue</p> <p>Secret Question 3 What was your first pet's name?</p> <p>Secret Answer 3 Pet</p>	<p>Address Line 1 123 ABC Street</p> <p>Address Line 2 Suite 200</p> <p>City ABC</p> <p>State / Province / Territory Maryland</p> <p>Zip Code (Postal Code) 20901</p> <p>Country / Area UNITED STATES</p>

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

Modify
Submit

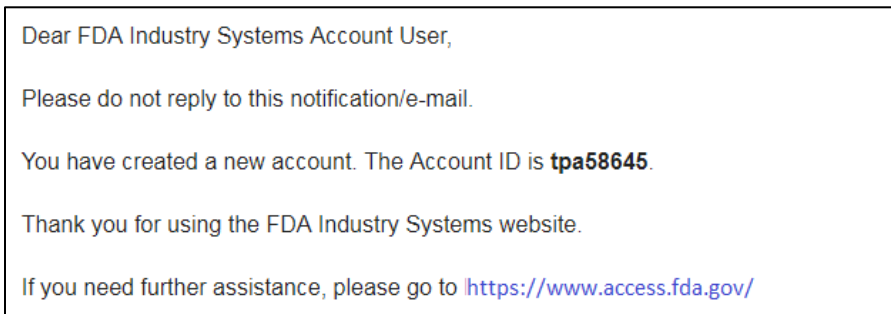
When you click “Submit,” the system displays a message that the account was created successfully. The message displays your Account ID (Figure 3.12). You will need to retain your account ID and password to login to the system in the future.

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



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

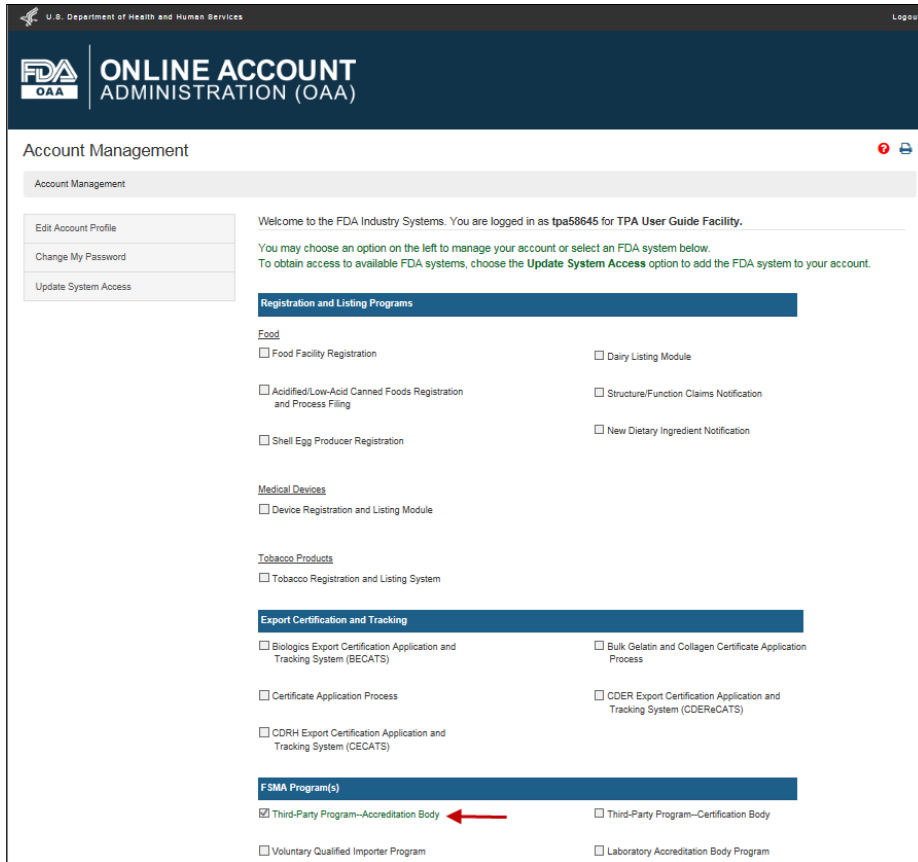
Figure 4.1 – OAA Login



The screenshot shows the FDA Online Account Administration (OAA) login page. At the top, it features the U.S. Department of Health and Human Services logo and the FDA OAA logo. The main heading is "ONLINE ACCOUNT ADMINISTRATION (OAA)". Below this, the page is titled "FDA Industry Systems". The "Login" section includes a prompt for existing account holders to enter their account ID and password. There are two input fields: "Account ID" and "Password". A disclaimer states: "Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties." Below the disclaimer is a checkbox labeled "I understand." At the bottom, there are three buttons: "Login", "Forgot Account ID", and "Forgot Password".

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.”

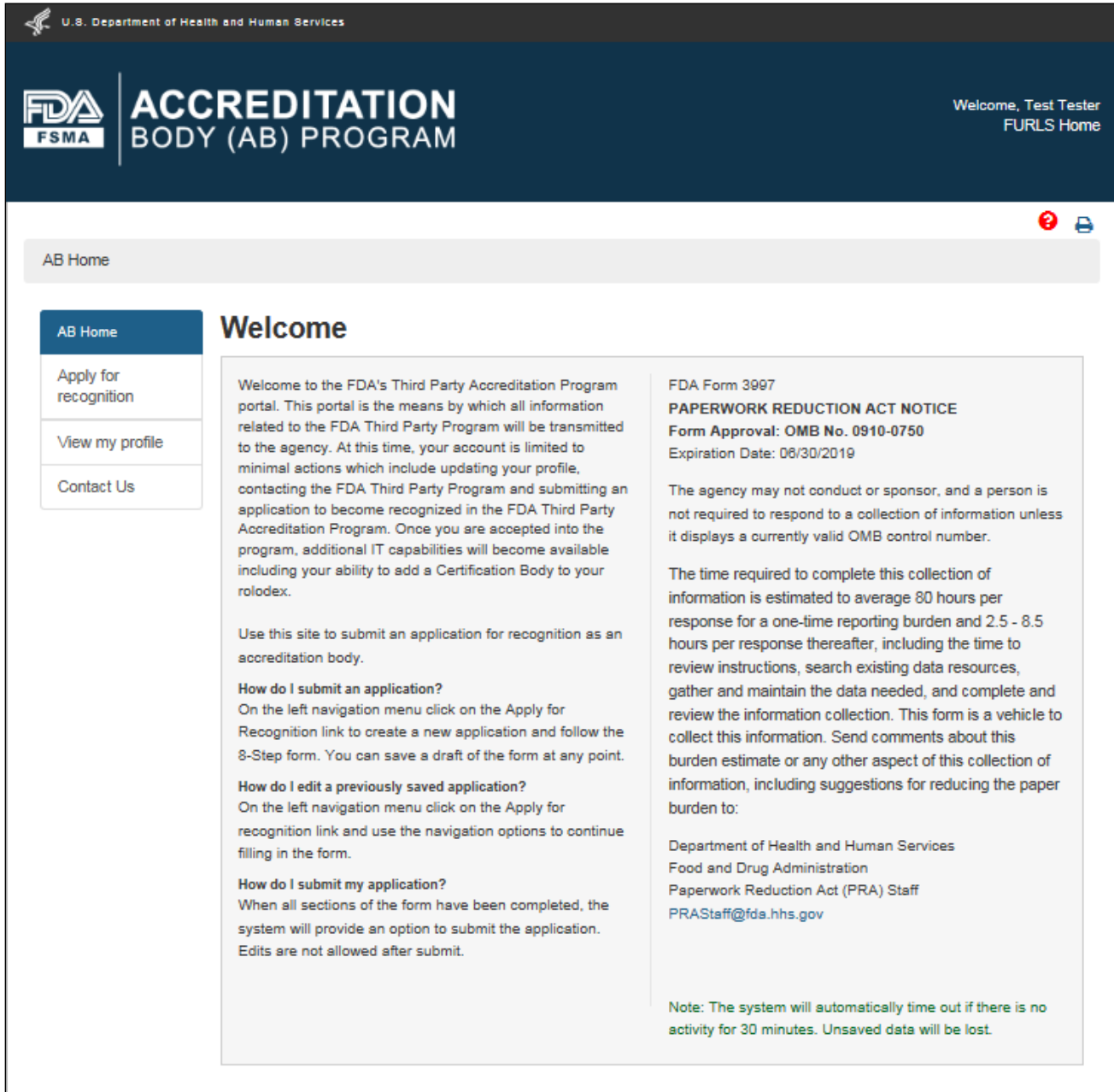
Figure 4.2 – OAA - FURLS Account Management Home Page



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



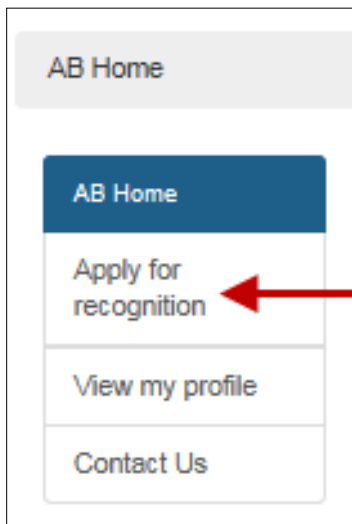
The screenshot shows the 'AB Home' page of the FDA's Third Party Accreditation Program. At the top, there is a dark blue banner with the FDA logo, the text 'ACCREDITATION BODY (AB) PROGRAM', and a user greeting 'Welcome, Test Tester' with a 'FURLS Home' link. Below the banner is a navigation bar with 'AB Home' and a search icon. A left-hand navigation menu contains links for 'AB Home', 'Apply for recognition', 'View my profile', and 'Contact Us'. The main content area is titled 'Welcome' and contains several sections: a general welcome message, instructions on how to use the site, and three FAQ-style sections: 'How do I submit an application?', 'How do I edit a previously saved application?', and 'How do I submit my application?'. On the right side, there is a 'PAPERWORK REDUCTION ACT NOTICE' for FDA Form 3997, including an expiration date and contact information for the PRA Staff. A note at the bottom right states that the system will time out after 30 minutes of inactivity.

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

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


All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable. 🖨️

[AB Home](#) > [Applicant Information](#)

Applicant Information
Revocation
Scope
Eligibility
Attachments
Summary
e-Signature

Applicant Information

This page contains the information from your Account ID.
 If you need to update your Account, go to the FURLS Home page and select Edit Account Profile.

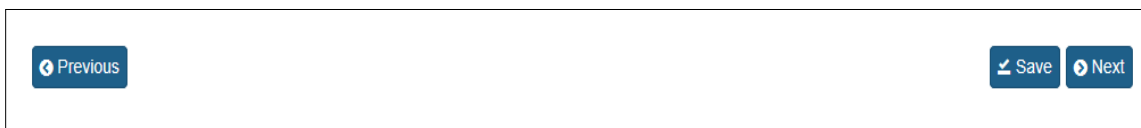
<p>Firm Name Accreditation Body Inc.</p> <p>Address 123 ABC Street Suite 200 ABC Maryland 20901 United States</p> <p>Web Address http://www.abc123.com</p>	<p>Contact Name Test Q Tester</p> <p>Contact Number Telephone Number 1 (555) 5555555 Ext. 505 Fax Number 1 (555) 5555555</p> <p>Email Address test123@test.com</p> <p>Unique Facility Identifier --</p>
---	---

⏪ Previous
📄 Save
Next ⏩

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

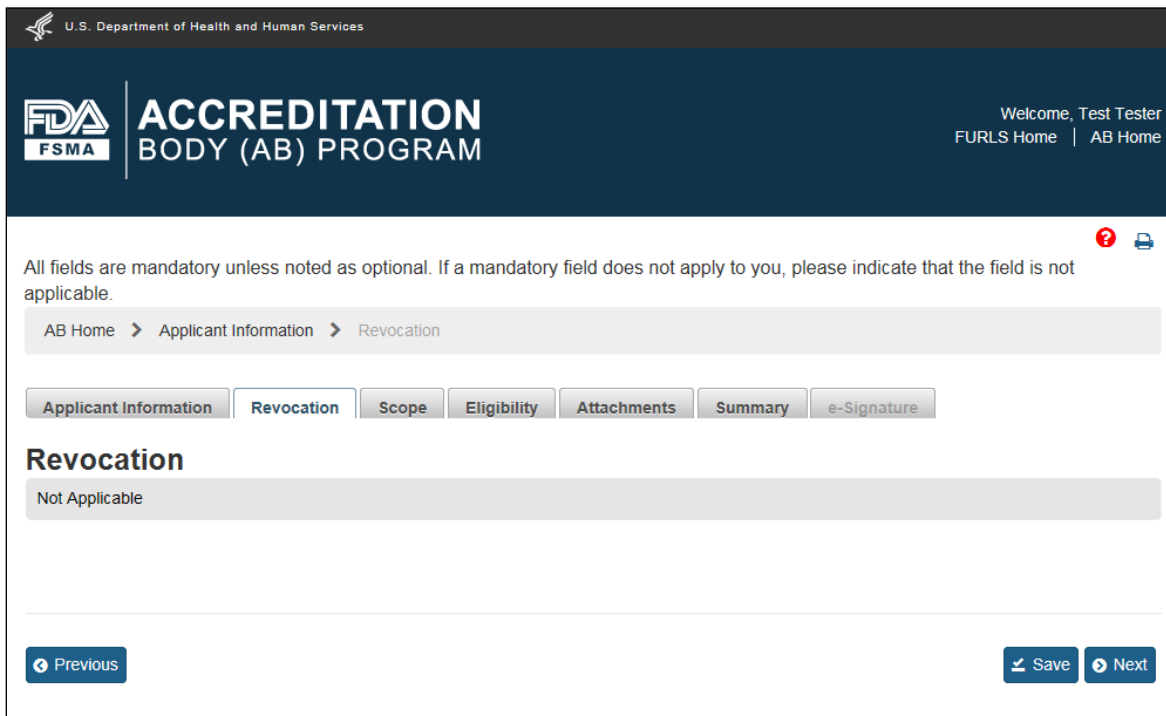
- **Previous** – Directs you to the previous page; this saves any user input from other pages, **only during the current session**.
- **Save** – Saves any input from the current page (from session to session), even if the application has not been completed.
- **Next** – Directs you to the next page;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

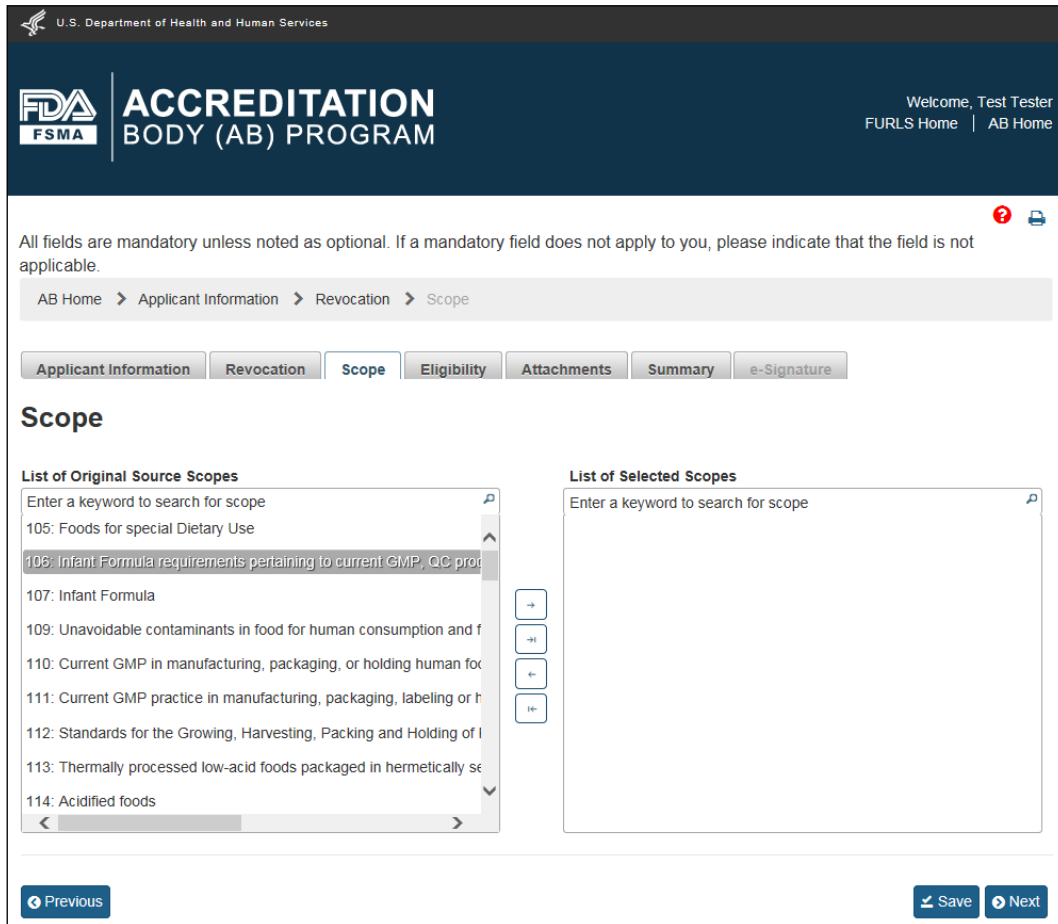
Figure 5.4 – Revocation



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.”

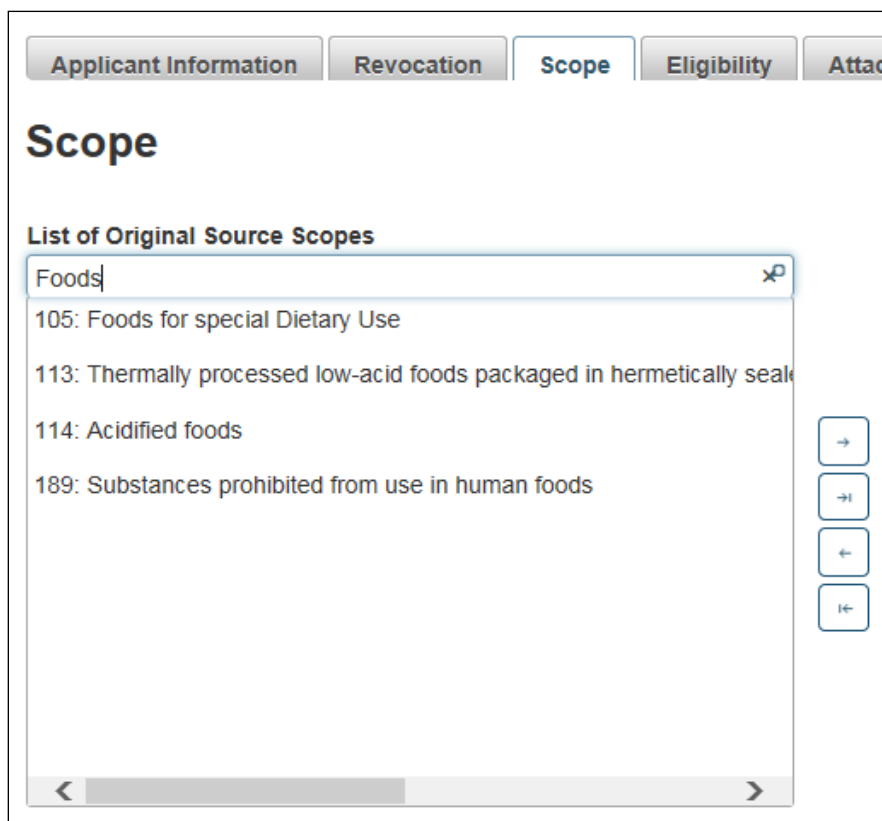
Use the scroll bar at the bottom of the “List of Original Source Scopes” to see full titles of scopes.

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

List of Selected Scopes


Enter a keyword to search for scope

105: Foods for special Dietary Use

106: Infant Formula requirements pertaining to current GMP, QC proced

107: Infant Formula

< | >

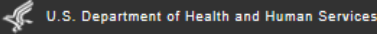
 Save Next


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





ACCREDITATION BODY (AB) PROGRAM

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable. ? 🖨

AB Home > Dashboard > Applicant Information > Revocation > Scope > Eligibility

Applicant Information

Revocation

Scope

Eligibility

Attachments

Summary

e-Signature

Eligibility

Please use the left hand directory to move from question to question.

▾ Legal Authority

Q1

Q2

Q3

Q4

Q5

Q6

▸ Responsibility

▸ Capacity

▸ Competency

▸ Monitoring

▸ Conflict of Interest

▸ Quality Assurance

▸ Records

▸ Accreditation Program

Legal Authority

An "accreditation body" includes: (1) a governmental accreditation body; and (2) a registered legal entity that offers accreditation services (described as a "non-governmental accreditation body" in this portal). The term, "certification bodies," is used to refer to bodies that are also known as "third-party auditors" and "conformity assessment bodies."

"Food" includes food for human consumption, pet food, and non-medicated animal feed. It excludes products regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) under the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act and FSIS regulations.

The term "food safety requirements" includes applicable requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations and implementing FDA regulations in Title 21, of the Code of Federal Regulations. Requirements of the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act and regulations issued by the U.S. Department of Agriculture's Food Safety and Inspection Service are excluded from this definition and are outside the scope of this program.

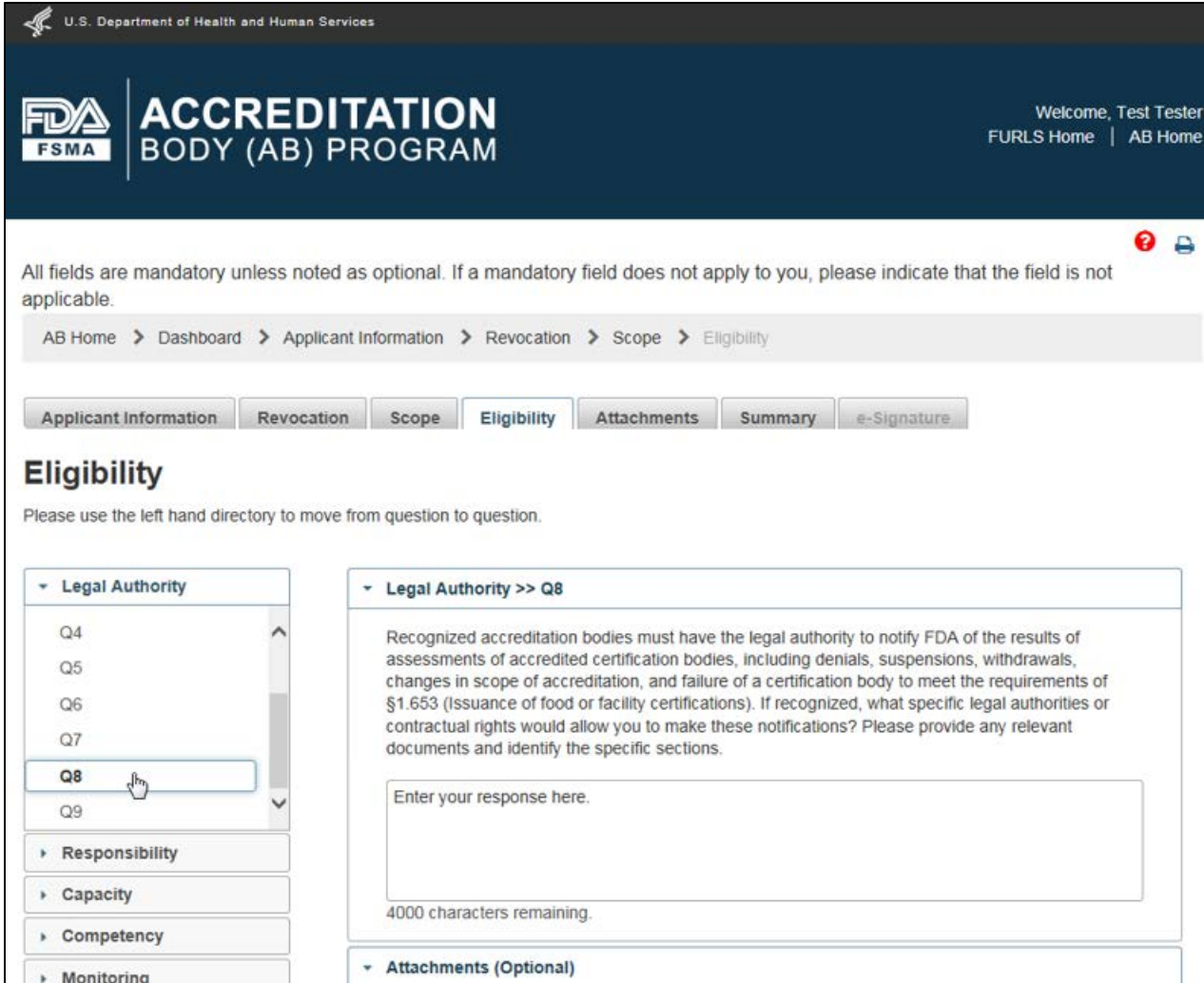
You may respond to the questions by answering in the text boxes provided or by uploading one or more documents to satisfy the requirement and identifying the relevant provision(s). Or, if the document was previously uploaded, please identify the document by title and the relevant provision within.

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



The screenshot shows the FDA Accreditation Body (AB) Program application interface. At the top, it displays the U.S. Department of Health and Human Services logo and the FDA FSMA Accreditation Body (AB) Program logo. A welcome message for 'Test Tester' is visible in the top right corner. Below the header, a navigation breadcrumb trail reads: 'AB Home > Dashboard > Applicant Information > Revocation > Scope > Eligibility'. A series of tabs at the bottom of the header includes 'Applicant Information', 'Revocation', 'Scope', 'Eligibility' (which is currently selected), 'Attachments', 'Summary', and 'e-Signature'. The main content area is titled 'Eligibility' and includes a note: 'Please use the left hand directory to move from question to question.' On the left, a directory tree is shown with 'Legal Authority' expanded to show questions Q4 through Q9. Question Q8 is highlighted with a mouse cursor. The main content area displays the text for Q8: 'Recognized accreditation bodies must have the legal authority to notify FDA of the results of assessments of accredited certification bodies, including denials, suspensions, withdrawals, changes in scope of accreditation, and failure of a certification body to meet the requirements of §1.653 (Issuance of food or facility certifications). If recognized, what specific legal authorities or contractual rights would allow you to make these notifications? Please provide any relevant documents and identify the specific sections.' Below the text is a large text input field with the placeholder 'Enter your response here.' and a character count of '4000 characters remaining.' At the bottom of the main content area, there is an 'Attachments (Optional)' section.

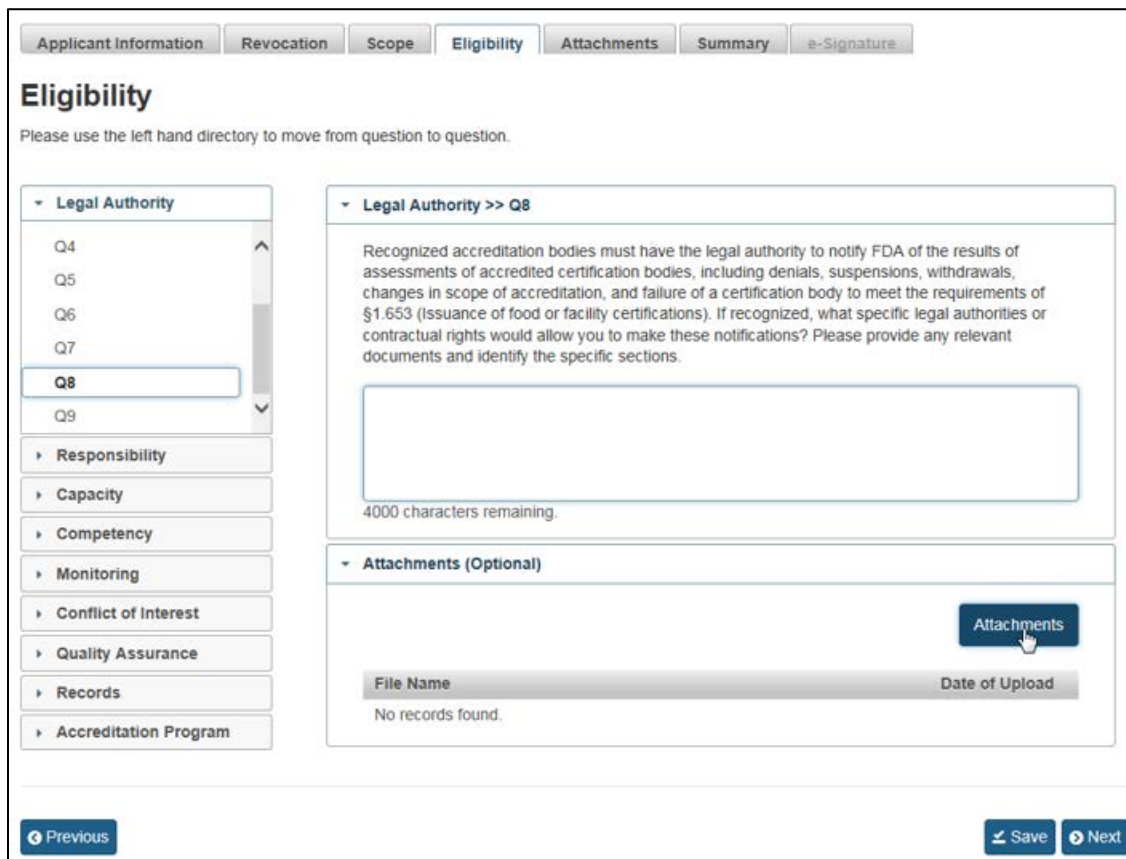
Attachments may be uploaded with each response. Attachments must be a document type supported by the system.

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



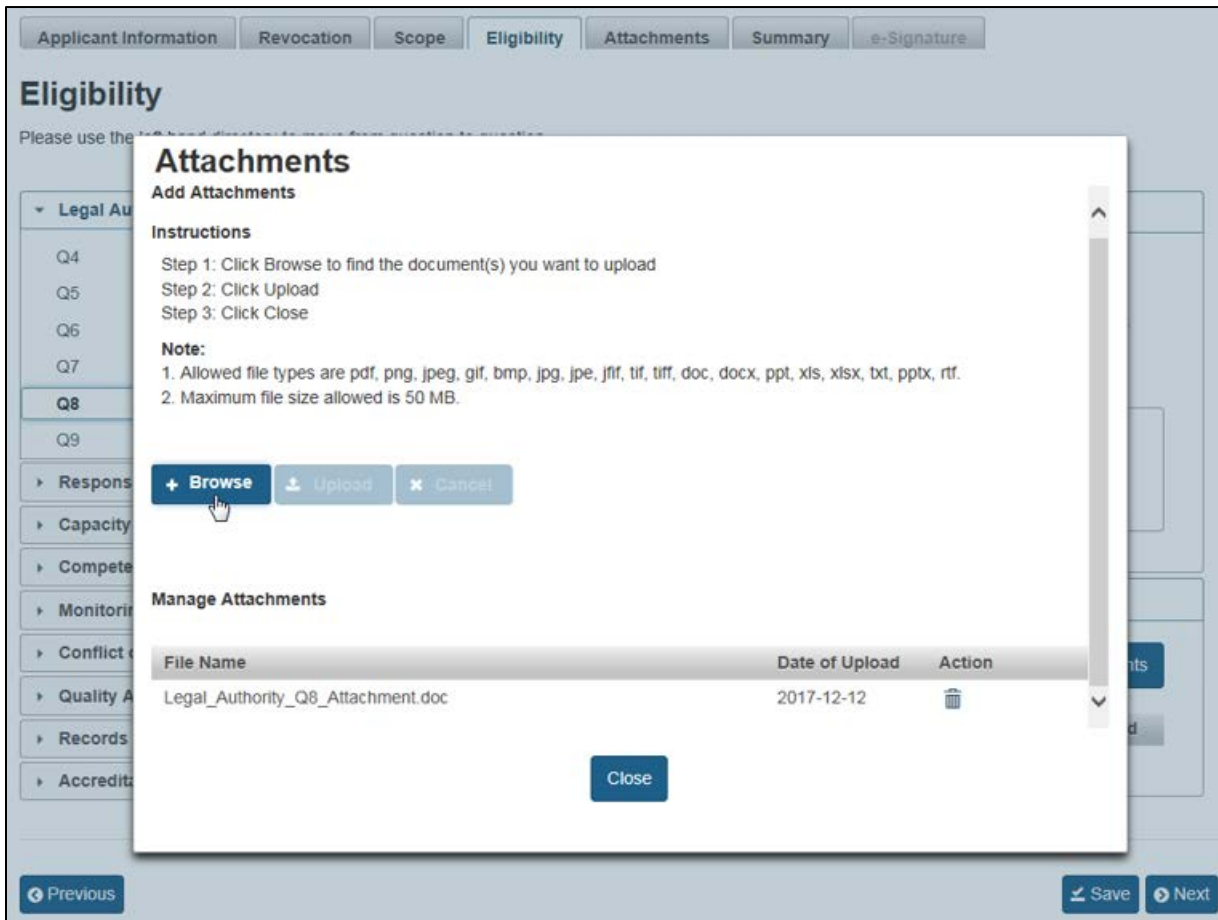
The system will display a pop-up window (Figure 5.11).

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).

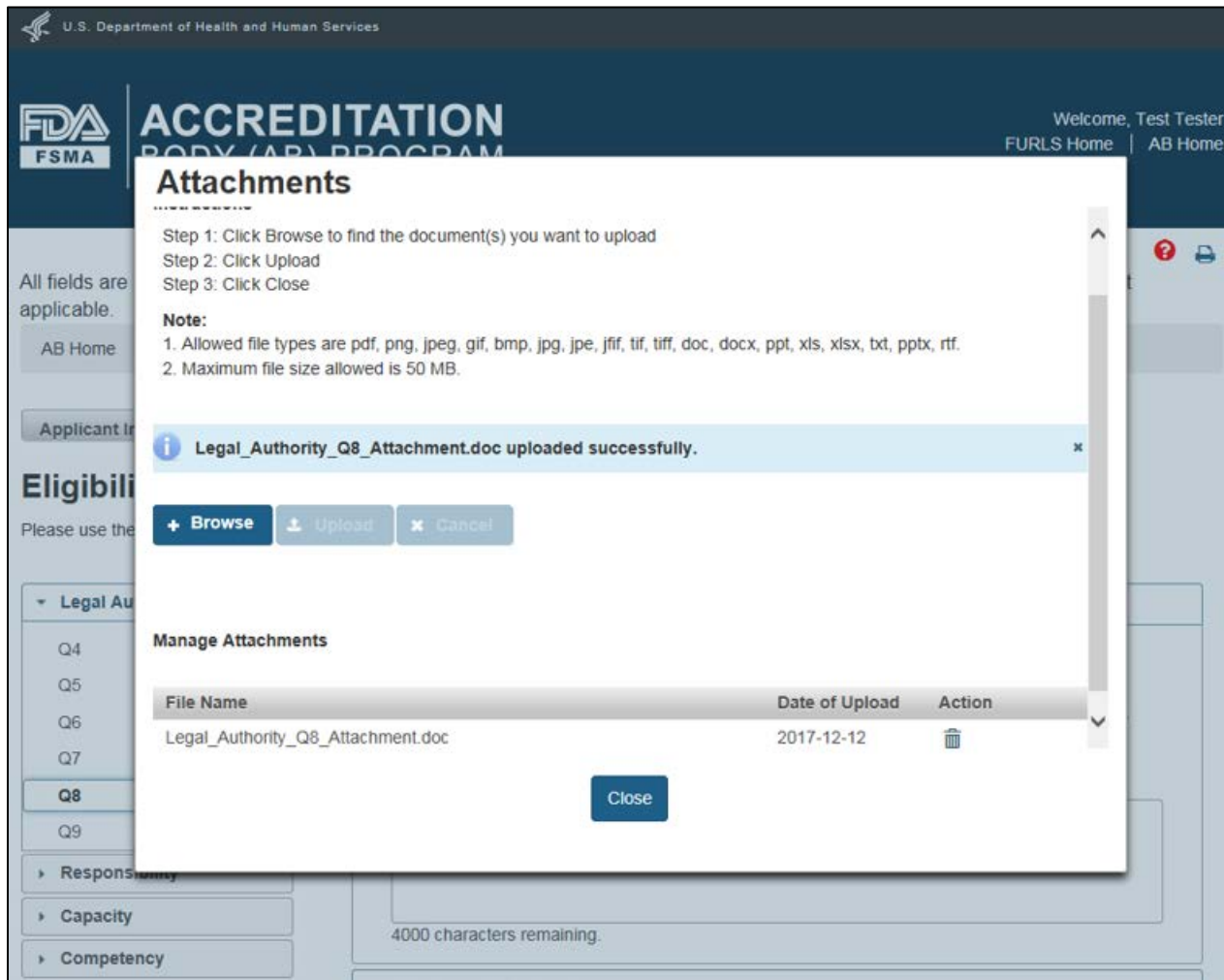
Figure 5.11 – Attachments Window



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

U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

[AB Home](#) > [Dashboard](#) > [Applicant Information](#) > [Revocation](#) > [Scope](#) > [Eligibility](#) > [Attachments](#)

Applicant Information
Revocation
Scope
Eligibility
Attachments
Summary
e-Signature

Attachments (Optional)

Add Attachment(s)

Instructions

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

Note:

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

Type of Attachment

Please Select One

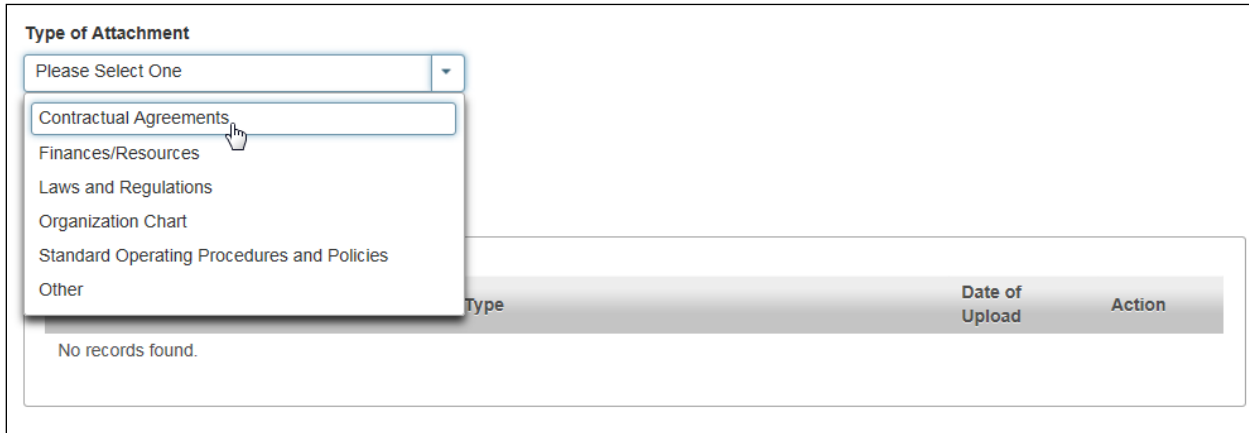
Browse
Upload
Cancel

File Name	Type	Date of Upload	Action
No records found.			

Previous
Save
Next

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

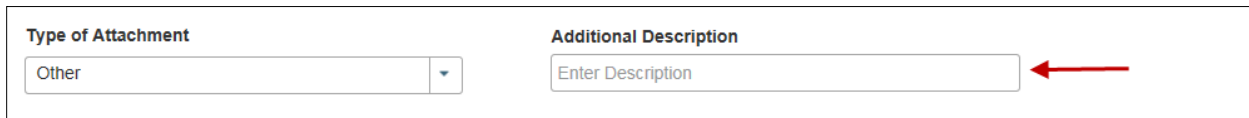
Figure 5.14 - Type of Attachment



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

Applicant Information | Revocation | Scope | Eligibility | **Attachments** | Summary | e-Signature

Attachments (Optional)

Add Attachment(s)

Instructions

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

Note:

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

Type of Attachment

Contractual Agreements

+ Browse **↓ Upload** *** Cancel**

Optional_Attachments_Test_File.docx 12.4 KB *

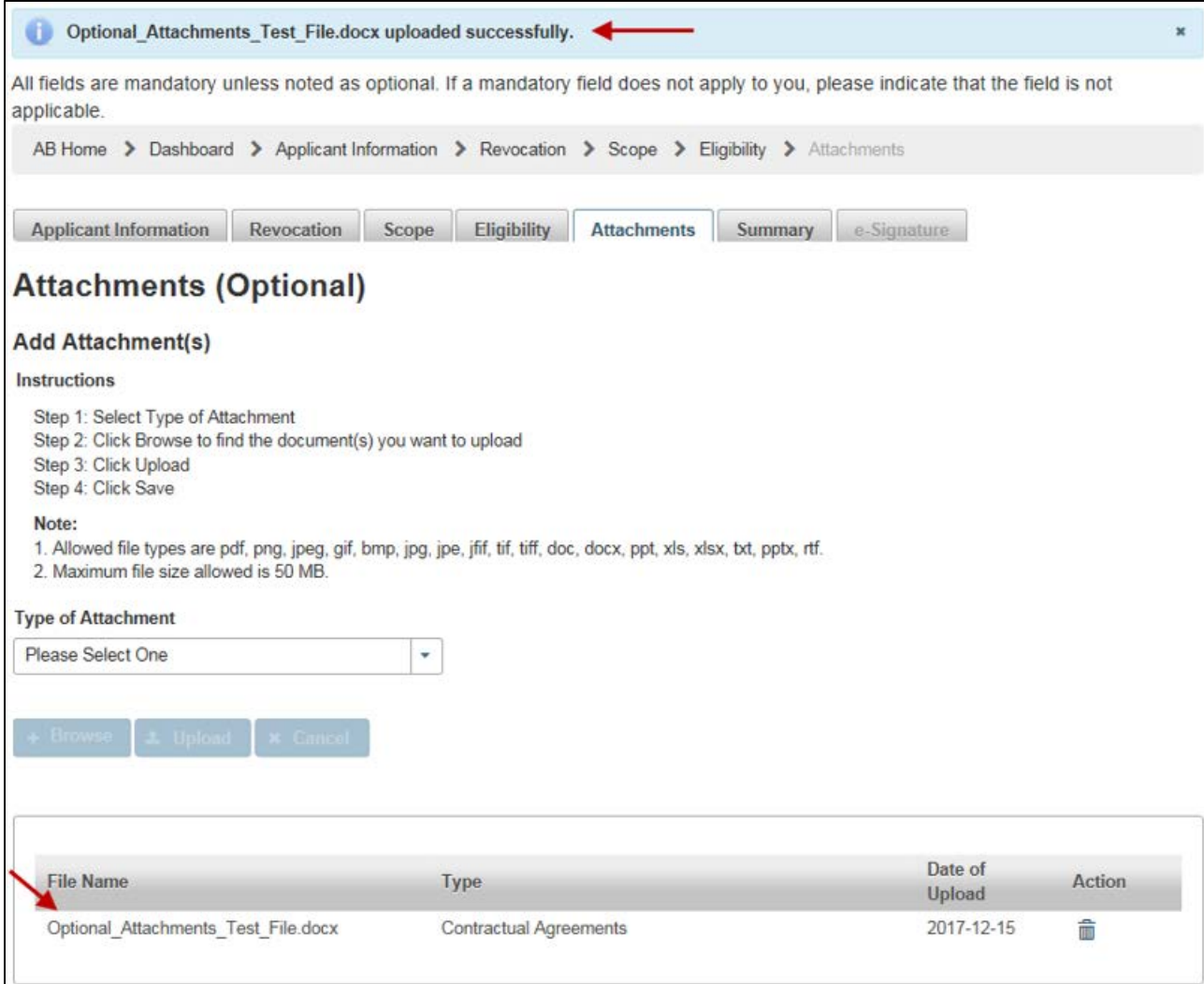
File Name	Type	Date of Upload	Action
No records found.			

Previous **Save** **Next**

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



Optional_Attachments_Test_File.docx uploaded successfully.

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

AB Home > Dashboard > Applicant Information > Revocation > Scope > Eligibility > Attachments

Applicant Information | Revocation | Scope | Eligibility | **Attachments** | Summary | e-Signature

Attachments (Optional)

Add Attachment(s)

Instructions

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


Note:

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

Type of Attachment

Please Select One

+ Browse | Upload | × Cancel


File Name	Type	Date of Upload	Action
Optional_Attachments_Test_File.docx	Contractual Agreements	2017-12-15	

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

U.S. Department of Health and Human Services



ACCREDITATION BODY (AB) PROGRAM

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

[AB Home](#) > [Dashboard](#) > [Applicant Information](#) > [Revocation](#) > [Scope](#) > [Eligibility](#) > [Attachments](#) > [Summary](#)

Applicant Information

Revocation

Scope

Eligibility

Attachments

Summary

e-Signature

Summary

Review the following information for correctness and edit as needed.

Applicant Information

<p>Firm Name Accreditation Body Inc.</p> <p>Address 123 ABC Street Suite 200 ABC Maryland 20901 United States</p> <p>Web Address http://www.abc123.com</p>	<p>Contact Name Test Q Tester</p> <p>Contact Number Phone Number 1 (555) 5555555 Ext. 505 Fax Number 1 (555) 5555555</p> <p>Email Address test123@test.com</p> <p>Unique Facility Identifier --</p>
---	---

Revocation

Not Applicable ✎ Edit

Scope

✎ Edit

- 105: Foods for special Dietary Use
- 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications
- 107: Infant Formula

Eligibility

✎ Edit

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

Attachments (Optional)

✎ Edit

File Name	Type	Date of Upload
Optional_Attachments_Test_File.docx	Standard Operating Procedures and Policies	2018-05-03

⏪ Previous

Save

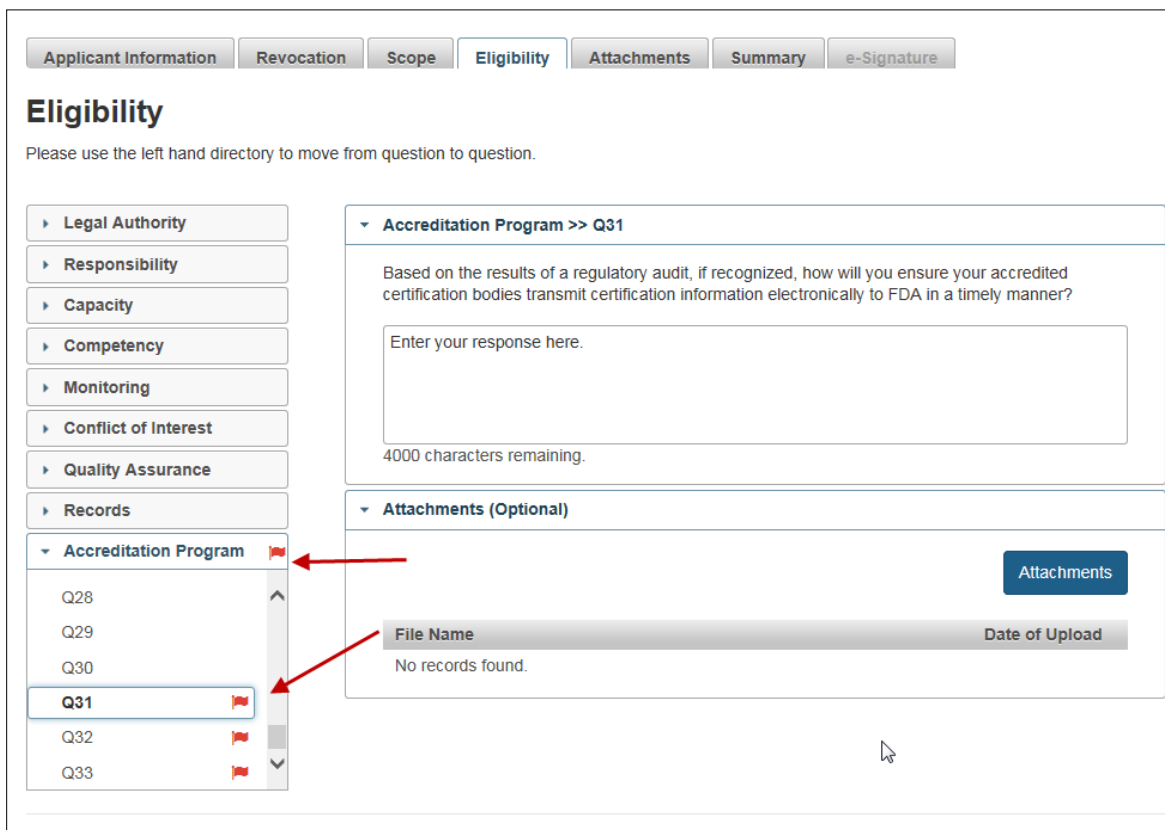
Next ⏩

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.

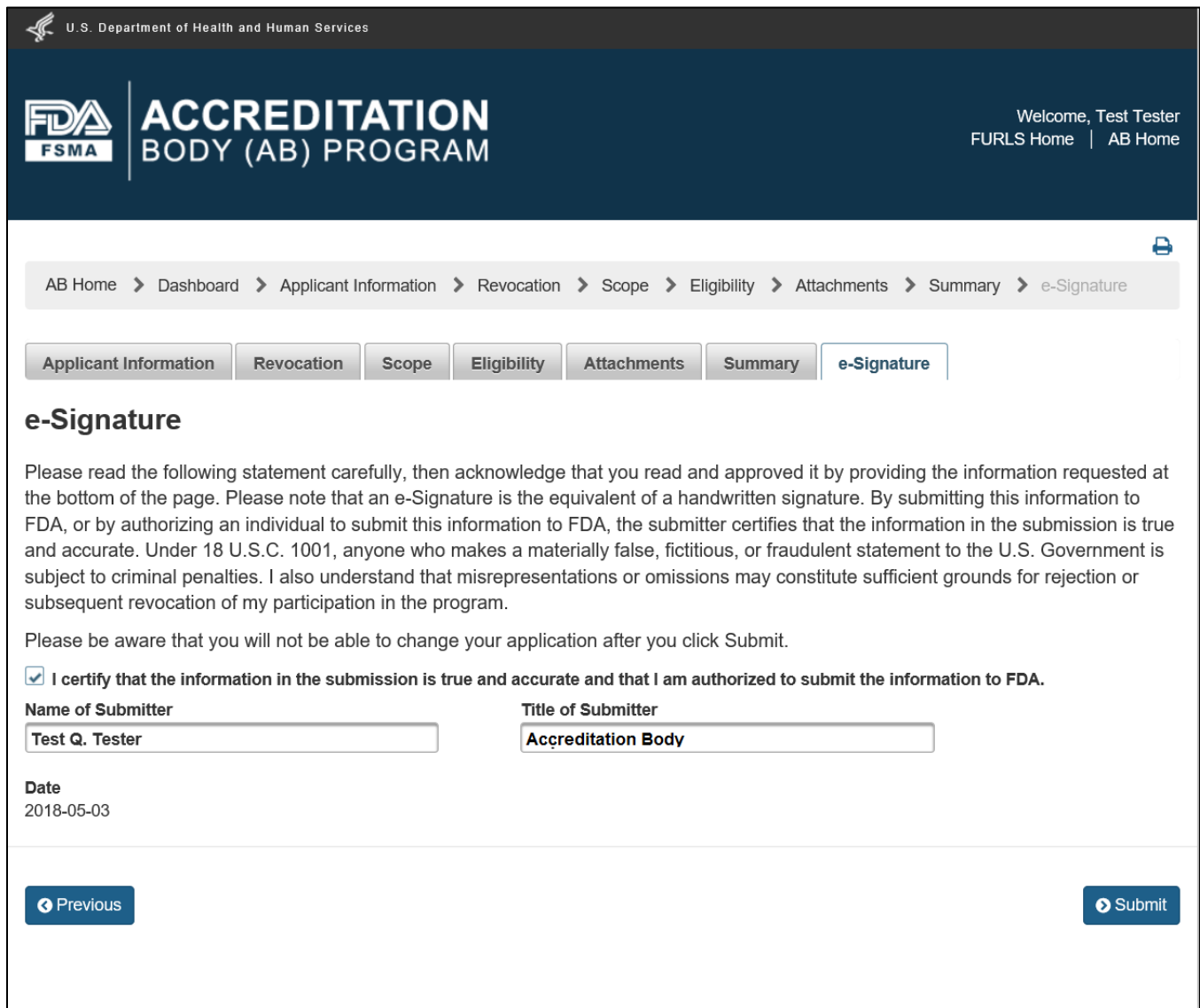
Click the check mark to indicate you certify the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA.

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



U.S. Department of Health and Human Services

FDA FSMA | **ACCREDITATION BODY (AB) PROGRAM**

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Dashboard > Applicant Information > Revocation > Scope > Eligibility > Attachments > Summary > e-Signature

Applicant Information | Revocation | Scope | Eligibility | Attachments | Summary | **e-Signature**

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Test Q. Tester

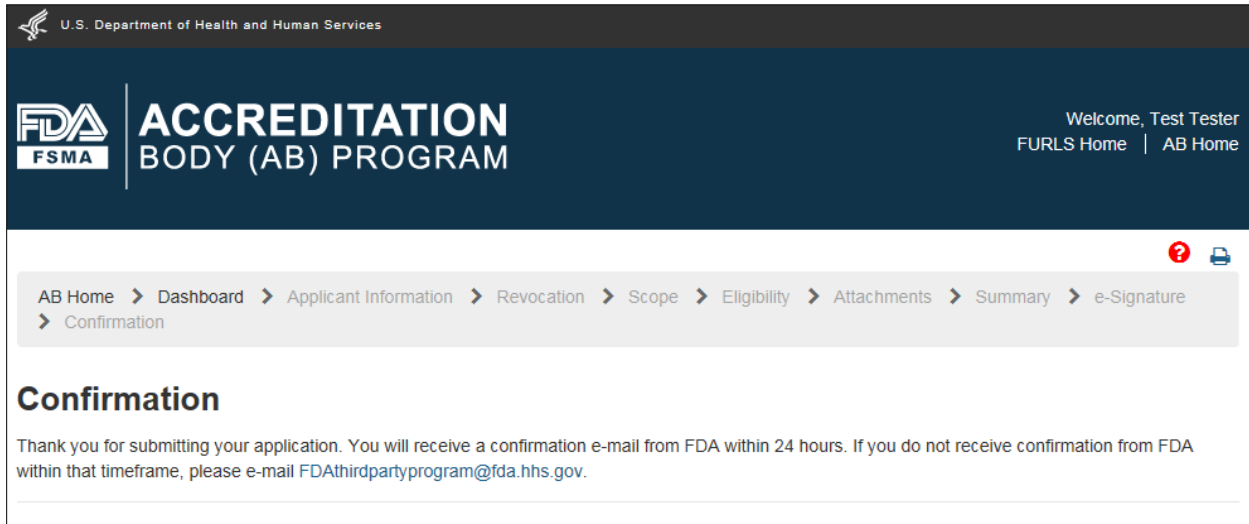
Title of Submitter
Accreditation Body

Date
2018-05-03

Previous Submit

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

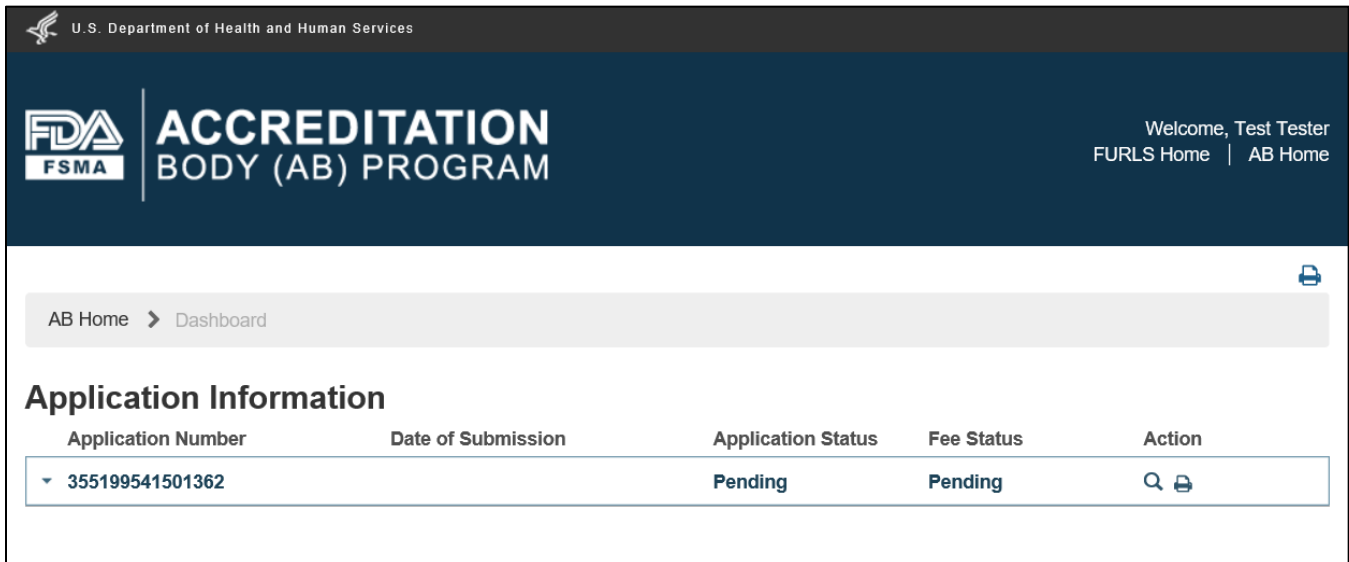
Figure 5.21 – Confirmation Message



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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

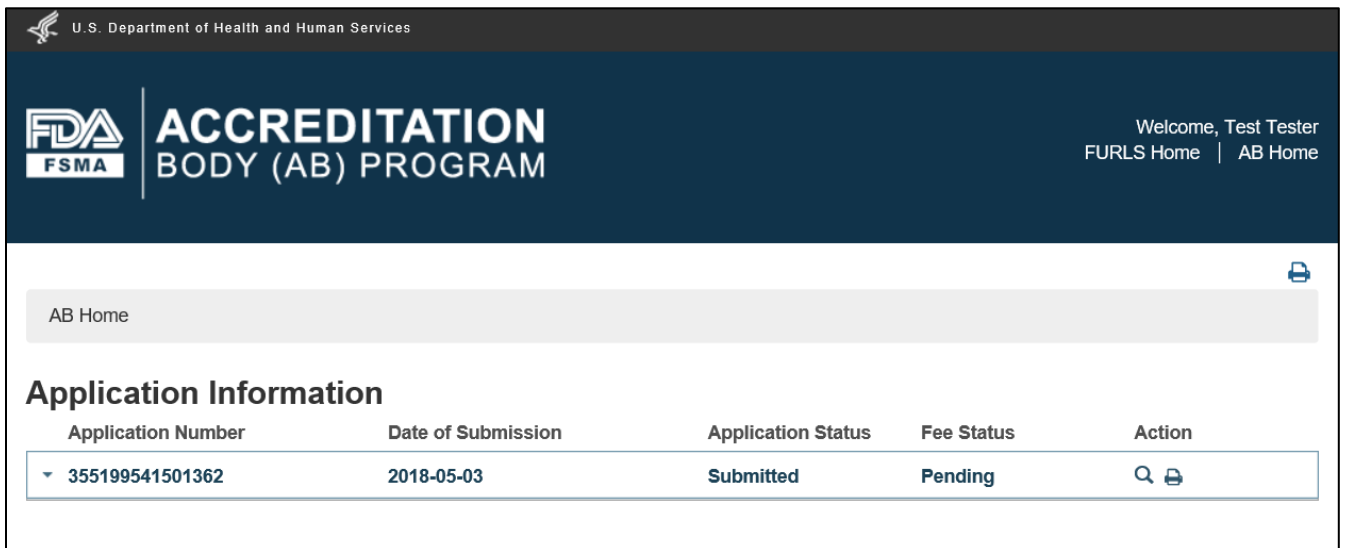
AB Home > Dashboard

Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
355199541501362		Pending	Pending	Search Print

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

Figure 5.23 – Application “Submitted” Status



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home

Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
355199541501362	2018-05-03	Submitted	Pending	Search Print

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.

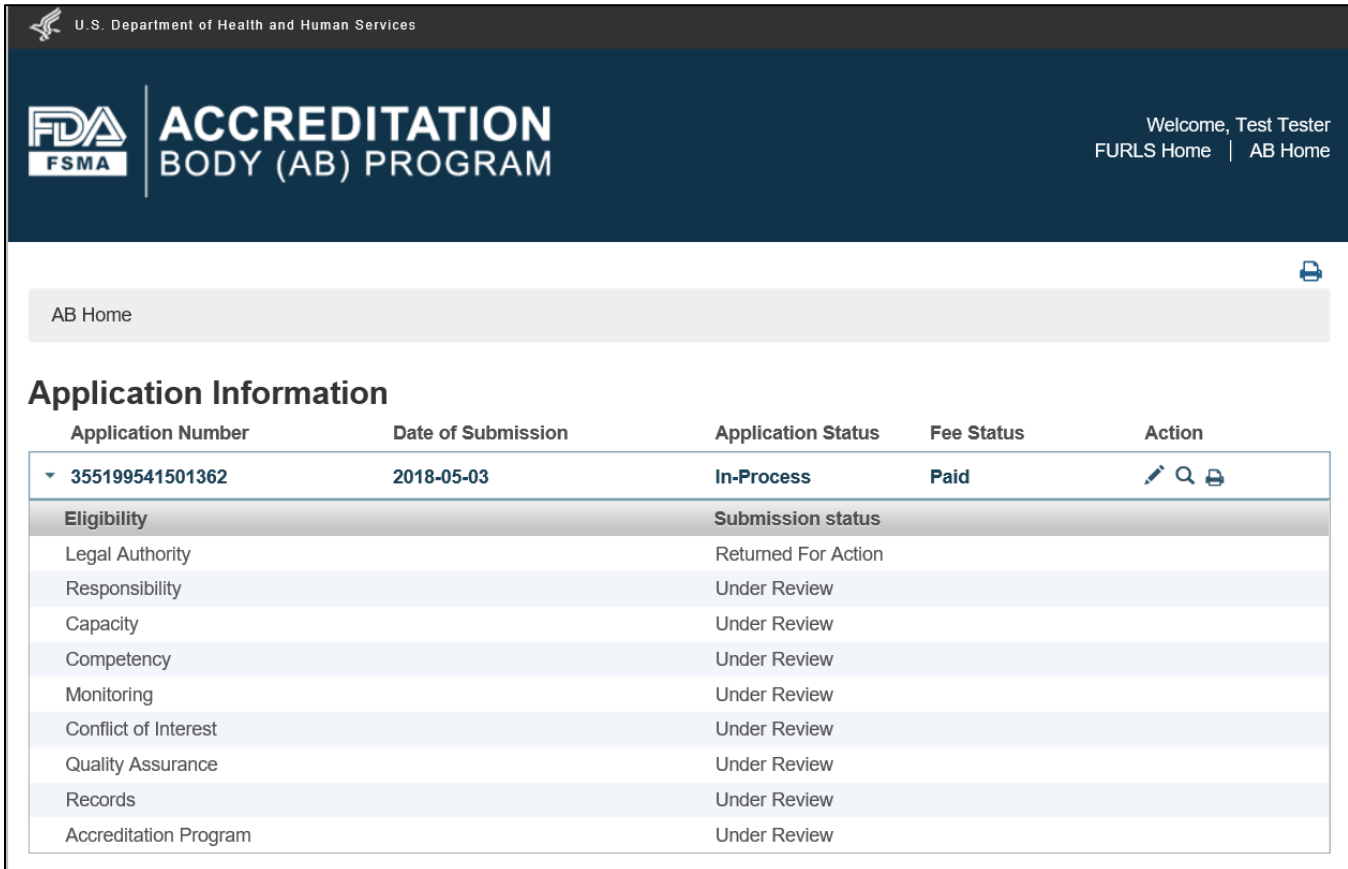
The applicant must submit the requested information before the FDA will continue the application review process.

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






U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

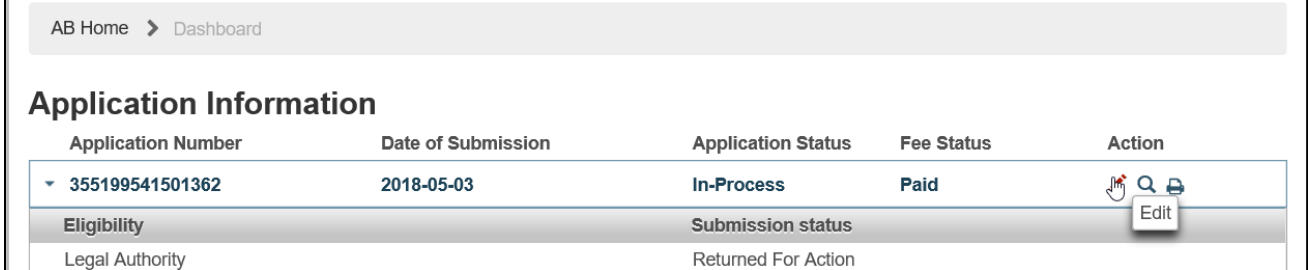
[AB Home](#)





Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
355199541501362	2018-05-03	In-Process	Paid	  
Eligibility		Submission status		
Legal Authority		Returned For Action		
Responsibility		Under Review		
Capacity		Under Review		
Competency		Under Review		
Monitoring		Under Review		
Conflict of Interest		Under Review		
Quality Assurance		Under Review		
Records		Under Review		
Accreditation Program		Under Review		

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



Application Number	Date of Submission	Application Status	Fee Status	Action
355199541501362	2018-05-03	In-Process	Paid	   
Eligibility		Submission status		
Legal Authority		Returned For Action		

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).

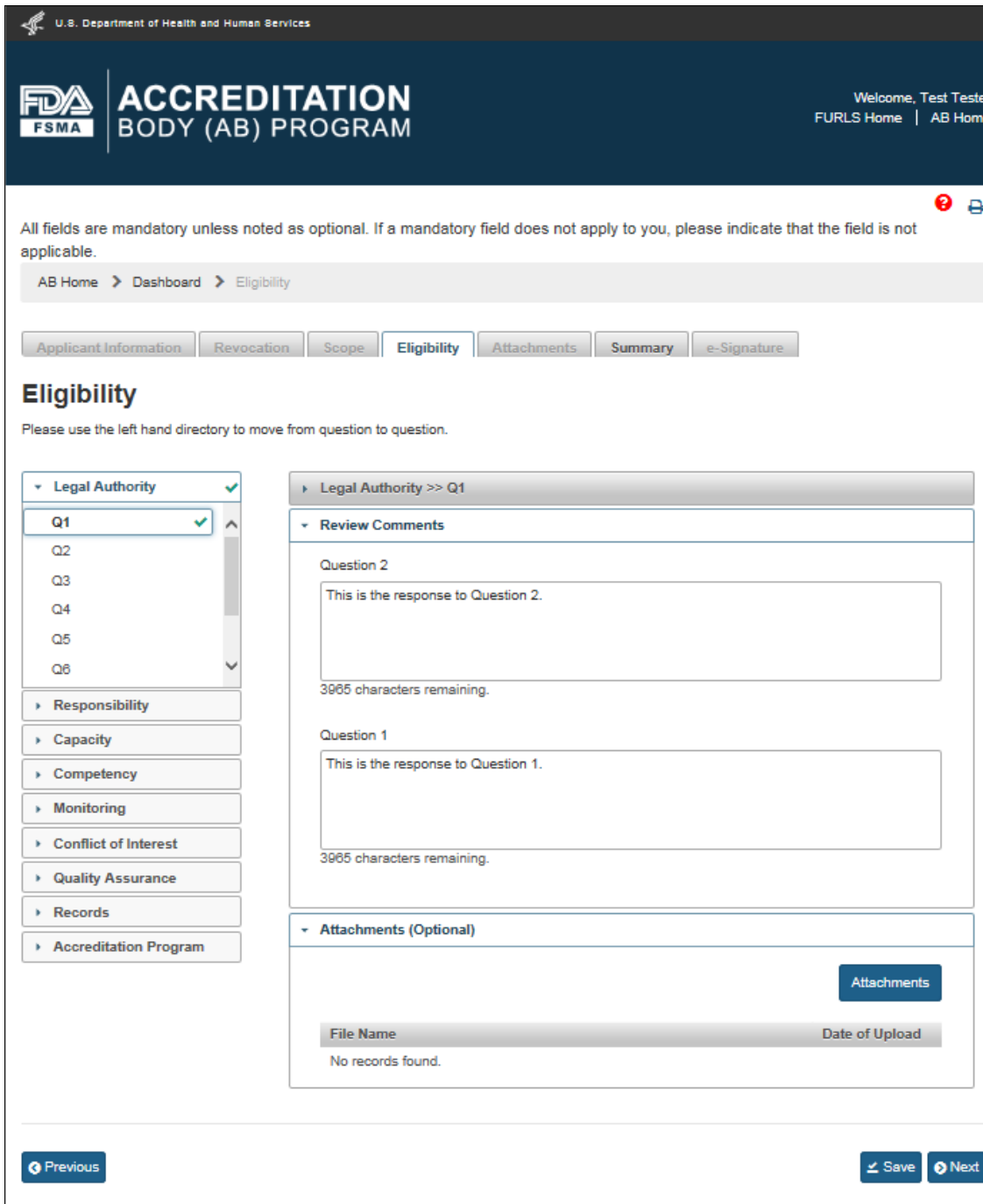
Go directly to the red-flagged standard(s) to provide the required answers, information and/or attachments.

Figure 6.3 – Eligibility Criteria Page with Red Flags

The screenshot shows the 'Eligibility' page of the FDA Accreditation Body (AB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'ACCREDITATION BODY (AB) PROGRAM'. A user greeting 'Welcome, Test Tester' and links for 'FURLS Home' and 'AB Home' are also present. A navigation breadcrumb shows 'AB Home > Dashboard > Eligibility'. A series of tabs includes 'Applicant Information', 'Revocation', 'Scope', 'Eligibility' (which is active), 'Attachments', 'Summary', and 'e-Signature'. Below the tabs, a message states: 'All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.' A left-hand directory lists categories: 'Legal Authority' (with a red flag icon), 'Responsibility', 'Capacity', 'Competency', 'Monitoring', 'Conflict of Interest', and 'Quality Assurance'. Under 'Legal Authority', a sub-list shows 'Q1' (with a red flag icon), 'Q2', 'Q3', 'Q4', 'Q5', and 'Q6'. The main content area is titled 'Legal Authority >> Q1' and contains a 'Review Comments' section. This section has two text input fields. The first is labeled 'Question 2' with a red arrow pointing to it, and the second is labeled 'Question 1' with a red arrow pointing to it. Both fields contain the placeholder text 'Enter your response here.' and a '4000 characters remaining' indicator.

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

[AB Home](#) > [Dashboard](#) > [Eligibility](#)

Applicant Information | Revocation | Scope | **Eligibility** | Attachments | Summary | e-Signature

Eligibility

Please use the left hand directory to move from question to question.

- Legal Authority
 - Q1**
 - Q2
 - Q3
 - Q4
 - Q5
 - Q6
- Responsibility
- Capacity
- Competency
- Monitoring
- Conflict of Interest
- Quality Assurance
- Records
- Accreditation Program

Legal Authority >> Q1

Review Comments

Question 2

This is the response to Question 2.

3965 characters remaining.

Question 1

This is the response to Question 1.

3965 characters remaining.

Attachments (Optional)

Attachments

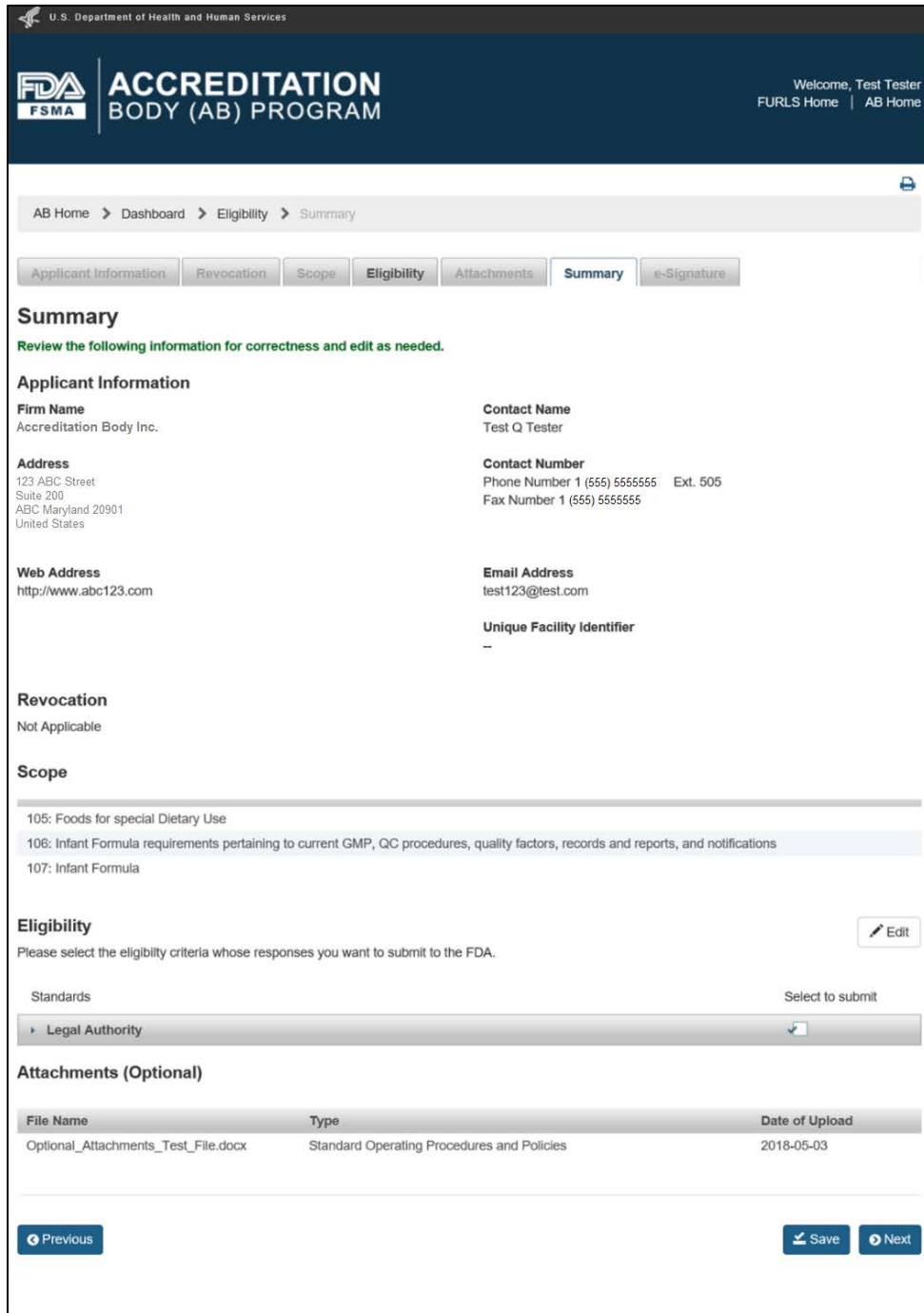
File Name	Date of Upload
No records found.	

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

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Dashboard > Eligibility > Summary

Applicant Information | Revocation | Scope | Eligibility | Attachments | **Summary** | e-Signature

Summary

Review the following information for correctness and edit as needed.

Applicant Information

Firm Name Accreditation Body Inc.	Contact Name Test Q Tester
Address 123 ABC Street Suite 200 ABC Maryland 20901 United States	Contact Number Phone Number 1 (555) 5555555 Ext. 505 Fax Number 1 (555) 5555555
Web Address http://www.abc123.com	Email Address test123@test.com
	Unique Facility Identifier -

Revocation

Not Applicable

Scope

- 105: Foods for special Dietary Use
- 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications
- 107: Infant Formula

Eligibility

Please select the eligibility criteria whose responses you want to submit to the FDA. [Edit](#)

Standards Select to submit

- Legal Authority

Attachments (Optional)

File Name	Type	Date of Upload
Optional_Attachments_Test_File.docx	Standard Operating Procedures and Policies	2018-05-03

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

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.

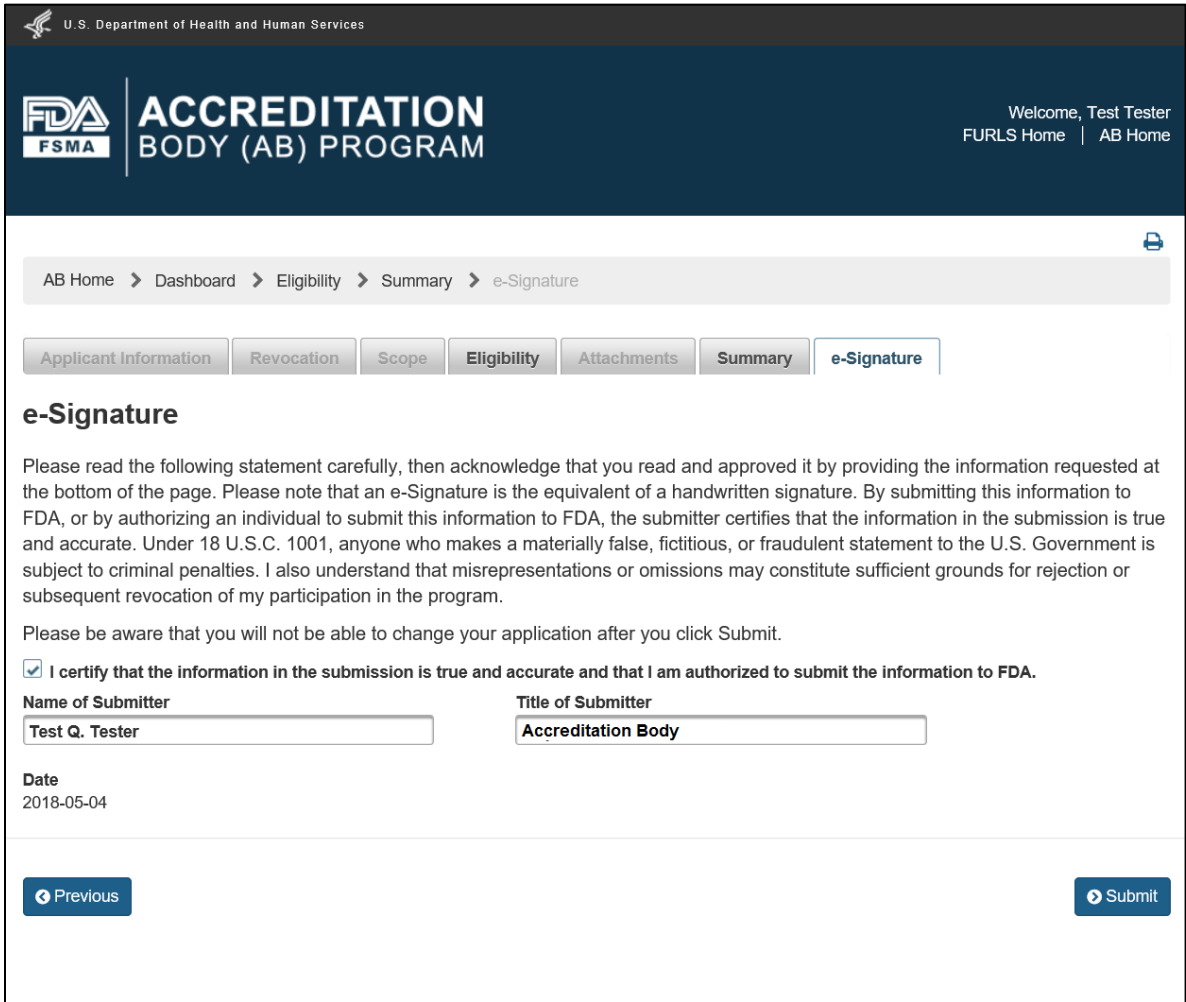
Click the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

AB Home > Dashboard > Eligibility > Summary > e-Signature

Applicant Information | Revocation | Scope | **Eligibility** | Attachments | Summary | **e-Signature**

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Test Q. Tester

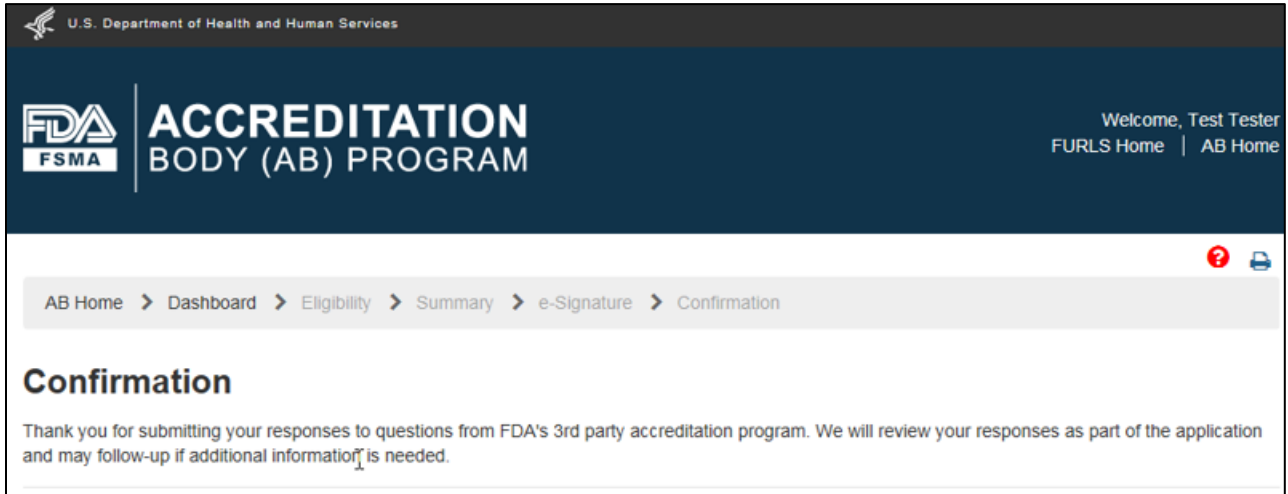
Title of Submitter
Accreditation Body

Date
2018-05-04

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

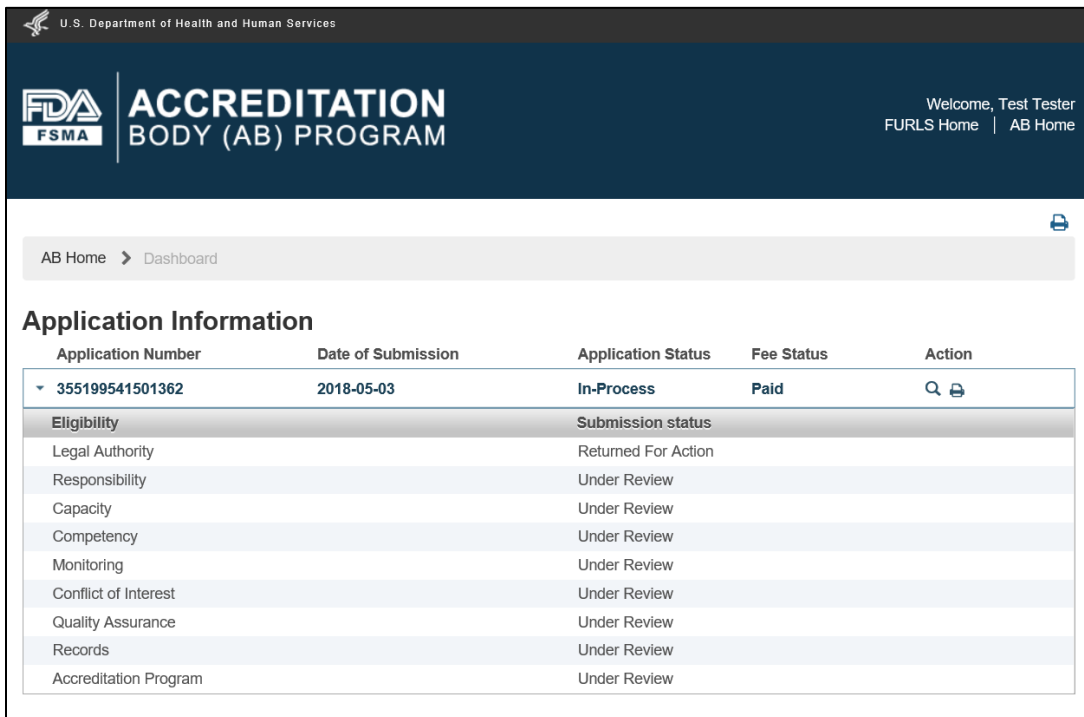
The system will post a confirmation message on the page (Figure 6.7).

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

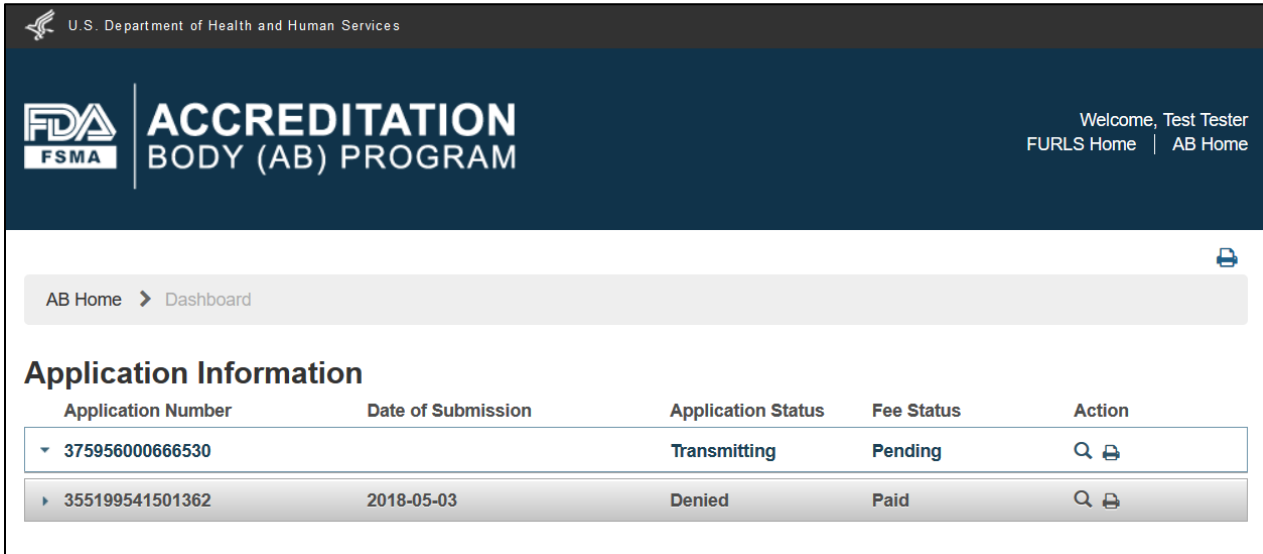


7 Reconsideration Request





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



The screenshot shows the FDA Accreditation Body (AB) Program dashboard. At the top, it says "U.S. Department of Health and Human Services" and "Welcome, Test Tester" with links for "FURLS Home" and "AB Home". The main header includes the FDA FSMA logo and "ACCREDITATION BODY (AB) PROGRAM". A breadcrumb trail shows "AB Home > Dashboard". Below this is a table titled "Application Information" with the following data:

Application Number	Date of Submission	Application Status	Fee Status	Action
375956000666530		Transmitting	Pending	 
355199541501362	2018-05-03	Denied	Paid	 

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

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home

AB Home

AB Home

View/Edit my application for recognition

Reconsideration Request

View my profile

Contact Us

Welcome

Welcome to the FDA's Third Party Accreditation Program portal. This portal is the means by which all information related to the FDA Third Party Program will be transmitted to the agency. At this time, your account is limited to minimal actions which include updating your profile, contacting the FDA Third Party Program and submitting an application to become recognized in the FDA Third Party Accreditation Program. Once you are accepted into the program, additional IT capabilities will become available including your ability to add a Certification Body to your rolodex.

Use this site to submit an application for recognition as an accreditation body.

How do I submit an application?
On the left navigation menu click on the Apply for Recognition link to create a new application and follow the 8-Step form. You can save a draft of the form at any point.

How do I edit a previously saved application?
On the left navigation menu click on the View/Edit my application for recognition link and use the navigation options to continue filling in the form.

How do I submit my application?
When all sections of the form have been completed, the system will provide an option to submit the application. Edits are not allowed after submit.

FDA Form 3997
PAPERWORK REDUCTION ACT NOTICE
Form Approval: OMB No. 0910-0750
Expiration Date: 06/30/2019

The agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 80 hours per response for a one-time reporting burden and 2.5 - 8.5 hours per response thereafter, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. This form is a vehicle to collect this information. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

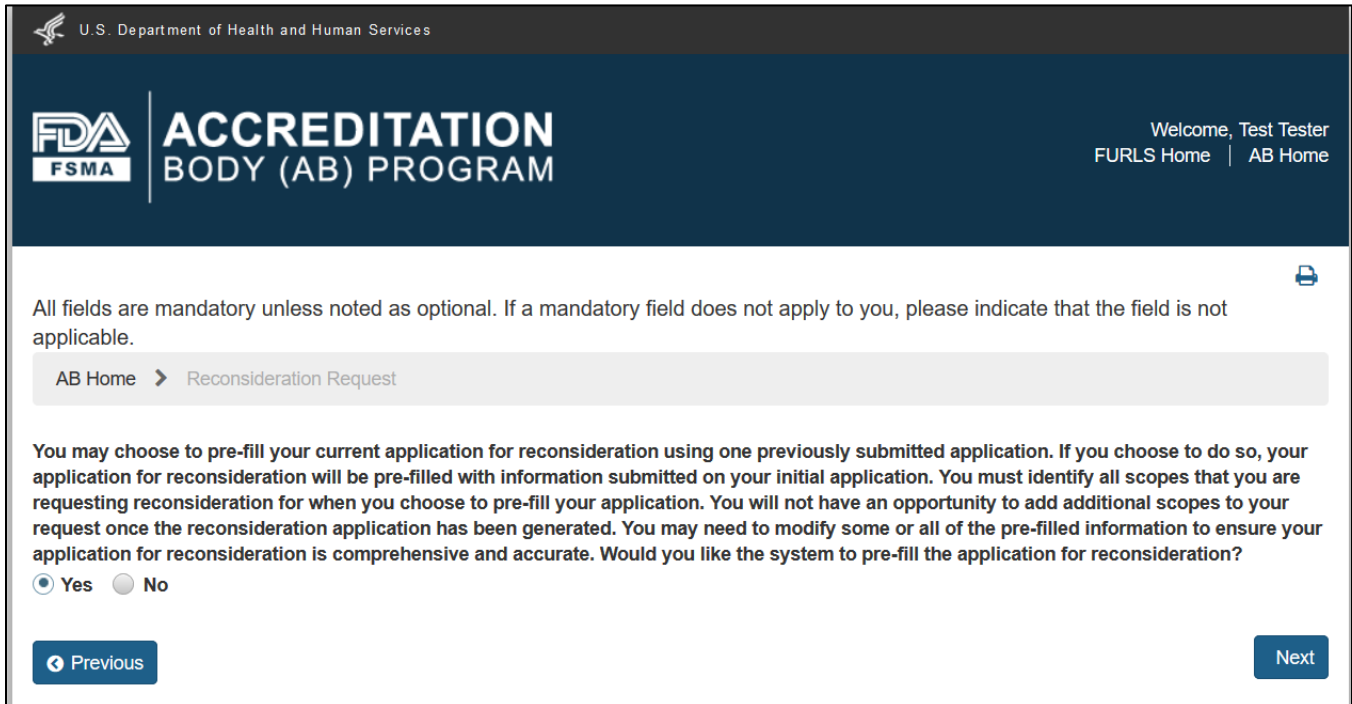
Department of Health and Human Services
Food and Drug Administration
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Note: The system will automatically time out if there is no activity for 30 minutes. Unsaved data will be lost.

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 pre-filled 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”)



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

[AB Home](#) > [Reconsideration Request](#)

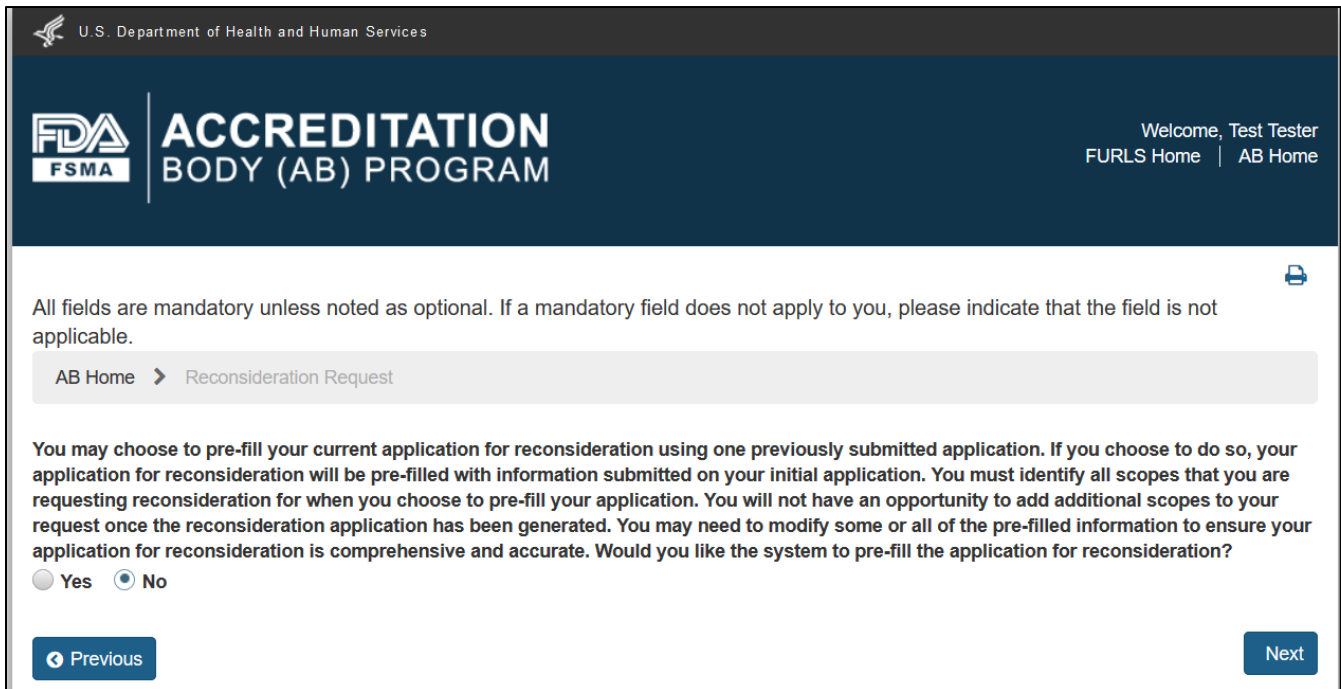
You may choose to pre-fill your current application for reconsideration using one previously submitted application. If you choose to do so, your application for reconsideration will be pre-filled with information submitted on your initial application. You must identify all scopes that you are requesting reconsideration for when you choose to pre-fill your application. You will not have an opportunity to add additional scopes to your request once the reconsideration application has been generated. You may need to modify some or all of the pre-filled information to ensure your application for reconsideration is comprehensive and accurate. Would you like the system to pre-fill the application for reconsideration?

Yes No

[← Previous](#) [Next](#)

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

Figure 7.4 – Reconsideration Page (“No”)



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

AB Home > Reconsideration Request

You may choose to pre-fill your current application for reconsideration using one previously submitted application. If you choose to do so, your application for reconsideration will be pre-filled with information submitted on your initial application. You must identify all scopes that you are requesting reconsideration for when you choose to pre-fill your application. You will not have an opportunity to add additional scopes to your request once the reconsideration application has been generated. You may need to modify some or all of the pre-filled information to ensure your application for reconsideration is comprehensive and accurate. Would you like the system to pre-fill the application for reconsideration?

Yes No

Previous Next

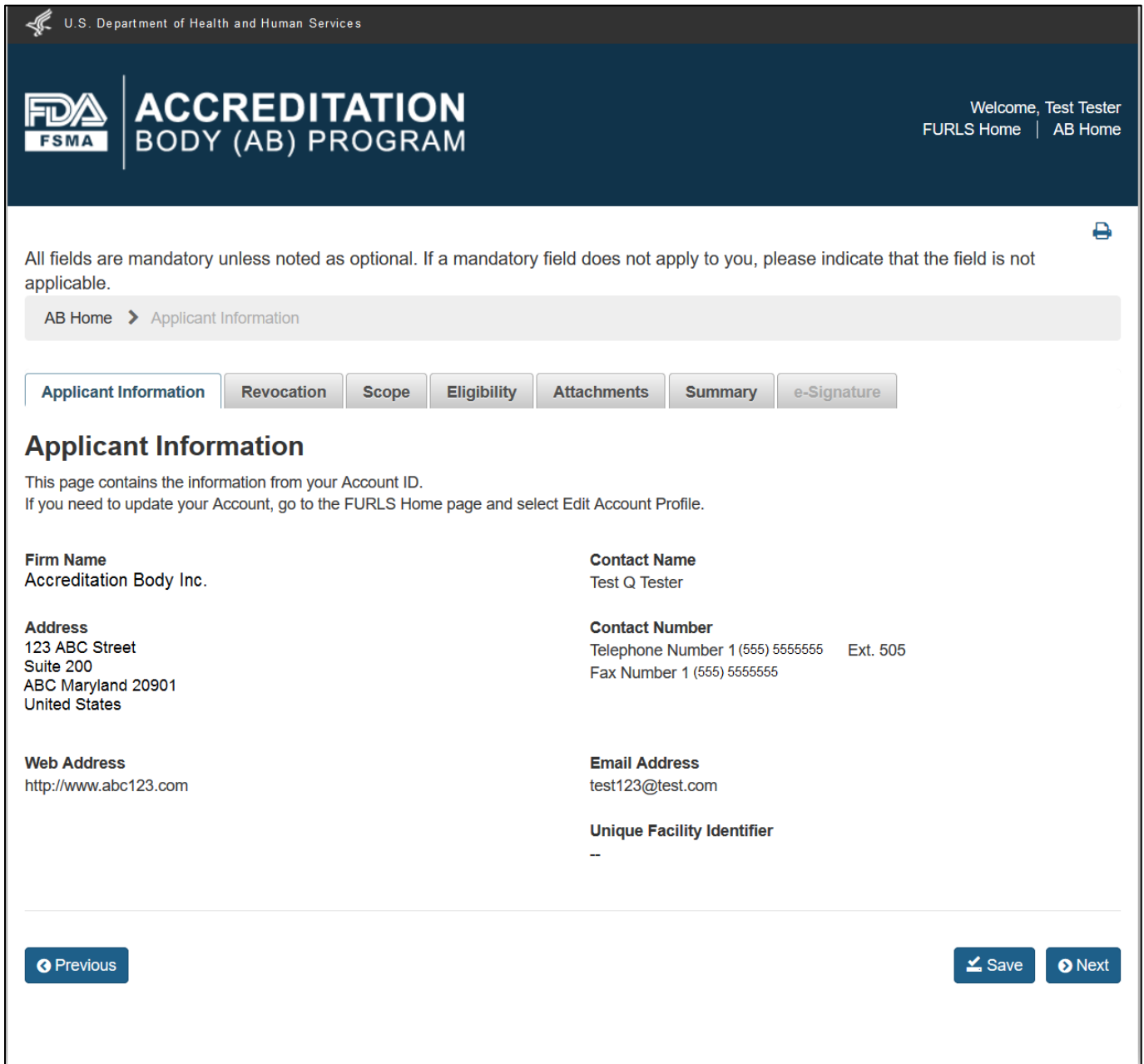
The “Next” button will appear at the bottom of the screen once a radio button is selected.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

[AB Home](#) > [Applicant Information](#)

[Applicant Information](#) | [Revocation](#) | [Scope](#) | [Eligibility](#) | [Attachments](#) | [Summary](#) | [e-Signature](#)

Applicant Information

This page contains the information from your Account ID.
If you need to update your Account, go to the FURLS Home page and select Edit Account Profile.

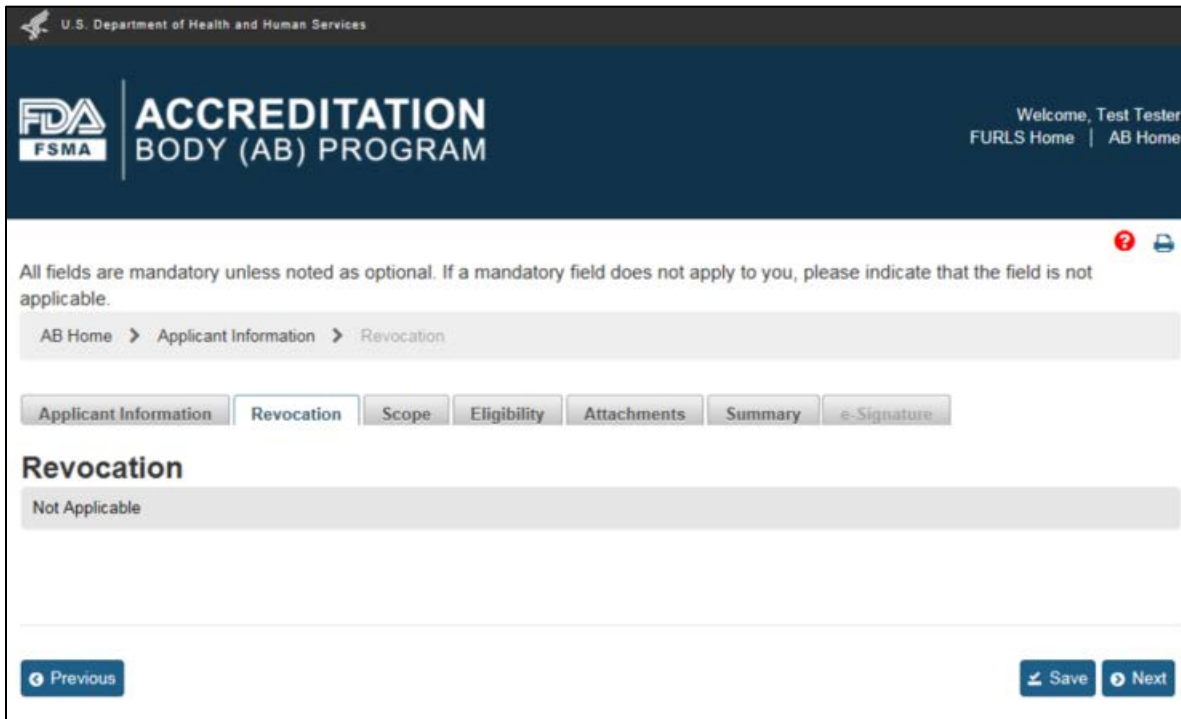
Firm Name Accreditation Body Inc.	Contact Name Test Q Tester
Address 123 ABC Street Suite 200 ABC Maryland 20901 United States	Contact Number Telephone Number 1 (555) 5555555 Ext. 505 Fax Number 1 (555) 5555555
Web Address http://www.abc123.com	Email Address test123@test.com
	Unique Facility Identifier --

[← Previous](#) [Save](#) [Next →](#)

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

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

[AB Home](#) > [Applicant Information](#) > [Revocation](#) > [Scope](#)

[Applicant Information](#)
[Revocation](#)
[Scope](#)
[Eligibility](#)
[Attachments](#)
[Summary](#)
[e-Signature](#)

Scope

List of Original Source Scopes

Enter a keyword to search for scope

- 109: Unavoidable contaminants in food for human consumption and food-packaging material
- 110: Current GMP in manufacturing, packaging, or holding human food
- 111: Current GMP practice in manufacturing, packaging, labeling or holding operations for dietary supplements
- 112: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption
- 113: Thermally processed low-acid foods packaged in hermetically sealed containers
- 114: Acidified foods
- 115: Shell eggs

List of Selected Scopes

Enter a keyword to search for scope

- 105: Foods for special Dietary Use
- 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications
- 107: Infant Formula

[→](#)
[→+](#)
[←](#)
[←+](#)

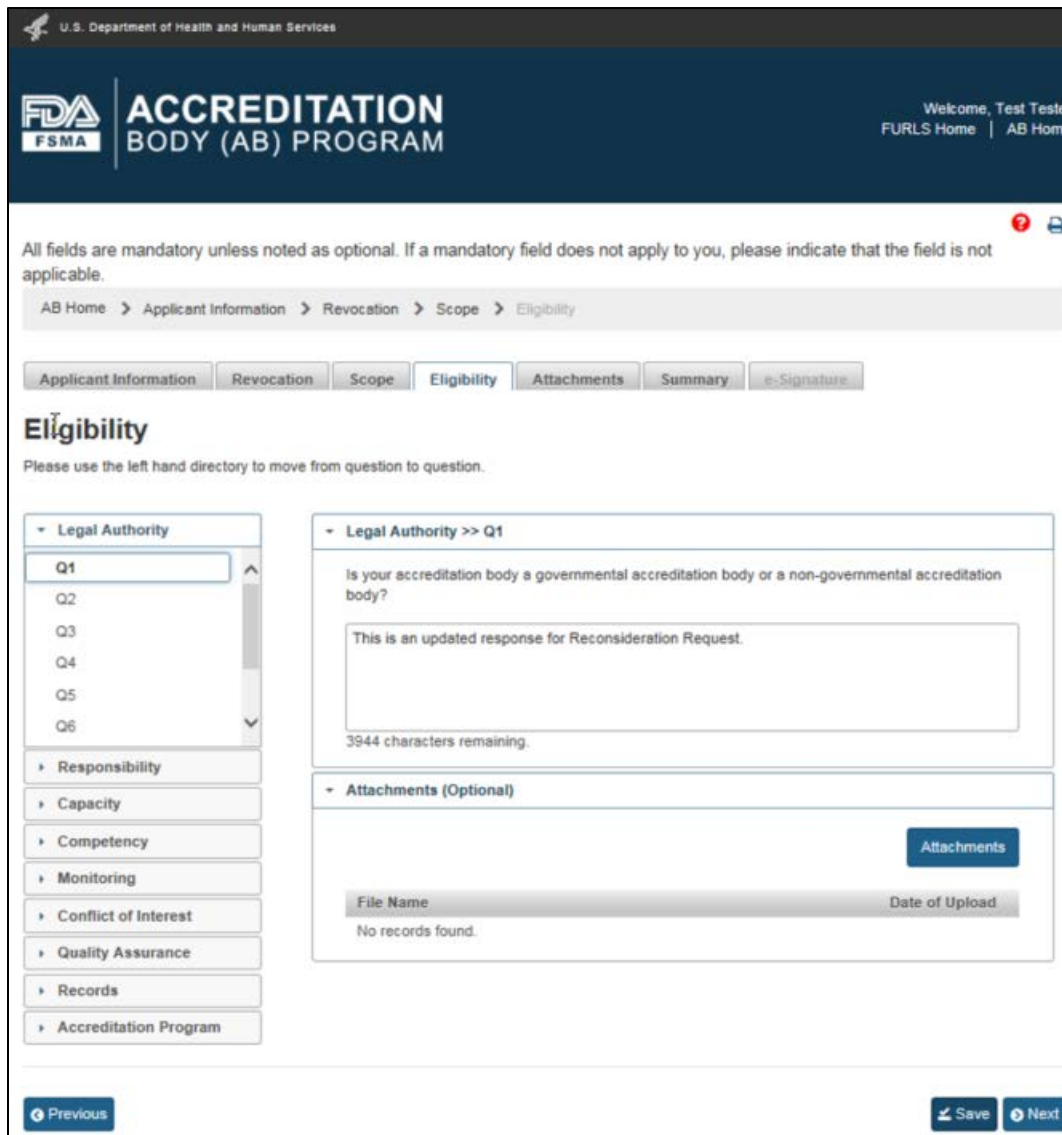
[Previous](#)
[Save](#)
[Next](#)

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

[AB Home](#) > [Applicant Information](#) > [Revocation](#) > [Scope](#) > [Eligibility](#)

Applicant Information | Revocation | Scope | **Eligibility** | Attachments | Summary | e-Signature

Eligibility

Please use the left hand directory to move from question to question.

- Legal Authority
 - Q1**
 - Q2
 - Q3
 - Q4
 - Q5
 - Q6
- Responsibility
- Capacity
- Competency
- Monitoring
- Conflict of Interest
- Quality Assurance
- Records
- Accreditation Program

Legal Authority >> Q1

Is your accreditation body a governmental accreditation body or a non-governmental accreditation body?

This is an updated response for Reconsideration Request.

3944 characters remaining.

Attachments (Optional)

Attachments

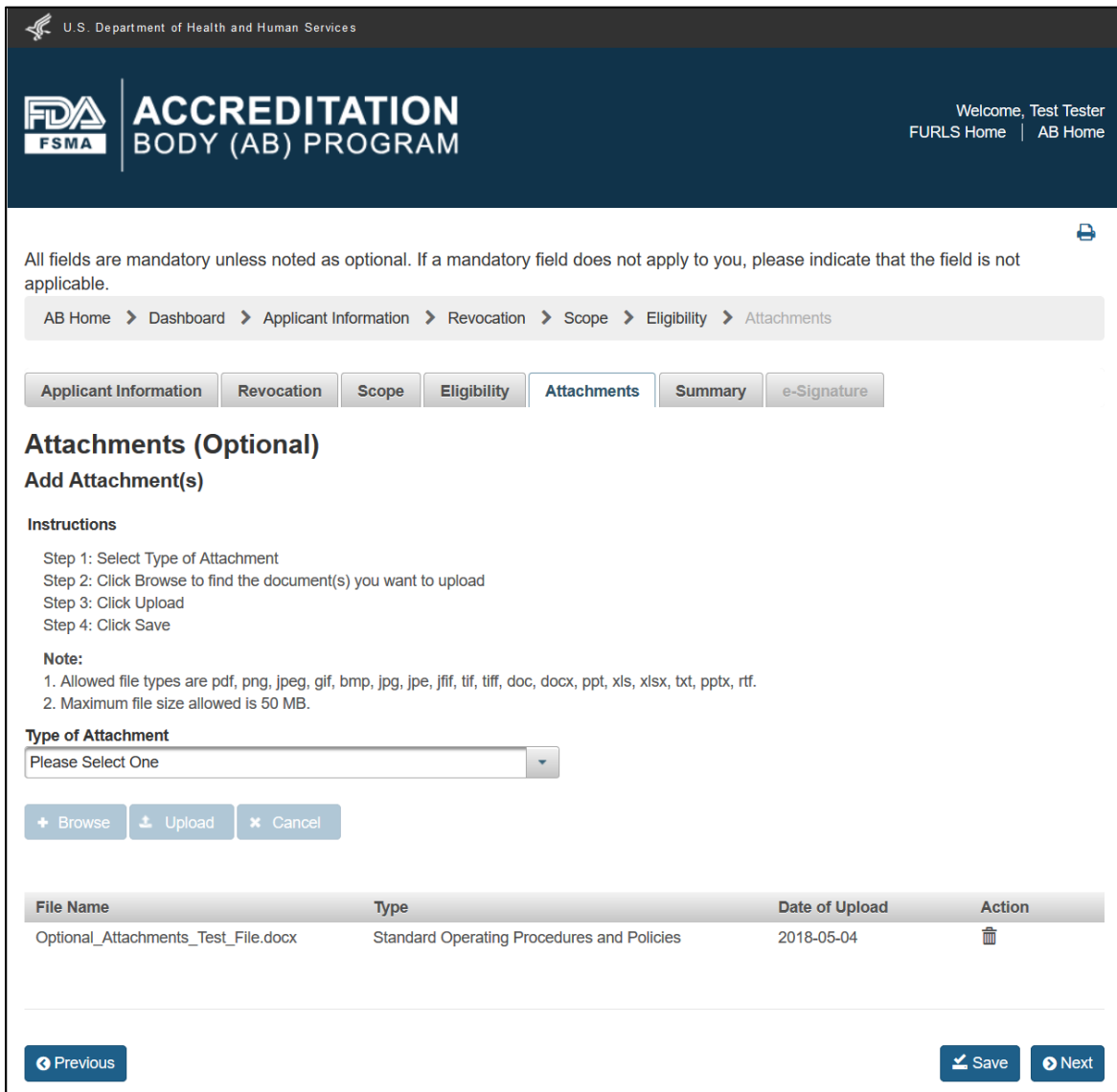
File Name	Date of Upload
No records found.	

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

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please indicate that the field is not applicable.

[AB Home](#) > [Dashboard](#) > [Applicant Information](#) > [Revocation](#) > [Scope](#) > [Eligibility](#) > [Attachments](#)

[Applicant Information](#) [Revocation](#) [Scope](#) [Eligibility](#) **[Attachments](#)** [Summary](#) [e-Signature](#)

Attachments (Optional)

Add Attachment(s)

Instructions

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

Note:

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

Type of Attachment

Please Select One

[+ Browse](#) [Upload](#) [Cancel](#)

File Name	Type	Date of Upload	Action
Optional_Attachments_Test_File.docx	Standard Operating Procedures and Policies	2018-05-04	

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

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

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Dashboard > Applicant Information > Revocation > Scope > Eligibility > Attachments > Summary

Applicant Information | Revocation | Scope | Eligibility | Attachments | **Summary** | e-Signature

Summary

Review the following information for correctness and edit as needed.

Applicant Information

Firm Name Accreditation Body Inc.	Contact Name Test Q Tester
Address 123 ABC Street Suite 200 ABC Maryland 20901 UNITED STATES	Contact Number Phone Number 1 (555) 5555555 Ext. 505 Fax Number 1(555) 5555555
Web Address http://www.abc123.com	Email Address test123@test.com
	Unique Facility Identifier -

Revocation

Not Applicable [Edit](#)

Scope

[Edit](#)

- 105: Foods for special Dietary Use
- 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications
- 107: Infant Formula

Eligibility

[Edit](#)

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

Attachments (Optional)

[Edit](#)

File Name	Type	Date of Upload
Optional_Attachments_Test_File.docx	Standard Operating Procedures and Policies	2018-05-03

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

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.

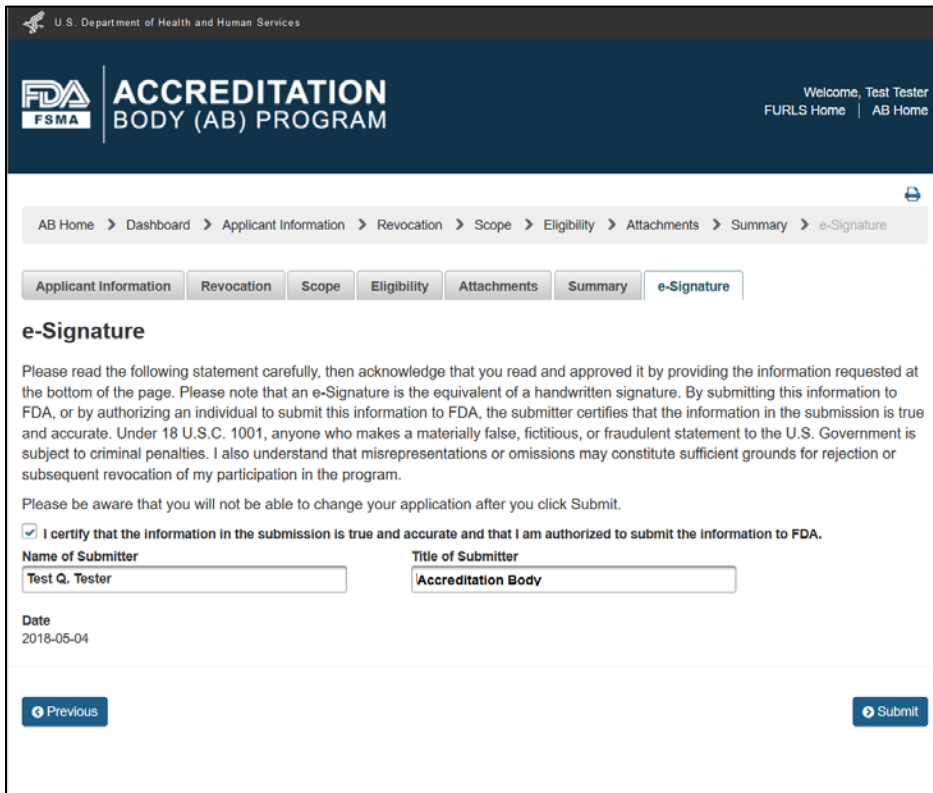
Click the check mark to certify that the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA.

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.

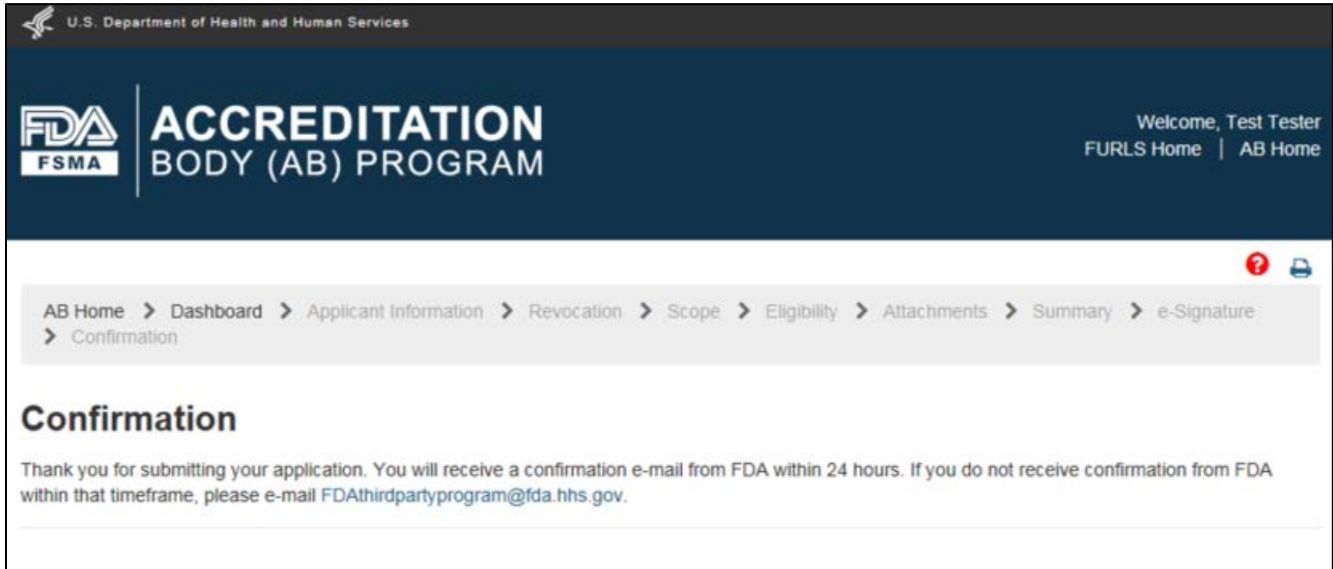
Figure 7.11 – e-Signature Page



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

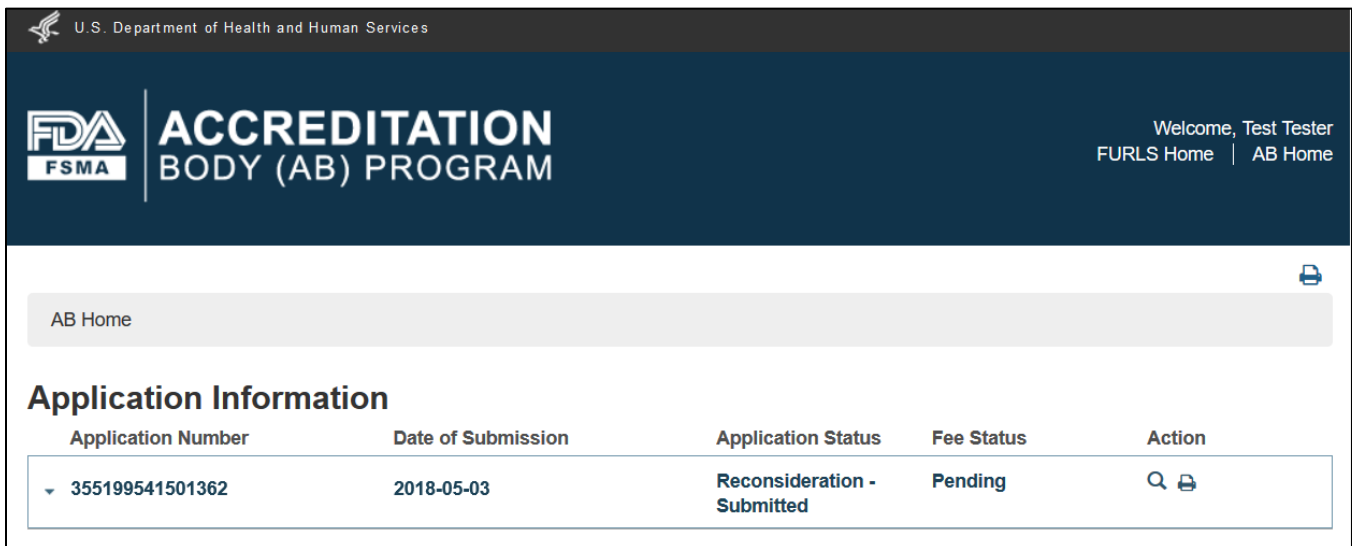
message on the page (Figure 7.12).

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


U.S. Department of Health and Human Services



ACCREDITATION BODY (AB) PROGRAM



Welcome, Test Tester

[FURLS Home](#) | [AB Home](#)

Recognition Status: Recognized 

[AB Home](#)

Application Information

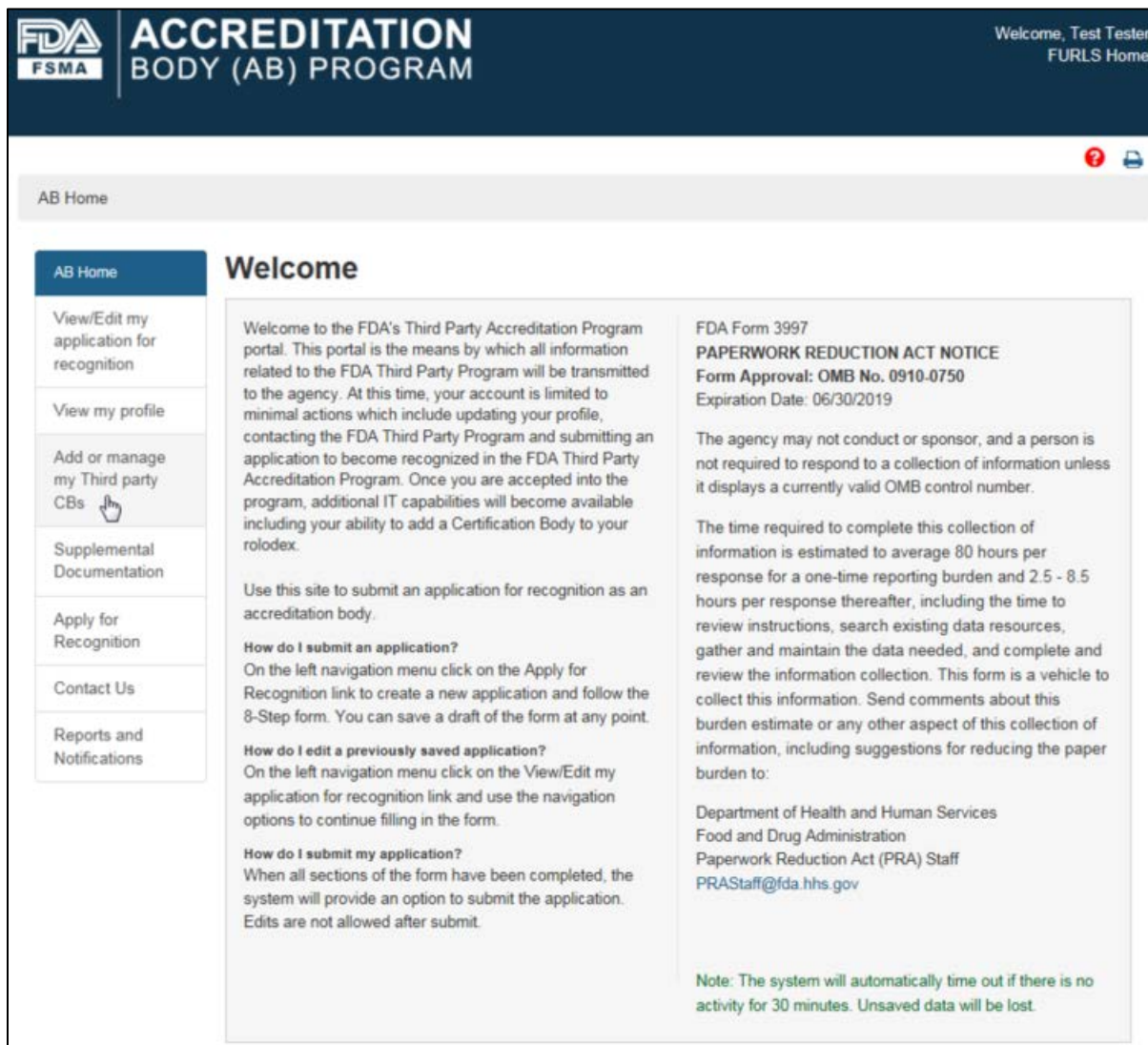
Application Number	Date of Submission	Application Status	Fee Status	Action
355199541501362	2018-05-03	Reconsideration - Recognized	Pending	 

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



ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home

AB Home

AB Home

- View/Edit my application for recognition
- View my profile
- Add or manage my Third party CBs**
- Supplemental Documentation
- Apply for Recognition
- Contact Us
- Reports and Notifications

Welcome

Welcome to the FDA's Third Party Accreditation Program portal. This portal is the means by which all information related to the FDA Third Party Program will be transmitted to the agency. At this time, your account is limited to minimal actions which include updating your profile, contacting the FDA Third Party Program and submitting an application to become recognized in the FDA Third Party Accreditation Program. Once you are accepted into the program, additional IT capabilities will become available including your ability to add a Certification Body to your rolodex.

Use this site to submit an application for recognition as an accreditation body.

How do I submit an application?
On the left navigation menu click on the Apply for Recognition link to create a new application and follow the 8-Step form. You can save a draft of the form at any point.

How do I edit a previously saved application?
On the left navigation menu click on the View/Edit my application for recognition link and use the navigation options to continue filling in the form.

How do I submit my application?
When all sections of the form have been completed, the system will provide an option to submit the application. Edits are not allowed after submit.

FDA Form 3997
PAPERWORK REDUCTION ACT NOTICE
Form Approval: OMB No. 0910-0750
Expiration Date: 06/30/2019

The agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 80 hours per response for a one-time reporting burden and 2.5 - 8.5 hours per response thereafter, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. This form is a vehicle to collect this information. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

Department of Health and Human Services
Food and Drug Administration
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

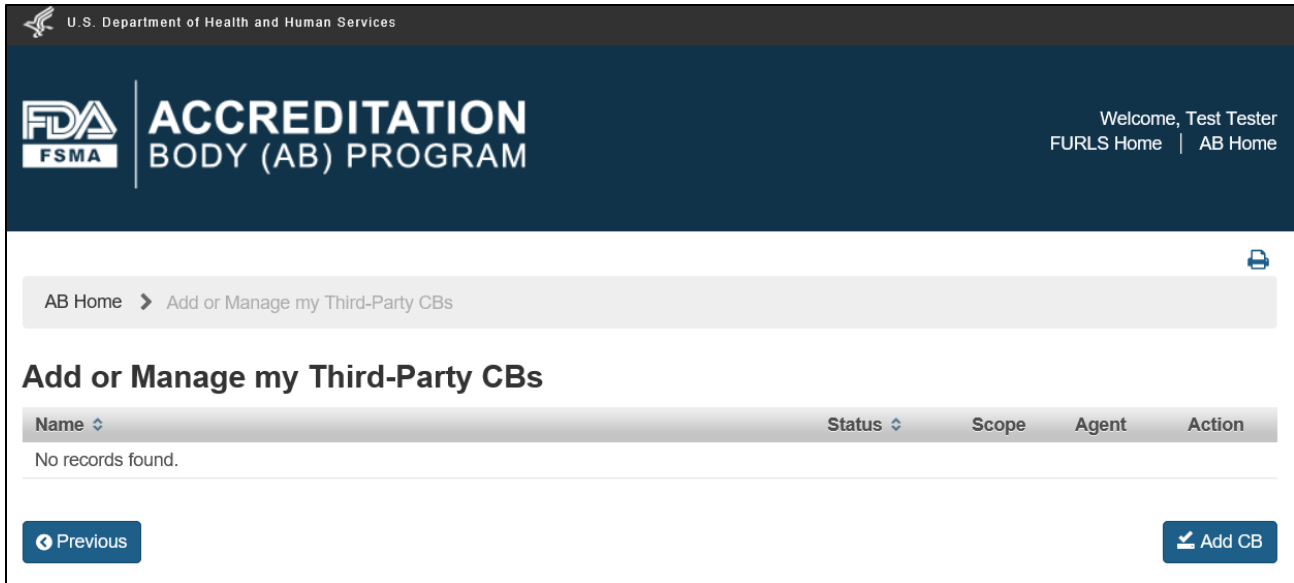
Note: The system will automatically time out if there is no activity for 30 minutes. Unsaved data will be lost.

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

U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | BODY (AB) PROGRAM

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

AB Home > Add or Manage my Third-Party CBs > Add CB

Add Accredited Third-Party CB

E-mail Address:

Third-Party Certification Body Name:

Country:

Address 1:

Address 2 (Optional):

City:

State/Province/Territory:

Zip Code (Postal Code):

Contact Name:

First Name MI (Optional) Last Name

Phone Number:

Country Area Phone Number Extension

Fax Number (Optional):

Country Area Fax Number

Status:
 Accredited

Web Address (Optional):

Officer(s):

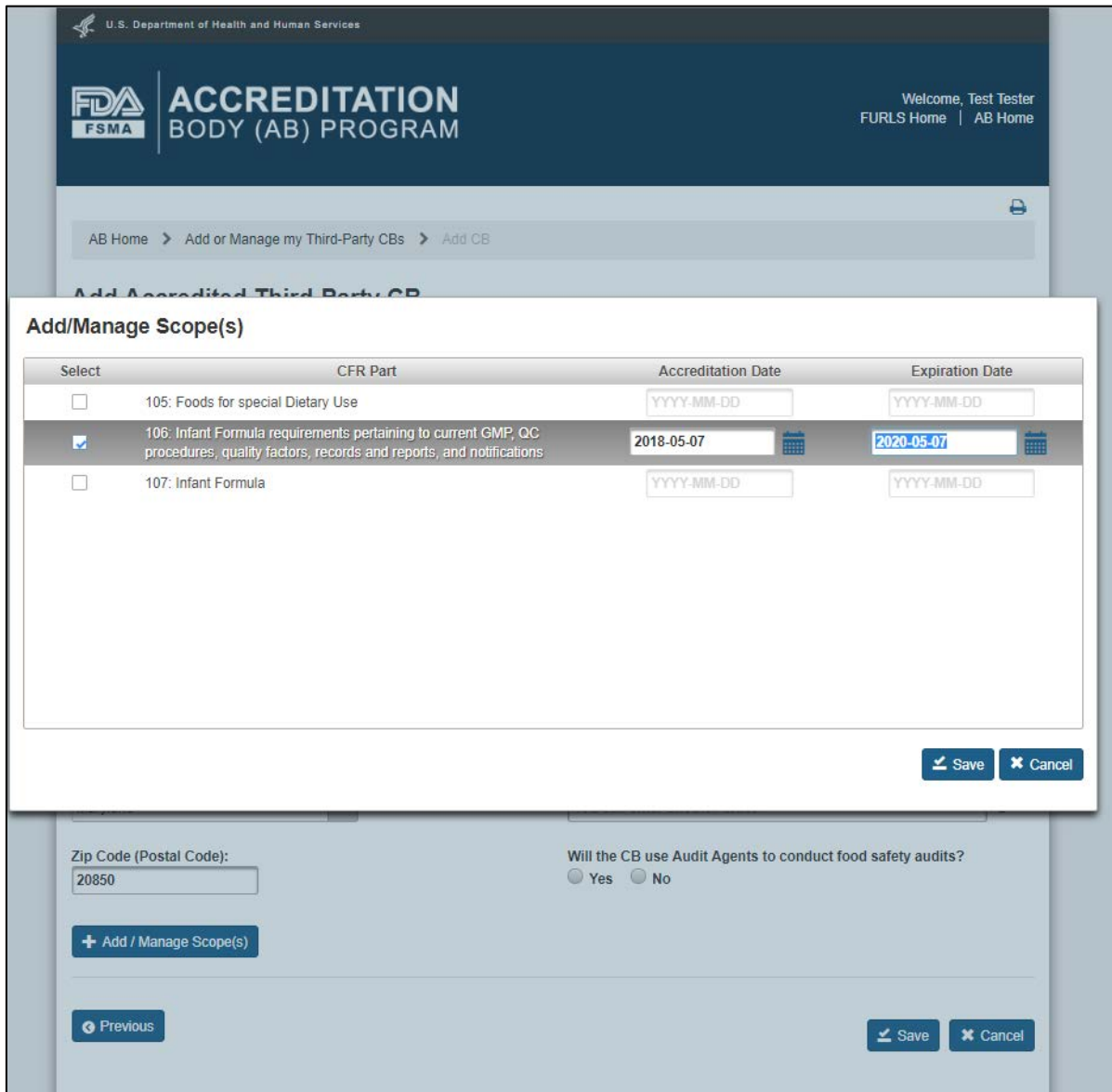
Will the CB use Audit Agents to conduct food safety audits?
 Yes No

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Add or Manage my Third-Party CBs > Add CB

Add Accredited Third-Party CB

Add/Manage Scope(s)

Select	CFR Part	Accreditation Date	Expiration Date
<input type="checkbox"/>	105: Foods for special Dietary Use	YYYY-MM-DD	YYYY-MM-DD
<input checked="" type="checkbox"/>	106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07
<input type="checkbox"/>	107: Infant Formula	YYYY-MM-DD	YYYY-MM-DD

Save Cancel

Zip Code (Postal Code):
20850

Will the CB use Audit Agents to conduct food safety audits?
 Yes No

+ Add / Manage Scope(s)

Previous

Save Cancel

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

U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Add or Manage my Third-Party CBs > Add CB

Add Accredited Third-Party CB

E-mail Address:

Third-Party Certification Body Name:

Country:

Address 1:

Address 2 (Optional):

City:

State/Province/Territory:

Zip Code (Postal Code):

Search CB

Contact Name:

First Name MI (Optional) Last Name

Phone Number:

Country Area Phone Number Extension

Fax Number (Optional):

Country Area Fax Number

Status:
 Accredited

Web Address (Optional):

Officer(s):

Will the CB use Audit Agents to conduct food safety audits?
 Yes No

Scopes of Accredited Third-Party Certification Body

CFR Part	Accreditation Date	Expiration Date
106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07

[+ Add / Manage Scope\(s\)](#)

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

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.

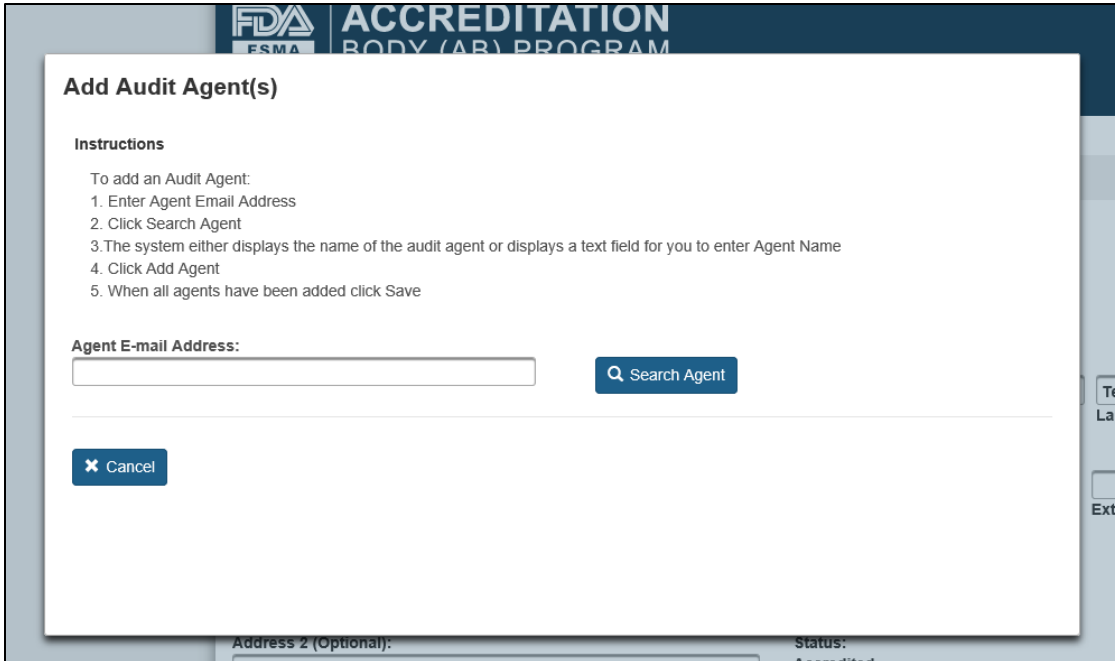
If you select “Yes” the “Add Audit Agent(s)” window displays over the page. Enter an e-mail address and click the “Search Agent” button (Figure 8.1.5).

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



The screenshot shows a web application window titled "Add Audit Agent(s)" with the following content:

- Instructions:**
 - To add an Audit Agent:
 - 1. Enter Agent Email Address
 - 2. Click Search Agent
 - 3. The system either displays the name of the audit agent or displays a text field for you to enter Agent Name
 - 4. Click Add Agent
 - 5. When all agents have been added click Save
- Agent E-mail Address:** A text input field.
- Search Agent:** A blue button with a magnifying glass icon.
- Cancel:** A blue button with a close icon.

At the bottom of the window, there are labels for "Address 2 (Optional):" and "Status: Accredited".

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

ACCREDITATION
BODY (AB) PROGRAM

Add Audit Agent(s)

Instructions

To add an Audit Agent:

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

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

Agent E-mail Address:

Agent Name:

Agent 2 x

Address 2 (Optional):
Status: Accredited

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

ACCREDITATION
BODY (AB) PROGRAM

Add Audit Agent(s)

Instructions

To add an Audit Agent:

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

Agent E-mail Address:

Audit Agent(s)

Agent Name	Email	Action
Agent 2	test2@test.com	<input type="button" value="Delete"/>

Address 2 (Optional):
Status: Accredited

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

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

AB Home > Add or Manage my Third-Party CBs > Add CB

Add Accredited Third-Party CB

E-mail Address:

Third-Party Certification Body Name:

Country:

Address 1:

Address 2 (Optional):

City:

State/Province/Territory:

Zip Code (Postal Code):

Contact Name:

Phone Number:

Fax Number (Optional):

Status:
 Accredited

Web Address (Optional):

Officer(s):

Will the CB use Audit Agents to conduct food safety audits?
 Yes No

Audit Agent(s)

Agent Name	Email	Action
Agent 2	test2@test.com	

[+ Add Agent](#)

Scopes of Accredited Third-Party Certification Body

CFR Part	Accreditation Date	Expiration Date
106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07

[+ Add / Manage Scope\(s\)](#)

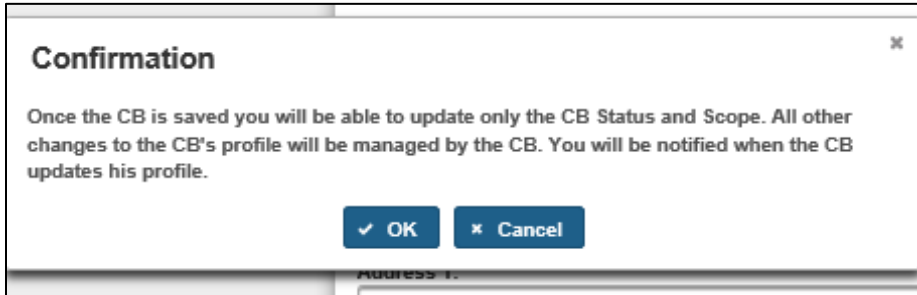
[Previous](#)

[Save](#)

[Cancel](#)

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).

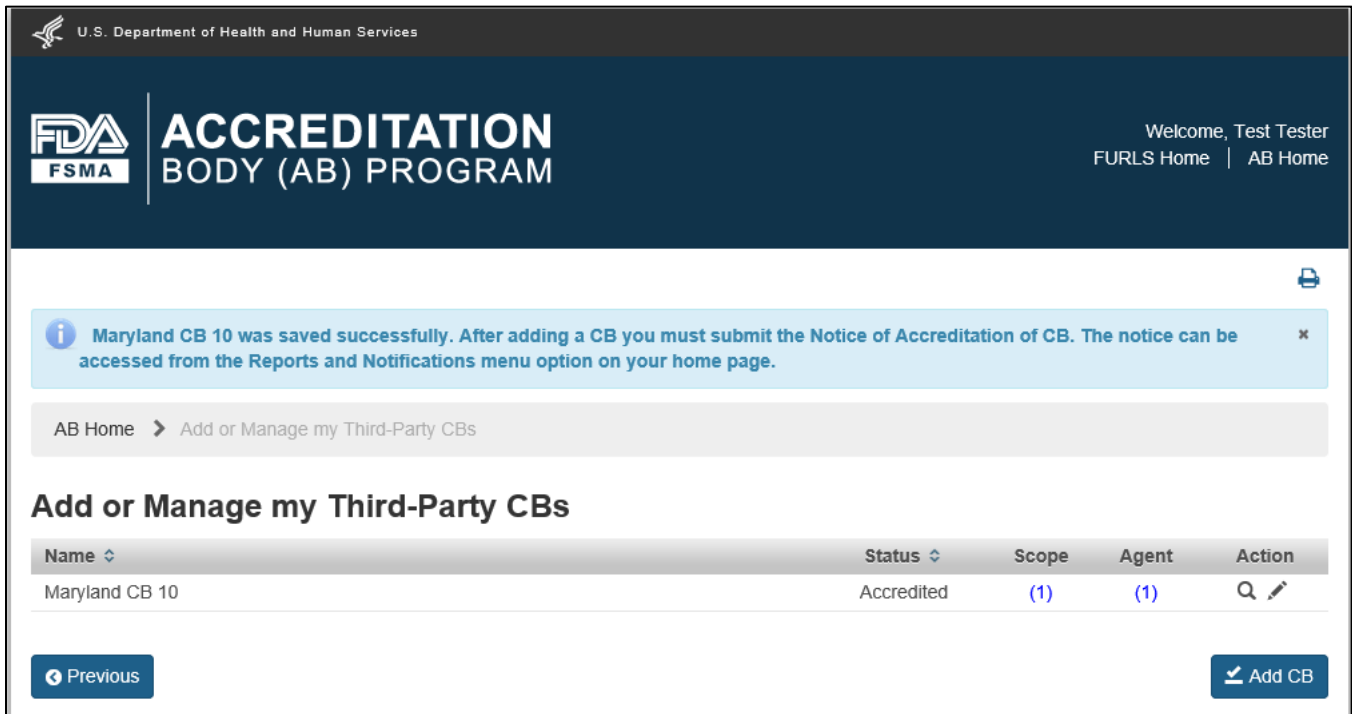
Figure 8.1.9 – Confirmation Message



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



U.S. Department of Health and Human Services



FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

Maryland CB 10 was saved successfully. After adding a CB you must submit the Notice of Accreditation of CB. The notice can be accessed from the Reports and Notifications menu option on your home page.

[AB Home](#) > [Add or Manage my Third-Party CBs](#)

Add or Manage my Third-Party CBs

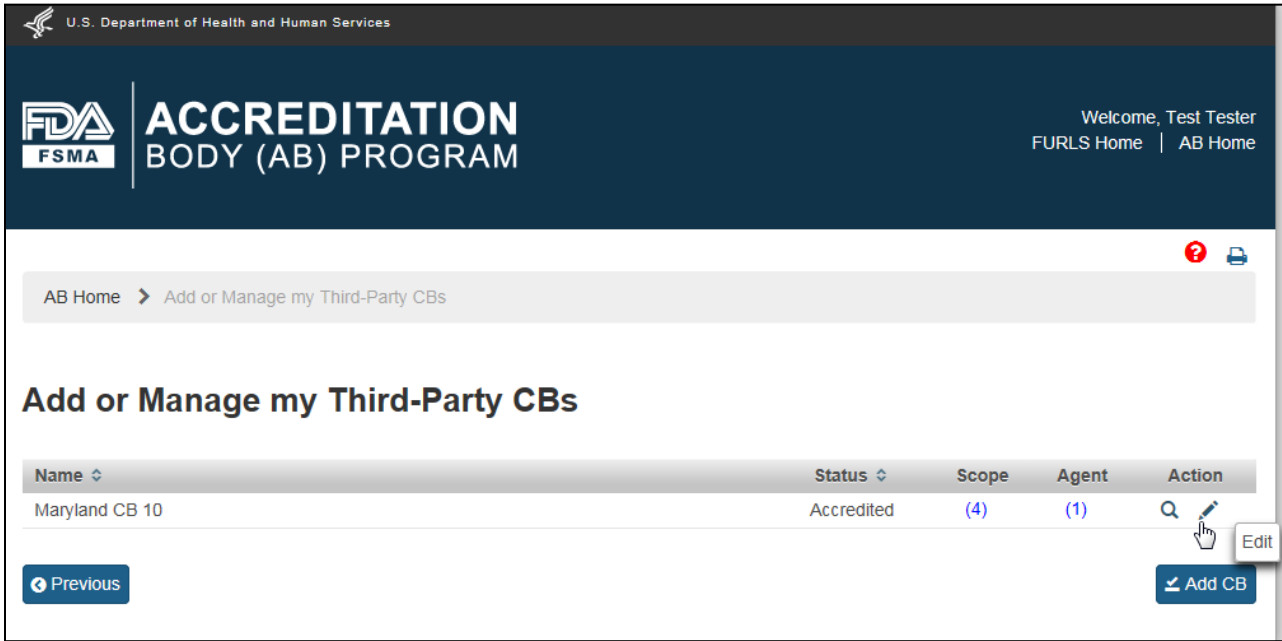
Name	Status	Scope	Agent	Action
Maryland CB 10	Accredited	(1)	(1)	 

[Previous](#) [Add CB](#)

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




U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Add or Manage my Third-Party CBs


Add or Manage my Third-Party CBs

Name ↕	Status ↕	Scope	Agent	Action
Maryland CB 10	Accredited	(4)	(1)	  Edit

[Previous](#) [Add CB](#)

Figure 8.2.2 – Update Accredited Third-Party CB Page

U.S. Department of Health and Human Services



ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester

[FURLS Home](#) | [AB Home](#)

[AB Home](#) > [Add or Manage my Third-Party CBs](#) > [Update Accredited Third-Party CB](#)

Update Accredited Third-Party CB

When you withdraw, suspend or reduce the scope of a CB you must submit the Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB. When you expand the scope of a CB you must submit the Notice of Expansion of Scope of Accredited CB. Both notices can be accessed from the Reports and Notifications menu option on your home page.

<p>Third-Party Certification Body Name Maryland CB 10</p> <p>Address 123 ABC Street ABC Maryland 20901 UNITED STATES</p> <p>Web Address --</p> <p>Status Accredited</p>	<p>Contact Name CB Tester</p> <p>Contact Number Phone Number 1 (555) 5555555 Ext. -- Fax Number --</p> <p>Email user@me.com</p> <p>Effective Date --</p>
--	--

Scope(s)	Accreditation Date	Expiration Date	Status
106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07	Accredited

▶ [Agent\(s\) List](#)

▶ [Officer\(s\) List](#)

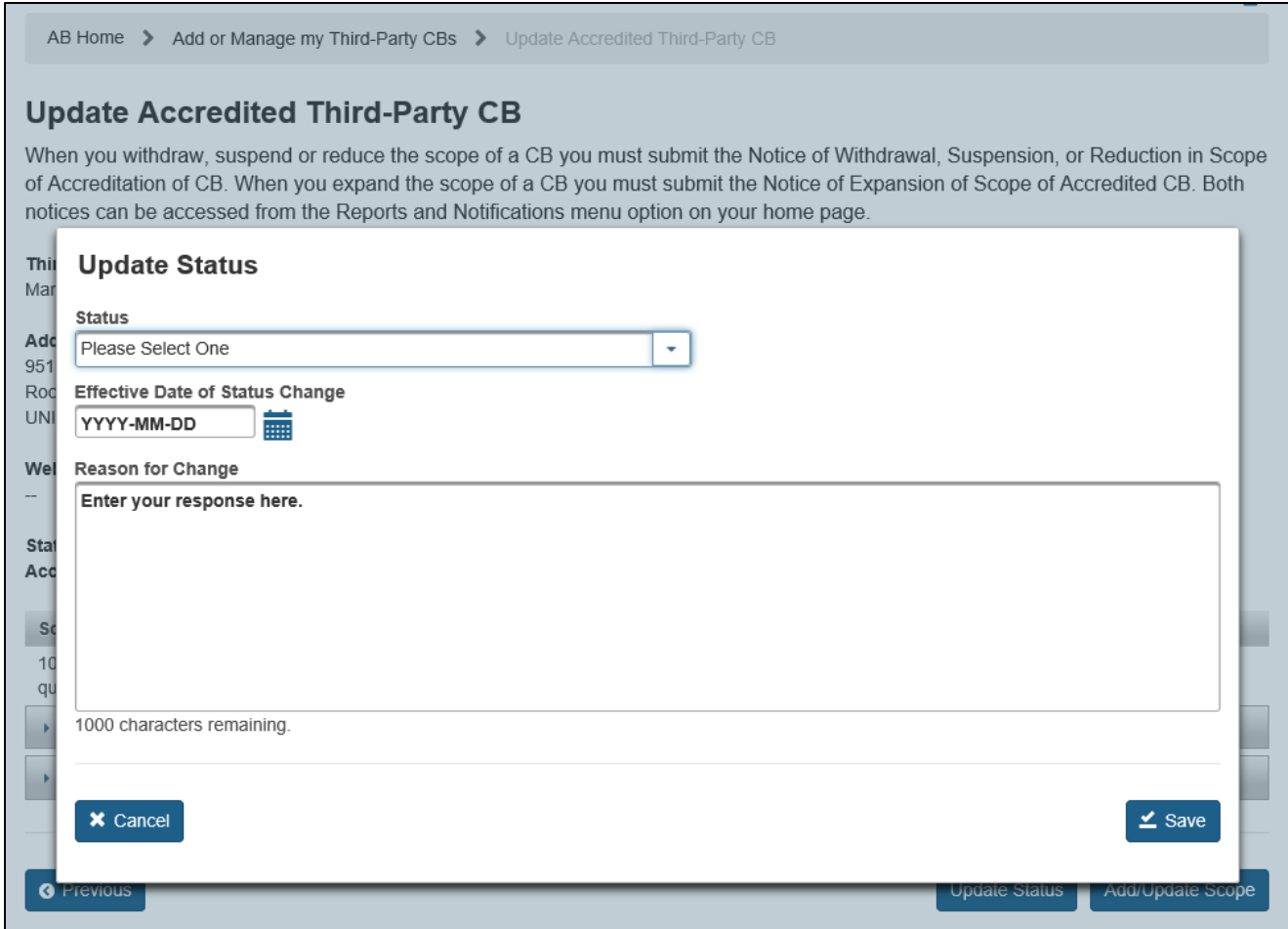
[◀ Previous](#)

[Update Status](#)

[Add/Update Scope](#)

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



AB Home > Add or Manage my Third-Party CBs > Update Accredited Third-Party CB

Update Accredited Third-Party CB

When you withdraw, suspend or reduce the scope of a CB you must submit the Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB. When you expand the scope of a CB you must submit the Notice of Expansion of Scope of Accredited CB. Both notices can be accessed from the Reports and Notifications menu option on your home page.

Update Status

Status
Please Select One

Effective Date of Status Change
YYYY-MM-DD

Reason for Change
Enter your response here.

1000 characters remaining.

Previous

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).

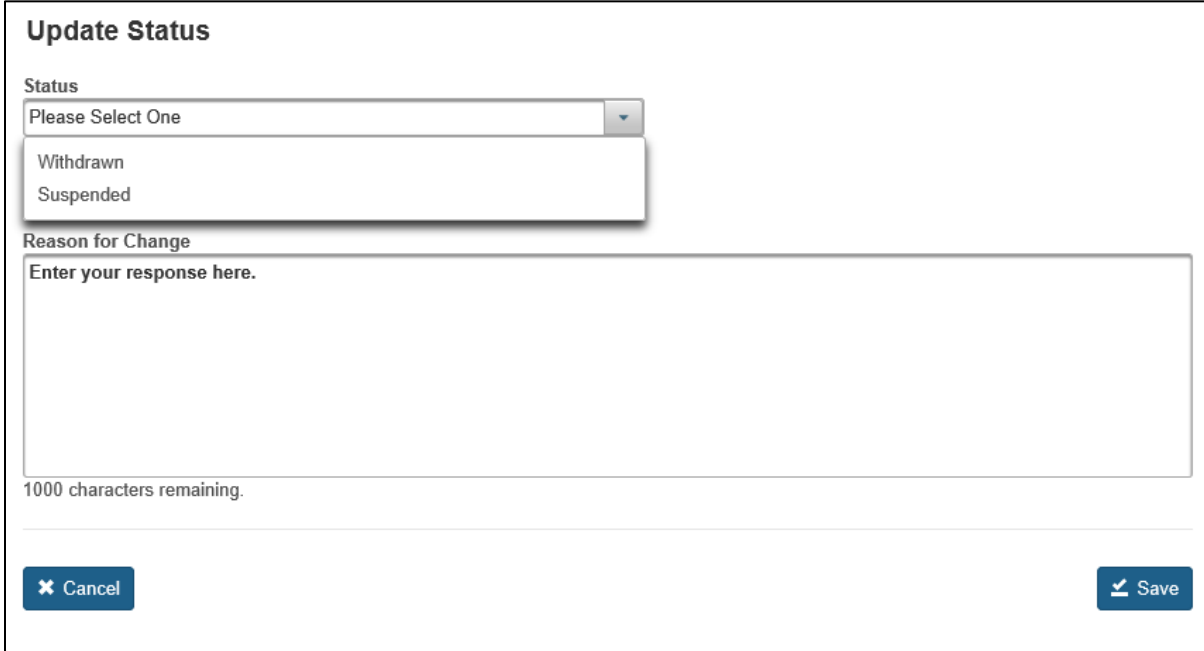
An AB cannot update CB statuses that were updated by the FDA.

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

U.S. Department of Health and Human Services



ACCREDITATION BODY (AB) PROGRAM

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

Third-Party CB Information 🖨️

<p>Third-Party Certification Body Name Maryland CB 10</p> <p>Address 123 ABC Street ABC Maryland 20901 UNITED STATES</p> <p>Web Address --</p> <p>Status Suspended</p> <p>Reason for Status Change Enter reason here</p>	<p>Contact Name CB Tester</p> <p>Contact Number Phone Number 1 (555) 5555555 Ext. -- Fax Number --</p> <p>Email user@me.com</p> <p>Effective Date 2018-05-09</p>
--	--

Scope(s)	Accreditation Date	Expiration Date	Status
106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07	Accredited

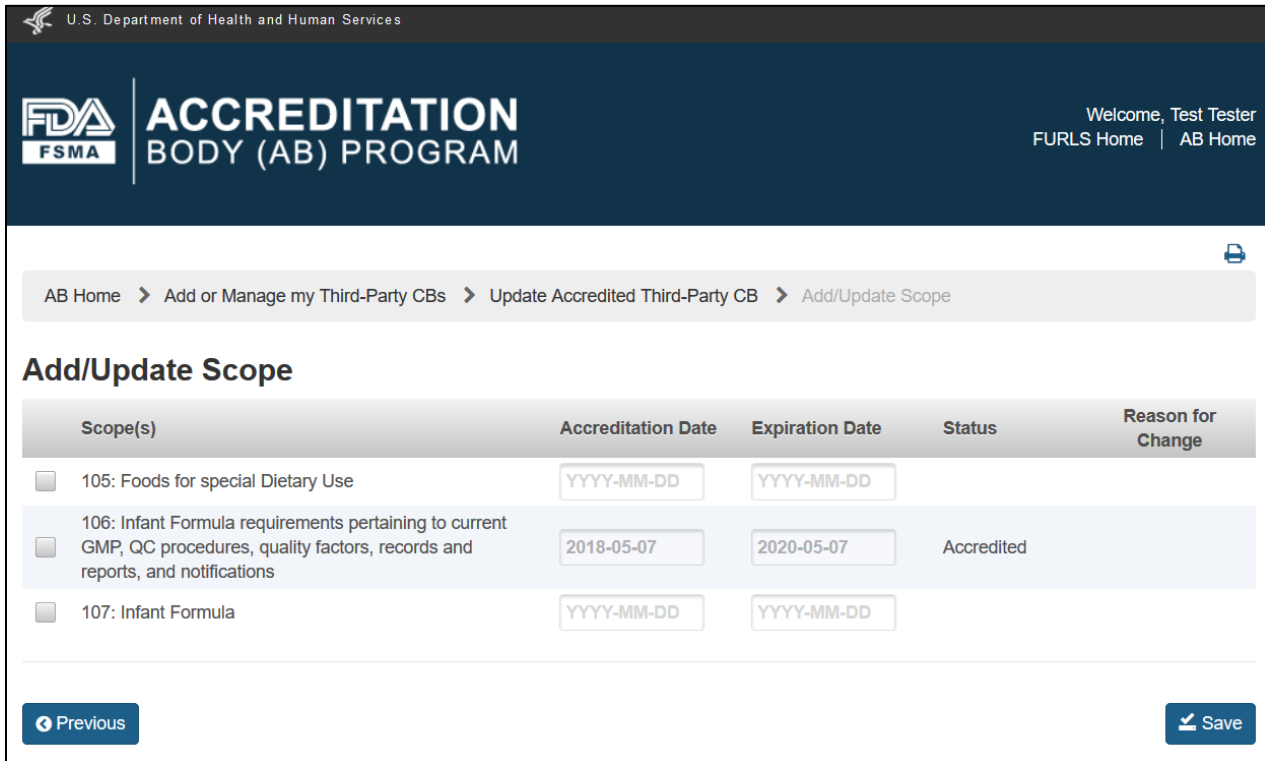
▶ Agent(s) List

▶ Officer(s) List

[◀ Previous](#)

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Add or Manage my Third-Party CBs > Update Accredited Third-Party CB > Add/Update Scope

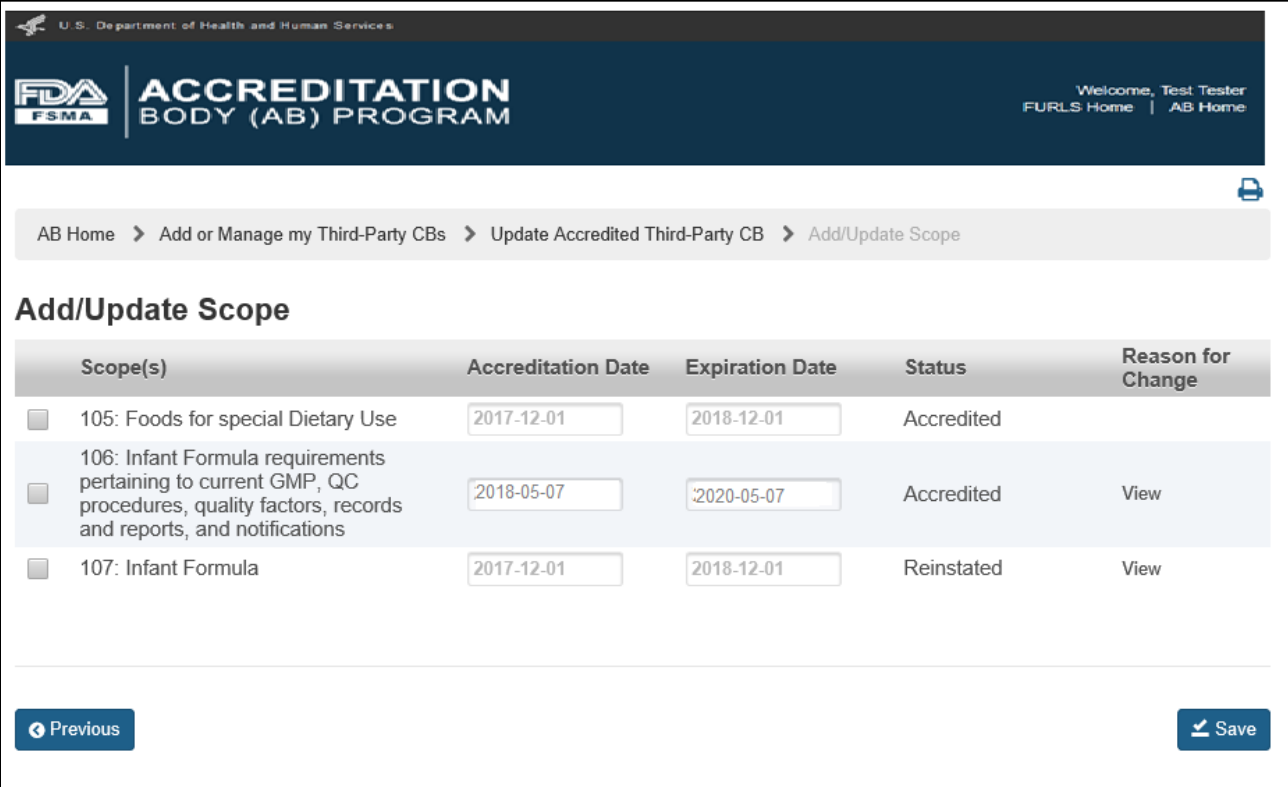
Add/Update Scope

Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> 105: Foods for special Dietary Use	YYYY-MM-DD	YYYY-MM-DD		
<input type="checkbox"/> 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07	Accredited	
<input type="checkbox"/> 107: Infant Formula	YYYY-MM-DD	YYYY-MM-DD		

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

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Add or Manage my Third-Party CBs > Update Accredited Third-Party CB > Add/Update Scope

Add/Update Scope

Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> 105: Foods for special Dietary Use	2017-12-01	2018-12-01	Accredited	
<input type="checkbox"/> 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07	Accredited	View
<input type="checkbox"/> 107: Infant Formula	2017-12-01	2018-12-01	Reinstated	View

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

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.

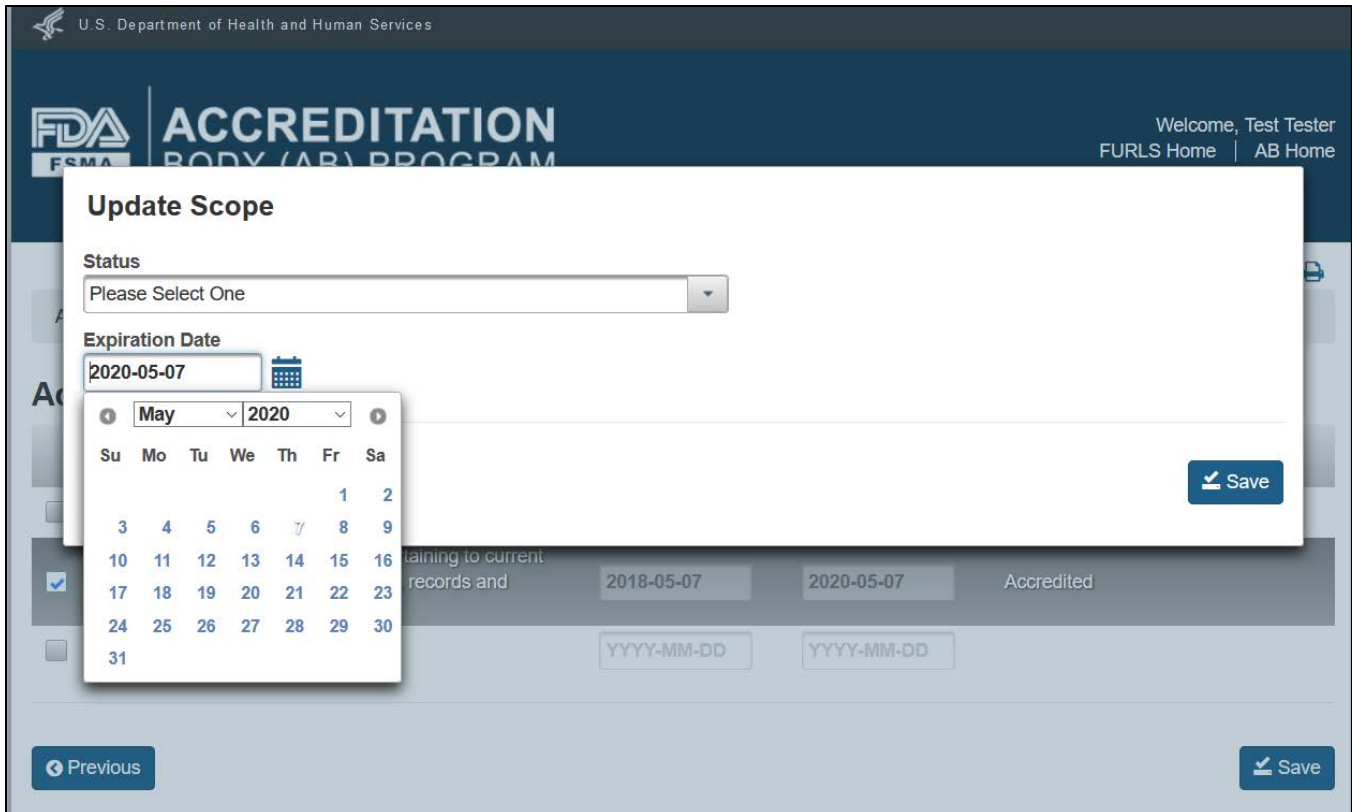
The following data fields are present:

- **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

U.S. Department of Health and Human Services

FDA ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

Update Scope

Status: Suspended

Effective Date: 2018-05-08

Expiration Date: 2020-05-07

Reason for Change: This field will appear if you select a value from 'Status' column

935 characters remaining.

Cancel Save


Previous Save

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



i Changes saved successfully. ×

AB Home > Add or Manage my Third-Party CBs > Update Accredited Third-Party CB > Add/Update Scope

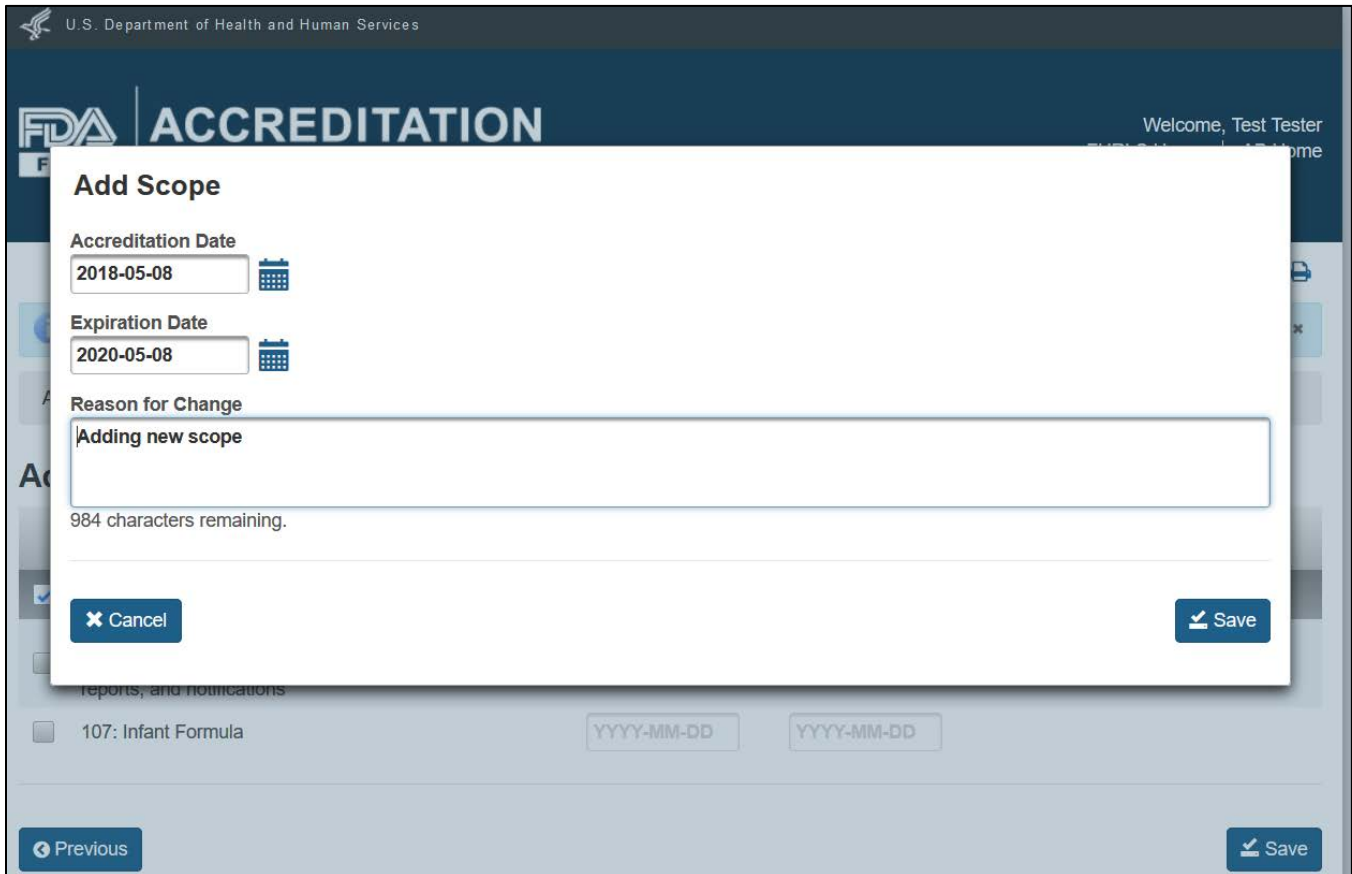
Add/Update Scope

Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> 105: Foods for special Dietary Use	<input type="text" value="2017-12-01"/>	<input type="text" value="2018-12-01"/>	Accredited	
<input type="checkbox"/> 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	<input type="text" value="2018-05-08"/>	<input type="text" value="2020-05-07"/>	Suspended	View
<input type="checkbox"/> 107: Infant Formula	<input type="text" value="2017-12-01"/>	<input type="text" value="2018-12-01"/>	Reinstated	View

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.

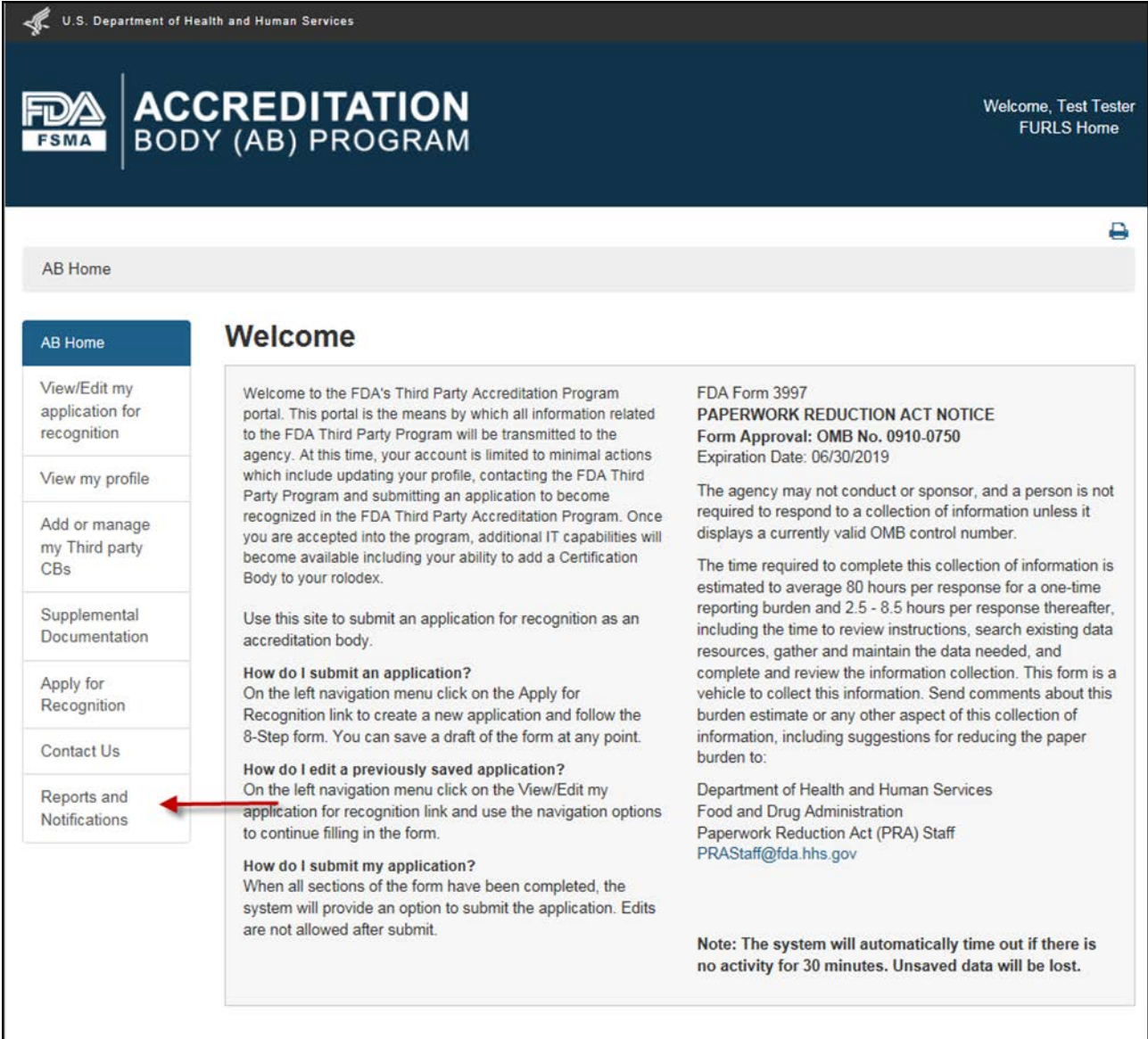
Click “Save.”

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

Welcome, Test Tester
FURLS Home

AB Home

AB Home

- View/Edit my application for recognition
- View my profile
- Add or manage my Third party CBs
- Supplemental Documentation
- Apply for Recognition
- Contact Us
- Reports and Notifications**

Welcome

Welcome to the FDA's Third Party Accreditation Program portal. This portal is the means by which all information related to the FDA Third Party Program will be transmitted to the agency. At this time, your account is limited to minimal actions which include updating your profile, contacting the FDA Third Party Program and submitting an application to become recognized in the FDA Third Party Accreditation Program. Once you are accepted into the program, additional IT capabilities will become available including your ability to add a Certification Body to your rolodex.

Use this site to submit an application for recognition as an accreditation body.

How do I submit an application?
On the left navigation menu click on the Apply for Recognition link to create a new application and follow the 8-Step form. You can save a draft of the form at any point.

How do I edit a previously saved application?
On the left navigation menu click on the View/Edit my application for recognition link and use the navigation options to continue filling in the form.

How do I submit my application?
When all sections of the form have been completed, the system will provide an option to submit the application. Edits are not allowed after submit.

FDA Form 3997
PAPERWORK REDUCTION ACT NOTICE
Form Approval: OMB No. 0910-0750
Expiration Date: 06/30/2019

The agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The time required to complete this collection of information is estimated to average 80 hours per response for a one-time reporting burden and 2.5 - 8.5 hours per response thereafter, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. This form is a vehicle to collect this information. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

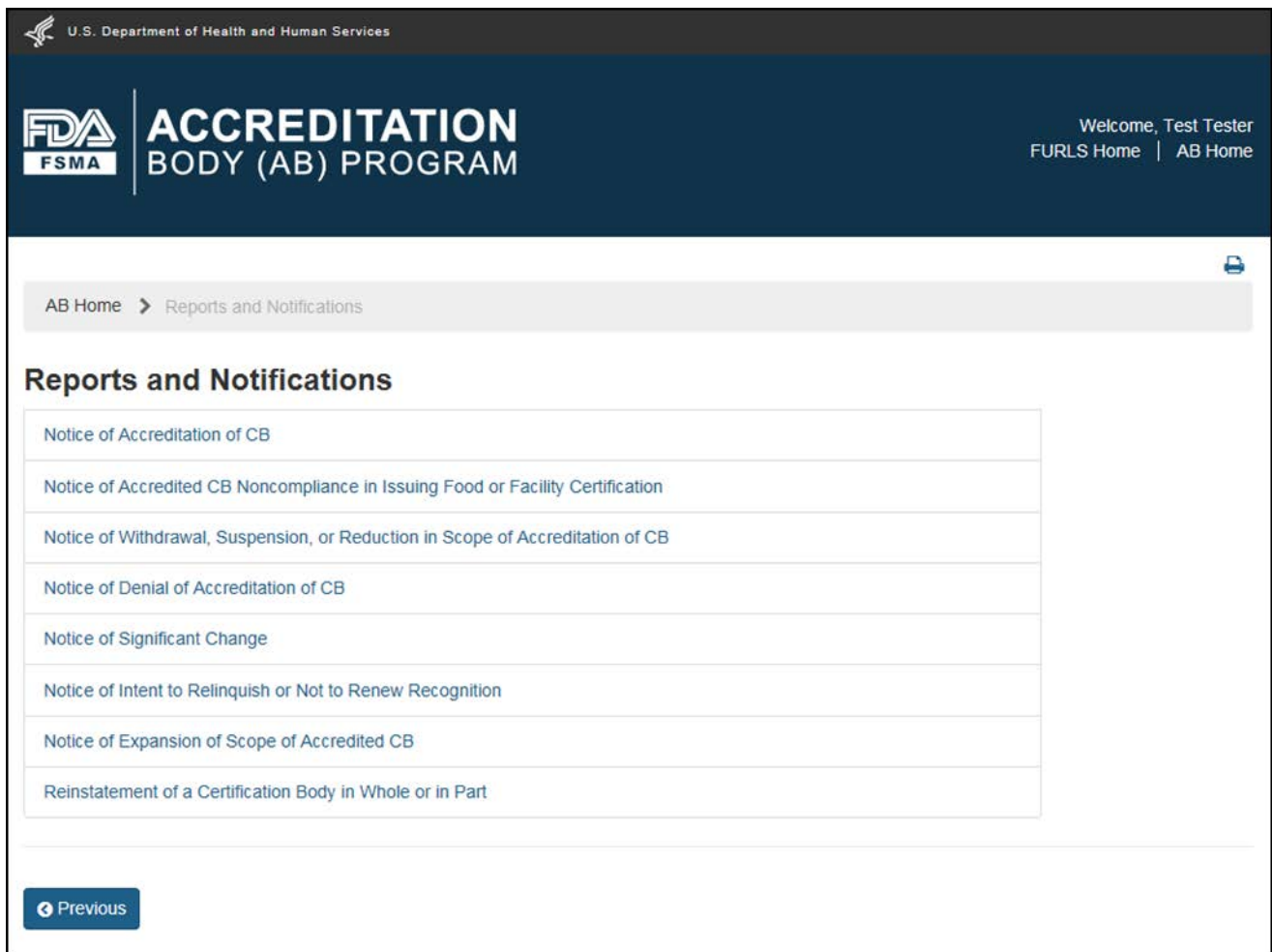
Department of Health and Human Services
Food and Drug Administration
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

Note: The system will automatically time out if there is no activity for 30 minutes. Unsaved data will be lost.

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



The screenshot shows the 'Reports and Notifications' page of the FDA Accreditation Body (AB) Program. The page features a dark blue header with the FDA FSMA logo and the text 'ACCREDITATION BODY (AB) PROGRAM'. A user greeting 'Welcome, Test Tester' and links for 'FURLS Home' and 'AB Home' are visible in the top right. A breadcrumb trail below the header shows 'AB Home > Reports and Notifications'. The main content area is titled 'Reports and Notifications' and contains a list of eight notification types, each in a separate row with a light blue background and a right-pointing arrow:

- Notice of Accreditation of CB
- Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
- Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
- Notice of Denial of Accreditation of CB
- Notice of Significant Change
- Notice of Intent to Relinquish or Not to Renew Recognition
- Notice of Expansion of Scope of Accredited CB
- Reinstatement of a Certification Body in Whole or in Part

At the bottom left of the page, there is a blue button with a left-pointing arrow and the text 'Previous'.

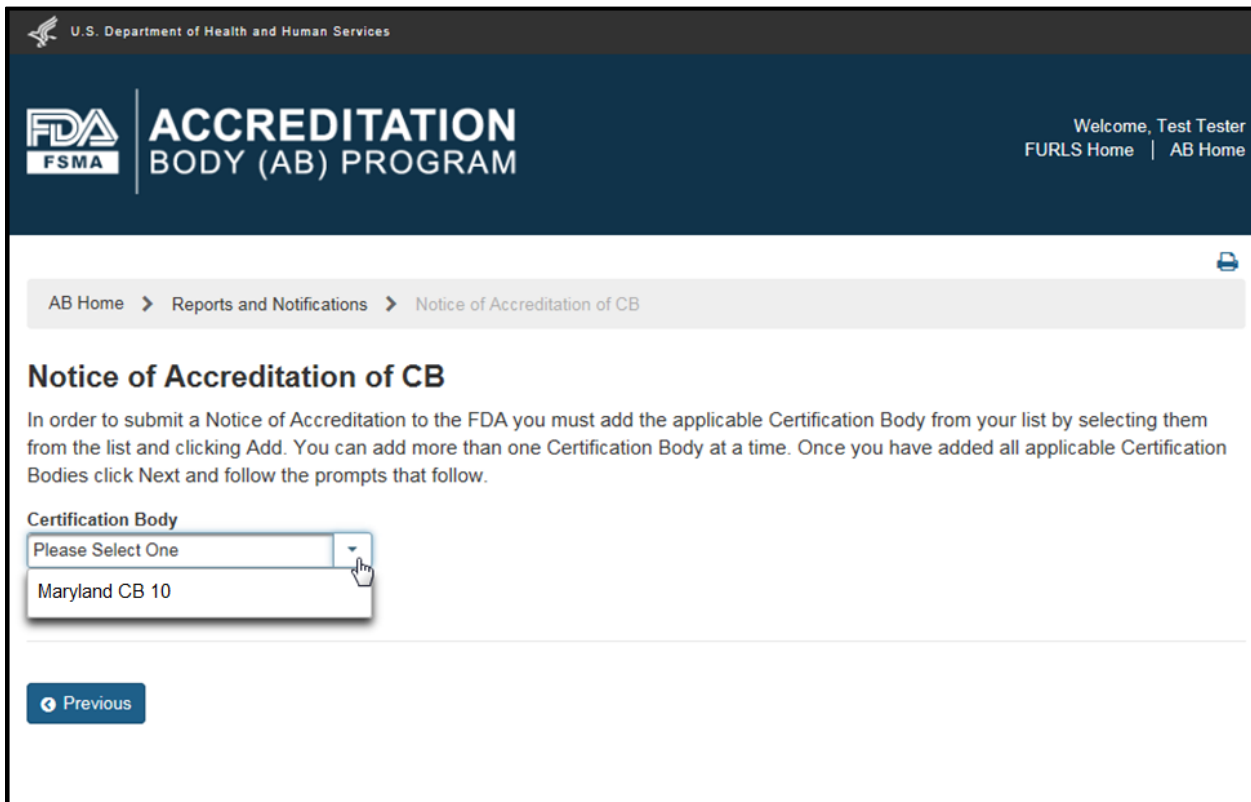
9.1 Notice of Accreditation of CB

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

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Reports and Notifications > Notice of Accreditation of CB

Notice of Accreditation of CB

In order to submit a Notice of Accreditation to the FDA you must add the applicable Certification Body from your list by selecting them from the list and clicking Add. You can add more than one Certification Body at a time. Once you have added all applicable Certification Bodies click Next and follow the prompts that follow.

Certification Body
 Maryland CB 10

Address
 123 ABC Street
 ABC Maryland 20901

Contact Number
 Telephone Number 1 (555) 5555555 Ext. --
 Fax Number --

Web Address
 --

Email
 user@me.com

Officer(s)
 Test Officer

Agent(s)

Agent Name	Email Address
Agent 2	test2@test.com

Scope of Accreditation

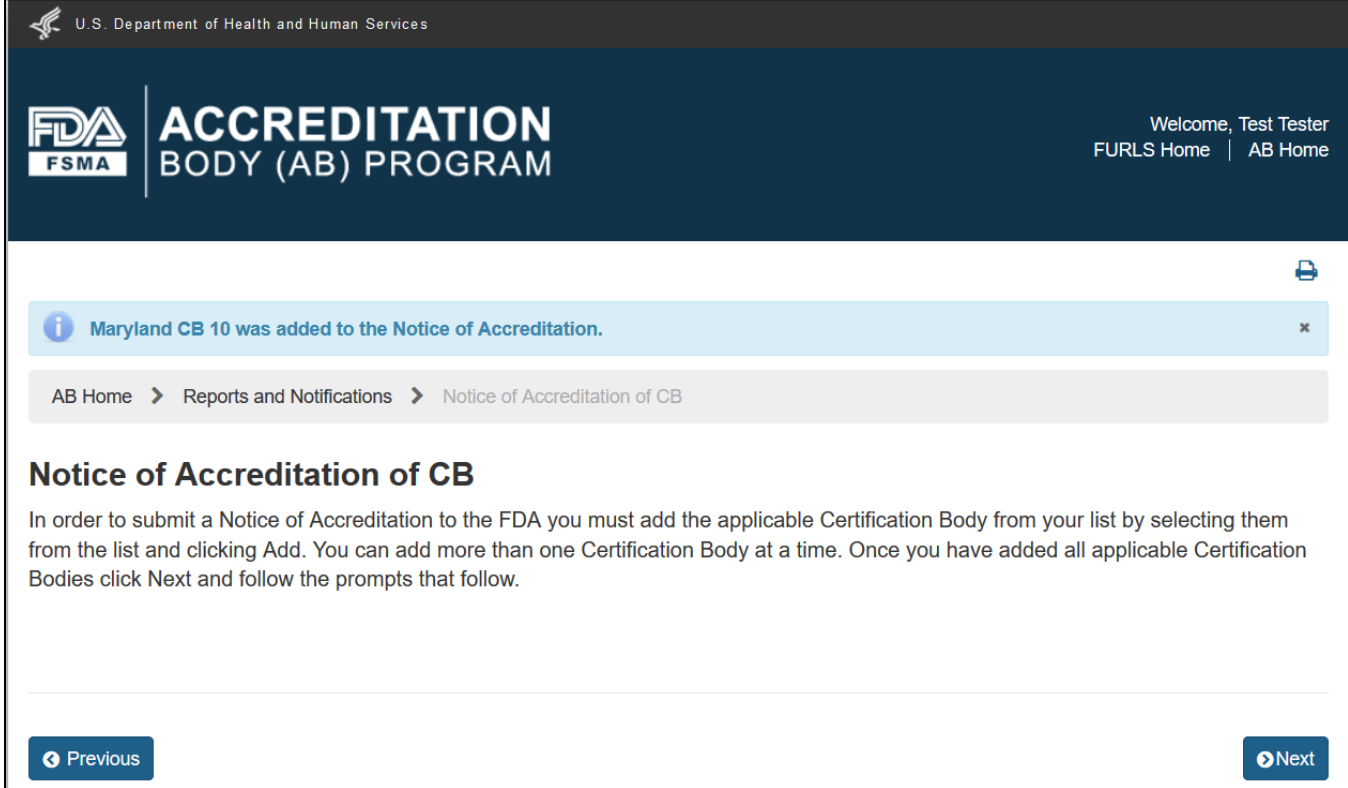
Scope(s)	Accreditation Date	Expiration Date
105: Foods for special Dietary Use	2018-05-08	2020-05-08
106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-05-07	2020-05-07

[+ Add](#)

[Previous](#)

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



U.S. Department of Health and Human Services

FDA FSMA | **ACCREDITATION BODY (AB) PROGRAM**

Welcome, Test Tester
FURLS Home | AB Home

Maryland CB 10 was added to the Notice of Accreditation.

AB Home > Reports and Notifications > Notice of Accreditation of CB

Notice of Accreditation of CB

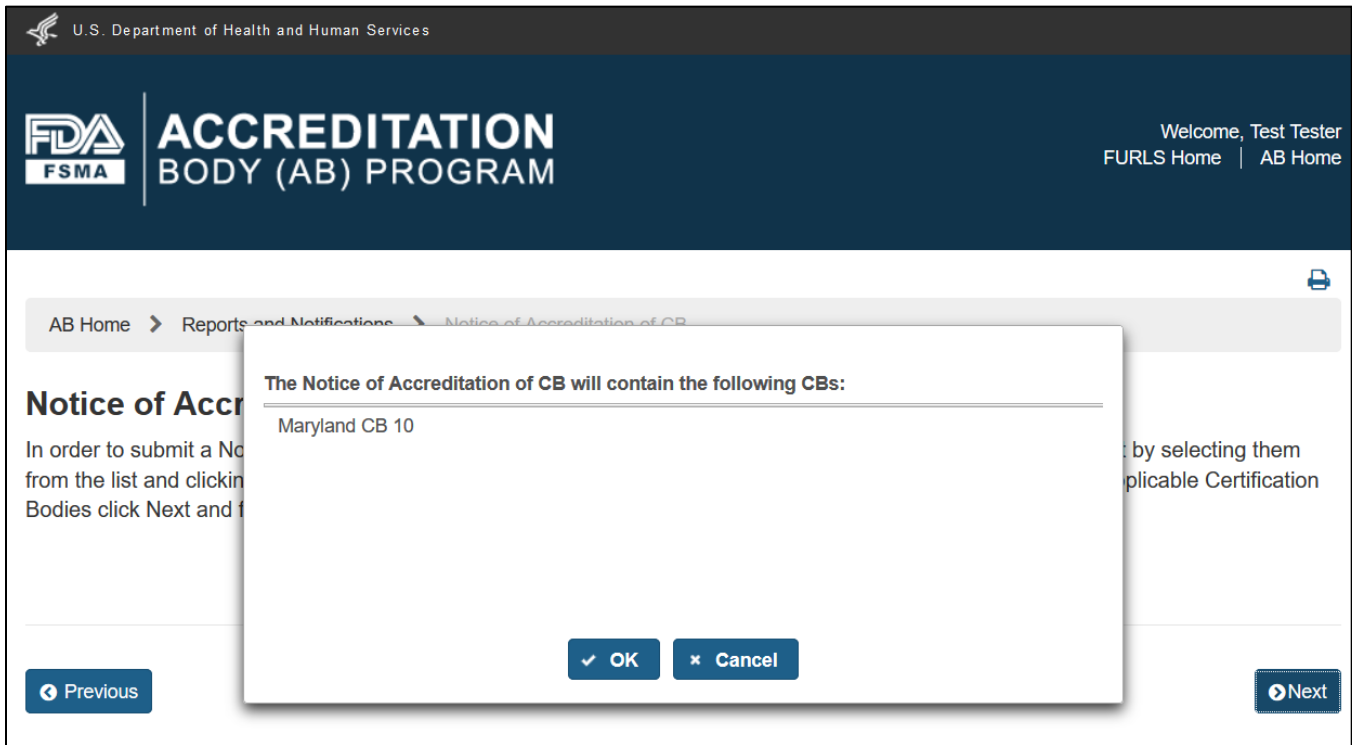
In order to submit a Notice of Accreditation to the FDA you must add the applicable Certification Body from your list by selecting them from the list and clicking Add. You can add more than one Certification Body at a time. Once you have added all applicable Certification Bodies click Next and follow the prompts that follow.

Previous Next

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

U.S. Department of Health and Human Services

 **ACCREDITATION
BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#) > [Notice of Accreditation of CB](#) > [e-Signature](#)

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter

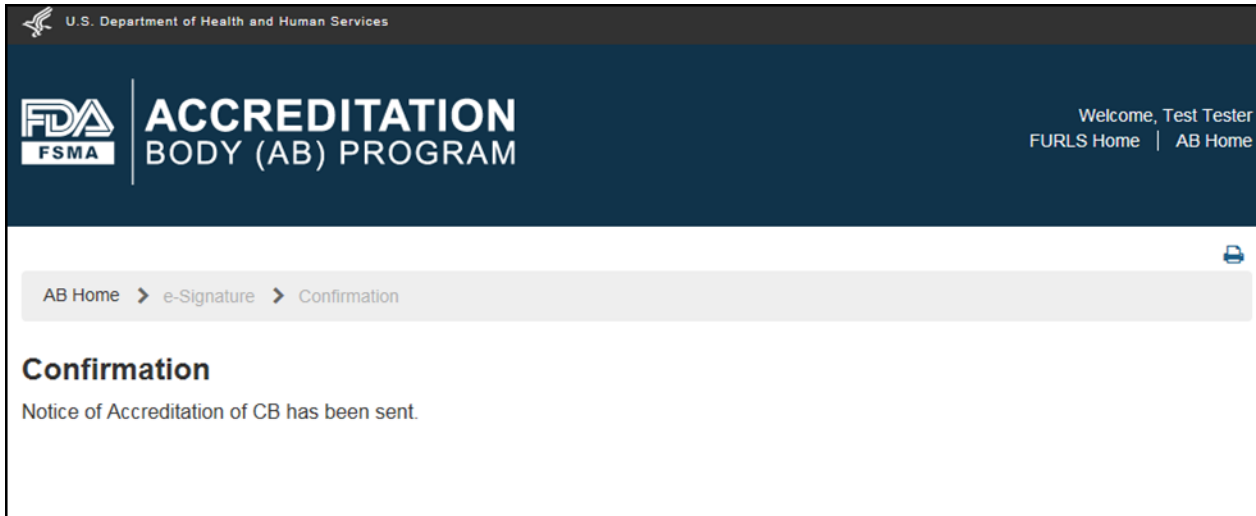
Title of Submitter

Date
2018-05-10

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

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).

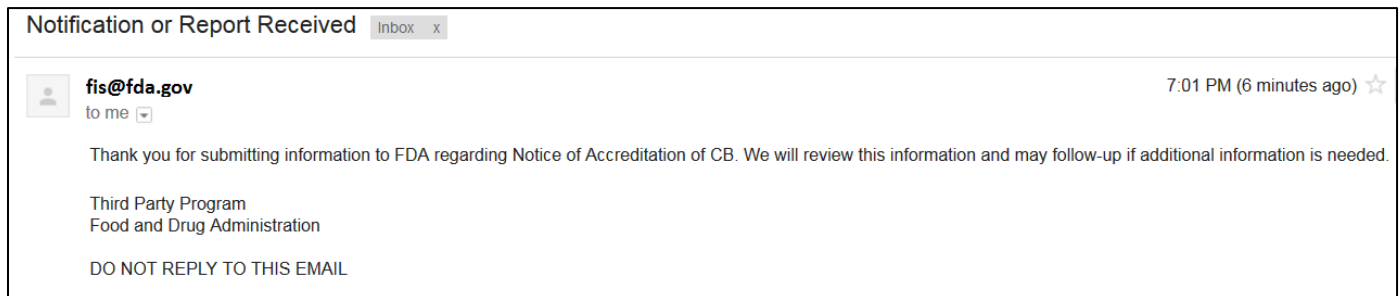
Figure 9.1.6 – Confirmation Message Page



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

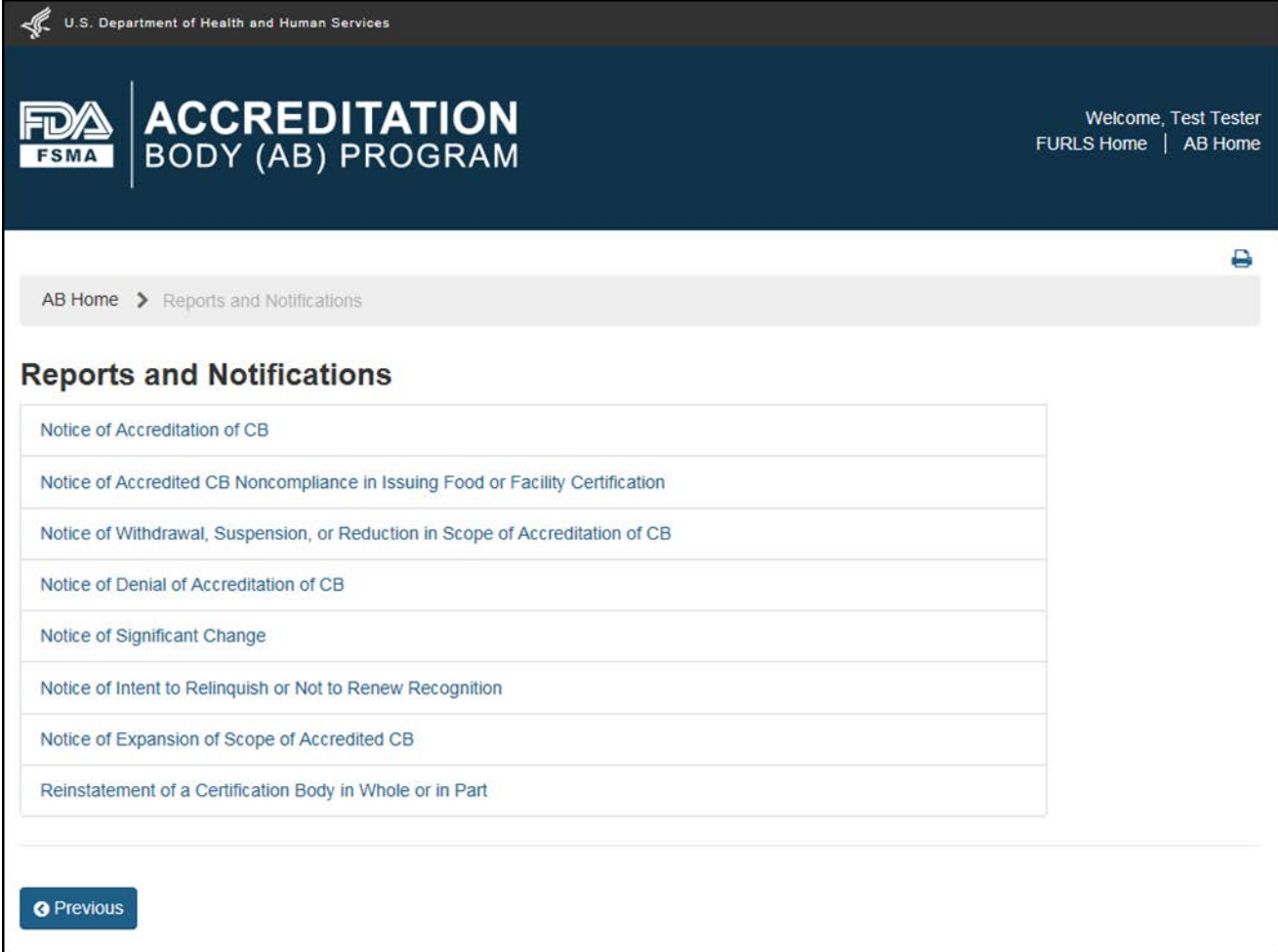
home page. This will complete the accreditation notification to the FDA.

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



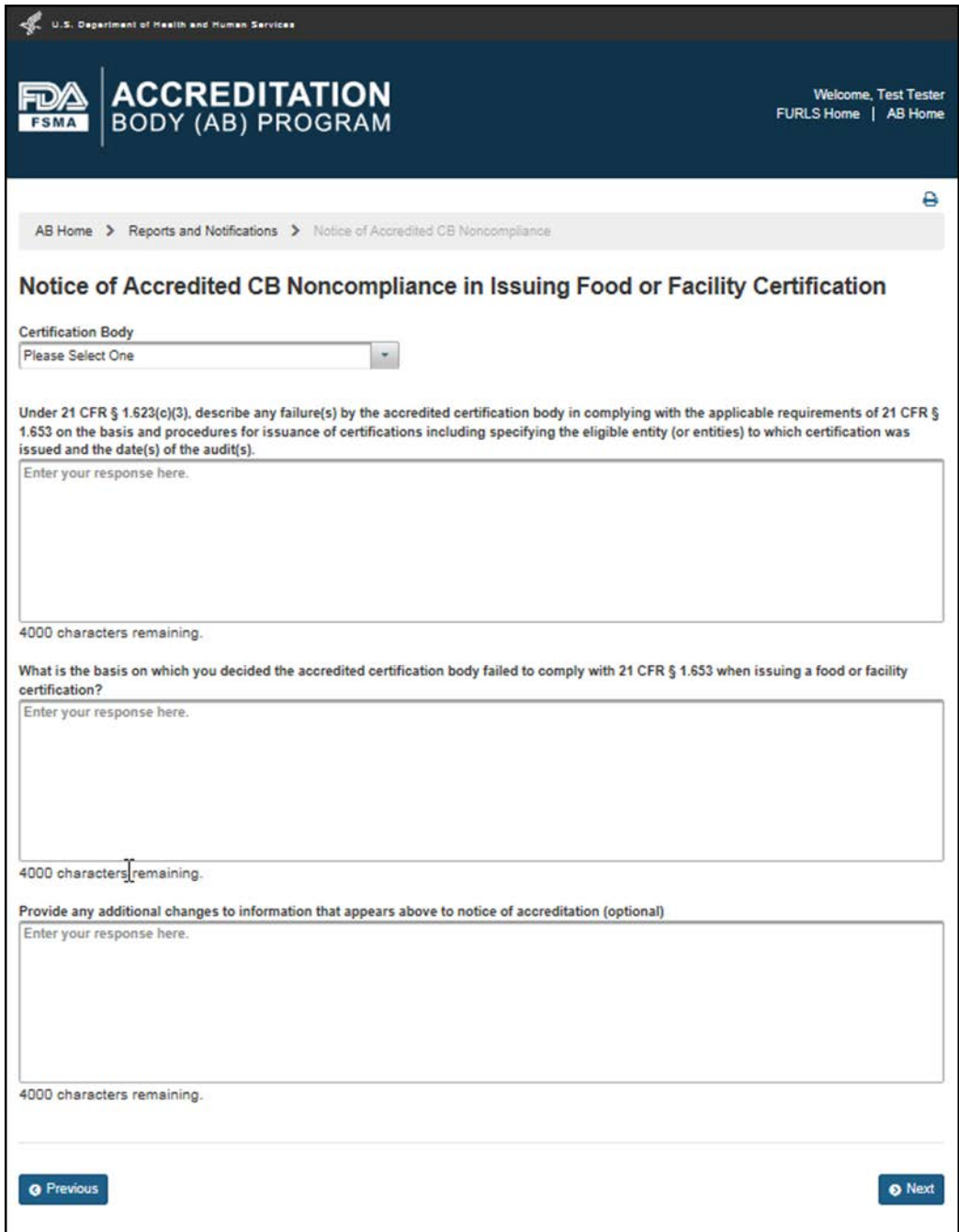
The screenshot shows the 'Reports and Notifications' page of the FDA Accreditation Body (AB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'ACCREDITATION BODY (AB) PROGRAM'. A user greeting 'Welcome, Test Tester' and links for 'FURLS Home' and 'AB Home' are visible in the top right. A breadcrumb trail shows 'AB Home > Reports and Notifications'. The main content area is titled 'Reports and Notifications' and contains a list of eight notification types, each in a separate row:

- Notice of Accreditation of CB
- Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
- Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
- Notice of Denial of Accreditation of CB
- Notice of Significant Change
- Notice of Intent to Relinquish or Not to Renew Recognition
- Notice of Expansion of Scope of Accredited CB
- Reinstatement of a Certification Body in Whole or in Part

A 'Previous' button is located at the bottom left of the 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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

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

Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

Certification Body
Please Select One

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).

Enter your response here.

4000 characters remaining.

What is the basis on which you decided the accredited certification body failed to comply with 21 CFR § 1.653 when issuing a food or facility certification?

Enter your response here.

4000 characters remaining.

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

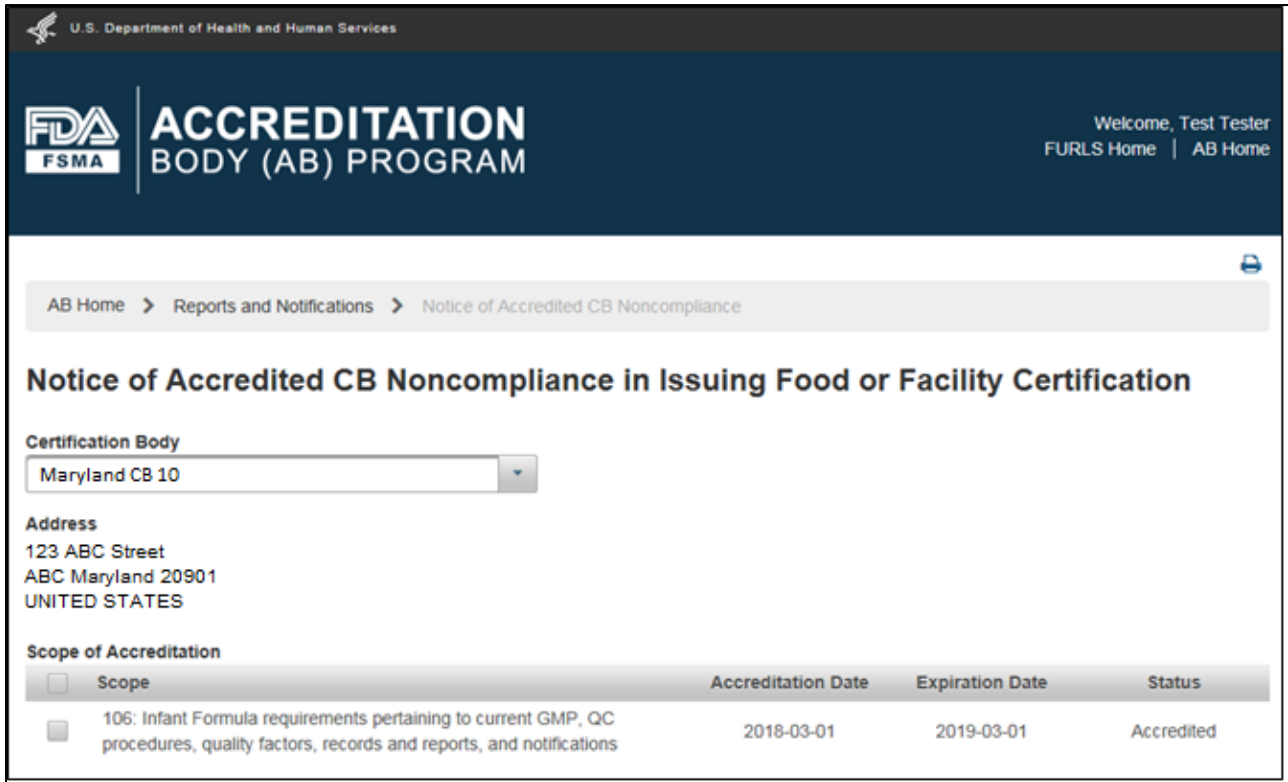
Enter your response here.

4000 characters remaining.

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

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

AB Home > Reports and Notifications > Notice of Accredited CB Noncompliance

Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

Certification Body
 Maryland CB 10

Address
 123 ABC Street
 ABC Maryland 20901
 UNITED STATES

Scope of Accreditation

<input type="checkbox"/> Scope	Accreditation Date	Expiration Date	Status
<input checked="" type="checkbox"/> 106: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2018-03-01	2019-03-01	Accredited

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

Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

Certification Body
 Maryland CB 10

Address
 123 ABC Street
 ABC Maryland 20901
 UNITED STATES

Scope of Accreditation 

<input checked="" type="checkbox"/> Scope	Accreditation Date	Expiration Date	Status
<input checked="" type="checkbox"/> 117: cGMPs, Hazard Analysis and Risk Based Preventive Controls for Human Food	2018-03-22	2019-03-01	Accredited
<input checked="" type="checkbox"/> 118: Production, storage, and transportation of shell eggs	2018-03-22	2019-03-01	Accredited
<input checked="" type="checkbox"/> 119: Dietary supplements that present a significant or unreasonable risk	2018-03-22	2020-03-01	Accredited
<input checked="" type="checkbox"/> 120: HACCP	2018-03-22	2020-03-01	Reinstated

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).

This is the explanation.

3976 characters remaining.

What is the basis on which you decided the accredited certification body failed to comply with 21 CFR § 1.653 when issuing a food or facility certification?


This is the basis of the decision.

3986 characters remaining.

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

Enter your response here.

4000 characters remaining.

Select Applicable Item(s) 

Select one	Certification Number	Certification Issued To	Address	Type of Certification
<input checked="" type="checkbox"/>	TTT-UUU-18-000001		Itasca IL	Facility

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.

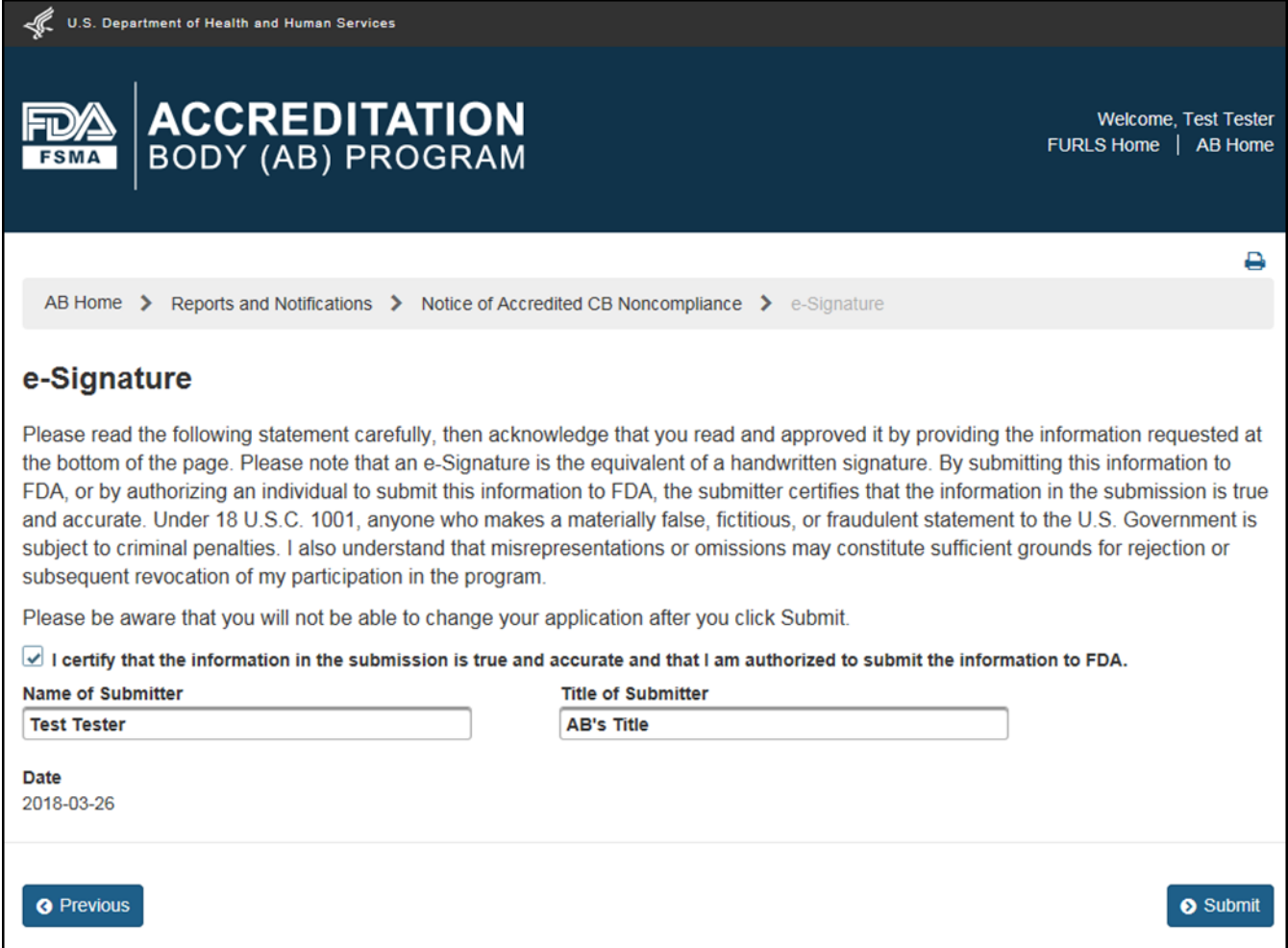
Click the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#) > [Notice of Accredited CB Noncompliance](#) > [e-Signature](#)

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter

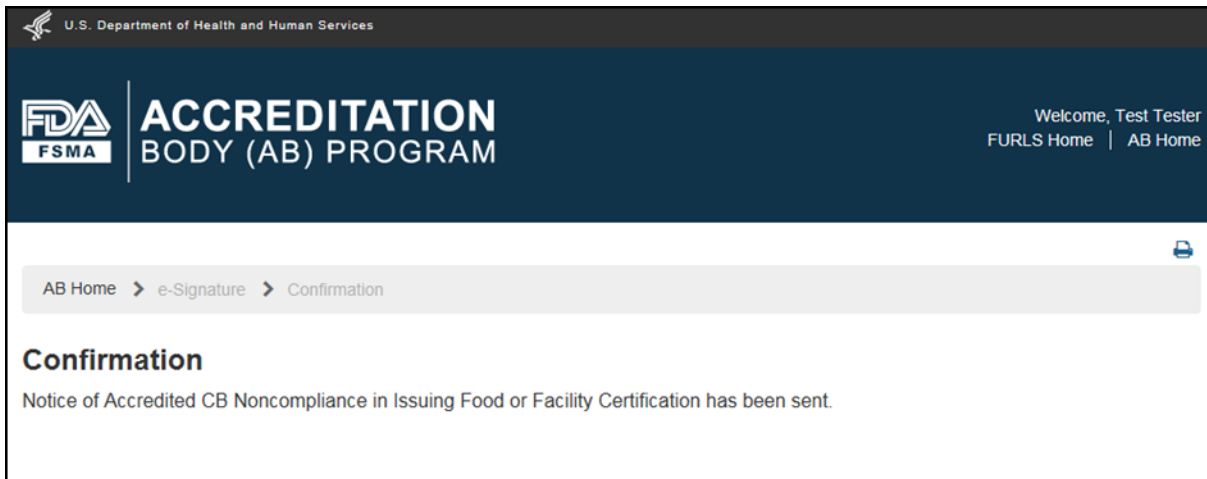
Title of Submitter

Date
2018-03-26

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

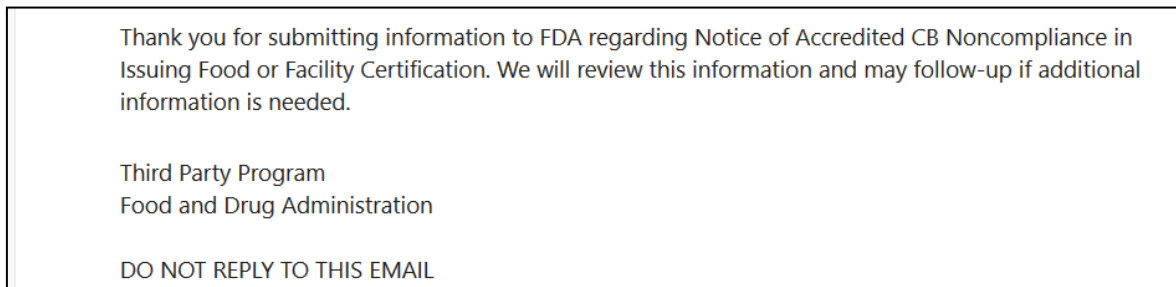
After you click the “Submit” button the system will display the confirmation message (Figure 9.2.6).

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

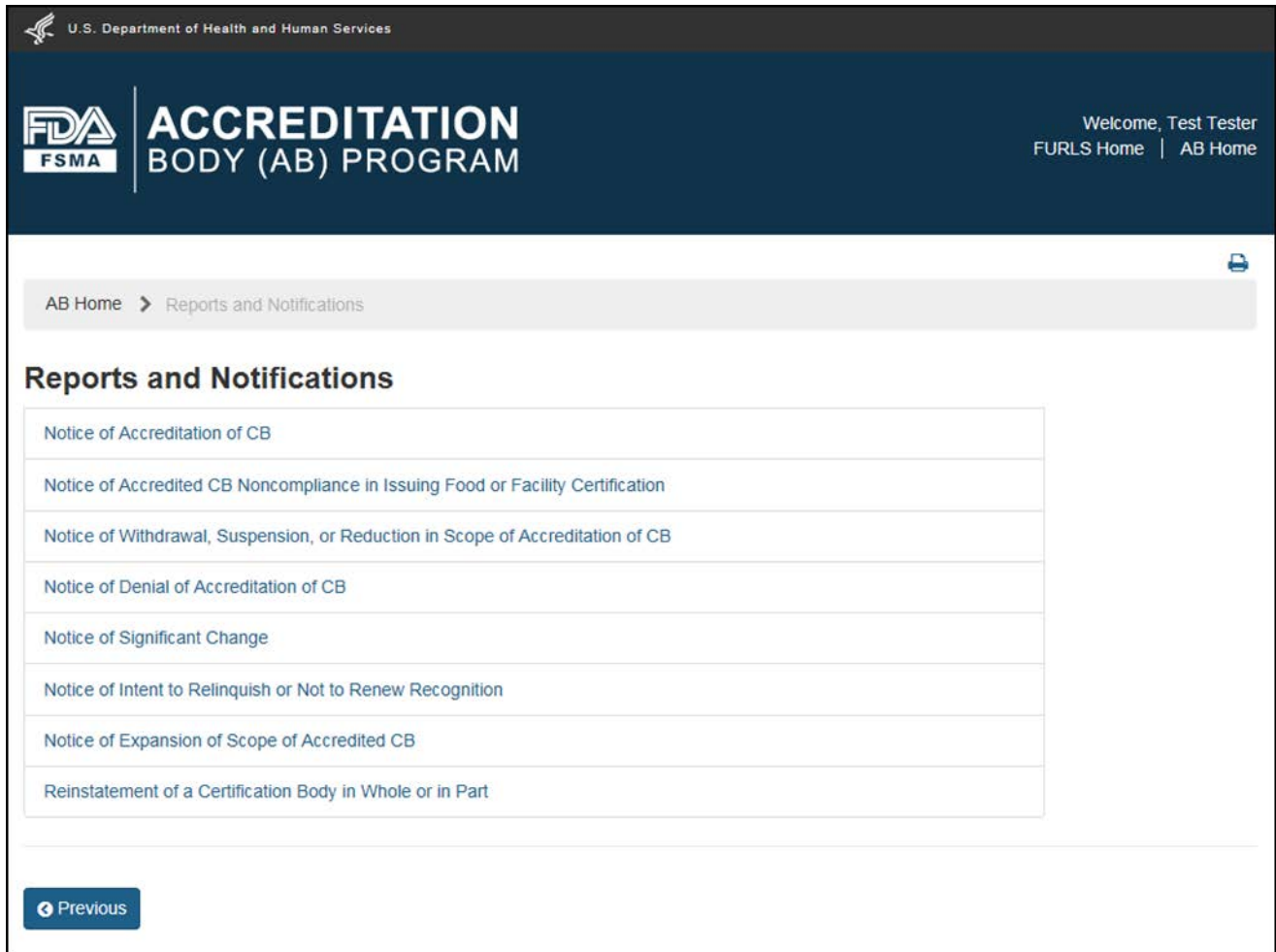


Return to the “Reports and Notifications” page by clicking on the “AB Home” link on the top of the banner.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#)

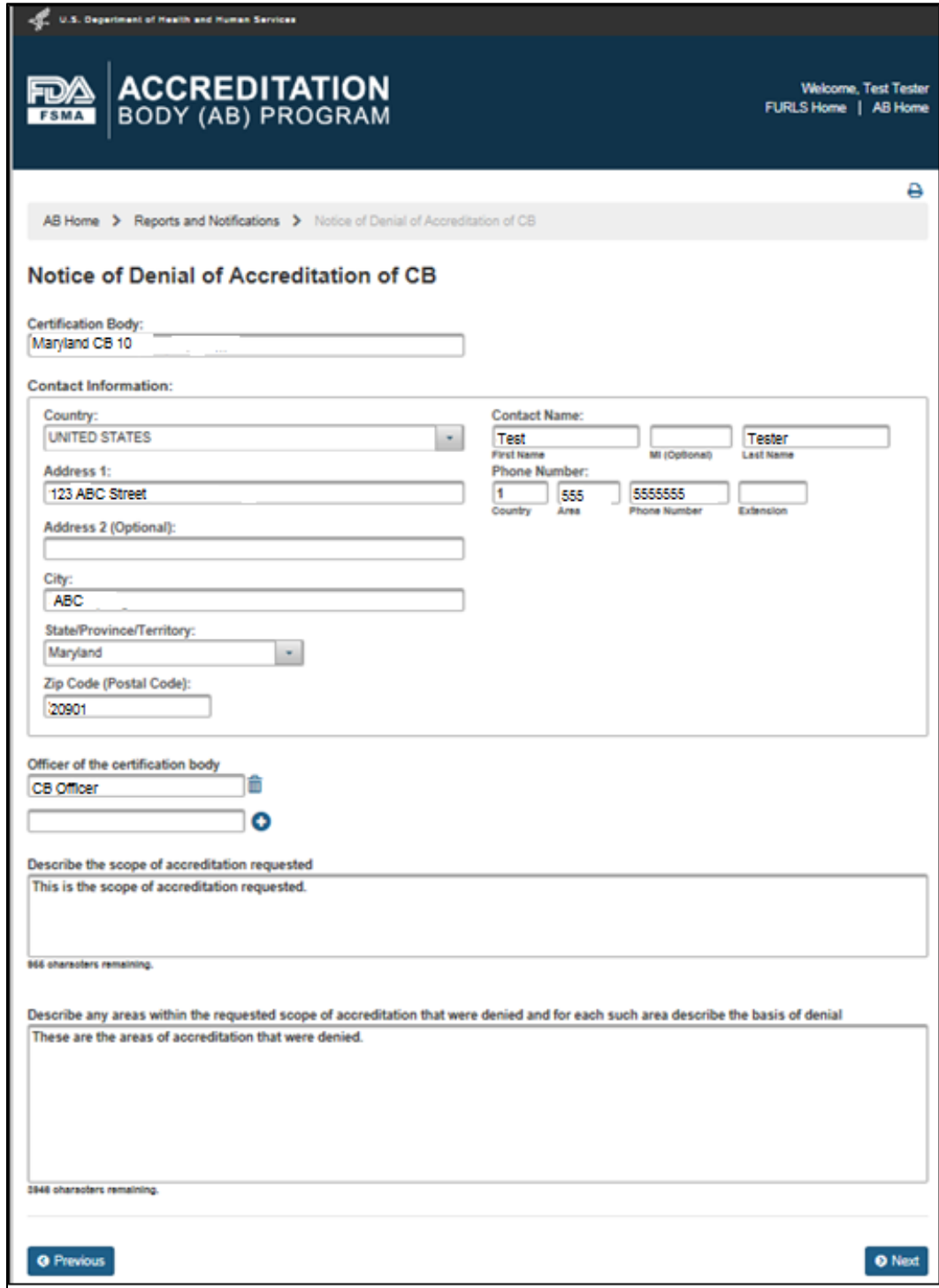
Reports and Notifications

Notice of Accreditation of CB
Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
Notice of Denial of Accreditation of CB
Notice of Significant Change
Notice of Intent to Relinquish or Not to Renew Recognition
Notice of Expansion of Scope of Accredited CB
Reinstatement of a Certification Body in Whole or in Part

[Previous](#)

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#) > [Notice of Denial of Accreditation of CB](#)

Notice of Denial of Accreditation of CB

Certification Body:

Contact Information:

Country:

Address 1:

Address 2 (Optional):

City:

State/Province/Territory:



Zip Code (Postal Code):

Contact Name:

First Name MI (Optional) Last Name

Phone Number:

Country Area Phone Number Extension

Officer of the certification body
 
 

Describe the scope of accreditation requested

866 characters remaining.

Describe any areas within the requested scope of accreditation that were denied and for each such area describe the basis of denial

3848 characters remaining.

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

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** – The 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.

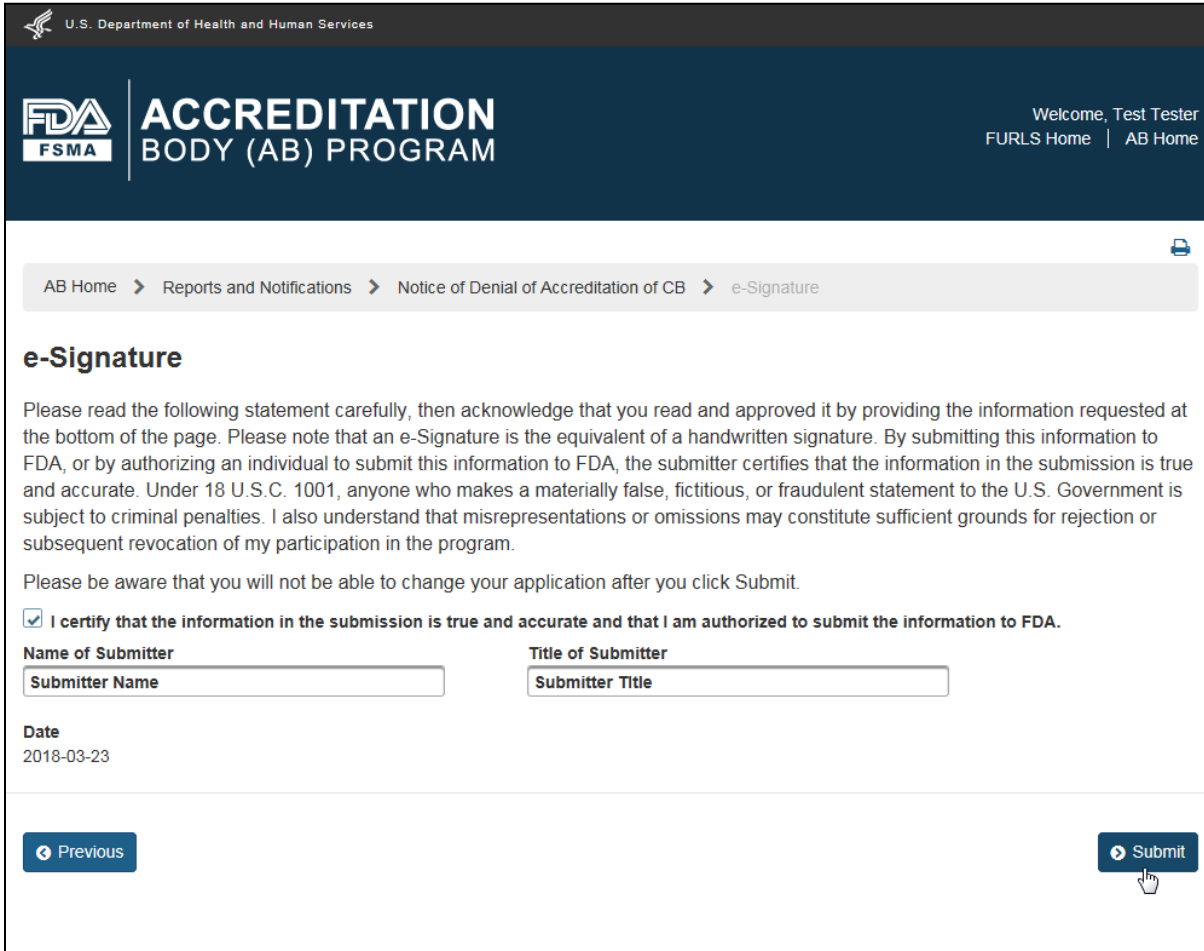
Click the check mark to certify that the information in the submission is true and accurate and, that you are authorized to submit the information to the FDA.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#) > [Notice of Denial of Accreditation of CB](#) > [e-Signature](#)

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter

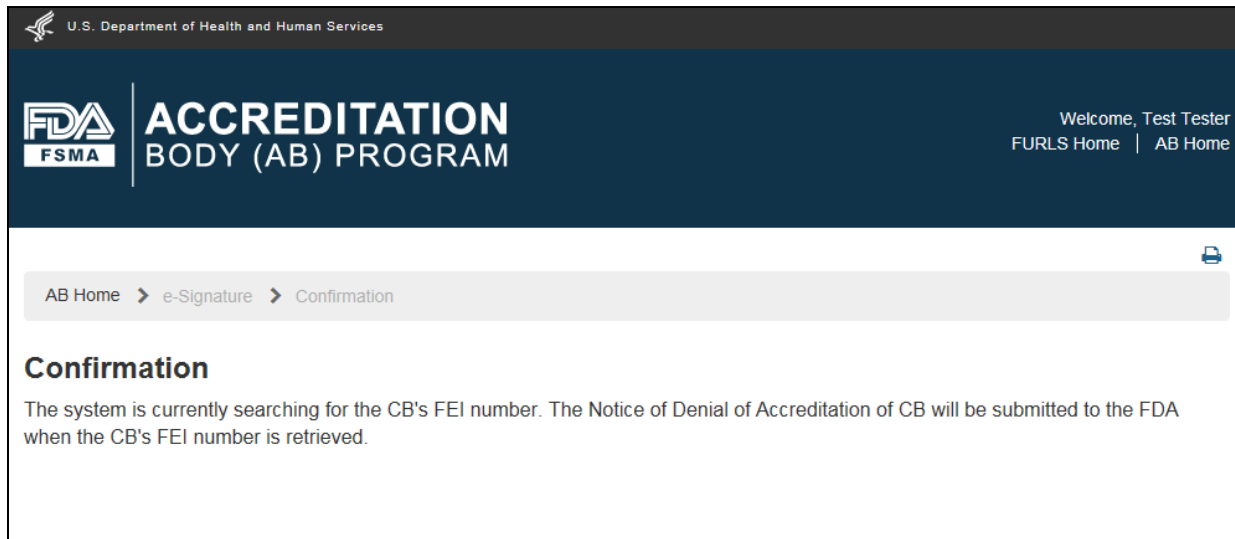
Title of Submitter

Date
2018-03-23

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

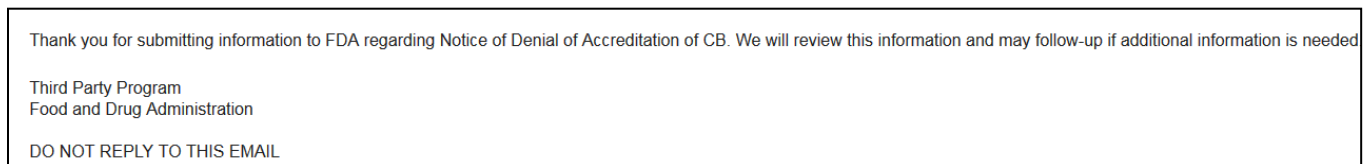
After you click the “Submit” button the system will display the confirmation message (Figure 9.3.4).

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

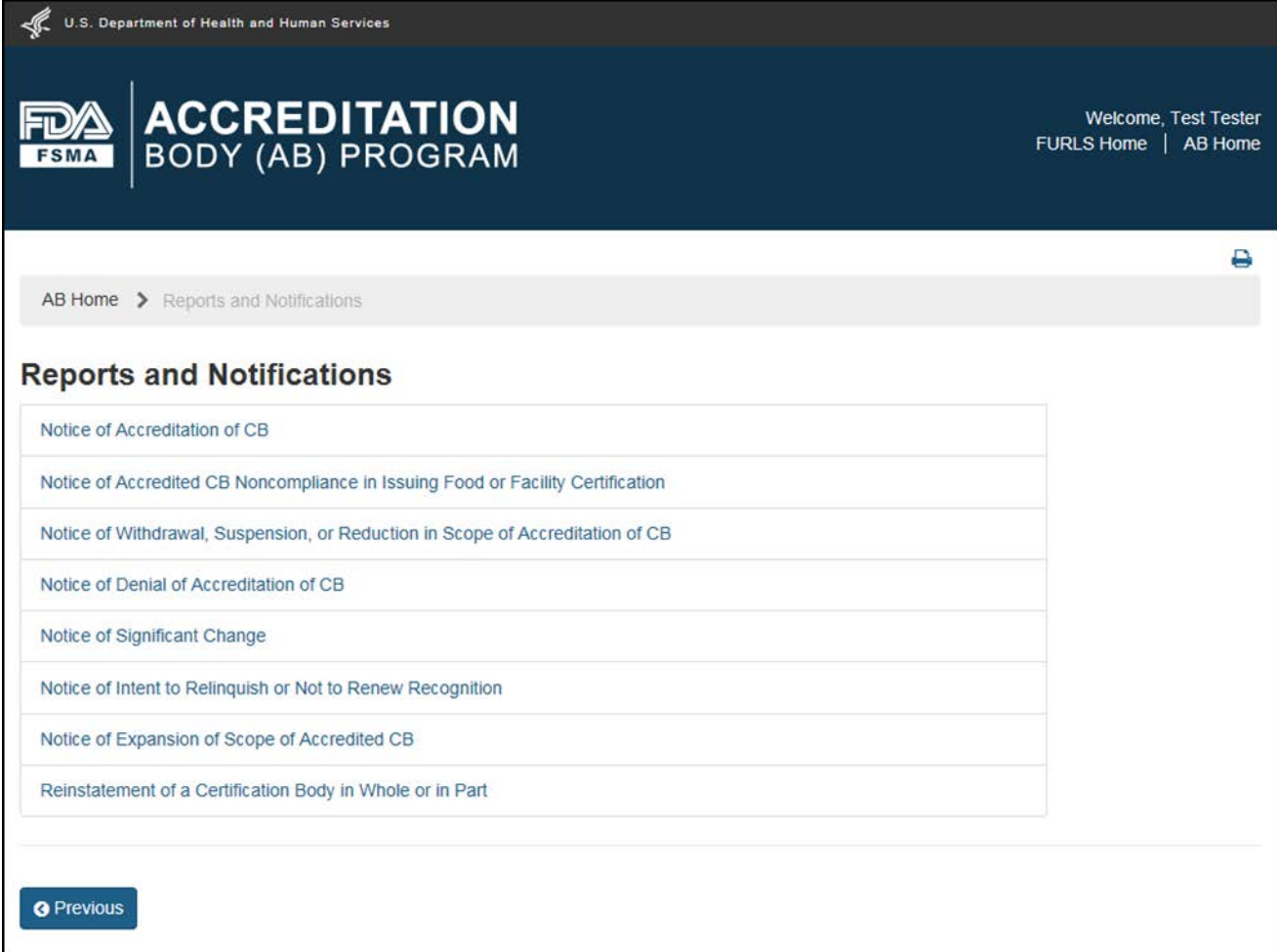


Return to the “Reports and Notifications” page by clicking on the “AB Home” link on the top of the banner.

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

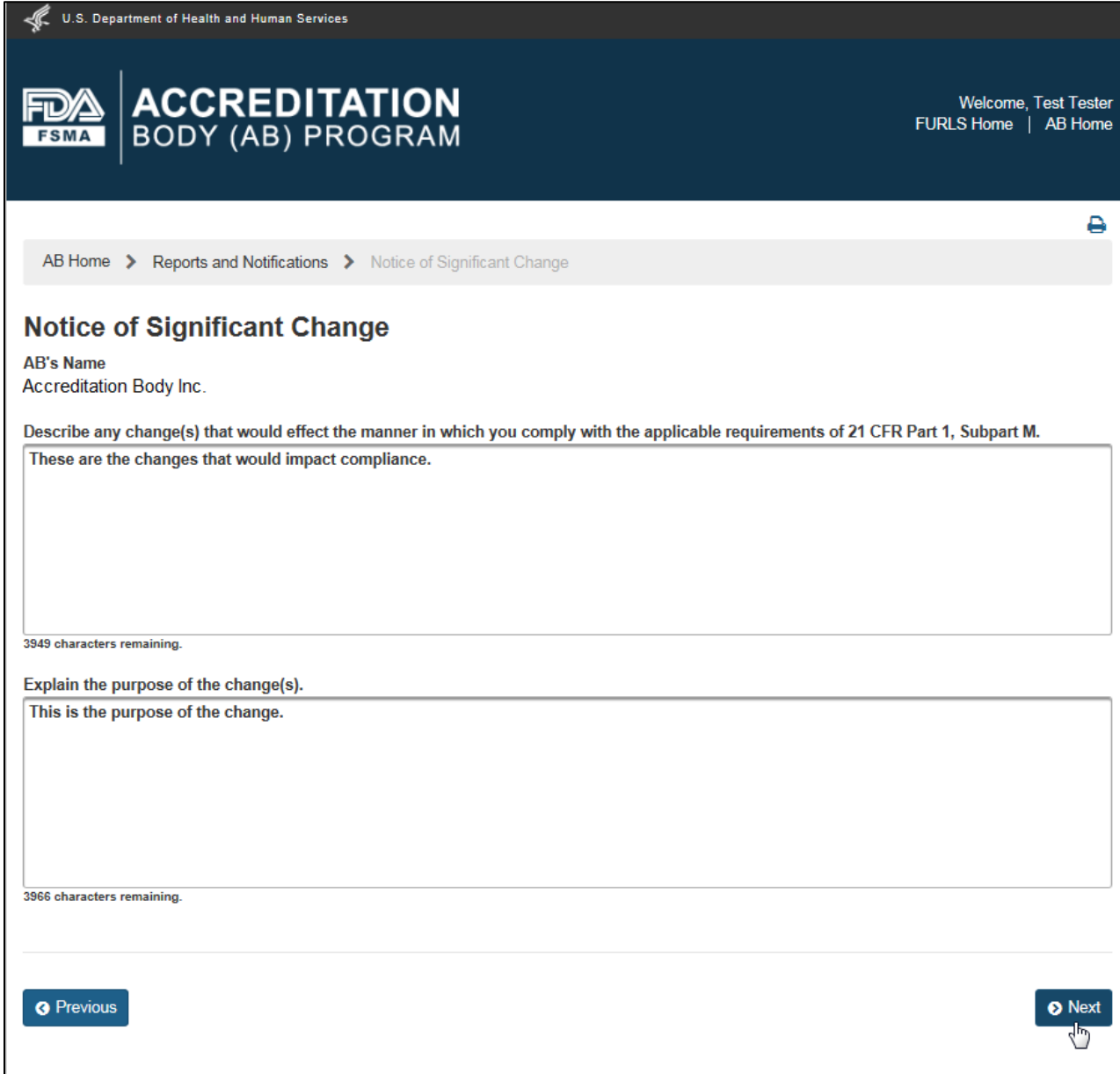


The screenshot shows the FDA Accreditation Body (AB) Program website. The header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "ACCREDITATION BODY (AB) PROGRAM". A user greeting "Welcome, Test Tester" and links for "FURLS Home" and "AB Home" are visible. A breadcrumb trail shows "AB Home > Reports and Notifications". The main content area is titled "Reports and Notifications" and contains a list of eight links: "Notice of Accreditation of CB", "Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification", "Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB", "Notice of Denial of Accreditation of CB", "Notice of Significant Change", "Notice of Intent to Relinquish or Not to Renew Recognition", "Notice of Expansion of Scope of Accredited CB", and "Reinstatement of a Certification Body in Whole or in Part". A "Previous" button is located at the bottom left.

Report/Notification Type
Notice of Accreditation of CB
Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
Notice of Denial of Accreditation of CB
Notice of Significant Change
Notice of Intent to Relinquish or Not to Renew Recognition
Notice of Expansion of Scope of Accredited CB
Reinstatement of a Certification Body in Whole or in Part

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

Figure 9.4.2 – Notice of Significant Change Page



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Significant Change

Notice of Significant Change

AB's Name
Accreditation Body Inc.

Describe any change(s) that would effect the manner in which you comply with the applicable requirements of 21 CFR Part 1, Subpart M.

These are the changes that would impact compliance.

3949 characters remaining.

Explain the purpose of the change(s).

This is the purpose of the change.

3966 characters remaining.

Previous Next

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.

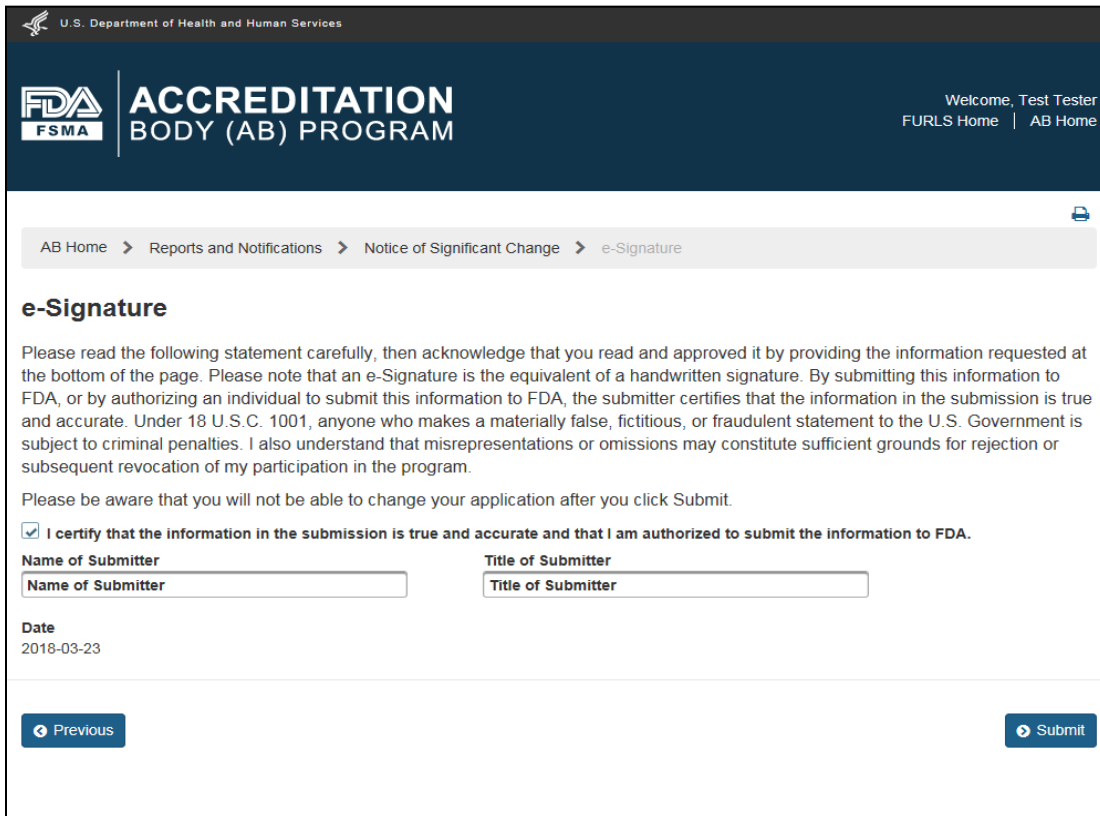
Click the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

AB Home > Reports and Notifications > Notice of Significant Change > e-Signature

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter

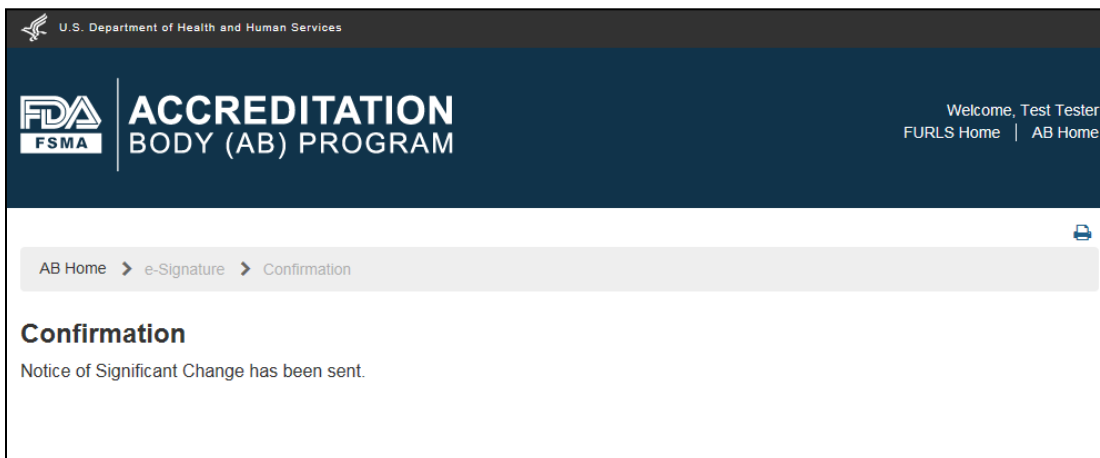
Title of Submitter

Date
2018-03-23

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

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

Figure 9.4.4 – Confirmation Message Page



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

AB Home > e-Signature > Confirmation

Confirmation

Notice of Significant Change has been sent.

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

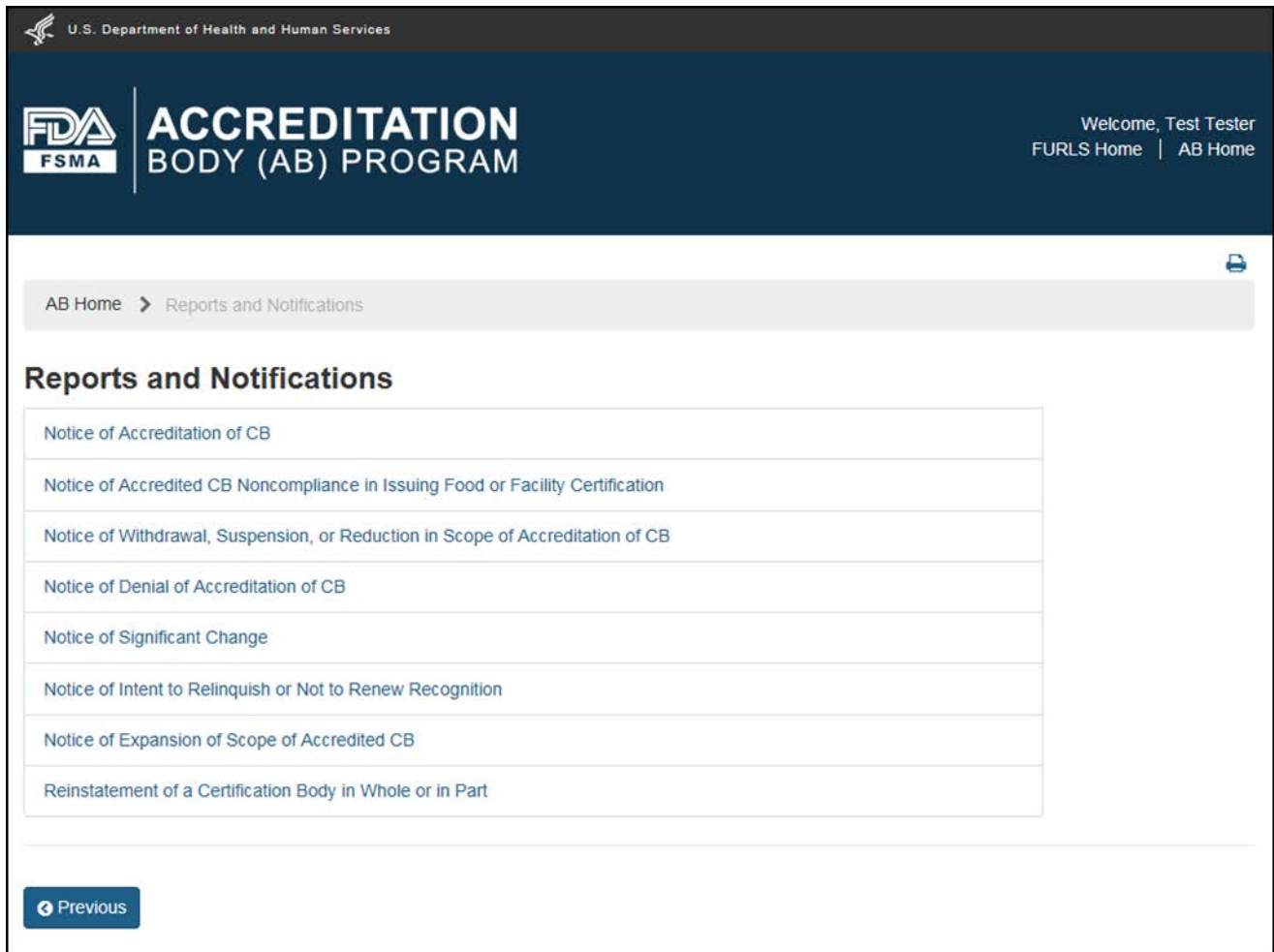
DO NOT REPLY TO THIS EMAIL

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).

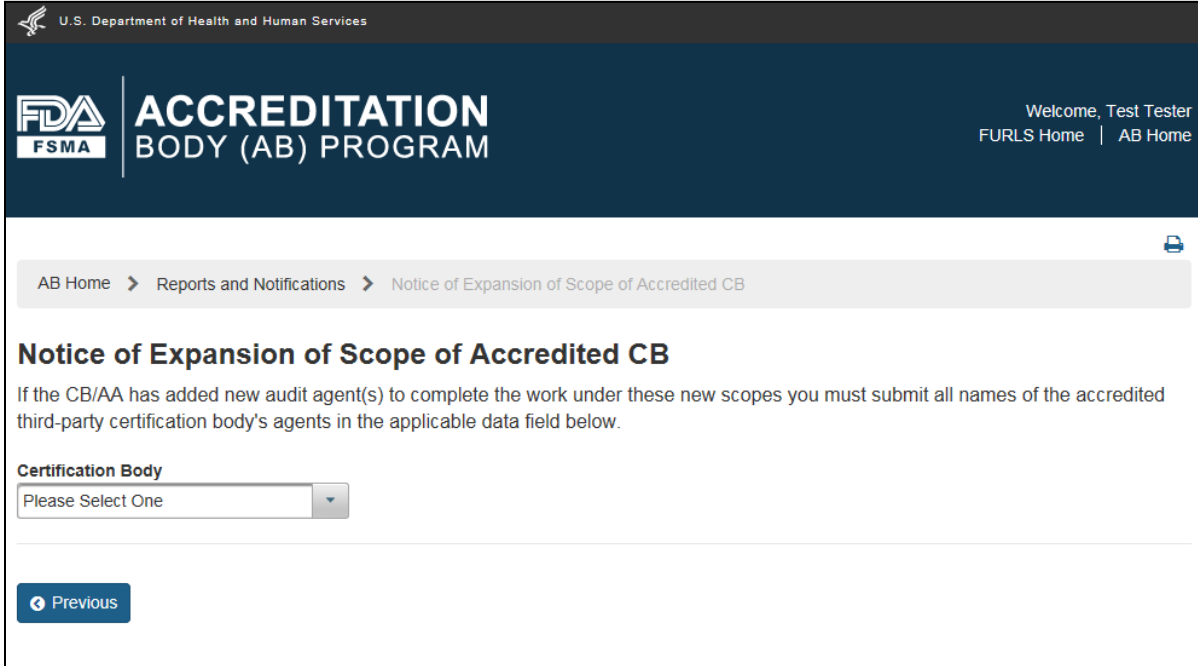
Figure 9.5.1 – Reports and Notifications Page



The screenshot shows the 'Reports and Notifications' page of the Accreditation Body (AB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'ACCREDITATION BODY (AB) PROGRAM'. A user greeting 'Welcome, Test Tester' and links for 'FURLS Home' and 'AB Home' are visible in the top right. A breadcrumb trail shows 'AB Home > Reports and Notifications'. The main content area is titled 'Reports and Notifications' and contains a list of eight links: 'Notice of Accreditation of CB', 'Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification', 'Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB', 'Notice of Denial of Accreditation of CB', 'Notice of Significant Change', 'Notice of Intent to Relinquish or Not to Renew Recognition', 'Notice of Expansion of Scope of Accredited CB', and 'Reinstatement of a Certification Body in Whole or in Part'. A 'Previous' button is located at the bottom left of the 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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#) > [Notice of Expansion of Scope of Accredited CB](#)

Notice of Expansion of Scope of Accredited CB

If the CB/AA has added new audit agent(s) to complete the work under these new scopes you must submit all names of the accredited third-party certification body's agents in the applicable data field below.

Certification Body

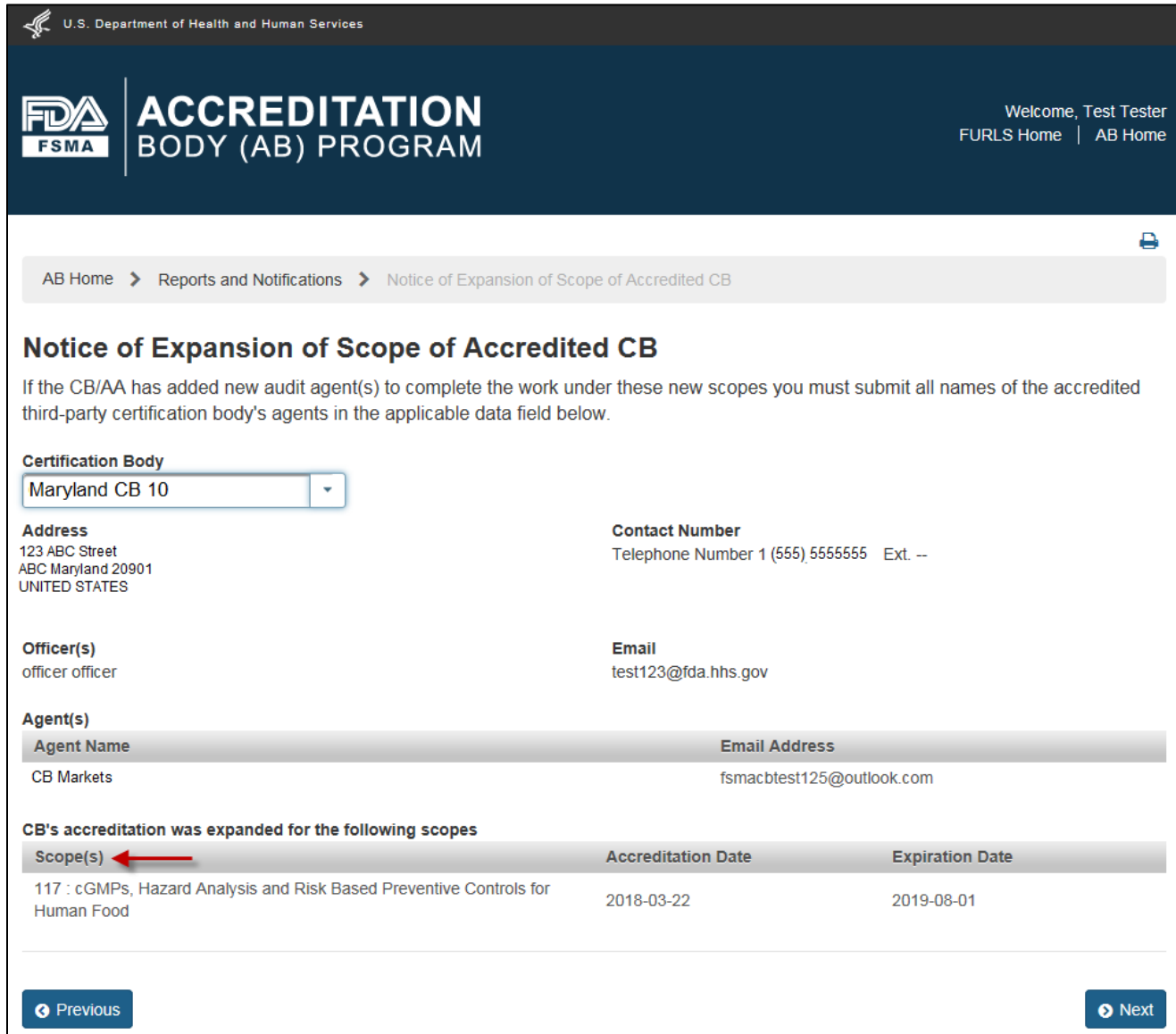
Please Select One

[Previous](#)

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Reports and Notifications > Notice of Expansion of Scope of Accredited CB

Notice of Expansion of Scope of Accredited CB

If the CB/AA has added new audit agent(s) to complete the work under these new scopes you must submit all names of the accredited third-party certification body's agents in the applicable data field below.

Certification Body
 Maryland CB 10

Address
 123 ABC Street
 ABC Maryland 20901
 UNITED STATES

Contact Number
 Telephone Number 1 (555) 5555555 Ext. --

Officer(s)
 officer officer

Email
 test123@fda.hhs.gov

Agent(s)

Agent Name	Email Address
CB Markets	fsmacbttest125@outlook.com

CB's accreditation was expanded for the following scopes

Scope(s)	Accreditation Date	Expiration Date
117 : cGMPs, Hazard Analysis and Risk Based Preventive Controls for Human Food	2018-03-22	2019-08-01

Previous Next

Click the “Next” button.

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

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

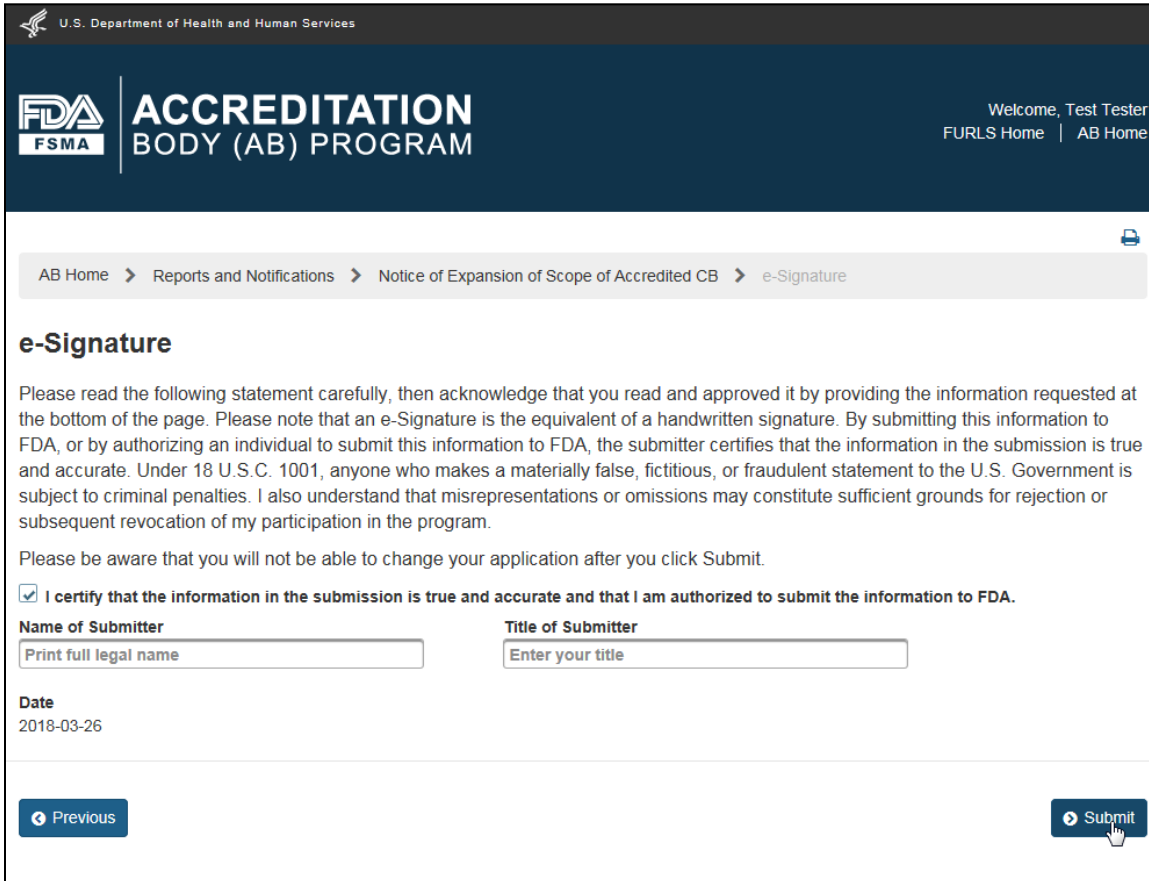
Click on the check mark to indicate that you certify that the information in the submission is true and accurate and that you are authorized to submit the information to the FDA.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#) > [Notice of Expansion of Scope of Accredited CB](#) > [e-Signature](#)

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Print full legal name

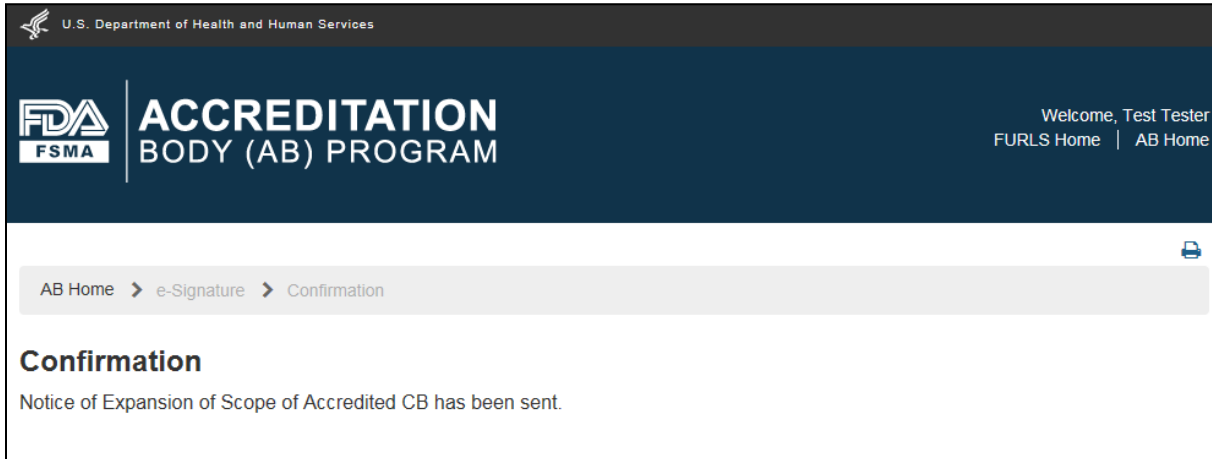
Title of Submitter
Enter your title

Date
2018-03-26

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

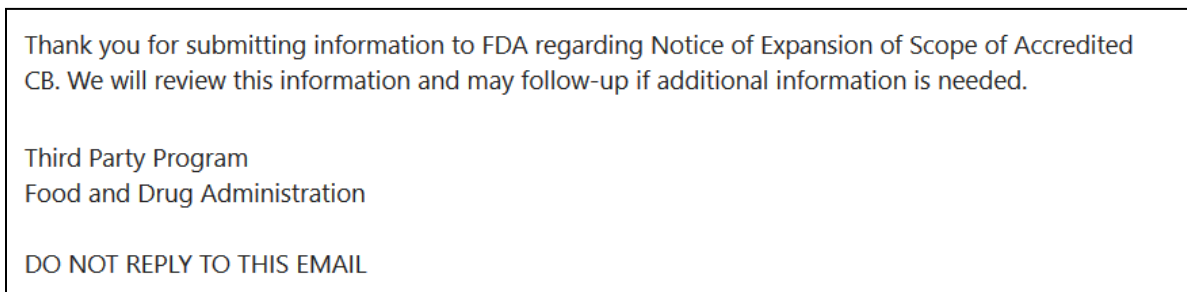
The system will display the confirmation message (Figure 9.5.5).

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

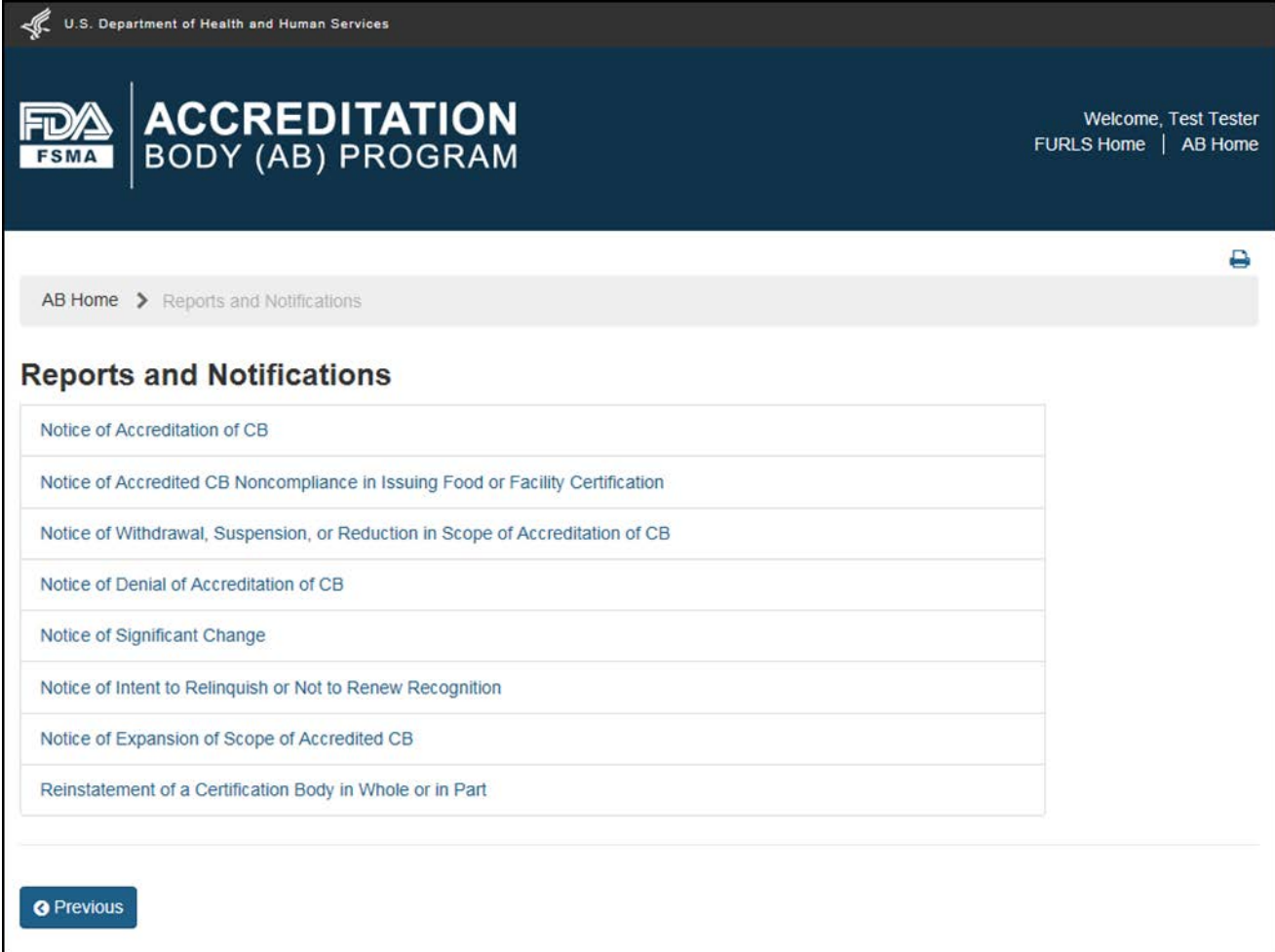


Return to the “Reports and Notifications” page by clicking on the “AB Home” link on the top of the banner.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#)

Reports and Notifications

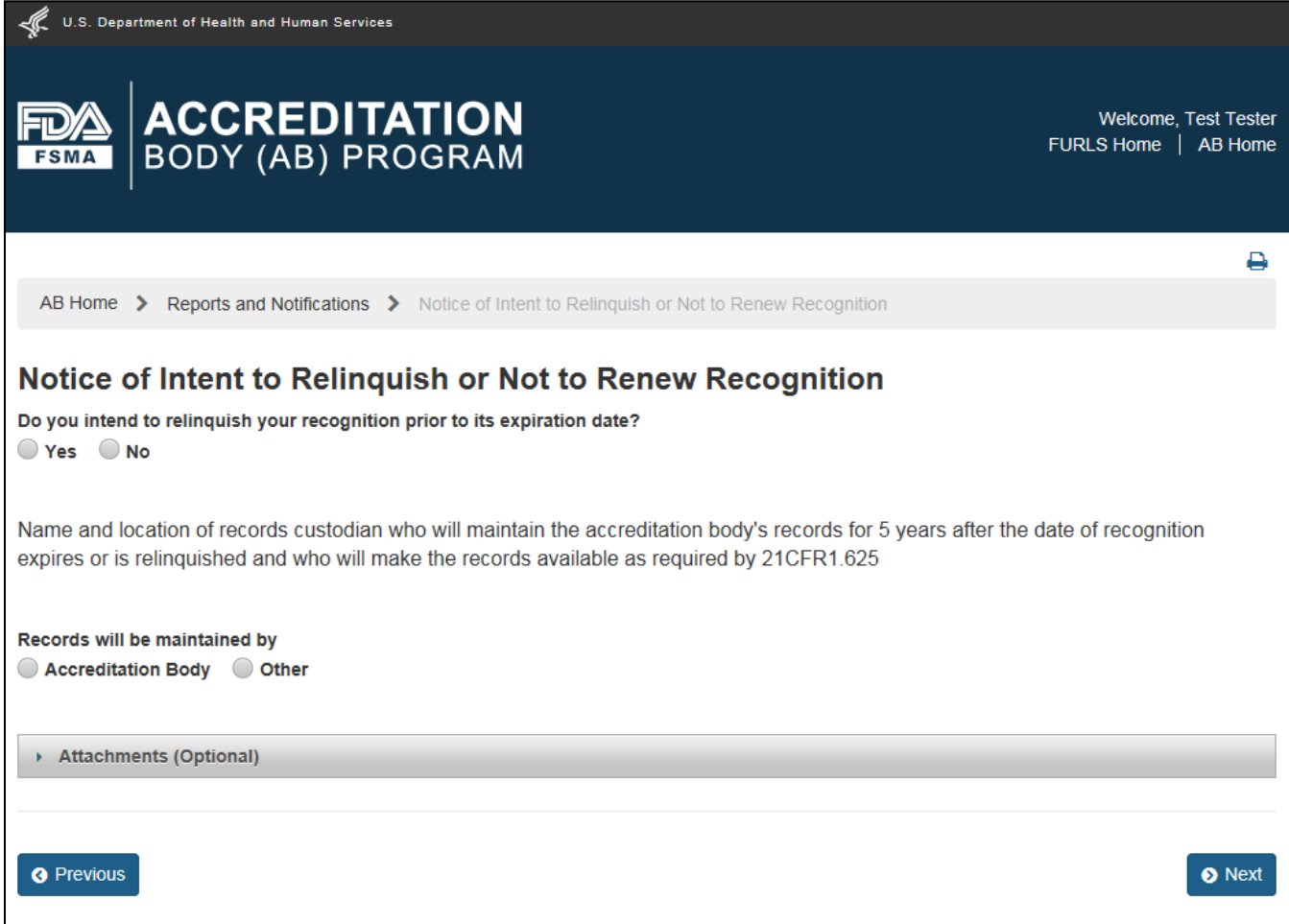
Notice of Accreditation of CB
Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
Notice of Denial of Accreditation of CB
Notice of Significant Change
Notice of Intent to Relinquish or Not to Renew Recognition
Notice of Expansion of Scope of Accredited CB
Reinstatement of a Certification Body in Whole or in Part

[Previous](#)

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



The screenshot shows a web page for the FDA Accreditation Body (AB) Program. At the top, it says "U.S. Department of Health and Human Services" and "Welcome, Test Tester" with links for "FURLS Home" and "AB Home". The main header includes the "FDA FSMA" logo and "ACCREDITATION BODY (AB) PROGRAM". A breadcrumb trail shows "AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition". The main heading is "Notice of Intent to Relinquish or Not to Renew Recognition". Below this is a question: "Do you intend to relinquish your recognition prior to its expiration date?" with radio buttons for "Yes" and "No". A text field is provided for the "Name and location of records custodian who will maintain the accreditation body's records for 5 years after the date of recognition expires or is relinquished and who will make the records available as required by 21CFR1.625". Below this is another question: "Records will be maintained by" with radio buttons for "Accreditation Body" and "Other". There is an "Attachments (Optional)" section. At the bottom, there are "Previous" and "Next" navigation buttons.

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

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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

AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition

Notice of Intent to Relinquish or Not to Renew Recognition

Do you intend to relinquish your recognition prior to its expiration date?

Yes No

Intended Date of Relinquishment or Date of Expiration of Recognition

2018-03-27

Mar 2018

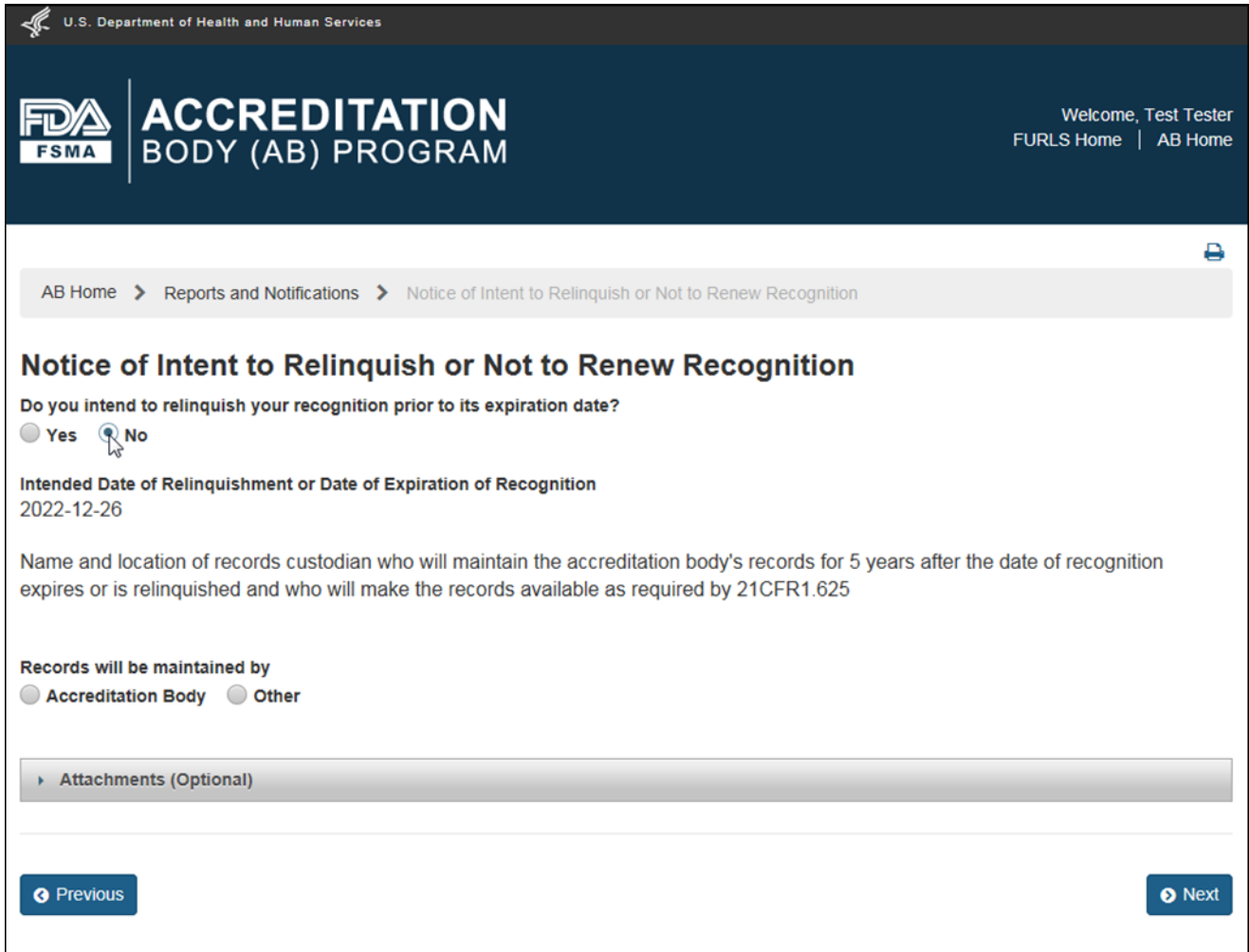
Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

Attachments (Optional)

Previous Next

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition

Notice of Intent to Relinquish or Not to Renew Recognition

Do you intend to relinquish your recognition prior to its expiration date?

Yes No

Intended Date of Relinquishment or Date of Expiration of Recognition
2022-12-26

Name and location of records custodian who will maintain the accreditation body's records for 5 years after the date of recognition expires or is relinquished and who will make the records available as required by 21CFR1.625

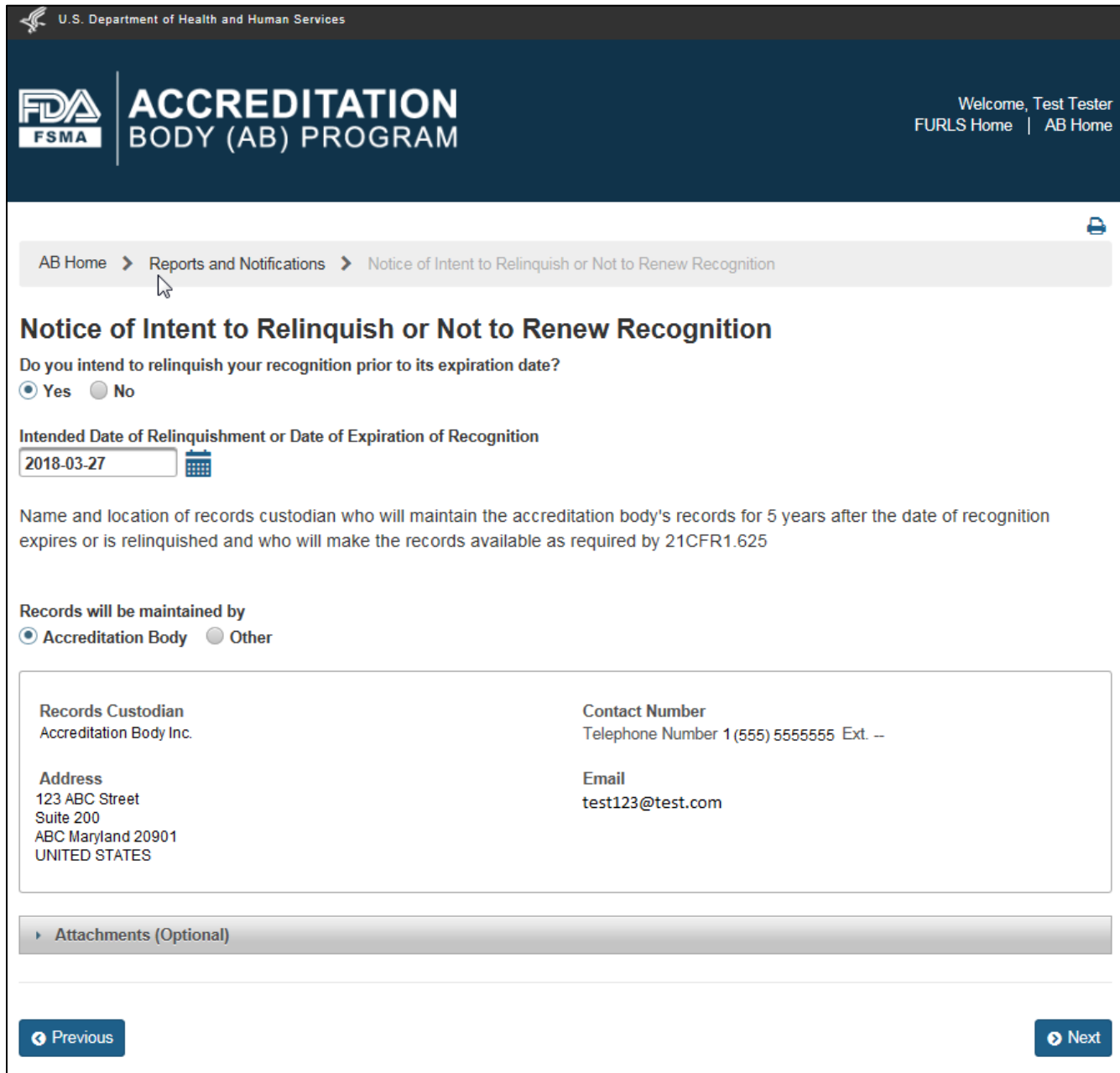
Records will be maintained by
 Accreditation Body Other

▶ Attachments (Optional)

◀ Previous ▶ Next

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



U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM


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

AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition

Notice of Intent to Relinquish or Not to Renew Recognition

Do you intend to relinquish your recognition prior to its expiration date?

Yes No

Intended Date of Relinquishment or Date of Expiration of Recognition
 

Name and location of records custodian who will maintain the accreditation body's records for 5 years after the date of recognition expires or is relinquished and who will make the records available as required by 21CFR1.625

Records will be maintained by
 Accreditation Body Other

Records Custodian Accreditation Body Inc.	Contact Number Telephone Number 1 (555) 5555555 Ext. --
Address 123 ABC Street Suite 200 ABC Maryland 20901 UNITED STATES	Email test123@test.com

▶ Attachments (Optional)

[◀ Previous](#) [Next ▶](#)

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

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

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


AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition

Notice of Intent to Relinquish or Not to Renew Recognition

Do you intend to relinquish your recognition prior to its expiration date?

Yes No

Intended Date of Relinquishment or Date of Expiration of Recognition

2018-03-27 

Name and location of records custodian who will maintain the accreditation body's records for 5 years after the date of recognition expires or is relinquished and who will make the records available as required by 21CFR1.625

Records will be maintained by

Accreditation Body Other

Records Custodian:

Telephone (Optional):
Country Area Phone Number Extension

Country:

E-mail Address:

Address 1:

Address 2 (Optional):

City:

State/Province/Territory:

Zip Code (Postal Code):

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.

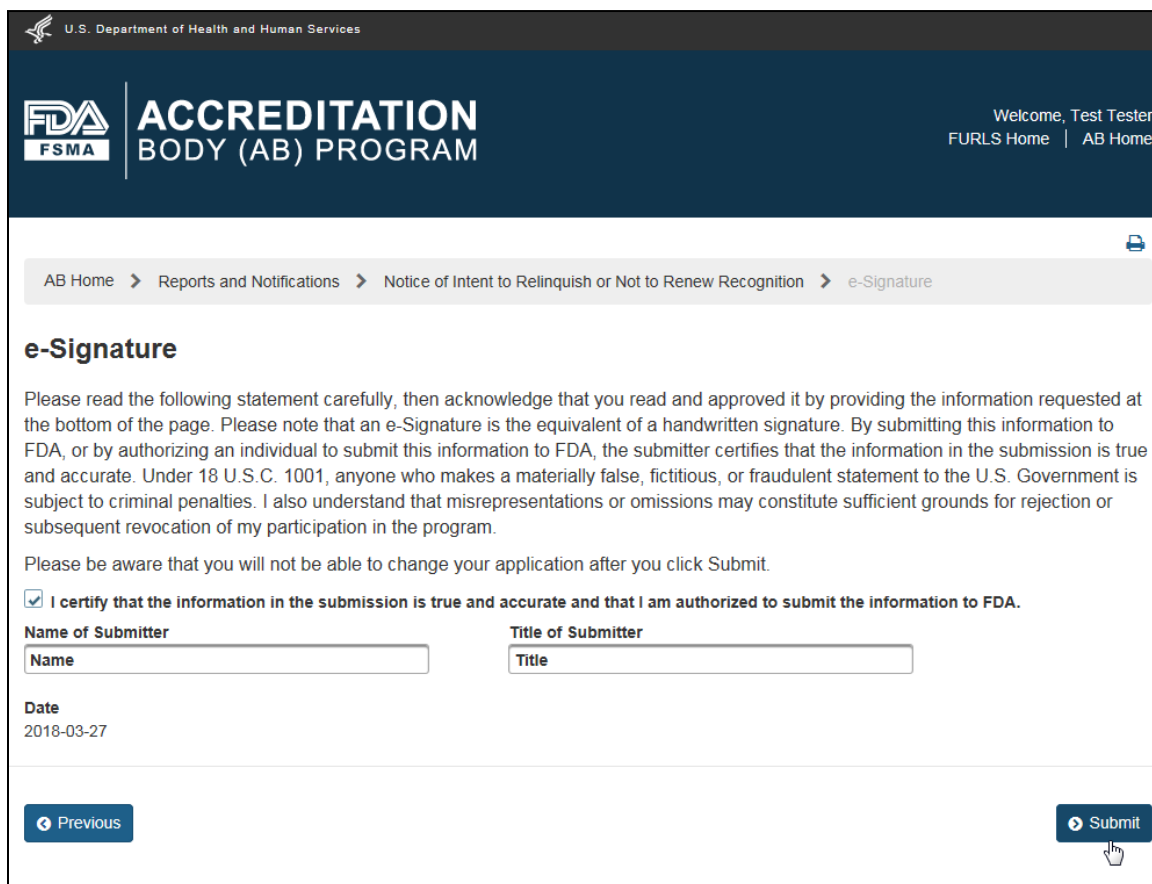
The system displays the “e-Signature” page (Figure 9.6.7).

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition > e-Signature

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Name

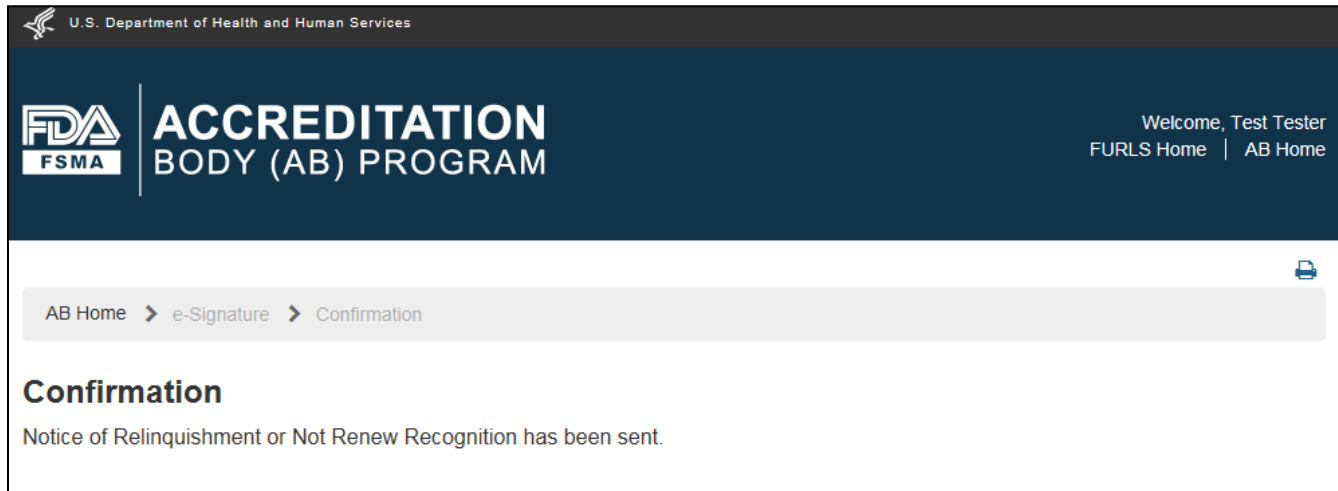
Title of Submitter
Title

Date
2018-03-27

Previous Submit

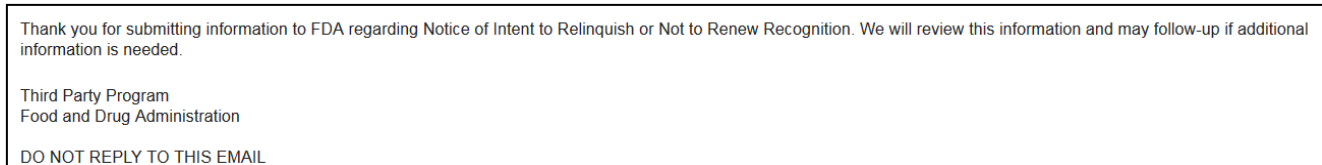
The system will display the confirmation message (Figure 9.6.8).

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

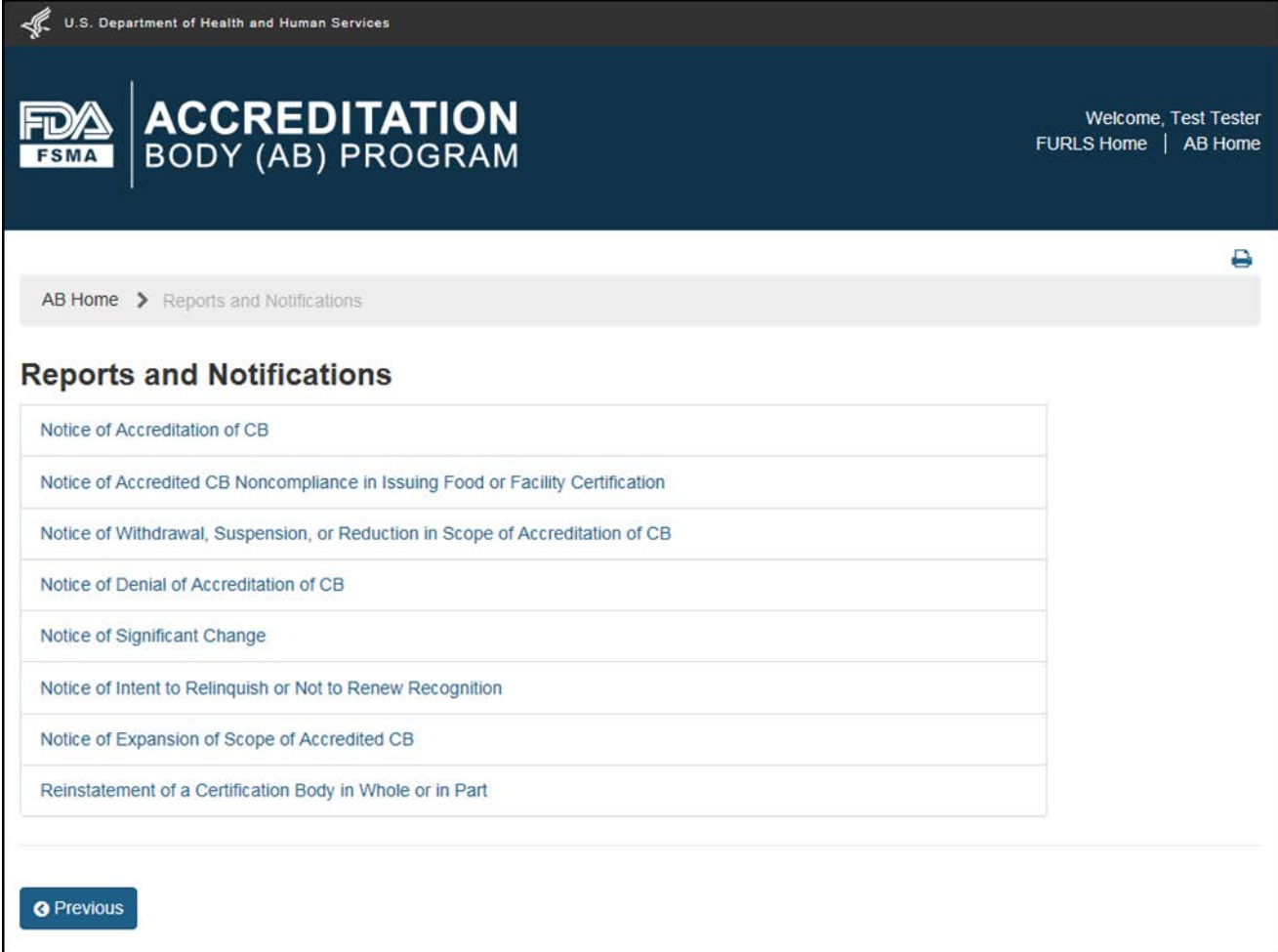


You can return to the “Reports and Notifications” page by clicking the “AB Home” link in the top of the banner.

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#)

Reports and Notifications

- [Notice of Accreditation of CB](#)
- [Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification](#)
- [Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB](#)
- [Notice of Denial of Accreditation of CB](#)
- [Notice of Significant Change](#)
- [Notice of Intent to Relinquish or Not to Renew Recognition](#)
- [Notice of Expansion of Scope of Accredited CB](#)
- [Reinstatement of a Certification Body in Whole or in Part](#)

[Previous](#)

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

AB Home > Reports and Notifications > Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB

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

Certification Body

Type of Action

 Withdraw accreditation in whole
 Suspend accreditation in whole
 Withdraw, Suspend or Reduce specific Scope(s)

Date of Action
 

4000 characters remaining.

Any additional changes to information submitted under the Notice of Accreditation for the CB (Optional)
 Enter your response here.

4000 characters remaining.

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

[AB Home](#) > [Reports and Notifications](#) > [Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB](#)

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

Certification Body

Type of Action

Scope

Select One	Scope	Date of Accreditation	Date of Expiration	Current Status	Reason for Change
<input type="checkbox"/>	117: cGMPs, Hazard Analysis and Risk Based Preventive Controls for Human Food	2018-04-19	2020-04-19	Accredited	
<input type="checkbox"/>	118: Production, storage, and transportation of shell eggs	2018-04-19	2020-04-19	Accredited	
<input type="checkbox"/>	119: Dietary supplements that present a significant or unreasonable risk	2018-04-19	2020-04-19	Accredited	
<input type="checkbox"/>	120: HACCP	2018-04-19	2020-04-19	Accredited	

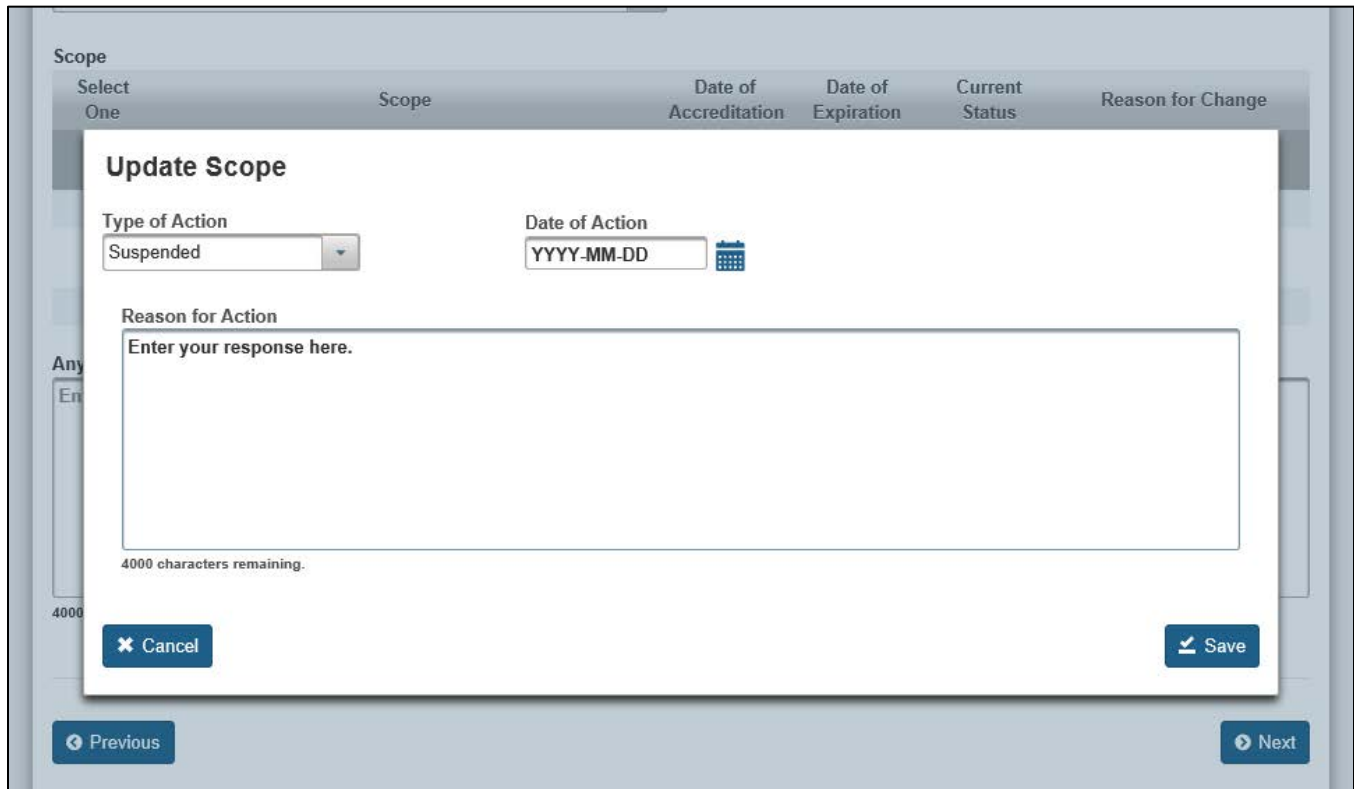
Any additional changes to information submitted under the Notice of Accreditation for the CB (Optional)

Enter your response here.

4000 characters remaining.

← Previous

Figure 9.7.4 – Update Scope



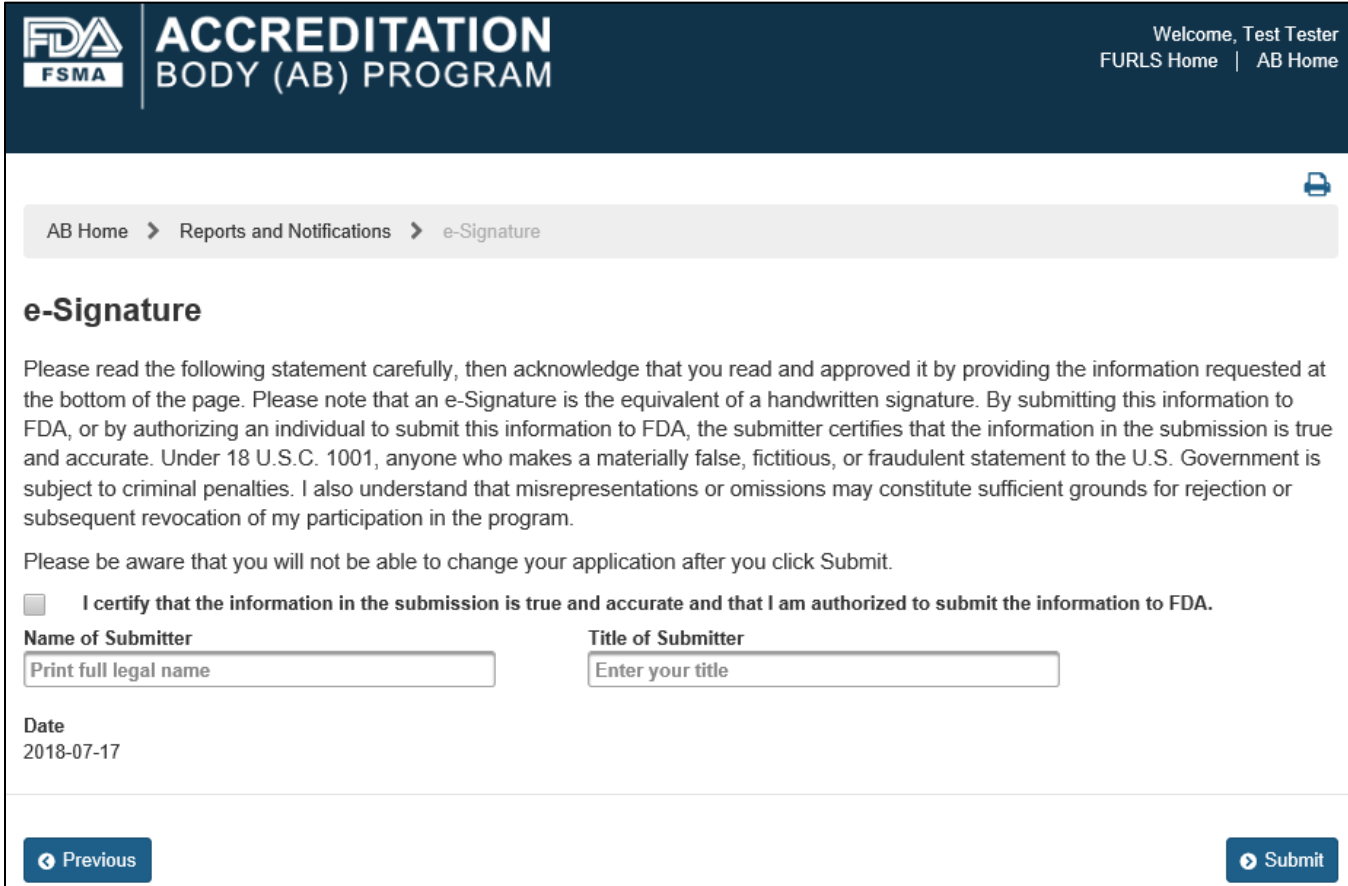
The system displays the “e-Signature” page (Figure 9.7.5).

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



FDA FSMA ACCREDITATION BODY (AB) PROGRAM Welcome, Test Tester
FURLS Home | AB Home

AB Home > Reports and Notifications > e-Signature

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Print full legal name

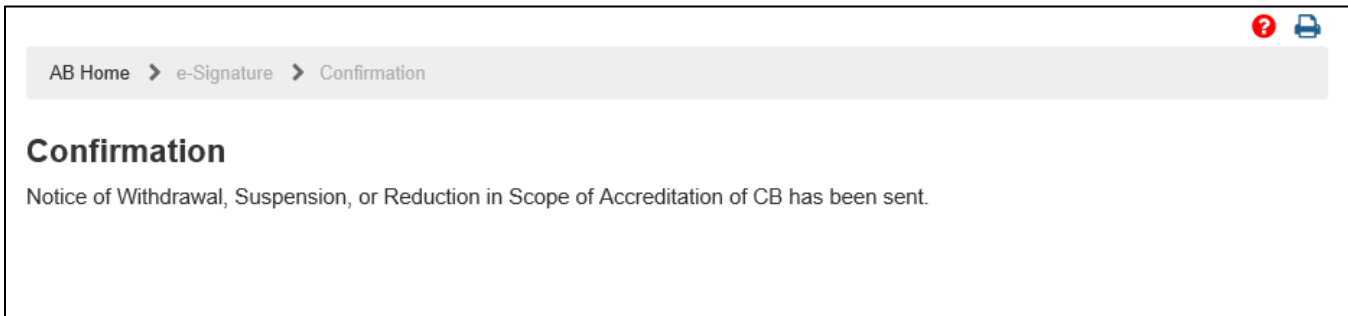
Title of Submitter
Enter your title

Date
2018-07-17

Previous Submit

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

Figure 9.7.6 – Confirmation Message Page



AB Home > e-Signature > Confirmation

Confirmation

Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB has been sent.

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

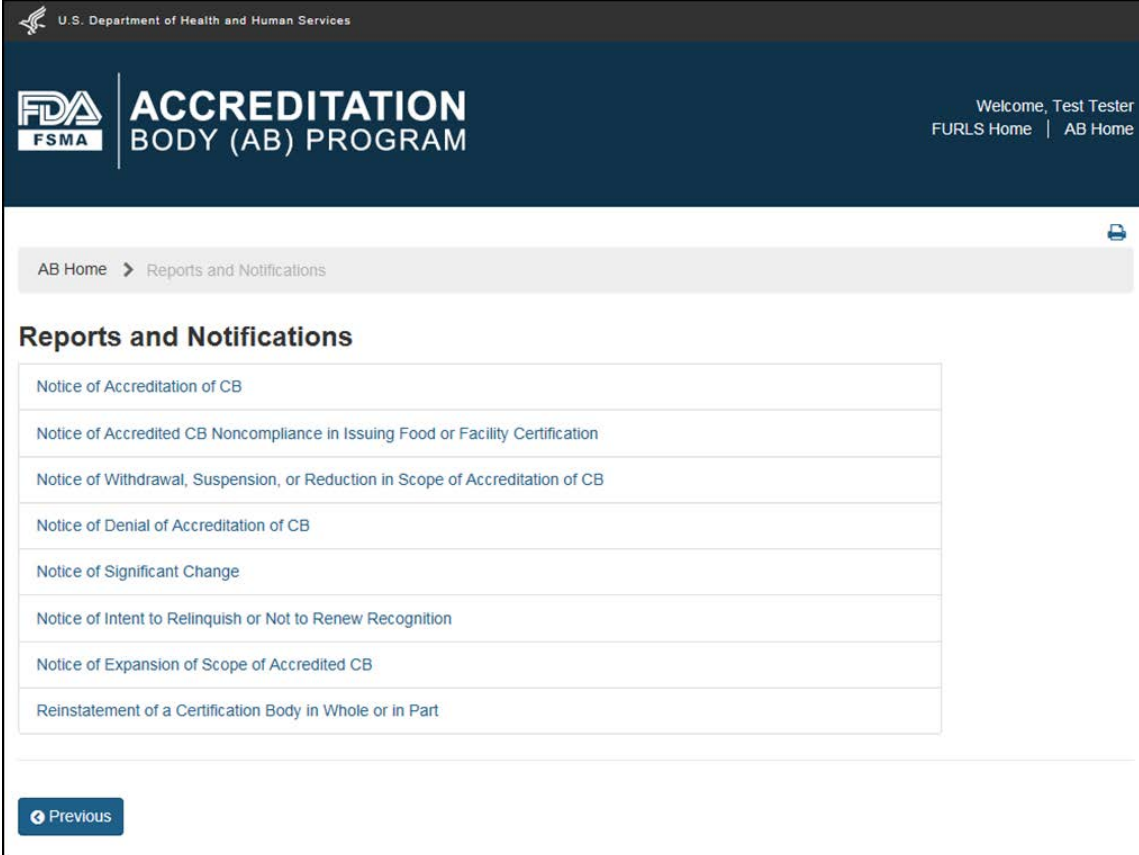
DO NOT REPLY TO THIS EMAIL

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



U.S. Department of Health and Human Services

FDA | **ACCREDITATION**
FSMA | **BODY (AB) PROGRAM**

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

[AB Home](#) > [Reports and Notifications](#)

Reports and Notifications

Notice of Accreditation of CB
Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification
Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
Notice of Denial of Accreditation of CB
Notice of Significant Change
Notice of Intent to Relinquish or Not to Renew Recognition
Notice of Expansion of Scope of Accredited CB
Reinstatement of a Certification Body in Whole or in Part

[Previous](#)

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 – Reinstatement in whole

AB Home > Reports and Notifications > Reinstatement of a Certification Body in Whole or in Part

Reinstatement of a Certification Body in Whole or in Part

Please select the Certification Body who you wish to reinstate in whole or in part.

CB Test

Type of Action

Reinstatement in whole

Scopes that are to be reinstated.

Scope
119: Dietary supplements that present a significant or unreasonable risk
109: Unavoidable contaminants in food for human consumption and food-packaging material

Please provide detailed information supporting your decision to reinstate the above scopes in the field below. If you have documentation to support your decision to reinstate a CB that you have suspended then after submitting this notice please go to the Supplemental Documentation menu option on the home page, select attachment type "Request for Reinstatement" for each file that you upload, and click Save. If you do provide documentation under the Supplemental Documentation then please include a note in the field below to indicate that supportive documentation has been provided under a Supplemental Documentation.

Enter your response here.

4000 characters remaining.

Previous Next

Figure 9.8.4 – Reinstatement scope(s)

AB Home > Reports and Notifications > Reinstatement of a Certification Body in Whole or in Part

Reinstatement of a Certification Body in Whole or in Part

Please select the Certification Body who you wish to reinstate in whole or in part.

CB Test

Type of Action
Reinstatement scope(s)

Scopes that are to be reinstated.

Select One	Scope
<input checked="" type="checkbox"/>	119: Dietary supplements that present a significant or unreasonable risk
<input type="checkbox"/>	109: Unavoidable contaminants in food for human consumption and food-packaging material

Please provide detailed information supporting your decision to reinstate the above scopes in the field below. If you have documentation to support your decision to reinstate a CB that you have suspended then after submitting this notice please go to the Supplemental Documentation menu option on the home page, select attachment type "Request for Reinstatement" for each file that you upload, and click Save. If you do provide documentation under the Supplemental Documentation then please include a note in the field below to indicate that supportive documentation has been provided under a Supplemental Documentation.

Enter your response here.

4000 characters remaining.

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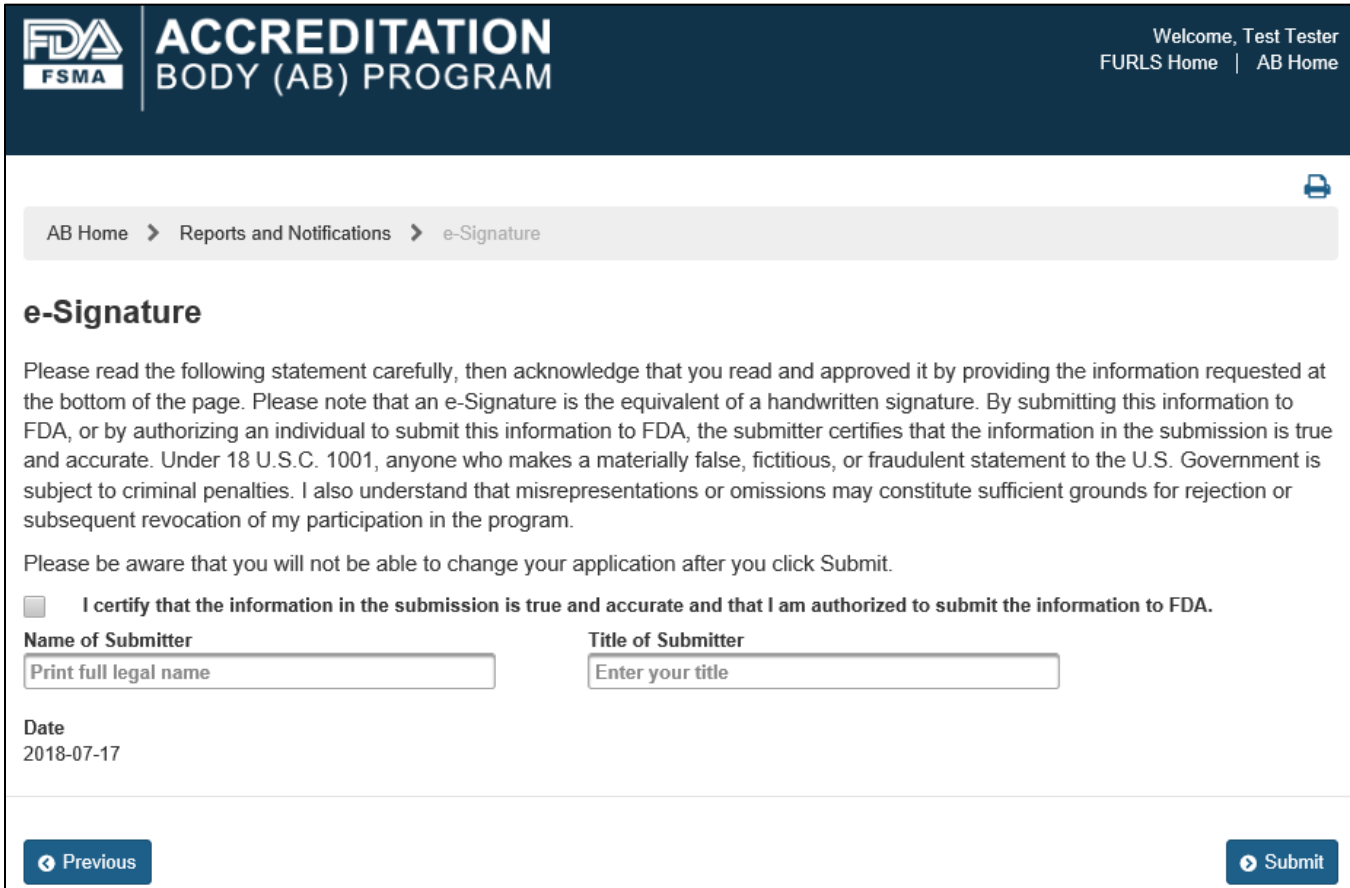
The system displays the “e-Signature” page (Figure 9.8.5).

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



FDA FSMA ACCREDITATION BODY (AB) PROGRAM Welcome, Test Tester
FURLS Home | AB Home

AB Home > Reports and Notifications > e-Signature

e-Signature

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

Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Print full legal name

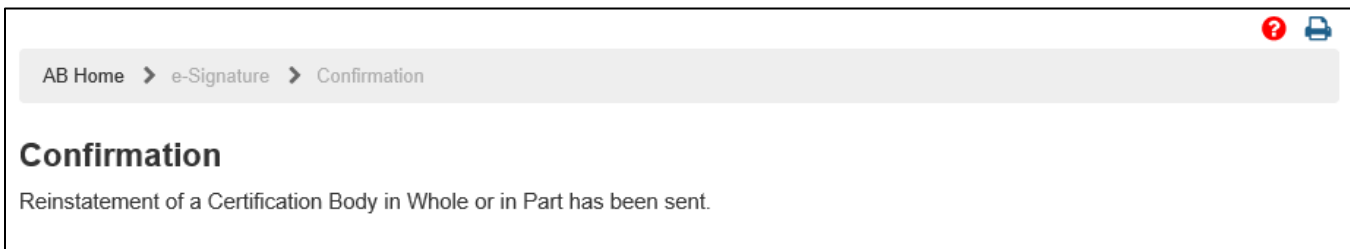
Title of Submitter
Enter your title

Date
2018-07-17

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

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

Figure 9.8.6 – Confirmation Message Page



AB Home > e-Signature > Confirmation

Confirmation

Reinstatement of a Certification Body in Whole or in Part has been sent.

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.

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.