



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

U.S. Food and Drug Administration

Accredited Third-Party Certification Program Portal

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

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1 Introduction

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

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

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

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

FDA Industry Systems (FIS)

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

FDA's Unified Registration and Listing System (FURLS)

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

Adding Attachments

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

The electronic Accredited Third-Party Certification Program system supports attachments of the following document types: .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

The maximum file size allowed is 50 MB.

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

Supported Browsers

FURLS may be accessed using Microsoft Edge, Chrome, or Firefox. Please visit the “Systems Requirements” section of the FURLS page for a list of approved browsers and browser versions. The “Systems Requirements” section can be found by navigating to Access.fda.gov.

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

Obtain an FDA Account through the FDA FIS Electronic Portal

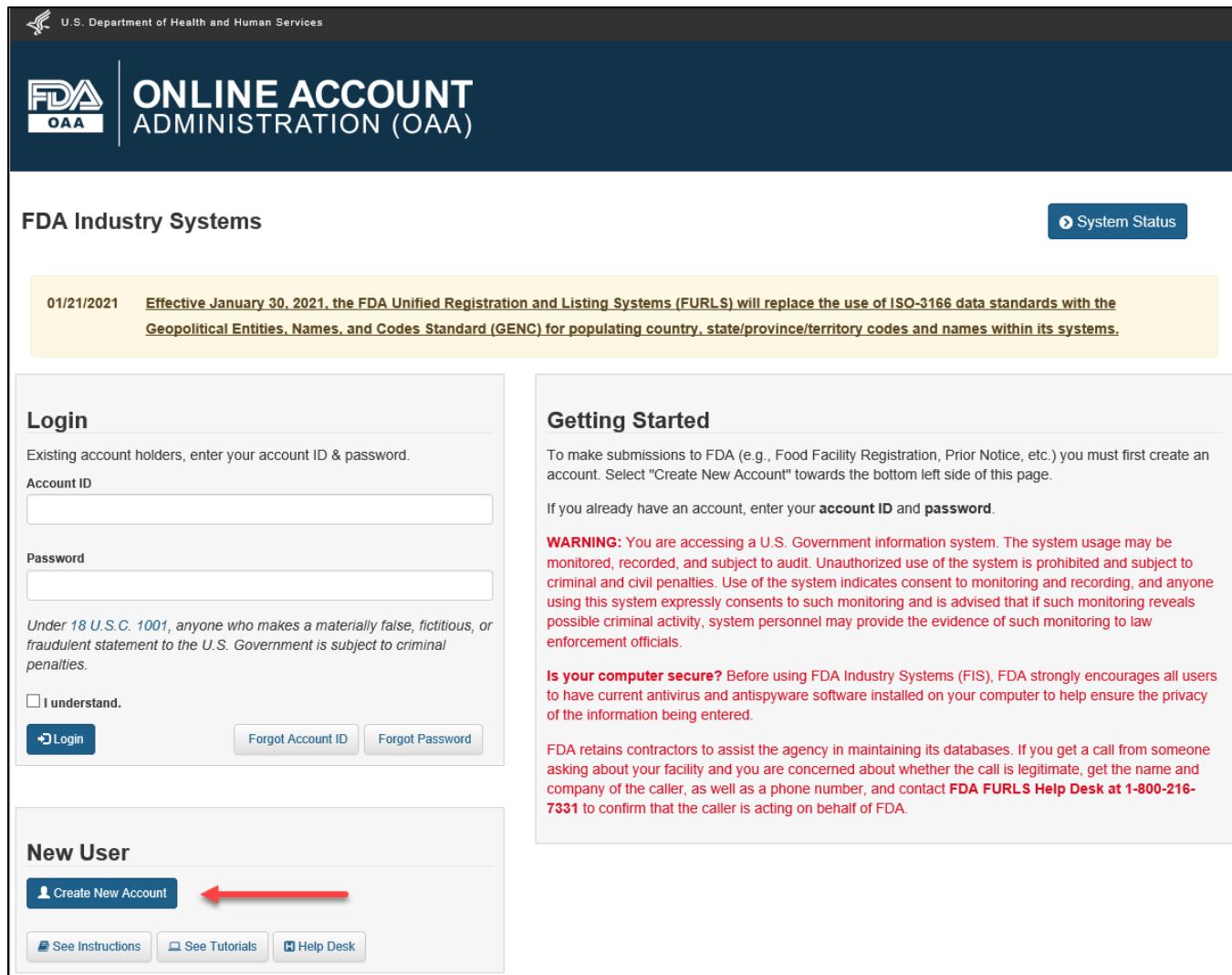
Each person who uses this system needs a personal FDA Account ID and password. To access the FIS electronic portal, navigate to the [Access.fda.gov OAA site](https://Access.fda.gov). Click the “Create New Account” button (near the bottom of the page) in the “New User” section. Follow the instructions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

3 Create an FDA Online Account

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

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

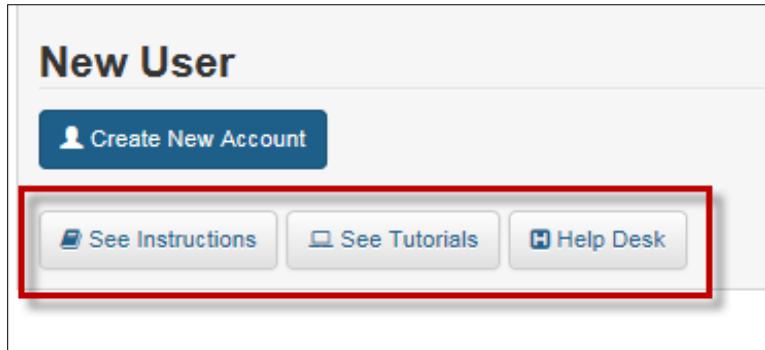
Figure 3.1 – FIS Online Account Administration (OAA) Page



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

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

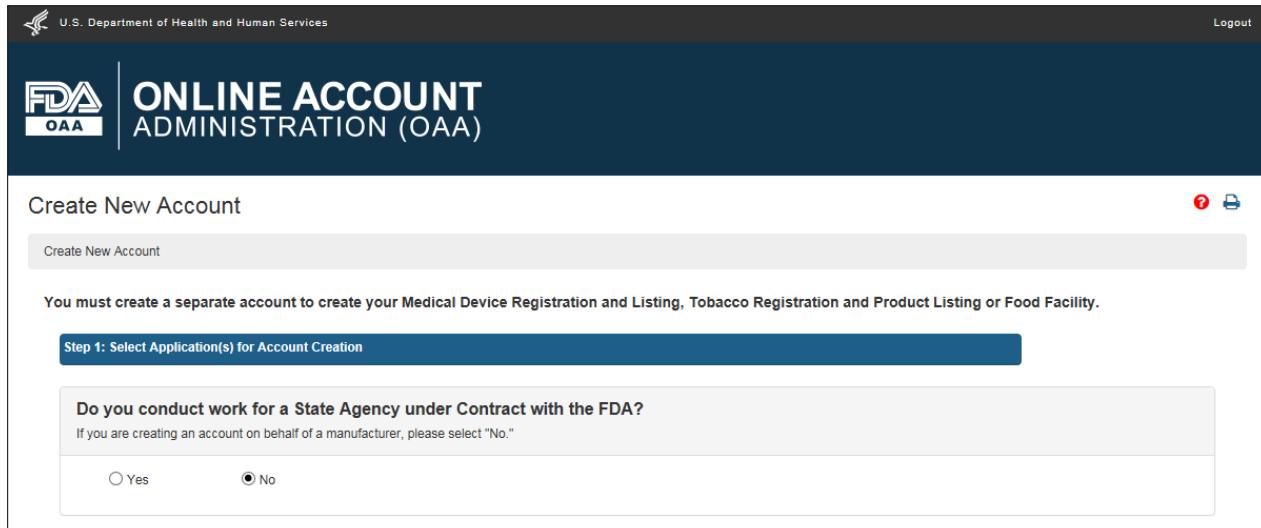
Figure 3.2 – Additional Buttons



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

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

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



U.S. Department of Health and Human Services

Logout

**ONLINE ACCOUNT
ADMINISTRATION (OAA)**

Create New Account

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 will display the various programs available in OAA.

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

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

FSMA Program(s)
<input checked="" type="checkbox"/> Accredited Third-Party Certification Program-- Accreditation Body Check this box if you are an AB and are submitting an application for FDA recognition.
<input type="checkbox"/> Accredited Third-Party Certification Program-- Certification Body Check this box if you are a CB who needs to create an account. You must have a verification code to complete your account setup. FDA will send you the verification code via email after you have been accredited by a recognized AB.
<input type="checkbox"/> FSVP Importer Portal for FSVP Records Submission Check this box if you are an FSVP importer who needs to use a secure portal to submit FSVP records requested by FDA.
<input type="checkbox"/> Laboratory Accreditation for Analyses of Foods Program-- Accreditation Body Check this box if you are an AB and are submitting an application for FDA recognition.
<input type="checkbox"/> Laboratory Accreditation for Analyses of Foods Program-- Accredited Lab Check this box if you are an accredited lab and are creating an account. You must have a verification code to complete your account setup. FDA will send you the verification code via email after you have been accredited by a recognized LAAF AB.
<input type="checkbox"/> Voluntary Qualified Importer Program

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

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

U.S. Department of Health and Human Services [Logout](#)

**ONLINE ACCOUNT
ADMINISTRATION (OAA)**

Create New Account

Step 2: Enter Your Account Information

2A: Point of Contact Information

First Name Country / Area

Middle Initial (Optional) Address Line 1

Optional Address Line 2 (Optional)

Last Name / Surname Optional

Job Title City

Company Name State / Province / Territory

Web Address (Optional) Zip Code (Postal Code)

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

Phone Number Unique Facility Identifier (Optional)

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

Yes No

2B: Account Information

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

Confirm Password

Secret Question 1
Please select a question

Secret Answer 1

Secret Question 2
Please select a question

Secret Answer 2

Secret Question 3
Please select a question

Secret Answer 3

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

[Previous](#) [Clear](#) [Continue](#)

The following navigation buttons can be found throughout the system:

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

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

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

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

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

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

Figure 3.6 – Step 2A: Point of Contact Information

2A: Point of Contact Information

First Name

Middle Initial (Optional)
 Optional

Last Name / Surname

Job Title

Company Name

Web Address (Optional)

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

Phone Number

Country Area Telephone 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)

Country Area Fax Number

E-mail Address

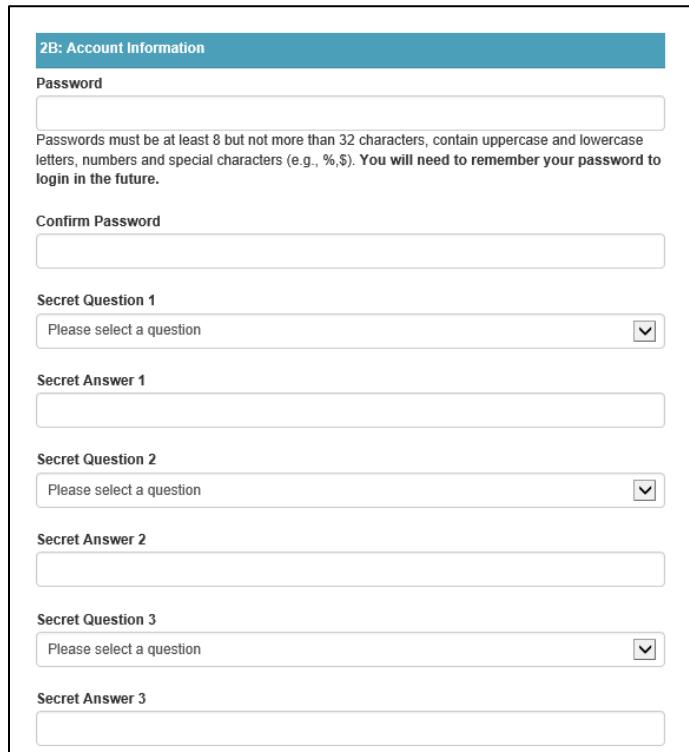
Confirm E-mail Address

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

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

- **Password** – Use this field to create the password for the AB account. Use this password for each system login.
- **Confirm Password** – Re-enter the password in the “Password” field. The entry must match the “Password” field.
- **Secret Question 1** – This is the first secret question used to protect the account. Select a question from the dropdown list.
- **Secret Answer 1** – This is the answer to the first secret question. Enter your response to the question selected in “Secret Question 1.”
- **Secret Question 2** – This is the second secret question used to protect the account. Select a question from the dropdown list.
- **Secret Answer 2** – This is the answer to the second secret question. Enter your response to the question selected in “Secret Question 2.”
- **Secret Question 3** – This is the third secret question used to protect the account. Select a question from the dropdown list.
- **Secret Answer 3** – This is the answer to the third secret question. Enter your response to the question selected in “Secret Question 3.”

Figure 3.7 – Step 2B: Account Information



2B: Account Information

Password

Confirm Password

Secret Question 1

Please select a question

Secret Answer 1

Secret Question 2

Please select a question

Secret Answer 2

Secret Question 3

Please select a question

Secret Answer 3

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.

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

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

2C: Physical Address (Business) of Account Holder

Country / Area
Please Select Country

Address Line 1

Address Line 2 (Optional)
Optional

City

State / Province / Territory
Please Select

Zip Code (Postal Code)

Unique Facility Identifier (Optional)
Optional

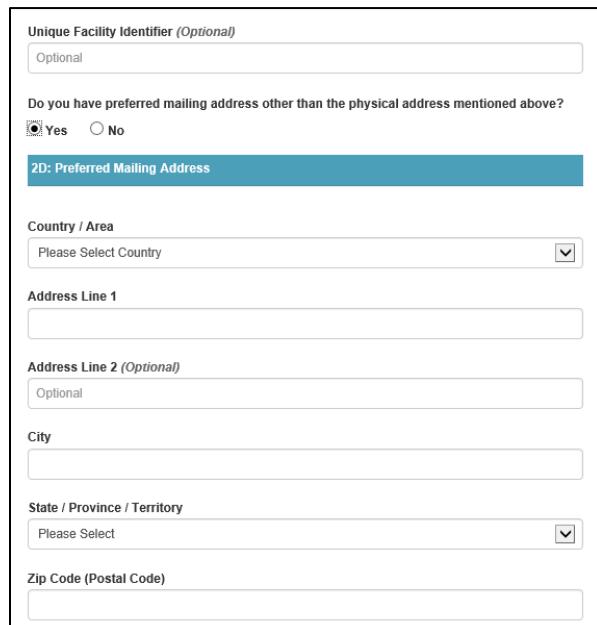
Do you have preferred mailing address other than the physical address mentioned above?

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 dropdown list.
- **Address Line 1** – The address where the business is physically located
This includes the number, street, quadrant, etc.
- **Address Line 2 (Optional field)** – The field to enter additional information about the physical location of the company
This may include a suite or apartment number, if applicable.
- **City** – The city where the business is physically located
- **State/Province/Territory** – The state/province/territory where the business is physically located
- **Zip Code (Postal Code)** – The zip code (domestic) or postal code (foreign) where the business is physically located
- **Unique Facility Identifier (Optional field)** – This may be a DUNS number or FDA Establishment Identifier (FEI)
- **Do you have preferred mailing address other than the physical address mentioned above?** – Select the “Yes” or “No” radio buttons to answer this question.
 - If you select “No,” click the checkbox for “I understand” at the bottom of the page (Figure 3.9). The physical address will be used as the mailing address.
 - If you select “Yes,” “Section 2D: Preferred Mailing Address” will display. Complete the required information for the Preferred Mailing Address to proceed to the next step. Select the checkbox for “I understand” at the bottom of the page (Figure 3.10). The address entered in Section 2D will be used as the mailing address.

Figure 3.9 – Step 2D: Preferred Mailing Address



Unique Facility Identifier (Optional)
Optional

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

2D: Preferred Mailing Address

Country / Area
Please Select Country

Address Line 1

Address Line 2 (Optional)
Optional

City

State / Province / Territory
Please Select

Zip Code (Postal Code)

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

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.

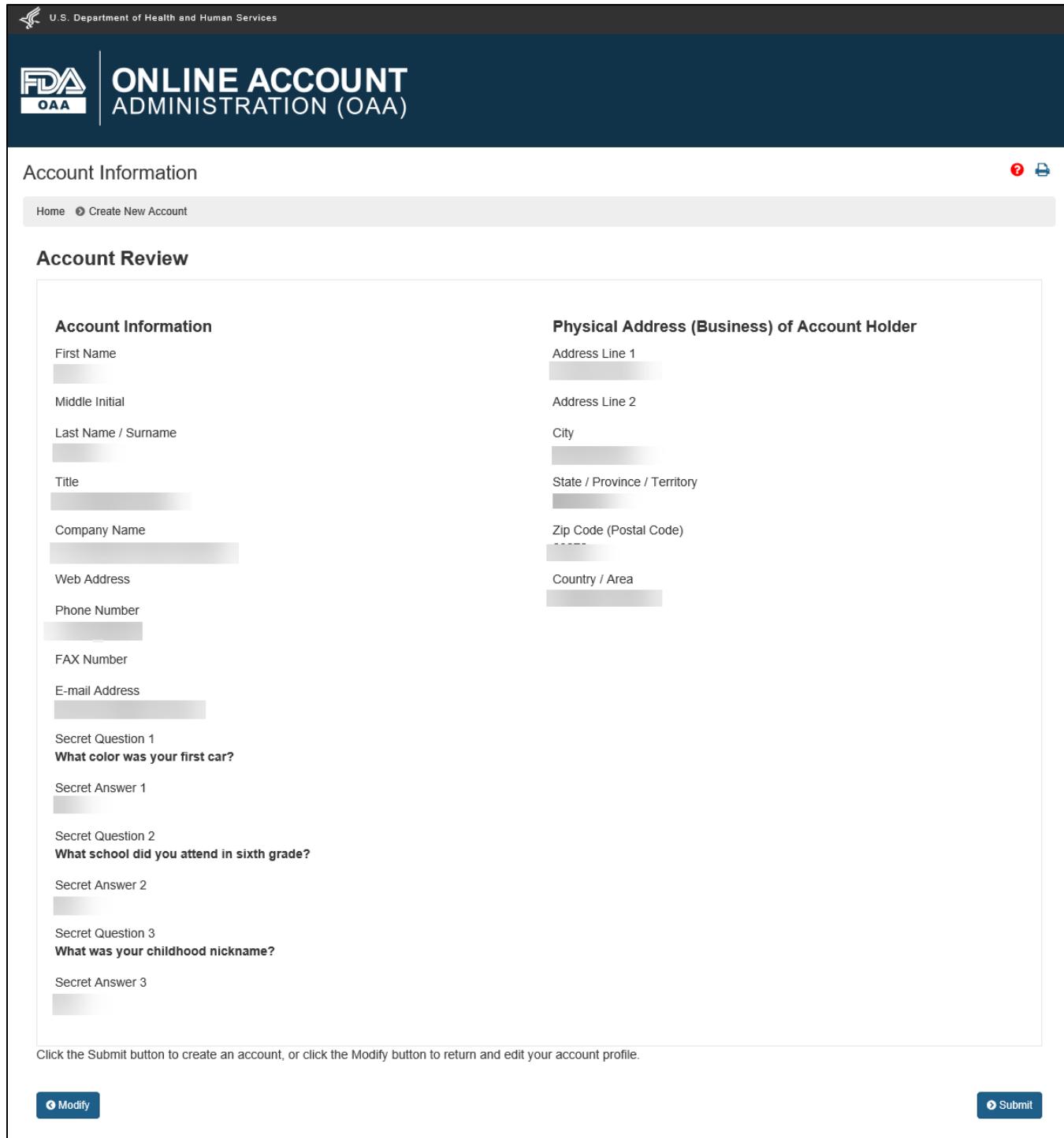
I understand. ←

Previous Clear Continue →

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

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

Figure 3.11 – Account Review Page



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	
First Name		Address Line 1	
Middle Initial		Address Line 2	
Last Name / Surname		City	
Title		State / Province / Territory	
Company Name		Zip Code (Postal Code)	-----
Web Address		Country / Area	
Phone Number			
FAX Number			
E-mail Address			
Secret Question 1 What color was your first car?			
Secret Answer 1			
Secret Question 2 What school did you attend in sixth grade?			
Secret Answer 2			
Secret Question 3 What was your childhood nickname?			
Secret Answer 3			

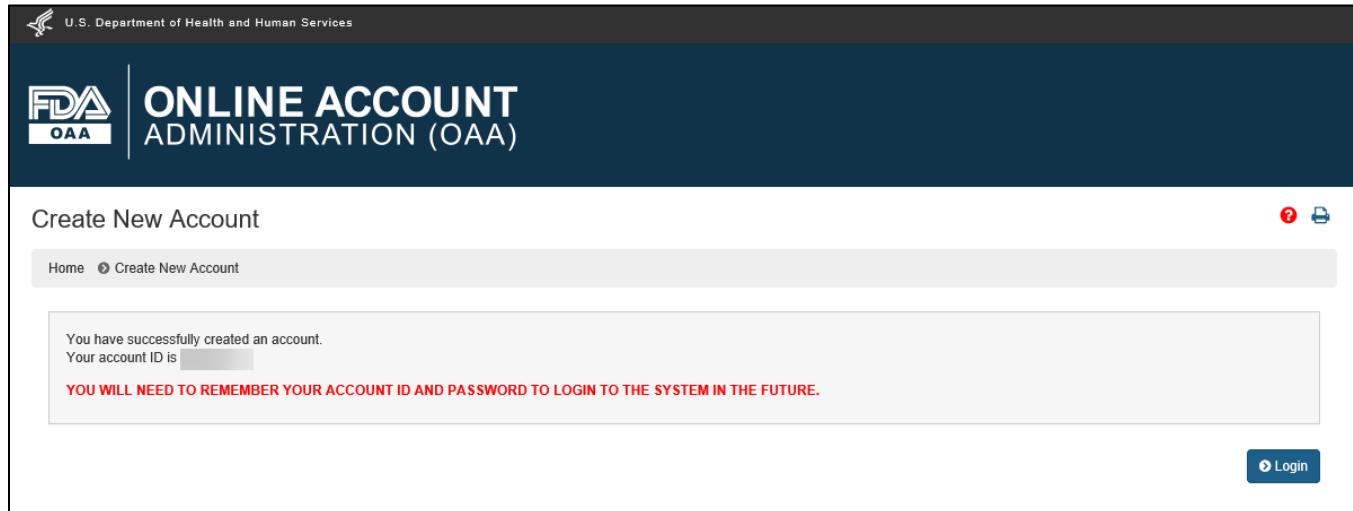
Click the Submit button to create an account, or click the Modify button to return and edit your account profile.

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

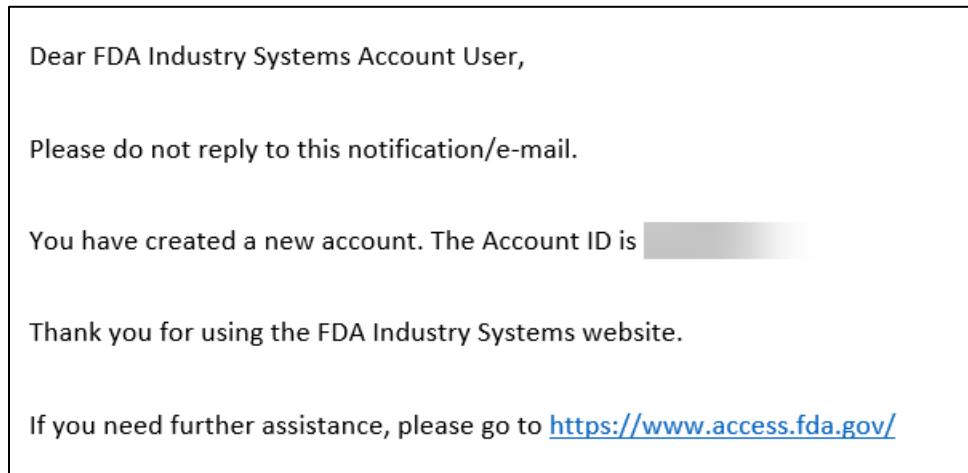
You will need to retain the account ID and password to log into the system in the future.

Figure 3.12 – Successful Account Creation Message



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

Figure 3.13 – User Account Information E-mail Notification



4 Log into the AB Portal

Log into the [FDA “OAA” page](#). This is the same page used to begin the process of creating a new OAA account (Figure 4.1).

Figure 4.1 – OAA Login



U.S. Department of Health and Human Services

ONLINE ACCOUNT ADMINISTRATION (OAA)

FDA Industry Systems

Login

Existing account holders, enter your account ID & password.

Account ID

Password

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

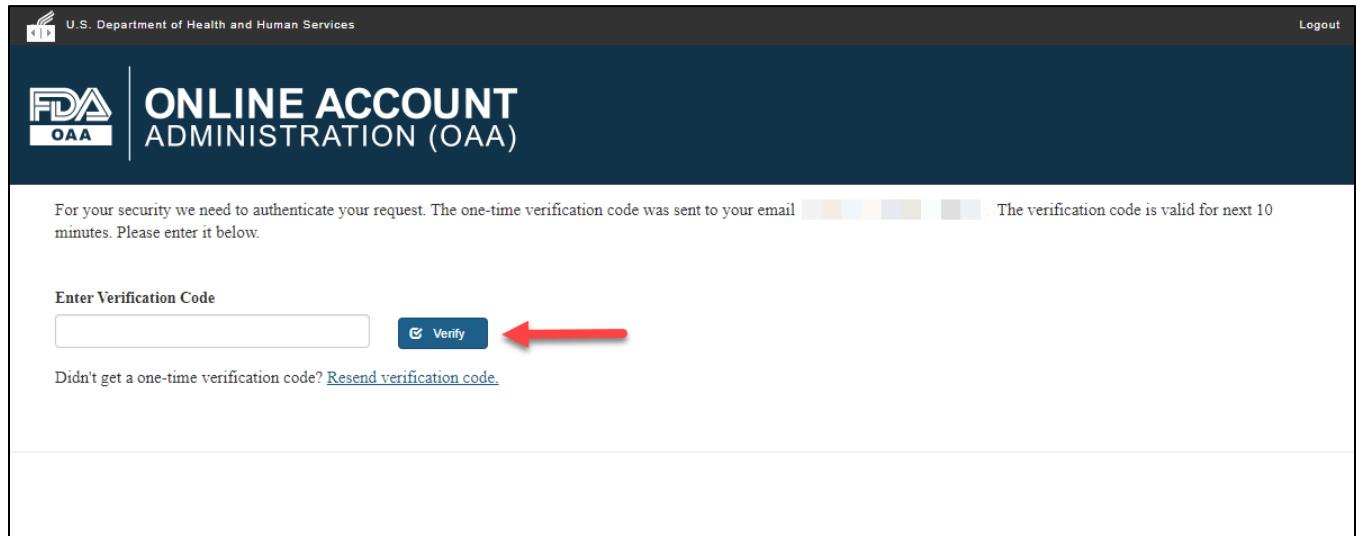
I understand.

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

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

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

Figure 4.2 – Enter Verification Code



U.S. Department of Health and Human Services

Logout

**ONLINE ACCOUNT
ADMINISTRATION (OAA)**

For your security we need to authenticate your request. The one-time verification code was sent to your email [REDACTED] The verification code is valid for next 10 minutes. Please enter it below.

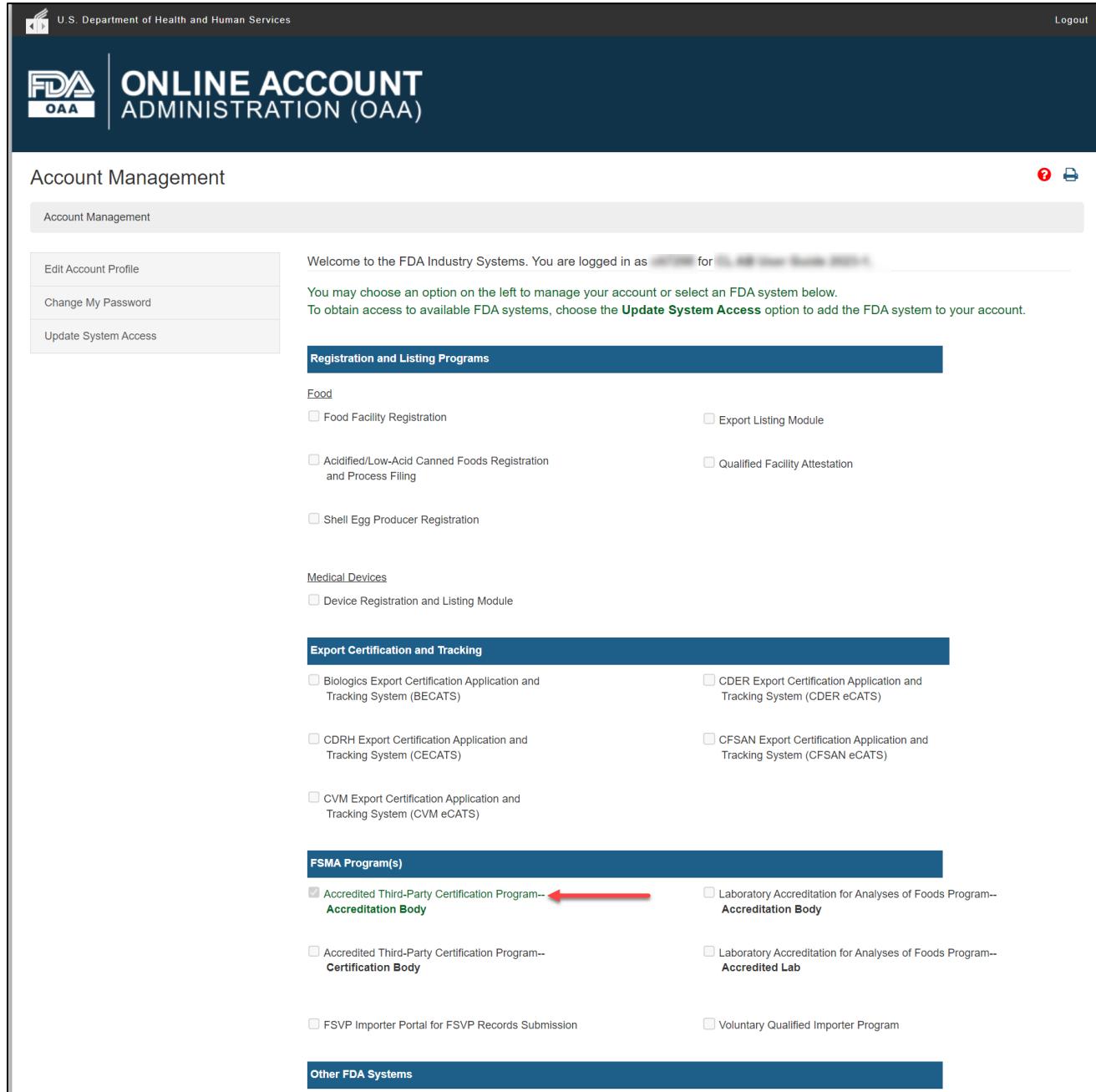
Enter Verification Code

←

Didn't get a one-time verification code? [Resend verification code.](#)

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

Figure 4.3 – OAA – FURLS Account Management Home Page



U.S. Department of Health and Human Services Logout

**ONLINE ACCOUNT
ADMINISTRATION (OAA)**

Account Management

Account Management

Welcome to the FDA Industry Systems. You are logged in as [REDACTED] for [REDACTED]. [View User Guide](#) [Logout](#)

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

Registration and Listing Programs

Food

Food Facility Registration Export Listing Module

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

Shell Egg Producer Registration

Medical Devices

Device Registration and Listing Module

Export Certification and Tracking

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

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

CVM Export Certification Application and Tracking System (CVM eCATS)

FSMA Program(s)

Accredited Third-Party Certification Program--**Accreditation Body** ← Laboratory Accreditation for Analyses of Foods Program--**Accreditation Body**

Accredited Third-Party Certification Program--**Certification Body** Laboratory Accreditation for Analyses of Foods Program--**Accredited Lab**

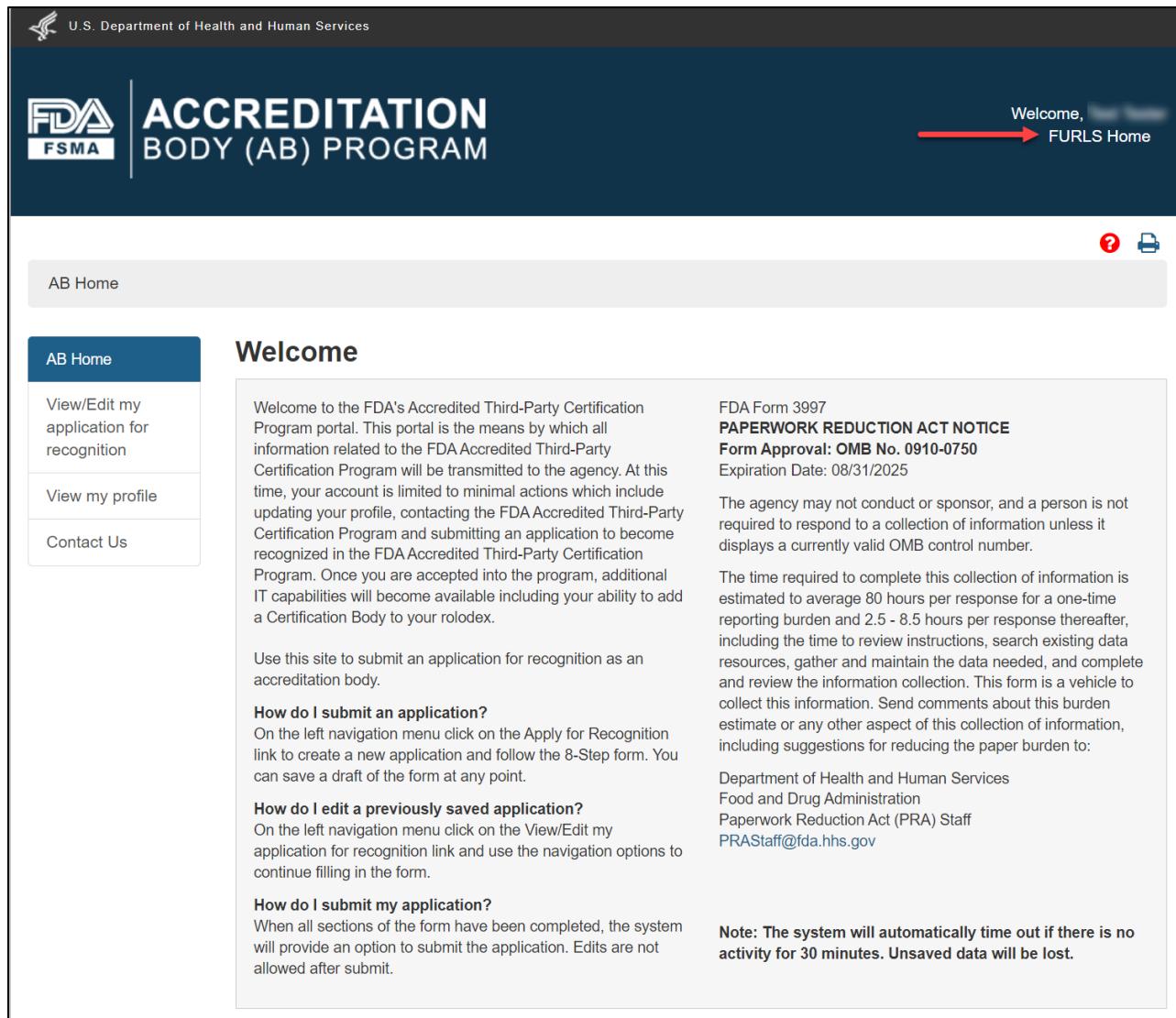
FSVP Importer Portal for FSVP Records Submission Voluntary Qualified Importer Program

Other FDA Systems

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

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

Figure 4.4 – AB Home Page



U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome, [User Name]   

AB Home

Welcome

Welcome to the FDA's Accredited Third-Party Certification Program portal. This portal is the means by which all information related to the FDA Accredited Third-Party Certification 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 Accredited Third-Party Certification Program and submitting an application to become recognized in the FDA Accredited Third-Party Certification 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: 08/31/2025

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

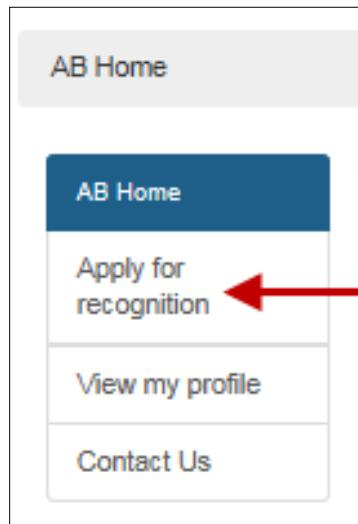
Note: The system will automatically time out if there is no activity for 30 minutes. Unsaved data will be lost.

5 Apply for Recognition

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

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

Figure 5.1 – Navigation Menu



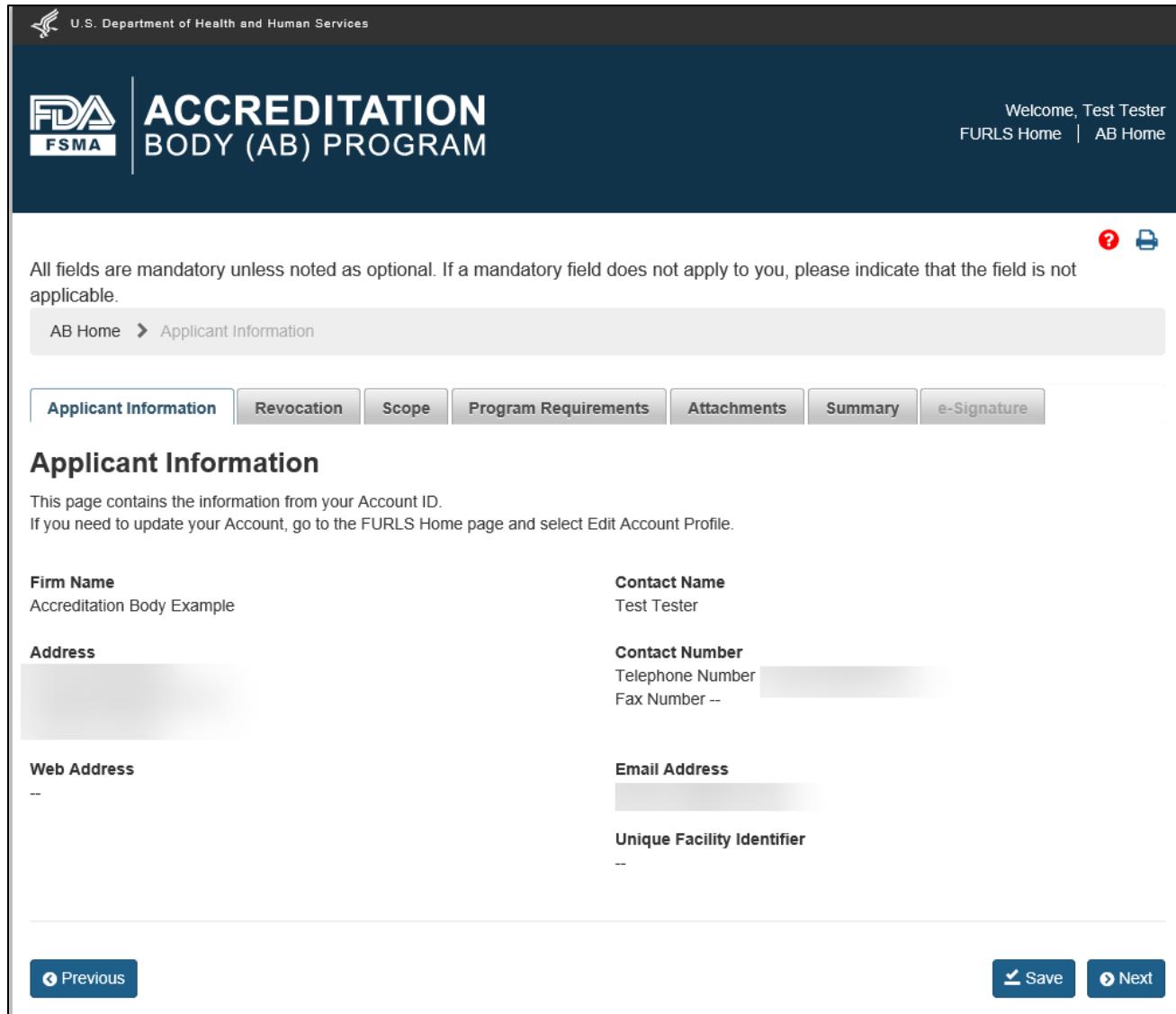
The “Applicant Information” page will open (Figure 5.2).

5.1 Applicant Information Page

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

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

Figure 5.2 – Applicant Information Page



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

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 Example	Contact Name Test Tester
Address [Redacted]	Contact Number Telephone Number [Redacted] Fax Number --
Web Address --	Email Address [Redacted]
Unique Facility Identifier --	

Previous **Save** **Next**

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

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

Figure 5.3 – Previous, Save, and Next Buttons



A screenshot showing a horizontal row of three buttons. From left to right: a blue 'Previous' button with a left arrow icon, a blue 'Save' button with a checkmark icon, and a blue 'Next' button with a right arrow icon.

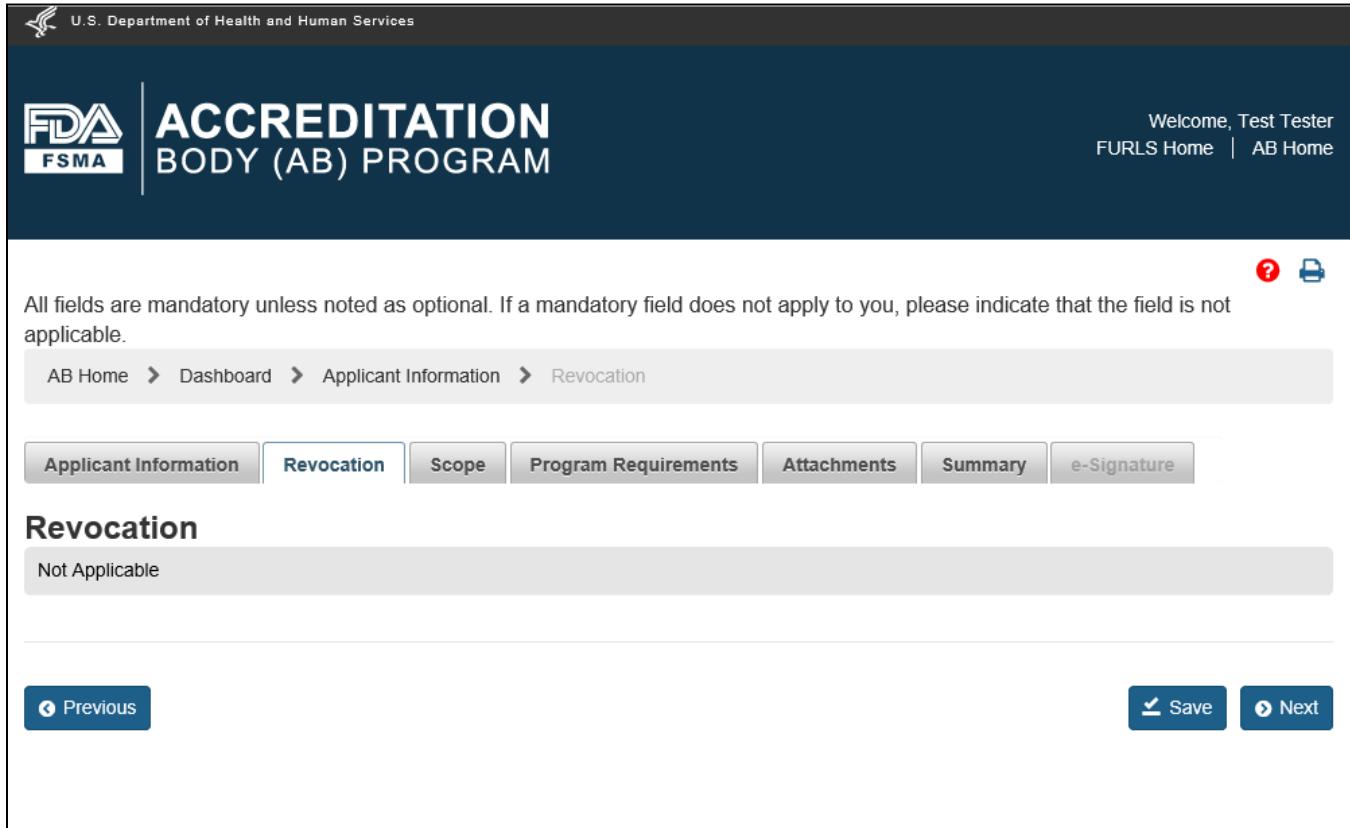
Click the “Next” button to proceed to the next page or, click on the “Revocation” tab.

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

5.2 Revocation Page

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

Figure 5.4 – Revocation Page



A screenshot of a web page for the FDA Accreditation Body (AB) Program. The header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "ACCREDITATION BODY (AB) PROGRAM". On the right, it says "Welcome, Test Tester" and provides links to "FURLS Home" and "AB Home". The main content area has a note: "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." Below this is a breadcrumb navigation: "AB Home > Dashboard > Applicant Information > Revocation". A horizontal navigation bar includes tabs for "Applicant Information", "Revocation" (which is highlighted in blue), "Scope", "Program Requirements", "Attachments", "Summary", and "e-Signature". The "Revocation" section displays the text "Not Applicable". At the bottom are "Previous" and "Next" buttons, along with a "Save" button with a checkmark icon.

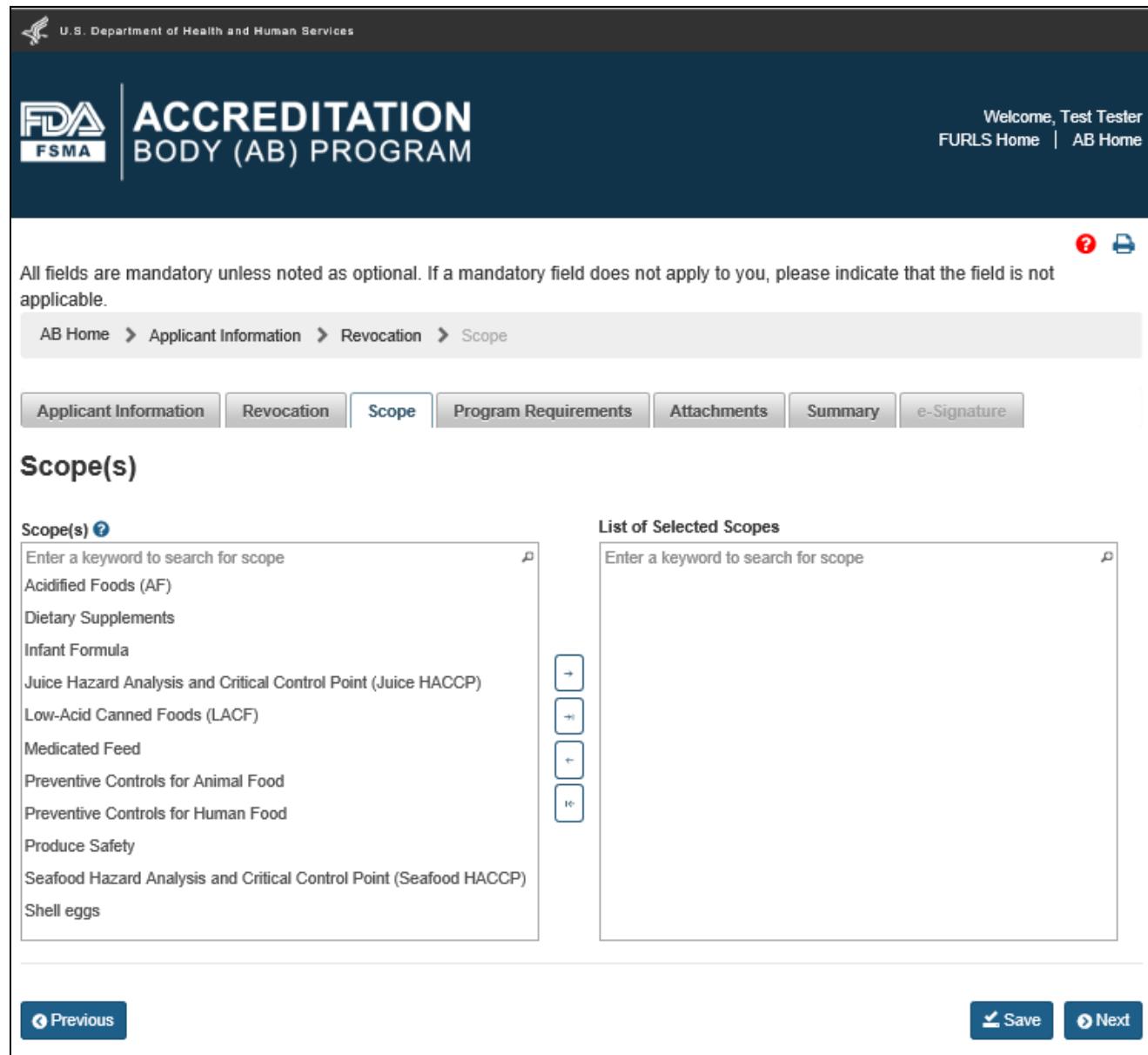
Click the “Next” button to proceed to the next page or, click on the “Scope” tab.

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

5.3 Scope(s) Page

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

Figure 5.5 – Scope Page



The screenshot shows the FDA Accreditation Body (AB) Program Scope page. At the top, there is a navigation bar with links for "Welcome, Test Tester", "FURLS Home", and "AB Home". Below the navigation bar, the page title is "ACCREDITATION BODY (AB) PROGRAM". The main content area has a heading "Scope(s)". On the left, there is a list of scopes with a search bar above it. On the right, there is a list of selected scopes with a search bar above it. There are four buttons between the two lists: a plus sign (+), a plus sign with a minus sign (-), a plus sign with a plus sign (+), and a minus sign (-). At the bottom, there are navigation buttons for "Previous" and "Next", and a "Save" button.

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 Program Requirements Attachments Summary e-Signature

Scope(s)

Scope(s) ?

Enter a keyword to search for scope

- Acidified Foods (AF)
- Dietary Supplements
- Infant Formula
- Juice Hazard Analysis and Critical Control Point (Juice HACCP)
- Low-Acid Canned Foods (LACF)
- Medicated Feed
- Preventive Controls for Animal Food
- Preventive Controls for Human Food
- Produce Safety
- Seafood Hazard Analysis and Critical Control Point (Seafood HACCP)
- Shell eggs

List of Selected Scopes

Enter a keyword to search for scope

- +
-
- +
-

Previous Save Next

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

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

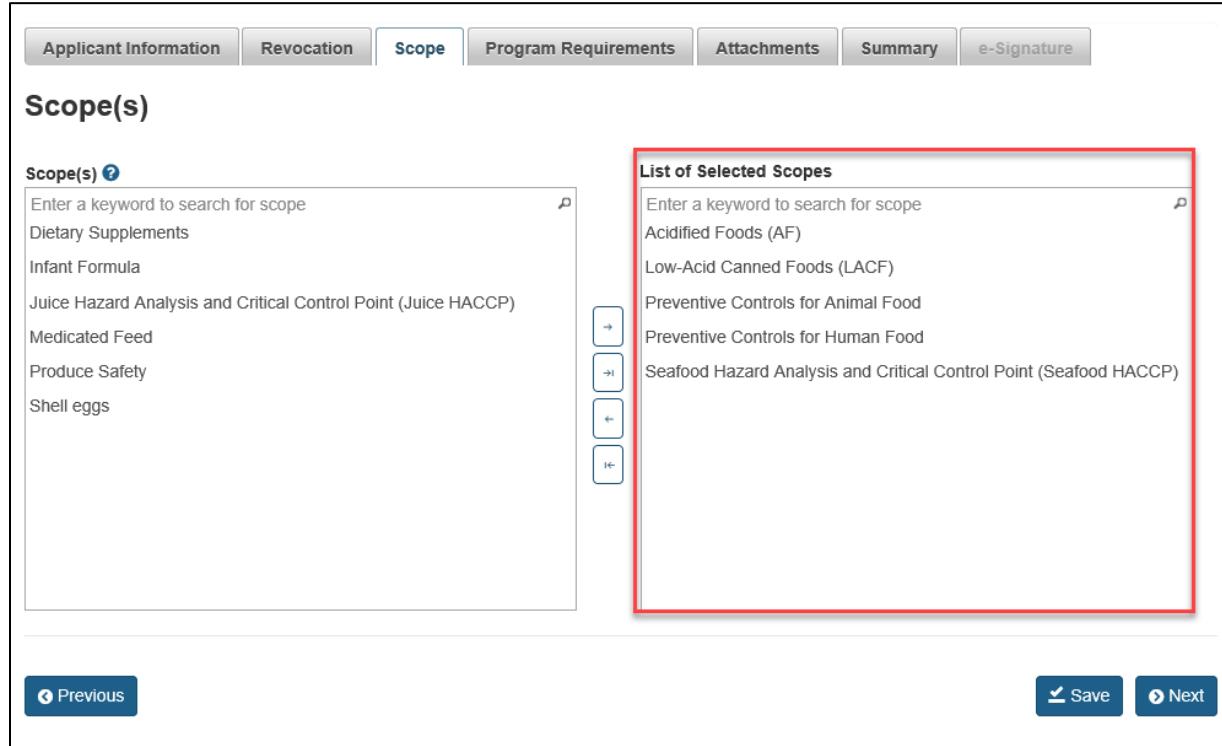
To select a scope, double click on the scope name to move it between sections. You may also left click on the scope name and it will appear highlighted. Select at least one scope and add it to the “List of Selected Scopes” section (on the right-hand side of the page) to complete the application.

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

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

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

Figure 5.6 – List of Selected Scopes



Applicant Information Revocation **Scope** Program Requirements Attachments Summary e-Signature

Scope(s)

Scope(s) ?
Enter a keyword to search for scope

- Dietary Supplements
- Infant Formula
- Juice Hazard Analysis and Critical Control Point (Juice HACCP)
- Medicated Feed
- Produce Safety
- Shell eggs

List of Selected Scopes
Enter a keyword to search for scope

- Acidified Foods (AF)
- Low-Acid Canned Foods (LACF)
- Preventive Controls for Animal Food
- Preventive Controls for Human Food
- Seafood Hazard Analysis and Critical Control Point (Seafood HACCP)

Previous **Save** Next

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

The system will display the “Program Requirements” page.

5.4 Program Requirements Page

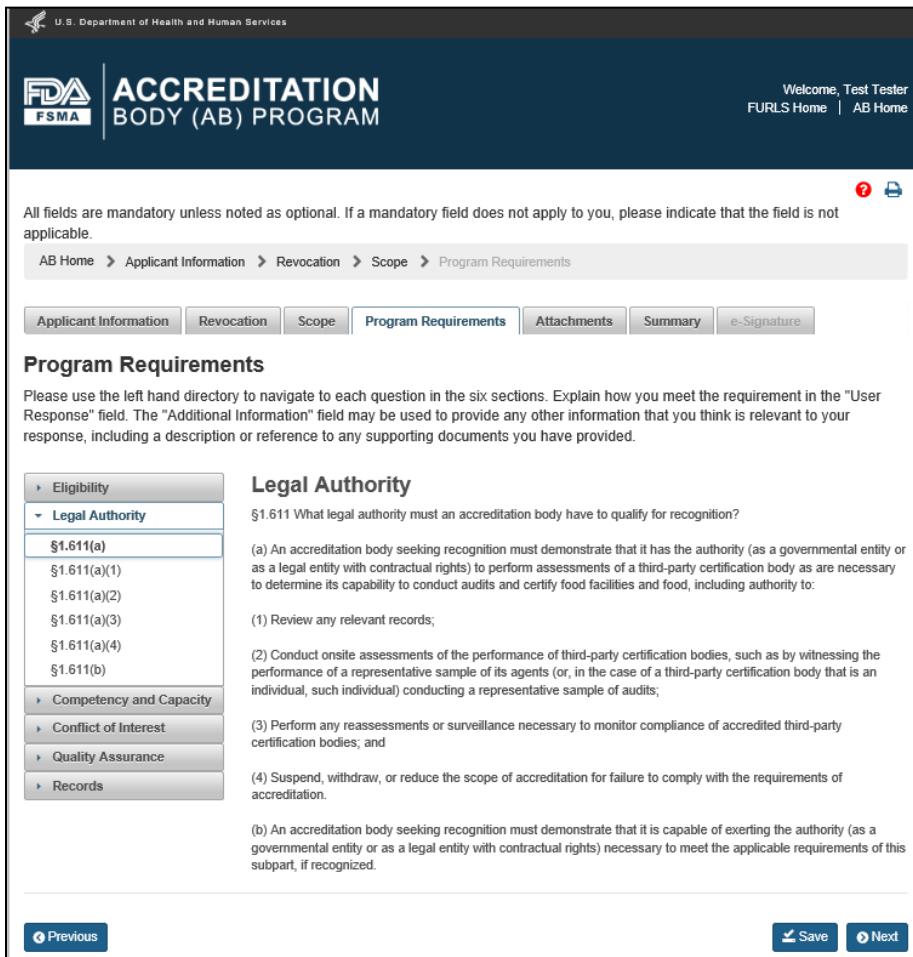
The “Program Requirements” page is where you will answer questions and attach files in accordance with the following requirement sections:

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

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

Note: The “Eligibility” section is informational only.

Figure 5.7 – Program Requirements Page Default View



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 > Applicant Information > Revocation > Scope > Program Requirements

Applicant Information Revocation Scope Program Requirements **Program Requirements** Attachments Summary e-Signature

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Legal Authority

§1.611 What legal authority must an accreditation body have to qualify for recognition?

(a) An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

(1) Review any relevant records;

(2) Conduct onsite assessments of the performance of third-party certification bodies, such as by witnessing the performance of a representative sample of its agents (or, in the case of a third-party certification body that is an individual, such individual) conducting a representative sample of audits;

(3) Perform any reassessments or surveillance necessary to monitor compliance of accredited third-party certification bodies; and

(4) Suspend, withdraw, or reduce the scope of accreditation for failure to comply with the requirements of accreditation.

(b) An accreditation body seeking recognition must demonstrate that it is capable of exerting the authority (as a governmental entity or as a legal entity with contractual rights) necessary to meet the applicable requirements of this subpart, if recognized.

Previous Save Next

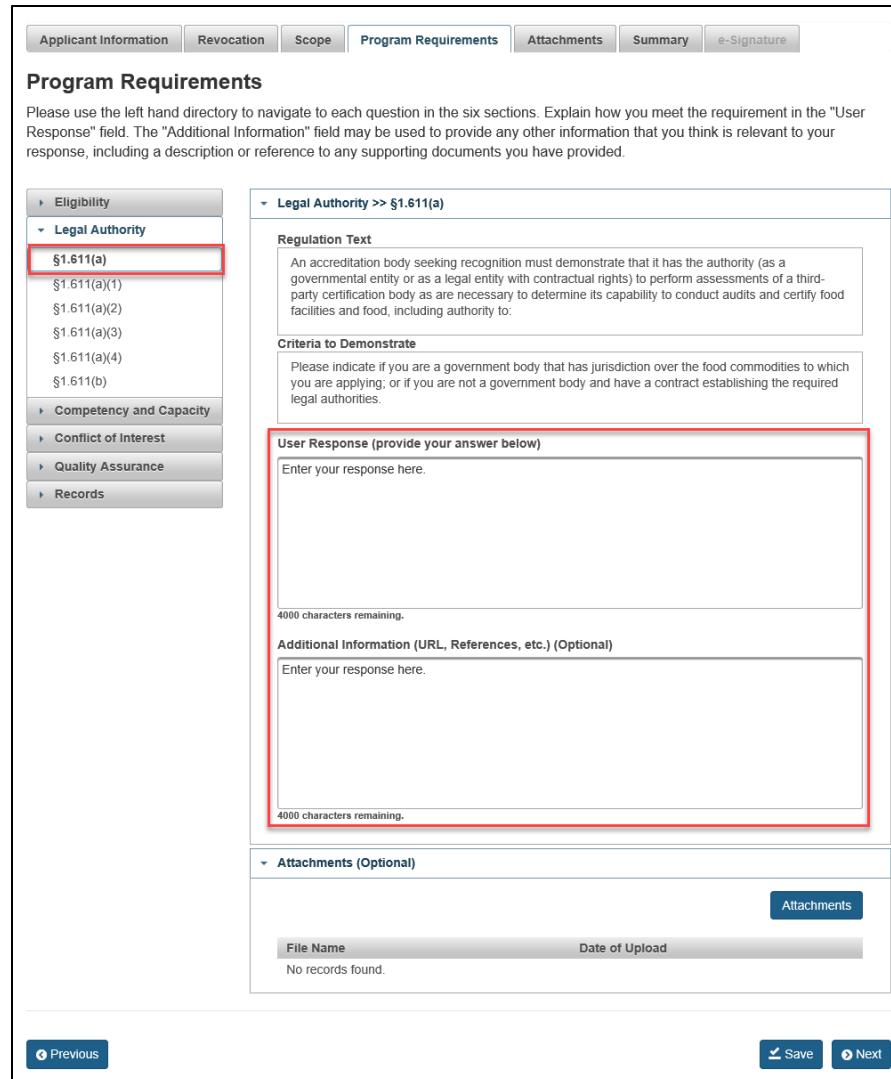
Each section has a definition and associated questions. Click the section heading to display the question links. Click on each requirement to display the user input fields (Figure 5.8).

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

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

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

Figure 5.8 – Program Requirements User Input Fields



Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Eligibility

Legal Authority

§1.611(a) (boxed)

- §1.611(a)(1)
- §1.611(a)(2)
- §1.611(a)(3)
- §1.611(a)(4)
- §1.611(b)

Competency and Capacity

Conflict of Interest

Quality Assurance

Records

Legal Authority >> §1.611(a)

Regulation Text

An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

Criteria to Demonstrate

Please indicate if you are a government body that has jurisdiction over the food commodities to which you are applying; or if you are not a government body and have a contract establishing the required legal authorities.

User Response (provide your answer below)

Enter your response here.

4000 characters remaining.

Additional Information (URL, References, etc.) (Optional)

Enter your response here.

4000 characters remaining.

Attachments (Optional)

Attachments

File Name	Date of Upload
No records found.	

Previous  Save  Next 

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

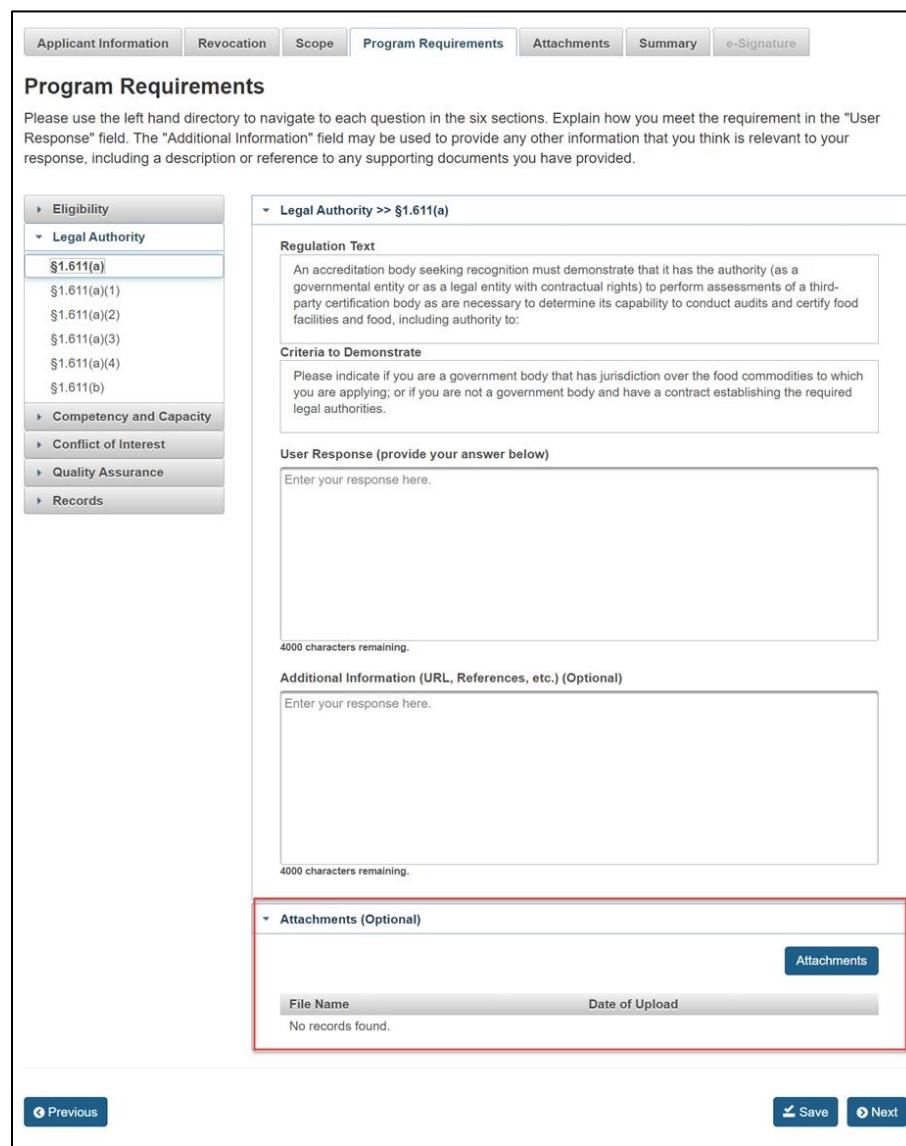
Attachments must be a document type supported by the system.

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

The maximum file size allowed is 50 MB.

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

Figure 5.9 – Attachments Section



The screenshot shows a web-based application for program requirements. At the top, there is a navigation bar with tabs: Applicant Information, Revocation, Scope, Program Requirements, **Attachments** (which is the active tab), Summary, and e-Signature. Below the navigation bar, the main content area is titled "Program Requirements". A sidebar on the left contains a tree view of sections: Eligibility, Legal Authority (which is expanded, showing §1.611(a) with sub-options 1 through 4, and §1.611(b)), Competency and Capacity, Conflict of Interest, Quality Assurance, and Records. The main content area for "Legal Authority >> §1.611(a)" includes a "Regulation Text" section with a box containing text about accreditation bodies, and a "Criteria to Demonstrate" section with a box containing text about jurisdiction or contracts. Below these are "User Response (provide your answer below)" and "Additional Information (URL, References, etc.) (Optional)" sections, each with a text area and a character count of "4000 characters remaining". At the bottom of the main content area, there is a section titled "Attachments (Optional)" with a table showing "File Name" and "Date of Upload", and a note "No records found." To the right of this table is a blue "Attachments" button. At the very bottom of the page are navigation buttons: "Previous", "Save" (with a back arrow), and "Next".

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

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

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

Click the “Upload” button to complete the upload.

Figure 5.10 – Attachments Window

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Attachments

Add Attachments

Instructions

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

Note:

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

+ Browse

Upload

Cancel

Manage Attachments

File Name	Date of Upload	Action
No records found.		

Close

4000 characters remaining.

Attachments (Optional)

Attachments

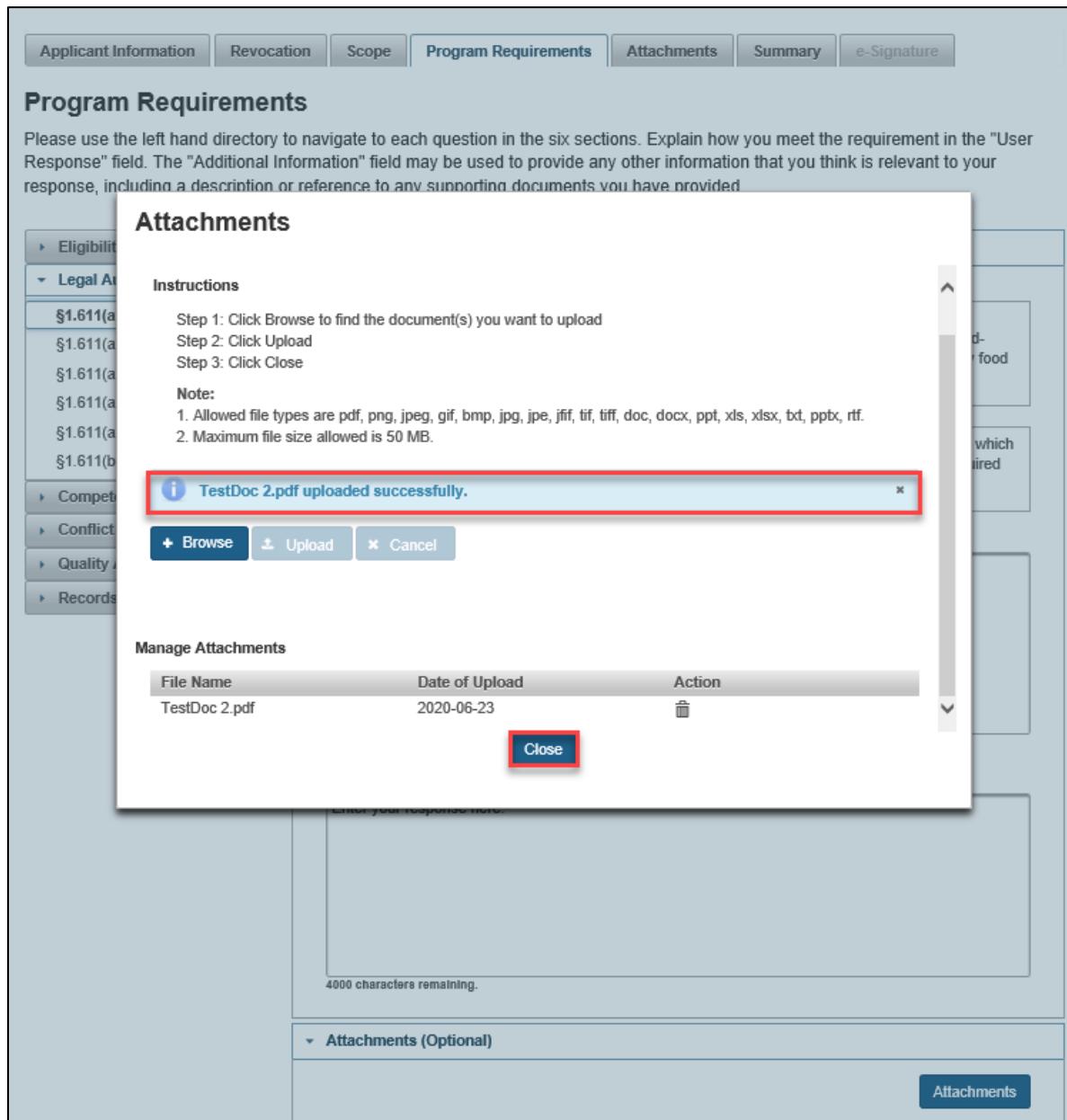
File Name	Date of Upload
No records found.	

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

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

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

Figure 5.11 – Attachments to Program Requirements Questions



Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Attachments

Instructions

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

Note:

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

TestDoc 2.pdf uploaded successfully.

+ Browse  Upload  Cancel

Manage Attachments

File Name	Date of Upload	Action
TestDoc 2.pdf	2020-06-23	

Close

4000 characters remaining.

Attachments (Optional)

Attachments

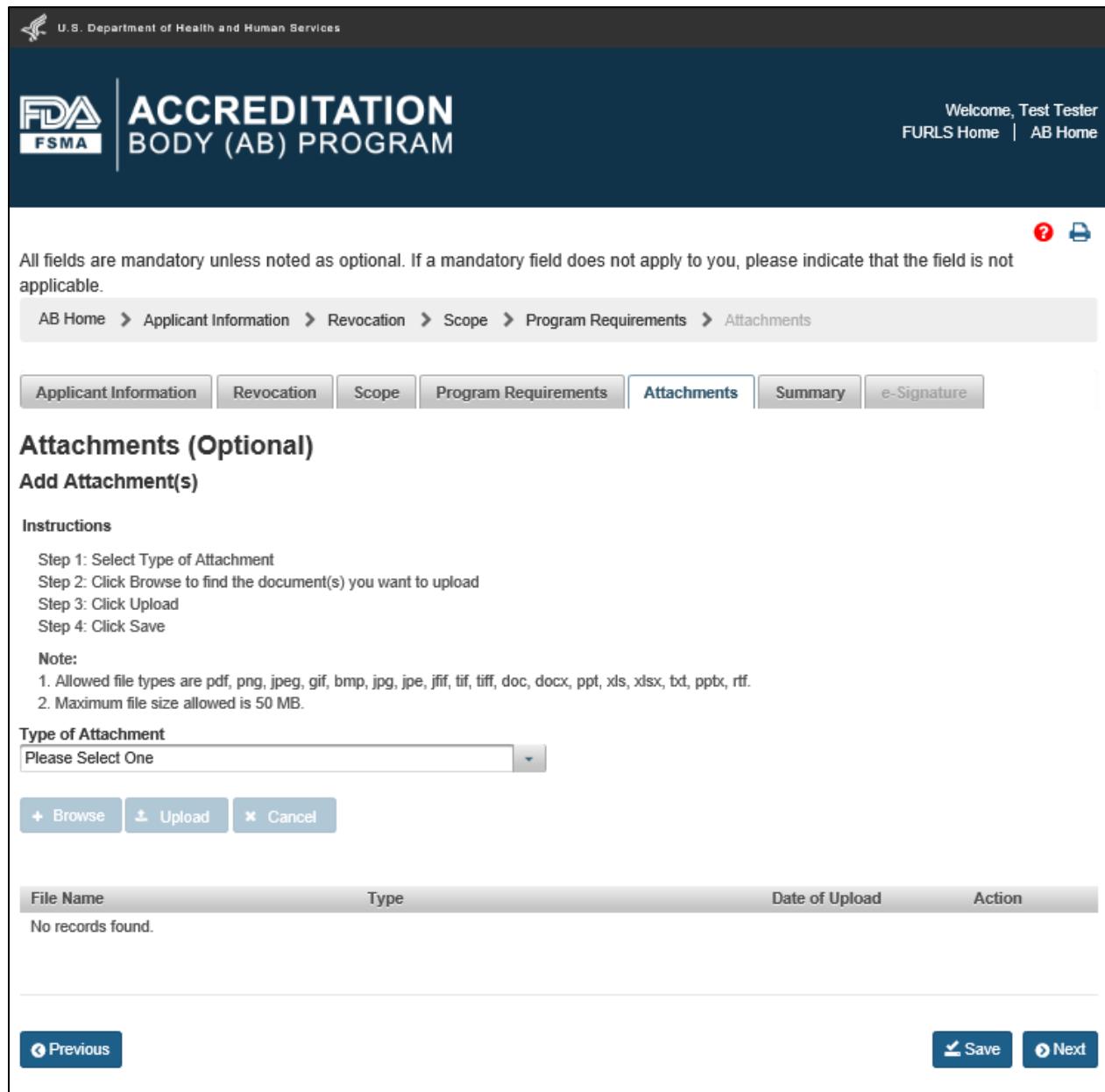
****Important:** Click the “Save” button upon completion.

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

5.5 Attachments Page

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

Figure 5.12 – Attachment Instructions



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 > Program Requirements > Attachments

Applicant Information Revocation Scope Program Requirements **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, jifif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

Type of Attachment

Please Select One

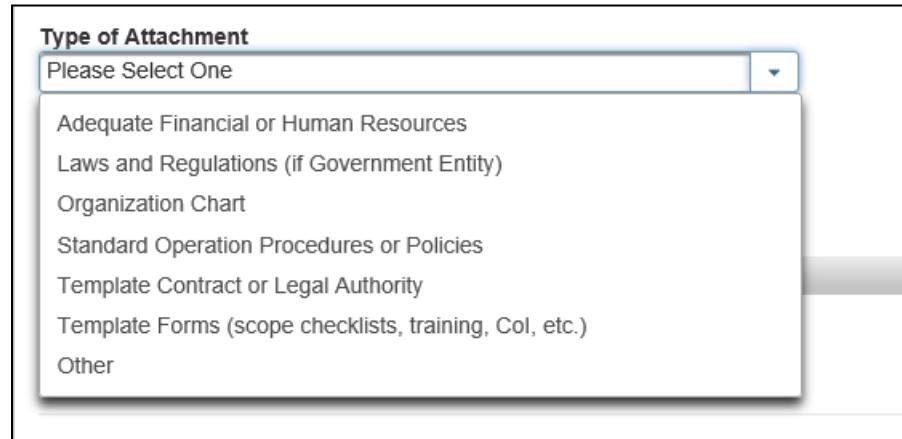
+ Browse Upload × Cancel

File Name	Type	Date of Upload	Action
No records found.			

◀ Previous Save ▶ Next

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

Figure 5.13 – Type of Attachment



Type of Attachment

Please Select One

- Adequate Financial or Human Resources
- Laws and Regulations (if Government Entity)
- Organization Chart
- Standard Operation Procedures or Policies
- Template Contract or Legal Authority
- Template Forms (scope checklists, training, Col, etc.)
- Other

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

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

Figure 5.14 – Other Attachments

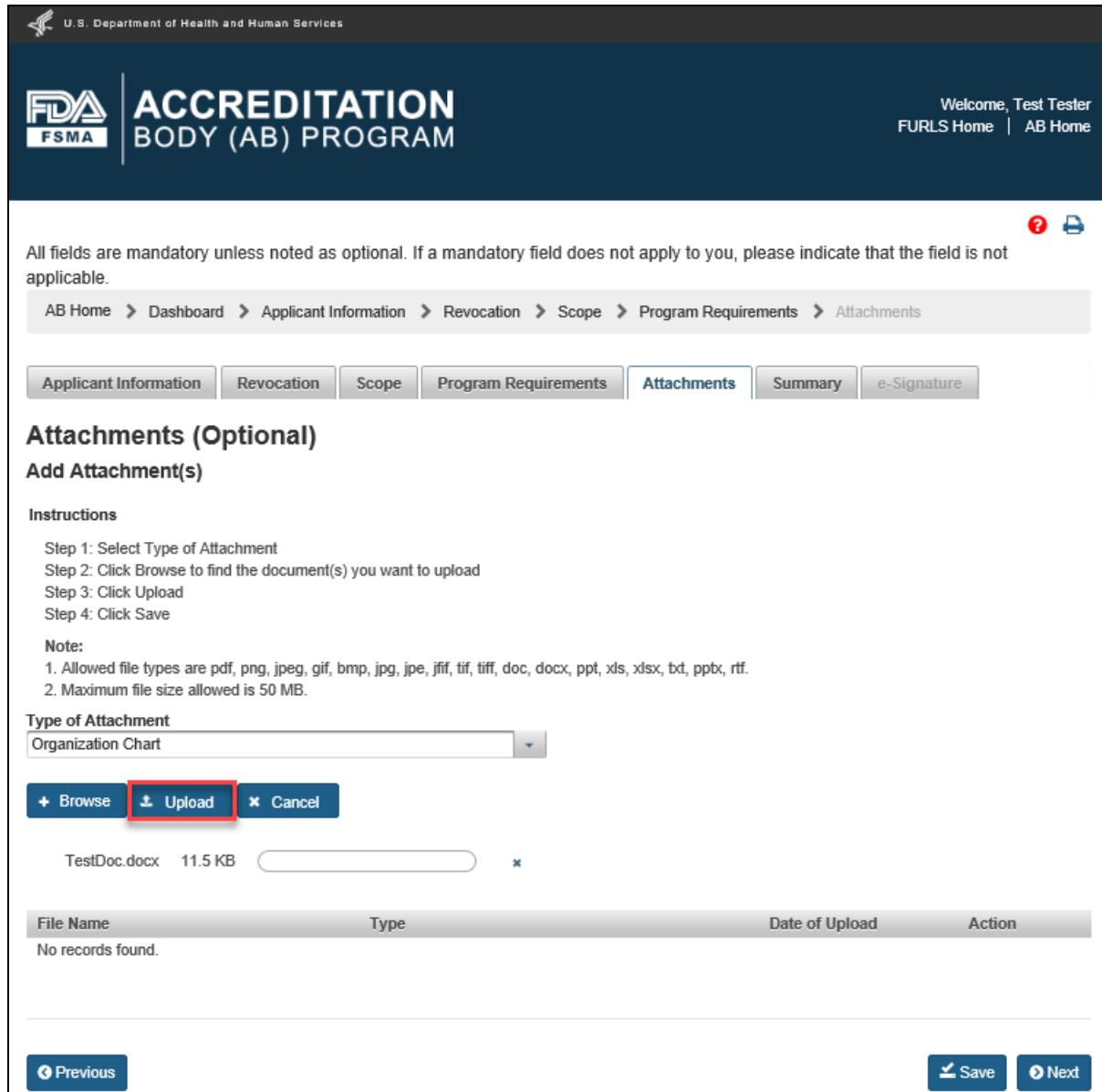


Type of Attachment	Additional Description
Other	Enter Description

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

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

Figure 5.15 – Upload and Cancel Buttons



U.S. Department of Health and Human Services

FDA | **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 > Program Requirements > Attachments

Applicant Information Revocation Scope Program Requirements **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, jifif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, ppbx, rtf.
2. Maximum file size allowed is 50 MB.

Type of Attachment

Organization Chart

+ Browse **Upload** Cancel

TestDoc.docx 11.5 KB

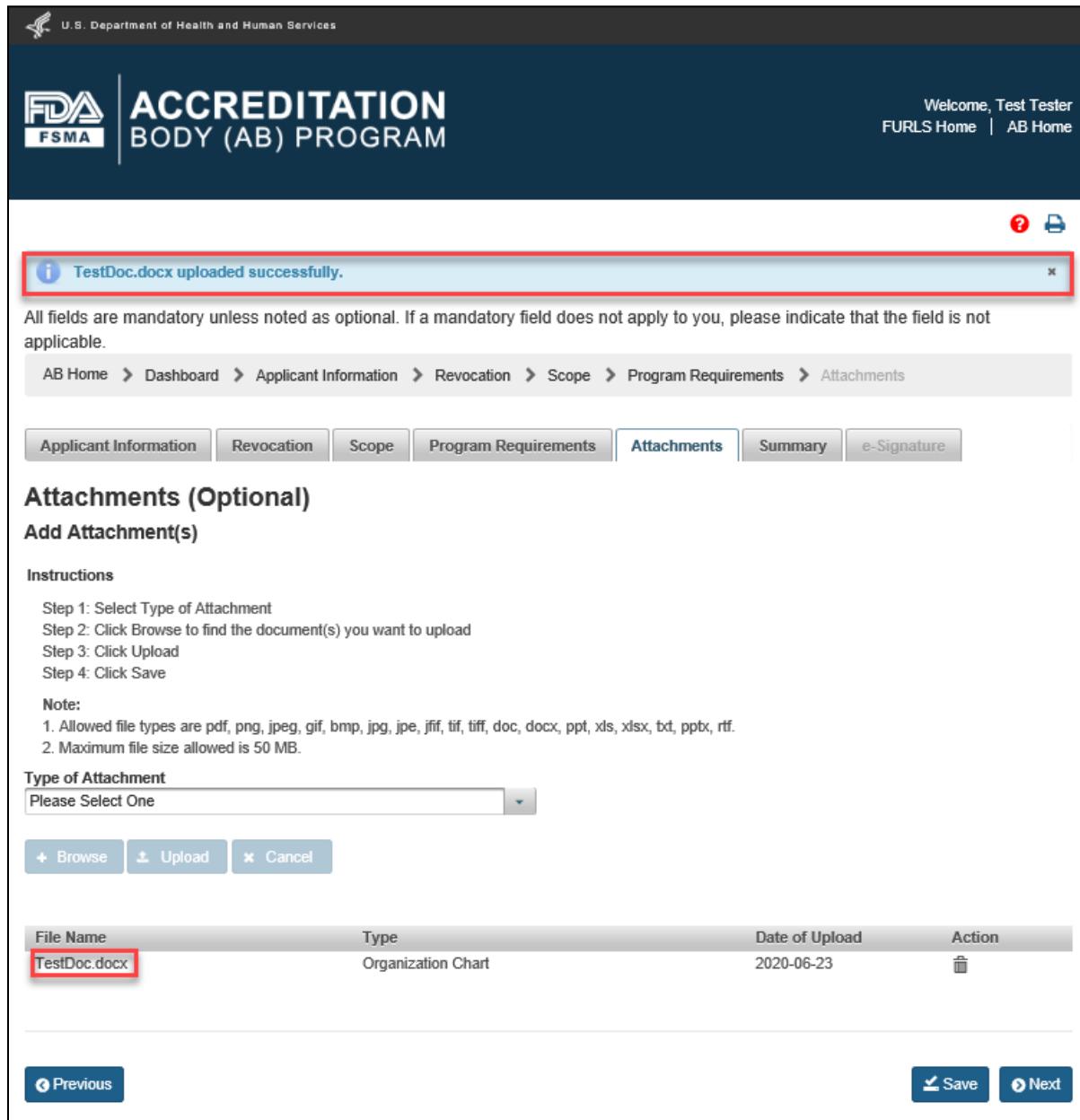
File Name	Type	Date of Upload	Action
No records found.			

Previous **Save** Next

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

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

Figure 5.16 – Successful Upload Message



The screenshot shows the FDA Accreditation Body (AB) Program website. At the top, the FDA logo and "U.S. Department of Health and Human Services" are visible. The header also includes "Welcome, Test Tester" and links to "FURLS Home" and "AB Home". The main content area shows a message: "TestDoc.docx uploaded successfully." Below this, a note 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." The breadcrumb navigation shows: "AB Home > Dashboard > Applicant Information > Revocation > Scope > Program Requirements > Attachments". The "Attachments" tab is selected. The "Attachments (Optional)" section contains an "Add Attachment(s)" button. Below it, "Instructions" provide a four-step process: 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. A "Note" section specifies allowed file types (pdf, png, jpeg, gif, bmp, jpg, jpe, jifif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf) and a maximum file size of 50 MB. A "Type of Attachment" dropdown is set to "Please Select One". Below it are "Browse", "Upload", and "Cancel" buttons. A table lists the uploaded file: "TestDoc.docx" (Type: Organization Chart, Date of Upload: 2020-06-23). At the bottom are "Previous", "Save", and "Next" buttons.

File Name	Type	Date of Upload	Action
TestDoc.docx	Organization Chart	2020-06-23	

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

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

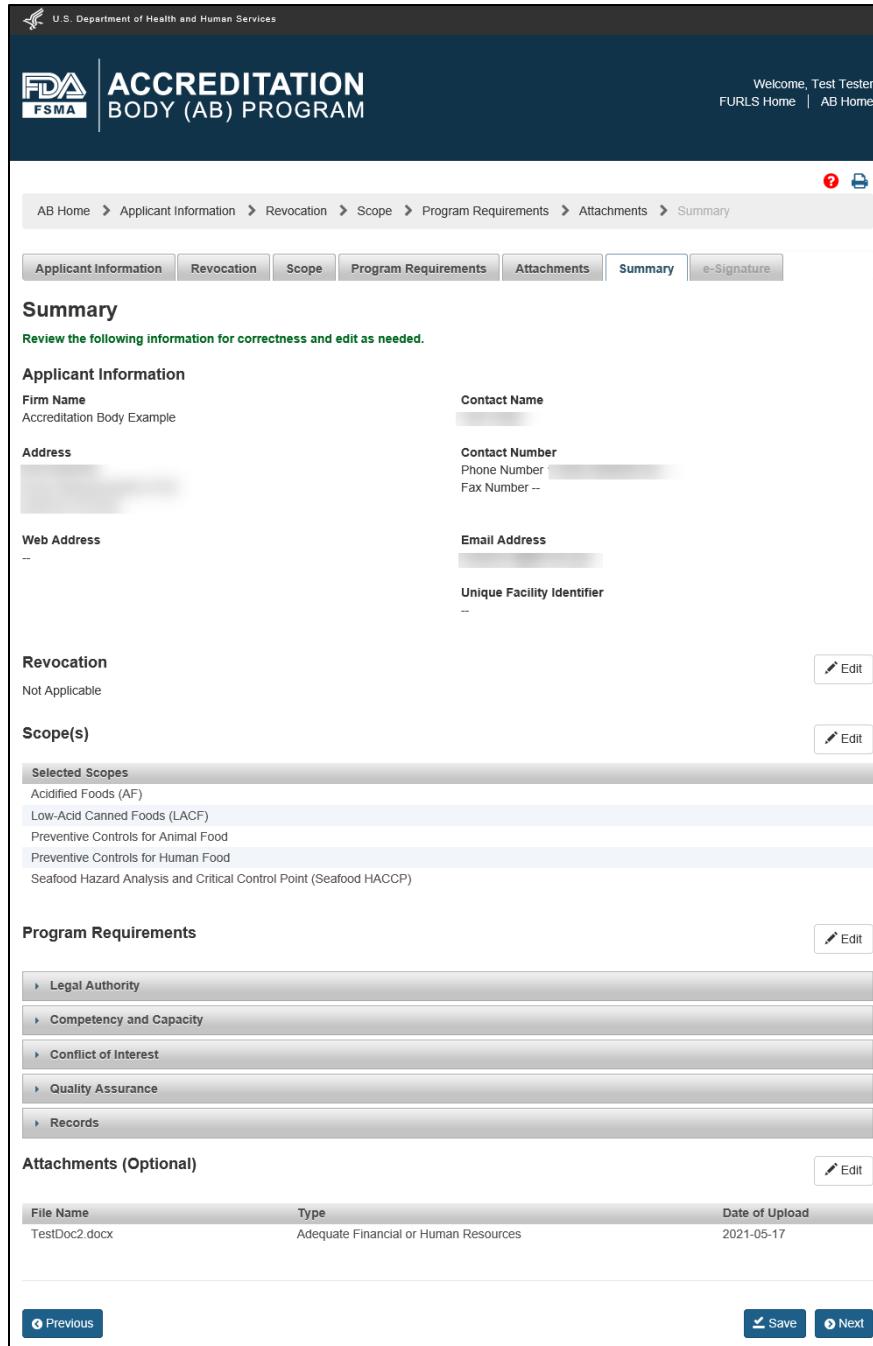
Click the “Next” button to proceed to the next page or, click on the “Summary” tab.

The system will display the “Summary” page.

5.6 Summary Page

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

Figure 5.17 – Summary Page



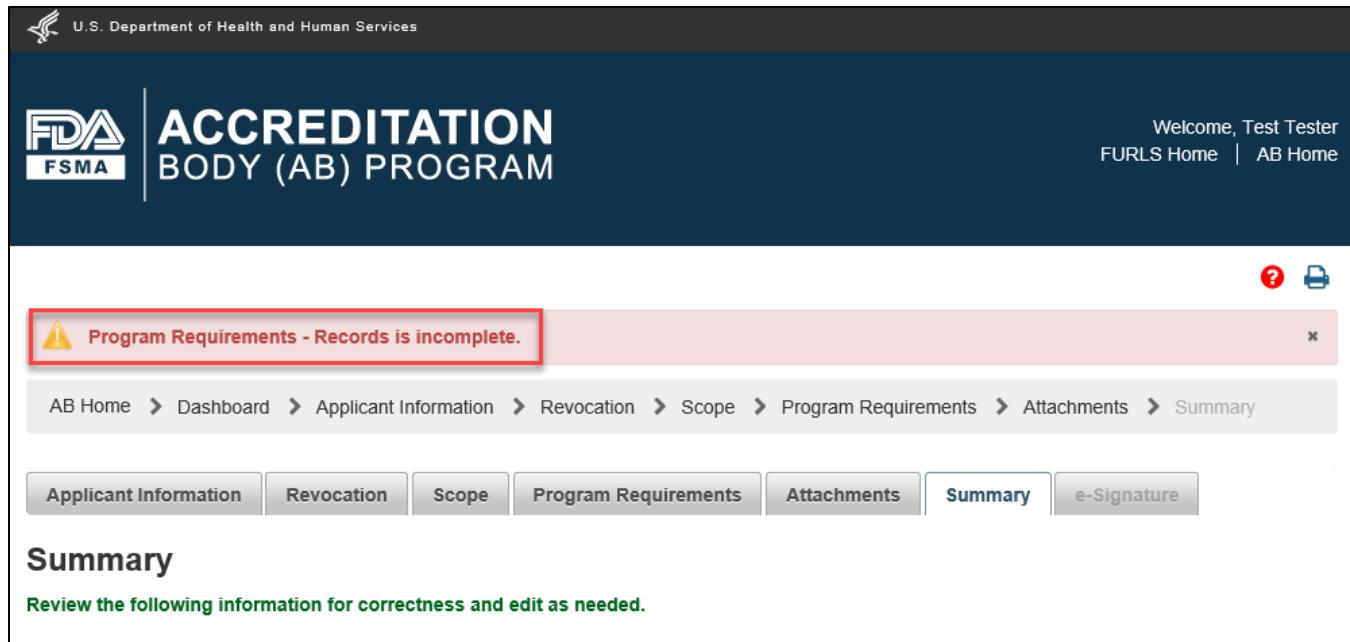
The screenshot shows the "Summary" page of the FDA FSMA Accreditation Body (AB) Program. The page is titled "ACCREDITATION BODY (AB) PROGRAM". The navigation bar at the top includes links for "Welcome, Test Tester", "FURLS Home", and "AB Home". The main content area is titled "Summary" and contains the following sections:

- Applicant Information:** Fields include Firm Name (Accreditation Body Example), Address (redacted), Web Address (redacted), Contact Name (redacted), Contact Number (Phone Number and Fax Number both redacted), Email Address (redacted), and Unique Facility Identifier (redacted).
- Revocation:** Status is "Not Applicable".
- Scope(s):** "Selected Scopes" list includes Acidified Foods (AF), Low-Acid Canned Foods (LACF), Preventive Controls for Animal Food, Preventive Controls for Human Food, and Seafood Hazard Analysis and Critical Control Point (Seafood HACCP).
- Program Requirements:** A list of requirements with "Edit" buttons: Legal Authority, Competency and Capacity, Conflict of Interest, Quality Assurance, and Records.
- Attachments (Optional):** A table showing one attachment: TestDoc2.docx, Type: Adequate Financial or Human Resources, Date of Upload: 2021-05-17.

At the bottom, there are buttons for "Previous", "Save" (with a checkmark icon), and "Next".

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

Figure 5.18 – Summary Page Error Message



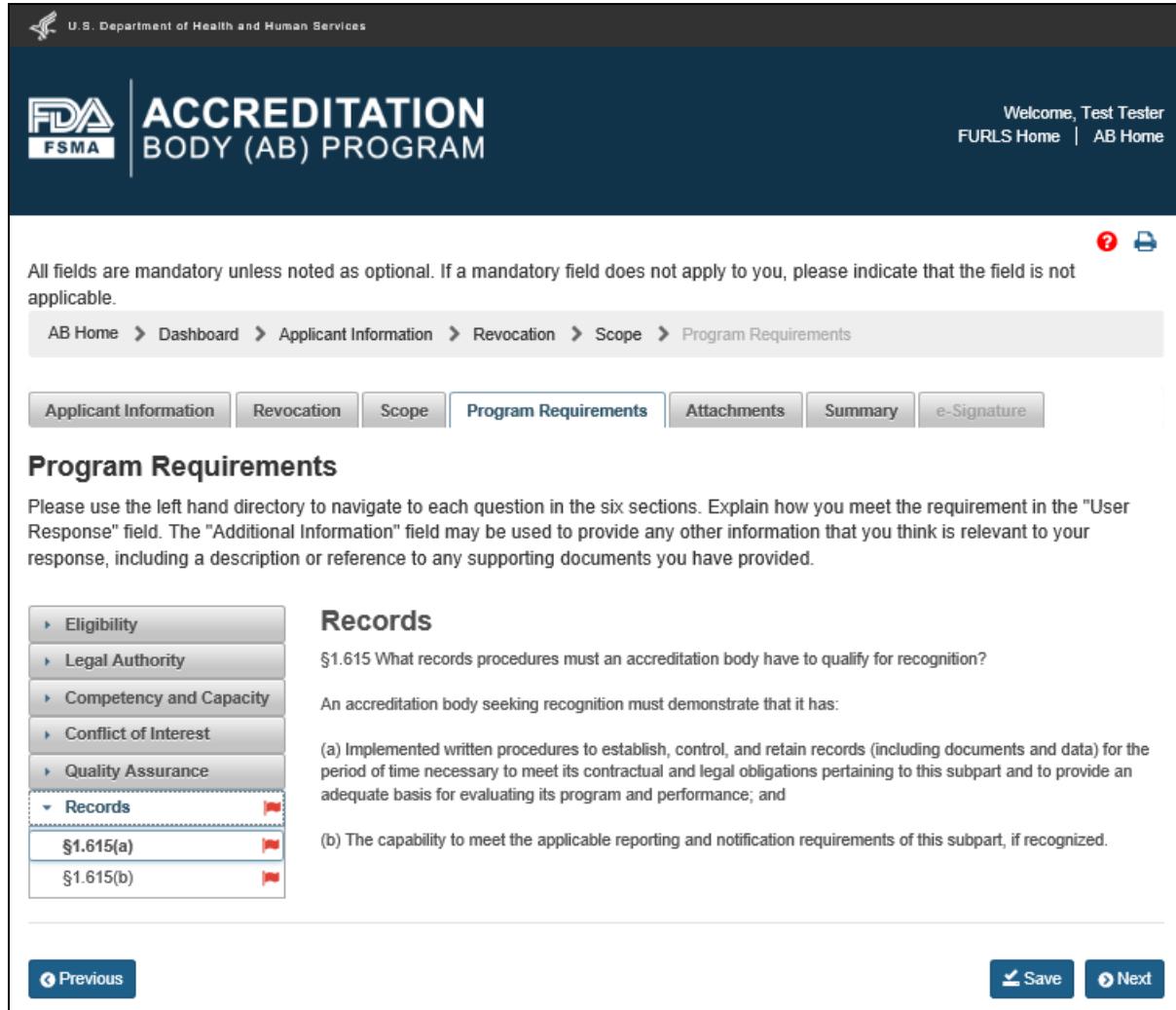
The screenshot shows the FDA Accreditation Body (AB) Program Summary page. At the top, the FDA FSMA logo is on the left, and the text "U.S. Department of Health and Human Services" is on the right. The main title "ACCREDITATION BODY (AB) PROGRAM" is centered. On the right side, there is a "Welcome, Test Tester" message with links to "FURLS Home" and "AB Home". Below the title, a red alert box contains the message "Program Requirements - Records is incomplete." A red flag icon is positioned next to the word "Program". The navigation menu at the top includes links for "AB Home", "Dashboard", "Applicant Information", "Revocation", "Scope", "Program Requirements", "Attachments", "Summary" (which is highlighted in blue), and "e-Signature". The "Summary" section is expanded, showing the message "Review the following information for correctness and edit as needed.".

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

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

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

Figure 5.19 – Flagged Program Requirements



U.S. Department of Health and Human Services

FDA | **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 > Program Requirements

Applicant Information Revocation Scope **Program Requirements** Attachments Summary e-Signature

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Eligibility
Legal Authority
Competency and Capacity
Conflict of Interest
Quality Assurance
Records
§1.615(a)
§1.615(b)

Records

§1.615 What records procedures must an accreditation body have to qualify for recognition?

An accreditation body seeking recognition must demonstrate that it has:

(a) Implemented written procedures to establish, control, and retain records (including documents and data) for the period of time necessary to meet its contractual and legal obligations pertaining to this subpart and to provide an adequate basis for evaluating its program and performance; and

(b) The capability to meet the applicable reporting and notification requirements of this subpart, if recognized.

Previous Save Next

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

5.7 e-Signature and Confirmation Page

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

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

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

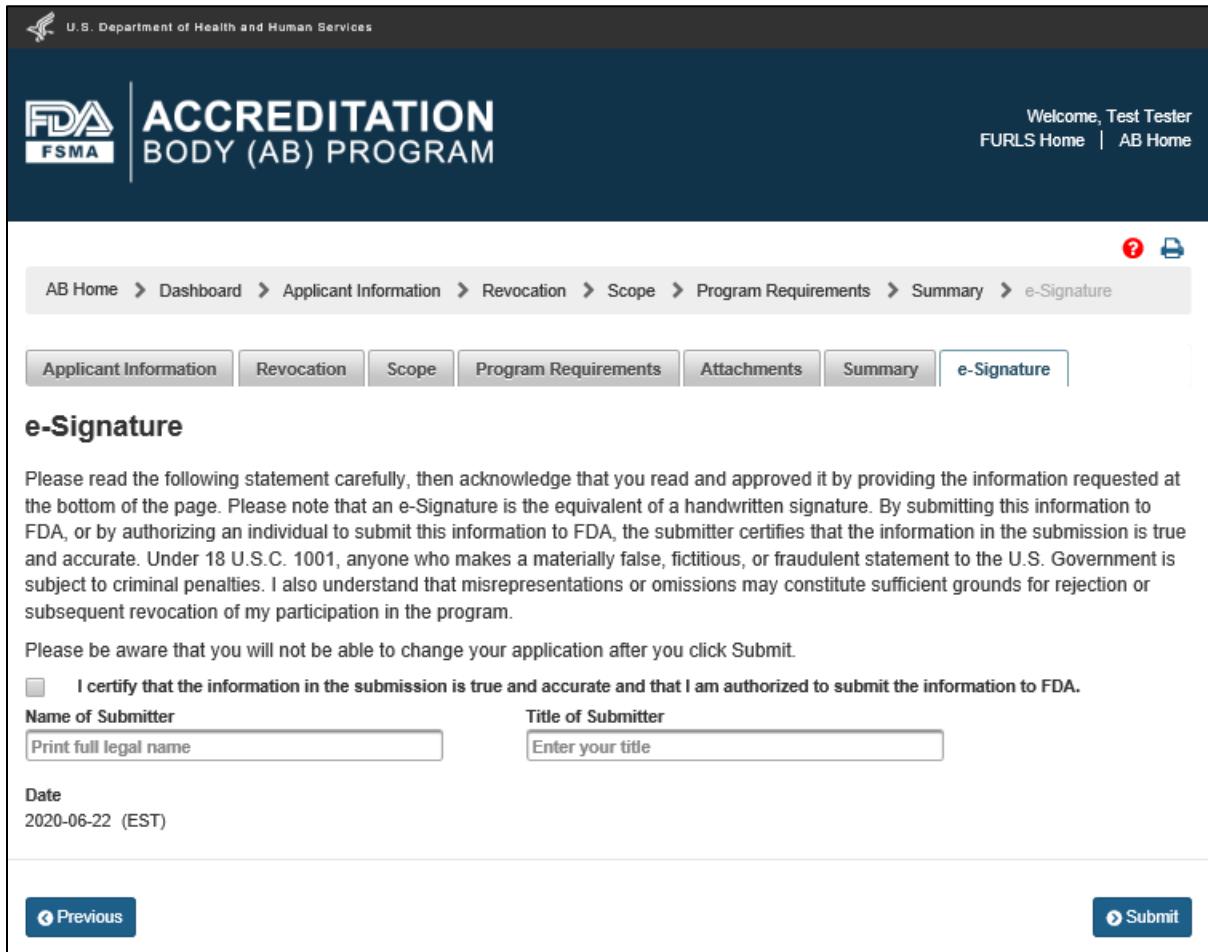
Complete the following data fields:

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

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

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

Figure 5.20 – e-Signature Page



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 > Program Requirements > Summary > e-Signature

Applicant Information Revocation Scope Program Requirements 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
Print full legal name

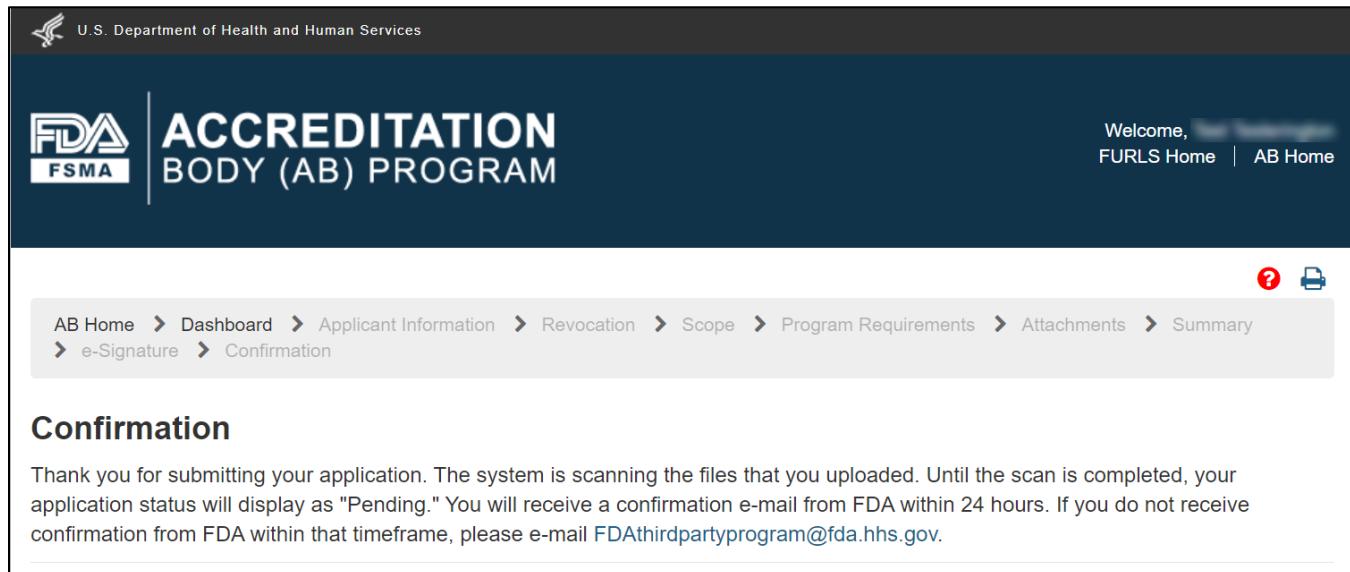
Title of Submitter
Enter your title

Date
2020-06-22 (EST)

Previous Submit

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

Figure 5.21 – Confirmation Page



U.S. Department of Health and Human Services

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

Welcome, [Redacted]
FURLS Home | AB Home

AB Home > Dashboard > Applicant Information > Revocation > Scope > Program Requirements > Attachments > Summary
e-Signature > Confirmation

Confirmation

Thank you for submitting your application. The system is scanning the files that you uploaded. Until the scan is completed, your application status will display as "Pending." You will receive a confirmation e-mail from FDA within 24 hours. If you do not receive confirmation from FDA within that timeframe, please e-mail FDAthirdpartyprogram@fda.hhs.gov.

?

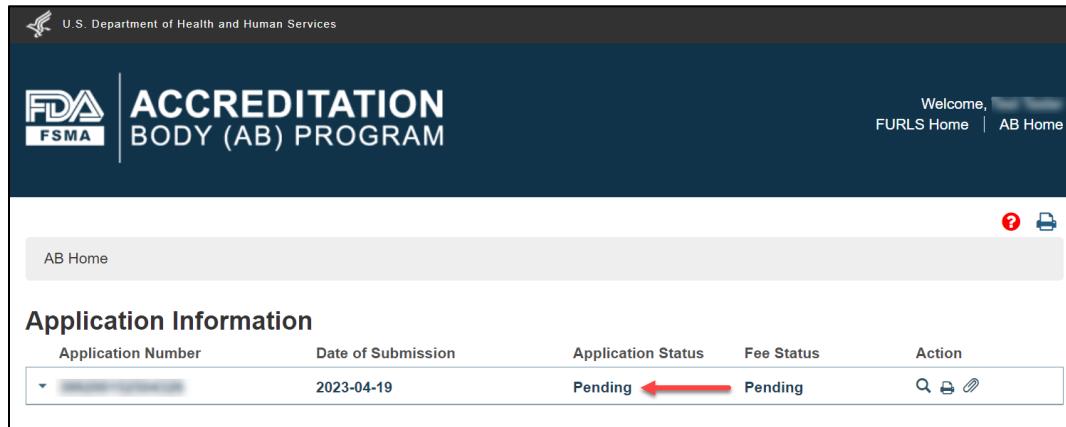
Print

5.8 Application Status

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

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

Figure 5.22 – Pending Application Status



U.S. Department of Health and Human Services

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

Welcome, [Redacted]
FURLS Home | AB Home

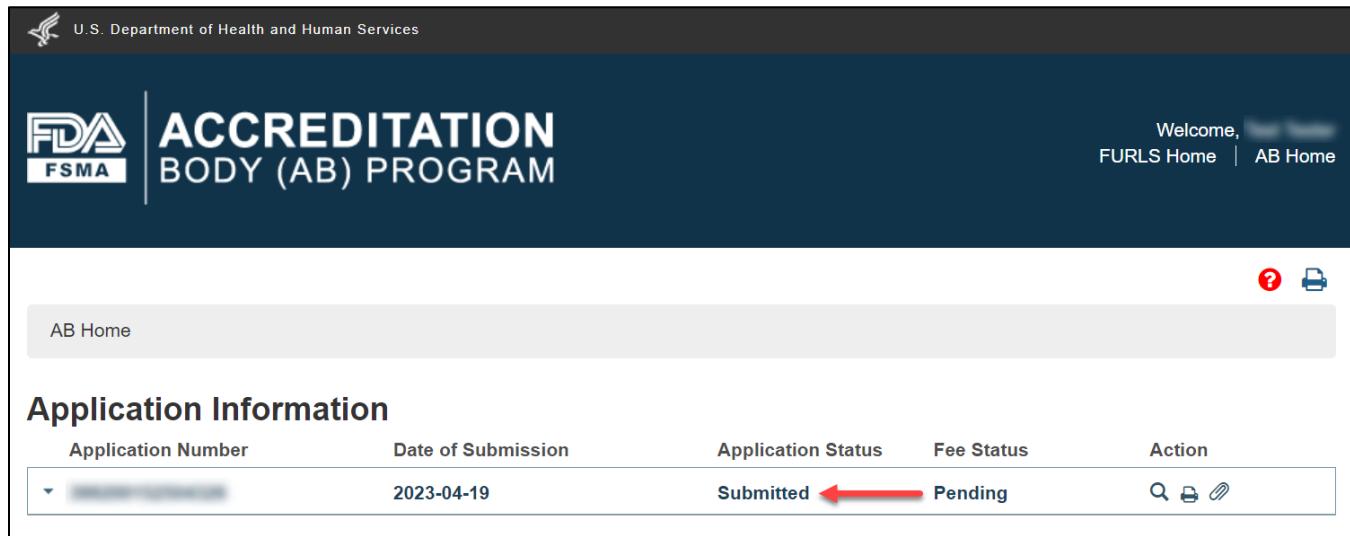
AB Home

Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
Redacted	2023-04-19	Pending	Pending	

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

Figure 5.23 – Submitted Application Status

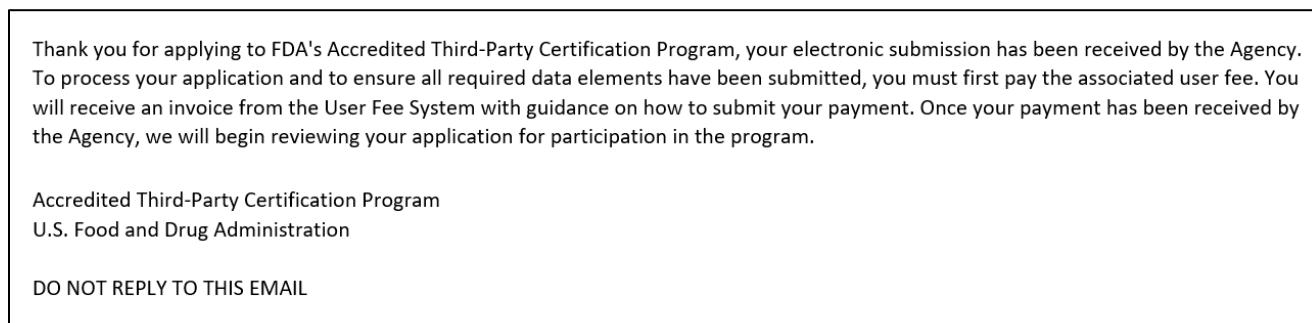


The screenshot shows the FDA Accreditation Body (AB) Program Application Information page. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and a Welcome message with links to FURLS Home and AB Home. Below the header, a sub-navigation bar has an AB Home link. The main content area is titled "Application Information" and displays a table with columns: Application Number, Date of Submission, Application Status, Fee Status, and Action. The table row shows an application with the Application Number partially redacted, a Date of Submission of 2023-04-19, an Application Status of "Submitted" (with a red arrow pointing to it), a Fee Status of "Pending", and a "Action" column with a search icon, a print icon, and a clipboard icon.

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

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

Figure 5.24 – E-mail Notification



The email notification text is as follows:

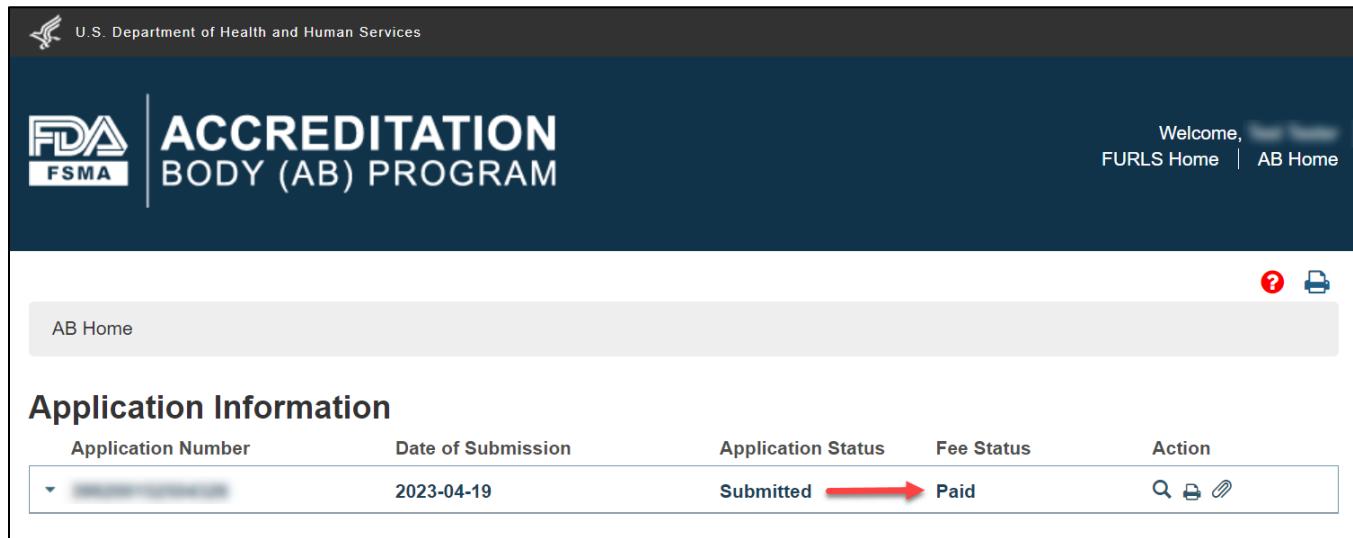
Thank you for applying to FDA's Accredited Third-Party Certification Program, your electronic submission has been received by the Agency. To process your application and to ensure all required data elements have been submitted, you must first pay the associated user fee. You will receive an invoice from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

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

DO NOT REPLY TO THIS EMAIL

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

Figure 5.25 – Paid Fee Status



The screenshot shows the FDA Accreditation Body (AB) Program Application Information page. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and links for Welcome, FURLS Home, and AB Home. The main content area is titled "Application Information" and displays a table with columns for Application Number, Date of Submission, Application Status, Fee Status, and Action. The table shows one row with the Application Number as a redacted placeholder, the Date of Submission as 2023-04-19, the Application Status as Submitted, and the Fee Status as Paid. A red arrow points to the "Paid" status. The Action column contains icons for search, print, and edit.

Application Number	Date of Submission	Application Status	Fee Status	Action
...	2023-04-19	Submitted	Paid	

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

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

Figure 5.26 – E-mail Notification

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

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

The scope of your recognition includes:

[REDACTED]

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

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

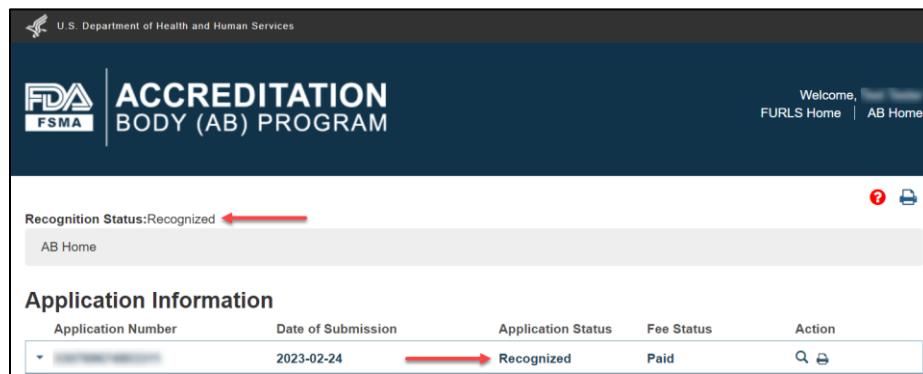
We look forward to working with you, thank you for your participation in FDA's Accredited Third-Party Certification Program.

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

DO NOT REPLY TO THIS EMAIL

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

Figure 5.27 – Recognized Status



U.S. Department of Health and Human Services

FDA | **ACcreditation**
BODY (AB) PROGRAM

Welcome, [REDACTED]
FURLS Home | AB Home

Recognition Status:Recognized ←

AB Home

Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
[REDACTED]	2023-02-24 →	Recognized	Paid	🔍 🔗

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



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

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

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

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

6 Application Returned for Action

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

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

Figure 6.1 – E-mail Notification

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

§1.611 - Legal Authority.

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

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

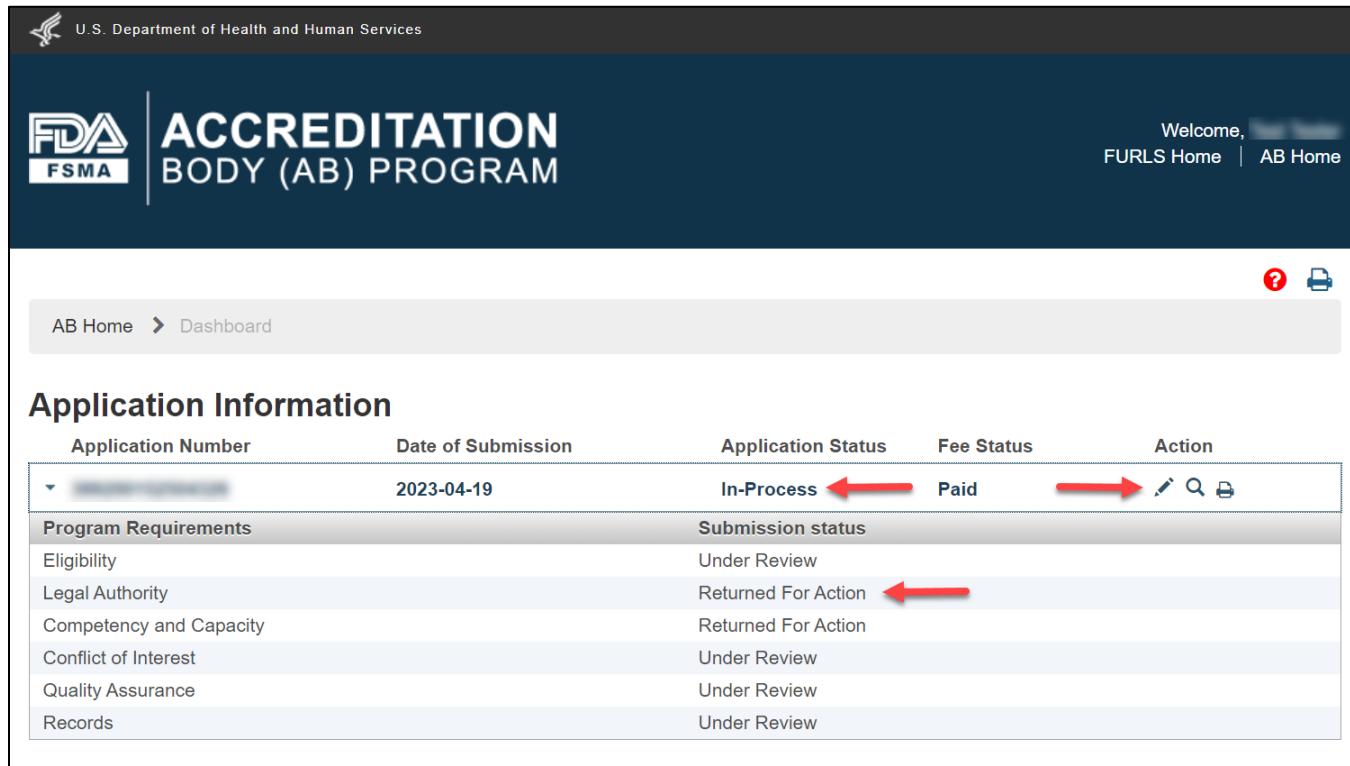
DO NOT REPLY TO THIS EMAIL

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

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

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

Figure 6.2 – In-Process Application Status and Edit Icon

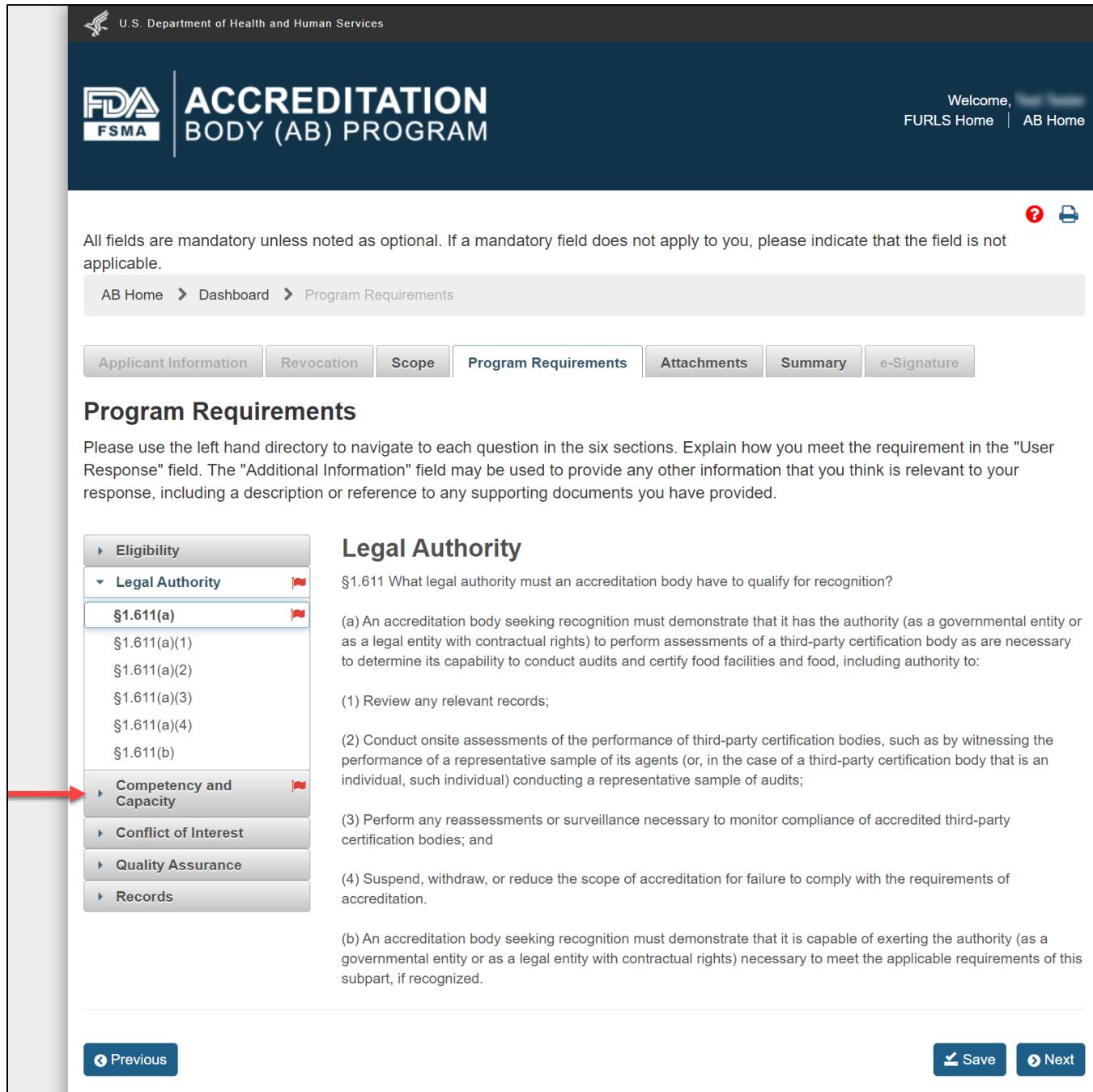


Application Number	Date of Submission	Application Status	Fee Status	Action
██████████	2023-04-19	In-Process 	Paid 	  
Program Requirements		Submission status		
Eligibility		Under Review		
Legal Authority		Returned For Action 		
Competency and Capacity		Returned For Action		
Conflict of Interest		Under Review		
Quality Assurance		Under Review		
Records		Under Review		

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

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

Figure 6.3 – Program Requirements Page with Red Flags



U.S. Department of Health and Human Services

FDA FSMA | ACCREDITATION BODY (AB) PROGRAM

Welcome, [User Name](#) | [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 > Program Requirements

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

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Eligibility

Legal Authority 

§1.611(a) 

§1.611(a)(1)
§1.611(a)(2)
§1.611(a)(3)
§1.611(a)(4)
§1.611(b)

Competency and Capacity 

Conflict of Interest

Quality Assurance

Records

Legal Authority

§1.611 What legal authority must an accreditation body have to qualify for recognition?

(a) An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

(1) Review any relevant records;

(2) Conduct onsite assessments of the performance of third-party certification bodies, such as by witnessing the performance of a representative sample of its agents (or, in the case of a third-party certification body that is an individual, such individual) conducting a representative sample of audits;

(3) Perform any reassessments or surveillance necessary to monitor compliance of accredited third-party certification bodies; and

(4) Suspend, withdraw, or reduce the scope of accreditation for failure to comply with the requirements of accreditation.

(b) An accreditation body seeking recognition must demonstrate that it is capable of exerting the authority (as a governmental entity or as a legal entity with contractual rights) necessary to meet the applicable requirements of this subpart, if recognized.

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

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

Figure 6.4 – Review Comments Section

Applicant Information
Revocation
Scope
Program Requirements
Attachments
Summary
e-Signature

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

▶ Eligibility

▶ Legal Authority !

▶ §1.611(a) !

▶ §1.611(a)(1)

▶ §1.611(a)(2)

▶ §1.611(a)(3)

▶ §1.611(a)(4)

▶ §1.611(b)

▶ Competency and Capacity !

▶ Conflict of Interest

▶ Quality Assurance

▶ Records

▼ Legal Authority >> §1.611(a)

Regulation Text

An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

Criteria to Demonstrate

Please indicate if you are a government body that has jurisdiction over the food commodities to which you are applying; or if you are not a government body and have a contract establishing the required legal authorities.

User Response

This is a question from FDA. Enter your response here.

Additional Information

This is a question from FDA. Enter your response here.

▼ Review Comments

This is a question from FDA.

Enter your response here.

4000 characters remaining.

▶ Attachments (Optional)

Previous
Save
Next

Page | 45

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

Attachments must be a document type supported by the system.

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

The maximum file size allowed is 50 MB.

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

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

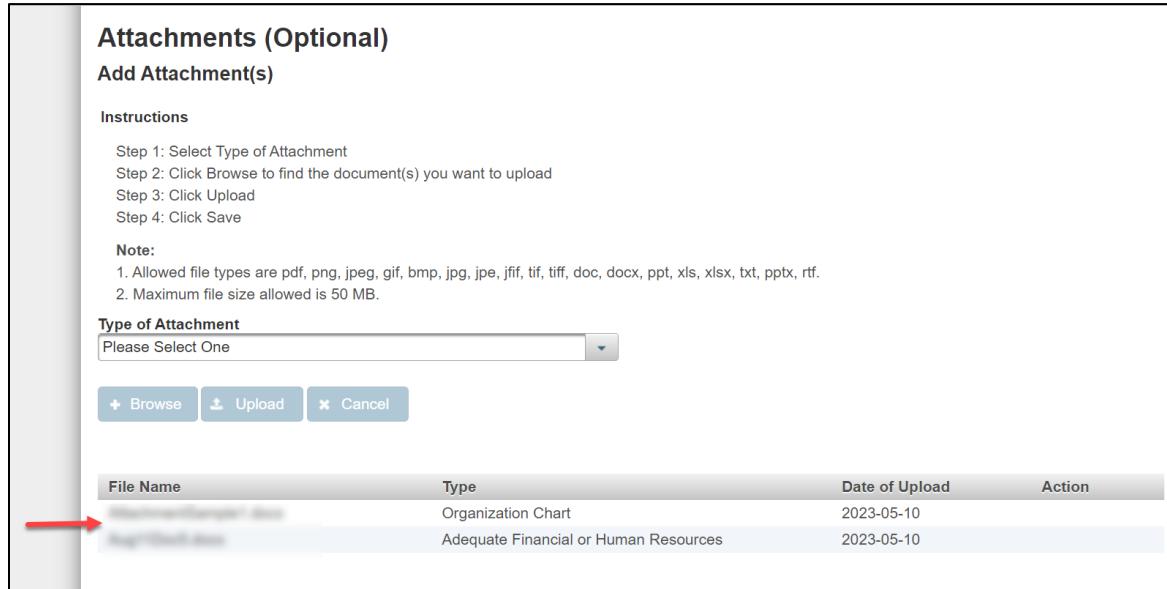
Refer to Section 5.4 of this document for instructions on completing the “Program Requirements” section, if needed.

Additional Revisions

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

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

Figure 6.5 – Attachments from Initial Application Submission



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

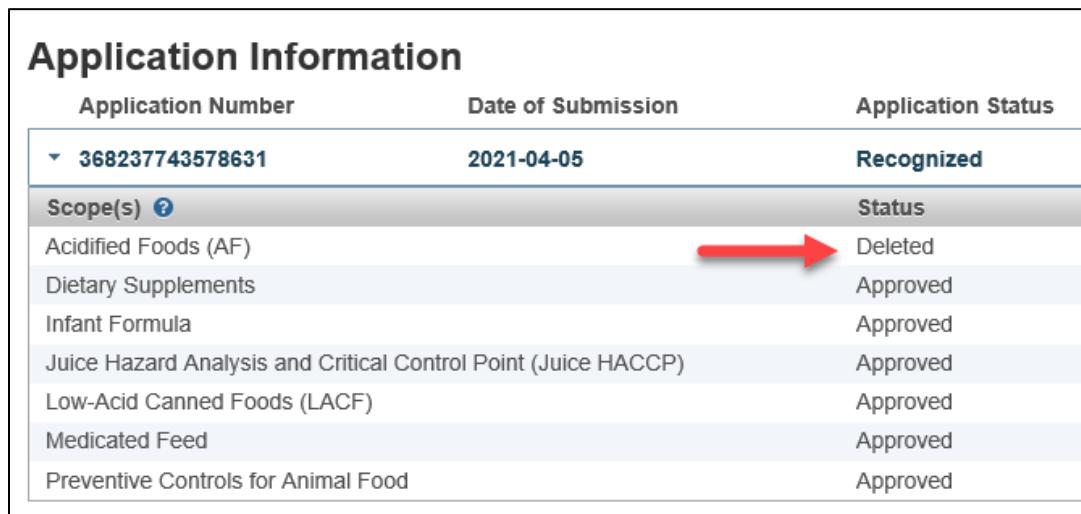
+ Browse Upload Cancel

File Name	Type	Date of Upload	Action
Organization Chart	Organization Chart	2023-05-10	
Adequate Financial or Human Resources	Adequate Financial or Human Resources	2023-05-10	

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

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

Figure 6.6 – Deleted Scope



Application Information

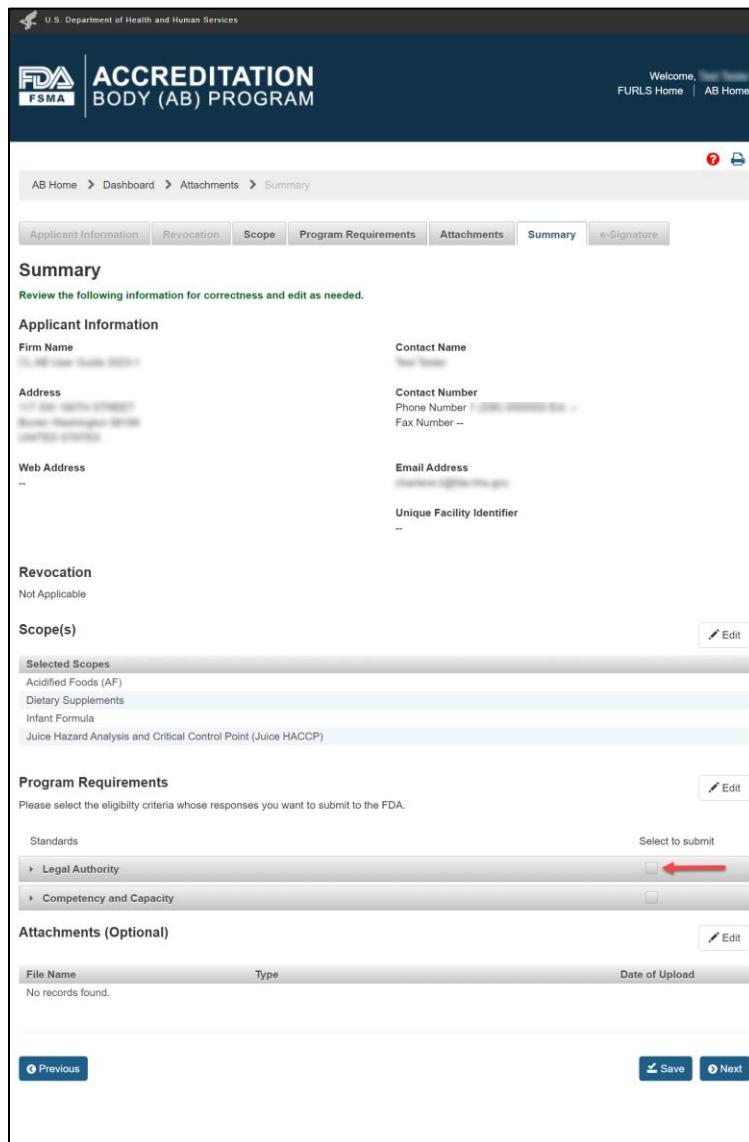
Application Number	Date of Submission	Application Status
368237743578631	2021-04-05	Recognized
Scope(s) ?		Status
Acidified Foods (AF)		Deleted
Dietary Supplements		Approved
Infant Formula		Approved
Juice Hazard Analysis and Critical Control Point (Juice HACCP)		Approved
Low-Acid Canned Foods (LACF)		Approved
Medicated Feed		Approved
Preventive Controls for Animal Food		Approved

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

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

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

Figure 6.7 – Summary Page



The screenshot shows the FDA Accreditation Body (AB) Program Summary page. The top navigation bar includes links for AB Home, Dashboard, Attachments, and Summary. The main content area is titled "Summary" and contains the following sections:

- Applicant Information:** Fields for Firm Name (FDA-000000000000), Address (FDA-000000000000), Web Address (FDA-000000000000), Contact Name (FDA-000000000000), Contact Number (Phone Number: FDA-000000000000, Fax Number: FDA-000000000000), Email Address (FDA-000000000000), and Unique Facility Identifier (FDA-000000000000).
- Revocation:** Status: Not Applicable.
- Scope(s):** Selected Scopes: Acidified Foods (AF), Dietary Supplements, Infant Formula, and Juice Hazard Analysis and Critical Control Point (Juice HACCP). An "Edit" button is present.
- Program Requirements:** A section titled "Please select the eligibility criteria whose responses you want to submit to the FDA." It includes a "Standards" section with "Legal Authority" and "Competency and Capacity" options, and a "Select to submit" checkbox. A red arrow points to the "Legal Authority" checkbox. An "Edit" button is also present.
- Attachments (Optional):** A table showing file names, types, and dates of upload. It indicates "No records found." An "Edit" button is present.

At the bottom are "Previous" and "Next" buttons, along with "Save" and "Next" buttons.

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

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

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

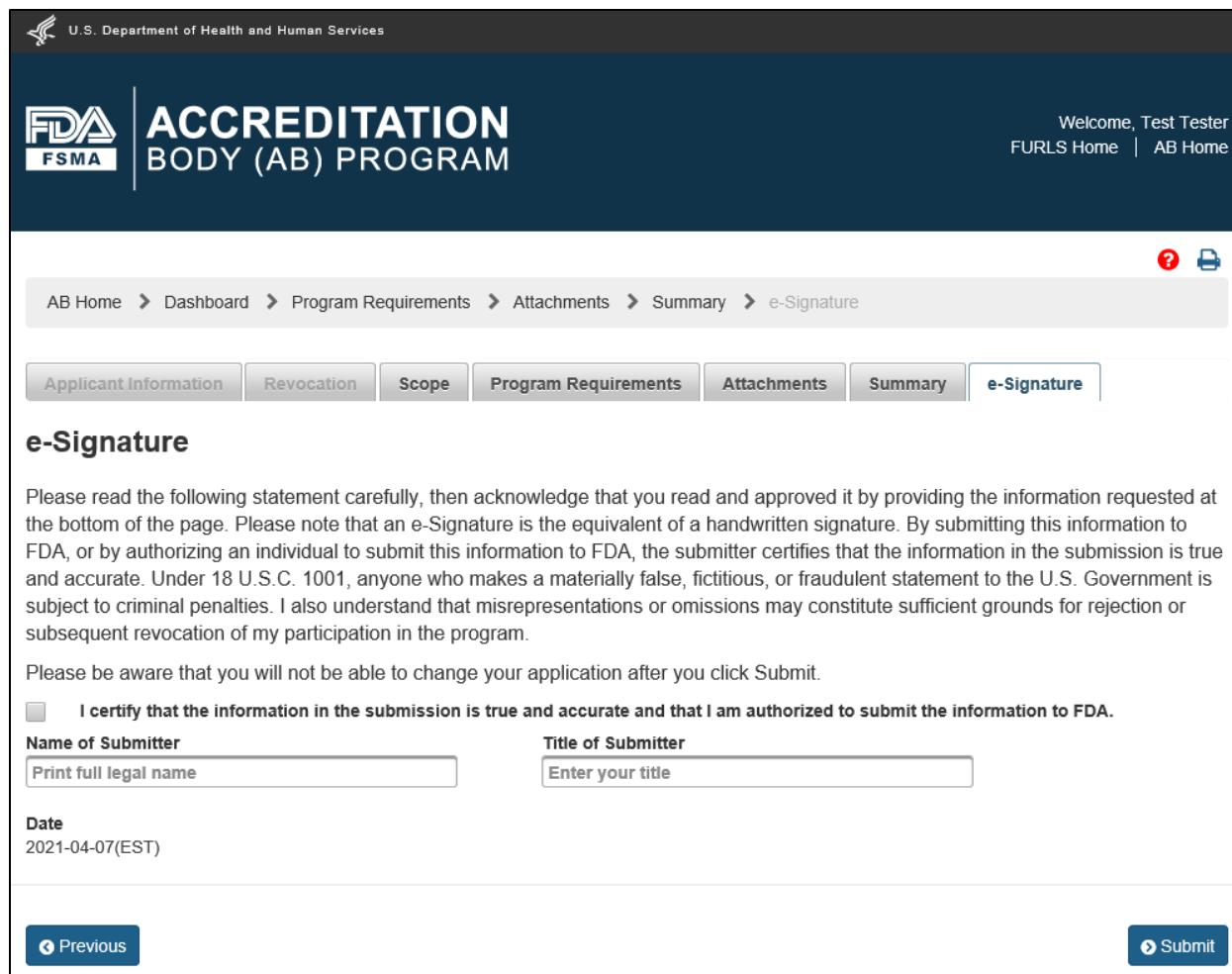
Complete the following data fields:

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

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

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

Figure 6.8 – e-Signature Page



U.S. Department of Health and Human Services

FDA **ACCREDITATION**
BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Dashboard > Program Requirements > Attachments > Summary > e-Signature

Applicant Information Revocation Scope Program Requirements 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
Print full legal name

Title of Submitter
Enter your title

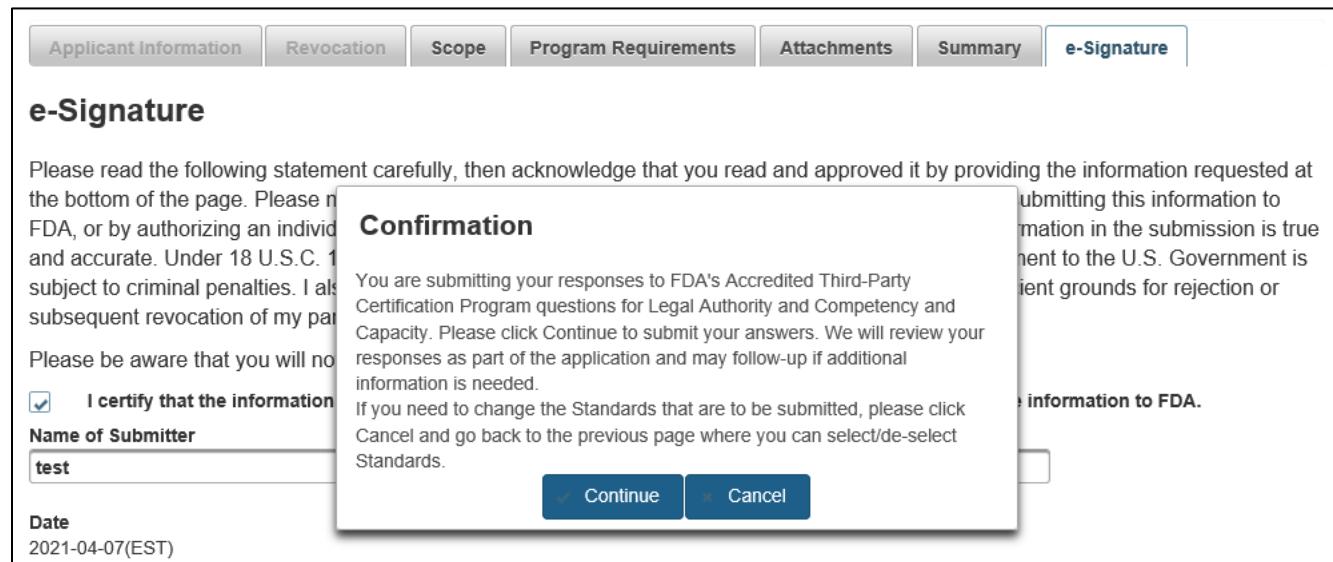
Date
2021-04-07(EST)

Previous **Submit**

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

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

Figure 6.9 – Confirmation Pop-up



Applicant Information Revocation Scope Program Requirements 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 by signing this statement, you are certifying that the information you provided is true and accurate. Under 18 U.S.C. 1731, it is a criminal offense to provide false information to FDA, or by authorizing an individual to do so, and subject to criminal penalties. I also understand that my responses may be subject to subsequent revocation of my participation in the program.

Please be aware that you will no longer be able to edit this application after submission.

I certify that the information provided is true and accurate.

Name of Submitter
test

Date
2021-04-07(EST)

Confirmation

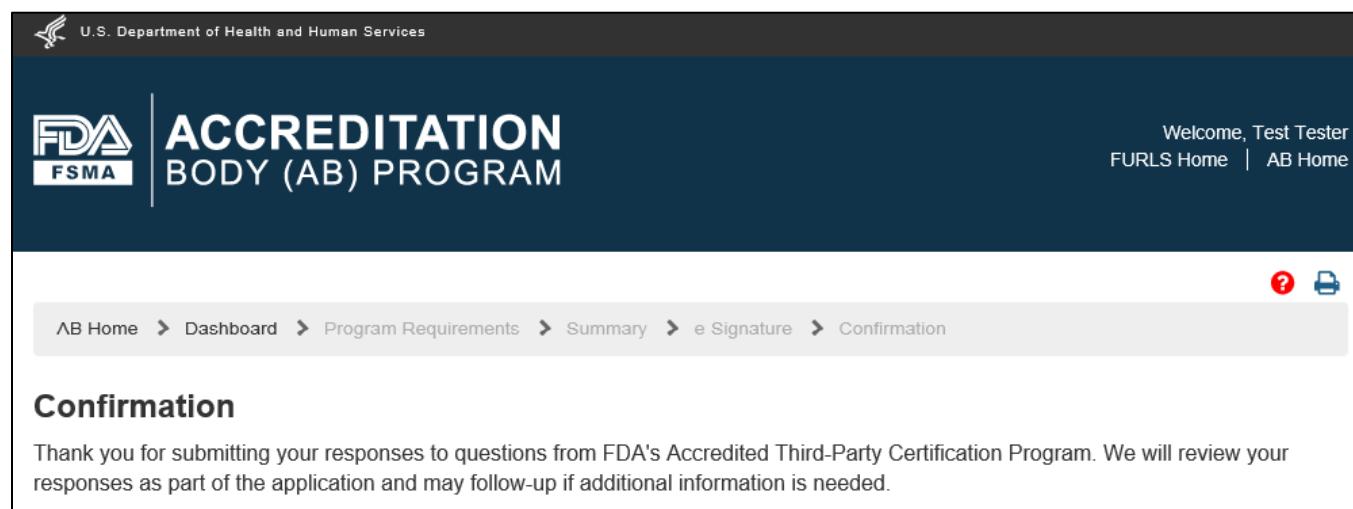
You are submitting your responses to FDA's Accredited Third-Party Certification Program questions for Legal Authority and Competency and Capacity. Please click Continue to submit your answers. We will review your responses as part of the application and may follow-up if additional information is needed.

If you need to change the Standards that are to be submitted, please click Cancel and go back to the previous page where you can select/de-select Standards.

Continue **Cancel**

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

Figure 6.10 – Confirmation Page



U.S. Department of Health and Human Services

ACREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Dashboard > Program Requirements > Summary > e Signature > Confirmation

Confirmation

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

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

Figure 6.11 – E-mail Notification

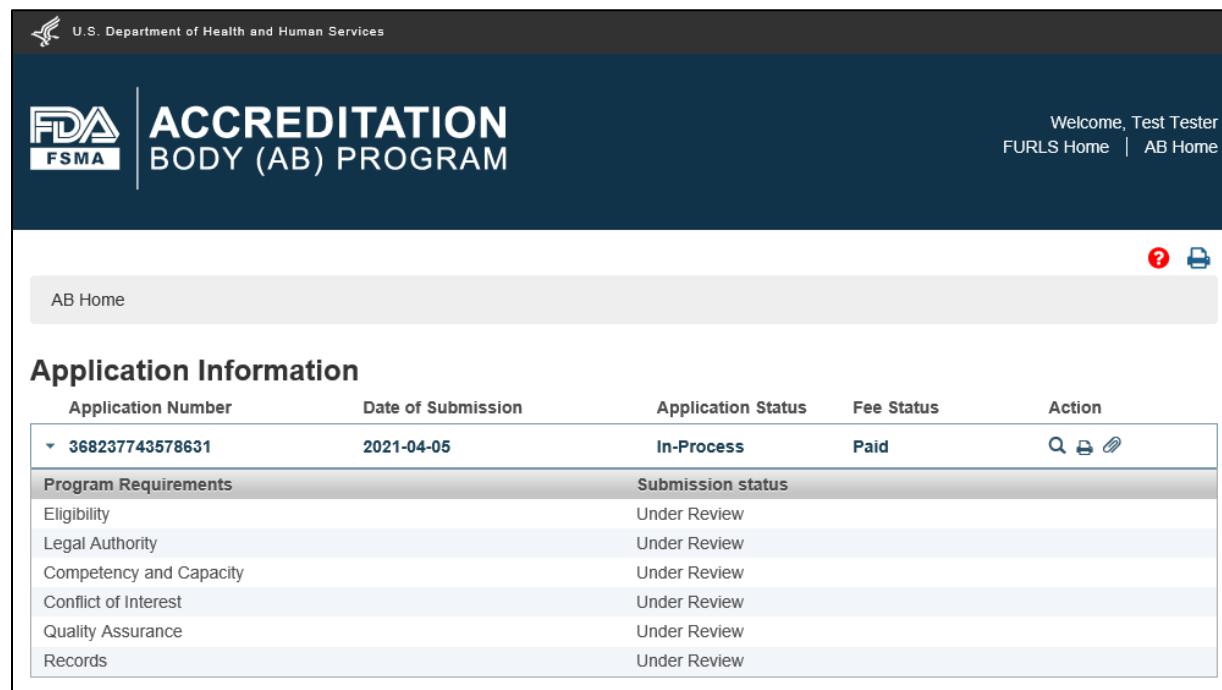
Thank you for submitting your responses to questions from FDA's Accredited Third-Party Certification Program. We will review your responses as part of your application and may follow-up if additional information is needed.

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

DO NOT REPLY TO THIS EMAIL

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

Figure 6.12 – In-Process Application Status



U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

AB Home

?

Print

Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
368237743578631	2021-04-05	In-Process	Paid	
Program Requirements		Submission status		
Eligibility		Under Review		
Legal Authority		Under Review		
Competency and Capacity		Under Review		
Conflict of Interest		Under Review		
Quality Assurance		Under Review		
Records		Under Review		

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

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

7 Submit Reconsideration Request

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

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

Figure 7.1 – E-mail Notification

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

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



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



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

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

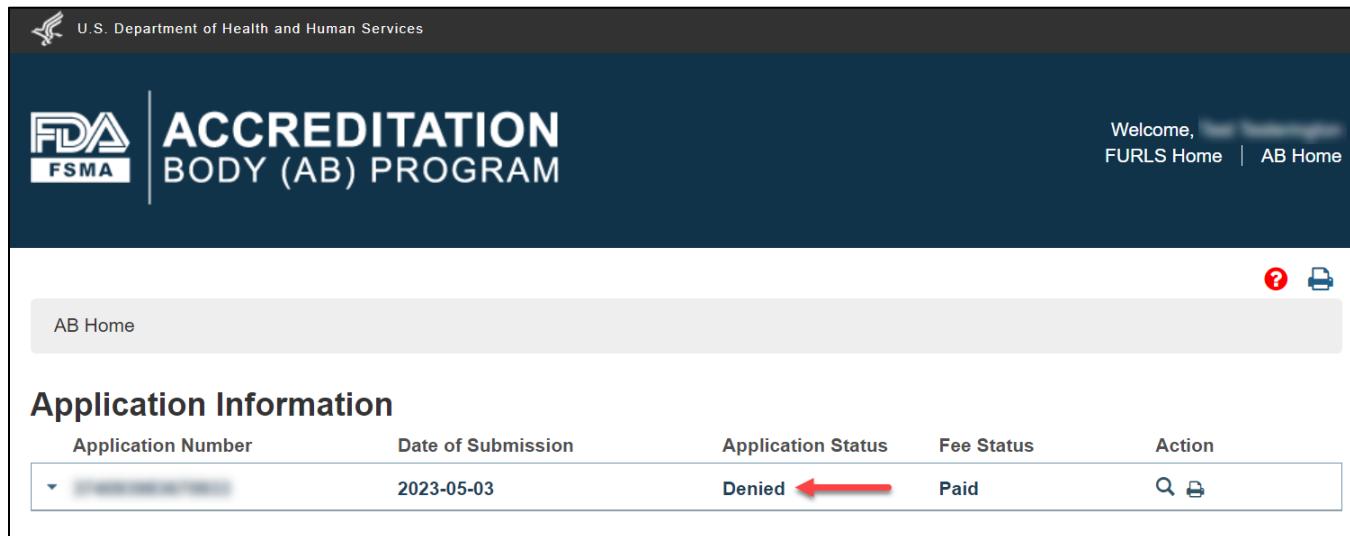
DO NOT REPLY TO THIS EMAIL

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

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

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

Figure 7.2 – Denied Application Status



U.S. Department of Health and Human Services

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

Welcome, [User Name](#) | [FURLS Home](#) | [AB Home](#)

AB Home

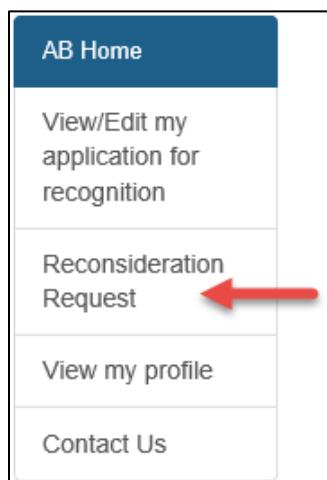
Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
████████████████	2023-05-03	Denied	Paid	

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

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

Figure 7.3 – Navigation Menu

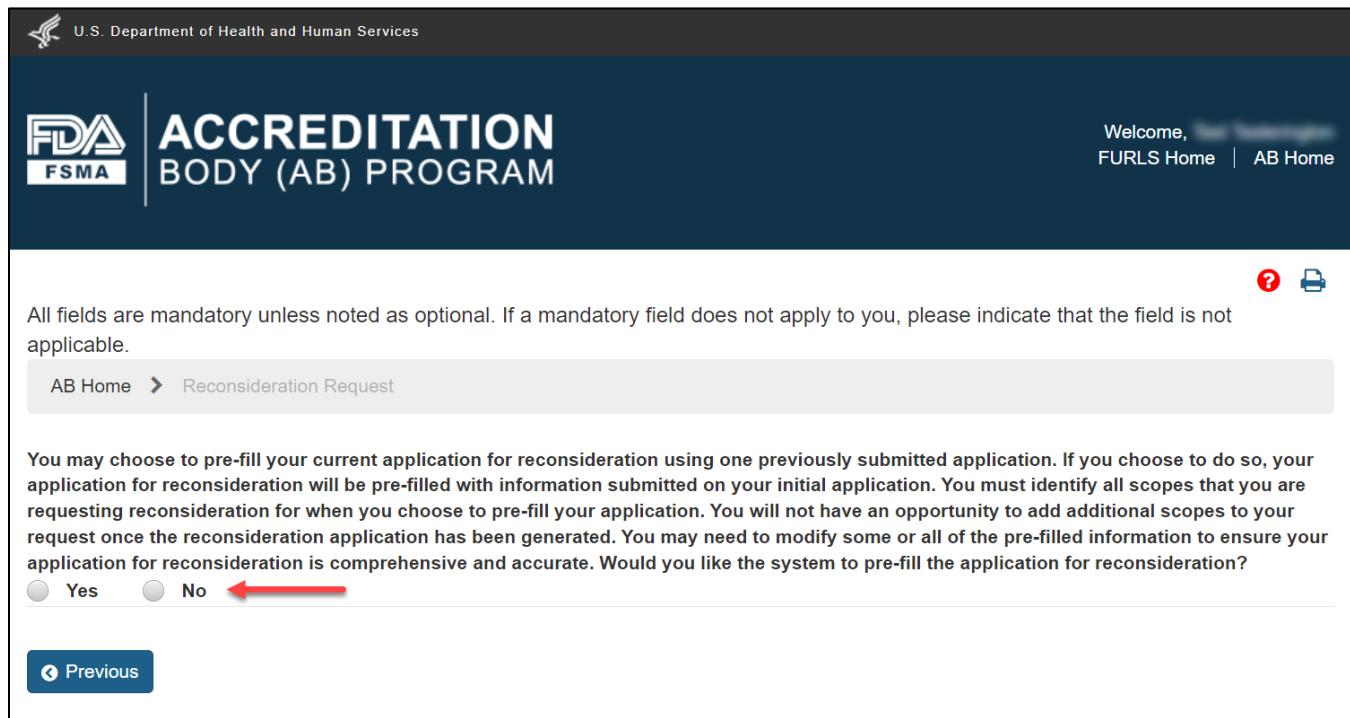


- AB Home
- View/Edit my application for recognition
- Reconsideration Request
- View my profile
- Contact Us

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

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

Figure 7.4 – Reconsideration Request Page



U.S. Department of Health and Human Services

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

Welcome, [User Name](#) | [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

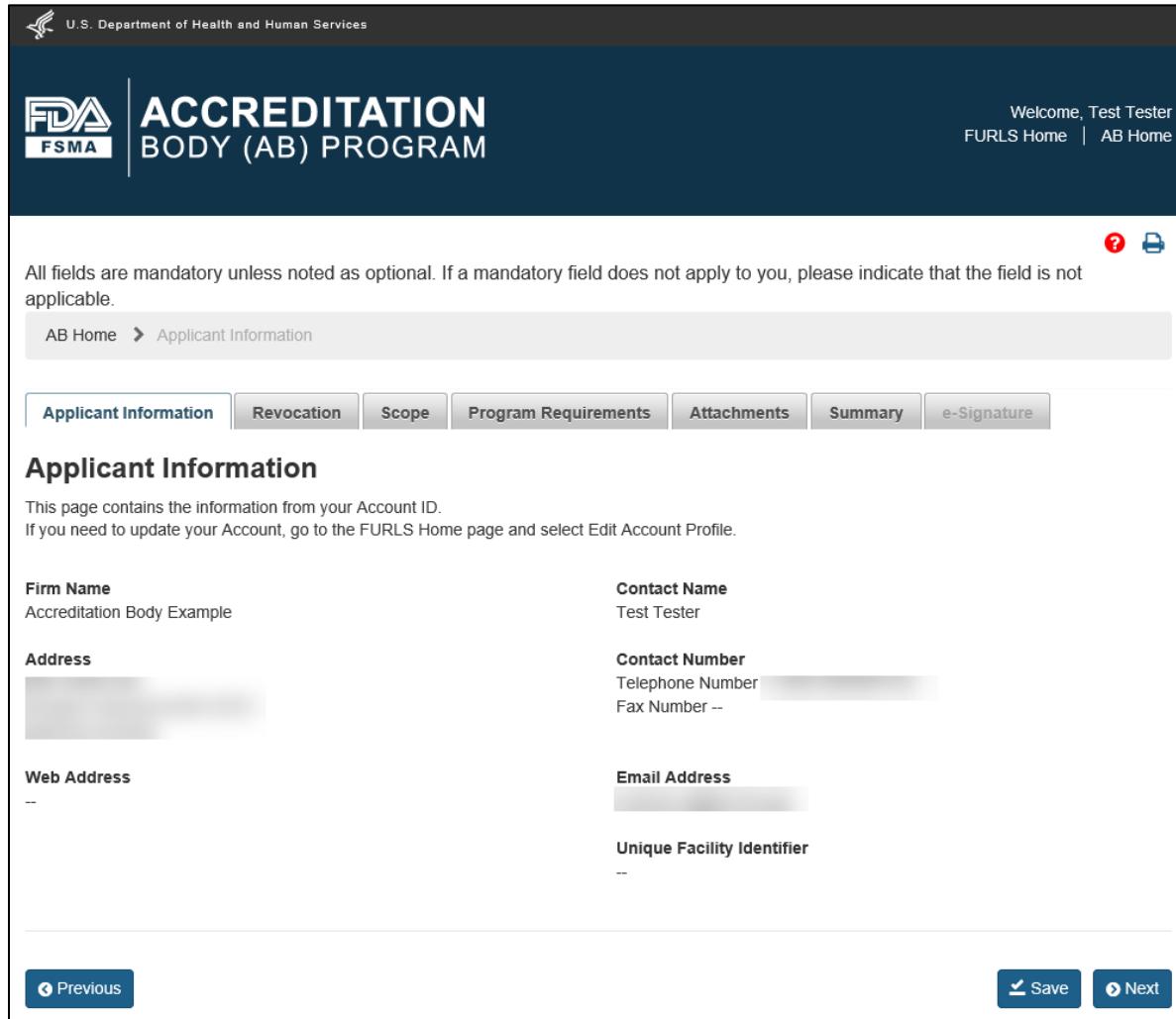
- If you select “Yes,” the system will display the “Applicant Information” page of the application, pre-filled with the read-only profile information (Figure 7.5). The remainder of the application will be pre-filled with the information submitted in the original application and is editable.

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

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

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

Figure 7.5 – Applicant Information Page



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 > Applicant Information

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 Example	Contact Name Test Tester
Address [REDACTED]	Contact Number Telephone Number [REDACTED] Fax Number --
Web Address --	Email Address [REDACTED]
	Unique Facility Identifier --

Previous **Save** **Next**

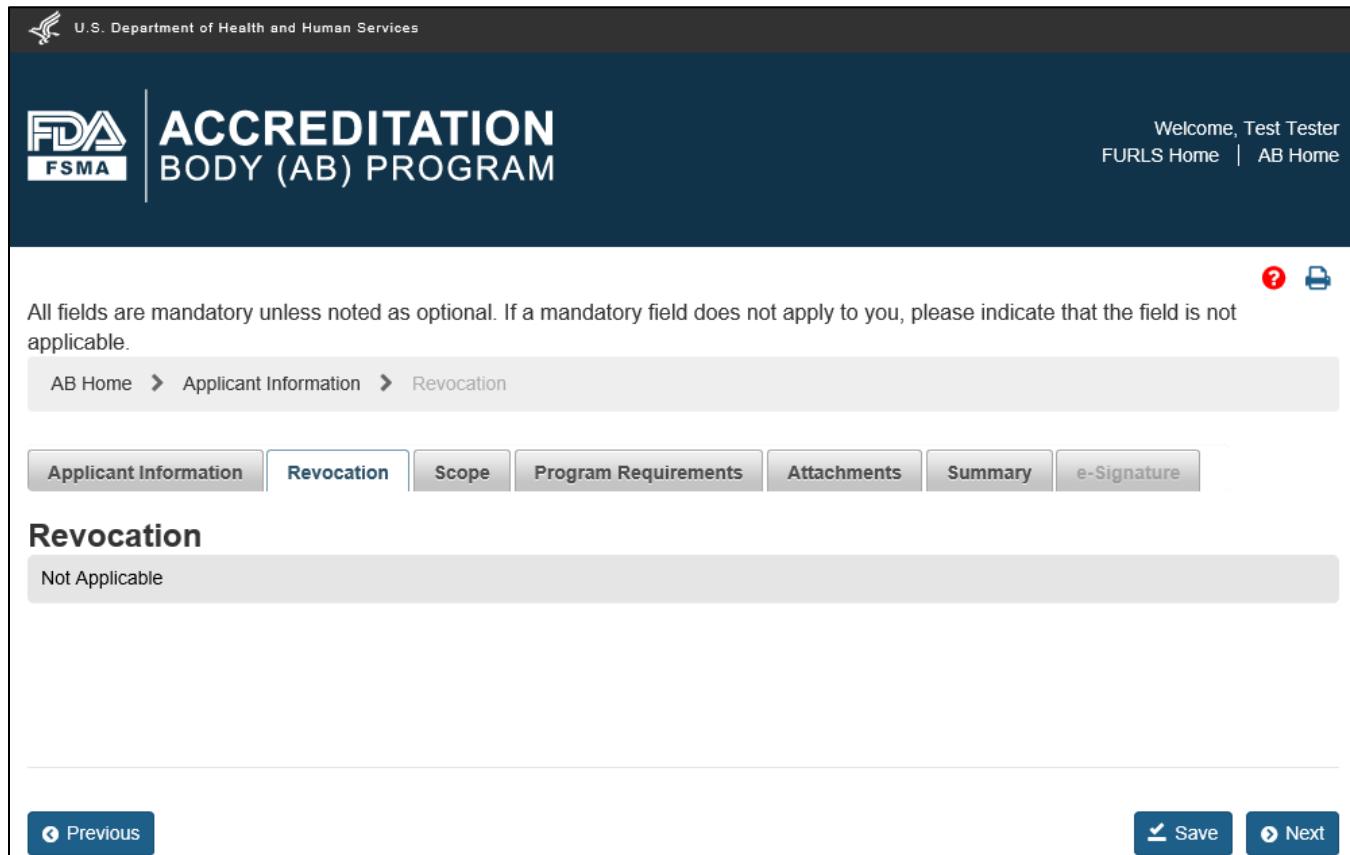
The following navigation buttons are available:

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

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

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

Figure 7.6 – Revocation Page



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

Applicant Information Revocation Scope Program Requirements Attachments Summary e-Signature

Revocation

Not Applicable

Previous Save Next

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

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

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

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

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

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

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

Figure 7.7 – Scopes Page

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 > Applicant Information > Revocation > Scope

Applicant Information

Revocation

Scope

Program Requirements

Attachments

Summary

e-Signature

Scope(s)

Scope(s)

Enter a keyword to search for scope

Acidified Foods (AF)

Dietary Supplements

Infant Formula

Juice Hazard Analysis and Critical Control Point (Juice HACCP)

Low-Acid Canned Foods (LACF)

Medicated Feed

Preventive Controls for Animal Food

List of Selected Scopes

Enter a keyword to search for scope

Previous

Save

Next

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

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

- If you selected “Yes” at the beginning of the reconsideration request, this page will be pre-filled with the information provided in the initial application. You may edit responses submitted on the original application in the “Program Requirements” page (as needed) to support the reconsideration request. You also may add attachments, if desired.
- If you selected “No” at the beginning of the reconsideration request, the “Applicant Information” page will be pre-filled with the read-only profile information. All other application information will not be pre-filled and will need to be entered manually.

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

Figure 7.8 – Program Requirements Page

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 > Program Requirements

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Eligibility

Legal Authority

§1.611(a)

- §1.611(a)(1)
- §1.611(a)(2)
- §1.611(a)(3)
- §1.611(a)(4)
- §1.611(b)

Competency and Capacity

Conflict of Interest

Quality Assurance

Records

Legal Authority >> §1.611(a)

Regulation Text

An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

Criteria to Demonstrate

Please indicate if you are a government body that has jurisdiction over the food commodities to which you are applying; or if you are not a government body and have a contract establishing the required legal authorities.

User Response (provide your answer below)

This is the prefilled User Response answer.

3957 characters remaining.

Additional Information (URL, References, etc.) (Optional)

This is the optional answer for Additional Information.

3945 characters remaining.

Attachments (Optional)

Attachments

File Name	Date of Upload
No records found.	

Previous **Save** **Next**

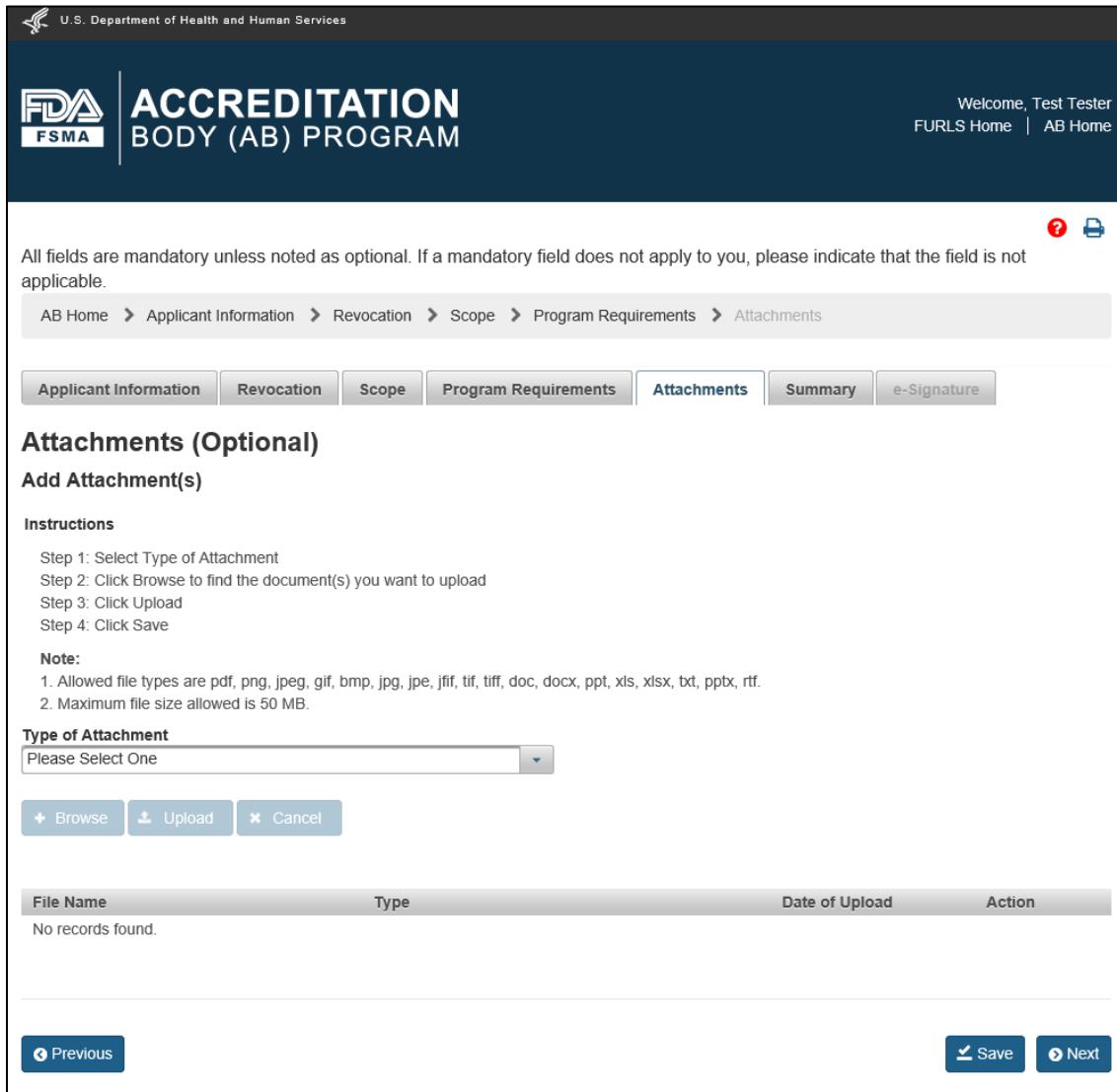
Click the “Save” button to save any changes. Click the “Next” button to proceed to the next page or, click on the “Attachments” tab. The system will display the “Attachments” page (Figure 7.9).

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

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

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

Figure 7.9 – Attachments Page



U.S. Department of Health and Human Services

ACREDITATION 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 > Program Requirements > Attachments

Applicant Information Revocation Scope Program Requirements **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
No records found.			

Previous Save Next



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

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

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

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

Figure 7.10 – Summary Page

U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Applicant Information > Revocation > Scope > Program Requirements > Attachments > Summary

Summary

Review the following information for correctness and edit as needed.

Applicant Information

Firm Name Accreditation Body Example	Contact Name Test Tester
Address [Redacted]	Contact Number Phone Number [Redacted] Fax Number --
Web Address --	Email Address [Redacted]
Unique Facility Identifier --	

Revocation

Not Applicable Edit

Scope(s)

Edit

Selected Scopes

- Acidified Foods (AF)
- Dietary Supplements
- Infant Formula
- Juice Hazard Analysis and Critical Control Point (Juice HACCP)
- Low-Acid Canned Foods (LACF)

Program Requirements

Edit

Legal Authority
Competency and Capacity
Conflict of Interest
Quality Assurance
Records

Attachments (Optional)

Edit

File Name	Type	Date of Upload
No records found.		

Previous Save Next

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

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

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

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

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

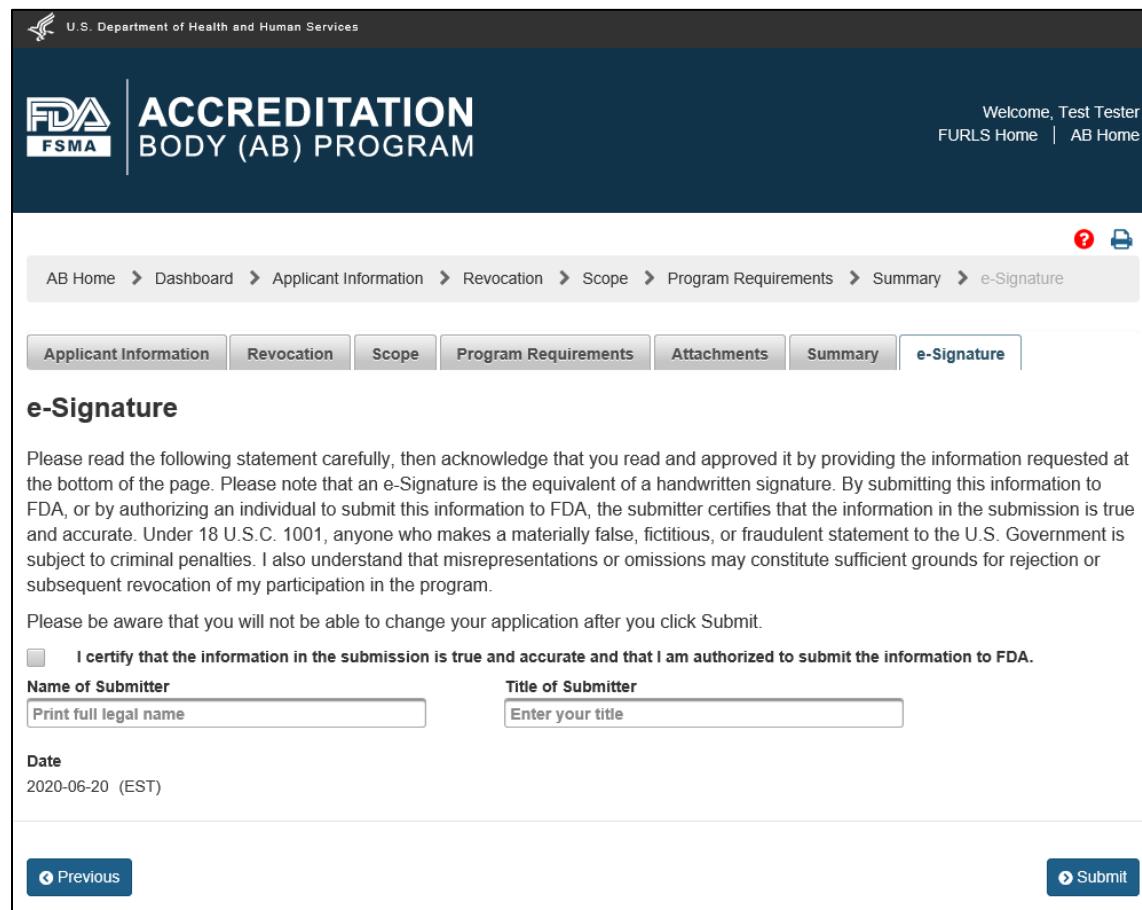
Complete the following data fields:

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

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

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

Figure 7.11 – e-Signature Page



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 > Program Requirements > Summary > e-Signature

Applicant Information Revocation Scope Program Requirements 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
Print full legal name

Title of Submitter
Enter your title

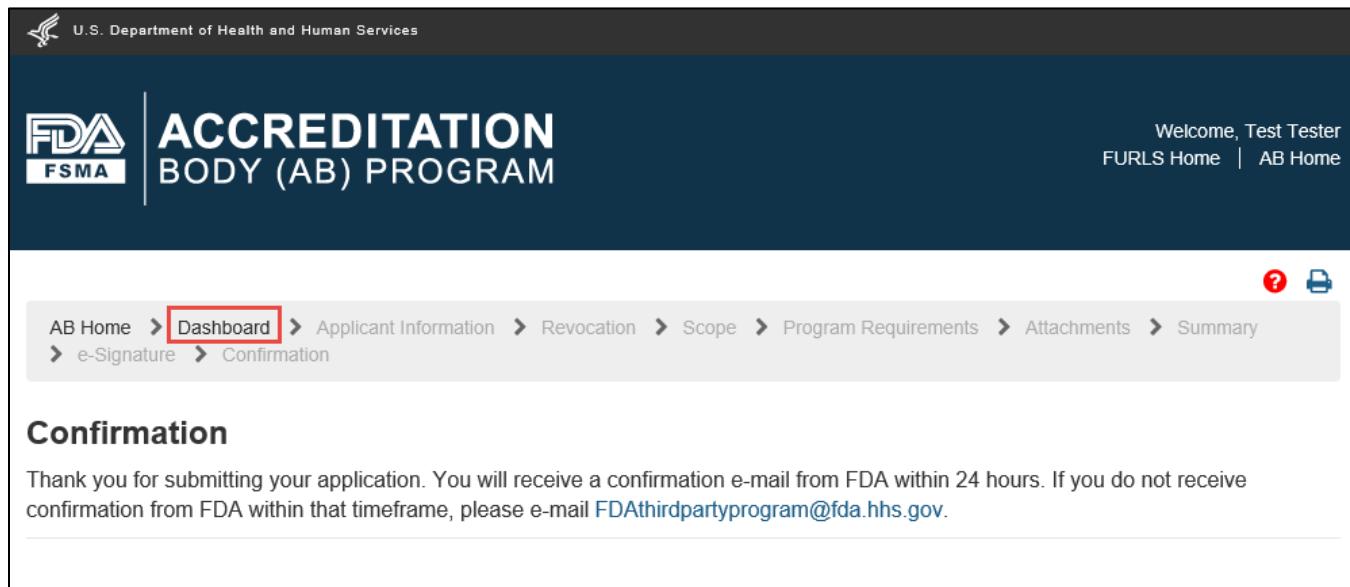
Date
2020-06-20 (EST)

Previous Submit

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

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

Figure 7.12 – Confirmation Page



U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

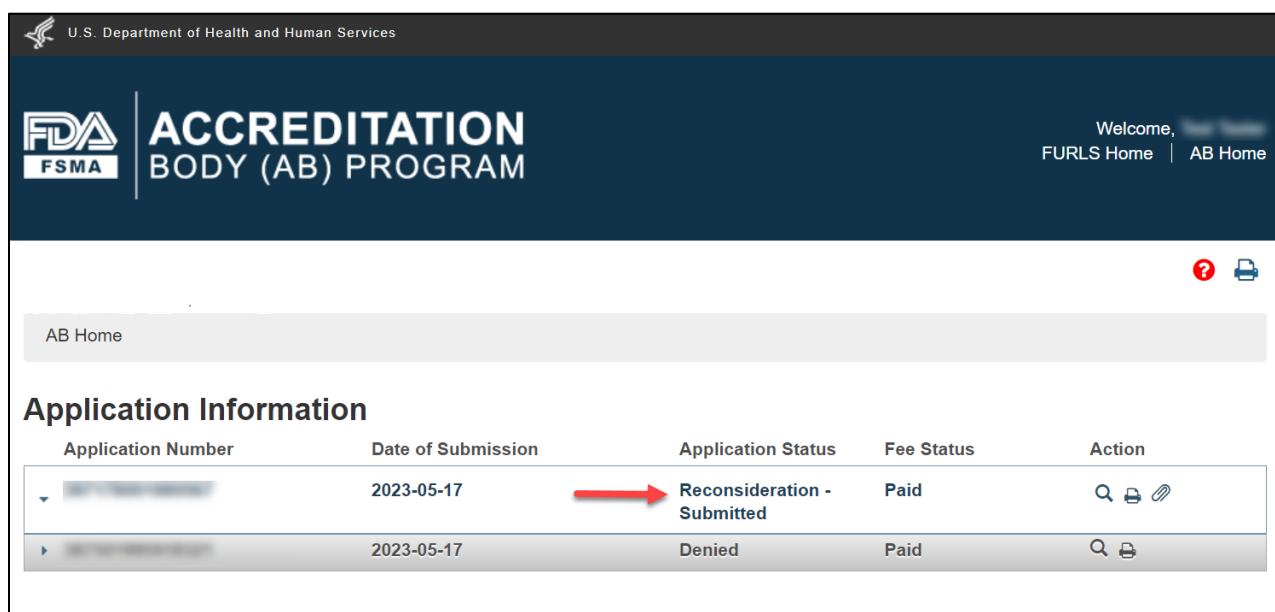
AB Home > **Dashboard** > Applicant Information > Revocation > Scope > Program Requirements > Attachments > Summary
e-Signature > Confirmation

Confirmation

Thank you for submitting your application. You will receive a confirmation e-mail from FDA within 24 hours. If you do not receive confirmation from FDA within that timeframe, please e-mail FDAt thirdpartyprogram@fda.hhs.gov.

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

Figure 7.13 – Reconsideration Request – Submitted Status



U.S. Department of Health and Human Services

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

Welcome, [REDACTED]
FURLS Home | AB Home

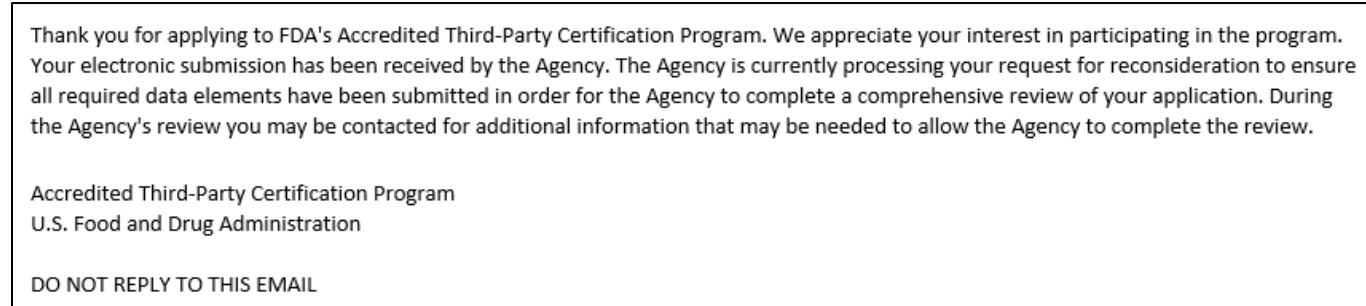
AB Home

Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
[REDACTED]	2023-05-17	Reconsideration - Submitted	Paid	
[REDACTED]	2023-05-17	Denied	Paid	

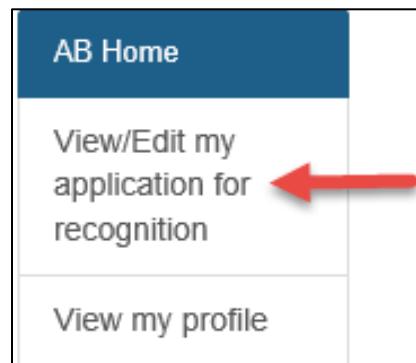
The system will send an e-mail to the address entered on the “Account Management” page indicating the reconsideration request was received by FDA (Figure 7.14). Note that the image below only depicts the e-mail notification text.

Figure 7.14 – E-mail Notification



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

Figure 7.15 – Navigation Menu



7.1 Reconsideration – Recognized

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

Figure 7.16 – E-mail Notification

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

[REDACTED]

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

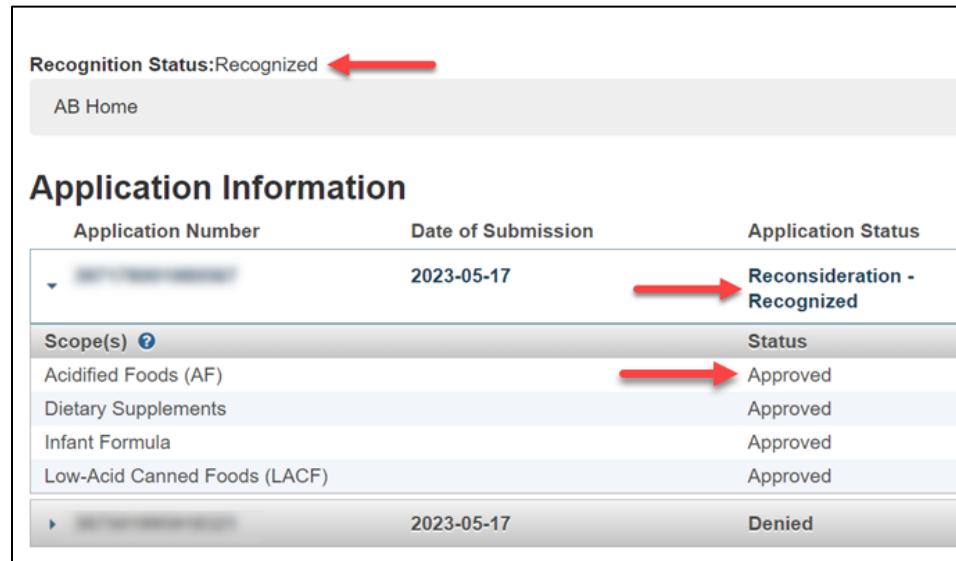
We look forward to working with you, thank you for your participation in FDA's Accredited Third-Party Certification Program.

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

DO NOT REPLY TO THIS EMAIL

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

Figure 7.17 – Reconsideration – Recognized Status and Approved Scopes



The screenshot shows the “Application Information” page with the following data:

Application Number	Date of Submission	Application Status
[REDACTED]	2023-05-17	Reconsideration - Recognized
Scope(s) <small>?</small>		Status
Acidified Foods (AF)		Approved
Dietary Supplements		Approved
Infant Formula		Approved
Low-Acid Canned Foods (LACF)		Approved
[REDACTED]		Denied

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

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

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

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

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

7.2 Reconsideration – Denied

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

Figure 7.18 – E-mail Notification

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

[REDACTED]

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

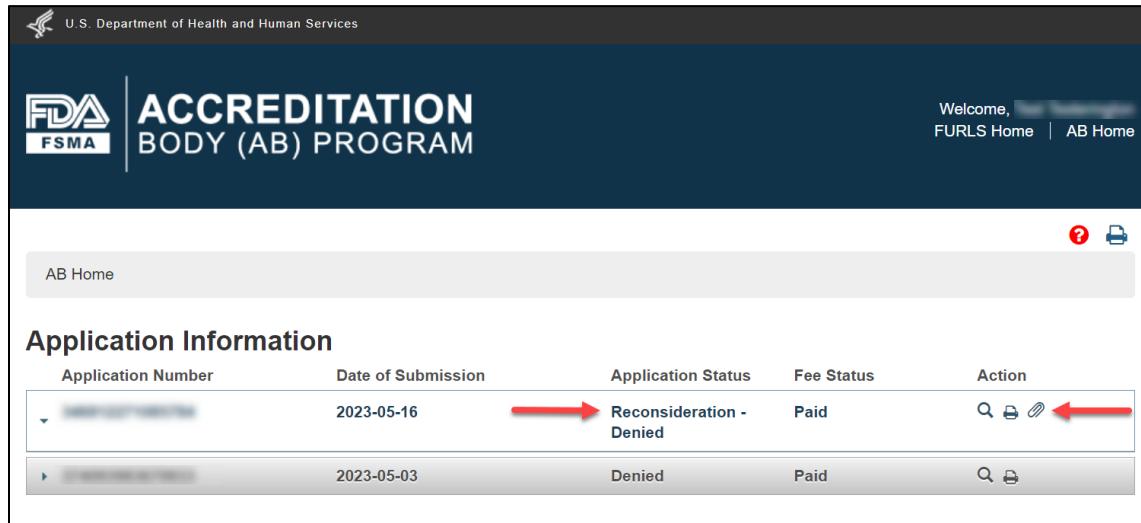
If you would still like to seek recognition, you must submit a new application.

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

DO NOT REPLY TO THIS EMAIL

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

Figure 7.19 – Reconsideration – Denied Status

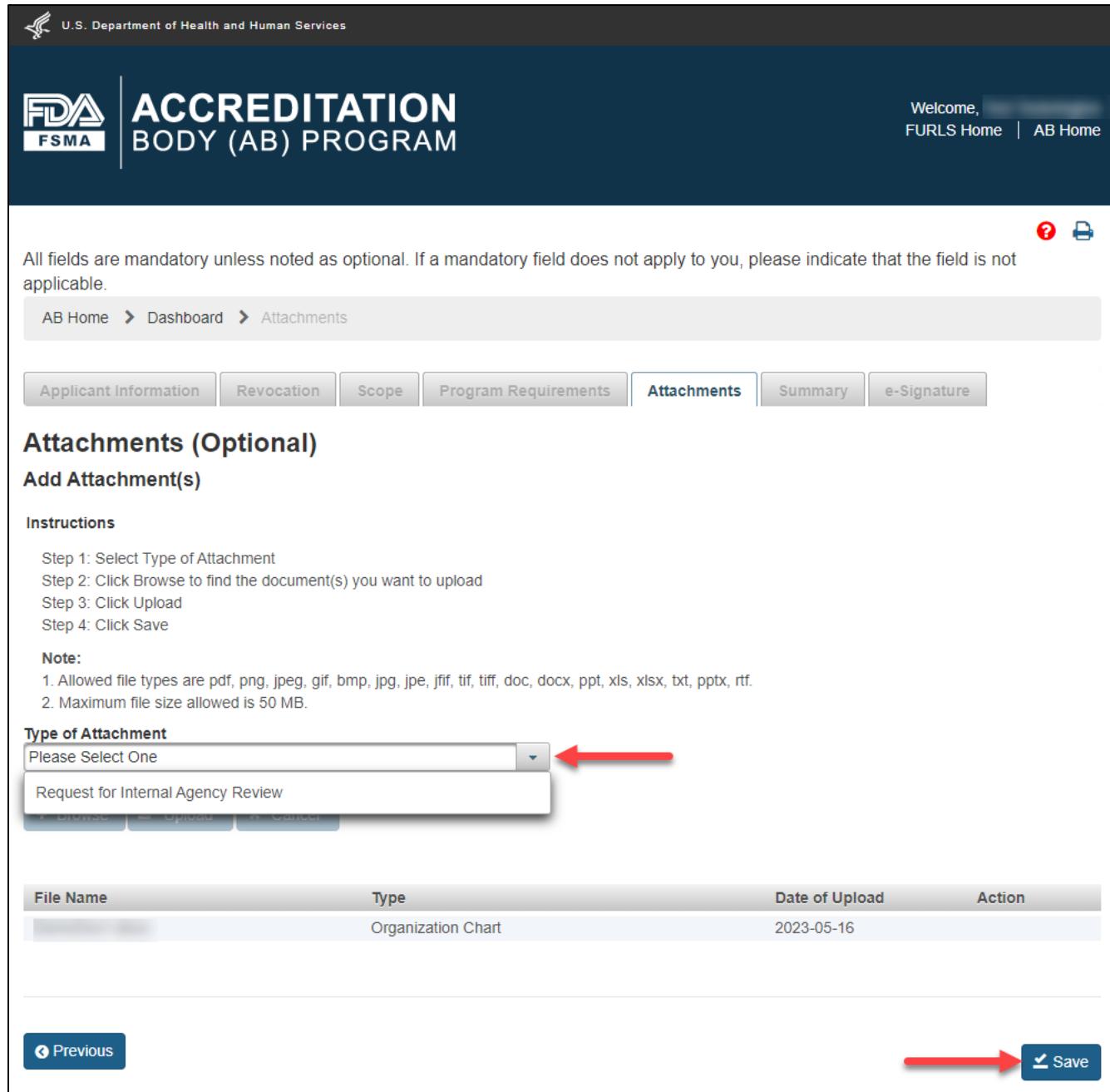


The screenshot shows the FDA Accreditation Body (AB) Program application status page. At the top, the FDA logo and "U.S. Department of Health and Human Services" are visible. The main header reads "ACCREDITATION BODY (AB) PROGRAM". On the right, a welcome message and links to "FURLS Home" and "AB Home" are present. Below the header, a navigation bar includes "AB Home" and icons for help and print. The main content area is titled "Application Information" and displays a table of applications. The table has columns for "Application Number", "Date of Submission", "Application Status", "Fee Status", and "Action". The first row shows an application with Application Number [REDACTED], Date of Submission 2023-05-16, Application Status Reconsideration - Denied (highlighted with a red arrow), Fee Status Paid, and Action buttons (search, download, edit, delete). The second row shows an application with Application Number [REDACTED], Date of Submission 2023-05-03, Application Status Denied, Fee Status Paid, and Action buttons (search, download).

Application Number	Date of Submission	Application Status	Fee Status	Action
[REDACTED]	2023-05-16	Reconsideration - Denied	Paid	
[REDACTED]	2023-05-03	Denied	Paid	

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

Figure 7.20 – Attachments Page



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 > Attachments

Applicant Information Revocation Scope Program Requirements **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

Request for Internal Agency Review

File Name Type Date of Upload Action

	Organization Chart	2023-05-16	
--	--------------------	------------	--

Previous  Save

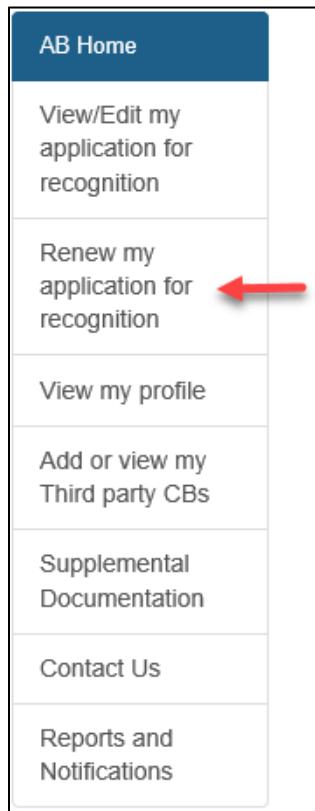
8 Apply for Renewal of Recognition

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

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

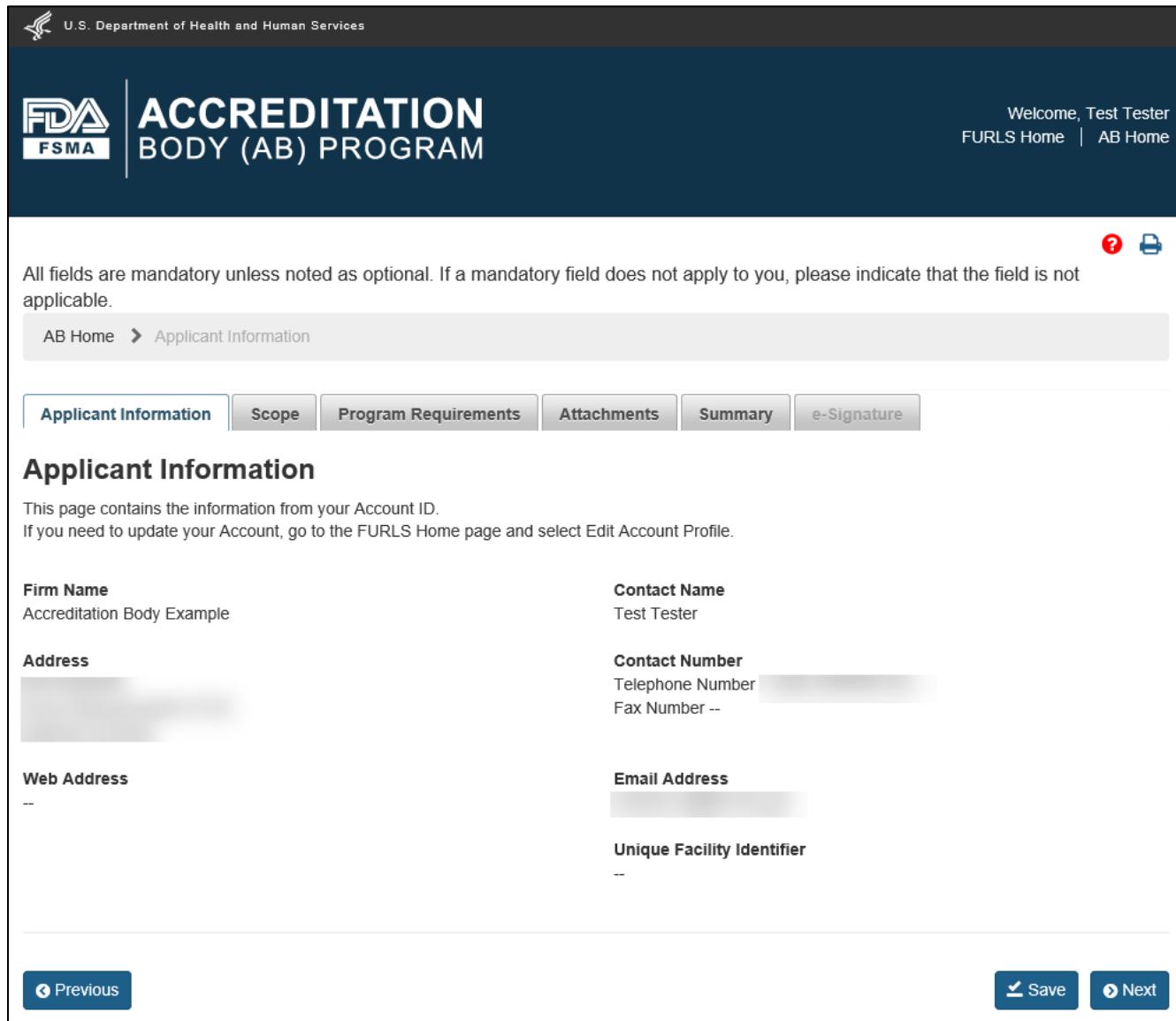
Click the “Renew my application for recognition” link on the navigation menu (Figure 8.1).

Figure 8.1 – Navigation Menu



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

Figure 8.2 – Applicant Information Page



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

Applicant Information | Scope | Program Requirements | 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 Example	Contact Name Test Tester
Address [Redacted]	Contact Number Telephone Number [Redacted] Fax Number --
Web Address --	Email Address [Redacted]
Unique Facility Identifier --	

Previous **Save** **Next**

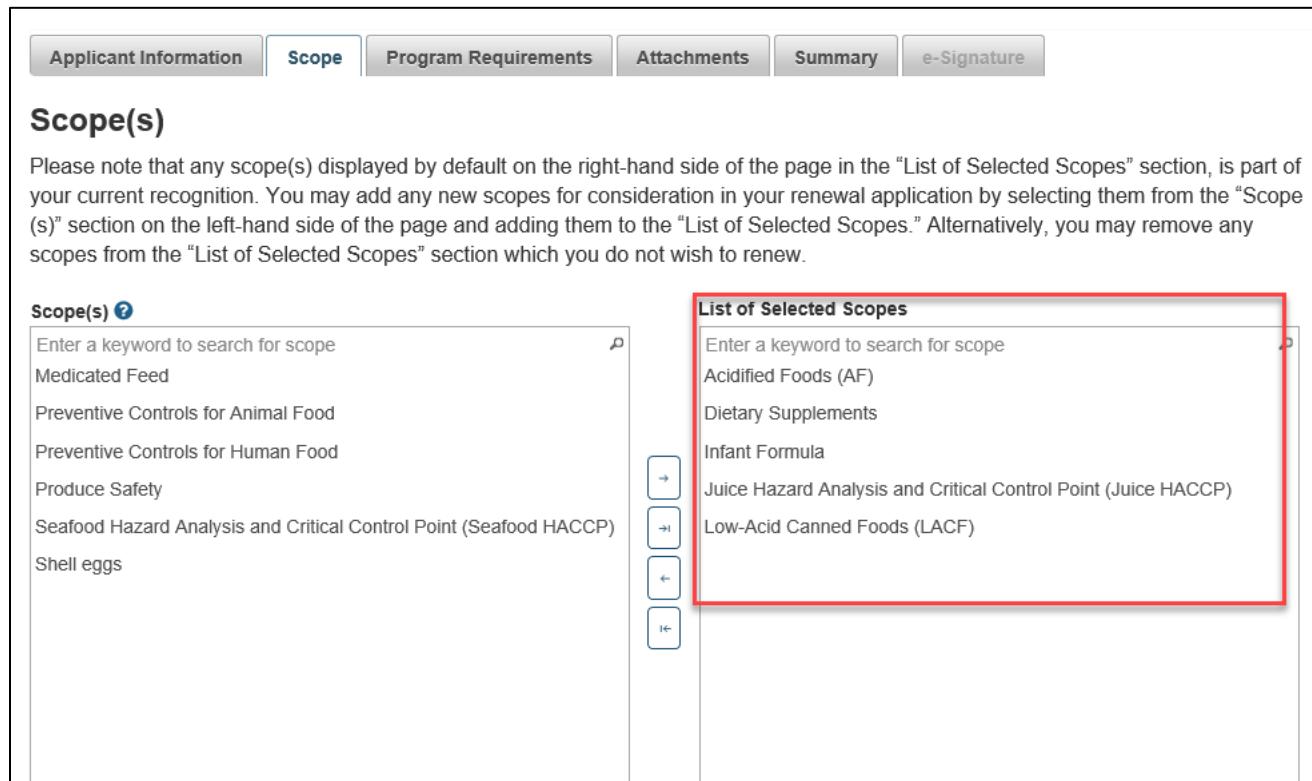
Refer to Chapter 5 “Apply for Recognition” for instructions to complete each of the pages of the application, with the following considerations for renewal:

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

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

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

Figure 8.3 – Scope Page



The screenshot shows a software interface for managing food safety scopes. At the top, there is a navigation bar with tabs: Applicant Information, Scope, Program Requirements, Attachments, Summary, and e-Signature. The 'Scope' tab is currently selected.

Scope(s)

Please note that any scope(s) displayed by default on the right-hand side of the page in the “List of Selected Scopes” section, is part of your current recognition. You may add any new scopes for consideration in your renewal application by selecting them from the “Scope(s)” section on the left-hand side of the page and adding them to the “List of Selected Scopes.” Alternatively, you may remove any scopes from the “List of Selected Scopes” section which you do not wish to renew.

Scope(s) ?

Enter a keyword to search for scope

- Medicated Feed
- Preventive Controls for Animal Food
- Preventive Controls for Human Food
- Produce Safety
- Seafood Hazard Analysis and Critical Control Point (Seafood HACCP)
- Shell eggs

Operations buttons: +, +i, ←, ←i

List of Selected Scopes

Enter a keyword to search for scope

- Acidified Foods (AF)
- Dietary Supplements
- Infant Formula
- Juice Hazard Analysis and Critical Control Point (Juice HACCP)
- Low-Acid Canned Foods (LACF)

Operations buttons: +, +i, ←, ←i

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

- **Program Requirements Page** – Complete each of the fields, as applicable.

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

Figure 8.4 – No Change Response

Applicant Information
Scope
Program Requirements
Attachments
Summary
e-Signature

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided. If there has been no change to how you are meeting the requirements for a specific question and the documentation supporting your response has not changed, enter "No change" for your response, where applicable.

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

Legal Authority >> §1.611(a)

Regulation Text

An accreditation body seeking recognition must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform assessments of a third-party certification body as are necessary to determine its capability to conduct audits and certify food facilities and food, including authority to:

Criteria to Demonstrate

Please indicate if you are a government body that has jurisdiction over the food commodities to which you are applying; or if you are not a government body and have a contract establishing the required legal authorities.

User Response (provide your answer below)

No Change

3991 characters remaining.

Additional Information (URL, References, etc.) (Optional)

No Change

3991 characters remaining.

Attachments (Optional)

Attachments

File Name	Date of Upload
No records found.	

Previous
Save
Next

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

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

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

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

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

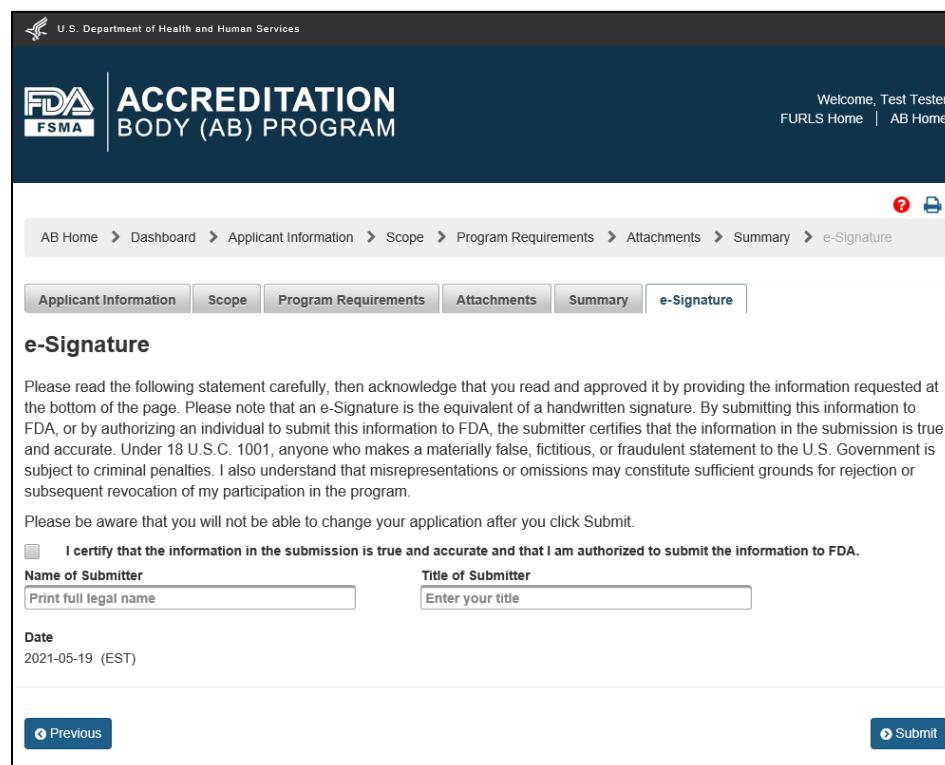
Complete the following data fields:

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

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

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

Figure 8.5 – e-Signature Page



U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Dashboard > Applicant Information > Scope > Program Requirements > Attachments > Summary > e-Signature

Applicant Information | Scope | Program Requirements | 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
Print full legal name

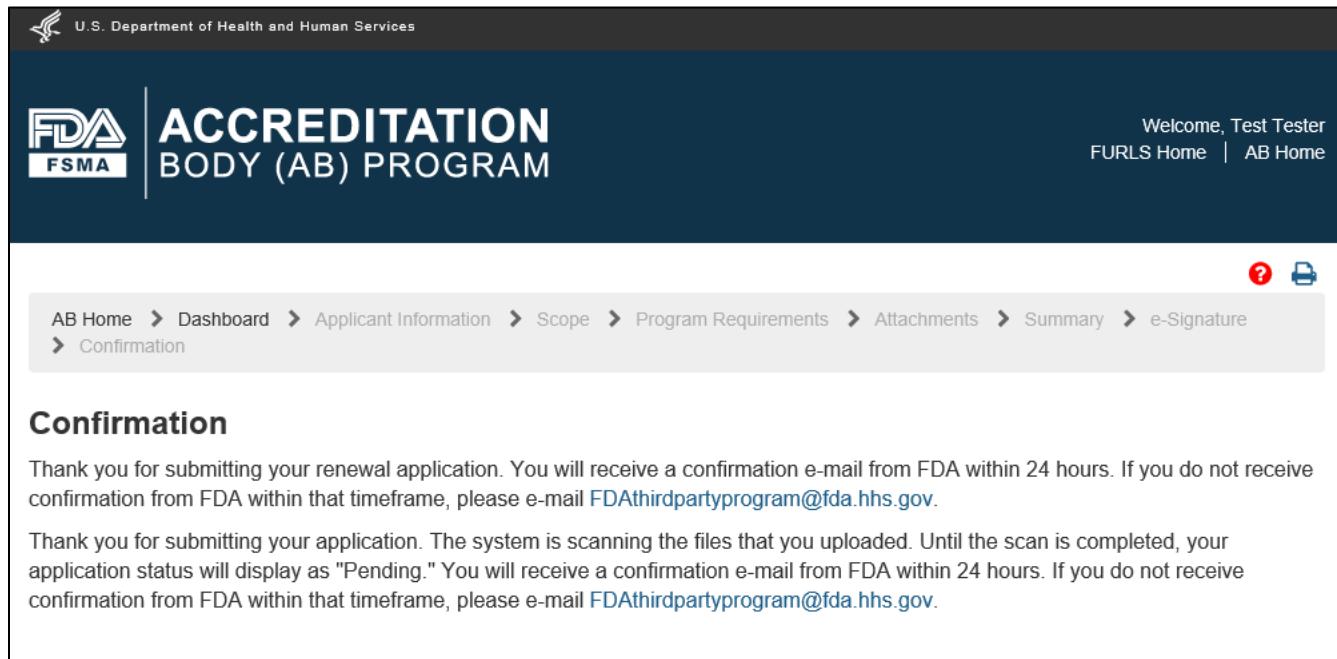
Title of Submitter
Enter your title

Date
2021-05-19 (EST)

Previous | Submit

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

Figure 8.6 – Confirmation 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 > Scope > Program Requirements > Attachments > Summary > e-Signature > Confirmation

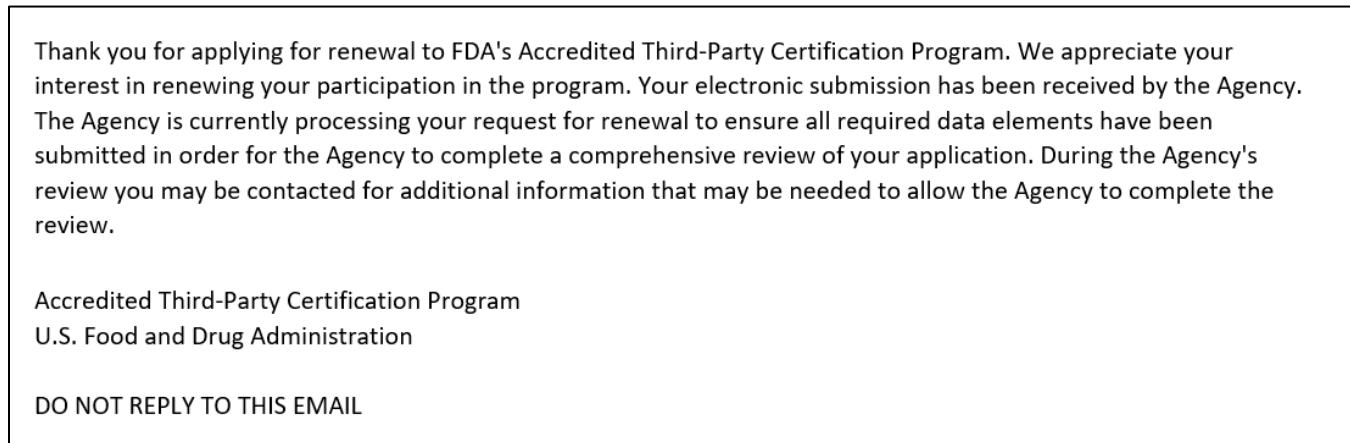
Confirmation

Thank you for submitting your renewal application. You will receive a confirmation e-mail from FDA within 24 hours. If you do not receive confirmation from FDA within that timeframe, please e-mail FDAt thirdpartyprogram@fda.hhs.gov.

Thank you for submitting your application. The system is scanning the files that you uploaded. Until the scan is completed, your application status will display as "Pending." You will receive a confirmation e-mail from FDA within 24 hours. If you do not receive confirmation from FDA within that timeframe, please e-mail FDAt thirdpartyprogram@fda.hhs.gov.

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

Figure 8.7 – E-mail Notification



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

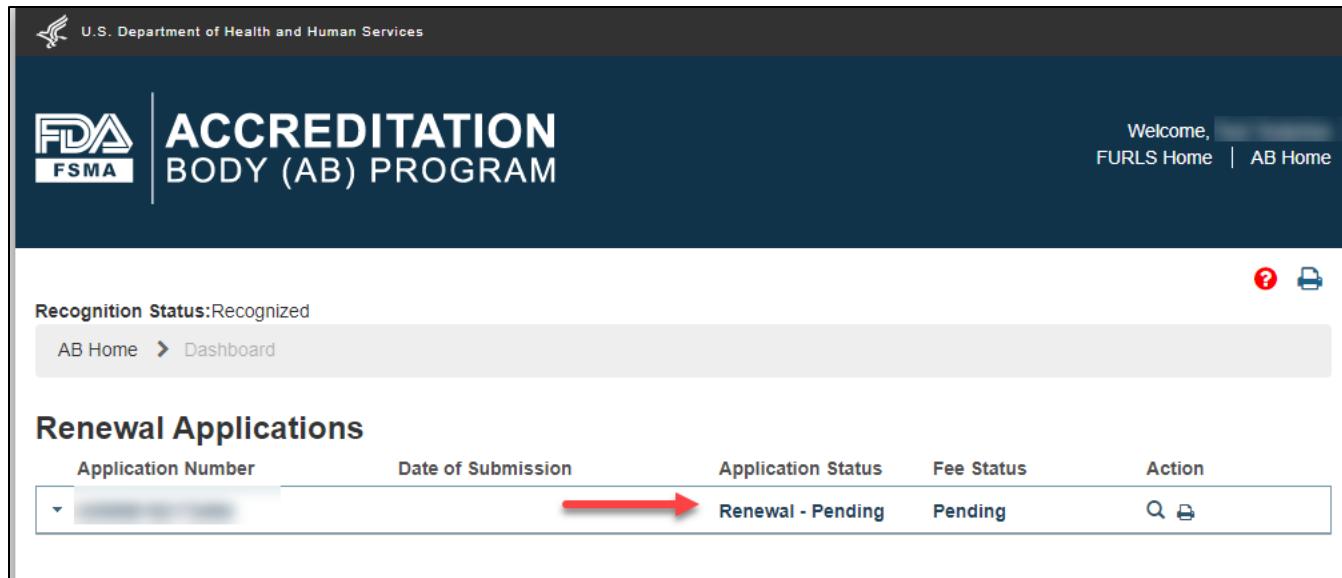
Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

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

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

Figure 8.8 – Renewal - Pending Application Status



U.S. Department of Health and Human Services

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

Welcome, [REDACTED]
FURLS Home | AB Home

Recognition Status: Recognized

AB Home > Dashboard

Renewal Applications

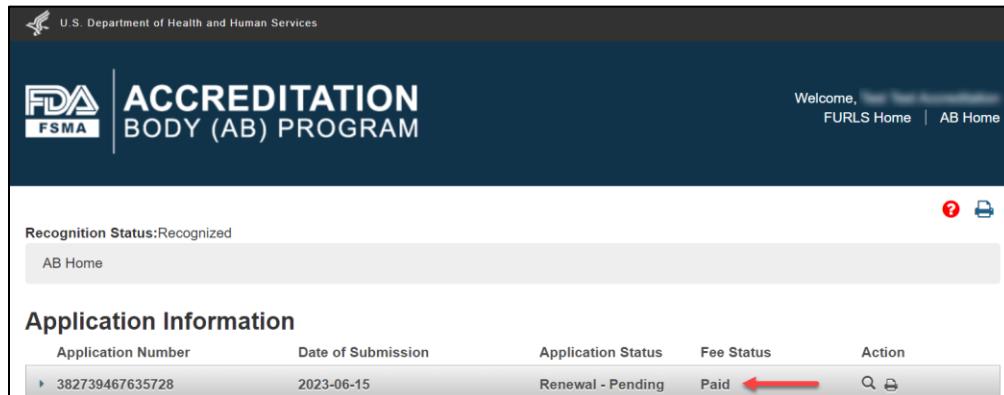
Application Number	Date of Submission	Application Status	Fee Status	Action
[REDACTED]		Renewal - Pending	Pending	

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

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

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

Figure 8.9 – Paid Fee Status



U.S. Department of Health and Human Services

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

Welcome, [REDACTED]
FURLS Home | AB Home

Recognition Status: Recognized

AB Home

Application Information

Application Number	Date of Submission	Application Status	Fee Status	Action
382739467635728	2023-06-15	Renewal - Pending	Paid	

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

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

Figure 8.10 – E-mail Notification

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

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

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

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

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

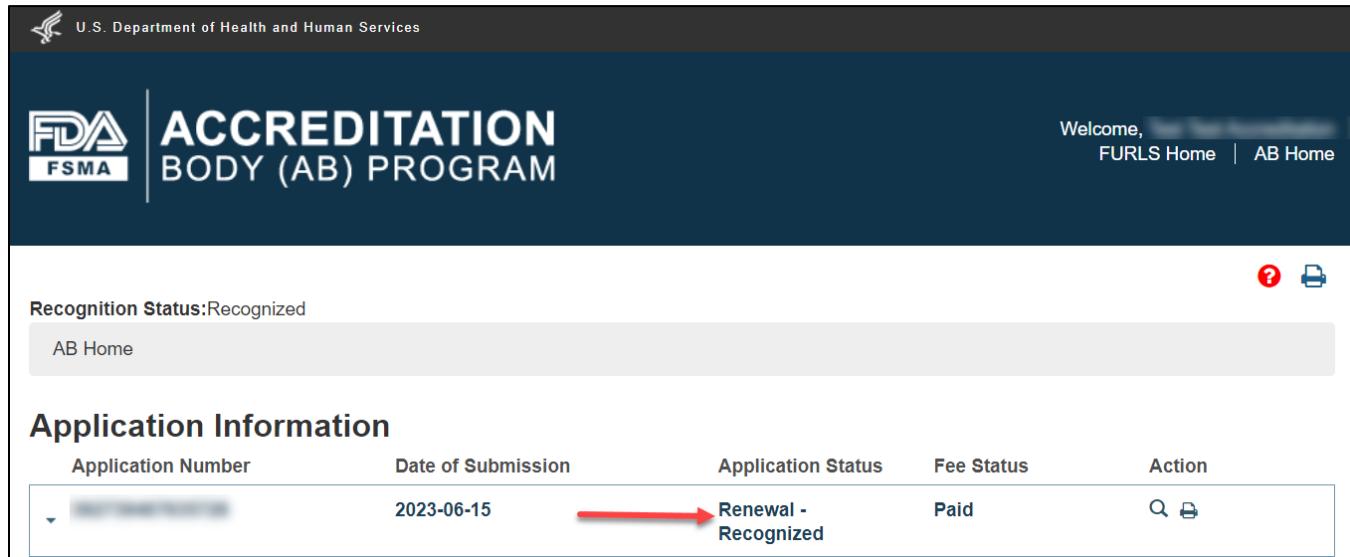
Accredited Third-Party Certification Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

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

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

Figure 8.11 – Renewal - Recognized Status



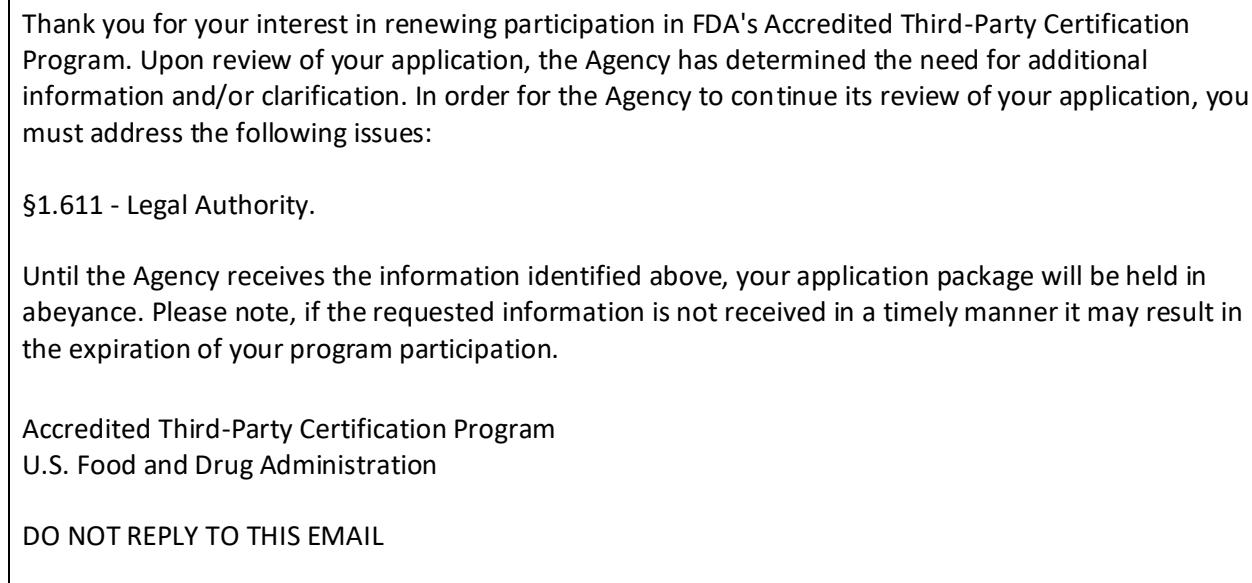
The screenshot shows a web page for the FDA Accreditation Body (AB) Program. At the top, there is a header with the FDA logo, the text 'U.S. Department of Health and Human Services', and a navigation bar with 'Welcome' and links to 'FURLS Home' and 'AB Home'. The main content area is titled 'ACCREDITATION BODY (AB) PROGRAM'. Below this, a message says 'Recognition Status: Recognized' with links to 'AB Home' and a help icon. A table titled 'Application Information' is shown, with columns for 'Application Number', 'Date of Submission', 'Application Status', 'Fee Status', and 'Action'. A red arrow points to the 'Application Status' column for a row where the status is 'Renewal - Recognized'. The 'Action' column for this row contains a magnifying glass icon and a pencil icon.

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

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

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

Figure 8.12 – E-mail Notification



The e-mail notification is from the Accredited Third-Party Certification Program. It starts with a thank you message for interest in renewing participation. It then states that upon review, additional information is needed and provides a list of issues to address. It includes a section on legal authority, a note about holding the application in abeyance, and contact information for the FDA. At the bottom, it says 'DO NOT REPLY TO THIS EMAIL'.

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

§1.611 - Legal Authority.

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

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

DO NOT REPLY TO THIS EMAIL

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

Figure 8.13 – E-mail Notification

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

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

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

DO NOT REPLY TO THIS EMAIL

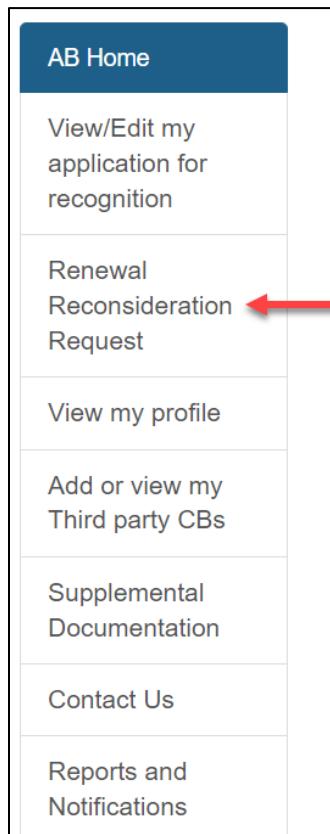
You may submit a renewal application reconsideration request for any scopes that have been denied on the initial application to be reconsidered by FDA.

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

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

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

Figure 8.14 – Navigation Menu



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

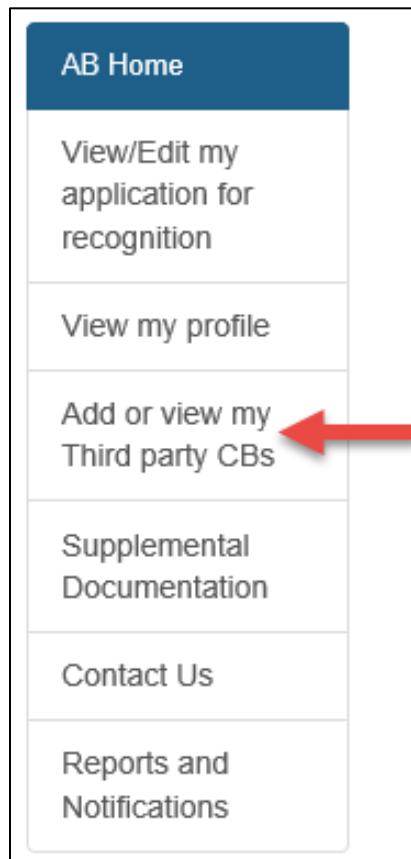
The “Add or view my Third-Party CBs” feature may be used to perform the following two functions:

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

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

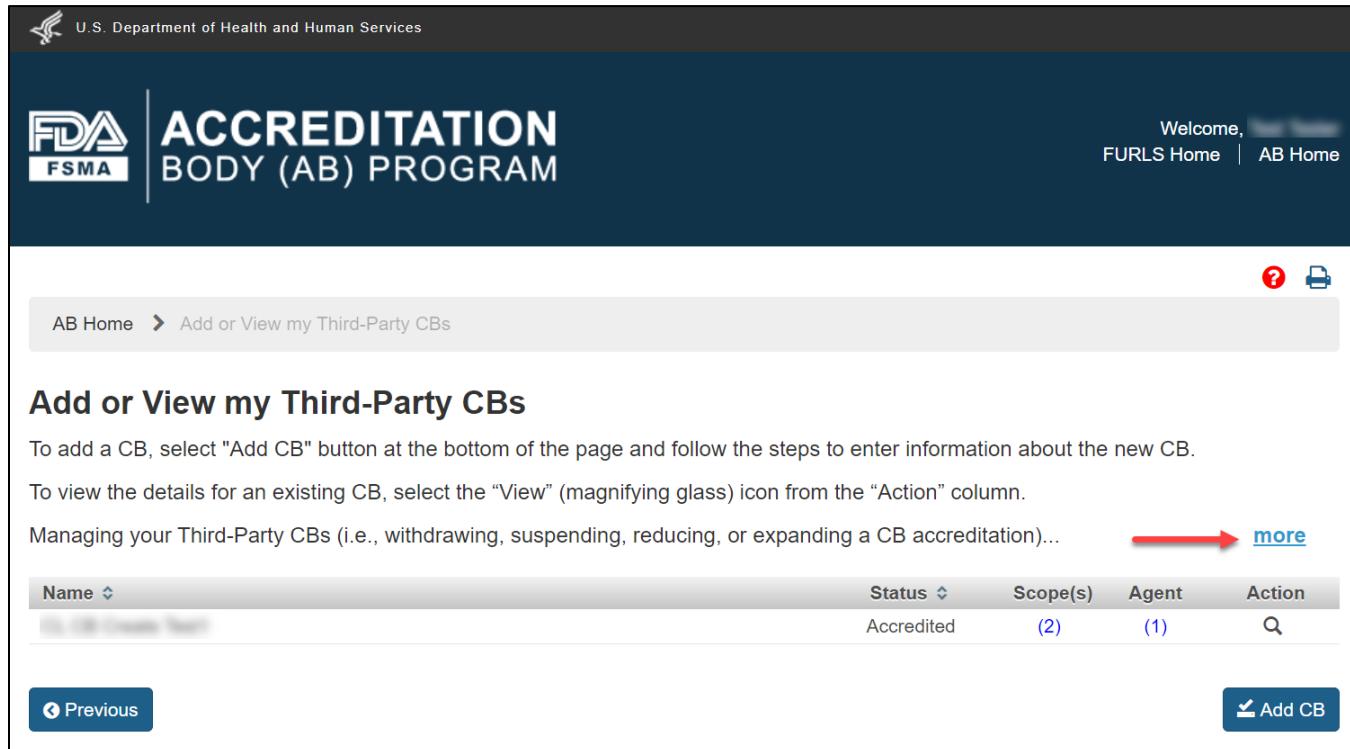
Note: To renew the accreditation of a CB refer to Section 11.6 of this document, “Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB.”

Figure 9.1 – Navigation Menu



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

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



U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome, [User Name]
FURLS Home | AB Home

AB Home > Add or View my Third-Party CBs

Add or View my Third-Party CBs

To add a CB, select "Add CB" button at the bottom of the page and follow the steps to enter information about the new CB.

To view the details for an existing CB, select the "View" (magnifying glass) icon from the "Action" column.

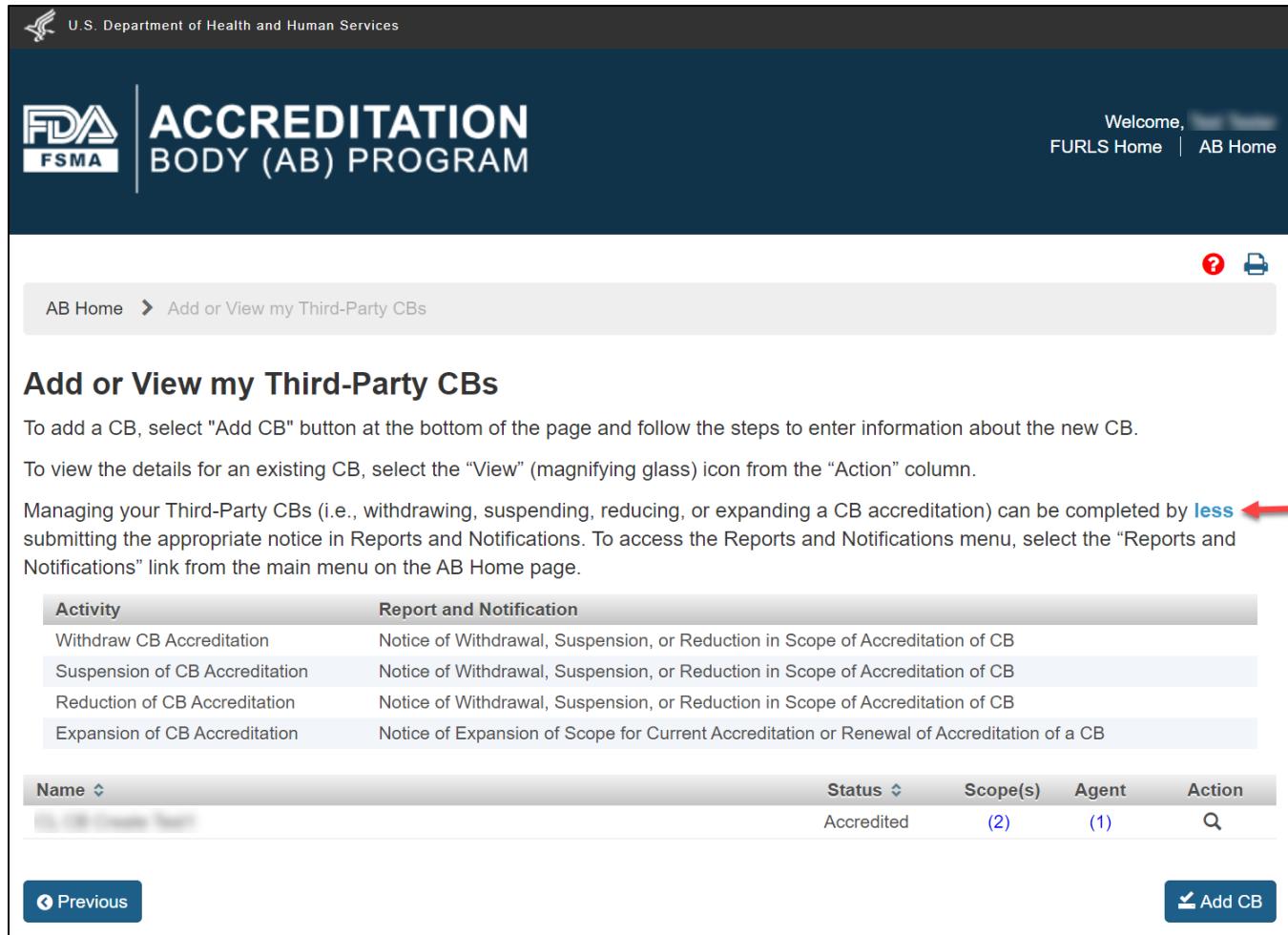
Managing your Third-Party CBs (i.e., withdrawing, suspending, reducing, or expanding a CB accreditation)... → [more](#)

Name	Status	Scope(s)	Agent	Action
Accredited	(2)	(1)		

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

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

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



The screenshot shows the 'Add or View my Third-Party CBs' page. At the top, there is a navigation bar with the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and a 'Welcome' message. Below the navigation bar, the page title is 'Add or View my Third-Party CBs'. A sub-navigation bar shows 'AB Home' and 'Add or View my Third-Party CBs'. On the right, there are 'Help' and 'Print' icons. The main content area has a heading 'Add or View my Third-Party CBs'. Below it, a text block says: 'To add a CB, select "Add CB" button at the bottom of the page and follow the steps to enter information about the new CB. To view the details for an existing CB, select the "View" (magnifying glass) icon from the "Action" column. Managing your Third-Party CBs (i.e., withdrawing, suspending, reducing, or expanding a CB accreditation) can be completed by [less](#)  submitting the appropriate notice in Reports and Notifications. To access the Reports and Notifications menu, select the "Reports and Notifications" link from the main menu on the AB Home page.' A table titled 'Activity' and 'Report and Notification' lists four activities: Withdraw CB Accreditation, Suspension of CB Accreditation, Reduction of CB Accreditation, and Expansion of CB Accreditation, each with a corresponding report/notification. Below this, a table lists accredited CBs with columns for Name, Status, Scope(s), Agent, and Action. The 'Action' column contains a magnifying glass icon. At the bottom, there are 'Previous' and 'Add CB' buttons.

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

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

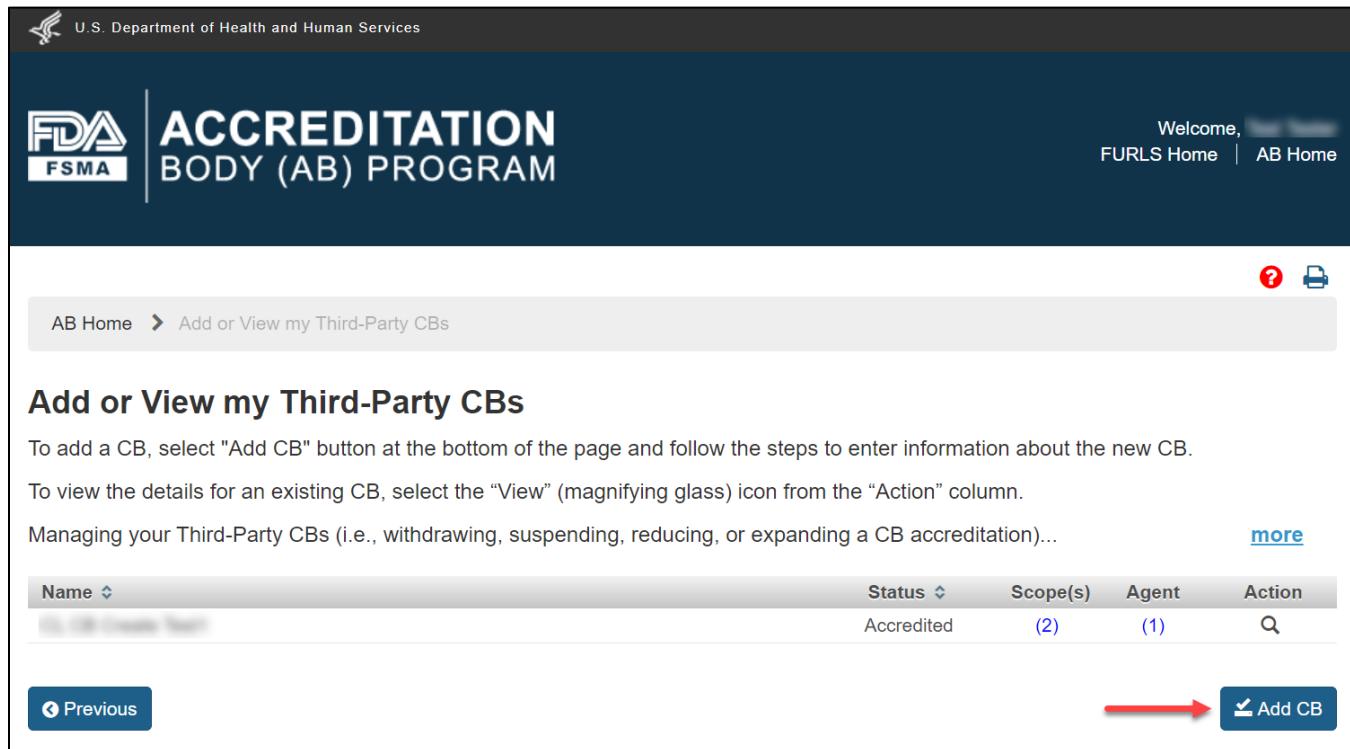
Note: To manage CB(s) (i.e., withdraw, suspend, reduce, expand or, renew a CB accreditation), identify the activity from the “Activity” column of the table on the “Add or View my Third-Party CBs” page and find the corresponding notice listed in the “Reports and Notifications” column of the same table.

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

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

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

Figure 9.4 – Add CB Button



U.S. Department of Health and Human Services

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

Welcome, [User Name](#)
FURLS Home | AB Home

AB Home > Add or View my Third-Party CBs

Add or View my Third-Party CBs

To add a CB, select "Add CB" button at the bottom of the page and follow the steps to enter information about the new CB.

To view the details for an existing CB, select the "View" (magnifying glass) icon from the "Action" column.

Managing your Third-Party CBs (i.e., withdrawing, suspending, reducing, or expanding a CB accreditation)... [more](#)

Name	Status	Scope(s)	Agent	Action
...	Accredited	(2)	(1)	

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

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

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

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

U.S. Department of Health and Human Services

FDA | **ACcreditation
BODY (AB) PROGRAM**

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Add or View my Third-Party CBs > Add and Notify CB

Add Accredited Third-Party CB

To add a CB, enter the CB's e-mail address. Click "Search CB." The system will populate the CB profile information if the system finds [...more](#)

[...more](#) 

E-mail Address: **Search CB**

Third-Party Certification Body Name:

Contact Name:
First Name MI (Optional) Last Name

Country: Please Select One

Phone Number:
Country Area Phone Number Extension

Address 1:

Fax Number (Optional):
Country Area Fax Number

Address 2 (Optional):

Status: Accredited

City:

Web Address (Optional):

State/Province/Territory: Please Select One

Officer(s): You can enter another officer

Zip Code (Postal Code):

Audit Agent(s)

Agent Name	Email	Action
No Data Found		

+ Add Agent

Scopes of Accredited Third-Party Certification Body

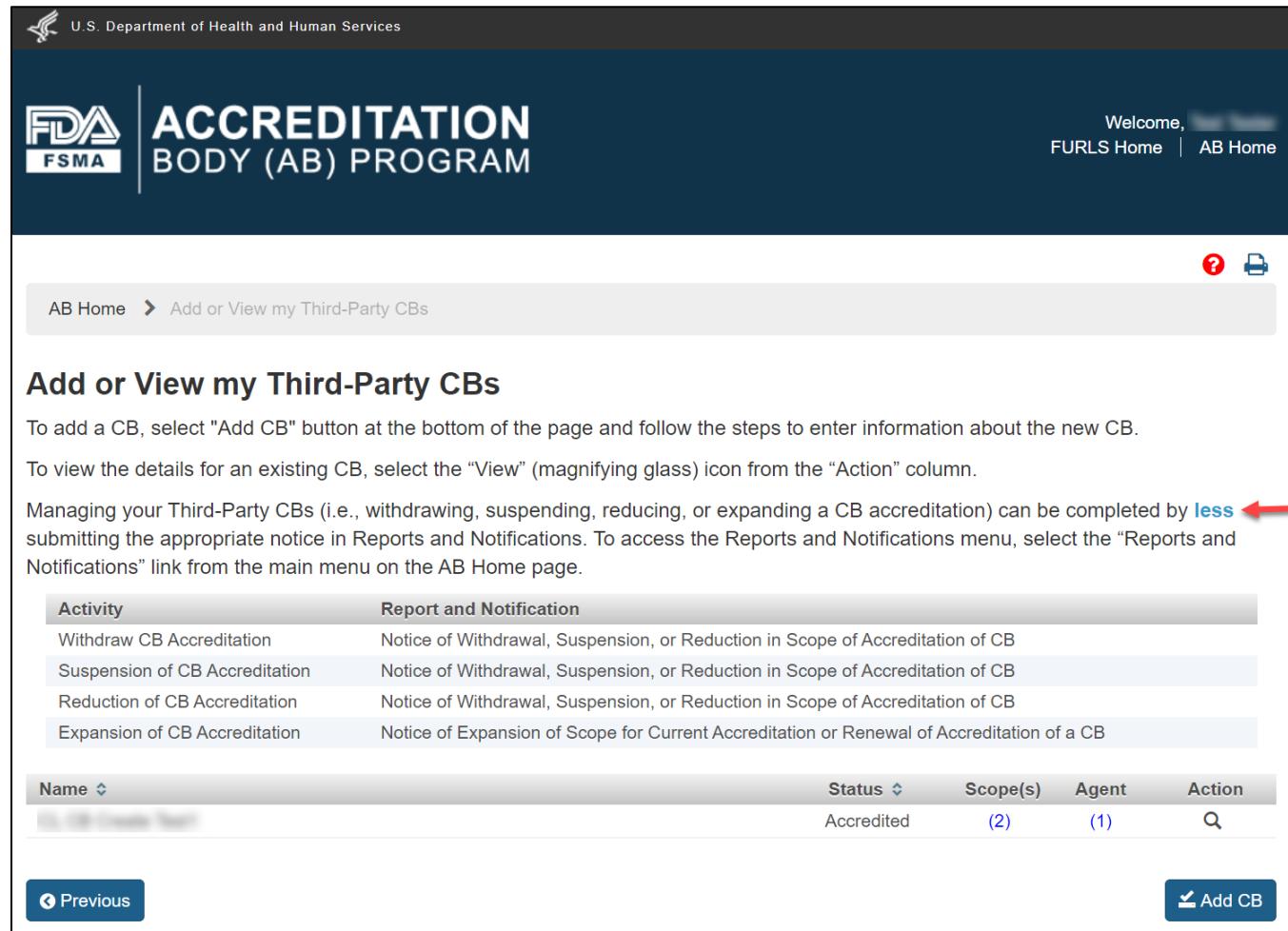
Scope(s)	Accreditation Date	Expiration Date
No Data Found		

+ Add / Manage Scope(s)

Previous **Cancel** **Next**

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

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



U.S. Department of Health and Human Services

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

Welcome, [User Name](#)
FURLS Home | AB Home

AB Home > Add or View my Third-Party CBs

Add or View my Third-Party CBs

To add a CB, select "Add CB" button at the bottom of the page and follow the steps to enter information about the new CB.

To view the details for an existing CB, select the "View" (magnifying glass) icon from the "Action" column.

Managing your Third-Party CBs (i.e., withdrawing, suspending, reducing, or expanding a CB accreditation) can be completed by [less](#) 

submitting the appropriate notice in Reports and Notifications. To access the Reports and Notifications menu, select the "Reports and Notifications" link from the main menu on the AB Home page.

Activity	Report and Notification
Withdraw CB Accreditation	Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
Suspension of CB Accreditation	Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
Reduction of CB Accreditation	Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB
Expansion of CB Accreditation	Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB

Name	Status	Scope(s)	Agent	Action
[REDACTED]	Accredited	(2)	(1)	

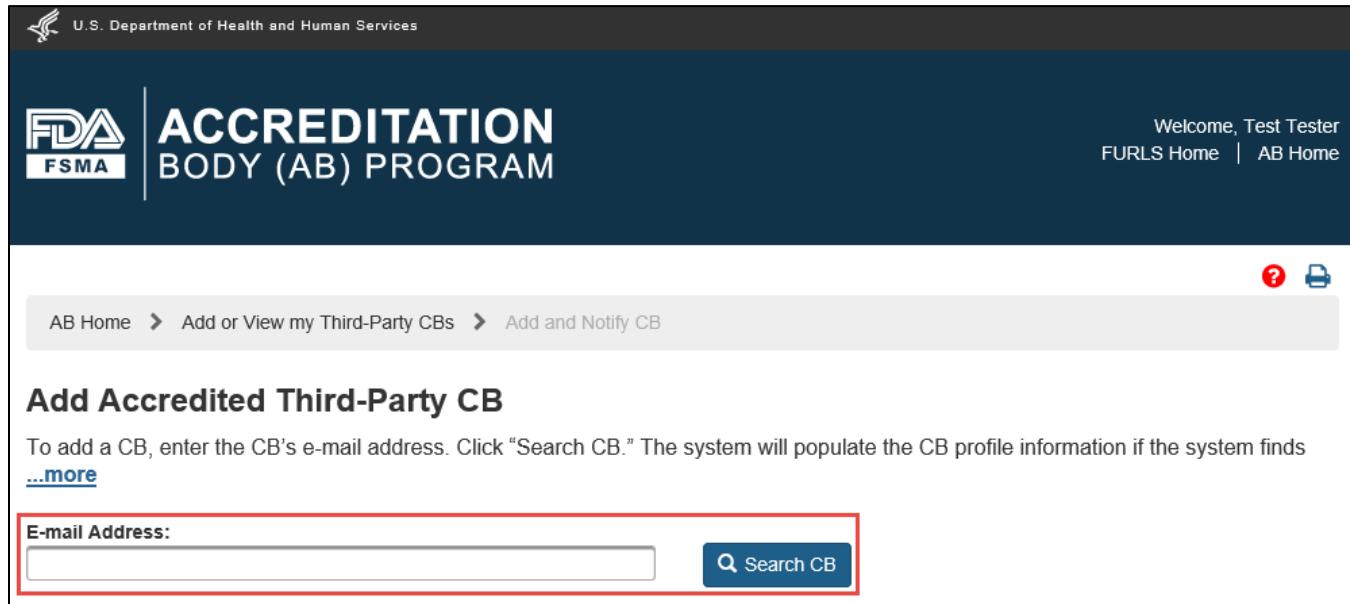
 

Enter the e-mail address of the new CB in the “E-mail Address” field and click the “Search CB” button (Figure 9.7). If the system returns a match (i.e., the CB’s e-mail address already exists in the system), the field will be pre-filled with the CB’s information.

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

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

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



The screenshot shows the FDA Accreditation Body (AB) Program website. At the top, there is a navigation bar with the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "ACCREDITATION BODY (AB) PROGRAM". On the right side of the top bar, it says "Welcome, Test Tester" and provides links to "FURLS Home" and "AB Home". Below the top bar, there is a breadcrumb navigation: "AB Home" > "Add or View my Third-Party CBs" > "Add and Notify CB". On the right side of this navigation bar are a help icon (a question mark) and a print icon. The main content area is titled "Add Accredited Third-Party CB". It contains a sub-instruction: "To add a CB, enter the CB's e-mail address. Click "Search CB." The system will populate the CB profile information if the system finds [...more](#)". Below this instruction is a form field with a red border. The field has the label "E-mail Address:" and a text input box. To the right of the input box is a blue button with a magnifying glass icon and the text "Search CB".

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

- **E-mail Address** – The e-mail address for the Point of Contact
- **Third-Party Certification Body Name** – The name of the CB the Point of Contact represents
- **Country** – The country where the CB is physically located
- **Address 1** – The address where the CB is physically located (includes the number, street, quadrant, etc.)
- **Address 2 (Optional)** – The additional information about the physical location of the CB (may include a suite or apartment number, if applicable)
- **City** – The city where the CB is physically located
- **State/Province/Territory** – The state/province/territory of the CB
- **Zip Code (Postal Code)** – The zip code or postal code of the CB
- **Contact Name**
 - **First Name** – The first name of the Point of Contact
 - **MI (Optional)** – The first letter of the Point of Contact’s middle name
 - **Last Name** – The last name of the Point of Contact
- **Phone Number (Country/Area/Phone Number/Extension)** – The telephone number of the Point of Contact
 - “Country” is the country code.
 - “Area” is the area code.
 - “Phone Number” is the phone number.
 - “Extension” is the local phone extension to dial of the Point of Contact, if applicable.
- **Fax Number (Country/Area/Fax Number)** – The fax number of the Point of Contact
 - “Country” is the country code.

- “Area” is the area code.
- “Fax Number” is the fax number.
- **Web Address (Optional field)** – The URL of the company
- **Officer(s)** – The Officer(s) of the company

Complete the data fields.

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

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 View my Third-Party CBs > Add and Notify CB

Add Accredited Third-Party CB

To add a CB, enter the CB's e-mail address. Click "Search CB." The system will populate the CB profile information if the system finds [...more](#)

E-mail Address: **Search CB**

Third-Party Certification Body Name: **Contact Name:**
 First Name **MI (Optional)** **Last Name**

Country: **Phone Number:**
 Country **Area** **Phone Number** **Extension**

Address 1: **Fax Number (Optional):**
 Country **Area** **Fax Number**

Address 2 (Optional): **Status:** Accredited

City: **Web Address (Optional):**

State/Province/Territory: **Officer(s):** **+
You can enter another officer**

Zip Code (Postal Code):

Audit Agent(s)

Agent Name	Email	Action
No Data Found		

+ Add Agent

Scopes of Accredited Third-Party Certification Body

Scope(s)	Accreditation Date	Expiration Date
No Data Found		

+ Add / Manage Scope(s)

Previous **Cancel** **Next**

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

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

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

Figure 9.9 – Add Agent Button

Audit Agent(s)		
Agent Name	Email	Action
No Data Found		 + Add Agent

Scopes of Accredited Third-Party Certification Body		
Scope(s)	Accreditation Date	Expiration Date
No Data Found		

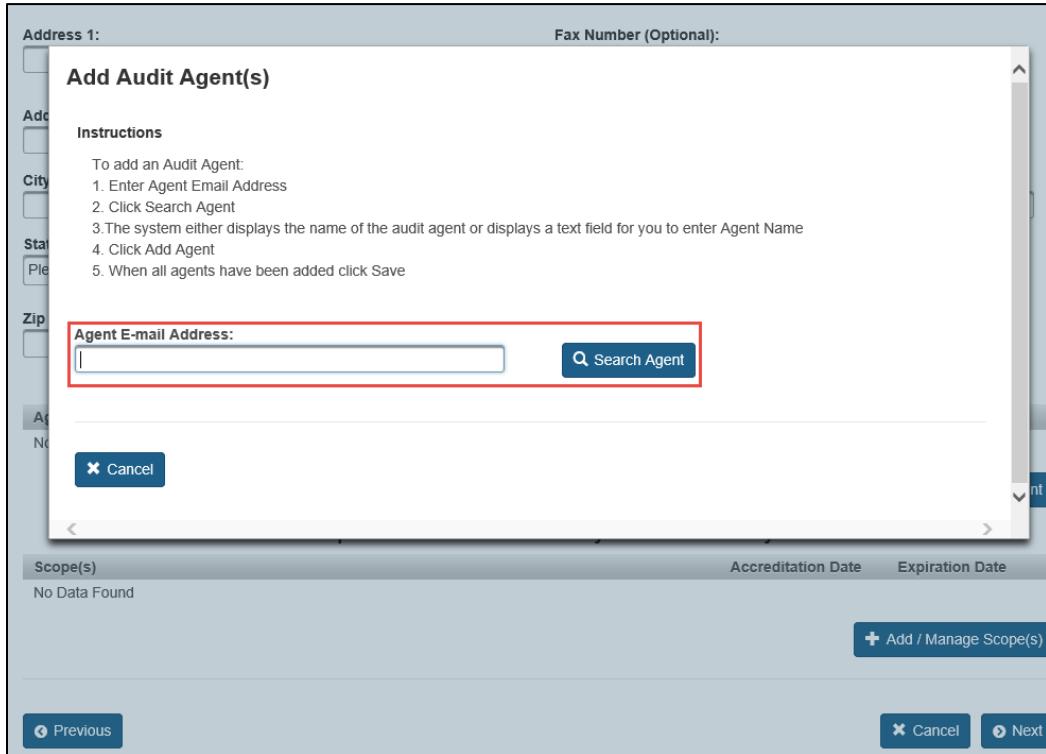
[!\[\]\(3a69404570c7e2b85694621a73965ca5_img.jpg\) Previous](#) [!\[\]\(e5304047b6f233cc510ea3314eeed834_img.jpg\) Cancel](#) [!\[\]\(b705952be60477da561fa0f48a2c4032_img.jpg\) Next](#)

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

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

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

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



Address 1: Fax Number (Optional):

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: Search Agent

Cancel

Scope(s)

No Data Found

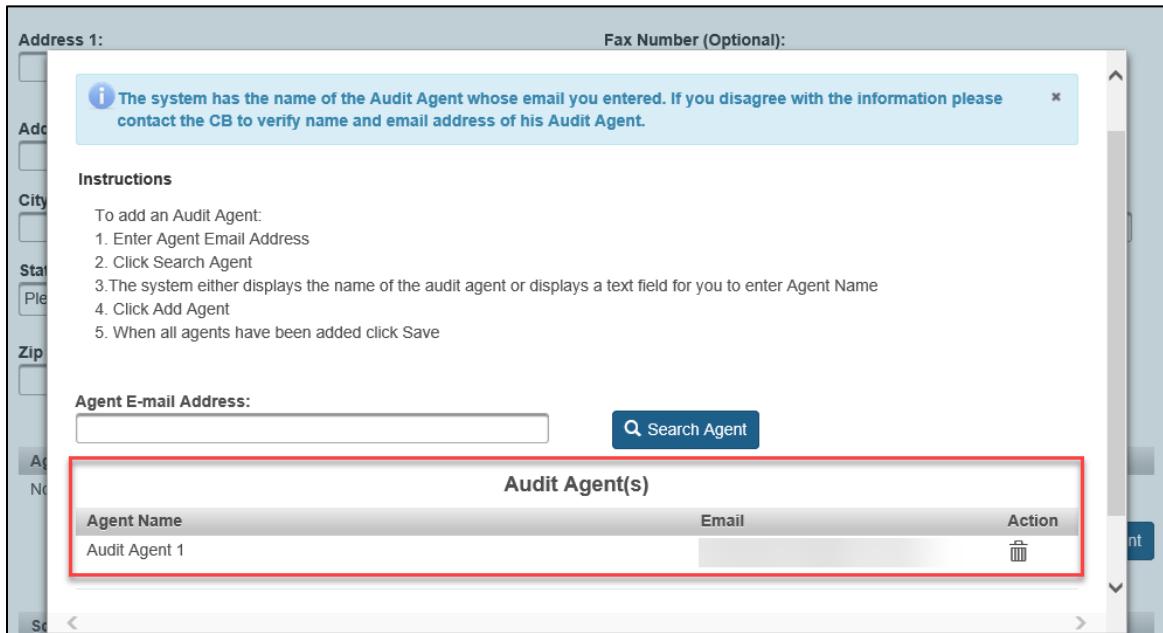
Add / Manage Scope(s)

Accreditation Date Expiration Date

Previous Next

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

Figure 9.11 – Audit Agent(s) Table



Address 1: Fax Number (Optional):

Instructions

The system has the name of the Audit Agent whose email you entered. If you disagree with the information please contact the CB to verify name and email address of his Audit Agent.

Agent E-mail Address: Search Agent

Audit Agent(s)

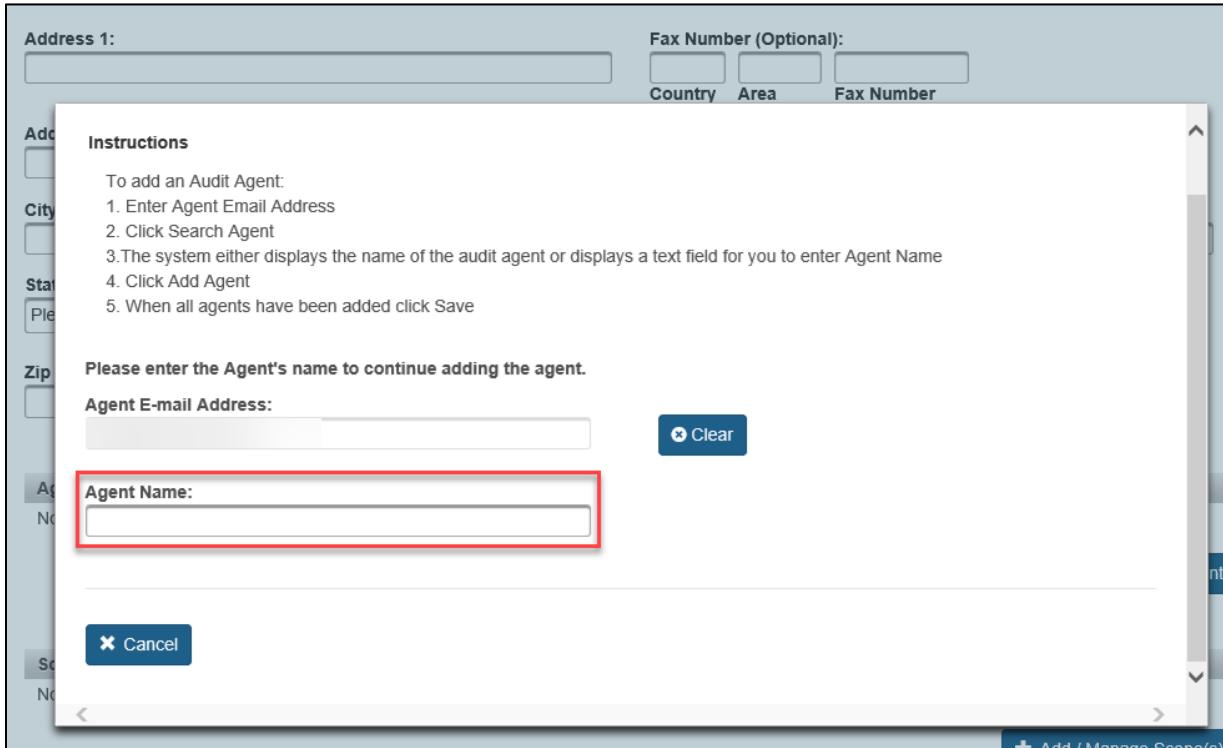
Agent Name	Email	Action
Audit Agent 1	<input type="text"/>	trash

Previous Next

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

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

Figure 9.12 – Agent Name Field



The screenshot shows a web-based form for adding an audit agent. At the top, there are fields for 'Address 1' and 'Fax Number (Optional)' (Country, Area, Fax Number). Below these are sections for 'City', 'State', 'Zip', and 'Phone'. A large 'Instructions' box contains the following steps: 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. A note below says 'Please enter the Agent's name to continue adding the agent.' There are fields for 'Agent E-mail Address' and 'Agent Name', the latter of which is highlighted with a red box. At the bottom are 'Clear' and 'Cancel' buttons.

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

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

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

Figure 9.13 – Audit Agent(s) Table

Audit Agent(s)		
Agent Name	Email	Action
██	██	
		

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

Figure 9.14 – Add/Manage Scope(s) Button

Scopes of Accredited Third-Party Certification Body		
Scope(s)	Accreditation Date	Expiration Date
No Data Found		
		
		

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

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

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

Address 1:	Fax Number (Optional):		
Add/Manage Scope(s)			
Select	Scope(s)	Accreditation Date	Expiration Date
<input type="checkbox"/>	Acidified Foods (AF)	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Dietary Supplements	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Infant Formula	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Juice Hazard Analysis and Critical Control Point (Juice HACCP)	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Low-Acid Canned Foods (LACF)	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Medicated Feed	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Preventive Controls for Animal Food	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Preventive Controls for Human Food	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Produce Safety	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Seafood Hazard Analysis and Critical Control Point (Seafood HACCP)	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Shell eggs	YYYY-MM-DD	YYYY-MM-DD
<input type="button" value="Save"/> <input type="button" value="Cancel"/>			
			
			

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

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

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

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

Add/Manage Scope(s)

Select	Scope(s)	Accreditation Date	Expiration Date
<input checked="" type="checkbox"/>	Acidified Foods (AF)	YYYY-MM-DD 	YYYY-MM-DD 
<input type="checkbox"/>	Dietary Supplements	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Infant Formula	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Juice Hazard Analysis and Critical Control Point (Juice HACCP)	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Low-Acid Canned Foods (LACF)	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Medicated Feed	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Preventive Controls for Animal Food	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Preventive Controls for Human Food	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Produce Safety	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Seafood Hazard Analysis and Critical Control Point (Seafood HACCP)	YYYY-MM-DD	YYYY-MM-DD
<input type="checkbox"/>	Shell eggs	YYYY-MM-DD	YYYY-MM-DD

Save
Cancel

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

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

Scopes of Accredited Third-Party Certification Body		
Scope(s)	Accreditation Date	Expiration Date
Acidified Foods (AF)	2020-06-01	2024-06-01
Dietary Supplements	2020-06-01	2024-06-01
Infant Formula	2020-06-01	2024-06-01

+ Add / Manage Scope(s)

◀ Previous

✖ Cancel **▶ Next**

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

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

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

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

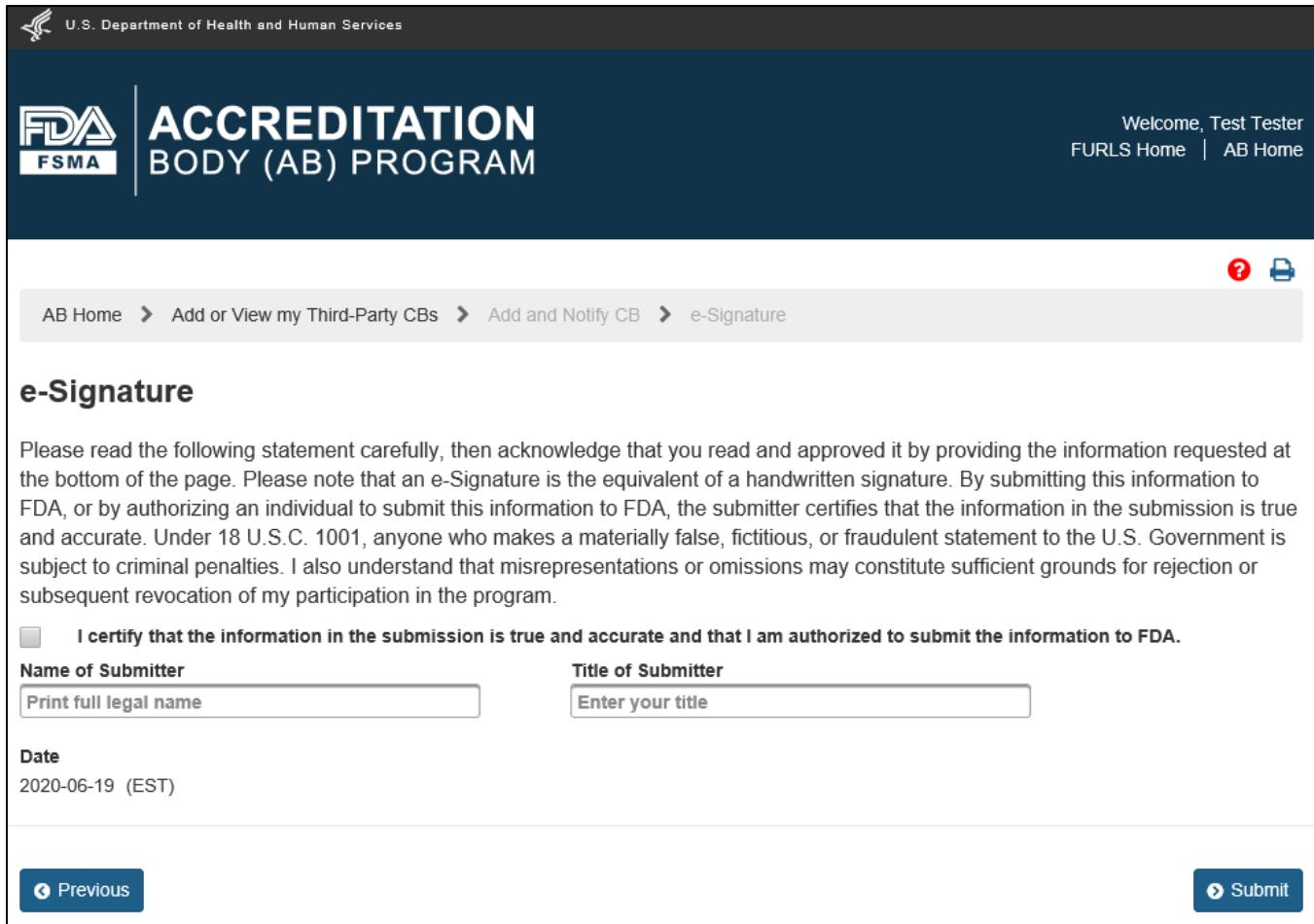
Complete the following data fields:

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

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

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

Figure 9.18 – e-Signature Page



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 View my Third-Party CBs > Add and Notify 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.

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

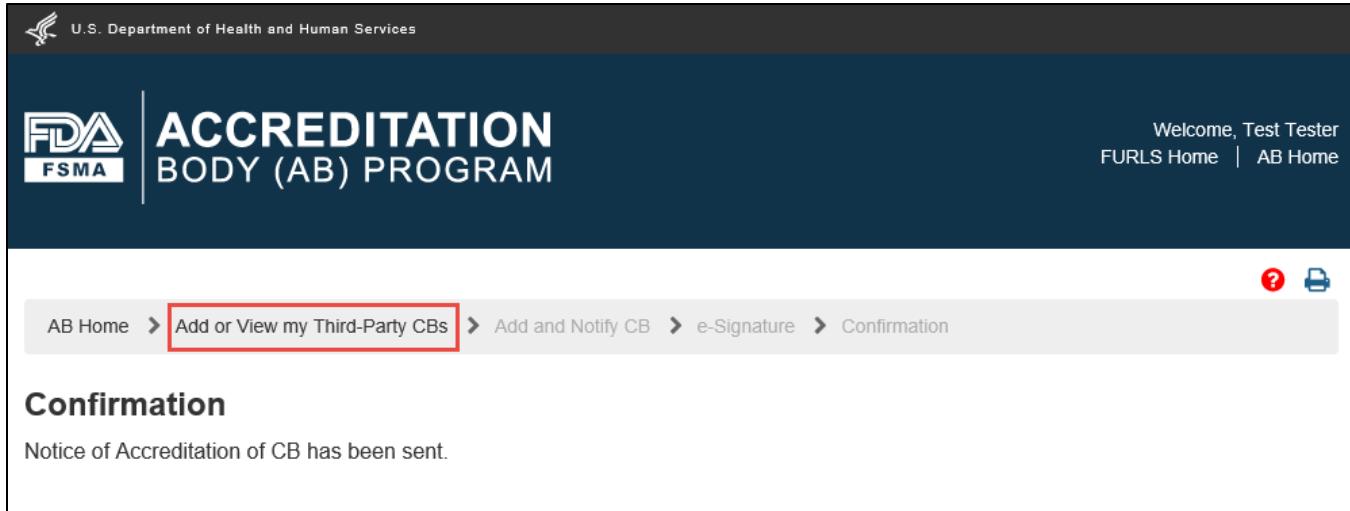
Date
2020-06-19 (EST)

Previous **Submit**

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

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

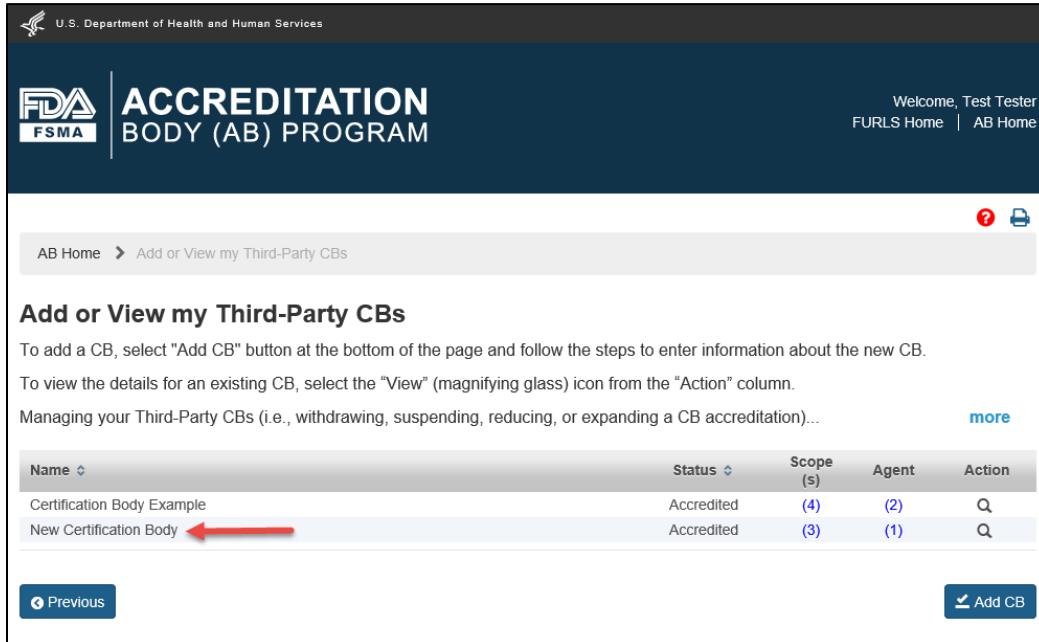
Figure 9.19 – Confirmation Page



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

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

Figure 9.20 – New CB Added

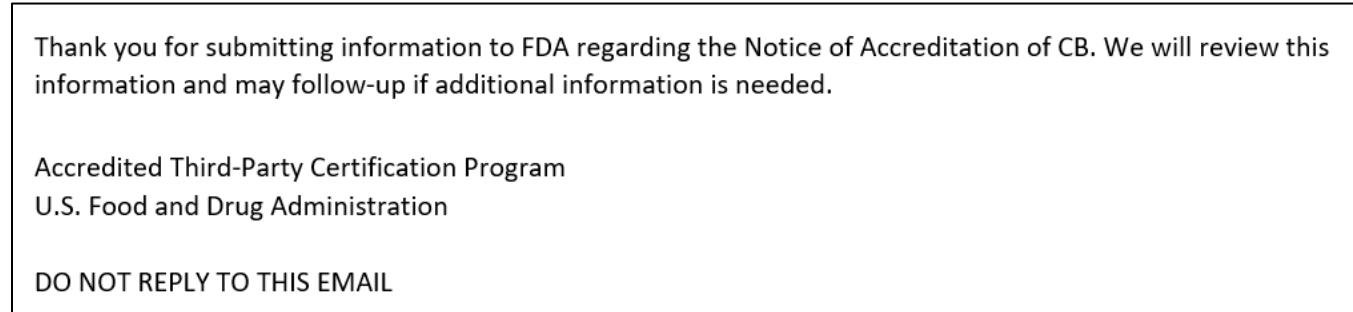


Name	Status	Scope (s)	Agent	Action
Certification Body Example	Accredited	(4)	(2)	Q
New Certification Body	Accredited	(3)	(1)	Q

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

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

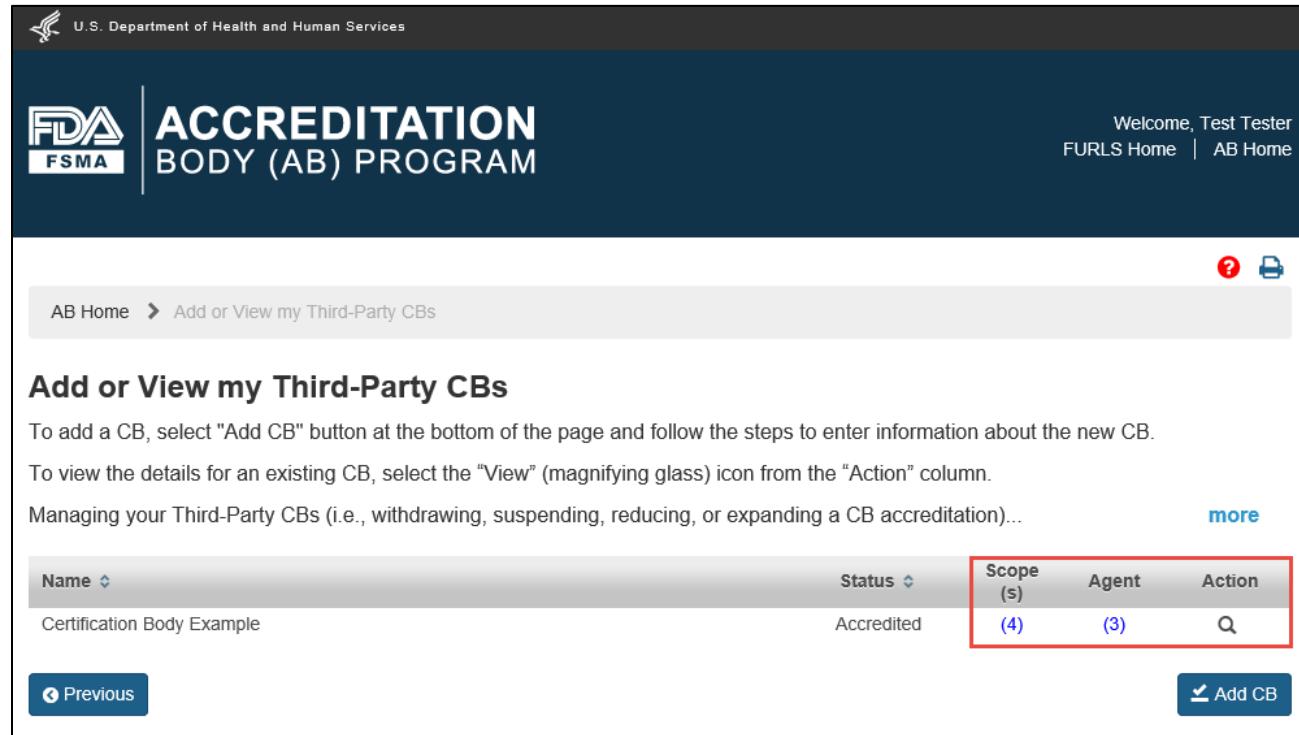
Figure 9.21 – E-mail Notification



9.2 View the Details of Accredited CBs

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

Figure 9.22 – Links to View CB Details



U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Add or View my Third-Party CBs

Add or View my Third-Party CBs

To add a CB, select "Add CB" button at the bottom of the page and follow the steps to enter information about the new CB.

To view the details for an existing CB, select the "View" (magnifying glass) icon from the "Action" column.

Managing your Third-Party CBs (i.e., withdrawing, suspending, reducing, or expanding a CB accreditation)... [more](#)

Name	Status	Scope (s)	Agent	Action
Certification Body Example	Accredited	(4)	(3)	

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

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

Figure 9.23 – Scope(s) Hyperlink

Name	Status	Scope(s)	Agent	Action
Certification Body Example	Accredited	(4)	(2)	

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

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

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

Figure 9.24 – Scope(s) Pop-up Window

Scope(s)		
Scope(s)	Accreditation Date	Expiration Date
Acidified Foods (AF)	2020-06-01	2021-06-01
Dietary Supplements	2020-06-01	2021-06-01
Infant Formula	2020-06-01	2021-06-01
Juice Hazard Analysis and Critical Control Point (Juice HACCP)	2020-06-01	2021-06-01

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

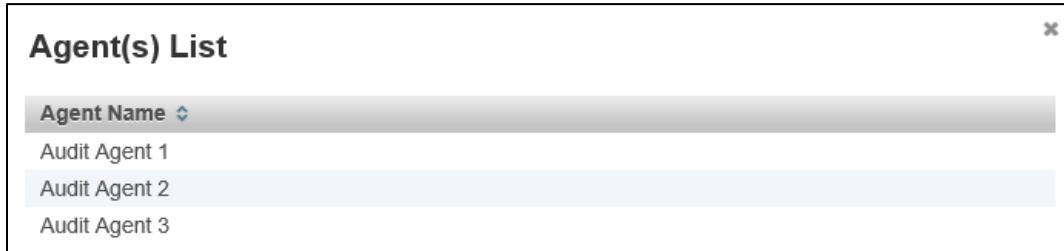
Figure 9.25 – Agent Hyperlink

Name	Status	Scope(s)	Agent	Action
Certification Body Example	Accredited	(4)	(2)	

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

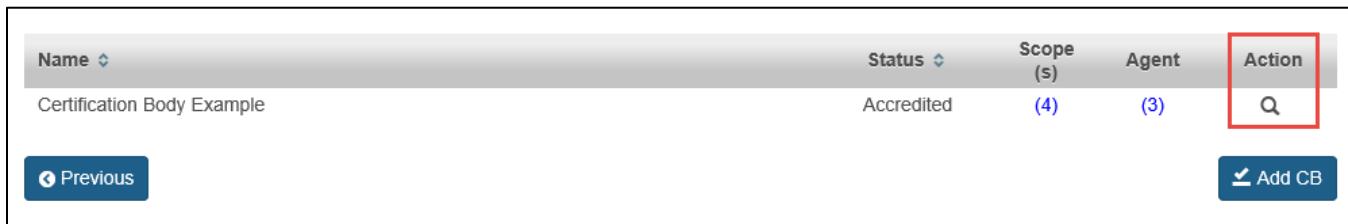
Click the “x” icon in the upper right corner of the window to return to the “Add or View my Third-Party CBs” page.

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



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

Figure 9.27 – View Icon



Name	Status	Scope (s)	Agent	Action
Certification Body Example	Accredited	(4)	(3)	

At the bottom of the table are two buttons: "Previous" and "Add CB".

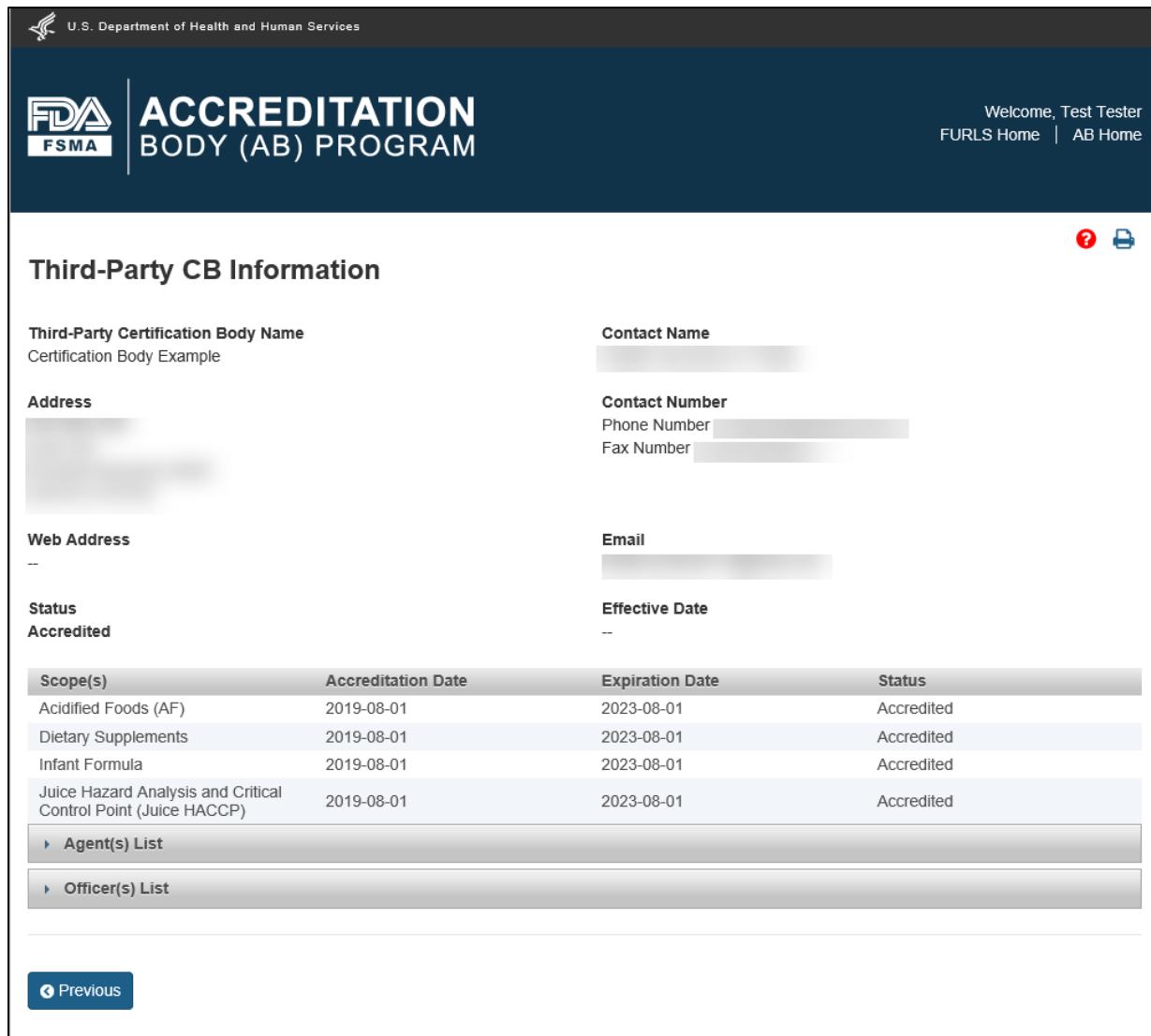
The system will display the “Third-Party CB Information” page with read-only details for the selected CB (Figure 9.28). The CB’s profile information and scopes will display by default.

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

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

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

Figure 9.28 – Third-Party CB Information Page



U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

Third-Party CB Information

Third-Party Certification Body Name
Certification Body Example

Contact Name
[Redacted]

Address
[Redacted]

Contact Number
Phone Number [Redacted]
Fax Number [Redacted]

Web Address
--

Email
[Redacted]

Status
Accredited

Effective Date
--

Scope(s)	Accreditation Date	Expiration Date	Status
Acidified Foods (AF)	2019-08-01	2023-08-01	Accredited
Dietary Supplements	2019-08-01	2023-08-01	Accredited
Infant Formula	2019-08-01	2023-08-01	Accredited
Juice Hazard Analysis and Critical Control Point (Juice HACCP)	2019-08-01	2023-08-01	Accredited

Agent(s) List

Officer(s) List

Previous

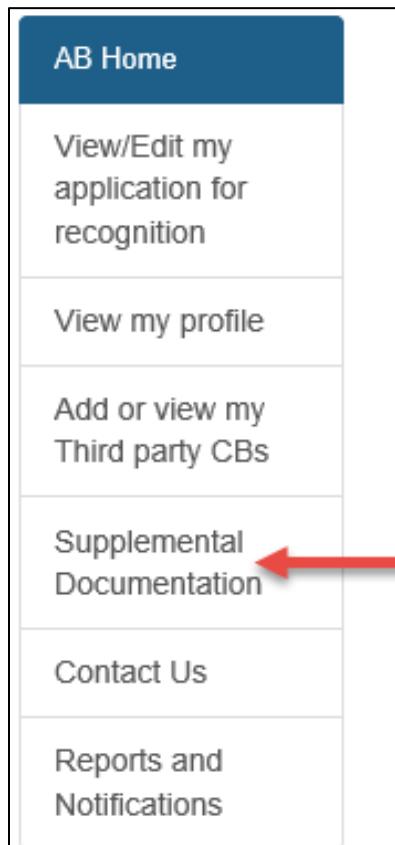
10 Supplemental Documentation

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

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

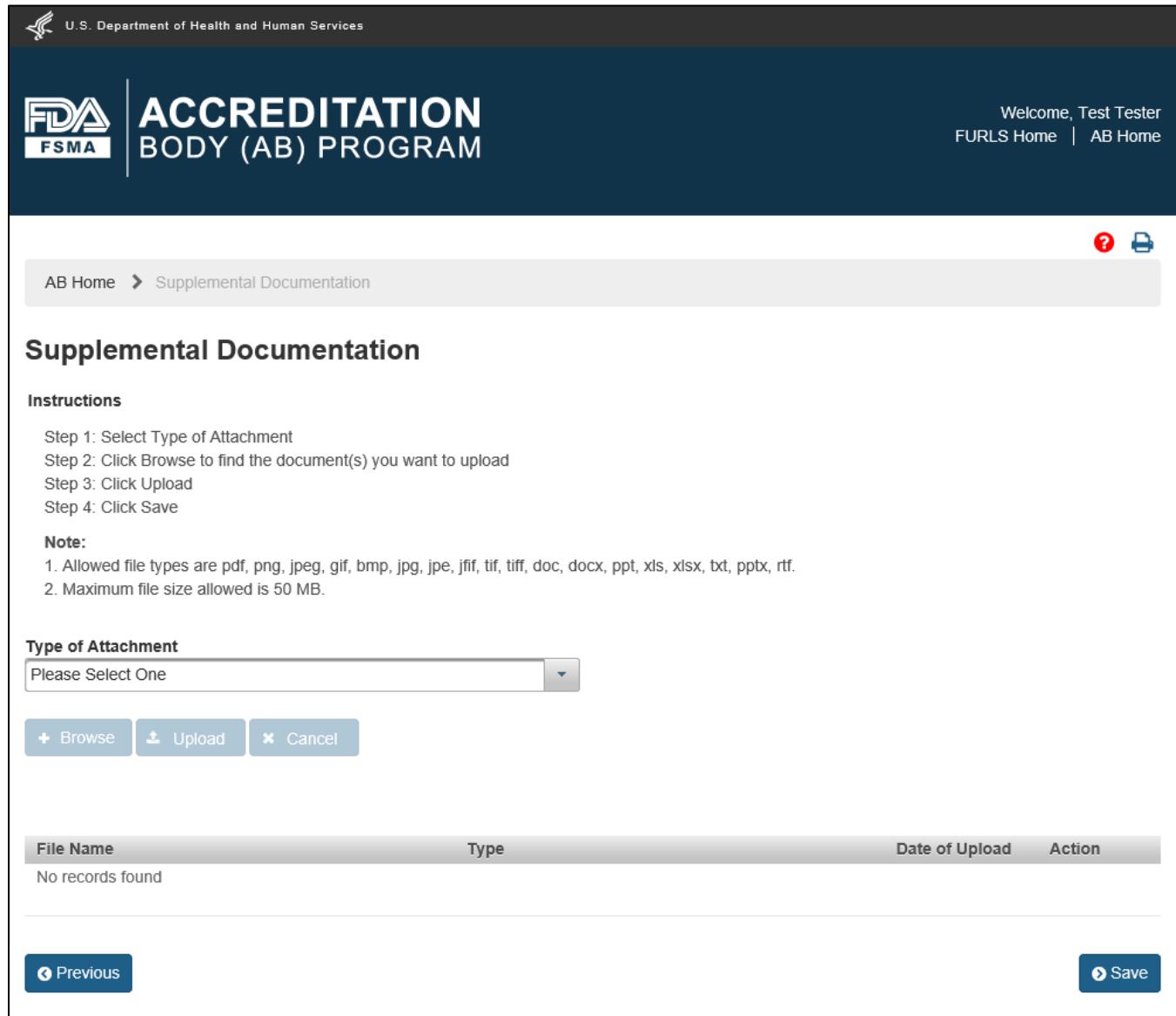
To upload documents to the AB portal or view documents you have submitted to FDA, click the “Supplemental Documentation” link from the navigation menu on the “AB Home” page (Figure 10.1).

Figure 10.1 – Navigation Menu



The system will display the “Supplemental Documentation” page (Figure 10.2). Any document(s) you previously submitted to FDA will display in a table at the bottom of the page. Click on the hyperlinked document name in the “File Name” column if you wish to view the document. Follow Steps 1 – 4 from the “Instructions” section of the page to upload attachments.

Figure 10.2 – Supplemental Documentation Page



U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Supplemental Documentation

Supplemental Documentation

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
No records found			

◀ Previous Save ▶

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

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

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

Figure 10.3 – Type of Attachment Dropdown Menu

Type of Attachment

Please Select One

Adequate Financial or Human Resources

Comprehensive CB Assessment Report

Corrective Action Plan

Laws and Regulations (if Government Entity)

Organization Chart

Records Custodian Information

Request for Internal Agency Review

Request for Reinstatement

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

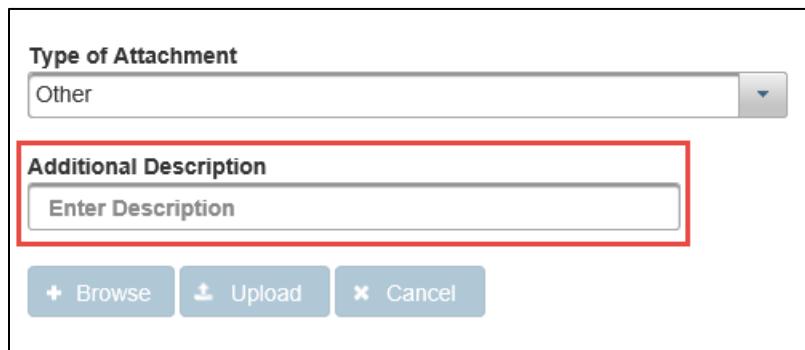
- **Request for Regulatory Hearing** – Select this list value when requesting a regulatory hearing after FDA has revoked recognition. This list value will only display in the “Type of Attachment” list if the current program status is “Revoked.”
- **Request for Internal Agency Review** – Select this list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

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

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

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

Figure 10.4 – Other Attachment Type and Additional Description Field



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

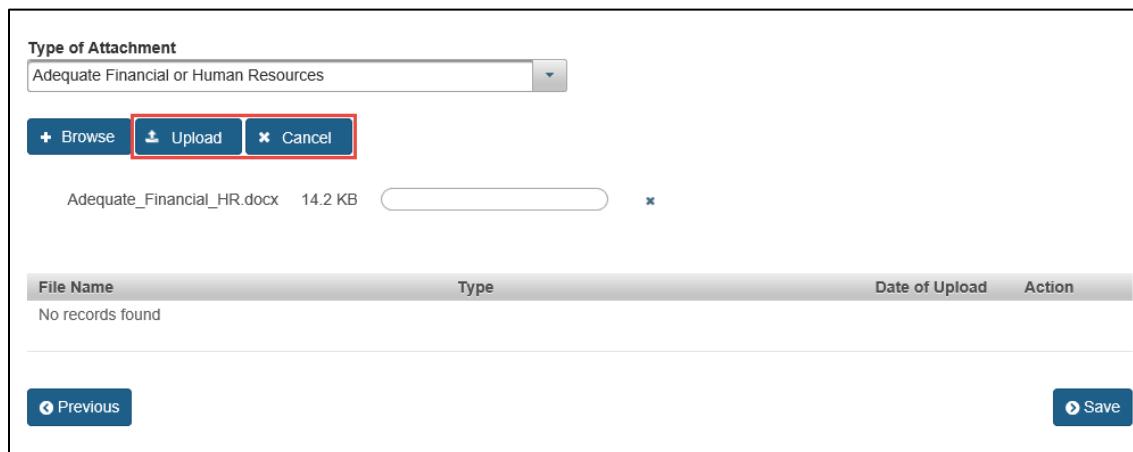
A pop-up window will appear, prompting you to access the file system.

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

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

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

Figure 10.5 – Upload and Cancel Buttons



Attachments must be a document type supported by the system.

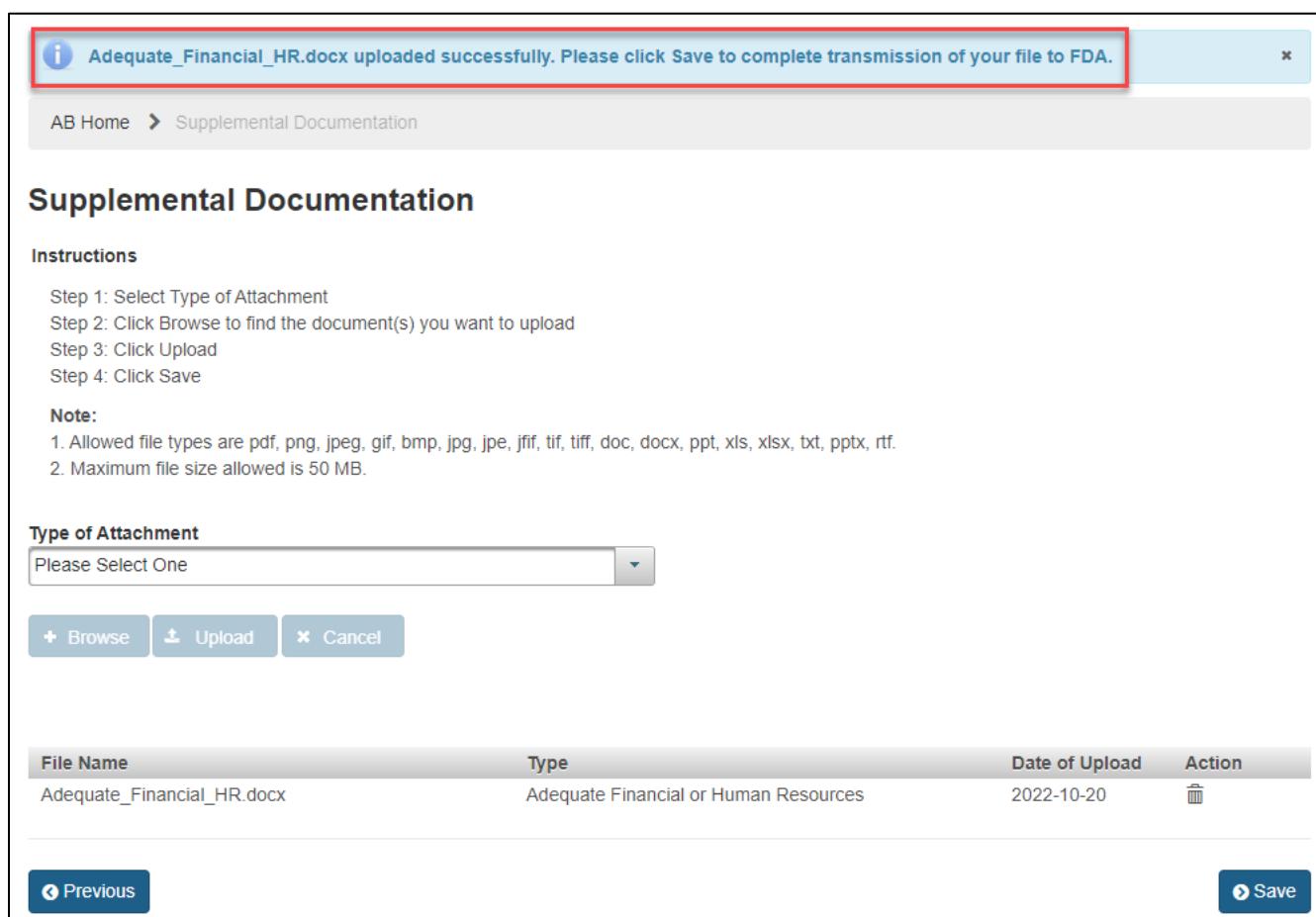
Note: The system supports the following document types: .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

The maximum file size allowed is 50 MB.

Once the upload is complete, a confirmation message indicating a successful upload (along with the file name) will be displayed at the top of the page (Figure 10.6).

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

Figure 10.6 – Successful Upload Message

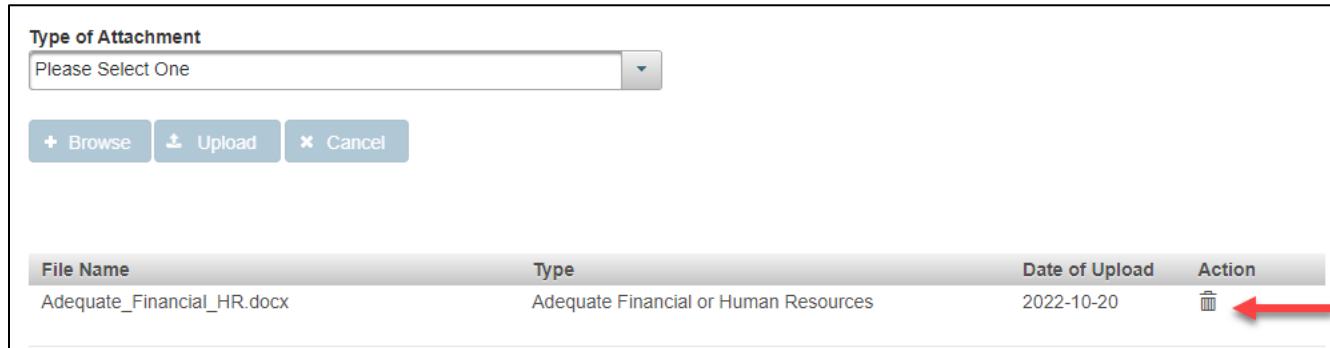


A screenshot of a web-based application for supplemental documentation. At the top, a success message is displayed: "Adequate_Financial_HR.docx uploaded successfully. Please click Save to complete transmission of your file to FDA." Below this, the breadcrumb navigation shows "AB Home > Supplemental Documentation". The main section is titled "Supplemental Documentation" and contains "Instructions" with four steps: 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. It also includes a "Note" section with two points: 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. A "Type of Attachment" dropdown menu is set to "Please Select One". Below it are three buttons: "+ Browse", "Upload", and "Cancel". A table lists the uploaded file "Adequate_Financial_HR.docx" with type "Adequate Financial or Human Resources", date of upload "2022-10-20", and an "Action" column containing a trash can icon. At the bottom are "Previous" and "Save" buttons.

File Name	Type	Date of Upload	Action
Adequate_Financial_HR.docx	Adequate Financial or Human Resources	2022-10-20	

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

Figure 10.7 – Delete Attachment

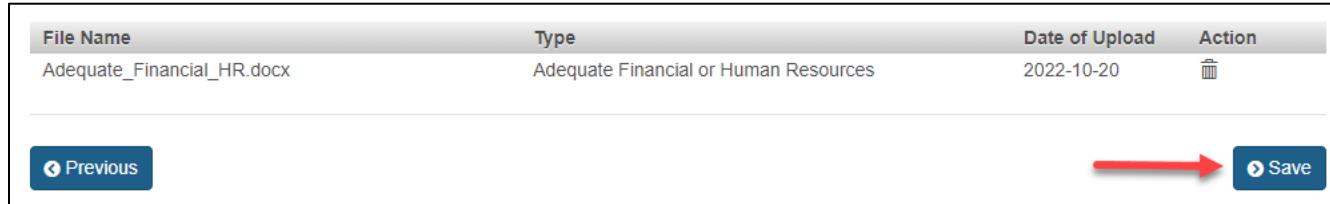


File Name	Type	Date of Upload	Action
Adequate_Financial_HR.docx	Adequate Financial or Human Resources	2022-10-20	

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

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

Figure 10.8 – Save Attachment

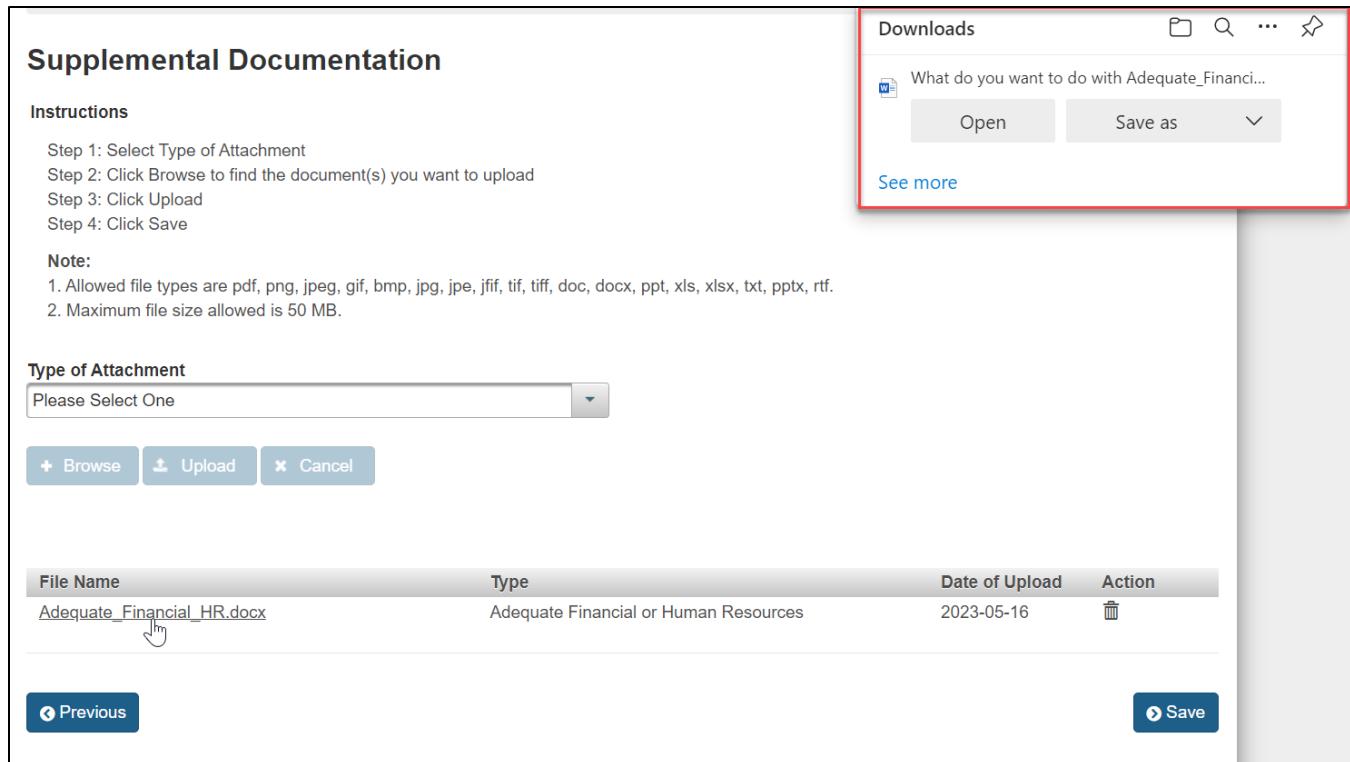


File Name	Type	Date of Upload	Action
Adequate_Financial_HR.docx	Adequate Financial or Human Resources	2022-10-20	

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

Figure 10.9 – Hyperlinked File Name



The screenshot shows the FDA Supplemental Documentation interface. On the left, there is a sidebar with 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. Below these are notes about file types and size. The main area shows a table of uploaded attachments. One file, "Adequate_Financial_HR.docx", is highlighted with a red box and a cursor icon, indicating it is a hyperlink. A download dialog box is overlaid on the interface, showing options to "Open" or "Save as".

File Name	Type	Date of Upload	Action
Adequate_Financial_HR.docx	Adequate Financial or Human Resources	2023-05-16	

Supplemental Documentation

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**

Adequate_Financial_HR.docx Adequate Financial or Human Resources 2023-05-16 

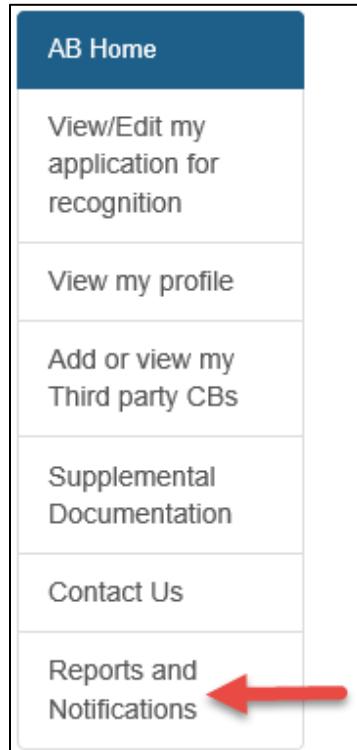
11 Reports and Notifications

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

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

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

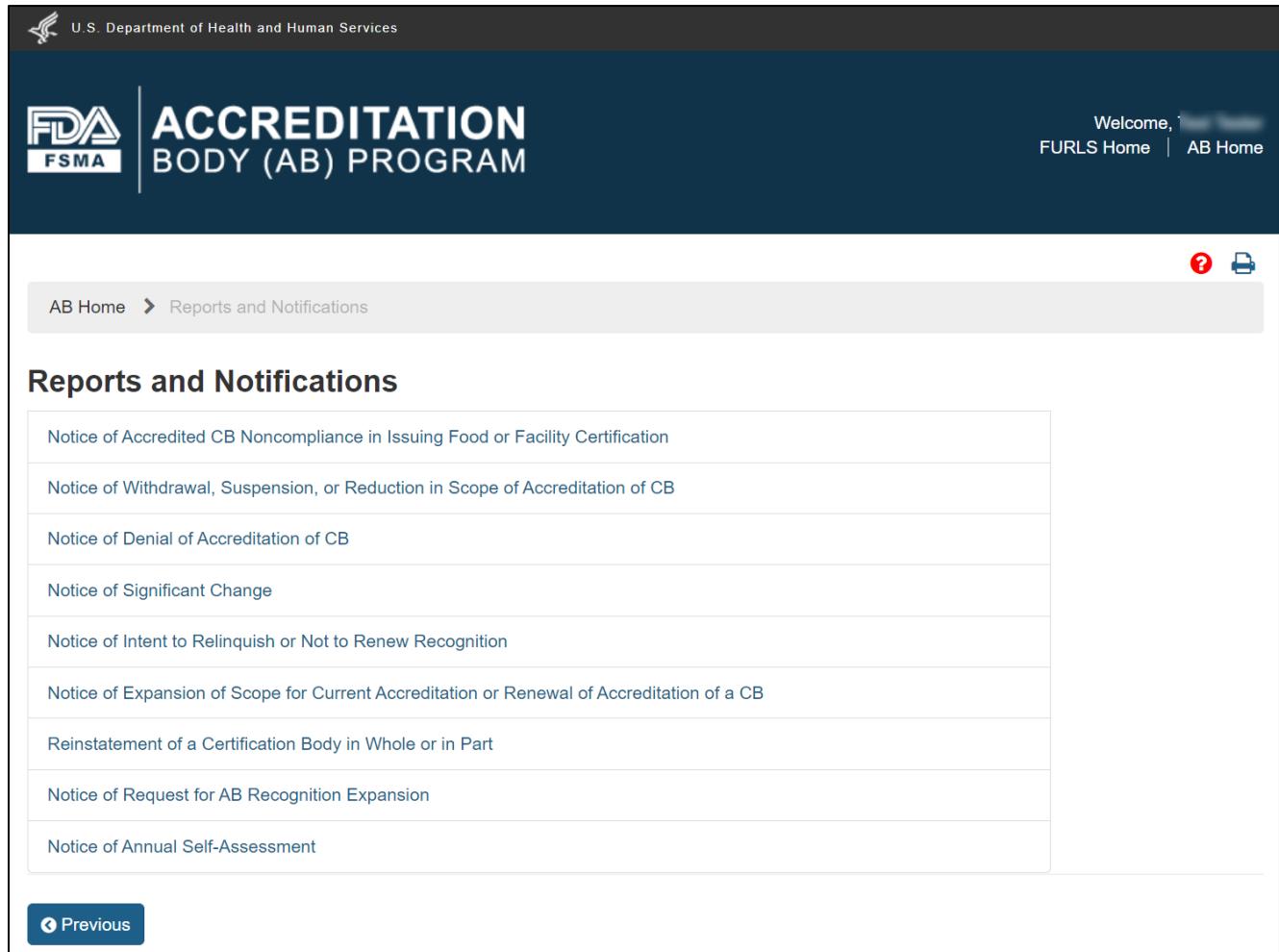
Figure 11.1 – Navigation Menu



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

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

Figure 11.2 – Reports and Notifications Page



U.S. Department of Health and Human Services

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

Welcome, [redacted]
FURLS Home | AB Home

AB Home > Reports and Notifications

Reports and Notifications

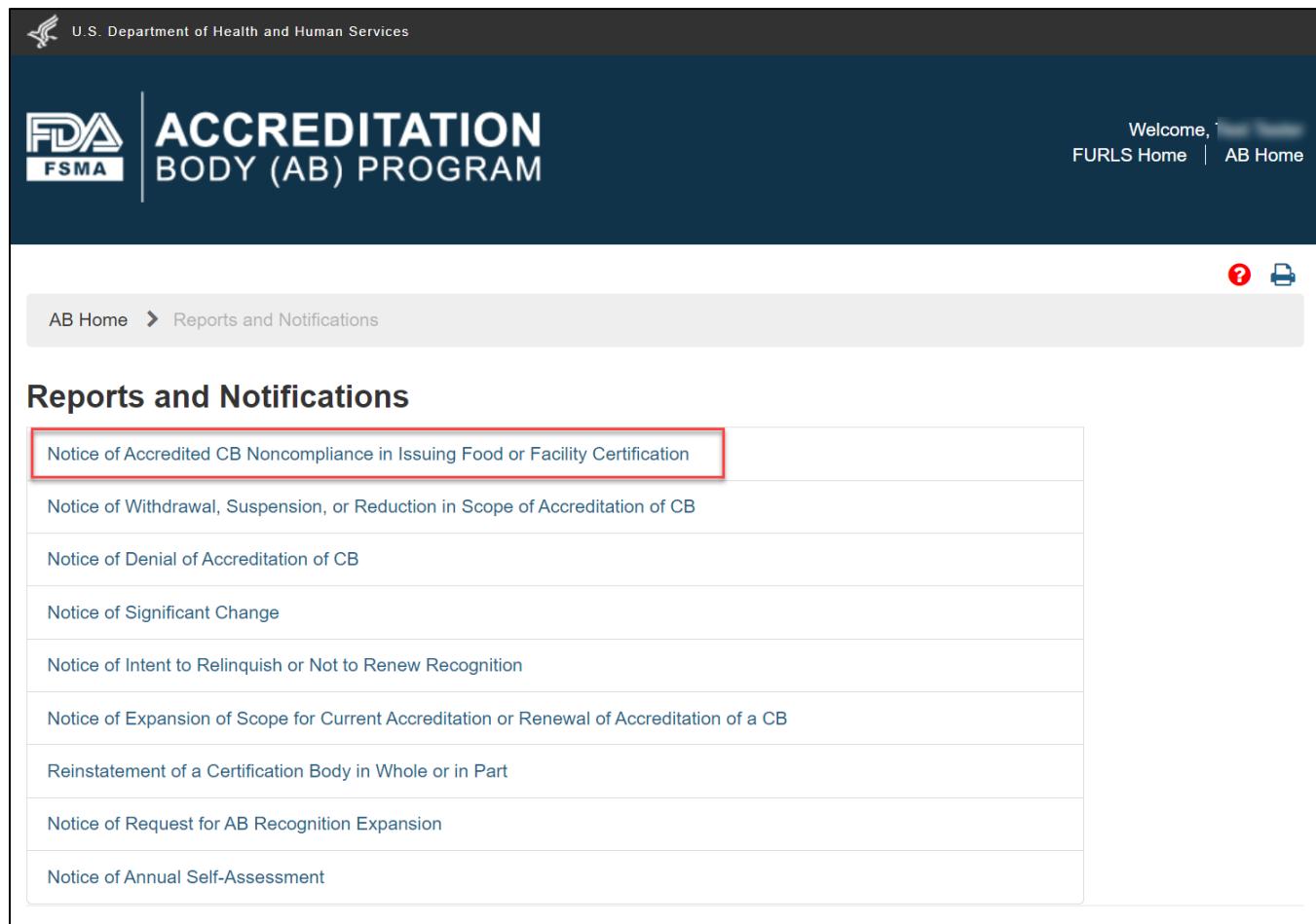
- [Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification](#)
- [Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB](#)
- [Notice of Denial of Accreditation of CB](#)
- [Notice of Significant Change](#)
- [Notice of Intent to Relinquish or Not to Renew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

[Previous](#)

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

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

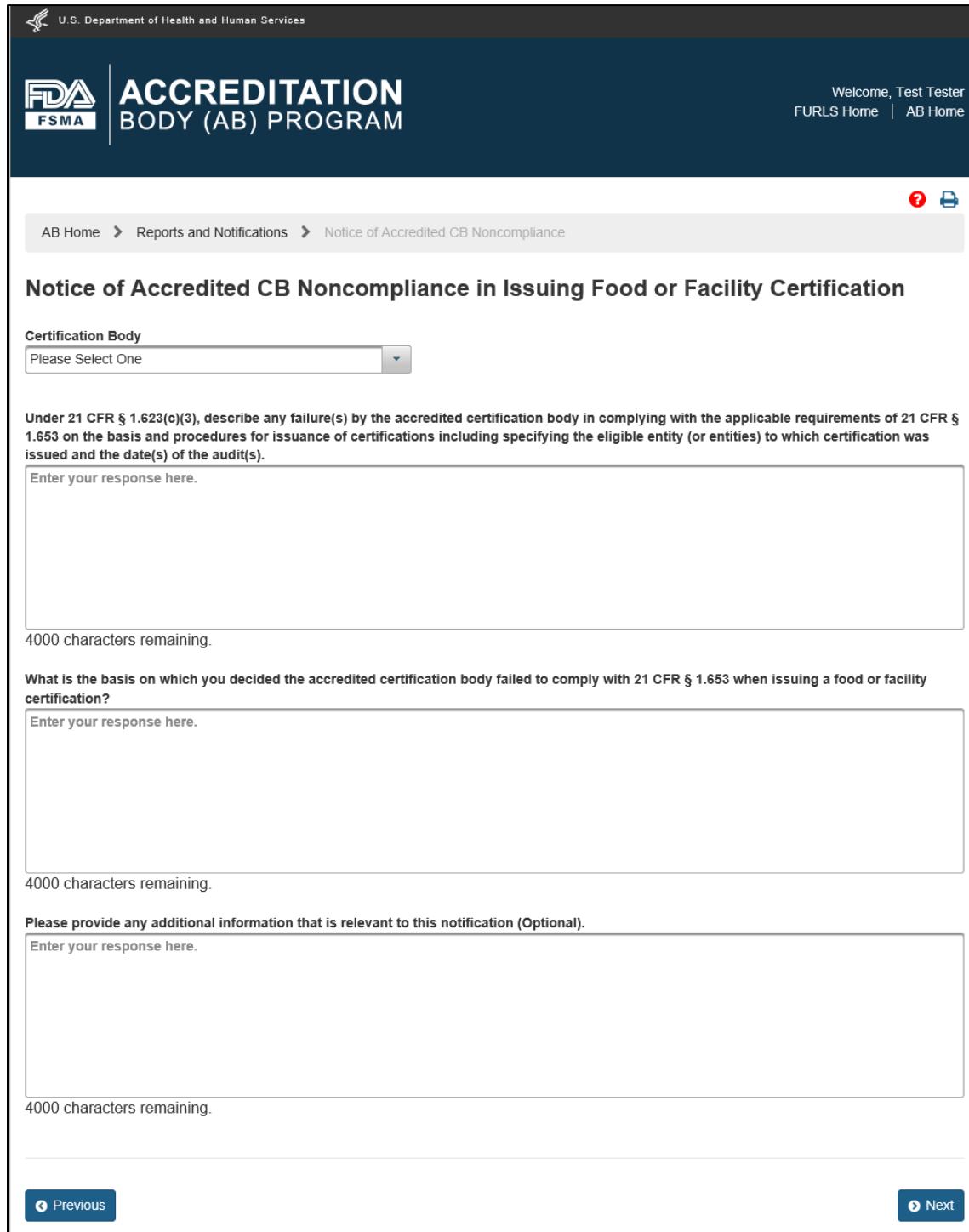
Figure 11.3 – Reports and Notifications Page



The screenshot shows the FDA Accreditation Body (AB) Program website. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and links for Welcome, FURLS Home, and AB Home. Below the navigation is a breadcrumb trail: AB Home > Reports and Notifications. The main content area is titled "Reports and Notifications" and lists several options: Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification (highlighted with a red box), 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 for Current Accreditation or Renewal of Accreditation of a CB, Reinstatement of a Certification Body in Whole or in Part, Notice of Request for AB Recognition Expansion, and Notice of Annual Self-Assessment.

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

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



U.S. Department of Health and Human Services

FDA | **ACcreditation**
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.

Please provide any additional information that is relevant to this notification (Optional).
Enter your response here.
4000 characters remaining.

Previous

Next

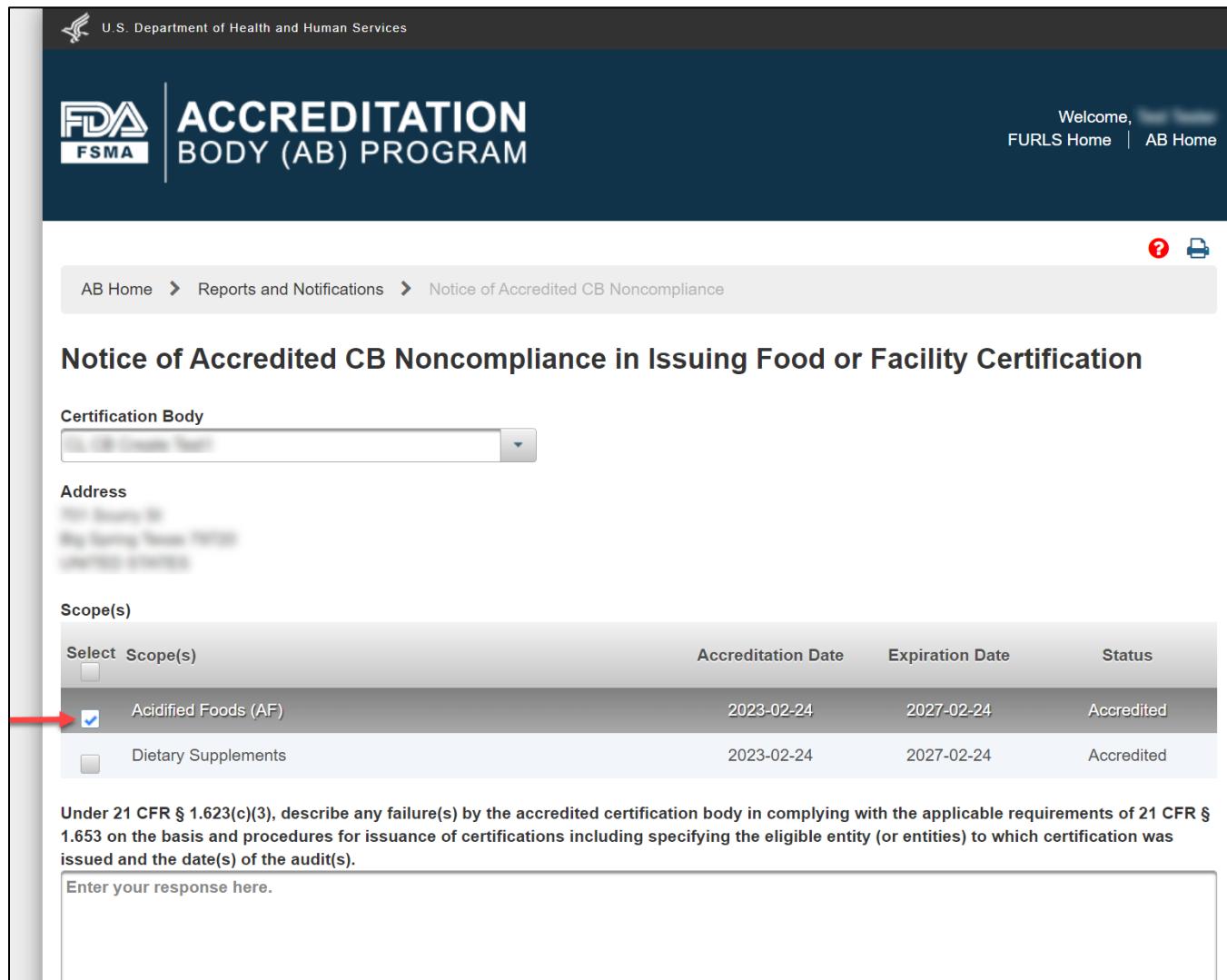
Select the CB name from the “Certification Body” dropdown menu.

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

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

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

Figure 11.5 – CB Address and Scope Information



The screenshot shows the FDA AB Program website. The header includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and a navigation bar with links for AB Home, FURLS Home, and AB Home. The main content area is titled "Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification". It has sections for "Certification Body" (a dropdown menu), "Address" (a text area with placeholder text), and "Scope(s)" (a table). The "Scope(s)" table has columns for "Select Scope(s)" (checkboxes), "Accreditation Date", "Expiration Date", and "Status". Two rows are shown: "Acidified Foods (AF)" with accreditation on 2023-02-24, expiration on 2027-02-24, and status "Accredited", and "Dietary Supplements" with accreditation on 2023-02-24, expiration on 2027-02-24, and status "Accredited". A red arrow points to the checkbox for "Acidified Foods (AF)". Below the table is a text area for "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).". A placeholder text "Enter your response here." is provided.

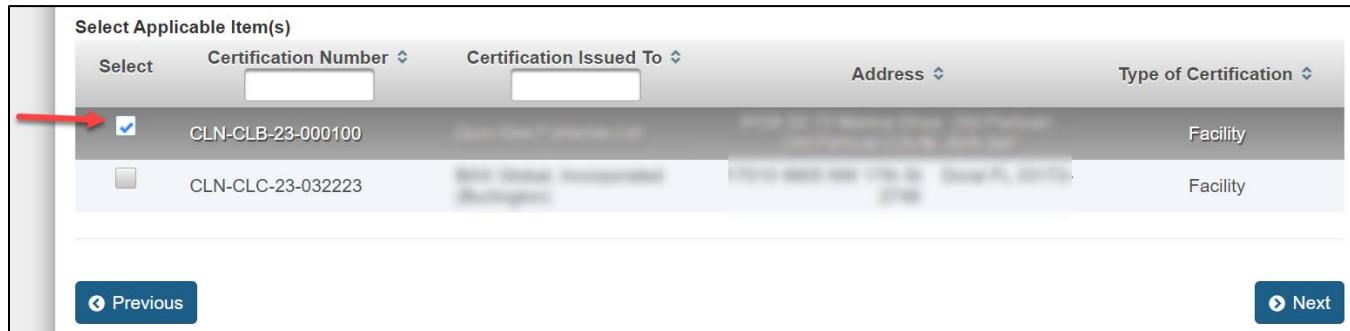
Select Scope(s)	Accreditation Date	Expiration Date	Status
<input checked="" type="checkbox"/> Acidified Foods (AF)	2023-02-24	2027-02-24	Accredited
<input type="checkbox"/> Dietary Supplements	2023-02-24	2027-02-24	Accredited

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

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

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

Figure 11.6 – Notice with Certification Selected



Select Applicable Item(s)				
Select	Certification Number	Certification Issued To	Address	Type of Certification
<input checked="" type="checkbox"/>	CLN-CLB-23-000100	CLN-CLB-23-000100	CLN-CLB-23-000100	Facility
<input type="checkbox"/>	CLN-CLC-23-032223	CLN-CLC-23-032223	CLN-CLC-23-032223	Facility

Previous **Next**

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

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

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

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

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

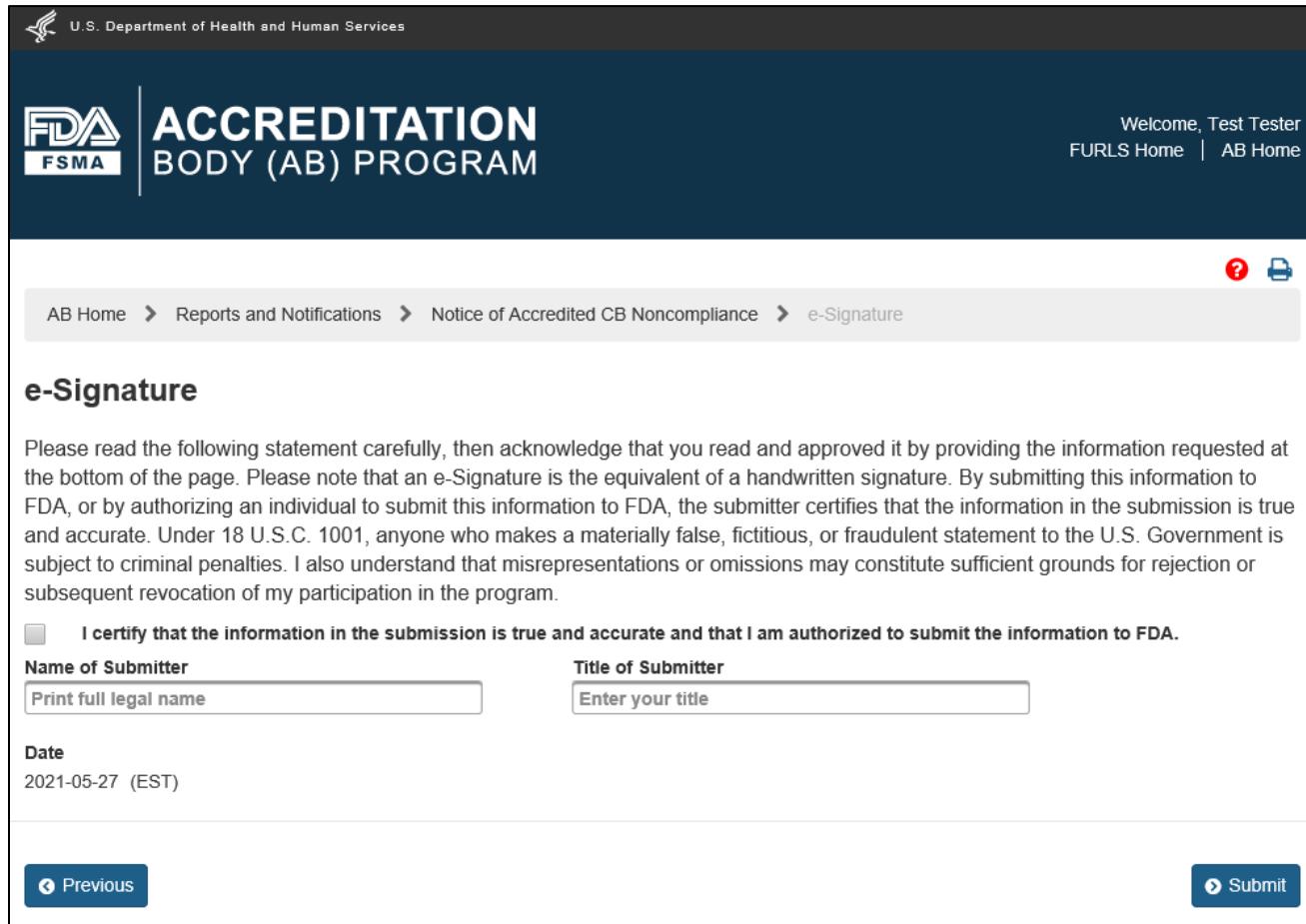
Complete the following data fields:

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

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

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

Figure 11.7 – e-Signature Page



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 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.

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

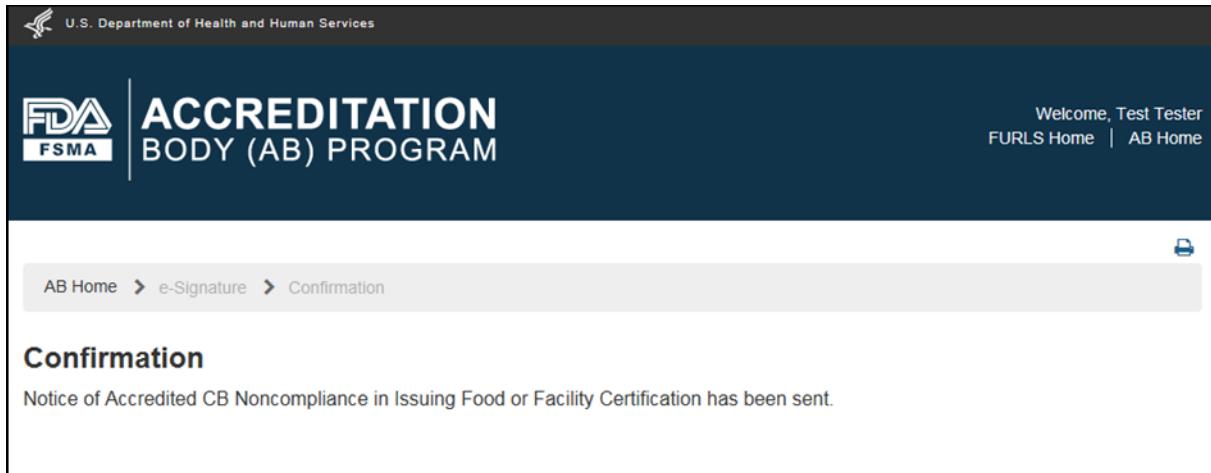
Title of Submitter
Enter your title

Date
2021-05-27 (EST)

Previous **Submit**

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

Figure 11.8 – Confirmation Page



U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

AB Home > e-Signature > Confirmation

Confirmation

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

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

Figure 11.9 – E-mail Notification

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

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

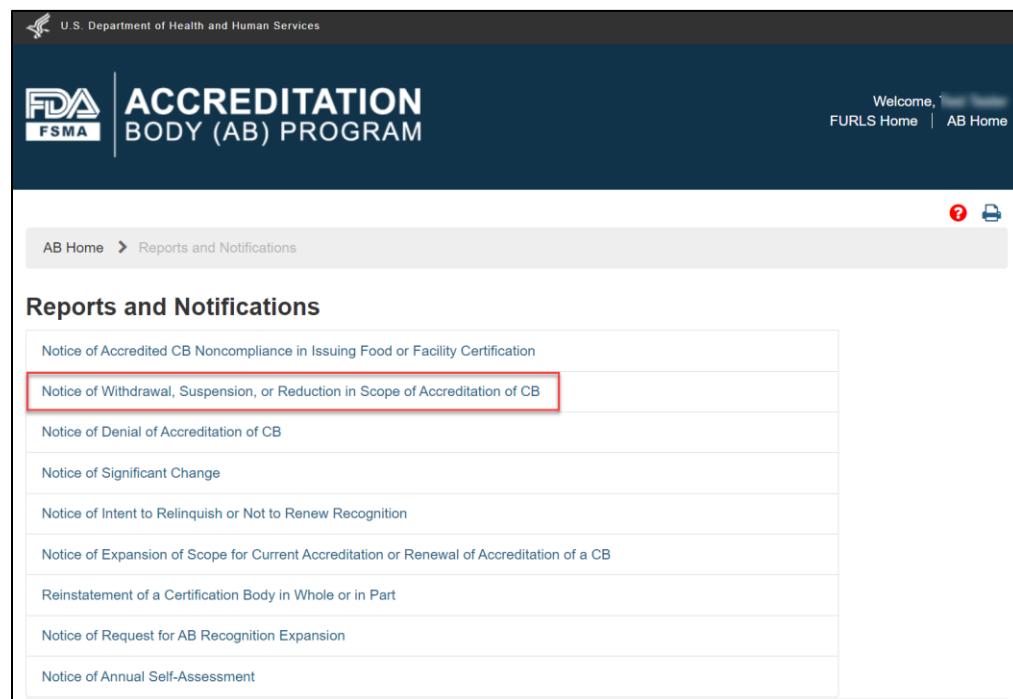
DO NOT REPLY TO THIS EMAIL

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

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

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

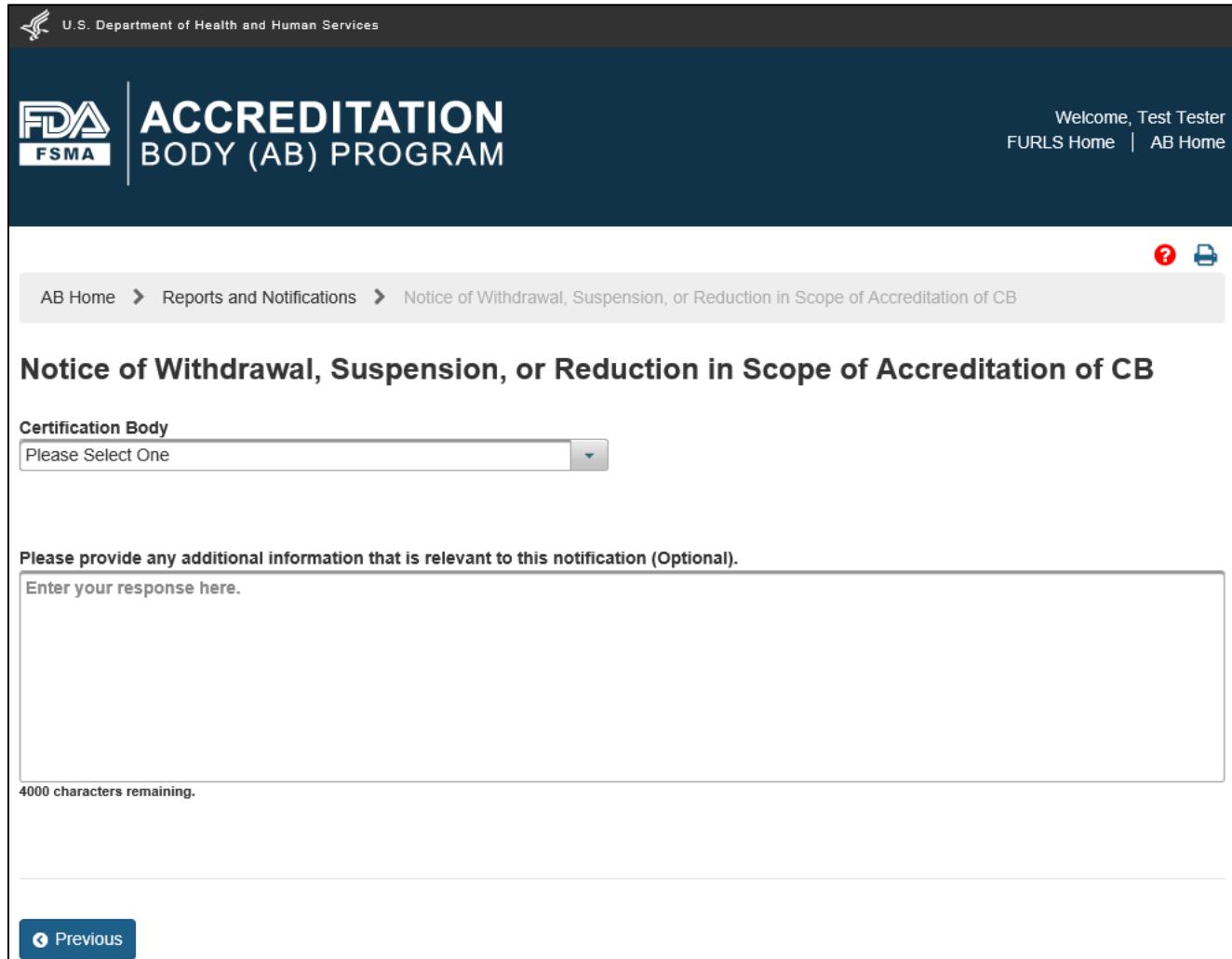
Figure 11.10 – Reports and Notifications Page



The screenshot shows the FDA Accredited Third-Party Certification Program website. The top navigation bar includes links for "AB Home", "Reports and Notifications", "Help", and "Logout". The main content area is titled "Reports and Notifications". A list of notices is provided, with the "Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB" link highlighted by a red box. Other listed notices include: "Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification", "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 for Current Accreditation or Renewal of Accreditation of a CB", "Reinstatement of a Certification Body in Whole or in Part", "Notice of Request for AB Recognition Expansion", and "Notice of Annual Self-Assessment".

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

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



The screenshot shows the FDA U.S. Food & Drug Administration Accreditation Body (AB) Program website. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "ACCREDITATION BODY (AB) PROGRAM". The top right corner shows a welcome message for "Test Tester" and links to "FURLS Home" and "AB Home". The main content area has a breadcrumb navigation: "AB Home > Reports and Notifications > Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB". Below the breadcrumb is the title "Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB". A "Certification Body" dropdown menu is set to "Please Select One". A text area for "Please provide any additional information that is relevant to this notification (Optional)" contains the placeholder "Enter your response here." with a character count of "4000 characters remaining". At the bottom left is a "Previous" button.

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

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

Figure 11.12 – Certification Body and Type of Action

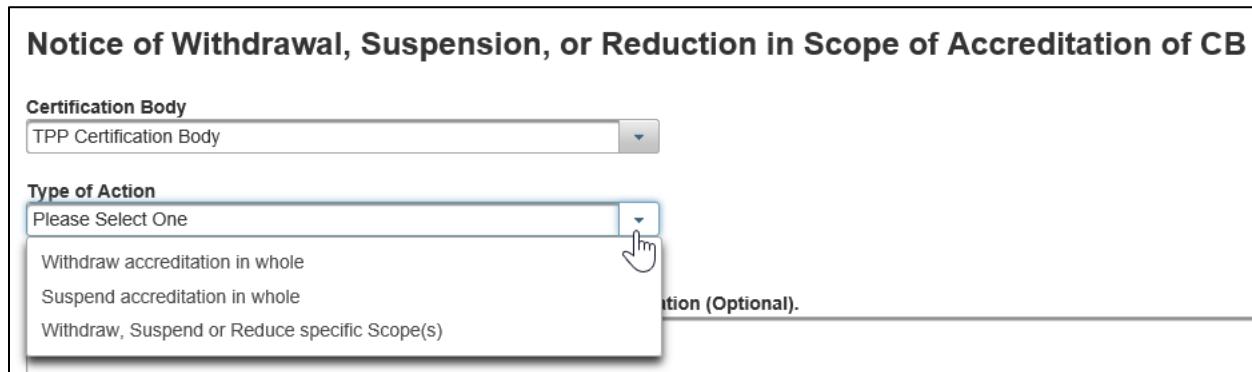
Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB

Certification Body
TPP Certification Body

Type of Action
Please Select One

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

ation (Optional).

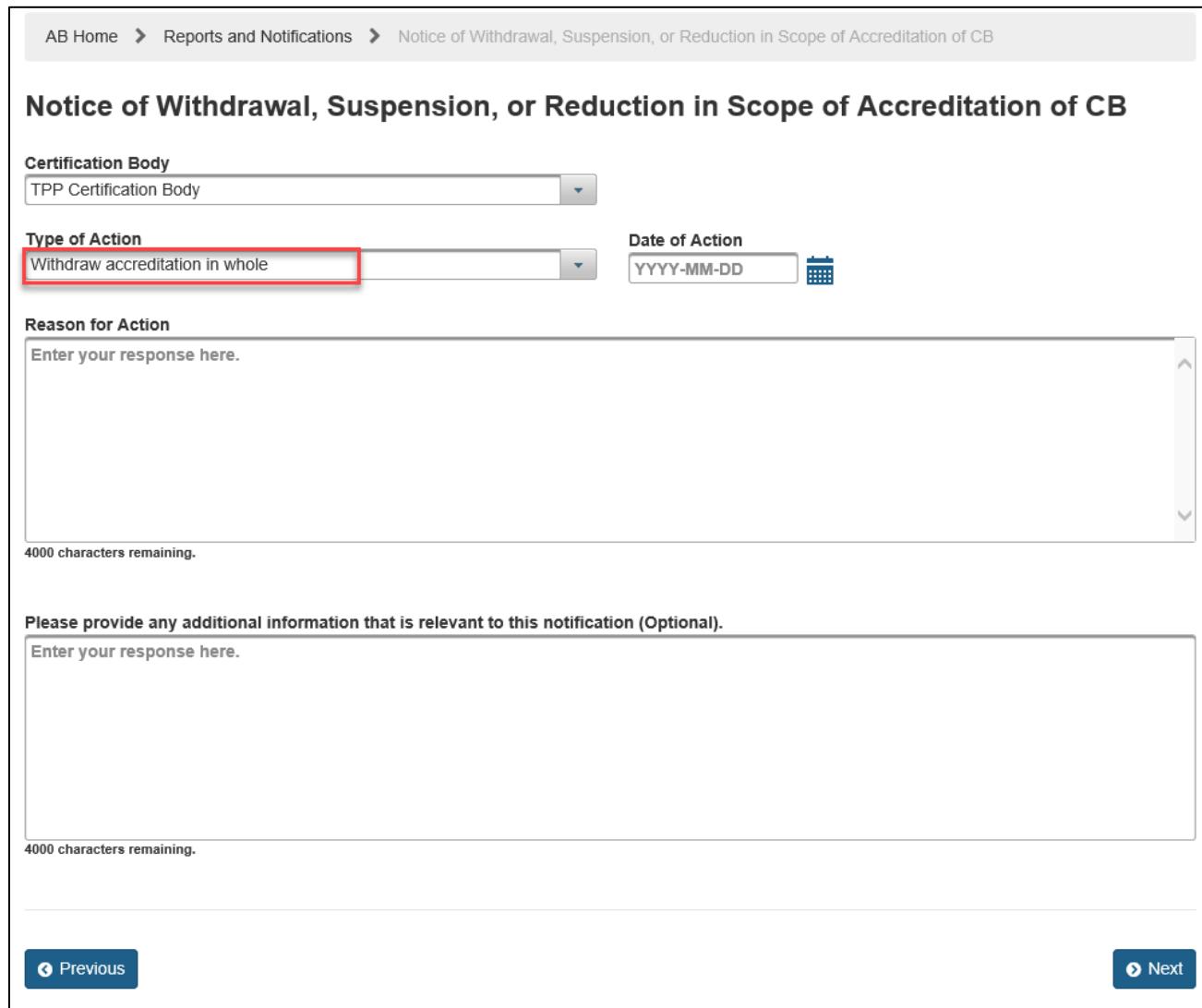


11.2.1 Withdraw Accreditation in Whole

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

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

Figure 11.13 – Withdraw Accreditation in Whole



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
TPP Certification Body

Type of Action
Withdraw accreditation in whole

Date of Action
YYYY-MM-DD 

Reason for Action
Enter your response here.
4000 characters remaining.

Please provide any additional information that is relevant to this notification (Optional).
Enter your response here.
4000 characters remaining.

Complete the data entry fields.

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

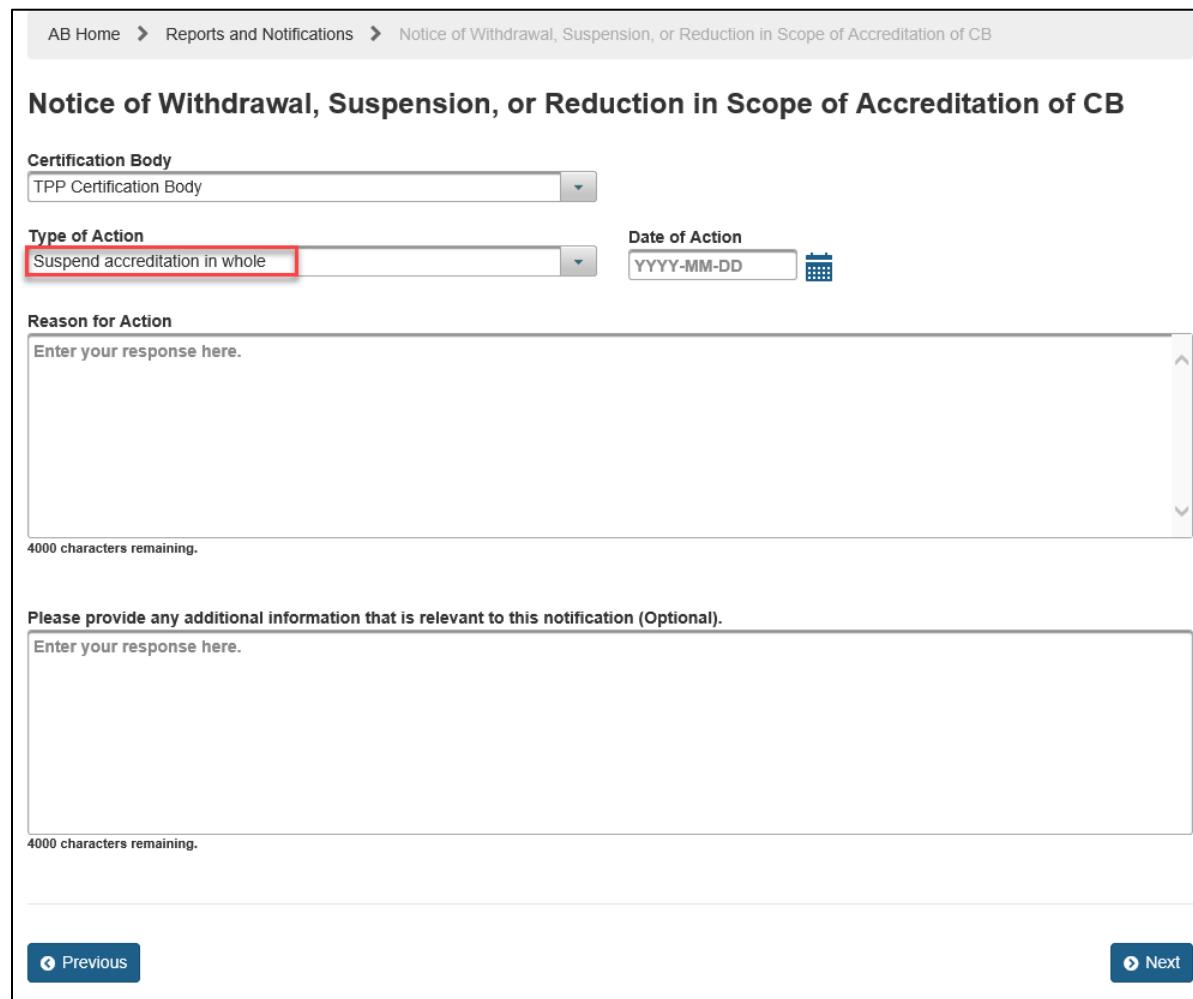
Proceed to Section 11.2.4 of this chapter for instructions to submit the notice.

11.2.2 Suspend Accreditation in Whole

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

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

Figure 11.14 – Suspend Accreditation in Whole



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
TPP Certification Body

Type of Action
Suspend accreditation in whole

Date of Action
YYYY-MM-DD 

Reason for Action
Enter your response here.
4000 characters remaining.

Please provide any additional information that is relevant to this notification (Optional).
Enter your response here.
4000 characters remaining.

Complete the data entry fields.

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

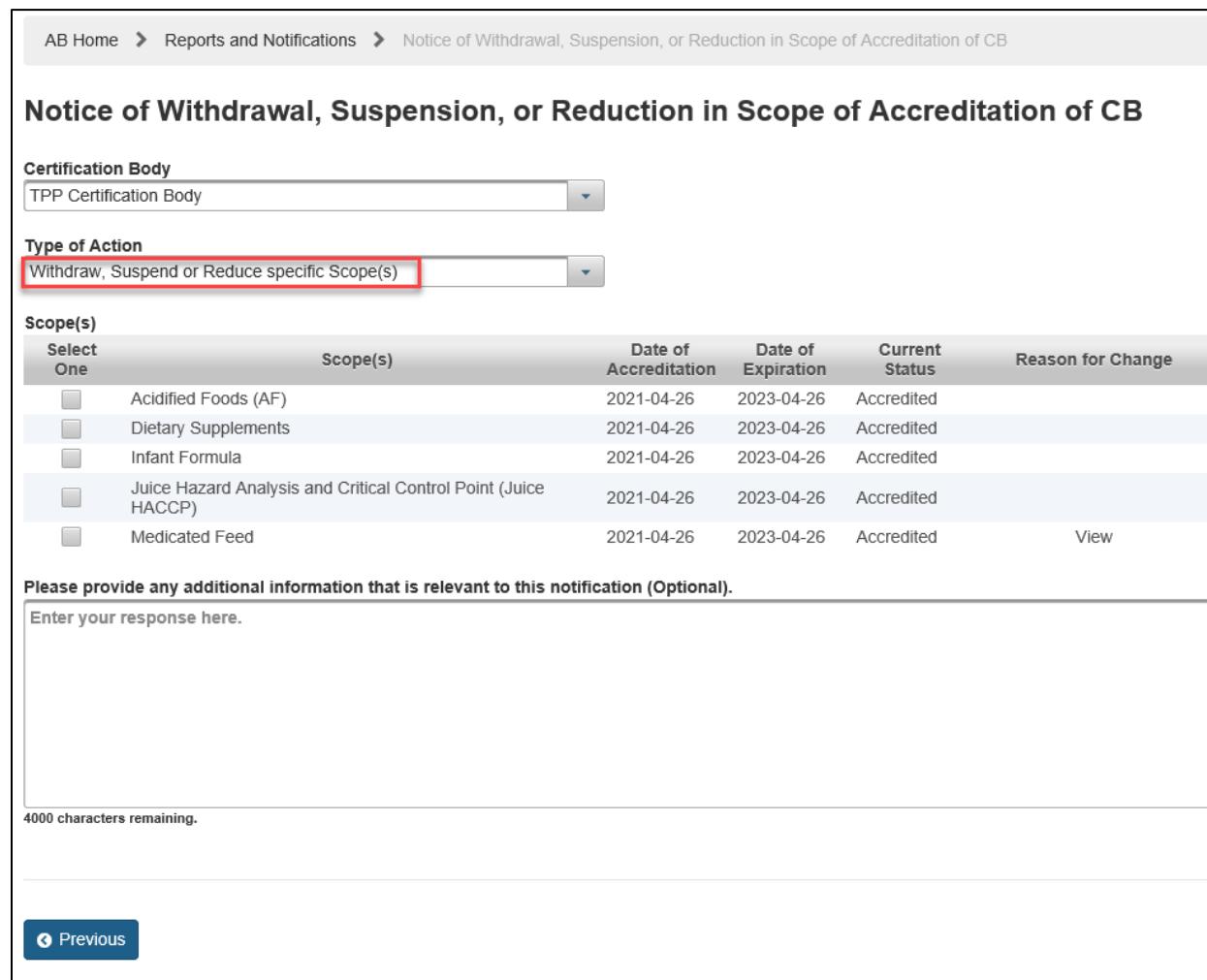
Proceed to Section 11.2.4 of this chapter for instructions to submit the notice.

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

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

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

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



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
TPP Certification Body

Type of Action
Withdraw, Suspend or Reduce specific Scope(s)

Scope(s)

Select One	Scope(s)	Date of Accreditation	Date of Expiration	Current Status	Reason for Change
<input type="checkbox"/>	Acidified Foods (AF)	2021-04-26	2023-04-26	Accredited	
<input type="checkbox"/>	Dietary Supplements	2021-04-26	2023-04-26	Accredited	
<input type="checkbox"/>	Infant Formula	2021-04-26	2023-04-26	Accredited	
<input type="checkbox"/>	Juice Hazard Analysis and Critical Control Point (Juice HACCP)	2021-04-26	2023-04-26	Accredited	
<input type="checkbox"/>	Medicated Feed	2021-04-26	2023-04-26	Accredited	View

Please provide any additional information that is relevant to this notification (Optional).

Enter your response here.

4000 characters remaining.

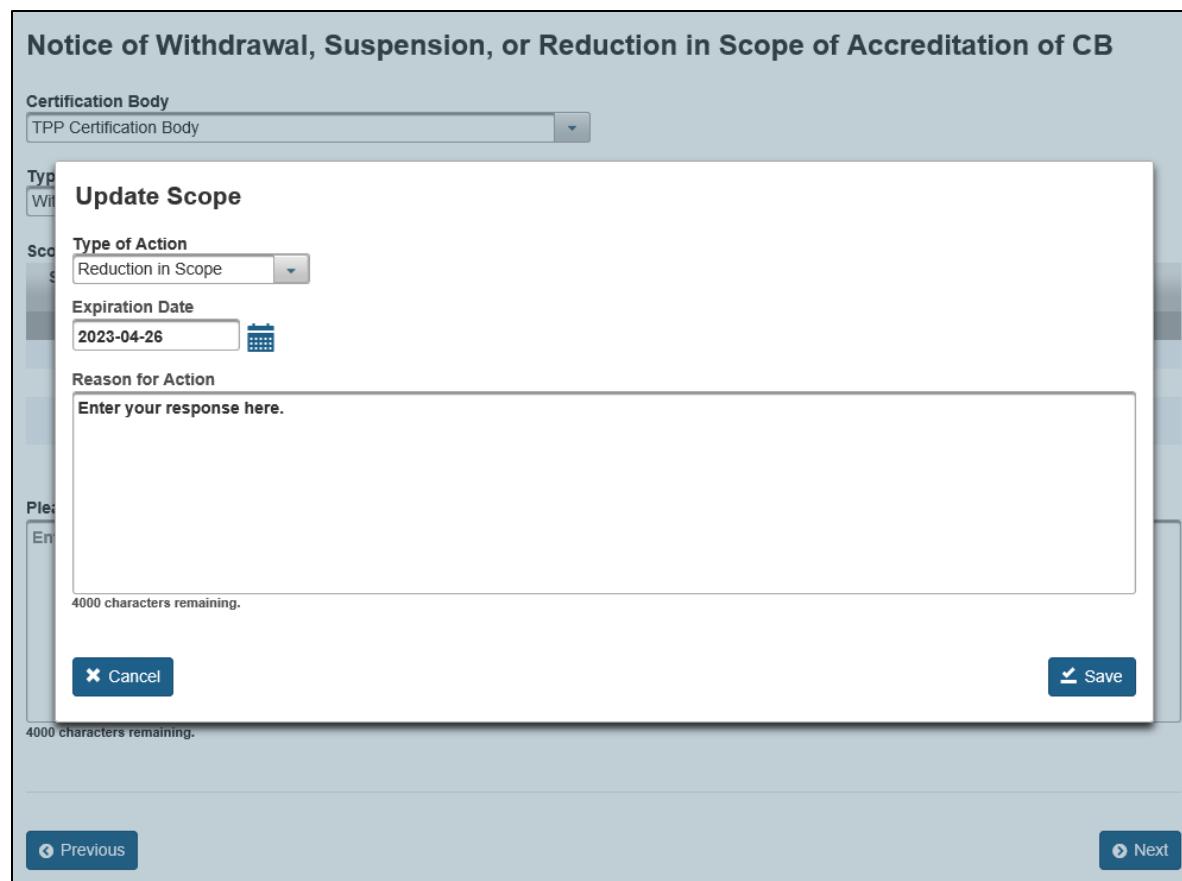
[Previous](#)

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

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

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

Figure 11.16 – Update Scope Pop-up Window



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

Certification Body
TPP Certification Body

Type of Action
Reduction in Scope

Expiration Date
2023-04-26

Reason for Action
Enter your response here.

4000 characters remaining.

Cancel Save

4000 characters remaining.

Previous Next

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

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

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

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

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

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

11.2.4 Notice Submission

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

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

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

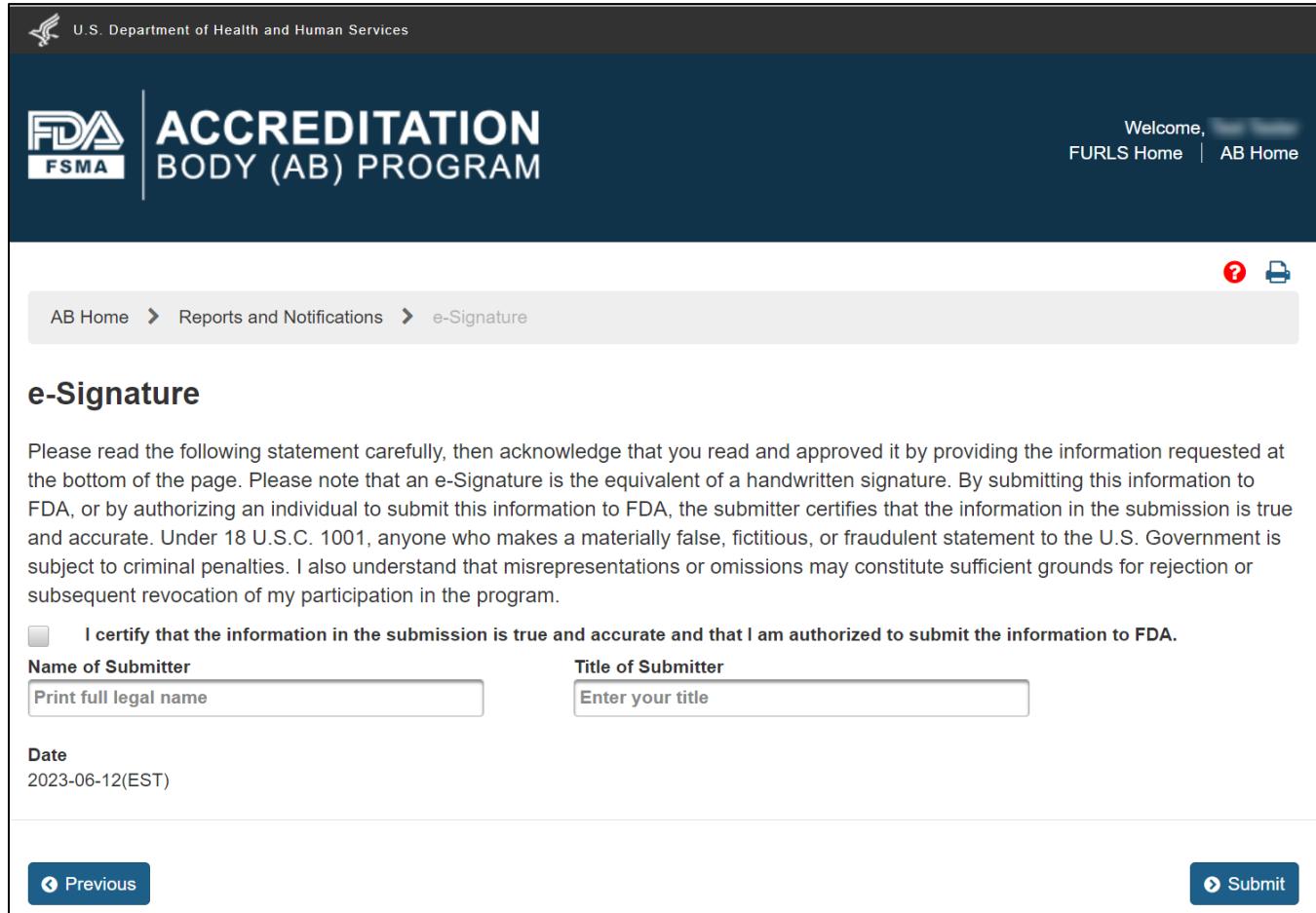
Complete the following data fields:

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

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

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

Figure 11.17 – e-Signature Page



U.S. Department of Health and Human Services

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

Welcome,  [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.

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**

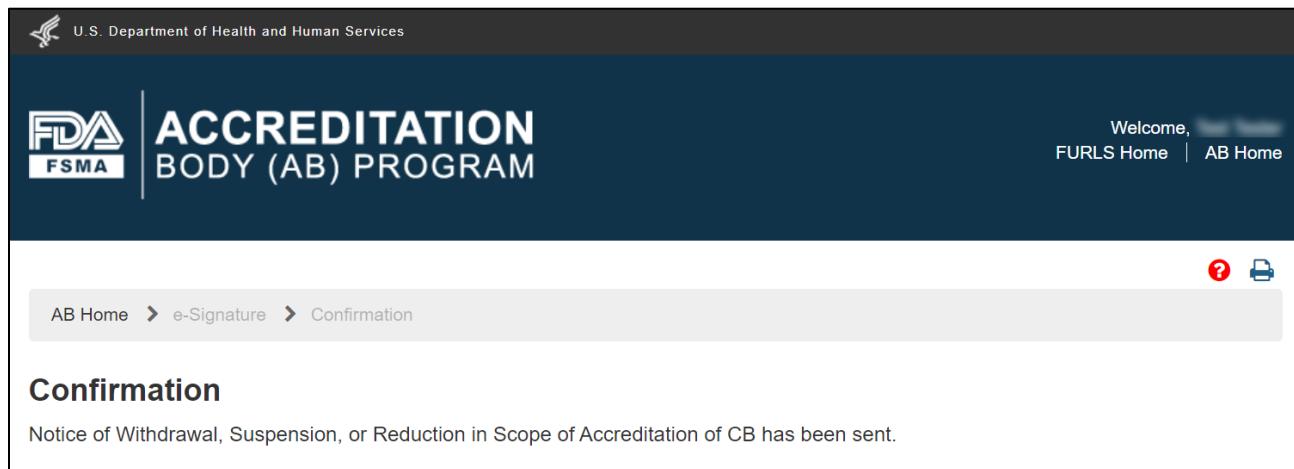
Print full legal name Enter your title

Date
2023-06-12(EST)

Previous **Submit**

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

Figure 11.18 – Confirmation Page



U.S. Department of Health and Human Services

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

Welcome,  [AB Home](#)

[AB Home](#) > [e-Signature](#) > [Confirmation](#)

Confirmation

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

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

Figure 11.19 – E-mail Notification

Thank you for submitting information to FDA regarding the Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB. We will review this information and may follow-up if additional information is needed.

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

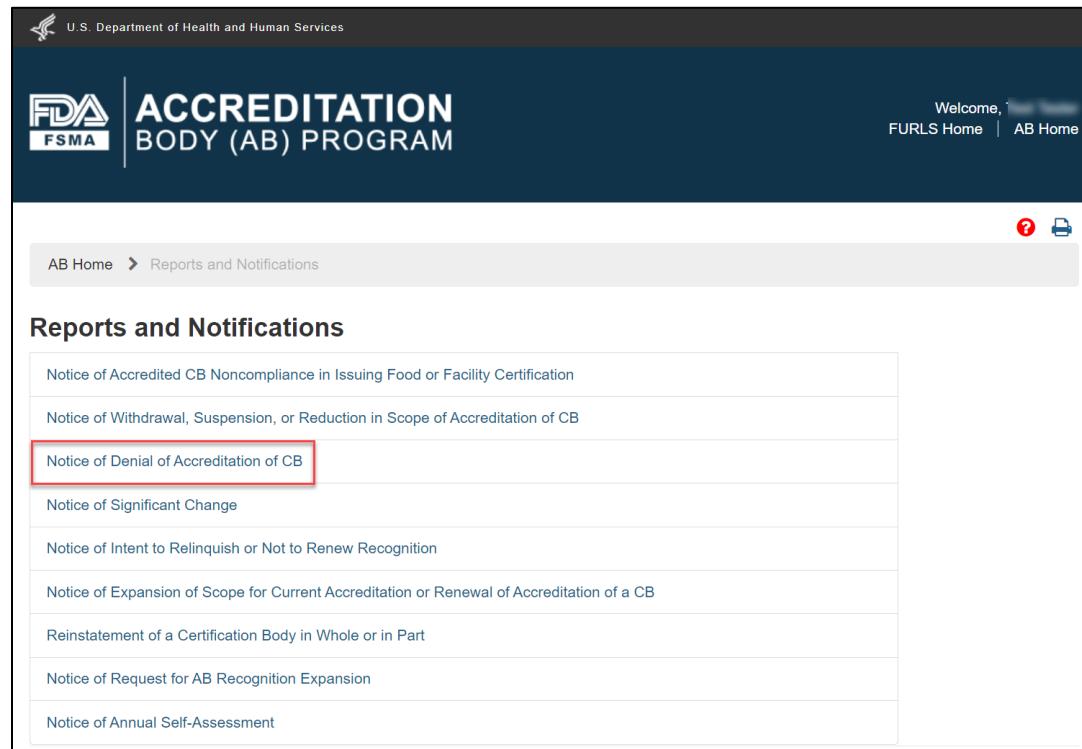
DO NOT REPLY TO THIS EMAIL

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

11.3 Notice of Denial of Accreditation of CB

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

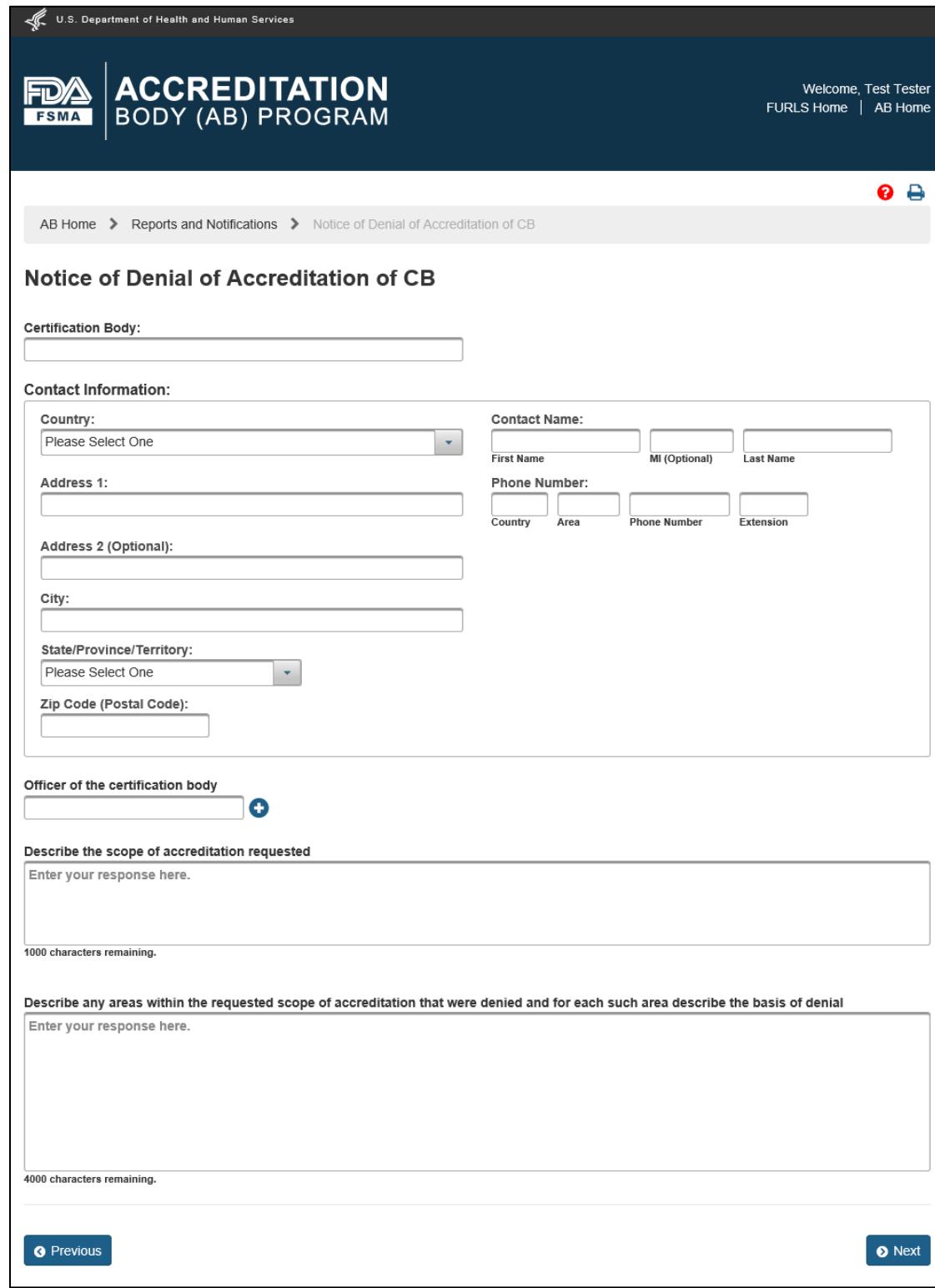
Figure 11.20 – Reports and Notifications Page



The screenshot shows the FDA Accreditation Body (AB) Program website. The top navigation bar includes links for "U.S. Department of Health and Human Services", "FDA FSMA", "ACREDITATION BODY (AB) PROGRAM", "Welcome", "FURLS Home", and "AB Home". The breadcrumb navigation shows "AB Home > Reports and Notifications". The main content area is titled "Reports and Notifications" and lists several options: "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" (which is highlighted with a red box), "Notice of Significant Change", "Notice of Intent to Relinquish or Not to Renew Recognition", "Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB", "Reinstatement of a Certification Body in Whole or in Part", "Notice of Request for AB Recognition Expansion", and "Notice of Annual Self-Assessment".

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

Figure 11.21 – Notice of Denial of Accreditation of CB



The screenshot shows the 'Notice of Denial of Accreditation of CB' page. At the top, the FDA FSMA Accreditation Body (AB) Program logo is visible. The page title is 'Notice of Denial of Accreditation of CB'. The main content area includes fields for 'Certification Body', 'Contact Information' (with sub-fields for Country, Address 1, Address 2, City, State/Province/Territory, Zip Code, and Contact Name/Phone Number), 'Officer of the certification body', 'Describe the scope of accreditation requested', and 'Describe any areas within the requested scope of accreditation that were denied and for each such area describe the basis of denial'. Navigation buttons for 'Previous' and 'Next' are at the bottom.

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 Denial of Accreditation of CB

Notice of Denial of Accreditation of CB

Certification Body:

Contact Information:

Country: Please Select One

Contact Name:
First Name MI (Optional) Last Name

Address 1:

Phone Number:
Country Area Phone Number Extension

Address 2 (Optional):

City:

State/Province/Territory: Please Select One

Zip Code (Postal Code):

Officer of the certification body 

Describe the scope of accreditation requested
Enter your response here.
1000 characters remaining.

Describe any areas within the requested scope of accreditation that were denied and for each such area describe the basis of denial
Enter your response here.
4000 characters remaining.

Complete the following data fields:

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

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

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

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

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

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

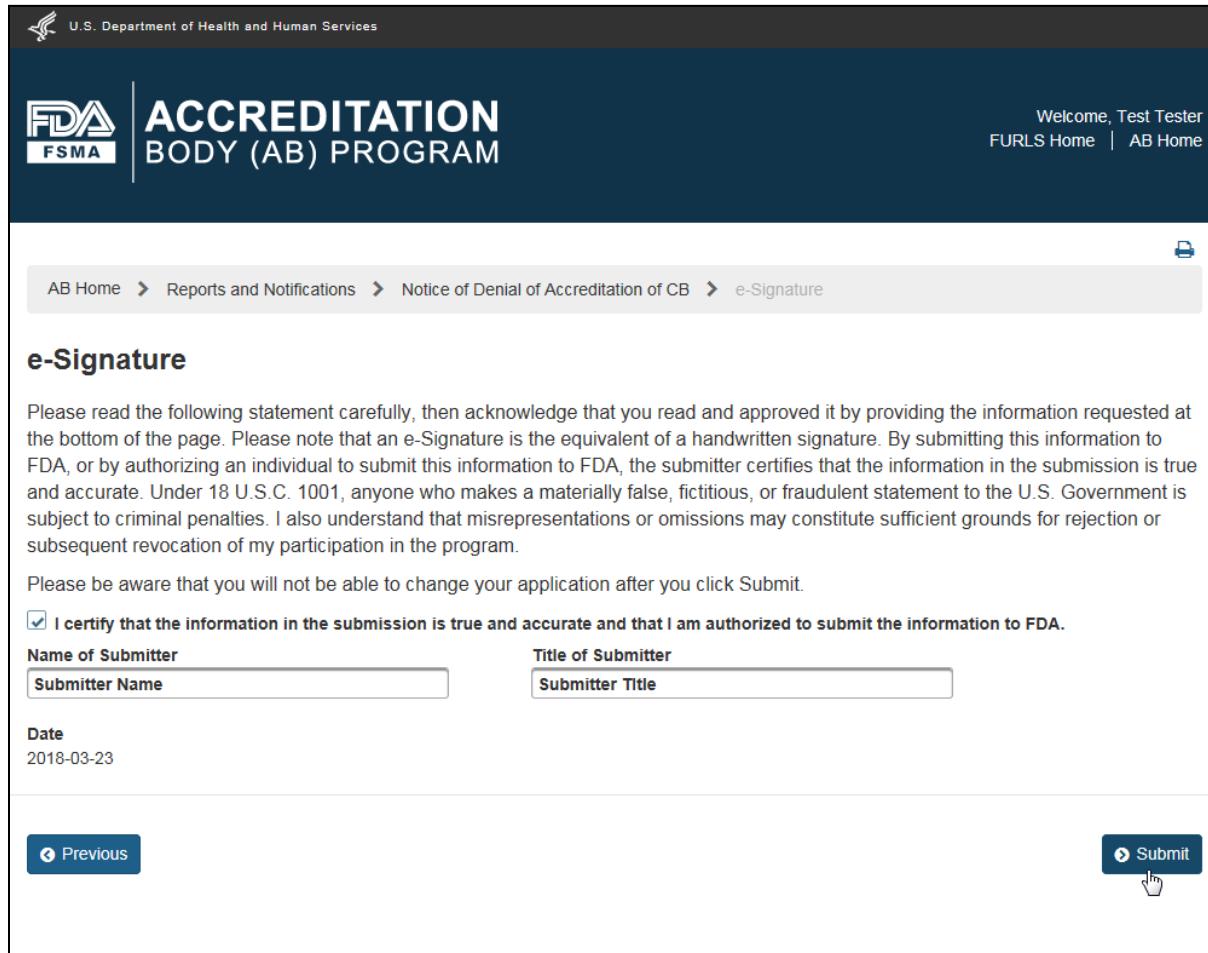
Complete the following data fields:

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

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

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

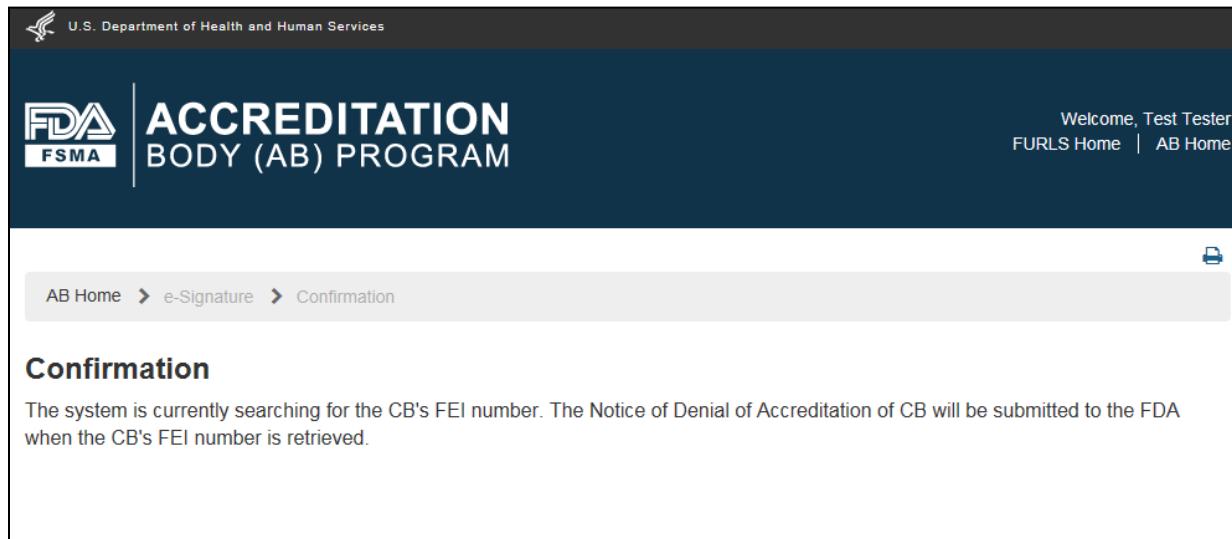
Figure 11.22 – e-Signature Page



The screenshot shows a web page for the FDA Accreditation Body (AB) Program. At the top, there is a navigation bar with the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "ACCREDITATION BODY (AB) PROGRAM". On the right side of the top bar, it says "Welcome, Test Tester" and provides links to "FURLS Home" and "AB Home". Below the top bar, there is a breadcrumb navigation: "AB Home > Reports and Notifications > Notice of Denial of Accreditation of CB > e-Signature". To the right of the breadcrumb is a small print icon. The main content area is titled "e-Signature". It contains a statement about the submission being equivalent to a handwritten signature and the legal consequences of providing false information. Below the statement, it says "Please be aware that you will not be able to change your application after you click Submit." There is a checked checkbox labeled "I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA." To the left of the checkbox is the "Name of Submitter" section, which includes a "Submitter Name" input field containing "Submitter Name". To the right of the checkbox is the "Title of Submitter" section, which includes a "Submitter Title" input field containing "Submitter Title". Below these sections is a "Date" section with the value "2018-03-23". At the bottom left is a "Previous" button, and at the bottom right is a "Submit" button with a hand cursor icon.

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

Figure 11.23 – Confirmation Page



U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

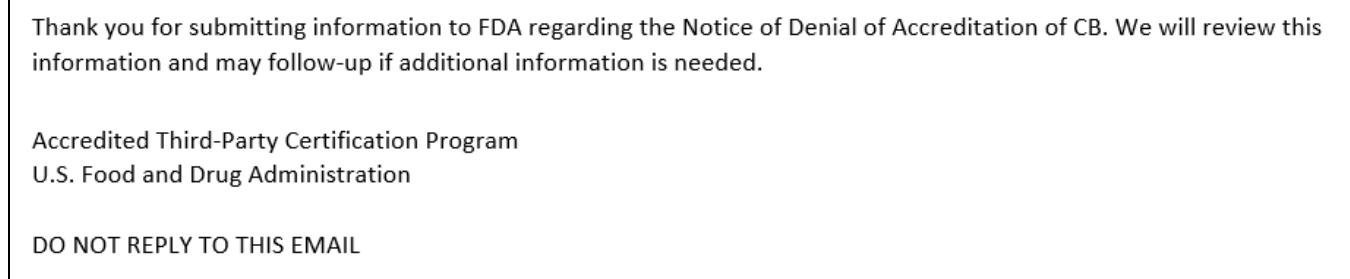
AB Home > e-Signature > Confirmation

Confirmation

The system is currently searching for the CB's FEI number. The Notice of Denial of Accreditation of CB will be submitted to the FDA when the CB's FEI number is retrieved.

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

Figure 11.24 – E-mail Notification



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

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

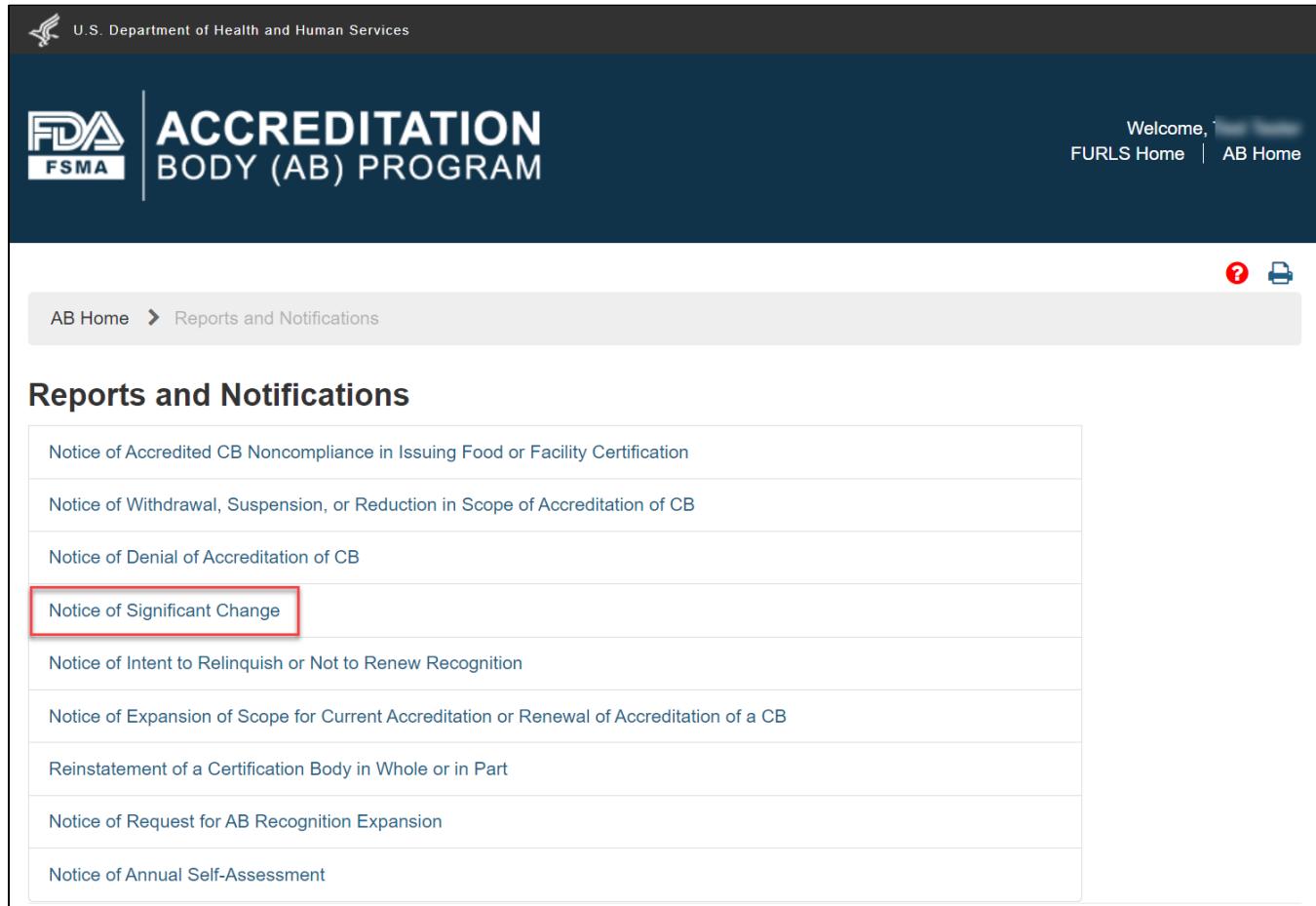
DO NOT REPLY TO THIS EMAIL

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

11.4 Notice of Significant Change

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

Figure 11.25 – Reports and Notifications Page



The screenshot shows the FDA Accreditation Body (AB) Program website. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and a 'Welcome' message with links to FURLS Home and AB Home. The main content area is titled 'Reports and Notifications' and lists several document types. The 'Notice of Significant Change' link is highlighted with a red box.

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, [User Name](#)
FURLS Home | AB Home

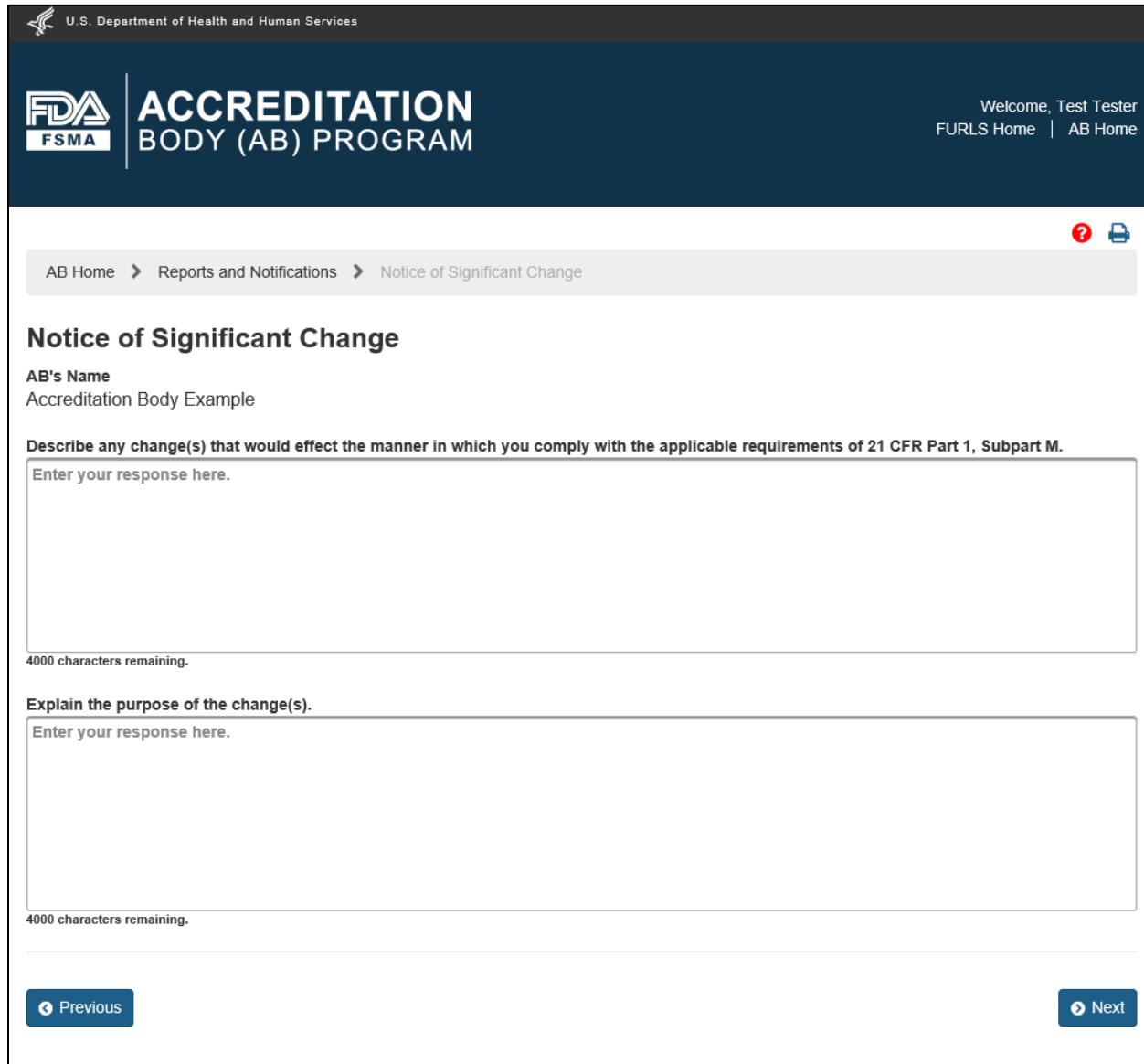
AB Home > Reports and Notifications

Reports and Notifications

- 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 for Current Accreditation or Renewal of Accreditation of a CB
- Reinstatement of a Certification Body in Whole or in Part
- Notice of Request for AB Recognition Expansion
- Notice of Annual Self-Assessment

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

Figure 11.26 – Notice of Significant Change



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 Significant Change

Notice of Significant Change

AB's Name
Accreditation Body Example

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

4000 characters remaining.

Explain the purpose of the change(s).
Enter your response here.

4000 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** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.
- **Explain the purpose of the change(s)** – Enter the response in the text entry field, which allows a maximum of 4,000 characters.

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

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

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

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

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

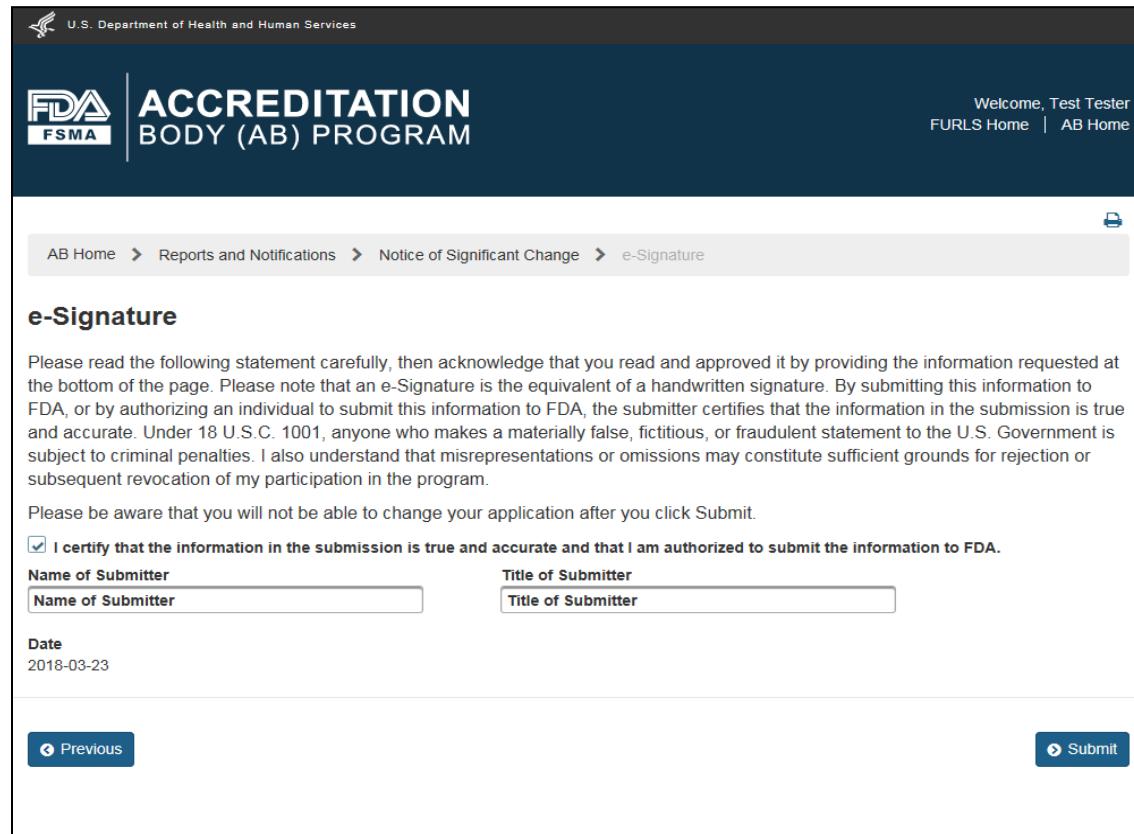
Complete the following data fields:

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

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

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

Figure 11.27 – e-Signature Page



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 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.

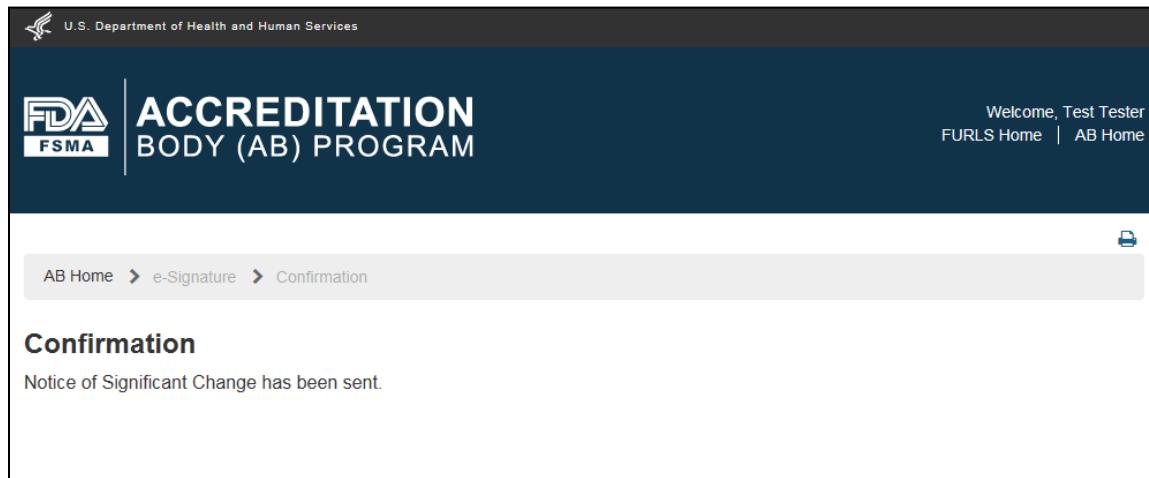
Name of Submitter	Title of Submitter
Name of Submitter	Title of Submitter

Date
2018-03-23

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

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

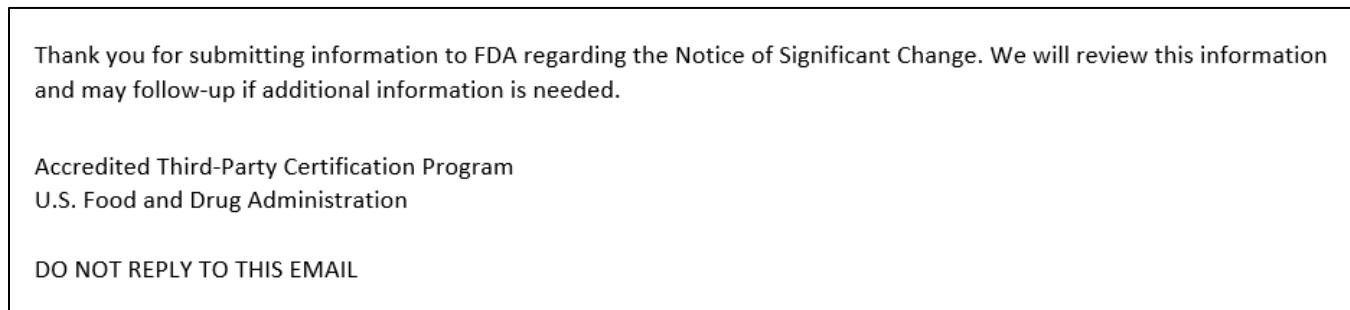
Figure 11.28 – Confirmation Page



The screenshot shows a confirmation page from the FDA Accreditation Body (AB) Program. The top banner includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and a welcome message for 'Test Tester'. The breadcrumb navigation shows 'AB Home > e-Signature > Confirmation'. The main content area is titled 'Confirmation' and contains the message 'Notice of Significant Change has been sent.' There is a small print icon in the top right corner of the content area.

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

Figure 11.29 – E-mail Notification



The email notification text is as follows:

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

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

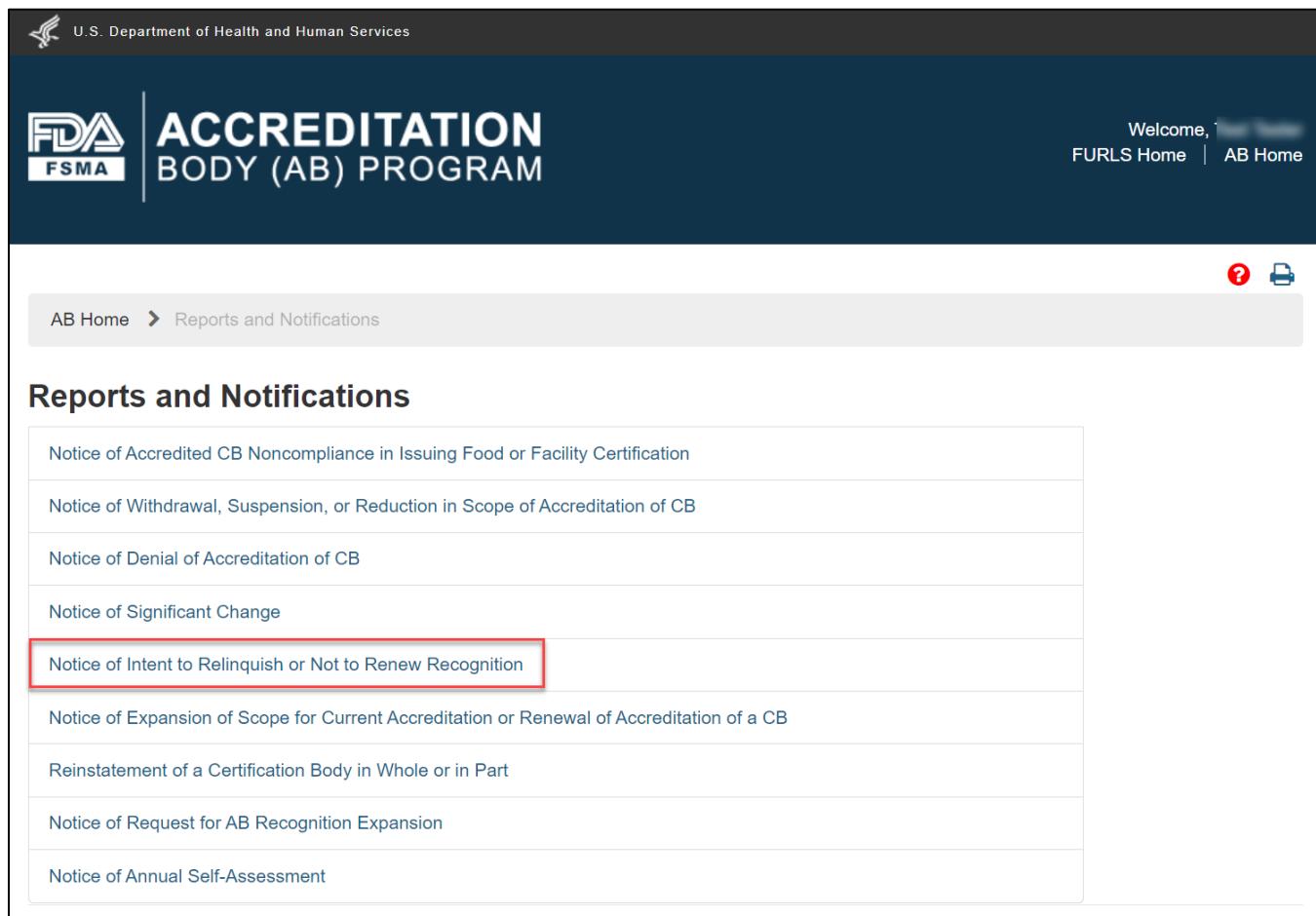
DO NOT REPLY TO THIS EMAIL

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

11.5 Notice of Intent to Relinquish or Not to Renew Recognition

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

Figure 11.30 – Reports and Notifications Page

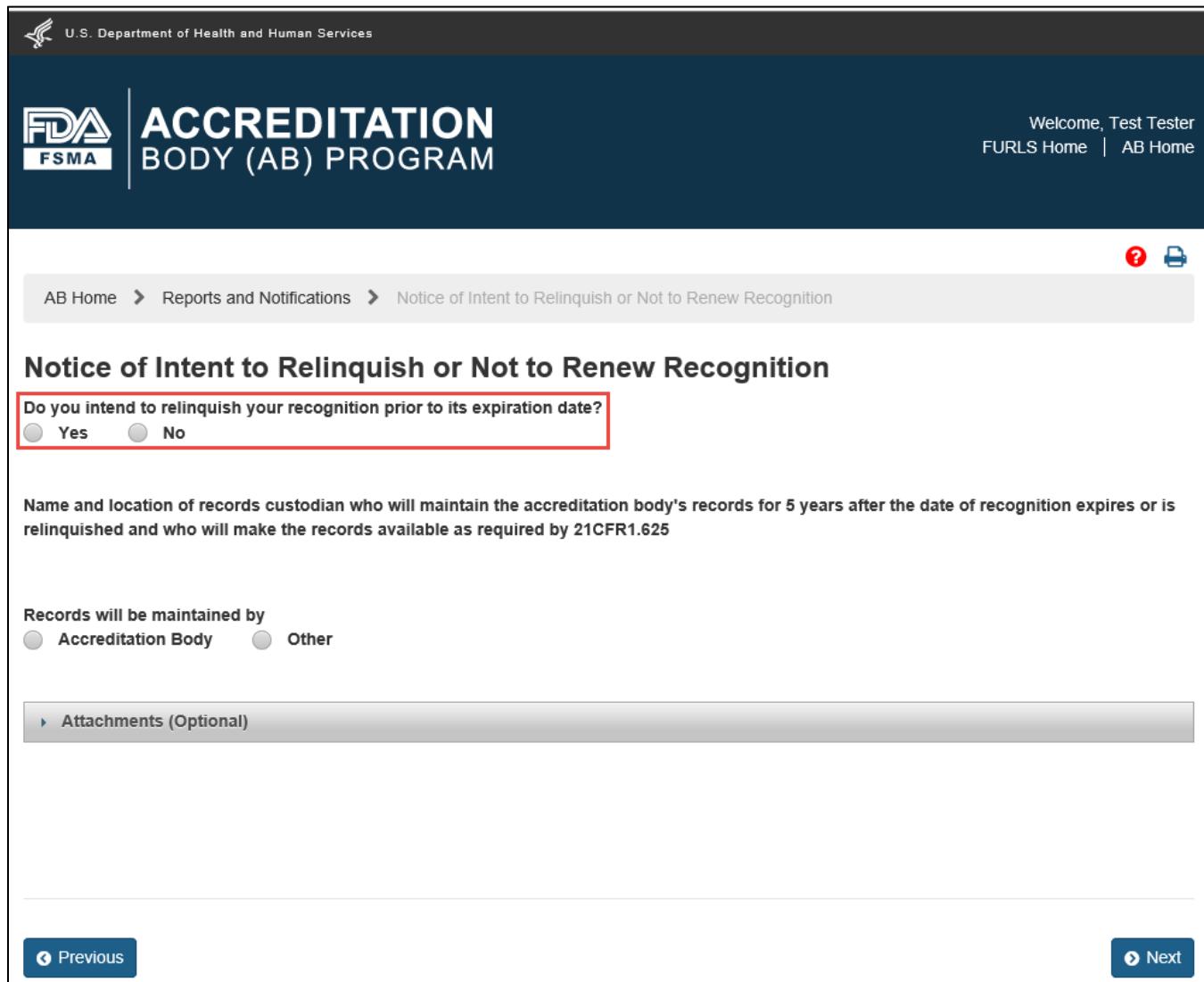


The screenshot shows the FDA Accreditation Body (AB) Program website. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and links for Welcome, FURLS Home, and AB Home. The main navigation menu on the left lists various reports and notifications, with the 'Notice of Intent to Relinquish or Not to Renew Recognition' link highlighted by a red box. The page title is 'Reports and Notifications'.

- 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 for Current Accreditation or Renewal of Accreditation of a CB
- Reinstatement of a Certification Body in Whole or in Part
- Notice of Request for AB Recognition Expansion
- Notice of Annual Self-Assessment

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

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



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

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 ▶

The system will display the following data field:

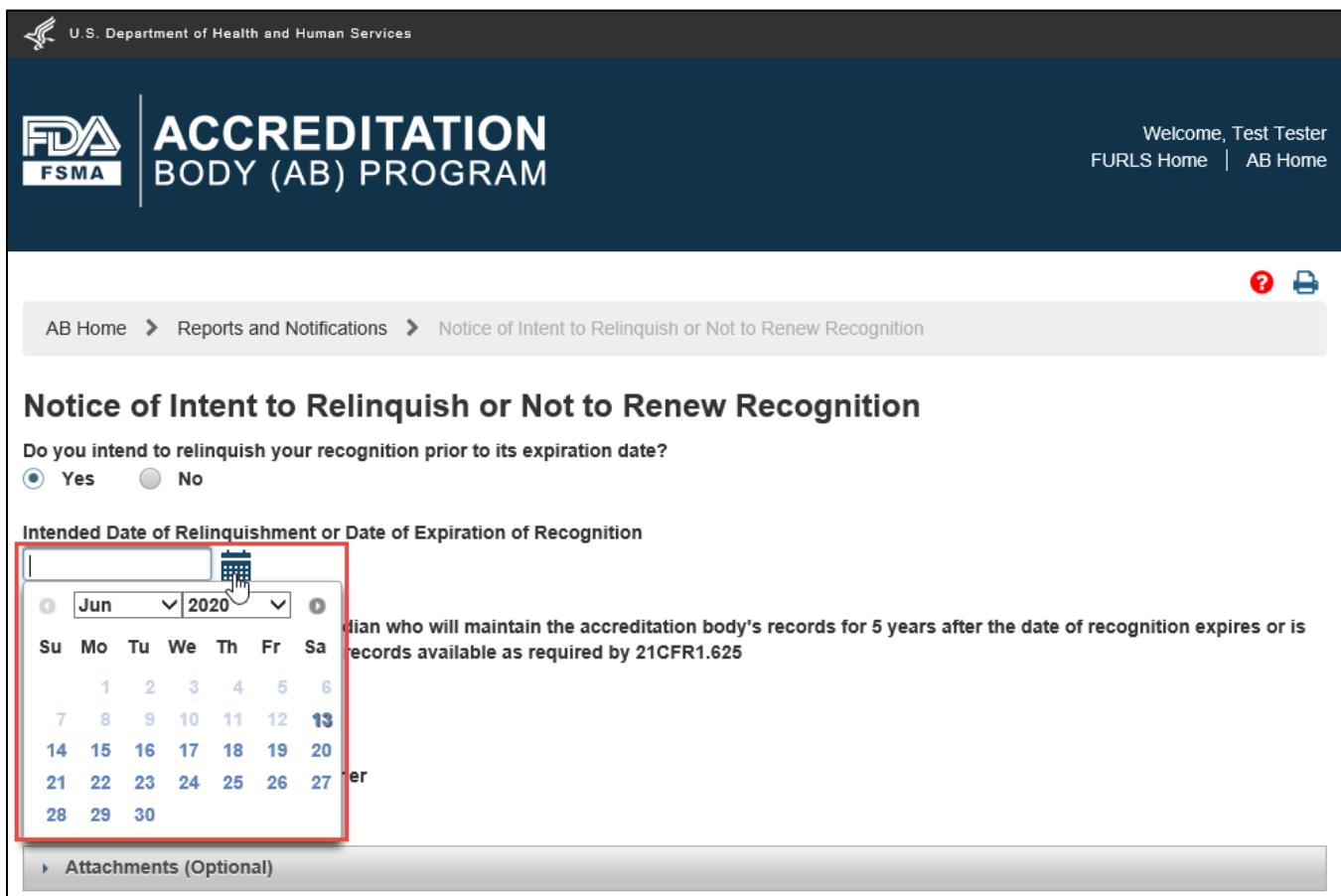
- **Do you intend to relinquish your recognition prior to its expiration date?** – Select “Yes” or “No” by clicking its radio button.
 - Click the radio button next to “Yes” to report your intent to relinquish recognition prior to your expiration date. If “Yes” is selected, proceed to Section 11.5.1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

11.5.1 Intent to Relinquish Recognition

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

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

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



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

Jun 2020

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

Attacks (Optional)

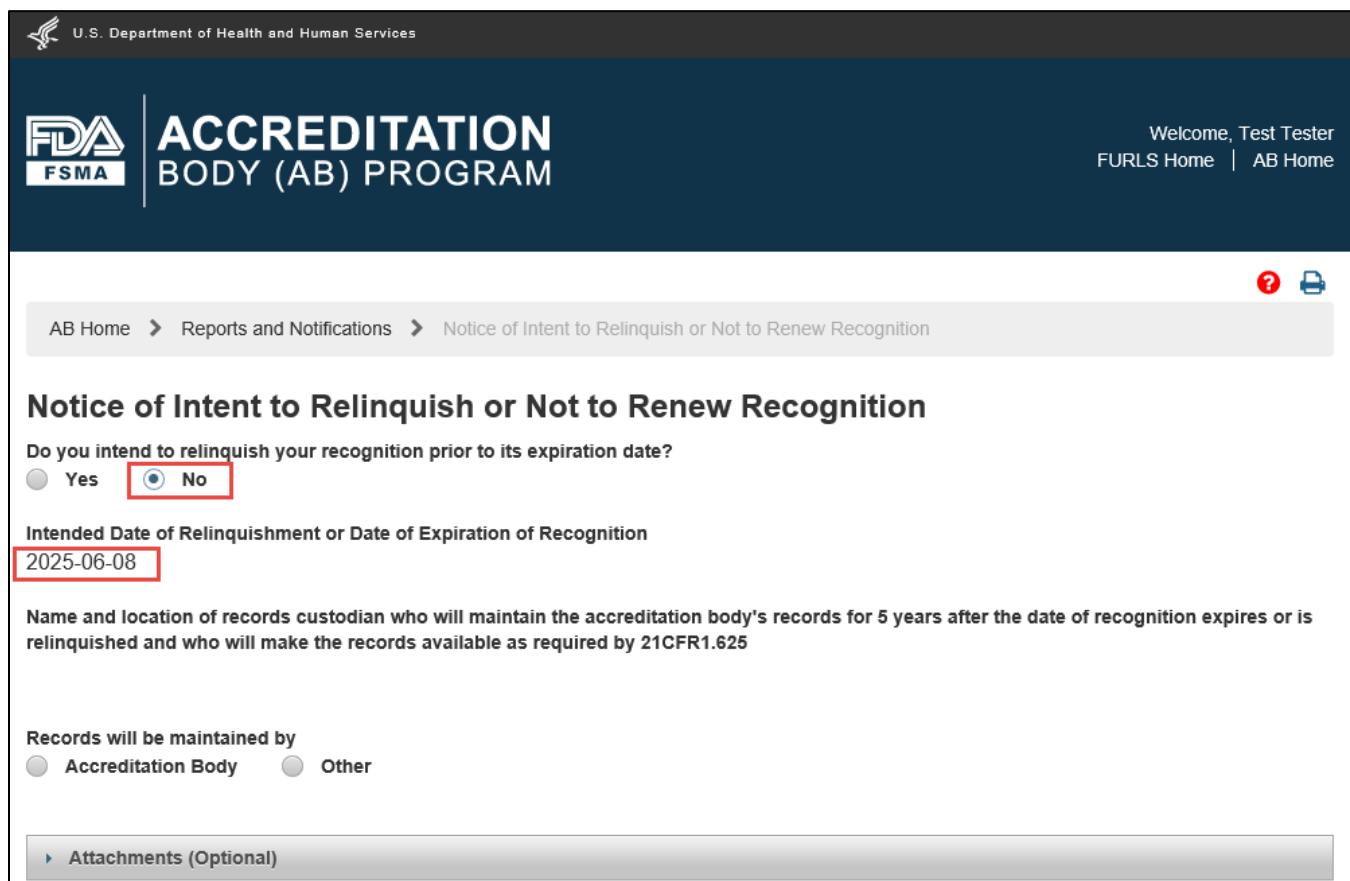
Select or enter the date of relinquishment and proceed to Section 11.5.3 of this chapter for the next steps.

11.5.2 Intent Not to Renew Recognition

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

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

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



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
2025-06-08

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)

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

11.5.3 Records Custodian and Attachments

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

- Accreditation Body – Select this option if you will be maintaining your records. Select “Accreditation Body” by clicking its radio button to display your read-only contact information.
- Other – Select this option if someone other than you will be maintaining your records. Select “Other” by clicking its radio button to display fields to enter the contact information for the designated records custodian.

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

Figure 11.34 – Records Will Be Maintained By



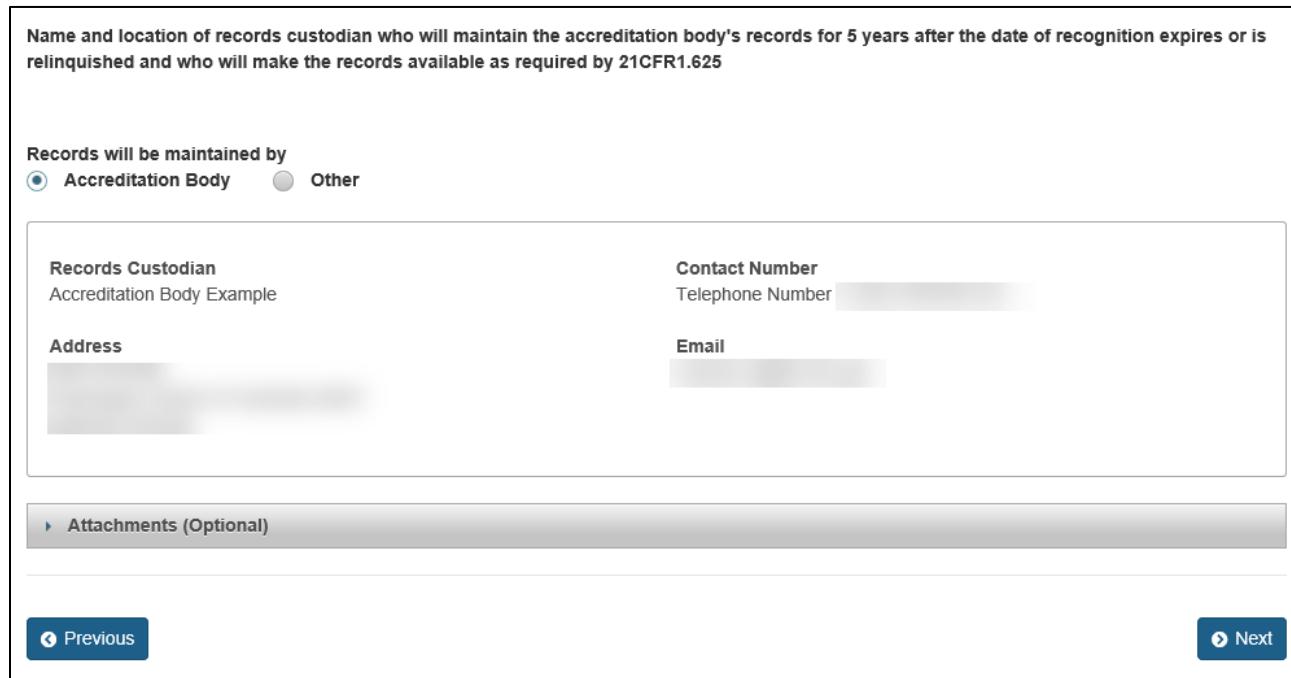
Records will be maintained by

Accreditation Body Other

▶ Attachments (Optional)

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

Figure 11.35 – Records Will Be Maintained by Accreditation Body



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 Example	Contact Number Telephone Number <input type="text"/>
Address <input type="text"/>	Email <input type="text"/>

▶ Attachments (Optional)

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

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

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

Figure 11.36 – Records Maintained by Other

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):
<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Country:	Country <input type="text"/> Area <input type="text"/> Phone Number <input type="text"/> Extension <input type="text"/>
<input type="text"/>	E-mail Address: <input type="text"/>
Address 1:	<input type="text"/>
Address 2 (Optional):	<input type="text"/>
City:	<input type="text"/>
State/Province/Territory:	<input type="text"/>
Zip Code (Postal Code):	<input type="text"/>
▶ Attachments (Optional)	
<input type="button" value="Previous"/>	<input type="button" value="Next"/>

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

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

Follow the four-step process to upload attachments.

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

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

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

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

The maximum file size allowed is 50 MB.

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

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

Figure 11.37 – Attachments (Optional) Section

▼ **Attachments (Optional)**

Instructions

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

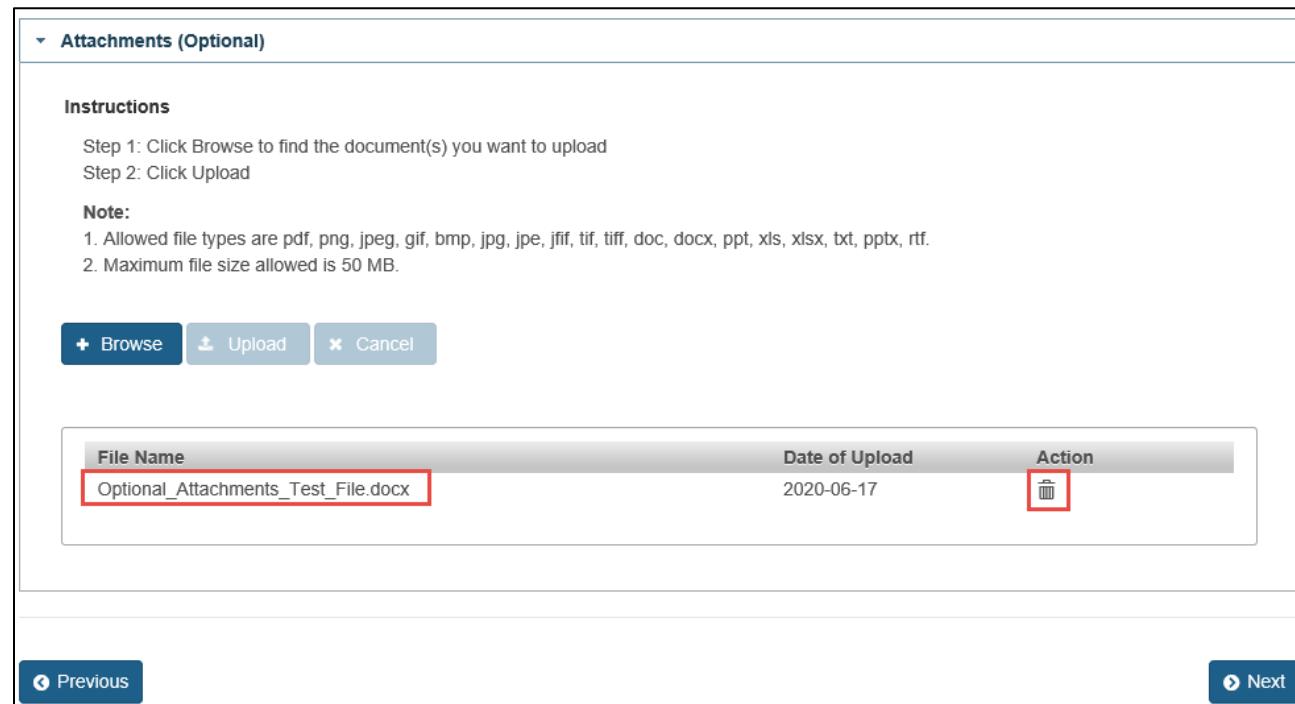
Note:

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

File Name **Date of Upload** **Action**

File Name	Date of Upload	Action
Optional_Attachments_Test_File.docx	2020-06-17	

Previous **Next**



Repeat the previous steps to upload additional attachments.

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

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

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

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

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

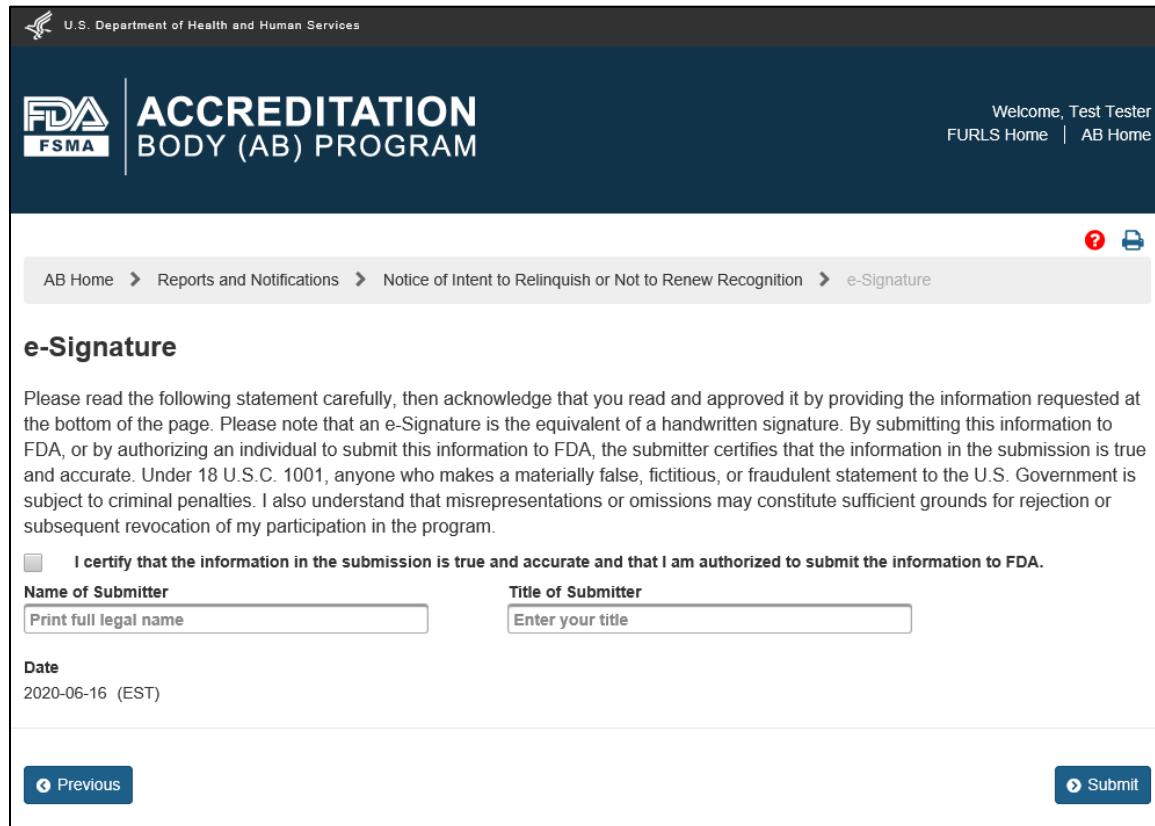
Complete the following data fields:

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

Click the “Previous” button if you wish to return to the “Notice of Intent to Relinquish or Not to Renew Recognition” page.

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

Figure 11.38 – e-Signature Page



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 > e-Signature

e-Signature

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

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

Name of Submitter

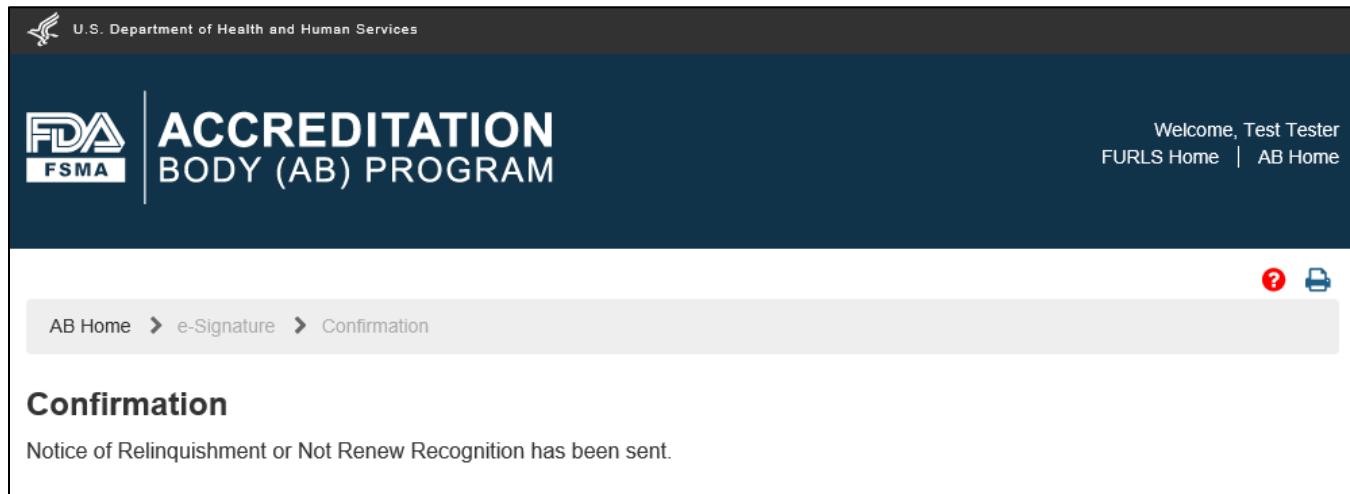
Title of Submitter

Date
2020-06-16 (EST)

Previous **Submit**

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

Figure 11.39 – Confirmation Page



U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

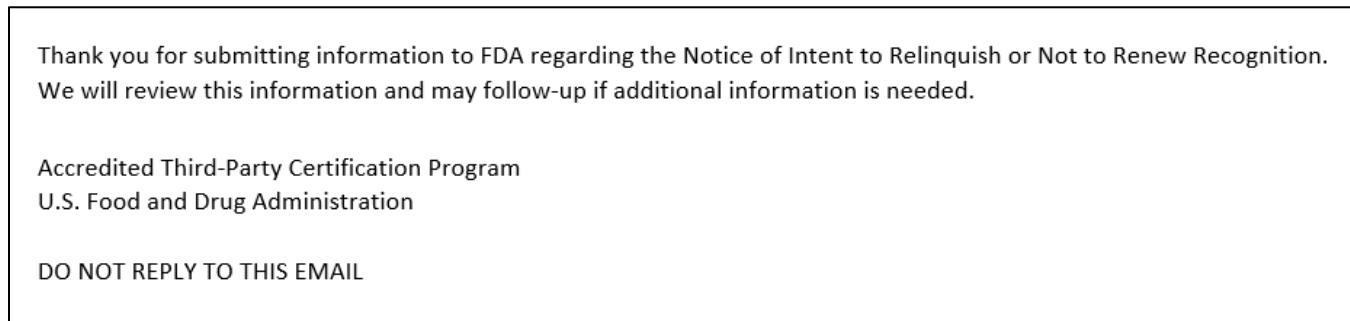
AB Home > e-Signature > Confirmation

Confirmation

Notice of Relinquishment or Not Renew Recognition has been sent.

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

Figure 11.40 – E-mail Notification



Thank you for submitting information to FDA regarding the Notice of Intent to Relinquish or Not to Renew Recognition. We will review this information and may follow-up if additional information is needed.

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

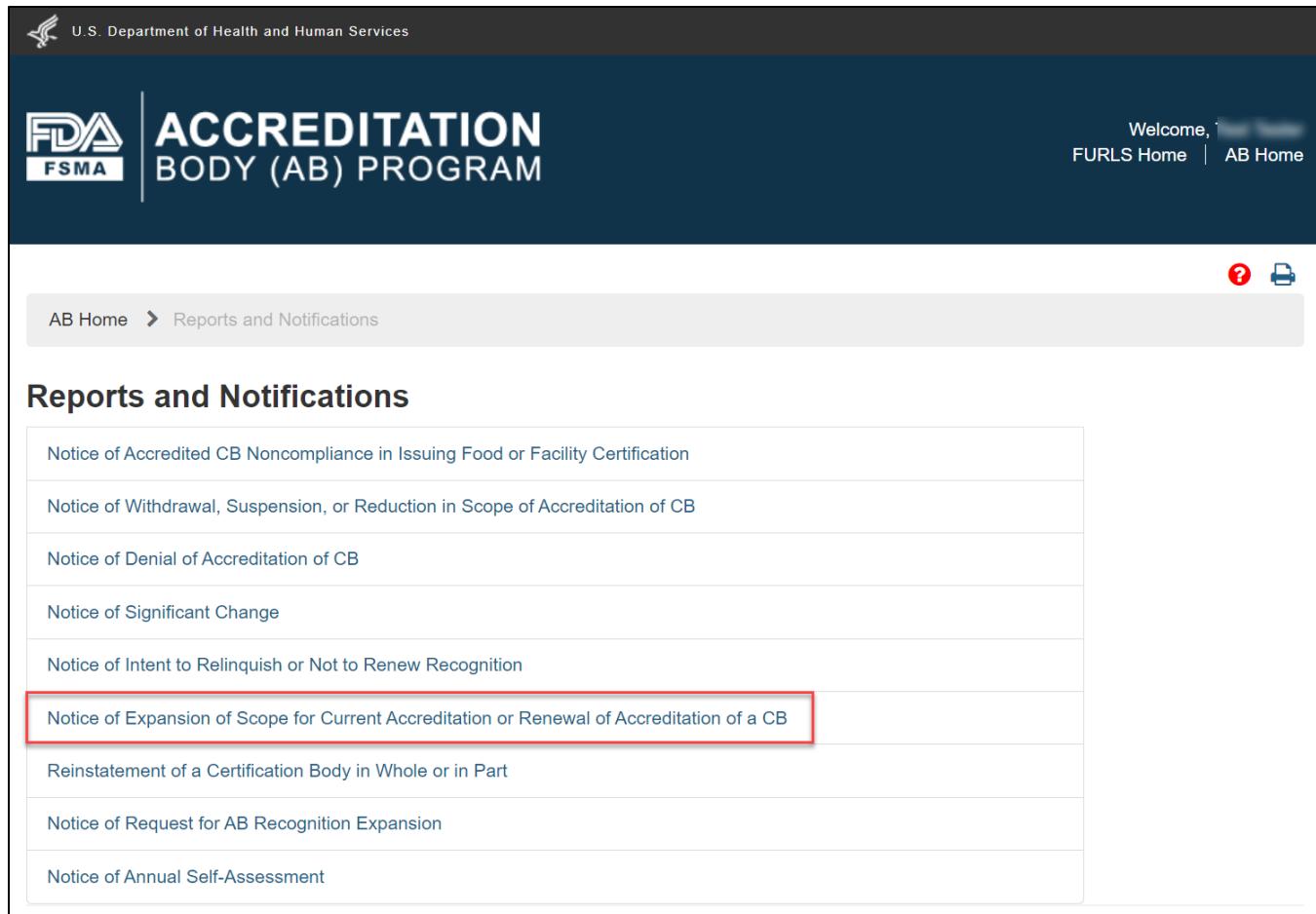
DO NOT REPLY TO THIS EMAIL

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

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

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

Figure 11.41 – Reports and Notifications Page



U.S. Department of Health and Human Services

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

Welcome, [REDACTED]
FURLS Home | AB Home

AB Home > Reports and Notifications

Reports and Notifications

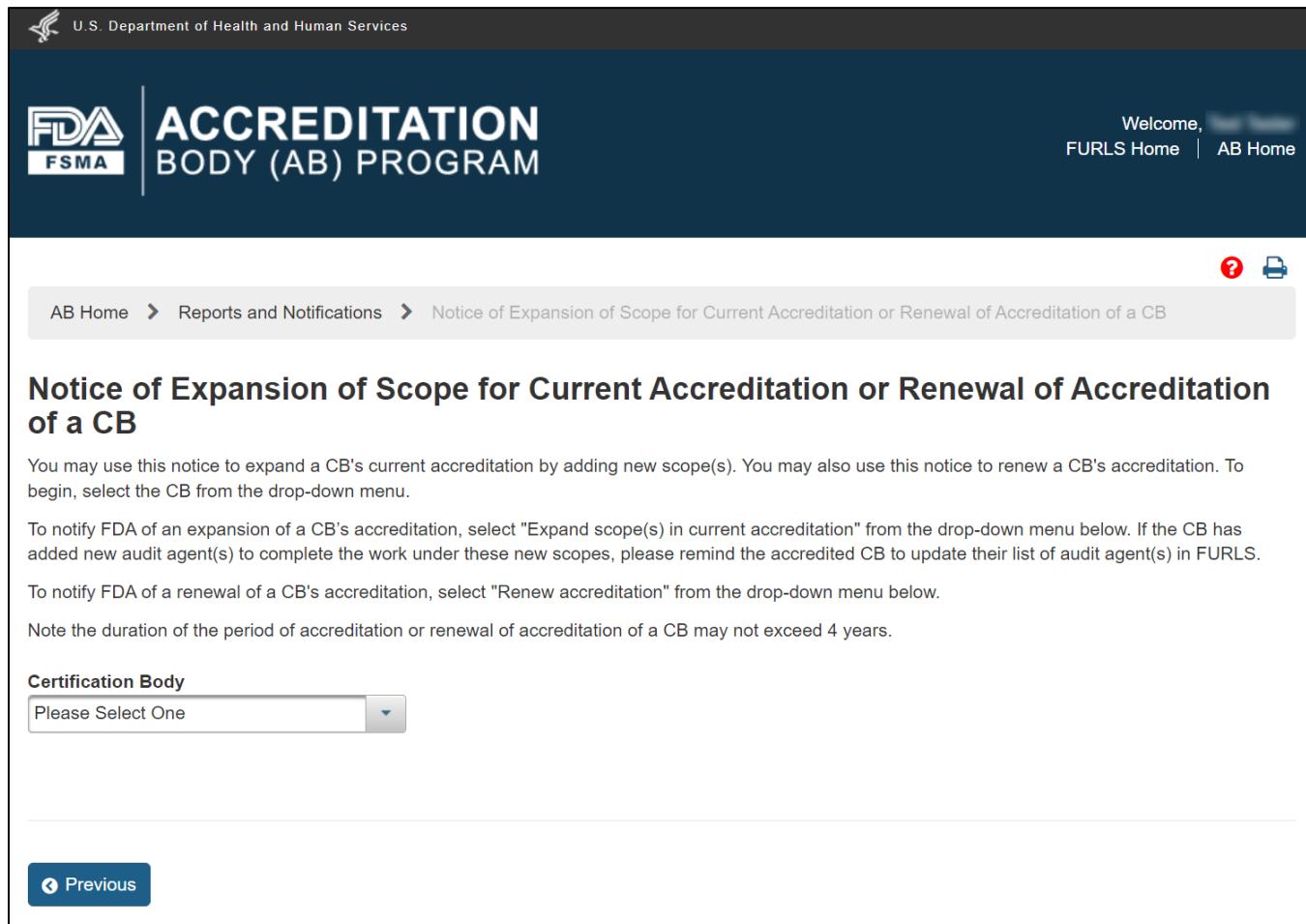
- [Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification](#)
- [Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB](#)
- [Notice of Denial of Accreditation of CB](#)
- [Notice of Significant Change](#)
- [Notice of Intent to Relinquish or Not to Renew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

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

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

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

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

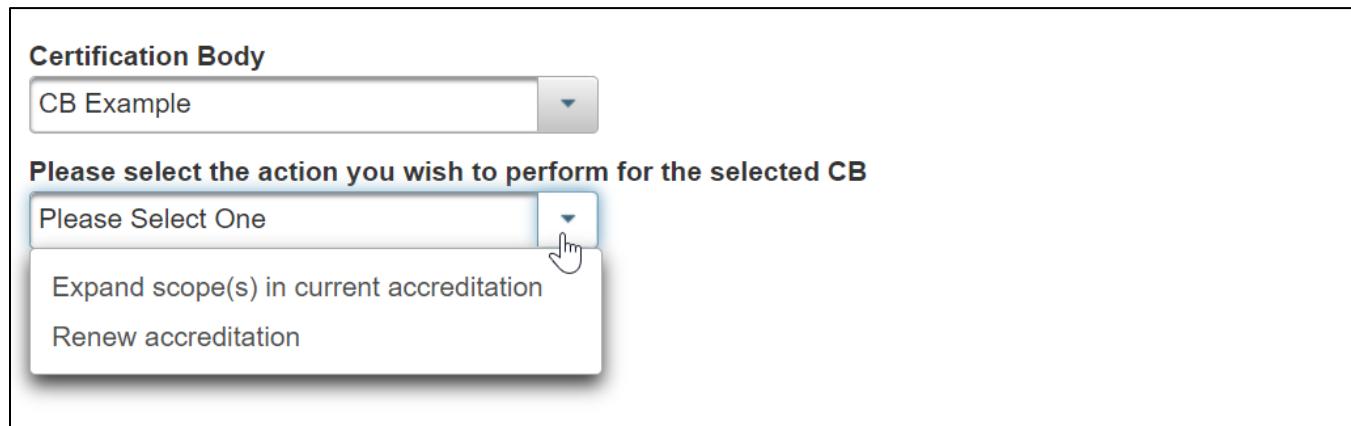


The screenshot shows the FDA Accreditation Body (AB) Program website. The header includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and a navigation bar with links for Welcome, FURLS Home, and AB Home. The main content area has a breadcrumb navigation: AB Home > Reports and Notifications > Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB. The page title is "Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB". Below the title, there is a note about using the notice to expand a CB's current accreditation or renew a CB's accreditation. It also provides instructions for notifying FDA of an expansion or renewal. A dropdown menu for "Certification Body" is shown, with "Please Select One" as the current selection. A "Previous" button is at the bottom left.

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

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

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



Certification Body
CB Example

Please select the action you wish to perform for the selected CB

Please Select One

Expand scope(s) in current accreditation
Renew accreditation

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

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

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

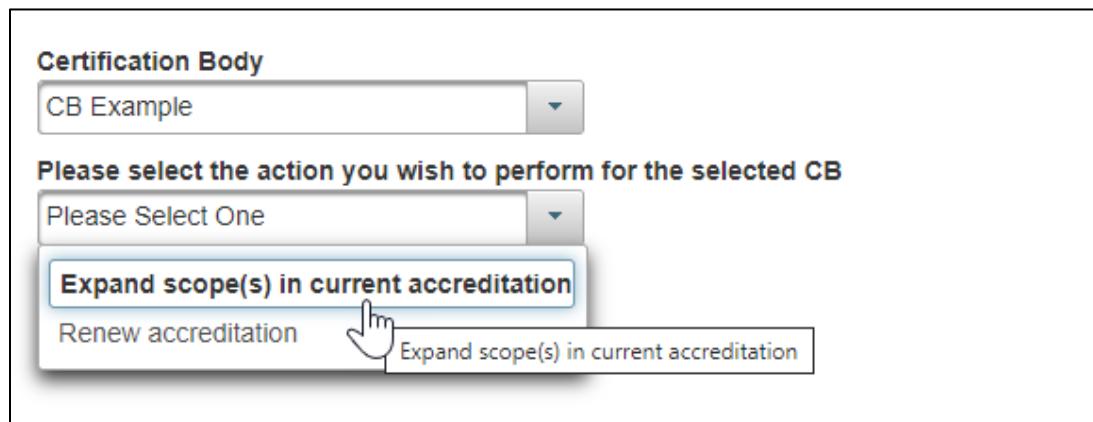
11.6.1 Expand Scope(s) for an Accredited CB

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

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

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

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



Certification Body
CB Example

Please select the action you wish to perform for the selected CB

Please Select One

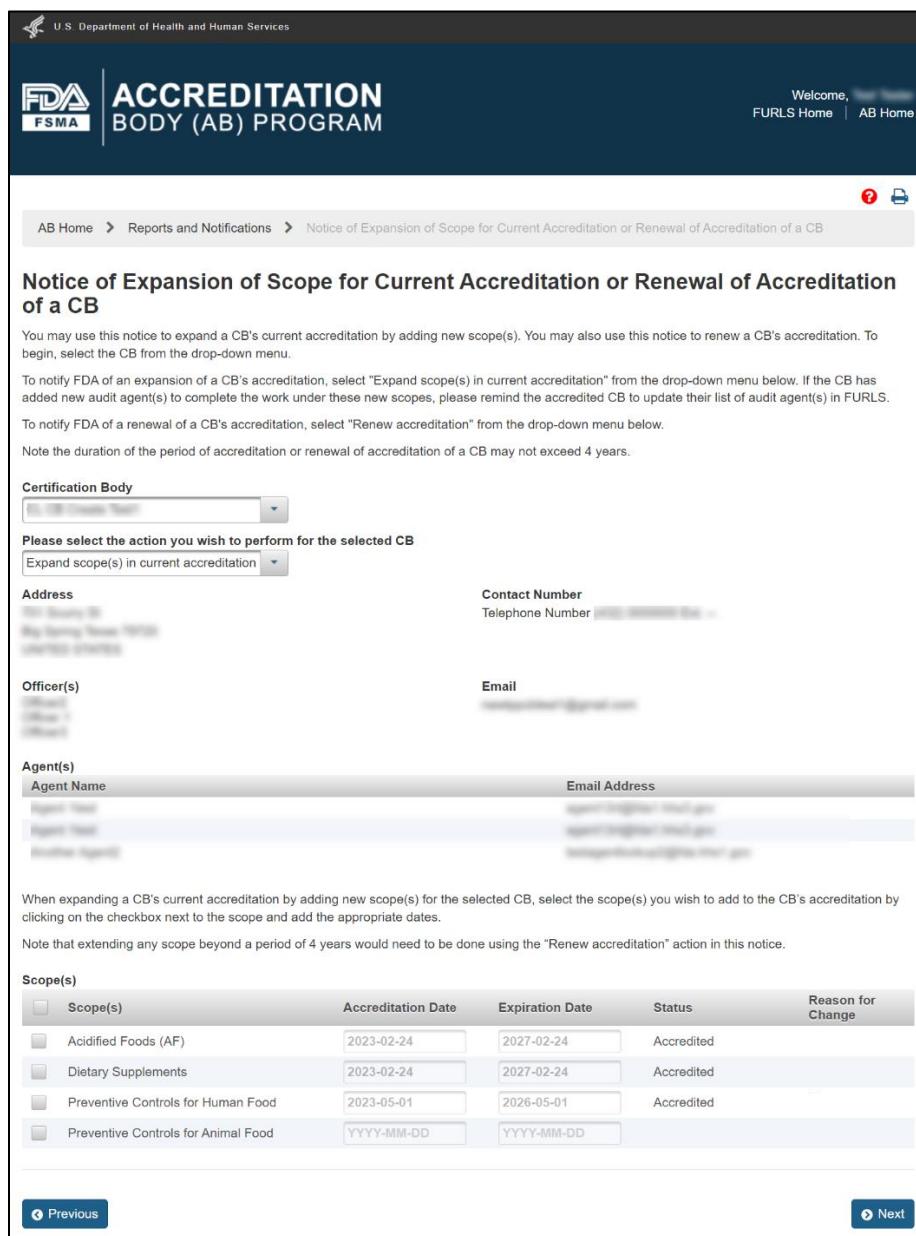
Expand scope(s) in current accreditation
Renew accreditation

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

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

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

Figure 11.45 – Additional Notice Information Displayed After Expansion Selection



U.S. Department of Health and Human Services

ACREDITATION BODY (AB) PROGRAM

Welcome, [User Name](#) [FURLS Home](#) | [AB Home](#)

AB Home > Reports and Notifications > Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB

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

You may use this notice to expand a CB's current accreditation by adding new scope(s). You may also use this notice to renew a CB's accreditation. To begin, select the CB from the drop-down menu.

To notify FDA of an expansion of a CB's accreditation, select "Expand scope(s) in current accreditation" from the drop-down menu below. If the CB has added new audit agent(s) to complete the work under these new scopes, please remind the accredited CB to update their list of audit agent(s) in FURLS.

To notify FDA of a renewal of a CB's accreditation, select "Renew accreditation" from the drop-down menu below.

Note the duration of the period of accreditation or renewal of accreditation of a CB may not exceed 4 years.

Certification Body

Please select the action you wish to perform for the selected CB

Address 12345 Main Street, Anytown, USA 12345 Main Street, Anytown, USA	Contact Number Telephone Number <input type="text" value=""/>
Officer(s) John Doe, CEO	Email <input type="text" value=""/>
Agent(s) Agent Name <input type="text" value=""/> Email Address <input type="text" value=""/>	

When expanding a CB's current accreditation by adding new scope(s) for the selected CB, select the scope(s) you wish to add to the CB's accreditation by clicking on the checkbox next to the scope and add the appropriate dates.

Note that extending any scope beyond a period of 4 years would need to be done using the "Renew accreditation" action in this notice.

Scope(s)

<input type="checkbox"/> Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> Acidified Foods (AF)	2023-02-24	2027-02-24	Accredited	
<input type="checkbox"/> Dietary Supplements	2023-02-24	2027-02-24	Accredited	
<input type="checkbox"/> Preventive Controls for Human Food	2023-05-01	2026-05-01	Accredited	
<input type="checkbox"/> Preventive Controls for Animal Food	YYYY-MM-DD	YYYY-MM-DD		

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

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

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

Figure 11.46 – Checkbox for Scope Selection

Scope(s)				
Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input checked="" type="checkbox"/> Acidified Foods (AF)	2021-09-01	2023-09-01	Accredited	
<input type="checkbox"/> Dietary Supplements	2021-09-01	2023-09-01	Accredited	
<input type="checkbox"/> Preventive Controls for Animal Food	YYYY-MM-DD	YYYY-MM-DD		

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

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

Figure 11.47 – Update Scope Pop-up Window

Agent Name Email Address

Update Scope

Expiration Date 

Reason for Change
Enter your response here.
1000 characters remaining.

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

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

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

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

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

Figure 11.48 – Updated Scope with View Link

Scope(s)				
Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input checked="" type="checkbox"/> Acidified Foods (AF)	2021-09-01	2025-09-01	Accredited	View 

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

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

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

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

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

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

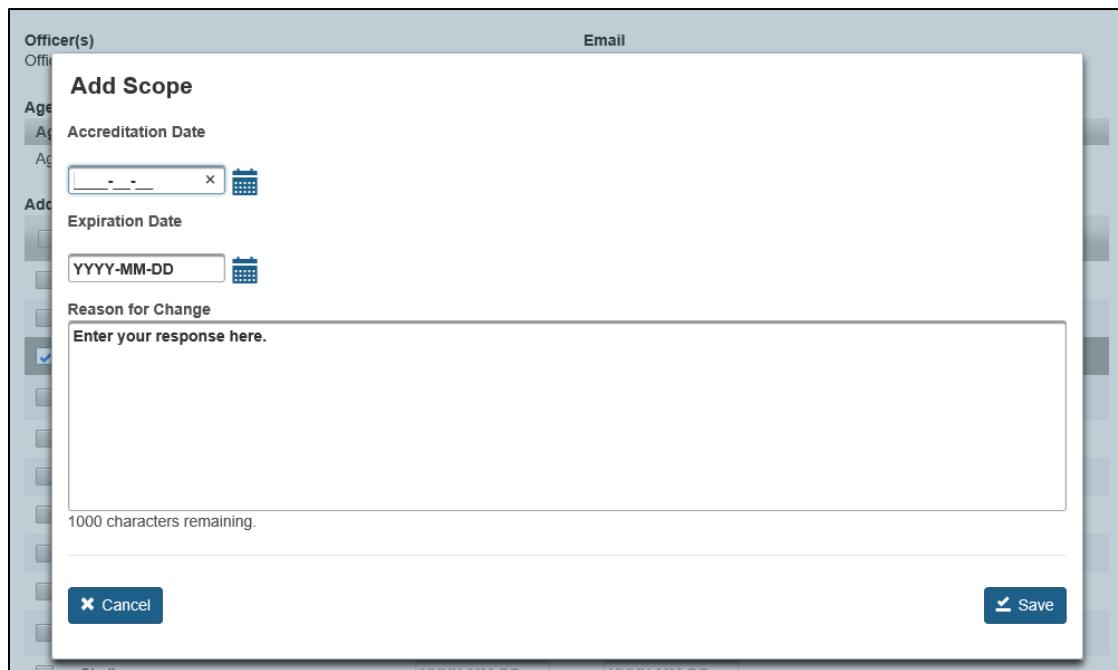
Figure 11.49 – Checkbox for Scope Selection

Scope(s)				
Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> Acidified Foods (AF)	2021-09-01	2023-09-01	Accredited	
<input type="checkbox"/> Dietary Supplements	2021-09-01	2023-09-01	Accredited	
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	YYYY-MM-DD	YYYY-MM-DD		

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

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

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



The screenshot shows a modal dialog box titled "Add Scope". Inside the dialog, there are three input fields: "Accreditation Date" with a date picker icon, "Expiration Date" with a date picker icon, and a large text area for "Reason for Change" with a character limit of "1000 characters remaining". At the bottom of the dialog are two buttons: "Cancel" and "Save".

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

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

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

Figure 11.51 – Added Scope

Scope(s)				
Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> Acidified Foods (AF)	2021-09-01	2023-09-01	Accredited	
<input type="checkbox"/> Dietary Supplements	2021-09-01	2023-09-01	Accredited	
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	2022-11-01	2024-11-01		

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

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

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

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

11.6.2 Renew the CB's Current Accreditation

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

Figure 11.52 – Renew Accreditation Menu Option

Certification Body
 

Please select the action you wish to perform for the selected CB



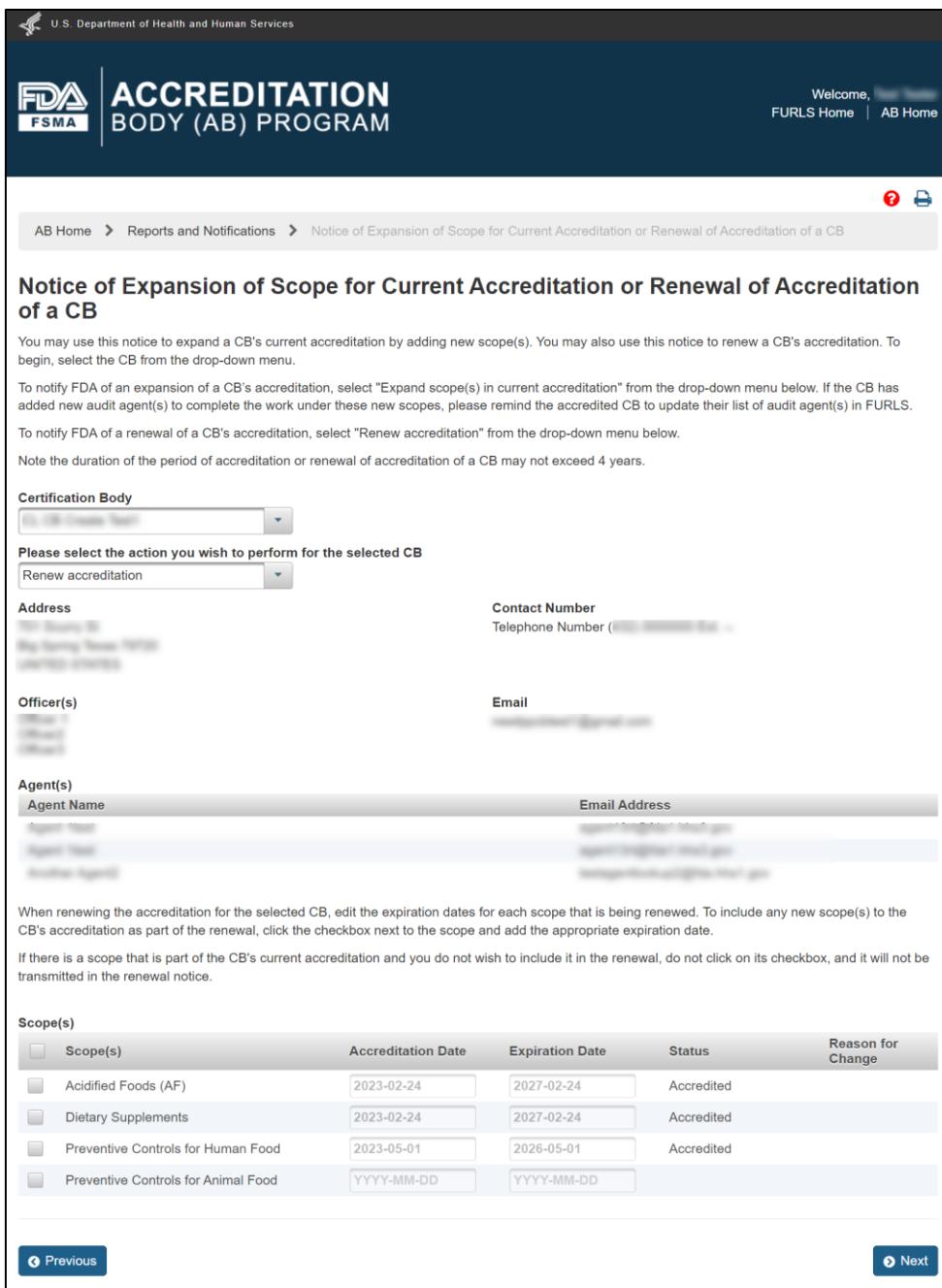
Renew accreditation 

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

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

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

Figure 11.53 – Additional Notice information Displayed After Renew Selection



U.S. Department of Health and Human Services

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

Welcome, [User Name](#)
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a CB

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

You may use this notice to expand a CB's current accreditation by adding new scope(s). You may also use this notice to renew a CB's accreditation. To begin, select the CB from the drop-down menu.

To notify FDA of an expansion of a CB's accreditation, select "Expand scope(s) in current accreditation" from the drop-down menu below. If the CB has added new audit agent(s) to complete the work under these new scopes, please remind the accredited CB to update their list of audit agent(s) in FURLS.

To notify FDA of a renewal of a CB's accreditation, select "Renew accreditation" from the drop-down menu below.

Note the duration of the period of accreditation or renewal of accreditation of a CB may not exceed 4 years.

Certification Body
[Redacted]

Please select the action you wish to perform for the selected CB
Renew accreditation

Address
[Redacted]

Contact Number
Telephone Number ([Redacted])

Officer(s)
[Redacted]

Email
[Redacted]

Agent(s)

Agent Name	Email Address
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]

When renewing the accreditation for the selected CB, edit the expiration dates for each scope that is being renewed. To include any new scope(s) to the CB's accreditation as part of the renewal, click the checkbox next to the scope and add the appropriate expiration date.

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

Scope(s)

Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> Acidified Foods (AF)	2023-02-24	2027-02-24	Accredited	
<input type="checkbox"/> Dietary Supplements	2023-02-24	2027-02-24	Accredited	
<input type="checkbox"/> Preventive Controls for Human Food	2023-05-01	2026-05-01	Accredited	
<input type="checkbox"/> Preventive Controls for Animal Food	YYYY-MM-DD	YYYY-MM-DD		

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

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

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

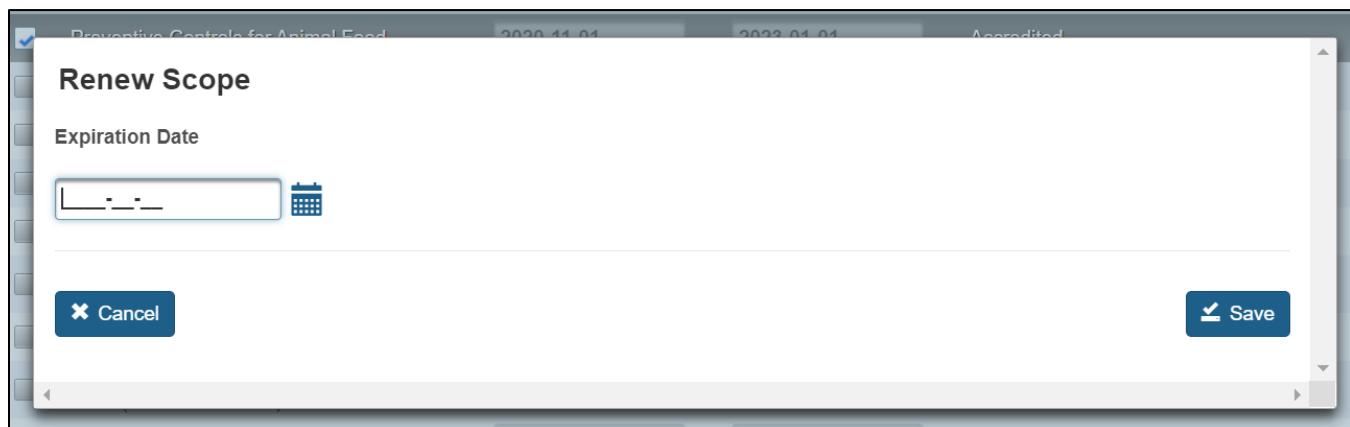
Figure 11.54 – Checkbox for Scope Selection

Scope(s)					
Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change	
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	2020-11-01	2023-01-01	Accredited		

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

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

Figure 11.55 – Renew Scope Pop-up Window



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

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

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

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

Figure 11.56 – Renewed Scope

Scope(s)					
Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change	
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	2020-11-01	2027-01-01	Accredited		

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

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

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

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

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

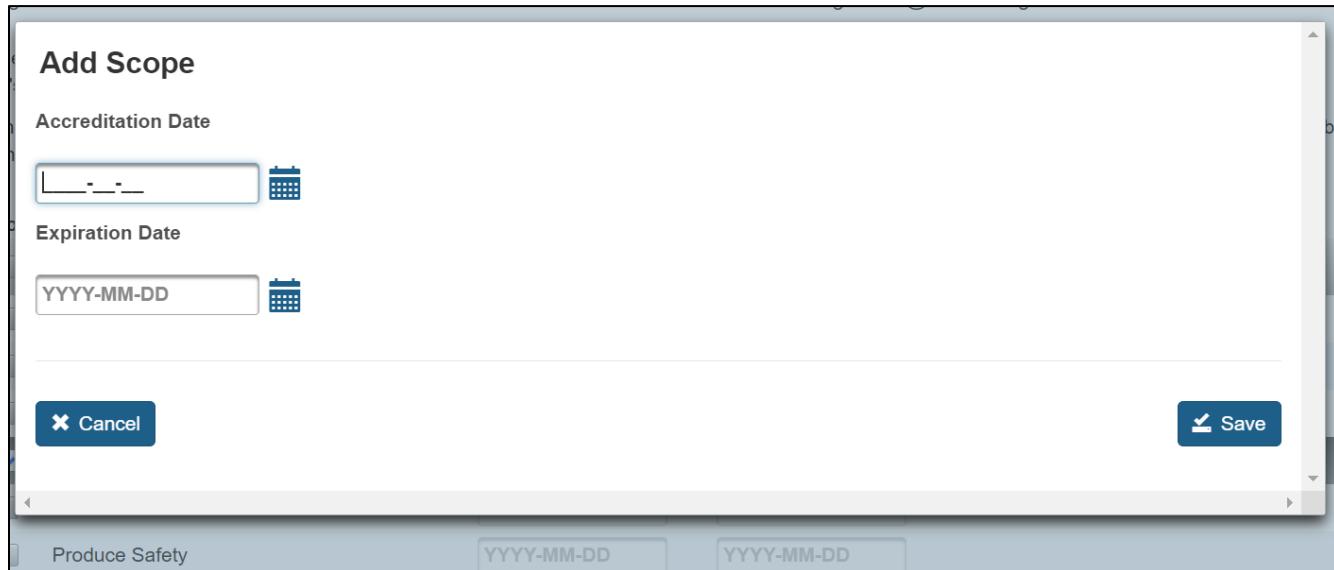
Figure 11.57 – Checkbox for Scope Selection

Scope(s)					
Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change	
<input type="checkbox"/> Acidified Foods (AF)	2021-09-01	2023-09-01	Accredited		
<input type="checkbox"/> Dietary Supplements	2021-09-01	2023-09-01	Accredited		
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	YYYY-MM-DD	YYYY-MM-DD			

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

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

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



Add Scope

Accreditation Date

Expiration Date

Produce Safety YYYY-MM-DD YYYY-MM-DD

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

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

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

Figure 11.59 – Added Scope

Scope(s)					
<input type="checkbox"/> Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change	
<input type="checkbox"/> Acidified Foods (AF)	2023-02-24	2027-02-24	Accredited		
<input type="checkbox"/> Dietary Supplements	2023-02-24	2027-02-24	Accredited		
<input checked="" type="checkbox"/> Preventive Controls for Animal Food	2023-06-02	2025-06-01			

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

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

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

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

11.6.3 Notice Submission

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

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

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

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

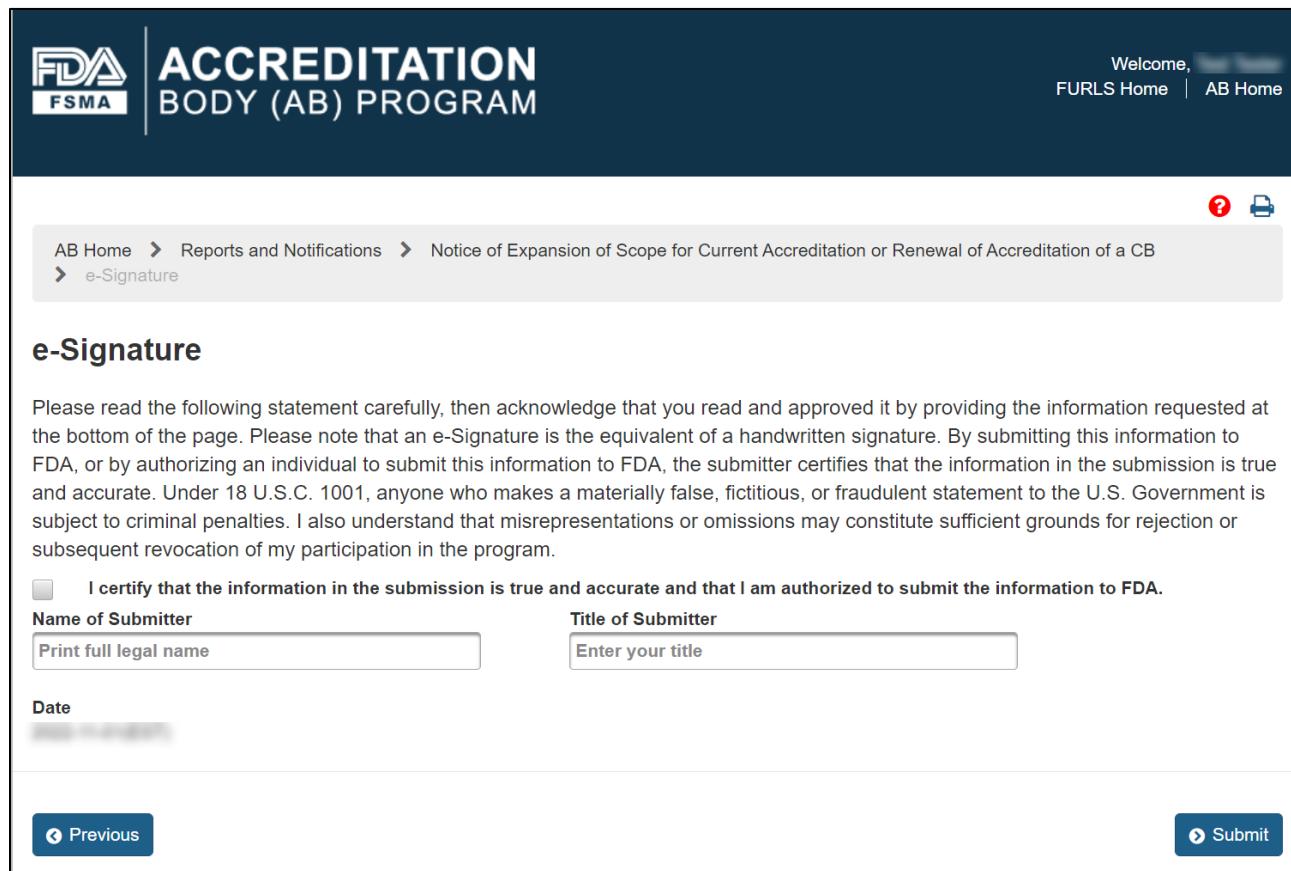
Complete the following data fields:

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

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

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

Figure 11.60 – e-Signature Page



AB Home > Reports and Notifications > Notice of Expansion of Scope for Current Accreditation or Renewal of Accreditation of a 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.

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

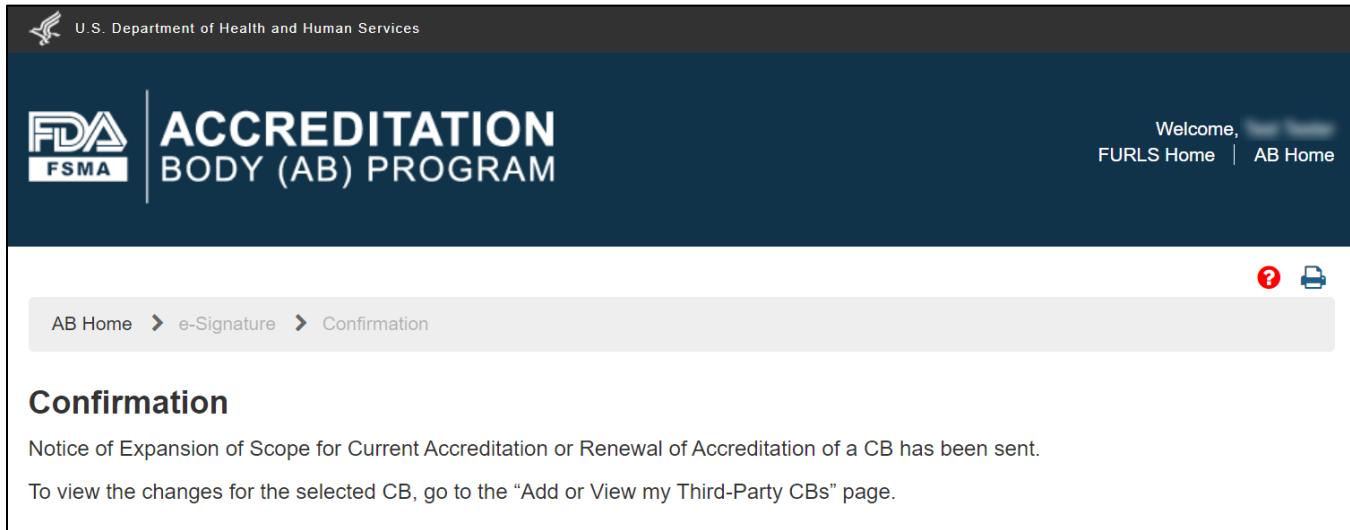
Title of Submitter
Enter your title

Date
[Redacted Signature]

Previous Submit

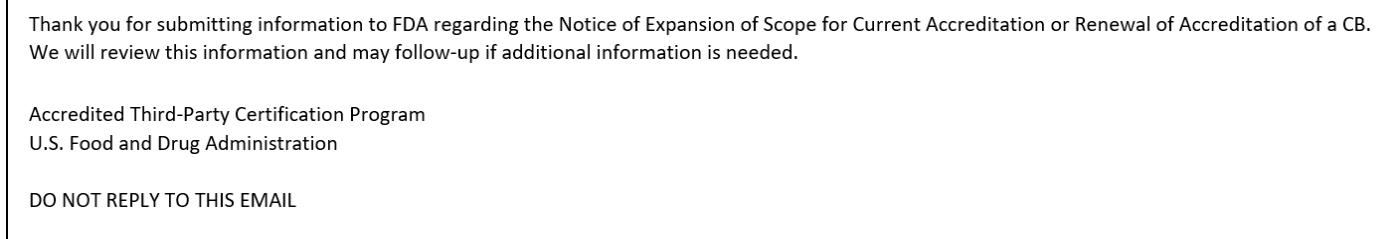
After you click the “Submit” button, the system will display the “Confirmation” page (Figure 11.61).

Figure 11.61 – Confirmation Page



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

Figure 11.62 – E-mail Notification

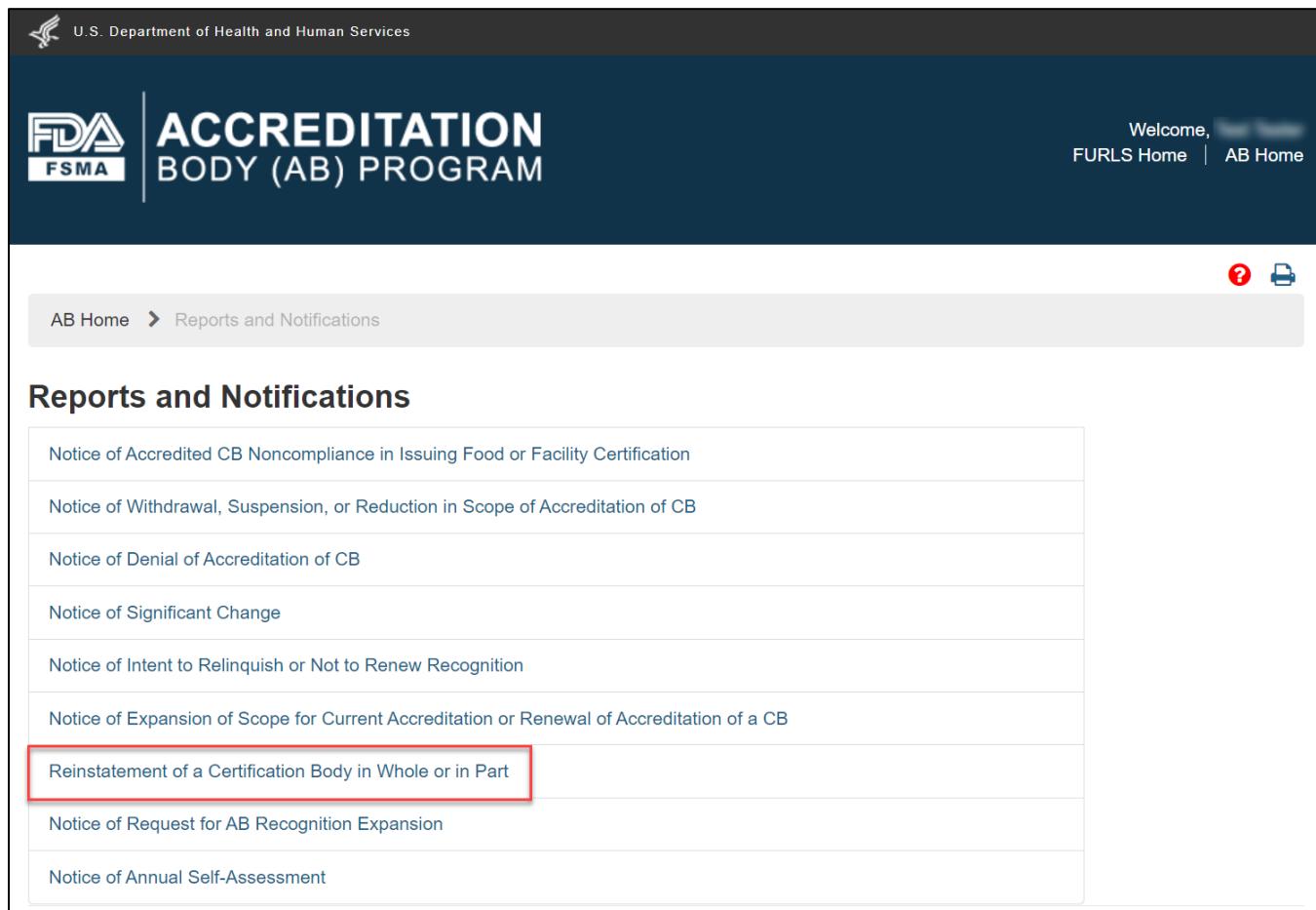


Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

11.7 Reinstatement of a Certification Body in Whole or in Part

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

Figure 11.63 – Reports and Notifications Page



U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome,  FURLS Home | AB Home

AB Home > Reports and Notifications

Reports and Notifications

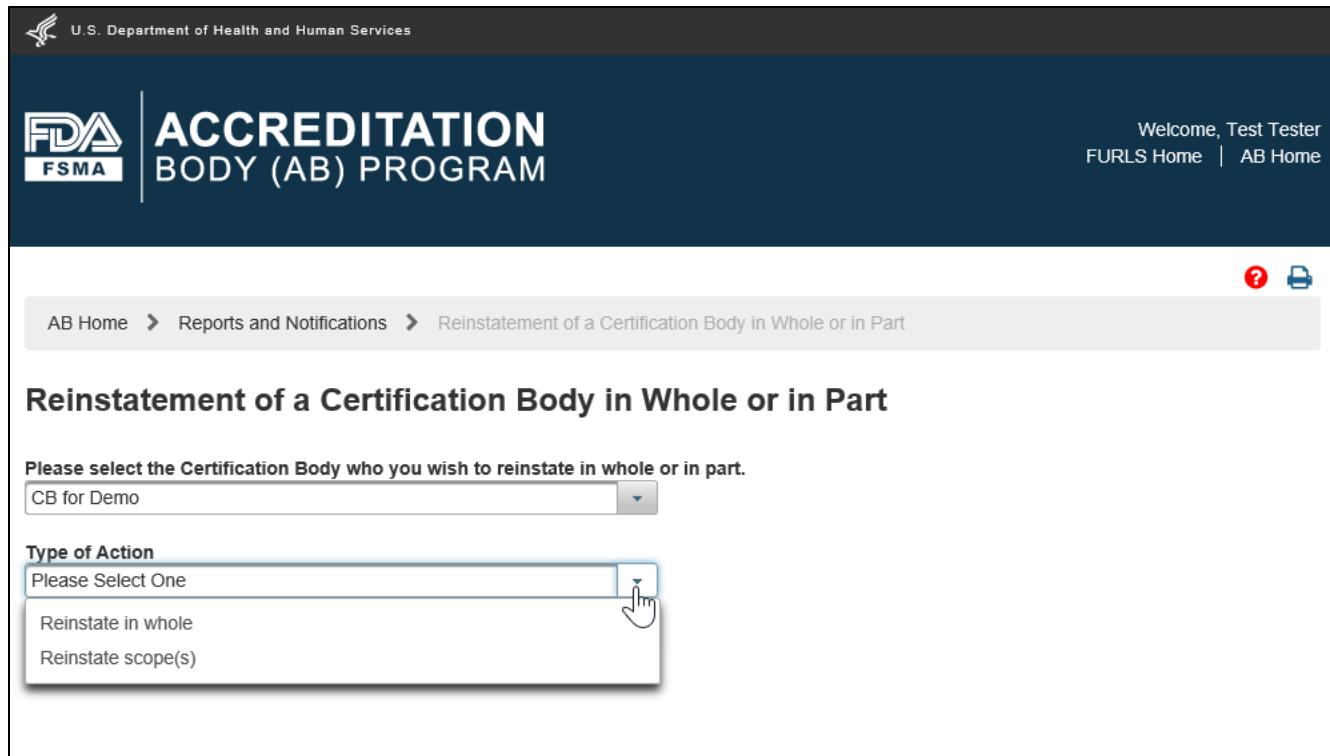
- [Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification](#)
- [Notice of Withdrawal, Suspension, or Reduction in Scope of Accreditation of CB](#)
- [Notice of Denial of Accreditation of CB](#)
- [Notice of Significant Change](#)
- [Notice of Intent to Relinquish or Not to Renew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

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

Complete the following data fields:

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

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



The screenshot shows the FDA Accreditation Body (AB) Program interface. At the top, there is a navigation bar with the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text "ACCREDITATION BODY (AB) PROGRAM". On the right side of the header, there is a welcome message "Welcome, Test Tester" and links to "FURLS Home" and "AB Home". Below the header, the breadcrumb navigation shows "AB Home > Reports and Notifications > Reinstatement of a Certification Body in Whole or in Part". The main content area is titled "Reinstatement of a Certification Body in Whole or in Part". It contains a form with the following fields:

- A dropdown menu labeled "Please select the Certification Body who you wish to reinstate in whole or in part." with an option "CB for Demo".
- A dropdown menu labeled "Type of Action" with an option "Please Select One". A sub-menu is open, showing "Reinstate in whole" and "Reinstate scope(s)".

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

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

Figure 11.65 – Reinstate in Whole

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.

TPP Certification Body

Type of Action
Reinstate in whole

Scopes that are to be reinstated.

Scope(s)
Dietary Supplements
Infant Formula
Juice Hazard Analysis and Critical Control Point (Juice HACCP)
Low-Acid Canned Foods (LACF)
Medicated Feed

1 2

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 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 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 Documentaion.

Enter your response here.

4000 characters remaining.

Previous

Next

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

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

Figure 11.66 – Reinstate Scope(s)

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.

TPP Certification Body

Type of Action

Reinstate scope(s)

Select the Scopes that are to be reinstated.

Select One	Scope(s)
<input type="checkbox"/>	Dietary Supplements
<input type="checkbox"/>	Infant Formula
<input type="checkbox"/>	Juice Hazard Analysis and Critical Control Point (Juice HACCP)
<input type="checkbox"/>	Low-Acid Canned Foods (LACF)
<input type="checkbox"/>	Medicated Feed

1 2

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 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 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 Documentaion.

Enter your response here.

4000 characters remaining.

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

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

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

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

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

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

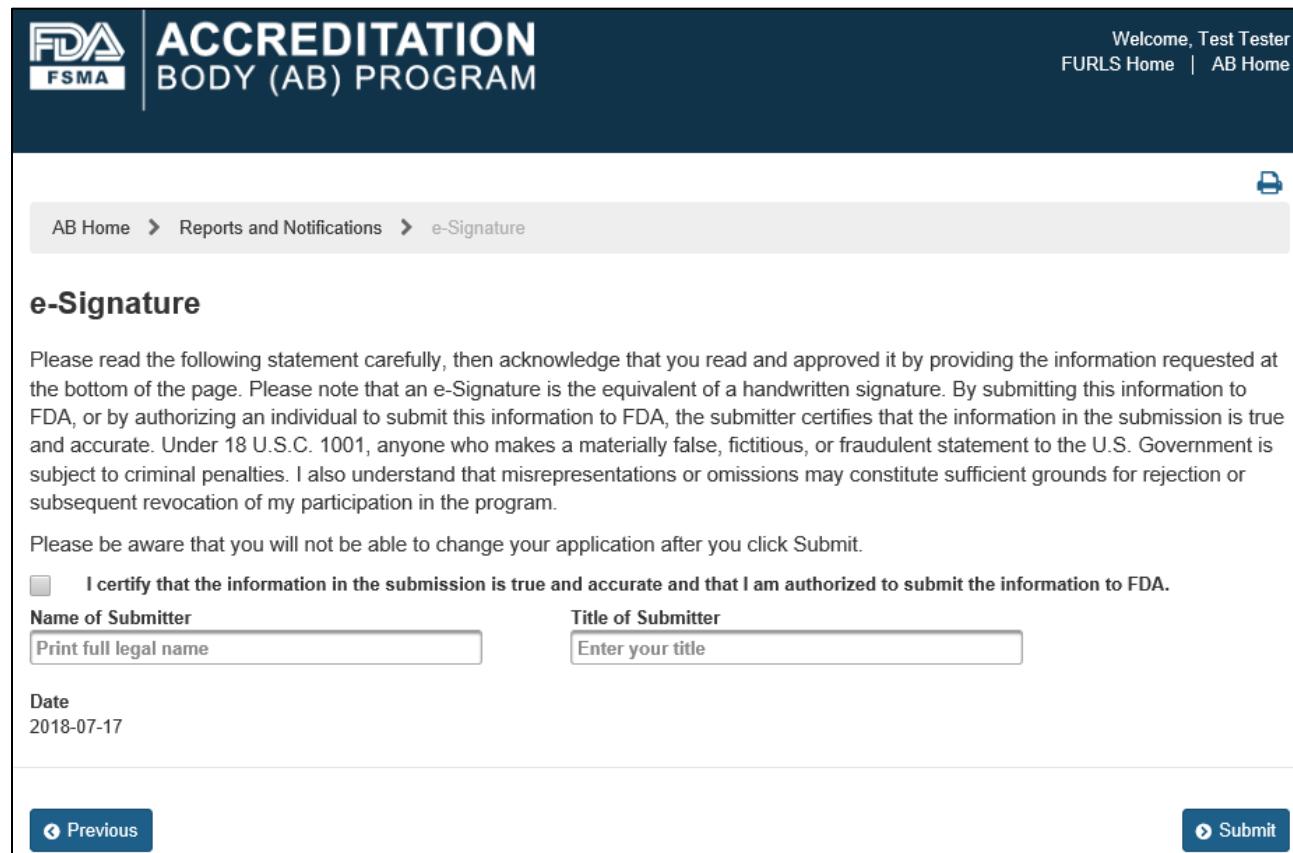
Complete the following data fields:

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

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

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

Figure 11.67 – e-Signature Page



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.

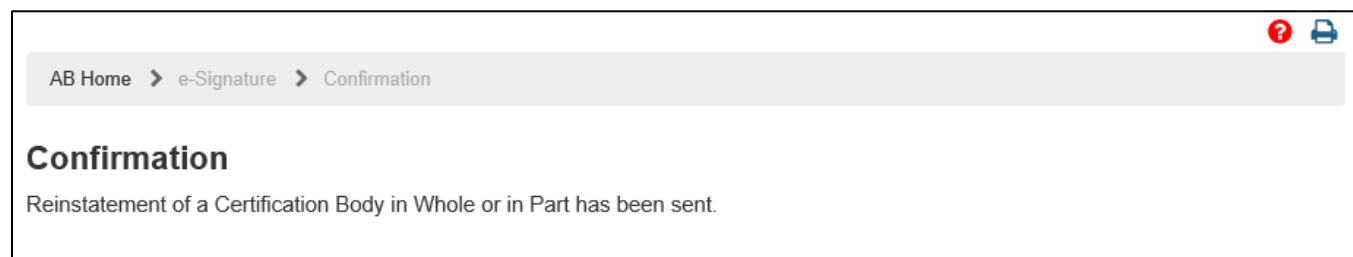
Name of Submitter Print full legal name	Title of Submitter Enter your title
---	---

Date
2018-07-17

Previous **Submit**

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

Figure 11.68 – Confirmation Page



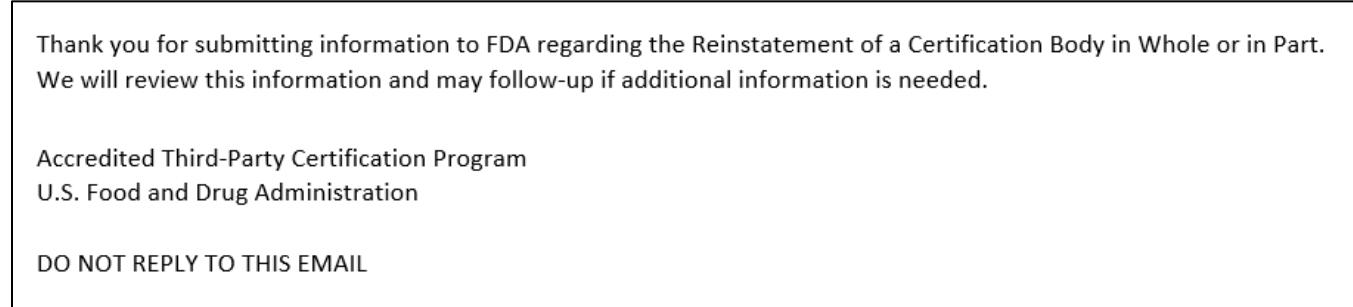
AB Home > e-Signature > Confirmation

Confirmation

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

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

Figure 11.69 – E-mail Notification



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

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

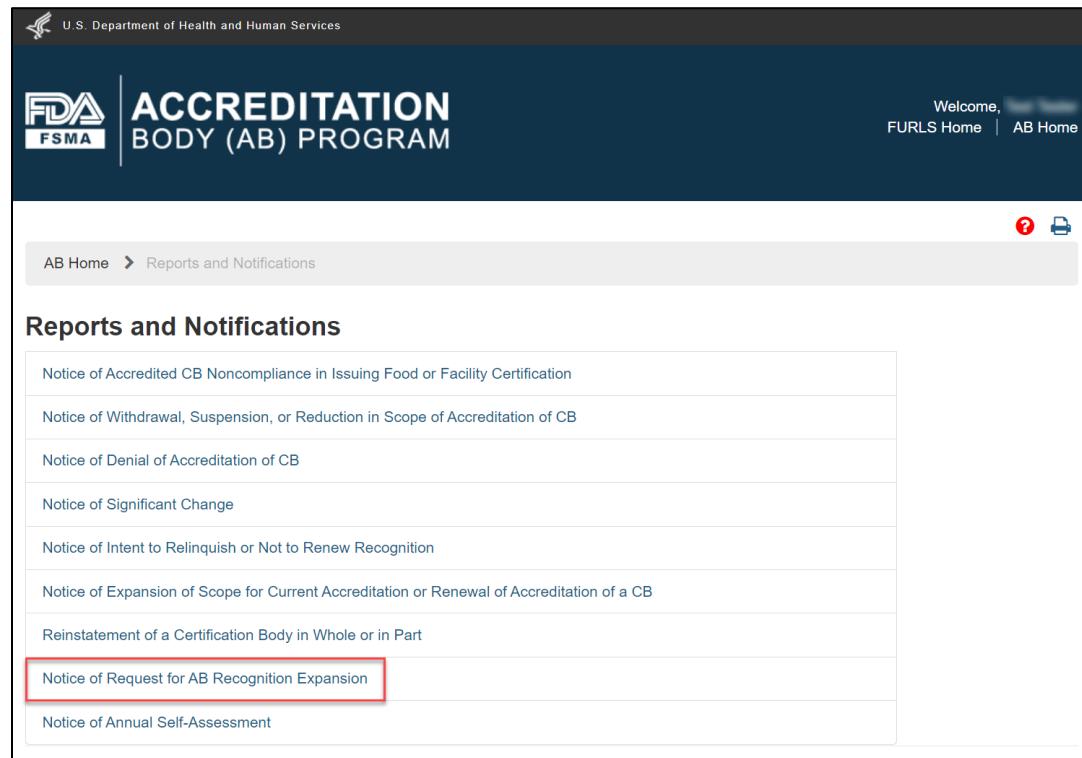
DO NOT REPLY TO THIS EMAIL

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

11.8 Notice of Request for AB Recognition Expansion

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

Figure 11.70 – Reports and Notifications Page



U.S. Department of Health and Human Services

ACREDITATION BODY (AB) PROGRAM

Welcome, [Your Name](#)
FURLS Home | AB Home

AB Home > Reports and Notifications

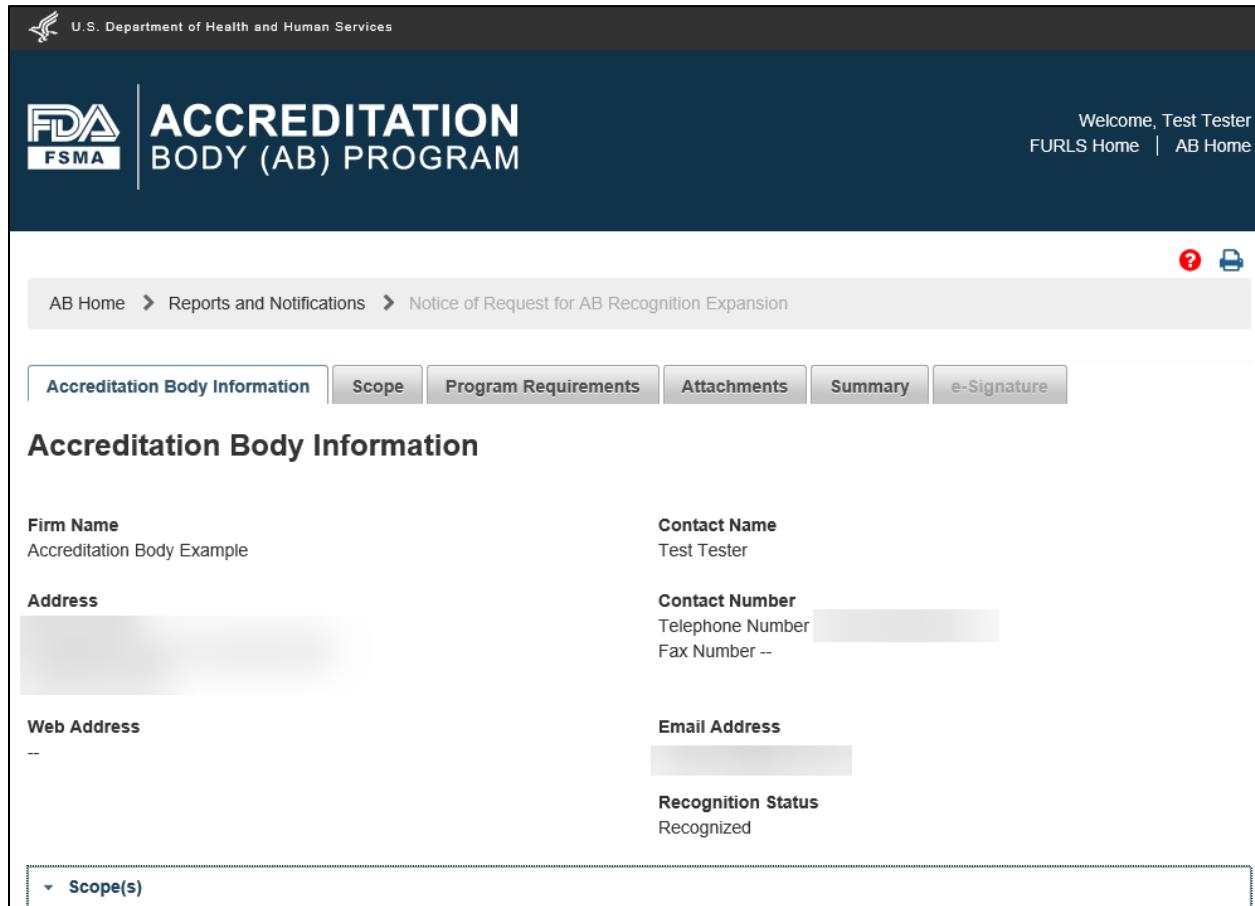
Reports and Notifications

- [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 for Current Accreditation or Renewal of Accreditation of a CB](#)
- [Reinstatement of a Certification Body in Whole or in Part](#)
- [Notice of Request for AB Recognition Expansion](#)
- [Notice of Annual Self-Assessment](#)

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

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

Figure 11.71 – Notice of Request for AB Recognition Expansion



The screenshot shows the 'Accreditation BODY (AB) PROGRAM' section of the FDA website. The 'Accreditation Body Information' tab is active. The page displays the following data:

- Firm Name:** Accreditation Body Example
- Contact Name:** Test Tester
- Address:** (Redacted)
- Contact Number:** Telephone Number (Redacted), Fax Number --
- Web Address:** --
- Email Address:** (Redacted)
- Recognition Status:** Recognized

A 'Scope(s)' button is located at the bottom left of the main content area.

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

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

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

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

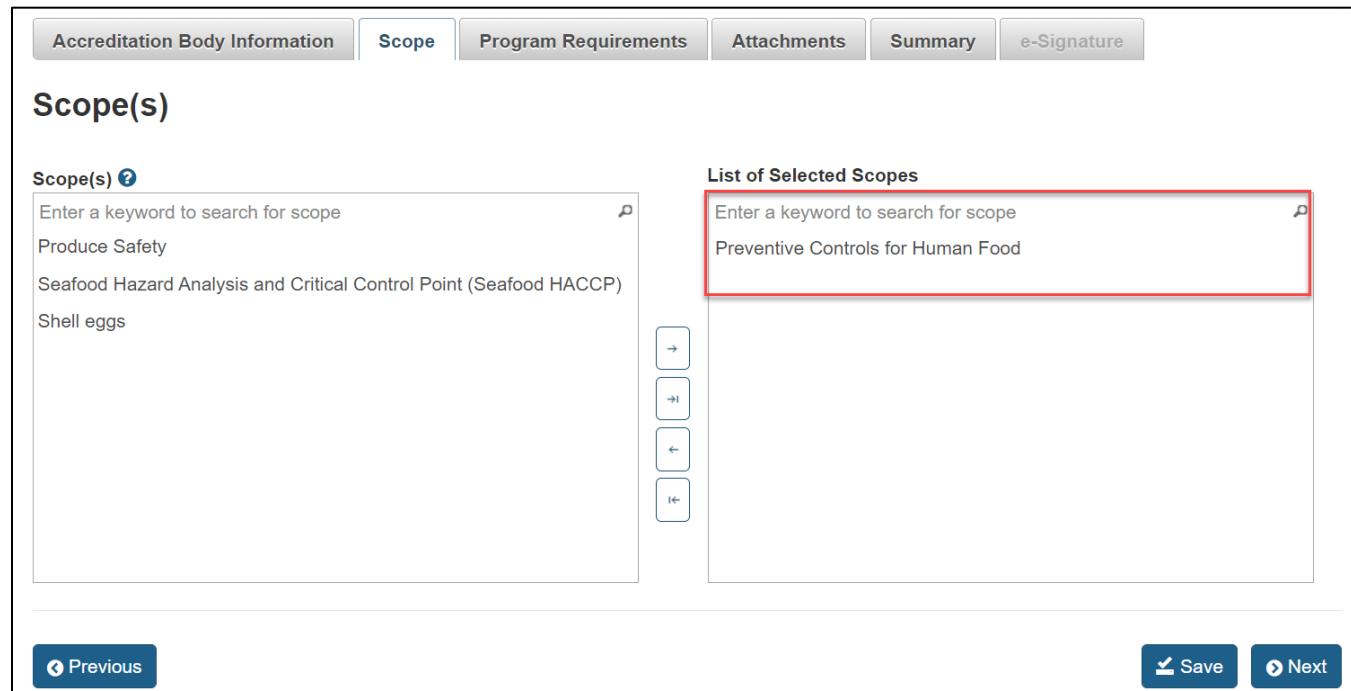
The “Scope” section (on the left-hand side of the page) contains a list of available scopes (i.e., scopes that are not currently part of your recognition).

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

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

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

Figure 11.72 – Scope Page



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

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

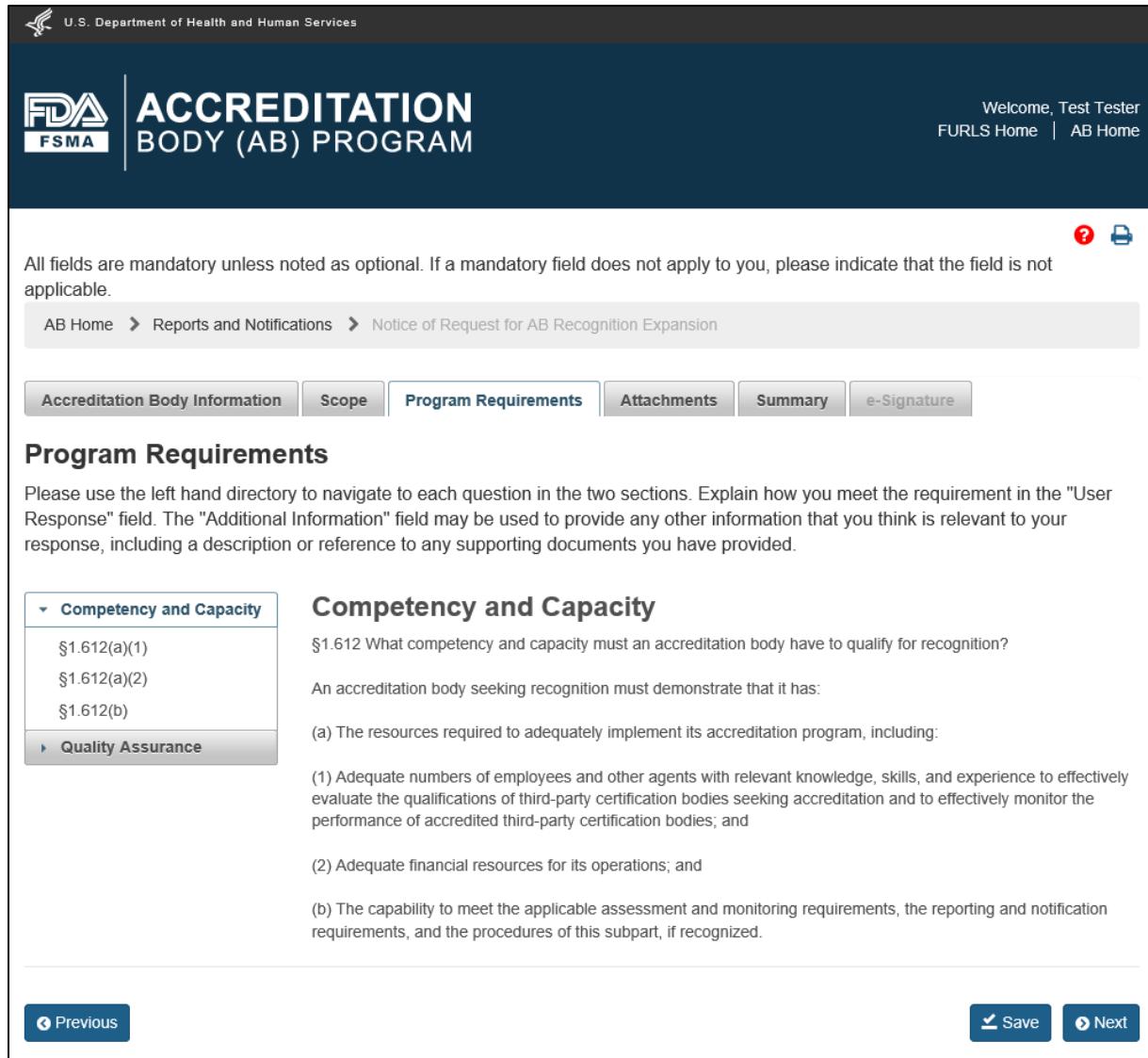
The system will display the “Program Requirements” page, where you will answer questions and attach files in accordance with the following requirement sections (Figure 11.73):

- Competency and Capacity
- Quality Assurance

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

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

Figure 11.73 – Program Requirements Page



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

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

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

Figure 11.74 – Program Requirements User Input Fields

Accreditation Body Information
Scope
Program Requirements
Attachments
Summary
e-Signature

Program Requirements

Please use the left hand directory to navigate to each question in the two sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

▼ Competency and Capacity
▼ Competency and Capacity >> §1.612(a)(1)

§1.612(a)(1)
Regulation Text

§1.612(a)(2)
§1.612(b)

► Quality Assurance
Criteria to Demonstrate

Please provide documentation to demonstrate you have an adequate number of employees and other agents.

Please provide documentation to demonstrate the training and experience possessed by your employees and other agents.

User Response (provide your answer below)

Enter your response here.

4000 characters remaining.

Additional Information (URL, References, etc.) (Optional)

Enter your response here.

4000 characters remaining.

▼ Attachments (Optional)
Attachments

File Name	Date of Upload
No records found.	

◀ Previous
Save
Next

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

Page | 166

Attachments must be a document type supported by the system.

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

The maximum file size allowed is 50 MB.

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

Figure 11.75 – Attachments Section

File Name	Date of Upload
No records found.	

Attachments

Save Next

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

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

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

Click the “Upload” button to complete the upload.

Figure 11.76 – Attachments Window

Program Requirements

Please use the left hand directory to navigate to each question in the six sections. Explain how you meet the requirement in the "User Response" field. The "Additional Information" field may be used to provide any other information that you think is relevant to your response, including a description or reference to any supporting documents you have provided.

Attachments

Add Attachments

Instructions

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

Note:

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

+ Browse **Upload** **Cancel**

Manage Attachments

File Name	Date of Upload	Action
No records found.		

Close

4000 characters remaining.

Attachments (Optional)

Attachments

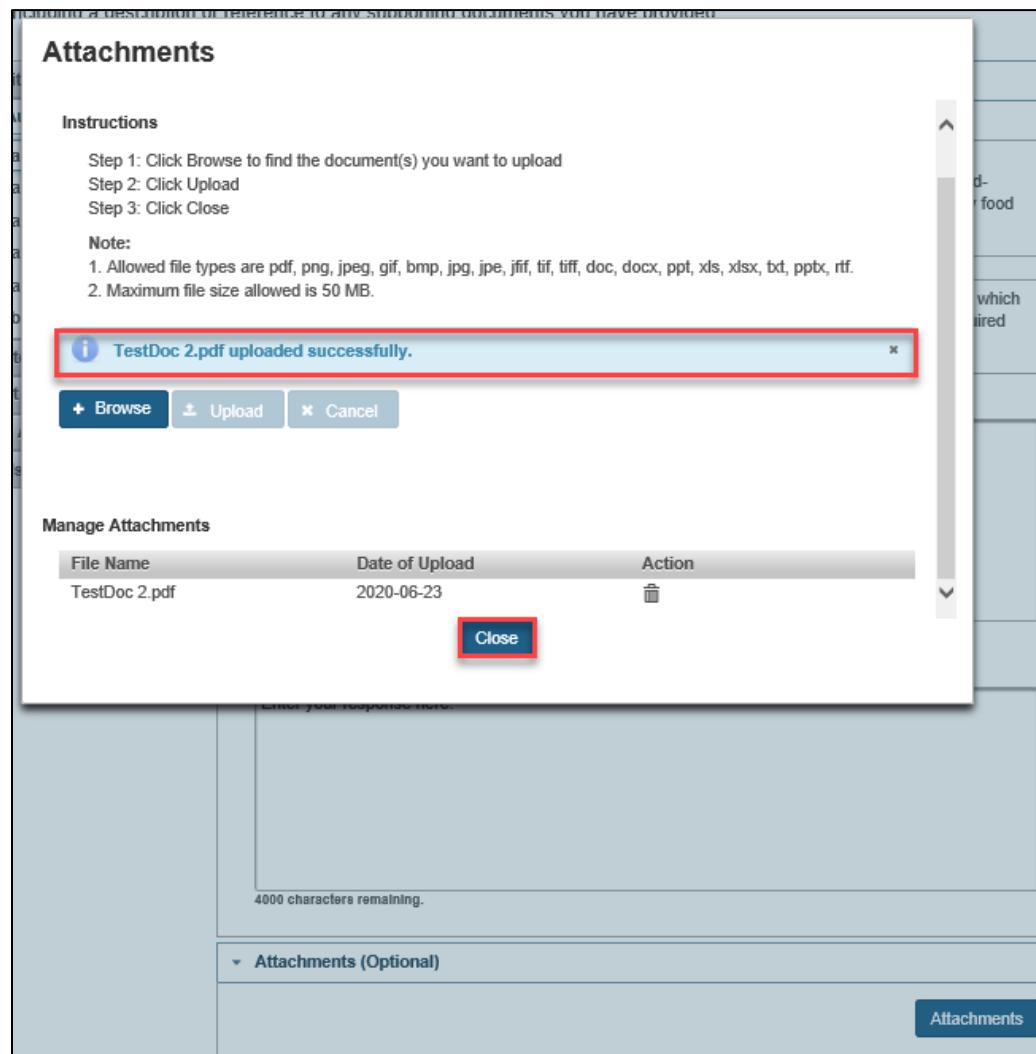
File Name	Date of Upload
No records found.	

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

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

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

Figure 11.77 – Attachments to Program Requirements Questions



The screenshot shows a modal window titled "Attachments" with the following content:

- Instructions**
 - Step 1: Click Browse to find the document(s) you want to upload
 - Step 2: Click Upload
 - Step 3: Click Close
- Note:**
 - 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfff, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
 - 2. Maximum file size allowed is 50 MB.
- Message:** **TestDoc 2.pdf uploaded successfully.** (This message is highlighted with a red box.)
- Buttons:** + Browse, Upload, Cancel

Below the modal, the main page shows a "Manage Attachments" table:

File Name	Date of Upload	Action
TestDoc 2.pdf	2020-06-23	

At the bottom of the page, there is a text area with a character limit of 4000 characters and a "Attachments (Optional)" section with a "Attachments" button.

****Important:** Click the “Save” button upon completion.

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

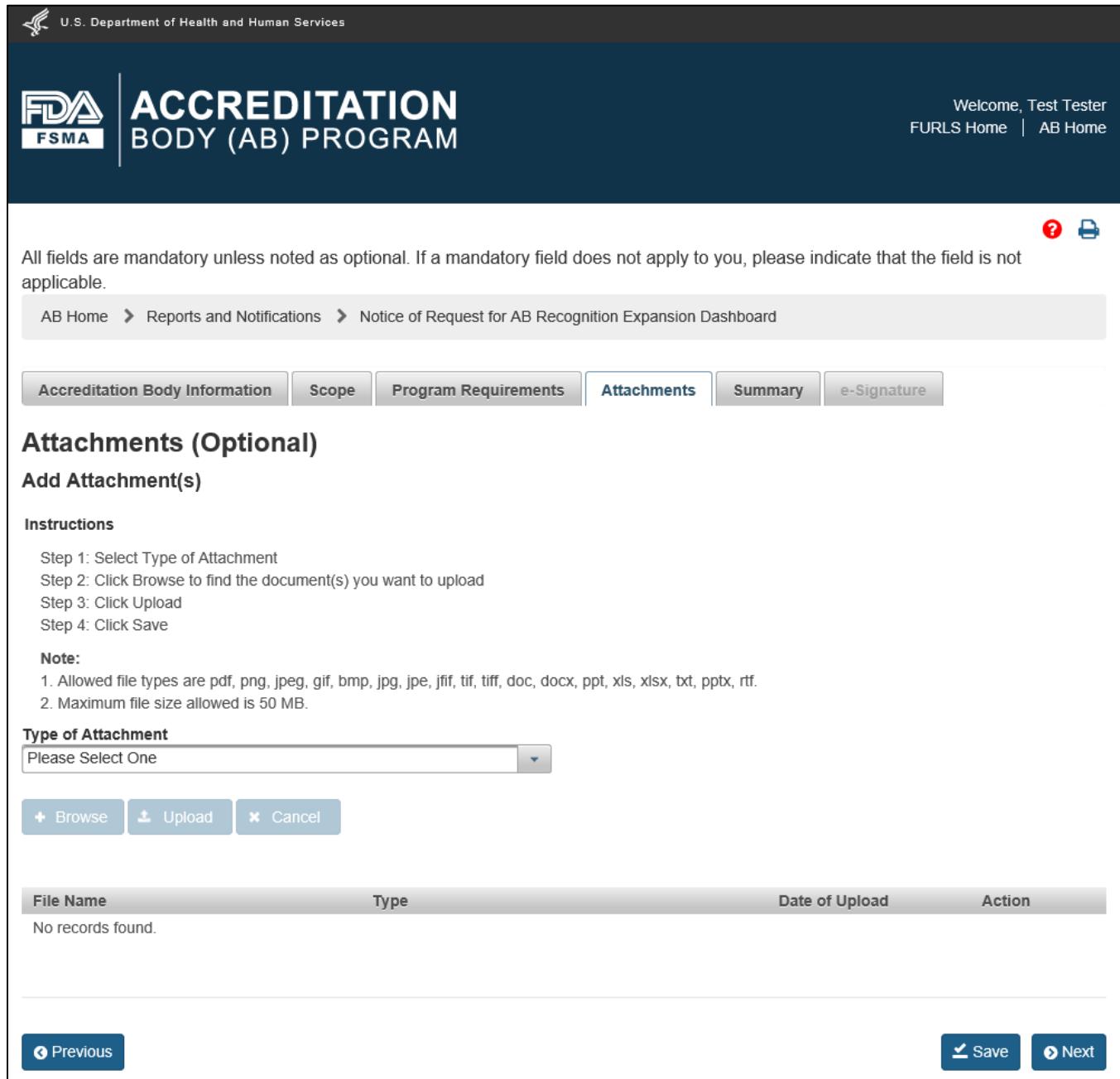
The system will display the “Attachments” page (Figure 11.78).

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

This page is optional.

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

Figure 11.78 – Attachments Page



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 > Reports and Notifications > Notice of Request for AB Recognition Expansion Dashboard

Accreditation Body Information Scope Program Requirements **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

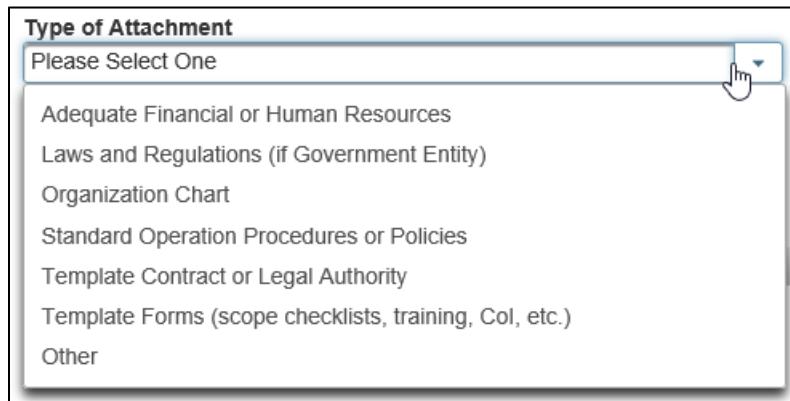
+ Browse - Upload × Cancel

File Name	Type	Date of Upload	Action
No records found.			

◀ Previous Save Next ▶

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

Figure 11.79 – Type of Attachment



Type of Attachment

Please Select One

- Adequate Financial or Human Resources
- Laws and Regulations (if Government Entity)
- Organization Chart
- Standard Operation Procedures or Policies
- Template Contract or Legal Authority
- Template Forms (scope checklists, training, Col, etc.)
- Other

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

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

Figure 11.80 – Other Attachments

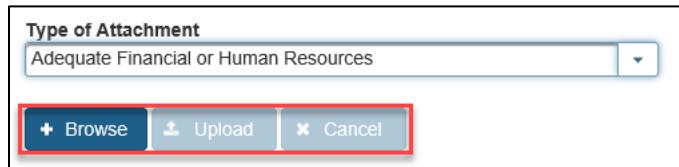


Type of Attachment	Additional Description
Other	Enter Description

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

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

Figure 11.81 – Browse, Upload, and Cancel Buttons

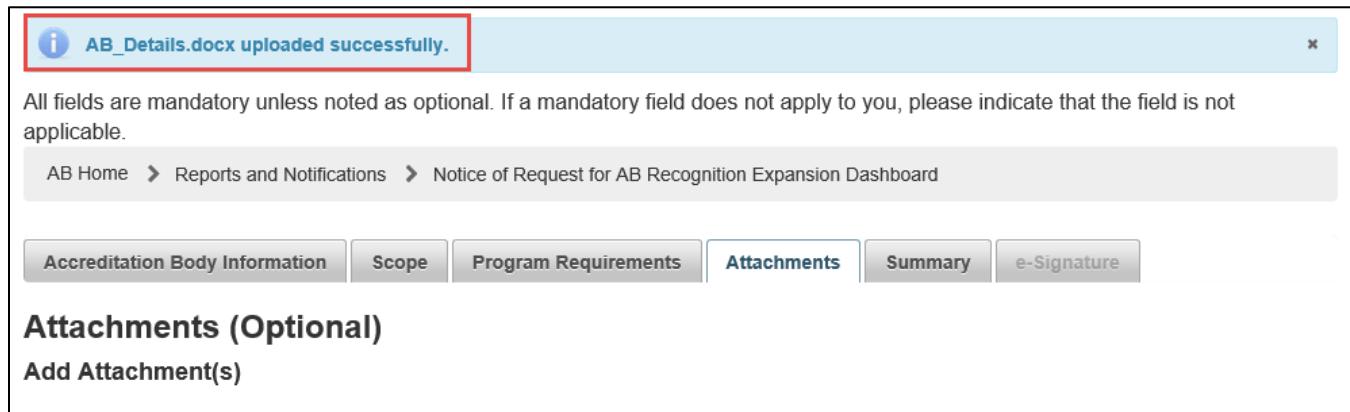


Type of Attachment		
Adequate Financial or Human Resources		
+ Browse	Upload	Cancel

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

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

Figure 11.82 – Successful Upload Message



The screenshot shows a web interface for a 'Notice of Request for AB Recognition Expansion Dashboard'. At the top, a message box displays 'AB_Details.docx uploaded successfully.' with an information icon. Below this, a navigation bar includes 'AB Home', 'Reports and Notifications', and 'Notice of Request for AB Recognition Expansion Dashboard'. A tab navigation bar at the bottom includes 'Accreditation Body Information', 'Scope', 'Program Requirements', 'Attachments' (which is highlighted in blue), 'Summary', and 'e-Signature'. The main content area is titled 'Attachments (Optional)' and contains a link 'Add Attachment(s)'. A red box highlights the successful upload message.

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

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

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

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

Figure 11.83 – Summary Page

U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Request for AB Recognition Expansion

Accreditation Body Information | Scope | Program Requirements | Attachments | **Summary** | e-Signature

Summary

Review the following information for correctness and edit as needed.

Accreditation Body Information

Firm Name Accreditation Body Example	Contact Name Test Tester
Address [REDACTED]	Contact Number Phone Number [REDACTED] Fax Number --
Web Address --	Email Address [REDACTED]
Recognition Status Recognized	

Scope(s)

Selected Scopes
Preventive Controls for Animal Food

Edit

Program Requirements

Edit

- ▶ Competency and Capacity
- ▶ Quality Assurance

Attachments (Optional)

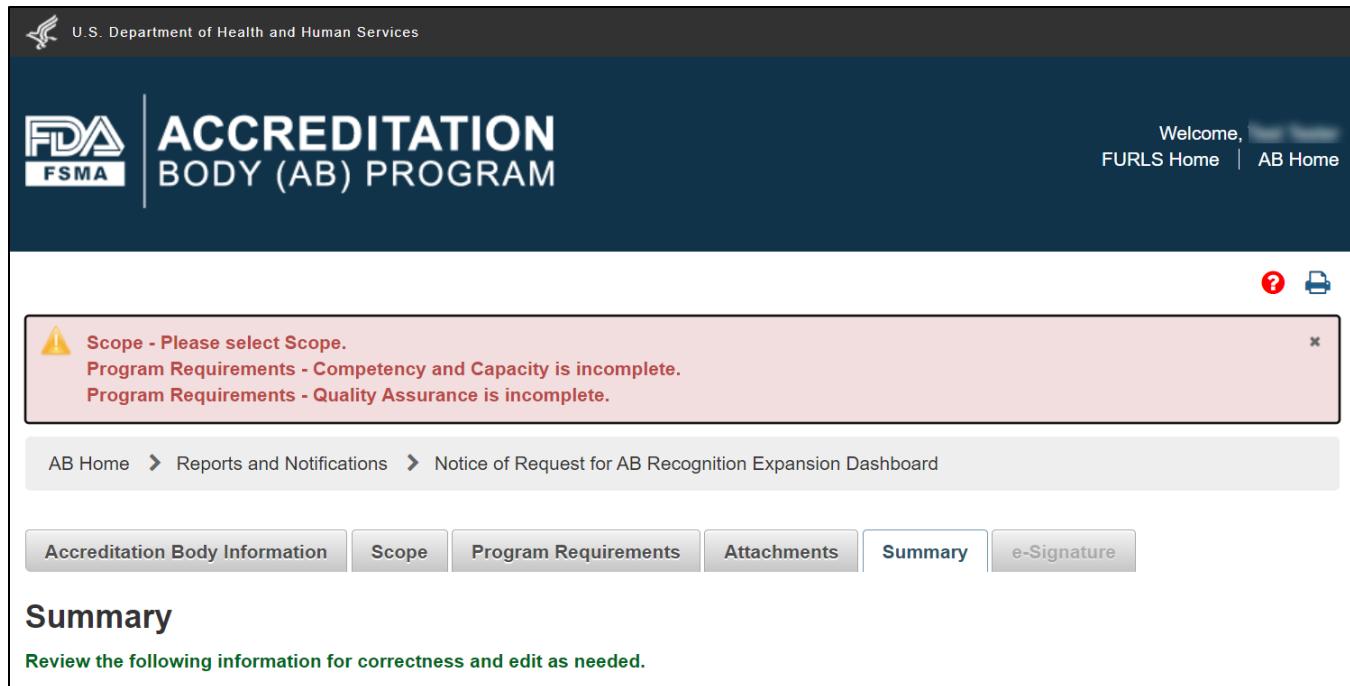
Edit

File Name	Type	Date of Upload
AttachmentSample1.docx	Adequate Financial or Human Resources	2021-05-21

Previous **Save** **Next**

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

Figure 11.84 – Summary Page Error Messages



The screenshot shows the FDA Accreditation Body (AB) Program Summary page. At the top, there is a navigation bar with the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and a welcome message for the user. Below the navigation bar, there is a red error message box containing the following text:

⚠ Scope - Please select Scope.
Program Requirements - Competency and Capacity is incomplete.
Program Requirements - Quality Assurance is incomplete.

Below the error message box, the page displays the breadcrumb navigation: AB Home > Reports and Notifications > Notice of Request for AB Recognition Expansion Dashboard. There is a row of tabs: Accreditation Body Information, Scope, Program Requirements, Attachments, Summary (which is highlighted in blue), and e-Signature. The main content area is titled "Summary" and contains the instruction: "Review the following information for correctness and edit as needed."

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

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

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

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

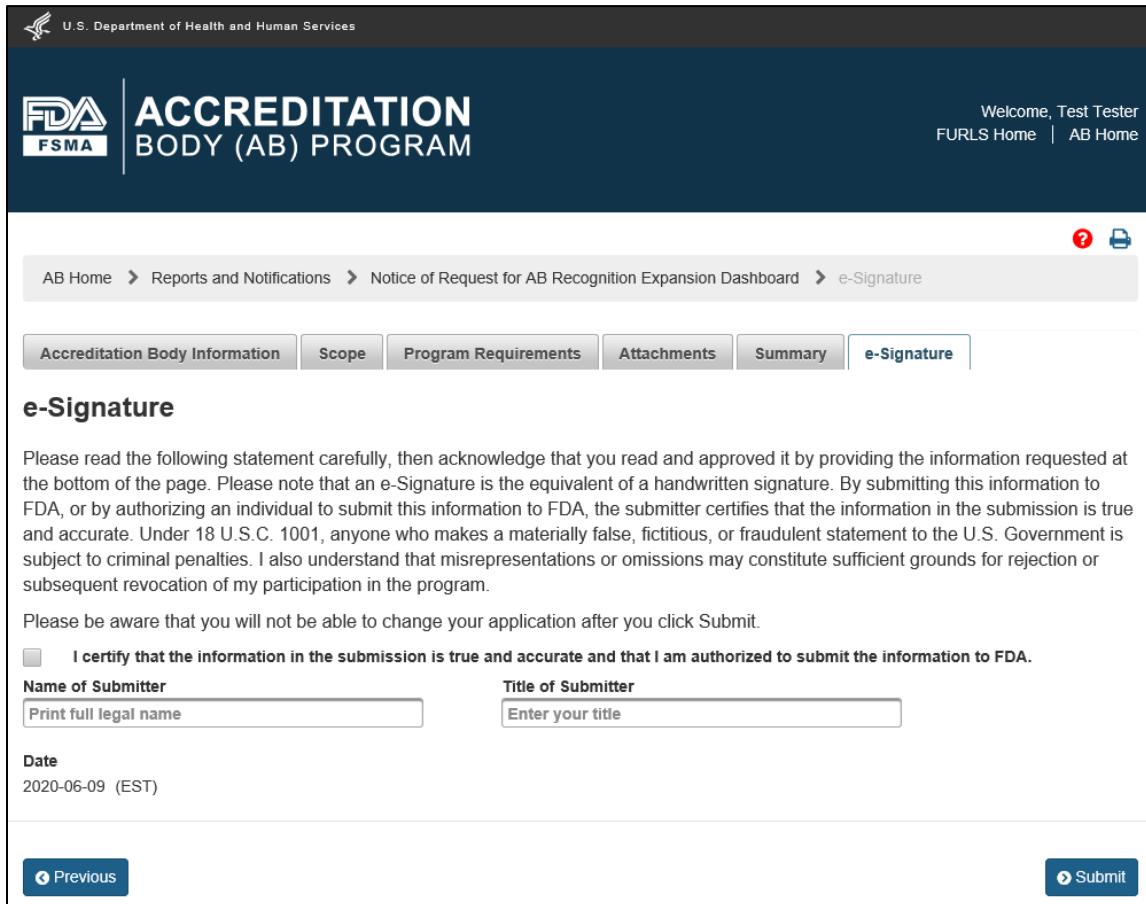
Complete the following data fields:

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

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

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

Figure 11.85 – e-Signature Page



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 Request for AB Recognition Expansion Dashboard > e-Signature

Accreditation Body Information Scope Program Requirements 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
Print full legal name

Title of Submitter
Enter your title

Date
2020-06-09 (EST)

Previous Submit

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

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

Figure 11.86 – Confirmation Page

here to view the status your request.' There are also a question mark icon and a print icon in the top right corner." data-bbox="85 153 912 401"/>

U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome, Test Tester
FURLS Home | AB Home

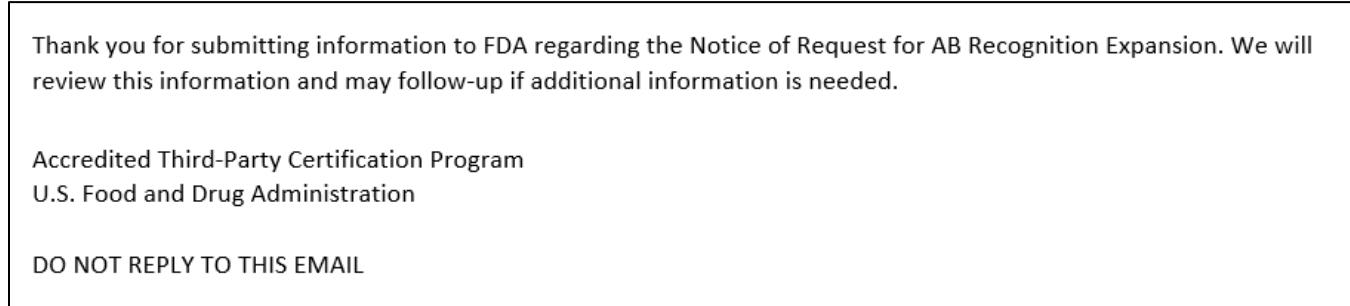
AB Home > Reports and Notifications > Notice of Request for AB Recognition Expansion Dashboard

Confirmation

Thank you for submitting your Notice of Request for AB Recognition Expansion. Click [here](#) to view the status your request.

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

Figure 11.87 – E-mail Notification



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

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

DO NOT REPLY TO THIS EMAIL

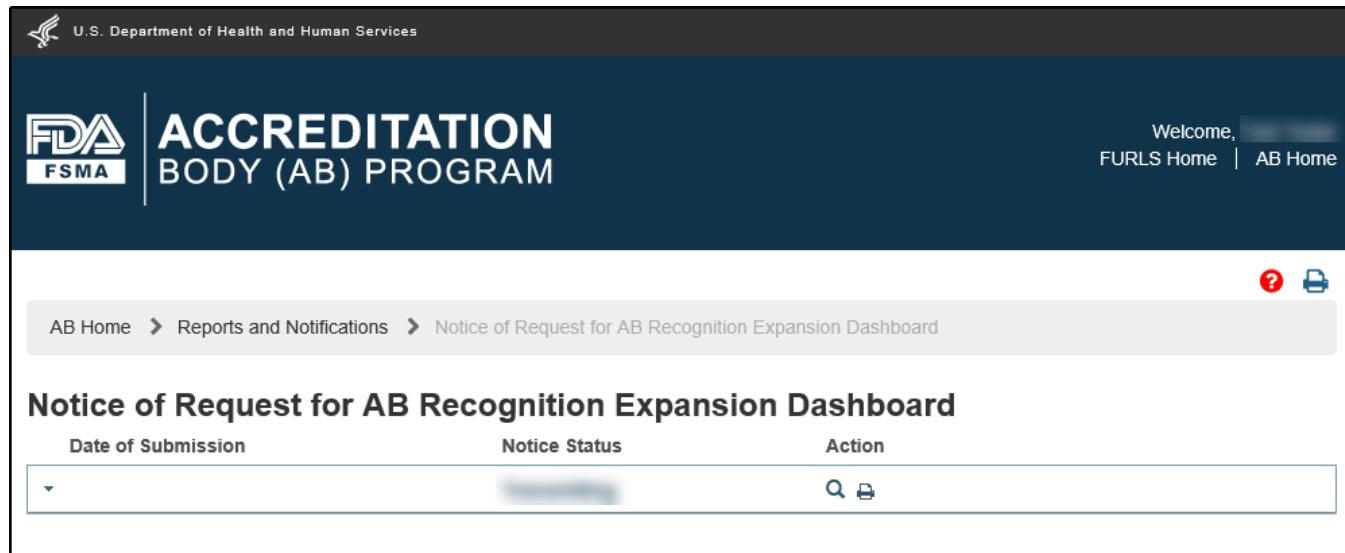
11.8.1 Notice Dashboard

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

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

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

Figure 11.88 – Notice of Request for AB Recognition Expansion Dashboard



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

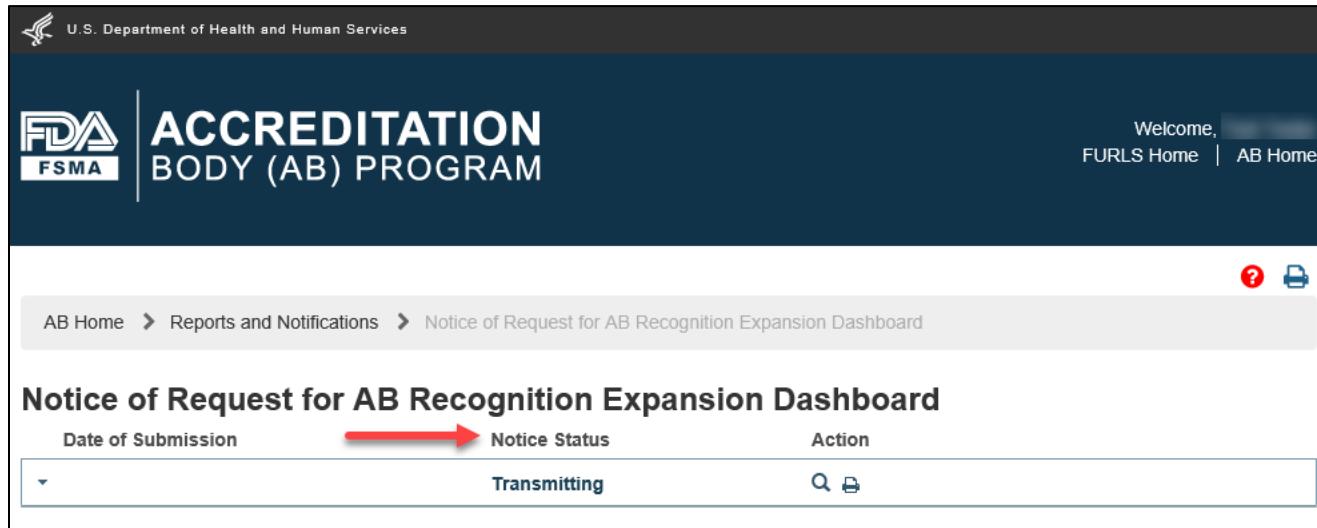
If you wish to delete or edit a draft of the previously saved notice, refer to Section 11.8.3 of this chapter.

11.8.2 View the Status of the Notice

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

- **Draft** – The notice has been saved but not yet submitted to FDA.
- **Pending** – The notice has been submitted to FDA and is undergoing a scan of attachment(s) included with the submission. Once the attachment(s) passes the scan, it will update to “Transmitting.”
- **Transmitting** – The notice has been submitted and is in the process of being downloaded by FDA. This status may only appear briefly before it is updated to the next status. Once it has been downloaded by FDA, the status will update to “Submitted.”
- **Submitted** – The notice has been successfully received by FDA.
- **Denied** – FDA has completed the review of the notice request and denied the request for additional scope(s) to be added to your recognition. You may submit a new notice if you wish FDA to reconsider the decision.
- **Approved** – FDA has completed the review of the notice request and approved the request for additional scope(s) to be added to your recognition.

Figure 11.89 – Notice Status



U.S. Department of Health and Human Services

ACCREDITATION BODY (AB) PROGRAM

Welcome, [REDACTED]
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Request for AB Recognition Expansion Dashboard

Notice of Request for AB Recognition Expansion Dashboard

Date of Submission	Notice Status	Action
▼	Transmitting	

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

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

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

Figure 11.90 – E-mail Notification

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

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

[REDACTED]

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

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

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

DO NOT REPLY TO THIS EMAIL

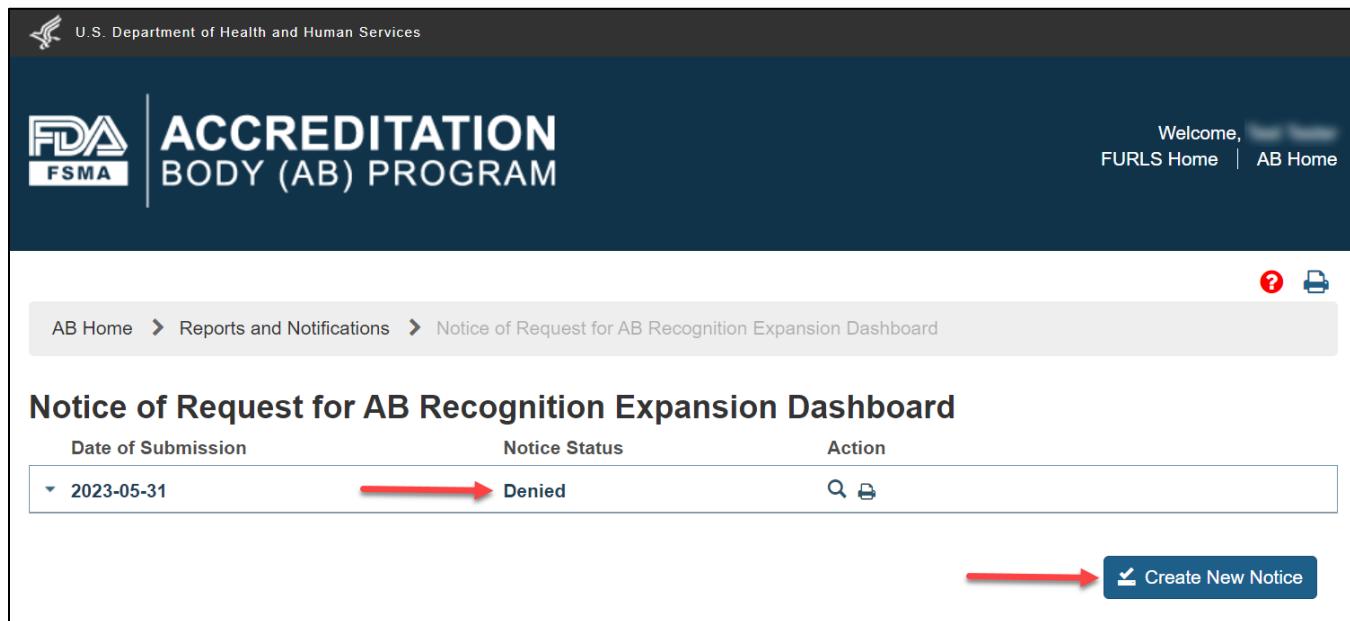
The “Notice Status” will display as “Approved” on the “Dashboard” page and the approved scope(s) will be listed.

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

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

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

Figure 11.91 – Denied Notice Status and Create New Notice Button

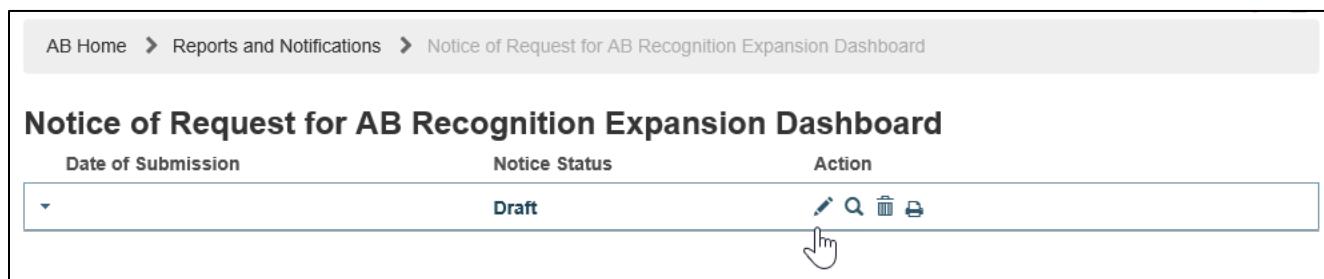


Date of Submission	Notice Status	Action
2023-05-31	Denied	

11.8.3 Delete or Edit the Notice in Draft Status

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

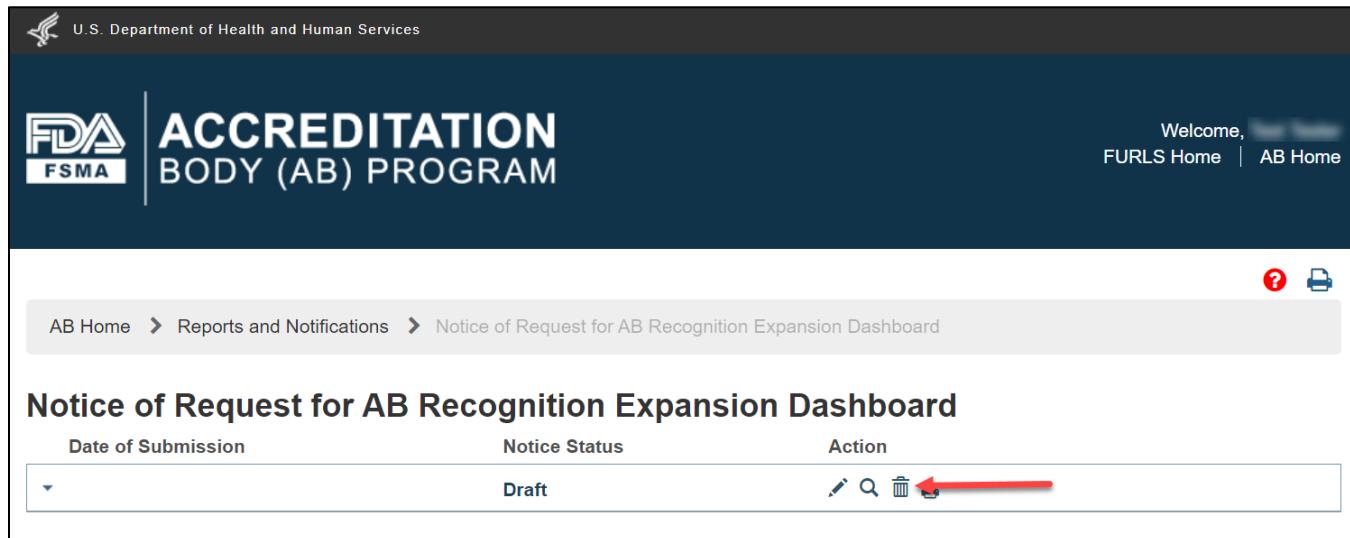
Figure 11.92 – Notice Dashboard



Date of Submission	Notice Status	Action
	Draft	

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

Figure 11.93 – Trash Icon

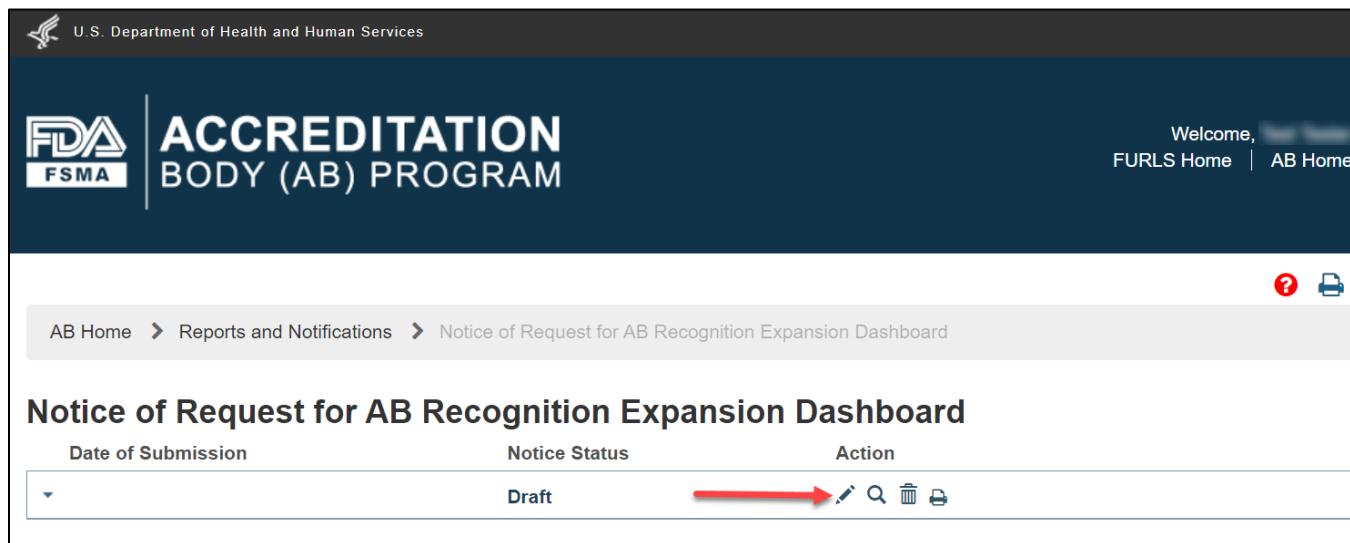


The screenshot shows the FDA Accreditation Body (AB) Program dashboard. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and links for Welcome, FURLS Home, and AB Home. The main title is "ACCREDITATION BODY (AB) PROGRAM". The breadcrumb navigation shows AB Home > Reports and Notifications > Notice of Request for AB Recognition Expansion Dashboard. The dashboard table has columns for Date of Submission, Notice Status (which shows "Draft"), and Action. The Action column for the single row contains icons for edit (pencil), search (magnifying glass), delete (trash can), and print (printer). A red arrow points to the delete icon.

Date of Submission	Notice Status	Action
▼	Draft	

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

Figure 11.94 – Edit Icon



The screenshot shows the FDA Accreditation Body (AB) Program dashboard, identical to Figure 11.93. The breadcrumb navigation shows AB Home > Reports and Notifications > Notice of Request for AB Recognition Expansion Dashboard. The dashboard table has columns for Date of Submission, Notice Status (which shows "Draft"), and Action. The Action column for the single row contains icons for edit (pencil), search (magnifying glass), delete (trash can), and print (printer). A red arrow points to the edit icon.

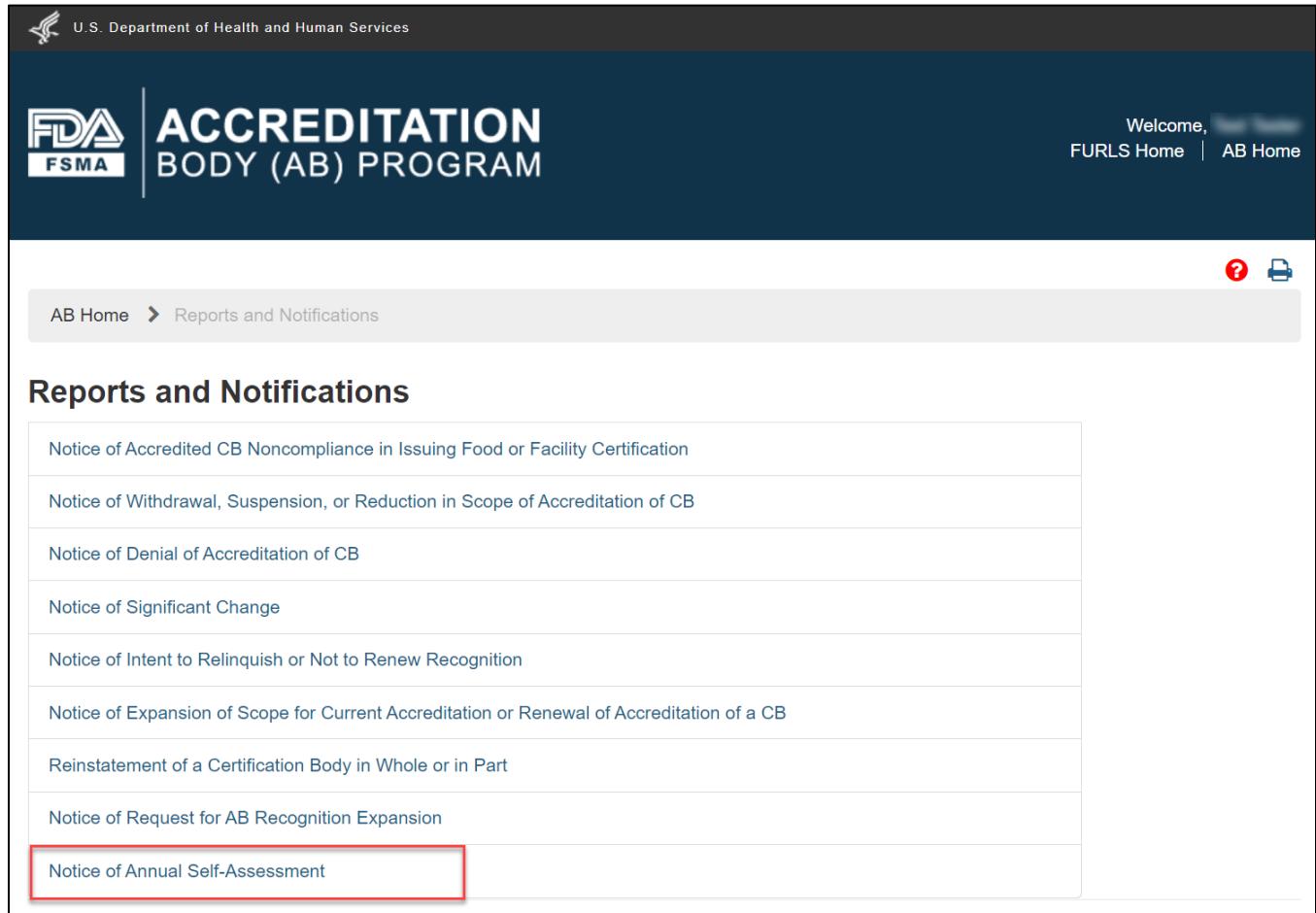
Date of Submission	Notice Status	Action
▼	Draft	

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

11.9 Notice of Annual Self-Assessment

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

Figure 11.95 – Reports and Notifications Page

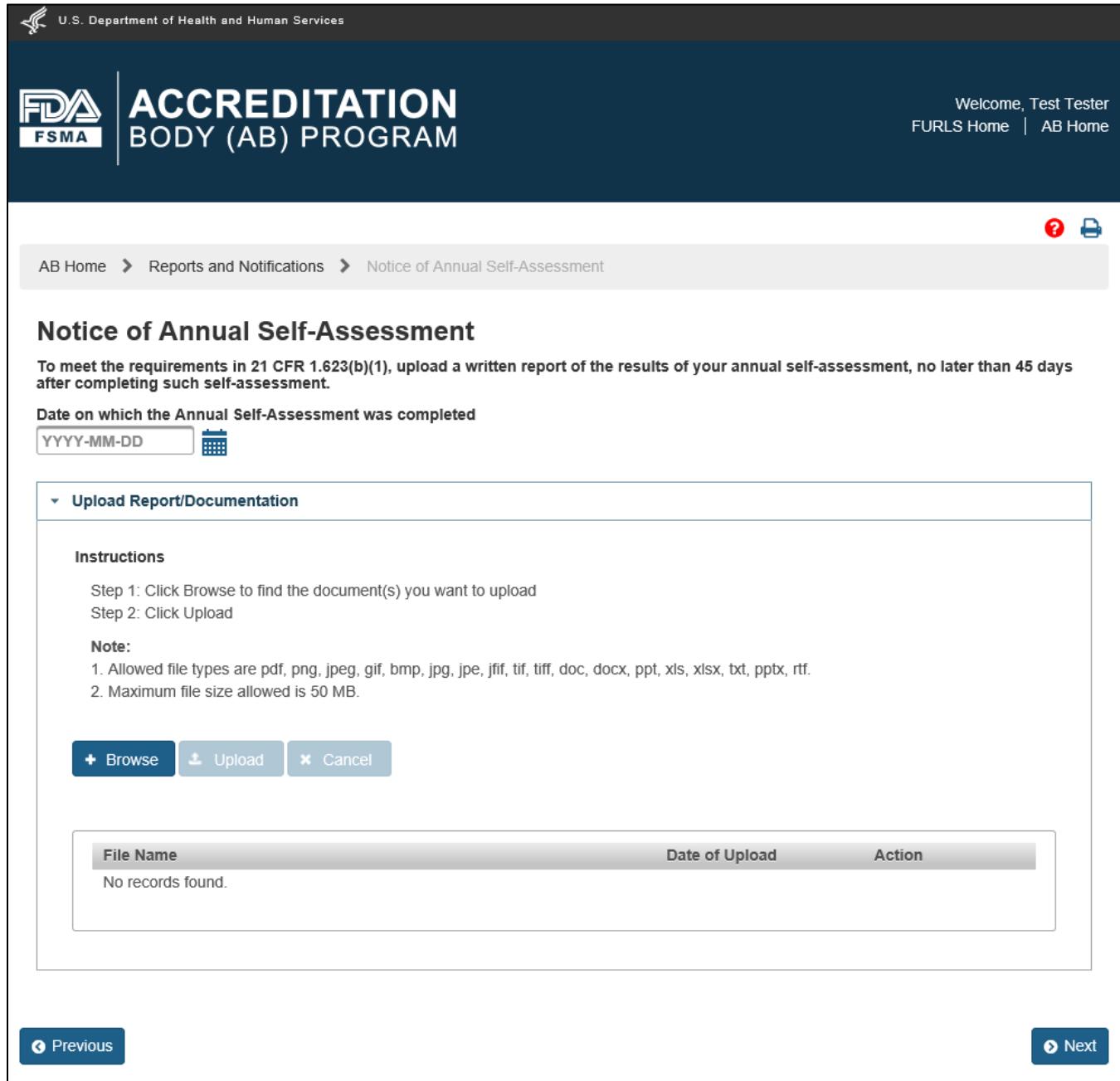


The screenshot shows the FDA Accreditation Body (AB) Program's Reports and Notifications page. The top navigation bar includes the U.S. Department of Health and Human Services logo, the FDA FSMA Accreditation Body (AB) Program logo, and links for Welcome, FURLS Home, and AB Home. The main navigation bar shows the current location: AB Home > Reports and Notifications. The 'Reports and Notifications' section lists several document types, with 'Notice of Annual Self-Assessment' highlighted by a red box.

- 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 for Current Accreditation or Renewal of Accreditation of a CB
- Reinstatement of a Certification Body in Whole or in Part
- Notice of Request for AB Recognition Expansion
- Notice of Annual Self-Assessment**

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

Figure 11.96 – Notice of Annual Self-Assessment



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 Annual Self-Assessment

Notice of Annual Self-Assessment

To meet the requirements in 21 CFR 1.623(b)(1), upload a written report of the results of your annual self-assessment, no later than 45 days after completing such self-assessment.

Date on which the Annual Self-Assessment was completed
YYYY-MM-DD

Upload Report/Documentation

Instructions

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

Note:

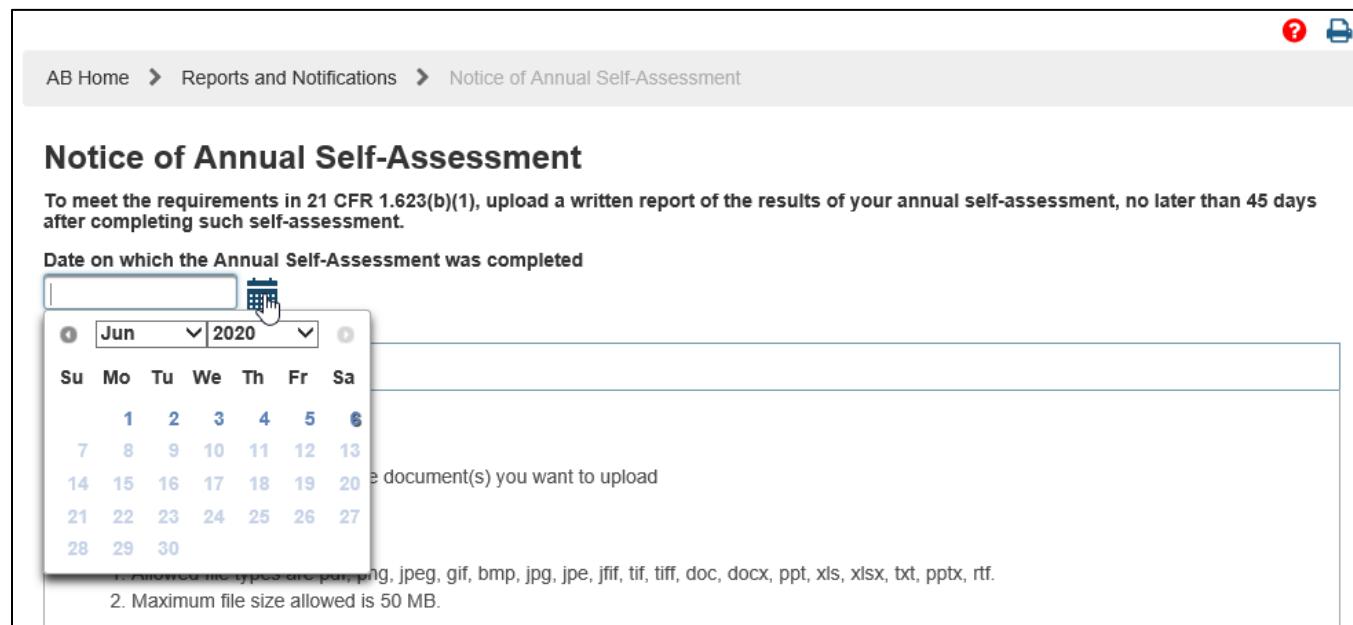
1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.
2. Maximum file size allowed is 50 MB.

File Name	Date of Upload	Action
No records found.		

Complete the following data field:

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

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



AB Home > Reports and Notifications > Notice of Annual Self-Assessment

Notice of Annual Self-Assessment

To meet the requirements in 21 CFR 1.623(b)(1), upload a written report of the results of your annual self-assessment, no later than 45 days after completing such self-assessment.

Date on which the Annual Self-Assessment was completed

Jun 06 2020

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				

Attachment(s) you want to upload

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.

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

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

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

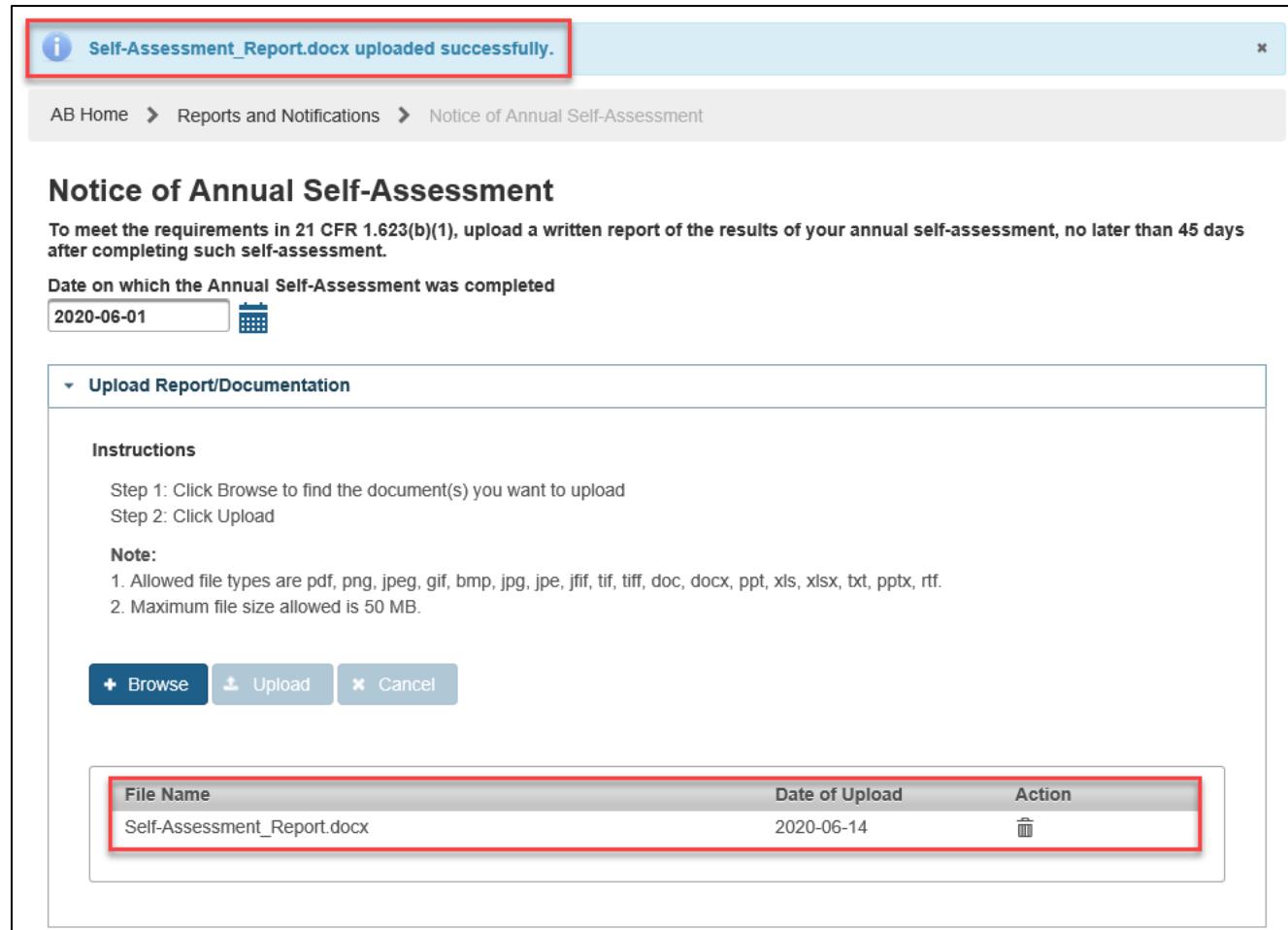
The browsing window will close once a file is selected. The “Upload” and “Cancel” buttons will be enabled once the browsing window closes.

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

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

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

Figure 11.98 – Upload Report/Documentation Section



Self-Assessment_Report.docx uploaded successfully.

AB Home > Reports and Notifications > Notice of Annual Self-Assessment

Notice of Annual Self-Assessment

To meet the requirements in 21 CFR 1.623(b)(1), upload a written report of the results of your annual self-assessment, no later than 45 days after completing such self-assessment.

Date on which the Annual Self-Assessment was completed
2020-06-01 

Upload Report/Documentation

Instructions

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

Note:

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

File Name	Date of Upload	Action
Self-Assessment_Report.docx	2020-06-14	

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

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

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

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

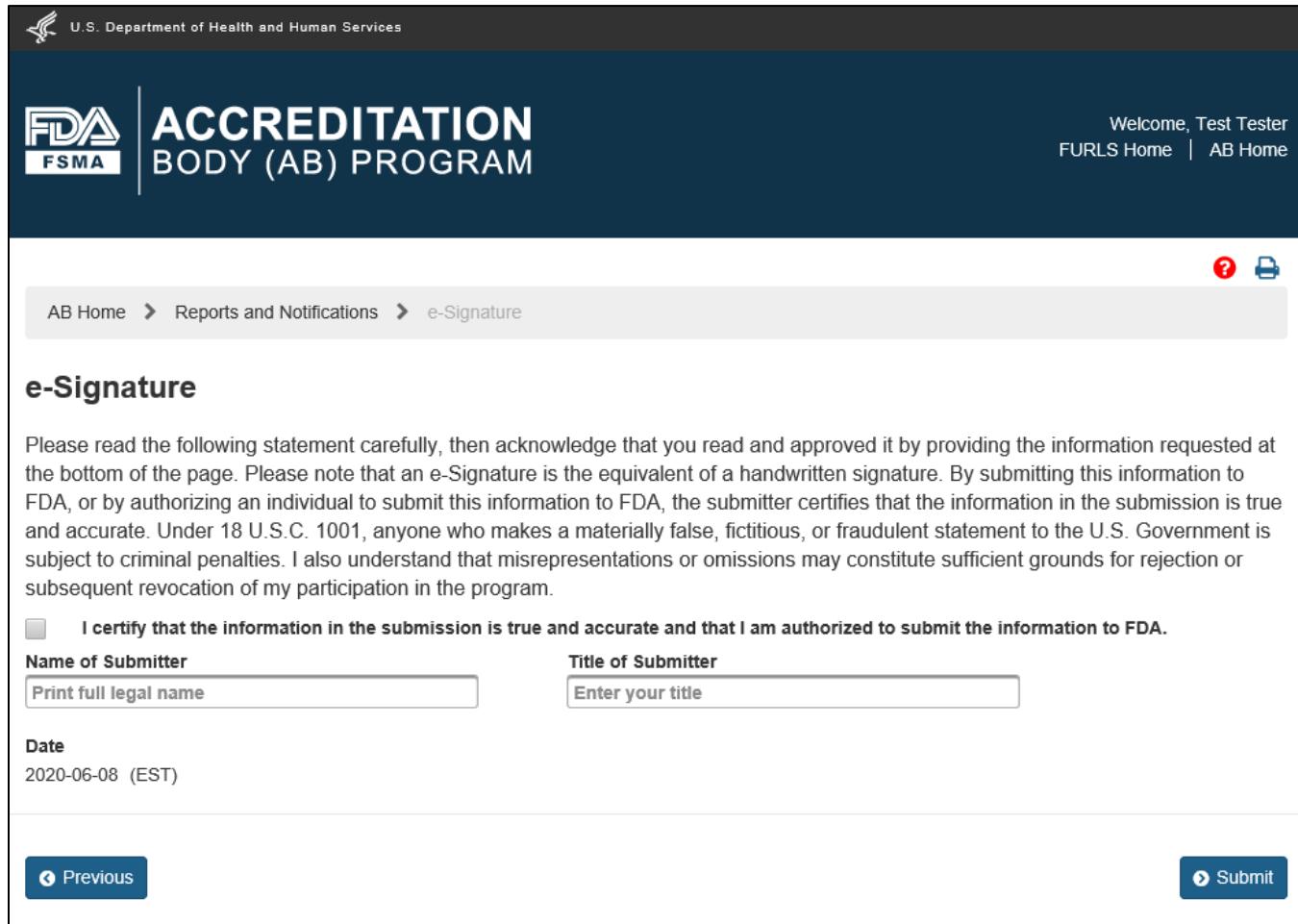
Complete the following data fields:

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

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

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

Figure 11.99 – e-Signature Page



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 > e-Signature

e-Signature

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

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

Name of Submitter
Print full legal name

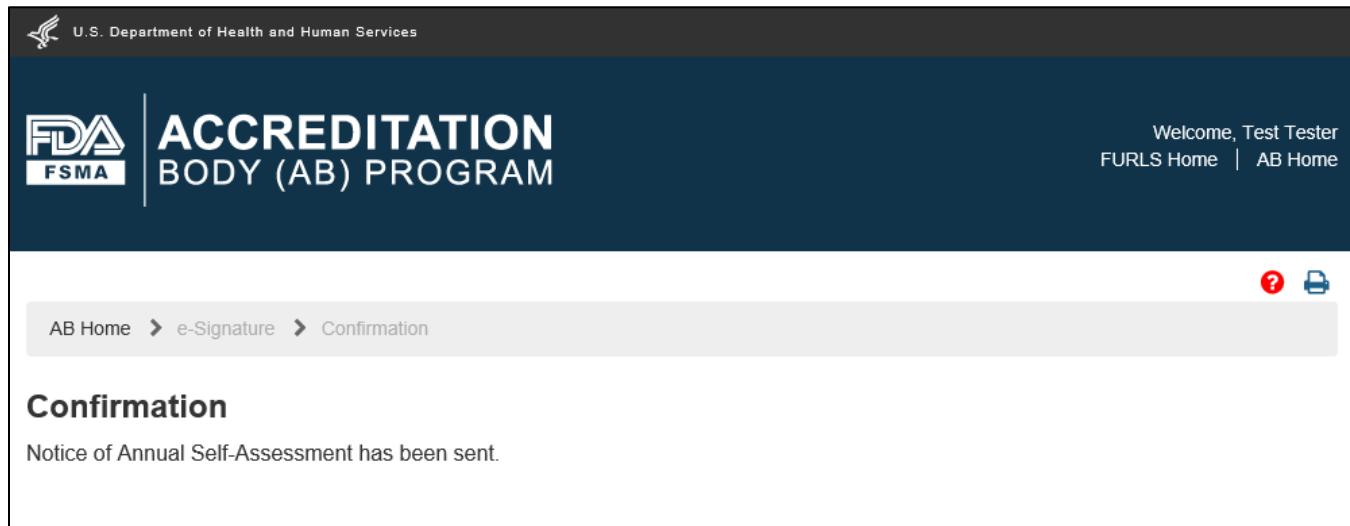
Title of Submitter
Enter your title

Date
2020-06-08 (EST)

Previous **Submit**

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

Figure 11.100 – Confirmation Page



U.S. Department of Health and Human Services

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

Welcome, Test Tester
FURLS Home | AB Home

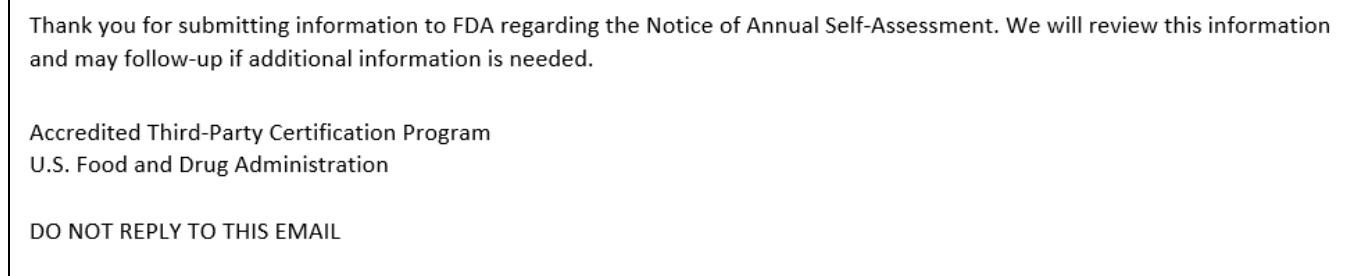
AB Home > e-Signature > Confirmation

Confirmation

Notice of Annual Self-Assessment has been sent.

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

Figure 11.101 – E-mail Notification



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

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

DO NOT REPLY TO THIS EMAIL

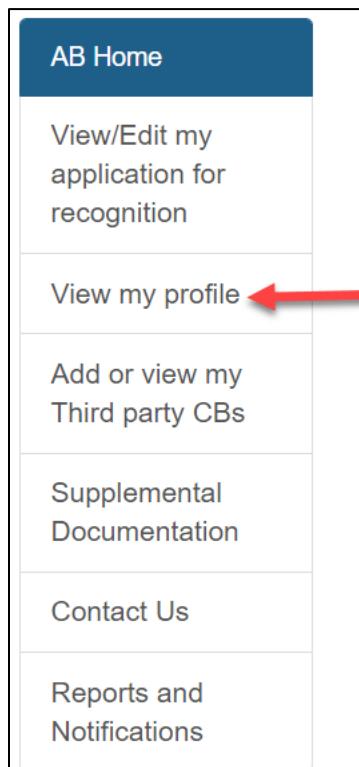
Click the “AB Home” link from the top of the banner (or from the breadcrumb) to return to the “Reports and Notifications” page.

12 View My Profile

The “View My Profile” feature may be used to view and edit the account information submitted during the OAA account creation.

To access the “View My Profile” feature, click the “View my profile” link from the navigation menu on the “AB Home” page (Figure 12.1).

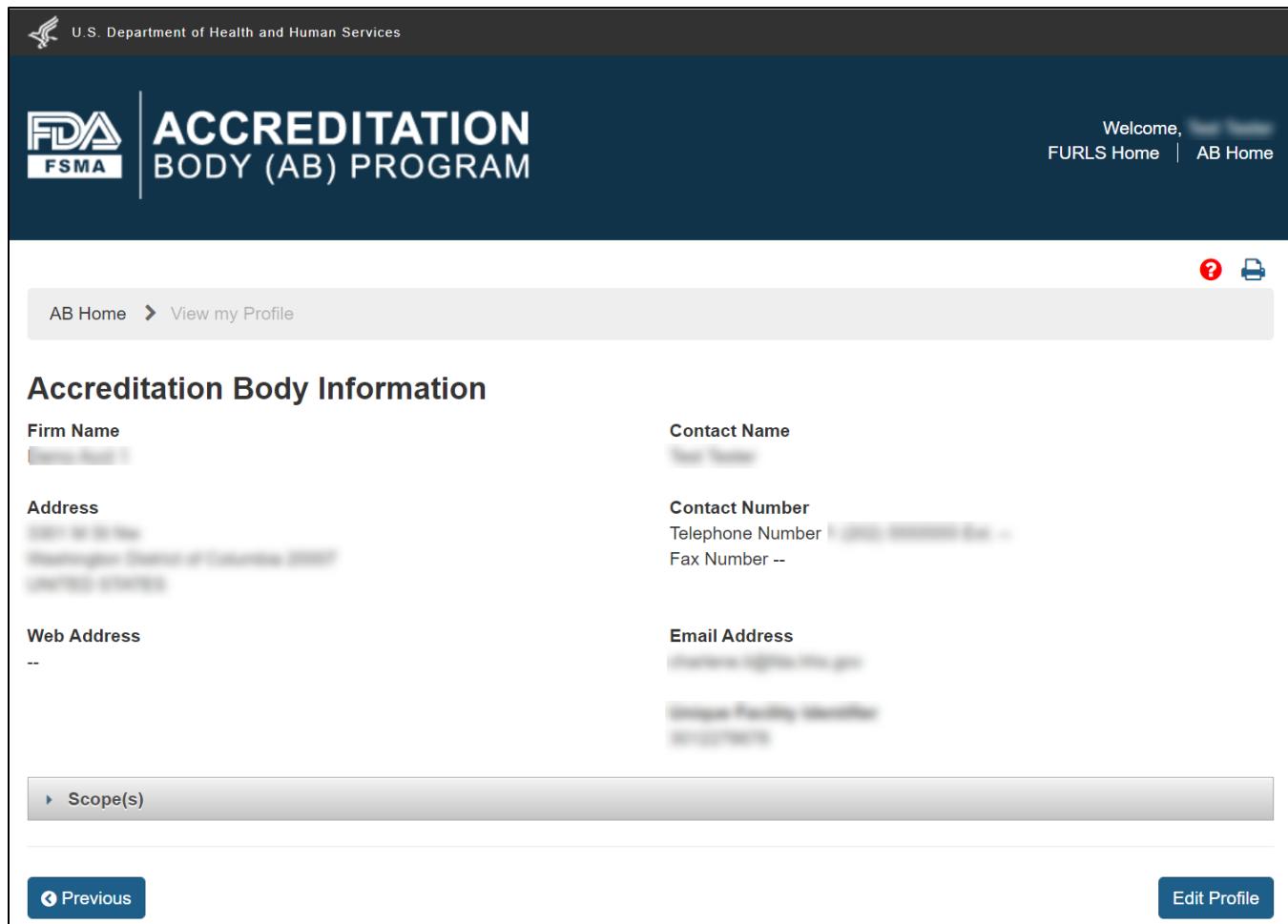
Figure 12.1 – Navigation Menu



The system will display the “Accreditation Body Information” page, which contains your read-only profile information from OAA (Figure 12.2).

The page also will display the “Scope(s)” accordion panel, which contains each scope in your recognition, as well as their status, accreditation, and expiration dates.

Figure 12.2 – Accreditation Body Information



U.S. Department of Health and Human Services

**ACcreditation
BODY (AB) PROGRAM**

Welcome, [View my Profile](#) | [FURLS Home](#) | [AB Home](#)

AB Home > View my Profile

Accreditation Body Information

Firm Name [REDACTED]	Contact Name [REDACTED]
Address [REDACTED]	Contact Number Telephone Number [REDACTED] Fax Number --
Web Address --	Email Address [REDACTED] Unique Facility Identifier [REDACTED]

▶ **Scope(s)**

Previous **Edit Profile**

Click the accordion section's title bar to view the scope details (Figure 12.3).

Figure 12.3 – Scope(s) Accordion Section



Scope(s)

To edit your account profile information in OAA, click the “Edit Profile” button from the bottom of the “View my Profile page” (Figure 12.4).

Click the “Previous” button to return to the “AB Home” page.

Figure 12.4 – Edit Profile and Previous Buttons



The system will display the “Edit Account Profile” page of Account Management (Figure 12.5).

Note: All of the fields will be editable.

The following buttons will display:

- **Clear** – Removes all of the account information on the page
- **Note:** If you clicked “Clear” and wish to restore your account information, click the “Cancel” button and navigate back to the “View my Profile” page.
- **Cancel** – Discards any changes and returns to the main OAA page
- **Continue** – Navigates users to the review page where you may confirm your changes before submitting

Figure 12.5 – Edit Account Profile Page

U.S. Department of Health and Human Services Logout

**ONLINE ACCOUNT
ADMINISTRATION (OAA)**

Account Management ? Print

Home Edit Account Profile

Edit Account Profile

You are editing account ID [REDACTED] for [REDACTED].

Edit the account information.

Point of Contact Information

First Name

Middle Initial (Optional)

Last Name / Surname

Job Title

Company / Last Name (Surname)

Web Address (Optional)

(Example: http://www.name.domain or http://name.domain)

Phone Number Country 000 0000000 Ext

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) Country Area Fax Number

Country Area Fax Number

E-mail Address

Confirm E-mail Address

Secret Question 3

Secret Answer 3

Physical Address (Business) of Account Holder

Country / Area

Address Line 1

Address Line 2 (Optional)

City

State / Province / Territory

Zip Code (Postal Code)

Unique Facility Identifier (Optional)

Do you have preferred mailing address other than the physical address mentioned above?

Yes No

Cancel Clear Continue

After you click “Continue,” the system will display the “Edit Account Profile” page as read-only for you to review.

Click the “Modify” button if you wish to make additional changes before submitting. Click the “Submit” button once you have verified the changes (Figure 12.6).

Figure 12.6 – Edit Account Profile – Read-Only View with Submit and Modify Buttons

Edit Account Profile

Review Account Information.

Account Information	Physical Address (Business) of Account Holder
First Name [REDACTED]	Address Line 1 [REDACTED]
Middle Initial [REDACTED]	Address Line 2 [REDACTED]
Last Name / Surname [REDACTED]	City [REDACTED]
Title [REDACTED]	State / Province / Territory [REDACTED]
Company Name [REDACTED]	Zip Code (Postal Code) [REDACTED]
Web Address [REDACTED]	Country / Area [REDACTED]
Phone Number [REDACTED]	
FAX Number [REDACTED]	
E-mail Address [REDACTED]	
Secret Question 1 [REDACTED]	
Secret Answer 1 [REDACTED]	
Secret Question 2 [REDACTED]	
Secret Answer 2 [REDACTED]	
Secret Question 3 [REDACTED]	
Secret Answer 3 [REDACTED]	

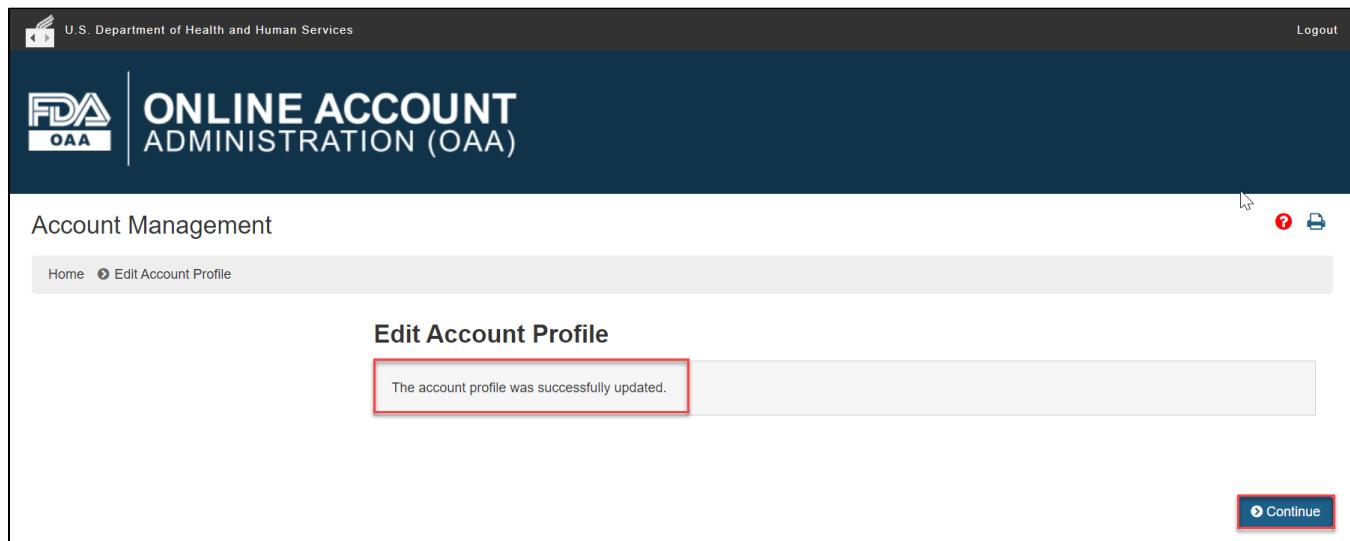
Click the Submit button to update the account, or click the Modify button to return and edit your account profile.

Modify **Submit**

Once you click the “Submit” button, the system will display a confirmation message stating the update was successful (Figure 12.7).

Click the “Continue” button to navigate back to the “View my Profile” page.

Figure 12.7 – Successful Update Message

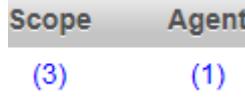


APPENDIX A: Abbreviations

AB	Accreditation Body
CB	Certification Body
FDA	U.S. Food and Drug Administration
OAA	Online Account Administration

APPENDIX B: Icon Behavior

Standardized icons are used throughout the system. Each icon performs a specific system function. The icon description and system function are described below:

Icon Description	Icon	System Function
Magnifying Glass		View the associated item.
Pencil		Edit the associated item.
Numbers within parenthesis		<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 accredited CB. The AB may click the link to view the three scopes records. • Example, "(1)" indicates that there is one audit agent associated to the accredited CB. The AB may click the link to view a list of active audit agent(s).
Trash Can		Delete the associated item.
Printer		Print the associated item.