U.S. Food and Drug Administration

Laboratory Accreditation for Analyses of Foods (LAAF) Program Portal

Electronic User Guide

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

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1 Introduction

This document is intended for Accreditation Bodies (ABs) or persons who are authorized to act on their behalf, who are applying or seeking renewal for recognition in FDA's Laboratory Accreditation for Analyses of Foods (LAAF) Program. If approved by FDA, ABs can manage their profiles, including the Accredited Laboratories (ALs).

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

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

1.1 Overview of FDA Portals for Electronic Laboratory Accreditation for Analyses of Foods Program Submissions

FDA Industry Systems (FIS)

FDA Industry Systems (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 Laboratory Accreditation for Analyses of Foods Program.

1.2 Adding Attachments

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

The electronic Laboratory Accreditation for Analyses of Foods 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.

1.3 Supported Browsers

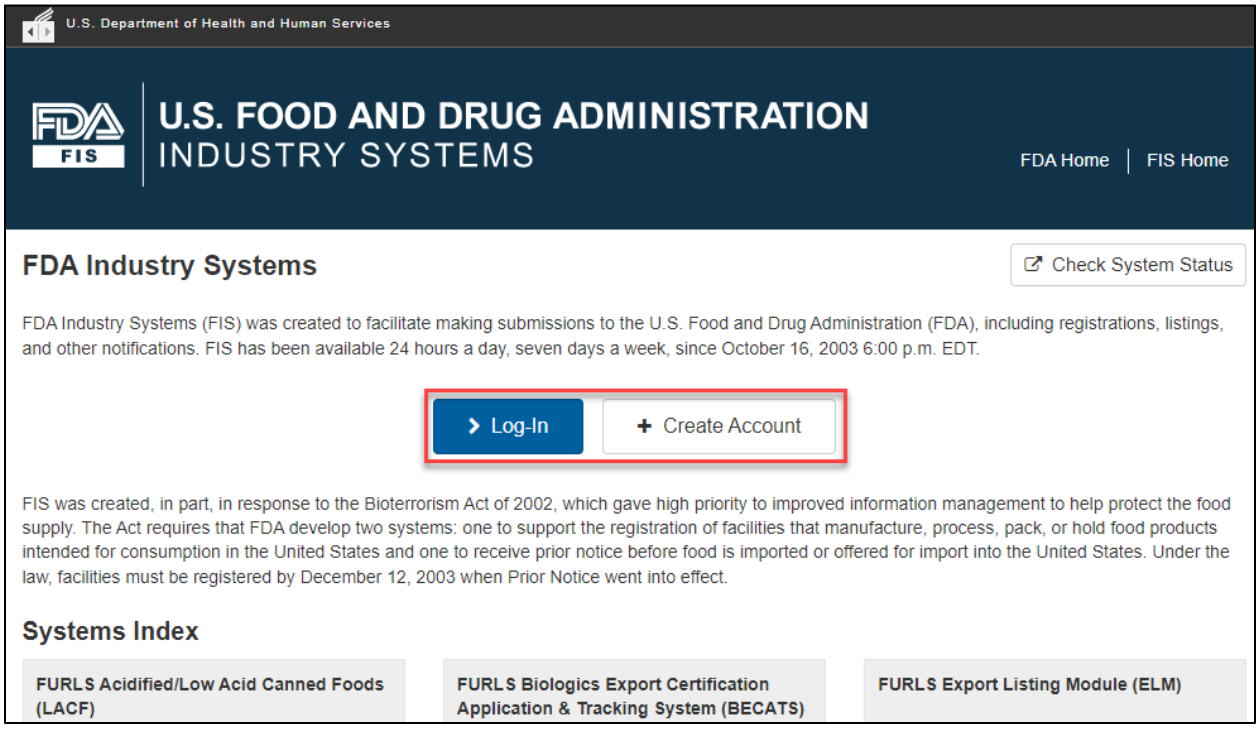
FURLS may be accessed using Microsoft Edge, Google Chrome, or Firefox. Please visit the “Systems Requirements” section of the FURLS page for a list of approved browsers and browser versions. The “Systems Requirements” section can be found by navigating to https://www.access.fda.gov.

Obtain an FDA Account through the FDA FIS Electronic Portal.

Each person who uses this system needs a personal FDA Account ID and password. To access the FIS electronic portal, they can go to https://www.access.fda.gov/oaa/. Then they can click the “Create New Account” button near the bottom of the page, in the New User section and then follow the instructions for obtaining an FDA Account ID and password below. Once the account has been created, the user will be able to log into the “Online Account Administration” (OAA) system.

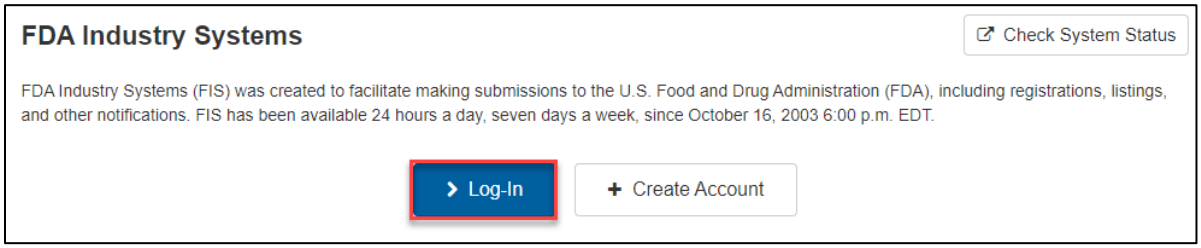
2 Access FDA FIS Electronic Portal

An Accreditation Body (AB) seeking recognition by FDA is required to create an online account first. Once the account has been created, the applicant can then log into the FURLS "OAA" page with valid account credentials to apply for recognition by FDA. The AB user should navigate to https://www.access.fda.gov and click the "Log-In" or "Create Account" button, depending on which is applicable to the user (Figure 2.1).



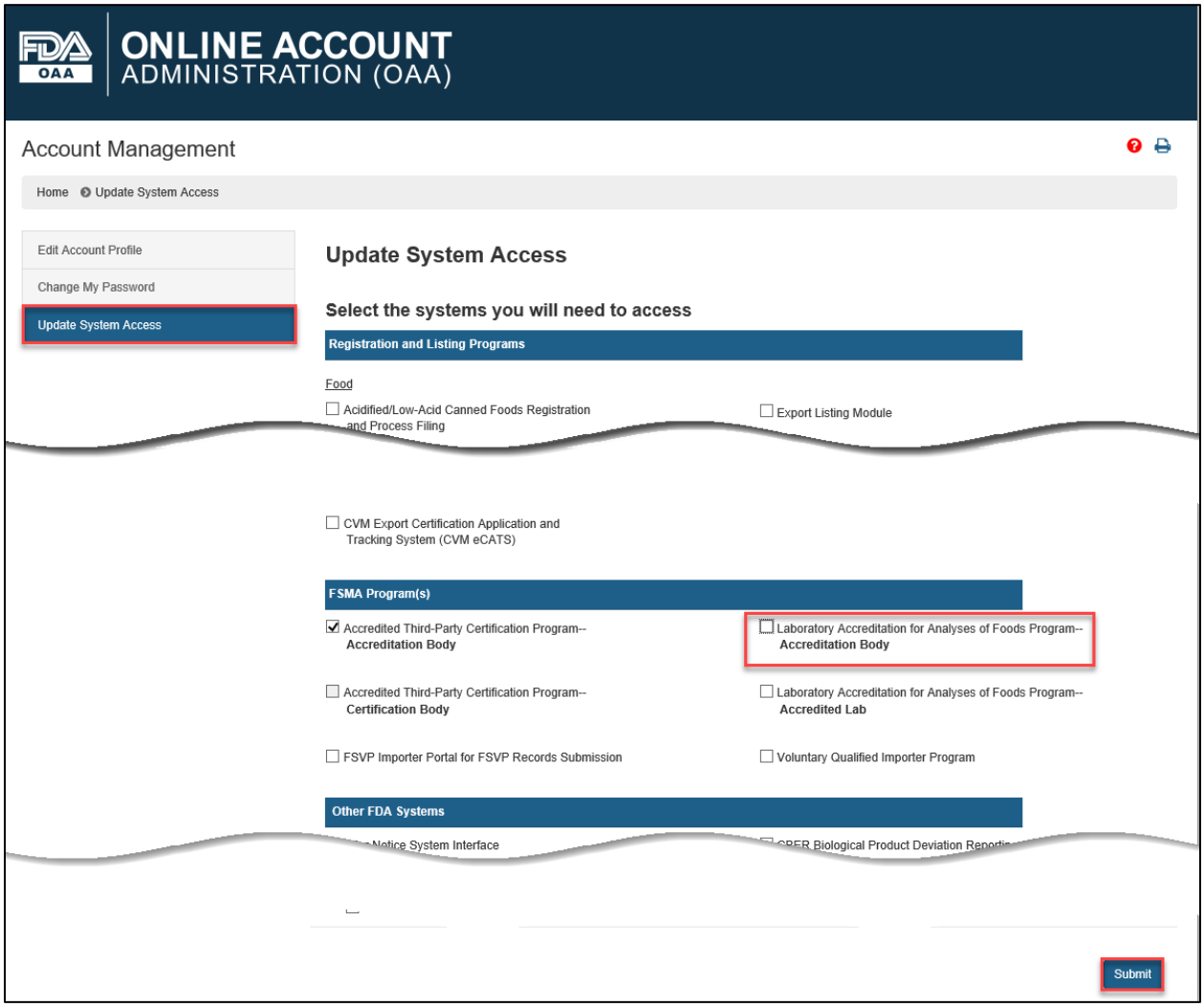
2.1 Log in With an Existing Account

If the AB user has previously created an FIS account, they should click the "Log-In" button on the "FDA Industry Systems" page (Figure 2.2).

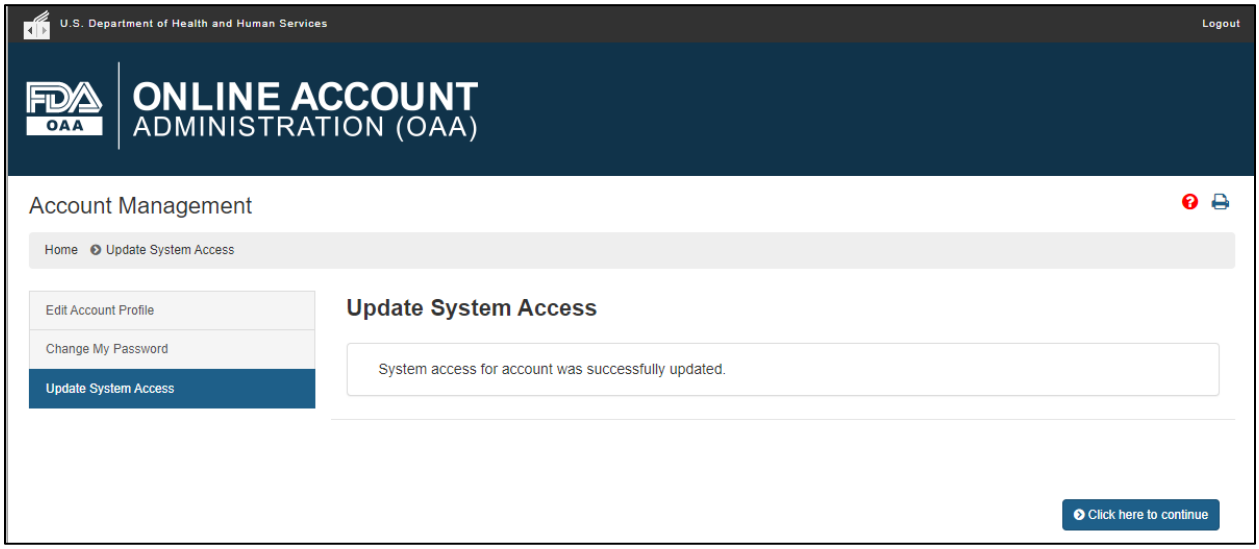


The user will be directed to the Online Account Administration (OAA) “Login” page. They can enter the Account ID and password to log in, then click the “Update System Access” link from the upper-left corner of the OAA “Account Management” Page (Figure 2.3).

The page will display instructions to select the system(s) the AB user will need to access. The user will click on the checkbox for “Laboratory Accreditation for Analyses of Foods Program – Accreditation Body”, and then click the “Submit” button.

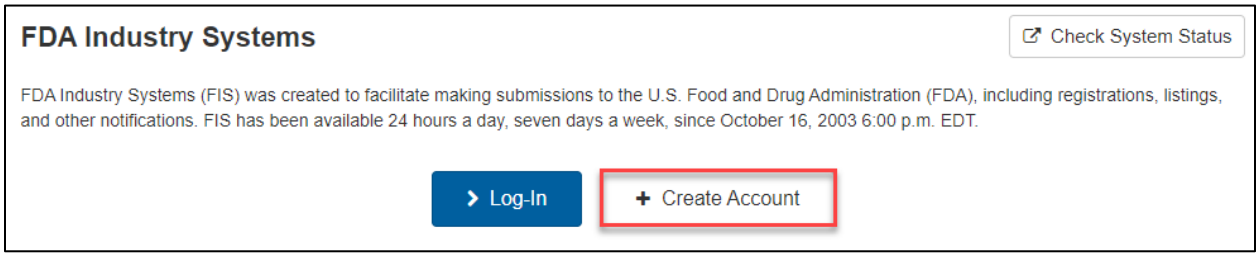


The system will display a message confirming the user's system access was successfully updated (Figure 2.4).

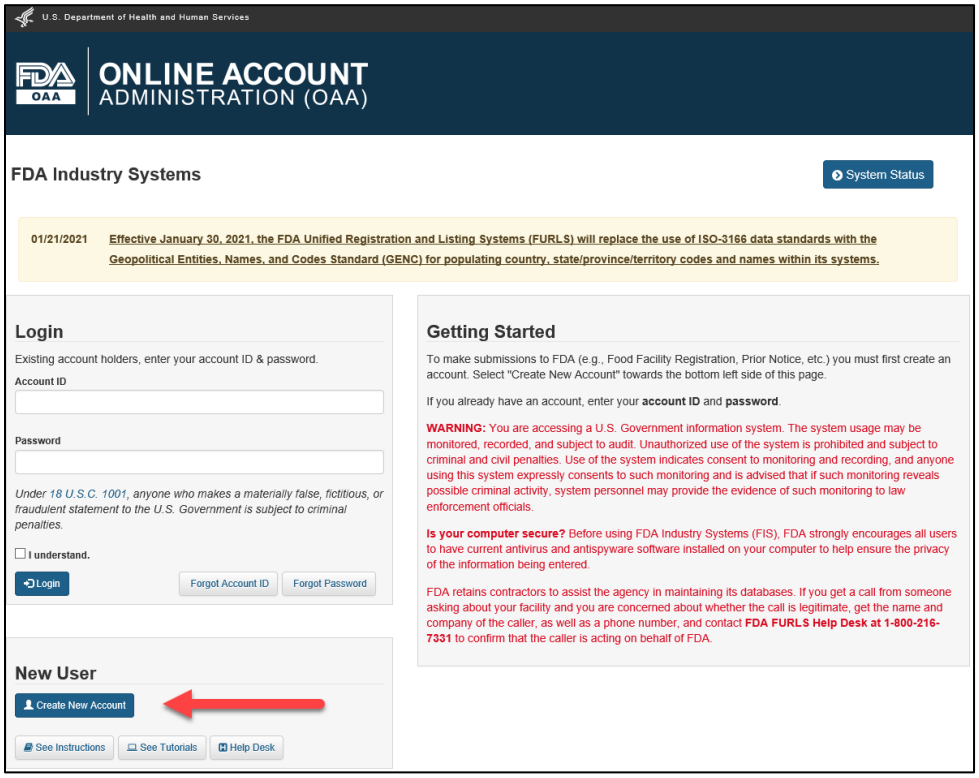


2.2 Create An Account

If the AB user has not previously created a FIS account, they should click the “Create Account” button on the FDA Industry Systems page (Figure 2.5).



The user will be directed to the Online Account Administration (OAA) “Login” page (Figure 2.6). The AB can sign up for an account by clicking the “Create New Account” button on the “FDA Industry Systems” (FIS) Online Account Administration (OAA) page.

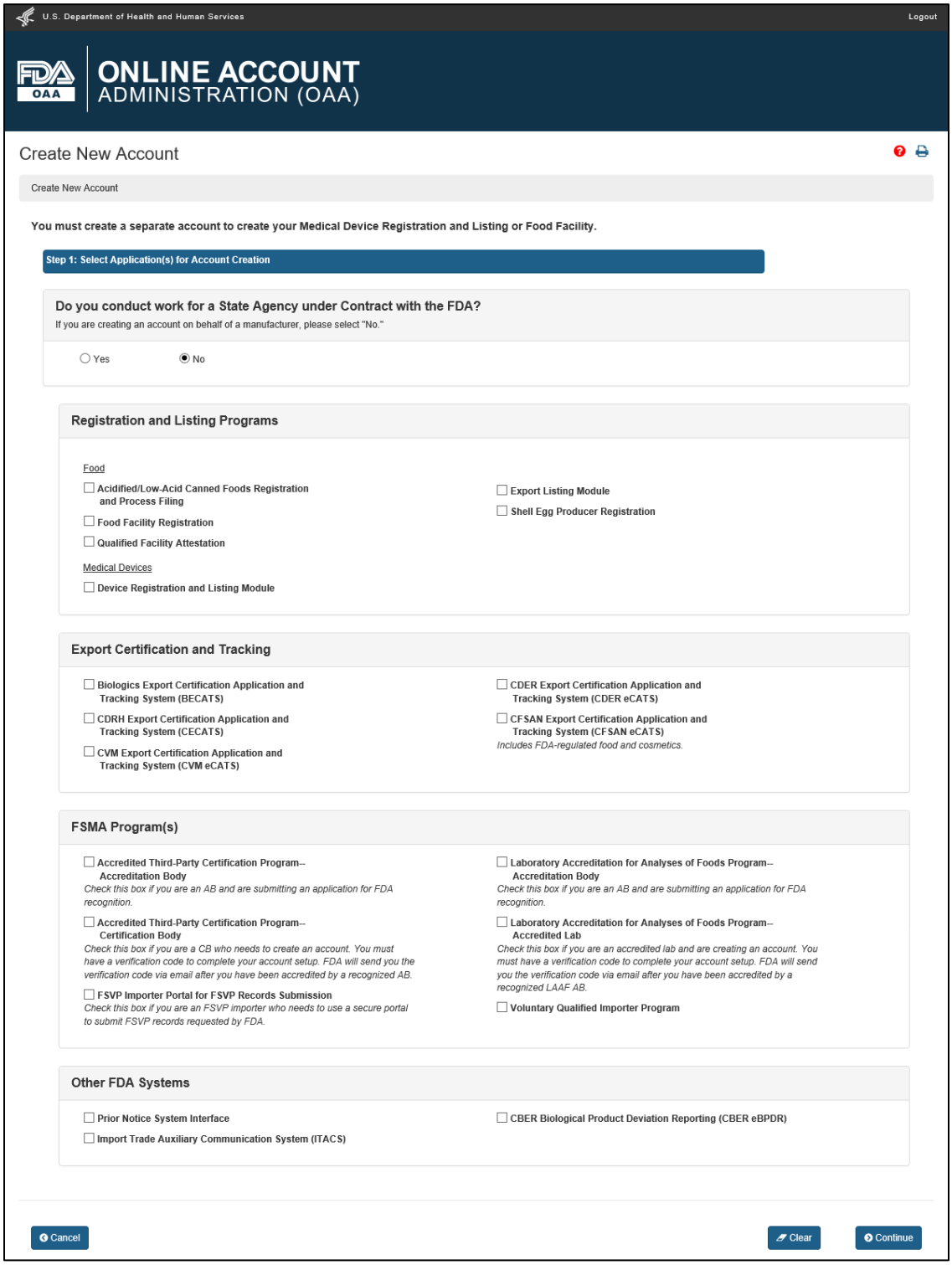


The system will display the “Create New Account” page (Figure 2.7).

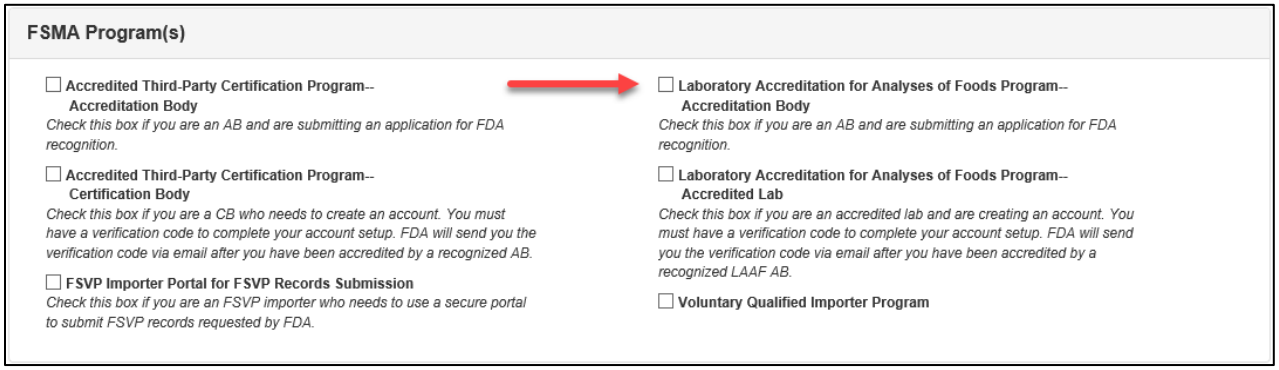
Two radio buttons will display at the top of the page, “Yes” and “No;” “No” is selected by default.

Note: The radio buttons should remain in their default state. Selecting “Yes” will direct users to a program which is not part of the scope of this document.

The system will display the various programs available in OAA.

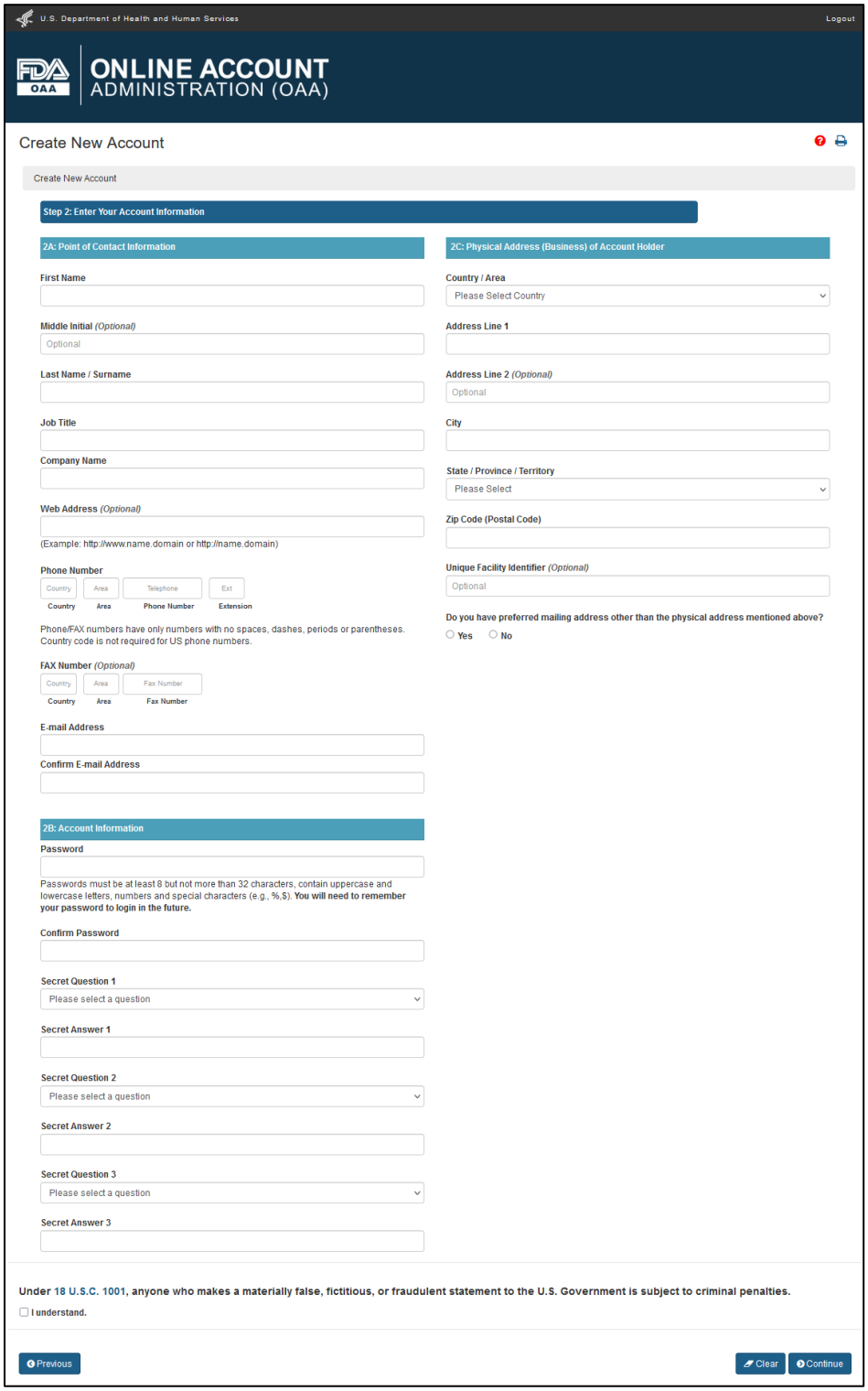

U.S. Department of Health and Human Services
Logout
ONLINE ACCOUNT ADMINISTRATION (OAA)
Create New Account
Create New Account
You must create a separate account to create your Medical Device Registration and Listing or Food Facility.
Step 1: Select Application(s) for Account Creation
Do you conduct work for a State Agency under Contract with the FDA?
If you are creating an account on behalf of a manufacturer, please select "No."
Yes
No
Registration and Listing Programs
Food
Acidified/Low-Acid Canned Foods Registration and Process Filing
Food Facility Registration
Qualified Facility Attestation
Export Listing Module
Shell Egg Producer Registration
Medical Devices
Device Registration and Listing Module
Export Certification and Tracking
Biologics Export Certification Application and Tracking System (BECATS)
CDRH Export Certification Application and Tracking System (CECATS)
CVM Export Certification Application and Tracking System (CVM eCATS)
CDER Export Certification Application and Tracking System (CDER eCATS)
CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
Includes FDA-regulated food and cosmetics.
FSMA Program(s)
Accredited Third-Party Certification Program-- Accreditation Body
Check this box if you are an AB and are submitting an application for FDA recognition.
Accredited Third-Party Certification Program-- Certification Body
Check this box if you are a CB who needs to create an account. You must have a verification code to complete your account setup. FDA will send you the verification code via email after you have been accredited by a recognized AB.
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.
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.
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.
Voluntary Qualified Importer Program
Other FDA Systems
Prior Notice System Interface
Import Trade Auxiliary Communication System (ITACS)
CBER Biological Product Deviation Reporting (CBER eBPDR)
Cancel
Clear
Continue

The AB user will select the “Laboratory Accreditation for Analyses of Foods Program – Accreditation Body" checkbox under “FSMA Program(s),” and click the “Continue” button to continue to the next step (Figure 2.8).



The system will display the “Create New Account” page (Figure 2.9). In the “Step 2: Enter Your Account Information” section, the AB user will provide their Point of Contact information, account information, and the account holder’s physical address.

Note: The account holder’s physical address may include a street address and/or post office box.


U.S. Department of Health and Human Services
Logout
ONLINE ACCOUNT ADMINISTRATION (OAA)
Create New Account
Create New Account
Step 2: Enter Your Account 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
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
Fax Number
E-mail Address
Confirm E-mail Address
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
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
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 data fields in the “Step 2A: Point of Contact Information” section include:

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

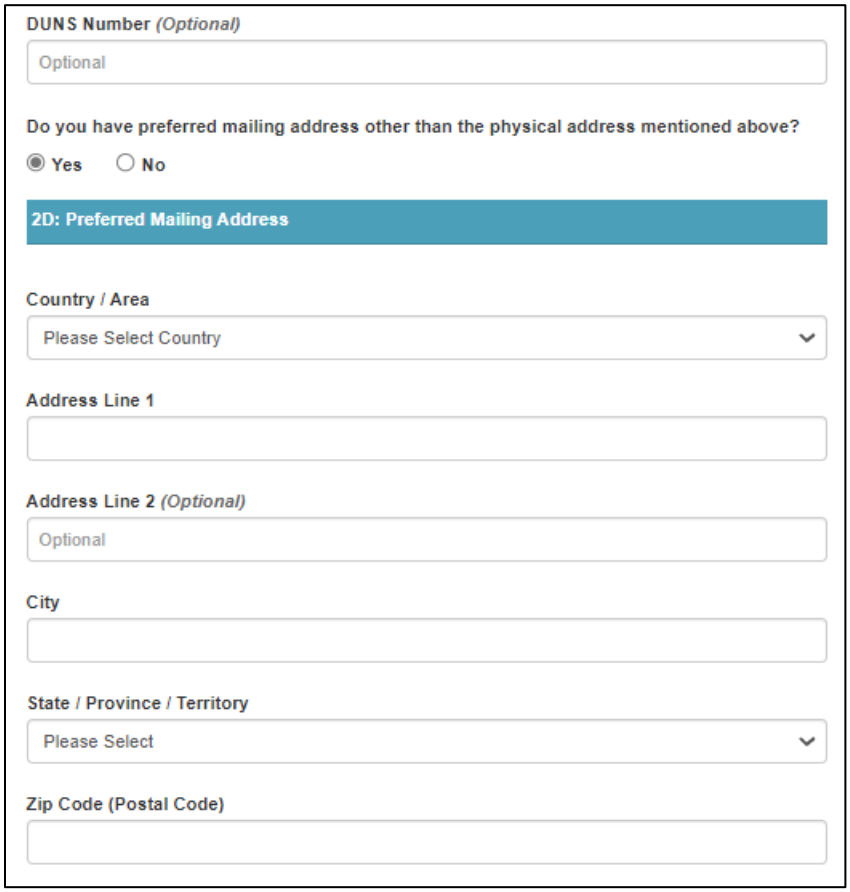
The data fields in Step 2B: Account Information include:

- **Password –** The field to create password for the AB’s account. This password will be used every time the AB user logs into the system.
- **Confirm Password –** The field to enter password created 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 –** The second secret question used to protect the account. Select a question from the drop-down list.

- **Secret Answer 2 –** This is the answer to the second secret question. Enter your response to the question selected in “Secret Question 2.”
- **Secret Question 3 –** This is the third secret question used to protect the account. Select a question from the 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.”

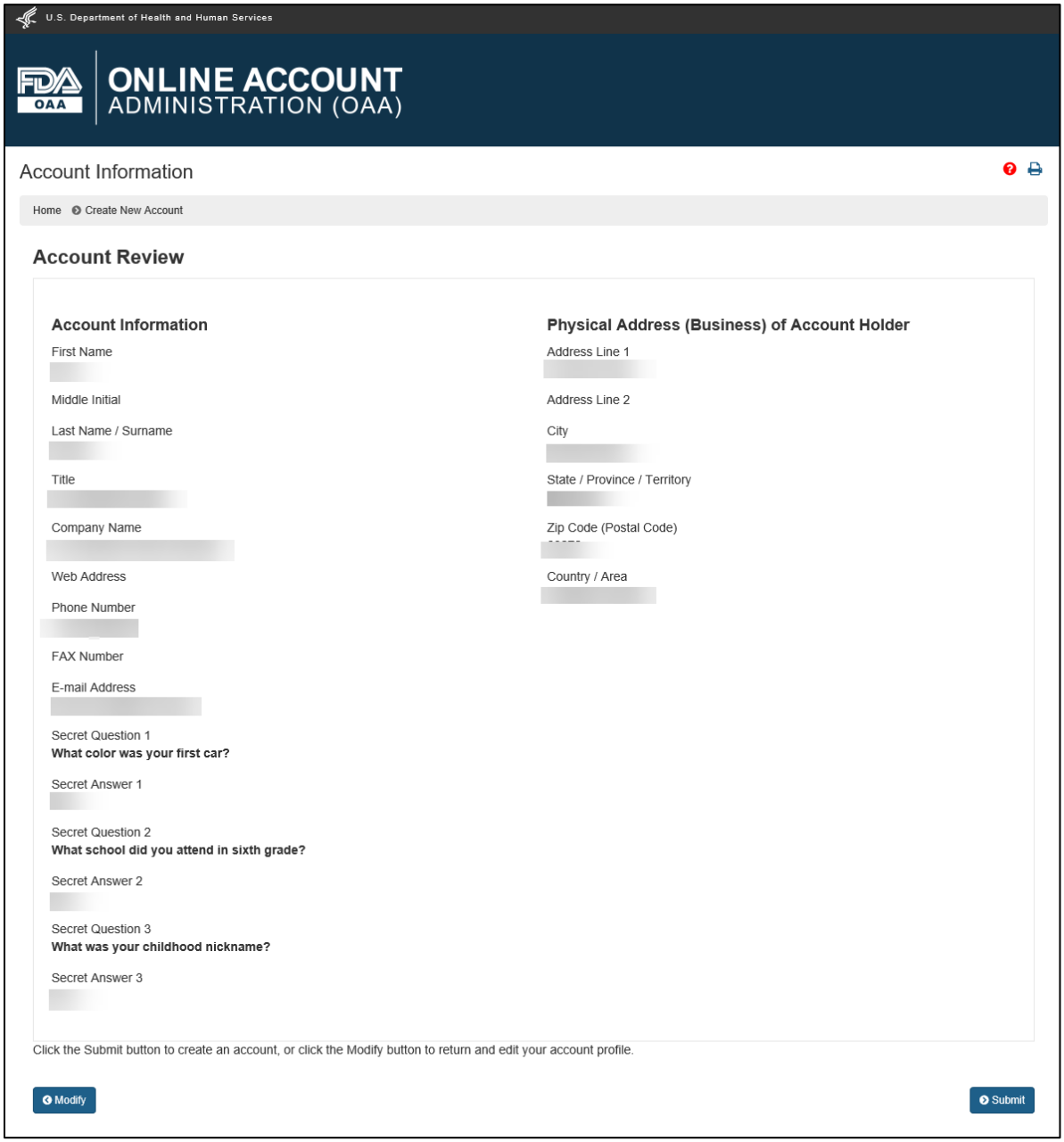
The data fields in “Step 2C: Physical Address (Business) of Account Holder” include:

- **Country/Area –** The country/area where the business is located
  Select a country/area from the drop-down list.
- **Address Line 1 –** The address where the business is physically located
  This includes the number, street, quadrant, etc.
- **Address Line 2 (Optional field) –** The field to enter additional information about the physical location of the company.
  This may include a suite or apartment number, if applicable.
- **City –** The city where the business is physically located.
- **State/Province/Territory –** The state/province/territory where the business is physically located.
- **Zip Code (Postal Code) –** The zip code (domestic) or postal code (foreign) where the business is physically located.
- **Unique Facility Identifier (Optional field) –** The firm’s DUNS number.
- **Do you have preferred mailing address other than the physical address mentioned above? –** The “Yes” and “No” radio buttons provided to answer this question:
  - If “No” is selected, the physical address will be used as the mailing address.
  - If “Yes” selected, the system will display “Step 2D: Preferred Mailing Address” which must be completed (Figure 2.10). The address entered in Step 2D will be used as the mailing address.

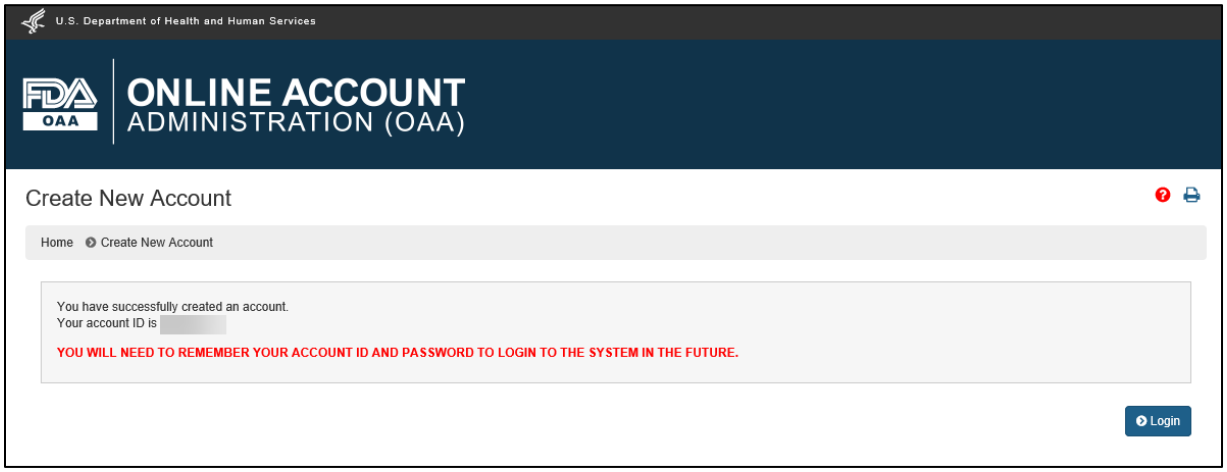


After completing all mandatory fields, the AB applicant must click the “I understand” checkbox and the “Continue” button at the bottom of the page. The system will display the “Account Review” page (Figure 2.11).

The AB user can then click the “Submit” button to finalize the account creation or, click the “Modify” button to edit the profile information.



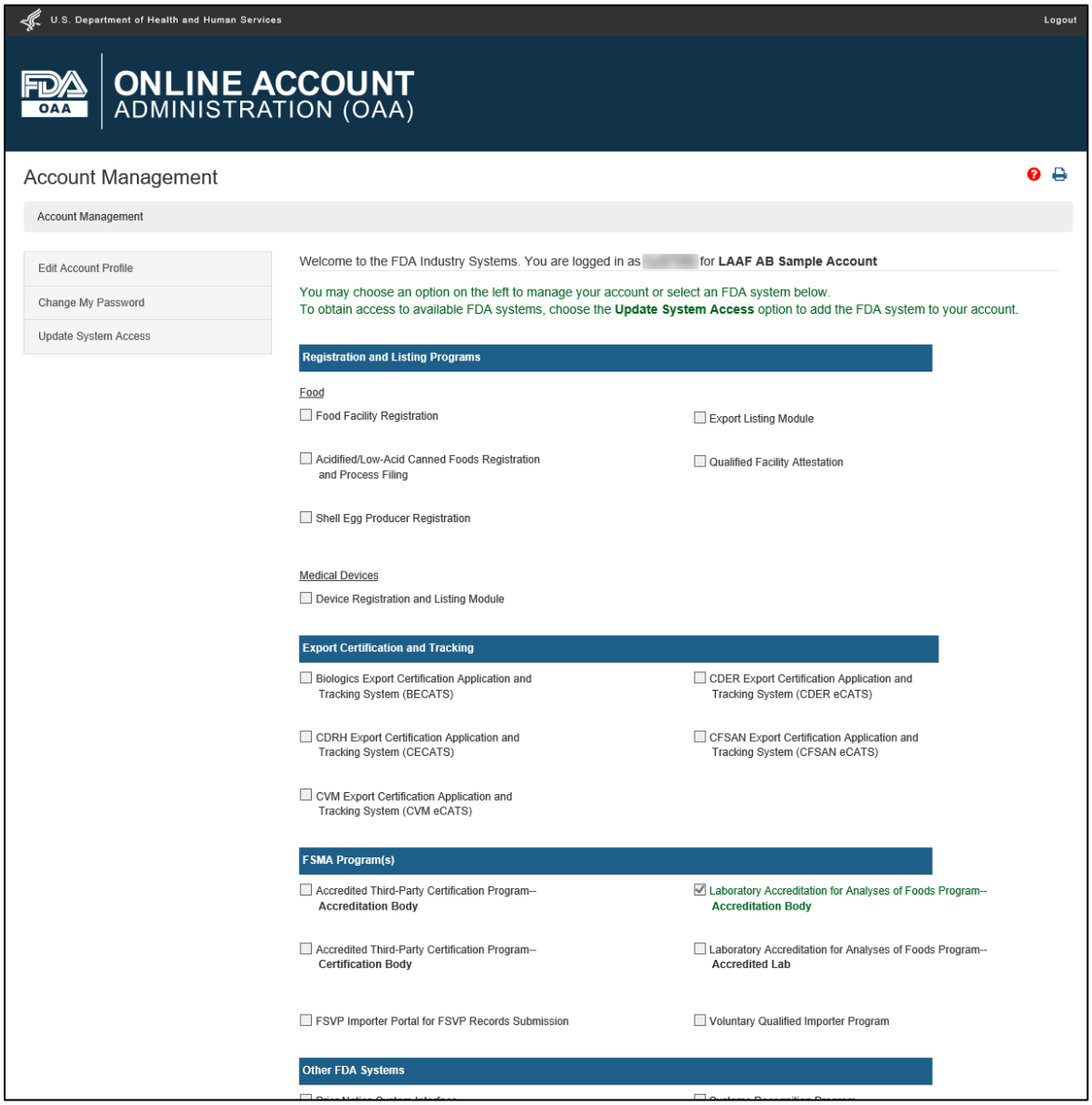
When the AB user clicks the “Submit” button, the system will display a page with a message stating their account was created successfully. The message will also display the account ID the user will use to log in and submit an application for recognition as an AB (Figure 2.12).



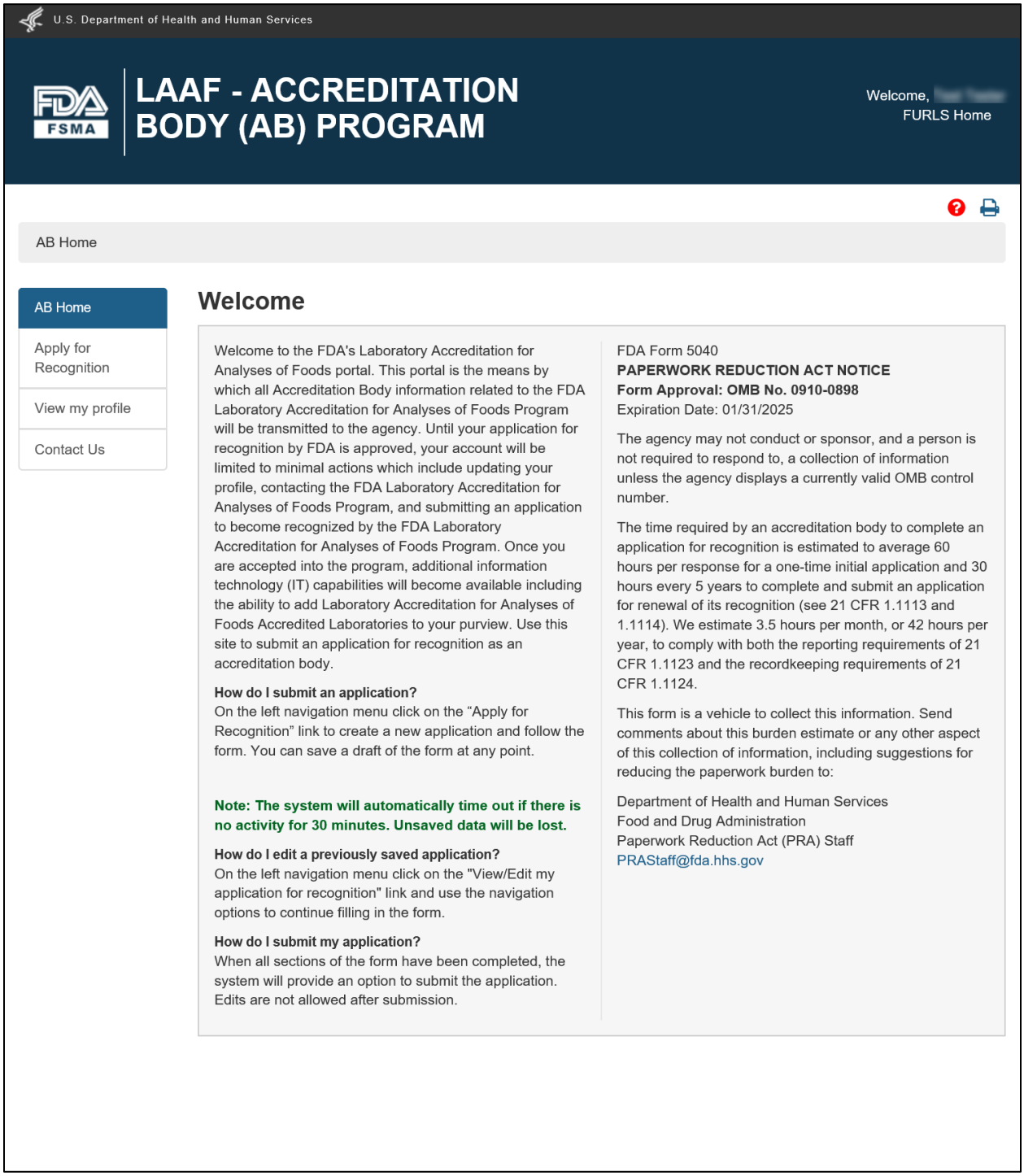
Once the AB user has created an account, they will receive an e-mail notification containing the account ID, which will be sent to the e-mail address entered on the “Create New Account” page.

3 Access the Laboratory Accreditation for Analyses of Foods Program – Accreditation Body

After the AB user logs into the FDA “OAA” page, the FURLS “Account Management” page will display. The AB user will select the **“**Laboratory Accreditation for Analyses of Foods Program – Accreditation Body" checkbox under “FSMA Program(s),” and continue to the next step (Figure 3.1).



This system will navigate the user to the “AB Home” page with the “LAAF - Accreditation Body (AB) Program” banner (Figure 3.2).



Each screen in the AB electronic submission process has the banner “LAAF –

Accreditation Body (AB) Program." The "FURLS Home" link (on the right side of the banner) will navigate them to the "Account Management" page, where the AB user is able to log out of the system.

4 Apply for Recognition as an Accreditation Body (AB)

To create a new application for recognition as an Accreditation Body, the AB user can select the “Apply for Recognition” link from the navigation menu on the “AB Home” page (Figure 4.1).

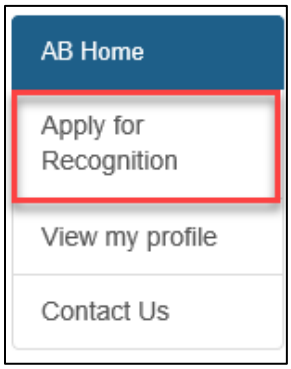


Figure 4.1: Navigation Menu

The system will navigate to the first page of the application, “Applicant Information” (Figure 4.2). This page displays read-only information from the AB user’s profile submitted while creating the account in OAA.

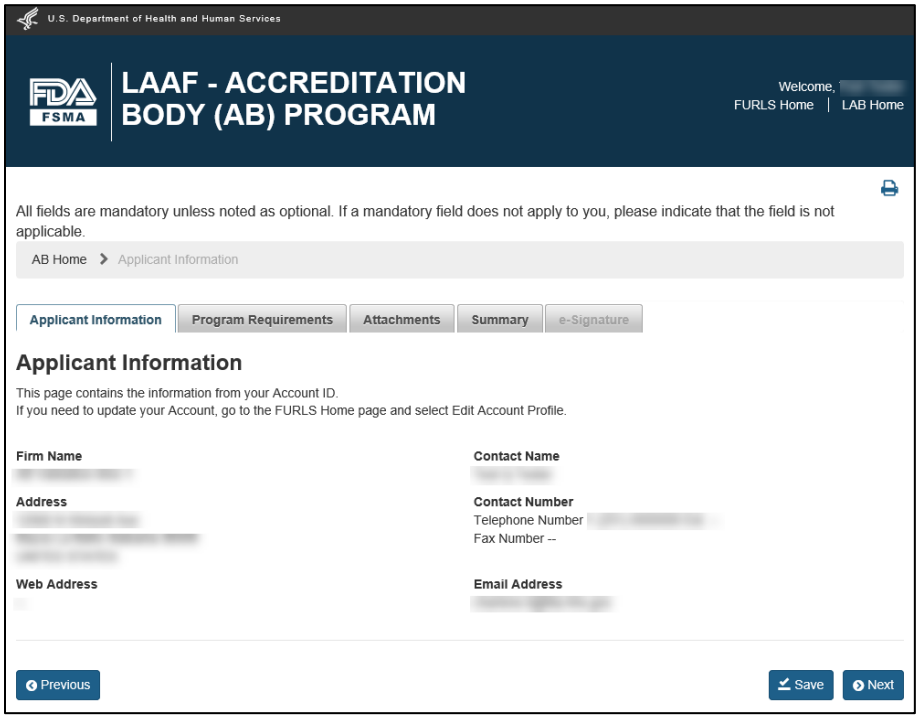


Figure 4.2: Applicant Information Page

The “AB Home” link will navigate the AB user to the main menu on the “AB Home” page.

The system allows navigation between the pages of the application using the “Previous” and “Next” buttons or, by selecting the tab of the desired page directly.

The “Program Requirements” page allows the AB user to enter information and attach files for the following regulatory requirements:

- Eligibility
- Competency and Capacity
- Conflict of Interest
- Oversight Requirements
- Reports and Notifications
- Records

The regulatory requirements are listed on the left side of the page. The “Eligibility” regulatory requirement is expanded by default upon navigating to the page (Figure 4.3).

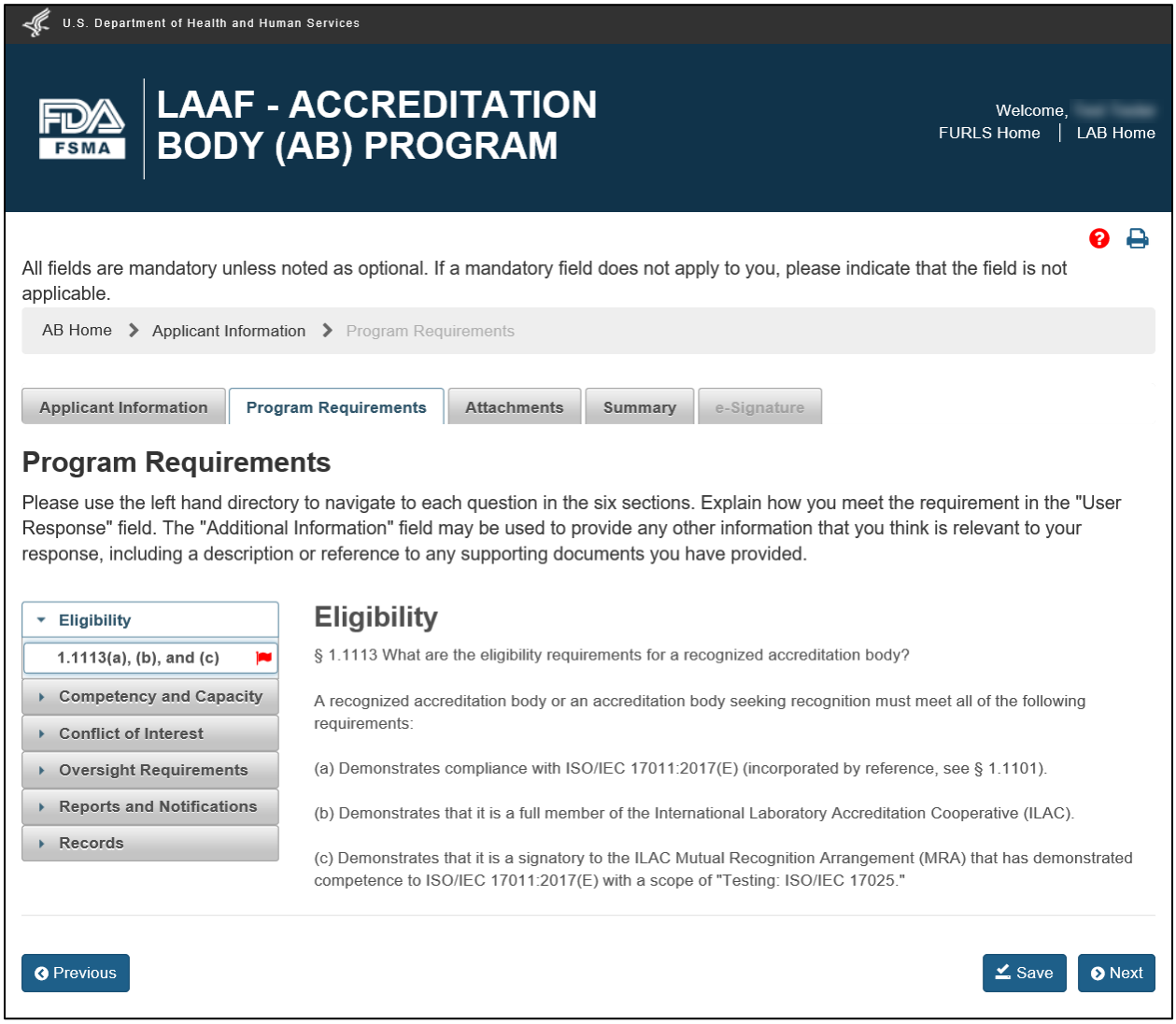


Figure 4.3: Program Requirements Page

The definition of the regulatory requirement is displayed when the AB user clicks on its heading (Figure 4.4 shows an example for “Eligibility”).

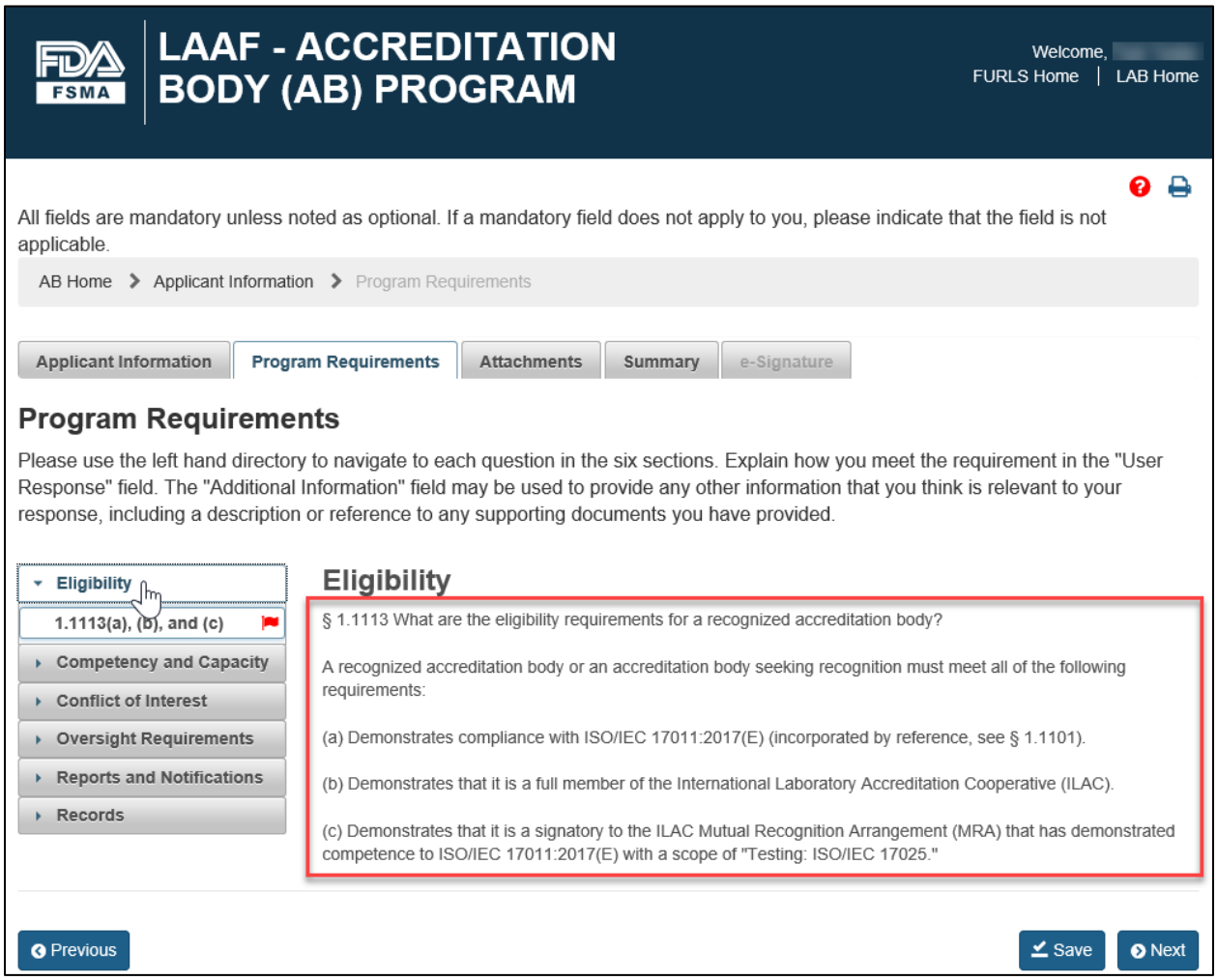


Figure 4.4: Definition of Eligibility

Each regulatory requirement has regulation text displayed when expanded.

When the AB user clicks on the element for “Eligibility” (i.e., “1.1113(a), (b), and (c)”) the system displays three accordion sections, containing the following data fields (Figure 4.5):

1) “Eligibility” section:
    - **Regulatory Requirement** and **Criteria to Demonstrate –** Contain(s) read-only information.

- **User Response –** Text entry field, which allows up to 4,000 characters.
- **Additional Information –** Optional text entry field, which allows up to 4,000 characters.

2) "Certificate Attachments" section:
   - **Attachments button** – To provide the ability to upload certification documents.
   - **Table of attachments (empty by default) –** Any uploaded documents related to certificates will be listed here.
   - **Evaluation Date –** Date field for the accreditation evaluation date listed in the certificate attachment, which will display once a file has been uploaded to this section.
   - **Expiration Date –** Optional date field for the expiration of the accreditation as listed in the certificate attachment, which will display once a file has been uploaded to this section.
3) "Other Supporting Documents" section – Optional section, which contains the following:
   - **Attachments button –** To provide file upload functionality for documents not related to certification.
   - **Table of attachments (empty by default) –** Any documents uploaded in this section will be listed here.

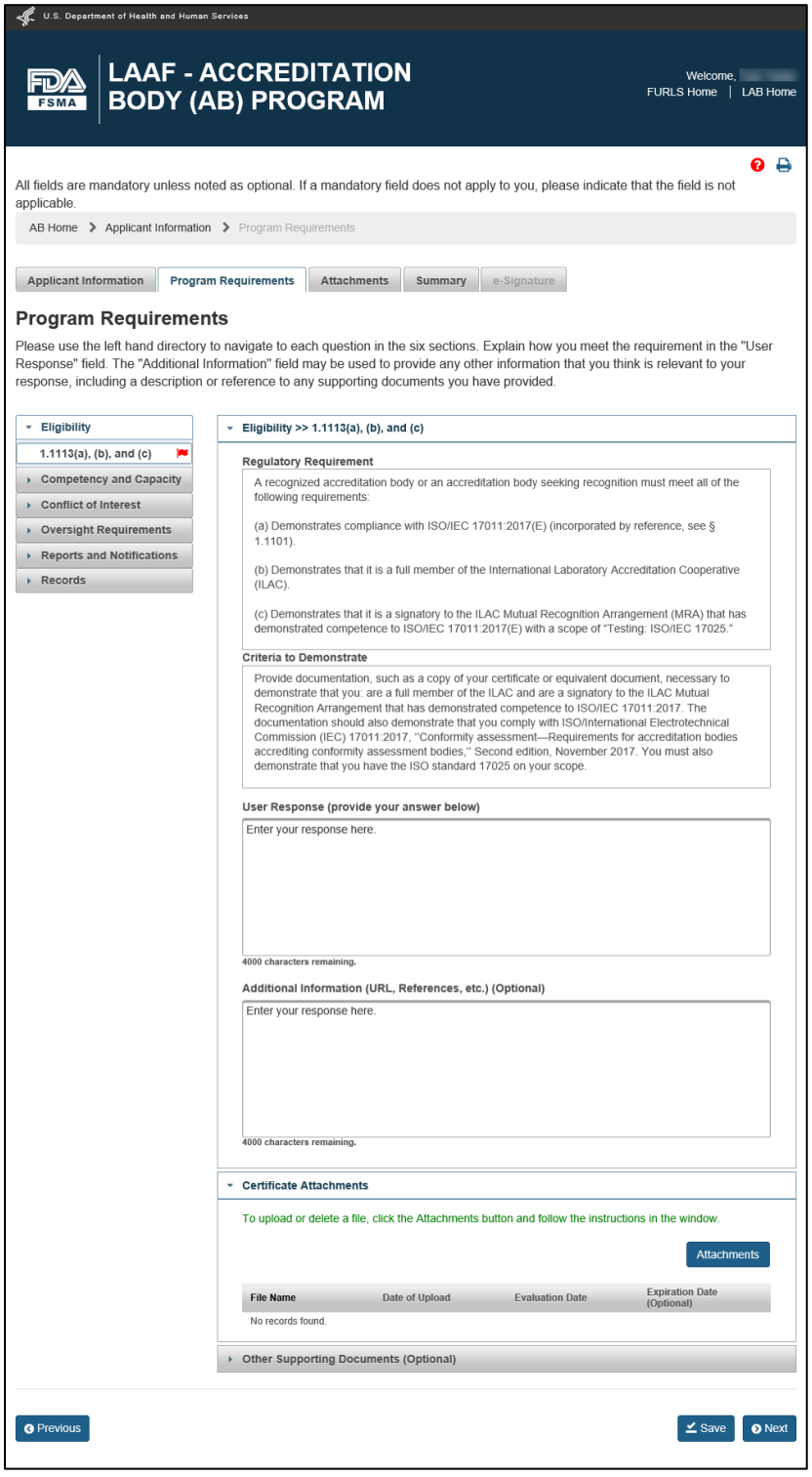


Figure 4.5: Eligibility Section

Each element is red-flagged by default for all of the regulatory requirements, indicating the required field of the element has not been completed (Figure 4.5). The system will remove the red flag when the AB user provides a response in the “User Response” field.

All other regulatory requirements (other than “Eligibility”) contain the following two accordion sections. Figure 4.6 shows an example for “Records”:

- “<Regulatory requirement name>”:
    - **Regulatory Requirement** and **Criteria to Demonstrate –** Contain(s) read-only information.
    - **User Response –** Text entry field which allows up to 4,000 characters.
    - **Additional Information –** Optional text entry field, which allows up to 4,000 characters.
- “Attachments” – Optional section, which contains the following:
    - **Attachments button –** To provide file upload functionality for documents not related to certificates.
    - **Table of attachments (empty by default) –** Any uploaded files uploaded in this section will be listed here.

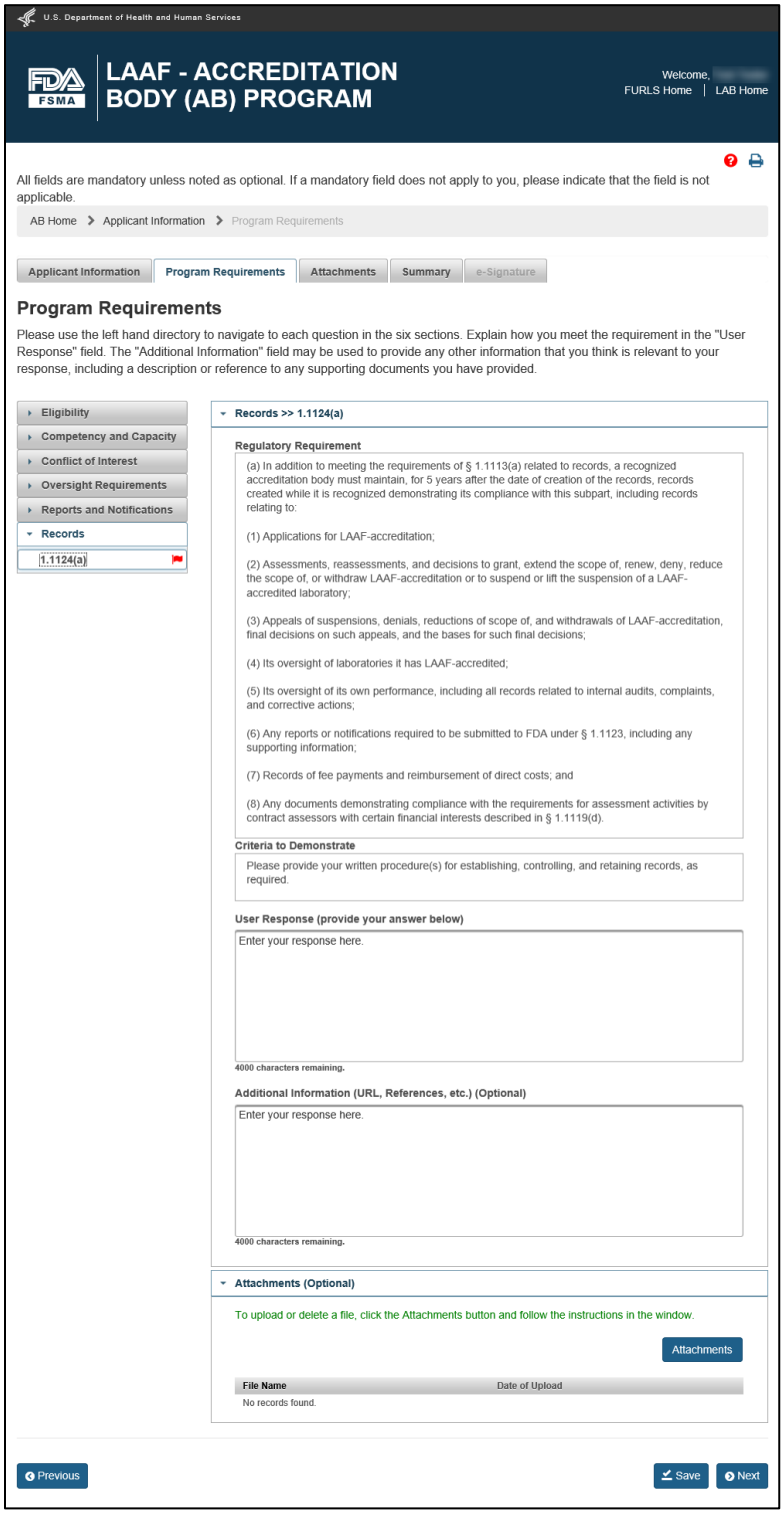


Figure 4.6: Records Section

Attachments may be uploaded with each response using the “Attachments” button. Figure 4.7 shows an example for the regulatory requirement “Eligibility”.

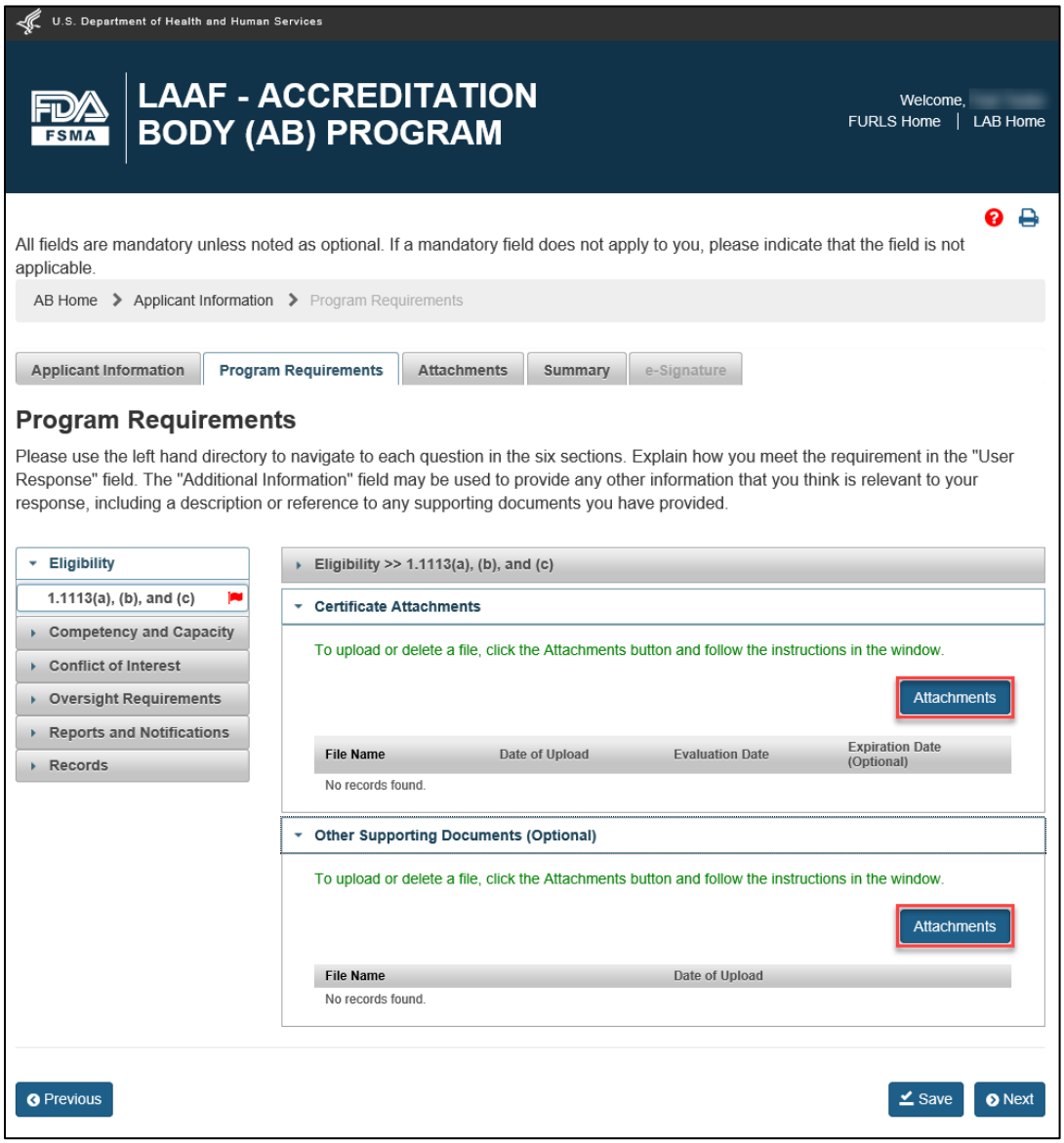


Figure 4.7: Attachments Button

To upload an attachment, the AB applicant will click the “Attachments” button. The system will display the “Attachments” pop-up window which contains the following (Figure 4.8):

- Upload instructions:

    - Step 1: Click “Browse” to find the document(s) you want to upload
    - Step 2: Click “Upload”
    - Step 3: Click “Close”
- Browse, Upload, Cancel, and Close buttons
- Manage Attachments table with three columns:
    - File Name
    - Date of Upload
    - Action

Note: File types permitted are .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.

The AB applicant will select a file using the “Browse” button. After a file has been selected, the “Upload” and “Cancel” buttons will be enabled.

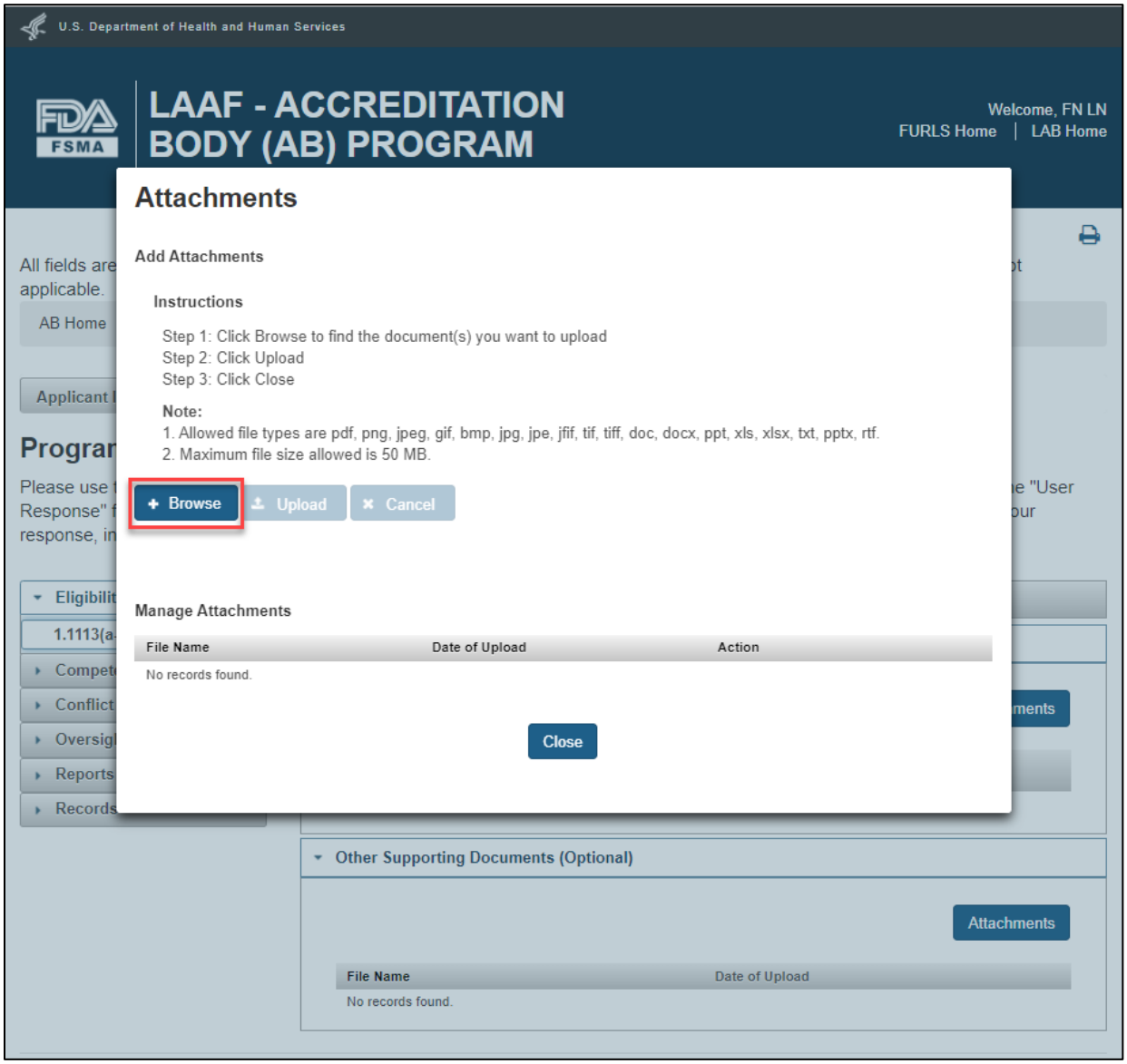


Figure 4.8: Attachments Pop-Up Window

The AB user can click the “Upload” button to complete the upload or, click the “Cancel” button to cancel the upload process.

On a successful upload, the system will disable all three buttons, and will post a confirmation message with the file name displayed in the “Attachments” window and on the main page (Figure 4.9).

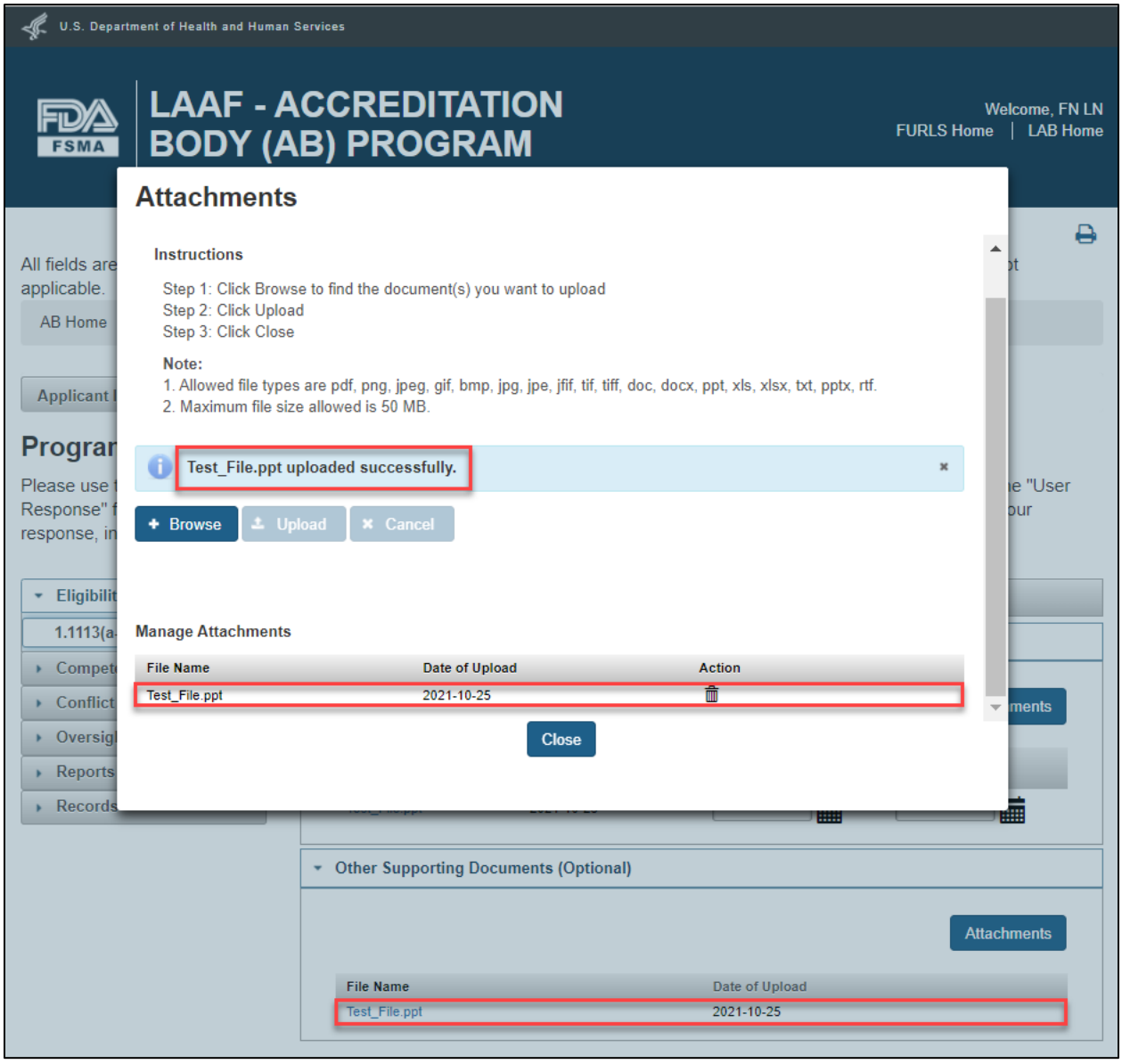


Figure 4.9: Confirmation of Successful Upload

To remove the attachment, the AB applicant can click the trash/delete icon in the "Action" column. The system will display a confirmation message (Figure 4.10).

The AB user can click the "Close" button to close the "Attachments" window.

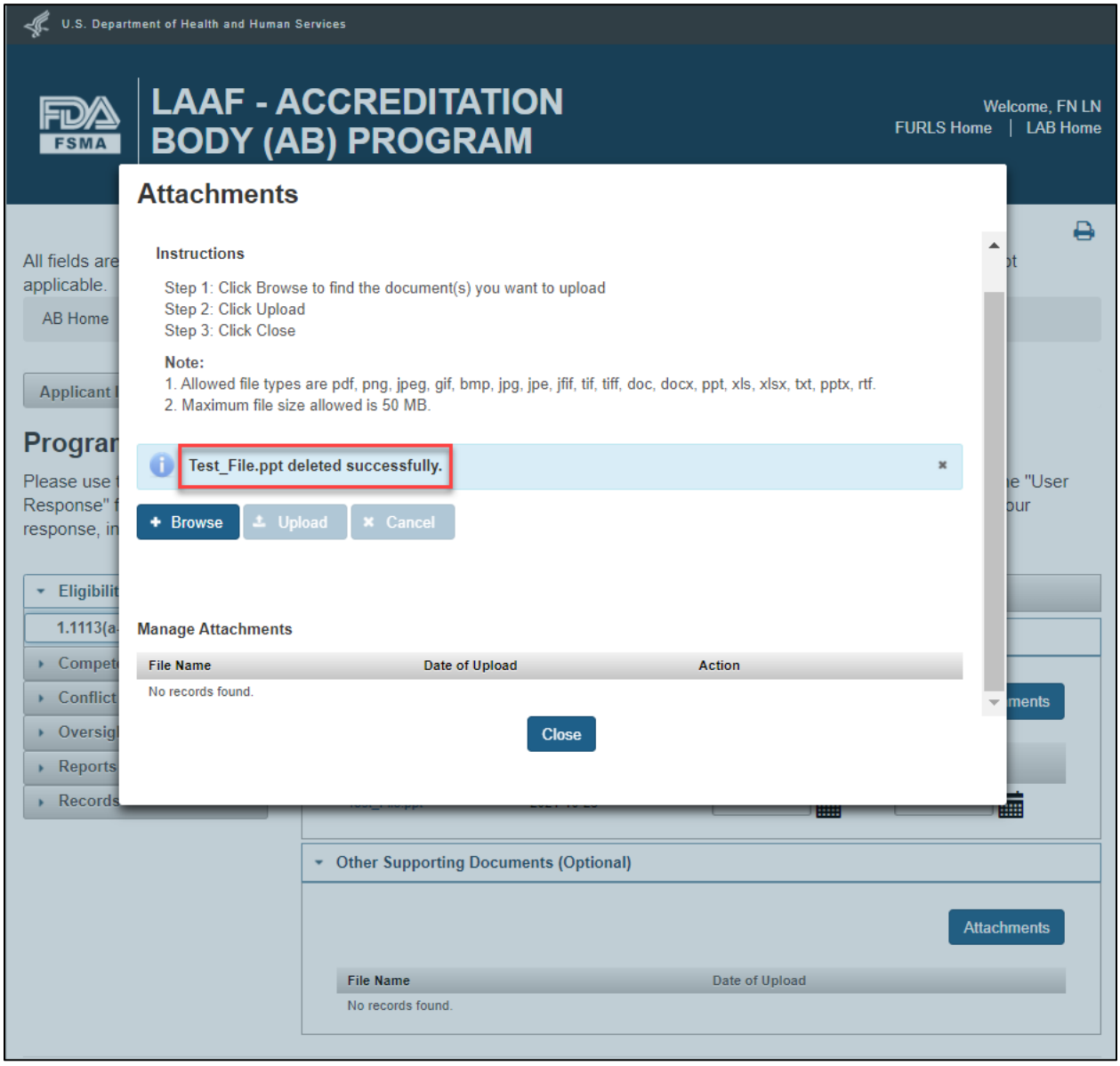


Figure 4.10: Confirmation of Successful Deletion

Important: The user must click the “Save” button upon completion of all the regulatory requirements.

The AB applicant can proceed to the “Attachments” page, where the AB user can upload additional documents to include with the application submission. The user can follow the instructions listed on the “Attachments” page. This page is optional (Figure 4.11).

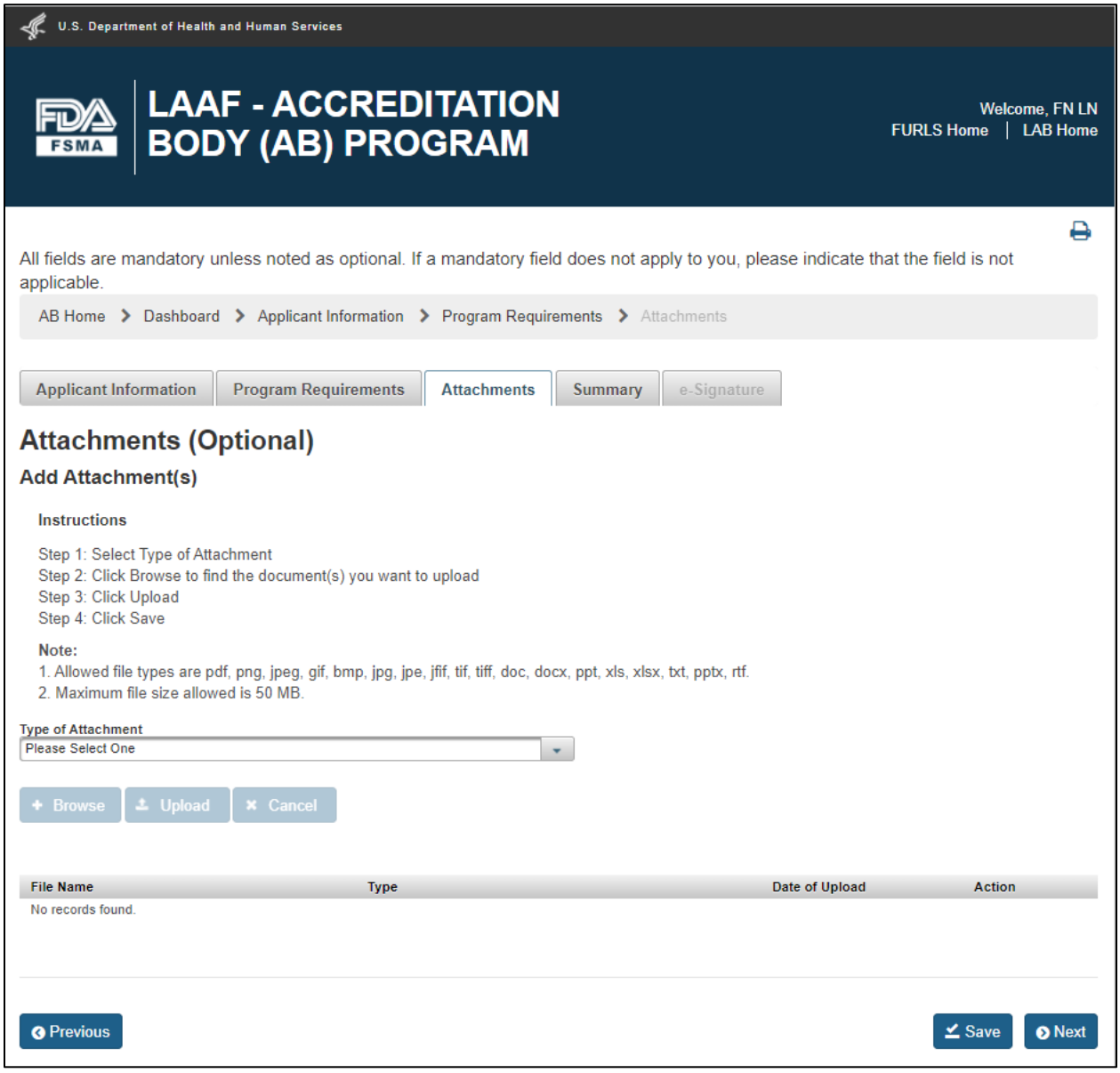


Figure 4.11: Attachments Page

The AB user will make a selection from the “Type of Attachment” menu. If “Other” is selected, the text field “Additional Description” will display and must be completed to proceed to the next page of the application (Figure 4.12). After that, the “Browse” button will become enabled allowing them to search for a file to upload.

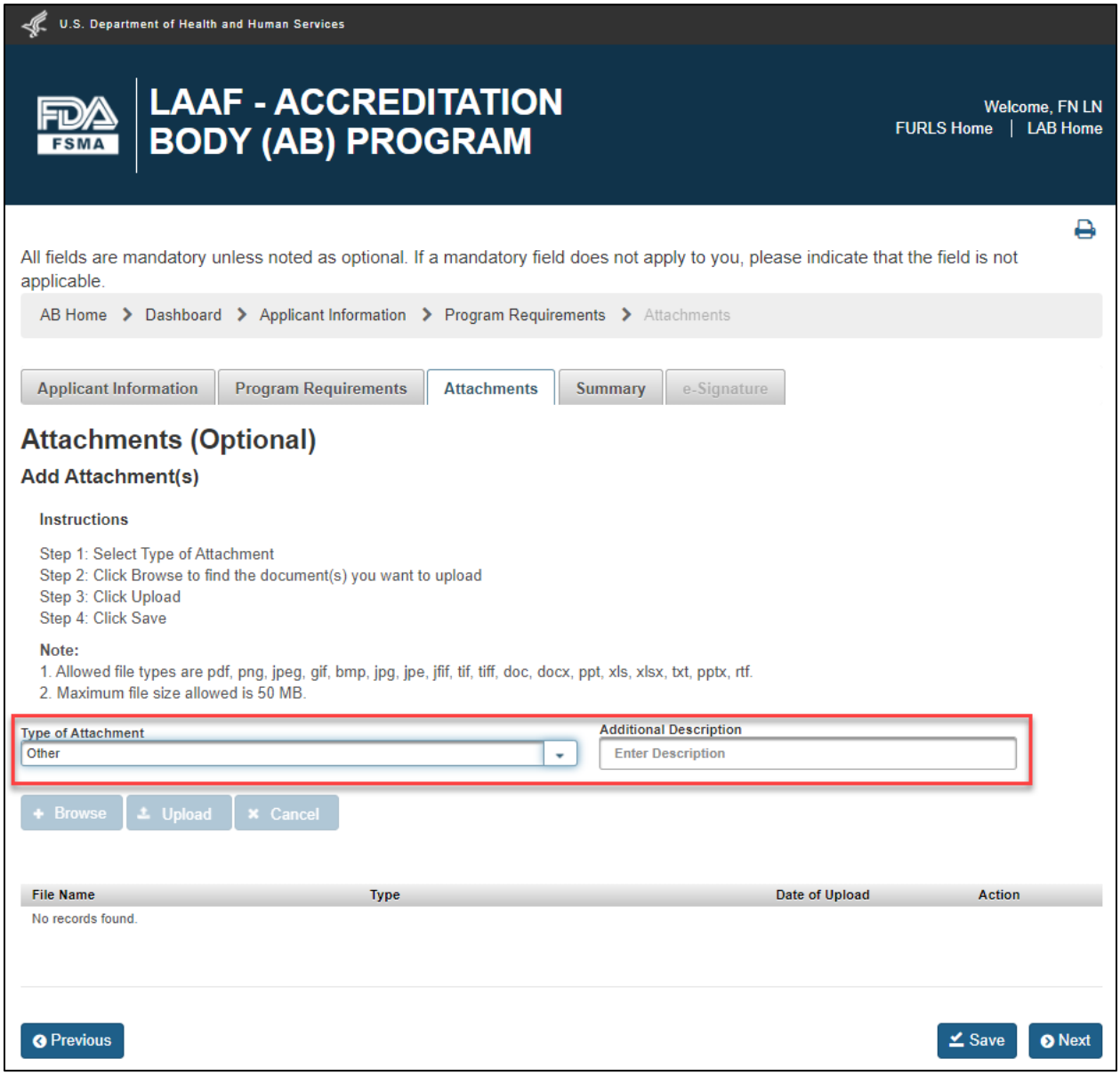


Figure 4.12: Attachments Page

When a file has been selected, the “Upload” and “Cancel” buttons will become enabled. Clicking the “Upload” button will complete the upload; clicking the “Cancel” button will cancel the upload process.

Upon a successful upload, the system will disable all three buttons. A confirmation message will display the file name in the table with the following four columns (Figure 4.13):

- File Name
- Type
- Date of Upload
- Action

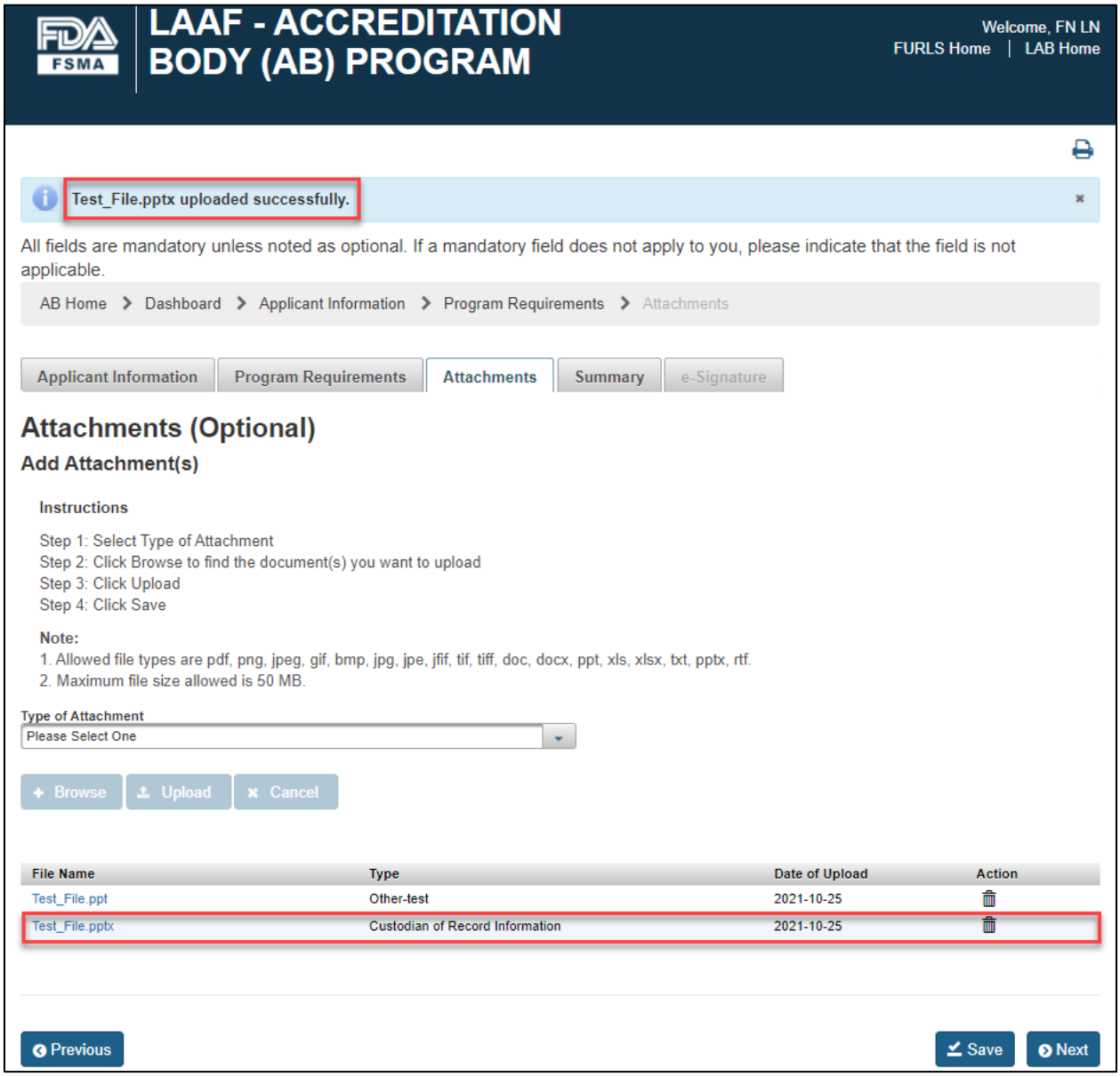


Figure 4.13: Confirmation of Successful Upload

To remove the attachment, the AB applicant can click the trash/delete icon in the "Action" column of the table. The system will display a confirmation message (Figure

4.14).

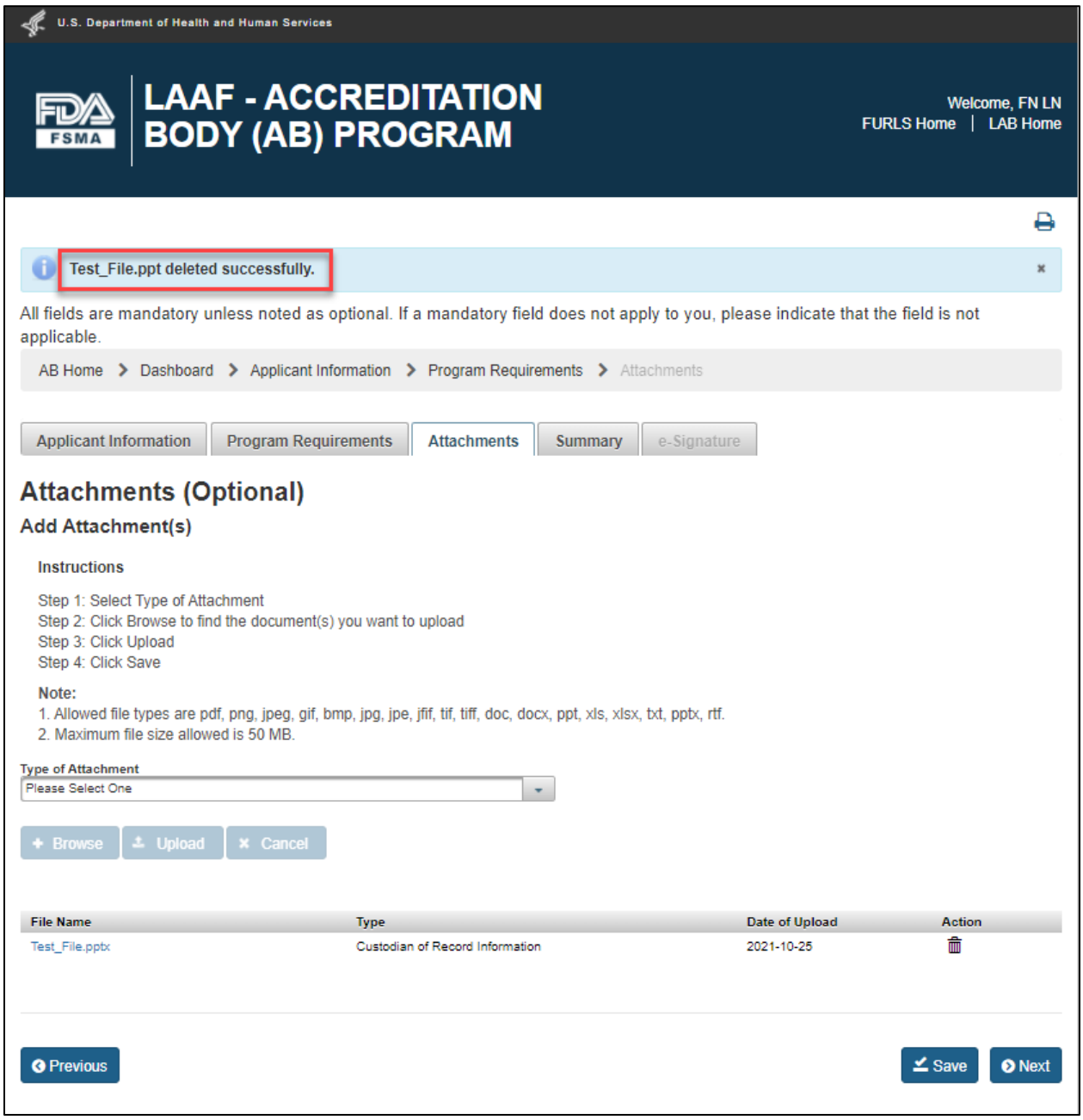


Figure 4.14: Confirmation of Successful Deletion

After all the files have been uploaded, the AB applicant can click the “Save” button. The applicant will then click the “Next” button or the “Summary” tab to proceed to the “Summary” page.

The “Summary” page allows the AB applicant to review all application data for accuracy prior to its submission (Figure 4.15).

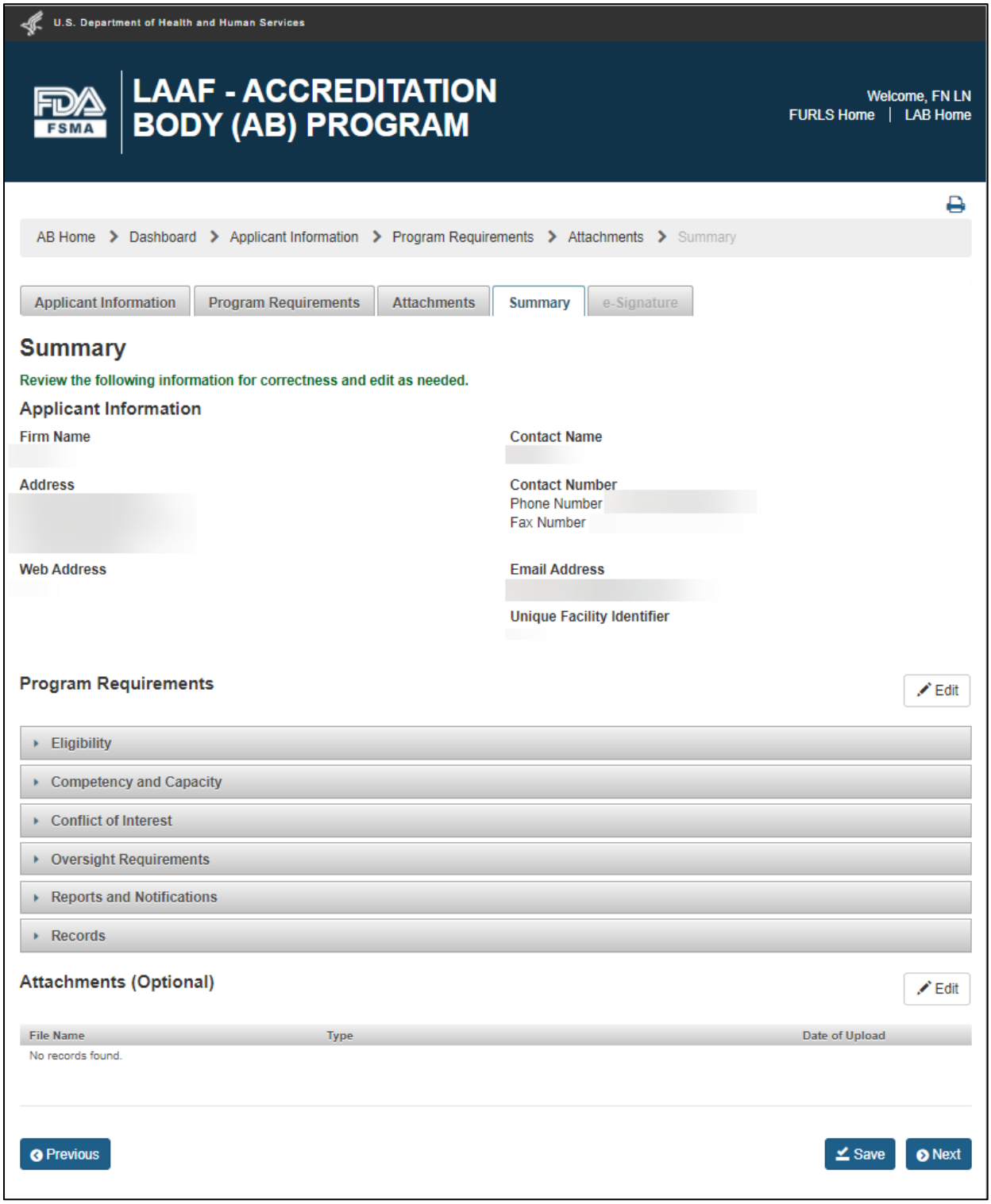


Figure 4.15: Summary Page

After reviewing the “Summary” page, the AB applicant will click the “Next” button. The system will validate all the information entered. If the validation fails, the system will display error message(s) (Figure 4.16).

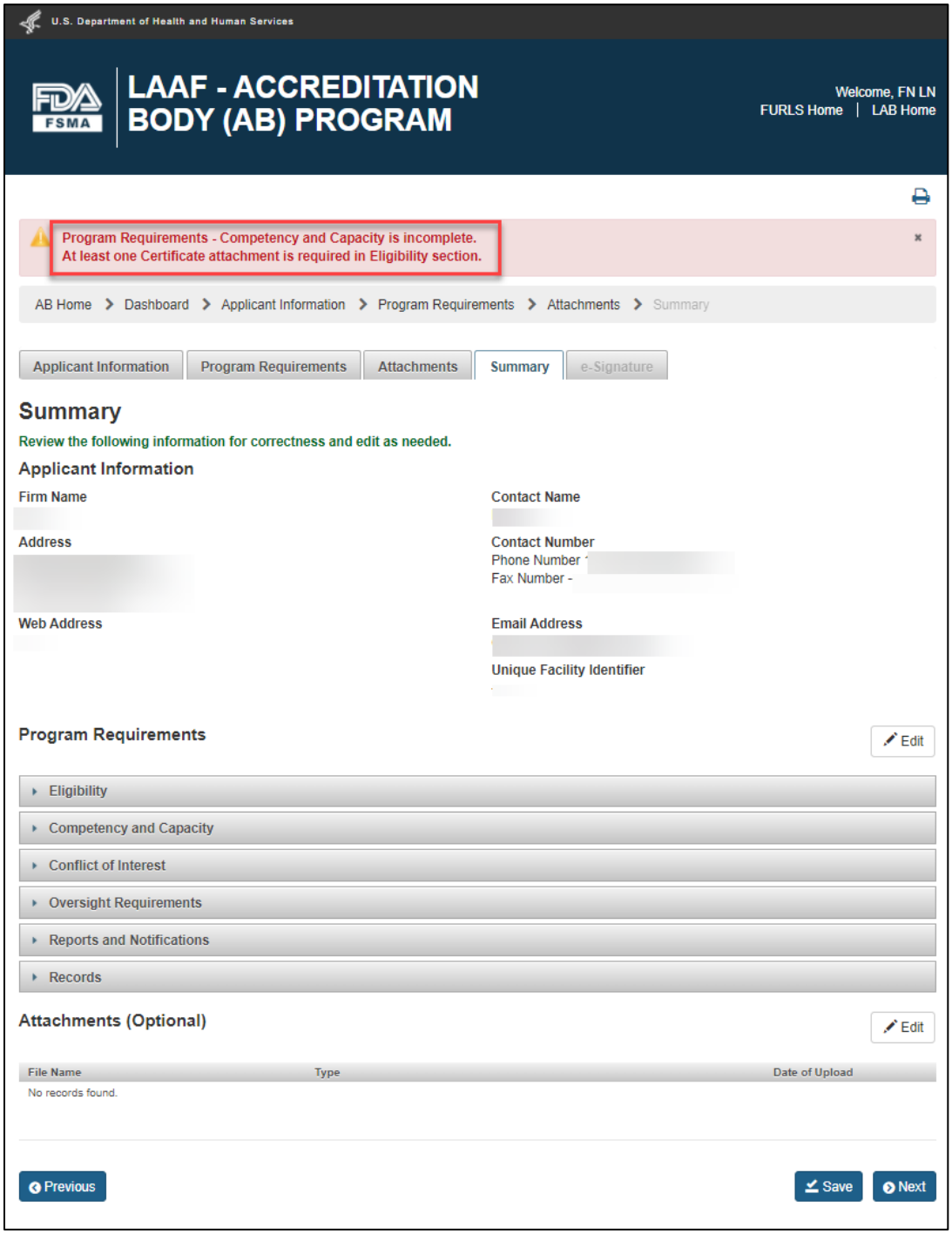


Figure 4.16: Error Messages on Summary Page

The AB applicant must correct any identified issue(s) to be able to submit the application.

After correcting the error(s,) the applicant will click the “Save” button to preserve the changes made.

If the system validation on the “Summary” page is successful, the system will navigate to the “e-Signature” page (Figure 4.17).

The applicant will follow the directions provided on the “e-Signature” page, complete the following user entry fields, and then click the “Submit” button:

- **Checkbox** (unchecked by default) **–** “I certify that the information in the submission is true and accurate and that I am authorized to submit the information to FDA. Further, I certify that the accreditation body will comply with all requirements for recognized accreditation bodies under 21 CFR part 1, subpart R while recognized.”
- **Name of Submitter –** The first and last name of the submitter.
- **Title of Submitter –** The title of the submitter.

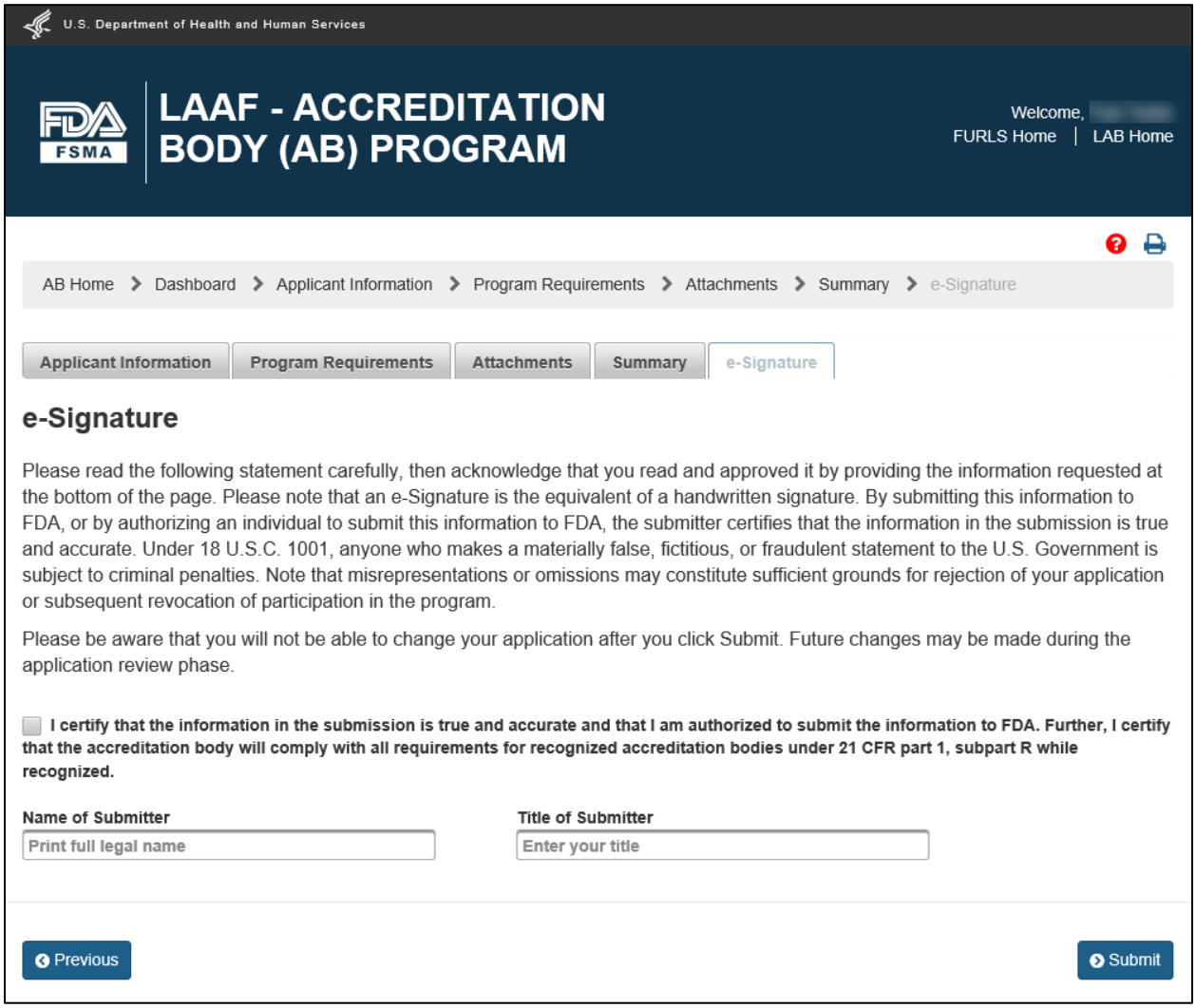


Figure 4.17: e-Signature Page

The system will display a confirmation message on the page after the application has been submitted (Figure 4.18).

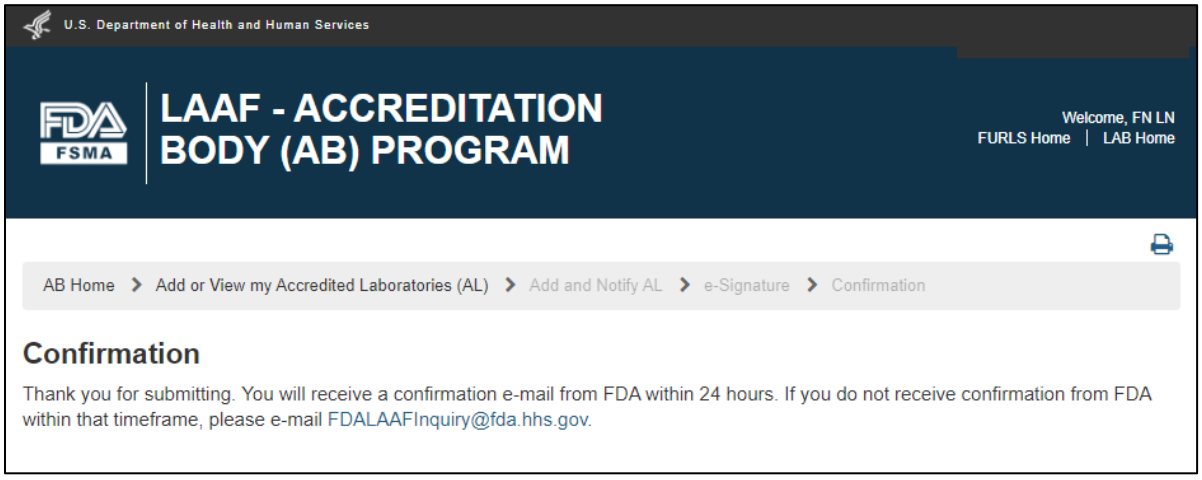


Figure 4.18: Confirmation Message

If the AB user wishes to view the status of their application, they can select the "View/Edit my application for recognition" link from the navigation menu on the "AB Home" page (Figure 4.19).

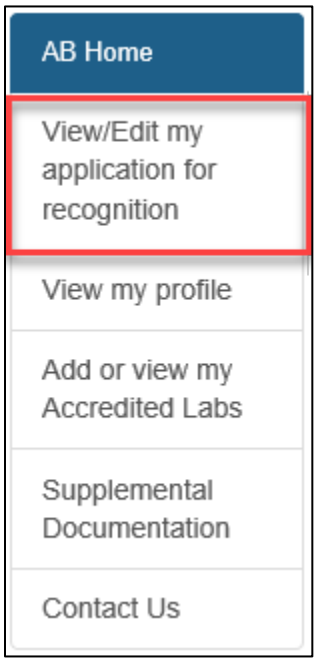


Figure 4.19: Navigation Menu

The system will display the "Application Information" page. The application status will update from "Pending," to "Transmitting," to "Submitted" (Figure 4.20).

- **Pending –** Interim status to indicate the application is undergoing a virus scan of any attachments.
- **Transmitting –** Interim status to indicate the application has passed the virus scan and is in the process of being downloaded/transmitted to FDA.
- **Submitted –** Indicates the application has been successfully downloaded/transmitted to FDA.

Note: “Pending” and “Transmitting” statuses may remain for up to (approximately) 15 minutes each before updating to the "Submitted" status.

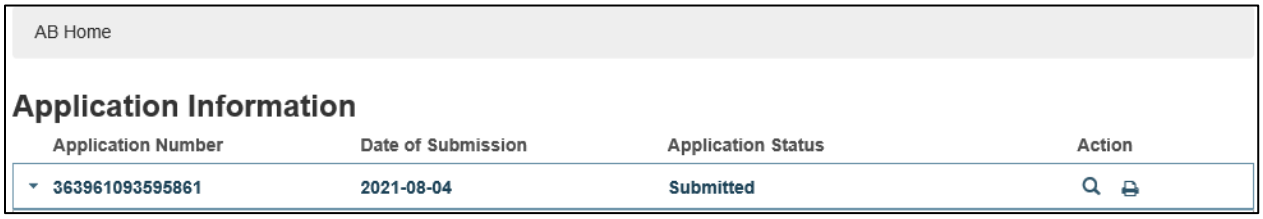


Figure 4.20: Application Status

5 Application Returned for Action

FDA may return an application if it determines additional information is needed. FDA will notify the applicant of any insufficiencies and information needed to address the insufficiencies.

Note: The AB user must submit the requested information before FDA will continue the application review process. When the application has been returned with additional information, the application status will display on the “Application Information” page as “In-Process.”

The submission status will be displayed as follows:

- **Returned for Action –** For regulatory requirements in question.
- **Under Review –** For all other regulatory requirements.

The status of all other program requirements criteria will display as “Under Review” (Figure 5.1).

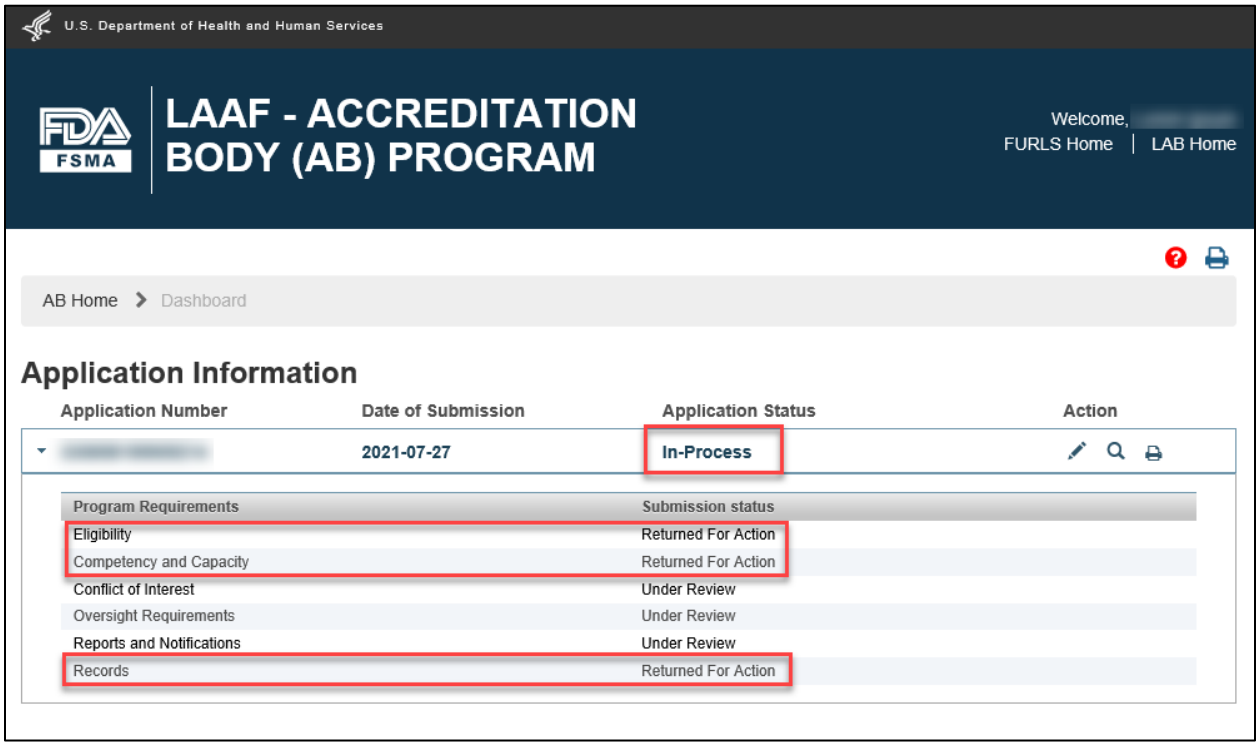


Figure 5.1: Application In-Process/Returned for Action Submission Statuses

To address the information request from FDA, the AB user will click the pencil/edit icon in the “Action” column on the “Application Information” page (Figure 5.2).

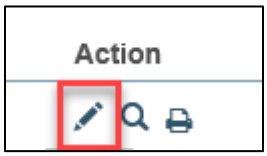


Figure 5.2: Edit Icon

The system will open the “Program Requirements” page (Figure 5.3). “Program Requirements” criteria displayed with red flags associated with them indicate a response is needed. The AB user will navigate to the red-flagged regulatory requirement(s) to provide the required answers, information, and/or attachments.

The AB user will click on the dropdown to expand the section. The user will then click on the element under the flagged regulatory requirement to view the question(s) from FDA in the “Review Comments” section.

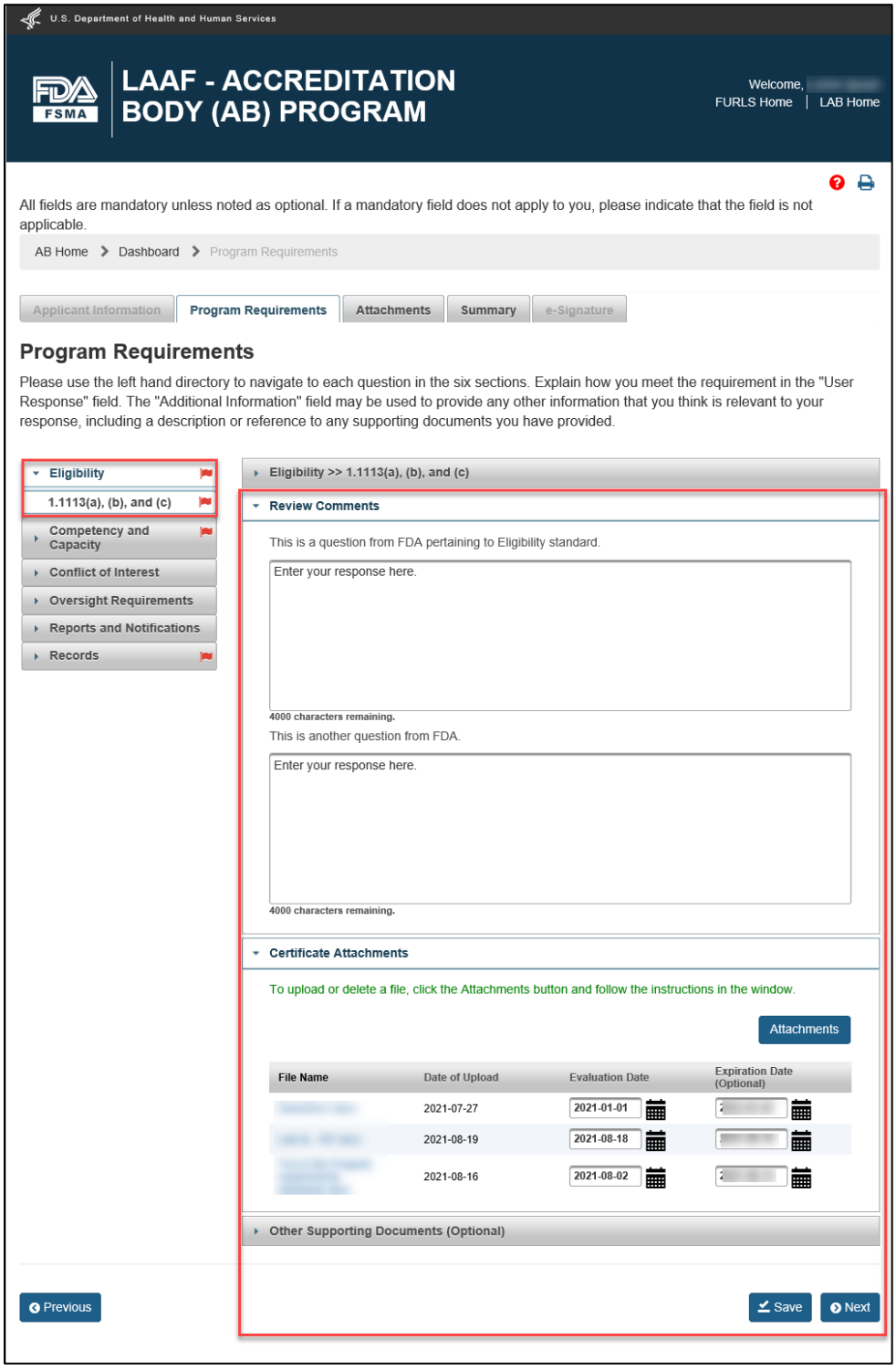


Figure 5.3: Eligibility Element with a Question from FDA

After answering all of the questions on the “Program Requirements” page, the AB applicant can add more documents on the “Attachments” page, if needed. They may then proceed to the “Summary” page to review and verify the information entered before the application’s re-submission.

When AB users select the regulatory requirement(s) for re-submission and click the “Next” button on the “Summary” page, the system will validate the information. If all system validations pass, the system will navigate to the “e-Signature” page (Figure 5.4). If the validation fails, the system will post error message(s) relevant to the issue(s) in need of correction before the application can be resubmitted.

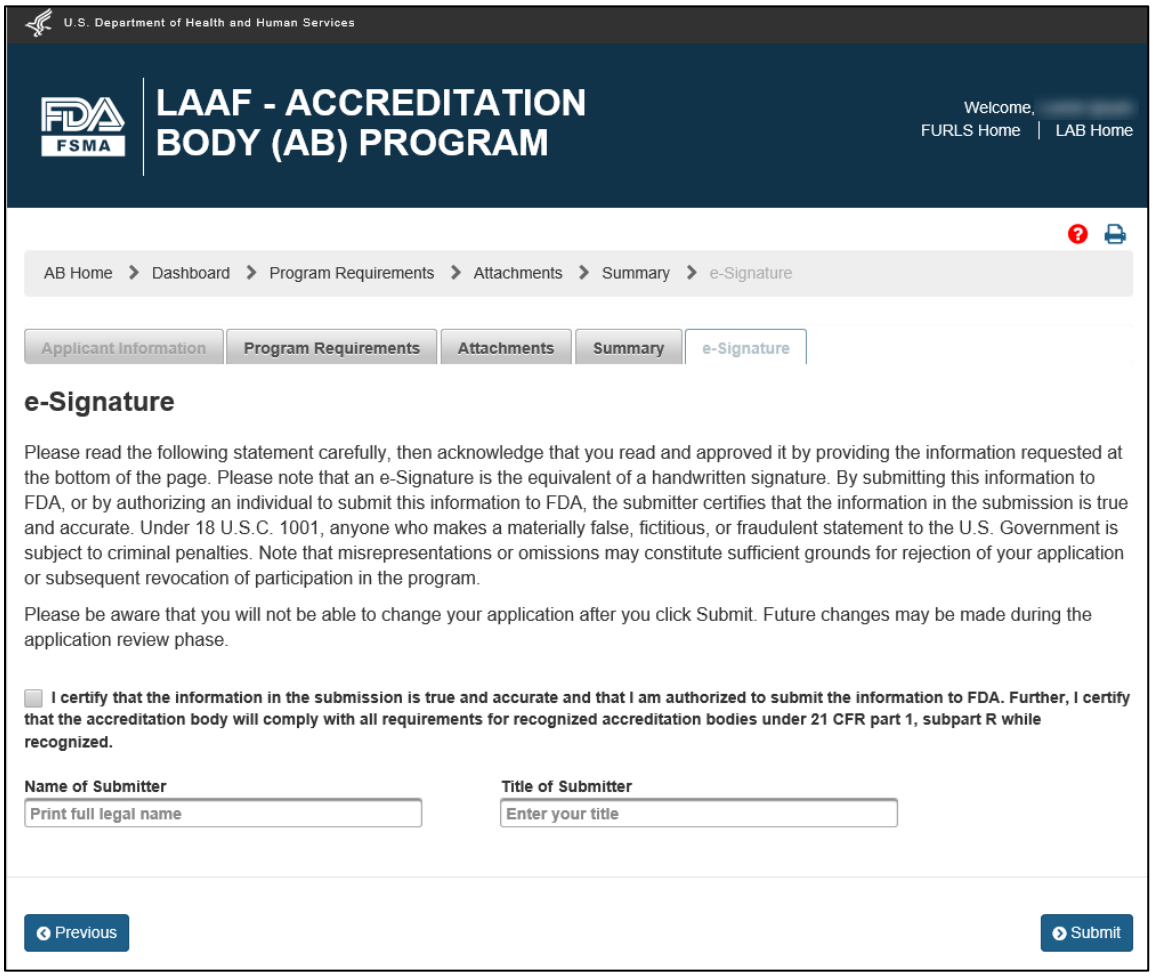


Figure 5.4: e-Signature Page

Once the user clicks “Submit” from the “e-Signature” page, the system will display a “Confirmation” message (Figure 5.5.) The applicant will also receive an e-mail

confirmation.

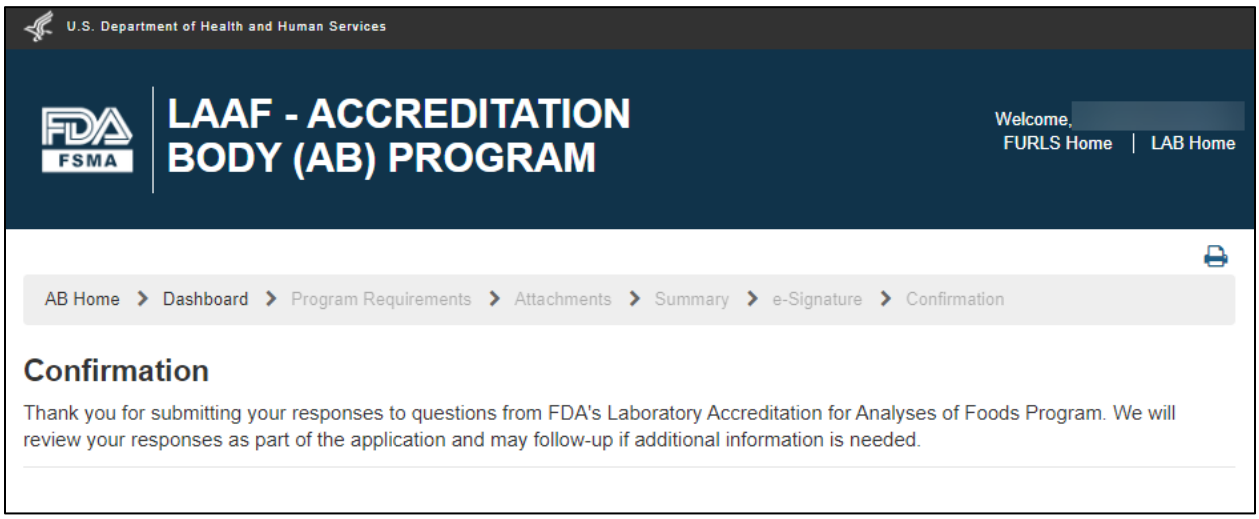


Figure 5.5: Confirmation Message

After the application has been resubmitted, the “Application Status” will remain “In-Process” until FDA has made a decision regarding the application.

6 Application Decision by FDA

When FDA has made a decision regarding the AB's application an email notification will be sent to the AB applicant, notifying them of the decision.

6.1 Application Approval

If FDA approves the application, the AB applicant will receive the following email notification (Figure 6.1):

Subject: FDA's Laboratory Accreditation for Analyses of Foods Program - Recognition Approved

We are pleased to inform you that you have been accepted into FDA's Laboratory Accreditation for Analyses of Foods Program and are now a recognized Accreditation Body (AB) with FDA.

Your acceptance into the program is valid from DEC 10, 2021. Any work you perform under this recognition is subject to the requirements under 21 CFR Part 1, Subpart R. All notifications must be made through your FDA Online Account Administration (OAA) account.

We look forward to working with you, thank you for your participation in FDA's Laboratory Accreditation for Analyses of Foods Program.

For other questions please contact us at FDALAAFInquiry@fda.hhs.gov.

Laboratory Accreditation for Analyses of Foods Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

Figure 6.1: Application Approval Email from FDA

The "Recognition Status and Application Status will display on the "Application Information" page will display as "Recognized" (Figure 6.2).

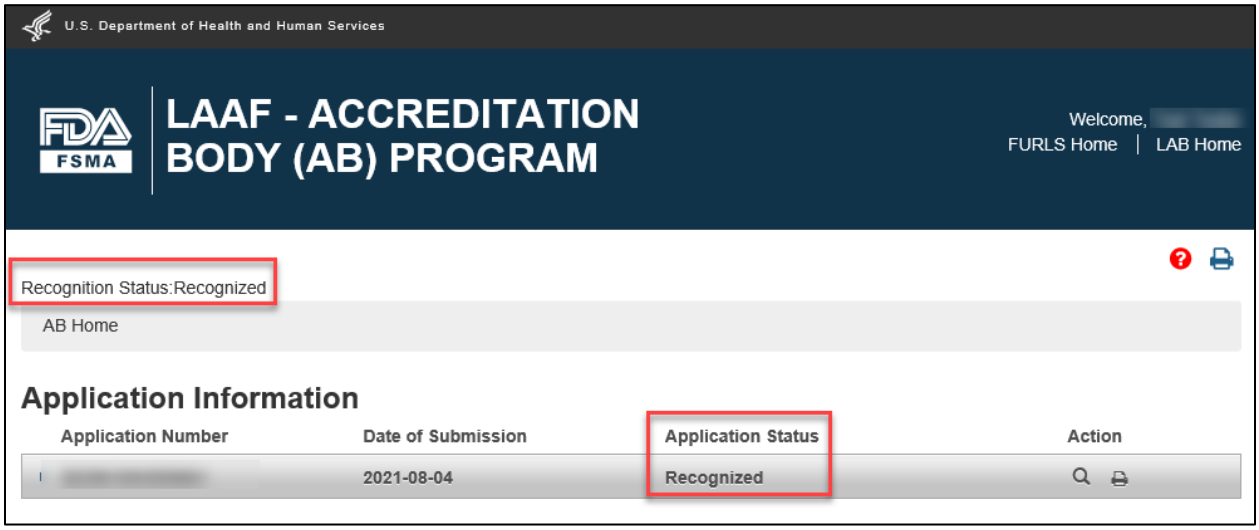


Figure 6.2: Application Recognized Status

Once recognized, the applicant will have the full privileges of a recognized AB, including the ability to add a LAAF-accredited laboratory, and submit supplemental documents to FDA. The related features items will display on the “AB Home” page (Figure 6.3).

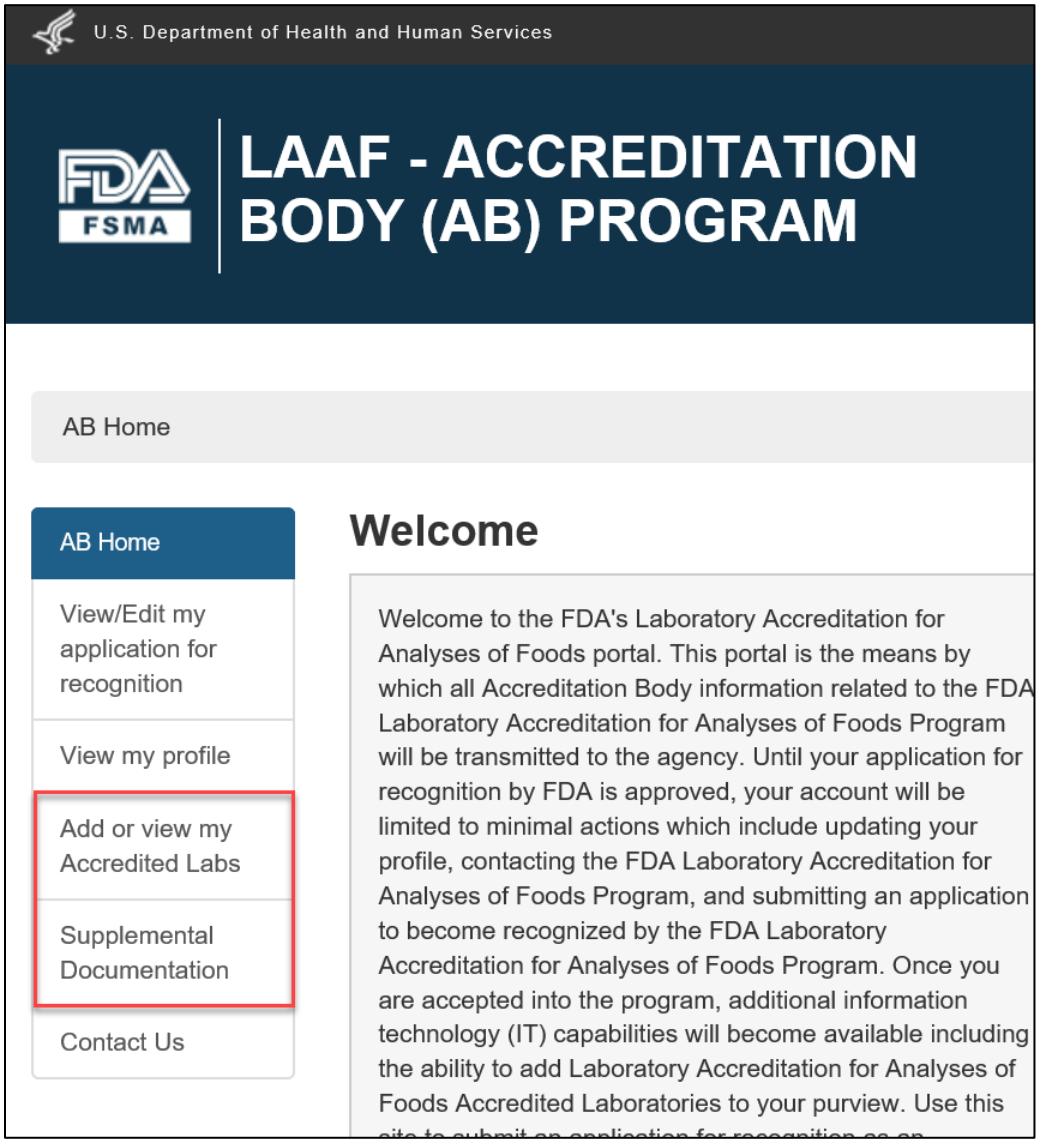


Figure 6.3: Additional Features Displayed to Recognized AB

6.2 Application Denial

If FDA denies the application for recognition, the AB applicant will receive the following email notification from FDA (Figure 6.4):

Subject: FDA's Laboratory Accreditation for Analyses of Foods Program - Decision on your Application

Thank you for your interest in participating in FDA's Laboratory Accreditation for Analyses of Foods Program.

The Agency has reviewed your application and has determined that your program does not meet recognition requirements for the following reasons: [redacted]

As outlined in 21 CFR 1.1171, you may seek reconsideration of FDA's decision to deny your application no later than 10 business days after the date of this issuance. The request to reconsider must be signed by accreditation body, as appropriate, or by an individual authorized to act on its behalf. Your request must include a response to the reasons for denial stated in this issuance. The request for reconsideration must be made by submitting a new application through your FDA Online Account Administration (OAA) account.

For other questions please contact us at FDALAAFInquiry@fda.hhs.gov.

Laboratory Accreditation for Analyses of Foods Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

Figure 6.4: Application Denial Email from FDA

The “Application Status” will display on the “Application Information” page as “Denied” (Figure 6.5).

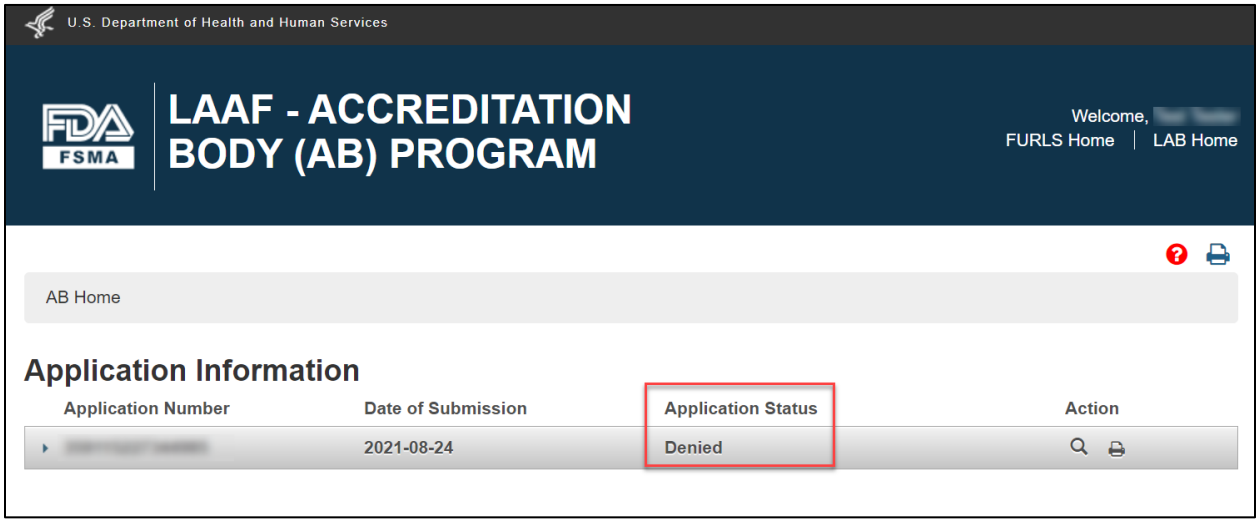


Figure 6.5: Application Denied Status

As stated in the email notification, the applicant can create a new application and submit it to FDA. When the AB user logs into the LAAF AB system after receiving the application denial notification from FDA, the system will display the “Apply for Recognition” menu option in the navigation menu on the “AB Home” page (Figure 6.6).

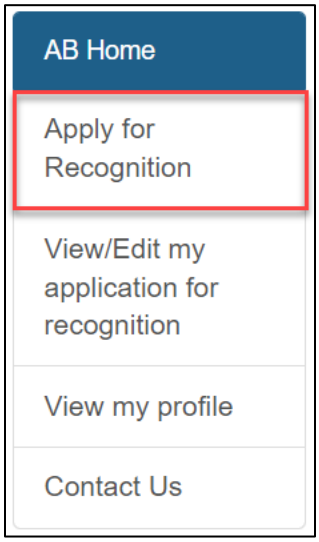


Figure 6.6: Navigation Menu

When the AB user clicks the “Apply for Recognition” link, the system will display the “Application Pre-fill Option” for a new application with “Yes” and “No” radio buttons (Figure 6.7).

If the AB user selects “Yes,” the system will navigate to the “Applicant Information” page of a new application. When the AB user proceeds to the “Program Requirements” page, all the responses provided in the previous application will be pre-filled in the new application.

Note: All pre-filled responses are editable. In addition, any attachments (either from the “Program Requirements” or “Attachments” pages) will be pre-filled from the previous application as well.

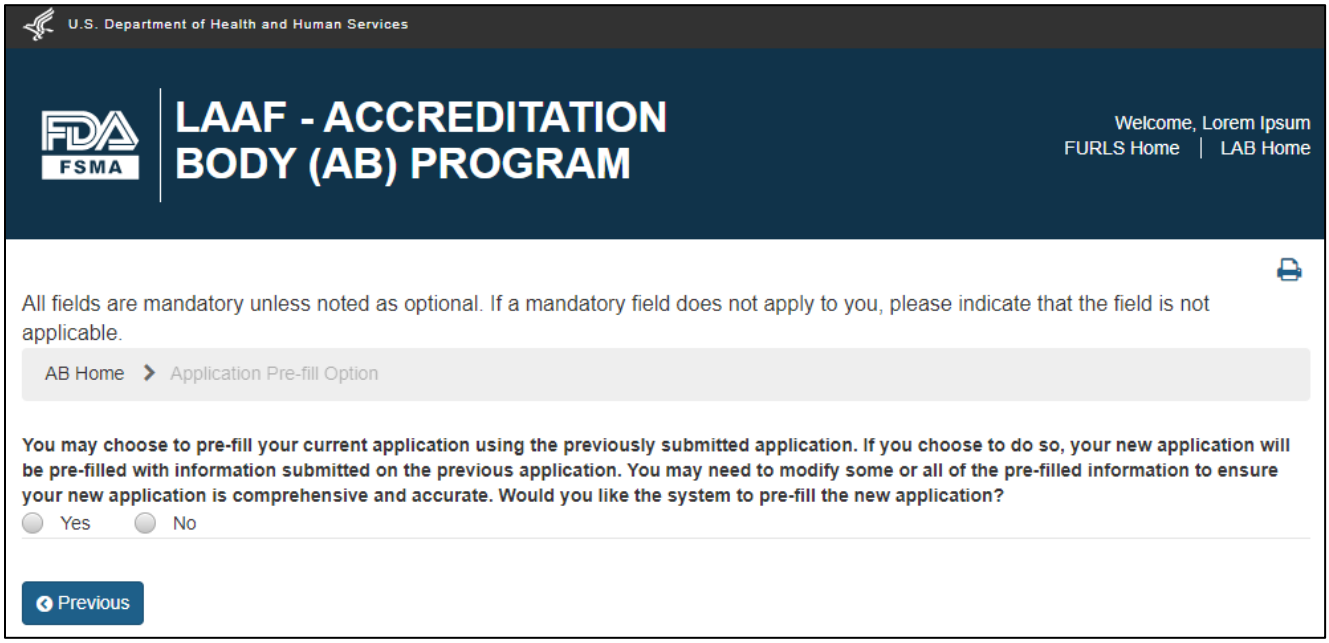


Figure 6.7: Application Pre-fill Option

The AB user can delete any pre-filled attachments they do not wish to submit in the new application by clicking the trash/delete icon where the attachment is listed (Figure 6.8).

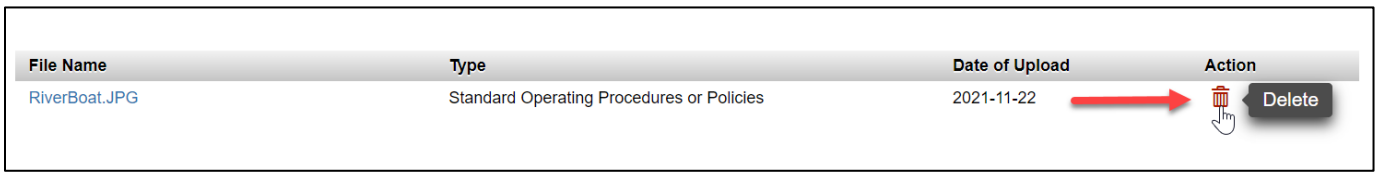


Figure 6.8: Trash/Delete Icon

The AB applicant will follow the “Apply for Recognition” workflow described in Chapter 4 – Apply for Recognition as an Accreditation Body (AB), to submit the new application.

If the AB user selects the radio button for “No,” the AB user will click the “Next” button from the “Application Pre-fill Option” page and navigate to the “Applicant Information” page of the application (Figure 6.9). When the AB user proceeds to the “Program Requirements” and “Attachments” pages, no data will be pre-filled. The AB user can follow the instructions in Chapter 4 – Apply for Recognition as an Accreditation Body (AB), to complete and submit the application.

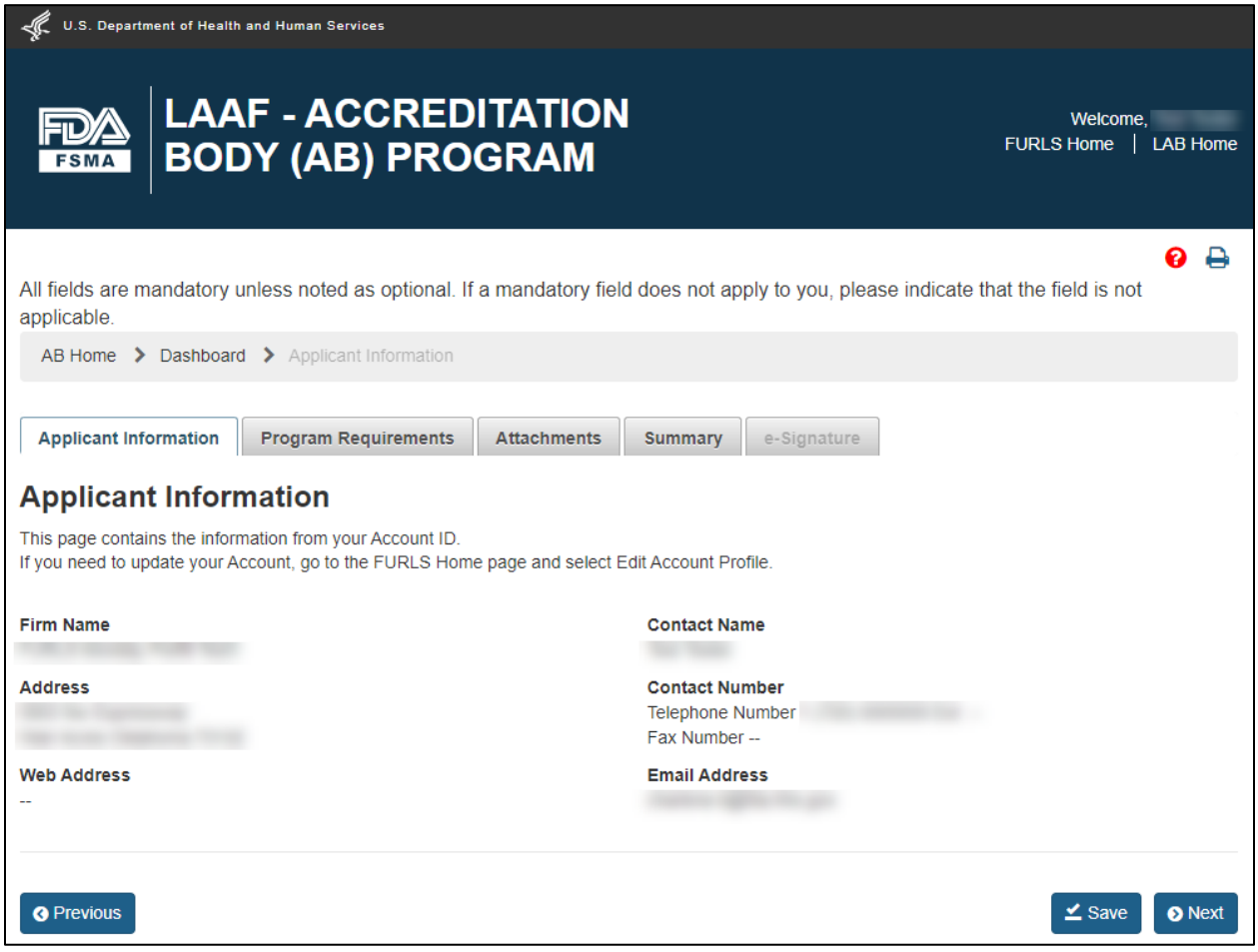


Figure 6.9: New Application Pages

7 Add or View Accredited Laboratories (AL)

A recognized AB can add a LAAF-Accredited Laboratory (AL). To add and accredit an AL, the AB user will select the “Add or View my Accredited Laboratories (AL)” link from the navigation menu on the “AB Home page” (Figure 7.1).

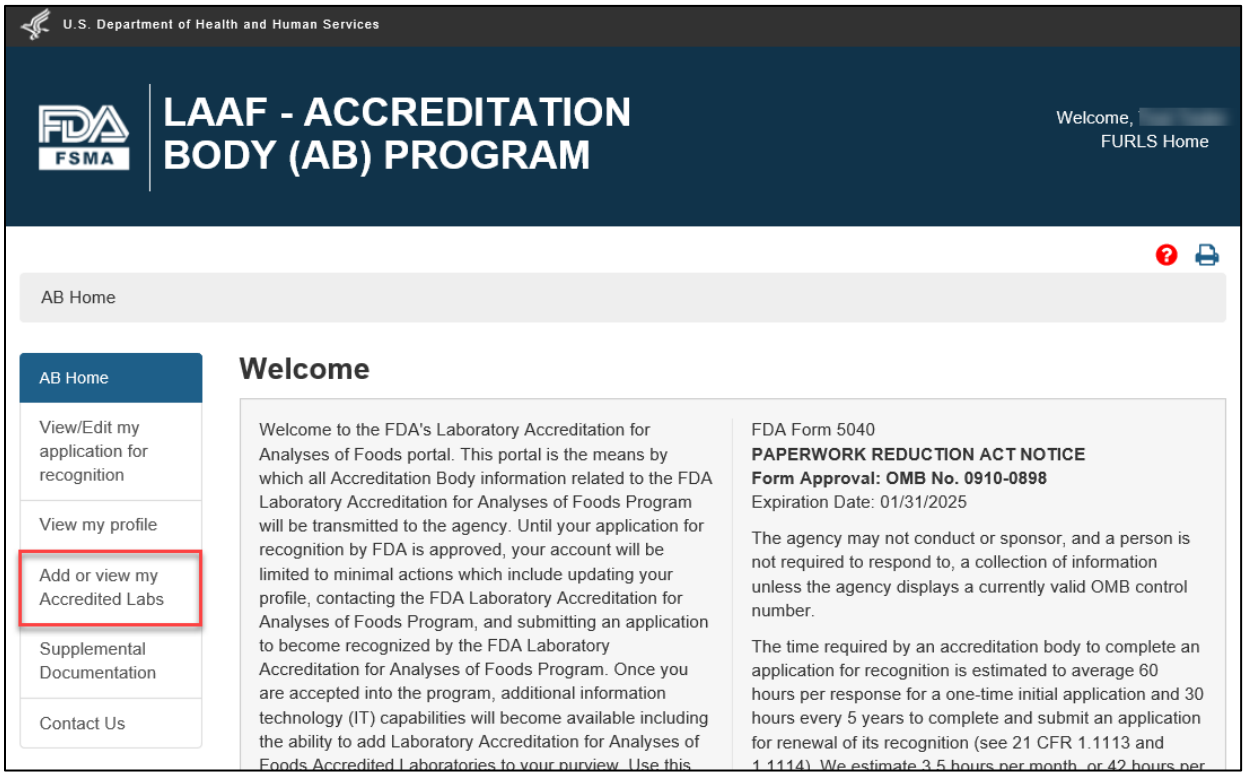


Figure 7.1: Navigation Menu

The system will navigate to the “Add or View my Accredited Laboratories (AL)” page with the following page elements displayed (Figure 7.2):

- Instructional text to add or view an Accredited Lab.
- Table of existing Accredited Labs (displays the message “No records found” if there are no existing ALs under the AB user).
- “Previous” and “Add AL” buttons.

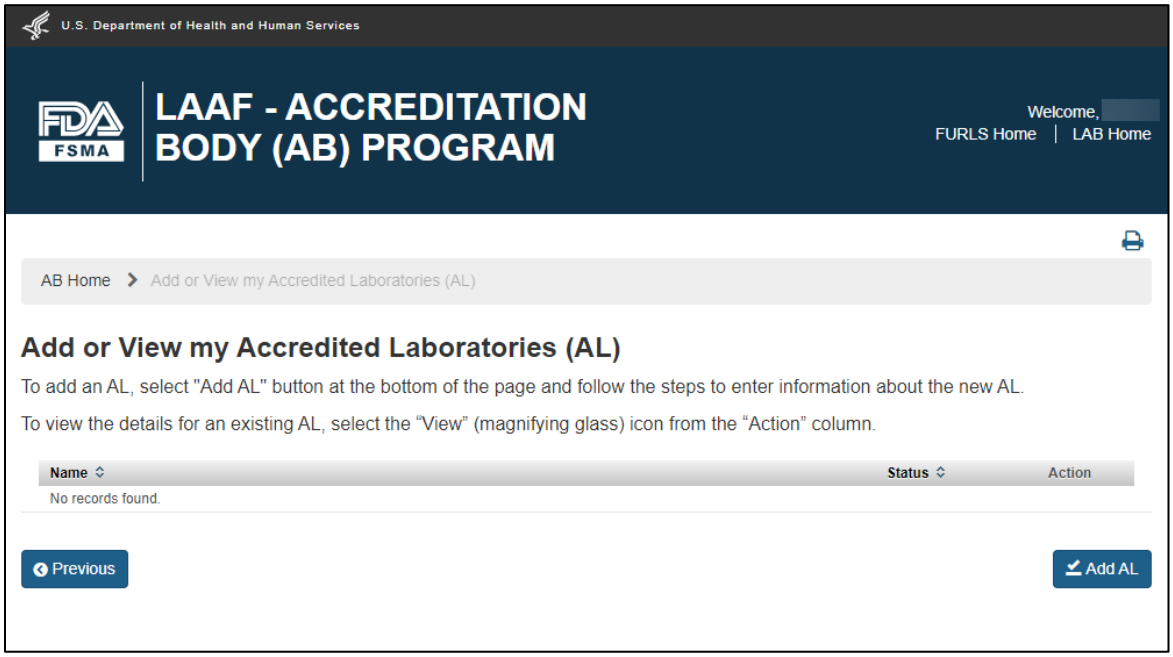


Figure 7.2: Add or View my Accredited Laboratories (AL) Page

To add an AL, the AB user will click the “Add AL” button.

The system will display the “Add Accredited Laboratories (AL)” page and display instructions regarding how to add an AL (Figure 7.3). The instructional text can be expanded and collapsed using the “…more/less” link.

The page contains four sections, contained within accordion panels, which can be expanded to display their content:

- Accredited Laboratories (AL) (expanded by default)
- Accreditation Information
- Certification Information
- Disciplines, Analyses, and Test Methods

There are two navigational buttons at the bottom of the page, “Previous” and “Next.”

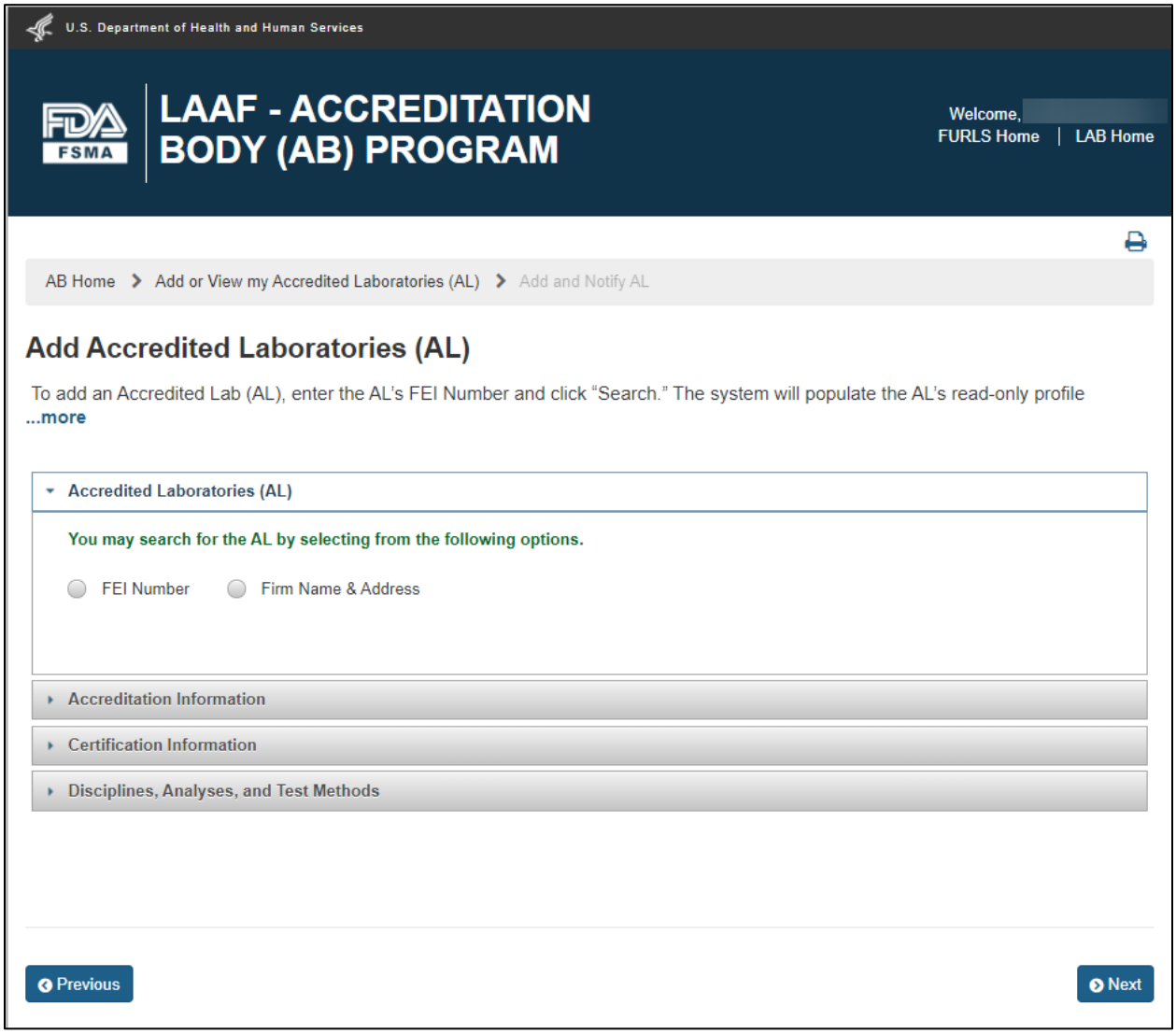


Figure 7.3: Add Accredited Laboratories (AL) Page

7.1 Accredited Laboratories (AL) Section

The “Accredited Laboratories” section contains instructional text and radio buttons for “FEI Number” and “Firm Name & Address” to allow the AB user to select one of those two possible methods to search for an AL (Figure 7.4).

****Important:** LAAF accreditation is based on individual lab location, not by a parent or corporate lab. If a lab has more than one location, the AB user should enter the FEI number or name and address of the physical location to be accredited.

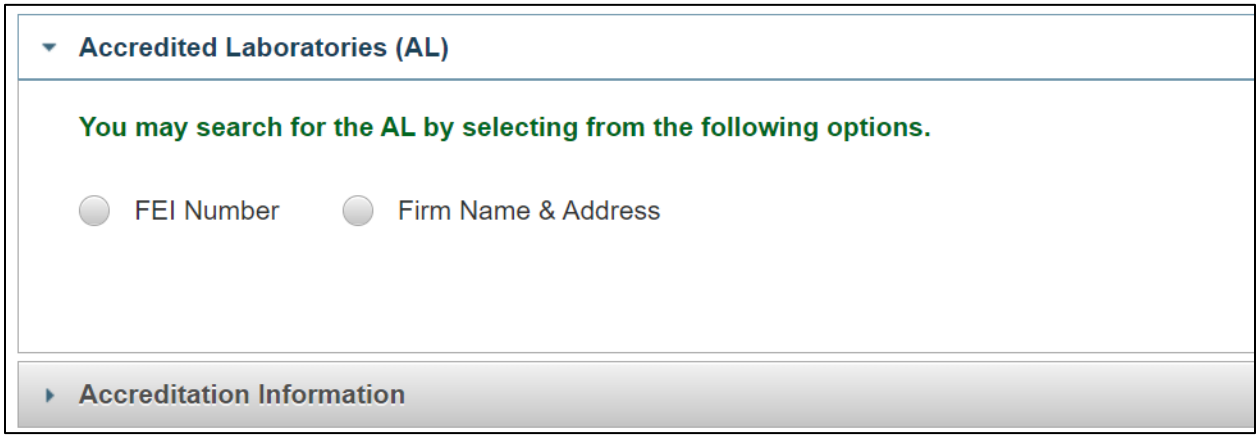


Figure 7.4: Accredited Laboratories (AL) Section

Note: The AB user can change their selection by selecting the radio button for the alternate option. If the AB user changes their selection at any point, the system will display a warning message in a pop-up window (Figure 7.5).

If the user selects “Yes” from the pop-up, the system will dismiss the pop-up and change to the new selection. If the user selects “No,” the pop-up will be dismissed and the original selection will be maintained.

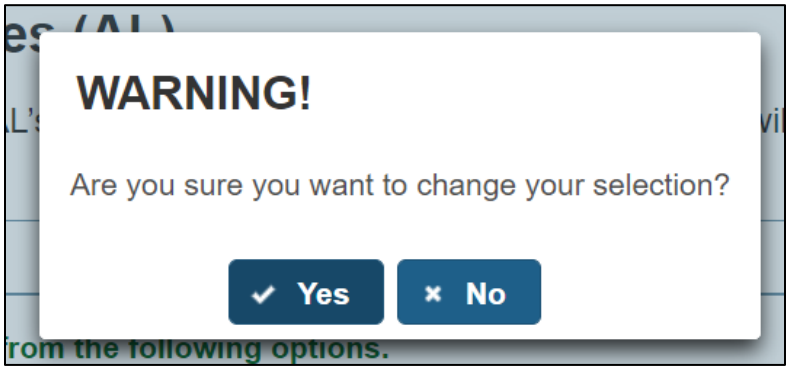


Figure 7.5: Warning Pop-Up Message

7.1.1 Search for the AL by FEI

To search an AL by its FEI Number, the AB will select the radio button for “FEI Number” in the “Accredited Laboratories (AL)” section. The system will display a user input field and a “Search” button (Figure 7.6).

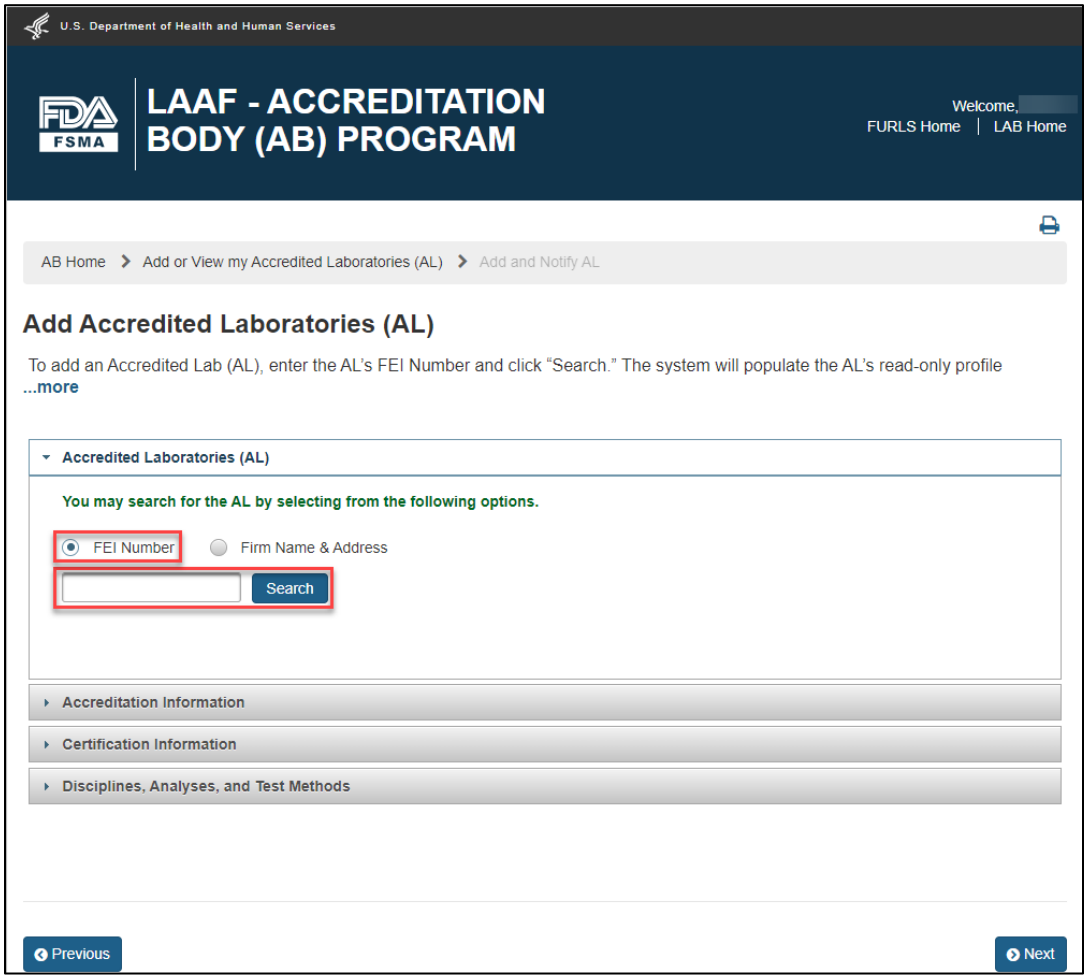


Figure 7.6: Search by FEI Number

The AB user will enter the FEI number in the input field and click the "Search" button.

- If the system finds a match for the FEI number that was searched, the AL's information will be displayed in the fields in the left-hand column within the "Accredited Laboratories (AL)" accordion section (Figure 7.7).
- Additional fields will be displayed in the right column for the AB user to provide the AL's contact information.

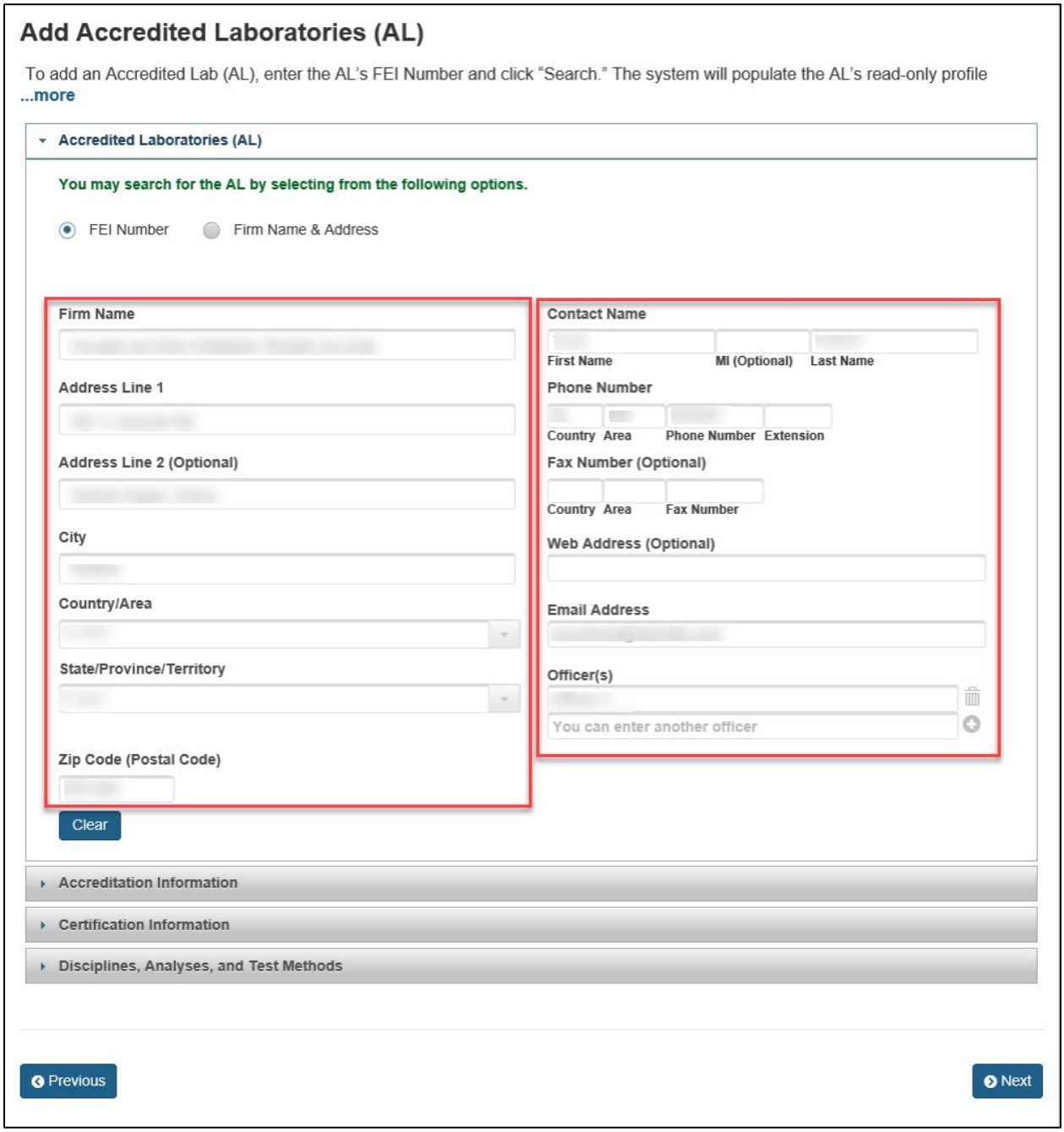


Figure 7.7: FEI Number Search Result

If the system returns a match for the FEI number searched, which belongs to an AL that is already accredited by another AB, the system will pre-fill the AL's information in both the left and right columns within the section. It will also post a message at the top

of the page: “The system has the information below for the AL whose FEI number or Firm Name and Address you searched. If you disagree with the information please contact the AL. The AL may have to update its account profile” (Figure 7.8).

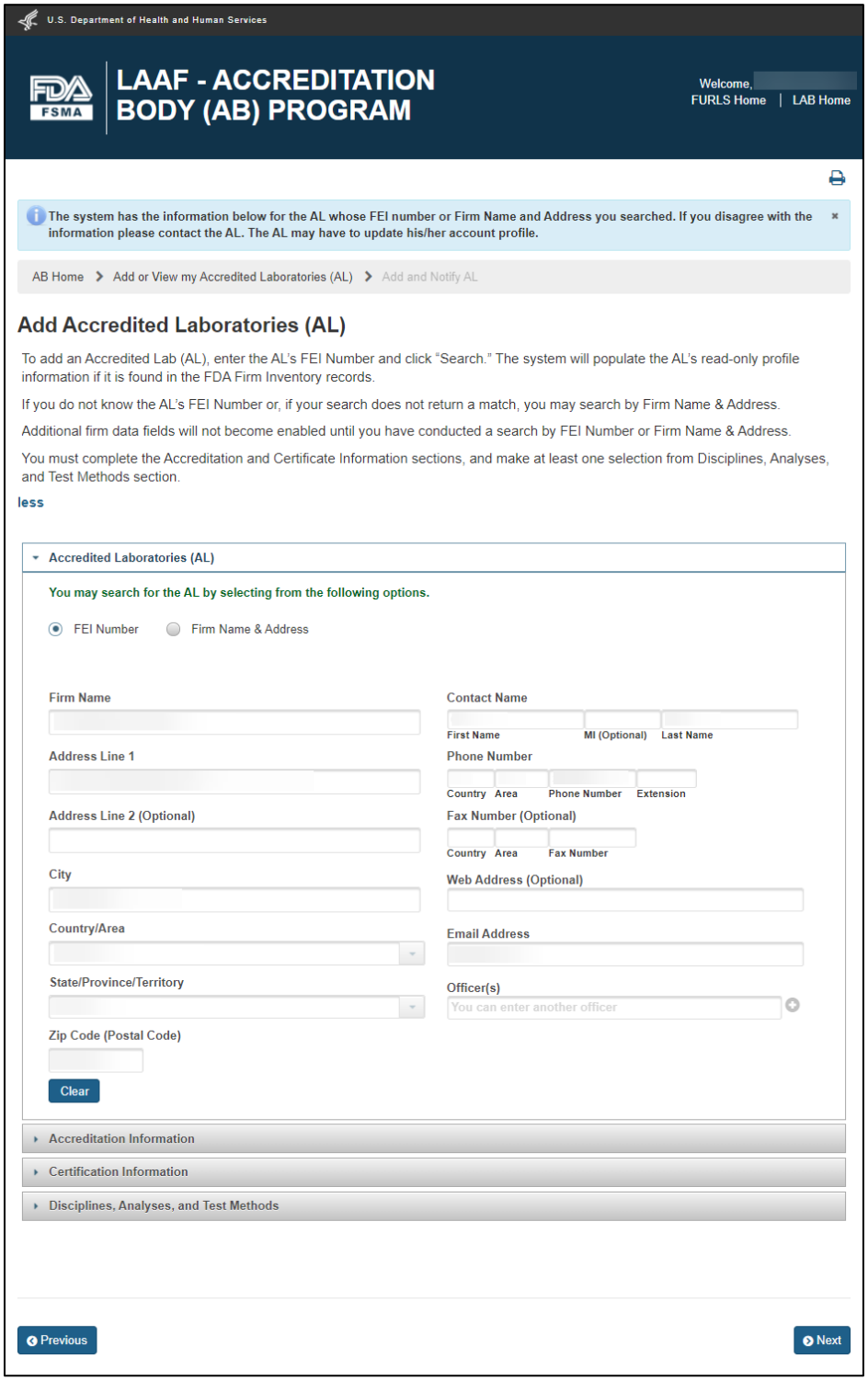


Figure 7.8: FEI Number Search Result of an AL Accredited by Another AB

If the system does not find a match for the FEI number which was searched, the system will display a message at the top of the page: “FEI number <FEI_Number> is invalid.” (Figure 7.9).

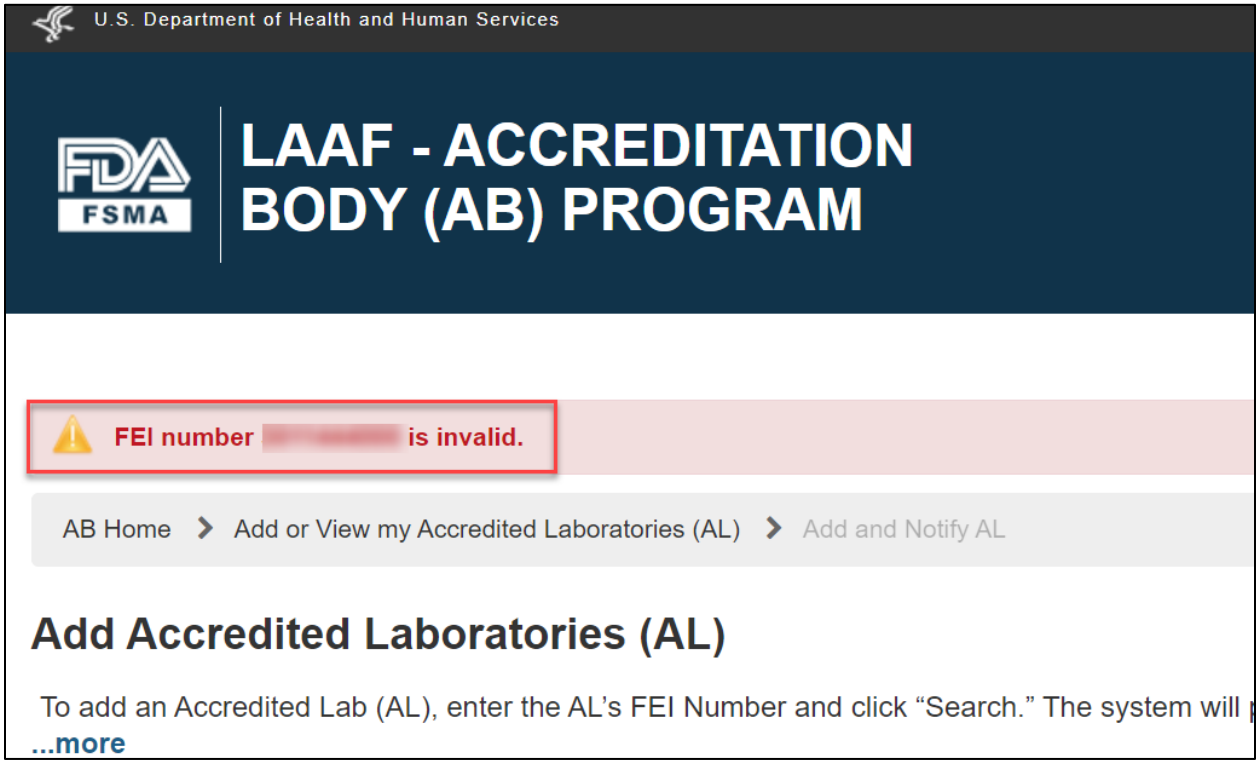


Figure 7.9: Invalid FEI Number Message

If the AB user wishes to execute a new FEI Number search, they can click the “Clear” button at the bottom of the “Accredited Laboratories (AL)” section and remove all data displayed in the fields. The system will post the warning message: “WARNING! You are about to clear all data in this section. Are you sure you want to proceed?” The users may respond by clicking either the “Yes” or “No” buttons (Figure 7.10).

If the user selects “Yes,” the system will remove all data returned from the search results and display the user input field. A “Search” button will display and the AB user can execute a new search by an FEI number.

If the user selects “No,” the system returns to the “Add Accredited Laboratories (AL)” page and maintains the results of the FEI number search.

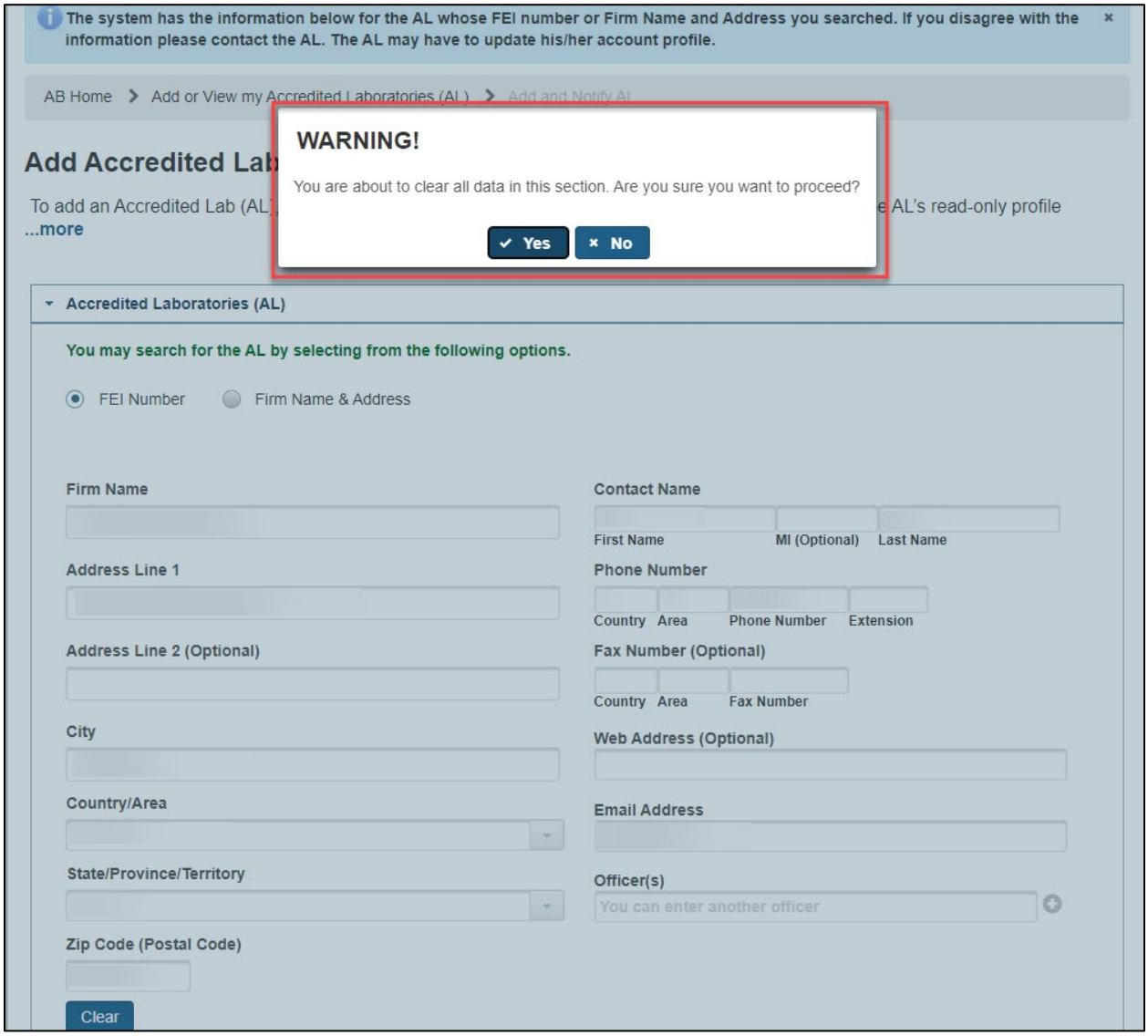


Figure 7.10: Warning Message

7.1.2 Search for the AL by Firm Name & Address

To search an AL by its Firm Name & Address, the AB will select the "Firm Name & Address" button. The system will display the following user input fields, and a "Search" button (Figure 7.11):

- **Firm Name –** The name of the firm.
- **Address Line 1 –** The address where the firm is physically located – this includes the number, street, quadrant, etc.

- **Address Line 2 –** The field to enter additional information about the physical location of the firm, such as a suite or building number; this field is optional.
- **City –** The city where the firm is physically located.
- **Country/Area –** The country/area where the firm is physically located.
- **State/Province/Territory –** The state/province/territory where the firm is physically located.
- **Zip Code (Postal Code) –** The zip code (domestic) or postal code (foreign) where the firm is physically located.

Note: "Zip Code" is only required for U.S. addresses. However, including the postal code may help refine the search results.

Once the AB user has entered the information in the search fields, they can click the "Search" button.

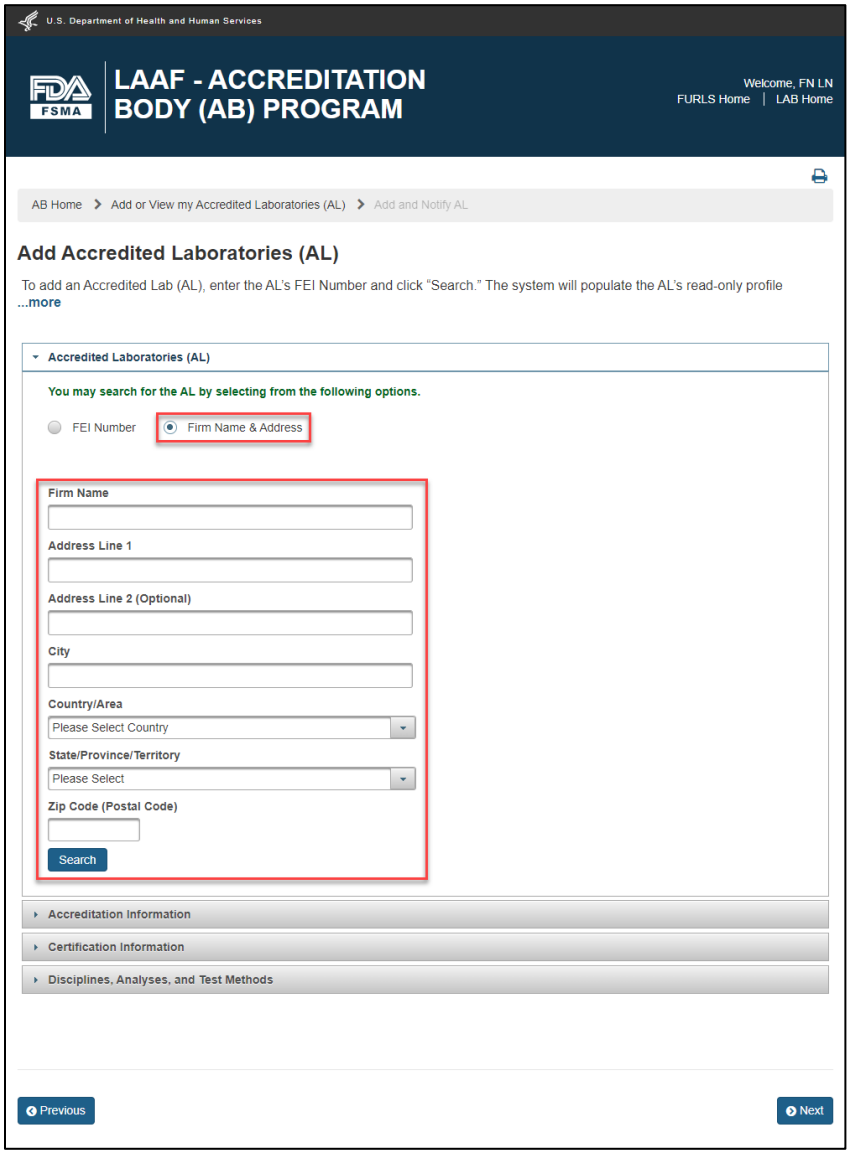


Figure 7.11: Search by Firm Name and Address

The system will perform a search from the FDA Firm Inventory database for the information provided. If the system does not return a match for the searched firm information, the system will display the firm information in the left column – which will remain editable, as well as additional user input fields in the right column (Figure 7.12).

Note: The "Country" code of the phone number will be automatically prefilled when the user selects a country in the "Country/Area" dropdown.

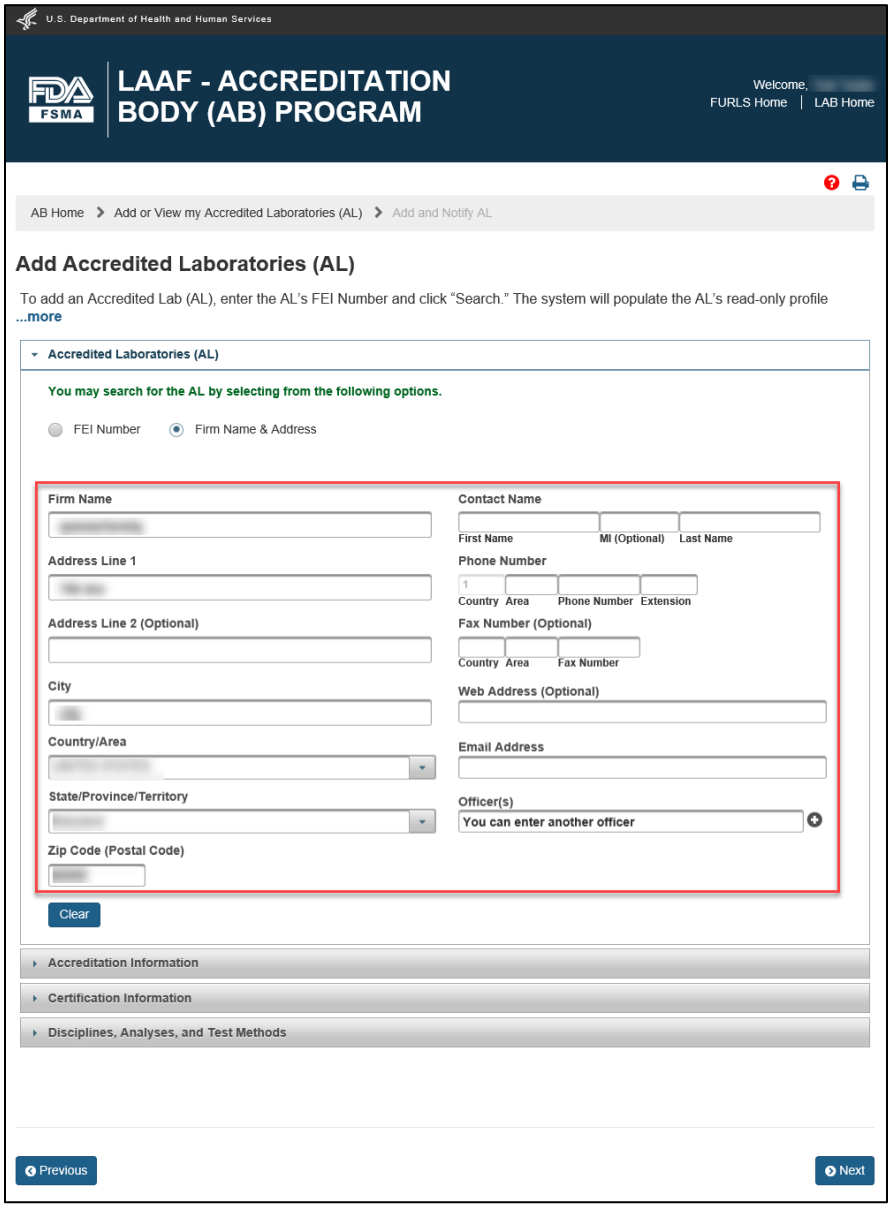


Figure 7.12: No Result Returned for the AL Name and Address

The system will perform a search from the FDA Firm Inventory database for the information provided. If the system returns a single match for the AL's information, the system will display the AL's read-only information in both the left and right columns, with the message "The system has the information below for the AL whose FEI number or Firm Name and Address you searched. If you disagree with the information please contact the AL. The AL may have to update its account profile." (Figure 7.13).

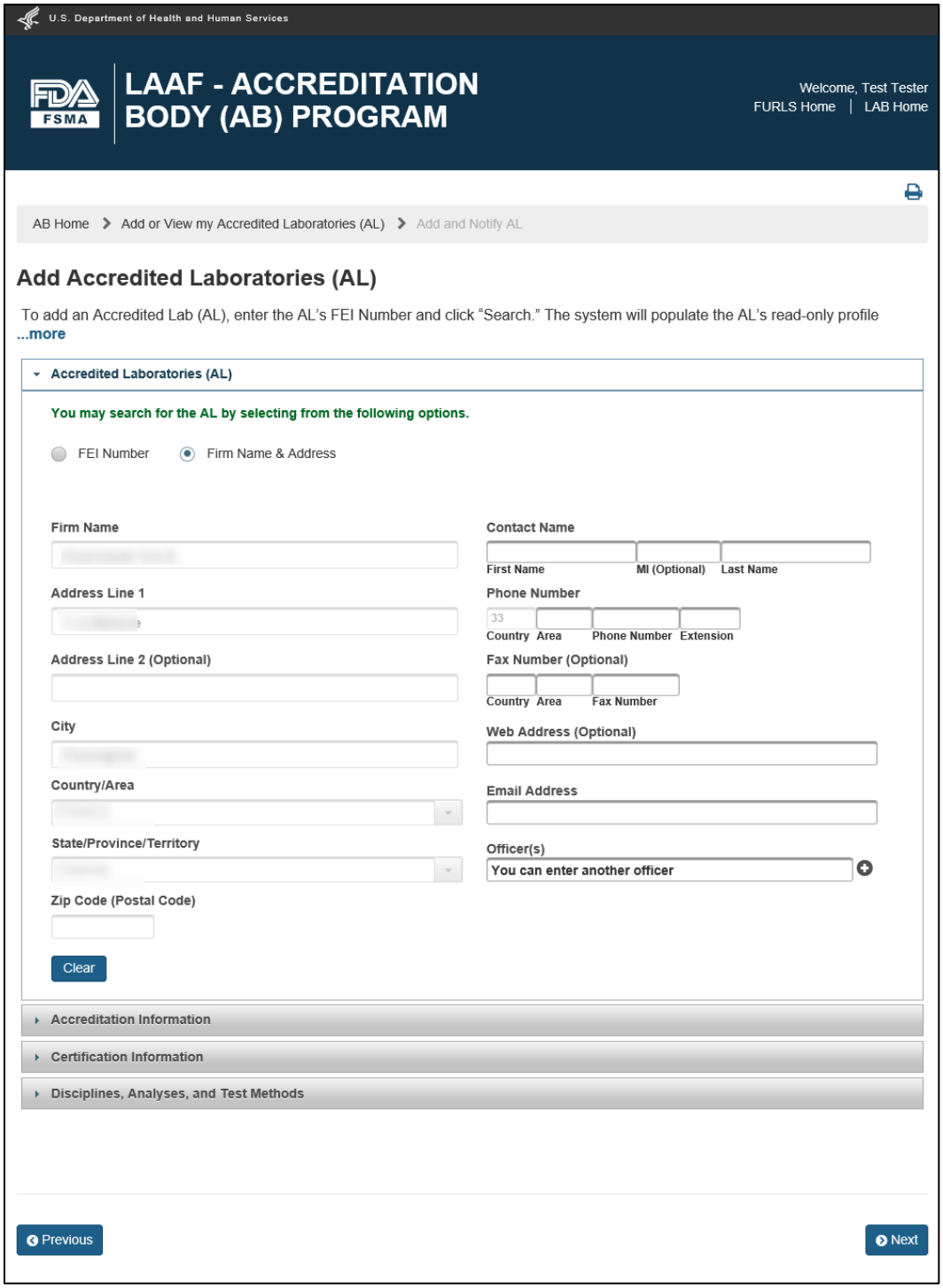


Figure 7.13: Single Match Returned

The system will perform a search from the "FDA Firm Inventory" database for the

information provided. If the system returns multiple results for the AL information searched, the system will display the results in a pop-up window. The AB user will click the “Select & Continue” button to select the correct match (Figure 7.14).

Alternatively, the AB can click the “Return to Search” button to return to the “Add Accredited Laboratories (AL)” page without selecting a record, to execute a new search.

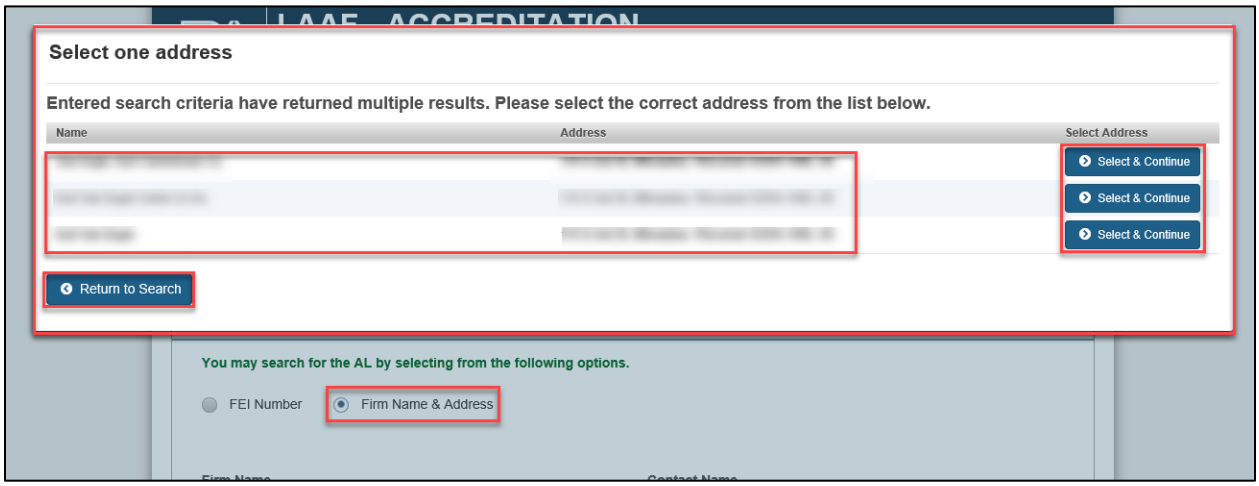


Figure 7.14: Multiple Results Pop-up

Once the AB user selects a result, the system will dismiss the pop-up and display the read-only firm name and address for the selected result on the “Add Accredited Laboratories (AL)” page. The additional fields will remain blank and editable (Figure 7.15).

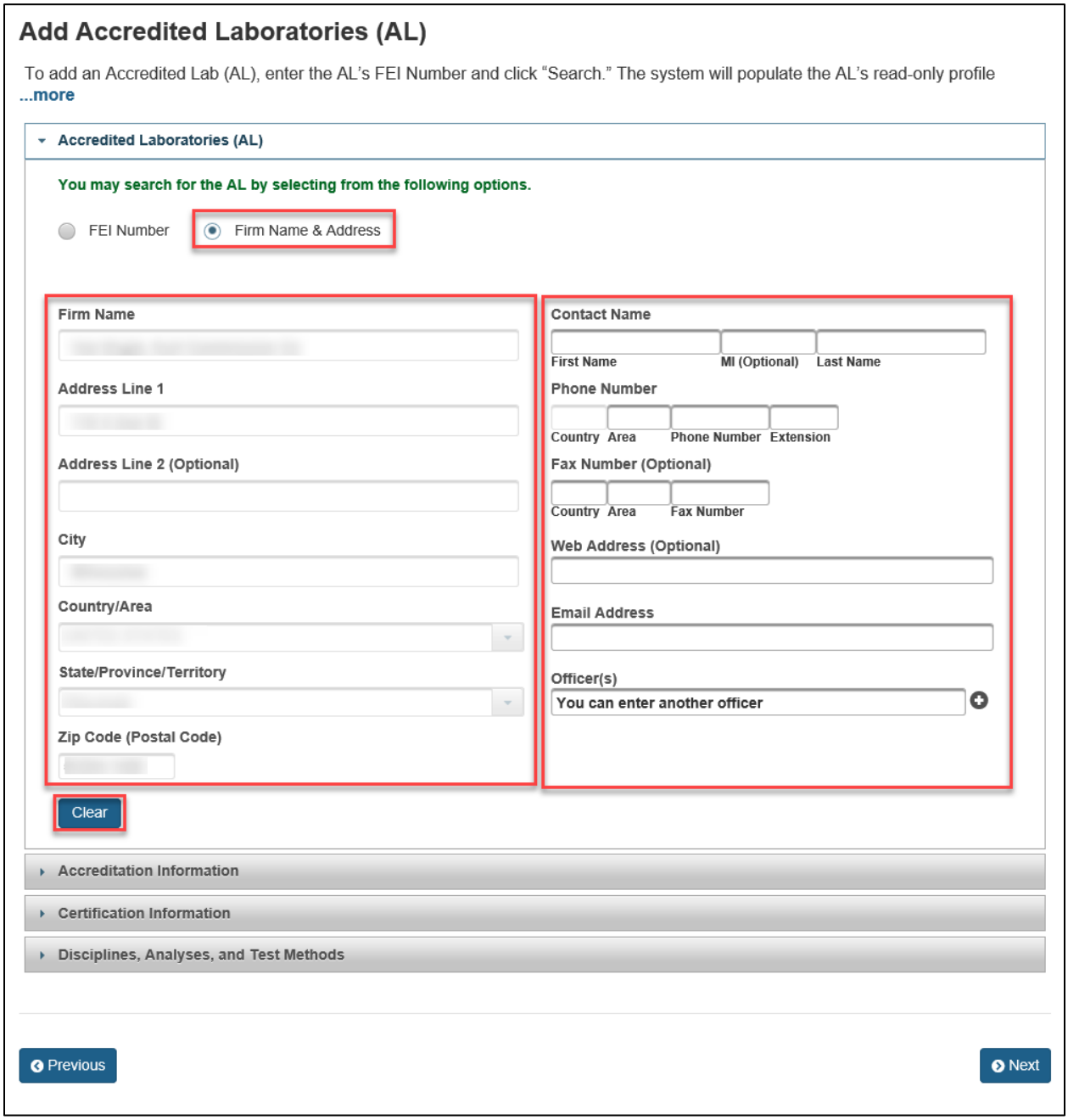


Figure 7.15: Result Selected from Multiple Matches

If desired, the AB can clear all data using the "Clear" button and start the process over.

To complete the process of adding an AL, the AB user must complete the three

remaining accordion sections:

- Accreditation Information
- Certification Information
- Disciplines, Analyses, and Test Methods

7.2 Accreditation Information Section

The “Accreditation Information” section contains the following mandatory date fields (Figure 7.16):

- **Accreditation Date –** The date of the accredited laboratory’s LAAF accreditation by the AB user.
- **Expiration Date –** The expiration date of the accredited laboratory’s accreditation by the AB user.

Each date field allows picking a date from the calendar or entering date manually in the “YYYY-MM-DD” format.

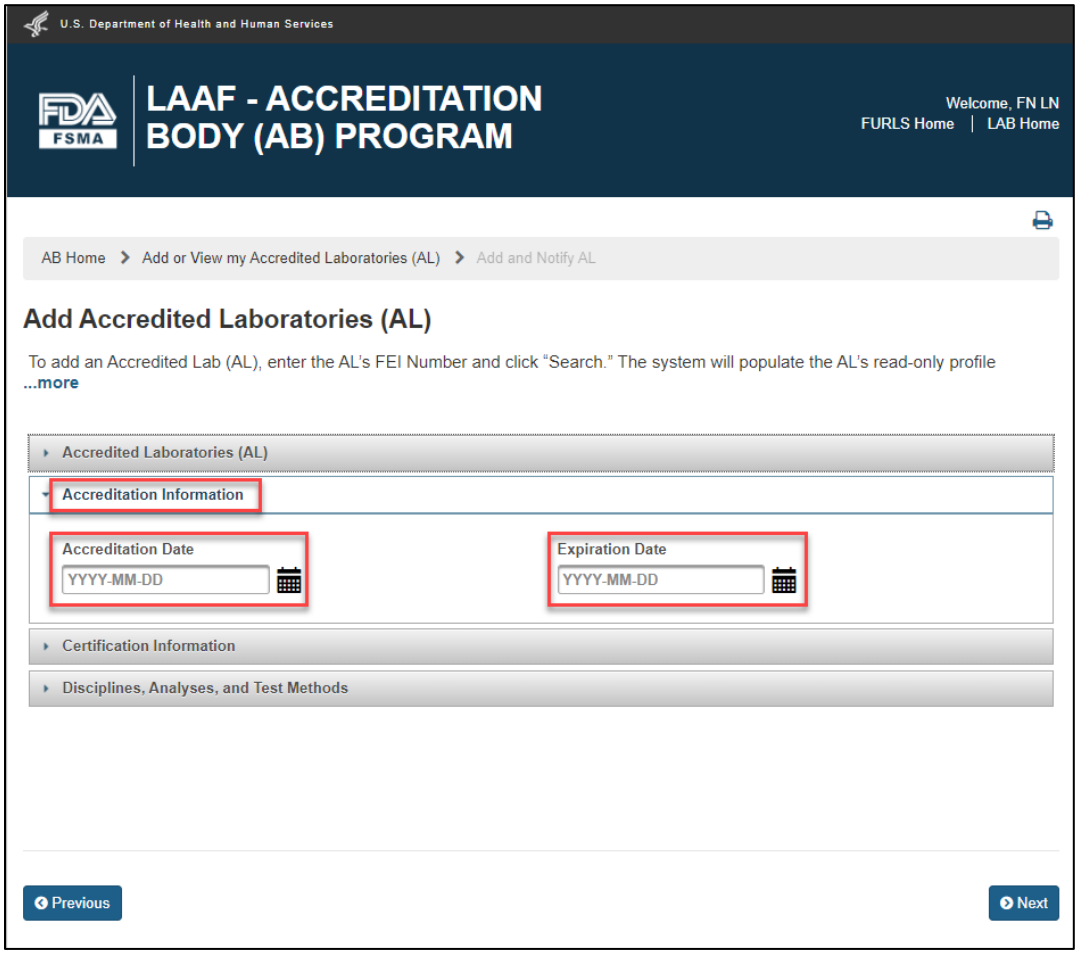


Figure 7.16: Additional Information Section

7.3 Certification Information Section

The "Certification Information" section contains the following elements related to the lab's LAAF accreditation (Figure 7.17):

- **Instructional text** – How to upload the certificate.
- **Certificate Number** – Required text field; accepts 15 alphanumeric characters.
- **Date of Issuance** – Optional date field.
- **Certificate Expiration Date** – Required date field.

Note: Each date field allows picking a date from the calendar or entering date manually in the "YYYY-MM-DD" format.

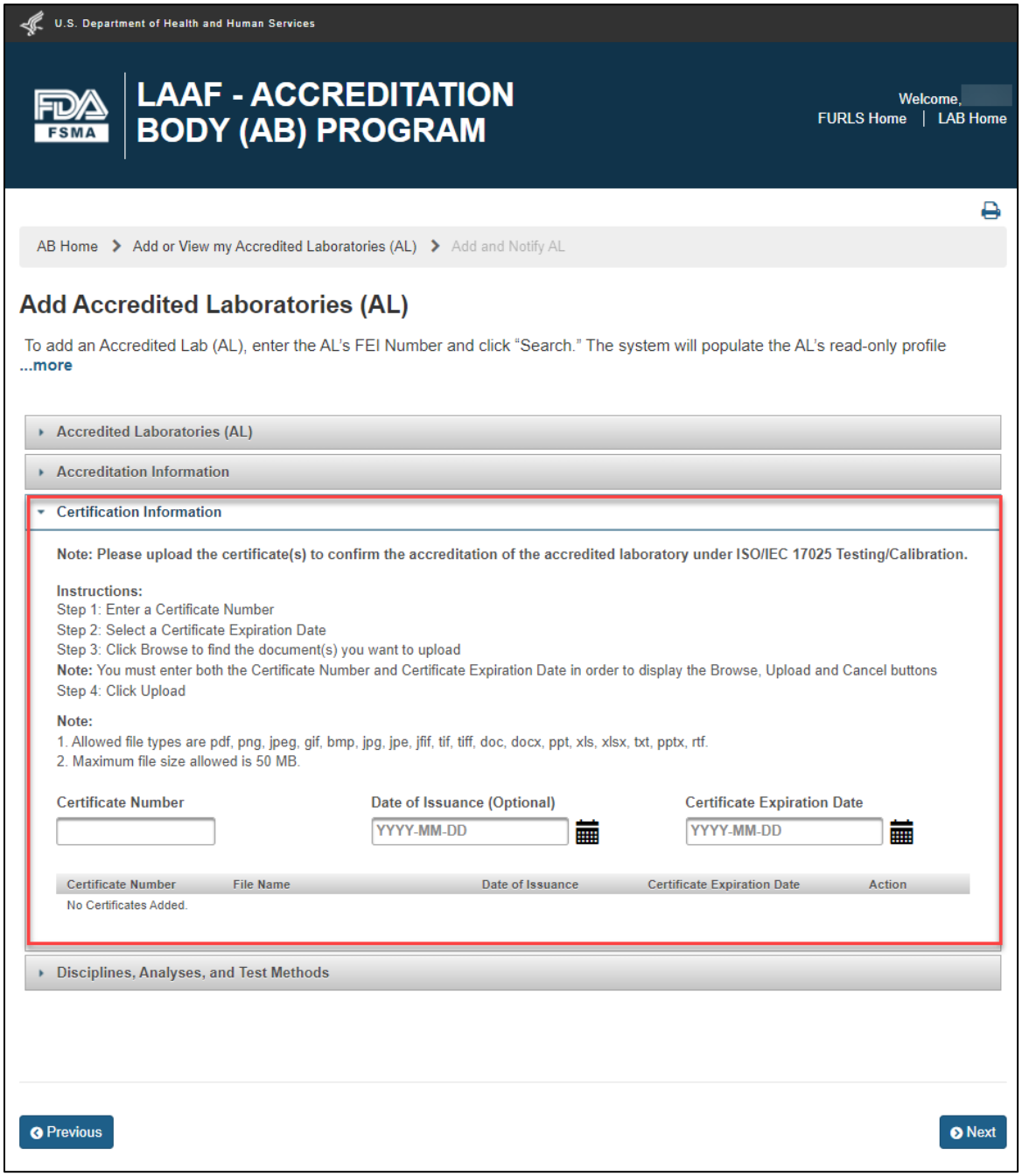


Figure 7.17: Certification Information Section

When the AB user enters the "Certificate Number" and "Certificate Expiration Date," the system will allow the user to upload documents related to the certificate by displaying the "Browse," "Upload," and "Cancel" buttons (Figure 7.18).

Note: The AB user can upload more than one certificate.

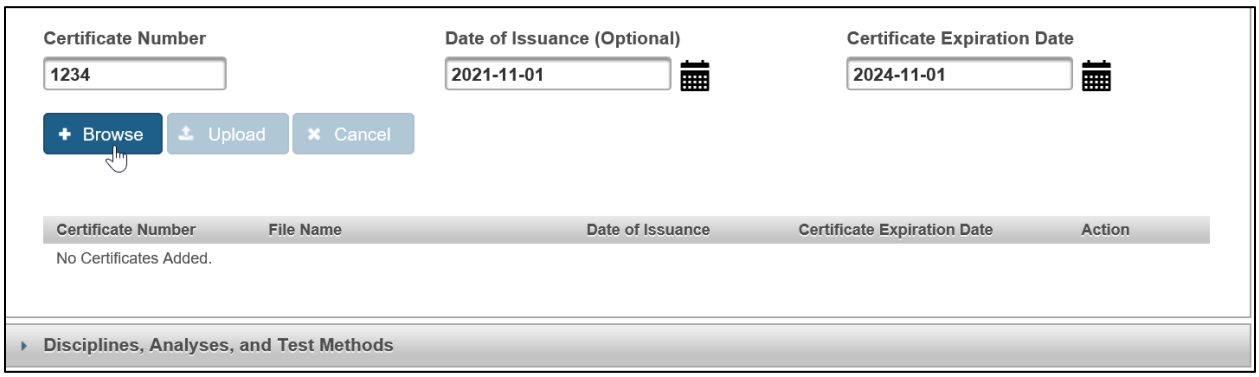


Figure 7.18: Browse, Upload and Cancel Buttons

The table at the bottom of the “Certification Information” section will be populated once the AB user completes the data input fields and uploads a file (Figure 7.19). The AB user can click the trash/delete icon in the “Action” column of the attachment table to remove a file.

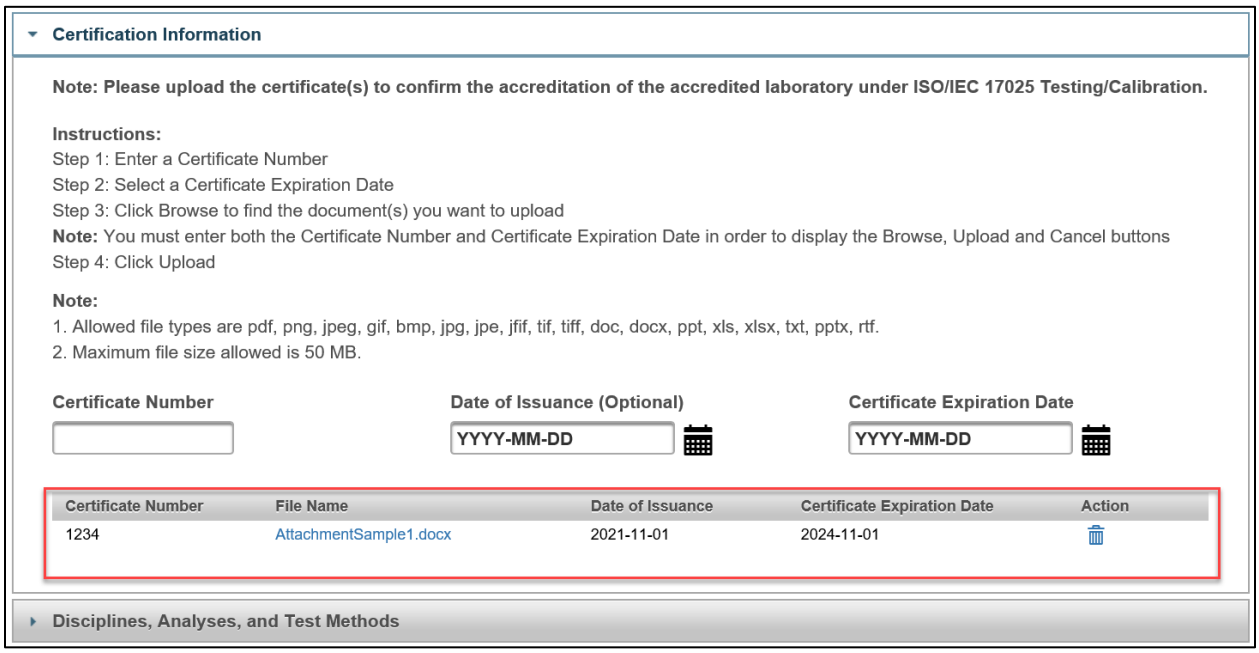


Figure 7.19: Table of Certificate Attachments

7.4 Disciplines, Analyses, and Test Methods Section

The “Disciplines, Analyses, and Test Methods” section contains the instructions on how to select value(s) from the “List of Available Disciplines, Analyses, and Test Methods” table displayed in the section.

The table is paginated and contains read-only information in three searchable columns:

- **Discipline**
- **Analysis**
- **Test Method**

The value(s) selected by the user will be added to, and displayed in, the second table, “List of Selected Disciplines, Analyses, and Test Methods” located at the bottom of the section. This table displays the text “No Records Added” by default, and contains the following columns (Figure 7.20):

- **Discipline**
- **Analysis**
- **Test Method**
- **Action**

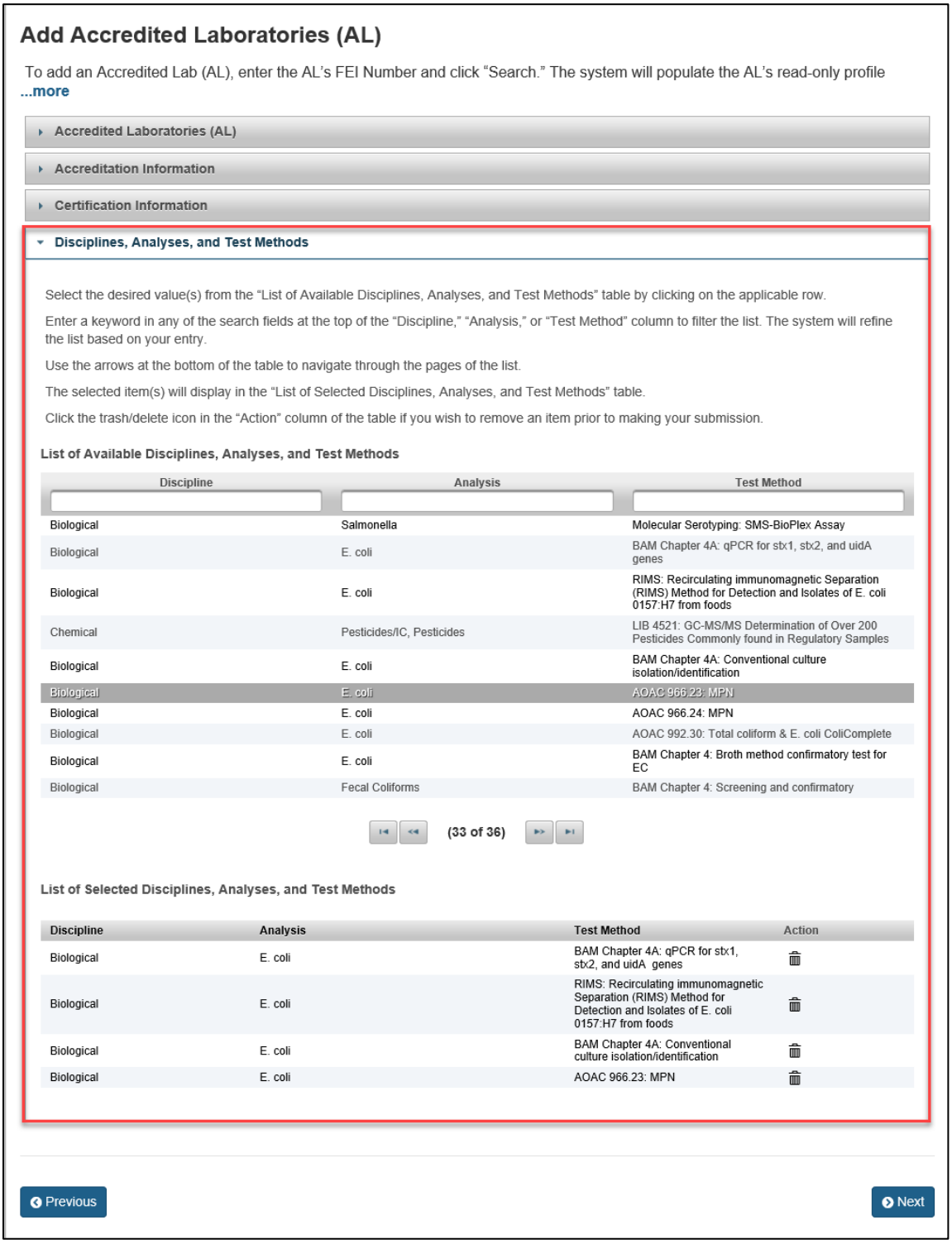


Figure 7.20: Disciplines, Analyses, and Test Methods Section

The AB user will click the “Next” button to navigate to the “e-Signature” page. The system will validate the data entered in the four accordion sections of the “Add Accredited Laboratories (AL)” page. If any of the system validations fail, the system will post the appropriate error message at the top of the page. The AB user must address the error before submitting the AL accreditation information.

If the validation was successful, the system will navigate to the “e-Signature” page. The AB user will complete all fields on the page and click the “Submit” button to send the information to FDA (Figure 7.21).

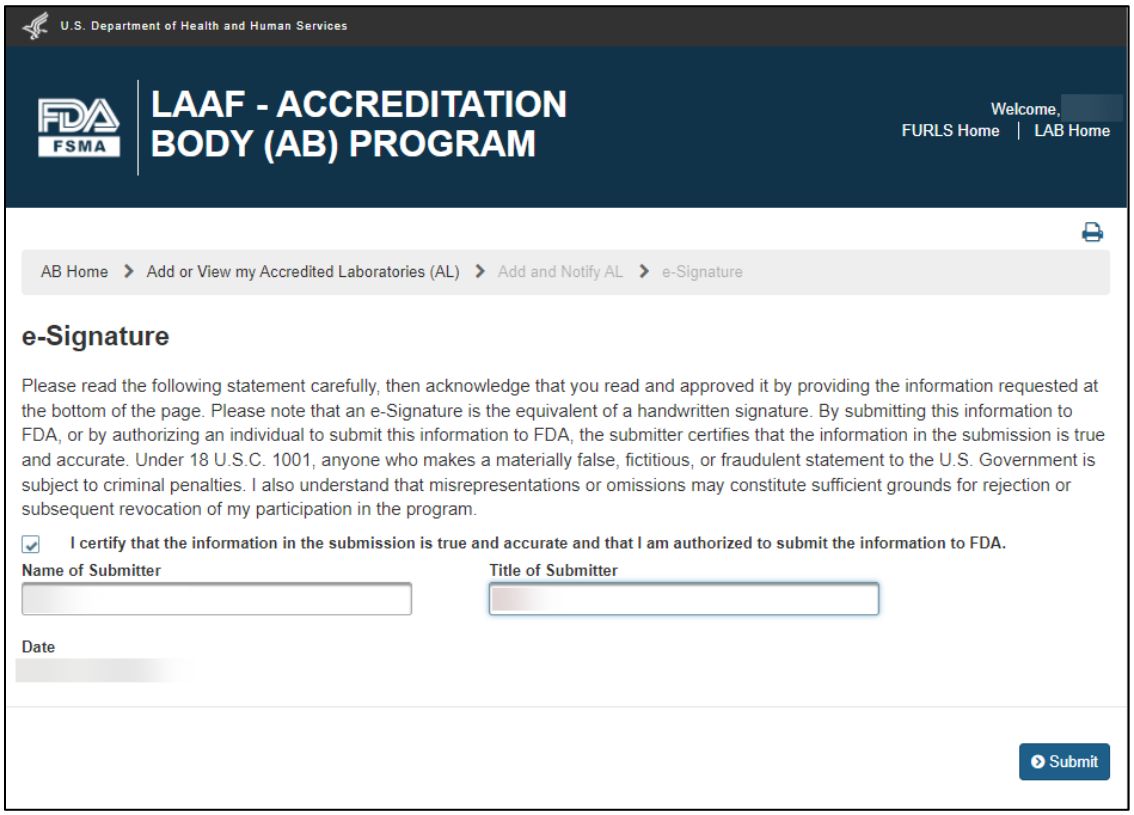


Figure 7.21: e-Signature Page

The system will display the “Confirmation” page (Figure 7.22).

Figure 7.22: Confirmation Page

The AB user can view the details for its ALs by navigating to the “Add or View my Accredited Laboratories (AL)” page. The ALs will display in the table on the page.

To view the details for an AL, the AB user can click the “View” icon from the “Action” column of the table (Figure 7.23).

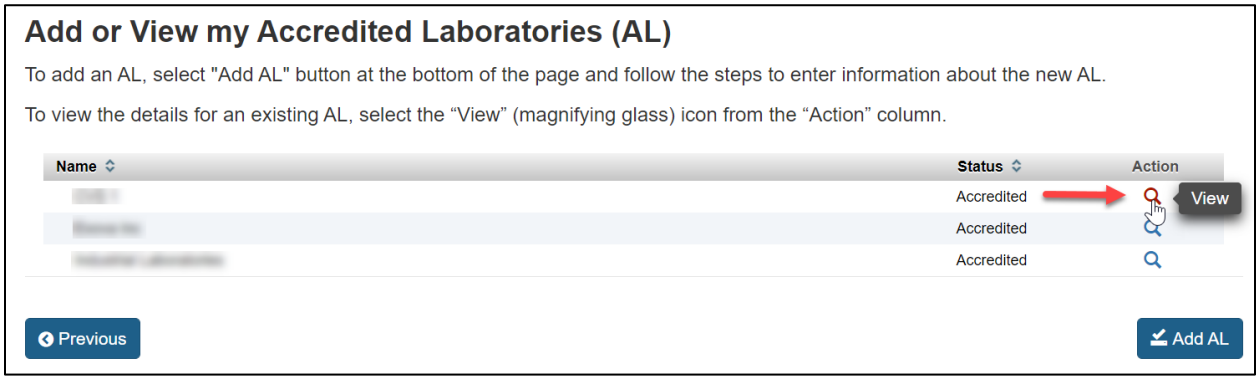


Figure 7.23: View Icon

The system will display the AL’s read-only accreditation details of the AB user on a new page: “Accredited LAB Information” (Figure 7.24).

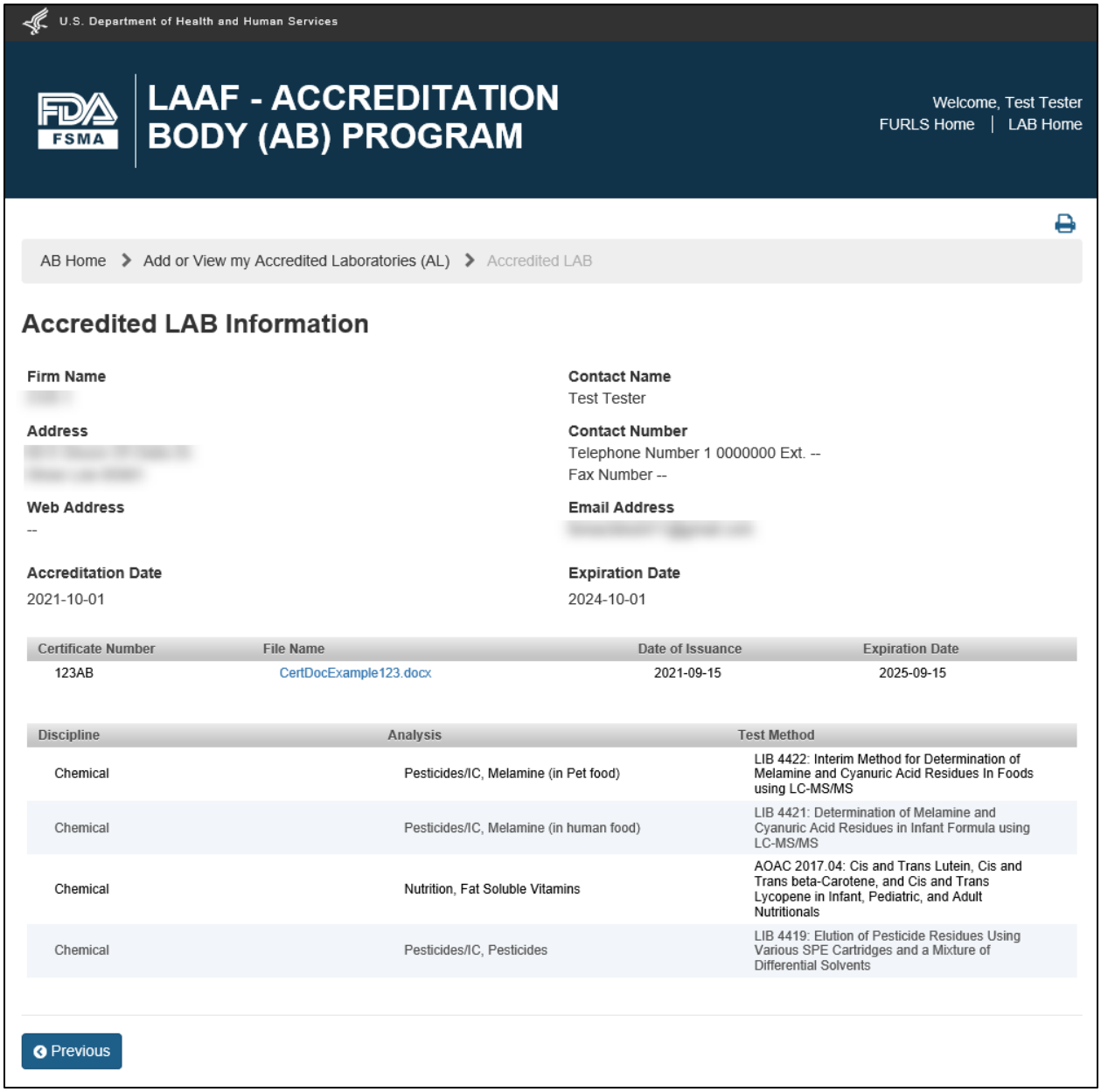


Figure 7.24: AL Accreditation Details

8 Submit Supplemental Documentation

The “Supplemental Documentation” feature allows the AB user to perform two main functions related to supplemental documents:

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

To upload new documents or view documents already submitted to FDA, the AB user will click the “Supplemental Documentation” link from the navigation menu on the “AB Home” page (Figure 8.1).

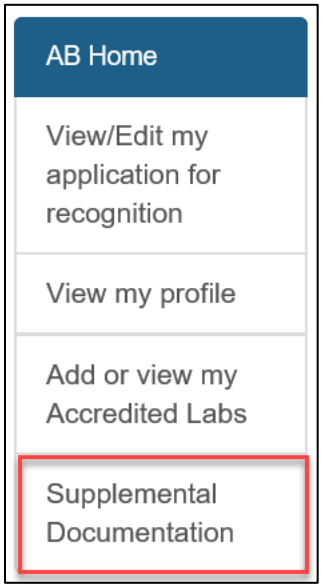


Figure 8.1: Navigation Menu

The system will display the “Supplemental Documentation” page (Figure 8.2). Any document(s) previously submitted to FDA will display in a table at the bottom of the page. The AB user can click on the hyperlinked document name in the “File Name” column to view the document.

The AB user will follow Steps 1 - 5 from the “Instructions” section of the page to upload attachments.

Note: The AB will click the “Previous” button at the bottom of the “Supplemental Documentation” page to return to the “AB Home” page.

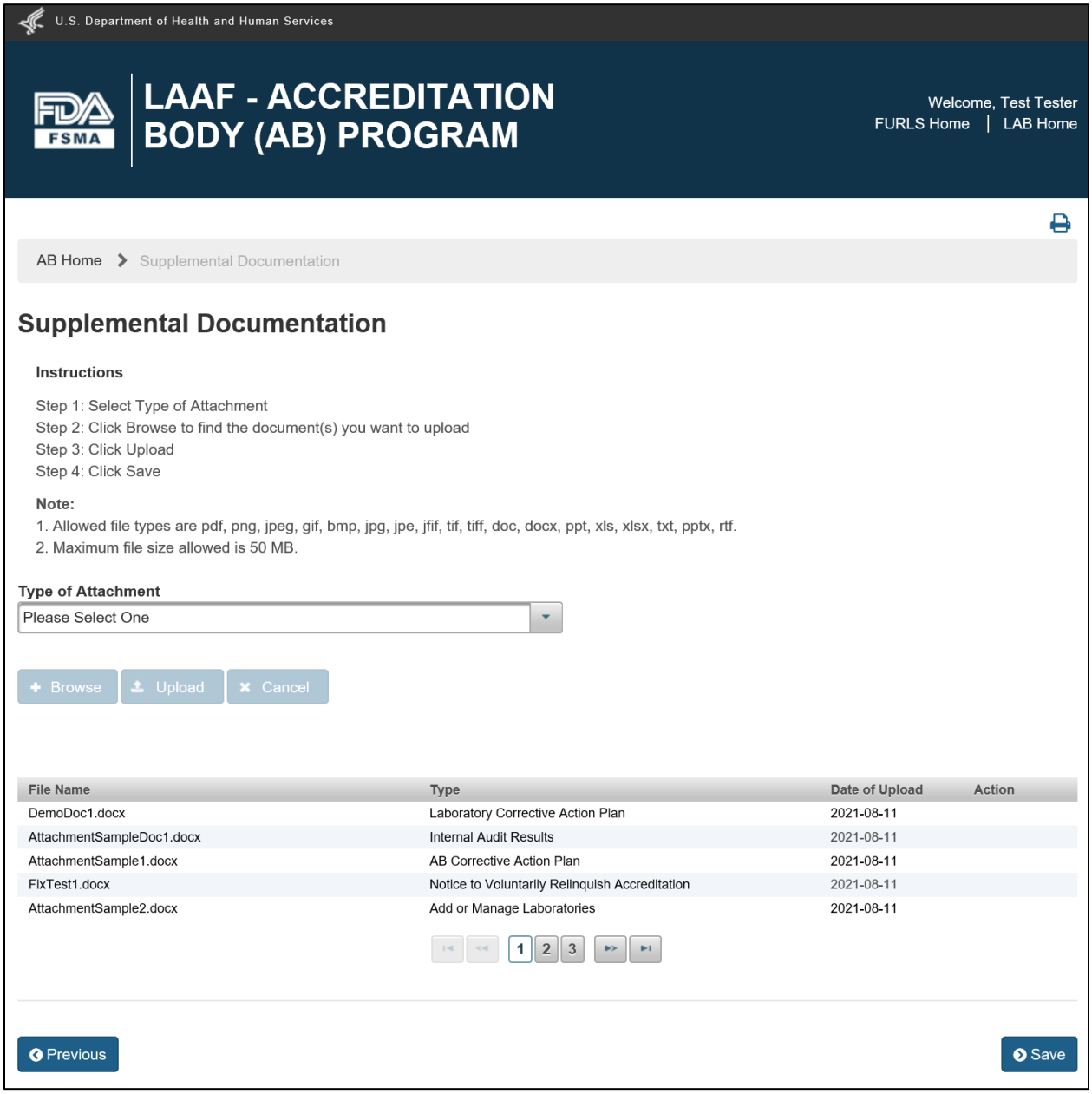


Figure 8.2: Supplemental Documentation Page

The AB user will select a document description from the list displayed in the “Type of Attachment” dropdown menu (Figure 8.3).

The complete list of values in the “Type of Attachment” menu is as follows:

- AB Corrective Action Plan
- Add or Manage Laboratories
- Internal Audit Results
- Laboratory Corrective Action Plan
- Notice of Change in AB Recognition
- Notice of Records Custodian
- Notice of Records Custodian of Lab
- Notice to Voluntarily Relinquish Accreditation
- Notice to Voluntarily Relinquish Recognition
- Request for Regulatory Hearing
- Submit Internal Audit Results
- Other

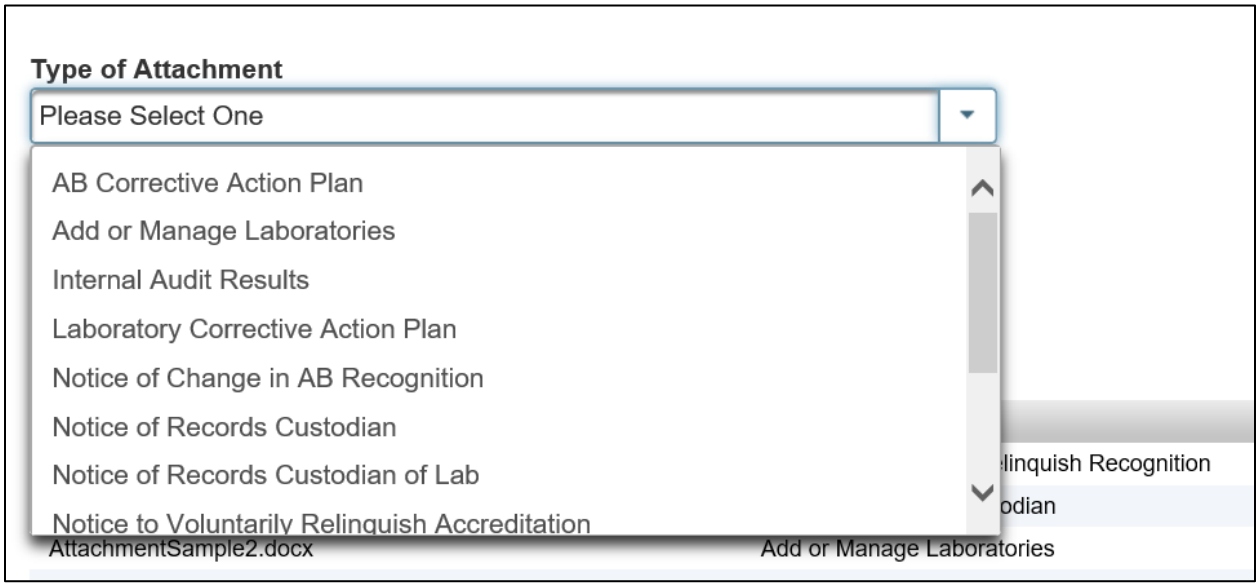


Figure 8.3: Type of Attachment Menu

Note: A text box labeled “Additional Description” will display if the AB user selects “Other” from the list (Figure 8.4).

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

The user must enter a description in the “Additional Description” field to proceed to the

next step.

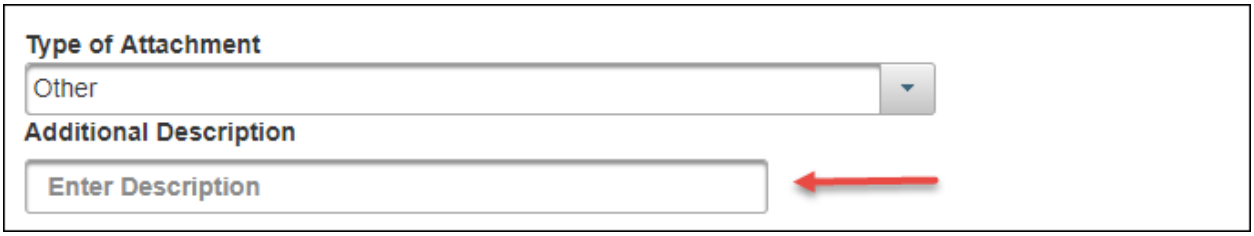


Figure 8.4: "Other" Attachment Type

A pop-up window will appear, prompting the AB user to access their file system.

The AB user will select one or more file attachments. The "Upload" and "Cancel" buttons will be enabled after a file is chosen (Figure 8.5). The system will close the browsing window.

The AB user can click the "Upload" button to complete the attachment upload or, click the "Cancel" button to discard the attachment upload.

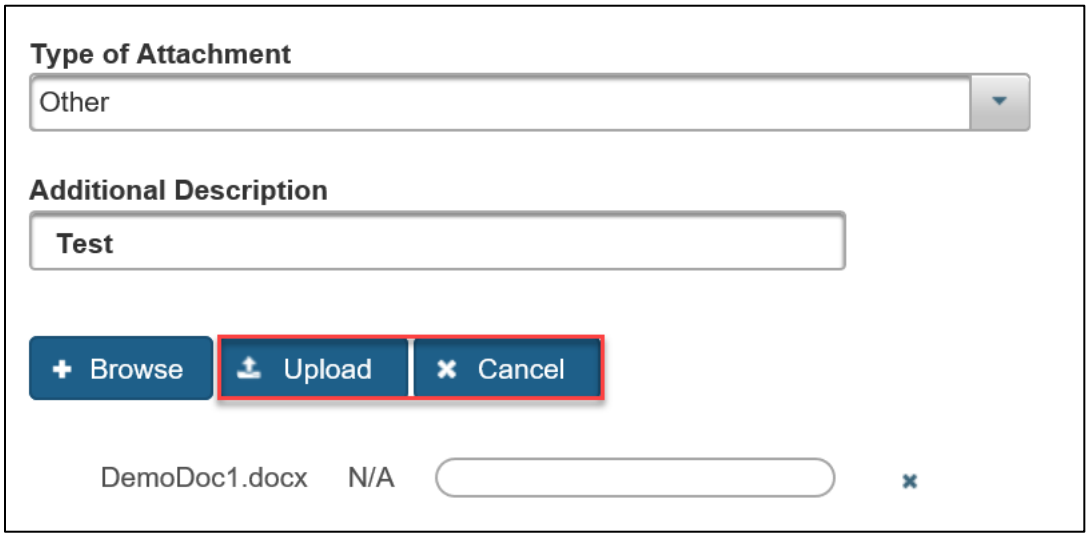


Figure 8.5: Upload and Cancel Buttons

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

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

The maximum file size allowed is 50 MB.

Once the upload is complete, a confirmation message indicating a successful upload (along with the file name) will display at the top of the page (Figure 8.6).

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

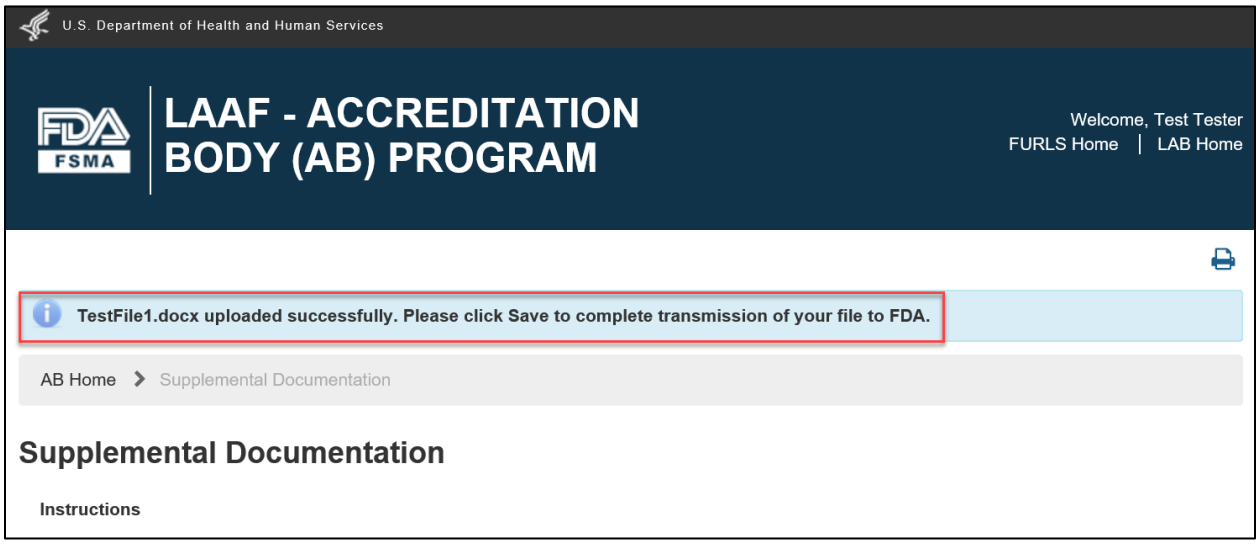


Figure 8.6: Successful Upload Message

To remove the attachment from the table at the bottom of the page, the AB user can click the trash/delete icon in the “Action” column (Figure 8.7).

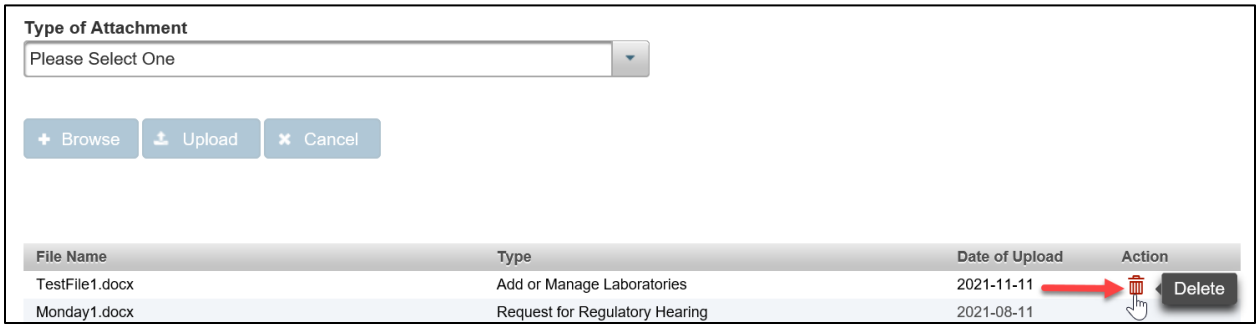


Figure 8.7: Trash/Delete Icon

After the additional files have been uploaded, the AB user will click the “Save” button (Figure 8.8).

****Important:** Uploaded files cannot be deleted once “Save” is clicked. The AB user must click the “Save” button to complete file transmission to FDA.

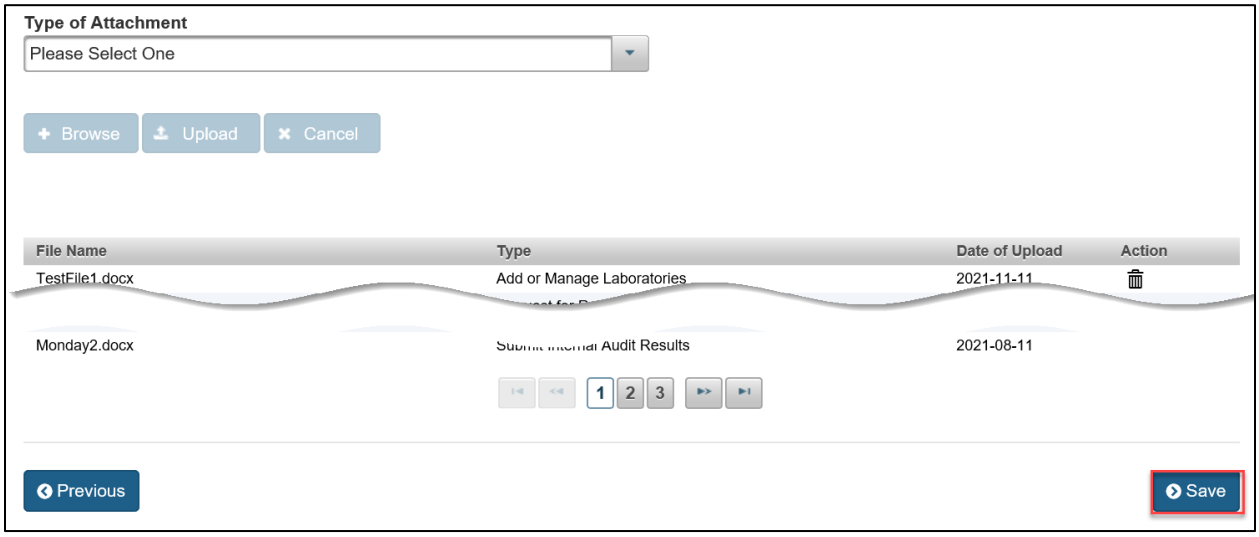


Figure 8.8: Save Attachment

Once a file has been uploaded and added to the "Attachments" table, the file name will become hyperlinked. If the AB user clicks on the hyperlinked file name, they will be prompted to open or save the file (Figure 8.9).

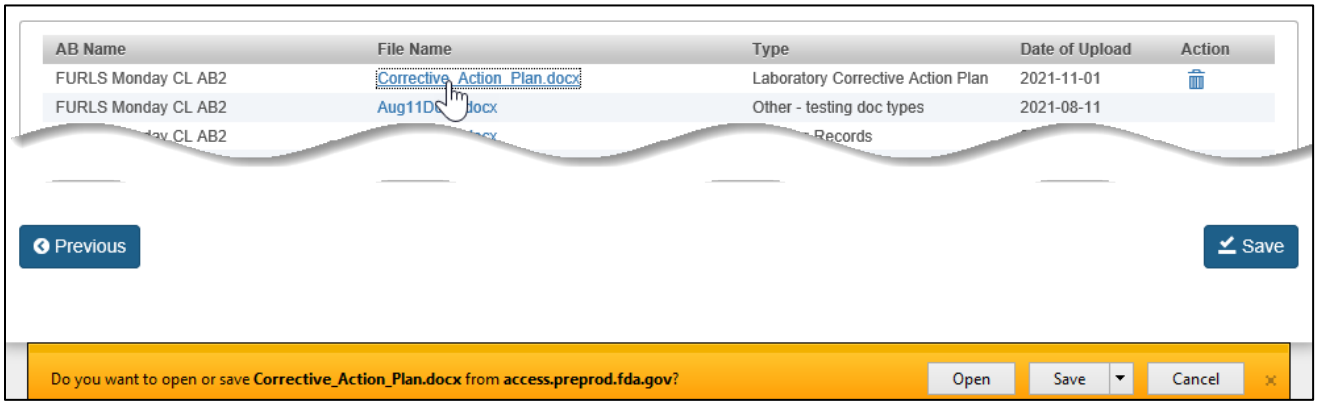


Figure 8.9: Hyperlinked File Name

9 Contact Us

The “Contact Us” feature allows the AB user to contact the LAAF program by email.

To access the feature, the AB user will click the “Contact Us” link from the navigation menu on the “AB Home” page (Figure 9.1). This feature is available to the AB upon account creation.

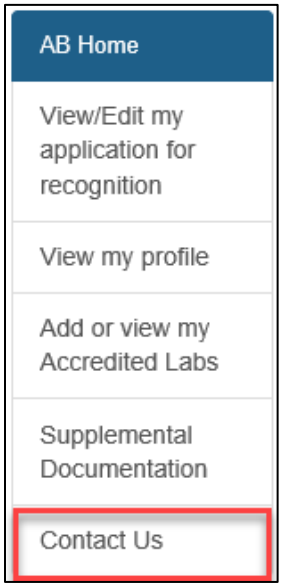


Figure 9.1: Navigation Menu

The system will display the “Contact Us” page in an email template format, with a “Subject” field allowing up to 150 characters and a “Message” field up to 4,000 characters (Figure 9.2). Once the AB has completed the “Subject” and “Message” fields, they will click the “Send” button to send the email.

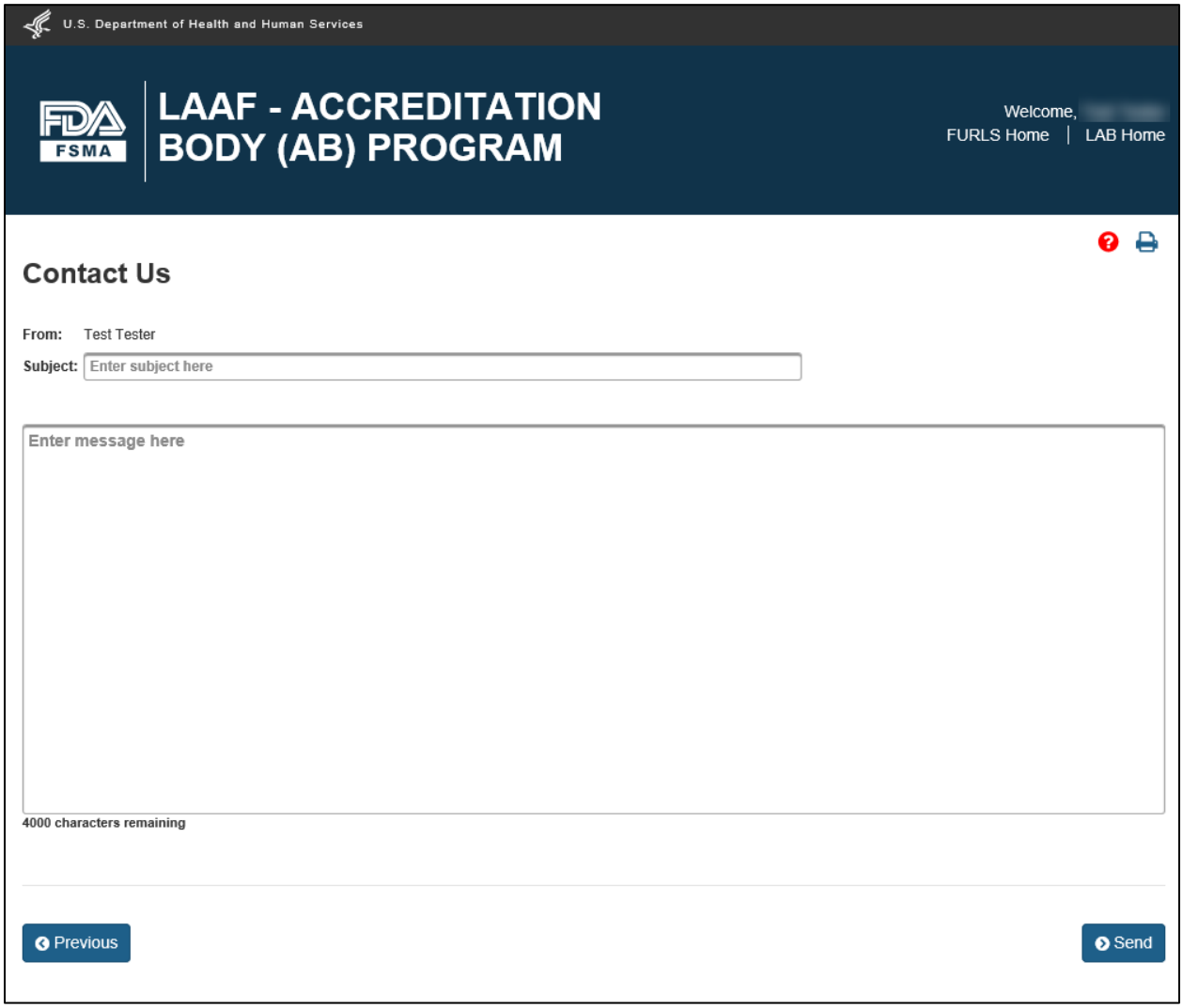


Figure 9.2: Contact Us Page

The system will display a confirmation message on the “AB Home” page stating the message has been sent (Figure 9.3).

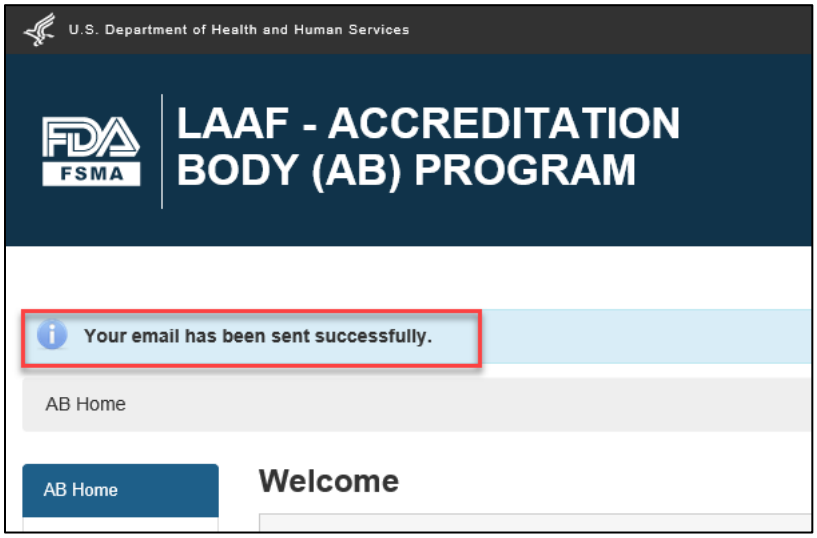


Figure 9.3: **Email Sent Successfully**

APPENDIX

Abbreviations

AB	Accreditation Body
AL	Accredited Laboratory
CFSAN	Center for Food Safety and Applied Nutrition
CVM	Center for Veterinary Medicine
FDA	U.S. Food and Drug Administration
LAAF	Laboratory Accreditation for Analyses of Foods
OAA	Online Account Administration
ORA	Office of Regulatory Affairs

Icon Behavior

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

Icon Description	Icon	System Function
Magnifying Glass		View the associated item.
Pencil		Edit the associated item.
Trash Can		Delete the associated item.
Printer		Print the associated item.