U.S. Food and Drug Administration

Laboratory Accreditation for Analyses of Foods (LAAF) Program

Electronic User Guide

Step-by-Step Instructions for an Accredited Laboratory to Manage Accreditation Status in the Program

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1 Introduction

This document is intended for Accredited Laboratories (ALs), or persons authorized to act on their behalf, who are participating in FDA's Laboratory Accreditation for Analyses of Foods (LAAF) Program.

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

- Complete account setup
- Manage an AL profile
- Submit test method verification/validation studies
- Submit commodity specific analytical packages*
- Submit request for permission to begin abridged import analytical submission
- Communicate with FDA

***Note:** Import-related testing submissions should be submitted through the ITACS Program. Users should log into FURLS and select the "Import Trade Auxiliary Communication System (ITACS)" link under the "Other FDA Systems" section.

1.1 Overview of FDA Portals for Electronic Laboratory Accreditation for Analyses of Foods 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)

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 (LAAF) Program.

1.2 Add 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., analytical reports, method validations and verifications, corrective action reports, or other supporting information).

The electronic LAAF Program's 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 Mozilla Firefox. Users should 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 the FDA FIS page.

2 Access FDA FIS Electronic Portal

An Accredited Laboratory (AL) participating in FDA's LAAF Program is required to create an online account first. Once the account has been created, the user can then log into the FURLS Online Account Administration (OAA) page with valid account credentials. The user should navigate to the FIS page and click the "Log-In" or "Create Account" button, depending on which is applicable (Figure 2.1).

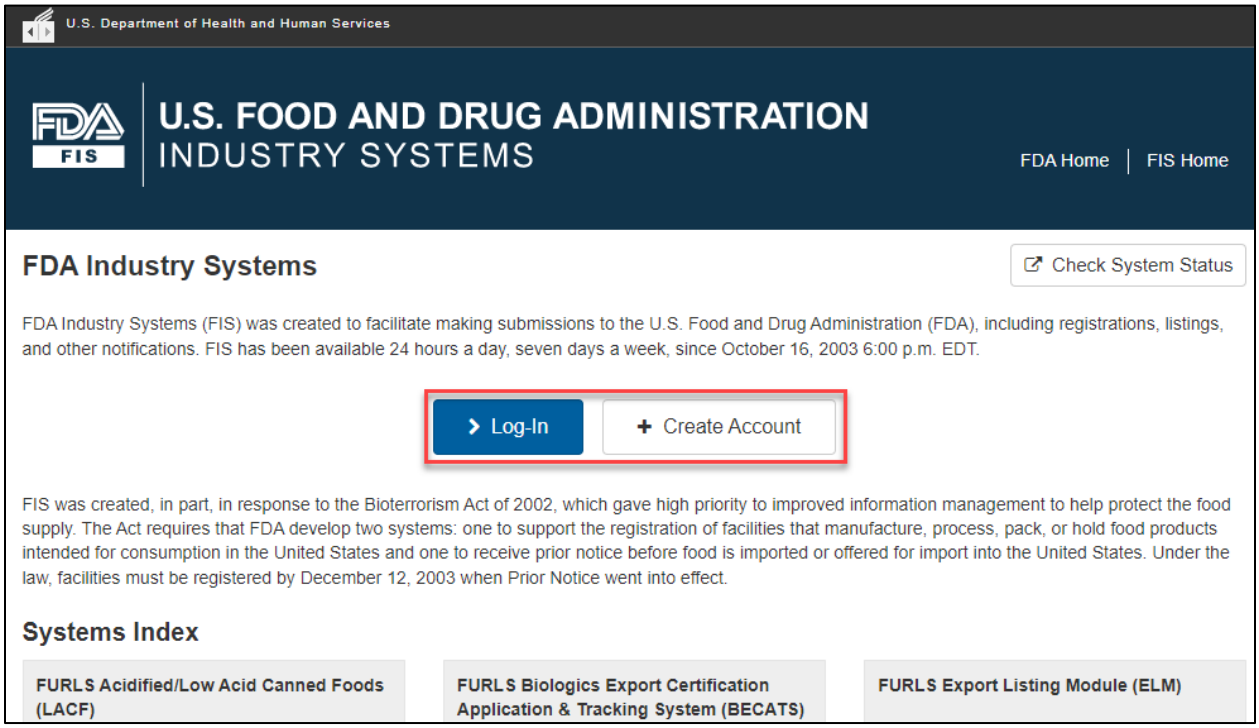


Figure 2.1: FDA Industry Systems Page

2.1 Log In with an Existing Account

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

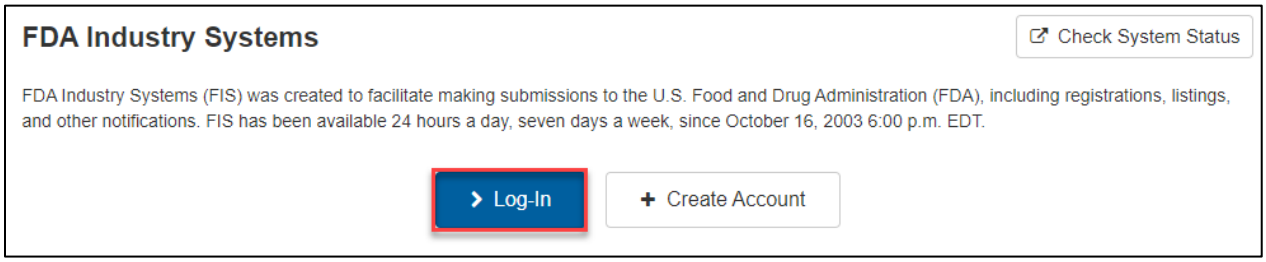


Figure 2.2: Log-In Button

The user will be directed to the 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 the system(s) the user needs to access. The user will click on the checkbox for “Laboratory Accreditation for Analyses of Foods Program – Accredited Lab,” and then click the “Submit” button.

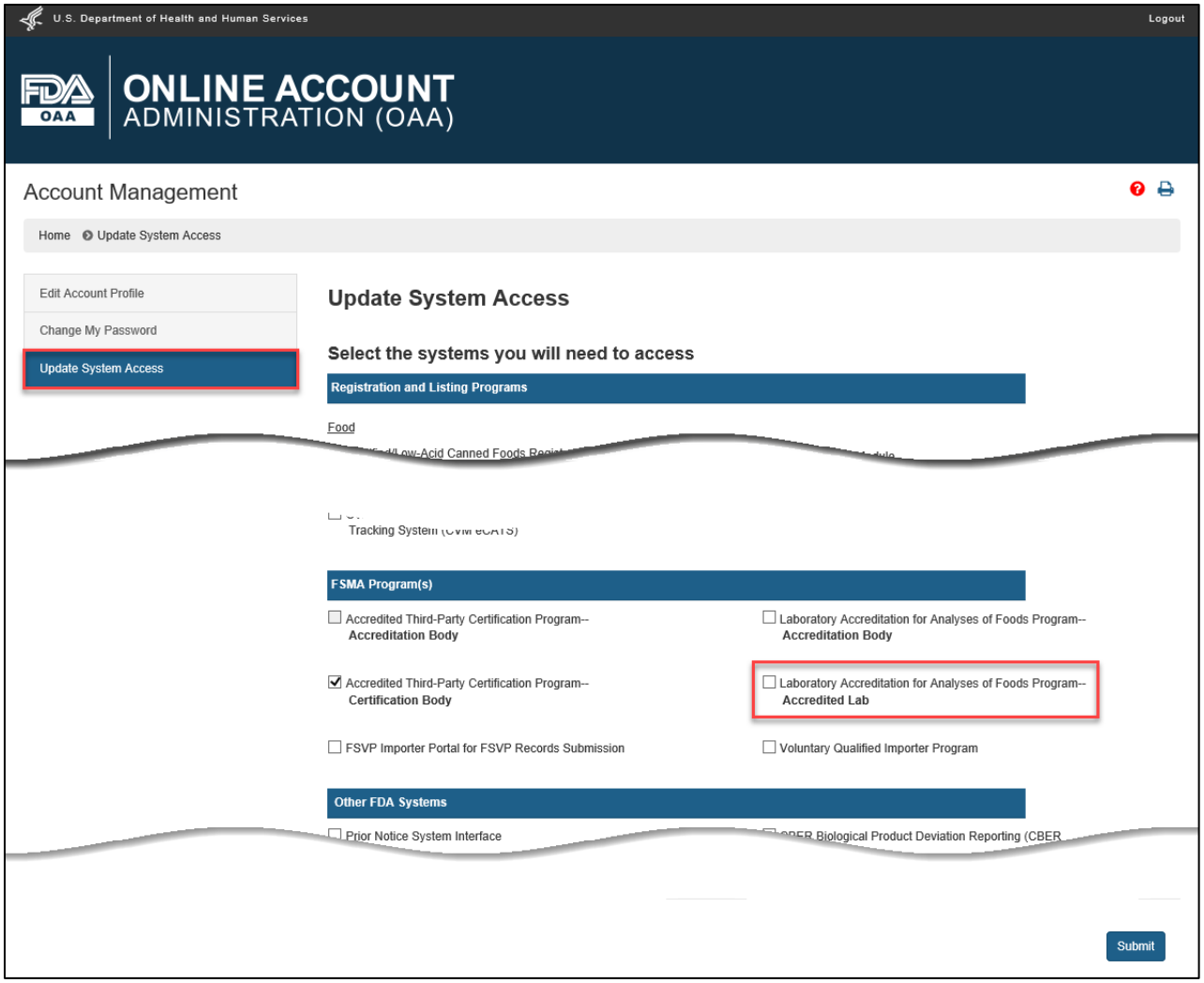


Figure 2.3: Update System Access

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

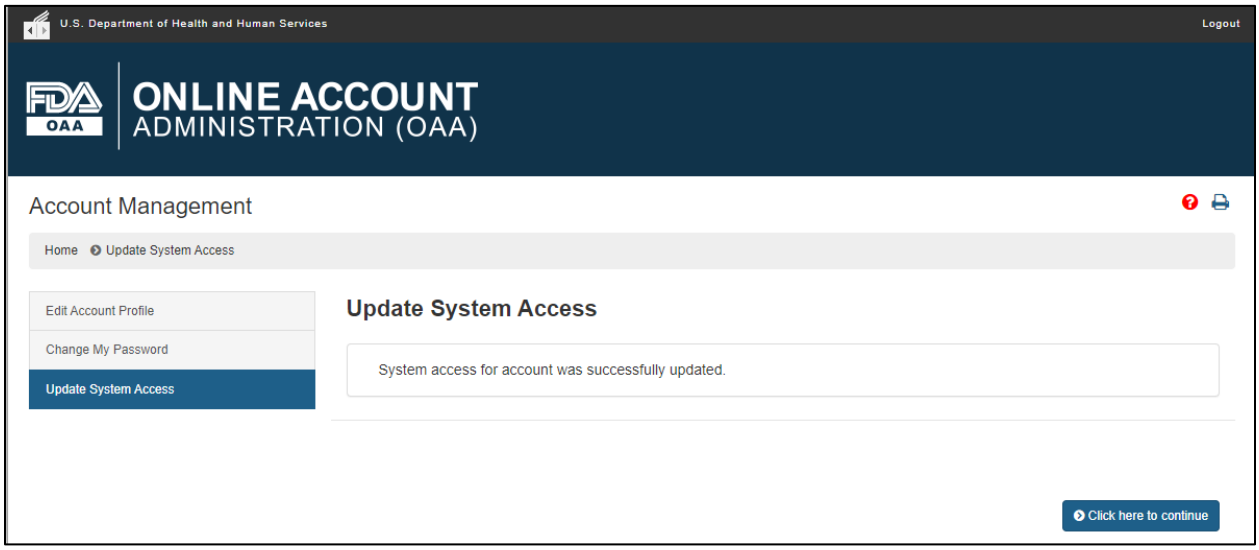


Figure 2.4: Successful Update Message

2.2 Create an Account

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

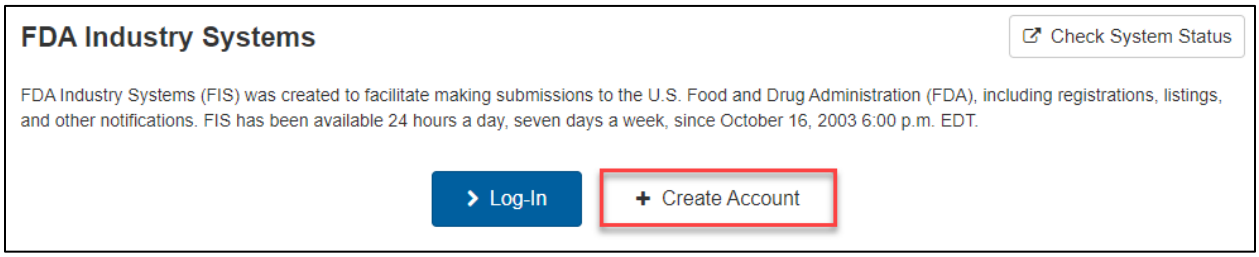


Figure 2.5: Create Account Button

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

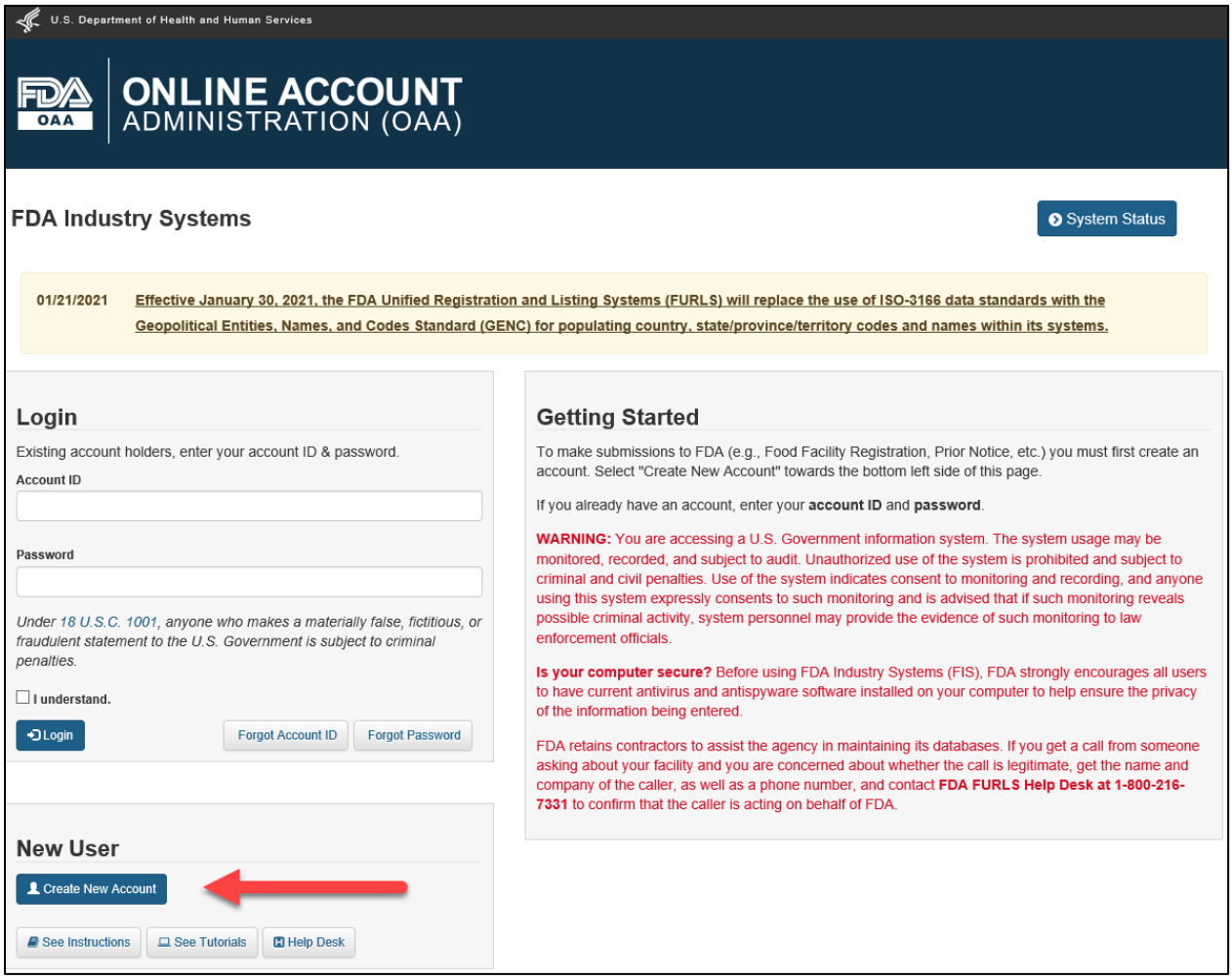


Figure 2.6: FIS OAA Page

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.

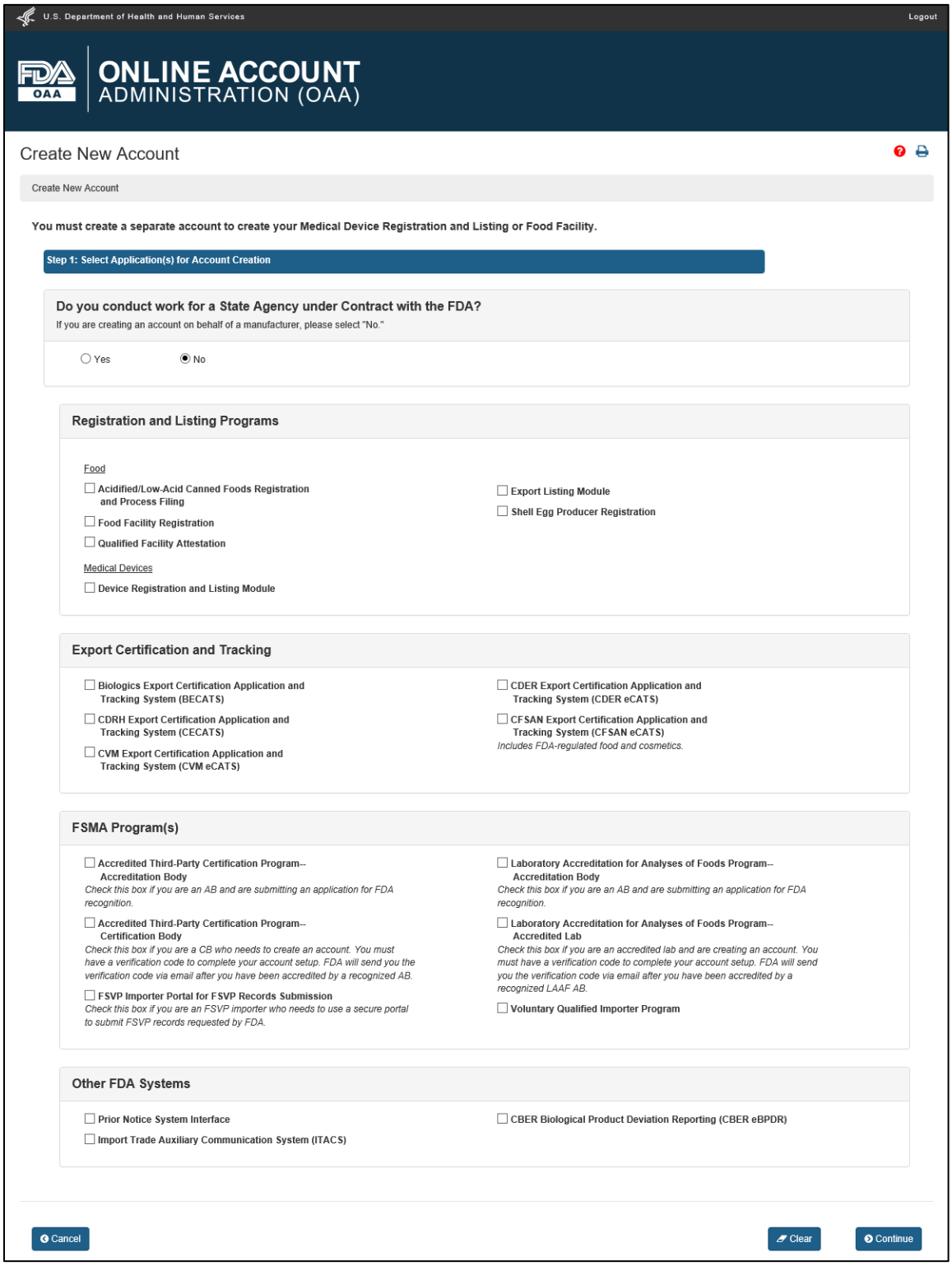


Figure 2.7: Create New Account Page

The user will select the “Laboratory Accreditation for Analyses of Foods Program – Accredited Lab” checkbox under “FSMA Program(s)” and click the “Continue” button to proceed to the next step (Figure 2.8).

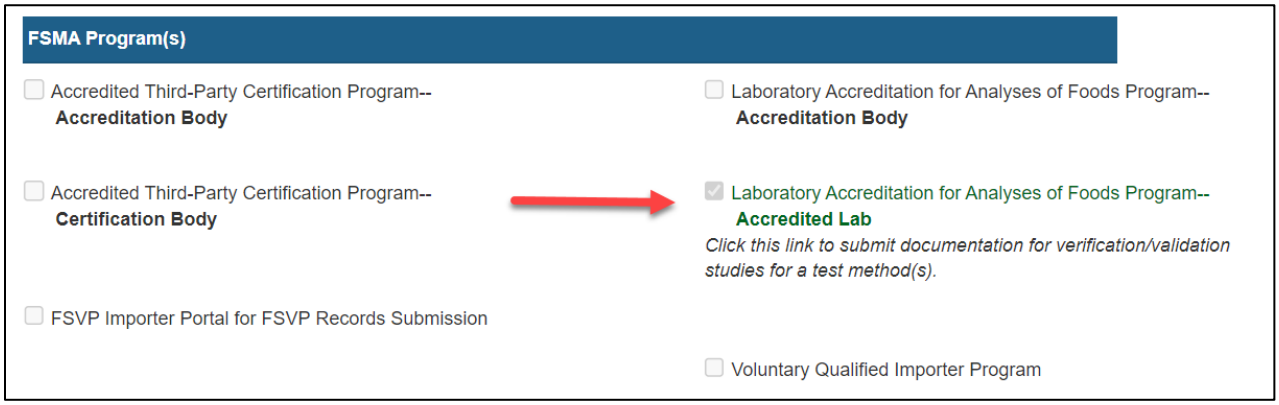


Figure 2.8: Laboratory Accreditation for Analyses of Foods Program – AL Link

The system will display the “Step 1a: Enter Verification Code for Account Creation” screen. The user will receive a system-generated e-mail containing the verification code, once the accrediting AB submits the laboratory accreditation via FURLS.

The user will enter the verification code in the field and click the “Verify” button. After the code is verified, the user will be able to create an account for accessing the AL Portal (Figure 2.9).

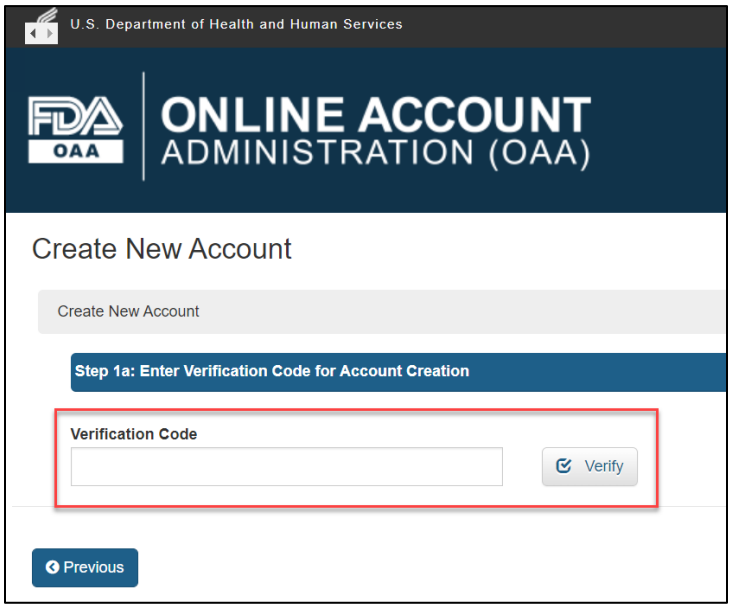


Figure 2.9: Step 1a: Enter Verification Code for Account Creation

The system will display the “Step 2: Enter Your Account Information” section, where the accrediting AB provided point of contact information, account information, and the account holder’s physical address (Figure 2.10). The user may edit any of the existing information. They must also provide additional information (i.e., passwords, secret questions and answers, and an alternate mailing address,) if applicable.

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

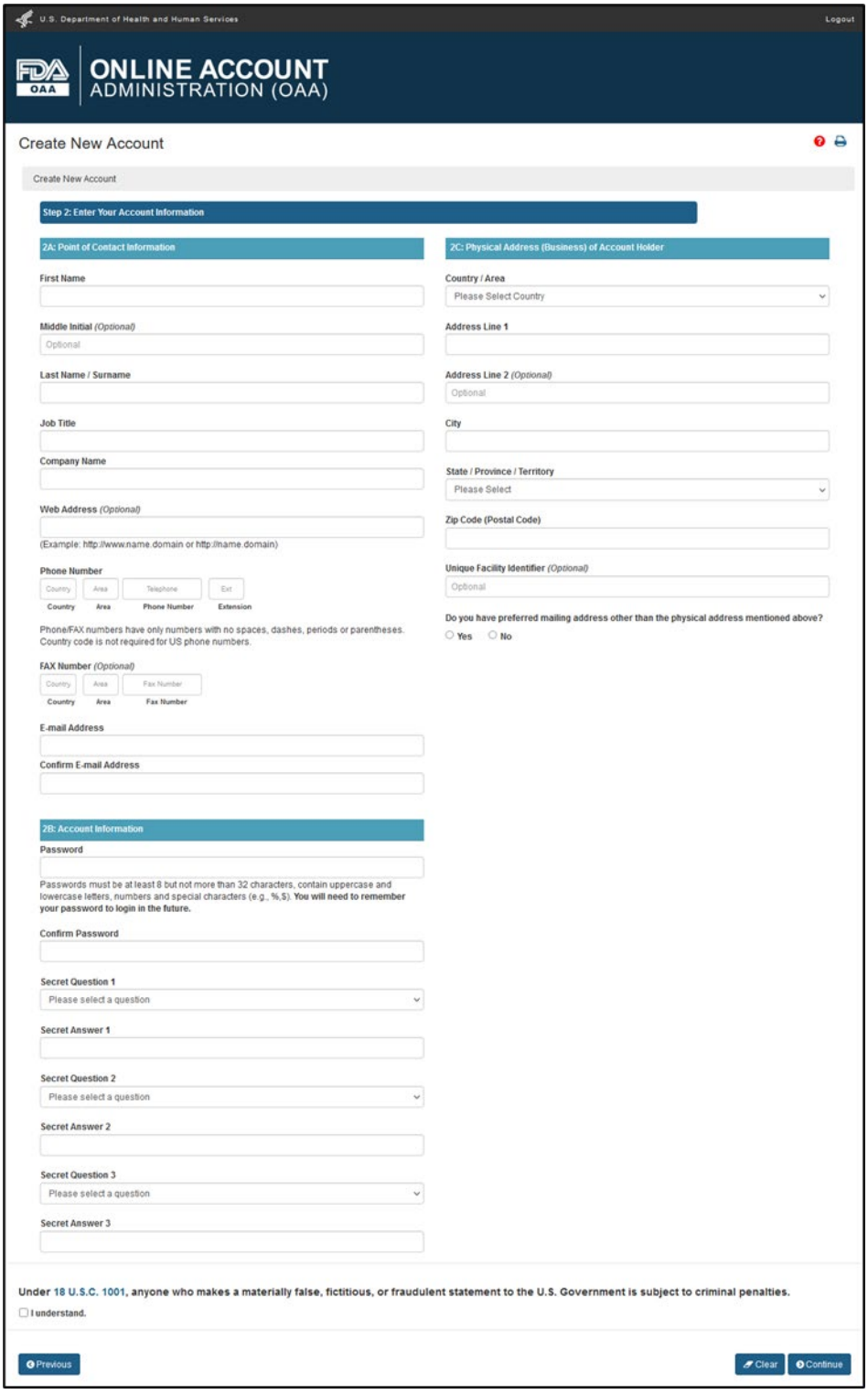


Figure 2.10: Step 2: Enter Your Account Information

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

- **First Name –** The first name of the Point of Contact.
- **Middle Initial (Optional field) –** The first letter of the Point of Contact’s middle name.
- **Last Name/Surname –** The last name of the Point of Contact.
- **Job Title –** The job title of the Point of Contact.
- **Company Name –** The name of the company the Point of Contact represents.
- **Web Address** (Optional field) **–** The URL of the company.
- **Phone Number (Country/Area/Phone Number/Extension) –** The telephone number of the Point of Contact.
    - “Country” is the country code.
    - “Area” is the 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 AL’s account. This password will be used every time the AL 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. The user will select a question from the dropdown list.
- **Secret Answer 1 –** This is the answer to the first secret question. The user will enter the response to the question selected in “Secret Question 1”.
- **Secret Question 2 –** The second secret question used to protect the account. The user will select a question from the drop-down list.
- **Secret Answer 2 –** This is the answer to the second secret question. The user

will enter the response to the question selected in “Secret Question 2”.

- **Secret Question 3 –** This is the third secret question used to protect the account. The user will select a question from the dropdown list.
- **Secret Answer 3 –** This is the answer to the third secret question. The user will enter the 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. The user will 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” is selected, the system will display the “Step 2D: Preferred Mailing Address,” which must be completed (Figure 2.11). The address entered in Step 2D will be used as the mailing address.

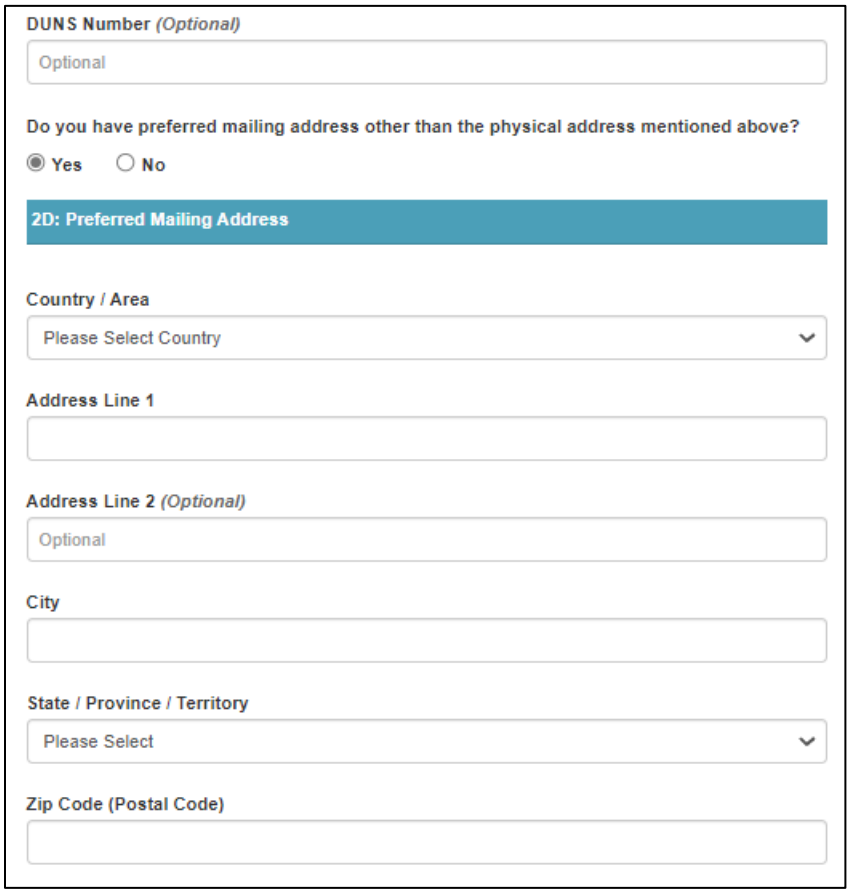


Figure 2.11: Step 2D: Preferred Mailing Address

After completing all of the mandatory fields, the user 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 2.12).

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

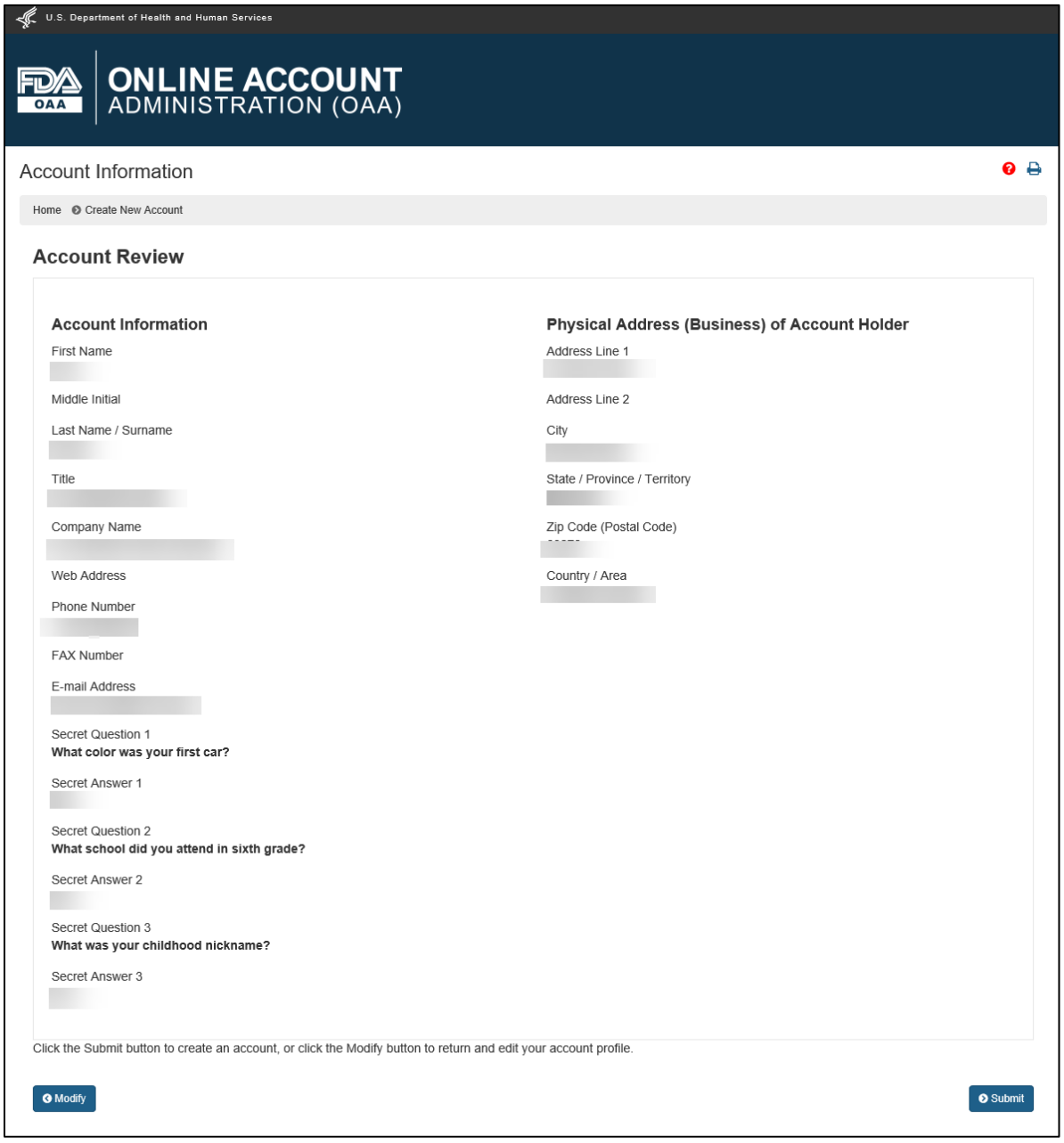


Figure 2.12: Account Review Page

When the user clicks the “Submit” button, the system will display a page with a message stating their account was created successfully. The message will show the account ID the user must use to log in as a LAAF AL (Figure 2.13).

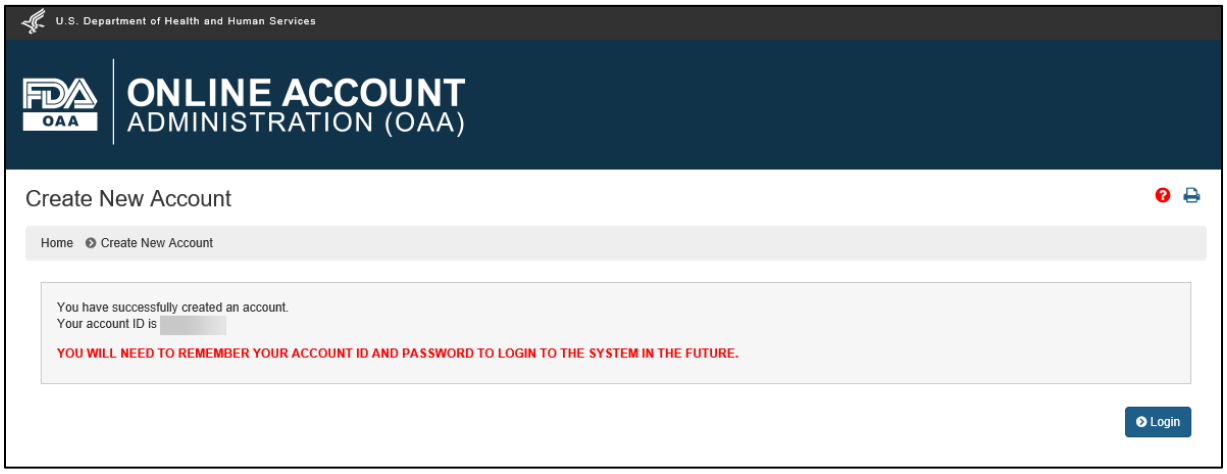


Figure 2.13: Successful Account Creation Message with Account ID

3 Access the Laboratory Accreditation for Analyses of Foods Program – Accredited Laboratory (AL)

The user can log into the FDA "OAA" page. This is the same page used to begin the process of creating a new OAA account (Figure 3.1).

The user will use the account ID and password from the account creation process for the "Account ID" and "Password" fields. The user should click the "I understand" checkbox, and then click the "Login" button.

Figure 3.1: OAA Login

Once logged into the FDA "OAA" page, the user will be prompted to enter a verification code (Figure 3.2). The verification code will be sent to the e-mail address entered on the "Account Information" page. If the user does not receive the verification code within ten minutes, click "Resend verification code" on the page. Once the user has received the code, enter it in the box labeled "Enter Verification Code," then click the "Verify" button.

Note: Users will be prompted to enter a verification code each time they login.

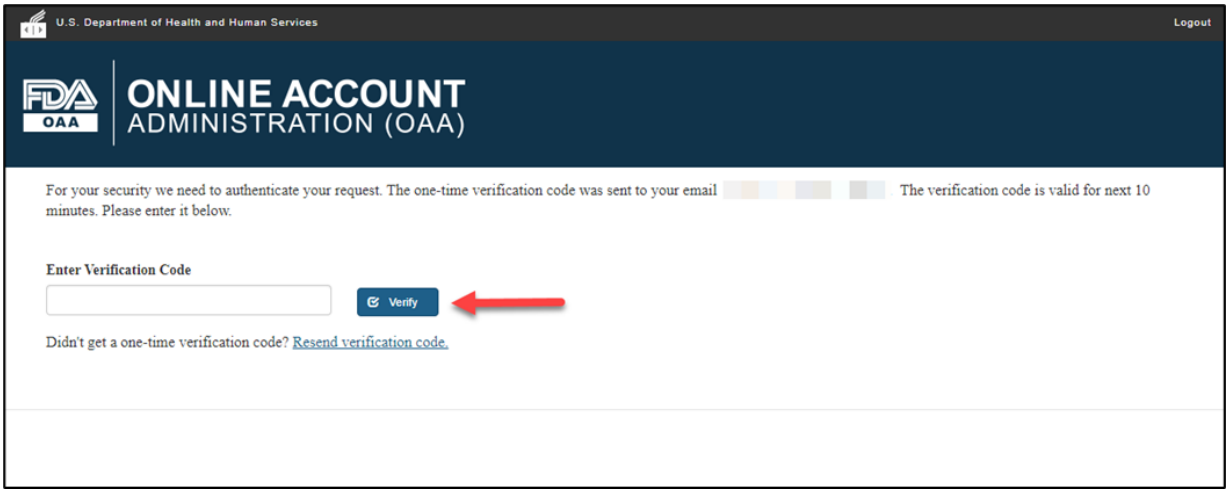


Figure 3.2: Enter Verification Code

Users will be directed to the FURLS "Account Management" page after the verification code is verified (Figure 3.3).

The user will navigate to the "FSMA Program(s)" section of the page and click the hyperlink for "Laboratory Accreditation for Analyses of Foods Program – Accredited Lab".

Note: The user should click the link to submit documentation for verification/validation studies for the test method(s). To submit the analytical package documentation for import-related products, click the "Import Trade Auxiliary Communication System (ITACS)" link under the "Other FDA Systems" section.

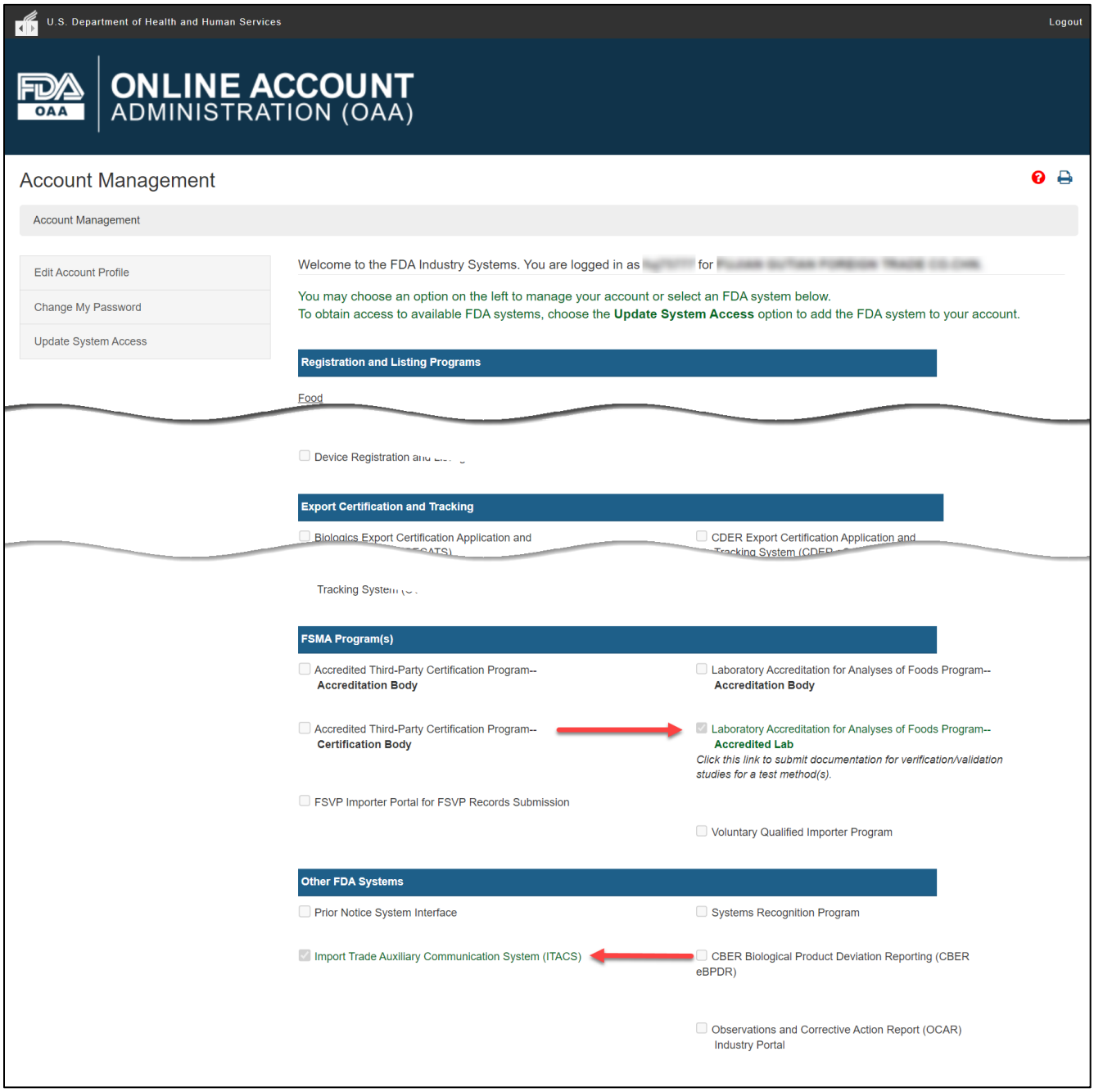


Figure 3.3: OAA – FURLS Account Management Page

The system will display the “AL Home” page and the features available to the AL (Figure 3.4).

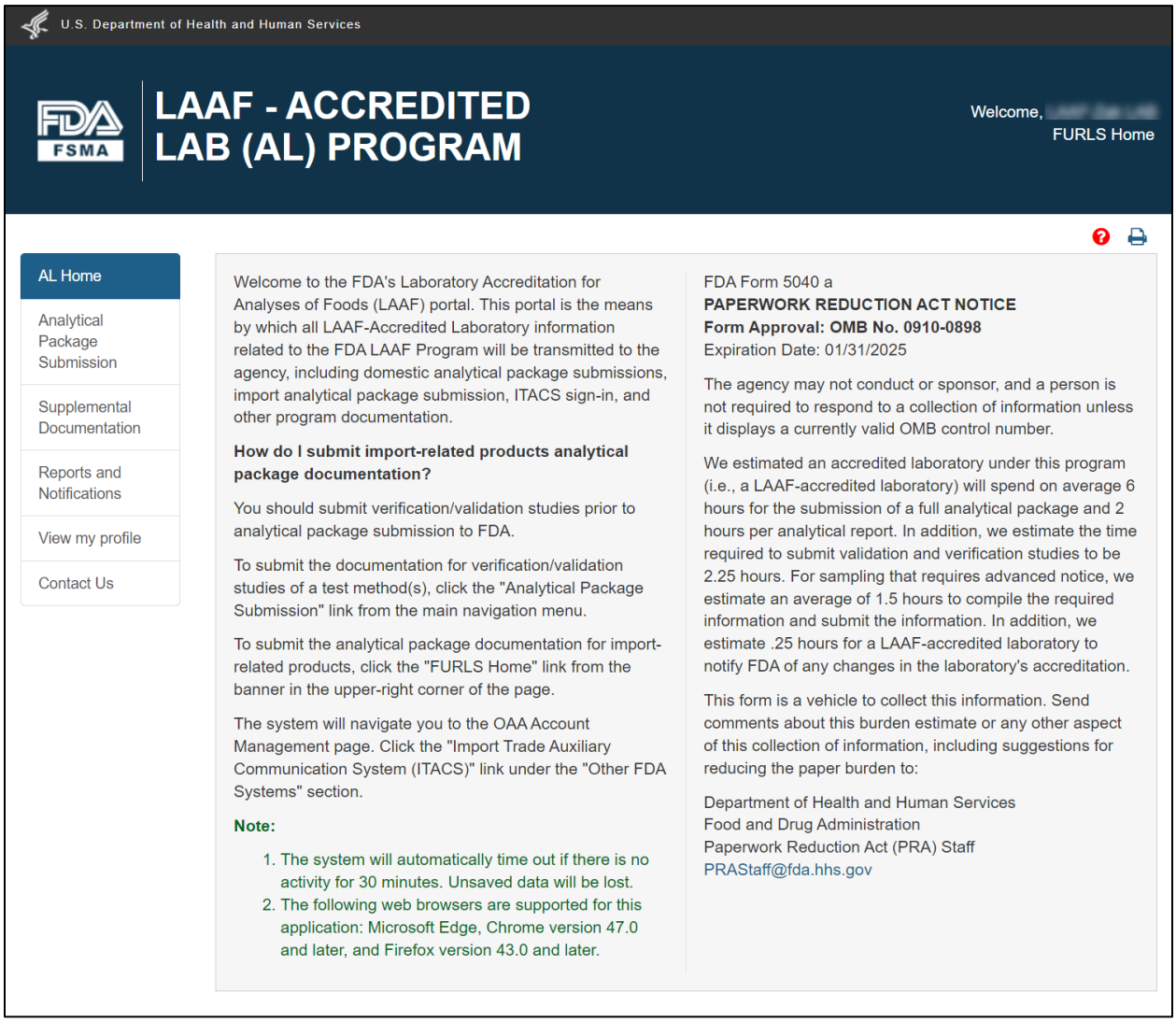


Figure 3.4: AL Home Page

4 Submit a Commodity Specific Analytical Package

*Commodity Specific packages are those packages submitted for testing circumstances under § 1.1107 (a)(1)(i, ii, iii).

The Analytical Package Submission feature allows the AL to perform three main functions related to analytical packages:

- Submitting test method verification/validation studies
- Uploading and submitting **commodity specific** analytical packages to FDA*
- Viewing the **commodity specific** analytical packages that have been submitted to FDA

***Important:** To submit the analytical package documentation for **import-related** products:

- If the user is logged into FURLS, they will click the “Import Trade Auxiliary Communication System (ITACS)” link under the “Other FDA Systems” section.
- If the user is already logged into the AL Portal, they will click the “FURLS Home” link from the banner in the upper right corner of the page. The system will navigate the user to the OAA “Account Management” page. The user will click the “Import Trade Auxiliary Communication System (ITACS)” link under the “Other FDA Systems” section.

To upload packages to the AL portal or view documents that have already been submitted to FDA, the user will click the “Analytical Package Submission” link from the navigation menu on the “AL Home” page (Figure 4.1).

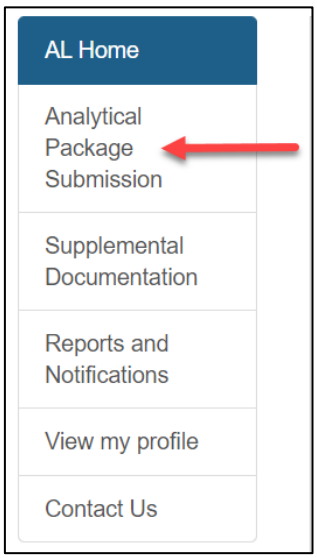


Figure 4.1: Navigation Menu

The system will display the Analytical Package Submission “Dashboard” page (Figure 4.2). Any document(s) the AL previously submitted to FDA will display in the table on the page, grouped by AB.

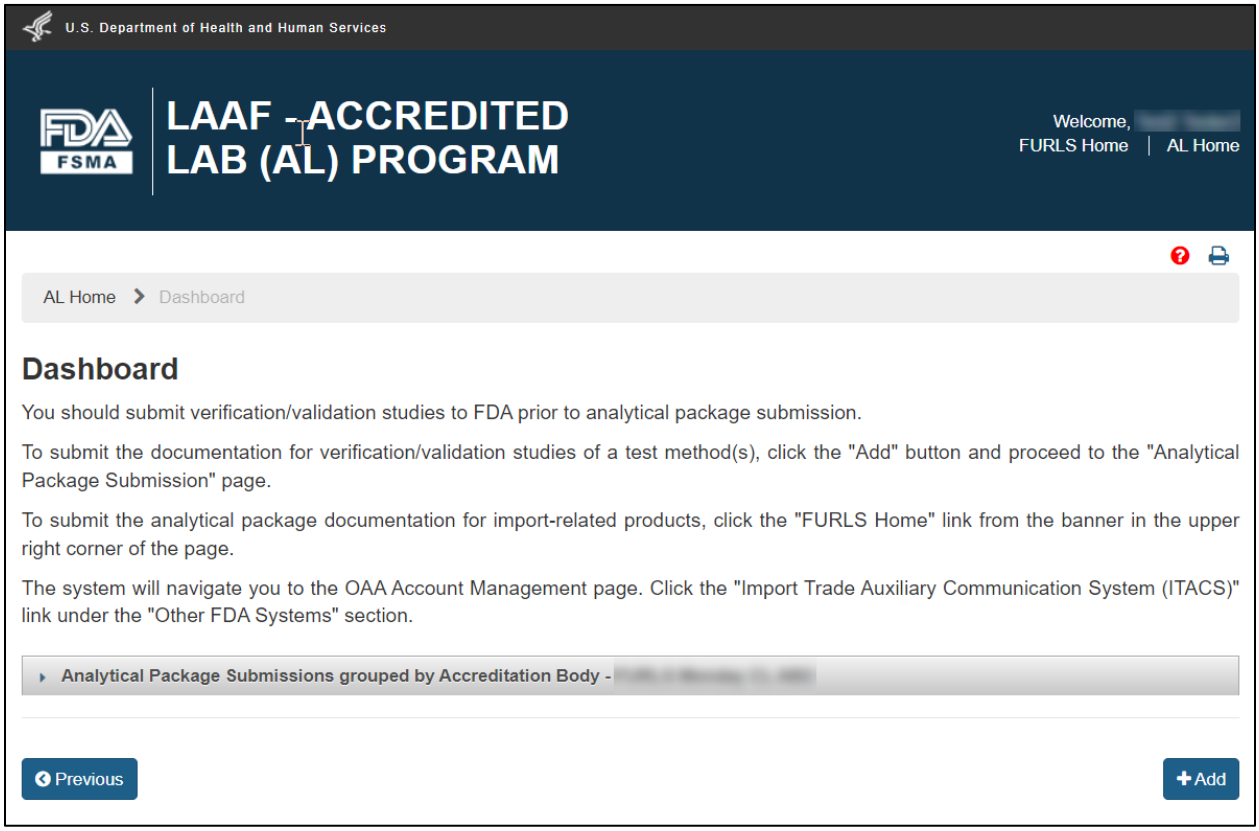


Figure 4.2: Analytical Package Submission Dashboard

The user can view the analytical packages submitted under an AB by clicking the accordion section's title bar (Figure 4.3).

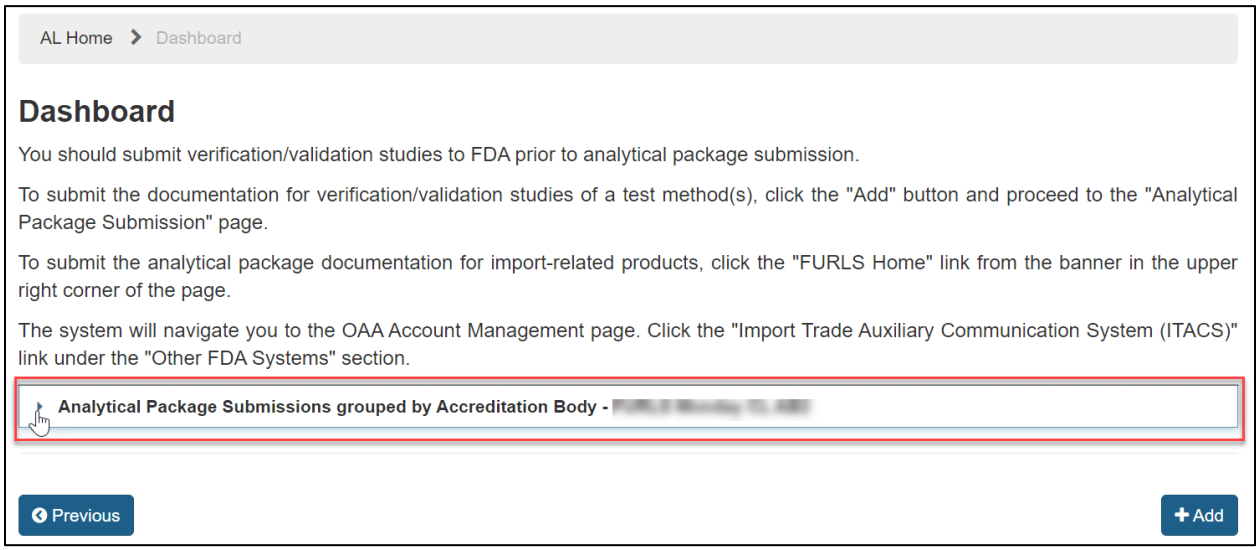


Figure 4.3: Accordion Section's Title Bar

The user can view additional details for previous submissions by clicking on the "View" icon of the "Action" column of the "Dashboard" page (Figure 4.4).

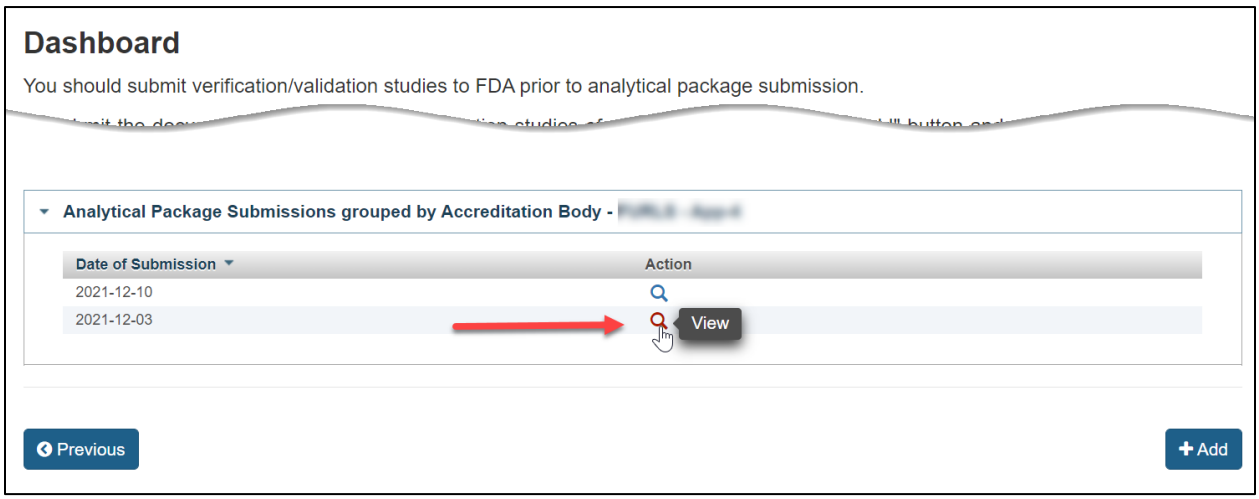


Figure 4.4: View Icon

The system will display the file name, file type, date of upload, and "AB Name" for the selected package (Figure 4.5).

The user can click on the hyperlinked document name in the "File Name" column to download or save the document.

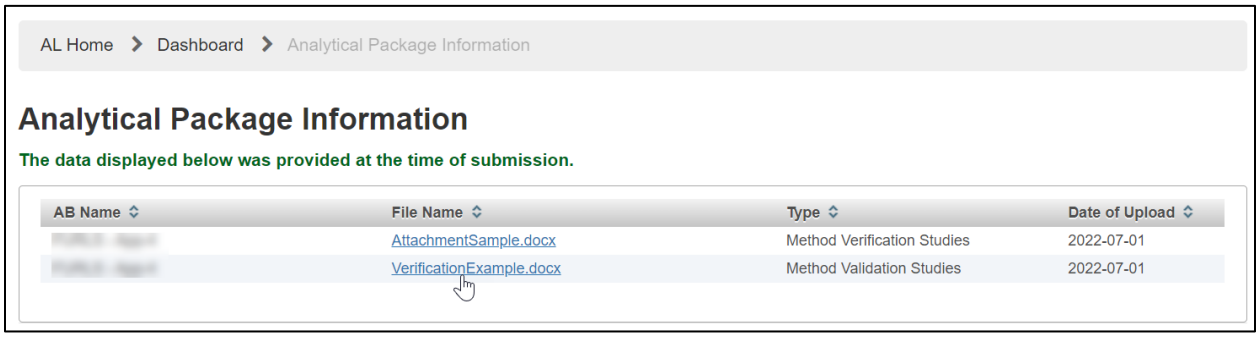


Figure 4.5: Submission Details

To add a new commodity-specific analytical package, the user will click the "+ Add" button on the "Dashboard" page (Figure 4.6).

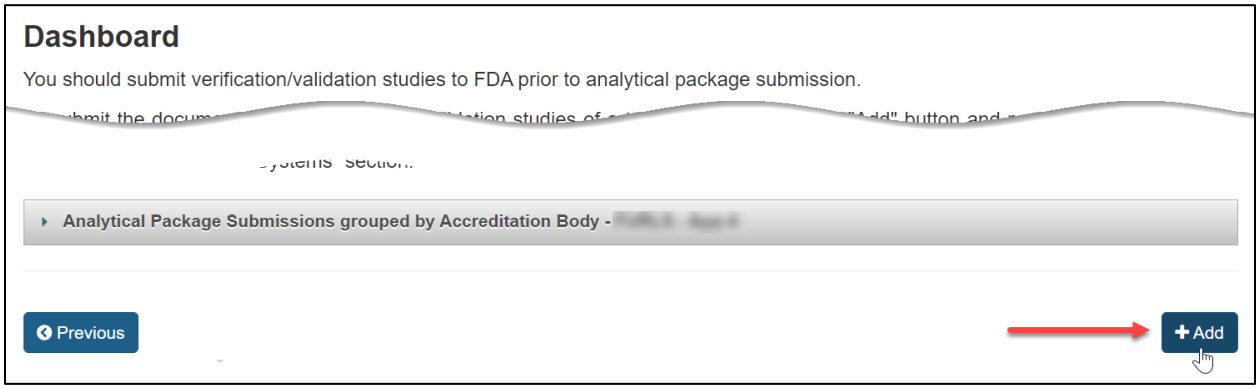


Figure 4.6: Add Button

The system will display the "Analytical Package Submission" page (Figure 4.7).

The user can follow Steps 1 - 6 from the "Instructions" section of the page to upload files.

The user will select the AB from the "AB Name" dropdown menu. If the AL is only accredited by one AB, the field will be pre-filled with the AB Name. If the AL is accredited by multiple ABs, the user should select only one AB per package submission.

Note: The user can click the “Previous” button at the bottom of the “Analytical Package Submission” page to return to the “AL Home” page.

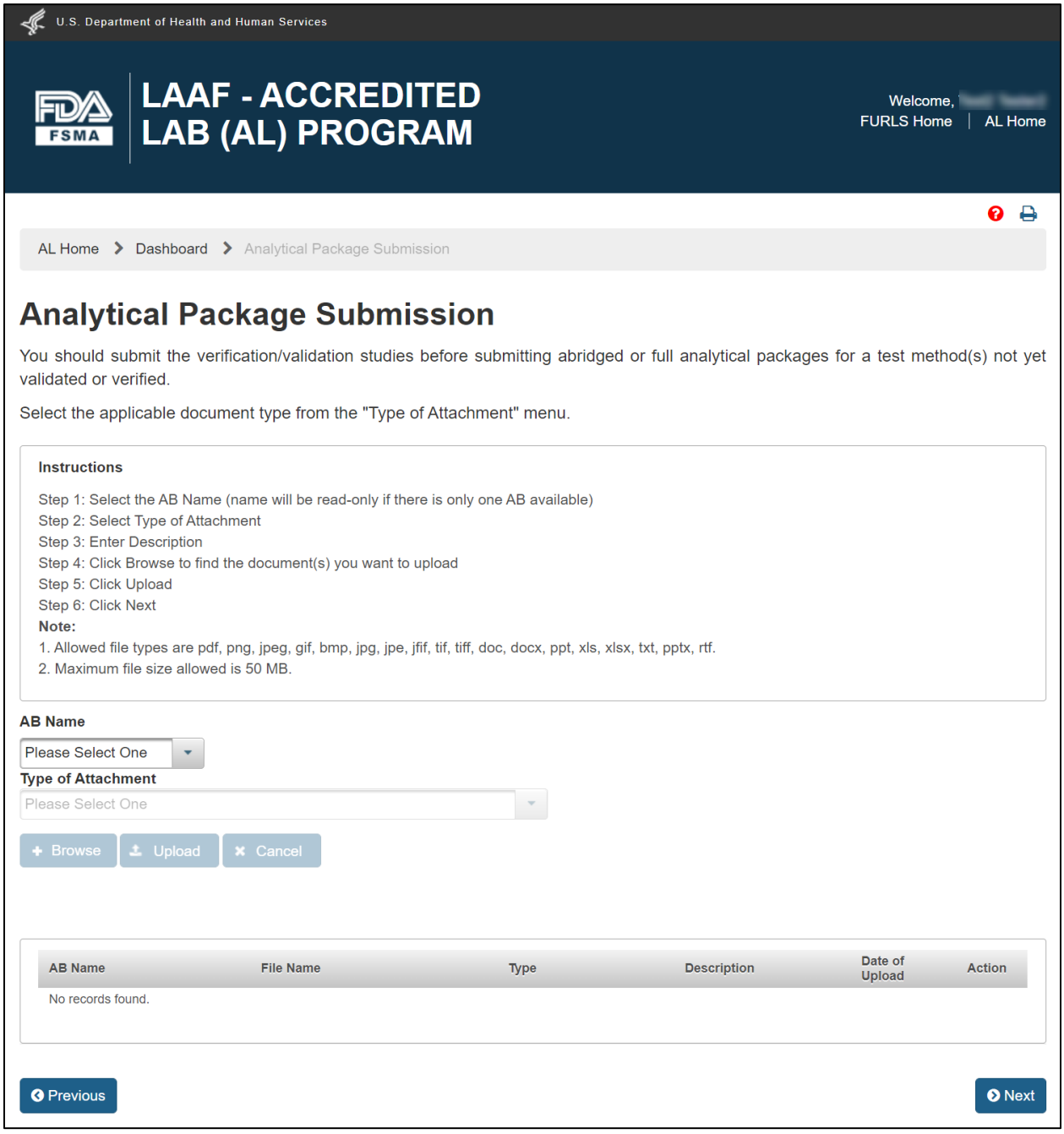


Figure 4.7: Analytical Package Submission Page

The user will select a document description from the “Type of Attachment” dropdown menu (Figure 4.8).

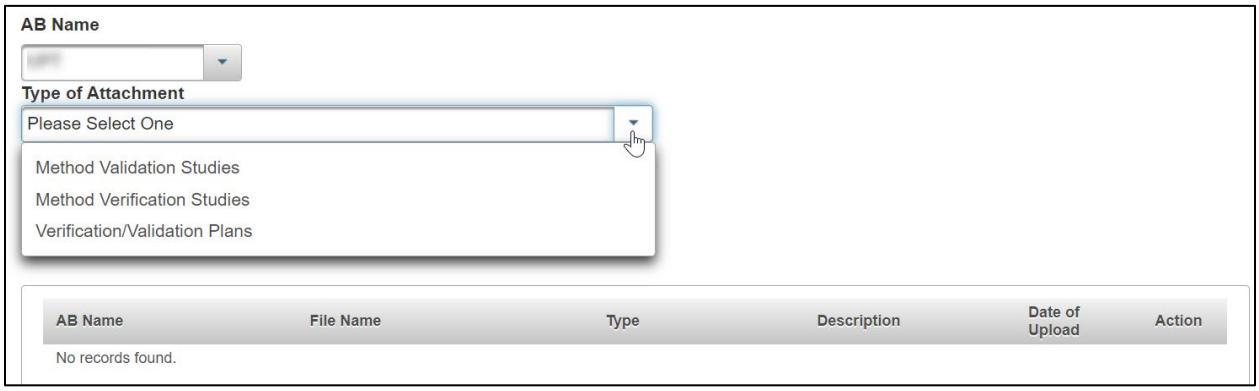


Figure 4.8: Type of Attachment Menu

A textbox labeled “Description” will display once a selection has been made from the “Type of Attachment” list (Figure 4.9).

The user will enter a detailed description of the document type in the “Description” field, which allows a maximum of 200 characters. The description should include the method name as it appears on the laboratory’s scope of accreditation.

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

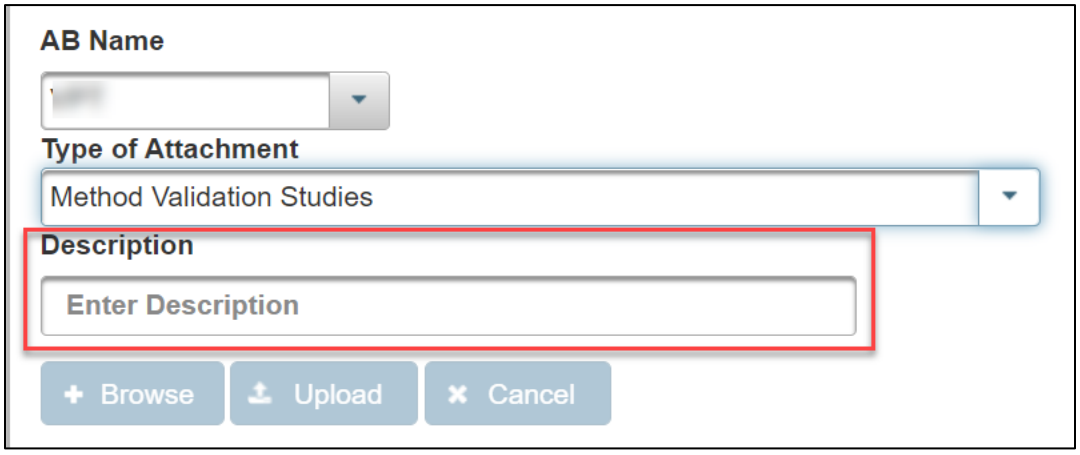


Figure 4.9: Description Field

Once the user has selected an option from the “Type of Attachment” dropdown menu, the “Browse” button will be enabled and the user will click it. A pop-up window will appear, prompting the user to access their file system.

The user can select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after choosing a file (Figure 4.10). The browsing window will close.

The user can click the “Upload” button to complete the attachment upload or, click the “Cancel” button to discard the file upload.

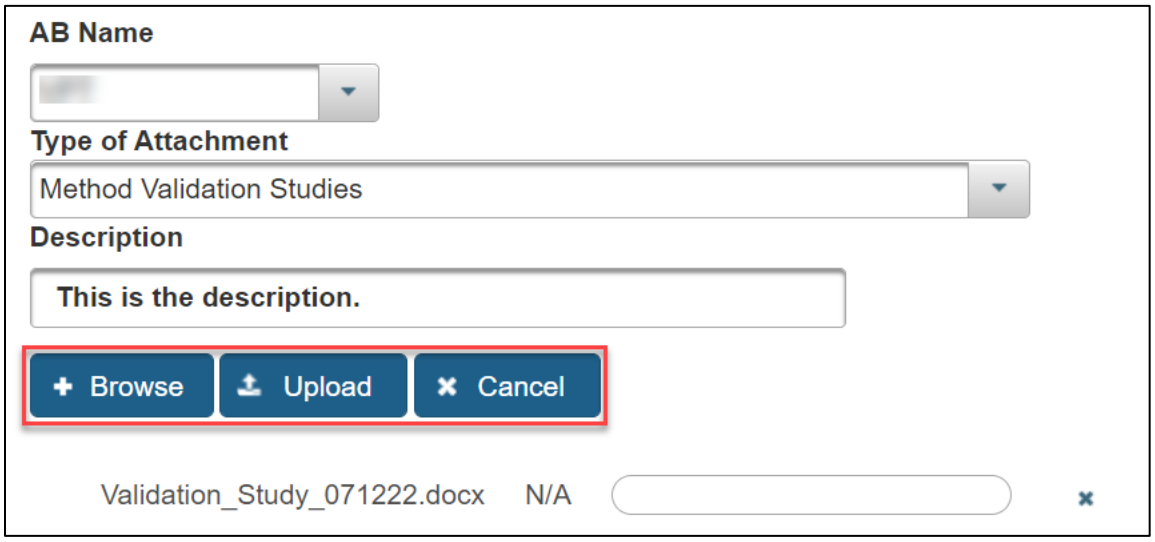


Figure 4.10: Upload and Cancel Buttons

Attachments must be configured as a document type supported by the system. Attachments should be uploaded in as few files as possible and if they are for the same method, a designation of “1, 2, 3” or “a, b,c”.

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 will display at the top of the page (Figure 4.11).

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

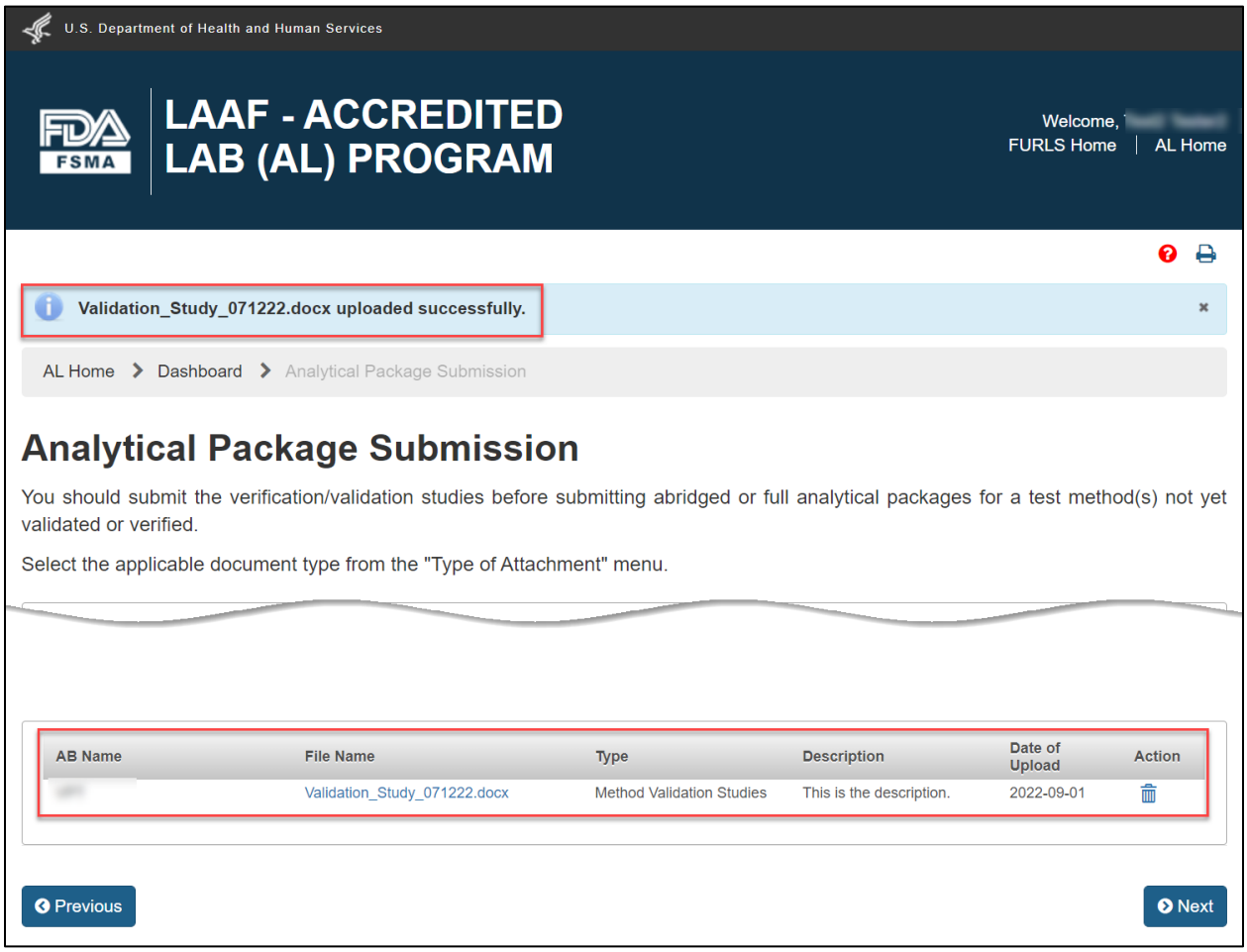


Figure 4.11: Successful Upload Message

To remove the attachment from the table at the bottom of the page, the user can click the “trash/delete” icon in the “Action” column (Figure 4.12).

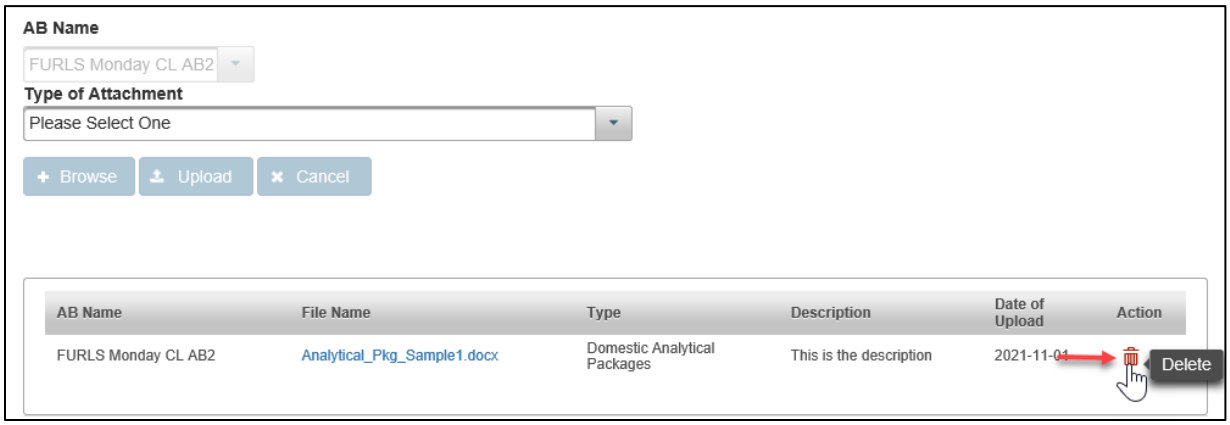


Figure 4.12: Trash/Delete Icon

After completion of the notice, the user will click the “Next” button. The system will navigate them to the “e-Signature” page (Figure 4.13).

The user will follow the directions provided on the “e-Signature” page, complete the following user entry fields, 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.”
- **Name of Submitter –** The first and last name of the submitter.
- **Title of Submitter –** The title of the submitter.

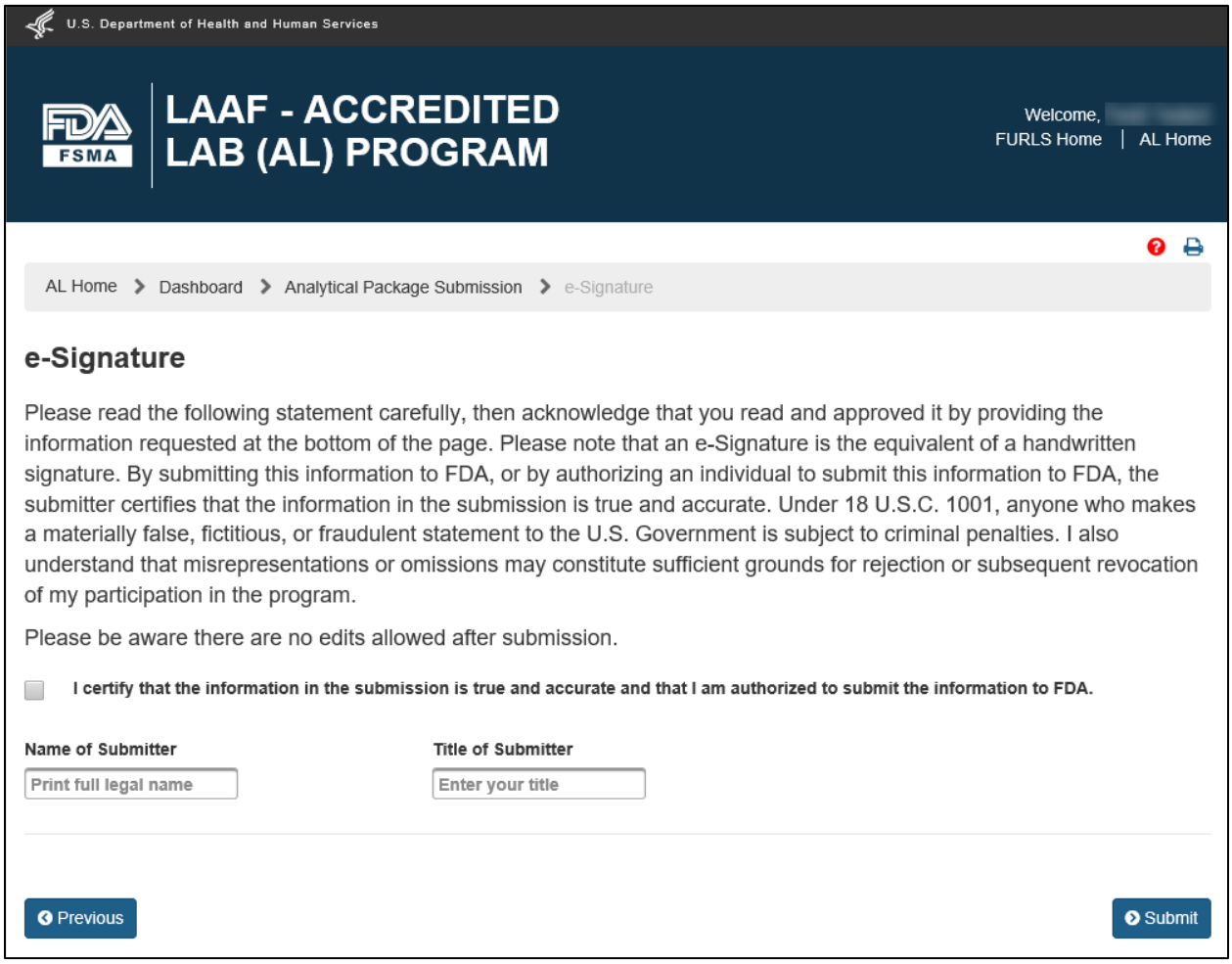


Figure 4.13: e-Signature Page

Upon successful submission, the system will post a message on the “Confirmation” page (Figure 4.14).

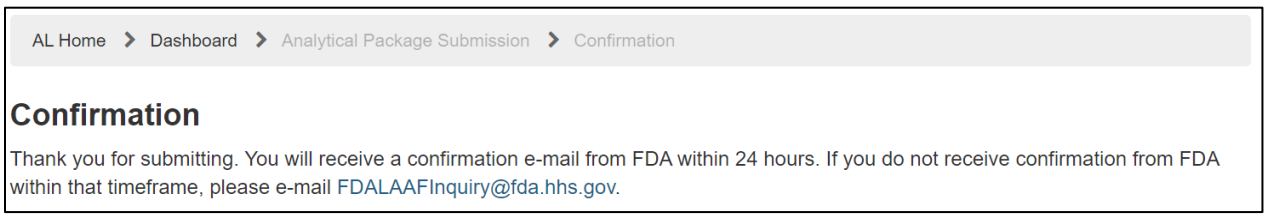


Figure 4.14: Confirmation Message

The user may click the “AL Home” link on the top of the banner (or from the breadcrumb) to return to “AL Home” page (Figure 4.15).

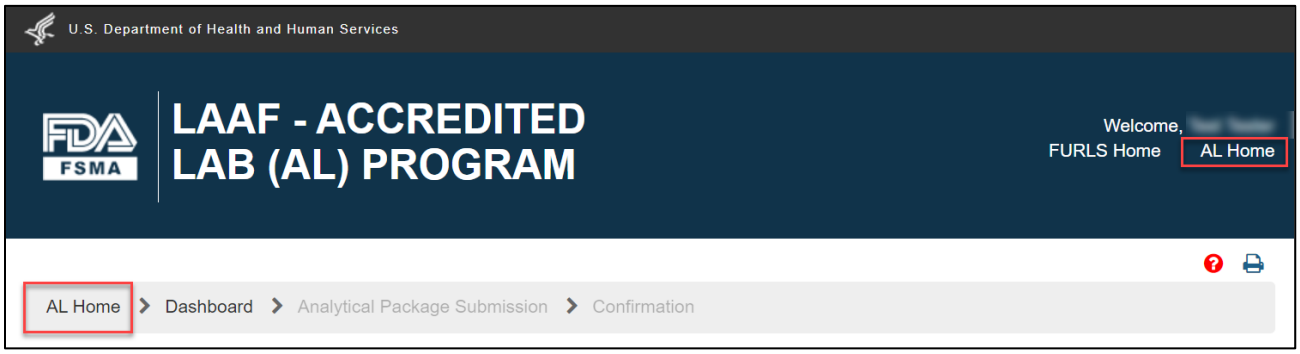


Figure 4.15: Links to the AL Home Page

5 Submit Supplemental Documentation

The “Supplemental Documentation” feature allows the 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 documents to the AL portal or view documents that have already been submitted to FDA, the user will click the “Supplemental Documentation” link from the navigation menu on the “AL Home” page (Figure 5.1).

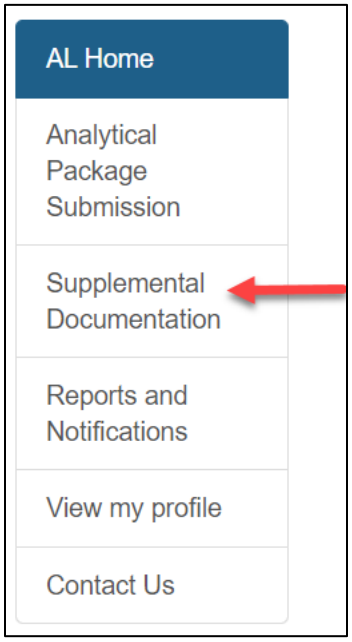


Figure 5.1: Navigation Menu

The system will display the “Supplemental Documentation” page (Figure 5.2). Any document(s) previously submitted to FDA will display in a table at the bottom of the page. The user can click on the hyperlinked document name in the “File Name” column to view the document.

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

Note: The user can click the “Previous” button at the bottom of the “Supplemental Documentation” page to return to the “AL Home” page.

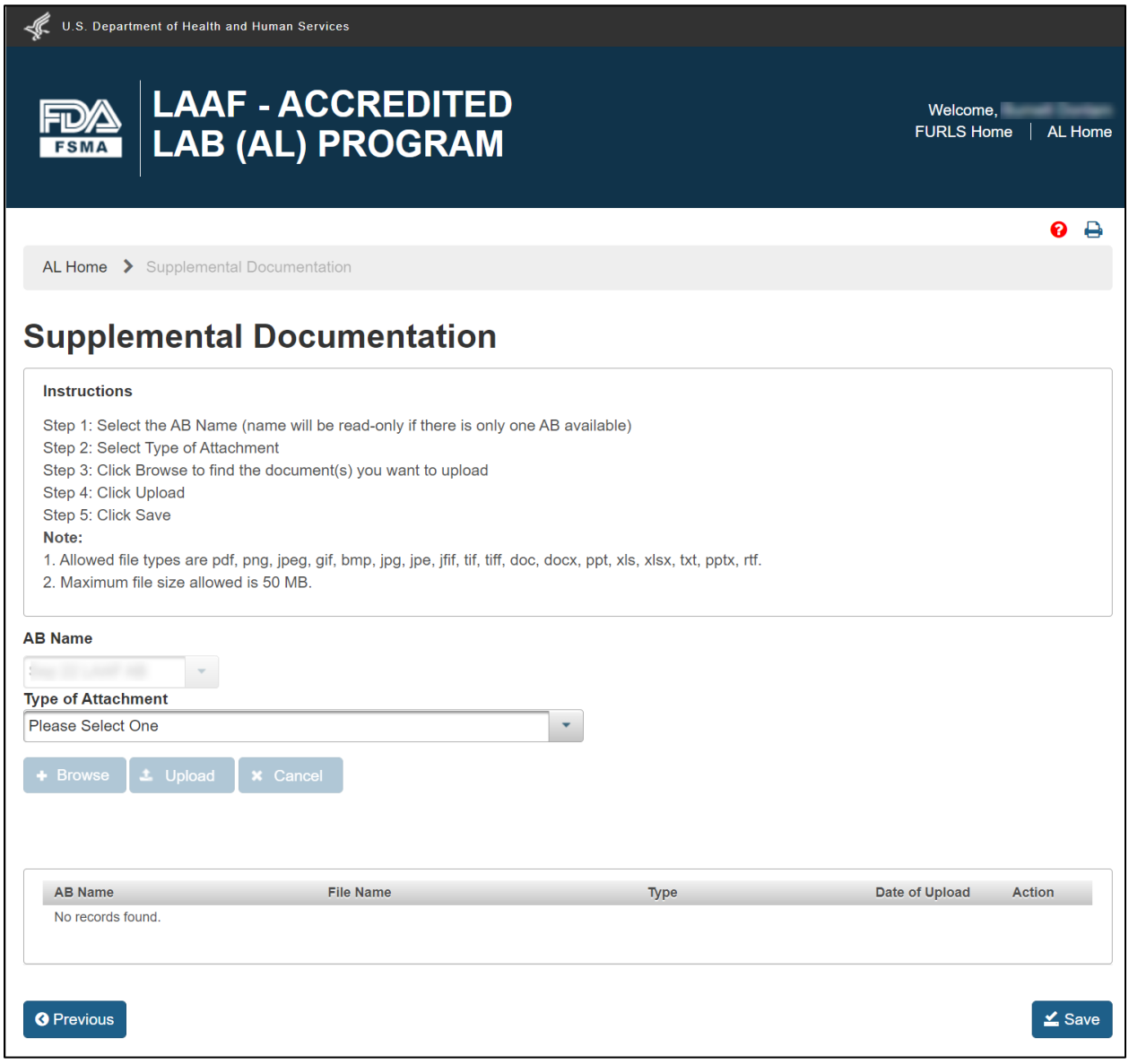


Figure 5.2: Supplemental Documentation Page

The user will select the AB from the “AB Name” dropdown menu.

If the AL is only accredited by one AB, the field will be pre-filled with the AB name.

The user will select a document description from the list in the “Type of Attachment” dropdown menu (Figure 5.3).

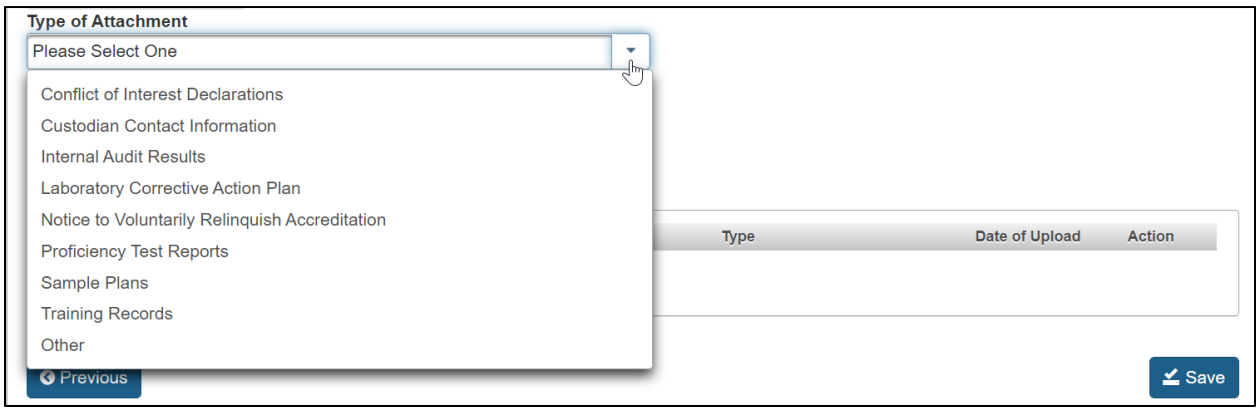


Figure 5.3: Type of Attachment Menu

A text box labeled “Additional Description” will display if the user selected “Other” from the list (Figure 5.4).

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

Note: The user must enter a description in the “Additional Description” field to proceed to the next step.

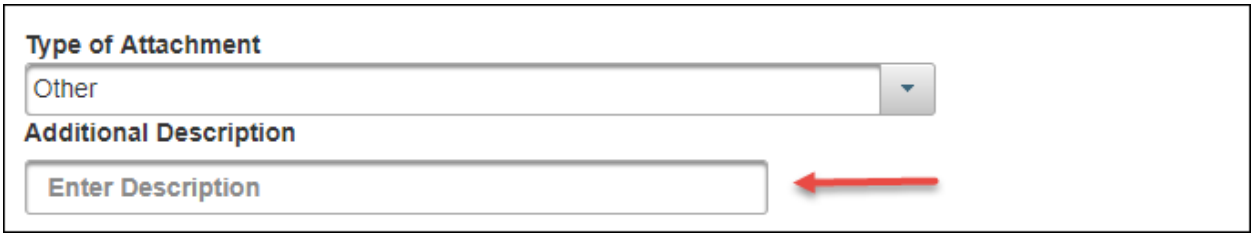


Figure 5.4: “Other” Attachment Type

The user will click the “Browse” button. A pop-up window will appear, prompting the user to access their file system.

The user will select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after a file is chosen (Figure 5.5). The system will close the browsing window.

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

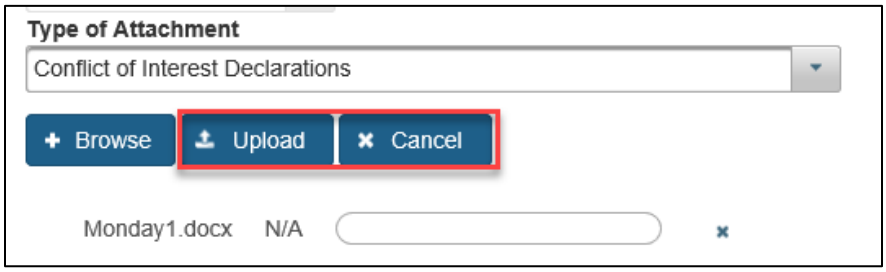


Figure 5.5: Upload and Cancel Buttons

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 will display at the top of the page (Figure 5.6).

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

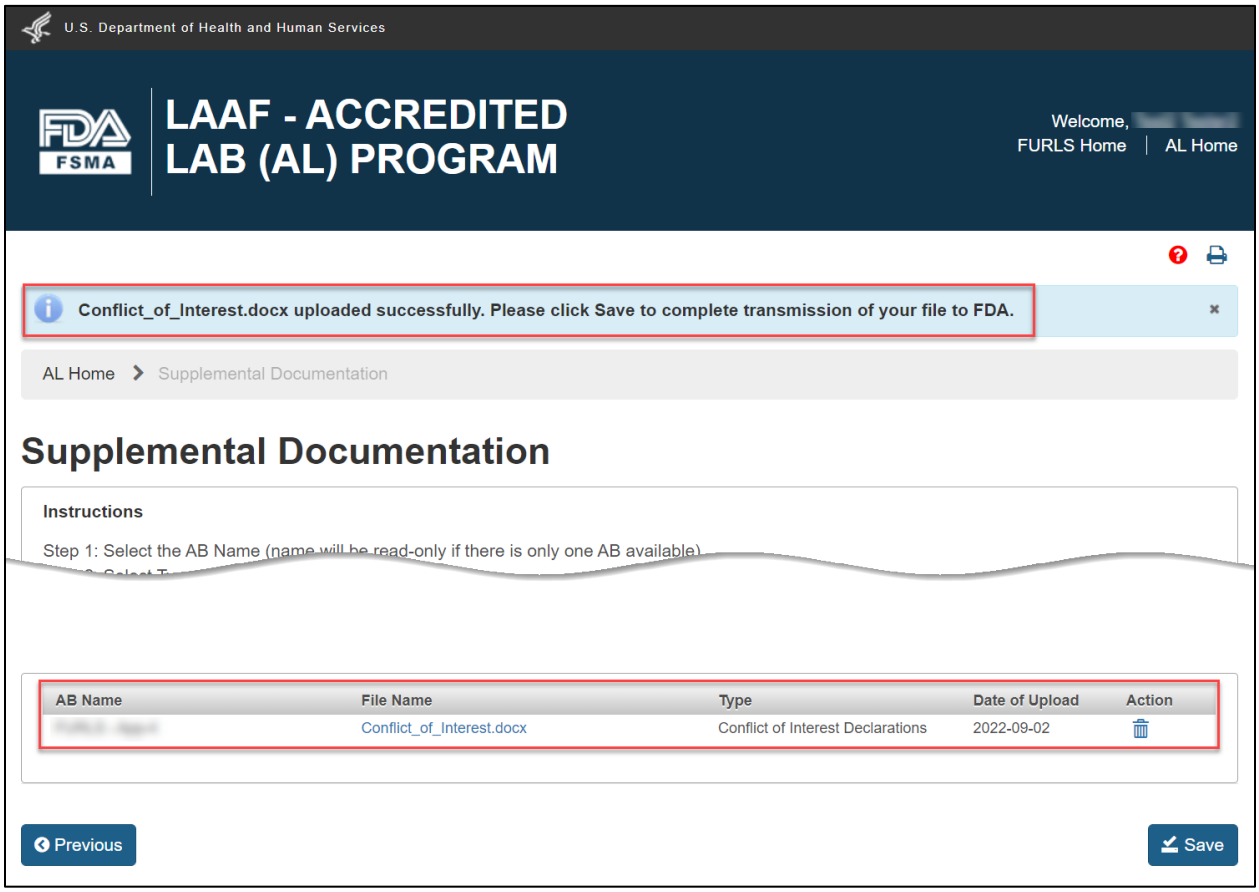


Figure 5.6: Successful Upload Message

To remove the attachment from the table at the bottom of the page, the user can click the “trash/delete” icon in the “Action” column (Figure 5.7).

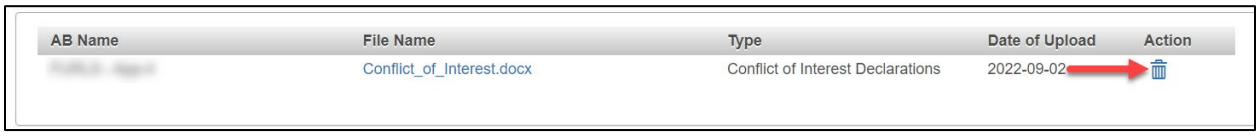


Figure 5.7: Trash/Delete Icon

After the additional files have been uploaded, the user will click the “Save” button (Figure 5.8).

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

Figure 5.8: Save Attachment

Once a file has been uploaded and added to the attachments table, the file name will become hyperlinked. If the user clicks on the hyperlinked file name, they will be prompted to open or save the file (Figure 5.9).

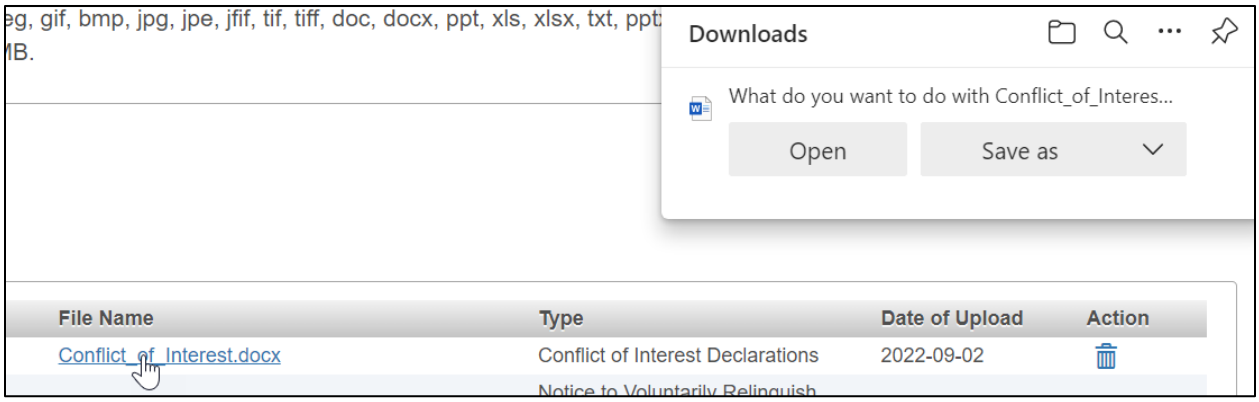


Figure 5.9: Hyperlinked File Name

6 Reports and Notifications

The “Reports and Notifications” feature allows the user to (electronically) notify FDA of events or updates.

To access the “Reports and Notifications” feature, the user will click the “Reports and Notifications” link from the navigation menu on the “AL Home” page (Figure 6.1).

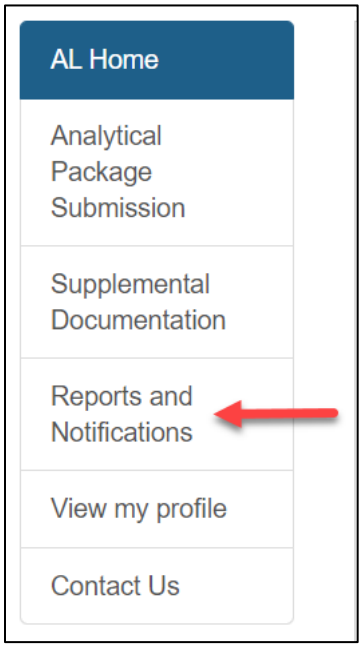


Figure 6.1: Navigation Menu

The system will display the “Reports and Notifications” page with the following report and notification available (Figure 6.2):

- **Notice of Request for Submission of Abridged Analytical Packages** – Generates a notice to FDA when an AL submits a request for submission of abridged **import** analytical packages for a food testing discipline.

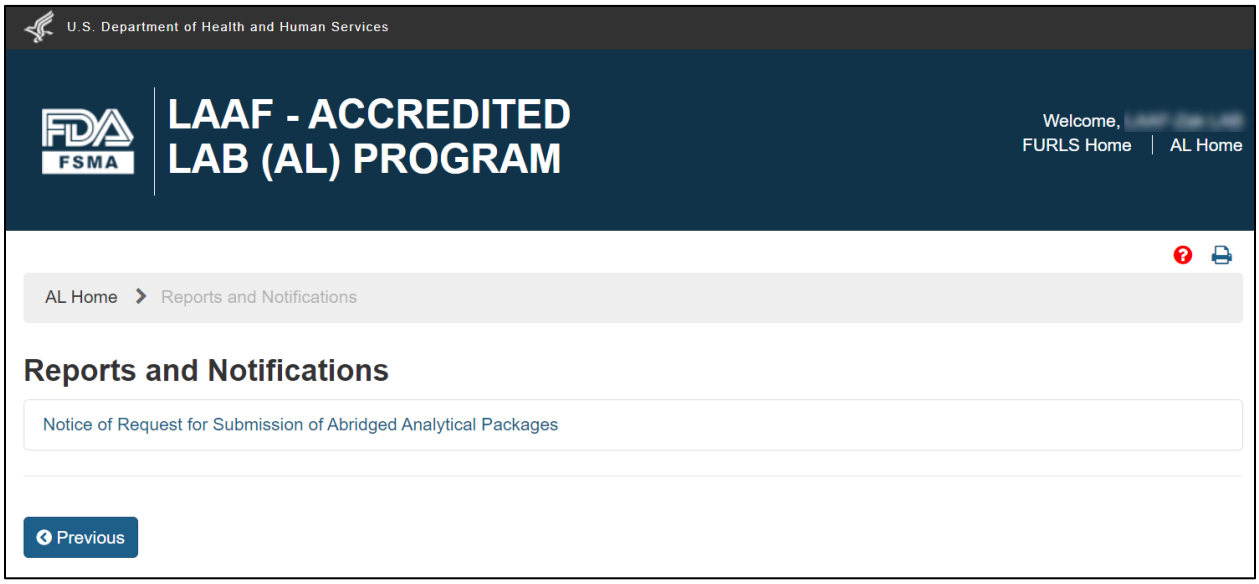


Figure 6.2: Reports and Notifications Page

6.1 Notice of Request for Submission of Abridged Analytical Packages

To notify FDA of a request for submission of abridged **import** analytical packages for a food testing discipline, the user will click the “Notice of Request for Submission of Abridged Analytical Packages” link on the “Reports and Notifications” page (Figure 6.3).

The user may click the “Previous” button to return to the “AL Home” page.

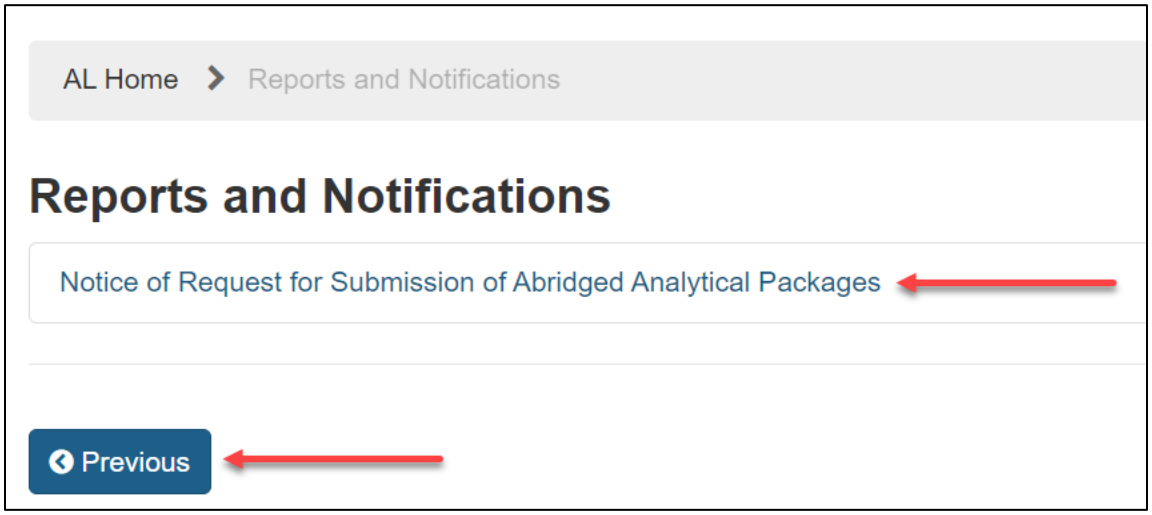


Figure 6.3: Notice Link and Previous Button

The system will display the “Notice of Request for Submission of Abridged Analytical Packages” page (Figure 6.4).

Note: The user can click the “Previous” button at the bottom of the notice to return to the “AL Home” page.

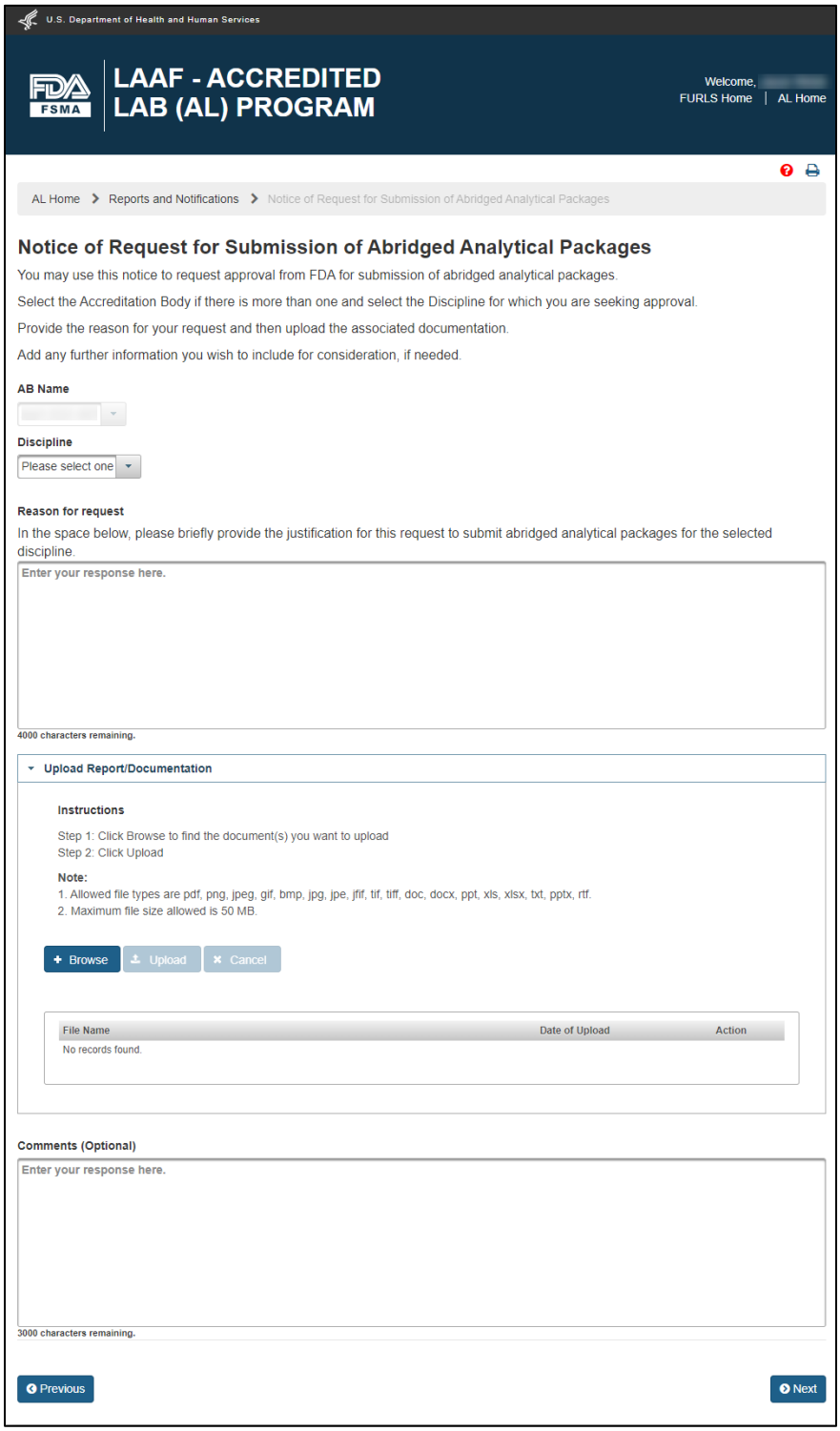


Figure 6.4: Notice of Request for Submission of Abridged Analytical Packages

The user will select the AB from the “AB Name” dropdown menu (Figure 6.5). If the AL is only accredited by one AB, the “AB Name” field will be pre-filled.

Figure 6.5: AB Name Menu

The user will select a testing discipline from the “Discipline” dropdown menu (Figure 6.6).

Note: One discipline may be submitted per notice.

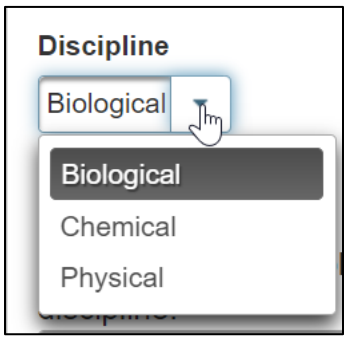


Figure 6.6: Discipline Menu

The user will enter a detailed justification for the request in the “Reason for Request” field (Figure 6.7). This is a free-type field which allows a maximum of 4,000 characters.

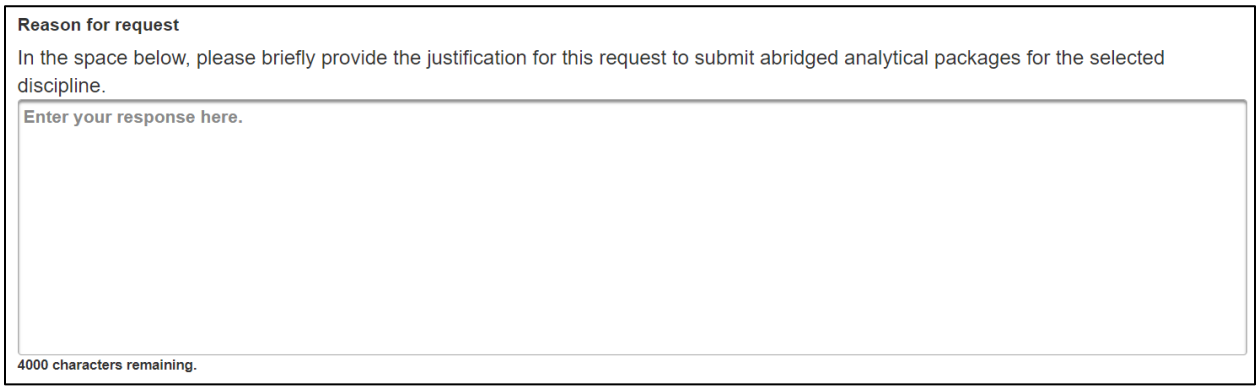


Figure 6.7: Reason for Request Field

The user can follow Steps 1 and 2 from the “Instructions” section of the page to upload files (Figure 6.8).

The user is required to upload at least one file in order to submit the notice.

The user will click the “Browse” button, which will be enabled by default (Figure 6.8). A pop-up window will appear, prompting the user to access their file system.

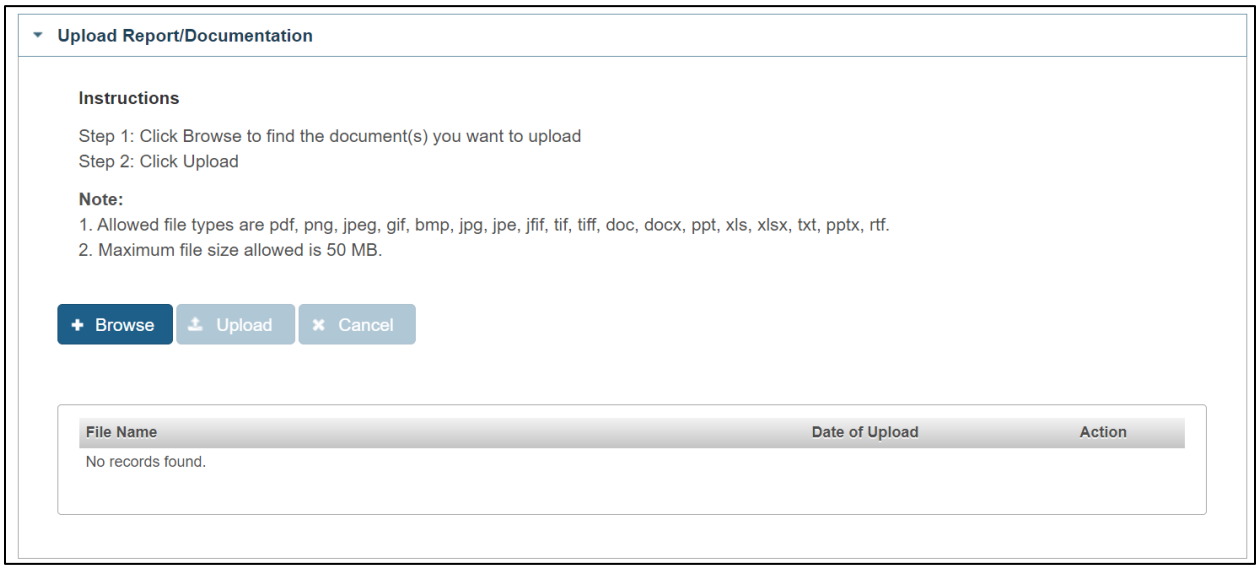


Figure 6.8: Upload Report/Documentation Section with Browse Button Enabled

The user can select one or more file attachments. The “Upload” and “Cancel” buttons will be enabled after choosing a file (Figure 6.9). The browsing window will close.

The user can click the “Upload” button to complete the attachment upload or, click the “Cancel” button to discard the file upload.

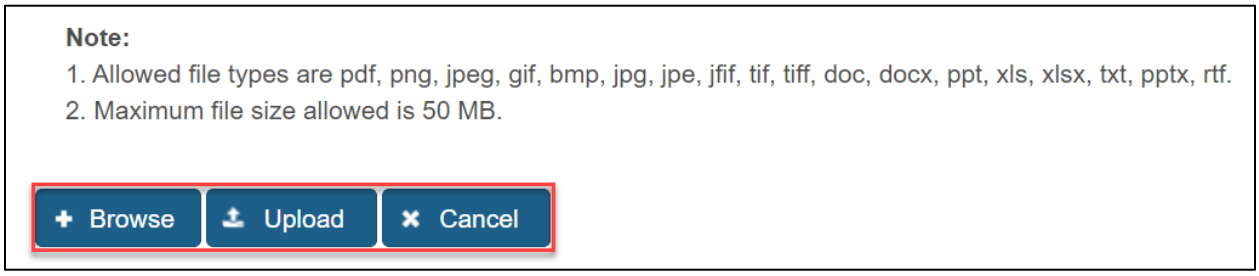


Figure 6.9: Upload and Cancel Buttons

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

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

The maximum file size allowed is 50 MB.

Once the upload is complete, a confirmation message indicating a successful upload will display at the top of the page (Figure 6.10).

The system will display the uploaded files in the table in the “Upload Report/Documentation” section. To remove the attachment from the table, the user can click the “trash/delete” icon in the “Action” column.

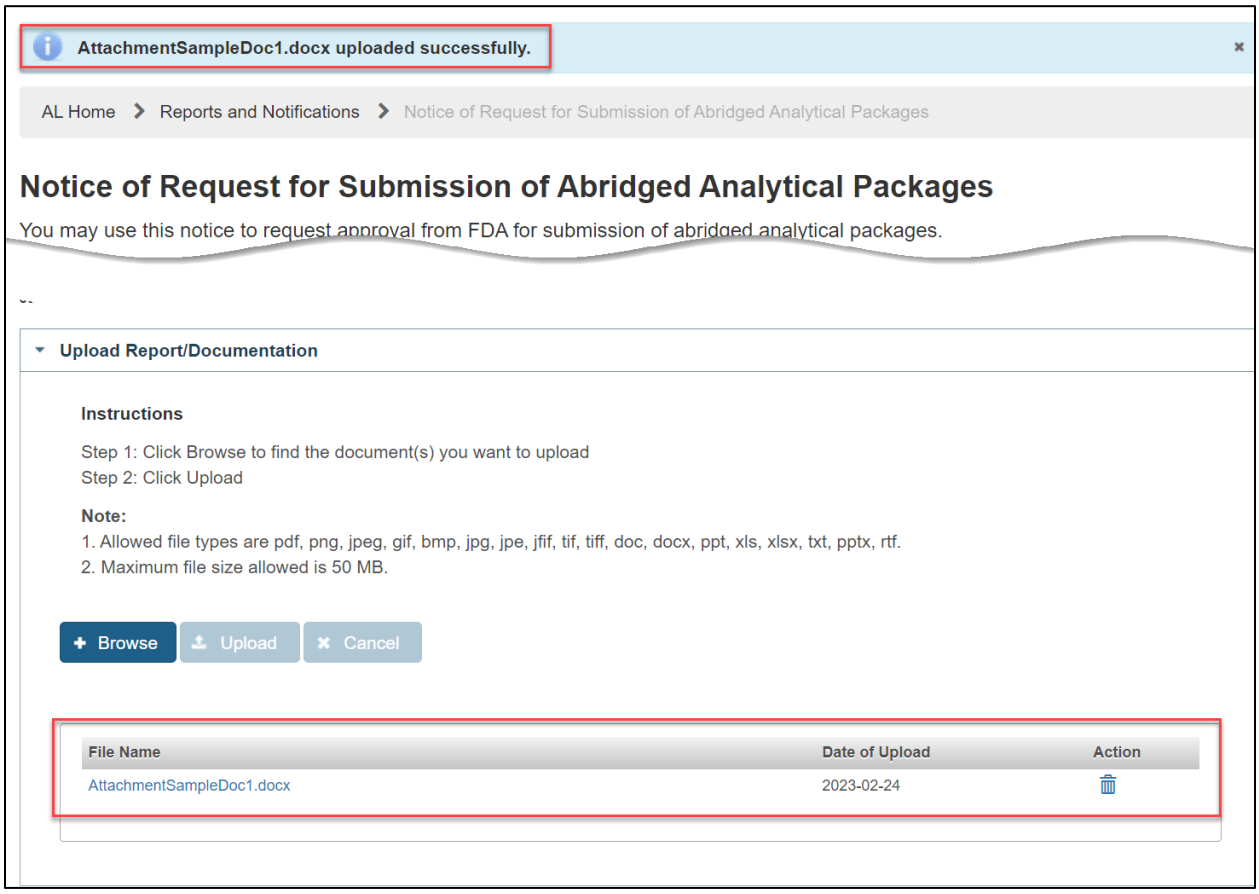


Figure 6.10: Successful Upload Message

The user may enter additional comments in the “Comments” section (Figure 6.11). This is an optional, free-type field which allows up to 3,000 characters.

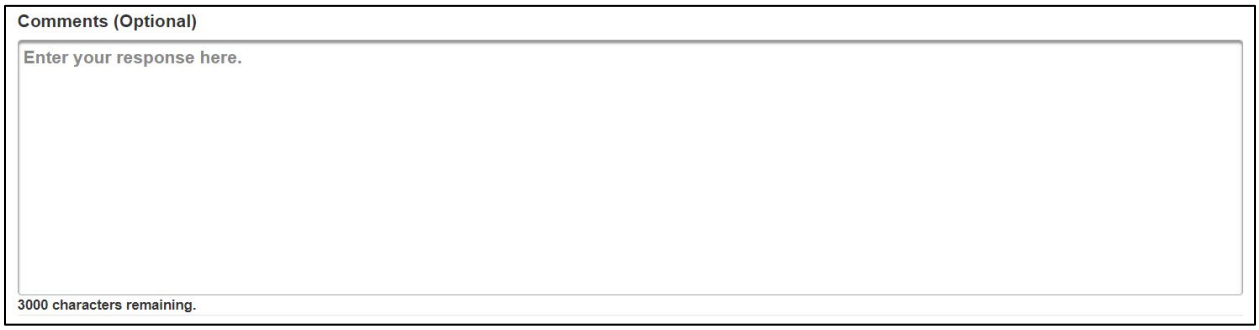


Figure 6.11: Comments Field

After completion of the notice, the user will click the “Next” button. The system will navigate them to the “e-Signature” page (Figure 6.12).

The user will follow the directions provided on the “e-Signature” page, complete the following user entry fields, 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.”
- **Name of Submitter** – The first and last name of the submitter.
- **Title of Submitter** – The title of the submitter.

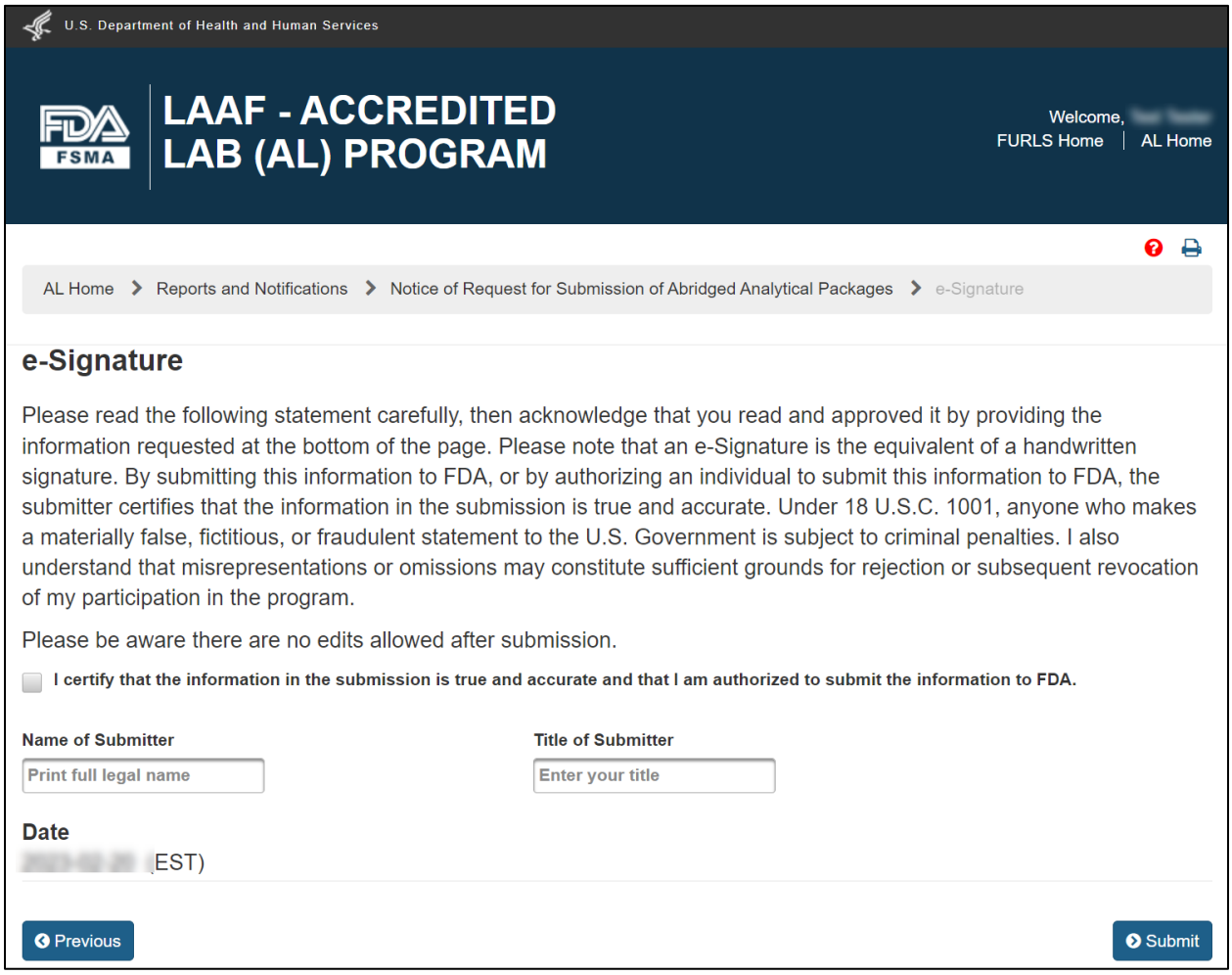


Figure 6.12: e-Signature Page

Upon successful submission, the system will post a message on the “Confirmation” page (Figure 6.13).

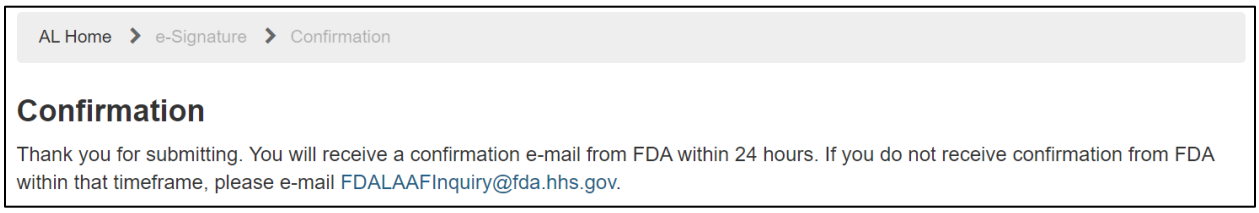


Figure 6.13: Confirmation Message

The user may click the “AL Home” link on the top of the banner (or from the breadcrumb) to return to the “AL Home” page (Figure 6.14).

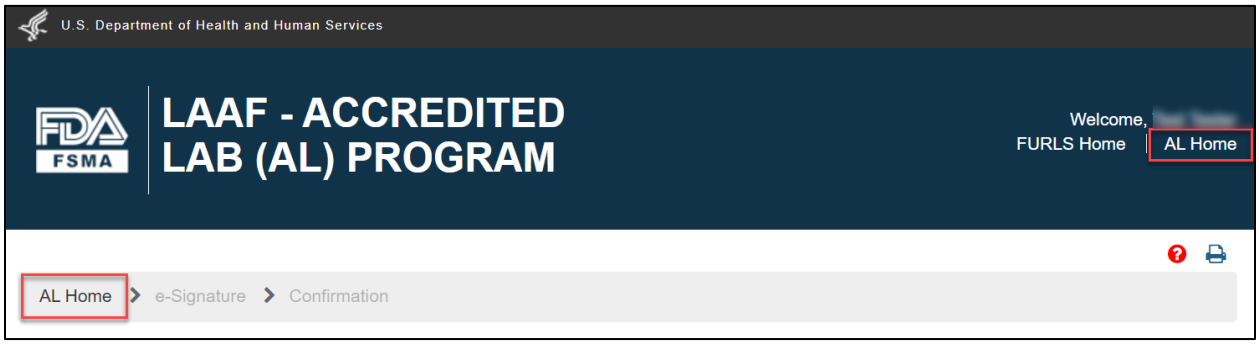


Figure 6.14: Links to AL Home Page

The system will send the user an e-mail indicating the notice was received by FDA (Figure 6.15).

Note: The image (below) only depicts the e-mail notification text.

Subject: Notification or Report Received

Thank you for submitting information to FDA regarding the Notice of Request for Submission of Abridged Analytical Packages. We will review this information and may follow-up if additional information is needed.

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

DO NOT REPLY TO THIS EMAIL

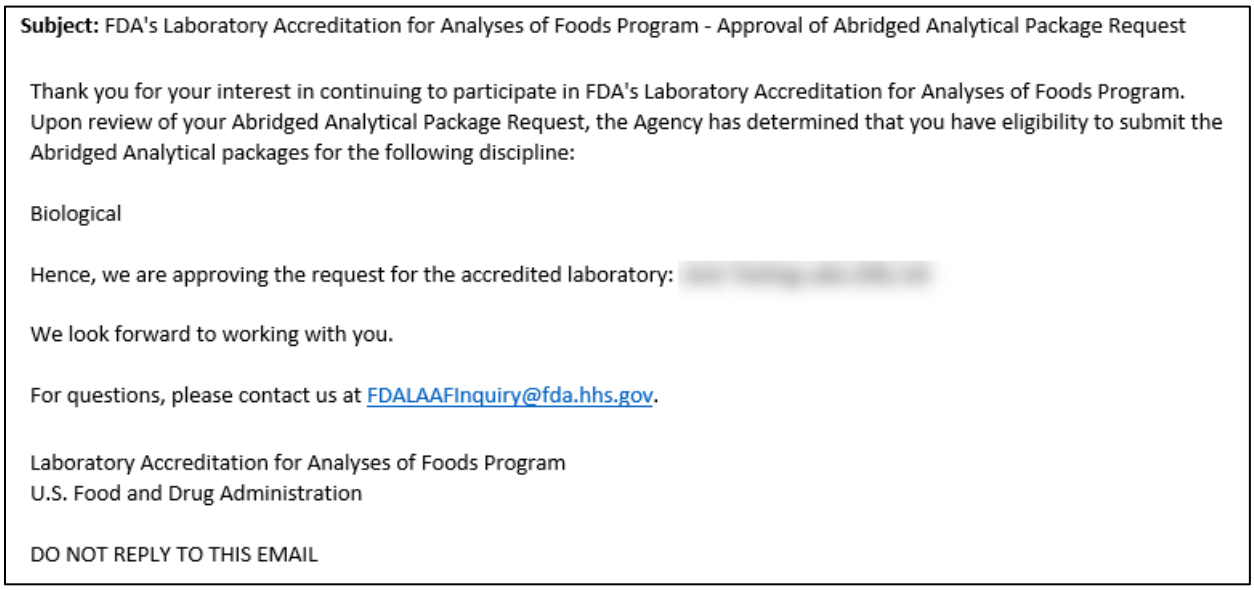
Figure 6.15: E-mail Confirmation

The Notice of Request for Submission of Abridged Analytical Packages is subject to approval or denial by FDA. The user will be notified by email regarding the decision.

If FDA has approved the submission, the user will receive the following notification (Figure 6.16):

Note: The images (below) only depict the e-mail notification subject and text.

The content are examples of the notifications. The actual testing discipline listed in the user's version of the notification may vary, based on the user's submission.



Subject: FDA's Laboratory Accreditation for Analyses of Foods Program - Approval of Abridged Analytical Package Request

Thank you for your interest in continuing to participate in FDA's Laboratory Accreditation for Analyses of Foods Program. Upon review of your Abridged Analytical Package Request, the Agency has determined that you have eligibility to submit the Abridged Analytical packages for the following discipline:

Biological

Hence, we are approving the request for the accredited laboratory: [redacted]

We look forward to working with you.

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

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

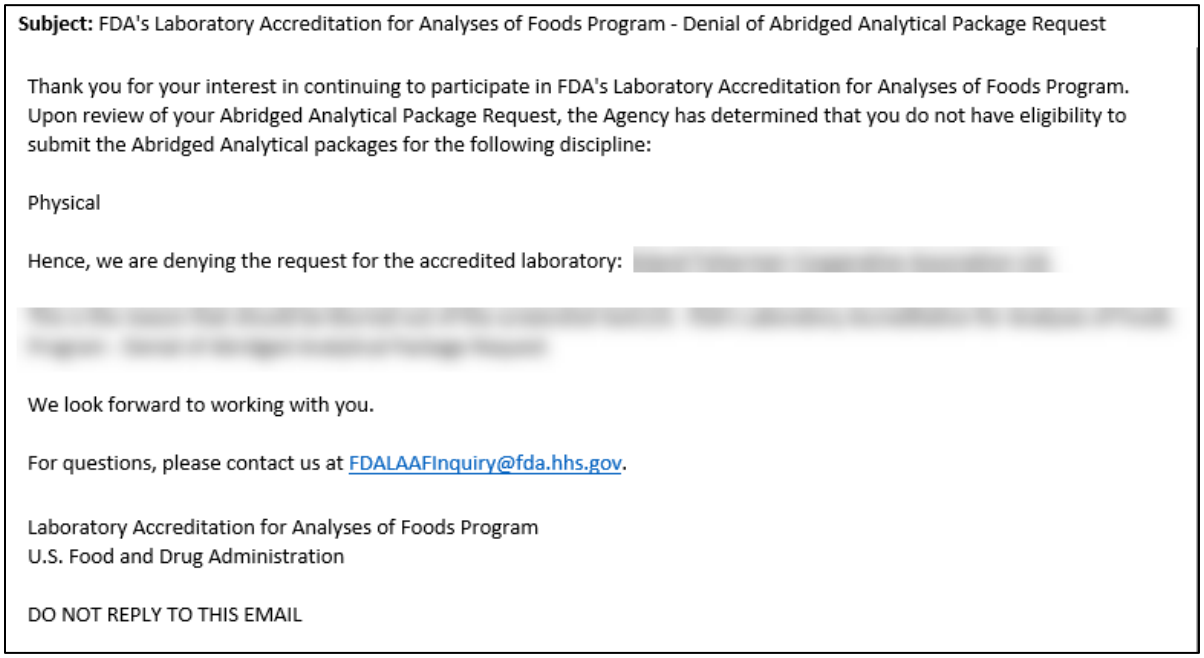
DO NOT REPLY TO THIS EMAIL

Figure 6.16: Approval of Abridged Analytical Package Request Notification

If FDA has approved the notice, the status under "Approved Package Submission" on the "Accredited Laboratory Information" page – (accessed by the "View my Profile" feature on the main navigation menu) – will be updated from default status "Full" to "Abridged".

Refer to Chapter 7 "View My Profile" for more information.

If FDA has denied the notice for the selected discipline, the user will receive the following notification (Figure 6.17):



Subject: FDA's Laboratory Accreditation for Analyses of Foods Program - Denial of Abridged Analytical Package Request

Thank you for your interest in continuing to participate in FDA's Laboratory Accreditation for Analyses of Foods Program. Upon review of your Abridged Analytical Package Request, the Agency has determined that you do not have eligibility to submit the Abridged Analytical packages for the following discipline:

Physical

Hence, we are denying the request for the accredited laboratory: [redacted]

[redacted]

We look forward to working with you.

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

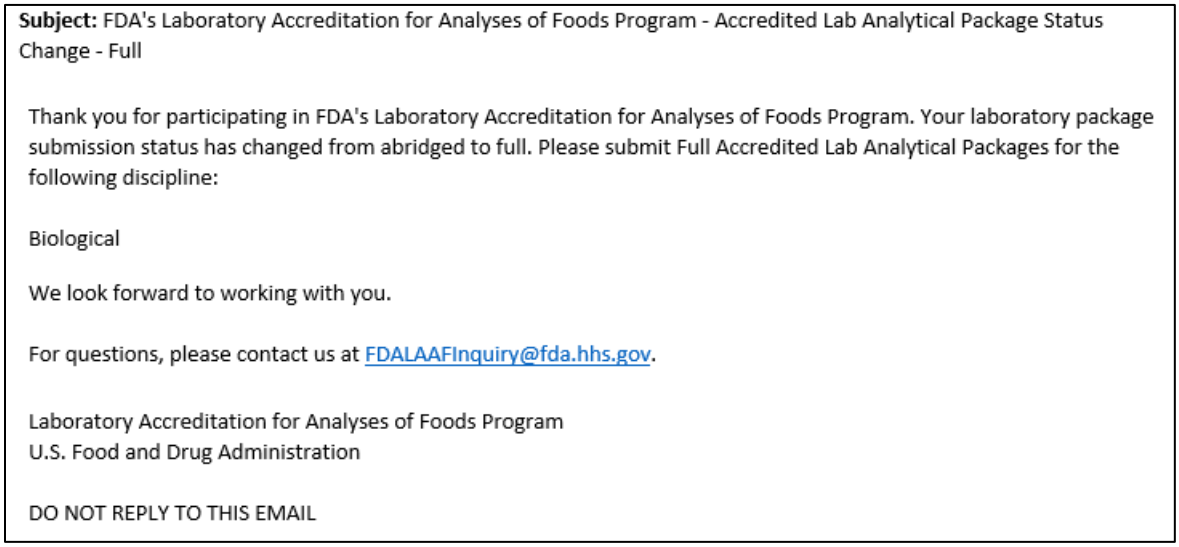
Laboratory Accreditation for Analyses of Foods Program
U.S. Food and Drug Administration

DO NOT REPLY TO THIS EMAIL

Figure 6.17: Denial of Abridged Analytical Package Request Notification

Following a denial decision, the user may resubmit the notice by following the same steps listed in this chapter for submission of the notice.

Note: If FDA had previously approved a submission for a testing discipline and then determined that full package submission should resume, the user will receive the following notification (Figure 6.18):



Subject: FDA's Laboratory Accreditation for Analyses of Foods Program - Accredited Lab Analytical Package Status Change - Full

Thank you for participating in FDA's Laboratory Accreditation for Analyses of Foods Program. Your laboratory package submission status has changed from abridged to full. Please submit Full Accredited Lab Analytical Packages for the following discipline:

Biological

We look forward to working with you.

For 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 6.18: Package Status Change to Full Notification

The status of the applicable testing discipline will be updated from “Abridged” back to “Full” on the “Accredited Laboratory Information” page.

Refer to Chapter 7 “View My Profile” for more information.

7 View My Profile

The “View My Profile” feature allows the user to perform the following functions:

- View and verify AL account information submitted during the OAA account creation
- View accreditation details
- View testing method verification status
- View approval status for submission of abridged or full **import** analytical packages for a testing discipline

To access the “View My Profile” feature, the user will click the “View my profile” link from the navigation menu on the “AL Home” page (Figure 7.1).

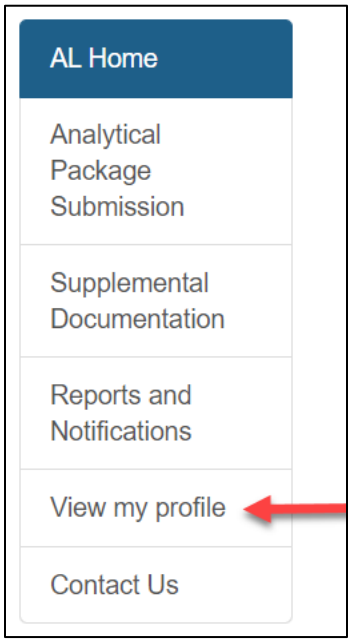


Figure 7.1: Navigation Menu

The system will display the “Accredited Laboratory Information” page, which contains the user’s read-only profile information from OAA (Figure 7.2).

The user’s scope of accreditation is contained within the accordion section with the name of the AB as the title. The accordion section will collapse upon navigating to the page.

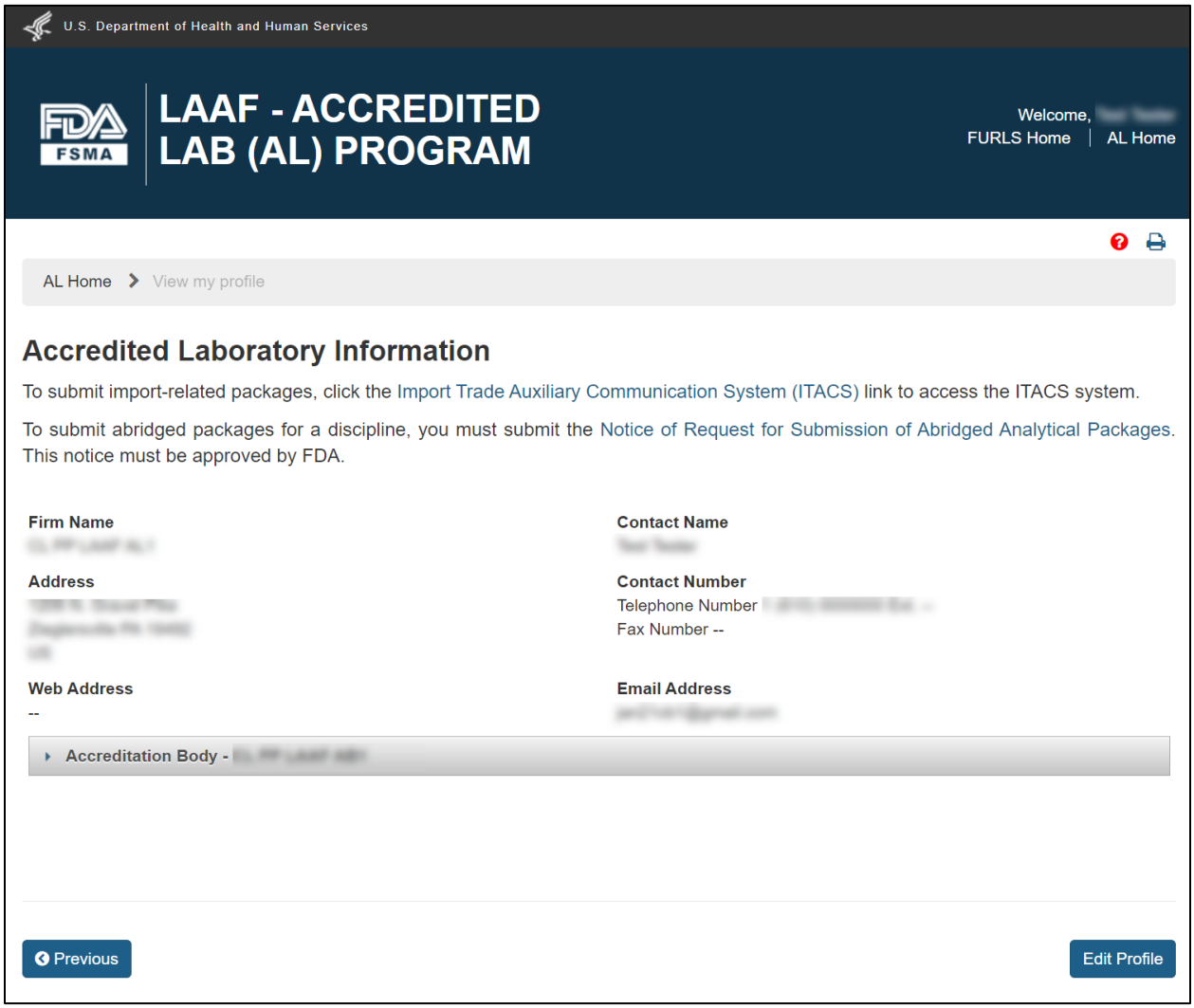


Figure 7.2: Accredited Laboratory Information Page

The user can view the scope of their accreditation by clicking on the accordion section's title bar (Figure 7.3). The content of the accordion section includes the accreditation period under the AB, verification status of each testing method, and import package submission type allowed for each testing discipline.

The user can click the "Previous" button to return to the "AL Home" page.

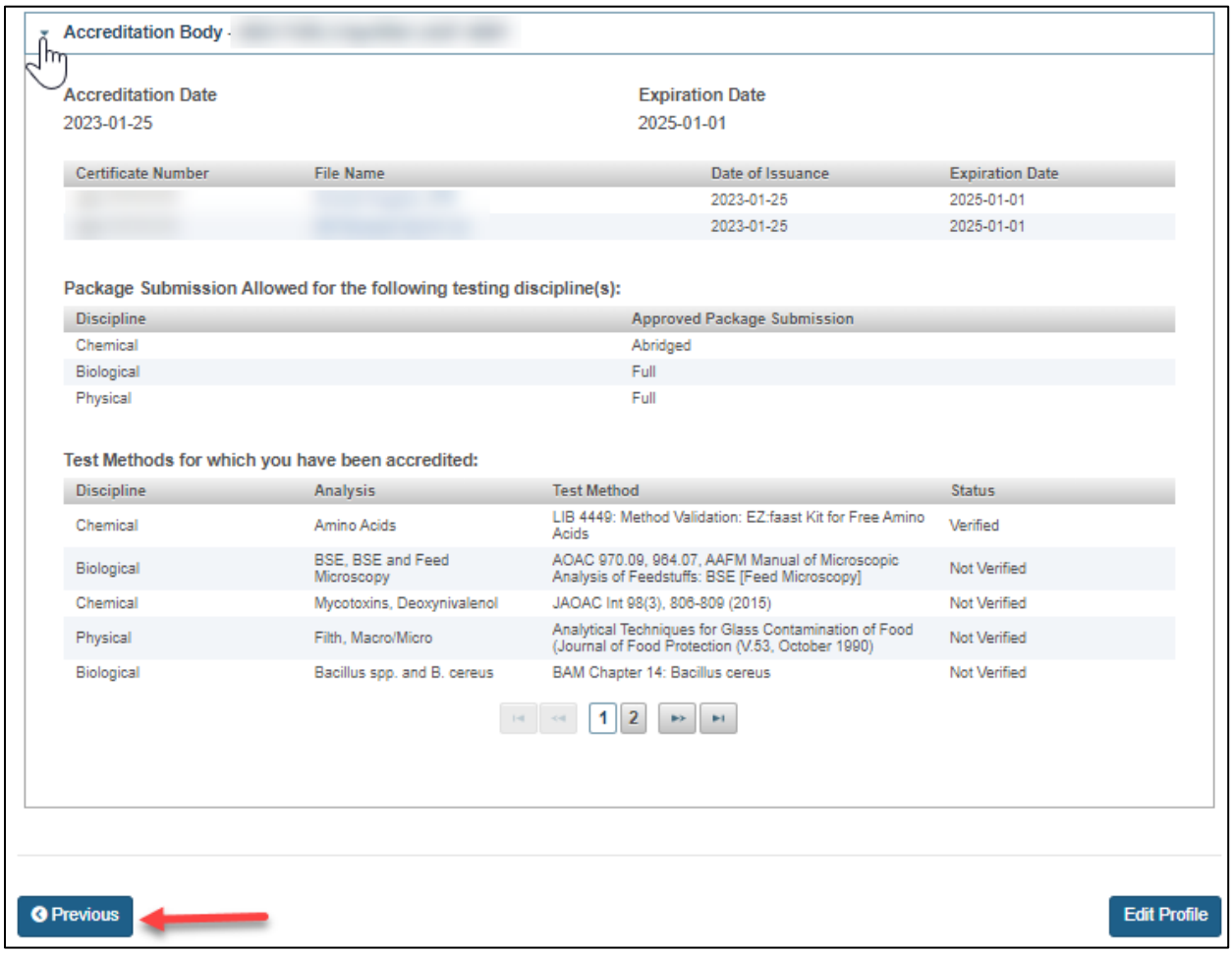


Figure 7.3: Accordion Section Content

- To edit account profile information in OAA, the user may proceed to Section 7.1.
- To view the verification status of a test method, the user may proceed to Section 7.2.
- To view the import package submission type that is allowed for a testing discipline, the user may proceed to Section 7.3.

7.1 Edit Account Profile

If the user wishes to edit their account profile information in OAA, they may click the "Edit Profile" button from the bottom of the "Accredited Laboratory Information" page (Figure 7.4).

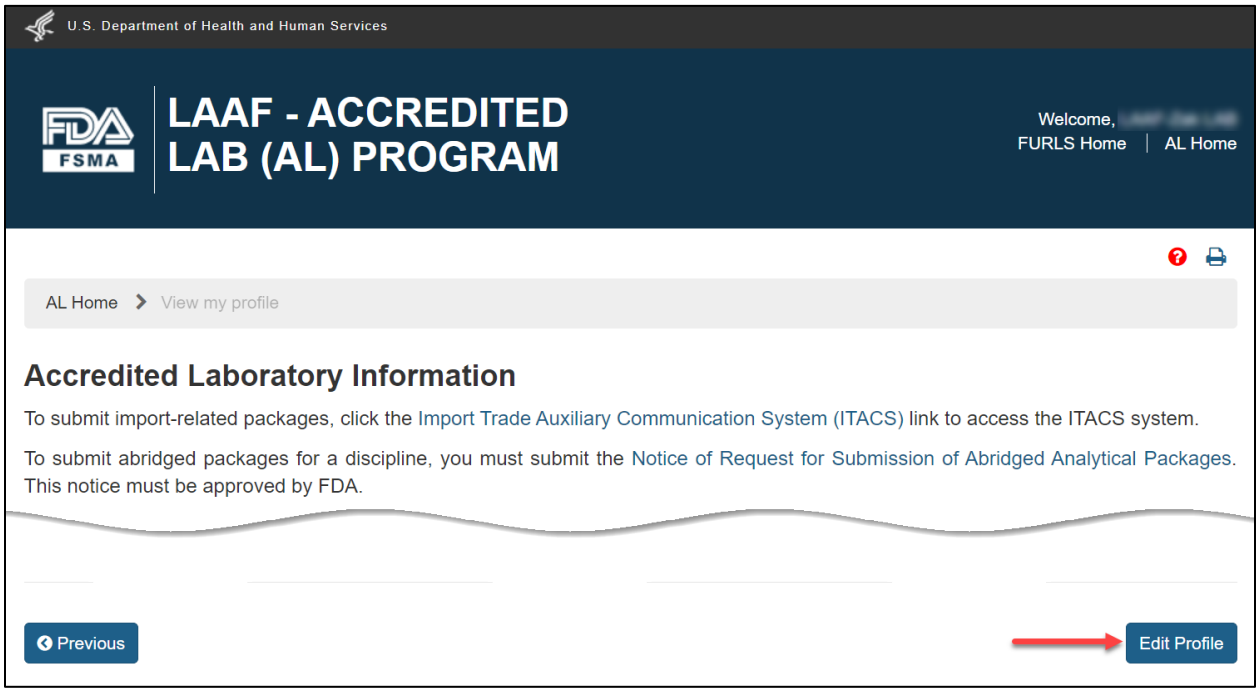


Figure 7.4: Edit Profile Button

The system will display the “Edit Account Profile” page of Account Management (Figure 7.5). All of the fields will be editable.

If the user wishes to discard any changes and return to the main OAA page, they should click the “Cancel” button.

Once the user has completed all updates, they will click the “Continue” button at the bottom of the page.

Note: If the user clicks the “Clear” button, all of the account information on the page will be cleared. To restore account information, the user should click the “Cancel” button and navigate back to the OAA “Account Management” page.

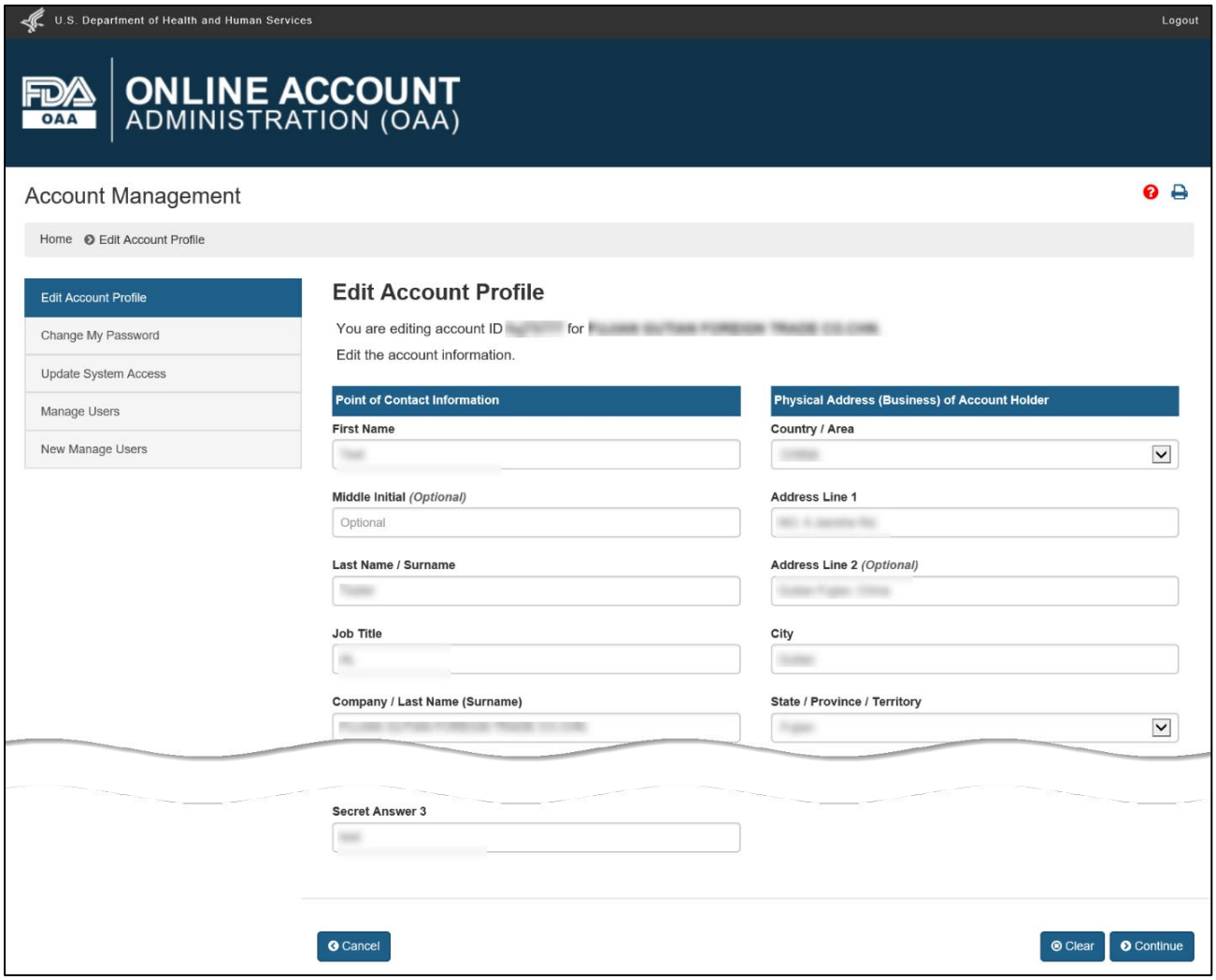


Figure 7.5: Edit Account Profile Page

The system will display the “Edit Account Profile” page as read-only for the user to review.

If the user would like to make additional changes, they will click the “Modify” button.

Once all changes have been completed, the user will click the “Submit” button (Figure 7.6).

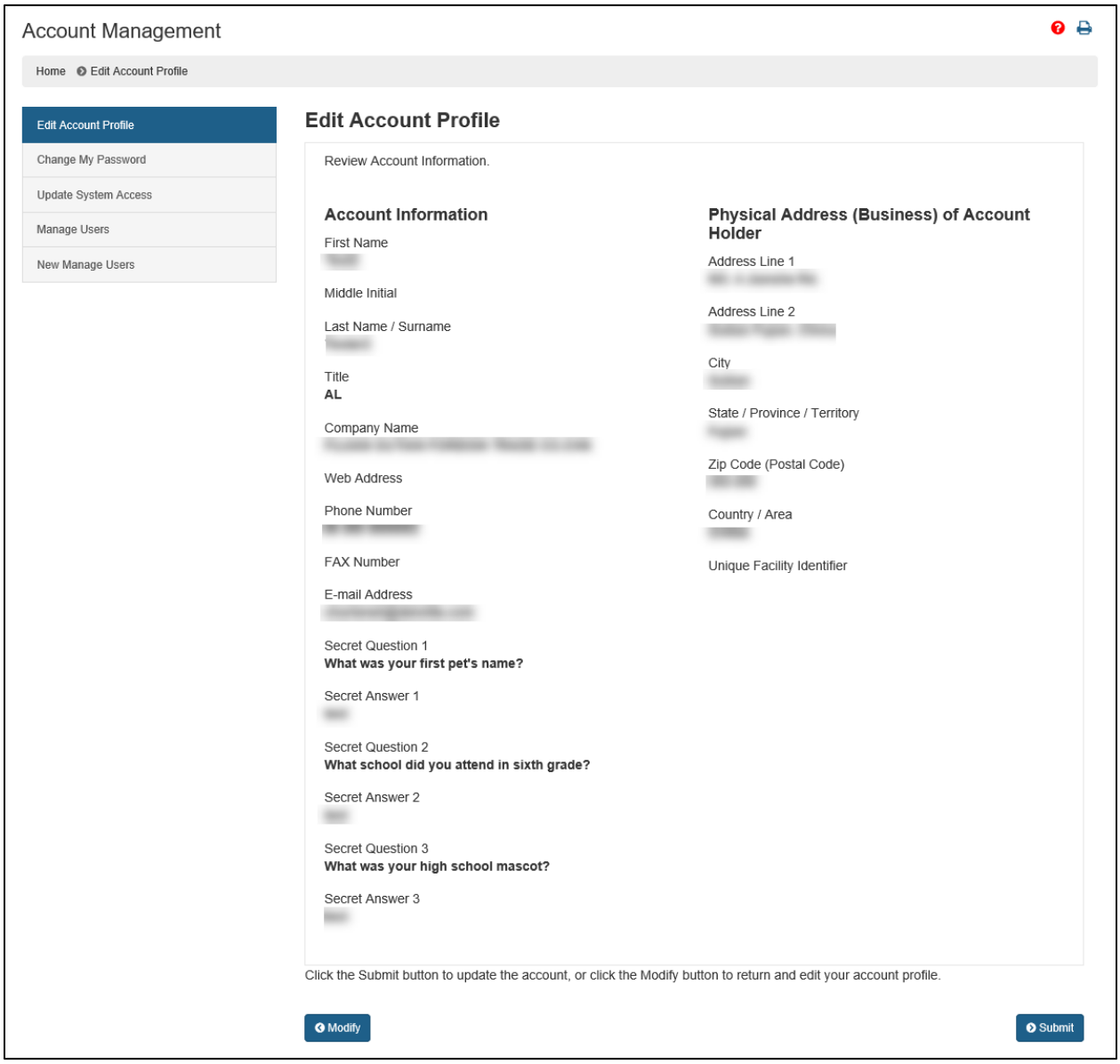


Figure 7.6: Edit Account Profile – Read-Only View

The system will display a confirmation message stating the submission was successful (Figure 7.7). The user can click the “Continue” button to navigate back to “Laboratory Accreditation for Analyses of Foods – Accredited Laboratory”.

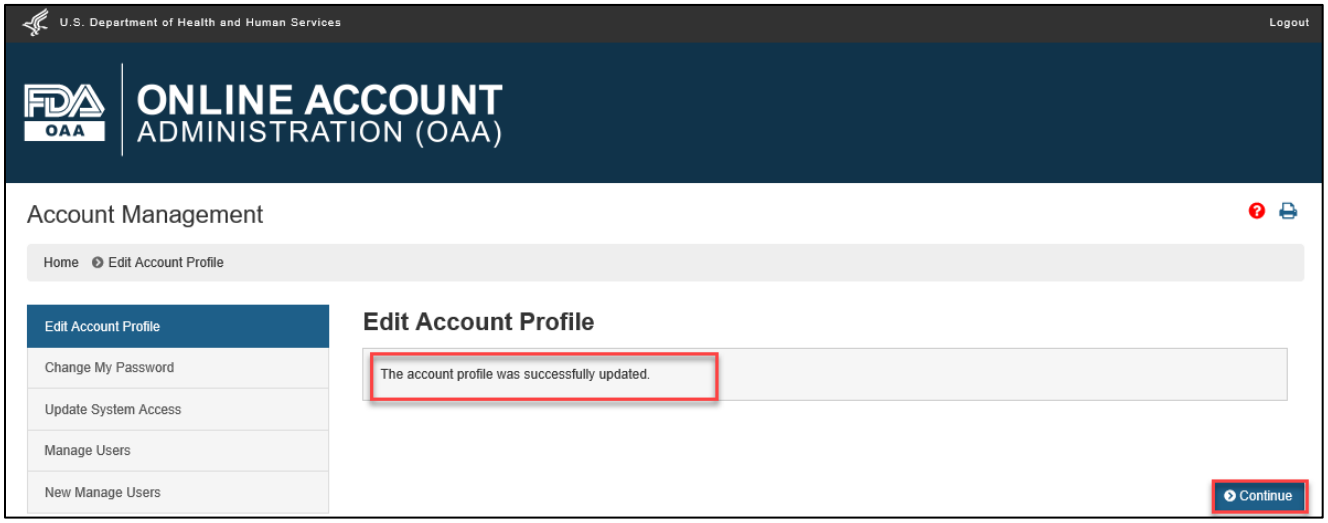


Figure 7.7: Successful Account Profile Update Message

7.2 View the Verification Status of a Test Method

The user can expand the accordion section to view the list of test methods and their statuses as “Verified” or “Not Verified” under the “Test Methods for which you have been accredited” table (Figure 7.8).

The default status of a test method is “Not Verified”.

If a test method has been verified by FDA, it will display as “Verified” in the “Status” column of the table. The user will be able to submit analyses to FDA for the “Verified” test method.

If a test method has not yet been verified, or it has been reverted back by FDA from previous “Verified” status, it will display as “Not Verified” in the “Status” column.

Test Methods for which you have been accredited:

Discipline	Analysis	Test Method	Status
Physical	Evisceration	Visual Examination	Verified
Biological	Virus, Hepatitis A	BAM Compendium: Concentration, Extraction, and Detection of Norovirus and Hepatitis A virus in Soft Fruit	Not Verified
Chemical	Pesticides/IC, Pesticides	JAFC 2011, 59, 6383ff: Modified QuEChERS - LCMS	Not Verified
Chemical	Melamine	LIB 4421: Determination of Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS	Not Verified
Biological	Shigella	BAM Chapter 6: conventional nested PCR assay	Not Verified

Figure 7.8: Test Methods for Which You Have Been Accredited Table

The user will receive a notification for “Verified” (Figure 7.9) and “Not Verified” testing methods (Figure 7.10).

Note: The images (below) only depict the e-mail notification subject and text.

The content are examples of the notifications; the actual testing method listed in the user’s version of the notifications may vary.

Subject: FDA's Laboratory Accreditation for Analyses of Foods Program - Testing Method Status - Verified

We are pleased to inform you that the verification/validation for the below testing method submitted has been accepted by the Laboratory Accreditation for Analyses of Foods Program team. You may now submit analyses for this method.

JAOAC Intl. 87, No.5, (2004), pp. 1224ff: GC-MSD in SIM Mode for NSOs (Pesticides Containing Nitrogen, Sulfur, Oxygen, or no Heteroatoms) under the testing discipline Chemical

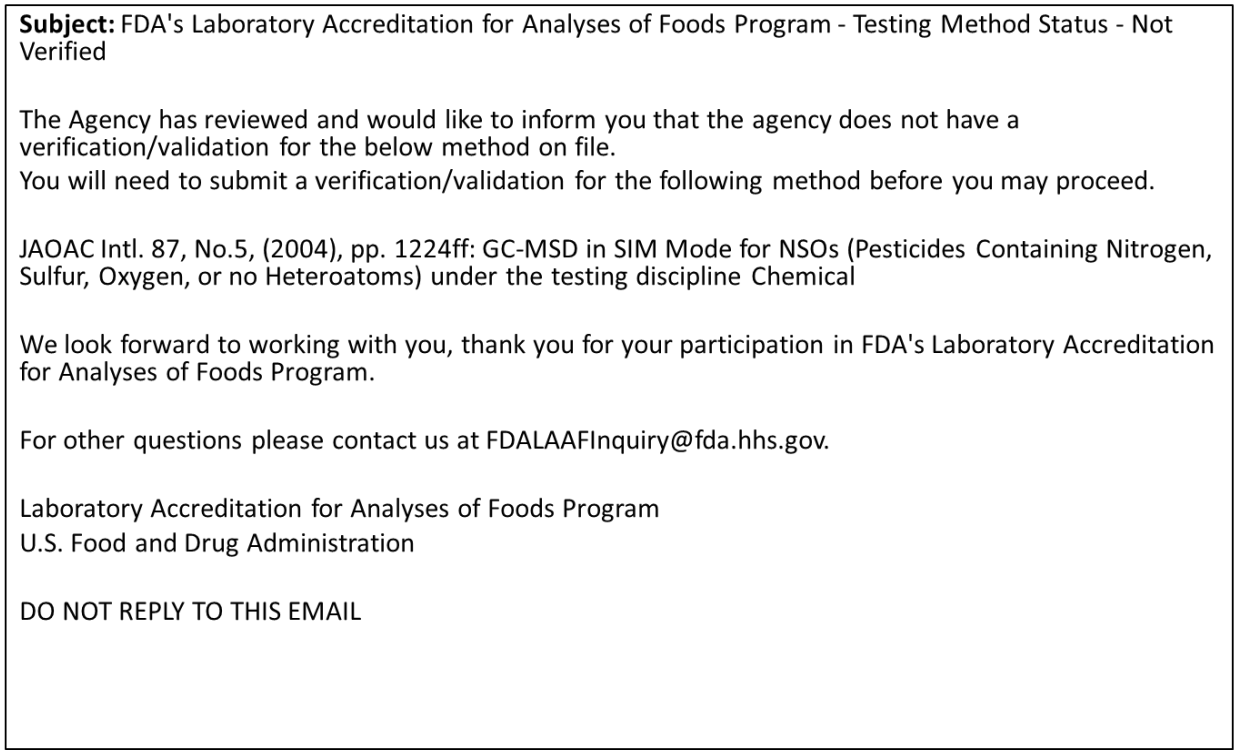
We look forward to working with you, thank you for your participation in FDA's Laboratory Accreditation for Analyses of Foods Program.

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 7.9: Notification of Testing Method Status – Verified



Subject: FDA's Laboratory Accreditation for Analyses of Foods Program - Testing Method Status - Not Verified

The Agency has reviewed and would like to inform you that the agency does not have a verification/validation for the below method on file.
You will need to submit a verification/validation for the following method before you may proceed.

JAOAC Intl. 87, No.5, (2004), pp. 1224ff: GC-MSD in SIM Mode for NSOs (Pesticides Containing Nitrogen, Sulfur, Oxygen, or no Heteroatoms) under the testing discipline Chemical

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 7.10: Notification of Testing Method Status – Not Verified

7.3 View Package Submission Allowed for a Testing Discipline

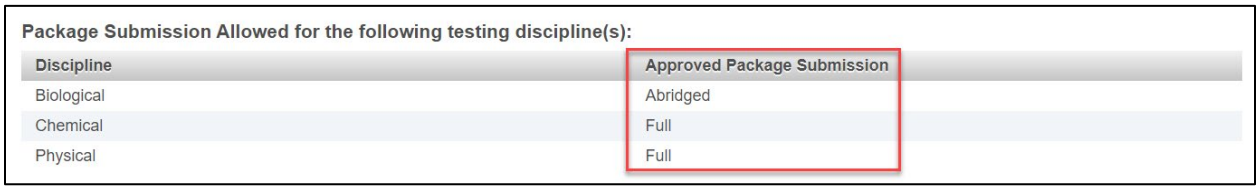
To view the approval status for submission of abridged or full **import** analytical packages for a testing discipline, the user may go to the “Package Submission Allowed for the following testing discipline(s)” portion of the accordion section (Figure 7.11).

The status under the “Approved Package Submission” column will default as “Full”.

If the user has submitted the Notice of Request for Submission of Abridged Analytical Packages for a testing discipline and it has been approved by FDA, it will display as “Abridged” for that testing discipline in the “Approved Package Submission” column.

If FDA determines the user should resume full **import** analytical package submission for a discipline, the user will receive a notification and the status will change from “Abridged” to “Full”.

The user may resubmit the Notice of Request for Submission of Abridged Analytical Packages for the testing discipline that has been reverted from “Abridged” to “Full,” if appropriate.



Package Submission Allowed for the following testing discipline(s):

Discipline	Approved Package Submission
Biological	Abridged
Chemical	Full
Physical	Full

Figure 7.11: Approved Package Submission Status

Refer to Chapter 6 “Reports and Notifications” for instructions for submission of the Notice of Request for Submission of Abridged Analytical Packages.

8 Contact Us

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

To access the feature, the user will click the “Contact Us” link from the navigation menu on the “AL Home” page (Figure 8.1).

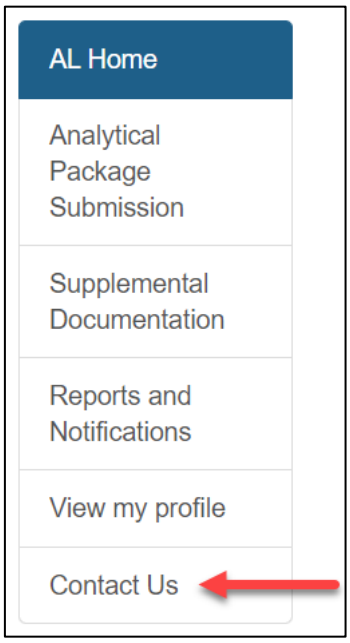


Figure 8.1: Navigation Menu

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 8.2). Once the user has completed the “Subject” and “Message” fields, they will click the “Send” button to send the email.

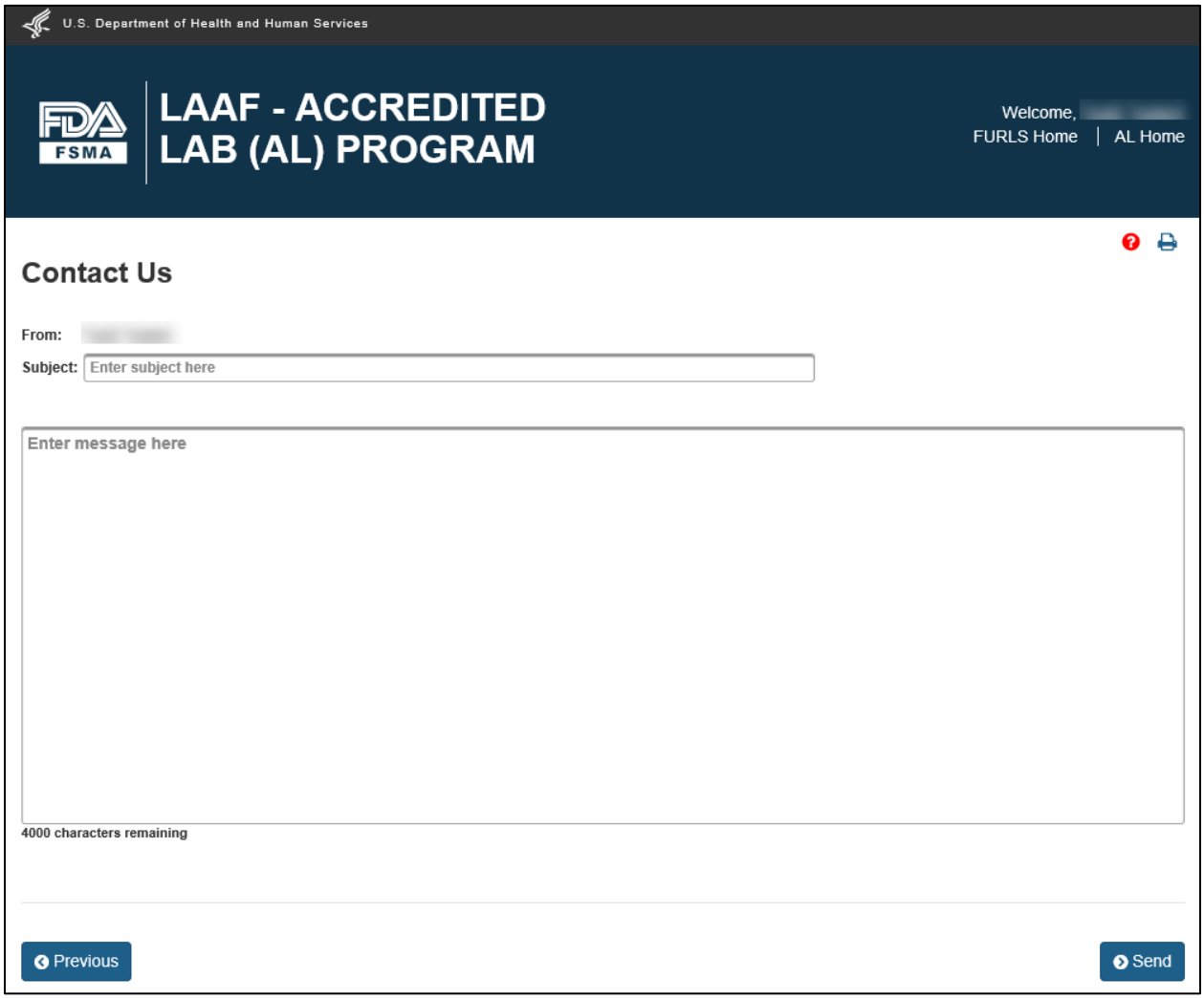


Figure 8.2: Contact Us Page

The system will display a confirmation message on the “AL Home” page, stating the message has been sent (Figure 8.3).

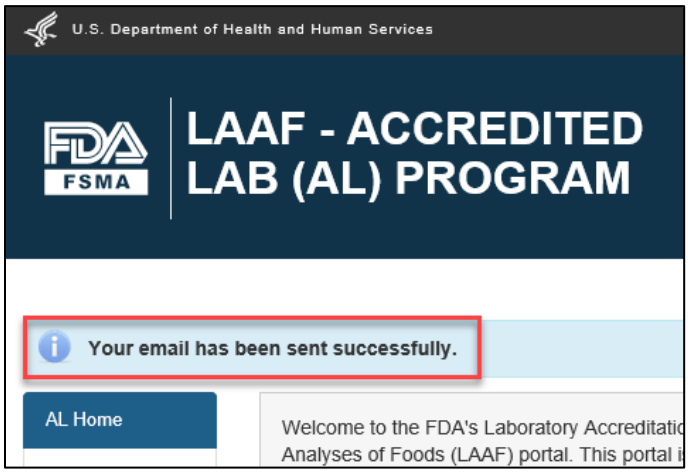


Figure 8.3: **Email Sent Successfully**

APPENDIX

Abbreviations

Abbreviation	Acronym Description
AB	Recognized Accreditation Body
AL	LAAF Accredited Laboratory
CFSAN	Center for Food Safety and Applied Nutrition
FDA	U.S. Food and Drug Administration
ITACS	Import Trade Auxiliary Communication System
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