

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 LAAF 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 <u>Access.fda.gov</u>.

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 the <u>OAA site</u>. 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 <u>Access.fda.gov</u> and click the "Log-In" or "Create Account" button, depending on which is applicable to the user (Figure 2.1).

U.S. Department of Health and Human Services		
FIS U.S. FOOD AND	DRUG ADMINISTRATIO	N FDA Home FIS Home
FDA Industry Systems		C Check System Status
	e making submissions to the U.S. Food and Drug Adm ours a day, seven days a week, since October 16, 200 > Log-In + Create Account	
supply. The Act requires that FDA develop two syste	vrism Act of 2002, which gave high priority to improved ems: one to support the registration of facilities that ma one to receive prior notice before food is imported or o 2003 when Prior Notice went into effect.	anufacture, process, pack, or hold food products
FURLS Acidified/Low Acid Canned Foods (LACF)	FURLS Biologics Export Certification Application & Tracking System (BECATS)	FURLS Export Listing Module (ELM)

Figure 2.1: FDA Industry Systems Page

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).

FDA Industry Systems	Creck System Status
FDA Industry Systems (FIS) was created to facilitate making submissions to th and other notifications. FIS has been available 24 hours a day, seven days a v	 luding registrations, listings,

Figure 2.2 Log-In Button



The user will be directed to the Online Account Administration (OAA) "Login" page.

The user can log into the <u>FDA "OAA" page</u>. This is the same page used to begin the process of creating a new OAA account (Figure 2.3).

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.

U.S. Department of Health and Human Services ONLINE ACCOUNT ADMINISTRATION (OAA)		
FDA Industry	Systems	
Login		
Existing account holde Account ID	rs, enter your account ID & password.	
Password		
	, anyone who makes a materially false, fictitious, or o the U.S. Government is subject to criminal	
☐ I understand.	Forgot Account ID Forgot Password	

Figure 2.3: OAA Login

Once logged into the FDA "OAA" site, the user will be prompted to enter a verification code (Figure 2.4). 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 10 minutes, they will click the "Resend verification code" link on the page. Once the user has received the code, they will 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 log in.



U.S. Department of Health and Human Services	Logout
ONLINE ACCOUNT ADMINISTRATION (OAA)	
For your security we need to authenticate your request. The one-time verification code was sent to your email The verification code is valid for next 10 minutes. Please enter it below.	
Enter Verification Code	
Didn't get a one-time verification code? <u>Resend verification code</u> .	

Figure 2.4: Enter Verification Code

Users will be directed to the FURLS "Account Management" page after the verification code has been verified (Figure 2.5).

Account Management			0
Account Management			
Edit Account Profile Change My Password	Welcome to the FDA industry Systems. You are logged You may choose an option on the left to manage your a To obtain access to available FDA systems, choose the	NATION SAMPLES AND	
Update System Access	Registration and Listing Programs		
	Food		
	Food Facility Registration	Export Listing Module	
	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation	
	Shell Egg Producer Registration		
	Medical Devices		
	Device Registration and Listing Module		
	Export Certification and Tracking		
	 Biologics Export Certification Application and Tracking System (BECATS) 	CDER Export Certification Application and Tracking System (CDER eCATS)	
	CDRH Export Certification Application and Tracking System (CECATS)	CFSAN Export Certification Application and Tracking System (CFSAN eCATS)	

Figure 2.5: Account Management Page

On the FURLS "Account Management" page click the "Update System Access" link from the upper left-hand corner of the OAA "Account Management" page (Figure 2.6).

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.



ONLINE AC	CCOUNT TION (OAA)		
Account Management			0
Home O Update System Access			
Edit Account Profile	Update System Access		
Change My Password Update System Access	Select the systems you will need to access		
	Registration and Listing Programs		
	Food Kodidfied/Low Acid Canned Foods Registration and Process Filing	Export Listing Module	
	CVM Export Certification Application and Tracking System (CVM eCATS) FSMA Program(s)		
	Accredited Third-Party Certification Program- Accreditation Body	Laboratory Accreditation for Analyses of Foods Program- Accreditation Body	
	Accredited Third-Party Certification Program- Certification Body	Laboratory Accreditation for Analyses of Foods Program- Accredited Lab	
	SVP Importer Portal for FSVP Records Submission	Voluntary Qualfied Importer Program	
	Other FDA Systems		
	Motice System Interface	OPER Biological Product Deviation Reporting	
	н		
			Submit

Figure 2.6: Update System Access

The system will display a message confirming the user's access was successfully updated (Figure 2.7).



U.S. Department of Health and Human Servic	ies	Logout
ONLINE A ADMINISTRA	CCOUNT TION (OAA)	
Account Management		0
Home O Update System Access		
Edit Account Profile	Update System Access	
Change My Password Update System Access	System access for account was successfully updated.	
		Click here to continue

Figure 2.7: Successful Update Message

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 FIS page (Figure 2.8).

FDA Industry Systems	Check System Status
FDA Industry Systems (FIS) was created to facilitate making submissions to and other notifications. FIS has been available 24 hours a day, seven days	cluding registrations, listings,

Figure 2.8: Create Account Button

The user will be directed to the OAA "Login" page (Figure 2.9). 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.

FDA	U.S. FOOD & DRUG
	ADMINISTRATION

U.S. Department of Health and Human Services ONLINE ACCOUNT ADMINISTRATION (OAA) FDA Industry Systems	System Status
Contract of the second s	on and Listing Systems (FURLS) will replace the use of ISO-0166 data standards with the INC) for populating country, state/province/territory codes and names within its systems.
Login	Getting Started
Existing account holders, enter your account ID & password. Account ID	To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" towards the bottom left side of this page. If you already have an account, enter your account ID and password .
Password Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I understand. Clogin Forgot Account ID Forgot Password	 WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penatites. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to subcrime and uside that if such monitoring are recording, and anyone using this system expressly consents to subcrime and uside that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials. Is your computer secure? Before using FDA industry Systems (FIS), FDA strongly encourages all users to have current antilvirus and antispyware software installed on your computer to help ensure the privacy of the information being entered. FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone
New User	asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact FDA FURLS Help Desk at 1-800-216- 7331 to confirm that the caller is acting on behalf of FDA.
Create New Account See Instructions Gest Gest	

Figure 2.9: FIS OAA Page

The system will display the "Create New Account" page (Figure 2.10).

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.



<image/> <form><form></form></form>	U.S. Department of Health and Human Services	
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CVM Export Certification Application and Tracking System (CVM eCATS)	CDRH Export Certification Application and	CFSAN Export Certification Application and
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Prior Notice System Interface CBER Biological Product Deviation Reporting (CBER eBPDR) Import Trade Auxiliary Communication System (ITAC S)	Check this box if you are an FSVP importer who needs to use a secure portal	Voluntary Qualified Importer Program
Import Trade Auxiliary Communication System (ITAC S)	Other FDA Systems	
	Prior Notice System Interface	CBER Biological Product Deviation Reporting (CBER eBPDR)
O Cancel	Import Trade Auxiliary Communication System (ITAC S)	
© Cancel		
	© Cancel	

Figure 2.10: Create New Account Page



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 2.11).

Accredited Third-Party Certification Program-	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.	Check this box if you are an AB and are submitting an application for FDA recognition.
Accredited Third-Party Certification Program- Certification Body	Laboratory Accreditation for Analyses of Foods Program- Accredited Lab
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.	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
□ ΓSVP Importer Portal for ΓSVP Records Submission	recognized LAAF AB.
Check this box if you are an FSVP importer who needs to use a secure portal to submit FSVP records requested by FDA.	Uoluntary Qualified Importer Program

Figure 2.11: Laboratory Accreditation for Analyses of Foods Program – Accreditation Body 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 2.12).

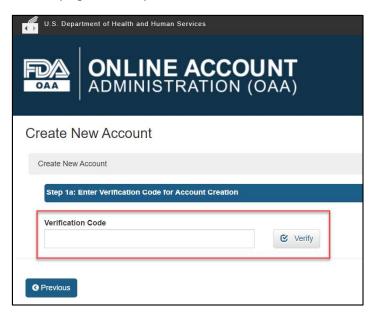


Figure 2.12: Step 1a: Enter Verification Code for Account Creation



The system will display the "Step 2: Enter Your Account Information" section, where the accrediting AB will provide Point of Contact information, account information, and the account holder's physical address (Figure 2.13). They must also provide additional information (i.e., passwords, secret questions and answers, and an alternate mailing address,) if applicable. The user may edit any of the <u>existing</u> information.

Note: The account holder's physical address may include a street address and/or Post Office Box.

FDA	U.S. FOOD & DRUG
	ADMINISTRATION

	6
create New Account	
Step 2: Enter Your Account Information	
2A: Point of Contact Information	2C: Physical Address (Business) of Account Holder
First Name	Country / Area
	Please Select Country
Middle Initial (Optional) Optional	Address Line 1
Last Name / Surname	Address Line 2 (Optional)
	Optional
Job Title	City
Company Name	State / Province / Territory
	Please Select 🗸
Web Address (Optional)	Zip Code (Postal Code)
(Example: http://www.name.domain or http://name.domain)	
Phone Number	Unique Facility Identifier (Optional)
Country Area Telephone Ext Country Area Phone Number Extension	Optional
E-mail Address	
E-mail Address	
Confirm E-mail Address 28: Account Information	
Confirm E-mail Address 28: Account Information Password Password Passwords must be at least 0 but not more than 32 characters, contain uppercase and workcase letters, numbers and special characters (e.g., %,\$) You will need to remem your password to login in the future.	
Confirm E-mail Address 28: Account Information Password Password Password Password Confirm Password to be iterated by the future in the second	
Confirm E-mail Address 28: Account Information Password Password must be at least 0 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., %,\$) You will need to remem your password to login in the future. Confirm Password Secret Question 1	ber
Confirm E-mail Address 2B: Account Information Password Reserved must be at least 0 but not more than 32 characters, contain uppercase and towercase letters, numbers and special characters (e.g., %,S) You will need to remem your password to login in the future. Confirm Password Secret Question 1 Please select a question	ber
Confirm E-mail Address 28: Account Information Password Password must be at least 0 but not more than 32 characters, contain uppercase and lowercase letters, numbers and special characters (e.g., %,§). You will need to remem your password to login in the future. Confirm Password Secret Question 1 Please select a question Secret Answer 1	ber
Confirm E-mail Address	•
Confirm E-mail Address	• •
Confirm E-mail Address	•

Figure 2.13: Create New Account Page



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 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 dropdown list.
- Secret Answer 2 This is the answer to the second secret question. Enter your response to the question selected in "Secret Question 2."
- Secret Question 3 This is the third secret question used to protect the account. Select a question from the dropdown list.



• **Secret Answer 3 –** This is the answer to the third secret question. Enter your response to the question selected in "Secret Question 3."

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

- **Country/Area** The country/area where the business is located Select a country/area from the dropdown list.
- Address Line 1 The address where the business is physically located This includes the number, street, quadrant, etc.
- Address Line 2 (Optional field) The field to enter additional information about the physical location of the company. This may include a suite or apartment number, if applicable.
- **City** The city where the business is physically located.
- **State/Province/Territory –** The state/province/territory where the business is physically located.
- **Zip Code (Postal Code)** The zip code (domestic) or postal code (foreign) where the business is physically located.
- **DUNS 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 2.11). The address entered in Step 2D will be used as the mailing address.

FDA	U.S. FOOD & DRUG
	ADMINISTRATION

DUNS Number (Optional)	_
Optional	
Do you have preferred mailing address other than the physical addres	as mentioned above?
2D: Preferred Mailing Address	
Country / Area	
Please Select Country	~
Address Line 1	
Address Line 2 (Optional)	
Optional	
City	
State / Province / Territory	
Please Select	~
Zip Code (Postal Code)	

Figure 2.14: Step 2D: Preferred 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 2.15).

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



ADMINISTRATION (OAA)	
count Information	
me O Create New Account	
ccount Review	
Account Information	Physical Address (Business) of Account Holder
First Name	Address Line 1
Middle Initial	Address Line 2
Last Name / Surname	City
Title	State / Province / Territory
Company Name	Zip Code (Postal Code)
Web Address	Country / Area
Phone Number	Commy / Pice
FAX Number	
E-mail Address	
Secret Question 1	
What color was your first car?	
Secret Answer 1	
Secret Question 2	
What school did you attend in sixth grade?	
Secret Answer 2	
Secret Question 3 What was your childhood nickname?	
Secret Answer 3	

Figure 2.15: Account Review Page

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 2.16).



U.S. Department of Health and Human Services ONLINE ACCOUNT ADMINISTRATION (OAA)	
Create New Account	0 🕀
Home O Create New Account	
You have successfully created an account. Your account ID is YOU WILL NEED TO REMEMBER YOUR ACCOUNT ID AND PASSWORD TO LOGIN TO THE SYSTEM IN THE FUTURE.	
	⊘ Login

Figure 2.16: Account Created Successfully Message and Account ID

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 – AB

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).

U.S. Department of Health and Human Services			Logout
ONLINE AC ADMINISTRAT	CCOUNT TON (OAA)		
Account Management			0 🖶
Account Management			
Edit Account Profile	Welcome to the FDA Industry Systems. You are logged in as	for LAAF AB Sample Account	
Change My Password	You may choose an option on the left to manage your account or sel To obtain access to available FDA systems, choose the Update Sys		
Update System Access	Registration and Listing Programs		
	Food		
	Food Facility Registration	Export Listing Module	
	Acidified/Low-Acid Canned Foods Registration and Process Filing	Qualified Facility Attestation	
	Shell Egg Producer Registration		
	Medical Devices Device Registration and Listing Module		
	Export Certification and Tracking		
	Biologics Export Certification Application and Tracking System (BECATS)	CDER Export Certification Application and Tracking System (CDER eCATS)	
	CDRH Export Certification Application and Tracking System (CECATS)	CFSAN Export Certification Application and Tracking System (CFSAN eCATS)	
	CVM Export Certification Application and Tracking System (CVM eCATS)		
	FSMA Program(s)		
	Accredited Third-Party Certification Program- Accreditation Body	Laboratory Accreditation for Analyses of Foods Program Accreditation Body	
	Accredited Third-Party Certification Program- Certification Body	Laboratory Accreditation for Analyses of Foods Program- Accredited Lab	
	FSVP Importer Portal for FSVP Records Submission	Voluntary Qualified Importer Program	
	Other FDA Systems		
		Contract December December	

Figure 3.1: Account Management Page



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

🐇 U.S. Department of	Health and Human Services		
	AAF - ACCREDITATION ODY (AB) PROGRAM	Welcome	
AB Home		08	
AB Home	Welcome		
Apply for Recognition View my profile	Welcome to the FDA's Laboratory Accreditation for Analyses of Foods portal. This portal is the means by which all Accreditation Body information related to the FDA Laboratory Accreditation for Analyses of Foods Program will be transmitted to the agency. Until your application for recognition by FDA is approved, your account will be limited to minimal actions which include updating your profile, contacting the FDA Laboratory Accreditation for	FDA Form 5040 PAPERWORK REDUCTION ACT NOTICE Form Approval: OMB No. 0910-0898 Expiration Date: 01/31/2025	
View Test Methods		The agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency displays a currently valid OMB control number.	
Contact Us	Analyses of Foods Program, and submitting an application to become recognized by the FDA Laboratory Accreditation for Analyses of Foods Program. Once you are accepted into the program, additional information technology (IT) capabilities will become available including the ability to add Laboratory Accreditation for Analyses of Foods Accredited Laboratories to your purview. Use this site to submit an application for recognition as an accreditation body.	The time required by an accreditation body to complete an application for recognition is estimated to average 60 hours per response for a one-time initial application and 30 hours every 5 years to complete and submit an application for renewal of its recognition (see 21 CFR 1.1113 and 1.1114). We estimate 3.5 hours per month, or 42 hours per year, to comply with both the reporting requirements of 21 CFR 1.1123 and the recordkeeping requirements of 21 CFR 1.1124.	

Figure 3.2: AB Home Page

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

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).

AB Home
Apply for Recognition
View my profile
Contact Us

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.

off U.S. Department of Health and Human Services			
LAAF - ACCREDITATION FSMA BODY (AB) PROGRAM	Weicome, FURLS Home LAB Home		
All fields are mandatory unless noted as optional. If a mandatory fiele applicable.	d does not apply to you, please indicate that the field is not		
AB Home > Applicant Information			
Applicant Information Program Requirements Attachments Applicant Information This page contains the information from your Account ID. If you need to update your Account, go to the FURLS Home page and select E	Summary e-Signature		
Firm Name	Contact Name		
Address	Contact Number Telephone Number Fax Number		
Web Address	Email Address		
G Previous	Save Next		

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).



📲 U.S. Department of Health and Human Services			
FSMA BODY	- ACCREDITATION (AB) PROGRAM	Welcome, FURLS Home LAB Home	
applicable.	s noted as optional. If a mandatory field does not apply to you, please indic ation > Program Requirements		
Program Requirem Please use the left hand direct Response" field. The "Addition	Attachments Summary e-Signature Attachments Summary e-Signature Attachments Attachments Summary e-Signature Attachments Attachments Summary Benefits and Information" field may be used to provide any other information that you ion or reference to any supporting documents you have provided.	-	
✓ Eligibility	Eligibility		
1.1113(a), (b), and (c) 🛛 🖊	§ 1.1113 What are the eligibility requirements for a recognized accreditation bo	dy?	
Competency and Capacity A recognized accreditation body or an accreditation body seeking recognition must meet all of the following requirements:			
Oversight Requirements	(a) Demonstrates compliance with ISO/IEC 17011:2017(E) (incorporated by ref	erence, see § 1.1101).	
Reports and Notifications	(b) Demonstrates that it is a full member of the International Laboratory Accredit	itation Cooperative (ILAC).	
 Records 	(c) Demonstrates that it is a signatory to the ILAC Mutual Recognition Arrangen competence to ISO/IEC 17011:2017(E) with a scope of "Testing: ISO/IEC 1702		
Previous		Z Save Next	

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").

	F - ACCRED Y (AB) PRO		N		Welcome, FURLS Home LAB Home
applicable.	Inless noted as optional. If		ld does not aj	oply to you, please indic	?
Applicant Information	Program Requirements	Attachments	Summary	e-Signature	
Response" field. The "Ad		nay be used to p	provide any ot	her information that you	t the requirement in the "User u think is relevant to your
1.1113(a), (b), and (c) Competency and Cap: Conflict of Interest	 § 1.1113 What are acity A recognized accorrequirements: 	editation body or a	n accreditation		must meet all of the following
 Oversight Requirement Reports and Notificati Records 	(b) Demonstrates (c) Demonstrates	that it is a full men that it is a signator	iber of the Inter		ditation Cooperative (ILAC). ment (MRA) that has demonstrated
Previous					🗹 Save 🚺 🔊 Next

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.

	ACCREDITATION Welcome, AB) PROGRAM FURLS Home LAB Home					
FSMA BODY (A	AB) PROGRAM FURLS Home LAB Home					
41 18. 						
and the second	0 🔒					
il fields are mandatory unless no oplicable.	ted as optional. If a mandatory field does not apply to you, please indicate that the field is not					
AB Home > Applicant Information	n > Program Requirements					
Applicant Information Progra	m Requirements Attachments Summary e-Signature					
Program Requirement	nts					
esponse" field. The "Additional I	to navigate to each question in the six sections. Explain how you meet the requirement in the "User information" field may be used to provide any other information that you think is relevant to your or reference to any supporting documents you have provided.					
 Eligibility 	 Eligibility >> 1.1113(a), (b), and (c) 					
1.1113(a), (b), and (c)						
Competency and Capacity	Regulatory Requirement A recognized accreditation body or an accreditation body seeking recognition must meet all of the					
Conflict of Interest	following requirements:					
Oversight Requirements	(a) Demonstrates compliance with ISO/IEC 17011:2017(E) (incorporated by reference, see §					
Reports and Notifications	1.1101). (b) Demonstrates that it is a full member of the International Laboratory Accreditation Cooperative					
Records	(b) Demonstrates that it is a full member of the International Laboratory Accreditation Cooperative (ILAC).					
	(c) Demonstrates that it is a signatory to the ILAC Mutual Recognition Arrangement (MRA) that has demonstrated competence to ISO/IEC 17011.2017(E) with a scope of "Testing. ISO/IEC 17025."					
	Criteria to Demonstrate					
	Provide documentation, such as a copy of your certificate or equivalent document, necessary to demonstrate that you: are a full member of the LLAC and are a signatory to the LLAC Mutual Recognition Arrangement that has demonstrated competence to ISO/IEC 17011:2017. The documentation should also demonstrate that you comply with ISO/International Electrotechnical Commission (IEC) 17011:2017. "Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies," Second edition, November 2017. You must also demonstrate that you have the ISO standard 17025 on your scope.					
	User Response (provide your answer below)					
	Enter your response here.					
	4000 characters remaining.					
	Additional Information (URL, References, etc.) (Optional)					
	Enter your response here.					
	4000 characters remaining.					
	✓ Certificate Attachments					
	To upload or delete a file, click the Attachments button and follow the instructions in the window. Attachments					
	File Name Date of Upload Evaluation Date (Optional)					
	No records found.					
	Other Supporting Documents (Optional)					

Figure 4.5: Eligibility Section

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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.

FDA U.S. FOOD & DRUG

🐇 U.S. Department of Health and Human S	Services				
BODY (A	CCREDITATION Welcome, B) PROGRAM FURLS Home LAB Home				
All fields are mandatory unless not applicable.	ed as optional. If a mandatory field does not apply to you, please indicate that the field is not				
AB Home > Applicant Information	> Program Requirements				
Program Requirement Please use the left hand directory t Response" field. The "Additional In	Requirements Attachments Summary +-Dignature ts to navigate to each question in the six sections. Explain how you meet the requirement in the "User formation" field may be used to provide any other information that you think is relevant to your r reference to any supporting documents you have provided.				
Eligibility	Records >> 1.1124(a)				
Competency and Capacity					
Conflict of Interest	Regulatory Requirement (a) In addition to meeting the requirements of § 1.1113(a) related to records, a recognized				
Oversight Requirements Reports and Notifications Records	(a) in addition to intercurg the tequirements of g + 1 in log readed to tectors, a tecogritce of accessibility of the tecords, a tecogritce of the tecords accessibility of the tecords, tecords created while it is recognized demonstrating its compliance with this subpart, including records relating to: (1) Applications for LAAF-accreditation;				
<u>[1.1124(a)</u>	(2) Assessments, reassessments, and decisions to grant, extend the scope of, renew, deny, reduce the scope of, or withdraw LAAF-accreditation or to suspend or lift the suspension of a LAAF- accredited laboratory;				
	(3) Appeals of suspensions, denials, reductions of scope of, and withdrawals of LAAF-accreditation, final decisions on such appeals, and the bases for such final decisions;				
	(4) Its oversight of laboratories it has LAAF-accredited;				
	(5) Its oversight of its own performance, including all records related to internal audits, complaints, and corrective actions;				
	(6) Any reports or notifications required to be submitted to FDA under § 1.1123, including any supporting information;				
	 (7) Records of fee payments and reimbursement of direct costs; and (8) Any documents demonstrating compliance with the requirements for assessment activities by 				
	contract assessors with certain financial interests described in § 1.1119(d).				
	Criteria to Demonstrate Please provide your written procedure(s) for establishing, controlling, and retaining records, as required.				
	User Response (provide your answer below)				
	Enter your response here.				
	4000 characters remaining. Additional Information (URL, References, etc.) (Optional)				
	Enter your response here.				
	4000 characters remaining.				
	- Attachments (Optional)				
	To upload or delete a file, click the Attachments button and follow the instructions in the window.				
	File Name Date of Upload No records found.				
© Previous	✓ Save Save				

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 "Eligibility" requirement.

🐗 U.S. Department of Health and Human	Services	
EDA LAAF - A BODY (A	CCREDITATION B) PROGRAM	Welcome, FURLS Home LAB Home
All fields are mandatory unless no applicable. AB Home > Applicant Information	ed as optional. If a mandatory field does not apply to Program Requirements	you, please indicate that the field is not
Program Requirement Please use the left hand directory Response" field. The "Additional In	-	ormation that you think is relevant to your
Eligibility 1.1113(a), (b), and (c) Competency and Capacity Conflict of Interest Oversight Requirements Dependence and Medianteese	Eligibility >> 1.1113(a), (b), and (c) Certificate Attachments To upload or delete a file, click the Attachments button	and follow the instructions in the window.
Reports and Notifications Records	File Name Date of Upload No records found.	Evaluation Date Expiration Date (Optional)
	Other Supporting Documents (Optional) To upload or delete a file, click the Attachments button	and follow the instructions in the window.
	File Name No records found.	Date of Upload
Previous		≤ Save Next

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
 - \circ 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.



or U.S. Depa	rtment of Health and Human S	Services		
	LAAF - A BODY (A	Welcome, FN LN FURLS Home LAB Home		
	Attachments			
All fields are applicable.	Add Attachments			e e e e e e e e e e e e e e e e e e e
AB Home	Instructions			
	Step 1: Click Brows Step 2: Click Upload Step 3: Click Close	e to find the document(s) you want to upload d		
Applicant	Note:	are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif,	iff dag dags ant sig sizes tot pats off	
Program	2. Maximum file size		ini, doc, docx, ppi, xis, xisx, ixi, ppix, ru.	
Please use Response" f	+ Browse 🗳 Up	load × Cancel		ie "User our
response, in				
✓ Eligibilit				
1.1113(a	Manage Attachments			
Compete	File Name	Date of Upload	Action	
Conflict	No records found.			
Oversig		Close		ments
 Reports 				
Records				
		Other Supporting Documents (Optio	nal)	
		• • • • • • • • • • • • • • • • • • • •		
				Attachments
		File Name	Date of Upload	
		No records found.		

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.

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



or U.S. Depar	rtment of Health and Human S	ervices					
FSMA	LAAF - A BODY (A	CCREDITATION B) PROGRAM		Welcome, FN LN FURLS Home LAB Home			
	Attachments						
All fields are applicable. AB Home Applicant I	Step 2: Click Upload Step 3: Click Close Note:	are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, t		≏ ot			
Program Please use t Response' f response, in	Test_File.ppt uploaded successfully. * * Browse Upload Cancel						
1.1113(a	Manage Attachments						
 Competence 	File Name	Date of Upload	Action				
 Conflict Oversigit Reports Records 	Test_File.ppt	2021-10-25		→ ments			
		Other Supporting Documents (Optio	nal)				
				Attachments			
		File Name	Date of Upload				
		Test_File.ppt	2021-10-25				

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.



🦑 U.S. Depa	tment of Health and Human Services						
FDA FSMA	LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, FN LN FURLS Home LAB Home					
	Attachments	A					
All fields are	Instructions	t					
applicable. AB Home	Step 1: Click Browse to find the document(s) you want to upload Step 2: Click Upload Step 3: Click Close						
Applicant	Note: 1. Allowed file types are pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf. 2. Maximum file size allowed is 50 MB.						
Program							
Please use	Test_File.ppt deleted successfully.	* ie "User					
Response" f response, in	+ Browse Lupload × Cancel						
1.1113(a	Manage Attachments						
Compete	File Name Date of Upload Action						
Conflict	No records found.	✓ ments					
Oversig	Close						
Reports							
 Records 							
	Other Supporting Documents (Optional)						
	• Other supporting bocuments (optional)						
		Attachments					
	File Name Date of Upload						
	No records found.						

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).



of Health and Human Services		
ESMA LAAF - ACCR BODY (AB) P	EDITATION ROGRAM	Welcome, FN LN FURLS Home LAB Home
All fields are mandatory unless noted as optio applicable.	onal. If a mandatory field does not apply to you	u, please indicate that the field is not
AB Home > Dashboard > Applicant Informa	ation > Program Requirements > Attachments	
Applicant Information Program Requirement	ents Attachments Summary e-Signa	sture
2. Maximum file size allowed is 50 MB.	i want to upload jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx,	rtf.
Type of Attachment Please Select One		
+ Browse 🛛 ± Upload 🗍 × Cancel		
and the second	Гуре	Date of Upload Action
No records found.		∠ Save Next

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). The "Browse" button will become enabled, allowing them to search for a file to upload.



🐗 U.S. Department of Healt	h and Human Services						
	AF - ACCRED DY (AB) PRO	ITATION GRAM				Weld FURLS Home	come, FN LN LAB Home
All fields are mandatory applicable.	unless noted as optional. If	a mandatory field d	loes not app	bly to you, ple	ease indicate t	hat the field is not	₽
AB Home 💙 Dashboar	rd > Applicant Information	Program Requirem	ents 📏 Atta	achments			
Applicant Information	Program Requirements	Attachments	Summary	e-Signature			
Step 3: Click Upload Step 4: Click Save Note:	ind the document(s) you want to pdf, png, jpeg, gif, bmp, jpg, jpe		ppt, xls, xlsx,	txt, pptx, rtf.			
Type of Attachment			Additional	Description			1
+ Browse L Upload	i X Cancel		Enter De	scription]
File Name	Туре				Date of Upload	Action	I
No records found.						Z Save	Next

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

	- ACCREDI (AB) PROG	TATION GRAM			FU	Welcome, F RLS Home LAB	
							0
Test_File.pptx uploaded	successfully.						×
All fields are mandatory unles applicable.	s noted as optional. If a	a mandatory field o	loes not ap	ply to you, please	indicate that th	he field is not	
AB Home > Dashboard >	Applicant Information >	Program Requirem	ents 📏 Att	achments			
Applicant Information Pr	ogram Requirements	Attachments	Summary	e-Signature			
Attachments (Opti Add Attachment(s) Instructions Step 1: Select Type of Attachm Step 2: Click Browse to find the Step 3: Click Upload Step 4: Click Save Note: 1. Allowed file types are pdf, pn 2. Maximum file size allowed is Type of Attachment Please Select One	ent e document(s) you want to ng, jpeg, gif, bmp, jpg, jpe,	jfif, tif, tiff, doc, docx,	ppt, xls, xlsx	, txt, pptx, rtf.			
	* Cancel	•					
File Name	Туре			Date	e of Upload	Action	
Test_File.ppt	Other-test	1890 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 - 1990 -			1-10-25	<u> </u>	_
Test_File.pptx		of Record Information			1-10-25	â	Next

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).

🐇 U.S. Department of Health	and Human Services			
	AF - ACCRED DY (AB) PRO	ITATION GRAM		Welcome, FN LN FURLS Home LAB Home
				8
Test_File.ppt delete	d successfully.			×
All fields are mandatory u applicable.	unless noted as optional. If	a mandatory field does not a	pply to you, please indicate th	nat the field is not
AB Home 💙 Dashboard	d > Applicant Information	Program Requirements > /	dtachments	
Applicant Information	Program Requirements	Attachments Summary	e-Signature	
Step 3: Click Upload Step 4: Click Save Note:	nd the document(s) you want to df, png, jpeg, gif, bmp, jpg, jpe	o upload , jfif, tif, tiff, doc, docx, ppt, xls, xl	sx, txt, pptx, rtf.	
Type of Attachment Please Select One				
+ Browse 🕹 Upload	× Cancel			
File Name	Туре		Date of Upload	Action
Test_File.pptx	Custodiar	t of Record Information	2021-10-25	the second se
Previous				∠ Save Next

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).

of U.S. Department of Health and Human Services		
LAAF - ACCREDITATION BODY (AB) PROGRAM		Welcome, FN LN FURLS Home LAB Home
		₽
AB Home > Dashboard > Applicant Information > Program Require	ments > Attachments > Summary	2
Applicant Information Program Requirements Attachments	Summary e-Signature	
Summary		
Review the following information for correctness and edit as needed. Applicant Information		
Firm Name	Contact Name	
	Contact Number	
Address	Phone Number	
	Fax Number	
Web Address	Email Address	
	Unique Facility Identifier	
Program Requirements		🖍 Edit
Eligibility		
Competency and Capacity		
Conflict of Interest		
Oversight Requirements		
Reports and Notifications		
 Records 		
Attachments (Optional)		🖍 Edit
File Name Type		Date of Upload
No records found.		
• Previous		🗹 Save 💿 Next

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).

4 U.S. Department of Health and Human Services		
LAAF - ACCREDITATION BODY (AB) PROGRAM	٩	Welcome, FN LN FURLS Home LAB Home
		0
Program Requirements - Competency and Capacity is incomplete At least one Certificate attachment is required in Eligibility sector		×
AB Home > Dashboard > Applicant Information > Program Requi	rements > Attachments > Summary	
Applicant Information Program Requirements Attachments	Summary e-Signature	
Summary Review the following information for correctness and edit as needed. Applicant Information		
Firm Name	Contact Name	
Address	Contact Number Phone Number * Fax Number -	
Web Address	Email Address Unique Facility Identifier	
Program Requirements		✓ Edit
Eligibility		
Competency and Capacity		
Conflict of Interest		
Oversight Requirements		
Reports and Notifications		
Records		
Attachments (Optional)		✓ Edit
File Name Type		Date of Upload
No records found.		
© Previous		≤ Save Next

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.



🖑 U.S. Department of Health	and Human Services		
	AF - ACCREDIT DY (AB) PROG	TATION RAM	Welcome, FURLS Home LAB Home
AB Home > Dashboard	d > Applicant Information > P	Program Requirements > Attachments > Summar	? y > e-Signature
Applicant Information	Program Requirements A	Attachments Summary e-Signature	
the bottom of the page. F FDA, or by authorizing an and accurate. Under 18 U subject to criminal penalt or subsequent revocation Please be aware that you application review phase	Please note that an e-Signature n individual to submit this inform U.S.C. 1001, anyone who mak ties. Note that misrepresentation of participation in the program u will not be able to change you ation in the submission is true a	nowledge that you read and approved it by prov e is the equivalent of a handwritten signature. By mation to FDA, the submitter certifies that the in res a materially false, fictitious, or fraudulent stat ons or omissions may constitute sufficient groun n. ur application after you click Submit. Future cha and accurate and that I am authorized to submit the the for recognized accreditation bodies under 21 CF	y submitting this information to formation in the submission is true tement to the U.S. Government is ads for rejection of your application anges may be made during the e information to FDA. Further, I certify
recognized.			
Name of Submitter Print full legal name		Title of Submitter Enter your title	
Previous			Submit

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).

or U.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, FN LN FURLS Home LAB Home
	8
AB Home > Add or View my Accredited Laboratories (AL) > Add and Notify AL > e-Signature > Confirmation	tion
Confirmation Thank you for submitting. You will receive a confirmation e-mail from FDA within 24 hours. If you do not within that timeframe, please e-mail FDALAAFInquiry@fda.hhs.gov.	receive confirmation from FDA

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).

AB H	ome
View	/Edit my
appli	cation for
reco	gnition
View	my profile
Add	or view my
Accre	edited Labs
Supp	lemental
Docu	imentation
Cont	act Us

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.

AB Home			
pplication Information	ation		
Application Number	Date of Submission	Application Status	Action
* 363961093595861	2021-08-04	Submitted	Q 🖶

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).

	ACCREDITATIC (AB) PROGRAM		Welcome, FURLS Home LAB H
			0
	A MERCE 1		
plication Informa	Date of Submission	Application Status	Action
		Application Status	Action
	Date of Submission		
Application Number	Date of Submission	In-Process	
Application Number Program Requirements	Date of Submission	In-Process Submission status	
Application Number Program Requirements Eligibility	Date of Submission	In-Process Submission status Returned For Action	
Application Number Program Requirements Eligibility Competency and Capacity	Date of Submission	In-Process Submission status Returned For Action Returned For Action	
Program Requirements Eligibility Competency and Capacity Conflict of Interest	Date of Submission	In-Process Submission status Returned For Action Returned For Action Under Review	

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).

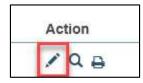


Figure 5.2: Edit Icon

The system will open the "Program Requirements" page (Figure 5.3). "Program Requirements" criteria displayed with red flags 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.

FDA	U.S. FOOD & D	RUG
	ADMINISTRATION	

🖧 U.S. Department of Health and Human	Services			
	CCREDITA B) PROGR/	TION AM		Welcome, FURLS Home LAB Home
All fields are mandatory unless not applicable.		atory field does not app	oly to you, please indicate	e that the field is not
AB Home > Dashboard > Prog	ram Requirements			
		nments Summary	e-Signature	
Program Requiremen Please use the left hand directory I Response" field. The "Additional In response, including a description of	o navigate to each quest formation" field may be ι	used to provide any othe	er information that you th	
🝷 Eligibility 📁	Eligibility >> 1.1113(a)	a), (b), and (c)		
1.1113(a), (b), and (c) 📁	 Review Comments 			
Competency and Capacity	I his is a question from	n FDA pertaining to Eligibili	ty standard.	
Conflict of Interest	Enter your response	here.		
Oversight Requirements				
Reports and Notifications Records				
	4000 characters remaining This is another questi Enter your response i	on from FDA.		
	4000 characters remaining			
	To upload or delete a	file, click the Attachments I	button and follow the instruct	ions in the window. Attachments
	File Name	Date of Upload	Evaluation Date	Expiration Date (Optional)
		2021-07-27	2021-01-01	
		2021-08-19	2021-08-18	
		2021-08-16	2021-08-02	
	Other Supporting Do	cuments (Optional)		
Previous				Save Next

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 resubmission.

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.

U.S. Department of Health and Human Services	
	0 🖶
AB Home > Dashboard > Program Requirements >	Attachments > Summary > e-Signature
Applicant Information Program Requirements A	ttachments Summary e-Signature
the bottom of the page. Please note that an e-Signature FDA, or by authorizing an individual to submit this inform and accurate. Under 18 U.S.C. 1001, anyone who mak subject to criminal penalties. Note that misrepresentation or subsequent revocation of participation in the program	nowledge that you read and approved it by providing the information requested at e is the equivalent of a handwritten signature. By submitting this information to mation to FDA, the submitter certifies that the information in the submission is true as a materially false, fictitious, or fraudulent statement to the U.S. Government is ons or omissions may constitute sufficient grounds for rejection of your application n. ur application after you click Submit. Future changes may be made during the
	and accurate and that I am authorized to submit the information to FDA. Further, I certify its for recognized accreditation bodies under 21 CFR part 1, subpart R while
Name of Submitter Print full legal name	Title of Submitter
Previous	Submit

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.

🐗 U.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, FURLS Home LAB Home
	0
AB Home > Dashboard > Program Requirements > Attachments > Summary > e-Signature > Co	onfirmation
Confirmation	
Thank you for submitting your responses to questions from FDA's Laboratory Accreditation for Analyse review your responses as part of the application and may follow-up if additional information is needed.	

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 e-mail 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 e-mail 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).



U.S. Department of Health and Hu	man Services		
	ACCREDITATIO		Welcome, FURLS Home LAB Home
Recognition Status:Recognized AB Home			0 🔒
	ation Date of Submission	Application Status	Action
1 (1997)	2021-08-04	Recognized	QB

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 (AL), and submit supplemental documents to FDA. The related features items will display on the "AB Home" page (Figure 6.3).

AB Home	
AB Home	Welcome
View/Edit my application for recognition	Welcome to the FDA's Laboratory Accreditation for Analyses of Foods portal. This portal is the means by which all Accreditation Body information related to the FDA
View my profile	Laboratory Accreditation for Analyses of Foods Program will be transmitted to the agency. Until your application for reservice with EDA is extended and a second acceleration of the second s
View Test Methods	recognition by FDA is approved, your account will be limited to minimal actions which include updating your profile, contacting the FDA Laboratory Accreditation for Analyses of Foods Program, and submitting an application
Add or view my Accredited Labs	to become recognized by the FDA Laboratory Accreditation for Analyses of Foods Program. Once you are accepted into the program, additional information
Reports and Notifications	technology (IT) capabilities will become available including the ability to add Laboratory Accreditation for Analyses of Foods Accredited Laboratories to your purview. Use this
Supplemental Documentation	site to submit an application for recognition as an accreditation body.
Contact Us	How do I submit an application? On the left navigation menu click on the "Apply for

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 e-mail notification from FDA (Figure 6.4):



Figure 6.4: Application Denial Email from FDA

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

U.S. Department of Health and H	uman Services		
	- ACCREDITATIC (AB) PROGRAM		Welcome, FURLS Home │ LAB Home
			8 🖶
AB Home			
Application Inform	ation Date of Submission	Application Status	Action
· International	2021-08-24	Denied	Q 🔒

Figure 6.5: Application Denied Status



As stated in the e-mail notification, the applicant can create 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 from the navigation menu on the "AB Home" page (Figure 6.6).

AE	B Home
	pply for ecognition
ap	ew/Edit my plication for cognition
Vi	ew my profile
С	ontact Us

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 of the responses provided in the previous application will be pre-filled in the new application.

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

U.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, Lorem Ipsum FURLS Home LAB Home
All fields are mandatory unless noted as optional. If a mandatory field does not apply to you, please ind applicable.	icate that the field is not
AB Home > Application Pre-fill Option	
You may choose to pre-fill your current application using the previously submitted application. If you choose be pre-filled with information submitted on the previous application. You may need to modify some or all of the your new application is comprehensive and accurate. Would you like the system to pre-fill the new application Yes No	e pre-filled information to ensure
Previous	

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).

File Name	Туре	Date of Upload	Action
RiverBoat.JPG	Standard Operating Procedures or Policies	2021-11-22	

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 complete and 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.

Ķ U.S. Department of Health	and Human Services				
	F - ACCREDI Y (AB) PROC				Welcome, FURLS Home LAB Hom
applicable.	nless noted as optional. If a	mandatory field o	does not ap	ply to you, please	indicate that the field is not
Applicant Information Applicant Inform This page contains the inform If you need to update your Act			Summary	e-Signature	
Firm Name			Contact Nar	ne	
Address			Contact Nur Telephone N Fax Number	lumber	
Web Address			Email Addre	255	
G Previous					≤ Save Next

Figure 6.9: New Application Pages



7 Add or View Accredited Laboratories

A recognized AB can add a LAAF 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".

The system will navigate to the "Add or View my Accredited Laboratories (AL)" page with the following page elements displayed (Figure 7.1):

- 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

K U.S. Department of Health and Human Services		
LAAF - ACCREDITATION BODY (AB) PROGRAM	V FURLS Home	Vekcome, : LAB Home
		0
AB Home > Add or View my Accredited Laboratories (AL)		
Add or View my Accredited Laboratories (AL) To add an AL, select "Add AL" button at the bottom of the page and follow the steps to enter information abor	ut the new Al	
To view the details for an existing AL, select the "View" (magnifying glass) icon from the "Action" column.		
Name Sta No records found.	tus ≎	Action
Previous		Z Add AL

Figure 7.1: 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 7.2). The instructional text can be expanded and collapsed using the "…more/less" link.

The page contains four sections 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".

of U.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, FURLS Home LAB Home
	0
AB Home > Add or View my Accredited Laboratories (AL) > Add and Notify AL	
Add Accredited Laboratories (AL) To add an Accredited Lab (AL), enter the AL's FEI Number and click "Search." The system will populate the A more	\L's read-only profile
 Accredited Laboratories (AL) 	
You may search for the AL by selecting from the following options.	
Accreditation Information	
Certification Information	
Disciplines, Analyses, and Test Methods	
@ Previous	● Next

Figure 7.2: Add Accredited Laboratories (AL) Page

7.1 Accredited Laboratories 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 the two possible methods to search for an AL (Figure 7.3).

****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.



 Accredited Lab 	ooratories (AL)
You may searc	h for the AL by selecting from the following options.
FEI Numbe	r 🥥 Firm Name & Address
Accreditation I	nformation

Figure 7.3: 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 7.4).

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



Figure 7.4: Warning Pop-Up Message

7.1.1 Search for the AL by FEI

To search an AL by its FEI Number, the AB user 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 7.5).

FDA	U.S. F00D &	DRUG
	ADMINISTRATION	

U.S. Department of Health and Human Services	
Image: Laaf - Accreditation Welcome, FSMA BODY (AB) PROGRAM	ne
e	•
AB Home > Add or View my Accredited Laboratories (AL) > Add and Notify AL	
Add Accredited Laboratories (AL)	
To add an Accredited Lab (AL), enter the AL's FEI Number and click "Search." The system will populate the AL's read-only profilemore	
→ Accredited Laboratories (AL)	
You may search for the AL by selecting from the following options. FEI Number Firm Name & Address Search	
Accreditation Information	ī
Certification Information	
Disciplines, Analyses, and Test Methods	
Q Previous	

Figure 7.5: 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 from the left-hand column within the "Accredited Laboratories (AL)" accordion section (Figure 7.6).
- Additional fields will be displayed in the right column for the AB user to provide the AL's contact information.



Accredited Laboratories (AL)	
ou may search for the AL by selecting from the following op FEI Number Firm Name & Address	tions.
Firm Name	Contact Name
	First Name MI (Optional) Last Name
Address Line 1	Phone Number Country Area Phone Number Extension
Address Line 2 (Optional)	Fax Number (Optional) Country Area Fax Number
City	Web Address (Optional)
Country/Area	Email Address
State/Province/Territory	Officer(s)
Zip Code (Postal Code)	You can enter another officer
Clear Accreditation Information	
Certification Information	
Disciplines, Analyses, and Test Methods	

Figure 7.6: 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 7.7).



ESMA LAAF - ACCREDITAT	
The system has the information below for the AL whose FI information please contact the AL. The AL may have to up	El number or Firm Name and Address you searched. If you disagree with the
AB Home > Add or View my Accredited Laboratories (AL) >	
formation if it is found in the FDA Firm Inventory records. you do not know the AL's FEI Number or, if your search d dditional firm data fields will not become enabled until you	and click "Search." The system will populate the AL's read-only profile loes not return a match, you may search by Firm Name & Address. I have conducted a search by FEI Number or Firm Name & Address. ation sections, and make at least one selection from Disciplines, Analyses,
Accredited Laboratories (AL)	
Firm Name	Contact Name
Address Line 1 Address Line 2 (Optional)	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number
	Phone Number Country Area Phone Number Extension Fax Number (Optional)
Address Line 2 (Optional) City Country/Area	Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number
Address Line 2 (Optional)	Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number Web Address (Optional) Email Address
Address Line 2 (Optional) City Country/Area State/Province/Territory Zip Code (Postal Code)	Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number Web Address (Optional) Email Address Officer(s)
Address Line 2 (Optional) City Country/Area State/Province/Territory Zip Code (Postal Code) Clear	Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number Web Address (Optional) Email Address Officer(s)

Figure 7.7: FEI Number Search Result of an AL Accredited by another AB

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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 7.8).

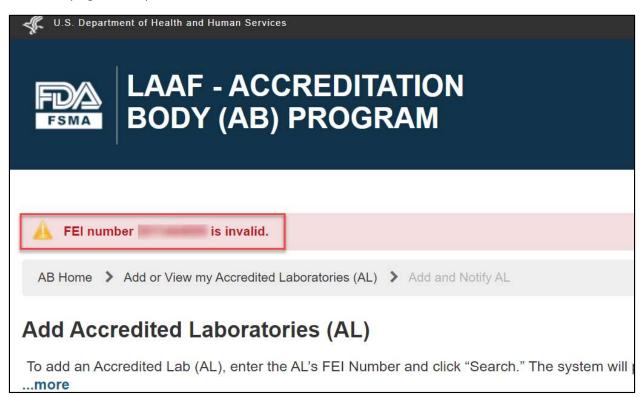


Figure 7.8: Invalid FEI Number Message

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?" Users may respond by clicking either the "Yes" or "No" buttons (Figure 7.9).

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. 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.



Home > Add or View my Accredited Laboratories (AL) > Add an	d Nority Al
WARNING!	
dd an Accredited Lab (AL)	section. Are you sure you want to proceed?
Accredited Laboratories (AL)	
You may search for the AL by selecting from the following option	2
To a may search for the AC by selecting non-the following option	э.
FEI Number Firm Name & Address	
Firm Name	
	Contract Nama
rinn Name	Contact Name
rini Name	Contact Name First Name MI (Optional) Last Name
Address Line 1	
	First Name MI (Optional) Last Name Phone Number
	First Name MI (Optional) Last Name
Address Line 1	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension
Address Line 1 Address Line 2 (Optional)	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension
Address Line 1	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension Fax Number (Optional)
Address Line 1 Address Line 2 (Optional)	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number
Address Line 1 Address Line 2 (Optional)	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number
Address Line 1 Address Line 2 (Optional) City	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number Web Address (Optional)
Address Line 1 Address Line 2 (Optional) City Country/Area	First Name MI (Optional) Last Name Phone Number Country Area Phone Number Extension Fax Number (Optional) Country Area Fax Number Web Address (Optional)

Figure 7.9: Warning Message



7.1.2 Search for the AL by Firm Name & Address

To search an AL by its Firm Name & Address, the AB user will select the "Firm Name & Address" button. The system will display the following user input fields, and a "Search" button (Figure 7.10):

- 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.

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EXAMPLE ADDRESSION DEVELOPMENT ADDRESSION DEVELOPMENT DE VALOR DE
AB Home > Add or View my Accredited Laboratories (AL) > Add and Notify AL Add Accredited Laboratories (AL) To add an Accredited Lab (AL), enter the AL's FEI Number and click "Search." The system will populate the AL's read-only profilemore Accredited Laboratories (AL) Vou may search for the AL by selecting from the following options. FEI Number FII Numbe
Add Accredited Laboratories (AL) To add an Accredited Lab (AL), enter the AL's FEI Number and click "Search." The system will populate the AL's read-only profilemore
To add an Accredited Lab (AL), enter the AL's FEI Number and click "Search." The system will populate the AL's read-only profilemore
To add an Accredited Lab (AL), enter the AL's FEI Number and click "Search." The system will populate the AL's read-only profilemore
You may search for the AL by selecting from the following options. FEI Number FII Number Address Address Line 1 Address Line 2 (Optional) City City Please Select Country State/Province/Territory Please Select
You may search for the AL by selecting from the following options. FEI Number FII Number Address Address Line 1 Address Line 2 (Optional) City City Please Select Country State/Province/Territory Please Select
Address Line 1 Address Line 2 (Optional) City Country/Area Please Select Country State/Province/Territory Please Select
Address Line 2 (Optional) City Country/Area Please Select Country State/Province/Territory Please Select
City Country/Area Please Select Country State/Province/Territory Please Select
Country/Area Please Select Country State/Province/Territory Please Select
Please Select Country • State/Province/Territory Please Select
State/Province/Territory Please Select
Please Select
Search
Accreditation Information
Certification Information
Disciplines, Analyses, and Test Methods
© Previous

Figure 7.10: 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 7.11).

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

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	ADMINISTRATION	

d Accredited Laboratories (AL)	
dd an Accredited Lab (AL), enter the AL's FEI Number	and click "Search." The system will populate the AL's read-only profile
re	
Accredited Laboratories (AL)	
You may search for the AL by selecting from the following	options.
FEI Number Firm Name & Address	
Firm Name	Contact Name
Firm Name	
	First Name MI (Optional) Last Name
Address Line 1	Phone Number:
	Country Area Phone Number Extension
Address Line 2 (Optional)	Fax Number (Optional):
City	Country Area Fax Number
ony on the second se	Web Address (Optional):
Country/Area	Email Address
UNITED STATES	7
State/Province/Territory	Officer(s)
	You can enter another officer
Zip Code (Postal Code)	
Clear	
Accreditation Information	
Certification Information	

Figure 7.11: No Result Returned for the AL Name and Address

If the system returns a single match from its search 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.

11



The AL may have to update its account profile." (Figure 7.12).

U.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Wetcome, Test Tester FURLS Home LAB Home
	8
AB Home > Add or View my Accredited Laboratories (AL) > Add and	NOUY AL
dd Accredited Laboratories (AL) o add an Accredited Lab (AL), enter the AL's FEI Number and clic more	k "Search." The system will populate the AL's read-only profile
Accredited Laboratories (AL)	
You may search for the AL by selecting from the following options FEI Number • Firm Name & Address	
Firm Name	Contact Name
	First Name MI (Optional) Last Name
Address Line 1	Phone Number
	33 Country Area Phone Number Extension
Address Line 2 (Optional)	Fax Number (Optional)
	Country Area Fax Number
City	Web Address (Optional)
Country/Area	Email Address
State/Province/Territory	Officer(s)
·	You can enter another officer
Zip Code (Postal Code)	
Accreditation Information	
Certification Information	
Disciplines, Analyses, and Test Methods	
Previous	S Next

Figure 7.12: 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 search 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 7.13).

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.

art Model, Science (Mr. 1971)	 Select & Continue Select & Continue
and Master Street Street St.	Select & Continue
and the second distance of the second distanc	
	Select & Continue
tions.	
	tions.

Figure 7.13: 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 7.14).



Accredited Laboratories (AL)		
FEI Number Firm Name & Address	options.	
Firm Name	-	Contact Name
Address Line 1		First Name MI (Optional) Last Name Phone Number
		Country Area Phone Number Extension
Address Line 2 (Optional)		Fax Number (Optional) Country Area Fax Number
Sity		Web Address (Optional)
Country/Area	w.	Email Address
State/Province/Territory		Officer(s) You can enter another officer
Σip Code (Postal Code)		
Clear		•
Accreditation Information		
Certification Information		
Disciplines, Analyses, and Test Methods		

Figure 7.14: Result Selected from Multiple Matches

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

If the user enters the same e-mail address associated with another AL, the system will display a warning at the top of the page: "The email you entered is associated with another accredited lab in the system. Please enter a different email address." (Figure 7.15).

FDA	U.S. F00D &	DRUG
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	tories (AL) > Add and	Notify AL
Accredited Laboratories	(AL)	
	5 5 7	"Search." The system will populate the AL's read-only profile
re	FEI NUITIDEL and one	C Sedicit. The system will populate the AL's read-only prome
Accredited Laboratories (AL)		
You may search for the AL by selecting from	n the following options	
fou may search for the ML by selecting non	II the following options.	
FEI Number Firm Name & Addre	SS	
Firm Name		Contact Name
Contraction and the		First Name MI (Optional) Last Name
Address Line 1		Phone Number:
Charlen Schull		245
		Country Area Phone Number Extension
		Fax Number (Optional):
Address Line 2 (Optional)	1	
Address Line 2 (Optional)		Country Area Fax Number
		Country Area Fax Number Web Address (Optional):
Address Line 2 (Optional) City		
City		
City		Web Address (Optional):
City Country/Area		Web Address (Optional):
	•	Web Address (Optional): Email Address Officer(s) Ofc-1
City Country/Area		Web Address (Optional): Email Address Officer(s)
City Country/Area		Web Address (Optional): Email Address Officer(s) Ofc-1
City Country/Area		Web Address (Optional): Email Address Officer(s) Ofc-1

Figure 7.15: Warning Message Displays when Same Email Address is Used



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 AL's LAAF accreditation by the AB user
- Expiration Date The expiration date of the AL's accreditation by the AB user

Note: Each date field allows the user to pick a date from the calendar or enter a date manually in "YYYY-MM-DD" format.

of U.S. Department of Health and Human Services			
ESMA LAAF - ACCREDI BODY (AB) PROC	TATION Welcome, FN LN FURLS Home LAB Home		
	8		
AB Home > Add or View my Accredited Laboratories (A	L) > Add and Notify AL		
more	v umber and click "Search." The system will populate the AL's read-only profile		
Accredited Laboratories (AL)			
Accreditation Information			
Accreditation Date	Expiration Date YYYY-MM-DD		
Certification Information			
 Disciplines, Analyses, and Test Methods 			
Previous	O Next		

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 the user to pick a date from the calendar or enter a date manually in "YYYY-MM-DD" format.

🦸 U.S. Department of Health and Human Servic	ies	
EDA LAAF - AC BODY (AB)	CREDITATION PROGRAM	Welcome, FURLS Home LAB Hom
AB Home > Add or View my Accredited	Laboratories (AL) > Add and Notify AL	e
Add Accredited Laborate	ories (AL)	
o add an Accredited Lab (AL), enter t more	he AL's FEI Number and click "Search." The sy	ystem will populate the AL's read-only profile
Accredited Laboratories (AL)		
Accreditation Information		
 Certification Information 		
Step 4: Click Upload		o display the Browse, Upload and Cancel buttons
Note: 1. Allowed file types are pdf, png, jpeg, 2. Maximum file size allowed is 50 MB.	gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx,	, txt, pptx, rtf.
Certificate Number	Date of Issuance (Optional)	Certificate Expiration Date
	YYYY-MM-DD	YYYY-MM-DD
Certificate Number File Name	Date of Issuance	Certificate Expiration Date Action
No Certificates Added.		
 Disciplines, Analyses, and Test Meth 	iods	
O Previous		S Nex

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.

Certificate Number 1234	Date of Issuance (Optional)	Certificate Expiration I 2024-11-01	Date
+ Browse			
Certificate Number File Name	Date of Issuance	Certificate Expiration Date	Action
No Certificates Added.			
Disciplines, Analyses, and Test Methods			

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.

Certification Information	on			
Note: Please upload th	e certificate(s) to confirm the	accreditation of the accredited	laboratory under ISO/IEC 17025	Testing/Calibration
Instructions:				
Step 1: Enter a Certifica	te Number			
Step 2: Select a Certific	ate Expiration Date			
Step 3: Click Browse to	find the document(s) you want t	o upload		
Note: You must enter be	oth the Certificate Number and (Certificate Expiration Date in orde	er to display the Browse, Upload an	d Cancel buttons
Step 4: Click Upload				
Note:				
1. Allowed file types are	pdf. pna. ipea. aif. bmp. ipa. ipe	e, jfif, tif, tiff, doc, docx, ppt, xls, x	lsx. txt. pptx. rtf.	
2. Maximum file size allo		· · · · · · · · · · · · · · · · · · ·		
Certificate Number	Date	of Issuance (Optional)	Certificate Expiration	Date
	YYY	Y-MM-DD	YYYY-MM-DD	
Certificate Number	File Name	Date of Issuance	Certificate Expiration Date	Action
1234	AttachmentSample1.docx	2021-11-01	2024-11-01	â
Disciplines, Analyses,	and Test Methods			

Figure 7.19: Table of Certificate Attachments



7.4 Disciplines, Analyses, and Test Methods Section

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

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

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Accredited Laborate	ories (AL)			
Accreditation Inform	nation			
Certification Information	ation			
Disciplines, Analyse	es, and Test Methods			
	of the search fields at th	17.1 E E E	Fest Methods" table by clicking on the a ," or "Test Method" column to filter the	
Use the arrows at the b	ottom of the table to nav	igate through the pages of the list	0 7	
The selected item(s) w	ill display in the "List of S	elected Disciplines, Analyses, an	d Test Methods" table.	
Click the trash/delete in	on in the "Action" colum	n of the table if you wish to remov	e an item prior to making your submiss	ion.
			1 37	
List of Available Disci	plines, Analyses, and T	est Methods		
Dise	cipline	Analysis	Т	est Method
Biological		Salmonella	Molecular Serotyping:	SMS-BioPlex Assay
Biological		E. coli	BAM Chapter 4A: qPC genes	R for stx1, stx2, and uidA
Biological		E. coli	nmunomagnetic Separation tection and Isolates of E. coli	
Chemical				Determination of Over 200 found in Regulatory Samples
Biological		E. coli BAM Chapter 4A: Conven isolation/identification		ventional culture
Biological		E. coli	AGAC 366.23: MPN	
Biological		E. coli	AOAC 966.24: MPN	
Biological		E. coli	AOAC 992.30: Total c	oliform & E. coli ColiComplete
Biological		E. coli	BAM Chapter 4: Broth EC	method confirmatory test for
Biological		Fecal Coliforms	BAM Chapter 4: Scree	ning and confirmatory
		(33 of 36)	82 81	
	lines, Analyses, and Te	est Methods		
Discipline	Analysis		Test Method	Action
Biological	E. coli		BAM Chapter 4A: qPCR for stx1, stx2, and uidA genes	Ô
Biological	E. coli		RIMS: Recirculating immunomagr Separation (RIMS) Method for Detection and Isolates of E. coli 0157:H7 from foods	ietic Î
Biological	E. coli		BAM Chapter 4A: Conventional culture isolation/identification	â
Biological	E. coli		AOAC 966.23: MPN	â

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).

or U.S. Department of Health and Human Services		
LAAF - ACCREDI BODY (AB) PROC		Welcome, FURLS Home LAB Home
		8
AB Home > Add or View my Accredited Laboratories (A	AL) > Add and Notify AL > e-Signature	
e-Signature Please read the following statement carefully, then ac the bottom of the page. Please note that an e-Signatu FDA, or by authorizing an individual to submit this infr and accurate. Under 18 U.S.C. 1001, anyone who ma subject to criminal penalties. I also understand that m subsequent revocation of my participation in the prog	ure is the equivalent of a handwritten signatu ormation to FDA, the submitter certifies that t akes a materially false, fictitious, or fraudulen hisrepresentations or omissions may constitut gram.	re. By submitting this information to the information in the submission is true at statement to the U.S. Government is te sufficient grounds for rejection or
 I certify that the information in the submission is t Name of Submitter 	true and accurate and that I am authorized to su Title of Submitter	bmit the information to FDA.
Date		
		O Submit

Figure 7.21: e-Signature Page



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

u.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, FN LN FURLS Home LAB Home
	8
AB Home > Add or View my Accredited Laboratories (AL) > Add and Notify AL > e-Sig	nature > Confirmation
Confirmation Thank you for submitting. You will receive a confirmation e-mail from FDA within 24 ho within that timeframe, please e-mail FDALAAFInquiry@fda.hhs.gov.	urs. If you do not receive confirmation from FDA

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).

Add or View my Accredited Laboratories (AL)		
To add an AL, select "Add AL" button at the bottom of the page and follow the steps to enter	r information about the new A	L.
To view the details for an existing AL, select the "View" (magnifying glass) icon from the "Ac	tion" column.	
Name 🗘	Status ≎	Action
101	Accredited	- View
forei fii	Accredited	Q
totally desired	Accredited	Q
Previous		🗹 Add AL

Figure 7.23: View Icon

The system will display the AL's read-only accreditation details for the AB user on a new page: "Accredited LAB Information" (Figure 7.24).



U.S. Department of Health	and Human Services		
	F - ACCREDITATIONY (AB) PROGRAM	ON I	Welcome, Lest Lester FURLS Home LAB Home
			0
AB Home > Add or Vie	w my Accredited Laboratories (AL) > Accr	redited LAB	
Accredited LAB	Information		
Firm Name		Contact Name Test Tester	
Address		Contact Number Telephone Number 1 000 Fax Number	00000 Ext
Web Address		Email Address	
Accreditation Date 2021-10-01		Expiration Date 2024-10-01	
Certificate Number	File Name	Date of Issuance	Expiration Date
123AB Discipline	CertDocExample123.docx Analysis	2021-09-15	2025-09-15 Test Method
Chemical	Pesticides/IC, Mela		LIB 4422: Interim Method for Determination of Melamine and Cyanuric Acid Residues In Foods using LC-MS/MS
Chemical	Pesticides/IC, Mela	mine (in human food)	LIB 4421: Determination of Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS
Chemical	Nutrition, Fat Solub	le Vitamins	AOAC 2017.04: Cis and Trans Lutein, Cis and Trans beta-Carotene, and Cis and Trans Lycopene in Infant, Pediatric, and Adult Nutritionals
Chemical	Pesticides//C, Pesti	icides	LIB 4419: Elution of Pesticide Residues Using Various SPE Cartridges and a Mixture of Differential Solvents
Previous			

Figure 7.24: AL Accreditation Details



8 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 "AB Home" page (Figure 8.1).

AB Home	
AB Home	Welcome
View/Edit my application for recognition	Welcome to the FDA's Laboratory Accreditation for Analyses of Foods portal. This portal is the means by which all Accreditation Body information related to the FDA
View my profile	Laboratory Accreditation for Analyses of Foods Program will be transmitted to the agency. Until your application for
View Test Methods	recognition by FDA is approved, your account will be limited to minimal actions which include updating your profile, contacting the FDA Laboratory Accreditation for Analyses of Foods Program, and submitting an application
Add or view my Accredited Labs	to become recognized by the FDA Laboratory Accreditation for Analyses of Foods Program. Once you are accepted into the program, additional information
Reports and Notifications	technology (IT) capabilities will become available including the ability to add Laboratory Accreditation for Analyses of Foods Accredited Laboratories to your purview. Use this
Supplemental Documentation	site to submit an application for recognition as an accreditation body.
Contact Us	How do I submit an application? On the left navigation menu click on the "Apply for Recognition" link to create a new application and follow th form. You can save a draft of the form at any point.

Figure 8.1: Navigation Menu



The system will display the "Reports and Notifications" page with the following reports and notifications available (Figure 8.2):

• Notice of Addition or Removal of Test Methods for an Accredited Laboratory (AL) – Generates a notice to FDA when an AB submits a Notice of Addition or Removal of Test Methods for an Accredited Laboratory.

	0 🖯
AB Home > Reports and Notifications	
Reports and Notifications	
Notice of Addition or Removal of Test Methods for an Accredited Laboratory (AL)	
@ Previous	

Figure 8.2: Reports and Notifications Page



8.1 Notice of Addition or Removal of Test Methods for an AL

To notify FDA of any addition or removal of test methods, the user will click the "Notice of Addition or Removal of Test Methods for an Accredited Laboratory (AL)" link on the "Reports and Notifications" page (Figure 8.3).

The user may click the "Previous" button to return to the "AB Home" page.

	0 🖨
AB Home > Reports and Notifications	
Reports and Notifications	
Notice of Addition or Removal of Test Methods for an Accredited Laboratory (AL)	
© Previous	

Figure 8.3: Notice Link and Previous Button

The system will display the "Notice of Addition or Removal of Test Methods for an Accredited Laboratory (AL)" page (Figure 8.4).

When AB doesn't have at least one AL, system will display the below message to the user: -

"Before notifying the Laboratory Accreditation for Analyses of Foods Program about your accreditation of an AL, you must first add the AL to the system. To add an AL to the system, select the Add or View my Accredited Laboratories (AL) menu option on the Home page. After the AL is added, return to this page to submit the notice of accreditation of AL."

Note: The user can click the "Previous" button at the bottom of the notice to return to the "AB Home" page.

						0 🗧
AB Home > Re	eports and Notificatio	ns > Notice of Add	ilion or Removal of Te	est Methods for an Accred	lited Laboratory (AL)	
lotice of A	ddition or F	Removal of	Test Method	s for an Accre	dited Laborate	ory (AL)
stem. To add a A	L to the system, se		my Accredited Labo		n of a AL, you must first on on the Home page. A	

FDA U.S. FOOD & DRUG

Figure 8.4: Message displayed when no AL added

When at least one AL is added, the system will display the "List of Available Disciplines, Analyses, and Test Methods" (Figure 8.5) and "List of Current Accredited or Selected Disciplines, Analyses, and Test Methods" (Figure 8.6).

FDA	U.S. FOOD & D	RUG
	ADMINISTRATION	

AB Home > Reports and Notific		0 🖶
	cations > Notice of Addition or Removal of Test Meth	hods for an Accredited Laboratory (AL)
otice of Addition or	r Removal of Test Methods fo	r an Accredited Laboratory (AL)
u may use this notice to notify F	DA of addition or removal of test methods for the	scope of accreditation for an accredited lab (AL).
	is more than one. Add or remove test methods to o nods in the same notice submission.	or from the lab's accreditation as needed; you may perform
load an updated certificate (if ap	oplicable) and enter the Certificate Number and Da	te of Issuance.
d any further information you wi	ish to include for consideration, if needed.	
rrent Accredited or Selected Discip ter a keyword in any of the search your entry.	ist of Available Disciplines, Analyses, and Test Method plines, Analyses, and Test Methods" table. fields at the top of the "Discipline," "Analysis," or "Test	is" table, directly below, by clicking on the row to add it to the "List t Method" column to filter the list. The system will refine the list bas
e the arrows at the bottom of the ta	able to navigate through the pages of the list.	
Discipline	Analysis	Test Method
Discipline	Analysis	Test Method
	Analysis Pesticides/IC, Pesticides	JAFC 2011, 59, 8383ff: Modified QuEChERS - LCMS
hemical		
nemical	Pesticides/IC, Pesticides	JAFC 2011, 59, 6383ff: Modified QuEChERS - LCMS JACAC Inst. 87, No.6, (2001), pp. 12214F. GC MS Determination of Pestidide Containing Nitrogen, Sulfur,
hemical hemical	Pesticides/IC, Pesticides Pesticides/IC, Pesticides	JAFC 2011, 59, 8383ff. Modified QuEChERS - LCMS UNOXC Intl. 67, No.6, (2004), pp. 1224ff. GC MB Determination of Festicides Containing Nitrogen, Sulfur, Oxygen in Fruits and Vegetables LIB 419: Elution of Pesticide Residues Using Various
hemical hemical hemical	Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides	JAFC 2011, 59, 6383ff, Modified QuEChERS - LCMS JAOAC Intl. 87, No.6, (2004), pp. 1224ff. GC MG Determination of Pesticides Containing Nitrogen, Sulfur, Oxygen in Fruits and Vegetables LIB 4419: Elution of Pesticide Residues Using Various SPE Carridges and a Mixture of Differential Solvents LIB 4694. Modified QuEChERS - GC/MS-MS utilizing
hemical hemical hemical hemical	Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides	JAFC 2011, 59, 6383ff. Modified QuEChERS - LCMS UACHAC Intl. 87, No.6, (2004), pp. 1224ff. GC ME Determination of Pesticide Containing Nitrogen, Sulfur, Oxygen in Fruits and Vegetables LIB 4419: Elution of Pesticide Residues Using Various SFE Cartridges and a Muture of Differential Solvents LIB 4594: Modified QuECHERS - GC/MS-MS utilizing ethyl acetate AOAC 2007.01: Modified QuECHERS - GC/MS-MS with
hemical hemical hemical hemical hemical	Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides	JAFC 2011, 59, 6383ff. Modified QuEChERS - LCMS JACAC Intl. 67, No.6, (2004), pp. 1224ff: GC ME Determination of Pesticides Containing Nitrogen, Suifur, Oxygen in Fruits and Vegetables LIB 4419: Eutition of Pesticides Realicues Using Various SPE Cartridges and a Mixture of Differential Solvents LIB 4994: Modified QuEChERS - GC/MS-MS utilizing ethyl acetate ADAC 2007.01: Modified QuEChERS - GC/MS-MS with solvent exchange to toluene JAFC 2012, 00, 1991-9999; GC-MS/MS for the Analysis
Discipline.	Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides	JAFC 2011, 59, 8383ff. Modified QuEChERS - LCMS JAOAC Intl. 67, No.6, (2004), pp. 1224ff: GC MS Determination of Pesticides Containing Nitrogen, Sulfur, Oxygen in Fruits and Vegetables LIB 4419: Euton of Pesticide Residues Using Various SFE Cartridges and a Mixture of Differential Solvents LIB 4964: Modified QuEChERS - GC/MS-MS utilizing ethyl acetate AOAC 2007.01: Modified QuEChERS - GC/MS-MS with solvent exchange to toluene JAFC 2012, 80, 1991-9999; GC-MS/MS for the Analysis of Drived Botanicals AOAC 2007.07: Determination of Pesticide Residues by
hemical hemical hemical hemical hemical hemical	Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides Pesticides/IC, Pesticides	JAFC 2011, 59, 6383ff: Modified QuEChERS - LCMS JACAC Intl. 67, No.6, (2004), pp. 1224ff: GC ME Determination of Pestidiades Containing Nitrogen, Sulfur, Oxygen in Fruits and Vegetables LIB 4419: Elution of Pestidiade Residues Using Various SPE Cartridges and a Mixture of Differential Solvents LIB 4504: Modified QuEChERS - GC/MS-MS utilizing ethyl acetate AOAC 2007.01: Modified QuECHERS - GC/MS-MS with solvent exchange to toluene JAFC 2012, 80, 1991-9999: GC-MS/MS for the Analysis of Dried Bonnicals AOAC 2007.07: Determination of Pesticide Residues by LC-M/SMS LIB 4422: Interim Method for Determination of Melamine

Figure 8.5: Notice of Addition or Removal of Test Methods for an AL



		(1 of 55) ++ +1		
	Accredited or Selected Disciplines			
he disciplines, a ccreditation.	analyses, and test methods that are o	isplayed in the list below, upon first navigating to this pa	ge, are currently par	t of the selected lab's
o remove a test	method from the lab's current accred	station, click the Delete (trash) icon in the Action column	ÈC	
		elect it from the table above, "List of Available Discipliner ent Accredited or Selected Test Methods" table, below	a, Analysea, and Tes	t Methods" by clicking or
Discipline	Analysis	Test Method	Accreditation	Action
Biological	Fish Speciation, Economic Adulteration	DNA Based Fall Identification Method Version 2 November 2011	Accredited.	8
Chemical	Pesticides/IC. Pesticides	ADAC 2007.07: Determination of Pesticide Residues by LC-MS/MS	Accredited	0
Physical	Fith, Macro Moro	FDA Technical Bulletinx # 2	Accredited	8
Chemical	Melarrine	LIB 4421: Determination of Melamine and Cyanuto Acid Residues in Infant Formula using LC-MS/MS	Accredited	8
Physical	Evaceration	Vaual Examination	Accredited	8
	Upload (Optional)	elevant to this notification (Optional).		
Enter your resp	interesting with the second			

Figure 8.6: Notice of Addition or Removal of Test Methods for an AL Page

The user will select the AL from the "Accredited Laboratory" dropdown menu (Figure 8.7). If the AL is only accredited by one AB, the "AL Name" field will be pre-filled.

Accredit	ed Laboratory	

Figure 8.7: Accredited Laboratory Dropdown Menu

The system displays the "List of available Disciplines, Analyses and Test Methods" table which lists all the test methods. (Figure 8.8).



The system displays the "List of Current Accredited or Selected Disciplines, Analyses and Test Methods" table, displaying those accredited by the AB (Figure 8.8).

elect the desired values from the "List of urrent Accredited or Selected Disciplines		Is" table, directly below, by clicking on the row to add it to the "Lis
nter a keyword in any of the search fields n your entry. se the arrows at the bottom of the table t		Method" column to filter the list. The system will refine the list b.
Discipline	Analysis	Test Method
Chemical	Pesticides/IC, Pesticides	JAFC 2011, 59, 6383ff: Modified QuEChERS - LCMS
Chemical	Pesticides/IC, Pesticides	JAOAC Intl. 87, No.5, (2004), pp. 1224ff; GC-MS Determination of Pesticides Containing Nitrogen, Sulfur, Oxygen in Fruits and Vegetables
Chemical	Pesticides/IC, Pesticides	LIB 4419: Elution of Pesticide Residues Using Various SPE Cartridges and a Mixture of Differential Solvents
Chemical	Pesticides/IC, Pesticides	LIB 4594: Modified QuEChERS - GC/MS-MS utilizing ethyl acetate
Chemical	Pesticides/IC, Pesticides	AOAC 2007.01: Modified QuECHERS - GC/MS-MS with solvent exchange to toluene
Chemical	Pesticides/IC, Pesticides	JAFC 2012, 60, 1991-9999: GC-MS/MS for the Analysis of Dried Botanicals
Chemical	Pesticides/IC, Pesticides	AOAC 2007.07: Determination of Pesticide Residues by LC-MS/MS
Chemical	Melamine	LIB 4422: Interim Method for Determination of Melamine and Cyanuric Acid Residues In Foods using LC-MS/MS
Chemical	Melamine	LIB 4423: GC-MS Screen for the Presence of Melamine, Ammeline, Ammelide, and Cyanuric Acid
Chemical	Melamine	LIB 4421: Determination of Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS

Figure 8.8: List of Available Disciplines, Analyses, and Test Methods

When the user selects test methods from the "List of available Disciplines, Analyses, and Test Methods" table, the selected test methods will display under the table "List of Current Accredited or Selected Disciplines, Analyses and Test Methods". The newly added test methods display an accreditation status of "Selected". Users can delete any test methods from "List of Current Accredited or Selected Disciplines, Analyses, and Test Methods" table by clicking the trash can/delete icon under the "Action" column.

The system displays the "List of Current Accredited or Selected Disciplines, Analyses and Test Methods" table, displaying those accredited by the AB (Figure 8.9).



List of Current Accredited or Selected Disciplines, Analyses, and Test Methods

The disciplines, analyses, and test methods that are displayed in the list below, upon first navigating to this page, are currently part of the selected lab's accreditation.

To remove a test method from the lab's current accreditation, click the Delete (trash) icon in the Action column.

To add a new test method to the lab's accreditation, select it from the table above, "List of Available Disciplines, Analyses, and Test Methods" by clicking on its row in the table. It will be added to the "List of Current Accredited or Selected Test Methods" table, below.

Discipline	Analysis	Test Method	Accreditation	Action
Chemical	Melamine	LIB 4421: Determination of Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS	Accredited	Ē
Biological	Fish Speciation, Economic Adulteration	DNA Based Fish Identification Method Version 2: November 2011	Accredited	â
Chemical	Pesticides/IC, Pesticides	AOAC 2007.07: Determination of Pesticide Residues by LC-MS/MS	Accredited	Ē
Physical	Evisceration	Visual Examination	Accredited	â
Physical	Filth, Macro/Micro	FDA Technical Bulletins # 2	Accredited	â
Chemical	Melamine	LIB 4423: GC-MS Screen for the Presence of Melamine, Ammeline, Ammelide, and Cyanuric Acid	Selected	đ
Chemical	Melamine	LIB 4422: Interim Method for Determination of Melamine and Cyanuric Acid Residues In Foods using LC-MS/MS	Selected	â

Figure 8.9: List of Current Accredited or Selected Disciplines, Analyses, and Test Methods

Note: The "Certificate Upload (Optional)" section functionality is the same as that which is noted in Section 7.3 Certification Information Section.

ote. I lease aproud the ot	ertificate(s) to co	onfirm the accreditation of the accredite	ed laboratory under ISO/IEC 17025 Testing/Calibration
Instructions:			
Step 1: Enter a Certific	ate Number		
Step 2: Select a Certific	cate Expiration Da	ate	
Step 3: Click Browse to	find the docume	nt(s) you want to upload	
Note: You must enter b	ooth the Certificate	e Number and Certificate Expiration Date	in order to display the Browse, Upload and Cancel
buttons			
Step 4: Click Upload			
Note:			
1. Allowed file types are	e pdf. pna. ipea. c	if, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt,	xis, xisx, txt, pptx, rtf.
2. Maximum file size al			
Certificate Number		Date of Issuance (Optional)	Certificate Expiration Date
		YYYY-MM-DD	YYYY-MM-DD
			Certificate Expiration Date Action
Certificate Number	File Name	Date of Issuance	
Certificate Number No Certificates Added.	File Name	Date of Issuance	

Figure 8.10: Additional Information (Optional).

The user can enter additional information in the "Please provide any additional information that is relevant to this notification (Optional)" field (Figure 8.11). This is a free-type optional field which allows a maximum of 4,000 characters.



Enter your response here.		
000 characters remaining.		
Previous		O Ne

Figure 8.11: Additional Information (Optional).

After completion of the notice, the user will click the "Next" button. The system will navigate them to the "e-Signature" page (Figure 8.12).

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.

AB Home > Reports and Notifications	Notice of Addition or Removal of Test Methods for an Accredited Laboratory (AL) $>$ e-Sig	nature
e-Signature		
the bottom of the page. Please note tha FDA, or by authorizing an individual to s and accurate. Under 18 U.S.C. 1001, ar	fully, then acknowledge that you read and approved it by providing the information an e-Signature is the equivalent of a handwritten signature. By submitting this info bmit this information to FDA, the submitter certifies that the information in the sub one who makes a materially false, fictitious, or fraudulent statement to the U.S. G stand that misrepresentations or omissions may constitute sufficient grounds for re n in the program.	rmation to mission is true overnment is
that the accreditation body will comply wit	ssion is true and accurate and that I am authorized to submit the information to FDA. F all requirements for recognized accreditation bodies under 21 CFR part 1, subpart R w	and the second sec
		and the second se
that the accreditation body will comply wit recognized.	all requirements for recognized accreditation bodies under 21 CFR part 1, subpart R w	and the second se
that the accreditation body will comply wit recognized. Name of Submitter	all requirements for recognized accreditation bodies under 21 CFR part 1, subpart R w	and the second se
that the accreditation body will comply wit recognized. Name of Submitter Print full legal name	all requirements for recognized accreditation bodies under 21 CFR part 1, subpart R w	and the second se

Figure 8.12: e-Signature Page

Upon successful submission, the system will post a message on the "Confirmation" page (Figure 8.13).

April 2024



	0 🖨
AB Home > e-Signature > Confirmation	
Confirmation	
Notice of Addition or Removal of Test Methods for an Accredited Laboratory (AL) has been sent.	

Figure 8.13: Confirmation Message

The user may click the "AB Home" link on the top of the banner (or from the breadcrumb) to return to the "AB Home" page (Figure 8.13).

The system will send the user an e-mail indicating the notice was received by FDA (Figure 8.14).

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 8.14: Email Confirmation

Once the notice is submitted successfully, the newly added/deleted test methods and certificate updates will show up on the "Accredited Lab Information" page (Figure 8.15).

FDA	U.S. FOOD & DRUG
	ADMINISTRATION

ccredited LAE	Information				
Firm Name dis Limited			Contact Name		
Address			Contact Number		
			Fax Number		
Veb Address			Email Address		
Accreditation Date			Expiration Date 2025-02-28		
Certificate Number	File Name		Date of Issuance		Expiration Date
Sec. 11	O-Michaeler		2024-02-09		2028-10-10
			2024-02-20		2025-10-10
100110			2024-02-23		2027-02-18
			2024-02-23		2027-02-18
Concernance of the second s					2028-02-28
	Children Ch				2028-02-28
Discipline		Analysis		Test Method	
Chemical		Pesticides/IC, Pesticides		AOAC 2007.07: De Residues by LC-M	termination of Pesticide S/MS
Chemical		Melamine		LIB 4421: Determin Cyanuric Acid Resi LC-MS/MS	ation of Melamine and dues in Infant Formula using
Biological		Fish Speciation, Economic	Adulteration	DNA Based Fish Id November 2011	entification Method Version 2:
Physical		Filth, Macro/Micro		FDA Technical Bull	etins # 2
Physical		Evisceration		Visual Examination	

Figure 8.15: Accredited Lab Information Page



9 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 documents 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 9.1).

AB Home
/iew/Edit my
pplication for
ecognition
/iew my profil
/iew Test
Aethods
Add or view m
Accredited La
Reports and
Notifications
Supplemental
Documentatio
Contact Us

Figure 9.1: Navigation Menu

The system will display the "Supplemental Documentation" page (Figure 9.2). 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 user will click the "Previous" button at the bottom of the "Supplemental Documentation" page to return to the "AB Home" page.



U.S. Department of Health and Human Servic	ces	
ESMA LAAF - AC BODY (AB	CREDITATION) PROGRAM	Welcome, Test Teste FURLS Home LAB Home
		0
AB Home > Supplemental Documenta	tion	
Supplemental Documen	tation	
Instructions		
Step 1: Select Type of Attachment Step 2: Click Browse to find the documen Step 3: Click Upload Step 4: Click Save Note: 1. Allowed file types are pdf, png, jpeg, gi 2. Maximum file size allowed is 50 MB. Type of Attachment Please Select One * Browse & Upload * Cancel	t(s) you want to upload f, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf.	
File Name	Туре	Date of Upload Action
DemoDoc1.docx	Laboratory Corrective Action Plan	2021-08-11
AttachmentSampleDoc1.docx	Internal Audit Results	2021-08-11
AttachmentSample1.docx	AB Corrective Action Plan	2021-08-11
FixTest1.docx	Notice to Voluntarily Relinquish Accreditation	2021-08-11
AttachmentSample2.docx	Add or Manage Laboratories	2021-08-11
Previous		Save

Figure 9.2: Supplemental Documentation Page



The AB user will select a document description from the list displayed in the "Type of Attachment" dropdown menu (Figure 9.3).

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

Please Select One	•	
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		Recognition
Notice to Voluntarily Relinquish Accreditation AttachmentSample2.docx	odian Add or Manage Laboratories	

Figure 9.3: Type of Attachment Menu

Note: A text box labeled "Additional Description" will display if the AB user selects "Other" from the list (Figure 9.4).

The AB user 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.



Other	
Other	
Additional Description	
Enter Description	

Figure 9.4: "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 9.5). 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.

Other	•
Additional Description	
Test	
+ Browse 🗳 Upload 🗙 Cancel	
+ Browse 🚨 Upload 🗙 Cancel	

Figure 9.5: 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 9.6).

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



U.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, Test Tester FURLS Home LAB Home
	Ð
1 TestFile1.docx uploaded successfully. Please click Save to complete transmission of your file to FDA.	
AB Home > Supplemental Documentation	
Supplemental Documentation	

Figure 9.6: 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 9.7).

Please Select One	*		
+ Browse 1 Upload X Cancel			
File Name	Туре	Date of Upload	Action
TestFile1.docx	Add or Manage Laboratories	2021-11-11	🔶 🛍 🖌 Dele
	Request for Regulatory Hearing	2021-08-11	, Im

Figure 9.7: Trash/Delete Icon

After the additional files have been uploaded, the AB user will click the "Save" button (Figure 9.8).

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



Type of Attachment			
Please Select One	•		
+ Browse 🕹 Upload 🗙 Cancel			
File Name	Туре	Date of Upload	Action
TestFile1.docx	Add or Manage Laboratories	2021-11-11	Î
Monday2.docx		2021-08-11	
			_
Previous			Save

Figure 9.8: 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 9.9).

AB Name	File Name	Туре	Date of Upload	Action
FURLS Monday CL AB2	Corrective Action Plan.docx	Laboratory Corrective Action Plan	2021-11-01	Î
FURLS Monday CL AB2	Aug11D docx	Other - testing doc types	2021-08-11	
day_CL AB2	X	Records		-
Previous				2
Previous				⊻ s

Figure 9.9: Hyperlinked File Name



10 Contact Us

The "Contact Us" feature allows the AB user to contact the LAAF program by e-mail.

To access the feature, the AB user will click the "Contact Us" link from the navigation menu on the "AB Home" page (Figure 10.1). This feature is available to the AB upon account creation.

AB Home	
View/Edit m	ıy
application	for
recognition	
View my pro	ofile
Add or view	/ my
Accredited	Labs
Supplemen	tal
Documenta	
Contact Us	

Figure 10.1: Navigation Menu

The system will display the "Contact Us" page in an e-mail template format, with a "Subject" field allowing up to 150 characters and a "Message" field allowing up to 4,000 characters (Figure 10.2). Once the AB user has completed the "Subject" and "Message" fields, they will click the "Send" button to send the e-mail.



I.S. Department of Health and Human Services	
LAAF - ACCREDITATION BODY (AB) PROGRAM	Welcome, FURLS Home LAB Home
Contact Us	€ 🖨
From: Test Tester Subject: Enter subject here	
Subject: Enter subject nere	
Enter message here	
4000 characters remaining	
© Previous	Send

Figure 10.2: Contact Us Page

The system will display a confirmation message on the "AB Home" page stating the message has been sent (Figure 10.3).



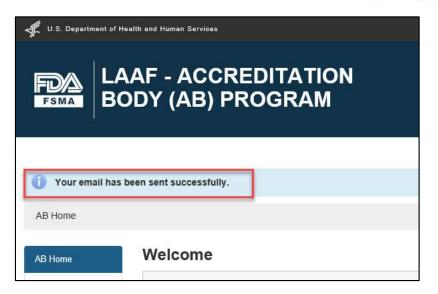


Figure 10.3: Email Sent Successfully



APPENDIX

Abbreviations

Acronyms	Definitions
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	lcon	System Function
Magnifying Glass	α	View the associated item.
Pencil	1	Edit the associated item.
Trash Can	â	Delete the associated item.
Printer	8	Print the associated item.