

Food and Drug Administration



Third Party Accreditation (TPA) Program

Screens for OMB approval

Version: 5.0
January 2016

VERSION HISTORY

Version Number	Implemented By	Revision Date	Description of Change
1.0	FURLS Team	10/04/2016	Provided screenshots
2.0	DRT Team	10/21/2016	Updated with data elements definitions
3.0	Peer Review	11/29/2016	Review complete
4.0	DRT Team	12/18/2016	Updated AB and CB homepage with revised OMB language
5.0	DRT Team	1/20/2017	Updated to include OCC edits

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Legend

OCC has reviewed the contents of this document and all their edits were completed in red font.

Please note in a future release, when it noted that “All fields are mandatory unless noted as optional,” the additional statement will be added “If a mandatory field does not apply to you, please indicate that the field is not applicable.”

1. Create FDA Online Account

An accreditation body (AB) seeking to be recognized by the FDA needs to first create an online account. The AB can sign up for an account by clicking on “Create New Account” on the FDA Unified Registration and Listing Systems (FURLS) Online Account Administration (OAA) page (Figure 1.1).

Once the account has been created, the AB can log into the FURLS OAA page with valid account credentials to apply for recognition by the FDA.

U.S. Department of Health and Human Services

FDA
OAA

ONLINE ACCOUNT ADMINISTRATION (OAA)

FDA Industry Systems

[System Status](#)

Login

Existing account holders, enter your account ID & password.

Account ID

Password

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

I understand.

[Login](#) [Forgot your password](#)

New User

[Create New Account](#)

[See Instructions](#) [See Tutorials](#) [Help Desk](#)

Getting Started

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**.

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 penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised 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 antivirus 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 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.

Figure 1.1 – FDA OAA Page

The system displays the “Create New Account” screen. The user can select the option “Center for Food Safety & Applied Nutrition” (CFSAN) under the first section “Step 1: Select Applicable Center for Account Creation”. (Figure 1.2)

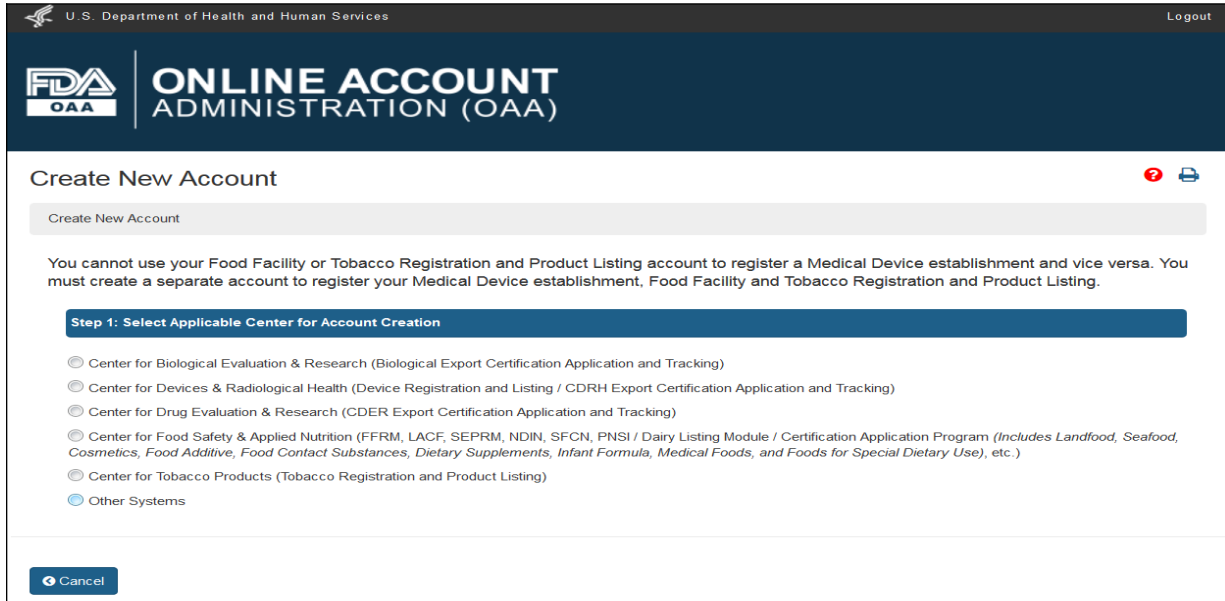


Figure 1.2 – Create New Account Page

The system displays the various programs available in CFSAN. The AB user can select “Third Party Program - Accreditation Body” under the FSMA Programs. (Figure 1.3)

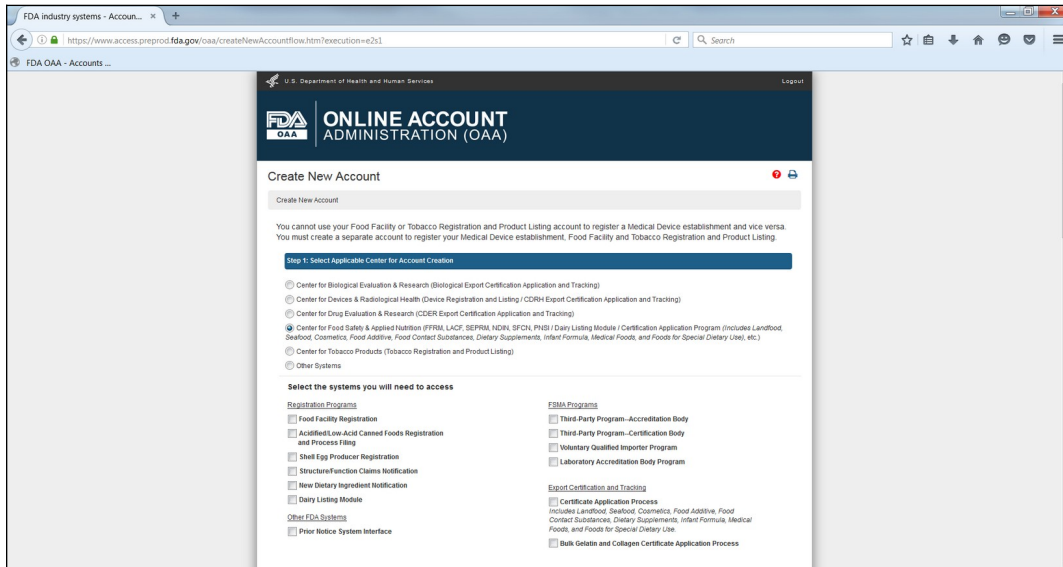


Figure 1.3 – Create New Account Page Contd.

The next section includes the “Account Information” that an AB applicant can enter all their information into. (Figure 1.4)

Step 2: Enter Your Account Information

2A: Point of Contact Information	2C: Physical Address (Business) of Account Holder
First Name <input type="text"/>	Country / Area <input type="text" value="Please Select Country"/>
Middle Initial (Optional) <input type="text" value="Optional"/>	Address Line 1 <input type="text"/>
Last Name / Surname <input type="text"/>	Address Line 2 (Optional) <input type="text" value="Optional"/>
Job Title <input type="text"/>	City <input type="text"/>
Company Name <input type="text"/>	State / Province / Territory <input type="text" value="Please Select"/>
Web Address (Optional) <input type="text"/> <small>(Example: http://www.name.domain or http://name.domain)</small>	Zip Code (Postal Code) <input type="text"/>
Phone Number <input type="text" value="Country"/> <input type="text" value="Area"/> <input type="text" value="Telephone"/> <input type="text" value="Ext"/> Country Area Phone Number Extension	Unique Facility Identifier (Optional) <input type="text" value="Optional"/>
<small>Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.</small>	Do you have preferred mailing address other than the physical address mentioned above? <input type="radio"/> Yes <input type="radio"/> No
FAX Number (Optional) <input type="text" value="Country"/> <input type="text" value="Area"/> <input type="text" value="Fax Number"/> Country Area Fax Number	
E-mail Address <input type="text"/>	
Confirm E-mail Address <input type="text"/>	

2B: Account Information

Password

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

Confirm Password

Secret Question 1

Secret Answer 1

Secret Question 2

Secret Answer 2

Secret Question 3

Secret Answer 3

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

I understand.

Figure 1.4 – Create New Account Page – Enter Account Information

The data fields in the Enter Account Information section include:

Point of Contact Information

- **First Name** - the first name of the point of contact
- **Middle Initial** - (Optional field)
- **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 to which the point of contact represents
- **Web Address** - (Optional field)
- **Phone Number (Country/Area/Phone Number/Extension)** - the telephone number of point of contact
- **Fax Number (Country/Area/Fax Number)** - the fax number of the point of contact
- **E-mail Address** - the e-mail address of the point of contact
- **Confirm E-mail Address** - the second entry of the e-mail address of the point of contact to confirm e-mail address is correct

Account Information

- **Password** - the password for the point of contact's account
- **Confirm Password** - the second entry of the password for the point of contact's account
- **Secret Question 1** - the first secret question to protect the account for the point of contact
- **Secret Answer 1** - the answer to the first secret question to protect the account for the point of contact
- **Secret Question 2** - the second secret question to protect the account for the point of contact
- **Secret Answer 2** - the answer to the second secret question to protect the account for the point of contact
- **Secret Question 3** - the third secret question to protect the account for the point of contact
- **Secret Answer 3** - the answer to the third secret question to protect the account for the point of contact

Physical Address (Business) of Account Holder

- **Country/ Area** - the country or area where the business is located
- **Address Line 1** - the address (number, street etc.) where the business is located
- **Address Line 2** - (Optional field)
- **City** - the city where the business is located
- **State/ Province/ Territory** - the state/province/territory where the business is located
- **Zip Code (Postal Code)** - the zip code (domestic) or Postal Code (foreign) of the business
- **Unique Facility Identifier** - (Optional field)

After the user has completed filling out all the mandatory account information, the user can click on “Create Account” which will display the “Account Review” screen (Figure 1.5). The user can click on “Submit” to create an account or click on “Modify” to edit the profile information.

Please note in a future release, when it noted that “All fields are mandatory unless noted as optional,” the additional statement will be added “If a mandatory field does not apply to you, please indicate that the field is not applicable.”

The screenshot displays the 'Account Review' page for the FDA OAA Online Account Administration. The page is titled 'Account Information' and includes a navigation bar with 'Home' and 'Create New Account'. The main content area is divided into two columns: 'Account Information' and 'Physical Address (Business) of Account Holder'. The 'Account Information' column lists fields such as First Name, Middle Initial, Last Name / Surname, Title, Company Name, Web Address, Phone Number, FAX Number, E-mail Address, and three Secret Questions. The 'Physical Address' column lists fields such as Address Line 1, Address Line 2, City, State / Province / Territory, Zip Code (Postal Code), and Country / Area. At the bottom of the page, there are 'Modify' and 'Submit' buttons.

Account Information	Physical Address (Business) of Account Holder
First Name	Address Line 1
Test First Name	4245 N. Fairfax Drive
Middle Initial	Address Line 2
Last Name / Surname	City
Test Last Name	Arlington
Title	State / Province / Territory
Tester	Virginia
Company Name	Zip Code (Postal Code)
BU Test Co	22203
Web Address	Country / Area
	UNITED STATES
Phone Number	
001 703 7896543	
FAX Number	
E-mail Address	
dpoovaiya@drtsstrategies.com	
Secret Question 1	
What is your favorite food?	
Secret Answer 1	
test	
Secret Question 2	
What is your mother's maiden name?	
Secret Answer 2	
test	
Secret Question 3	
What was your first pet's name?	
Secret Answer 3	
test	

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

[Modify](#) [Submit](#)

Figure 1.5 –Account Review Page

When the user clicks on “Submit”, the system displays a page with a message that account was created successfully and also the account ID that the user can use to log into the application and submit an application for recognition as an accreditation body. (Figure 1.6)

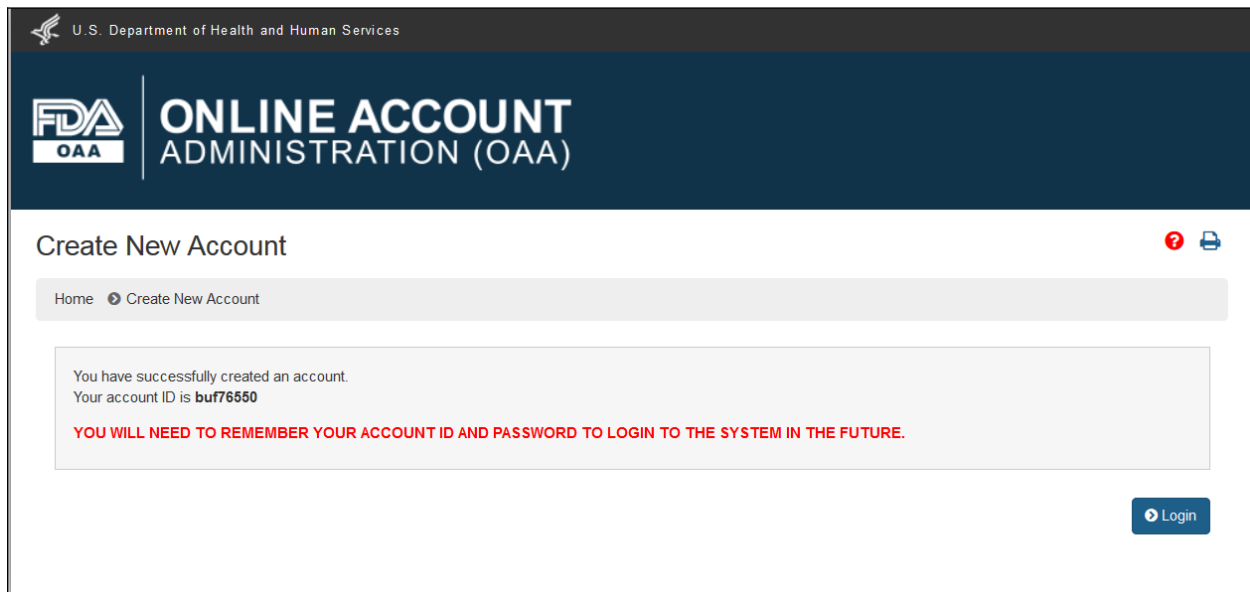


Figure 1.6 –Account Created Successfully Message Page

2. Submitting an application for recognition as an accreditation body (AB)

After the AB has signed into the FDA OAA page, the FURLS homepage (Figure 2.1) is displayed where the AB can then select the link "*Third-Party Program - Accreditation Body*" from the list of systems available in the "*FSMA Programs*" section. This will take the AB to the "*AB Home*" webpage with the banner "*Accreditation Body (AB) Program*" (Figure 2.2).

U.S. Department of Health and Human Services Logout

ONLINE ACCOUNT
ADMINISTRATION (OAA)

Account Management ? 🖨️

Account Management

Edit Account Profile

Change My Password

Update System Access

Welcome to the FDA Industry Systems. You are logged in as **fda74682** for FDA.

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

CFSAN - Center for Food Safety and Applied Nutrition

Click to launch the Application(s)

<input type="checkbox"/> Food Facility Registration	<input type="checkbox"/> Certificate Application Process
<input type="checkbox"/> Acidified/Low-Acid Canned Foods Registration and Process Filing	<input type="checkbox"/> Structure/Function Claims Notification
<input type="checkbox"/> Shell Egg Producer Registration	<input type="checkbox"/> New Dietary Ingredient Notification
<input type="checkbox"/> Dairy Listing Module	<input type="checkbox"/> Bulk Gelatin and Collagen Certificate Application Process

FSMA Programs

Click to launch the Application(s)

<input checked="" type="checkbox"/> Third-Party Program--Accreditation Body	<input type="checkbox"/> Third-Party Program--Certification Body
<input type="checkbox"/> Voluntary Qualified Importer Program	<input type="checkbox"/> Laboratory Accreditation Body Program

Other FDA Systems

Click to launch the Application(s)

<input type="checkbox"/> Prior Notice System Interface	<input type="checkbox"/> Systems Recognition Program
--	--

Figure 2.1 - FURLS Homepage

AB Home

- AB Home
- View/Edit my application for recognition
- View my profile
- Add or manage my Third party CBs.
- Supplemental Documentation
- Contact Us
- Reports and Notifications

Welcome

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

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

How do I submit an application?

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

How do I edit a previously saved application?

On the left navigation menu click on the View/Edit my application for recognition link and use the navigation options to continue filling in the form.

How do I submit my application?

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

FDA Form 3997

PAPERWORK REDUCTION ACT NOTICE

Form Approval: OMB No. 0910-0750

Expiration Date: 06/30/2019

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

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

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

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

Figure 2.2 – AB Homepage

Each screen in the AB electronic submission process has the banner “Accreditation Body (AB) Program”. The link “FURLS Home” on the right side of the banner will take the user to the FURLS Homepage, from where the user will be able to log out of the program

2.1. Apply for recognition and implementing FDA regulations

To create a new application for recognition as an accreditation body, the AB can select the link “Apply for Recognition” from the left navigation menu which will take the user to the next page, the “Applicant Information” (Figure 2.1.1). This page displays read-only information from the user’s profile.

“AB Home” will take the user to the Main Menu on AB Home page.

U.S. Department of Health and Human Services

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

Welcome, Beverly Watson
FURLS Home | AB Home

All fields are mandatory unless noted as optional.

AB Home > Dashboard > Applicant Information

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

Applicant Information

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

Firm Name Medco Express	Contact Name Beverly X Watson
Address The Canberra Centre, City Walk Shop DF44 Bunda St Canberra Queensland 2600 AUSTRALIA	Contact Number Telephone Number 61 (743) 123456 Ext. 11 Fax Number 61 (743) 123457
Web Address --	Email Address Oleg.Keyzman@fda.hhs.gov
	Unique Facility Identifier 987654321

Previous Save Next

Figure 2.1.1 - Applicant Information

The user can click on the Scope tab to navigate to the “Scope” page (Figure 2.1.2). This page contains a list of all original source scopes. The user needs to select at least one scope from the “List of Original Source Scopes” and move it to the “List of Selected Scopes” using button “->”. Alternatively, the user can use button “->|” to move all scopes from the original list.

Similarly, the user can use button labeled “<-” to move one scope back to the original list or use the button “|<-” to move all scopes back to the original list.

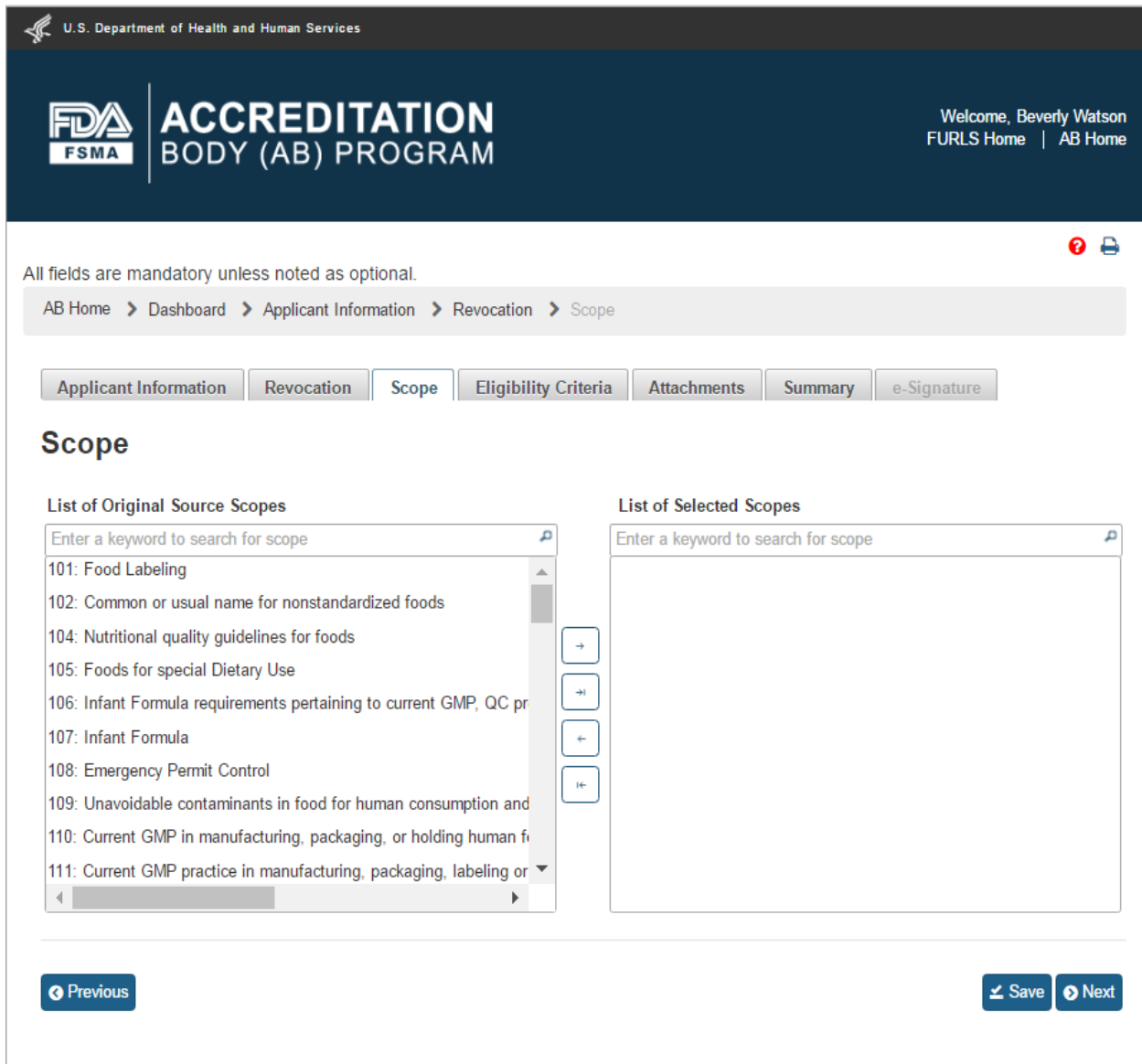


Figure 2.1.2 – Scope – *Please note, in a future release the scope list will be updated to reflect changes made by the OCC.*

After the user clicks “Save” and then “Next” button or “Eligibility” tab, the system will bring up the “Eligibility” page (Figure 2.1.3).

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Beverly Watson
FURLS Home | AB Home

All fields are mandatory unless noted as optional.

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

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

Eligibility Criteria

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

Legal Authority

Q1
Q2
Q3
Q4
Q5

Legal Authority

"An "accreditation body" includes: (1) a governmental accreditation body; and (2) a registered legal entity that offers accreditation services (described as a "non-governmental accreditation body" in this portal). The term, "certification bodies," is used to refer to bodies that are also known as "third-party auditors" and "conformity assessment bodies." "Food" includes food for human consumption, pet food, and non-medicated animal feed. It excludes products regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) under the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act and FSIS regulations. The term "food safety requirements" includes applicable requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations in Title 21, of the Code of Federal Regulations. Requirements of the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act and regulations issued by the U.S. Department of Agriculture's Food Safety and Inspection Service are excluded from this definition and are outside the scope of this program. You may respond to the questions by answering in the text boxes provided or by uploading one or more documents to satisfy the requirement and identifying the relevant provision(s). Or, if the document was previously uploaded, please identify the document by title and the relevant provision within."

Previous Save Next

Figure 2.1.3 – Eligibility Criteria page - *Please note in a future release, the “Eligibility Criteria” tab will be renamed to “Eligibility” tab*

The “Eligibility” page allows the AB user to answer questions, and attach supporting files, for the following 9 standards:

- **Legal Authority**
- **Responsibility**
- **Capacity**
- **Competency**
- **Monitoring**
- **Conflict of Interest**
- **Quality Assurance**

- **Records**
- **Accreditation Program**

The user clicks a question's number e.g. Q1 in the "*Legal Authority*" standard and provides an answer in the textbox on the right. To upload an attachment, user clicks "Attachments" button and the system will display a pop-up window (Figure 2.1.4).

U.S. Department of Health and Human Services

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

Welcome, Beverly Watson
[FURLS Home](#) | [AB Home](#)

All fields are mandatory unless noted as optional.

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

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

Eligibility Criteria

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

▼ Legal Authority

Q1

Q2

Q3

Q4

Q5

◀ ▶

► Responsibility

► Capacity

► Competency

► Monitoring

► Conflict of Interest

► Quality Assurance

► Records

► Accreditation Program

▼ Legal Authority >> Q1

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

Enter your response here.

4000 characters remaining.

▼ Attachments

[Attachments](#)

File Name	Date of Upload
No records found.	

[◀ Previous](#)
[Save](#) [Next ▶](#)

Figure 2.1.4 - Eligibility Criteria - Q&A - Please note in a future release, the "Eligibility Criteria" tab will be renamed to "Eligibility" tab

The user clicks Browse button in the “Attachments” window to select a file. The “Upload” button will become enabled after a file has been chosen to attach. The user will click on the “Upload” button to complete the attachment (Figure 2.1.5).

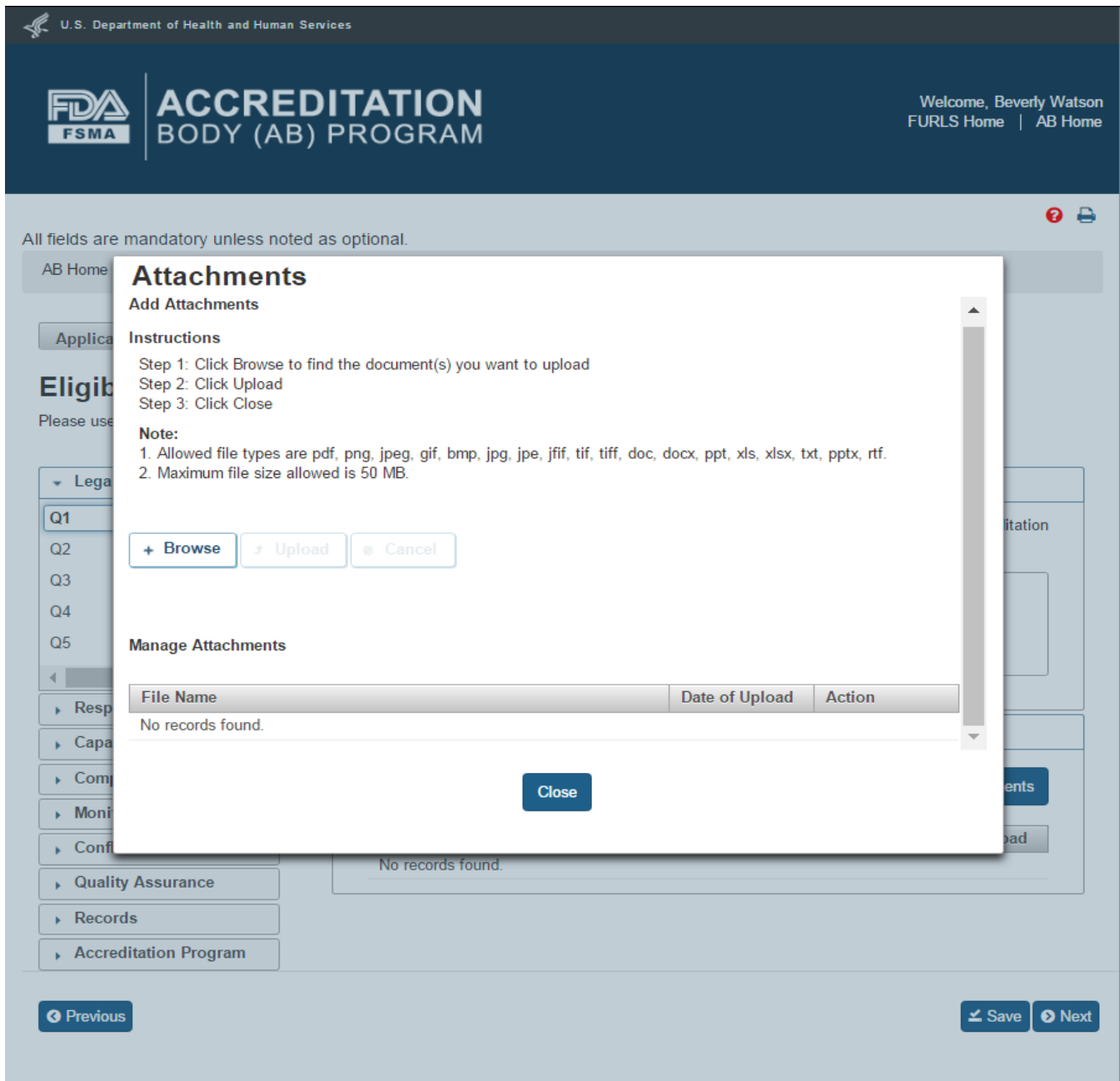


Figure 2.1.5 - Attachments window

The system will confirm when the file is uploaded. A confirmation message with the file name will be displayed in the “Attachments” window (Figure 2.1.6).

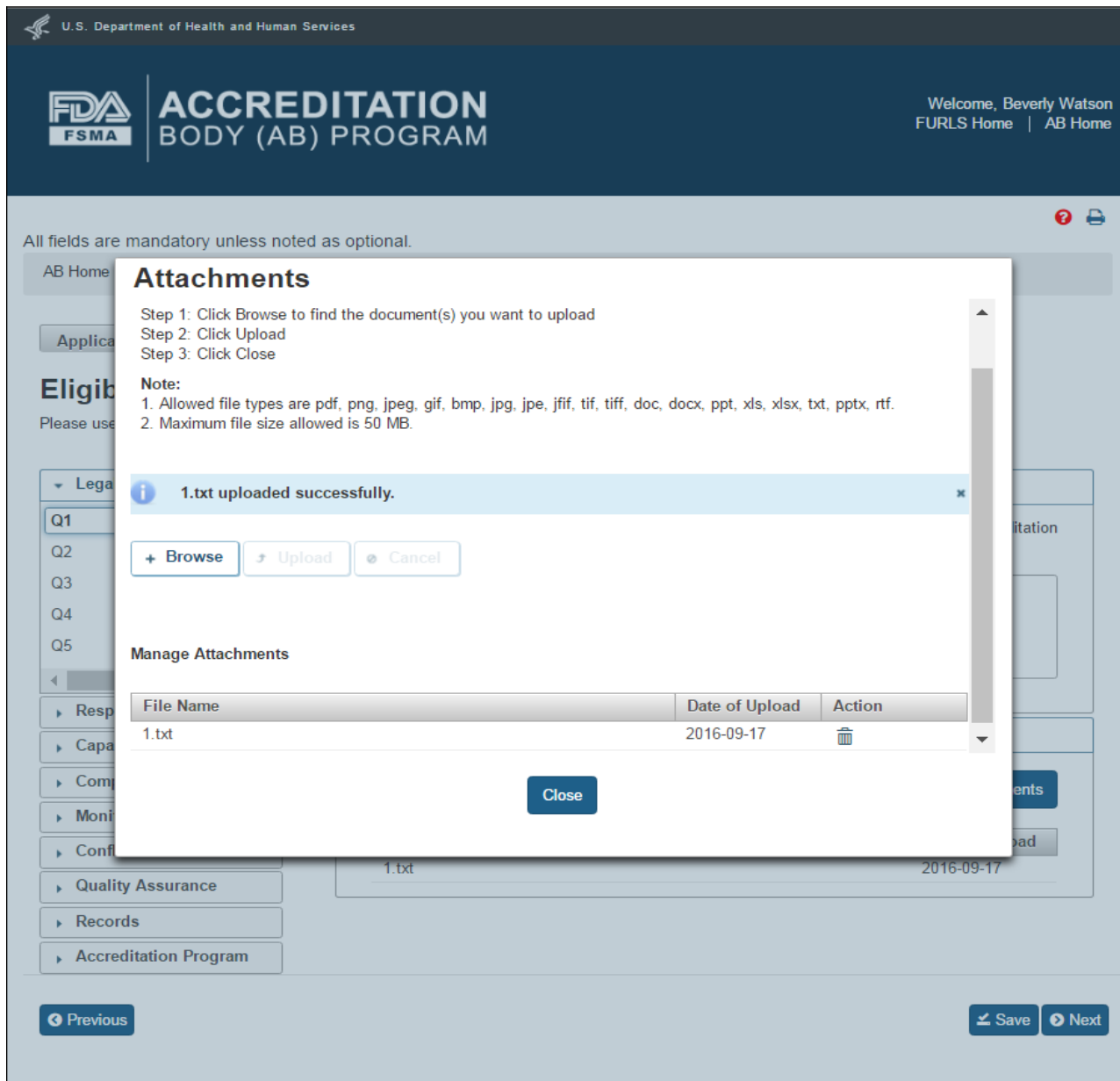


Figure 2.1.6 – Attachments to Eligibility Criteria questions

The user can close the “*Attachments*” window and then click “Save” and “Next” button on the “*Eligibility Criteria*” page. The user can also click on the “*Attachments*” tab. This will bring up the optional “*Attachments*” page. This page allows the user to upload additional files. The user can follow the 4-step instructions provided on the page (Figure 2.1.7). If the user selects ‘Other’ value from the dropdown options, the system will provide a text box labeled “Additional Description”, in which the user must enter a short meaningful description.



All fields are mandatory unless noted as optional.

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

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

Attachments (Optional)

Add Attachment(s)

Instructions

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

Note:

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

Type of Attachment

Please Select One

File Name	Type	Date of Upload	Action
No records found.			

Figure 2.1.7 - Optional Attachments page

After the additional files have been uploaded, the user can click on the “Save” and “Next” button or the user can click on “Summary” tab. The system will display the “Summary” page (Figure 2.1.8). This page allows the user to review the data entries for completeness.

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Beverly Watson
[FURLS Home](#) | [AB Home](#)

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

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

Summary

Review the following information for correctness and edit as needed.

Applicant Information

Firm Name Medoo Express	Contact Name Beverly X Watson
Address The Canberra Centre, City Walk Shop DF44 Bunda St Canberra Queensland 2600 AUSTRALIA	Contact Number Phone Number 81 (743) 123456 Ext. 11 Fax Number 81 (743) 123457
Web Address -	Email Address Oleg.Klyziman@fda.hhs.gov
	Unique Facility Identifier 887884321

Revocation

Not Applicable [Edit](#)

Scope

[Edit](#)

Scope

- 101: Food Labeling
- 108: Emergency Permit Control
- 111: Current GMP practice in manufacturing, packaging, labeling or holding operations for dietary supplements
- 164: Tree nut and peanut products
- 889: Substances prohibited from use in animal food or feed

Eligibility Criteria

[Edit](#)

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

Attachments (Optional)

[Edit](#)

File Name	Type	Date of Upload
No records found.		

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

Figure 2.1.8 – Summary page

The user can click on “Save” and “Next” button after reviewing the “Summary” page. The system validates all the information entered by the user into AB application. If a violation is found, the system will post a relevant error message. To be able to submit the application, the user has to correct any issues that were found. If there are no violations, the system brings up the “e-Signature” page (Figure 2.1.9).

U.S. Department of Health and Human Services

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

Welcome, Oliver Corkscrew Jr.
FURLS Home | AB Home

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

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

e-Signature

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

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

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-18

Previous Submit

Figures 2.1.9 – e-Signature page - *Please note in a future release, language will be changed to say “may constitute sufficient grounds” instead of “will constitute sufficient grounds.”*

The user can follow the directions provided on the “*e-Signature*” page and fill the following data fields and then click the ‘Submit’ button:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

The system will post a “*Confirmation*” message on the page (Figure 2.1.10).

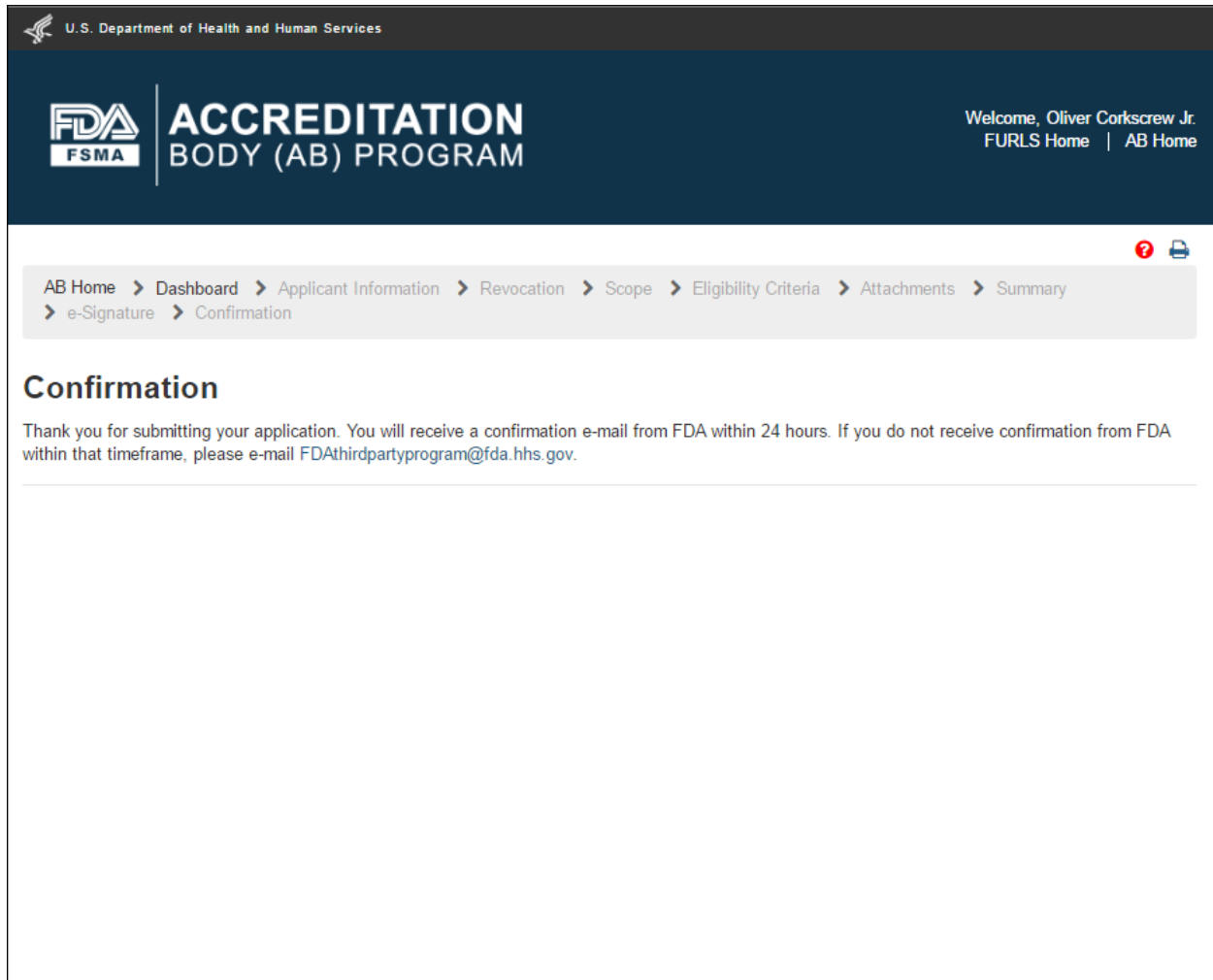


Figure 2.1.10 - Confirmation message

After the application has been submitted, it gets an Application Number and has “Pending” status on the Dashboard (Figure 2.1.11).

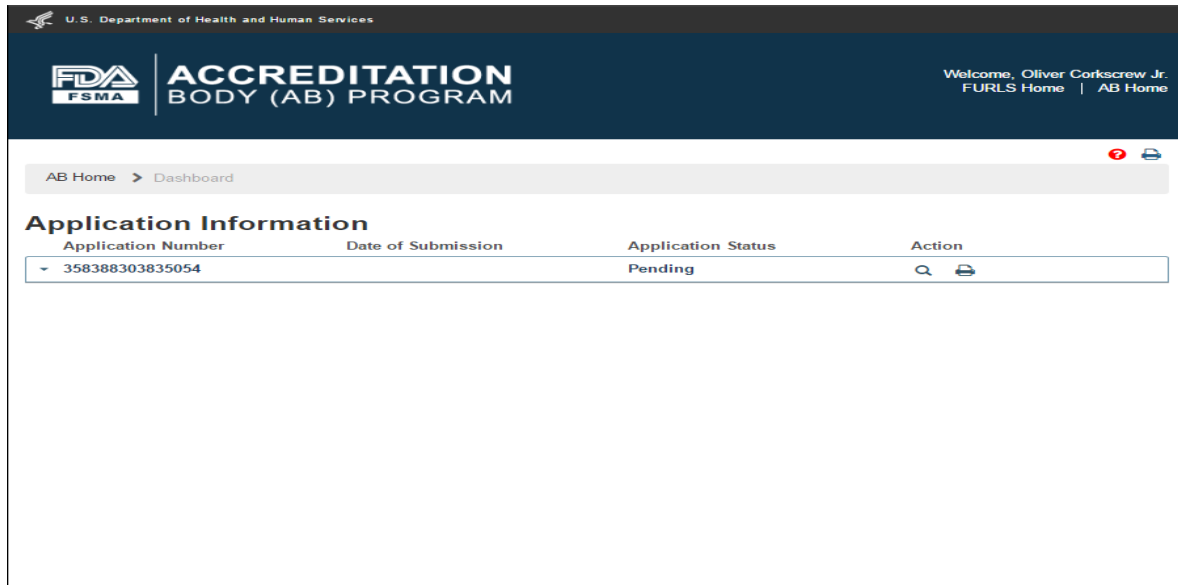



Figure 2.1.11 - Application ‘Pending’ status

As soon as CMS (FDA) receives the application, the status on the dashboard changes to “Submitted” (Figure 2.1.12).

U.S. Department of Health and Human Services

 **ACCREDITATION**
BODY (AB) PROGRAM

Welcome, Olivia Brown
[FURLS Home](#) | [AB Home](#)

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

Application Information



Application Number	Date of Submission	Application Status	Action
389701105518973	2015-09-03	Submitted	 

Figure 2.1.12 - Application 'Submitted' status

3. Returned for Action

FDA reviews the submitted AB application to consider for recognition. FDA may return the application to the applicant with some questions that need to be answered, for FDA to continue with the review process. The AB application is placed in “In-Process” status on the Dashboard (Figure 3.1).

The screenshot shows the FDA Accreditation Body (AB) Program Dashboard. At the top, it displays the U.S. Department of Health and Human Services logo and the FDA FSMA Accreditation Body (AB) Program logo. A welcome message for Bernard Murdock is visible in the top right corner. Below the header, there is a breadcrumb trail: AB Home > Dashboard. The main content area is titled "Application Information" and contains a table with the following data:

Application Number	Date of Submission	Application Status	Action
335256182296803	2016-03-08	In-Process	
Eligibility criteria		Submission status	
Legal Authority		Under Review	
Responsibility		Under Review	
Capacity		Under Review	
Competency		Returned For Action	
Monitoring		Under Review	
Conflict of Interest		Under Review	
Quality Assurance		Under Review	
Records		Under Review	
Accreditation Program		Returned For Action	

Figure 3.1 – Application ‘In-Process’ status

To address the questions from FDA, AB user clicks “Edit” (“Pencil”) icon in the ‘Action’ column. The system will open the “Eligibility Criteria” page (Figure 3.2). This page allows AB user to go directly to the flagged standard(s) in ‘red’ which require answers and/or attachments to be provided.

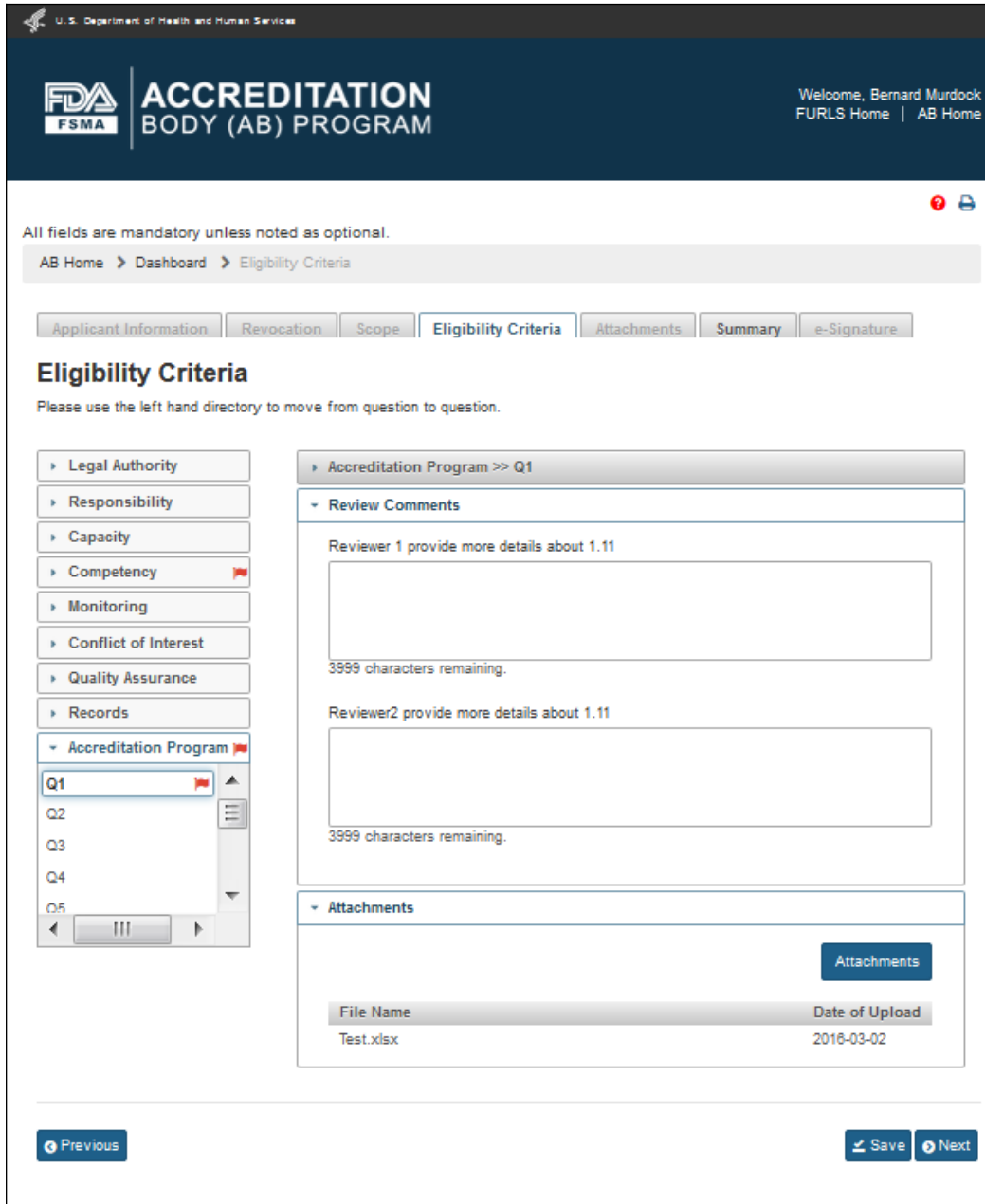


Figure 3.2 – Eligibility Criteria Page with red flags

After all the questions have been answered, the questions and their standards are flagged by a green checkmark (Figure 3.3)

U.S. Department of Health and Human Services

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

Welcome, Bernard Murdock
FURLS Home | AB Home

All fields are mandatory unless noted as optional.

AB Home > Dashboard > Eligibility Criteria

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

Eligibility Criteria

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

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

Competency >> Q1

Review Comments

Reviewer 1 provide more details about 1.11

AB user provides more details about question 1.11.

3950 characters remaining.

Reviewer2 provide more details about 1.11

AB user provides more details about question 1.11, and attaches a file.

3929 characters remaining.

Attachments

File Name	Date of Upload
1.txt	2018-09-28

Previous Save Next

Figure 3.3 - Eligibility Criteria Page with green flags

Once all the questions have been answered, the user can go to the “Summary” page (Figure 3.4), by clicking ‘Save’ and ‘Next’ buttons or clicking the ‘Summary’ tab.

FSMA | BODY (AB) PROGRAM

AB Home > Dashboard > Eligibility Criteria > Summary

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

Summary

Review the following information for correctness and edit as needed.

Applicant Information

Firm Name Murdock Incorporated	Contact Name Bernard W Murdock
Address 2249 Carling Ave Suite 403 Ottawa Ontario K2B CANADA	Contact Number Telephone Number 1 (613) 8205626 Ext. 581 Fax Number 1 (613) 8205625
Web Address ..	Email Address Oleg.Keyzman@fda.hhs.gov
	Unique Facility Identifier 123456789

Revocation

Not Applicable

Scope

1 2

Scope

- 101: Food Labeling
- 102: Common or usual name for nonstandardized foods
- 104: Nutritional quality guidelines for foods
- 105: Foods for special Dietary Use
- 108: Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications

1 2

Eligibility Criteria

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

Standards	Select to submit
Competency	<input checked="" type="checkbox"/>
Accreditation Program	<input checked="" type="checkbox"/>

Attachments (Optional)

File Name	Type	Date of Upload
No records found.		

Previous Save Next

Figure 3.4 – Summary Page

The user can verify the application information and re-submit the application. The user then clicks the 'Save' and 'Next' buttons. The system validates all the information and if no violations are found, the "e-Signature" page is displayed (Figure 3.5). If a violation is found, the system will post a relevant error message. To be able to submit the application, the user has to correct any issues that were found.

U.S. Department of Health and Human Services

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

Welcome, Bernard Murdock
FURLS Home | AB Home

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

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

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions will constitute sufficient grounds for rejection or subsequent revocation of my participation in the program. Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-28

Previous Submit

Figure 3.5 - e-Signature Page - *Please note in a future release, language will be changed to say "may constitute sufficient grounds" instead of "will constitute sufficient grounds."*

The user can follow the directions provided on the "e-Signature" page and fill the following data fields and then click the 'Submit' button:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

The system will post a "Confirmation" message on the page (Figure 3.6).

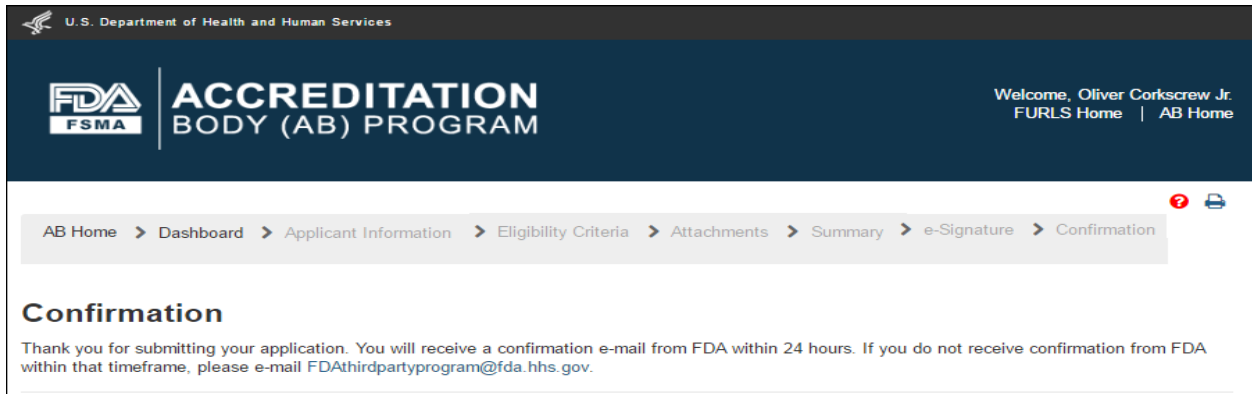


Figure 3.6 - Confirmation message

After the application has been submitted, the Dashboard application status displays “Pending” (Figure 3.7).

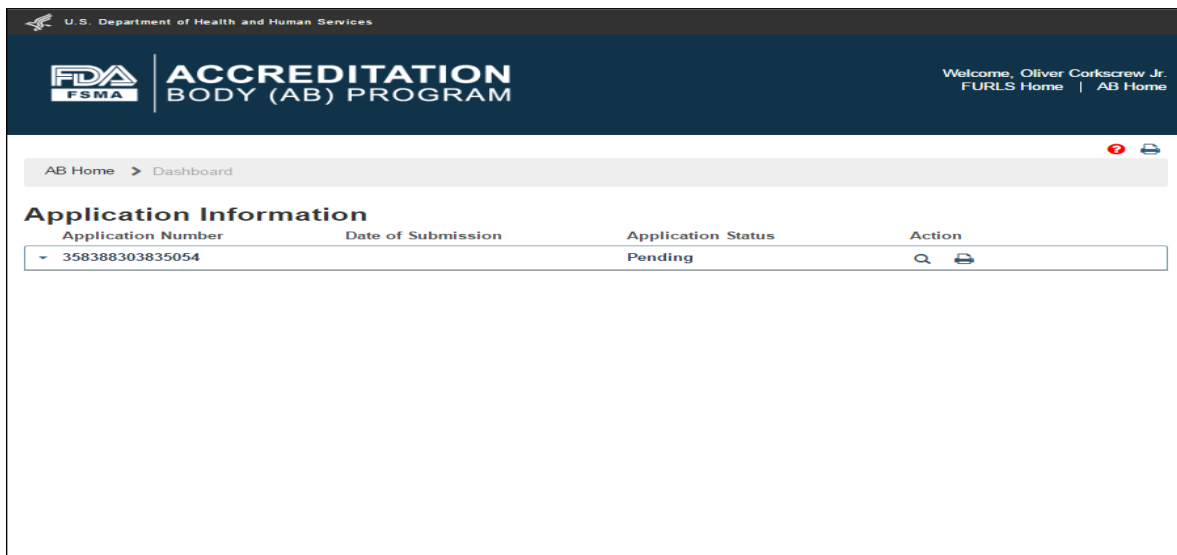



Figure 3.7 - Application ‘Pending’ Status

As soon as CMS (FDA) receives the application, the status on the dashboard changes to “Submitted” (Figure 3.8).

U.S. Department of Health and Human Services

 **ACCREDITATION**
BODY (AB) PROGRAM

Welcome, Olivia Brown
[FURLS Home](#) | [AB Home](#)

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

Application Information



Application Number	Date of Submission	Application Status	Action
389701105518973	2015-09-03	Submitted	 

Figure 3.8- Application 'Submitted' Status

4. Reconsideration Request

An AB user can apply for reconsideration on the AB Home page by selecting 'Reconsideration Request' option on the left navigation menu (Figure 4.1). The system will open the "Reconsideration" page (Figure 4.2).

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Greg Cadwell
FURLS Home

AB Home

AB Home

View/Edit my application for recognition

Apply for Reconsideration

View my profile

Contact Us

Welcome

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

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

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

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

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

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

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

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

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

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

Figure 4.1 - AB Homepage with 'Reconsideration Request' menu option - *Please note in a future release, language will be changed to say "Reconsideration Request" instead of "Apply for Reconsideration."*

The AB user is provided with two options 'Yes' or 'No', on the "Reconsideration" page. The user can select one of the two options to prefill the application information (Figure 4.2).

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Greg Cadwell
FURLS Home | AB Home

All fields are mandatory unless noted as optional.

AB Home > Reconsideration

Would you like the system to prefill the application for reconsideration with the information you submitted for your initial application for recognition?

Yes No

Previous Next

Figure 4.2 – Reconsideration page

The user can then click the 'Next' button to go to the next page "Applicant Information" (Figure 4.3). The information on this page is 'Read only'. The user can review the information and go to the next page.

The screenshot shows the 'Applicant Information' page of the FDA FSMA Accreditation Body (AB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'ACCREDITATION BODY (AB) PROGRAM'. A welcome message for Greg Cadwell is displayed in the top right corner, along with links for 'FURLS Home' and 'AB Home'. Below the header, a navigation breadcrumb shows 'AB Home > Dashboard > Applicant Information'. A row of tabs includes 'Applicant Information', 'Revocation', 'Scope', 'Eligibility Criteria', 'Attachments', 'Summary', and 'e-Signature'. The main heading is 'Applicant Information', followed by a note that the page contains information from the user's Account ID and instructions on how to update the account. The page displays the following information:

Firm Name Test Again	Contact Name Greg Cadwell
Address 23 Customs Street East PO Box 3429 Auckland Otago 1140 NEW ZEALAND	Contact Number Telephone Number 64 (9) 3071904 Ext. 001 Fax Number --
Web Address http://www.triplei.com	Email Address oleg.oleg.keyzman@fda.hhs.gov
	Unique Facility Identifier 123456780

At the bottom of the page, there are two buttons: 'Previous' and 'Next'. The 'Next' button is highlighted, indicating the user's current position in the application process.

4.3 - Applicant Information page

The AB user can click the 'Next' button to go to the next "Revocation" page (Figure 4.4).

The screenshot shows the user interface for the Accreditation Body (AB) Program. At the top, the U.S. Department of Health and Human Services logo is on the left, and the FDA FSMA logo is next to the text "ACCREDITATION BODY (AB) PROGRAM". On the right, a user is logged in as "Welcome, Greg Cadwell" with links for "FURLS Home" and "AB Home". Below the header, a message states "All fields are mandatory unless noted as optional." followed by a breadcrumb trail: "AB Home > Dashboard > Applicant Information > Revocation". A horizontal menu contains buttons for "Applicant Information", "Revocation", "Scope", "Eligibility Criteria", "Attachments", "Summary", and "e-Signature". The "Revocation" section displays the text "Not Applicable" in a grey box. At the bottom, there are three buttons: "Previous" on the left, and "Save" and "Next" on the right.

4.4 - Revocation page

The user can directly go the “Scope” page by clicking the ‘Scope’ tab. The user can also click the ‘Next’ button on the “Revocation” page to get to the “Scope” page (Figure 4.5). This page provides the user with the list of original scopes (left box). The user can select the scopes from this list and move them between the two boxes using the 4 buttons.

Note: Even though the user selected ‘Yes’ option on the “Reconsideration” page (Figure 4.2), the system will not prefill the scopes from the initial application because that selection was different from the one for reconsideration.

U.S. Department of Health and Human Services

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

Welcome, Greg Cadwell
FURLS Home | AB Home

All fields are mandatory unless noted as optional.

AB Home > Dashboard > Applicant Information > Revocation > Scope

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

Scope

List of Original Source Scopes

Enter a keyword to search for scope

- 101: Food Labeling
- 119: Dietary supplements that present a significant or unreasonable
- 120: HACCP
- 161: Fish and shellfish
- 165: Beverages
- 168: Sweeteners and table syrups
- 589: Substances prohibited from use in animal food or feed

List of Selected Scopes

Enter a keyword to search for scope

→

⇒

←

⇐

Previous Save Next

4.5 – Scope page - *Please note, in a future release the scope list will be updated to reflect changes made by the OCC.*

The user can click 'Next' button and go to the "Eligibility Criteria" page (Figure 4.6). This page will be filled out with the information from the initial application. AB user can update the page, as needed.

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Greg Cadwell
FURLS Home | AB Home

All fields are mandatory unless noted as optional.

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

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

Eligibility Criteria

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

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

Legal Authority >> Q1

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

Answer - Q1 Legal Authority

3973 characters remaining.

Attachments

File Name	Date of Upload
No records found.	

Attachments

Previous Save Next

4.6 - Eligibility Criteria page

The AB user can click 'Next' to go to the "Attachments" page (Figure 4.7). The AB user can upload files in the "Attachments" by following the 4-step process outlined on the page. The system displays uploaded files in the table at the bottom of the page.

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Greg Cadwell
[FURLS Home](#) | [AB Home](#)

All fields are mandatory unless noted as optional.

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

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

Attachments (Optional)

Add Attachment(s)

Instructions

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

Note:

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

Type of Attachment

Please Select One

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

File Name	Type	Date of Upload	Action
Supplemental Docs.PNG	Other-Additional Description	2016-09-29	

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

4.7 - Attachments page

The “*Attachments*” page is optional so the user may choose to click ‘Save’ button on the “*Eligibility Criteria*” page (Figure 4.6), and then select ‘Summary’ tab, which will open the “*Summary*” page (Figure 4.8). The user can review the application information and make any edits, if needed.

U.S. Department of Health and Human Services

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

Welcome, Greg Cadwell
FURLS Home | AB Home

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

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

Summary

Review the following information for correctness and edit as needed.

Applicant Information

Firm Name Test Again	Contact Name Greg Cadwell
Address 23 Customs Street East PO Box 3429 Auckland Otago 1140 NEW ZEALAND	Contact Number Telephone Number 64 (9) 3071904 Ext. 001 Fax Number --
Web Address http://www.triplei.com	Email Address oleg.oleg.keyzman@fda.hhs.gov
	Unique Facility Identifier 123456780

Revocation Edit
Not Applicable

Scope Edit
Scope
Not yet answered

Eligibility Criteria Edit

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

Attachments (Optional) Edit

File Name	Type	Date of Upload
Supplemental Docs.PNG	Other-Additional Description	2016-09-29

Previous Save Next

4.8 - Summary page

The user clicks 'Next' button and the system validates all the information provided by the user. If no violations are found, the system opens the "e-Signature" page (Figure 4.9). If a violation is

found, the system will post a relevant error message. To be able to submit the application, the user has to correct any issues that were found.

U.S. Department of Health and Human Services

FDA FSMA | ACCREDITATION BODY (AB) PROGRAM

Welcome, Greg Cadwell
FURLS Home | AB Home

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

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

e-Signature

Please read the following statement carefully, then acknowledge that you read and approved it by providing the information requested at the bottom of the page. Please note that an e-Signature is the equivalent of a handwritten signature. By submitting this information to FDA, or by authorizing an individual to submit this information to FDA, the submitter certifies that the information in the submission is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. I also understand that misrepresentations or omissions will constitute sufficient grounds for rejection or subsequent revocation of my participation in the program. Please be aware that you will not be able to change your application after you click Submit.

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-29

Previous Submit

4.9 - e-Signature page - Please note in a future release, language will be changed to say "may constitute sufficient grounds" instead of "will constitute sufficient grounds."

The user can follow the directions provided on the "e-Signature" page and fill the following data fields and then click the 'Submit' button:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

The system will post a "Confirmation" message on the page (Figure 4.10).

U.S. Department of Health and Human Services

FDA FSMA | ACCREDITATION BODY (AB) PROGRAM

Welcome, Oliver Corkscrew Jr.
FURLS Home | AB Home

AB Home > Dashboard > Applicant Information > Eligibility Criteria > Attachments > Summary > e-Signature > Confirmation

Confirmation

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

Figure 4.10 - Confirmation message

After the application has been submitted, the Dashboard application status displays “Pending” (Figure 4.11).

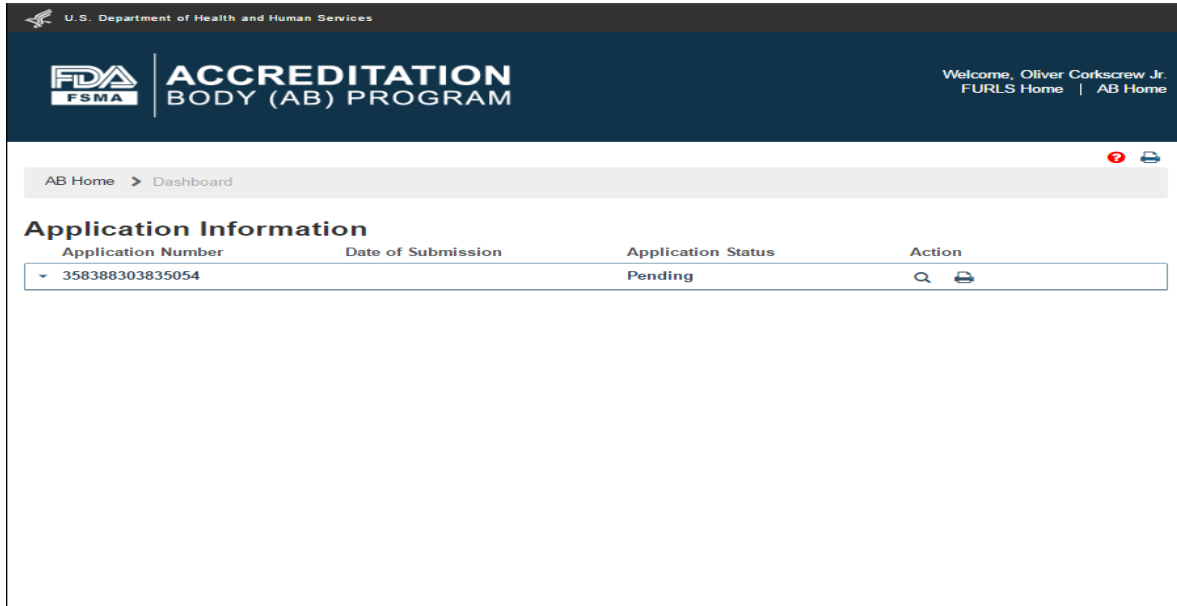


Figure 4.11 – Application ‘Pending’ Status

As soon as CMS (FDA) receives the application, the status on the dashboard changes to “Submitted” (Figure 4.12).

U.S. Department of Health and Human Services

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

Welcome, Olivia Brown
[FURLS Home](#) | [AB Home](#)

AB Home > Dashboard

Application Information

Application Number	Date of Submission	Application Status	Action
389701105518973	2015-09-03	Submitted	Q Print

Figure 4.12- Application 'Submitted' Status

5. Add or Manage Third Party CBs

The AB user can select 'Add or manage my Third party CBs' option from the left navigation menu on the AB homepage (Figure 5.1).

FDA FSMA ACCREDITATION BODY (AB) PROGRAM Welcome, Noah Wallaby FURLS Home

AB Home

AB Home

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

Welcome

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

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

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

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

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

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

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

The time required to complete this collection of information is estimated to average 80 hours per response for a one-time reporting burden and 2.0 - 8.0 hours per response thereafter, including the time to review instructions, search existing data resources, gather and maintain the data needed, and complete and review the information collection. This form is a vehicle to collect this information. Send comments about this burden estimate or any other aspect of this collection of information, including suggestions for reducing the paper burden to:

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

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

Figure 5.1 – AB Homepage with 'Add or manage my Third party CBs' menu option

5.1. Add CB

The system will display the “Add or manage Third party CBs” page (Figure 5.1.1). The AB user can click ‘Add CB’ button to add a new CB.

The screenshot displays the 'Add or Manage Third Party CBs' page. At the top, there is a header for the U.S. Department of Health and Human Services, FDA FSMA, and the Accreditation Body (AB) Program. A user greeting 'Welcome, Noah Wallaby' and links for 'FURLS Home' and 'AB Home' are visible. Below the header, a breadcrumb trail shows 'AB Home > Add or Manage Third Party CBs'. The main content area features a table with the following data:

Name ↕	Status ↕	Scope	Agent	Action
Company Name_1	Accredited	(3)	(4)	Q ✎
Du Chateau	Withdrawn	(3)	(4)	Q ✎
Papa Carlo & Sons	Accredited	(3)	(1)	Q ✎
The Oz	Accredited	(6)	(2)	Q ✎
Third Party Inc.	Accredited	(6)	(3)	Q ✎

At the bottom left, there is a 'Previous' button with a left arrow icon. At the bottom right, there is an 'Add CB' button with a plus icon.

Figure 5.1.1 - Add or manage Third party CBs page

The system will display the “*Add Accredited Third Party CB*” page (Figure 5.1.2). The AB user can enter the email address of the new CB and click “Search” button.



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

Add Accredited Third Party CB

E-mail Address:

Third Party Certification Body Name:

Contact Name:

First Name

MI (Optional)

Last Name

Country:

Phone Number:

Country

Area

Phone Number

Extension

Address 1:

Fax Number (Optional):

Country

Area

Fax Number

Address 2 (Optional):

Status:

Accredited

City:

Web Address (Optional):

State/Province/Territory:

Officer(s):

Zip Code (Postal Code):

Will the CB use Audit Agents to conduct food safety audits?

Yes No

Figure 5.1.2 - Add Accredited Third Party CB

If the system finds the email address in the database, it populates the relevant fields with the CB information (Figure 5.1.3). If the address does not exist, the user can fill the fields manually.

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
FURLS Home | AB Home

i The system has the information below for the CB whose email you entered. If you disagree with the information please contact the CB. The CB may have to update his/her account profile. **x**

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

Add Accredited Third Party CB

E-mail Address:
test@test.com **Q Search CB**

Third Party Certification Body Name:
Test

Country:
TAIWAN

Address 1:
1 Kwang-Fu Rd

Address 2 (Optional):

City:
Huko Hsin Chu

State/Province/Territory:
Changhua

Zip Code (Postal Code):
TW-HSZ 303

Contact Name:
FN MI (Optional) LN
First Name MI (Optional) Last Name

Phone Number:
886 123 1321322132
Country Area Phone Number Extension

Fax Number (Optional):
Country Area Fax Number

Status:
Accredited

Web Address (Optional):

Officer(s):
TW-HSZ 303

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

+ Add Scope

Previous **Save** **Cancel**

Figure 5.1.3 – Add Accredited Third Party CB with CB information

The data fields in the “Add Accredited Third Party CB” page that AB user can complete are:

- **Third Party Certification Body Name** - the name of the certification body that the accreditation body would like to add
- **Country** - the country of residence of the certification body
- **Address 1** - the street address of the certification body
- **Address 2** - (Optional field)
- **City** - the city of residence of the certification body
- **State/ Province/ Territory** - the State/ Province/ Territory of the certification body
- **Zip Code (Postal Code)** - the postal code of the certification body
- **Contact Name** -
 - o **First Name** - the first name of the point of contact
 - o **MI** - (Optional field)
 - o **Last Name** - the last name of the point of contact
- **Phone Number**
 - o **Country** - the country code of the point of contact
 - o **Area** - the area code of the point of contact
 - o **Phone Number** - the phone number of the point of contact
 - o **Extension** - the extension number of the point of contact
- **Fax Number** -(Optional field)
 - o **Country** - (Optional field)
 - o **Area** - (Optional field)
 - o **Fax Number** - (Optional field)
- **Web Address** - (Optional field)
- **Officer(s)** - the officer(s) of the certification body
- **Agent(s)** - the agent(s) of the certification body

After the CB information has been populated by the system, or entered manually, the AB user can click 'Add Scope' button. The system will display "Add Scope" window (Figure 5.1.4). AB user can select a scope from the list. The system enables the 'Accreditation Date' and 'Expiration Date' fields. The user enters the dates and clicks 'Save' button. The system closes the "Add Scope" window and returns to the main page.

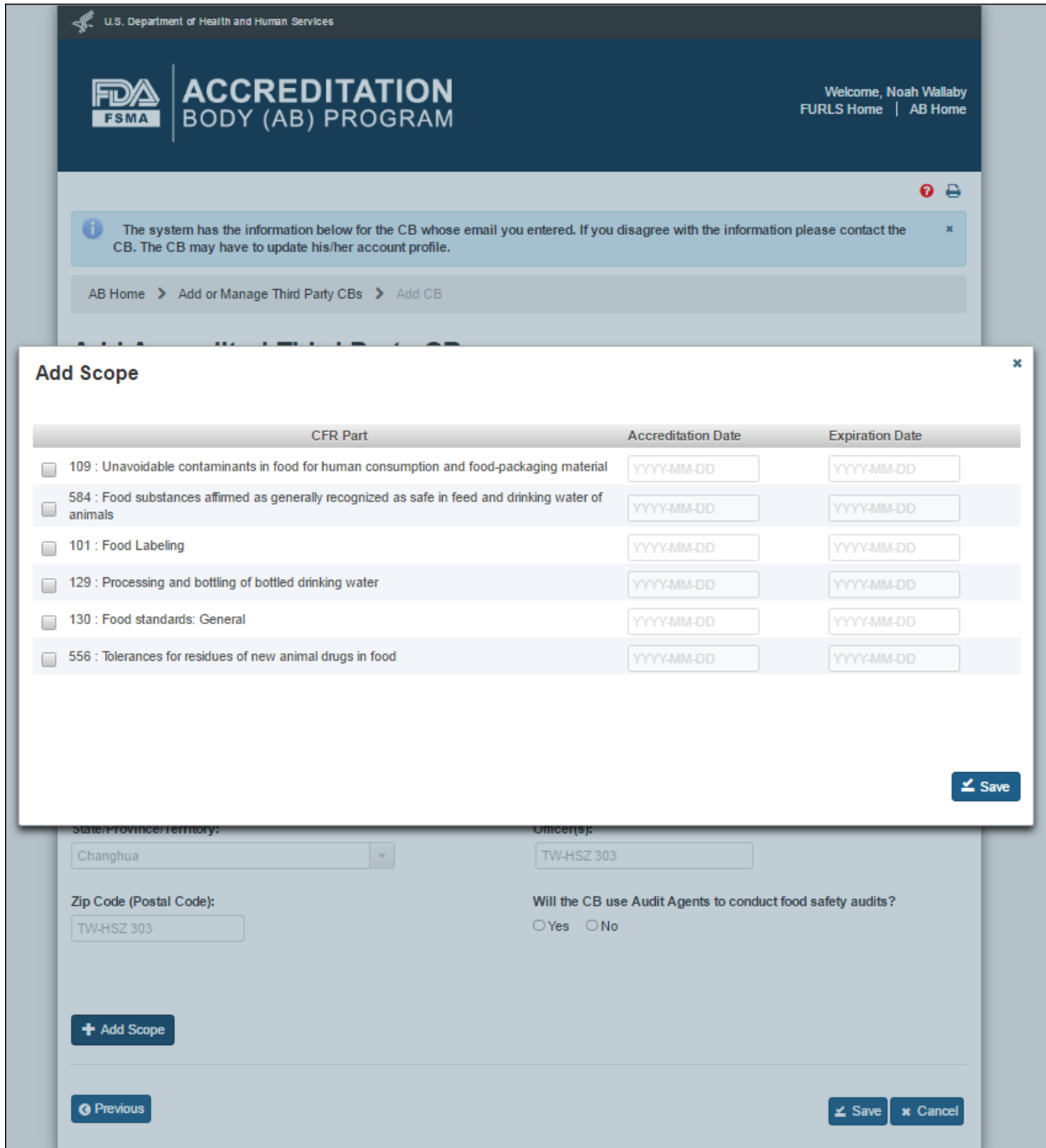


Figure 5.1.4 – Add Scope window

The newly added scopes are displayed in the “Scopes of Accredited Third Party Certification Body” table (Figure 5.1.5).

The user can also select one of the options for the question “Will the CB use Audit Agents to conduct food safety audits?” If AB user selects ‘No’, the system displays the “Agent(s)” field and pre-populates it with the CB’s name. If the user selects ‘Yes’ option, the system provides the following additional text fields to enter the relevant information manually (Figure 5.1.6).

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

Add Accredited Third Party CB

E-mail Address:

Third Party Certification Body Name:

Country:

Address 1:

Address 2 (Optional):

City:

State/Province/Territory:

Zip Code (Postal Code):

Agent(s):

Contact Name: FN MI (Optional) LN

Phone Number: Country Area Phone Number Extension

Fax Number (Optional): Country Area Fax Number

Status: Accredited

Web Address (Optional):

Officer(s):

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

CFR Part	Accreditation Date	Expiration Date
556 : Tolerances for residues of new animal drugs in food	2015-12-31	2019-12-31

Figure 5.1.6 – Scope table and Add Audit Agent

The AB user can click 'Save' button after entering all mandatory information. The system displays a confirmation message (Figure 5.1.7). The user can 'OK' on the Confirmation message and the system will add the newly added CB to a table on the "Add or Manage Third Party CBs" page (Figure 5.1.8).

Figure 5.1.7 - Confirmation message

Name	Status	Scope	Agent	Action
Company Name_1	Accredited	(3)	(4)	Q ✎
Du Chateau	Withdrawn	(3)	(4)	Q ✎
Papa Carlo & Sons	Suspended	(3)	(1)	Q ✎
Test	Accredited	(1)	(2)	Q ✎
The Oz	Accredited	(6)	(2)	Q ✎
Third Party Inc.	Accredited	(6)	(3)	Q ✎

Figure 5.1.8 - Add or Manage Third Party CBs page

5.2. Update Accredited Third Party CB

The AB user can update an accredited third party CB by clicking Edit ('Pencil') icon in the 'Action' column on the "Add or Manage Third Party CBs" page (Figure 5.2.1).

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
FURLS Home | AB Home

AB Home > Add or Manage Third Party CBs

Add or Manage Third Party CBs

Name	Status	Scope	Agent	Action
Company Name_1	Accredited	(3)	(4)	Q ✎
Du Chateau	Withdrawn	(3)	(4)	Q ✎
Papa Carlo & Sons	Accredited	(3)	(1)	Q ✎
The Oz	Accredited	(6)	(2)	Q ✎
Third Party Inc.	Accredited	(6)	(3)	Q ✎

Previous Add CB

Figure 5.2.1 - Add or Manage Third Party CBs page

The system displays the “Update Accredited Third Party CB” page (Figure 5.2.2). The AB user can view information about the scopes, agents and officers. The AB user can update the CB(s) status. The AB user can also add or update the scopes.

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Noah Wallaby
[FURLS Home](#) | [AB Home](#)

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

Update Accredited Third Party CB

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

Third Party Certification Body Name Papa Carlo & Sons	Contact Name Pinoccio Longnose
Address Via Galileo Galilei Carini Palermo 90044 ITALY	Contact Number Phone Number 39 (091) 8680786 Ext. 000 Fax Number 39 (091) 8680785
Web Address http://www.woodsrl.com	Email sarma.vemparala@fda.hhs.gov

Status
Accredited

Reason for Status Change
Test

Scope(s)	Accreditation Date	Expiration Date	Reason for Change
101 : Food Labeling	2015-01-01	2019-01-01	Reason for Change 1 Reaso... more
109 : Unavoidable contaminants in food for human consumption and food-packaging material	2015-11-19	2019-11-14	Test Flow from Withdrawn
130 : Food standards: General	2014-01-12	2018-01-12	Test Change to Suspended

▶ Agent(s) List

▶ Officer(s) List

[Previous](#) [Update Status](#) [Add/Update Scope](#)

Figure 5.2.2 - Update Accredited Third Party CB page

The AB user can update the CB(s) status by clicking the 'Update Status' button. The system displays an "Update Status" window (Figure 5.2.3).

If the CB's status is 'Accredited', the dropdown in the 'Status' field will have the following two values to choose from: 'Suspended' and 'Withdrawn'. The AB user completes the following data fields:

- **Status** - the dropdown options of 'Suspended'; 'Withdrawn'
- **Effective Date of Status Change** - the effective date of the status change
- **Reason for change** - the reason for status change

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
[FURLS Home](#) | [AB Home](#)

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

Update Accredited Third Party CB

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

Third Party Certification Body Name: _____ Contact Name: _____

Update Status

Status

Please Select One

Effective Date of Status Change

YYYY-MM-DD

Reason for Change

Enter your response here.

1000 characters remaining.

109 : Unavoidable contaminants in food for human consumption and food-packaging material	2015-11-19	2019-11-14	Test Flow from Withdrawn
130 : Food standards: General	2014-01-12	2018-01-12	Test Change to Suspended

Figure 5.2.3 - Update Status window

The AB user clicks the 'Save' button. The system closes the "Update Status" window and returns to the "Update Accredited Third Party CB" page. The updated CB status and the reason for change will be displayed (Figure 5.2.4).

U.S. Department of Health and Human Services

FDA FSMA ACCREDITATION BODY (AB) PROGRAM

Welcome, Noah Wallaby
[FURLS Home](#) | [AB Home](#)

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

Update Accredited Third Party CB

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

Third Party Certification Body Name Papa Carlo & Sons	Contact Name Pinoccio Longnose
Address Via Galileo Galilei Carini Palermo 90044 ITALY	Contact Number Phone Number 39 (091) 8680786 Ext. 000 Fax Number 39 (091) 8680785
Web Address http://www.woodsrl.com	Email sarma.vemparala@fda.hhs.gov

Status
Suspended

Reason for Status Change
Reason 1 for Change.

Scope(s)	Accreditation Date	Expiration Date	Reason for Change
101 : Food Labeling	2015-01-01	2019-01-01	Reason for Change 1 Reason for Change 2
109 : Unavoidable contaminants in food for human consumption and food-packaging material	2015-11-19	2019-11-14	Test Flow from Withdrawn
130 : Food standards: General	2014-01-12	2018-01-12	Test Change to Suspended

▶ Agent(s) List

▶ Officer(s) List

[Previous](#) [Update Status](#) [Add/Update Scope](#)

Figure 5.2.4 - Update Accredited Third Party CB page with updated CB status

The AB user can add and/or update the scopes by clicking the 'Add/Update Scope' button. The system displays the "Add/Update Scope" page (Figure 5.2.5).

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
FURLS Home | AB Home

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

Add/Update Scope

Scope(s)	Accreditation Date	Expiration Date	Status	Reason for Change
<input type="checkbox"/> 101 : Food Labeling	<input type="text" value="2015-01-01"/>	<input type="text" value="2019-01-01"/>	Accredited	Reason for Change 1 Reason... more
<input type="checkbox"/> 130 : Food standards: General	<input type="text" value="2014-01-12"/>	<input type="text" value="2018-01-12"/>	Accredited	Test Change to Suspended
<input type="checkbox"/> 584 : Food substances affirmed as generally recognized as safe in feed and drinking water of animals	<input type="text" value="YYYY-MM-DD"/>	<input type="text" value="YYYY-MM-DD"/>	Approved	
<input type="checkbox"/> 129 : Processing and bottling of bottled drinking water	<input type="text" value="YYYY-MM-DD"/>	<input type="text" value="YYYY-MM-DD"/>	Approved	
<input type="checkbox"/> 556 : Tolerances for residues of new animal drugs in food	<input type="text" value="YYYY-MM-DD"/>	<input type="text" value="YYYY-MM-DD"/>	Approved	
<input type="checkbox"/> 109 : Unavoidable contaminants in food for human consumption and food-packaging material	<input type="text" value="2015-11-19"/>	<input type="text" value="2019-11-14"/>	Accredited	Test Flow from Withdrawn

Figure 5.2.5 - Add/Update Scope page

The AB user can update the scopes by selecting a scope on the “Add/Update Scope” page that has accreditation and expiration dates (e.g., scope 130 in Figure 5.2.5). The system displays an ‘Add/Update Scope’ window (Figure 5.2.6). The AB user completes the following data fields:

- **Status** - the dropdown option of ‘Suspended’ or ‘Withdrawn’
- **Expiration date** - the expiration date of the added or updated scope

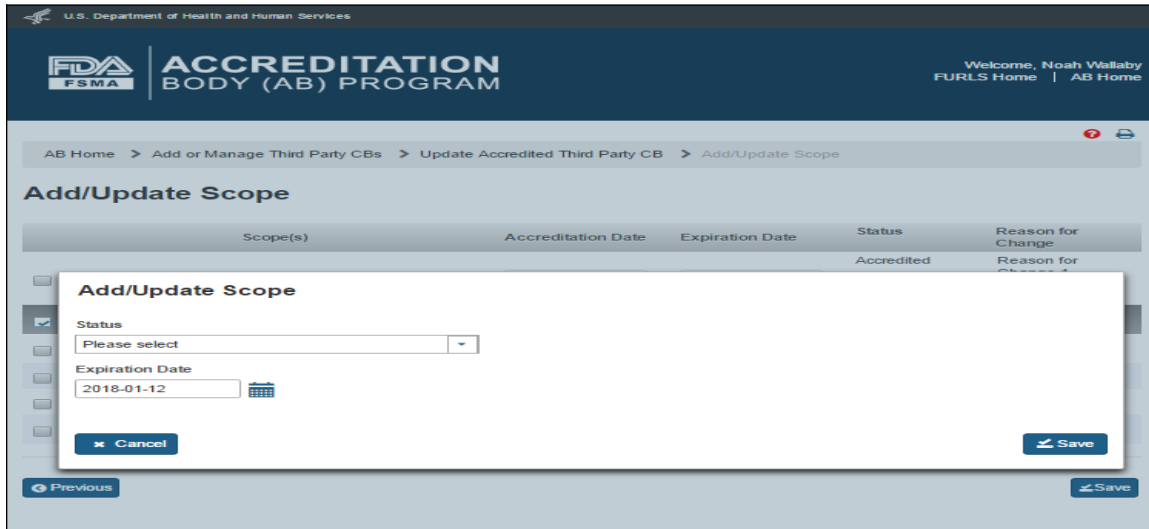


Figure 5.2.6 – Add/Update Scope window

When the AB user selects a ‘Status’ in the ‘Add/Update Scope’ window, the system refreshes to display the following data fields (Figure 5.2.6.1) that the AB user can complete:

- **Effective date** - the effective date of the added or updated scope
- **Reason for change** - the reason for the addition or updating of scope change

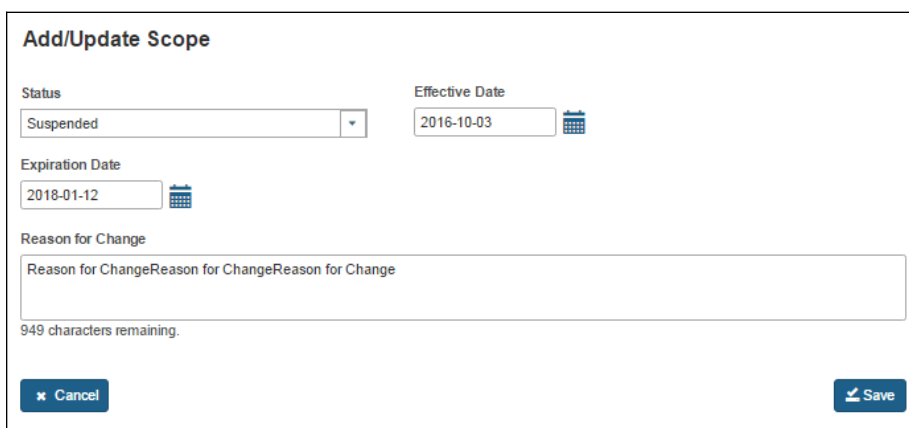


Figure 5.2.6.1 – Add/Update Scope window with Effective date and reason for change fields

The AB user clicks 'Save' button. The system closes the 'Add/Update Scope' window and returns to the main "Add/Update Scope" page (Figure 5.2.5).

The AB user can add a scope by selecting a scope on the "Add/Update Scope" page that does not have any accreditation and expiration dates (e.g., scope 584). The system displays an 'Add/Update Scope' window (Figure 5.2.7). The AB user can complete the following data fields:

- **Accreditation Date** - the date of the accreditation of the certification body
- **Expiration date** - the date of expiration for the accreditation of the certification body
- **Reason for change** - the reason for the addition or updating of scope change

The AB user clicks 'Save' button. The system closes the 'Add/Update Scope' window and returns to the main "Add/Update Scope" page.

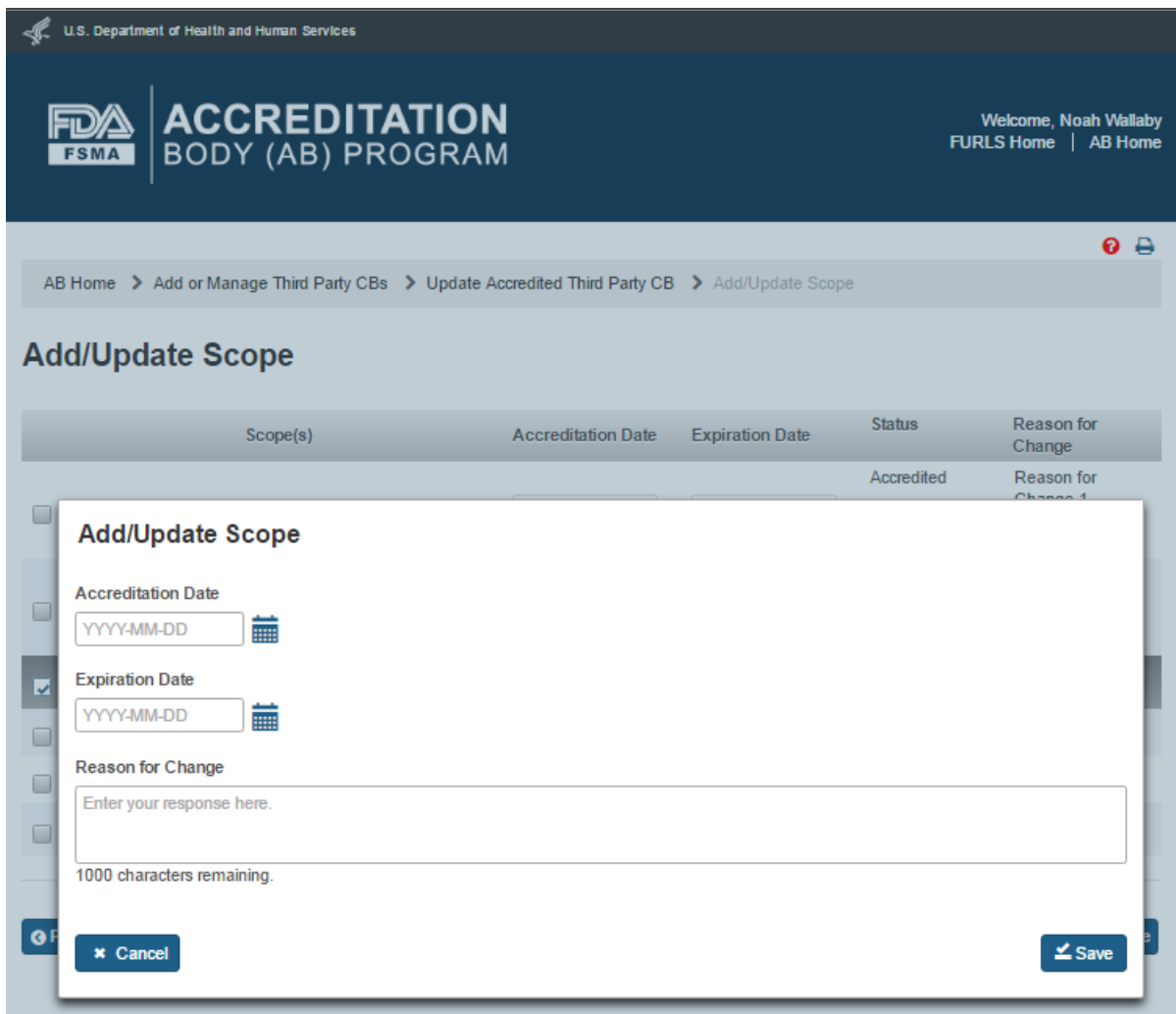


Figure 5.2.7 - Add/Update Scope window with Effective date and reason for change fields

6. Reports and Notifications

The AB user can select 'Reports and Notifications' option from the left navigation menu on the AB homepage (Figure 6.1).

FDA FSMA | **ACCREDITATION BODY (AB) PROGRAM** | Welcome, William Cadwell | FURLS Home

AB Home

AB Home

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

Welcome

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

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

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

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

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

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

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

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

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

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

Figure 6.1 – AB Homepage with 'Reports and Notifications' menu option

The system will display the “*Reports and Notifications*” page (Figure 6.2) with the list of Reports and Notices. Currently, there are six Notices available to the user.

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, William Cadwell
FURLS Home | AB Home

AB Home > Reports and Notifications

Reports and Notifications

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

[Previous](#)

Figure 6.2 – ‘Reports and Notifications’ page

6.1. Notice of Accreditation of CB'

The AB user can select 'Notice of Accreditation of CB' in the "Reports and Notifications" page. The system displays the "Notice of Accreditation of CB" page (Figure 6.1.1). The user can select the CB that the user would like to send the notice to.

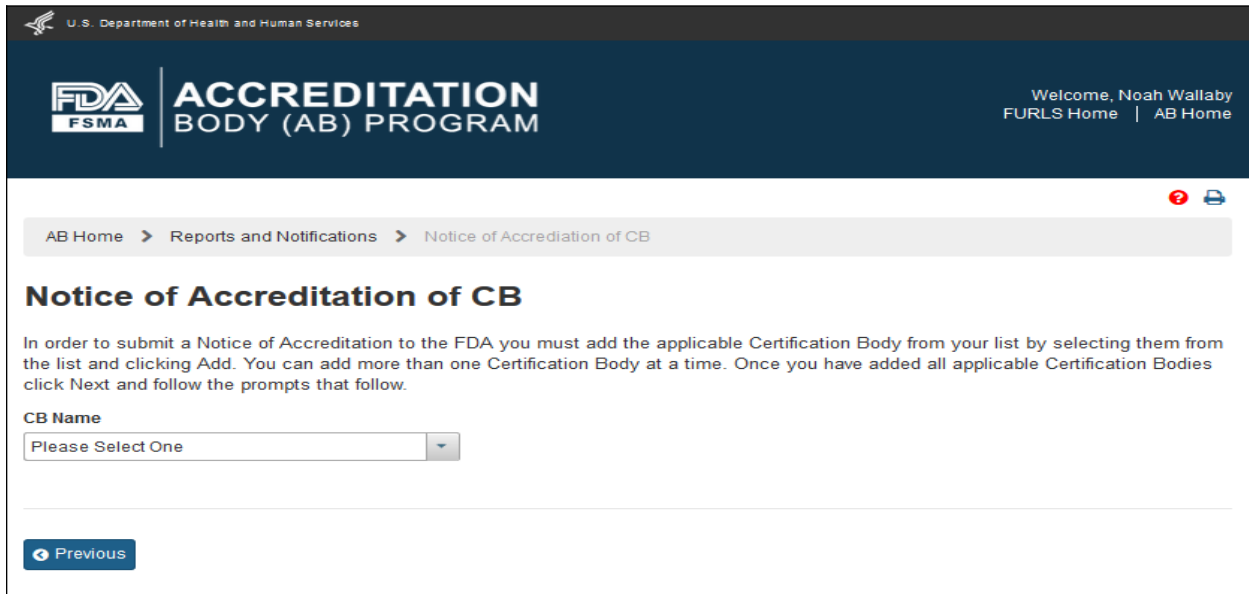


Figure 6.1.1 - Notice of Accreditation of CB page

The AB user can select a CB from the 'CB Name' dropdown options. These options include the names of all CBs working with the AB.

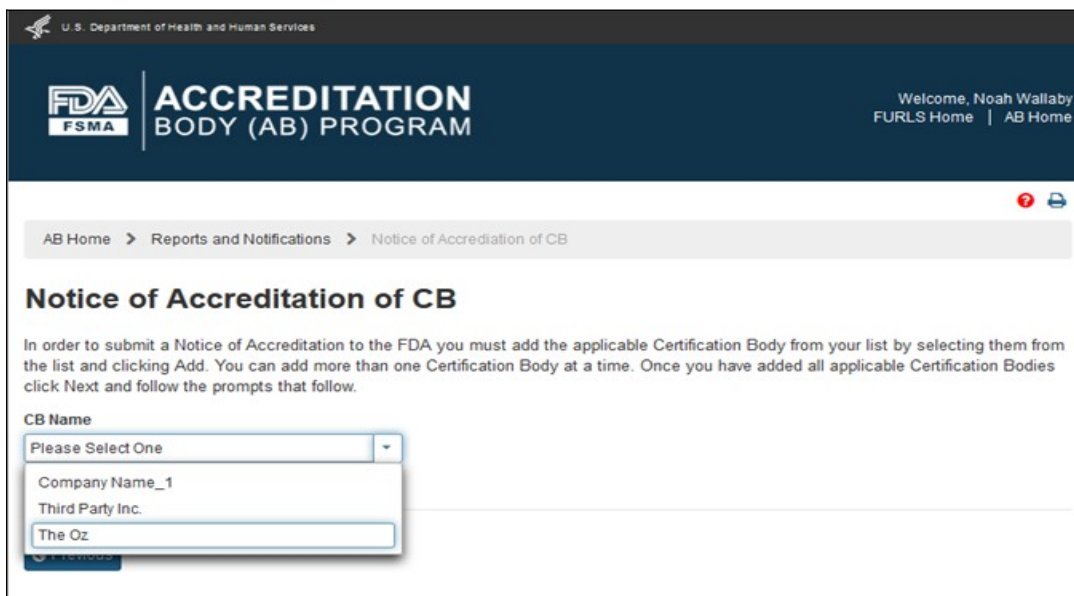


Figure 6.1.2 - Notice of Accreditation of CB page with CB name options

The system expands the page (Figure 6.1.3) when the AB user selects a CB from the drop down list. This page displays the CB information and accredited scopes. The user can click 'Add' button to add the CB to the Notice of Accreditation.

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
[FURLS Home](#) | [AB Home](#)

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

Notice of Accreditation of CB

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

CB Name

Address
 141 Queen St.
 Brisbane Queensland 4000

Contact Number
 Telephone Number 61 (743) 1300305721 Ext. 11
 Fax Number 61 (743) 1300305722

Web Address
<http://www.australia.com>

Email
okeyzman@iiinfo.com

Officer(s)
 Officer Officer 1

Agent(s)
 The Oz
 Agent Agent 2

Scope of Accreditation

Scope(s)	Accreditation Date	Expiration Date
558:Tolerances for residues of new animal drugs in food	2014-02-03	2018-02-01
584:Food substances affirmed as generally recognized as safe in feed and drinking water of animals	2018-07-28	2018-07-31
109:Unavoidable contaminants in food for human consumption and food-packaging material	2015-11-19	2019-11-11
129:Processing and bottling of bottled drinking water	2018-07-28	2017-07-20
101:Food Labeling	2015-11-19	2019-11-15
130:Food standards: General	2015-11-19	2019-11-11

[+ Add](#)

[Previous](#)

Figure 6.1.3 – Notice of Accreditation of CB page with CB and scope information

The system confirms that the CB has been added to the Notice of Accreditation (Figure 6.1.4). The CB's name that was added to the notice is removed from the 'CB Name' dropdown list (compare Figures 6.1.2 and 6.1.4).

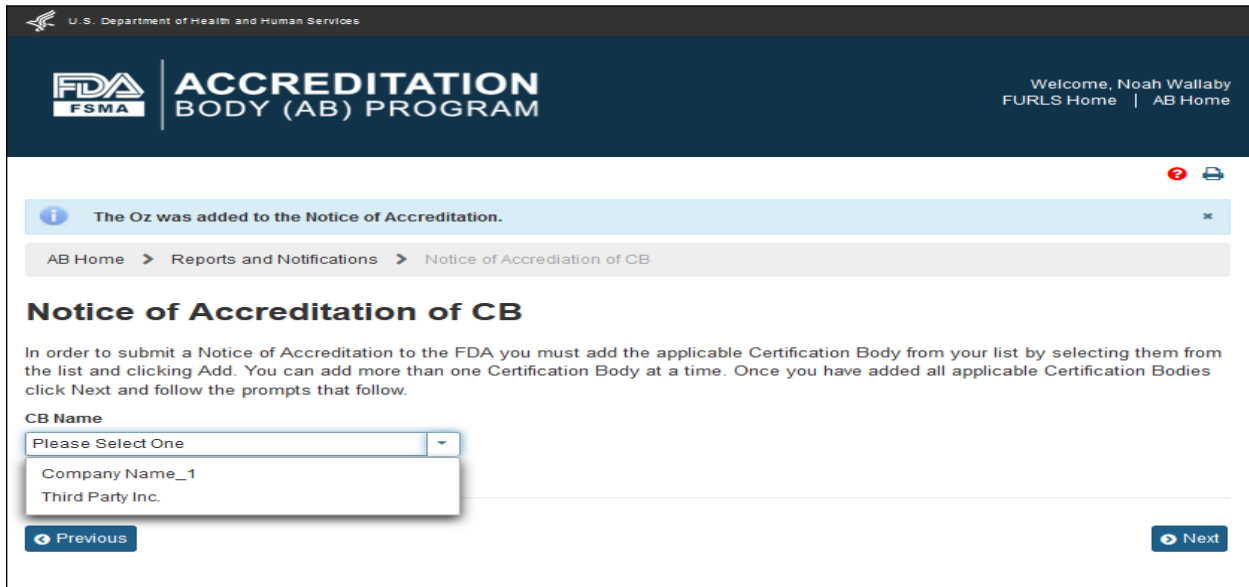


Figure 6.1.4 - Message that CB was added to Notice of Accreditation

The AB user can click 'Next' button and the system will display a confirmation message (Figure 6.1.5). The user can choose to Cancel the action, and return to the "Notice of Accreditation of CB" page or proceed with the notice, by clicking 'OK' button.

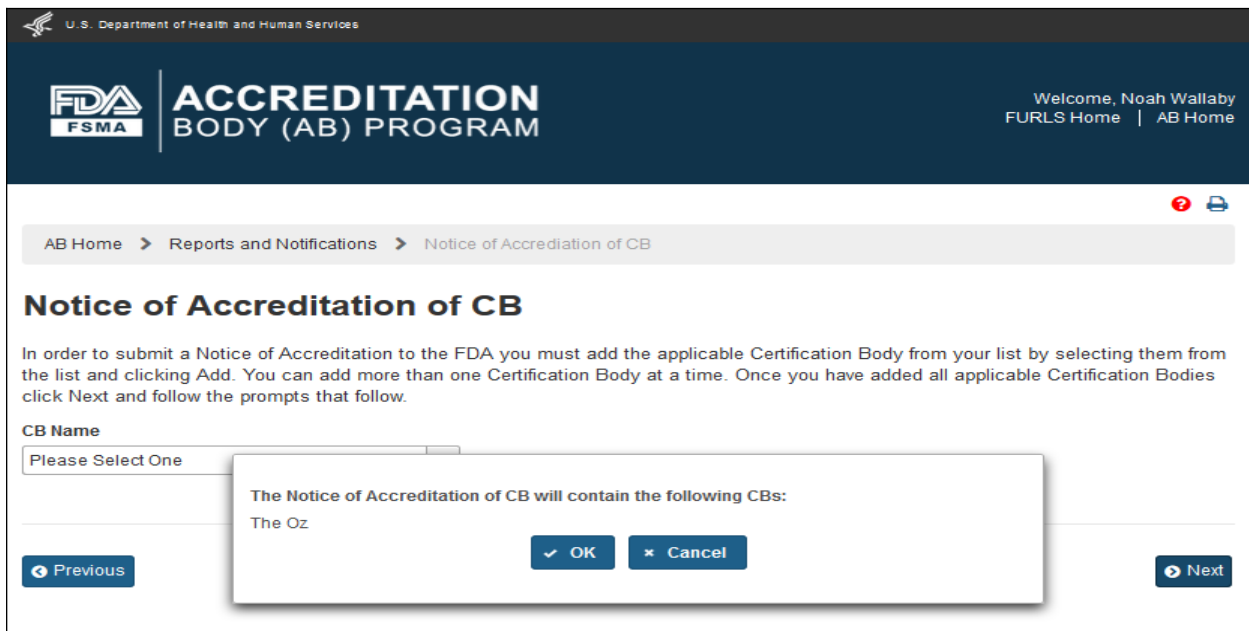


Figure 6.1.5 - Confirmation Message

The AB user can clicking 'OK' button to confirm the addition of the CB to the Notice of Accreditation. The system displays the "e-Signature" page (Figure 6.1.6). The user fills out the following data fields:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Noah Wallaby
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Accreditation of CB > e-Signature

e-Signature

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

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

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-29

Previous Submit

Figure 6.1.6 – e-Signature page - *Please note in a future release, language will be changed to say "may constitute sufficient grounds" instead of "will constitute sufficient grounds."*

The AB user can click 'Submit' button and the system will display the 'Confirmation' message (Figure 6.1.7)

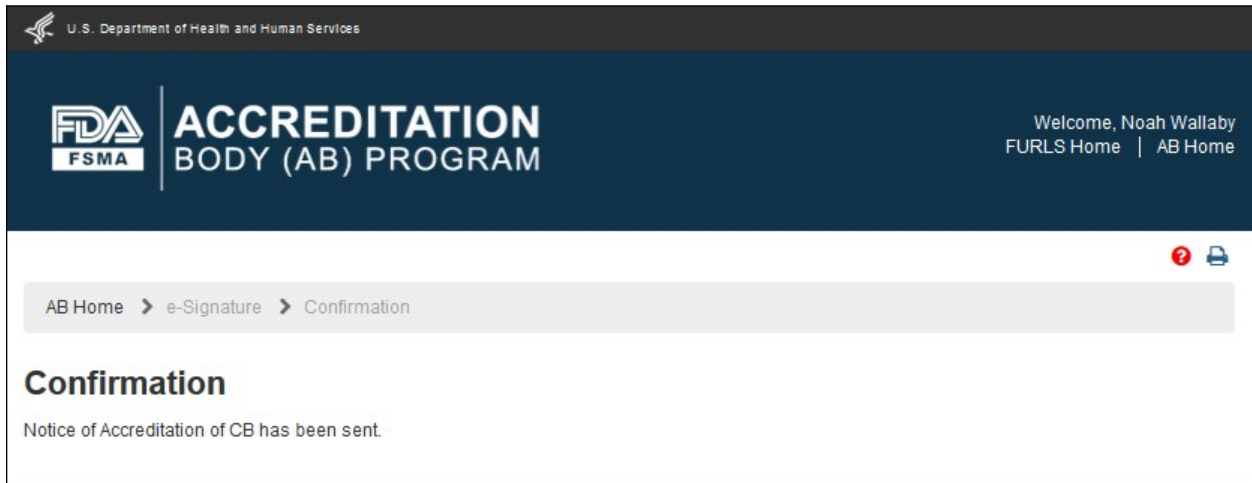


Figure 6.1.7 - Confirmation message page

An email is also sent to the AB user indicating the Notice of Accreditation was received by FDA (Figure 6.1.8).

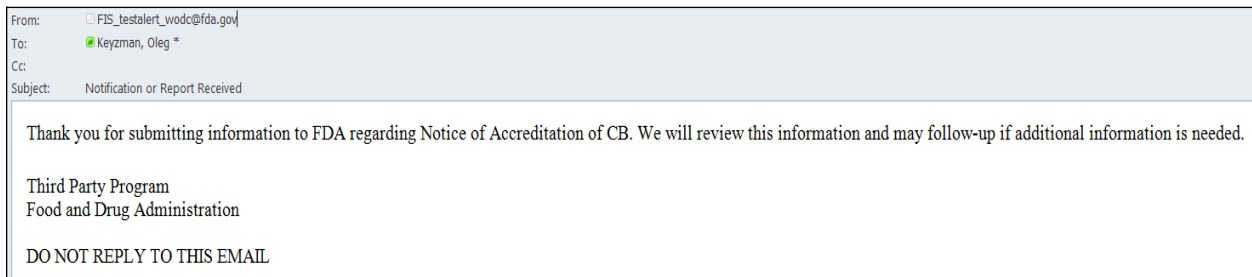


Figure 6.1.8 - Email sent to AB user

The AB user can return to the "Reports and Notifications" page via 'AB Home' link on the top of the Banner or by selecting the "Reports and Notifications" menu.

6.2. Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

The AB user can select 'Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification' in the "Reports and Notifications" page (Figure 6.2.1).

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

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

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

Figure 6.2.1 - 'Reports and Notifications' page

The system displays the “Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification” page (Figure 6.2.2).

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
FURLS Home | AB Home

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

Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

Certification Body
Please Select One

Under 21 CFR § 1.623(c)(3), describe any failure(s) by the accredited certification body in complying with the applicable requirements of 21 CFR § 1.653 on the basis and procedures for issuance of certifications including specifying the eligible entity (or entities) to which certification was issued and the date(s) of the audit(s).

Enter your response here.

4000 characters remaining.

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

Enter your response here.

4000 characters remaining.

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

Enter your response here.

4000 characters remaining.

Previous Next

Figure 6.2.2 – ‘Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification’ page

The AB user can select a CB from the 'Certification Body' dropdown options. The system displays the information about the CB's address and the scopes (Figure 6.2.3).

FDA FSMA ACCREDITATION BODY (AB) PROGRAM Welcome, Noah Wallaby
FURLS Home | AB Home

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

Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification

Certification Body:

Address: 141 Queen St.
Brisbane Queensland 4000
AUSTRALIA

Scope of Accreditation

- 584 : Food substances affirmed as generally recognized as safe in feed and drinking water of animals
- 129 : Processing and bottling of bottled drinking water
- 109 : Unavoidable contaminants in food for human consumption and food-packaging material
- 101 : Food Labeling
- 556 : Tolerances for residues of new animal drugs in food
- 130 : Food standards: General

Under 21 CFR § 1.623(c)(3), describe any failure(s) by the accredited certification body in complying with the applicable requirements of 21 CFR § 1.653 on the basis and procedures for issuance of certifications including specifying the eligible entity (or entities) to which certification was issued and the date(s) of the audit(s).

3893 characters remaining.

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

3918 characters remaining.

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

3920 characters remaining.

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

Figure 6.2.3 - CB Address and Scope Information

The AB user completes the following questions in the data fields:

- Describe any failures by the accredited certification body in complying with the applicable requirements
- What is the basis on which you decided the accredited certification body failed to comply
- Provide additional changes to information that appears above to notice of accreditation (optional)

The user then clicks 'Next' button and the system displays the "*e-Signature*" page (Figure 6.2.4). The user fills out the following data fields:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
[FURLS Home](#) | [AB Home](#)

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

e-Signature

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

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

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

Name of Submitter

Title of Submitter

Date
2016-10-01

[← Previous](#) [Submit →](#)

Figure 6.2.4 – e-Signature page - *Please note in a future release, language will be changed to say “may constitute sufficient grounds” instead of “will constitute sufficient grounds.”*

The AB user can click ‘Submit’ button and the system will display the ‘Confirmation’ message (Figure 6.2.5)

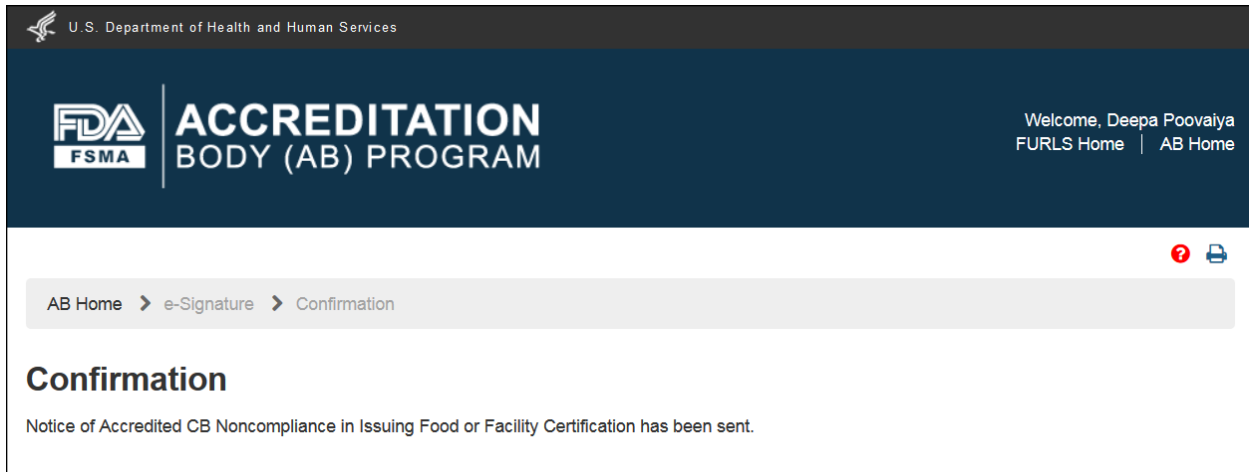


Figure 6.2.5 – Confirmation message

An email is also sent to the AB user indicating the Notice of Accredited CB Noncompliance in Issuing Food or Facility Certification was received by FDA (Figure 6.2.6).

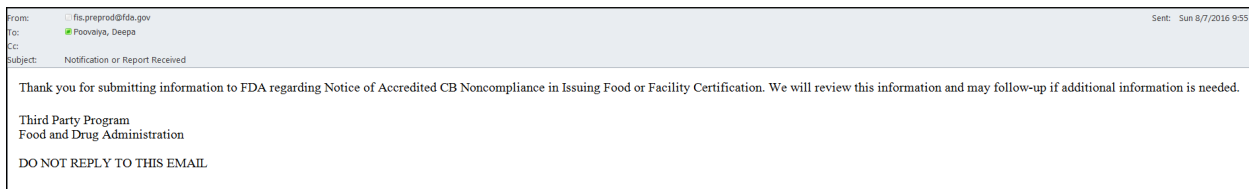
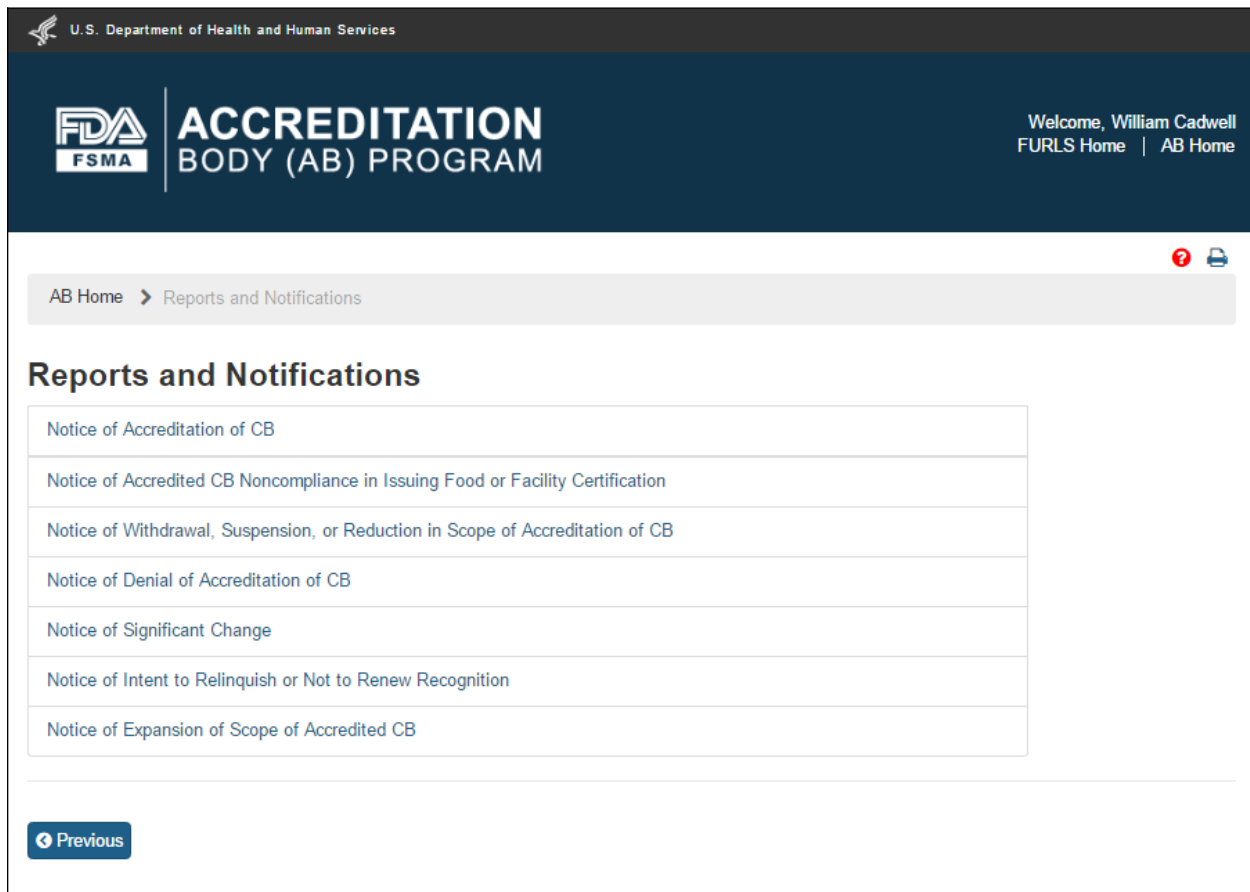


Figure 6.2.6 – Email to AB user

The AB user can return to the “*Reports and Notifications*” page via ‘AB Home’ link on the top of the Banner or by selecting the “*Reports and Notifications*” menu.

6.3. Notice of Denial of Accreditation of CB

The AB user can select 'Notice of Denial of Accreditation of CB' in the "Reports and Notifications" page (Figure 6.3.1).



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

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

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

Figure 6.3.1 – 'Reports and Notifications' page

The system displays the “Notice of Denial of Accreditation of CB” page (Figure 6.2.2).

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

Notice of Denial of Accreditation of CB

Certification Body

Contact Information (optional):

Country: <input type="text" value="Please Select Country"/>	Contact Name: <input type="text"/>	<input type="text"/>	<input type="text"/>
	First Name	MI (Optional)	Last Name
Address 1: <input type="text"/>	Phone Number: <input type="text"/>	<input type="text"/>	<input type="text"/>
	Country	Area	Phone Number
Address 2 (Optional): <input type="text"/>			Extension
City: <input type="text"/>			
State/Province/Territory: <input type="text" value="Please Select"/>			
Zip Code (Postal Code): <input type="text"/>			

Officer of the certification body

Describe the scope of accreditation requested

Enter your response here.

1000 characters remaining.

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

Enter your response here.

4000 characters remaining.

Figure 6.3.2 - ‘Notice of Denial of Accreditation of CB’ page

The AB user completes the following data fields:

- **Certification Body** - the name of the certification body that the accreditation body would like to add
- **Contact Information (Optional)**
 - o **Country** - the country of residence of the certification body
 - o **Address 1** - the street address of the certification body
 - o **Address 2 (Optional)**
 - o **City** - the city of residence of the certification body
 - o **State/ Province/ Territory** - the State/ Province/ Territory of the certification body
 - o **Zip Code (Postal Code)** - the postal code of the certification body
 - o **Contact Name**
 - **First Name**- the first name of the point of contact
 - **MI(Optional)**
 - **Last Name**- the last name of the point of contact
 - o **Phone Number**
 - **Country** - the country code of the point of contact
 - **Area** - the area code of the point of contact
 - **Phone Number** - the phone number of the point of contact
 - **Extension** - the extension number of the point of contact
- **Officer of the Certification Body** - the officer(s) of the certification body
- **Describe the scope of accreditation requested** - a description of the scope of accreditation being included in the notice
- **Describe any areas within the requested scope of accreditation that were denied and for each such area describe the basis of denial** - a description of the areas within the scope of accreditation that were denied and the basis of denial

The AB user can click 'Next' button. The system displays the “e-Signature” page (Figure 6.3.3). The user fills out the following data fields:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Noah Wallaby
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Accreditation of CB > e-Signature

e-Signature

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

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

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-29

Previous Submit

Figure 6.3.3 – e-Signature page - *Please note in a future release, language will be changed to say “may constitute sufficient grounds” instead of “will constitute sufficient grounds.”*

The AB user can click 'Submit' button and the system will display the 'Confirmation' message (Figure 6.3.4)

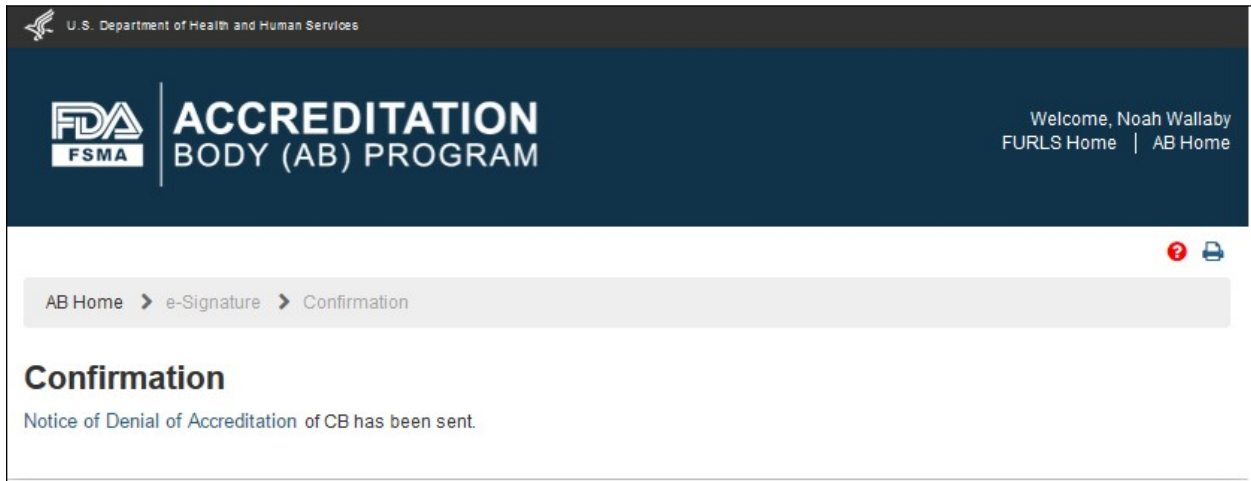


Figure 6.3.4 - Confirmation message page

An email is also sent to the AB user indicating the Notice of Denial of CB was received by FDA (Figure 6.3.5).

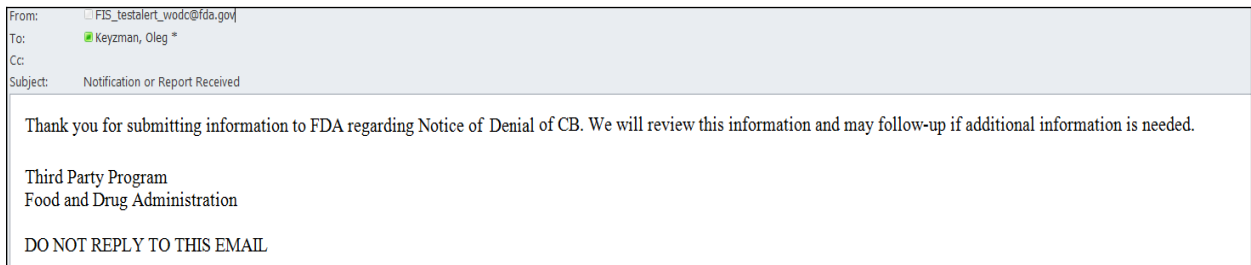
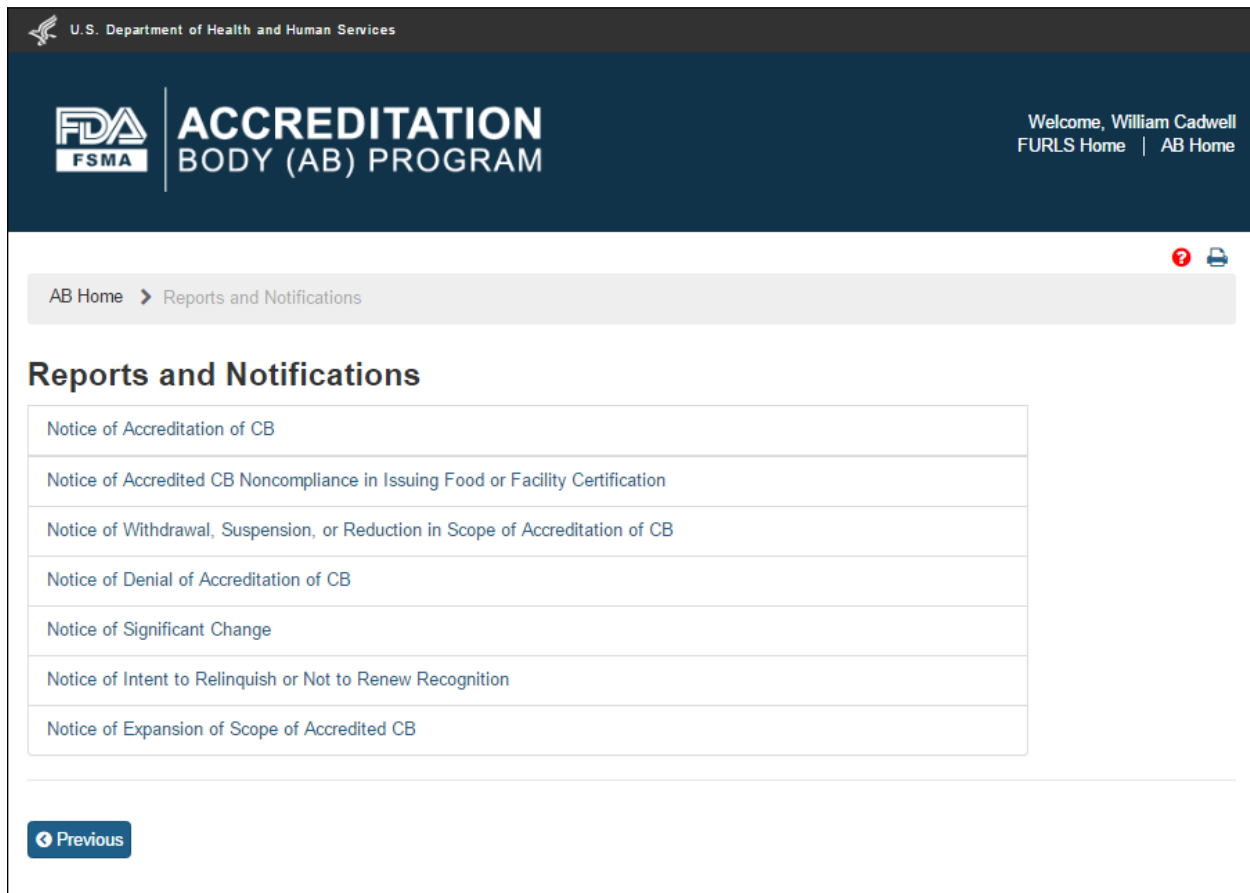


Figure 6.3.5 - Email sent to AB user

The AB user can return to the "Reports and Notifications" page via 'AB Home' link on the top of the Banner or by selecting the "Reports and Notifications" menu.

6.4. Notice of Significant Change

The AB user can select 'Notice of Significant Change' in the "Reports and Notifications" page (Figure 6.4.1).



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

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

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

Figure 6.4.1 – 'Reports and Notifications' page

The system displays the “Notice of Significant Change” page (Figure 6.4.2).

U.S. Department of Health and Human Services

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

Welcome, Noah Wallaby
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Significant Change

Notice of Significant Change

AB's Name
SBS Group Ltd

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

Change(s) that would effect the manner in which you comply with the applicable requirements.

3908 characters remaining.

Explain the purpose of the change(s).

The purpose of the change(s).

3971 characters remaining.

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

Figure 6.4.2 – ‘Notice of Significant Change’ page

The AB user completes the following data fields:

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

The AB user can click 'Next' button. The system displays the “e-Signature” page (Figure 6.4.3). The user fills out the following data fields:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Noah Wallaby
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Accreditation of CB > e-Signature

e-Signature

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

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

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-29

Previous Submit

Figure 6.4.3 – e-Signature page - *Please note in a future release, language will be changed to say “may constitute sufficient grounds” instead of “will constitute sufficient grounds.”*

The AB user can click 'Submit' button and the system will display the 'Confirmation' message (Figure 6.4.4)

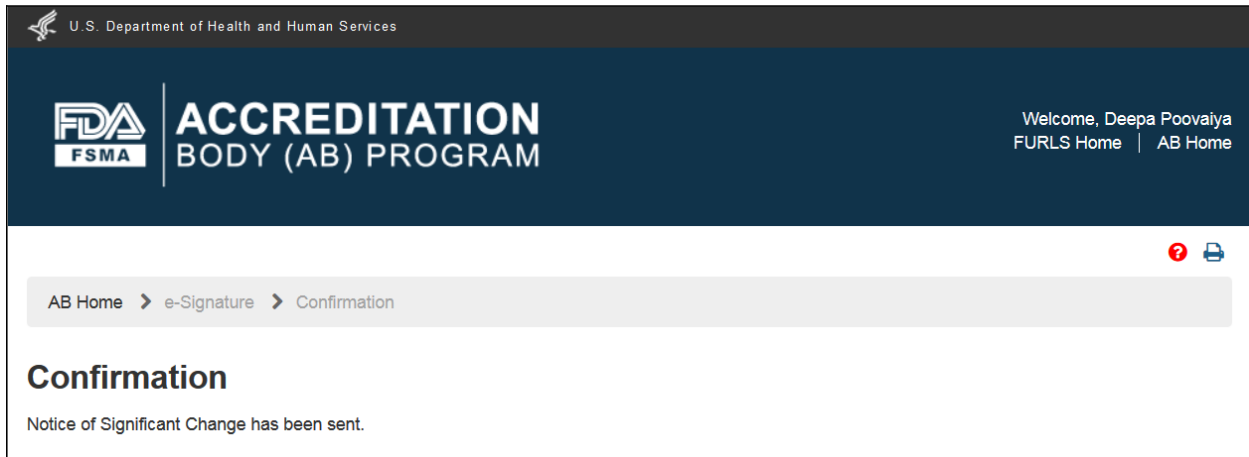


Figure 6.4.4 – Confirmation message page

An email is also sent to the AB user indicating the Notice of Significant Change was received by FDA (Figure 6.4.5).

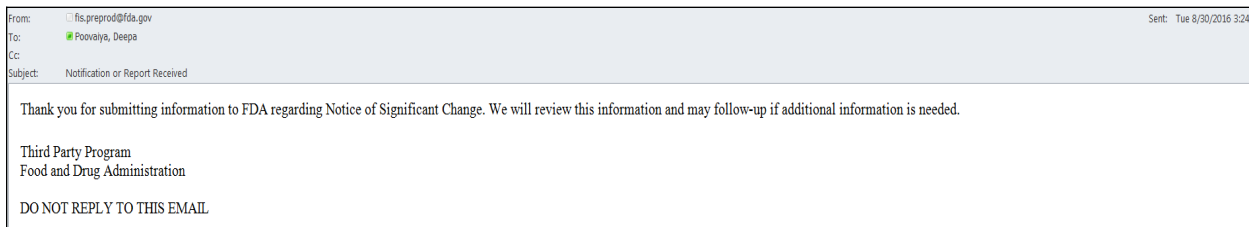


Figure 6.4.5 – Email sent to AB user

The AB user can return to the “*Reports and Notifications*” page via ‘AB Home’ link on the top of the Banner or by selecting the “*Reports and Notifications*” menu.

6.5. Notice of Intent to Relinquish or Not to Renew Recognition

The AB user can select 'Notice of Intent to Relinquish or Not to Renew Recognition' in the "Reports and Notifications" page (Figure 6.5.1).

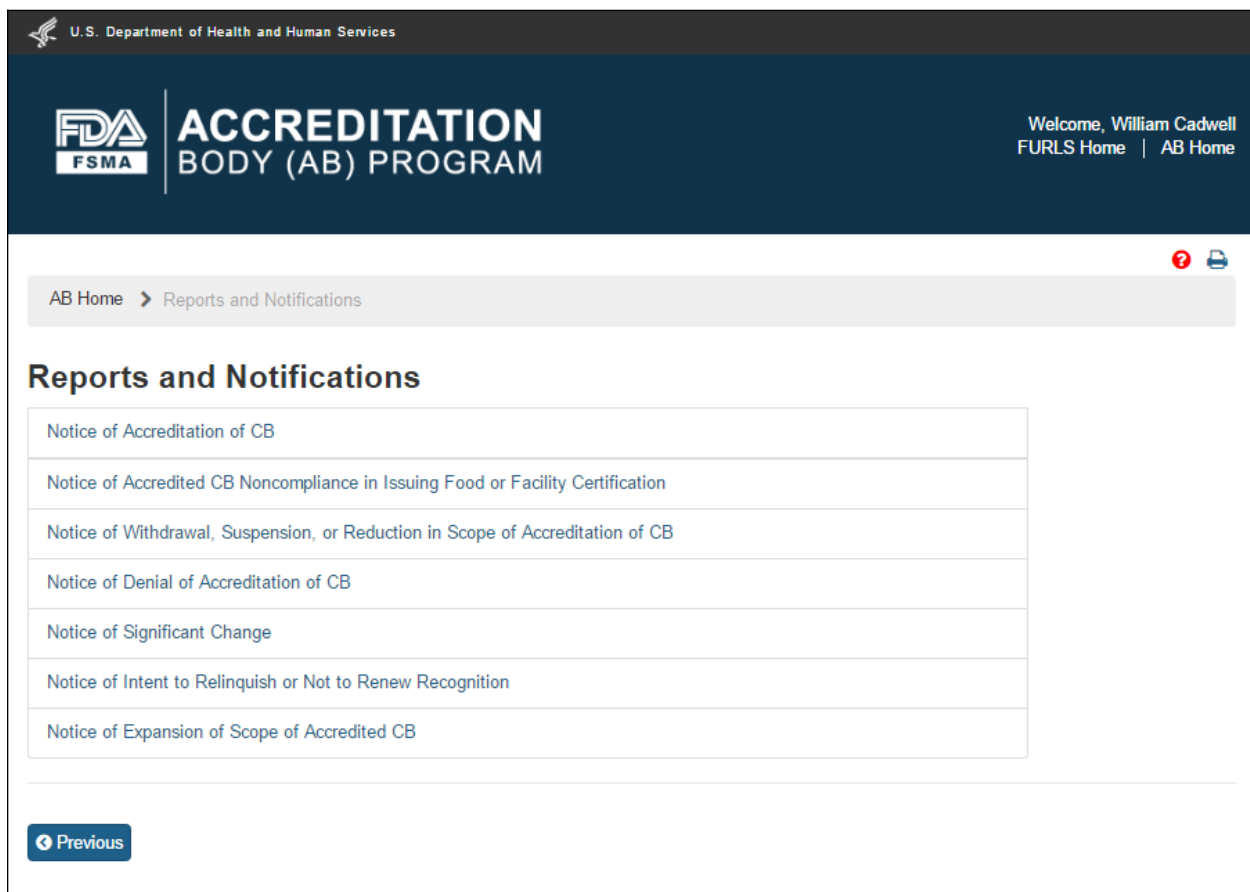


Figure 6.5.1 - 'Reports and Notifications' page

The system displays the “Notice of Intent to Relinquish or Not to Renew Recognition” page (Figure 6.5.2).

The screenshot shows a web page with a dark blue header. On the left, it features the FDA FSMA logo and the text 'ACCREDITATION BODY (AB) PROGRAM'. On the right, it says 'Welcome, Noah Wallaby' with links for 'FURLS Home' and 'AB Home'. Below the header is a breadcrumb trail: 'AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition'. The main heading is 'Notice of Intent to Relinquish or Not to Renew Recognition'. The first question is 'Do you intend to relinquish your recognition prior to its expiration date?' with radio buttons for 'Yes' and 'No'. The second question is 'Name and location of records custodian who will maintain the accreditation body's records for 5 years after the date of recognition expires or is relinquished and who will make the records available as required by 21CFR1.625'. Below this is another question: 'Records will be monitored by' with radio buttons for 'Accreditation Body' and 'Other'. There is an 'Attachments (Optional)' section with a plus sign icon. At the bottom, there are 'Previous' and 'Next' navigation buttons.

Figure 6.5.2 – ‘Notice of Intent to Relinquish or Not to Renew Recognition’ page

The AB user can answer the question, “Do you intend to relinquish your recognition prior to its expiration date?” by selecting one of the two options ‘Yes’ or ‘No’. If the user selects ‘Yes’ the system displays the calendar feature and the user can pick or enter the ‘Intended Date of Relinquishment or Date of Expiration of Recognition’ (Figures 6.5.3).

The screenshot shows the FDA FSMA Accreditation Body (AB) Program web interface. The header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'ACCREDITATION BODY (AB) PROGRAM'. A user greeting 'Welcome, Noah Wallaby' and links for 'FURLS Home' and 'AB Home' are visible in the top right. The breadcrumb trail reads 'AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition'. The main heading is 'Notice of Intent to Relinquish or Not to Renew Recognition'. The form contains the following elements:

- A question: 'Do you intend to relinquish your recognition prior to its expiration date?' with radio buttons for 'Yes' (selected) and 'No'.
- A label: 'Intended Date of Relinquishment or Date of Expiration of Recognition'.
- A date input field with a placeholder 'YYYY-MM-DD' and a calendar icon.
- A text area for 'Name and location of records custodian who will maintain the accreditation body's records for 5 years after the date of recognition expires or is relinquished and who will make the records available as required by 21CFR1.625'.
- A label: 'Records will be monitored by'.
- Radio buttons for 'Accreditation Body' and 'Other'.
- An 'Attachments (Optional)' section with a plus icon.
- 'Previous' and 'Next' navigation buttons at the bottom.

Figure 6.5.3 - Intended Date of Relinquishment or Date of Expiration of Recognition

If the user selects 'No' the system displays the read-only date of 'Intended Date of Relinquishment or Date of Expiration of Recognition' (Figures 6.5.4).

The screenshot shows the FDA FSMA Accreditation Body (AB) Program interface. The header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'ACCREDITATION BODY (AB) PROGRAM'. A user greeting 'Welcome, Noah Wallaby' and links for 'FURLS Home' and 'AB Home' are visible in the top right. The breadcrumb trail indicates the user is in 'AB Home > Reports and Notifications > Notice of Intent to Relinquish or Not to Renew Recognition'. The main heading is 'Notice of Intent to Relinquish or Not to Renew Recognition'. The form contains the following elements:

- A question: 'Do you intend to relinquish your recognition prior to its expiration date?' with radio buttons for 'Yes' and 'No'. The 'No' option is selected.
- A label: 'Intended Date of Relinquishment or Date of Expiration of Recognition' with a read-only value of '2019-11-19'.
- A text field: 'Name and location of records custodian who will maintain the accreditation body's records for 5 years after the date of recognition expires or is relinquished and who will make the records available as required by 21CFR1.625'.
- A label: 'Records will be monitored by' with radio buttons for 'Accreditation Body' and 'Other'.
- An 'Attachments (Optional)' section.
- 'Previous' and 'Next' navigation buttons at the bottom.

Figure 6.5.4 – Read only Date of 'Intended Date of Relinquishment or Date of Expiration of Recognition'

The AB user can select one of the options for, “Records will be maintained by”. The two options available to the AB user are ‘Accreditation Body’ or ‘Other’. If the user selects ‘Accreditation Body’ the system displays the ABs information (Figure 6.5.5).

U.S. Department of Health and Human Services

FDA
FSMA

**ACCREDITATION
BODY (AB) PROGRAM**

Welcome, Noah Wallaby
FURLS Home | AB Home

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

Notice of Intent to Relinquish or Not to Renew Recognition

Do you intend to relinquish your recognition prior to its expiration date?
 Yes No

Intended Date of Relinquishment or Date of Expiration of Recognition
2019-11-19

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

Records will be monitored by
 Accreditation Body Other

Records Custodian SBS Group Ltd	Contact Number Telephone Number 64 (06) 7513080 Ext. 987
Address 142A Pioneer Rd Spotswood New Plymouth Otago 4310 NEW ZEALAND	Email Oleg.Keyzman@fda.hhs.gov

▶ Attachments (Optional)

◀ Previous Next ▶

Figure 6.5.5 – Records monitored by AB information

If the user selects 'Other' the system displays (Figure 6.5.6) the following data fields that the user can complete:

- **Records Custodian** - the name of the accreditation body's records custodian
- **Country** - the country of residence of the accreditation body's records custodian
- **Address 1** - the street address of the accreditation body's records custodian
- **Address 2** - (Optional field)
- **City** - the city of the accreditation body's records custodian
- **State/ Province/ Territory** - the State/ Province/ Territory of the accreditation body's records custodian
- **Zip Code (Postal Code)** - the postal code of the accreditation body's records custodian
- **Telephone** - (Optional field)
 - o **Country** - (Optional field)
 - o **Area** - (Optional field)
 - o **Phone Number** - (Optional field)
 - o **Extension** - (Optional field)
- **E-mail Address** - the electronic mail address of the accreditation body's records custodian

The user can also upload files to the notice, as needed, using "Attachment" feature.

Notice of Intent to Relinquish or Not to Renew Recognition

Do you intend to relinquish your recognition prior to its expiration date?
 Yes No

Intended Date of Relinquishment or Date of Expiration of Recognition
2019-11-19

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

Records will be monitored by
 Accreditation Body Other

Records Custodian: <input type="text" value="Records Custodian"/>	Telephone (Optional): <input type="text" value="1"/> <input type="text" value="808"/> <input type="text" value="5796000"/> <input type="text"/> Country Area Phone Number Extension
Country: <input type="text" value="UNITED STATES"/>	E-mail Address: <input type="text" value="info@paiainn.com"/>
Address 1: <input type="text" value="123 Hana Road"/>	
Address 2 (Optional): <input type="text"/>	
City: <input type="text" value="Paia"/>	
State/Province/Territory: <input type="text" value="Hawaii"/>	
Zip Code (Postal Code): <input type="text" value="96779"/>	

Attachments (Optional)

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

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

File Name	Date of Upload	Action
No records found.		

[Previous](#)

[Next](#)

Figure 6.5.6 - Records monitored by information

The AB user can click 'Next' button. The system displays the “e-Signature” page (Figure 6.5.7). The user fills out the following data fields:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Noah Wallaby
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Accreditation of CB > e-Signature

e-Signature

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

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

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-29

Previous Submit

Figure 6.5.7 – e-Signature page - *Please note in a future release, language will be changed to say “may constitute sufficient grounds” instead of “will constitute sufficient grounds.”*

The AB user can click 'Submit' button and the system will display the 'Confirmation' message (Figure 6.5.8)

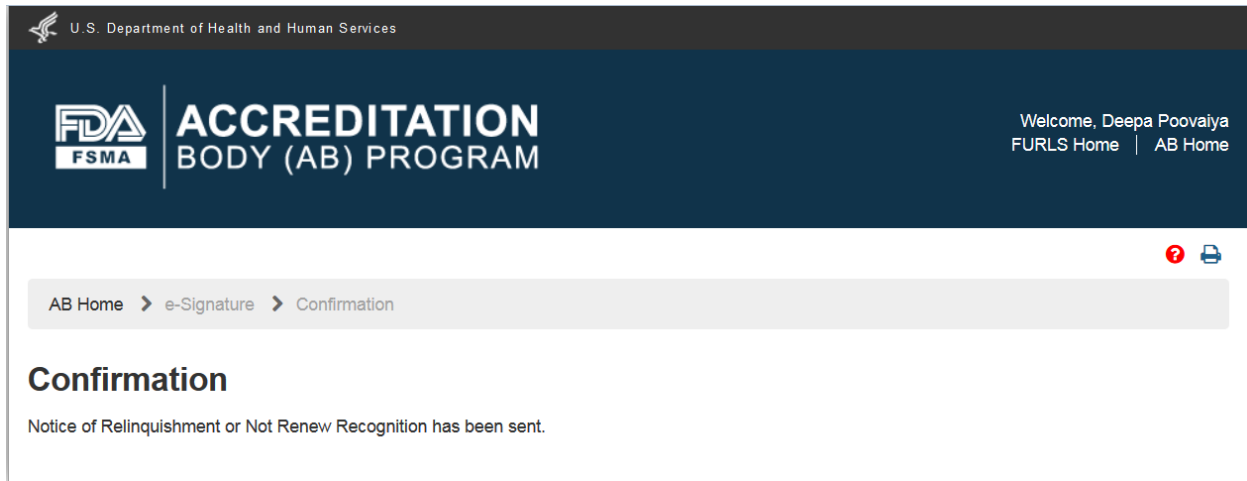


Figure 6.5.8 – Confirmation message page

An email is also sent to the AB user indicating the Notice of Intent to Relinquish or not to Renew Recognition was received by FDA (Figure 6.5.9).

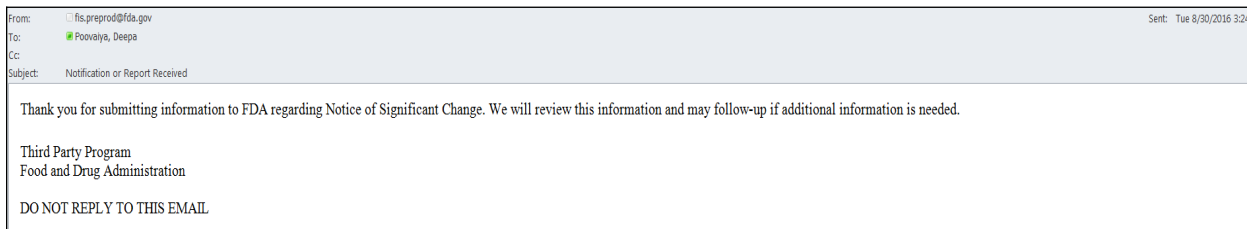


Figure 6.5.9 – Email sent to AB user

The AB user can return to the “*Reports and Notifications*” page via ‘AB Home’ link on the top of the Banner or by selecting the “*Reports and Notifications*” menu.

6.6. Notice of Expansion of Scope of Accredited CB

The AB user can select 'Notice of Expansion of Scope of Accredited CB' in the "Reports and Notifications" page (Figure 6.5.1).

The screenshot displays the 'Reports and Notifications' page of the Accreditation Body (AB) Program. The page header includes the U.S. Department of Health and Human Services logo, the FDA FSMA logo, and the text 'ACCREDITATION BODY (AB) PROGRAM'. A welcome message for William Cadwell is visible in the top right corner. The main content area features a list of seven report types, with 'Notice of Expansion of Scope of Accredited CB' at the bottom. A 'Previous' button is located at the bottom left of the page.

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

Figure 6.6.1 - 'Reports and Notifications' page

The system displays the “Notice of Expansion of Scope of Accredited CB” page (Figure 6.6.2).

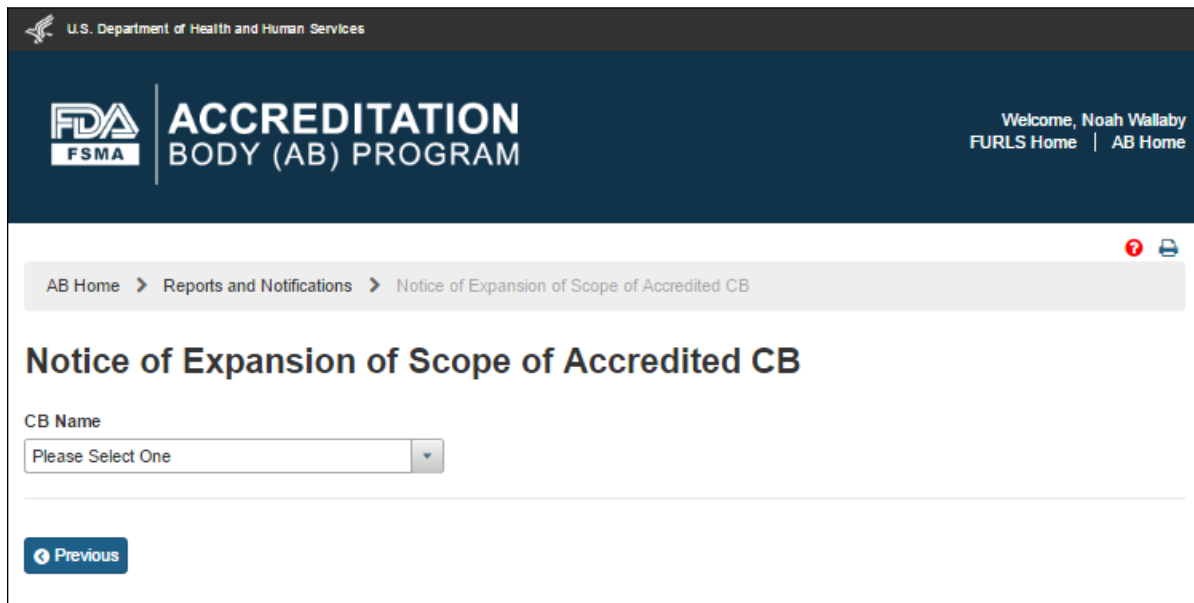


Figure 6.6.2 – ‘Notice of Expansion of Scope of Accredited CB’ page

The AB user can select a 'CB Name' from the dropdown menu options. The system displays the CB's information along with the list of expanded scope(s) (Figure 6.6.3).

The screenshot shows the FDA FSMA Accreditation Body (AB) Program interface. At the top, it displays the U.S. Department of Health and Human Services logo and the text 'U.S. Department of Health and Human Services'. Below this, the FDA FSMA logo is shown next to the text 'ACCREDITATION BODY (AB) PROGRAM'. On the right side, there is a welcome message: 'Welcome, Oliver Corkscrew Jr.' with links for 'FURLS Home' and 'AB Home'.

The main content area has a breadcrumb trail: 'AB Home > Reports and Notifications > Notice of Expansion of Scope of Accredited CB'. The title of the page is 'Notice of Expansion of Scope of Accredited CB'. Below the title, there is a dropdown menu for 'CB Name' with 'Test PapaCarlo' selected. To the right of the dropdown, there are icons for help and print.

The interface displays the following information for the selected CB:

- Address:** 11820 Parklawn dr, rockville Maryland 20852, UNITED STATES
- Contact Number:** Telephone Number 1 (301) 1237894 Ext. --
- Officer(s):** Duremar, Officer 2, test, Officer 3, Officer 1, Lisa Alisa, Officer 4
- Email:** abaddcb1@gmail.com
- Agent(s):** Test PapaCarlo

Below this information, it states: 'CB's accreditation was expanded for the following scopes'. This is followed by a table with three columns: 'Scope(s)', 'Accreditation Date', and 'Expiration Date'.

Scope(s)	Accreditation Date	Expiration Date
106 : Infant Formula requirements pertaining to current GMP, QC procedures, quality factors, records and reports, and notifications	2016-09-29	2018-07-18

At the bottom of the page, there are two buttons: 'Previous' and 'Next'.

Figure 6.6.3 – CB and scope information

The AB user can click 'Next' button. The system displays the “e-Signature” page (Figure 6.6.4). The user fills out the following data fields:

- **Name of Submitter** - the first and last name of the application submitter
- **Title of Submitter** - the titles of the application submitter

U.S. Department of Health and Human Services

FDA
FSMA

ACCREDITATION
BODY (AB) PROGRAM

Welcome, Noah Wallaby
FURLS Home | AB Home

AB Home > Reports and Notifications > Notice of Accreditation of CB > e-Signature

e-Signature

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

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

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

Name of Submitter
Print full legal name

Title of Submitter
Enter your title

Date
2016-09-29

Previous Submit

Figure 6.6.4- e-Signature page - *Please note in a future release, language will be changed to say “may constitute sufficient grounds” instead of “will constitute sufficient grounds.”*

The AB user can click 'Submit' button and the system will display the 'Confirmation' message (Figure 6.6.5)

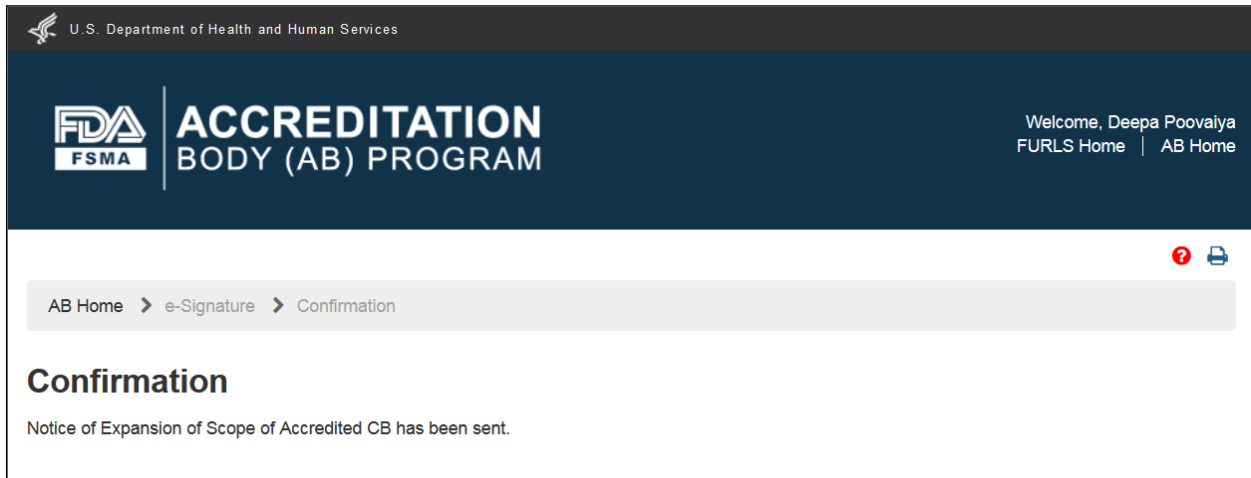


Figure 6.6.5 – Confirmation message page

An email is also sent to the AB user indicating the Notice of Intent to Relinquish or not to Renew Recognition was received by FDA (Figure 6.6.6).

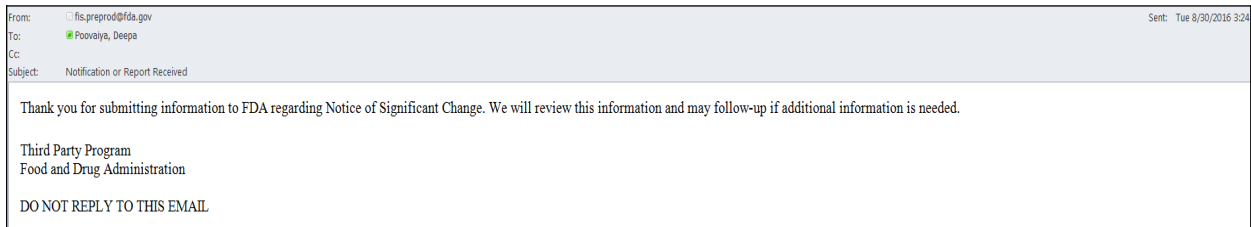


Figure 6.6.6 – Email sent to AB user

The AB user can return to the “*Reports and Notifications*” page via ‘AB Home’ link on the top of the Banner or by selecting the “*Reports and Notifications*” menu.