



U.S. Food and Drug Administration

Observations and Corrective Action Report (OCAR) Industry Portal

User Guide

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1 Introduction

This document is intended for users of the Observations and Corrective Action Report (OCAR) Industry Portal.

This document provides detailed instructions on how users of the portal can perform the following:

- Create an FDA online account
- Add and manage subaccounts
- Search observations
- View observation details
- Add a corrective action

1.1 Overview of FDA Portals for Electronic Program Submissions

FDA Industry Systems (FIS)

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

FDA's Unified Registration and Listing System (FURLS)

FURLS is a specific component of FIS. Persons with an FDA account ID and password for the FIS electronic portal can use the FURLS systems to exchange information with the Agency.

1.2 Adding Attachments

FURLS users may need to provide supporting documentation to the Agency while working in the portal. This documentation can be provided by attaching an electronic file (e.g., processing records, schematics, photographs, or other supporting information).

The electronic Observations and Corrective Action Report (OCAR) Industry Portal supports the following document attachment types:

- .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

Note: The maximum file size allowed is 50 MB. Relevant sections of this document will identify opportunities for adding attachments.

1.3 Supported Browsers

FURLS can be accessed using the following browsers:

- Microsoft Edge
- Google Chrome

Please visit the “Systems Requirements” section of the FURLS page for a list of approved browsers and browser versions. The “Systems Requirements” section can be found by navigating to <https://www.access.fda.gov/>.

2 Accessing FDA FIS Electronic Portal

Each FURLS user needs a personal FDA account ID and password, which can be obtained through the FDA FIS portal. To access the FIS electronic portal, go to <https://www.access.fda.gov/oa/>. Follow the instructions for obtaining an FDA account ID and password below. Once the account has been created you will be able to log into the Online Account Administration (OAA) system and gain access to FURLS.

The owner, operator, or agent in charge of the firm – the individual with the ultimate authority and responsibility – will have the ability to set up the primary enterprise account for the OCAR Industry Portal. This individual will be the Industry Portal Representative (IPR) for the firm and may set up sub-accounts for other individuals in the firm, as described in Section 3.2 below. FDA will require the IPR’s name and email address to provide access to the portal. FDA will send a system-generated email notification to the IPR, including a FURLS OAA account link and a verification code (Figure 2.1).

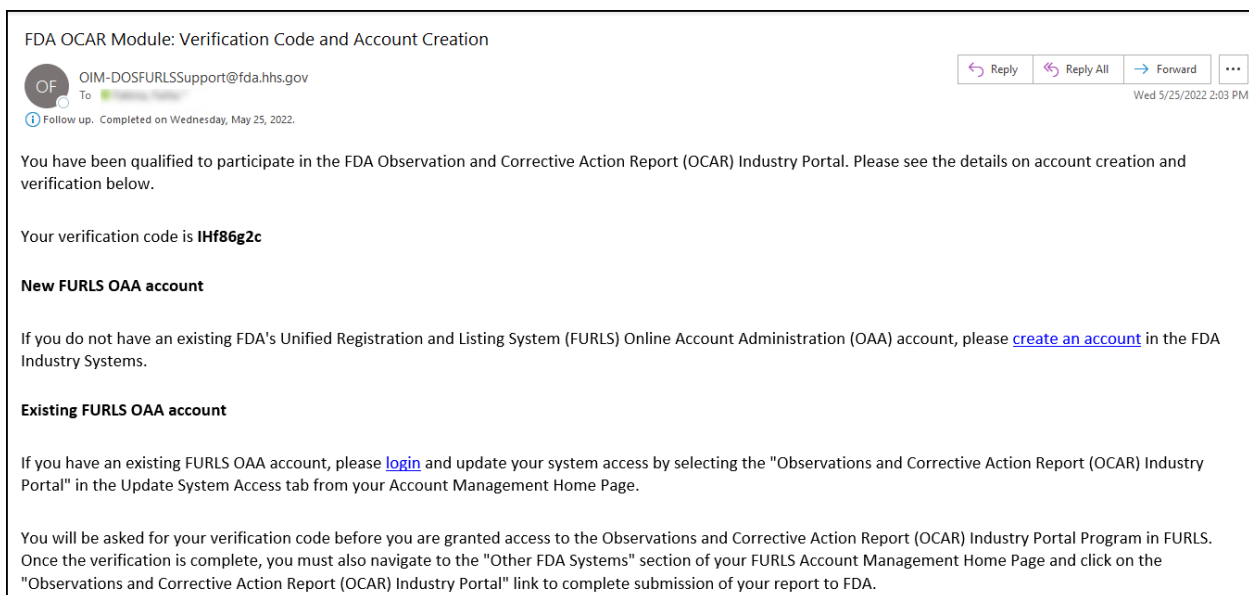


Figure 2.1 – System-Generated Email Notification Containing Verification Code

To log into the OAA system and gain access to FURLS, you will need to create an FDA online account; to do so, you may choose one of two options:

Option 1: Go to <https://www.access.fda.gov/oa/>. Click the “Create New Account” button on the OAA - FDA Industry Systems page (Figure 2.2). You will be directed to the “Create New Account” page.

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 Account ID Forgot 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 antispymware 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 2.2 – FDA OAA Login Page

The system displays the “Create New Account” page (Figure 2.3). You will see “Step 1: Select Application(s) for Account Creation.” Two radio buttons are displayed: “Yes” and “No.” Note that “No” is selected by default.

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

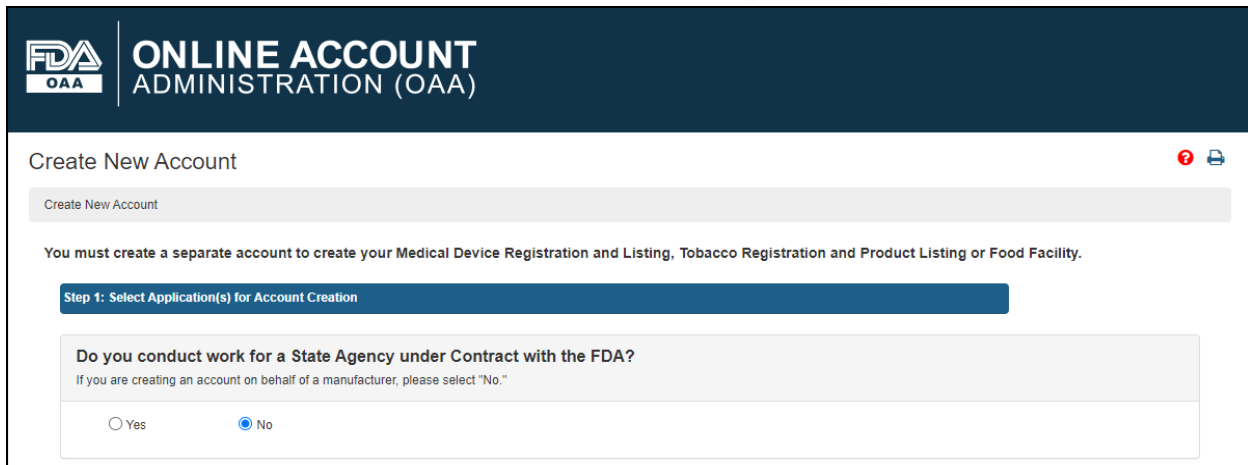


Figure 2.3 – Create New Account – Step 1: Select Application(s) for Account Creation

The system will display various FDA programs available in OAA.

Click the “Observations and Corrective Action Report (OCAR) Industry Portal” checkbox under the “Other FDA Systems” section (Figure 2.4). Click the “Continue” button at the bottom of the page to proceed to the next step. You will be directed to the “Step 1a: Enter Verification Code for Account Creation” page.

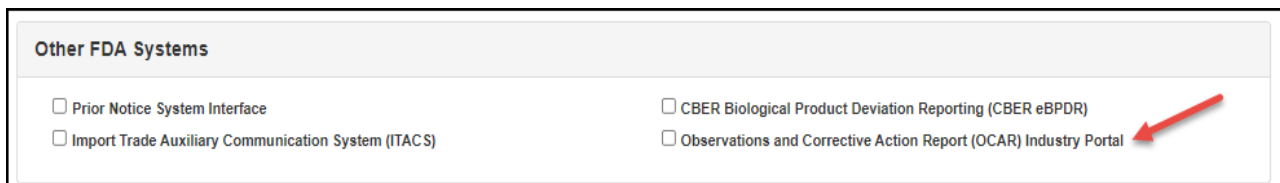


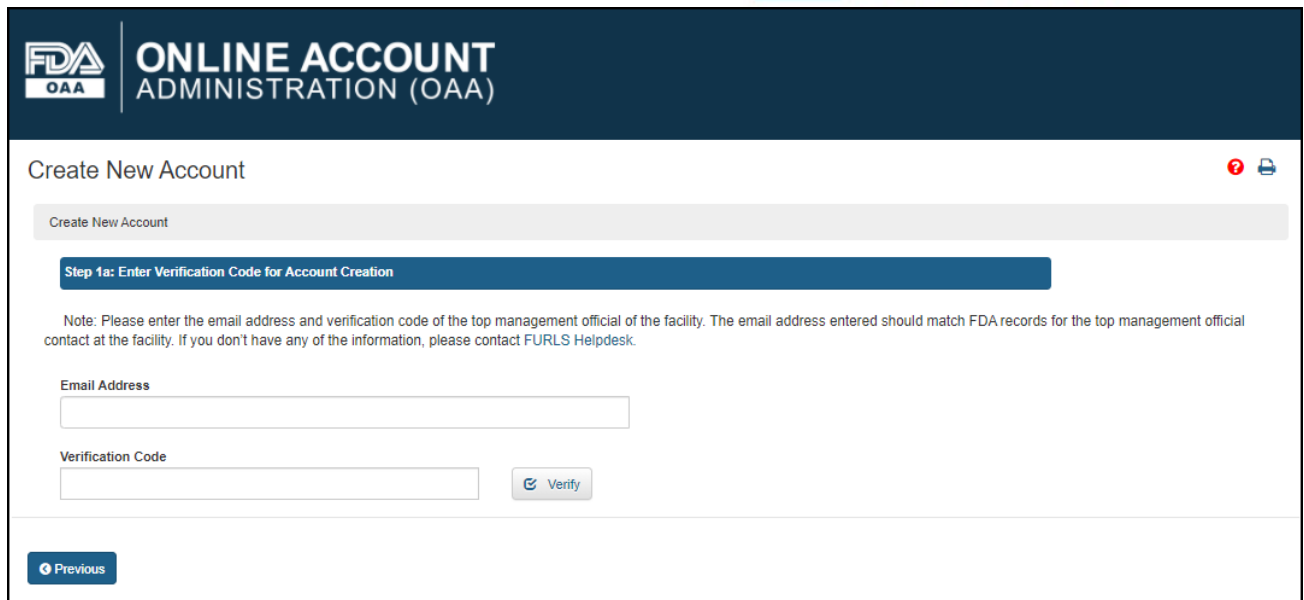
Figure 2.4 – Create New Account – Other FDA Systems

Option 2: Click on the “Create an account” link from the system-generated email you received containing the verification code. Refer to Figure 2.1.

The system will display the “Step 1a: Enter Verification Code for Account Creation” page (Figure 2.5).

Enter the verification code and click the “Verify” button. After the code is verified, you will be able to create an account for accessing the OCAR Industry Portal.

Note: The email address used to receive the verification code must be used to create new account.



FDA ONLINE ACCOUNT ADMINISTRATION (OAA)

Create New Account

Create New Account

Step 1a: Enter Verification Code for Account Creation

Note: Please enter the email address and verification code of the top management official of the facility. The email address entered should match FDA records for the top management official contact at the facility. If you don't have any of the information, please contact FURLS Helpdesk.

Email Address

Verification Code
 [Verify](#)

[Previous](#)

Figure 2.5 – Step 1a: Enter Verification Code for Account Creation

The system will display the “Step 2: Enter Your Account Information” screen (Figure 2.6). The system will pre-populate IPR’s information (i.e., “First Name”, “Last Name”, “Company Name”, “Email Address”, and “Physical Address.”) However, you will need to complete the remaining data entry fields.

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

Create New Account 🔔 📄

Create New Account

Step 2: Enter Your Account Information

<div style="background-color: #0070c0; color: white; padding: 2px; margin-bottom: 5px;">2A: Point of Contact Information</div> <p>First Name <input type="text"/></p> <p>Middle Initial (Optional) <input type="text" value="Optional"/></p> <p>Last Name / Surname <input type="text"/></p> <p>Job Title <input type="text"/></p> <p>Company Name <input type="text"/></p> <p>Web Address (Optional) <input type="text"/> <small>(Example: http://www.name.domain or http://name.domain)</small></p> <p>Phone Number</p> <table border="0" style="width: 100%; font-size: small;"> <tr> <td><input type="text" value="Country"/></td> <td><input type="text" value="Area"/></td> <td><input type="text" value="Telephone"/></td> <td><input type="text" value="Ext"/></td> </tr> <tr> <td>Country</td> <td>Area</td> <td>Phone Number</td> <td>Extension</td> </tr> </table> <p><small>Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.</small></p> <p>FAX Number (Optional)</p> <table border="0" style="width: 100%; font-size: small;"> <tr> <td><input type="text" value="Country"/></td> <td><input type="text" value="Area"/></td> <td><input type="text" value="Fax Number"/></td> </tr> <tr> <td>Country</td> <td>Area</td> <td>Fax Number</td> </tr> </table> <p>E-mail Address <input type="text"/></p> <p>Confirm E-mail Address <input type="text"/></p>	<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	<input type="text" value="Country"/>	<input type="text" value="Area"/>	<input type="text" value="Fax Number"/>	Country	Area	Fax Number	<div style="background-color: #0070c0; color: white; padding: 2px; margin-bottom: 5px;">2C: Physical Address (Business) of Account Holder</div> <p>Country / Area <input type="text" value="UNITED STATES"/></p> <p>Address Line 1 <input type="text"/></p> <p>Address Line 2 (Optional) <input type="text" value="Optional"/></p> <p>City <input type="text"/></p> <p>State / Province / Territory <input type="text" value="Florida"/></p> <p>Zip Code (Postal Code) <input type="text" value="33823"/></p> <p><small>Do you have preferred mailing address other than the physical address mentioned above?</small> <input type="radio"/> Yes <input type="radio"/> No</p>
<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												
<input type="text" value="Country"/>	<input type="text" value="Area"/>	<input type="text" value="Fax Number"/>													
Country	Area	Fax Number													

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 2.6 – Create New Account – Step 2: Enter Your Account Information

Select the “I understand” checkbox at the bottom of the page (Figure 2.7).

Click the “Continue” button after you enter the required account information.



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

I understand. 


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

Figure 2.7 – Checkbox

The “Account Review” page will display (Figure 2.8). Review the data entered to ensure it is correct.

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

FDA OAA ONLINE ACCOUNT ADMINISTRATION (OAA)

Account Information ?

[Home](#) [Create New Account](#)

Account Review

Account Information	Physical Address (Business) of Account Holder
First Name [Redacted]	Address Line 1 [Redacted]
Middle Initial [Redacted]	Address Line 2 [Redacted]
Last Name / Surname [Redacted]	City Newark
Title CEO	State / Province / Territory New Jersey
Company Name [Redacted]	Zip Code (Postal Code) 07102
Web Address [Redacted]	Country / Area UNITED STATES
Phone Number [Redacted]	
FAX Number [Redacted]	
E-mail Address [Redacted]	
Secret Question 1 What is your mother's maiden name?	
Secret Answer 1 [Redacted]	
Secret Question 2 What was your childhood nickname?	
Secret Answer 2 [Redacted]	
Secret Question 3 What is your year of birth?	
Secret Answer 3 [Redacted]	

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

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

Figure 2.8 – Account Review Page

When you click the “Submit” button, the system will display a message indicating the account was created successfully. The message displays your account ID (Figure 2.9). You must retain your account ID and password to log into the system in the future.

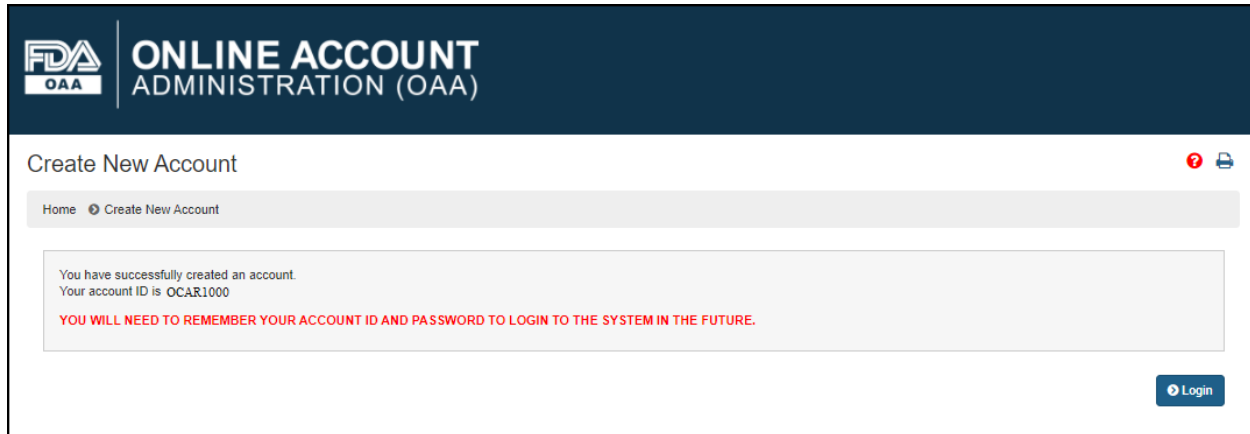


Figure 2.9 – Successful Account Creation Message

Once you create an account, you will receive an email notification (sent to the email address entered in the “Account Information” page) which contains the account ID (Figure 2.10).

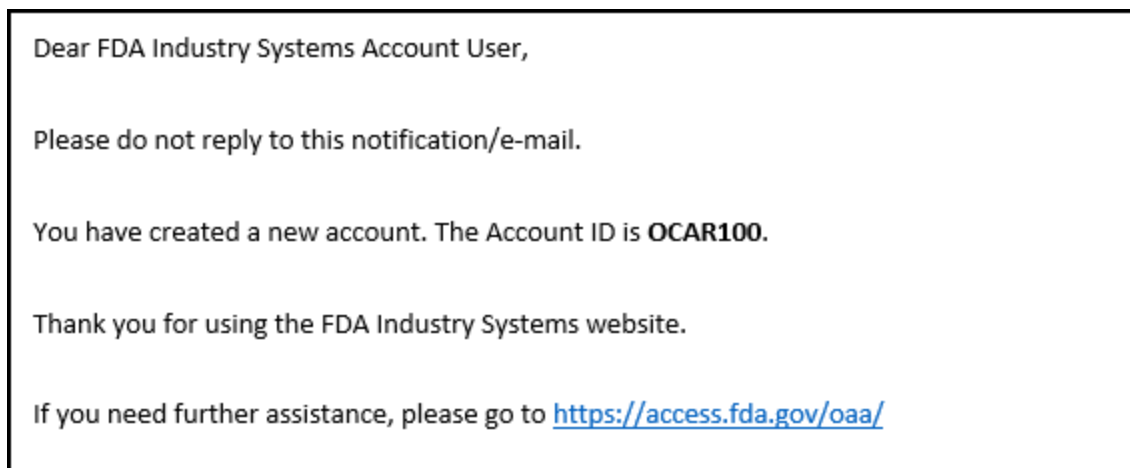


Figure 2.10 – Account Creation Confirmation Email

Click the “Login” button to access the OCAR Industry Portal (Figure 2.11). Select “Observations and Corrective Action Report (OCAR) Industry Portal” under “Other FDA Systems.” Log into the OCAR Industry Portal to ensure the information was successfully submitted to FDA.

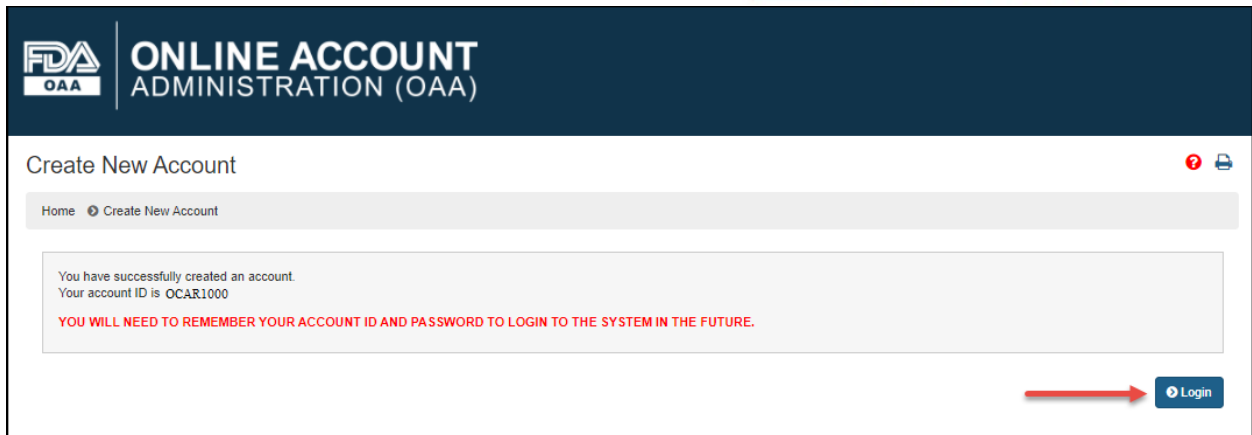


Figure 2.11 – Login

If you have previously created an FDA online account, enter your account ID and password to log in (Figure 2.12).

The screenshot shows the 'Login' page of the FDA Online Account Administration (OAA). The heading is 'Login'. Below the heading, it says 'Existing account holders, enter your account ID & password.' There are two input fields: 'Account ID' and 'Password'. Below the input fields is a disclaimer: '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.' There is a checkbox labeled 'I understand.' Below the checkbox are three buttons: 'Login', 'Forgot Account ID', and 'Forgot Password'.

Figure 2.12 – OAA Login

Update your system access by selecting the "Observations and Corrective Action Report (OCAR) Industry Portal" in the "Update System Access" tab from your "Account Management" home page (Figure 2.13).

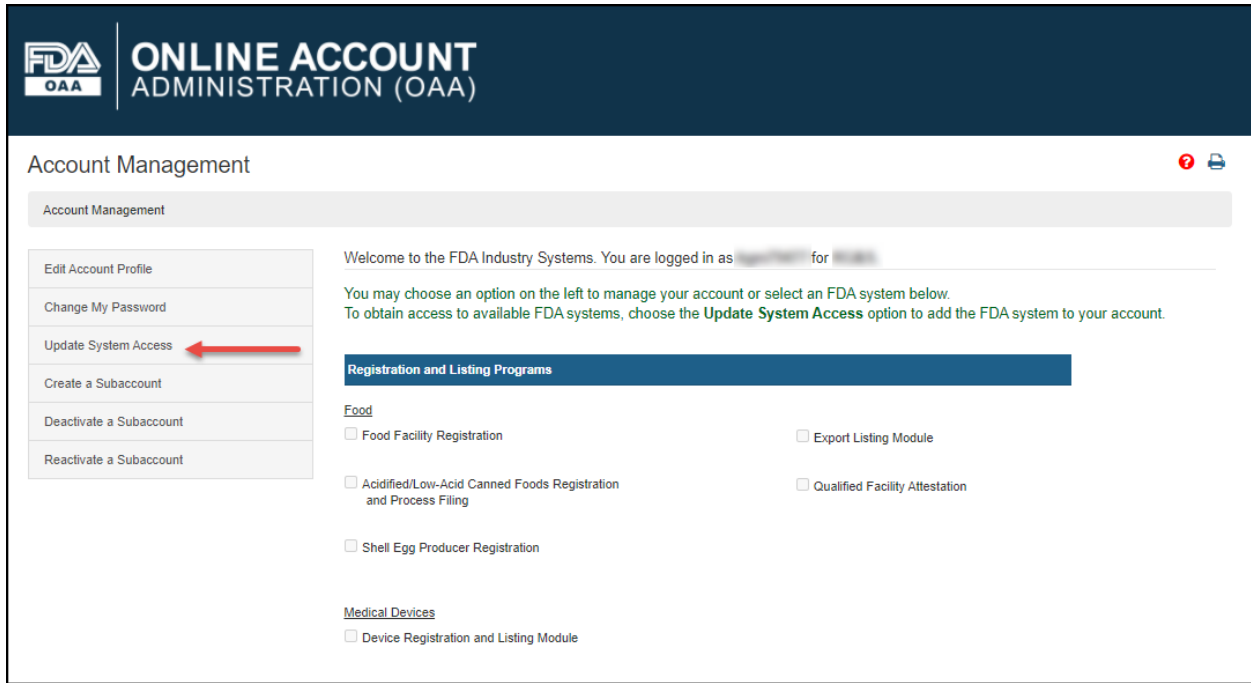


Figure 2.13 – Update System Access

You will be asked for your verification code.

Note: A verification code is required before you can update your system access to log into the OCAR Industry Portal in FURLS. Refer to Figure 2.1.

2.1 Logging into your OAA Account

After providing the requested IPR information under “Create New Account,” you will receive the final account setup details via email.

Once you log in, you may add a subaccount by selecting the “Create a Subaccount” tab from your “Account Management” home page (Figure 2.14).

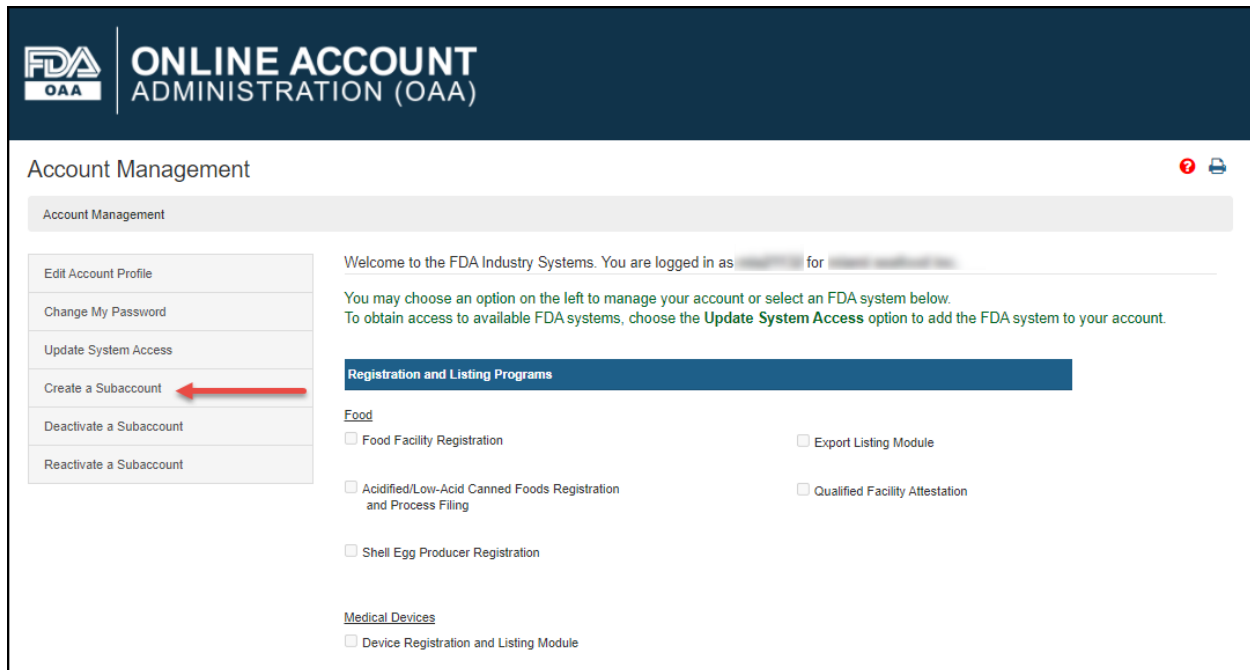


Figure 2.14 – Create a Subaccount

The system will ask for subaccount holder’s information such as “Point of Contact” and “Physical Business Address” (Figure 2.15). You must enter all the required information in the data entry fields and select “Continue” to review.

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

Account Management
?

Home ➤ Create a Subaccount

- Edit Account Profile
- Change My Password
- Update System Access
- Create a Subaccount
- Deactivate a Subaccount
- Reactivate a Subaccount

Create a Subaccount

Company Name is XXXXXXXXXXXX

Enter information for the subaccount holder.

Point of Contact Information

First Name

Middle Initial (Optional)

Last Name / Surname

Job Title

Subaccount Company Name (Optional)

Phone Number

Country Area Phone Number Extension

Phone/FAX numbers have only numbers with no spaces, dashes, periods or parentheses. Country code is not required for US phone numbers.

FAX Number (Optional)

Physical Address (Business) of Account Holder

Country / Area

Address Line 1

Address Line 2 (Optional)

City

State / Province / Territory

Zip Code (Postal Code)

Figure 2.15 – Subaccount Holder’s Information

The “Create Subaccount – Review Account Information” page will display (Figure 2.16). Review the data entered to ensure it is correct.

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

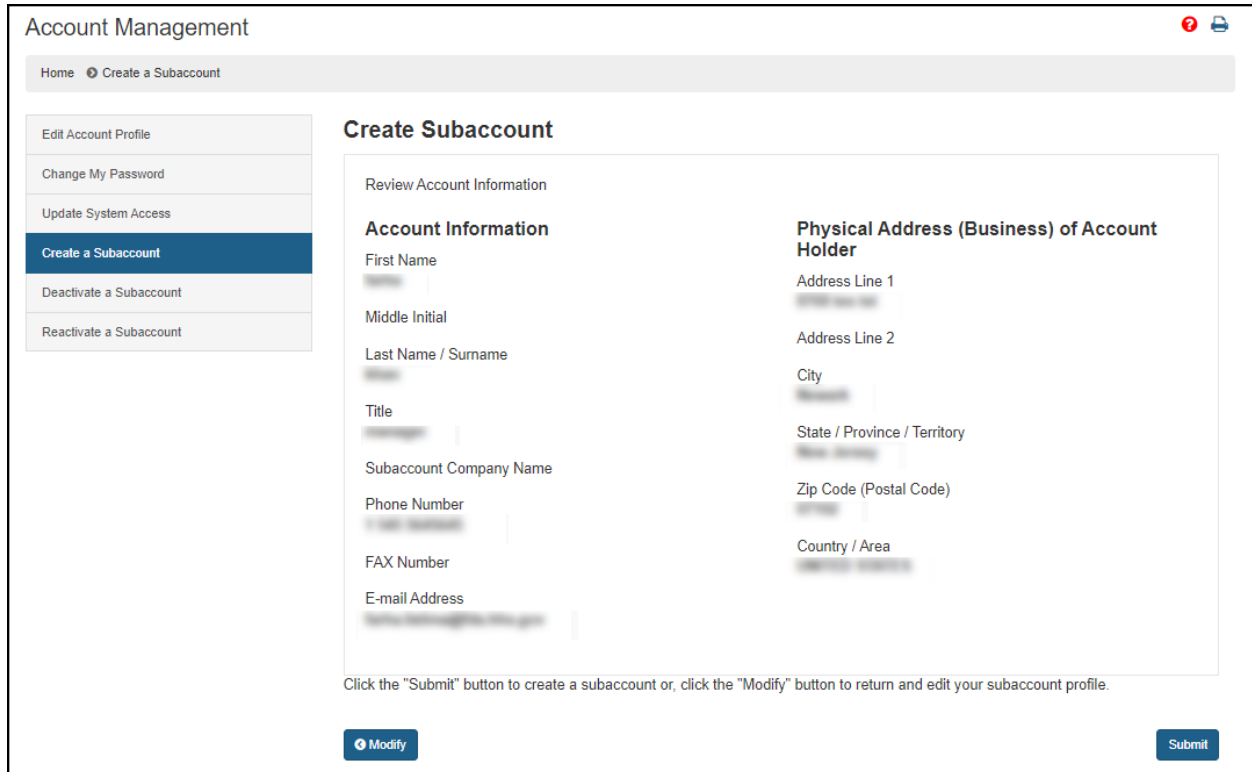


Figure 2.16 – Create Subaccount – Review Account Information Page

A subaccount ID and temporary password will be sent in two separate emails to the email account submitted (Figures 2.17 and 2.18).

Note: Subaccount ID is for the OCAR account.

Dear FDA Industry Systems Subaccount User,

Please do not reply to this notification/e-mail.

A subaccount has been created for you. The subaccount ID is [REDACTED]. For security reasons, your password has been sent in a separate notification/e-mail.

Thank you for using the FDA Industry Systems website.

If you need further assistance, please go to <https://www.access.fda.gov/>

Figure 2.17 – Subaccount ID Email Notification

Dear FDA Industry Systems Subaccount User,

Please do not reply to this notification/e-mail.

A subaccount has been created for you. For security reasons, your subaccount ID was sent in a separate notification/e-mail. The temporary password is o5A#s#3%

The temporary password will give you access to your existing account. You will be prompted for a new password. Passwords must be at least 8 characters but no more than 32, contain uppercase and lowercase letters, numbers and special characters (e.g. ;,%,\$).

Thank you for using the FDA Industry Systems website.

If you need further assistance, please go to <https://www.access.fda.gov/>

Figure 2.18 – Subaccount Temporary Password Email Notification

To access your OCAR Industry Portal subaccount, enter your account ID and temporary password under the OAA “Login” page. The system will take you to the OAA “Account Management” page where you can view your account ID, change your password, update your system access, and create security questions for logging in. You will then be able to scroll down to the “Other FDA Systems” section and select the “Observations and Corrective Action Report (OCAR) Industry Portal” link (Figure 2.19).



ONLINE ACCOUNT ADMINISTRATION (OAA)

Account Management



Account Management

Edit Account Profile

Change My Password

Update System Access

Create a Subaccount

Deactivate a Subaccount

Reactivate a Subaccount

Welcome to the FDA Industry Systems. You are logged in as [redacted] for [redacted]

You may choose an option on the left to manage your account or select an FDA system below.

To obtain access to available FDA systems, choose the **Update System Access** option to add the FDA system to your account.

Registration and Listing Programs

Food

- Food Facility Registration
- Export Listing Module
- Acidified/Low-Acid Canned Foods Registration and Process Filing
- Qualified Facility Attestation
- Shell Egg Producer Registration

Medical Devices

- Device Registration and Listing Module

Export Certification and Tracking

- Biologics Export Certification Application and Tracking System (BECATS)
- CDER Export Certification Application and Tracking System (CDER eCATS)
- CDRH Export Certification Application and Tracking System (CECATS)
- CFSAN Export Certification Application and Tracking System (CFSAN eCATS)
- CVM Export Certification Application and Tracking System (CVM eCATS)

FSMA Program(s)

- Accredited Third-Party Certification Program-- Accreditation Body
- Laboratory Accreditation for Analyses of Foods Program-- Accreditation Body
- Accredited Third-Party Certification Program-- Certification Body
- Laboratory Accreditation for Analyses of Foods Program-- Accredited Lab
- FSVP Importer Portal for FSVP Records Submission
- Voluntary Qualified Importer Program

Other FDA Systems

- Prior Notice System Interface
- Systems Recognition & Regulatory Partnership Program
- Import Trade Auxiliary Communication System (ITACS)
- CBER Biological Product Deviation Reporting (CBER eBPDR)
- Observations and Corrective Action Report (OCAR) Industry Portal



Figure 2.19 – Account Management Page

3 Making Submissions in the OCAR Industry Portal

As an OCAR Industry Portal user you will be directed to the “Home” page, which outlines frequently asked questions to assist you in navigating the Portal. The left navigation menu displays “Certification Agreement” (Figure 3.1).

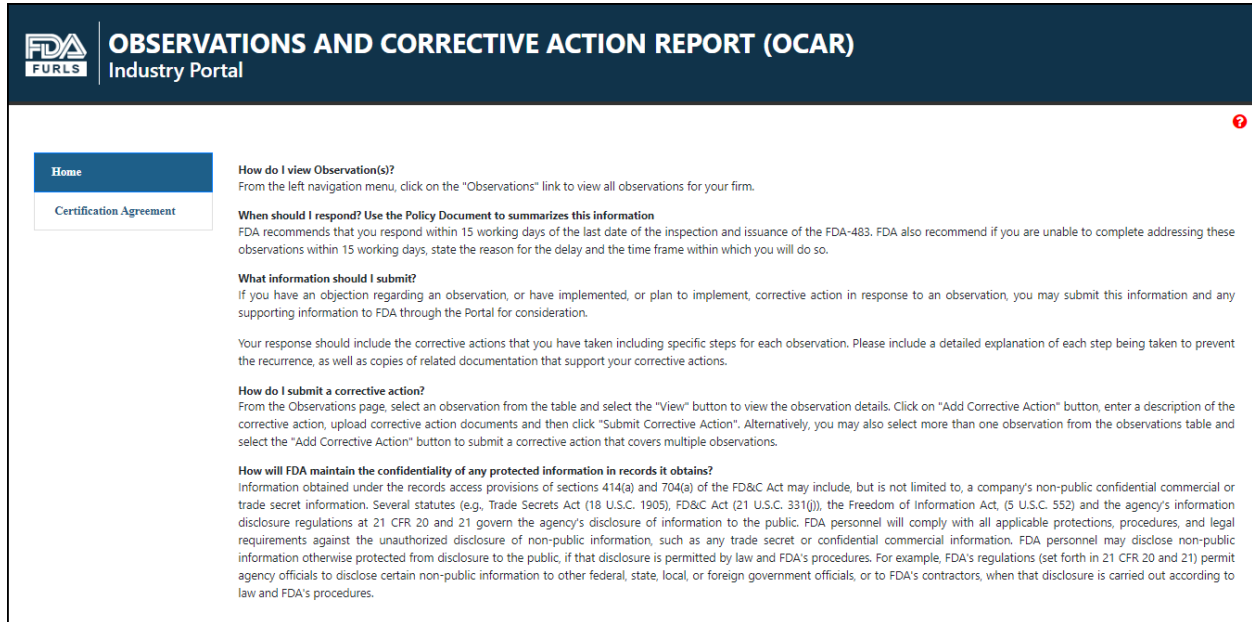
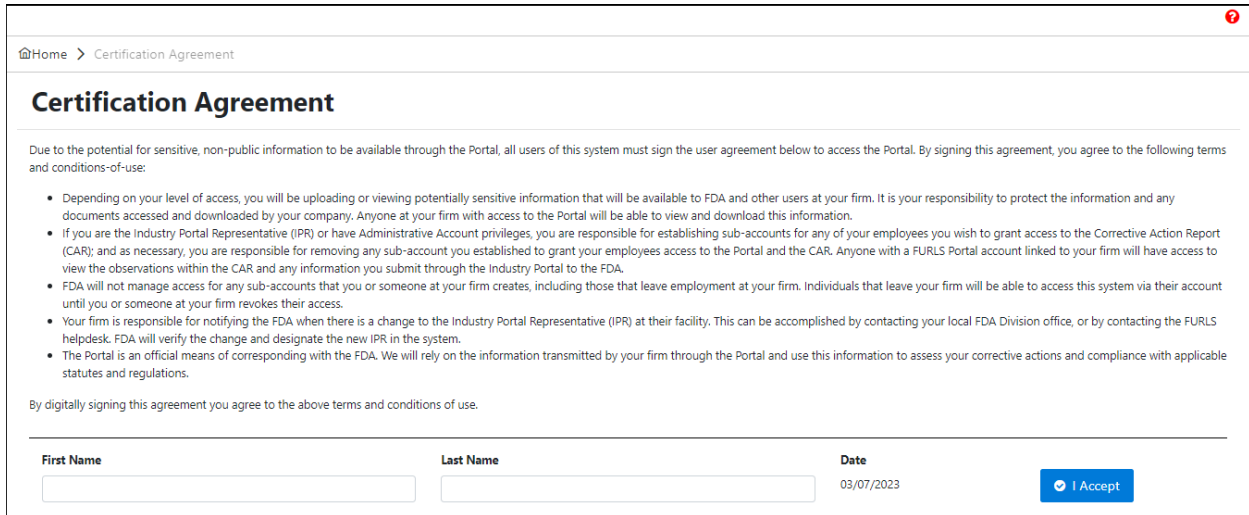


Figure 3.1 – OCAR Industry Portal Home Page

Click “Certification Agreement” from the navigation menu to proceed. The system will direct you to the “Certification Agreement” page (Figure 3.2). Complete the required fields and click the “I Accept” button.



Home > Certification Agreement

Certification Agreement

Due to the potential for sensitive, non-public information to be available through the Portal, all users of this system must sign the user agreement below to access the Portal. By signing this agreement, you agree to the following terms and conditions-of-use:

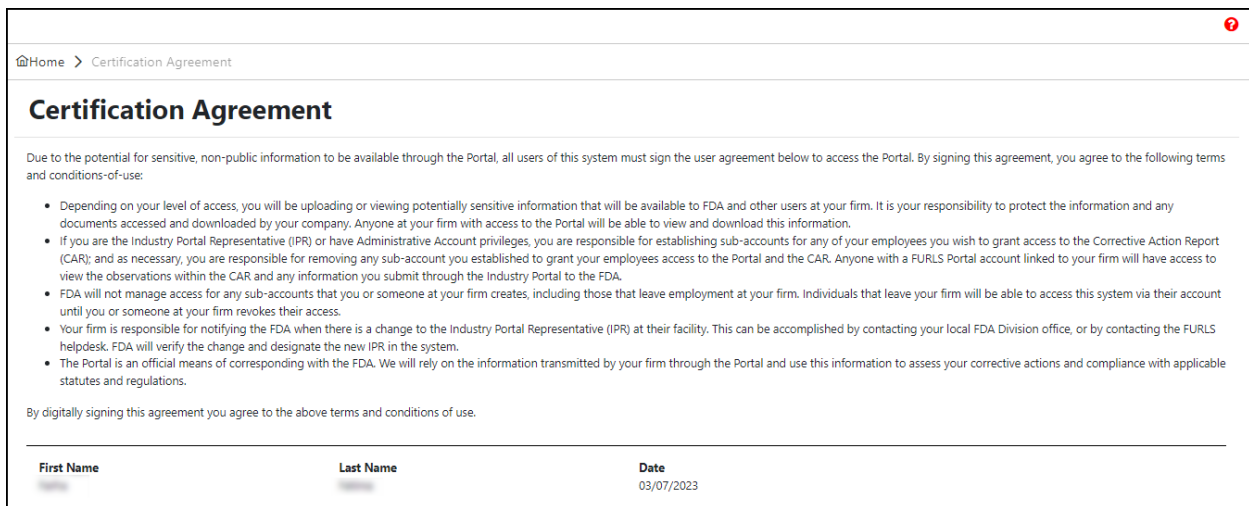
- Depending on your level of access, you will be uploading or viewing potentially sensitive information that will be available to FDA and other users at your firm. It is your responsibility to protect the information and any documents accessed and downloaded by your company. Anyone at your firm with access to the Portal will be able to view and download this information.
- If you are the Industry Portal Representative (IPR) or have Administrative Account privileges, you are responsible for establishing sub-accounts for any of your employees you wish to grant access to the Corrective Action Report (CAR); and as necessary, you are responsible for removing any sub-account you established to grant your employees access to the Portal and the CAR. Anyone with a FURLS Portal account linked to your firm will have access to view the observations within the CAR and any information you submit through the Industry Portal to the FDA.
- FDA will not manage access for any sub-accounts that you or someone at your firm creates, including those that leave employment at your firm. Individuals that leave your firm will be able to access this system via their account until you or someone at your firm revokes their access.
- Your firm is responsible for notifying the FDA when there is a change to the Industry Portal Representative (IPR) at their facility. This can be accomplished by contacting your local FDA Division office, or by contacting the FURLS helpdesk. FDA will verify the change and designate the new IPR in the system.
- The Portal is an official means of corresponding with the FDA. We will rely on the information transmitted by your firm through the Portal and use this information to assess your corrective actions and compliance with applicable statutes and regulations.

By digitally signing this agreement you agree to the above terms and conditions of use.

First Name: Last Name: Date: 03/07/2023

Figure 3.2 – Certification Agreement Page

Once the acknowledgement is complete, the system will update the “Certification Agreement” page with the completed information and display the OCAR Industry Portal “Home” page (Figure 3.3).



Home > Certification Agreement

Certification Agreement

Due to the potential for sensitive, non-public information to be available through the Portal, all users of this system must sign the user agreement below to access the Portal. By signing this agreement, you agree to the following terms and conditions-of-use:

- Depending on your level of access, you will be uploading or viewing potentially sensitive information that will be available to FDA and other users at your firm. It is your responsibility to protect the information and any documents accessed and downloaded by your company. Anyone at your firm with access to the Portal will be able to view and download this information.
- If you are the Industry Portal Representative (IPR) or have Administrative Account privileges, you are responsible for establishing sub-accounts for any of your employees you wish to grant access to the Corrective Action Report (CAR); and as necessary, you are responsible for removing any sub-account you established to grant your employees access to the Portal and the CAR. Anyone with a FURLS Portal account linked to your firm will have access to view the observations within the CAR and any information you submit through the Industry Portal to the FDA.
- FDA will not manage access for any sub-accounts that you or someone at your firm creates, including those that leave employment at your firm. Individuals that leave your firm will be able to access this system via their account until you or someone at your firm revokes their access.
- Your firm is responsible for notifying the FDA when there is a change to the Industry Portal Representative (IPR) at their facility. This can be accomplished by contacting your local FDA Division office, or by contacting the FURLS helpdesk. FDA will verify the change and designate the new IPR in the system.
- The Portal is an official means of corresponding with the FDA. We will rely on the information transmitted by your firm through the Portal and use this information to assess your corrective actions and compliance with applicable statutes and regulations.


By digitally signing this agreement you agree to the above terms and conditions of use.

First Name: Last Name: Date: 03/07/2023

Figure 3.3 – Certification Agreement Page After “I Accept” Selection

The system will display the updated “Home” page, with additional options displayed in the left navigation menu (Figure 3.4):

- Manage Sub-Accounts
- Observations


OBSERVATIONS AND CORRECTIVE ACTION REPORT (OCAR)
 Industry Portal

Home
Certification Agreement
Manage Sub-Accounts
Observations 7

How do I view Observation(s)?
 From the left navigation menu, click on the "Observations" link to view all observations for your firm.

When should I respond? Use the Policy Document to summarize this information
 FDA recommends that you respond within 15 working days of the last date of the inspection and issuance of the FDA-483. FDA also recommend if you are unable to complete addressing these observations within 15 working days, state the reason for the delay and the time frame within which you will do so.

What information should I submit?
 If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may submit this information and any supporting information to FDA through the Portal for consideration.

Your response should include the corrective actions that you have taken including specific steps for each observation. Please include a detailed explanation of each step being taken to prevent the recurrence, as well as copies of related documentation that support your corrective actions.

How do I submit a corrective action?
 From the Observations page, select an observation from the table and select the "View" button to view the observation details. Click on "Add Corrective Action" button, enter a description of the corrective action, upload corrective action documents and then click "Submit Corrective Action". Alternatively, you may also select more than one observation from the observations table and select the "Add Corrective Action" button to submit a corrective action that covers multiple observations.

How will FDA maintain the confidentiality of any protected information in records it obtains?
 Information obtained under the records access provisions of sections 414(a) and 704(a) of the FD&C Act may include, but is not limited to, a company's non-public confidential commercial or trade secret information. Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), FD&C Act (21 U.S.C. 331(j)), the Freedom of Information Act, (5 U.S.C. 552) and the agency's information disclosure regulations at 21 CFR 20 and 21 govern the agency's disclosure of information to the public. FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as any trade secret or confidential commercial information. FDA personnel may disclose non-public information otherwise protected from disclosure to the public, if that disclosure is permitted by law and FDA's procedures. For example, FDA's regulations (set forth in 21 CFR 20 and 21) permit agency officials to disclose certain non-public information to other federal, state, local, or foreign government officials, or to FDA's contractors, when that disclosure is carried out according to law and FDA's procedures.

Figure 3.4 – OCAR Home Page with Additional Menu Options

3.1 Viewing Observation Details and Adding Corrective Actions

Click “Observations” from the navigation menu to proceed. The system will direct you to the “Observations” page. The “Observations” page lists all observations assigned to the FDA Establishment Identification (FEI) number associated with your firm’s name and address (Figure 3.5).

Note: You have the option to search observation information based on date, status, etc.

Observations

FEI Number: [Redacted] Firm Name: [Redacted] Firm Address: [Redacted] Number of Observations: **3** Open Observations: **3**

The table below displays the list of Observation(s) for the FEI [Redacted]. Use the checkbox(es) to select the observation(s) to add a corrective action. You can view the details of an observation by clicking on the icon.

Search Observations Data: [Reload Observations](#) [Add Corrective Action](#)

<input type="checkbox"/>	Details	Correction Status	Category	Citation Text	Specifics	Date Created
<input type="checkbox"/>	View	Not Corrected	Approved supplier procedures - importer established	You did not establish written procedures to ensure that you import foods only from approved foreign suppliers.	Specifically, [Redacted]	03/09/2021
<input type="checkbox"/>	View	Pending Review	Evaluation - performance, risk	You did not document that you conducted an evaluation or reviewed and assessed an evaluation conducted by another entity to determine a foreign supplier's performance.	Specifically,	03/09/2021
<input type="checkbox"/>	View	Pending Review	Conflict of interest	A qualified individual's financial conflict of interest influenced the results of a foreign supplier verification activity.	Specifically,	03/09/2021

Figure 3.5 – Observations Page

The “Details” column displays a “View” button (Figure 3.6). Clicking the View button opens the Observation Details Screen, as further described in 3.9 below.

Search Observations Data: [Reload Observations](#) [Add Corrective Action](#)

<input type="checkbox"/>	Details	Correction Status	Category	Citation Text	Specifics	Date Created
<input type="checkbox"/>	View	Not Corrected	Approved supplier procedures - importer established	You did not establish written procedures to ensure that you import foods only from approved foreign suppliers.	Specifically, [Redacted]	03/09/2021
<input type="checkbox"/>	View	Pending Review	Evaluation - performance, risk	You did not document that you conducted an evaluation or reviewed and assessed an evaluation conducted by another entity to determine a foreign supplier's performance.	Specifically,	03/09/2021
<input type="checkbox"/>	View	Pending Review	Conflict of interest	A qualified individual's financial conflict of interest influenced the results of a foreign supplier verification activity.	Specifically,	03/09/2021

Figure 3.6 – Observations Page – View Observation Details

To view descriptions of the “Correction Status” listed in the table, use your mouse to hover over the corresponding status displayed under the "Correction Status" column (Figure 3.7).

<input type="text" value="Search Observations Data"/> Reload Observations Add Corrective Action						
<input type="checkbox"/>	Details	Correction Status ↑↓	Category ↑↓	Citation Text ↑↓	Specifics ↑↓	Date Created ↑↓
<input type="checkbox"/>	View	Pending Review	Requirements	You did not establish records documenting the training of principles of animal food hygiene and animal food safety for individuals engaged in the manufacturing, processing, packing or holding of animal food.	Specifically, [redacted]	03/21/2023

A corrective action has been submitted by the firm and FDA has 1) not reviewed or 2) has not completed the review and assessment of the firm's corrective actions.

Figure 3.7 – Observations Page – Correction Status Tooltip

Once you select an observation by selecting its checkbox, the “Add Corrective Action” button will be enabled (Figure 3.8).

Note: You may also select more than one observation from the Observations table and click the “Add Corrective Action” button to submit a corrective action that covers multiple observations.

<input type="text" value="Search Observations Data"/> Reload Observations Add Corrective Action						
<input type="checkbox"/>	Details	Correction Status ↑↓	Category ↑↓	Citation Text ↑↓	Specifics ↑↓	Date Created ↑↓
<input checked="" type="checkbox"/>	View	Not Corrected	Approved supplier procedures - importer established	You did not establish written procedures to ensure that you import foods only from approved foreign suppliers.	Specifically, [redacted]	03/09/2021
<input type="checkbox"/>	View	Pending Review	Evaluation - performance, risk	You did not document that you conducted an evaluation or reviewed and assessed an evaluation conducted by another entity to determine a foreign supplier's performance.	Specifically, [redacted]	03/09/2021
<input type="checkbox"/>	View	Pending Review	Conflict of interest	A qualified individual's financial conflict of interest influenced the results of a foreign supplier verification activity.	Specifically, [redacted]	03/09/2021

Figure 3.8 – Observations Page – Add Corrective Action

Click the “View” button to display the “Observation Details” page (Figure 3.9).

Home > Observations > Observation Details

Observation Details

Correction Status Pending Review	Category Record Requirements	Printed on 483/4056 Yes	Date Created 05/25/2022
--	--	-----------------------------------	-----------------------------------

Citation Text
You did not establish records documenting the training of principles of animal food hygiene and animal food safety for individuals engaged in the manufacturing, processing, packing or holding of animal food.

Specifics
Specifically, [REDACTED]

Observations [Add Corrective Action](#)

Details	Attachment(s)	Date Added	Created By	Description of Corrective Action(s)
		05/25/2022	[REDACTED]	[REDACTED]
		05/27/2022	FDA	This is a comment made in Field Check to note that the Federal Comment Indicator requirement is different online. The Federal Comment should be associated with a TC value.

[Return to Observations](#)

Figure 3.9 – Observations Details Page After Selecting View Button

The “Observation Details” page will display the “Observation Details” section and a table that lists all the corrective actions sent by the Firm and those entered by FDA (Figure 3.10).

Home > Observations > Observation Details

Observation Details

Correction Status Pending Review	Category Record Requirements	Printed on 483/4056 Yes	Date Created 05/25/2022
--	--	-----------------------------------	-----------------------------------

Citation Text
You did not establish records documenting the training of principles of animal food hygiene and animal food safety for individuals engaged in the manufacturing, processing, packing or holding of animal food.

Specifics
Specifically, [REDACTED]

Observations [Add Corrective Action](#)

Details	Attachment(s)	Date Added	Created By	Description of Corrective Action(s)
		05/25/2022	[REDACTED]	[REDACTED]
		05/27/2022	FDA	This is a comment made in Field Check to note that the Federal Comment Indicator requirement is different online. The Federal Comment should be associated with a TC value.

[Return to Observations](#)

Figure 3.10 – Observation Details Page – Corrective Actions

Click the “Add Corrective Action” button on the “Observation Details” page to add attachment(s) (Figure 3.11).

Home > Observations > Observation Details


Observation Details

Correction Status Pending Review	Category Record Requirements	Printed on 483/4056 Yes	Date Created 05/25/2022
--	--	-----------------------------------	-----------------------------------

Citation Text
You did not establish records documenting the training of principles of animal food hygiene and animal food safety for individuals engaged in the manufacturing, processing, packing or holding of animal food.

Specifics
Specifically, [REDACTED]

Observations

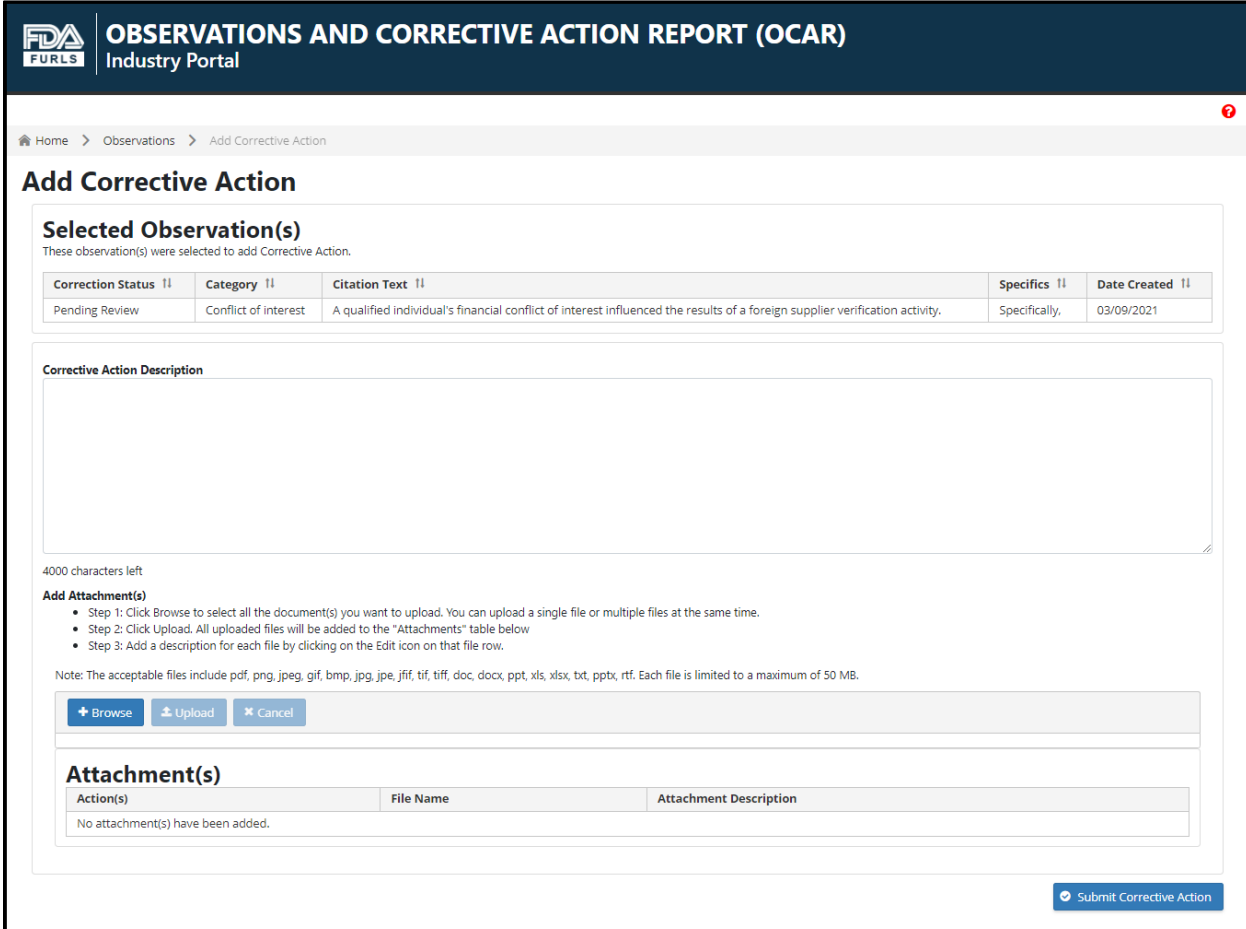

[+ Add Corrective Action](#)

Details	Attachment(s)	Date Added	Created By	Description of Corrective Action(s)
		05/25/2022	[REDACTED]	[REDACTED]
		05/27/2022	FDA	This is a comment made in Field Check to tell you the Federal Comment Indicator requirement is different online. The Federal Comment should be completed with a "Y" value.

[+ Return to Observations](#)

Figure 3.11 – Observation Details Page – Add Corrective Action Button

On the “Add Corrective Action” page, the “Corrective Action Description” and an uploaded document with attachment details are required in order to submit for FDA’s review (Figure 3.12). Your response should include the corrective actions you have taken, including specific steps for each observation. Include a detailed explanation of each step taken to prevent the recurrence, as well as copies of related documentation which support your corrective actions.



Selected Observation(s)
These observation(s) were selected to add Corrective Action.

Correction Status	Category	Citation Text	Specifics	Date Created
Pending Review	Conflict of Interest	A qualified individual's financial conflict of interest influenced the results of a foreign supplier verification activity.	Specifically,	03/09/2021

Corrective Action Description

4000 characters left

Add Attachment(s)

- Step 1: Click Browse to select all the document(s) you want to upload. You can upload a single file or multiple files at the same time.
- Step 2: Click Upload. All uploaded files will be added to the “Attachments” table below.
- Step 3: Add a description for each file by clicking on the Edit icon on that file row.

Note: The acceptable files include pdf, png, jpeg, gif, bmp, jpg, jpe, jfif, tif, tiff, doc, docx, ppt, xls, xlsx, txt, pptx, rtf. Each file is limited to a maximum of 50 MB.

+ Browse Upload Cancel

Attachment(s)

Action(s)	File Name	Attachment Description
No attachment(s) have been added.		

Submit Corrective Action

Figure 3.12 – Add Corrective Action Page

Note: You will not be able to update the attachment description or delete the uploaded document once it has been submitted to FDA.

Once you click the “Submit Corrective Action” button, the system will then notify FDA of your response and display the “Confirmation” page (Figure 3.13).

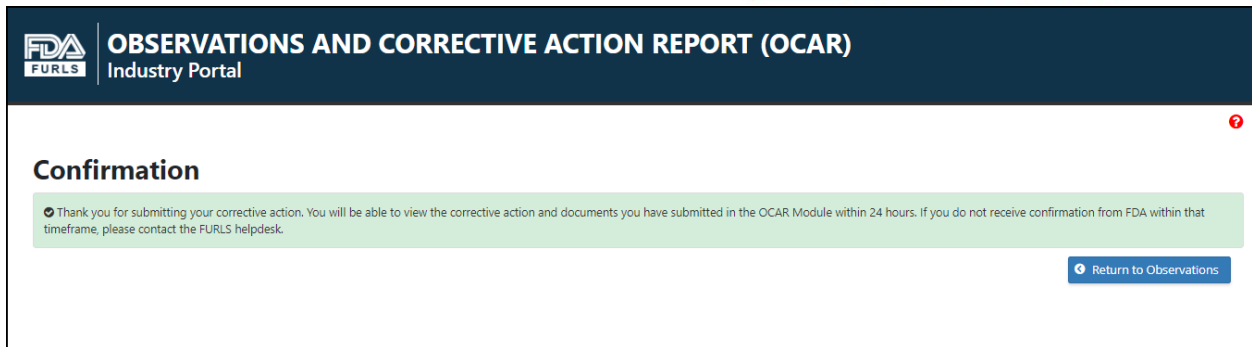


Figure 3.13 – Confirmation Page

Post-submission, ensure you uploaded and submitted all your OCAR records by navigating back to the “Observation Details” page to confirm all your documents are available. You can open/view the submitted attachment(s) by clicking on the document link in the “Attachment(s)” column and downloading from the “Attachment Details” pop-up on the “Observation Details” page (Figure 3.14).

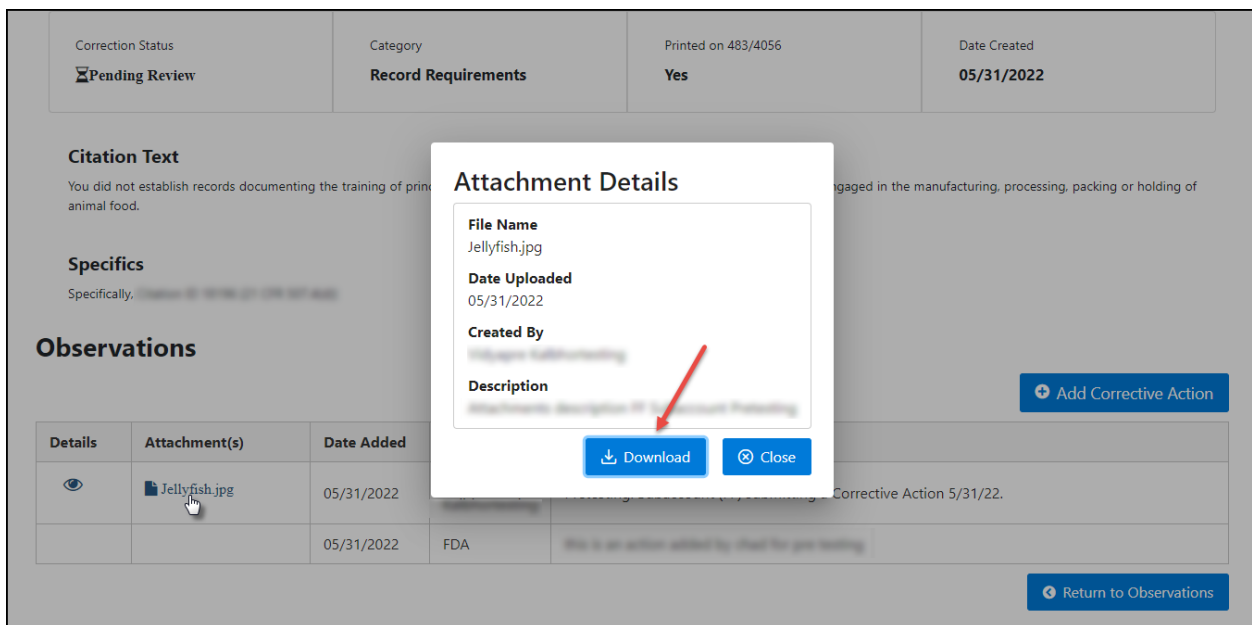


Figure 3.14 – Observation Details Page – View Corrective Action Attachments

Select the “Comments” icon from the details column to display the “FDA Comments Regarding Corrective Actions Submitted” pop-up (Figure 3.15). Once FDA has completed review of the corrective actions that have been submitted, any comments from FDA will be communicated via the portal and displayed in this pop-up.

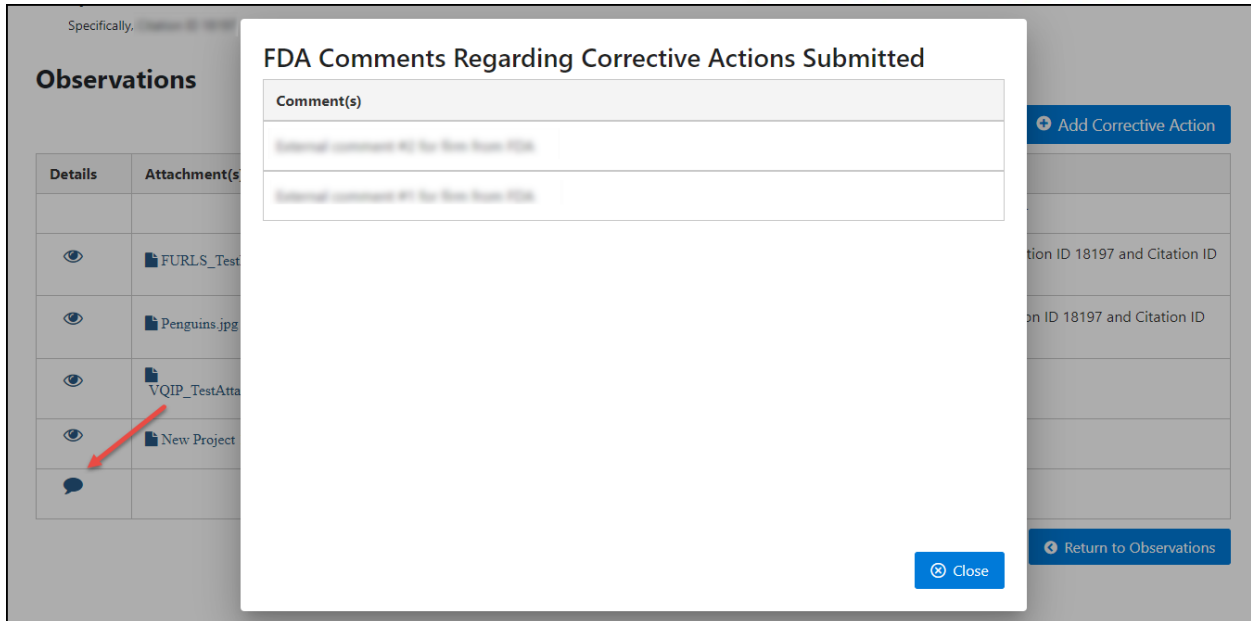


Figure 3.15 – Observation Details Page – FDA Comments Pop-up when Comments Icon is Selected

3.2 Managing Subaccounts

Once the subaccount has been created by the IPR, the IPR must grant access to the associated subaccount(s); refer to Figure 2.14. To grant access, log into the OCAR Industry Portal and navigate to the “Home” page. Select “Manage Sub-Accounts” on the left navigation menu to edit subaccount access by updating a role to one of the following (Figure 3.16):

- No Access – Cannot view observations or any documentation sent back and forth (default role when a subaccount is created)
- Read-Only – Can view observation details but cannot submit documentation
- Full Access – Can view observation details and submit documentation

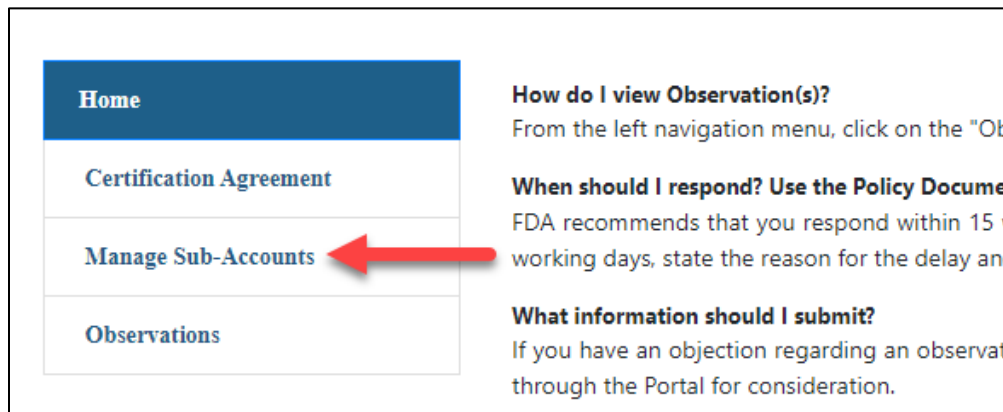


Figure 3.16 – Manage Sub-Accounts Menu Option

Selecting the “Account Admin” checkbox will grant the corresponding subaccount the privilege to manage or change a role for other subaccounts (Figure 3.17).

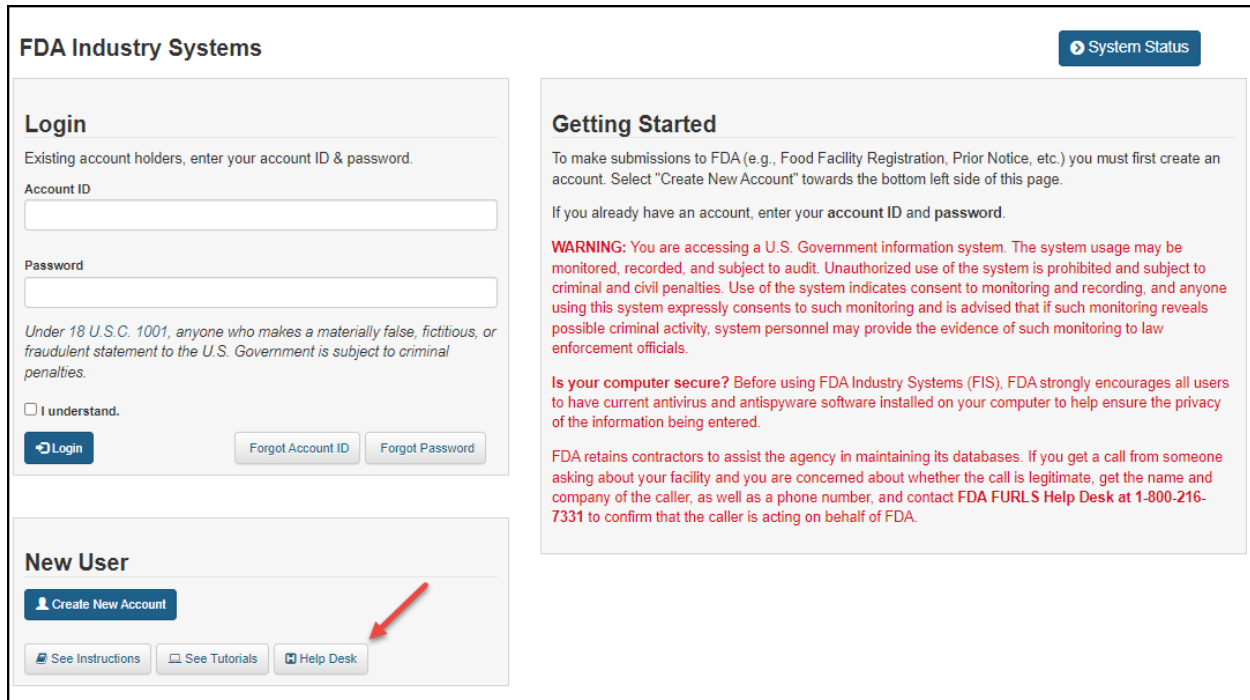


Figure 3.17 – Manage Sub-Accounts Page

Once the IPR activates the OCAR Industry Portal account for the subaccount, FDA will send an email notification to the corresponding subaccount member(s).

4 Troubleshooting Technical Issues in the FURLS Portal

If you encounter a technical issue that cannot be resolved using this document, you may reach out to the FURLS Help Desk for assistance. Click the “Help Desk” button on the “Login” page (Figure 4.1).



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 Account ID](#) [Forgot 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**.

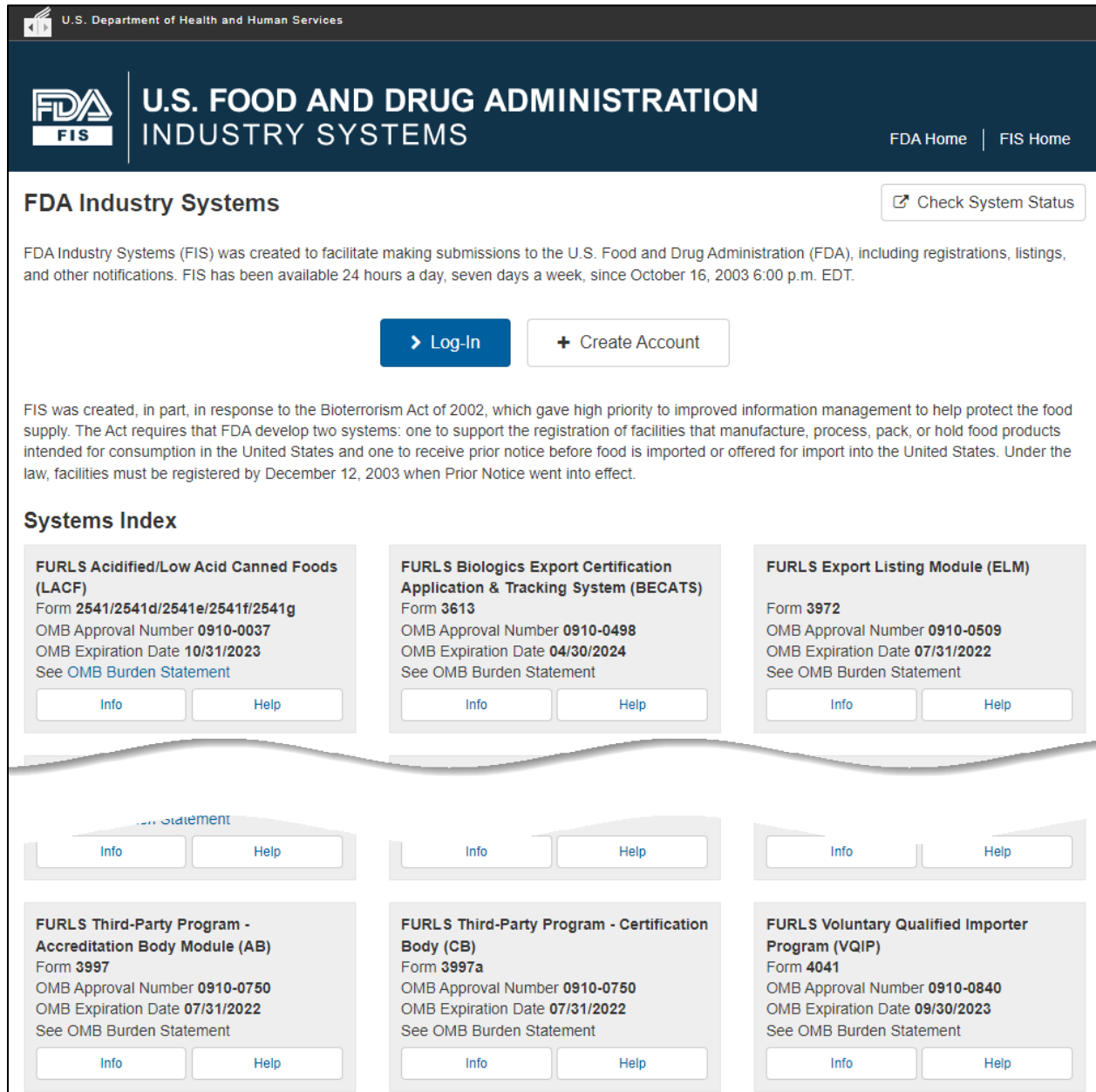
WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using 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 4.1 – FURLS Help Desk Button

Scroll down to select the applicable system from the “Systems Index” section (Figure 4.2).



FDA Industry Systems [Check System Status](#)

FDA Industry Systems (FIS) was created to facilitate making submissions to the U.S. Food and Drug Administration (FDA), including registrations, listings, and other notifications. FIS has been available 24 hours a day, seven days a week, since October 16, 2003 6:00 p.m. EDT.

[Log-In](#) [Create Account](#)

FIS was created, in part, in response to the Bioterrorism Act of 2002, which gave high priority to improved information management to help protect the food supply. The Act requires that FDA develop two systems: one to support the registration of facilities that manufacture, process, pack, or hold food products intended for consumption in the United States and one to receive prior notice before food is imported or offered for import into the United States. Under the law, facilities must be registered by December 12, 2003 when Prior Notice went into effect.

Systems Index

<p>FURLS Acidified/Low Acid Canned Foods (LACF) Form 2541/2541d/2541e/2541f/2541g OMB Approval Number 0910-0037 OMB Expiration Date 10/31/2023 See OMB Burden Statement</p> <p>Info Help</p>	<p>FURLS Biologics Export Certification Application & Tracking System (BECATS) Form 3613 OMB Approval Number 0910-0498 OMB Expiration Date 04/30/2024 See OMB Burden Statement</p> <p>Info Help</p>	<p>FURLS Export Listing Module (ELM) Form 3972 OMB Approval Number 0910-0509 OMB Expiration Date 07/31/2022 See OMB Burden Statement</p> <p>Info Help</p>
<p>FURLS Third-Party Program - Accreditation Body Module (AB) Form 3997 OMB Approval Number 0910-0750 OMB Expiration Date 07/31/2022 See OMB Burden Statement</p> <p>Info Help</p>	<p>FURLS Third-Party Program - Certification Body (CB) Form 3997a OMB Approval Number 0910-0750 OMB Expiration Date 07/31/2022 See OMB Burden Statement</p> <p>Info Help</p>	<p>FURLS Voluntary Qualified Importer Program (VQIP) Form 4041 OMB Approval Number 0910-0840 OMB Expiration Date 09/30/2023 See OMB Burden Statement</p> <p>Info Help</p>

Figure 4.2 – Systems Index Section

Scroll towards the bottom of the page to the “Help Desk” section to find the contact information for technical assistance (Figure 4.3).

Help Desk

FDA Industry Systems / FDA Unified Registration and Listing Systems (FURLS) / Technical Help
Electronic Submissions Gateway Approved Production Transaction Partners, Food Facility Registration Module, Low Acid & Acidified Canned Foods, and Account Management.

Phone: 1-800-216-7331 or 240-247-8804 9:00 a.m.- 6:00 p.m. Eastern Time
Fax: 301-436-2804 or 1-866-573-0846
To e-mail questions about the Bioterrorism Act [use this form](#)

[Account Management Help](#) [Electronic Submissions Gateway Help](#)

Effective January 14, 2004: The FDA Industry System Help Desk is available for technical assistance with online registration and listing systems, and regulated electronic submissions on U.S. Government business days (Monday to Friday, excluding U.S. government holidays) from 9:00 a.m.- 6:00 p.m. Eastern Time (see [Federal Holidays](#) and [Federal Government Operating Status](#)).

You may leave a message or send e-mail at other times. These will be addressed on the next business day.

Prior Notice / Policy Help
Phone: 1-866-521-2297

The Prior Notice Center staff can answer questions about Prior Notice policies, procedures, system navigation, and interpretations 24 hours a day, 7 days a week.

Electronic Submissions Gateway / Pre-Production Help

If you want to become a trading partner, or have a question about becoming a trading partner, for the Electronic Submissions Gateway, please visit the [FDA Electronic Submissions Gateway](#)






Figure 4.3 – FURLS Help Desk Contact Information

APPENDIX A: Abbreviations

OCAR	Observations and Corrective Action Report
CAR	Corrective Action Report
CFSAN	Center for Food Safety and Applied Nutrition
FDA	U.S. Food and Drug Administration
OAA	Online Account Administration
FURLS	FDA's Unified Registration and Listing System
FIS	FDA Industry Systems
ORA	Office of Regulatory Affairs
FEI	FDA Establishment Identification
FSMA	Food Safety Modernization Act
IPR	Industry Portal Representative

APPENDIX B: Icon Behavior

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

Icon Description	Icon	System Function
Magnifying Glass		Search the selected item.
Eye		View the associated item.
Comment		View comment(s).
Help		View the User Guide.
Printer		Print the associated item.