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:

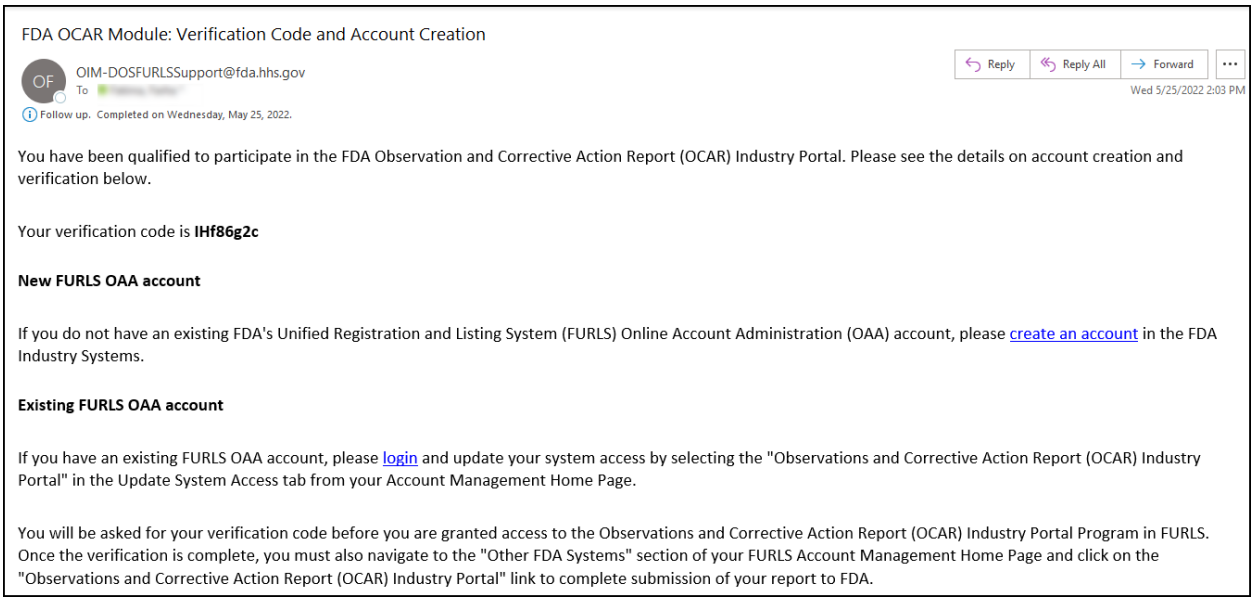
- Microsoft Edge
- Google Chrome

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/oaa/. 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).



FDA OCAR Module: Verification Code and Account Creation

OF OIM-DOSFURLSSupport@fda.hhs.gov
To [redacted]
Follow up. Completed on Wednesday, May 25, 2022.

Reply | Reply All | Forward | ...
Wed 5/25/2022 2:03 PM

You have been qualified to participate in the FDA Observation and Corrective Action Report (OCAR) Industry Portal. Please see the details on account creation and verification below.

Your verification code is **IHf86g2c**

New FURLS OAA account

If you do not have an existing FDA's Unified Registration and Listing System (FURLS) Online Account Administration (OAA) account, please create an account in the FDA Industry Systems.

Existing FURLS OAA account

If you have an existing FURLS OAA account, please login and 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.

You will be asked for your verification code before you are granted access to the Observations and Corrective Action Report (OCAR) Industry Portal Program in FURLS. Once the verification is complete, you must also navigate to the "Other FDA Systems" section of your FURLS Account Management Home Page and click on the "Observations and Corrective Action Report (OCAR) Industry Portal" link to complete submission of your report to FDA.

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/oaa/. 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.

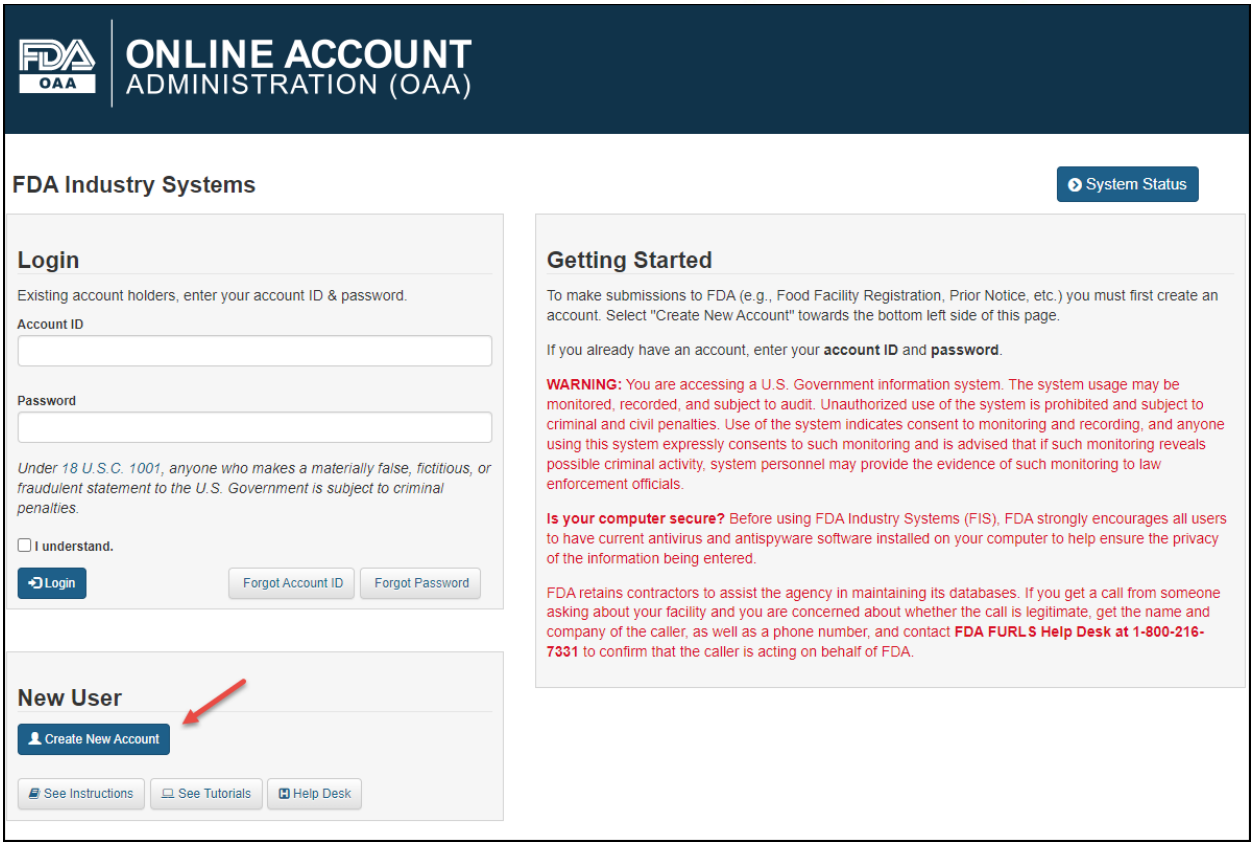


Figure 2.2 – FDA OAA Login Page

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.

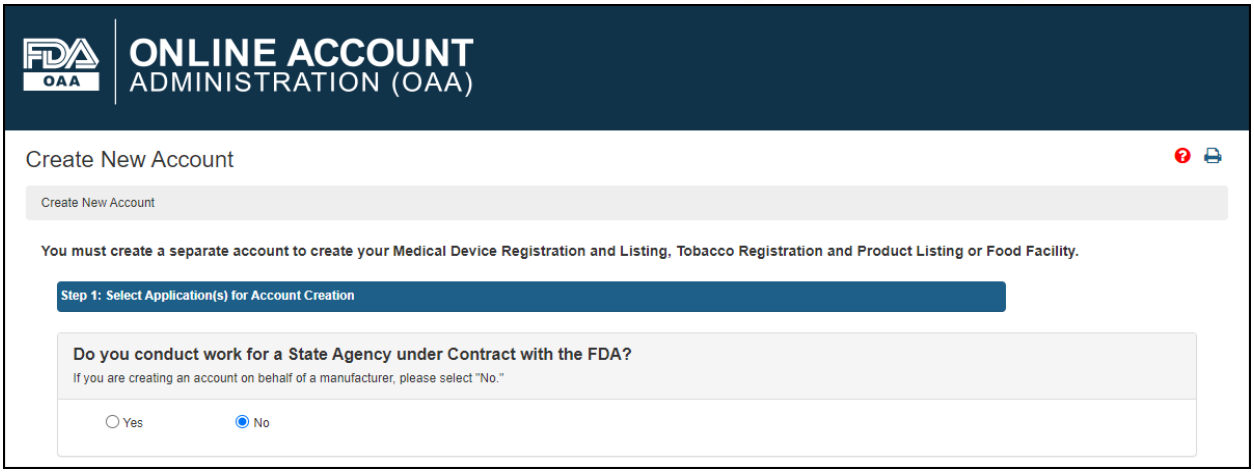


Figure 2.3 – Create New Account – Step 1: Select Application(s) for Account Creation

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.

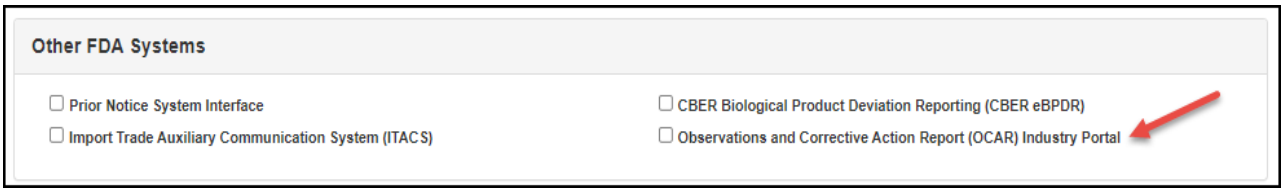


Figure 2.4 – Create New Account – Other FDA Systems

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.

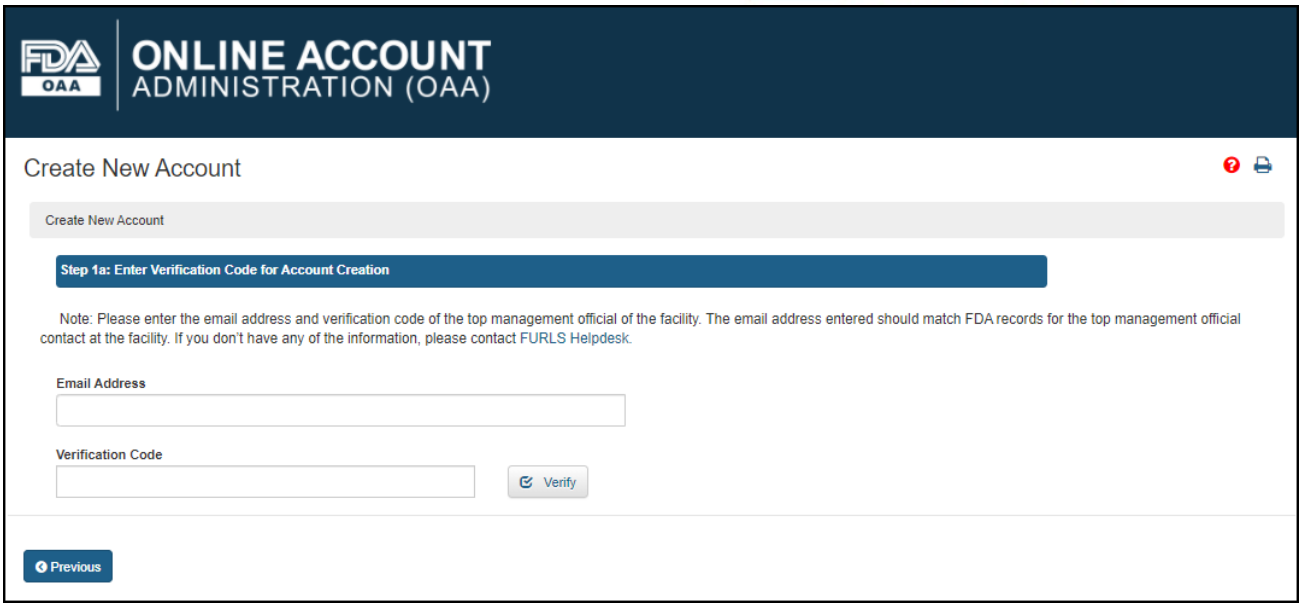


Figure 2.5 – Step 1a: Enter Verification Code for Account Creation

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."

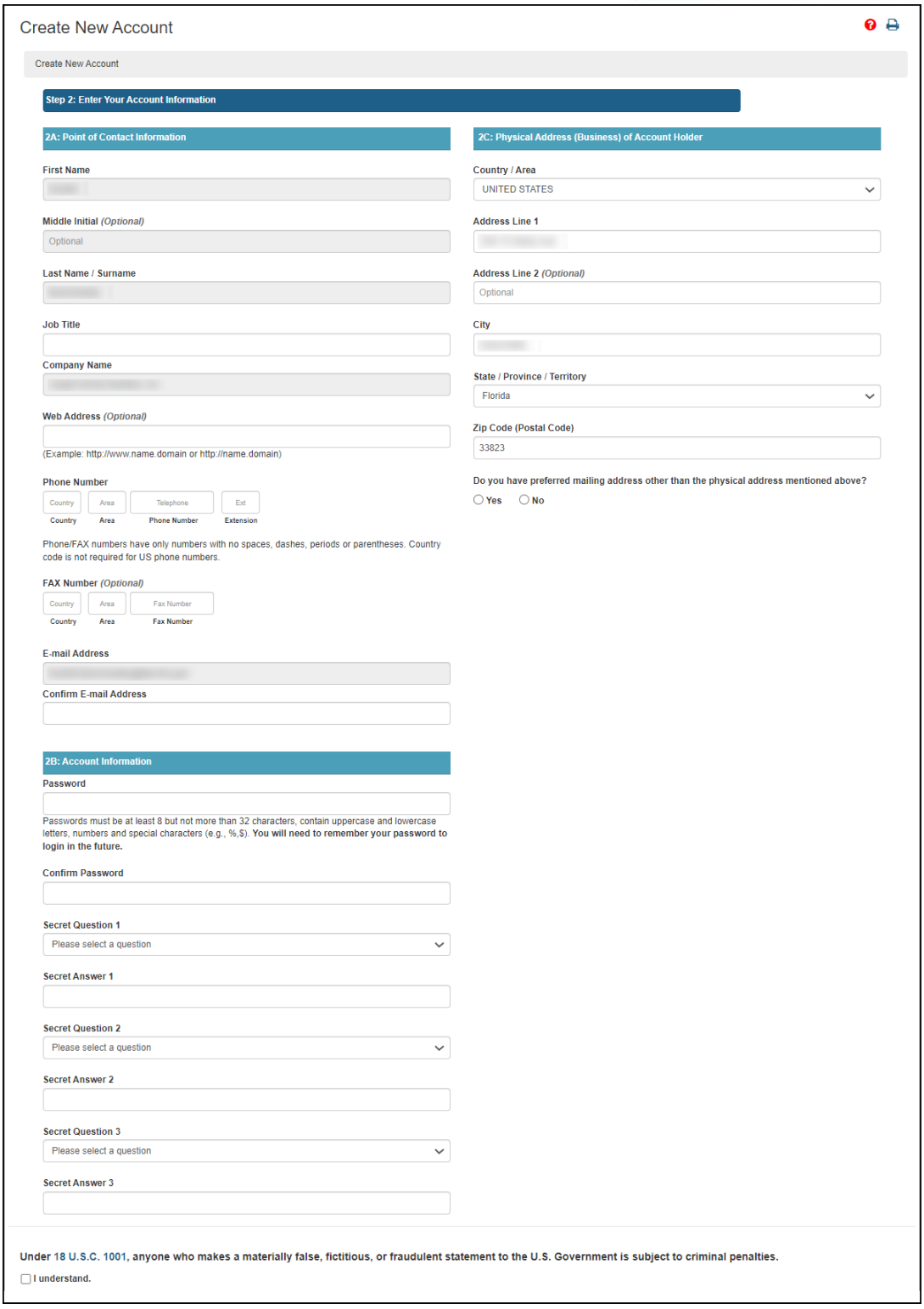


Figure 2.6 – Create New Account – Step 2: Enter Your Account Information

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.

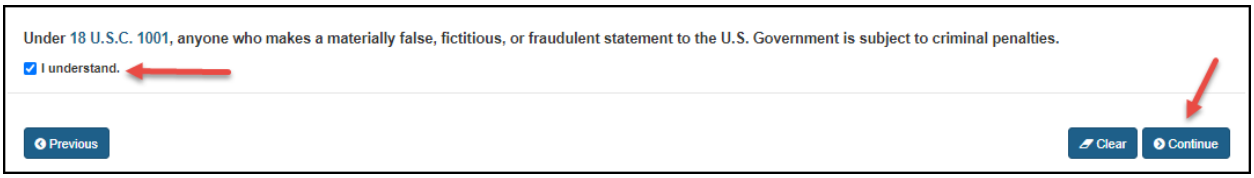


Figure 2.7 – Checkbox

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.

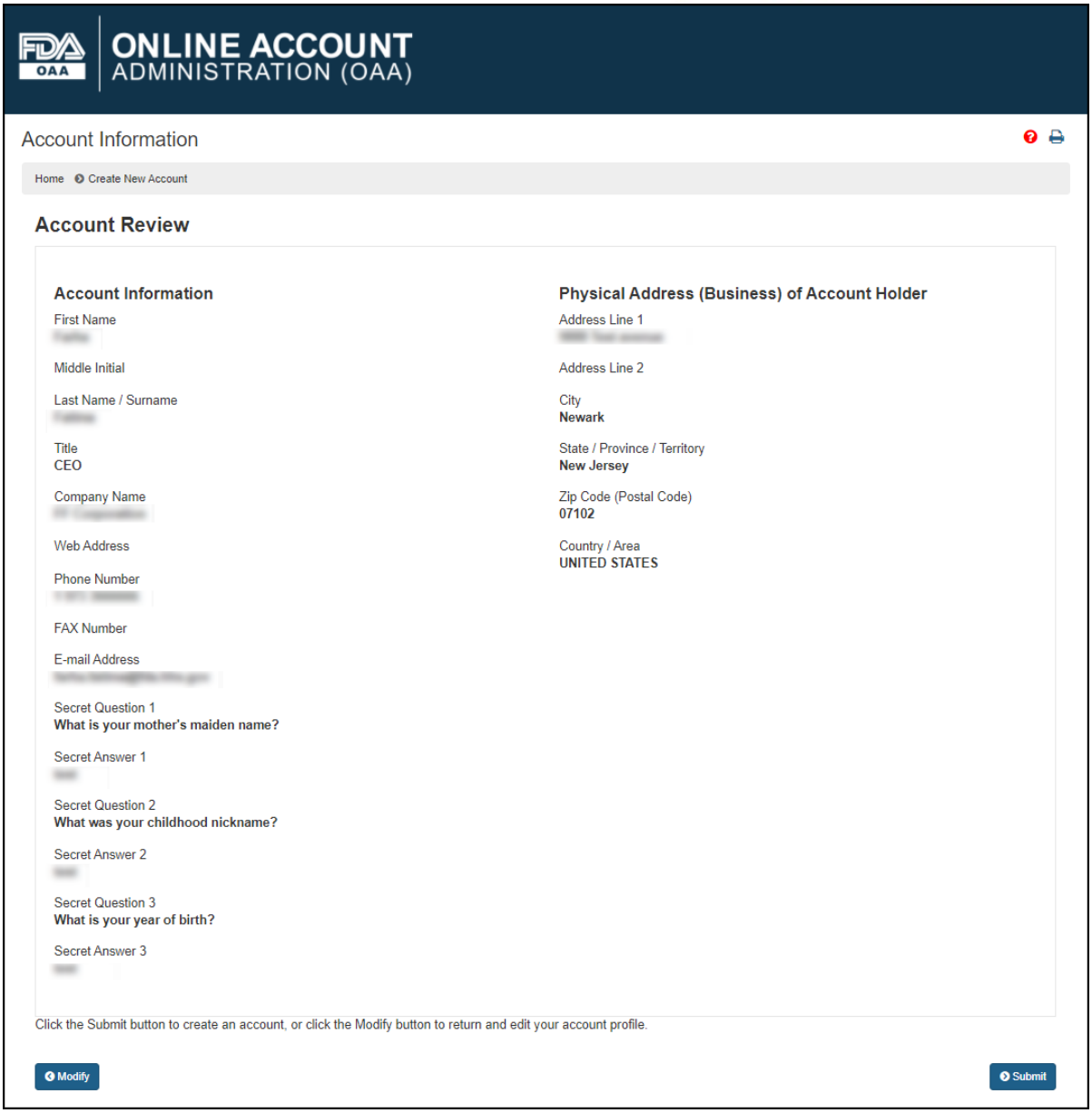


Figure 2.8 – Account Review Page

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.

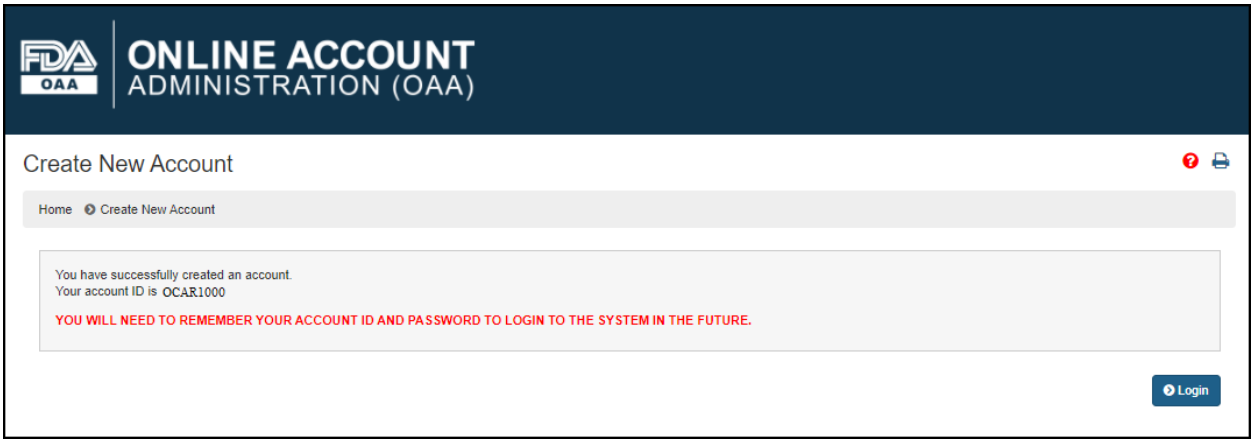


Figure 2.9 – Successful Account Creation Message

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).

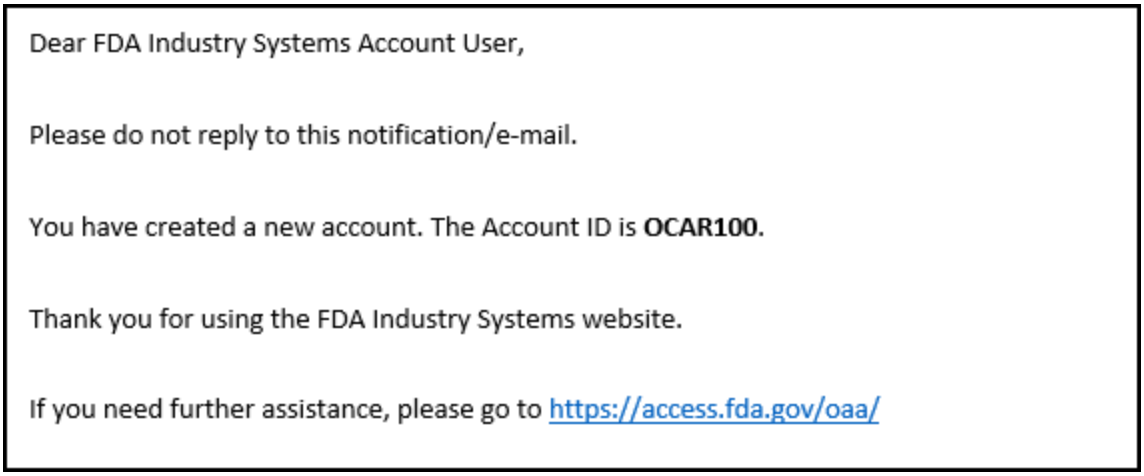


Figure 2.10 – Account Creation Confirmation Email

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).

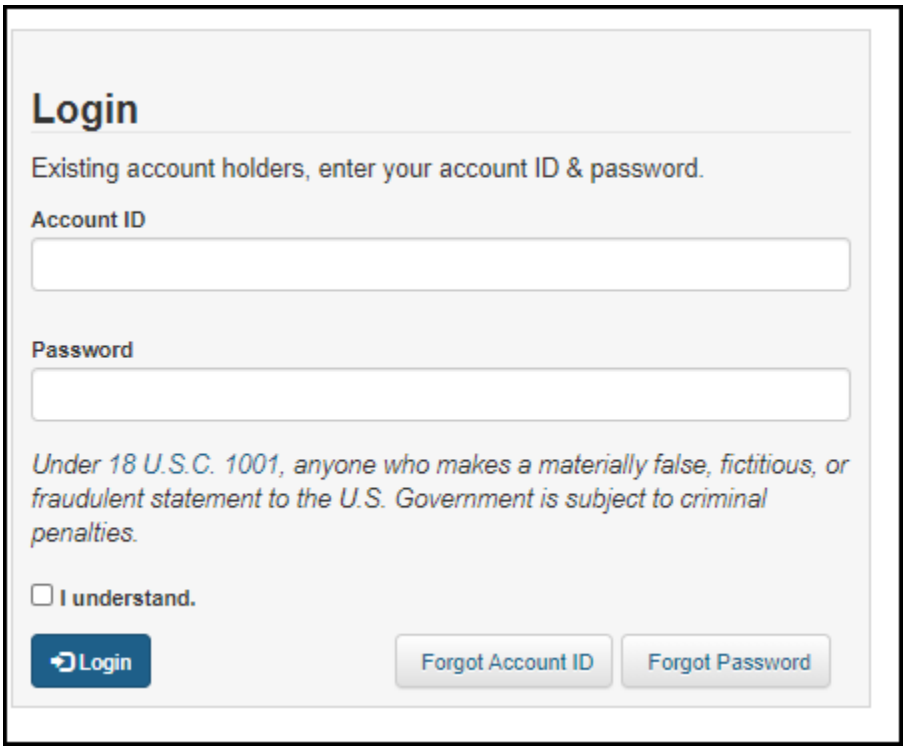


Figure 2.12 – OAA Login

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).

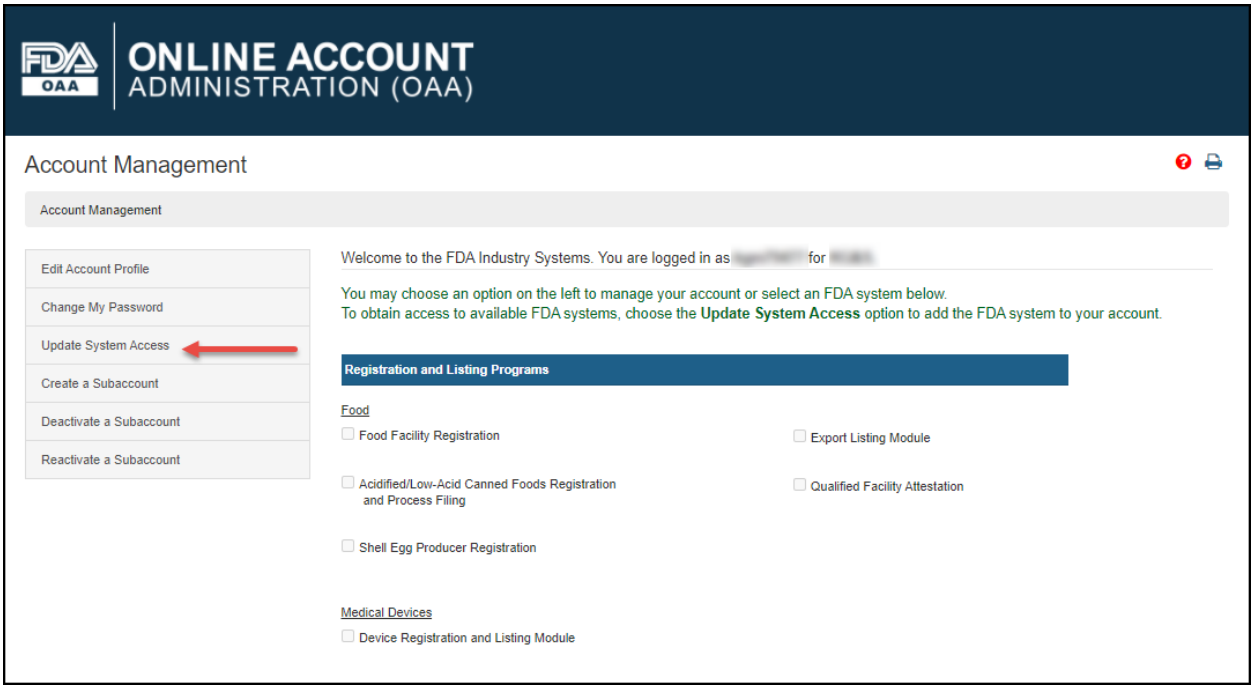


Figure 2.13 – Update System Access

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).

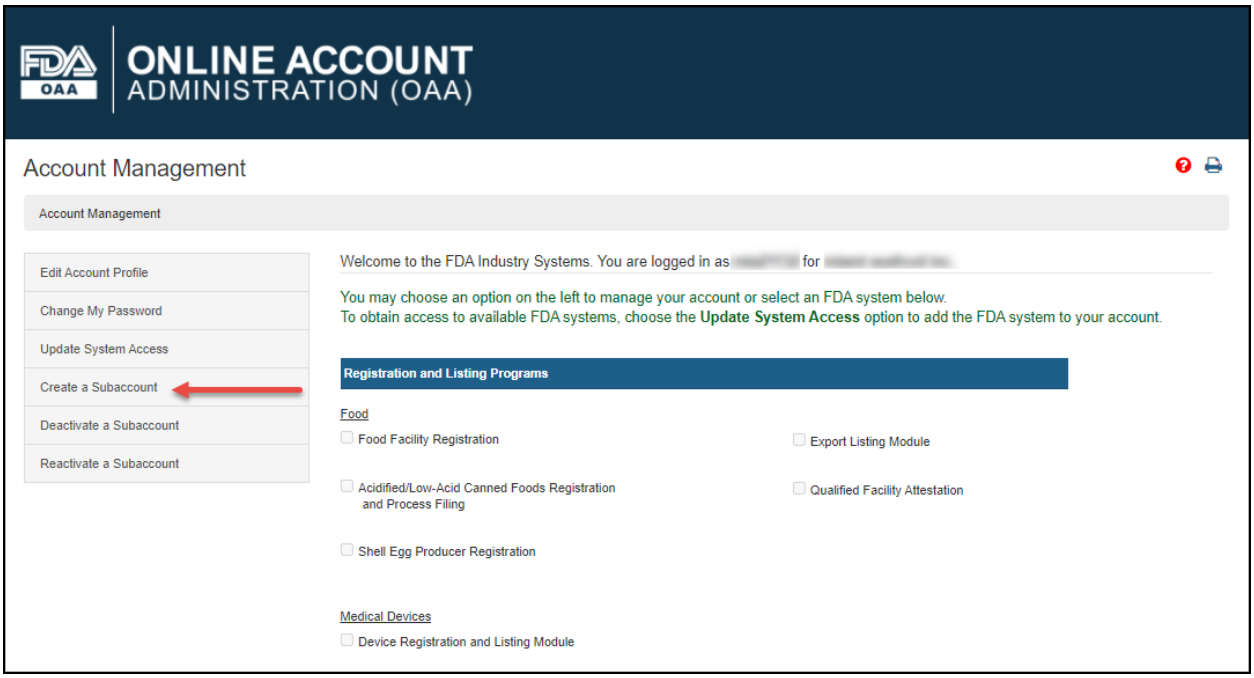


Figure 2.14 – Create a Subaccount

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."

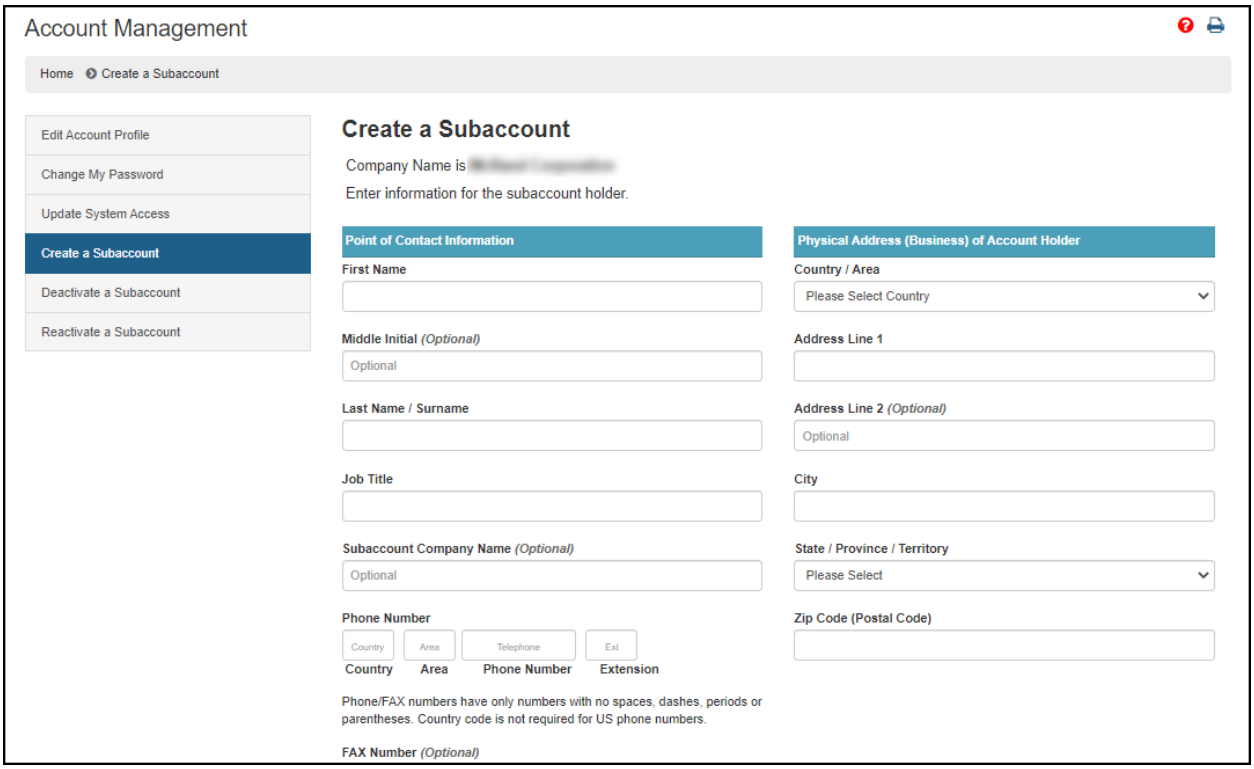


Figure 2.15 – Subaccount Holder's Information

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.

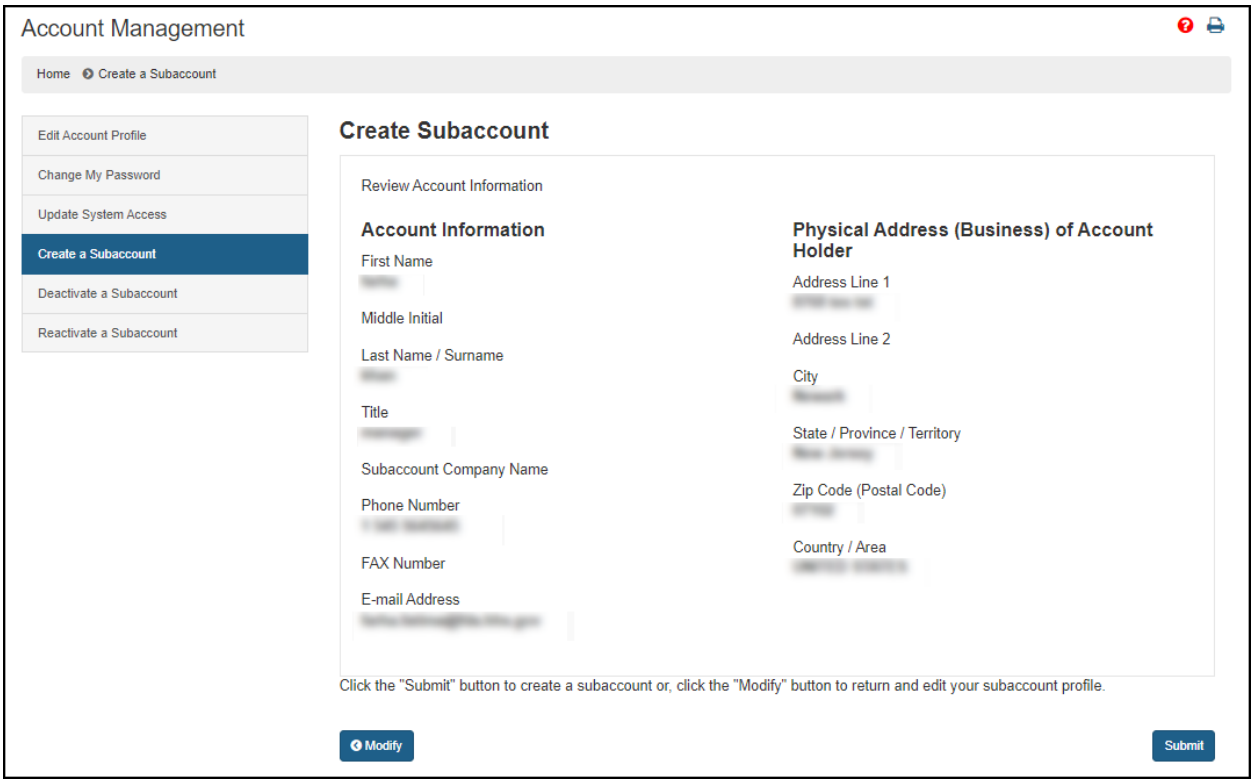
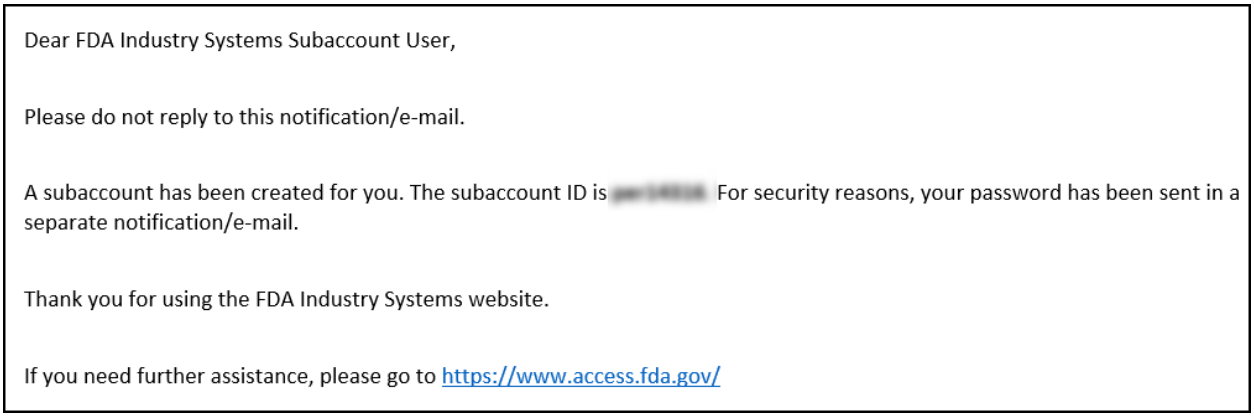


Figure 2.16 – Create Subaccount – Review Account Information Page

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,

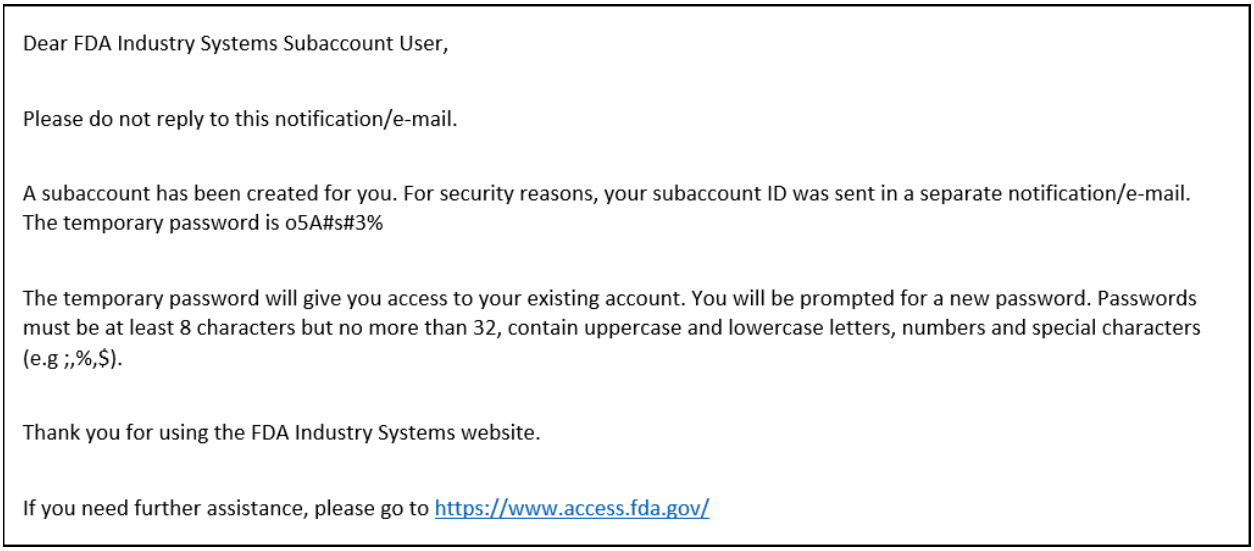
Please do not reply to this notification/e-mail.

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).

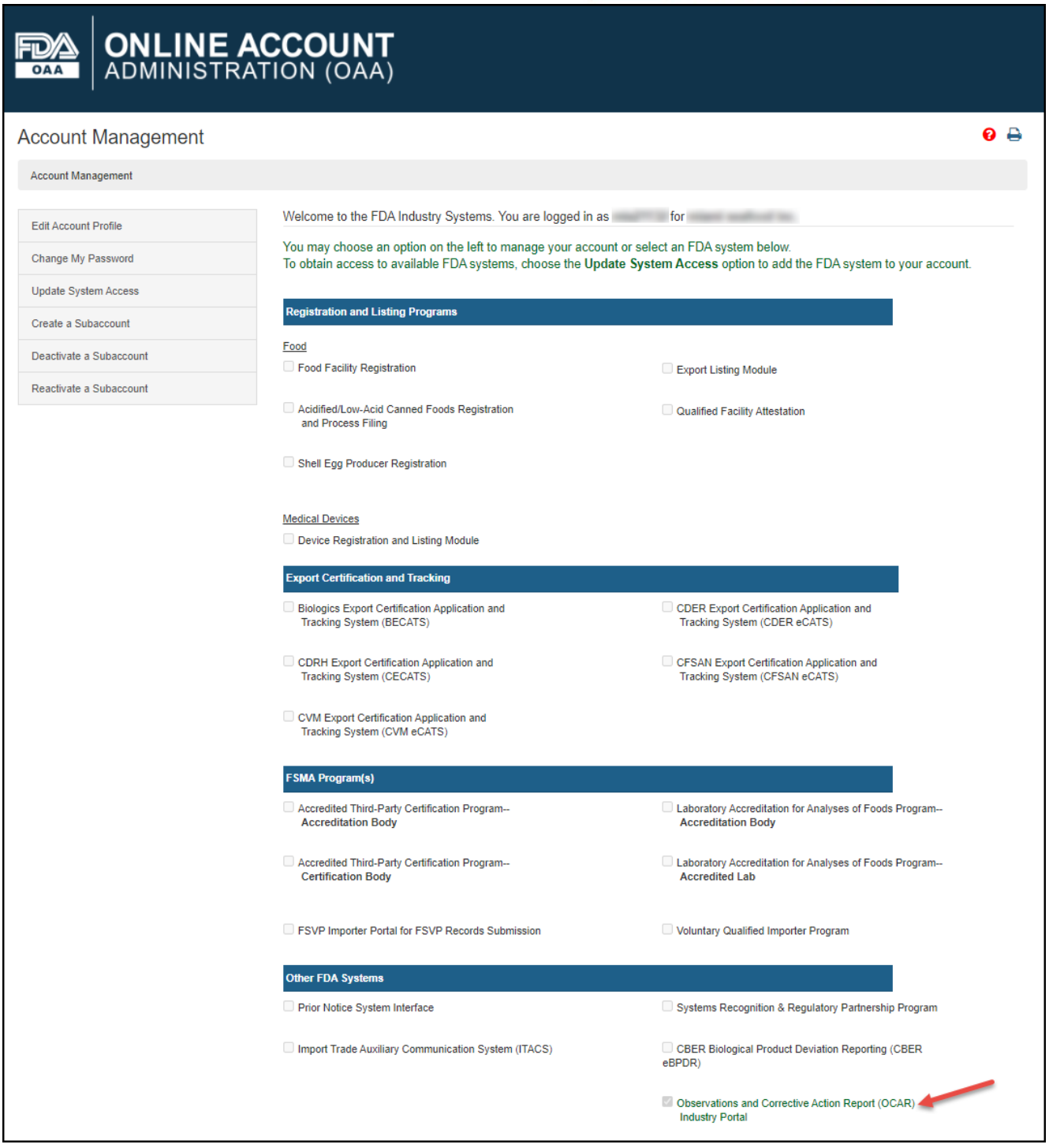


Figure 2.19 – Account Management Page

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).

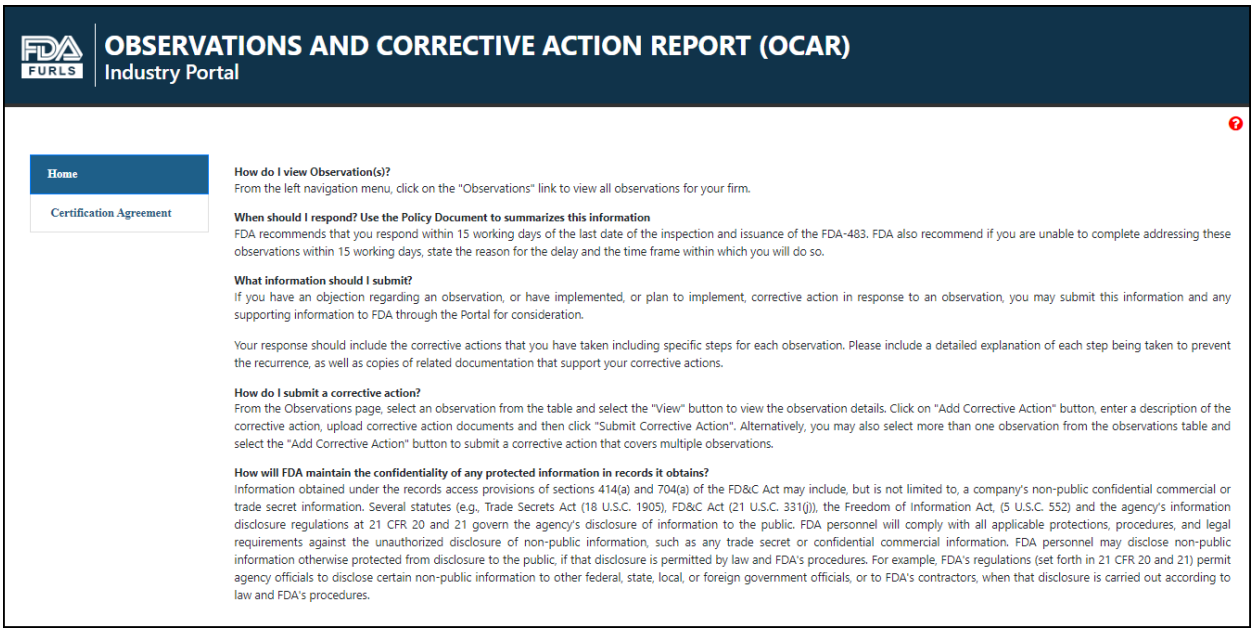


Figure 3.1 – OCAR Industry Portal Home Page

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.

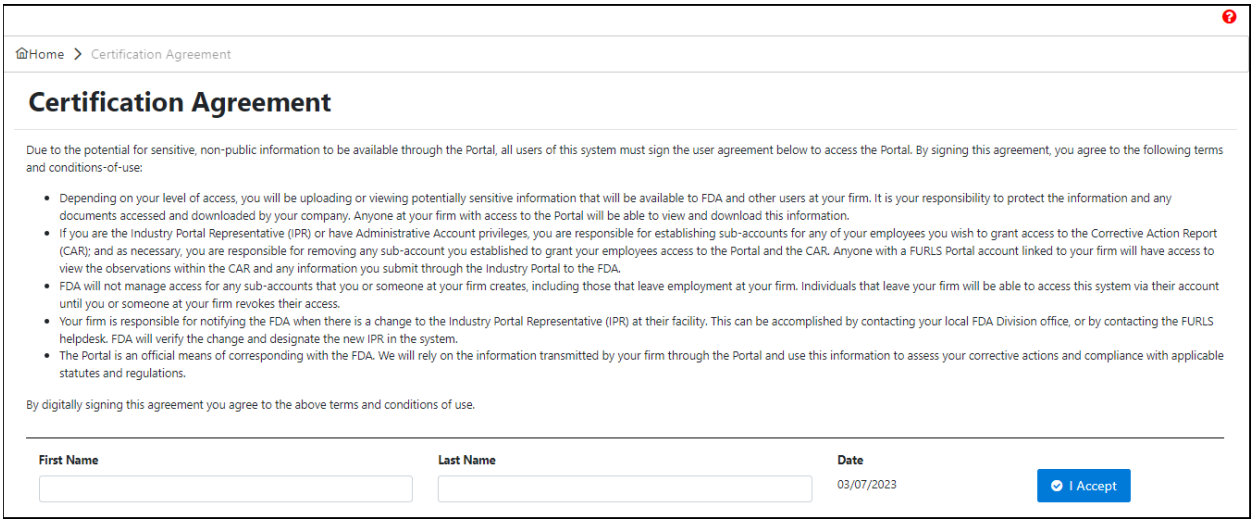


Figure 3.2 – Certification Agreement Page

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).

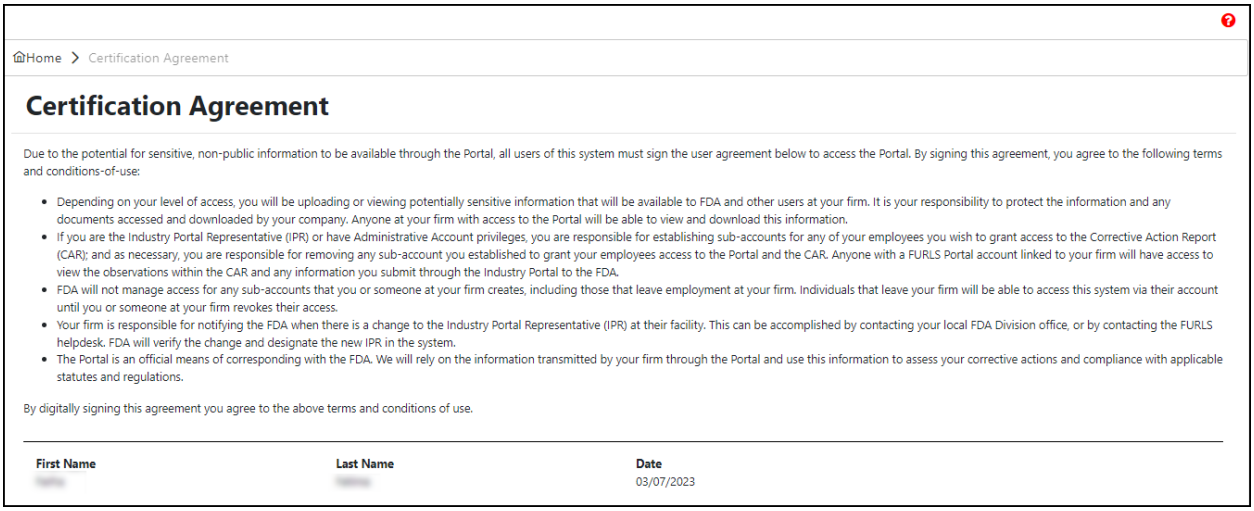


Figure 3.3 – Certification Agreement Page After “I Accept” Selection

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

- Manage Sub-Accounts
- Observations

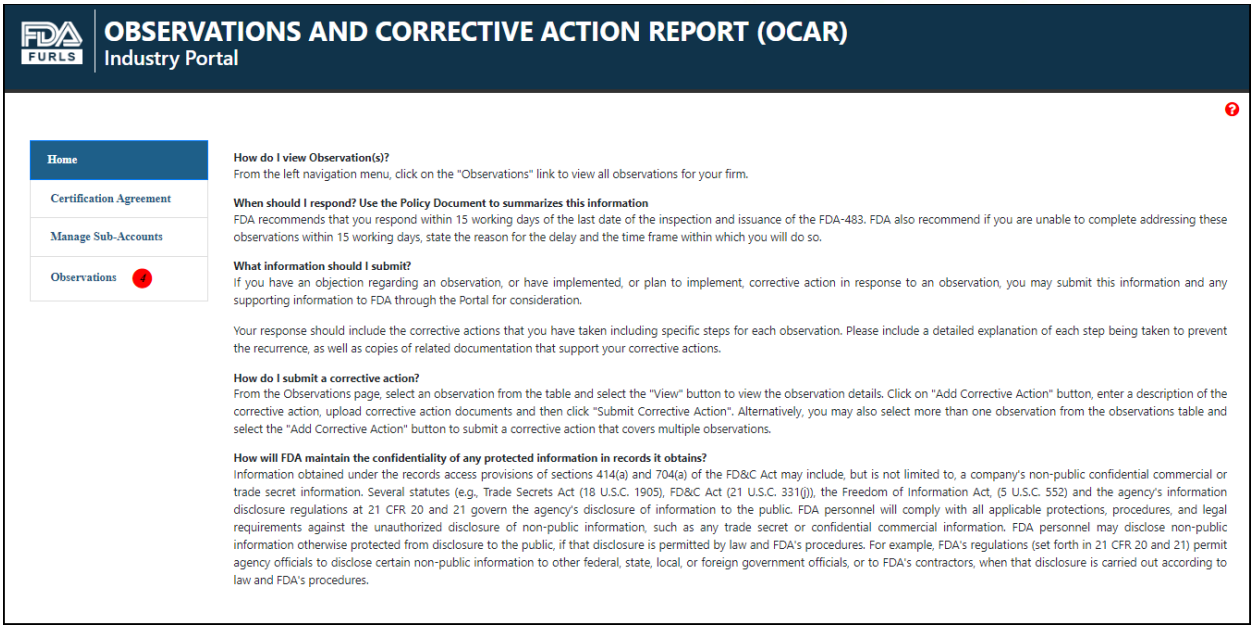


Figure 3.4 – OCAR Home Page with Additional Menu Options

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.

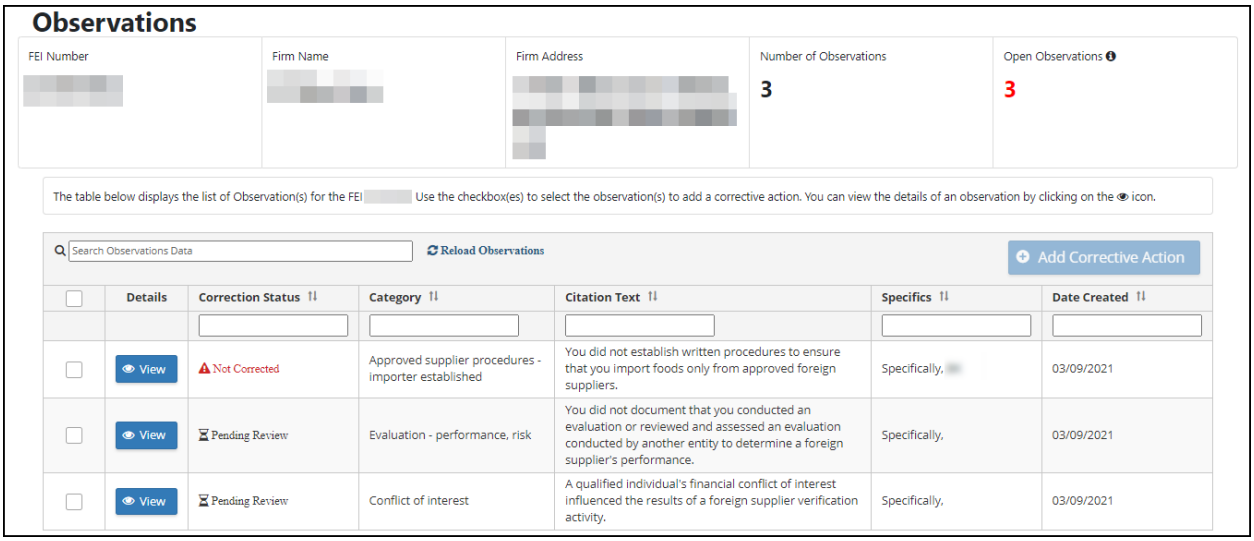


Figure 3.5 – Observations Page

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.

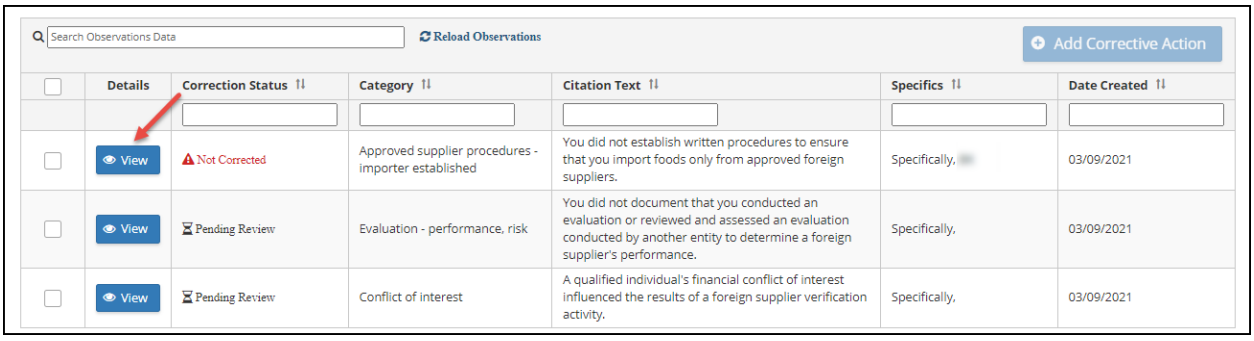


Figure 3.6 – Observations Page – View Observation Details

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).

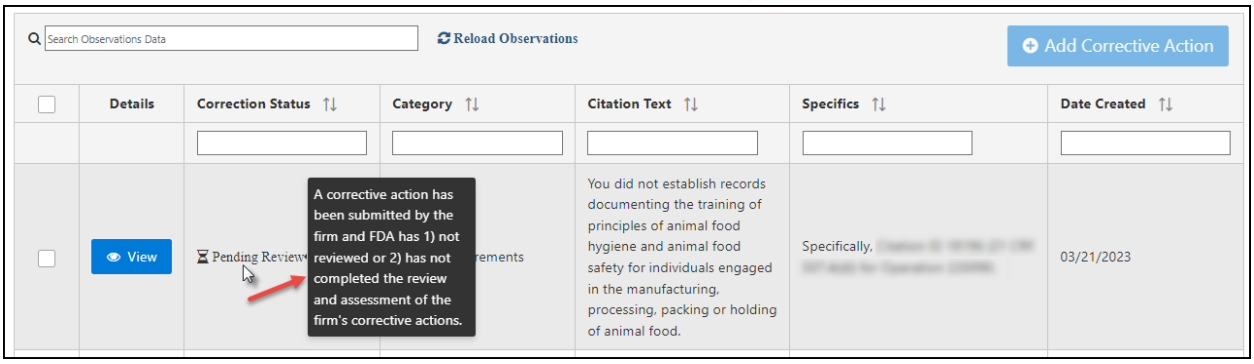


Figure 3.7 – Observations Page – Correction Status Tooltip

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.

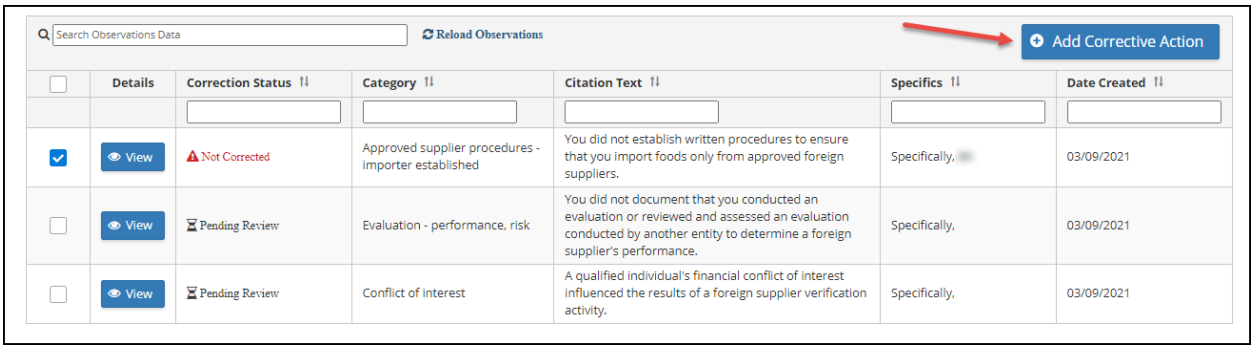


Figure 3.8 – Observations Page – Add Corrective Action

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

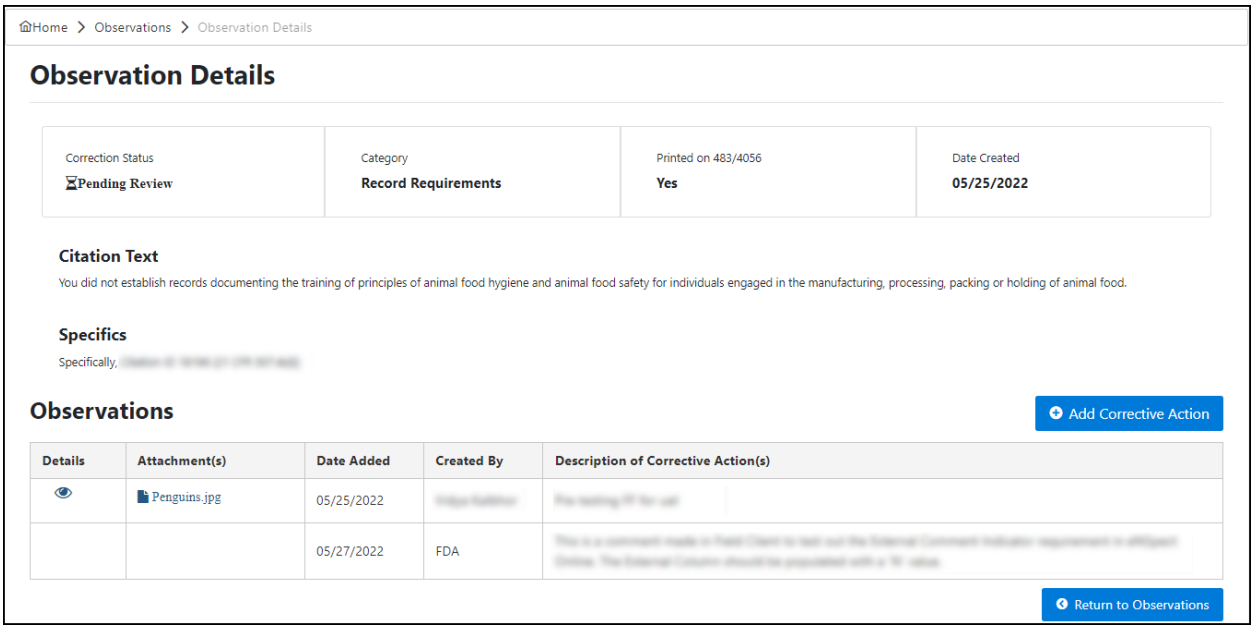


Figure 3.9 – Observations Details Page After Selecting View Button

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).

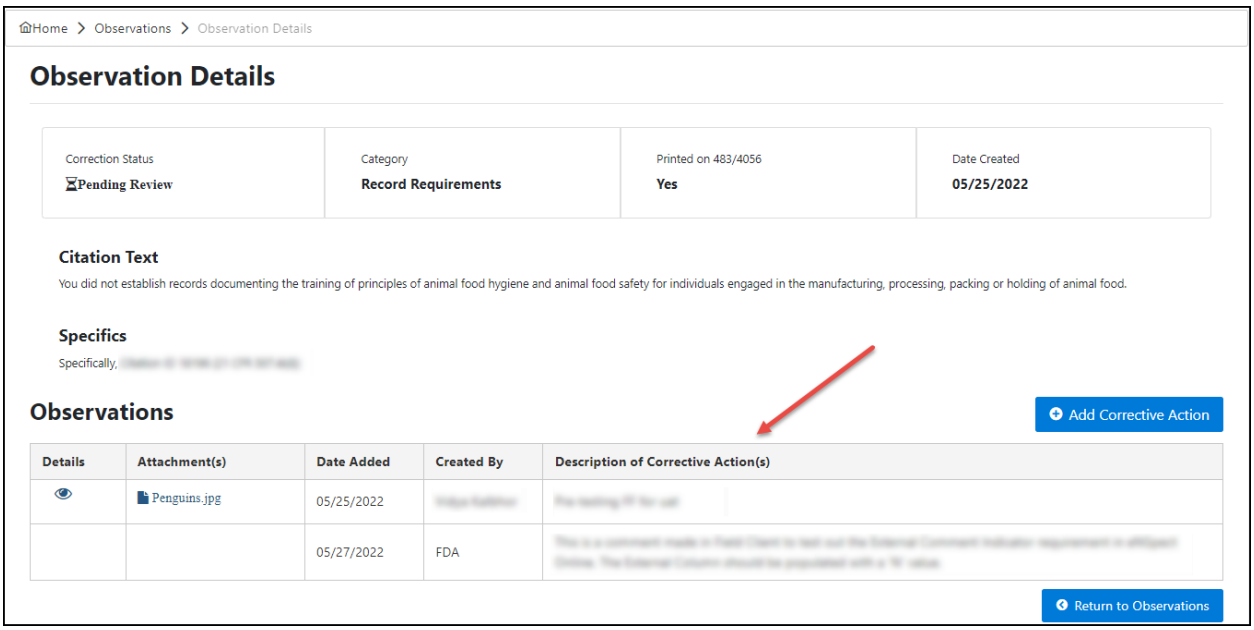


Figure 3.10 – Observation Details Page – Corrective Actions

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

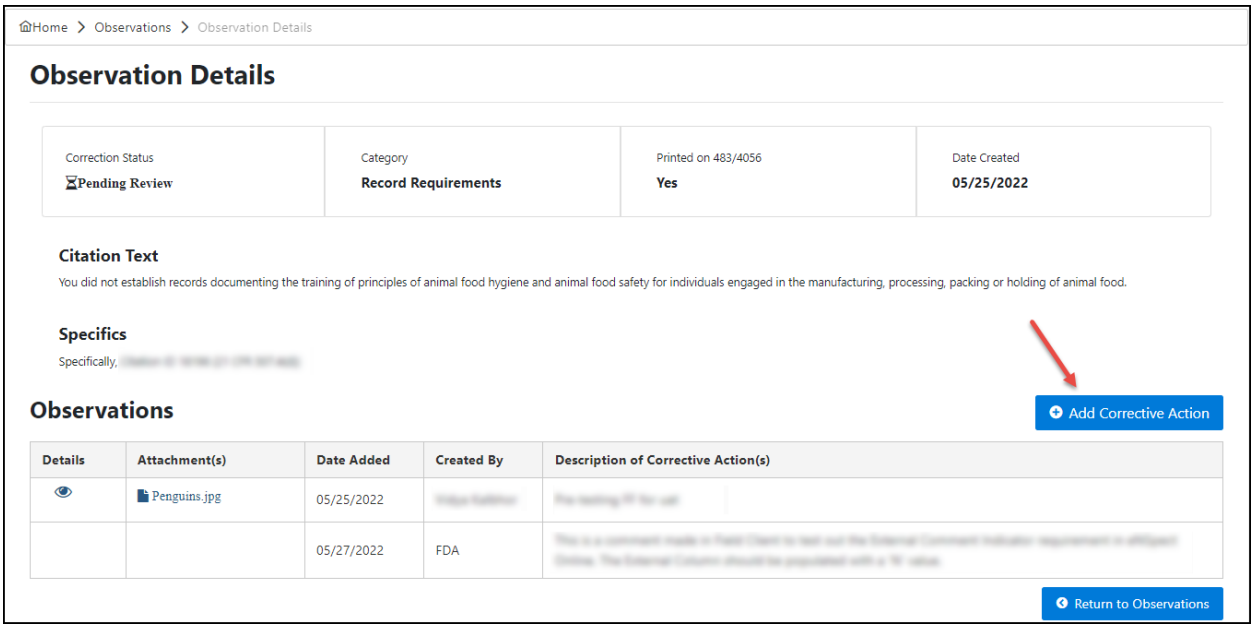


Figure 3.11 – Observation Details Page – Add Corrective Action Button

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.

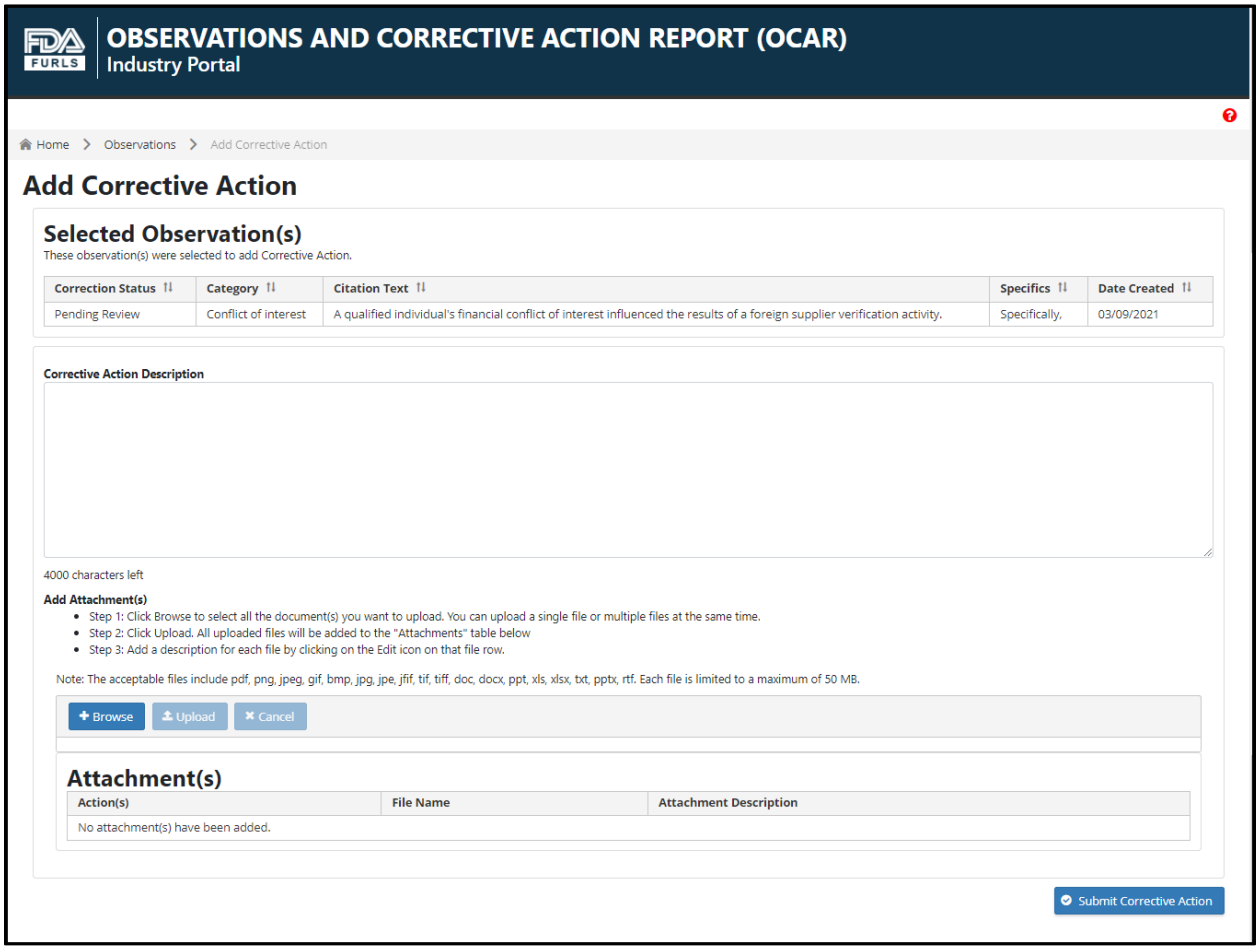


Figure 3.12 – Add Corrective Action Page

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).

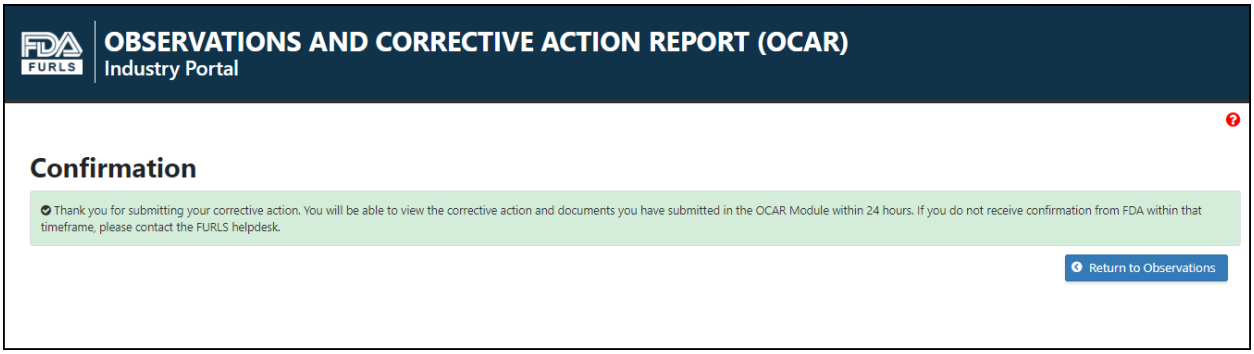


Figure 3.13 – Confirmation Page

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).

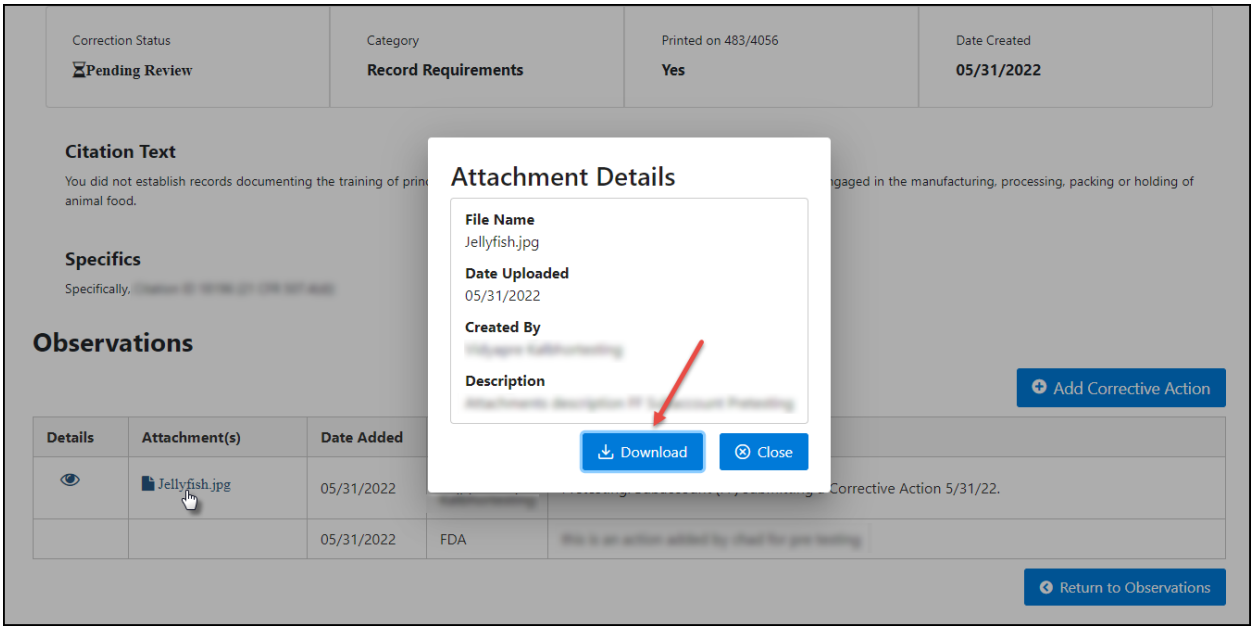


Figure 3.14 – Observation Details Page – View Corrective Action Attachments

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.

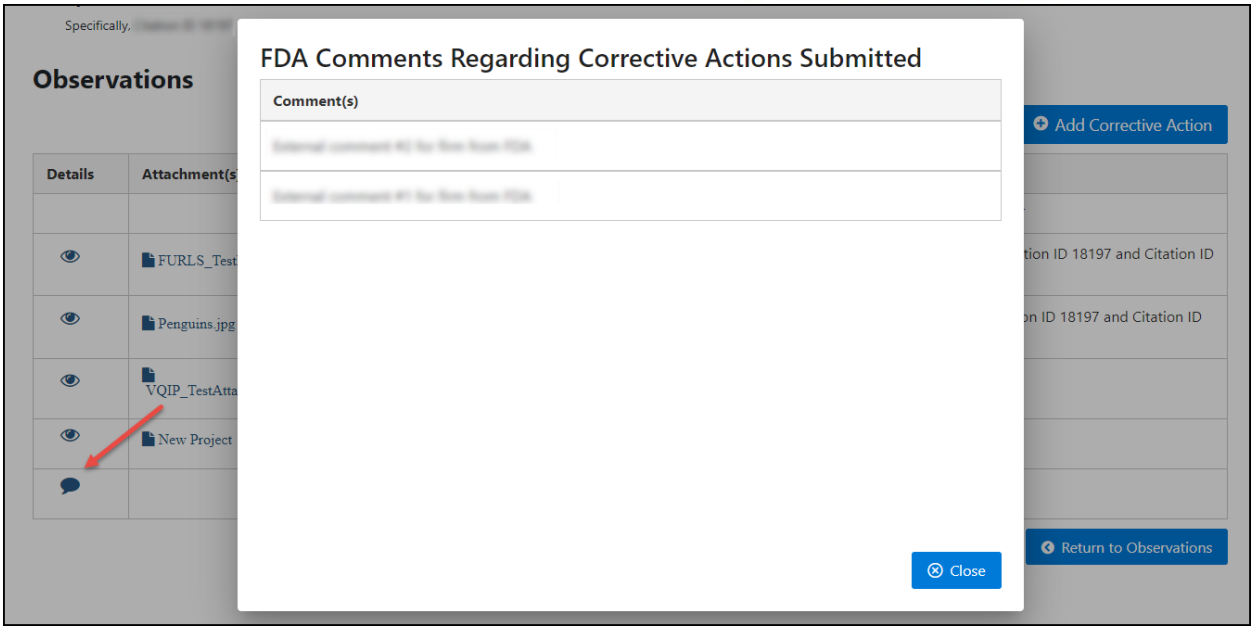


Figure 3.15 – Observation Details Page – FDA Comments Pop-up when Comments Icon is Selected

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

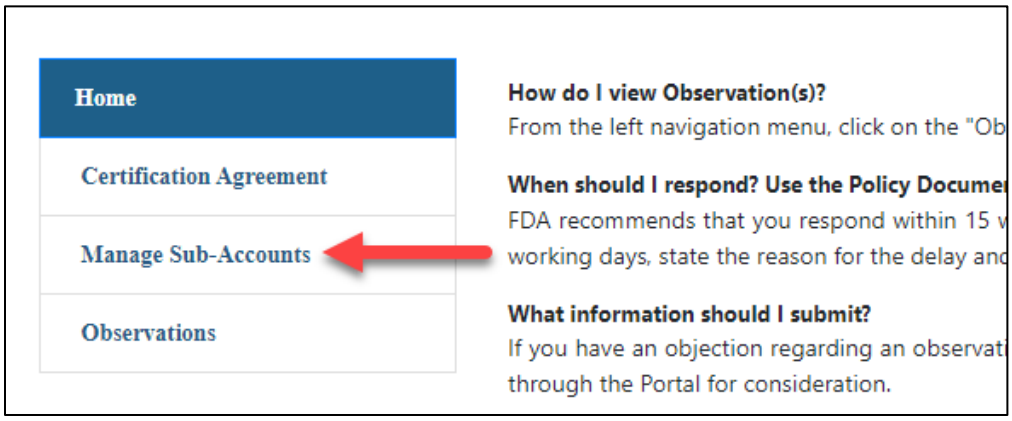


Figure 3.16 – Manage Sub-Accounts Menu Option

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).

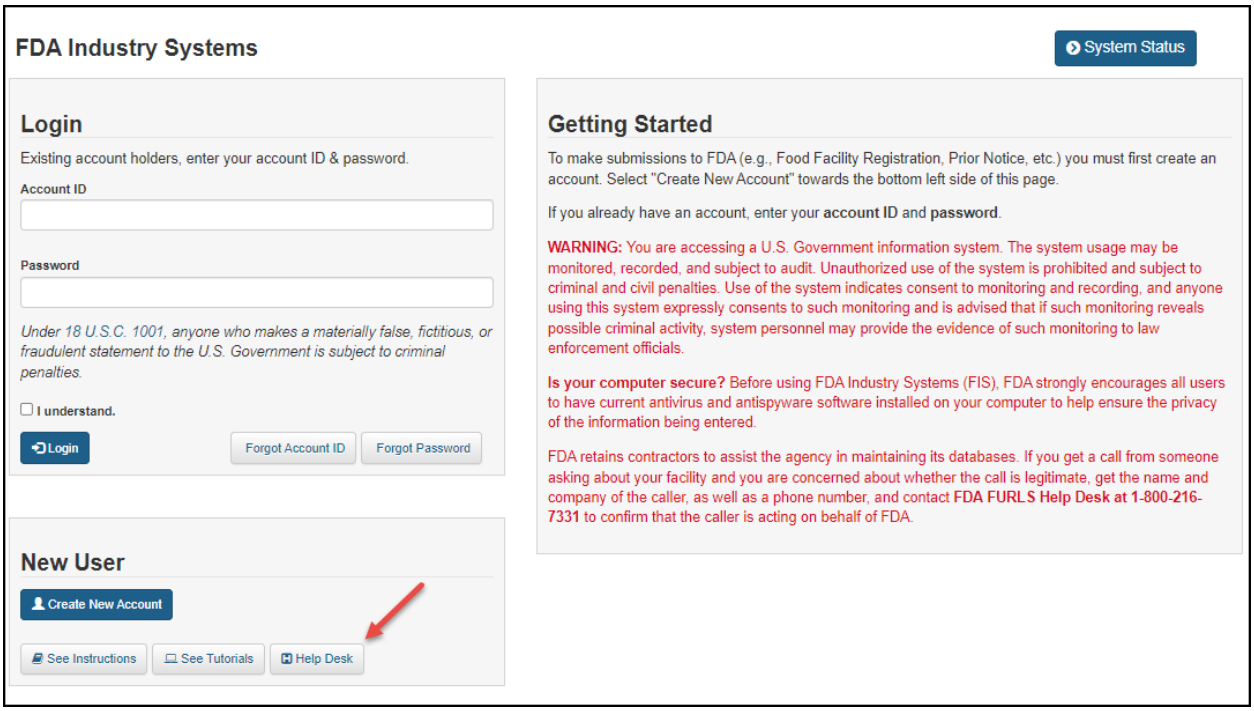


Figure 4.1 – FURLS Help Desk Button

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

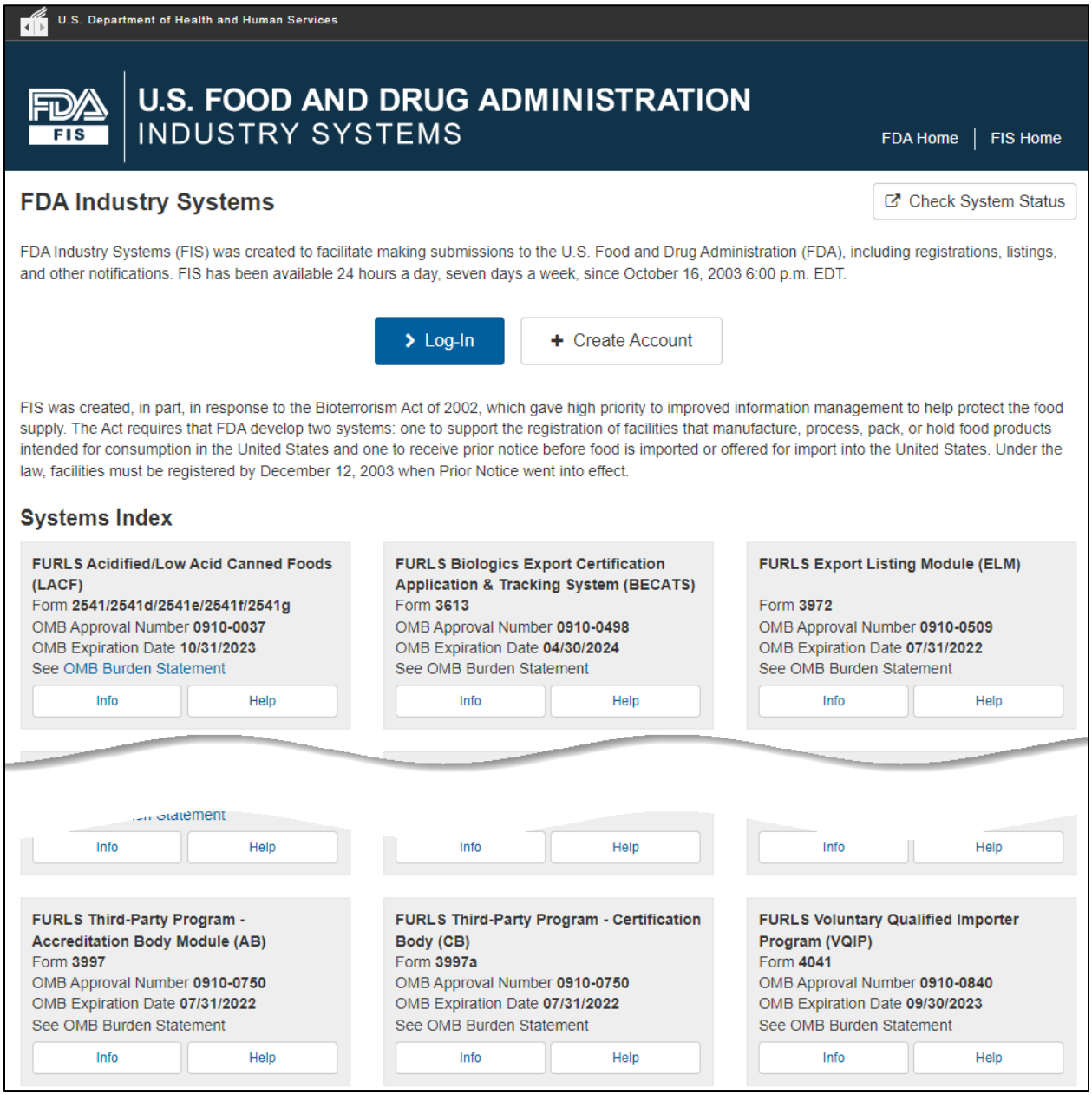


Figure 4.2 – Systems Index Section

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

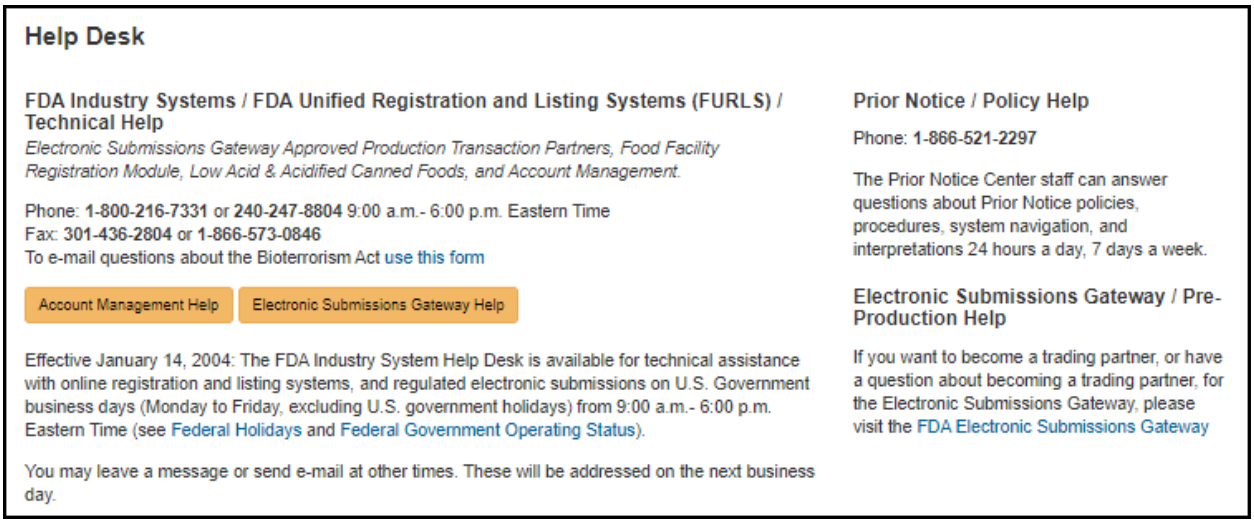


Figure 4.3 – FURLS Help Desk Contact Information

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.