



U.S. Food and Drug Administration

CDER Office of Manufacturing Quality (CDER OMQ e-Portal)

User Guide

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1 Introduction

This document is intended for users of the CDER Office of Manufacturing Quality (CDER OMQ e-Portal).

This document provides detailed instructions on how users of the e-Portal can perform the following:

- Create an FDA online account
- Add and manage sub-accounts
- Search submissions
- View submission details
- Add submission response

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 e-Portal. This documentation can be provided by attaching an electronic file (e.g., processing records, schematics, photographs, or other supporting information).

The electronic CDER Office of Manufacturing Quality (CDER OMQ e-Portal) supports the following document attachment types:

- .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, .rtf, .mp4, .mov, .wav, .avi, .eml, and .zip.

1.3 Supported Browsers

FURLS can be accessed using the following browsers:

- Microsoft Edge
- Google Chrome
- Mozilla Firefox

Please visit the “Systems Requirements” section of the FURLS page for a list of approved browsers and browser versions. The “Systems Requirements” section can be found by navigating to <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/oaal/>. Follow the instructions below regarding obtaining an FDA account ID and password. Once the account has been created, an FDA Administrator will review your account details and grant access to FURLS. Once the account has been approved, you will be able to log into the Online Account Administration (OAA) system and gain access to FURLS.

The individual in charge of the firm (i.e., the individual with the ultimate authority and responsibility) will have the ability to set up the enterprise account in the CDER OMQ e-Portal. This individual will be the primary point of contact for the firm and may set up sub-accounts for other individuals in the firm. Note: FDA requires the firm's primary point of contact's name and email address to send an email notification, including a FURLS OAA account link.

To log into the OAA system and gain access to FURLS, you will need to create an FDA online account. To do so, you have the following options:

Go to <https://www.access.fda.gov/oaal/>. Click the "Create New Account" button on the OAA - FDA Industry Systems page (Figure 2.1). You will be directed to the "Create New Account" page.

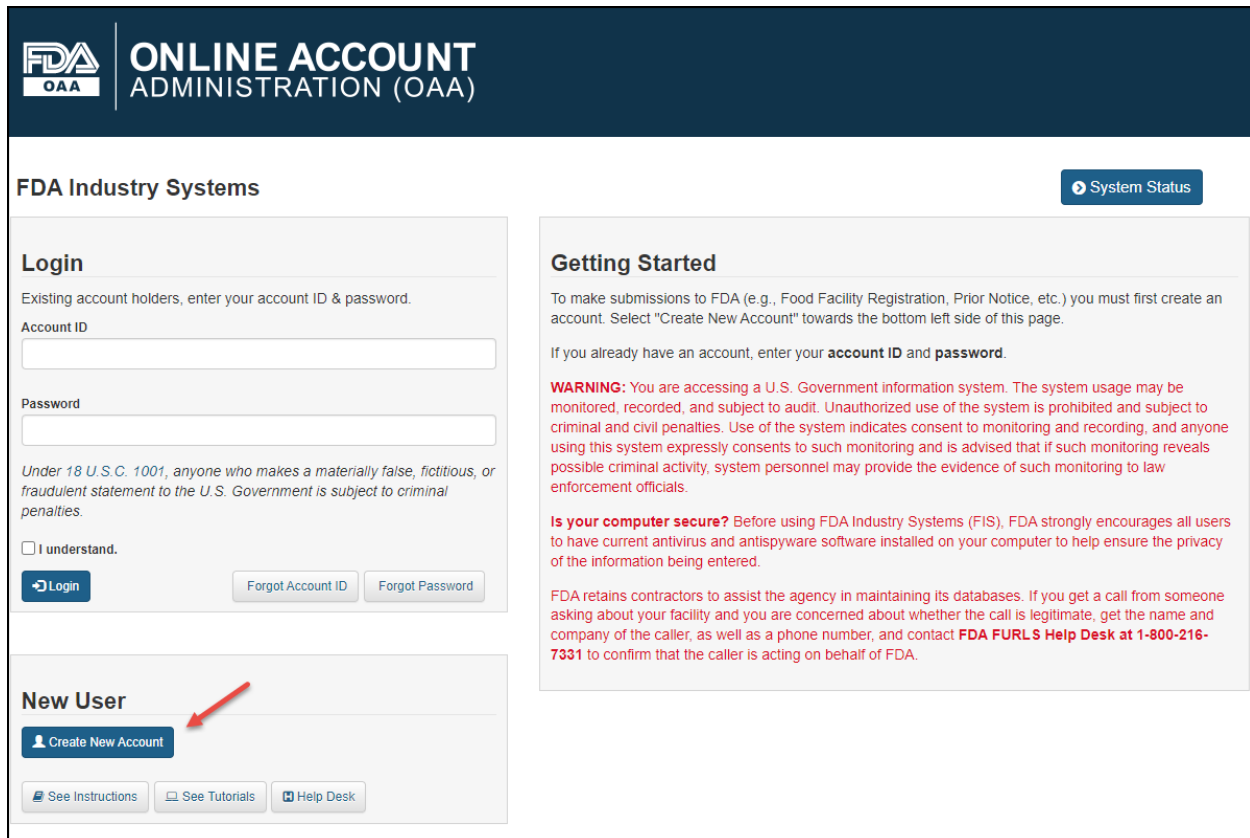
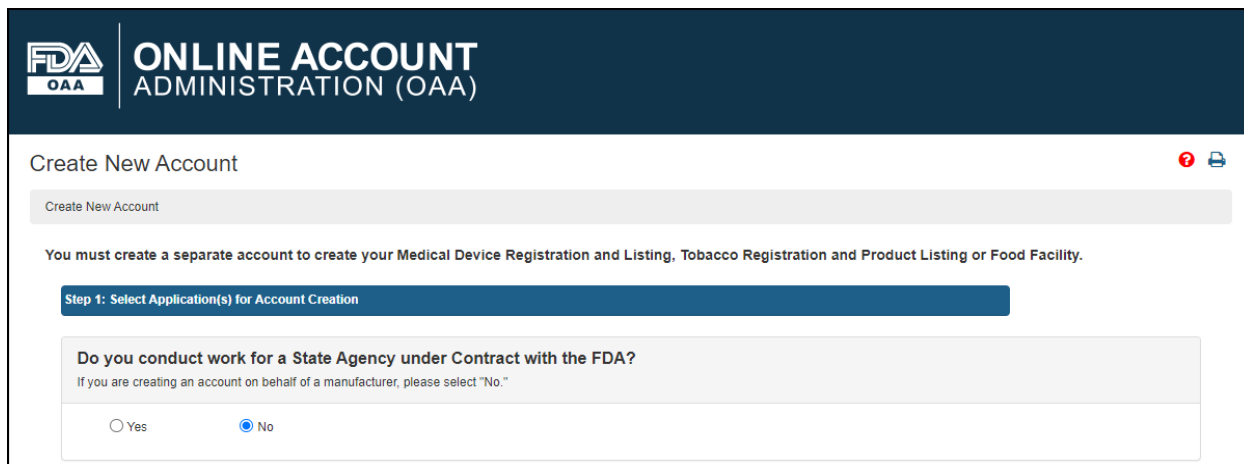


Figure 2.1 – FDA OAA Login Page

The system displays the “Create New Account” page (Figure 2.2). 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.



FDA ONLINE ACCOUNT ADMINISTRATION (OAA)

Create New Account

Create New Account

You must create a separate account to create your Medical Device Registration and Listing, Tobacco Registration and Product Listing or Food Facility.

Step 1: Select Application(s) for Account Creation

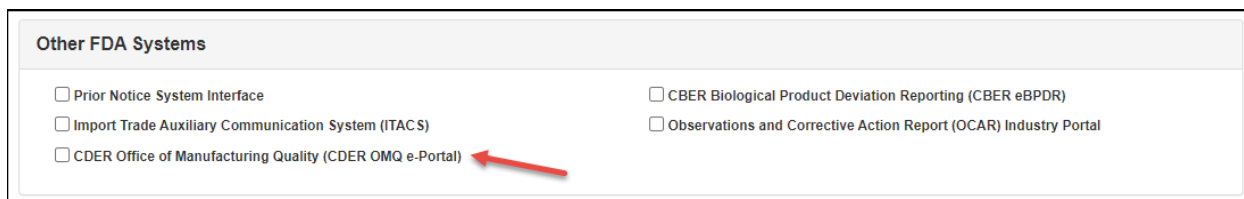
Do you conduct work for a State Agency under Contract with the FDA?
If you are creating an account on behalf of a manufacturer, please select "No."

Yes No

Figure 2.2 – Create New Account – Step 1: Select Application(s) for Account Creation

The system will display various FDA programs available in OAA.

Click the “CDER Office of Manufacturing Quality (CDER OMQ e-Portal)” checkbox under the “Other FDA Systems” section (Figure 2.3). Click the “Continue” button at the bottom of the page to proceed to the next step.



Other FDA Systems

Prior Notice System Interface CBER Biological Product Deviation Reporting (CBER eBPDR)

Import Trade Auxiliary Communication System (ITACS) Observations and Corrective Action Report (OCAR) Industry Portal

CDER Office of Manufacturing Quality (CDER OMQ e-Portal)

Figure 2.3 – Create New Account – Other FDA Systems

Note: The email address which received the initial FDA email must be used to create new account.

The system will display the “Step 2: Enter Your Account Information” page (Figure 2.4). You will need to complete the data entry fields in the “Point of Contact Information,” “Account Information,” and “Physical Address (Business) of Account Holder” sections.

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: #0056b3; 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: #0056b3; color: white; padding: 2px; margin-bottom: 5px;">2C: Physical Address (Business) of Account Holder</div> <p>Country / Area <input type="text" value="Please Select Country"/></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="Please Select"/></p> <p>Zip Code (Postal Code) <input type="text"/></p> <p>FEI Number <input type="text"/></p> <p>Do you have preferred mailing address other than the physical address mentioned above? <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 15 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 2.4 – Create New Account – Step 2: Enter Your Account Information

Select the “I understand” checkbox at the bottom of the page (Figure 2.5).

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 2.5 – Checkbox

The “Account Review” page will display (Figure 2.6). 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.



Account Information



Home > Create New Account

Account Review

Account Information

First Name
Middle Initial
Last Name / Surname
Title
Company Name
Web Address
Phone Number
FAX Number
E-mail Address

Secret Question 1
What was your high school mascot?
Secret Answer 1
Secret Question 2
What is your favorite food?
Secret Answer 2
Secret Question 3
What is your year of birth?
Secret Answer 3

Physical Address (Business) of Account Holder

Address Line 1
Address Line 2
City
State / Province / Territory
Zip Code (Postal Code)
Country / Area
UNITED STATES
FEI NUMBER

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

Modify

Submit

Figure 2.6 – Account Review Page

When you click the “Submit” button, the system will display a message indicating the account was created successfully and it is currently inactive. The message displays your account ID (Figure 2.7).

Note: You must retain your account ID and password to log into the system in the future.

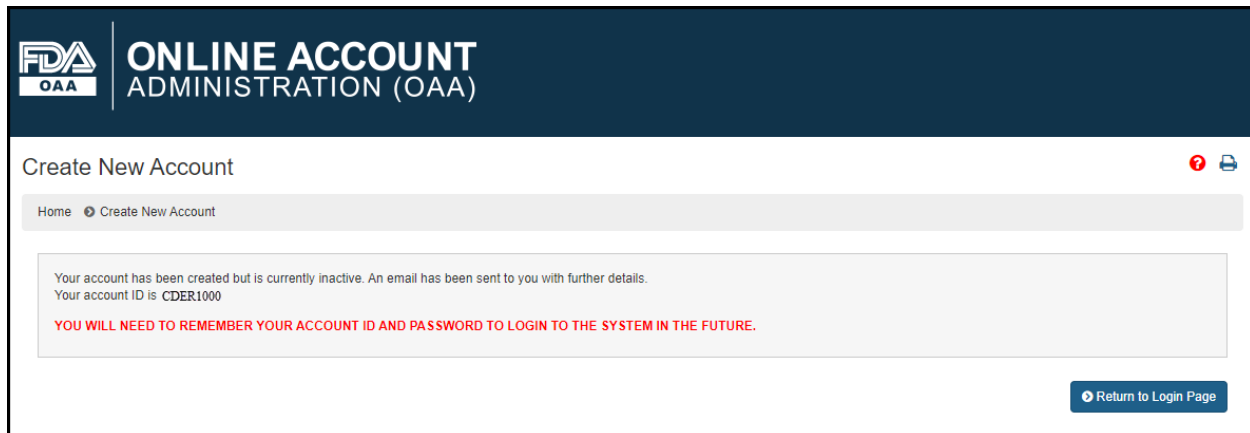


Figure 2.7 – Successful Account Creation Message

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. You will also see a confirmation message indicating the account request has been received and is pending review / approval (Figure 2.8).

May 22, 2023

Dear [REDACTED]

Your CDER Office of Manufacturing Quality (CDER OMQ e-Portal) account [REDACTED] request has been received and is currently **PENDING** review and approval.

If the request is approved, you will receive another notification email. Once received, you can login to FURLS at <https://www.access.fda.gov/oa/> and access CDER OMQ e-Portal for your firm.

If we are unable to approve your request based on the information provided, it will be returned to you with the reason(s) so you may provide additional or corrected information.

If you have any questions or concerns related to account creation or access, please direct inquiries to the following mailbox with "e-Portal question" in the subject line of your email: [REDACTED]

FDA CDER OMQ Support Team
Please do not reply to this email. Emails sent to this address cannot be answered. Thank you.

Figure 2.8 – Account Creation Confirmation Email

If the request is approved, you will receive another notification email. You can then log into FURLS and access the CDER OMQ e-Portal for your firm (Figure 2.9).

May 22, 2023

Dear [REDACTED]

Your CDER Office of Manufacturing Quality (CDER OMQ e-Portal) account [REDACTED] request has been **APPROVED**.

As an Enterprise Account user, you may now log into FURLS at <https://www.access.fda.gov/oa/>. Once logged in, you can access CDER OMQ e-Portal for your firm. For assistance with accessing CDER OMQ e-Portal functionality, please refer to the help link within the system.

If you have any questions or concerns related to account creation or access, please direct inquiries to the following mailbox with "e-Portal question" in the subject line of your email: [REDACTED]

FDA CDER OMQ Support Team
Please do not reply to this email. Emails sent to this address cannot be answered. Thank you.

Figure 2.9 – Account Access Approved Notification

If the request is not approved based on the information provided, the applicable email notification will be sent to you with the reason(s) so you may provide additional or corrected information.

The account may be temporarily rejected or denied for one of the following reasons, as indicated in the notification:

- Firm already has a CDER OMQ e-Portal firm account
- Invalid FEI number provided
- Information could not be validated based on the information provided
- Identity of requestor could not be verified
- Possible issue with firm and email address identified
- Temporary Deactivation of Existing Account
- Other

If your request has been rejected and requires additional action, you will receive the following notification (Figure 2.10):

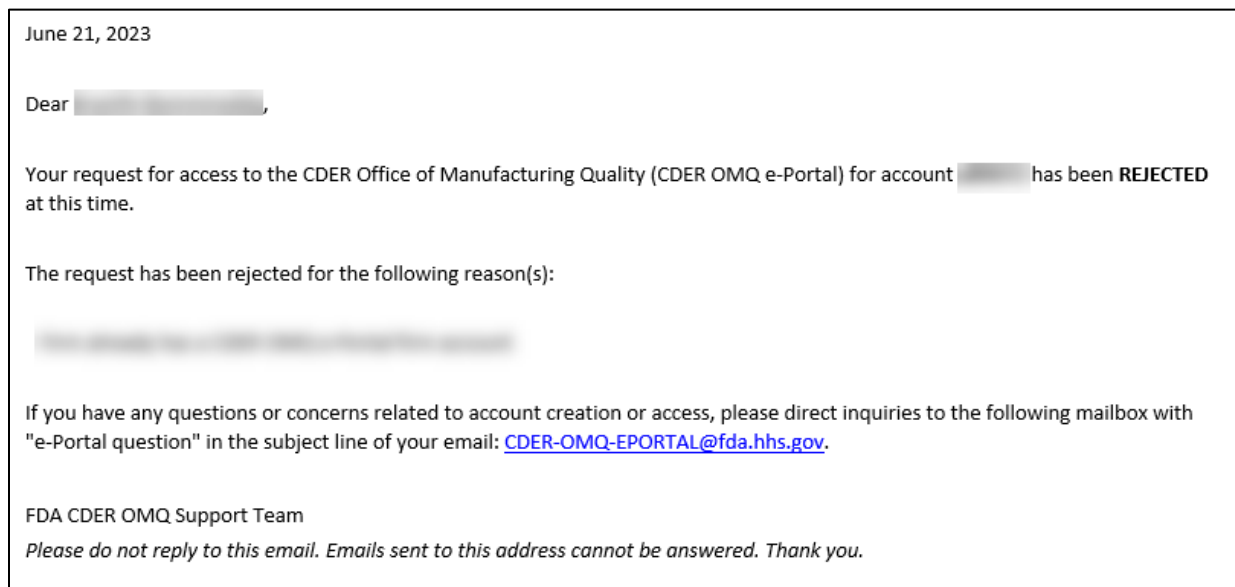


Figure 2.10 – Account Access Rejected Notification

If your request has been denied, you will receive the following notification (Figure 2.11):

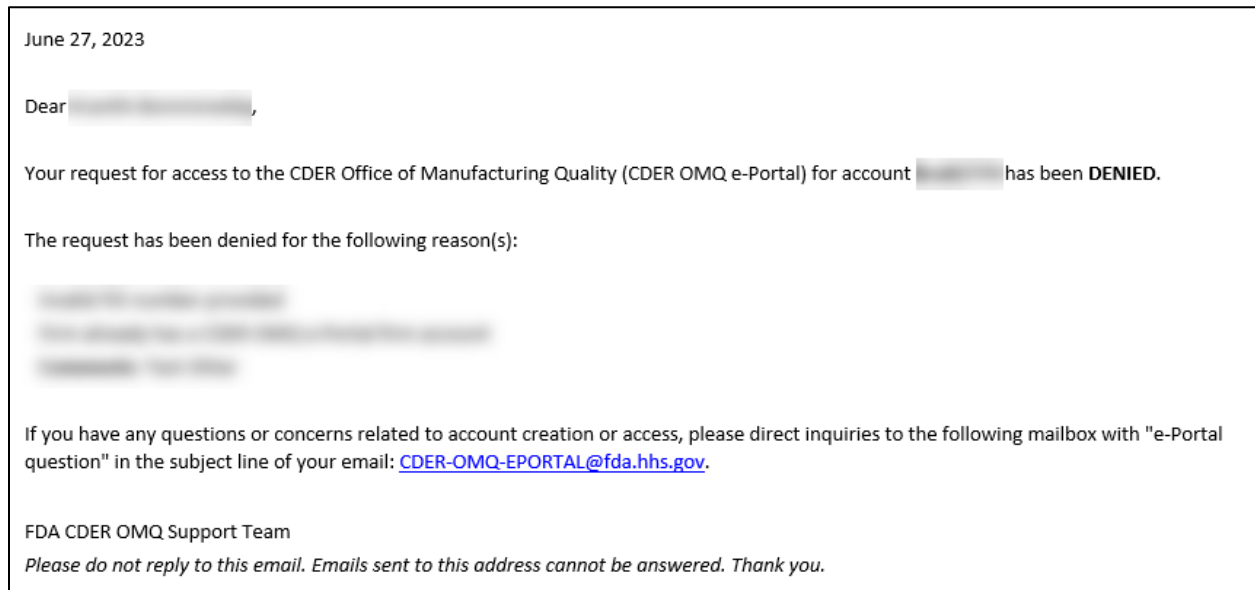


Figure 2.11 – Account Access Denied Notification

If you wish to edit your account profile or update your system access, select the “Edit Account Profile” or “Update System Access” tabs, respectively, from the “Account Management” home page (Figure 2.12). Follow the instructions displayed on the page.

Note: You may be asked for an FDA Establishment Identifier (FEI) number.

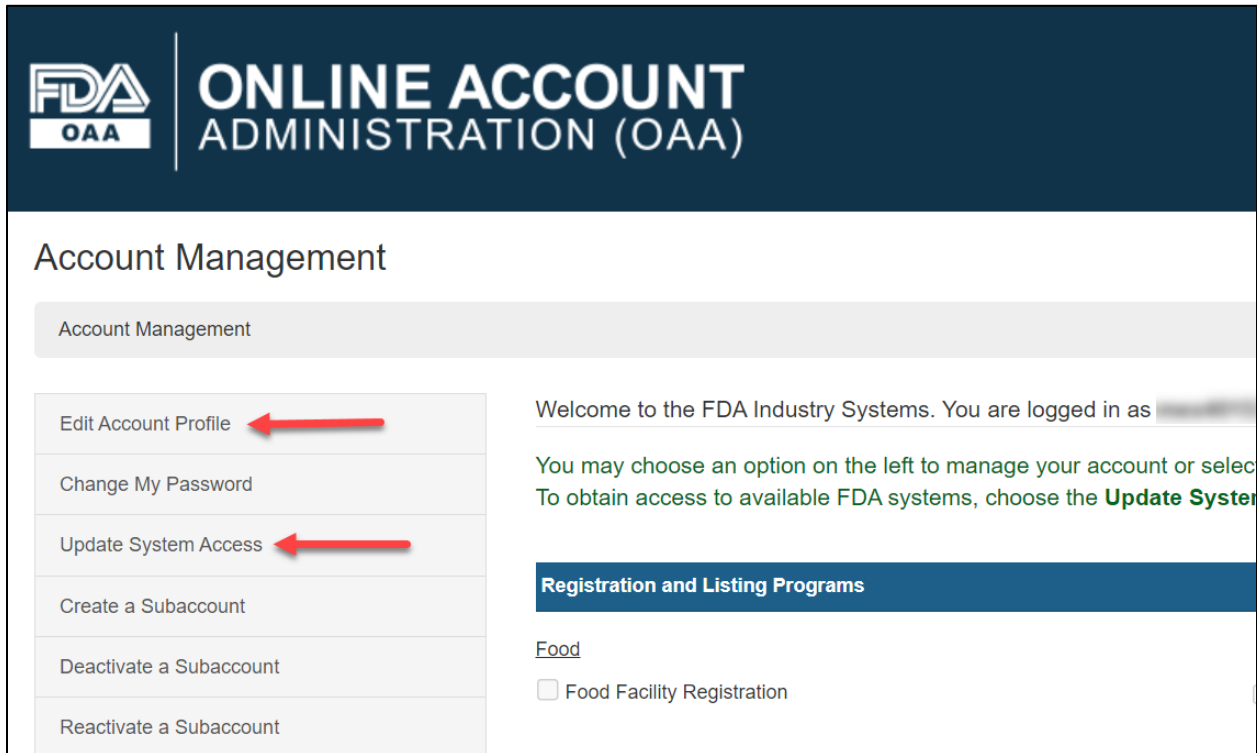


Figure 2.12 – Edit Account Profile and Update System Access Links

When you click the “Submit” button, the system will display a message indicating the system access for account was successfully updated. FDA approval is required to access the CDER OMQ e-Portal.

If you have previously created an FDA online account and wish to access CDER OMQ e-Portal, enter your account ID and password to log in (Figure 2.13).

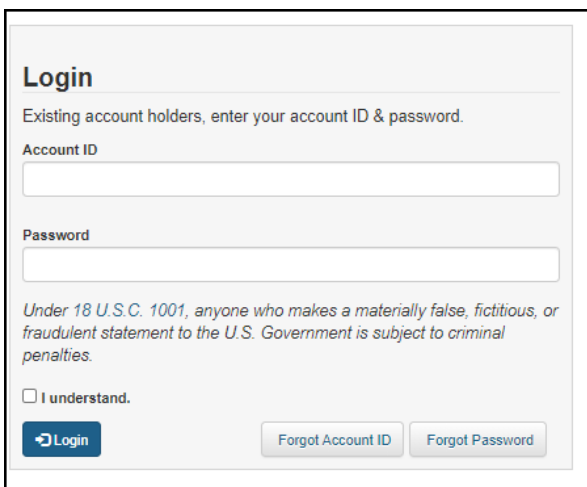
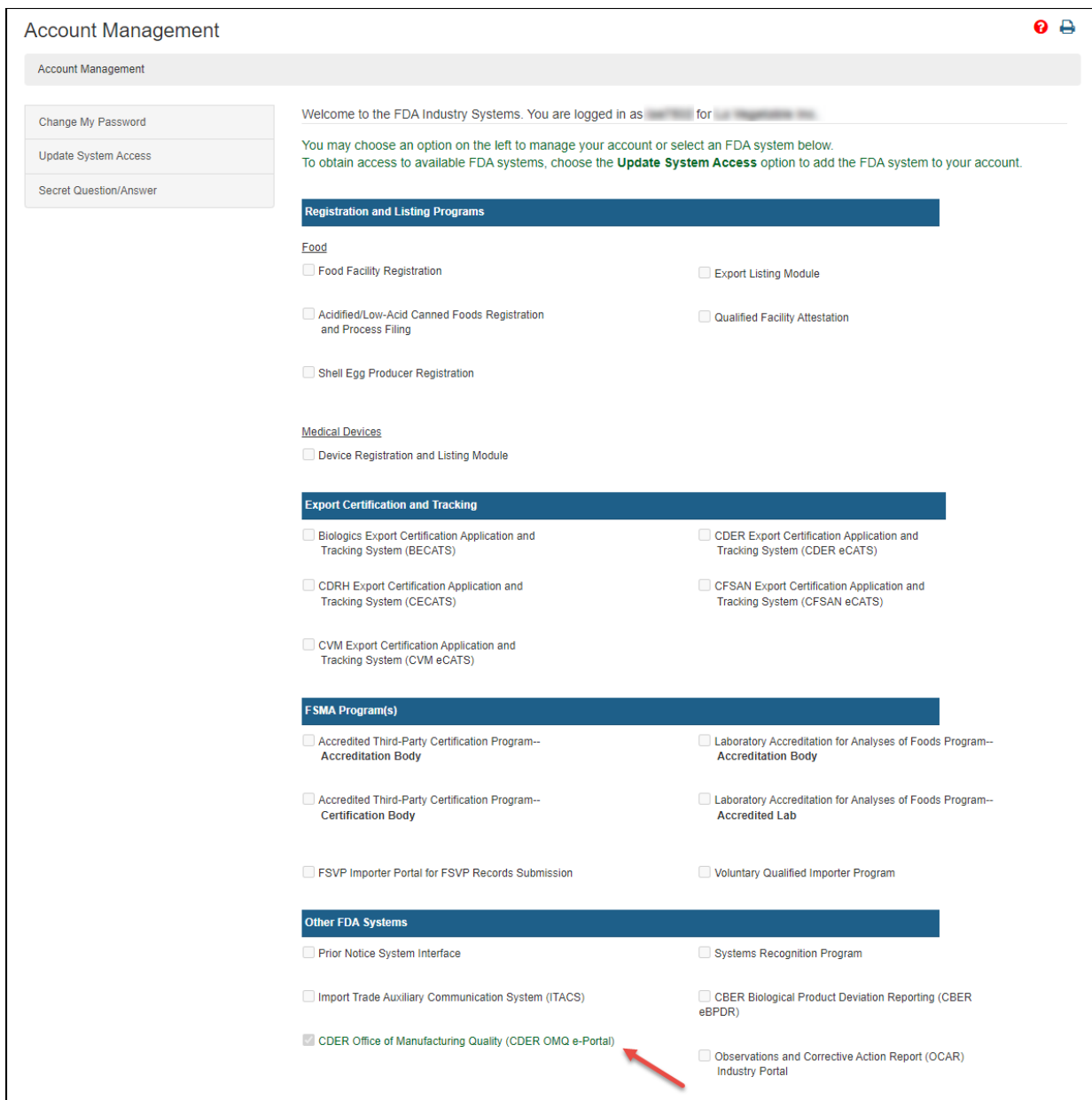


Figure 2.13 – OAA Login

2.1 Logging into and Navigating the CDER OMQ e-Portal

To access your CDER OMQ e-Portal account, enter your account ID and 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, and update your system access. You will then be able to scroll down to the “Other FDA Systems” section and select the “CDER Office of Manufacturing Quality (CDER OMQ e-Portal)” link (Figure 2.14).



The screenshot shows the 'Account Management' page with a sidebar on the left containing links for 'Change My Password', 'Update System Access', and 'Secret Question/Answer'. The main content area displays a welcome message and a list of available FDA systems. The 'Other FDA Systems' section is expanded, showing several options. A red arrow points to the 'CDER Office of Manufacturing Quality (CDER OMQ e-Portal)' option, which is checked with a radio button.

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 Program
- Import Trade Auxiliary Communication System (ITACS)
- CBER Biological Product Deviation Reporting (CBER eBPDR)
- CDER Office of Manufacturing Quality (CDER OMQ e-Portal)
- Observations and Corrective Action Report (OCAR) Industry Portal

Figure 2.14 – CDER Office of Manufacturing Quality (CDER OMQ e-Portal) Link

As a CDER OMQ e-Portal user, you will be directed to the “Home” page, which outlines frequently asked questions to assist you in navigating the e-Portal. The system will display the following options in the left navigation menu (Figure 2.15):

- Manage Sub-Accounts
- Submissions
- Large File Dashboard



CDER OFFICE OF MANUFACTURING QUALITY
(CDER OMQ e-Portal)

Home

Manage Sub-Accounts

Submissions

Large File Dashboard

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

When should I respond?
For Warning Letter Response, FDA recommends that you respond within 15 working days after receipt of the warning letter submission. FDA also recommends if you are unable to complete corrective actions within 15 working days, state the reason for the delay and the time frame within which you will do so.

For other responses to FDA (e.g., Regulatory Meeting questions, Request for Additional Information, etc.), please follow the timeframe noted in the submission.

What information should I submit?
You may submit response to FDA's request on Warning Letter, Regulatory Meeting, and any other requests for information based on the status along with the supporting documents.

How do I submit a response?
From the "Submissions" page, expand the Action Type by clicking the "View Submissions" ▾ down arrow from the "Actions" column to view FDA's request. Select the "View Submission Details" 👁 icon to navigate to the "Submission Details" page and click the "Add Firm Response" button to respond to FDA's request. To add a response to a new Submission Type, select the "Add Submission Responses" + icon. From the "Add Submission Response" page, select a Submission Type from the dropdown list (if not preselected), enter a firm response, select a document type, and upload a file. Once a file is uploaded, enter attachment description, and then click the "Submit Response" button.

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.

If you have any questions or concerns, please direct inquiries to the following mailbox with "e-Portal question" in the subject line of your email: CDER-OMQ-EPORTAL@fda.hhs.gov.

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

Figure 2.15 – CDER OMQ e-Portal Home Page

2.2 Adding and Managing Subaccounts

Once you log in, you may add a sub-account by selecting the “Create a Subaccount” tab from the “Account Management” home page (Figure 2.16).

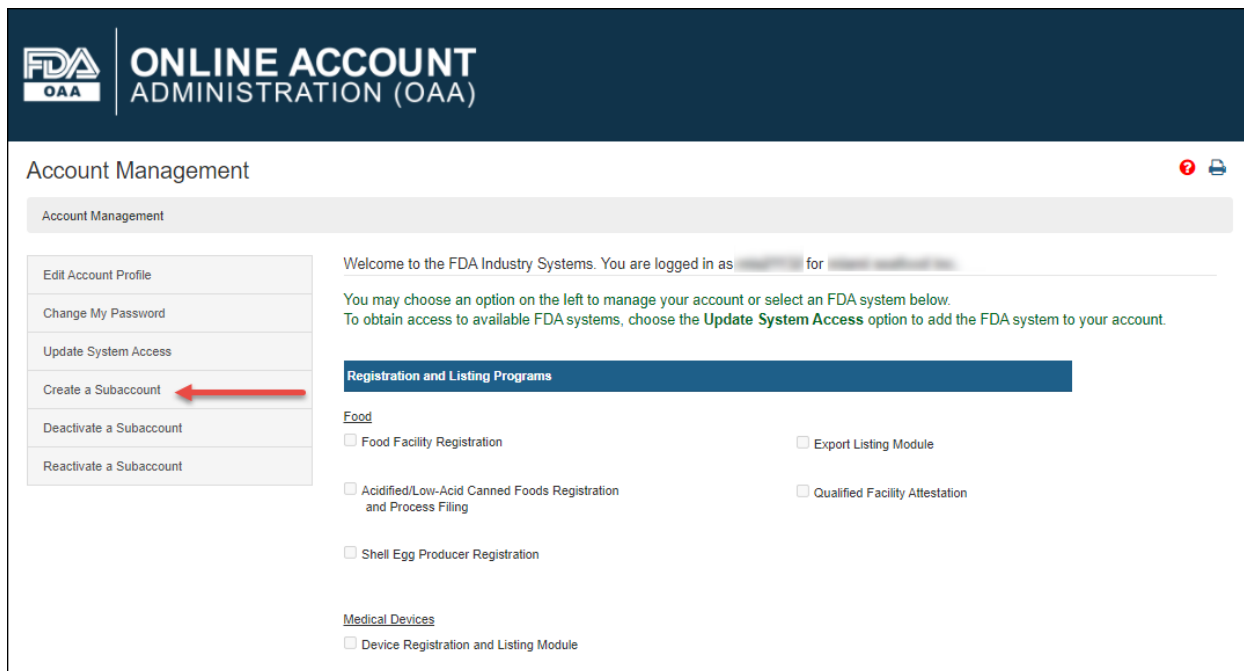



Figure 2.16 – Create a Sub-account

The system will ask for the sub-account holder’s information – such as “Point of Contact Information” and “Physical Address (Business) of Account Holder” (Figure 2.17). 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 XXXXXXXXXX

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	Telephone	Ext
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

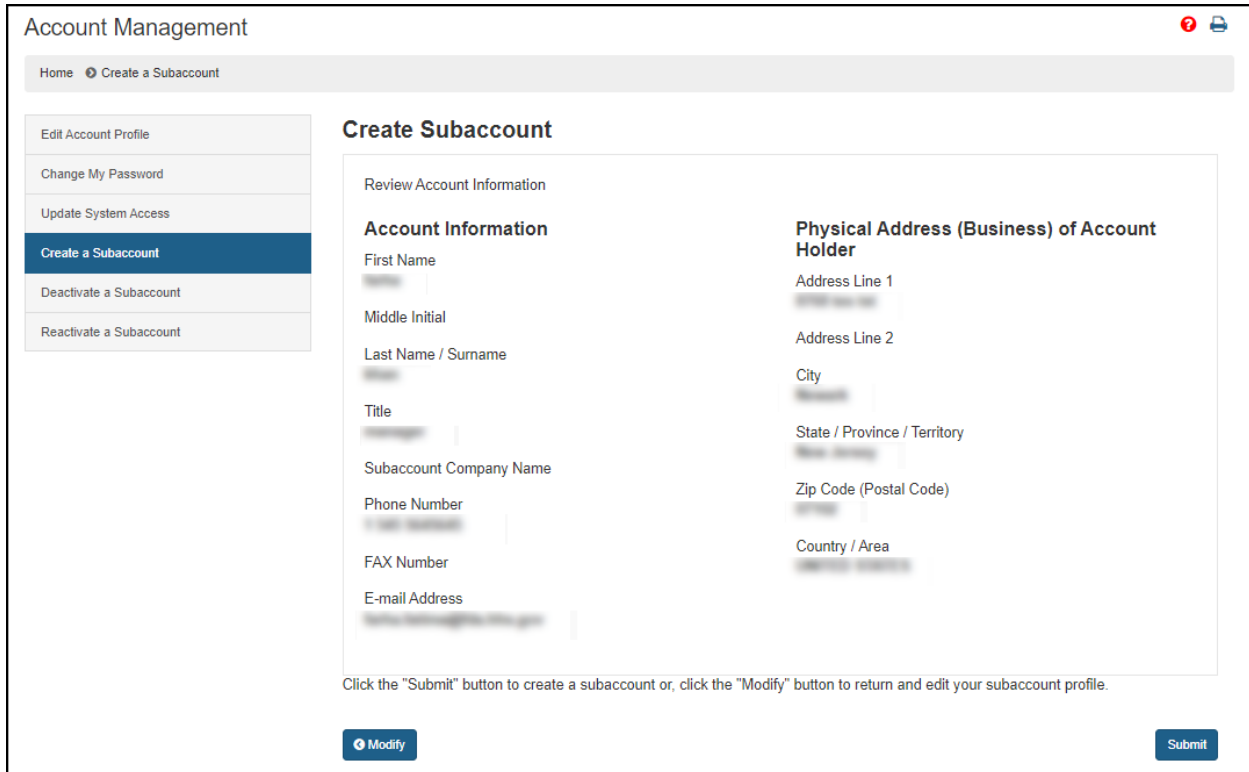
State / Province / Territory

Zip Code (Postal Code)

Figure 2.17 – Sub-account Holder’s Information

The “Create Subaccount – Review Account Information” page will display (Figure 2.18). 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.



The screenshot shows the 'Account Management' interface. The main heading is 'Create Subaccount'. On the left, a sidebar contains several menu items: 'Edit Account Profile', 'Change My Password', 'Update System Access', 'Create a Subaccount' (highlighted in blue), 'Deactivate a Subaccount', and 'Reactivate a Subaccount'. The main content area is titled 'Create Subaccount' and contains a 'Review Account Information' section. This section is divided into two columns: 'Account Information' and 'Physical Address (Business) of Account Holder'. The 'Account Information' column includes fields for First Name, Middle Initial, Last Name / Surname, Title, Subaccount Company Name, Phone Number, FAX Number, and E-mail Address. The 'Physical Address' column includes fields for Address Line 1, Address Line 2, City, State / Province / Territory, Zip Code (Postal Code), and Country / Area. At the bottom of the form, there is a note: 'Click the "Submit" button to create a subaccount or, click the "Modify" button to return and edit your subaccount profile.' Below this note are two buttons: 'Modify' and 'Submit'.

Figure 2.18 – Create Subaccount – Review Account Information Page

When you click the “Submit” button, the system will display a message indicating the sub-account was created successfully.

Note: The sub-account ID and temporary password will be sent in two separate emails to the sub-account holder.

Once the sub-account has been created by the firm’s Enterprise account holder, the Enterprise account holder must grant access to the associated sub-account(s).

To grant access, log into the CDER OMQ e-Portal and navigate to the “Home” page. Select “Manage Sub-Accounts” on the left navigation menu to edit sub-account access (Figure 2.19).

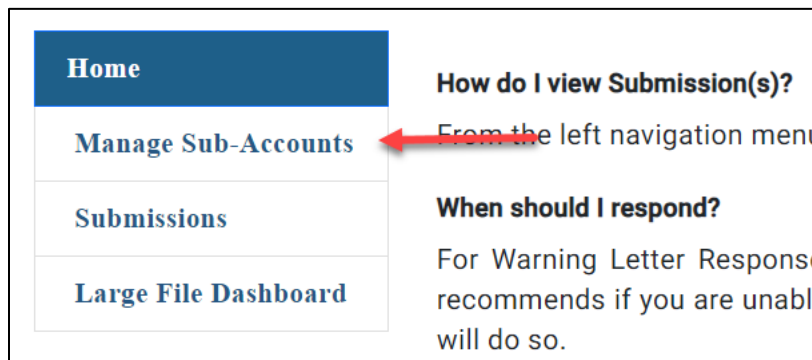


Figure 2.19 – Manage Sub-Accounts Menu Option

You may update a role to one of the following:

- No Access – Cannot view submission details or any documentation sent between FURLS and FDA (the default role when a subaccount is created)
- Read-Only – Can view submission details but cannot submit documentation
- Full Access – Can view submission details and submit documentation

Select the checkbox in the “Account Admin” column to grant the corresponding sub-account the privilege to manage or change a role for other subaccounts.

Click the “Save” button (Figure 2.20).

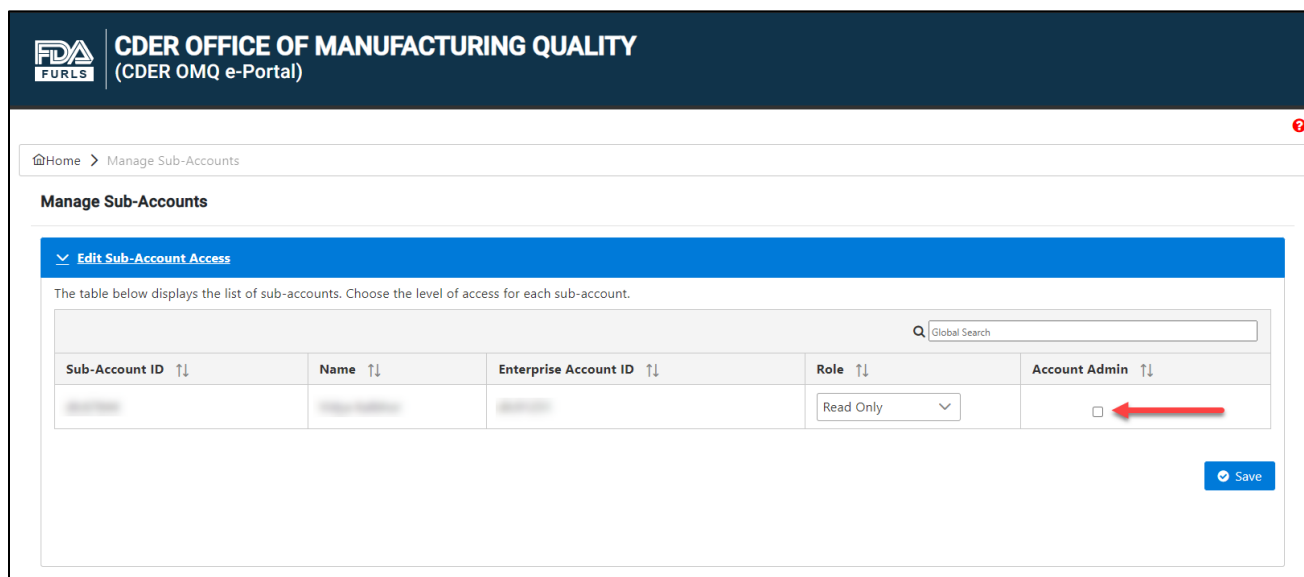


Figure 2.20 – Manage Sub-Accounts Page

Once the enterprise account holder activates the CDER OMQ e-Portal account for the sub-account, FDA will send an email notification to the corresponding sub-account member(s) indicating the level of access granted (Figure 2.21).

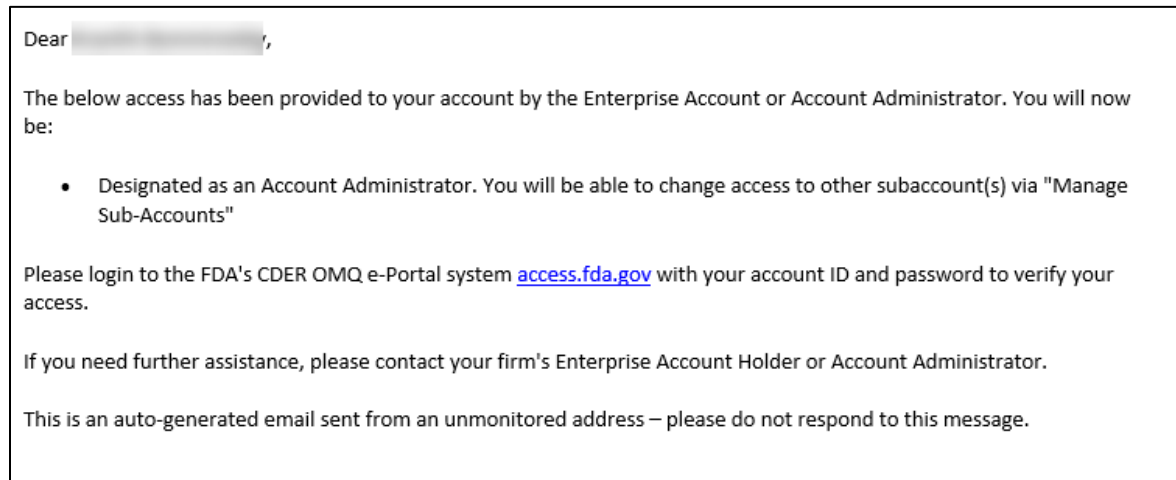


Figure 2.21 – Sub-account Creation Email Notification

3 Adding and Viewing Submissions

The “Submissions” page allows you to view submission details between the firm and FDA, as well as access the feature for submitting firm responses. Click “Submissions” from the navigation menu (Figure 3.1).

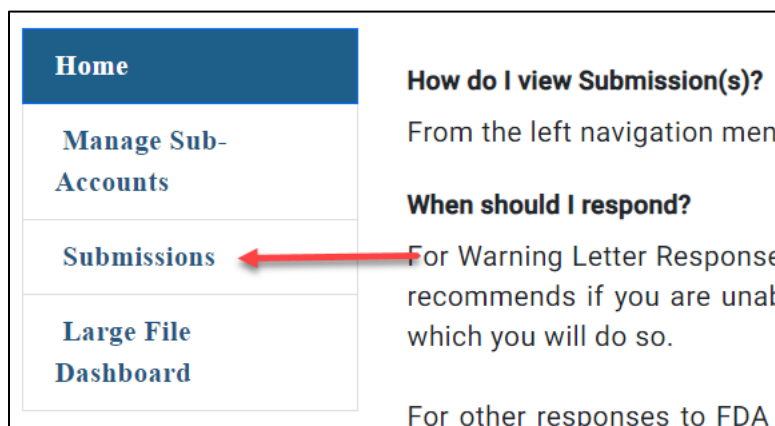


Figure 3.1 – Navigation Menu

The system will direct you to the “Submissions” page (Figure 3.2).

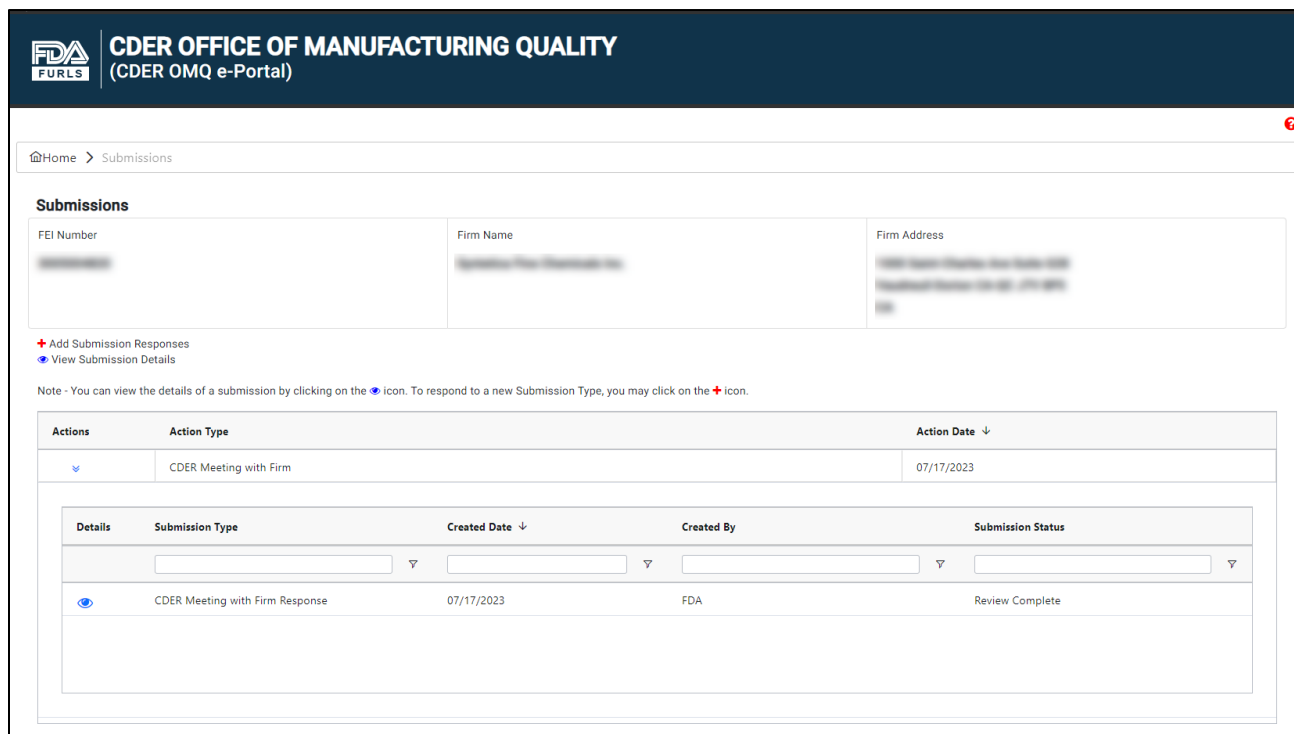


Figure 3.2 – Submissions Page

Proceed to Section 3.1 of this document for instructions to view submission details.

Proceed to Section 3.2 of this document for instructions to add a new firm response.

Proceed to Section 3.3 of this document for instructions to upload large files (i.e., over 100 MB).

Note: You must upload large files using the “Large File Dashboard” feature to include them in a firm response.

3.1 Viewing Submission Details

The “Submissions” page lists all submissions assigned to the FEI number associated with your firm’s name and address (Figure 3.3).

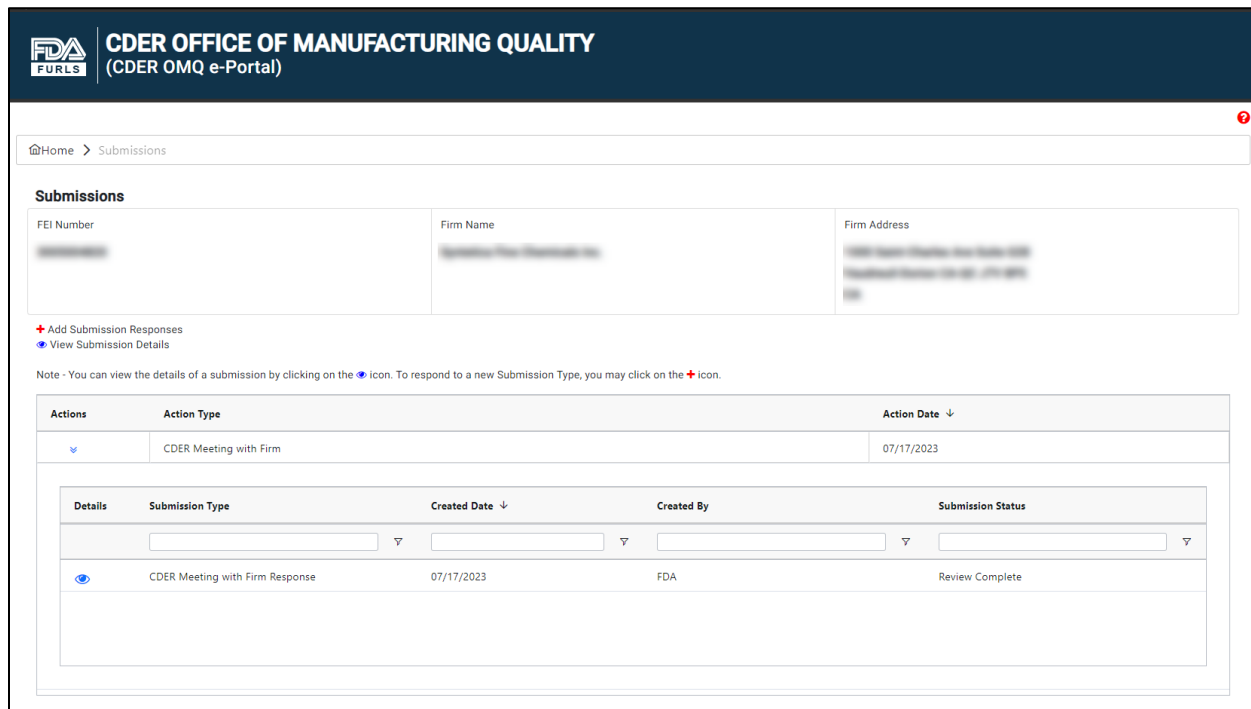


Figure 3.3 – Submissions Page

The “Actions” column displays a “View Submissions” (down arrow) icon (Figure 3.4). Click the “View Submissions” icon to expand the “Action Type” column.

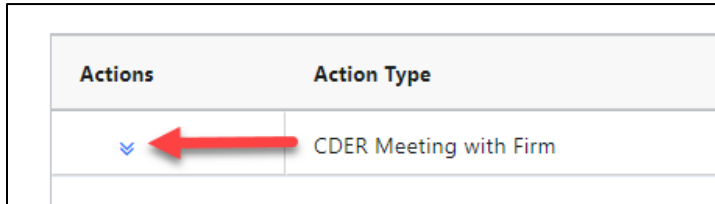


Figure 3.4 – View Submissions Icon

The possible Action Types and their corresponding Submission Types are as follows:

Action Type	Submission Type
CDER Meeting with Firm	CDER Meeting with Firm Response
GDUFA III Post Warning Letter Meeting	GDUFA III Post Warning Letter Meeting Response
GDUFA III Post Warning Letter Re-inspection	GDUFA III Post Warning Letter Re-inspection Response
Post-Inspection Letter	Post-Inspection Letter Response
Request for Additional Information	Request for Additional Information Response
Pre-Regulatory Meeting	Response to Pre-Regulatory Meeting Questions
Post-Regulatory Meeting	Response to Post-Regulatory Meeting Commitments
Warning Letter	<ul style="list-style-type: none"> • Warning Letter Sent • Warning Letter Response • GDUFA III Post Warning Letter Meeting Request • GDUFA III Post Warning Letter Re-Inspection Request

Once the “Action Type” column is expanded, the “Details” column displays a “View Submission Details” (eye) icon (Figure 3.5). Click the “View Submission Details” icon.

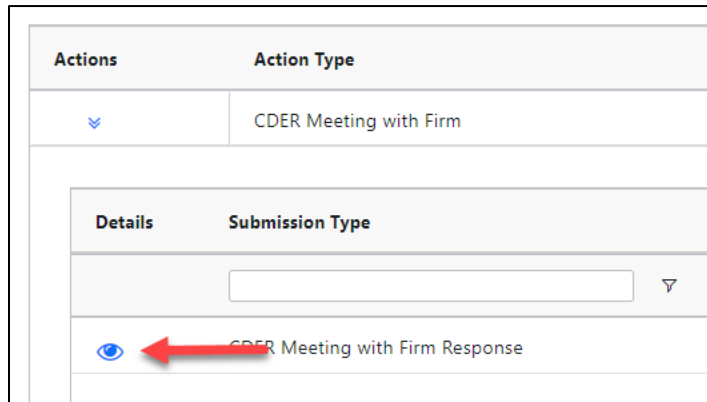


Figure 3.5 – View Submission Details Icon

The system will display the “Submission Details” page for the selected action type (Figure 3.6). The “Submission Details” page will display the “Submission Response(s)” section, listing the responses sent between the firm and FDA. Documents sent between the firm and FDA will display in the “Submission Document(s)” section.

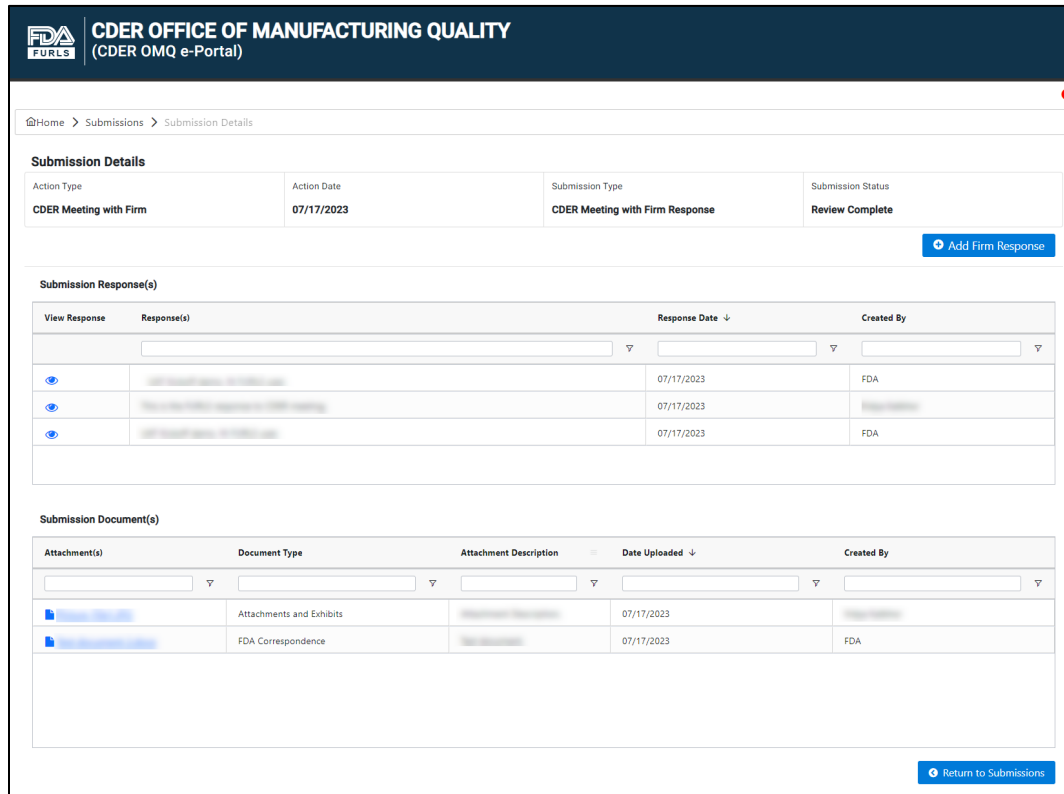


Figure 3.6 – Submission Details Page

To view the full response to a submission (if not displayed in its entirety in the “Response(s)” column,) click the “View Response” (eye) icon. The system will display the “View Response” pop-up window with the full response (Figure 3.7).

Click the “Close” button from the “View Response” window to dismiss the “View Response” pop-up and return to the “Submission Details” page.

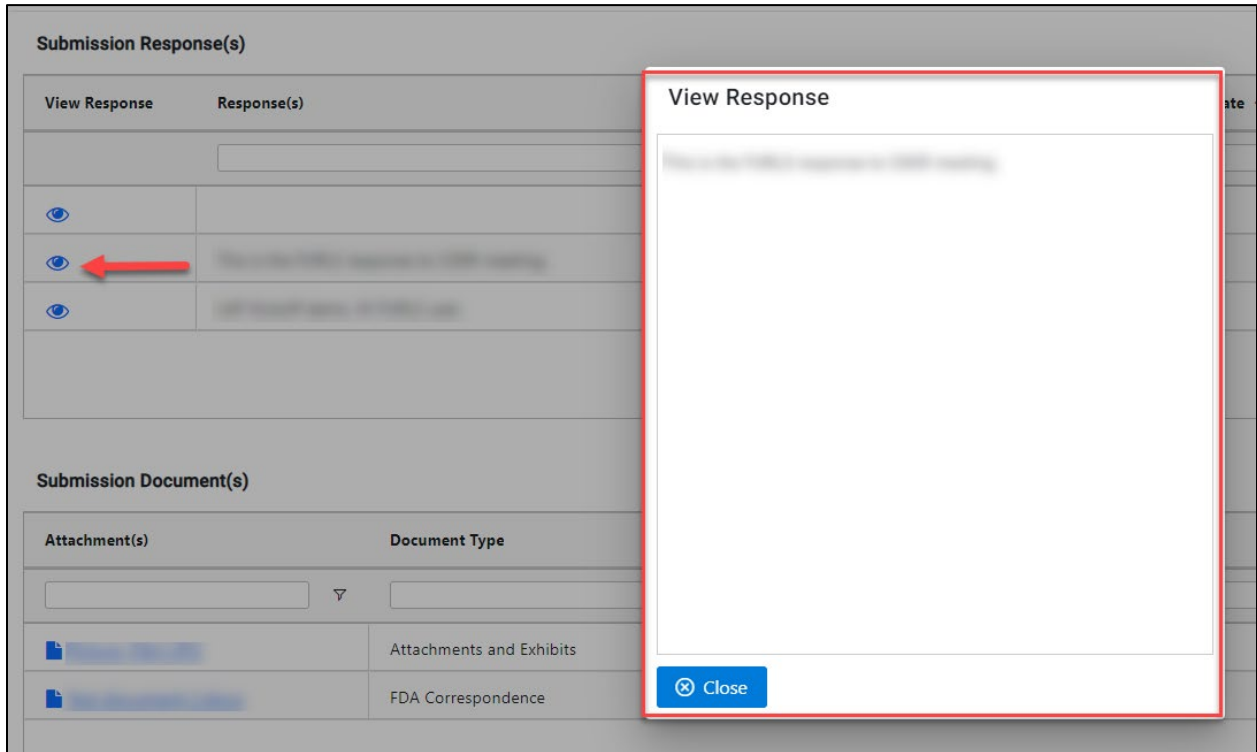


Figure 3.7 – View Response Pop-Up Window

To view the details of a submission document or download a file, click the hyperlinked file name from the “Attachment(s)” column of the “Submission Documents” section. The system will display the “Attachment Details” pop-up window.

Click the “Download” button to download the selected file. Click the “Close” button to close the window and return to the “Submission Details” page (Figure 3.8).

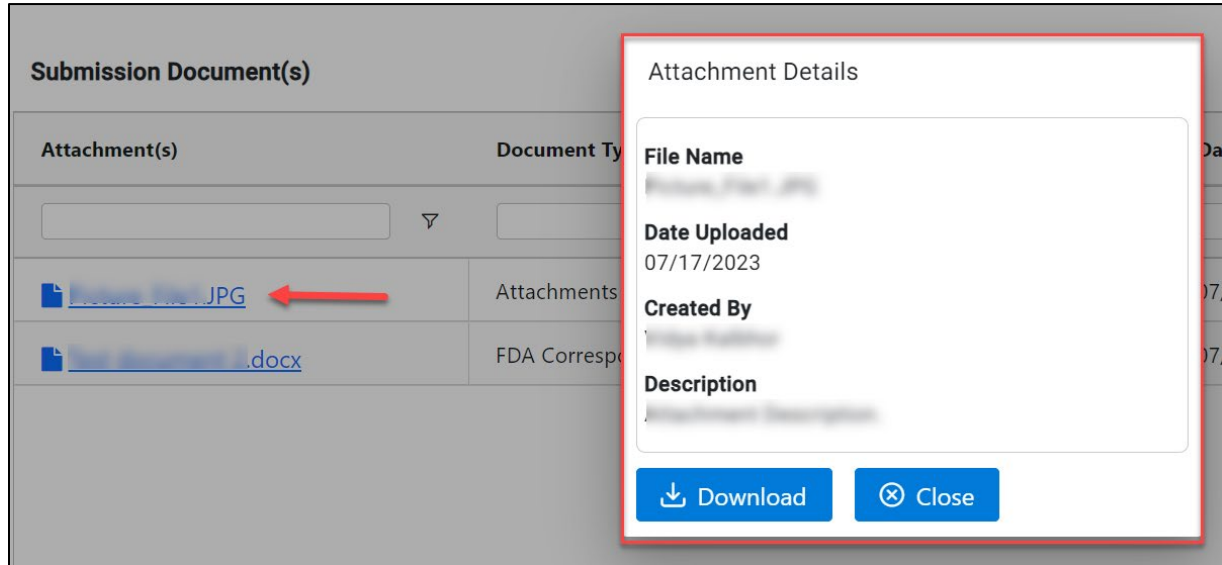


Figure 3.8 – Attachment Details Pop-Up Window

3.1.1 Searching Submission Information

You may search submission information based on “Submission Type,” “Created Date,” “Created By,” and “Submission Status” on the “Submissions” page. The data will be filtered dynamically as you type your entry (Figure 3.9). You may also click the “Filter” icon displayed for each column to refine your search.

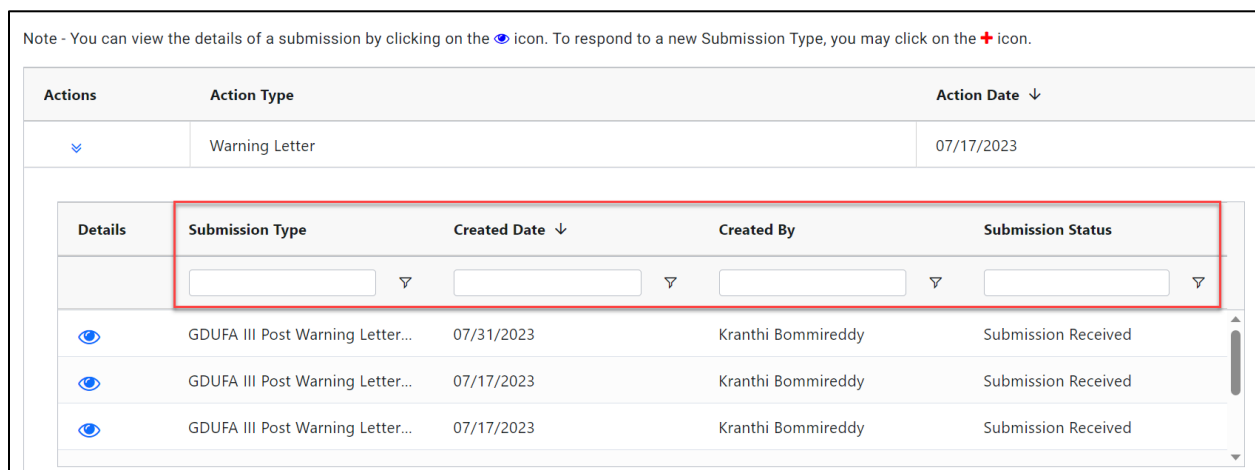


Figure 3.9 – Search Boxes on Submissions Page

You may also search within the “Submission Response(s)” section (Figure 3.10) and “Submission Document(s)” section (Figure 3.11) of the “Submission Details” page.

Submission Details			
Action Type	Action Date	Submission Type	Submission Status
Warning Letter	07/17/2023	GDUFA III Post Warning Letter Re-Inspection Request	Submission Received
			+ Add Firm Response
Submission Response(s)			
View Response	Response(s)	Response Date ↓	Created By
	<input type="text"/>	<input type="text"/>	<input type="text"/>
	View the attachment description for [redacted]	07/31/2023	[redacted]
	[redacted]	07/26/2023	[redacted]
	View the submission for GDUFA III Post Warning Letter Re-Inspection Request of [redacted]	07/18/2023	[redacted]

Figure 3.10 – Submission Response(s) Search Boxes

Submission Document(s)				
Attachment(s)	Document Type	Attachment Description	Date Uploaded ↓	Created By
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Executive Summary	View the attachment description for [redacted]	07/31/2023	[redacted]

Figure 3.11 – Submission Document(s) Search Boxes

3.2 Adding a Submission Response

To begin a firm response, you will need to navigate to the “Add Submission Response” page.

You may access the “Add Submission Response” page in one of two ways:

1. Click the red “Add Submission Responses” (plus) icon of the desired action type from the “Actions” column, if applicable (Figure 3.12).

Note: The “Add Submission Responses” icon will only display for the **first submission** from FDA for “Post-Regulatory Meeting” and “Warning Letter” action types. When present, you must click the “Add Submission Responses” icon to begin a **new** firm response.




Actions	Action Type
  	Post-Regulatory Meeting

Figure 3.12 – Add Submission Responses Icon

- Click the “View Submission Details” (down arrow) icon from the “Actions” column to **add a new submission to the action** (Figure 3.13). Once you have expanded the row to display the submission details, click the “View Submission Details” (eye) icon from the “Details” column, then click the “Add Firm Response” button.



Actions	Action Type
 	CDER Meeting with Firm

Figure 3.13 – View Submissions Icon

- Once you have expanded the row to display the submission details, click the “View Submission Details” (eye) icon from the “Details” column.
- Click the “Add Firm Response” button on the “Submission Details” (Figure 3.14).

Note: You may click the “Return to Submissions” button at the bottom of the page if you wish to return to the previous page.


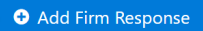
Submission Details			
Action Type	Action Date	Submission Type	Submission Status
CDER Meeting with Firm	07/17/2023	CDER Meeting with Firm Response	Review Complete
			 

Figure 3.14 – Add Firm Response Button

The system will display the “Add Submission Response” page, where you may add the firm response and supporting document(s) (Figure 3.15).

Follow the instructions listed at the top of the page.

U.S. Department of Health and Human Services | Welcome, Vidya Kalbhor | ePURLS Home

CDER OFFICE OF MANUFACTURING QUALITY
(CDER OMQ e-Portal)

Home > Submissions > Add Submission Response

Add Submission Response

Instructions

- Step 1: Select a Submission Type (if not pre-selected).
- Step 2: Add a Response.
- Step 3: Select a Document Type.
- Step 4: To add an attachment -
 - If the document is less than 100 MB each, click the **Browse** button to select a document(s) and click the Upload button.
 - If the document is larger than 100 MB each, it must first be uploaded to the [Large File Dashboard](#). Click the **Select and Add Large File** button to add the file to the submission response.
- Step 5: All uploaded files will be added to the Attachment(s) table, listed below.
- Step 6: Add a description for each file in the Attachment Description field within the Attachment(s) table. Once the description has been added, press Tab or hit the Enter key to save the description entered.
- Step 7: To submit the response, click the Submit Response button.

Selected Action Type

This action type was selected to add response.

Action Type	Action Date
CDER Meeting with Firm	07/17/2023

Submission Type

CDER Meeting with Firm Response

Response

4000 characters left

Document Type

Please Select One

Note: The acceptable file types include .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf. The file size of each document is limited to maximum of 100 MB.

+ Browse Upload Cancel

Note: The acceptable file types include .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, .rtf, .mp4, .mov, .wav, .eml and .zip. Documents with a file size larger than 100 MB must first be uploaded to the Large File Dashboard before it is added to a submission response.

Select and Add Large File

Attachment(s)

Action...	Attachment(s) ↑	Document Type	Attachment Description	Uploa...
No attachment(s) have been added.				

Submit Response

Figure 3.15 – Add Submission Response Page

Select the “Submission Type” from the dropdown menu, if applicable (Figure 3.16). The “Submission Type” may be pre-filled and read-only, depending on the action type.

Submission Type

Response to Pre-Regulatory Meeting Questions

Figure 3.16 – Submission Type Dropdown Menu

Enter your response in the “Response” field. The “Response” field is a free-type, text entry field which allows up to 4,000 English keyboard characters (Figure 3.17).

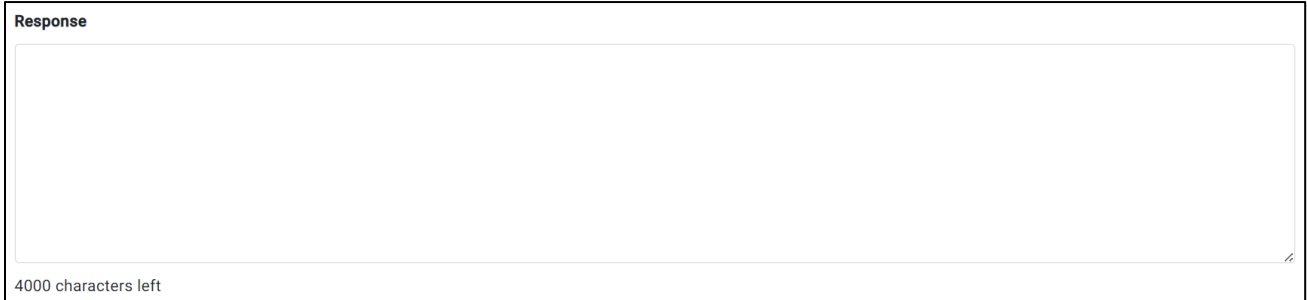


Figure 3.17 – Response Field

Select the document type from the “Document Type” dropdown menu (Figure 3.18).

Additional instructions will display, based on the document type selected.

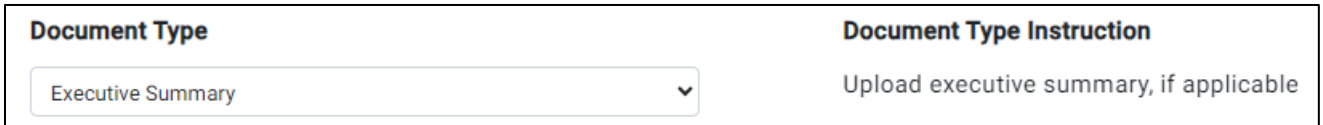


Figure 3.18 – Document Type Menu and Instruction

To upload a file less than 100 MB in size, click the “Browse” button (Figure 3.19). A pop-up window will appear, prompting you to access your file system. The acceptable file types include: .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, and .rtf.

Select the file and then click the “Upload” button to add the file(s) to the “Attachment(s)” table at the bottom of the page. You may select more than one file at a time to upload using this feature. Click the “Cancel” button if you wish to remove the file(s). Repeat the steps to upload additional files.

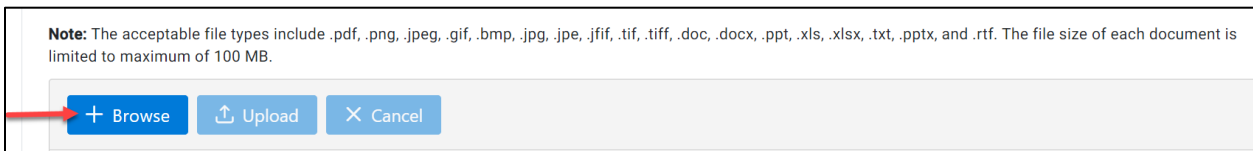


Figure 3.19 – Browse, Upload, and Cancel Buttons

If you wish to include a large file (i.e., over 100MB) to your submission, click the “Select and Add Large File” button above the “Attachment(s)” table (Figure 3.20).

Note: The acceptable file types include .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, .rtf, .mp4, .mov, .wav, .eml, and .zip. Documents with a file size larger than 100 MB must first be uploaded to the Large File Dashboard before it is added to a submission response.



Figure 3.20 – Select and Add Large File Button

The “Select large file(s) to add to Submission” pop-up window will display (Figure 3.21). Files that were uploaded using the “Large File Dashboard” feature will be listed.

Note: To include a file(s) over 100 MB in your submission, you must first upload the file(s) using the “Large File Dashboard” feature. Refer to Section 3.3 of this document, “Uploading Large Files” for additional information.

Click the “Select” button next the file name of the desired file, then click the “Add and Close” button. You may select more than one file from the pop-up window to add to the submission.

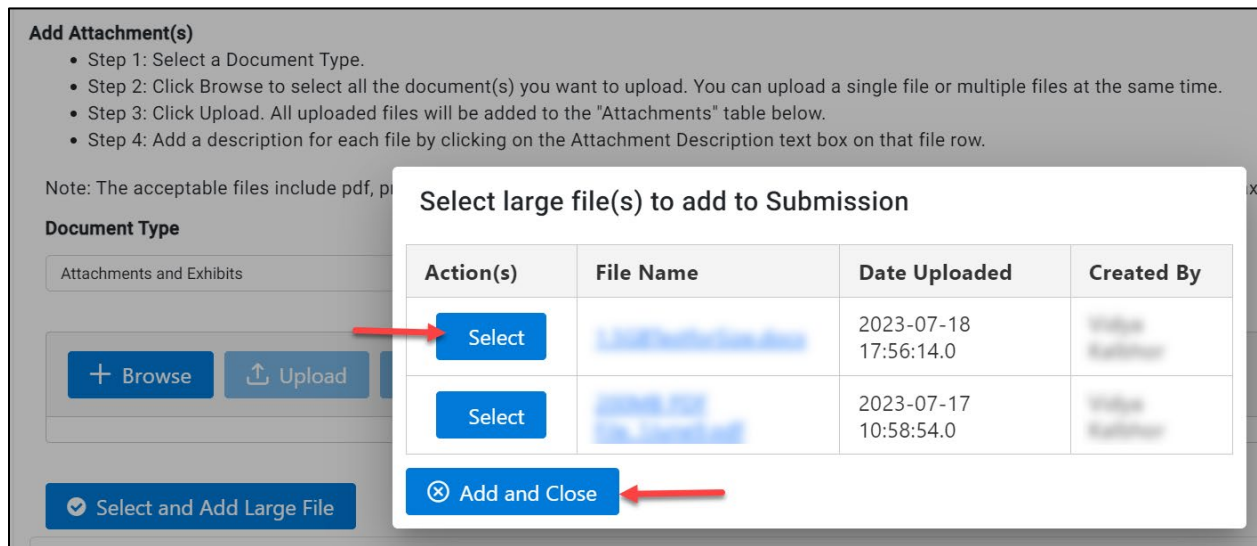


Figure 3.21 – Pop-Up Window – Select large file(s) to add to Submission

All of the files you have added to the submission response will be listed in the “Attachment(s)” table at the bottom of the page (Figure 3.22).

Enter a description for each uploaded file in the “Attachment Description” field, then hit the “Tab” or “Enter” key. If you wish to remove an uploaded file before submitting your response, click the “Delete” (trash) icon next to the file name in the “Action(s)” column.



Attachment(s)			
Action...	Attachment(s) ↑	Document Type	Attachment Description
 Delete		Executive Summary	Required field. Press Tab or hit Enter to save.

Figure 3.22 – Attachment(s) Table

Once you have completed the required fields and uploaded the attachment(s), click the “Submit Response” button at the bottom of the page (Figure 3.23).

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

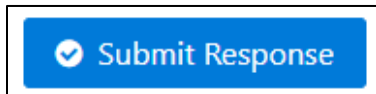



Figure 3.23 – Submit Response Button

After clicking the “Submit Response” button, the system will display the “Confirmation” page and notify FDA of your response (Figure 3.24).


CDER OFFICE OF MANUFACTURING QUALITY
 (CDER OMQ e-Portal)

Confirmation

☛ Thank you for submitting your submission response. You will be able to view the submission and documents you have submitted in the CDER OMQ Module within 24 hours. If you do not receive confirmation from FDA within that timeframe, please email CDER-OMQ-EPORTAL@fda.hhs.gov.

[Return to Submissions](#)

Figure 3.24 – Confirmation Page

When a firm responds to a Submission Type, the status will update to “Submission Received” on the “Submissions” page.

When FDA responds to the firm’s submission, the “Submission Status” on the “Submissions” page will update to either “Additional Information Required” (if applicable) or, “Review Complete” – depending on the submission.

3.3 Uploading Large Files

If you wish to upload a file over 100 MB to attach to a submission, click “Large File Dashboard” from the navigation menu on the “Home” page. The system will direct you to the “Large File Dashboard” page. This feature allows files up to 40 GB each to be uploaded.

Any previously uploaded files over 100 MB will display in the “Uploaded Large File(s)” section. The message “No file(s) have been uploaded.” will display if you have not yet uploaded any large files (Figure 3.25).

Click the “Upload Large File” button.

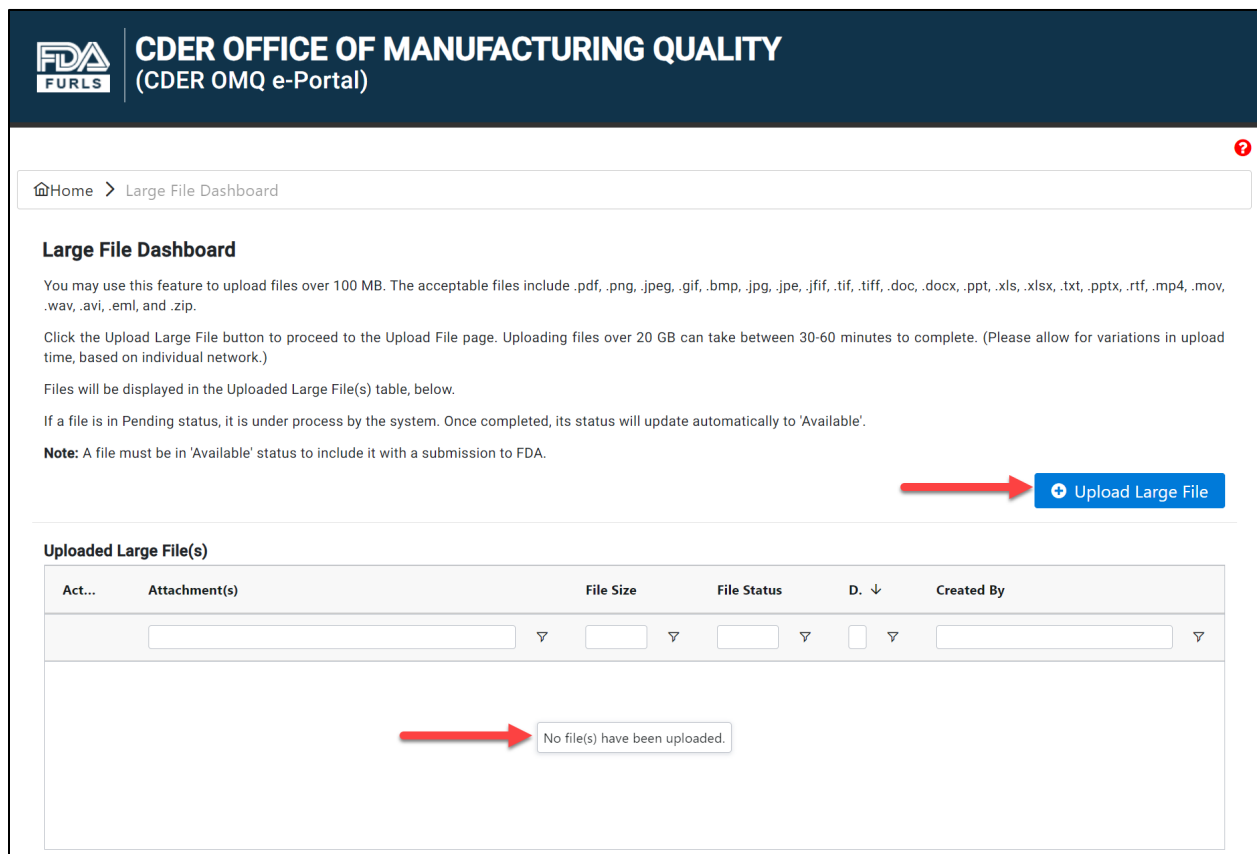


Figure 3.25 – Large File Dashboard Page

The system will display the “Upload File” page. Click the “Select File” button (Figure 3.26).

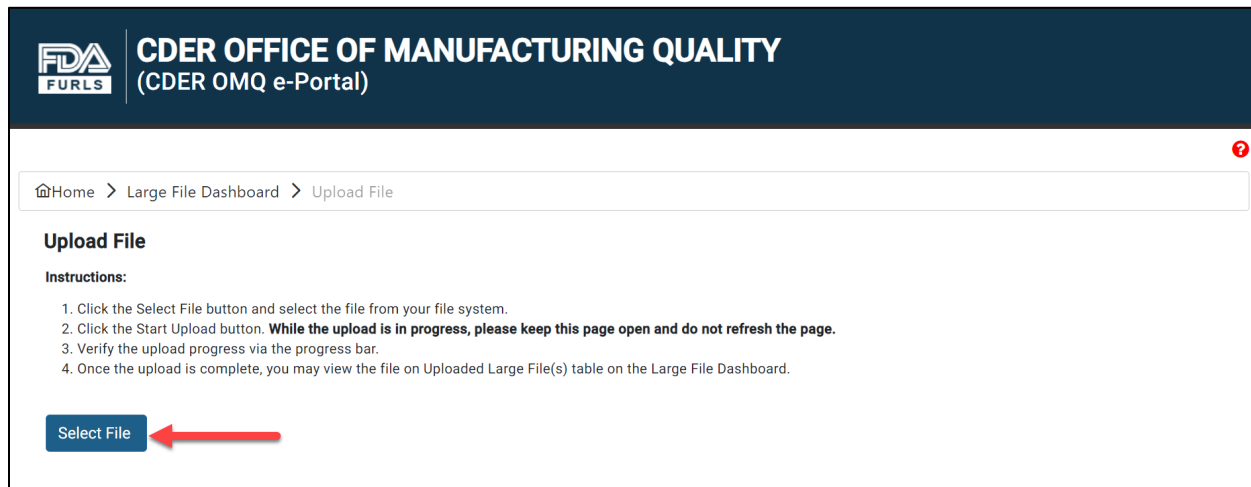


Figure 3.26 – Upload File Page and Select File Button

A pop-up window will appear, prompting you to access your file system.

Select the desired attachment. The acceptable file types include: .pdf, .png, .jpeg, .gif, .bmp, .jpg, .jpe, .jfif, .tif, .tiff, .doc, .docx, .ppt, .xls, .xlsx, .txt, .pptx, .rtf, .mp4, .mov, .wav, .avi, .eml, and .zip.

The “Start Upload” button will display once you have selected a file (Figure 3.27). Click the “Start Upload” button to begin the file upload.

Note: The system will allow you to select and upload one file at a time. However, you may add more than one file to your submission.

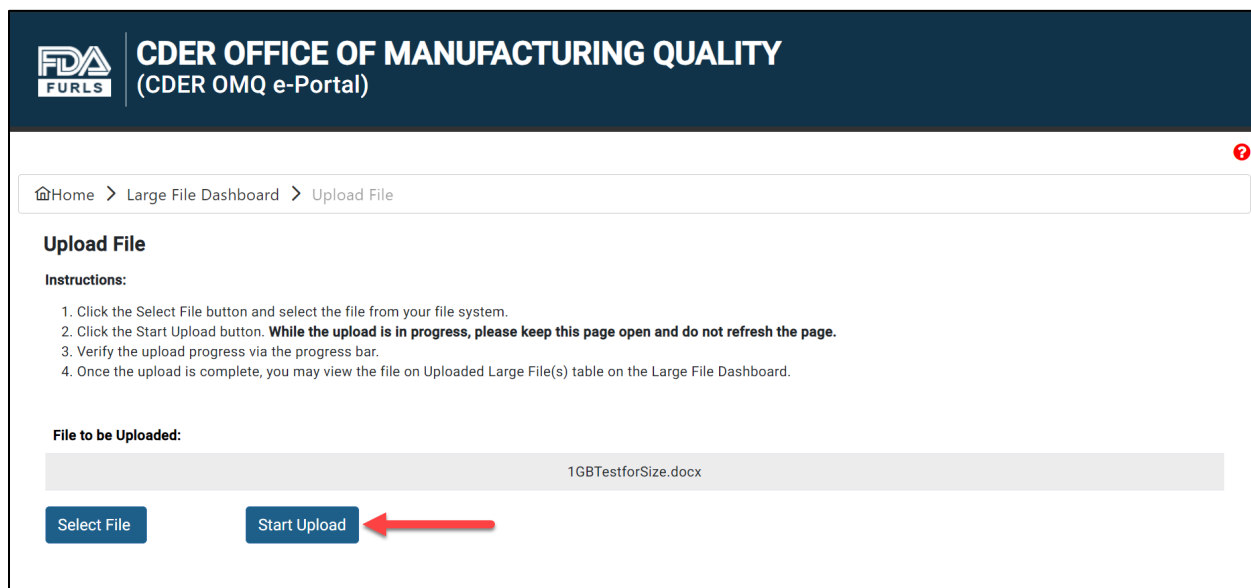
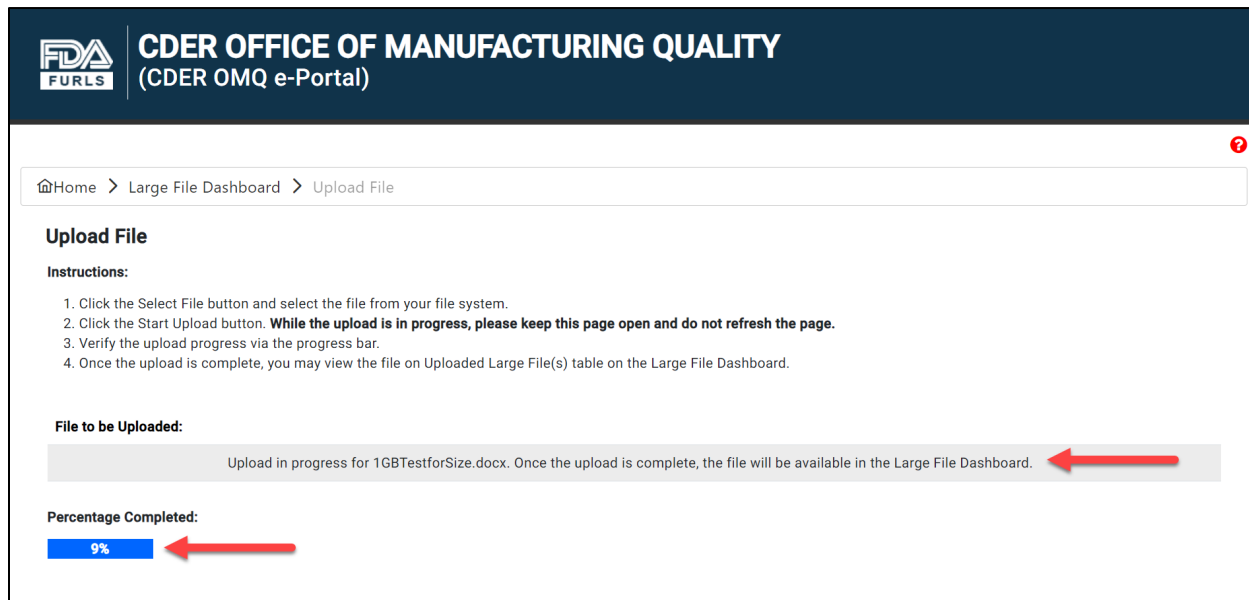


Figure 3.27 – Start Upload Button

****Important:** Your upload will be discarded if you refresh or leave the “Upload File” page or window while the upload is in progress.



FDA FURLS | **CDER OFFICE OF MANUFACTURING QUALITY**
(CDER OMQ e-Portal)

Home > Large File Dashboard > Upload File

Upload File

Instructions:

1. Click the Select File button and select the file from your file system.
2. Click the Start Upload button. **While the upload is in progress, please keep this page open and do not refresh the page.**
3. Verify the upload progress via the progress bar.
4. Once the upload is complete, you may view the file on Uploaded Large File(s) table on the Large File Dashboard.

File to be Uploaded:

Upload in progress for 1GBTestforSize.docx. Once the upload is complete, the file will be available in the Large File Dashboard.

Percentage Completed:

9%

Figure 3.28 – File Upload Progress

Once the upload is complete, the system will display a message confirming the file was successfully uploaded; the percentage complete will be updated to 100% (Figure 3.29). Click the “Back to Dashboard” button to return to the “Large File Dashboard” page to view your file.

The screenshot shows the 'Upload File' page in the CDER OMQ e-Portal. At the top left is the FDA FURLS logo. The main header reads 'CDER OFFICE OF MANUFACTURING QUALITY (CDER OMQ e-Portal)'. A breadcrumb trail shows 'Home > Large File Dashboard > Upload File'. A red question mark icon is in the top right corner. The page title is 'Upload File'. Under 'Instructions:', there are four numbered steps: 1. Click the Select File button and select the file from your file system. 2. Click the Start Upload button. **While the upload is in progress, please keep this page open and do not refresh the page.** 3. Verify the upload progress via the progress bar. 4. Once the upload is complete, you may view the file on Uploaded Large File(s) table on the Large File Dashboard. Below this, the 'File to be Uploaded:' section shows a grey progress bar with a red arrow pointing to the text 'Upload complete for 1GBTestforSize.docx'. The 'Percentage Completed:' section shows a blue progress bar that is 100% full, with a red arrow pointing to the '100%' label. At the bottom right, there is a 'Back to Dashboard' button with a red arrow pointing to it.

Figure 3.29 – Successful File Upload Message

Your file will be displayed in the “Uploaded Large File(s)” section of the “Large File Dashboard” page (Figure 3.30).

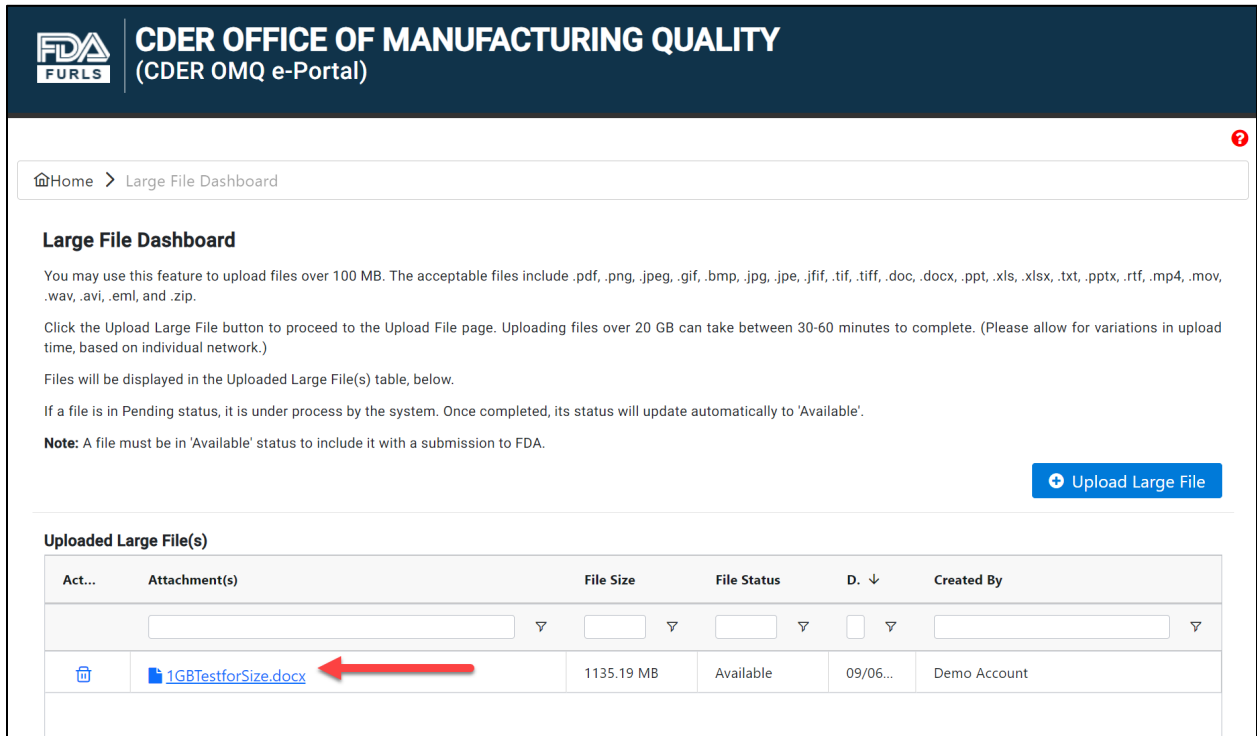


Figure 3.30 – Uploaded Large File(s) and Delete Icon

Click the “Delete” (trash) icon next to the file name if you wish to remove the file (Figure 3.31).

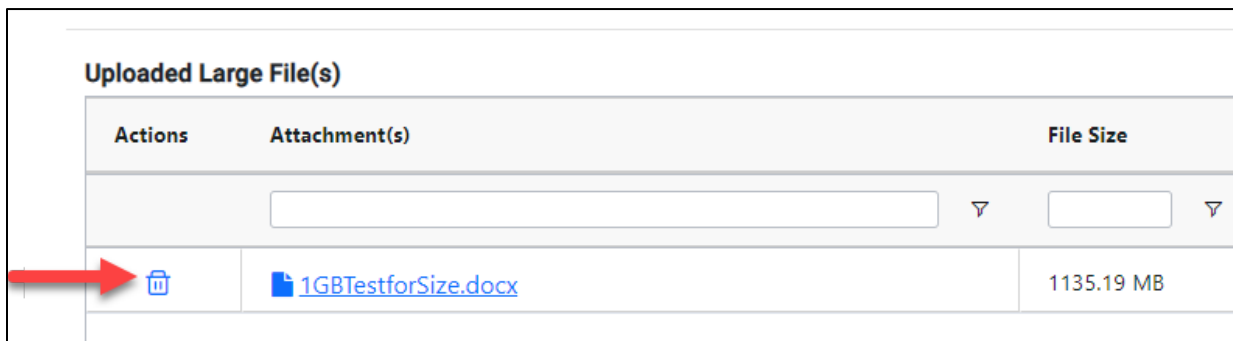


Figure 3.31 – Delete Icon

Proceed to the “Submissions” page to attach an uploaded large file to a submission. Refer to Section 3.2 of this document for instructions to add a submission response.

4 User Support

For questions related to the CDER OMQ program or system-related issues, contact CDER-OMQ-EPortal@fda.hhs.gov.

For issues related to CDER OMQ e-Portal account creation and login, please contact the Help Desk at FURLS@fda.hhs.gov.

For additional instruction, pre-recorded tutorials can be accessed via the “Tutorials” button on the FIS website (Figure 4.1).

U.S. Department of Health and Human Services

FDA | **U.S. FOOD AND DRUG ADMINISTRATION**
FIS | **INDUSTRY SYSTEMS**

FDA Home | FIS Home

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 08/31/2025 See OMB Burden Statement</p> <p>Info Help</p>
<p>Import Trade Auxiliary Communication System (ITACS) OMB Approval Number 0910-0842 OMB Expiration Date 06/30/2023 See OMB Burden Statement</p> <p>Info Help</p>	<p>Prior Notice System Interface (PNSI) Form 3540 OMB Approval Number 0910-0520 OMB Expiration Date 08/31/2023 See OMB Burden Statement</p> <p>Info Help</p>	<p>Validate FDA CVM Export Certificates (FECV) See System Requirements</p> <p>Info</p>
<p>CDER Office of Manufacturing Quality (CDER OMQ e-Portal) See System Requirements</p> <p>Tutorials Help</p>		









Figure 4.1 – CDER OMQ e-Portal Section

APPENDIX A: Abbreviations

CDER	Center for Drug Evaluation and Research
OMQ	Office of Manufacturing Quality
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

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
Plus		Add a new submission
Down Arrow		Expand the content of the row
Eye		View the associated item
Comment		View comment(s)
Help		View the User Guide
Printer		Print the associated item
Filter		Filter the content