3911 Platform

Reference Guide

Click here to access the 3911 Platform using CDER NextGen portal

Click here to email the Drug Notification Staff

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Introduction

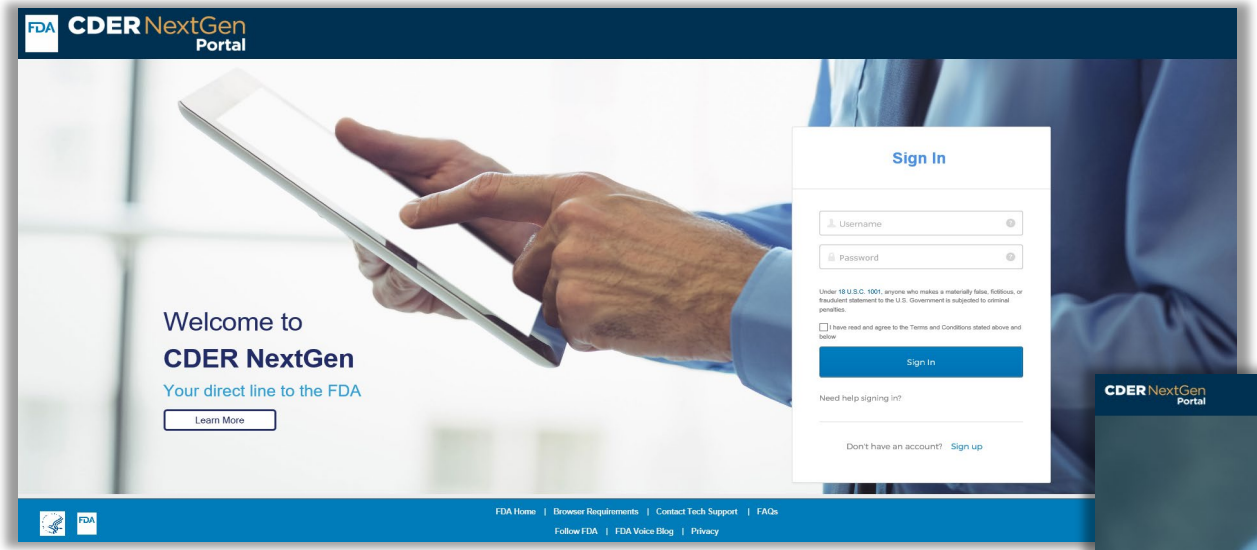
This guide provides information you need to use in the CDER NextGen Portal to create and submit a Drug Notification to FDA using the Form FDA 3911.

The 3911 Platform within the CDER NextGen Portal was created as a simple and efficient way for users to create and submit a Drug Notification to notify FDA when they have determined a product is illegitimate. The 3911 Platform also helps users generate a Form FDA 3911 and communicate with FDA regarding their submission.

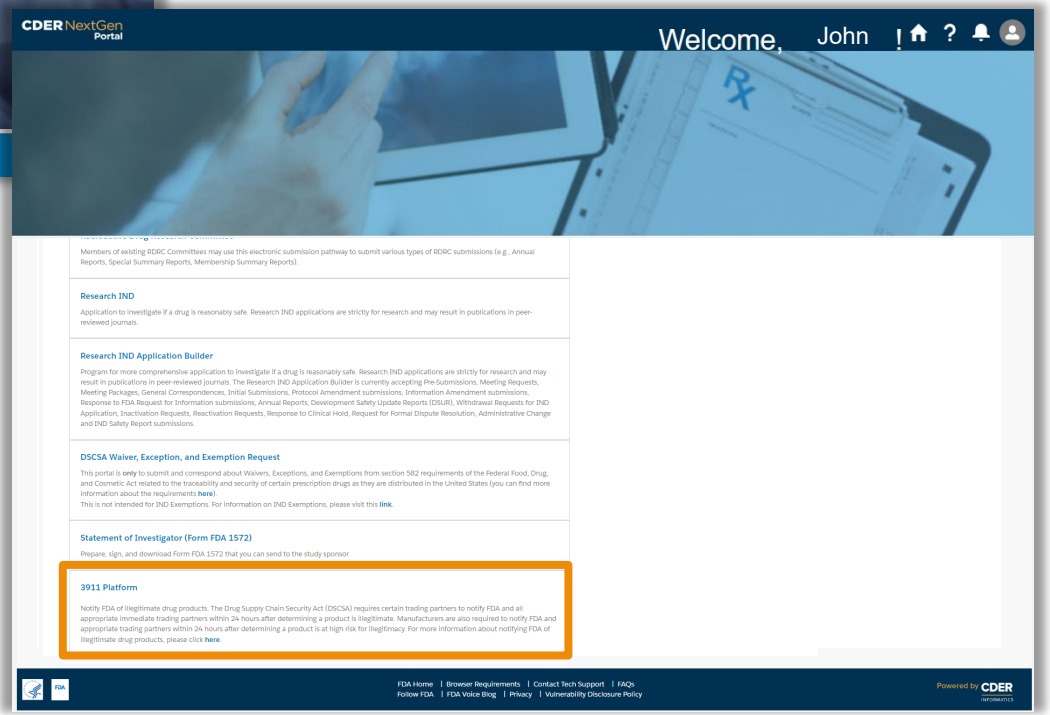
For technical assistance, the EDM Support Team (EDMSupport@fda.hhs.gov) is available to help.

3911 Platform

CDER NextGen Portal Home Page



Step 1. After you log into CDER NextGen Portal, click **3911 Platform** to begin.



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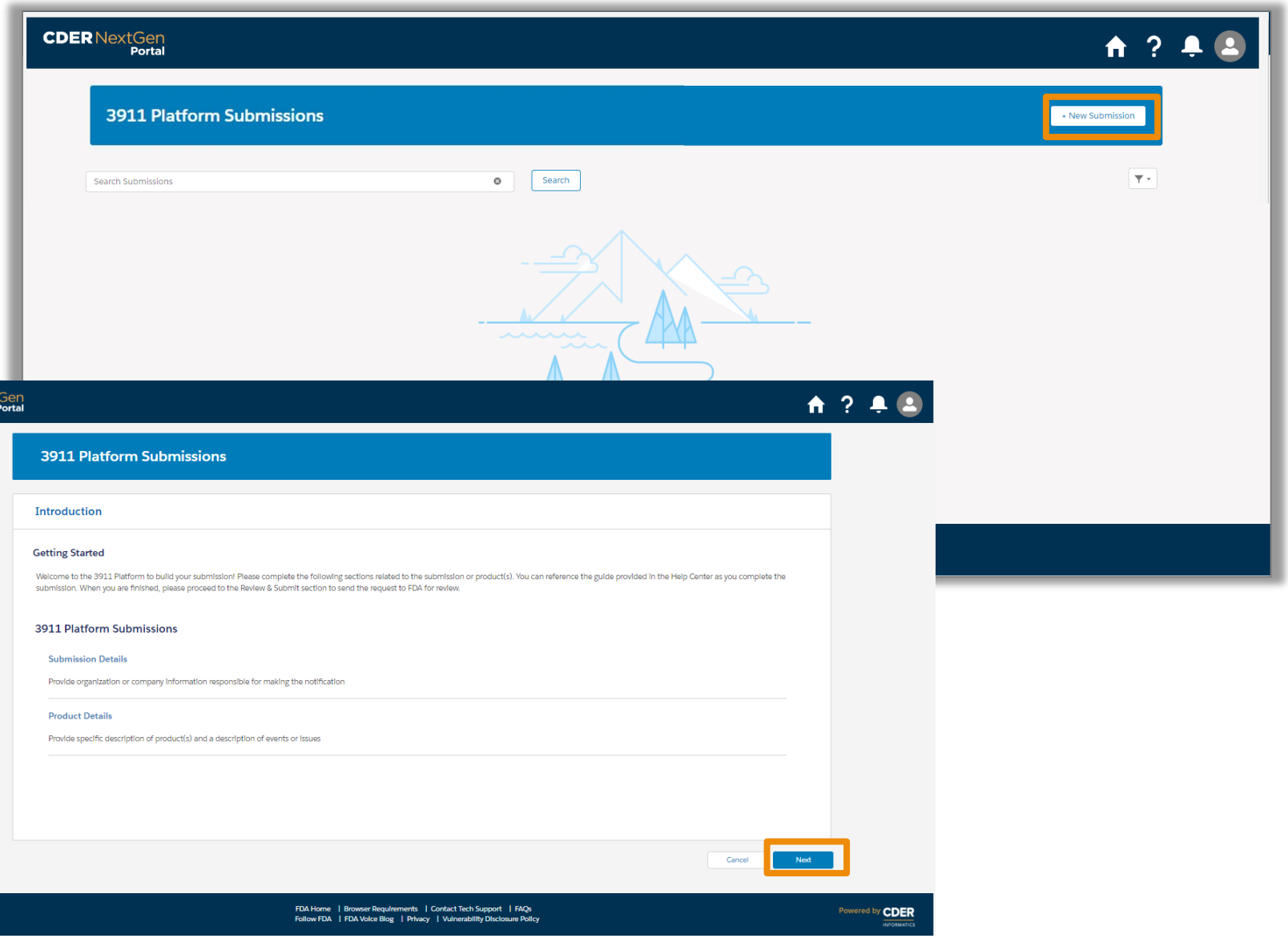
Submit a New Drug Notification

Step 2. Select **New Submission.**

Step 3. Review the *Getting Started* information for submitting a drug notification using the Form FDA 3911.

Step 4. Click **Next.**

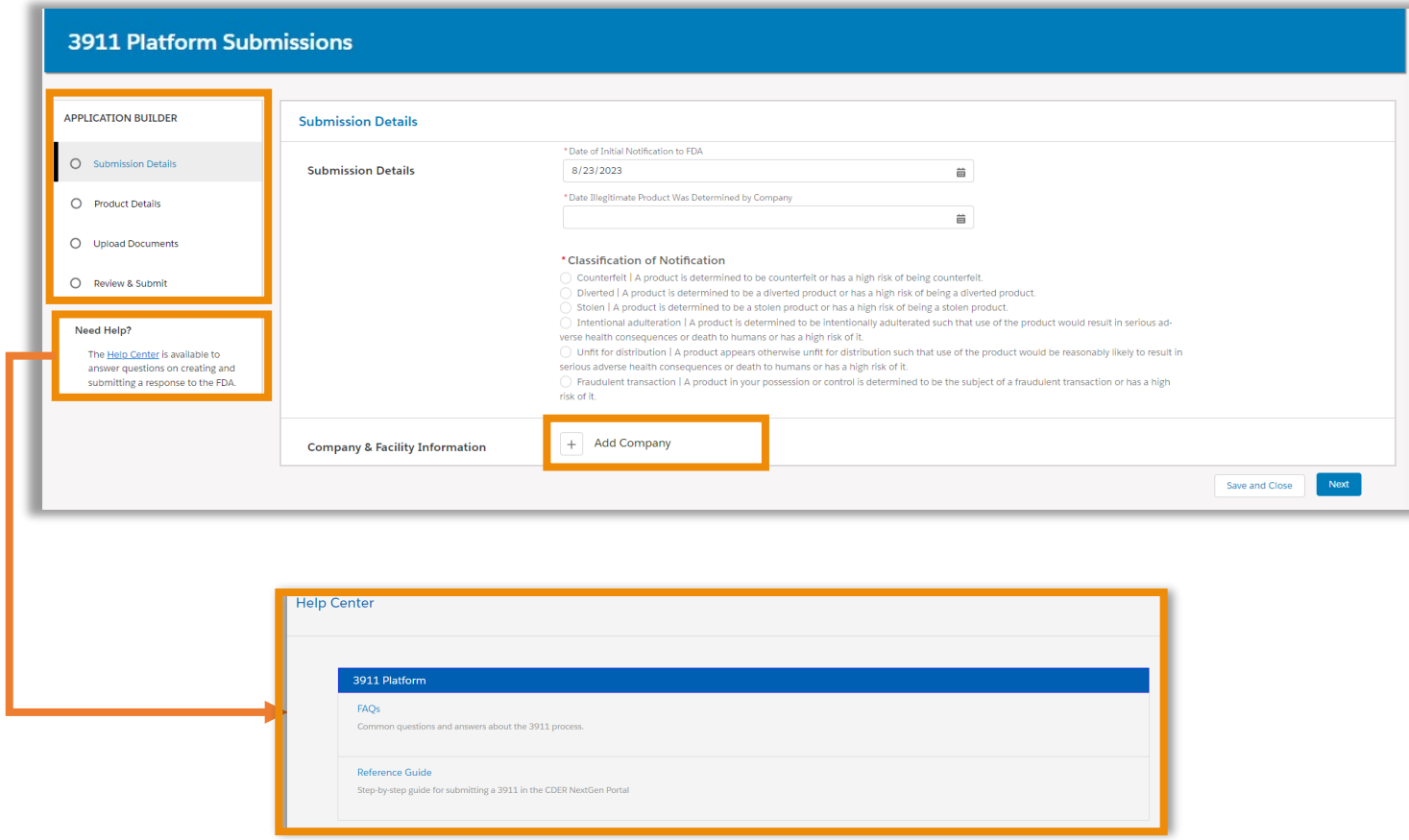


Keep in mind, if you have previously saved a submission as a draft or completed submitting the drug notification, you can view it on your *3911 Platform Submissions* landing page.

Submission Details

Step 5. *Date of Initial Notification to FDA* is pre-populated to show current date. Enter the remaining *Submission Details* including the *Date Illegitimate Product Was Determined by Company* and the *Classification of Notification*.

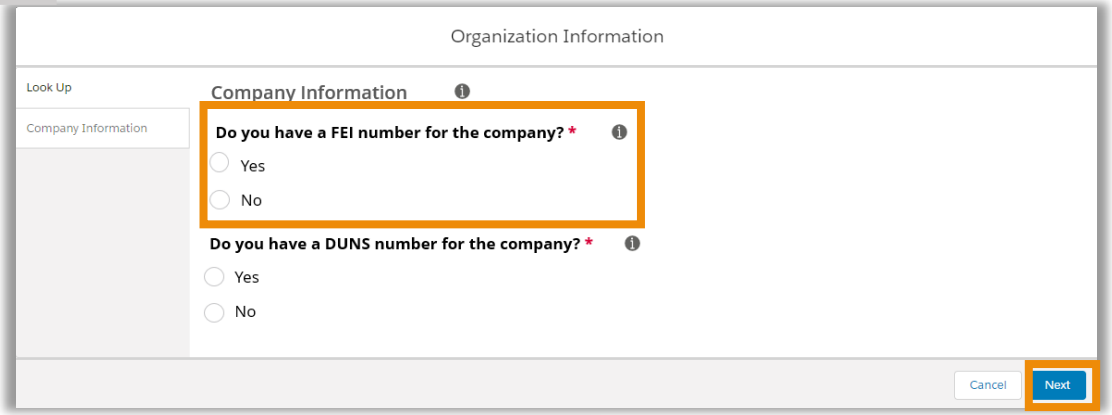
Step 6. To enter *Company & Facility Information* click the **+ Add Company** button. This should open a pop-up modal to enter *Organization Information*.

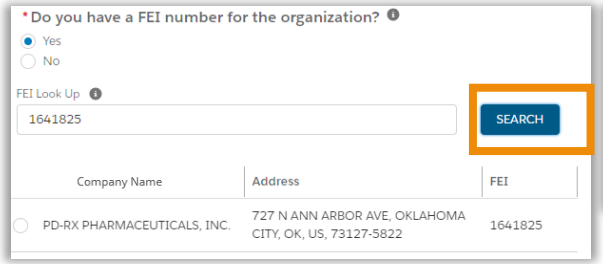


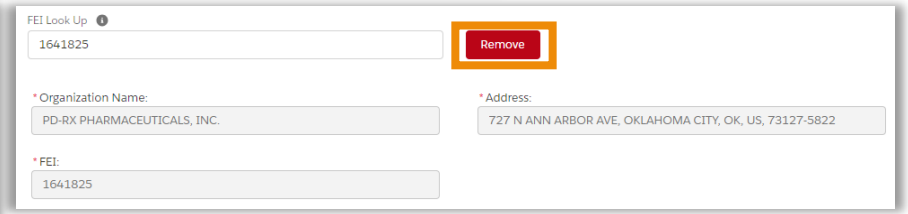
Note the *Application Builder* and the *Help Menu* on the left. The *Application Builder* helps users navigate through each section and will show when the section is complete.

Submission Details – Organization Information

- When *Yes* is selected for any of the questions on the *Look Up* tab, a search box appears. Enter the desired FEI/DUNS number and click on the **Search** button to view the related organization details below.
- To select the organization information, click on select. This will populate the *Organization Name, Address* and *FEI/DUNS* details in a non-editable format.
- When completed, click on the **Next** button to enter *Company Information*.







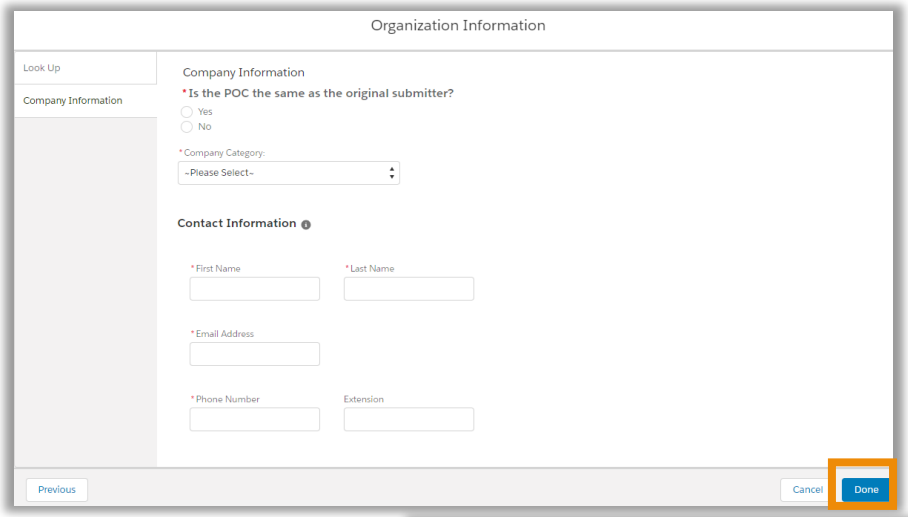
To edit the organization details, you can click on the **Remove** button and enter the corrected submission details following the steps above.

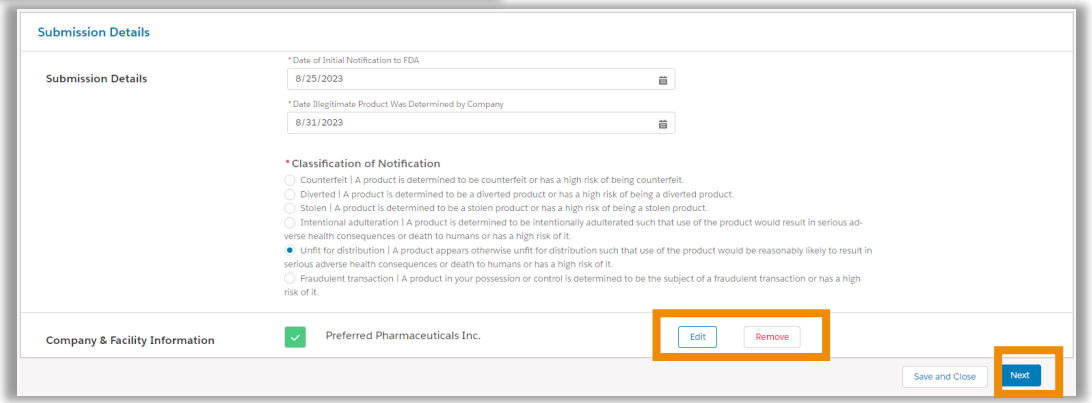
If *FEI/DUNS number* is not available or another *Unique Facility Identifier* is available. *Organization Information* can be entered manually by selecting *No* for both questions.

Submission Details

- Fill out the *Company Information* by answering the remaining fields. Click **Done** to finish adding the *Company & Facility Information.*

Step 7. Click **Next** to navigate to the *Product Details* page.





Note, if Yes is selected for *Is the POC the same as the original submitter?*, the *Contact Information* will be pre-populated with the details of the submitter accessing the portal account.

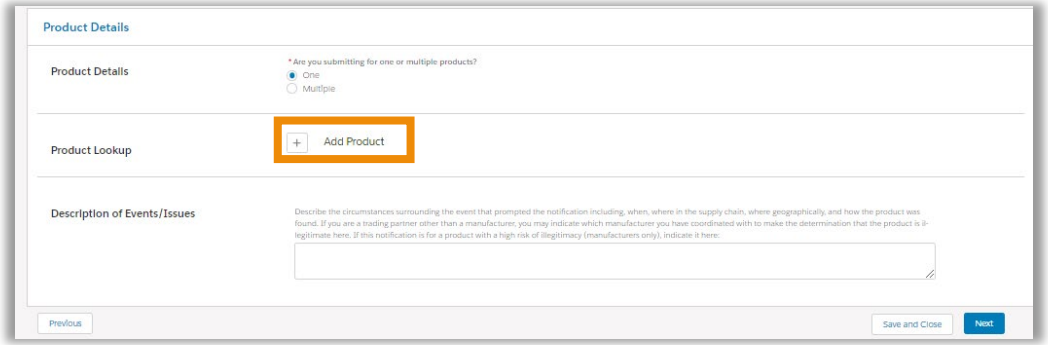
You can **Edit** the *Company & Facility Information* or **Remove** the selected information by clicking on the respective buttons.

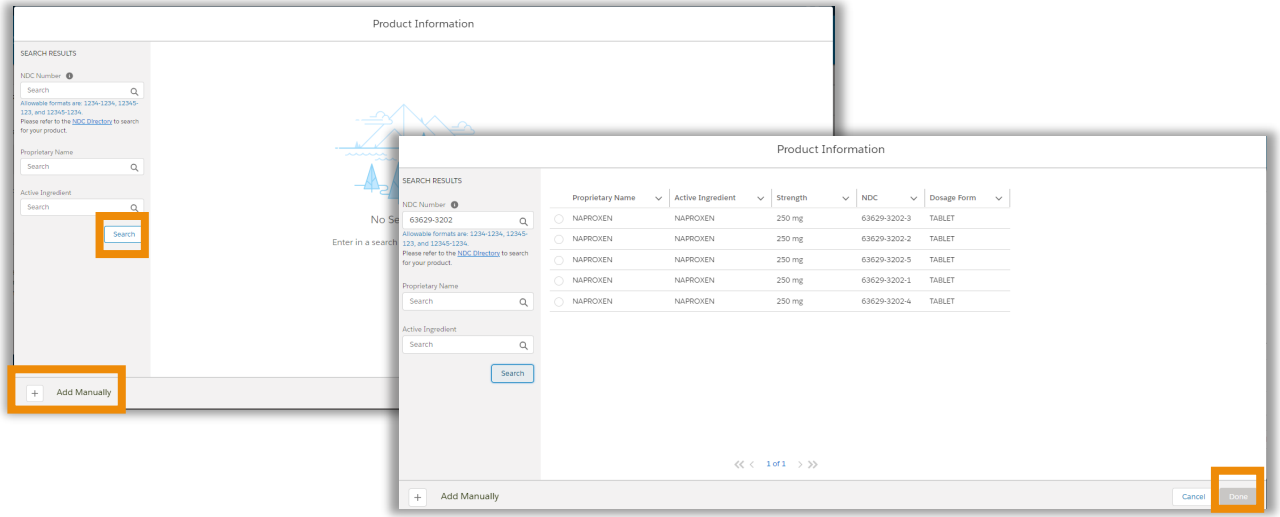
Product Details – One Product

Product Details has two pathways based on the number of products involved.

Step 8a. If the incident is related to one product, answer the question in *Product Details* section accordingly and click on the **+ Add Product** button to add *Product Information* in a new screen.

- Search by *NDC Number, Proprietary Name* or *Active Ingredient* by entering details in their respective search boxes and clicking on the **Search** button.
- Select the desired product and click on **Done** to add product information.





You can also add *Product Information* by clicking on **+ Add Manually** button and entering the product details if it is not available using the search function.

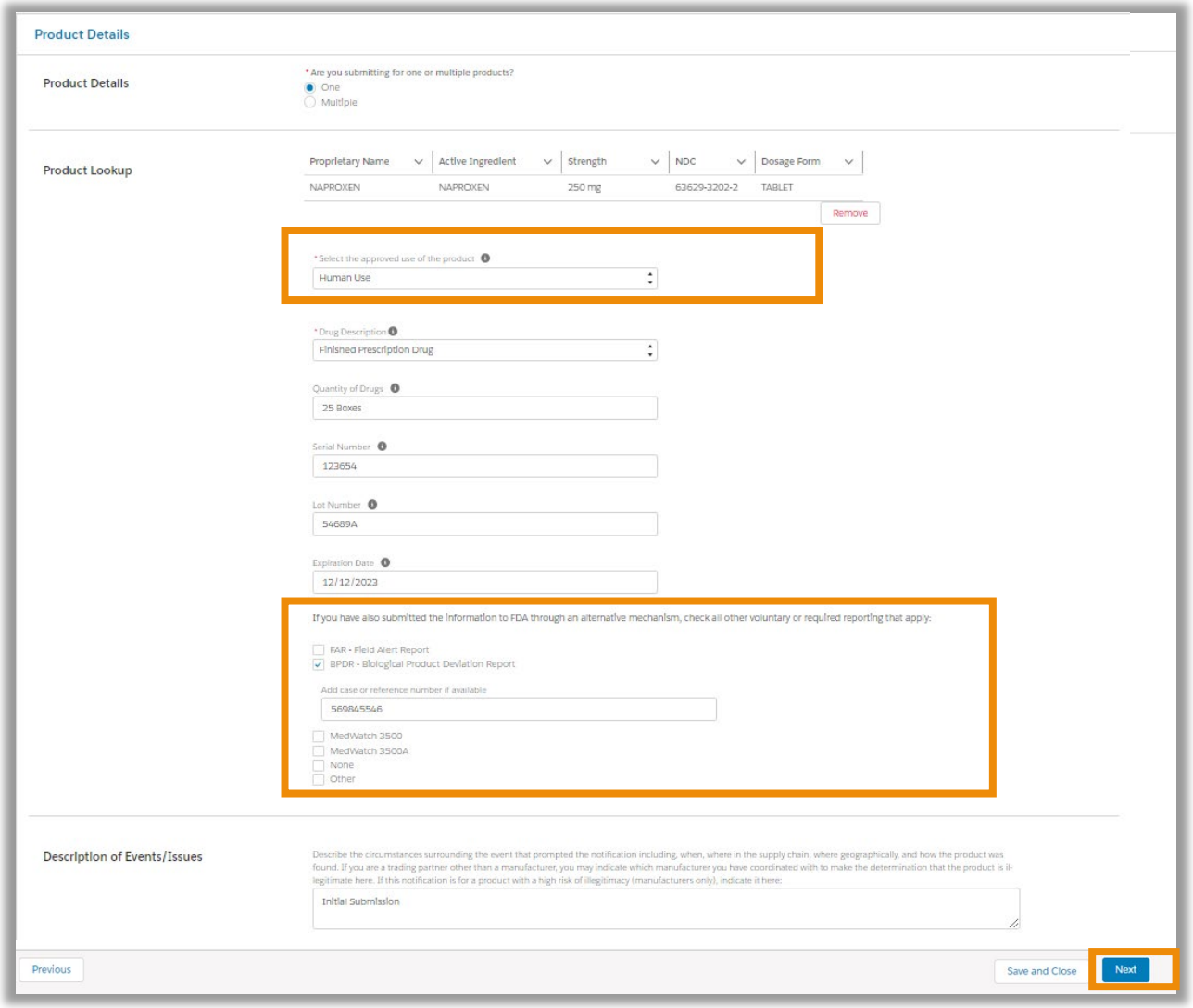
Product Details – One Product

Step 9a. The product information added can be viewed in a tabular form. Fill out the remaining fields in this page and click on **Next** to navigate to the *Upload Documents* page.

When *Other* is selected for the field *Select the approved use of the product*, enter additional information in the conditional text field.

If you have also submitted the information to FDA through an alternative mechanism, enter relevant information in the conditional text field (e.g., case or reference number) as applicable.

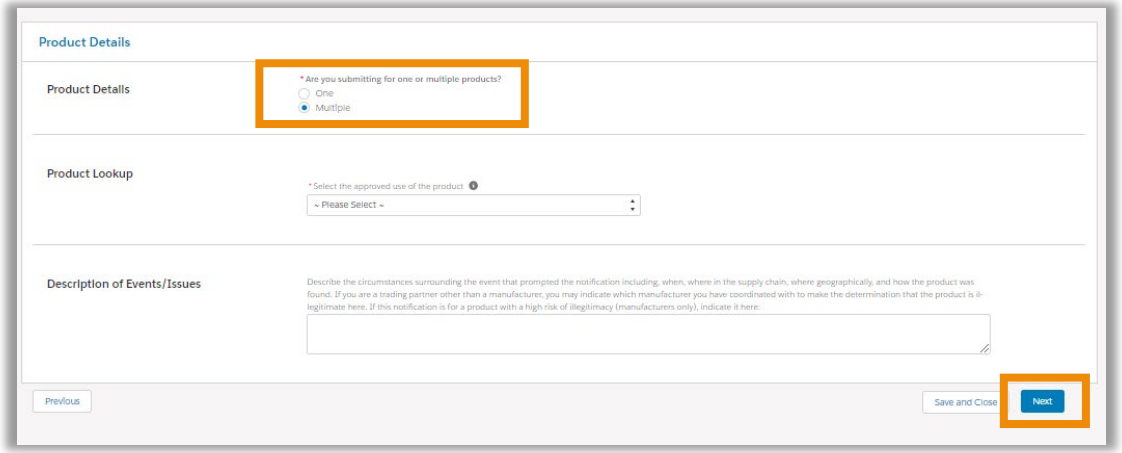
For an *Initial Submission* and *Follow-Up Notification*, describe the circumstances surrounding the incident in the description text box. When submitting a *Request for Termination*, explain why the notification is no longer needed including any corrective actions taken.



Product Details – Multiple Products

Step 8b. Select *Multiple* if you are submitting information for more than one product.

Step 9b. Fill out the remaining fields in this page and click on **Next** to navigate to the *Upload Documents* page.



Note the product information fields on your generated Form FDA 3911 will be populated with *Multiple*.

When *Other* is selected for the field *Select the approved use of the product*, enter additional information in the conditional text field.

For an *Initial Submission* and *Follow-Up Notification*, describe the circumstances surrounding the incident in the description text box. When submitting a *Request for Termination*, explain why the notification is no longer needed including any corrective actions taken.

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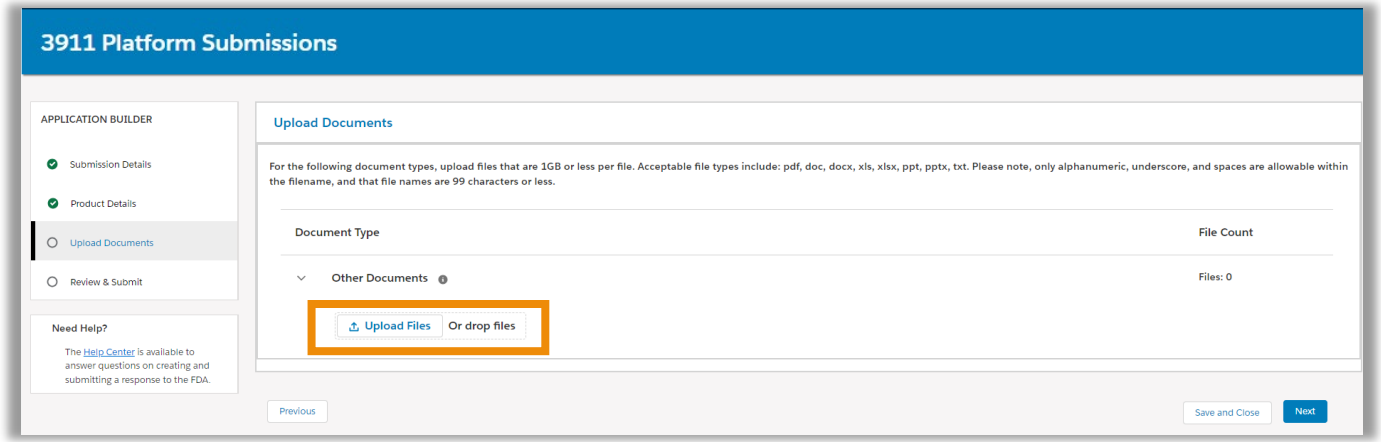
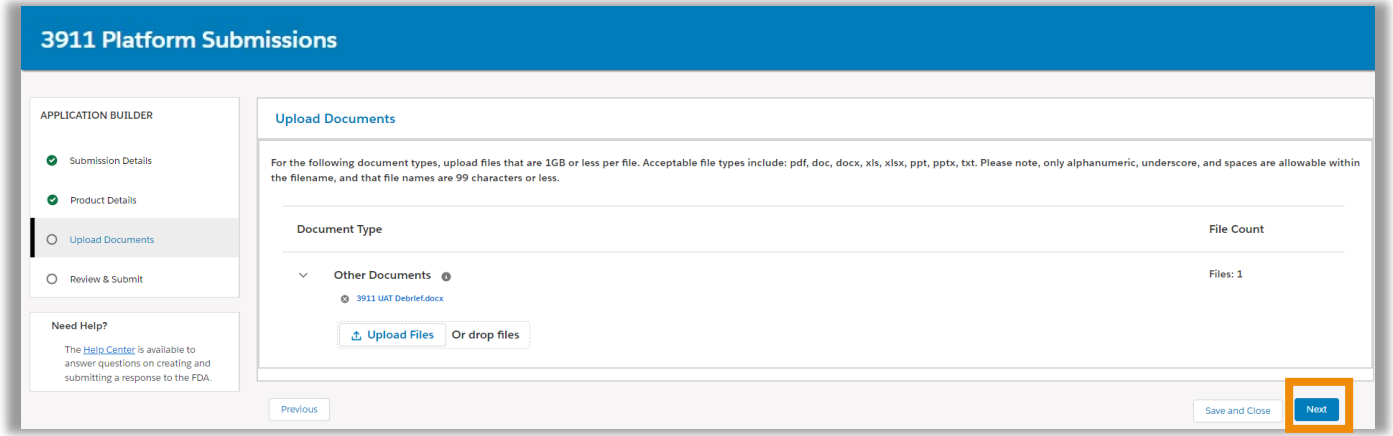
Upload Documents

Step 10. Documents can either be uploaded by clicking on the **Upload Files** button or you can drag and drop the desired file from your desktop in the *drop files* section.

Step 11. Once the file(s) has/have been selected, click on **Next** to go to the *Review & Submit* page.





When your submission involves multiple products, upload documents will be mandatory step to provide FDA with specific product information related to the multiple products.

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Review and Submit

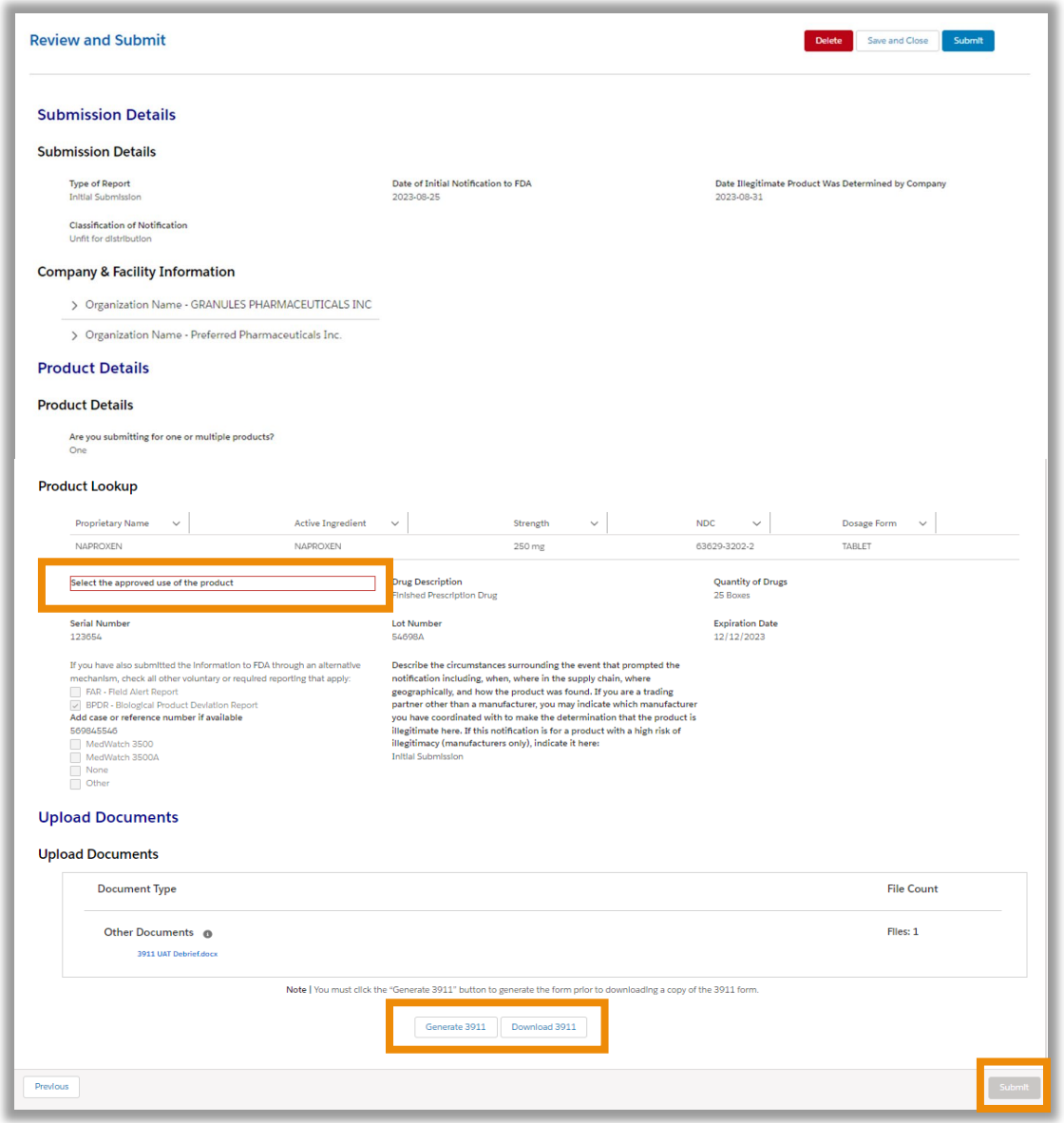
Step 12. Verify the information for the 3911 Notification and click on **Generate 3911** button. You can click on **Download 3911** if you would like to download a version of Form FDA 3911 in your desktop.

Step 13. Click on **Submit** to submit the Notification to FDA.

If there are mandatory fields that are not filled out, a red box will appear around those fields and **Submit** button will be disabled.

Form FDA 3911 can be downloaded only after clicking on the **Generate 3911** button.

Submit button will be enabled only after clicking on **Generate 3911** button



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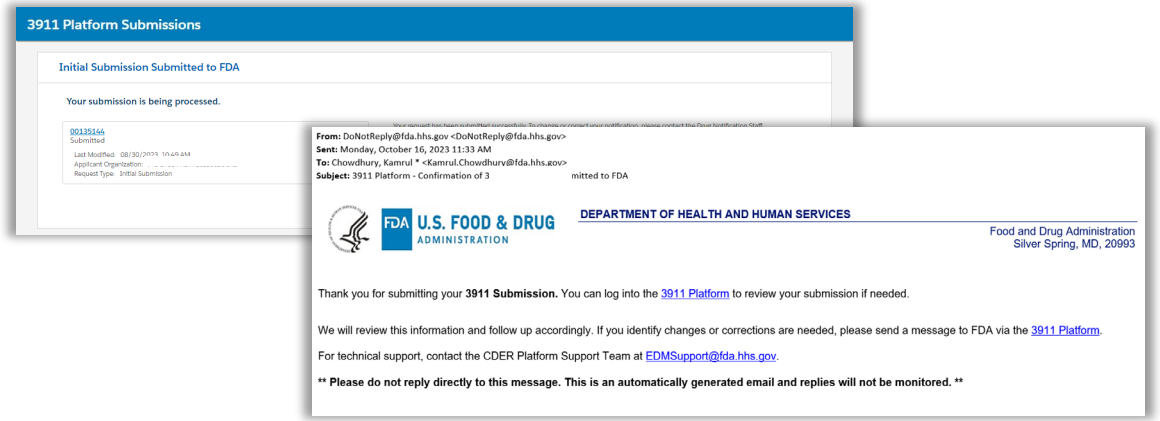
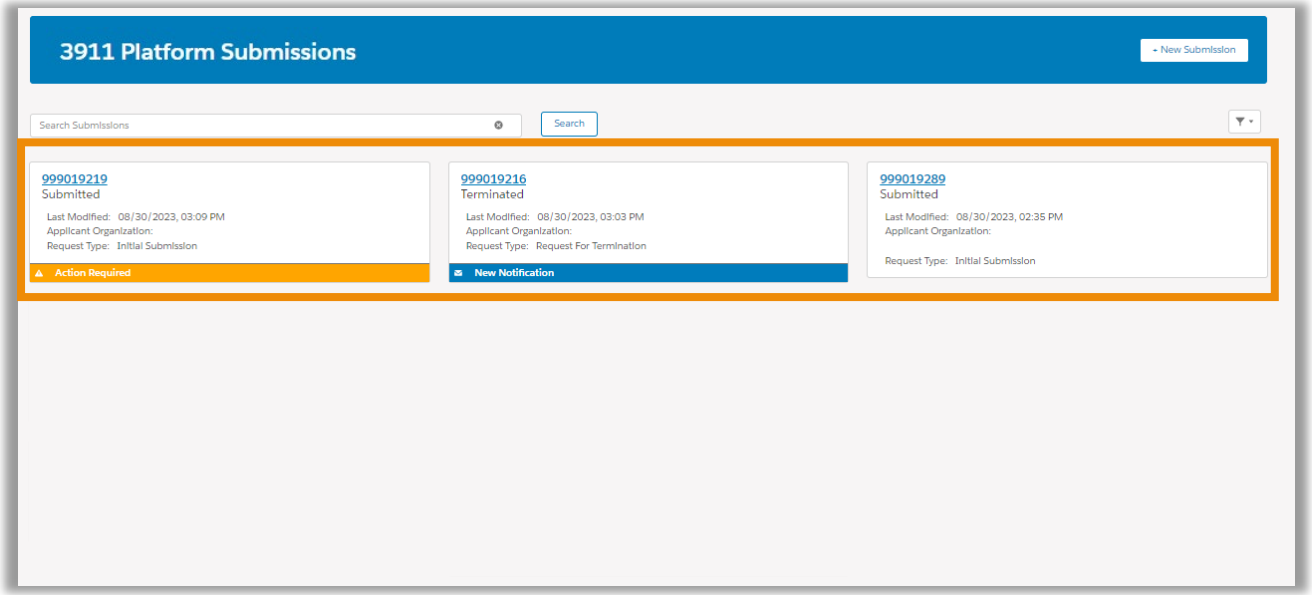
Receiving Confirmation(s) from FDA

You will view a confirmation screen to confirm your Notification was submitted to FDA and receive an email confirming the submission of your 3911 Notification. Please open the confirmation email: DoNotReply@fda.hhs.gov and review the information submitted.



Activity Log

After submitting your drug notification, you can view your submission and FDA notifications on your activity log page by clicking on the incident ID on your landing page tile.



Here, you can send a subsequent submission such as *Follow-Up Notification* or *Request For Termination*, view *Submission Summary*, or send a *General Correspondence*. You can also view communication(s) sent by FDA and respond to an *Information Request* from FDA.

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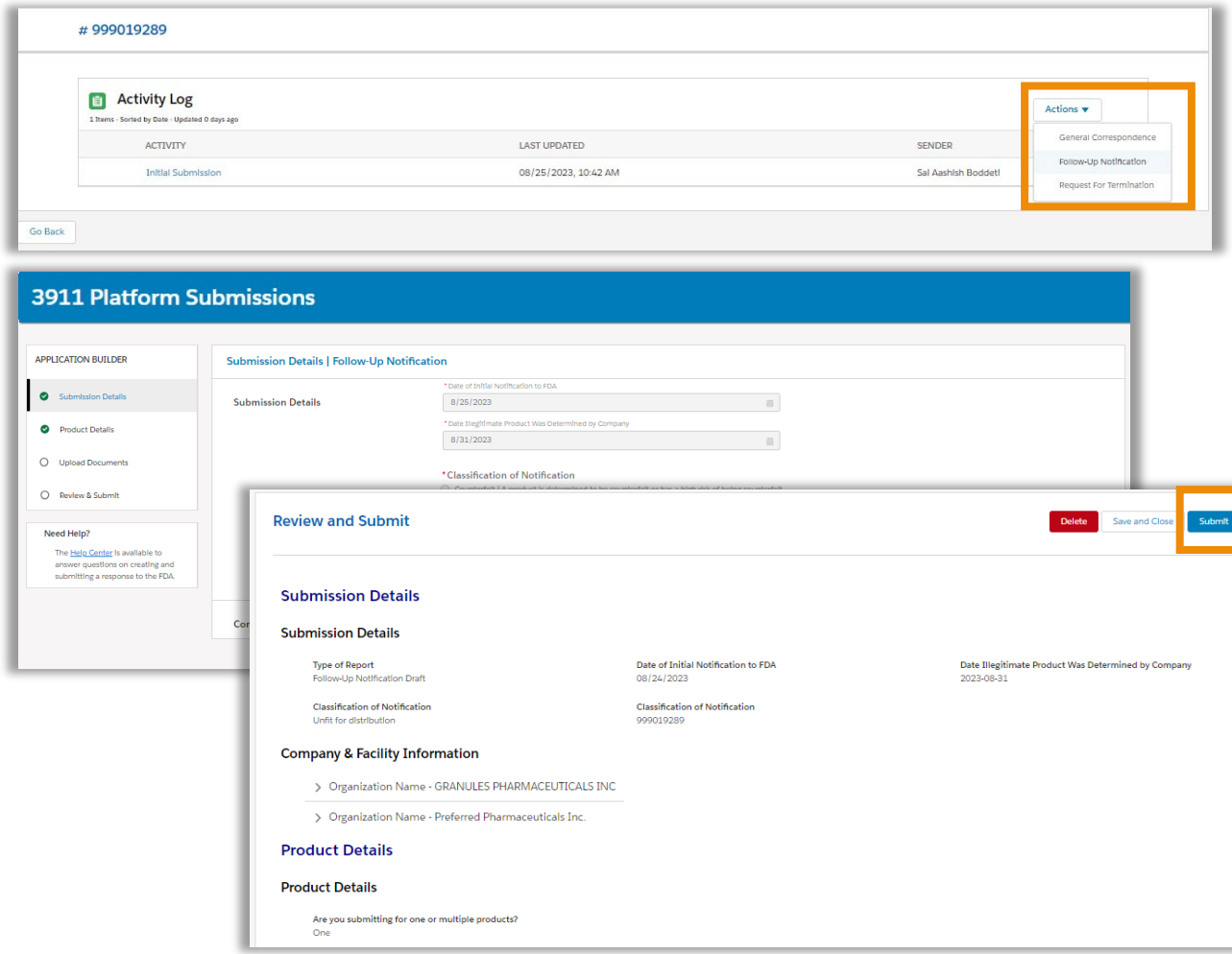
Subsequent Submission

Step 14. To send a subsequent submission click on **Actions** drop down and navigate to the desired submission (e.g., Follow-Up Notification)

Step 15. Review the *Follow-Up Notification* details, edit where necessary and click on **Submit** to send the *Follow-Up Notification* to FDA.

Step 16. You will receive an email confirmation regarding your submission to FDA. Navigate to the *Activity Log* to view the submission that was made.



The fields that are not editable are greyed out.

Follow the same steps to submit a *Request For Termination.*

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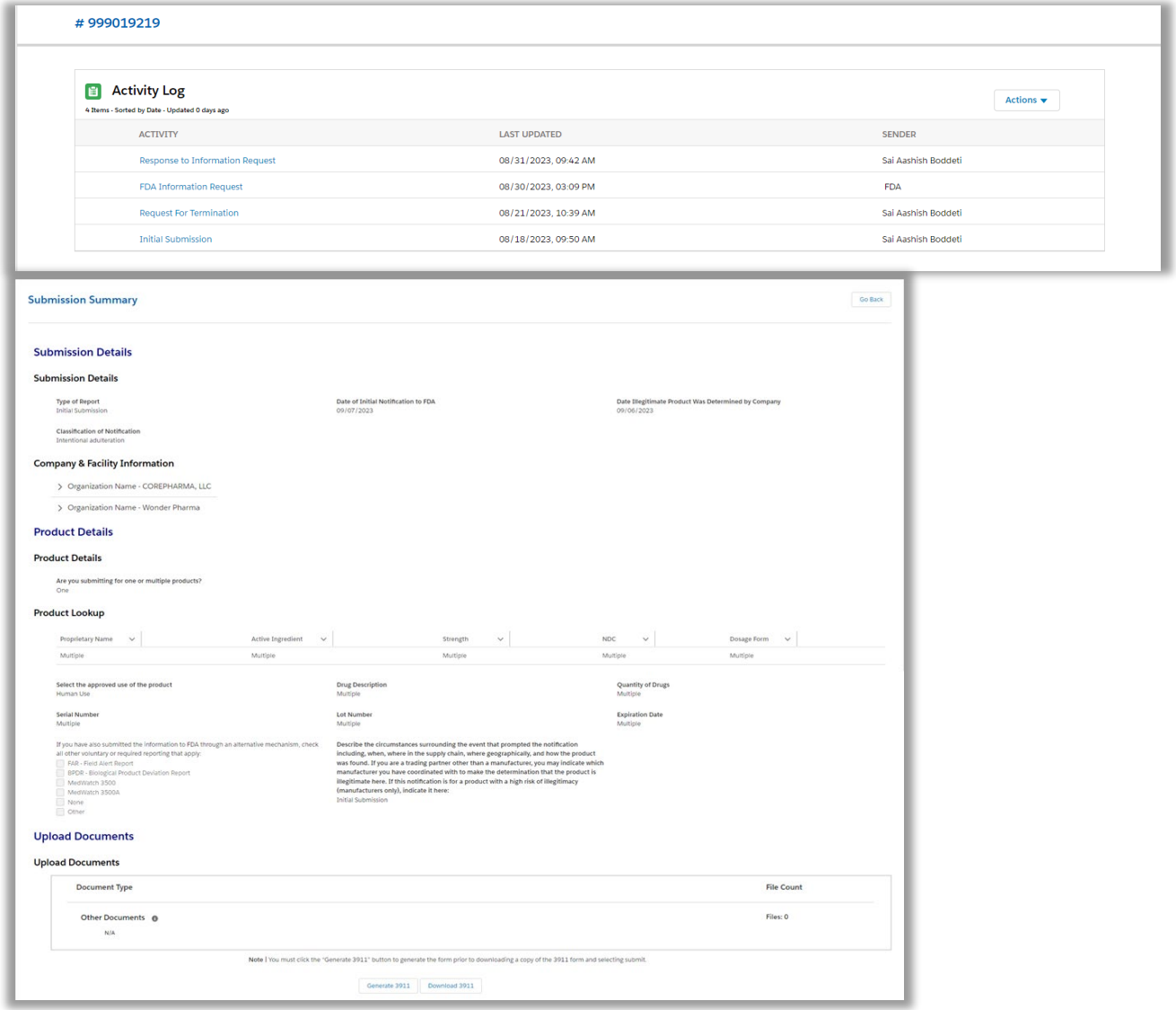
Submission Summary

You can select and view a specific *Submission Summary* from the *Activity Log.*

A *Submission Summary* can be viewed for an *Initial Submission, Follow-Up Notification* and *Request for Termination.*



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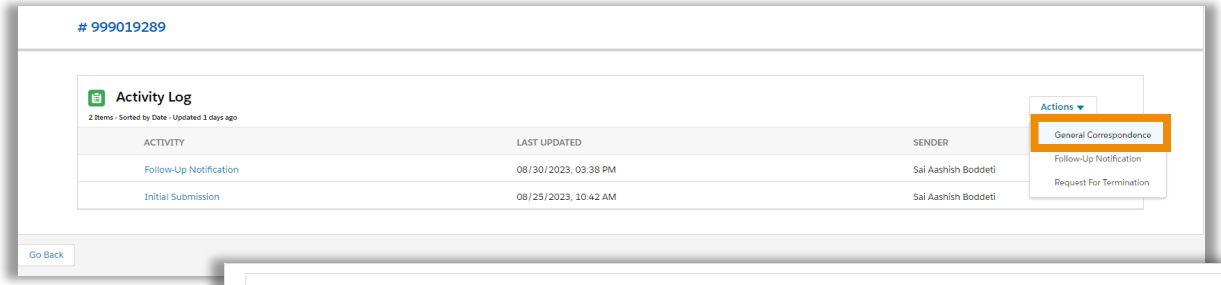
General Correspondence

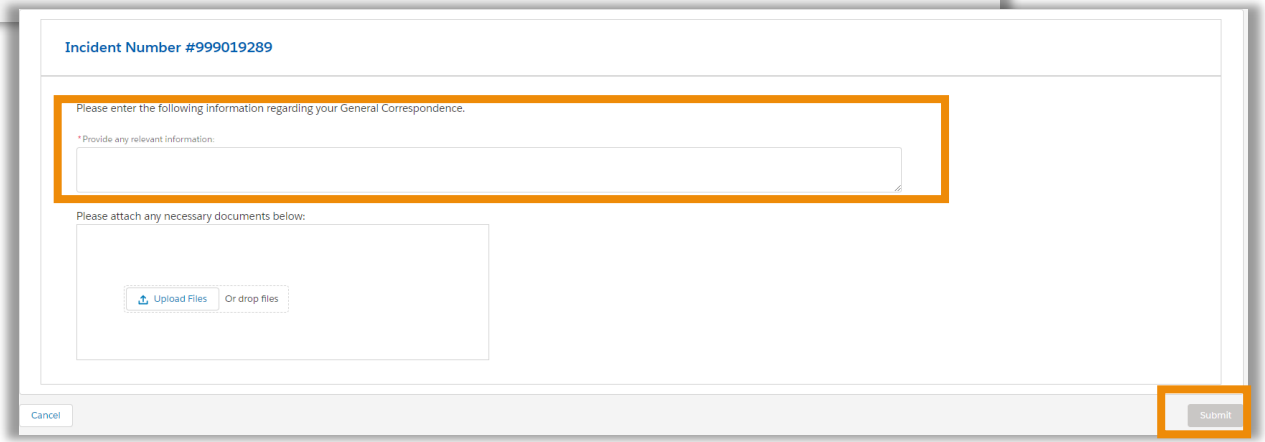
To send a General Correspondence to FDA, perform the following steps:

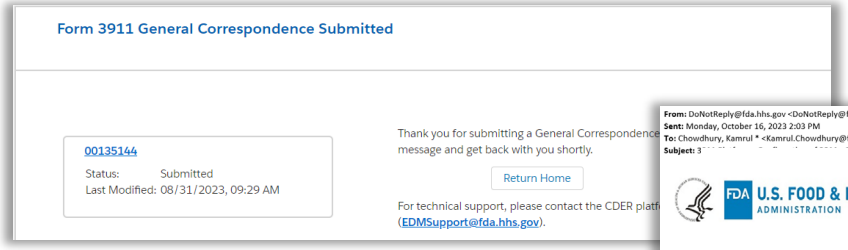
Step 1. Once you navigate to the Activity Log, click on the **Actions** dropdown and select *General Correspondence*.

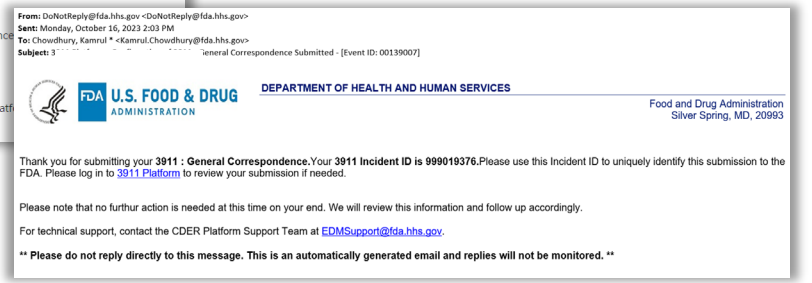
Step 2. Provide relevant information in the text box, attach any necessary documents (if any) and click **Submit** to send the *General Correspondence* to FDA.

Step 3. You will view a confirmation screen to confirm your *General Correspondence* was submitted to FDA and receive an email confirmation.









Submit button is enabled once text is entered in the text box

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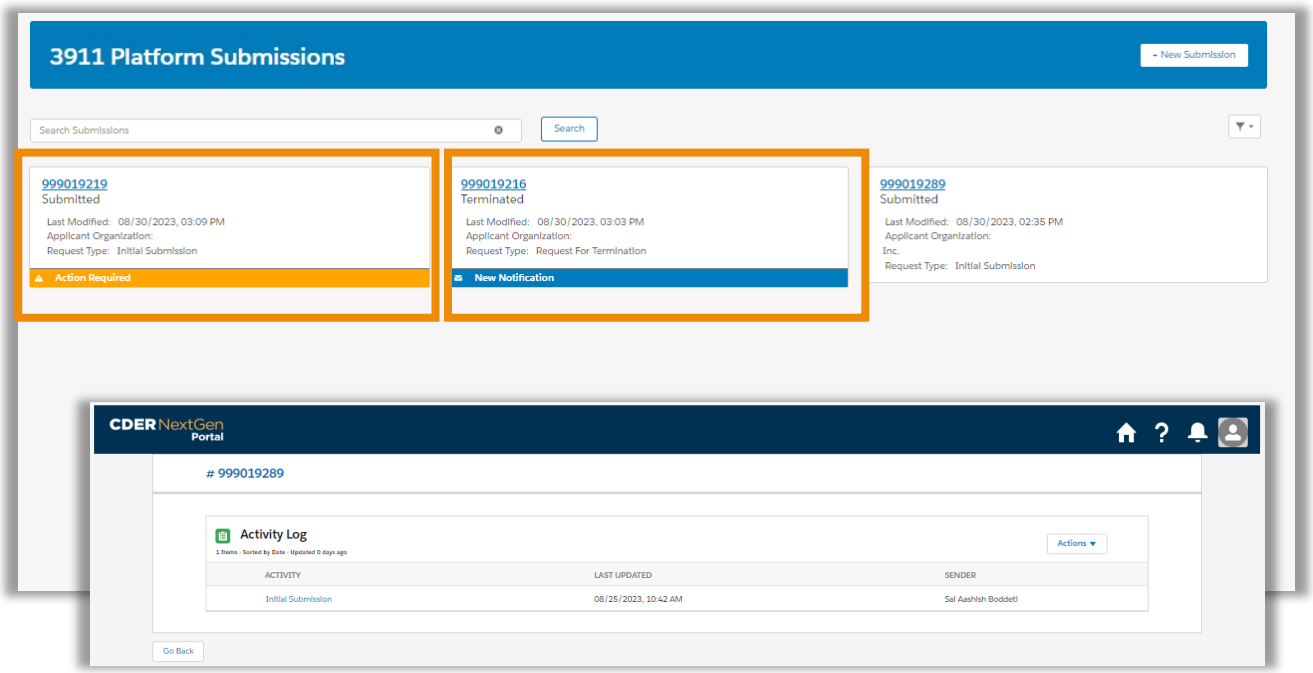
Activity Log

After submitting your drug notification, you can view your submission and FDA notifications on your activity log page by clicking on the incident ID on your landing page tile.

- An *Action Required* banner appears when FDA sends an *Information Request* or *FDA Reminder*
- A *New Notification* banner appears when the following responses are sent by the FDA:
  - Request for Termination Agreement
  - Request for Termination Disagreement
  - Not a Notification under DSCSA
  - FDA Response



Please notice banners will disappear after you view your notification in the *Activity Log*.

Click on the incident number to be redirected to the associated *Activity Log*. Here, you can send a subsequent submission such as *Follow-Up Notification* or *Request For Termination*, view *Submission Summary*, or send a *General Correspondence*. You can also view communication(s) sent by FDA and respond to an *Information Request* from FDA.

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Information Request

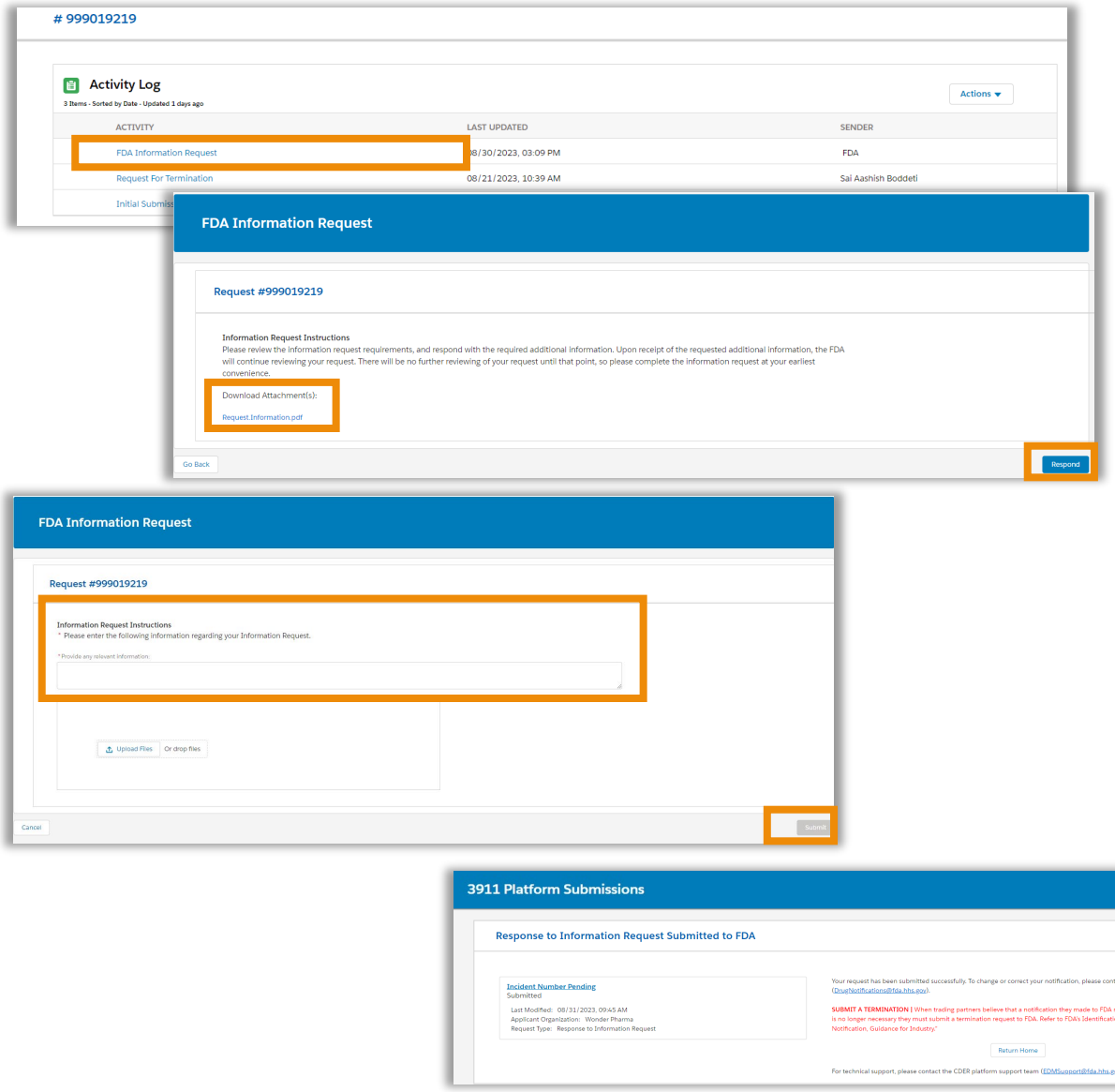
Step 1. Once FDA sends an *Information Request*, navigate to the *Activity Log* of the relevant notification and click on *FDA Information Request*.

Step 2. Review the information shown in the *Information Request* screen and click on the attachment to download the *Information Request.*

Step 3. Once reviewed, click on **Respond** to send a *Response to Information Request*.

Step 4. Provide relevant information in the text box, attach any necessary documents (if any) and click **Submit** to send the *Response to Information Request* to FDA.

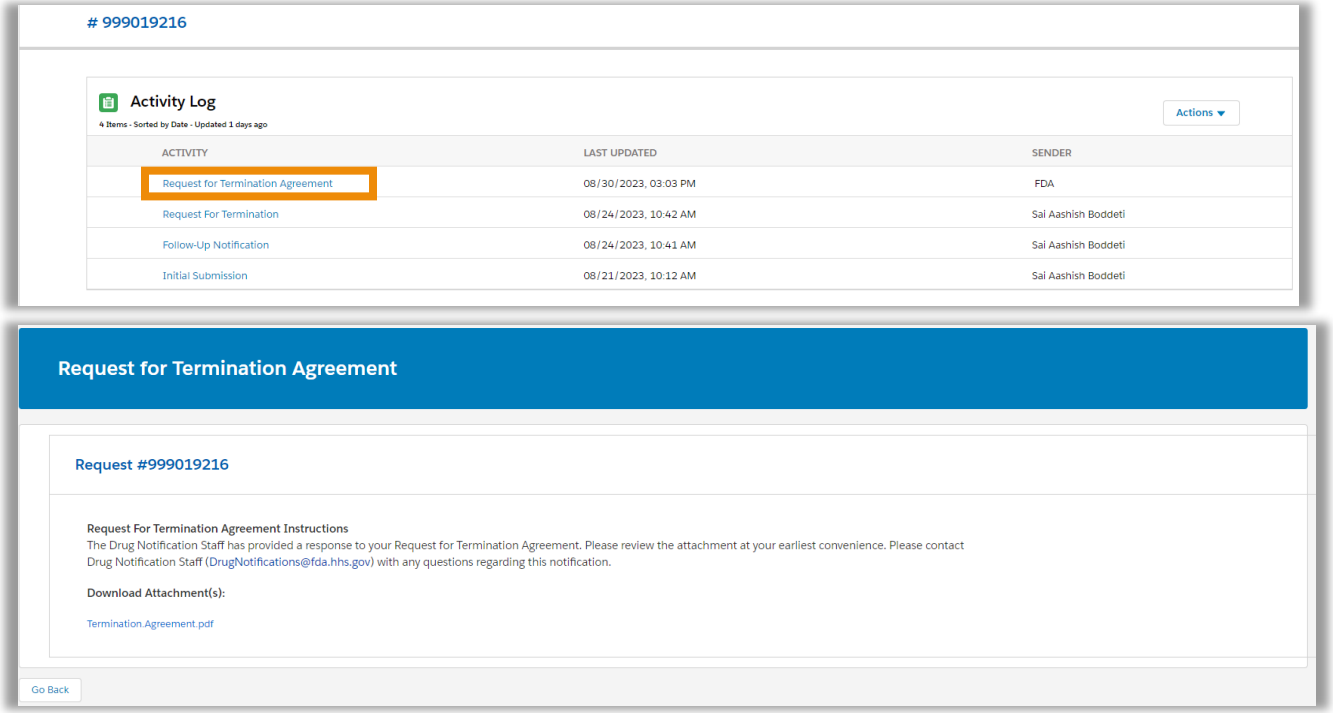
Step 5. You will view a confirmation screen to confirm your *Response to Information Request* was submitted to FDA and receive an email confirmation.



FDA Communication

Step 1. To view communication from FDA, navigate to the *Activity Log* of the incident and click on the desired FDA Communication, for example, *Request for Termination Agreement.*

Step 2. Review the information shown in the *Request for Termination Agreement* screen and click on the attachment to download the *Termination Agreement* message sent by FDA.



Follow the same steps to view other FDA communication such as *Request for Termination Disagreement, Not a Notification under DSCSA, FDA Response or FDA Reminder.*

These FDA communications are one-way so you cannot respond to them. If you have additional questions on these responses, you can send a *General Correspondence* to FDA.

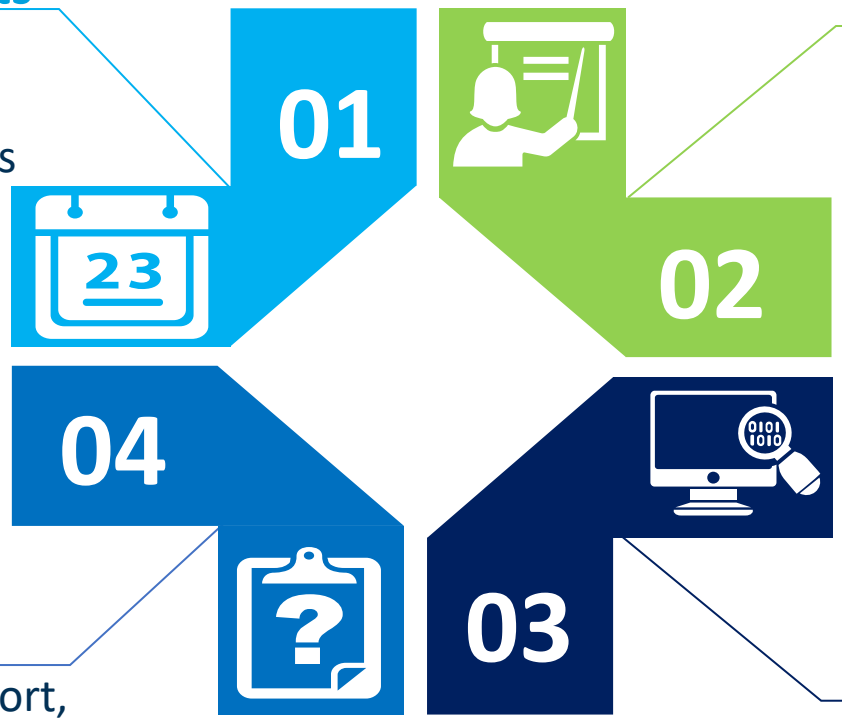
Technical Support and Resources

CDER NextGen Portal Support & Resources

The CDER NextGen Portal has many resources for support.

Portal Announcements

Your Portal home page contains **portal announcements** so users are always in the know.



Learn More Information

Everything related to the portal incidents can be found on the **"Learn More"** link. On the incident home page, users can find the "Learn More" link to **Reference Guides and FAQs.**

Technical Support

For all technical support, contact **CDER Platform Support Team** at EDMSupport@fda.hhs.gov.

Portal Video Tutorial

The "**Video Tutorial**" contains **1-4 minute video clips** on how to complete submissions for incidents on the portal.