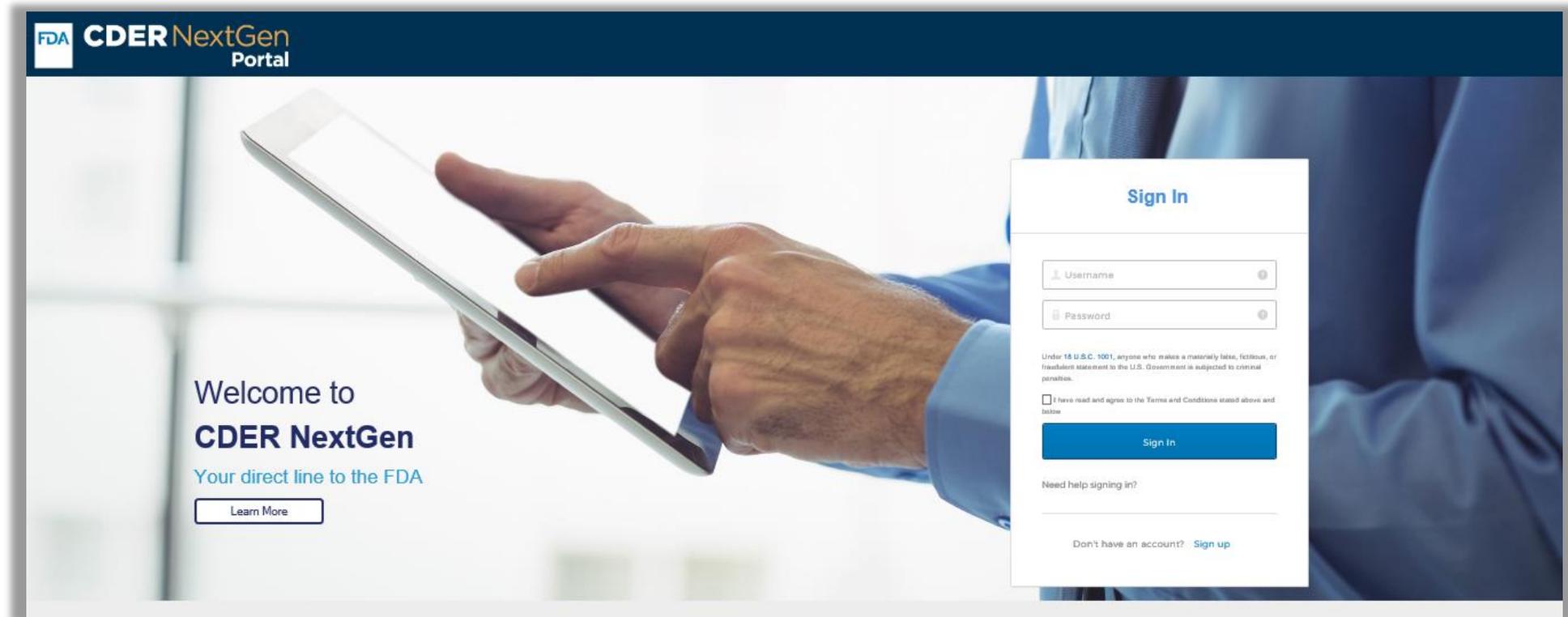




3911 Platform Reference Guide



Click [here](#) to access the 3911 Platform using CDER NextGen Portal

Click [here](#) to email the Drug Notification Staff

Table of Contents

Introduction	<u>3</u>
CDER NextGen Portal Home Page	<u>4</u>
Submit a New Drug Notification	<u>5</u>
Submission Details	<u>6</u>
Product Details	<u>9</u>
Upload Documents	<u>12</u>
Review and Submit	<u>13</u>
Subsequent Submission	<u>15</u>
Submission Summary	<u>16</u>
General Correspondence	<u>17</u>
Activity Log	<u>18</u>
Information Request	<u>19</u>
FDA Communication	<u>20</u>

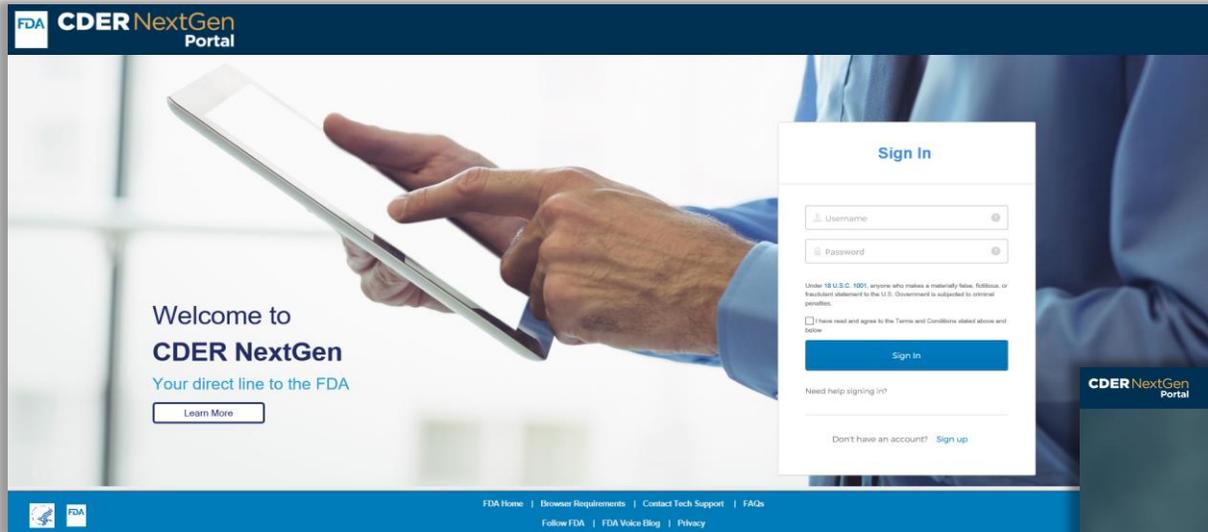
Introduction

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.

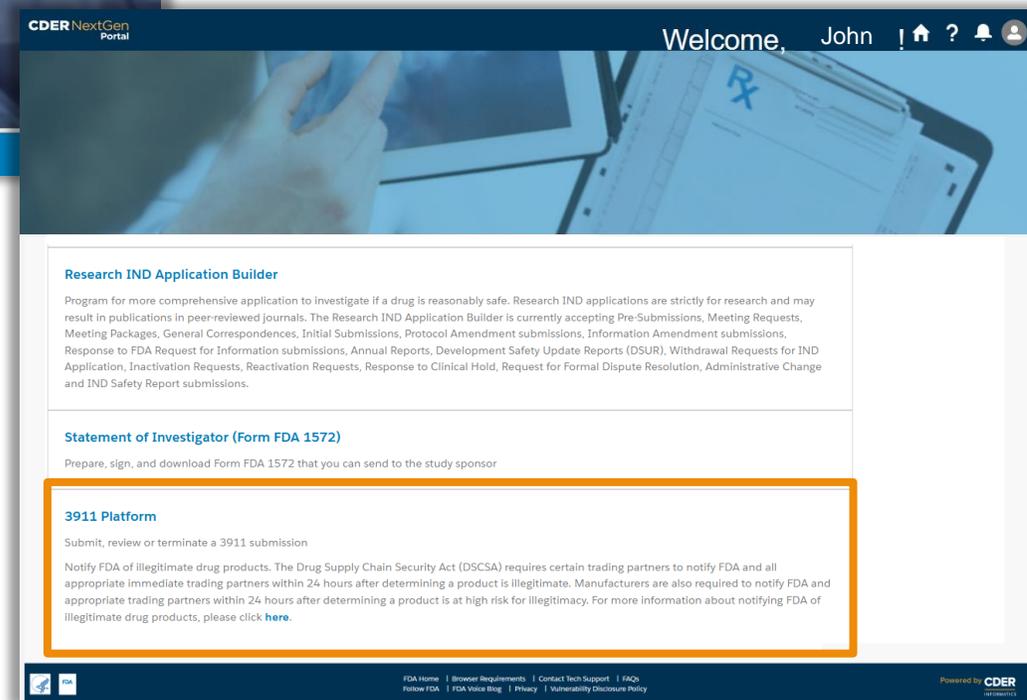
The 3911 Platform within the CDER NextGen Portal was created as a simple and efficient way for users to create and submit a Drug Notification to notify FDA when they have determined a product is illegitimate. The 3911 Platform also helps users generate a Form FDA 3911 and communicate with FDA regarding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

For technical assistance, please visit the [CDER NextGen Portal Help Center](#).

CDER NextGen Portal Home Page



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



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.**



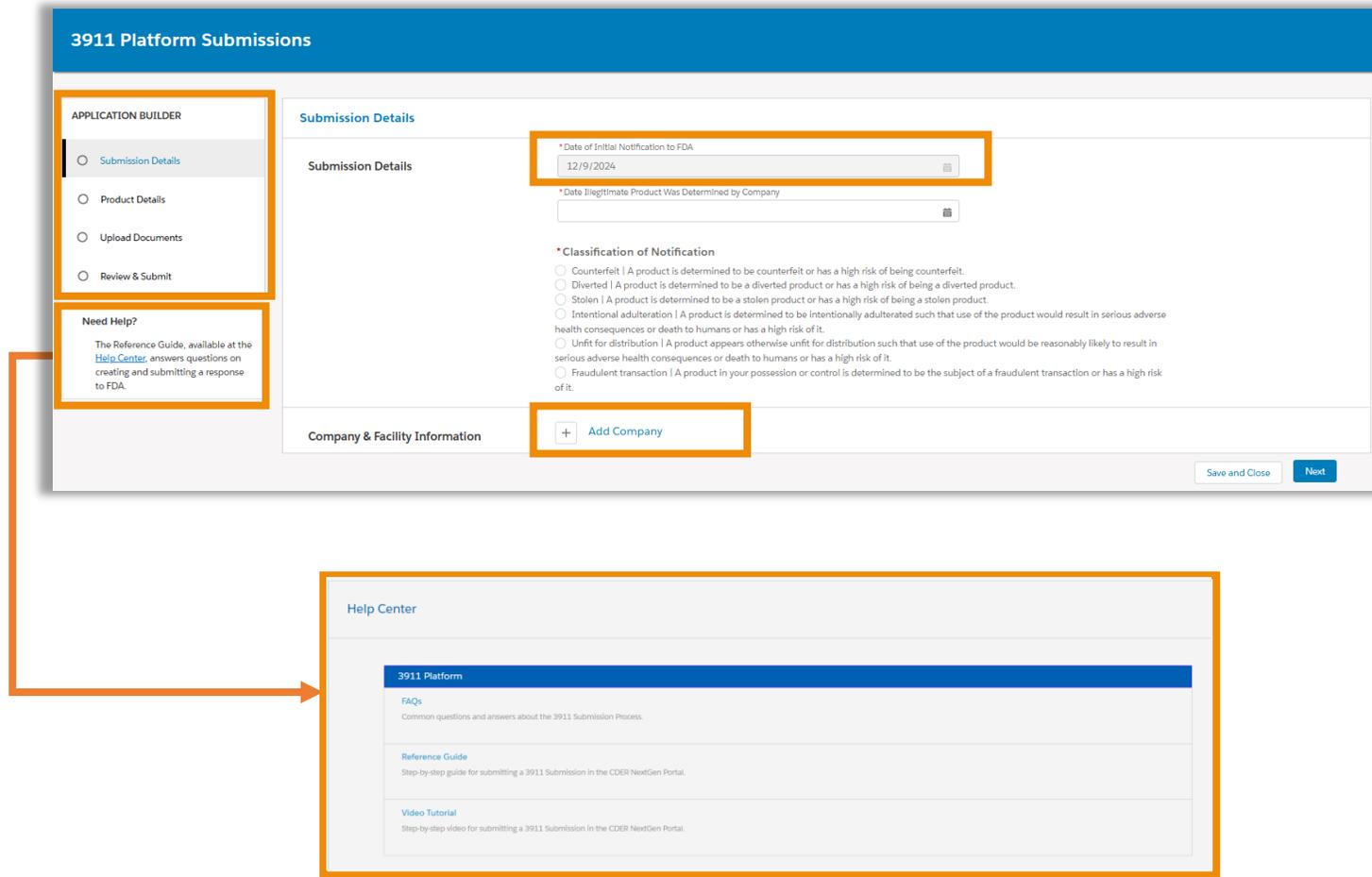
Keep in mind, if you have previously saved a submission as a draft or completed submitting the drug notification, you can view it on your *3911 Platform Submissions* landing page.

The screenshot shows the CDER NextGen Portal interface for the 3911 Platform Submissions page. The top navigation bar features the CDER NextGen Portal logo and user icons. The main header is "3911 Platform Submissions" with a "New Submission" button highlighted in orange. Below the header is a search bar and a decorative graphic. The main content area includes sections for "Introduction", "Getting Started", "3911 Platform Submissions", "Submission Details", "Product Details", and "Document Upload". At the bottom right, "Cancel" and "Next" buttons are visible, with "Next" highlighted in orange. The footer contains navigation links and the CDER logo.

Submission Details

Step 5. *Date of Initial Notification to FDA* is pre-populated to show current date. It is a non-editable field that is greyed out as shown in the screenshot. 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*.

Organization Information

Look Up

Company Information

Do you have a FEI number for the company? * ⓘ

Yes

No

Do you have a DUNS number for the company? * ⓘ

Yes

No

Cancel Next

*** Do you have a FEI number for the organization? ⓘ**

Yes

No

FEI Look Up ⓘ

1641825

SEARCH

Company Name	Address	FEI
<input type="radio"/> PD-RX PHARMACEUTICALS, INC.	727 N ANN ARBOR AVE, OKLAHOMA CITY, OK, US, 73127-5822	1641825

FEI Look Up ⓘ

1641825

Remove

* Organization Name: PD-RX PHARMACEUTICALS, INC.

* Address: 727 N ANN ARBOR AVE, OKLAHOMA CITY, OK, US, 73127-5822

* FEI: 1641825

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

i 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.

i 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.

i 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.

Product Details

Product Details

* Are you submitting for one or multiple products?
 One
 Multiple

Product Lookup

+ Add Product

Description of Events/Issues

Describe the circumstances surrounding the event that prompted the notification including, when, where in the supply chain, where geographically, and how the product was found. If you are a trading partner other than a manufacturer, you may indicate which manufacturer you have coordinated with to make the determination that the product is illegitimate here. If this notification is for a product with a high risk of illegitimacy (manufacturers only), indicate it here:

Previous Save and Close Next

Product Information

SEARCH RESULTS

NDC Number

Search

Proprietary Name

Search

Active Ingredient

Search

+ Add Manually

No Search Results Found

Enter in a search

SEARCH RESULTS

Proprietary Name	Active Ingredient	Strength	NDC	Dosage Form
<input type="radio"/> NAPROXEN	NAPROXEN	250 mg	63629-3202-3	TABLET
<input type="radio"/> NAPROXEN	NAPROXEN	250 mg	63629-3202-2	TABLET
<input type="radio"/> NAPROXEN	NAPROXEN	250 mg	63629-3202-5	TABLET
<input type="radio"/> NAPROXEN	NAPROXEN	250 mg	63629-3202-1	TABLET
<input type="radio"/> NAPROXEN	NAPROXEN	250 mg	63629-3202-4	TABLET

« < 1 of 1 > »

+ Add Manually Cancel Done



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.

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

i 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.

i 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.

The screenshot shows the 'Product Details' form. The 'Product Details' section contains a question: '* Are you submitting for one or multiple products?' with two radio buttons: 'One' and 'Multiple'. The 'Multiple' button is selected and highlighted with an orange box. The 'Product Lookup' section contains a dropdown menu with the text '* Select the approved use of the product' and a 'Please Select' option. The 'Description of Events/Issues' section contains a text area with a placeholder text: 'Describe the circumstances surrounding the event that prompted the notification including, when, where in the supply chain, where geographically, and how the product was found. If you are a trading partner other than a manufacturer, you may indicate which manufacturer you have coordinated with to make the determination that the product is illegitimate here. If this notification is for a product with a high risk of illegitimacy (manufacturers only), indicate it here:'. At the bottom of the form, there are three buttons: 'Previous', 'Save and Close', and 'Next'. The 'Next' button is highlighted with an orange box.



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.



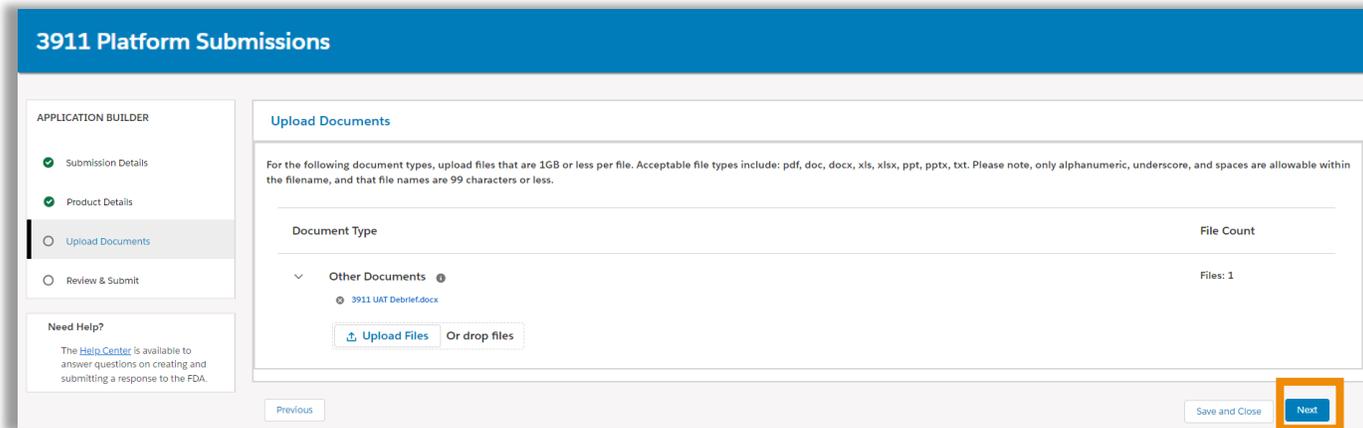
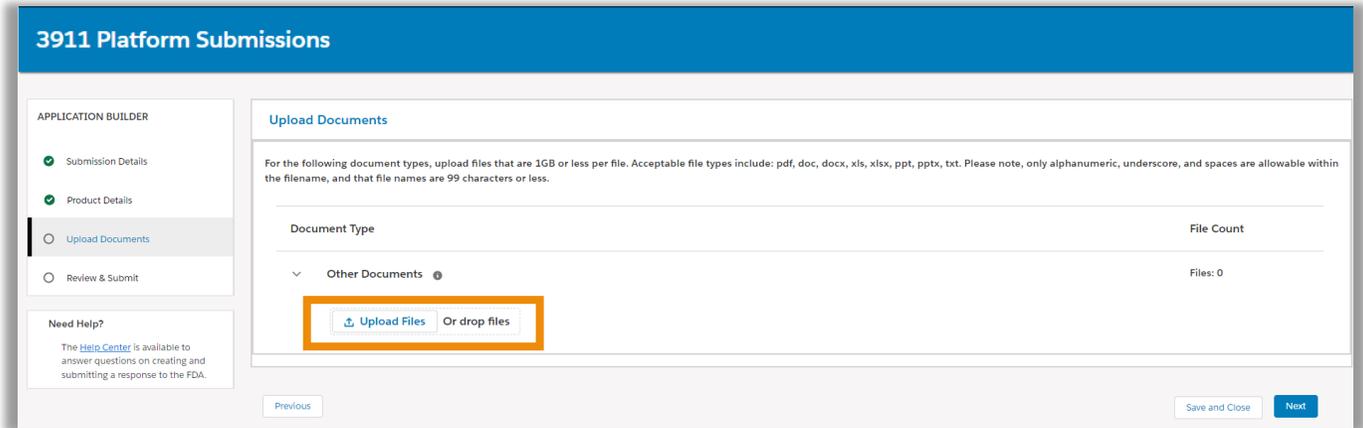
For an *Initial Submission* and *Follow-Up Notification*, describe the circumstances surrounding the incident in the description text box. When submitting a *Request for Termination*, explain why the notification is no longer needed including any corrective actions taken.

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.

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



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

The screenshot shows the 'Review and Submit' page of the 3911 platform. At the top right, there are buttons for 'Delete', 'Save and Close', and 'Submit'. The form is divided into several sections: 'Submission Details', 'Company & Facility Information', 'Product Details', 'Product Lookup', 'Upload Documents', and a footer with navigation buttons.

Submission Details

Type of Report Initial Submission	Date of Initial Notification to FDA 2023-08-25	Date Illegitimate Product Was Determined by Company 2023-08-31
Classification of Notification Unfit for distribution		

Company & Facility Information

- > Organization Name - GRANULES PHARMACEUTICALS INC
- > Organization Name - Preferred Pharmaceuticals Inc.

Product Details

Are you submitting for one or multiple products?
One

Product Lookup

Proprietary Name	Active Ingredient	Strength	NDC	Dosage Form
NAPROXEN	NAPROXEN	250 mg	63629-3202-2	TABLET

Serial Number	Lot Number	Expiration Date
123654	54698A	12/12/2023

Product Description
Finished Prescription Drug

Quantity of Drugs
25 Boxes

Select the approved use of the product (highlighted with a red box)

Other Documents

Document Type	File Count
Other Documents	Files: 1
3911 UAT Debrief.docx	

Note | You must click the "Generate 3911" button to generate the form prior to downloading a copy of the 3911 form.

Buttons: **Generate 3911** (highlighted with a red box), **Download 3911** (highlighted with a red box), **Submit** (highlighted with a red box)

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.

The screenshot displays the 3911 Platform Submissions interface. At the top, a blue header reads "3911 Platform Submissions" with a "New Submission" button on the right. Below the header is a search bar with a "Search" button. The main content area shows a list of submission tiles. Three tiles are visible, each with a title, status, last modified date, applicant organization, and request type. The first tile is titled "999019219 Submitted" and has an "Action Required" tag. The second tile is titled "999019216 Terminated" and has a "New Notification" tag. The third tile is titled "999019289 Submitted".

Overlaid on the screenshot is an email confirmation from the FDA. The email header includes the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION" and "DEPARTMENT OF HEALTH AND HUMAN SERVICES". The body of the email contains the following text:

Thank you for submitting your 3911 Submission. You can log into the [3911 Platform](#) to review your submission if needed.

We will review this information and follow up accordingly. If you identify changes or corrections are needed, please send a message to FDA via the [3911 Platform](#).

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

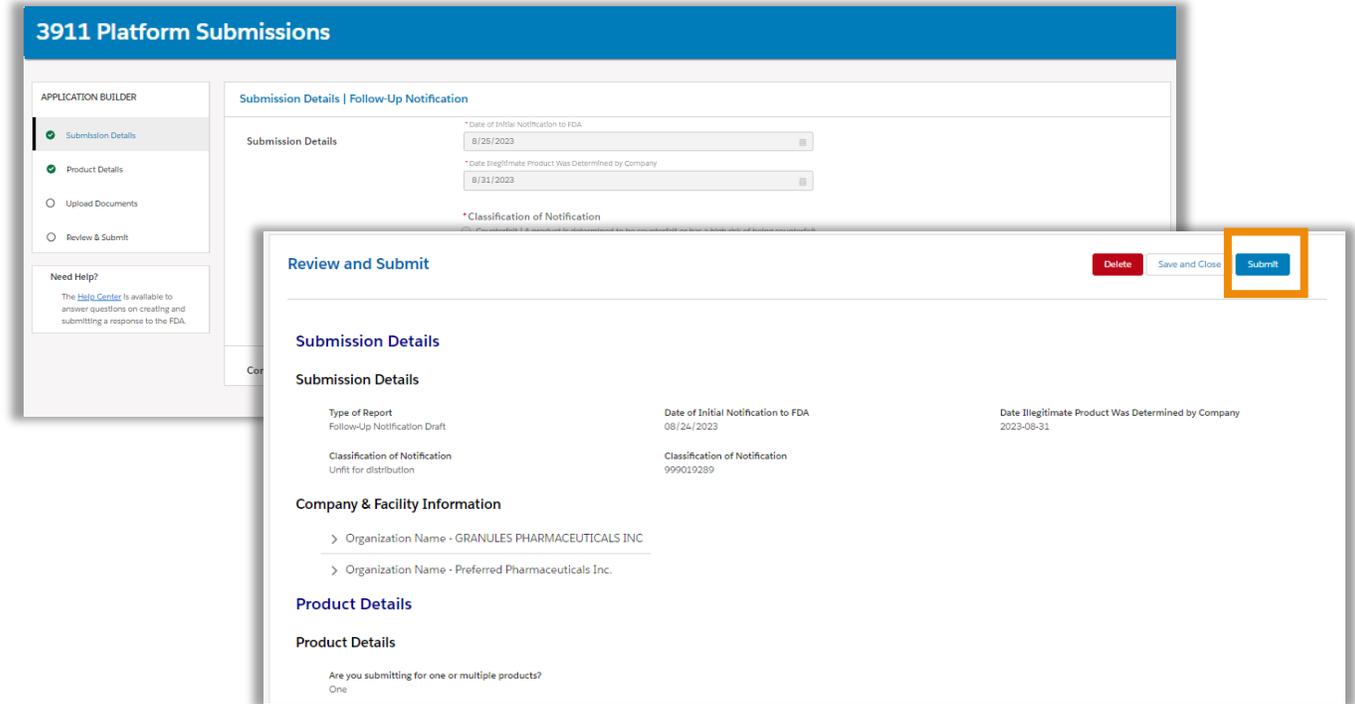
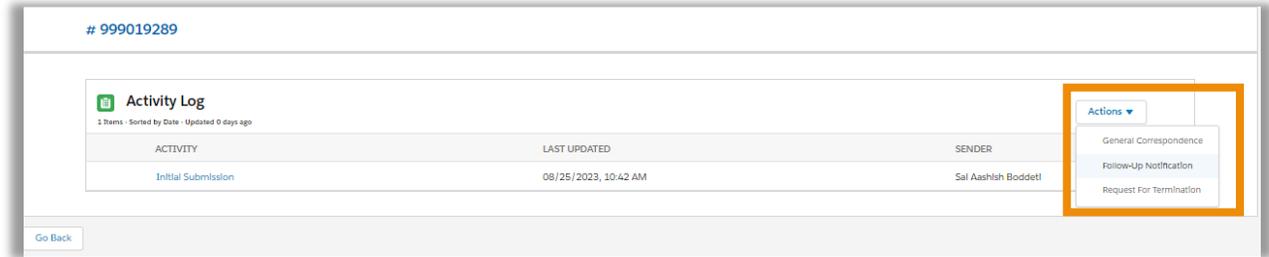
**** Please do not reply directly to this message. This is an automatically generated email and replies will not be monitored. ****

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*.

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*.

The screenshot displays two main components of the 3911 Platform interface. At the top, the submission ID # 999019219 is shown. Below it is the 'Activity Log' section, which contains a table of activities. The table has columns for 'ACTIVITY', 'LAST UPDATED', and 'SENDER'. The activities listed are: 'Response to Information Request' (08/31/2023, 09:42 AM, Sai Aashish Boddeti), 'FDA Information Request' (08/30/2023, 03:09 PM, FDA), 'Request For Termination' (08/21/2023, 10:39 AM, Sai Aashish Boddeti), and 'Initial Submission' (08/18/2023, 09:50 AM, Sai Aashish Boddeti). Below the activity log is the 'Submission Summary' section, which is currently empty. The 'Submission Summary' section includes sections for 'Submission Details', 'Company & Facility Information', 'Product Details', and 'Product Lookup'. The 'Submission Details' section shows 'Type of Report' as 'Initial Submission', 'Date of Initial Notification to FDA' as '09/07/2023', and 'Date Illegitimate Product Was Determined by Company' as '09/06/2023'. The 'Company & Facility Information' section shows 'Organization Name - COREPHARMA, LLC' and 'Organization Name - Wonder Pharma'. The 'Product Details' section shows 'Are you submitting for one or multiple products?' as 'One'. The 'Product Lookup' section shows 'Proprietary Name', 'Active Ingredient', 'Strength', 'NDC', and 'Dosage Form' as 'Multiple'. The 'Upload Documents' section shows 'Document Type' as 'Other Documents' and 'File Count' as 'Files: 0'. At the bottom, there are buttons for 'Generate 3911' and 'Download 3911'.

999019219

Activity Log

4 Items - Sorted by Date - Updated 0 days ago

ACTIVITY	LAST UPDATED	SENDER
Response to Information Request	08/31/2023, 09:42 AM	Sai Aashish Boddeti
FDA Information Request	08/30/2023, 03:09 PM	FDA
Request For Termination	08/21/2023, 10:39 AM	Sai Aashish Boddeti
Initial Submission	08/18/2023, 09:50 AM	Sai Aashish Boddeti

Submission Summary

Go Back

Submission Details

Submission Details

Type of Report Initial Submission	Date of Initial Notification to FDA 09/07/2023	Date Illegitimate Product Was Determined by Company 09/06/2023
Classification of Notification Intentional adulteration		

Company & Facility Information

- Organization Name - COREPHARMA, LLC
- Organization Name - Wonder Pharma

Product Details

Are you submitting for one or multiple products?
One

Product Lookup

Proprietary Name Multiple	Active Ingredient Multiple	Strength Multiple	NDC Multiple	Dosage Form Multiple
Select the approved use of the product Human Use	Drug Description Multiple	Quantity of Drugs Multiple		
Serial Number Multiple	Lot Number Multiple	Expiration Date Multiple		

If you have also submitted the information to FDA through an alternative mechanism, check all other voluntary or required reporting that apply:

- FDA - Field Alert Report
- EPDR - Biological Product Deviation Report
- MedWatch 3500
- MedWatch 3500A
- None
- Other

Describe the circumstances surrounding the event that prompted the notification including, when, where in the supply chain, where geographically, and how the product was found. If you are a trading partner other than a manufacturer, you may indicate which manufacturer you have coordinated with to make the determination that the product is illegitimate here. If this notification is for a product with a high risk of illegitimacy (manufacturers only), indicate it here.

Initial Submission

Upload Documents

Upload Documents

Document Type	File Count
Other Documents @ N/A	Files: 0

Note 1 You must click the "Generate 3911" button to generate the form prior to downloading a copy of the 3911 form and selecting submit.

Generate 3911 Download 3911

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.

ACTIVITY	LAST UPDATED	SENDER
Follow-Up Notification	08/30/2023, 03:38 PM	Sal Aashish Boddeti
Initial Submission	08/25/2023, 10:42 AM	Sal Aashish Boddeti

Incident Number #999019289

Please enter the following information regarding your General Correspondence.

*Provide any relevant information:

Please attach any necessary documents below:

Upload Files Or drop files

Submit

Form 3911 General Correspondence Submitted

00135144

Status: Submitted
Last Modified: 08/31/2023, 09:29 AM

Return Home

Thank you for submitting a General Correspondence message and get back with you shortly.

For technical support, please contact the CDER platform (EDMSupport@fda.hhs.gov).

From: DoNotReply@fda.hhs.gov <DoNotReply@fda.hhs.gov>
Sent: Monday, October 16, 2023 2:03 PM
To: Chowdhury, Kamrul * <Kamrul.Chowdhury@fda.hhs.gov>
Subject: 3911 - General Correspondence Submitted - [Event ID: 00139007]

Thank you for submitting your 3911 : General Correspondence. Your 3911 Incident ID is 999019376. Please use this Incident ID to uniquely identify this submission to the FDA. Please log in to 3911 Platform to review your submission if needed.

Please note that no further action is needed at this time on your end. We will review this information and follow up accordingly.

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

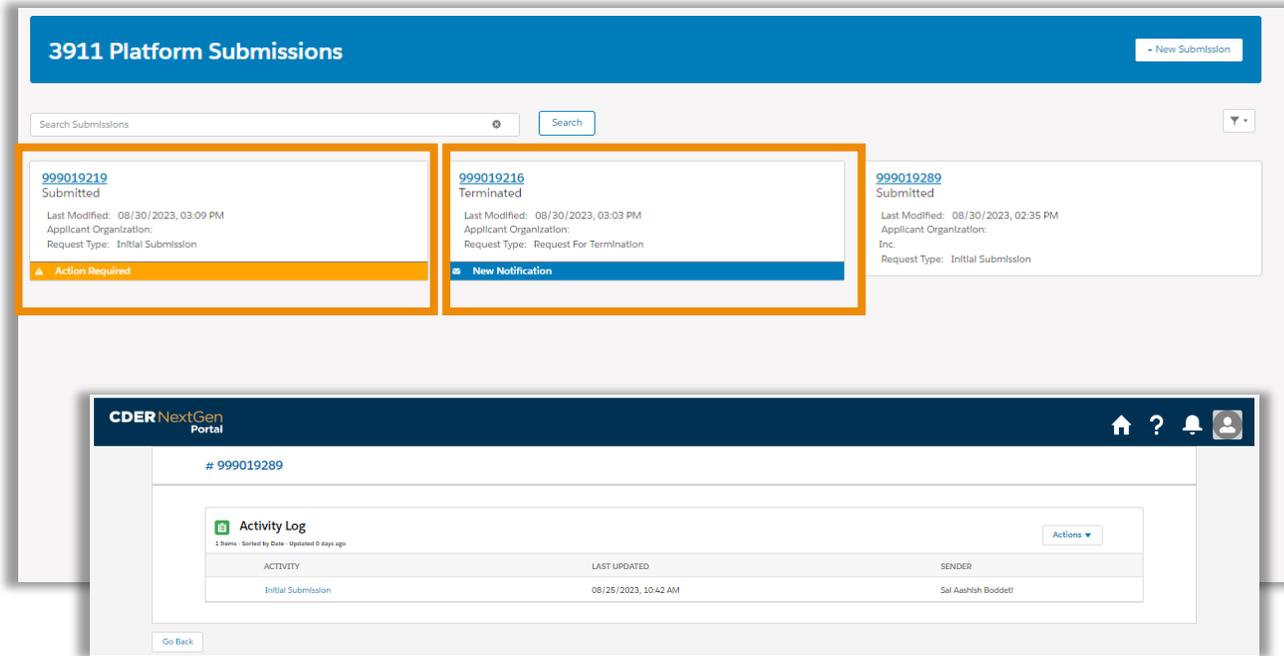
** Please do not reply directly to this message. This is an automatically generated email and replies will not be monitored. **

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

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
 - Transition from 3911 Platform to DSCSA Portal



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.

Information Request

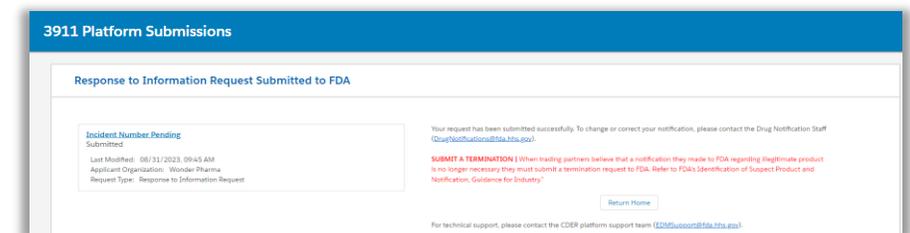
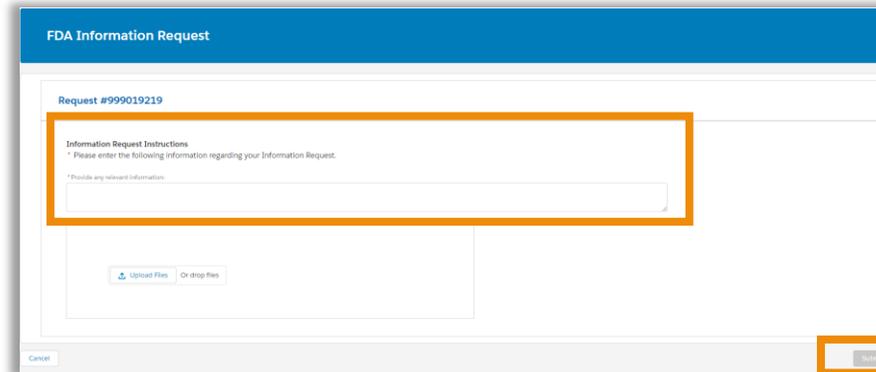
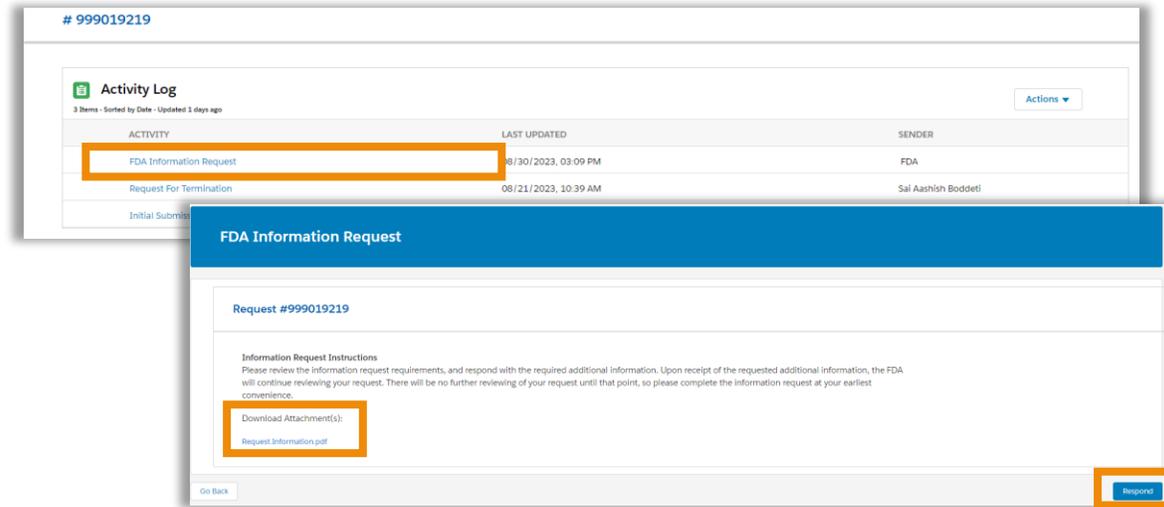
Step 1. Once FDA sends an *Information Request*, navigate to the *Activity Log* of the relevant notification and click on *FDA Information Request*.

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.

The screenshot shows the 3911 Platform interface for incident # 999019216. The top section is the 'Activity Log' with 4 items, sorted by date, updated 1 day ago. The table below shows the following activities:

ACTIVITY	LAST UPDATED	SENDER
Request for Termination Agreement	08/30/2023, 03:03 PM	FDA
Request For Termination	08/24/2023, 10:42 AM	Sai Aashish Boddeti
Follow-Up Notification	08/24/2023, 10:41 AM	Sai Aashish Boddeti
Initial Submission	08/21/2023, 10:12 AM	Sai Aashish Boddeti

The second screenshot shows the 'Request for Termination Agreement' screen. It displays the request details for #999019216, including 'Request For Termination Agreement Instructions' and a 'Download Attachment(s)' link for 'Termination.Agreement.pdf'. A 'Go Back' button is visible at the bottom left.



Follow the same steps to view other FDA communication such as *Request for Termination Disagreement*, *Not a Notification under DSCSA*, *FDA Response*, *FDA Reminder* or *Transition from 3911 Platform to DSCSA Portal*.



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.



Technical Support

For all technical support, please visit the [CDER NextGen Portal Help Center](#).

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**.

Portal Video Tutorial

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