



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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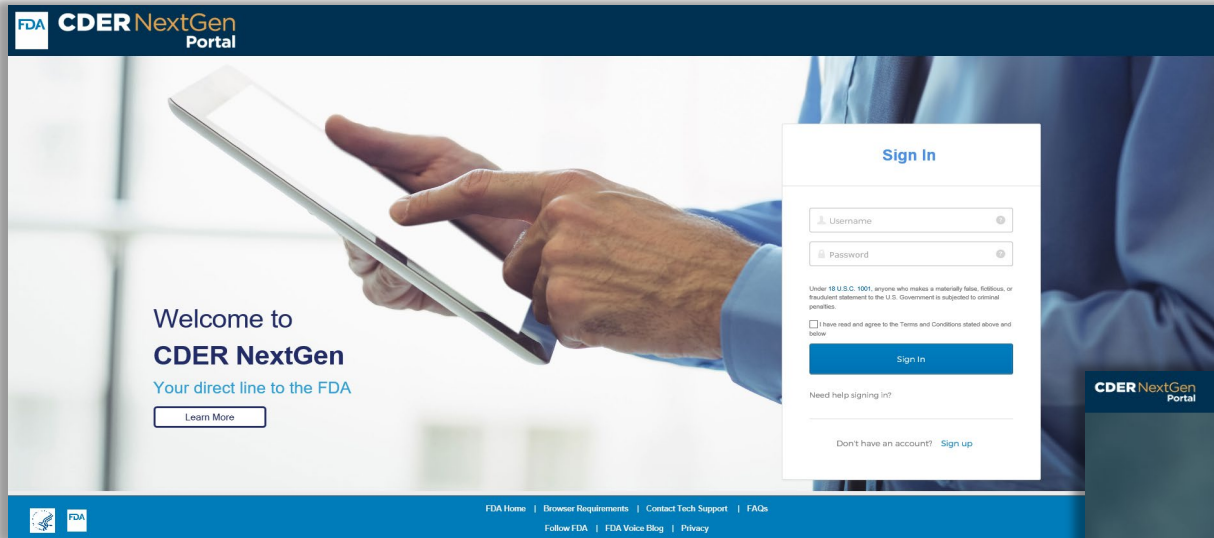
Introduction

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.

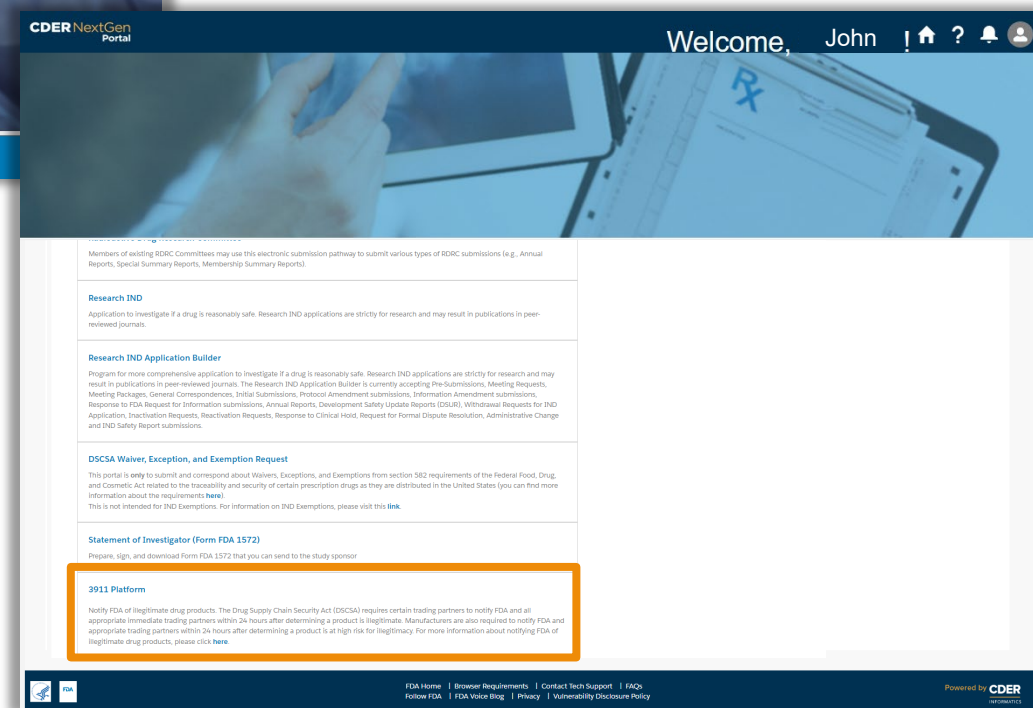
The 3911 Platform within the CDER NextGen Portal was created as a simple and efficient way for users to create and submit a Drug Notification to notify FDA when they have determined a product is illegitimate. The 3911 Platform also helps users generate a Form FDA 3911 and communicate with FDA regarding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

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

CDER NextGen Portal Home Page



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



Submit a New Drug Notification

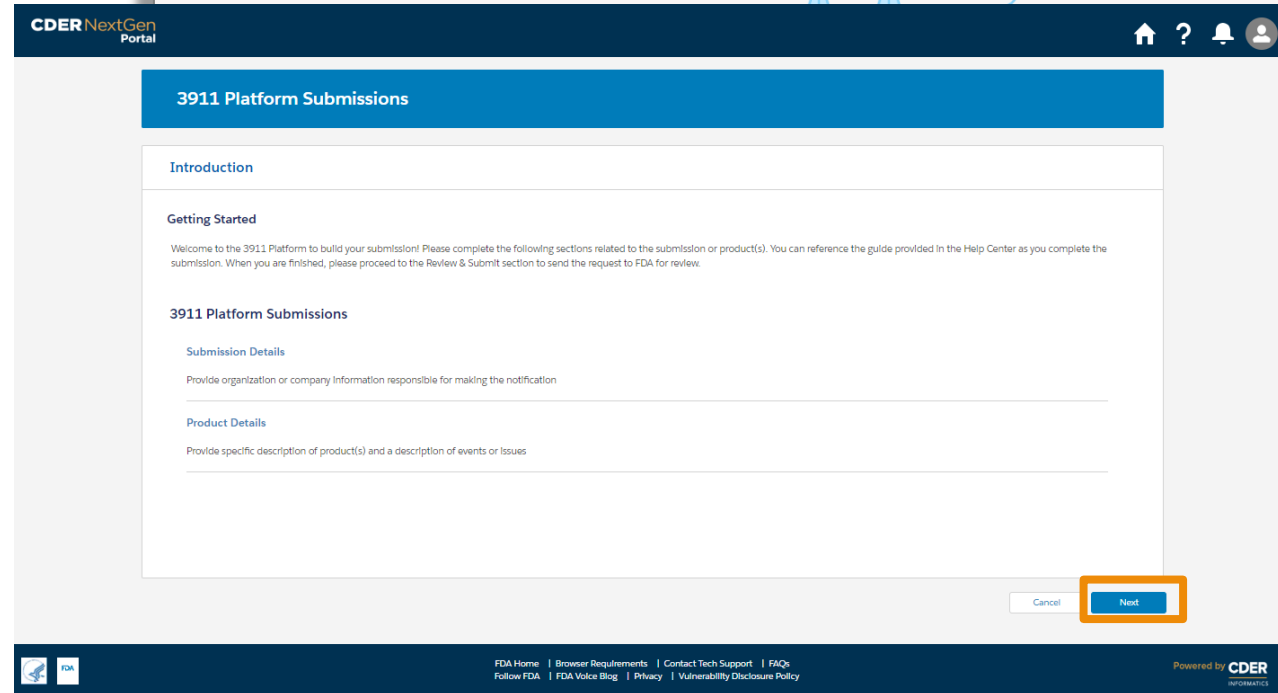
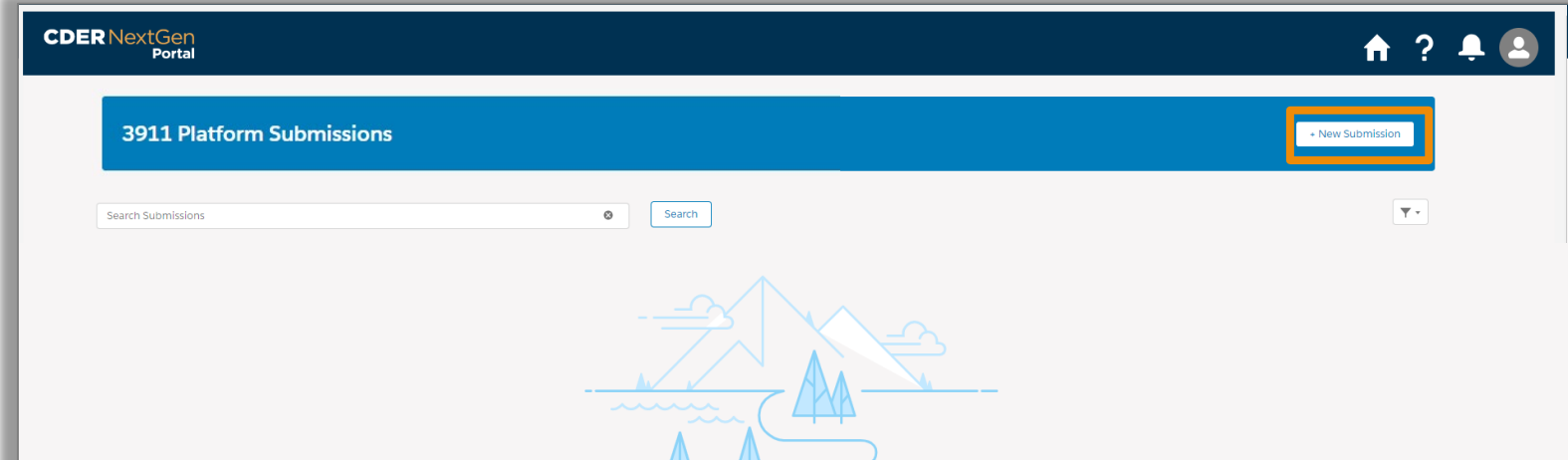
Step 2. Select **New Submission.**

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.



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*.

3911 Platform Submissions

APPLICATION BUILDER

- Submission Details
- Product Details
- Upload Documents
- Review & Submit

Need Help?
The [Help Center](#) is available to answer questions on creating and submitting a response to the FDA.

Submission Details

* Date of Initial Notification to FDA
8/23/2023

* Date Illegitimate Product Was Determined by Company

Classification of Notification

- Counterfeit | A product is determined to be counterfeit or has a high risk of being counterfeit.
- Diverted | A product is determined to be a diverted product or has a high risk of being a diverted product.
- Stolen | A product is determined to be a stolen product or has a high risk of being a stolen product.
- Intentional adulteration | A product is determined to be intentionally adulterated such that use of the product would result in serious adverse health consequences or death to humans or has a high risk of it.
- Unfit for distribution | A product appears otherwise unfit for distribution such that use of the product would be reasonably likely to result in serious adverse health consequences or death to humans or has a high risk of it.
- Fraudulent transaction | A product in your possession or control is determined to be the subject of a fraudulent transaction or has a high risk of it.

Company & Facility Information

+ Add Company

Save and Close Next

Help Center

3911 Platform

FAQs
Common questions and answers about the 3911 process.

Reference Guide
Step-by-step guide for submitting a 3911 in the CDER NextGen Portal



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

* 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 63629-3202
Allowable formats are: 1234-1234, 12345-123, and 12345-1234.
Please refer to the [NDC Directory](#) to search for your product.

Proprietary Name
Active Ingredient
Search

+ Add Manually

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

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

Product Details

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

Product Lookup

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

Remove

* Select the approved use of the product
Human Use

* Drug Description
Finished Prescription Drug

Quantity of Drugs
25 Boxes

Serial Number
123654

Lot Number
54689A

Expiration Date
12/12/2023

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

FAR - Field Alert Report
 BPDR - Biological Product Deviation Report

Add case or reference number if available
569843546

MedWatch 3500
 MedWatch 3500A
 None
 Other

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:

Initial Submission

Previous Save and Close Next

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.



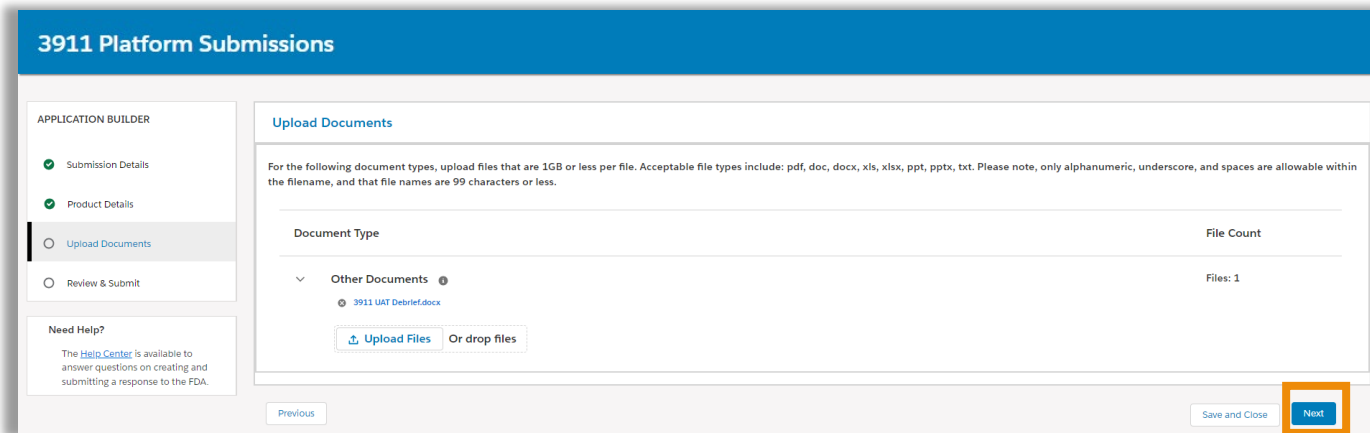
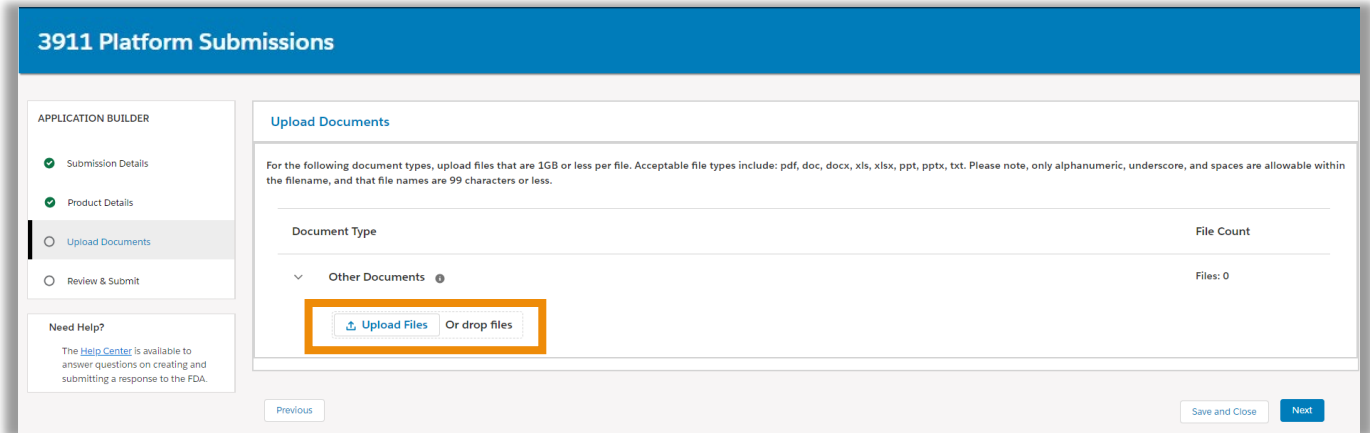
For an *Initial Submission* and *Follow-Up Notification*, describe the circumstances surrounding the incident in the description text box. When submitting a *Request for Termination*, explain why the notification is no longer needed including any corrective actions taken.

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' interface for a 3911 notification. 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 Unit 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

Product Information:

- Select the approved use of the product (highlighted with a red box)
- Drug Description: Finished Prescription Drug
- Quantity of Drugs: 25 Boxes
- Serial Number: 123654
- Lot Number: 54098A
- Expiration Date: 12/12/2023

Additional Information:

- If you have also submitted the information to FDA through an alternative mechanism, check all other voluntary or required reporting that apply:
 - FAIR - Field Alert Report
 - BPR - Biological Product Deviation Report
- Add case or reference number if available: 509845546
- 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

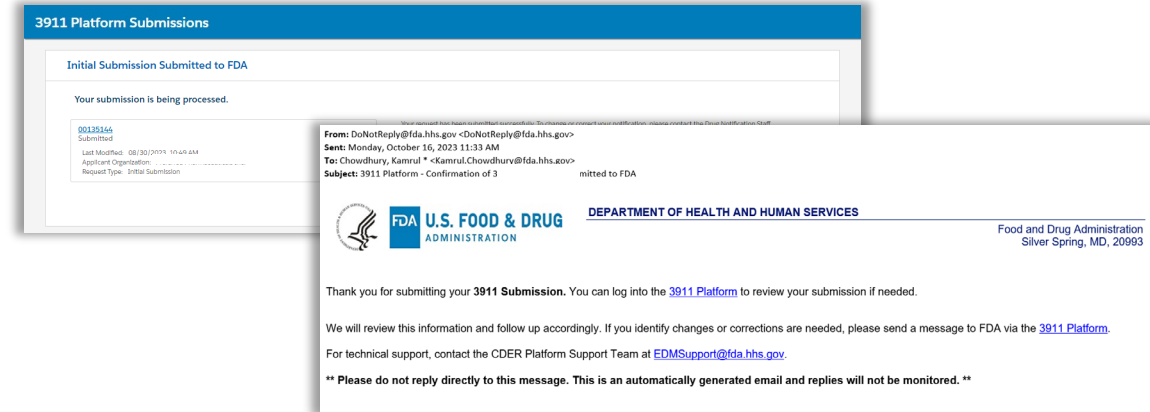
Document Type	File Count
Other Documents +	Files: 1
3911 UAT Debrief.docx	

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)

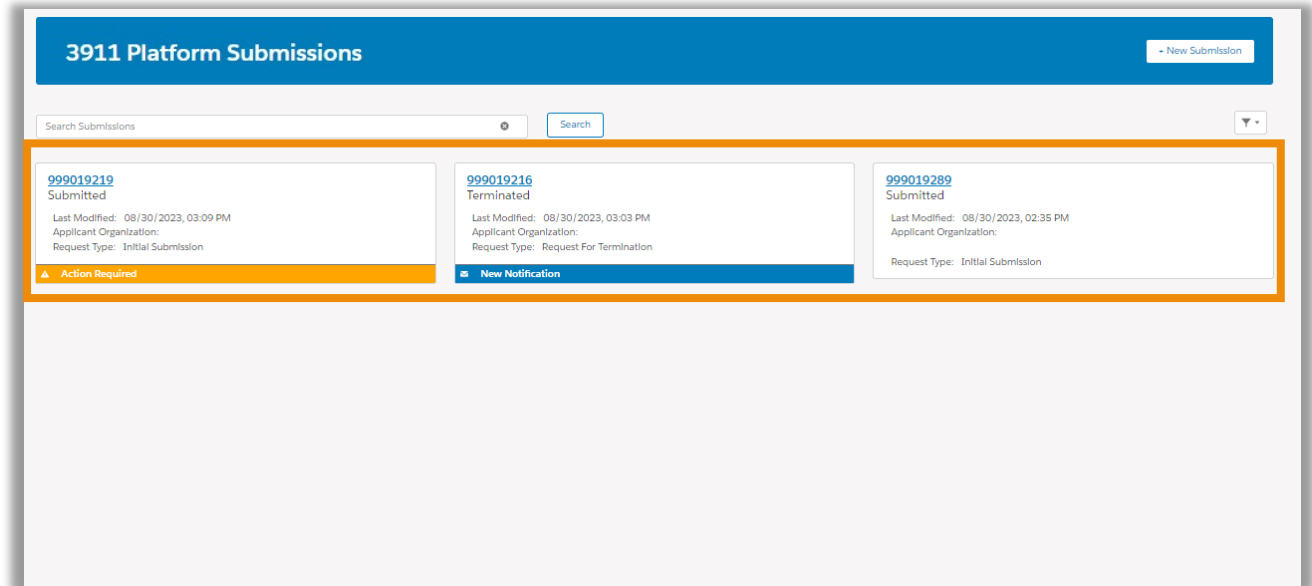
Receiving Confirmation(s) from FDA

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.



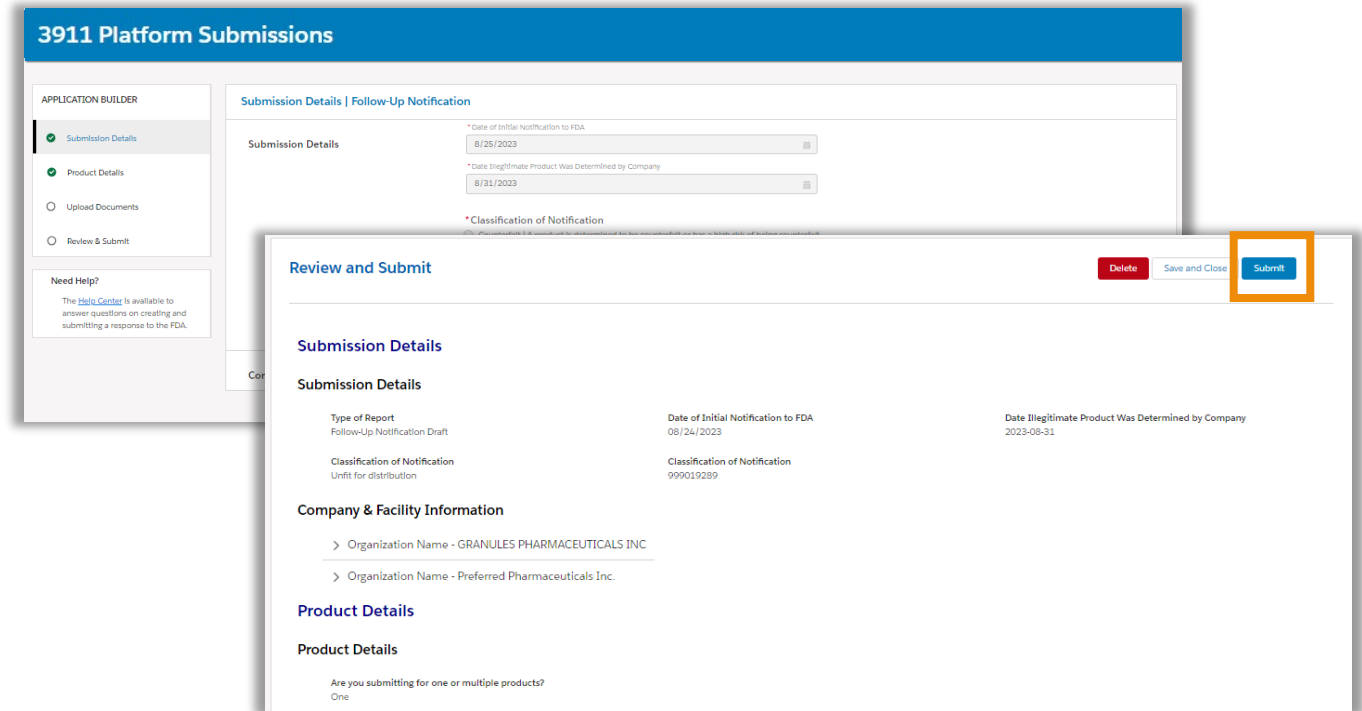
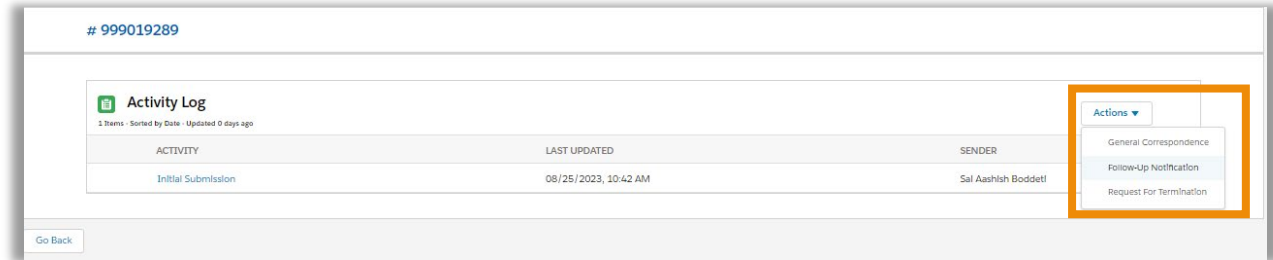
Here, you can send a subsequent submission such as *Follow-Up Notification* or *Request For Termination*, view *Submission Summary*, or send a *General Correspondence*. You can also view communication(s) sent by FDA and respond to an *Information Request* from FDA.

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*.

999019219

Activity Log 4 Items - Sorted by Date - Updated 0 days ago Actions

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 of Legitimate 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	Files: 0
N/A	

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](#)

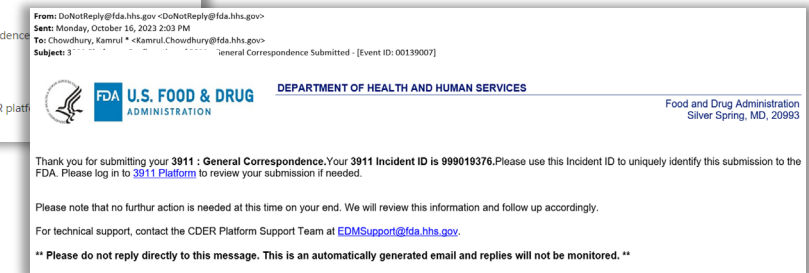
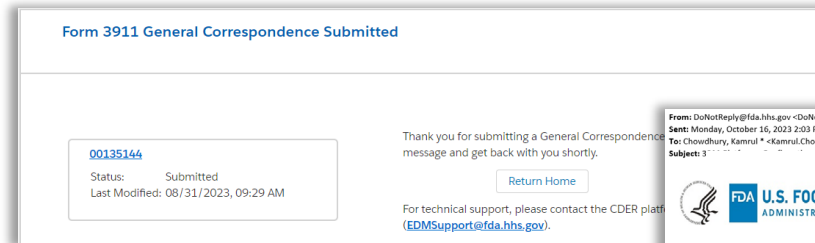
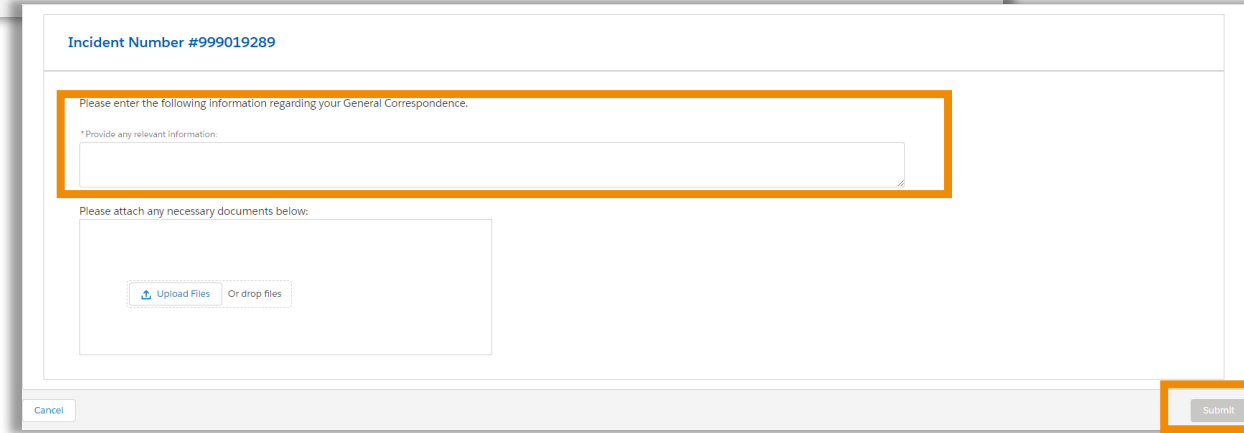
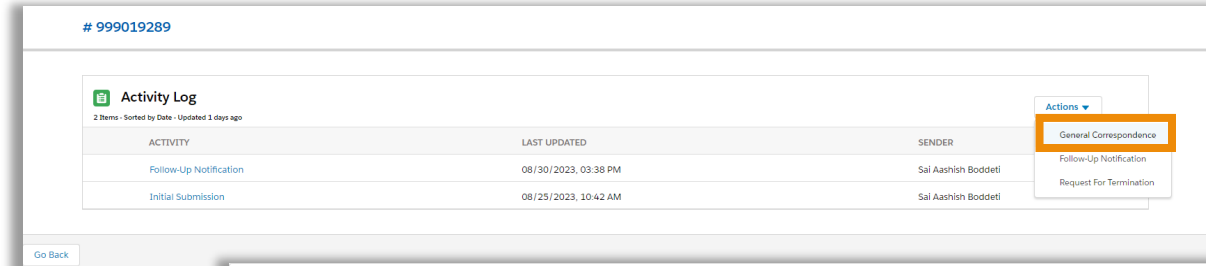
General Correspondence

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.



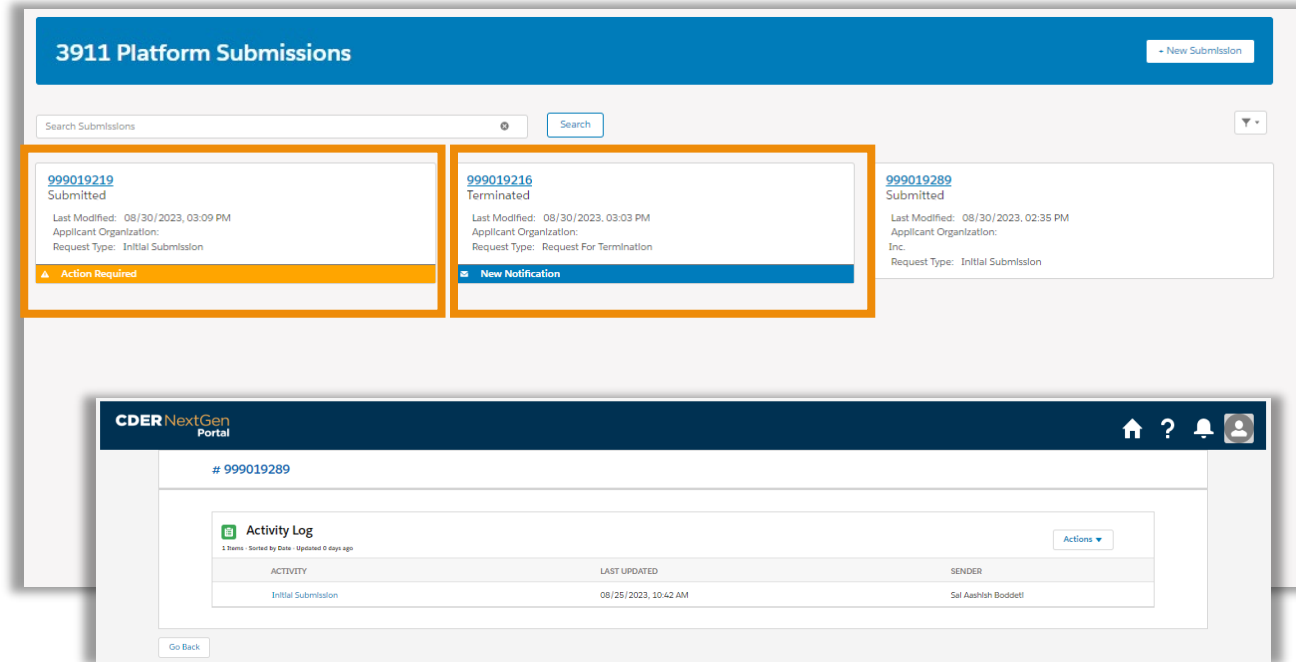
Submit button is enabled once text is entered in the text box

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

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.



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

Information Request

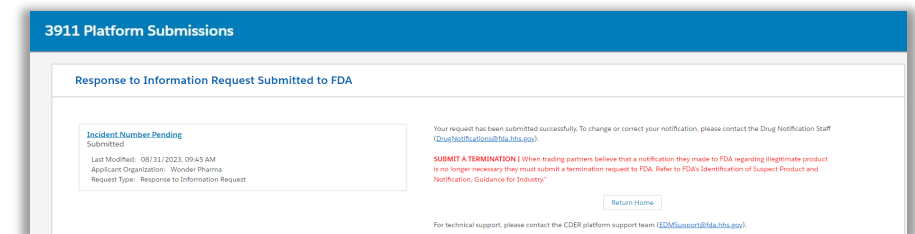
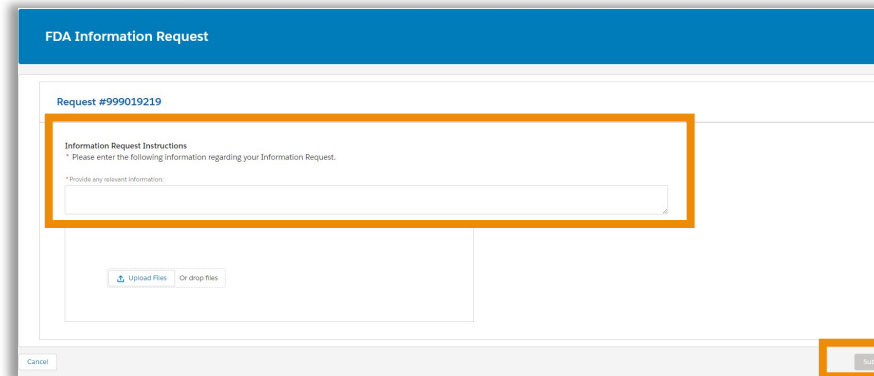
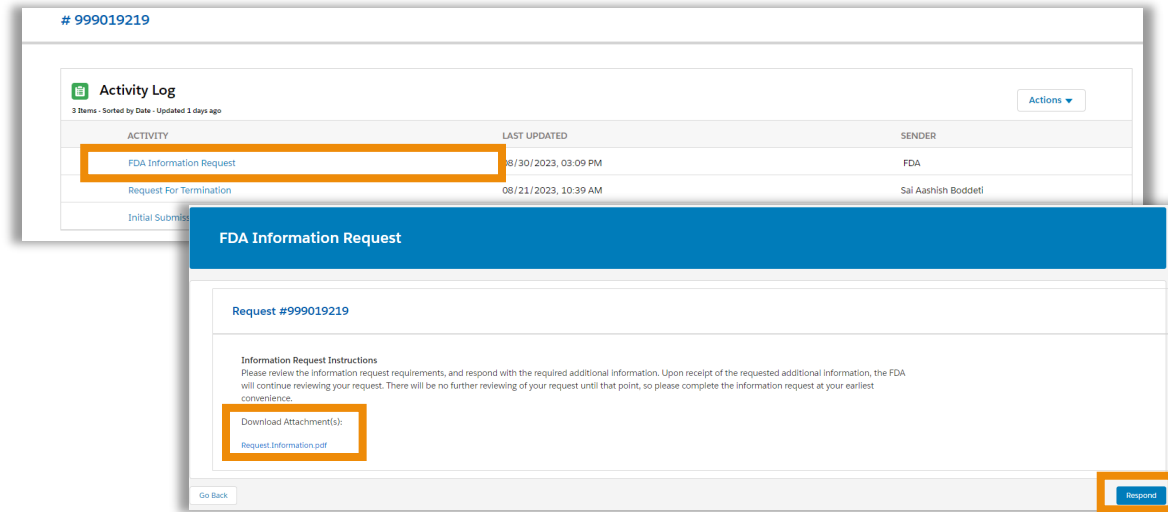
Step 1. Once FDA sends an *Information Request*, navigate to the *Activity Log* of the relevant notification and click on *FDA Information Request*.

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' table, which lists communication events. The 'Request for Termination Agreement' entry is highlighted with an orange box. Below the table is a detailed view of the 'Request for Termination Agreement' screen, which includes instructions and a PDF attachment for download.

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

Request for Termination Agreement

Request #999019216

Request For Termination Agreement Instructions
The Drug Notification Staff has provided a response to your Request for Termination Agreement. Please review the attachment at your earliest convenience. Please contact Drug Notification Staff (DrugNotifications@fda.hhs.gov) with any questions regarding this notification.

Download Attachment(s):
[Termination.Agreement.pdf](#)

[Go Back](#)



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.



Technical Support

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

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.