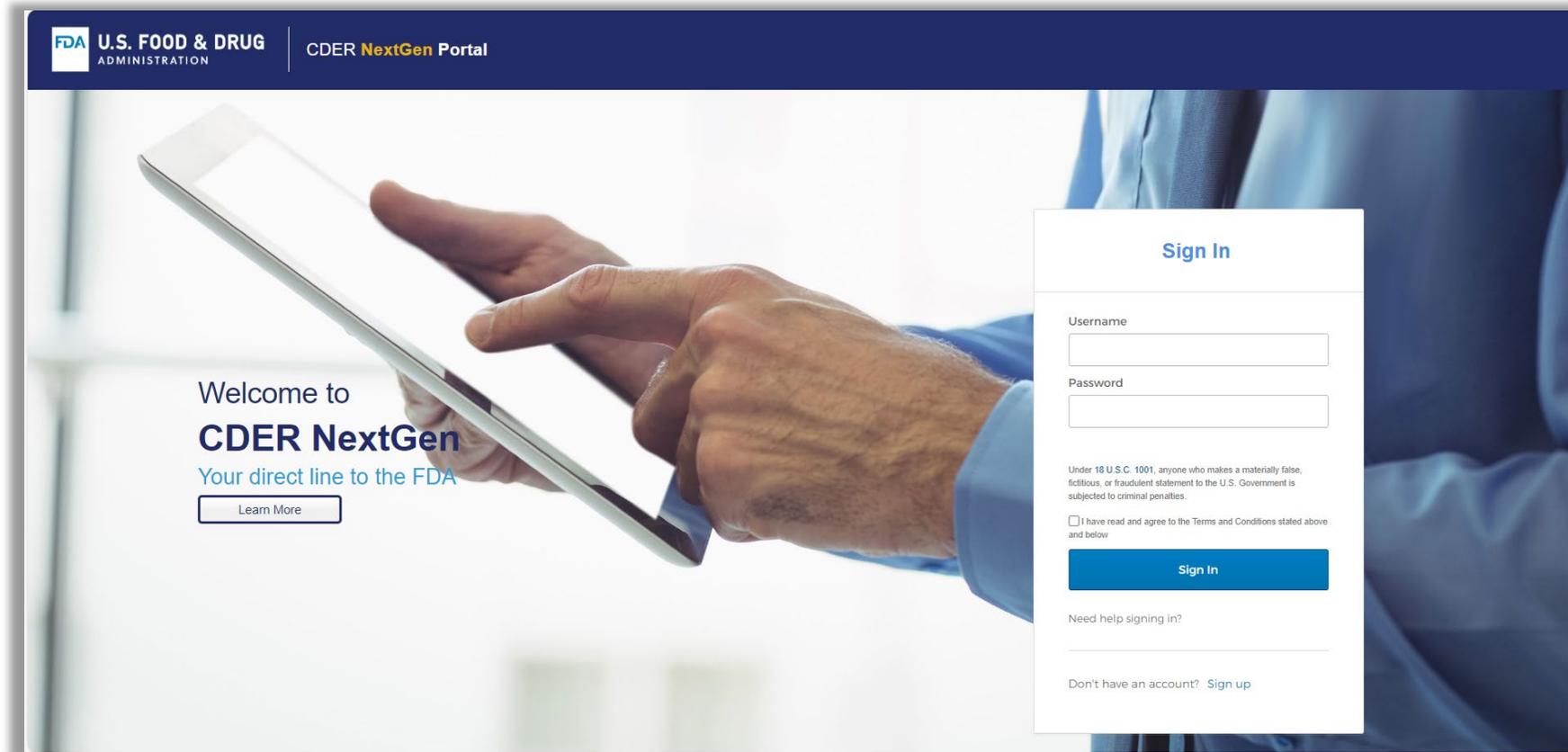


FDA's DSCSA Portal

Reference Guide



Click [here](#) to access the CDER NextGen Portal.

Click [here](#) to email the DSCSA Portal Team.

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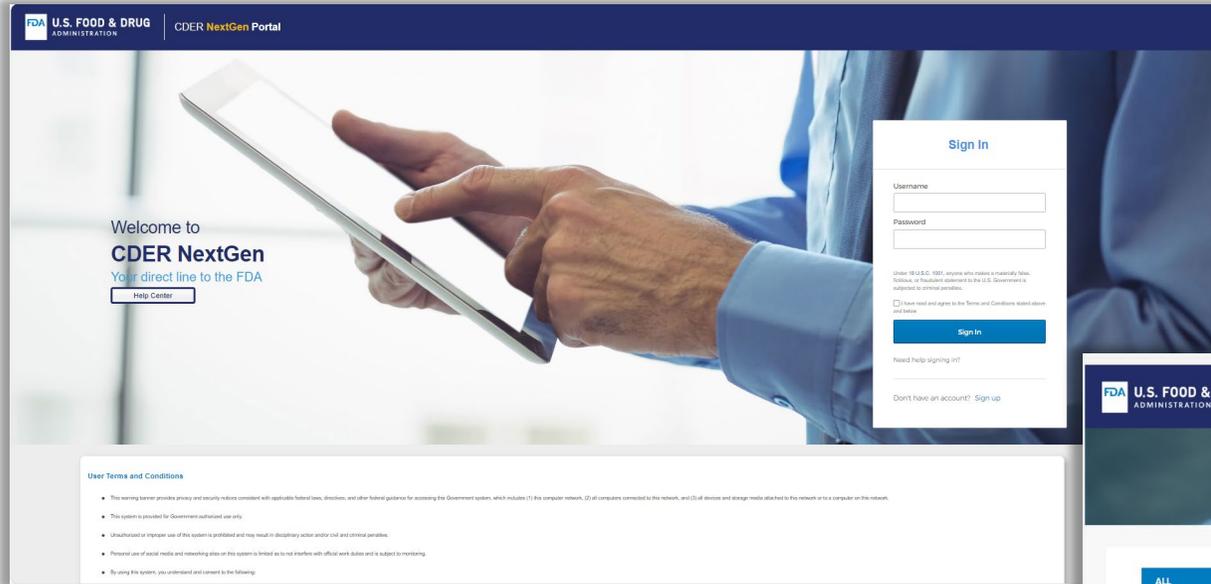
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Introduction

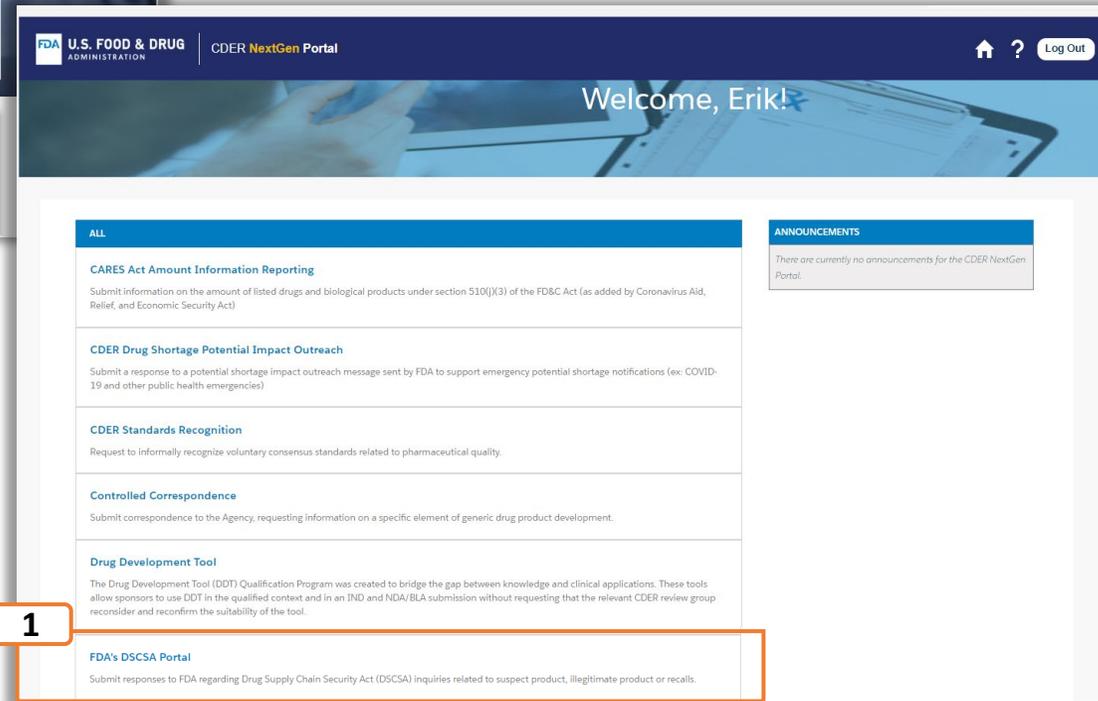
This guide provides the essential information you need to use in the CDER NextGen Portal to submit Information to FDA (for both CDER and CBER) regarding Drug Supply Chain Security Act (DSCSA) inquiries related to suspect product, illegitimate product or recalls.

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

Portal Homepage



Step 1. After you land on the CDER NextGen Portal homepage, scroll down and click **FDA's DSCSA Portal** to begin. You will be directed to your DSCSA Portal landing page.



Trading Partner Details

Step 2. Select **Trading Partner Confirmation** on your DSCSA Portal landing page.

Step 3. Review your Contact Details.

Step 4. Enter your **Request ID** (refer to your email from FDA to locate Request ID).

Step 5. Click **Validate**.



Keep in mind, if you have previously saved a request as a draft or submitted a request, you can view it on your FDA's DSCSA Portal landing page.

The screenshot displays the FDA's DSCSA Portal interface. At the top, the header includes the FDA logo, 'U.S. FOOD & DRUG ADMINISTRATION', and 'CDER NextGen Portal'. A navigation bar contains a home icon, a question mark, and a 'Log Out' button. Below the header, a blue banner reads 'FDA's DSCSA Portal'. A dropdown menu is open, showing 'Trading Partner Confirmation' as the selected option, indicated by a callout '2'. The main content area is titled 'Trading Partner Information' and includes a 'Need Help?' section with a link to the 'Help Center'. The 'Contact Details' section is highlighted with a callout '3' and contains the following fields: First Name (Anusha), Last Name (Eradala), Email Address (anusha.eradala@fda.hhs.gov), and Phone Number (8157645570). The 'Trading Partner Details' section is highlighted with a callout '4' and contains a text input field for the Request ID Number (Example ID | 123-ABC-00) with the value '464-EDM-1' entered. A 'Validate' button is highlighted with a callout '5'. At the bottom right, there are buttons for 'Delete', 'Save and Close', and 'Next'.

Trading Partner Details

Step 6. Answer Yes or No if the Trading Partner designated you as the **Point of Contact**.

Step 7. If No, enter **Contact Information**. If Yes, review the **Contact Information**.

Step 8. Answer if you are using a **Third-Party Representative** and provide the contact details as applicable.



You can **Save and Close** the Trading Confirmation at any point of the process. You can select the record on your FDA DSCSA Portal landing page to complete the process.

The screenshot shows the 'Trading Partner Details' form in the CDER NextGen Portal. The form includes a 'Request ID Number' field with a 'Validate' button, a question about being designated as the point of contact, a 'Contact Information' section with fields for first and last name, email address, phone number, and extension, and a question about using a third-party representative. A 'Facility Information' section with an 'Add Facility Information' button is at the bottom. At the bottom right, there are 'Delete', 'Save and Close', and 'Next' buttons. Three orange callout boxes with numbers 6, 7, and 8 highlight the 'Has the Trading Partner designated you as the point of contact?' question, the 'Contact Information' section, and the 'Are you using a Third Party Representative?' question, respectively.

Facility Information

Step 9. Click **Add Facility Information**

Step 10. Enter **FEI Number** if available and select **Search**.

Step 11. Select the relevant **Facility Record** and click **Save**.

Step 12. If you would like to add another Facility repeat steps 9-11. Click **Next** when complete.

Drug Manufacturing Site Name	Drug Manufacturing Site Address	FEI
<input type="checkbox"/> AMGEN INC.	12000 PLANTSIDE DR, LOUISVILLE, KY, US, 40299-6305	3003750095

 Please note that the Facility Information is optional. If you select the wrong facility information, you can remove the record by selecting the checkbox in the row and clicking the Remove button at the bottom of the section. If the FEI number is not searchable, you may also enter it manually.

Review and Submit Trading Partner Confirmation

Step 13. Review each section to ensure all information entered is correct.

Step 14. Enter your **First and Last Name** in the **Certification** section.

Step 15. Click **Submit** to send your request to the FDA for review, click **Save and Close** to keep your Trading Partner Confirmation and edit it later, or click **Delete** to permanently remove the request you have been working on.

Step 16. Click **Continue** to complete your submission.

The screenshot displays the FDA's DSCSA Portal interface. At the top, the header includes the FDA logo, 'U.S. FOOD & DRUG ADMINISTRATION', and 'CDER NextGen Portal'. The main content area is titled 'FDA's DSCSA Portal' and 'Review and Submit Trading Partner Confirmation'. It contains two sections: 'Contact Information' and 'Trading Partner Details'. The 'Contact Information' section includes fields for First Name (Erik), Last Name (Chen), Email (erika.chen@fda.hhs.gov), Phone Number (+12023053162), and Extension. The 'Trading Partner Details' section includes a field for Request ID Number (37-amgen-2) and a checkbox for 'Has the Trading Partner designated you as the point of contact?' (Yes). Below this is a smaller 'Contact Information' section with First Name (Erik) and Last Name (Chen).

Step 13 is indicated by a red box around the 'Review and Submit Trading Partner Confirmation' title.

The 'Certification' section is shown below, with a red box around the 'Type in your name to confirm certification' label. It includes a text area with a disclaimer, and input fields for First Name (Erik), Middle Name, and Last Name (Chen). A 'Current date' field shows 12/9/2024. Step 14 is indicated by a red box around the 'Type in your name to confirm certification' label.

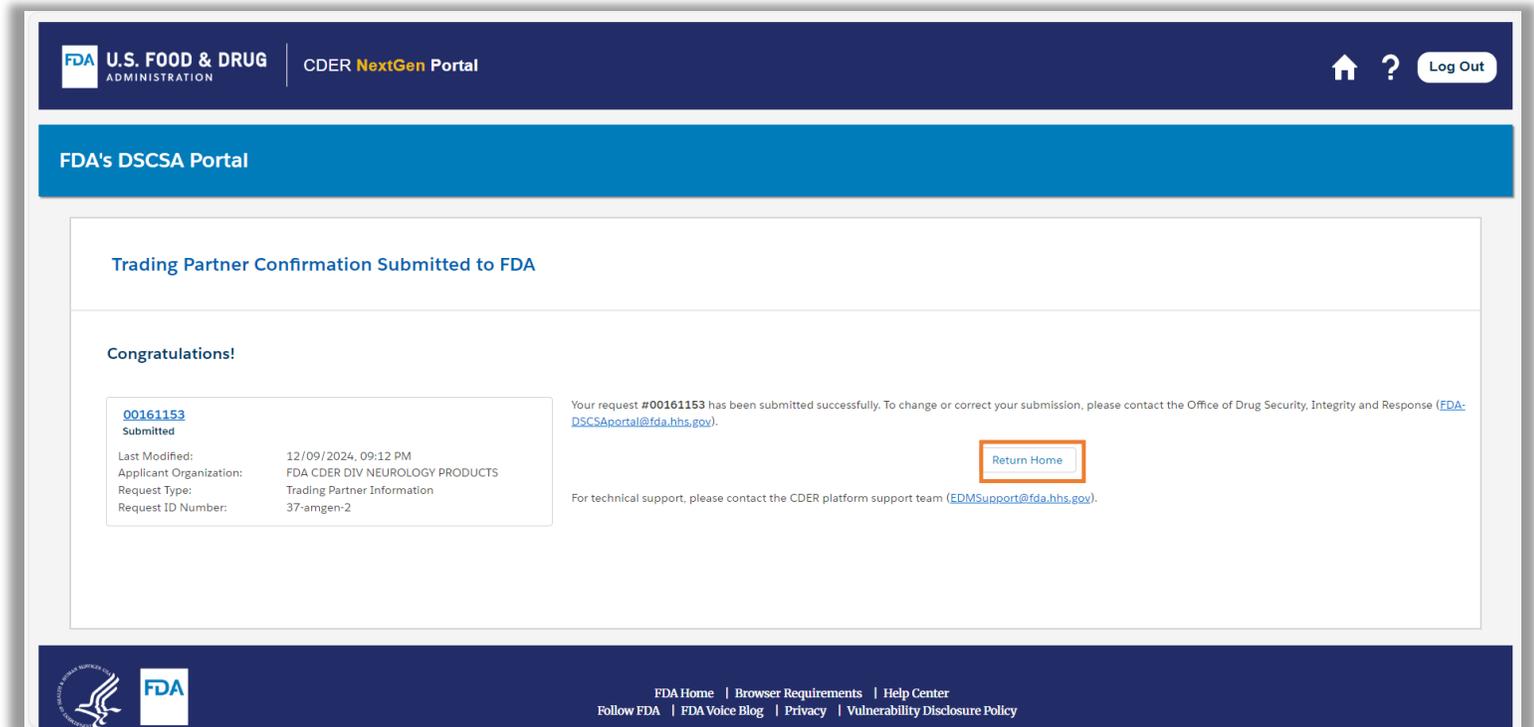
Step 15 is indicated by a red box around the 'Submit' button in the bottom right corner of the certification section.

A modal dialog box titled 'Complete & Submit Trading Partner Confirmation' is shown at the bottom, with a red box around the 'Continue' button. The dialog contains the text: 'Are you sure you would like to submit Trading Partner Confirmation? You will not be able to edit the submission once submitted.' Step 16 is indicated by a red box around the 'Continue' button.

Receiving Confirmation(s) from FDA

You will view a confirmation screen to confirm your **Trading Partner Confirmation** was submitted to the FDA and will receive an email confirming the submission of your Trading Partner Confirmation.

Please open the confirmation email from DoNotReply@fda.hhs.gov and review the information submitted.



Activity Log

After submitting your Trading Partner Confirmation, you can view your submissions and FDA notifications on your Activity Log page by clicking on the Event ID on your landing page.

Step 17. To view a notification, click on the **Event ID** on your landing page tile to be redirected to the Activity Log. Note the following:

- An **Action Required** banner is for the following messages: **Trading Partner POC | Not Confirmed, FDA Information Request, or Request for Documentation** from the FDA.
- A **New Notification** banner is for the following messages: **Trading Partner POC | Confirmed, Transition from DSCSA Portal.**

The screenshot shows the FDA's DSCSA Portal interface. At the top, there is a search bar and a '+ Trading Partner Confirmation' button. Below this is a grid of notification tiles. One tile, labeled '17', shows '00161232 Trading Partner POC | Not Confirmed' with an 'Action Required' banner. Another tile shows '00161139 Transitioned' with a 'New Notification' banner. A third tile shows '00161153 Trading Partner POC | Confirmed' with a 'New Notification' banner. Below the grid, the 'Event ID # 00161139' is expanded to show an 'Activity Log' table with 7 items.

ACTIVITY	LAST UPDATED	SENDER
Transition from DSCSA Portal	12/10/2024, 01:03 PM	FDA
Initial Submission Submitted	12/10/2024, 12:40 PM	Erik Chen
Request for Documentation	12/10/2024, 12:40 PM	FDA
Response to Information Request	12/10/2024, 07:42 AM	Erik Chen
Information Request	12/10/2024, 07:42 AM	FDA
Trading Partner POC Confirmed	12/09/2024, 08:09 PM	FDA
Trading Partner Confirmation Submitted	12/09/2024, 08:00 PM	Erik Chen



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

FDA Information Request

Step 1. Click on the **FDA Information Request** in the Activity Log.

Step 2. View FDA Information Request instructions and download attachments.

Step 3. Respond to an FDA Information Request by clicking **Respond**.

Event ID # 00161139

Activity Log
3 Items - Sorted by Date - Updated 0 days ago

	ACTIVITY	LAST UPDATED	SENDER
1	Information Request	12/10/2024, 07:26 AM	FDA
	Trading Partner POC Confirmed	12/09/2024, 08:09 PM	FDA
	Trading Partner Confirmation Submitted	12/09/2024, 08:00 PM	Name

Go Back

FDA U.S. FOOD & DRUG ADMINISTRATION | CDER NextGen Portal

Information Request

Request # 00161139

Information Request Instructions
FDA needs additional information to proceed with review of your submission. Please review the information request and provide the required additional information at your earliest convenience. Upon receipt of this information, FDA will resume review of your submission. For questions specific to your request, please contact the Office of Regulatory Integrity and Response (CDERDSCSA@mailbox.fda.hhs.gov)

Download Attachment(s):
[Information Request-FDA CDER DIV NEUROLOGY PRODUCTS.pdf](#)

Go Back

Respond

FDA Home | Browser Requirements | Help Center
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

FDA Information Request

Step 4. Enter **FDA Information Request** details

Step 5. Upload relevant files by selecting **Upload Files** to browse your computer and select a file to upload or drop a file into the designated area on the screen.

Step 6. Click **Submit**.

The screenshot shows a web form titled "Response to Information Request". At the top, it displays "Request # 00161139". Below this, there is a text input field with the prompt "Please enter the following information regarding your Information Request." and a sub-prompt "* Provide any relevant information:". This field is highlighted with an orange box and the number 4. Below the text field is a file upload area with the prompt "Please attach any necessary documents below:". It contains an "Upload Files" button with a cloud icon and the text "Or drop files". This area is highlighted with an orange box and the number 5. At the bottom of the form, there are two buttons: "Cancel" on the left and "Submit" on the right. The "Submit" button is highlighted with an orange box and the number 6.

Submission Confirmation

You will view a confirmation screen to confirm your **Response to FDA Information Request** was submitted to the FDA and will receive an email confirming the submission of your Response to FDA Information Request.

Please open the confirmation submission email from DoNotReply@fda.hhs.gov to review the information submitted.

The screenshot shows the 'FDA's DSCSA Portal' header. Below it, the page title is 'Response to Information Request Submitted to FDA'. A 'Congratulations!' message is displayed. A box contains the following details:

00161139
Trading Partner POC Confirmed
Last Modified: 12/10/2024, 07:42 AM
Applicant Organization: FDA CDER DIV NEUROLOGY PRODUCTS
Request Type: Trading Partner Information
Request ID Number: 37-amgen-1

Below the box, there is a 'Return Home' button and a note: 'Your request #00161139 has been submitted successfully. To change or correct your submission, please contact the Office of Drug Security, Integrity and Response (FDA: DSCSAportal@fda.hhs.gov).' At the bottom, it says: 'For technical support, please contact the CDER platform support team (EDMSupport@fda.hhs.gov).'

POC Not Confirmed

When the Trading Partner POC is not confirmed, you will see an **Action Required** notification. Follow the steps below to resolve this issue:

Step 1. Click on the **Trading Partner Confirmation** tile to be redirected to your Activity log.

Step 2. Click the **Trading Partner POC | Not Confirmed** next to the notification icon.

Step 3. Review the **PDF Attachment** for directions on how to successfully re-confirm your Trading Partner Details.

The screenshot displays the FDA's DSCSA Portal interface. At the top, there is a search bar and a notification icon. Below the search bar, there are several notification tiles. The first tile, labeled '00161232', is highlighted with a red box and a '1' in a red circle. It shows the status 'Trading Partner POC | Not Confirmed' and includes a yellow 'Action Required' banner. To the right of this tile is another notification for '00161139' with a 'New Notification' banner. Below these tiles is an 'Event ID # 00161232' section containing an 'Activity Log' table. The table has columns for 'ACTIVITY', 'LAST UPDATED', and 'SENDER'. The first row is highlighted with a red box and a '2' in a red circle, showing 'Trading Partner POC | Not Confirmed' with a warning icon, updated on 12/10/2024 at 01:24 PM, sent by FDA. The second row shows 'Trading Partner Confirmation Submitted' updated on 12/10/2024 at 01:19 PM, sent by Erik Chen. Below the activity log is an 'FDA Notification' section for 'Request # 00161232'. It contains instructions for re-confirming the Trading Partner Details and a 'Download Attachment(s)' link for a PDF file named 'POC Not Confirmed-FDA CDER DIV NEUROLOGY PRODUCTS.pdf', which is highlighted with a red box and a '3' in a red circle.

FDA's DSCSA Portal

+ Trading Partner Confirmation

Search Submissions

1

00161232
Trading Partner POC | Not Confirmed
Last Modified: 12/10/2024, 01:24 PM
Applicant Organization: FDA CDER DIV NEUR...
Request Type: Trading Partner Information
Request ID Number: 37-Wholesale Distribut...

Action Required

00161139
Transitioned
Last Modified: 12/10/2024, 01:03 PM
Applicant Organization: FDA CDER DIV NEUR...
Request Type: Initial Submission
Request ID Number: 37-amgen-1

New Notification

00161153
Trading Partner POC | Confirmed
Last Modified: 12/10/2024, 12:57 PM
Applicant Organization: FDA CDER DIV NEUR...
Request Type: Trading Partner Information
Request ID Number: 37-amgen-2

New Notification

00151834
Request for Documentation
Last Modified: 08/19/2024, 09:17 AM

00160374
Submitted
Last Modified: 11/19/2024, 07:56 AM

00157202
Trading Partner POC | Confirmed
Last Modified: 10/20/2024, 06:17 PM

Event ID # 00161232

Activity Log
2 Items - Sorted by Date - Updated 0 days ago

ACTIVITY	LAST UPDATED	SENDER
Trading Partner POC Not Confirmed	12/10/2024, 01:24 PM	FDA
Trading Partner Confirmation Submitted	12/10/2024, 01:19 PM	Erik Chen

Go Back

FDA Notification

Request # 00161232

Trading Partner POC | Not Confirmed Instructions
Please review the attached Trading Partner POC Not Confirmed Instructions and re-confirm your Trading Partner Details by selecting "Re-Confirm" from the Actions dropdown in your activity log. Upon receipt of the re-confirmation, the FDA will continue reviewing your Trading Partner details. Please re-confirm your information at your earliest convenience.

3

Download Attachment(s):
POC Not Confirmed-FDA CDER DIV NEUROLOGY PRODUCTS.pdf

Go Back

POC Reconfirmation

Step 4. Navigate back to the **Activity Log** for the relevant Trading Partner POC entry.

Step 5. Click the **Actions** button to reveal a dropdown menu.

Step 6. Select the **Re-Confirm** option. This will allow you to edit your Trading Partner Confirmation information. Review steps 6 - 15 of [Confirm Trading Partner Details](#) to complete your submission.

4

Event ID # 00161232

Activity Log
2 Items - Sorted by Date - Updated 0 days ago

5

6

ACTIVITY	LAST UPDATED	SENDER
Trading Partner POC Not Confirmed	12/10/2024, (Name
Trading Partner Confirmation Submitted	12/10/2024, 01:19 PM	Erik Chen

Go Back

Request # 00136149

Activity Log
3 Items - Sorted by Date - Updated 0 days ago

Actions

ACTIVITY	LAST UPDATED	SENDER
Trading Partner Re-Confirmation Submitted	09/05/2023, 02:17 PM	Name
Trading Partner POC Not Confirmed	09/05/2023, 02:17 PM	FDA
Trading Partner Confirmation Submitted	09/05/2023, 01:48 PM	Name

Go Back

POC Confirmed

When the Trading Partner POC is confirmed, you will see a **New Notification** banner. Follow the steps below to view:

Step 1. To view a notification, click on the **Event ID** in the landing page to be redirected to the Activity Log.

Step 2. Click on the **Trading Partner Confirmation** tile to be redirected to the Activity log.

Step 3. Click the **Trading Partner POC | Confirmed** link.

Step 4. Review the **PDF Attachment** for instructions.

FDA's DSCSA Portal

Trading Partner Confirmation

Search Submissions

00159830
Transitioned

00161153
Submitted

00161139
Submitted

Action Required

New Notification

Event ID # 00161139

Activity Log

2 Items - Sorted by Date - Updated 1 days ago

ACTIVITY	LAST UPDATED	SENDER
Trading Partner POC Confirmed	12/09/2024, 08:09 PM	FDA
Trading Partner Confirmation Submitted	12/09/2024, 08:00 PM	Name

Go Back

FDA Notification

Request # 00161139

Trading Partner POC | Confirmed Instructions
Please review the attached Trading Partner POC Confirmed instructions.

Download Attachment(s):
POC Confirmed-FDA CDER DIV NEUROLOGY PRODUCTS.pdf

Go Back

Request for Documentation

FDA will request documentation by sending a **Request for Documentation** communication to the FDA's DSCSA Portal.

Step 1: To view a notification, click on the **Event ID** in the landing page to be redirected to the Activity Log.

The screenshot shows the FDA's DSCSA Portal interface. At the top, there is a blue header with the text "FDA's DSCSA Portal" and a button labeled "+ Trading Partner Confirmation". Below the header is a search bar with the text "Search Submissions" and a "Search" button. The main content area displays a list of submissions. The first submission, with Event ID [00161139](#), is titled "Request for Documentation" and has a warning icon (a yellow triangle with an exclamation mark) and the text "Action Required" below it. This submission is highlighted with an orange border and a red box containing the number "1". The second submission, with Event ID [00159830](#), is titled "Transitioned" and also has a warning icon and "Action Required" text. The third submission, with Event ID [00161153](#), is titled "Submitted" and does not have a warning icon. Each submission card includes the following information: Last Modified, Applicant Organization, Request Type, and Request ID Number.

 Please note the warning icon for Request for Documentation will disappear after you submit the Initial Submission.

Request for Documentation

Step 2: Click on the **Request for Documentation** link to view the notification from the FDA.

Step 3: Review the **PDF Attachment** for instructions.

Event ID # 00161139

Activity Log
5 Items - Sorted by Date - Updated 0 days ago

ACTIVITY	LAST UPDATED	SENDER
Request for Documentation	12/10/2024, 10:22 AM	FDA
Response to Information Request	12/10/2024, 07:42 AM	Erik Chen
Information Request	12/10/2024, 07:42 AM	FDA
Trading Partner POC Confirmed	12/09/2024, 08:09 PM	FDA
Trading Partner Confirmation Submitted	12/09/2024, 08:00 PM	Erik Chen

Go Back

FDA Notification

Request # 00161139

Request for Documentation
Please review the attached Request for Documentation instructions and complete your "Initial Submission" from the Actions dropdown in your activity log. Please submit your information in the next 3 business days.

Download Attachment(s):
[Request for Documentation-FDA CDER DIV NEUROLOGY PRODUCTS.pdf](#)

Go Back

Initial Submission

Once the **Request for Documentation** has been sent from the FDA, an **Initial Submission** should be submitted to the FDA.

Step 1: Click on the **Actions** Dropdown in the top right corner of the Activity Log page.

Step 2: **Initial Submission** and **General Correspondence** options will be displayed. Select **Initial Submission** to begin your submission.

Event ID # 00161139

Activity Log

5 Items - Sorted by Date - Updated 0 days ago

ACTIVITY	LAST UPDATED	
Request for Documentation	12/10/2024, 10:22 AM	FDA
Response to Information Request	12/10/2024, 07:42 AM	Erik Chen
Information Request	12/10/2024, 07:42 AM	FDA
Trading Partner POC Confirmed	12/09/2024, 08:09 PM	FDA
Trading Partner Confirmation Submitted	12/09/2024, 08:00 PM	Erik Chen

1 Actions

2 Initial Submission

General Correspondence



Please note that the Initial Submission option will not be displayed in the Actions Dropdown once the submission is saved as draft. **Initial Submission Draft** will be displayed in the Activity Log page.

Initial Submission (Continued)

Step 3: Review the information on the **Getting Started** page.

Step 4: Click **Next**.

The screenshot shows the FDA's DSCSA Portal interface. At the top, there is a navigation bar with the FDA logo, 'U.S. FOOD & DRUG ADMINISTRATION', and 'CDER NextGen Portal'. A 'Log Out' button is in the top right corner. Below the navigation bar is a blue header with the text 'FDA's DSCSA Portal'. The main content area is titled 'Introduction' and contains a 'Getting Started' section. This section is highlighted with a blue border and a blue box containing the number '3'. The 'Getting Started' section includes a welcome message and instructions to complete the following sections: 'Contact Details', 'Request Information', 'Upload Documents', and 'Review & Submit'. Each section has a brief description and a horizontal line indicating where to enter information. At the bottom right of the page, there is a blue box containing the number '4' and a 'Next' button.

Initial Submission (Continued)

Step 5: Select Trading Partner or Third-Party Representative under the **Trading Partner Information** Section.

Step 6: Profile, Organization and Facility Information will be displayed.

This information is prepopulated from your CDER NextGen Portal registration as well as your Trading Partner Confirmation submission.

Verify the data and click **Next**.

If you notice any errors in your information, please visit the [CDER NextGen Portal Help Center](#) to submit a ticket.

The screenshot shows the FDA's DSCSA Portal interface. The top navigation bar includes the FDA logo, 'U.S. FOOD & DRUG ADMINISTRATION', 'CDER NextGen Portal', and a 'Log Out' button. The main header is 'FDA's DSCSA Portal'. On the left, there is an 'APPLICATION BUILDER' sidebar with options: 'Contact Details', 'Request Information', 'Upload Documents', and 'Review & Submit'. Below this is a 'Need Help?' section with a link to the Help Center. The main content area is titled 'Contact Details' and contains a 'Trading Partner Information' section. A red box labeled '5' highlights this section, which includes a question: '*Are you submitting as a Trading Partner or Third-Party Representative?' with radio buttons for 'Trading Partner' and 'Third-Party Representative'. Below this is a 'Profile Information' section, highlighted by a red box labeled '6'. This section contains fields for: First Name (Erik), Last Name (Chen), Phone Number (+12023083102), Extension, Email Address (erica.chen@fda.hhs.gov), Country (United States), Organization Name (FDA CDER DIV NEUROLOGY PRODUCTS), Address Line 1 (10903 NEW HAMPSHIRE AVE), Address Line 2, City (SILVER SPRING), State/Province (MD), Zip Code (20993), Country (US), and DUNS Number (078749601). At the bottom, there is a 'Facility Information' section with fields for FEI (30G3750095), Drug Manufacturing Site Name (AMGEN INC.), and Drug Manufacturing Site Address (12000 PLANTSIDE DR, LOUISVILLE, KY, US, 40299-6305). A 'Next' button is visible at the bottom right of the form.

Initial Submission (Continued)

Step 7: Select the type of submission requested by the FDA in the Request Information communication. **Product Tracing Request** or **Verification Request**

Step 8: If **Product Tracing Request** is selected then select all that apply from the following options:

- Transaction Information
- Transaction Statement
- Transaction History
- Other

Step 9: If **Verification Request** is selected then select all that apply from the following options:

- Transaction Information
- Transaction Statement
- Transaction History
- Product Identifier Information
- Other

Request Information

Request Information

*What are you submitting?

Select One

Product Tracing Request

Verification Request

FDA's DSCSA Portal

Request Information

Request Information

*What are you submitting?

Product Tracing Request

*For the checkboxes: Please select all types of information that is included in this submission.

Transaction Information

Transaction Statement

Transaction History

Other

Previous Save and Close Next

FDA's DSCSA Portal

Request Information

Request Information

*What are you submitting?

Verification Request

*For the checkboxes: Please select all types of information that is included in this submission.

Transaction Information

Transaction Statement

Transaction History

Product Identifier Information

Other

Previous Save and Close Next

Initial Submission (Product Tracing Request)

Product Tracing Request – Transaction Information:

Step 1: Select **Product Tracing Request** and select **Transaction Information**.

Step 2: Select **Yes** if you are uploading an XML/JSON file(s) for your submission and proceed to Step 3 and then the **Upload Documents** page to upload your XML/JSON file(s). If you do not intend to upload an XML/JSON file, select **No** and proceed through Steps 3-29.

Step 3: Click **Continue** on the pop up that appears stating that the selections cannot be changed after clicking on Continue.

FDA's DSCSA Portal

APPLICATION BUILDER

- Contact Details
- Request Information**
- Upload Documents
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all your DSCSA related questions.

Request Information

Request Information

1 What are you submitting?
Product Tracing Request

* For the checkboxes: Please select all types of information that is included in this submission.

- Transaction Information
- Transaction Statement
- Transaction History
- Other

2 * Are you submitting Information in XML/JSON format?
 Yes
 No

Previous Save and Close Next

DSCSA Initial Submission

You are submitting an Initial Submission for DSCSA. Select Continue to proceed with the selected data and submission type. After selecting Continue you will not be able to change these selections. If a change is required or you do not intend to submit please delete the submission in the Review and Submit page and start a new Initial submission in your Activity Log. Select Cancel to return to the previous page.

3 Cancel Continue

Initial Submission (Product Tracing Request)

Step 4: In the Transaction Information section add the **Date of Transaction** and **Date of Shipment**.

Step 5: Click on the **Add Product** button to add a product and its associated information.

Transaction Information

Date of Transaction

* Date of Shipment

Note: Please add date of shipment even if same as date of transaction.

Product Information

+ Add Product

Selling Trading Partner

Business from whom ownership is being transferred

+ Add DUNS/Selling Trading Partner

Purchasing Trading Partner

Business to whom ownership is being transferred

+ Add DUNS/Purchasing Trading Partner

Transaction Statement

* Did you provide a Transaction Statement (TS) if you are selling trading partner or receive a TS if you are a purchasing trading partner?

Yes

No

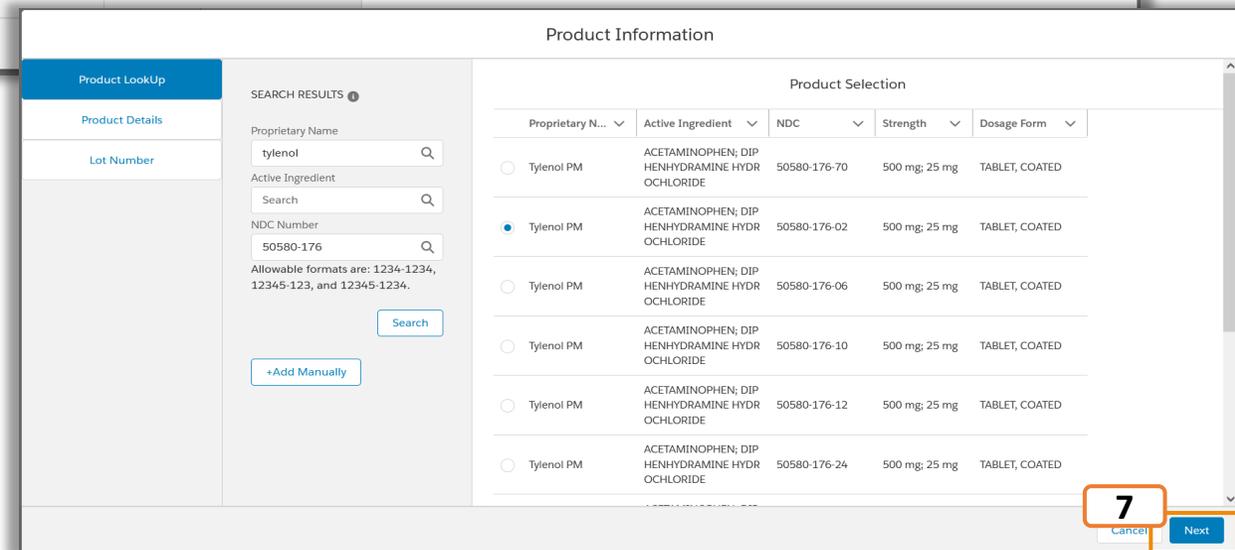
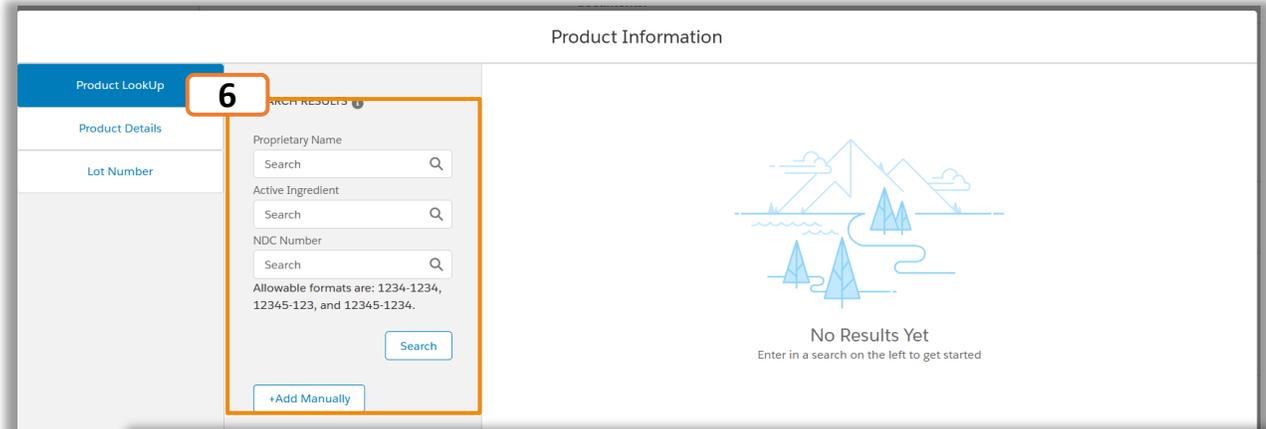
Previous Save and Close Next

 Please note only one product can be added at a time.

Initial Submission (Product Tracing Request)

Step 6: Search for a product by using **Proprietary Name, Active Ingredient** or **NDC Number**.

Step 7: Select the required product from the search results and click **Next**.

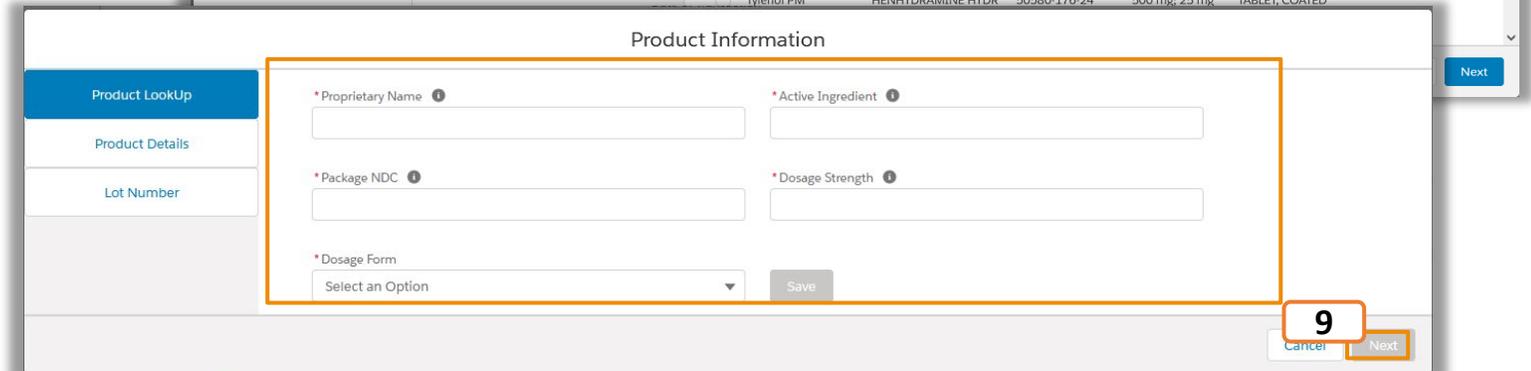
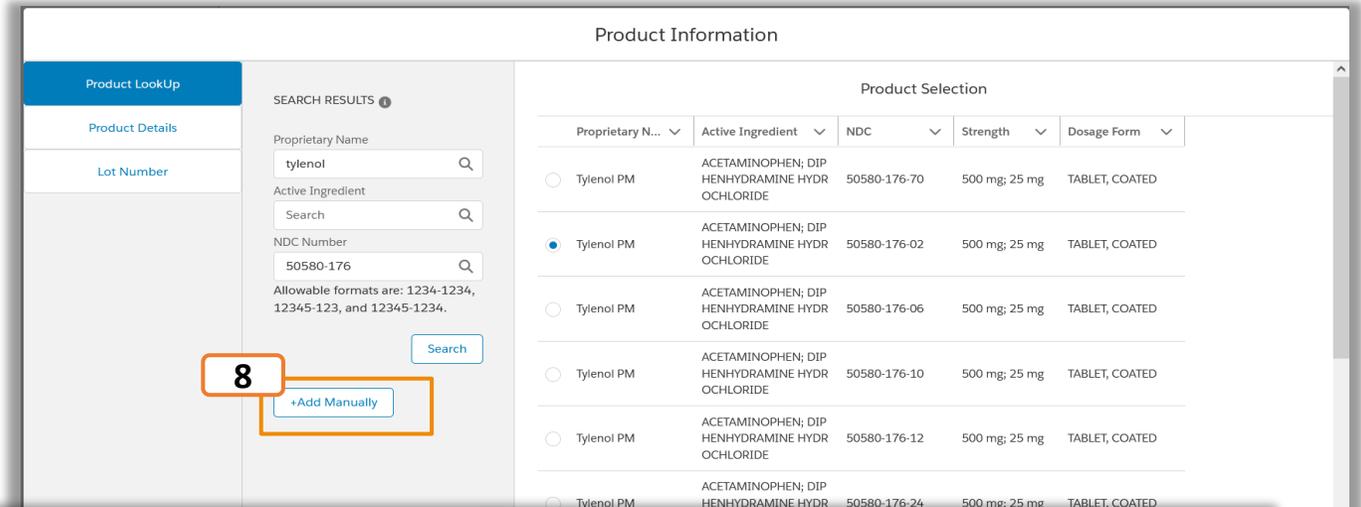


i Please note that the allowable search formats for your NDC search are: 1234-1234, 12345-123, and 12345-1234.

Initial Submission (Product Tracing Request)

Step 8: If your product is not displayed in the results, then click on the **Add Manually** button to add a product manually.

Step 9: Click **Next**.



Initial Submission (Product Tracing Request)

Step 10: Enter the relevant data in the Product Details page.

Step 11: Click **Save** and click **Next**.

Step 12: In the Lot Number section, upload a CSV file with lot and serial number(s). If unknown, select the checkbox.

Step 13: Click **Save**.

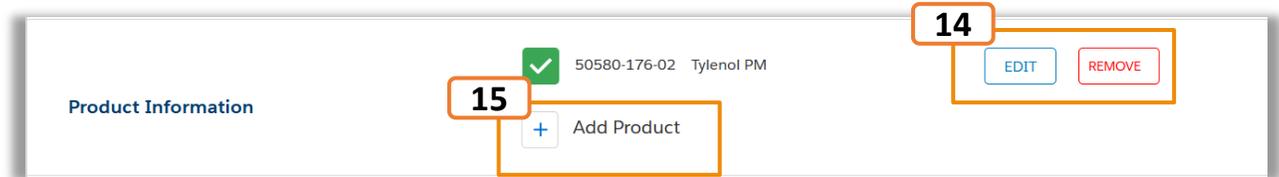
i Please note you can download the template and the instructions here:

- **Lot and Serial Number CSV Template.xlsx**
- **Lot and Serial Number CSV Template Instructions.pdf**

Initial Submission (Product Tracing Request)

Step 14: To edit or remove the added product, click the **Edit** or **Remove** buttons.

Step 15: To add multiple products, click the **Add Product** button again and follow steps 5-14.



Please note that it is optional to add a Product

Initial Submission (Product Tracing Request)

Step 16: Click on the **Add DUNS/Selling Trading Partner** button to add Selling Trading Partner or Purchasing Trading Partner.

Step 17: Search for an Organization with a 9-digit DUNS number and click on **Search**.

Step 18: Select the organization from the results and click on **Save**.

The screenshot displays the 'Add Organization Information' dialog box in the FDA DSCSA Portal. The dialog is titled 'Add Organization Information' and has a 'DUNS Look Up' section. In this section, the 'DUNS' field contains the number '123456789' and a 'Search' button is visible. Below the search field is a '+Add Manually' button. The search results are displayed in a table with two columns: 'Organization Name' and 'Address'. The table contains four entries: 'PKR PHARMA' (123 PKR STREET, PKR, 123456, NZ), 'ANGCHEN' (21031 VENTURA BLVD, WOODLAND HILLS, CA, 91364, US), 'TEST' (5100 CAMPUS DR, COLLEGE PARK, MD, 20740, US), and 'ESTABLISHMENT ONE' (5100 RIVER RD, COLLEGE PARK, MD, 20740, US). The 'ANGCHEN' entry is selected, indicated by a blue circle around its radio button. At the bottom right of the dialog, there is a 'Save' button.

16 Add DUNS/Selling Trading Partner

Add DUNS/Purchasing Trading Partner

17 DUNS 123456789 Search

+Add Manually

Organization Name	Address
<input type="radio"/> PKR PHARMA	123 PKR STREET , PKR, 123456, NZ
<input checked="" type="radio"/> ANGCHEN	21031 VENTURA BLVD , WOODLAND HILLS, CA, 91364, US
<input type="radio"/> TEST	5100 CAMPUS DR , COLLEGE PARK, MD, 20740, US
<input type="radio"/> ESTABLISHMENT ONE	5100 RIVER RD , COLLEGE PARK, MD, 20740, US

18 Save

Initial Submission (Product Tracing Request)

Step 19: If organization is not found, click on the **Add Manually** button to add an organization manually and click on **Save**.

Add Organization Information

DUNS Look Up

Organization Information

DUNS 123456789

Organization Name	Address
<input type="radio"/> PKR PHARMA	123 PKR STREET , PKR, 123456, NZ
<input checked="" type="radio"/> ANGCHEN	21031 VENTURA BLVD , WOODLAND HILLS, CA, 91364, US
<input type="radio"/> TEST	5100 CAMPUS DR , COLLEGE PARK, MD, 20740, US
<input type="radio"/> ESTABLISHMENT ONE	5100 RIVER RD , COLLEGE PARK, MD, 20740, US

Add Organization Information

DUNS Look Up

Organization Information

*Organization Name

*Country *Address Line 1

Address Line 2 *City

State/Province *Zip Code

Initial Submission (Product Tracing Request)

Step 20: To remove an added organization, click the **Remove** button.

Step 21: Select **Next** to go to **Upload Documents** page.

The screenshot displays a form with three sections: Product Information, Selling Trading Partner, and Purchasing Trading Partner. Each section has a green checkmark icon and a 'REMOVE' button. A blue 'EDIT' button is also present in the Product Information section. A blue '+ Add Product' button is located below the Product Information section. At the bottom of the form, there are 'Previous', 'Save', '21', and 'Next' buttons. An orange box highlights the 'REMOVE' buttons for the Selling Trading Partner and Purchasing Trading Partner sections, with a '20' in a box pointing to them. Another orange box highlights the 'Next' button at the bottom right, with a '21' in a box pointing to it.

Section	Item	Buttons
Product Information	50580-449-98 TYLENOL Extra Strength	EDIT, REMOVE
	+ Add Product	
Selling Trading Partner Business from whom ownership is being transferred	ANGCHEN	REMOVE
Purchasing Trading Partner Business to whom ownership is being transferred	PKR PHARMA	REMOVE

Navigation: Previous, Save, 21, Next

Initial Submission (Product Tracing Request)

Step 22: Click on the **Upload Files** button to upload any required documents.

Step 23: Click **Next** to go to the Review and Submit page.

Step 24: Review the information on the Review and Submit page and verify details entered.

Step 25: To update a section, click on the **Return to Section** button that takes you to the required page.

FDA's DSCSA Portal

APPLICATION BUILDER

- Contact Details
- Request Information
- Upload Documents**
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all your DSCSA related questions.

Upload Documents

For the following document types, upload files that are 45MB or less of the following types: pdf, doc, docx, xls,.xlsx, ppt, pptx. If the name is longer than 99 characters, it will be shortened automatically.

Document Type	Document Description	File Count
▼ *Upload Selected Files	Document Description	Files: 1
UPDATED_CSVCustomInstructionsForFinishedPackage 20241213.pdf	Enter description	

22 Upload Files Or drop files

Previous **23** Save and Close Next

FDA's DSCSA Portal

APPLICATION BUILDER

- Contact Details
- Request Information
- Upload Documents
- Review & Submit**

Need Help?
The [Help Center](#) is available to answer all your DSCSA related questions.

Review and Submit

Delete Save and Close Submit

Contact Details

Trading Partner Information

Are you submitting as a Trading Partner or Third-Party Representative?
Trading Partner

Profile Information

First Name Erik	Last Name Chen
Phone Number +12023083162	Extension
Email Address erica.chen@fda.hhs.gov	Country United States

Organization Information

Organization Name FDA CDER DIV NEUROLOGY PRODUCTS	Address Line 2
Address Line 1 10903 NEW HAMPSHIRE AVE	City/Providence MD
City SILVER SPRING	Country US
Zip Code 20993	
DIUNS Number 078749461	

Facility Information

FBI 3003750095	Drug Manufacturing Site Name AMGEN INC.	Drug Manufacturing Site Address 12000 PLANTSIDE DR, LOUISVILLE, KY, US, 40299-6305
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24 **25** Return to Section

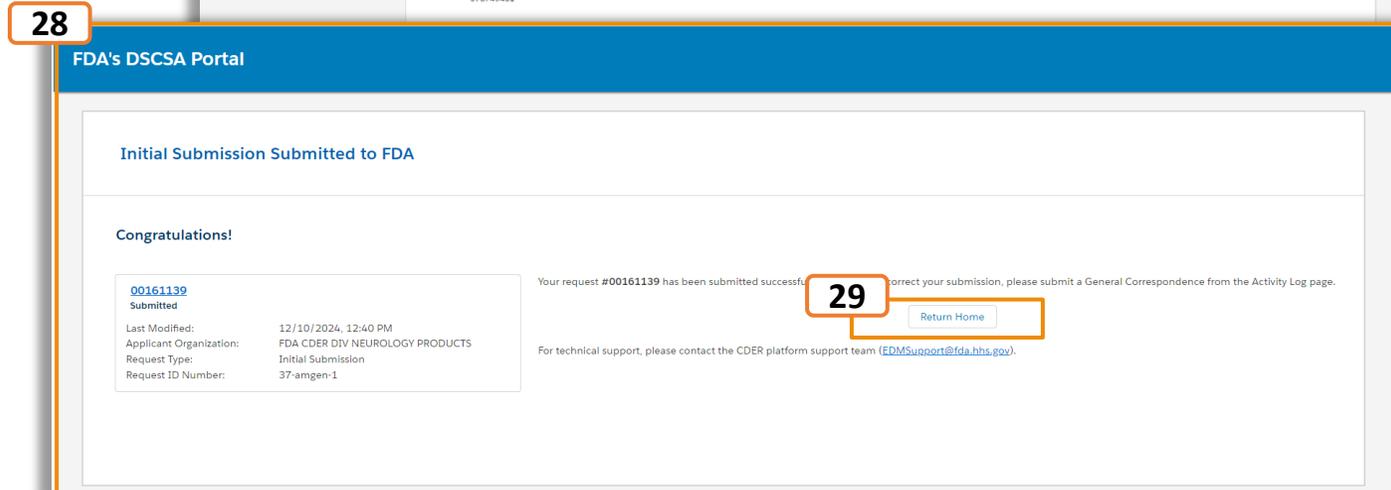
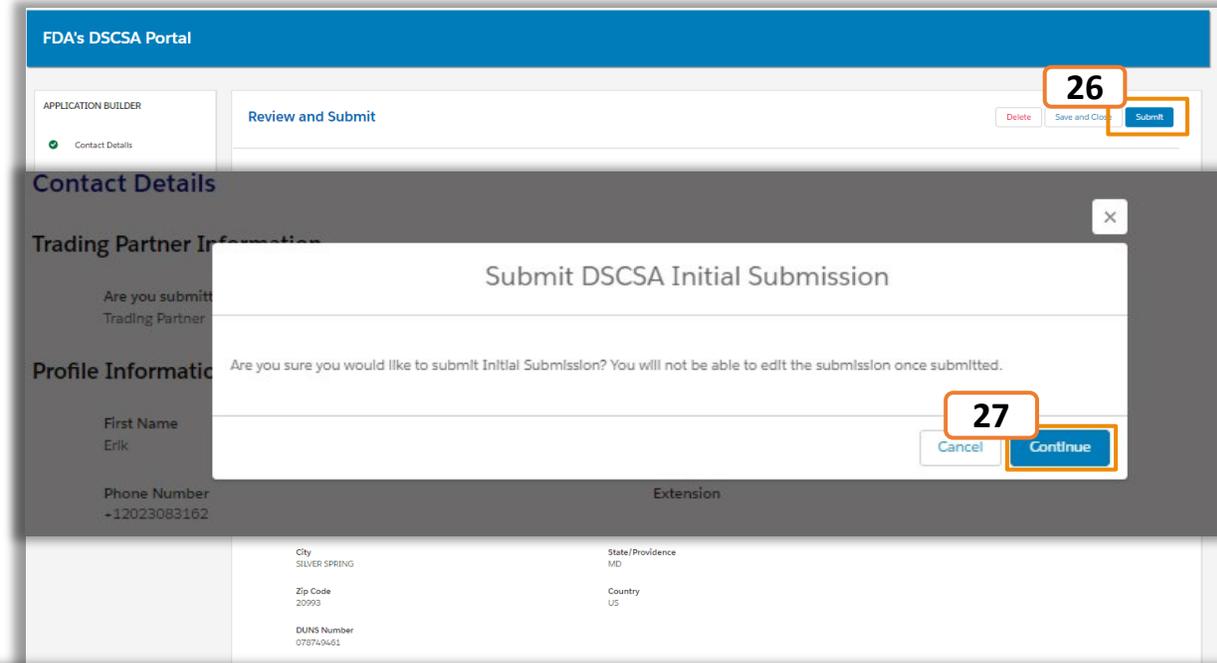
Initial Submission (Product Tracing Request)

Step 26: Click on the **Submit** button to submit your Initial Submission.

Step 27: Click **Continue** to confirm that you would like to proceed with your submission.

Step 28: Your submission confirmation page will be displayed with your Event ID.

Step 29: Click **Return to Home** to Navigate to the landing page.



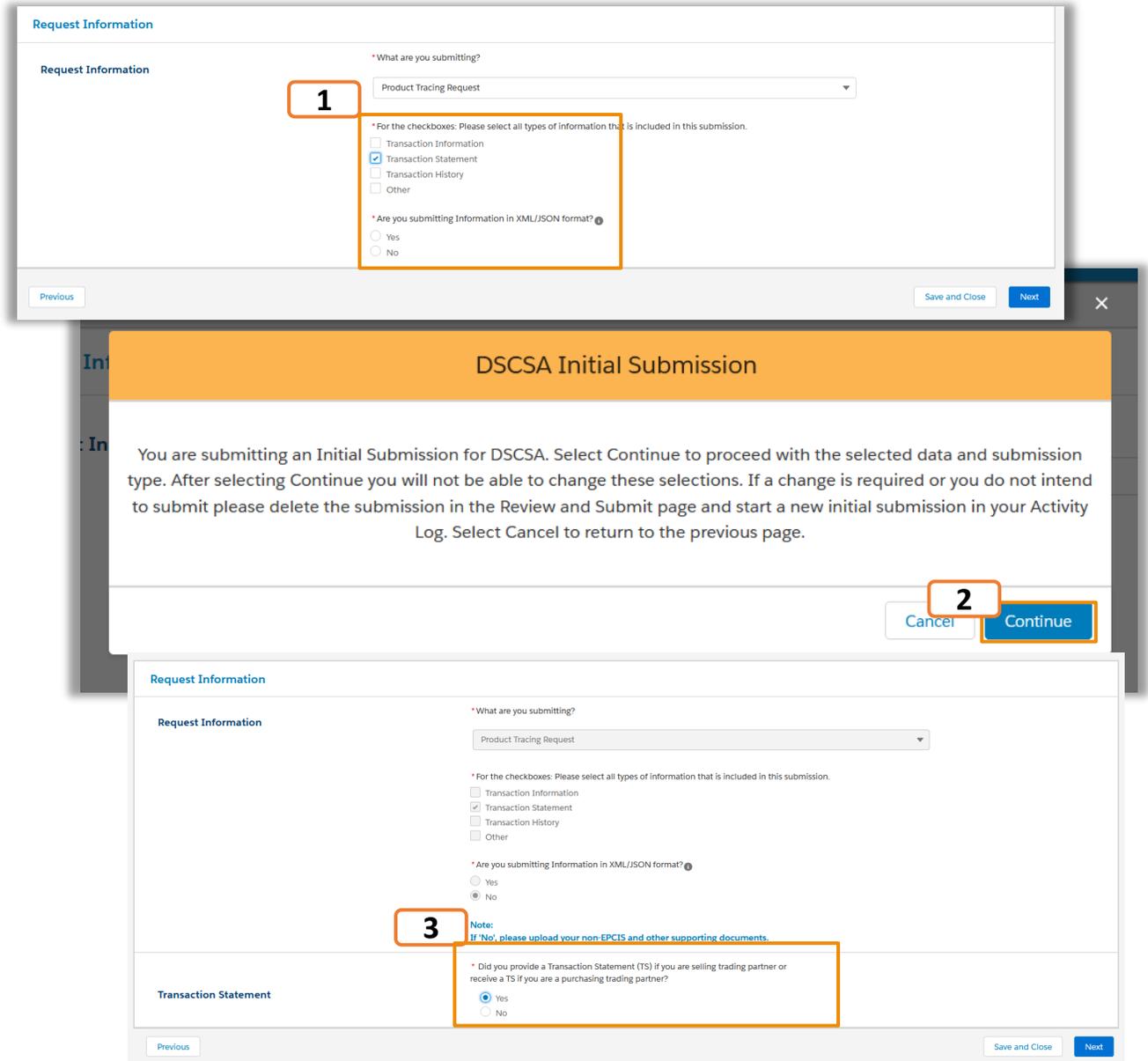
Initial Submission (Product Tracing Request)

Product Tracing Request – Transaction Statement:
If Transaction Statement is selected in the Request Information page, then follow the below steps to continue.

Step 1: Answer the additional question. If XML/JSON file is available, select **No**.

Step 2: Click Continue on the pop up that appears after selecting **Yes/No**.

Step 3: If **No** is selected, then answer the additional question “Did you provide a Transaction Statement (TS) if you are selling trading partner or receive a TS if you are a purchasing trading partner?:” with **Yes/No** and click **Next**.



Initial Submission (Product Tracing Request)

Step 4: Click on the **Upload Files** button to upload relevant documents.

Step 5: Click **Next** to navigate to Review and Submit page.

Step 6: Review the information on the Review and Submit page and verify details entered.

FDA's DSCSA Portal

APPLICATION BUILDER

- ✓ Contact Details
- ✓ Request Information
- **Upload Documents**
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all your DSCSA related questions.

Upload Documents

For the following document types, upload files that are 45MB or less of the following types: pdf, doc, docx, xls,xlsx, ppt, pptx. If the name is longer than 99 characters, it will be shortened automatically.

Document Type	Document Description	File Count
▼ * Upload Selected Files	Document Description	Files: 1
UPDATED_CSVCustomInstructionsForFinishedPackage 20241213.pdf	Enter description	

4 **Upload Files** Or drop files

5 **Next**

6 **Review and Submit**

Contact Details

Trading Partner Information

Are you submitting as a Trading Partner or Third-Party Representative?
Trading Partner

Profile Information

First Name Erik	Last Name Chen
Phone Number +12023083102	Extension
Email Address erica.chen@fda.hhs.gov	Country United States

Organization Information

Organization Name FDA CDER DIV NEUROLOGY PRODUCTS	Address Line 2
Address Line 1 10903 NEW HAMPSHIRE AVE	State/Province MD
City SILVER SPRING	Country US
Zip Code 20993	
DUNS Number 078749663	

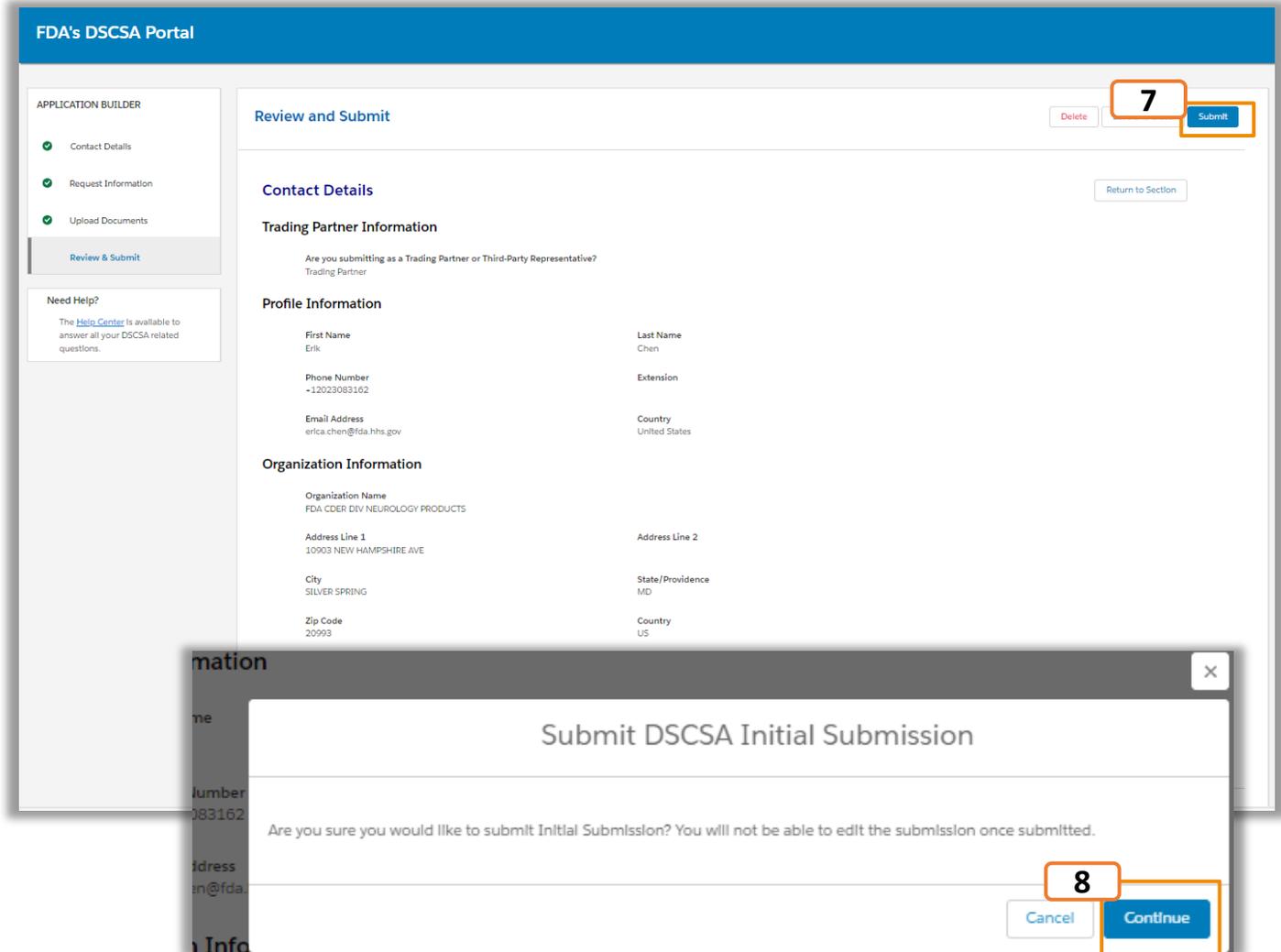
Facility Information

Facility - N/A

Initial Submission (Product Tracing Request)

Step 7: Click on the **Submit** button to submit your Initial Submission.

Step 8: Click **Continue** to confirm your submission. Once confirmed you will receive a confirmation email with your Event ID.

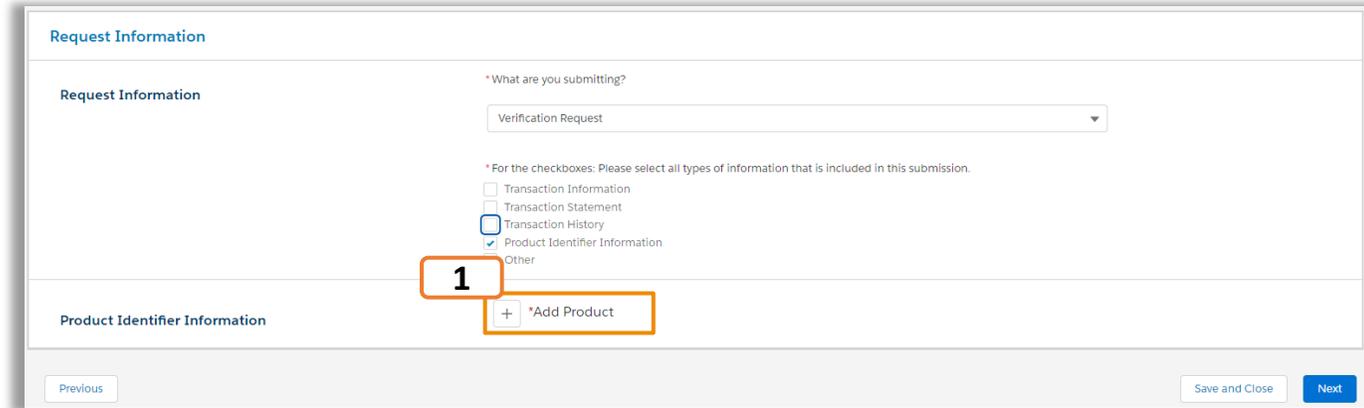


Initial Submission (Verification Request)

Verification Request - Product Identifier Verification:

If **Product Identifier Information** is selected in the Request Information page, then follow the below steps to continue.

Step 1: The Product Identifier Information section will be displayed. Click on the **Add Product** button to add Product Identifier Information.




Please note that depending on the information requested from the FDA you may need to also provide additional information for your verification request. Please refer to [page 22](#) for details on how to select your type of submission and applicable submission options.

- If you need to provide Transaction Information for your verification request, please refer to pages [23-33](#) and select “Verification Request” for your submission type.
- If you need to provide a Transaction Statement for your verification request, please refer to pages [34-36](#) and select “Verification Request” for your submission type.

Initial Submission (Verification Request)

Step 2: Enter the **NDC Number**, **Lot Number**, **Serial Number** and **Expiration Date** of the product that FDA has requested to verify.

Step 3: Select **Yes/No** to verify the Product Identifier Information.

Step 4: Select the applicable attributes of the product.

Product Identifier Information

Product Verification **2** Please indicate what product you are reporting on by entering the information provided by the FDA

* NDC **1**
1234-1234-12

* Lot Number
1234123412

* Serial Number
432132123

* Expiration Date **1**
12/10/2024

3 * Can you verify that the product identifier information provided by the FDA matches your product or product record(s)?
 Yes
 No

4 * Please select if any of these attributes apply to this product:
 Expired
 Expiration Extended
 Recalled
 Suspect
 Illegitimate
 None of the above apply

Please provide additional product details below: **1**

Cancel Save

Initial Submission (Verification Request)

Step 5: Add any additional information related to the product if needed.

Step 6: Click on **Save** to add the product.

Step 7: Confirm the product information displayed in the table one added.

Step 8: Select a product and click on the **Edit** or **Remove** buttons to edit or remove the product.

Step 9: To add multiple products, click on the **Add Product** button again and add as many product as needed.

Step 10: Click **Next** to navigate to the Upload document page.

Product Identifier Information

Product Verification

Please indicate what product you are reporting on by entering the information provided by the FDA

*NDC

*Lot Number

*Serial Number

*Expiration Date

*Can you verify that the product identifier information provided by the FDA matches your product or product record(s)?

Yes
 No

*Please select if any of these attributes apply to this product:

Expired
 Expiration Extended
 Recalled
 Suspect
 Illegitimate
 None of the above apply

5

6

Product Identifier Information

Verified	NDC	Expiration Date	Lot Number	Serial Number
<input type="checkbox"/> Yes	1234-1234-12	12/10/2024	1234123412	432132123

7

8

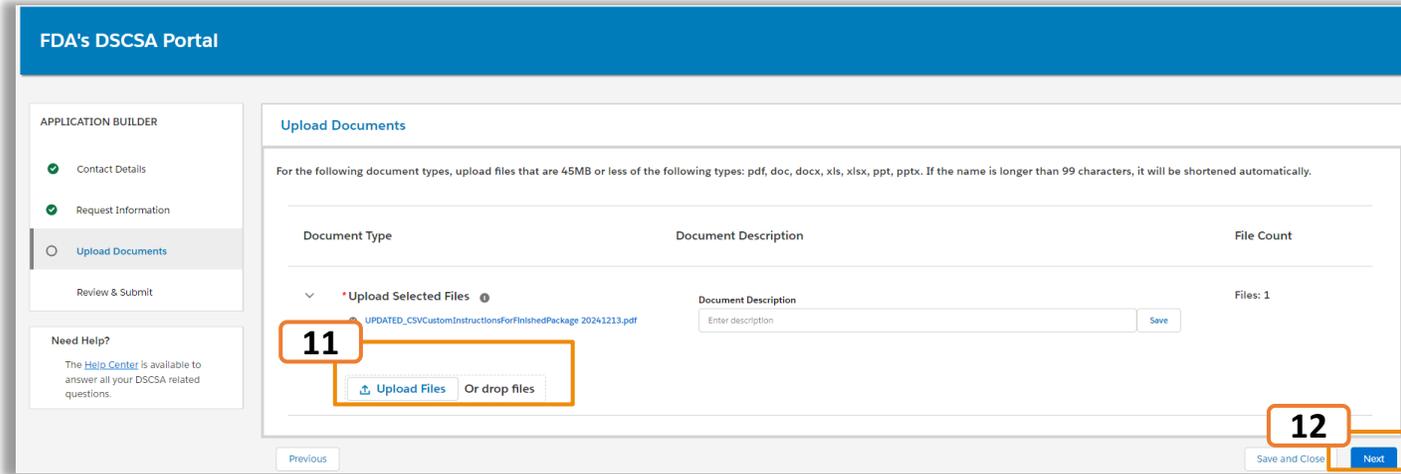
9

10

Initial Submission (Verification Request)

Step 11: Click on the **Upload Files** button to upload relevant documents.

Step 12: Click **Next** to navigate to Review and Submit page.



Initial Submission (Verification Request)

Step 13: Review the information on the Review and Submit page and verify details entered.

Step 14: Click on the **Submit** button to submit your Initial Submission.

Step 15: Click **Continue** to confirm your submission.

Initial Submission (Verification Request)

Step 16: The submission confirmation page will be displayed with your Event ID.

Step 17: Click **Return to Home** to Navigate to the landing page.

16

FDA's DSCSA Portal

Initial Submission Submitted to FDA

Congratulations!

[00161139](#)
Submitted

Last Modified:	12/10/2024, 12:40 PM
Applicant Organization:	FDA CDER DIV NEUROLOGY PRODUCTS
Request Type:	Initial Submission
Request ID Number:	37-amgen-1

Your request #00161139 has been submitted successfully. To change or correct your submission, please submit a General Correspondence from the Activity Log page.

17 [Return Home](#)

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

Submitting XML/JSON Files

XML/JSON File Upload

You may need to upload XML/JSON file(s) to support a Product Tracing and Verification Request from FDA.

Step 1: Select if you are submitting information related to a Product Tracing or Verification Request and select the all types of information that will be included in the submission.

Step 2: Select **Yes** for the question “Are you submitting in XML/JSON format?”

Step 3: Click **Continue** on the pop up that appears after selecting Yes/No stating that the selections cannot be changed once selected.

Step 4: Click **Next** to navigate to the upload documents page.

Submitting XML/JSON Files

Step 5: Click on the **Upload Files** button to upload a file in XML/JSON format. To upload multiple files, click the **Upload Files** button again and upload as needed.

Step 6: Click **Next** to navigate to Review and Submit page.

Step 7: Review the information and verify details entered.

Step 8: Click on the **Submit** button to submit your Initial Submission.

Upload Documents

For the following document types, upload files that are 45MB or less of the following types: pdf, doc, docx, xls, xlsx, ppt, pptx. If the name is longer than 99 characters, it will be shortened automatically.

Document Type	Document Description	File Count
▼ *Upload Files in XML/JSON ⓘ		Files: 0

5 [Upload Files](#) Or drop files

6 [Next](#)

FDA's DSCSA Portal

7

8 [Submit](#)

APPLICATION BUILDER

- Contact Details
- Request Information
- Upload Documents
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all your DSCSA related questions.

Review and Submit

Contact Details

Trading Partner Information

Are you submitting as a Trading Partner or Third-Party Representative?
Trading Partner

Profile Information

First Name: Erik
Last Name: Chen
Phone Number: +12023053162
Extension:
Email Address: erica.chen@fda.hhs.gov
Country: United States

Organization Information

Organization Name: FDA CDER DIV NEUROLOGY PRODUCTS
Address Line 1: 10903 NEW HAMPSHIRE AVE
Address Line 2:
City: SILVER SPRING
State/Province: MD
Zip Code: 20993
Country: US
DUNS Number: 07874963

Facility Information

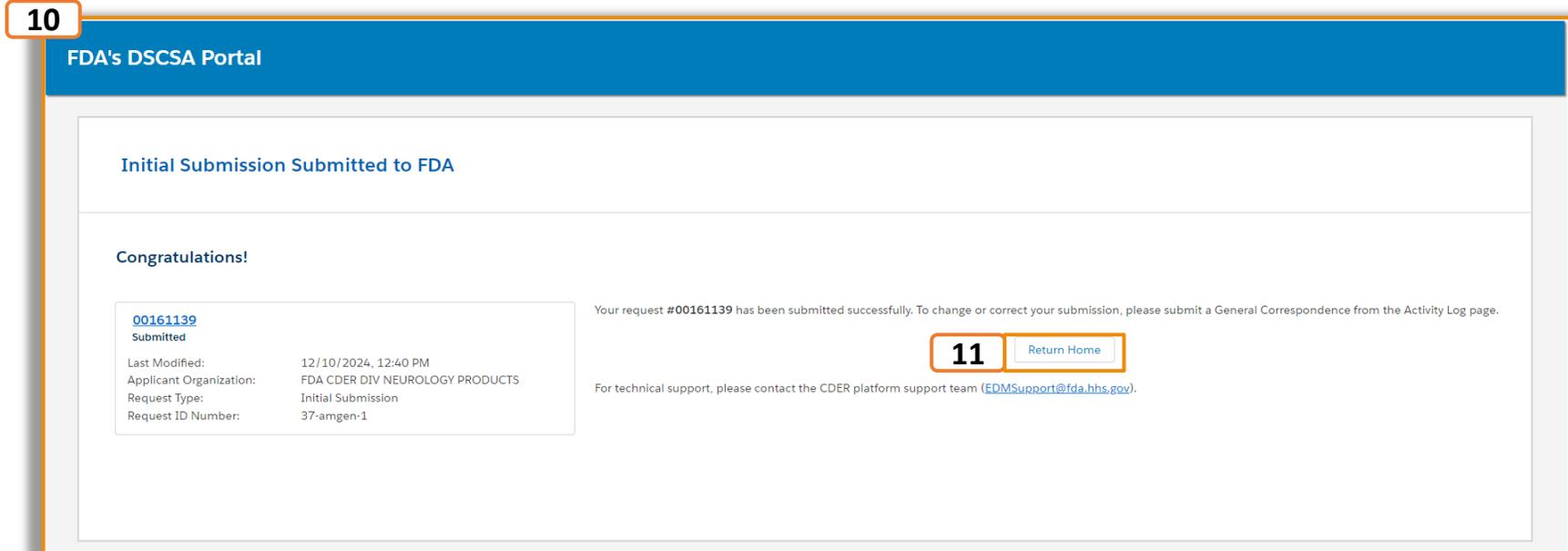
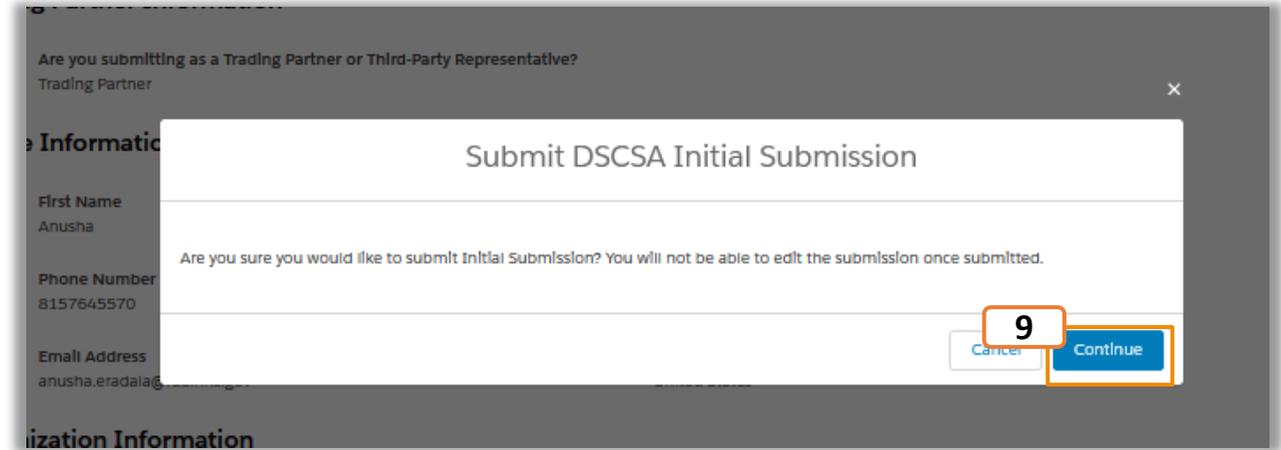
Facility - N/A

Submitting XML/JSON Files

Step 9: Click **Continue** to confirm your submission.

Step 10: The submission confirmation page will be displayed with the same Event ID.

Step 11: Click **Return to Home** to navigate to the landing page.



Submitting XML/JSON Files

Step 12: Once the XML/JSON file is processed successfully, you will receive a confirmation email shortly after with your unique Event ID.

Step 13: If you receive a parsing error email, please check the recommendations for the file format as provided by the following resources:

- [PDG](#)
- [GS1](#)
- Once you have corrected your file, please upload in the JSON/XML file upload section.
- If you continue to have issues, please visit the [CDER NextGen Portal Help Center](#) to submit a ticket.

12

FDA Message - Confirmation of Initial Submission of Documentation - Event ID: 00161139

 DoNotReply@fda.hhs.gov
To: Chen, Erik *

  Reply  Reply All  Forward  

Tue 12/10/2024 12:41 PM

 **FDA U.S. FOOD & DRUG ADMINISTRATION** DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD, 20993

Thank you for submitting documentation in response to FDA's Initial Submission Request. Please keep your Event ID for your records. You can log in to [FDA's DSCSA Portal](#) to review your submission.

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. All correspondence on this issue should be initiated from the FDA DSCSA Portal through General Correspondence from the Actions dropdown menu on the Activity Log page. ****

Transition From DSCSA Portal

FDA may transition a DSCSA Event to the 3911 Platform by sending a **Transition from DSCSA Portal** communication to the FDA's DSCSA Portal. Once this communication is sent, it will appear with a **New Notification** banner on the Home Screen.

Step 1. To view a notification, click on the **Event ID** in the landing page to be redirected to the Activity Log.

Step 2. Click on the **Transitioned** tile to be redirected to the Activity log.

Step 3. Click the **Transition from DSCSA Portal** link.

Step 4. Review the PDF Attachment for instructions.

The screenshot displays the FDA's DSCSA Portal interface. At the top, there is a search bar and a notification for 'Trading Partner Confirmation'. Below this, three event tiles are shown. The middle tile, labeled '00161139' and 'Transitioned', is highlighted with a red box and a '1' in a red circle. A red line connects this tile to a 'New Notification' banner, which is also highlighted with a red box and a '2' in a red circle. Below the banner, the 'Event ID # 00161139' is displayed. An 'Activity Log' section follows, showing a table with 7 items. The first row, 'Transition from DSCSA Portal', is highlighted with a red box and a '3' in a red circle. Below the table, an 'FDA Notification' section is shown for 'Request # 00161139'. It contains a message about the transition and a 'Download Attachment(s)' link, which is highlighted with a red box and a '4' in a red circle. The attachment is 'Transition from DSCSA Portal to 3911 Platform-FDA CDER DIV NEUROLOGY PRODUCTS.pdf'. A 'Go Back' button is visible at the bottom left.

ACTIVITY	LAST UPDATED	SENDER
Transition from DSCSA Portal	12/10/2024, 01:03 PM	FDA
Initial Submission Submitted	12/10/2024, 12:40 PM	Erik Chen
Request for Documentation	12/10/2024, 12:40 PM	FDA
Response to Information Request	12/10/2024, 07:42 AM	Erik Chen
Information Request	12/10/2024, 07:42 AM	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](#) to submit a ticket.

Learn More Information

Everything related to the portal events can be found on the “**Learn More**” link. On the event 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 events on the portal.