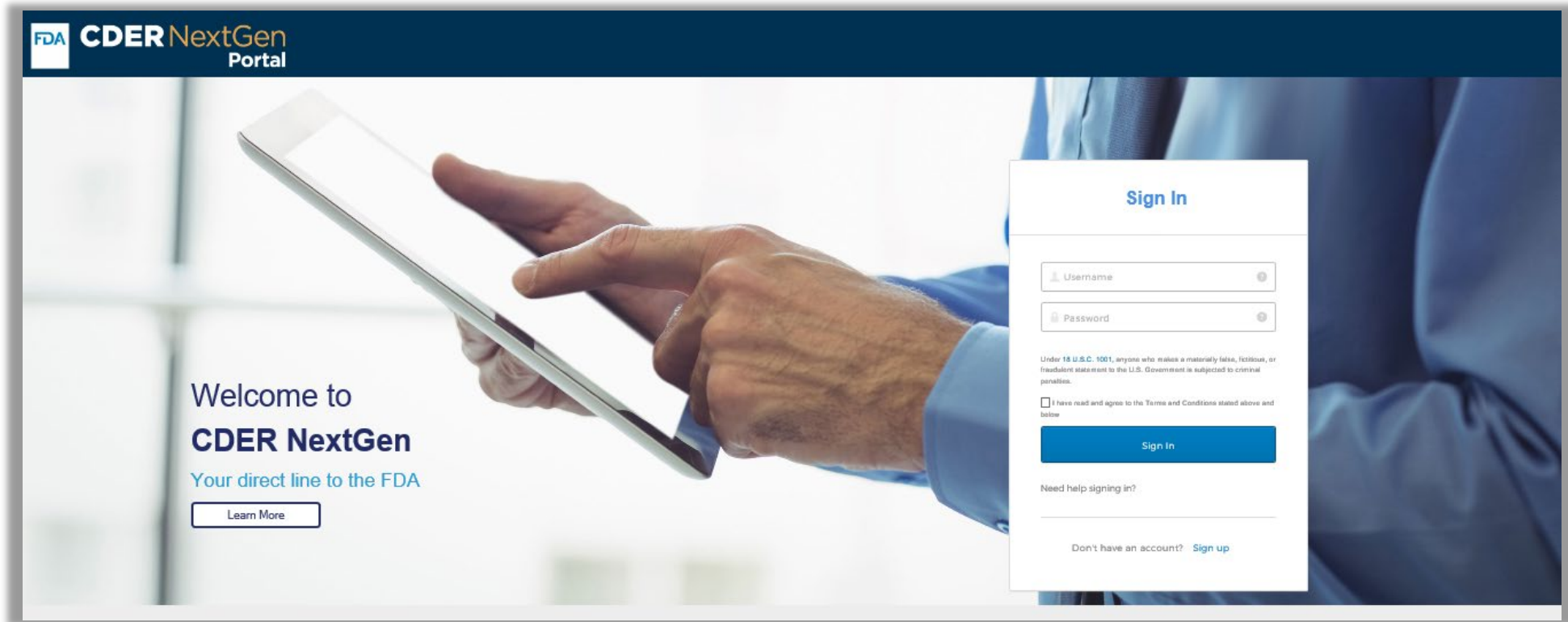# FDA's DSCSA Portal
Reference Guide

Click here to access the CDER NextGen Portal.

Click here to email the DSCSA Portal Team.

# Table of Contents

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

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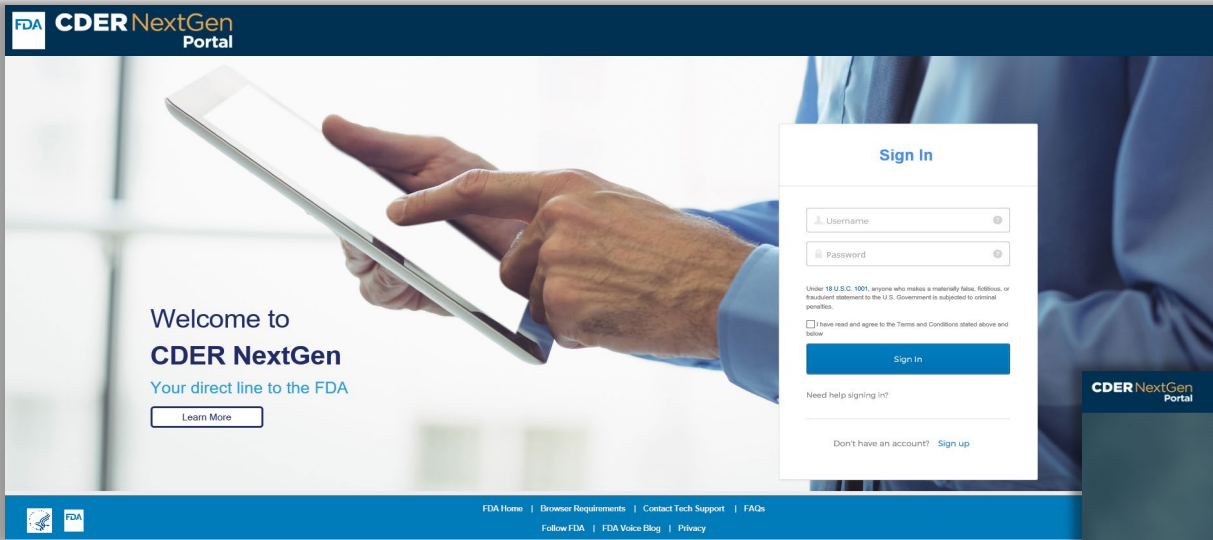
Step 1. After you land on the CDER NextGen Portal homepage, scroll down and click **FDA's DSCSA Portal** to begin. You will be directed to your DSCSA Portal landing page.
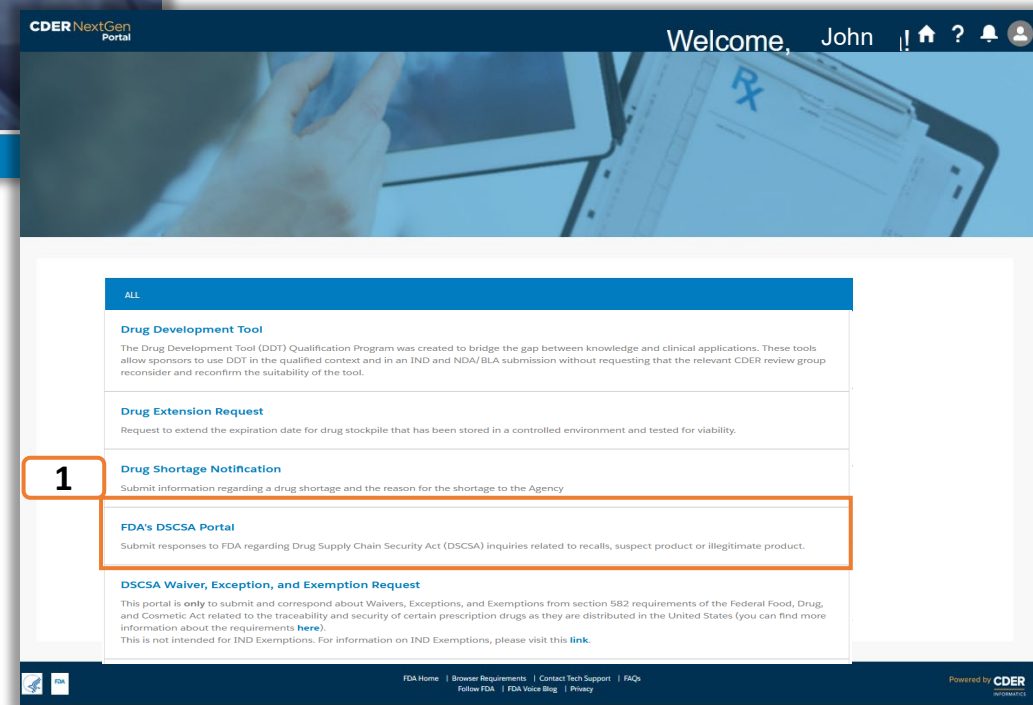
FDA's DSCSA Portal

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.

FDA's DSCSA Portal

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.

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.

ⓘ 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.

FDA's DSCSA Portal

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.

FDA's DSCSA Portal
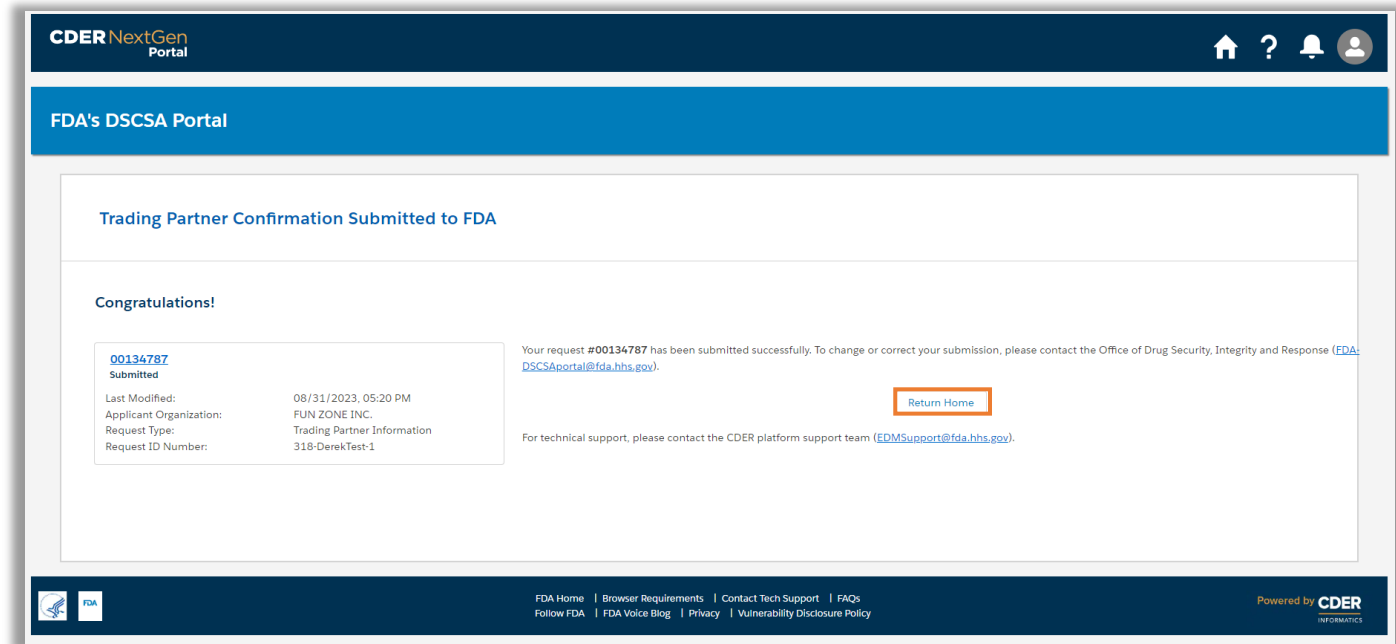
Receiving Confirmation(s) from FDA

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** .

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

FDA's DSCSA Portal

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.**
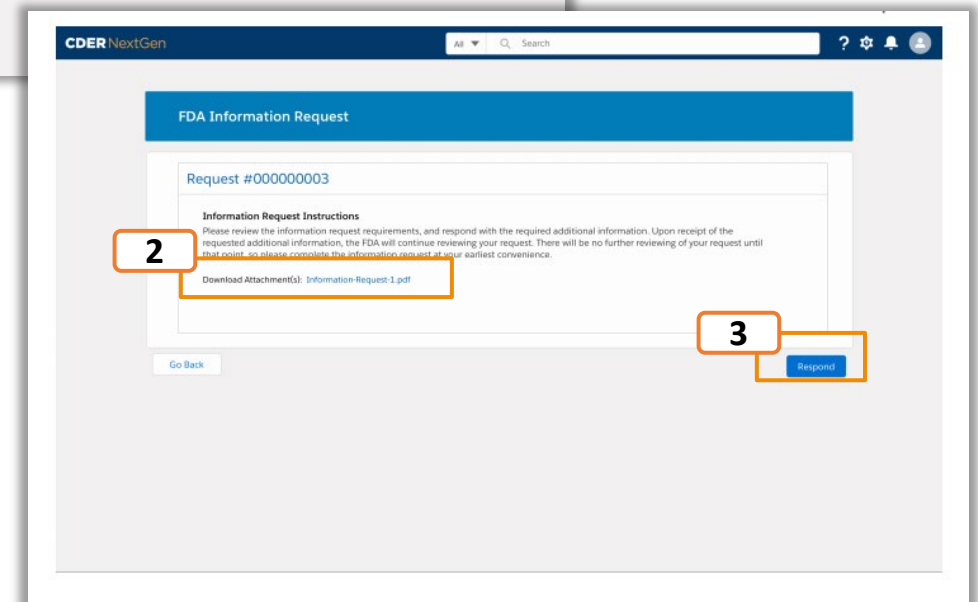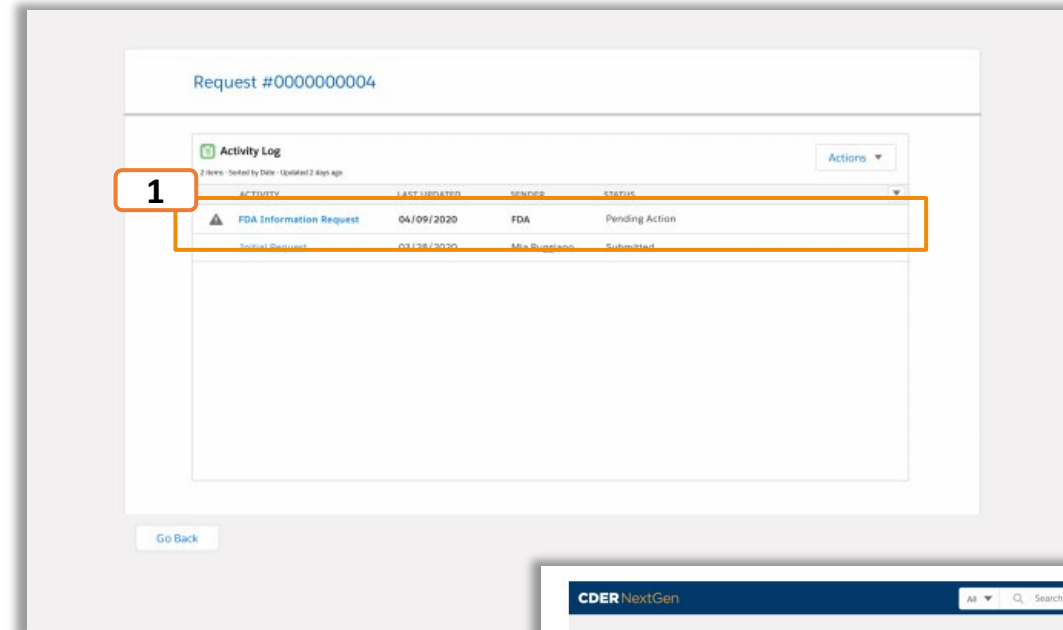
FDA Information Request

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**.

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.

FDA's DSCSA Portal
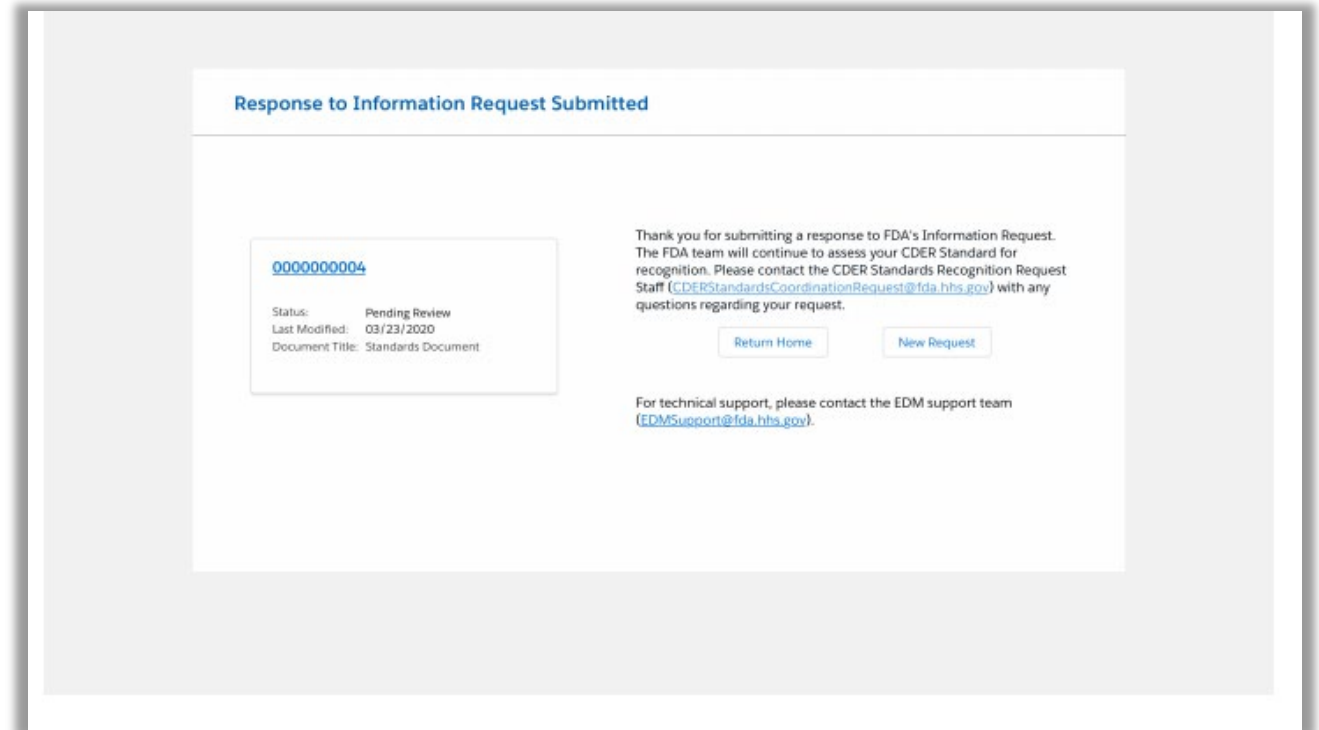
POC Not Confirmed

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.

FDA's DSCSA Portal

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.

FDA's DSCSA Portal

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.
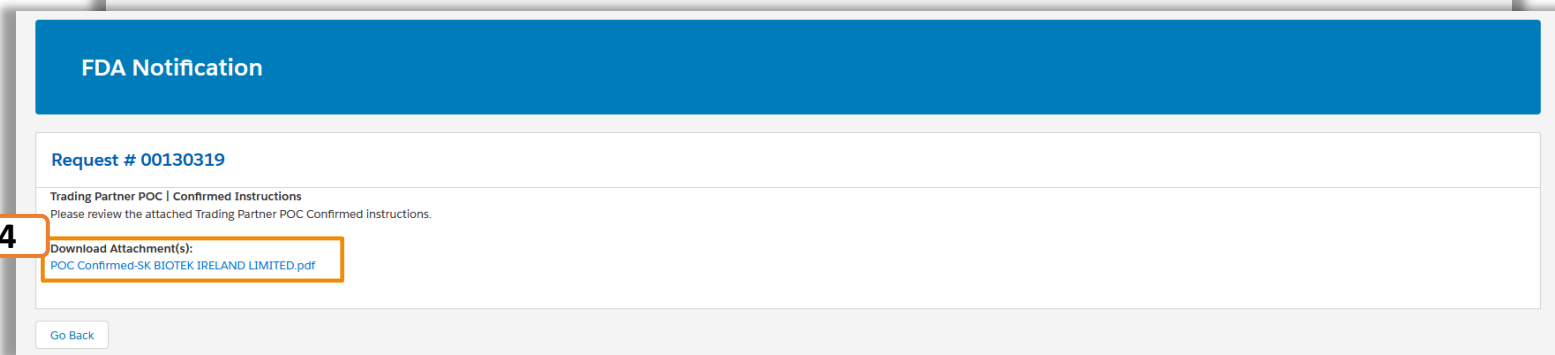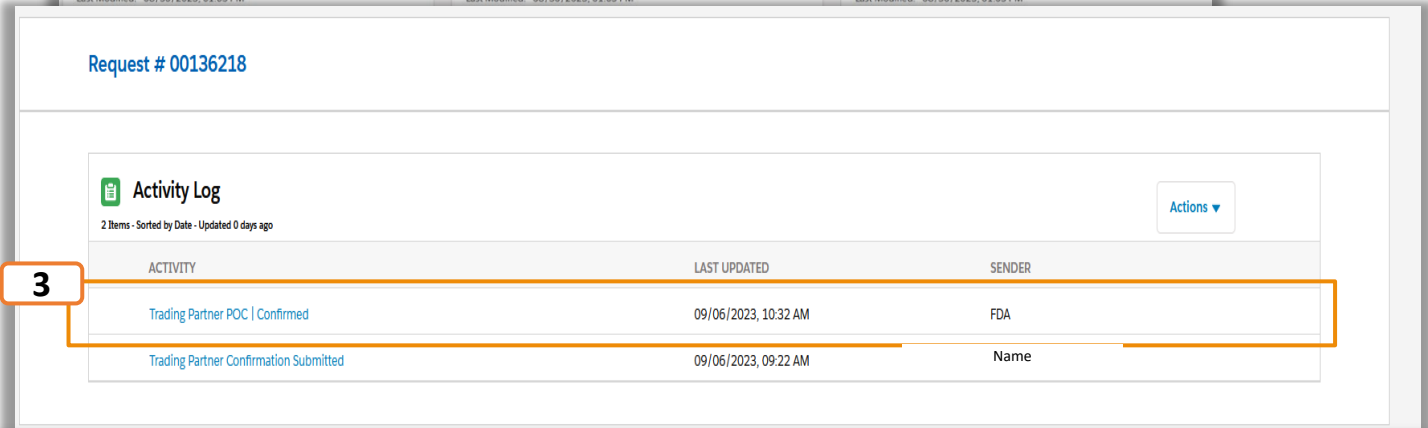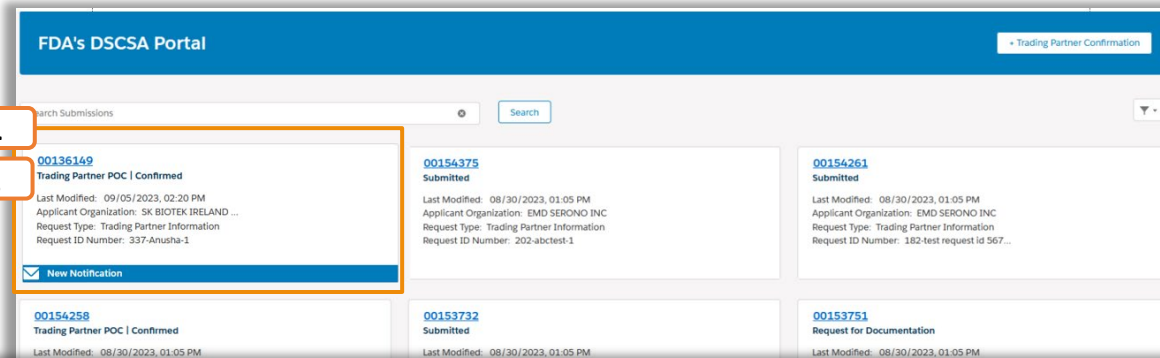
FDA's DSCSA Portal

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.

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

FDA's DSCSA Portal

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.

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.

Request # 00130318

Activity Log

5 Items - Sorted by Date - Updated 65 days ago

ACTIVITY	LAST UPDATED	SENDER
⚠ Request for Documentation	06/28/2023, 05:41 PM	FDA
Request For Documentation	06/28/2023, 12:22 PM	FDA
Trading Partner Re-Confirmation Submitted	06/22/2023, 10:57 AM	Name
Trading Partner POC | Not Confirmed	06/22/2023, 10:57 AM	FDA
Trading Partner Confirmation Submitted	06/21/2023, 03:43 PM	Name

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.

FDA's DSCSA Portal

Initial Submission (Continued)

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

Step 4: Click **Next.**
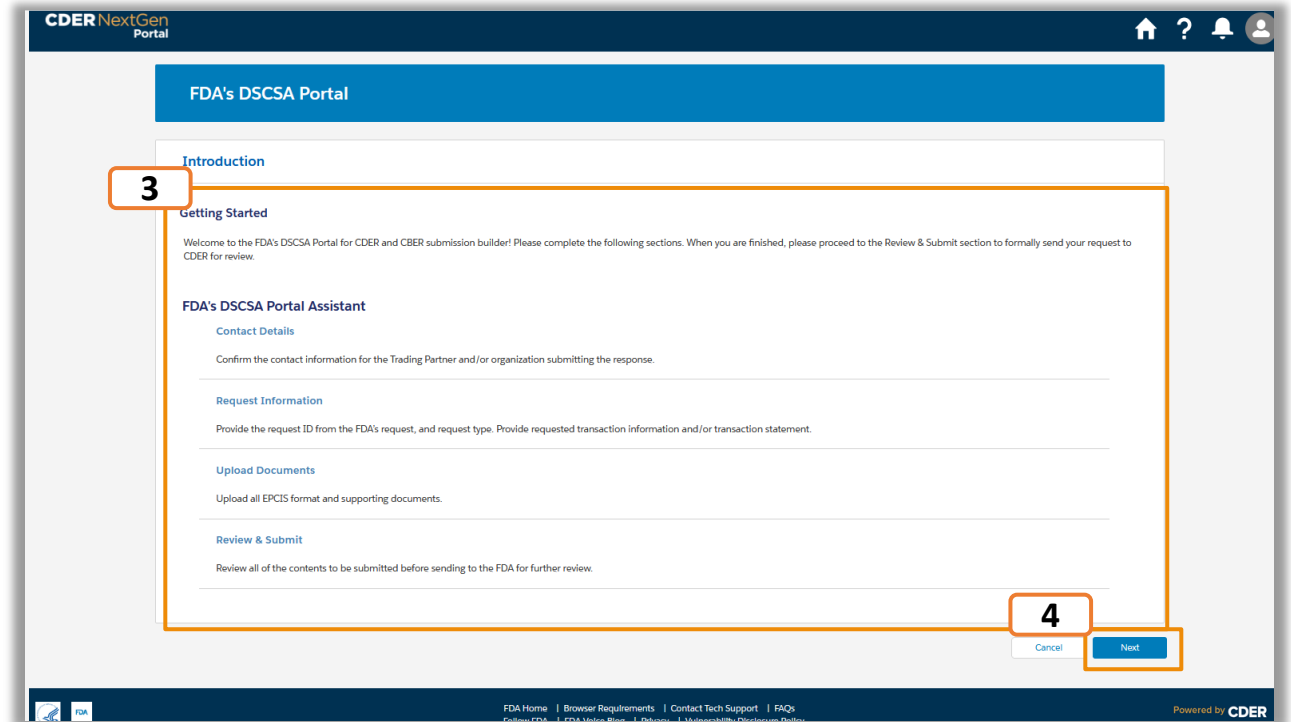
Initial Submission (Continued)

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 reach out to EDMSupport@fda.hhs.gov.
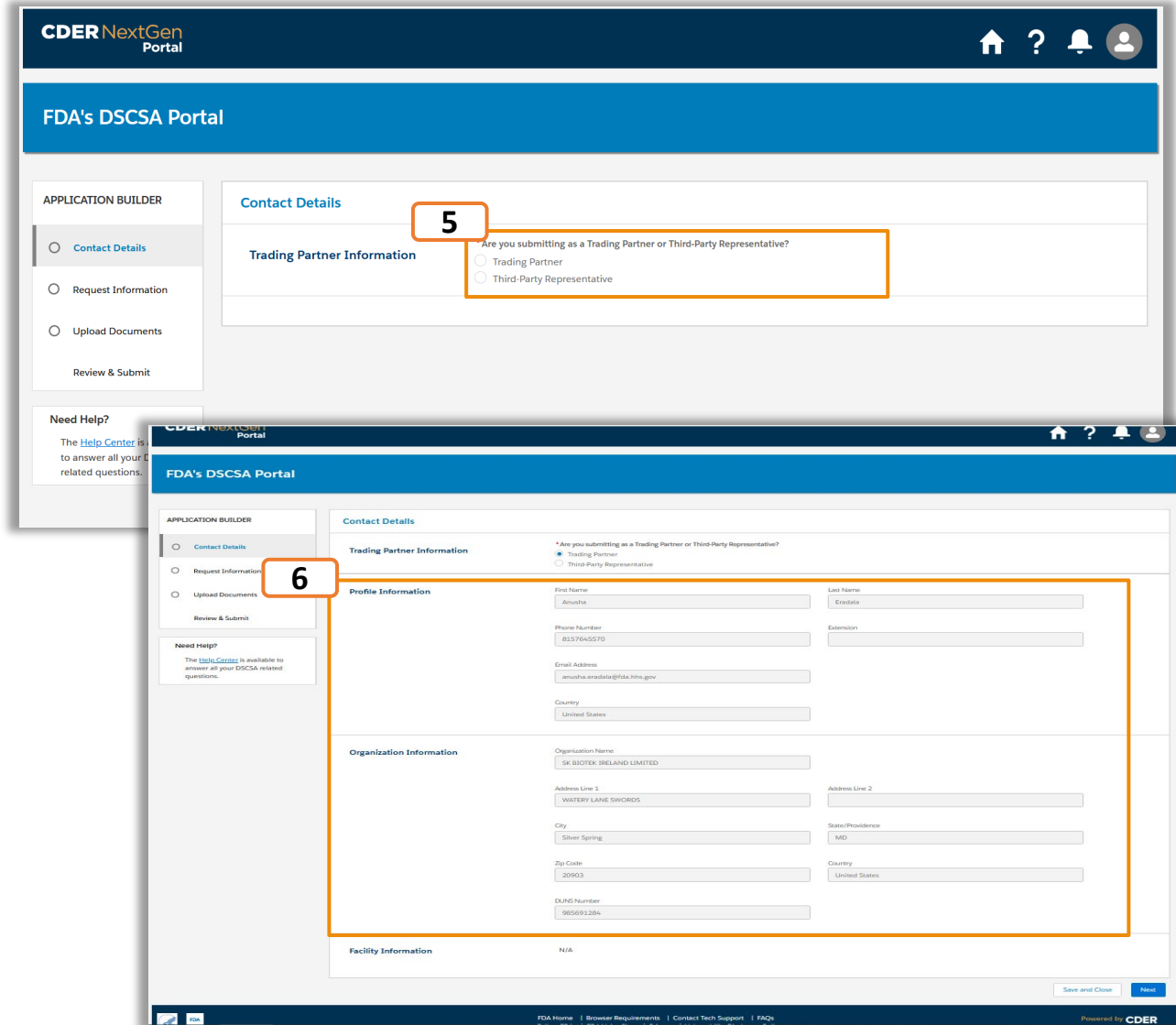
Initial Submission (Continued)

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

FDA's DSCSA Portal

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.

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.

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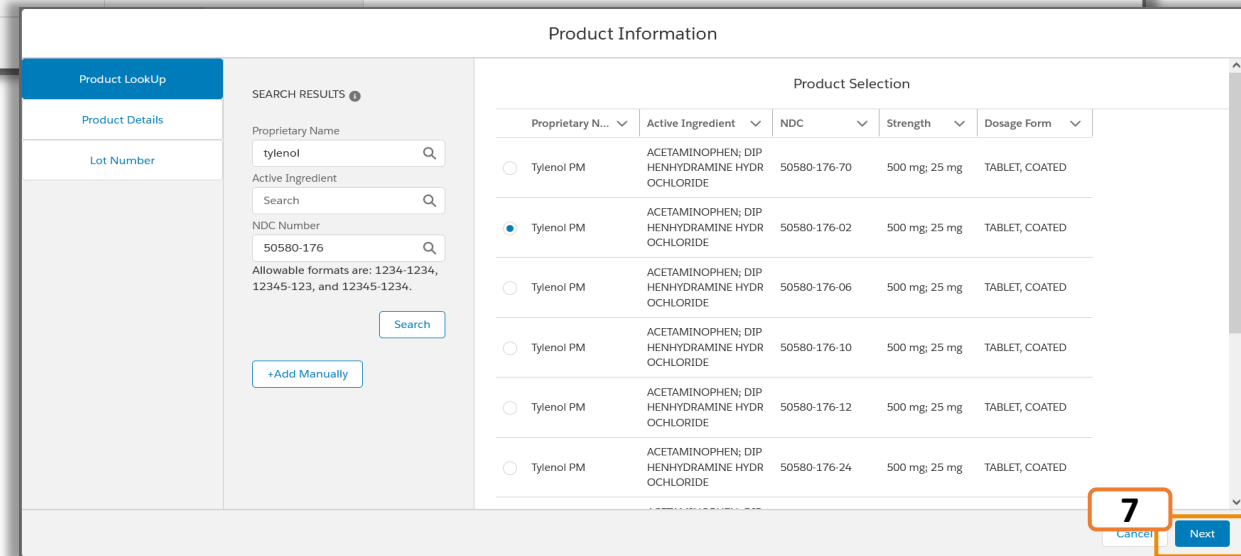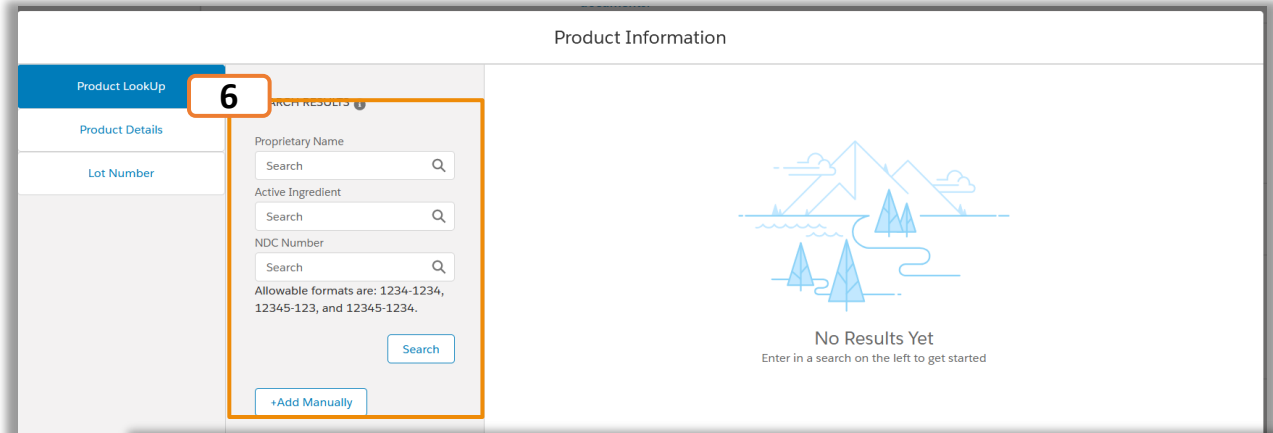
Please note that the allowable search formats for your NDC search are: 1234-1234, 12345-123, and 12345-1234.

FDA's DSCSA Portal

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**.
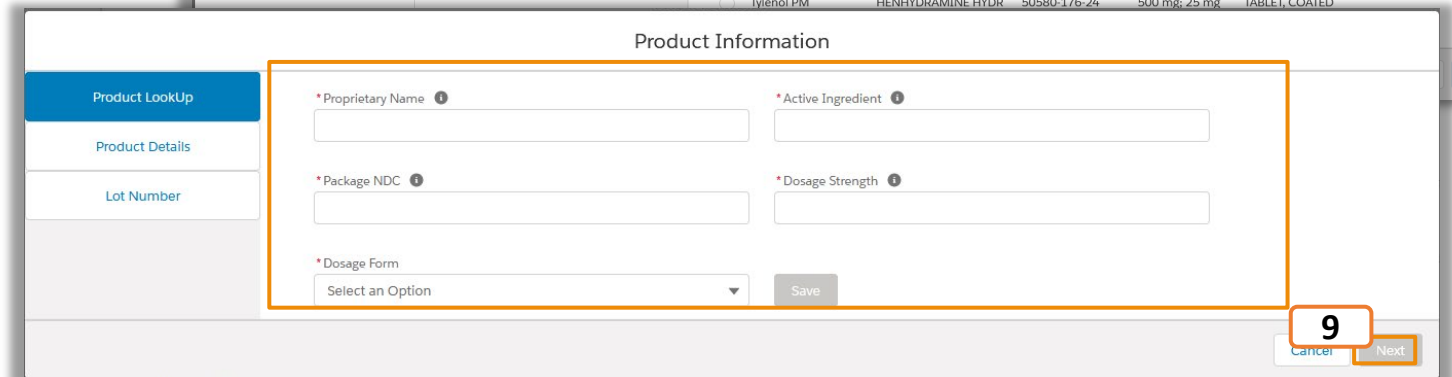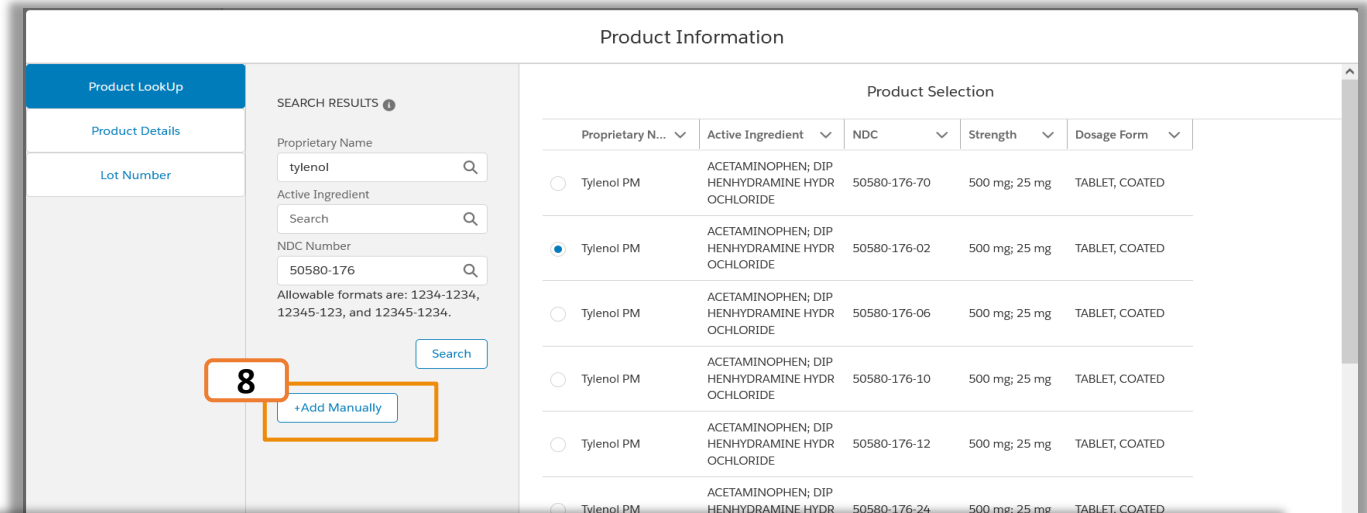
Initial Submission (Product Tracing Request)

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**.

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.
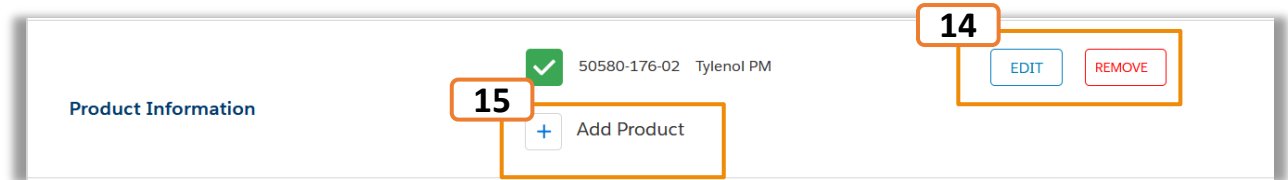
ℹ️ Please note that it is optional to add a Product

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**.

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**.

Initial Submission (Product Tracing Request)

Step 20: To edit or remove the added organization, click the **Edit** or **Remove** buttons.

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

FDA's DSCSA Portal
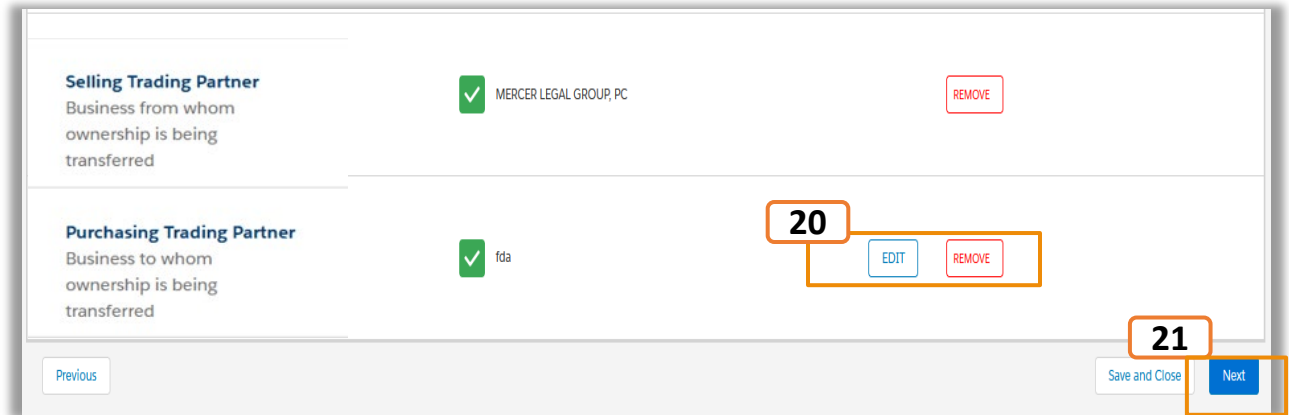
Initial Submission (Product Tracing Request)

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
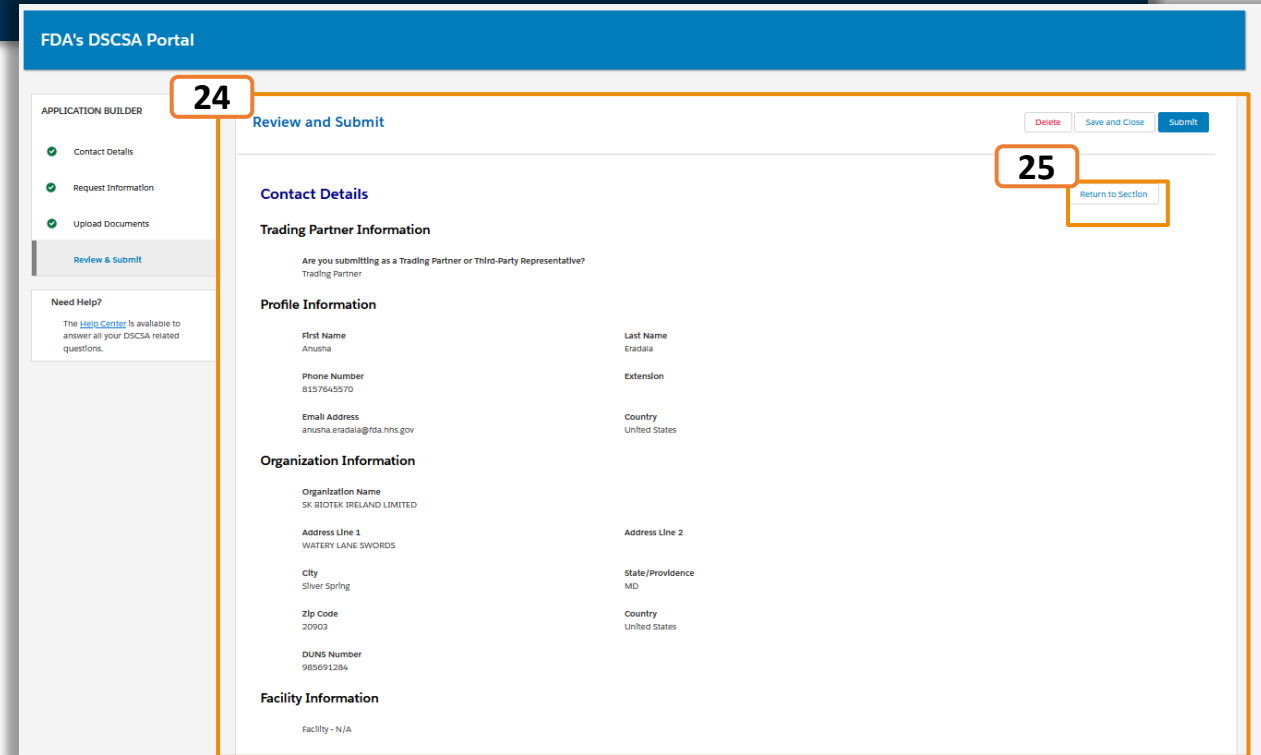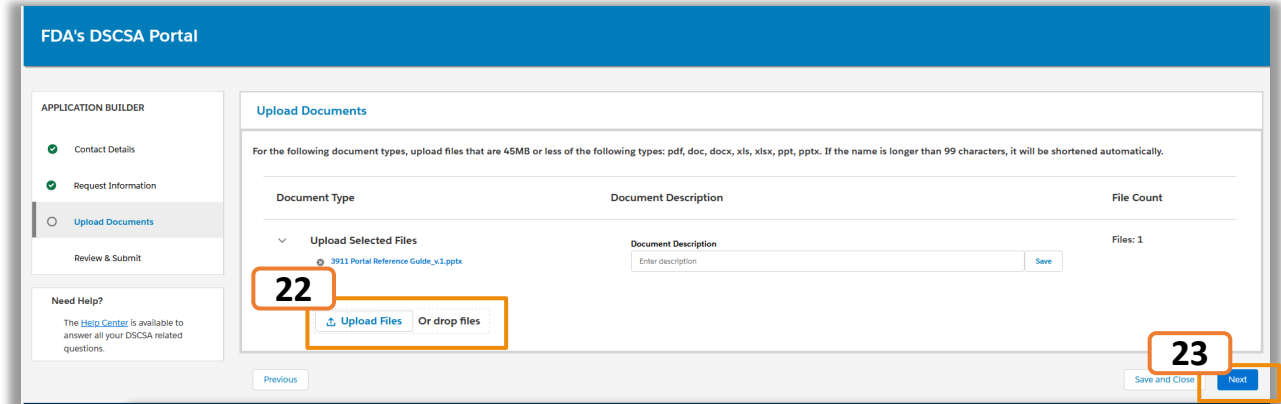
Initial Submission (Product Tracing Request)

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.**

FDA's DSCSA Portal
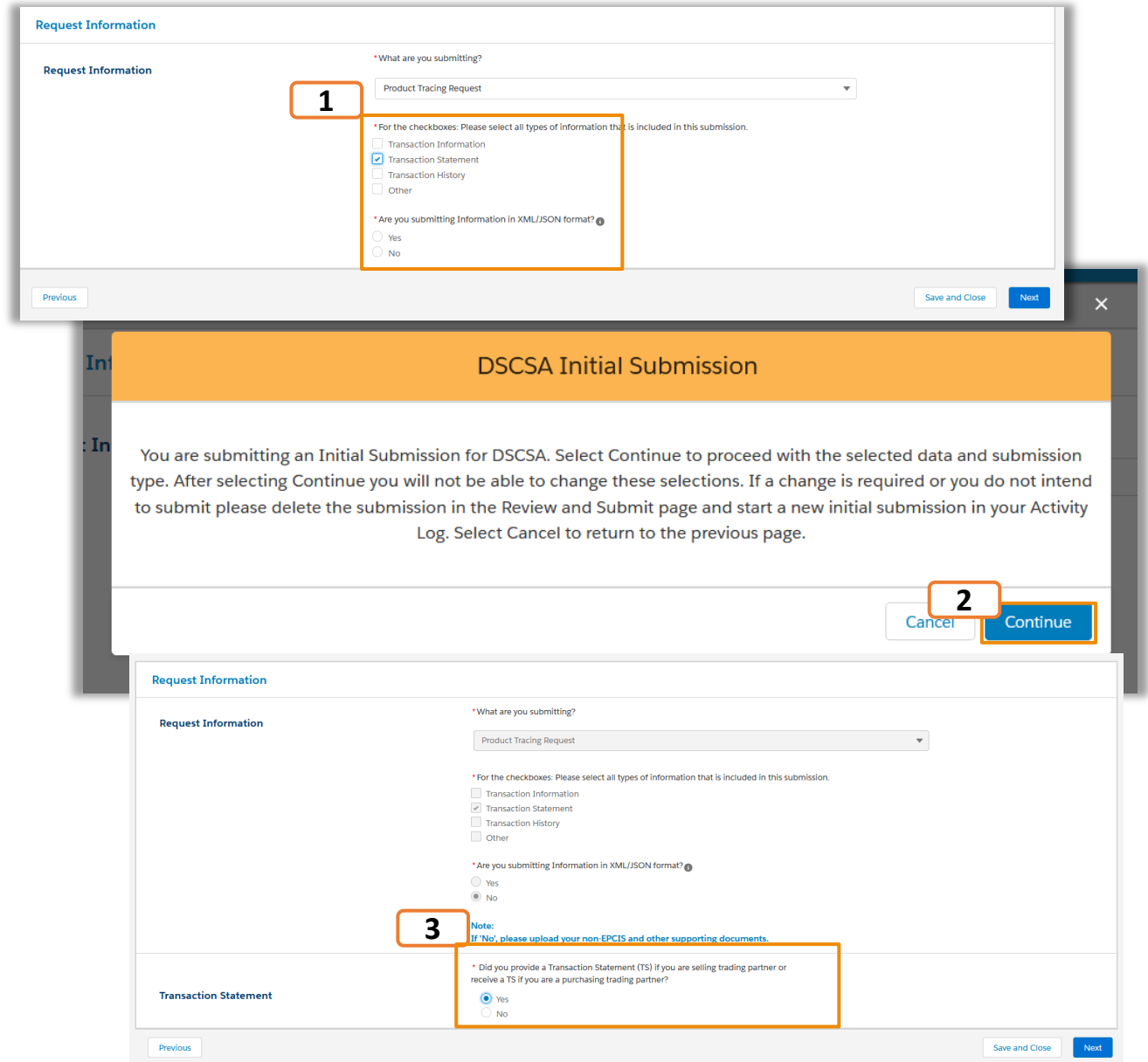
Initial Submission (Product Tracing Request)

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.
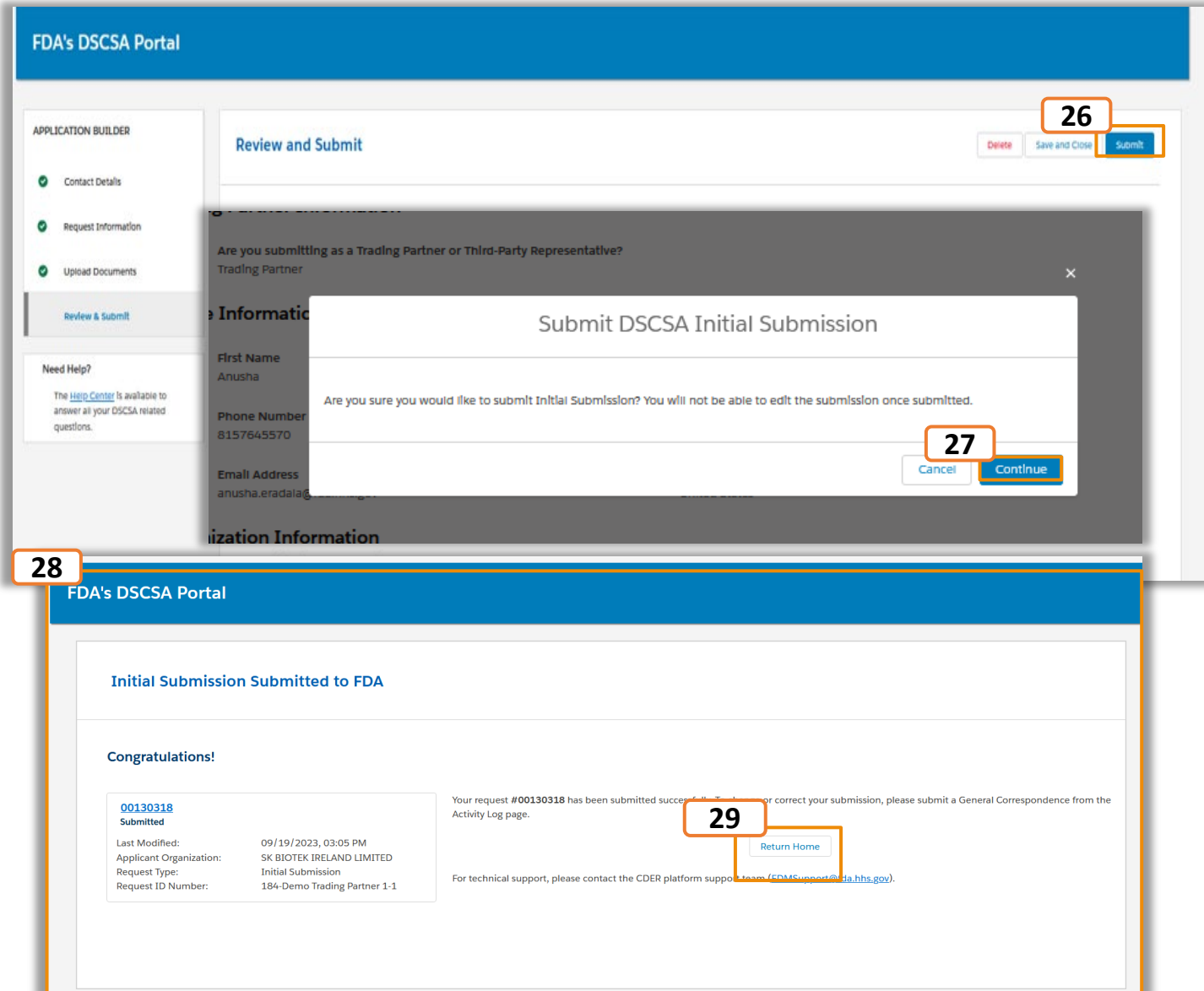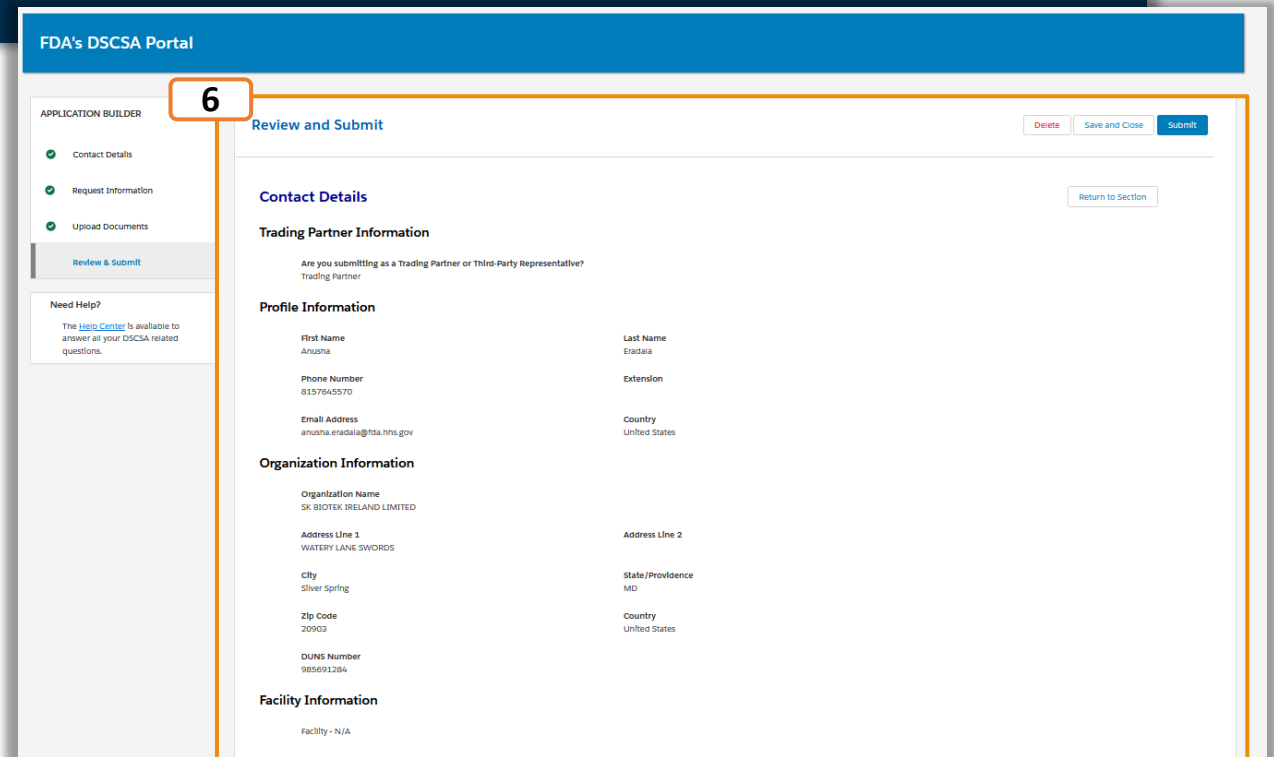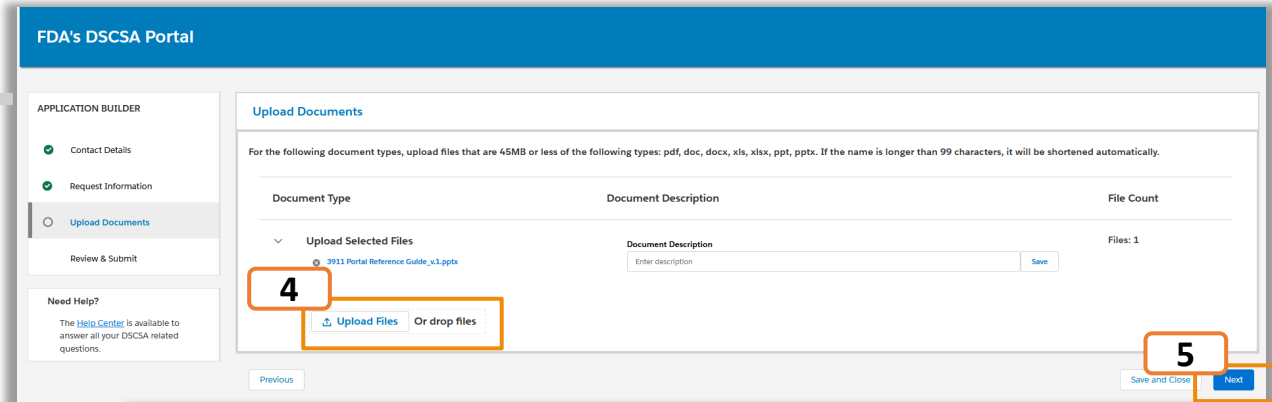
Initial Submission (Product Tracing Request)

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:

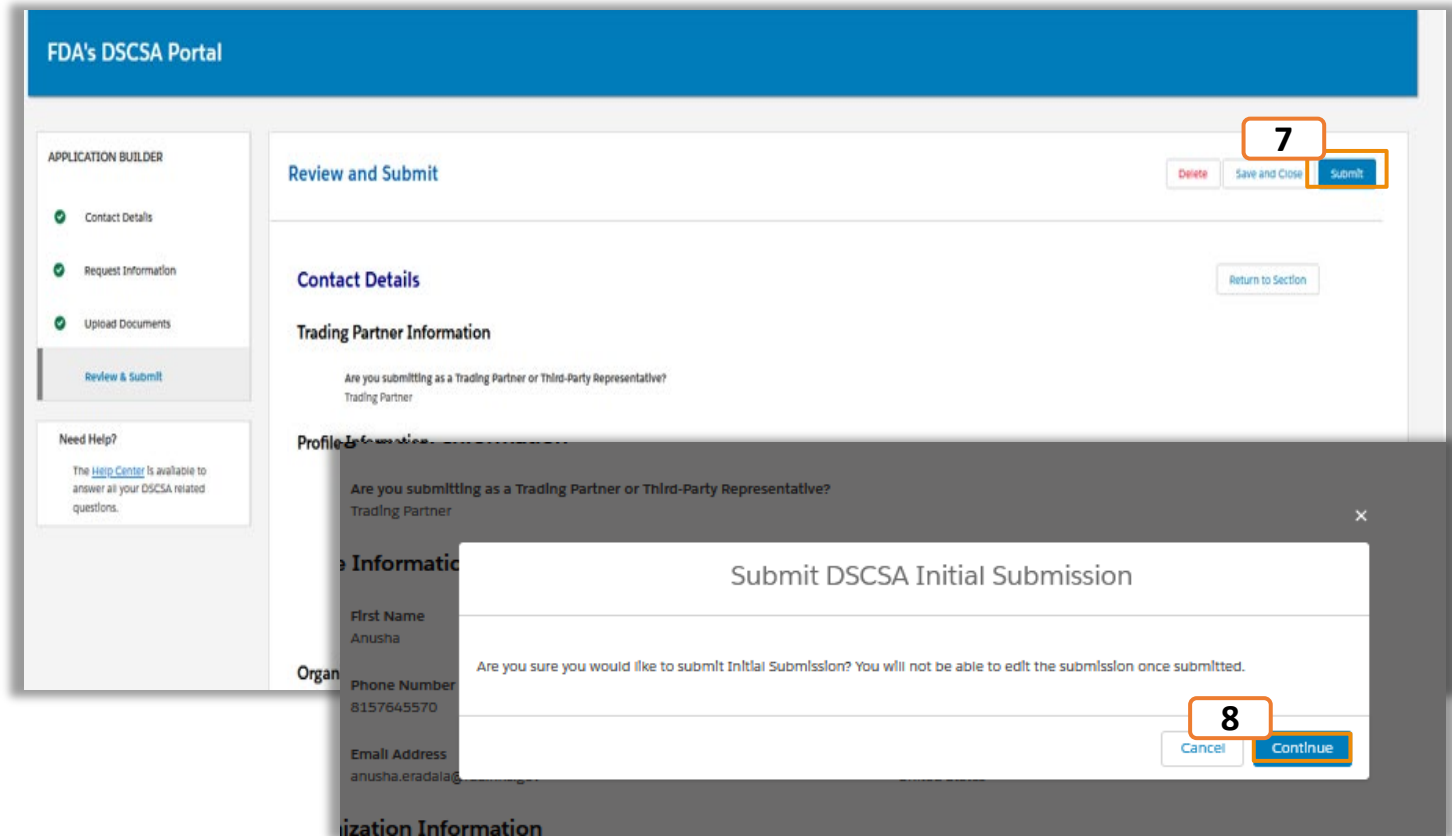If **Product Identifier Information** is selected in the Request Information page, then follow the below steps to continue.

Step 1: The Product Identifier Information section will be displayed. Click on the **Add Product** button to add Product Identifier Information.
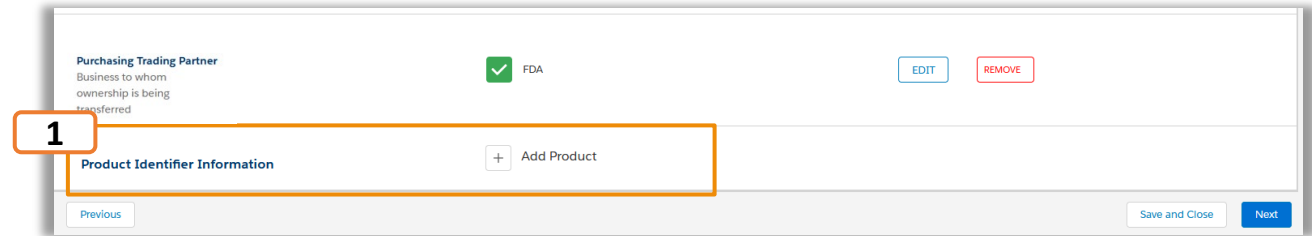
Please note that depending on the information requested from the FDA you may need to also provide additional information for your verification request. Please refer to page 22 for details on how to select your type of submission and applicable submission options.

- 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.

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 R**emove** 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.

FDA's DSCSA Portal

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.
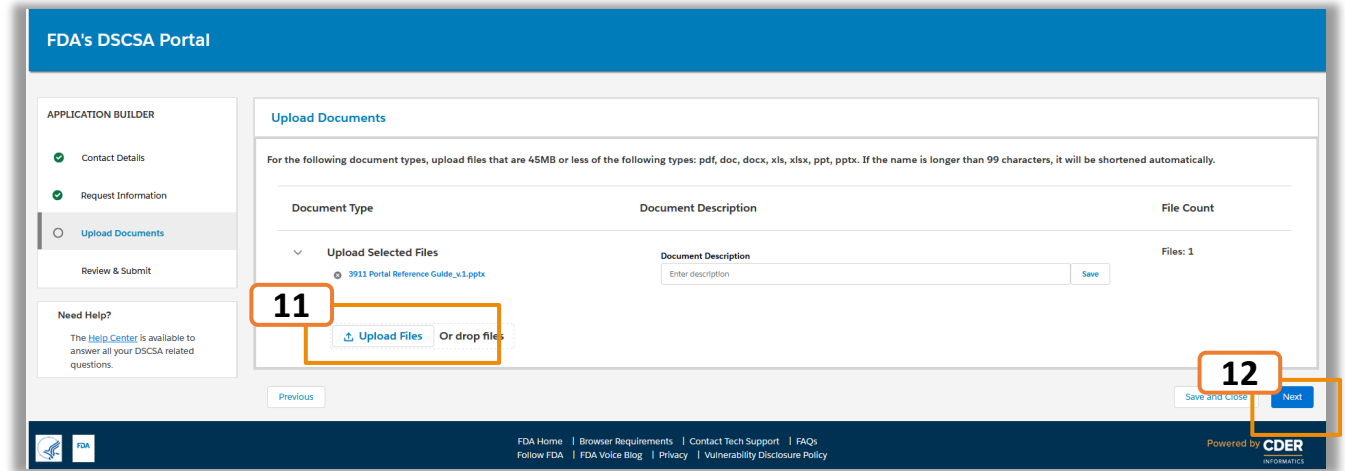
Initial Submission (Verification Request)

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.

FDA's DSCSA Portal

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.

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.

FDA's DSCSA Portal
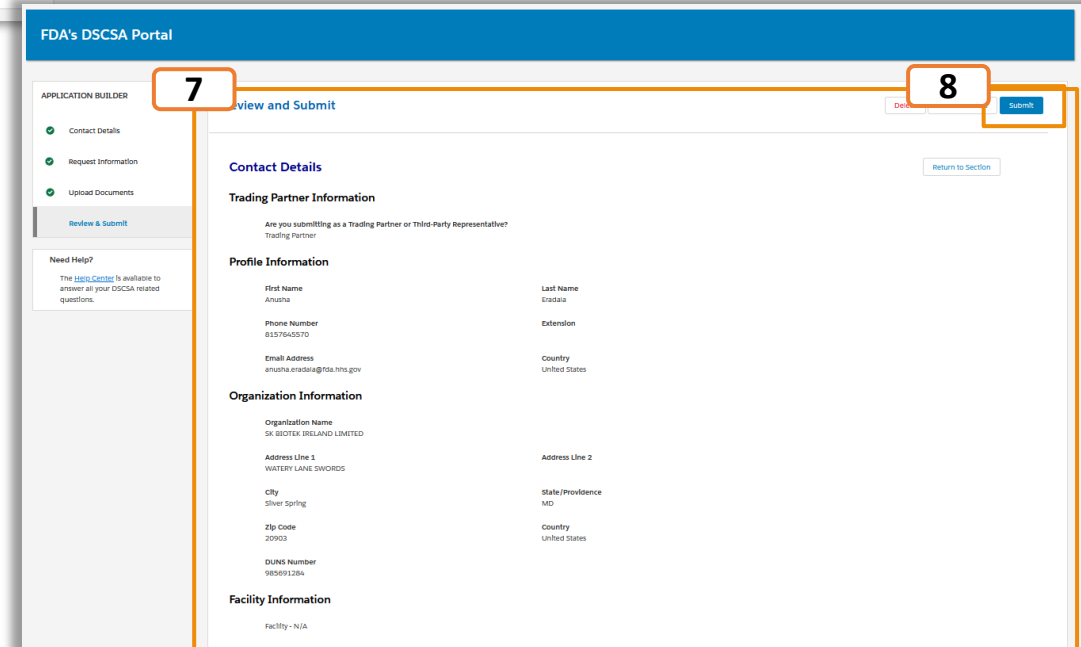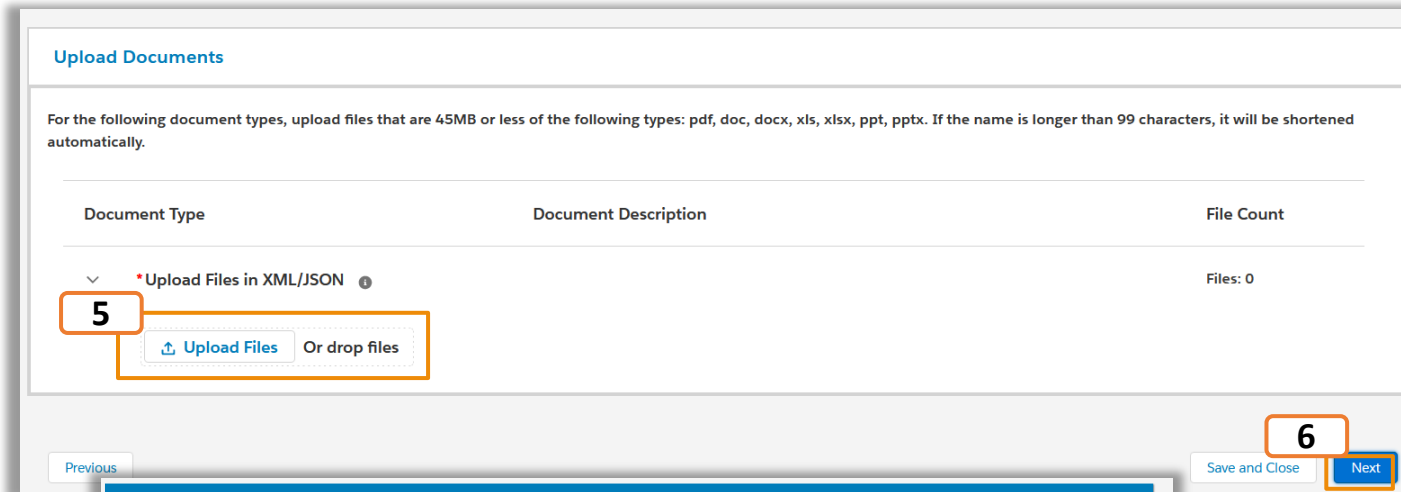
Submitting XML/JSON Files

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.

Submit DSCSA Initial Submission

Are you sure you would like to submit Initial Submission? You will not be able to edit the submission once submitted.

9
Cancel   Continue

FDA's DSCSA Portal

10

Initial Submission Submitted to FDA

Congratulations!

00130318
Submitted
Last Modified: 09/19/2023, 03:05 PM
Applicant Organization: SK BIOTEK IRELAND LIMITED
Request Type: Initial Submission
Request ID Number: 184-Demo Trading Partner 1-1

Your request #00130318 has been submitted successfully. To change or correct your submission, please submit a General Correspondence from the Activity Log page.

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Return Home

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

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 reach out to EDMSupport@fda.hhs.gov.

12

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FDA **U.S. FOOD & DRUG** ADMINISTRATION

Food and Drug Administration
Silver Spring, MD, 20993

Thank you for submitting your **DSCSA Initial Submission** for Event ID: **00130318**. Please keep your Event ID for your records. You can log in to the 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.** **

Technical Support and Resources

CDER NextGen Portal Support & Resources

FDA

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.

01

02

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.**

04

03

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

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