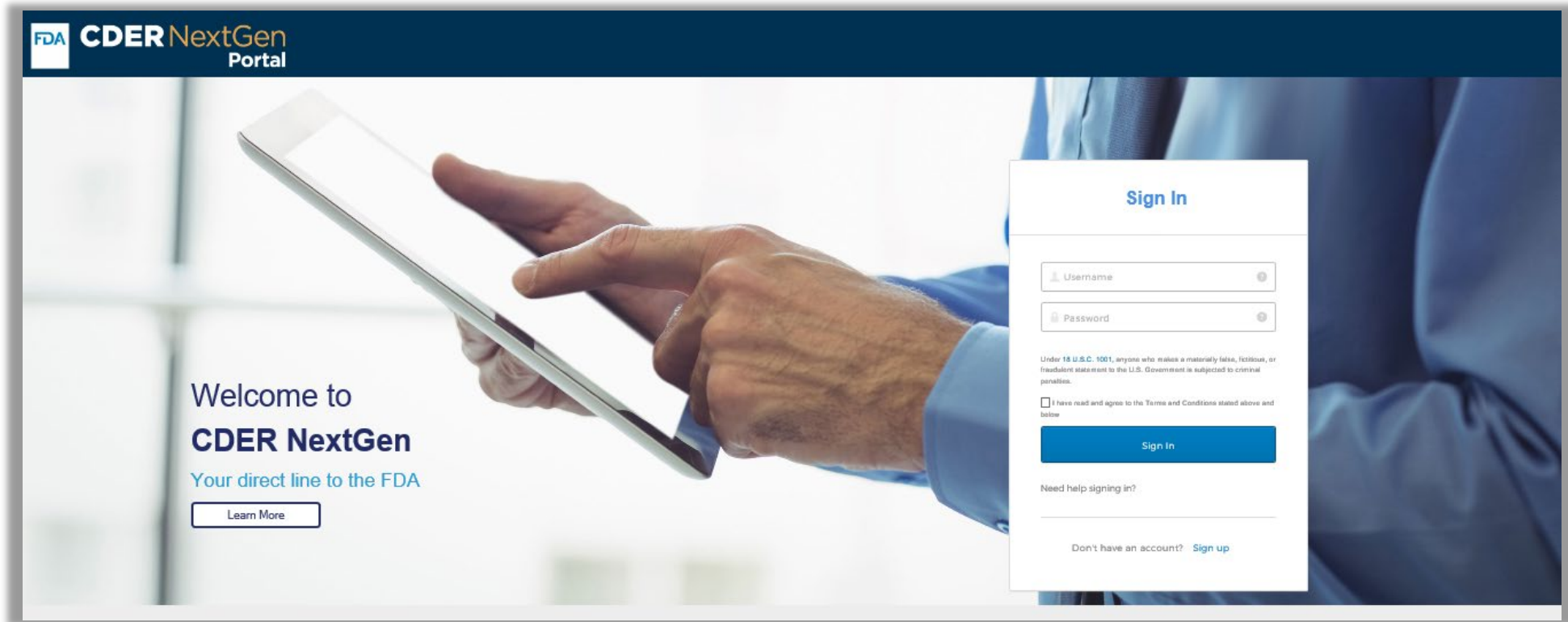


FDA's DSCSA Portal

Reference Guide



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

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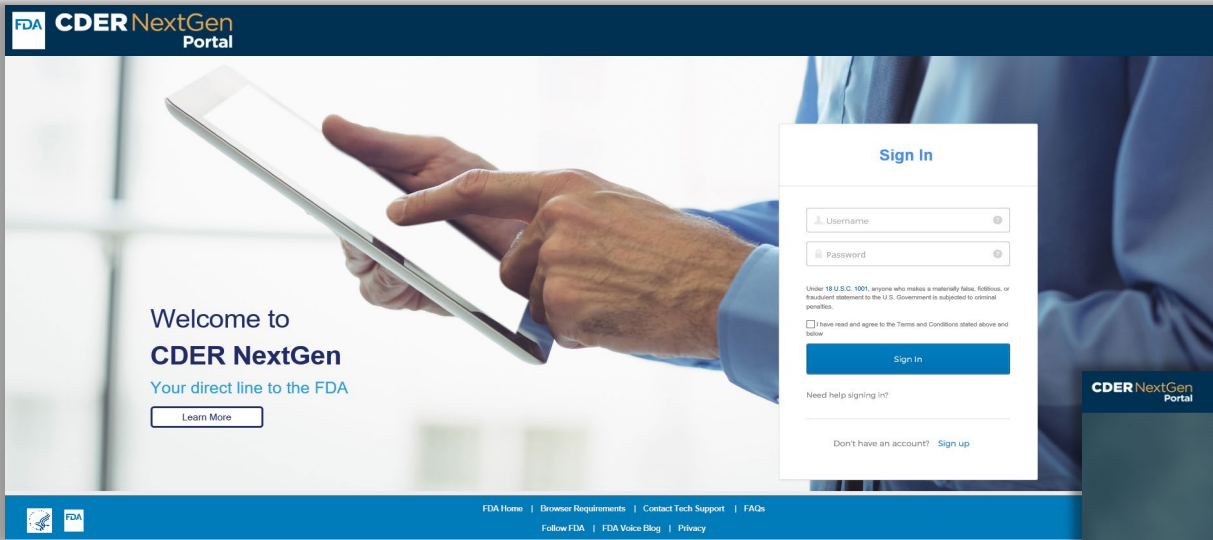
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Introduction

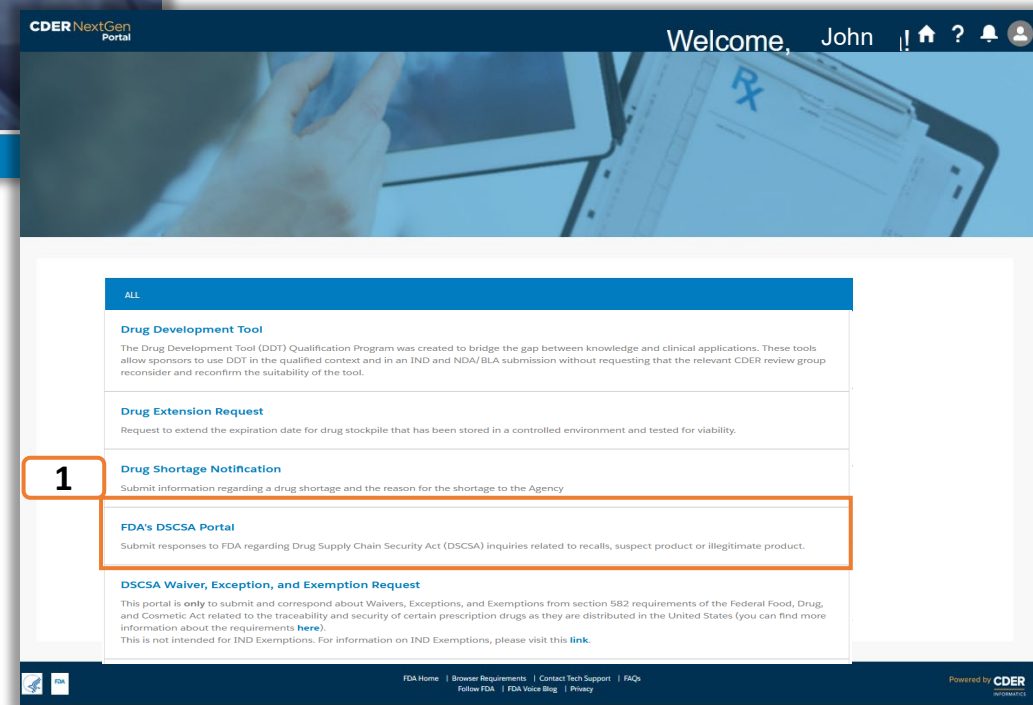
This guide provides the essential information you need to use in the CDER NextGen Portal to submit Information to FDA (for both CDER and CBER) regarding Drug Supply Chain Security Act (DSCSA) inquiries related to suspect product, illegitimate product or recalls.

For technical assistance, 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.



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 shows the CDER NextGen Portal interface. At the top, there is a navigation bar with a home icon, a question mark, a notification bell, and a 'Log Out' button. Below the navigation bar is a blue header with the text 'FDA's DSCSA Portal' and a '+ Trading Partner Confirmation' button, which is highlighted with a callout '2'. The main content area features a decorative illustration of a mountain range and a river. Below this is another blue header with 'FDA's DSCSA Portal'. The main form is titled 'Trading Partner Information' and contains several sections: 'Need Help?' with a link to the 'Help Center', 'Contact Details' (highlighted with callout '3'), and 'Trading Partner Details' (highlighted with callout '4'). The 'Contact Details' section includes fields for First Name (Anusha), Last Name (Eradala), Email Address (anusha.eradala@fda.hhs.gov), and Phone Number (8157645570). The 'Trading Partner Details' section has a field for the Request ID Number (Example ID | 123-ABC-00, with '464-EDM-1' entered) and a 'Validate' button (highlighted with 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.

CDER NextGen Portal

Trading Partner Details

Enter the Request ID Number (from the email)
Example ID | 123-ABC-00
318-DerekTest-1 Validate

6 *Has the Trading Partner designated you as the point of contact?
 Yes
 No

7 Contact Information

*First Name: Derek *Last Name: Gauthier
*Email Address: derek.gauthier@fda.hhs.gov
*Phone Number: +12022623781 Extension:

8 Are you using a Third Party Representative?
 Yes
 No

Facility Information + Add Facility Information

Delete Save and Close Next

FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy

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.

CDER NextGen Portal

Trading Partner Details

Enter the Request ID Number (from the email)
Example ID | 123-ABC-00
318-DerekTest-1 [Validate]

*Has the Trading Partner designated you as the point of contact?
 Yes
 No

Contact Information

*First Name: Derek *Last Name: Gauthier
*Email Address: derek.gauthier@fda.hhs.gov
*Phone Number: +12022623781 Extension: []

Are you using a Third Party Representative?
 Yes
 No

Facility Information

9 + Add Facility Information

12 [Next]

FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy

Add Facility Information

Facility Details

10 Facility Information


* FEI: 3000248560 [Search]

+ Add Manually

Drug Manufacturing Site Name	Drug Manufacturing Site Address	FEI
ESTEE LAUDER COSMETICS LTD.	161 COMMANDER BLVD. SCARBOROUGH, ONTARIO, CA, M1S 3K9	3000248560

11

11 [Save]

 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.

13 Contact Information

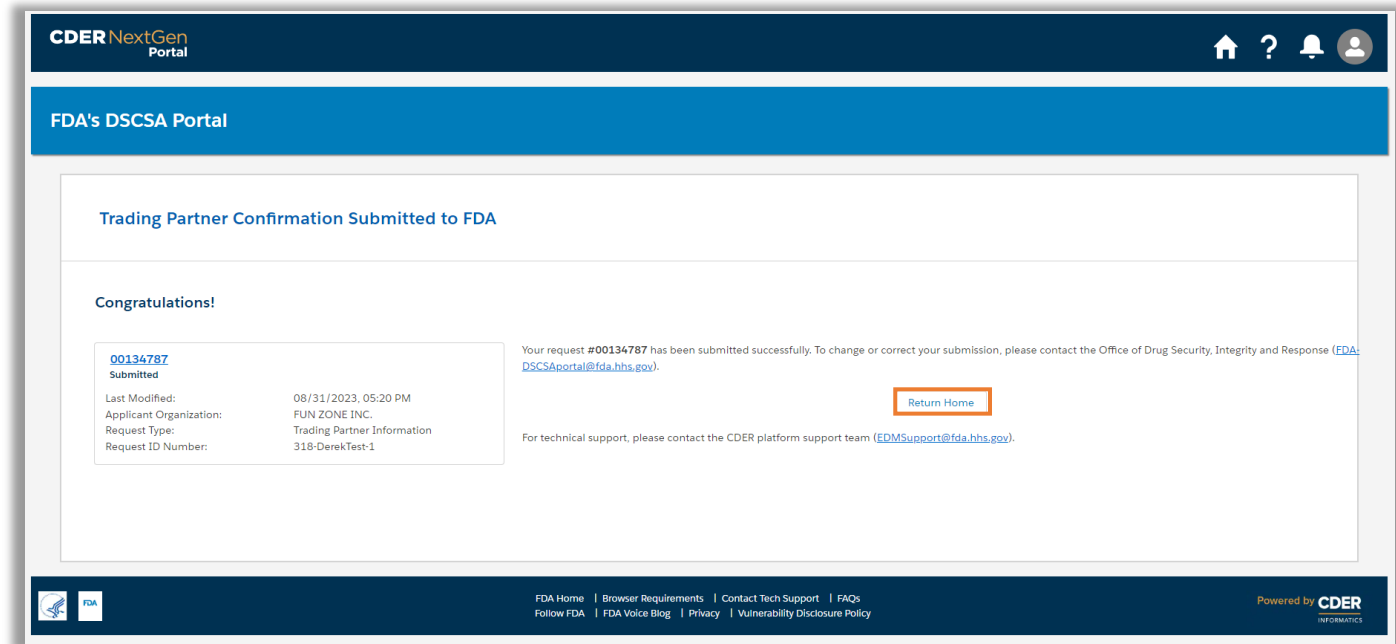
14 Certification

15 Submit

16 Continue

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** .

The screenshot shows the FDA's DSCSA Portal interface. At the top, there is a search bar and a 'Trading Partner Confirmation' button. Below the search bar, there are three notification tiles. The first two tiles, with Event IDs 00136257 and 00130318, are marked with an 'Action Required' banner. The third tile, with Event ID 00136149, is marked with a 'New Notification' banner. A callout box labeled '17' points to the first tile. Below the tiles, a detailed view of the Activity Log for request # 00136262 is shown. The Activity Log table contains the following data:

ACTIVITY	LAST UPDATED	SENDER
Initial Submission Submitted	09/06/2023, 12:17 PM	Name
Request for Documentation	09/06/2023, 12:17 PM	FDA
Trading Partner POC Confirmed	09/06/2023, 11:55 AM	FDA
Trading Partner Confirmation Submitted	09/06/2023, 11:46 AM	Name



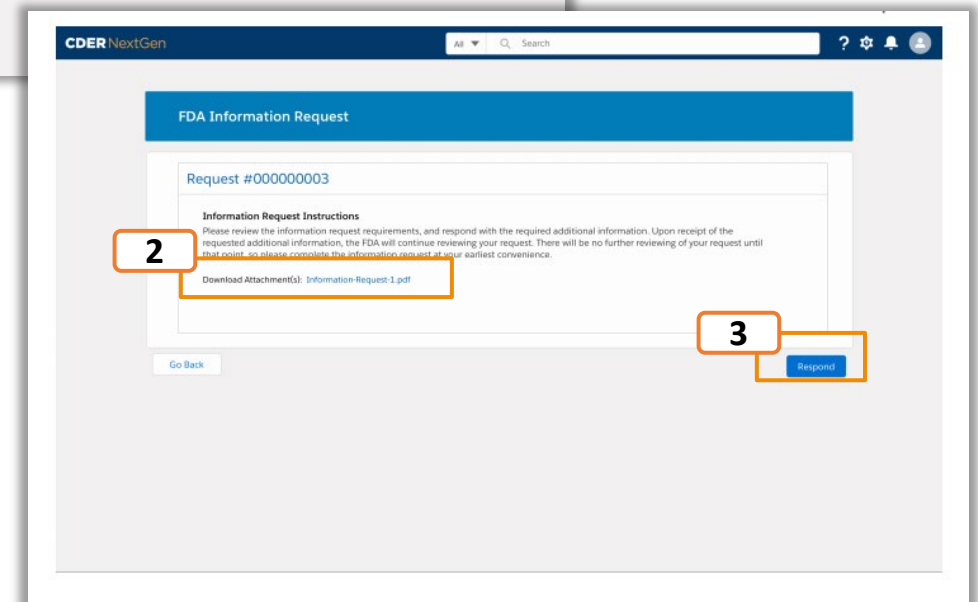
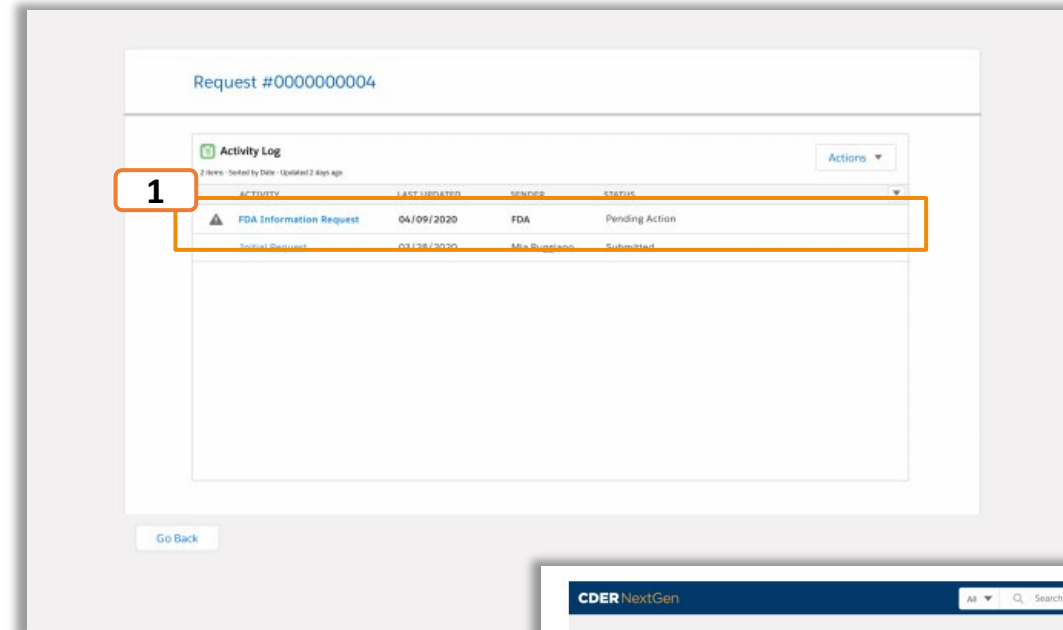
Please note banners will disappear after you view your notification in the Activity Log.

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**.



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**.

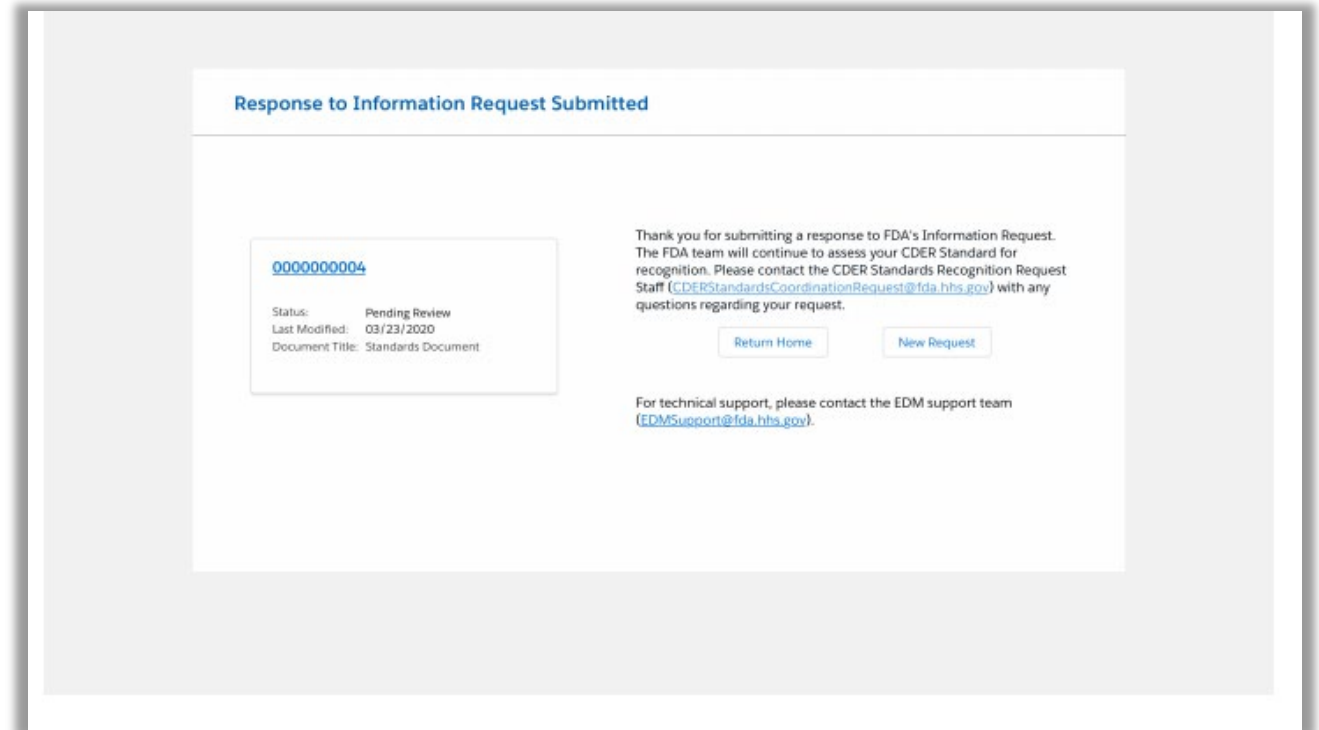
The screenshot shows the 'FDA Information Request' form. At the top, it says 'Request #000000003'. Below this, there are three main sections highlighted with orange boxes and numbered callouts:

- 4**: A text area for 'Provide any justification or comments for the request:'. Above this area is the 'Information Request Instructions' section, which states: 'Having reviewed the information request requirements, please respond with the required additional information. Upon receipt of the requested additional information, CDER will continue reviewing your request. There will be no further reviewing of your request until that point, so please complete the information request at your earliest convenience.'
- 5**: A file upload section. It includes the instruction: '* Please upload the necessary documents: Upload files that are 45 MB or less of the following file types: pdf, doc, docx, xls, xlsx, ppt, pptx, png, jpeg, jpg. If the name of the file is longer than 99 characters, it will be shortened automatically.' Below this is a dashed box containing an 'Upload Files' button and the text 'or Drop Files'.
- 6**: A blue 'Submit' button located at the bottom right of the form.

At the bottom left of the form, there is a 'Go Back' button.

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.



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 CDER NextGen Portal interface. At the top, the 'FDA's DSCSA Portal' header is visible, along with a 'Trading Partner Confirmation' button. Below the header, there is a search bar and a list of draft submissions. The first submission, with ID 00136149, is highlighted with an orange box and a '1' in a circle, indicating it is the 'Action Required' notification. The notification text reads: 'Trading Partner POC | Not Confirmed', 'Last Modified: 09/05/2023, 02:07 PM', 'Applicant Organization: SK BIOTEK IRELAND ...', 'Request Type: Trading Partner Information', and 'Request ID Number: 337-Anusha-1'. Below this, there are two more draft submissions with IDs 00135393 and 00135380. A second window, labeled with a '2' in a circle, shows the 'Activity Log' for request # 00136149. It contains two entries: 'Trading Partner POC | Not Confirmed' (dated 09/05/2023, 02:07 PM) and 'Trading Partner Confirmation Submitted' (dated 09/05/2023, 02:18 PM). A third window, labeled with a '3' in a circle, shows the 'FDA Notification' for request # 00136149. It includes the text: '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.', and a PDF attachment titled 'POC Not Confirmed-SK BIOTEK IRELAND LIMITED.pdf'.

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.

Request # 00136149

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

ACTIVITY	LAST UPDATED	SENDER
Trading Partner POC Not Confirmed	09/05/2023, 02:07 PM	FDA
Trading Partner Confirmation Submitted	09/05/2023, 01:48 PM	Name

Request # 00136149

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

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

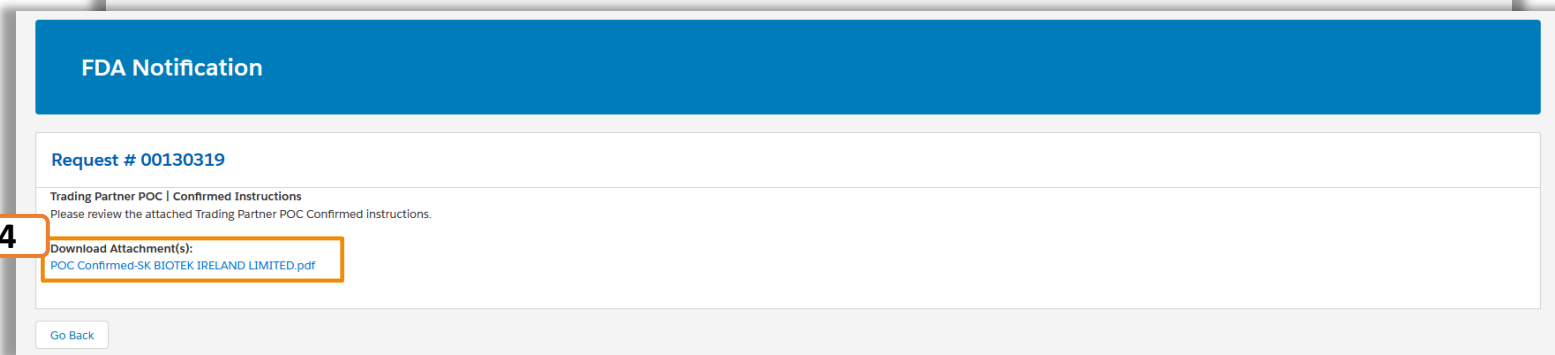
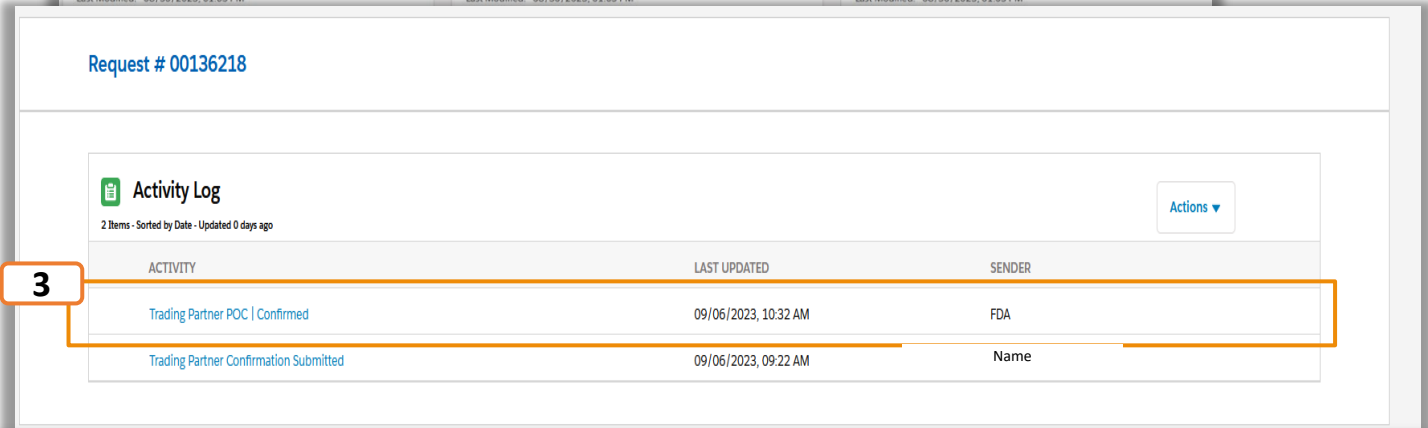
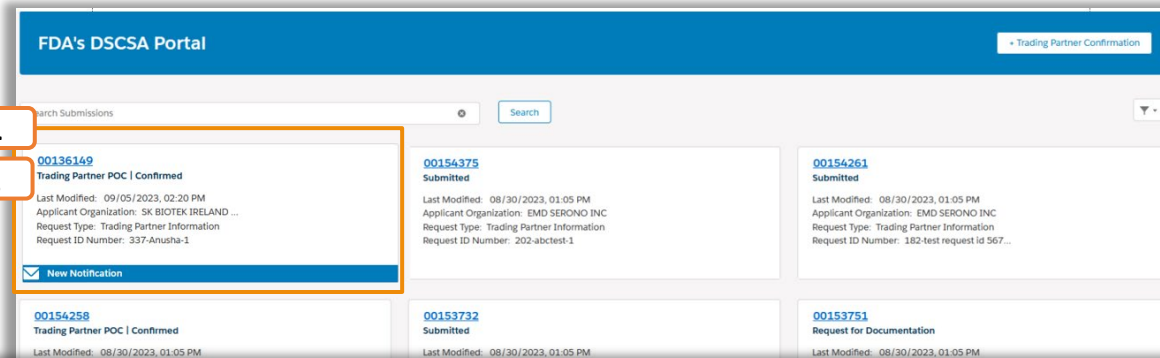
When the Trading Partner POC is confirmed, you will see a **New Notification** banner. Follow the steps below to view:

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.



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 for 'Trading Partner Confirmation'. Below the header is a search bar labeled 'Search Submissions' with a search button. The main content area displays a list of submissions. The first submission, with ID '00153708', is titled 'Request for Documentation' and is highlighted with an orange border and a '1' in a circle. It includes a warning icon and the text 'Action Required'. The other two submissions, '00154375 Submitted' and '00154261 Submitted', are in a 'Submitted' state. Each submission card displays the last modified date, 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.

Request # 00130318

Activity Log
5 Items - Sorted by Date - Updated 65 days ago Actions ▾

ACTIVITY	LAST UPDATED	SENDER
2 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	Anusha Eradala
Trading Partner POC Not Confirmed	06/22/2023, 10:57 AM	FDA
Trading Partner Confirmation Submitted	06/21/2023, 03:43 PM	Anusha Eradala

FDA Notification

Request # 00136262

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.

3 **Download Attachment(s):**
[Request for Documentation-SK BIOTEK IRELAND LIMITED.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.

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

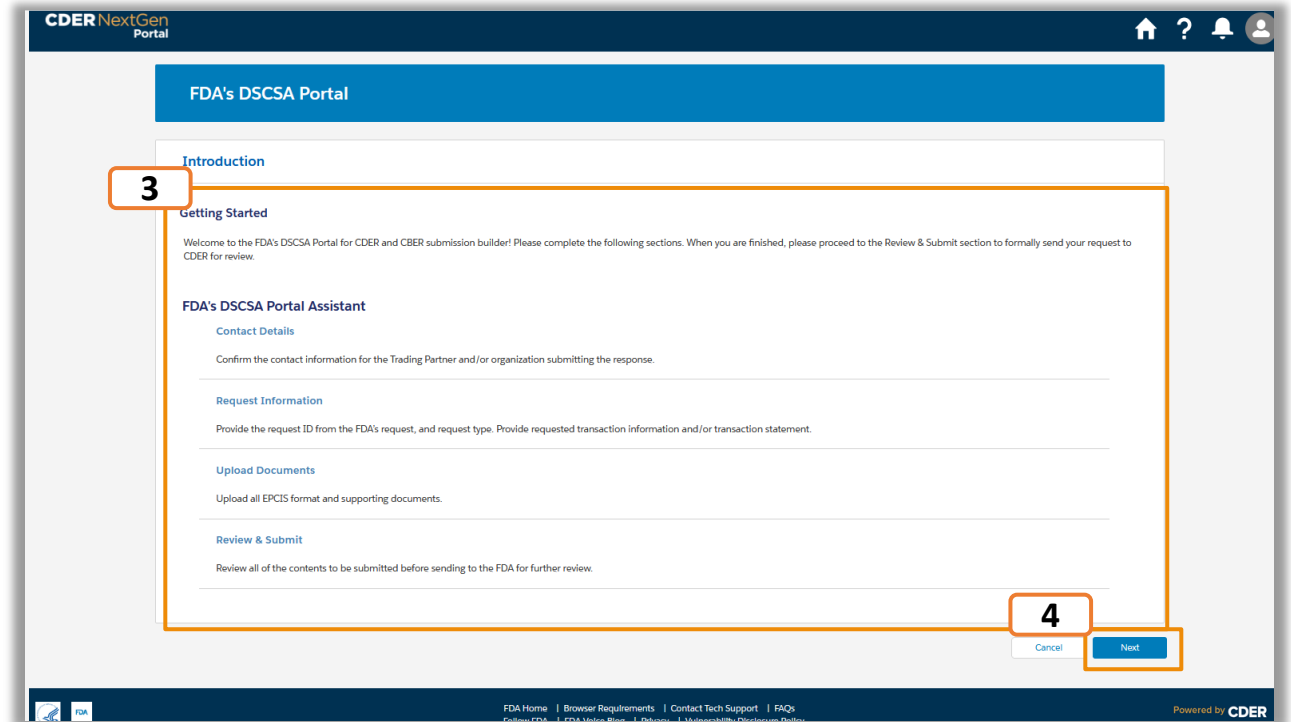


Please note that the Initial Submission option will not be displayed in the Actions Dropdown once the submission is saved as draft. **Initial Submission Draft** will be displayed in the Activity Log page.

Initial Submission (Continued)

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

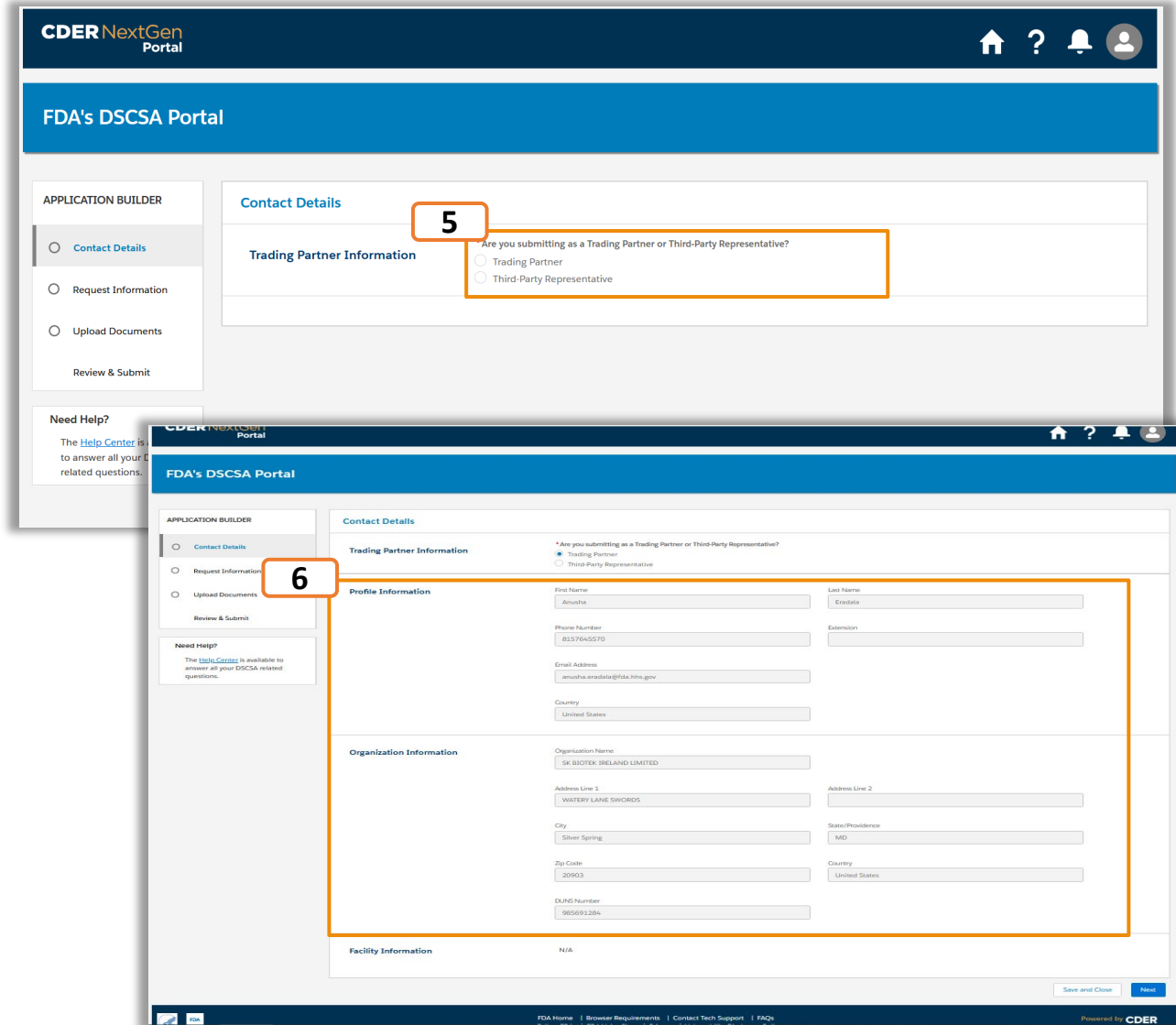
Step 4: Click **Next**.



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

Request Information

Request Information

7

*What are you submitting?

Select One

Product Tracing Request

Verification Request

FDA's DSCSA Portal

Request Information

Request Information

8

*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

9

*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.

1


2

3

Initial Submission (Product Tracing Request)

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

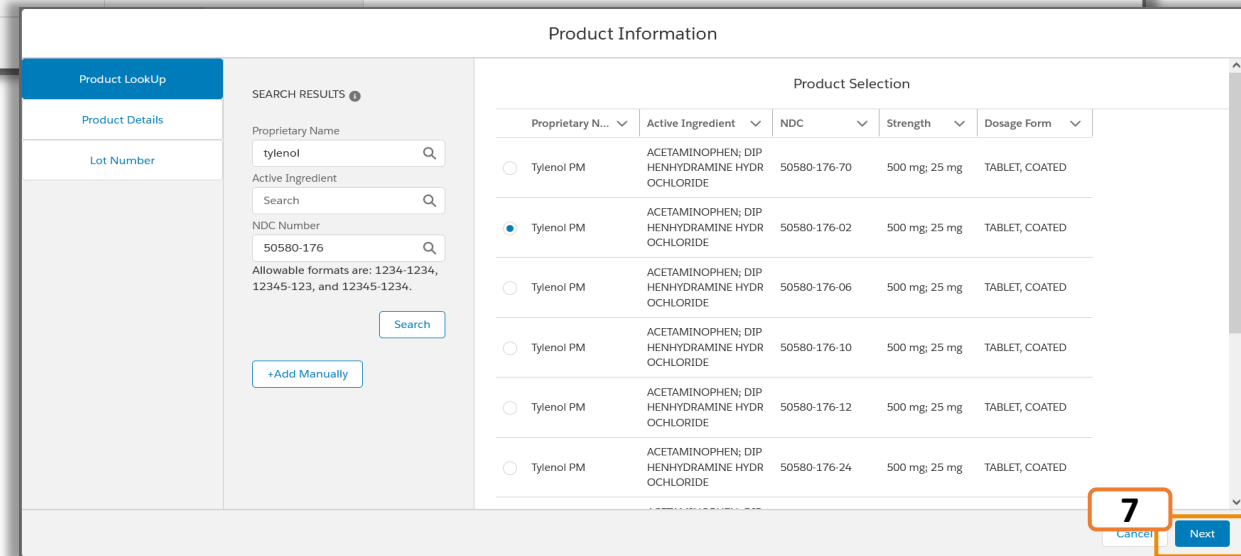
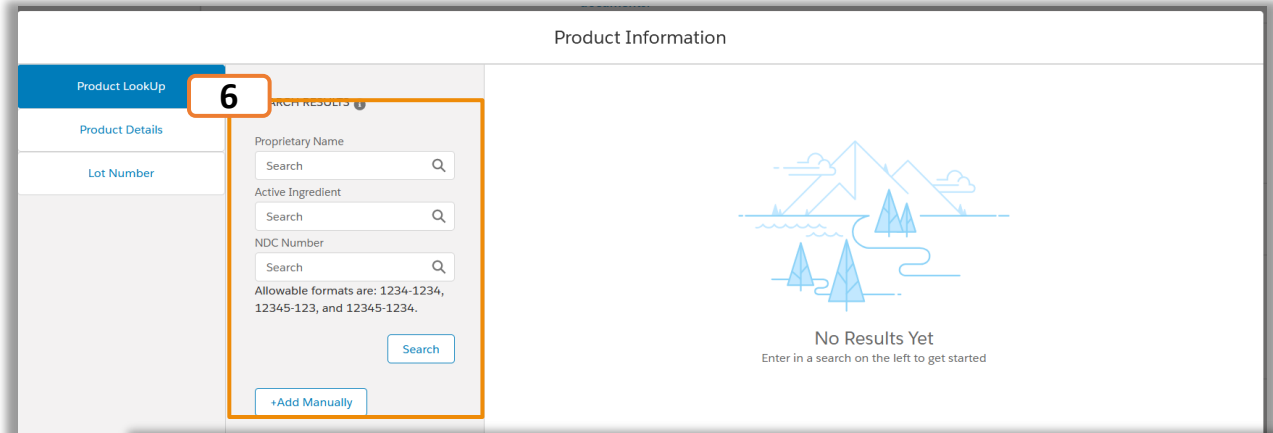
Step 5: Click on the **Add Product** button to add a product and its associated information.

 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**.

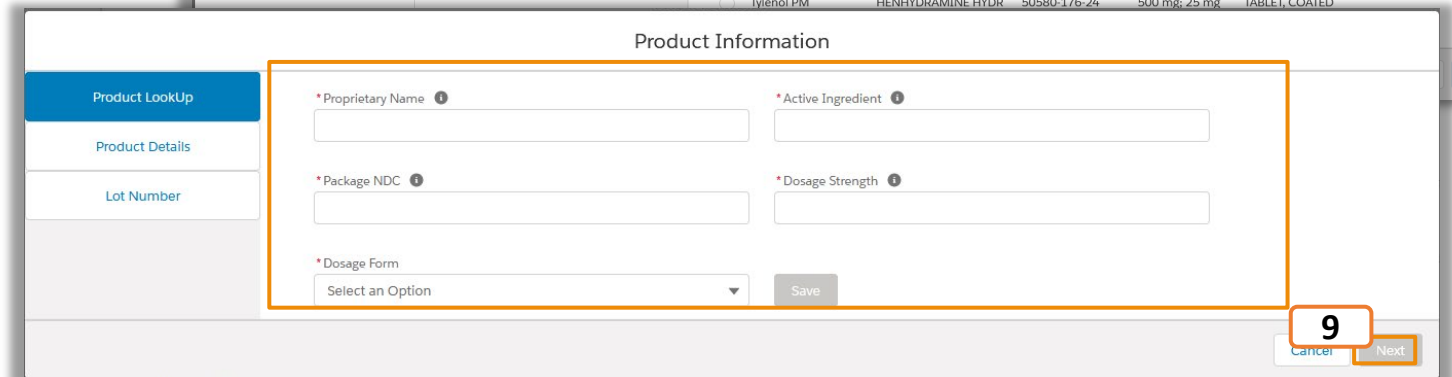
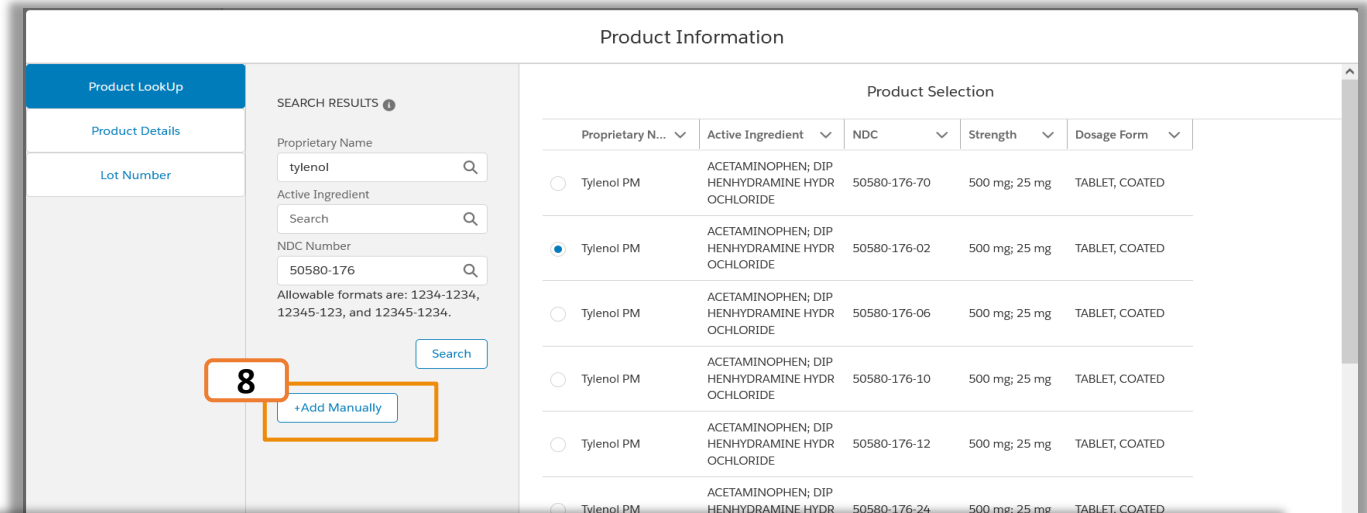


i Please note that the allowable search formats for your NDC search are: 1234-1234, 12345-123, and 12345-1234.

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**.

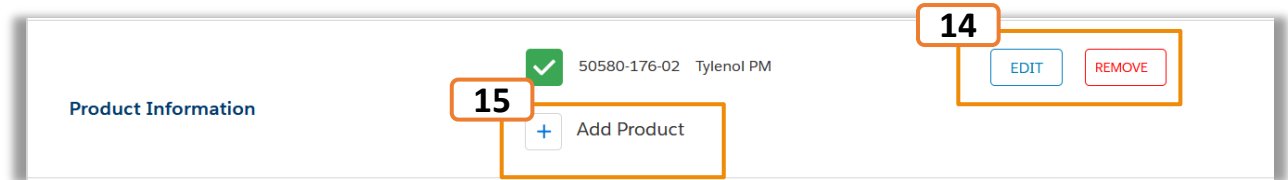
i Please note you can download the template and the instructions here:


- [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**.

Selling Trading Partner
Business from whom ownership is being transferred

Purchasing Trading Partner
Business to whom ownership is being transferred

16 + Add DUNS/Selling Trading Partner

+ Add DUNS/Purchasing Trading Partner

Add Organization Information

DUNS Look Up

17 Organization Information

DUNS ⓘ
123456789 Search

+Add Manually

Organization Name	Address
<input checked="" type="radio"/> MERCER LEGAL GROUP, PC	21031 VENTURA BLVD , WOODLAND HILLS, CA, 91364, US

18 Cancel 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**.

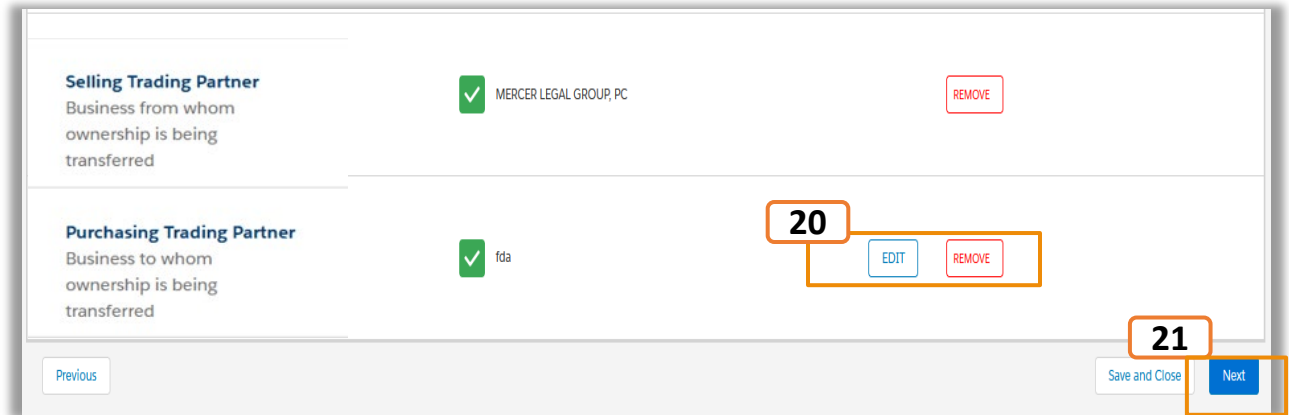
The screenshot shows the 'Add Organization Information' form. On the left is a 'DUNS Look Up' area. On the right, under 'Organization Information', there is a 'DUNS' field with the value '123456789' and a 'Search' button. Below this is a '+Add Manually' button, which is highlighted with an orange box and a callout '19'. Below the search area is a table with two columns: 'Organization Name' and 'Address'. The table contains one entry: 'MERCER LEGAL GROUP, PC' and '21031 VENTURA BLVD , WOODLAND HILLS, CA, 91364, US'. At the bottom right of the form are 'Cancel' and 'Save' buttons.

The screenshot shows the 'Add Organization Information' form with manual input fields. The 'DUNS Look Up' area is on the left. The 'Organization Information' section has the following fields: '* Organization Name' (text input), '* Country' (dropdown menu with '--None--' selected), '* Address Line 1' (text input), 'Address Line 2' (text input), '* City' (text input), 'State/Province' (text input), and '* Zip Code' (text input). At the bottom right of the form are 'Cancel' and 'Save' buttons. A callout '19' is positioned near the 'Save' button.

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.



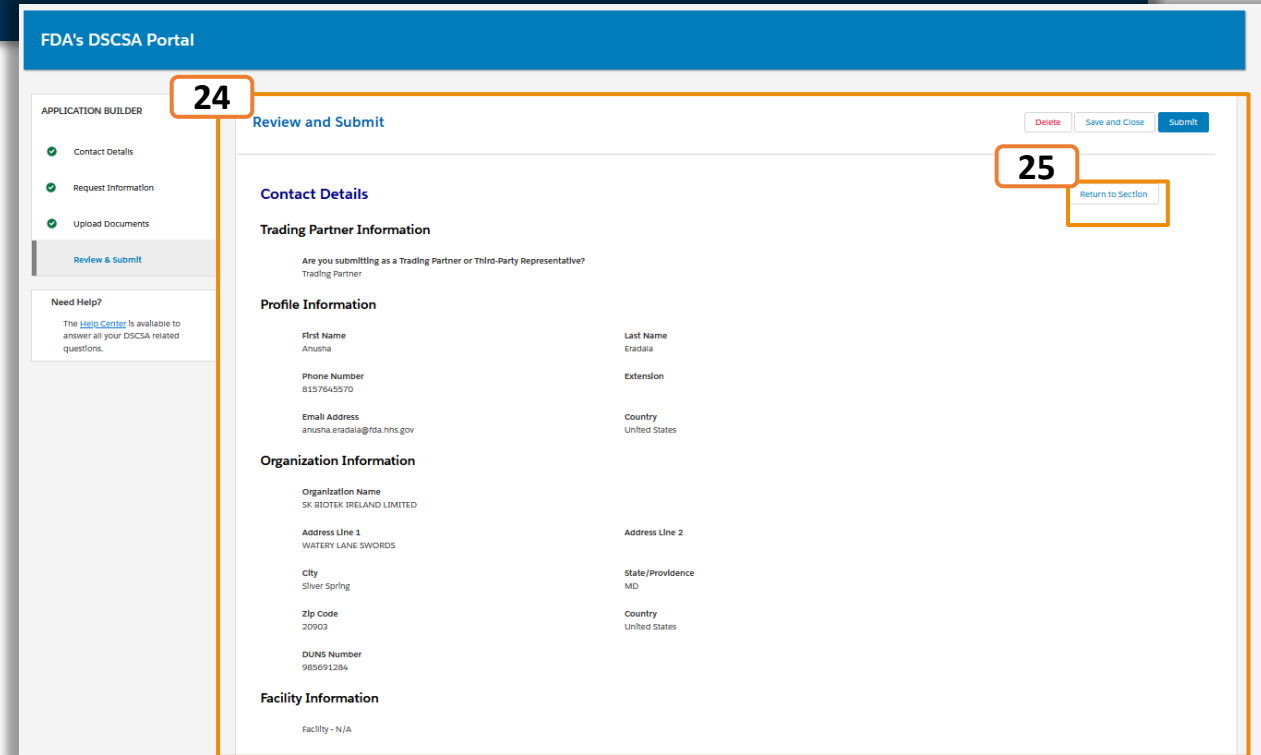
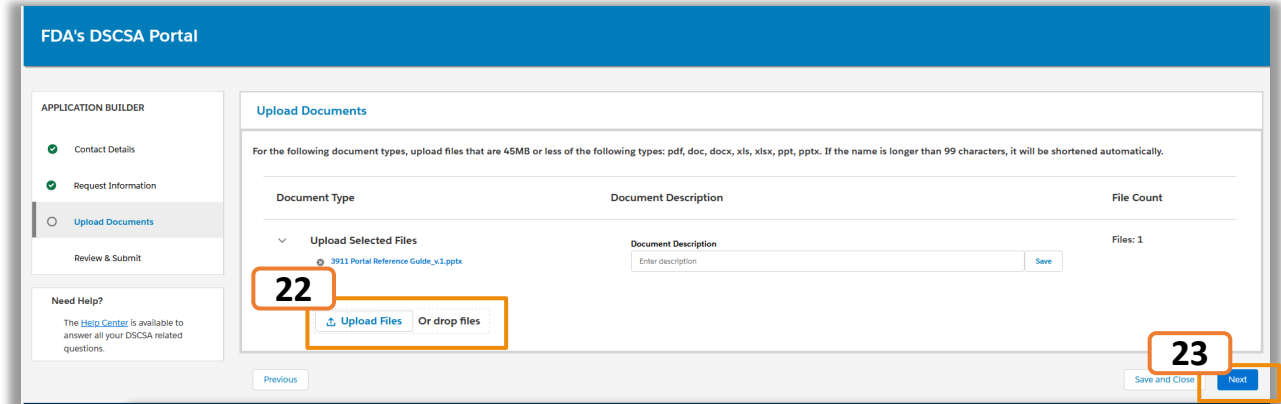
Initial Submission (Product Tracing Request)

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.



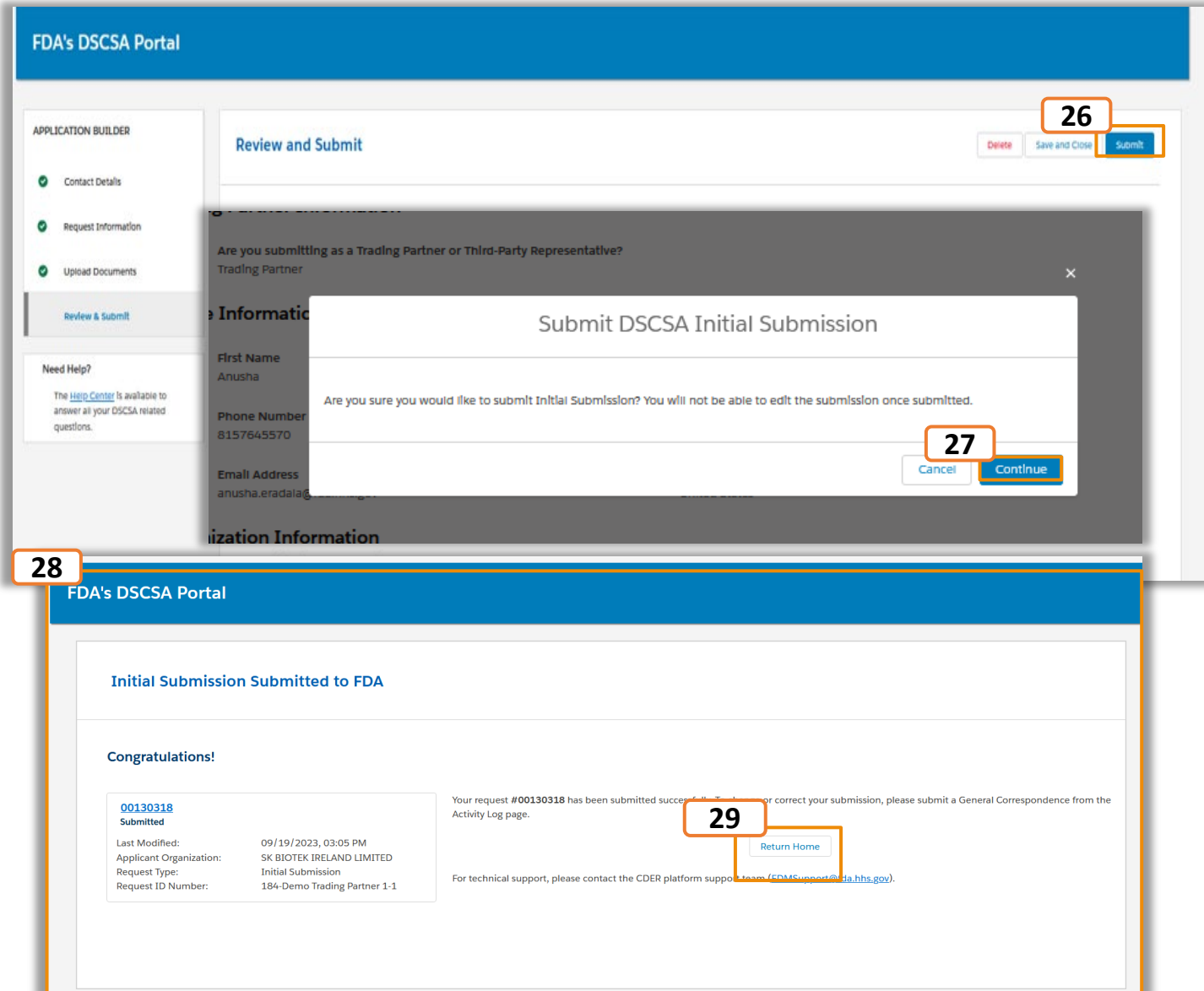
Initial Submission (Product Tracing Request)

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.



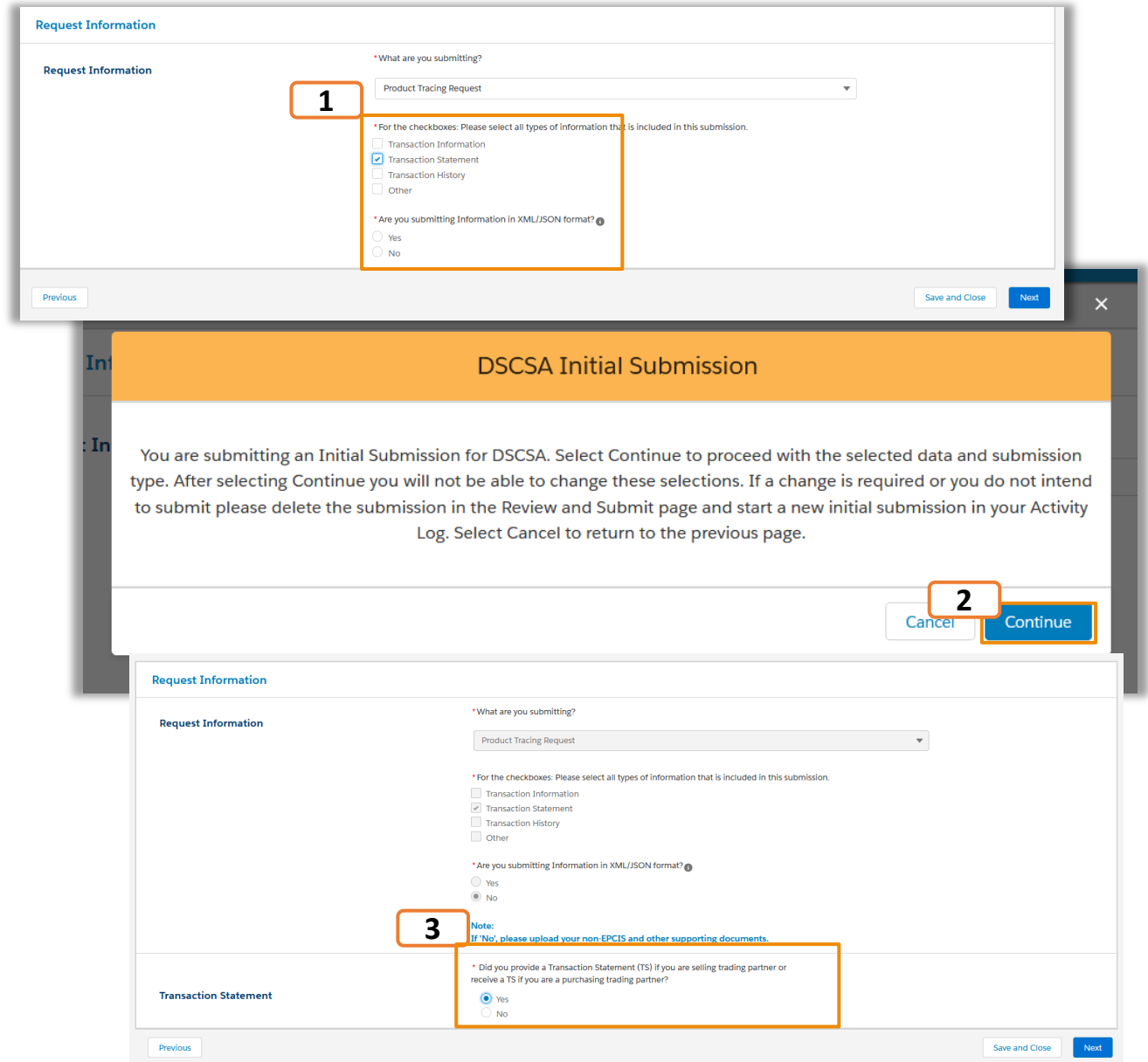
Initial Submission (Product Tracing Request)

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**.

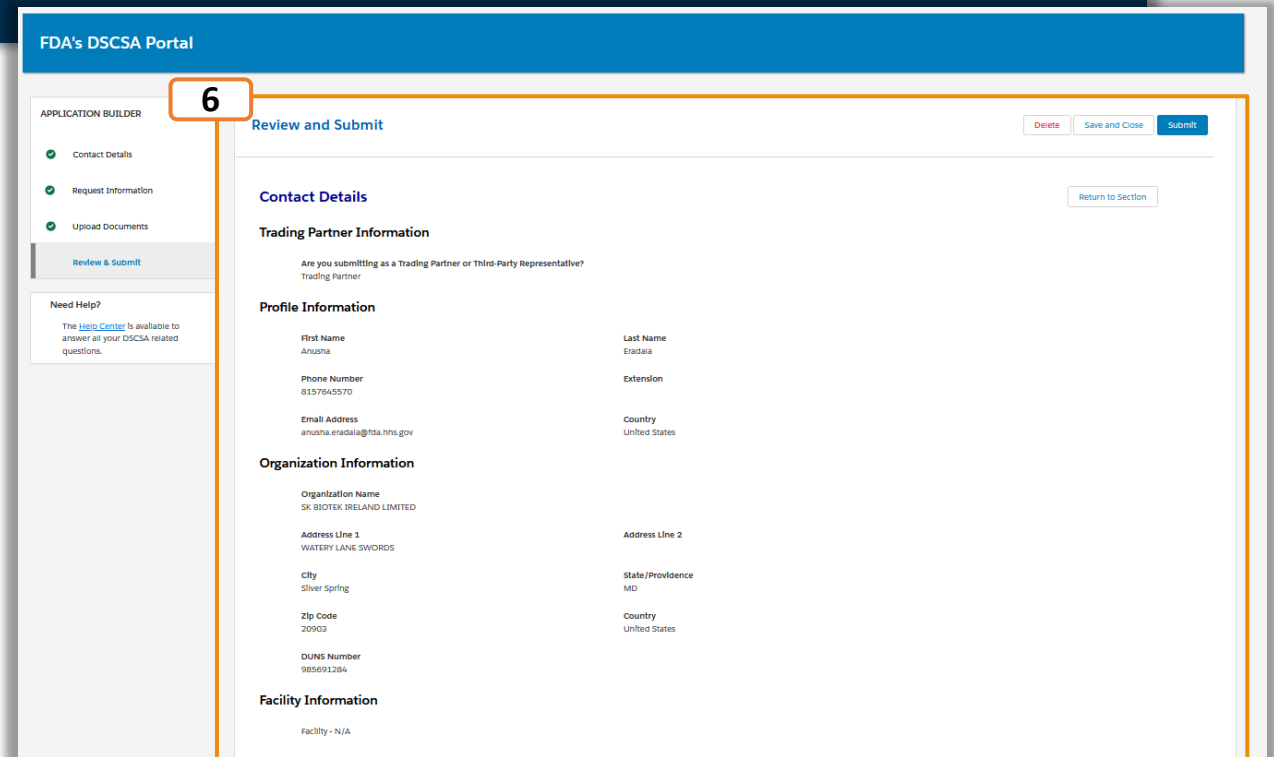
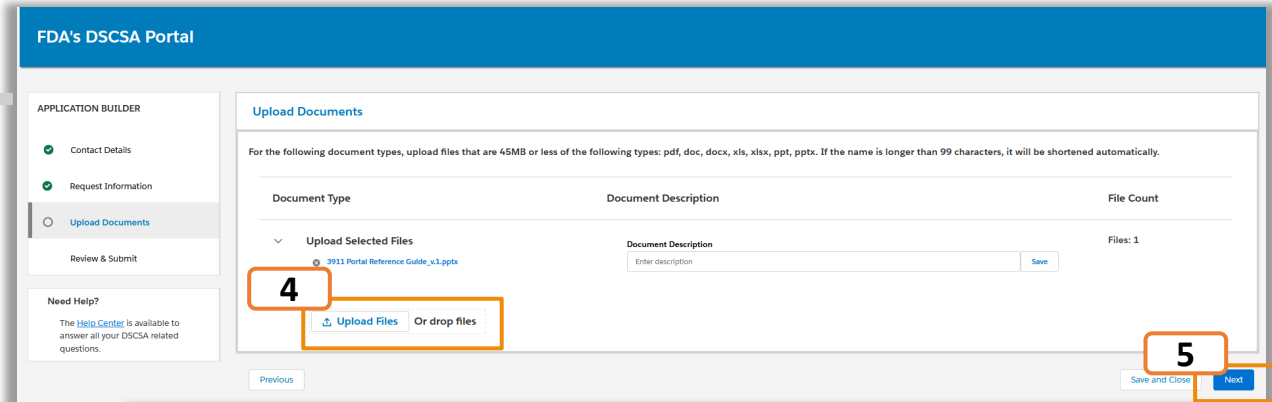


Initial Submission (Product Tracing Request)

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

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

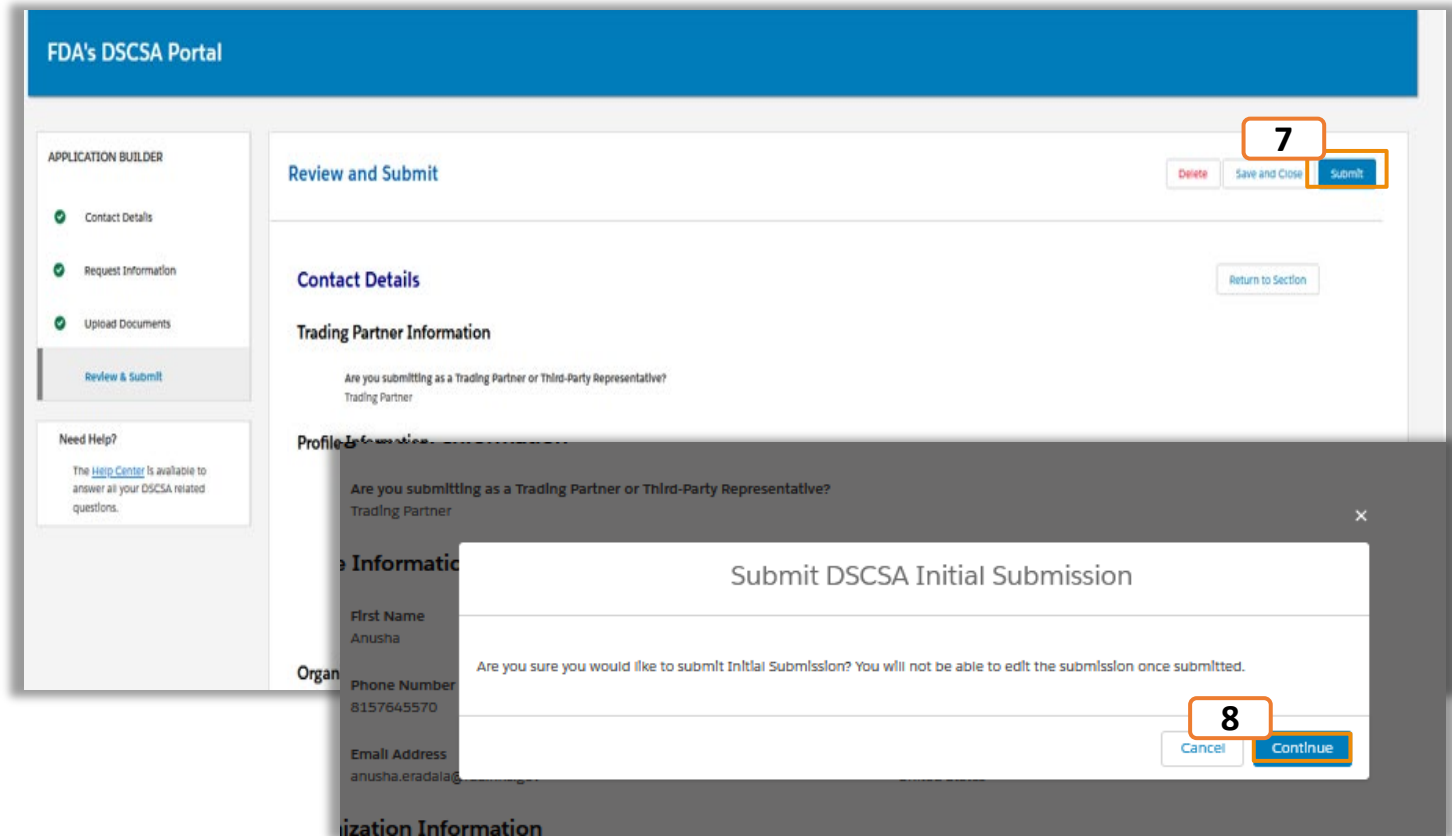
Step 6: Review the information on the Review and Submit page and verify details entered.



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.

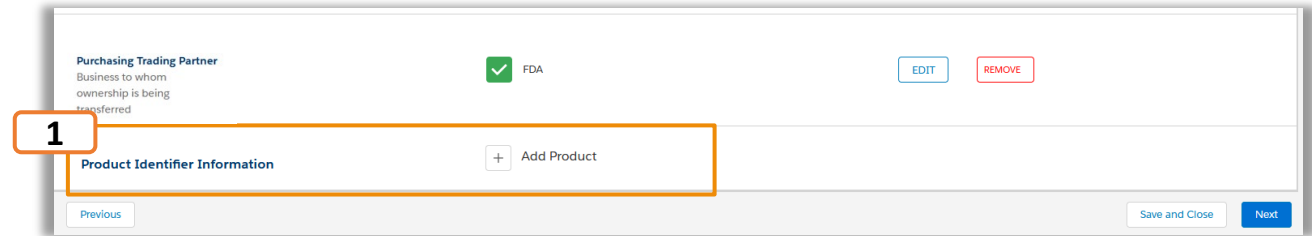


Initial Submission (Verification Request)

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.

The screenshot shows a web form titled "Product Identifier Information" with a close button in the top right corner. The form is divided into two main sections: "Product Verification" and "Product Identifier Information".

Step 2: A callout box labeled "2" points to the "Product Identifier Information" section, which contains the following fields:

- NDC:** 2332-1233-13
- Lot Number:** 123123412
- Serial Number:** 423123123
- Expiration Date:** 11/12/2023

Step 3: A callout box labeled "3" points to the question: "Can you verify that the product identifier information provided by the FDA is accurate?". The "Yes" radio button is selected.

Step 4: A callout box labeled "4" points to the section: "Please select if any of these attributes apply to this product:". The "Expired" checkbox is checked, while "Expiration Extended", "Recalled", "Suspect", "Illegitimate", and "None of the above apply" are unchecked.

At the bottom of the form, there is a text input field labeled "additional data" and two buttons: "Cancel" and "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: 2332-1233-13
- * Lot Number: 123123412
- * Serial Number: 423123123
- * Expiration Date: 11/12/2023

* Can you verify that the product identifier information provided by the FDA is accurate?
 Yes
 No

* 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:
additional data

Callout 5 points to the 'additional data' text input field. Callout 6 points to the 'Save' button.

Purchasing Trading Partner
Business to whom ownership is being transferred

✓ FDA [EDIT] [REMOVE]

Verified	NDC	Expiration Date	Lot Number	Serial Number
<input type="checkbox"/>	2332-1233-13	11/12/2023	123123412	423123123

Callout 7 points to the table header. Callout 8 points to the [EDIT] and [REMOVE] buttons for the first row. Callout 9 points to the '+ Add Product' button. Callout 10 points to the 'Next' button.

Product Identifier Information

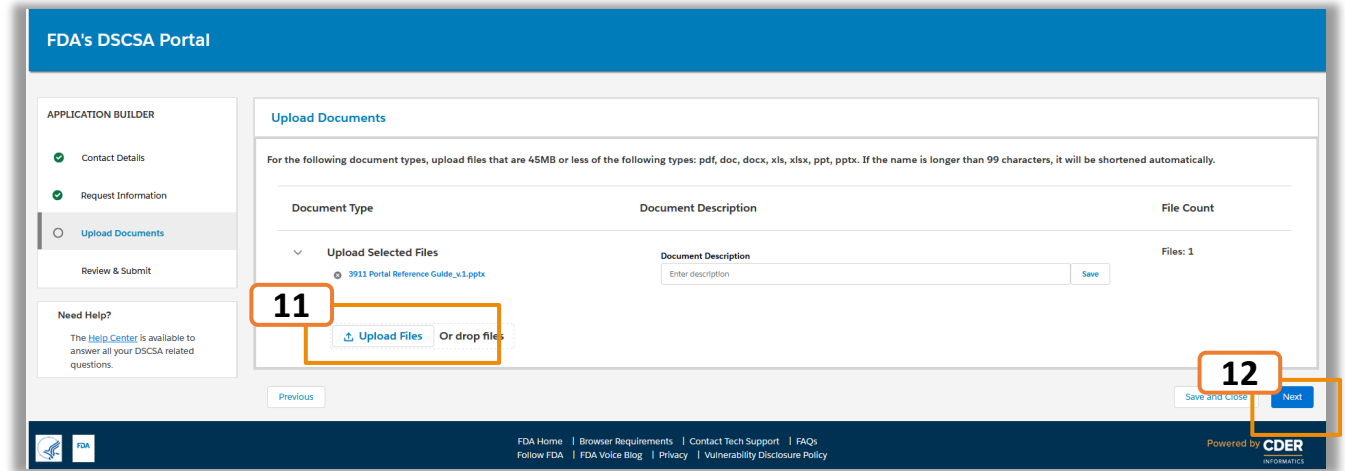
[+ Add Product]

[Previous] [Save and Close] [Next]

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

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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 Continue Submit

Return to Section

Contact Details

Trading Partner Information

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

Profile Information

First Name Anusha	Last Name Eradala
Phone Number 8157645570	Extension
Email Address anusha.eradala@fda.hhs.gov	Country United States

Organization Information

Organization Name SK BIOTEK IRELAND LIMITED	Address Line 2
Address Line 1 WATERY LANE SWORDS	City Silver Spring
City Silver Spring	State/Province MD
Zip Code 20903	Country United States
DUNS Number	

Facility Information

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

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.

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Cancel Continue

First Name
Anusha

Phone Number
8157645570

Email Address
anusha.eradala@fda.hhs.gov

Organization Information

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!

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.

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.

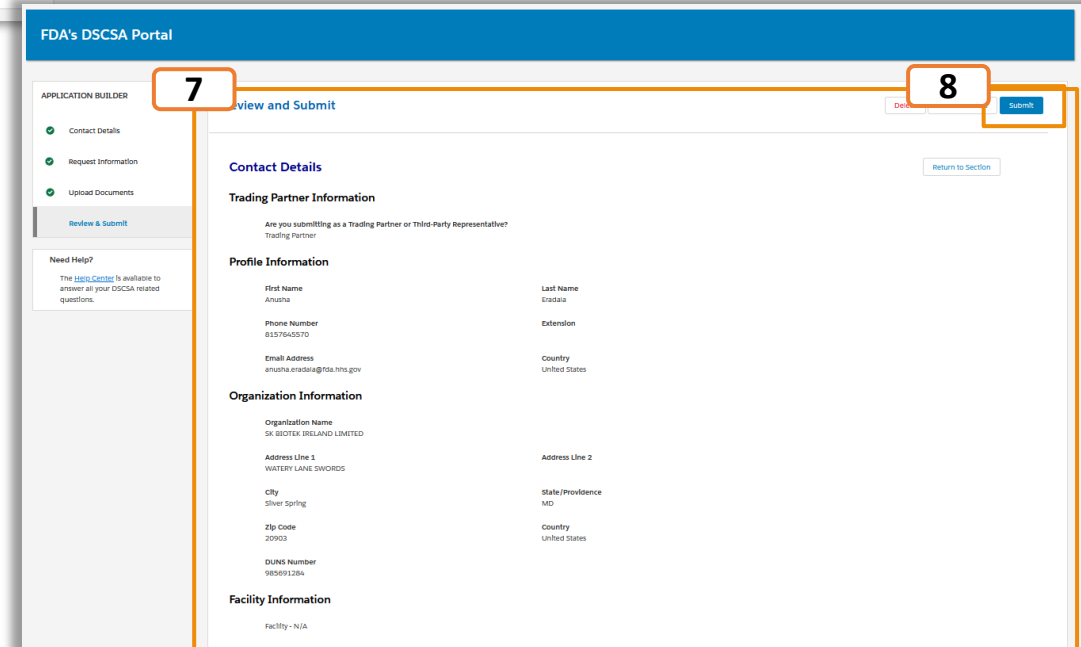
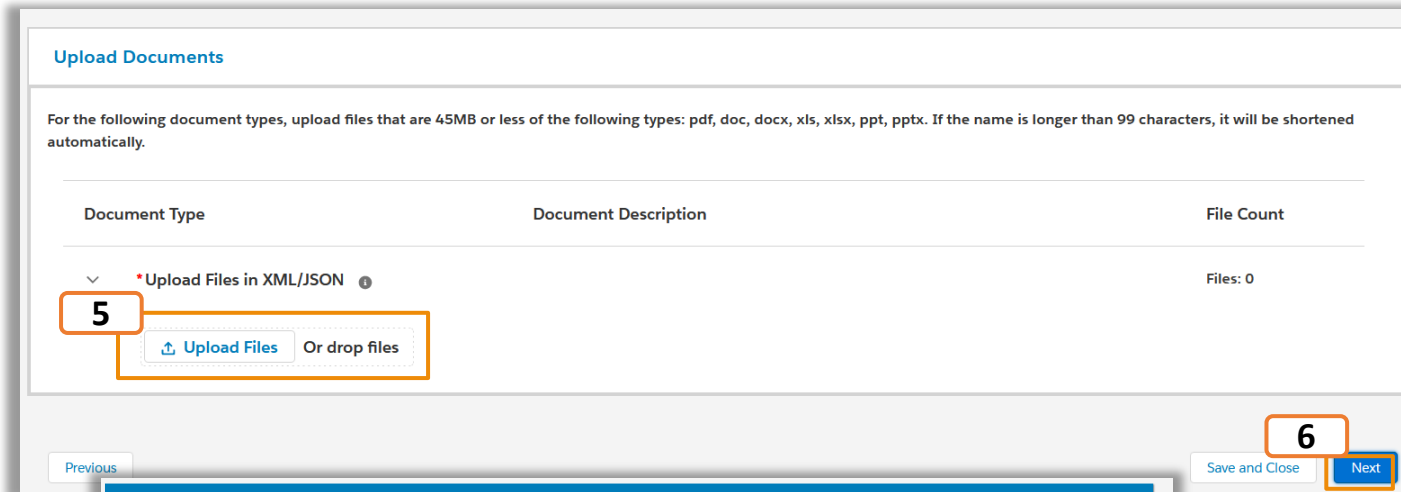
Submitting XML/JSON Files

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.

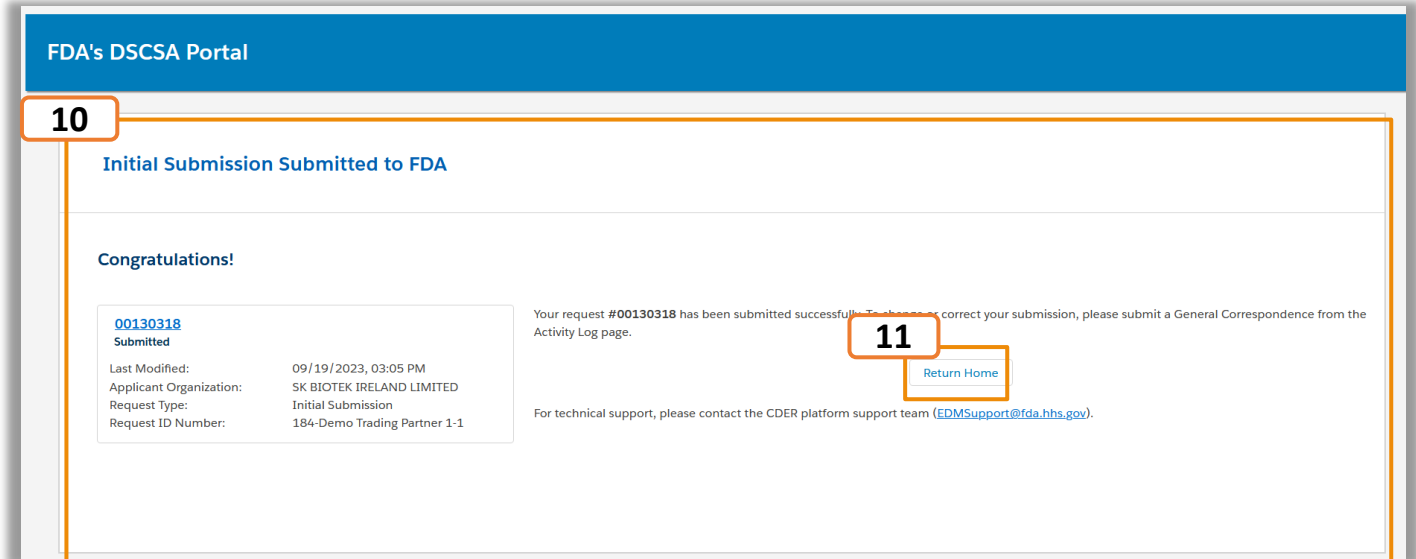
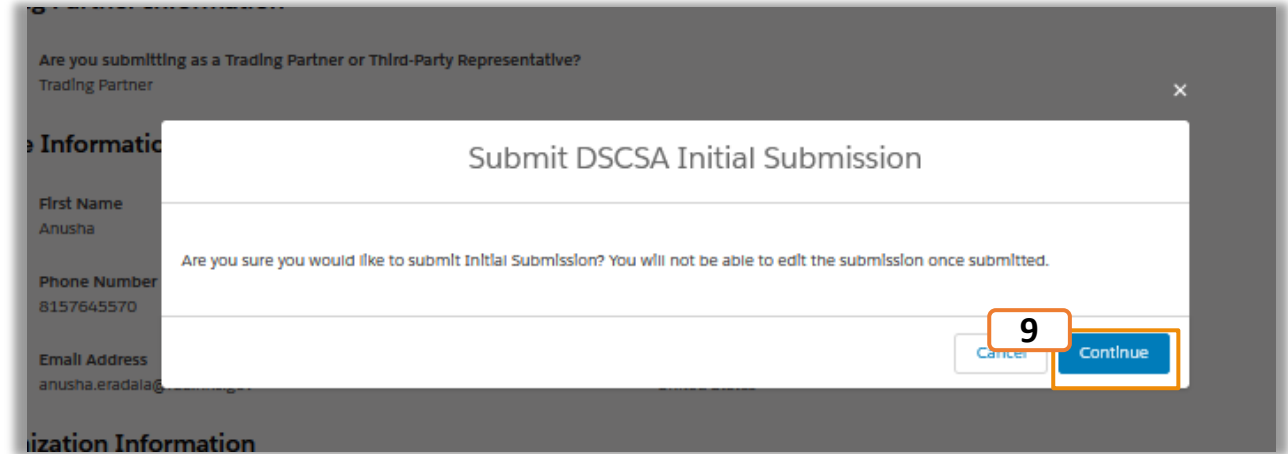


Submitting XML/JSON Files

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 reach out to EDMSupport@fda.hhs.gov.

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FDA U.S. FOOD & DRUG
ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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 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.