CDER Controlled Correspondence

Reference Guide

Click here to access the CDER NextGen Portal.

Click here to email the Center for Drugs and Evaluation and Research (CDER) Center for Office of Generic Drugs (OGD)

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Controlled Correspondence

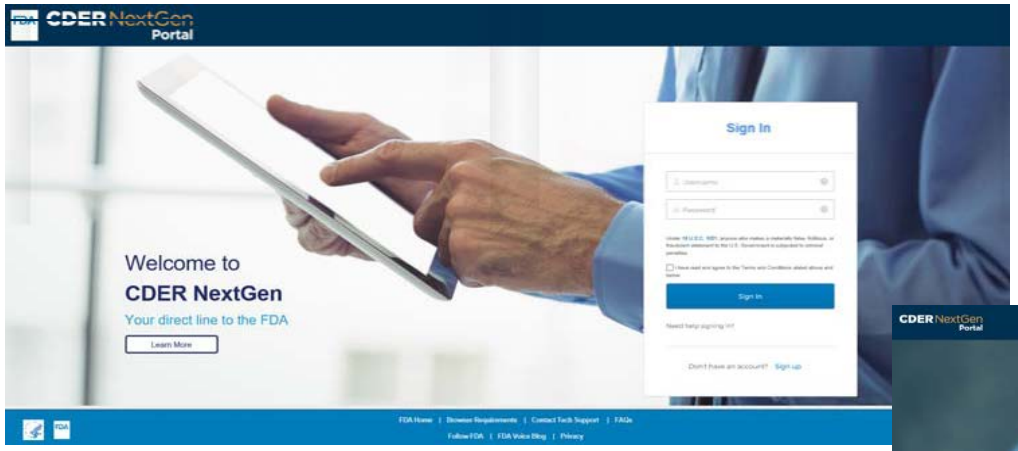
Introduction

Controlled correspondences are submitted to the FDA by external stakeholders seeking information on a specific element of generic drug product development. They are received by a Control Coordinator team within the Office of Regulatory Operations (ORO), a sub-office of the Office of Generic Drugs (OGD). They are then triaged to the appropriate discipline within OGD or the Office of Pharmaceutical Quality (OPQ) for review and response.

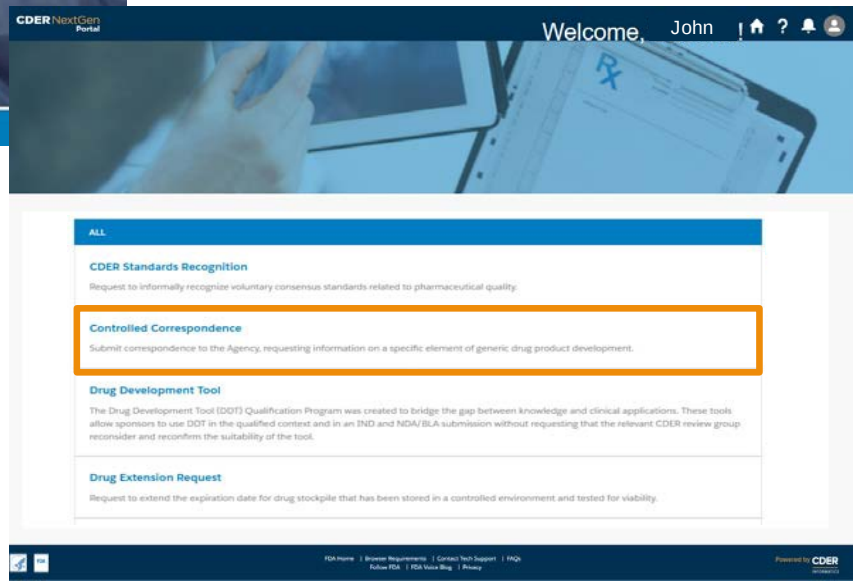
This guide provides the essential information you need to use in the CDER NextGen Portal to create and submit a Controlled Correspondence to the FDA.

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

CDER NextGen Portal Homepage



Step 1. Once you land on the CDER NextGen Portal homepage, Click **Controlled Correspondence** to begin**.**



Controlled Correspondence

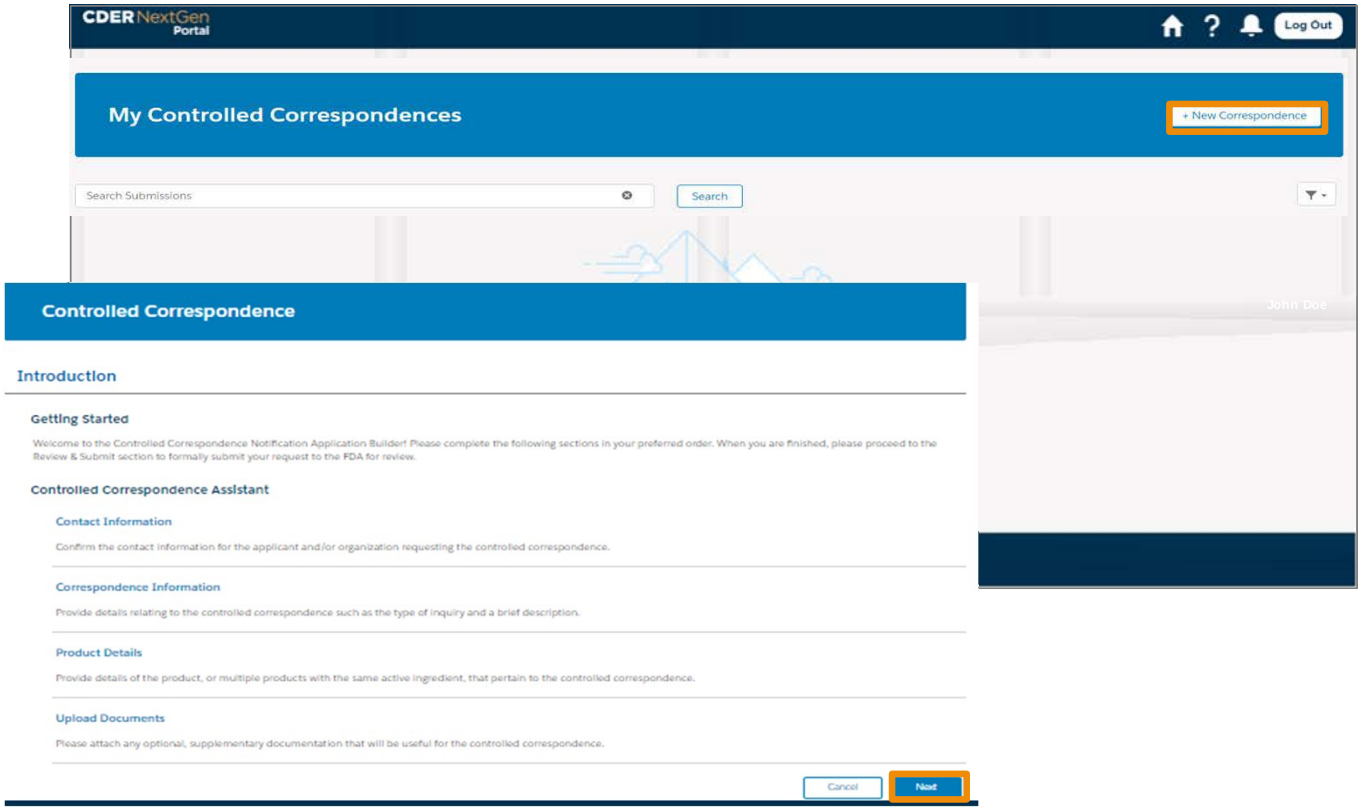
Submit a New Controlled Correspondence

Step 2. Select **New Correspondence** on the top right of your screen.

Step 3. Review the "Getting Started" information for submitting a Controlled Correspondence.

Step 4. Click **Next.**

Keep in mind, if you have previously saved a Correspondence as a draft or submitted a request, you can view it on your Controlled Correspondence landing page.

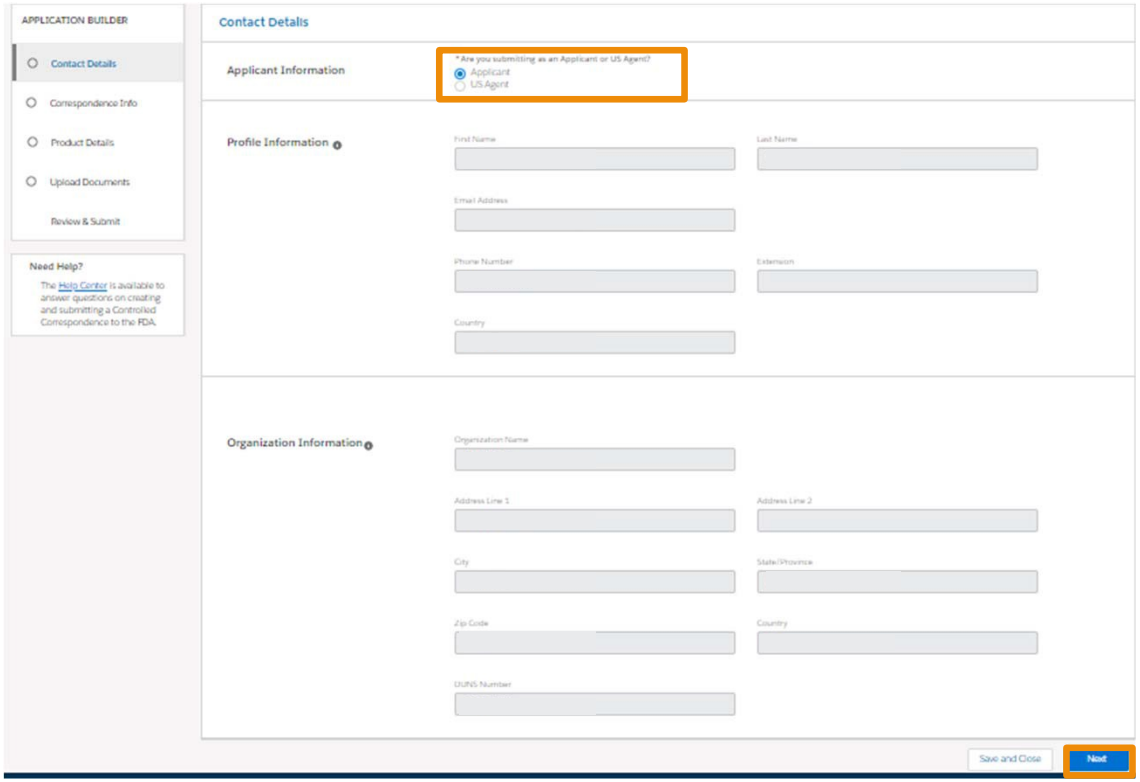


Contact Details

Step 5. Select if you are submitting as an **Applicant** or **U.S. Agent**.

Step 6. If you are submitting as an **Applicant**, review the prepopulated information in the Profile Information and Organization Information sections. Click **Next** and skip to **Step 9**.

If you are submitting as a U.S Agent proceed to **Step 7**.

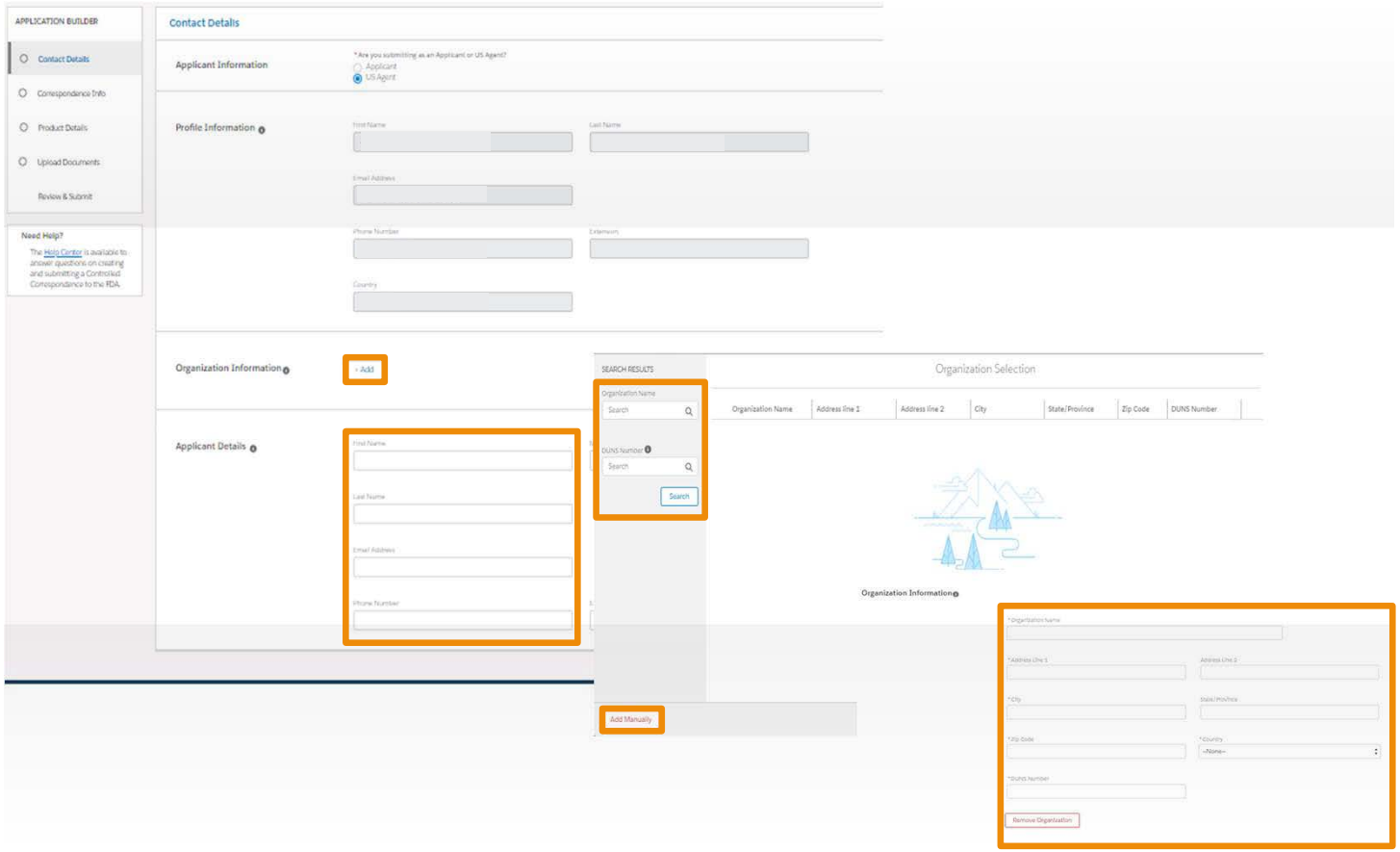


Controlled Correspondence

Contact Details

Step 7. In the Organization Information section click **Add** to search for your organization. You can also manually enter information for your Organization.

Step 8. Proceed to enter the requested Applicant contact information for the U.S. Agent in the Applicant Details section. Note that this step is optional and is not required.



Controlled Correspondence

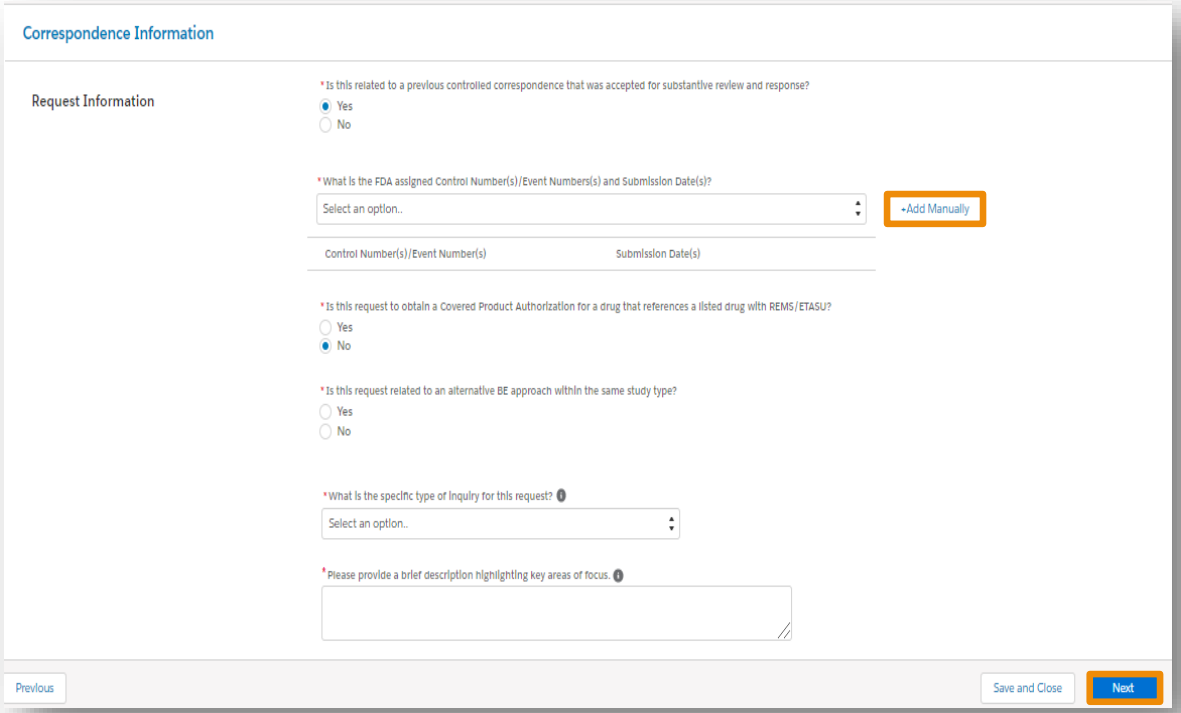
Correspondence Information

Step 9. Select **Yes** or **No** if this is related to a previous controlled corresponded that has been accepted for substance review or response. If **Yes**, Select the FDA Control Number(s)/Event Number(s) and Submission Date from the drop-down or **Add Manually**.

Step 10. Select **Yes** or **No** if this request is to obtain a Covered Product Authorization for a drug that references a listed drug with REMS/ETASU. If you selected **No,** select Yes or No if this is related to an alternative BE approach within the same study type.

Step 11. Select the **specific type** of inquiry from the drop-down menu.

Step 12. Provide a brief description highlighting the key areas of focus and click **Next.**

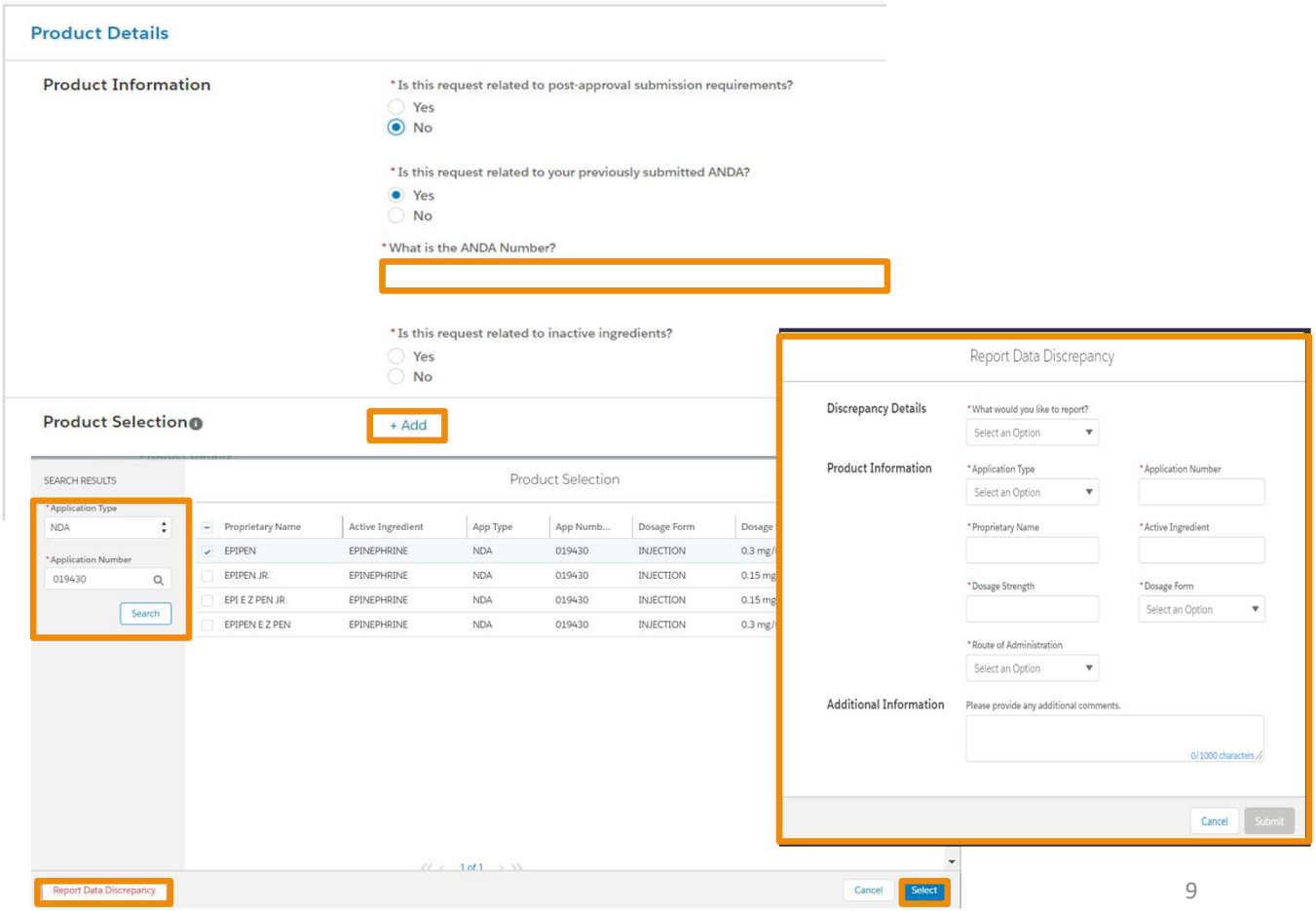


Product Details

Step 13. Select **Yes** or **No** if this request is related to a post-approval submission requirements.

Step 14. If Yes proceed to **Step 15**. If **No**, Select the **Add Icon** in the Product Selection section. From the drop down, select your application type and enter your reference number. Click the appropriate product and press **Select**. Click **Next** to proceed forward.

If your information is not found or if the information is incorrect, click **Report Data Discrepancy** and enter the information requested and click Submit.



Product Details

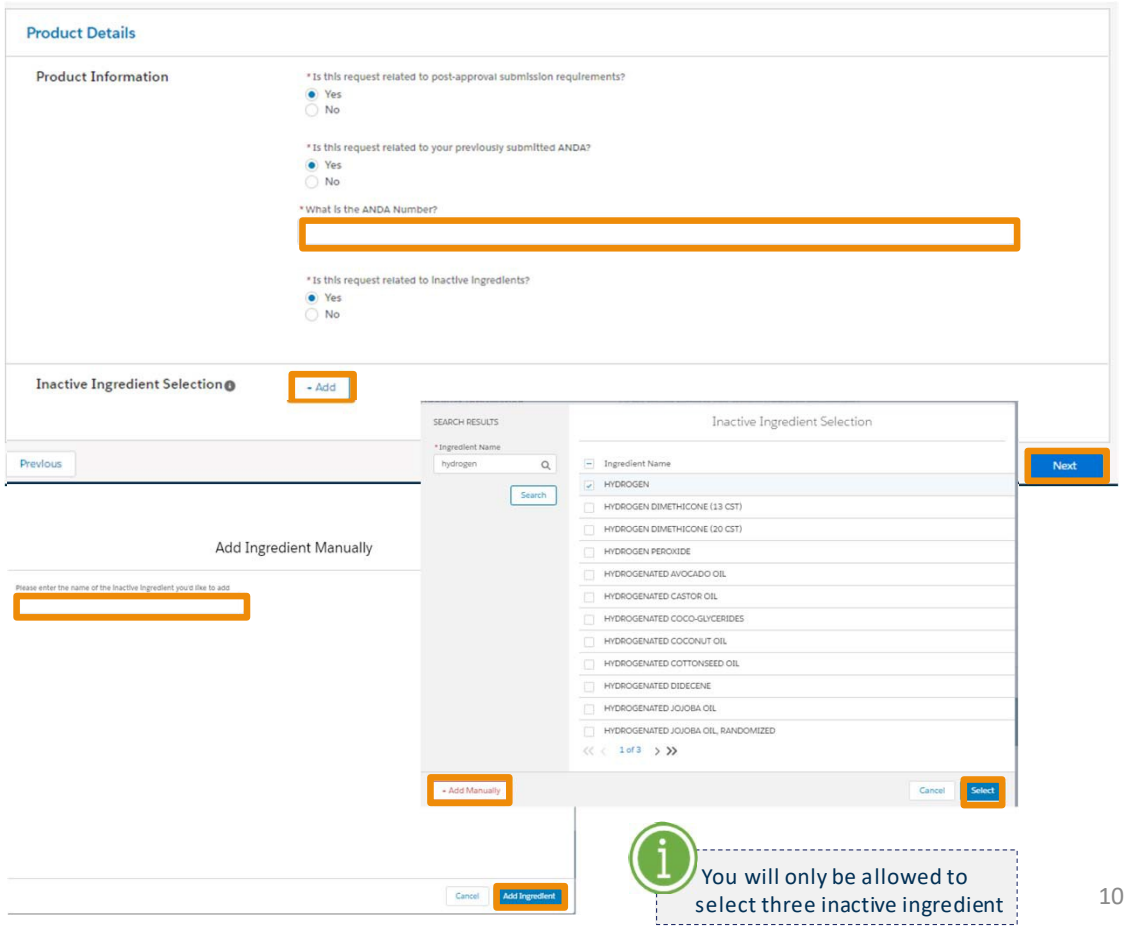
Step 15. Select if this request is related to your previously submitted ANDA. If **Yes**, enter your six-digit ANDA number.

Step 16. Select if this is related to Inactive Ingredients. If **Yes** select the **Add** icon in the Inactive Ingredient Selection section.

Step 17. In the search area, enter ingredient name. **Select** from the list and click **Select**.

Step 18. Click **Add Manually** to manually enter ingredient name. Type the name of inactive ingredient you'd like to add and click **Add Ingredient.**

Step 19. Click **Next**.



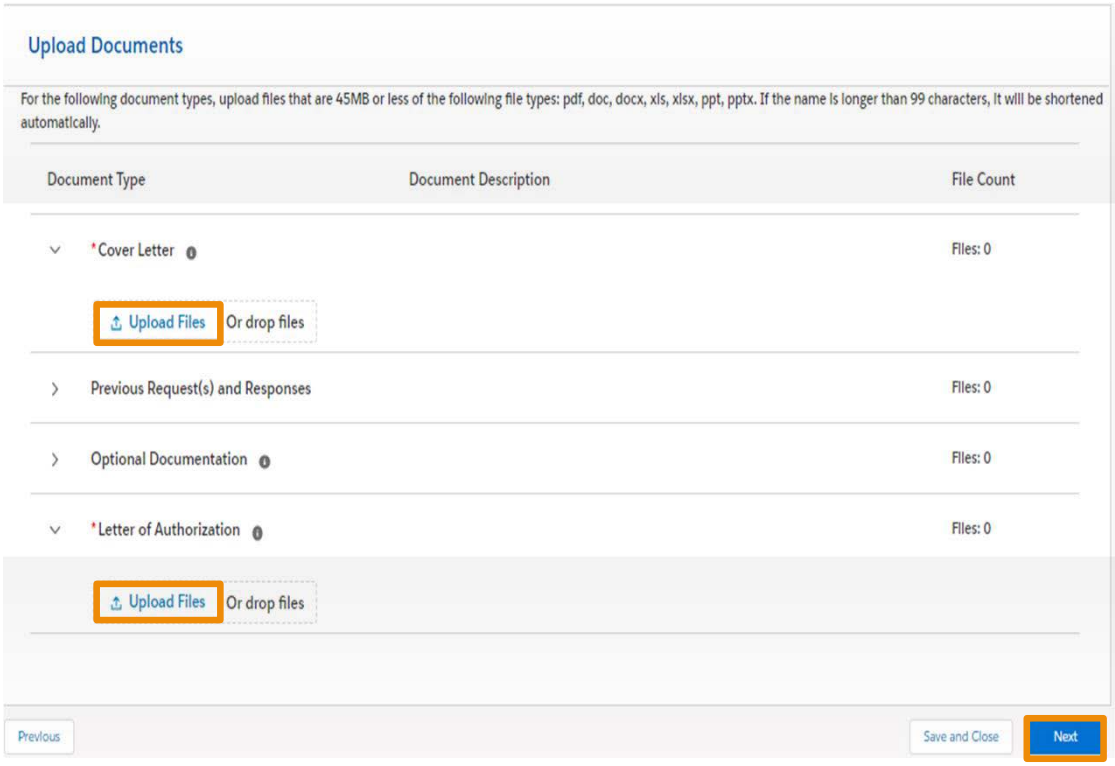
Upload Documents

Step 20. You will be asked to attach a **Cover Letter** for all Controlled Correspondence.

Step 21. Click on the arrow next to **Cover Letter** and click **Upload Files** to upload relevant document.

Step 22. If you are submitting as a **U.S. Agent**, you will also be asked to provide a Letter of Authorization.

Step 23. Click **Next**.



In order to upload any optional documentation, you will be required to provide a document description.

Controlled Correspondence

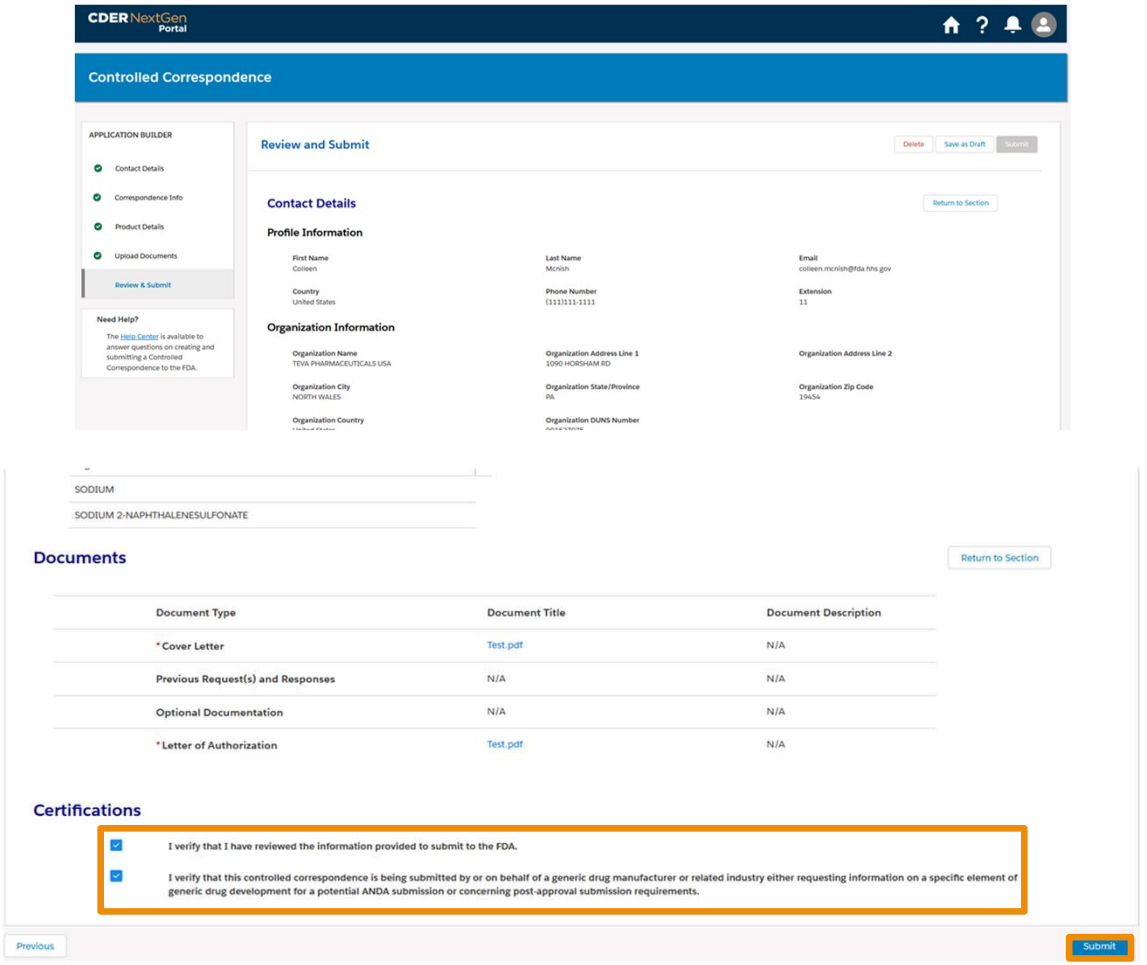
Review and Submit

Step 24. Review your entry for accuracy.

Step 25. Click the check box stating you have reviewed your information.

Step 26. Click the check box verifying that this controlled correspondence is being submitted on behalf of a generic drug manufacturer or related industry.

Step 27. Click **Submit**.



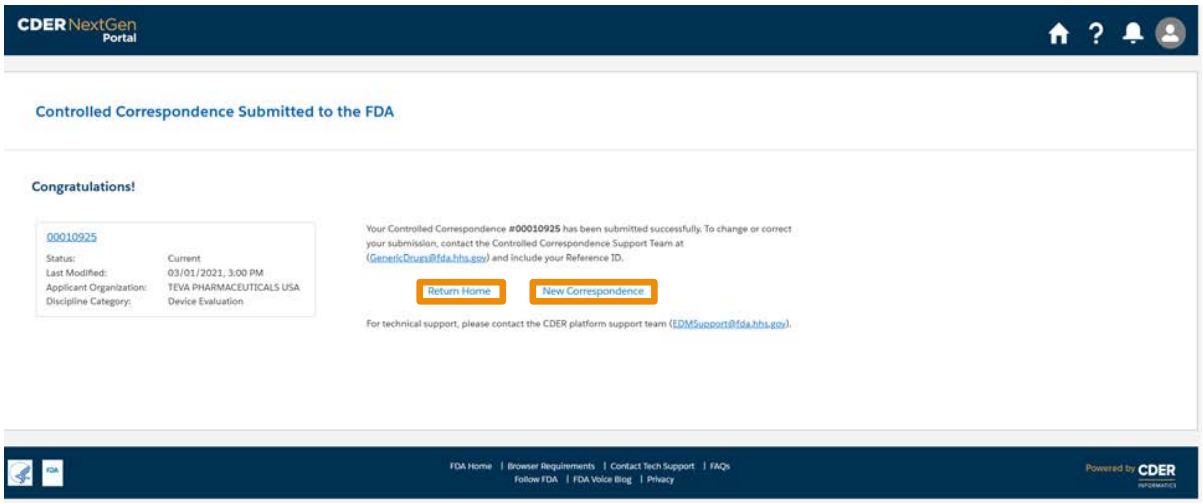
Controlled Correspondence

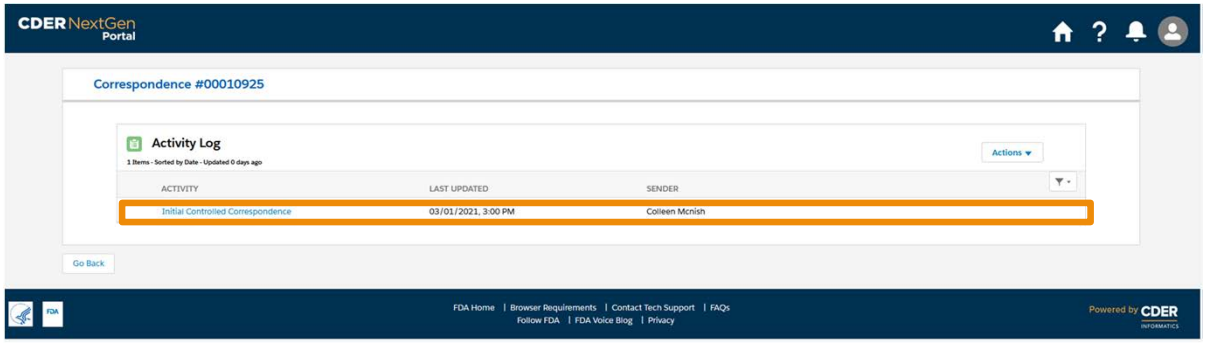
Review and Submit

Step 28. A confirmation message will appear, and a confirmation e-mail will be sent.

Step 29. You can **Return Home** or create a **New Correspondence.**

Step 30. To reference previous submissions, click on the Reference ID number hyperlinked on the landing page card for that specific control submission. You will then be navigated to the **Activity Log** and will be able to select any previously submitted correspondence.





Controlled Correspondence

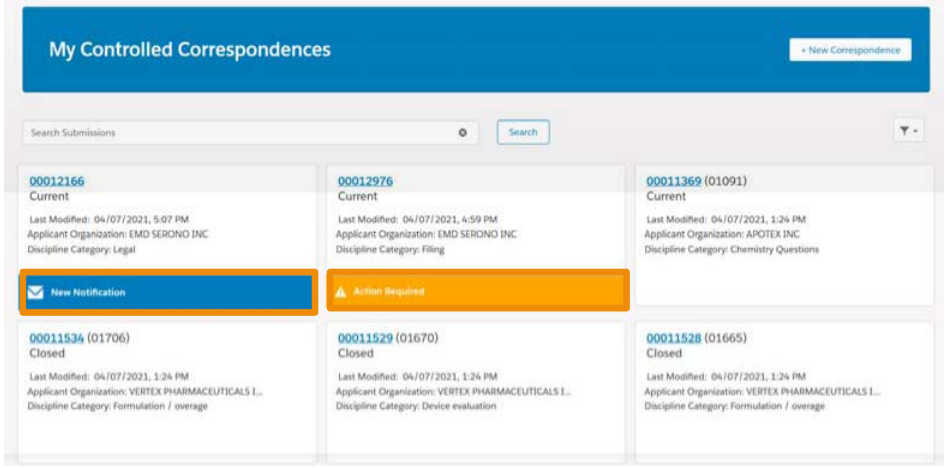
Activity Log

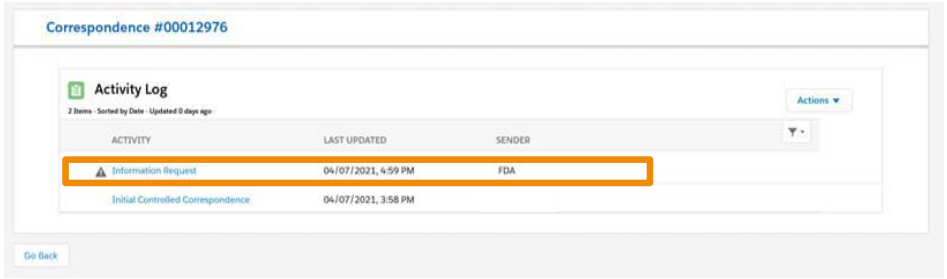
After submitting your Controlled Correspondence, you can view notifications from the FDA on your landing page, as indicated by the following banners:

- **Action Required**
- **New Notification**

Step 1. To view a notification, click on a Controlled Correspondence tile to be redirected to the **Activity Log**:

- An **Action Required** is an **Information Request** from the FDA
- A **New Notification** is the FDA's update or response to the Controlled Correspondence





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

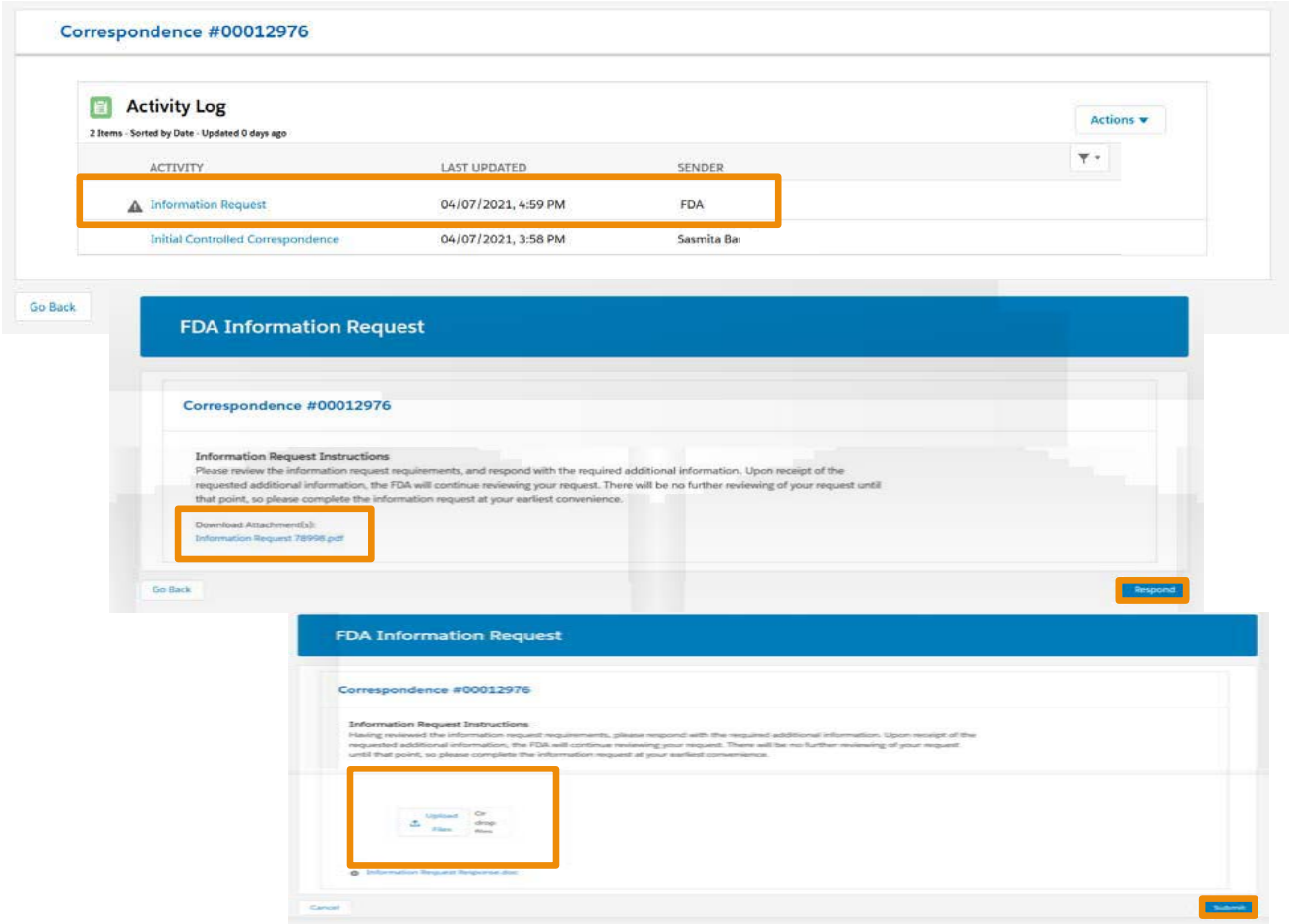
Controlled Correspondence

Information Request

Step 2. Click on the **Information Request** in the Activity Log to view **Information Request** instructions and download attachments.

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

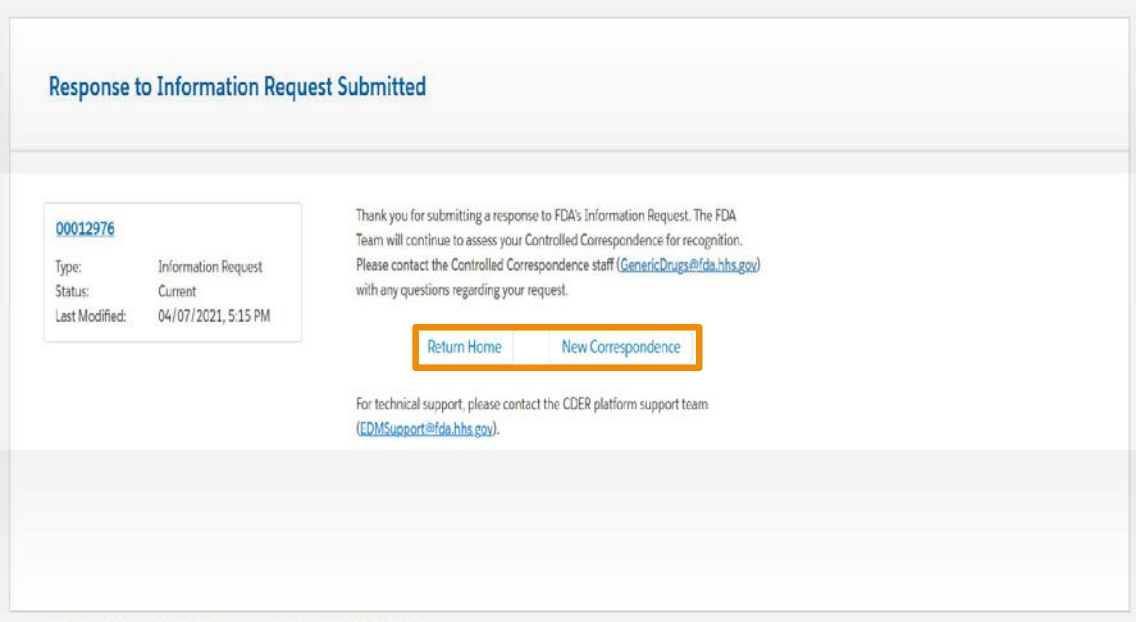
Step 4. Read **Information Request** details and upload relevant files by selecting **Upload Files** to browse your computer and select a file to upload or drop a file into the designated area on the screen and click **Submit**.



Controlled Correspondence

Receiving Notification(s) from FDA

You will view a confirmation screen to confirm your response to the Information Request was submitted to the FDA and receive an email confirming the submission of your Controlled Correspondence Information Request. Please open the confirmation submission email: DoNotReply@fda.hhs.gov and review the information submitted.

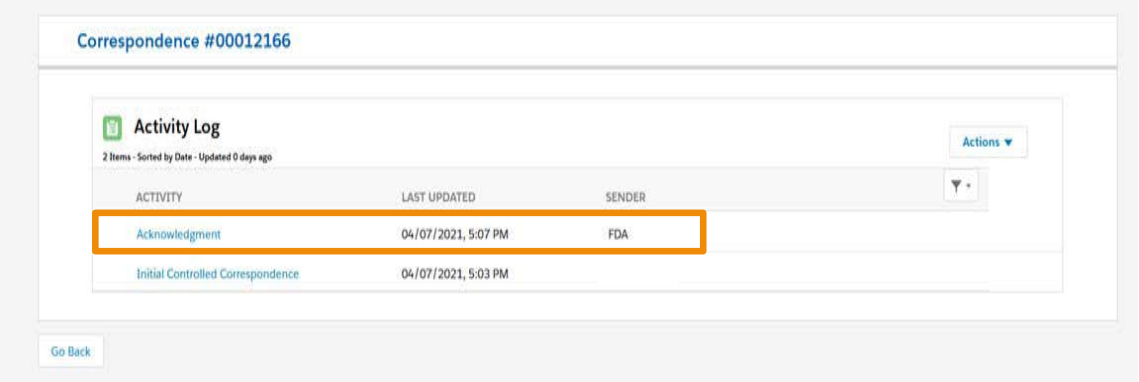


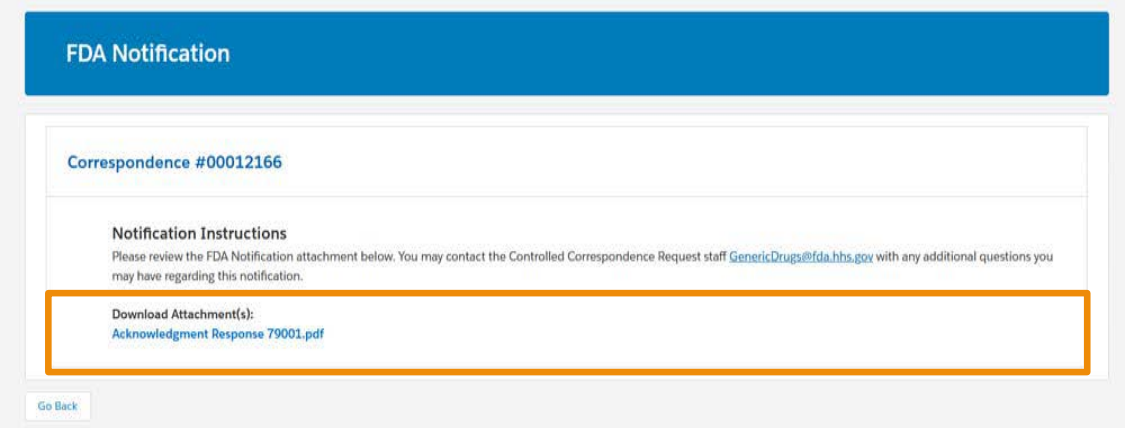
Controlled Correspondence

New Notification

Step 5. Click on the notification in the Activity Log to view the FDA's response to the Controlled Correspondence.

Step 6. Download Attachments to view the FDA's update or response to the Controlled Correspondence.





Controlled Correspondence

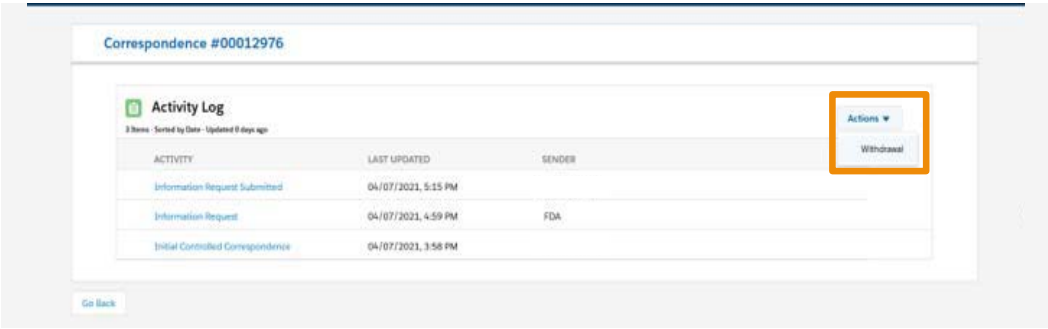
Submitting a Withdrawal

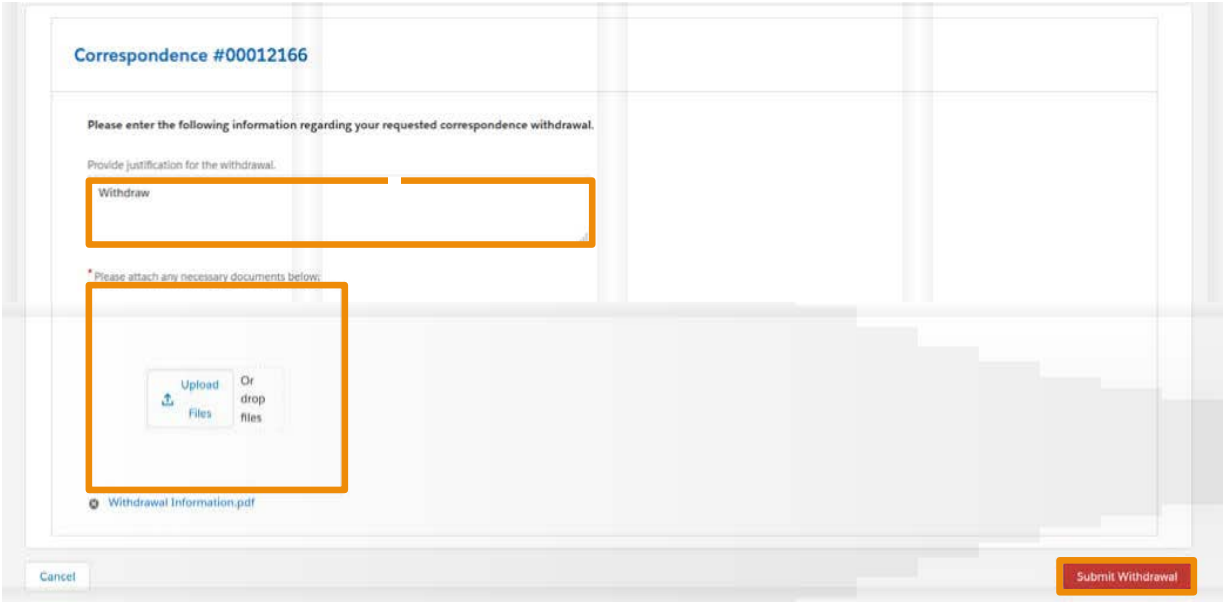
If you would like to **withdraw** your Controlled Correspondence, do the following:

Step 1. Click on the **Actions** dropdown from the Activity Log for your request and click **Withdrawal.**

Step 2. Enter withdrawal information and 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 3. Click **Submit Withdrawal**.

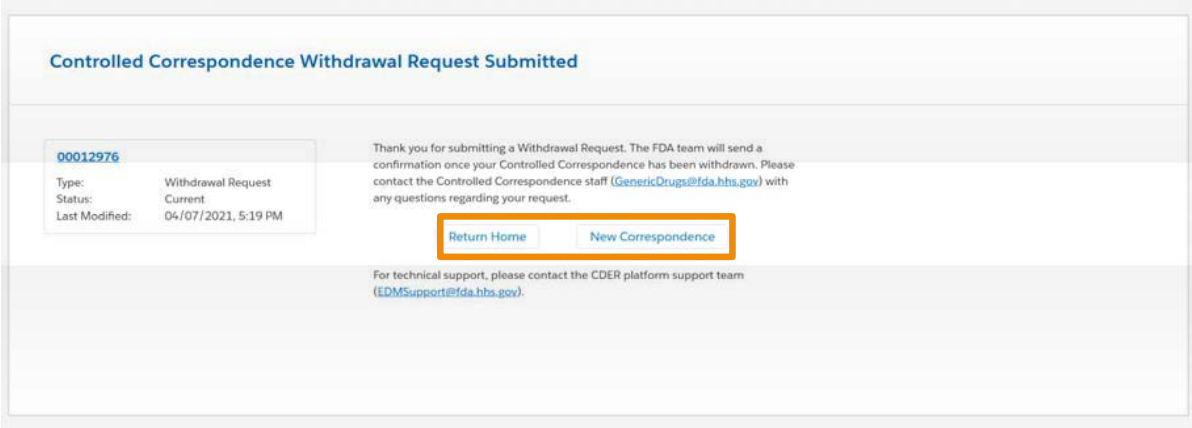


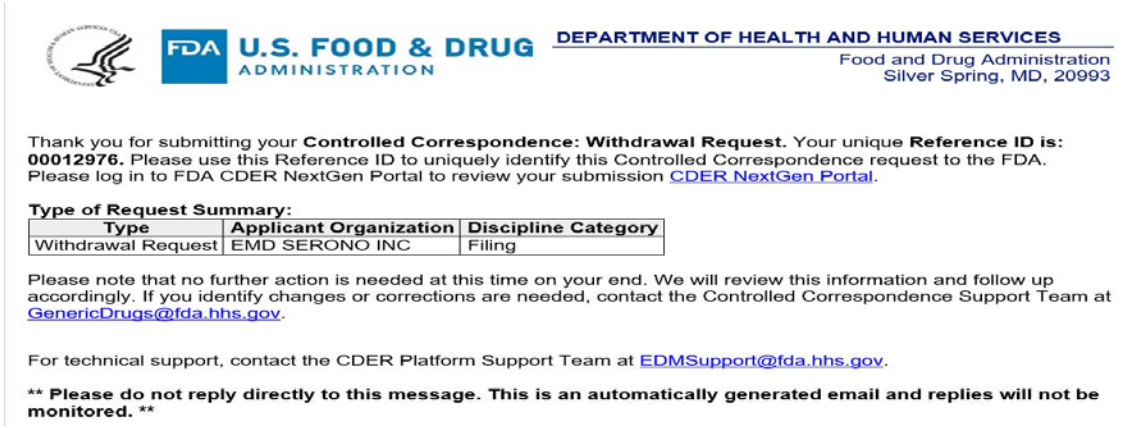


Controlled Correspondence

Receiving Notification(s) from FDA

You will view a confirmation screen to confirm your Controlled Correspondence Withdrawal was submitted to the FDA and receive an email confirming the submission of your Controlled Correspondence Withdrawal. Please open the confirmation submission email: DoNotReply@fda.hhs.gov and Review the information submitted.





U.S. FOOD & DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Silver Spring, MD, 20993

Thank you for submitting your **Controlled Correspondence: Withdrawal Request.** Your unique **Reference ID is: 00012976.** Please use this Reference ID to uniquely identify this Controlled Correspondence request to the FDA. Please log in to FDA CDER NextGen Portal to review your submission CDER NextGen Portal.

Type of Request Summary:

Type	Applicant Organization	Discipline Category
Withdrawal Request	EMD SERONO INC	Filing

Please note that no further action is needed at this time on your end. We will review this information and follow up accordingly. If you identify changes or corrections are needed, contact the Controlled Correspondence Support Team at GenericDrugs@fda.hhs.gov.

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

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

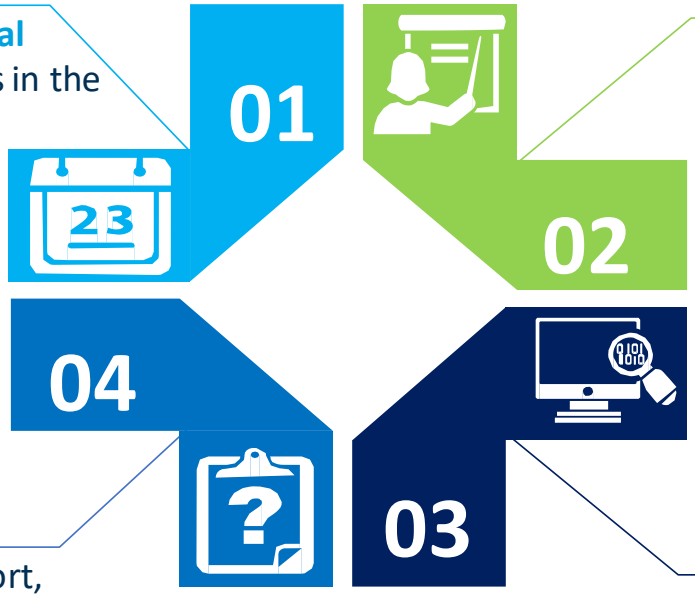
Technical Support and Resources

CDER NextGen Portal Support & Resources

The CDER NextGen Portal has many resources for support.

CDER NextGen Portal Announcements

Your Portal home page contains **portal announcements,** so users are always in the know.



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.**

Technical Support

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

CDER NextGen Portal Video Tutorial

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