

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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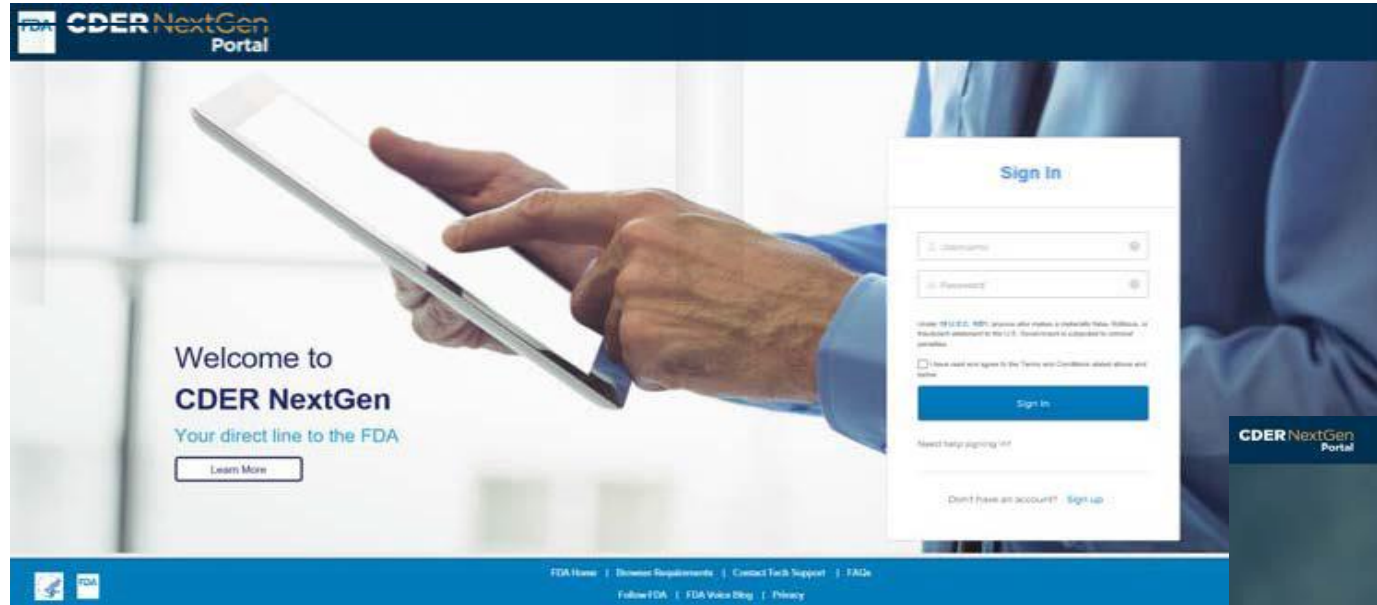
Introduction

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.

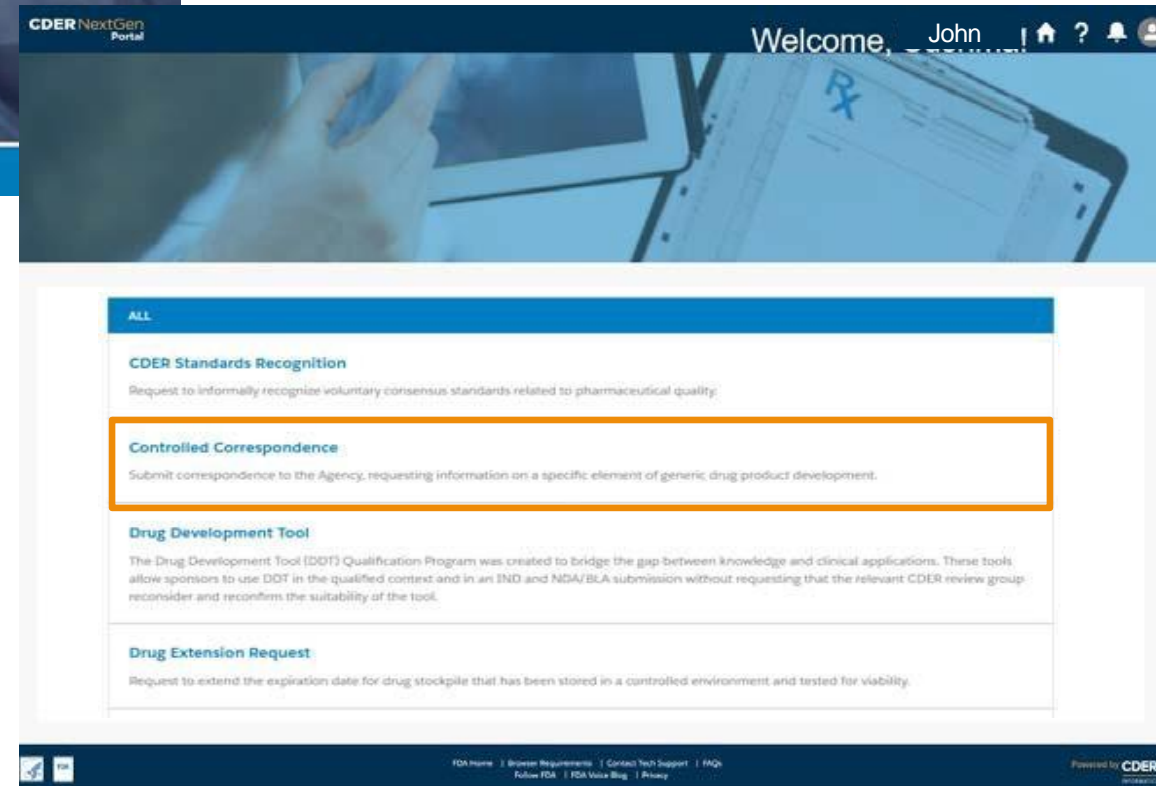
This guide provides the essential information you need to use in the CDER NextGen Portal to create and submit a Controlled Correspondence to the FDA.

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

CDER NextGen Portal Homepage



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



- ALL**
- CDER Standards Recognition**
Request to informally recognize voluntary consensus standards related to pharmaceutical quality.
- Controlled Correspondence**
Submit correspondence to the Agency, requesting information on a specific element of generic drug product development.
- Drug Development Tool**
The Drug Development Tool (DDT) Qualification Program was created to bridge the gap between knowledge and clinical applications. These tools allow sponsors to use DDT in the qualified context and in an IND and NDA/BLA submission without requesting that the relevant CDER review group reconsider and reconfirm the suitability of the tool.
- Drug Extension Request**
Request to extend the expiration date for drug stockpile that has been stored in a controlled environment and tested for viability.

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**.

APPLICATION BUILDER

- Contact Details
- Correspondence Info
- Product Details
- Upload Documents
- Review & Submit

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

Contact Details

Applicant Information

*Are you submitting as an Applicant or US Agent?
 Applicant
 US Agent

Profile Information

First Name: [Text Field] Last Name: [Text Field]

Email Address: [Text Field]

Phone Number: [Text Field] Extension: [Text Field]

Country: [Text Field]

Organization Information

Organization Name: [Text Field]

Address Line 1: [Text Field] Address Line 2: [Text Field]

City: [Text Field] State/Province: [Text Field]

Zip Code: [Text Field] Country: [Text Field]

DUNS Number: [Text Field]

Save and Close **Next**

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.

The screenshot displays the 'Contact Details' section of the FDA Application Builder. On the left sidebar, 'Contact Details' is selected. The main area is divided into several sections:

- Applicant Information:** Includes a question '*Are you submitting as an Applicant or US Agent?' with radio buttons for 'Applicant' and 'US Agent' (selected).
- Profile Information:** Contains input fields for 'First Name', 'Last Name', 'Email Address', 'Phone Number', 'Extension', and 'Country'.
- Organization Information:** Features an '+ Add' button to initiate a search.
- Applicant Details:** Contains input fields for 'First Name', 'Last Name', 'Email Address', and 'Phone Number'.

A search results overlay is active, showing a table with columns: Organization Name, Address line 1, Address line 2, City, State/Province, Zip Code, and DUNS Number. The overlay includes search input fields for 'Organization Name' and 'DUNS Number', and a 'Search' button. Below the table, there is an 'Add Manually' button.

A detailed view of the organization information form is shown in a separate box, highlighting the following fields: Organization Name, Address Line 1, Address Line 2, City, State/Province, Zip Code, Country (with a dropdown menu), and DUNS Number. A 'Remove Organization' button is located at the bottom of this form.

Correspondence Information

Step 9. Select **Yes** or **No** if this is related to a previous controlled correspondence 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**.

Correspondence Information

Request Information

* Is this related to a previous controlled correspondence that was accepted for substantive review and response?

Yes
 No

* What is the FDA assigned Control Number(s)/Event Numbers(s) and Submission Date(s)?

Select an option..

Control Number(s)/Event Number(s)	Submission Date(s)
-----------------------------------	--------------------

* Is this request to obtain a Covered Product Authorization for a drug that references a listed drug with REMS/ETASU?

Yes
 No

* Is this request related to an alternative BE approach within the same study type?

Yes
 No

* What is the specific type of Inquiry for this request? ⓘ

Select an option..

* Please provide a brief description highlighting key areas of focus. ⓘ

Previous

Controlled Correspondence

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

Product Information

* Is this request related to post-approval submission requirements?
 Yes
 No

* Is this request related to your previously submitted ANDA?
 Yes
 No

* What is the ANDA Number?

* Is this request related to inactive ingredients?
 Yes
 No

Product Selection + Add

SEARCH RESULTS

* Application Type
 NDA

* Application Number
 019430

Search

Proprietary Name	Active Ingredient	App Type	App Num...	Dosage Form	Dosage
<input checked="" type="checkbox"/> EPIPEN	EPINEPHRINE	NDA	019430	INJECTION	0.3 mg/...
<input type="checkbox"/> EPIPEN JR.	EPINEPHRINE	NDA	019430	INJECTION	0.15 mg/...
<input type="checkbox"/> EPI E Z PEN JR.	EPINEPHRINE	NDA	019430	INJECTION	0.15 mg/...
<input type="checkbox"/> EPIPEN E Z PEN	EPINEPHRINE	NDA	019430	INJECTION	0.3 mg/...

Report Data Discrepancy

Discrepancy Details *What would you like to report?

Product Information

* Application Type * Application Number

* Proprietary Name * Active Ingredient

* Dosage Strength * Dosage Form

* Route of Administration

Additional Information Please provide any additional comments.

0/1000 characters

Cancel Submit

Report Data Discrepancy
Select

Controlled Correspondence

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**.

The screenshot displays the 'Product Details' form with the following sections and highlighted elements:

- Product Information:**
 - * Is this request related to post-approval submission requirements? (Yes selected)
 - * Is this request related to your previously submitted ANDA? (Yes selected)
 - * What is the ANDA Number? (Empty text input field)
 - * Is this request related to Inactive Ingredients? (Yes selected)
- Inactive Ingredient Selection:**
 - Add (Highlighted button)
- Search Results Modal:**
 - SEARCH RESULTS
 - * Ingredient Name: hydrogen
 - Search button
 - Ingredient list:
 - HYDROGEN
 - HYDROGEN DIMETHICONE (13 CST)
 - HYDROGEN DIMETHICONE (20 CST)
 - HYDROGEN PEROXIDE
 - HYDROGENATED AVOCADO OIL
 - HYDROGENATED CASTOR OIL
 - HYDROGENATED COCO-GLYCERIDES
 - HYDROGENATED COCONUT OIL
 - HYDROGENATED COTTONSEED OIL
 - HYDROGENATED DIDECENE
 - HYDROGENATED JOJOBA OIL
 - HYDROGENATED JOJOBA OIL, RANDOMIZED
 - Navigation: << 1 of 3 >>
 - Add Manually (Highlighted button)
 - Cancel (Highlighted button)
 - Select (Highlighted button)
- Manual Entry Section:**
 - Add Ingredient Manually
 - Please enter the name of the inactive ingredient you'd like to add (Empty text input field)
 - Cancel (Highlighted button)
 - Add Ingredient (Highlighted button)
- Next Step:** Next (Highlighted button)

Information: You will only be allowed to select three inactive ingredient

Controlled Correspondence

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**.

Upload Documents

For the following document types, upload files that are 45MB or less of the following file 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
▼ *Cover Letter ⓘ		Files: 0
<div style="border: 1px dashed #ccc; padding: 2px; display: inline-block;"> 📁 Upload Files Or drop files </div>		
> Previous Request(s) and Responses		Files: 0
> Optional Documentation ⓘ		Files: 0
▼ *Letter of Authorization ⓘ		Files: 0
<div style="border: 1px dashed #ccc; padding: 2px; display: inline-block;"> 📁 Upload Files Or drop files </div>		

Previous
Save and Close
Next

i
 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**.

The screenshot shows the 'Controlled Correspondence' review and submit page in the CDER NextGen Portal. The page is divided into several sections:

- APPLICATION BUILDER:** A sidebar on the left with a progress indicator showing 'Contact Details', 'Correspondence Info', 'Product Details', and 'Upload Documents' as completed steps. The 'Review & Submit' step is currently active.
- Review and Submit:** The main content area, featuring a 'Delete', 'Save as Draft', and 'Submit' button bar at the top right.
- Contact Details:** A section with a 'Return to Section' button. It contains two sub-sections:
 - Profile Information:** Fields for First Name (Colleen), Last Name (McNish), Email (colleen.mcnish@fda.hhs.gov), Country (United States), and Phone Number ((111)111-1111).
 - Organization Information:** Fields for Organization Name (TEVA PHARMACEUTICALS USA), Organization Address Line 1 (1090 HORSHAM RD), Organization Address Line 2, Organization City (NORTH WALES), Organization State/Province (PA), Organization Zip Code (19454), and Organization DUNS Number.
- Documents:** A section with a 'Return to Section' button. It contains a table with the following data:

Document Type	Document Title	Document Description
* Cover Letter	Test.pdf	N/A
Previous Request(s) and Responses	N/A	N/A
Optional Documentation	N/A	N/A
* Letter of Authorization	Test.pdf	N/A
- Certifications:** A section with two checked checkboxes:
 - I verify that I have reviewed the information provided to submit to the FDA.
 - I verify that this controlled correspondence is being submitted by or on behalf of a generic drug manufacturer or related industry either requesting information on a specific element of generic drug development for a potential ANDA submission or concerning post-approval submission requirements.

At the bottom of the page, there are 'Previous' and 'Submit' buttons.

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.

CDER NextGen Portal

Controlled Correspondence Submitted to the FDA

Congratulations!

[00010925](#)

Status:	Current
Last Modified:	03/01/2021, 3:00 PM
Applicant Organization:	TEVA PHARMACEUTICALS USA
Discipline Category:	Device Evaluation

Your Controlled Correspondence #00010925 has been submitted successfully. To change or correct your submission, contact the Controlled Correspondence Support Team at GenericDrugs@fda.hhs.gov and include your Reference ID.

[Return Home](#) [New Correspondence](#)

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

[FDA Home](#) | [Browser Requirements](#) | [Contact Tech Support](#) | [FAQs](#)
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CDER NextGen Portal

Correspondence #00010925

Activity Log

1 Items - Sorted by Date - Updated 0 days ago

ACTIVITY	LAST UPDATED	SENDER
Initial Controlled Correspondence	03/01/2021, 3:00 PM	Colleen Mcnish

[Go Back](#)

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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

My Controlled Correspondences New Correspondence

Search Submissions

<p>00012166 Current</p> <p>Last Modified: 04/07/2021, 5:07 PM Applicant Organization: EMD SERONO INC Discipline Category: Legal</p> <p>New Notification</p>	<p>00012976 Current</p> <p>Last Modified: 04/07/2021, 4:59 PM Applicant Organization: EMD SERONO INC Discipline Category: Filing</p> <p>Action Required</p>	<p>00011369 (01091) Current</p> <p>Last Modified: 04/07/2021, 1:24 PM Applicant Organization: APOTEX INC Discipline Category: Chemistry Questions</p>
<p>00011534 (01706) Closed</p> <p>Last Modified: 04/07/2021, 1:24 PM Applicant Organization: VERTEX PHARMACEUTICALS L... Discipline Category: Formulation / overage</p>	<p>00011529 (01670) Closed</p> <p>Last Modified: 04/07/2021, 1:24 PM Applicant Organization: VERTEX PHARMACEUTICALS L... Discipline Category: Device evaluation</p>	<p>00011528 (01665) Closed</p> <p>Last Modified: 04/07/2021, 1:24 PM Applicant Organization: VERTEX PHARMACEUTICALS L... Discipline Category: Formulation / overage</p>

Correspondence #00012976

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

ACTIVITY	LAST UPDATED	SENDER
Information Request	04/07/2021, 4:59 PM	FDA
Initial Controlled Correspondence	04/07/2021, 3:58 PM	

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**.

The screenshots illustrate the process of responding to an information request:

- Top Screenshot:** Shows the 'Correspondence #00012976' page with an 'Activity Log' table. The 'Information Request' entry is highlighted with an orange box. The table has columns for 'ACTIVITY', 'LAST UPDATED', and 'SENDER'.

ACTIVITY	LAST UPDATED	SENDER
Information Request	04/07/2021, 4:59 PM	FDA
Initial Controlled Correspondence	04/07/2021, 3:58 PM	Sasmita Ba
- Middle Screenshot:** Shows the 'FDA Information Request' page with 'Information Request Instructions' and a 'Download Attachment(s): Information Request 76996.pdf' link highlighted with an orange box. A 'Respond' button is visible at the bottom right.
- Bottom Screenshot:** Shows the 'FDA Information Request' page with the 'Information Request Instructions' and an 'Upload Files' button highlighted with an orange box. A 'Submit' button is visible at the bottom right.

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.

The screenshot shows a confirmation page titled "Response to Information Request Submitted". On the left, there is a box with the ID "00012976" and the following details:

Type:	Information Request
Status:	Current
Last Modified:	04/07/2021, 5:15 PM

On the right, the text reads: "Thank you for submitting a response to FDA's Information Request. The FDA Team will continue to assess your Controlled Correspondence for recognition. Please contact the Controlled Correspondence staff (GenericDrugs@fda.hhs.gov) with any questions regarding your request." Below this text are two buttons: "Return Home" and "New Correspondence". At the bottom, it says: "For technical support, please contact the CDER platform support team (EDMSupport@fda.hhs.gov)." The buttons and the bottom text are highlighted with a light blue background.

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.

Correspondence #00012166

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

ACTIVITY	LAST UPDATED	SENDER
Acknowledgment	04/07/2021, 5:07 PM	FDA
Initial Controlled Correspondence	04/07/2021, 5:03 PM	

Go Back

FDA Notification

Correspondence #00012166

Notification Instructions
Please review the FDA Notification attachment below. You may contact the Controlled Correspondence Request staff GenericDrugs@fda.hhs.gov with any additional questions you may have regarding this notification.

Download Attachment(s):
[Acknowledgment Response 79001.pdf](#)

Go Back

Controlled Correspondence

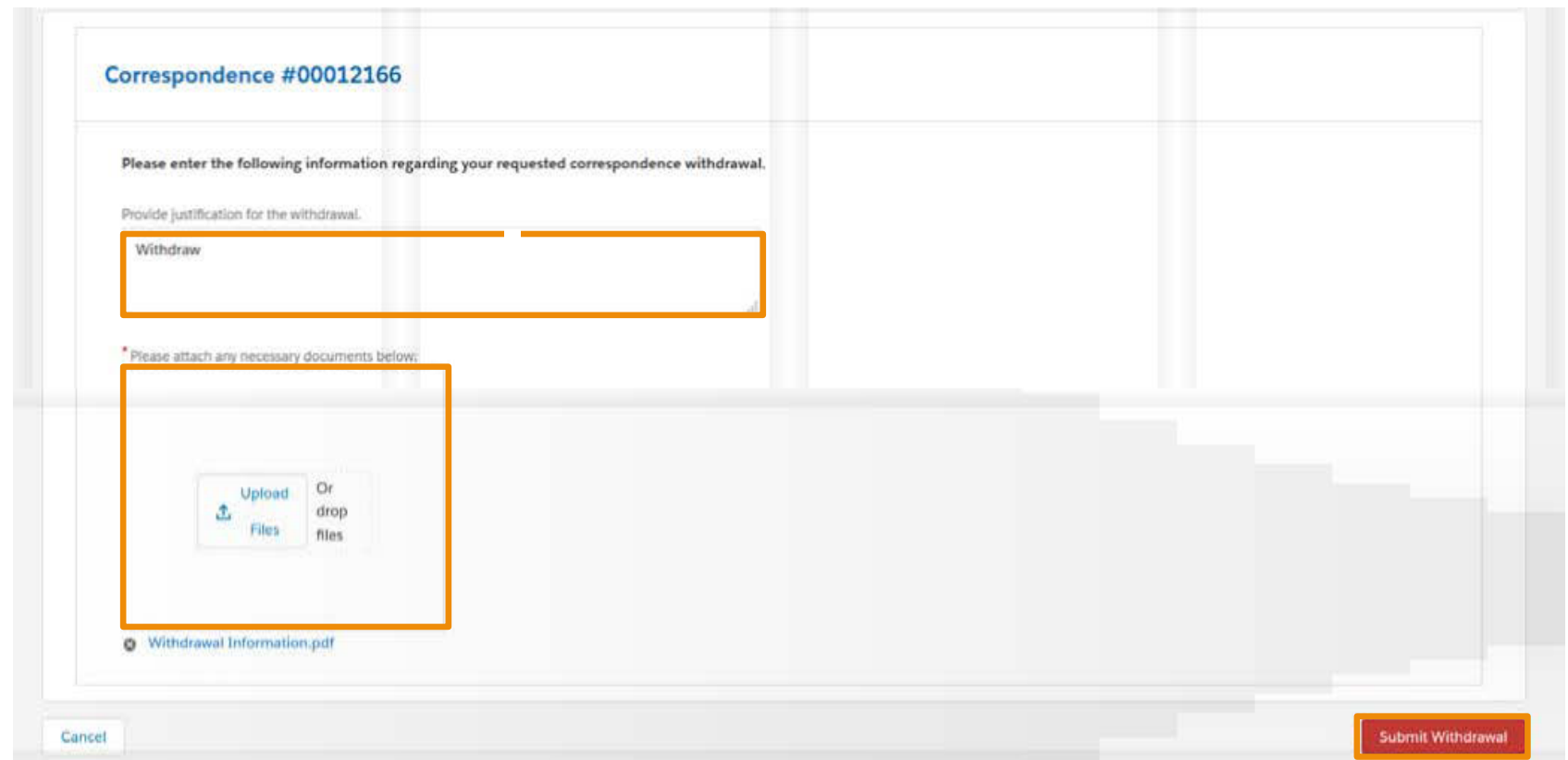
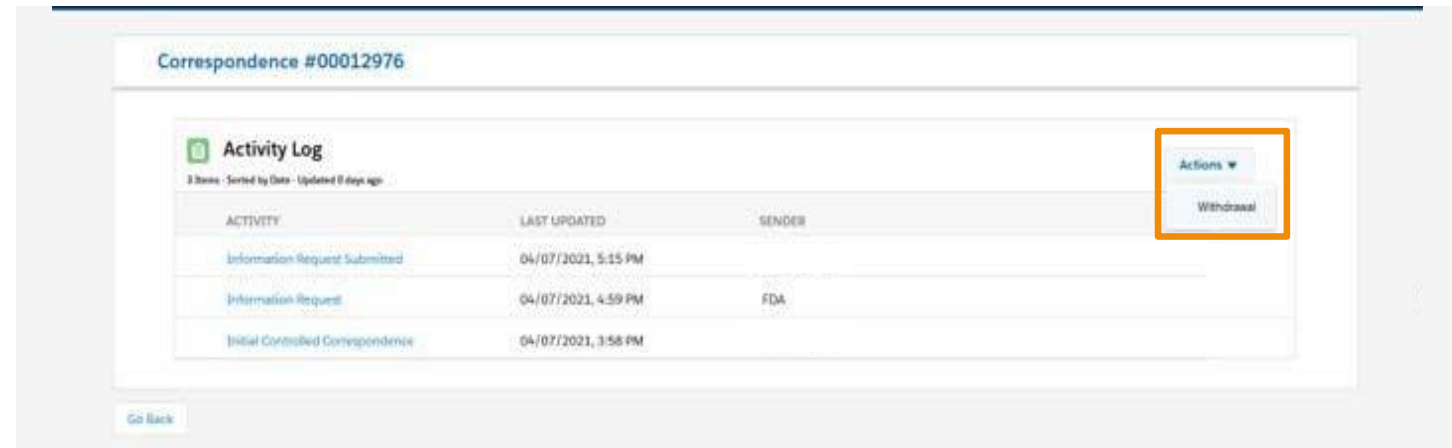
Submitting a Withdrawal

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**.

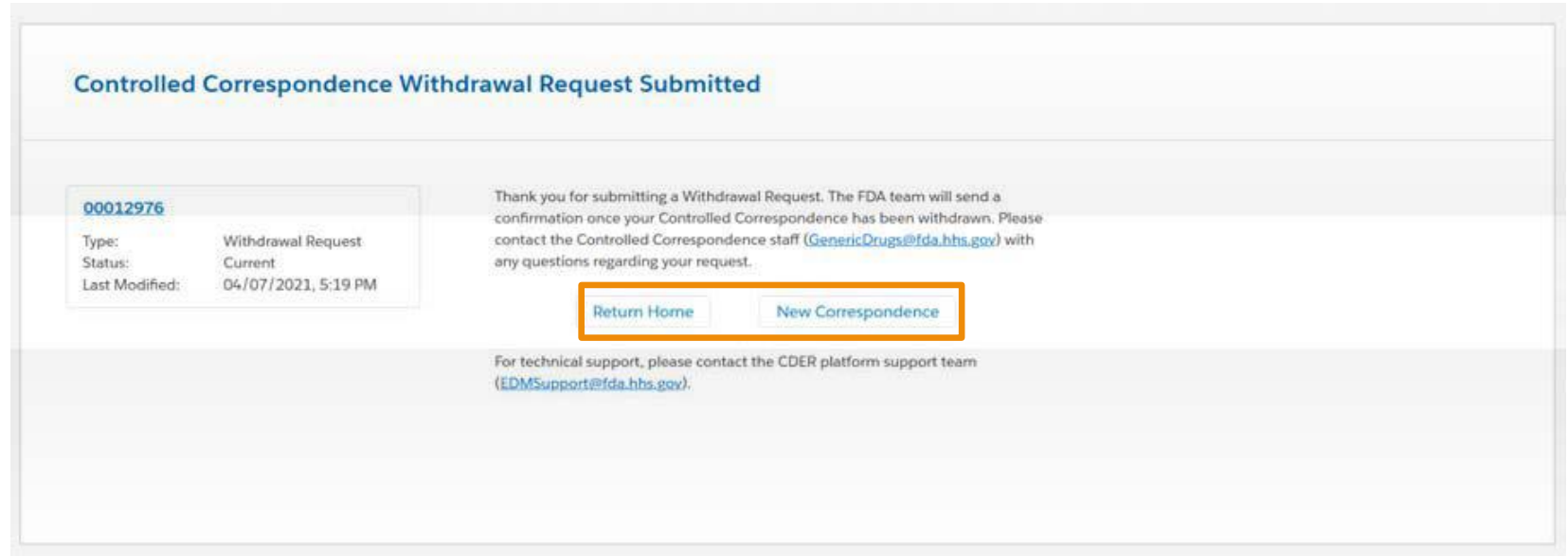
Step 2. Enter withdrawal information and upload relevant files by selecting **Upload Files** to browse your computer and select a file to upload or drop a file into the designated area on the screen.

Step 3. Click **Submit Withdrawal**.



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.



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 **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. ****

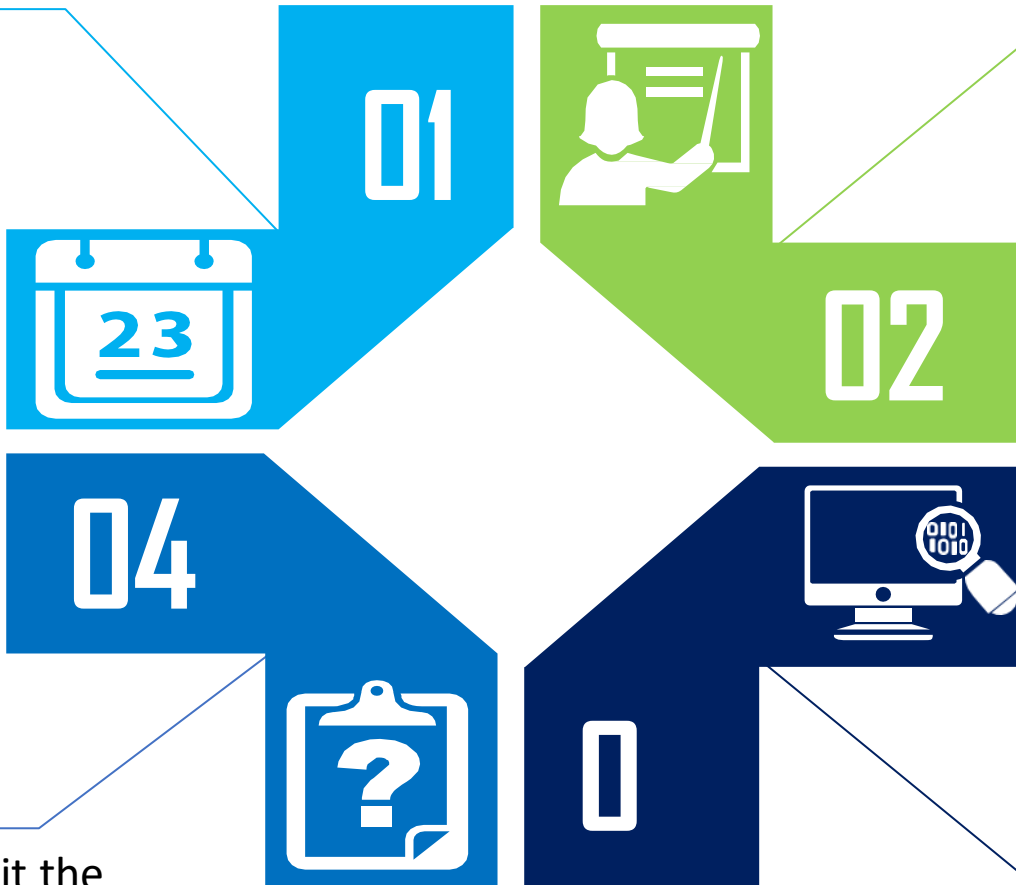
Technical Support and Resources

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 [NextGen Portal Help Center](#) that provides links to the Resource Center, which includes **Reference Guides and FAQs**.

Technical Support

For all technical support, contact visit the [NextGen Portal Help Center](#)

CDER NextGen Portal Video Tutorial

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