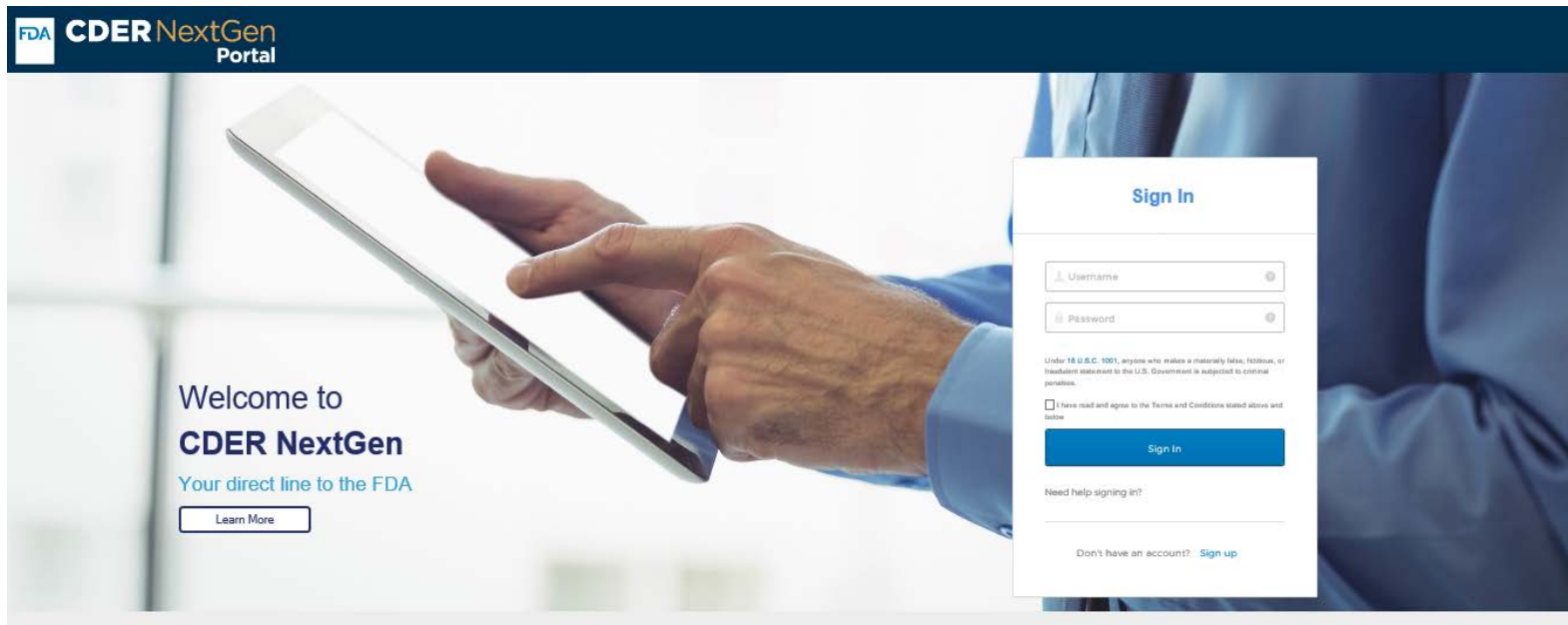


CDER Controlled Correspondence Reference Guide



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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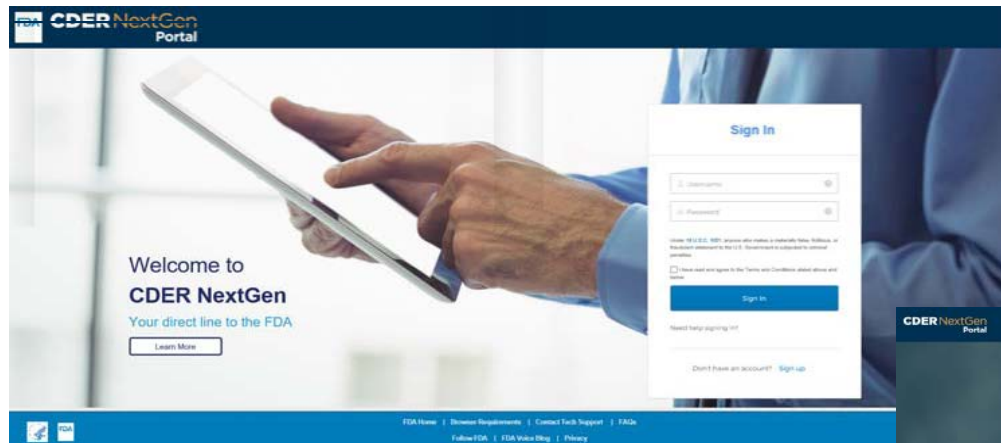
Introduction

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.

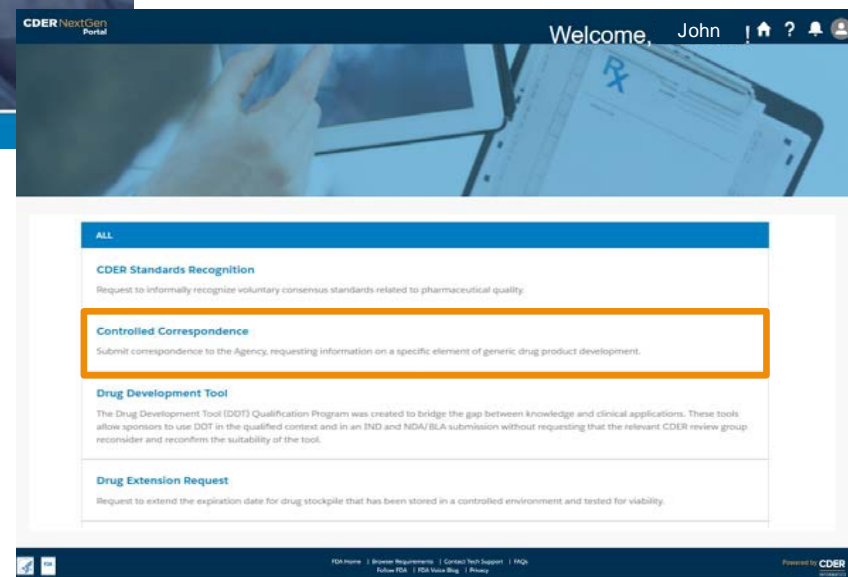
This guide provides the essential information you need to use in the CDER NextGen Portal to create and submit a Controlled Correspondence to the FDA.

For technical assistance, 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.

The screenshot displays the CDER NextGen Portal interface. At the top, the header includes the CDER NextGen Portal logo, navigation icons (home, help, notifications), and a 'Log Out' button. Below the header, a blue banner reads 'My Controlled Correspondences' with a '+ New Correspondence' button highlighted in orange. A search bar is visible below the banner. The main content area shows a 'Controlled Correspondence' section with an 'Introduction' tab. Under 'Introduction', there is a 'Getting Started' section with a welcome message and a 'Controlled Correspondence Assistant' section. The assistant has four sections: 'Contact Information', 'Correspondence Information', 'Product Details', and 'Upload Documents', each with a brief description. At the bottom right, there are 'Cancel' and 'Next' buttons, with the 'Next' button highlighted in orange.

Controlled Correspondence



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**.

The screenshot shows the 'APPLICATION BUILDER' interface for 'Contact Details'. On the left is a sidebar with a 'Need Help?' section. The main form area is titled 'Contact Details' and contains two sections: 'Applicant Information' and 'Profile Information'. In the 'Applicant Information' section, there is a question: '*Are you submitting as an Applicant or U.S. Agent?'. Below this question are two radio buttons: 'Applicant' (which is selected and highlighted with an orange box) and 'U.S. Agent'. The 'Profile Information' section contains several input fields: 'First Name', 'Last Name', 'Email Address', 'Phone Number', 'Extension', and 'Country'. Below this is the 'Organization Information' section, which includes input fields for 'Organization Name', 'Address Line 1', 'Address Line 2', 'City', 'State/Province', 'Zip Code', 'Country', and 'DUNS Number'. At the bottom right of the form are two buttons: 'Save and Close' and 'Next' (which is highlighted with an orange box).

APPLICATION BUILDER

Contact Details

Applicant Information

*Are you submitting as an Applicant or U.S. Agent?

☒ Applicant

☐ U.S. Agent

Profile Information

First Name

Last Name

Email Address

Phone Number

Extension

Country

Organization Information

Organization Name

Address Line 1

Address Line 2

City

State/Province

Zip Code

Country

DUNS Number

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.

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 Last Name

Email Address

Phone Number Extension

Country

Organization Information **Add**

Applicant Details

First Name

Last Name

Email Address

Phone Number

SEARCH RESULTS

Organization Name Search

DUNS Number Search

Organization Selection

Organization Name	Address Line 1	Address Line 2	City	State/Province	Zip Code	DUNS Number
-------------------	----------------	----------------	------	----------------	----------	-------------

Add Manually

Organization Information

Organization Name

Address Line 1 Address Line 2

City State/Province

Zip Code Country

DUNS Number

Controlled Correspondence



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 Number(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 Save and Close Next

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.

The screenshot displays the FDA Controlled Correspondence form. The **Product Details** section includes questions about post-approval submission requirements and previous ANDA submissions, with radio button options for Yes or No. A text field for the ANDA Number is highlighted with an orange box. The **Product Selection** section features a table of search results for EpiPen products. A search filter on the left is highlighted with an orange box. An orange box around the **+ Add** button indicates the next step. A **Report Data Discrepancy** modal is open, showing fields for application type, name, strength, and route, with a text area for additional comments. The **Report Data Discrepancy** button at the bottom left is also highlighted with an orange box.

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/l
<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/l

Report Data Discrepancy

Discrepancy Details

* What would you like to report?
Select an Option

Product Information

* Application Type
Select an Option

* Application Number

* Proprietary Name

* Active Ingredient

* Dosage Strength

* Dosage Form
Select an Option

* Route of Administration
Select an Option

Additional Information

Please provide any additional comments.

0/1000 characters

Cancel Submit

Report Data Discrepancy

Cancel 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**.

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**.



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

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><div>Upload Files</div>Or drop files</div>		
> Previous Request(s) and Responses		Files: 0
> Optional Documentation ⓘ		Files: 0
▼ *Letter of Authorization ⓘ		Files: 0
<div><div>Upload Files</div>Or drop files</div>		

Previous

Save and Close

Next

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**.

CDERNextGenPortal

Controlled Correspondence

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.

Review and Submit

Deny

Save as Draft

Submit

Contact Details

Return to Section

Profile Information

First Name

Coleen

Last Name

Murkin

Email

coleen.murkin@fda.hhs.gov

Country

United States

Phone Number

(313)313-1133

Extension

11

Organization Information

Organization Name

TEVA PHARMACEUTICALS USA

Organization Address Line 1

1090 HOBBSHAM RD

Organization State/Province

PA

Organization Zip Code

19454

Organization City

NORTH WALES

Organization DUNS Number

123456789

Organization Country

United States

SODIUM

SODIUM 2-NAPHTHALENESULFONATE

Documents

Return to Section

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

☒

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.

Previous

Submit

12

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.

The screenshot shows the CDER NextGen Portal with a dark blue header. The main content area has a title 'Controlled Correspondence Submitted to the FDA' and a 'Congratulations!' message. A box on the left displays the Reference ID '00010925' and submission details: Status: Current, Last Modified: 03/01/2023, 3:00 PM, Applicant Organization: TEVA PHARMACEUTICALS USA, and Discipline Category: Device Evaluation. A message on the right states that the correspondence has been submitted successfully and provides contact information for the support team. Two buttons, 'Return Home' and 'New Correspondence', are highlighted with orange boxes. A footer bar contains links to FDA Home, Browser Requirements, Contact Tech Support, FAQs, Follow FDA, FDA Voice Blog, and Privacy, along with a 'Powered by CDER' logo.

The screenshot shows the CDER NextGen Portal with a dark blue header. The main content area has a title 'Correspondence #00010925' and an 'Activity Log' section. The activity log shows a table with three columns: ACTIVITY, LAST UPDATED, and SENDER. The first row is highlighted with an orange box and contains the text 'Initial Controlled Correspondence', '03/01/2023, 3:00 PM', and 'Colleen McNish'. A 'Go Back' button is located below the table. A footer bar contains links to FDA Home, Browser Requirements, Contact Tech Support, FAQs, Follow FDA, FDA Voice Blog, and Privacy, along with a 'Powered by CDER' logo.

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

The screenshot shows the 'My Controlled Correspondences' dashboard with a grid of correspondence tiles. The first tile (00012166) is marked 'Current' and has a 'New Notification' banner. The second tile (00012976) is marked 'Current' and has an 'Action Required' banner. The third tile (00011369) is marked 'Current'. Below these are three 'Closed' tiles. The bottom section shows the 'Activity Log' for correspondence #00012976, which contains two items: an 'Information Request' from the FDA dated 04/07/2021, 4:59 PM, and an 'Initial Controlled Correspondence' dated 04/07/2021, 3:58 PM. The 'Information Request' item is highlighted with an orange border.

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 image displays three overlapping screenshots of the FDA Information Request web interface. The top screenshot shows the 'Correspondence #00012976' page with an 'Activity Log' table. The table has columns for 'ACTIVITY', 'LAST UPDATED', and 'SENDER'. The first row, 'Information Request', is highlighted with an orange border. Below it is a row for 'Initial Controlled Correspondence'. The middle screenshot shows the 'FDA Information Request' page with 'Information Request Instructions' and a link to 'Download Attachment(s): Information Request 78996.pdf', which is highlighted with an orange border. The bottom screenshot shows the same page with the 'Upload Files' button highlighted by an orange border. The interface includes 'Go Back' and 'Respond' buttons, and a 'Submit' button at the bottom right.

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

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.

Response to Information Request Submitted

00012976

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

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.

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

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

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	

Actions

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**.

Correspondence #00012976

Activity Log

3 Items - Sorted by Date - Updated 8 days ago

ACTIVITY	LAST UPDATED	SENDER
Information Request Submitted	04/07/2021, 5:15 PM	
Information Request	04/07/2021, 4:59 PM	FDA
Initial Controlled Correspondence	04/07/2021, 3:58 PM	

Go Back

Actions ▾

Withdrawal

Correspondence #00012166

Please enter the following information regarding your requested correspondence withdrawal.

Provide justification for the withdrawal.

Withdraw

* Please attach any necessary documents below:

Upload Files Or drop files

Withdrawal Information.pdf

Cancel

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.

Controlled Correspondence Withdrawal Request Submitted

00012976

Type: Withdrawal Request
Status: Current
Last Modified: 04/07/2021, 5:19 PM

Thank you for submitting a Withdrawal Request. The FDA team will send a confirmation once your Controlled Correspondence has been withdrawn. Please contact the Controlled Correspondence staff (GenericDrugs@fda.hhs.gov) with any questions regarding your request.

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

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



**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 “**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.