

Reference Guide: Over-the-Counter Monograph Order Request (OMOR)



Table of Contents

Introduction	<u>3</u>
Welcome to CDER NextGen Portal	
CDER NextGen Portal Homepage	<u>4</u>
Logging into the CDER NextGen Portal	
Over-the-Counter (OTC) Monograph	<u>6</u>
Navigating to the OTC Monograph Application	
Submitting an OMOR	
Appendix	<u>53</u>
Monograph File Application Statuses	
Technical Support Resources	<u>55</u>
CDER NextGen Portal Support & Resources	

Introduction

Welcome to CDER NextGen Portal

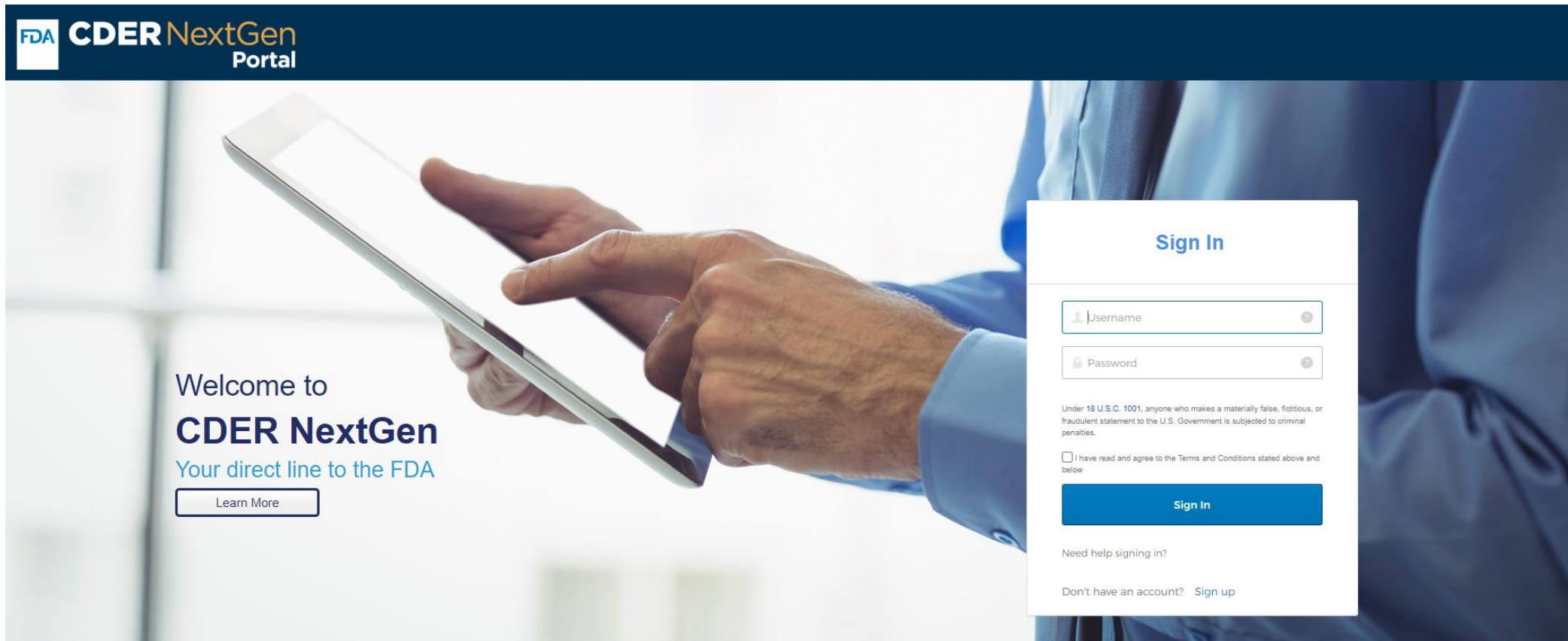
This guide provides the essential information you need to submit an Over-the-Counter Monograph Order Request (OMOR) in the CDER NextGen Portal. The sections described below cover navigating into the OTC Monograph application and submitting your request. For technical support, email CDER Platform Support staff at edmsupport@fda.hhs.gov.

CDER NextGen Portal Homepage

Logging into the CDER NextGen Portal

This section describes how to complete the first step in the OMOR submission process: Logging into the CDER NextGen Portal.

Step 1. Log into your CDER NextGen Portal account by accessing: <https://edm.fda.gov>. For technical support, email CDER Platform Support staff at edmsupport@fda.hhs.gov.



Over-the-Counter (OTC) Monograph – OMOR

Navigating to the OTC Monograph Application

This section describes how to complete the next step in the OMOR submission process: Navigating to the OTC Monograph application.

Step 2. From the Homepage, click **Over-the-Counter (OTC) Monograph**.

Orphan Drugs

Submit information regarding Orphan Drugs

Over-the-Counter (OTC) Monograph

Submit certain OTC Monograph submissions.

Pre-Launch Activities Importation Requests

Submit a Pre-launch activities importation request (PLAIR) to FDA. FDA grants PLAIRs in certain circumstances to allow product sponsors anticipating approval of a drug application to import unapproved finished drug products to prepare for market launch. For more information about PLAIR, please follow this [link](#)

Submitting an OMOR

This section describes how to complete the next step in the OMOR submission process: Initiating an OMOR.

Step 3. The next screen is the Over-the-Counter Monograph landing page. Click on the **MGF application card** you would like to submit an OMOR under.

The screenshot shows the CDER NextGen Portal interface. At the top left is the logo "CDER NextGen Portal". On the top right are navigation icons for home, help, notifications, and user profile. Below the header is a blue banner with the text "Over-the-Counter Monograph" and a "+ New Submission" button. A red warning message is displayed: "Warning: Under 18 U.S.C. 1001, it is illegal to knowingly and willfully make a materially false, fictitious, or fraudulent statement or representation in any matter within FDA's jurisdiction." Below the warning is a search bar with the placeholder "Search MGF Number" and a "Search" button. A dropdown menu is visible on the right side of the search bar. The main content area displays a card for "MGF - 402060" with the following details: Requestor: Uyen Truong, Status: Pending, and Last Modified: 7/11/2023, 11:14 AM. The card is highlighted with an orange border.

Submitting an OMOR

Step 4. The next screen is the **Activity Log**. Select the Actions button and click **Submit OMOR**.

The screenshot shows the CDER NextGen Portal interface. At the top, there is a dark blue header with the CDER NextGen Portal logo on the left and navigation icons (home, help, notifications, user profile) on the right. Below the header is a blue banner with the text "Over-the-Counter Monograph". Underneath, the main content area displays "MGF - 401658". A section titled "Activity Log" contains a table with the following data:

ACTIVITY	SENDER	LAST UPDATED
1 Pre-Assignment Request	Uyen Truong	5/16/2023, 09:09 AM

To the right of the table is an "Actions" dropdown menu with two options: "Submit Meeting Request" and "Submit OMOR". The "Submit OMOR" option is highlighted with an orange border. A "Go Back" button is located at the bottom left of the activity log section.

Submitting an OMOR

Notice the Submission Builder on the left. When a section is complete, a green check mark will be displayed. If some, but not all, required fields are complete within a section, an orange half-moon will be displayed. An open circle indicates that no required information has been entered for that section. You can navigate directly to section by clicking on it.

Step 5. On the **Submission Information** screen, review the **Requestor Information**.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The **Help Center** is available to answer all of your Over-the-Counter Monograph related questions.

Submission Information

Requestor Information

Organization Name	Agent Organization	Address Line 1	Address Line 2	City	State	Cour
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Point of Contact

Please enter the Point of Contact Information for this OMOR ⓘ

This is the same person as entered when the MGF was created

Salutation: Job Title: Credentials:

First Name: _____ Middle Name: _____ Last Name: _____

Submitting an OMOR

Step 6. Next, enter the **Point of Contact** information for this OMOR.

Point of Contact

Please enter the Point of Contact Information for this OMOR ?

This is the same person as entered when the MGF was created

Salutation

Ms. ▼

Job Title

Analyst

Credentials

PhD

First Name

Uyen

Middle Name

Last Name

Truong

Address Line 1

123 Main St

Address Line 2

City

Washington

Country

United States ▼

State

District of Columbia ▼

Postal Code

20009

Phone

2021119922

* Email

khanhuyen.truong@fda.hhs.gov

Submitting an OMOR

Step 7. If your Requestor Information includes a Foreign Requestor, you will be asked to review the **U.S. Agent Information**. Select **Yes** or **No** if you would like to change the information.

Step 8. If you have selected Yes, review the current U.S. Agent Information and click the **Add Organization** button to search for the U.S. Agent organization by the **DUNS number**. When done, click **Next**.

U.S. Agent Information

* Do you want to change the U.S. Agent Information?

Yes
 No

U.S. Agent's Organization Name	Requestor's Organization Name	Address Line 1	Address Line 2	City	State	Cou

* Enter U.S. Agent's Organization Information

Add Organization +

Organization Selection: Search

DUNS Number	Organization Name	Address line 1	Address line 2	City	State/Province	Postal Code	DUNS Number
<input type="text"/>	<input checked="" type="radio"/>						

Submitting an OMOR

Step 9. On the next screen, enter the **U.S. Agent's Contact Information**. When done, click **Next**.

Organization Selection: U.S. Agent Contact Information

Salutation	Job Title	Credentials
Ms. ▼	U.S. Agent	JD
First Name	Middle Name	Last Name
Susan		Williams
Address Line 1	Address Line 2	City
1400 15th St NW		Washington
Country	State	Postal Code
United States ▼	District of Columbia ▼	20005
Phone	Email	
2023738844	swilliams@agents.com	

Previous



Cancel

Next

Submitting an OMOR

Step 10. On the next screen, specify which Requestor(s) the U.S. Agent is representing. When done, click **Save**.


Please note, each Foreign Sponsor/Requestor must have a corresponding U.S. Agent Organization. To add additional U.S. Agent Information, repeat **Steps 8-10**.

Organization Selection: U.S. Agent Representation

* Please select the Organization the U.S. Agent is representing

<input checked="" type="checkbox"/>	Organization Name	Address line 1	Address line 2	City	State/Province	Postal Code	DUNS Number
<input checked="" type="checkbox"/>	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
<input checked="" type="checkbox"/>	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Previous



CancelSave

Submitting an OMOR

Step 11. Next, select the proposed **OMOR Classification** and **Proposed Change(s)**.

Please note:

- If you selected **Tier 1** as your proposed classification, you will be required to select one or more Proposed Change(s)
- Please select all relevant Proposed Change(s)
- If you selected the **Other** option, you may provide a write-in response

OMOR Classification

* Proposed Classification of the OMOR:

Tier 1
 Tier 2

* Please specify the proposed change (select all that apply):

Add or Strengthen a contraindication, warning, or precaution
 Add or Strengthen a statement about risk associated with misuse or abuse
 Add or Strengthen an instruction about dosage and administration that is intended to increase the safe use of the monograph drug product
 Addition of new ingredient
 Addition of new indication
 Addition of new fixed-dose combination of ingredients
 Addition of new test method
 Addition of new route of administration
 Addition of new dose or concentration for a GRASE ingredient
 Addition of new monograph therapeutic category
 Other

Update dosing frequency

OMOR Classification

* Proposed Classification of the OMOR:

Tier 1
 Tier 2

Please specify the proposed change (select all that apply):

Reordering of existing information in the drug facts label of an OTC monograph drug
 Addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations)
 Modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A)
 Standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph
 Change to ingredient nomenclature to align with nomenclature of a standards-setting organization
 Addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations)

Submitting an OMOR

Step 12. Next, add applicable **OTC Monographs**. Select the **OTC Monograph** button and choose from the list of options.

Please note:

- If you intend to propose a new monograph, select **New Monograph**
- You may add multiple applicable OTC monographs to your OMOR submission

Applicable OTC Monograph(s)

Choose applicable OTC monograph(s).

OTC Monograph +

Add Applicable OTC Monograph(s)

* OTC Monograph

Select an Option

New Monograph

M001 - Antacid Products for OTC Human Use

M002 - Antiflatulent Products for OTC Human Use

M003 - First Aid Antiseptic Drug products for OTC Human Use

M004 - First Aid Antibiotic Drug Products for OTC Human Use

M005 - Topical Antifungal Drug Products for Over-the-Counter Human Use

M006 - Topical Acne Drug Products for Over-the-Counter Human Use

M007 - Laxative Drug Products for OTC Human Use

Submitting an OMOR

Step 13. Next, add relevant **Active Ingredients**. Select the **Active Ingredient** button and search for an ingredient by the **UNII Number**. When done, click **Next**.

Proposed Changes to Condition(s) of Use Provide information about the proposed changes to the OTC monograph condition(s) of use including active ingredient(s), strength/concentration, dosage form, route of administration, therapeutic class/subclass, where applicable.

Active Ingredient +

SEARCH RESULTS

* UNII

Ingredient Selection

UNII	Ingredient Name
<input checked="" type="radio"/> SOI2LOH54Z	ZINC OXIDE

< 1 of 1 >

Submitting an OMOR

Step 14. On the next screen, provide the **Strength/Concentration** information for your Active Ingredient, if applicable. Select **Yes** or **No** if the Active Ingredient Strength/Concentration is in a range and enter the **Strength Value**.

Step 15. Select the corresponding Strength/Concentration **Unit**. Please note, if you have selected a Unit containing a fraction (i.e., mg/mL, g/L, etc.) please enter the **Strength Value Denominator**.

Step 16. Enter the **Dosage Frequency** value and select the frequency from the list of options.

Step 17. Select the applicable **Age Group** from the list of options. Please note, you may select multiple Age Groups.

To add additional Strength/Concentration information, select the **Add Strength/Concentration** button and repeat **Steps 14-17**. When done, click **Next**.

Ingredient Selection

Strength / Concentration ⓘ

Is the strength/concentration in a range?

Yes No

* Minimum Strength Value * Unit

* Maximum Strength Value

* Strength Value Denominator

* Dosage Frequency * Per

Age Group

Selected Age Groups:

Submitting an OMOR

Step 18. Next, select the **Dosage Form(s)**, **Route(s) of Administration**, **Therapeutic Class(es)**, and **Therapeutic Sub-Class(es)**, if applicable. When done, click **Save**.

Please note:

- Use the right and left arrows to move values between the **Available** and **Selected** columns
- You may select all Dosage Form(s), Route(s) of Administration, Therapeutic Class(es), and Therapeutic Sub-Class(es) that apply
- If you would like to add an additional Active Ingredient, repeat **Steps 13-18**.

Ingredient Selection

Dosage Form		Selected
Available		
CONTROLLED RELEASE TABLET DO...	▶	CREAM ▲
CRYSTAL		CREAM, AUGMENTED ▼
CUBE DOSAGE FORM		
CULTURE DOSAGE FORM		
Route of Administration		
Available		Selected
TRANS CERVICAL ROUTE OF ADMIN...	▶	TOPICAL ▲
TRANSDERMAL	◀	
TRANSLUMINAL ROUTE OF DRUG A...		
Therapeutic Class		
Available		Selected
relief of oral discomfort	▶	skin protectant ▲
skin bleach		sunscreen ▼

[Previous](#) [Cancel](#) [Save](#)

Submitting an OMOR

Step 19. Next, add proposed changes or additions to the **Indication(s)** where applicable. Select the **Indication** button and enter the Proposed Indication/Use. When done, click **Next**.

Step 20. On the next screen, select the Active Ingredient(s) associated with the Proposed Indication, if applicable. When done, click **Save**.

If you would like to add an additional Indication, repeat **Steps 19-20**.

Provide the proposed change or addition to the indication(s), where applicable.

Indication +

Add Indication

* Proposed Indication/Use

Prevent sunburn

Add Indication

Proposed Indication/Use

Please select the Active Ingredient(s) associated with the Proposed Indication/Use

<input checked="" type="checkbox"/>	UNII	Active Ingredient	Strength/Co...	Dosing Frequency	Age Group	Dosage Form	Route of Administration	Therape... Class	T S
<input checked="" type="checkbox"/>	SOI2LOH54Z	ZINC OXIDE	10-15 mg / 50 mL	4 per Day	Adults and children over 12 years of age	CREAM	TOPICAL	skin protectant;sun	v
<input checked="" type="checkbox"/>	SOI2LOH54Z	ZINC OXIDE	10-15 mg / 50 mL	4 per Day	Adults and children over 12 years of age	CREAM, AUGMENTED	TOPICAL	skin protectant;sun	v

Submitting an OMOR

Step 21. Next, select **Yes** or **No** if the Requestor(s) own or are affiliated with an OTC monograph drug facility.

Step 22. If you selected No, proceed to the next screen. If you selected Yes, click the **Add Facility** button to search for a Facility.

Facility Information

* Does the Requestor or their affiliate(s) own, or owned in the past 12 months, one or more OTC monograph drug facilities, including contract manufacturing organization facilities? ⓘ

Yes
 No

Add Facility +

Step 23. On the Facility Selection window, search for a Facility by entering the **DUNS** and optional **FEI numbers**. When done, click **Next**.

Facility Selection: Search

FEI Number ⓘ	FEI Number	Facility Name	Facility Address	DUNS Number	Facility Owner Name	Facility Owner Address
<input type="text"/>	<input checked="" type="radio"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

* DUNS Number ⓘ

Submitting an OMOR

Step 24. On the next screen, enter the **Facility Contact Information**. When done, click **Next**.

Facility Selection: Facility Contact Information

Salutation	Job Title	Credentials
Ms.	Facility Manager	PMP
* First Name	Middle Name	* Last Name
Sarah		Johnson
Address Line 1	Address Line 2	City
2375 Third St		Riverside
Country	State	Postal Code
United States	California	92507
* Phone	* Email	
9516839212	sjohnson@email.com	

Previous ✓ ○ ○ Cancel **Next**

Submitting an OMOR

Step 25. On the next screen, specify which Requestor(s) the Facility is associated with. When done, click **Save**. If you would like to add additional Facilities, repeat **Steps 22-25**.

Facility Selection: Requestor Association

Requestor Association
* Please select the Requestor(s) associated with this Facility

<input checked="" type="checkbox"/>	Organization Name	Address Line 1	Address Line 2	City	State	Country	Postal Code	DUNS Number	DUNS Number
<input checked="" type="checkbox"/>	██████████	██████████		██████████	██	██	██████	██████	██████
<input checked="" type="checkbox"/>	██████████	██████████		██████████	██	██	██████	██████	██████

Previous

✓ ————— ✓ ————— ○

Cancel Save

Submitting an OMOR

Step 26. On the **Module 1: Administrative Information** screen, upload relevant documents. Select the **+** button to the left of each section to open the document upload window.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information**
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 1: Administrative Information

Administrative Information

Upload contents of your Module 1: Administrative Information

- Table of Contents
- Cover Letter
- Administrative Information
- References
- Meetings
- Labeling

[Previous](#) [Save and Close](#) [Save](#) [Next](#)

Submitting an OMOR

Step 27. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

The screenshot shows the 'SUBMISSION BUILDER' interface with a 'Table of Contents' dialog box open. A green success message at the top reads 'Success! File uploaded successfully'. The dialog box contains instructions on file naming and upload limits. Below the instructions is an 'Upload Files' button (highlighted with an orange box) and an 'Or drop files' area. A table lists the uploaded file 'Monograph Table of Contents.pdf' with a description 'Table of Contents Document' and a 'Save' button. At the bottom of the dialog are 'Cancel' and 'Save' buttons (the latter is highlighted with an orange box). The background shows a sidebar with 'Submission Information' selected and 'Module 1: Administrative Information' active.

Table of Contents

Please upload unique file names and refrain from uploading files with the same names.

Table of Contents

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls,xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

Or drop files

Document Name	Document Description	File Count : 1
<input type="checkbox"/> Monograph Table of Contents.pdf	<input type="text" value="Table of Contents Document"/>	<input type="button" value="Save"/>

Submitting an OMOR

Step 28. Within Module 1, in the **References** window, provide **Information Previously Submitted to FDA**, if applicable.

Select the **Add Reference** button and choose from the list of **Submission Type** options. Provide the six-digit **Submission Number**, then click **Save**.

Please note, you may add multiple references to your submission.

References

Information Previously Submitted to FDA Provide applications, OMORs, or other submissions applicable to, or referenced in this request

Add Reference +

Progress bar: 0% to 100%

Add Applicable Reference

Add the following information:

* Submission Type * Submission ID/Number

Meetings

Labeling

Submitting an OMOR

Step 29. Within Module 1, in the **Meetings** window, provide relevant monograph meetings, if applicable.

Select the **Add Meeting** button and enter the **MGF Number**. Next, select the **Meeting ID** and review the Meeting Information. When done, click **Save**.

Please note, you may add multiple meetings to your submission.

Meetings

Relevant Meeting(s) List meetings applicable to this OMOR submission ⓘ

Add Meeting +

Progress indicator: 1 of 2 steps

Add Applicable Meeting

* Please enter the 6-digit MGF Number to search for Meetings

MGF -

* Please select the Meeting ID

Meeting Information:

Submitted Date: 2/27/2023, 01:33 PM

Requested Meeting Type: Type Y

Submitting an OMOR

Step 30. On the **Module 2: Summaries** screen, upload relevant documents. Select the **+** button to the left of each section to open the document upload window.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries**
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 2: Summaries

Summary Documents

Upload contents of your Module 2: Summaries

- 2.1 Table of Contents
- 2.2 Introduction to the Summary Documents
- 2.3 Quality Overall Summary
- 2.4 Nonclinical Overview
- 2.5 Clinical Overview
- 2.6 Nonclinical Written and Tabulated Summaries
- 2.7 Clinical Summary

[Previous](#) [Save and Close](#) [Save](#) [Next](#)

Submitting an OMOR

Step 31. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

The screenshot displays the 'SUBMISSION BUILDER' interface. A green success message at the top reads 'Success! File uploaded successfully'. The main area is titled 'Module 2: Summary Documents' with the subtitle 'Upload contents of your Module 2: Summaries'. A dialog box titled '2.1 Table of Contents' is open, containing the following text: 'Please upload unique file names and refrain from uploading files with the same names.' Below this, it says 'Table of Contents' and provides upload recommendations: 'Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls,xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.' An 'Upload Files' button with an upload icon and the text 'Or drop files' is highlighted with an orange box. Below the text is a table with three columns: 'Document Name', 'Document Description', and 'File Count : 1'. The table contains one row with a file named 'Monograph Table of Contents.pdf', a description of 'Table of Contents Document', and a 'Save' button. At the bottom of the dialog are 'Cancel' and 'Save' buttons.

Success! File uploaded successfully

2.1 Table of Contents

Please upload unique file names and refrain from uploading files with the same names.

Table of Contents

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

Upload Files Or drop files

Document Name	Document Description	File Count : 1
Monograph Table of Contents.pdf	Table of Contents Document	Save

Cancel Save

Submitting an OMOR

Step 32. For sections containing additional sub-sections, navigate to a sub-section directly by clicking on the sub-section title. If the selected sub-section contains additional categories, select the carrot icon to reveal the Upload Files button. When done, click **Save**.

2.3 Quality Overall Summary

Please upload unique file names and refrain from uploading files with the same names.

- 2.3.I Introduction
- 2.3.S Drug Substance
- 2.3.P Drug Product
- 2.3.A Appendices**
- 2.3.R Regional Information

2.3.A Appendices

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

Document Type	Document Description	File Count
✓ 2.3.A.1 Facilities and Equipment		Files: 1
	<p>Document Description ⓘ</p> <input type="text" value="Enter a description, up to 300 characters"/> <input type="button" value="Save"/>	
	<p>⊗ Module 2.3.A.pdf</p> <p><input type="button" value="Upload Files"/> Or drop files</p>	
> 2.3.A.2 Adventitious Agents Safety Evaluation		Files: 0

Submitting an OMOR

Step 33. On the **Module 3: Quality** screen, upload relevant documents. Select the + button to the left of each section to open the document upload window.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality**
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 3: Quality

Quality Documents

Upload contents of your Module 3: Quality

3.1 Module 3 Table of Contents

3.3 Literature References

Provide the relevant 3.2 Body of Data you intend to include in your request.

[Add Data +](#)

[Previous](#)

[Save and Close](#)

[Save](#)

[Next](#)

Submitting an OMOR

Step 34. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

Success!
File uploaded successfully

3.1 Module 3 Table of Contents

Please upload unique file names and refrain from uploading files with the same names.

Table of Contents

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls,xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

[Upload Files](#) Or drop files

Document Name	Document Description	File Count : 1
<input type="checkbox"/> Monograph Table of Contents.pdf	<input type="text" value="Table of Contents Document"/>	<input type="button" value="Save"/>

Submitting an OMOR

Step 35. Next, provide relevant **Body of Data** documents. Select the **Add Data** button to open the 3.2 Body of Data window. Then, select the **Data Type** and **Document Type**. When done, click **Next**.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality**
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 3: Quality

Quality Documents

Upload contents of your Module 3: Quality

- + 3.1 Module 3 Table of Contents
- + 3.3 Literature References

Provide the relevant 3.2 Body of Data you intend to include in your request.

Add Data +

[Previous](#) [Save and Close](#) [Save](#) [Next](#)

3.2 Body of Data

* Data Type: 3.2.S Drug Substance

* Document Type: 3.2.S.2 Manufacture

[Cancel](#) **[Next](#)**

Submitting an OMOR

Step 36. If applicable, review the document categories on the lefthand panel and upload documents for all relevant sections. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

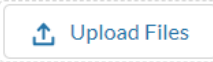
3.2 Body of Data


Please upload unique file names and refrain from uploading files with the same names.


- 3.2.S.2.1 Manufacturer(s)
- 3.2.S.2.2 Description of Manufacturing Process and Process Controls
- 3.2.S.2.3 Control of Materials
- 3.2.S.2.4 Controls of Critical Steps and Intermediates
- 3.2.S.2.5 Process Validation and/or Evaluation
- 3.2.S.2.6 Manufacturing Process Development

3.2.S.2.1 Manufacturer(s)

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls,xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

 Or drop files

Document Name	Document Description	File Count : 1
 Module 3.2.S.2.1.pdf	<input type="text" value="Enter a description, up to 300 characters"/>	<input type="button" value="Save"/>



Submitting an OMOR

Step 37. Review the entered Body of Data. If you would like to add additional Data, select the Add Data button and repeat **Steps 35-37**. To make additional edits or delete a Data record, select the arrow to reveal the **Edit** and **Delete** buttons.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality**
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 3: Quality

Quality Documents

Upload contents of your Module 3: Quality

- 3.1 Module 3 Table of Contents Edit
- + 3.3 Literature References

Provide the relevant 3.2 Body of Data you intend to include in your request.

Add Data +

Data Type	Document Type	
3.2.S Drug Substance	3.2.S.2 Manufacture	Edit Delete

Previous

Save and Close

Save

Next

Submitting an OMOR

Step 38. On the **Module 4: Nonclinical Study Reports** screen, upload relevant documents. Select the + button to the left of each section to open the document upload window.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports**
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 4: Nonclinical Study Reports

Nonclinical Studies

Upload contents of your Module 4: Nonclinical Study Reports

4.1 Module 4 Table of Contents

4.3 Literature References

Provide the relevant 4.2 Study Reports you intend to include in your request.

[Add Study +](#)

[Previous](#)

[Save and Close](#)

[Save](#)

[Next](#)

Submitting an OMOR

Step 39. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

The screenshot displays a web application interface for submitting an OMOR. A green notification banner at the top indicates a successful file upload: "Success! File uploaded successfully". Below this, a modal window titled "4.1 Module 4 Table of Contents" is open. The modal contains instructions: "Please upload unique file names and refrain from uploading files with the same names." and "Table of Contents". It provides upload recommendations: "Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls,xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? \" < > | are not allowed." Below the text is an "Upload Files" button (highlighted with an orange box) and the text "Or drop files". A table below shows the uploaded file:

Document Name	Document Description	File Count : 1
Monograph Table of Contents.pdf	Table of Contents Document	Save

At the bottom of the modal are "Cancel" and "Save" buttons (the "Save" button is highlighted with an orange box). The background shows a sidebar with navigation options: "SUBMISSION BU...", "Submission Inform...", "Module 1: Adminis...", "Module 2: Summar...", "Module 3: Quality...", "Module 4: Nonclin...", "Module 5: Clinical...", and "Review & Submit".

Submitting an OMOR

Step 40. Next, provide relevant **Study Report** documents by selecting the **Add Study** button.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports**
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 4: Nonclinical Study Reports

Nonclinical Studies

Upload contents of your Module 4: Nonclinical Study Reports

- 4.1 Module 4 Table of Contents [Edit](#)
- 4.3 Literature References

Provide the relevant 4.2 Study Reports you intend to include in your request.

[Add Study +](#)

[Previous](#)

[Save and Close](#)

[Save](#)

[Next](#)

Submitting an OMOR

Step 41. On the 4.2 Study Reports window, enter the **Study ID** and **Study Title**. Next, select the **Study Type**, **Secondary Study Type**, and **Tertiary Study Type**, if applicable.

Step 42. Next, select the **Document Type(s)**. Use the right and left arrows to move values between the **Available** and **Selected** columns. When done, click **Next**.

The screenshot shows the "4.2 Study Reports" window. It contains the following fields and options:

- * Study ID:** Text input field containing "123456".
- * Study Title:** Text input field containing "Nonclinical Study".
- * Study Type:** Dropdown menu with "4.2.3 Toxicology" selected.
- * Secondary Study Type:** Dropdown menu with "4.2.3.3 Genotoxicity" selected.
- * Tertiary Study Type:** Dropdown menu with "4.2.3.3.1 In vitro" selected.
- * Document Type:** A selection interface with two columns:
 - Available (33):** A list of document types including "Protocol or amendment", "Signatures investigators", "Audit certificates report", "Statistical methods interim analysis plan", "Inter-laboratory standardisation methods qualit...", and "Publications based on study".
 - Selected (4):** A list of selected document types including "Legacy clinical study report", "Pre clinical study report", "Synopsis", and "Study report body".
 - Orange arrows indicate the movement of items between the two columns.

At the bottom right, there are "Cancel" and "Next" buttons. A progress indicator is visible at the bottom center.

Submitting an OMOR

Step 43. On the next screen, review the selected Document Types on the lefthand panel and upload documents for all relevant sections. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

4.2 Study Reports

Please upload unique file names and refrain from uploading files with the same names.

- Legacy clinical study report
- Pre clinical study report
- Synopsis
- Study report body

Legacy clinical study report

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

Or drop files

Document Name	Document Description	File Count : 1
<input type="text" value="Module 4.2.pdf"/>	<input type="text" value="Enter a description, up to 300 characters"/>	<input type="button" value="Save"/>

Submitting an OMOR

Step 44. Review the entered Study Report. If you would like to add additional Study Reports, select the Add Study button and repeat **Steps 40-44**. To make additional edits or delete a Study Report, select the arrow to reveal the **Edit** and **Delete** buttons.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports**
- Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 4: Nonclinical Study Reports

Nonclinical Studies

Upload contents of your Module 4: Nonclinical Study Reports

4.1 Module 4 Table of Contents

4.3 Literature References

Provide the relevant 4.2 Study Reports you intend to include in your request.

Study ID	Study Title	Study Type	<input type="button" value="Edit"/>
123456	Nonclinical Study	4.2.3 Toxicology	<input type="button" value="Delete"/>

Submitting an OMOR

Step 45. On the **Module 5: Clinical Study Reports** screen, upload relevant documents. Select the + button to the left of each section to open the document upload window.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports**
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 5: Clinical Study Reports

Clinical Study Reports

Upload contents of your Module 5: Clinical Study Reports

- 5.1 Module 5 Table of Contents
- 5.2 Tabular Listing of All Clinical Studies
- 5.4 Literature References

Provide the relevant 5.3 Clinical Study reports and related information you intend to include in your request.

[Add Study +](#)

[Previous](#)

[Save and Close](#)

[Save](#)

[Next](#)

Submitting an OMOR

Step 46. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

The screenshot displays a web application interface for submitting an OMOR. A green notification banner at the top reads "Success! File uploaded successfully". Below it, a modal window titled "5.1 Module 5 Table of Contents" is open. The modal contains a message: "Please upload unique file names and refrain from uploading files with the same names." Underneath, the heading "Table of Contents" is followed by upload recommendations: "Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls,xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed." A button labeled "Upload Files" with an upward arrow icon is highlighted with an orange border, next to the text "Or drop files". Below this is a table with three columns: "Document Name", "Document Description", and "File Count : 1". The table contains one entry: "Monograph Table of Contents.pdf" with a description of "Table of Contents Document" and a "Save" button. At the bottom of the modal, there are "Cancel" and "Save" buttons, with the "Save" button highlighted in orange. In the background, a sidebar shows a list of modules, with "Module 5: Clinical Reports" selected. A "Need Help?" section is visible at the bottom left of the sidebar.

SUBMISSION BU

- ✓ Submission Inform
- ✓ Module 1: Adminis Information
- ✓ Module 2: Summar
- ✓ Module 3: Quality
- ✓ Module 4: Nonclin Reports
- Module 5: Clinical Reports
- Review & Submit

Need Help?

The Help Center is availa
all of your Over-the-Coun
Monograph related questions

Success!
File uploaded successfully

5.1 Module 5 Table of Contents

Please upload unique file names and refrain from uploading files with the same names.

Table of Contents

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

Upload Files Or drop files

Document Name	Document Description	File Count : 1
✕ Monograph Table of Contents.pdf	Table of Contents Document	Save

Cancel Save

Save Next

Submitting an OMOR

Step 47. Next, provide relevant **Study Report** documents by selecting the **Add Study** button.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports**
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 5: Clinical Study Reports

Clinical Study Reports

Upload contents of your Module 5: Clinical Study Reports

- 5.1 Module 5 Table of Contents [Edit](#)
- 5.2 Tabular Listing of All Clinical Studies
- 5.4 Literature References

Provide the relevant 5.3 Clinical Study reports and related information you intend to include in your request.

[Add Study +](#)

[Previous](#) [Save and Close](#) [Save](#) [Next](#)

Submitting an OMOR

Step 48. On the 5.3 Study Reports window, enter the **Study ID** and **Study Title**. Next, select the **Study Type**, and **Secondary Study Type**.

Step 49. Next, select the **Document Type(s)**. Use the right and left arrows to move values between the **Available** and **Selected** columns. When done, click **Next**.

5.3 Clinical Study Reports

* Study ID
987654

* Study Title
Clinical Study

* Study Type
5.3.1 Reports of biopharmaceutical studies ▼

* Secondary Study Type
5.3.1.1 Bioavailability (BA) Study reports and relate... ▼

* Document Type

Available (54)

- Sample case report form (E3 16.1.2)
- IEC-IRB consent form list (E3 16.1.3)
- List description investigator site (E3 16.1.4)
- Signatures investigators (E3 16.1.5)
- List patients with batches (E316.1.6)
- Randomisation scheme (E3 16.1.7)

Selected (4)

- Legacy clinical study report
- Synopsis (ICH E3, section 2)
- Study report body (E3 1, 3 to 15)
- Protocol or amendment (E3 16.1.1)

Progress indicator: [●] ————— [●]

Cancel Next

Submitting an OMOR

Step 50. On the next screen, review the selected Document Types on the lefthand panel and upload documents for all relevant sections. Click the **Upload Files** button to browse your computer and select a file to upload or drag and drop a file into the designated area on the screen. Prior to attaching your file, review the allowed document file types and file size. When done, click **Save**.

Please note, you may provide an optional **Document Description** for each uploaded file.

5.3 Clinical Study Reports

Please upload unique file names and refrain from uploading files with the same names.

Legacy clinical study report

Synopsis (ICH E3, section 2)

Study report body (E3 1, 3 to 15)

Protocol or amendment (E3 16.1.1)

Legacy clinical study report

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls,xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : * ? " < > | are not allowed.

[Upload Files](#) Or drop files

Document Name	Document Description	File Count : 1
<input type="text" value="Module 5.3.pdf"/>	<input type="text" value="Enter a description, up to 300 characters"/>	<input type="button" value="Save"/>

Submitting an OMOR

Step 51. Review the entered Study Report. If you would like to add additional Study Reports, select the Add Study button and repeat **Steps 47-50**. To make additional edits or delete a Study Report, select the arrow to reveal the **Edit** and **Delete** buttons.

MGF 401658 - OMOR

SUBMISSION BUILDER

- Submission Information
- Module 1: Administrative Information
- Module 2: Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports**
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Module 5: Clinical Study Reports

Clinical Study Reports

Upload contents of your Module 5: Clinical Study Reports

- 5.1 Module 5 Table of Contents Edit
- 5.2 Tabular Listing of All Clinical Studies
- 5.4 Literature References

Provide the relevant 5.3 Clinical Study reports and related information you intend to include in your request.

[Add Study +](#)

Study ID	Study Title	Study Type	
987654	Clinical Study	5.3.1 Reports biopharmaceut studies	<div style="text-align: right; padding: 2px;">Edit Delete</div>

PreviousSave and CloseSaveNext

Submitting an OMOR

Step 52. On the **Review & Submit** screen, review all information previously entered. If you need to edit a section of your submission, click **Return to Section** to update the information. .

MGF 401658 - OMOR

SUBMISSION BUILDER

- ✓ Submission Information
- ✓ Module 1: Administrative Information
- ✓ Module 2: Summaries
- ✓ Module 3: Quality
- ✓ Module 4: Nonclinical Study Reports
- ✓ Module 5: Clinical Study Reports
- Review & Submit

Need Help?

The [Help Center](#) is available to answer all of your Over-the-Counter Monograph related questions.

Review & Submit

Submission Information

[Return to Section](#)

Requestor Information

Organization Name	Agent Organization	Address Line 1	Address Line 2	City	State	Country
CIPHER PHARMACEUTICALS INC	FDA CONNECT, INC.	2345 ARGENTIA RD SUITE 100A		MISSISSAUGA	ON	CA
SEABOARD CORPORATION		9000 W 67TH ST		MERRIAM	KS	US

Point of Contact

Please enter the Point of Contact Information for this OMOR ?

This is the same person as entered when the MGF was created

Salutation	Job Title	Credentials
Ms.	Analyst	PhD
First Name	Middle Name	Last Name
Uyen		Truong
Address Line 1	Address Line 2	City
123 Main St		Washington

Submitting an OMOR

Step 53. For each Module section, click the **Open** button to open the respective Module section and review your uploaded documents.




Step 54. Once you have reviewed and confirmed all information, click **Submit** to finalize your submission to FDA.

Please note:


- If you have any documents pending scanning, the Submit button will be disabled.
- You may click the **Save and Close** button to exit the screen as your documents continue to scan. You must return to the screen and click Submit to finalize your submission.
- **Please review any uploaded documents that have been identified as a threat.**

Module 5: Clinical Study Reports

[Return to Section](#)

Section	Scan Status
 5.1 Module 5 Table of Contents	In Progress Open
 5.2 Tabular Listing of All Clinical Studies	
 5.4 Literature References	

Study ID	Study Title	Study Type	Scan Status
987654	Clinical Study	5.3.1 Reports of biopharmaceutical studies	In Progress Open

 Submission documents with the yellow warning symbol are still pending scan. Please wait a few minutes to click Submit.


[Previous](#) [Save and Close](#) [Save](#) [Submit](#)

5.1 Module 5 Table of Contents

Please upload unique file names and refrain from uploading files with the same names.

Table of Contents

Upload Recommendations: Users can upload up to 25 files, each file can be no larger than 500MB. For files larger than 500MB, user can upload individually with each file no larger than 1GB. File uploads must be one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf, sas, xml, xpt. CDER NextGen Portal requires using only letters, numbers, spaces, and underscores when naming files. Special characters such as: \ / : " ? " < > | are not allowed.

Document Name	Document Description	File Count : 1
 Monograph Table of Contents.pdf		

[Close](#)

Submitting an OMOR

Step 55. On the **OMOR Confirmation** screen, review the submission confirmation message.

Step 56. If you would like to return to the landing page, select **Return Home**. If you would like to navigate to the **Activity Log** for your MGF application, select the **MGF Number**.

The screenshot shows the CDER NextGen Portal interface. At the top, there is a dark blue header with the CDER NextGen Portal logo on the left and navigation icons (home, help, notifications, user profile) on the right. Below the header is a blue banner with the text "Over-the-Counter Monograph". The main content area is white and contains a confirmation message: "OMOR Submitted to FDA" followed by "Congratulations! Your OMOR has been submitted successfully." Below this, there are two columns of text. The left column provides instructions to return to the Activity Log and make a subsequent submission, with a button labeled "MGF - 401658" highlighted in orange. Below the button, it lists the Requestor as Uyen Truong, Status as Pending, and Last Modified as 5/24/2023, 01:35 PM. The right column provides instructions to return to the Over-the-Counter Monograph Overview page, with a button labeled "Return Home" highlighted in orange. Below the button, it provides contact information for technical support: "For technical support, please contact the CDER NextGen Portal support team (EDMSupport@fda.hhs.gov). Please include OMUFA in the subject line of your email."

Submitting an OMOR

Step 57. To review your submitted OMOR, return to the **Activity Log** and select the **OMOR** activity.

The screenshot shows the CDER NextGen Portal interface. At the top, there is a dark blue header with the CDER NextGen Portal logo on the left and navigation icons (home, help, notifications, user profile) on the right. Below the header is a blue banner with the text "Over-the-Counter Monograph". Underneath, the identifier "MGF - 401658" is displayed. The main content area features an "Activity Log" section with a table of activities. The "OMOR (SDN-1)" activity is highlighted with an orange border. Below the table is a "Go Back" button.

ACTIVITY	SENDER	LAST UPDATED	
OMOR (SDN-1)	Uyen Truong	8/1/2023, 12:11 PM	Actions ▼
Pre-Assignment Request	Uyen Truong	7/20/2023, 01:58 PM	

Submitting an OMOR

Step 58. On the Submission Summary page, review your submitted information. To return to the Activity Log, click **Go Back** at the bottom of the page.

Over-the-Counter Monograph

MGF 401658

Submission Summary - OMOR (SDN-1)

Submission Information

Requestor Information

Organization Name	Agent Organization	Address Line 1	Address Line 2	City	State	Count...	Postal Code	DUNS Number	Contact
[Redacted]	[Redacted]	[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]		[Redacted]		[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Point of Contact

Please enter the Point of Contact Information for this OMOR ⓘ

This is the same person as entered when the MGF was created

Salutation	Job Title	Credentials
Ms. ▼	Analyst	PhD
First Name	Middle Name	Last Name
Uyen		Truong
Address Line 1	Address Line 2	City
123 Main St		Washington

Appendix

Application Statuses

Application Status	Description
Pre-Assignment	MGFs with this Application Status indicate that a Pre-Assignment Request has been submitted and an MGF number has been assigned.
Pre-Submission	MGFs with this Application Status indicate that a Meeting Request has been submitted. The Application Status will remain in the Pre-Submission status for subsequent Meeting related submissions (i.e., Meeting Package, Meeting Other, Meeting Withdrawal/Cancelation, etc.).
Pending	MGFs with this Application Status indicate that an OMOR has been submitted and under FDA review.
Unacceptable – User Fee Not Paid	MGFs with this Application Status indicate that FDA has deemed the Meeting Request or OMOR submission unacceptable due to unpaid user fees (i.e., Facility Fees, OMOR User Fees, etc.). The user must remit outstanding user fees before proceeding with subsequent submissions.
Refuse to File	MGFs with this Application Status indicate that FDA has deemed the OMOR to be unacceptable for filing. The user may submit a File over Protest under the same MGF number or request a new MGF number to submit an OMOR after Refuse to File.
Proposed Order Issued	MGFs with this Application Status indicate that FDA has issued a Proposed Order regarding their OMOR.
Final Order Issued	MGFs with this Application Status indicate that FDA has issued a Final Order regarding their OMOR.
Withdrawn	MGFs with this Application Status indicate that an OMOR Withdrawal has been submitted and FDA has acknowledged the withdrawal.

Technical Support Resources

CDER NextGen Portal Support & Resources

The CDER NextGen Portal (<https://edm.fda.gov>) has many resources for support. For technical support, please contact the CDER NextGen Portal support team (EDMSupport@fda.hhs.gov). Please include OMUFA in the subject line of your email.

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 **user guides and FAQs**.

Technical Support

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

Portal Training Videos

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