

OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

Any person that owns a facility identified as an OTC monograph facility on December 31 of the fiscal year or at any time during the preceding 12-month period is required to pay facility fee for that fiscal year. For additional information, please refer to: <https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa>.

** Please note that Contract Manufacturing Organization (CMO) facility will have a different fee than OTC Monograph Drug Facility (MDF). The CMO facility fee is equal to two-thirds of the amount of fee for a MDF facility fee. For more information regarding the facility fee rates, please refer to the Federal Register.

Steps to create OMUFA facility fee cover sheet:

1. Access the User Fee website: https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp
2. Review the statement and select the "I Understand" radio button.
3. For users who have an existing user account, proceed to step 4.
 - a. If you do not have an existing account, please refer to the FDA User Fee Account Creation Process guide at https://userfees.fda.gov/OA_HTML/UserFee_Account_Creation.pdf for step-by-step instructions on how to create an account. For additional assistance on account creation, please contact the User Fee Help Desk at userfees@fda.gov.
4. Enter a valid User Name and Password.
5. Click the "Login" button.

Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [OMUFA OMOR Fee Cover Sheet Creation: Step-by-Step Instructions](#)
- [OMUFA Facility Fee Cover Sheet Creation: Step-by-Step Instructions](#)

Log in to the User Fee System

User Name: Password:

[Forgot User Name/Password?](#)

[New User? Please register...](#)

User Fee System Alerts

Please note the FDA's user fee credit card limit is \$24,999.99. You will not be able to make an online payment with a credit card for payments over this limit. The ACH online payment option is still available for amounts exceeding the credit card limit.

[System for Award Management](#)

If you are a domestic entity and are requesting a refund, we recommend that you create an account with the System for Award Management (SAM). SAM validates the registrant information and electronically shares the encrypted data securely with the FDA to facilitate your refund. Click [here](#) to access SAM.

[Privacy Act Notice](#)

Note: There are "Help" prompts throughout the cover sheet process. When you click on a "Help" link, a new window will open with helpful hints and tips to guide you through answering the questions.

6. Click the "Go" button next to "OTC Monograph User Fee".

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User Fee Website

Welcome Jun Wang

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2021	FURLS Device Facility User Fee	<input type="button" value="Go"/>

2021 Cover Sheets

FY 2021 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2020 through September 30th, 2021.

User Fee	Description	
ANIMAL DRUG USER FEE 2021	ADUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>
ANIMAL GENERIC DRUG USER FEE 2021	AGDUFA Cover Sheets	<input type="button" value="Go"/>
Biosimilar User Fee 2021	BsUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2021	GDUFA Cover Sheets	<input type="button" value="Go"/>
Medical Device User Fee 2021	MDUFA Cover Sheets (PMA, 510k, etc.)	<input type="button" value="Go"/>
OTC Monograph User Fee 2021	OMUFA Cover Sheets (OMOR and Facility)	<input type="button" value="Go"/>
Prescription Drug User Fee 2021	PDUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>

2020 Cover Sheets

FY 2020 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2019 through September 30th, 2020.

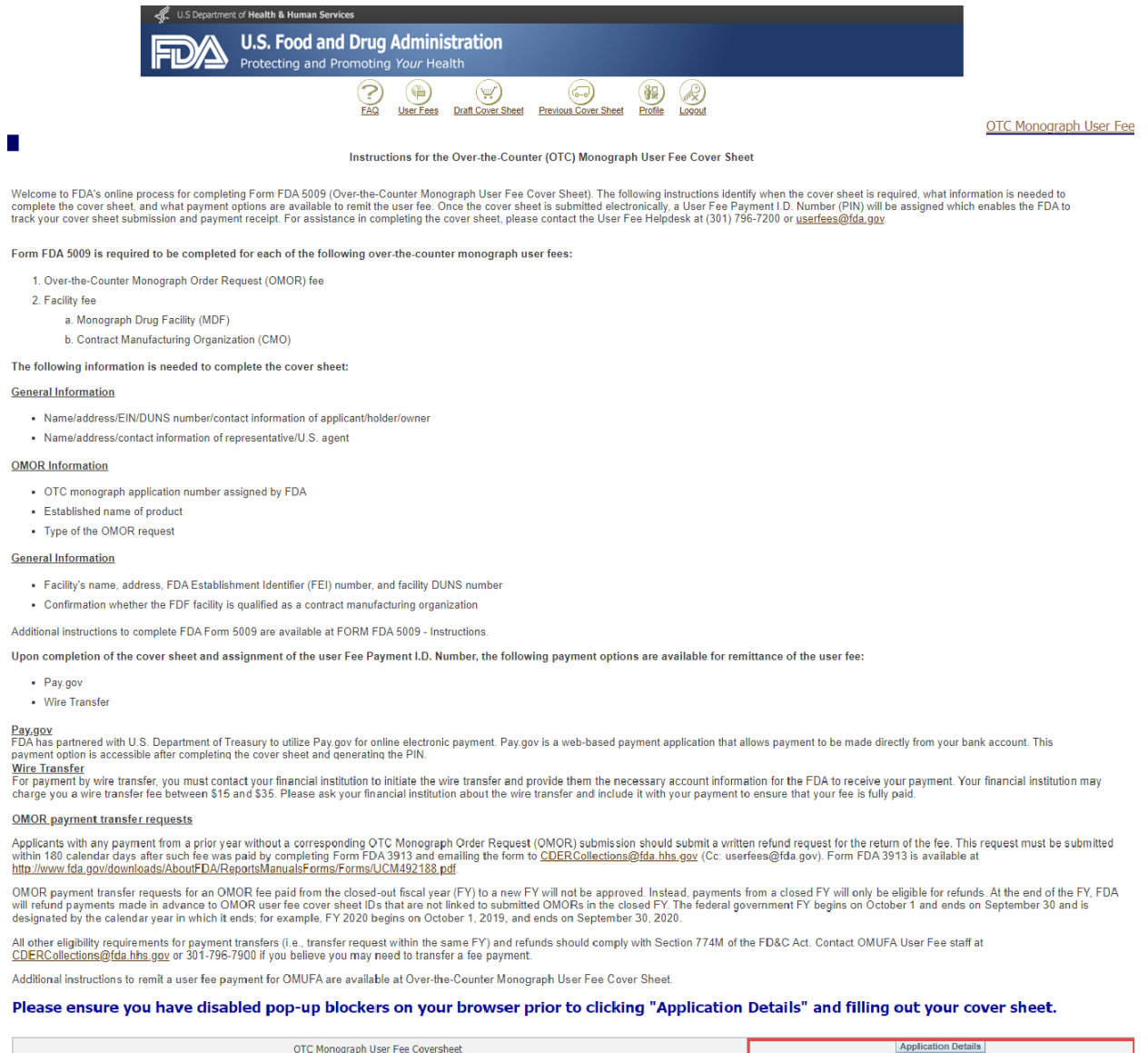
User Fee	Description	
Generic Drug User Fee 2020	GDUFA Cover Sheets	<input type="button" value="Go"/>

***To view the 2021 fees, please see the Federal Register Notices below:**

[ADUFA 2021 FR Notice](#)
[AGDUFA 2021 FR Notice](#)
[BsUFA 2021 FR Notice](#)
[GDUFA 2021 FR Notice](#)
[MDUFA 2021 FR Notice](#)
[OMUFA 2021 FR Notice](#)
[MCM PRV 2021 FR Notice](#)
[PDUFA 2021 FR Notice](#)
[PRV 2021 FR Notice](#)
[RPD PRV 2021 FR Notice](#)

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7. Scroll down to the bottom of the page and select the “Application Details” button.



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[OTC Monograph User Fee](#)

Instructions for the Over-the-Counter (OTC) Monograph User Fee Cover Sheet

Welcome to FDA's online process for completing Form FDA 5009 (Over-the-Counter Monograph User Fee Cover Sheet). The following instructions identify when the cover sheet is required, what information is needed to complete the cover sheet, and what payment options are available to remit the user fee. Once the cover sheet is submitted electronically, a User Fee Payment I.D. Number (PIN) will be assigned which enables the FDA to track your cover sheet submission and payment receipt. For assistance in completing the cover sheet, please contact the User Fee Helpdesk at (301) 796-7200 or userfees@fda.gov.

Form FDA 5009 is required to be completed for each of the following over-the-counter monograph user fees:

1. Over-the-Counter Monograph Order Request (OMOR) fee
2. Facility fee
 - a. Monograph Drug Facility (MDF)
 - b. Contract Manufacturing Organization (CMO)

The following information is needed to complete the cover sheet:

General Information

- Name/address/EIN/DUNS number/contact information of applicant/holder/owner
- Name/address/contact information of representative/U.S. agent

OMOR Information

- OTC monograph application number assigned by FDA
- Established name of product
- Type of the OMOR request

General Information

- Facility's name, address, FDA Establishment Identifier (FEI) number, and facility DUNS number
- Confirmation whether the FDF facility is qualified as a contract manufacturing organization

Additional instructions to complete FDA Form 5009 are available at [FORM FDA 5009 - Instructions](#).

Upon completion of the cover sheet and assignment of the user Fee Payment I.D. Number, the following payment options are available for remittance of the user fee:

- Pay.gov
- Wire Transfer

Pay.gov
 FDA has partnered with U.S. Department of Treasury to utilize Pay.gov for online electronic payment. Pay.gov is a web-based payment application that allows payment to be made directly from your bank account. This payment option is accessible after completing the cover sheet and generating the PIN.

Wire Transfer
 For payment by wire transfer, you must contact your financial institution to initiate the wire transfer and provide them the necessary account information for the FDA to receive your payment. Your financial institution may charge you a wire transfer fee between \$15 and \$35. Please ask your financial institution about the wire transfer and include it with your payment to ensure that your fee is fully paid.

OMOR payment transfer requests

Applicants with any payment from a prior year without a corresponding OTC Monograph Order Request (OMOR) submission should submit a written refund request for the return of the fee. This request must be submitted within 180 calendar days after such fee was paid by completing Form FDA 3913 and emailing the form to CDERCollections@fda.hhs.gov (Cc: userfees@fda.gov). Form FDA 3913 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.

OMOR payment transfer requests for an OMOR fee paid from the closed-out fiscal year (FY) to a new FY will not be approved. Instead, payments from a closed FY will only be eligible for refunds. At the end of the FY, FDA will refund payments made in advance to OMOR user fee cover sheet IDs that are not linked to submitted OMORs in the closed FY. The federal government FY begins on October 1 and ends on September 30 and is designated by the calendar year in which it ends; for example, FY 2020 begins on October 1, 2019, and ends on September 30, 2020.

All other eligibility requirements for payment transfers (i.e., transfer request within the same FY) and refunds should comply with Section 774M of the FD&C Act. Contact OMUFA User Fee staff at CDERCollections@fda.hhs.gov or 301-796-7900 if you believe you may need to transfer a fee payment.

Additional instructions to remit a user fee payment for OMUFA are available at [Over-the-Counter Monograph User Fee Cover Sheet](#).

Please ensure you have disabled pop-up blockers on your browser prior to clicking "Application Details" and filling out your cover sheet.

OTC Monograph User Fee Coversheet [Application Details](#)

8. Select the “Facility” radio button, then click the “Next” button.

Over-the-Counter (OTC) Monograph User Fee Cover Sheet

Select cover sheet fee type:

OTC Monograph Order Request (OMOR)

Facility

OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

9. Enter or confirm the facility owner's name and address. Enter all required fields that are notated with an asterisk (e.g., Facility Owner's Name, Country, and Address). Click the "Next" button to continue.

Over-the-Counter (OTC) Monograph User Fee Cover Sheet

Enter facility owner's name and address:

* Facility Owner's Name	<input type="text" value="Malecha"/>
* Country	<input type="text" value="United States"/>
* Address Line 1	<input type="text" value="123 Main street"/>
Address Line 2	<input type="text"/>
* City	<input type="text" value="Columbia"/>
* State	<input type="text" value="MD"/>
* Postal Code	<input type="text" value="21044"/>
EIN	<input type="text"/>
DUNS Number	<input type="text"/>

* Indicates required field

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10. Enter or confirm the facility owner's representative or U.S. agent information. Enter all required fields (e.g., First Name, Last Name, Job Title, Telephone Number, and Email Address). Click the "Next" button to continue.

Over-the-Counter (OTC) Monograph User Fee Cover Sheet

Enter facility owner's representative or U.S. agent information:

Note: The facility owner's representative or U.S. Agent must be authorized to respond to questions posed by the FDA regarding the applicant's cover sheet. If the applicant is a foreign entity, a U.S. Agent is required.

* First Name:

* Last Name:

* Job Title: x

* Telephone Number:

* Email Address:

* Indicates required field

11. Enter all required fields (e.g., Facility Name, Country, FEI Number, Facility DUNS Number, and Address). Click the "Next" button.

Over-the-Counter (OTC) Monograph User Fee Cover Sheet

Provide the facility's name, address, FDA Establishment Identifier (FEI) number and facility DUNS number for the facility:

* Facility Name: * FDA Establishment Identifier:

* Country: * Facility DUNS Number: x

* Address Line 1:

Address Line 2:

* City:

* State:

* Postal Code:

* Indicates required field

12. Indicate what the facility produces for the manufacture of over-the-counter monograph drugs (API and/or FDF). If the facility produces OTC FDF monograph drug, indicate if the facility qualifies as the "Contract Manufacturing Organization".

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Over-the-Counter (OTC) Monograph User Fee Cover Sheet

Indicate what the facility produces for human over-the-counter (OTC) monograph drugs

- Facility manufactures ONLY active pharmaceutical ingredient (API) for OTC monograph drug products
- Facility manufactures, or process, or packs, or labels the final dosage form (FDF) for OTC monograph drug products
- Does the facility qualify as a Contract Manufacturing Organization (CMO) per section 744LJ2) of the FD and C Act. Yes No

Cancel Back **Finish**

13. On the Draft Cover Sheet page, verify the amount owed for the cover sheet. You have four options on this page:
- Click the "Next" button to continue.
 - You can click the "Modify Application Details" button to make changes to the draft cover sheet. To view the draft cover sheet, click on the "OTC Monograph User Fee Cover Sheet" link.
 - If you do not save or submit your cover sheet, it will be available for 30 days in the "Draft Cover Sheet" menu.
 - You can save the cover sheet by clicking on the "Save Cover Sheet" button.

** Please note that the cover sheet amount in this example is based on options chosen and for demonstration purposes only. The amount calculated during your cover sheet creation process may be different than the amount stated in the example.

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OTC Monograph User Fee Cover Sheet

Cover Sheet Saved Cover Sheets

Draft Cover Sheet

Items

You now have four options to proceed:

- If you have one draft cover sheet, click the "Next" button to submit your cover sheet to FDA and receive a Payment Identification Number (PIN).
Note: If you do not receive a Payment Identification Number (PIN), your cover sheet was not submitted to FDA.
- If you would like to modify your cover sheet selections, click the "Modify Application Details" button to make changes to the draft form. To view your draft cover sheet, please click on the cover sheet link.
- If you choose not to save or submit your cover sheet at this time, your draft cover sheet will be automatically saved for 30 days before it expires.
- If you would like to save your cover sheet for future submission, click the "Save Cover Sheet" button and provide a name for your cart. If you are saving more than one cover sheets, please make sure you save each cover sheet under a different cart name.
Note: To modify or submit a saved cover sheet, click the "Draft Cover Sheet" icon, and select the "Saved Cover Sheets" link to access your carts. Saved cover sheets remain active for 90 days before they expire.

Select All	Clear Selections	Cover Sheet	Creation Date	Last Update Date	Net: \$6,000.00
<input type="checkbox"/>		OTC Monograph User Fee Coversheet Modify Application Details	27-OCT-2020 20:37:34	27-OCT-2020 20:44:56	

Delete Selected Draft(s) Save Cover Sheet **Next**

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14. Confirm the "Bill To" information and click the "Next" button to proceed.

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Note: If you would like to change the billing information, click the “Change” button to create a new address.

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Checkout: Facility Contact Information

Bill To

Customer: Maleeha

Contact: Maleeha Ajaz
 222-2223333
 maleeha.ajaz@fda.hhs.gov

Address: BCC
 green st
 dolumbia, MD 21044
 UNITED STATES

Facility Owner

Facility Owner: Maleeha
 DUNS Number:
 EIN:

Facility

Facility Name: Red box
 Facility DUNS Number: 987654321
 Facility FEI: 987654
 Facility Address: 123 branch in
 columbia MD 21044
 United States

- Confirm the details of your cover sheet on the Checkout: Review and Submit Draft Cover Sheet page. Click the “Submit Cover Sheet to FDA” button to electronically submit your OMUFA cover sheet.

OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

OTC Monograph User Fee

Checkout: Review and Submit Draft Cover Sheet

Cover Sheet	Creation Date	Last Update Date	
FY 2021 OTC Monograph User Fee Coversheet Print/View Draft Cover Sheet	27-OCT-2020 20:37:34	27-OCT-2020 20:49:15	Net: \$6,000.00
			Total: \$6,000.00
Customer Information	Customer: Maleeha Maleeha Ajaz 222-2223333 maleeha.ajaz@fda.hhs.gov		
Applicant Contact Information	Bill To: Maleeha Ajaz Maleeha BCC green st columbia, MD 21044 UNITED STATES		
Facility Owner	Facility Owner: Maleeha DUNS Number: EIN:		
Facility	Facility Name: Red box Facility DUNS Number: 987654321 Facility FEI: 987654 Facility Address: 123 branch in columbia MD 21044 United States		

16. A confirmation of your cover sheet submission and a Payment Identification Number (PIN) appears. On this page, you may:
- Click the "Print/View Final Cover Sheet" button to view and/or print the cover sheet.
 - Click the "Pay Now" button to make an online payment.
 - Click the "Create Another Cover Sheet" button to create another cover sheet. Refer to steps 6 through 15.

Note: Your cover sheet is your invoice. To view and/or print your cover sheet at any time, select the "Previous Cover Sheets" menu at the top of the page. From this menu, click on the "Payment Identification Number" under the search results and a new window will open. Scroll down to the bottom of the window and click on the link to print the cover sheet.

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Confirmation
YOUR PAYMENT IDENTIFICATION NUMBER IS: **OM7200070**

Your cover sheet has been electronically submitted. Next, please follow the payment instructions on the coversheet print out.

- For the OTC facility fee coversheet, you do not need to print any documents at this time.
- For the OTC Monograph Order Request (OMOR) coversheet *only*, you must print and sign the original copy and include the original with your application.

Thank you for visiting the FDA User Fee Website. As part of our efforts to improve customer service, we would like to hear from you.

Please [click here](#) to fill out a short survey. This will only take approximately 2 minutes to complete.

Cover Sheet	Creation Date	Last Update Date	
FY 2021 OTC Monograph User Fee Coversheet Print/View Final Cover Sheet	1	19-MAY-2021 15:20:28	19-MAY-2021 15:21:39 Net: \$13,548.00
			Total: \$13,548.00

Note: You can submit payment online by credit card or Automated Clearing House (ACH) electronic check (eCheck) or by wire/bank transfer. There is a credit card payment limit of \$24,999.99. The preferred payment method is online. If you prefer to Federal wire transfer, please **include the PIN (Payment Identification Number)** with your wire transfer payment. FDA will not be able to process your payment correctly without your PIN.

If you have any further questions about the cover sheet creation process, please contact the User Fee Helpdesk at userfees@fda.gov.