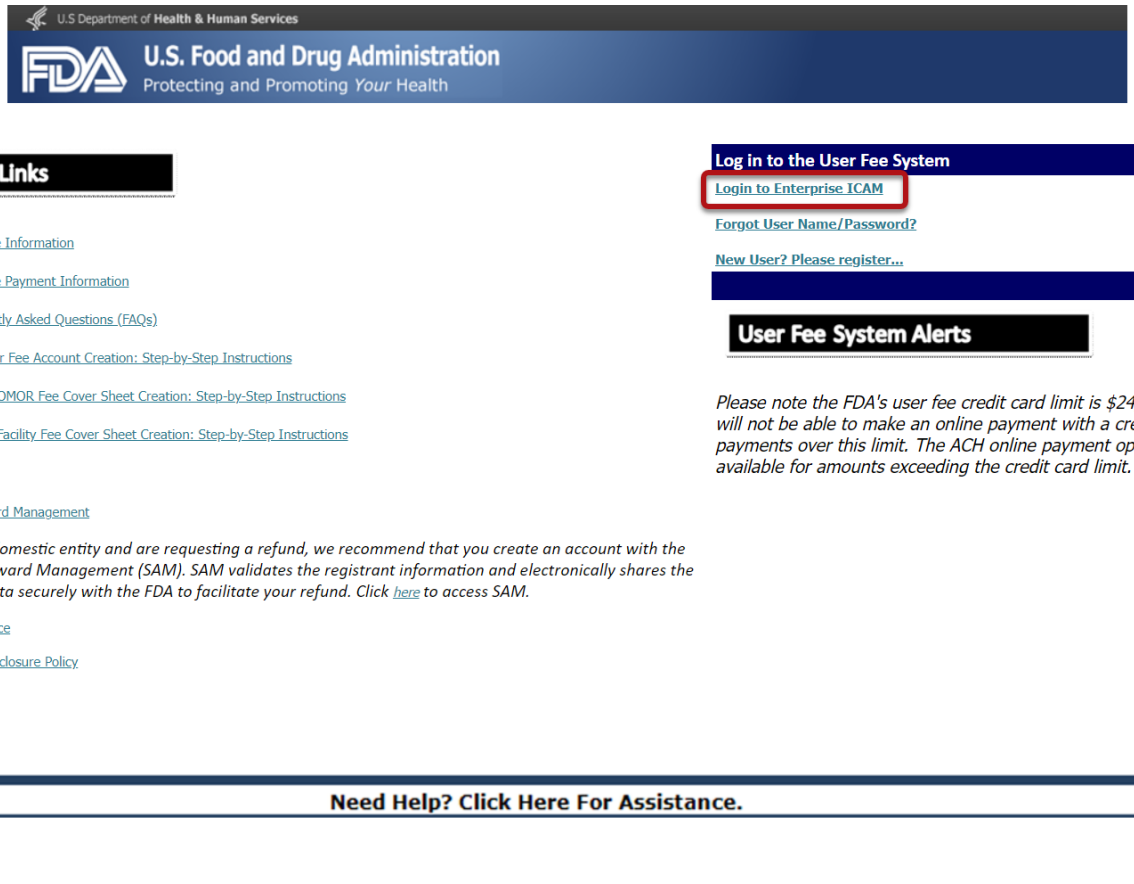
OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

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.

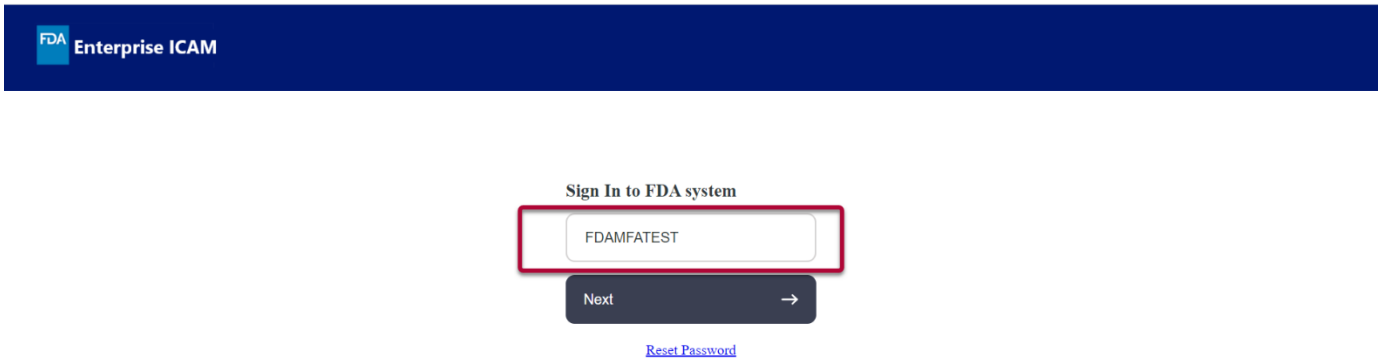
Steps to create OMUFA facility fee cover sheet:

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. Click on the 'Login to Enterprise ICAM' hyperlink.

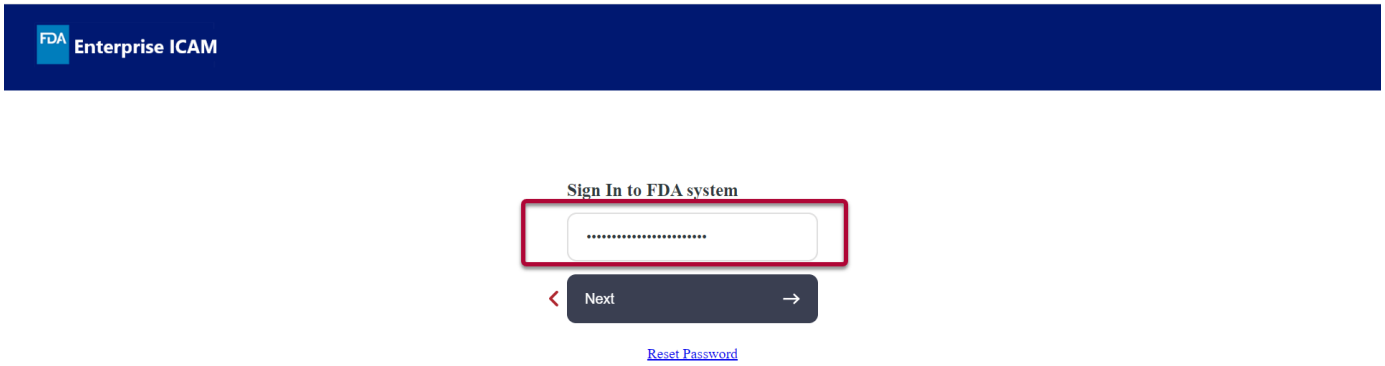


OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

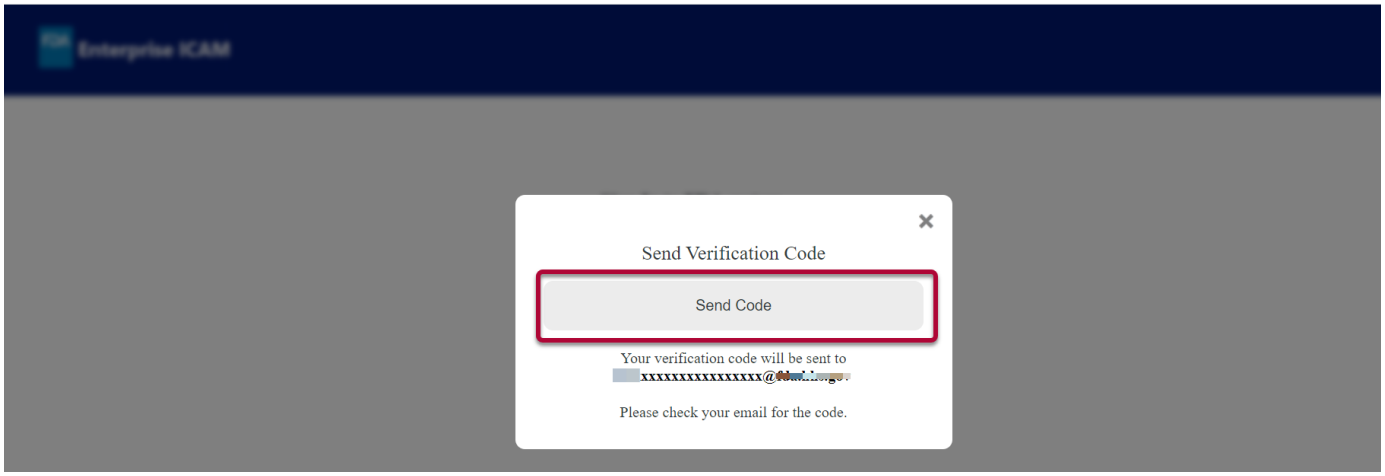
5. You are navigated to “Enterprise ICAM Login page”, Enter “Username“ to login to your UFS account, click on “Next” button you are navigated to the “Password” entry page.



6. Enter the “Password “to login to your UFS account, click on “Next” button you are navigated to the “Send Verification Code” screen.

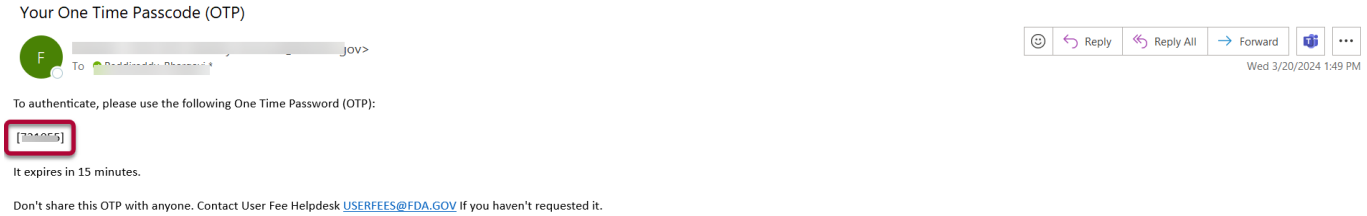


7. Click “Send Code” button to receive OTP to your Registered email address. After clicking on “Send Code button you will be navigated to Verification Code Sent Screen.

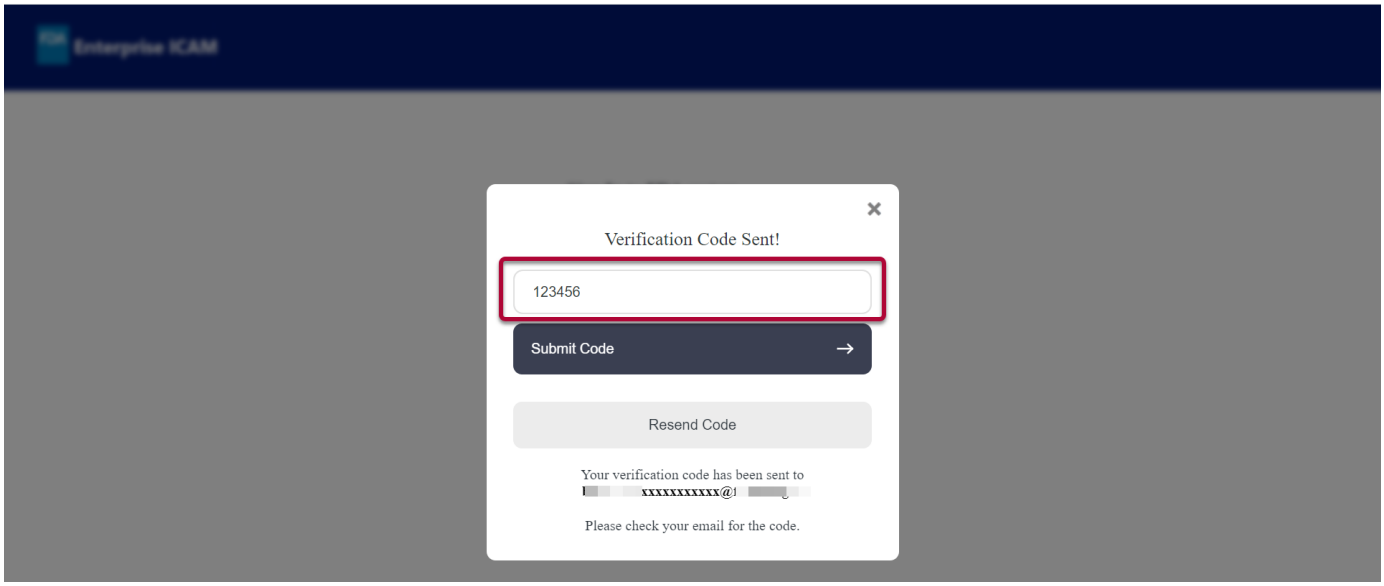


OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

8. You will receive an email with "OTP" code to your registered email address.



9. Return to "Verification Code Sent" screen and enter the "OTP" code received into your registered email address. Click on "Submit Code" button.



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.

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

10. Click the “Go” button next to “OTC Monograph User Fee”.

User Fee Website

Welcome FDA Test User

Annual Establishment Registration

FY 2024 MDUFA Establishment Registration User Fee cover sheets should be created for payments associated with registrations for the period October 1st, 2023 through September 30th, 2024.

User Fee	Description	
MDUFA Establishment Registration User Fee 2024	FURLS Device Facility User Fee	Go

2024 Cover Sheets

FY 2024 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2023 through September 30th, 2024.

User Fee	Description	
ANIMAL DRUG USER FEE 2024	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2024	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2024	BsUFA Cover Sheets	Go
Generic Drug User Fee 2024	GDUFA Cover Sheets	Go
Medical Device User Fee 2024	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
OTC Monograph User Fee 2024	OMUFA Cover Sheets (OMOR Only)	Go
Prescription Drug User Fee 2024	PDUFA Pre-Market Cover Sheets	Go

2023 Cover Sheets

FY 2023 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2022 through September 30th, 2023.

User Fee	Description	
OTC Monograph User Fee 2023	OMUFA Cover Sheets (Facility Only)	Go

***To view the 2023 fees, please see the Federal Register Notices below:**

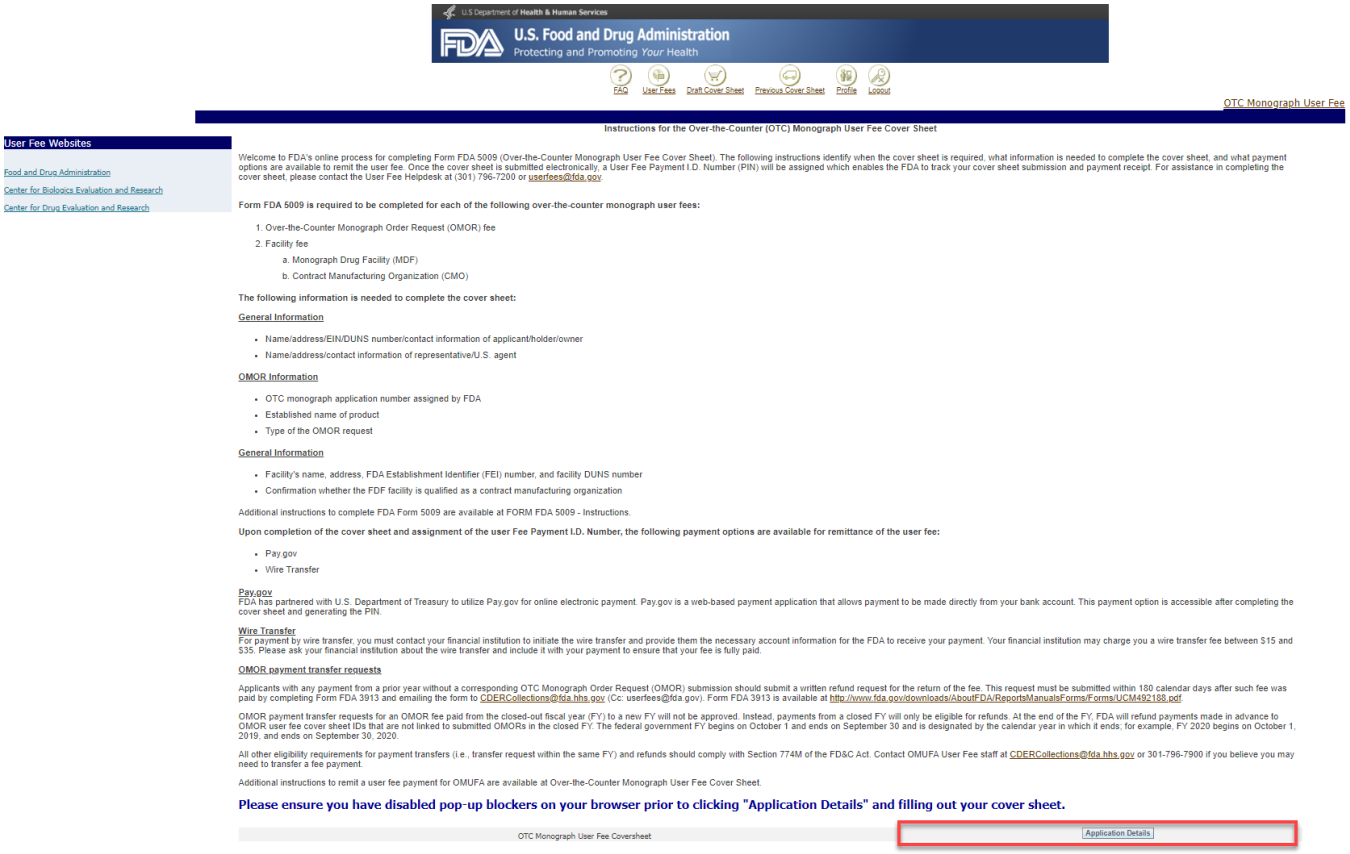
OMUFA 2023 FR Notice (Facility Only)

***To view the 2024 fees, please see the Federal Register Notices below:**

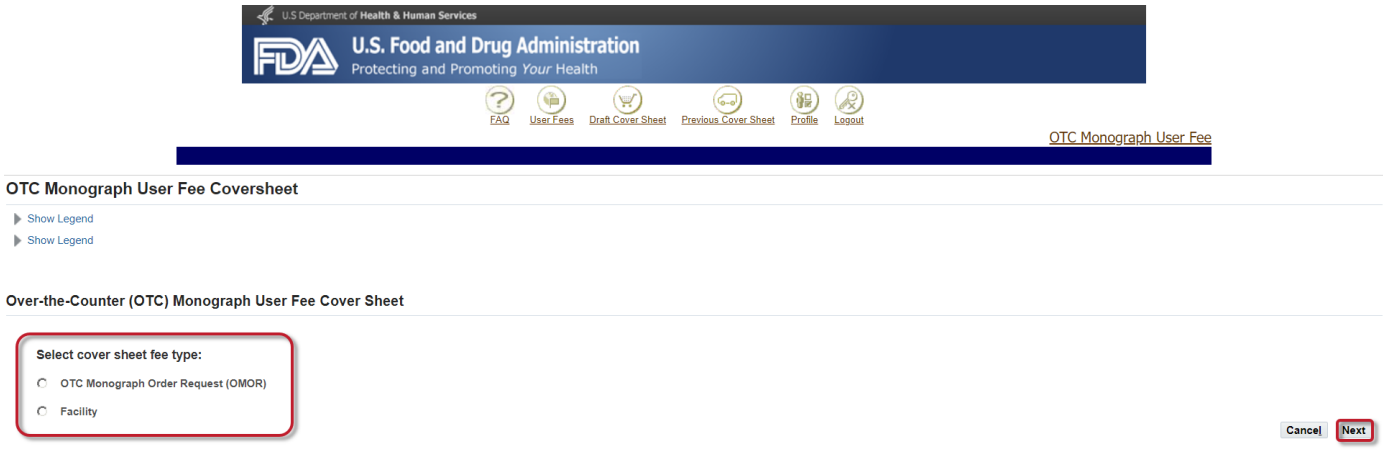
ADUFA 2024 FR Notice
AGDUFA 2024 FR Notice
BsUFA 2024 FR Notice
GDUFA 2024 FR Notice
MDUFA 2024 FR Notice
OMUFA 2024 FR Notice (OMOR Only)
PDUFA 2024 FR Notice
PRV 2024 FR Notice

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

11. Scroll down to the bottom of the page and select the "Application Details" button.

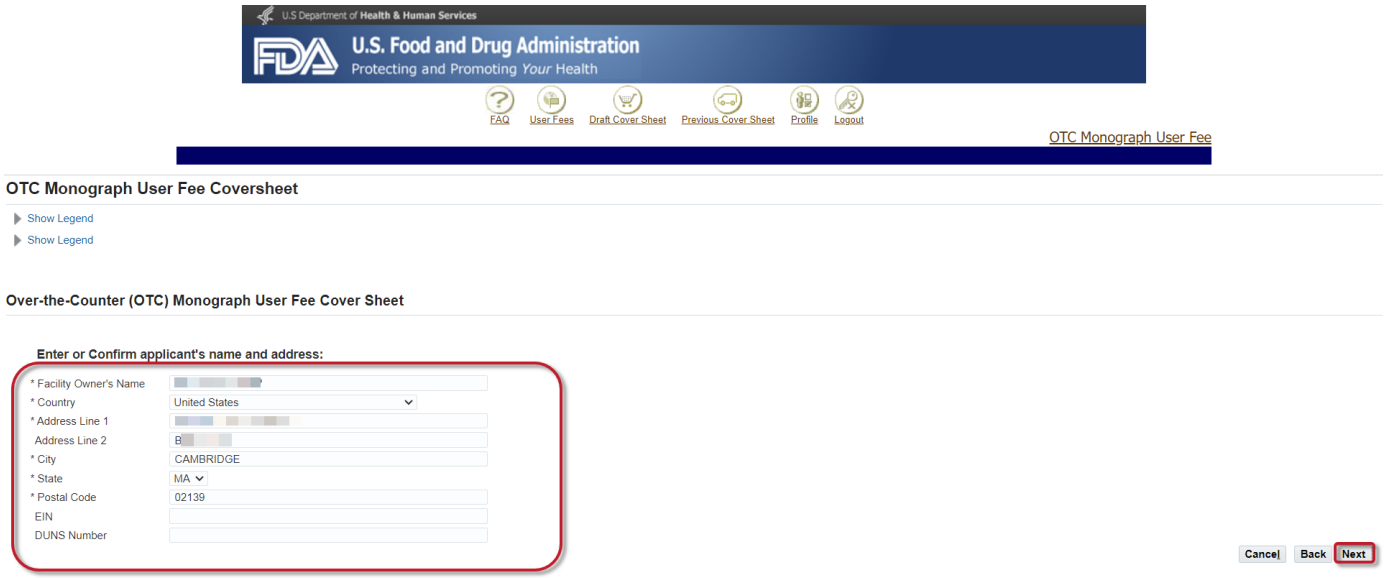


12. Select the "Facility" radio button, then click the "Next" button.

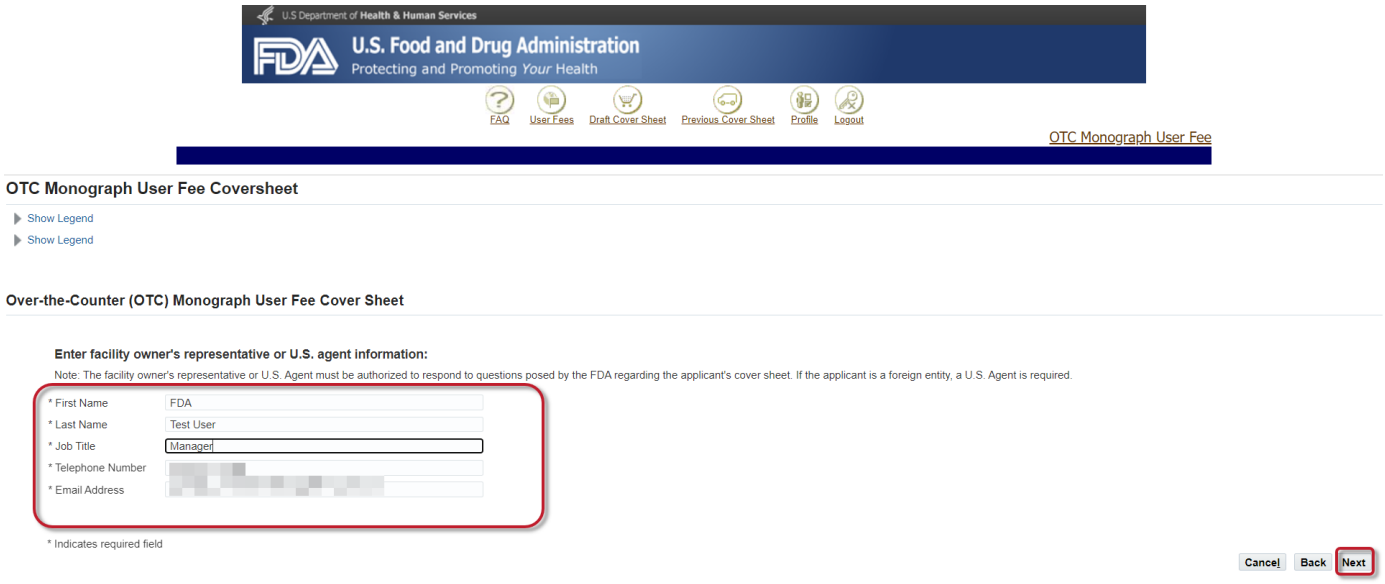


OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

13. 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.

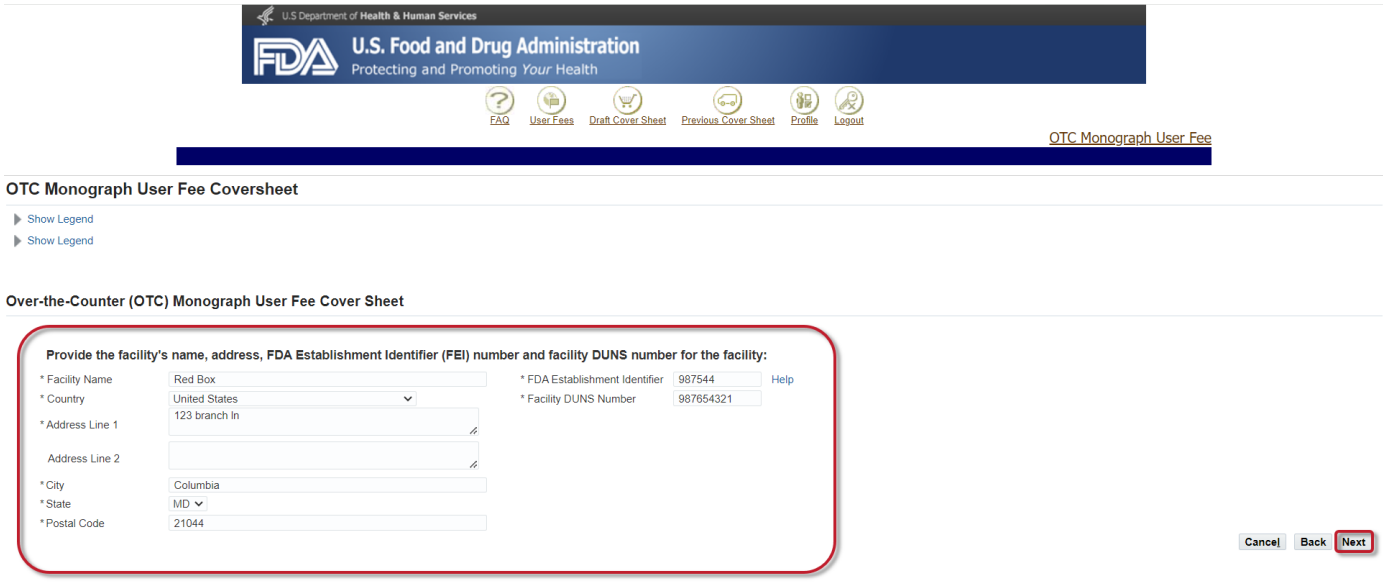


14. Enter or confirm the facility owner's representative or U.S. agent information. Enter all required fields (e.g., First Name, Last Name, Job Title, Telephone Number, and Email Address). Click the "Next" button to continue.

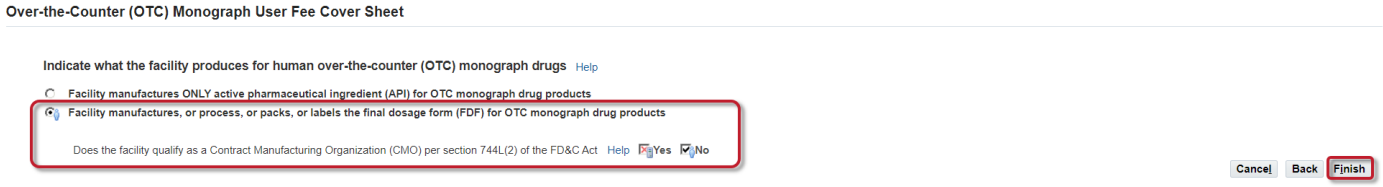


OMUFA Monograph Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

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



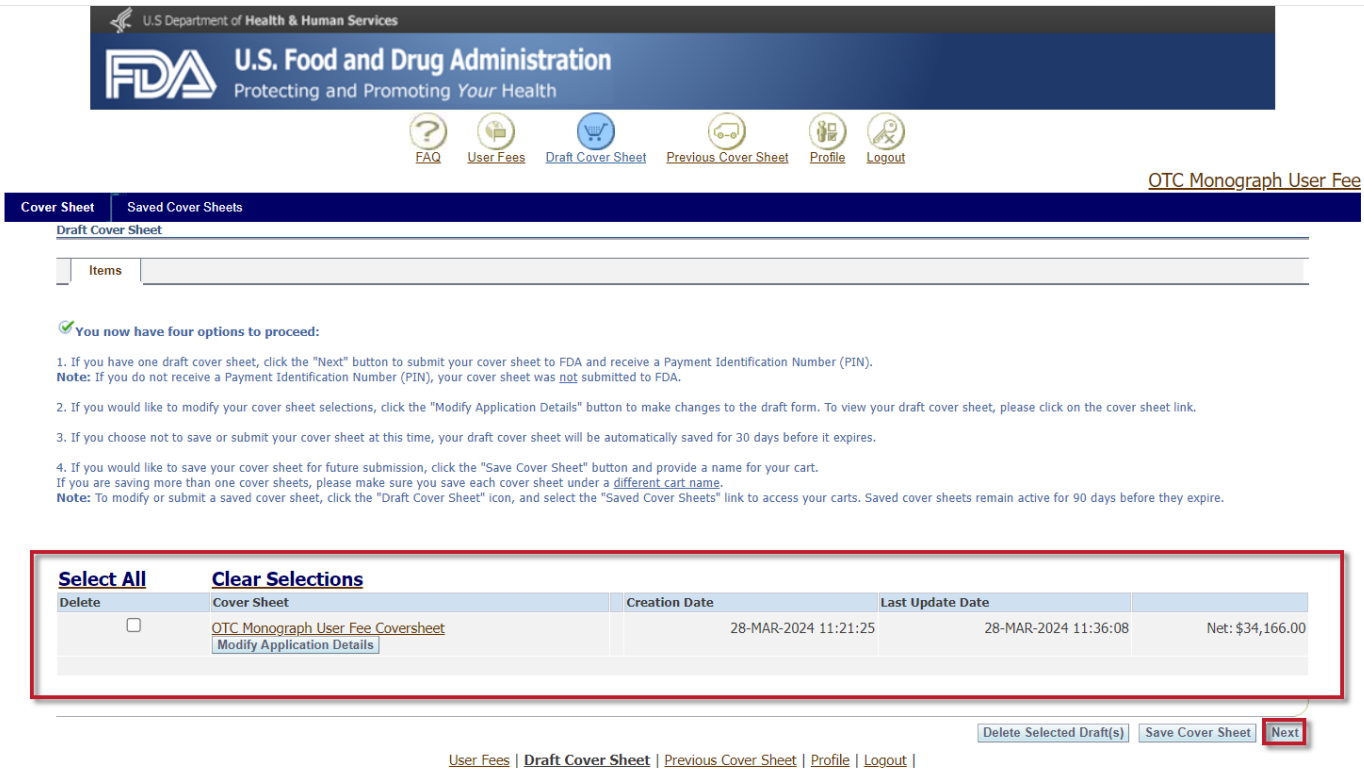
16. Indicate what the facility produces for the manufacture of over-the-counter monograph drugs (API and/or FDF). If the facility produces OTC FDF monograph drug, indicate if the facility qualifies as the "Contract Manufacturing Organization".



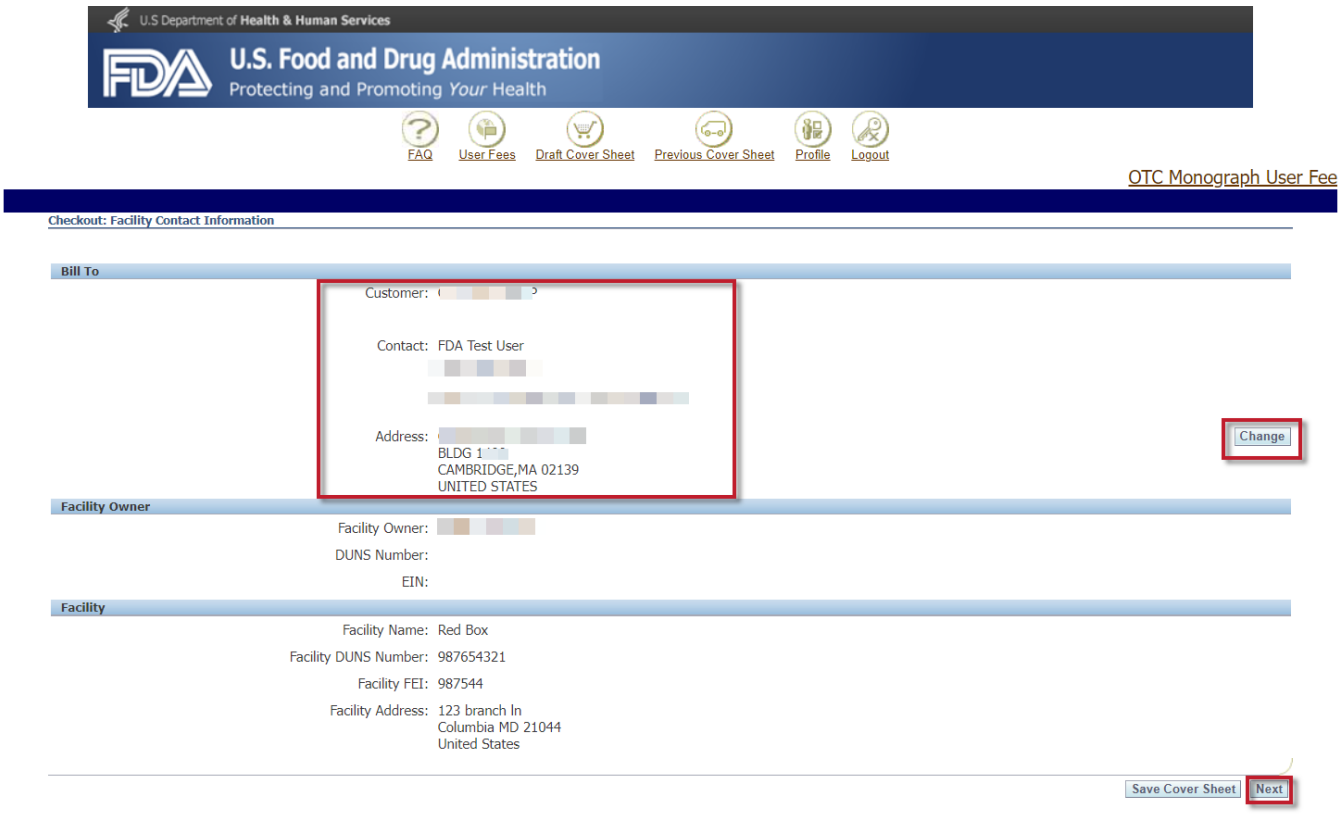
17. On the Draft Cover Sheet page, verify the amount owed for the cover sheet. You have four options on this age:
    a) Click the "Next" button to continue.
    b) You can click the "Modify Application Details" button to make changes to the draft cover sheet. To view the draft cover sheet, click on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

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

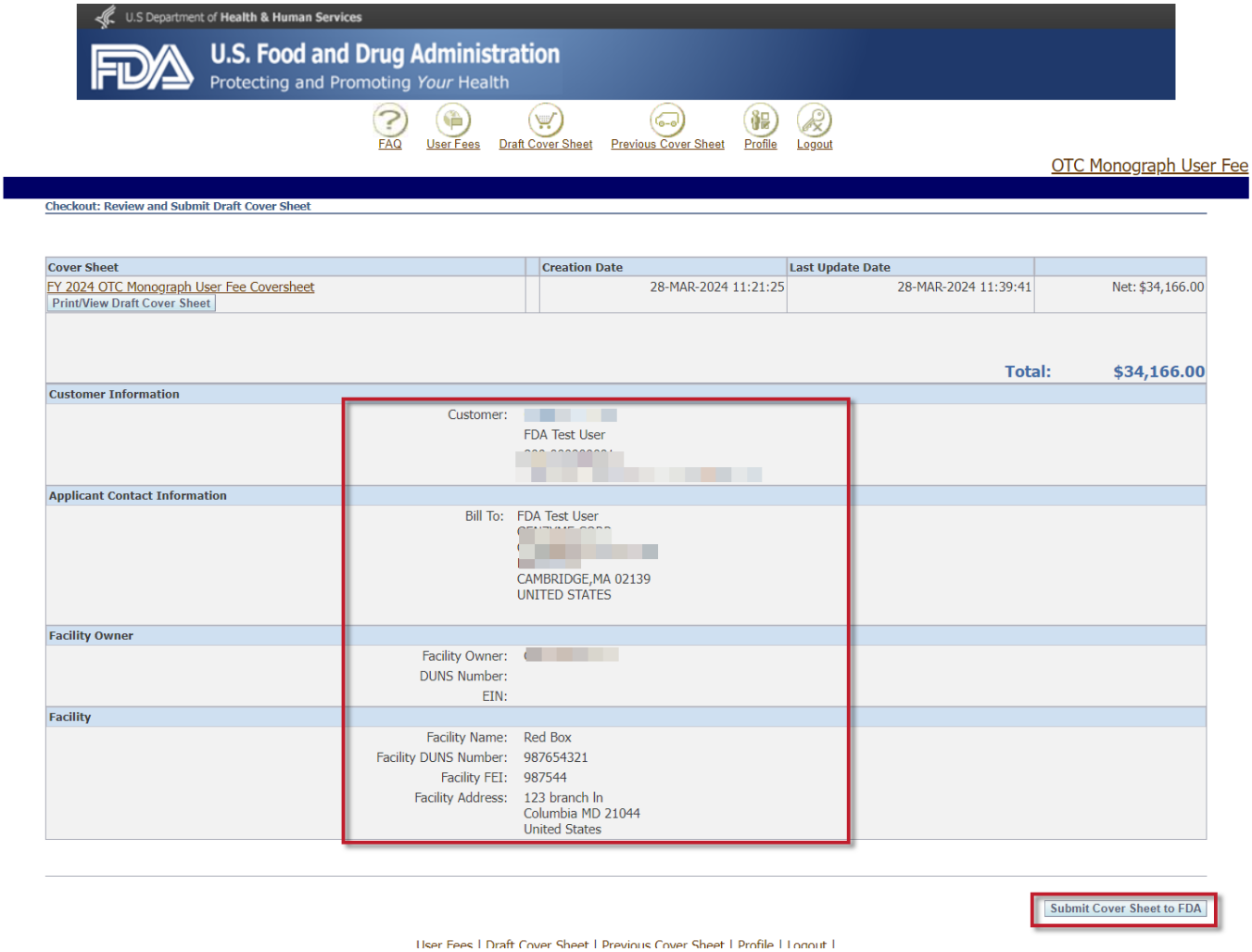


18. Confirm the “Bill To” information and click the “Next” button to proceed.
    Note: If you would like to change the billing information, click the “Change” button to create a new address.



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

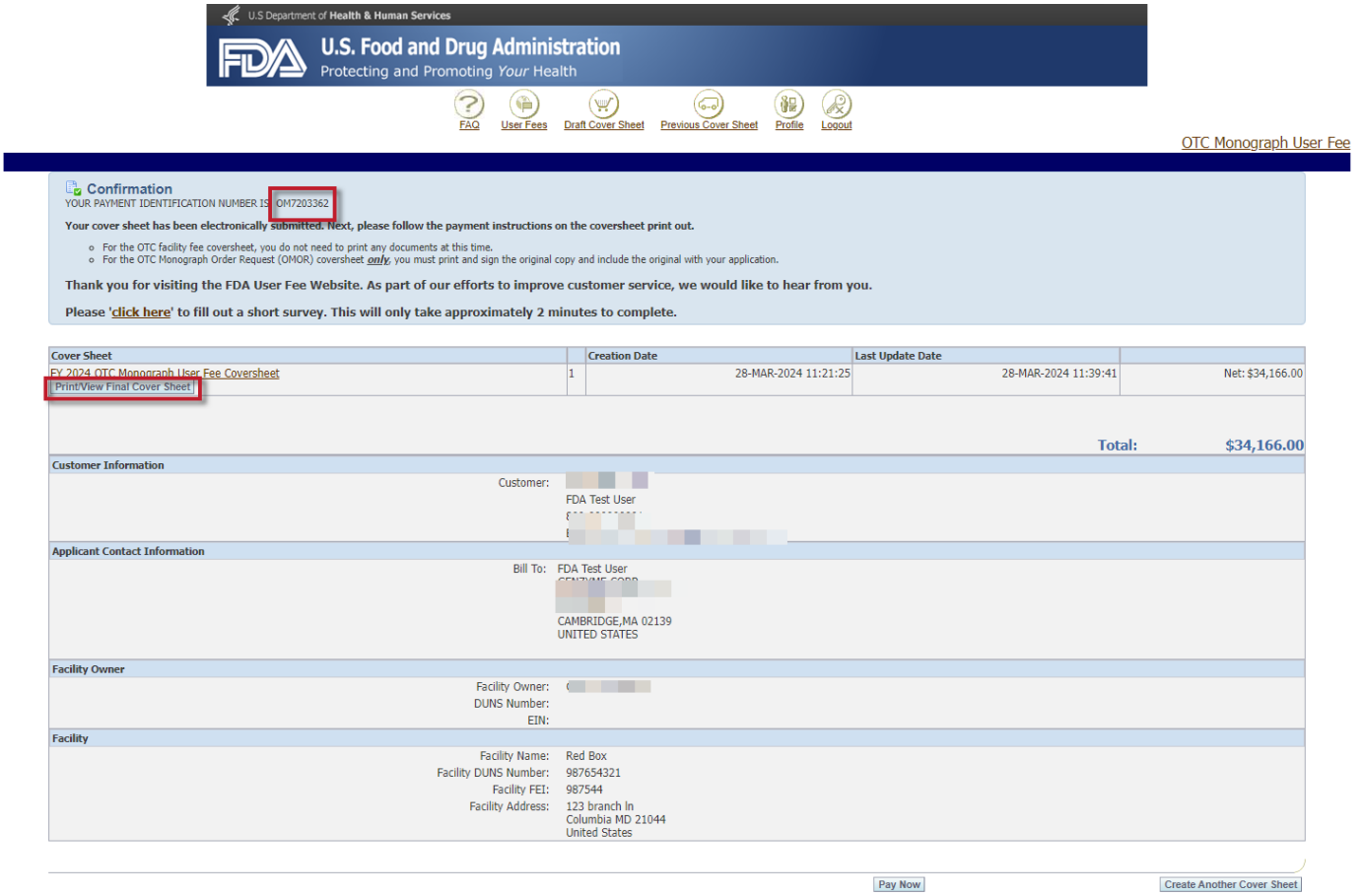
19. Confirm the details of your cover sheet on the Checkout: Review and Submit Draft Cover Sheet page. Click the "Submit Cover Sheet to FDA" button to electronically submit your OMUFA cover sheet.



20. A confirmation of your cover sheet submission and a Payment Identification Number (PIN) appears. On this page, you may:
    a) Click the "Print/View Final Cover Sheet" button to view and/or print the cover sheet.
    b) Click the "Pay Now" button to make an online payment.
    c) Click the "Create Another Cover Sheet" button to create another cover sheet. Refer to steps 11 through 20.

    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.

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



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.