

PDUFA Cover Sheet Creation: Step-by-Step Instructions

On September 30, 2022 the President signed into law the Food and Drug Administration User Fee Reauthorization Act of 2022. This new law includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products. The new law ensures that FDA will continue to receive a source of stable and consistent funding during fiscal years 2023-2027 that will allow the agency to fulfill its mission to protect and promote public health by helping to bring to market critical new medicines for patients.

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992 and renewed in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), 2017 (PDUFA VI) and 2022 (PDUFA VII). It authorizes FDA to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process.

For additional information, please refer to:

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm>

- 1) Access the User Fee Website: https://userfees.fda.gov/OA_HTML/pdufaCAcdLogin.jsp
- 2) Review the statement and select the "I Understand" radio button.
- 3) For users who have an existing user name and password, proceed to Step 4;
 - a) If you do not have an existing account, see the [FDA User Fee Account Creation: Step-by-Step Instructions](#) for step-by-step instructions on how to create an account. For additional assistance, contact the User Fee Helpdesk at userfees@fda.gov.
- 4) Click on the 'Login to Enterprise ICAM' hyperlink.



At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted application in the previous FY. Applicants with any payment from a prior year without a corresponding application submission should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to CDERCollections@fda.hhs.gov and cc: userfees@fda.gov. Form FDA 3913 is available at <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.

Starting in FY 2021, a payment made to a user fee cover sheet within the FY that is not linked to an application submitted in that FY will not be transferred to the new FY. Previous FY payment without an application submission will be refunded and the applicant will have to submit a new user fee cover sheet with a new payment for the new FY.

Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Useful Links

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

[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](#)

[Vulnerability Disclosure Policy](#)

Log in to the User Fee System

[Login to Enterprise ICAM](#)

[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.

PDUFA Cover Sheet Creation: Step-by-Step Instructions

5) Enter the “Username” to login to your UFS account, Click on “Next” button you are navigated to the “Password” entry page.



Sign In to FDA system

Next →

[Reset Password](#)

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

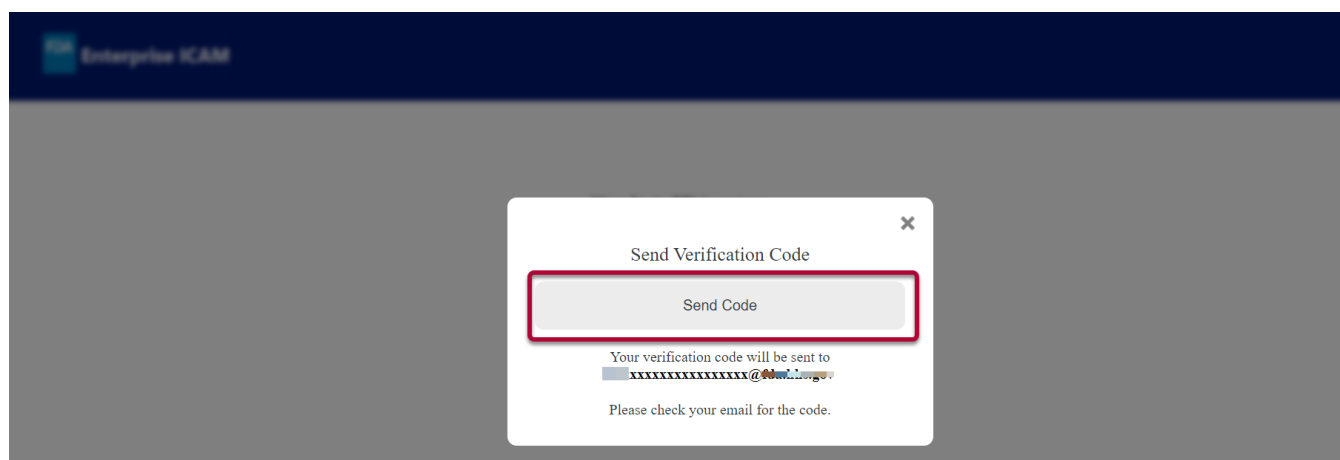


Sign In to FDA system

< Next →

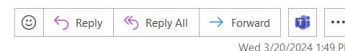
[Reset Password](#)

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.



PDUFA Cover Sheet Creation: Step-by-Step Instructions**8) You will receive an email with “OTP” code to your registered email address.**

Your One Time Passcode (OTP)

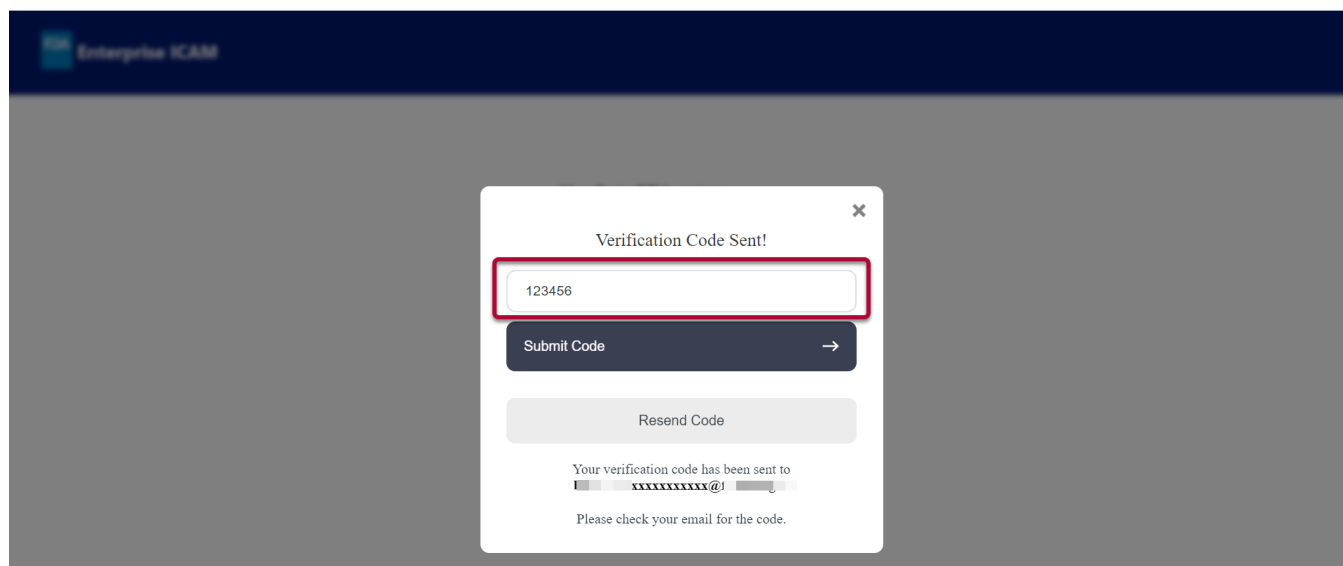


Wed 3/20/2024 1:49 PM

To authenticate, please use the following One Time Password (OTP):

123456

It expires in 15 minutes.

Don't share this OTP with anyone. Contact User Fee Helpdesk USERFEES@FDA.GOV if you haven't requested it.**9) Return to “Verification Code Sent” screen and enter the “OTP” code received into your registered email address. Click on “Submit Code” button.**

Enterprise KAM

Verification Code Sent!

123456

Submit Code →

Resend Code

Your verification code has been sent to [redacted email address]

Please check your email for the code.

PDUFA Cover Sheet Creation: Step-by-Step Instructions

10) Click the “Go” button next to “PDUFA Pre-Market Cover Sheets”.



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

11) Select ‘Continue’ button at the bottom of the page.

U.S. Food and Drug Administration
 Protecting and Promoting Your Health

FAQ
User Fees
Draft Cover Sheet
Previous Cover Sheet
Profile
Logout

[Prescription Drug User Fee](#)

User Fee Websites

[Prescription Drug User Fee Act](#)
[Center for Biologic Evaluation and Research](#)
[Center for Drug Evaluation and Research](#)

Please review the important message below regarding a change in policy on payment transfers across FYs before proceeding to the next step.

At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted application in the previous FY. Applicants with any payment from a prior year without a corresponding application submissions should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to CDERCollections@fda.hhs.gov and cc: userfees@fda.gov. Form FDA 3913 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.

Starting in FY2021, a payment made to a user fee cover sheet within the FY that is not linked to an application submitted in that FY will not be transferred to the new FY. Previous FY payments without an application submission will be refunded and the applicant will have to submit a new user fee cover sheet with a new payment for the new FY.

Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Click "Continue" if you still want to proceed with creating your cover sheet or click "Go Back" to choose the correct FY's cover sheet.

[Go Back](#)
[Continue](#)

[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#)

[FDA Home Page](#) | [Search FDA Site](#) | [Contact FDA](#) | [Privacy](#) | [Vulnerability Disclosure Policy](#) | [Accessibility](#) | [FDA Website Management Staff](#)

PDUFA Cover Sheet Creation: Step-by-Step Instructions

12) Scroll to the bottom of the page and select the 'Application Details' button.

User Fee Websites

[Prescription Drug User Fee Act](#)

[Center for Biologic Evaluation and Research](#)

[Center for Drug Evaluation and Research](#)

U.S. Food and Drug Administration
 Protecting and Promoting Your Health

[Prescription Drug User Fee](#)

INSTRUCTIONS FOR COMPLETING PRESCRIPTION DRUG USER FEE COVER SHEET FORM FDA 3397

I. Form FDA 3397 is to be completed for and submitted with each new drug or biologic product original application submitted to the Agency. Form FDA 3397 should be placed in the first volume of the application with the application (FORM FDA 356(h)) form. Form FDA 3397 is to be completed on-line at https://userfees.fda.gov/OA_HTML/jpdufaCAccilLogin.jsp. If you need assistance in completing the form call 301-796-7200 or email: userfees@fda.gov

Complete this form 3397 for:

- 505(b) and 351(a) Original Applications
- Resubmission of 505(b) and 351(a) Original Applications after a Refuse to File
- Resubmissions of 505(b) and 351(a) Original Applications Withdrawn before the filing date

ITEM NO.	INSTRUCTIONS
1-2.	Self-explanatory
3.	PRODUCT NAME: Include generic or proper name and trade name, as applicable.
4.	BLA STN / NDA NUMBER: Please include only a NDA number or a BLA STN, as applicable. FOR AN ORIGINAL BIOLOGIC LICENSE APPLICATION (BLA): Indicate the 6-digit BLA number (Submission Tracking Number (STN)) if pre-assigned, otherwise leave blank. FOR DRUG PRODUCTS: Indicate the new drug application (NDA) number. NDA numbers can be obtained by completing the information at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/cgm114927.htm CLINICAL DATA: The definition of "clinical data" for the assessment of user fees is found in FDA's Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees. FDA's guidance on the definition of clinical data can be found on FDA's web site: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM078320.pdf
6.	USER FEE I.D. NUMBER: Please include the ID number (generated when completing Form FDA 3397) on the application payment check.
7-8.	PRIORITY REVIEW VOUCHER: If you are redeeming a priority review voucher awarded to a sponsor of a tropical disease product application (see section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), please include the priority review voucher number assigned when the tropical disease or medical countermeasure product was approved. See FDA's Guidance for Industry: Tropical Disease Priority Review Vouchers for further information. FDA's guidance can be found on FDA's web site: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080599.pdf If you are redeeming a priority review voucher awarded to a sponsor of a medical countermeasures application (see section 565A of the Federal Food, Drug, and Cosmetic Act), please include the priority review voucher number assigned when the medical countermeasure product was approved. See FDA's Draft Guidance for Industry: Material Threat Medical Countermeasure Priority Review Vouchers for further information. FDA's guidance can be found on FDA's web site: https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM592548.pdf
9.	EXCEPTIONS: The application is for an orphan drug product or for a skin-test diagnostic product. ORPHAN EXCEPTION: Under section 736(a) (1) (F) of the FD&C Act, a human drug application is not subject to an application fee if the proposed product is for a rare disease or condition designated under section 526 of the FD&C Act (the applicant has an approved orphan drug designation) AND the application does not include an indication that is not designated. A copy of the FDA letter granting orphan designation should be included with the BLA/ANDA submission. SKIN-TEST DIAGNOSTIC PRODUCT EXCEPTION: The application is for a skin-test diagnostic product. Under section 736 of the FD&C Act, a human drug application for a skin-test diagnostic product shall not be subject to an application fee.
10.	WAIVER: Complete this section only if a waiver of user fees, including a small business waiver, has been granted for this application. A copy of the official FDA notification that a waiver has been granted must be provided with the BLA/ANDA submission.

II. 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:

Payment Options:

The preferred payment method is online using Automated Clearing House (ACH) electronic check (eCheck) via Pay.gov; paying online ensures that your payment will be processed in a timely manner. The additional payment options include paper check, bank draft, money order, or wire transfer.

- Pay.gov can be used to submit secure online payments for cover sheets to the FDA. Payments can be made through the Automated Clearing House (ACH) method, which can come directly from your bank account or an eCheck. The FDA has partnered with the US Department of the Treasury to use Pay.gov, a web-based payment application, for online electronic payment. The Treasury has compiled a comprehensive list of Pay.gov FAQs which can be assessed at <https://www.pay.gov/Web/HeloHTML/about.html>
- Make your check payable to the U.S. Food and Drug Administration and include 1 copy of the FDA PDUFA cover sheet. Please write the payment identification number (PIN) beginning with "PD" on your check: **FDA will not be able to process your payment correctly without your PDUFA cover sheet PIN.**

Mail your check and one copy of the PDUFA cover sheet to:
 The Food and Drug Administration
 P.O. Box 979107
 St. Louis, MO 63197-9000
Note: Please do not send your application to this address, only your payment.

If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to:
 U.S. Bank
 ATTN: Government Lockbox 979107
 3180 Rider Trail S.
 Earth City, MO 63045
Note: Please do not send your application to this address, only your payment! This address is for courier delivery only. If you have any questions concerning courier delivery, contact the US Bank at 800.495.4981.

3. If paying by wire transfer, please ask your financial institution about the wire transfer fee and include it with your user fee payment to ensure that your fee is fully paid. The wire transfer must reference the User Fee Payment I.D. Number (PIN) which was generated upon submission of the cover sheet. **FDA will not be able to process your payment correctly without your PIN.** Please include your PDUFA cover sheet PIN and the NDA/BLA number with your wire transfer and send your payment to the address show below. Please note that the review of your application can not begin until full payment is received.

If your financial institution is located outside the U.S., they will need to send the payment to us using a US-based intermediary bank. They will be able to handle this detail for you.

Some banks also have two separate SWIFT numbers beginning with FRNYUS33. You should choose the one which reflects the correct address (33 Liberty Street). Below are full details on sending us a wire payment.

You may send your wire payment using the following information.

Wire transfer payment
 US Department of Treasury
 TREAS NYC
 33 Liberty Street
 New York, NY 10045

FDA Deposit Account Number: 75060099
 US Department of Treasury Routing/Transit number: 021030004
 SWIFT Number: FRNYUS33
 Beneficiary: FDA
 1350 Piccard Drive
 Suite 200A
 Rockville, MD 20850

If needed for accounting purposes, FDA's tax identification number is 53-0196965

Note: Wire transfers to the Department of Treasury are distinct from online ACH payments via Pay.gov.

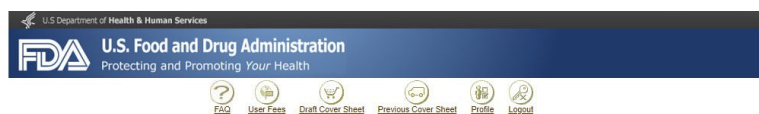
Please ensure you have disabled pop-up blockers on your browser prior to clicking "Application Details" and filling out your cover sheet.

PRESCRIPTION USER FEE COVER SHEET

Application Details

PDUFA Cover Sheet Creation: Step-by-Step Instructions

- 13) Make the appropriate selections and provide the requested information as applicable:**
- a) Select 'CDER Submission' or 'CBER Submission'
 - b) Provide the 'Established Name/Proper Name', 'Trade Name', 'NDA Number', and 'BLA Submission Tracking Number (STN)'
 - c) Select the type of application requested.
 - d) Select 'Yes' or 'No' to the application requiring clinical data for approval question.
 - e) Select 'The required clinical data are contained in the application' or 'The required clinical data are submitted by reference to:'
 - a) If 'The required clinical data are submitted by reference to:' is selected, provide either the 'Application Number Containing the Data' or 'Supplement Number Containing the Data'
 - f) Select 'Yes' or 'No' to the Priority Review Voucher for the treatment of tropical diseases question
 - a) If 'Yes', provide the Priority Review Voucher number



PREScription USER FEE COVER SHEET

► Show Legend

► Show Legend

☐ CDER Submission ☐ CBER Submission

Provide Application Number [Help](#)

NDA Number BLA Number

Include Established Name/Proper Name and Trade Name as applicable

Established Name/Proper Name

Trade Name

Is this an Original Application? [Help](#)

☐ Yes ☐ No

Does this application require clinical data for approval? [Help](#)

☐ Yes ☐ No

PDUFA Cover Sheet Creation: Step-by-Step Instructions

14) If applicable, select the 'Exceptions and Waivers' button; otherwise make the appropriate selections and click 'Done' to continue.

Are you redeeming a Priority Review Voucher for the treatment of tropical diseases? [Help](#)

☒ Yes ☒ No

Are you redeeming a Priority Review Voucher for Medical Countermeasures? [Help](#)

☒ Yes ☒ No

Does this application have an exception or a waiver (e.g., orphan exception, small business waiver, etc.)?

☒ Yes ☐ No

☐ The applicant qualifies for the Orphan Exception under section 736(a)(1)(F) of the Federal Food Drug and Cosmetic Act [Help](#)

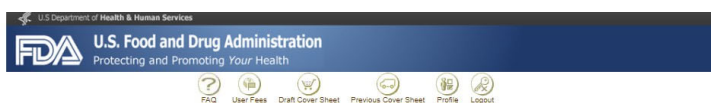
☐ The applicant qualifies for the Skin Test Diagnostic Product Exception under Section 736 of the Federal Food, Drug, and Cosmetic Act [Help](#)

☐ The application is submitted by State or Federal Government entity for a drug that is not distributed commercially

☐ A waiver of an application fee has been granted for this application [Help](#)

Done Cancel

15) Click 'Done' to continue.



Prescription Drug User Fee

PRESCRIPTION USER FEE COVER SHEET

[Show Legend](#)

[Show Legend](#)

☒ CDER Submission ☐ CDER Submission

Provide Application Number [Help](#)

NDA Number: 2345677 BLA Number:

Include Established Name/Proper Name and Trade Name as applicable

Established Name/Proper Name: FDA TEST PRODUCT

Trade Name: FDA TEST

Is this an Original Application? [Help](#)

☒ Yes ☐ No

Does this application require clinical data for approval? [Help](#)

☒ Yes ☐ No

Are you redeeming a Priority Review Voucher for the treatment of tropical diseases? [Help](#)

☐ Yes ☐ No

Are you redeeming a Priority Review Voucher for Medical Countermeasures? [Help](#)

☐ Yes ☐ No

Does this application have an exception or a waiver (e.g., orphan exception, small business waiver, etc.)?


☐ Yes ☒ No


Done Cancel







PDUFA Cover Sheet Creation: Step-by-Step Instructions

16) After arriving at the Draft Cover Sheet page, scroll to the bottom and select the 'Next' button to review the contact and address information.

A. Note: you may save the cover sheet by selecting the 'Save Cover Sheet' button. You may return to the 'Draft Cover Sheet' menu to access your saved draft cover sheet. Select the checkbox under the 'Delete' column and select the 'Delete Selected Draft(s)' button to delete a draft cover sheet.


U.S. Department of Health & Human Services



U.S. Food and Drug Administration
Protecting and Promoting Your Health


FAQ

User Fees

Draft Cover Sheet

Previous Cover Sheet

Profile

Logout

[Prescription Drug User Fee](#)

Cover Sheet | Saved Cover Sheets

Draft Cover Sheet

Items
<div>  You now have four options to proceed: </div> <ol style="list-style-type: none"> 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 <u>not</u> 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 <u>different cart name</u>. 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

Delete	Cover Sheet	Creation Date	Last Update Date	
<input type="checkbox"/>	PRESCRIPTION USER FEE COVER SHEET Modify Application Details	25-MAR-2024 15:28:29	25-MAR-2024 15:37:58	Net: \$2,024,348.00


Delete Selected Draft(s)
Save Cover Sheet
Next







[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#) |

Last Updated: March 25, 2024

PDUFA Cover Sheet Creation: Step-by-Step Instructions

- 17) On the 'Checkout: Applicant Contact Information' page, you will see the billing information for this cover sheet. You can change the address by selecting the 'Change' button and follow the instructions to update the address. Once the information has been verified and is accurate, select 'Next' to proceed.





U.S. Food and Drug Administration
 Protecting and Promoting Your Health

Prescription Drug User Fee

Checkout: Applicant Contact Information

Bill To

Customer: 
 Contact: FDA Test User

 Address: 
 CAMBRIDGE, MA 02135
 UNITED STATES

Change

Payment Information

Online payments (preferred):
 The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Credit Card payments (Discover, VISA, MasterCard, American Express) are acceptable for amounts less than \$25,000.
 Make an online payment at <https://userfees.fda.gov/pay>. (Note: only full payments are accepted. No partial payments can be made online.)

Alternative Payment Options	
Checks: Mail payment and copy of your invoice to: Food and Drug Administration R.O. Box 979107 St. Louis, MO 63197-9000 For overnight courier use only: U.S. Bank ATTN: Government Lockbox 979107 1005 Convention Plaza St. Louis, MO 63101 If a phone number is also required for courier delivery, use 314-418-4013.	Wire Transfers: US Department of the Treasury TREAS NYC 33 Liberty Street New York, NY 10045 FDA Deposit Account Number: 75060099 Routing/Transit Number: 021030004 SWIFT Number: FRNYUS33 Reference - Cite PIN # Payments should include the payment number(PIN) with the payment. All fees assessed by your financial institution for wire transfers should be added to your payment to ensure that the full invoice amount is received.

Note:

- FDA will not be able to process your payment correctly without your PIN.
- Wire transfers to the Department of Treasury are distinct from online ACH payments via Pay.gov.

Save Cover Sheet

Next

PDUFA Cover Sheet Creation: Step-by-Step Instructions

- 18) Review and verify your information and select the 'Submit Cover Sheet to FDA' button to obtain your Payment Identification Number (PIN).

U.S. Food and Drug Administration
 Protecting and Promoting Your Health

Prescription Drug User Fee

Checkout: Review and Submit Draft Cover Sheet

Cover Sheet	Creation Date	Last Update Date	
FY 2024 PRESCRIPTION USER FEE COVER SHEET	25-MAR-2024 15:46:57	25-MAR-2024 15:49:27	Net: \$2,024,348.00
Print/View Draft Cover Sheet			

Total: **\$2,024,348.00**

Customer Information

Customer: FDA Test User

Applicant Contact Information

Bill To: FDA Test User
 UNITED STATES

Submit Cover Sheet to FDA

[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#)

- 19) After reading the message, select 'Submit Cover Sheet to FDA'.

U.S. Food and Drug Administration
 Protecting and Promoting Your Health

Prescription Drug User Fee

Please review the important message below regarding a change in policy on payment transfers across FYs before proceeding to the next step.

At the end of fiscal year (FY) 2020, FDA will change its policies regarding the transfer of payments across fiscal years to align with the Treasury Accounting Treatment Manual. The Agency will refund payments made to user fee cover sheet ID that are not linked to a submitted application in the previous FY. Applicants with any payment from a prior year without a corresponding application submissions should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to CDERCollections@fda.hhs.gov and cc: userfees@fda.gov. Form FDA 3913 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM492188.pdf>.

Starting in FY2021, a payment made to a user fee cover sheet within the FY that is not linked to an application submitted in that FY will not be transferred to the new FY. Previous FY payment without an application submission will be refunded and the applicant will have to submit a new user fee cover sheet with a new payment for the new FY.

Payment transfers occurring within the same FY will not be affected by this change in policy. If you have any questions regarding this change, please contact the User Fee Staff at userfees@fda.gov.

Cancel

Submit Cover Sheet to FDA

[User Fees](#) | [Draft Cover Sheet](#) | [Previous Cover Sheet](#) | [Profile](#) | [Logout](#)

PDUFA Cover Sheet Creation: Step-by-Step Instructions

- 20) A unique User Fee PIN will be generated with your cover sheet upon submission. Please note that your completed cover sheet is your invoice. To obtain an invoice copy for your records, select on the 'Print/View Final Cover Sheet' button on the confirmation page.

Once you submit your cover sheet and obtain your PIN, you may pay online by selecting the 'Pay Now' button.

You can create and submit another PDUFA cover sheet by selecting the 'Create Another Cover Sheet' button.

U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
 Protecting and Promoting Your Health

FAQ User Fees Draft Cover Sheet Previous Cover Sheet Profile Logout

[Prescription Drug User Fee](#)

Confirmation
 YOUR PAYMENT IDENTIFICATION NUMBER IS PD3018486

Your Cover Sheet has been submitted electronically. You must print two copies and sign the original. Please include the original with your application and include a copy with your payment.

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 2024 PRESCRIPTION USER FEE COVER SHEET Print/View Final Cover Sheet	1 25-MAR-2024 15:46:57	25-MAR-2024 15:49:27	Net: \$2,024,348.00
			Total: \$2,024,348.00

Customer Information
 Customer: FDA Test User

Applicant Contact Information
 Bill To: FDA Test User
 UNITED STATES

[Pay Now](#) [Create Another Cover Sheet](#)

Note: You can submit payment online by credit card or Automated Clearing House (ACH) electronic check (eCheck), by paper check or by wire/bank transfer. There is a credit card payment limit of \$24,999.99. Any payment above the limit will need to be paid using another payment method. The preferred payment method is online. If you prefer to pay via check or wire transfer, please write the PIN on the check or include the PIN 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.