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 <u>FDA User Fee Account Creation: Step-by-Step Instructions</u> for step-by-step instructions on how to create an account. For additional assistance, contact the User Fee Helpdesk atuserfees@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 <u>Form FDA 3913</u> and email the form to <u>CDERCollections@fda.hbs.gov</u> and cc: <u>userfees@fda.gov</u>. 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
- <u>User Fee Payment Information</u>
- 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.

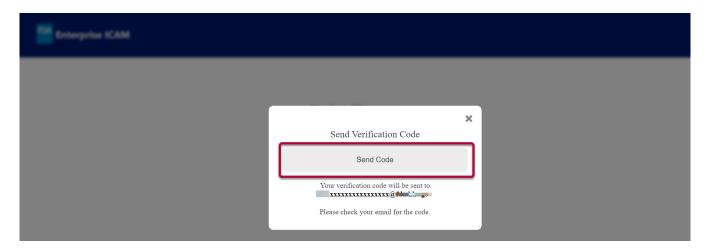
5) Enter the "Username "to login to your UFS account, Click on "Next" button you are navigated to the "Password" entry page.



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



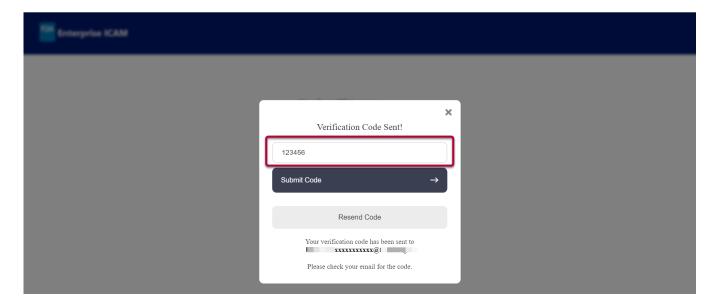
7) Click "Send Code" button to receive OTP to your Registered email address. After clicking on "Send Code button you will be navigated to Verification Code Sent Screen.



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.



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	G	io

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.

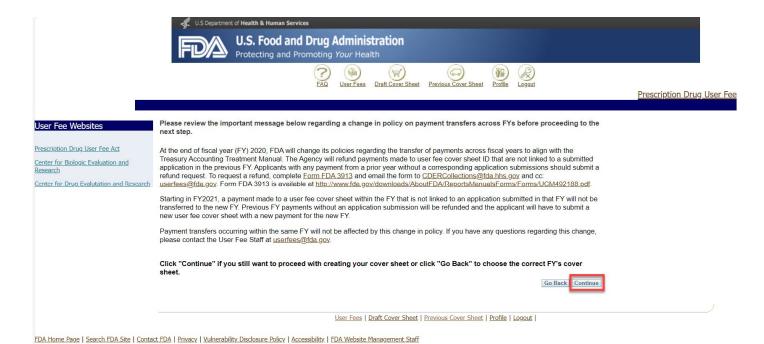
User Fee	Description	
ANIMAL DRUG USER FEE 2024	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2024	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2024	BsUFA Cover Sheets	Go
Generic Drug User Fee 2024	GDUFA Cover Sheets	Go
Medical Device User Fee 2024	MDUFA Cover Sheets (PMA, 510k, etc.)	Go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



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



Center for Biologic Evaluation and Research Center for Drug Evalutation and Research

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/pdu/aCA.cdl.ogin.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
 Resubmission 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 PRODUCT'S: Indicate the new drug application (NDA) number. NDA numbers can be obtained by completing the information at http://www.fda.gov/brugns/disublences-compleance-Begularien/formation/cityada news.umi 142927,min
5.	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 set http://www.fda.gov/downloads/pungs/Guidance.Com/lance-Regulatory/information/Guidances/LUCM/97330_df.
6.	USER FEE I.D. NUMBER: Please include the ID number (generated when completing Form FDA 3397) on the application payment check.
	PRIORITY REVIEW YOUCHER: 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 (FIGSC Act)), please include the priority review voucher number assigned when the tropical disease or moderal conventmensary product was approved. See FDA's Guidance for industry. Tropical Disease Priority Review Vouchers for further information, FDA's liguidance can be found on FDA's web after the priority review voucher such assigned when the priority review vouchers available to a sponsor of a medical countermeasures application (see section 554 of the Federal Food, Drug, and Cosmetic Act), please include the priority review voucher awarded to a sponsor of a medical countermeasures application (see section 555 of the Federal Food, Drug, and Cosmetic Act), please include the priority review vouchers awarded to a sponsor of a medical countermeasures application (see section 555 of the Federal Food, Drug, and Cosmetic Act), please include the priority review vouchers for further information FDA's guidance can be found on FDA's web
	site: https://www.fsia.gov/downloads/Requisitor/information/Guidances/UCM592548.edf
9.	EXCEPTIONS: The application is for an orphan drug product or for a skin-test disgnostic product. ORPHAN EXCEPTIONE 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/NDA 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.	application rec. WAWER: 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 BLANDA 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:

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.

- 1. Pay gov can be used to submit secure eniline 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 oritine electronic payment. The Treasury has compiled a comprehensive list of Pay gov FAGs which can be assessed at https://www.avy.org/Yeb/self-III/Labout.html
- 2 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. <u>FDA will not be able to process your payment correctly without your PDUFA cover sheet PIN</u>.

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 y

nd 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 Tail 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 net 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 SW/IFT 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: 7506099 US Department of Treasury Routing/Transit number: 021030004 SWIFT Number: FRNYUS33 Beneficiary: FDA 1350 Piccard Drive Suite 2004 Rockville, Mb 20850

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

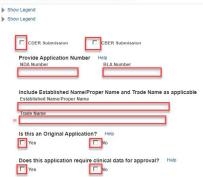
Note: Wire transfers to the Department of Treasury are distinct from online ACH payments via Pay.gov.

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

- 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:'
 - 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
 - If 'Yes', provide the Priority Review Voucher number



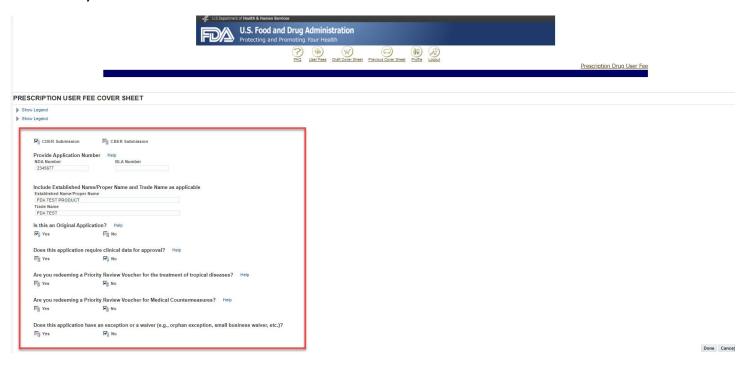
PRESCRIPTION USER FEE COVER SHEET



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

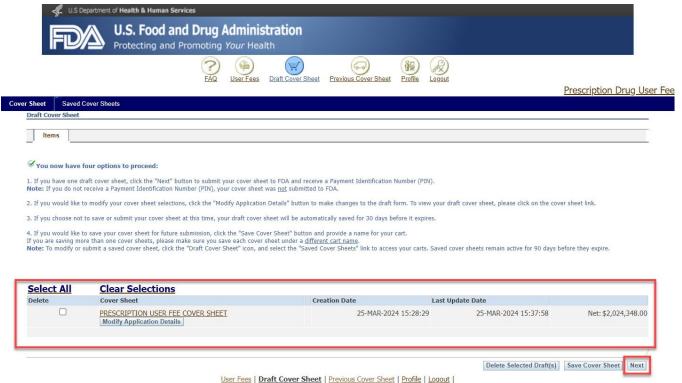


15) Click 'Done' to continue.



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.

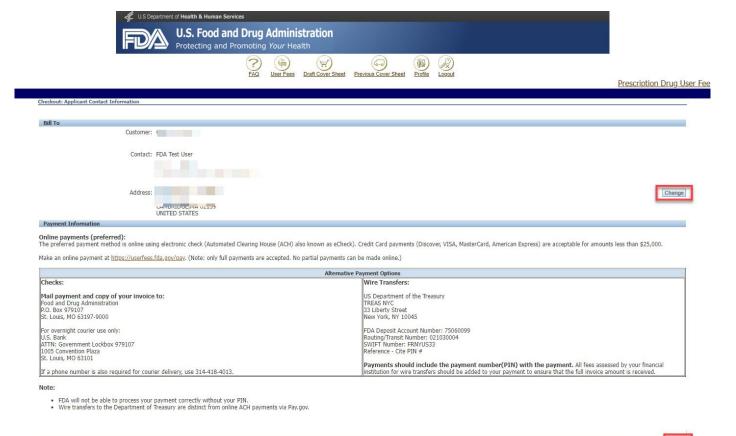
A. Note: you may save the cover sheet by selecting the 'Save Cover Sheet' button. You may return to the 'Draft Cover Sheet' menu to access your saved draft cover sheet. Select the checkbox under the 'Delete' column and select the 'Delete Selected 'Draft(s)' button to delete a draft cover sheet.



Save Cover Sheet Next

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.



Prescription Drug User Fee

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).



User Fees Draft Cover Sheet Previous Cover Sheet Profile

Checkout: Review and Submit Draft 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: CENTURE CO. FDA Test User Applicant Contact Information Bill To: FDA Test User UNITED STATES Submit Cover Sheet to FDA

<u>User Fees</u> | <u>Draft Cover Sheet</u> | <u>Previous Cover Sheet</u> | <u>Profile</u> | <u>Logout</u> |

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



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.

User Fees Draft Cover Sheet Previous Cover Sheet Profile

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.hbs.gov and co: 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.

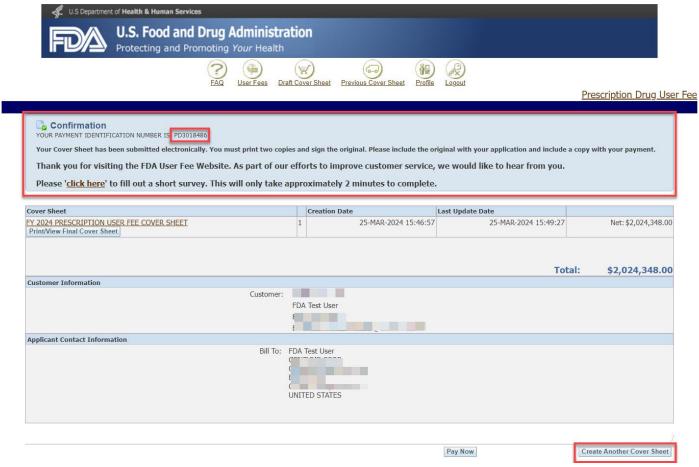
Cancel Submit Cover Sheet to FDA

<u>User Fees</u> | <u>Draft Cover Sheet</u> | <u>Previous Cover Sheet</u> | <u>Profile</u> | <u>Logout</u> |

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.



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 <u>userfees@fda.gov</u>.