

## PDUFA Cover Sheet Creation: Step-by-Step Instructions

On August 18, 2017 the President signed into law the Food and Drug Administration Reauthorization Act (FDARA). 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 2018-2022 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), and 2017 (PDUFA VI). 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](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](mailto:userfees@fda.gov).
- 4) Enter a valid user name and password.
- 5) Click the “Login” button.



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](mailto:CDERCollections@fda.hhs.gov) and cc: [userfees@fda.gov](mailto:userfees@fda.gov). Form FDA 3913 is available at <http://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](mailto: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](#)

**Log in to the User Fee System**

User Name:  Password:

[Forgot User Name/Password?](#)

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

**User Fee System Alerts**

Please be advised that the FDA User Fee System will be unavailable from 9:00 AM-12:00 PM EST on Saturday, July 18, 2020 for scheduled maintenance.

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.

**If you are an agent representing another company, please refer to the [FAQs](#) and follow the proper procedures.**

In order to register, you will need either your organization number (provided by FDA) or your organization's Employer Identification Number (EIN). If you have any questions or concerns, contact the User Fee Helpdesk at 301-796-7200 or email [userfees@fda.gov](mailto:userfees@fda.gov)

**Need Help? Click Here For Assistance.**

## PDUFA Cover Sheet Creation: Step-by-Step Instructions

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



#### User Fee Website

##### Welcome FDA Tester

##### Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2020	FURLS Device Facility User Fee	<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	
ANIMAL DRUG USER FEE 2020	ADUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>
ANIMAL GENERIC DRUG USER FEE 2020	AGDUFA Cover Sheets	<input type="button" value="Go"/>
Biosimilar User Fee 2020	BsUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2020	GDUFA Cover Sheets	<input type="button" value="Go"/>
Medical Device User Fee 2020	MDUFA Cover Sheets (PMA, 510k, etc.)	<input type="button" value="Go"/>
Prescription Drug User Fee 2020	PDUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>

##### 2019 Cover Sheets

FY 2019 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2018 through September 30th, 2019.

User Fee	Description	
Generic Drug User Fee 2019	GDUFA Cover Sheets	<input type="button" value="Go"/>

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



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 submission should submit a refund request. To request a refund, complete [Form FDA 3913](#) and email the form to [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov) and cc: [userfees@fda.gov](mailto: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](mailto: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.


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

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#)

[FDA Website Management Staff](#)

## PDUFA Cover Sheet Creation: Step-by-Step Instructions

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



**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](#)

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

1. 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/DA\\_HTML/pdufaCAcdi.cfm](https://userfees.fda.gov/DA_HTML/pdufaCAcdi.cfm). If you need assistance in completing the form call 301-796-7200 or email [userfees@fda.gov](mailto: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.	<b>Self explanatory</b>
3.	<b>PRODUCT NAME:</b> Include generic or proper name and trade name, as applicable.
4.	<b>BLA STN / NDA NUMBER:</b> Please include only a NDA number or a BLA STN, as applicable.  <b>FOR AN ORIGINAL BIOLOGIC LICENSE APPLICATION (BLA):</b> Indicate the 6-digit BLA number (Submission Tracking Number (STN)) if pre-assigned, otherwise leave blank.  <b>FOR DRUG PRODUCTS:</b> Indicate the new drug application (NDA) number. NDA numbers can be obtained by completing the information at <a href="http://www.fda.gov/oc/ugs/GuidanceComplianceRegulatoryInformation/Guidance/ucm114022.htm">http://www.fda.gov/oc/ugs/GuidanceComplianceRegulatoryInformation/Guidance/ucm114022.htm</a> .
5.	<b>CLINICAL DATA:</b> 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: <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf</a> .
6.	<b>USER FEE I.D. NUMBER:</b> Please include the ID number (generated when completing Form FDA 3397) on the application payment check.
7.	<b>PRIORITY REVIEW VOUCHER:</b> 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: <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080589.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080589.pdf</a> .  For a medical countermeasure voucher, the instructions provided in this guidance apply as well.
8.	<b>EXCEPTIONS:</b> The application is for an orphan drug product. Under section 735(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 (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.
9.	<b>WAIVER:</b> 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/NDA 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.

1. 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 FDAs which can be accessed at <https://www.pay.gov/WebHelp/HTML/About.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. **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.

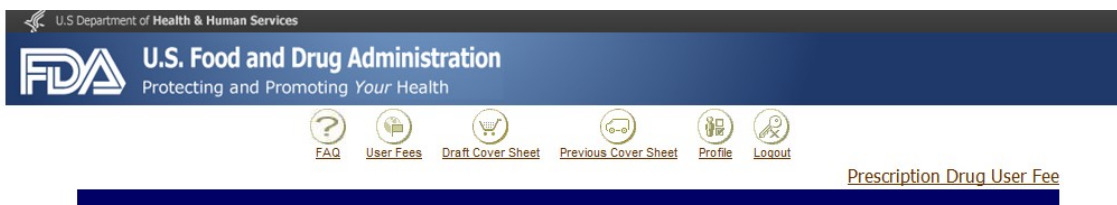
If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to:  
U.S. Bank  
ATTN: Government Lockbox 979107  
1006 Commencement Plaza  
St. Louis, MO 63101  
Note: Please do not send your application to this address, only your payment. This address is for courier delivery only. If you have any questions concerning courier delivery, contact the US Bank at (314) 418-4013.
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 shown 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**

- 9) 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

CDER Submission       CBER Submission

Include Established Name/Proper Name and Trade Name, as applicable

ESTABLISHED NAME/PROPER NAME      TRADE NAME  
     

NDA NUMBER      BLA SUBMISSION TRACKING NUMBER (STN)  
     

Is this an Original Application?

Yes       No

Does this application require clinical data for approval?

Yes       No

The required clinical data are contained in the application

The required clinical data are submitted by reference to:

(Application Number Containing the Data)

(Supplement Number Containing the Data)

**PRESCRIPTION USER FEE COVER SHEET**

>Show Legend

CDER Submission
  CBER Submission

**Include Established Name/Proper Name and Trade Name, as applicable**

ESTABLISHED NAME/PROPER NAME 
 TRADE NAME

NDA NUMBER 
 BLA SUBMISSION TRACKING NUMBER(STN)

**Is this an Original Application?**

Yes  No

**Does this application require clinical data for approval?**

Yes  No

The required clinical data are contained in the application

The required clinical data are submitted by reference to:

(Application Number Containing the Data)

(Supplement Number Containing the Data)

## PDUFA Cover Sheet Creation: Step-by-Step Instructions

**10) If applicable, select the 'Exceptions and Waivers' button; otherwise, proceed to step 11 to continue.**

Are you redeeming a Priority Review Voucher for the treatment of tropical diseases?

Yes  No

Are you redeeming a Priority Review Voucher for Medical Countermeasures?

Yes  No

If you have an exception or a waiver (e.g., orphan exception, small business waiver, etc.), please click the button below:

[Exceptions or Waivers](#)

[Done](#) [Cancel](#)

**11) Make the appropriate selections and select 'Return to Cover Sheet' to continue.**

The screenshot shows the FDA PDUFA Waivers and Exceptions section. At the top, there is a navigation bar with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below the navigation bar are several icons: a question mark (FAQ), a person (User Fees), a document (PDUFA Cover Sheet), a document with a checkmark (Previous Cover Sheet), a document with a checkmark (Profile), and a document with a checkmark (Logout). On the right side of the navigation bar, there is a link for "Prescription Drug User Fee".

The main content area is titled "PDUFA Waivers and Exceptions". It includes a "Show Legend" link and three checkboxes with corresponding text:

- A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD DRUG AND COSMETIC ACT BEFORE 9/1/92
- THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(F) OF THE FEDERAL FOOD DRUG AND COSMETIC ACT
- THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALY

Below these checkboxes is a "WAIVER" section with the following text: "WAIVER - Complete this section only if a waiver of user fees including the small business waiver has been granted for this application. A copy of the official FDA notification that the waiver has been granted must be provided with the submission."

At the bottom of the section, there is a checkbox with the text: "Please check this box if a waiver of an application fee has been granted for this application."

At the bottom left of the section, there is a button labeled "Return to Cover Sheet".

## PDUFA Cover Sheet Creation: Step-by-Step Instructions

12) Review and verify that your information is accurate.

13) Click 'Done' to continue.

### PRESCRIPTION USER FEE COVER SHEET

[Show Legend](#)

CDER Submission
  CBER Submission

**Include Established Name/Proper Name and Trade Name, as applicable**

ESTABLISHED NAME/PROPER NAME	TRADE NAME
FDA TEST PRODUCT	FDA TEST

NDA NUMBER	BLA SUBMISSION TRACKING NUMBER(STN)
111111	

**Is this an Original Application?**

Yes
  No

**Does this application require clinical data for approval?**

Yes
  No

The required clinical data are contained in the application

The required clinical data are submitted by reference to:

(Application Number Containing the Data)	(Supplement Number Containing the Data)

**Are you redeeming a Priority Review Voucher for the treatment of tropical diseases?**

Yes
  No

**Are you redeeming a Priority Review Voucher for Medical Countermeasures?**

Yes
  No

If you have an exception or a waiver (e.g., orphan exception, small business waiver, etc.), please click the button below:

[Exceptions or Waivers](#)

[Done](#) [Cancel](#)

## PDUFA Cover Sheet Creation: Step-by-Step Instructions

14) 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  
**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

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.  
**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.

Delete	Cover Sheet	Creation Date	Last Update Date	
<input type="checkbox"/>	<a href="#">PRESCRIPTION USER FEE COVER SHEET</a> <a href="#">Modify Application Details</a>	22-SEP-2017 09:42:01	22-SEP-2017 10:18:40	Net: \$1,029,241.00

Prescription Drug User Fee  
 User Fees | **Draft Cover Sheet** | Previous Cover Sheet | Profile | Logout |



**PDUFA Cover Sheet Creation: Step-by-Step Instructions**

- 15) 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.

The screenshot displays the FDA's Prescription Drug User Fee checkout interface. At the top, the U.S. Department of Health & Human Services logo and the FDA logo are visible, along with the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this, a navigation bar contains icons for FAQ, User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout. The main heading is "Checkout: Applicant Contact Information". Underneath, there are sections for "Payment Information" and "Bill To". The "Bill To" section contains the following information: Customer: FDA; Contact: FDA Test, 999-987878, XX\_fda@fda.hhs.gov\_FDA; Address: 8455 Colesville Road, Silver Spring, MD 20109, UNITED STATES. A "Change" button is located to the right of the address. At the bottom right, there are "Save Cover Sheet" and "Next" buttons. A footer at the bottom of the page includes the text "Prescription Drug User Fee" and a list of navigation links: "User Fees | Draft Cover Sheet | Previous Cover Sheet | Profile | Logout |".

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

Checkout: Applicant Contact Information

Payment Information

Bill To

Customer: FDA

Contact: FDA Test  
999-987878  
XX\_fda@fda.hhs.gov\_FDA

Address: 8455 Colesville Road  
Silver Spring, MD 20109  
UNITED STATES

Change

Save Cover Sheet Next

Prescription Drug User Fee  
User Fees | Draft Cover Sheet | Previous Cover Sheet | Profile | Logout |

## PDUFA Cover Sheet Creation: Step-by-Step Instructions

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

Prescription Drug User Fee

Checkout: Review and Submit Draft Cover Sheet

Cover Sheet	Creation Date	Last Update Date	
FY 2018 PRESCRIPTION USER FEE COVER SHEET Print/View Draft Cover Sheet	22-SEP-2017 09:42:01	22-SEP-2017 10:24:09	Net: \$1,029,241.00
			<b>Total: \$1,029,241.00</b>

**Customer Information**

Customer: FDA  
 FDA Test  
 999-987878  
 XX\_fda@fda.hhs.gov\_FDA

**Applicant Contact Information**

Bill To: FDA Test  
 FDA  
 8435 Colesville Road  
 Silver Spring, MD 20109  
 UNITED STATES

[Submit Cover Sheet to FDA](#)

- 17) 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.

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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](mailto: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

18) 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.

Prescription Drug User Fee


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

FAQ User Fees Draft Cover Sheet Previous Cover Sheet Profile Logout

**Confirmation**  
 YOUR PAYMENT IDENTIFICATION NUMBER IS: PD3017121

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	
<a href="#">FY 2018 PRESCRIPTION USER FEE COVER SHEET</a> <small>Print/View Final Cover Sheet</small>	1	22-SEP-2017 09:42:01	22-SEP-2017 10:24:09
			<b>Total: \$1,029,241.00</b>

**Customer Information**

Customer: FDA  
 FDA Test  
 999-987878  
 XX\_fda@fda.hhs.gov\_FDA

**Applicant Contact Information**

Bill To: FDA Test  
 FDA  
 8455 Colesville Road  
 Silver Spring, MD 20109  
 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.

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