PDUFA Cover Sheet Creation: Step-by-Step Instructions

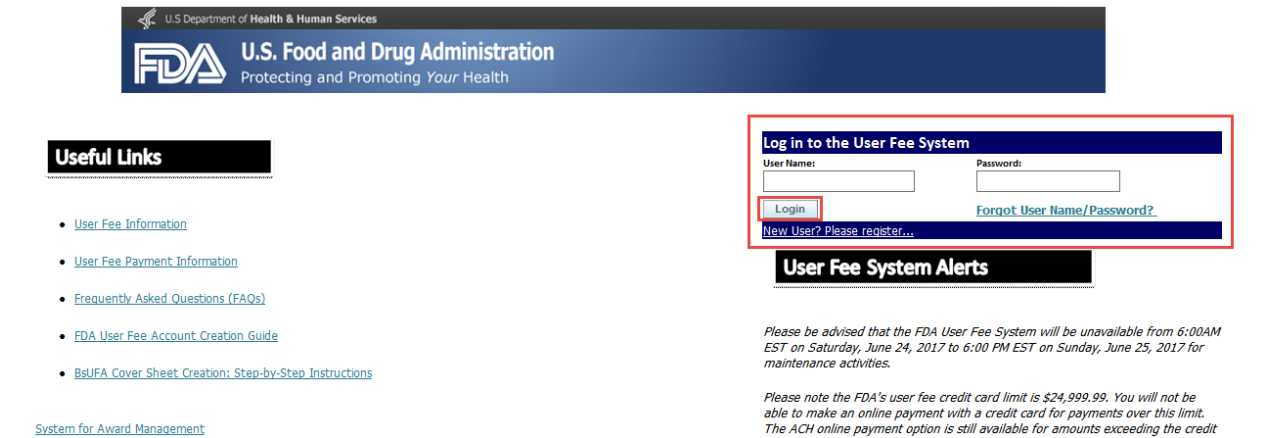
On August 18, 2017 the President signed into law the Food and Drug Administration Reauthorization Act (FDARA). This new law includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process 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**
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) **Enter a valid user name and password.**
5) **Click the "Login" button.**



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 Test

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2017	FURLS Device Facility User Fee	Go
MDUFA Establishment Registration User Fee 2018	FURLS Device Facility User Fee	Go

2016 Cover Sheets

FY 2016 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2015 through September 30th, 2016.

User Fee	Description	
Generic Drug User Fee 2016	GDUFA Cover Sheets	Go

2017 Cover Sheets

FY 2017 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2016 through September 30th, 2017.

User Fee	Description	
ANIMAL DRUG USER FEE 2017	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2017	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2017	BsUFA Cover Sheets	Go
Generic Drug User Fee 2017	GDUFA Cover Sheets	Go
Medical Device User Fee 2017	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
Prescription Drug User Fee 2017	PDUFA Pre-Market Cover Sheets	Go

2018 Cover Sheets

FY 2018 cover sheets should be created for payments associated with submissions to the FDA for the period October 1st, 2017 through September 30th, 2018.

User Fee	Description	
ANIMAL DRUG USER FEE 2018	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2018	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2018	BsUFA Cover Sheets	Go
Generic Drug User Fee 2018	GDUFA Cover Sheets	Go
Medical Device User Fee 2018	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
Prescription Drug User Fee 2018	PDUFA Pre-Market Cover Sheets	Go

PDUFA Cover Sheet Creation: Step-by-Step Instructions

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

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

User Fee Websites

Prescription Drug User Fee Act

Center for Biologic Evaluation and Research

Center for Drug Evaluation 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/pdufaCAcdLogin.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/ucm114027.htm.
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 site: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf
6.	**USER FEE I.D. NUMBER:** Please include the ID number (generated when completing Form FDA 3397) on the application payment check.
7.	**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 For a medical countermeasure voucher, the instructions provided in this guidance apply as well.
8.	**EXCEPTIONS:** The application is for an orphan drug product. 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 (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.	**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/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 FAQs which can be assessed 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
1005 Convention 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 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

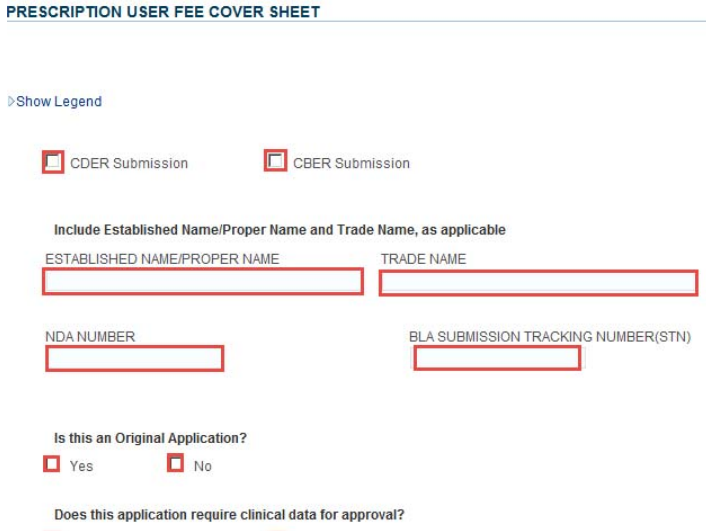
FDA Deposit Account Number: 75060099
US Department of Treasury Routing/Transit number: 021030004
SWIFT Number: FRNYUS33
Beneficiary: FDA
1350 Piccard Drive
Suite 200A
Rockville, MD 20850

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.

PDUFA Cover Sheet Creation: Step-by-Step Instructions

8) 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

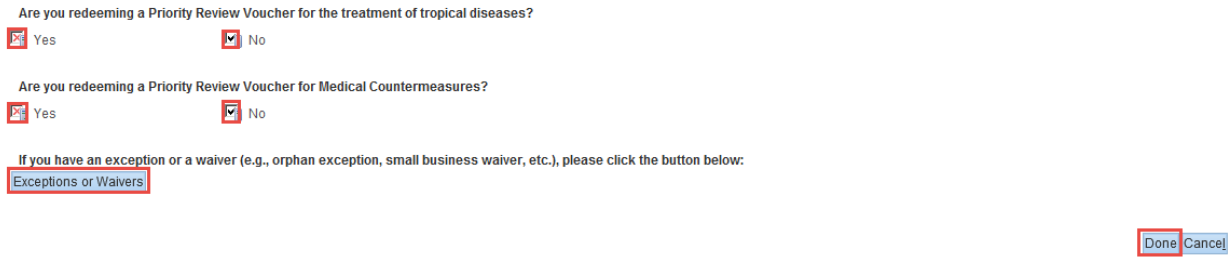
☐ The required clinical data are submitted by reference to:

(Application Number Containing the Data)

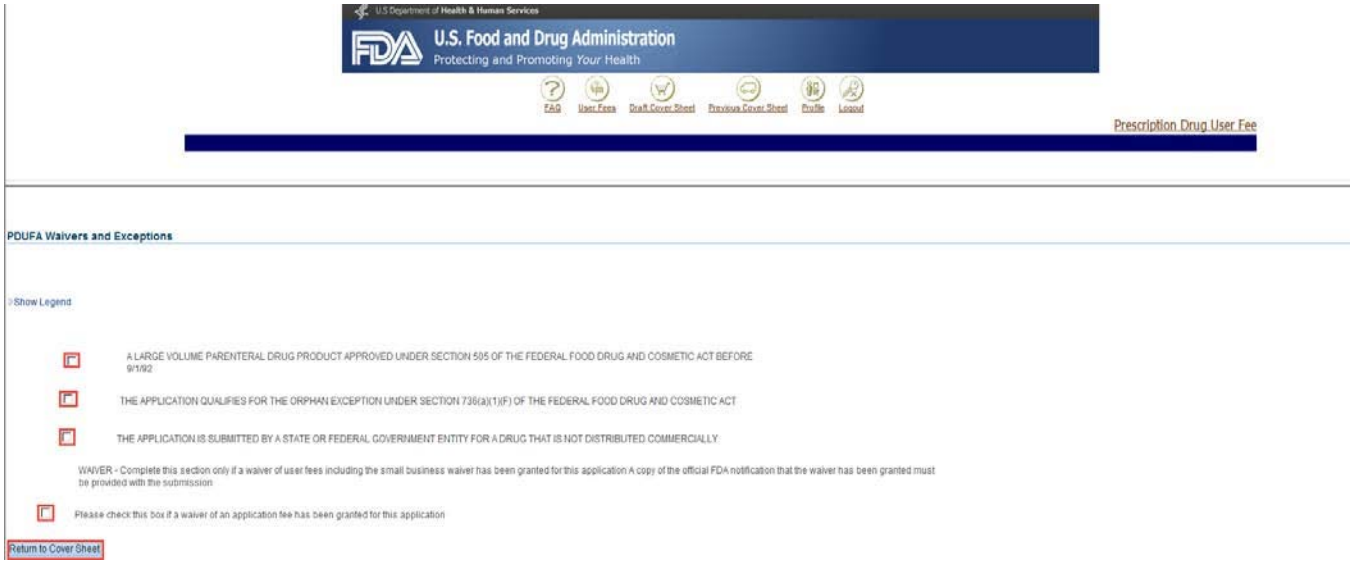
(Supplement Number Containing the Data)

PDUFA Cover Sheet Creation: Step-by-Step Instructions

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



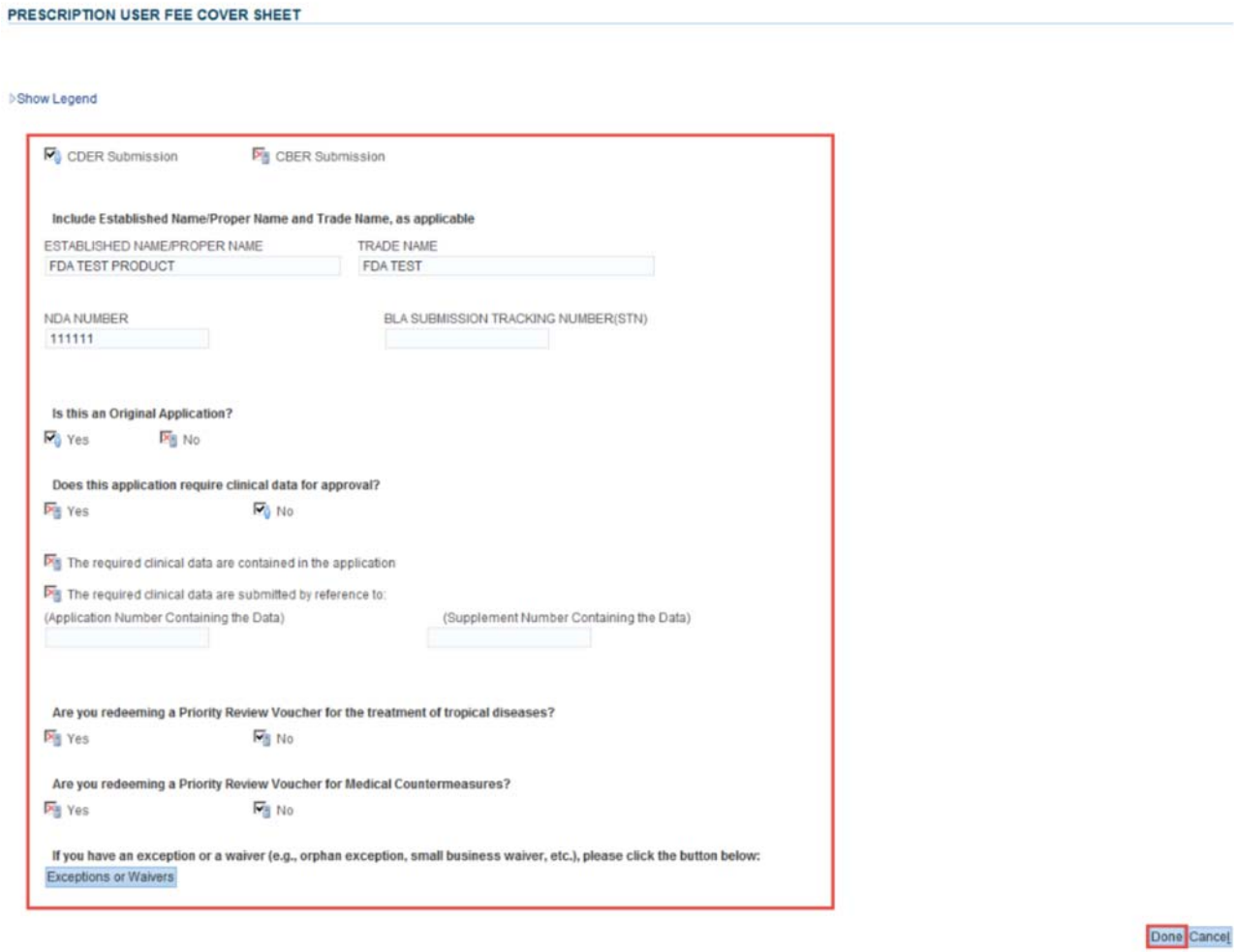
10) Make the appropriate selections and select 'Return to Cover Sheet' to continue.



PDUFA Cover Sheet Creation: Step-by-Step Instructions

11) Review and verify that your information is accurate.

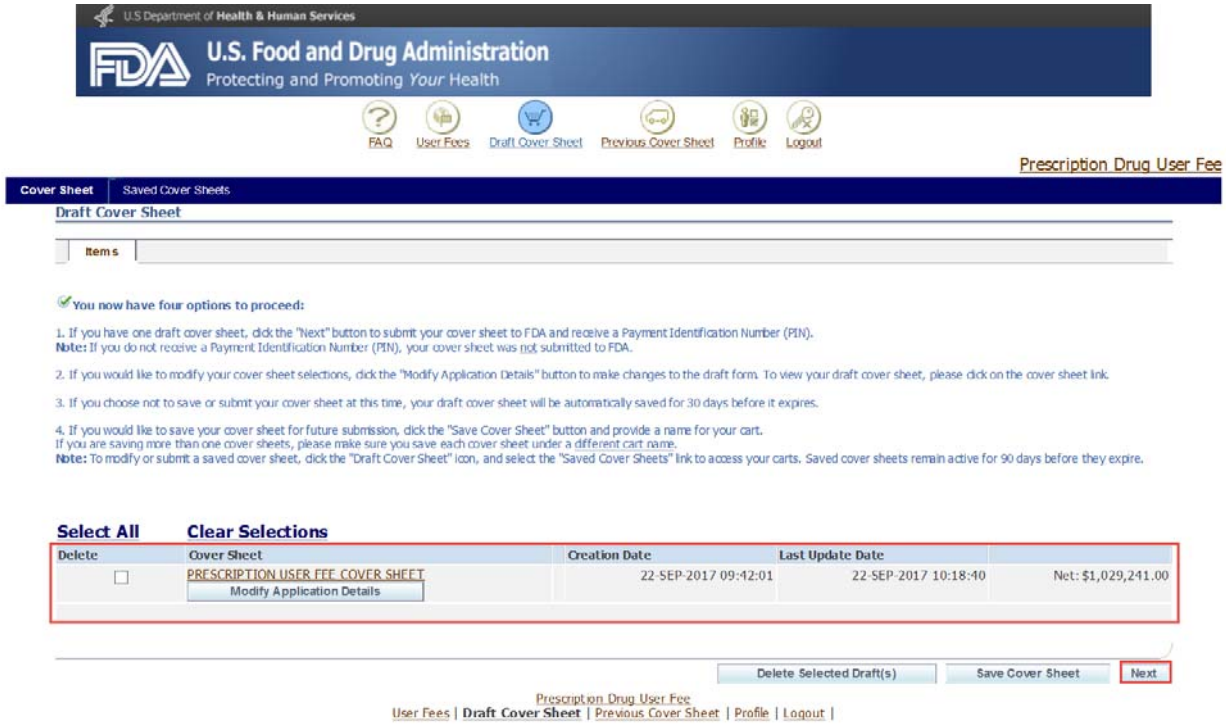
12) Click 'Done' to continue.



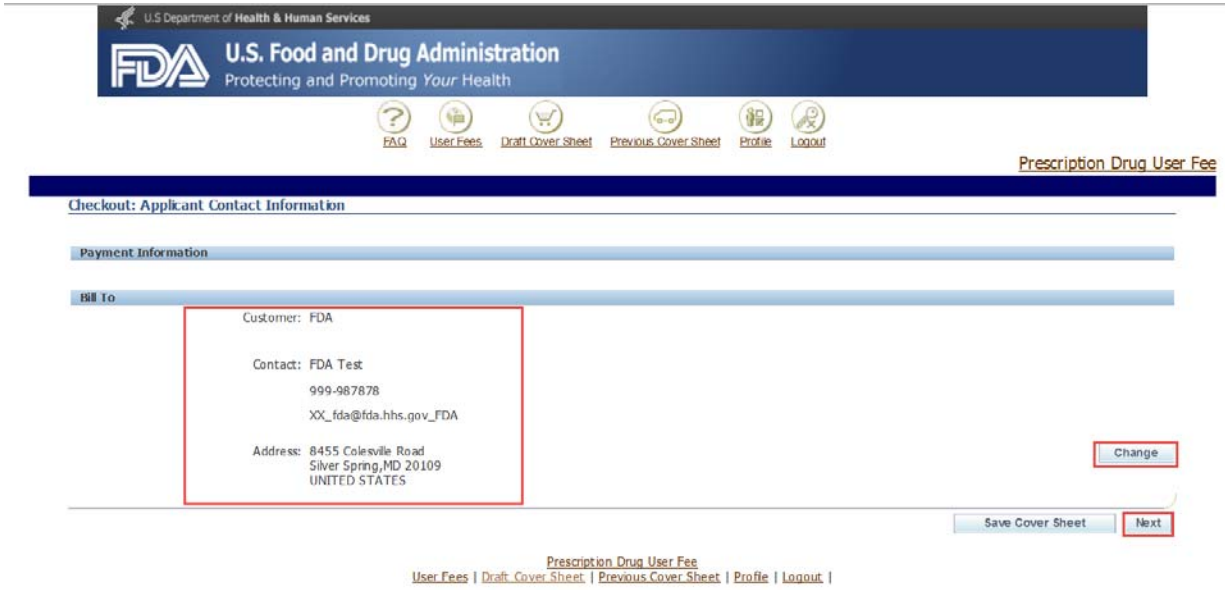
PDUFA Cover Sheet Creation: Step-by-Step Instructions

13) 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.

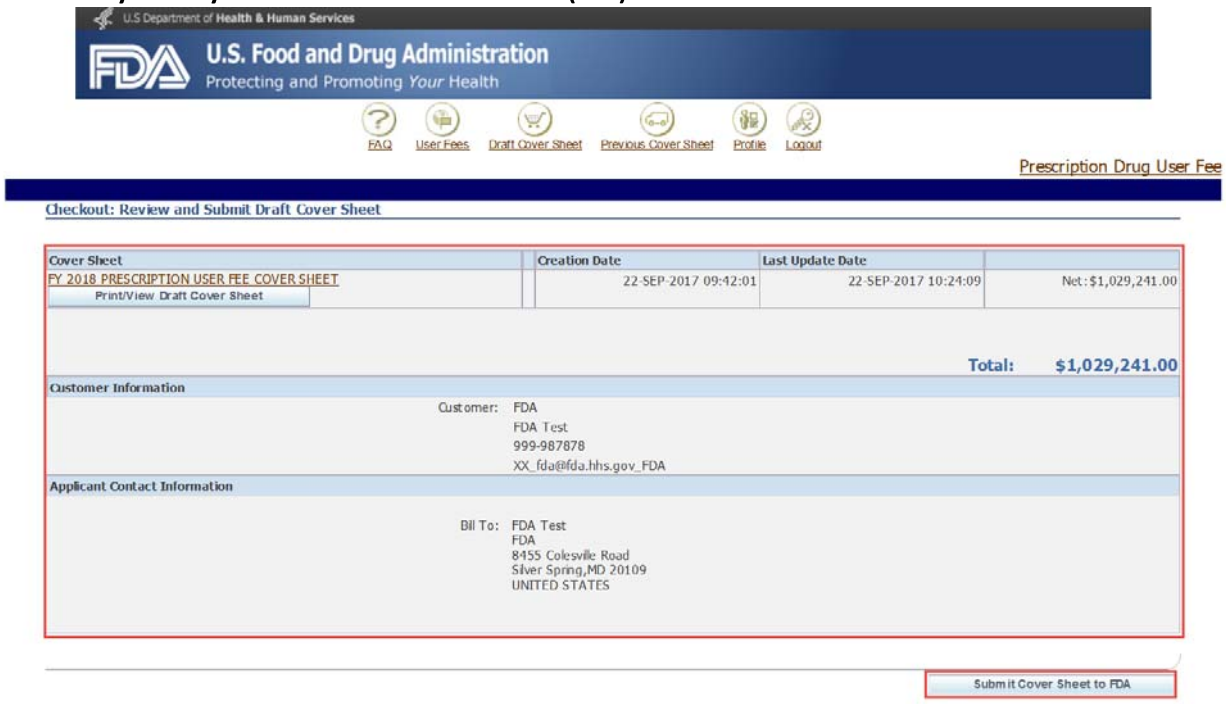


14) On the 'Checkout: Applicant Contact Information' page, you will see the billing information for this cover sheet. You can change the address by selecting the 'Change' button and follow the instructions to update the address. Once the information has been verified and is accurate, select 'Next' to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



PDUFA Cover Sheet Creation: Step-by-Step Instructions

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

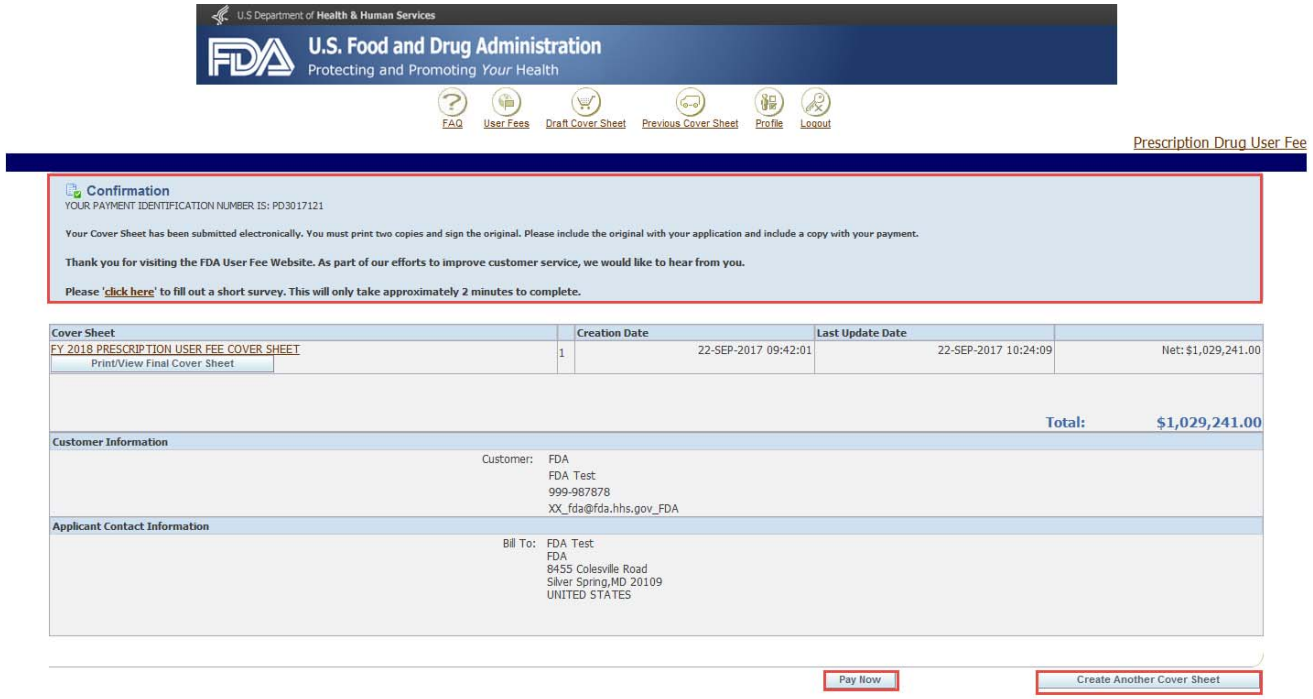


PDUFA Cover Sheet Creation: Step-by-Step Instructions

16) **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>Note:</u> 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.