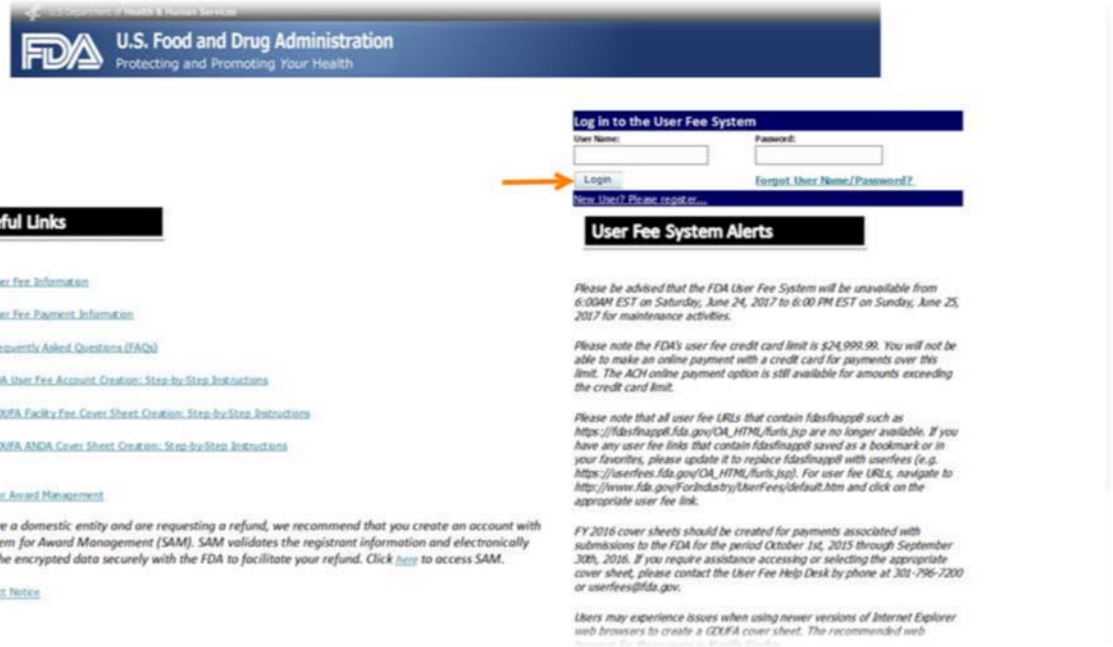
GDUFA Facility Fee Cover Sheet Creation Process: Step-by-Step Instructions

Any person that owns a facility that is identified or intended to be identified in at least one generic drug submission that is pending or approved to produce one or more generic drug FDFs and/or APIs is required to pay facility fees. For additional information, please refer to:
http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm319566.htm

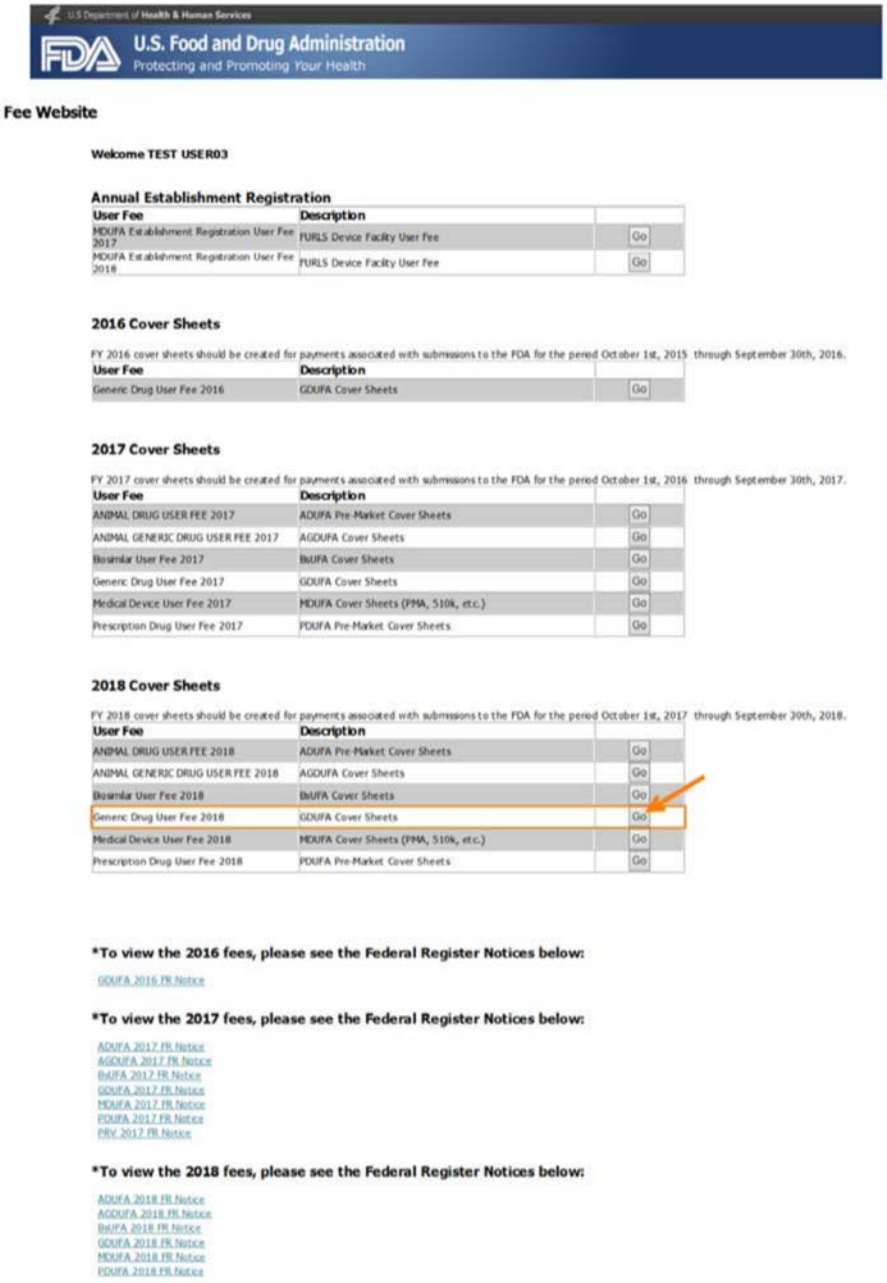
**** Please note that domestic (based in the U.S. and its territories) facilities will have a different fee than foreign facilities. For more information regarding the facility fee rates, please refer to the Federal Register**

1. **Access the User Fee website: https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp**
2. **Review the statement and select the "I Understand" radio button.**
3. **For users who have an existing user account, proceed to Step 4.**
    a. **If you do not have an existing account, please see the FDA User Fee Account Creation Process guide. If you do not have this document for reference, please email the User Fee Help Desk at userfees@fda.gov and request it.**
4. **Enter a valid User Name and Password.**
5. **Click the "Login" button.**



Note: There are Help prompts throughout the cover sheet process. When you click on a Help link, a new window will

6. Click the “Go” button next to “Generic Drug User Fee”.



U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Protecting and Promoting Your Health

User Fee Website

Welcome TEST USER03

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2017	FURLS Device Facility User fee	Go
MDUFA Establishment Registration User Fee 2016	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

***To view the 2016 fees, please see the Federal Register Notices below:**

GDUFA 2016 FR Notice

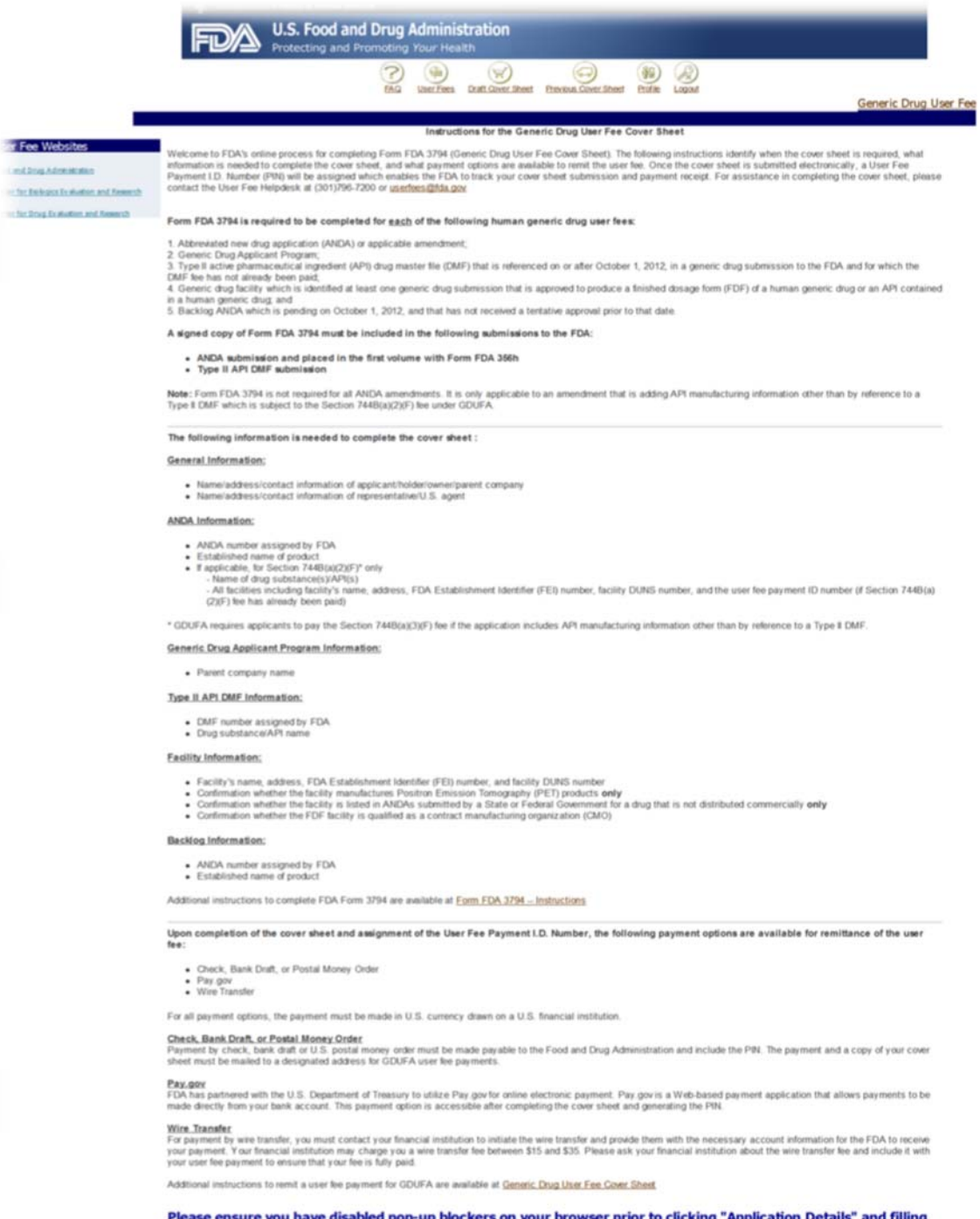
***To view the 2017 fees, please see the Federal Register Notices below:**

ADUFA 2017 FR Notice
AGDUFA 2017 FR Notice
BsUFA 2017 FR Notice
GDUFA 2017 FR Notice
MDUFA 2017 FR Notice
PDUFA 2017 FR Notice
PRV 2017 FR Notice

***To view the 2018 fees, please see the Federal Register Notices below:**

ADUFA 2018 FR Notice
AGDUFA 2018 FR Notice
BsUFA 2018 FR Notice
GDUFA 2018 FR Notice
MDUFA 2018 FR Notice
PDUFA 2018 FR Notice

7. **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

Generic Drug User Fee

Instructions for the Generic Drug User Fee Cover Sheet

Fee Websites

Welcome to FDA's online process for completing Form FDA 3794 (Generic Drug User Fee Cover Sheet). The following instructions identify when the cover sheet is required, what information is needed to complete the cover sheet, and what payment options are available to remit the user fee. Once the cover sheet is submitted electronically, a User Fee Payment I.D. Number (PIN) will be assigned which enables the FDA to track your cover sheet submission and payment receipt. For assistance in completing the cover sheet, please contact the User Fee Helpdesk at (301)796-7200 or userfees@fda.gov

Form FDA 3794 is required to be completed for each of the following human generic drug user fees:

1. Abbreviated new drug application (ANDA) or applicable amendment;
2. Generic Drug Applicant Program;
3. Type II active pharmaceutical ingredient (API) drug master file (DMF) that is referenced on or after October 1, 2012, in a generic drug submission to the FDA and for which the DMF fee has not already been paid;
4. Generic drug facility which is identified at least one generic drug submission that is approved to produce a finished dosage form (FDF) of a human generic drug or an API contained in a human generic drug; and
5. Backlog ANDA which is pending on October 1, 2012, and that has not received a tentative approval prior to that date.

A signed copy of Form FDA 3794 must be included in the following submissions to the FDA:

- **ANDA submission and placed in the first volume with Form FDA 356h**
- **Type II API DMF submission**

Note: Form FDA 3794 is not required for all ANDA amendments. It is only applicable to an amendment that is adding API manufacturing information other than by reference to a Type II DMF which is subject to the Section 744B(a)(2)(F) fee under GDUFA.

The following information is needed to complete the cover sheet :

General Information:

- Name/address/contact information of applicant/holder/owner/parent company
- Name/address/contact information of representative/U.S. agent

ANDA Information:

- ANDA number assigned by FDA
- Established name of product
- If applicable, for Section 744B(a)(2)(F)* only
  - Name of drug substance(s)/API(s)
  - All facilities including facility's name, address, FDA Establishment Identifier (FEI) number, facility DUNS number, and the user fee payment ID number (if Section 744B(a)(2)(F) fee has already been paid)

* GDUFA requires applicants to pay the Section 744B(a)(3)(F) fee if the application includes API manufacturing information other than by reference to a Type II DMF.

Generic Drug Applicant Program Information:

- Parent company name

Type II API DMF Information:

- DMF number assigned by FDA
- Drug substance/API name

Facility Information:

- Facility's name, address, FDA Establishment Identifier (FEI) number, and facility DUNS number
- Confirmation whether the facility manufactures Positron Emission Tomography (PET) products **only**
- Confirmation whether the facility is listed in ANDAs submitted by a State or Federal Government for a drug that is not distributed commercially **only**
- Confirmation whether the FDF facility is qualified as a contract manufacturing organization (CMO)

Backlog Information:

- ANDA number assigned by FDA
- Established name of product

Additional instructions to complete FDA Form 3794 are available at Form FDA 3794 – Instructions

---

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:

- Check, Bank Draft, or Postal Money Order
- Pay.gov
- Wire Transfer

For all payment options, the payment must be made in U.S. currency drawn on a U.S. financial institution.

Check, Bank Draft, or Postal Money Order
Payment by check, bank draft or U.S. postal money order must be made payable to the Food and Drug Administration and include the PIN. The payment and a copy of your cover sheet must be mailed to a designated address for GDUFA user fee payments.

Pay.gov
FDA has partnered with the U.S. Department of Treasury to utilize Pay.gov for online electronic payment. Pay.gov is a Web-based payment application that allows payments to be made directly from your bank account. This payment option is accessible after completing the cover sheet and generating the PIN.

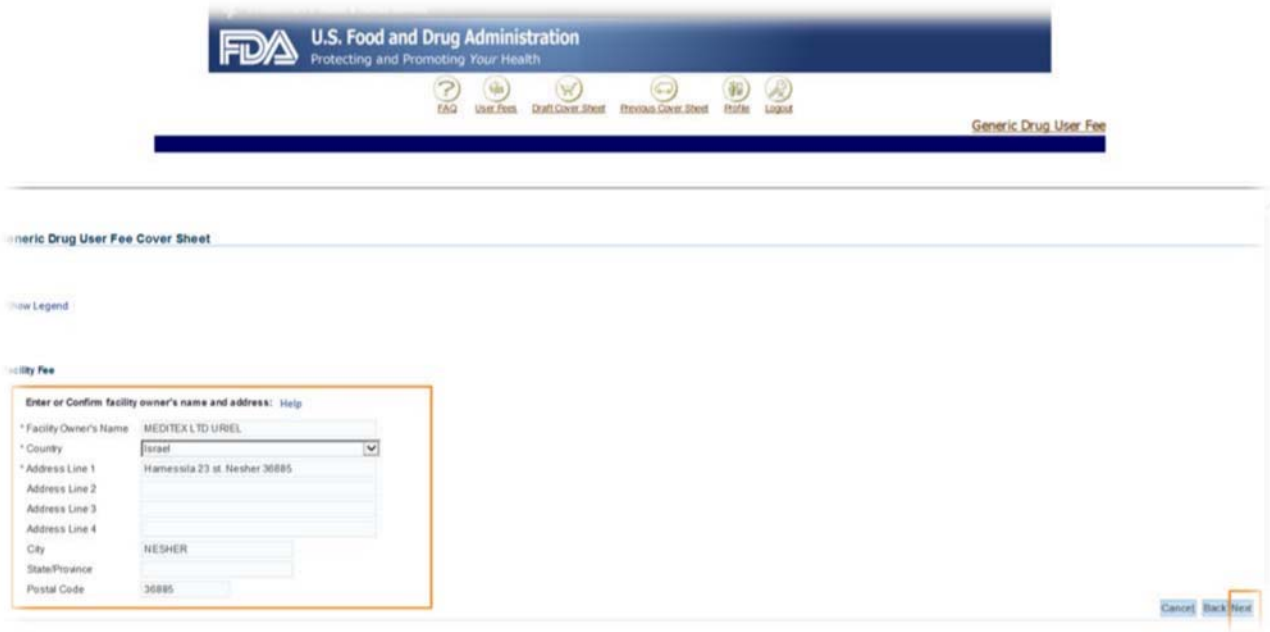
Wire Transfer
For payment by wire transfer, you must contact your financial institution to initiate the wire transfer and provide them with the necessary account information for the FDA to receive your payment. Your financial institution may charge you a wire transfer fee between $15 and $35. Please 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.

Additional instructions to remit a user fee payment for GDUFA are available at Generic Drug User Fee Cover Sheet

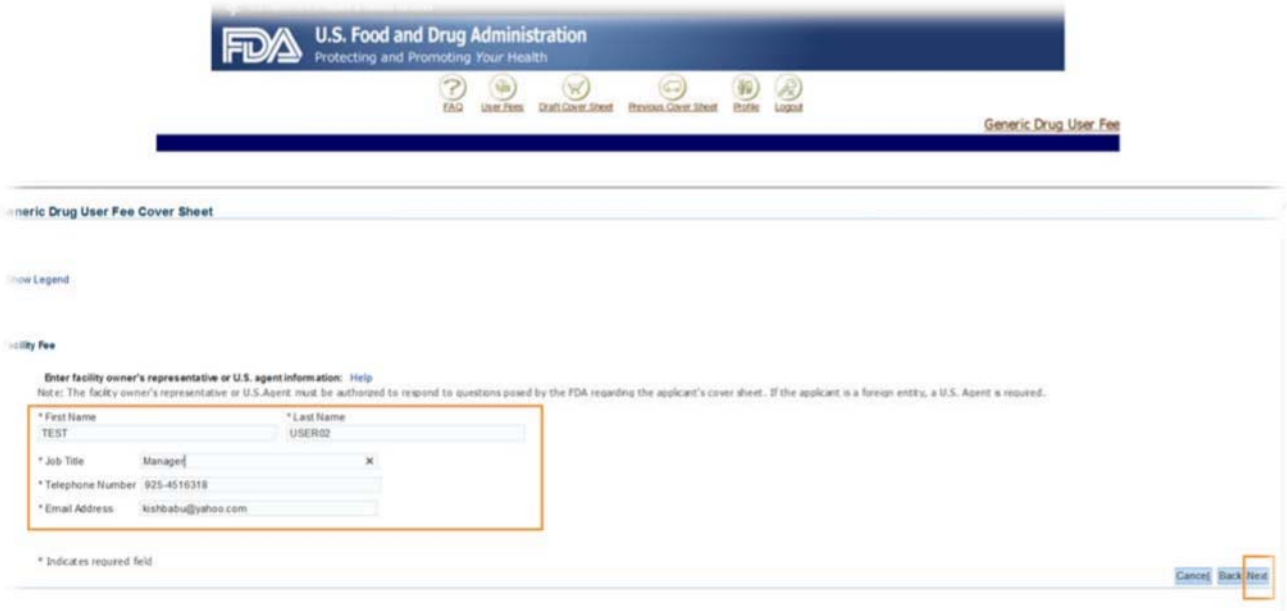
Please ensure you have disabled pop-up blockers on your browser prior to clicking "Application Details" and filling

8. **Select the "Facility Fee" checkbox then click the "Next" button.**

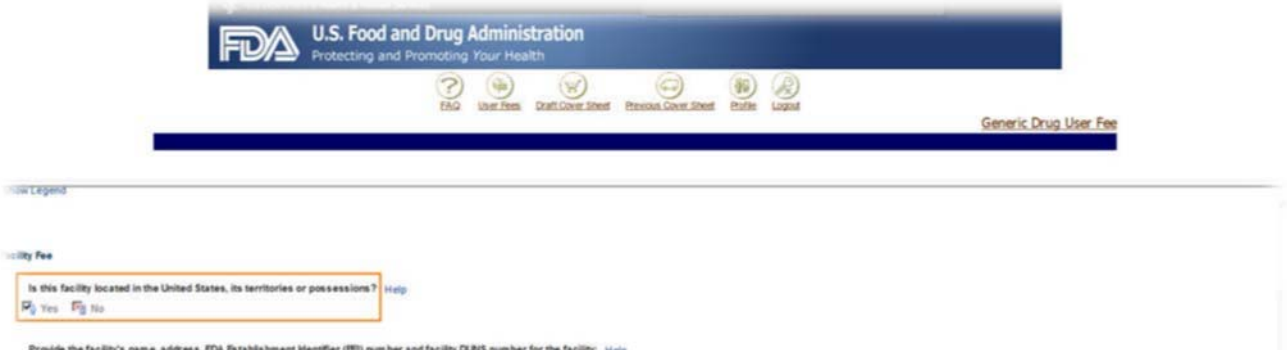
9. Enter or confirm the facility owner's name and address. Enter all required fields that are notated with an asterisk (e.g., Facility Owner's Name, Country, and Address). Click the "Next" button to continue.



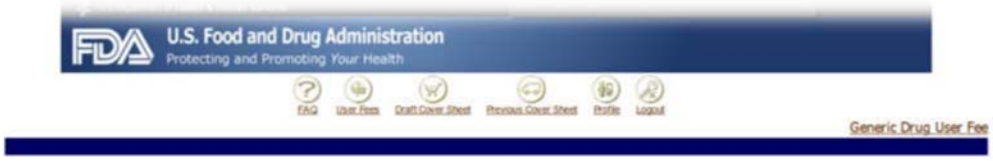
10. Enter or confirm the facility owner's representative or U.S. agent information. Enter all required fields (e.g., First Name, Last Name, Job Title, Telephone Number, and Email Address). Click the "Next" button to continue.

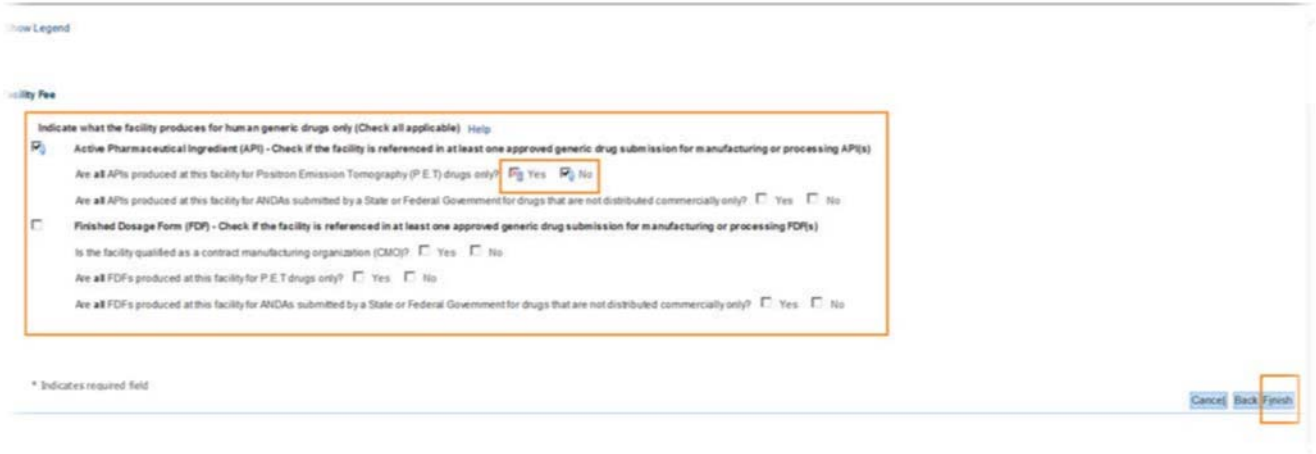


11. Select whether the facility is located in the United States, its territories or possessions.
Enter the physical address of the facility for which the facility fee is being paid. Enter all required fields (e.g., Facility Name, Country, FEI Number, Facility DUNS Number, and Address). Click the "Next" button.



12. Indicate what the facility produces for the manufacture of human drugs (API and/or FDF). Check all options that apply. Answer the corresponding Positron Emission Tomography (PET) question for API and/or FDF if applicable.
    Next, answer the question regarding whether or not the facility produces human drugs other than human generic drugs. Click the "Next" button to continue.
    Note: For clarification on this question, please contact the GDUFA Policy Team at AskGDUFA@fda.hhs.gov.

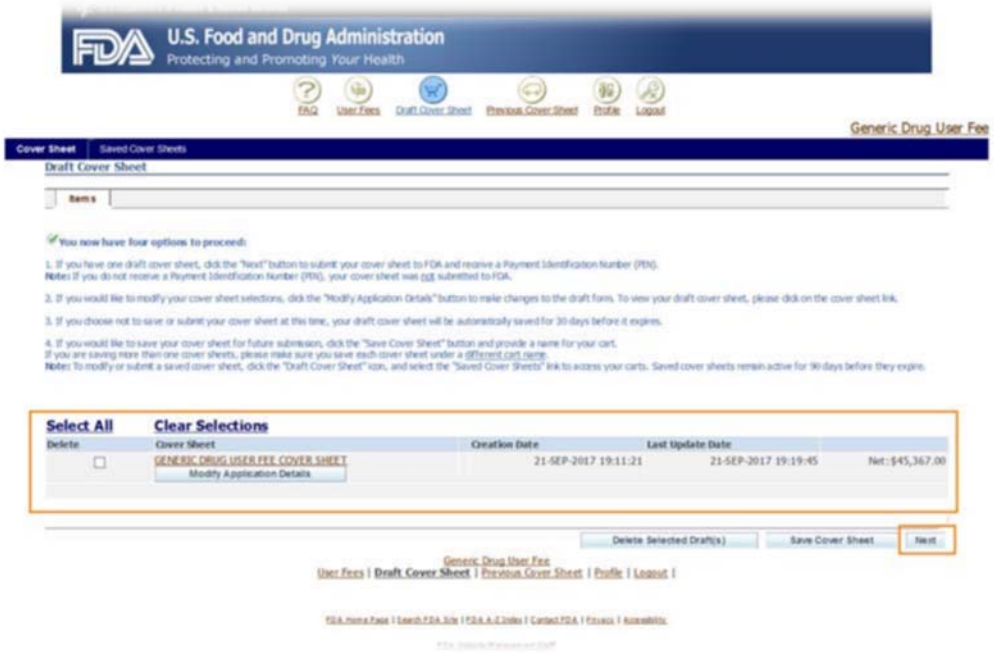




13. On the Draft Cover Sheet page, verify the amount owed for the cover sheet. You have four options on this page:
    a) Click the “Next” button to continue.
    b) You can click the “Modify Application Details” button to make changes to the draft cover sheet. To view the draft cover sheet, click on the “GENERIC DRUG USER FEE COVER SHEET” link.
    c) If you do not save or submit your cover sheet, it will be available for 30 days in the “Draft Cover Sheet” menu.
    d) You can save the cover sheet by clicking on the “Save Cover Sheet” button.

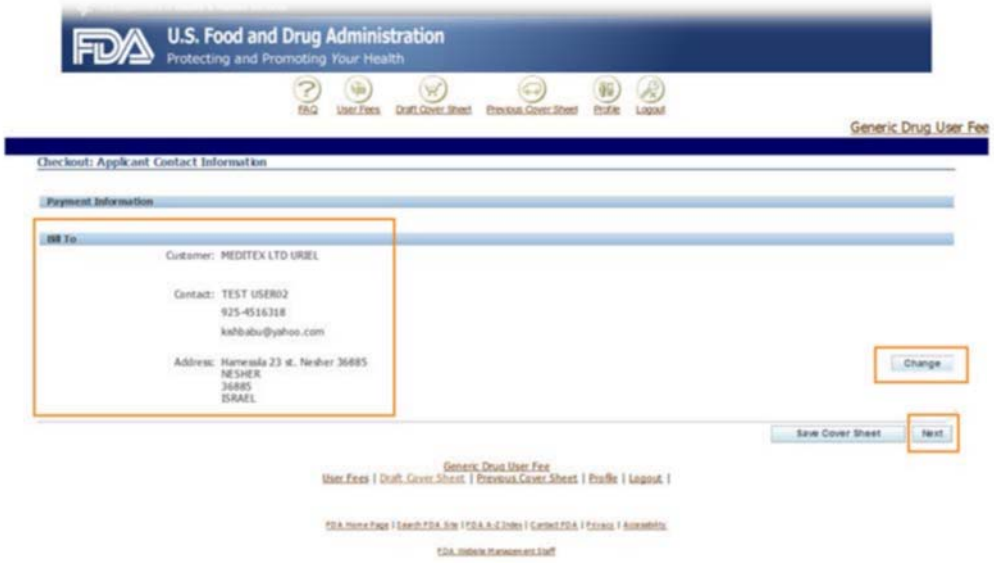
    In this scenario, click the “Next” button to continue.

    **Please note that the cover sheet amount in this example is based upon options chosen and for demonstration purposes only. The amount calculated during your cover sheet creation process may be different than the amount stated in the example.

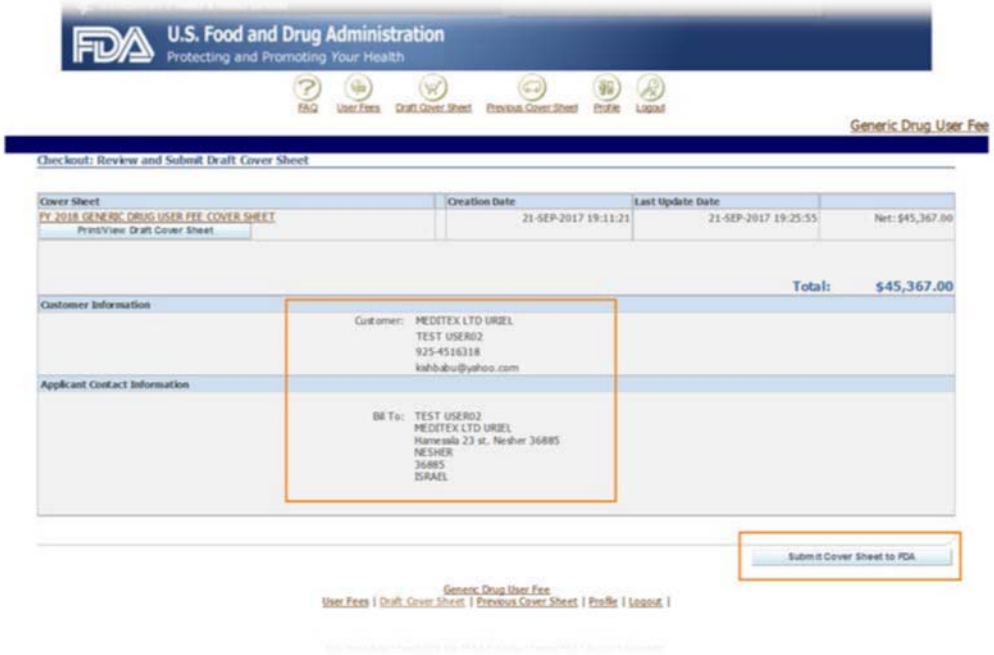


14. Confirm the Bill To information and click the “Next” button to proceed.

    Note: If you would like to change the billing information, click the “Change” button to create a new address.

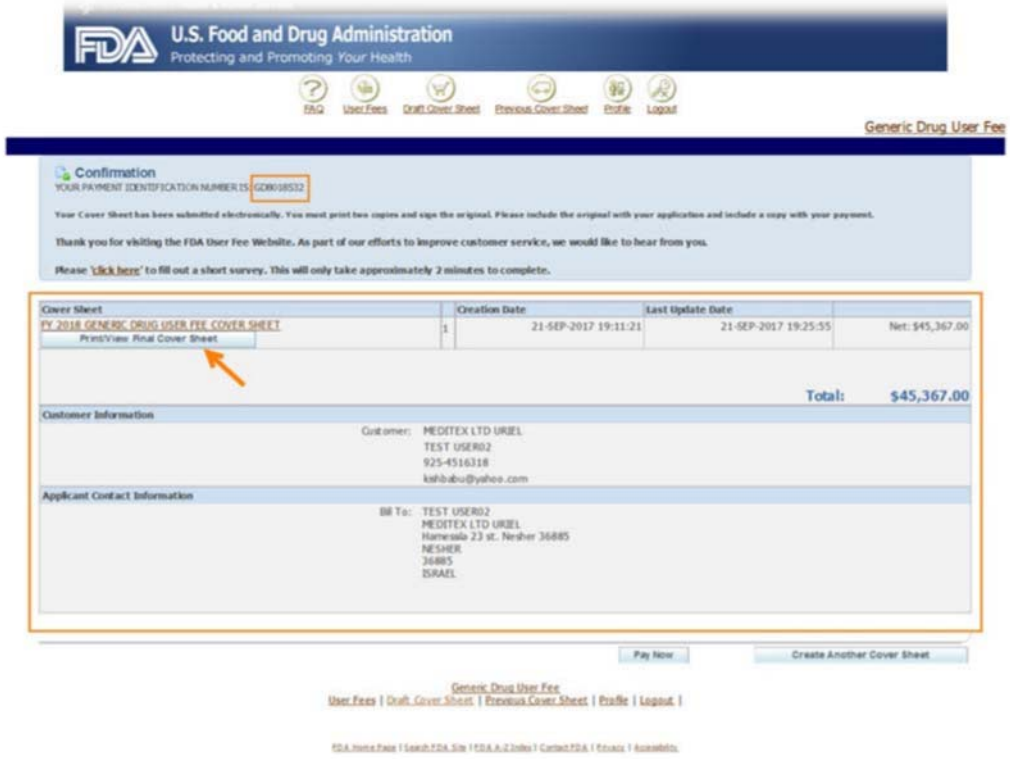


15. Confirm the details of your cover sheet on the Checkout: Review and Submit Draft Cover Sheet page. Click the "Submit Cover Sheet to FDA" button to electronically submit your GDUFA cover sheet.



16. A confirmation of your cover sheet submission and a Payment Identification Number appears. On this page, you may:
    a) Click the "Print/View Final Cover Sheet" button to view and/or print the cover sheet.
    b) Click the "Pay Now" button to make an online payment.
    c) Click the "Create Another Cover Sheet" button to create another cover sheet. Refer to steps 6 through 15.

Note: Your cover sheet is your invoice. To view and/or print your cover sheet at any time, select the "Previous Cover Sheets" menu at the top of the page. From this menu, click on the Payment Identification Number under the search results and a new window will open. Scroll down to the bottom of the window and click on the link to print the cover sheet.



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