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 open with helpful hints and tips to guide you through answering the questions.

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

User Fee Website

Welcome FDA Tester

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2020	FURLS Device Facility User Fee	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.

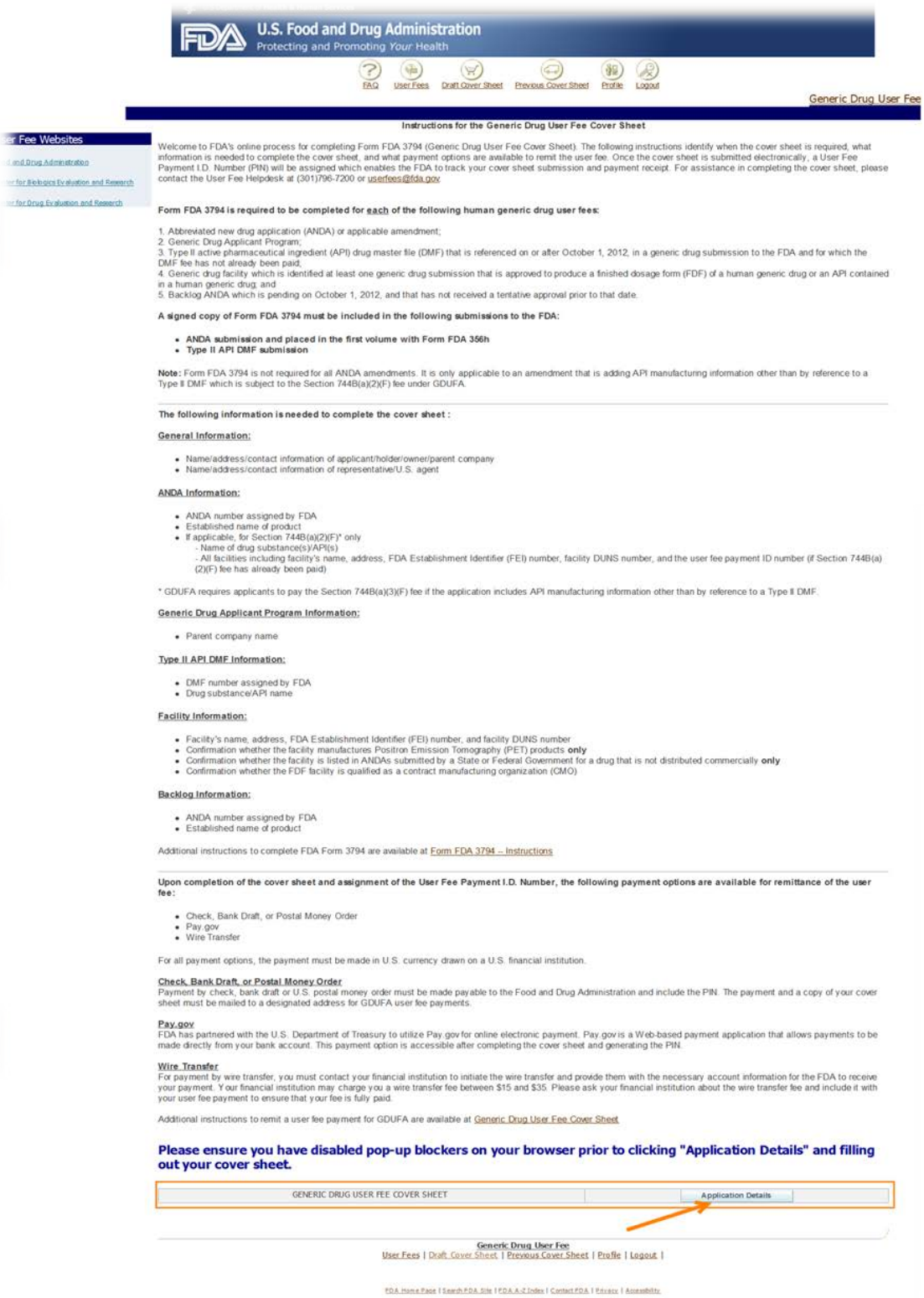
User Fee	Description	
ANIMAL DRUG USER FEE 2020	ADUFA Pre-Market Cover Sheets	Go
ANIMAL GENERIC DRUG USER FEE 2020	AGDUFA Cover Sheets	Go
Biosimilar User Fee 2020	BsUFA Cover Sheets	Go
Generic Drug User Fee 2020	GDUFA Cover Sheets	Go
Medical Device User Fee 2020	MDUFA Cover Sheets (PMA, 510k, etc.)	Go
Prescription Drug User Fee 2020	PDUFA Pre-Market Cover Sheets	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	Go

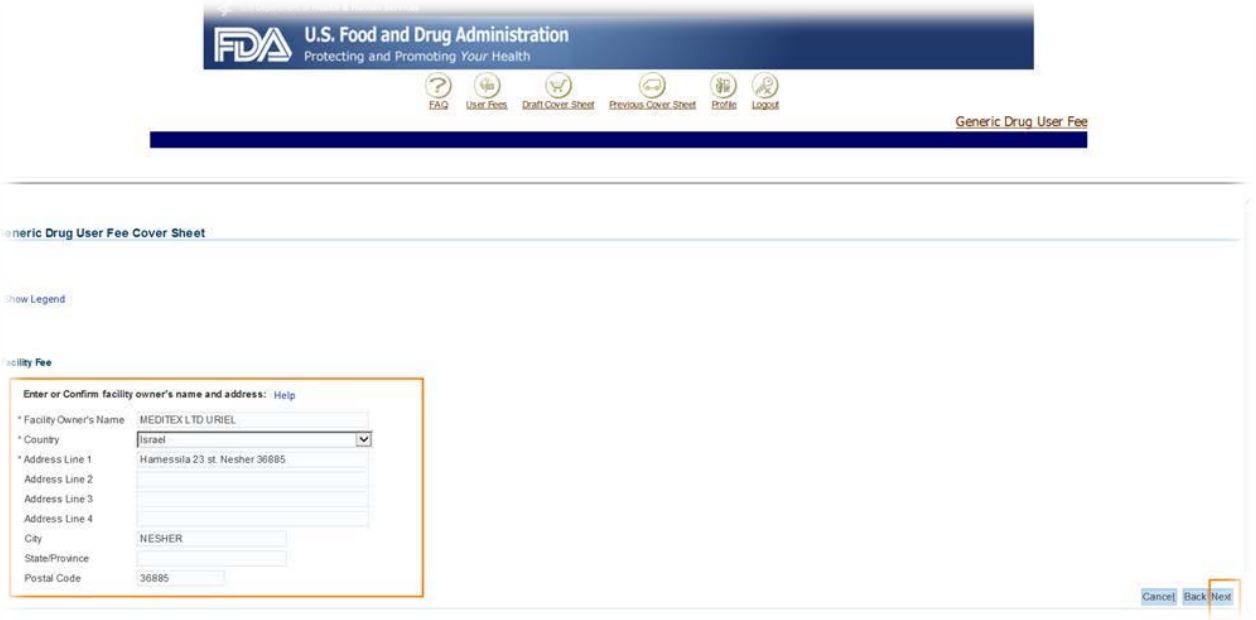
7. Scroll to the bottom of the page and select the 'Application Details' button.



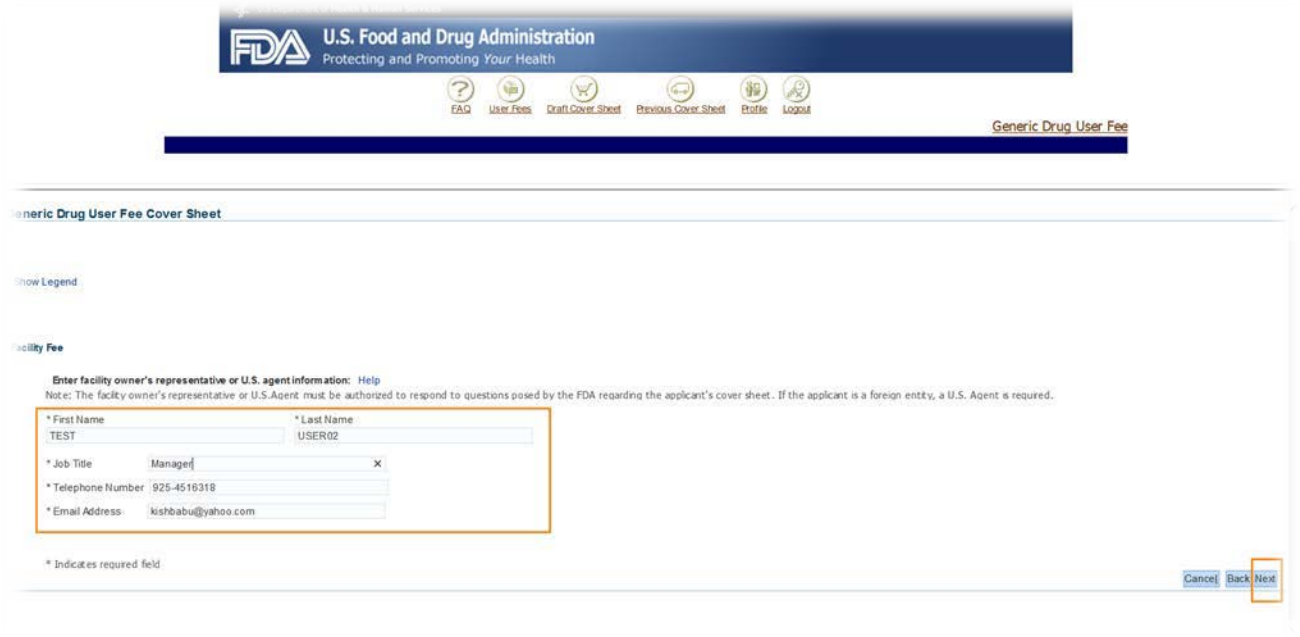
8. Select the "Facility Fee" checkbox then click the "Next" button.

Note: By clicking on Help above, system will provide more info on what to enter.

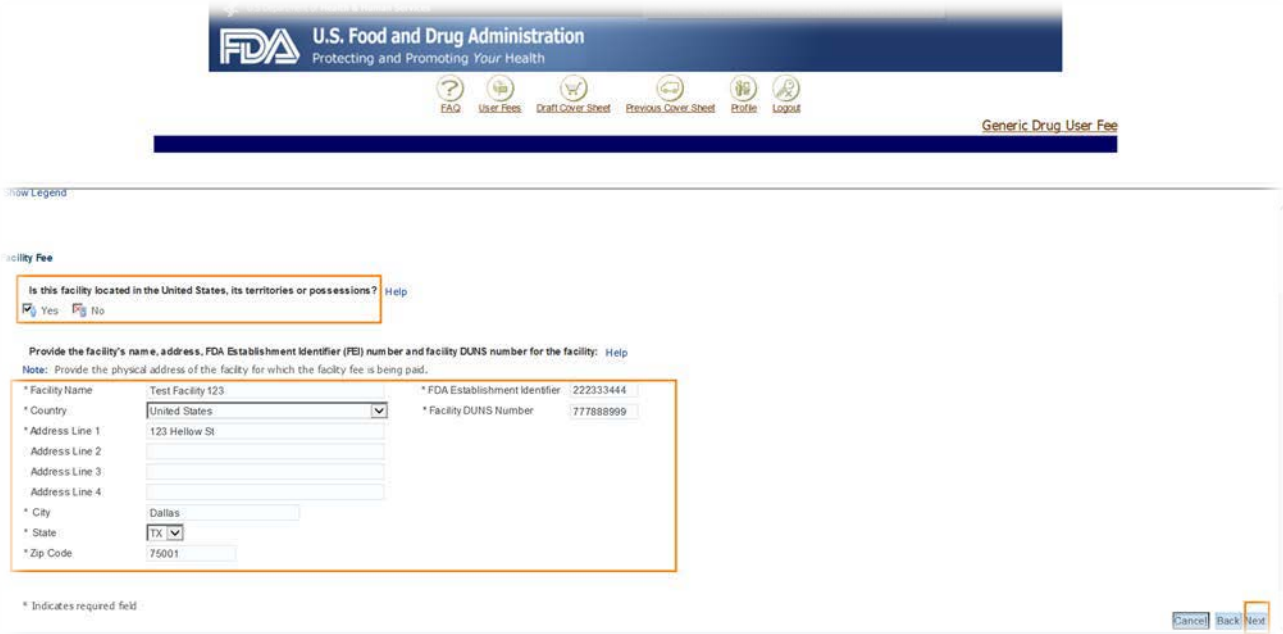
9. Enter or confirm the facility owner's name and address. Enter all required fields that are notated with an asterisk (e.g., Facility Owner's Name, Country, and Address). Click the "Next" button to continue.



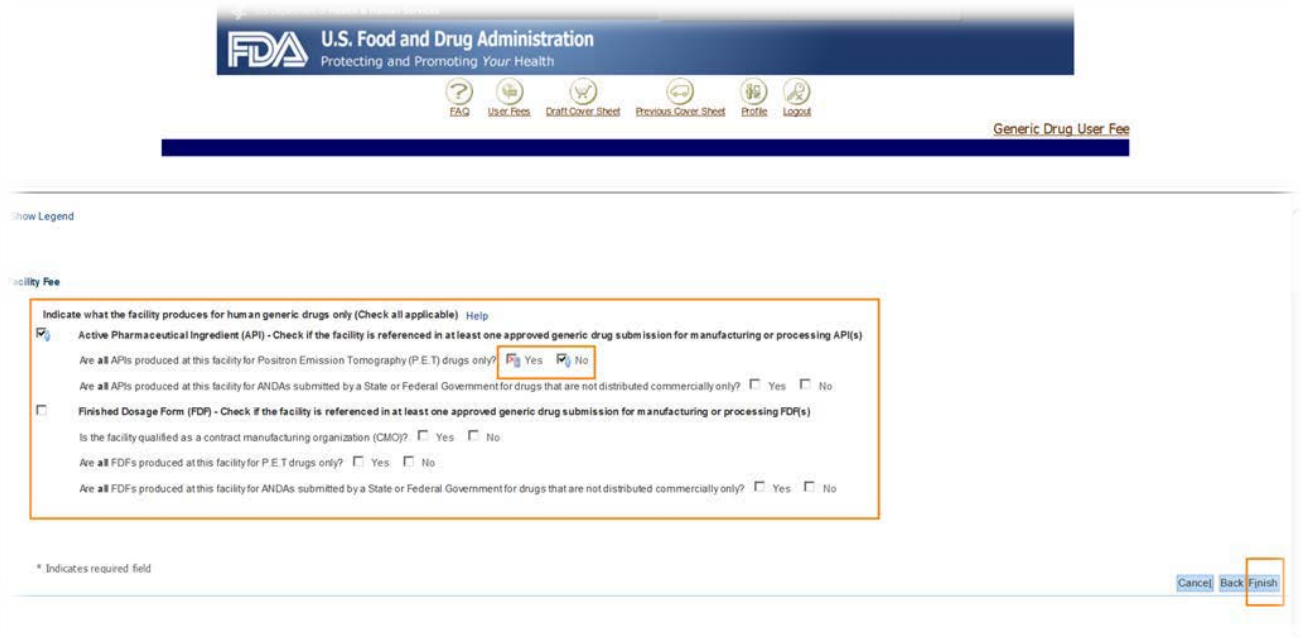
10. Enter or confirm the facility owner's representative or U.S. agent information. Enter all required fields (e.g., First Name, Last Name, Job Title, Telephone Number, and Email Address). Click the "Next" button to continue.



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.

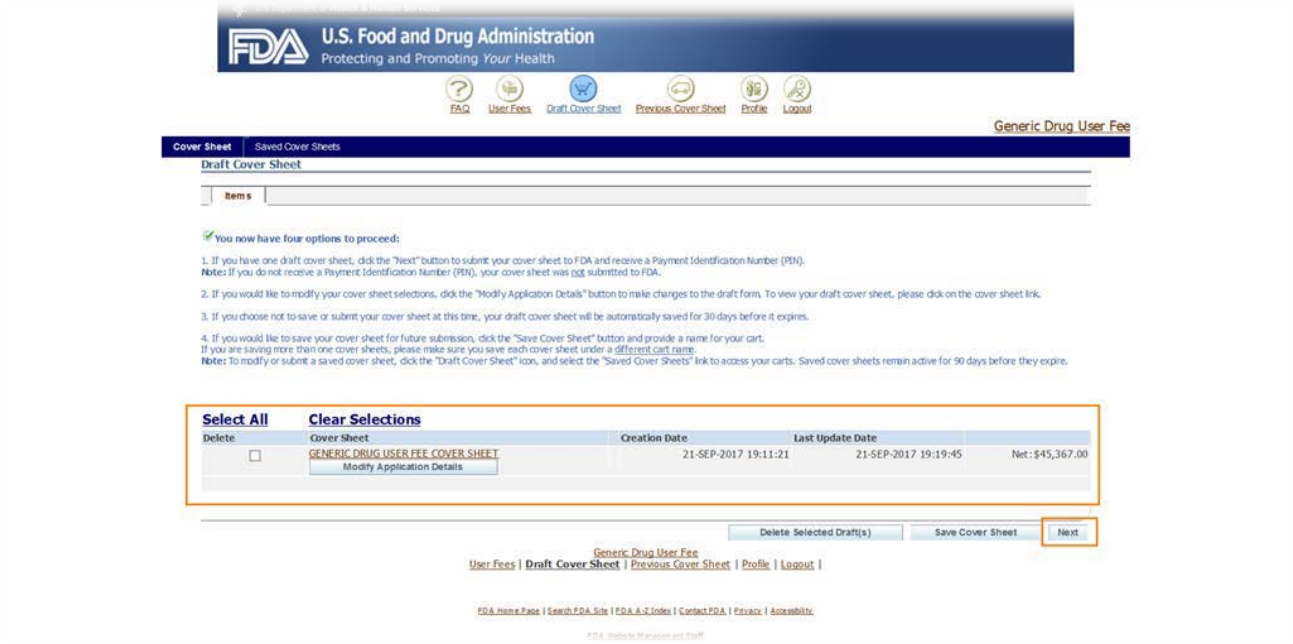
b) You can click the "Modify Application Details" button to make changes to the draft cover sheet. To view the draft cover sheet, click on the "GENERIC DRUG USER FEE COVER SHEET" link.

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.

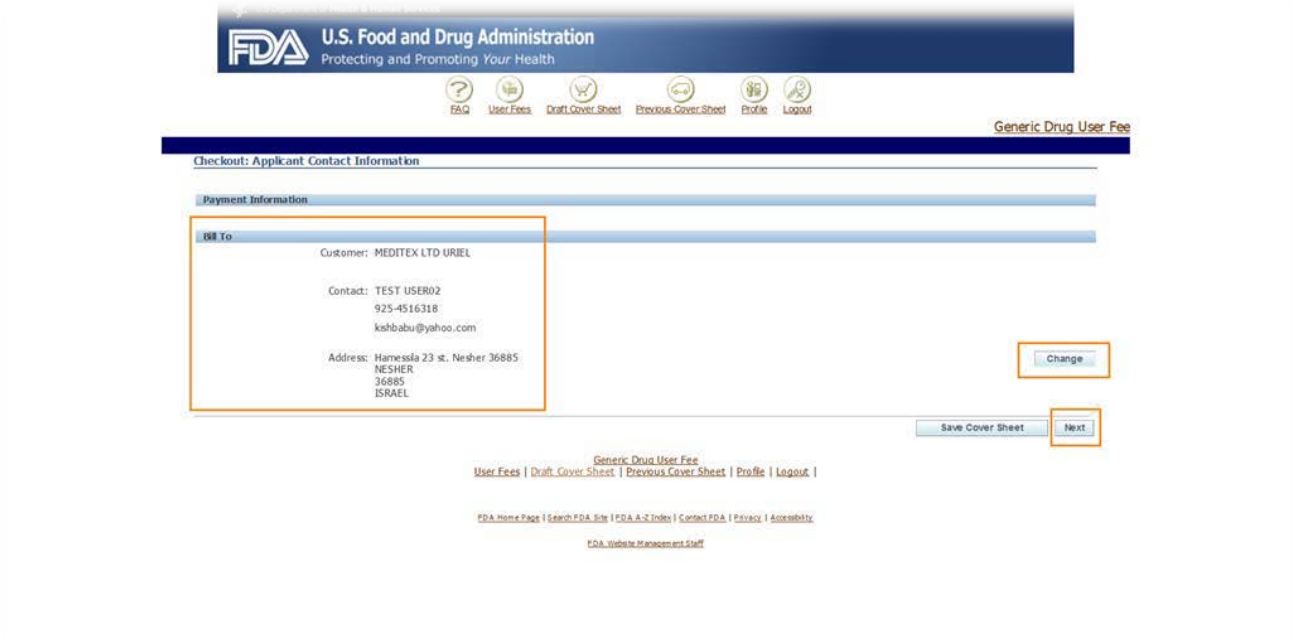
In this scenario, click the "Next" button to continue.

**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.

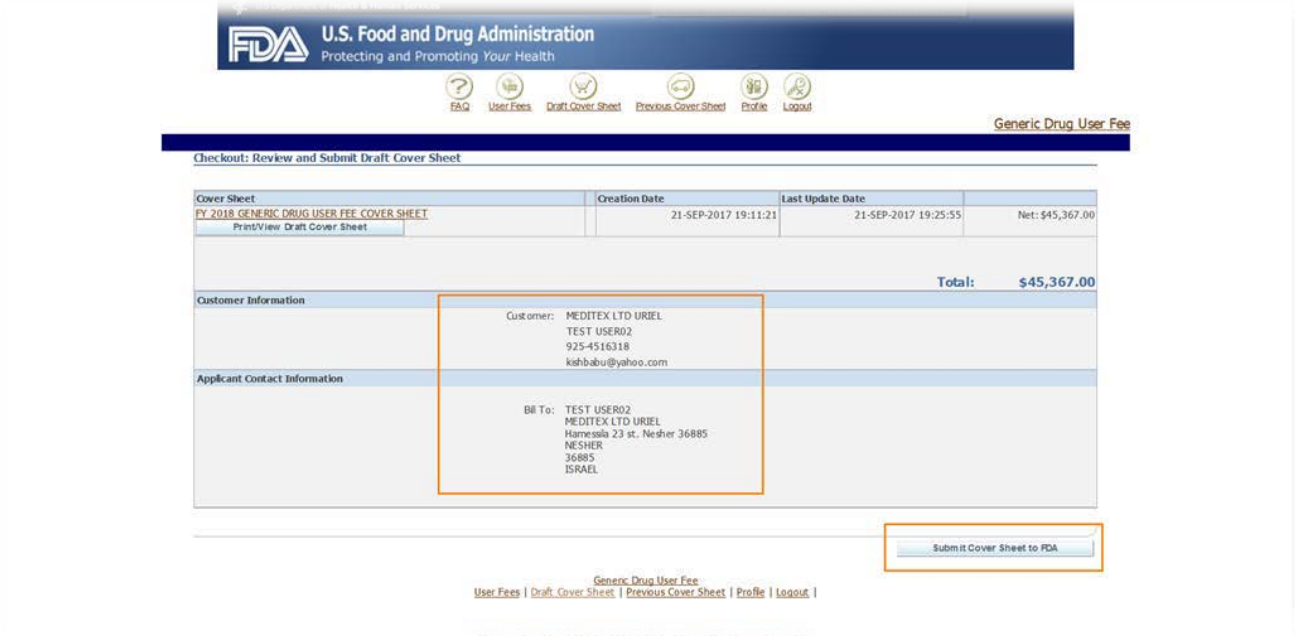


14. Confirm the Bill To information and click the "Next" button to proceed.

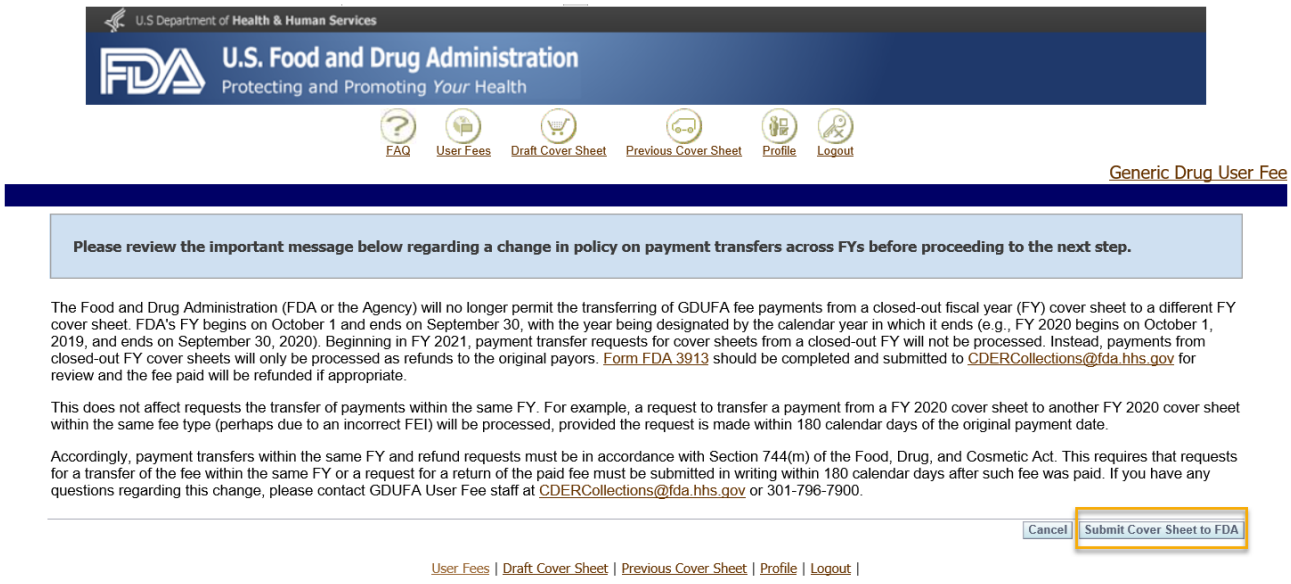
Note: If you would like to change the billing information, click the "Change" button to create a new address.



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.



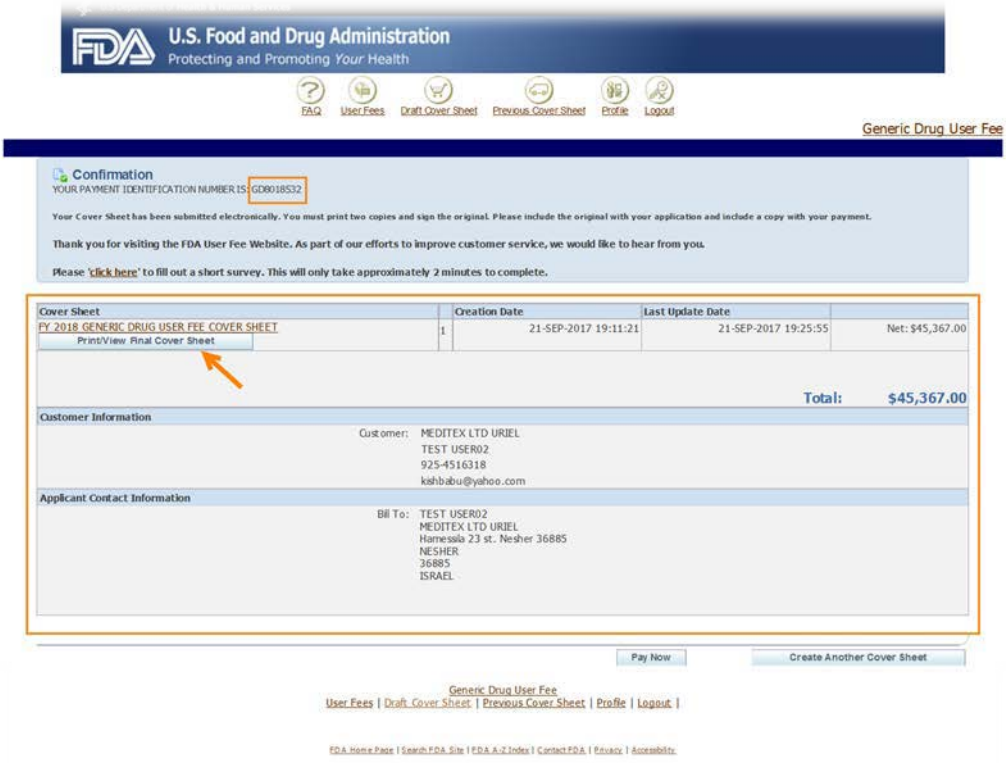
16. After reading the message, select 'Submit Cover Sheet to FDA'.



17. 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 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.