

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.



The Food and Drug Administration (FDA or the Agency) will no longer permit the transferring of GDUFA fee payments from a closed-out fiscal year (FY) cover sheet to a different FY cover sheet. FDA's FY begins on October 1 and ends on September 30, with the year being designated by the calendar year in which it ends (e.g., FY 2020 begins on October 1, 2019, and ends on September 30, 2020). Beginning in FY 2021, payment transfer requests for cover sheets from a closed-out FY will not be processed. Instead, payments from closed-out FY cover sheets will only be processed as refunds to the original payors. [Form FDA 3913](#) should be completed and submitted to CDERCollections@fda.hhs.gov for review and the fee paid will be refunded if appropriate.

This does not affect requests the transfer of payments within the same FY. For example, a request to transfer a payment from a FY 2020 cover sheet to another FY 2020 cover sheet within the same fee type (perhaps due to an incorrect FEI) will be processed, provided the request is made within 180 calendar days of the original payment date.

If you have any questions regarding this change, please contact GDUFA User Fee staff at CDERCollections@fda.hhs.gov or 301-796-7900.

Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [GDUFA Facility Fee Cover Sheet Creation: Step-by-Step Instructions](#)
- [GDUFA ANDA 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: <input style="width: 90%;" type="text"/>	Password: <input style="width: 90%;" type="password"/>
<input type="button" value="Login"/>	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.

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.

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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	<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"/>
Biocimilar User Fee 2020	Bel IFA 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"/>

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


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Generic Drug User Fee

Instructions for the Generic Drug User Fee Cover Sheet

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:

- Abbreviated new drug application (ANDA) or applicable amendment;
- Generic Drug Applicant Program;
- 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;
- 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
- 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
- Play.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.

Play.gov
 FDA has partnered with the U.S. Department of Treasury to utilize Play.gov for online electronic payment. Play.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 out your cover sheet.

GENERIC DRUG USER FEE COVER SHEET
Application Details

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

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

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

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FAQ User Fees Draft Cover Sheet Previous Cover Sheet Profile Logout

Generic Drug User Fee

Generic Drug User Fee Cover Sheet

Show Legend

Cover Sheet Fee Types

Select cover sheet fee type:

- Abbreviated New Drug Application (ANDA) Fee
- Generic Drug Applicant Program Fee
- Type II Active Pharmaceutical Ingredient (API) Drug Master File (DMF) Fee
- Facility Fee

Cancel Next

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Generic Drug User Fee

Generic Drug User Fee Cover Sheet

Show Legend

Facility Fee

Enter or Confirm facility owner's name and address: [Help](#)

* Facility Owner's Name: MEDITEX LTD URIEL

* Country: Israel

* Address Line 1: Hameessila 23 st. Neshet 36885

Address Line 2:

Address Line 3:

Address Line 4:

City: NESHER

State/Province:

Postal Code: 36885

Cancel Back Next

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

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- 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.

Generic Drug User Fee

Generic Drug User Fee Cover Sheet

Show Legend

Facility Fee

Enter or Confirm facility owner's name and address: [Help](#)

* Facility Owner's Name	MEDITEXLTD URIEL
* Country	Israel
* Address Line 1	Harnessila 23 st. Nesher 36885
Address Line 2	
Address Line 3	
Address Line 4	
City	NESHER
State/Province	
Postal Code	36885

Cancel Back Next

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

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.

Generic Drug User Fee

Generic Drug User Fee Cover Sheet

Show Legend

Facility Fee

Enter facility owner's representative or U.S. agent information: [Help](#)
 Note: The facility owner's representative or U.S. Agent must be authorized to respond to questions posed by the FDA regarding the applicant's cover sheet. If the applicant is a foreign entity, a U.S. Agent is required.

* First Name	* Last Name
TEST	USER02
* Job Title	Manager
* Telephone Number	925-4516318
* Email Address	kishbabu@yahoo.com

* Indicates required field

[Cancel](#) [Back](#) [Next](#)

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.

Generic Drug User Fee

Show Legend

Facility Fee

Is this facility located in the United States, its territories or possessions? [Help](#)
 Yes No

Provide the facility's name, address, FDA Establishment Identifier (FEI) number and facility DUNS number for the facility: [Help](#)
 Note: Provide the physical address of the facility for which the facility fee is being paid.

* Facility Name	Test Facility 123	* FDA Establishment Identifier	222333444
* Country	United States	* Facility DUNS Number	777888999
* Address Line 1	123 Hellow St		
* Address Line 2			
* Address Line 3			
* Address Line 4			
* City	Dallas		
* State	TX		
* Zip Code	75001		

* Indicates required field

[Cancel](#) [Back](#) [Next](#)

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- 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.

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Generic Drug User Fee

Show Legend

Facility Fee

Indicate what the facility produces for human generic drugs only (Check all applicable) [Help](#)

Active Pharmaceutical Ingredient (API) - Check if the facility is referenced in at least one approved generic drug submission for manufacturing or processing API(s)

Are all APIs produced at this facility for Positron Emission Tomography (P.E.T) drugs only? Yes No

Are all APIs produced at this facility for ANDAs submitted by a State or Federal Government for drugs that are not distributed commercially only? Yes No

Finished Dosage Form (FDF) - Check if the facility is referenced in at least one approved generic drug submission for manufacturing or processing FDF(s)

Is the facility qualified as a contract manufacturing organization (CMO)? Yes No

Are all FDFs produced at this facility for P.E.T drugs only? Yes No

Are all FDFs produced at this facility for ANDAs submitted by a State or Federal Government for drugs that are not distributed commercially only? Yes No

*. Indicates required field

[Cancel](#) [Back](#) [Next](#) [Finish](#)

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

13. On the Draft Cover Sheet page, verify the amount owed for the cover sheet. You have four options on this page:
- Click the “Next” button to continue.
 - 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.
 - If you do not save or submit your cover sheet, it will be available for 30 days in the “Draft Cover Sheet” menu.
 - 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.

The screenshot shows the FDA website interface for the Draft Cover Sheet page. 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 this are several icons for navigation: FAQ, User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout. The main content area is titled "Draft Cover Sheet" and includes a "Items" list. A message states: "You now have four options to proceed:" followed by four numbered instructions. Below the instructions is a table with the following data:

Delete	Cover Sheet	Creation Date	Last Update Date	Net
<input type="checkbox"/>	GENERIC DRUG USER FEE COVER SHEET Modify Application Details	21-SEP-2017 19:11:21	21-SEP-2017 19:19:45	Net: \$45,367.00

At the bottom of the table, there are buttons for "Delete Selected Draft(s)", "Save Cover Sheet", and "Next". The "Next" button is highlighted with a red box. Below the table, there is a navigation bar with links for "User Fees", "Draft Cover Sheet", "Previous Cover Sheet", "Profile", and "Logout". At the very bottom, there are links for "FDA Home Page", "Search FDA Site", "FDA A-Z Index", "Contact FDA", "Privacy", and "Accessibility".

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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.

The screenshot shows the FDA's Generic Drug User Fee payment information screen. The header includes the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below the header are navigation icons for FAQ, User Fees, Draft Cover Sheet, Previous Cover Sheet, Profile, and Logout. The page title is "Generic Drug User Fee". The main content area is titled "Checkout: Applicant Contact Information" and contains a "Payment Information" section. The "Bill To" information is highlighted with an orange box and includes the following details:

Customer:	MEDITEX LTD URIEL
Contact:	TEST USER02 925-4516318 kshbabu@yahoo.com
Address:	Harnessla 23 st., Neshet 36885 NESHET 36885 ISRAEL

To the right of the "Bill To" information is a "Change" button. Below the "Bill To" information are two buttons: "Save Cover Sheet" and "Next". At the bottom of the page, there is a navigation menu with links for "Generic Drug User Fee", "User Fees", "Draft Cover Sheet", "Previous Cover Sheet", "Profile", and "Logout". Below this menu are links for "FDA Home Page", "Search FDA Site", "FDA A-Z Index", "Contact FDA", "Privacy", and "Accessibility". At the very bottom, there is a link for "FDA Website Management Staff".

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

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.

Generic Drug User Fee

Checkout: Review and Submit Draft Cover Sheet

Cover Sheet	Creation Date	Last Update Date	Net
FY 2018 GENERIC DRUG USER FEE COVER SHEET Print/View Draft Cover Sheet	21-SEP-2017 19:11:21	21-SEP-2017 19:25:55	\$45,367.00
			Total: \$45,367.00

Customer Information

Customer: MEDITEX LTD URIEL
TEST USER02
925-4516318
kshbabu@yahoo.com

Applicant Contact Information

Bill To: TEST USER02
MEDITEX LTD URIEL
Hamessila 23 st. Neshet 36885
NESHET
36885
ISRAEL

[Submit Cover Sheet to FDA](#)

Generic Drug User Fee
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16. After reading the message, select ‘Submit Cover Sheet to FDA’.

Generic 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.

The Food and Drug Administration (FDA or the Agency) will no longer permit the transferring of GDUFA fee payments from a closed-out fiscal year (FY) cover sheet to a different FY cover sheet. FDA's FY begins on October 1 and ends on September 30, with the year being designated by the calendar year in which it ends (e.g., FY 2020 begins on October 1, 2019, and ends on September 30, 2020). Beginning in FY 2021, payment transfer requests for cover sheets from a closed-out FY will not be processed. Instead, payments from closed-out FY cover sheets will only be processed as refunds to the original payors. [Form FDA 3913](#) should be completed and submitted to CDERCollections@fda.hhs.gov for review and the fee paid will be refunded if appropriate.

This does not affect requests the transfer of payments within the same FY. For example, a request to transfer a payment from a FY 2020 cover sheet to another FY 2020 cover sheet within the same fee type (perhaps due to an incorrect FEI) will be processed, provided the request is made within 180 calendar days of the original payment date.

Accordingly, payment transfers within the same FY and refund requests must be in accordance with Section 744(m) of the Food, Drug, and Cosmetic Act. This requires that requests for a transfer of the fee within the same FY or a request for a return of the paid fee must be submitted in writing within 180 calendar days after such fee was paid. If you have any questions regarding this change, please contact GDUFA User Fee staff at CDERCollections@fda.hhs.gov or 301-796-7900.

[Cancel](#) [Submit Cover Sheet to FDA](#)

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17. A confirmation of your cover sheet submission and a Payment Identification Number appears. On this page, you may:
- Click the “Print/View Final Cover Sheet” button to view and/or print the cover sheet.
 - Click the “Pay Now” button to make an online payment.
 - 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.

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Generic Drug User Fee

Confirmation
YOUR PAYMENT IDENTIFICATION NUMBER IS: GD9018532

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	
PY 2018 GENERIC DRUG USER FEE COVER SHEET Print/View Final Cover Sheet	1	21-SEP-2017 19:11:21	21-SEP-2017 19:25:55 Net: \$45,367.00
			Total: \$45,367.00

Customer Information
Customer: MEDITEK LTD URIEL
TEST USER02
925-4516318
kshbabu@yahoo.com

Applicant Contact Information
Bill To: TEST USER02
MEDITEK LTD URIEL
Hamesela 23 st. Neshet 36885
NESHET
36885
ISRAEL

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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.