

Animal Generic Drug User Fee Act Cover Sheet
OMB Control Number 0910-0632
Form FDA 3728

1. Log in

U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQ\)](#)
- [FDA User Fee Account Question Step-by-Step Instructions](#)
- [ADURA Cover Sheet Question 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:

[Log in](#) [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 4:00 AM EST to 6:00 PM EST on Saturday, April 8, 2017 for maintenance activities.

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.

Please note that all user fee URLs that contain `fdasfrapp8` such as `https://fdasfrapp8.fda.gov/CD4_HTML/URLs.jsp` are no longer available. If you have any user fee links that contain `fdasfrapp8` saved as a bookmark or in your favorites, please update it to replace `fdasfrapp8` with `userfees` (e.g. `https://userfees.fda.gov/CD4_HTML/URLs.jsp`). For user fee URLs, navigate to `https://www.fda.gov/ForIndustry/UserFees/dfa/du.htm` and click on the appropriate user fee link.

Need Help? Click Here For Assistance.

2. Select appropriate cover sheet

User Fee Website

Welcome Tara Phillips

Annual Establishment Registration

User Fee	Description	
MDUFA Establishment Registration User Fee 2017	FURLS Device Facility User Fee	<input type="button" value="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	<input type="button" value="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	<input type="button" value="Go"/>
ANIMAL GENERIC DRUG USER FEE 2017	AGDUFA Cover Sheets	<input type="button" value="Go"/>
Biosimilar User Fee 2017	BsUFA Cover Sheets	<input type="button" value="Go"/>
Generic Drug User Fee 2017	GDUFA Cover Sheets	<input type="button" value="Go"/>
Medical Device User Fee 2017	MDUFA Cover Sheets (PMA, 510k, etc.)	<input type="button" value="Go"/>
Prescription Drug User Fee 2017	PDUFA Pre-Market Cover Sheets	<input type="button" value="Go"/>

***To view the 2015 fees, please see the Federal Register Notices below:**

[GDUFA 2015 FR Notice](#)

***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](#)

3. Select options for cover sheet and select "Finish." The system fills in the user contact information, calculates the required fee amount, generates a unique payment identification number used by FDA to track the payment, and provides the user the option to electronically submit the cover sheet and payment.

The screenshot shows the FDA's online form for the Animal Generic Drug User Fee Cover Sheet. 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 is a menu with icons for "FAQ", "Account Management", "User Fees", "Draft Cover Sheet", "Previous Cover Sheet", "Profile", and "Logout". The current page title is "Animal Generic Drug User Fee".

The main form area is titled "Animal Generic Drug User Fee Cover Sheet" and includes "Cancel" and "Finish" buttons. A "Show Legend" link is also present. The form contains several sections:

- Select an Application Type:** A radio button is selected for "Original".
- Select an Application Type:** Two checkboxes are present:
 - Abbreviated New Animal Drug Application (ANADA) - under provisions of 512(b)(2) of the FDCA
 - Abbreviated New Animal Drug Application (ANADA) of certain combination pioneer products approved under provisions of 512(d)(4) of the FDCA
- Waivers or Reductions?** A checkbox is present:
 - The sole purpose of the application is to support conditions of use for minor use or minor species (741(d)).

Below the "Waivers or Reductions?" section, there is a label "GM Waiver No." followed by a text input field.

At the bottom right of the form, there are "Cancel" and "Finish" buttons.

4. Instructions

U.S. Department of Health & Human Services
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Animal Generic Drug User Fee

Animal Generic Drug User Fee

Welcome to FDA's online Animal Generic Drug User Fee Act (AGDUFA) cover sheet process. FDA offers you the ability to complete an AGDUFA cover sheet online and submit it electronically. The AGDUFA cover sheet must accompany each original abbreviated new animal drug application subject to fees. Once you complete the cover sheet and click "Submit Cover Sheet to FDA", an electronic payment identification number will appear in the upper right-hand corner beginning with "AG". This will enable the FDA to track your application submission and receipt of payment at the bank in order to begin the application review process.

To properly submit your application and fee payment you must follow the following 3 steps:

STEP 1 – COMPLETING COVER SHEET:

1. Complete the on-line questions. When you have verified that your information is correct, click "Submit Cover Sheet to FDA". This will create the FDA AGDUFA cover sheet form electronically.
2. Please follow the instructions to print. You may want an additional copy for your records.
3. Click "Submit Cover Sheet to FDA" and the completed FDA AGDUFA cover sheet will be sent electronically to the FDA.

STEP 2 – PAYMENT OPTIONS:

1. Make your check payable to the U.S. Food and Drug Administration and include 1 copy of the FDA AGDUFA cover sheet. Please write the payment identification number (beginning with "AG") on your check.
 - o Mail your check and one copy of the FDA AGDUFA cover sheet to:
The Food and Drug Administration
P.O. Box 979033
St. Louis MO 63197-9000
(Note: Please do not send your application to this address only your payment.)
 - o If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to:
US Bank
Attn: Government Lockbox 979033
1000 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. Contact US Bank at 314-418-4013 if you have any questions concerning courier delivery.)
2. If paying by wire transfer, you may send your payment using the following information. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution regarding additional fees. Please note that the review of your application can not begin until full payment is received. Also include your user fee payment identification number from your user fee cover sheet when you send payment by wire transfer. Please ensure that the fee that your bank will charge for the wire transfer is added to your fee payment.
US Department of Treasury
TBSPS-INC
33 Liberty Street
New York, NY 10045
FDA Deposit Account Number: 75060099
US Department of Treasury routing/transit number: 021030004
SWIFT Number: RRWUS33
3. Paygov 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 Paygov, a web-based payment application, for online electronic payment. The Treasury has compiled a comprehensive list of Paygov FAQs which can be accessed at <https://www.paygov.com/faq/HTML/about.html>.

STEP 3 – MAILING APPLICATION AND COVER SHEET

Mail your application and include one copy of the FDA AGDUFA cover sheet in volume one of the application when submitting to the FDA at the following address:

Food and Drug Administration
Center for Veterinary Medicine
Document Control Unit (HVM-159)
7500 Standish Place
Rockville, MD 20855

Animal Generic Drug User Fee Cover Sheet Application Details

Animal Generic Drug User Fee
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