

# Animal Drug User Fee Act Cover Sheet Form FDA 3546

1. Log into your User Fee account.



## Useful Links

- [User Fee Information](#)
- [User Fee Payment Information](#)
- [Frequently Asked Questions \(FAQs\)](#)
- [FDA User Fee Account Creation: Step-by-Step Instructions](#)
- [ADUFA 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 type="text"/>	Password:	<input type="password"/>
<input type="button" value="Login"/>		<a href="#">Forgot User Name/Password?</a>	

[New User? Please register...](#)

## User Fee System Alerts

*Please be advised that the FDA User Fee System will be unavailable from 6:00AM EST on Saturday, June 24, 2017 to 6:00 PM EST on Sunday, June 25, 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 `fdasfinapp8` such as `https://fdasfinapp8.fda.gov/OA_HTML/furls.jsp` are no longer available. If you have any user fee links that contain `fdasfinapp8` saved as a bookmark or in your favorites, please update it to replace `fdasfinapp8` with `userfees` (e.g. `https://userfees.fda.gov/OA_HTML/furls.jsp`). For user fee URLs, navigate to `http://www.fda.gov/ForIndustry/UserFees/default.htm` and click on the appropriate user fee link.*

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**Need Help? Click Here For Assistance.**

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## 2. Select appropriate cover sheet

### User Fee Website

Welcome Help Desk

#### 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"/>

### 3. Application instructions are provided on this page. Click on Application Details.

## Animal Drug User Fee

Welcome to FDA's online Animal Drug User Fee Act (ADUFA) cover sheet process. FDA offers you the ability to complete an ADUFA cover sheet online and submit it electronically. The ADUFA cover sheet must accompany each original new animal drug application or supplemental 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 "AD". 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 online questions. When you have verified that your information is correct, click "Submit Cover Sheet to FDA". This will create the FDA ADUFA 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 ADUFA 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 ADUFA cover sheet. Please write the payment identification number (beginning with "AD") on your check.

- o Mail your check and one copy of the FDA ADUFA 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  
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. 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  
TREAS NYC  
33 Liberty Street  
New York, NY 10045**

**FDA Deposit Account Number: 75060099  
US Department of Treasury routing/transit number: 021030004  
SWIFT Number: FRNVUS33**

3. 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 accessed at <https://www.pay.gov/WebHelp/HTML/about.html>.

#### STEP 3 – MAILING APPLICATION AND COVER SHEET

Mail your application and include one copy of the FDA ADUFA 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 (HFV-199)  
7500 Standish Place  
Rockville, MD 20855**

ANIMAL DRUG USER FEE COVER SHEET



[Application Details](#)

4. Select the 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.

**Animal Drug User Fee Cover Sheet**

Cancel Continue Finish

› Show Legend

Select an Application Type

New Animal Drug Application

Abbreviated New Animal Drug Application - under provisions of 512(b)(1) of the FFDCa

Select the type of application requested

Original Application

Supplemental Application

\*\*\*Click the 'Continue' button to select waivers or reductions

Cancel Continue Finish

5. To view a draft version of the cover sheet click on ANIMAL DRUG USER FEE COVER SHEET.

[Animal Drug User Fee Cover Sheet](#)

**Cover Sheet** | **Saved Cover Sheets**

Draft Cover Sheet

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Items

✓ **You now have four options to proceed:**

1. If you have one draft cover sheet, click the "Next" button to submit your cover sheet to FDA and receive a Payment Identification Number (PIN).  
**Note:** If you do not receive a Payment Identification Number (PIN), your cover sheet was not submitted to FDA.
2. If you would like to modify your cover sheet selections, click the "Modify Application Details" button to make changes to the draft form. To view your draft cover sheet, please click on the cover sheet link.
3. If you choose not to save or submit your cover sheet at this time, your draft cover sheet will be automatically saved for 30 days before it expires.
4. If you would like to save your cover sheet for future submission, click the "Save Cover Sheet" button and provide a name for your cart.  
If you are saving more than one cover sheets, please make sure you save each cover sheet under a different cart name.  
**Note:** To modify or submit a saved cover sheet, click the "Draft Cover Sheet" icon, and select the "Saved Cover Sheets" link to access your carts. Saved cover sheets remain active for 90 days before they expire.

**Select All** | **Clear Selections**

Delete	Cover Sheet	Creation Date	Last Update Date	
<input type="checkbox"/>	<a href="#">ANIMAL DRUG USER FEE COVER SHEET</a> <a href="#">Modify Application Details</a>	13-JUL-2017 11:41:10	13-JUL-2017 11:42:13	Net: \$350,700.00

[Delete Selected Draft\(s\)](#) | [Save Cover Sheet](#) | [Next](#)

6. Select 'Next', and 'Submit Cover Sheet to FDA' to complete the process.



Checkout: Review and Submit Draft Cover Sheet

Cover Sheet	Creation Date	Last Update Date	
<a href="#">FY 2017 ANIMAL DRUG USER FEE COVER SHEET</a> <a href="#">Print/View Draft Cover Sheet</a>	13-JUL-2017 11:41:10	13-JUL-2017 11:48:53	Net: \$350,700.00
			<b>Total: \$350,700.00</b>
<b>Customer Information</b>			
Customer:			
<b>Applicant Contact Information</b>			
Bill To:			



[Submit Cover Sheet to FDA](#)

7. A final confirmation page that provides PIN number and an option to online via the Pay Now button should be displayed.

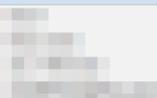
 **Confirmation**  
YOUR PAYMENT IDENTIFICATION NUMBER (PIN) IS 1000 

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	
<a href="#">FY 2017 ANIMAL DRUG USER FEE COVER SHEET</a> <a href="#">Print/View Final Cover Sheet</a>	1	13-JUL-2017 11:41:10	13-JUL-2017 11:48:53
			Net: \$350,700.00
			<b>Total: \$350,700.00</b>

**Customer Information**  
Customer: 

**Applicant Contact Information**  
Bill To: 

 [Pay Now](#) [Create Another Cover Sheet](#)