On August 18, 2017 the President signed into law the Food and Drug Administration Reauthorization Act (FDARA). This new law includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products. The new law ensures that FDA will continue to receive a source of stable and consistent funding during fiscal years 2018-2022 that will allow the agency to fulfill its mission to protect and promote public health by helping to bring to market critical new medicines for patients.

The Prescription Drug User Fee Act (PDUFA) was enacted in 1992 and renewed in 1997 (PDUFA II), 2002 (PDUFA III), 2007 (PDUFA IV), 2012 (PDUFA V), and 2017 (PDUFA VI). It authorizes FDA to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process.

For additional information, please refer to:

http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/default.htm

1) Access the User Fee Website: https://userfees.fda.gov/OA_HTML/pdufaCacLogin.jsp
2) Review the statement and select the “I Understand” radio button.
3) For users who have an existing user name and password, proceed to Step 4;
   a) If you do not have an existing account, see the FDA User Fee Account Creation: Step-by-Step Instructions for step-by-step instructions on how to create an account. For additional assistance, contact the User Fee Helpdesk at userfees@fda.gov.
4) Enter a valid user name and password.
5) Click the “Login” button.
6) Click the “Go” button next to “PDUFA Pre-Market Cover Sheets”.

<table>
<thead>
<tr>
<th>User Fee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDﬂFA Establishment Registration User Fee 2017</td>
<td>MDﬂFA Pre-Market Cover Sheets</td>
</tr>
<tr>
<td>MDﬂFA Establishment Registration User Fee 2018</td>
<td>MDﬂFA Pre-Market Cover Sheets</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>User Fee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Drug User Fee 2016</td>
<td>PDUFA Cover Sheets</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>User Fee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANIMAL DRUG USER FEE 2017</td>
<td>PDUFA Pre-Market Cover Sheets</td>
</tr>
<tr>
<td>ANIMAL GENERIC DRUG USER FEE 2017</td>
<td>PDUFA Pre-Market Cover Sheets</td>
</tr>
<tr>
<td>Biosimilar User Fee 2017</td>
<td>BUPA Cover Sheets</td>
</tr>
<tr>
<td>Generic Drug User Fee 2017</td>
<td>BUPA Cover Sheets</td>
</tr>
<tr>
<td>Medical Device User Fee 2017</td>
<td>MDﬂFA Cover Sheets (PMA, 510k, etc.)</td>
</tr>
<tr>
<td>Prescription Drug User Fee 2017</td>
<td>PDUFA Pre-Market Cover Sheets</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>User Fee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANIMAL DRUG USER FEE 2018</td>
<td>PDUFA Pre-Market Cover Sheets</td>
</tr>
<tr>
<td>ANIMAL GENERIC DRUG USER FEE 2018</td>
<td>PDUFA Pre-Market Cover Sheets</td>
</tr>
<tr>
<td>Biosimilar User Fee 2018</td>
<td>BUPA Cover Sheets</td>
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<tr>
<td>Generic Drug User Fee 2018</td>
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</tr>
<tr>
<td>Prescription Drug User Fee 2018</td>
<td>PDUFA Pre-Market Cover Sheets</td>
</tr>
</tbody>
</table>
7) Scroll to the bottom of the page and select the 'Application Details' button.
PDUFA Cover Sheet Creation: Step-by-Step Instructions

8) Make the appropriate selections and provide the requested information as applicable:
   a) Select 'CDER Submission' or 'CBER Submission'
   b) Provide the 'Established Name/Proper Name', 'Trade Name', 'NDA Number', and 'BLA Submission Tracking Number (STN)'
   c) Select the type of application requested
   d) Select 'Yes' or 'No' to the application requiring clinical data for approval question
   e) Select 'The required clinical data are contained in the application' or 'The required clinical data are submitted by reference to:'
      a) If 'The required clinical data are submitted by reference to:' is selected, provide either the 'Application Number Containing the Data' or 'Supplement Number Containing the Data'
   f) Select 'Yes' or 'No' to the Priority Review Voucher for the treatment of tropical diseases question
      a) If 'Yes', provide the Priority Review Voucher number
PRESCRIPTION USER FEE COVER SHEET

Show Legend

CDER Submission  CBER Submission

Include Established Name/Proprietary Name and Trade Name, as applicable

ESTABLISHED NAME/PROPRIETARY NAME  TRADE NAME

NDA NUMBER  BLA SUBMISSION TRACKING NUMBER (STN)

Is this an Original Application?

Yes  No

Does this application require clinical data for approval?

Yes  No

The required clinical data are contained in the application

The required clinical data are submitted by reference to:

(Application Number Containing the Data)  (Supplement Number Containing the Data)
9) If applicable, select the ‘Exceptions and Waivers’ button; otherwise, proceed to step 11 to continue.

10) Make the appropriate selections and select ‘Return to Cover Sheet’ to continue.
11) Review and verify that your information is accurate.
12) Click ‘Done’ to continue.
13) After arriving at the Draft Cover Sheet page, scroll to the bottom and select the ‘Next’ button to review the contact and address information.

A. Note: you may save the cover sheet by selecting the ‘Save Cover Sheet’ button. You may return to the ‘Draft Cover Sheet’ menu to access your saved draft cover sheet. Select the checkbox under the ‘Delete’ column and select the ‘Delete Selected ‘Draft(s)’ button to delete a draft cover sheet.
14) On the ‘Checkout: Applicant Contact Information’ page, you will see the billing information for this cover sheet. You can change the address by selecting the ‘Change’ button and follow the instructions to update the address. Once the information has been verified and is accurate, select ‘Next’ to proceed.
15) Review and verify your information, and select the 'Submit Cover Sheet to FDA' button to obtain your Payment Identification Number (PIN).
**PDUFA Cover Sheet Creation: Step-by-Step Instructions**

16) A unique User Fee PIN will be generated with your cover sheet upon submission. Please note that your completed cover sheet is your invoice. To obtain an invoice copy for your records, select on the 'Print/View Final Cover Sheet' button on the confirmation page.

Once you submit your cover sheet and obtain your PIN, you may pay online by selecting the 'Pay Now' button.

You can create and submit another PDUFA cover sheet by selecting the ‘Create Another Cover Sheet’ button.

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.