

PDUFA User Fee Cover Sheet

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

PDUFA User Fee Cover Sheet

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), FDA has the authority to assess and collect user fees for

certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay fees for certain new human drug applications, biologics applications, and supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee has been submitted. Form FDA 3397, the PDUFA user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee

is required for review of an application, to determine the amount of the fee required, and to help FDA track payments.

The form provides a cross-reference of the fee submitted for an application with

the actual application by using a unique number tracking system to assign the user fee payment identification number. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

How to Fill Out the PDUFA User Fee Cover Sheet On-line:

FDA offers you the ability to complete a PDUFA User Fee Cover Sheet on-line and submit it electronically. To fill out the form online, you need Microsoft Internet Explorer 5.5 or higher or Netscape Navigator 4.7 or higher. To view instructions for checking and updating your browser, please go to: www.fda.gov/cber/browser.htm.

Read the instructions below and then go to the PDUFA User Fee Coversheet to fill out the form.

1. You will register on-line by providing the following information:

- Employer Identification Number (EIN)
- Contact Name
- Company Name
- Address, City, State, Zip Code, Country
- Daytime Telephone
- Facsimile Number
- E-mail
- Dun & Bradstreet Number (DUNS)

2. Fill out the PDUFA User Fee Cover Sheet. Please answer a series of questions regarding the type of application being submitted for FDA's review. You will have the opportunity to view the cover sheet in draft form before submitting it to FDA. You have not submitted your cover sheet until you receive a user fee payment identification number.

3. When you are done, click the SUBMIT button to complete the cover sheet submission process. A form will appear with an electronically generated user fee

payment identification number that is located in the upper right-hand corner, beginning with the letters PD. This number will assist FDA in tracking your payment and submission for the review process. Please print a copy for your files to send with your payment and for your submission to CDER and CBER.

Submitting Payment

Please send a printed copy of the completed PDUFA User Fee Cover Sheet along with a check, bank draft, or U.S. Postal money order made payable to the Food and Drug Administration for the fee amount due. Remember to include the user fee

payment identification number, beginning with "PD", the BLA/NDA number, and the

FDA P.O. Box on the enclosed check.
Mail payment and copy of PDUFA user fee cover sheet to:
Food and Drug Administration
P.O. Box 360909
Mellon Client Service Center -- Room 670
500 Ross Street
Pittsburgh, PA 15251-6909

Note: In no case should payment be submitted with the application.
If checks are to be sent by a courier that requires a street address, the
courier can deliver the checks to:
Food and Drug Administration (360909)
Mellon Client Service Center - Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

Note: This address is for courier delivery only.

If You Have Problems:

If you are unsure whether or not you need to file an application with FDA or are

unsure what type of application to file:

Contact: Bev Friedman or Mike Jones at 301-594-2041

FDA Center for Drug Evaluation and Research

Contact: Carla Vincent at 301-827-3503

FDA Center for Biologics Evaluation and Research

If you need technical assistance with your cover sheet or are unsure how to
proceed.

Contact: FDA User Fee Financial Support Team at (301) 827-9539 or
userfees@fda.gov.

PDUFA User Fee Cover Sheet

OMB No. 0910-0297

Form FDA 3397 (12/06)

[PDUFA Home Page](#)

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

[FDA Website Management Staff](#)