
Manual of Standard Operating Procedures and Policies

Regulatory - License Applications

Verification of User Fee Data Sheet and Payment

SOPP 8406

Version #3

Date: August 10, 2001

1. Purpose

The purpose of this document is to describe the procedures used to determine the accuracy of information submitted by an applicant relative to the Prescription Drug User Fee Act of 1992, as amended by the FDA Modernization Act of 1997, and to verify that payment owed has been received.

2. Definitions

Application

An original Biologics License Application (BLA), or New Drug Application (NDA).

Supplement

Any submission requesting approval of a change to an approved BLA or NDA.

Unacceptable for Filing

The application/supplement is not accepted by the Food and Drug Administration for review. The Prescription Drug User Fee Act of 1992 requires this action in situations in which an applicant is determined to be in arrears for **ANY**

user fees owed the federal government. (This is a different status from an application that has been refused to file based on deficiencies as described in SOPP 8404.)

Arrears Status - There are *two* types of arrears status:

- In Arrears for Non-payment of Fees Invoiced:** An applicant will be determined to be in arrears for any prescription drug user fee owed the federal government if that applicant has not paid all fees by the payment due date to the satisfaction of the FDA Office of Financial Management (OFM). All fees include annual product fees, establishment fees, and application fees *for which they have been invoiced*. Failure to submit timely payment of the invoice results in the applicant being listed on the Arrears & Payment Report.
- In Arrears for a specific submission:** An applicant will be determined to be in arrears for a *particular submission* if OFM has not received confirmation that an application fee has been received by the designated bank within five calendar days of the date the submission is received by FDA. The application will not be accepted for filing until payment is made. **However, this does not result in the applicant being placed on the Arrears & Payment Report or being invoiced.** Unrelated applications or supplements from the same

applicant may be accepted for filing as long as any required fees for those submissions are paid.

Arrears & Payment Report

A daily report from OFM sent via e-mail to the Regulatory Information Management Staff (RIMS) which shows CBER and CDER regulated applicants who are in arrears for non-payment of fees, or who have made payment for outstanding fees owed. This report is posted in CBER's "Outlook Public Folder," *User Fee Information*.

CBER Check Receipt Report

A daily report from OFM sent via e-mail to RIMS which shows payment made by applicants for incoming CBER submissions. This report is forwarded by RIMS to the designated contact in the review office receiving the submission.

3. Background

On October 29, 1992, the President signed the Prescription Drug User Fee Act of 1992 (PDUFA). The law authorizes FDA to collect user fees from applicants for certain new drug and biological product applications and supplements pending on, or submitted after, September 1, 1992. PDUFA was amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

The Act authorizes FDA to collect an application fee from each person that submits certain human drug applications. Human drug applications or supplements covered by fees are:

- those submitted under section 505(b)(1) of the Food, Drug and Cosmetic Act (FD&C Act);
- those submitted under 505(b)(2) of the FD&C Act after September 30, 1992 and which request approval of a molecular entity which is an active ingredient or new indication for use not previously approved under 505(b)(1) application;
- applications for initial certification or initial approval of an antibiotic drug under section 507;
- or an application for licensure of a biological product under section 351 of the Public Health Service Act.

The Act also provides for certain exclusions and waivers of user fees. See the following web site for additional information: <http://www.fda.gov/cder/pdufa/default.htm>

FDA Form 3397, *User Fee Cover Sheet*,

is used to submit information regarding human drug applications and supplements subject to user fees. See the following web site for a copy of the form and instructions:

<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>.

4. Policy

Each application and supplement should be accompanied by a Form FDA 3397, *User Fee Cover Sheet*. Information submitted must be verified to determine that the correct fee has been submitted.

Note: Human blood, blood components, blood grouping reagents, and blood bags; licensed *in vitro* diagnostic devices; and allergenics are non-PDUFA products.

The *User Fee Cover Sheet* need not be included with applications for these products, nor for any manufacturing supplements that do not require clinical data for approval. The form instructions will be updated with the next revision.

Each fiscal year FDA is required to announce prescription drug user fee rates. Rates are set for annual establishment fees, for annual product fees, and for application fees (which vary according to the content of the submission). The fees are announced in the Federal Register on an annual basis. The current prescription drug user fee rates are posted in CBER's "Outlook Public Folder," *User Fee Information*.

5. Responsibilities

Person or Area	Responsibility
<p>OFM Office of Financial Management</p>	<ul style="list-style-type: none"> • annually establishes PDUFA user fee rates and publishes them in the Federal Register • receives PDUFA payments • sends daily notification to RIMS of <i>Arrears and Payment Report</i> • sends daily CBER Check Receipt Report to RIMS
<p>RIMS Regulatory Information Management Staff in CBER's Office of Management</p>	<ul style="list-style-type: none"> • posts current user fee rates in CBER public folder • assigns User Fee Billing I.D. Numbers to applicant and enters in RMS-BLA • reviews CBER payment check receipt reports received from OFM and verifies proper payment for submissions • forwards notification of CBER payment checks received to designated contacts - official payment date for resetting action due dates is on the report • distributes <i>Arrears and Payment Report</i> to designated contacts in each review office and posts report in CBER public folder • reviews faxed copy of <i>User Fee Cover Sheet</i> from RPM • notifies applicant of payment discrepancies and follows through to resolution; coordinates with RPM as appropriate • promptly notifies office designated contact and RPM of payment by applicant when firm in Arrears submits payment • monitors status of all applications and supplements that have been designated as Unacceptable for Filing • serves as primary point of contact for questions or challenges regarding user fee assessments
<p>Designated review office contacts (usually RIS\RHIS)</p>	<ul style="list-style-type: none"> • reviews <i>Arrears and Payment Report</i> and distributes according to office policy • forwards notification of CBER payment checks received to appropriate RPM • ensures correct user fee flags have been selected in RMS-BLA as part of QC (<i>Submission Information screen</i>)
<p>RPM Regulatory Project Manager(s) in the review office (or office designee)</p>	<ul style="list-style-type: none"> • checks <i>User Fee Cover Sheet</i> for accuracy and completeness; if not accurate or complete RPM will contact applicant to resolve • ensures User Fee Cover Sheet is faxed to RIMS (<i>original applications and efficacy supplements only</i>) • ensures payment is received from applicant for submission • checks Arrears & Payment report in CBER's "Outlook Public Folder" before Acknowledgement letter is prepared • ensures user fee flags have been selected in RMS-BLA (<i>Submission Information screen</i>) • notifies applicant when application is unacceptable for filing

- notifies review committee when application is unacceptable for filing that review is halted
- ensures communication for Unacceptable for Filing letter is entered in RMS-BLA when appropriate
- when notified by RIMS that the applicant is up-to-date on payments
 - reactivates review
 - ensures close date for Unacceptable for Filing milestone is entered in RMS-BLA using the "official payment date" provided by RIMS or as indicated on the CBER payment check report

6. Procedures

Routine Processing

1. Each application and supplement requiring a fee under PDUFA, must be assigned a User Fee I.D. Number. RIMS assigns the User Fee I.D. Number to the applicant and enters the number into the Regulatory Management System-Biologics License Application (RMS-BLA). All inquiries related to issuance or generation of these numbers should be referred to RIMS at 301-827-3503.
2. Each application and supplement should be accompanied by FDA Form 3397, *User Fee Cover Sheet* (see exceptions under the Policy section of this SOPP). The *User Fee Cover Sheet* will be forwarded by the Document Control Center (DCC) with the application to the appropriate review division.

The original *User Fee Cover Sheet* will be retained with the original copy of the application in DCC.

3. The RPM will review the *User Fee Cover Sheet* and verify that any exclusions checked on the cover sheet are accurate (e.g., orphan drug designation, pediatric supplement only, etc.). A complete list of exclusions can be found on the *User Fee Cover Sheet*.
4. The RPM will fax a copy of the *User Fee Cover Sheet* to RIMS (*all original applications and efficacy supplements, only*) at 301-827-2875.
5. An STN (Submission Tracking Number) will be assigned to the application following division standard operating procedures.
6. At the time of STN assignment, as part of the initial administrative regulatory review, the RPM will compare the *User Fee Cover Sheet* with the submission to determine if the application is subject to user fees. The RPM will also check the current Arrears and Payment Report to ensure the applicant is not in arrear
 - a. If the submission is NOT subject to fees and the applicant is not in arrears, *there are no further steps to follow.*
 - b. *Whether or not the submission is subject to fees, if the applicant is in arrears the submission will be deemed Unacceptable for Filing.*
The RPM will contact the applicant to advise of the unacceptable status, prepare an Unacceptable for Filing acknowledgment letter (See Appendix 1), and notify RIMS.
7. Next, for submissions subject to user fees, the RPM will confirm as necessary with RIMS that payment has been received for the submission.

If the payment was received and there is a discrepancy in the amount received, RIMS will notify the applicant of the correct amount to be submitted or refunded

Note: Review of the submission should continue while payment discrepancies

are resolved.

Submissions Received Without a *User Fee Cover Sheet* or With an Incomplete Sheet

If an application or supplement is received without an accompanying *User Fee Cover Sheet*, the RPM will contact the applicant by telephone and request immediate submission of a completed form.

If an incomplete or inaccurate form is submitted with an application, the RPM will contact the firm by telephone to obtain the necessary information or relay the inaccuracy.

An application or supplement should not proceed to a filing action until the information is obtained.

Failure to Submit Payment

1. If no payment is received within 5 days of the CBER receipt date of the submission, the RPM (or office designee) will:
 - a. notify the review committee to halt the review
 - b. notify the applicant by telephone that the application is unacceptable for filing
 - c. prepare a notification letter using the CBER Unacceptable for Filing letter template (Appendix 1)
 - d. enter a communication in RMS-BLA for the Unacceptable for Filing letter. This entry changes the status of the submission to Unacceptable for Filing and removes the due/hold dates of any pending milestones.

Note: The Act stipulates that the failure to pay an application fee causes that application to be unacceptable for filing. This is a different status from an application that has been refused for filing based on deficiencies in content of the submission.

2. The application may be sent to DCC for storage until the review is reactivated. (This is the exception to the rule, please contact DCC if this is necessary.)
3. Any applications from the in-arrears applicant that were pending prior to the applicant going into arrears will continue to be reviewed.
4. Any applications submitted by the applicant *while* the applicant is in arrears will be deemed Unacceptable for Filing.
5. When RIMS notifies the review office that fees owed have been paid, the review process will be reactivated. The RPM will:
 - a. notify the committee that the review process may proceed
 - b. if the application was stored in DCC, instruct DCC to forward the submission to the committee
 - c. prepare a notification letter using CBER Notification of Receipt of Fees Owed letter template (Appendix 2)
 - d. reset the user fee action due dates; enter close date for the Unacceptable for Filing milestone in RMS-BLA. The RPM should use the payment date indicated on the *CBER Check Receipt Report*. RMS-BLA automatically calculates the new action due dates based on the close date.

7. Effective Date

August 10, 2001

8. Appendices

[Appendix 1](#) - Unacceptable for Filing (Standard letter)

[Appendix 2](#) - Notification of Receipt of Fees Owed (Standard letter)

9. History

Written By	Approved By	Approval Date	Version Number	Comment
CBER Application Policy Task Force	M. Beatrice	3/23/1994	1	Reissued as SOPP 8406 in August 1997. No change to Guide content
Roger Eastep Gilliam Conley Chris Nemoff Darcel Bigelow Carla Vincent	Robert Yetter, PhD	4/11/2001	2	This revision further clarifies the responsibilities and procedures. It supercedes version 1 of this SOPP issued August 27, 1997 [originally issued as #OD-R-6-94 on March 23, 1994]
Roger Eastep	Robert Yetter, PhD	8/10/2001	3	Removal of plasma volume expanders from the non-User Fee list in Section 5

Updated: August 16, 2001