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# Manual of Standard Operating Procedures and Policies

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## License Applications

### Verification of Medical Device User Fee Data Sheet and Payment

SOPP 8704

Version #1

Date: January 12, 2005

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#### 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 user fees for devices under the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), and to verify that payment owed has been received.

#### 2. Definitions

**Biologics License Application (BLA)** - original licensed product application.

**Blood Logging and Tracking (BLT)**

- the database used to track premarket approval applications (PMA), premarket reports (PMR), supplements, product development protocols (PDP), and premarket notifications (510k).

**Efficacy supplement** - biologics license supplement with clinical data.

**In Arrears for Non-payment of Fees**

- An applicant will be determined to be in arrears for any medical device user fee owed the federal government if that applicant has not paid the fee specified in the Federal Register, February 25, 2003 according to the type of application being submitted. The arrears list will initially include only the specific firm that is in arrears and not the parent, partner and affiliate firms.

**Incomplete and unacceptable for filing**

- If a fee is not paid, the device submission shall be considered incomplete and shall not be accepted for filing until the fee is paid in full. The Food and Drug Administration (FDA) will not begin its review of a device submission until the fee for that submission is paid and all fees for previous submissions have been paid.

**MDUFMA BLT Submissions Complete List that do not have Full Payments** - A weekly report from Information Management Consultants (IMC), the contractor supporting BLT, sent via email to individual reviewers, Regulatory Project Managers (RPMs) and Regulatory Information Management Staff (RIMS) which shows submissions that have been invoiced by Office of Financial Management (OFM) but have not made full payment.

**MDUFMA Fee Discrepancy Report**

- A daily report from the OFM sent via e-mail to the Center for Devices and Radiological Health (CDRH), Center for Biologics Evaluation and Review (CBER), and RIMS and which shows CBER and CDRH regulated applicants who are in arrears for non-payment of fees, or who have made partial payment for outstanding fees owed.

**MDUFMA Payment Report**

- A daily report from OFM sent via e-mail to CDRH, CBER, and RIMS which shows payment made by applicants for incoming CBER submissions.

**Panel-track supplement**

- a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness. Includes PMAs, PMRs and PDPs.

**PreMarket Application (PMA)** - Any premarket approval application for a class III medical device.

**Premarket reports (PMRs)** - Any premarket application for a reprocessed single-use device.

**Product Development Protocol (PDP)**- mechanism for the regulation of Class III medical devices that would allow a sponsor to come to early agreement with the FDA as to what would be done to demonstrate the safety and effectiveness of a new device.

**Real-time supplement**

- a supplement to an approved premarket application or premarket report under section 515 that requests a minor change to a device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement. Includes PMAs, PMRs and PDPs.

**Regulatory Management System/Biologics License Application (RMS-BLA)** - the database used to track biologics license device applications and efficacy supplements.

**180-day supplement**

- a supplement to an approved premarket application or premarket report under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additive, and labeling. Includes PMAs, PMRs and PDPs.

**510(k)**

- a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval.

### 3. Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law. The law authorizes FDA to collect user fees from applicants for certain premarket reviews (i.e. premarket approval applications, premarket reports, supplements, premarket notifications, biologics license applications and efficacy supplements including those applications received on or after October 1, 2002. FDA could not begin to collect the user fees until enabling appropriations were enacted which occurred on February 20, 2003.

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

- those submitted under section 102 of the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 including:
  - PMAs, PDPs, premarket reports, panel-track supplements, 180-day supplements, and real-time supplements;
  - BLAs and efficacy supplements;
  - 510(k)s

The Act also provides for certain exclusions and waivers of user fees. See the following web site for additional information: [www.fda.gov/cdrh/mdufma/](http://www.fda.gov/cdrh/mdufma/)

An Electronic Medical Device User Fee Cover Sheet is used to submit information regarding medical device applications and supplements subject to user fees. The cover sheet and instructions can be located at <http://www.fda.gov/oc/mdufma/coversheet.html>.

Each fiscal year FDA is required to announce medical device user fee rates. Rates are set for PMAs, PDPs, premarket reports, panel-track supplements, 180-day supplements, and real-time supplements, BLAs and efficacy supplements, and 510(k)s. The fees are announced in the Federal Register 60 days before the start of the fiscal year. The current medical device user fee rates are posted at [www.fda.gov/cdrh/mdufma](http://www.fda.gov/cdrh/mdufma).

**4. Policy**

Each application and supplement should be accompanied by the Medical Device User Fee Cover Sheet which electronically generates a payment identification number. The user fee must be paid to FDA through the U.S. Bank and will not be considered paid until receipt of payment has been verified by OFM. In no case should payment be submitted with the premarket application. The review clock does not start until verification of payment.

**5. Responsibilities**

Person or Area	Responsibility
<b>OC Office of the Commissioner</b>	<ul style="list-style-type: none"> <li>○ annually establishes MDUFMA user fee rates and publishes them in the Federal Register</li> </ul>
<b>OFM Office of Financial Management</b>	<ul style="list-style-type: none"> <li>○ receives notice of MDUFMA payments from US Bank</li> <li>○ sends daily notification of MDUFMA Payment Report to RIMS</li> <li>○ sends daily MDUFMA Fee Discrepancy Report to RIMS</li> <li>○ sends daily MDUFMA Arrears Report to RIMS</li> <li>○ sends weekly MDUFMA Bill Payment Report to RIMS</li> </ul>
<b>RIMS Regulatory Information Management Staff in CBER's Office of Management</b>	<ul style="list-style-type: none"> <li>○ posts current user fee rates in CBER Outlook public folder</li> <li>○ posts current MDUFMA Arrears Report in CBER Outlook public folder</li> <li>○ reviews MDUFMA Fee Discrepancy Report, MDUFMA Payment, MDUFMA Arrears, and MDUFMA Bill Payment reports received from OFM and MDUFMA BLT Submissions Complete List that do not have Full Payments Report received from IMC and verifies proper payment for submissions</li> <li>○ forwards notification of CBER payment checks received to designated contacts - official payment date for resetting action due dates is on the report</li> <li>○ reviews faxed copy of Medical Device User Fee Cover Sheet from RPM and verifies the reduction in fees claim from an applicant</li> </ul>

	<ul style="list-style-type: none"> <li>○ notifies applicant of payment discrepancies and follows through to resolution; coordinates with RPM as appropriate</li> <li>○ within 1 day, confirms automated system update and notifies office designated contact and RPM of payment by applicant when firm on MDUFMA Fee Discrepancy Report submits payment</li> <li>○ monitors status of all applications and supplements that have been designated as incomplete and unacceptable for filing</li> <li>○ ensures review clocks are reset in BLT and RMS-BLA after receipt of payment</li> <li>○ serves as primary point of contact for questions or challenges regarding user fee assessments</li> </ul>
<b>Designated review office contacts (usually RIS/RHIS)</b>	<ul style="list-style-type: none"> <li>○ forwards notification from RIMS to appropriate RPM of MDUFMA user fee payment checks received</li> <li>○ ensures correct user fee flags have been selected in BLT as part of QC</li> </ul>
<b>RPM Regulatory Project Manager(s) in the review office (or office designee)</b>	<ul style="list-style-type: none"> <li>○ receives device submission and determines type of application</li> <li>○ ensures user fee flags have been selected in BLT and RMS-BLA</li> <li>○ checks Medical Device User Fee Cover Sheet for accuracy and completeness; if missing, inaccurate or incomplete, RPM will contact applicant to resolve· faxes cover sheet to RIMS, 7-2875, <ul style="list-style-type: none"> <li>● if any discrepancy in the cover sheet or in payment is not resolved by contacting the applicant</li> <li>● if applicant has claimed a small business reduction in fees, or any fee exception or waiver</li> <li>● the submission is for a licensed product</li> </ul> </li> <li>○ ensures payment is received from applicant for submission before reviewing</li> <li>○ notifies applicant by faxing Incomplete; Unacceptable for Filing letter that payment has not been received for application and review will be put on hold. Issue fax/letter no later than 2 working days</li> <li>○ notifies review committee when application is incomplete and unacceptable for filing that review will not begin. The designated review office will attach an orange cover sheet to alert reviewers that company should not be contacted under any circumstances and review should not be initiated until further notice from the RPM that payment has been received and review can begin.</li> <li>○ ensures communication for Incomplete;Unacceptable for Filing letter is entered in BLT database if submission is a premarket review. If submission is a licensing application or an efficacy supplement, the RPM will enter an Unacceptable for Filing letter into the RMS-BLA database.</li> <li>○ ensures that clock is automatically stopped upon issuance of an Unacceptable for Filing letter for a licensing application or efficacy supplement or issuance of an Incomplete;Unacceptable for Filing letter for a premarket review.</li> <li>○ when notified by RIMS that the applicant is up-to-date on payments <ul style="list-style-type: none"> <li>● activates review</li> <li>● generates an Acknowledgement letter and ensures Consumer Safety Technician (CST) faxes to company</li> </ul> </li> <li>○ ensures review clocks are reset after receipt of payment. BLT automatically resets clock upon payment. RPM will have to contact SRA</li> </ul>

International (SRA), the contractor supporting RMS-BLA, to manually change review clock in RMS-BLA.

## 6. Procedures

### Routine Processing

1. Each application and supplement requiring a fee under MDUFMA, must be assigned a unique payment identification number (PIN). The PIN is automatically generated after an applicant completes and prints the Medical Device User Fee Cover Sheet found at <http://www.fda.gov/oc/mdufma/coversheet.html>.
2. A check, bank draft, or U.S. postal money order along with a copy of the completed cover sheet should be sent to the FDA through the U.S. Bank. The PIN must be written on the check.
3. Each application and supplement (volume 1) requiring a fee under MDUFMA should be accompanied by the Medical Device User Fee Cover Sheet. The Medical Device User Fee Cover Sheet will be forwarded by the Document Control Center (DCC) with the application to the appropriate review division.

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

4. The RPM will review the Medical Device User Fee Cover Sheet and verify that any exclusions checked on the cover sheet are accurate (e.g., first PMA submitted by a qualified small business, pediatric supplement only, for further manufacturing use only, state or federal government entity) (See Section 5, Medical Device User Fee Cover Sheet for the complete list of exclusions).
5. The RPM will fax a copy of the Medical Device User Fee Cover Sheet to RIMS (all small business claims, exemptions, unresolved discrepancies or cover sheets for a licensed product only) at 301-827-2875.
6. For BLAs and BLA efficacy supplements, a Submission Tracking Number (STN) will be assigned to the application following division standard operating procedures. For PMAs, PMRs, PDPs, panel-track supplements, 180-day supplements, and real-time supplements, a submission identification number will be assigned following division standard operating procedures
7. At the time of STN or Submission Identification Number assignment, as part of the initial administrative regulatory review, the RPM will compare the Medical Device User Fee Cover Sheet with the submission to determine if the application is subject to user fees.
  - a. If the submission is NOT subject to fees, the RPM would follow standard office procedures to assign STN or submission identification number and continue the review process.
  - b. If the submission is subject to fees, the RPM will confirm as necessary with RIMS that payment has been received for the submission. Review of the submission should begin only if full payment has been received. 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.
  - c. If the submission is subject to fees and the applicant has not paid the user fees, go to Failure to Submit Payment section below.

### Submissions Received Without a Medical Device User Fee Cover Sheet or With an Incomplete Sheet

1. If an application or supplement is received without an accompanying Medical Device User Fee Cover Sheet, the RPM will contact the applicant by telephone and ask the status of cover sheet and payment. If the cover sheet was just omitted but payment was made, the RPM will request immediate completion of the form from the internet and then request a faxed copy. If the applicant failed to pay, the RPM will issue an Incomplete; Not Acceptable for Filing letter and notify the applicant that the submission is on hold and payment must be received within 30 days or FDA will 'close out' the application.
2. 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.
3. An application or supplement should not be reviewed or proceed to a filing action until the information and payment is obtained. If not received within 30 days, RPM will issue another letter informing the applicant that the application was 'closed out' and they cannot market.

### **Failure to Submit Payment**

1. If no payment is received, the RPM (or office designee) will:
  - a. notify the review committee that review is on hold and the applicant should not be contacted about the submission under any circumstances (the designated review office will attach an orange cover sheet to the submission)
  - b. notify the applicant by telephone that the application is incomplete and unacceptable for filing
  - c. prepare a notification letter using the CBER Incomplete; Unacceptable for Filing letter template
  - d. when the RPM creates a submission identification number for premarket reviews that doesn't have a PIN, a communication automatically gets entered into BLT for payment not received. This entry changes the status of the submission to clock stopped/awaiting response. When the RPM creates a user fee STN for licensing applications or efficacy supplements which is not accompanied by a Medical Device User Fee Cover Sheet, the RPM will issue an Unacceptable for Filing letter (review clock should not have started) but will have to contact SRA to manually stop the review clock in RMS-BLA as of the receipt date (this is because RMS-BLA currently uses PDUFA schedules). When payment is received for licensed applications or efficacy supplements, the RPM will again notify SRA to start the clock using the payment receipt date.
  - e. if payment is not received within 30 days, RPM will issue another letter informing the applicant that the application was 'closed out' and they cannot market.
2. When RIMS notifies the review office (RPM or designee) that fees owed have been paid, the review will begin. The RPM will:
  - a. notify the committee that the review process may begin
  - b. instruct DCC to forward the submission to the committee
  - c. prepare and fax to the applicant an Acknowledgement letter using CBER Acknowledgement letter template ensure that the user fee action due dates are reset; BLT system automatically generates correspondence for premarket reviews with a purpose of Full Payment Received which restarts the clock. BLT automatically calculates the new action due dates based on the received payment date. SRA should be contacted to manually reset the clock for licensing applications or efficacy supplements in RMS-BLA.

### **7. Effective Date**

January 12, 2005

### **8. Appendix**

Appendix 1 - [Medical Device User Fee Cover Sheet \(PDF\)](#)

## 9. History

<b>Comment / Revision</b>	<b>Approved By</b>	<b>Approval Date</b>	<b>Version Number</b>	<b>Comment</b>
Daria Reed	Robert A. Yetter	1/12/2005	1	Original version; Written jointly with RMCC Device Review Subcommittee

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