SOPP 8704: Managing MDUFA User Fee Payments and Billing Activities

Version: 4

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I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff to determine the accuracy of information submitted by an applicant relative to user fees for medical devices and to verify that payment owed has been received under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended most recently by the Food and Drug Administration (FDA) Reauthorization Act of 2017, which reauthorized the Medical Device User Fee Amendments (MDUFA).

II. Scope

A. This SOPP describes the responsibilities and procedures related to billing applicants for user fees for medical devices, including billing for establishments.

B. This document identifies other user fee activities for which the Office of the Director's Regulatory Information Management Staff (RIMS) is responsible.

III. Background

A. The Medical Device User Fee and Modernization Act (MDUFMA) was enacted in 2002 and renewed in 2007 (MDUFMA II), 2012 (MDUFA III) and 2017 (MDUFA IV). It authorizes FDA to collect user fees from applicants for certain medical device submissions.

B. Medical device submissions covered by user fees are those submitted under section 102 of the FD&C Act, as amended by the Medical Device User Fee Amendments of 2017 and include:

- Premarket Approval Applications (PMAs), including Product Development Protocols (PDPs), premarket reports (PMRs), panel-track supplements, 180-day supplements, real-time supplements, 30-day notices, and PMA annual reports (ARs);
- Device BLAs (original) and efficacy supplements (BLSs)
- De Novo Requests
- 510(k)s
- 513(g)s
- Establishment Registrations

C. The FD&C Act also provides for certain exclusions and waivers of user fees. See reference section for additional information.

D. An Electronic *Medical Device User Fee Cover Sheet* is used to submit information on user fees owed or not owed with all medical device submissions. It is not used for medical device establishment user fees or PMA annual reports. A Web link to the cover sheet can be located in the reference section.

E. Each fiscal year FDA is required to promulgate current medical device user fee rates for the coming fiscal year. Rates are set for PMAs, PDPs, premarket reports, PMA annual reports, panel-track supplements, 180-day supplements, 30-day notices, real-time supplements, device BLAs and efficacy BLSs, De Novo Requests, 513(g)s, 510(k)s and establishment registration fees. The fees are published in the Federal Register 60 days before the start of the fiscal year. A link to the current medical device user fee rates can be located in the reference section.

IV. Definitions

A. Applicant - For purposes of this SOPP, the term "applicant" includes sponsors, submitters, requestors, applicants, manufacturers, etc. Any person who submits or plans to send an application to FDA for premarket review.

B. Blood Establishment Registration (BER) - The CBER registration database used to track blood establishments, including those that manufacture in vitro diagnostics devices (IVDs) that are licensed under section 351 of the Public Health Service Act.

C. Biologics License Application (BLA) - An application for licensure of a biological product submitted under section 351 of the Public Health Service Act.

D. Blood Logging and Tracking (BLT) - A CBER system that tracks and supports managed review processes associated with medical device submissions [premarket approval applications (PMA) including humanitarian device exemptions (HDEs), PMA/HDE modules, premarket reports (PMR), supplements, annual reports, product development protocols (PDP), 513(g)s, De Novo Requests, Q-submissions (Q-subs) and associated amendments].

E. De Novo Classification - A pathway to Class I or Class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. Note: The submission is referred to as a De Novo Request.

F. Device Submission (Submission) - Any correspondence that includes information and/or data relevant to the review of a medical device; including but not limited to premarket approval applications (PMA) including

humanitarian device exemptions (HDEs), PMA/HDE modules, premarket reports (PMR), supplements, annual reports, product development protocols (PDP), premarket notification submissions (510(k)s), 513(g)s, De Novo Requests, Q-submissions (Q-subs) and associated amendments to a pending file, etc.

G. **Device Submission Tracking (DST) System –** A CBER system that tracks and supports managed review processes associated with medical device submissions [premarket notification submissions (510(k)s and associated amendments].

H. **Efficacy supplement -** a supplement to an approved premarket application (i.e., BLA) under section 351 of the Public Health Service Act that requires substantive clinical data.

I. **Establishment Registration Fee -** A fee due to FDA once each fiscal year either upon the initial registration of the establishment or upon the annual registration under section 510 of the Food, Drug, and Cosmetic Act.

J. **FDA's Unified Registration and Listing System (FURLS) -** The Agency database used to track electronic device establishment registrations and listings (other than those registered in BER).

K. **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 annually according to the type of submission.

L. **Incomplete and unacceptable for filing -** If a fee is not paid, the fee liable device submission shall be considered incomplete and shall not be accepted for acceptance review or filing until the fee is paid in full. The 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.

M. **MDUFA Unpaid Cover Sheet Report -** A daily report from the FDA's Office of Financial Management (OFM) sent via e-mail to the Center for Devices and Radiological Health (CDRH), Center for Biologics Evaluation and Review (CBER) Office of the Director (OD), and RIMS which shows CBER and CDRH regulated applicants that have submitted MDUFA cover sheets but have not submitted the payment.

N. **MDUFA Payment Report -** A daily report from OFM sent via e-mail to CDRH, CBER/OD, RIMS, CBER/Office of Blood Research and Review (OBRR), and CBER/Office of Tissues and Advanced Therapies (OTAT) which shows payment made by applicants for incoming CBER submissions.

O. **Panel-track supplement -** A supplement to an approved premarket approval application or premarket report under section 515 of the FD&C Act 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. A panel track supplement may be filed to an existing PMA, PMR, or PDP.

P. Payment Identification Number (PIN) - A unique payment identification number (PIN) that is assigned to each submission for which a fee is required under MDUFA. Note: The PIN is automatically generated after an applicant completes and prints the *Medical Device User Fee Cover* Sheet.

Q. Premarket Approval Application (PMA) - Any premarket approval application for a class III medical device, including all information submitted with or incorporated by reference therein (21 CFR 814.3(e)).

R. Premarket Approval Application (PMA) Annual Report - A post approval report which summarizes information pertaining to the original PMA and any subsequent PMA supplements. Annual reports are required to be submitted at intervals of 1 year from the date of approval of the original PMA.

S. Premarket notification - A submission that is formatted consistent with 21 CFR 807.87 and submitted under Section 510(k) of the FD&C Act by a device manufacturer or his/her agent to FDA at least ninety days before introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use. Also known as a "510(k) submission."

T. Premarket reports (PMRs) - A premarket application for a reprocessed single-use device.

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

V. Real-time supplement - A supplement to an approved PMA, PMR, or PDP under section 515 of the FD&C Act that requests a minor change to a medical device. Example: 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.

W. Regulatory Management System/Biologics License Application (RMS-BLA) - The CBER database used to track Biologics License Applications and related submissions, including licensed IVD device applications and efficacy supplements.

X. Submission - For the purpose of this SOPP, in order to be concise the term "submission" will be used for any user fee liable application, supplement, report, request or submission.

Y. 180-day supplement - A supplement to an approved premarket approval application or premarket report under section 515 of the FD&C Act 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.

Z. 510(k) - A submission made to the FDA prior to marketing a medical device to demonstrate that the device to be marketed is at least as safe and effective (that is, substantially equivalent (SE)) to a legally marketed device that is not subject to premarket approval. See also the Premarket Notification definition.

AA. 30-day notice - A supplement to an approved premarket approval application or premarket report under section 515 of the FD&C Act that involves modifications to manufacturing procedures or method of manufacture affecting the safety and effectiveness of the device. Note: If the 30-day notice is not adequate, but contains data that meets appropriate content requirements for a PMA supplement, then the 30-day notice will become a 135-day supplement.

BB. 513(g) - A request for information regarding the class in which a medical device has been classified or the requirements applicable to a device under the FD&C Act.

V. Policy

A. Submissions:

1. Each submission, except PMA annual reports, should be accompanied by the *Medical Device User Fee Cover Sheet, Form FDA 3601.* The cover sheet is created on-line by the applicant; the payment identification number (PIN) is electronically generated. A completed cover sheet should be electronically transferred by the applicant to OFM ***before*** payment is sent.

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. Applicants also have the option to make online electronic payments via Automated Clearing House (ACH) which is an electronic debit from a checking or savings account. Applicants may register for electronic payments through Pay.gov.

3. 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.

4. Volume 1 of each submission requiring a fee under MDUFA, except PMA annual reports, should be accompanied by the *Medical Device User Fee Cover Sheet.*

5. **In no case should payment be submitted with the premarket submission.**

6. **The review clock does not start until verification of payment is received and all other regulatory requirements have been met**

B. Establishments:

1. Each owner or operator of an establishment engaged in the manufacture, preparation, propagation, compounding, assembly or processing of a device intended for human use must register and submit listing information to FDA for those devices in commercial distribution annually.

2. Medical device establishments that register must pay an establishment registration fee. A unique payment identification number (PIN) will be assigned when registering electronically through FDA's Unified Registration and Listing System (FURLS). FURLS will generate an establishment registration invoice that should be printed. See reference section for a link to the registration websites.

3. Registrations are required to be submitted electronically unless FDA grants a waiver.

4. The registration fee must be paid before submitting the establishment registration electronically. A payment identification number (PIN) and a payment confirmation number (PCN) will be received for payment and are required before proceeding with the registration.

    a. A check or wire transfer, along with a copy of the invoice should be sent to the FDA at P.O. Box 979108, St. Louis, MO. This is a different address than the payment of submission and annual report fees.

    b. If check is sent by a courier to a street address, the address is U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. The PIN must be written on the check.

    c. Applicants also have the option to make online electronic payments via Automated Clearing House (ACH) which is an electronic debit from a checking or savings account. Applicants may register for electronic payments through Pay.gov.

5. Manufacturers of CBER licensed IVD devices are required to register electronically through the BER system. BER does not create payment cover sheets with unique identifiers; therefore, RIMS will send annual invoices to licensed IVD device establishments after the December registration due date.

C. PMA Annual Reports

1. Invoices for PMA annual reports are sent at the end of each quarter in which the PMA annual report is due. Payment details are included on the invoice.

VI. Responsibilities

A. FDA/Office of the Commissioner (OC)

1. Annually establishes MDUFA user fee rates and publishes them in the Federal Register

B. FDA/Office of Financial Management (OFM)

1. Receives notice of MDUFA payments from the U.S. Bank
2. Sends daily notification of MDUFA Payment Report to RIMS
3. Sends daily notification of MDUFA Unpaid Coversheet Report to RIMS
4. Generates device establishment user fee invoices for CBER license device establishments

C. CBER's Regulatory Information Management Staff (RIMS)

1. Posts current user fee rates in CBER Outlook public folder
2. Checks *Medical Device User Fee Cover Sheet* for accuracy and completeness upon characterization of submission in the regulatory system
3. Reviews CBER payment check receipt reports received from OFM and verifies proper payment for submissions
4. Coordinates with appropriate Regulatory Project Manager (RPM) to resolve payment discrepancies
5. Confirms automated system update and notifies office designated contact and RPM of payment by applicant when the firm listed on MDUFA Unpaid Cover Sheet Report submits payment
6. Monitors status of all submissions that have been designated as incomplete and unacceptable for filing or placed on user fee hold
7. Updates user fee payment information if necessary
8. Sends invoices for PMA annual reports and licensed device establishment registration user fees
9. Serves as primary point of contact for questions or challenges regarding user fee assessments

D. Other User Fee Activities for which RIMS alone is responsible (procedures are not included in this SOPP)

1. Bills licensed device establishments for annual registration fee

2. Sends invoices for PMA annual reports

3. Responds to waiver and refund requests for licensed devices

4. Responds to inquiries from the review offices and the public on user fee issues

5. Produces reports on user fee receipts and performance

E. RPM - Regulatory Project Manager(s) in the review office (or office designee) Note: RPM role also includes the office designee in the Office of the Director (OD) who handles 513(g) requests.

1. Receives medical device submission and determines type of application/submission

2. Checks *Medical Device User Fee Cover Sheet* for accuracy and completeness; if missing, inaccurate or incomplete, RPM will coordinate with RIMS, as appropriate, and contact applicant to resolve

3. Provides RIMS access to electronic cover sheet if:

    a. There is any discrepancy in the cover sheet or payment that was not resolved by contacting the applicant

    b. The submission is for a licensed product.

4. Ensures payment is received from applicant for submission before the review begins

5. Notifies applicant of payment discrepancies and follows through to resolution; coordinates with RIMS as appropriate

6. Notifies applicant by generating an *Incomplete; Unacceptable for Filing* letter for BLAs or a *User Fee Hold* letter for PMAs, 510(k)s, 513(g)s and De Novo Requests alerting the applicant that payment has not been received for the submission and the review will be put on hold

7. Notifies Review Committee when submission is incomplete and unacceptable for filing or on a user fee hold that review will not begin

    a. The designated review office will alert reviewers that the applicant 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

8. Ensures communication for:

a. *User Fee Hold* letter is entered in BLT/DST database if submission is for a non-licensed device, e.g., PMA, PMR, PDP, 510(k), 513(g), De Novo Request

b. *Unacceptable for Filing* letter is entered into RMS-BLA if the submission is a BLA or an efficacy BLS

9. Ensures that the review clock is automatically stopped upon issuance of a/an:

a. *User Fee Hold* letter for a non-licensed device, e.g., PMA, PMR, PDP, 510(k), 513(g), De Novo Request

b. *Unacceptable for Filing* letter for a BLA or an efficacy BLS

10. When notified by RIMS that the applicant is up-to-date on payments

a. Activates acceptance review if the submission is a 510(k), De Novo Request, or PMA

b. Activates review and generates an Acknowledgement letter using the most recent approved letter template on CBER's Intranet and either faxes the letter to the applicant or ensures Regulatory Information Specialist (RIS) or Consumer Safety Technician (CST) faxes the letter to the applicant, if the submission is a BLA or Efficacy BLS

11. Ensures review clocks are reset after receipt of the *Medical Device User Fee Cover Sheet* and verification of the payment.

a. BLT/DST automatically resets clock upon payment.

b. RPM will notify RIMS to manually change review clock in RMS-BLA.

12. Ensures that device facility information is correctly entered into RMS-BLA for licensed IVD devices.

F. Blood Establishment Registration Coordinator

1. Ensures that information on registration and product listing is entered properly and accurately

VII. Procedures

A. Routine Processing of Submission Cover Sheets

1. Process incoming submissions **[CBER Document Control Center (DCC)]**.

a. Forward the *Medical Device User Fee Cover Sheet* to the appropriate review office.

b. Retain the original *Medical Device User Fee Cover Sheet* with the original copy of the submission

2. 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). **[RIMS/RPM]**

3. Assign a Submission Tracking Number (STN) to the submission. **[RIMS/RPM/CST]**

4. Compare the *Medical Device User Fee Cover Sheet* with the submission to determine if the submission is subject to user fees. **[RIMS/RPM]**

a. If the submission is NOT subject to fees follow standard procedures to assign an STN and continue the review process. **[RIMS]**

b. If the submission is subject to fees confirm as necessary with RIMS that payment has been received for the submission. **[RPM]**

c. 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, notify the applicant of the correct amount to be submitted or refunded. **[RPM]**

d. If the submission is subject to fees and the applicant has not paid the user fees, go to Failure to Submit Payment section below. [**RIMS/RPM]**

B. Submissions Received Without a *Medical Device User Fee Cover Sheet* or With an Incomplete *Medical Device User Fee Cover Sheet*

1. Notify the RPM that submission was received without a cover sheet. **[RIMS]**

2. Contact the applicant by telephone or email to ask the status of cover sheet and payment. **[RPM]**

a. If the cover sheet was just omitted but payment was made, request immediate completion of the form from the Internet and then request an email copy.

b. If the applicant failed to pay, issue *Incomplete; Unacceptable for Filing* letter for BLAs and efficacy BLS or a *User Fee Hold* letter for PMAs, 510(k)s, 513(g)s, and De Novo Requests and notify the

applicant that the submission is on hold and payment must be received within 180 days or FDA will consider the submission withdrawn.

3. Incomplete or inaccurate forms submitted with a submission:

a. Notify the RPM that submission was received with an incomplete cover sheet. **[RIMS]**

b. Contact the applicant by telephone to obtain the necessary information or relay the inaccuracy. Request that the applicant create a new cover sheet. **[RPM]**

c. Notify RIMS of the new PIN when the new cover sheet is received. **[RPM]**

d. Contact the FDA/OFM to have the funds transferred to the new PIN. **[RIMS]**

Note: A submission should not be reviewed or proceed to an acceptance review or filing action until the information and payment are obtained.

C. Failure to Submit Payment

1. If no payment or partial payment is received:

a. Notify the RPM that submission is received with no payment or partial payment. **[RIMS]**

b. Notify the Review Committee via email that review is on hold and the applicant should not be contacted about the submission under any circumstances. **[RPM]**

c. Notify the applicant by telephone or email that the submission is incomplete and unacceptable for filing. **[RPM]**

d. Prepare a notification letter using the CBER *Incomplete; Unacceptable for Filing* letter template for BLAs and efficacy BLS or a *User Fee Hold* letter template for PMAs, 510(k)s, 513(g)s, and De Novo Requests using the most recent approved letter template on CBER's Intranet or CBER DRS SharePoint site. **[RPM]**

e. When RIMS creates an STN for a non-licensed medical device submission that doesn't have a PIN, a communication (memo) automatically gets entered into BLT for payment not received. This entry changes the status of the submission to clock stopped/awaiting response. **[RIMS]**

f. When the RPM creates a user fee STN for a BLA or efficacy BLS which is not accompanied by a *Medical Device User Fee Cover Sheet*, the RPM will issue an Unacceptable for Filing letter but will have to contact RIMS to manually stop the review clock as of the receipt date (this is because RMS-BLA currently uses PDUFA schedules). When payment is received for BLAs or efficacy BLS, the RPM will again notify RIMS to start the clock using the payment receipt date. **[RPM, RIMS]**

D. Notification that fees owed have been paid

1. Notify the review office that fees owed have been paid. **[RIMS]**

2. Notify the Review Committee that the review process may begin. **[RPM]**

3. Instruct DCC to forward the submission to the Review Committee, as applicable. **[RPM]**

4. Prepare and fax to the applicant an Acknowledgement letter using the most recent approved letter template on CBER's Intranet if the submission is a BLA or Efficacy BLS. **[RPM]**

5. Ensure that the user fee action due dates are reset **[RPM]**

a. BLT system automatically generates correspondence for non-licensed devices, e.g., PMAs, PMRs, PDPs, 510(k)s, 513(g)s, De Novo Requests with a purpose of Full Payment Received which restarts the clock. BLT/DST automatically calculates the new action due dates based on the received payment date.

b. RIMS should be contacted to manually reset the clock for BLAs or efficacy BLS in RMS-BLA.

E. Processing of Device Establishment Registration Payment

1. Request a licensed IVD device establishment report in January from RMS-BLA contractor. **[RIMS]**

2. Generate annual invoices through the OFM billing portal for licensed IVD device establishments after the December registration due date. **[RIMS]**. **NOTE:** OFM sends the generated invoices.

3. Ensure facility and product information is accurately entered into the CBER regulatory databases. **[RPM]**

F. Processing of PMA Annual Report Payment

1. Generate PMA annual report invoices through the OFM billing portal at the end of the quarter in which the PMA annual report is due. **[RIMS]**

2. Send invoices to PMA holders at the end of the quarter in which the PMA annual report is due. **[OFM]**

VIII. Appendix

Not Applicable

IX. References

A. References below can be found on the Internet:

1. Medical Device User Fee Cover Sheet
2. User Fee Rates
3. Blood Establishment Registration
4. Medical Device Registration and Listing
5. MDUFA Establishment Registration User Fee/FURLS Device Facility User Fee (DFUF)

   https://userfees.fda.gov/OA_HTML/furls.jsp
6. User Fee Financial Support Team: userfees@fda.gov

II. History

Comment / Revision	Approved By	Approval Date	Version Number	Comment
Daria Grove	Chris Joneckis	January 28, 2018	4	Updated to include revisions for MDUFA IV
Daria Reed	Robert A. Yetter	October 15, 2012	3	Updated by Kochman, Hamill, Reed
Daria Reed	Robert A. Yetter	May 6, 2010	2	
Daria Reed	Robert A. Yetter	Jan 12, 2005	1	Original version; Written jointly with RMCC Device Review Subcommittee