SOPP 8704: Managing MDUFA User Fee Payments and Billing Activities

Version: 9
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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 2022, 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 Regulatory Operations (ORO), Division of Regulatory Operations and Programs (DROP), Regulatory Programs Branch (RPB) 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), 2017 (MDUFA IV), and 2022 (MDUFA V). 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 2022, 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.

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 is 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 web link to the current medical device user fee rates is 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 system 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. **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.

E. **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.

F. **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.

G. **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.

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

I. **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.

J. **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.

K. **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), CBER's Office of the Director (OD), CBER's ORO, Division of Informatics (DI), Regulatory Information Branch (RIB), and CBER's ORO, Division of Regulatory Operations and Programs (DROP), Regulatory Programs Branch (RPB) which shows CBER and CDRH regulated

applicants that have submitted MDUFA cover sheets but have not submitted the payment.

L. **MDUFA Payment Report -** A daily report from OFM sent via e-mail to CDRH, CBER/OD, CBER/ORO/DROP/RPB, CBER/Office of Blood Research and Review (OBRR), and CBER/Office of Therapeutic Products (OTP) which shows payment made by applicants for incoming CBER submissions.

M. **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.

N. **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.

O. **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)).

P. **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.

Q. **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.”

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

S. **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.

T. **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.

U. 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.

V. 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.

W. 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.

X. 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.

Y. 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; this includes selecting the appropriate Center and the appropriate submission type. Once completed 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. If the applicant does not select the appropriate Center (e.g., CBER), the submission will be placed on user fee hold for them to correct the cover sheet and resubmit to OFM and to CBER.

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 a 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 a 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.**

7. If payment is not received within 180 days of submission, FDA reserves the right to withdraw the application. The applicant will be notified in writing if the application is considered withdrawn by the FDA. Following a withdrawal due to non-payment, a new application must be submitted for FDA review.

B. Refunds

1. Applicants should refer to the User Fees and Refunds guidances listed in the on the Medical Device User Fee Amendments (MDUFA) web page for details on the circumstances that qualify for a refund of user fees that have been paid**.**

2. A refund request should be submitted through the FDA User Fee Programs | FDA. Submit an online form at https:/userfees.fda.gov/fdarefund to request a refund for user fees paid to the FDA as directed by the Food, Drug, and Cosmetic Act (FD&C Act). If assistance is needed in completing the online User Fee Payment Refund Request, e-mail the CBER User Fee Staff for guidance.

C. 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 the Reference section for a link to the registration web sites.

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. Refer to Device Registration and Listing – Payment Process for additional information on how to submit payment.

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, ORO/DROP/RPB will send annual invoices to licensed IVD device establishments after the December registration due date.

D. 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 a U.S. bank.

2. Sends daily notification of MDUFA Payment Report to CBER User Fee Staff.

3. Sends daily notification of MDUFA Unpaid Coversheet Report to CBER User Fee Staff.

4. Generates device establishment user fee invoices for CBER license device establishments.

C. CBER's Office of Regulatory Operations (ORO), Division of Regulatory Operations and Programs (DROP), Regulatory Programs Branch (RPB)

1. Monitors the CBER User Fee Staff email account.

2. Posts current user fee rates in CBER Outlook public folder.

3. Provides guidance to review offices on whether or not a submission is subject to user fees.

4. Reviews the *Medical Device User Fee Cover Sheet* for accuracy and completeness upon characterization of submission in the regulatory system.

5. Reviews CBER payment check receipt reports received from OFM and verifies proper payment for submissions.

6. Verifies that any exclusion checked on the MDUFA User Fee Cover Sheet is accurate. Enters user fee payment data in the regulatory systems based on reconciliation of the subject MDUFA User Fee Cover Sheet with the MDUFA Receipts Report.

7. Coordinates with the appropriate Regulatory Project Manager (RPM) to resolve payment discrepancies.

8. 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.

9. Monitors status of all submissions that have been designated as incomplete and unacceptable for filing or placed on user fee hold.

10. Updates user fee payment information if necessary.

11. Sends invoices for PMA annual reports and licensed device establishment registration user fees.

12. Serves as primary point of contact for questions or challenges regarding user fee assessments.

13. Reviews automated refund requests and verifies whether the submissions are eligible for a refund according to the User Fee guidances.

D. Other User Fee Activities for which ORO/DROP/RPB 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 whether the type of application/submission is subject to user fee.

2. Reviews the *Medical Device User Fee Cover Sheet* for accuracy and completeness; and if it is missing, inaccurate or incomplete, coordinates with CBER User Fee Staff, as appropriate, and contacts applicant to resolve.

3. Provides CBER User Fee Staff 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. Notifies the applicant of payment discrepancies and follows through to resolution, coordinating with CBER User Fee Staff as appropriate.

5. 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.

6. Notifies the review committee when a 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.

7. Ensures communication for:

a. *User Fee Hold* letter is entered in the regulatory system 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 the regulatory system if the submission is a BLA or an efficacy BLS.

8. Ensues 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.

9. When notified by CBER User Fee Staff that the applicant is up to date on payments.

a. Notifies review committee to resume review when payment for the application is received and to perform 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 Review Resources SharePoint Online (SPO) site and emails the letter to the applicant.

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

11. Ensures that device facility information is correctly entered into the regulatory systems 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), Electronic Submission Program Manager (ESPM)]**

2. Assign a Submission Tracking Number (STN) to the submission and alert review office of STN assignment and RPB of incoming submission for user fee check and validation. **[RIB/RPM or designee]**

3. Send an email request to CBER User Fee Staff to begin the payment verification process for received licensed device submissions, e.g., a BLA or a BLA efficacy supplement. **[RPM]**

4. 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). **[RPB/RPM]**

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

a. If the submission is NOT subject to fees, follow standard procedures and continue the review process. **[RPB/RPM]**

b. If the submission is subject to fees, confirm as necessary with CBER User Fee Staff 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. **[RPB/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. **[RPB]**

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 as an amendment to their submission.

i. Notify RIB and CBER User Fee Staff of the new PIN when the new cover sheet is received. **[RPM]**

ii. Contact the FDA/OFM to have the funds transferred to the new PIN. **[RPB]**

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. **[RPM]**

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 with the application:

Note: Payments may take 2 calendar days from the CBER receipt date of the submission to be processed within our systems.

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

i. CBER User Fee Staff investigates the payment issue or verifies no payment, or a partial payment was received.

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 or being placed on hold. **[RPM]**

d. Prepare and issue a 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 Review Resources SPO site. **[RPM]**

e. Ensure that the submission is placed on "user fee hold" in the appropriate regulatory system. **[RIB/RPM]** Note: the review clock will not begin until a response is received with a valid MDUFA User Fee Cover Sheet and full payment.

2. If payment is not received within 180 days, issue an FDA Withdrawal (DELE) letter located on the CBER Review Resources Letter Template SPO site. **[RPM]**

D. Notification that fees owed have been paid

1. Receive the Response to the *Incomplete; Unacceptable for Filing* letter or *User Fee Hold* letter by email from the applicant. **[RPM]**

2. Send the response email to CBER DCC EDR in accordance with DCC Procedure Guide #26. **[RPM]**

3. Receive, process, and load into the CBER Electronic Repository (CER) in accordance with DCC Procedure Guide #22 (CER). **[DCC]**

4. Notify the RPM/RPM Chief/RPB that the amendment is assigned an STN and characterized in the regulatory system. **[RIB]**

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

6. Review the *Medical Device User Fee Cover Sheet* and verify that the fees owed have been paid. **[RPB]**

7. Notify the review office that fees owed have been paid and processed within our systems within 2 calendar days. **[RPB]**

8. Prepare and issue to the applicant an Acknowledgement letter using the most recent approved letter template within CBER Review Resources SPO site. **[RPM]**

9. Ensure that the user fee action due dates are reset within the regulatory systems. **[RIB/RPB/RPM]**

E. Processing of Device Establishment Registration Payment

1. Request a licensed IVD device establishment report in December from RIB. **[RPB]**

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

3. Ensure facility and product information are accurately entered into the CBER regulatory systems. **[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. **[RPB]**

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

G. Processing of MDUFA Automated Refunds

1. Receive refund request from OFM for review and approval. **[RPB]**

2. Ensure the refund request is eligible for a refund according to the User Fee Guidances and confirm the status of the submission is withdrawn and closed within CBER's Regulatory Systems. **[RPB]**

3. Review and approve the applicant's refund request after verification. The refund request gets routed to the Division of User Fee Program (DUF) Approvers within OFM for refund transaction in the User Fee System. **[RPB]**

4. Finalize and approve refund requests by DUF Approvers; refund debit memos are processed and created automatically in the User Fee System. **[OFM]**

VIII. Appendix

Not Applicable

IX. References

A. References below are CBER internal:

1. DCC Procedure Guide #22: Procedure for Processing, Routing, and Storing Electronic Applications
2. DCC Procedure Guide #26: Use of Email for Regulatory Communications

B. 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)
6. FDA User Fee Programs
7. Medical Device User Fee Amendments
8. User Fee Financial Support Team: userfees@fda.gov
9. CBER User Fee Staff: CBERUserFeeStaff@fda.hhs.gov

X. History

Written/Revised	Approved By	Approval Date	Version Number	Comment
Franco Mesarina	Sonday Kelly, MS, RAC, PMP Director, DROP/ORO	March 21, 2024	9	Updated include the CBER MDUFA Automation Refund Process
Ward-Peralta, Russell	Darlene Martin, MS, PMP	January 12, 2023	8	Updated to transfer responsibilities of User Fee verification and billing to CBER/ORO/DROP/RPB staff and minor MDUFA V revisions
Monser	N/A	February 27, 2022	7	Technical Update due to 2022 CBER Reorganization

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Franco Mesarina	Sonday Kelly, MS, RAC, PMP Director, DROP/ORO	March 21, 2024	9	Updated include the CBER MDUFA Automation Refund Process
Monser	N/A	December 11, 2020	6	Technical Update to replace “database” with “system”
Monser	N/A (reviewed by the Job Aid Coordinator)	September 24, 2019	5	Technical revision to correct hyperlinks and minor typos, and to update to current font/format
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