Contains Nonbinding Recommendations

User Fees for 513(g) Requests for Information

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes "User Fees and Refunds for 513(g) Requests for Information" issued on October 2, 2017.

For questions regarding submissions to the Center for Devices and Radiological Health (CDRH), contact the Office of Regulatory Programs / Division of Submission Support / 510(k), De Novo, 513(g), Device Determinations and Custom Devices Lifecycle Team at 301-796-5640, or by email at OPEQSubmissionSupport@fda.hhs.gov.

For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov..

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2010-D-0144. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1709 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Building 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or by e-mail, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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User Fees for 513(g) Requests for Information

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Medical Device User Fee Amendments of 2022[1] (MDUFA V), amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2022,[2] including requests for information under section 513(g) of the FD&C Act ("513(g) request").[3] The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the medical device review process to meet certain performance goals and implement improvements for the medical device review process as outlined in the letter from the Secretary of Health and Human Services to Congress.[4]

The purpose of this guidance document is to assist FDA staff and regulated industry by describing the user fees associated with 513(g) requests.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of

[1] See Title II of the FDA User Fee Reauthorization Act of 2022 (Public Law 117-180).
[2] For additional information on medical device user fees, please see https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.
[3] A "request for classification information" is "a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device." This guidance and other FDA publications use the term "513(g) request" and "Request for Information" as a synonym for this term. FDA's response to a 513(g) request will provide information regarding device classification and/or applicable regulatory requirements.
[4] See 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization). The MDUFA V Commitment Letter is also available at https://www.fda.gov/media/158308/download.

the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Frequently Asked Questions Concerning User Fees for 513(g) Requests

1. Are all 513(g) requests subject to a user fee?

Yes. Section 738(a)(2)(A)(ix) of the FD&C Act requires you to pay a user fee for any 513(g) request that you submit to FDA. Unlike other types of medical device application fees, the law does not provide any exception to the requirement to pay the fee for a 513(g) request.[5] For example, you will have to pay a user fee for your 513(g) request even if your submission is for a device intended solely for a pediatric population or you are a State or Federal Government entity, because neither the exception in section 738(a)(2)(B)(v)(I) of the FD&C Act nor the one in section 738(a)(2)(B)(iii) extends to requests for classification information.

FDA will not accept your 513(g) request for review until you have paid all fees owed.[6] FDA's review of your 513(g) request will begin on the date that all owed fees have been received.

2. What are the 513(g) user fees?

User fees for the current fiscal year are established under section 738 of the FD&C Act and shown on the FDA MDUFA User Fees website at https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

3. How do I pay my user fee(s)?

As outlined below, there are three ways you may submit your user fee.[7] Be sure to include the Payment Identification Number (PIN, beginning with MD) and the FDA P.O. Box on your check, bank draft, or U.S. Postal Money Order. A PIN is obtained after creating a User Fee Cover Sheet and selecting "Submit Cover Sheet to FDA." Also, you should include a copy of your User Fee Cover Sheet (Form FDA-3601, accessible through FDA's User Fee System at https://userfees.fda.gov/OA_HTML/fdaCAcdLogin.jsp) with your payment.

1) Preferred method: Credit Card or Electronic Check (ACH): FDA has partnered with the U.S. Department of the Treasury to utilize https://www.pay.gov/, a Web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. To pay online, select the "Pay Now" button. Credit card transactions for cover sheets are limited to $24,999.99.

[5] Section 738(a)(2)(B) of the FD&C Act provides certain exceptions to medical device user fees. However, none of these apply to 513(g) requests.
[6] See section 738(f) of the FD&C Act.
[7] Additional information regarding payment of user fees is available at https://userfees.fda.gov/OA_HTML/mdufmaFAQ.html.

2) Check: All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Please write your unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover sheet, on the check and mail the check to the appropriate address listed below. FDA will not be able to process your payment correctly without your cover sheet PIN.

   Check payments by mail:
   Food and Drug Administration
   P.O. Box 979033
   St. Louis, MO 63197-9000
   Note: In no case should payment be submitted with the application.

   Check payments delivered by a courier service:
   U.S. Bank
   ATTN: Government Lockbox 979033
   1005 Convention Plaza
   St. Louis, MO 63101
   Note: This address is for courier delivery only. If a phone number is also required for courier delivery, use (314) 418-4013.

3) Wire Transfer: Please include your 513(g) request's unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover sheet, in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your 513(g) request will be delayed.

   The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your cover sheet is fully paid.

   Wire Transfer information:
   US Department of Treasury
   TREAS NYC
   33 Liberty Street
   New York, NY 10045

   FDA Deposit Account Number: 75060099
   US Department of Treasury routing/transit number: 021030004
   SWIFT Number: FRNYUS33

4. Will FDA refund my user fee payment if you determine that my submission is not a 513(g) Request for Information?

Yes. Section 513(g) of the FD&C Act governs requests "for information respecting the class in which a device has been classified or the requirements applicable to a device under [the] Act." Submissions that do not request such information are outside the scope of section 513(g) and do not require a response from FDA. If FDA determines that a submission is not a 513(g) Request for Information and therefore cannot be reviewed, FDA intends to refund the user fee.

5. Are there other circumstances under which FDA will refund my user fee payment for a 513(g) Request for Information?

No. When a 513(g) request is submitted to FDA for review and the user fee is paid, the request will undergo review and FDA will not refund your user fee payment, regardless of the decision.

6. Do I have to pay a new user fee if I submit a 510(k), De Novo Request, or Premarket Approval Application (PMA) for my device following my 513(g) Request for Information?

Yes. You must pay any applicable fee for any new submission type following your 513(g) request.[8]

7. After I submit a 513(g) Request for Information, can I subsequently add a new question, use, or technology without submitting a new user fee?

No. Once FDA has received your 513(g) Request for Information and user fee, you may not modify that 513(g) request by subsequently adding a new question, use, or technology. We consider the addition of a new question, use, or technology to be a new 513(g) request subject to an additional user fee, to which we intend to respond separately.

8. Will FDA refund my user fee payment if I withdraw my 513(g) request?

No. When a 513(g) request is submitted to FDA for review and the user fee is paid, the request will undergo review and FDA will not refund your user fee payment.

9. If FDA requests additional information about my product, must I submit a new user fee with such information?

No. Information submitted in response to direct FDA requests for additional information does not require an additional user fee payment.

10. Is the completion of a medical device user fee cover sheet required?

Yes. You must complete and submit FDA Form 3601, Medical Device User Fee Cover Sheet, along with your request for information on classification. FDA Form 3601 is designed to provide the minimum necessary information to determine whether a fee is required for review of an application submission, to determine the amount of the fee required, and to help FDA track payments. The form may be found at https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-cover-sheets.

[8] See section 738(a) of the FD&C Act.