Contains Nonbinding Recommendations

User Fees for 513(g) Requests for Information

Guidance for Industry and Food and Drug Administration Staff

Document issued on October 2, 2017.

Document originally issued on April 6, 2012.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0705 (expires 5/31/2018).

See additional PRA statement in Section III of this guidance.

For questions for the Center for Devices and Radiological Health regarding this document contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document contact the Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-8010.

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

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. 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 to identify the guidance you are requesting.

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, 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/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Table of Contents

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 2017[1] (MDUFA IV), 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, 2017, including 513(g) requests for information. 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.[2]

Medical device user fees were initially authorized by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).[3] Since MDUFMA was first enacted in 2002, it has been reauthorized three times (the Medical Device User Fee Amendments of 2007 (MDUFA II),[4] the Medical Device User Fee Amendments of 2012 (MDUFA III),[5] and the Medical Device User Fee Amendments of 2017 (MDUFA IV)[6]). For additional information on medical device user fees, please see https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/default.htm.

The Medical Device User Fee Amendments of 2007[7] extends FDA's authority to collect medical

[1] See Title II of the FDA Reauthorization Act of 2017 (Public Law 115-52).
[2] See 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf.
[3] See the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250).
[4] See Title II of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85).
[5] See Title II of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144).
[6] See Title II of the FDA Reauthorization Act of 2017 (Public Law 115-52).
[7] See Title II of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85).

device user fees by establishing a fee for "a request for classification information." 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."[8] 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.

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

FDA's guidance documents, including this guidance document, 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 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 (21 U.S.C. 379j(a)(2)(A)(ix)) 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.[9] 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[10] or you are a State or Federal Government entity,[11] because neither the exception in section 738(a)(2)(B)(v) of the FD&C Act (21 U.S.C. 379j(a)(2)(B)(v)) nor the one in section 738(a)(2)(B)(iii) (21 U.S.C. 379j(a)(2)(B)(iii)) is specific to requests for classification information.

FDA will not accept your 513(g) for review until you have paid all fees owed, including all required establishment registration fees.[12] FDA's review of your 513(g) Request for Information will begin the date that all owed fees have been received.

2. 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 (21 U.S.C. 360c(g)) governs requests "for information respecting the class in which a device has been classified or the requirements applicable to a device

[8] Section 737(6) of the FD&C Act (21 U.S.C. 379i(6)).
[9] Section 738(a)(2)(B) of the FD&C Act (21 U.S.C. 379j(a)(2)(B)) provides certain exceptions to medical device user fees. However, none of these apply to 513(g) requests.
[10] See section 738(a)(2)(B)(v)(I) of the FD&C Act (21 U.S.C. 379j(a)(2)(B)(v)(I)).
[11] See section 738(a)(2)(B)(iii) of the FD&C Act (21 U.S.C. 389j(a)(2)(B)(iii).
[12] See section 738(g) of the FD&C Act (21 U.S.C. 379j(g)).

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, FDA intends to refund the user fee.

3. Will FDA refund my user fee payment if my product does not appear to be a medical device?

No. The FD&C Act does not contain any provision with respect to refunding fees for 513(g) requests.[13]

4. Will FDA refund my user fee payment if my device appears to be exempt from 510(k) premarket notification?

No. The FD&C Act does not contain any provision with respect to refunding fees for 513(g) requests.[13]

5. 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.[14]

6. 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 would consider the addition of a new question, use, or technology to a pending 513(g) Request for Information to be a new 513(g) request subject to an additional user fee, to which we intend to respond separately.

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

No. The FD&C Act does not provide FDA authority to refund a user fee payment after you have submitted a 513(g) request and have paid the full fee.

8. 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.

---

[13] See section 738(a)(2)(D) of the FD&C Act (21 U.S.C. 379j(a)(2)(D)).
[14] See section 738(a) of the FD&C Act (21 U.S.C. 379j(a)).

9. 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/forindustry/userfees/medicaldeviceuserfee/ucm452525.htm.

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

User fees for the current fiscal year are shown on the FDA MDUFA User Fees website at https://www.fda.gov/forindustry/userfees/medicaldeviceuserfee/ucm452519.htm.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The time required to complete this information collection is estimated to average 12 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff
Office of Operations
Food and Drug Administration
PRAStaff@fda.hhs.gov

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 807 subpart E have been approved under OMB control number 0910-0120 and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0705 (expires 5/31/2018).