Contains Nonbinding Recommendations
Draft - Not for Implementation

Draft Guidance for Industry and FDA Staff

User Fees for 513(g) Requests for Classification Information

DRAFT GUIDANCE

This guidance document is for comment purposes only.
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Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding 513(g) submissions to the Center for Devices and Radiological Health, contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions regarding 513(g) submissions to the Center for Biologics Evaluation and Research, contact the Office of Communication, Outreach and Development at 1-800-835-4709 or 301-827-1800.

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

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1709 to identify the guidance you are requesting. Copies of the guidance are also available from:

Office of Communication, Outreach and Development, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448
Phone: 800-835-4709 or 301-827-1800

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA), also termed the Medical Device User Fee Amendments of 2007, P.L. 110-85, extends FDA's authority to collect medical device user fees[1] 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."[2] 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 additional funds obtained from user fees will enable FDA to improve the device review process in order to

[1] Medical device user fees were first authorized by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107-250. MDUFMA amended the Federal Food, Drug, and Cosmetic Act (the Act) to authorize FDA to collect user fees for the review of certain premarket submissions. Title II of FDAAA extends FDA's authority to collect medical device user fees through September 30, 2012, and adds new types of fees to section 738 of the Act (21 U.S.C. 379j). For additional information on medical device user fees, see: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm

[2] Section 737(6) of the Act (21 U.S.C. 379i(6)).

meet performance goals identified in letters from the Secretary of Health and Human Services to Congress.[3] 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, 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.

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 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.[4] 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[5] or you are a State or Federal Government entity.[6]

FDA may not accept your 513(g) for review until you have paid all fees owed, including all required establishment registration fees. See section 738(f)(1) of the Act (21 U.S.C. 379j(f)(1)). When FDA has received all fees owed, our review of your 513(g) Request for Information will begin as of that date.

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

Yes. Section 513(g) of the 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 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 return the user fee.

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[3] The commitment letter outlining the goals for FY 2008 – FY 2012 is available at www.fda.gov/cdrh/mdufma/commitmentletter.pdf.

[4] Section 738(a)(2)(B) of the Act provides certain exceptions to medical device user fees. However, none of these apply to 513(g) requests.

[5] See section 738(a)(1)(B)(v)(I) of the Act.

[6] See section 738(a)(1)(B)(iii) of the Act.

3. Will FDA refund my fee payment if the agency determines that my product does not appear to be a medical device?

No. The Act does not does not contain any provision with respect to refunding fees for 513(g) requests. See section 738(a)(2)(D) of the Act.

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

No. The Act does not contain any provision with respect to refunding fees for 513(g) requests. See section 738(a)(2)(D) of the Act.

5. Do I have to pay a new user fee if I submit a 510(k) or premarket approval application (PMA) for my device following my 513(g) request?

Yes. You must pay any applicable fee for any new submission following your 513(g) request; you do not receive a "credit" for the fee paid for your 513(g) request. See section 738(a) of the Act.

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 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 fee payment if I withdraw my 513(g) request?

No. The Act does not provide FDA authority to refund a fee payment after you have submitted a 513(g) request and have paid the full fee. See section 738(a)(2)(D) of the Act.

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 fee payment.

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 513(g) Request for Information. The form can be found at http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFeeandModernizationAct/ucm155274.htm

10. What are the 513(g) User Fees for FY 2008 –FY 2012?

Fiscal Year	Standard Fee	Fee for a Small Business
FY 2008	$2,498	$1,249
FY 2009	$2,710	$1,355
FY 2010	$2,941	$1,470
FY 2011	$3,191	$1,595
FY 2012	$3,462	$1,731