Guidance for Industry and FDA Staff

User Fees and Refunds for Premarket Notification Submissions (510(k)s)

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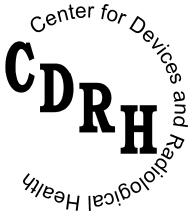
This document supersedes "User Fees and Refunds for Premarket Notification Submissions (510(k)s)" dated May 28, 2004.

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

For questions regarding submissions to the Center for Biologics Evaluation and Research, contact the Office of Communication, Outreach and Development at 800-835-4709 or 301-827-1800 or ocod@fda.hhs.gov.



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

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/1511.html. 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 (**1511**) 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
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Contains Nonbinding Recommendations

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This guidance represents 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

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), Public Law 107-250, amends the Federal Food, Drug, and Cosmetic Act (the Act) to authorize the Food and Drug Administration (FDA) to collect user fees for the review of certain premarket submissions, including premarket notification submissions (510(k)s).[1] The additional funds obtained from user fees will enable FDA, with the cooperation of industry, to improve the device review process in order to meet the performance goals identified in letters from the Secretary of Health and Human Services to Congress.[2] The purpose of this document is to assist FDA staff and regulated industry by describing the user fees and refunds associated with the 510(k) Program.

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.

[1] 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 through September 30, 2012. For additional information on the 2007 Amendments, see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm.

[2] The commitment letter outlining the goals for FY 2008 – FY 2012 is available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM109102.pdf.

Frequently Asked Questions (FAQ)

1. Are all 510(k)s subject to user fees?

No. Section 738(a)(2)(A)(viii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)(2)(A)(viii)), requires you to pay a user fee for any 510(k) (traditional, abbreviated, or special[3]) that you submit to FDA, unless you qualify for one of the exceptions listed below. You will not have to pay a user fee for your 510(k) if —

- your submission is reviewed by an FDA-accredited third party who submits it to FDA, with the third party's recommendation concerning whether your device is substantially equivalent to a legally-marketed predicate;[4] see section 738(a)(2)(B)(iv) of the Act (21 U.S.C. 379j(a)(2)(A)(iv));
- your submission is for a device intended solely for a pediatric population; see section 738(a)(2)(B)(v)(I) of the Act (21 U.S.C. 379j(a)(2)(B)(v)(I));
- you are a state or federal government entity and your device will not be distributed commercially; see section 738(a)(2)(B)(iii) of the Act (21 U.S.C. 379j(a)(2)(B)(iii)).[5]

2. If my 510(k) was reviewed by a third party, will I have to pay a user fee if FDA determines that my device was not eligible for review by the third party?

No. A user fee is not required for a premarket submission reviewed by an accredited person; see section 738(a)(2)(B)(iv) of the Act (21 U.S.C. 379j(a)(2)(B)(iv)). If your device appears to be on FDA's list of devices eligible for third-party review,[6] but FDA determines that your device was not appropriate for third-party review, you will not have to pay a user fee. Among the reasons[7] FDA may determine that a particular device is not appropriate for third party review are:

- The device requires clinical data to demonstrate substantial equivalence; see section 523(a)(3)(A)(iii) of the Act (21 U.S.C. 360m(a)(3)(A)(iii)).

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[3] These terms are explained in "A New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications," available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm.

[4] See section 523 of the Act. For general information concerning third-party review of 510(k)s, see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094450.htm.

[5] For guidance on the type of safety and effectiveness information needed to support marketing of pediatric devices and on measures to be used to help protect pediatric subjects during the course of clinical trials involving such devices, see the guidance entitled, "Premarket Assessment of Pediatric Medical Devices" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm.

[6] The list of eligible device types is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm.

[7] Each third-party review of a 510(k) must meet the statutory eligibility requirements set out in section 523 of the Act. The two criteria identified here are the two most likely to be subject to errors of interpretation.

- The device requires review by multiple FDA centers (e.g., by CDRH and CBER, or CDRH and CDER)[8].

If you employ a third party reviewer to review a device that is not eligible for third-party review, the exemption is not applicable and you will have to pay the appropriate 510(k) user fee then in effect for your submission.

3. Will FDA refund my user fee payment if I submit a 510(k) that is not required?

Statutory exception. If we determine that you have mistakenly paid a fee for a type of 510(k) that does not require a fee because of a statutory exception (see FAQ 1), FDA will refund your payment for that submission.

Device is exempt from 510(k) requirements of the Act. If you submit a 510(k) for a device that is exempt from 510(k), we will not refund your fee payment. See FAQ 4.

Not a device. If you submit a 510(k) for a product that we determine is not a medical device, we will not refund your fee payment. See FAQ 5.

Change or modification to a device. FDA reviews all 510(k) submissions, including those for a change to a legally-marketed device, for an equivalency determination. Therefore, the agency does not intend to refund user fees if, for example, a manufacturer later decides that the change may not have been of a type that required a new 510(k) and wishes to withdraw the submission. FDA encourages manufacturers who intend to modify a legally marketed device to consult the guidance entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device."[9] Also note that a guidance document applicable to a specific type of device would supersede the above referenced general guidance document.

FDA applies a risk-based approach to device regulation, which includes identifying device types where FDA premarket review is not necessary to provide reasonable assurance of device safety and effectiveness. See section 510(l) of the Act (21 U.S.C. 360(l)).Therefore, we encourage all 510(k) submitters to first review the classification regulations, which identify device types that are exempt from 510(k) requirements.[10] Consultation with FDA personnel before submitting 510(k)s for products that may not require review will serve to conserve both FDA and industry resources.[11]

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[8] The third party review program was not intended to include 510(k)s that would require reviews by additional centers. (See 66 FR 13937.)

[9] This guidance can be found at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm.

[10] CDRH identifies the devices that are exempt from the 510(k) submission requirements by regulation at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm. This resource also explains your responsibilities with regard to devices reserved from exemption and the limitations to exemption.

[11] Among the resources to help you ascertain whether your device is exempt by regulation are the Division of Small Manufacturers, International, and Consumer Assistance, the Program Operations Staff, the review

In addition, in order to obtain information regarding the class in which a device type has been classified or the requirements applicable to a device type or product, a manufacturer may submit a request under section 513(g) of the Act (21 U.S.C. 360c(g)).[12]

4. Will FDA refund my fee payment if it determines my device is exempt from 510(k)?

No. It is your responsibility to review the classification regulations[13] that pertain to your type of device and to determine whether a regulation exempts your device from the 510(k) requirements.[14] If you submit a 510(k) for a device where a regulation exempts that device from 510(k) requirements, FDA will not refund your fee payment. You may wish to consult with FDA personnel if you are unsure whether a particular classification regulation exempts a device from the 510(k) requirements.

5. Will FDA refund my fee payment if it determines that my product is not a medical device?

No. If you submit a 510(k) for a product that FDA determines is not a device, FDA will not refund your fee payment.

6. Do I have to pay for a new submission if I previously received a not substantially equivalent (NSE) determination for my device?

Any new submission for a device found NSE is subject to the fee associated with the submission type, if the type is subject to fees.

If we determine your device is NSE because no predicate device, as defined in 21 CFR 807.92(a)(3), exists, your device has a new intended use compared to the predicate, or different technological characteristics that raise different questions of safety and effectiveness,[15] you may petition for Evaluation of Automatic Class III Designation (*de*

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division, and product classification resources on the CDRH website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm.

[12] For products regulated by CDRH, requests for classification information under section 513(g) of the Act should be submitted as a 513(g) to the attention of the U.S. Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center – WO66-0609, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002. For products regulated by CBER, 513(g) requests should be submitted to the CBER Ombudsman, Center for Biologics Evaluations and Research, Suite 200 North, HFM-4, 1401 Rockville Pike, Rockville, MD 20852-1448. Such requests are subject to a user fee. See 21 USC 379j(a)(2)(A)(ix).

[13] See 21 C.F.R. Parts 862 *et seq.*

[15] See the guidance document entitled, **FDA and Industry Actions of Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment** at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm.

novo classification under section 513(f)(2)(A) of the Act (21 U.S.C. 360c(f)(2)(A)),[16] submit a humanitarian device exemption (HDE) application, or submit a Premarket Approval (PMA) application. *De novo* petitions and HDEs are not subject to user fees. However, if you submit a PMA, FDA will assess the PMA fee in effect at the time of submission.[17]

We may determine that your device is NSE based on the fact that the performance data provided in your submission did not demonstrate your device to be at least as safe and effective as a legally marketed device of that type. You may submit a new 510(k) if you believe you have additional data showing that your device is substantially equivalent. Because FDA considers this submission a new 510(k), it intends to assess the fee in effect for a 510(k) at the time of the new 510(k) submission.

7. Do I have to pay an additional fee if I submit additional information to a pending 510(k)?

No. There are no fees when you submit additional information to a 510(k) for which FDA has not yet rendered a final decision. However, if you submit unsolicited additional information that constitutes a *new indication for use* or *new technology*, you will be required to submit a new 510(k) and the associated fee.[18]

8. Will FDA refund the user fee if I withdraw my 510(k)?

No. The Act does not identify withdrawal as a basis for a refund; see section 738(a)(2)(D) of the Act (21 U.S.C. 379j(a)(2)(D)). Although the Act provides FDA limited authority to provide a partial refund when a *premarket application*[19] is withdrawn, that authority does not extend to a withdrawal of a 510(k).

9. Must I pay a new user fee if I withdraw and resubmit my 510(k)?

Yes. If you withdraw your 510(k) and resubmit at a later time, you must pay the fee in effect at the time of the new submission.

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[16] See the guidance entitled, **New Section 513(f)(2) – Evaluation of Automatic Class III Designation** at: http://www.fda.gov/http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htmMedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm.

[17] For fees in effect at the time of submission, see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm.

[18] See 21 CFR 807.81(a)(3).

[19] This term is defined by section 737(1) of the Act (21 U.S.C. 379i(1)).

10. If FDA considers my 510(k) withdrawn because I failed to supply requested information, will FDA require a new user fee if I resubmit my 510(k)?

Yes. If you fail to respond to an FDA request for additional information FDA will issue a notice of withdrawal stating that it considers your 510(k) to be withdrawn.[20] You must pay the 510(k) fee in effect at the time of the new 510(k) submission.

The following Tables provide a summary of the fees and refunds discussed in this document.

Table 1. When is a 510(k) Subject to a User Fee?

510(k) Submission Type	510(k) Fee Required
Original 510(k) submission	Yes
Additional information for a pending 510(k)	No
510(k) submitted by a state or federal government sponsor, *and* the device will not be commercially distributed	No
510(k) eligible for review, and reviewed, by an FDA-accredited third-party	No
510(k) intended solely for a pediatric population	No
510(k) submission for a device previously found NSE	Yes

[20] See 21 CFR 807.87(l).

Table 2. What are the 510(k) User Fees for FY 2008 – FY 2012?

Fiscal Year	Standard Fee	Fee for a Small Business
FY 2008	$3,404	$1,702
FY 2009	$3,693	$1,847
FY 2010	$4,007	$2,004
FY 2011	$4,348	$2,174
FY 2012	$4,717	$2,359

Table 3. When Will FDA Refund a 510(k) User Fee?

FDA Determination or Submitter Action	Will FDA Refund My Fee Payment?
FDA determines my 510(k) is not required. Basis for FDA's decision: • I qualify for one of the fee exceptions provided by section 738(a)(1)(B) of the Act	Yes
• My product is not a device	No
• My device is exempt from premarket notification requirements	No
FDA determines my device is "NSE." Basis for FDA's decision:	
• No predicate exists	No
• New intended use	No
• Different technology raises different question(s) of safety and effectiveness	No
• Lack of Performance Data	No
I withdraw my 510(k).	No
FDA considers my 510(k) to be withdrawn. See 21 CFR 807.87(l).	No

Table 4. What Fee Must I Pay for a New Submission Following a 510(k) "NSE" Determination?

Submission Type	Must I Pay a Fee?
New 510(k)	Yes. You must pay the applicable fee for a 510(k).
De Novo Petition. See section 513(f)(2) of the Act.	No
Reclassification Petition	No
PMA	Yes. You must pay the applicable fee for a PMA.
HDE	No