Guidance for Industry and FDA Staff

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

Document issued on: May 28, 2004

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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 Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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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 provide the Food and Drug Administration (FDA) new responsibilities and resources. A provision of MDUFMA authorizes FDA to collect user fees for the review of certain premarket submissions received on or after October 1, 2002, including premarket notification submissions (510(k)s). 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 the letter from the Secretary of Health and Human Services to Congress (http://www.fda.gov/cdrh/mdufma/pgoals.html). 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.

Stakeholder Input

On February 4, 2003, FDA published a notice in the Federal Register (68 FR 5643) to establish a public docket, 02N-0534, so that we could share information on the implementation of MDUFMA and to provide interested persons an opportunity to share their

views. On December 3, 2003, the agency held an open public meeting to update its stakeholders on its progress in implementing the new law, discuss some of MDUFMA's more challenging provisions, and obtain input from interested parties. Since establishing the docket over a year ago, the agency has received quite a few comments from its stakeholders on a number of MDUFMA provisions, including the application and refund of user fees. During the drafting of this guidance, the agency specifically solicited comments to the docket in recognition of the interest in this issue.

The agency considered all comments received to date and believes that the approach presented below is a fair application of its refund policy. FDA wishes to emphasize that the agency and industry should work to limit the amount of resources that may be expended unnecessarily on devices that do not require agency review. FDA believes that those resources are better spent on reviewing applications that require and will benefit from regulatory oversight. Therefore, we encourage submitters to take advantage of all resources available to them before submitting a premarket notification. By availing themselves of the assistance that is available in the classification regulations, guidances, and consultation with CDRH and CBER staff, both FDA and industry can focus their limited resources on those devices that will most benefit from agency oversight.

Frequently Asked Questions

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

In accordance with MDUFMA,[1] all 510(k)s (traditional, abbreviated, and specials)[2] are subject to user fees, except those listed below. The 510(k)s that are **not** subject to user fees are those:

- reviewed by an FDA-accredited third party pursuant to section 523 of the act (section 738(a)(1)(B)(iv) of MDUFMA)
- submitted for devices intended solely for a pediatric population (section 738(a)(1)(B)(v)(I) of MDUFMA)[3,4]

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[1] See section 738(a)(a)(A)(vii).

[2] For more information on the 510(k) Program generally, please refer to Device Advice at: www.fda.gov/cdrh/devadvice/; for more information on traditional, abbreviated, and special 510(k)s, see **The New 510(k) Paradigm** at www.fda.gov/cdrh/ode/parad510.html.

[3] There may be situations in which, upon review of the device and its intended population, FDA determines that the submission qualified for the pediatric exemption although the manufacturer did not request a waiver. In such a case, FDA intends to refund the user fee.

[4] 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 Medical Devices" at www.fda.gov/cdrh/mdufma/guidance/1220.html.

- submitted by a state or federal government entity, unless the device involved is to be distributed commercially (section 738(a)(1)(B)(iii) of MDUFMA).

If you mistakenly submit a fee with any of these types of 510(k)s, FDA will refund the fee.

2. Are 510(k)s reviewed by a European Union Conformity Assessment Body (EU CAB) subject to user fees?

Although not addressed by MDUFMA, FDA does not intend to assess user fees for 510(k)s reviewed by EU CABs.[5] FDA believes that because EU CABs are serving the same function as FDA-accredited third parties, no fee should be assessed.

3. Will the agency assess a fee if FDA determines that my device was not eligible for review by a third party or an EU CAB?

Generally, no. If a third party submits a recommendation for a device that appears to be on the list of eligible device types, FDA will not assess a user fee if the agency determines that the device was not appropriate for third party review (e.g., because the device requires clinical data or review by multiple FDA centers).[6] If, however, the device does not appear on the list and it is not eligible for third party review, FDA plans to assess the user fee.[7]

4. Will FDA refund the user fee if I submit a 510(k) that is not required?

Yes, under certain circumstances. FDA will refund user fees for submissions that are not required because the agency determines that a product is not a device or because there is a classification regulation that exempts the device from 510(k) review.[8] However, if the device exceeds the limitations to exemption from the 510(k) requirements of the act, a new 510(k) and user fee would be required.

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[5] See **Implementation of Third Party Programs Under the FDA Modernization Act of 1997** at: http://www.fda.gov/cdrh/thirdparty/apguide13.html and **Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)** at: http://www.fda.gov/cdrh/modact/eurma.html.

[6] Devices eligible for third party review are accessible from http://www.fda.gov/cdrh/thirdparty/.

[7] A device may be eligible for third party review even if it does not appear of the list if it is a Class I or II device that has been exempted from 510(k) by regulation but requires a 510(k) because it exceeds the limitations of the exemption (as discussed in FDA's device classification regulations).

[8] This would include general purpose articles and other products that are exempt from registration and listing under 21 CFR 807.65.

The agency does not intend to refund fees for any other 510(k)s that are submitted for review. FDA reviewed comments that urged the agency to refund fees for a variety of other 510(k)s, including 510(k)s for transitional devices or 510(k)s that are withdrawn by the submitter prior to a final decision.

The agency does not agree with these comments. With the exception of products that are not a device or devices that are exempt from the 510(k) requirements by regulation, the agency will review the submission and issue a final decision. We will issue an NSE for a device that FDA determines to be a transitional device as well as for any device that will require a PMA because there is no legally marketed device.[9] The agency spends significant review resources to make these determinations and does not believe there is any basis to distinguish among NSE decisions for purposes of refunding fees. FDA acknowledges that the Office of Device Evaluation (ODE) annual reports that appear to categorize some of these decisions as "administrative" may have created confusion about the real nature of the review process that is associated with 510(k) review of these submissions. Those reports, however, were generated **before** FDA implemented the user fee legislation. The agency will modify future reports to reflect the categories discussed in this guidance.

In addition, the agency wants to clarify that it does not review 510(k)s submitted for a change or modification to a legally marketed device to determine whether the change required submission of a new 510(k). Rather, FDA reviews all 510(k)s, including those submitted 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."[10]

FDA believes that the agency and industry should work to limit the amount of resources that may be expended unnecessarily on products that do not require review. The agency believes that those resources are better spent on reviewing applications that require and will benefit from FDA oversight. Therefore, we encourage all submitters first to review the classification regulations. The regulations identify when device types are exempt from 510(k) requirements.[11] Consultation with agency personnel before submitting 510(k)s for

[9] See 21 CFR 807.92(a)(3).
[10] This guidance can be found at: www.fda.gov/cdrh/ode/510kmod.html.
[11] 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.

products that may not require review will serve to conserve both FDA and industry resources.[12]

In addition, a manufacturer may obtain information regarding the regulatory status of its device or product by submitting a request under section 513(g) of the act.[13] There are no user fees associated with such requests.

5. Are there fees 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 exists, your device has a new intended use compared to the predicate, or different technological characteristics than the predicate that raise different questions of safety and effectiveness,[14] you may petition for automatic evaluation of the class III designation (*de novo* classification under section 513(f)(2)(A)) or the act),[15] submit a humanitarian device exemption (HDE) application, or submit a PMA. *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.[16]

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 as safe and effective as a legally marketed device. You may submit a new 510(k) if you have additional data showing that your device is substantially equivalent. Because we consider this

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[12] The Division of Small Manufacturers, International, and Consumer Assistance, the Program Operations Staff, the review division, and product classification resources on the CDRH website at http://www.fda.gov/cdrh/devadvice/313.html, can help you ascertain whether your device is exempt by regulation.

[13] For products regulated by CDRH, requests for classification information under section 513(g) of the act should be submitted to the attention of the 513(g) Coordinator, Food and Drug Administration, Center for Devices and Radiological Health, 510(k) Document Mail Center (HFZ-401), 9200 Corporate Boulevard, Rockville, MD 20850. 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.

[14] See the guidance document entitled, FDA and Industry Actions of Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment at: www.fda/gov/cdrh/mdufma/guidance/1219.html.

[15] See the guidance entitled, **New Section 513(f)(2) – Evaluation of Automatic Class III Designation** at: http://www.fda.gov/cdrh/modact/classiii.htm.

[16] For fees in effect at the time of submission, see www.fda.gov/cdrh/mdufma/index.html.

submission a new 510(k), we intend to assess the fee in effect for a 510(k) at the time of the new submission.

6. Are there fees assessed 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 we have 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.[17]

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

No, FDA will not refund user fees for submissions that are withdrawn.

The agency disagrees with comments that suggested refunds should be available when a submitter withdraws a 510(k). Because the statute and the goals letter establish short time frames for 510(k) review, it is likely that significant agency resources will already be expended on review at the time there is a request for withdrawal. Refunding fees in those circumstances would be inconsistent with the statute and would undermine the need to equitably distribute fees among 510(k) submitters.

In many cases, a firm's decision to withdraw a 510(k) is made after FDA reviewers have completed a cycle of review and asked for additional information. The submitter may decide it will not or cannot provide the additional information the agency is requesting. In some cases, submitters elect to withdraw a 510(k) because they believe the final agency decision will be an NSE. Although a submitter may request to withdraw a 510(k) at any time and for any reason before FDA issues a final decision, the fee will not be returned.

The agency notes that its decision to retain fees for 510(k)s that are withdrawn is consistent with the provisions of MDUFMA, which anticipate the possibility that some refund may be appropriate for a PMA submission that is withdrawn but create no similar provision for 510(k) withdrawals.[18]

8. Will FDA require 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, we plan to assess the fee in effect at the time of the new submission.

[17] See 21 CFR 807.81.
[18] See section 738(a)(1)(D) of MDUFMA.

9. If my 510(k) is considered 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 FDA's request for additional information and we issue a notice of withdrawal stating that we consider your 510(k) to be withdrawn (see 21 CFR 807.87(l)), we intend to assess the fee in effect at the time of the new submission.

Please refer to Tables 1-3 below for a summary of fees and refunds discussed in this document.

Table 1. 510(k) User Fees

510(k) Submission Type	510(k) Fee Required
Original 510(k) Submission	Yes
510(k) Reviewed by Third Party • FDA-Accredited 3rd Party pursuant to section 523 of the act • EU CAB	 No No
510(k) Intended Solely for a Pediatric Population	No
510(k) Submitted by State/Federal Government, unless Device will be Commercially Distributed	No
510(k) Submission for Device Previously Found NSE	Yes
Additional Information for Pending 510(k)	No

Table 2. Refunds of 510(k) Fees

FDA Determination/Industry Action	Refund of Fee
510(k) Not Required. Basis for Decision: • "Not a Device" • "Exempt" by Regulation	 Yes Yes
FDA Determines NSE. Basis for Decision: • No Predicate Exists • New Intended Use • Different Technology Raises Different Questions of Safety and Effectiveness • Lack of Performance Data	 No No No No
FDA Determines that the Device is Intended Solely for Use in Pediatric Population	Yes
Submitter Withdraws 510(k)	No
FDA Considers Submission to be Withdrawn (21 CFR 807.87(l))	No

Table 3. Fees for Resubmission Following NSE Determination

Submission Type	Fee
New 510(k)	Yes (510(k) Fee)[A]
De Novo Petition (Section 513(f)(2)of the act)	No
Reclassification Petition	No
PMA	Yes (PMA Fee)[A]
HDE	No

[A] In accordance with MDUFMA, FDA will adjust the fees each year to account for inflation, changes in workload, and other factors. FDA will announce the new fees in a Federal Register notice, no later than 60 days before the start of that fiscal year, see also http://www.fda.gov/cdrh/mdufma/index.html.