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

Guidance for Industry and Food and Drug Administration Staff

Document issued on: April 2, 2013

This document supersedes “User Fees and Refunds for Premarket Notification Submissions (510(k)s)” issued August 27, 2009.

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

For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact CBER’s 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

Public Comment

You may submit written comments and suggestions 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. Submit electronic comments to www.regulations.gov.

Identify all comments with Docket No. 2003D-0537. 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. 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 301-827-8149 to receive a hard copy. Please use the document number (1511) to identify the guidance you are requesting.

Additional copies of this guidance document are also available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or by e-mail at ocod@fda.hhs.gov, or from the Internet at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>.

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Guidance for Industry and Food and Drug Administration Staff

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

During the review of a premarket submission, the review clock is impacted by both FDA's and Industry's action. The Medical Device User Fee Amendments of 2012¹ (MDUFA III), 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, 2012, 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 medical device review process to meet certain performance goals and implement improvements for the medical device review process.

The purpose of this guidance document is to identify: (1) the types of 510(k)s subject to user fees; (2) exceptions to user fees; and (3) the actions that may result in refunds of user fees that have been paid. This document incorporates the impact of process improvements from MDUFA III.

FDA's guidance documents, including this guidance document, do not establish legally enforceable responsibilities. Instead, guidance documents 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 guidance documents means that something is suggested or recommended, but not required.

¹ See the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA, Public Law 112-114).

Frequently Asked Questions (FAQ)

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

No. Section 738(a)(2)(A)(viii) of the FD&C Act (21 U.S.C.

379j(a)(2)(A)(viii)), requires you to pay a user fee for any 510(k) (traditional, abbreviated, or special²) 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 party³ who submits it to FDA with the third party's recommendation concerning whether your device is substantially equivalent to a legally-marketed predicate; see section 738(a)(2)(B)(iv) of the FD&C Act; or
- your submission is for a device intended solely for a pediatric population; see section 738(a)(2)(B)(v)(I) of the FD&C Act;⁴ or
- 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 FD&C Act.

Refer to Appendix 1 for a summary of when a 510(k) is subject to user fees ([Table 1](#)).

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

As outlined below, there are three ways you may submit your user fee.⁵ Be sure to include the Payment Identification Number (PIN, beginning with MD)⁶ and the FDA P.O. Box on your check, bank draft, or U.S. Postal Money Order. Also, you should include a printed 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 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 \$5,000.

² These terms are explained in "[A New 510\(k\) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications](#)," issued on March 20, 1998. Web addresses for all guidance documents referenced within this guidance can be found in Appendix 2 – List of References.

³ See Section 523 of the Act. For general information concerning third-party review of 510(k)s, see "[Implementation of Third Party Programs Under the FDA Modernization Act of 1997: Final Guidance for Staff, Industry and Third Parties](#)" issued February 2, 2001.

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 Pediatric Medical Devices](#)," issued May 14, 2004.

⁵ Additional information regarding payment of user fees is available at https://userfees.fda.gov/OA_HTML/mdufmaFAQ.html

⁶ A PIN is obtained after creating a User Fee Cover Sheet and selecting "Submit Cover Sheet to FDA."

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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 956733
St. Louis, MO 63195-6733

Note: In no case should payment be submitted with the application.

Check Payments delivered by a courier service:

US Bank
ATTN: Government Lockbox 956733
1005 Convention Plaza
St. Louis, MO 63101

Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact the US Bank at (314) 418-4013.

3) Wire Transfer: Please include your application'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 application 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:

New York Federal Reserve Bank
US Department of the 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
Beneficiary: FDA
1350 Piccard Drive
Rockville, MD 20850

3. If FDA has indicated that my device is eligible for third party review, and my 510(k) was reviewed by a third party, but FDA later determines that

my device is not eligible for review by the third party, will I have to pay a user fee?

No. You do not have to pay a user fee if FDA had indicated your device is eligible for third party review, but determines during the course of review of the third party submission that your device is not appropriate for third party review. Among the reasons FDA may later determine that a particular device is not appropriate for third party review are:⁷

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

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

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

Devices are eligible for third-party review if any of the following criteria are met:³

- The device appears on FDA's list of eligible devices.⁹
- CDRH staff indicates the device meets the requirements of the pilot expansion program.
- The reviewing branch that regulates the device indicates that the application may be reviewed by a third-party.

5. What are the circumstances when FDA will refund my user fee payment?

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.

Failure to supply an electronic copy (eCopy): see [FAQ 8](#) and Appendix 1 ([Table 2](#))

Withdrawal of submission if acceptance criteria are not met: see [FAQ 9](#) and Appendix 1 ([Table 2](#))

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.

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 The list of third party eligible device types is available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>.

6. What are the circumstances when FDA will not refund my user fee payment?

1) *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. It is your responsibility to review the classification regulations¹⁰ that pertain to your device and to determine whether a regulation exempts your device from the 510(k) requirements.¹¹ Consultation with FDA personnel before submitting 510(k)s for products that may not require review will serve to conserve both FDA and industry resources¹².

2) *Not a device:* If you submit a 510(k) for a product that FDA determines does not meet the definition of a device under section 201(h) of the FD&C Act, or is not a combination product with a device constituent part, we will not refund your fee payment.

3) *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](#),” issued January 10, 1997. Also, note that a guidance document applicable to a specific type of device would supersede the above referenced general guidance document.

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)). For more information on submitting a 513(g), please see the FDA guidance “User Fees for 513(g) Requests for Information,” issued on April 6, 2012.

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

Yes. 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.

As described in FDA’s guidance entitled, “FDA and Industry Actions on Premarket

¹⁰ See 21 C.F.R. Parts 862 *et seq.*

¹¹ FDA identifies the devices that are exempt from the 510(k) submission requirements by regulation at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm>. This resource also explains your responsibilities with regard to devices reserved from exemption and the limitations to exemption

¹² 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 division; and product classification resources on the [CDRH website](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm). (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>)

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Notification (510(k) Submissions: Effect on FDA Review Clock and Goals,” issued on October 15, 2012, if we determine your device is NSE for one of the following three reasons:

- 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
- your device has different technological characteristics that raise different questions of safety and effectiveness,

you have three options. You may petition for Evaluation of Automatic Class III Designation (*de novo* classification under section 513(f)(2)(A) of the FD&C Act (21 U.S.C. 360c(f)(2)(A)), 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](#).

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ucm310929.htm>)

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), we intend to assess the fee in effect for a 510(k) at the time of the new 510(k) submission.¹³ This information is summarized in Appendix 1 ([Table 3](#)).

8. If FDA considers my 510(k) withdrawn because I failed to supply an electronic copy (eCopy), will FDA refund my fee payment?

Yes. Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), provides statutory authority to require eCopies after issuance of final guidance (*See Public Law No: 112-144*). As outlined in FDA’s guidance “[eCopy Program for Medical Device Submissions](#),” issued on December 31, 2012, if FDA does not receive an eCopy, or receives an eCopy that cannot be accepted because it does not meet our technical standards, the omission or reasons for that failure will be communicated to you in writing to aid in your creation of a valid replacement eCopy. If a valid eCopy is not received within 180 days of this notification, the submission will be deleted from our system and FDA will refund the fee paid upon written request.

9. If acceptance criteria are not met for my 510(k) submission, will FDA refund my user fee payment?

Yes. FDA will conduct an acceptance review of your submission as detailed in FDA’s guidance “[Refuse to Accept Policy for 510\(k\)s](#)” issued on December 31, 2012. If FDA determines required elements are not present in your submission, you will be notified

¹³ See 21 CFR 807.81

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within 15 days of receipt that your submission is incomplete and has not been accepted. You may submit the missing information to the 510(k) submission without submitting a new user fee. Alternatively, you may send a written request to withdraw the submission and request a refund of the fee paid if you decide not to provide the missing information. If you do not respond with either the missing information or a request to withdraw the submission and obtain a refund within 180 days of FDA's refuse to accept notification, the submission will be considered withdrawn and a refund will not be issued.

10. 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.¹⁴

11. Will FDA refund the user fee if I withdraw my 510(k) after it has been accepted for review?

No. The FD&C 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 FD&C Act provides FDA limited authority to provide a partial refund when a *premarket application*¹⁵ is withdrawn, that authority does not extend to a withdrawal of a 510(k).

12. Must I pay a new user fee if I withdraw and resubmit my 510(k) after it has been accepted for review?

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.

13. 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.¹⁶ You must pay the 510(k) fee in effect at the time of the new 510(k) submission.

14. If eligible, how do I request a refund?

To request a refund you must submit a written request to the appropriate Center in FDA to the address below no later than 180 days after the fee was due.¹⁷

¹⁴ See 21 CFR 807.81(a)(3).

¹⁵ This term is defined by section 737(a) of the Act (21 U.S.C. 379i(1)).

¹⁶ See 21 CFR 807.87(l)

¹⁷ See section 738(j) of the FD&C Act.

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For products regulated by CDRH:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center – WO66 – G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

For products regulated by CBER:

U.S. Food and Drug Administration
Document Control Center, HFM-99
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448.

Appendix 1 – Information Summary Tables

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 provided for existing 510(k) in response to Refuse to Accept notification	No
Additional information for a pending 510(k)	No
510(k) submitted by a state or federal government sponsor, <i>and</i> 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

Table 2. When Will FDA Refund a 510(k) User Fee?

FDA Determination or Submitter Action	Will FDA Refund My Fee Payment?
<p>FDA determines my 510(k) is not required.</p> <p>Basis for FDA’s decision:</p> <ul style="list-style-type: none"> I qualify for one of the fee exceptions provided by section 738(a)(1)(B) of the Act 	Yes
<ul style="list-style-type: none"> My product is not a device 	No
<ul style="list-style-type: none"> My device is exempt from premarket notification requirements 	No
<p>FDA determines my device is “NSE.”</p> <p>Basis for FDA’s decision:</p> <ul style="list-style-type: none"> No predicate exists New intended use Different technology raises different question(s) of safety and effectiveness Lack of Performance Data 	No
<p>I withdraw my 510(k).</p>	No
<p>FDA considers my 510(k) to be withdrawn.</p> <p>See 21 CFR 807.87(l).</p>	No

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If I fail to submit an e-copy	Yes, upon request
If FDA determines my submission does not meet the acceptance criteria	Yes, upon request

Table 3. 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).
<i>De Novo</i> 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

Appendix 2 – List of References

For the most recent version of a guidance, check the CDRH guidance webpage at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

[A New 510\(k\) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm>

[Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094450.htm)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094450.htm>

[Premarket Assessment of Pediatric Medical Devices](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm>

[Deciding When to Submit a 510\(k\) for a Change to an Existing Device](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm>

[User Fees for 513\(g\) Requests for Information](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm>

[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm)

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>

[eCopy Program for Medical Device Submissions](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf)

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>

[Refuse to Accept Policy for 510\(k\)s](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf)

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>