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User Fees and Refunds for De Novo Classification Requests

Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact CDRH's Division of Industry and Consumer Education (DICE) at 1-800-638-2041, 301-796-7100, or DICE@fda.hhs.gov, or CBER's Office of Communication, Outreach and Development at 1-800-835-4709, 240-402-8010 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

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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

During the review of a premarket submission, the review clock is impacted by both FDA's and Industry's actions. 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 De Novo classification requests (De Novo requests). 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]

The purpose of this guidance document is to identify: (1) the types of De Novo requests 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 IV.

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

[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/media/102699/download.

requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Frequently Asked Questions (FAQs)

1. Are all De Novo requests subject to user fees?

No. Section 738(a)(2)(A)(xi) of the FD&C Act (21 U.S.C. 379j(a)(2)(A)(xi)), requires you to pay a user fee for any De Novo request 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 De Novo request if:

- 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 (21 U.S.C. 379j(a)(2)(B)(v)(I));[3] 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 (21 U.S.C. 379j(a)(2)(B)(iii)).

Refer to Appendix 1 for a summary of when a De Novo request 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.[4] Be sure to include the Payment Identification Number (PIN, beginning with MD) and the FDA P.O. Box on your check, bank draft, or U.S. Postal Money Order. A PIN is obtained after creating a User Fee Cover Sheet and selecting "Submit Cover Sheet to FDA." Also, you should include a 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 https://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,

[3] 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, please see the guidance entitled "Premarket Assessment of Pediatric Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-assessment-pediatric-medical-devices.

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

select the "Pay Now" button. Credit card transactions for cover sheets are limited to $24,999.99.

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:
   US Bank Lock Box
   P.O. Box 956733
   St. Louis, MO 63195-6733
   Note: In no case should payment be submitted with the De Novo request.

   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 US Bank at (314) 418-4013.

3) Wire Transfer: Please include your De Novo request'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 De Novo request 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. 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 De Novo request that does not require a fee because of a statutory exception (see FAQ 1 and Appendix 1 (Table 1)), FDA will refund your payment for that submission.

Failure to supply an electronic copy (eCopy): See FAQ 6 and Appendix 1 (Table 2).

Withdrawal of submission if acceptance criteria are not met: See FAQ 7 and Appendix 1 (Table 2).

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

1) *Your De Novo request is accepted for review*: After the user fee is paid and a validated eCopy is provided to FDA, FDA will conduct an acceptance review of your submission as detailed in the FDA guidance, "Acceptance Review for De Novo Classification Requests."[5] If the De Novo request is accepted for review, we will not refund your user fee payment. Note that FDA considers acceptance of a De Novo request to be synonymous to "filing" for the purposes of refunds as outlined in section 738(a)(2)(D) of the FD&C Act (21 U.S.C. 379j(a)(2)(D)).

2) *Your De Novo request is declined:* If your De Novo request is accepted for review and declined, we will not refund your fee payment. Please note that there are multiple reasons for declining a De Novo request, including that the product in the De Novo request is not a device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)), or that the device is ineligible for De Novo classification. Please see the FDA guidance document entitled "FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals"[6] for more information.

Consultation with FDA personnel before submitting De Novo requests for products for which a De Novo request is not appropriate will serve to conserve both FDA and industry resources. Among the resources to help you ascertain whether your device is eligible for De Novo classification are the Division of Industry and Consumer Education; the CDRH or CBER review staff; and product classification resources on the CDRH website, available at https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

[5] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals

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 FD&C Act (21 U.S.C. 360c(g)). For more information on submitting a 513(g) Request for Information, please see the guidance document entitled "User Fees for 513(g) Requests for Information."[7]

5. Do I have to pay for a new submission if I previously received a De Novo decline order for my device?

Yes. Any new submission for a device for which a previous De Novo request was issued a decline order is subject to the fee associated with the submission type, if the type is subject to fees.[8]

If we decline your De Novo request for any of the reasons outlined in FDA's guidance entitled, "FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals,"[9] you have three options. You may submit a premarket notification (510(k)), submit a humanitarian device exemption (HDE) application, or submit a Premarket Approval (PMA) application. HDEs are not subject to user fees. However, if you submit a 510(k) or PMA, FDA will assess the 510(k) or PMA fee in effect at the time of submission (https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2017-mdufa-iv).

You may submit a new De Novo request if you believe you have additional information, including performance data, demonstrating that the probable benefits of the device outweigh the probable risks and that either general controls alone, or general and special controls, mitigate the probable risks to health. Because FDA considers this submission a new De Novo request, we intend to assess the fee in effect for a De Novo request at the time of the new De Novo request. This information is summarized in Appendix 1 (Table 3).

6. If FDA considers my De Novo request 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 (21 U.S.C 379k-1(b)), 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.[10] As outlined in FDA's guidance "eCopy Program for Medical Device Submissions,"[11] if FDA does not receive an eCopy, or receives an eCopy that cannot be accepted because it does not

[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information
[8] Section 738(a)(2)(A)(xi) of the FD&C Act (21 U.S.C. 379j(a)(2)(A)(xi)).
[9] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals
[10] Public Law No: 112-144.
[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions

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 of an original submission is not received within 180 days of this notification, the Agency may consider a De Novo request to be withdrawn. A notice of withdrawal is sometimes referred to as a "deletion letter." The term "deletion" is used to differentiate a lack of timely response from a request to withdraw a pending De Novo request by the requester. If the De Novo request is withdrawn in this manner, FDA will refund the fee paid upon written request.

7. If acceptance criteria are not met for my De Novo request, will FDA refund my user fee payment?

Yes. FDA will conduct an acceptance review of your submission as detailed in the FDA guidance, "Acceptance Review for De Novo Classification Requests."[12] If FDA determines required elements are not present in your submission, you will be notified within 15 days of receipt that your submission is incomplete and has not been accepted. You may submit the missing information to the De Novo request 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, FDA will consider the De Novo request to be withdrawn and a refund will not be issued.

8. Do I have to pay an additional fee if I submit additional information to a pending De Novo request?

No. There are no fees when you submit additional information to a De Novo request for which FDA has not yet rendered a final decision.

9. Will FDA refund the user fee if I withdraw my De Novo request after it has been accepted for review?

No. The FD&C Act does not identify withdrawal of a De Novo request as a basis for a refund; see section 738(a)(2)(D) of the FD&C 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*[13] is withdrawn, that authority does not extend to a withdrawal of a De Novo request.

10. Must I pay a new user fee if I withdraw and resubmit my De Novo request after it has been accepted for review?

[12] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests

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

Yes. If you withdraw your De Novo request and resubmit at a later time, you must pay the fee in effect at the time of the new De Novo request.

11. If FDA considers my De Novo request withdrawn because I failed to supply requested information, will FDA require a new user fee if I resubmit my De Novo request?

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 De Novo request to be withdrawn. You must pay the De Novo fee in effect at the time of the new De Novo request.

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

To request a refund, you must submit a written request[14] to the appropriate Center in FDA to the address below no later than 180 days after the fee was due.[15]

For products regulated by CDRH:
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66 – G609
10903 New Hampshire Avenue
Silver Spring, MD 20993

For products regulated by CBER:
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

[14] The user fee payment refund request form is available at https://www.fda.gov/media/96650/download
[15] See section 738(k) of the FD&C Act (21 U.S.C. 379j(k)).

Appendix 1 – Information Summary Tables

Table 1. When Is a De Novo Request Subject to a User Fee?

De Novo Request Type	De Novo Fee Required
Original De Novo request	Yes
Additional information for a pending De Novo request	No
De Novo request submitted by a state or federal government sponsor, *and* the device will not be commercially distributed	No
De Novo request intended solely for a pediatric population	No
De Novo request for a device for which the previous De Novo request was declined	Yes

Table 2. When Will FDA Refund a De Novo User Fee?

FDA Determination or Submitter Action	Will FDA Refund My Fee Payment?
I qualify for one of the fee exceptions provided by section 738(a)(2)(B) of the FD&C Act.	Yes
FDA declines my De Novo request.	No
I withdraw my De Novo request after acceptance for review.	No
FDA considers my De Novo request to be withdrawn.	No
I fail to submit a valid eCopy before my Original De Novo request enters acceptance review.	Yes, upon request
I fail to submit a valid eCopy for a De Novo amendment or supplement.	No
FDA determines my submission does not meet the acceptance criteria during acceptance review.	Yes, upon request

Table 3. What Fee Must I Pay for a New Submission Following a De Novo "Decline" Determination?

Submission Type	Must I Pay a Fee?
New De Novo request	Yes. You must pay the applicable fee for a De Novo request.
510(k)	Yes. You must pay the applicable fee for a 510(k).
Reclassification petition	No
PMA	Yes. You must pay the applicable fee for a PMA.
HDE	No