Contains Nonbinding Recommendations

User Fees and Refunds for De Novo Classification Requests

Guidance for Industry and Food and Drug Administration Staff

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This document supersedes User Fees and Refunds for De Novo Classification Requests issued October 5, 2021.

For questions regarding submissions to the Center for Devices and Radiological Health (CDRH), contact the Office of Regulatory Programs / Division of Submission Support / Premarket Notification (510(k)) Staff at 301-796-5640 or by email at OPEQSubmissionSupport@fda.hhs.gov.

For questions regarding submissions to the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at 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

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov/. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2017-D-5713. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 16057 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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User Fees and Refunds for De Novo Classification Requests

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

The Medical Device User Fee Amendments of 2022[1] (MDUFA V), 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, 2022, including De Novo classification requests (De Novo requests).[2] 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.[3]

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 also incorporates MDUFA V process improvements.

In general, FDA's guidance documents 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

[1] See Title II of the FDA User Fee Reauthorization Act of 2022 (Public Law 117-180).
[2] For additional information on medical device user fees, please see https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa
[3] See 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization). The MDUFA V Commitment Letter is also available at https://www.fda.gov/media/158308/download.

use of the word *should* in Agency guidances 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?

Most De Novo requests are subject to user fees. Section 738(a)(2)(A)(xi) of the FD&C Act 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[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 De Novo request is subject to user fees (Table 1).

2. What are the De Novo user fees?

User fees for the current fiscal year are established under section 738 of the FD&C Act and shown on the FDA MDUFA User Fees website at https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

3. 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) 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.

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[4] For guidance on the type of safety and effectiveness information that may be needed to support marketing of pediatric devices and on protection of 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.

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

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, 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:
   Food and Drug Administration
   P.O. Box 979033
   St. Louis, MO 63197-9000
   Note: In no case should payment be submitted with the De Novo request.

   Check payments delivered by a courier service:
   U.S. Bank
   ATTN: Government Lockbox 979033
   1005 Convention Plaza
   St. Louis, MO 63101
   Note: This address is for courier delivery only. If a phone number is also required for courier delivery, use (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:
   US Department of 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

4. 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 upon request.

Failure to supply a valid electronic copy (eCopy) or an electronic submission template: See FAQ 7 and Appendix 1 (Table 2).

Withdrawal of submission if acceptance criteria are not met: See FAQ 8 and Appendix 1 (Table 2).

Withdrawal of an electronic submission template which did not pass technical screening and is placed on hold: See FAQ 9 and Appendix 1 (Table 2).

5. 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 valid eCopy is provided to FDA, FDA intends to conduct an acceptance review of your submission within 15 calendar days, in accordance with 21 CFR 860.230 and as detailed in the FDA guidance, "Acceptance Review for De Novo Classification Requests."[6] If the De Novo request is accepted for review, we will not refund your user fee payment.

2) *Your De Novo request submitted via eSTAR has passed technical screening:* When submitting an electronic submission (eSubmission) using an electronic submission template (e.g., electronic Submission Template And Resource (eSTAR)[7,8]), the refuse to accept (RTA) requirements of 21 CFR 860.230 have been automated within the eSTAR.[9] However, FDA intends to employ a virus scanning and technical screening process for an eSTAR. The technical screening process is anticipated to occur within 15 calendar days of FDA receiving the De Novo

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

[7] For more information see FDA's website regarding the eSTAR program (https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program). This website provides current information regarding eSTAR program for CDRH and CBER.

[8] eSTAR is the only type of electronic submission template that is currently available to facilitate the preparation of De Novo requests as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR.

[9] For more information on the RTA process, please see "Acceptance Review for De Novo Classificaiton Requests" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests.

eSTAR. FDA intends to begin the technical screening for De Novo electronic submissions after confirmation of user fee payment. If the eSTAR does not pass the technical screening process, FDA will notify the submitter via email[10] and identify the inaccurate or irrelevant information, and the De Novo will be placed and remain on hold until a complete replacement eSTAR is submitted to FDA. FDA will not refund user fees paid for eSTARs that have passed technical screening.

3) *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 that are identified in 21 CFR 860.260(c), including that the product in the De Novo request is not a device under section 201(h) of the FD&C Act and is not a combination product as defined at 21 CFR 3.2(e) (21 CFR 860.260(c)(4)). Please see the FDA guidance document entitled "FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals"[11] for more information.

Consultation with FDA personnel before submitting De Novo requests for products for which a De Novo request is not the appropriate pathway 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 (DICE) for CDRH and the Manufacturers Assistance and Technical Training Branch (MATTB) for CBER ; 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. DICE can be reached by phone at (800) 638-2041 or (301) 796-7100, or by email at DICE@fda.hhs.gov. MATTB can be reached at (800) 835-4709 or (240) 402 8020, or by email at Industry.Biologics@fda.hhs.gov.

In addition, in order to obtain information regarding the class in which a device has been classified or the requirements applicable to a device, a manufacturer may submit a request under section 513(g) of the FD&C Act. 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."[12]

[10] For additional information about email communications with CBER, please see the "SOPP 8119: Use of Email for Regulatory Communications," available at https://www.fda.gov/media/108992/download.
[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals
[12] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information

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

Yes, unless a statutory exception applies. 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.[13]

If we decline your De Novo request for any of the reasons set forth in 21 CFR 860.260(c),[14] it may be appropriate to submit a different type of marketing application for the product that was the subject of the request, such as a premarket notification (510(k)), a humanitarian device exemption (HDE) application, or a premarket approval application (PMA). HDEs are not subject to user fees.[15] 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/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa).

You may also submit a new De Novo request if you believe you have additional information, including performance data, demonstrating that either general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the device. Because FDA considers this submission a new De Novo request, we will 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).

7. If FDA considers my De Novo request withdrawn because I failed to supply a valid electronic copy (eCopy) or an eSTAR, will FDA refund my fee payment?

Yes. Section 745A(b) of the FD&C Act provides statutory authority to require eCopies or submission solely in electronic format (e.g., eSTAR) after issuance of final guidance. As outlined in FDA's guidance "eCopy Program for Medical Device Submissions,"[16] 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 of an original submission is not received within 180 calendar days of this notification, the Agency considers a De Novo request to be withdrawn. A notice of withdrawal in these circumstances is sometimes referred to as a "deletion letter." The term "deletion" is used to differentiate withdrawal due to a lack of timely response (21 CFR 860.250(a)(1)-(2)) from a request to withdraw a pending

[13] Section 738(a)(2)(A) of the FD&C Act.
[14] For more information, see FDA's guidance entitled, "FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals.
[15] Section 738(a)(2)(B)(i) of the FD&C Act.
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions

De Novo request submitted by the requester (21 CFR 860.250(a)(4)). If the De Novo request is withdrawn (deleted) in this manner, FDA will refund the fee paid upon request. If you decide not to submit a valid replacement eCopy of your original submission in response to the eCopy hold notification, you may also send a written request to withdraw your submission (see 21 CFR 860.250(a)(4)) before receiving a deletion letter and request a refund of the fee paid. FDA intends to follow a similar process should an eSTAR be submitted that does not pass an automatic verification process.[17] Note that your fee will not be refunded if you fail to provide a valid eCopy or an eSTAR for a response to an additional information request after the De Novo request has been accepted for review (see FAQ 14 and Appendix 1 (Table 2)).

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

Yes. FDA intends to conduct an acceptance review[18] of your submission in accordance with 21 CFR 860.230 and as detailed in the FDA guidance, "Acceptance Review for De Novo Classification Requests."[19] If FDA refuses to accept your submission, you will be notified within 15 calendar days of receipt that your submission has not been accepted (21 CFR 860.230(a) and 21 CFR 860.230(c)). You may submit additional information to the De Novo request to address the reasons for the refusal without submitting a new user fee. Alternatively, you may send a written request to withdraw the submission (see 21 CFR 860.250(a)(4)) and request a refund of the fee paid if you decide not to provide additional information. See FAQ 15 below for more information on how to request a refund.

9. Will FDA refund the user fee if I submit a De Novo request using eSTAR, the eSTAR does not pass technical screening and is placed on hold, and I withdraw the De Novo request?

Yes. You will be notified within 15 calendar days of receipt if your eSTAR does not pass technical screening and is placed on hold. You may submit additional information to the De Novo request to address the reasons for the technical screening hold without submitting a new user fee. Alternatively, you may send a written request to withdraw the submission (see 21 CFR 860.250(a)(4)) and request a refund of the fee paid if you decide not to provide additional information. Additionally, Section V, Question 5 of FDA's guidance "Acceptance Review for De Novo Classification Requests"[20] explains that FDA may refuse to accept a De Novo request, if, on its face, the De Novo request is ineligible for De Novo classification due to the existence of a legally marketed predicate, an existing classification regulation exists for the same device type, or an

[17] https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
[18] As stated above in FAQ5, for De Novo requests submitted using eSTAR, RTA requirements of 21 CFR 860.230 have been automated within the eSTAR.
[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests

approved PMA(s) exists for the same device type. For eSTARs, FDA intends to refund user fee payments, upon request, for an eSTAR that FDA determines to be ineligible on its face for the same reasons as outlined above. In such instances, FDA will use the technical screening process to place the eSTAR on hold within 15 calendar days of eSTAR receipt. The requester may then request withdrawal of the eSTAR and request a refund.

10. Will FDA refund the user fee if I submit an eSTAR and the eSTAR passes technical screening?

No. The RTA requirements of 21 CFR 860.230 have been automated within eSTAR, and therefore, FDA will consider a De Novo eSTAR that passes the technical screening process to have fulfilled the acceptance review requirements. As such, we will not refund user fees paid for eSTARs that have passed technical screening.

11. 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.

12. 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 under substantive review as a basis for a refund; see section 738(a)(2)(D) of the FD&C Act. Although the FD&C Act provides FDA limited authority to provide a partial refund when a *premarket application, premarket report, or supplement*[21] is withdrawn after filing,[22] that authority does not extend to De Novo requests.

13. Must I pay a new user fee if I withdraw and resubmit my De Novo request after it has been accepted for review (or my eSTAR passes technical screening)?

Yes. If you withdraw your De Novo request after it has been accepted for review (or, for an eSTAR, after it passes technical screening), and resubmit at a later time, you must pay the fee in effect at the time of the new De Novo request.

14. If FDA considers my De Novo request withdrawn after it has been accepted because I failed to supply requested information, will FDA require a new user fee if I resubmit my De Novo request?

[21] These terms are defined by sections 737(1), 737(2), and 737(4)(A), of the FD&C Act.
[22] See section 738(a)(2)(D)(iii) of the FD&C Act.

Yes. If you fail to respond to an FDA request for additional information pursuant to 21 CFR 860.240(b)(1) (i.e., a supplement or amendment to revise existing information or provide additional information), FDA will issue a notice of withdrawal (deletion letter) stating that it considers your De Novo request to be withdrawn (21 CFR 860.250(a)(1)). You must pay the De Novo fee in effect at the time of the new De Novo request.

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

To facilitate the Agency's orderly issuance of refunds, you should submit a written request[23] for a refund to the appropriate Center in FDA within 180 calendar days after the fee was due.

For devices regulated by CDRH, requests for refunds should be submitted to the current mailing address displayed on the website https://www.fda.gov/cdrhsubmissionaddress.

For devices regulated by CBER, requests for refunds should be submitted to the current mailing address displayed on the website https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper.

[23] The user fee payment refund request form is available at https://www.fda.gov/media/96650/download

Appendix 1 – Information Summary Tables

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

De Novo Request Submission Type	De Novo Fee Required
Original De Novo request	Yes
Additional information for a De Novo request that has not yet been accepted	No
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
De Novo resubmitted after it has been withdrawn	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 after acceptance for review.	No
I fail to submit a valid eCopy or eSTAR before my Original De Novo request is accepted for review.	Yes
I fail to submit a valid eCopy or eSTAR for a De Novo amendment or supplement and FDA considers the De Novo request withdrawn.	No
FDA determines my De Novo request does not meet the acceptance criteria during acceptance review.	Yes
FDA determines my eSTAR is incomplete and places the submission on hold.	Yes
I withdraw my eSTAR after it passes technical screening.	No

Table 3. What Fee Must I Pay for a New Device 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