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# **FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals**

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## **Guidance for Industry and Food and Drug Administration Staff**

**Document issued on September 9, 2019.**

**Document originally issued on October 2, 2017.**

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](mailto:DICE@fda.hhs.gov), or CBER's Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709, 240-402-8010 or [ocod@fda.hhs.gov](mailto: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. Identify all comments with the docket number FDA-2017-D-5712. Comments may not be acted upon by the Agency until the document is next revised or updated.

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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**

The Medical Device User Fee Amendments of 2017<sup>1</sup> (MDUFA IV) amended the Federal Food, Drug, and Cosmetic Act (the 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 device review process to meet certain performance goals and implement improvements for the medical device review process.

Performance goals were negotiated and agreed to under MDUFA IV for De Novo requests received in FY 2018-2022. These performance goals and process improvements are outlined in the MDUFA IV Commitment Letter from the Secretary of Health and Human Services (the Secretary) to Congress<sup>2</sup> and are further described below.

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<sup>1</sup> See Title II of the FDA Reauthorization Act of 2017 (Public Law 115-52).

<sup>2</sup> 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>.

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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 guidance means that something is suggested or recommended, but not required.

## **II. Scope**

This document describes:

- the different FDA actions that may be taken on De Novo requests;
- the effect each action has on goals under MDUFA IV for De Novo requests received in FY 2018-2022; and
- the different industry actions that may be taken on De Novo requests.

## **III. FDA Actions**

When a De Novo request has been accepted for substantive review, FDA may take any of the following actions after FDA conducts its review:

- issue an order granting a De Novo request for classification (granting order);
- issue an order declining a De Novo request for classification (decline order); or
- issue a request for additional information (AI request).

Further, the Agency may consider a De Novo request to be withdrawn if additional information is not provided within 180 days following issuance of a request for AI. In this instance, FDA may issue a notice of withdrawal. 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.

Of these FDA actions, issuing a granting order and issuing a decline order are considered MDUFA decisions, as defined in the MDUFA IV Commitment Letter.

The following sections describe the actions FDA may take on a De Novo request, explain when these actions may be appropriate, and discuss the effect that each action has on the review clock.

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### **A. Issue an Order Granting the Request to Classify the Device**

An order granting the De Novo request to classify the device (granting order) is a letter issued to the De Novo requester stating that FDA has determined that the device meets the criteria for classification into either class I or class II.<sup>3</sup> A granting order authorizes marketing of the device in the United States (U.S.), subject to specific statutory and regulatory requirements.

The criteria for granting a De Novo request are described in section 513(f)(2) of the FD&C Act. An order classifying the device shuts off the review clock, marks the end of FDA review, and is considered a final action.

### **B. Issue an Order Declining the Request**

An order declining the De Novo request (decline order) is a letter issued to a De Novo requester stating that FDA has determined that either: a) the device is not eligible for De Novo classification; or b) the device is eligible for De Novo classification, but the requester has not demonstrated that the device described in the De Novo request meets the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)) for classification into class I or class II. Therefore, the request is declined and the device remains in class III (Premarket Approval).

In general, FDA issues a decline order in the following situations:

- the product does not meet the definition of a medical device under section 201(h) of the FD&C Act (21 U.S.C. 321(h));
- the device is not eligible for De Novo classification because an approved PMA exists for the device type;
- the device is not eligible for De Novo classification because it is of a type which has already been classified into class I, class II, or class III in an existing classification regulation;
- the device is not eligible for De Novo classification because it is probable that the device could be determined to be substantially equivalent (SE) to a predicate device (i.e., a device that has already been classified within an existing class I or class II classification regulation or an unclassified preamendments device), and the requester should submit a 510(k) instead;
- the device is eligible for De Novo classification, but the information provided, including performance data, was insufficient (e.g., data that are inadequate or

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<sup>3</sup> See section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)).

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- inconclusive) to demonstrate that the probable benefits of the device outweigh the probable risks; or
- the device is eligible for De Novo classification, but the information provided, including performance data, was insufficient (e.g., data that are inadequate or inconclusive) to demonstrate that general controls alone or that general and special controls together are sufficient to mitigate the probable risks to health so as to provide a reasonable assurance of safety and effectiveness.

A decline order shuts off the review clock, marks the end of FDA review, and is considered a final action.

### **C. Request for Additional Information**

FDA issues a request for additional information (AI request) when the De Novo request lacks information necessary for the Agency to continue or complete the substantive review and determine whether to grant or decline the De Novo request. AI requests are issued by email with an attachment document identifying deficiencies.<sup>4</sup> These requests inform the requester that the De Novo is being placed on hold pending receipt of a complete response to all of the identified deficiencies. The hold starts on the issue date of the AI request.

FDA generally issues an AI request when FDA believes the additional information needed from the requester is not suitable for interactive review and/or cannot be provided within a reasonable period of time (i.e., such that the review would be unduly delayed if the submission were not placed on hold).

An AI request is an interim action that stops the review clock and marks the end of an FDA review cycle. The review clock will resume upon the receipt of a complete response to the AI request in the appropriate Document Control Center (DCC).

### **D. Issue a Notice of Withdrawal**

A notice of withdrawal informs the De Novo requester that FDA considers the De Novo request to be withdrawn. The notice of withdrawal represents an FDA decision to discontinue its review of the De Novo request because the requester failed to submit a timely and complete response to an AI request that placed the submission on hold or the FDA receives a request to withdraw a De Novo request from the requester.

FDA intends to consider a De Novo request to be withdrawn if FDA does not receive, in a submission to the appropriate Center's Document Control Center, a complete response to all of the deficiencies in the AI request within 180 days of the date of that AI request.

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<sup>4</sup> Please note that AI requests from CBER will be issued according to [SOPP 8119: Use of Email for Regulatory Communications](#).

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Because the De Novo request is on hold at the time the Agency issues a notice of withdrawal, an FDA notice of withdrawal does not affect the review clock. Issuance of the notice of withdrawal shuts off the review clock, marks the end of FDA review, and is considered a final action.

### **IV. De Novo Performance Goals for MDUFA IV**

The performance goals for De Novo requests received from FY 2018 through FY 2022 (the time frame defined for MDUFA IV) are defined in the MDUFA IV Commitment Letter. Performance goals and associated changes to be implemented in MDUFA IV include:

- most De Novo requests are subject to a user fee;
- FDA will issue draft and final guidance that includes a submission checklist to facilitate a more efficient and timely review process;
- De Novo requests are subject to a one-tier MDUFA decision goal (there are no “cycle” (or review cycle) goals for interim actions); and
- for De Novo requests for which a MDUFA decision has not been rendered within 180 FDA days, at the requester’s request and resources permitting, FDA will discuss with the requester all outstanding issues with the submission preventing FDA from reaching a decision.

#### **A. Submission**

Most De Novo requests will be subject to a user fee as described in the guidance document entitled “[User Fees and Refunds for De Novo Classification Requests](#),”<sup>5</sup> and all De Novo requests will be subject to the requirement for an eCopy. FDA is authorized by section 745A(b)(1) of the FD&C Act (21 U.S.C. 379k-1(b)(1)) to implement eCopy requirements for De Novo requests after the issuance of final guidance. Please see the guidance entitled “[eCopy Program for Medical Device Submissions](#),”<sup>6</sup> for more information about eCopy requirements.

De Novo requests will not be processed and distributed to the appropriate Office for review without confirmation of user fee payment and a validated eCopy.

#### **B. Acceptance Review**

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<sup>5</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-de-novo-classification-requests>

<sup>6</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>



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Within 15 calendar days of receipt, FDA will conduct an Acceptance Review to determine whether the submission is complete and can be accepted for substantive review. If the submission has been found incomplete, within 15 calendar days FDA will notify the requester that the submission has not been accepted and identify those items that are the basis for the refuse to accept (RTA) decision and are therefore necessary for the submission to be considered accepted. The submission will be placed on hold and the review clock will not start until the missing elements are provided. For additional information, please refer to the guidance, “[Acceptance Review for De Novo Classification Requests](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests).”<sup>7</sup>

This communication represents an administrative review of the submission and is not indicative of deficiencies that may be identified later in the review cycle.

### **C. Substantive Interaction**

Once the submission has been accepted for review (i.e., after the RTA phase of review), FDA will conduct a substantive review and communicate with the requester through a Substantive Interaction. The Substantive Interaction communication can be an AI request (which stops the clock) or an email stating that FDA will attempt to resolve any outstanding deficiencies interactively in real-time, without stopping the FDA review clock (Interactive Review).

Following a Substantive Interaction, FDA intends to work with the requester via Interactive Review to reach a MDUFA decision.

### **D. MDUFA IV Goals**

MDUFA IV includes a goal for a MDUFA decision (see Table 1 below), defined in terms of FDA Days, which are calendar days when a submission is considered to be under review at the Agency. FDA Days begin on the date of receipt of the submission (i.e., user fee is paid and a validated eCopy is provided).

**Table 1. De Novo Performance Goals**

Action	Review Time (FDA days)	Performance Level (by Fiscal Year)				
		FY2018	FY2019	FY2020	FY2021	FY2022
MDUFA Decision (grant/decline)	150	50%	55%	60%	65%	70%

### **E. Missed MDUFA Decision Communication**

At Industry’s request and as resources permit, but not to the detriment of meeting the quantitative review timelines, if a final decision has not been rendered within 180 FDA days, FDA will discuss with the requester, in a meeting or teleconference, all outstanding issues with the submission preventing FDA from reaching a decision. This discussion will reflect

<sup>7</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests>

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appropriate management input and approval, and will include action items for FDA and/or the requester, as appropriate, with an estimated date of completion for each party to complete their respective tasks.

## **V. Requester Actions**

Actions taken by the requester of a pending De Novo request may include submission of a response to FDA's AI request (i.e., not a request made via interactive review) or withdrawal of the De Novo request (either by submission of a request for withdrawal to the respective Center's DCC or by not responding to an FDA AI request within 180 days). The information below describes the actions a requester may take and the effect each action has on the FDA review clock.

As with the original De Novo request, any amendment or supplement to a De Novo request or a request to withdraw a De Novo request will need to include an eCopy as part of the submission to the appropriate DCC for the submission to be processed as described in the guidance document entitled "[eCopy Program for Medical Device Submissions](#)."<sup>8</sup>

### **A. Response to an AI Request**

A response to an FDA AI request is the submission of additional information, addressing all of the deficiencies identified in that AI request, that allows FDA to continue or complete the substantive review and reach a decision on the De Novo request.

The requester should provide a complete response to an AI request from FDA. The response should address all of the deficiencies identified by FDA in its AI request to be considered a complete response.

The requester's submission of a response to an AI request is an action that, upon receipt by FDA, resumes the FDA review clock (i.e., the 150-day review clock resumes upon receipt of the additional information).

Note: If FDA determines that the requester has not addressed one or more of the deficiencies identified in the AI request, the review cycle will be terminated until FDA receives a response addressing the remaining deficiencies. In such a case, FDA informs the requester by letter, fax, or e-mail that the response is incomplete and the De Novo request will be placed back on hold as of the date of the original AI request; therefore, the review clock has not resumed. The requester will have 180 days from the date of the original AI request in which to submit a complete response, or the De Novo request will be considered to be withdrawn.

### **B. Request for Withdrawal of the De Novo Request**

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<sup>8</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions>

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A request to withdraw a De Novo request informs FDA of the requester's intent to discontinue its pursuit of FDA review of the De Novo request.

The De Novo requester may request withdrawal of the pending De Novo request at any time, and for any reason, after it is submitted for review but before FDA renders its final decision. FDA does not consider requests for withdrawal after a final decision has been rendered.

The requester's request to withdraw a pending De Novo request shuts off the review clock, marks the end of FDA review, and is considered a final action. If the De Novo request is under review at the time FDA receives the withdrawal request, the review clock will stop on that date. If the De Novo request is on hold at the time FDA receives the withdrawal request, the review clock will remain stopped as of the date the De Novo request was last placed on hold.