



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6069]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0844. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

De Novo Classification Process (Evaluation of Automatic Class III Designation)

OMB Control Number 0910-0844--Revision

The draft guidance entitled “Acceptance Review for De Novo Classification Requests” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests>) explains the procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review. The draft guidance discusses De Novo acceptance review policies and procedures, “Refuse to Accept” principles, and the elements of the De Novo Acceptance Checklist and the Recommended Content Checklist and was issued to be responsive to an explicit deliverable identified in the Medical Device User Fee Amendments of 2017.

To aid in the acceptance review, the guidance recommends that requesters complete and submit with their De Novo request an Acceptance Checklist that identifies the location of supporting information for each acceptance element and a Recommended Content Checklist that identifies the location of supporting information for each recommended content element.

Therefore, we request revision of OMB control number 0910-0844, “De Novo Classification Process (Evaluation of Automatic Class III Designation)” to include the Acceptance Checklist and the Recommended Content Checklist in the hourly burden estimate for De Novo requests.

Respondents to the information collection are medical device manufacturers seeking to market medical device products through submission of a De Novo classification request under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)).

In the *Federal Register* of October 30, 2017 (82 FR 50135), FDA published a 60-day notice requesting public comment on the draft guidance and the proposed collection of information. We received various comments on the draft guidance. We describe and respond to the comments related to the proposed information collection in the following paragraphs. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same set of comments and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

(Comment 1) One comment proposed that, in section VII.B of the draft guidance (“Prior Submission(s) Relevant to the De Novo Request Under Review”), FDA revise the phrase “For certain De Novo requests, the requester may have previously provided other submissions for the same device for which FDA provided feedback related to the data or information needed to support De Novo classification (e.g., a pre-submission request, investigational device exemption, prior Not Substantially Equivalent (NSE) determination, or prior 510(k) or De Novo that was deleted or withdrawn)” to read, “For certain De Novo requests, the requester may have previously provided other submissions, or there may be related FDA correspondence or other relevant information for the same device, for which FDA provided feedback related to the data or information needed to support De Novo classification...” The commenter noted that there may be informal correspondence that is pertinent to the De Novo and this should be explicitly requested in the “Recommended Content Checklist” in Appendix B.

(Response 1) FDA does not agree with the proposed revision. This element was intended to specifically focus on pertinent premarket submissions and formal communications that have undergone supervisory review.

(Comment 2) One comment suggested that elements identified as “N/A” should require an accompanying rationale because an inadvertent selection of a N/A answer may result in a “Refuse to Accept” (RTA) decision.

(Response 2) We do not agree with this comment. Selection of “N/A” for any element would not lead to an RTA decision. As explained in section VI.C of the guidance, “...the item should receive an answer of “yes” or “N/A” for the De Novo request to be accepted for substantive review.”

(Comment 3) Two commenters suggested that the preliminary questions in Appendix A (“Acceptance Checklist for De Novo Classification Requests”) of the guidance should be removed and included in a document to be used by FDA reviewers or should clarify that these are to be completed by FDA personnel only. FDA recommends that requesters complete the checklists in Appendices A and B (“Recommended Content Checklist for De Novo Classification Requests”); however, the preliminary questions are intended for FDA reviewers.

(Response 3) We do not agree with these commenters. The instructions for the Preliminary Questions within the checklist in Appendix A clearly state that “Boxes checked in this section represent FDA’s preliminary assessment of these questions at the time of administrative review.”

(Comment 4) Two commenters proposed that the Organizational Elements in Appendix A be removed or included in Appendix B instead. The commenters noted that these

organizational elements should not result in an RTA designation and, as such, should not be present in Appendix A.

(Response 4) We decline to make this change. These are important administrative elements that will allow the FDA reviewer to determine if the submission is sufficiently organized in order to perform the subsequent RTA review.

(Comment 5) Two commenters proposed that, in Appendix A of the draft guidance, under the section “Elements of a Complete De Novo Request,” we remove the second and third paragraphs from Question 1a, or move them to Appendix B. Question 1a requests “[a] description of the technology (features, materials, and principles of operation) for achieving the intended effect.” The commenters assert that the second and third paragraphs begin to assess “the sufficiency” of the device description by necessitating detailed device information for acceptance of the De Novo request. In addition, the commenter believes the language in the second paragraph (“Where necessary to describe the device,...”) is subjective and would necessitate a substantive review of the device description to determine adequacy.

(Response 5) We do not agree with the commenters’ description. Because of the wide variety of device types reviewed through the De Novo Program, the reviewer needs flexibility to determine if engineering or representative drawings are necessary for a complete device description. This element is only requesting the inclusion of such information; it is not asking the reviewer to determine the adequacy of the information.

(Comment 6) One comment proposed that, in Appendix A of the draft guidance, under section C of “Elements of a Complete De Novo Request,” FDA remove the phrase “detailed information and” in the prefaces to questions 3 through 7. The commenter believes that this

request for “detailed information” exceeds the intention of the RTA review which would simply assess the presence of information or a rationale, if not present.

(Response 6) We do not agree with this suggestion. The language in question states “To the extent that the submission relies upon the following information to provide detailed information and reasons for the recommended classification, the De Novo request provides the following...”--therefore the request for the purposes of the Checklist is not for the “detailed information,” per se, but rather identifying aspects of the submission for which detailed information will be evaluated during substantive review. Consistent with the policy outlined in the guidance, reviewers will not conduct a detailed review of such information during the RTA phase.

(Comment 7) A comment requested clarity on the extent of information, and location of such information, to be included regarding clinical studies conducted outside the United States.

(Response 7) The element requesting a summary and full study report for clinical studies (Appendix B, Section E, Question 6) does not require or specify the source of clinical study information. Therefore, we disagree that additional revision to this element is necessary--this pertains to clinical data from studies conducted either within or outside the United States.

(Comment 8) A comment proposed we remove questions 2b and 2c from section D of the Acceptance Checklist, requesting information to be included as part of the Financial Certification (Form FDA 3454) and Financial Disclosure (Form FDA 3455) forms. The commenter believes that the requested information in these questions should be reviewed during substantive review of the De Novo request.

(Response 8) We do not agree. These questions are ensuring that required content in the Financial Certification Forms are included for review. We are not assessing the adequacy of the content.

(Comment 9) A comment proposed that we move element 1 in Appendix B, Section A, requesting “all content used to support the De Novo request is written in English,” to the Acceptance Checklist in Appendix A. One would expect that content be provided in English in order to conduct a substantive review of the De Novo request.

(Response 9) We decline to make this change. There is no statutory requirement for providing documentation in English.

(Comment 10) A comment recommends that further guidance “explicitly and specifically incorporate least burdensome concepts.” The commenter believes that the draft guidance outlines processes that may not embody least burdensome principles.

(Response 10) We have not made changes based on this comment. FDA defines least burdensome to be the minimum amount of information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time. The least burdensome provisions and guiding principles do not change the applicable regulatory or statutory requirements. We believe the recommendations in the guidance are consistent with the least burdensome provisions and guiding principles, and we apply them in identifying what FDA believes to be the minimum information that the Agency relies on to complete premarket submission review in the most efficient manner. For information on the least burdensome provisions, refer to FDA’s guidance for industry, “The Least Burdensome Provisions: Concept and Principles” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles>).

(Comment 11) A comment requested that FDA provide clarification on the RTA process, as the draft guidance suggests a De Novo request could be refused based upon “immaterial issues.” The commenter recommends addition of a “materiality standard” that would limit refusal to accept a De Novo request “to instances where the missing information is both material and relevant to the assessment of the safety or efficiency [sic]of the device.”

(Response 11) We consider the “materiality standard” that the commenter proposes, i.e., that the scope for denial of a review is limited to instances where the missing information is both material and relevant to the assessment of the safety or effectiveness of the device, to be the fundamental basis for the Acceptance Checklist in Appendix A. Elements requested in Appendix A are required by statute and applicable regulations and, as such, we consider these to be material and relevant to the substantive review of the De Novo request.

(Comment 12) One comment proposed that FDA staff should be able to use discretion in order to request missing checklist items interactively, rather than to RTA when there are one or more items missing from the Acceptance Checklist as described in section III.A of the guidance. This would aid in ensuring a least burdensome approach was applied to this process.

(Response 12) We do not believe that revisions are necessary in response to this comment. Within section III.A, the guidance states that “FDA staff also has discretion to request missing checklist items interactively from requesters during the RTA review. Interaction during the RTA reviews is dependent on FDA staff’s determination that outstanding issues are appropriate for interactive review and that adequate time is available for the requester to provide supporting information and for FDA staff to assess responses.”

We believe the recommendations in the guidance are consistent with the least burdensome provisions and guiding principles, and we apply them in identifying what FDA

believes to be the minimum information that the Agency relies on to complete premarket submission review in the most efficient manner. For information on the least burdensome provisions, refer to FDA’s guidance, “The Least Burdensome Provisions: Concept and Principles.”

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Total Operating and Maintenance Costs
De Novo requests						
De Novo request under 21 U.S.C. 513(f)(2)(A)(i)						
CDRH	2	1	2	100	200	
CBER	1	1	1	100	100	
De Novo request under 21 U.S.C. 513(f)(2)(A)(ii)						
CDRH	56	1	56	180	10,080	
CBER	1	1	1	180	180	
Acceptance Checklist	60	1	60	1	60	
Recommended Content Checklist	60	1	60	1	60	
Total De Novo requests			60		10,680	\$7,278
Request for withdrawal <sup>2</sup>	5	1	5	10	50	\$5
Total					10,730	\$7,283

<sup>1</sup> There are no capital costs associated with this collection of information.

<sup>2</sup> No change from approved information collection. This information is retained for the convenience of the reader.

Based on updated program data and trends, we expect to receive approximately 60 De Novo requests per year. We have not changed our estimates of the Average Burden per Response for De Novo requests.

We estimate that it will take approximately 1 hour to prepare an Acceptance Checklist and 1 hour to prepare a Recommended Content Checklist. Our estimate assumes that each De Novo request will include both checklists.

Approved operating and maintenance costs for a De Novo request include printing, shipping, and eCopy costs. We have updated the operating and maintenance costs to account for

the updated burden estimate for De Novo requests (resulting in an increase of \$970 to the total estimated operating and maintenance costs). However, we believe any increase of the operating and maintenance cost resulting from the addition of the Acceptance Checklist and Recommended Content Checklist to be de minimis.

The operating and maintenance cost for a De Novo submission includes the cost of printing, shipping, and the eCopy. We estimate the cost burden for a De Novo submission, including the Acceptance Checklist and Recommended Content Checklist, to be \$121.30 (\$90 printing + \$30 shipping + \$1.30 eCopy). The annual cost estimate for De Novo submissions is \$7,278 (60 submissions × \$121.30). We estimate the cost for a request for withdrawal to be \$1 (rounded) (\$0.09 printing 1 page + \$0.03 shipping + \$1.30 eCopy). The annual cost estimate for requests for withdrawal is \$5.

Our estimated burden for the information collection reflects an overall increase of 3,400 hours. We attribute this adjustment to the addition of the Acceptance Checklist and the Recommended Content Checklist and to an increase in the number of submissions we received during the approval period. For clarity, we have separated the Acceptance Checklist and Recommended Content Checklist into distinct line-items in table 1.

Dated: June 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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