Dated: December 17, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2149]

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) 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: Submit written comments (including recommendations) on the collection of information by January 29, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 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.*

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)—21 CFR Part 860, Subpart D

OMB Control Number 0910–0844—Revision

This information collection supports FDA regulations and information collection discussed in associated guidance. Sections 201(h), 513(a) and (f), 701(a), and 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(h), 360c(a) and (f), 371(a), and 374) establish a comprehensive system for the regulation of medical devices intended for human use. Section 513(f)(2) of the FD&C Act provides for a ''De Novo'' classification process, most recently amended by section 3101 of the 21st Century Cures Act (Pub. L. 114–255). The final rule ''Medical Device De Novo Classification Process'' (86 FR 54826), established part 860, subpart D (21 CFR part 860, subpart D) (§§ 860.200 through 860.260) to implement provisions in section 513(f)(2) of the FD&C Act. These regulations govern format and content elements for De Novo device classification requests, as well as withdrawal of the requests, and explain FDA procedures for acceptance, review, and granting or denying a request.

FDA's guidance for industry and FDA staff, ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'', provides guidance on the process for the submission and review of a De Novo classification request under section 513(f)(2) of the FD&C Act, also known as the De Novo classification process. This process provides a pathway to class I or class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

In addition to regulatory requirements set forth in part 860, subpart D, the guidance document entitled ''Acceptance Review for De Novo Classification Requests'' communicates our thinking on criteria set out in § 860.230, in assessing whether a De Novo request should be accepted for substantive review. The guidance document includes an ''Acceptance Checklist'' to assist respondents in this regard.

The guidance document ''Electronic Submission Template for Medical Device De Novo Requests,'' provides the standards for the submission of De Novo requests by electronic format, a timetable for establishment of these standards, and criteria for waivers of and exemptions from the requirements to meet a statutory requirement. This guidance is also intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.

The collections of information described by this notice are necessary to satisfy the previously mentioned statutory requirements for administration of this voluntary submission program. FDA uses the information to evaluate whether a medical device may be reclassified from class III into class I or II and, if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device. Respondents to this information collection are private sector or other for-profit businesses.

In the **Federal Register** of May 29, 2024 (89 FR 46402), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part 860, subpart D; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 860.210, 860.220, 860.230; De Novo requests—format, content, and acceptance elements.	79	1	79	182	14,378
§ 860.230; FDA acceptance of request (*GFI Acceptance Checklist;* Appendix A) [1].	79	1	79		

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR part 860, subpart D; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 860.250; withdrawal of request	5	1	5	0.17 (10 mins.)	1
Total					14,379

[1] FDA assumes activities associated with review of the Acceptance Checklist are included in burden for submission of requests captured in row 1.

Our estimated burden for the information collection reflects an overall increase of 2,002 hours and a corresponding increase of 11 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years. Since the publication of the 60-day notice, we issued the guidance document entitled ''Electronic Submission Template for Medical Device De Novo Requests'' (August 23, 2024, 89 FR 68166; *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-de-novo-requests*) and are including it in this information collection. Given that all submissions were previously received electronically and the ability to voluntarily submit De Novo requests using eSTAR was included in the previous information collection request (ICR), inclusion of the guidance in this ICR is not expected to impact the estimated burden.

Dated: December 13, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Request for Nominations of Individuals and Industry Organizations for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is requesting that any industry organizations interested in participating in the selection of a pool of nonvoting industry representatives to serve as temporary nonvoting members on the Patient Engagement Advisory Committee (the Committee) in the Center for Devices and Radiological Health notify FDA in writing. FDA is also requesting nominations for temporary nonvoting industry representatives to be included in a pool of individuals to serve on the Committee. Nominees recommended to serve as a temporary nonvoting industry representative may either be self-nominated or nominated by an industry organization. This position may be filled by representatives from different medical device areas based on expertise relevant to the topics being considered by the Committee. Nominations will be accepted for upcoming vacancies effective with this notice. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest must send a letter stating that interest to the FDA by January 29, 2025, (see sections I and II of this document for details). Concurrently, nomination materials for prospective candidates should be sent to FDA by January 29, 2025.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of a pool of nonvoting industry representatives should be sent electronically to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5213, Silver Spring, MD 20993–0002, 301–796–5960, email: *margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for a pool of nonvoting industry representatives for the Committee. The list of needed expertise on May 1, 2025, is identified below:

- Cybersecurity
- Communication of Benefit & Risk Information to Patients; Medical Device Labeling
- Digital Health Technology/Artificial Intelligence
- Health Equity
- Patient Engagement
- Patient Preference Elicitation
- Patient-Reported Outcomes Development, Validation, and Use in Regulatory Studies or Clinical Practice
- Postmarket Studies, Including Observational and Registry-Based Studies
- Human Factors

FDA is publishing separate documents regarding:

1. Request for Nominations for Voting Members for the Patient Engagement Advisory Committee
2. Request for Nominations for Consumer Representative for the Patient Engagement Advisory Committee

I. General Description of the Committee's Duties

The Committee provides advice on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or