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.

[FR Doc. 2024–31014 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

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

health status issues are among the topics that may be considered by the Committee. Members are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks and clinical outcomes to patients and research subjects. The Commissioner of Food and Drugs (the Commissioner), or designee, shall have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic(s).

II. Qualifications

Persons nominated for the Patient Engagement Advisory Committee should be full-time employees of firms that manufacture medical device products, or consulting firms that represent manufacturers or have similar appropriate ties to industry.

III. Selection Procedure

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 contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current résumés or curriculum vitae. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate or candidates (to serve in a pool of individuals with varying areas of expertise) to represent industry interest for the Committee, within 60 days after the receipt of the FDA letter. The interested organizations are not bound by the list of nominees in selecting a candidate or candidates. However, if no individual is selected within 60 days, the Commissioner will select temporary nonvoting members (or pool of individuals) to represent industry interests.

IV. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a temporary nonvoting industry representative. Nominations must include a cover letter and a current, complete résumé or curriculum vitae for each nominee, including current business and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**). Nominations should specify the advisory committee for which the nominee is recommended within 30 days of publication of this document (see **DATES**). In addition, nominations should acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the Committee. Only interested industry organizations participate in the selection process. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31272 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0846]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled ''National Agriculture and Food Defense Strategy Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

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: On August 15, 2024, the Agency submitted a proposed collection of information entitled ''National Agriculture and Food Defense Strategy Survey'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0855. The approval expires on November 30, 2027. A copy of the supporting statement for this information collection is available on the internet at *https://www.reginfo.gov/public/do/PRAMain.*

Dated: December 16, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31298 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4597]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Shortages Data Collection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled ''Shortages Data Collection'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 20, 2024, the Agency submitted a proposed collection of information entitled ''Shortages Data Collection'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of