b. What are the categories of expertise, viewpoints, or voices that may not be relevant given the topic or product type that is the focus of the committee?

2. Are there ways that FDA can better ensure that a variety of diverse perspectives and experiences are incorporated into advisory committee meetings, and if so, how?

3. In some cases, there is a legal requirement to include a consumer or patient representative on advisory committees. In other cases, the charter of an advisory committee may allow for there to be a consumer or patient representative who is a voting member of the committee. Consumers and patients may also participate in the open public hearing or submit written comments to the docket for a particular advisory committee meeting. Are there ways that FDA can better incorporate the consumer or patient voice into advisory committee meetings, and if so, how?

B. Topic 2: Service on an Advisory Committee as a Special Government Employee (SGE)

4. Service on an advisory committee as an SGE gives individuals an opportunity to provide advice and recommendations on decisions that are often critical to protecting public health, but we understand that administrative burdens (*e.g.,* amount of onboarding paperwork and processing time) are sometimes a deterrent to SGE service. FDA is exploring ways to streamline the administrative requirements on SGEs for initial hiring and meeting preparation. While FDA must remain in compliance with federal laws around federal service, how might we mitigate administrative barriers to service for SGEs?

5. How can FDA otherwise improve the experience of advisory committee members?

C. Topic 3: Public Perception and Understanding of Advisory Committees

6. What do you perceive to be the public's awareness and understanding of the role of FDA advisory committees?

7. What steps can FDA take to improve public awareness and understanding of advisory committees and their role in providing advice and recommendations for FDA to consider in its decision-making?

8. How can FDA better communicate with the public about advisory committee meetings?

9. FDA's regulatory decisions are often, but not always, aligned with advisory committee recommendations. What steps can FDA take to clarify for the public that its regulatory decisions take the committee's recommendation into account, but that the committee's recommendations are only one of several factors considered?

10. There appears to be a persistent misconception that advisory committee votes are the final decision of the Agency on the matter considered by the committee. Is there a way that FDA could adjust the processes for discussion and/or voting that would improve public understanding of how FDA receives external advice through the exchange of information at advisory committee meetings, and the ultimate import of the advisory committee's discussion?

III. Participating in the Public Meeting

Registration: To register for the free public meeting, please visit the following website: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-meeting-optimizing-fdas-use-and-processes-advisory-committees-06132024.* Non-speaking attendees may register any time before or during the listening session. Individuals who wish to make presentations at the public meeting must register by the deadline described below.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in making an oral presentation at this public meeting must register by 3 p.m. EDT on May 13, 2024. Early registration is recommended. FDA may limit the number of participants from each organization due to technology constraints on the total number of participants. Registrants will receive confirmation when they have been accepted.

Information on requests for special accommodations due to a disability will be provided during registration.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the listening session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the deadline to register to make an oral presentation, we will determine the amount of time allotted to each presenter (which we expect to be approximately 5 minutes), the approximate time each oral presentation is to begin, and will select and notify participants by June 3, 2024. All requests to make oral presentations must be received by May 13, 2024, at 3 p.m. EDT. If selected for presentation, any presentation materials must be emailed to *ACfeedback@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) no later than June 7, 2024. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09014 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 May 30, 2024.

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 0910–0249. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

FDA Recall Regulations—21 CFR Part 7

OMB Control Number 0910–0249—Extension

This information collection helps support implementation of section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) pertaining to product recalls, and regulations in 21 CFR part 7, subpart C (21 CFR 7.40 through 7.59) promulgated to clarify and explain associated practices and procedures by FDA. Sections 7.49, 7.50, and 7.59 (21 CFR 7.49, 7.50, and 7.59) of the regulations apply specifically to product recalls, which may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Agency.

Recalls are terminated when all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy. The regulations also provide for corrective actions to be taken regarding violative products and establish specific guidelines that enable us to monitor and assess the effectiveness of a firm's efforts in this regard. The provisions include reporting to FDA on the initiation and termination of a recall, as well as submitting recall status reports and making required communication disclosures. The regulations also permit FDA to evaluate whether a recall has been completed in a manner which assures that unreasonable risk of substantial harm to the public health has been eliminated and that violative products have been corrected or removed from the market. Specific guidance regarding recalls is set forth in § 7.59, although product-specific guidance documents may also be developed to assist respondents to the information collection. Agency guidance documents are issued in accordance with our good guidance regulations in 21 CFR 10.115, which provide for public comment at any time.

Consistent with § 7.50, all recalls monitored by FDA are included in an ''Enforcement Report'' once they are classified and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Recall data in the Enforcement Report can be accessed through the weekly report publication, the quick and advanced search functionalities, and an Application Programming Interface (API). Instructions for navigating the report, accessing and using the API, and definitions of the report contents are found at *https://www.fda.gov/safety/enforcement-reports/enforcement-report-information-and-definitions.*

In the **Federal Register** of October 13, 2023, (88 FR 70995), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received offering general support for the information collection. The comment also suggested that reporting might be enhanced through the use of automated technology and that FDA monitor and utilize such technology to track improvement. Finally, the comment questioned the rationale for our estimate of the time necessary for preparing and submitting recall reports. Based on experience with compiling and submitting a report along with its attachments, the commenter communicated that less time was likely needed.

We appreciate this feedback and will continue to monitor burden associated with product recall activity. We also continue to look for ways to enhance our IT systems as our limited resources allow and public health priorities require. With regard to our current estimates, we note that our figures reflect what we believe to be the average burden incurred among more than 2,000 respondents, and in conjunction with more than 30,000 reports, annually, and therefore we have made no adjustment in our assumptions at this time.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm initiated recall; § 7.46	2,309	1	2,309	25	57,725
Termination of recall; § 7.55	2,128	1	2,128	10	21,280
Recall status reports; § 7.53	2,309	13	30,017	10	300,170
Total			34,454		379,175

[1] There are no capital or operating and maintenance costs associated with this collection.

A review of Agency data shows that 6,928 recall events were conducted during fiscal years 2020 through 2022, for an average of 2,309 recalls annually. We assume an average of 25 hours is needed to submit the requisite notification to FDA, for a total annual burden of 57,725 hours. Similarly, during the same period, 6,385 recalls were terminated, for an average of 2,128 recall terminations annually, and we assume an average of 10 hours is needed for the corresponding information collection activity. To determine burden associated with recall status reports, we multiplied the average number of annual respondents (2,309) by the average number of status reports per recall (13), producing the number annual submissions (30,017), which, assuming 10 hours per response, results in a burden of 300,170 hours annually.

TABLE 2—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall communications; § 7.49	2,309	1,108	2,559,200	0.05 (3 minutes)	127,960

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

To determine burden associated with recall communication disclosures described in § 7.49, we calculated an average of 1,108 disclosures per recall and attribute 3 minutes for each disclosure, resulting in 127,960 burden hours annually. We provide no estimate for recordkeeping in § 7.59 as these activities are provided as guidance only, and we regard them to be usual and customary to these respondents.

Cumulatively, these adjustments reflect an overall decrease in our estimate, which we attribute to a corresponding decrease in FDA-regulated product recalls since our last evaluation of the information collection.

Dated: April 24, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09177 Filed 4–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Research Opportunities for New Investigators to Promote Workforce Diversity.

Date: May 23, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Boulevard, Room 8351, Bethesda, MD 20892, (301) 451–6339, *kellya2@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; U01 Cooperative Agreement for Clinical Trials in Hearing Disorders.

Date: May 28, 2024.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Sonia Elena Nanescu, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496–8683, *sonia.nanescu@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; R25 Education Grant Review.

Date: May 29, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Boulevard, Room 8351, Bethesda, MD 20892, (301) 451–6339, *kellya2@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Cooperative Agreement for Clinical Trials in Communication Disorders.

Date: May 31, 2024.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Sonia Elena Nanescu, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496–8683, *sonia.nanescu@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Inner Ear Imaging RFA.

Date: June 6, 2024.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852, 301–402–3587, *rayk@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing and Balance Fellowships Review.

Date: June 12, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852, 301–402–3587, *rayk@nidcd.nih.gov.*

Name of Committee: Communication Disorders Review Committee.

Date: June 13–14, 2024.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, Bethesda, One Bethesda Metro Center, Bethesda, MD 20814 (In-Person and Virtual).

Contact Person: Katherine Shim, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Bethesda, MD 20892, 301–496–8683, *shimk@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Chemosensory Fellowship Review.

Date: June 17, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Boulevard, Room 8351, Bethesda, MD 20892, (301) 451–6339, *kellya2@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Voice, Speech, and Language Fellowship Review.

Date: June 18, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Sonia Elena Nanescu, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496–8683, *sonia.nanescu@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Clinical Research Center Grant (P50) Review.

Date: June 26, 2024.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).