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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1809]

Listening Session: Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled "Listening Session: Optimizing FDA's Use of and Processes for Advisory Committees." The purpose of the listening session is to solicit feedback on the Agency's use of and processes for its advisory committee system.

DATES: The virtual listening session will be held on June 13, 2024, from 9 a.m. to 4 p.m. Eastern Daylight Time (EDT) or until after the last public commenter has spoken, whichever occurs first. Submit requests to make oral presentations at the listening session by 3 p.m. EDT, May 13, 2024. Electronic or written comments on this listening session must be submitted to the docket by August 13, 2024. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: Additional details, such as registration information, are available at: www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-meeting-optimizing-fdas-use-and-processes-advisory-committees-06132024.

FDA is establishing a public docket for this listening session. You may submit comments as follows. Please note that late, untimely filed comments may not be considered. Electronic comments must be submitted on or before August 13, 2024. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. EDT on August 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper

submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2024-N-1809 for " Listening Session: Optimizing FDA's Use of and Processes for Advisory Committees." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed

confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Jill Wasserman, Stakeholder Engagement Staff, Office of External Affairs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5367, Silver Spring, MD 20993, 240-623-6945, (this is not a toll-free number), email: ACfeedback@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Advisory committees comprised of external advisors support FDA's mission of protecting and promoting the public health by providing us with independent advice on scientific, technical, and policy matters. FDA makes the final decisions on any matters considered by an advisory committee.

Committees are either mandated by statute or established at FDA's discretion. Advisory committees must meet the requirements set forth in the Federal Advisory Committee Act (5 U.S.C. 1001 et seq.). General procedures for FDA advisory committees are included in FDA's regulations at 21 CFR part 14.

The products that FDA regulates can impact the daily lives of the American public, and advisory committee are an important part of FDA's regulatory processes. While the Agency hears frequently from certain groups about advisory committees, we are interested in more broadly hearing from all parties interested in the advisory committee process and how advisory committees inform FDA's decisions. We are hosting this virtual public meeting to give an open and transparent platform for feedback on advisory committees.

II. Topics for Comment at the Public Meeting

We have listed the specific topics on which FDA is seeking input below. Input may be provided orally, during the virtual public meeting on June 13, 2024, or via written comments to the docket referenced above. In all cases, FDA encourages respondents to provide the specific rationale and basis for their comments, including any available supporting data and information. Respondents need not address all topics listed. Please identify your answers as responses to a specific topic.

A. Topic 1: Composition of Advisory Committees:

1. The membership of a committee, which is set by each committee's charter, typically varies depending on the focus of the committee and topics for particular meetings. In some cases, the composition of a particular committee may be set by law.[1] To the extent there is flexibility in determining the composition of a committee or the expertise present at particular meetings:

a. What are the categories of expertise, viewpoints, or voices that are particularly important for representation on advisory committees?

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):

[1] *E.g.*, 21 U.S.C. 387q (detailing requirements for composition of the Tobacco Products Scientific Advisory Committee).

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: 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.

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