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# **Draft Guidance for FDA Advisory Committee Members and FDA Staff: Voting Procedures for Advisory Committee Meetings**

## *Draft Guidance*

**This guidance is for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document, please contact the Advisory Committee Oversight and Management Staff at 301-827-1220

**U.S. Department of Health and Human Services  
Food and Drug Administration**

**November 2007**

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**U.S. Department of Health and Human Services  
Food and Drug Administration**

**November 2007  
Voting Procedures for Advisory Committee Meetings**

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate staff, call the appropriate number listed on the title page of this guidance.

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<sup>1</sup> This guidance has been prepared by the Office of Policy, Planning, and Preparedness in the Office of the Commissioner in conjunction with the Agency's Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM), Center for Devices and Radiological Health (CDRH), Center for Biologic Evaluation and Research (CBER), and Center for Food Safety and Applied Nutrition (CFSAN).

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#### **I. Introduction**

This draft guidance provides guidance on advisory committee voting procedures and is intended for use by FDA advisory committee members and FDA staff involved with advisory committee matters. This document recommends uniform procedures that can be used for the voting process when votes are taken during advisory committee meetings. This document does not define when votes should be taken.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

#### **II. Background**

FDA's advisory committees provide independent expert advice to the agency on a range of complex scientific, technical, and policy issues, including questions related to the development and evaluation of products regulated by FDA. Advisory committees are a valuable resource to FDA, and they make an important contribution to the agency's decision-making processes. Although advisory committees provide recommendations to FDA, FDA makes the final decisions.

Advisory committees typically communicate advice or recommendations to the agency in two ways. First, committee members routinely share their individual thoughts and recommendations during the discussion of a particular matter at an advisory committee meeting. Second, advisory committees often vote on a question or series of questions posed to the committee during a committee meeting. As the agency makes its final decision, FDA seriously considers the recommendations made by advisory committees, including the advisory committee deliberations and voting.

This document provides guidance on the procedures used for voting.

There are some advisory committee meetings at which votes are not taken. For example, votes are typically not taken at meetings to discuss the development of a clinical trial design or the development of a guidance document.

At other advisory committee meetings, members cast a formal vote on issues related to the approvability of a product submission. In others, different questions may be posed to a committee for a formal vote. Votes can be an effective means of communicating with FDA because they provide feedback on discrete questions. These questions are generally scientific in nature and can involve a range of subjects, including evaluation of post-market safety data or pre-market assessment of a product's risk/benefit profile.

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Since all members vote on the same question, the results help FDA gauge a committee's collective view on complex, multi-faceted issues. FDA recognizes that many of the questions voted on by advisory committee members are complex and that the discussion that accompanies the voting is an important element in understanding the voting. The discussion, together with the votes, helps inform the agency's own deliberations on scientific and regulatory matters.

Accordingly, FDA recommends adopting uniform voting procedures to help maximize the integrity and meaning of voting results. In developing these recommendations, FDA is mindful of the legal requirements of the Federal Advisory Committee Act (FACA), other relevant statutes (e.g., the Federal Food, Drug, and Cosmetic Act), regulations (e.g., 21 CFR Part 14), guidance, and policies, and the goals of FDA's advisory committee program.

Transparency and public participation are critical features of the advisory committee process. The use of secret ballots, long a hallmark of the American electoral experience, generally is not appropriate in the advisory committee context because the expert opinion of each member should be clearly understood and identified with that expert. Nevertheless, even with public balloting, the voting process can be managed to help maximize the integrity and utility of the outcome.

There has been much discussion inside and outside FDA regarding sequential versus simultaneous voting. Some have expressed concern that sequential voting, in which members cast public votes in turn, has the potential to compromise the integrity of the result.

For example, scholars and social scientists have studied the risk of "momentum" in sequential voting, exploring whether some sequential voters may be influenced, perhaps even subconsciously, by the votes that precede theirs, especially if those votes are nearly identical or signal a clear trend<sup>2</sup>. This potential risk may be aggravated in the advisory committee setting, where votes are often conducted in full view of a passionate public and participatory audience. In the case of sequential voting, there is also a potential risk that comments made by a committee member or a designated federal officer (DFO) during the vote could inappropriately affect the deliberations of those who have not yet voted. Another potential risk is that comments could alter the meaning (or interpretation) of the question at issue in such a way as to cast doubt on whether all the members voted on the identical question.

### **III. Policy**

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<sup>2</sup> See, e.g., Callander, S. (2007): "Bandwagons and Momentum in Sequential Voting," *Review of Economic Studies*, 74, 653-684; Banerjee, A. (1992): "A Simple Model of Herd Behavior," *Quarterly Journal of Economics*, 107, 797-817.

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Accordingly, to help maximize the integrity, consistency, and utility of advisory committee voting results, FDA recommends that the voting process include the following procedures:

- The Chair and DFO of an advisory committee are encouraged to generate a robust discussion about the matter at issue before any voting takes place. As part of this process, the Chair or DFO should solicit the views of all members so that any comment, insight, or concern that could influence a member's conclusions on the matter at issue is heard and considered *before* a vote related to that matter occurs, not afterward. The Chair or DFO should also consider in advance of the vote the need for the advisory committee members to have an opportunity following the vote to further explain any important qualifications related to their votes.
- When presenting a question for a vote, the Chair, DFO, or other senior agency officials should solicit and answer questions about its meaning before the vote begins. The objective is to reduce any potential confusion and maximize the meaning of the voting results by ensuring that the votes are based on a consistent and collective understanding of the question at issue.
- Voting should be done simultaneously. The objective is to avoid any potential order bias associated with sequential voting and thereby enhance the integrity and meaning of the voting results. The committee Chair or DFO has discretion to decide the precise method of voting on a meeting-by-meeting basis. Examples include a simultaneous show of hands, a simultaneous show of “yes” or “no” cards, or a balloting method in which members simultaneously cast written votes. Whatever method of voting is employed, the names of the committee members and their respective votes should be read aloud or otherwise made part of the public record shortly after the vote is taken.
- The question put to the vote should not be the subject of further discussion or clarification while the voting is underway (i.e., whereas a discussion and clarification of the question is encouraged before the vote, there should be no discussion of the meaning of the question while members actually cast their simultaneous votes). Once voting on a particular question has begun, that vote generally should not be terminated until the vote is complete. Following completion of the vote, consistent with the first bullet above, advisory committee members may explain their vote. Additional clarification of the question after a vote and a re-vote on a re-worded question may occur at the discretion of the DFO or committee chair.
- In some instances, the Chair of an advisory committee may believe the committee should vote on a related or relevant question not posed by FDA. If the Chair wants to put another question to a vote on his/her own initiative, the

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Chair should first check with the DFO or other senior FDA officials present to be sure that the question is appropriate for the meeting, that it is consistent with the topic identified in the meeting notices, and that it will not affect the conflict-of-interest screening that had been completed prior to the meeting. If a determination is made that the question should be posed, the Chair should discuss the matter with the committee members before the voting begins to ensure that the committee members collectively understand the question and feel adequately prepared (either through the background materials or their own expertise) to render a meaningful/informed vote on the new question.

- Briefing materials provided to advisory committee members as background materials before an advisory committee meeting should be thorough and, to the extent possible, include the questions that will be voted upon by the committee. The objective is to maximize the meaning and utility of the voting results by ensuring that the voters have had ample opportunity to study background materials before the day of the meeting.

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- For more information about FDA's advisory committee procedures, see <http://www.fda.gov/oc/advisory/default.htm>.