Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: The Open Public Hearing at FDA Advisory Committee Meetings

FINAL GUIDANCE

Comments and suggestions may be submitted at anytime for agency consideration 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 is published in the *Federal Register*.

For questions regarding this document, contact Michael Ortwerth at 301-796-8220.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner

May 15, 2013

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Additional copies are available from:

Office of Special Medical Programs
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue,
Building 32, rm. 5103
Silver Spring, Maryland 20993

http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm

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I. INTRODUCTION

The Food and Drug Administration's (FDA's) advisory committees play an essential role in FDA's activities to protect and promote public health through the regulation of human and animal drugs, biological products, medical devices, foods, and tobacco products. FDA's advisory committees provide independent expert advice and recommendations to the Agency on scientific, technical, and policy matters related to FDA-regulated products. Advisory committees enhance FDA's ability to protect and promote public health by ensuring FDA has access to such advice through the public hearing process as provided in existing laws and regulations. Although advisory committees provide recommendations to FDA, FDA makes the final decisions on any matters considered by an advisory committee. General procedures for FDA advisory committees are described at 21 CFR Part 14.

[1] This guidance applies to all FDA advisory committees including the panels of the Medical Devices Advisory Committee. This guidance has been prepared by the Office of Special Medical Programs in the Office of the Commissioner at the Food and Drug Administration.

FDA encourages participation from all public stakeholders in its decision-making processes. Every advisory committee meeting includes an open public hearing (OPH) session, during which interested persons may present relevant information or views orally or in writing (21 CFR 14.25(a)). FDA's regulation, 21 CFR 14.29, requires that a minimum of 60 minutes per meeting be dedicated to an OPH session for oral presentations, unless public participation does not last that long. For meetings that extend more than 1 day and/or meetings with multiple topics, the OPH session can be divided into multiple parts. If there is an overwhelming interest by the advisory committee in a specific topic, then the committee chair[2] may extend the OPH session. The time and location of the meeting and the OPH session is published in the *Federal Register* (21 CFR 14.20) at least 15 days before a meeting.

This guidance is intended to answer questions about how the public may participate at an OPH session. This includes, but is not limited to, general members of the public; individuals or spokespersons from the regulated industry (except the sponsor whose product is under review); consumer advocacy groups; and professional organizations, societies, or associations.

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.

[2] The chair is a committee member appointed to preside at committee meetings and ensure that all rules of order and conduct are maintained during each session (21 CFR 14.30). He or she is typically an experienced committee member.

II. ORAL PARTICIPATION IN AN FDA ADVISORY COMMITTEE OPEN PUBLIC HEARING

A. Providing a Request to Speak at the OPH

An interested person who wishes to be assured of the opportunity to make an oral presentation at an advisory committee meeting should inform FDA orally or in writing before the meeting (21 CFR 14.29(b)). The interested person should submit the request to the FDA contact person designated in the *Federal Register* (FR) notice announcing the advisory committee meeting by the listed deadline date (21 CFR 14.29(b)). FDA staff makes every effort to accommodate a speaker's request. FDA recommends that the request be submitted by mail, telephone, facsimile, or e-mail. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. FDA staff intends to contact speakers regarding their request to speak at least one week prior to the deadline for written submissions announced in the FR notice.

The interested person should include the following with the request:

- Name of the individual or;
- Name of the group, including the name of the spokesperson making the presentation, a description of the constituency that the group represents, and a brief mission statement of the group; and
- Contact information (mailing address, e-mail address, telephone, and fax numbers).

The interested person shall also include the following in the submission:

- A description of the general nature of the presentation, pursuant to 21 CFR 14.29(b)(1). The submitter may include an outline of the presentation to satisfy this requirement. Whenever possible, all written information to be discussed by the submitter at the meeting should be furnished in advance to FDA, pursuant to 21 CFR14.29(b)(1) (see II.D below).
- Amount of time requested for the presentation, pursuant to 21 CFR 14.29(b)(1). The time that FDA allocates to each person who wishes to make a presentation is dependent upon the number of requests. FDA usually allots 5 to 10 minutes per person. However, if a large number of people have requested to address the committee, FDA may reduce the time allotment for each speaker pursuant to 21 CFR 14.29(b)(2) and/or extend the time of the OPH session. In the interest of obtaining as many points of view as possible, FDA may require speakers with similar statements to consolidate their presentations into a single presentation, pursuant to 21 CFR 14.29(b)(2). Alternatively, individuals and/or groups may choose to make a joint presentation. In the interest of fairness, all speakers are asked to adhere to their allotted time. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled OPH session, FDA may conduct a lottery to determine the speakers for the OPH session. If necessary, FDA may choose to extend the time for the OPH session to accommodate registrants.

Audio-visual/media equipment is available at advisory committee meetings. FDA asks that an interested person provide a written request for use of the equipment along with an electronic version of the presentation or any overheads at least one week in advance of the meeting. The interested person should consult with the FDA Designated Federal Officer (DFO)[3] on issues related to the compatibility of software/hardware for his or her presentation.

B. Confirmation to Speak at the OPH

1. FDA staff intends to contact speakers by e-mail, facsimile, or telephone to confirm their participation.
2. FDA may decline a request to speak at an OPH if the person wishes to address a matter that is unrelated to the advisory committee's work (21 CFR 14.25(a)).
3. As discussed in II.A above, FDA intends to assign a time allocation to each speaker. In the event of scheduling changes and if time permits, FDA staff intends to contact speakers concerning these changes.
4. If a speaker is delayed or is unable to attend the meeting, FDA recommends that an FDA representative be contacted. If the speaker would still like to make a presentation and time and resources permit, it may be possible to arrange for an alternative time to speak during the meeting, to have the speaker's statement read by a speaker representative, or to have the statement, or a summary of the speaker's statement, made part of the public record via the public docket. If the confirmed speaker would like a representative to speak

[3] The DFO who coordinates the activities of the advisory committee serves as the link between committee members, FDA, industry, and the public.

on his or her behalf, the confirmed speaker should provide a written authorization to the designated FDA staff for the substitution. However, once the public hearing portion of the meeting has ended, further oral comments from the public will only be accepted at the discretion of the FDA advisory committee chair.

C. Confirmed Speaker Check-In the Day of the Meeting

1. Check-in is at the registration table. Speakers should introduce themselves to the DFO or other FDA staff. FDA intends to provide a designated seating area for OPH speakers.
2. Speakers should work with the DFO or other designated FDA staff to facilitate their presentation (e.g., slides). Any handouts should be submitted by the deadline listed in the *Federal Register* Notice for the meeting.

D. Submissions and Presentations

1. FDA distributes to the advisory committee before or at the meeting those copies of handouts received from public speakers prior to the deadline announced in the FR notice, pursuant to 21 CFR 14.29(b)(1).

A copy of the written information provided by the speakers is included in the permanent record of the meeting (see 21 CFR 14.60(b)(3)).

E. Logistics of an Oral Presentation

1. FDA recommends that the Chair make a statement at the beginning of the OPH session encouraging committee members that it is appropriate to ask questions of OPH speakers if doing so might lead to information that is helpful to the committee's deliberations. The Chair should remind the public and members of the importance of the OPH session to the advisory committee process and that all speakers should be treated in a courteous and respectful manner.
2. FDA generally will make available to speakers a podium or lapel microphone.
3. A timer is used to monitor each speaker. A visual signal (e.g., green/yellow/red light system), the Committee Chair, or the DFO should alert the speaker when his or her allotted time has nearly expired. If the allotted time ends before the speaker has concluded his or her presentation, the Chair or DFO should advise the speaker to complete his or her final remarks and conclude the presentation. In the event that the speaker chooses not to conclude the presentation after being asked to do so, the microphone may be turned off to end the presentation.
4. When the speaker's presentation concludes, the Chair may ask the speaker to remain at the podium for questions from the advisory committee.
5. All oral statements are recorded in the transcript of the meeting. Meeting transcripts are posted on the FDA web site approximately three to four weeks after the meeting takes place.

III. FINANCIAL DISCLOSURE

The law requires that FDA's advisory committee members who are special Government employees (SGEs) or regular Government employees (RGEs) disclose to FDA potential financial interests related to the topic of the advisory committee meeting, including relationships that they may have with the sponsor and competitors of the product(s) under discussion, when the committee addresses a particular matter involving specific parties[4] or a particular matter of general applicability[5]. The financial interests that must be reported include stocks, grants, consulting, teaching, speaking and writing engagements, expert testimony, patents, and royalties. In addition, the financial interests of a spouse, minor child, employer, officer, director, trustee, or partner are imputed to the committee member.[6]

Likewise, FDA encourages OPH speakers to disclose financial relationships they may have with the topic of the meeting and parties (e.g., sponsor and competitors of the product(s) under discussion). At the commencement of each OPH session, the Chair of the advisory committee meeting should read one of the statements set forth in III.A and III.B below, addressing the issue of financial disclosure for <u>all</u> open public hearing speakers.

A. Instructive Statement for Particular Matters Involving Specific Parties Meetings

[4] See 5 CFR 2640.102(l)
[5] See 5 CFR 2640.102(m)
[6] If a SGE or RGE has certain financial interests, he or she may not participate in the meeting unless granted a waiver for conflict of interest, see 18 U.S.C. 208(b)(1) and (b)(3). The basis for granting a waiver will include, as appropriate, the public health interest in having the expertise of the member with respect to a particular matter. 21 U.S.C. 379(d)-1. When a member is granted a waiver, the financial interest(s) associated with the waiver are posted on FDA's website and read into the transcript of the meeting. *See*, "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers," http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/LawsRegulationsGuidance/default.htm.

Welcome to the Open Public Hearing. Please state your name, and your affiliation if relevant to this meeting. The Food and Drug Administration (FDA) believes that the Agency and public benefit from a transparent process that helps ensure that FDA decisions are well-informed by the advice and information FDA receives from its advisory committees. If you have any financial interests relevant to this meeting, FDA encourages you to state the interest as you begin. Such interests may include a company's or group's payment of your travel or other expenses, or grant money that your organization receives from the sponsor or a competitor. If you do not have any such interests, you may wish to state that for the record. If you prefer not to address financial interests, you can still give your comments.

B. Instructive Statement on Particular Matters of General Applicability Meetings

Welcome to the Open Public Hearing. Please state your name, and your affiliation if relevant to this meeting. The Food and Drug Administration (FDA) believes that the Agency and public benefit from a transparent process that helps ensure that FDA decisions are well-informed by the advice and information FDA receives from its advisory committees. If you have any financial interests relevant to this meeting, such as a financial relationship with any company or group that may be affected by the topic of this meeting, FDA encourages you to state the interest as you begin. If you do not have any such interests, you may wish to state

that for the record. If you prefer not to address financial interests, you can still give your comments.

After each presentation, the Chair or a committee member may question the person concerning his or her presentation. However, neither the Chair nor any committee member should further question the person regarding any potential financial relationships.

IV. REFERENCES

A. FDA Advisory Committee Home Page – http://www.fda.gov/AdvisoryCommittees/default.htm

B. FDA Advisory Committee Annual Calendar of Meetings (Most current calendar year link can be found on the FDA Advisory Committee Home Page)

C. CODE OF FEDERAL REGULATIONS (21 CFR PART 14) – http://www.gpo.gov/fdsys/bulkdata/CFR/2013