

Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ohrms/dockets/default.htm> or <http://www.regulations.gov>.

Dated: August 1, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-18002 Filed 8-4-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0196] (formerly Docket No. 2007D-0449)

Guidance for Food and Drug Administration Advisory Committee Members and Food and Drug Administration Staff: Voting Procedures for Advisory Committee Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for FDA advisory committee members and FDA staff entitled "Voting Procedures for Advisory Committee Meetings." This document is intended to provide guidance on advisory committee voting procedures that should be used when votes are taken during advisory committee meetings. It does not define when votes should be taken. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of three additional guidances and one draft guidance, intended to improve FDA's advisory committee procedures.

DATES: The guidance is effective August 5, 2008. Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF-11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy, Planning, and Preparedness (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3370.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for FDA advisory committee members and FDA staff entitled "Voting Procedures for Advisory Committee Meetings," dated August 2008. FDA's advisory committees provide independent and expert advice on scientific, technical, and policy matters 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 decisionmaking processes. Although advisory committees provide recommendations to FDA, the agency makes the final decisions.

Advisory committees typically communicate advice or recommendations to the agency in two ways. First, FDA learns from the discussion and exchange that occurs among advisory committee members, and from individual recommendations and suggestions made during the discussion of any advisory committee meeting. Second, advisory committees often vote on a question or series of questions posed to the committee during a committee meeting.

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 postmarket safety data or premarket assessment of a product's risk/benefit profile. Because all members vote on the same question, the results help FDA gauge a committee's collective view on complex, multi-faceted issues. This view helps inform the agency's own deliberations on scientific and regulatory matters.

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

FDA issued a draft of this guidance on November 19, 2007 (72 FR 65046), and gave interested persons an opportunity to comment on the agency's proposal. FDA carefully evaluated the comments submitted to that docket and considered them in preparation of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on uniform procedures that should be used for the voting process when votes are taken during advisory committee meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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Electronic Access:

Persons with access to the Internet may obtain the document at: <http://www.regulations.gov>.

Dated: August 1, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0425] (formerly Docket No. 2007D-0021)

Guidance for Industry: Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members,” dated August 2008. This document provides guidance to industry sponsors, applicants, and petitioners who develop, prepare, or submit briefing materials that will be given to advisory committee members as background information before an open FDA advisory committee meeting. The guidance announced in this notice finalizes the draft guidance of the same title dated February 2007. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of three additional guidances and one draft guidance, intended to improve FDA’s advisory committee procedures.

DATES: The guidance is effective August 5, 2008. Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF-11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800-835-4709 or 301-827-1800. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy, Planning, and Preparedness (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3370.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Guidance for Industry: Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members,” dated August 2008. This guidance is intended to provide information to industry sponsors, applicants, and petitioners on the development, preparation, and submission of briefing materials that will be provided to advisory committee members as background information prior to open FDA advisory committee meetings. The guidance is intended to help minimize the time and resources spent in preparing such materials for public availability. The guidance also describes the process FDA intends to follow when we make briefing materials available to the public.

An important goal of the guidance is to help ensure that briefing materials are made available to the public in accordance with section 10(b) of the Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2). We interpret FACA to require that, with respect to any open advisory committee meeting convened under FACA, whenever practicable and subject to any applicable exemptions under the Freedom of Information Act (FOIA) (5 U.S.C. 552), those materials that we provide to advisory committee members in connection with that meeting must be made available for public inspection and copying either before or at the time of the advisory committee meeting.

In the guidance, the term “briefing materials” is used to describe the package of information that FDA provides to advisory committee members before a meeting. The briefing materials for a particular meeting generally include information prepared by FDA and/or the sponsor (if the meeting involves a product application or otherwise involves a particular

product). This guidance includes (in the Appendices) timelines for preparing and submitting briefing materials to FDA.

For open advisory committee meetings for which the briefing materials may contain information that, under certain circumstances, could be considered to be exempt from public disclosure under FOIA, we intend to:

- Post a publicly available version of the briefing materials on FDA’s Web site at least 2 full business days before the meeting is scheduled to occur.

For meetings for which the briefing materials do not contain information that, under certain circumstances, could be considered to be exempt from public disclosure under FOIA, such as many meetings concerning guidance documents and policy issues, we will try to:

- Make the briefing materials available on FDA’s Web site more than 2 full business days before the meeting.

In the **Federal Register** of February 28, 2007 (72 FR 9008), FDA announced the availability of the draft guidance of the same title dated February 2007. FDA received a number of comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. This guidance finalizes the draft guidance and replaces three previously issued draft guidance documents entitled: (1) “Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000,” dated December 1999; (2) “Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research,” dated February 2001; and (3) “Availability of Information Given to Advisory Committee Members in Connection With CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff,” dated July 18, 2001.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.