accepted by FDA only through FDMS at *http://www.regulations.gov*.

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.

[FR Doc. E8–18001 Filed 8–4–08; 8:45 am]

BILLING CODE 4160–01–S

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 The guidance announced in this notice finalizes the draft guidance of the same title dated February 2007.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in this issue of the **Federal Register**, FDA is announcing the availability of three additional guidances and one draft guidance, intended to improve FDA's advisory committee procedures.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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and received comments are available for public examination 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 guidance at *http://www.regulations.gov*.

Dated: August 1, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–17997 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–0424] (formerly Docket No. 2007D–0101)

Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees; 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 the public, FDA advisory committee members, and FDA staff entitled ''Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees'' dated August 2008. This guidance describes the factors and analyses that should be used in considering whether an advisory committee member has a potential conflict of interest and whether participation in a meeting is appropriate. This guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA policy in applying the applicable statutory and regulatory requirements. This guidance finalizes the draft guidance of the same title dated March 2007 and replaces the guidance document entitled ''FDA Waiver Criteria 2000.'' 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: This guidance is effective for advisory committee meetings scheduled on or after December 3, 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 phone 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 the Public, FDA Advisory Committee Members, and FDA Staff; Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees,'' 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.

FDA is committed to strictly adhering to the laws and regulations governing the process for selecting advisory committee members. FDA for many years has screened, prior to each meeting, all potential members who are special government employees or regular government employees, to determine whether the potential for a financial conflict of interest exists. The agency may grant a waiver to allow an individual to participate in a meeting when statutory criteria are met; for example, when the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. FDA administers several laws and regulations that govern conflict of interest determinations. The applicable laws have recently changed with the enactment of the Food and Drug Administration Amendments Act (FDAAA). Title VII of FDAAA added section 712 of the Federal Food, Drug, and Cosmectic Act (the act), which became effective October 1, 2007, replaced the conflict of interest provisions in section 505(n)(4) of the act, and introduced new requirements. In addition, the agency must apply 18 U.S.C. section 208, which contains different standards for assessing conflicts of interest. FDA's Waiver Criteria 2000 guidance, which this guidance replaces, attempted to comprehensively address the complex set of variables that can be applied in reaching a determination about an individual advisory committee participant. However, because of its complexity and discretionary elements, FDA staff found it difficult to achieve consistent results that the public could readily understand. As part of FDA's recent internal assessment of its advisory committee process, the agency has targeted its assessment of potential conflicts of interest and granting of waivers as an area that needs improvement. This guidance implements a more stringent approach for considering eligibility for participation in FDA advisory committee meetings. The purpose of this guidance is to simplify and streamline the process by which FDA considers meeting participation, increase the transparency, clarity, and consistency of the process, and enhance public trust in this important function.

In the **Federal Register** of March 23, 2007 (72 FR 13805), FDA announced the availability of the draft guidance of the same title dated March 2007. FDA received a number of comments on the draft guidance and those comments were considered as the guidance was