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]

BILLING CODE 4160–01–S

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 This guidance finalizes the draft guidance of the same title dated March 2007 and replaces the guidance document entitled ''FDA Waiver Criteria 2000.''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

finalized. In addition, changes necessitated by the enactment of FDAAA were incorporated into the final guidance. A summary of changes includes the following:

- FDA is choosing to limit the waivers the agency grants and harmonize our implementation of the various statutory provisions by applying a generally stricter test for granting waivers than would be required in some cases. FDA will ensure that all waivers meet the standard established by section 712(c)(2)(B) of the act that the waiver is ''necessary to afford the advisory committee essential expertise.''
- The guidance incorporates a progressively more stringent cap on the numbers of waivers issued per fiscal year in accordance with FDAAA.
- Advisory committee members will be considered for meeting participation under a rigorous policy regarding the value of their personal financial interests and those of their immediate family that potentially could be affected by the meeting deliberations. If an individual or his spouse or minor child has disqualifying financial interests whose combined value exceeds $50,000, she generally would not participate in the meeting, regardless of the need for her expertise. Financial interests imputed to the member (e.g., the financial interests of a university that employs the member) are not subject to the $50,000 maximum.
- FDA will not issue a waiver in certain circumstances where the agency has determined that the conflict of interest is significant.
- Waivers may be voting or non-voting at the discretion of the agency.
- Past financial interests that are outside of the scope of 18 U.S.C. 208 and section 712 of the act are not addressed in this guidance.
- New section 712 of the act harmonizes with 18 U.S.C. 208 those exempted interests considered too remote or inconsequential to affect the integrity of the services of advisory committee members; therefore, the guidance incorporates such exemptions.
- The guidance removes references to administrative steps (e.g., submission of internal memoranda) that staff should follow; internal staff instructions will be developed separately.

In addition, editorial changes were made to improve clarity.

This guidance is effective for advisory committee meetings scheduled on or after (see **DATES**). FDA staff begin planning and preparing for advisory committee meetings well in advance of the meeting date, in order to initiate and complete conflict of interest screening, among other things, for potential advisory committee participants. Accordingly, while staff will begin using the guidance directly, its impact on advisory committee meetings will not be fully apparent until 120 days after publication.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on procedures for considering conflict of interest and eligibility for participation in FDA advisory committees. 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, at any time, 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at: *http://www.fda.gov/ohrms/dockets/default.htm*

Dated: July 31, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–17998 Filed 8–4–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2002–D–0094] (formerly Docket No. 2002D–0049)

Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers; 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: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers.'' This guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA procedures regarding public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting. The guidance announced in this notice finalizes the draft guidance of the same title dated October 2007 and FDA's ''Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees'' dated January 2002. 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 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