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]

BILLING CODE 4160–01–S

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

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: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers,'' 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 implements a rigorous process for soliciting and vetting candidates for advisory committee meetings to minimize any potential for financial conflicts of interest. The agency is authorized by statute to grant waivers to allow individuals with potentially conflicting financial interests to participate in meetings where we conclude, after close scrutiny, that certain criteria are met. See 18 U.S.C. 208(b)(1), (b)(3) and section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (added by the Food and Drug Administration Amendments Act of 2007, Public Law No. 110–85, section 701 (effective October 1, 2007)).

In January 2002, FDA issued ''Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees,'' and requested comments on the draft guidance (Docket No. 2002D–0049). The draft guidance was limited in application to Special Government Employees (SGEs) participating in advisory committee meetings at which particular matters relating to particular products were discussed.

FDA has recently undertaken an internal assessment of its advisory committee process. As a result of this review, and based on the comments submitted to the docket for the January 2002 draft guidance, FDA has revised the 2002 draft guidance to broaden its applicability, to bring as much transparency as possible to FDA's waiver process, and to increase the consistency and clarity of the process. The guidance revises procedures, consistent with section 712(c)(3) of the act, to make publicly available relevant information regarding financial interests and waivers granted by the agency for SGEs and regular Government employees invited to participate in FDA advisory committee meetings.

The guidance also includes a template for disclosing to the public the disqualifying financial interests for which waivers are sought and a template for all waivers that FDA grants. The guidance further describes FDA's process for making these documents available on its Web site in advance of each advisory committee meeting.

In the **Federal Register** of October 31, 2007 (72 FR 61657), FDA announced the availability of the draft guidance of the same title dated October 2007. FDA received one comment on the draft guidance generally supporting the guidance. Editorial changes were made to improve clarity.

This guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance document represents the agency's current thinking on public availability of information regarding advisory committee members' financial interests and waivers granted by FDA to permit participation in 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, 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 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 *http://www.fda.gov/opacom/morechoices/industry/guidedc.htm* or *http://www.regulations.gov*.

Dated: July 31, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–17999 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–2008–D–0434]

Draft Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Humanitarian Device Exemption Regulation: Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Humanitarian Device Exemption (HDE) Regulation: Questions and Answers.'' This draft guidance answers commonly asked questions about Humanitarian Use Devices (HUDs) and applications for HDE. This draft guidance is neither final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 3, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Humanitarian Device Exemption (HDE) Regulation: Questions and Answers'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of