

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 2002D-0049] (formerly Docket No. 02-0049)

**Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for the public, FDA advisory committee members, and FDA staff entitled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public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 The draft guidance announced in this notice supersedes FDA's "Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," dated January 2002.

**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guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Policy (HF-11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jill Hartzler Warner, Office of Policy and Planning (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 draft guidance entitled “Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members’ Financial Interest Information and Waivers,” dated October 2007. 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) and (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 the **Federal Register** of January 12, 2002 (67 FR 6545), 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. 02D–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 is revising this draft guidance to broaden its applicability, bring as much transparency as possible to FDA’s waiver process, and increase the consistency and clarity of the process. The draft guidance proposes revised 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 draft 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.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance 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 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.

Dated: OCT 24 2007  
October 24, 2007.

*Jeffrey Shuren*

Jeffrey Shuren,  
Assistant Commissioner for Policy.

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COPY OF THE ORIGINAL**

*Dawn P. Hawkins*