

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2002D0094] (formerly Docket No. 02D0049)

Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee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.

SUMMARY:

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for the public, FDA advisory committee members, and FDA staff entitled Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public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 This draft guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA procedures regarding public availability of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 The draft guidance would provide even greater transparency to FDA's advisory committee process than current guidance. The draft guidance announced in this notice, when finalized, would replace guidance of the same title dated August 2008.

DATES:

Although you may comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by [insert date 60 days after date of publication in the Federal Register].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 guidance to Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 8008354709 or 3018271800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit written comments on the draft guidance to the Division of Dockets

Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Michael Ortwerth, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993, 3017968220.

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. 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), section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379d-1) (added by the Food and Drug Administration Amendments Act of 2007, Public Law No. 11085), and section 701 (21 U.S.C. 371) (effective October 1, 2007)).

In January 2002, FDA issued the 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 (formerly Docket No. 02D0049 now Docket No. FDA2002D0094). 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.

In August 2008, after an internal assessment of FDA's advisory committee process and based on the comments submitted to the docket for the January 2002 draft guidance and a revised draft guidance published for public comment in October 2007, the agency issued guidance that expanded public availability of relevant information, brought additional transparency to FDA's waiver process, and increased the consistency and clarity of the process (www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125647.pdf).

FDA is now making available for public comment revisions to the August 2008 guidance that provide even greater transparency. The agency has tentatively concluded that it is appropriate to request that individuals receiving a waiver of conflict of interest to participate in an FDA advisory committee meeting disclose the name of the company or institution when identifying the nature of

the disqualifying financial interest.

In determining how much information to publicly disclose, FDA needs to provide enough detail so the public can understand the nature of the potential conflict and FDA's decisionmaking regarding participation, while not disclosing so much detail that the agency would be unable to attract essential expertise to its advisory committees. Under the August 2008 guidance, the nature of the financial interest was identified only as sponsor, competitor, or other affected firm. This approach was informed, in part, by a survey in 2001 of active advisory committee members that asked whether members would decline to participate based on varying levels of disclosure.

FDA is now proposing to disclose more detail than it did under its August 2008 guidance. Specifically, the agency proposes to disclose the name of the company or institution associated with the financial interest. New information indicates that this additional detail would not be a deterrent to current and potential advisory committee members. For example, the agency notes that academic institutions, peer-reviewed journals, and scientific symposia, among other entities/venues, have in recent years developed more rigorous policies for disclosure of potential conflicts of interest with the work that is being presented or discussed. (See Conflict of Interest in Medical Research, Education, and Practice, Committee on Conflict of Interest in Medical Research, Education, and Practice, Board on Health Sciences Policy, Institute of Medicine of the National Academies (see p. 62 at <http://books.nap.edu/openbook.php?record_id&equal;12598>). While policies differ among organizations, many provide for disclosure of the name of the company or entity constituting the potential conflict of interest. (See Uniform Format for Disclosure of Competing Interests in ICMJE Journals that describes a disclosure policy and format that includes identification of the entity that is the source of the financial interest; adopted by all International Committee of Medical Journal Editors (ICMJE) journals (accessed at <http://content.nejm.org/cgi/content/full/361/19/1896>)). In addition, FDA informally polled several active advisory committee members. While not a representative sample, the survey indicated that disclosing the names of companies would not adversely affect FDA's ability to attract and retain expert advisors. Accordingly, we have tentatively concluded that the public now expects this level of detail to help them understand the nature of a potential conflict and that individuals would accept this level of detail as a routine part of required disclosures.

To help us in issuing a final guidance, FDA is requesting comments on whether disclosing the name of the company or institution associated with the financial interest would: (1) Increase the transparency of FDA's decisions regarding advisory committee member participation and (2) not significantly deter current and potential advisory committee members from service on those committees.

The draft guidance also includes a template for disclosing to the public the financial interests for which waivers are granted and a template for disclosing to the public all waivers that FDA grants. The draft 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, when finalized, will represent 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.

II. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm> or <http://www.regulations.gov>.

Dated: April 19, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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