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Guidance for the Public, FDA Advisory Committee Members, and FDA Staff:

Public Availability of Advisory Committee Members' Financial Interest Information and Waivers

DRAFT GUIDANCE

This guidance document is for comment purposes only.

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit written comments 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.fda.gov/dockets/ecomments>. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of this guidance, contact Office of Policy (Office of the Commissioner) at 301-827-3360.

**U.S. Department of Health and Human Services
Food and Drug Administration
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Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to help the public, Food and Drug Administration (FDA) advisory committee members, and FDA staff to understand and implement statutory requirements and FDA policy regarding public availability of information about financial interests and waivers¹ granted by FDA to permit individuals to participate in advisory committee meetings subject to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). This guidance describes the basis and provides a format for public disclosure of certain financial interests by special Government employees (SGEs) and regular Government employees participating in these advisory committee meetings, and provides a format for FDA waivers allowing

¹ For purposes of this guidance, the term "waiver" refers to waivers that FDA is authorized to issue under section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), effective October 1, 2007 (added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, § 701) as well as determinations and certifications that the Agency is authorized to issue under 18 U.S.C. § 208(b)(1) and (b)(3), respectively.

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participation in these meetings.² This guidance also explains how and when these documents will be made publicly available by FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. APPLICABILITY

This guidance applies to SGEs and regular Government employees invited to participate in FDA advisory committees subject to FACA. The types of advisory committee meetings within the scope of this guidance are meetings involving particular matters as defined in regulations issued by the Office of Government Ethics (OGE). *See* 5 CFR § 2640.103(a)(1).³

III. BACKGROUND AND PURPOSE

Advisory committees provide independent, expert advice on scientific, technical, and policy matters related to the development and evaluation of products regulated by FDA, such as human and animal drugs, biological products, medical devices, and foods. The advisory committee system enhances FDA's ability to protect and

² FDA recently made available for comment the March 2007 "Draft 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," (<http://www.fda.gov/oc/advisory/waiver/COIguidedft.html>). That document, when finalized, would describe FDA's policy for considering whether an individual invited to participate in an FDA advisory committee meeting has a potential conflict of interest and whether participation in an advisory committee meeting is appropriate.

³ Particular matters involve deliberation, decision, or action that is focused upon the interests of specific persons or a discrete and identifiable class of persons, and include matters involving specific parties and matters of general applicability. *See also* 5 CFR § 2640.102(l)-(m).

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promote the public health and maintain the public trust by enabling the agency to obtain the benefit of independent, professional expertise. Although advisory committees provide recommendations to FDA, final decisions are made by FDA. *See* 5 U.S.C. App. 2 § 9(b); 21 CFR § 14.5.

Most FDA advisory committee members are appointed as special Government employees. Advisory committee members may also be regular Government employees; for example, FDA may request participation by employees of the United States Department of Agriculture, the Centers for Disease Control and Prevention, or other Federal agencies for matters where such employees' expertise is needed.

FDA implements a rigorous process for soliciting and vetting candidates for advisory committee meetings to minimize any potential for financial conflicts of interest. In preparation for advisory committee meetings involving particular matters, SGEs invited to participate in the meetings are required to report to FDA any financial interests related to the subject matter of the advisory committee meeting. *See* 5 CFR § 2634.903(b)(3). Regular Government employees also report financial interests on a yearly basis and/or just prior to the advisory committee meeting they are planning to attend. *See* 5 CFR § 2634.903(a) and (b)(3). FDA reviews these reports in advance of each upcoming meeting, once the meeting topics have been identified, to determine whether any financial conflicts of interest may exist for these individuals. Moreover, FDA screens advisory committee members broadly for relationships that could present even the appearance that they have conflicts of interest that could affect their impartiality. *See* 5 CFR § 2635.502.

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FDA seeks to identify all potential financial conflicts related to the matter before a committee. FDA reviews not only the financial interests of a potential advisory committee participant and his immediate family members, but also those of the participant's business partners, organizations for which he serves as officer, director, trustee, general partner, or employee, and any prospective employer of the member (if there are ongoing employment negotiations). *See* 18 U.S.C. § 208(a).

FDA is authorized by statute to grant waivers to allow individuals with potentially conflicting financial interests to participate in meetings where it concludes, after close scrutiny, that certain criteria are met. *See* 18 U.S.C. § 208(b)(1), (b)(3) and § 712(c)(2)(B) of the Act (added by FDAAA § 701 (effective October 1, 2007)). The Agency has recently issued a draft guidance that proposed a stringent policy for considering eligibility for advisory committee participation.⁴

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. 02D-0049). The 2002 draft guidance provided information on the type and amount of information to be made publicly available when an SGE is granted a waiver for a conflict of interest related to certain advisory committee meetings. The 2002 draft guidance was limited in application to SGEs participating in advisory committee meetings at which particular matters relating to particular products are discussed.

⁴ *See* FDA's "Draft 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" (Mar. 2007), <http://www.fda.gov/oc/advisory/waiver/COIguideft.html>.

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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, to bring as much transparency as possible to FDA's waiver process, and to increase the consistency and clarity of the process. As set forth in this document, FDA's revisions are designed to ensure public availability of 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.

IV. LEGAL FRAMEWORK

FDA administers several laws and regulations that govern conflict of interest determinations; these laws set forth different standards for determining whether participation in advisory committee meetings may be permitted. For example, two separate statutes govern whether the SGEs and regular Government employees subject to this guidance are prohibited from participating in advisory committee meetings because of financial interests that may be affected by the work the committee is to perform. First, 18 U.S.C. § 208 prohibits an SGE or regular government employee with disqualifying financial interests from participating in an advisory committee meeting unless a waiver is granted. Second, section 712(c)(2) of the Act (effective October 1, 2007), which replaces former 21 U.S.C. § 355(n)(4) and expands its applicability, prohibits advisory committee members from participating if they (or any immediate family members) have a disqualifying financial interest,

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unless a waiver is granted. Both statutes specify the circumstances under which FDA may grant waivers to permit participation in specific meetings.

Section 712(c)(3) of the Act (effective October 1, 2007) also requires that FDA disclose on its website the type, nature, and magnitude of the financial interests of each advisory committee member who has received a waiver under section 712(c)(2) of the Act or 18 U.S.C. § 208. Section 712(c)(3) also requires that FDA's reasons for granting each waiver be disclosed on the FDA website. FDA is required to disclose the information described above regarding financial interests and waivers within specified time frames before advisory committee meetings. *See* § 712(c)(3) of the Act.

In addition to these statutory requirements regarding the disclosure of information about financial interests and corresponding FDA waivers, FDA also has the authority to establish policies regarding the operation of advisory committees and participation of advisory committee members. *See* 21 U.S.C. § 393; 41 CFR §§ 102-3.105 and 102-3.130.

V. DISCLOSURE OF CERTAIN FINANCIAL INTERESTS AND WAIVERS

To increase the transparency, consistency, and clarity of the advisory committee process, consistent with the FDAAA requirements described above, FDA has concluded that it is desirable to implement agency-wide procedures regarding disclosure of financial interest information that apply to all SGE and regular Government employees invited to participate in FDA advisory committee meetings

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subject to FACA. In preparation for each advisory committee meeting, FDA intends to request that individuals within the scope of this guidance publicly disclose the type, nature, and magnitude of any disqualifying financial interests. FDA does not intend that these individuals will participate in advisory committee meetings until they publicly disclose these interests.

To facilitate such disclosure, FDA plans to ask each individual to execute a document acknowledging the disqualifying financial interests for which a waiver is sought and instructing FDA to disclose this information on the individual's behalf if a waiver is granted. A template that FDA intends to use when preparing this document, based on information already submitted by the individual⁵, is found in Appendix 1.

In addition, FDA is providing a template for all waivers that the agency grants, found in Appendix 2. FDA intends to draft the waivers such that information protected from disclosure by statute or regulation does not appear in the waivers. The waivers would therefore not typically require redaction when publicly disclosed as described in the following paragraph. However, if confidential information appears in other documents submitted, completed, or generated in the course of FDA's review of financial interests and waiver requests, this information will continue to be protected from public disclosure in accordance with applicable statutory and regulatory requirements. *See, e.g., 21 CFR Part 20.*

For waivers that are granted, the disclosure statement signed by the advisory committee member will be posted on FDA's website, along with the agency's waiver.

⁵ See section III above.

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FDA will post these documents on the FDA website (<http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>) at least 15 days prior to the relevant advisory committee meeting, except for disqualifying financial interests that do not become known to FDA until shortly before the meeting. For disqualifying financial interests that FDA becomes aware of less than 30 days prior to the meeting and for which a waiver is issued, FDA will post the documents as soon as practicable and no later than the day of the meeting. These time frames are consistent with the requirements of section 712(c)(3) of the Act (effective October 1, 2007). The agency also plans to make the disclosure statements and waiver documents public at corresponding advisory committee meetings.

Additionally, FDA plans to post a roster (<http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>) of all advisory committee members expected to attend a specific meeting at the same time briefing materials for that meeting are posted. *See* FDA's Draft Guidance for Industry: Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members (Feb. 2007), <http://www.fda.gov/oc/advisory/ACGuidanceOnInfo.html>.

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Appendix 1

**Food and Drug Administration Advisory Committee Member
Acknowledgment of Financial Interests**

Name of Advisory Committee Member:

Committee:

Meeting Date:

I acknowledge that contingent upon public disclosure of the following financial interest(s) related to the agenda item:

[Describe relevant agenda item],

I may be considered for participation in the advisory committee meeting described above.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
[Describe type of interest; e.g.: Stocks/investments; Employment; Work as consultant/advisor; Contracts/grants; Patents/royalties/trademarks Work as an expert witness Teaching/speaking/writing]	[Describe nature of interest; e.g.: sponsor, competitor, affected firm]	[Describe magnitude of interest; e.g.: \$0 – 5,000; \$5001 – 10,000; \$10,001 – 25,000; \$25,001 – 50,000]

I hereby request that FDA make this information publicly available on my behalf if the agency grants a waiver⁶ allowing me to participate in the meeting described above. I understand that without public disclosure of these interests, I will not participate in the advisory committee meeting described above.

Signature

Date

⁶ Includes waivers under section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act, determinations under 18 U.S.C. § 208(b)(1), and certifications under 18 U.S.C. § 208(b)(3).

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Appendix 2

**Waiver to Allow Participation in Food and Drug Administration
Advisory Committee**

Name of Advisory Committee Member:

Committee:

Meeting Date:

Description of the Facts on Which the Waiver is Based:

Nature of Financial Interest(s):

Description of the Particular Matter to Which the Waiver Applies:

Additional Facts (if any):

Basis for Granting the Waiver:

Limitations on the Regular Government Employee or Special Government Employee's
Ability to Act:

Certification: [Use one of the first two statements for a 208 waiver, depending on whether the individual is a regular Government employee or SGE. Use the third or fourth statement for 712(c)(2)(B) waivers.]

The Regular Government Employee's financial interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual.

The need for the Special Government Employee's services outweighs the potential for a conflict of interest.

The individual's voting participation is necessary to afford the advisory committee essential expertise.

The individual's nonvoting participation is necessary to afford the advisory committee essential expertise.

Signature
Authorized FDA Official

Date