Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers

FINAL GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration

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This guidance represents 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 waivers[2] 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

[1] This guidance has been prepared by the Advisory Committee Oversight and Management Staff in the Office of the Commissioner at the Food and Drug Administration.

[2] 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) (21 U.S.C. § 379d-1(c)(2)(B)), 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.

provides a format for FDA waivers allowing participation in these meetings.[3] 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).[4]

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, foods, and tobacco products. The advisory committee system enhances FDA's ability to protect and

[3] *See* "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/RegulatoryInformation/Guidances/ucm122045.htm. That document describes FDA's policy for considering whether an individual invited to participate in an FDA advisory committee meeting has a potential conflict of interest under 18 U.S.C. 208 or section 712(c)(2) of the Act, and whether, under those statutes, a waiver to allow participation in an advisory committee meeting is appropriate.

[4] 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).

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, called Confidential Financial Disclosure Reports[5] 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.[6]

[5] In rare cases, an individual who is a regular Government employee may file a Public Financial Disclosure Report.

[6] In addition, FDA screens advisory committee members broadly for covered relationships that could present even the appearance that they have conflicts of interest that could affect their impartiality. *See* 5 CFR 2635.502. This guidance does not address this screening process.

FDA seeks to identify all potential financial conflicts related to the particular matter before a committee. FDA reviews not only the financial interests of a potential advisory committee participant and his immediate family, but also the financial interests, of which he has knowledge, 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 also issued a guidance document describing our policy for considering eligibility for advisory committee participation.[7]

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).[8] 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.

[7] *See* FDA's "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" (August 2008) http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm.
[8] 67 FR 6545 (February 12, 2002).

In October 2007, shortly after § 712 of the Act was enacted, FDA issued a revised draft guidance to implement the new law's public disclosure provisions.[9] In addition to the new law, the draft guidance was informed by the results from an internal assessment of FDA's advisory committee process and comments submitted to the docket for the January 2002 draft guidance. FDA issued the final guidance in August 2008.[10] This guidance expanded public availability of relevant information to include regular Government employees and SGEs, brought additional transparency to FDA's waiver process, and increased the consistency and clarity of the process. In March 2010, FDA issued a revised draft guidance[11] to the August 2008 guidance that provided for even greater transparency and solicited public comments. After considering the public comments, FDA is finalizing the March 2010 draft guidance with minor revision for clarity and is replacing the August 2008 guidance of the same title.

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 particular matter the advisory committee is considering. First, 18 U.S.C. § 208 prohibits an SGE or regular Government employee with a financial interest that can be affected by the particular matter from participating in an advisory committee meeting unless a waiver is granted or the financial interest is

[9] 72 FR 61657 (October 31, 2007).
[10] 73 FR 45459 (August 5, 2008).
[11] 75 FR 21000 (April 22, 2010).

covered by one of the regulatory exemptions found at 5 CFR Part 2640. Second, section 712(c)(2) of the Act, 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 financial conflict of interest, 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 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 requirements of section 712(c) of the Act 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 subject to FACA. In preparation for each advisory committee meeting, to ensure individuals understand what information about their financial interests will be made public, FDA intends to request that individuals within the scope of this guidance acknowledge that FDA intends to publicly disclose the type, nature, and magnitude of any waived financial interests. FDA further intends to make the individuals' participation in advisory committee meetings contingent upon their acknowledgement of FDA's intention to publicly disclose this information.

To facilitate such disclosure, FDA plans to prepare a document listing the financial interests for which a waiver is sought. A template that FDA intends to use when preparing this document, based on information already submitted by the individual,[12] is found in Appendix 1. Using the template format, FDA will list personal and immediate family interests separately from other imputed interests. Other imputed financial interests are those that are attributed to the individual through his employer (i.e., the employer has a relevant financial interest) or through his position as an officer, director, trustee, or general partner. Even though the individual may have no personal involvement in these interests, they are considered conflicts of interest under the applicable law. First, FDA will identify the type of interest. The template provides several examples, such as stocks/investments and employment. Second, FDA will identify the nature of the interest. The template now instructs that the name of the company or institution be identified, along with indicating whether the firm is the sponsor, a competing firm, or other affected entity. This increases the transparency of the agency's procedures. This is a change from the August 2008 guidance, where the nature

[12] *See* section III above.

of the interest was identified only as sponsor, competitor, or other affected firm. Third, FDA will indicate the magnitude of an interest by a dollar range, such as $0-5000. The agency will request that the individual in need of a waiver review the document and acknowledge their understanding that FDA will publicly disclose the information.

FDA does not intend to publicly disclose financial interest information if the information is exempt under the Freedom of Information Act or otherwise protected from disclosure by statute or regulation, other than due to the fact that it is personal financial information reported on a Confidential Financial Disclosure Report. For example, FDA would not disclose the name of a company or institution if doing so would reveal that company's confidential commercial information.

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 will be posted on FDA's website, along with the agency's waiver. FDA will post these documents on the FDA website (http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/default.htm) at

least 15 days prior to the relevant advisory committee meeting, except for financial conflicts of interest that do not become known to FDA until shortly before the meeting. For conflicts of interest 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. 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/AdvisoryCommittees/CommitteesMeetingMaterials/default.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 Guidance for Industry: Advisory Committee Meetings – Preparation and Public Availability of Information Given to Advisory Committee Members (August 2008), http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm.

Appendix 1

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

Name of Advisory Committee Member:

Committee:

Meeting Date:

I acknowledge my understanding that my participation in the advisory committee meeting described above is 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.

Type of Interest	Nature	Magnitude
I. Personal/Immediate Family		
[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; i.e.: name of company or institution and whether it is the sponsor, a competing firm, or other affected entity]	[Describe magnitude of interest; e.g.: $0 – 5,000; $5001 – 10,000; $10,001 – 25,000; $25,001 – 50,000]
II. Other Imputed Interests[13]		
[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; i.e.: name of company or institution and whether it is the sponsor, a competing firm, or other affected entity]	[Describe magnitude of interest; e.g.: $0 – 50,000; $50,001 – 100,000; $100,001 – 300,000; over $300,000]

[13] Other imputed interests include those that are attributed to the individual through his employer (i.e., the employer has a relevant financial interest) or through his position as an officer, director, trustee, or general partner.

I hereby acknowledge that FDA will make this information publicly available if the agency grants a waiver[14] 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

[14] Includes waivers under section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 379d-1(c)(2)(B)), determinations under 18 U.S.C. § 208(b)(1), and certifications under 18 U.S.C. § 208(b)(3).

Appendix 2

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

Name of Advisory Committee Member:

Committee:

Meeting Date:

Description of the Facts on Which the Waiver is Based:

Type, Nature, and Magnitude of Financial Interest(s):

Description of the Particular Matter to Which the Waiver Applies:

Additional Facts (if any):

Basis for Granting the Waiver:

Certification: [Use one of the first two statements when describing a waiver granted under 18 U.S.C. § 208(b), depending on whether the individual is a regular Government employee or SGE. Use the third statement when describing a waiver granted under section 712(c)(2)(B) of the Federal Food Drug and Cosmetic Act.]

_____ The individual may participate, pursuant to 18 U.S.C. 208(b)(1) – 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 individual may participate, pursuant to 18 U.S.C. 208(b)(3) – The need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved.

_____ The individual may participate, pursuant to 21 U.S.C. 379d-1 – The individual's service is necessary to afford the advisory committee essential expertise.

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

____Non-voting

____Other (specify)

_____ _____

Signature Date

Authorized FDA Official