

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 3-21-2007 <sup>11:43</sup> 16  
Publication Date 3-23-2007  
Certifier L. CLAWSON  
DSM

[Docket No. 2007D-0101]

**Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA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; Availability**

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

**ACTION:** Notice.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document for the public, FDA advisory committee members, and FDA staff entitled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees" dated March 2007. This draft guidance describes the factors and analyses that should be used in considering whether an advisory committee member has a potential conflict of interest and whether participation in a meeting is appropriate. This guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA policy in applying the applicable statutory and regulatory requirements. This draft guidance, when finalized, will replace the guidance document entitled "FDA Waiver Criteria 2000."

**DATES:** Submit written or electronic comments on the draft guidance by May 21, 2007. General comments on agency guidance documents are welcome at any time.

oc0782

2007D-0101

NAD 1

**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. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 <http://www.fda.gov/dockets/ecomments>. 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 document, entitled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff; Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees," dated March 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 is committed to strictly adhering to the laws and regulations governing the process for selecting advisory committee members. FDA for many years has screened, prior to each meeting, all advisory committee members who are special government employees or regular government

employees, to determine whether the potential for a financial conflict of interest exists. The agency may grant a waiver to allow an individual to participate in a meeting when statutory criteria are met; for example, when the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved. FDA administers several laws and regulations that govern conflict of interest determinations; these laws are not entirely consistent and set out different standards. FDA's Waiver Criteria 2000 guidance, which this draft guidance would replace, attempted to comprehensively address the complex set of variables that can be applied in reaching a determination about an individual advisory committee participant. However, because of its complexity and discretionary elements, FDA staff found it difficult to achieve consistent results that the public could readily understand. As part of FDA's recent internal assessment of its advisory committee process, the agency has targeted its assessment of potential conflicts of interest and granting of waivers as an area that needs improvement. This draft guidance will implement a more stringent approach for considering eligibility for participation in FDA advisory committee meetings. The purpose of this draft guidance is to simplify and streamline the process by which FDA considers meeting participation, increase the transparency, clarity, and consistency of the process, and enhance public trust in this important function.

We welcome comments on the draft guidance and specifically seek comment on (1) whether the draft approach, due to its stringency, could unduly restrict eligibility of needed experts for advisory committee meetings, (2) whether the \$50,000 figure generally employed as the maximum amount for disqualifying financial interests, after applying certain exemptions, is appropriate or, alternatively, whether a different figure (higher or lower)

should be used, and (3) whether and what additional examples should be provided for the steps described in this draft guidance for determining conflicts of interest and eligibility for participating in an 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 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**

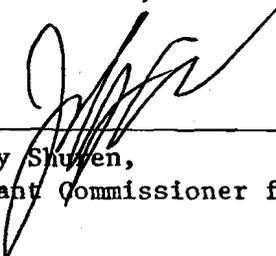
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at: <http://www.fda.gov/opacom/morechoices/industry/guidedc.htm>

Dated: \_\_\_\_\_

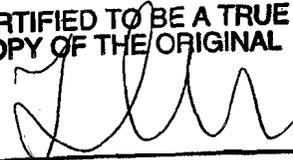
3/20/07  
March 20, 2007.

  
\_\_\_\_\_  
Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

  
\_\_\_\_\_