

Updated on a regular basis, the CDRH Web site includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments on the draft guidance by May 13, 2002. Submit two copies of any comments, except individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 29, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02-3280 Filed 2-11-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0049]

Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees." This draft document is intended to provide guidance for industry, FDA staff (including special Government employees (SGEs), and

other interested stakeholders concerning disclosure of financial interests for which FDA advisory committee SGEs have received conflict of interest waivers. This draft guidance describes a new policy of disclosing specific information concerning the financial interests that give rise to the waiver of a conflict of interest.

DATES: Submit written or electronic comments by March 14, 2002, to ensure adequate consideration in preparation of the final guidance document. Comments on this guidance may be submitted at any time.

ADDRESSES: Submit written comments or requests for copies of the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Linda Ann Sherman, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

SUPPLEMENTARY INFORMATION:

I. Background

Two separate statutes govern whether FDA advisory committee SGEs are prohibited from participating in a particular meeting because of a conflict of interest with the work the committee is to perform: (1) Section 505(n)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(n)(4)), which is applicable to FDA SGEs working on advisory committees concerning a clinical investigation of a drug or approval for marketing of a drug or biologic; and (2) 18 U.S.C. 208, which is applicable to all Federal Government employees, including SGEs. Both statutes provide for waivers of conflicts of interest under certain conditions. Both statutes also provide for public disclosure of any conflict of interest for which a waiver has been granted. The regulation in 18 U.S.C. 208 provides for disclosure of waiver information upon request but permits agencies to redact any information that would be exempt under the Freedom of Information Act, 5 U.S.C. 552. In addition, section 505(n)(4) of the act requires SGEs to publicly disclose all conflicts of interest.

The Office of Government Ethics (OGE) has concluded that 18 U.S.C. 208 grants agencies discretion in disclosing information under 18 U.S.C. 208 where there is no foreseeable harm that will be caused by the disclosure. Similarly, the Office of Legal Counsel (OLC), Department of Justice, has concluded

that FDA has discretion under section 505(n)(4) of the act to tailor the scope of the disclosure to achieve the statute's goal. FDA may weigh the competing public interests at stake. For example, the statute does not intend that the disclosure be so intrusive or onerous as to make many individuals unwilling to serve on advisory committees.

In making a decision concerning how much information to disclose in any given case, FDA has always had to balance the following competing public interests: (1) Providing as much information to the public as possible about the qualifications and abilities of the SGEs involved in the advisory committee process so that individuals may weigh the advice, (2) protecting the reasonable privacy expectations of the SGEs in their personal financial affairs, and (3) protecting FDA's interest in being able to attract sufficient expertise to the committee to provide the most reliable advice.

In the past, FDA has struck a balance between these interests by disclosing the names of individual SGEs who had received waivers and whether the waiver was granted under 18 U.S.C. 208 or section 505(n)(4) of the act, without disclosing any details about the actual financial interest at stake. In the interest of increasing transparency, FDA is now proposing to strike a different balance by disclosing more details. This disclosure, of course, will provide the public with more information concerning the financial interests of the SGEs participating, but it will also entail additional exposure of what may be private financial interests of the SGEs.

II. The Proposed New Procedures

FDA is proposing that, for advisory committee meetings to consider particular matters relating to particular products, additional disclosure of certain details concerning conflicts of interest that have been waived is warranted. In the interest of uniformity, FDA is further proposing to provide for the same degree of disclosure for waivers granted under either 18 U.S.C. 208 or section 505(n)(4) of the act for all centers and will follow similar procedures for both. With regard to committees considering general matters, see the discussion in section III of this document.

The reasons why FDA is proposing this change are twofold. First, FDA recently surveyed SGEs as to whether they were willing to provide greater public disclosure of financial interests giving rise to conflicts of interest for which waivers are received. FDA sent a detailed questionnaire to all SGEs asking for their opinion on whether

additional disclosure would be advisable. The survey and its tabulated results can be obtained by sending an electronic request to the Dockets Management Branch (address above). The results of that survey showed that, in general, SGEs were willing to tolerate greater disclosure of the financial interests than FDA had been providing.

Second, OLC concluded that section 505(n)(4) of the act required meaningful public disclosure that will adequately enable a reasonable person to understand the nature of the conflict and the degree to which it could be expected to influence the recommendations the SGE will make.

III. General Matters Waivers Excluded

Unlike advisory committee meetings to consider particular matters relating to particular products, committee meetings to consider more general matters do not have a unique impact on any personal or imputed financial interests. Such matters are likely to affect classes of similarly situated products and manufacturers to the same extent. Matters of such general applicability give no particular advantage to any individual manufacturer. Therefore, it is recognized that participation in committee meetings to consider general matters poses less risk of a conflict of interest. For that reason, FDA will continue to address committees considering general matters in a way that reflects these inherent differences. FDA will continue its global screening process for each general matter meeting, but in the public's interest of time and utility, it will read an abbreviated statement concerning conflicts of interest.

IV. Significance of Guidance

The draft guidance entitled "Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees" is being issued as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency'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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

V. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance to ensure adequate

consideration in preparation of the final guidance document by March 14, 2002. However, interested persons may submit written or electronic comments at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at <http://www.fda.gov/oc/guidance/advisorycommittee.html>.

Dated: February 5, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 02-3279 Filed 2-11-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Cancellation of a Fiscal Year (FY) 1999 Funding Opportunities Notice

AGENCY: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Cancellation of future application receipt dates under SAMHSA/CSAT Comprehensive Community Treatment Program (PA 99-050).

SUMMARY: This notice is to inform the public that the SAMHSA/CSAT program announcement, PA 99-050, Comprehensive Community Treatment Program, is being cancelled. Effective immediately, no new applications will be received, reviewed, or funded under this announcement.

A notice of funding opportunities under the Comprehensive Community Treatment Program was published in the **Federal Register** on March 8, 1999 (Vol. 64, Number 44, pages 11027-11031). Subsequent modification/clarification notices for this program were published in the **Federal Register** on December 13, 1999, and on April 27, 2001. This cancellation notice applies to both the original funding opportunity and to the subsequent modification/clarification notices.

Information related to this notice may be obtained from: Tom Edwards, Division of Practice and Systems Development, Center for Substance Abuse Treatment, SAMHSA, Tele: 301-443-8453, e-mail: tedwards@samhsa.gov.

Dated: February 6, 2002.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 02-3389 Filed 2-11-02; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-030-00-1020-24]

Sierra Front-Northwestern Great Basin Resource Advisory Council; Notice of Meeting Location and Time

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting location and time for the Sierra Front-Northwestern Great Basin Resource Advisory Council (Nevada)

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Sierra Front-Northwestern Great Basin Resource Advisory Council (RAC), Nevada, will be held as indicated below. Topics for discussion will include manager's reports of field office activities; BLM public lands disposal and acquisition processes; fire rehabilitation projects progress reports; discussion of a recreation fee demonstration program for Sand Mountain; review and RAC recommendations on the Walker River Basin EIS; and other topics the council may raise.

DATES AND TIMES: The RAC will meet on Thursday, March 28, 2002, from 9 a.m. to 5 p.m., and Friday, March 29, 2002, from 8 a.m. to 3 p.m., at the BLM-Carson City Field Office, 5665 Morgan Mill Road, Carson City, Nevada. All meetings are open to the public. A general public comment period will be held on Thursday, March 28, 2002, at 4 p.m.

A detailed agenda will be available on the internet by March 7, 2002, at www.nv.blm.gov/rac; hard copies can also be mailed or sent via FAX. Individuals who need special assistance such as sign language interpretation or other reasonable accommodations, or who wish a hard copy of the agenda, should contact Mark Struble, Carson