

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 2012.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2012-5674 Filed 3-8-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2002-D-0094; (formerly Docket No. 02D-0049)]

#### **Guidance for the Public, Food and Drug Administration (FDA) Advisory Committee Members, and FDA 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 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." We are issuing the guidance to help the public, FDA advisory committee members, and FDA staff to understand the public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting. The guidance provides additional transparency to FDA's advisory committee process beyond current guidance. This guidance finalizes the draft guidance of the same title dated March 2010 and replaces the guidance of the same title dated August 2008.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to Advisory Committee Oversight and Management Staff, 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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Michael Ortwerth, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5104, Silver Spring, MD 20993, email: [Michael.Ortwerth@fda.hhs.gov](mailto:Michael.Ortwerth@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. The Guidance**

FDA is announcing the availability of a 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 issues guidance documents for FDA staff, applicants and sponsors, and the public that describe the Agency's current views on a subject.

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 (formerly Docket No. 02D-0049, now Docket No. FDA-2002-D-0094, 67 FR 6545, February 12, 2002). 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 October 2007, after an internal assessment of FDA's advisory committee process, FDA published a revised draft guidance for public comment (72 FR 61657, October 31, 2007). The Agency reviewed the submitted comments on the January 2002 draft guidance, the October 2007 draft guidance, and the results of the internal assessment of FDA's advisory committee process and issued guidance that 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 (73 FR 45459, August 5, 2008) ([www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125647.pdf](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125647.pdf)).

In the **Federal Register** of April 22, 2010 (75 FR 21000), FDA issued for public comment "Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee

Members' Financial Interest Information and Waivers," dated March 2010. The Agency explained that it tentatively concluded it is appropriate for additional information to be disclosed for individuals receiving a waiver of conflict of interest prior to participating in an FDA advisory committee meeting. Specifically, FDA proposed disclosure of the name of the company or institution associated with the financial interest. The Agency based its draft guidance on the expectation that: (1) This information would help the public understand the nature of the potential conflict and FDA's decision-making and that (2) individuals invited as advisory committee members would agree to the inclusion of this level of detail as a routine part of required disclosures. FDA specifically requested 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 included a template for disclosing to the public the financial interests for which waivers are granted, a template for public disclosure of waivers that FDA grants, and FDA's process for making these documents available on its Web site.

We received several comments on the draft guidance. No commenter indicated that the proposed policies would deter participation and most noted that it would increase transparency.

FDA is issuing the draft guidance with minor revisions to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the public availability of financial interest information and waivers relating to the disclosure of conflicts of interest for advisory committee members participating in FDA 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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/AdvisoryCommittees/default.htm>.

Dated: February 28, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Preparation for International Cooperation on Cosmetics Regulations; Public Meeting

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

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "International Cooperation on Cosmetics Regulations (ICCR)—Preparation for ICCR-6 Meeting in Rockville, Maryland" to provide information and receive comments on the International Cooperation on Cosmetics Regulations (ICCR) as well as the upcoming meetings in Rockville, MD. The topics to be discussed are the topics for discussion at the forthcoming ICCR Steering Committee meeting. The purpose of the meeting is to solicit public input prior to the next steering committee and expert working group meetings in Rockville, MD on July 10 to 13, 2012.

**Date and Time:** The meeting will be held on May 15, 2012, from 2 to 4 p.m.

**Location:** The meeting will be held in the Washington Theater Room at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

**Contact Person:** All participants must register with Kimberly Franklin, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, by email: [Kimberly.Franklin@fda.hhs.gov](mailto:Kimberly.Franklin@fda.hhs.gov) or FAX: 301-595-7937.

**Registration and Requests for Oral Presentations:** Send registration information (including: Name, title, firm name, address, telephone, and fax number), written material and requests

to make oral presentation, to the contact person by May 9, 2012.

If you need special accommodations due to a disability, please contact Kimberly Franklin (see *Contact Person*) at least 7 days in advance.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by May 9, 2012, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, telephone number, FAX and email of the proposed participants, and an indication of the approximate time requested to make their presentation.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg. Rockville, MD 20857.

**SUPPLEMENTARY INFORMATION:** The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the: United States, Japan, the European Union, and Canada. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics' industry trade associations. Currently, the ICCR members are: Health Canada; the European Directorate General for Enterprise and Industry; the Ministry of Health, Labor and Welfare of Japan; and the U.S. Food and Drug Administration. All decisions made by consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will require input from stakeholders.

Interested persons may present data, information, or views orally or in

writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by April 22, 2011, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, telephone number, fax, and email of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on the Internet at <http://www.fda.gov/Cosmetics/InternationalActivities/ConferencesMeetingsWorkshops/InternationalCooperationonCosmeticsRegulationsICCR/default.htm>.

Dated: March 6, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-5744 Filed 3-8-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary Studies for ISC Consortium.

**Date:** March 29, 2012.

**Time:** 2 p.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301)