

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P-0074]

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees:
Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee.

General Function of the Committees:
To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 18 and 19, 2007, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2007P-0074—Final Monograph for Cough, Cold, Allergy, Bronchodilator, Antiasthmatic Drug Products for Over-the-Counter Human Use" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, by close of business on August 28, 2007.

Location: The National Labor College, Lane Kirkland Center, Solidarity Hall, 10000 New Hampshire Ave., Silver Spring, MD. The phone number is 301-431-6400.

Contact Person: Darrell Lyons, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: darrell.lyons@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512541 and 8732310001. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly

enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committees will meet in joint session to discuss the safety and efficacy of over-the-counter (OTC) cough and cold products marketed for pediatric use. A citizen petition was submitted to FDA on March 1, 2007, that raised concerns about the safety and efficacy of cough and cold products in children under 6 years of age. The petition requested among other things that FDA amend the OTC drug monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (CCABADP) in 21 CFR Part 341 to require that labeling for OTC antitussive, expectorant, nasal decongestant, antihistamine, and combination cough and cold products state that these products have not been found to be safe or effective in children under 6 years of age for the treatment of cough and cold, and that these products should not be used for the treatment of cough and cold in children under 6 years of age. In addition, the petitioner requested the agency to notify manufacturers of these products whose labeling either uses such terms as "infant" or "baby" or displays images of children under the age of 6, that such marketing is not supported by scientific evidence and that manufacturers will be subject to enforcement action at any time. The petition and additional information can be found at the following Web site: <http://www.fda.gov/ohrms/dockets/dockets/07p0074/07p0074.htm>.

The committee's discussion will focus on several areas of interest which include: The extrapolation of efficacy data from adults to children of any age for cough and cold products; the safety profile of these products in children; the basis for dosing recommendations in the CCABADP monograph and the use of extrapolation of pharmacokinetic data to determine appropriate dosing in children; the basis of dosing recommendations for various age intervals of less than 2 years, 2 to 5 years of age, and 6 to 11 years of age; the use of the products in children less than 2 years of age; the potential for misuse, unintentional overdose, and excessive dosing; the ability of parents or caregivers to correctly dose and administer cough and cold products to their children; and the potential labeling changes recommended by the petitioner

and the effects they will have on the use of these products in children and the recommendations of health providers.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>; click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 3, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on October 18, 2007. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 25, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 26, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Darrell Lyons at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 9, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7-16169 Filed 8-15-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Processing Methods for Orthopedic, Cardiovascular, and Skin Allografts; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and Office of Regulatory Affairs (ORA) and the Centers for Disease Control and Prevention (CDC) are announcing a public workshop entitled "Processing Methods for Orthopedic, Cardiovascular, and Skin Allografts." The purpose of the public workshop is to discuss various methods used to process tissue allograft, pre- and post-processing cultures, and disinfection and sterilization of tissues.

Date and Time: The public workshop will be held on October 11, 2007, from 8:30 a.m. to 5 p.m., and October 12, 2007, from 8:30 a.m. to 1 p.m.

Location: The public workshop will be held at the Masur Auditorium, Building 10 Clinical Center, National Institutes of Health, Bethesda, MD 20892.

Contact: Bernadette Kawaley, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-2000, FAX: 301-827-3079, e-mail: CBERTrainingSuggestions@fda.hhs.gov (Subject line: Tissue Processing Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by September 18, 2007. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the

public workshop will be provided on a space available basis beginning at 8 a.m.

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

SUPPLEMENTARY INFORMATION: The public workshop will feature presentations by experts from the government, the medical field and the tissue industry. The first day of the workshop will include discussions on: (1) Surgeon clinical practices, experiences, expectations, and assumptions regarding tissue allografts and patient safety; and (2) Pre- and Post-Processing cultures for microorganisms—usefulness, reliability, and validation. The second day of the workshop will focus on disinfection and sterilization of tissues—experiences, expectations, and challenges.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: August 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-16182 Filed 8-15-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: October 24-25, 2007.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: 1. Approval of Minutes; 2. Reports from Dr. John E. Niederhuber, NCI Director;

3. Reports on NCI Budget; Legislative Activity; NCI Scientific Initiatives reported by NCI staff; 4. Presentations on Eliminating Cancer Health Disparities; Translational Working Group; and the Adolescent and Young Adult Oncology (AYAO) Progress Review Group (PRG) 5. Public Comment; 6. Action Items and Conclusion.

Place: National Institutes of Health, Building 31, 9000 Rockville Pike, C Wing, 6th Floor, Conference Rm. 6, Bethesda, MD 20892.

Contact Person: Barbara Guest, Executive Secretary, Office of Liaison Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd, Room 2202, Bethesda, MD 20892-8324, Bethesda, MD 20892-8324, 301-496-0307, guestb@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show on form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/dclg/dclg.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 9, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-4016 Filed 8-15-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.