

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs 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 Committee: Nonprescription Drugs Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on May 6, 2004, from 8 a.m. to 5:30 p.m. and May 7, 2004, from 8 a.m. to 11 a.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Karen Templeton-Somers or Kimberly Littleton Topper, 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, e-mail: topperk@cder.fda.gov or somersk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512541 or 3014512534. Please call the Information Line for up-to-date information on this meeting. The background materials for this meeting will become available no later than 1 business day before the meeting and will be posted at www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2004 and scroll down to the Nonprescription Drugs Advisory Committee or the Dermatologic and Ophthalmic Drugs Advisory Committee).

Agenda: On both days, the committee will discuss efficacy and labeling issues for over-the-counter drug products used in the treatment of tinea pedis (interdigital) in patients 12 years of age and over.

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 by April 23, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 6, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 23, 2004, 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.

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 Karen Templeton-Somers or Kimberly Littleton Topper at least 7 days in advance of the meeting.

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

Dated: March 22, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-6974 Filed 3-29-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs 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 Committee: Oncologic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on May 3 and 4, 2004, from 8 a.m. to 5 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, 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 or e-mail: cliffordj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 3, 2004, the committee will discuss these items: (1) New drug application (NDA) 21-649, GENASENSE (oblimersen sodium) Genta, Inc., proposed indication for use in combination with DTIC DOME (dacarbazine), Bayer Pharmaceuticals Corp., proposed for the treatment of patients with advanced malignant melanoma; and (2) NDA 21-661, RSR 13 Injection (efaproxiral sodium) Allos Therapeutics, Inc., proposed indication for use as an adjunct to whole brain radiation therapy in the treatment of brain metastases from primary breast cancer. On May 4, 2004, the committee will discuss these items: (1) Safety concerns associated with ARANESP (darbepoetin alfa) Amgen, Inc., and PROCIT (epoetin alfa) Ortho Biotech, L.P., both of which are indicated for the treatment of anemia associated with cancer chemotherapy; and (2) colorectal cancer endpoints as a followup to the November 2003 FDA Workshop.

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 by April 26, 2004. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., and 2:30 p.m. and 3 p.m. on May 3, 2004. On May 4, 2004, oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., and 2:30 p.m. and 3 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 26, 2004, 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.

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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 Trevelin Prysock at 301-827-7001, at least 7 days in advance of the meeting.

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

Dated: March 22, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-6973 Filed 3-29-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Seventh Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference "Solutions to Regulatory Challenges"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing its seventh annual educational conference entitled "Solutions to Regulatory Challenges" cosponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the drug, device, and biologics industries with an opportunity to interact with FDA reviewers and compliance officers from FDA's centers and district offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive question and answer, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 2 and 3, 2004, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at The Irvine Marriott, 18000 Von Karman Ave., Irvine, CA.

Contact: Ramlah Moussa, Office of Regulatory Affairs (HFR-PA200), Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, 949-608-4408, FAX: 949-608-4456, or Orange County Regulatory Affairs Discussion Group, Attention to Detail, 5319 University Dr., suite 641, Irvine, CA 92612, 949-387-9046, FAX: 949-387-

9047, Web site: <http://www.ocra-dg.org>. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Registration and Meeting Information: See OCRA Web site at <http://www.ocra-dg.org>. Contact Attention to Detail at 949-387-9046.

Before May 20, 2004, registration fees are as follows: \$495.00 for members, \$545.00 for nonmembers, and \$325.00 for FDA/government/full-time students with proper identification. After May 20, 2004, \$545.00 for members, \$595.00 for nonmembers, and \$325.00 for FDA/government/full-time students with proper identification.

The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses.

If you need special accommodations due to a disability, please contact Ramlah Moussa at least 10 days in advance.

Dated: March 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-7106 Filed 3-29-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on Nurse Education and Practice (NACNEP).

Dates and Times: April 14, 2004, 8:30 a.m.-5 p.m.; April 15, 2004, 8:30 a.m.-5 p.m.; April 16, 2004, 8:30 a.m.-2 p.m.

Place: The Wyndham Washington DC Hotel, 1400 M Street, NW., Washington, DC 20005.

Status: The meeting will be open to the public.

Agenda: Agency and Bureau administrative updates will be provided. The purpose of the meeting will be to address issues related to Geriatric Care with implications for the nursing workforce. An opening presentation will provide a comprehensive view of geriatric care to be followed by presentations on the nursing workforce. The National Center for Health Workforce Analysis, Bureau of Health Professions (BHP), staff will present reports on the health care workforce and long term care models for the geriatric workforce. A presentation on long term care challenges

and initiatives will be followed by a panel on geriatric perspectives across acute, home health and community and public health care settings. The National Center for Health Workforce Analysis, BHP, staff will report on a study of nursing aides, home health aides and related health care occupations identifying local workforce shortages and associated data needs. Interdisciplinary issues for the geriatric workforce will be the last formal presentation. Council workgroups will then deliberate on the content of the meeting and develop recommendations on geriatric care with implications for the nursing workforce.

FOR FURTHER INFORMATION

CONTACT: Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Ms. Elaine G. Cohen, M.S., R.N., Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9-35, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-1405.

Dated: March 24, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-7042 Filed 3-29-04; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Research Resources Council.

The meeting will be open to the public as indicated below, 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.

The meeting 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.