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.

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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 PROCRIT (epoetin alfa) Ortho Biotech, L.P., both of which are indicated for the treatment of anemia associated with cancer chemotherapy; and (2) colo-rectal 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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