

presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on March 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 13, 2003, 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 Jeanne E. Latham 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: February 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03-4089 Filed 2-19-03; 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 March 12 and 13, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, 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 email: cliffordj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug applications approved under 21 CFR 314.500 (Subpart H, accelerated approval) in an open session on March 12 and 13, 2003, to: (1) Review the status of phase IV clinical studies; (2) identify difficulties associated with completion of phase IV commitments; and (3) provide advice to sponsors to assist in the planning and execution of postmarketing commitments of newly approved drugs. On March 12, 2003, the committee will discuss phase IV commitments of: (1) new drug application (NDA) 50-718 DOXIL (doxorubicin HCl, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of Kaposi's Sarcoma in acquired immune deficiency syndrome (AIDS) patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy; (2) NDA 50-718/S-006 DOXIL (Doxorubicin HCl, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of metastatic ovarian cancer in patients with disease that is refractory to both paclitaxel and platinum-based chemotherapy regimens; (3) biologics license application (BLA) 97-1325 ONTAK (deneluekin diftotox, Ligand Pharmaceuticals) for the treatment of persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor; and (4) NDA 20-221/S-002, ETHYOL injection (amifostine, MedImmune Oncology, Inc.) for reducing the cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced nonsmall cell lung cancer. On March 13, 2003, the committee will discuss phase IV commitments of: (1) NDA 21-174, MYLOTARG (gemtuzumab ozogamicin, Wyeth-Ayerst Laboratories, Inc.) for the treatment of CD33 positive acute

myeloid leukemia in first relapse of patients who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy; (2) NDA 21-041, DEPOCYT (cytarabine, SkyePharma, Inc.) for the intrathecal treatment of lymphomatous meningitis; (3) NDA 21-156 CELEBREX (celecoxib, Pharmacia Corp.) indicated in the reduction in number of adenomatous colorectal polyps in familial adenomatous polyposis patients; and (4) NDA 21-029, TEMODAR (temozolomide, Schering Corp.) for the treatment of adult patients with refractory anaplastic astrocytoma.

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 March 3, 2003. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m. and 12:30 p.m. to 1 p.m. on both days. Time allotted for each presentation may be limited. Additional open public sessions may be conducted after the presentations for interested persons who have submitted their request to speak by March 3, 2003, to address issues specific to the topic before the committee. Those desiring to make formal oral presentations should notify the contact person before March 3, 2003, 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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Dated: February 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03-4000 Filed 2-19-03; 8:45 am]

BILLING CODE 4160-01-S