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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). At least one portion of the meeting will be closed 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 June 7 and 8, 1999, 8 a.m. to 5:30 p.m.

Location: Town Center Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20057, 301-827-7001, 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: (1) The use of time-to-progression as the primary endpoint in breast cancer drug trials; and (2) new drug application (NDA) 21-010, epirubicin hydrochloride for injection, Pharmacia and Upjohn Co., indicated for use as a component of adjuvant therapy in patients with evidence of axillary-node-tumor involvement following resection of primary breast cancer (Stage II & III). Epirubicin is indicated for the therapy of patients with locally advanced or metastatic breast cancer. On June 8, 1999, the committee will discuss: (1) NDA 50-718/S-006, Doxil® (doxorubicin HCl liposome injection), Alza Corp., indicated for the

treatment of patients with metastatic carcinoma of the ovary who are refractory to both paclitaxel- and platinum-based chemotherapy regimens and who may also be refractory to topotecan.

Refractory is defined as a patient having progressive disease while on treatment, or within 6 months of completing treatment; and (2) NDA 20-221/S-012, Ethyol® (amifostine) for injection, U.S. Bioscience, Inc., indicated for use to reduce the incidence and severity of radiation induced xerostomia.

Procedure: On June 7, 1999, from 10:30 a.m. to 5:30 p.m., the meeting is open to the public. 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 May 28, 1999. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11 a.m. and 1:45 p.m. and 2:15 p.m. on June 7, 1999, and between approximately 8:15 a.m. and 8:45 a.m. on June 8, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 28, 1999, 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. After the scientific presentations, a 15-minute open public session will be conducted for interested persons who have submitted their request to speak by May 28, 1999, to address issues specific to the submission or topic before the committee.

Closed Committee Deliberations: On June 7, 1999, from 8 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.

FDA regrets that it was unable to publish this notice 15 days prior to the June 7 and 8, 1999, Oncologic Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Oncologic Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the

public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: May 14, 1999

MA Friedman

Michael A. Friedman
Deputy Commissioner for Operations

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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