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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). 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 December 13, 2000, 8:30 a.m. to 5:30 p.m. and December 14, 2000, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

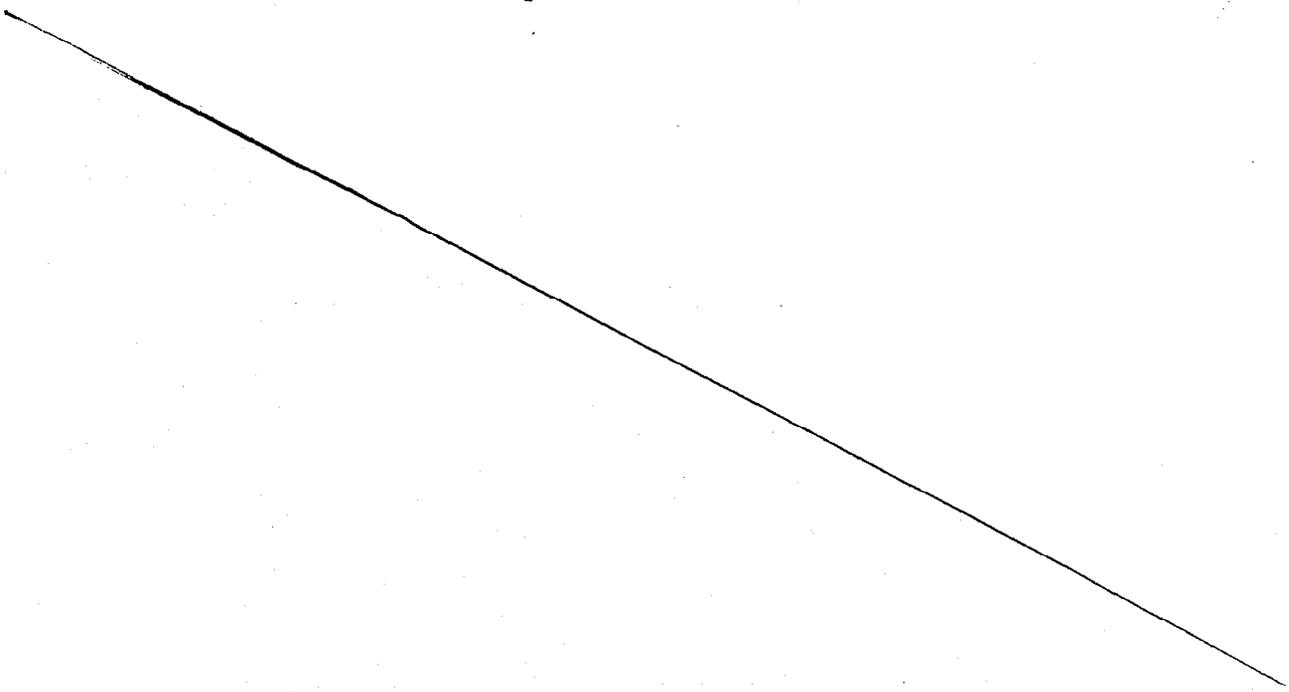
Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 13, 2000, the committee will discuss: (1) New drug application (NDA)20-726/S-006, Femara® (letrozole) Tablets, 2.5 mg, Novartis Pharmaceuticals Corp., indicated as first-line therapy in postmenopausal women with advanced breast cancer; and (2) NDA 21-240, histamine hydrochloride injection (1 mg/ml), Maxim Pharmaceuticals, Inc., indicated for adjunctive use with interleukin-2 (aldesleukin) in the treatment of adult patients with advanced metastatic melanoma that has metastasized to the liver. On December 14, 2000, the committee

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will discuss: (1) Biologics license application (BLA) 99-0786, Campath®, (alemtuzumab), Ilex™ Oncology Services and Millenium Pharmaceuticals, indicated for the treatment of patients with chronic lymphocytic leukemia who have been treated with alkylating agents and who have failed fludarabine therapy; and (2) single patient exemptions to the use of nonapproved oncology drugs and biologics.

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 December 6, 2000. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and 1:30 p.m. and 1:45 p.m. on December 13, 2000, and between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:15 p.m. on December 14, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 6, 2000, 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 30-minute open public session may be conducted for interested persons who have submitted their request to speak by December 6, 2000, to address issues specific to the submission or topic before the committee.



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

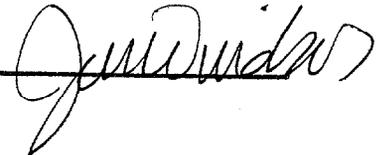
2).

Dated: 11/8/00
November 8, 2000



Linda A. Suydam,
Senior Associate Commissioner.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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