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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.

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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 regulatory issues.

*Date and Time:* The meeting will be held on January 12, 1999, 8:30 a.m. to 5:30 p.m., and January 13, 1999, 8 a.m. to 5 p.m.

*Location:* Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-2 1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 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:* On January 12, 1999, the committee will discuss: (1) New drug application (NDA) 21-029, Temodal® (temozolomide) Capsules, Schering Corp., indicated for the treatment of adult patients with malignant glioma (glioblastoma multiforme and anaplastic astrocytoma) at first relapse, and (2) NDA 50-766 Prograf® (tacrolimus) capsules, 1 milligram (mg) and 5 mg, and Prograf (tacrolimus) injection 5 mg (for IV infusion only), Fujisawa Healthcare, Inc., indicated

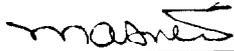
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for the prophylaxis of graft-versus-host disease in patients receiving allogenic bone marrow transplants. On January 13, 1999, the committee will discuss: (1) NDA 20-954 Busulfex™ (busulfan) Injection, Orphan Medical, Inc., indicated for use in combination with other chemotherapeutic agents and/or radiotherapy as a conditioning regimen prior to hematopoietic progenitor cell transplantation. Diseases in which patient benefit from this mode of therapy has been demonstrated include acute lymphocytic leukemia, acute nonlymphocytic leukemia, acute myeloid leukemia, chronic myeloid leukemia, non-Hodgkins lymphoma, Hodgkins disease, multiple myeloma, myelodysplastic syndrome, breast cancer, ovarian cancer, and genetic diseases, and (2) NDA 20-765 OraTest™ (tolonium chloride), Zila, Inc., an oral rinse that is indicated for use as a diagnostic adjunct in patients with oral lesions suspected or known to be malignant, to help in detection of all sites of cancer, definition of borders or cancerous lesions, and selection of sites to be biopsied.

*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 January 4, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9 a.m., and 1:45 p.m. and 2 p.m. on January 12, 1999; and between approximately 8:15 a.m. and 8:30 a.m., and 1:15 p.m. and 1:30 p.m. on January 13, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 4, 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 30-minute open public session will be conducted for interested persons, who have submitted their request to speak by January 4, 1999, 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: December 8, 1998



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Michael A. Friedman  
Deputy Commissioner for  
Operations

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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