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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**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). 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 March 23, 1999, 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 20057, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301443-0572 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 application (NDA) 21-051 Temodal® (temozolomide) Capsules, Schering Corp., indicated for the treatment of patients with advanced metastatic malignant melanoma.

*Procedure:* On March 23, 1999, from 8 a.m. to 12:15 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 March 8, 1999. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m.

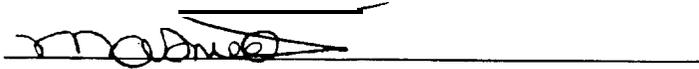
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a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish 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 March 8, 1999, to address issues specific to the submission or topic before the committee.

*Closed Committee Deliberations:* On March 23, 1999, from 1 p.m. to 5:30 p.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)). The investigational new drug application and Phase I and Phase II drug products in process will be presented, and recent action on selected NDA's will be discussed. This portion of the meeting will be closed to permit discussion of this information.

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

Dated: February 22, 1999



Michael A. Friedman  
Deputy Commissioner for  
Operations

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

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