

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.

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 September 10, 2001, from 8:30 a.m. to 5:30 p.m., and September 11, 2001, from 8 a.m. to 5:30 p.m.

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

Contact: 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 September 10, 2001, the committee will discuss: (1) Clinical trial designs for first-line hormonal treatment of metastatic breast cancer; and (2) new drug application (NDA) 21-236, IntraDose® (cisplatin/epinephrine) Injectable Gel, Matrix Pharmaceutical, Inc., indicated for the treatment of recurrent or refractory squamous cell carcinoma of the head and neck in patients who are not considered curable with surgery or radiotherapy. On September 11, 2001, the committee will discuss: (1) Biologics license application (BLA) 125019, Zevalin™ (ibritumomab

tiuxetan), IDEC Pharmaceuticals Corp., indicated for the treatment of patients with relapsed or refractory low grade, follicular or CD20+ transformed B cell non-Hodgkins lymphoma (NHL) and rituximab refractory follicular NHL; and (2) supplemental NDA 20-637/S016, Gliadel® Wafer (carmustine), Guilford Pharmaceuticals, Inc., indicated for use as a treatment to significantly prolong survival and maintain overall function (as measured by preservation of Karnovsky Performance Status) and neurological function in patients with malignant glioma undergoing primary and/or recurrent surgical resection.

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 August 31, 2001. 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 September 10, 2001, and between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:15 p.m. on September 11, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentation should notify the contact person before August 31, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and address 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 August 31, 2001, to address issues specific to the topic before the committee.

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

2).
