

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.

DMB

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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's regulatory issues.

Date and Time: The meeting will be held on December 5, 2001, from 8:30 a.m. to 5:30 p.m., and on December 6, 2001, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, 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 December 5, 2001, the committee will discuss: (1) The development of diagnostic immunohistochemistry (IHC) and fluorescence in situ hybridization (FISH) assays intended to identify patients who might benefit from treatment with a particular therapeutic product, with a focus on the characterization and interpretation of assay results; and (2) biologics licensing application 103792\5008, a labeling supplement for HERCEPTIN (trastuzumab), Genentech, Inc., indicated for the treatment of patients with metastatic breast cancer who have tumors which

overexpress HER-2. The proposed labeling supplement would include the use of FISH testing using the PATH VYSION HER-2 DNA Probe Kit, Vysis, Inc., as a diagnostic method to select patients for HERCEPTIN therapy. On December 6, 2001, the committee will discuss: (1) postmarketing safety issues associated with the use of CAMPTOSAR Injection (irinotecan hydrochloride injection), Pharmacia & Upjohn Co., combined with 5FU/leucovorin ("Saltz" regimen) approved for the first-line treatment of patients with metastatic colorectal cancer. Potential labeling changes and issues regarding clinical trials to address the relevant safety and efficacy concerns will be discussed; and (2) supplemental new drug application (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 November 27, 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 December 5, 2001, and between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:15 p.m. on December 6, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 27, 2001, 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

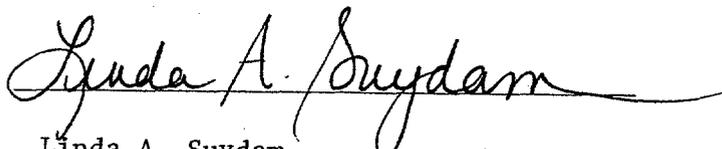
be conducted for interested persons who have submitted their request to speak by November 27, 2001, to address issues specific to the topic before the committee.

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

2).

Dated: 11/16/01

November 16, 2001.



Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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