FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–28942 Filed 11–9–01; 8:45 am]

BILLING CODE 6750–01–M

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 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 1037925008, 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 Perfomance 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: November 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–29137 Filed 11–16–01; 2:50 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0269]

Draft Guidance for Industry on the Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until November 26, 2001, the comment period for the draft guidance for industry entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format'' that appeared in the **Federal Register** of July 9, 2001 (66 FR 35797). This draft guidance is part of a comprehensive effort to improve the format and content of prescription drug labeling. The agency is taking this action in response to a request for an extension and to allow interested parties additional time to submit comments.

DATES: Submit written or electronic comments on the draft guidance by November 26, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 1–888–CBERFAX, or Voice Information System at 800–835–4709 or 301–827–1800. Send one self-addressed, adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit