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

electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Janet M. Jones, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758, or Toni Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 2001 (66 FR 35797), FDA announced the availability of a draft guidance for industry entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format.'' As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners—clearer, more informative, more accessible, and more consistent from drug to drug. Recently the agency published a proposed rule to revise the overall format of prescription drug labeling (65 FR 81082, December 22, 2000). The agency also is developing a number of guidance documents that focus on the content of certain labeling sections. The first draft guidance entitled ''Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics'' was made available for public comment on June 21, 2000 (65 FR 38563).

The draft guidance entitled ''Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format'' is the second guidance document on the content and format of individual labeling sections. Among other things, the draft guidance discusses what studies to include in the Clinical Studies section, how to describe those studies, and how to present clinical study data in graphs and tables. The agency also is trying to raise awareness, with this draft guidance, of the implications for product promotion of information contained in the Clinical Studies section. This section exists in the current labeling and is expected to continue to exist when the proposed rule to revise the format for prescription drug labeling is made final.

On October 1, 2001, FDA received a request from the Pharmaceutical Research and Manufacturers of America (PhRMA) to extend the comment period. PhRMA indicated that it needed additional time to coordinate comments from its member companies. In response to this request, and to provide all interested persons additional time to comment on this draft guidance, FDA is reopening the comment period until November 26, 2001.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm, or at http://www.fda.gov/cber/guidelines.htm.

Dated: November 14, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–28961 Filed 11–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0489]

Draft ''Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees'' dated November 2001. The draft guidance document, when finalized, will assist sponsors of clinical trials in determining when a data monitoring committee (DMC) is needed for optimal study monitoring and how such committees should operate.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by February 19, 2002. General comments on agency guidance documents are welcome at any time. Submit written or electronic comments on the collections of information by January 22, 2002.

ADDRESSES: Submit written requests for single copies of the draft guidance to 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; the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844; or the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210;

Robert Temple, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758; or

Joanne Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION: