a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30214 Filed 11-18-99; 8:45 am]

BILLING CODE 4160–01–F

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). 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 December 13, 1999, 9 a.m. to 5:30 p.m. and December 14, 1999, 8 a.m. to 5 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 20857, 301–827–7001, 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 13, 1999, the committee will discuss: (1) New drug application (NDA) 21–055, Targretin® (bexarotene) Capsules, 75 milligrams, Ligand Pharmaceuticals, Inc., indicated for the treatment of patients with all clinical stages (IA–IVB) of cutaneous T-cell lymphoma (CTCL) in the following categories: Patients with early stage CTCL who have not tolerated other therapies, patients with refractory or persistent early stage CTCL, and patients with refractory advanced stage CTCL; and (2) NDA 20–449/S–011, Taxotere® (docetaxel) for Injection Concentrate, Rhone-Poulenc Rorer Pharmaceuticals, Inc., indicated for the treatment of patients with locally advanced or metastatic Non-small Cell Lung Cancer after failure of prior chemotherapy. On December 14, 1999, the committee will discuss: (1) The design and analysis of active control clinical trials; and (2) NDA 21–156, Celebrex™ (celecoxib), G. D. Searle & Co., indicated for the regression and prevention of adenomatous polyps, which may lead to the development of colorectal cancer in patients with familial adenomatous polyposis.

Procedure: On December 13, 1999, from 9 a.m. to 5:30 p.m., and on December 14, 1999, from 8 a.m. to 3 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 December 3, 1999. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:30 a.m., and between approximately 1:30 p.m. and 1:45 p.m. on December 13, 1999, and between approximately 10:15 a.m. and 11 a.m. on December 14, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 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 30-minute open public session will be conducted for interested persons who have submitted their request to speak by December 3, 1999, to address issues specific to the submission or topic before the committee.

Closed Committee Deliberations: On December 14, 1999, from 3 p.m. to 5 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 (IND) 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 this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 2, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30213 Filed 11-18-99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science

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 14, 1999, 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Kimberly L. Topper at Topperk@cder.fda.gov or Angie Whitacre at Whitacrea@cder.fda.gov, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss collaborative approaches to scientific research issues of common interest to the pharmaceutical industry, universities, the public, and FDA. Specific areas of focus will be in the nonclinical studies areas of: (1) Interspecies biomarkers of toxicity, (2) high-resolution magnetic imaging, (3) positron emission tomography imaging, and (4) methods to facilitate early human assessments.

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 December 9, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 9, 1999, and