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

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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 10, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30192 Filed 11–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Proposed Collection; Comment Request The Jackson Heart Study, Full Scale Exam I—Phase III

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The Jackson Heart Study, Full Scale Exam I—Phase III; Type of Information Collection Request: New. Need and Use of Information Collection: The Jackson Heart Study is a prospective epidemiologic investigation of Cardiovascular Disease (CVD) among African-American adults ages 30 years and older from the Jackson, Mississippi metropolitan area. The examination phase of the study is scheduled to begin in the fall of 2000 and will take approximately three years to complete. An extensive examination is planned and will include a series of questionnaires (dealing with lifestyle habits, medical history, medications, social and cultural factors), physical assessments (height, weight, body size, blood pressure, electrocardiogram, ultrasound measurements of the heart and arteries in the neck, and lung function) and laboratory measurements (cholesterol and other lipids, glucose, indicators related to clotting of the blood, among others). Data collected in this study will include both conventional risk factors and new or emerging factors that may be related to CVD. Some of the newer areas of focus will include early indicators of disease, genetics, socio-cultural influences such as socioeconomic status and discrimination, and physiological relations between common disorders such as high blood pressure, obesity and diabetes and their influence on CVD. The information collected will be used by the public and private sector for public health planning, medical education, other epidemiologic studies, and biomedical research. Frequency of Response: One-time. Affected Public: Individuals or families; Business or other for profit; not-for-profit institutions. Type of Respondents: Adults age 30 years and older, next-of-kin, and physicians.

The annual reporting burden is as follows: Estimated Number of Respondents: 2,567. Estimated Number of Responses per Respondent: 1. Average Burden Hours Per Response are shown in the table below; and Estimated Total Annual Burden Hours Requested: 68,658. The annualized cost to respondents is estimated at: $791,246 consist of their time and assumes a rate of $11.50 per hour for the cohort and next-of-kin decedents and $45 per hour for physicians.

Estimates of the annual reporting burden to respondents.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
JHS individuals of families	2,167	1	31.65	68,575
Morbidity & Mortality AFU next-of-kin decedents	200	1	0.17	33
Morbility & Mortality AFU Physicians	200	1	0.25	50
Total	2,567	.....	.....	68,658

The average annual Capital Costs are $52,800. The average annual Operating and Maintenance Costs are $5,402,000.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Cheryl Nelson, Jackson Heart Study Project Officer, 6701 Rockledge Drive, Room 8152, MSC 7934, Rockville, MD 20892–7934, or call non-toll-free number (301) 435–0451 or E-mail your request, including your address to: cn80n@.nih.gov

Comments Due Date

Comment regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: November 5, 1999.

Lawrence Friedman,

Director, Division of Epidemiology and Clinical Applications.

[FR Doc. 99–30197 Filed 11–18–99; 8:45 am]

BILLING CODE 4140–01–M