

the strategic goals of the Developmental Disabilities Branch (DDB) is to investigate causal factors for cerebral palsy and other serious neurodevelopmental disabilities for the purposes of prevention. The proposed workshop, organized by the DDB, National Center for Environmental Health, in collaboration with the National Center for HIV, STD and TB Prevention National Center for Infectious Diseases, and the National Center for Chronic Disease Prevention and Health Promotion, is designed to assist in the development of a prevention research agenda concerning the role of maternal/fetal infection during pregnancy, especially subclinical infection, on subsequent adverse neurodevelopmental outcomes of affected offspring. The agenda would guide extramural research activities by establishing research priorities and providing a research framework for CDC's extramural partners in the area of infection in pregnancy and neurodevelopment.

Contact Persons for More Information: Diana E. Schendel, Ph.D., telephone (770) 488-7359, or Marilyn Deal, telephone (770) 488-7695, Division of Birth Defects, Child Development, and Disability and Health (DBDCH), NCEH, CDC, 4770 Buford Highway, NE, Mailstop F-15, Atlanta, Georgia 30341. Fax (770) 488-7361.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-1109]

Mercury Compounds in Drugs and Food; List and Analysis; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Mercury Compounds in Drugs and Food." The document discusses drugs (including biologics) and foods that contain intentionally introduced mercury compounds. In addition, for those products that contain intentionally introduced mercury compounds, the document provides a quantitative and qualitative analysis of

the mercury compounds in the products. This document has been prepared in response to the Food and Drug Administration Modernization Act of 1997 (FDAMA), section 413, entitled "Food and Drug Administration Study of Mercury Compounds in Drugs and Food."

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the document entitled "Mercury Compounds in Drugs and Food" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Copies of the document are available on the Internet at <http://www.fda.gov/cder/index.htm>. 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.

FOR FURTHER INFORMATION CONTACT:

For human drug products: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

For human biological products: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

For veterinary drug products: William C. Keller, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6641.

For food and dietary supplement products: Sharon A. Ross, Center for Food Safety and Applied Nutrition (HFS-456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5343.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Mercury Compounds in Drugs and Food." This document discusses drugs (including biologics) and foods that contain intentionally introduced mercury compounds. In addition, for those products that contain intentionally introduced mercury compounds, the document provides a quantitative and

qualitative analysis of the mercury compounds in the products.

This document is part of FDA's implementation of FDAMA (Public Law 105-115), enacted on November 21, 1997. Section 413 of FDAMA required FDA to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. FDAMA required the agency to compile the list and provide the analysis within 2 years after the date of its enactment.

The statute did not differentiate whether the mercury compound was present in a product as an active or inactive ingredient, whether the product was for human or veterinary use, or whether the product was sold by prescription or over-the-counter. Food products include dietary supplements.

In the **Federal Register** of December 14, 1998 (63 FR 68775) and April 29, 1999 (64 FR 23083), FDA published notices requesting data and information on any intentionally introduced mercury compounds in these types of products. The agency asked manufacturers of affected products to provide: (1) The commercial name of the product that contains the mercury compound; (2) the chemical name, quantitative amount, and purpose of the mercury compound present; (3) a copy of the product's labeling; and (4) an estimate of the amount of the mercury compound used annually in manufacturing the product.

The agency received 41 responses to the two request-for-data notices. The agency also reviewed information contained in its Drug Registration and Listing System and other sources to identify additional products that contain intentionally introduced mercury compounds. The document discusses the information that the agency reviewed and provides a list and analysis of the products that were identified. The document is intended to provide information and does not set forth any requirements.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments may be seen in the Dockets Management Branch between 9

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]

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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]

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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