

the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailing.)

2. Late Applications: Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

#### Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Albertha Carey, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers For Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E-13, Atlanta, GA 30305, telephone (404) 842-6508.

Programmatic technical assistance may be obtained from Judy Pruden, M.Ed., R.D., Division of Nutrition, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mail Stop K-26, Atlanta, GA, 30341-3724, telephone (404) 488-4260.

Please refer to Announcement Number 537 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report; Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report; Stock No. 017-001-00473-1) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: May 15, 1995.

#### Joseph R. Carter

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC)

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### Food and Drug Administration

#### Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

**MEETINGS:** The following advisory committee meetings are announced:

#### Oncologic Drugs Advisory Committee

*Date, time, and place.* June 8 and 9, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

*Type of meeting and contact person.* Open public hearing, June 8, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open committee discussion, June 9, 1995, 8 a.m. to 11:30 a.m.; closed committee deliberations, 11:30 a.m. to 4 p.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD-9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make

formal presentations should notify the contact person before June 5, 1995, 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 required to make their comments.

*Open committee discussion.* On June 8, 1995, the committee will discuss: (1) New drug application (NDA) 50-704, Daunoxome® Injection (liposomal daunorubicin, Vestar, Inc.) "as the primary therapy for the palliative management of advanced, HIV-associated Kaposi's Sarcoma," and (2) NDA 20-449, Taxotere® (docetaxel, Rhone-Poulenc Rorer), for treatment of "patients with locally advanced or metastatic breast carcinoma in whom previous therapy has failed; prior therapy should have included an anthracycline unless clinically contraindicated." On June 9, 1995, the committee will discuss NDA 20-221, Ethyol (amifostine injection, U.S. Bioscience, Inc.) "as a cytoprotective agent against the cumulative renal toxicities associated with cisplatin and the cumulative hematologic toxicity associated with cyclophosphamide and cisplatin in patients with advanced solid tumors of non-germ cell origin."

*Closed committee deliberations.* On June 9, 1995, the committee will discuss trade secret and/or confidential commercial information relevant to investigational new drugs (IND's) and pending NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

#### Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

*Date, time, and place.* June 12, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 and reference the FDA panel meeting block. Reservations will be confirmed at the group rate based on availability.

*Type of meeting and contact person.* Open public hearing, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 12 m.; closed committee deliberations, 12 m. to 1:30 p.m.; open public hearing, 1:30 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 5 p.m.; Paula J. Wilkerson,

Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Orthopedic and Rehabilitation Panel, code 12521.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before June 1, 1995, 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 required to make their comments.

*Open committee discussion.* The committee will discuss general issues relating to a premarket approval application for a total knee replacement device. The committee will also hear an FDA presentation on conditions of approval and the gathering of long-term data. The afternoon session will include presentations and committee discussion on hip replacement systems. Speakers will examine components of clinical protocol design including: Medical and clinical aspects, rating systems, patient selection, controls, and statistical considerations.

*Closed committee deliberations.* The committee will discuss trade secret and/or confidential commercial information relating to orthopedic devices. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

#### **Blood Products Advisory Committee**

*Date, time, and place.* June 23, 1995, 8 a.m., Marriott—Bethesda, Congressional Salons I, II, and III, 5151 Pooks Hill Rd., Bethesda, MD.

*Type of meeting and contact person.* Open committee discussion, 8 a.m. to 10:45 a.m.; open public hearing, 10:45 a.m. to 11:45 a.m., unless public participation does not last that long; open committee discussion, 11:45 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 3:30 p.m.; Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-

1448, 301-594-6700, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Blood Products Advisory Committee, code 12388.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before June 12, 1995, 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 required to make their comments.

*Open committee discussion.* In the morning, the committee will discuss and provide recommendations on human immunodeficiency virus (HIV) antigen screening of blood donors. In the afternoon, the committee will discuss and review the report of the intramural research site visit of the Laboratory of Cellular Hematology, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research.

*Closed committee deliberations.* The committee will discuss the intramural scientific program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, a disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open

public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits

such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters

involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: May 17, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*

[FR Doc. 95-12661 Filed 5-23-95; 8:45 am]

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**Office of Inspector General**

**Program Exclusions: April 1995**

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of April 1995, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all other Federal non-procurement programs.

Subject, City, State	Effective Date
<b>Program-Related Convictions</b>	
Appel, Neal G, Brick, NJ .....	05/07/95
Bessette, Marcia F, Somerset, MA .....	05/04/95
Campbell, Rose, Lubec, ME .....	05/04/95
Campis, Eva B, Miami Beach, FL .....	05/09/95
Casey, Kathleen M, Monson, MA .....	05/04/95
Chaudhry, Baber Z, Metairie, LA .....	05/07/95
Curtis, Marianne, Costa Mesa, CA .....	05/04/95
Doshi, Bhupendrakumar, Brooklyn, NY .....	05/07/95
Ehrlich, Leah L, Fort Collins, CA .....	05/04/95
Garcia, Jose A, Miami, FL .....	05/09/95
Garrigo, Luis E, Miami, FL .....	05/09/95
Gomez, Jose M, Miami, FL .....	05/09/95
Goss, Louis, Montgomery, PA .....	05/07/95
Health Careers, Inc., North Wales, PA .....	05/09/95
Kheang, Rithik, Ontario, CA .....	05/04/95
McAfee, Robert W, Firebaugh, CA .....	05/04/95
McDermott, Robert T, Easton, PA .....	05/09/95
Mom's Taxi Corp, Carmel, NY .....	05/07/95
Muhammad, Bilal, I, Fremont, CA .....	05/04/95
Nnamdie, Oku J, Miami, FL .....	05/09/95
Raggi, Mindi, North Wales, PA .....	05/09/95
Recovery Management Corp. III, Newport News, VA .....	05/11/95
Rodriguez-Suarez, Mercedes, FL .....	05/09/95
Tan, Teresita V, Brooklyn, NY .....	05/07/95
Vallen, Jerry, Carmel, NY .....	05/07/95
Waters, Larry E, Canal Point, FL .....	05/04/95
<b>Patient Abuse/Neglect Convictions</b>	
Araujo, Maria, Medford, MA .....	05/04/95