

Please refer to Announcement Number 794 when requesting information and submitting an application.

This and other CDC announcements are also available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

CDC will not send application kits by facsimile or express mail.

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 20, 1997.

Joseph R. Carter,

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

[FR Doc. 97-13744 Filed 5-23-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreement for Research Projects for Persons With Disabilities and Prevention of Secondary Conditions, Program Announcement 731, Part 2: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreement for Research Projects for Persons with Disabilities and Prevention of Secondary Conditions, Program Announcement 731, Part 2.

Time and Date: 8:30 a.m.-2:00 p.m., June 13, 1997

Place: Koger Office Park, Vanderbilt Building, Room 1004-A, 2939 Flowers Road, South, Atlanta, Georgia 30341.

Status: Closed.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 731, Part 2.

The meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), Title 5 U.S.C., and

the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92-463.

Contact Person For More Information: James S. Belloni, Associate Director, State and Community Activities, National Center for Injury Prevention and Control, CDC, M/S K02, 4770 Buford Highway, NE, Atlanta, Georgia 30341-3724, telephone 770/488-4538.

Dated: May 14, 1997.

Carolyn J. Russell,

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

[FR Doc. 97-13747 Filed 5-23-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for HIV, STD, and TB Prevention (NCHSTP) of the Centers for Disease Control and Prevention (CDC); Announces the Following Meeting

Name: Consultation on Guidelines for HIV Partner Notification Conducted in Disease Control Efforts by Public Health Programs in the United States.

Times and Dates: 8:30 a.m.-5 p.m., June 17, 1997, 8:30 a.m.-12 p.m., June 18, 1997.

Place: Wyndham Gardens Hotel, 125 10th Street, NE (Midtown), Atlanta, Georgia, 30309, telephone 404/873-4800, fax 404/870-1530.

Status: Open to the public for participation, comment, and observation, limited only by the space available. The meeting room accommodates approximately 25 people.

Purpose: To invite comment from representatives of public health agencies and the public on revising the existing HIV partner notification guidelines. Currently CDC requires all health department recipients of HIV prevention funding to "establish standards and implement procedures for partner notification consistent with State/local needs, priorities, and resource availability."

Matters to be Discussed: Agenda items will focus on discussion of HIV partner notification guidelines that will accompany the announcement for FY 98 HIV Prevention Cooperative Agreements. Discussion will also include directions of supplemental HIV partner notification guidelines for the purpose of disease control in the United States concerning HIV and STD.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Jill Leslie, Division of HIV/AIDS Prevention, NCHSTP, CDC, M/S E40, 1600 Clifton Road, NE, Atlanta, Georgia 30303, telephone 404/639-2918.

Dated: May 19, 1997.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97-13746 Filed 5-23-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M-0203]

Bard Vascular Systems Division, C. R. Bard, Inc.; Premarket Approval of Bard® Albumin Coated DeBakey® Vasculour®-II Vascular Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by C. R. Bard, Inc., Billerica, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Bard® Albumin Coated DeBakey® Vasculour®-II Vascular Prosthesis. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on October 21, 1994, of the approval of the application.

DATES: Petitions for administrative review by June 26, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Dorothy B. Abel, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8262.

SUPPLEMENTARY INFORMATION: On January 14, 1993, C. R. Bard, Inc., Billerica, MA 01821, submitted to CDRH an application for premarket approval of Bard® Albumin Coated DeBakey® Vasculour®-II Vascular Prosthesis. The device is a vascular graft prosthesis and is indicated for replacement or bypass procedures in aneurysmal and occlusive diseases of the abdominal arteries.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On October 21, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 26, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this

document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 18, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97-13824 Filed 5-23-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

MEETING: The following advisory committee meeting is announced:

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. June 26 and 27, 1997, 9 a.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack

Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center visitor area is reserved for Clinical Center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times.

Type of meeting and contact person.

Open public hearing, June 26, 1997, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5:30 p.m.; closed committee deliberations, June 27, 1997, 9 a.m. to 12 m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD-110), 419-259-6211, or Danyiel D'Antonio (HFD-21), 301-443-5455, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533. Please call the hotline for information concerning any possible changes.

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 cardiovascular and renal disorders.

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, 1997, 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 26, 1997, the committee will discuss new drug application (NDA) 19-922, Corlopam™ (fenoldopam mesylate, Neurex), for the short-term treatment of hypertension when oral therapy is not feasible or possible and for use in hypertensive crisis; NDA 20-164, Lovenox® Injection (enoxaparin sodium, Rhone-Poulenc Rorer), to be indicated for the treatment of unstable angina and non-Q-wave myocardial infarction, concurrently administered with aspirin.

Closed committee deliberations. On June 27, 1997, the committee will review trade secret and/or confidential commercial information relevant to pending investigational new drug applications and/or NDA's. This portion