Application Submission and Deadline

On or before *July 3, 1995*, submit the original and two copies of the application (Form PHS 5161–1—OMB Number 0937–0189) and one electronic copy on disk to: Henry S. Cassell III, Grants Management Officer, Procurement and Grants Office, Grants Management Branch, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–16, Atlanta, GA 30305.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are:

A. Received on or before the deadline or

B. Sent on or before the deadline date and received in time for submission to the independent review committee. (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 will not be acceptable proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.A. or 1.B. are considered late applications and will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from: Manuel Lambrinos, 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, Mailstop E–16, Atlanta, GA 30305, telephone (404) 842–6777. Programmatic technical assistance may be obtained from: Sevgi Aral, Ph.D., Division of STD/HIV Prevention, National Center for Prevention Services, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–02, Atlanta, GA 30333, telephone (404) 639–8259.

Please refer to Announcement 523 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: April 14, 1995.

Joseph R. Carter,

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

[FR Doc. 95–9879 Filed 4–20–95; 8:45 am]

BILLING CODE 4163–18–P

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for National/Regional Minority Organization Human Immunodeficiency Virus/Sexually Transmitted Diseases Prevention, Immunization, and Tuberculosis Projects—Program Announcement 305b: Amendment of Time and Date

Federal Register Citation of Previous Announcement 60 FR 13728—dated March 14, 1995.

This notice announces an amendment in the time and date of a previously announced meeting.

Previously Announced Time and Date: 8:30 a.m.–4:30 p.m., April 18, 1995.

Amendment in Meeting Time and Date: 8:30 a.m.–4:30 p.m., April 18, 1995. 8:30 a.m.–4:30 p.m., April 19, 1995.

Dated: April 18, 1995.

Carolyn J. Russell,

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

[FR Doc. 95–10009 Filed 4–19–95; 10:14 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95M–0072]

Cardiac Pacemakers, Inc., Premarket Approval of VENTAK® P2 AICD™ System: Model 1625 VENTAK® P2 Pulse Generator, Model 2835 Software Module, and Model 2815 VENTAK® ECD External Cardioverter Defibrillator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Cardiac Pacemakers, Inc., St. Paul, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the VENTAK® P2 AICD™ System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 10, 1995, of the approval of the application.

DATES: Petitions for administrative review by May 22, 1995.

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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Carole C. Carey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On August 30, 1993, Cardiac Pacemakers, Inc., St. Paul, MN 55112, submitted to CDRH an application for premarket approval of VENTAK® P2 AICD™ System consists of the following: Model 1625 VENTAK® P2 pulse generator; Model 2835 Software Module to be used with commercially available Cardiac Pacemakers, Inc., (CPI®) Model 2035 Handheld Programmer and Model 6575 or 6577 Telemetry Wand; Model 2815 VENTAK® ECD External Cardioverter Defibrillator (which includes the Model 6873 High Voltage Cable with Model 6838 Thumbscrew, Model 6843 Bipolar Cable with Model 6838 Thumbscrew, Model 6874 Bipolar Cable, and related CPI® commercially available accessories); commercially available CPI® ENDOTAK® 60–Series Lead System and accessories; commercially available CPI® epicardial defibrillation leads and accessories; and commercially available pace/sense leads and accessories. The device is an automatic implantable cardioverter defibrillator system and is indicated for the treatment of patients with ventricular fibrillation and/or ventricular tachyarrhythmias who are at high risk of sudden cardiac death. Such patients are defined as having experienced the following situations: (1) The survival of at least one episode of cardiac arrest presumably due to hemodynamically unstable ventricular tachyarrhythmia not associated with acute myocardial infarction, and/or (2) a poorly tolerated, sustained ventricular tachycardia (VT) and/or ventricular fibrillation (VF) which recurs spontaneously or can be induced despite the best antiarrhythmic drug therapy. Note: The clinical outcome of hemodynamically stable, sustained VT patients is not fully known. A study of the safety and effectiveness of the VENTAK® P2 system on this selected subgroup of VT patients has not been conducted.

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 March 10, 1995, 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 (21 U.S.C. 360e(d)(3)) 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 part 12 (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 § 10.33(b) (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 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 May 22, 1995, 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 6, 1995.

Joseph A. Levitt,

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

[FR Doc. 95–9950 Filed 4–20–95; 8:45 am]

BILLING CODE 4160–01–F

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:

Subcommittee Meeting of the Food Advisory Committee

Date, time, and place. May 8 and 9, 1995, 8:30 a.m., Days Inn—Downtown Convention Center, Franklin Square I Ballroom, 1201 K St. NW., Washington, DC.

Type of meeting and contact person. Open subcommittee discussion, May 8, 1995, 8:30 a.m. to 5:15 p.m.; open subcommittee discussion, May 9, 1995, 8:30 a.m. to 10 a.m.; open public hearing, 10 a.m. to 11 a.m., unless public participation does not last that long; open subcommittee discussion, 11 a.m. to 2 p.m.; Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, Catherine M. DeRoever, Advisory Committee Staff (HFS–22), 202–205–4251, FAX 202–205–4970, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Food Advisory Committee, code 10564.

General function of the committee. The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

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 by close of business May 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. If necessary, comments may be limited to 5 minutes.

Open committee discussion. The subcommittee will review the Center for Food Safety and Applied Nutrition's Microbiology Research Program in the context of the Center's science program. A peer review panel will be asked to present its findings to the subcommittee. More detailed information regarding the meeting agenda that may become available prior to the meeting will be provided to the public via the 800 number listed above.

Circulatory System Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. May 8 and 9, 1995, 8:30 a.m., Holiday Inn—Gaithersburg, Walker and Whetstone Ballrooms, 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, May 8, 1995, 8:30 a.m. to 9:30 a.m., unless public