Dated: October 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–30443 Filed 11–27–96; 8:45 am]

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[Docket No. 96M–0451]

Cardiac Pacemakers, Inc.; Premarket Approval of VIGOR® DR Pacemaker System/VIGOR® SR Pacemaker System

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 VIGOR® DR Pacemaker System/ VIGOR® SR Pacemaker System. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on June 21, 1995, of the approval of the application.

DATES: Petitions for administrative review by December 30, 1996.

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: 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 September 30, 1994, Cardiac Pacemakers, Inc., St. Paul, MN 55112, submitted to CDRH an application for premarket approval of the following: VIGOR® DR (dual chamber) Model 1230/1235 Pulse Generators, VIGOR® SR (single chamber) Model 1130/1135 Pulse Generators, and the Model 2075 Software Module to be used with commercially available CPI® Model 2035 Handheld Programmer and Model 6575 or 6577 Telemetry Wand; Model 6942 Bidirectional Torque Wrench; Model 6562 Horseshoe Magnet; Model 6580 Electrogram Cable; Model 6589 Printer Paper; and commercially available pacemaker leads and accessories that are compatible with the pulse generators. The devices are generally indicated for long-term cardiac pacing. Generally accepted indications for long-term pacing include, but are not limited to, sick sinus syndrome; chronic sinus arrhythmias; including sinus bradycardia; sinus arrest; and sinoatrial (SA) block; second- and third-degree atrioventricular (AV) block; bradycardia-tachycardia syndrome; and carotid sinus syndrome. Patients who demonstrate hemodynamic improvement from AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require restoration of rate and AV synchrony, including varying degrees of AV block; low cardiac output or congestive heart failure related to bradycardia; and certain tachyarrhythmias. The adaptive-rate pacing modes of the VIGOR® DR and VIGOR® SR pulse generators are indicated for patients exhibiting chronotropic incompetence and who would benefit by increased pacing rates concurrent with physical activity.

On May 9, 1995, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 21, 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 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 December 30, 1996, 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: November 7, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–30508 Filed 11–27–96; 8:45 am]

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[Docket No. 96N–0443]

Review of Clinical Safety Data in Marketing Applications; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop, as part of its ''good review practices'' (GRP's), to provide an opportunity for input from the pharmaceutical industry, academia, and the public on the principles and methods being used by FDA in the review of clinical safety data in new drug product applications. Information and ideas generated at the workshop will be used to develop a guidance for reviewers who participate in the agency's clinical review process. A working draft of that guidance, ''Draft Guidance for Reviewers: Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review,'' along with a tentative

workshop agenda, will be available 3 weeks before the workshop.

DATES: The public workshop will be held on Wednesday, December 18, 1996, from 8:30 a.m. to 5 p.m. Because space is limited, interested parties are encouraged to register as soon as possible, or at least by December 13, 1996. There is no registration fee for the workshop. The administrative docket will remain open until January 31, 1997, to receive written comments, data, information, or views on the draft guidance or the workshop.

ADDRESSES: The public workshop will be held at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD. Persons interested in attending can register by faxing their name and title, organization name, if any, address, telephone and fax numbers to Paul A. David at FAX 301–594–2859.

Three weeks prior to the workshop, a copy of the draft guidance for reviewers, along with a tentative workshop agenda, will be available through CDER's Fax-on-Demand, 301–827–0577 or 800–342–2722, under the index, document no. 0506. Information on the workshop and registration also will be available via the Internet using the World Wide Web (WWW). To connect to the CDER home page, type http://www.fda.gov/cder and go to the ''What's Happening'' section. A transcript of the workshop will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 business days after the workshop at a cost of 10 cents per page.

Written comments on the draft reviewer guidance or on the workshop can be submitted until January 31, 1997, to the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be viewed at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Paul A. David, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–120), 5600 Fishers Lane, Rockville, MD 20857, 301–594–5530.

SUPPLEMENTARY INFORMATION: In March 1994, FDA launched a major initiative to develop and implement GRP's. The goal of the GRP's initiative is to identify and implement methods for improving the quality and efficiency of the clinical reviews of new product applications.

To manage this large initiative, the agency developed a multitrack plan to be implemented in stages. Tasks currently under development include: Defining the critical elements of the clinical review; designing a process for feedback, evaluation, and evolution in review practices and procedures; developing a data base on regulatory policy for clinical review; and defining good data handling practices.

The December 18, 1996, workshop is a part of an effort to define the critical elements of the clinical safety review process and develop a guidance for reviewers that describes those elements and sets institutional expectations for each level of review. The guidance being developed is intended for use by agency officers and other clinical reviewers during the review of new drug product applications. The draft guidance will be discussed at the workshop.

The primary goal of the workshop is to provide an opportunity for input from industry, academia, and the public on the principles and methods for the review of clinical safety data in new drug applications. To encourage the exchange of ideas and comments, the day-long workshop has been divided into the following four major sessions: (1) Characterizing the exposed population, establishing the common adverse events profile, establishing the serious adverse events profile, and integrating important safety findings using the review of systems approach. Each session will include a panel discussion and a period at the end for public comment.

The agency hopes to answer the following questions during the workshop: (1) What approaches to safety data review could speed the overall review process? (2) What steps could be taken to standardize the presentation of safety review data? (3) Are there review or review-related issues that are especially troublesome for those submitting safety data? (4) Do some approaches to data presentation make the reviewer's job easier or more difficult?

As it proceeds with the finalization of the guidance for reviewers, the agency will consider carefully all data and information presented at the workshop and submitted in writing on the guidance and workshop

Dated: November 21, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–30509 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Uncompensated Services Reporting and Recordkeeping—42 CFR 124, Subpart F (OMB No. 0915–0077)—Extension and Revision

Titles VI and XVI of the PHS Act, commonly known as the Hill-Burton Act, provide for government grants and loans for construction or renovation of health care facilities. As a condition of receiving this construction assistance, facilities are required to provide a ''reasonable volume'' of services to persons unable to pay. Facilities are also required to provide assurances periodically that the required level of uncompensated care is being provided, and to follow certain notification and recordkeeping procedures. These requirements are referred to as the uncompensated services assurance.

Certain types of facilities can apply for one of four compliance alternatives which reduce the reporting, recordkeeping, and notification requirements. A new compliance alternative has been added to this clearance package.

The regulations contain provision for reporting to the government the amount of free care provided, as well as provisions for following certain notification and recordkeeping procedures. The regulations also define the procedures for applying for certification (and annual recertification) under a compliance alternative. All of these regulations are included in this clearance request. The Uncompensated