[Docket No. 95M–0057]

Medtronic CardioRhythm; Premarket Approval of Atakr Radio Frequency Catheter Ablation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medtronic CardioRhythm, San Jose, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Atakr Radio Frequency Catheter Ablation 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 of February 9, 1995, of the approval of the application.

DATES: Petitions for administrative review by May 30, 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: Mark Massi, 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 26, 1993, Medtronic CardioRhythm, San Jose, CA 95134, submitted to CDRH an application for premarket approval of the Atakr Radio Frequency Catheter Ablation System. The device is a radio frequency power cardiac catheter ablation system, and it is indicated for interruption of accessory atrioventricular (AV) conduction pathways associated with tachycardia, for the treatment of AV nodal re-entrant tachycardia, and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia.

On December 5, 1994, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On February 9, 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 (*insert date 30 days after date of publication in the* Federal Register), 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 3, 1995.

Joseph A. Levitt,

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

[FR Doc. 95–10429 Filed 4–27–95; 8:45 am]

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Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the months of May and June 1995.

Name: Advisory Commission on Childhood Vaccines (ACCV) Subcommittee on Vaccine Safety.

Date and Time: May 31, 1995; 9:00 am–5:00 pm.

Place: Parklawn Building, Conference Room D, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

Purpose: The subcommittee will review issues relevant to vaccine safety and adverse reactions to vaccines.

Agenda: Agenda items will include, but not be limited to: establishing a charge for the Subcommittee; reviewing current vaccine safety efforts; and examining the current status of vaccine safety research.

Name: Advisory Commission on Childhood Vaccines (ACCV)

Date and Time: June 1, 1995; 9:00 am–5:00 pm.

Place: Parklawn Building, Conference Room D, 5600 Fishers Lane, Rockville, Maryland 20857.

Purpose: The Commission: (1) advises the Secretary on the implementation of the Program, (2) on its own initiative or as the result of the filing of a petition, recommends changes in the Vaccine Injury Table, (3) advises the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions, (4) surveys Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advises the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and (5) recommends to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the National Vaccine Injury Compensation Program.

Agenda: Agenda items will include, but not be limited to: a report on Acellular Pertussis Vaccine Clinical Trials; a vaccine safety update from the Centers for Disease Control and Prevention and the Food and Drug Administration; and routine Program reports.

Public comment will be permitted before the Subcommittee adjourns on May 31; and at the end of the full Commission meeting on June 1. Oral presentations will be limited to 5 minutes per public speaker.

Persons interested in providing an oral presentation should submit a written request,

along with a copy of their presentation to Mr. Jerry Anderson, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–35, 5600 Fishers Lane, Rockville, MD 20852; Telephone (301) 443–6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for presentation, but desire to make an oral statement, may sign up in Conference Room D on May 31 and June 1. These persons will be allocated time as time permits. Anyone requiring information regarding the Commission should contact Mr. Anderson, Division of Vaccine Injury Compensation, Bureau of Health Professions, Room 8A–35, 5600 Fishers Lane, Rockville, Maryland 20852; Telephone (301) 443–6593.

Name: National Advisory Committee on Rural Health

Date and Time: June 11–14, 1995; 1:00 p.m.

Place: The Sheraton Tara Hotel, 363 Maine Mall Road, South Portland, ME 04016, (207) 775–6161.

The meeting is open to the public.

Purpose: The Committee provides advice and recommendations to the Secretary with respect to the delivery, financing, research, development and administration of health care services in rural areas.

Agenda: The Plenary Session will begin on Sunday, June 11 with an update on legislation that affects rural health care delivery. This will be followed by a presentation on Rural Health Perspectives from the Department of Health and Human Services. Dr. Jo Ivey Boufford, Deputy Assistant Secretary for Health, has agreed to make this presentation. The Committee will devote the remainder of the plenary session to a discussion of managed care and network development in rural areas and to medicare's payment methodology for managed care risk contracts—the Adjusted Average Per Capita Costs (AAPCC) methodology.

The Committee will be making site visits to selected rural health delivery facilities all day on Monday. The meeting is open to the public; however, no transportation will be provided to the sites.

The Education and Health Services Work Group and the Health Care Finance Work Group will meet all day on Tuesday to continue developing recommendations and strategies for improving health services delivery in rural areas. The meeting will adjourn on Wednesday, June 14, at noon.

Anyone requiring information regarding the subject Committee should contact Dena S. Puskin, Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Ms. Arlene Granderson, Office of Rural Health Policy, Health Resources and Services Administration, Telephone (301) 443–0835.

Agenda Items are subject to change as priorities dictate.

Dated: April 25, 1995.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

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BILLING CODE 4160–15–P

Public Health Service

Agency Forms Undergoing Paperwork Reduction Act Review

Each Friday the Public Health Service (PHS) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the PHS Reports Clearance Officer on 202–690–7100.

The following requests have been submitted for review since the list was last published on Friday, April 7.

1. Survey to Evaluate the Impact of the Coronary Primary Prevention Trial on Medical Practice: 1995—0925–0356 (Reinstatement with change)—The National Heart, Lung, and Blood Institute will sponsor a survey of practicing physicians to assess attitudes and behavior regarding blood cholesterol in order to evaluate the impact of the findings of the Coronary Primary Prevention Trial and the Adult Treatment Panel Guidelines On clinical practices and to discern continuing educational needs for physicians. Respondents: Business or other for-profit; Number of Respondents: 1,600; Number of Responses per Respondent: 1; Average Burden per Response: .501 hours; Estimated Annual Burden: 800 hours. Send comments to Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

2. An Epidemiologic Study of the Relation Between Maternal and Parental Preconception Exposure to Ionizing Radiation and Childhood Leukemia—New—This study is designed to determine whether preconception gonadal doses from ionizing radiation are higher in the parents of children with leukemia than in parents of healthy children. The study is designed as a multicenter case-control study. Cases will be children with leukemia and controls will be children without leukemia selected at random from the same population as the cases. Respondents: Individuals or households; Number of Respondents: 911; Number of Responses per Respondent: 1; Average Burden per Response: 1.75 hours; Estimated Annual Burden: 1595 hours. Send comments to Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

3. Confidentiality of Alcohol and Drug Abuse Patient Records—0930–0092 (Extension, no change)—States require Federally conducted, regulated, or directly or indirectly assisted alcohol and drug abuse programs to keep patient records confidential. Information requirements are (1) written disclosures to patients, and (2) documenting ''medical personnel'' status of receipt of a disclosure to meet a medical emergency. Respondents: Not-for-profit institutions, Federal Government, State, Local or Tribal Government; Number of Respondents: 10,000; Number of Responses Per Respondent: 348; Average Burden per Response: .0287 hour; Estimated Burden: 100,110 Hours. Send comments to James Scanlon, Office of the Assistant Secretary for Health, Room 737–F, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC 20201.

4. Assessment of Demographic Information on Death Certificates Survey—New—Demographic characteristics of decedents collected on death certificates are a critical source of information for public health surveillance, analysis, and program planning. This information is used in the tracking and analysis of diseases and injuries occurring among different subgroups in the population, which is integral to the mission of CDC. The purpose of this survey is to ascertain the methods currently used by funeral directors. Respondents: Business or other for-profit, State, Local or Tribal Government; Number of Respondents: 100; Number of Responses Per Respondent: 1; Average Burden Per Response: 1 hour; Estimated Annual Burden: 100 hours. Send comments to Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

5. Application for the National Institutes of Health AIDS and Clinical Research Loan Repayment Programs—0925–0361 (Reinstatement with change)—The information collection will be used by the PHS to determine an applicant's eligibility for participation in the NIH AIDS and Clinical Research Loan Repayment Programs. Respondents: Individuals or household,