4068. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 29, 1996, of the approval of the application.

DATES: Petitions for administrative review by November 7, 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: Tara A. Ryan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On November 1, 1993, Medtronic, Inc., Minneapolis, MN 55432–3576, submitted to CDRH an application for premarket approval of the CapSureFix® Pacing Lead, Model 4068. The device is a permanent implantable cardiac pacemaker electrode (lead) and is designed to be used with a pulse generator as part of a cardiac pacing system. The lead has application where implantable atrial or ventricular, single chamber or dual chamber pacing systems are indicated.

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 29, 1996, 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 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 November 7, 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: September 20, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–25812 Filed 10–7–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given to the meetings of the National Cancer Institute Special Emphasis Panel (SEP):

Name of SEP: Development of Dosage Forms & Delivery Systems for Antitumor and Anti-AIDS Agents.

Date: October 4, 1996.

Time: October 4—8:30 am.

Place: Executive Plaza North, Conference Room G, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Dr. Courtney Michael Kerwin, Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 601, 6130 Executive Boulevard MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–7421.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of a grant application.

Name of SEP: Modulation of Apoptosis to Improve Cancer Therapy.

Date: October 6–7, 1996.

Time: October 6—8 pm, October 7—8 am.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW, Washington, DC 20007.

Contact Person: Dr. David Irwin, Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 635E, 6130 Executive Boulevard MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/406–0371.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of a grant application.

Name of SEP: Evaluation of Chemopreventive Agents by In Vitro Techniques.

Date: October 7, 1996.

Time: October 7—2 pm.

Place: Executive Plaza North, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Dr. Lalita D. Palekar, Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 601, 6130 Executive Boulevard MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–7575.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of a grant application.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being submitted less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: October 3, 1996.

Paula N. Hayes,

Acting Management Officer, NIH.

[FR Doc. 96–25861 Filed 10–3–96; 4:51 pm]

BILLING CODE 4140–01–M