DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98M–0038]

Guidant Corp.; Premarket Approval of VENTAK® AV™ AICD™ Model 1810/ Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Guidant Corp., St. Paul, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the VENTAK® AV™ AICD™ System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of July 18, 1997, of the approval of the application.

DATES: Petitions for administrative review by February 26, 1998.

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 August 20, 1996, Guidant Corp., St. Paul, MN 55112–5798, submitted to CDRH an application for premarket approval of VENTAK® AV™ AICD™ Model 1810/ Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application which consists of the following: Model 1810/Model 1815 pulse generator and Model 2833 Software Application to be used with commercially available Cardiac Pacemakers, Inc., Programmer/ Recorder/Monitor (PRM). The device is a multiprogrammable automatic, implantable dual-chamber pacemaker and cardioverter defibrillator, and is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations: (1) Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia; (2) recurrent, poorly tolerated sustained ventricular tachycardia (VT); (3) prior myocardial infarction, left ventricular ejection fraction of ≤ 35 percent, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied. *NOTE: The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known.* Safety and effectiveness studies have not been conducted. The VENTAK® AV™ AICD™ pulse generator is not intended for use solely as a primary bradycardia support device.

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 July 18, 1997, 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 February 26, 1998, 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: January 5, 1998.

Joseph A. Levitt,

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

[FR Doc. 98–1943 Filed 1–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Anesthetic and Life Support Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 5, 1998, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4090, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and discuss the occurrence of spinal/epidural hematomas with the concurrent use of approved low molecular weight heparins or heparinoids and spinal/epidural anesthesia or spinal puncture. The committee will also consider labeling for low molecular weight heparins and heparinoids concerning these adverse events. The approved drug products under discussion and their sponsors are: (1) Lovenox® (enoxeparin sodium) Injection, Rhone-Poulenc Rorer Pharmaceuticals, Inc.; (2) Fragmin® (dalteparin sodium) Injection, Pharmacia & Upjohn; (3) Orgaran® (danaparioid sodium) Injection, Organon, Inc.; and (4) Normiflo™ (ardeparin sodium) Injection, Wyeth Laboratories, Inc.

Procedure: On February 5, 1998, from 8 a.m. to 3:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 29, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 29, 1998, 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 requested to make their presentation.

Closed Committee Deliberations: On February 5, 1998, from 3:45 p.m. to 5:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The investigational new drug and Phase I and II drug products in process will be presented and recent action on selected new drug applications will be discussed.

FDA regrets that it was unable to publish this notice 15 days prior to the February 5, 1998, Anesthetic and Life Support Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Anesthetic and Life Support Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2024 Filed 1–23–98; 11:47 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 11, 12, and 13, 1998, 8:30 a.m. to 5 p.m.

Location: DoubleTree Hotel, Pentagon City, 300 Army Navy Dr., Arlington, VA.

Contact Person: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4251, FAX 202–205–4970, E-mail CDEROEVE@BANGATE.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 11, 12, and 13, 1998, the committee will undertake discussions on dietary supplements. Issues raised in the report of the White House Commission on Dietary Supplement Labeling relating to postmarket surveillance and consumer research will be discussed. Also, two aspects relating to good manufacturing practices (GMP's) for dietary supplements will be addressed. The agency is interested in recommendations for ensuring the identity for different types of dietary ingredients and on recordkeeping requirements. On February 13, 1998, two committee working groups will continue discussing assignments stemming from the Keystone report on health claims.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 9, 1998. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on February 11 and 12, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 9, 1998, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C., app. 2).

Dated: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2023 Filed 1–23–98; 11:47 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting For Representatives of Health Professional Organizations

AGENCY: Food and Drug Administration

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. The agenda will include presentations and discussions on the topics of the FDA Modernization Act of 1997, and the role of FDA in the regulation of products used in complementary and alternative medicine. There will also be a brief update on tobacco.

DATES: The meeting will be held on Monday, February 9, 1998, from 1:30 p.m. to 3 p.m.

ADDRESSES: The meeting will be held at the Bethesda Hyatt, One Metro Center, Bethesda, MD.