Agency for Health Care Policy and Research

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

AGENCY: Agency for Health Care Policy and Research, HHS.

ACTION: Notice.

SUMMARY: This notice announces the Agency for Health Care Policy and Research's (AHCPR) intention to request the Office of Management and Budget (OMB) to reinstate two expired information collection projects as one: Formerly the 1987 Health Insurance Plans Survey (HIPS) and the 1994 National Employer Health Insurance Survey (NEHIS), now to be combined in the 1997 Medical Expenditure Panel Survey—Insurance Component (MEPS–IC). In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3507(a)(1)(D)), AHCPR invites the public to comment on this reinstatement.

DATES: Comments on this notice must be received by November 25, 1996.

ADDRESSES: Written comments for the proposed information collection should be submitted within 30 working days of this notice directly to the OMB Desk Officer at the following address: Allison Eydt, Human Resources and Housing Branch, Office of Information and Regulatory Affairs, OMB; New Executive Office Building, Room 10235; Washington, D.C. 20503.

All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Ruth A. Celtnieks, AHCPR Reports Clearance Officer, (301) 594–1406, ext. 1497.

SUPPLEMENTARY INFORMATION:

Proposed Project

Pretest for the 1997 Medical Expenditure Survey—Insurance Component (MEPS–IC).

AHCPR intends to conduct a survey of establishments in 1997 to collect information from employers concerning employer-sponsored health insurance. This survey will be an integration of two previous surveys, now components of MEPS–IC. The two surveys which collected similar information are:

1. The 1987 Health Insurance Plans Survey (HIPS) sponsored by AHCPR's predecessor, the National Center for Health Services Research; and

2. The 1994 National Employer Health Insurance Survey (NEHIS) sponsored by AHCPR, the National Center for Health Statistics (NCHS) and the Health Care Financing Administration (HCFA).

Due to the integration of these two previous survey operations into the MEPS–IC, AHCPR is updating the questionnaire and data collection methodology. A data collection pretest is being proposed using a sample of potential respondents. Based upon the results of this test, the AHCPR will develop and refine the final methodology for the 1997 MEPS–IC.

Burden Estimates Follow:

Number of Respondents: 350.

Number of Surveys per Respondent: 1.

Average Burden/Respondent: .75 Hours.

Estimated Total Burden: 263 Hours.

Copies of these data collection plans and instruments can be obtained from the AHCPR Reports Clearance Officer (see above).

Dated: October 17, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–27279 Filed 10–23–96; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 96M–0371]

Guidant Corp.; Premarket Approval of SELUTE® Steroid Eluting Endocardial Lead Models 4185 and 4285

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 SELUTE® Steroid Eluting Endocardial Lead Models 4185 and 4285. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of May 8, 1996, of the approval of the application.

DATES: Petitions for administrative review by November 25, 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: Lynette A. Gabriel, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On January 13, 1995, Guidant Corp., St. Paul, MN 55112–5798, submitted to CDRH an application for premarket approval of SELUTE® Steroid Eluting Endocardial Lead Models 4185 and 4285. The device is a permanent pacing lead and is indicated for chronic pacing and sensing of the ventricle when used with a compatible pulse generator.

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 May 8, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH. In that letter, CDRH also notified the applicant that the device requires tracking under section 519(e) of the act (21 U.S.C. 360i(e)).

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 25, 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. 96–27202 Filed 10–23–96; 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:

Gastrointestinal Drugs Advisory Committee

Date, time, and place. November 4 and 5, 1996, 9 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, November 4, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, November 5, 1996, 9 a.m. to 5 p.m.; Joan C. Standaert (HFD–180), 419–259–6211, or Mae Brooks (HFD–21), 301–443–5455, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Gastrointestinal Drugs Advisory Committee, code 12538. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases.

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 before October 28, 1996, 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.

Open committee discussion. On November 4, 1996, the committee will discuss data concerning the safety of long-term antisecretory therapy in patients with *Helicobacter pylori*; new drug application (NDA) 19–810, Prilosec® (omeprazole, Astra Merck), delayed release capsules; and NDA 20–406, Prevacid® (lansoprazole, TAP Holding Co.), delayed release capsules. On November 5, 1996, the committee will discuss NDA 20–675 (ureodeoxycholic acid, Axcan Pharma), for the treatment of patients with primary biliary cirrhosis.

FDA regrets that it was unable to publish this notice 15 days prior to the Gastrointestinal Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Gastrointestinal 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.

Peripheral and Central Nervous System Drugs Advisory Committee

Date, time, and place. November 15, 1996, 8:30 a.m., Holiday Inn—Gaithersburg, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, 8:30 a.m. to 1 p.m.; open public hearing, 1 p.m. to 2 p.m., unless public participation does not last that long; open committee discussion, 2 p.m. to 5 p.m.; Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Peripheral and Central Nervous System Drugs Advisory Committee, code 12543. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in neurological disease

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 before November 8, 1996, 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.

Open committee discussion. The committee will discuss the safety and effectiveness of NDA 20–648, Diastat® (diazepam emulsion, Athena Neurosciences, Inc.), as a treatment for acute repetitive seizures.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee