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.

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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