postmarket surveillance order, for example, might be whether there are alternative postmarket data collection mechanisms to obtain the same kind of information about the device. The agency could use such criteria to guide its decision whether to impose tracking or postmarket surveillance in a particular case.

The agency requests that comments or presentations be provided concerning the statutory requirements for medical device tracking and postmarket surveillance and related proposed risk assessment criteria which may be useful to the agency to determine whether tracking orders or postmarket surveillance orders should be issued for devices that meet the basic statutory requirements of section 519(e) or 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e) or 360l). The agency would like to encourage comments, discussion and proposals from the industry, the professional community, consumers, and any other interested parties or organizations. Written comments may be submitted in advance of the meeting to the Dockets Management Branch (address above).

To help focus discussion, FDA requests answers to the following questions:

(1) What factors (or criteria) should lead FDA to order tracking and/or postmarket surveillance?

(2) What factors (or criteria) should lead FDA not to order tracking and/or postmarket surveillance?

(3) Under what circumstances should FDA order both tracking and postmarket surveillance for a device?

(4) Under what circumstances should FDA order tracking but not postmarket surveillance, or vice versa?

Electronic Access

Additional information regarding the public meeting may be found on the Internet on the home page for the Center for Devices and Radiological Health under the ''New Items on the Internet'' section at www.cdrh.fda.gov. This will be an informal meeting conducted in accordance with 21 CFR 10.65.

Dated: December 15, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–33090 Filed 12–15–97; 3:02 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0500]

Telectronics Pacing Systems, Inc.; Premarket Approval of Telectronics Guardian™ ATP II Model 4211 Implantable Cardioverter Defibrillator System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Telectronics Pacing Systems, Inc., Englewood, CO, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Guardian™ ATP II Model 4211 Implantable Cardioverter Defibrillator System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of July 3, 1997, of the approval of the application.

DATES: Petitions for administrative review by January 20, 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: Doris J. Terry, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On July 8, 1994, Telectronics Pacing Systems, Inc., Englewood, CO 80112, submitted to CDRH an application for premarket approval of the Guardian™ ATP II Model 4211 Implantable Cardioverter Defibrillator System. The Guardian™ ATP II Model 4211 Implantable Cardioverter Defibrillator System is indicated for use in patients who are at high risk of sudden death due to ventricular fibrillation and/or ventricular tachyrhythmias and who have experienced one of the following situations:

- survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyrhythmia
- recurrent, poorly tolerated sustained ventricular tachycardia (VT). Note: The clinical outcome for hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.

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 3, 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 January 20, 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: October 31, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–32968 Filed 12–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–265]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement without change of a previously approved collection for which approval has expired; *Title of Information Collection:* Independent Renal Dialysis Facility Cost Report Form and Supporting Regulations 42 CFR 413.198, 413.20; *Form No.:* HCFA–265; *Use:* The Medicare Independent Renal Dialysis Facility Cost Report provides for determinations and allocation of costs to the components of the Renal Dialysis facility in order to establish a proper basis for Medicare payment. *Frequency:* Annually; *Affected Public:* Business or other for profit; *Number of Respondents:* 2,472; *Total Annual Responses:* 2,472; *Total Annual Hours:* 484,512.

2. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Evaluation of the Oregon Medicaid Reform Demonstration: Phase II Adult Interview, Phase II Child Interview, Survey of Agency Providers; *Form No.:* HCFA–R–221; *Use:* These survey instruments will be used to evaluate the Oregon Medicaid Reform Demonstration. The Phase II Adult and Phase II Child interviews are designed to collect information on health status, access to care and past health insurance status for adults and children participating in Phase II of the Oregon Health Plan (OHP). The survey of Agency providers is designed to collect information on the experience under OHP of agencies that traditionally treat disabled and elderly Medicaid beneficiaries. *Frequency:* One Time; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Governments; *Number of Respondents:* 4,150; *Total Annual Responses:* 4,150; *Total Annual Hours:* 1,730.

3. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Health Maintenance Organizations & Competitive Medical Plans National Data Reporting Requirements and Supporting Regulations 42 CFR 417.100, .940, .126, .478, .162; *Form No.:* HCFA–906; *Use:* This form captures information which governs qualification of new Health Maintenance Organizations (HMOs) and the eligibility of Competitive Medical Plans (CMPs), employer compliance, recovery of Federal loan and loan guarantees, financial disclosure, and continuing regulation of qualified HMOs and CMPs which provide health care services to beneficiaries for a fixed fee which is paid on a periodic basis. *Frequency:* Other; Annually, Quarterly; *Affected Public:* Federal Government, Business or other for-profit, Not-for-profit institutions, State, local or Tribal Government; *Number of Respondents:* 313; *Total Annual Responses:* 953; *Total Annual Hours:* 3,130.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 11, 1997.

John P. Burke III,

HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.

[FR Doc. 97–33064 Filed 12–17–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Document Identifier: HCFA–179

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Transmittal and Notice of Approval of State Plan Material and Supporting Regulations in 42 CFR 430.10–430.20 and 440.167; *Form No.:* HCFA–179 (OMB #0938–