Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal, J.D.,

Acting Director, Office of Research Integrity.

[FR Doc. 97–33035 Filed 12–17–97; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request, Proposed Projects

Title: IRS Project 1099.

OMB No.: New Collection.

Description: A voluntary program which provides States' Child Support Enforcement agencies upon there request access to all of the earned and unearned income information reported to IRS by employers and financial institutions. The IRS 1099 information is used to locate noncustodial parents and to verify income and employment, which has proven essential to accurately establishing and enforcing child support obligations.

Respondents: State, Local, or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE 1099 Request Records	43	12	1	1,032

Estimated Total Annual Burden Hours: 1,032.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 15, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–33083 Filed 12–17–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0517]

Changes in Medical Device Tracking and Postmarket Surveillance Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Changes in medical device tracking and postmarket surveillance authority under the Food and Drug Administration Modernization Act of 1997. The topic to be discussed is postmarket controls, including tracking and/or surveillance of devices.

Date and Time: The meeting will be held on January 15, 1998, 9 a.m. to 3 p.m.

Location: The meeting will be held at the University of Maryland Auditorium, 9640 Gudelsky Dr., Rockville, MD.

Contact: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4692, FAX 301–594–4610.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number) and written material and requests to make oral presentations to the contact person by January 5, 1998. Written comments may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, by January 5, 1998.

If you need special accommodations due to a disability, please contact Casper E. Uldriks at least 7 days in advance of the meeting.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

The agency is interested in discussing the statutory changes concerning tracking and postmarket surveillance under the Food and Drug Administration Modernization Act of 1997 and whether the agency should develop additional criteria to use to determine whether tracking or postmarket surveillance requirements should be ordered by FDA. The agency would like to supplement the statutory criteria with additional nonbinding criteria to help determine which devices may need to be added or removed from the list of devices subject to tracking and/or postmarket surveillance requirements. FDA intends to publish its revised lists by February 19, 1998, the effective date of the new law.

By way of example, additional criteria that would support a tracking order might include the likelihood of a recall, or the likelihood of irreversible clinical outcomes. Additional criteria that might not support a tracking order, for example, might include current, standard clinical practices that mitigate risk. Additional criteria that would support a postmarket surveillance order might include, for example, the use of a new technology or the need to assess a new public health issue based on measurable outcomes. Additional criteria that would not support a

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,