conducted throughout the State of Florida.

Board of Governors of the Federal Reserve System, May 13, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–12991 Filed 5–16–97; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities: Submission for Office of Management and Budget (OMB) Review; Comment Request

Title: Performance (Progress) Reports for Title IV Training, Research, and Discretionary Projects and Programs Grantees

Description: Project performance reports provide an understanding of how projects funded by Title IV of the Older Americans Act are being administered by grantees, in conformance with legislative requirements, pertinent federal regulations, and other applicable instructions and guidelines issued by the Administration on Aging (AoA). This information will be used for federal oversight of the Title IV Training, Research, and Discretionary Projects and Programs.

Respondents: Applicants who have been awarded Title IV grants.

Annual Burden Estimates:

Instrument	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
Performance Report for Title IV Grantees	75	2	16	2400

Additional Information: Copies of the collection may be obtained by writing to the Administration on Aging, Office of the Executive Secretariat, 330 Independence Avenue, S.W., Washington, DC 20201, Attn.: AoA Reports Clearance Officer.

OMB Comment: OMB is required to make a decision, concerning the collection of information, between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 60 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, DC 20503, Attn.: Ms. Wendy Taylor.

Dated: May 8, 1997.

William F. Benson,

Acting Principal Deputy, Assistant Secretary for Aging.

[FR Doc. 97–10384 Filed 5–16–97; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0185]

ELA Medical, Inc.; Premarket Approval of Chorus RM Model 7034 DDDR Pacemaker System and Opus RM Model 4534 SSIR Pacemaker System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by ELA Medical, Inc., Plymouth, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Chorus RM Model 7034 DDDR Pacemaker System and Opus RM Model 4534 SSIR Pacemaker System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 10, 1997, of the approval of the application.

DATES: Petitions for administrative review by June 18, 1997.

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: Marian Kroen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION: On January 18, 1996, ELA Medical, Inc., Plymouth, MN 55441, submitted to CDRH an application for premarket approval of Chorus RM Model 7034 DDDR Pacemaker System and Opus RM Model 4534 SSIR Pacemaker System which includes an IBM compatible microcomputer which has been configured and furnished by ELA Medical, Inc., with CSO 2.46 programming software and is connected to a CPR1 programming lead. These devices are implantable cardiac pacemakers and are indicated for: (1) Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in minute ventilation; (2) The generally accepted patient conditions warranting chronic cardiac pacing which include:

- Symptomatic paroxysmal or permanent second or third-degree AV block;
- Symptomatic bilateral bundle branch block;
- Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders;
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; and
- Vaso-vagal syndromes or hypersensitive carotid sinus syndromes.

The Chorus RM is also indicated for dual-chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output; and
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this 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 March 10, 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 (21 U.S.C. 360e(d)(3)) 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 June 18, 1997, 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: April 22, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–13023 Filed 5–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Blood Products 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 June 19, 1997, 9 a.m. to 2:30 p.m., and June 20, 1997, 8:30 a.m. to 1:30 p.m.

Location: Quality Suites Hotel, Potomac Ballrooms I, II, and III, Three Research Ct., Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 19, 1997, the committee will sit as a Medical Device Panel to review agency recommendations for the following reclassification changes under 21 CFR part 860, subpart C: (1) Inclusion of automated infectious disease test systems used for donor screening, and (2) reclassification of class I medical devices used in collection and processing of blood. On June 20, 1997, the committee will hear discussion and provide recommendations regarding inadvertent contamination of plasma used for fractionation.

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 June 13, 1997. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before June 13, 1997, 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 presentation.

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

Dated: May 13, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–13020 Filed 5–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Antiviral 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 July 14 and 15, 1997, 8:30 a.m. to 5 p.m..

Location: Armory Place, rm. 204, 925 Wayne Ave., Silver Spring, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, 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 Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 14 and 15, 1997, the committee will discuss the utility of plasma human immunodeficiency virus (HIV) RNA measurement as an endpoint in clinical trials for drugs to treat HIV infection. In light of the rapid changes