human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 7, 1993. The applicant claims June 4, 1993, as the date the new drug application (NDA) for MYOVIEW™ (NDA 20–372) was initially submitted. However, FDA records indicate that NDA 20–372 was submitted on June 7, 1993.

3. *The date the application was approved:* February 9, 1996. FDA has verified the applicant's claim that NDA 20–372 was approved on February 9, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 491 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 28, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 28, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 20, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–30387 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0450]

Advanced Technology Laboratories; Premarket Approval of Ultramark® 9 High Definition™ Imaging (HDI™) Ultrasound System With L10–5 Scanhead

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Advanced Technology Laboratories, Bothell, WA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Ultramark® 9 HDI™ Ultrasound System with L10–5 Scanhead. After reviewing the recommendation of the Radiological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on April 11, 1996, of the approval of the application.

DATES: Petitions for administrative review by December 30, 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: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212.

SUPPLEMENTARY INFORMATION: On February 17, 1994, Advanced Technology Laboratories, Bothell, WA 98041–3003, submitted to CDRH an application for premarket approval of the Ultramark® 9 HDI™ Ultrasound System with L10–5 Scanhead. The device is an Ultrasonic Pulse-Echo Imaging System. The Ultramark® 9 HDI™ Ultrasound System with L10–5 Scanhead is indicated as an adjunct to mammography and physical breast examination to provide a high degree of physician confidence in differentiating benign from malignant or suspicious breast lesions. This device provides the physician with additional information to guide a biopsy decision. Utility of this system has been demonstrated for lesions with an indeterminate level of suspicion (LOS 2–4) by conventional diagnostic modalities. Using the HDI™ system in the evaluation of solid mass characteristics can reduce the number of biopsies performed on indeterminate lesions.

On December 11, 1995, the Radiological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On April 11, 1996, 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 December 30, 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: October 24, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–30443 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0451]

Cardiac Pacemakers, Inc.; Premarket Approval of VIGOR® DR Pacemaker System/VIGOR® SR Pacemaker System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Cardiac Pacemakers, Inc., St. Paul, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the VIGOR® DR Pacemaker System/ VIGOR® SR Pacemaker System. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter on June 21, 1995, of the approval of the application.

DATES: Petitions for administrative review by December 30, 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: Carole C. Carey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION: On September 30, 1994, Cardiac Pacemakers, Inc., St. Paul, MN 55112, submitted to CDRH an application for premarket approval of the following: VIGOR® DR (dual chamber) Model 1230/1235 Pulse Generators, VIGOR® SR (single chamber) Model 1130/1135 Pulse Generators, and the Model 2075 Software Module to be used with commercially available CPI® Model 2035 Handheld Programmer and Model 6575 or 6577 Telemetry Wand; Model 6942 Bidirectional Torque Wrench; Model 6562 Horseshoe Magnet; Model 6580 Electrogram Cable; Model 6589 Printer Paper; and commercially available pacemaker leads and accessories that are compatible with the pulse generators. The devices are generally indicated for long-term cardiac pacing. Generally accepted indications for long-term pacing include, but are not limited to, sick sinus syndrome; chronic sinus arrhythmias; including sinus bradycardia; sinus arrest; and sinoatrial (SA) block; second- and third-degree atrioventricular (AV) block; bradycardia-tachycardia syndrome; and carotid sinus syndrome. Patients who demonstrate hemodynamic improvement from AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require restoration of rate and AV synchrony, including varying degrees of AV block; low cardiac output or congestive heart failure related to bradycardia; and certain tachyarrhythmias. The adaptive-rate pacing modes of the VIGOR® DR and VIGOR® SR pulse generators are indicated for patients exhibiting chronotropic incompetence and who would benefit by increased pacing rates concurrent with physical activity.

On May 9, 1995, the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On June 21, 1995, 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 December 30, 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: November 7, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–30508 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0443]

Review of Clinical Safety Data in Marketing Applications; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop, as part of its ''good review practices'' (GRP's), to provide an opportunity for input from the pharmaceutical industry, academia, and the public on the principles and methods being used by FDA in the review of clinical safety data in new drug product applications. Information and ideas generated at the workshop will be used to develop a guidance for reviewers who participate in the agency's clinical review process. A working draft of that guidance, ''Draft Guidance for Reviewers: Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review,'' along with a tentative