eligibility for patent term restoration. In a letter dated September 10, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TAXOTERE® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TAXOTERE® is 2,016 days. Of this time, 1,358 days occurred during the testing phase of the regulatory review period, while 658 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: November 8, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on November 8, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: July 27, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for TAXOTERE® (NDA 20–449) was initially submitted on July 27, 1994.

3. *The date the application was approved*: May 14, 1996. FDA has verified the applicant's claim that NDA 20–449 was approved on May 14, 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 1,035 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. 96–30386 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0275]

Determination of Regulatory Review Period for Purposes of Patent Extension; MYOVIEW™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MYOVIEW™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MYOVIEW™ (technetium tc99m tetrofosmin). MYOVIEW™ is indicated for the scintigraphic delineation of regions of reversible ischemia in the presence or absence of infarcted myocardium. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MYOVIEW™ (U.S. Patent No. 5,045,302) from Amersham International PLC, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 10, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MYOVIEW™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for MYOVIEW™ is 2,062 days. Of this time, 1,084 days occurred during the testing phase of the regulatory review period, while 978 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* June 20, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on June 20, 1990.

2. *The date the application was initially submitted with respect to the*

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).