

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

0084 '02 JAN 15 PM 41

DMB
1-19-02
1-18-02
R. LEDESMA

[Docket No. 99E-0117]

Determination of Regulatory Review Period for Purposes of Patent Extension; Heart Laser System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for the Heart Laser System 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 medical device.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Claudia V. Grillo,
Office of Regulatory Policy (HFD-007),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g) (3) (B).

FDA recently approved for marketing the medical device Heart Laser System. Transmyocardial revascularization with the Heart Laser System is indicated for the treatment of patients with stable angina refractory to medical treatment and secondary to objectively demonstrated coronary artery atherosclerosis not amenable to direct coronary revascularization. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for the Heart Laser System (U.S. Patent No. 5,125,926) from PLC Medical Systems, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 16, 1999, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of the Heart Laser System represented the first permitted commercial marketing or use of the product. Subsequently, 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 the Heart Laser System is 3,135 days. Of this time, 2,586 days occurred during the testing phase of the regulatory review period, while 549 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: January 21, 1990. The applicant claims that the

investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on November 30, 1990. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on January 21, 1990, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): February 18, 1997. FDA has verified the applicant's claim that the premarket approval application (PMA) for the Heart Laser System (PMA P950015) was initially submitted February 18, 1997.

3. The date the application was approved: August 20, 1998. FDA has verified the applicant's claim that PMA P950015 was approved on August 20, 1998.

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 695 days of patent term extension.

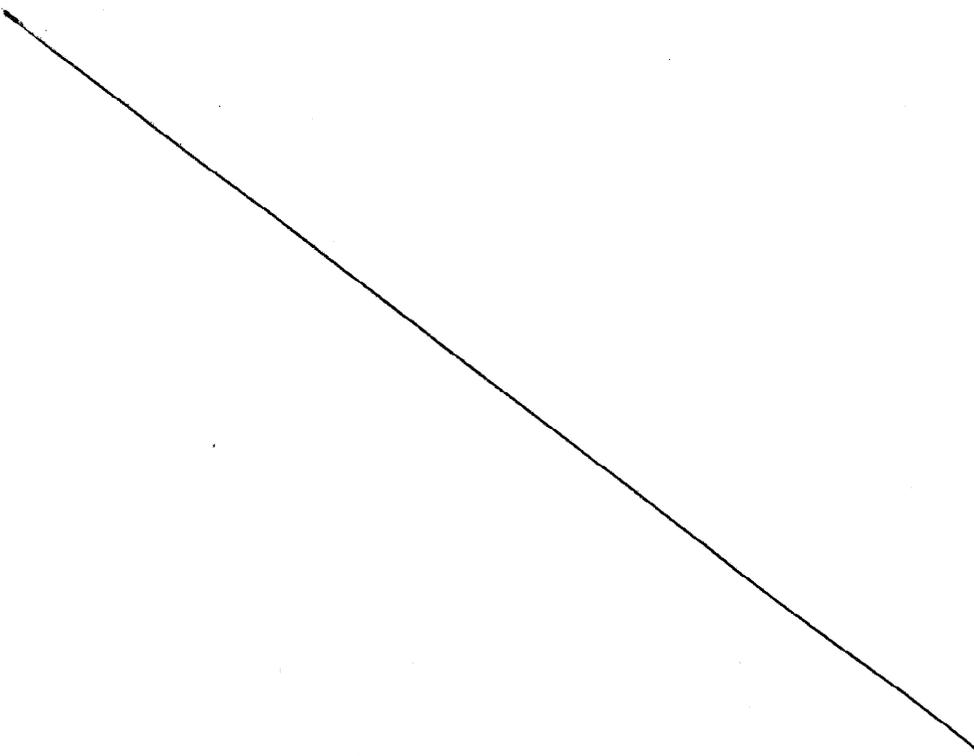
Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by [insert

date 60 days after date of publication in the FEDERAL REGISTER].

Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by [insert date 180 days after date of publication in the FEDERAL REGISTER].

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. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be 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: September 28, 2001
September 28, 2001.

Jane A. Axelrad

Jane A. Axelrad,
Associate Director for Policy,
Center for Drug Evaluation and Research.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Regina Sedona