

DDM
Display Date 2-10-09
Publication Date 2-11-09
Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-E-0091; Docket No. FDA-2008-E-0099; Docket No. FDA-2008-E-0204]

Determination of Regulatory Review Period for Purposes of Patent Extension;

MACROPLASTIQUE IMPLANTS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MACROPLASTIQUE IMPLANTS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that medical device.

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

FOR FURTHER INFORMATION CONTACT:

Beverly Friedman,
Office of Regulatory Policy,
Food and Drug Administration,
10903 New Hampshire Ave., Bldg. 51, rm. 6222,
Silver Spring, MD 20993-0002,

301-796-3602.

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 Director 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 MACROPLASTIQUE IMPLANTS. MACROPLASTIQUE IMPLANTS are indicated for transurethral injection in the treatment of adult women diagnosed with stress urinary incontinence (SUI) primarily due to intrinsic sphincter deficiency (ISD). Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for MACROPLASTIQUE IMPLANTS (U.S.

Patent Nos. 5,258,028; 5,336,263; and 5,571,182) from Uroplasty, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In a letter dated May 6, 2008, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of MACROPLASTIQUE IMPLANTS represented the first permitted commercial marketing or use of the product. 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 MACROPLASTIQUE IMPLANTS is 2,651 days. Of this time, 1,973 days occurred during the testing phase of the regulatory review period, while 678 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective: July 30, 1999. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective on June 30, 1999. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on July 30, 1999, which represents the IDE effective date.

2. The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e): December 22, 2004. The applicant claims December 21, 2004, as the date the premarket approval application (PMA) for MACROPLASTIQUE IMPLANTS (PMA P040050) was initially submitted. However, FDA records indicate that PMA P040050 was submitted on December 22, 2004.

3. The date the application was approved: October 30, 2006. FDA has verified the applicant's claim that PMA P040050 was approved on October 30, 2006.

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 1,640 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) written or electronic 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: 1/17/09
January 17, 2009.



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

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

