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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98E-0485 and 98E-0850]

Determination of Regulatory Review Period for Purposes of Patent Extension; Therma Choice™ Uterine Ballon Therapy System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Therma Choice™ Uterine Ballon Therapy 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: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Brian J. Malkin,
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Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-827-6620.

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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 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 Therma Choice™ Uterine Ballon Therapy System. Therma Choice™ Uterine Ballon Therapy System is indicated for use as a thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for Therma Choice™ Uterine Ballon Therapy System (U.S. Patent Nos. 5,105,808 and 4,949,718) from Gynelab Products, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated December 17, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Therma Choice™ Uterine Ballon Therapy System 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 Therma Choice™ Uterine Ballon Therapy System is 1,031 days. Of this time, 852 days occurred during the testing phase of the regulatory review period, while 179 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: February 17, 1995. 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, 1994. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on February 17, 1995, which represents the IDE effective date.

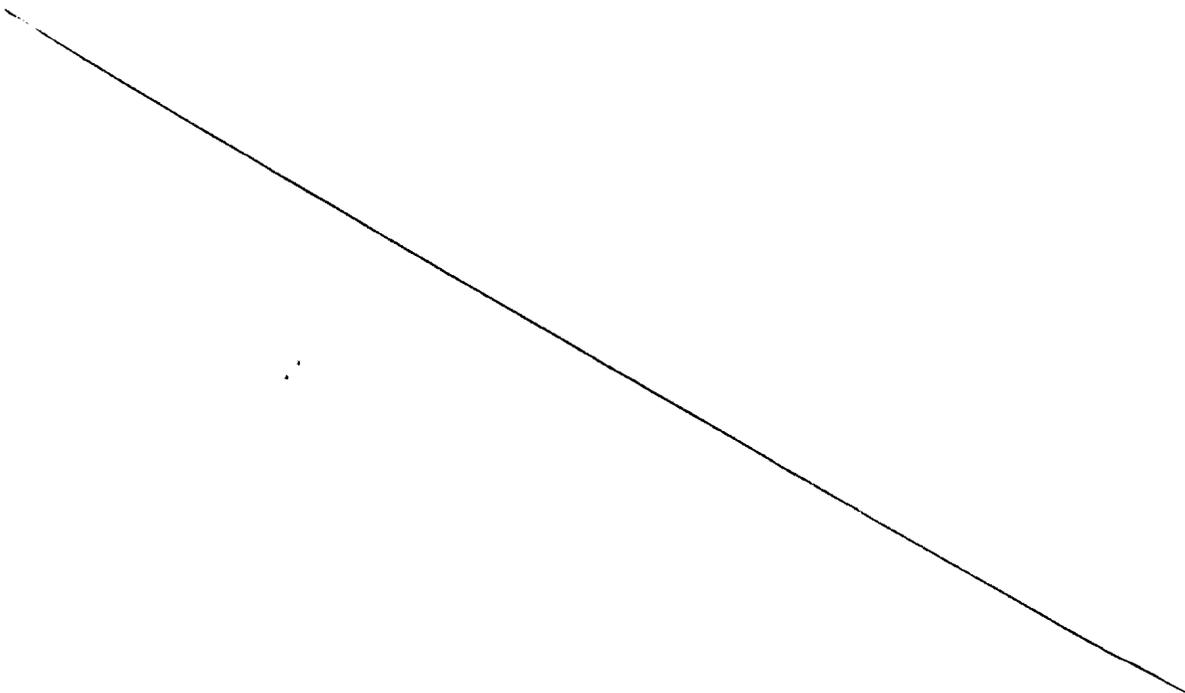
2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): June 17, 1997. The applicant claims June 16, 1997, as the date the premarket approval application (PMA) for Therma Choice™ Uterine Ballon Therapy System (PMA P970021) was initially submitted. However, FDA records indicate that PMA P970021 was submitted on June 17, 1997.

3. The date the application was approved: December 12, 1997. FDA has verified the applicant's claim that PMA P970021 was approved on December 12, 1997.

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 applications for patent extension, this applicant seeks 446 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before (insert date 60 days after date of publication in the FEDERAL REGISTER), 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 (insert date 180 days after date of publication in the FEDERAL REGISTER), 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: 5/7/99.

May 7, 1999

Thomas J. McGinnis

Thomas J. McGinnis,

Deputy Associate Commissioner

for Health Affairs

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Michael W. Bell