DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2003E-0033]

Determination of Regulatory Review Period for Purposes of Patent Extension; DERMAGRAFT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DERMAGRAFT 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 Director 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/docket/ecomments.

FOR FURTHER INFORMATION CONTACT:

Claudia V. Grillo,

Office of Regulatory Policy (HFD-013),

Food and Drug Administration,

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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 DERMAGRAFT. DERMAGRAFT is indicated for use in the treatment of full-thickness diabetic foot ulcers greater than 6-weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure. DERMAGRAFT should be used in conjunction with standard wound care regimens and in patients that have adequate blood supply to the involved foot. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Dermagraft (U.S. Patent No. 4,963,489) from Advanced Tissue Sciences, 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 10, 2003, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of DERMAGRAFT 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 DERMAGRAFT is 4,050 days. Of this time, 3,650 days occurred during the testing phase of the regulatory review period, while 400 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 involving this device became effective: August 29, 1990. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on September 2, 1992. FDA records confirm that one IDE for this medical device did become effective on September 2, 1992. However, FDA records also indicate that another IDE for this medical device was determined substantially complete for clinical studies to have begun on August 29, 1990, which represents the IDE effective date. Although this IDE was for a different indication, it is material to the approval of DERMAGRAFT. FDA considers all investigational exemptions for a particular product to be material to the approval of the product regardless of any difference between the indications studied and those ultimately approved.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): August 25, 2000. The applicant claims August 24, 2000, as the date the premarket approval application (PMA) for DERMAGRAFT (PMA P00036) was initially submitted. However, FDA records indicate that PMA P00036 was submitted on August 25, 2000.

3. The date the application was approved: September 28, 2001. FDA has verified the applicant's claim that PMA P00036 was approved on September 28, 2001.

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 5 years of patent term extension.

Anyone with knowledge that any of the dates as published is 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 and 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.

Dated: August 30, 2004.

August 30, 2004.

Jane A. Axelrad

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

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