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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E-0147]

Determination of Regulatory Review Period for Purposes of Patent Extension; OP-1 IMPLANT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OP-1 IMPLANT 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 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 Grillo,

Office of Regulatory Policy (HFD-013),

Food and Drug Administration,

5600 Fishers Lane,

Rockville, MD 20857,

301-827-3460.

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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 OP-1 IMPLANT. OP-1 IMPLANT is indicated for use as an alternative to the patient's own bone (autograft) in recalcitrant long bone nonunions where autograft is unfeasible and alternative treatments have failed. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OP-1 IMPLANT (U.S. Patent No. 5,258,494) from Stryker Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 31, 2001, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of OP-1 IMPLANT 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 OP-1 IMPLANT is 3,627 days. Of this time, 3,485 days occurred during the testing phase of the regulatory review period, while 142 days occurred during the approval phase. These periods of time were derived from the following dates:

1. <u>The date a clinical investigation involving this device was begun</u>: November 14, 1991. FDA has verified the applicant's claim that the date 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 November 14, 1991.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): May 29, 2001. The applicant claims May 25, 2001, as the date the premarket approval application (PMA) for OP-1 IMPLANT (PMA HO10002/A01) was initially submitted. However, FDA records indicate that PMA HO10002/A01 was submitted on May 29, 2001.

3. The date the application was approved: October 17, 2001. FDA has verified the applicant's claim that PMA HO10002/A01 was approved on October 17, 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 1,837 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may by submit to the Dockets Management Branch (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 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: Feb. 7, 2003
February 7, 2003.

Jane A. Axelrad

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

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