

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration for Children and Families****President's Committee on Mental Retardation; Notice of Meeting**

*Agency Holding the Meeting:* President's Committee on Mental Retardation.

*Time and Date:* 8:30 a.m.–12 Noon, August 24, 1997.

*Place:* The Washington Court Hotel, 525 New Jersey Avenue, NW., Washington, DC 20001.

*Status:* Full Committee Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All meeting sites are barrier free.

*To be Considered:* The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness.

The PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs and supports for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

*Contact Person for More Information:* Gary H. Blumenthal, 352–G Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201–0001 (202) 619–0634.

Dated: July 17, 1997.

**Gary H. Blumenthal,**

*Executive Director, PCMR.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 96N–0502]

**Determination of Regulatory Review Period for Purposes of Patent Extension; BAK™ Interbody Fusion System**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for BAK™ Interbody Fusion 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

**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 BAK™ Interbody Fusion System. BAK™ Interbody Fusion System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2–S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BAK™

Interbody Fusion System (U.S. Patent No. 5,015,247) from Karlin Technology, 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 12, 1997, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of BAK™ Interbody Fusion System represented the first commercial marketing 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 BAK™ Interbody Fusion System is 1,731 days. Of this time, 1,341 days occurred during the testing phase of the regulatory review period, while 390 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:* December 27, 1991. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) for human tests to begin became effective April 30, 1992. However, FDA records indicate that the IDE for clinical studies of the BAK™ Interbody Fusion System was approved on December 27, 1991, 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):* August 28, 1995. The applicant claims January 17, 1995, as the date the premarket approval application (PMA) for BAK™ Interbody Fusion System (PMA P950002) was initially submitted. FDA records confirm that an incomplete PMA P950002 was received on January 17, 1995. PMA P950002 was amended a number of times and was determined to be adequate for filing based on a submission received on August 28, 1995, which is considered the initially submitted date for the PMA.

3. *The date the application was approved:* September 20, 1996. FDA has verified the applicant's claim that PMA P950002 was approved on September 20, 1996.

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,