

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.

[FR Doc. 97–19983 Filed 7–29–97; 8:45 am]

BILLING CODE 4184–01–M

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,

this applicant seeks 829 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 29, 1997, 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 January 27, 1998, 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: July 15, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97-19984 Filed 7-29-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4200-N-90]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: September 29, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing and Urban Development, 451—

7th Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: John Coonts, Telephone number (202) 708-3046 (this is not a toll-free number) for copies of the proposed form and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Insurance for Home Equity Conversion Mortgages/ Residential Loan Application for Reverse Mortgages.

OMB Control Number: New Collection.

Description of the need for the information and the proposed use: Streamlined application for reverse mortgage customers, used to determine if borrowers qualify for HECM loans.

Agency form numbers: N/A.

Members of affected public: Individuals/households, business/non-profits, Federal Government.

An estimation of the total number of hours needed to prepare the information collection is 5,000, the number of respondents is 5,000, frequency of response is on occasion and the hours of response is 1 hour.

Status of the proposed information collection: New collection.

Authority: Sec. 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: July 23, 1997.

Nicolas P. Retsinas,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 97-19991 Filed 7-29-97; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4200-N-95]

Notice of Proposed Information Collection for Public Comments

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: September 28, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Humman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4238, Washington, DC 20410-5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708-3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information