this applicant seeks 1,628 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 31, 2000, 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 July 31, 2000, 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: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–2030 Filed 1–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–1115]

Determination of Regulatory Review Period for Purposes of Patent Extension; Lumbar I/F Cage®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Lumbar I/F Cage® 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: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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 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 Lumbar I/F Cage®. Lumbar I/F Cage® is indicated for an open posterior approach using autogenous bone graft in patients with degenerative disc disease at one or two spinal levels from L2–S1 whose condition requires the use of interbody fusion combined with posterolateral fusion and posterior pedicle screw fixation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Lumbar I/F Cage® (U.S. Patent No. 4,834,757) from DePuy AcroMed, 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 May 10, 1999, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Lumbar I/F Cage® 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 Lumbar I/F Cage® is 2,631 days. Of this time, 1,708 days occurred during the testing phase of the regulatory review period, while 923 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:* November 22, 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 22, 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):* July 25, 1996. FDA has verified the applicant's claim that the premarket approval application (PMA) for Lumbar I/F Cage® (PMA P960025) was initially submitted July 25, 1996.

3. *The date the application was approved:* February 2, 1999. FDA has verified the applicant's claim that PMA P960025 was approved on February 2, 1999.

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 1,776 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 31, 2000, 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 July 31, 2000, 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: December 23, 1999.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 00–2032 Filed 1–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

HCFA–4012–N

Medicare Program; Meeting of the Advisory Panel on Medicare Education—February 15, 2000

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Advisory Panel on Medicare Education. This Committee advises and makes recommendations regarding our National Medicare Education Program as well as other programs. These programs help Medicare beneficiaries understand the expanded range of Medicare options available with the passage of the Medicare+Choice program. This meeting is open to the public, but attendance is limited to space available.

DATES: The meeting is scheduled for Tuesday, February 15, 2000, from 10 a.m. until 5:00 p.m., e.s.t. This session is open to the public in accordance with the Federal Advisory Committee Act. There will be an additional executive session from 8 a.m. to 10 a.m., not open to the public, for the processing and swearing in of the members.

ADDRESSES: The meeting will be held at the Washington Court Hotel, 525 New Jersey Avenue, NW, Washington, DC 20001, (202) 628–2100.

FOR FURTHER INFORMATION CONTACT: Susana Perry, Executive Director, Health Care Financing Administration, Center for Beneficiary Services, Partnership Development Group, 7500 Security Boulevard, S1–08–07, Baltimore, MD 21244–1850, (410) 786–1076.

SUPPLEMENTARY INFORMATION: The Advisory Panel on Medicare Education (the Panel) advises us on opportunities to enhance the effectiveness of consumer education materials serving the Medicare program. The goals of the Panel are as follows:

- Developing and implementing a national Medicare education program that describes the expanding options for selecting a health plan under Medicare.
- Enhancing the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities; in the context of a national Medicare education program.
- Assembling an information base of ''best practices'' for helping consumers evaluate health plan options and building a community infrastructure for information, counseling and assistance.

The agenda is as follows:

- Appointments Process and Procedural Details (closed session).
- Introductory Remarks.
- Summary of HCFA Activities in Beneficiary Education: The National Medicare Education Program and the materials, assessments, evaluations, and research efforts that support it.
- Committee Discussion.
- Committee Work Plan and Next Steps.
- Public Comment.

AUTHORITY: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 27, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–2076 Filed 1–28–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Health Professions and Nurse Education Special Emphasis Panel; Notice of Meeting Cancellation

In **Federal Register** Document 99–23335 appearing on pages 48844–48846 in the issue for Wednesday, September 8, 1999, the March 6–9, 2000, meeting of the ''Public Health Special Projects Review Group'' will be cancelled.

Dated: January 20, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–2033 Filed 1–28–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4410–FA–11]

Announcement of Funding Awards for the Youthbuild Program, Fiscal Year 1999

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of funding awards.

SUMMARY: In accordance with section 102 (a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Super Notice of Funding Availability (SuperNOFA) for the Youthbuild Program. This announcement contains the names of the awardees and the amounts of the awards made available by HUD.

FOR FURTHER INFORMATION CONTACT: Mr. Donner Buchet, Director, Community and Economic Development Services, Office of Community Planning and Development, 451 7th Street, SW, Washington, DC 20410; telephone (202) 708–2290 (this is not a toll-free number). Hearing-and speech-impaired persons may access this number via TTY by calling the Federal Relay Service toll-free at 1–800–877–8339. For general information on this and other HUD programs, call Community Connections at 1–800–998–9999 or visit the HUD Website at http://www.hud.gov.

SUPPLEMENTARY INFORMATION: The Youthbuild Program was enacted in 1992 and is authorized under Subtitle D of title IV of the Cranston-Gonzalez National Affordable Housing (the Act), as added by section 164 of the Housing and Community Development Act of 1992 (Pub. L. 102–550, 106 Stat. 3723, 42 U.S.C. 12899. The competition was announced in the SuperNOFA published in the **Federal Register** on February 26, 1999. Applications were rated and selected for funding on the basis of selection criteria contained in that Notice.

The Catalog of Federal Domestic Assistance number for this program is 14.243.