

indicate that PMA P990078 was submitted on November 3, 1999.

3. *The date the application was approved:* June 30, 2000. FDA has verified the applicant's claim that PMA P990078 was approved on June 30, 2000.

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 1,644 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 16, 2003. 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 October 14, 2003. 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 (see **ADDRESSES**). Three copies of any mailed 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: March 31, 2003.

Jane A. Axelrad,

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

[FR Doc. 03-9535 Filed 4-16-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 23, 2003, from 8:30 a.m. to 3:30 p.m.

Location: Gaithersburg Marriott, Salons A, B and C, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, ext. 127, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an intraocular lens for primary implantation in the capsular bag for the correction of aphakia in an adult in whom a cataractous lens has been removed and who may benefit from improved near, intermediate and distance vision without spectacles. Background information for the day's topic, including the attendee list, agenda, and questions for the committee, will be available to the public one business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panel/index.html>. Material will be posted on May 22, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 16, 2003. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and for 30 minutes near the end of the committee deliberations on the PMA. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 16, 2003 and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the

agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-594-1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03-9386 Filed 4-16-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 3, 2003 (68 FR 16292). The notice announced a meeting of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science, which was scheduled for April 22-23, 2003. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03-8011, appearing on page 16292 in the **Federal Register** of Thursday, April 3, 2003, the following correction is made:

1. On page 16292, in the first column, in the "Location" section, "5600" is corrected to read "5630".

Dated: April 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03-9384 Filed 4-16-03; 8:45 am]

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