

premarket approval application (PMA) for Apligraf™ (PMA P950032) was initially submitted on October 4, 1995.

3. *The date the application was approved:* May 22, 1998. FDA has verified the applicant's claim that PMA P950032 was approved on May 22, 1998.

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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 29, 1999, 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 October 27, 1999, 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: April 20, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99-10795 Filed 4-29-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Subcommittee Meeting of the Advisory Committee for Reproductive Health Drugs; 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: Subcommittee of the Advisory Committee for Reproductive Health Drugs, Pregnancy Labeling.

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 June 3, 1999, 8 a.m. to 5 p.m..

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD 20910-3763.

Contact Person: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 301-827-7001, FAX 301-827-6776, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss possible changes to pregnancy labeling as a result of the September 12, 1997, part 15 (21 CFR part 15) public hearing (see 62 FR 41061), the development of various draft guidance documents, and risk communications.

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 21, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 21, 1999, 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.

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

Dated: April 23, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99-10799 Filed 4-29-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0872]

Revocation of Office of Generic Drug's Interim Policy Statement on Inactive Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking an interim policy statement on inactive ingredients in parenteral, ophthalmic, otic, and topical generic drug products (Interim Inactive Ingredient Policy). These generic drug products are the subjects of abbreviated new drug applications (ANDAs). The Interim Inactive Ingredient Policy was issued as a memorandum from the Acting Director of the Center for Drug Evaluation and Research's (CDER's) Office of Generic Drugs, FDA, to CDER's Associate Director for Science and Medical Affairs, FDA. FDA is taking this action because the Interim Inactive Ingredient Policy no longer represents current agency policy.

EFFECTIVE DATE: April 30, 1999.

ADDRESSES:

Address questions about individual applications to the Regulatory Support Branch, Center for Drug Evaluation and Research (HFD-615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5862.

Address questions about the use of inactive ingredients in a drug product for which you plan to submit an ANDA to the Office of Generic Drugs, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5845.

FOR FURTHER INFORMATION CONTACT: Rita R. Hassall, Office of Generic Drugs (HFD-600), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5845.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417) (the Hatch-Waxman Amendments) established procedures for approval of ANDAs for drug products that are generic versions of previously approved drug products. In the **Federal Register** of April 28, 1992 (57 FR 17950), FDA