requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Gonal–F® is 2,044 days. Of this time, 569 days occurred during the testing phase of the regulatory review period, while 1,475 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: February 26, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 26, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 16, 1993. FDA has verified the applicant's claim that the new drug application (NDA) for Gonal–F® (NDA 20–378) was initially submitted on September 16, 1993.

3. *The date the application was approved*: September 29, 1997. FDA has verified the applicant's claim that NDA 20–378 was approved on September 29, 1997.

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 1,605 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. 99–10846 Filed 4–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0846]

Determination of Regulatory Review Period for Purposes of Patent Extension; Apligraf™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Apligraf™ 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: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Apligraf™. Apligraf™ is indicated for use with standard therapeutic compression in the treatment of uninfected partial and/or full-thickness skin loss ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Apligraf™ (U.S. Patent No. 4,485,096) from Organogenesis, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 16, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Apligraf™ 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 Apligraf™ is 4,013 days. Of this time, 3,051 days occurred during the testing phase of the regulatory review period, while 962 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*: May 29, 1987. The applicant claims that 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 on July 2, 1987. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on May 29, 1987, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: October 4, 1995. FDA has verified the applicant's claim that the

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]

BILLING CODE 4160–01–F

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]

BILLING CODE 4160–01–F

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 (ANDA's). 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 ANDA's for drug products that are generic versions of previously approved drug products. In the **Federal Register** of April 28, 1992 (57 FR 17950), FDA