Dated: March 28, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–8474 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 95E–0418 and 95E–0419]

Determination of Regulatory Review Period for Purposes of Patent Extension; FLOLAN®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FLOLAN® 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 human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., 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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. 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 (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product FLOLAN® (epoprostenol sodium). FLOLAN® is indicated for the long-term intravenous treatment of primary pulmonary hypertension in New York Heart Association Class III and Class IV patients. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for FLOLAN® (U.S. Patent Nos. 4,338,325 and 4,883,812) from Glaxo Wellcome Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In letters dated February 8, 1996 (U.S. Patent No. 4,338,325), and February 22, 1996 (U.S. Patent No. 4,883,812), FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FLOLAN® 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 FLOLAN® is 5,927 days. Of this time, 5,357 days occurred during the testing phase of the regulatory review period, while 570 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355(i)) became effective*: July 1, 1979. The applicant claims June 29, 1979, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 1, 1979, which was 30 days after FDA receipt of IND 16,459 on June 1, 1979

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: February 28, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for FLOLAN® (NDA 20–444) was initially submitted on February 28, 1995.

3. *The date the application was approved*: September 20, 1995. FDA has verified the applicant's claim that NDA 20–444 was approved on September 20, 1995.

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 730 days (U.S. Patent No. 4,338,325) and 1,346 days (U.S. Patent No. 4,883,812) of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 4, 1996, 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 2, 1996, 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: March 28, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–8363 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

Small Business Participation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a small business exchange meeting to create a dialogue between the small business community, particularly businesses owned and operated by minorities and women, and FDA officials. The meeting will be chaired by Arthur J. Beebe, Jr., Regional Food and Drug Director, Northeast Region, and it

is intended to provide a better understanding of the agency's operations and policies and to assist these businesses in complying with the agency's regulations.

DATES: The meeting will be held on Thursday, April ll, l996, 9 a.m. to l2:30 p.m.

ADDRESSES: The meeting will be held at York College, Academic Core Bldg., Lecture Hall 4M05, 94–20 Guy R. Brewer Blvd., Jamaica, NY 11433. There is no registration fee for this meeting. Interested persons are encouraged to register early because space is limited. To register contact George R. Walden (address below).

FOR FURTHER INFORMATION CONTACT: George R. Walden, Small Business Representative, Food and Drug Administration, 850 Third Ave., Brooklyn, NY ll232, 7l8–965–5300 ext. 5528.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between the small business community, particularly businesses owned and operated by minorities and women, and FDA officials. This meeting will provide a forum to express concerns, discuss the effects of regulations, and convey knowledge about the agency's operations and policies.

Dated: March 30, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8476 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[OPL–009–N]

Medicare Program; April 22, 1996, Meeting of the Practicing Physicians Advisory Council

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 Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for April 22, 1996, from 8:30 a.m. until 4:30 p.m. edt (Additional meetings are tentatively scheduled for July 8, September 23, and December 16, 1996.)

ADDRESSES: The meeting will be held in Room 800, 8th Floor, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Samuel Shekar, M.D., Executive Director, Practicing Physicians Advisory Council, Room 425–H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, (202) 260–5463.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act, as added by section 4112 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, enacted on November 5, 1990), to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publications of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are: Richard Bronfman, D.P.M.; Gary C. Dennis, M.D.; Catalina E. Garcia, M.D.; Kenneth D. Hansen, M.D.; Ardis Hoven, M.D.; Sandral Hullett, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D. (Renominated-pending selection); Marc Lowe, M.D.; Katherine L. Markette, M.D.; Maisie Tam, M.D.; Kenneth M. Viste, Jr., M.D.; and James C. Waites, M.D. (Renominated-pending selection). The chairperson is Kenneth M. Viste, Jr., M.D.

The next meeting of the Council will be held on April 22, 1996. The Council agenda will provide for discussion and comment on three items:

- The Medicare Coverage Regulation.
- The National Provider Identification Project.
- End of Life Care.

Council members will also receive a legislative and managed care update. In addition, four new members will be sworn in to serve on the Council. Those individuals or organizations who wish to make 5-minute oral presentations on the three issues listed should contact the Executive Director by 12:00 noon, April 5, 1996, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director no later than 12:00 noon, April 11, 1996. For the name, address, and telephone number of the Executive Director, see the **FOR FURTHER INFORMATION CONTACT** section at the beginning of this notice. Anyone who is not scheduled to speak may also submit written comments to the Executive Director by 12:00 noon, April 11, 1996. The meeting is open to the public, but attendance is limited to the space available on a first-come basis.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a)); 45 CFR Part 11)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program)

Dated: March 20, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 96–8552 Filed 4–3–96; 9:32 am]

BILLING CODE 4120–01–P

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services National Advisory Council Meeting in April

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA).

ACTION: Correction of Meeting Notice.

SUMMARY: Public notice was given in the Federal Register on March 7, 1996 (Vol. 61, No. 46, page 9189) that the Center for Mental Health Services National Advisory Council would be meeting in open session on April 11 and 12.

It has become necessary to add a presentation and detailed discussion of information about the Center's procurement plans. Therefore, a portion of the meeting will be closed to the public as determined by the