to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to receive an update from the Inter-tribal Council on Hanford Health Projects; to review and approve the Minutes of the previous meeting; to receive updates from ATSDR/NCEH and NIOSH; to receive reports from the Outreach, Public Health Assessment, Public Health Activities, and the Studies Workgroups; and to address other issues and topics, as necessary.

Matters To Be Discussed: Agenda items include a presentation and discussion on the Nevada Test Site Fallout Study, implications for proposed Hanford Medical Monitoring Program, results of the Hanford Thyroid Disease Study, and worker health surveillance programs.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Leslie C. Campbell, Executive Secretary HHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE m/s E–56, Atlanta, Georgia 30333. Telephone 1–888/42–ATSDR(28737), Fax 404/639–6075.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 22, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–1991 Filed 1–27–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Administration on Aging

[Program Announcement No. AoA–99–1]

Fiscal Year 1999 Program Announcement; Availability of Funds and Notice Regarding Applications

AGENCY: Administration on Aging, HHS.

ACTION: Announcement of availability of funds and request for applications to carry out cooperative agreement awards to train retired persons to serve in their communities as volunteer expert resources and educators in combating health care waste, fraud, and abuse.

SUMMARY: The Administration on Aging (AoA) announces that under this program announcement it will hold a competition for ''Senior Medicare Patrol Projects'' that demonstrate effective ways of utilizing retired persons as volunteer expert resources and educators in community efforts to combat health care waste, fraud and abuse. The deadline date for the submission of applications is March 31, 1999.

Public and/or nonprofit agencies, organizations, and institutions are eligible to apply under this program announcement. However, consistent with the terms of Senate Report 105–300, which accompany the Omnibus Consolidated Appropriations Act of 1999 (Pub.L.105–277), preference will be given in the making of cooperative agreement awards to projects that will be carried out by consortia headed by community-based public or non-profit agencies or organizations. In addition, the AoA is currently funding ''Senior Medicare Patrol Projects'' in twelve states—California, Hawaii, Illinois, Iowa, Maryland, Minnesota, Missouri, New Hampshire, New York, Pennsylvania, Rhode Island, and Wisconsin. No further awards will be made in these states.

Application kits are available by writing to the Department of Health and Human Services, Administration on Aging, Office of Governmental Affairs and Elder Rights, 330 Independence Avenue, SW., Room 4748, Washington, DC 20201, telephone: (202) 619–7592 or (202) 690–7525.

Dated: January 21, 1999.

Jeanette C. Takamura,

Assistant Secretary for Aging.

[FR Doc. 99–2056 Filed 1–27–99; 8:45 am]

BILLING CODE 4150–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Office of the Director, Centers for Disease Control and Prevention (CDC), Announces the Following Meeting

Name: Guide to Community Preventive Services (GCPS) Task Force Meeting.

Times and Dates: 9 a.m.–4:45 p.m., February 10, 1999. 8 a.m.–3:30 p.m., February 11, 1999.

Place: The Sheraton Buckhead Hotel Atlanta, 3405 Lenox Road, Atlanta, Georgia 30326. Telephone 404/261–9250.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: The mission of the Task Force is to develop and publish a Guide to Community Preventive Services, which is based on the best available scientific evidence and current expertise regarding essential public health services and what works in the delivery of those services.

Matters to be Discussed: Agenda items include an update on the Healthy Aging Project by the Health Care Financing Administration; a progress report on the development of the Guide; a discussion of the key issues for methods development; a discussion on the key decisions for chapter development: review of logic frameworks and proposed interventions for the Sociocultural Environment, Sexual Behavior, and Cancer chapters; a discussion of the implementation and evaluation plans for the Guide; a discussion of cost effectiveness; a progress report on the draft manuscripts: Methods, Data Collection Procedures and Instrument for Systematic Reviews, Quality of Execution, and Scope and Organization of the Guide; a discussion on the timeline for the development of the Guide; an update on the revisions and field test results of the Vaccine Preventable Diseases chapter; a discussion on the prevention research agenda issues and a discussion on planning the evidentiary database.

Agenda items are subject to change as priorities dictate.

Persons interested in reserving a space for this meeting should call 404/639–4301 by close of business on February 5, 1999.

Contact Person for Additional Information: Marguerite Pappaioanou, Chief, CPS Guide Development Activity, Division of Prevention Research and Analytic Methods, Epidemiology Program Office, CDC, 1600 Clifton Road, NE, M/S D–01, Atlanta, Georgia 30333. Telephone 404/639–4301.

The Director, Management Analysis and Services office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 22, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–2012 Filed 1–27–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Occupational Exposure to Asphalt; NIOSH Meeting

National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Scientific Review of Draft NIOSH Hazard Review Document, ''Health Effects of Occupational Exposure to Asphalt.''

Time and Date: 1 p.m.–5 p.m., February 26, 1999.

Place: Robert A. Taft Laboratories, Auditorium, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: To provide peer review of the draft NIOSH Hazard Review Document, ''Health Effects of Occupational Exposure to Asphalt.'' Participants will provide NIOSH with their individual advice and comments regarding the technical and scientific aspects of the document. Persons wishing to attend or make a presentation at the meeting (limited to 5 minutes), or obtain a copy of the draft document should respond by February 19, 1999, to the contact person listed below.

Contact Person for General Information: Kellie Pierson, Education and Information Division (EID), NIOSH, CDC, 4676 Columbia Parkway, m/s C–34, Cincinnati, Ohio 45226. Telephone 513/533–8362, e-mail kmp0@cdc.gov. Information is also available from the NIOSH Internet Homepage: http://www.cdc.gov/niosh/homepage.html.

Contact Person for Technical Information: Joann Wess, Education and Information Division (EID), NIOSH, CDC, 4676 Columbia Parkway, m/s C–32, Cincinnati, Ohio 45226. Telephone 513/533–8342, e-mail jew4@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 22, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–2011 Filed 1–27–99; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0616]

Determination of Regulatory Review Period for Purposes of Patent Extension; Prandin™ (5,216,167)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Prandin™ 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, 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 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 Prandin™ (repaglinide). Prandin™ is indicated for use as an adjunct to diet and exercise to lower the blood glucose in patients with type 2 diabetes mellitus (non-insulin dependent diabetes mellitus) whose hyperglycemia cannot be controlled satisfactorily by diet and exercise alone. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Prandin™ (U.S. Patent No. 5,216,167) from Dr. Karl Thomae GmbH, 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 10, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Prandin™ 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 Prandin™ is 2,091 days. Of this time, 1,916 days occurred during the testing phase of the regulatory review period, while 175 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*: April 3, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 3, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: July 1, 1997. The applicant claims June 1, 2797, as the date the new drug application (NDA) for Prandin™ (NDA 20–741) was initially submitted. However, FDA records indicate that NDA 20–741 was submitted on July 1, 1997.

3. *The date the application was approved*: December 22, 1997. FDA has verified the applicant's claim that NDA 20–741 was approved on December 22, 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 922 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 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 July 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