Recordkeeping: The FTC estimates that approximately 190,000 automotive fuel industry members retain records at an average annual burden of 6 minutes per industry member, for a total recordkeeping burden of 19,000 hours. *Disclosures:* The FTC also estimates that approximately 24,000 distributors make required disclosures at an average annual burden of 1 hour per industry member, for a total disclosure burden of 24,000 hours.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 96–21799 Filed 8–23–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 93N–0371]

Prescription Drug Information for Patients: Notice of Request for Collaboration to Develop an Action Plan

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (the Department) is requesting that national organizations which have an interest in providing prescription drug information to patients collaborate to develop a long-range action plan for distributing useful written prescription information to 75 percent of individuals receiving new prescriptions by the year 2000, and to 95 percent of individuals receiving new prescriptions by the year 2006. This document also describes the mechanism that the Department is instituting to facilitate collaboration among national organizations. This action is being taken under certain provisions of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1997.

DATES: Submit written requests for participation in this process by September 3, 1996.

ADDRESSES: Submission of notice of desire to participate should be addressed to: Keystone Center; 1001 G Street, NW., Suite 430 West, Washington, DC. 20001.

FOR FURTHER INFORMATION CONTACT: Kevin S. Curtis, Keystone Center, 1001 G Street, NW., 430 West, Washington, DC., 20001, 202–783–0248 or via FAX 202–783–0328, or Internet KCurtis@Keystone.ORG; or Betty Palsgrove, (HFY–40), Office of Health Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1652, or via FAX 301–443–2446, or Internet Epalsgro@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 601 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 1997 (Pub. L. 104–180) (The Appropriations Act), the Department is requesting the collaborative development and submission of an acceptable long-range, comprehensive action plan that will meet the goals for providing useful written prescription drug information to patients. This notice summarizes the Appropriations Act's requirements for the development and submission of the plan. It also describes a mechanism to facilitate development of a single unified plan.

A. Summary of the Appropriations Act

The Appropriations Act directs the Secretary of Health and Human Services (the Secretary) to request that national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient information data base companies, and other relevant parties collaborate to develop a long-range, comprehensive action plan. The goals of this long-range, comprehensive action plan are the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000, and to 95 percent of individuals receiving new prescriptions by the year 2006.

The Appropriations Act identifies six elements that must be part of this plan: (1) Goal identification, (2) assessment of the effectiveness of current private-sector approaches to providing oral and written information, (3) development of guidelines for providing effective oral and written information, (4) inclusion of elements necessary for the transmittal of useful information (scientifically accurate, nonpromotional in tone and content, sufficiently specific and comprehensive, and presented in an understandable and legible format readily comprehensible to product users), (5) development of a mechanism for periodic assessment of information quality and frequency of provision, and (6) provision for compliance with State Board regulations.

If an acceptable long-range, comprehensive action plan is submitted to the Secretary not later than 120 days after the enactment of this Appropriations Act (i.e., by December 4, 1996), the Secretary will have no authority to implement FDA's proposed rule, Prescription Drug Product Labeling: Medication Guide Requirements (60 FR 44182, August 24, 1995). The Secretary is to, in good faith and after due consideration, accept, reject, or suggest modifications to the plan within 30 days of the plan's submission. If the Secretary takes no action on the plan within 30 days of its submission, the submitted plan commences within 60 days of its submission. The Appropriations Act also states that the Secretary may confer with and assist private parties in the development of this plan.

The Appropriations Act requires that, not later than January 1, 2001, the Secretary is to review the status of the private sector initiative. If the specified goals are not achieved, the limitation on the Secretary's authority to implement the proposed rule would not apply. At that juncture, the Department would seek public comment on other initiatives that could be carried out to meet the previously stated goals.

B. The Collaborative Process

The Appropriations Act specifies that the Department request a collaborative process to develop this plan, which would include a full range of representative national organizations. The Appropriations Act envisions the development of a single plan that would be submitted for review. However, the Appropriations Act does not specify a mechanism to ensure that a single plan be submitted, or how the Secretary should react if multiple plans are submitted. Thus, it is important to assure that a single unified plan representing the broad range of national organizations be submitted so that all parties interested in and responsible for the provision of patient information understand the goals and criteria for evaluating progress towards meeting these goals.

Numerous national organizations representing health care professionals, consumer organizations, voluntary health agencies, the pharmaceutical industry, drug wholesalers, patient drug information data base companies, and other relevant parties have an interest in patient information. Many of these organizations have commented on FDA's proposed rule or attended conferences or meetings hosted by FDA and others to discuss this topic. However, no one single organization fully represents all of the interests, views, and capabilities of all the relevant organizations. Therefore, in order to assure a broad and balanced collaborative process and to aid in the

development of an acceptable, long-range, comprehensive action plan, the Department has asked the Keystone Center to serve as a facilitator to provide the organizational and logistical services and expertise for the development of this plan. The Keystone Center is a private, nonprofit public policy, science, and education organization that has broad experience in bringing together the diverse views of industry, consumer, and health professional groups. Additionally, the Department has asked the Keystone Center to form, in consultation with the Department, a steering committee that will solicit and coordinate input from all interested parties and oversee the development of the plan.

The Department requests that all parties who represent national organizations and wish to participate on the steering committee, submit the following information to the Keystone Center (address above): (1) Name of individual and organization, (2) specification or certification that the organization is of national standing, (3) type of group represented (e.g., health care professionals, consumers, pharmaceutical manufacturers), (4) size of membership, (5) relevance of the organization to the plan goals or organizational interest in participation in development of the plan, and (6) address, e-mail, telephone number, and facsimile number of individual and alternate contact. Due to the shore timeframes specified in the Appropriations Act, this submission should be received [by] no later than 5 p.m. (EDT), September 3, 1996.

The Keystone Center, in consultation with the Department, will select organization representatives from the submissions to become members of the steering committee. The committee will then solicit input from *all* interested parties and may hold a series of meetings to allow the parties to discuss and develop the plan. The first meeting of the steering committee will be hosted by the Department at a time and place to be announced. Invitations will be issued to the selected representatives. At this meeting, representatives from the Department and from the Keystone Center will discuss the development of an action plan and be available to answer questions.

Dated: August 23, 1996.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–21942 Filed 8–23–96; 12:08 am]

BILLING CODE 4110–60–M

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory (INEL) Health Effects Subcommittee.

Times and Dates: 8 a.m.–5 p.m., September 10, 1996, 7 p.m.–9 p.m., September 10, 1996, 8 a.m.–12:15 p.m., September 11, 1996.

Place: Best Western Canyon Springs Inn, 1357 Blue Lakes Boulevard North, Twin Falls, Idaho 83301, telephone 208/734–5000.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The Subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at respective DOE sites. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health, and ATSDR, on the progress of current studies. On September 10, at 7 p.m., the meeting will continue in order to allow more time for public input and comment.

Agenda items are subject to change as priorities dictate.

Contact Persons For More Information: Arthur J. Robinson or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: August 21, 1996.

Carolyn J. Russell,

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

[FR Doc. 96–21780 Filed 8–23–96; 8:45 am]

BILLING CODE 4163–18–M

Administration for Children and Families

President's Committee on Mental Retardation; Notice of Meeting

Agency Holding the Meeting: President's Committee on Mental Retardation.

Time and Date: Full Committee Meeting, September 26, 1996, 2:00 p.m.–8:00 p.m.

Place: Crystal City Courtyard by Marriott, 2899 Jefferson Davis Highway, Arlington, Virginia 22202.

Status: Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All locations are barrier free.

To Be Considered: The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness.

The PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs and services for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

Contact Person for More Information: Gary H. Blumenthal, 352–G Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201–0001, (202) 619–0634.

Dated: August 19, 1996.

Gary H. Blumenthal,

Executive Director, PCMR.

[FR Doc. 96–21648 Filed 8–23–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

Blood Donor Incentive Programs for Volunteer (Non-remunerated) Donors; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) and the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health are announcing a public workshop to discuss the use of donor