Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.283.

Other Requirements

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Women, Racial, and Ethnic Minorities

It is the policy of the CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. In conducting review for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment of scoring.

This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947–47951, Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (Revised 7/92, OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, on or before August 9, 1996.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications which do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistance may be obtained from Glynnis D. Taylor, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, telephone (404) 842–6593, fax (404) 842–6513, or Internet or CDC WONDER electronic mail at <gld1@opspgo1.em.cdc.gov>. Programmatic technical assistance may be obtained from Hani Atrash, Division of Reproductive Health, Pregnancy and Infant Health Branch, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K–23, Atlanta, GA 30341, telephone (770) 488–5187, fax (770) 488–5628, or Internet or CDC WONDER electronic mail at <hka1@ccddrh1.em.cdc.gov>.

Please refer to Announcement 661 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

There may be delays in mail delivery and difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics. Therefore, CDC suggests applicants use Internet, follow all instructions in this announcement and leave messages on the contact person's voice mail for more timely responses to any questions.

Dated: July 3, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–17528 Filed 7–9–96; 8:45 am]

BILLING CODE 4163–18–P

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): International Training and Research in Environmental and Occupational Health, Program Announcement TW–96–003: Meeting

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 committee meeting.

Name: Disease, Disability, and Injury Prevention and Control SEP: International Training and Research in Environmental and Occupational Health, Program Announcement TW–96–003.

Time and Date: 8 a.m.–5 p.m., July 25–26, 1996.

Place: The Lawton Chiles International House (Building 16) National Institutes of Health Campus, 31 Center Drive, Bethesda, Maryland 20892.

Status: Closed.

Matters to be Discussed: The Special Emphasis Panel will review and evaluate all responsive applications received under Program Announcement TW–96–003. The intent of announcement TW–96–003 is to support the development of international training and research programs related to environmental and occupational health for foreign scientists, clinicians, and other allied health workers from developing countries and emerging democracies. It is anticipated that this training and research program will have significant benefits globally, as well as in the United States (US) and the

collaborating countries. Research collaboration may include other industrialized nations in addition to the US. Substantial emphasis will be placed upon chronic disease prevention and the control of injuries. A successful program will allow the accumulated knowledge and experience of US environmental and occupational health experts to be available to assist and work with their colleagues on a global basis in order to address common global problems.

The meeting will be closed to the public in accordance with provisions set forth in 5 U.S.C. 552b(c) (4) and (6), and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Contact Person for More Information: Pervis C. Major, Ph.D., Health Science Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26505, telephone 304/285–5979 or 404/639–2535.

Dated: July 3, 1996.

Nancy C. Hirsch,

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

[FR Doc. 96–17525 Filed 7–9–96; 8:45 am]

BILLING CODE 4163–18–M

Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Savannah River Site Health Effects Subcommittee and Savannah River Site Environmental Dose Reconstruction Project—Phase II Public Workshop: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC), announce the following meetings.

Name: Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Savannah River Site Health Effects Subcommittee (SRS).

Times and Dates: 8:30 a.m.–5:15 p.m., July 25, 1996. 8:30 a.m.–12 noon, July 26, 1996.

Place: Holiday Inn Coliseum, 630 Assembly Street, Columbia, South Carolina 29201, telephone 803/799–7800, FAX 803/252–5909.

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

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ASTDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This 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 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 the Agency for Toxic Substances and Disease Registry on the progress of current studies; presentation on environmental monitoring; an update from the Radiological Assessments Corporation; and updates on the membership and the workgroup report.

Agenda items are subject to change as priorities dictate.

Name: Savannah River Site Environmental Dose Reconstruction Project—Phase II: Public Workshop.

Time and Date: 7 p.m.–9 p.m., July 25, 1996.

Place: Holiday Inn Coliseum, 630 Assembly Street, Columbia, South Carolina 29201, telephone 803/799–7800, FAX 803/252–5909.

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

Purpose: The Savannah River Site (SRS) Dose Reconstruction Project supports research which evaluates past releases of radioactive materials and chemicals from the SRS to the surrounding environment. The Project has already undergone a first phase. Phase I involved searching the site to identify and retrieve important documents to be used for dose reconstruction. Phase II will use this information to calculate chemical and radiological source terms and identify possible intake pathways (eating, drinking, and inhalation) for people who have lived in the SRS area. This workshop will focus on the identification and evaluation of environmental data to support dose reconstruction. Public input and the promise to provide clear and easily obtained sources of information are important parts of this study. Individuals with information of possible value to the study are encouraged to attend.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Paul G. Renard or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Due to difficulty in location of meeting facility, this notice is being published less than 15 days prior to the meeting.

Dated: July 3, 1996.

John C. Burckhardt,

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

[FR Doc. 96–17524 Filed 7–9–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96P–0083]

Determination that Acetaminophen and Codeine Tablets USP, 325 Milligrams (mg)/45 mg, was not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow abbreviated new drug applications (ANDA's) for acetaminophen and codeine phosphate tablets USP, 325 mg/45 mg to be approved.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions,