accurate, complete, and current accounting of all financial transactions on a site-specific basis, i.e., individual time, travel, and associated cost including indirect cost, as appropriate for the site. The recipient will retain the documents and records to support these financial transactions, for possible use in a cost recovery case, for a minimum of 10 years after submission of a final Financial Status Report (FSR), unless there is a litigation, claim, negotiation, audit, or other action involving the specific site, then the records will be maintained until resolution of all issues on the specific site.

F. Third Party Agreements

Project activities which are approved for contracting pursuant to the prior approval provisions shall be formalized in a written agreement that clearly establishes the relationship between the grantee and the third party. The written agreement shall, at a minimum:

1. State or incorporate by reference all applicable requirements imposed on the contractors under the grant by the terms of the grant, including requirements concerning technical review (ATSDR selected reviewers), release of data, ownership of data, and the arrangement for copyright when publications, data or other copyrightable works are developed under or in the course of work under a PHS grant supported project or activity.

2. State that any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal government purposes.

3. State that whenever any work subject to this copyright policy may be developed in the course of a grant by a contractor under a grant, the written agreement (contract) must require the contractor to comply with these requirements and can in no way diminish the government's right in that work.

4. State the activities to be performed, the time schedule for those activities, the policies and procedures to be followed in carrying out the agreement, and the maximum amount of money for which the grantee may become liable to the third party under the agreement.

5. The written agreement required shall not relieve the grantee of any part of its responsibility or accountability to DHHS under the grant. The agreement shall, therefore, retain sufficient rights and control to the grantee to enable it to fulfill this responsibility and accountability.

G. *Animal Subjects*

If the proposed project involves research on animal subjects, the applicant must comply with the ''PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in DHHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

Application Submission Deadline

The original and two copies of the application Form PHS 5161–1 (Revised 7/92, OMB Number 0937–0189) must be submitted to Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, Mail Stop E–13, Atlanta, Georgia 30305, on or before July 15, 1997. (By formal agreement, the CDC Procurement and Grants Office will act on behalf of and for ATSDR on this matter.)

A. *Deadline*

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

1. Received on or before the deadline date, or

2. 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.)

B. *Late Applications*

Applications which do not meet the criteria in A.1. or A.2. 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

To receive an application kit, call (404) 332–4561. You will be asked your name, address, and telephone number and will need to refer to Announcement 747. In addition, this announcement is also available through the CDC Home Page on the Internet. The address for the CDC Home Page is http://www.cdc.gov. If you have questions after reviewing the contents of all the documents, business management assistance may be obtained from Kathy Raible, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mail Stop E–13, Atlanta, Georgia 30305, telephone (404) 842–6803. Programmatic assistance may be obtained from Dr. Moiz Mumtaz, Project Officer, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mail Stop E–29, Atlanta, Georgia 30333, telephone (404) 639–6306.

Please refer to Announcement 747 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) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: May 29, 1997.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 97–14525 Filed 6–4–97; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[INFO–97–12]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the

use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Childbearing-age Women, Folic Acid, and the Prevention of Spina Bifida and Anencephaly: Interventions and Evaluation in a Managed Care Setting-New—Spina bifida and anencephaly are neural tube defects (NTDs) that are common and serious birth defects. In 1992, the Public Health Service (PHS) issued the recommendation that all women capable of becoming pregnant should consume daily 0.4 mg of folic acid to prevent spina bifida and anencephaly. An estimated 50% to 70% of spina bifida and anencephaly could be prevented with the use of periconceptional folic acid, but at least 70% of the 60 million U.S. women of childbearing age do not consume adequate folic acid to prevent these defects. The Division of Birth Defects and Developmental Disabilities (DBDDD) at the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) promotes increased consumption of folic acid to prevent these birth defects, with a goal of increasing the number of women of childbearing age who consume folic acid-containing vitamins. In mounting efforts to promote folic acid use, there is a need to (1) improve the understanding of the factors that shape women's behaviors relative to folic acid supplement use, (2) design and carry out interventions to increase folic acid use, and (3) evaluate the effectiveness of these interventions using pre- and post-intervention assessments. This project will address these needs in a managed care setting, where a large proportion of childbearing age women receive their health care. Interventions will include providing folic-acid containing vitamins to child-bearing age women, educating members and health care providers regarding folic acid and prevention of neural tube defects, and raising member and provider awareness through campaigns. Focus groups will be used to design the educational and awareness campaigns (i.e., message development). At one site primary health care providers will participate in educational sessions about the link between folic acid NTDs; a subset of those providers primarily involved in women's health care will receive additional training on how to best tailor folic acid educational messages to women. Pre- and post-intervention telephone surveys of child-bearing age women members regarding their knowledge and behaviors relative to supplement use and the prevention of NTD defects will be performed to evaluate the effectiveness of the interventions. Pre- and post-intervention serum folate levels will also be used to evaluate the effectiveness of the interventions. Serum folate levels will be obtained from a sample of pregnant women at the time of their first prenatal visit. Blood drawn for other routine prenatal care purposes will be used, and therefore will not require an additional blood draw. A shorter telephone survey of a smaller sample of pregnant women after their first prenatal visit will be done to determine vitamin supplement use prevalence early in pregnancy. The total cost to respondents is 0.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Child bearing age women	4800	1	.20	960
Pregnant women	720	1	.083	59.7
Focus group, childbearing age women	40	1	1.5	60
Primary health care providers	350	1	1.0	350
Primary women's health care providers	150	1	2.0	300
Total				1729.7

2. Health Effects from Exposure to High Levels of Sulfate in Drinking Water-New—The Safe Drinking Water Act Amendments of August 1996 require the Centers for Disease Control and Prevention, in collaboration with the U.S. Environmental Protection Agency, to conduct a dose-response study of the health effects of exposure of susceptible populations to drinking water that contains sulfate. There is concern that individuals who are not used to drinking water containing sulfate will experience diarrhea when they first drink tap water containing high levels of sulfate. The effect is acute and temporary. However, becoming acclimated, or used to, water with high levels of sulfate may take approximately two weeks, during which time individuals, particularly those who cannot control their fluid intake, i.e., infants, may become dehydrated. Previous studies of the effects of sulfate on the incidence of diarrhea have suffered from a number of limitations, including small sample size, failure to account for other causes of diarrhea, and inadequate characterization of the water itself. This study will analyze the incidence of diarrhea in non-acclimated infants and adults exposed to drinking water containing a range of sulfate concentrations by collecting data from mothers of newborn infants living in areas with a range of naturally-occurring sulfate levels and adult volunteers who will consume drinking water containing specific levels of sulfate. The total cost to the respondents is $0.00.

DATA COLLECTION

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Recruiting project participants	2500	1	0.16	400
Training for project participants: interview	1250	1	1	1250
Follow-up phone calls	1250	3	0.2	750
Mothers with newborn infants: diary	1250	28	0.1	3500
Adult volunteers: questionnaire.	100	1	0.34	34

DATA COLLECTION—Continued

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Adult volunteers: diary	100	6	0.1	60
Total				5994

Dated: May 28, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–14674 Filed 6–4–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service (PHS) 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 Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Idaho National Engineering Laboratory (INEL) Health Effects Subcommittee.

Times and Dates: 8:30 a.m.–5 p.m., June 26, 1997. 8:30 a.m.–5 p.m., June 27, 1997.

Place: Holiday Inn, 1399 Bench Road, Pocatello, Idaho 83201, telephone 208/237–1400, FAX 208/238–0225.

Status: Open to the public, 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) was 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 ATSDR 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 and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide 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) regarding current activities, the National Institute for Occupational Safety and Health and ATSDR will provide updates on the progress of current studies, and working group discussions.

Agenda items are subject to change as priorities dictate.

Contact Persons For More Information: Arthur J. Robinson, Jr., 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.

Dated: May 30, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–14677 Filed 6–4–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Oversight Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the remaining 1997 meetings of its clinical hold oversight committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. For each meeting, FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The next meetings will be held on August 12, 1997, and November 12, 1997. Biological product companies may submit review requests for the August meeting by July 1, 1997, and for the November meeting by October 1, 1997.

ADDRESSES: Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–5), Food and Drug Administration, 1401