

Dated: March 14, 1997.

Wendy M. Comes,
Executive Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 DAY-197]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Office on (404) 639-7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

The following requests have been submitted for review since the last publication date on March 12, 1997.

Proposed Project

1. Examination of Barriers to Participant Compliance in a Flexible Sigmoidoscopy Screening Program. Kaiser Foundation, Oakland—New—With colorectal cancer comprising the second highest mortality rate among all U.S. cancers and ranked as the fourth most common form of cancer, the active promotion of population-based screening and early detection is becoming increasingly important. Recognizing the importance of screening, American Cancer Society guidelines and the new US Preventive Services Task Force guidelines recommend colorectal cancer screening for individuals over the age of 50. Still, although early detection of colorectal neoplasms has been effectively demonstrated to significantly reduce morbidity and mortality and associated economic costs, compliance is very low. This three-year study involving investigators at one of the nation's largest Health Maintenance Organizations' research foundation (Kaiser Foundation of Northern California) seeks to identify barriers associated with low compliance in a

colorectal cancer screening program utilizing flexible sigmoidoscopy.

Phase I will target and recruit participants from an existing pool of Health Maintenance Organization enrollees who are at a relatively high age-related risk (ages 50-64) for developing colorectal cancers via short survey and invitation to screening. In Phase II, investigators will conduct a telephone survey to identify the relative impact of economic, psychological, and related factors on participation and non-participation in the mass screening programs. In phase III, investigators will analyze and widely disseminate results of the study via publication in the professional literature. Results will also be made available to participants upon request. Interventions designed to mitigate the barriers identified through this study will be incorporated into future screening efforts and general health education/health promotion efforts.

Participation in this study is voluntary and subsequent follow-up and treatment, if indicated, will be provided at no cost to participants. Informed consent will be obtained where appropriate and oversight will be provided by federal and institutional review. The total annual burden hours are 2,141.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
HMO Enrollees	6165	1	.3473

2. Reliability and Validity Assessment of the Use of Scales of Stressful Life Events in Black Women of Reproductive Age (0920-0356)—Extension—A CDC review of studies of psychosocial factors and adverse pregnancy outcome supports the hypothesis that high levels of exposure to stressful life experiences put black women at increased risk for adverse reproductive outcome, particularly Preterm Delivery (PTD) and Very Low Birth Weight (VLBW). The purpose of this study is to evaluate the reliability and validity of existing instruments that measure stressful life events in black women of reproductive

age. Respondents will consist of reproductive age residents who live in the Atlanta area and may attend a health care facility that has a behavioral prenatal unit. Approximately one half the women will be pregnant at the time of data collection.

Women enrolled in the study respond to a series of demographic and psychosocial questionnaires. They also ask that women provide a 24 hour urine sample and saliva sample. Both samples are used to correlate reported levels of stress with laboratory measures of stress.

Participation in this study is voluntary and participants will receive a reimbursement for their time. A written informed consent will be obtained and local institutional review will provide oversight.

The study is ongoing and by December 31, 1996, approximately two-thirds of data collected was completed. Approximately 130 women need to be interviewed. This leaves 130 women in the validity study, of which 30 women will repeat the process for the reliability study. The total annual burden hours are 1,134.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Screening	300	1	.083	25
Validity study group—African-American Women for the ages of 18 to 45	100	1	7.07	707
Reliability study group—African-American Women for the ages of 18 to 45	30	1	13.4	402

3. Survey Component of the CDC's Prevention Marketing Initiative Local Demonstration Site Project Evaluation—NEW—The Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention, Behavioral Intervention Research Branch is planning to conduct a cross-sectional tracking study as part of the evaluation of a five-city HIV prevention demonstration program. The program involves the integration of social marketing strategies and community participation in an effort to develop and implement HIV prevention activities.

Charged with developing programs for those 25 years of age and younger, community groups in the local demonstration sites chose to segment the target audience even further, and to mount a variety of types of interventions. Decisions about segmentation and the nature of local interventions were based on formative research conducted in each community. It is hoped that this demonstration project will result in reductions in HIV risk behavior among members of the target audiences, as well as in enhanced collaboration among individuals and

organizations in the participating communities.

As part of the evaluation of the effectiveness of the interventions, questionnaire data will be collected in three of the demonstration communities. These data will be collected at four time points over a two year period after prevention activities and message campaigns are launched. Baseline survey data have been collected recently under OMB No.0920-0343 (Evaluation of the National AIDS information and Education Program Activities). The total annual burden hours are 4,260.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Eligibility Screening	157,680	1	0.01667	2,628
Consent	5,768	1	0.05	289
Young People under 25 years of age in targeted prevention program communities	3,504	1	0.3833	1,343

Dated: March 13, 1997.

Wilma G. Johnson,

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

[FR Doc. 97-6887 Filed 3-18-97; 8:45 am]

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Meeting Announcement

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Preventing Birth Defects Due to Thalidomide Exposure.

Time and date: 8 a.m.-5 p.m., March 26, 1997.

Place: Sheraton Colony Square Hotel, 188 14th Street, NE, Atlanta, Georgia 30361.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people. Registration is not required.

Purpose: The meeting will enable academic and public health professionals to discuss strategies to prevent birth defects due to exposure to thalidomide and other human teratogens. Thalidomide, a potent human teratogen, is now available as an investigational drug in the USA. Although the drug is currently being considered for approval only for the treatment of leprosy, its potential applications appear to be numerous. This meeting will bring together leaders from the fields of birth defects research, clinical practice, bioethics, and public health to review existing strategies for limiting intrauterine exposure to human teratogens, and to discuss and provide individual input on new approaches for preventing birth defects due to future teratogens such as thalidomide.

Matters to be discussed: Agenda items will include presentations on the following topics: (1) Assessment of the Accutane Pregnancy Prevention Program, (2) use and limitations of drug registries, (3) contraception efficacy, (4) ethical issues on teratogen exposure, and (5) measures to assure appropriate use of pharmaceuticals. Group discussions on strategies for health care provider education, patient education, and appropriate use of pharmaceuticals will follow the presentations. Written materials may be submitted to CDC until March 21, 1997, for distribution to meeting participants.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION
CONTACT: Dwight Jones, Division of Birth Defects and Developmental Disabilities, NCEH, CDC, 4770 Buford Highway, NE, M/ S F-45, Atlanta, Georgia 30341-3724, telephone 770/488-7160, Fax 770/488-7197.

Dated: March 13, 1997.

Carolyn J. Russell,

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

[FR Doc. 97-7017 Filed 3-18-97; 8:45 am]

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Food and Drug Administration

Request for Nominations for a Nonvoting Representative of Industry Interests on a Public Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for a nonvoting industry representative to serve on the

Nonprescription Drugs Advisory Committee in the Center for Drug Evaluation and Research. This vacancy will occur on June 1, 1997.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, the agency encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations should be received by April 18, 1997.

ADDRESSES: All nominations and curricula vitae for the industry representative should be sent to Andrea G. Neal (address below).

FOR FURTHER INFORMATION CONTACT: Andrea G. Neal, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FAX 301-443-0699.

SUPPLEMENTARY INFORMATION: FDA is requesting that any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter to the contact person (address above). After 30 days, a letter will be sent to each organization that has made a nomination, and to those organizations indicating an interest in participating in the selection process, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each organization indicating an interest in participating in the selection process to consult with the others in selecting a