DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Program Announcement 03054]

Disease Progression in Persons Exposed to Asbestos Contaminated Vermiculite Ore; Notice of Availability of Funds

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 104(i)(1)(E), (6), (7), (14) and (15) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980 as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 (42 U.S.C. 9604(i)(1)(E), (6), (7), (14), and (15)). The Catalog of Federal Domestic Assistance number is 93.161.

B. Purpose

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program to conduct health studies of disease occurrence and progression in persons exposed to vermiculite ore in Libby, Montana (MT) or shipped from Libby to other locations for packaging and processing. This program addresses the ''Healthy People 2010'' focus area of Environmental Health.

The purpose of the program is to conduct follow-up medical screening programs for persons exposed to vermiculite ore in Libby, MT or shipped from Libby to other locations for packaging and processing, who had past exposures to asbestos-contaminated vermiculite ore during processing and/or packaging, and who underwent past medical testing for asbestos related diseases. The findings of the follow-up medical screening program will then be compared with the pre-existing medical data on the same group of individuals to evaluate occurrence, severity, and progression of asbestos-related abnormalities. (*See* Attachment 1 of the announcement, as posted on the CDC Web site.)

Measurable outcomes of the program will be in alignment with the following performance goals for ATSDR:

1. Evaluate the human health risk from toxic sites and releases, and take action in a timely and responsive manner.

2. Ascertain the relationship between exposure to toxic substances and disease.

C. Eligible Applicants

Applications may be submitted by state and local governments or their bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments, and political subdivisions of states (in consultation with states)).

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

D. Funding

Availability of Funds

Approximately $160,000 is available in FY 2003 to fund one to two awards. It is expected that the average award will be $80,000. It is expected that the awards will begin on or about July 1, 2003, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds may be expended for reasonable program purposes, such as personnel, travel, supplies, and services. Funds for contractual services may be requested; however, the grantee, as the direct and primary recipient of grant funds, must perform a substantive role in carrying out project activities, and not merely serve as a conduit for an award to another party or provide funds to an ineligible party. Equipment may be purchased with grant funds; however, justification must be provided. This should include a cost comparison of a lease versus purchase. The title to the equipment will be retained by ATSDR.

Recipient Financial Participation

Matching funds are not required for this program.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities, and ATSDR will be responsible for the activities listed in 2. ATSDR Activities.

1. Recipient Activities

a. Develop a protocol, conduct an evaluation of the target population and prepare a final report of the project. The protocol and report will each undergo scientific peer review as required by ATSDR.

b. Using an existing dataset, locate and trace individuals outside of Libby, MT who were exposed to vermiculite shipped from Libby. These individuals must have undergone previous medical screening (at least chest x-rays or spirometry, but optimally both chest x-rays and spirometry) for asbestos-related pulmonary abnormalities. Elapsed time should allow for latent abnormalities to become evident, *e.g.*, minimum 20 years latency.

c. Recipient must have access to medical records, previous x-rays and spirometry records related to past screening activities conducted for the eligible population.

d. Provide follow-up medical screening to the eligible population (as defined in b. and c. above), to include chest x-rays, spirometry, symptom questionnaire. The questionnaire should also ascertain details of potential exposures to asbestos.

e. Compare previous records to current findings and evaluate occurrence, severity, and progression of abnormalities consistent with asbestos exposure.

f. Provide results of testing and related education and counseling to the eligible population. Inform participants of actions that they and their health care providers can take to prevent or decrease the adverse impact of these potential asbestos exposure and related health effects, if any.

g. Identify deceased individuals among those who originally underwent testing. Obtain death certificates for these deceased persons and evaluate causes of mortality for inclusion in the final report. Specific attention should be given to asbestos-related mortality (*e.g.*, lung cancer, asbestosis, Mesothelioma, *etc.*).

2. ATSDR Activities

a. Work closely with the recipient in the design, review and development of the protocol and evaluation of the data. ATSDR will prepare and submit materials to the CDC Institutional Review Board (IRB) and external peer review.

b. Assist with the tracing and locating of individuals with past exposure.

c. Work with recipient to review available medical records for the eligible population.

d. Review data with the recipient in the evaluation of the severity and progression of abnormalities.

e. Facilitate meetings between recipient and ATSDR to coordinate planned efforts and review progress.

f. Assist with the preparation of final reports and fact sheets documenting the results of testing and related education and counseling materials for the eligible population.

F. Content

Applications

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 20 pages, double spaced, printed on one side, with one inch margins, and unreduced 12-point font.

The narrative should consist of, at a minimum, a Plan, Objectives, Methods, Evaluation and Budget. The program plan timeline should briefly address activities to be conducted over the entire three-year project period.

G. Submission and Deadline

Application Forms

Submit the signed original and two copies of PHS 5161–1 (OMB 0920–0428). Forms are available at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. Eastern Time June 19, 2003. Submit the application to: Technical Information Management—PA#03054, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd., Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

CDC Acknowledgement of Application Receipt

A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

Deadline

Applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will, upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals as stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

An independent review group appointed by ATSDR will evaluate each application against the following criteria:

1. Proposed Program (50 percent). The criteria will include the extent to which the applicant's proposal and protocol addresses (a) the approach, feasibility, adequacy, and rationale of the proposed project design; (b) the technical merit of the proposed project, including the degree to which the project can be expected to yield results that meet the program objective as described in the purpose section of this announcement, and the technical merit of the methods and procedures (including quality assurance and quality control procedures) for the proposed project; (c) the proposed timeline, including clearly established project objectives for which progress toward attainment can and will be measured; and (d) the proposed method to disseminate the results to state and local public health officials, participants, community residents, and other concerned individuals and organizations.

2. Program Personnel (30 percent). The criteria will include the extent to which the proposal has described (a) the qualifications, experience and commitment of the principal investigator (or project director), and his or her ability to devote adequate time and effort to provide effective leadership; and (b) the competence of associates to accomplish the proposed activity, their commitment, and the time they will devote.

3. Applicant Capability and Coordination Efforts (20 percent). The criteria will include the extent to which the proposal has described (a) the capability of the applicant's administrative structure to foster successful scientific and administrative management of a study; and (b) the capability of the applicant to demonstrate an appropriate plan for interaction with the community.

4. Program Budget—(not scored). The criteria will include the extent to which the budget is reasonable, clearly justified, and consistent with intended use of cooperative agreement/grant funds.

5. Human Subjects (not scored). The criteria will include the extent to which the application adequately addresses the requirements of Title 45 CFR Part 46 for the protection of human subjects. Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

2. The proposed justification when representation is limited or absent.

3. A statement as to whether the design of the study is adequate to measure differences when warranted.

4. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the

budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, *see* Attachment I of the program announcement as posted on the CDC Web site.

AR–1—Human Subjects.
AR–2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.
AR–7—Executive Order 12372 Review.
AR–9—Paperwork Reduction Act Requirements.
AR–10—Smoke-Free Workplace Requirements.
AR–11—Healthy People 2010.
AR–12—Lobbying Restrictions.
AR–17—Peer and Technical Reviews of Final Reports of Health Studies—ATSDR.
AR–18—Cost Recovery—ATSDR.
AR–19—Third Party Agreements—ATSDR.
AR–22—Research Integrity.

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov.*

Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd., Atlanta, GA 30341–4146, *Telephone:* (770) 488–2700.

For business management and budget assistance, contact: Edna Green, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2743, E-mail address: *ecg4@cdc.gov.*

For business management and budget assistance in the territories, contact: Jamie Legier, Contract Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd., Atlanta, GA 30341–4146, Telephone: (770) 488–2635, E-mail address: *bzl3@cdc.gov.*

For program technical assistance, contact:

Dr. Vikas Kapil, Senior Medical Officer, Division of Health Studies, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd., NE., MS E–31, Atlanta, GA 30333, Telephone: (404) 498–0545, E-mail address: *vck3@cdc.gov.*

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Maggie Warren, Public Health Advisor, Division of Health Studies, Agency for Toxic Substances, 1600 Clifton Rd., NE., MS E–31, Atlanta, GA 30303, Telephone: (404) 498–0546, E-mail address: *mcs9@cdc.gov.*

Dated: April 30, 2003.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–64]

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) 498–1210.

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 or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Evaluation Of Educational Materials Promoting Informed Decision-Making About Prostate Cancer Screening—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Prostate cancer is the second most commonly diagnosed cancer among men in the United States. An estimated 220,900 new cases of prostate cancer will be diagnosed, and 28,900 men will die from the disease in 2003. The effectiveness of prostate cancer screening has not been established. A number of clinical guidelines recommend that the potential risks and benefits of prostate cancer screening be explained to patients so that they may make an informed decision about screening. The purpose of this project is to evaluate the effectiveness of an informed-decision making booklet about prostate cancer screening developed by CDC.

The proposed study will consist of 3 tasks. In Task 1, the reliability and validity of a measurement instrument assessing prostate cancer knowledge and related variables will be tested. Two hundred men of all races aged 50 to 70 years and 200 African-American men aged 40 to 70 years will read the CDC booklet and complete the measurement instrument. In Task 2, 250 primary care physicians will complete a survey measuring their prostate cancer screening practices. The survey will be administered once and then again several months later. In Task 3, 600 men aged 50–70 years will take part in a randomized controlled trial. Men in the intervention group will be asked to read the CDC booklet and complete the measurement instrument tested in Task 1, and men in the control group will complete the measurement instrument without reading the CDC booklet. There is no cost to respondent except for their time.