

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03190]

Monitoring, Evaluation, and Prevention of HIV/AIDS in the Cooperative Republic of Guyana; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2003 funds for a cooperative agreement program for monitoring, evaluation, and information systems improvement to implement integrated care and prevention of HIV/AIDS in the Cooperative Republic of Guyana. The Catalog of Federal Domestic Assistance number for this program is 93.941.

B. Eligible Applicant

Assistance will be provided only to the Ministry of Health (MOH) of Guyana. The MOH is the only appropriate and qualified organization to conduct a specific set of activities supportive of the CDC Global AIDS Program's technical assistance to Guyana for the following reasons: (1) The MOH is uniquely positioned, in terms of legal authority, ability, and credibility among Guyanese citizens, to collect crucial data on HIV/AIDS as well as to provide care to HIV infected patients; (2) The MOH is mandated by Guyanese laws to implement care and treatment activities necessary for the control of epidemics, including HIV/AIDS; (3) The MOH already has an established network of health care facilities throughout the country. These treatment facilities include treatment centers, maternal-child health clinics, and infectious disease centers which take care of a significant number of HIV/AIDS patients. These facilities are accessible and provide health information and care for patients with HIV/AIDS, enabling the Ministry to become immediately engaged in the activities listed in this announcement; and (4) The MOH has trained physicians, nurses, and social workers already working in their network of health care facilities around the country who can carry out the activities listed in this announcement. On April 4, 2003, the United States Department of Health and Human Services signed a memorandum of understanding with the Guyanese Ministry of Health to collaborate on program implementation

related to HIV/AIDS, including operations research.

C. Funding

Approximately \$200,000 is available in FY 2003 to fund this award. It is expected that the award will begin on or before September 15, 2003, and will be made for a 12-month budget period within a project period of up to five years. Funding estimate may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700. For technical questions about this program, contact: Okechukwu C. Nwanyanwu, Ph.D., Director, Global AIDS Program, Guyana, Centers for Disease Control and Prevention, Department of Health and Human Services, c/o U.S. Embassy, 100 Young and Duke Streets, Georgetown, Guyana, South America, Telephone: (592) 223-6501 or (592) 223-6503, Fax: (592) 225-8497, e-mail: ocn1@cdc.gov.

Dated: August 8, 2003.

Edward Schultz,

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

[FR Doc. 03-20706 Filed 8-13-03; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03150]

Expansion of Youth and Young Adult-Focused HIV & STD Prevention Activities In the Republic of Tanzania; Notice of Availability of Funds

Application Deadline: September 15, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 307 of the Public Health Service Act, (42 U.S.C. 241(a) and 242l) as amended. The Catalog of Federal Domestic Assistance number is 93.941.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement

program for the expansion of youth-focused HIV/STD prevention activities in the Republic of Tanzania.

The purpose of this program is to provide assistance to a Tanzania-based public, private non-profit, or faith-based organization in the provision of a youth-focused HIV/STD prevention program that includes information, education and communication (IEC), voluntary counseling and testing (VCT), and support services for HIV positive youth in Tanzania; and in the development of strategies for extending successful youth-focused services to other private and public sector organizations.

Information on HIV prevention methods (or strategies) can include abstinence, monogamy, *i.e.*, being faithful to a single sexual partner, or using condoms consistently and correctly. These approaches can avoid risk (abstinence) or effectively reduce risk for HIV (monogamy, consistent and correct condom use).

Measurable outcomes of this program will be in alignment with one or more of the following performance goals for the National Center for HIV, STD and TB Prevention (NCHSTP), Global AIDS Program (GAP): Working with other countries, U.S. Agency for International Development (USAID), and U.S. government agencies, reduce the number of new HIV infections among 15-24 year olds in sub-Saharan Africa from an estimated two million by 2005.

C. Eligible Applicants

Applications may be submitted by public and private non-profit organizations, and faith-based organizations based in Tanzania, with current capacity for providing IEC, VCT, and support services to 25,000 youth per year. Organizations based outside Tanzania are not eligible to apply.

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 \$250,000 is available in FY 2003 to fund one award. It is expected that the award will begin on or about September 15, 2003 and will be made for a 12-month budget period within a project period of up to five 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

(1) Funds may be used only for activities associated with HIV/AIDS. CDC funds may be used for direct costs such as salaries; necessary travel; operating costs, including supplies, fuel, utilities, etc.; staff training costs, including registration fees and purchase and rental of training related equipment; and purchase of HIV testing reagents, test kits, and laboratory equipment for HIV testing.

(2) The purchase of antiretroviral drugs, reagents, and laboratory equipment for antiretroviral treatment projects requires prior approval in writing by CDC officials.

(3) No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic use of any illegal drug.

(4) Applicants may contract with other organizations under this program; however, the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention and care services for which funds are requested).

(5) The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of American University, Beirut, the Gorghas Memorial Institute, and the World Health Organization, indirect costs will not be paid (either directly or through a sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

(6) All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

(7) A fiscal Recipient Capability assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

(8) You must obtain an annual audit of these CDC funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Priority

Priority will be given to eligible applicants who can demonstrate:

(1) A history of working with youth and organizations of young adults on HIV/STD prevention.

(2) The capacity to coordinate multi-agency projects.

(3) A well-organized program for training their own staff.

(4) The capability of training other sites to develop and implement successful HIV/STD prevention programs.

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 CDC will be responsible for the activities listed in 2. CDC Activities.

1. Recipient Activities

a. Develop and implement IEC strategies targeting youth ages 15–24 and young adults attending tertiary institutions. Use existing IEC materials and/or develop new materials in collaboration with Ministry of Education (MOE), Ministry of Health (MOH), and CDC. Information on HIV prevention methods (or strategies) should include abstinence, monogamy, *i.e.*, being faithful to a single sexual partner, or using condoms consistently and correctly. These approaches can avoid risk (abstinence) or effectively reduce risk for HIV (monogamy, consistent and correct condom use).

b. Provide technical assistance and training to institutions working with youth to strengthen their capacity to implement successful IEC strategies.

c. Work within existing health services to extend or initiate VCT and services for the treatment and prevention of sexually transmitted diseases (STD) services specifically targeting youth.

d. Provide technical assistance and training to existing health facilities to strengthen their capacity to routinely provide youth-focused VCT and STD services.

e. Work within existing health or community services to extend or initiate support services for HIV positive youth.

f. Provide technical assistance and training to existing health or community organizations to strengthen their capacity to routinely provide support services for HIV positive youth.

2. CDC Activities

a. Collaborate with the grantee on designing and implementing the activities listed above, including, but not limited to:

(1) Providing technical guidance to process of developing IEC materials and effective communication strategies;

(2) Developing and implement youth-targeted IEC training module;

(3) Developing HIV testing quality assurance plan for tertiary institutions;

(4) Developing a referral logistics plan and integrate a care and treatment referral strategy into VCT/STI prevention services;

(5) Developing support strategies linking community organizations with youth prevention activities of tertiary institutions;

(6) Providing overall guidance and technical support to project data management and analysis, dissemination of results and findings, and management and tracking of finances; and

(7) Participating on project-related advisory board.

b. Provide input into, and approve the selection of key personnel to be involved in the activities performed under this cooperative agreement.

c. Assist in training and capacity building to ensure successful implementation of program and activities.

d. Monitor project and budget performance.

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 30 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 should address activities to be conducted over the entire five-year project period. The budget must cover the first one-year budget period. Prepare an appropriate plan for financial management and accounting for the activities in this proposal that are consistent with an annual workplan.

G. Submission and Deadline*Application Forms*

Submit the original and two copies of PHS 5161-1 (OMB Number 0920-0428). Forms are available in the application kit and at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm.

Application forms must be submitted in the following order: Cover Letter, Table of Contents, Application, Budget Information Form, Budget Justification, Checklist, Assurances, Certifications, Disclosure Form, HIV Assurance Form, Indirect Cost Rate Agreement, and Narrative.

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 September 15, 2003. Submit the application to: Technical Information Management—PA# 03150, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146.

Applications may be e-mailed to PGOTIM@cdc.gov. If you e-mail your application, you must follow up by mailing a copy of the application face page showing original signatures.

Deadline

Applications shall be considered as meeting the deadline if they are received in the CDC Procurement and Grants Office 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 goal 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 CDC will evaluate each application against the following criteria:

1. Ability to Carry Out the Project (40 points).

The extent to which the applicant understands and describes activities which are realistic, achievable, time-framed and appropriate to effectively plan, coordinate, and complete these activities. Applicant must show how and at what intervals the effectiveness and productivity of this program activity will be monitored and evaluated. Applicant should include a description of applicant organizational structure and use it to explain how the work will be carried out.

2. Technical and Programmatic Approach (20 points)

The extent to which the applicant's proposal demonstrates understanding of the technical and organizational aspects of conducting all included HIV testing and care activities and computerization of client record data.

3. Personnel (20 points)

The adequacy of personnel, including training, availability, and experience, in order to carry out the technical and organizational aspects of all proposed activities.

4. Administrative and Accounting Plan (20 points)

(a) The adequacy of the plans to account for, prepare reports, monitor, and audit expenditures under this agreement; (b) The extent to which the application demonstrates ability to administer and manage the budget; (c) The extent to which the budget is itemized and well justified; and (d) Demonstration of plans to engage an outside accounting firm to design and manage the financial system to meet CDC and the recipient's accounting requirements.

5. Budget (Reviewed, but not scored)

The extent to which the budget is detailed, clear, justified, provides direct support, and is consistent with the proposed program activities.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with an original, plus two copies of:

1. Interim progress reports. Include copies of all surveillance reports and plans completed and program accomplishments during the reporting 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; and

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-4, HIV/AIDS Confidentiality Provisions

AR-5, HIV Program Review Panel Requirements

AR-9, Paperwork Reduction Act Requirements

AR-10, Smoke-Free Workplace Requirements

AR-12, Lobbying Restrictions.

Executive Order 12372 does not apply to this program.

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: 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 Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For business management and budget assistance, contact: Terri Brown, International Territories Acquisitions and Assistance Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920

Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2638, E-mail address: aie9@cdc.gov.

For program technical assistance, contact: Eddas Bennett, MBA, MPH, Deputy Director, CDC Tanzania AIDS Program, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 140 Msese Road, Dar es Salaam, Tanzania, Telephone: 2 666 010 x4155, e-mail: ebennett@tancdc.co.tz.

Dated: August 8, 2003.

Edward Schultz,

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

[FR Doc. 03-20705 Filed 8-13-03; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N-0516]

Agency Information Collection Activities; Announcement of OMB Approval; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "A Request for Samples and Protocols" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 21, 2003 (68 FR 27820), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0206. The approval expires on July 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-20684 Filed 8-13-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 17, 2003, from 8:30 a.m. to 5 p.m. and on September 18, 2003, from 8:30 a.m. to 3 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or e-mail: SCHARENH@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 17, 2003, the subcommittee will discuss quality by design and how it is distinct from approaches that attempt to test in quality. On September 18, 2003, the subcommittee will discuss and define principles by which risk management is integrated into decisionmaking.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by September 10, 2003. Oral presentations from the public will be scheduled between approximately 11:30

a.m. and 12:30 p.m. on September 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 10, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Hilda Scharen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 7, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-20683 Filed 8-13-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which