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Dated: July 5, 2000.

Ron Van Duyn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00134]

Leadership and Investment in Fighting an Epidemic (LIFE) Global AIDS Activity; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program to increase United States support for sub-Saharan African countries and India to limit the further spread of HIV and to care for those affected by this devastating disease.

This additional funding is an action by the United States (U.S.) Government recognizing the impact that AIDS continues to have on individuals, families, communities and nations, and the need to do more. Over the next 5 years, it is expected that these activities will contribute to global targets established by the Joint United Nations Programme on AIDS (UNAIDS), in cooperation with the United States Agency of International Development (USAID) and other bilateral and multi-lateral partners. These goals represent the result of the total worldwide contribution of resources and effort. The U.S. Government seeks to further these goals through the LIFE Initiative:

- The incidence of HIV infection will be reduced by 25% among 15-24 year olds by 2005. (Currently 2 million young adults are infected each year in sub-Saharan Africa.)

- At least 75% of HIV infected persons will have access to basic care and support services at the home and community levels, including drugs for common opportunistic infections (TB, pneumonia, and diarrhea). (Currently, less than 1% of HIV infected persons have such access.)

- Orphans will have access to education and food on an equal basis with their non-orphaned peers.

- By 2002, domestic and external resources available for HIV/AIDS efforts in Africa will have doubled to \$300 million per year. (Currently, approximately \$150 million per year is spent on HIV/AIDS prevention in sub-Saharan Africa.)

- By 2005, 50% of HIV infected pregnant women will have access to interventions to reduce mother-to-child HIV transmission. (Currently, less than 1% of HIV infected pregnant women have access to such services in sub-Saharan Africa.) As a key partner in the U.S. Government's Leadership and Investment in Fighting an Epidemic (LIFE) Initiative, CDC, through its Global AIDS Activity (GAA) is working in a collaborative manner with national governments, USAID and other international partners to develop programs of assistance to address the HIV/AIDS epidemic in countries designated as LIFE countries by the U.S. Congress. At present, those countries are Botswana, Cote D'Ivoire, Kenya, South Africa, Uganda, Rwanda, Zimbabwe, Ethiopia, Mozambique, Malawi, Tanzania, Nigeria, Senegal, Zambia and India.

The overall objectives of the CDC's GAA are to:

- Reduce HIV transmission through primary prevention of sexual, mother-to-child, and blood transmission.

- Strengthen the capacity of countries to collect and use surveillance data and to manage national HIV/AIDS programs.

- Improve community and home based care and treatment of HIV and sexually transmitted diseases (STDs) and opportunistic infections.

B. Eligible Applicants

Applicants must: (1) Be a U.S. Private Volunteer Organization (PVO), and have been granted tax-exempt status under Section 501(c)(3), evidenced by an Internal Revenue Service (IRS) determination letter; and (2) have at least 2 years experience in delivering HIV, STD, or TB prevention and care programs and/or prenatal/obstetric/

reproductive programs in accordance with GAA objectives in at least 5 of the 15 countries (Botswana, Cote d'Ivoire, Ethiopia, Kenya, Malawi, Mozambique, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zambia, Zimbabwe, India).

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

C. Availability of Funds

Approximately \$5,000,000 is available to fund up to 4 awards in FY 2000. It is expected that awards will begin September 30, 2000, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates are subject to change.

CDC expects to allocate \$5,000,000 into 2 categories of program activities and services: (A) primary prevention (approximately 70% of available funds), and (B) care, support, and treatment (approximately 30% of available funds). These estimates may vary. In making these awards, CDC will use the "CDC Global AIDS Activities Technical Strategies" as a guide for selecting collaborative activities to be funded (See Attachment I).

Continuation awards within an approved project period will be made on the basis of the availability of funds and the applicant's satisfactory progress toward achieving defined objectives.

Satisfactory progress toward achieving objectives will be determined by progress reports and site visits conducted by CDC representatives.

Use of Funds

Funds received from this announcement will not be used for the purchase of antiretroviral drugs for treatment of established HIV infection, occupational exposures, and non-occupational exposures and will not be used for the purchase of machines and reagents to conduct the necessary laboratory monitoring for patient care.

Applicants may contract with other organizations under these cooperative agreements, however, applicants must perform a substantial portion of the activities (including program management and operations and delivery of prevention services for which funds are requested).

Funding Preference

Funding will be given to ensuring a geographic distribution of awards covering the 15 GAA countries in African and India.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under number 1. (Recipient Activities) and CDC will be responsible for activities under number 2. (CDC Activities).

1. Recipient Activities

a. Collaborate with CDC, partner governments, USAID missions, and other partners to ensure that: (1) There is country ownership of the activities, (2) proposed activities complement existing efforts both by the country and with other partners, and (3) activities are supportive of indigenous expertise and institutions.

b. Provide services in collaboration with CDC, partner governments and other partners for the development of capacity for the Ministry of Health and other in-country partners to deliver the services.

c. Provide assistance to countries to develop behavior change intervention programs with vulnerable populations such as youth (age 15–29 years old) and commercial sex workers and their clients. Intervention programs may include support of information, education and communication (IEC) campaigns, social marketing of condoms and behavior change.

d. Focus on no more than three of the following activities:

1. Voluntary Counseling and Testing (VCT)—implement, monitor, and evaluate HIV counseling and testing programs. Identify barriers and concerns raised in providing VCT and coordinate with campaigns to help reduce the fear, stigma, discrimination, and isolation associated with HIV infection and AIDS.

2. Mother To Child Transmission (MTCT)—implement feasible, sustainable interventions to decrease HIV MTCT, and assure that these interventions are integrated within maternal and child health (MCH) programs, strengthen antenatal care, promote the health of the mother, and enhance HIV prevention programs at the family and community level.

3. Blood safety—build or strengthen a national blood transfusion service to manage a national program, improve the safety and quality of the blood supply, decrease the demand for blood transfusion, and increase the supply of blood from low-risk volunteer blood donors.

4. STD prevention and care—expand and improve the diagnosis and treatment of STDs, including risk reduction counseling and education, as a means of reducing the continued transmission of HIV.

5. Prevention and Youth—implement youth-focused prevention/intervention programs, testing prevention programs, secondary prevention for HIV-positive youth, and build youth development programs.

6. Public-private partnerships—engage business and labor unions in a number of countries and provide technical assistance and materials for the development and implementation of public-private partnerships to address the spread of HIV/AIDS.

7. Care, support and treatment—improve the local capacity to prevent and treat HIV and related opportunistic infections with a special emphasis on TB and the implementation of palliative AIDS care programs.

e. Serve on a coordinating council with representatives of CDC as well as other collaborating organizations that will meet in Atlanta on a semi-annual basis. This council will review and coordinate program assistance plans and routine program performance measures to ensure consistent support of LIFE Initiative and global UNAIDS goals and objectives.

f. Participate in specific country-based workgroups that develop and review ongoing country assistance activities. The product of these workgroups will define the activities of the collaborating agencies as detailed in items a through d above.

2. CDC Activities

a. Collaborate with partner governments, USAID missions and other partners to assist recipients in the development of plans for program assistance based on the country needs, the CDC technical assistance portfolio, and HIV prevention activities conducted by other partners.

b. Provide consultation and scientific and technical assistance based on the “CDC Global AIDS Activities Technical Strategies” document to promote the use of best practices known at this time. See Attachment I, “CDC Global AIDS Activities Technical Strategies”.

c. Facilitate semi-annual planning and review meetings in Atlanta for the purposes of coordinating recipient assistance programs in LIFE countries to ensure consistency in collaborative technical assistance activities.

d. Facilitate in-country planning and review meetings for the purposes of ensuring coordination of country-based program technical assistance activities.

E. Application Content

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 double-spaced pages, printed on one side, with one inch margins, and un-reduced font. Number each page clearly, and provide a complete Table of Contents to the application and its appendices. Please begin each separate section of the application on a new page. The original and each copy of the application set must be submitted unstapled and unbound. The following format should be used when developing your narrative:

Format

1. Background
2. Documented Needs
3. Eligibility and Capacity
4. Proposed Program Plan
 - a. Goals
 - b. Objectives
 - c. Plan of Operation
 - d. Evaluation Plan
 - e. Collaboration
5. Budget and Staffing Breakdown and Justification

F. Submission and Deadline

Submit the original and two copies of PHS 5161–1 (OMB Control Number 0937–0189). Forms are available at the following Internet address: www.cdc.gov, or in the application kit. On or before August 24, 2000, submit the application to the Grants Management Specialist identified in the “Where to Obtain Additional Information” section of this announcement.

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 independent 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.)

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

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Capacity (30 Points)

a. The extent to which the applicant describes the ability to deliver HIV, STD, or TB prevention and care programs and/or prenatal/obstetric/reproductive programs in accordance with GAA objectives.

b. The extent to which the applicant documents personnel staff positions, experience, training, and recruitment.

2. Proposed Program Plan (40 Points)

a. The appropriateness of proposed activities and interventions and extent to which they are targeted to address the priority needs;

b. The quality of the proposed objectives and extent to which they are specific, realistic, measurable, and time-phased;

c. Extent to which proposed activities, if well-executed, are capable of attaining project objectives; the likelihood that the proposed activities, interventions, and services will achieve the stated program goals and intent of this program announcement.

3. Collaboration (15 Points)

Extent to which the applicant organization can document a history of successful collaborations with the U.S. government and/or non-governmental organizations in carrying out projects of public health impact.

4. Evaluation (15 Points)

Quality of the plan for evaluating the proposed program activities and the likelihood that the evaluation will provide information that will lead to improvement of the program.

5. Budget (Not Scored)

Extent to which budget is reasonable, clearly justified, consistent with the intended use of the funds, and allowable. All budget categories should be itemized.

H. Other Requirements**Technical Reporting Requirements**

Provide CDC with the original plus two copies of:

1. Annual progress report
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial report and performance report, 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.

For descriptions of the following Other Requirements, see Attachment II.

Some of the more complex requirements have some additional information provided below:

- AR-1 Human Subjects Requirements
- AR-4 HIV/AIDS Confidentiality Provisions
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 307 of the Public Health Service Act, 42 U.S.C. 241 and 2421, and section 104 of the Foreign Assistance Act of 1961, 22 U.S.C. 2151b. The Catalog of Federal Domestic Assistance Number is 93.939, HIV Prevention Activities—Nongovernmental Organization.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov>. Scroll down the page, click on "Funding", then "Grants and Cooperative Agreements."

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Dorimar Rosado, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, MailStop E-15, Atlanta, GA 30341-4146, Telephone (770) 488-2736, E-mail address: dpr7@cdc.gov.

For program technical assistance, contact: Leo Weakland, Deputy Coordinator, Global AIDS Activity (GAA), National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, M/S E-07, Atlanta, GA 30333, Telephone number (404) 639-8016, Email address: lfw0@cdc.gov.

Dated: July 5, 2000.

Ron Van Duyne,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Disease Control and Prevention****Advisory Committee to the Director, Centers for Disease Control and Prevention: 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 Advisory Committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and Date: 8:30 a.m.—4 p.m., August 4, 2000.

Place: The Sheraton Colony Square Hotel, 188 14th Street, N.E., Atlanta, Georgia 30361.

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

Purpose: The committee will anticipate, identify, and propose solutions to strategic and broad issues facing CDC.

Matters to Be Discussed: Agenda items will include updates from Dr. Jeffrey P. Koplan, Director, CDC regarding the current CDC Director's priorities with a focus on selected CDC programs including Immunizations, Prevention Research, and Tobacco.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Kathy Cahill, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D-24, Atlanta, Georgia 30333. Telephone 404/639-7060.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 3, 2000.

Carolyn J. Russell,

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

[FR Doc. 00-17448 Filed 7-10-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 00P-1280]

Medical Devices; Exemptions From Premarket Notification; Class II Devices: Triiodothyronine Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.