DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00138]

Youth-Focused HIV/AIDS Prevention Program Development and Technical Assistance Collaboration With Countries Targeted by the Leadership and Investment in Fighting the Epidemic (LIFE) Initiative; 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 for HIV/AIDS Prevention Program Development and Technical Assistance Collaboration with Countries Targeted by the LIFE (Leadership and Investment in Fighting an Epidemic) Initiative.

In July 1999, the Administration announced the LIFE Initiative to address the global AIDS pandemic. The LIFE Initiative, an effort to expand and intensify the global response to the growing AIDS pandemic and its serious impact, is part of the United States (U.S.) Government's participation in the International Partnership Against HIV/AIDS in Africa (IPAA). A central feature of the LIFE Initiative is a $100 million increase in U.S. support for sub-Saharan African countries and India, which are working to prevent the further spread of HIV and to care for those affected by this devastating disease. This additional funding is a critical step by the U.S. Government in recognizing the impact that AIDS continues to have on individuals, families, communities, and nations and responding to the imperative to do more. The Department of Health and Human Services (HHS), through its agency, the Centers for Disease Control and Prevention (CDC) is administering $35 million of the $100 million allocated to the LIFE Initiative by the U.S. Congress.

The purpose of the program is to support HIV/AIDS prevention program development and technical assistance for countries designated by the U.S. Congress under the LIFE Initiative. 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 countries targeted represent those with the most severe epidemic and the highest number of new infections. They also represent countries where the potential for impact is greatest and where U.S. government agencies are already active.

The goals of the program are to address and support three program elements of the LIFE initiative: Primary Prevention, Capacity and Infrastructure Development, and Community and Home-Based Care and Treatment. The program described in this announcement calls for the delivery of HIV/AIDS prevention program development and technical assistance to the LIFE countries through a variety of recipient activities. The technical assistance will enhance the skills of LIFE country national AIDS program officials in strategic planning, evaluation, and communication relating to youth HIV/AIDS prevention care programs.

B. Eligible Applicants

Assistance will be provided only to a non-profit non-governmental organization. The eligible applicant must meet these criteria:

1. Have been granted tax-exempt status under Section 501(c)(3), as evidenced by an Internal Revenue Service (IRS) determination letter.
2. Have youth representation on their governing body, board, or on an advisory committee.
3. Have a minimum of one year documented experience in operating and centrally administering a coordinated program to serve youth with HIV prevention education and services within a major portion or region (multi-state or multi-territory) of the United States.

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 $1 million is available in FY 2000 to support one award. It is expected that the award will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to 3 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 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.

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

D. Program Requirements

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

1. Recipient Activities

a. Provide technical assistance to national AIDS control programs in LIFE countries on how to collect, synthesize, and disseminate global youth-focused best-practices information. This will also help the youth-serving organizations (YSOs) and non-governmental organizations working with national AIDS control programs in the LIFE countries to meet the needs of young people. Activities could include, but are not limited to, peer education, adolescent development, adolescent sexual and reproductive health issues, and youth development as a prevention strategy.

b. Identify and implement peer-to-peer training opportunities and technical assistance needs for young people and their providers from national AIDS control programs in LIFE countries. This peer-to-peer training and technical assistance will help LIFE country public health providers plan, implement, and evaluate HIV/AIDS prevention and care programs to meet the in-country needs of young people. Such peer-to-peer technical assistance may include, but is not limited to, identifying and facilitating training experiences for young people or their providers from LIFE countries; bringing young people or their providers from LIFE countries to the U.S. to participate in conferences, meetings, and/or developmental experiences; and/or agency or its approved representatives embarking on temporary assignments in LIFE countries. Topics may include but are not limited to counseling and testing with young people, how to make HIV/AIDS medical services youth accessible, mother-to-child transmission, contraception supply and accessibility for youth, and development for vulnerable youth.

c. Provide public health officials, young people, youth-serving providers from national AIDS control programs, NGOs and YSOs in LIFE countries with technical assistance throughout the project period on developing and implementing strategic youth-focused HIV/AIDS prevention and care plans. Such plans will consist of goals and measurable objectives. This technical assistance will include how to monitor implementation of objectives in order to assess effectiveness and how to determine the timing and content of mid-course corrections to accomplish objectives.

d. Provide public health officials from national AIDS control programs, YSOs, and young people in LIFE countries with technical assistance, working with such officials to identify local HIV/AIDS prevention and care program and policy issues as they are evolving, and helping to determine how to use this feedback to refine and improve HIV prevention and care plans and programs.

e. Provide partnering organizations in LIFE countries with technical assistance to develop systems for timely distribution and dissemination of youth-specific HIV/AIDS program and policy information for continuing modification and improvement of AIDS control policies.

f. Develop and sustain, beyond project period, a communications systems to keep all stakeholders (officials from LIFE country national AIDS control programs, U.S. partners, CBOs, young people, YSOs, CDC, and others) informed of project progress and to share technical assistance and capacity building information.

g. Document, monitor, and record outcome indicators of successful activities under this cooperative agreement and include such evaluation information in the required annual progress reports.

2. CDC Activities

a. Provide technical advice to partners and national AIDS control programs of LIFE countries on development of systems to identify and improve youth-focused HIV/AIDS program and policy issues.

b. Provide consultation, scientific and technical assistance to partners and national AIDS control programs of LIFE countries on planning, operating, analyzing, and evaluating youth-focused HIV prevention programs.

c. Provide program and policy information to partners and national AIDS control programs of LIFE countries for rapid dissemination, coordination, and implementation of youth-focused HIV prevention efforts.

d. Assist in assessing program operations and evaluating overall effectiveness of programs.

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 20 double-spaced pages, printed on one side, with one inch margins, and unreduced font. Pages should be numbered and a complete index to the application and its appendixes must be included. Begin each separate section 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. Abstract
2. Justification of Need
3. Organizational Capacity
4. Staffing Plans
5. Collaboration
6. Management and Evaluation Plan
7. Budget

F. Submission and Deadline

Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189). Forms are in the application kit. On or before August 21, 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 reviewed and evaluated against the following criteria by an independent review group appointed by CDC:

1. Justification of Need (20 Points)

The extent to which the applicant demonstrates understanding of the requirements, problems, objectives, complexities, and interactions required of the cooperative agreement.

2. Organizational Capacity (30 Points)

a. Degree to which the applicant provides evidence of an ability to carry-out the proposed project and the extent to which the applicant institution documents the capability to achieve objectives similar to those of this project.

b. Degree to which applicant has developed their expertise, services, and experience in youth-oriented HIV prevention, rather than just adapting such resources from an adult to a youth perspective.

c. Degree to which applicant has established mechanisms for communicating youth-focused HIV/AIDS prevention information in LIFE countries.

d. Degree to which proposed objectives are clearly stated, realistic, measurable, time-phased, related to the purpose of this project.

3. Staffing Plan (20 Points)

Extent to which professional personnel involved in this project are qualified, including evidence of past achievements relevant to this project.

4. Collaboration (10 Points)

a. Degree to which applicant possess established networks of contacts and knowledge of youth-serving HIV prevention institutions, people, and resources in order to identify people and programs for technical assistance and capacity building in LIFE countries.

b. Degree to which applicant has already developed national and global networks among officials in governments, non-governmental organizations (NGOs), and community-based organizations (CBOs) throughout the U.S. and in the LIFE countries.

5. Management and Evaluation Plan (20 Points)

Extent to which applicant demonstrates the adequacy of plans for administering and evaluating the project.

6. Budget (Not Scored)

Extent to which project budget is reasonable.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of

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

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–4 HIV/AIDS Confidentiality Provisions
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k) (2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2). The Catalog of Federal Domestic Assistance number is 93.941, HIV Demonstration, Research, Public and Professional Education Projects.

J. Where To Obtain Additional Information

This and other CDC [ATSDR] announcements can be found on the CDC home page Internet: http://www.cdc.gov. 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: Annie H. Camacho, Grants Management Specialist, Centers for Disease Control and Prevention (CDC), Procurement and Grants Office, Room 3000, 2920 Brandywine Road, Mailstop E–15, Atlanta, GA 30341–4146, Telephone: (770) 488–2735, Email: atc4@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, Mailstop E–07, Atlanta, GA 30333, Telephone number (404) 639–8016, Email address: lfw0@cdc.gov.

Dated: June 29, 2000.

John L. Williams,

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

[FR Doc. 00–17011 Filed 7–5–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1353]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirement relating to the regulation of FDA's current good manufacturing practice (CGMP) and related regulations for blood and blood components.

DATES: Submit written comments on the collection of information by September 5, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components—Parts 606 and 640 (21 CFR Parts 606 and 640) (OMB Control Number 0910–0116)—Extension

Under the statutory requirements contained in the Public Health Service Act (42 U.S.C. 262), no blood, blood component, or derivative may move in interstate commerce unless: (1) It is propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license; (2) the product complies with regulatory standards designed to ensure safety, purity, and potency; and (3) it bears a label plainly marked with the product's proper name, manufacturer, and expiration date.

The CGMP and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood