

Dated: August 14, 2000.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00132]

Cooperative Agreement to the Joint United Nations Programme on HIV/AIDS (UNAIDS); Notice of the Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC), National Center for HIV/STD/TB Prevention (NCHSTP), announces the availability of funds for fiscal year (FY) 2000 for a sole source cooperative agreement with the Joint United Nations Programme on HIV/AIDS (UNAIDS).

The purpose of this agreement is to help support and ensure implementation of the Leadership and Investment in Fighting an Epidemic (LIFE) Initiative, a United States Government program that seeks to reduce the impact of HIV/AIDS in sub-Saharan African countries and India by strengthening the capacity of national AIDS control programs in the areas of (1) HIV primary prevention, (2) HIV care, support, and treatment, and (3) capacity and infrastructure development. 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.

This agreement supports a framework of interventions, grounded in a series of goals and objectives consistent with those established for the international community by UNAIDS in support of the International Partnership Against AIDS in Africa (IPAA).

According to recent estimates from UNAIDS and the World Health Organization (WHO), 32.4 million adults and 1.2 million children will be living with HIV by the end of 1999. Of the total estimate, approximately 23.3 million (69% of the total world-wide)

adults and children are living with AIDS in sub-Saharan Africa alone. Of that total, approximately 3.8 million adults and children represent those newly infected with HIV in 1999. India carries the majority of the burden associated with an additional 1.3 million adults and children newly infected with HIV in 1999. As a key partner in the U.S. Government's LIFE Initiative, CDC, through its Global AIDS Activity (GAA), is working in a collaborative manner with national governments, USAID and other Federal agencies, and other international donor agency partners to develop programs of assistance to address the HIV/AIDS epidemic in LIFE Initiative countries.

B. Eligible Applicants

Assistance will be provided only to the Joint United Nations Programme on HIV/AIDS (UNAIDS) in support of the LIFE Initiative. No other applications will be solicited.

UNAIDS is the most appropriate and qualified agency to conduct the activities under this cooperative agreement because:

1. As the Joint Programme for the entirety of the United Nations' efforts in the HIV/AIDS arena, UNAIDS is uniquely positioned to assist national AIDS control programs and other public health partners in development of capacity for HIV prevention and care.

2. UNAIDS is spearheading the International Partnership Against HIV/AIDS (IPAA) in Africa, an international umbrella effort to increase support and visibility for a multi-lateral emergency response to the AIDS epidemic in Africa. The LIFE Initiative is a key supporter of the IPAA.

3. The UNAIDS Secretariat currently administers a "multi-bi" instrument, the Programme Acceleration Fund (PAF), a mechanism for allocating resources through multiple UN Executing Agencies for multiple purposes in multiple countries, including those designated under the LIFE Initiative (UN Executing Agencies in countries are primarily the Cosponsoring Agencies of UNAIDS; World Health Organization (WHO), United Nations Children's Fund (UNICEF), United Nations Fund for Population Activities (UNFPA), United Nations Development Programme (UNDP), United Nations Education, Scientific and Cultural Organization (UNESCO), United Nations Drug Control Programme (UNDCP), and the World Bank.

4. UNAIDS, has the primary responsibility to foster expanded national responses to the epidemic, to promote strong commitments by governments to an expanded response,

to strengthen and coordinate the United Nations' action of HIV/AIDS at the global and national levels, and to identify, develop and advocate international best practice.

C. Availability of Funds

Approximately \$2,000,000 dollars is available in FY 2000 to fund this project. It is anticipated that the award will begin on September 30, 2000, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds.

Use of Funds

General Use

Funds may be used for strengthening the technical capacity of national AIDS control programs, the purchase of drugs for primary prevention (e.g., Sexually Transmitted Diseases (STD) and Tuberculosis (TB) treatment, prevention of perinatal HIV transmission, and other opportunistic infections related to AIDS illness) and for equipment, supplies and reagents for rapid screening for HIV and STDs, and in support of the delivery of HIV prevention and care and treatment services.

General Non-Use

Funds received from this announcement will not be used for capital expenditures such as the purchase of off-road and multi-passenger vehicles, large volume (greater than 50) purchase of computers and data storage systems, space renovations and other significant improvements to physical environments where activities are carried out.

Specific Non-Use

Funds received from this announcement will not be used for the direct purchase of antiretroviral drugs for treatment of established HIV infection, occupational exposures, and non-occupational exposures and will not be used for the direct purchase of equipment and reagents to conduct hospital-based laboratory monitoring for patient care or confirmatory tests.

D. Submission and Deadline

Submit the original and two copies of PHS 5161 (OMB Number 0937-0189). Forms are in the application kit.

On or before September 15, 2000 submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional

Information" section of this announcement.

E. 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, then click on "Funding" then "Grants and Cooperative Agreements."

To receive additional written information and to request an application kit, call 1-888-GRANTS (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: Roslyn Curington, 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) 488-2767, E-mail: zlp8@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: August 14, 2000.

John L. Williams,

*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

[Program Announcement 00078]

National Conference of State Legislatures; Notice of Availability of Funds

A notice announcing the availability of Fiscal Year 2000 funds for a grant program with the National Conference of State Legislatures was published in the **Federal Register** on May 23, 2000 [Vol. 65 FR No. 100, pages 33327-33329] [FR Doc. 00-12882]. The notice is hereby rescinded in its entirety, due to the availability of new information. It appears that there may be other eligible applicants. Due to time constraints to award FY 2000 fund, funds will not be

awarded under Program 00078. We anticipate that a new Program Announcement may be published in the **Federal Register** in FY2001, if funds are available.

Dated: August 14, 2000.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1441]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection regarding the manufacturer of infant formula, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping.

DATES: Submit written comments on the collection of information by October 17, 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: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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 a proposed 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.

Infant Formula Requirements (OMB Control Number 0910-0256)—Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements