

While U.S.-based organizations are eligible to apply, we will give preference to existing national/Ethiopian organizations. It is possible for one organization to apply as lead grantee with a plan that includes partnering with other organizations, preferably local. Although matching funds are not required, preference will be given to organizations that can leverage additional funds to contribute to program goals.

Applications will be funded in order by score and rank determined by the review panel. HHS/CDC will provide justification for any decision to fund out of rank order.

### V.3. Anticipated Announcement and Award Dates

September 23, 2005.

## VI. Award Administration Information

### VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the HHS/CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and HHS/CDC. An authorized Grants Management Officer will sign the NoA, and mail it to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

### VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-8 Public Health System Reporting Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements

Applicants can find additional information on these requirements on the HHS/CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

You need to include an additional Certifications form from the PHS5161-1 application in the Grants.gov electronic submission only. Please refer to <http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf>. Once you

have filled out the form, attach it to the Grants.gov submission as Other Attachments Form.

### VI.3. Reporting Requirements

You must provide HHS/CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due 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. Budget.
- e. Measures of Effectiveness.
- f. Additional Requested Information.

2. Annual progress report, due 90 days after the end of the budget period.

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

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

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

## VII. Agency Contacts

We encourage inquiries concerning this announcement.

For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Tadesse Wuhib, MD, MPH, Country Director, CDC-Ethiopia, PO Box 1014, Entoto Road, Addis Ababa, Telephone: (Office) 251-1-66-95-33; (Cell) 251-9-228543, E-mail address: [wuhibt@etcdc.com](mailto:wuhibt@etcdc.com).

For financial, grants management, or budget assistance, contact: Shirley Wynn, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-1515, E-mail: [SWynn@cdc.gov](mailto:SWynn@cdc.gov).

## VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: [www.cdc.gov](http://www.cdc.gov). Click on "Funding", then "Grants and Cooperative Agreements."

Dated: August 17, 2005.

**William P. Nichols,**

Director, Procurement and Grants Office,  
Centers for Disease Control and Prevention.  
[FR Doc. 05-16832 Filed 8-23-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Implementation of Multi-Disciplinary HIV Care for Sexually Abused Children in Zambia, as Part of the President's Emergency Plan for AIDS Relief

*Announcement Type:* New.

*Funding Opportunity Number:* CDC-RFA-AA172.

*Catalog of Federal Domestic Assistance Number:* 93.067.

*Key Dates: Application Deadline:* September 19, 2005.

### I. Funding Opportunity Description

*Authority:* This program is authorized under Sections 301(a) and 307 of the Public Health Service Act [42 U.S.C. 241 and 242], as amended, and under Public Law 108-25 (United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [U.S.C. 7601].

*Background:* President Bush's Emergency Plan for AIDS Relief has called for immediate, comprehensive and evidence-based action to turn the tide of global HIV/AIDS. The initiative aims to treat more than two million HIV-infected people with effective combination anti-retroviral therapy by 2008; care for ten million HIV-infected and affected persons, including those orphaned by HIV/AIDS, by 2008; and prevent seven million infections by 2010, with focus on 15 priority countries, including 12 in sub-Saharan Africa. The five-year strategy for the Emergency Plan is available at the following Internet address: <http://www.state.gov/s/gac/rl/or/c11652.htm>.

Over the same time period, as part of a collective national response, the Emergency Plan goals specific to Zambia are to treat at least 120,000 HIV-infected individuals and care for 600,000 HIV-affected individuals, including orphans.

Under the leadership of the U.S. Global AIDS Coordinator, as part of the President's Emergency Plan, the U.S. Department of Health and Human Services (HHS) works with host countries and other key partners to assess the needs of each country and design a customized program of

assistance that fits within the host nation's strategic plan.

HHS focuses on two or three major program areas in each country. Goals and priorities include the following:

- Achieving primary prevention of HIV infection through activities such as expanding confidential counseling and testing programs, building programs to reduce mother-to-child transmission, and strengthening programs to reduce transmission via blood transfusion and medical injections.

- Improving the care and treatment of HIV/AIDS, sexually transmitted diseases (STDs) and related opportunistic infections by improving STD management; enhancing care and treatment of opportunistic infections, including tuberculosis (TB); and initiating programs to provide anti-retroviral therapy (ART).

- Strengthening the capacity of countries to collect and use surveillance data and manage national HIV/AIDS programs by expanding HIV/STD/TB surveillance programs and strengthening laboratory support for surveillance, diagnosis, treatment, disease-monitoring and HIV screening for blood safety.

To carry out its activities in these countries, HHS works in a collaborative manner with national governments and other agencies to develop programs of assistance to address the HIV/AIDS epidemic. In particular, HHS' mission in Zambia is to work with the Ministry of Health, and its partners, to develop and apply effective interventions to prevent and treat HIV infection and associated illness and death from AIDS.

*Purpose:* The Demographic and Health Survey (2001-2002) from Zambia indicates that in the age group 15 to 19 the HIV prevalence among women is 6.6 percent, compared to a prevalence of 1.9 percent in men of the same age. Reports from South Africa indicate that death rates among girls between 15 to 19 years have increased by over 50 percent in the last ten years. In the last few years, there has been a disturbing rise in the number of cases of child rape and sexual abuse reported in the media. In some sub-Saharan African countries, including Zambia, there are myths surrounding HIV, such as that sex with a virgin can cure a man of HIV. In addition, older men seek sex with very young partners in the belief the young are free from HIV. These practices expose young children to HIV infection, and have consequences on the child's physical, psychological and social development. The actual extent of this problem is often unclear, because the perpetrators are sometimes close family members.

The University Teaching Hospital (UTH) is the main referral hospital for pediatric care in Zambia. Cases of sexual abuse reported to the hospital are seen first at the Police Post based there. In 2003, a total of 659 cases of child sexual abuse were reported at the Police Post. Currently, 15 to 20 sexually abused children are seen in the clinic each week. However, many other cases might be missed because of a lack of awareness of attending clinicians of evidence of sexual abuse, or reluctance to discuss such issues with parents and guardians. This leads to lost opportunities to provide post-exposure prophylaxis and psychological support to the child, and increases the possibility of HIV infection.

The Zambian UTH Department of Pediatrics, the National AIDS Council Technical Group on Orphans and Vulnerable Children and the Zambian Society for the Prevention of Child Abuse and Neglect (ZSPCAN), in collaboration with international partners, has instituted various activities on child sexual abuse, and the purpose of the program is to strengthen the human capacity in Zambia to provide a child-friendly and parent sensitive environment in which to provide counseling and support; clinical care; and ongoing care including post-exposure prophylaxis and anti-retroviral treatment (ART), as required, to children who have suffered sexual abuse.

Measurable outcomes of the program will be in alignment with the numerical goals of the President's Emergency Plan for AIDS Relief and one (or more) of the following performance goal(s) for the National Center for HIV, Sexually Transmitted Diseases and Tuberculosis Prevention (NCHSTP) of the Centers for Disease Control and Prevention (CDC) within HHS: Increase the proportion of HIV-infected people who are linked to appropriate prevention, care and treatment services and to strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions and evaluate prevention programs.

This announcement is only for non-research activities supported by HHS, including CDC. If research is proposed, the application will not be reviewed. For the definition of "research," please see the HHS/CDC Web site at the following Internet address: <http://www.cdc.gov/od/ads/opspoll1.htm>.

*Activities:* The recipient of these funds is responsible for activities in multiple program areas designed to target underserved populations in Zambia. Either the awardee will implement activities directly or will

implement them through its subgrantees and/or subcontractors; the awardee will retain overall financial and programmatic management under the oversight of HHS/CDC and the strategic direction of the Office of the U.S. Global AIDS Coordinator. The awardee must show a measurable, progressive reinforcement of the capacity of indigenous organizations and local communities to respond to the national HIV epidemic, as well as, progress towards the sustainability of activities.

Applications should describe activities in detail as part of a four-year action plan (U.S. Government Fiscal Years 2005-2008 inclusive) that reflects the policies and goals outlined in the five-year strategy for the President's Emergency Plan.

The grantee will produce an annual operational plan in the context of this four-year plan, which the U.S. Government Emergency Plan team on the ground in Zambia will review as part of an annual Emergency Plan for AIDS Relief Country Operational Plan review and approval process managed by the Office of the U.S. Global AIDS Coordinator. The grantee may work on some of the activities listed below in the first year and in subsequent years, and then progressively add others from the list to achieve all of the Emergency Plan performance goals, as cited in the previous section. HHS/CDC, under the guidance of the U.S. Global AIDS Coordinator, will approve funds for activities on an annual basis, based on documented performance towards achieving Emergency Plan goals, as part of the annual Emergency Plan for AIDS Relief Country Operational Plan review and approval process.

Awardee activities for this program are as follows:

1. Train health workers in the Zambia UTH Departments of Pediatrics and Obstetrics and Gynecology to recognize and care for child sexual abuse.
  2. Train health care workers to provide post-exposure prophylaxis and ART, in general, for pediatric HIV care.
  3. Provide culturally and age-appropriate psycho-social support in local languages to sexually abused children and their families.
  4. Develop a system to record accurately cases of child sexual abuse, and to follow up such cases in the community.
  5. Strengthen links with the Zambian Society for Child Abuse and Neglect, and design activities to increase community awareness.
  6. Develop a multi-disciplinary team to provide pediatric HIV care.
- Administration: The winning applicant must comply with all HHS

management requirements for meeting participation and progress and financial reporting for this cooperative agreement (See HHS Activities and Reporting sections below for details), and comply with all policy directives established by the Office of the U.S. Global AIDS Coordinator.

In a cooperative agreement, HHS staff is substantially involved in the program activities, above and beyond routine grant monitoring.

HHS/CDC activities for this program are as follows:

1. Provide scientific and technical assistance in developing the awardee's operational plan.
2. Provide ongoing technical assistance in program implementation.
3. Assist the awardee in assessments of the program's operations to determine the overall effectiveness of the program, including developing a monitoring and evaluation tool for the activities in the program.
4. Design the program activities in conjunction with the UTH Department of Pediatrics and other partners.
5. Participate in training of health staff.
6. Provide technical assistance from HHS-headquarters and the in-country HHS office in Zambia to assure other related U.S. Government activities are well-coordinated with the national program.
7. Organize an orientation meeting with the grantee to brief it on applicable U.S. Government, HHS, and Emergency Plan expectations, regulations and key management requirements, as well as report formats and contents. The orientation could include meetings with staff from HHS agencies and the Office of the U.S. Global AIDS Coordinator.
8. Review and approve the process used by the grantee to select key personnel and/or post-award subcontractors and/or subgrantees to be involved in the activities performed under this agreement, as part of the Emergency Plan for AIDS Relief Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.
9. Review and approve grantee's annual work plan and detailed budget, as part of the Emergency Plan for AIDS Relief Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.
10. Review and approve grantee's monitoring and evaluation plan, including for compliance with the strategic information guidance established by the Office of the U.S. Global AIDS Coordinator.

11. Meet on a monthly basis with grantee to assess monthly expenditures in relation to approved work plan and modify plans as necessary.

12. Meet on a quarterly basis with grantee to assess quarterly technical and financial progress reports and modify plans as necessary.

13. Meet on an annual basis with grantee to review annual progress report for each U.S. Government Fiscal Year, and to review annual work plans and budgets for subsequent year, as part of the Emergency Plan for AIDS Relief review and approval process for Country Operational Plans, managed by the Office of the U.S. Global AIDS Coordinator.

14. Provide technical assistance, as mutually agreed upon, and revise annually during validation of the first and subsequent annual work plans. This could include expert technical assistance and targeted training activities in specialized areas, such as strategic information, project management, confidential counseling and testing, palliative care, treatment literacy, and adult learning techniques.

15. Provide in-country administrative support to help grantee meet U.S. Government financial and reporting requirements.

## II. Award Information

*Type of Award:* Cooperative Agreement.

HHS involvement in this program is listed in the Activities Section above.

*Fiscal Year Funds:* 2005.

*Approximate Total Funding:* \$225,000. (This amount is an estimate, and is subject to availability of funds.)

*Approximate Number of Awards:* One.

*Approximate Average Award:* \$75,000. (This amount is for the first 12-month budget period, and includes direct costs.)

*Floor of Award Range:* None.

*Ceiling of Award Range:* \$95,000. (This ceiling is for the first 12-month budget period.)

*Anticipated Award Date:* September 23, 2005.

*Budget Period Length:* 12 months.

*Project Period Length:* Three years.

Throughout the project period, HHS' commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government, through the annual Country Operational Plan review and approval process, managed by the Office of the U.S. Global AIDS Coordinator.

## III. Eligibility Information

### III.1. Eligible Applicants

We will provide assistance only to university teaching hospitals that are referral hospitals and provide a full range of care, including pediatric care, and have a mandate and specialty in caring for sexually abused children. Eligible applicants must already have established activities to monitor cases of child sexual abuse by working with the local police post, to which all such cases, are initially referred.

### III.2. Cost-Sharing or Matching Funds

Matching funds are not required for this program. Although matching funds are not required, preference will go to organizations that can leverage additional funds to contribute to program goals.

### III.3. Other

If you request a funding amount greater than the ceiling of the award range, we will consider your application non-responsive, and it will not enter into the review process. We will notify you that your application did not meet the submission requirements.

*Special Requirements:* If your application is incomplete or non-responsive to the special requirements listed in this section, it will not enter into the review process. We will notify you that your application did not meet the submission requirements.

- HHS/CDC will consider late applications non-responsive. See section "IV.3. Submission Dates and Times" for more information on deadlines.

- **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.

## IV. Application and Submission Information

### IV.1. Address to Request Application Package

To apply for this funding opportunity use application form PHS 5161-1.

HHS strongly encourages you to submit your application electronically by using the forms and instructions posted for this announcement on <http://www.grants.gov>.

Application forms and instructions are available on the HHS/CDC Web site, 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 HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at 770-488-2700. We can mail application forms to you.

#### IV.2. Content and Form of Submission

**Application:** You must submit a project narrative with your application forms. You must submit the narrative in the following format:

- Maximum number of pages: 25. If your narrative exceeds the page limit, we will only review the first pages within the page limit.
- Font size: 12 point un-reduced.
- Double spaced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

- Application must be written in English.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Justification for program.
- Eligibility and organizational capacity.
- Proposed program plan, including goals, objectives and plan of operation.
- Program Management, staffing, collaborations, and infrastructure.
- Evaluation plan.
- Budget and justification (will not be counted in the stated page limit).

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitae.
- Organizational Charts.
- Letters of support.
- Applicants must document eligibility by submitting verification of their Zambian registration status.
- Job descriptions of proposed key positions to be created for the activity.
- Quality-Assurance, Monitoring-and-Evaluation, and Strategic-Information Forms.
- Applicant's Corporate Capability Statement.
- Evidence of Legal Organizational Structure.

You must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS

number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711.

For more information, see the HHS/CDC Web site at: <http://www.cdc.gov/od/pgo/funding/grantmain.htm>. If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that could require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

#### IV.3. Submission Dates and Times

**Application Deadline Date:**

September 19, 2005.

**Explanation of Deadlines:**

Applications must be received in the HHS/CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date.

You may submit your application electronically at <http://www.grants.gov>. We consider applications completed on-line through Grants.gov as formally submitted when the applicant organization's Authorizing Official electronically submits the application to <http://www.grants.gov>. We will consider electronic applications as having met the deadline if the applicant organization's Authorizing Official has submitted the application electronically to Grants.gov on or before the deadline date and time.

If you submit your application electronically through Grants.gov, your application will be electronically time/date stamped, which will serve as receipt of submission. You will receive an e-mail notice of receipt when HHS/CDC receives the application.

If you submit your application by the United States Postal Service or commercial delivery service, you must ensure the carrier will be able to guarantee delivery by the closing date and time. If HHS/CDC receives your submission after the closing date because: (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, you will have the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, HHS/CDC will consider the submission as received by the deadline.

If you submit a hard copy application, HHS/CDC will not notify you upon receipt of your submission. If you have

a question about the receipt of your application, first contact your carrier. If you still have a question, contact the PGO-TIM staff at (770)488-2700. Before calling, please wait two to three days after the submission deadline. This will allow time for us to process and log submissions.

This announcement is the definitive guide on application content, submission address, and deadline. It supersedes information provided in the application instructions. If your submission does not meet the deadline above, it will not be eligible for review, and we will discard it. We will notify you that you did not meet the submission requirements.

#### IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

#### IV.5. Funding Restrictions

Restrictions, which you must take into account while writing your budget, are as follows:

- Funds may not be used for research.
- Reimbursement of pre-award costs is not allowed.
- Needle Exchange—No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
- Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services. Equipment may be purchased if deemed necessary to accomplish program objectives; however, prior approval by HHS/CDC officials must be requested in writing.
- All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, HHS/CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.
- 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 the American University, Beirut, and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the U.S. or to international organizations, regardless of their location.
- The applicant 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 services for which funds are required).

- You must obtain an annual audit of these HHS/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 standards(s) approved in writing by HHS/CDC.

- 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.

#### Prostitution and Related Activities

The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document ("recipient") cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any recipient must have a policy explicitly opposing prostitution and sex trafficking. The preceding sentence shall not apply to any "exempt organizations" (defined as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization and its six Regional Offices, the International AIDS Vaccine Initiative or any United Nations agency).

The following definition applies for purposes of this clause:

- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

All recipients must insert provisions implementing the applicable parts of this section, "Prostitution and Related Activities," in all subagreements under this award. These provisions must be express terms and conditions of the subagreement, must acknowledge that compliance with this section, "Prostitution and Related Activities," is a prerequisite to receipt and expenditure of U.S. government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that relate to the organization's compliance with this section, "Prostitution and Related Activities."

All prime recipients that receive U.S. Government funds ("prime recipients") in connection with this document must certify compliance prior to actual receipt of such funds in a written statement that makes reference to this document (e.g., "[Prime recipient's name] certifies compliance with the section, 'Prostitution and Related Activities.'" ) addressed to the agency's grants officer. Such certifications by prime recipients are prerequisites to the payment of any U.S. Government funds in connection with this document.

Recipients' compliance with this section, "Prostitution and Related Activities," is an express term and condition of receiving U.S. Government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event HHS determines the recipient has not complied with this section, "Prostitution and Related Activities."

You may find guidance for completing your budget on the HHS/CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

#### IV.6. Other Submission Requirements

**Application Submission Address:** HHS/CDC strongly encourages you to submit electronically at: <http://www.grants.gov>. You will be able to download a copy of the application package from <http://www.grants.gov>, complete it offline, and then upload and submit the application via the Grants.gov site. We will not accept e-mail submissions. If you are having technical difficulties in Grants.gov, you may reach them by e-mail at [support@grants.gov](mailto:support@grants.gov), or by phone at 1-800-518-4726 (1-800-518-GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. eastern time, Monday through Friday.

HHS/CDC recommends that you submit your application to Grants.gov early enough to resolve any unanticipated difficulties prior to the deadline. You may also submit a back-up paper submission of your application. We must receive any such paper submission in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement.

You must clearly mark the paper submission: "BACK-UP FOR ELECTRONIC SUBMISSION."

The paper submission must conform to all requirements for non-electronic submissions. If we receive both electronic and back-up paper submissions by the deadline, we will consider the electronic version the official submission.

We strongly recommended that you submit your grant application by using Microsoft Office products (e.g., Microsoft Word, Microsoft Excel, etc.). If you do not have access to Microsoft Office products, you may submit a PDF file. You may find directions for creating PDF files on the Grants.gov Web site. Use of files other than Microsoft Office or PDF could make your file unreadable for our staff.

or

Submit the original and two hard copies of your application by mail or express delivery service to the following address:

Technical Information Management—AA172, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341.

#### V. Application Review Information

##### V.1. Criteria

Applicants must 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 stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. Applicants must submit these measures of effectiveness with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. *Plan (30 Points)*. Does the applicant demonstrate an understanding of the national cultural and political context and the technical and programmatic areas covered by the project? Does the applicant display knowledge of the five-year strategy and goals of the President's Emergency Plan, such that it can build on these to develop a comprehensive, collaborative project to reach underserved populations in Zambia and meet the goals of the Emergency Plan? Is the plan adequate to carry out the proposed objectives? How complete and comprehensive is the plan for the entire project period? Does the plan include a quantitative process to measure outcomes?

2. *Personnel (20 Points)*. Do the staff members have appropriate experience? Are the staff roles clearly defined? As described, will the staff be sufficient to meet the goals of the Emergency Plan?

3. *Need (20 Points)*. To what extent does the applicant justify the need for this program within the target community?

4. *Methods (15 Points)*. Does the application include an overall design strategy, including measurable time lines, clear monitoring and evaluation procedures, and specific activities for meeting the proposed objectives? Does the applicant describe a plan to build progressively the capacity of local organizations and of target beneficiaries and communities to respond to the epidemic?

5. *Ability to carry out the project (15 Points)*. Does the applicant provide a clear plan for the administration and management of the proposed activities, to manage the resources of the program, prepare reports, monitor and evaluate activities and audit expenditures?

6. *Budget and Justification* (Reviewed, but not scored).

#### V.2. Review and Selection Process

The HHS/CDC Procurement and Grants Office (PGO) staff will review applications for completeness, and HHS Global AIDS program will review them for responsiveness. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will receive

notification that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above. All persons who serve on the panel will be external to the U.S. Government Country Program Office. The panel may include both Federal and non-Federal participants.

In addition, the following factors could affect the funding decision:

Applications will be funded in order by score and rank determined by the review panel. HHS/CDC will provide justification for any decision to fund out of rank order.

#### V.3. Anticipated Announcement and Award Dates

September 23, 2005.

### VI. Award Administration Information

#### VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the HHS/CDC Procurement and Grants Office. The NoA shall be the only binding, authorizing document between the recipient and HHS/CDC. An authorized Grants Management Officer will sign the NoA, and mail it to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

#### VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-4 HIV/AIDS Confidentiality Provisions
- AR-6 Patient Care Requirements
- AR-10 Smoke-Free Workplace Requirements

Applicants can find additional information on these requirements on the HHS/CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

An additional Certifications form from the PHS5161-1 application needs to be included in the Grants.gov electronic submission only. Please refer to <http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf>. Once you have filled out the form, please attach it to the Grants.gov submission as Other Attachments Form.

#### VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due 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. Budget.

e. Measures of Effectiveness, including progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Zambia.

f. 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, due no later than 90 days after the end of the project period.

4. Annual progress report, due no later than 90 days after the end of the budget period. Reports should include progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Zambia.

Recipients must mail these reports to the Grants Management or Contract Specialist listed in the "Agency Contacts" section of this announcement.

### VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact:

Technical Information Management Section, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact:

Marc Bulterys, Project Officer, 1600 Clifton Road MS E-04, Atlanta, GA 30333, Telephone: 011 260 1 250 955 ext 246, E-mail: [bulterysm@cdc.gov](mailto:bulterysm@cdc.gov).

For financial, grants management, or budget assistance, contact:

Shirley Wynn, Grants Management Specialist, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770/488-1515, E-mail: [zbx6@cdc.gov](mailto:zbx6@cdc.gov).

### VIII. Other Information

Applicants can find this and other HHS funding opportunity

announcements on the HHS/CDC Web site, Internet address: <http://www.cdc.gov> (Click on "Funding" then "Grants and Cooperative Agreements"), and on the Web site of the HHS Office of Global Health Affairs, Internet address: <http://www.globalhealth.gov>.

Dated: August 17, 2005.

**William P. Nichols,**

Director, Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004N-0442]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations (Guidelines)**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by September 23, 2005.

**ADDRESSES:** The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Food and Drug Administration Recall Regulations (Guidelines)—(OMB Control Number 0910-0249)—Extension**

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7 (21 CFR part 7), subpart C sets forth the recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA-regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall; providing FDA with complete details of the recall including

reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official; notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm; submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things evaluation return reply cards, effectiveness checks and product returns; and providing the opportunity for a firm to request in writing that FDA terminate the recall.

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2003. The resulting number of recalls from this database search (2,375) is used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the above information to 201,875 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary reporting requirements of FDA's recall regulations.

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates on average the burden of collection for recall information to be as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Recall Strategy	2,375	1	2,375	15	35,625
Firm Initiated Recall & Public Warnings Recall Communications	2,375	1	2,375	20	47,500
Recall Status Reports & Followup	2,375	4	9,500	10	95,000
Termination of a Recall	2,375	1	2,375	10	23,750
<b>Total</b>					<b>201,875</b>

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual reporting burdens are explained as follows:

*Recall Strategy*

Requests firms to develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of

information, the agency estimates it will receive 2,375 responses annually.

*Firm Initiated Recall and Recall Communications*

Requests firms that voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical

devices, and biologicals to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk, evaluation, quantity produced, distribution information, firm's recall strategy, and a contact official as well as requires firms to