

holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 30, 2005.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Bank of America Corporation*, Charlotte, North Carolina; to acquire 100 percent of the voting shares of MBNA Corporation, Wilmington, Delaware, and thereby indirectly acquire MBNA America Bank, National Association, Wilmington, Delaware, and MBNA America (Delaware), N.A., Wilmington, Delaware. In connection with the proposal Bank of America Corporation has applied to acquire 19.9 percent of the voting shares of MBNA Corporation, Wilmington, Delaware, in certain circumstances.

B. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Young Partners, L.P. and Young Corporation*, and Citizens Bancshares Company, all of Chillicothe, Missouri, to directly and indirectly acquire shares of Clayco Banc Corporation, Claycomo, Missouri and thereby indirectly acquire share of CSB Bank, Claycomo, Missouri.

Board of Governors of the Federal Reserve System, July 28, 2005.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 05-15269 Filed 8-2-05; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Sunshine Meeting Notice

TIME AND DATE: 12 p.m., Monday, August 8, 2005.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

FOR FURTHER INFORMATION CONTACT:

Michelle A. Smith, Director, Office of Board Members; 202-452-2955.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: July 29, 2005.

Robert dev. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05-15378 Filed 7-29-05; 4:47 pm]

BILLING CODE 6210-01-P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Notice

TIME AND DATE: 9 a.m. (EDT), August 15, 2005.

PLACE: 4th Floor Conference Room, 1250 H Street, NW., Washington, DC.

STATUS: Open (Telephonic).

MATTERS TO BE CONSIDERED:

1. Approval of the minutes of the July 18, 2005, Board member meeting.

2. Thrift Savings Plan activity report by the Executive Director.

CONTACT PERSON FOR MORE INFORMATION: Thomas J. Trabucco, Director, Office of External Affairs, (202) 942-1640.

Dated: August 1, 2005.

Elizabeth S. Woodruff,

Secretary to the Board, Federal Retirement Thrift Investment Board.

[FR Doc. 05-15475 Filed 8-1-05; 4:12 pm]

BILLING CODE 6760-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

President's Malaria Initiative

Announcement Type: New.

Funding Opportunity Number: AA197.

Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates: Application Deadline: September 2, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under sections 307 and 317(k)(2) of the

Public Health Service Act, [42 U.S.C. sections 242l and 247b(k)(2)], as amended.

Purpose: The purpose of the program is to support malaria prevention and control and relevant ancillary activities (e.g., baseline evaluation, strategy development, training, monitoring and program evaluation) in the countries included in President Bush's initiative to fight malaria in Africa.

On June 30, 2005, the President pledged to increase U.S. Government funding of malaria prevention and treatment by more than \$1 billion over five years. The President made this commitment through the G-8 process as the U.S. contribution to a larger international effort needed to reduce malaria deaths, and called on other donors, foundations, private, public, and voluntary organizations to match U.S. commitments by providing \$1.2 billion annually in additional funding by 2008.

The President's commitment will more than triple the current U.S. funding of malaria prevention and treatment programs in Africa, and is in addition to the \$200 million each year the United States spends today on malaria prevention, treatment, and research. It will increase U.S. funding for malaria to more than \$500 million annually. The current U.S. Government malaria budget for Fiscal Year (FY) 2005 is \$213.6 million, and of that amount the operating budget of the U.S. Department of Health and Human Services (HHS) provides \$102.4 million, or nearly half of that amount. The U.S. Government is also currently supporting malaria control and prevention through the Global Fund to Fight AIDS, Tuberculosis and Malaria, which has so far been the largest vehicle for U.S. Government assistance to anti-malaria activities; the Global Fund has invested over \$1 billion in malaria and prevention control activities over two years, roughly one-third underwritten by the U.S. contribution to the Global Fund. These additional resources will complement those of the Global Fund and the World Bank's malaria program.

The President will launch the initiative first in three countries: Angola, Tanzania and Uganda. (Uganda and Tanzania are also countries under the President's Emergency Plan for AIDS Relief), and will add public-private partnerships in Equatorial Guinea and Zambia in FY 2006. Over the next several years, the initiative could expand, with other partner involvement, to a maximum of 25

countries. An inter-agency group selected the first countries according to an agreed set of criteria, including significant burden of malaria; national policies and practices for malaria control consistent with international guidelines; country capacity to achieve large-scale impact; other donor involvement; U.S. Government on-ground presence; performance in other malaria programs, including the Global Fund; and demonstrated political will by national government leadership to mount a comprehensive effort to control malaria.

The goal of the President's initiative is to accomplish the following after three years of full implementation:

- Reduce malaria deaths in each of the target countries by 50 percent;
- Achieve 85 percent coverage of proven malaria prevention, control and treatment interventions among high-risk groups, particularly children and pregnant women;
- Procure directly drugs and other commodities and provide training and technical assistance needed to achieve these objectives.

Specific interventions will include the following:

- Expanding access to long-lasting insecticide treated bed nets and indoor household residual spraying with approved insecticides to greatly reduce the transmission of malaria.
- Providing effective treatment of malaria through the prompt use of new artemisinin combination therapies, now internationally accepted as the treatment of choice against malaria. Provision of these drugs will be available through public- and private-sector outlets in target countries and supported by information and education campaigns to improve access and delivery of care.
- Providing effective, internationally agreed priority interventions for addressing malaria in pregnancy, such as preventive treatment of pregnant women; more than 30 million African women who live in malaria-endemic areas become pregnant each year and are at risk for malaria infection, which contributes to low birth weight and deaths among infants.

Please see <http://www.whitehouse.gov/news/releases/2005/06/20050630-8.html> for more information on the President's announcement. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

Measurable outcomes of the program will be in alignment with the numerical goals of the President's Malaria Initiative and the following performance goal for the National Center for

Infectious Diseases (NCID) within the Centers for Disease Control (CDC) and Prevention of the U.S. Department of Health and Human Services (HHS): Protect Americans from infectious diseases.

This announcement is only for non-research activities supported by HHS/CDC as part of the President's malaria initiative. If an applicant proposes research, HHS/CDC will not review the application. 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: Awardee activities for this program are as follows:

- The applicants and their partner(s) in the malaria-endemic countries must:
 - Enhance local capacity for implementing methods that will reduce malaria transmission and the morbidity and mortality from malaria infection in Angola, Equatorial Guinea, Tanzania, Uganda, or Zambia. Applicants, in collaboration with the national governments and non-governmental partners, including faith-based organizations, must base their activities on the assessments made U.S. Government interagency teams in each of the targeted countries of the President's Malaria Initiative (if available prior to the application due date), and plan to implement, in collaboration with a partner organization in the host country, the priority malaria prevention activities identified through the U.S. Government analysis.
 - Priority program areas are listed below, and are examples of activities that would be appropriate to propose under this announcement. The applicant should not duplicate existing efforts. Based on their competitive advantage and proven field experience, applicants may propose to undertake activities in one or more of the priority program areas in a defined population area that will contribute to the accomplishment of the numerical Emergency Plan targets outlined above. For each of these activities, the grantee will give priority to evidence-based, yet culturally adapted, innovative approaches. Details and example activities for each appear in the attachments, as posted with this announcement on the HHS/CDC *Grants and Cooperative Agreements Web site page*:
 - Public health capacity-building for governments or institutions so as to contribute to malaria prevention and control. (Attachment 1, as posted with

this announcement on the HHS/CDC *Grants and Cooperative Agreements Web site page*).

- Increasing the public's access to effective antimalarial drugs and appropriate management of malaria illness to reduce malaria-associated mortality or the severity and duration of malaria illness. (Attachment 2, as posted with this announcement on the HHS/CDC *Grants and Cooperative Agreements Web site page*).
- Reducing exposure to malaria, particularly among young children and pregnant women, through the use of proven malaria-control interventions, which should include the provision of long-lasting insecticide-treated nets and indoor household residual insecticide spraying. (Attachment 3, as posted with this announcement on the HHS/CDC *Grants and Cooperative Agreements Web site page*).
- Preventing malaria and its adverse consequences during pregnancy. (Attachment 4, as posted with this announcement on the HHS/CDC *Grants and Cooperative Agreements Web site page*).
- Linking activities described here with related HIV care and other social services, and promoting coordination at all levels, including through bodies such as village, district, regional and national malaria coordination committees and networks of faith-based organizations.
- Program evaluation, particularly assessment of progress against the numerical goals of the President's Malaria Initiative. (Attachments 5 and 6, as posted with this announcement on the HHS/CDC *Grants and Cooperative Agreements Web site page*).
- Attend and participate in an annual meeting of grantee representatives and the in-country management of the President's Malaria Initiative to present, discuss, and evaluate program activities.

Administration

The winning applicants 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.) The winning applicants must also comply with all policy directives established by the interagency Malaria Coordinator, housed at the U.S. Agency for International Development.

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

HHS Activities for this program are as follows:

- Organize an orientation meeting with the grantees to brief them on applicable expectations, regulations and key management requirements for the U.S. Government, HHS, and the President's Malaria Initiative, as well as report formats and contents. The orientation could include meetings with staff from HHS agencies and the staff of the interagency Malaria Coordinator.

- Review and approve the process used by the grantees 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 annual review and approval of country plans for the President's Malaria Initiative, managed by the interagency Malaria Coordinator.

- Provide consultation and assistance with training curricula and materials, as necessary and appropriate for in-country training programs.

- Provide consultation and assistance on methods for treatment of malaria, enhancing local capacity to increase use of insecticide-treated bed nets and indoor household residual insecticide spraying, and/or prevention of malaria and its adverse consequences during pregnancy.

- Provide consultation on program evaluation design.

- Review and approve grantees' annual work plan and detailed budget, as part of the annual review and approval of country plans for the President's Malaria Initiative, managed by the interagency Malaria Coordinator.

- Review and approve grantees' monitoring and evaluation plans, including for compliance with the strategic information guidance established by the interagency Malaria Coordinator.

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

- Participate in an annual meeting of grantee representatives to present, discuss, and evaluate program activities.

II. Award Information

Type of Award: Cooperative Agreement.

HHS involvement in this program appears in the Activities Section above.

Fiscal Year Funds: 2005.

Approximate Current Fiscal Year Funding: \$600,000.

Approximate Total Project Period Funding: \$1,800,000 (This amount is an estimate, and is subject to availability of funds. This includes direct or indirect costs.).

Approximate Number of Awards: Four.

Approximate Average Award: \$150,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Individual Award Range: None.

Ceiling of Individual Award Range: \$250,000 (This ceiling is for the first 12-month budget period. This is for total costs, which would include indirect costs.)

Anticipated Award Date: September 15, 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 annual review and approval of country plans for the President's Malaria Initiative, managed by the interagency Malaria Coordinator.

III. Eligibility Information

III.1. Eligible applicants

Eligible applicants that can apply for this funding opportunity are listed below:

- Public, non-profit organizations
- Private, non-profit organizations
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- Indian tribal organizations
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

A Bona Fide Agent is an agency/organization identified by a State as eligible to submit an application under the State eligibility in lieu of a State application. If applying as a bona fide agent of a State or local government, an applicant must provide a letter of endorsement from the State or local government concerned as

documentation of its status as bona fide agent. Please place this documentation behind the first page of the application form.

While both U.S.-based and organizations indigenous to Angola, Equatorial Guinea, Tanzania, Uganda, or Zambia are eligible to apply, we will give preference to well-established organizations indigenous to those countries mentioned above, legally incorporated in those countries, that have well-developed management and financial control systems and established malaria activities that reach to rural areas of those countries.

Preference will also go to applicants with demonstrated experience in working with their identified indigenous country partner(s) on malaria prevention and control activities.

III.2. Cost-Sharing or Matching

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 achieving the numerical goals of the President's Malaria Initiative.

III.3. Other

If applicants request funding greater than the ceiling of the award range, HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

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

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

- This program is not designed or intended to support research, therefore this cooperative agreement will not support any research.

- **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 that constitute an award, grant, or loan.

- Applicants must show an established relationship with indigenous partner organization(s) in the country/countries they propose for their project by submitting a letter, on the partner's (or partners') letterhead, of

support that shows an established relationship with indigenous partner organization(s) in the country/countries the applicant proposes for the project.

IV. Application and Submission Information

IV.1. Address To Request Application Package

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

Electronic Submission: HHS/CDC strongly encourages applicants to submit the application electronically by using the forms and instructions posted for this announcement on <http://www.Grants.gov>, the official Federal agency-wide E-grant Web site. Only applicants who apply on-line are permitted to forego paper copy submission of all application forms.

Paper Submission: 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 access to the Internet is not available, or if there is difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at 770-488-2700, and we can mail the application forms to you.

IV.2. Content and Form of Submission

Application: Applicants must submit a project narrative the application forms, in the following format:

- Maximum number of pages: 25. If your narrative exceeds the page limit, we will only review the pages that are within the page limit.
- Font size: 12-point, unrounded
- Single-spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- All pages of the application numbered sequentially from page 1 (Application Face Page) to the end of the application, including charts, figures, tables, and appendices.
- Printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way

The narrative should address activities the applicant proposes to conduct over the entire project period, and must include the following items in the order listed:

- Background and Need
- Objectives
- Plan
- Methods
- Performance Methods
- Timeline
- Staff

- Budget Justification (the budget justification will be counted in the stated page limit)
- Evidence that the applicant has notified the appropriate agency in the government of the partner country/countries of the application
- Applicants must show an established relationship with partner organization(s) in the country they propose for their project. Applicants must include after the face page of the application a letter with the indigenous partner's (partners') letterhead that provides a brief description of the past and anticipated collaboration between the applicant and the partner organization(s) in the host country/countries must be included. Applicants must also include evidence (e.g. a letter) that they have notified the appropriate agency or Ministry of Health (MOH) in the partner country/countries of their intention to apply.

Applicants may include additional information included in the application appendices. The appendices will not count toward the narrative page limit. This additional information includes the following:

- *Curricula Vitae*
- Résumés
- Organizational Charts
- Letters of Support
- Country Malaria Plan

The agency or organization is required to 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 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 the application form does not have a DUNS number field, please write the DUNS number at the top of the first page of the application, and/or include the DUNS number in the application cover letter.

Additional requirements that might require submittal of additional documentation with the application are found in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

Application Deadline Date:
September 2, 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.

Applicants may submit applications electronically at www.grants.gov. Applications completed on-line through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to <http://www.grants.gov>. HHS/CDC 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 applicants submit material electronically through Grants.gov (<http://www.grants.gov>), the application will be electronically time/date stamped, which will serve as receipt of submission. Applicants will receive an e-mail notice of receipt when HHS/CDC receives the application.

If applicants submit material by the United States Postal Service or commercial delivery service, the applicant must ensure the carrier will be able to guarantee delivery of the application by the closing date and time. If HHS/CDC receives the application after closing date because of one of the following: (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, the applicant 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 having been received by the deadline.

If applicants submit material in hard copy, HHS/CDC will not notify the applicant upon receipt of the submission. If questions arise on the receipt of the application, the applicant should first contact the carrier. Applicants with further questions should please contact the PGO-TIM staff at (770) 488-2700. The applicant should wait two to three days after the submission deadline before calling. This will allow time for HHS/CDC 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 the submission does not meet the deadline above, it will not be eligible for review, and we will discard it. We will notify the applicant if the application did not meet the submission requirements.

IV.4. Intergovernmental Review of Applications

The application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed Federal assistance applications. Contact the state single point-of-contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on the state's process. Visit the following Web address to get the current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

IV.5. Funding Restrictions

Restrictions, which applicants must take into account while writing their budgets, are as follows:

- Funds may not support research.
- Reimbursement of pre-award costs is not allowed.
- Grantees may expend funds for reasonable program purposes, including personnel, travel, supplies, and services. Grantees may purchase equipment if deemed necessary to accomplish program objectives; however, grantees must make any purchases through a transparent and competitive process, after having requested and received prior approval by HHS/CDC officials in writing.
- 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, the Gorgas Memorial Institute, 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 United States 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.)
- Applicants shall state all requests for funds contained in the budget in U.S. dollars. After making an award, HHS/CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.
- You must obtain 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 standard(s) approved in writing by HHS/CDC.

- HHS/CDC can require a fiscal Recipient Capability Assessment, prior to or post award, to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the indirect cost rate is a provisional rate, the agreement should be less than 12 months old.

Applicants can find guidance for completing the 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:
Electronic Submission: HHS/CDC strongly encourages applicants to submit applications electronically at <http://www.Grants.gov>. Applicants can download the application package from <http://www.Grants.gov>. Applicants are able to complete it off-line, and then upload and submit the application via the Grants.gov Web site. We will not accept e-mail submissions. Applicants that have technical difficulties in Grants.gov can reach customer service by E-mail at <http://www.grants.gov/CustomerSupport> 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 submittal of the application to Grants.gov should be early to resolve any unanticipated difficulties prior to the deadline. Applicants may also submit a back-up paper submission of the 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. Applicants must clearly mark the paper submission: "BACK-UP FOR ELECTRONIC SUBMISSION." The paper submission must conform to all requirements for non-electronic submissions. If HHS/CDC receives both electronic and back-up paper submissions by the deadline, we will consider the electronic version the official submission.

We strongly recommend applicants submit the grant application by using Microsoft Office products (e.g., Microsoft Word, Microsoft Excel, etc.). If applicants do not have access to

Microsoft Office products, they may submit a PDF file. Applicants can find directions for creating PDF files on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may make the file unreadable for our staff.

OR

Paper Submission: Applicants should submit the original and two hard copies of the application by mail or express delivery service to: Technical Information Management-RFA#AA197, 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 they will be an element of evaluation. HHS/CDC will evaluate the application against the following criteria:

1. Plan of Operation (45 Points)

- a. Do the key personnel have the ability and program skills to develop and carry out the proposed activities, including by undertaking those activities in the appropriate local languages?
- b. Is there good evidence to show the applicant and malaria-endemic partner(s) have conducted a collaborative review of the priority needs for malaria in the malaria-endemic country/countries?
- c. Do the proposed objectives match the priority issues and interventions of the President's Malaria Initiative?
- d. Are the proposed methods reasonable? Will they accomplish the program goals? Is the proposed plan reasonable? Does it address major project components in both the applicant and malaria-endemic country/countries (i.e., leadership, staffing, administrative coordination, planning, and measurement activities)? Does the timetable incorporate the major numerical milestones of the President's Malaria Initiative and have a coherent plan to meet those targets?
- e. Is the plan consistent with malaria prevention best practices and the

announced priorities of the President's Malaria Initiative?

f. If the applicant proposes capacity-building for public health activities in malaria, do the planned activities relate to capacity improvements that will help achieve the numerical goals of the President's Malaria Initiative in the partner country/countries?

2. Collaborative Arrangement(s) (25 Points)

a. Does the collaboration between the applicant and partner organization(s) in the partner country/countries reflect an effective working relationship? Will the collaboration enable implementation of the proposed activities and serve to achieve the numerical goals of the President's Malaria Initiative?

b. Does the collaboration include the organization(s) responsible for policy and implementation of malaria prevention and control in the target area (e.g., Ministry of Health and/or district office)?

c. Are there formal letters of support from appropriate groups (universities, non-governmental organizations, etc.) within the malaria-endemic country that demonstrate the appropriate and necessary cooperation to support malaria prevention and control programs?

3. Background and Need (15 Points)

a. Does the proposal define and provide evidence that malaria in the partner malaria-endemic country/countries is well-established as an important cause of morbidity and mortality across the country/countries?

b. Is it clear what the existing malaria control program is and what its prevention and control strategies are?

c. Does the application clearly describe the existing surveillance, monitoring and evaluation methods and capability?

d. Does the application clearly describe the gaps and priorities in malaria prevention and control implementation?

4. Evaluation Plan (15 Points)

a. Does the application include a reasonable detailed plan for monitoring the implementation of the activities and evaluating the extent to which the proposed activities strengthen local and national capacity for malaria prevention and control?

b. Does the monitoring and evaluation plan build on existing monitoring and evaluation systems in the project area? Will it be able to demonstrate progress towards the objectives and numerical targets of the President's Malaria Initiative?

5. Budget (Not Scored)

Is the budget detailed, clear, justified, and does it describe in-kind or other project support? Is it consistent with the proposed program activities and the President's Malaria Initiative?

V.2. Review and Selection Process

The Procurement and Grants Office (PGO) will review applications for completeness, staff, and HHS/CDC/NCID will review them for responsiveness. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. We will notify applicants 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. The objective review panel will be composed of HHS/CDC employees outside of the funding division.

HHS/CDC will provide justification for any decision to fund out of rank order.

V.3. Anticipated Announcement and Award Dates

Anticipated Award Date: September 15, 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. 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 by mail of the results of the application review.

VI.2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 and Part 92 as appropriate. The following additional requirements apply to this project:

- AR-7 Executive Order 12372
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-14 Accounting System Requirements
- AR-15 Proof of Non-Profit Status
- AR-23 States and Faith-Based Organizations

Applicants may 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>.

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>.

Applicants must include an additional Certifications form from the PHS5161-1 application in the Grants.gov electronic submission only. Applicants should refer to <http://www.cdc.gov/od/pgo/funding/PHS5161-1-Certificates.pdf>. Once applicants have filled out the form, they should attach it to the Grants.gov submission as Other Attachments Form.

VI.3. Reporting Requirements

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

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as the application for continuation, 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 specific numerical targets of the President's Malaria Initiative.
- f. Additional Requested Information.

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

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

The grantee must mail these reports to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

HHS encourages inquiries concerning this announcement.

For general questions, please contact the following office: 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, please contact the following: Christi Murray, Project Officer, National Center

for Infectious Diseases, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 4770 Buford Highway, Mailstop F-22, Atlanta, GA 300341. Telephone: 770-488-3601. E-mail: cxm6@cdc.gov.

For financial, grants management, or budget assistance, please contact the following: Jeff Napier, Grants Management Specialist, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2614. E-mail: jln1@cdc.gov.

VIII. Other Information

Other HHS funding opportunity announcements can be found on the HHS/CDC web site, Internet address: <http://www.cdc.gov> (Click on "Funding," then "Grants and Cooperative Agreements"), and on the HHS Office of Global Health Affairs Web site, Internet address: <http://www.globalhealth.gov> (Click on "What's new," then "Funding Opportunities.").

Dated: July 28, 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. 2005N-0290]

Agency Information Collection Activities; Proposed Collection; Comment Request; Importer's Entry Notice

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

information collection provisions for the Importer's Entry Notice.

DATES: Submit written or electronic comments on the collection of information by October 3, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, 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 Robbins, Office of Management Programs (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 an existing collection, 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 these topics: (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.

Importer's Entry Notice (OMB Control Number 0910-0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) charges FDA with the following responsibilities: (1) Ensuring that foreign-origin FDA-regulated foods, drugs, cosmetics, medical devices, and radiological health products offered for import into the United States meet the same requirements of the act as do domestic products; and (2) preventing shipments from entering the country if they are not in compliance.

The information collected by FDA consists of the following: (1) Product code, an alpha-numeric series of characters that identifies each product FDA regulates; (2) FDA country of origin, the country where the FDA-registered or FDA-responsible firm is located; (3) FDA manufacturer, the party who manufactured, grew, assembled, or otherwise processed the goods (if more than one, the last party who substantially transformed the product); (4) shipper, the party responsible for packing, consolidating, or arranging the shipment of goods to their final destinations; (5) quantity and value of the shipment; and (6) if appropriate, affirmation of compliance, a code that conveys specific FDA information, such as registration number, foreign government certification, etc. This information is collected electronically by the entry filer via the U.S. Customs Service's Automated Commercial System at the same time he/she files an entry for import with the U.S. Customs Service. FDA uses this information to make admissibility decisions about FDA-regulated products offered for import into the United States.

The annual reporting burden is derived from the basic processes and procedures used in fiscal year (FY) 1995. The total number of entries submitted to the automated system in FY 2004 was 6,626,827. The total number of entries less the disclaimer entries will represent the total FDA products entered into the automated system. A total of 53 percent of all entries entered into the automated system were entries dealing with FDA-regulated products. The number of respondents is a count of filers who submit entry data for foreign-origin FDA-regulated products. The estimated reporting burden is based on information obtained by FDA contacting some potential respondents. Disclaimer entries are not FDA commodities.

FDA estimates the burden for this collection of information as follows: