

- AR-12 Lobbying Restrictions
 - AR-14 Accounting System Requirements
 - AR-15 Proof of Non-Profit Status
- Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

An additional Certifications form from the PHS 5161-1 application needs to be included in your Grants.gov electronic submission only. Refer to <http://www.cdc.gov/od/pgo/funding/PHS5161-1Certificates.pdf>. Once the form is filled out, attach it to your Grants.gov submission as Other Attachment Forms.

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.
 - 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 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, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2700.

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

For financial, grants management, or budget assistance, contact: Shirley Wynn, Contract Specialist, CDC

Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-1515. E-mail: SWynn@cdc.gov.

VIII. Other Information

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

Dated: April 26, 2005.

William P. Nichols,

Director, Procurement and Grants Office,
Centers for Disease Control and Prevention.
[FR Doc. 05-8760 Filed 5-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Application (RFA) 05076]

National Training and Mentoring Program To Strengthen Voluntary Counseling and Testing (VCT) Programs in Malawi; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2005 funds for a cooperative agreement program to strengthen voluntary counseling and testing (VCT) services in Malawi by providing financial and technical assistance for the development and implementation of a national VCT training and post-training mentoring program in Malawi. The Catalog of Federal Domestic Assistance number for this program is 93.067.

B. Eligible Applicant

This program has only one eligible applicant, Malawi AIDS Counseling Resource Organization (MACRO) in Lilongwe, Malawi. No other applications will be considered. MACRO is a non-profit, non-governmental organization (NGO), which has been providing VCT services in all three major regions of Malawi for more than five years. No other NGO has services reaching all the major regions of the country. The annual patient volume for MACRO services ranges from 45,000 to 50,000, which is well beyond any other service provider, including the Ministry of Health (MOH). This NGO also is the only organization in Malawi, which has VCT sites that are physically large enough to

accommodate the practical sessions for 20 course participants in all three regions of the country.

MACRO has five experienced counselors that have already attended training of trainers (TOT) courses for CT. This is more than any other VCT service provider in Malawi. The recipient of this cooperative agreement as a training organization will also be expected to serve as a model provider of VCT services. MACRO's VCT sites have been visited and certified by the MOH, and MACRO has in place a program to ensure quality of VCT services at its sites. MACRO is currently called upon to provide CT training for MOH counselors and other organizations in Malawi. The organization is currently serving as the largest de facto provider of CT training in Malawi. Unfortunately, these training requests divert experienced counselors from their normal duties as service delivery providers. This cooperative agreement will assist MACRO in establishing and maintaining the capacity to carry out a formal, well-organized national training and mentoring program without diverting its service delivery resources. It will also support the national expansion of VCT services at a critical time in the scale-up of anti-retroviral (ART) in Malawi.

C. Funding

Approximately \$175,000 is available in FY 2005 to fund this award. It is expected that the award will begin on or before July 1, 2005, and will be made for a 12-month budget period within a project period of up to 3 years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone: 770-488-2700.

For program technical assistance, contact: Margaret Davis, MD, MPH, Project Officer, Kang'ombe Building 8 West, City Centre, Lilongwe 3, Malawi, Telephone: 265-1-775-188, E-mail: MDavis@cdcmw.org.

For financial, grants management, or budget assistance, contact: Shirley Wynn, Contract Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-1515, E-mail: zbx6@cdc.gov.

Dated: April 26, 2005.

William P. Nichols,

*Acting Director, Procurement and Grants
Office, Centers for Disease Control and
Prevention.*

[FR Doc. 05-8747 Filed 5-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0436]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Medical Device Registration and Listing

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Medical Device Registration and Listing" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of January 13, 2005 (70 FR 2413), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0387. The approval expires on April 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-8735 Filed 5-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0437]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Third-Party Review Under the Food and Drug Administration Modernization Act, Third-Party Premarket Submission Review, and Quality System Inspections Under the United States/European Community Mutual Recognition Agreement

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Third Party Review Under the Food and Drug Administration Modernization Act, Third-Party Premarket Submission Review, and Quality System Inspections Under the United States/European Community Mutual Recognition Agreement" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of January 5, 2005 (70 FR 821), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0378. The approval expires on April 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-8736 Filed 5-2-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0157]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Drug Experience Reporting

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 postmarketing adverse drug experience reporting and recordkeeping requirements.

DATES: Submit written or electronic comments on the collection of information by July 5, 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirement 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