30341. Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to 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. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Understanding the issues, principles and systems requirements involved in delivering community and home-based VCT which provides access to the whole population of a district in the context of Uganda (25 points): Does the applicant demonstrate an understanding of the ethical, clinical, social, managerial and other practical issues involved in delivering comprehensive VCT in a cost effective and sensitive manner in the setting of a Ugandan district?

2. Ability to carry out the proposal (25 points): Does the applicant demonstrate the capability to achieve the purpose of this proposal?

3. Work Plan (25 points): Does the applicant describe activities, which are realistic, achievable, time-framed and appropriate to complete this program?

4. Personnel (15 points): Are the personnel, including qualifications, training, availability, and experience adequate to carry out the proposed activities?

5. Administrative and Accounting Plan (10 points): Is there a plan to prepare reports, monitoring and audit expenditures under this agreement, manage the resources of the program and produce, collect and analyze performance data?

6. Budget (not scored): Is the budget for conducting the activity itemized and well-justified and consistent with stated activities and planned program activities?

7. Human Subjects (not scored, but evaluated): Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff and for responsiveness by National Center for HIV, STD, and TB Prevention (NCHSTP). Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified 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.

V.3. Anticipated Announcement and Award Dates

September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of their 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–1 Human Subjects Requirements
- AR–10 Smoke-Free Workplace Requirements

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*.

VI.3. Reporting Requirements:

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

1. Semi-annual progress reports, no less than 30 days after the end of the reporting period.

2. Interim progress report, 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. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

f. Measures and Effectiveness.

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

For general questions about this announcement, 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: Jonathan Mermin, MD, MPH, Global AIDS Program [GAP], Uganda Country Team, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention [CDC], PO Box 49, Entebbe, Uganda. Telephone +256–41320776, E-mail: *jhm@cdc.gov*.

For financial, grants management, or budget assistance, contact: Shirley Wynn, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–1515, E-mail: *Zbx6@cdc.gov*.

Dated: July 23, 2004.

William P. Nichols,

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

[FR Doc. 04–17280 Filed 7–28–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04256]

Expansion of Psychosocial Support and Peer Counseling Services to HIV-Infected Women and Their Families in Botswana—Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for Expansion of Psychosocial Support and Peer Counseling Services to HIV-

Infected Women and Their Families in Botswana was published in the **Federal Register** on July 20, 2004, volume 69, number 138, pages 43421–43425. The notice is amended as follows:

- Page 43421, second column, the correct Catalog of Federal Domestic Assistance number is 93.941.
- Page 43421, second column, the correct application due date is August 19, 2004.

Dated: July 23, 2004.

William P. Nichols,

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

[FR Doc. 04–17281 Filed 7–28–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee and committee meetings:

Name: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH), and Subcommittee for Dose Reconstruction and Site Profile Reviews of ABRWH, NIOSH.

Times and Dates: 1 p.m.–4 p.m., August 23, 2004, Subcommittee. 9 a.m.–8:30 p.m., August 24, 2004, Full Committee. 8 a.m.–4 p.m., August 25, 2004, Full Committee.

Place: Shilo Inn Suites, 780 Lindsay Boulevard, Idaho Falls, Idaho 83402, telephone 208/523–0088, fax 208/525–8420.

Status: Open to the public, limited only by the space available. The subcommittee meeting room accommodates approximately 20 people and the committee meeting room accommodates approximately 65 people.

Background: The Advisory Board on Radiation and Worker Health (''the Board'') was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, through the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, evaluation of the scientific validity and quality of dose reconstructions conducted by the NIOSH for qualified cancer claimants, and advice on petitions to add classes of workers to the Special Exposure Cohort.

In December 2000 the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, and renewed on August 3, 2003.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Discussed: Agenda for this meeting will focus on a subcommittee working session; program status reports from NIOSH and Department of Labor; site profile status; Privacy Act and FACA requirements; conflict of interest and quality assurance plan; use of uncertainty in dose reconstruction; scientific research issues update; subcommittee status; and a Board working session. There will be an evening public comment period scheduled for August 24, 2004, and a public comment period at midday on August 25, 2004.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–6825, fax 513/533–6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 22, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–17214 Filed 7–28–04; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002E–0342]

Determination of Regulatory Review Period for Purposes of Patent Extension; LEA'S SHIELD

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LEA'S SHIELD and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device LEA'S SHIELD. LEA'S SHIELD is indicated for use by