FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, contact Representative or Renee Hallman, Case Management Assistant, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 04–11630 Filed 5–21–04; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2004S–0233]

Solicitation of Comments on Stimulating Innovation in Medical Technologies

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is seeking public comment on how HHS and its agencies can work together to facilitate the development and approval of new medical technologies.

DATES: Submit written or electronic comments by August 23, 2004.

ADDRESSES: Submit written comments concerning this document to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

For general questions about this document: Lisa Rovin, Office of the Commissioner (HFP–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1443.

For information about the seven specific questions listed in the **SUPPLEMENTARY INFORMATION** *section of this document*: Tom Kuchenberg, Office of the Secretary, Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201, 202–205–8644.

SUPPLEMENTARY INFORMATION:

I. Background

HHS is seeking comment on how to stimulate innovation in medical technologies, such as drug and biological products and medical devices. We are interested in hearing about ways HHS and its agencies (e.g., National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), and Centers for Disease Control and Prevention (CDC), can work together to facilitate the development and approval of new medical technologies.

Recent advances in basic sciences, such as genomics, proteomics, and bioinformatics, have created the potential for the development of innovative medical technologies that can provide new hope and better quality of life for many Americans. At the same time, more funds are being invested in biomedical science in America than ever before. NIH, which is just completing a 5-year doubling of its budget to $27 billion (Ref. 1), has launched its Roadmap initiative (Ref. 2). The Roadmap initiative aims to transform the nation's medical research enterprise and help speed the movement of research discoveries from the laboratory to the patient.

During the past decade, pharmaceutical firms have increased their research and development investments to more than $30 billion (Ref. 3). Considering the many other organizations involved in medical research in this country (e.g., Department of Defense, Department of Energy, Department of Veteran's Affairs, academic organizations, and foundations), the total amount spent each year in the development of medical technology in the United States could conceivably approach $100 billion.

With an aging population it is worth noting that in 2002 Medicare expenditures for new drugs and devices were approximately $4 to 6 billion. To help speed access to these new technologies, CMS is working on novel ways to better coordinate coverage, payment, and coding for a more timely reimbursement process.

Nonetheless, there is concern that new discoveries in basic sciences are not rapidly translating into new medical products for patients. In a recent report announcing its Critical Path initiative[1] (Ref. 4), FDA noted that the numbers of new drug and biologic applications being submitted to FDA are decreasing despite the dramatic increase in research and development spending over the past decade.[2] Current estimates suggest that it takes 10 to 15 years and $800 million in investment for a new drug to make it from the laboratory bench to a patient's bedside (Ref. 5). On April 22, 2004, FDA published a notice in the **Federal Register** (69 FR 21839) asking for input on the scientific and technical hurdles that cause delays and other problems during the product development process. That notice focused exclusively on FDA. In this notice we are requesting that all constituents comment on what HHS agencies can do together to stimulate innovation in medical technologies.

HHS, through its operating agencies (e.g., NIH, FDA, CMS, and CDC), is an important part of the nation's medical technology infrastructure. To help HHS understand what it can do to facilitate the development of innovative medical technologies, we are asking the following questions:

1. What strategies and approaches could HHS implement to accelerate the development and application of new medical technologies?

2. How can HHS help its agencies (e.g., NIH (and its grantees), FDA, CDC, and CMS) to work together more effectively to eliminate obstacles to development of medical technologies?

3. How can the HHS scientific and regulatory agencies work more effectively with CMS to eliminate obstacles to development?

4. What forums should HHS use to survey constituents about obstacles to innovation (e.g., public meetings, contract research, focus groups)?

5. How can the portability of information between HHS agencies be optimized?

6. Which HHS policies and programs effectively spur innovation? Which policies and programs at NIH (and its grantees), CMS, FDA, and CDC should be expanded to help spur innovation? Do any policies and programs pose obstacles to innovation?

7. What role should be played by nongovernmental partners in assisting the Federal Government in this process?

II. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

[1] The report lays out FDA plans to help make the critical path more predictable and efficient. If products that are likely to fail can be identified earlier in the development process, more research and development resources can be devoted to developing those products that are likely to succeed.

[2] Only one in five products that reach the clinical testing stage ever makes it to marketing.

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Elias A. Zerhouni, ''Statement of the Director to the House Subcommittee on Labor-HHS-Education Appropriations on the FY 2004 President's Budget Request,'' April 2, 2003.

2. National Institutes of Health, Roadmap Overview, September 2003.

3. Tufts Center for the Study of Drug Development, U.S. Pharmaceutical Industry Inflation-Adjusted R&R Expenditures and NCE Approvals, 1963–2002.

4. FDA, ''Innovation or Stagnation, Challenge and Opportunity on the Critical Path to New Medical Products,'' March 2004.

5. Tufts Center for the Study of Drug Development, ''Backgrounder: How New Drugs Move Through the Development and Approval Process,'' November 2001.

Dated: May 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11612 Filed 5–21–04; 1:17 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04195]

Strengthening the Masters-Level Public Health Training Program in Zimbabwe; 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) 2004 funds for a cooperative agreement program to strengthen masters-level graduate training programs in public health to more comprehensively address the HIV/AIDS epidemic in Zimbabwe. The Catalog of Federal Domestic Assistance number for this program is 93.283.

B. Eligible Applicant

Assistance will be provided only to the University of Zimbabwe (UZ), with the assistance targeted to the Department of Community Medicine (DCM). No other applications are solicited.

The UZ/DCM MPH program is an applied epidemiology training program founded through a collaborative effort between the Ministry of Health and Child Welfare (MOHCW) and the UZ/DCM. During the past three years, the MPH Program has trained 37 personnel in its two-year course. It also trained approximately 416 district health team members in health information for district management leading to a Certificate in Health Information for District Management (CHIDM).

The UZ/DCM MPH program is the only MPH program in the country and the only graduate public health program providing core public health trainings. The purpose of this agreement is to build upon the success of the program and allow it to expand without compromising the quality of the training.

Zimbabwe is among the countries in the world most affected by HIV/AIDS: HIV prevalence is estimated to be approximately 25 percent, there has been a ten-fold increase in the number of TB cases, and up to 35 percent of the children may be orphaned by AIDS at the end of this decade. At the same time, the public health response to the epidemic in Zimbabwe is inadequate due, in part, to insufficient manpower in the Zimbabwe public health system and lack of sufficient expertise in HIV/AIDS. This training program will enable Zimbabwe to train and place epidemiologists who are better equipped to address epidemics.

C. Funding

Approximately $173,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before July 15, 2004, and will be made for a 12-month budget period within a project period of up to three 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: Shannon Hader, M.D., Director, CDC Zimbabwe, 38 Samora Machel Avenue, Harare, Zimbabwe, telephone: +263 4 796040, E-mail: *haders@zimcdc.co.zw.*

For budget assistance, contact: Shirley Wynn, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2696, E-mail: *zbx6@cdc.gov.*

Dated: May 17, 2004.

William P. Nichols,

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

[FR Doc. 04–11634 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04142]

BECAUSE Kids Count! (Building and Enhancing Community Alliances United for Safety and Empowerment); Notice of Availability of Funds-Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for a cooperative agreement BECAUSE Kids Count! (Building and Enhancing Community Alliances United for Safety and Empowerment) was published in the **Federal Register**, May 10, 2004, Volume 69, Number 90, pages 25899–25903. The notice is amended as follows: Page 25899, second column, change Letter of Intent Deadline to May 28, 2004 and change Application Deadline Date to June 23, 2004. Page 25901, second column, change Letter of Intent (LOI) Deadline to May 28, 2004 and page 25901, first column, Pre-Application Conference Call: change time from 9:30 a.m. Eastern time to 12:30 p.m. Eastern time.

Dated: May 18, 2004.

William P. Nichols,

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

[FR Doc. 04–11636 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04138]

Evaluation of the Use of Rapid HIV Testing in the United States; Notice of Availability of Funds-Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for a cooperative agreement Evaluation of the Use of Rapid HIV testing in the United States was published in the **Federal Register** April 1, 2004, Volume 69, Number 63, pages 17163–17166. The notice is amended as follows: Page