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IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB Control Number 0910-0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB Control Number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 8, 2003.

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Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA 93-145, HRSA 04-076]

Cooperative Agreement for a Twinning Center (CATC)

AGENCIES: Health Resources and Services Administration, Centers for Disease Control and Prevention, and National Institutes of Health, Department of Health and Human Services; United States Agency for International Development.

ACTION: Notice of availability of funds.

SUMMARY: This notice announces the availability of funds for a Cooperative Agreement for the establishment of a Twinning Center (TC) to support twinning and volunteer activities as part of the implementation of the President's International Mother and Child HIV Prevention Initiative (Initiative). The Cooperative Agreement will be awarded for a 5-year project period.

Program Purpose: The purpose of this funding is to support the President's Initiative, focusing on the reduction/prevention of mother-to-child transmission (PMTCT) of HIV/AIDS. This 5-year Initiative, through a combination of improving care, prophylaxis of HIV-positive mothers, and building healthcare delivery capacity is expected to reach up to one million women annually and reduce mother-to-child HIV transmission by 40 percent within those 5 years in 14 targeted countries in Africa and the Caribbean. This is a unified government initiative, coordinated and implemented by a PMTCT Interagency Steering Committee, led by the Office of the Global AIDS Coordinator in the Department of State, that include as members the Offices of National AIDS Policy (ONAP) and Management and Budget in the White House, the United States Agency for International Development (USAID), the Department of State, and the Department of Health and Human Services (HHS) and its component agencies, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH).

Fourteen countries and one regional office in the Caribbean were initially selected to be part of the Initiative, based on high HIV burden, limited country resources, and host government and civil society commitment to fighting the HIV epidemic and scaling up PMTCT programs. The President's Initiative is intended to complement other bilateral and international support efforts, including support through the Global Fund to Fight AIDS, Tuberculosis, and Malaria. In addition, the Initiative represents specific U.S. Government assistance to help the Initiative countries reach the United Nations General Assembly Special Session on AIDS' goals for reducing mother-to-child HIV transmission.

A long term goal of the President's Initiative is capacity building in clinics and communities to deliver PMTCT. Two of the strategies outlined by the President for human and institutional capacity building are twinning and volunteer activities, which will be implemented through a TC and a Volunteer Health-Care Corps (VHC), although other strategies, including other forms of training, will be employed. The volunteer activities under this program will exist within the twinning partnerships, although the TC will also coordinate with the activities of target country volunteers outside of the twinning activities. The goal of the TC is to strengthen human and organizational capacity through twinning and healthcare volunteers to rapidly expand the pool of trained providers, managers, and allied health staff delivering quality HIV/AIDS services to HIV-infected pregnant women and HIV-exposed infants in 14 target countries in Africa and the Caribbean. The TC will work collaboratively with HRSA's HIV/AIDS Bureau, CDC, USAID, and ONAP to assist in the implementation of the President's Initiative at the country level. The guiding principle for the TC and VHC is that the implementation of this program will be based on the needs of the targeted country as identified by the USAID/CDC field offices' human resources plan.

The definition of "twinning" for the purposes of this Notice of Availability of Funds (NOAF) for a Cooperative Agreement for a Twinning Center (CATC) is the definition developed by the Canadian Interagency Coalition on AIDS and Development in its publication *Beyond Our Borders: A Guide to Twinning for HIV/AIDS Organizations*: A formal, substantive collaboration between two similar organizations. "Formal" means there is an agreement or contract, verbal or