Those wishing to speak should contact: Allen Rudman, Office of Clinical Pharmacology and Biopharmaceutics, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7691, e-mail: *RUDMANA@CDER.FDA.GOV*.

Those wishing to register for the meeting should contact: Drug Information Association, P.O. Box 827192, Philadelphia, PA 19182–7192, e-mail: *DIA@DIAHOME.ORG*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is embarking on a new initiative to develop guidance for the codevelopment of pharmacogenomic-based therapeutic drug and biological products and the diagnostic tests that are necessary for therapeutic decision making. A number of diagnostic tests could be developed for use with drug or biological products including, for example, tests related to treatment decisions, such as whether patients should be treated, the dose used for treatment, or to identify the risks associated with treatment. FDA expects to develop guidance for the codevelopment of therapeutic and diagnostic products where both will be necessary in the clinical management of patients.

In preparation for drafting the guidance, FDA and DIA have planned a 1-day mini-meeting, in collaboration with Pharmaceutical Research and Manufacturers of America, Biotechnology Industry Organization, Advanced Medical Technology Association, Medical Device Manufacturers Association, the DIA Biotechnology Special Interest Action Committee, and the Pharmacogenomics Working Group, to identify important issues related to the codevelopment of pharmacogenomic combination products. FDA believes it is important to receive input from industry and other interested parties through a public meeting before drafting the guidance.

Previously, FDA and industry have cosponsored two multi-day meetings on pharmacogenomics in May 2002 and November 2003, respectively. This collaboration between industry, FDA, and other interested parties has also facilitated the writing and issuance of the draft guidance for industry entitled ''Pharmacogenomic Data Submissions,'' which was issued in November 2003 and is currently being finalized.

II. Goals of the Meeting

The primary intent of this mini-meeting is to provide an interactive forum for discussing industry and other perspectives and experience derived from the development of recently approved pharmacogenomic combination products. This meeting is intended to be highly interactive, identify issues, and address questions that will provide FDA with valuable information to consider during development of guidance for industry on the codevelopment of pharmacogenomic combination products for therapeutic and diagnostic use.

Key areas identified for particular focus include the following:

- Industry vision of an ideal codevelopment process and regulatory framework,
- Clinical trial design and statistical challenges for the codevelopment of therapeutic and diagnostic pharmacogenomic products,
- Case studies to explore detailed considerations for the analytical validation of pharmacogenomic diagnostic products, and
- Clinical utility of pharmacogenomic diagnostic products.

Specific goals of the meeting include the following:

1. Provide greater awareness and understanding of the regulatory and scientific challenges of codeveloping pharmacogenomic combination products.

2. Obtain greater clarity on the clinical and statistical design issues that affect the codevelopment of drug and pharmacogenomic combination products.

3. Provide an opportunity to help define the elements that are needed in guidance for industry to enhance the codevelopment of pharmaogenomic combination products.

4. Provide pharmaceutical, biological product, device industries, and other public stakeholders with an opportunity to identify issues and propose recommendations for FDA consideration as it develops formal guidance on the codevelopment of pharmaogenomic combination products.

III. Intended Audience

This meeting is intended for developers and potential developers of therapeutic drug and biological products and pharmacogenomic-based diagnostic products to be developed and approved with them as combination products. Other interested persons may include regulatory/clinical decision-makers, designers of clinical and laboratory validation protocols, clinical pharmacologists, physicians, biostatisticians, and geneticists working in industry or academia.

IV. Request for Comments

Regardless of attendance at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics presented in this document. The agency welcomes comments before and after the meeting. Two paper copies of mailed comments are to be submitted, 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.

Dated: July 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15935 Filed 7–9–04; 2:24 pm]

BILLING CODE 4160–01–S

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, HHS.

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 Emergency Plan for AIDS Relief (the President's Emergency Plan). 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 Emergency Plan by strengthening human and organizational capacity through twinning and use of health care volunteers to rapidly expand the pool of trained providers, managers, and allied health staff delivering quality HIV/AIDS services to people with HIV/AIDS. Fourteen countries including 12 in African and two in the Caribbean (Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia), are the focus of the initiative, based on high HIV burden and limited country resources. A fifteenth country, outside of Africa and the Caribbean, will soon

be added to the initiative. The President's Emergency Plan is intended to complement other bilateral and international support efforts, including support through the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

Two of the strategies outlined in the President's Emergency Plan 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 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 U.S. Government country teams, including Department of Health and Human Services (HHS) field offices and United States Agency for International Development (USAID) missions.

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 written. ''Substantive'' means the interaction between the twinning partners is significant and lasts for a period of time. ''Collaboration'' means that the partner organizations work together on a specific project or exchange information and skills.

Additionally, the European ESTHER program (Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau) is a source of a hospital-to-hospital twinning model. ESTHER is a twinning initiative among hospitals in Western Europe and developing countries, created in 2002 to encourage the use of anti-retroviral therapy for people with HIV infection through developing the capacity of African and Latin American countries to provide treatment for people living with HIV/AIDS. The basis for this model is an exchange of expertise and experience in treating HIV/AIDS consisting of promoting partnerships between hospitals in France, Spain, Italy, Luxembourg, Belgium and health care facilities in developing countries with the close involvement of teams among those countries. The winner of the TC award will be expected to coordinate closely with ESTHER projects in Côte d'Ivoire, Haiti, Mozambique, Tanzania and Rwanda. Information on the ESTHER program may be found on ''*http://www.esther.fr*''.

A centrally-funded TC will broker and facilitate relationships between twinning partners, plan and fund logistics for the VHC, and fund in-country twinning partners. The twinning plan will build upon existing relationships between U.S. and target country institutions as well as initiate new twinning partnerships.

Eligible Applicants: Public or non-profit private entities, including schools of medicine, nursing, public health, management and public administration and academic health sciences centers, community-based organizations, and faith-based organizations, are eligible to apply for the TC. All applicants must have substantive experience (for at least five years) in establishing and monitoring an official twinning relationship anywhere in the world and providing or facilitating technical assistance and support on issues related to the prevention and treatment of HIV, including community outreach, social support programs, and the prevention of mother-to-child transmission, and must have substantiated experience with twinning of programs and institutions in the United States with counterparts overseas. Applicants must also demonstrate the ability to collect and analyze data for program monitoring and conduct program evaluation.

Authorizing Legislation: Department of Health and Human Services: Section 307 of the Public Health Service (PHS) Act, 42 U.S.C. 242l.

Availability of Funds: Funds are available under the appropriation included in Pub. L. 108–7 for International HIV/AIDS activities. Additional funds may be available from funds appropriated to support the President's Emergency Plan. It is estimated that up to $150,000,000 for up to 5 years may be available to support the TC and twinning activities in the focus countries. Initially, the TC will receive an award of up to $1,786,000, of which $893,000 will be for TC operational activities and $893,000 will be for focus country twinning activities. The TC will be funded for a six month budget period and a five year project period. Funding will be made toward the end of September 2004 to cover the six month period through March 2005. During March 2005, an additional award will be made of up to $4 million for an additional budget period of one year. This funding will also be for TC operations activities and focus country twinning activities. Continuation awards for the TC after the first budget award will be made based upon satisfactory performance and the availability of Federal funds. Funding for in-country twinning activities will occur on a specific project basis, with funding for up to six months and a project period of up to five years. Continuation funding for specific twinning activities will be based upon satisfactory performance of existing twinning partnerships, initiation of new twinning partnerships, and availability of Federal funds.

Application Deadline: Applications for this cooperative agreement must be received in the HRSA Grants Application Center (GAC) by close of business August 12, 2004. Applications shall be considered as meeting the deadline if they are RECEIVED on or before the deadline date. One original and two copies of an application will be required. Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that the applications are received on or before the deadline time and date. Mailed or handcarried applications received after 5:30 p.m. on the closing date will be classified as late. Grant applications received after the deadline will be returned.

Late applications: Applications which do not meet the criteria above are considered late applications. Health Resources and Services Administration (HRSA) shall notify each late applicant that its application will not be considered in the current competition.

The Chief Grants Management Officer (CGMO) or a higher level designee may authorize an extension of published deadlines when justified by circumstances such as acts of God (*e.g.* floods or hurricanes), widespread disruptions of mail service, or other disruptions of services, such as a prolonged blackout. The authorizing official will determine the affected geographical area(s).

Electronic Submission: HRSA encourages applicants to submit applications on-line. To register and/or log-in to prepare your application, go to *https://grants.hrsa.gov/webexternal/login.asp*. For assistance in using the on-line application system, call 877–GO4–HRSA (877–464–4772) between 8:30 am to 5:30 pm ET or e-mail *callcenter@hrsa.gov*.

Application narratives and spreadsheets will need to be created separately and submitted as attachments to the application. You will be prompted to ''upload'' your attachments

at strategic points within the application interface. The following document types will be accepted as attachments: WordPerfect (.wpd), Microsoft Word (.doc), Microsoft Excel (.xls), Rich Text Format (.rtf), Portable Document Format (.pdf).

To look for funding opportunities, go to *http://www.hrsa.gov/grants* and follow the links.

DUNS Number: All applicants are now required to have a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. To obtain a DUNS number, access www.dunandbradstreet.com or call 1–866–705–5711. Please include the DUNS number next to OMB Approval Number on the application face page. Applications will not be reviewed without a DUNS number.

Additionally, the applicant organization will be required to register with the Federal Government's Central Contractor Registry (CCR) in order to do business with the Federal Government, including electronic. Information about registering with the CCR can be found at *http://www.hrsa.gov/grants.htm*.

Where to Request and Send an Application: To prepare and submit an application, organizations must obtain: (1) the CATC Program Guidance and (2) the official Federal grant application kit required for these cooperative agreements, PHS Form 5161–1. The Program Guidance is available on the HIV/AIDS Bureau Web site at the following Internet address: *http://www.hab.hrsa.gov/grant.htm*. The PHS Form 5161–1 is available at the following Internet address: *http://www.hrsa.gov/grants/forms.htm*. The SF 424 is available at the following Internet addresses: *http://forms99.psc.gov/Forms/sf-424_2.htm*. For those organizations who do not have access to the Internet, hard copies of the Program Guidance, PHS Form 5161–1 and SF 424 may be obtained from the HRSA GAC. You can reach the HRSA GAC toll-free at (877) 477–2123, fax (877) 477–2345, or email: *hrsagac@hrsa.gov*. Please request the Office of Management and Budget Catalogue of Federal Domestic Assistance Number 93.145, HRSA 04–076 and Program Code CATC.

Notification of Letter of Intent: Letters of intent to apply are not required.

ADDRESSES: All Cooperative Agreement applications should be mailed or delivered to: HRSA Grant Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland 20879. Applications sent to any other address will be returned.

FOR FURTHER INFORMATION CONTACT: Additional information on the TC and the HRSA/DHHS technical assistance portion of the Cooperative Agreement may be obtained from Thurma Goldman, MD, MPH, HIV/AIDS Bureau, at (301) 443–1993; fax (301) 443–9645; e-mail: *tgoldman@hrsa.gov*; mail HIV/AIDS Bureau, HRSA 5600 Fishers Lane, Parklawn Building, Room 7–13, Rockville, Maryland 20857 or Mr. Robert Soliz, (301) 443–0349, at the same address.

Pre-Application Technical Assistance Conference Call: There will be a pre-application technical assistance conference call with potential applicants approximately 10 days after publication of the Notice of Availability of Funds (NOAF) for the CATC. The conference call will be with HRSA and USAID officials familiar with the NOAF requirements. The purpose of the call will be to answer questions which potential applicants may have about the application guidance or questions about completing the application. All questions to be discussed at the conference call must be submitted in advance of the call to HRSA, by fax, e-mail, or regular mail. Questions should be submitted to: Thurma Goldman, M.D., M.P.H., Program Director, Global HIV/AIDS, HIV/AIDS Bureau, HRSA, 5600 Fishers Lane, Room 7–13, Rockville, MD 20857, at (301–443–1993; fax: 301–443–9645; e-mail: *TGoldman@hrsa.gov*. To find out the exact date and time of the technical assistance conference call, and timeframe for submission of questions, please call the HRSA's HIV/AIDS Bureau main office on (301) 443–1993.

Technical Oversight of the Cooperative Agreement: The HHS/HRSA Project Officer, with assistance from the U.S. Government country teams, including USAID missions and HHS/CDC field staff, will provide technical oversight of this cooperative agreement. This will include (1) oversight and management of the cooperative agreement activities associated with the operation and management of the TC and VHC and (2) oversight of the activities associated with the award and monitoring of funds for in-country twinning partners and volunteer activities. HHS/HRSA will receive strategic direction for this cooperative agreement from the Office of the Global AIDS Coordinator. This guidance will provide overall direction for the TC's goals and objectives in the development and implementation of partnerships.

SUPPLEMENTARY INFORMATION: Cooperative Agreements are a type of Federal assistance that involves a substantial level of government participation in funded activities. Under the cooperative agreement, HRSA requires that certain activities be planned jointly and include approval from HRSA. HRSA responsibilities will be in the following areas:

a. Provide consultation and technical assistance in planning, operation, and evaluation activities, including the identification and selection of in-country partners;

b. Facilitate the coordination and collaboration among program partners, such as USAID, HHS and U.S. Government country teams;

c. Facilitate efforts in the provision of technical assistance and training in twinning to specified individuals and organizations;

d. Participate, as appropriate, in the planning and implementation of any meetings, training activities, or workgroups conducted during the period of the cooperative agreement;

e. Provide technical assistance to the TC to increase its capacity to succeed in this international collaboration;

f. Maintain an ongoing dialogue with the TC concerning program plans, policies, and other issues which have major implications for any activities undertaken by the applicants under the cooperative agreement;

g. Review, provide comments, recommendations, and approvals for documents, curricula, program plans, budgets, work to be contracted out, key personnel (including consultants and contractors), workplan revisions, etc., prior to printing, dissemination or implementation; and

h. Provide feedback to the TC on quarterly and other reports; and

i. Serve as the official interface between the Federal Agencies involved in the Twinning Center activities.

Detailed information on grantee responsibilities is provided in the application guidance.

The applicant receiving the award will be required to submit quarterly reports, a mid-term report during the 30th month of the project, and a final report at the end of the project. Additionally, the TC must provide information to the country U.S. Government focus country teams, including the HHS field offices and USAID missions, to enable them to provide six month reports on the President's Emergency Plan indicators.

The applicant receiving the award will not be required to match or share in project costs. Any matching or cost sharing will not be considered as part of the selection decision.

This program is subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Application packages made available under this Guidance will contain a listing of States which have chosen to set up such a review system and will provide a Single Point of Contact (SPOC) for the State's review. Information on states affected by this program and State Points of Contact may also be obtained from the Grants Management Specialist cited in the application guidance, as well as at *http://www.whitehouse.gov/omb/grants/spoc.html*. All applicants other than federally recognized American Indian tribes should contact their SPOCs as early as possible to alert them to prospective applications and receive any necessary instruction on the State process used under this Executive Order.

The activities proposed to be implemented through this award are not considered to be research activities.

Non-Federal reviewers will participate in the review of submitted applications. Applicants have the option of omitting from the application copies (but not from the original) specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

Review Process: Applications submitted in response to this NOAF will be reviewed for threshold criteria and technical merit by an Objective Review Committee. Each application must address and apply for both aspects of the TC: (a) Brokering, facilitation, and management of twinning partners; and (b) funding of in-country twinning and volunteer activity. The threshold criteria are: (1) Need (10 points); (2) Response (30 points); (3) Evaluative Measures (10 points); (4) Impact (10 points); (5) Resources/Capabilities (30 points); and (6) Support Requested (10 points). Technical Merit criteria are more completely defined in the Application Kit.

Paperwork Reduction Act: Should there be any data collection activities associated with this Cooperative Agreement that fall under the purview of the Paperwork Reduction Act of 1995, then OMB clearance will be sought.

Dated: June 25, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–15758 Filed 7–12–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Proposed Project: 2005 National Survey on Drug Use and Health—(OMB No. 0930–0110, Revision)—The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA), is a survey of the civilian, noninstitutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

For the 2005 NSDUH, questions on mental health and utilization of mental health services will be included. Questions on mental health, in conjunction with questions on substance use, treatment for substance use, and mental health services, will greatly enhance the ability to characterize and understand the co-occurrence and treatment of mental illness and substance use problems in the U.S. The remaining modular components of the questionnaire will remain essentially unchanged except for minor modifications to wording.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2005 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

	Number of responses	Responses/ respondent	Average burden/response (hr.)	Total burden (hrs.)
Electronic Screening	182,250	1	.083	15,127
Questionnaire & Verification	67,500	1	1.0	67,500
Screening Verification	5,494	1	0.067	372
Interview Verification	10,125	1	0.067	678
Total	249,750	.....	.....	183,673