ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lizzie Sanchez, Center for Drug Evaluation and Research (HFD–650), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled ''Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This draft guidance is intended to provide information to sponsors of ANDAs on the design of bioequivalence studies for modified-release dosage forms of potassium chloride. A document entitled ''Guidance for In Vivo Bioequivalence Study for Slow-Release Potassium Chloride Tablets/Capsules'' was issued on May 15, 1987, and revised on June 6, 1994. The guidance is now being revised to incorporate current thinking on the bioequivalence requirements for potassium chloride modified-release products.

In the previous guidance, the agency recommended a three-way crossover study design comparing the reference product (RLD) to the generic product and to a solution of potassium chloride. The earlier guidance also recommended analysis of covariance (ANCOVA) for the pharmacokinetic parameters. The revised draft guidance provides recommendations for a two-way crossover study design comparing the generic product to the RLD. In addition, in the revision, the use of ANCOVA is no longer recommended. The agency has found that the analysis of variance (ANOVA) with baseline correction is adequate for bioequivalence analysis of pharmacokinetic data obtained following oral administration of potassium chloride drug products. The recommendations for in vitro dissolution testing and the criteria for waivers of in vivo testing for lower strengths have been revised in accordance with the guidance entitled ''Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations,'' issued in October 2000.

The agency is issuing this product-specific draft guidance because of special considerations for potassium chloride testing that are not covered in other agency guidances.

This revised draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on studies to demonstrate the bioequivalence of potassium chloride modified-release tablets and capsules. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any 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 draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: July 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19863 Filed 8–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Peer Educator Training Sites and Resource and Evaluation Center Cooperative Agreements; Open Competition Announcement

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) announces that applications will be accepted for fiscal year (FY) 2002 awards for up to four Peer Educator Training Sites (PETS) and one Resource and Evaluation Center (REC) Demonstration Cooperative Agreements. HRSA will support up to four national, regional, or local organizations with a demonstrable record of providing PETS, or similar programs, and other technical assistance (TA) designed to strengthen HIV/AIDS peer education programs within Ryan White Comprehensive AIDS Resources Emergency (CARE) Act funded sites. Through the training of peer educators, the PETS program will expand and improve the delivery of HIV/AIDS primary health care services in underserved communities of color significantly affected by existing and emerging HIV/AIDS epidemics. Peer educators assist people who are infected or affected by HIV to access and remain in care, through outreach, education, and advocacy services to affected individuals and health care professionals. These peer educators are typically not clinically trained health care professionals and may include peer counselors; community health center workers; promoters; outreach workers; treatment educators; HIV peer educators, consumer trainers, and peer advocates. Also, PETS will provide TA to the community-based organizations (CBOs) that employ the peer educators trained by the PETS. The purpose of the TA is two fold. First, the PETS will work with CBO peer educator programs to identify training needs and potential for capacity building to enhance peer educator programs. Second, the PETS will provide TA to CBOs to maximize the impact of peer educator activities within care service programs.

One cooperative agreement will support a REC to provide TA to PETS to develop effective programs for monitoring and evaluating peer educator training activities. The REC will also coordinate the collection,

evaluation, and dissemination of training and professional tools to support the development, adaptation, and translation of new or existing tools and materials and to reduce duplication among PETS grantees.

Available Funding: It is anticipated that awards for up to four PETS and one REC Demonstration Cooperative Agreements will be made in FY 2002 for a total of $2,000,000 of available funds. HRSA expects that the average PETS award will be approximately $300,000 to $400,000 and the average REC award will be approximately $400,000. It is anticipated that project funding will be for 3 years. After the first year, continuation funding will depend on reasonable progress and the availability of funds. There are no matching requirements for this program.

Eligible Applicants: Funding will be directed to activities designed to deliver services specifically targeting racial and ethnic minority populations affected by HIV/AIDS. Eligible entities may include: not-for-profit community-based organizations, national organizations, colleges and universities, clinics and hospitals, research institutions, State and local government agencies and tribal government and tribal/urban Indian entities and organizations. Faith-based and community-based organizations are eligible to apply.

Authorizing Legislation: The authority for these cooperative agreements is in Section 2692(a) of the Public Health Service Act, as amended, 42 U.S.C. 300ff–111(a). This program is excluded from coverage under Executive Order 12372.

Where to Request and Send Applications: To obtain an application kit: Call the HRSA Grants Application Center at the toll free number, 877–477–2123 and request the OMB Catalogue of Federal Domestic Assistance number (CFDA) 93.145, and cite ''Peer Educator Training Sites and Resource and Evaluation Center Cooperative Agreements''.

To submit the completed kit: Send the original and 2 copies of your grant application to: HRSA Grants Application Center, Attention: HAB Grants Management Officer, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879. Applications sent to any other address are subject to being returned. **Federal Register** notices are available on the following web site: *http://www.hab.hrsa.gov.*

Application Dates: A letter of intent to submit an application is requested by August 21, 2002. Applications for this announced grant must be received in the HRSA Grant Application Center by close of business September 6, 2002. Applications shall be considered as meeting the deadline if they are (1) received on or before the deadline date or (2) are postmarked on or before the deadline date and received in time for orderly processing and submission to the review committee. Applicants should request a legibly dated receipt from a commercial carrier or U.S. Postal Service postmark. Private metered postmarks will not be accepted as proof of timely mailing. Applications postmarked after the due date will be returned to the applicant.

ADDRESSES: Brief letters of intent are requested for HAB to determine how many will apply. Letters of intent to apply for funding should be faxed, 301–594–2835 or mailed to Elijah Martin, Jr., HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 7–47, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Additional technical information may be obtained from Elijah Martin, Jr., HAB, HRSA, 5600 Fishers Lane 7–47 Rockville, MD 20857. His telephone number is (301) 443–0802; fax number (301) 594–2835; and e-mail emartin@hrsa.gov. You may also contact Ledia I. Martinez, M.D., Acting Chief, HIV Education Branch, Division of Training and Technical Assistance, HAB, HRSA, 5600 Fishers Lane, Room 7–46, Rockville, MD 20857. Her telephone number is (301) 443–5431 and e-mail *lmartinez@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Applications will be reviewed by an objective review committee. The review criteria will include: adequacy of needs assessment; adequacy of proposed plan; coordination and collaboration; management plan, staffing, project organization and resources; program documentation, program evaluation, and quality improvement; appropriateness and justification of budget; and adherence to program guidance.

The Secretary shall give preference to qualified projects which will—

(A) Train, or result in the training of, health professionals who will provide treatment for minority individuals with HIV disease and other individuals who are high risk of contracting such disease; and

(B) Train, or result in the training of, minority health professionals and minority allied health professionals to provide treatment for individuals with such disease.

As an active partner in this cooperative agreement, HRSA will have significant programmatic involvement with the applicant regarding program plans, policies and other issues which may have major implications for any activities undertaken by the applicant under the cooperative agreement. HRSA will provide consultation and technical assistance in planning, operating, and evaluating major program activities. HRSA's specific involvement will be to:

- Assist to facilitate collaborations with Ryan White grantees and other HIV community organizations to reach the target population;
- Participate, as appropriate, in planning and producing any conferences, meetings, or site visits conducted during the period of the project; and
- Attend and participate in advisory, consultant meeting, and other project planning meetings and conference calls.

Paper Reduction Act: Should any of the data collection activities associated with this cooperative agreement fall under the purview of the Paperwork Reduction Act of 1995, OMB clearance will be sought.

Dated: July 22, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02–19908 Filed 8–6–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Training and Technical Assistance Program Announcement; American Indian/Alaska Native Technical Assistance Center

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) announces that applications will be accepted for fiscal year (FY) 2002 for the award of a cooperative agreement to support an American Indian/Alaska Native Technical Assistance Center (AIANTAC). The purpose of this cooperative agreement is to provide funding for the operation of a technical assistance center to provide competitive proposal development and implementation services to American Indian/Alaska Natives (AI/AN) in Urban and Tribal programs and in the AI/AN communities to increase their involvement in the competitive proposal process. This center will provide professional staff who will assist participants in the development,