Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP), Office of Public Health and Science, Department of Health and Human Services (HHS), gives notice that a panel of experts was convened pursuant to the requirements of 45 CFR 46.407 for review of a proposed protocol entitled ''Precursors to Diabetes in Japanese American Youth.'' This proposed research would include children as research subjects. OHRP has reviewed the protocol and findings of the expert panel and proposes to recommend approval for HHS support of this research protocol, subject to the stipulation of a modification of the protocol and consent forms in accordance with expert recommendations. Public comment is solicited regarding this proposed recommendation pursuant to the requirements of 45 CFR 46.407.

DATES: To be considered, comments must be received on or before 5 p.m. on August 21, 2002.

ADDRESSES: Please send comments to: Clifford C. Scharke, Division of Policy Planning and Special Projects, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, The Tower Building, Rockville, MD 20852. Comments also may be sent via facsimile at (301) 402–2071 (not a toll free number) or by e-mail to *cscharke@osophs.dhhs.gov.*

FOR FURTHER INFORMATION CONTACT: Clifford C. Scharke, Division of Policy Planning and Special Projects, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, The Tower Building, Rockville, MD 20852; telephone number: (301) 402–5218 (not a toll free number) or by e-mail to *cscharke@osophs.dhhs.gov.*

SUPPLEMENTARY INFORMATION: The HHS regulations regarding the protection of human research subjects, 45 part 46, permit HHS to conduct or fund research involving children only if the research falls within one of the following categories: research not involving greater than minimal risk (45 CFR 46.404); research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (45 CFR 46.405); research involving greater than minimal risk and presenting no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.405); and research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407). In accordance with § 46.407, HHS will conduct or fund research involving children which an Institutional Review Board (IRB) has determined does not meet the requirements of 45 CFR 46.404–46.406 only if (a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and (b) the Secretary of HHS, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, has determined either: (1) That the research in fact satisfies the conditions of Section 46.404, Section 46.405, or Section 46.406, as applicable, or (2) the following: (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; (ii) the research will be conducted in accordance with sound ethical principles; (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

OHRP received a request from the University of Washington of Seattle, Washington to convene a panel of experts pursuant to 45 CFR 46.407 to review a protocol entitled ''Precursors to Diabetes in Japanese American Youth'' (1 R01 DK59234–01). The long-term aim of the proposed study is to increase understanding about the metabolic changes that precede the development of type 2 diabetes in children and the influence of Asian ethnicity on the diabetes risk. The institution's designated IRB determined that the research does not meet the requirements of 45 CFR 46.404, 46.405, or 46.406, but is suitable for review under 45 CFR 46.407. Although the IRB found that the research was not designed to provide direct benefit to subjects, it found that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

The panel of experts convened by OHRP, under authority delegated by the Secretary of HHS, found that the protocol presented a reasonable opportunity to further the understanding of a serious problem affecting the health or welfare of children and recommended modifications to the protocol to further minimize the risks to the children and to the consent forms. The experts found that if these recommended modifications are implemented, the research would be conducted in accordance with sound ethical principles, with adequate provisions for assent and permission, and would be in conformance with the requirements of 45 CFR 46.407 and 46.408. The summary report of the findings of the expert panel members is available from OHRP, upon request.

OHRP proposes to recommend approval of HHS support of this research protocol, subject to the stipulation that the protocol and consent forms be modified in accordance with the expert recommendations, to the satisfaction of the IRB and the funding authority, prior to the involvement of human subjects. Public review and comment on this proposal is hereby solicited pursuant to the requirements of 45 CFR 46.407.

Dated: June 27, 2002.

Eve E. Slater, F.A.C.C.,

Assistant Secretary for Health.

[FR Doc. 02–19871 Filed 8–6–02; 8:45 am]

BILLING CODE 4150–28–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0307]

Draft Guidance for Industry on Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing, Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration 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 document provides recommendations to sponsors of abbreviated new drug applications (ANDAs) on the design of bioequivalence studies for modified-release dosage forms of potassium chloride.

DATES: Submit written or electronic comments on the draft guidance by September 23, 2002. General comments on agency guidance documents are welcome at any time.

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,