single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''BA and BE Studies for Orally Administered Drug Products—General Considerations.'' This draft guidance provides recommendations to sponsors and applicants intending to provide BA and BE information in IND's, NDA's, ANDA's, and their amendments and supplements that complies with the BA and BE requirements in 21 CFR part 320 as they apply to dosage forms intended for oral administration.

This draft guidance focuses primarily on product quality BA and BE. Product quality BA encompasses information related to release of the drug substance from the drug product into systemic circulation. BE is a formal comparative test that uses: (1) Specified criteria for comparisons, (2) BE limits (goal posts), and (3) confidence intervals to determine if the observed interval falls within the specified limit.

Many aspects of this draft guidance represent departures from past practices used to document BE. Although some aspects of this draft guidance may result in small increases of regulatory burden, the main intent of many of these changes is to reduce the regulatory burden while maintaining sound scientific principles consistent with public health objectives. Specific examples of reduction of the regulatory burden include: (1) Enable biowaivers for lower strengths of modified release dosage forms, (2) eliminate multiple dose BE studies for modified release dosage forms, (3) enable biowaivers for higher strength of immediate release dosage forms, and (4) reduce emphasis on measuring metabolites in BE studies. Respondents to the **Federal Register** notice are encouraged to provide data that can be used to support or refute proposals in the draft guidance.

In the past, BE studies have been performed as single-dose, crossover studies in healthy volunteers. To compare measures in these studies, data have been analyzed using an average BE criterion. In this draft guidance, FDA recommends the use of new criteria to allow comparison of BE. One, termed an individual BE criterion, means having study designs in which both the test and reference drug products are administered to the same individuals on two separate occasions (replicate study designs). Another, termed a population BE criterion, does not involve replicate study designs. The individual BE is recommended for use in in vivo BE studies submitted in: (1) ANDA's, and (2) NDA's and ANDA's when the need to redocument BE arises after approval. The population BE criterion is recommended for use by sponsors who conduct certain important in vivo BE studies (e.g., studies that compare clinical trial material with the to-be-marketed dose form). The use of the proposed individual BE criterion is based on the assessment of both means and variances of BA measures, to include a subject-by-formulation (S*F) interaction variance and within-subject variance for both test and reference products. Both population and individual criteria allow scaling of the BE limit according to variability of the reference product.

FDA has expended substantial effort in determining whether S*F interaction and increased within-subject variability occur with sufficient frequency to affect a conclusion of switchability between test and reference products. FDA believes that additional information on the frequency and the magnitude of the different variance terms, as well as other information, is needed. For this reason, this draft guidance is recommending that sponsors conduct all in vivo BE studies for: (1) IND's, (2) NDA's, (3) ANDA's, and (4) amendments and supplements to NDA's and ANDA's using replicate designs for a 2-year period following the publication of the final version of this guidance. For example, the current average BE criteria generally require 24 subjects in a two-period study design (total of 24 x 2 = 48 dosage administrations). The proposed replicate study design would require 12 subjects in a four-period study (total of 12 x 2 x 2 dosage administrations). However, there is no increase in total number of dosage administrations to be analyzed. Sponsors can analyze their data using either average or population criteria (IND's and NDA's) or average or individual criteria (ANDA's and supplements to NDA's and ANDA's). Sponsors should specify their choice in the study protocol submitted to the appropriate institutional review board prior to study initiation. At the sponsor's discretion, scaling may be used, under certain circumstances, to judge BE when either an individual or population criterion is specified. Because data from the recommended replicate studies may be powered for an average BE criterion, the burden of performing replicate BE studies is minimized. The agency in turn will perform individual BE analyses on all submitted data to determine subject x formulation interactions. Information from these studies will enable FDA to assess further the usefulness of the proposed individual and population BE criteria.

This draft guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on bioavailability and bioequivalence studies for orally administered drug products. 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 an approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23009 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

AIDS Education and Training Centers Evaluation Center Grant

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) 2000 grants for a discretionary grant to support a National AIDS Education and Training Centers Evaluation Center. The Center will be responsible for assisting HRSA in its capacity to document, evaluate and communicate the outcomes of education, training, and consultation activities provided by the regional AIDS Education and Training Centers (AETC) and by the National Minority AIDS Education and Training Center under section 2692 (a) of the Public Health Service Act as amended by Public Law 104–146, the Ryan White Comprehensive AIDS Resources Emergency Act Amendments of 1996.

AVAILABILITY OF FUNDS: It is anticipated that a single award will be made for the National AIDS Education and Training Centers Evaluation Center and is expected to range from $400,000 to $500,000 for the initial budget period. Funding will be made available for 12 months, with a project period of up to three years. Continuation awards within the approved project period will be made on the basis of satisfactory progress and the availability of funds.

ELIGIBLE APPLICANTS: Eligible applicants are public and nonprofit entities and schools and academic health science centers.

DATES: Applications for this grant must be received in the HRSA Grants Application Center by the close of business October 12, 1999 to be considered for competition. Applications will meet the deadline if they are either (1) received on or before the deadline date or (2) postmarked on or before the deadline date, and received in time for submission to the objective review panel. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted as proof if timely mailing. Applications received after the deadline will be returned to the applicant.

ADDRESSES: All applications should be mailed or delivered to: Grants Management Officer, HRSA Grants Application Center, Parklawn Building, 5600 Fishers Lane, Room 4–91, Rockville, Maryland 20857. Grant applications sent to any address other than that above are subject to being returned. **Federal Register** notices and application guidance for the HIV/AIDS Bureau program are available on the World Wide Web via the Internet. The web site for the HIV/AIDS Bureau is: http://www.hrsa.gov/hab/. Federal grant application forms are available at the following Internet address: http://forms.psc.gov/phsforms.htm. For those applicants who are unable to access application materials electronically, a hard copy of the official grant application kit (PHS Form 6025–1) must be obtained from the HRSA Grants Application Center (GAC). The Center may be contacted by telephone at 1–888–333–4772 until September 12, 1999, or 1–877–HRSA(4772)–123 after September 12, 1999. The e-mail address for the HRSA GAC after September 12, 1999, is hrsagac@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Additional information may be obtained from Mrs. Juanita Koziol, Deputy Chief, HIV Education Branch, Division of Training and Technical Assistance, HIV/AIDS Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 9A–39, Rockville, Maryland 20857; telephone number (301) 443–6364; FAX number (301) 443–9887.

Dated: August 30, 1999.

Claude Earl Fox,

Administrator.

[FR Doc. 99–23003 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4398–N–04]

1998 HUD Disaster Recovery Initiative Amendment

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This notice amends a notice published October 22, 1998, governing the allocation and use of Community Development Block Grant (CDBG) funds appropriated in the 1998 Supplemental Appropriations and Rescissions Act (Pub. L. 105–174) and made available through the HUD Disaster Recovery Initiative. It modifies the Department's policy position on the use of annual CDBG appropriations to meet non-Federal public matching funds requirements of that 1998 supplemental appropriations statute.

FOR FURTHER INFORMATION CONTACT: Jan C. Opper, Senior Program Officer, Office of Block Grant Assistance, Department of Housing and Urban Development, Room 7286, 451 Seventh Street, SW, Washington, DC 20410, telephone number (202) 708–3587. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. FAX inquiries may be sent to Mr. Opper at (202) 401–2044. (Except for the ''800'' number, these telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The 1998 Supplemental Appropriations and Rescissions Act (Pub. L. 105–174, 112 Stat. 58, approved May 1, 1998), required the publication of a notice governing the allocation and use of 1998 HUD Disaster Recovery Initiative grant funds. On October 22, 1998, at 63 FR 56764, HUD published a notice to address this requirement. The match requirement in the notice of October 22, 1998 is amended by this notice. Further legal review has clarified that annual appropriations of CDBG funds may be used to meet the ''25 percent in non-Federal public matching funds'' requirement in the 1998 Supplemental Appropriations and Rescissions Act (Public Law 105–174) (at 112 Stat. 76). Though the Department has the authority to specify alternative requirements, it has decided to adopt this legal position.

Accordingly, FR Doc. 98–28436, the 1998 HUD Disaster Recovery Initiative Notice, published in the **Federal Register** October 22, 1998, 63 FR 56764, is amended by revising paragraph I.F.9.a., on page 56766, in column 2, to read as follows:

a. Contributions made with or derived from Federal resources or funds, regardless of when the Federal resources or funds were received or expended. Use of CDBG funds (defined at § 570.3) under section 105(a)(9) of the Act for payment of the non-Federal share required in connection with a Federal grant-in-aid program is permissible;

Authority

1998 Supplemental Appropriations and Rescissions Act (Pub. L. 105–174, 112 Stat. 58, approved May 1, 1998).

Dated: August 27, 1999.

Cardell Cooper,

Assistant Secretary for Community Planning and Development.

[FR Doc. 99–22989 Filed 9–2–99; 8:45 am]

BILLING CODE 4210–29–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4432–N–35]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and