

Dated: February 5, 2003.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 03-6507 Filed 3-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0258]

Revised Guidance for Industry on Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a revised guidance for industry entitled “Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations.” This guidance revises the guidance of the same name that issued in October 2000.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the revised 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 guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Aida L. 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

The agency is announcing the availability of a revised guidance for industry entitled “Bioavailability and Bioequivalence Studies for Orally

Administered Drug Products—General Considerations.” This is a revision of the guidance of the same name issued in October 2000. The guidance is intended to provide information to sponsors and/or applicants planning to include bioavailability (BA) and bioequivalence (BE) information for orally administered drug products in investigational new drug applications (INDs), new drug applications (NDAs), and abbreviated new drug applications (ANDAs) and their supplements. Since the October 2000 guidance was issued there have been changes due to the following: (1) Agency thinking based, in part, on input from the Advisory Committee for Pharmaceutical Science, (2) experience with the guidance, and (3) outside comments. Therefore, the agency decided to revise the guidance.

A draft of the revision was published in the **Federal Register** of July 11, 2002, (67 FR 45983). Comments on the draft submitted to the docket were considered carefully during the finalization of this guidance. Only minor, clarifying editorial changes have been made to this final version.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any 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 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: March 10, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-6491 Filed 3-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB No. 0915-0174)—Revision

The Division of Facilities and Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under section 621 of title VI and section 1601 of title XVI of the Public Health Service Act, as well as loans insured under the section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to capital through the assumption of the mortgage credit risk by the Federal government.

Operating statistics and financial information are collected annually from hospitals with mortgages that are insured under these programs. The

information is used to monitor the financial stability of the hospitals to protect the Federal investment in these

facilities. The form used for the data collection is the Hospital Facility Data Abstract.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Hospital Facility Data Abstract	175	1	1	175

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 12, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Children and Youth Initiative

AGENCY: Indian Health Service, HHS.

ACTION: Notice of Availability of Funds for Competitive Grants for Youth Initiatives: Health promotion, intentional and unintentional injury prevention, youth wellness, recreation and education, and mentoring programs for American Indian and Alaska Native (AI/AN) youth.

SUMMARY: The Indian Health Service (IHS) announces the availability of approximately \$700,000 for competitive grants established under the authority of section 301(a) of the Public Health Service Act, as amended, to be awarded to Tribal, Urban and nonprofit Indian organizations for the support of AI/AN youth. There will be only one funding cycle during Fiscal Year (FY) 2003 (see Fund Availability and Period of Support). This program is described in the *Catalog of Federal Domestic Assistance* at 93.933. Executive Order 12372, which requires intergovernmental review, is not applicable to this program.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2010* a PHS led activity for setting priority areas. Potential applicants may obtain a printed copy of *Healthy People 2010*, (Summary Report No. 017-001-00549-5) or CD-ROM, Stock No. 017-001-00549-5, through the Superintendent of Documents, Government Printing

Office, P.O. Box 371954, Pittsburgh, PA 15250-7945, (202) 512-1800. You may also access this information at the following Web site: <http://www.health.gov/healthpeople/publication>.

Projects will be included in one of two categories: (1) Services assessment, which may include the demographics of Native American children and youth between the ages of 5 and 19, the development of a survey tool of youth services and needs, or the development of assessment tools or interdisciplinary teams; or (2) direct services with a prevention component, which may include the forming of children and youth-specific clinics/services/programs/camps/before and after school programs/recreation programs/programs for at risk youth with an injury prevention focus and/or the fostering of traditional values as well as family and intergenerational activities. This may involve children and youth with special needs, particularly at risk populations such as detained or incarcerated youth, or aftercare for youth in residential treatment programs.

Smoke-Free Workplace: The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Due Date: An original and two copies of the completed grant application must be submitted with all required documentation, to the Grants Management Branch, Division of Acquisition and Grants Management, 801 Thompson Avenue, Suite 120, Rockville, MD 20852, by 5 p.m., Eastern Standard Time, on May 15, 2003.

Applications shall be considered as meeting the deadline if they are either: (1) Received on or before the deadline, with hand carried applications received by 5 p.m.; or (2) postmarked on or before the deadline date and received in time to be reviewed along with all other timely applications. A legibly dated receipt from a commercial carrier or the U.S. Postal Service will be accepted as proof of timely mailing. Private metered postmarks will not be accepted as proof

of timely mailing. Applications received after the announced closing date will be returned to the applicants and will not be considered for funding.

Additional Dates:

(a) Application Review Date: June 19, 2003.

(b) Applicants Notified of Results (approved, approved unfunded, or disapproved): June 26, 2003.

(c) Anticipated Start Date: July 1, 2003.

Contacts for Assistance: For program information, contact Judith Thierry, D.O., Maternal and Child Health Coordinator, Office of Public Health, IHS, 801 Thompson Avenue, Suite 120, Rockville, Maryland, 20852; (301) 443-5070; jthierry@hqe.ihs.gov; or (301) 443-0114 (fax). For grant application and business information, contact Ms. Martha Redhouse, Grants Management Specialist, Grants Management Branch, Division of Acquisition and Grants Management, IHS, 801 Thompson Avenue, Suite 120, Rockville, MD 20852; (301) 443-5204. (The telephone numbers for Dr. Thierry and Ms. Redhouse are not toll-free.)

SUPPLEMENTARY INFORMATION: This announcement provides information on the general program goal, eligibility and documentation requirements, programmatic activities, funding availability, period of support, and application procedures.

General Program Goals: The goals are to support youth health promotion and wellness programs; to aid in the risk reduction of injuries, early morbidity, and premature mortality from injuries; to aid in the risk reduction of alcohol, tobacco, inhalant and substance abuse; to support a healthy learning environment and staying in school; and to support communities oriented to AI/AN children and youth, and their families. Injury coalitions, recreational programs and/or multidisciplinary evaluation and treatment teams will be considered for these communities. Another, non-exclusive goal is to survey and assess youth or youth programs to better define community needs and consider a plan of action.

Eligibility and Documentation Requirements: Any federally recognized Indian tribe, Indian Tribal organization,