

Dated: February 5, 2003.

Jane A. Axelrad,

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

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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.

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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