DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0350]

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Certifier R. LEDESMA

Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Handling and Retention of Bioavailability and Bioequivalence Testing Samples." Inspection of clinical and analytical sites that perform bioavailability (BA) and bioequivalence (BE) studies frequently reveals the absence of reserve samples at the testing facilities where the studies are conducted. The draft guidance is intended to clarify how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples.

EFFECTIVE DATE: Submit written or electronic comments on the draft guidance by [*insert date 30 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers

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Lane, rm. 1061, Rockville, MD. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Martin Yau, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5458.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Handling and Retention of Bioavailability and Bioequivalence Testing Samples." Following the generic drug crisis in the 1980s, FDA issued regulations to deter possible bias and fraud in BA and BE testing by study sponsors and/or drug manufacturers (58 FR 25918, April 28, 1993). In the preamble of the final rule, the agency stated that the study sponsor should not separate out the reserve samples of the test article and reference standard prior to sending the drug product to the testing facility. This is to ensure that the reserve samples are in fact representative of the same batches provided by the study sponsor for the testing. FDA's Division of Scientific Investigations and field investigators from the Office of Regulatory Affairs conduct inspections of clinical and analytical sites that perform BA and BE studies for sponsors and/or drug manufacturers seeking approval of generic and new drug products. A frequent finding from these inspections is the absence of reserve samples at the testing facility. This draft guidance clarifies the responsibilities of the involved parties for retention of samples used in BA and BE studies.

It includes recommendations for sampling techniques and responsibilities in various study settings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on retention of BA and BE testing samples. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments on the draft guidance. Two copies of 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 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.

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

Dated: August 13 2002

August 13, 2002.

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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