DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0350]

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 guidance for industry entitled ''Handling and Retention of BA and BE Testing Samples.'' The guidance is intended to provide recommendations for study sponsors and/or drug manufacturers, contract research organizations, site management organizations, clinical investigators, and independent third parties on the procedure for handling reserve samples from bioavailability (BA) and bioequivalence (BE) studies. The guidance clarifies how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples.

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

ADDRESSES: Submit written requests for single copies of this 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 Division of

Dockets Management (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: 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 guidance for industry entitled ''Handling and Retention of BA and BE Testing Samples.'' Following the generic drug crisis in the 1980s, FDA issued regulations to prevent 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 to 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. In the **Federal Register** of August 21, 2002 (67 FR 54219), the agency issued a draft guidance entitled ''Handling and Retention of Bioavailability and

Bioequivalence Testing Samples'' to clarify the responsibilities of the involved parties for retention of samples used in BA and BE studies. That draft guidance included recommendations for sampling techniques and responsibilities in various study settings. All comments received during the comment period have been carefully reviewed and changes were made to this final guidance where appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 Division of Dockets Management (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 Division of Dockets Management 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: May 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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