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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 02D-0350]

Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until *[insert date 60 days after date of publication in the Federal Register]*, the comment period for the draft guidance for industry entitled "Handling and Retention of Bioavailability and Bioequivalence Testing Samples." This draft guidance is intended to clarify how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain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. FDA published a notice of availability of the draft guidance in the **Federal Register** of August 21, 2002 (67 FR 54219). The agency is taking this action in response to a request for an extension of the comment period and to allow interested parties additional time to submit comments.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

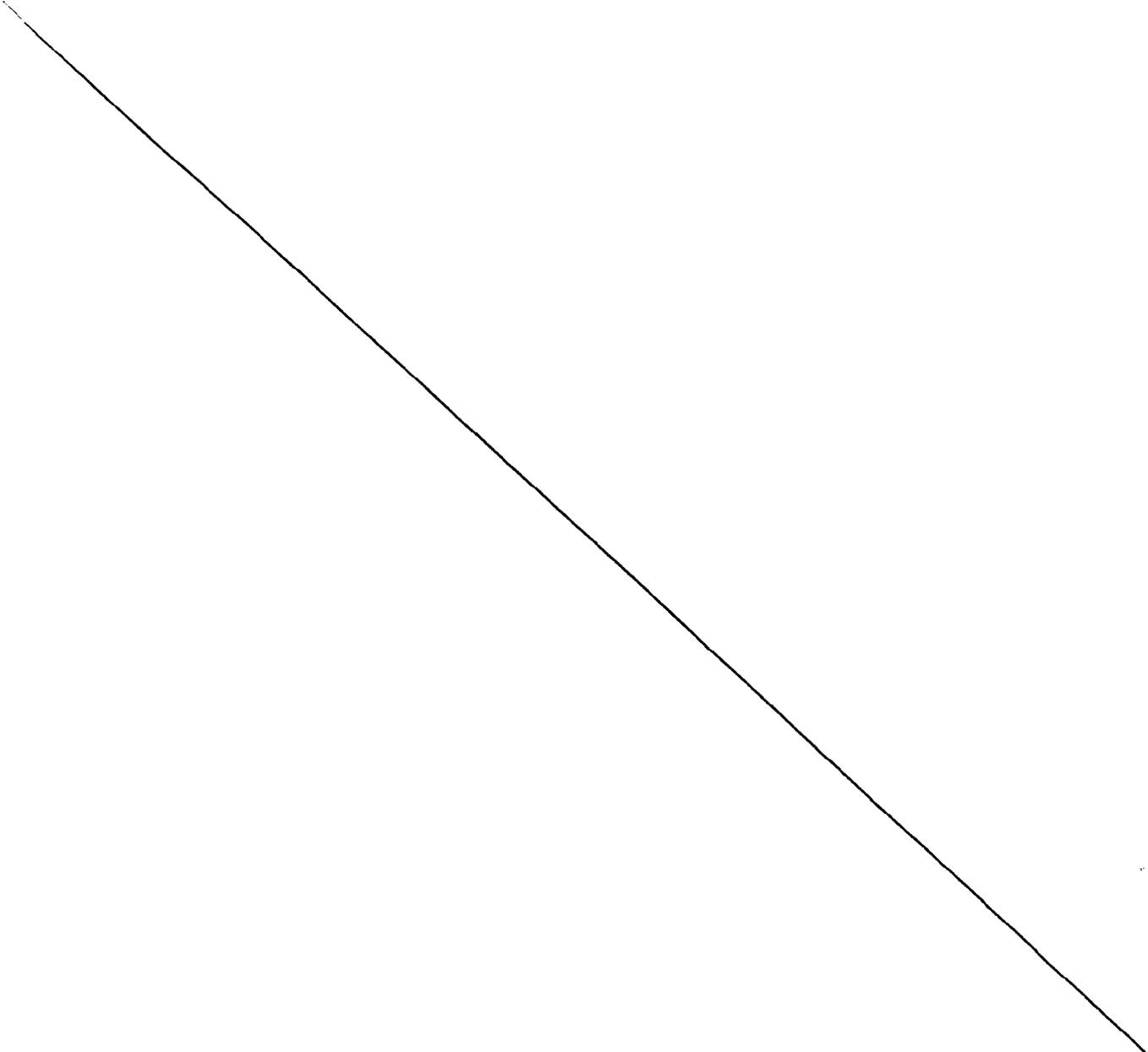
I. Background

In the **Federal Register** of August 21, 2002 (67 FR 54219), FDA announced the availability of a draft guidance for industry entitled "Handling and Retention of Bioavailability and Bioequivalence Testing Samples." The draft guidance had a 30-day comment period. The draft guidance clarifies the responsibilities of the involved parties for retention of samples used in bioavailability and bioequivalence studies. It includes recommendations for sampling techniques and responsibilities in various study settings.

In a letter dated September 20, 2002, FDA received a request from an interested party to extend the comment period. The party indicated that issues of importance to the pharmaceutical industry had been raised that warrant further discussion before filing comments. In response to this request, and to provide all interested persons additional time to comment on this draft guidance, FDA is reopening the comment period for 60 days.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic 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.



III. Electronic Access

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

Dated: 10/10/02

October 10, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins