

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	Lowell Oliver

Food and Drug Administration

[Docket No. 98D-1195]

Guidance for Industry on Bioanalytical Method Validation; 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 "Bioanalytical Method Validation." This guidance provides assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and their supplements in developing validation information on bioanalytical methods for pharmacokinetic (PK) evaluation of human clinical pharmacology, bioavailability (BA), and bioequivalence (BE) studies. The guidance also applies to bioanalytical methods used for nonhuman pharmacology/toxicology studies and preclinical studies. For studies related to the veterinary drug approval process, this guidance applies only to blood and urine BA, BE, and PK studies.

DATES: Submit written 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 Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD-350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5635.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Bioanalytical Method Validation." This guidance provides recommendations to sponsors of INDs, NDAs, ANDAs, and their supplements in developing validation information for bioanalytical methods for PK evaluations of human clinical pharmacology, BA studies, and BE studies. The information in this guidance generally applies to bioanalytical procedures such as gas chromatography (GC), high-pressure liquid chromatography (LC), combined GC and LC mass spectrometric (MS) procedures such as LC-MS, LC-MS-MS, GC-MS, GC-MS-MS, and immunological and microbiological procedures performed for quantitative determination of drugs and or metabolites in biological matrices such as serum, plasma, or urine. The guidance also applies to other bioanalytical matrices such as tissue and skin samples.

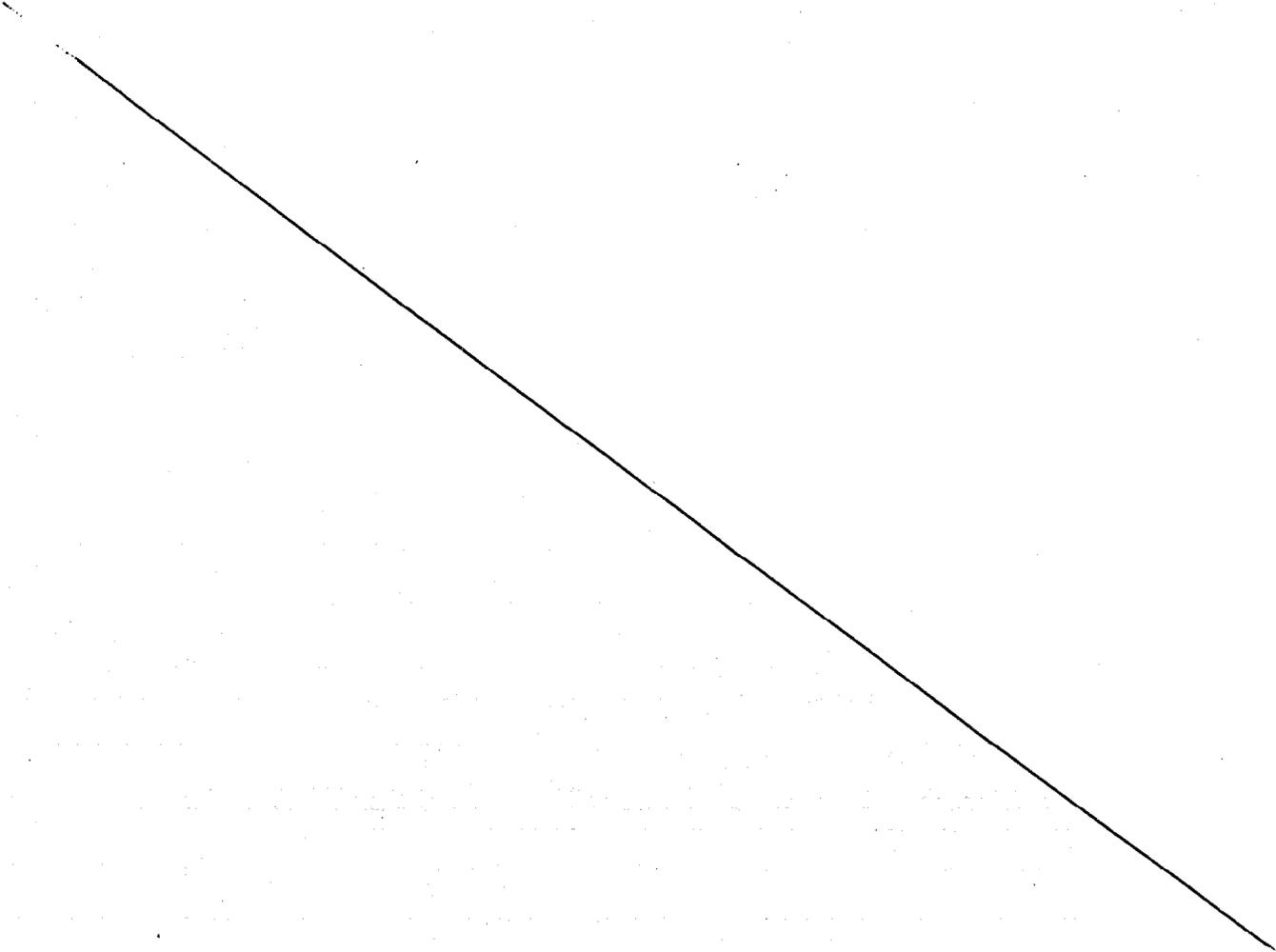
In the **Federal Register** of January 5, 1999 (64 FR 517), FDA announced the availability of a draft guidance entitled "Bioanalytical Methods Validation for Human Studies." This January 1999 document gave interested persons an opportunity to comment through March 8, 1999. The agency received a total of 36 comments. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance where appropriate. In addition, a workshop entitled "Bioanalytical Method Validation—A Revisit with a Decade of Progress" was held January 12 to 14, 2000. This guidance also incorporates the recommendations from the January 2000 workshop.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on the validation of methods for the assay of drugs and/or metabolites in human biological

matrices. 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

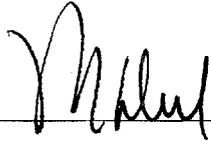
Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading 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 <http://www.fda.gov/cder/guidance/index.htm>.

Dated: 5/11/01
May 11, 2001



Margaret M. Dotzel
Associate Commissioner for Policy

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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