

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0194]

DMB

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Certifier	<i>FAJ</i>

Draft Guidance for Industry on the Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals." The purpose of this document is to provide guidance to sponsors on the design of animal carcinogenicity experiments, methods of statistical analysis of tumor data, interpretation of study results, presentation of data and results in reports, and the submission of tumor data to FDA statistical reviewers in the Center for Drug Evaluation and Research (CDER).

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karl K. Lin, Center for Drug Evaluation and Research (HFD-715), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals." Assessment of the risk of drug exposure in humans includes an assessment of carcinogenicity in tests in rodents. In a carcinogenicity study of a new drug using a series of increasing dose levels, statistical tests are an important component of the analysis. The Division of Biometrics in the Office of Biostatistics, CDER is responsible for conducting statistical reviews of long-term animal (rodent) carcinogenicity studies of pharmaceuticals submitted by drug sponsors to FDA.

In statistical reviews of carcinogenicity studies, statisticians evaluate the validity of the designs and the appropriateness of methods of data analysis used by the sponsor. They also use raw study data in electronic form to perform additional statistical analyses.

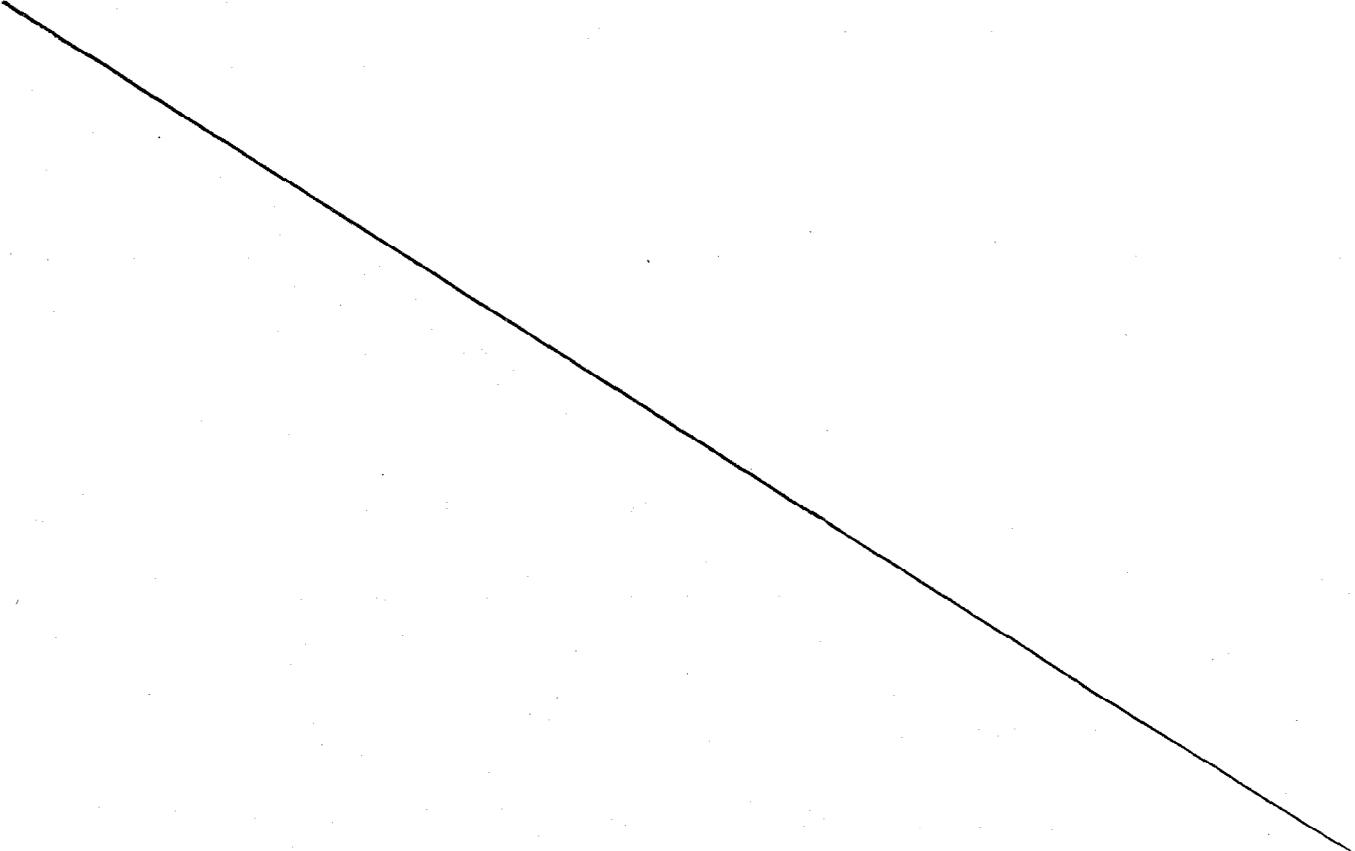
The purpose of this document is to provide guidance to sponsors on statistical issues related to the design of animal carcinogenicity experiments, methods of analysis of tumor data, interpretation of study results, presentation of data and results in reports, and the submission of tumor data to FDA statistical reviewers.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on the statistical aspects of the design, analysis, and interpretation of chronic rodent carcinogenicity studies of pharmaceuticals. 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

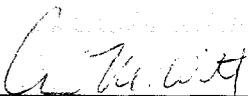
Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of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

Dated: April 30, 2001
April 30, 2001.



Ann M. Witt,
Acting Associate Commissioner for Policy.

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