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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01D-0488]

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Certifier M. Corbin

**Guidance for Industry on Food-Effect Bioavailability and Fed Bioequivalence Studies; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Food-Effect Bioavailability and Fed Bioequivalence Studies." This guidance provides recommendations to sponsors and/or applicants planning to conduct food-effect bioavailability (BA) and fed bioequivalence (BE) studies for orally administered drug products as part of investigational new drug applications (INDs), new drug applications (NDAs) and abbreviated new drug applications (ANDAs), and supplemental applications.

**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 Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://>

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[/www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Ameeta Parekh, Center for Drug Evaluation and Research (HFD-870), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5919.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Food-Effect Bioavailability and Fed Bioequivalence Studies.” This guidance document is intended to provide information to sponsors and/or applicants planning to include food-effect BA and fed BE studies for orally administered drug products in INDs, NDAs, ANDAs, and supplemental applications. This guidance provides recommendations for when studies are appropriate, as well as recommendations on study design, data analysis, and product labeling.

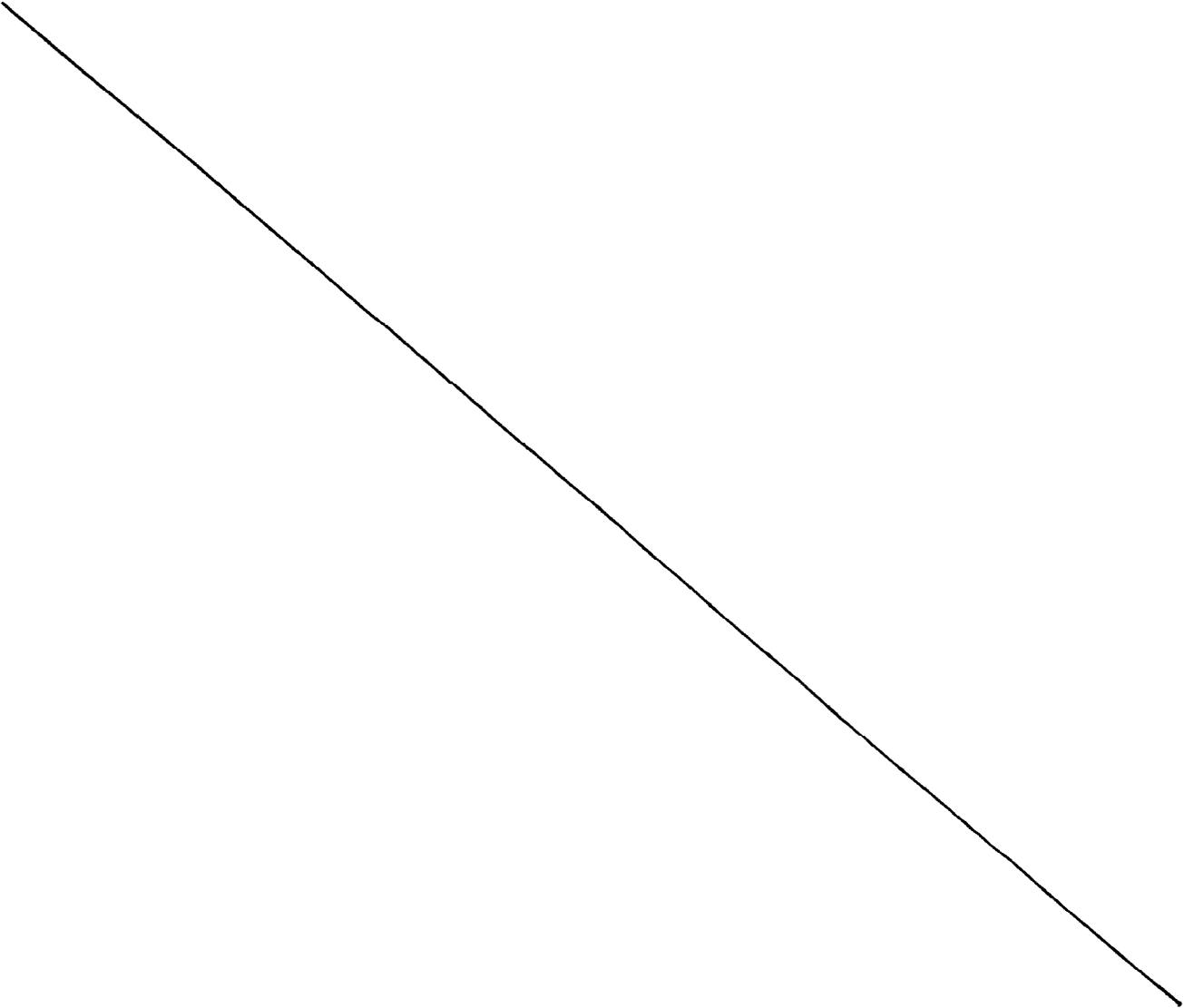
In the **Federal Register** of November 28, 2001 (66 FR 59433), FDA published a draft guidance entitled “Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling.” Based on comments received on the draft guidance and the refinement of agency thinking on the conduct of such studies, FDA has revised the guidance.

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 submitting food-effect BA and fed BE information as part of INDs, NDAs, and ANDAs. 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 statute and regulations.

## **II. Comments**

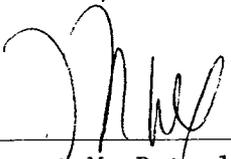
Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The 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: 1/21/03  
January 21, 2003.

  
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Margaret M. Dotzel,  
Assistant Commissioner for Policy.

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