

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0488]

DMB

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Draft Guidance for Industry on Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling." The draft guidance is intended for sponsors planning to conduct food-effect bioavailability (BA) and fed bioequivalence (BE) studies for oral immediate-release and modified-release dosage forms as part of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements to these applications. The draft guidance provides recommendations for study design, data analysis, and product labeling, and also indicates when food-effect BA and fed BE studies should be performed.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers

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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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Lawrence J. Lesko, Center for Drug Evaluation and Research (HFD-850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5690.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Food-Effect Bioavailability and Fed Bioequivalence Studies: Study Design, Data Analysis, and Labeling." This draft guidance is a revision of an October 1997 draft guidance entitled "Food-Effect Bioavailability and Bioequivalence Studies."

Food can delay gastric emptying, stimulate bile flow, change gastrointestinal (GI) pH, and increase splanchnic blood flow, thereby altering the BA of a drug product. Food can also change luminal metabolism of a drug substance and can physically or chemically interact with a dosage form or a drug substance to alter BA. Changes in BA can sometimes call for dosage adjustments or specific dosing instructions in relation to administration with meals. The physiological changes incurred due to food intake can influence the demonstration of BE between test and reference products.

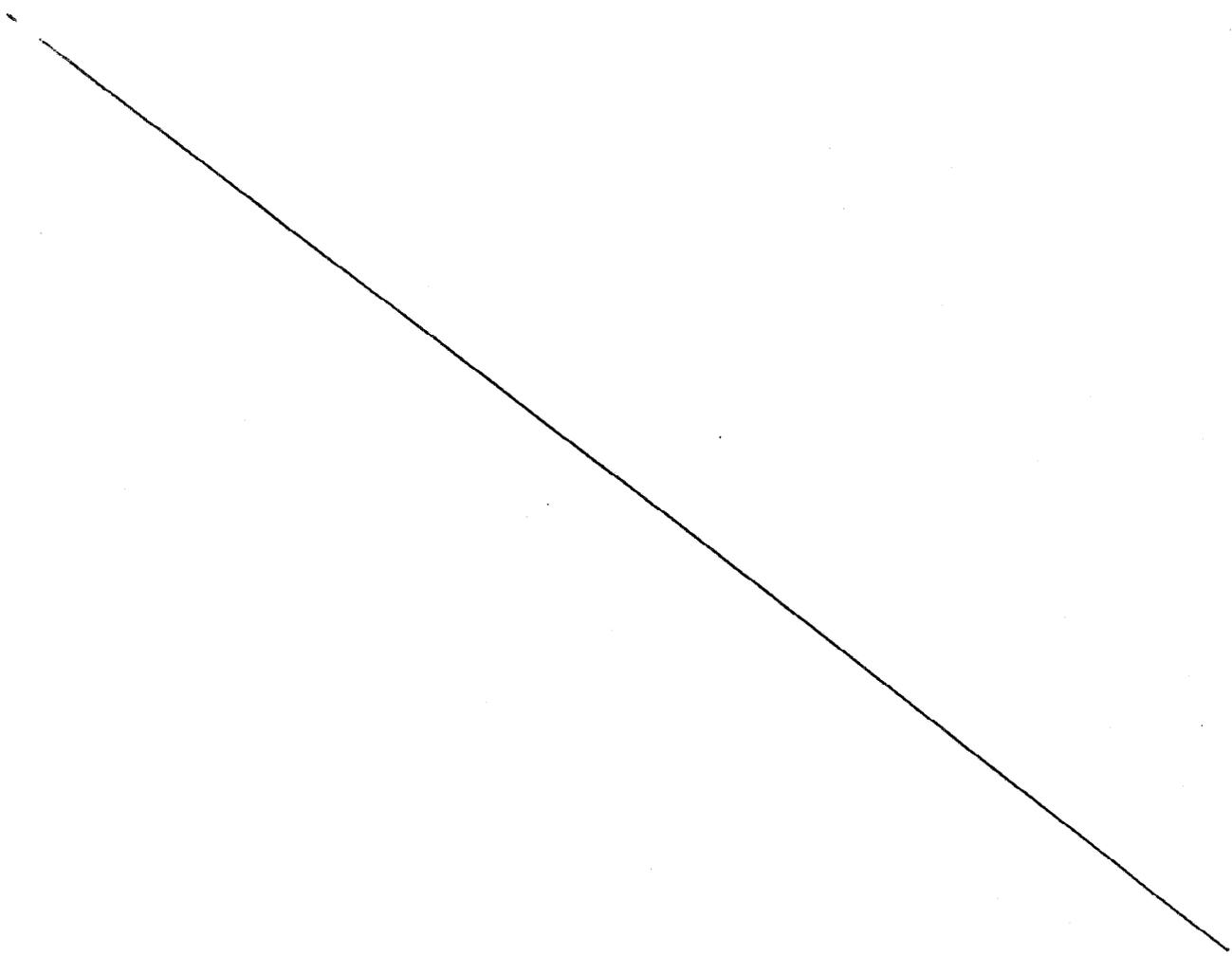
Several study design variables may have an impact on the outcome of a food-effect BA or fed BE study. This draft guidance provides general information on study design and data analysis to assess the magnitude of food impact on the BA and BE of a drug product and indicates how this information can be appropriately addressed in the labeling. In addition, the draft guidance makes recommendations on when food-effect BA and fed BE should be performed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking

on food-effect bioavailability and fed bioequivalence studies. 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 or electronic 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: 11-15-01
November 15, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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