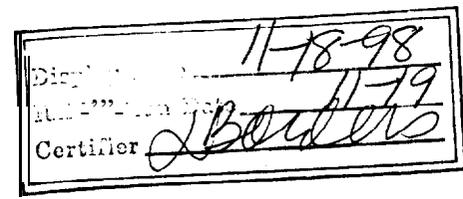


DMP



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98 D-1001]

**Draft Guidance for Industry: In Vivo Drug Metabolism/Drug Interaction Studies—
Study Design, Data Analysis, and Recommendations for Dosing 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.” This draft guidance is intended to provide recommendations to sponsors and applicants of new drug applications (NDA’s) and biologics license applications (BLA’s) for therapeutic biologics (hereafter drugs) on carrying out in vivo drug metabolism and metabolic drug-drug interaction studies. The draft guidance reflects the current view that the metabolism of a new drug should be defined during drug development and that its interactions with other drugs should be explored as part of an adequate assessment of the safety and effectiveness of the drug.

DATES: Written comments may be submitted on the draft guidance by (insert *date 60 days after date of publication in the Federal Register*).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: Copies of “In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling” are available on the Internet at “<http://www.fda.gov/cder/guidance/index.htm>” or “<http://www.fda.gov/cber/guidelines.htm>”. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-

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210) Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. 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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

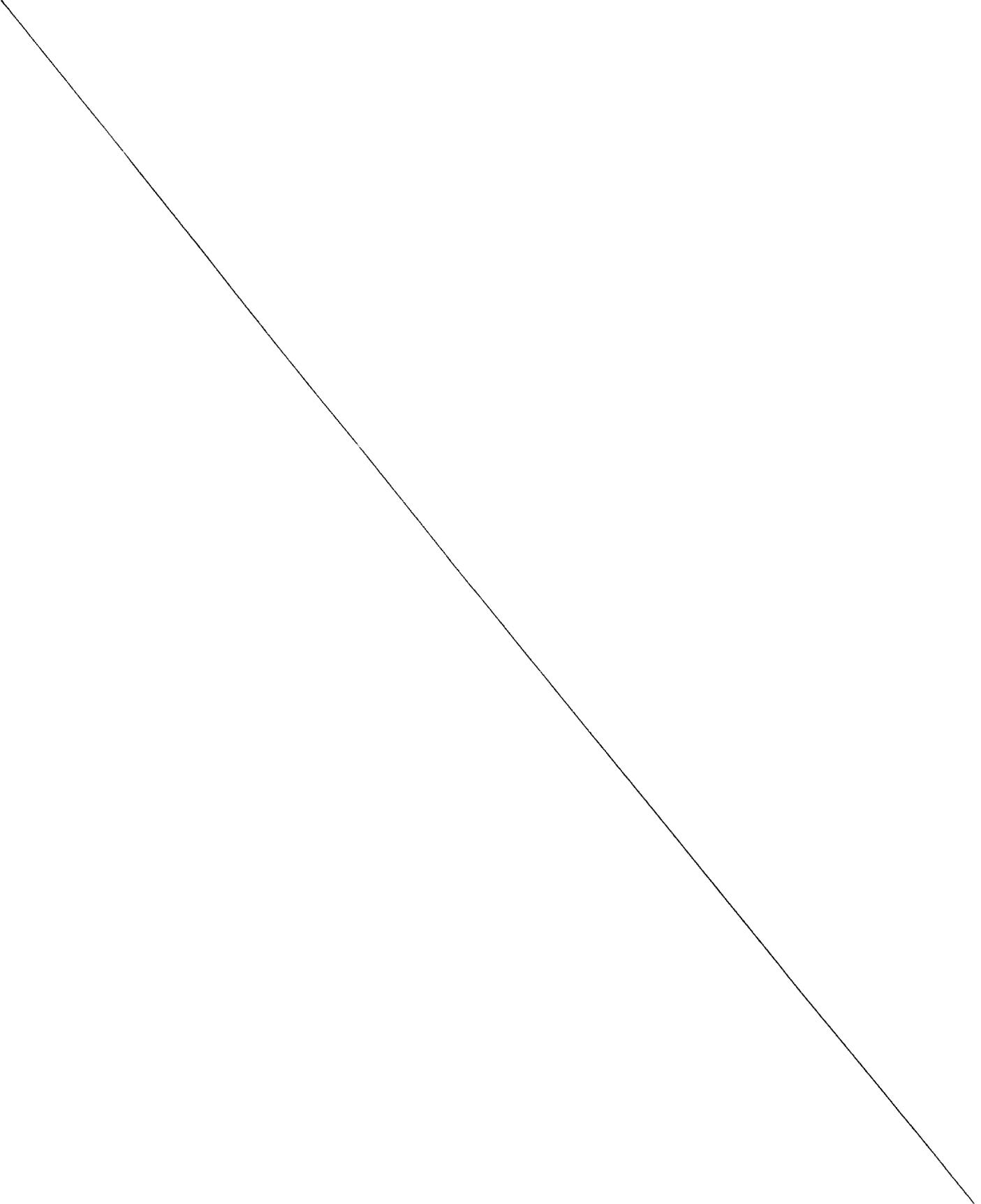
FOR FURTHER INFORMATION CONTACT: Shiew Mei Huang, Center for Drug Evaluation and Research (HFD-850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5671, or David Green, Center for Biologics Evaluation and Research (HFM-579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5349.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ‘‘In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling,’’ Previous guidance from FDA on the use of in vitro approaches to study metabolism and metabolic drug-drug interactions is available in a document entitled ‘‘Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies in Vitro.’’ The present guidance should be viewed as a companion to this earlier guidance. The present guidance discusses study design, choice of interacting drugs, and data analysis and provides recommendations for dosing and labeling.

This draft level 1 guidance document is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). It represents the agency’s current thinking on drug metabolism and drug-drug interactions. 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, regulations, or both.

Interested persons may, at any time, submit written comments on the draft 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 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.

Dated: November 13, 1998

November 13, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

[FR Dot, 98-??-?? Filed ??-??-98; 8:45 am]

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