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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99D-4718]

**Guidance for Industry on 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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.” This guidance provides recommendations to sponsors of new drug applications (NDA’s) and biologics license applications (BLA’s) for therapeutic biologics on carrying out in vivo drug metabolism and metabolic drug-drug interaction studies. The guidance reflects the agency’s 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:** 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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to 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 guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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**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:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling.” A draft of this guidance was published for comment in the **Federal Register** of November 19, 1998 (63 FR 64269). The guidance has been revised after careful consideration of public comments received between November 1998 and March 1999.

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” (April 1997). This guidance should be viewed as a companion to this earlier guidance. The earlier guidance addressed techniques and approaches for in vitro studies of drug metabolism and drug interactions and the correlation between in vitro and in vivo studies. This guidance discusses study design, choice of interacting drugs, and data analysis and provides recommendations for dosing and labeling.

This 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 statutes, regulations, or both.

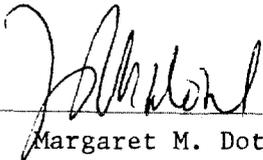
**II. Comments**

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the 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 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**

Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: 11/17/99  
November 17, 1999



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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