

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5047]

LMB
Display Date 5-29-03
Publication Date 5-30-03
Certifier S. Penley

Guidance for Industry on Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on 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 guidance for industry entitled "Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling." This guidance provides recommendations to sponsors planning to conduct studies to assess the influence of hepatic impairment on the pharmacokinetics and, where appropriate, the pharmacodynamics of drugs or therapeutic biologics.

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, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. 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://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Mehul U. Mehta, Center for Drug Evaluation and Research (HFD-860),
Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,
301-594-2567; 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 “Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.” This document provides guidance on: (1) When pharmacokinetic studies in patients with hepatic impairments should be conducted; (2) the recommended design and conduct of studies to characterize the effects of impaired hepatic function on the pharmacokinetics of a drug; (3) inclusion criteria for patient populations to be studied; (4) analysis, interpretation, and reporting of the results of the studies; and (5) the description of study results in drug labeling.

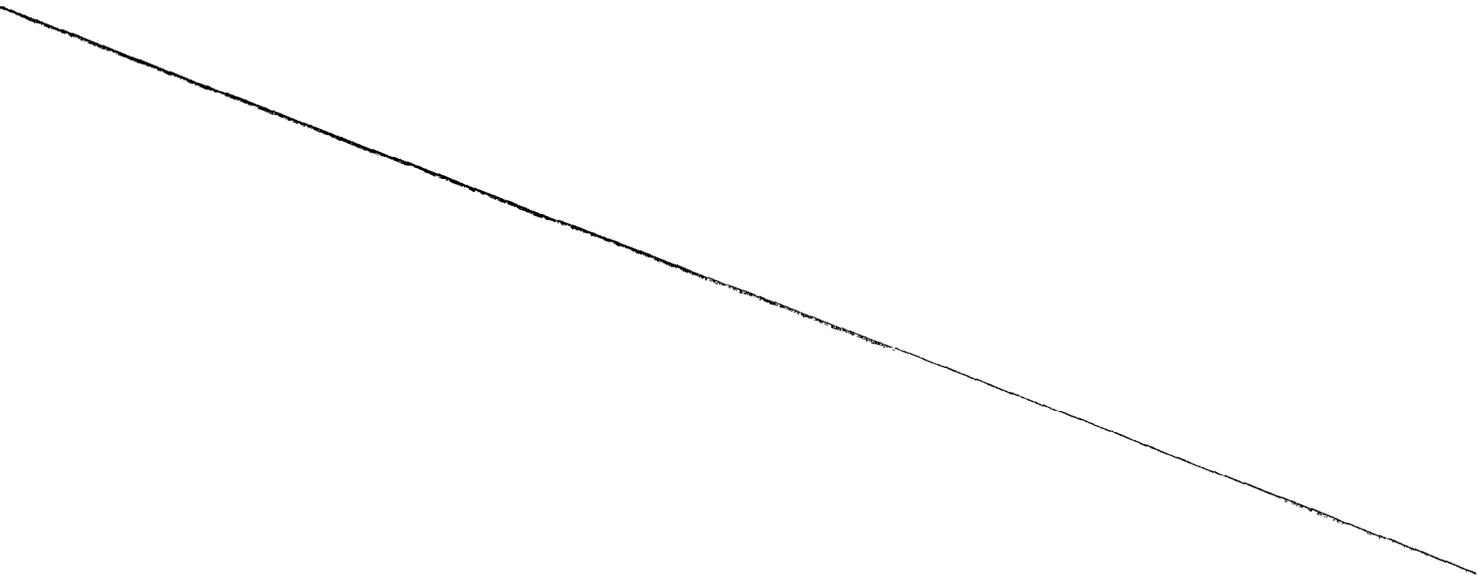
In the **Federal Register** of December 7, 1999 (64 FR 68357), FDA published a notice announcing the availability of a draft version of this guidance. A number of comments were received in the docket for the 1999 draft guidance.

After careful consideration of the comments, the draft guidance was revised. Although we made a number of clarifying edits and tried to make the guidance more user friendly, the only substantive change to the draft guidance was to correct the implication that certain drugs should be studied in patients with concurrent hepatic and renal impairment.

This level 1 final 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 pharmacokinetic studies in patients with impaired hepatic function. 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

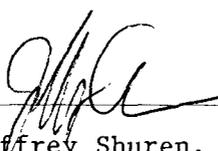
Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in 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 <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 5/22/03
May 22, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

