DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5047]

Draft Guidance for Industry on Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.'' This draft guidance provides recommendations to sponsors planning to conduct studies to assess the influence of hepatic impairment on the pharmacokinetics and, where appropriate,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DATES: Submit written comments on the draft guidance for industry by February 7, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance entitled ''Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling'' to the Drug Information Branch (HFD–210), 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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.'' This draft guidance provides recommendations on: (1) When pharmacokinetic studies in patients with hepatic impairments are or are not recommended; (2) the design and conduct of studies to characterize the effects of impaired hepatic function on the pharmacokinetics of a drug; (3) characteristics of 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.

The draft guidance reflects the current view that the liver generally plays an important role in the elimination (metabolism and/or excretion) of a drug and that the effect of hepatic impairment on the elimination of a new drug should generally be defined during drug development.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft 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 statute, regulations, or both.

Interested persons may, on or before February 7, 2000, submit to the Dockets Management Branch (address above) written 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.

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9004–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—First Quarter, 1999

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published during January, February, and March of 1999, relating to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that potentially may be covered under Medicare.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons.

Questions concerning Medicare items in Addendum III may be addressed to Bridget Wilhite, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–5248.

Questions concerning Medicaid items in Addendum III may be addressed to Betty Stanton, Center for Medicaid State Operations, Policy Coordination and Planning Group, Health Care Financing Administration, S2–26–13, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–3247.

Questions concerning Food and Drug Administration-approved investigational device exemptions may be addressed to Sharon Hippler, Office