
Guidance for Industry

Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication of the *Federal Register* notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of the draft document contact in CDER Mehul Mehta, 301-594-2567, FAX 301-480-3212, or mehta@cder.fda.gov; or, in CBER, David Green, 301-827-5349, FAX 301-827-5394, or greenm@cber.fda.gov.

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Center for Biologics Evaluation and Research (CBER)
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 Mrs. Rosalind A. Schnall
2584 Charney Road
University Heights, OH 44118



HKA
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Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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