Assessing the Effects of Food on Drugs in INDs and NDAs
Clinical Pharmacology Considerations Final Guidance

What Is Covered in This Guidance?
A final guidance has been issued providing recommendations on the conduct of food effect (FE) studies for orally administered drug products.

Assessing the Effects of Food on Drugs in INDs and NDAs - Clinical Pharmacology Considerations

Why is this guidance important?
Food can affect the absorption of drugs from the gastrointestinal (GI) tract. This can impact plasma levels of the drug resulting in changes in safety and efficacy. Sponsors should assess the effects of food on the pharmacokinetics (PK) of oral investigational drugs to inform the drug development program and product labeling.

Guidance Snapshots are a communication tool and are not a substitute for the guidance document. To learn more about assessing the effects of food on drugs, read the guidance:

www.fda.gov
Guidance Snapshots are a communication tool and are not a substitute for the guidance document.

To learn more about assessing the effects of food on drugs, read the guidance:
Background About the Guidance

This guidance finalizes draft guidance issued in February 2019. It revises and replaces the part of the 2002 FDA guidance titled Food-Effect Bioavailability and Fed Bioequivalence Studies. Information on fed bioequivalence studies to be submitted in abbreviated new drug applications (ANDAs) is now found in the FDA guidance for industry titled Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA. Specific recommendations concerning fed comparability trials are now described in the FDA guidance for industry titled Bioavailability Studies Submitted in NDAs or INDs — General Considerations.

Guidance Recap Podcast – Hear Highlights Straight From FDA Staff
Speakers: Vikram Arya, PhD, FCP, Associate Director for Therapeutic Review in the Division of Infectious Disease Pharmacology, and Brian Booth, PhD, Director of the Division of Cancer Pharmacology I.

Click here to listen  Click here to read transcript

Guidance Snapshots are a communication tool and are not a substitute for the guidance document.

To learn more about assessing the effects of food on drugs, read the guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-effects-food-drugs-inds-and-ndas-clinical-pharmacology-considerations

To see additional Guidance Snapshots, check out the pilot program: https://www.fda.gov/drugs/guidances-drugs/guidance-snapshot-pilot