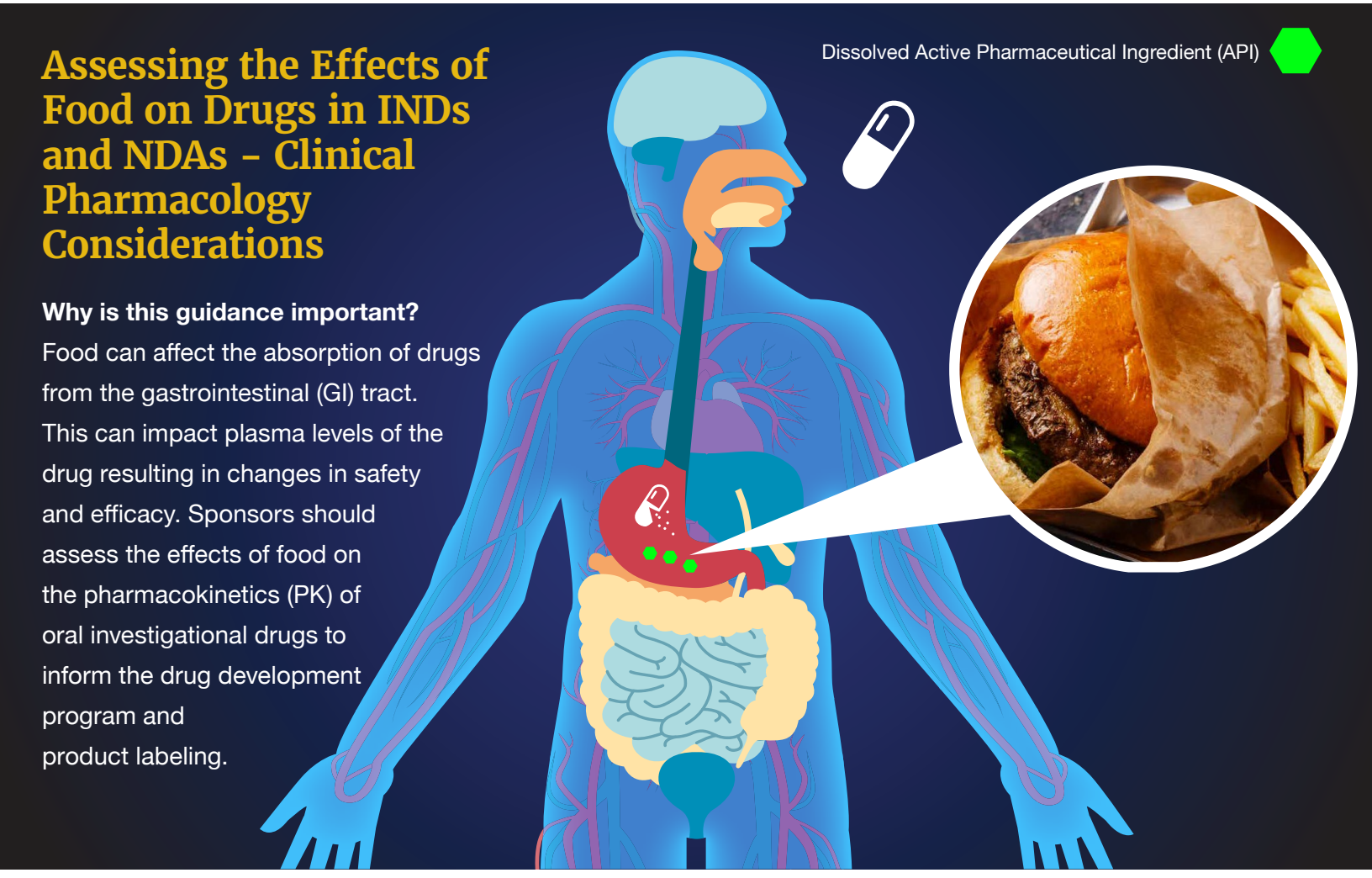
U.S. FOOD & DRUG ADMINISTRATION

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

FINAL GUIDANCE (MAY 2026)

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.



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/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM631941.pdf

WHAT

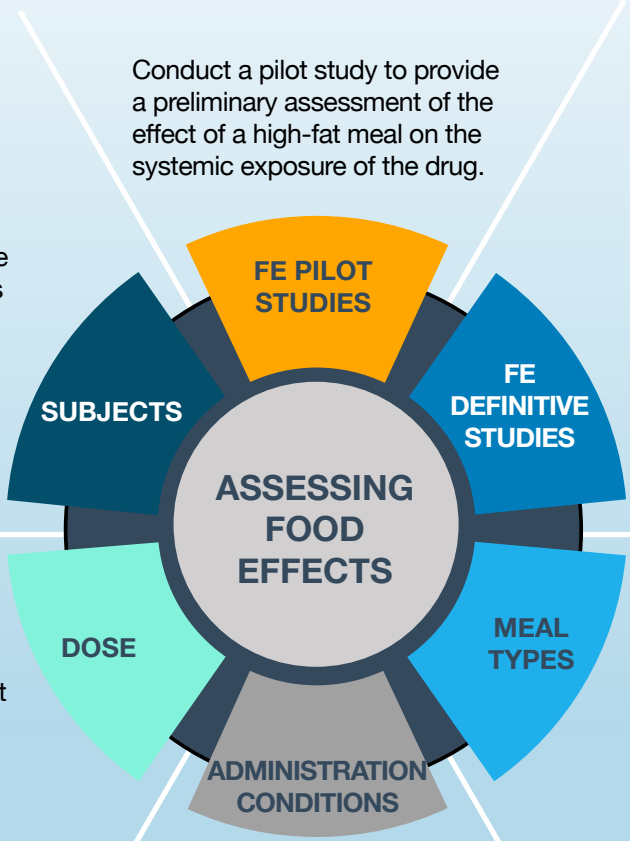
The guidance provides general considerations for designing FE studies, as well as recommendations for data analysis and labeling.

WHY

Food can have a significant impact on the safety or efficacy of orally administered drug products. In some cases, food can be used to improve tolerability of a drug that causes GI discomfort. Well-conducted FE studies can inform how, when, and why drugs should or should not be administered with food.

WHEN

Sponsors should assess the effect of food on the PK of a new drug early in its development to guide the overall drug development program and final product labeling. Sponsors should test the effect of food on a new drug in clinical trials before conducting the pivotal safety and efficacy trials to provide informed decisions regarding dosing with respect to food.



Conduct a pilot study to provide a preliminary assessment of the effect of a high-fat meal on the systemic exposure of the drug.

Conduct FE studies in an adequate number of healthy subjects, unless precluded by safety concerns, to sufficiently characterize the food effect.

Use a randomized, balanced, single-dose, two-treatment (i.e., fed versus fasted), two-period, crossover design.

Use the clinically recommended dose in the pivotal FE study; when several doses of a drug that exhibit linear PK will be marketed, use the highest clinically recommended dose unless safety concerns necessitate a lower dose.

Conduct an FE study with a high-fat meal for all orally administered drugs. When a significant FE is observed with a high-fat meal, evaluation of other meal types—such as a low-fat meal—can be performed to further inform labeling.

Incorporate specific fasting and fed recommendations, including meal content, timing, and water restrictions, into study design.

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Background About the Guidance

This guidance removed Appendix 3 'Labeling Examples' from the 2022 final guidance of the same name, which revised and replaced 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 provided in the FDA guidance for industry Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA (August 2021). Specific recommendations concerning fed comparability trials are described in the FDA guidance for industry Bioavailability Studies Submitted in NDAs or INDs — General Considerations. (April 2022).

Guidance Recommendations Apply Throughout the Drug Development Timeline

During Clinical Development: Food-drug interactions can have a significant impact on the safety and efficacy of a drug. These effects can be manifested in different ways. Assessing the effect of food on the absorption of an orally administered drug contributes to the optimization of the safety and efficacy of the product and helps provide adequate instructions for drug administration in relation to food. During new drug development, FE studies are conducted to determine if, and to what extent, food impacts the systemic exposure of the drug; whether food changes the variability of the systemic exposure of the drug; and if the effect of food is different across meals with varying fat or caloric contents.

Guidance Recap Podcast – Hear Highlights Straight From FDA Staff

Speakers: Vikram Arya, PhD, FCP, former Associate Director for Therapeutic Review in the Division of Infectious Disease Pharmacology, and Brian Booth, PhD, Director of the Division of Cancer Pharmacology I.

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To see additional Guidance Snapshots, check out the pilot program:

https://www.fda.gov/drugs/guidances-drugs/guidance-snapshot-pilot