What Clinical Pharmacology considerations were provided in CRLs as Additional Comments (i.e., Not an approval issue)?

See NDA 218317, NDA 217002, NDA 217724, NDA 761433, NDA 215244, NDA 215455, and NDA 220049.

The following trends were seen in additional comments in the Complete Response Letters issued by FDA between January 12, 2024 and August 18, 2025:
*Perform an exposure-response analysis.
*Conduct drug-drug interaction studies.
*Conduct a transporter study.
*Perform a renal impairment study.
*Perform a hepatic impairment study.
*Provide immunogenicity data.

If you read (or better yet, help author!) a lot of Complete Response Letters, it becomes clear that Clinical Pharmacology comments are always in the context of all other information on the drug. It takes experience to understand when organ impairment information is key to approval; when studies can be conducted post-approval or even addressed with existing data.

Note: This is my independent analysis of the Complete Response Letters released by FDA on September 4, 2025.
https://www.fda.gov/news-events/press-announcements/fda-announces-real-time-release-complete-response-letters-posts-previously-unpublished-batch-89

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