

Center for Drug Evaluation and Research (CDER)

Nonprescription Drugs Advisory Committee (NDAC) Meeting
September 11-12, 2023

QUESTIONS

1. **DISCUSSION:** Discuss the current scientific efficacy and pharmacokinetic data for phenylephrine.
2. **VOTE:** Do the current scientific data that were presented support that the monograph dosage of orally administered phenylephrine is effective as a nasal decongestant?
 - a. If yes, discuss what data you consider supportive.
 - b. If no, discuss what additional data, if any, are needed to assess phenylephrine pharmacokinetics or efficacy.
3. **DISCUSSION:** Discuss whether the current scientific data that were presented support that a dose of orally administered phenylephrine higher than the monograph dosage would be safe and effective.
4. **DISCUSSION:** Discuss the implications for and communication strategies to consumers of the current oral phenylephrine data.