

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
January 24, 2023

DRAFT QUESTIONS

1. **VOTE:** Is the overall benefit-risk assessment favorable for the use of rezafungin for treatment of candidemia/invasive candidiasis in adults with limited or no alternative treatment options?
 - If yes, it would help us to understand the context of use for rezafungin, that is, the clinical scenario(s) in which rezafungin fulfills an unmet need.
 - If no, please comment on the additional information that would be needed for the benefit-risk assessment to be favorable for the use of rezafungin in this/these population(s).