

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
September 9, 2024

QUESTIONS

- 1. DISCUSSION:** The Applicant is seeking an indication for sulopenem etzadroxil/probenecid in adult women ≥ 18 years of age for the treatment of uncomplicated urinary tract infection (UTI) caused by designated susceptible microorganisms. Discuss the overall benefits and risks for the use of sulopenem etzadroxil/probenecid for this indication.
- 2. DISCUSSION:** Considering the totality of the evidence in this application, discuss considerations that would be important for medical providers to know to ensure appropriate use of sulopenem etzadroxil/probenecid.