

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

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

**DRAFT QUESTIONS**

---

---

1. **DISCUSSION:** The Applicant is seeking an indication for sulopenem etzadroxil/probenecid in adult women  $\geq 18$  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.

DRAFT