

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting

DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom

8120 Wisconsin Avenue Bethesda, Maryland

May 2, 2018

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the safety and effectiveness of plazomicin for the treatment of complicated urinary tract infections in patients with limited or no treatment options?
 - a. If yes, please provide any recommendations regarding labeling.
 - b. If no, what additional studies/analyses are needed?

2. **VOTE:** Has the applicant provided substantial evidence of the safety and effectiveness of plazomicin for the treatment of bloodstream infections in patients with limited or no treatment options?
 - a. If yes, please provide any recommendations regarding labeling.
 - b. If no, what additional studies/analyses are needed?