

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting

College Park Marriott Hotel and Conference Center, General Vessey Ballroom

3501 University Blvd. East, Hyattsville, Maryland

January 11, 2018

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the safety and efficacy of ciprofloxacin dispersion for inhalation in delaying the time to first exacerbation after starting treatment in non-cystic fibrosis bronchiectasis patients with chronic lung infections with *Pseudomonas aeruginosa*?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed? Please discuss appropriate endpoints, drug regimens and trial duration.