

**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

**DRAFT 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.