

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Anti-Infective Drugs Advisory Committee (AIDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
September 5, 2012

Questions to the Committee

- 1) **DISCUSSION:** Please discuss the implications of the changes in minimum inhibitory concentrations (MICs) seen after treatment with tobramycin inhalation powder (TIP) compared to tobramycin solution for inhalation.
- 2) **VOTE:** Has the applicant demonstrated adequate evidence of safety and efficacy to support the use of tobramycin inhalation powder (TIP) in the management of cystic fibrosis patients infected with *Pseudomonas aeruginosa*?
 - a. If you voted “Yes” in question 2, please discuss any recommendations concerning labeling of the product.
 - b. If you voted “No” in question 2, please discuss what additional data are needed.