

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Meeting of the Anti-Infective Drugs Advisory Committee
Hilton Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, Maryland
November 4, 2011

FINAL QUESTIONS TO THE COMMITTEE

1. **DISCUSSION:** Please discuss the merits and limitations of the single trial plus supportive information proposal for Hospital-Acquired Bacterial Pneumonia/Ventilator-Associated Bacterial Pneumonia (HABP/VABP). Please discuss the types of supportive evidence that would be considered acceptable if only a single HABP/VABP trial is conducted.
2. **DISCUSSION:** Please discuss if a noninferiority margin of 10% will be acceptable if the active control mortality rate is less than 20%. Please discuss if the odds ratio or risk difference metric is preferred when the control mortality rate is less than 20%.
3. **DISCUSSION:** Please discuss the preferred timing for the all cause mortality endpoint. Would an assessment at an earlier time point be preferred to the 28-day assessment?
4. **DISCUSSION:** Please discuss the following scenarios regarding use of prior antibacterial drugs:
 - a. If empiric antibacterial treatment for HABP/VABP has begun prior to enrollment in the trial, what duration of therapy would be acceptable and unlikely to confound interpretation of the treatment effect of the study drug? Please describe your rationale. Please discuss what other information might be useful to address this question.
 - b. Should a patient who develops HABP/VABP while receiving antibacterial drugs for other infections be enrolled in a HABP/VABP trial? If so, please discuss some scenarios where this will be acceptable.