

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

June 9, 2016

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the safety and effectiveness of bezlotoxumab for the prevention of *C. difficile* infection recurrence in patients aged 18 years and older?
 - a. If yes, please discuss your rationale and provide any recommendations concerning labeling.
 - b. If no, please discuss your rationale and what additional studies/analyses are needed.