

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

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
March 31, 2014

DRAFT QUESTION

Afternoon Session on Dalbavancin

1. Has the applicant provided substantial evidence of the safety and effectiveness of dalbavancin for the treatment of acute bacterial skin and skin structure infections caused by susceptible isolates of the designated microorganisms?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed?

DRAFT