

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

July 26, 2018

QUESTIONS

1. **VOTE:** Has the applicant provided substantial evidence of the effectiveness of tafenoquine for the prevention of malaria in adults for up to 6 months of continuous dosing?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed?

2. **VOTE:** Has the applicant provided adequate evidence of the safety of tafenoquine for the prevention of malaria in adults for up to 6 months of continuous dosing?
 - a. If yes, please provide any recommendations concerning labeling.
 - b. If no, what additional studies/analyses are needed?