

**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

**DRAFT QUESTIONS**

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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?