

**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 12, 2018*

DRAFT AGENDA

The committee will discuss new drug application (NDA) 210795, tafenoquine tablet, 150 mg, sponsored by GlaxoSmithKline Intellectual Property Development Ltd. England, for the proposed indication of the radical cure (prevention of relapse) of Plasmodium vivax malaria.

8:30 a.m.	Call to Order and Introduction of Committee	Lindsey Baden, MD Chairperson, AMDAC
8:40 a.m.	Conflict of Interest Statement	Kalyani Bhatt, BS, MS Acting Designated Federal Officer, AMDAC
8:45 a.m.	FDA Opening Remarks	Yuliya Yasinskaya, MD Clinical Team Leader Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:55 a.m.	APPLICANT PRESENTATIONS	GlaxoSmithKline (GSK) Intellectual Property Development Ltd.
	Introduction	Dr. Joerg-Peter Kleim, PhD Director Clinical Development and Medicines Development Leader, GSK
	Unmet Need	Dr. Kevin Baird, PhD Professor of Malariology Head of Unit, Eijkman Oxford Clinical Research Unit Jakarta, Indonesia
	Study Design and Clinical Efficacy	Dr. Justin Green, MD Director, Clinical Development and Project Physician Lead, GSK
	Safety Results	Dr. Alison Webster, MD Head of Clinical Development Global Health, GSK
	Clinical Perspective	Dr. Richard (Ric) Price, MD Professor of Tropical Medicine The University of Oxford Menzies School of Health Darwin, Australia

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DRAFT AGENDA (cont.)

10:25 a.m. Clarifying Questions

10:40 a.m. **BREAK**

10:50 a.m. **FDA PRESENTATIONS**

Presentation of Clinical Efficacy

Xianbin Li, PhD
Statistical Reviewer
Division of Biometrics IV
Office of Biostatistics
Office of Translational Sciences, CDER, FDA

Presentation of Clinical Safety

Elizabeth O'Shaughnessy, MD
Medical Officer
DAIP, OAP, OND, CDER, FDA

12:20 p.m. Clarifying Questions

12:35 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. **BREAK**

2:40 p.m. Questions to the Committee/Committee Discussion

4:00 p.m. **ADJOURNMENT**