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 AGENDA

The committee will discuss new drug application (NDA) 210607, tafenoquine tablet, 100 milligram (mg), sponsored by 60 Degrees Pharmaceuticals, LLC, for the proposed indication of prevention of malaria in adults for up to 6 months of continuous dosing.

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**	**60 Degrees Pharmaceuticals, LLC**
	Overview and Background Development of ARAKODA™	**Geoffrey Dow, PhD** Chief Executive Officer 60 Degrees Pharmaceuticals, LLC
	Unmet Medical Need – Military	**Bryan Smith, MD** Chief Medical Officer 60 Degrees Pharmaceuticals, LLC
	Unmet Medical Need – Australia	**Mark Reid, MBA** Principal Consultant Clinical Network Services, Pty Ltd Australia
	Unmet Medical Need – Travelers	**Stephen Toovey, MD, PhD** Pegasus Research Switzerland
	Efficacy of ARAKODA™ in Clinical Trials	**Jonathan Berman, MD, PhD** Vice President Clinical Affairs Fast-Track Drugs & Biologics, LLC
	Safety of ARAKODA™ in Clinical Trials	**Bryan Smith, MD**
	Benefit/Risk Assessment	**Stephen Toovey, MD, PhD**

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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 Nonclinical Pharmacology and Toxicology	**Owen McMaster, PhD** Pharmacology/Toxicology Reviewer DAIP, OAP, OND, CDER, FDA
	Presentation of Clinical Safety	**Sheral Patel, 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**	