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
November 16, 2017

DRAFT AGENDA

The committee will discuss new drug application (NDA) 209367, ciprofloxacin inhalation powder, sponsored by Bayer HealthCare Pharmaceuticals, Inc., for the proposed indication of reduction of exacerbations in non-cystic fibrosis bronchiectasis (NCFB) adult patients (≥18 years of age) with respiratory bacterial pathogens.

8:30 a.m.	Call to Order and Introduction of Committee	**Lindsey R. Baden, MD** Chairperson, AMDAC
8:40 a.m.	Conflict of Interest Statement	**Lauren D. Tesh, PharmD, BCPS** Designated Federal Officer, AMDAC
8:45 a.m.	FDA Opening Remarks	**Thomas Smith, 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**	**Bayer HealthCare Pharmaceuticals, Inc.**
	Introduction	**Jana Napolitano, MSc** Vice President, Regulatory Affairs Strategy – Pulmonology, Anti-Infectives and Ophthalmology Bayer
	Medical Landscape in Non-Cystic Fibrosis Bronchiectasis	**Pamela McShane, MD** Assistant Professor of Medicine Section of Pulmonary and Critical Care Medicine University of Chicago
	Efficacy and Microbiology	**Jeff Alder, PhD** Senior Director, Global Clinical Development, Bayer
	Safety	**Gesa Schomakers, MD** Head of Therapeutic Area Anti-Infectives, Pharmacovigilance Benefit-Risk Management, Bayer
	Clinical Perspective on Ciprofloxacin DPI Safety & Effectiveness	**Timothy Aksamit, MD** Associate Professor of Medicine Pulmonary Disease and Critical Care Medicine Mayo Clinic, Rochester
	Conclusion	**Jeff Alder, 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	**Christopher Kadoorie, PhD** Statistical Reviewer Division of Biometrics IV Office of Biostatistics Office of Translational Sciences (OTS), CDER, FDA
	Presentation of Clinical Safety	**Peter Kim, MD, MS** Medical Officer DAIP, OAP, OND, CDER, FDA
	Summary Presentation	**Thomas Smith, MD**
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**	