

**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

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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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**