

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Antimicrobial Drugs Advisory Committee Meeting (AMDAC) and the  
Drug Safety and Risk Management Advisory Committee (DSaRM)***

FDA White Oak Campus, 10903 New Hampshire Avenue  
Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, Maryland  
November 5, 2015

**DRAFT AGENDA**

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*The committees will discuss the risks and benefits of the systemic fluoroquinolone antibacterial drugs for the treatment of acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis in patients who have chronic obstructive pulmonary disease, and uncomplicated urinary tract infections in the context of available safety information and the treatment effect of antibacterial drugs in these clinical conditions.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>CAPT Monica Parise, MD</b> Chairperson, AMDAC
8:10 a.m.	Conflict of Interest Statement	<b>Jennifer Shepherd, RPh.</b> Designated Federal Officer, AMDAC
8:15 a.m.	FDA Introductory Remarks	<b>Sumathi Nambiar, MD, MPH</b> Division Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	<b>FDA PRESENTATIONS</b>	
	ABS, ABECB-COPD, and uUTI Antibacterial Drug Treatment Effects	<b>Joseph Toerner, MD, MPH</b> Deputy Director for Safety DAIP, OAP, OND, CDER, FDA
	Oral Fluoroquinolone Utilization Patterns	<b>LT Travis Ready, PharmD</b> Drug Use Analyst Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Epidemiology of Selected Fluoroquinolone-associated Adverse Reactions – A Literature Review	<b>LCDR James Phillip Trinidad, MPH, MS</b> Epidemiologist Division of Epidemiology II Office of Pharmacovigilance and Epidemiology (OPE), OSE, CDER, FDA
	“Fluoroquinolone-Associated Disability” (FQAD) Cases in Patients Being Treated for Uncomplicated Sinusitis, Bronchitis, and/or Urinary Tract Infections	<b>Debra Boxwell, PharmD</b> Division of Pharmacovigilance II OPE, OSE, CDER, FDA
9:45 a.m.	Clarifying Questions to the Presenters	
10:00 a.m.	<b>BREAK</b>	

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**DRAFT AGENDA (cont.)**

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10:15 a.m. **INDUSTRY PRESENTATIONS**

Introduction

**Melissa Tokosh**

Director, Global Regulatory Affairs  
Established Products  
Janssen Research & Development, LLC

Medical Need for Fluoroquinolones

**Lionel A. Mandell MD, FRCPC, FRCP  
[LOND]**

Professor Emeritus  
Department of Medicine, McMaster University  
Hamilton, Ontario, Canada

Appropriate Role for Fluoroquinolones

**Jeff Alder, PhD**

Senior Director, Global Clinical Development  
Anti-Infectives/Primary Care  
Bayer HealthCare Pharmaceuticals Inc.

Safety of Fluoroquinolones

**Susan C. Nicholson, MD, FIDSA**

Vice President Safety Surveillance and Risk  
Management  
Johnson and Johnson Family of Companies

Benefits/Risks

**Stephen H. Zinner, MD**

Charles S. Davidson Distinguished Professor of  
Medicine  
Harvard Medical School  
Past Chair, Department of Medicine  
Mount Auburn Hospital  
Cambridge, MA

Conclusions

**Jeff Alder, PhD**

11:45 a.m. Clarifying Questions to the Presenters

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:45 p.m. **BREAK**

3:00 p.m. Questions to the Committee/Committee Discussion

6:00 p.m. **ADJOURNMENT**