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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
November 4, 2016

DRAFT AGENDA

The committee will discuss new drug applications 209006 and 209007, solithromycin capsules and solithromycin for injection, sponsored by Cempra Pharmaceuticals, Inc., respectively, for the proposed indication of treatment of community-acquired bacterial pneumonia.

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 Introductory Remarks	**Sumathi Nambiar, MD, MPH** Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:50 am.	**APPLICANT PRESENTATIONS**	**Cempra Pharmaceuticals, Inc.**
	Introduction	**Prabhavathi Fernandes, PhD** President and CEO Cempra, Inc.
	Unmet Need in CABP	**Julio Ramirez, MD** Professor of Medicine Chief, Division of Infectious Diseases University of Louisville
	Microbiology and PK/PD	**Prabhavathi Fernandes, PhD**
	Solithromycin Phase 3 Study Design	**David Oldach, MD** Chief Medical Officer Cempra, Inc.
	Efficacy	**Anita Das, PhD** Biostatistics Cempra Consultant
	Safety	**David Oldach, MD** **Paul Watkins, MD** Director, University of North Carolina School of Pharmacy Institute for Drug Safety Sciences

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Primary Care Perspective	**Steve Vacalis, DO** Family Medicine Physician CaroMont Family Medicine
10:20 a.m.	Clarifying Questions to the Presenters	
10:35 a.m.	**BREAK**	
10:50 a.m.	**FDA PRESENTATIONS**	
	Presentation of Clinical Efficacy	**Daniel B. Rubin, PhD** Statistical Reviewer Division of Biometrics IV Office of Biostatistics Office of Translational Sciences (OTS) CDER, FDA
	Presentation of Clinical Safety	**Ramya Gopinath, MD** Medical Officer DAIP, OAP, OND, CDER, FDA
	Presentation of Clinical Pharmacology	**Yongheng Zhang, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology IV Office of Clinical Pharmacology, OTS, CDER, FDA
12:20 p.m.	Clarifying Questions to the Presenters	
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	
5:00 p.m.	**ADJOURNMENT**	