FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE
CDER Advisory Committee Conference Room
5630 Fishers Lane, Rm. 1066
Rockville, MD

July 16, 2008

AGENDA (Draft)

The committee will discuss new drug application (NDA) 022–171, doripenem powder for reconstitution and intravenous administration, Johnson and Johnson Pharmaceutical Research and Development, LLC, proposed for the treatment of nosocomial pneumonia, including ventilator-associated pneumonia.

8:00 – 8:15 am	Call to Order and Opening Remarks	**Gregory Townsend, MD** Acting Chair, Anti-Infective Drugs Advisory Committee
	Introduction of Committee Conflict of Interest Statement	**LCDR Sohail Mosaddegh, PharmD, RPh** Designated Federal Officer FDA - USPHS
8:15 - 8:30 am	Welcome and Meeting Overview	**Katherine Laessig, MD** Deputy Director Division of Anti-infective and Ophthalmology Products CDER, FDA
	<u>Applicant Presentations</u>	
8:30 – 9:30 am	Applicant	Johnson and Johnson Pharmaceutical Research & Development, LLC (J&JPRD)
	Introduction	**Alysia Baldwin-Ferro** Senior Director, Regulatory Affairs J&JPRD
	Management of Nosocomial Pneumonia (NP)	**Richard G. Wunderink, MD** Professor, Division of Pulmonary & Critical Care The Feinberg School of Medicine Northwestern University Evanston, Illinois

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Agenda *Continued:*

	Microbiology PK/PD	**Robert Flamm, PhD** Director, Microbiology J&JPRD
	Clinical Study Design Clinical Efficacy	**Ian Friedland, MD** Franchise Medical Leader, Clinical Development J&JPRD
	Clinical Safety Benefit/Risk Conclusions: Doripenem for NP	**Rebecca Redman, MD** Senior Director, Clinical Development J&JPRD
9:30-9:45 am	Questions regarding Applicant's presentation	
	FDA Presentations	
9:45-10:30 am	Clinical Trials for NP and ventilator-associated pneumonia (VAP): Regulatory Approach to the Non-inferiority Margin Justification	**Alfred Sorbello, DO, MPH** Medical Officer Division of Anti-Infective and Ophthalmology Products CDER, FDA and **Scott Komo, DrPH** Statistical Reviewer Division of Anti-Infective and Ophthalmology Products CDER, FDA
10:30 – 10:45 am	**Break**	
10:45 – 11:15 am	Clinical Efficacy of Doripenem	**Thomas Smith, MD** Acting Clinical Team Leader Division of Anti-Infective and Ophthalmology Products CDER, FDA
11:15 – 12:15 pm	Open Public Hearing	

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Agenda *Continued:*

12:15 – 1:15 pm	**Lunch**	
1:15 – 1:30 pm	Clinical Safety of Doripenem	**Alfred Sorbello, DO, MPH** Medical Officer Division of Anti-Infective and Ophthalmology Products CDER, FDA
1:30 – 2:00 pm	Microbial Resistance	**Peter Coderre, PhD** Microbiology Reviewer Division of Anti-Infective and Ophthalmology Products CDER, FDA
2:00 – 2:15 pm	Questions/Clarifications	
2:15 –3:15 pm	Charge and questions to the Committee	**Katherine Laessig, MD** Deputy Director Division of Anti-infective and Ophthalmology Products CDER, FDA
3:15 - 3:30 pm	**Break**	
3:30 - 5:00 pm	Questions to the Committee	
5:00 pm	**Adjournment**	