FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH (CDER) Anti-Infective Drugs Advisory Committee CDER Advisory Committee Conference Room, Room 1066 5630 Fishers Lane, Rockville, MD				
AGENDA March 6, 2006				
The committee will discuss new drug application (NDA) 21-572/S-008, Cubicin (daptomycin for injection 500 mg/vial); Sponsor Cubist Pharmaceuticals, for the proposed indication of the treatment of Staphylococcus aureus bacteremia, including those with known or suspected endocarditis caused by methicillin-susceptible and methicillin-resistant strains.				
8:30	Call to Order and Introductions	James E. Leggett, Jr., M.D. Acting Committee Chair Anti-Infective Drugs Advisory Committee		
	Conflict of Interest Statement	LCDR Cathy Groupe, B.S.N. Acting Executive Secretary Anti-Infective Drugs Advisory Committee		
8:40	Introduction	Janice Soreth, M.D. Director Division of Anti-Infective and Ophthalmology Products CDER, FDA		
8:45	Food and Drug Administration Guest Speaker Presentation			
	S. <i>aureus</i> Bacteremia and Endocarditis: Epidemiologic Considerations	John Edwards, Jr., M.D. Professor of Medicine, UCLA School of Medicine Chief, Infectious Diseases, Department of Medicine Harbor-UCLA Medical Center Torrance, CA		
9:15	Cubist Pharmaceuticals Presentation			
	Overview of <i>S. aureus</i> Disease	Henry Chambers, M.D. Professor of Medicine Chief, Division of Infectious Diseases, San Francisco General Hospital San Francisco, CA		
9:45	Break			
10:00	Introduction	David Mantus, Ph.D. Vice President, Regulatory Affairs Cubist Pharmaceuticals		
	Efficacy Results	Helen Whamond Boucher, M.D. Assistant Professor of Medicine Division of Infectious Diseases and Geographic Medicine Tufts University - New England Medical Center Boston, MA		

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	Cubist Pharmaceuticals Presentation (Continued)		
	Microbiology	Jeff Alder, Ph.D. Vice President, Drug Discovery and Evaluation Cubist Pharmaceuticals	
	Safety Results	Gloria Vigliani, M.D. Vice President, Medical Strategy Cubist Pharmaceuticals	
	Overview of Benefits/Risks	G. Ralph Corey, M.D. Professor of Internal Medicine & Infectious Disease Duke University Medical Center Durham, NC	
11:00-11:15		Committee Questions to the Sponsor	
11:15	Food and Drug Administration Presentation		
	Efficacy Results	Alfred Sorbello, D.O. Medical Officer Division of Anti-Infective and Ophthalmology Products CDER, FDA	
	Microbiology	Peter Coderre, Ph.D. Microbiologist Division of Anti-Infective and Ophthalmology Products CDER, FDA	
	Safety Results	Charles Cooper, M.D. Medical Officer Division of Anti-Infective and Ophthalmology Products CDER, FDA	
12:15-12:30	Committee Questions to the FDA		
12:30	Lunch		
1:30	Open Public Hearing		
2:30	Committee Discussion		
3:00	Break		
3:15	Questions to the Committee		
5:00	Adjournment		