

**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. aureus Bacteremia and** **John Edwards, Jr., M.D.**
Endocarditis: Epidemiologic Professor of Medicine, UCLA School of Medicine
Considerations Chief, Infectious Diseases, Department of Medicine
 Harbor-UCLA Medical Center
 Torrance, CA
- 9:15** **Cubist Pharmaceuticals Presentation**
- Overview of S. aureus 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

