

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE (AIDAC) MEETING

AGENDA
March 5, 2003

Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD

Topic: Discussion of the Formation of a List of Pathogens of Public Health Importance/ Discussion of How
Preclinical Data and Clinical Data from One Disease State May Support Approval of Antimicrobial Drugs
in Another, Separate Disease State

9:00 a.m.	Call to Order	James E. Leggett, Jr., M.D. Acting Chair, AIDAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AIDAC
	Opening Comments	Mark Goldberger, M.D., M.P.H. Director Office of Drug Evaluation IV Food and Drug Administration
9:15 a.m.	Linkages of Resistance Determinants in Bacteria	James H. Jorgensen, Ph.D. Professor of Pathology University of Texas Health Science Center
9:45 a.m.	Questions from Committee	
10:00 a.m.	Industry Perspective on List of Pathogens	Francis P. Tally, M.D. Executive Vice President and Chief Scientific Officer Cubist Pharmaceuticals, Inc.
10:20 a.m.	Questions from Committee	
10:30 a.m.	Break	
10:45 a.m.	List of Pathogens of Public Health Importance	John H. Powers, M.D. Lead Medical Officer for Antimicrobial Drug Development Office of Drug Evaluation IV Food and Drug Administration
11:15 a.m.	Questions from Committee	

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| 12:30 p.m. | Lunch | |
| 1:30 p.m. | Open Public Hearing | |
| 2:00 p.m. | How Clinicians Use Data for Clinical Decision Making | John S. Bradley, M.D.
Director, Division of Infectious Diseases
Children's Hospital San Diego |
| 2:15 p.m. | Relating Clinical Data from One Disease State to Another | Edward Cox, M.D., M.P.H.
Deputy Director
Office of Drug Evaluation IV
Food and Drug Administration |
| 2:30 p.m. | Questions from Committee | |
| 2:45 p.m. | Committee Discussion | |
| 5:00p.m. | Summary and Adjourn | James E. Leggett, Jr., M.D. |