

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
Meeting of the Anti-Infective Drugs Advisory Committee
Hilton Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, Maryland
November 3, 2011

FINAL AGENDA

The committee will discuss clinical trial design issues for the development of antibacterials for the treatment of Community-Acquired Bacterial Pneumonia (CABP) and the draft document entitled "Guidance for Industry, Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment", published March 2009.

8:00 a.m.	Call to Order and Introduction of Committee	Thomas Moore, M.D. Committee Chair, Anti-Infective Drugs Advisory Committee (AIDAC)
	Conflict of Interest Statement	Minh Doan, Pharm.D. Designated Federal Officer, AIDAC
	<u>FDA Presentations</u>	
8:15 a.m.	Opening Remarks	Edward Cox, M.D., M.P.H. Director Office of Antimicrobial Products (OAP), Office of New Drugs (OND) CDER, FDA
8:30 a.m.	Regulatory Background	Sumati Nambiar, M.D., M.P.H. Deputy Director for Safety Division of Anti-Infective Products (DAIP), OAP, OND, CDER, FDA
	<u>Guest Speaker Presentations</u>	
9:00 a.m.	Issues in Clinical Trials for CABP	James Floyd, M.D., M.S. Representing Public Citizen Department of Epidemiology University of Washington
9:20 a.m.	Community-Acquired Pneumonia Drug Studies in Emergency Departments: The Perspective from a Practicing Emergency Physician	Jeff Dubin, M.D., M.B.A. Vice Chair Department of Emergency Medicine Washington Hospital Center
9:40 a.m.	BREAK	

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FINAL AGENDA (cont.)

Guest Speaker Presentations (cont.)

10:00 a.m.	Endpoints and Clinical Trial Issues in Community-Acquired Bacterial Pneumonia	Thomas M. File, Jr., M.D., M.Sc. Chair, Division of Infectious Disease Summa Health System Professor, Internal Medicine; Master Teacher; Chair, Infectious Disease Section Northeast Ohio Medical University
10:20 a.m.	Design of Clinical Trials in CABP	Barry Eisenstein, M.D., F.A.C.P., FIDSA Senior Vice President Scientific Affairs Cubist Pharmaceuticals
10:40 a.m.		Diana Zuckerman, Ph.D. President National Research Center for Women & Families
11:00 a.m.	Community-Acquired Pneumonia	John Bartlett, M.D. Professor of Medicine Johns Hopkins University School of Medicine
	<u>FDA Presentations (cont.)</u>	
11:20 a.m.	The Path Forward for CABP Drug Development	Katie Laessig, M.D. Deputy Director DAIP, OAP, OND, CDER, FDA
11:40 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the AIDAC and AIDAC Discussion	Edward Cox, M.D., M.P.H. Director OAP, OND, CDER, FDA
5:00 p.m.	ADJOURNMENT	