FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE
Sheraton College Park Hotel

April 1-2, 2008

AGENDA

Presentations, discussion, and questions will focus on clinical trial design issues in the development of products for the treatment of community acquired pneumonia (CAP). The primary objectives for the committee deliberations are to discuss issues relating to the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up.

Day one, April 1, 2008

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 – 8:45 am	FDA Introductory Remarks and Regulatory Background	Edward Cox, MD, MPH Director, Office of Antimicrobial Products CDER, FDA
8:45 – 9:15 am	Key Issues from FDA-IDSA Workshop	John Alexander, MD, MPH Medical Team Leader Division of Anti-Infective and Ophthalmology Products CDER, FDA
9:15 – 10:00 am	IDSA perspective	Dave Gilbert, MD Chief of Infectious Diseases Providence Portland Medical Center Portland, Oregon Brad Spellberg, MD Assistant Professor of Medicine Geffen School of Medicine at UCLA Division of Infectious Diseases Harbor-UCLA Medical Center Los Angeles, California
10:00 – 10:15 am	**Break**	
10:15 – 10:45am	ATS/ACCP statement	Richard Wunderink, MD Professor of Medicine Pulmonary and Critical Care Division Northwestern University Feinberg School of Medicine Chicago, Illinois

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10:45 – 11:30 pm	Ethical Considerations for Trials of CAP	Robert "Skip" Nelson, MD, PhD Pediatric Ethicist Office of Pediatric Therapeutics Office of the Commissioner, FDA Sara F. Goldkind, MD, MA Senior Bioethicist Good Clinical Practice Program Office of the Commissioner, FDA
11:30 – 12:00 pm	Non-inferiority Issues in Trials of Community Acquired Pneumonia	Tom Fleming, PhD Professor of Biostatistics University of Washington Seattle, Washington
12:00 – 12:15 pm	Questions/clarifications	
12:15 – 1:15 pm	**Lunch**	
1:15 – 2:00 pm	Treatment Effect of Antibacterial Drugs in CAP: A Historical Perspective	Mary Singer, MD, PhD Medical Officer Office of Antimicrobial Products CDER, FDA
2:00 – 2:30 pm	Contemporary CAP Trials and Determination of Treatment Effect	Sumathi Nambiar MD, MPH Medical Team Leader Division of Anti-infective and Ophthalmology Products
2:30 – 3:00 pm	Non-inferiority Margin for CAP Studies: Issues and Approaches	Thamban Valappil, PhD Statistical Team Leader CDER, FDA
3:00 – 3:30 pm	Exposure-Response Analysis for CAP	Christoffer Wenzel Tornoe, PhD Pharmacometrics Reviewer Pharmacometrics, Office of Clinical Pharmacology CDER, FDA
3:30 – 3:45 pm	**Break**	
3:45 – 4:15 pm	Critical Considerations in CAP Trial Design: A Consultant's Perspective	George Talbot, MD George H. Talbot, Talbot Advisors, LLC 564 Maplewood Avenue Wayne, Pennsylvania
4:15 – 5:00 pm	Questions/clarifications	
5:00 pm	**Adjourn**	

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Day two: April 2, 2008

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 – 8:45 am	A Clinician's Scientific Approach to Pneumonia	Daniel M. Musher, MD Head of Infectious Diseases Veterans Affairs Medical Center, Houston, Texas
8:45 – 9:15 am	Considerations in the Design of CAP Studies	Steve Gitterman, M.D., Ph.D. Deputy Director, Division of Special Pathogen and Transplant Products CDER, FDA
9:15 – 10:15 am	Questions/clarifications	
10:15 – 10:30 am	**Break**	
10:30 – 12:00 pm	Questions/Discussion	
12:00 – 1:00 pm	Open Public Hearing	
1:00 – 2:00 pm	**Lunch**	
2:00 – 5:00 pm	Charge to the Committee & Advisory Committee Questions	Edward Cox, MD, MPH Director, Office of Antimicrobial Products CDER, FDA
5:00 pm	**Adjournment**	