

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
ANTIINFECTIVE 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.

<i>April 1, 2008</i>		
8:00 am	Call to Order and Opening Remarks	Gregory Townsend, M.D. Acting Chair, Anti-infective Drugs Advisory Committee
8:15-8:45 am	Introduction of Committee Conflict of Interest Statement FDA Introductory Remarks and Regulatory Background	Sohail Mosaddegh, Pharm.D. R.Ph. Designated Federal Officer Edward Cox, MD, MPH Director, Office of Antimicrobial Products, CDER, FDA
8:45-9:15 am	Review of FDA-IDSAs Workshop	John Alexander, MD, MPH, FDA
9:15 – 10:00 am	IDSAs perspective	Dave Gilbert, MD Brad Spellberg, MD
10:00-10:15 am	Break	
10:15 – 11:00 am	ATS/ACCP statement	Richard Wunderink, M.D.
11:00-11:45 pm	Ethical Considerations for Trials of CAP	Skip Nelson, MD, FDA
11:45– 12:15 pm	Non-inferiority Issues in Trials of Community Acquired Pneumonia	Tom Fleming, PhD
12:15-12:30 pm	Questions/clarifications	
12:30-1:30 pm	Lunch	
1:30 –2:15 pm	Review of Historical Data on Community Acquired Pneumonia	Mary Singer, MD, PhD FDA
2:15 – 3:00 pm	PK/PD relationships for LRTI	Christoffer Tornøe, Ph.D., FDA
3:00 - 4:00 pm	A Clinician's Scientific Approach to Pneumonia	Daniel M. Musher, MD
4:00 – 4:15 pm	Break	
4:15 –5:00 pm	Questions/clarifications	

5:00 pm

Adjourn

*Day two:
April 2, 2008*

8:00 am	Call to Order and Opening Remarks	Gregory Townsend, M.D. Acting Chair, Anti-infective Drugs Advisory Committee
8:15 - 8:45 am	Introduction of Committee Conflict of Interest Statement Critical considerations in CAP Trial Design: A Consultant's Perspective	Sohail Mosaddegh, Pharm.D. R.Ph. Designated Federal Officer George Talbot, MD
9:15 – 9:45 am	Lessons learned from prior registrational CAP trials	Sumati Nambiar, MD, MPH, FDA
9:45 - 10:15 am	Questions/clarifications	
10:15 – 10:30 am	Break	
10:30 – 11:00 am	Clinical Trial Strawmen	Steve Gitterman, MD, PhD, FDA
11:00 am – 12pm	Questions/Discussion	
12:00 pm	Open Public Hearing	
1:00 pm	Lunch	
2:00 pm	AC Questions	
5:00 pm	Adjournment	