

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

DRAFT 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	Committee Chair, AIDAC
	Conflict of Interest Statement	Minh Doan, Pharm.D. Designated Federal Officer, AIDAC
	<u>FDA Presentations</u>	
8:15 a.m.	Opening Remarks	FDA
8:30 a.m.	Regulatory Background	FDA
	<u>Guest Speaker Presentations</u>	
9:00 a.m.		Guest Speaker
9:20 a.m.		Guest Speaker
9:40 a.m.	BREAK	
	<u>Guest Speaker Presentations (cont.)</u>	
10:00 a.m.		Guest Speaker
10:20 a.m.		Guest Speaker
10:40 a.m.		Guest Speaker
11:00 a.m.		Guest Speaker
	<u>FDA Presentation</u>	
11:20 a.m.	The Path Forward for CABP Drug Development	FDA
11:40 a.m.	Clarifying Questions to the Presenters	
12:00 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	

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DRAFT AGENDA (cont.)

2:00 p.m. Questions to the AIDAC and AIDAC
 Discussion

5:00 p.m. **ADJOURNMENT**

DRAFT