

**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 4, 2011

**FINAL AGENDA**

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*The committee will discuss clinical trial design issues in the development of antibacterials for the treatment of Hospital-Acquired Bacterial Pneumonia (HABP), including Ventilator-Associated Bacterial Pneumonia (VABP) and the draft document entitled "Guidance for Industry, Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment", published November 2010.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Thomas Moore, M.D.</b> Committee Chair, Anti-Infective Drugs Advisory Committee (AIDAC)
	Conflict of Interest Statement	<b>Minh Doan, Pharm.D.</b> Designated Federal Officer, AIDAC
8:15 a.m.	<b><u>FDA Presentations</u></b> Opening Remarks	<b>Edward Cox, M.D., M.P.H.</b> Director Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	Regulatory Background	<b>Joe Toerner, M.D., M.P.H.</b> Associate Director for Medical Affairs OAP, OND, CDER, FDA
9:00 a.m.	<b><u>Guest Speaker Presentations</u></b> Ventilator-Associated Pneumonia (VAP) Hospital-Acquired Pneumonia (HAP) Definitions, Diagnostics & Outcomes	<b>Donald Craven, M.D.</b> Chairman, Center for Infectious Diseases & Prevention Lahey Clinic Medical Center Professor of Medicine Tufts University School of Medicine
9:20 a.m.	Issues in Clinical Trials for HAP/VAP	<b>James Floyd, M.D., M.S.</b> Representing Public Citizen Department of Epidemiology University of Washington
9:40 a.m.	Endpoints and Clinical Trial Issues in Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia	<b>Thomas M. File, Jr., M.D., M.Sc.</b> Chair, Division of Infectious Disease Summa Health System Professor, Internal Medicine; Master Teacher; Chair, Infectious Disease Section Northeast Ohio Medical University
10:00 a.m.	<b>BREAK</b>	

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**FINAL AGENDA (cont.)**

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**Guest Speaker Presentations (cont.)**

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| 10:20 a.m. | Development of Drugs for HABP-VABP   | <b>Robert Fromtling, Ph.D.</b><br>Director of Worldwide Regulatory Affairs<br>Infectious Diseases<br>Merck & Co., Inc.                                  |
|            | <b><u>FDA Presentations (cont.)</u></b>  |   |
| 10:40 a.m. | HABP/VABP Trials: An FDA Clinical Perspective  | <b>Katie Laessig, M.D.</b><br>Deputy Director<br>Division of Anti-Infective Products, OAP<br>OND, CDER, FDA   |
| 11:00 a.m. | Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Proposed Development Pathways and Clinical Trial Design | <b>Scott Komo, Dr.P.H.</b><br>Statistical Reviewer<br>Division of Biometrics IV<br>Office of Biostatistics, Office of Translational Sciences, CDER, FDA |
| 11:20 a.m. | Clarifying Questions to the Presenters   |   |
| 12:00 p.m. | <b>LUNCH</b>   |   |
| 1:00 p.m.  | Open Public Hearing  |   |
| 2:00 p.m.  | Questions to the AIDAC and AIDAC Discussion  | <b>Edward Cox, M.D., M.P.H.</b><br>Director<br>OAP, OND, CDER, FDA  |
| 5:00 p.m.  | <b>ADJOURNMENT</b>   |   |