

Center for Drug Evaluation and Research (CDER) and Center for  
Biologic Evaluation and Research  
Food and Drug Administration  
Department of Health and Human Services

**Part 15 Hearing – December 12, 2008**  
**Designating Additions to the Current List of Tropical Diseases in Section**  
**1102 of the Food and Drug Administration Amendments Act**

**FDA Panel Members**

Nancy Boocker, J.D.  
Timothy R. Coté M.D., MPH  
Edward Cox, M.D., M.P.H.  
Michael D. Jones  
Diane Maloney, J.D.  
Dave Roeder  
Wellington Sun, M.D.

**Agenda**

**9:00 – 9:30 am**

Edward Cox, MD, MPH  
Director, Office of Antimicrobial Products, CDER  
*Logistics & Introduction of Panel Members*

David Roeder

Associate Director of Regulatory Affairs, Office of Antimicrobial Products, CDER  
*Introductory Remarks*

**9:30 – 10:30 am**

Wendy Taylor  
Founder and Vice President of Strategy and Operations  
*BIO Ventures for Global Health*

Ben Plumley, Vice President, Partnerships and Global Health Innovation, Tibotec-Virco  
Johnson & Johnson  
*Johnson & Johnson Pharmaceutical Group*

**10:30 – 10:50 am**

*Morning Break*

**10:50 am – 12:05 pm**

John C. Andrews, Ph.D.  
*Chiltern International*

Brad Smith, Ph.D.  
Senior Associate  
*Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC)*

W. James Jackson, Ph.D.  
Senior Vice President; Chief Scientific Officer  
*Emergent Biosolutions*

**12:05 – 1:05 pm**  
Lunch Break

**1:05 – 2:35 pm**  
Theodore (Ted) F. Tsai, MD MPH FIDSA  
Sr. VP, Scientific Affairs  
*Novartis Vaccines (\*Intercell partner for JEV in the USA)*

Greg Glen, MD  
Chief Scientific Officer  
*Intercell USA, Inc.*

Padma Natarajan MPH, MS  
Program Officer for Science and Research  
Public Policy & Government Relations  
*Infectious Diseases Society of America (IDSA)*

Colin Ohrt, MD, MPH, COL, MC  
US Army Program Director, Clinical Pharmacology Fellowship, Consultant to the Surgeon  
General for Clinical Pharmacology, Chief, Department of Clinical Pharmacology,  
Division of Experimental Therapeutics  
*Walter Reed Army Institute of Research*

**Meeting Web Page:**

[http://www.fda.gov/cder/meeting/tropical\\_diseases\\_2008.htm](http://www.fda.gov/cder/meeting/tropical_diseases_2008.htm)