

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE (AIDAC) MEETING

AGENDA
February 19, 2002

Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, MD

Topic: Proposed approach for selection of delta in non-inferiority (equivalence) clinical trials

8:00 a.m.	Call to Order and Introductions	L. Barth Reller, M.D. Chair, AIDAC
8:05 a.m.	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AIDAC
8:10 a.m.	Opening Comments	Mark Goldberger, M.D., M.P.H. Acting Director Office of Drug Evaluation IV, FDA
8:15 a.m.	Historical Perspective, Selection and Implications of Delta	Renata Albrecht, M.D. Acting Director Division of Special Pathogen and Immunologic Drug Products, FDA
8:35 a.m.	Active Control Non-Inferiority Studies: Theory, Assay Sensitivity, Choice of Margin	Robert Temple, M.D. Associate Director for Medical Policy Center for Drug Evaluation and Research, FDA
8:55 a.m.	Statistical Issues in Specification of Delta	Daphne Lin, Ph.D. Statistical Team Leader, FDA Erica Brittain, Ph.D. Statistical Reviewer, FDA
9:35 a.m.	Break	
9:50 a.m.	Medical Perspective: Bacterial Meningitis	George H. McCracken, Jr., M.D. University of Texas Southwestern Medical Center at Dallas
10:15 a.m.	Industry Presentation (PhRMA)	David Shlaes, M.D. Catherine Hardalo, M.D. Lianng Yuh, Ph.D. Christy Chuang-Stein, Ph.D.
10:45 a.m.	Industry Presentation	Francis Tally, M.D. Cubist Pharmaceuticals

11:15 a.m.	IDSA Presentation	Vincent T. Andriole, M.D. George H. Talbot, M.D. Dennis D. Wallace, Ph.D. John E. Edwards, Jr., M.D.
11:45 a.m.	Issues Regarding Choice of the Margin in Non-Inferiority Trials	Thomas R. Fleming, Ph.D. University of Washington
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	Kem Phillips, Ph.D. – Advanced Biologics, LLC (Statement for the Record)
1:30 p.m.	Medical Perspective: Hospital Acquired Pneumonia/Meningitis	John Powers, M.D. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
1:55 p.m.	Medical Perspective: Acute Exacerbation of Chronic Bronchitis	Susan Thompson, M.D. Medical Officer Division of Anti-Infective Drug Products, FDA
2:20 p.m.	Break	
2:35 p.m.	Summary and Charge to Committee	Mark Goldberger, M.D., M.P.H.
2:50 p.m.	Committee Discussion	
5:30 p.m.	Adjourn	