

Supplemental Background Materials

Anti-Infective Drugs Advisory Committee

February 19, 2002 Meeting

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

1. Shlaes DM, Moellering Jr RC. The United States Food and Drug Administration and the End of Antibiotics. *Clin Infect Dis.* 2002;34:420-422.
2. Powers JH, Ross DB, Brittain E, Albrecht R, Goldberger MJ. The U.S. Food and Drug Administration and Non-Inferiority Margins in Clinical Trials of Antimicrobial Agents. *Clin Infect Dis.* 2002 (in press).