## FOOD AND DRUG ADMINISTRATION (FDA) Center for Drug Evaluation and Research (CDER) ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE

## DRAFT AGENDA November 19, 2008 (Morning Session)

The committee will discuss NDA 022-110 Telavancin, Theravance, Inc. and Astellas Pharma, Inc., proposed indication for the treatment of complicated skin and skin structure infections (cSSSI)..

8:00 am	Call to Order and Opening Remarks	Acting Chair, Anti-Infective Drugs

Advisory Committee

Introduction of Committee Janie Kim, PharmD
Conflict of Interest Statement Designated Federal Officer

8:15 am Introduction/Background TBD

9:00 am Applicants presentation Theravance

10:00 am FDA Presentations TBD

9:45 am Questions/Clarification

10:30 am **Break** 

11:30 am Open Public Hearing

11:45 am Charge and Questions to the Committee

12:30 pm **Lunch**