

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee Meeting

HILTON WASHINGTON DC / SILVER SPRING
SILVER SPRING, MARYLAND

JUNE 17, 2008

AGENDA

The committee will discuss biologic licensing application (BLA) 125261, ustekinumab, a human monoclonal antibody, Centocor, Inc., proposed for the treatment of moderate to severe psoriasis.

- 8:00 a.m. Call to Order and Opening Remarks
- Introduction of Committee
- Conflict of Interest Statement
- 8:15 a.m. FDA Introductory Remarks
- INDUSTRY PRESENTATION**
- Questions to Presenters
- FDA PRESENTATION**
- Questions to Presenters
- 12:00 a.m. **LUNCH**
- 1:00 p.m. **OPEN PUBLIC HEARING**
- 2:00 p.m. Questions to the DODAC and Discussion
- 5:00 p.m. **ADJOURN**