

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

Psychopharmacologic Drugs Advisory Committee Meeting

CROWNE PLAZA SILVER SPRING
8777 GEORGIA AVENUE, SILVER SPRING, MARYLAND

FEBRUARY 6, 2008

AGENDA

The committee will discuss new drug application (NDA) 22-173 ZYPREXA ADHERA (olanzapine pamoate depot) long acting intramuscular (IM) injection 210 mg, 300 mg, and 405 mg per/vial, Eli Lilly and Company, for treatment of schizophrenia. A particular safety concern for discussion is the occurrence of severe somnolence in some patients who are administered this depot formulation of olanzapine.

8:00 a.m. Call to Order and Opening Remarks **Matthew Rudorfer, M.D.**
Acting Chair,
Psychopharmacologic Drugs Advisory Committee

Introduction of Committee

Conflict of Interest Statement

Diem-Kieu H. Ngo, Pharm.D., BCPS
Designated Federal Official

8:15 a.m. FDA Introductory Remarks **Thomas Laughren, M.D.**
Director, Division of Psychiatry Products,
OND1, CDER, FDA

FDA PRESENTATION

8:20 a.m. FDA Clinical Review of Olanzapine Pamoate Depot **Jing Zhang, M.D., Ph.D.**
Medical Officer, Division of Psychiatry Products,
OND1, CDER, FDA

8:50 a.m. Exposure-Effectiveness, Safety Assessment **Andre Jackson**
Division of Clinical Pharmacology 1,
OCP, OTS, CDER, FDA

9:00 a.m. Clarifying Questions

9:30 a.m. **BREAK**

9:45 a.m. **INDUSTRY PRESENTATION**

11:45 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions/Clarifications

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AGENDA
-CONTINUED-

- 3:00 p.m. **BREAK**
- 3:15 p.m. Panel Discussion/Questions
- 5:00 p.m. **ADJOURNMENT**

DRAFT