

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,
Office of Drug Evaluation I, OND, CDER, FDA

FDA PRESENTATION

8:20 a.m. FDA Clinical Review of Olanzapine Pamoate Depot in the Treatment of Schizophrenia **Jing Zhang, M.D., Ph.D.**
Medical Officer, Division of Psychiatry Products,
Office of Drug Evaluation I, OND, CDER, FDA

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

9:00 a.m. Clarifying Questions

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

INDUSTRY PRESENTATION

9:45 a.m. Introduction and Overview **Gregory Brophy, Ph.D.**
Director, U.S. Regulatory Affairs
Eli Lilly and Company

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AGENDA
-CONTINUED-

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|------------|---|---|
| 9:50 a.m. | Schizophrenia and Adherence to Medication | John Kane, M.D.
Chairman, Department of Psychiatry
Zucker Hillside Hospital, NY |
| 10:00 a.m. | Product and Development, Pharmacokinetics, OP Depot Efficacy in Schizophrenia | David McDonnell, M.D.
Clinical Research Physician
Eli Lilly and Company |
| 10:25 a.m. | OP Depot Safety in Schizophrenia | Sara Corya, M.D.
Medical Director
Eli Lilly and Company |
| 11:05 a.m. | Benefit-Risk Assessment & Conclusion | John Lauriello, M.D.
Professor and Vice Chair, Department of Psychiatry
University of New Mexico
Executive Medical Director of UNM Psychiatric Center |
| 11:15 a.m. | Clarifying Questions | |
| 11:30 a.m. | OP Depot Reconstitution Demonstration Video | Eli Lilly and Company |
| 12:00 p.m. | LUNCH | |
| 1:00 p.m. | Open Public Hearing | |
| 2:00 p.m. | Questions/Clarifications | |
| 3:00 p.m. | BREAK | |
| 3:15 p.m. | Panel Discussion/Questions | |
| 5:00 p.m. | ADJOURNMENT | |