

**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

QUESTIONS TO ADVISORY COMMITTEE

FEBRUARY 6, 2008

1. What are the public health consequences of a depot antipsychotic that leads unpredictably to profound sedation in 1% or more of patients exposed to this product (Discuss and Comment)?
2. If OP Depot were to be approved and marketed, what risk management procedures would be necessary, including labeling advice, to ensure the safe use of this product? For example, would the labeling changes include a second line status and a black box warning (Discuss and Comment)?
3. Has OP Depot been shown to be effective for the treatment of acutely exacerbated schizophrenic patients (Yes/No)?
4. Has OP Depot been shown to be effective for the maintenance treatment of schizophrenic patients (Yes/No)?
5. Has OP Depot been shown to be acceptably safe for the treatment of acutely exacerbated schizophrenic patients (Yes/No)?
6. Has OP Depot been shown to be acceptably safe for the maintenance treatment of schizophrenic patients (Yes/No)?