

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Psychopharmacologic Drugs Advisory Committee Meeting

HILTON WASHINGTON DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

QUESTIONS TO THE COMMITTEE

APRIL 8, 2009

The questions for discussion and comment are as follows:

1. What are the public health consequences of expanding the use of Seroquel XR into a much larger psychiatric population with MDD and GAD?
2. In particular, how should less well-defined concerns about longer-term metabolic risks, a potential risk for tardive dyskinesia, and a concern for an increased risk of sudden cardiac death be considered in this risk benefit discussion?

The questions for a vote by the committee are as follows:

1. Has Seroquel XR been shown to be effective for the treatment of MDD and GAD?
2. Has Seroquel XR been shown to be acceptably safe for the treatment of MDD and GAD?