

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 7, 2009

The questions for discussion and comment are as follows:

1. Has the cardiovascular risk for sertindole been adequately characterized and if so, does this risk pose an obstacle to the use of this drug in the treatment of schizophrenia?
2. Has sertindole been shown to have an advantage over other antipsychotic drugs with regard to reducing the risk of suicidality in the schizophrenic population?

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

1. Has sertindole been shown to be effective for the treatment of schizophrenia?
2. Has sertindole been shown to be effective for the treatment of suicidality in schizophrenia?
3. Has sertindole been shown to be acceptably safe for the treatment of schizophrenia?