

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting

FDA White Oak Campus, 10903 New Hampshire Avenue Building 31 Conference Center

The Great Room (Rm. 1503), Silver Spring, Maryland

February 3, 2016

QUESTIONS (*Morning session*)

1. **DISCUSSION:** Discuss whether cognitive dysfunction in MDD (Major Depressive Disorder) is an appropriate drug development target? If so, which cognitive domains are mainly affected by the cognitive dysfunction in MDD and what is the best method to assess these affected domains?

2. **DISCUSSION:** What are the acceptable primary efficacy endpoints for a claim of the treatment of cognitive dysfunction in MDD?

3. **DISCUSSION:** Discuss whether a functional assessment is necessary as a co-primary endpoint?