

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 (*Afternoon session*)

1. **DISCUSSION:** Discuss whether the Digital Symbol Substitution Test (DSST) is an adequate measure of cognitive function in MDD?
2. **DISCUSSION:** What, if any, additional data are needed pre- or post-approval to address outstanding issues? Please be clear whether you believe these data should be required prior to approval.
3. **DISCUSSION:** Does a claim for an effect on cognitive function require showing of superiority to another antidepressant (or more than one) or is it sufficient to show an effect vs placebo on cognitive function?
4. **VOTE:** Has substantial evidence been presented by the applicant to support a claim of effectiveness for vortioxetine for treating cognitive dysfunction in MDD?