Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee Meeting

February 3, 2016

Errata to the FDA Briefing Materials (Afternoon session)

1. Page 4: Table 5 and Table 6 under the "List of Tables" should be renumbered to Table 6 and Table 7, respectively. The additional table described below should have been included under the "List of Tables":

   "Table 5: Study 202 (CONNECT) Exploratory Endpoints—Self-Report Cognition ....21"

2. Page 20: The 1st paragraph should include an additional sentence between the 1st and 2nd sentences and the remainder of the paragraph should be revised. The new paragraph should read as follows:

   "As in Study 14122A, this study also included multiple additional exploratory endpoints. In addition to the PDQ, patients' subjective ratings of cognition were captured by the CPFQ. In this study, three Two of the exploratory endpoints could be considered functional measures: the UPSA, the CPFQ, and the WLQ. These results are summarized in Table 4 through and Table 6."

3. Page 21: The new Table 5 under the "List of Tables" on Page 4 as described above should be added here and should be displayed as follows:

Table 1: Study 202 (CONNECT) Exploratory Endpoints—Self-Report Cognition

| | Difference From Placebo at Week 8 | | | |
| | Vortioxetine 10–20 mg | | Duloxetine 60 mg | |
	LS Mean	95% CI	LS Mean	95% CI
Δ CPFQ total score, all subjects	-1.2	(-2.6, 0.2)	-1.7†	(-3.1, -0.4)
Δ CPFQ total score, subjects with baseline CPFQ>25	-1.7†	(-3.3, -0.1)	-1.8†	(-3.4, -0.2)

Δ=change from Baseline.
† p<0.05 versus placebo (nominal)
Note: A negative LS mean value indicates advantages compared to placebo.
(Extracted from Applicant's background document; Table 3.x; page 58)

4. Page 21: Table 5 should be renumbered to Table 6 because of the new Table 5 described above and the Note under the renumbered Table 6 should read as follows:

   "Note: A negative LS mean value on the WQL indicates advantages compared to placebo. (Extracted from Applicant's background document; Tables 3.y, and 3.z; pages 59-60)"

5. Page 21: Table 6 should be renumbered to Table 7 because of the new Table 5 described above.