

Food and Drug Administration

**Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety
and Risk Management Advisory Committee**

November 1, 2018

Errata to the FDA Briefing Materials

1. Page 9: the last provision of the first paragraph is deleted:

~~“; however, a samidorphan-only (plus SSRI/serotonin-norepinephrine reuptake inhibitor (SNRI)) arm was advised to ensure that efficacy of the buprenorphine-samidorphan combination was not due to samidorphan alone.”~~

2. Page 15: first sentence under the heading “Importance of a single patient to the nominally positive results for the BUP/SAM 2/2 group” is deleted:

~~A potential financial conflict of interest was reported at a study site in Pennsylvania that had enrolled one subject.~~

3. Page 15: The second sentence under the heading “Importance of a single patient to the nominally positive results for the BUP/SAM 2/2 group” should be changed from:

“In Stage 1, the subject was randomized to BUP/SAM 2/2, and their HAM-D17 decreased from 39 at baseline to 3” to “In Stage 1, the subject was randomized to BUP/SAM 2/2, and the HAMD-17 score for this individual decreased from 32 (at baseline) to 2 (week4)”