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)”