Errata to the FDA Briefing Document
Psychopharmacologic Drugs Advisory Committee (PDAC)
March 27, 2018

Note: Page numbers reflect the numbers at page bottom within document

FDA Errata to Briefing Document

Efficacy and Safety Summary	
• Page 16 and 75	Page 16 & 75 – The # of packages sold (1 pkg = 1 detox) ex-US from 1997-2016 is 302,932. The number ~214,000 should be corrected to 302,932 on p. 16 and the number 304,932 should be corrected to 302,932 on p.75.
• Page 32:	The second primary endpoint is described as "The second primary endpoint, time to dropout in the 5-day treatment phase, was analyzed using log rank test. Results are shown in Table 10." should be corrected to "The second primary endpoint, time to dropout in the 5-day treatment phase, was analyzed using log rank test. The descriptive statistics of time to dropout in 6-hour time quadrant and in day are summarized in Table 8. The retention rate was significantly higher (p=0.004) in the lofexidine group compared to the placebo group."
• Page 33:	The "baseline pain scores" in the bottom of the paragraph under "Sensitivity Analyses", which is continued on the top of page 33 should be replaced with "baseline SOWS-Gossop scores".
• Page 36:	The primary statistical method is described as: "To handle missing values, multiple imputation (MI) with Markov Chain Monte Carlo (MCMC) option was used with predictors sex, treatment, baseline value, and Day 1 through Day 7 SOWS-Gossop scores. The data was imputed 20 times and was then analyzed using the MMRM model. This method assumed that the data was missing at random (MAR)." The description should be changed to: "To handle missing values, a pattern mixture model with a control-based pattern imputation was used assuming that early withdrawals in the lofexidine group followed the trajectory of placebo subjects. The data were imputed 20 times and were then analyzed using an MMRM model with predictors sex, treatment, baseline value, and Day 1 through Day 7 SOWS-Gossop scores. This method assumed that the data were missing not at random (MNAR)."

• Page 39:	The first sentence under "Secondary Endpoint" should be changed to "Instead of treatment completion status on Day 7, a secondary endpoint of completion status on Day 5 was considered more clinically relevant and was analyzed using the same logistic regression model."
• Page 58:	The text above Table 36 should be corrected from "…the 3.2 mg group had a higher incidence than the 2.4 mg group for orthostatic hypotension and bradycardia and the difference exceeded a risk difference of 10%." to "…the 3.2 mg group had a higher incidence than the 2.4 mg group for orthostatic hypotension (risk difference of 13%) and bradycardia (risk difference of 8%)."
• Page 70	Figure 5 "series 2" and "series 3" in the legend to the right should be corrected to "lofexidine" and "placebo", respectively.