Errata – FDA Briefing Document, January 24-25, 2018, Meeting of the Tobacco Products Scientific Advisory Committee (TPSAC)

Note: Changes are in bold.

Page 8, Paragraph 2 – Starting from the third sentence, the paragraph should read: "A study of mentholated cigarettes for 23 brands available in the U.S. market indicates that menthol content ranges from 2.9 to **19.6** mg/cigarette (Ai et al., 2016). **There were 3 brands with extraordinarily high levels of menthol relative to the other mentholated products tested. If these products are excluded, the menthol range is 2.9–7.2 mg/cigarette with an average menthol content of 4.8 mg/cigarette."**

Page 10, Table 1 – In the second to last row of the table, the percent reduction for 53 HPHCs on a unit basis should read **54** – 99.9%, rather than 47 – 99.9%.

Page 11, Figure 2 caption should read "**Residual levels** of 54 HPHCs in *Marlboro HeatSticks* Compared to Reference Cigarette 3R4F."

Page 11, Paragraph 1 – The first sentence should read "Figure 2 shows the **residual levels** of 54 HPHCs in *Marlboro HeatSticks* compared to the reference cigarette 3R4F."

Page 12, Paragraph 4 – The fourth sentence should read "The applicant identified 53 compounds in the Marlboro *HeatSticks*, **58** compounds in the Marlboro Smooth Menthol *HeatSticks*, and **61** compounds in the Marlboro Fresh Menthol *HeatSticks* with higher quantities in the aerosol of the *Heatsticks* compared to the smoke of the 3R4F." The sixth sentence should read "The quantity of glycidol, acetol, propylene glycol are higher by 108 – **224**%, 35 – 67%, and 383 – 638%, respectively, in the aerosol of the *HeatSticks* compared to the smoke of the 3R4F."

Page 25, Paragraph 1 – The sentence should read "At the end of the 90-day ambulatory period, for mentholated products, the decreases in systemic levels of BOEs were less pronounced, ranging from 34% to **92**% (REXA-07-JP) and from **15**% to **82**% (REXA-08-US), most likely due to decreased compliance (dual use), but they remained statistically significant. **Note that these ranges do not include the percent changes for S-BMA and NEQ.**"

Page 28, Paragraph 2 – The last sentence should read "For example, the informed consent form from study REXC-04-JP study suggests the investigational product is less harmful than combusted cigarettes, stating, 'a number of clinical studies have been conducted… with the previous version of the device (THS 1.0 and THS 2.1)… showed reductions in exposure to selected smoke constituents in subjects who used the THS 1.0 or THS 2.1, as compared to subjects continuing smoking conventional cigarettes,' whereas **this language was not included in the informed consent form for study REXA-08-US.**"

Page 31, Table 5: [ZRHM-REXA-07-JP] – FEV_1 was analyzed in a post-hoc analysis. On the day of discharge from the ambulatory period, the difference in FEV_1 (% pred) without bronchodilator between THS m2.2 and mCC was 1.91 (95% CI: -0.14; 3.97). The difference between THS m2.2 and smoking abstinence was -0.02 (95% CI: -2.15, 2.11).

Page 31, Table 5: [ZRHM-REXA-08-US/FEV_1] – The footnote describing the per protocol analysis set should apply to all results in Table 5, not just the results for FEV_1.

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Page 41, Table 7 – The cell describing the population source for the Whole Offer Test should read "Market research consumer-based databases from **those respective countries.**"

Page 49, Paragraph 2 – The last sentence should read: "The applicant **does not propose** that these PMI Important Warnings replace the Surgeon General (SG) Warnings currently mandated for cigarette products."

Page 60, Paragraph 2 – The third sentence should read "Percentages responding "somewhat likely" were: 7-10% (no claim), **3**-6% (reduced risk claim 1), **3**-10% (reduced risk claim 2), and 3-**7**% (reduced exposure claim)."