Amendment – Supporting Documentation for Section VIII.E.2
Scientific Studies and Analyses
Consumer Perception

Quantitative Study to Develop VLN™ Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users

This amendment provides file corrections to the documentation submitted in support of M/A/R/C Research 2018, "Quantitative Study to Evaluate VLN Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users"; Protocol Number: 5180080-VLN-B2; Principal Investigator: Randall Wahl in 22nd Century Group Inc.'s Modified Risk Tobacco Product Application ("MRTPA"); STNs MR0000159 and MR0000160.

Reason for Amendment: The FDA requested clarification on what pack stimuli participants viewed in the <u>VLN Control</u> condition of the M/A/R/C Research 2018, "Quantitative Study to Evaluate VLN^{TM} Hypothetical Product Messages Among U.S. Adult Cigarette Smokers, Adult Former Cigarette Smokers and Adult Never Cigarette Users"; Protocol Number: 5180080-VLN-B2; Principal Investigator: Randall Wahl.

Confidentiality: No claim of confidentiality is being made on the information contained in this amendment.

Before responding to items about the risks of using VLN™ and intentions to use and purchase VLN™, participants in the VLN™ Control condition (also referred to in the Study Report and Protocol as the VLN No Messaging, Control 1, and No Claims Messaging condition) viewed the 3-D rotatable image of the VLN^{TM} pack (Menthol or Regular) and <u>also</u> viewed the flat images (Menthol or Regular). The VLN^{TM} flat images shown to the participant in the control condition were incorrectly identified in the study records. The flat images for the control condition, as used in the study, are shown in Figure 1 (Menthol) and Figure 2 (Regular). As noted by the FDA, the 3-D image did not have any wording other than the product name and flavor. The flat images coincided with the 3-D images and also did not have any additional text.

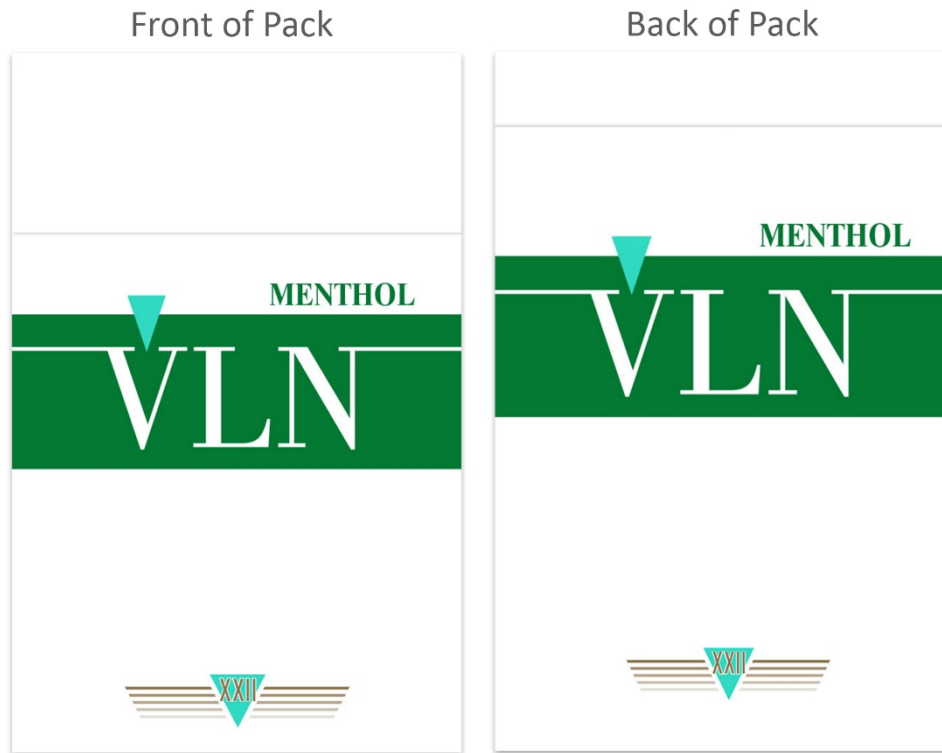Figure 1. Front and back pack images from VLN™ Menthol used as control stimuli.

Figure 2. Front and back pack images from VLN™ Regular used as control stimuli

STNs MR0000159 and MR0000160

The following files submitted with STNs MR0000159 and MR0000160 contain incorrect images – these images were not shown to the VLN^{TM} Control condition, and the files should be withdrawn or disregarded:

MARC_QN_Appx_H_Stimuli_C4_VLN M - Back.jpg

MARC_QN_Appx_H_Stimuli_C4_VLN M - Combined.jpg

MARC_QN_Appx_H_Stimuli_C4_VLN M - Front.jpg

MARC_QN_Appx_H_Stimuli_C4_VLN R - Back.jpg

MARC_QN_Appx_H_Stimuli_C4_VLN R - Combined.jpg

MARC_QN_Appx_H_Stimuli_C4_VLN R - Front.jpg

Enclosed with this amendment are the flat images that were shown to the VLN^{TM} Control condition. The 3D rotatable pack images, files MARC_QN_Appx_H_Stimuli_C4_VLN R - 3D.pdf and MARC_QN_Appx_H_Stimuli_C4_VLN M - 3D.pdf, that were submitted with our MRTPA dated May 17, 2019, containing no messaging were shown to participants in the VLN^{TM} control condition.