



February 19, 2019

22<sup>nd</sup> Century Group, Inc.  
Attn: (b) (6)  
8560 Main St, Williamsville, NY 14221

Dear (b) (6):

The quantitative *Brand A Package and Ad Evaluation Research* as well as the qualitative research that preceded it—used to gain *initial consumer reaction to the PARE pack design and print advertisement, and to provide direction for survey refinement and improvement*—were preliminary and purely exploratory in nature.

Those research studies were not executed in the same manner nor with the required regulatory rigor as the research completed by M/A/R/C® Research for 22<sup>nd</sup> Century, Inc. in 2018. Rather, the 2015 research studies were designed and executed with the expectation that they would inform 22<sup>nd</sup> Century, Inc. about general consumer perceptions only as a building block during the product and packaging development stages. Conversely, the overall design as well as the implementation of the 2018 research aligns with regulatory requirements for FDA submission. Further, there is no linkage between the stimuli tested nor the data sets and, as a result, we recommend using the 2018 research as a stand-alone initiative.

Sincerely,

(b) (6)

Brad Seipel  
Vice President and Account Director

c: Randy Wahl, (b) (6), & Lynn Dagar