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Senior Vice President
Regulatory Affairs

November 30, 2020

Via Electronic Submission

Food and Drug Administration
Docket Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0987 (85 Fed. Reg. 60,999 September 29, 2020) – Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

Altria Client Services (“ALCS”), on behalf of Philip Morris USA Inc. (“PM USA”), John Middleton Company (“JMC”), U.S Smokeless Tobacco Company LLC (“USSTC”), and Helix Innovations LLC (“Helix”),¹ submits these comments in response to the above-referenced docket.²

We support the Food and Drug Administration’s (“FDA” or “Agency”) use of “qualitative research including focus groups, usability testing, and/or in-depth interviews to assess knowledge and perceptions about tobacco-related topics with specific target audiences.”³ This work should meaningfully benefit Agency tobacco product communications.

While FDA indicates that this research will meet the “narrowly defined need for direct and informal public opinion on a specific topic,”⁴ the Agency has recently used this work for broader purposes, including informing the Proposed Rule for graphic health warnings.⁵

¹ PM USA, JMC, and USSTC are wholly-owned subsidiaries of Altria Group, Inc. (“Altria”). Helix is a majority-owned subsidiary of Altria Enterprises II LLC, which is a wholly-owned subsidiary of Altria. PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States and JMC manufactures cigars and pipe tobacco. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products. Helix manufactures oral tobacco-derived nicotine products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. “We” and “our” are used throughout to refer to PM USA, JMC, USSTC, and Helix.

² 85 Fed. Reg. 60,999 (September 29, 2020).

³ *Id.* at 61,000.

⁴ *Id.* at 61,001.

⁵ 84 Fed. Reg. 42,754 (August 16, 2019).

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The Tobacco Control Act⁶ and Administrative Procedure Act⁷ require that information used in this manner be made available for public stakeholder scrutiny and analysis. FDA should clarify the extent to which the Agency intends for the research described in this docket to inform rulemakings and the steps the Agency will take to publish underlying data sets when required.

Finally, FDA says it also plans to use such information to guide educational and public information programs to serve and respond to the “ever-changing demands of consumers of tobacco products.”⁸ To further this goal, we reiterate prior recommendations that the Agency develop the communication insights needed to lead a national dialogue on nicotine and address widespread misperceptions regarding the relative risks of different tobacco products.⁹ Greater clarity regarding the health effects of nicotine and the relative risks of different tobacco products would clearly advance the needs of adult tobacco consumers who are interested in potentially reduced risk products and entitled to receive truthful and accurate information about them.

We appreciate the opportunity to comment on FDA’s information collection. Please let us know if you have any questions or would like to discuss any of our suggestions further.

Sincerely,

A handwritten signature in black ink that reads "Paige C. Magness". The signature is written in a cursive, flowing style. The first name "Paige" is written in a larger, more prominent script, followed by the initials "C." and the last name "Magness". The signature is set against a light gray rectangular background.

⁶ In “[e]ach notice of proposed rulemaking,” FDA “shall set forth . . . the manner in which interested persons may examine data and other information on which the notice or findings is based.” 21 U.S.C. Section 387f(b)(1).

⁷ 5 U.S.C. Section 706(2).

⁸ 85 Fed. Reg. at 61,000.

⁹ See, ALCS Comments on “Citizen Petition of the National Tobacco Reform Initiative” (July 30, 2020). Available at, <https://www.altria.com/-/media/Project/Altria/Altria/about-altria/federal-regulation-of-tobacco/regulatory-filings/documents/Citizen-Petition-of-the-National-Tobacco-Reform-Initiative.pdf>.