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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2017-N-4678—Comments on “Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company.”

Altria Client Services LLC, on behalf of Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC, and Nu Mark Inc., submits these comments to the above-referenced Modified Risk Tobacco Product applications.¹ Altria expresses no opinion on the merits of Reynolds’ applications. We write instead to raise our concern that the modified risk tobacco product provisions of the Tobacco Control Act, as applied to Reynolds’ application, may violate the First Amendment by restricting manufacturers’ truthful speech regarding the health risks of their products.

FDA now recognizes that there is a scientific consensus that it is the combustion of tobacco and the resulting smoke—not the nicotine—that is the direct cause of most tobacco-related harm. FDA also recognizes that noncombustible tobacco products are lower on the continuum of risk than combustible cigarettes, and, therefore, have an important role to play in reducing that harm.² Smokers cannot be expected to switch to less harmful alternatives, however, if they aren’t told the truth about them. Yet today, the FDA regulatory system is preventing smokers from being told the full truth about relative risks of different tobacco products. And that imbalance of information is having real and disturbing consequences. Today, there is a widespread *misunderstanding* among smokers as to whether there is a difference in risk among tobacco products. The science is clear and undisputed: smokeless

¹ Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC, and Nu Mark Inc. are whollyowned subsidiaries of Altria Group, Inc. Altria Client Services LLC provides certain services, including regulatory affairs, to the Altria family of companies. “We” and “our” collectively refer to Philip Morris USA Inc., U.S. Smokeless Tobacco Company LLC and Nu Mark Inc.

² FDA now recognizes that the “nicotine in cigarettes is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year.” Remarks of Commissioner Scott Gottlieb, M.D., FDA, *Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (July 28, 2017), <https://goo.gl/P2iMj3>. Accordingly, FDA’s goal is to “move addicted smokers down [the] continuum of risk to . . . less harmful products,” and away from combustible products like cigarettes. *Id.*