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- To: Caryn Cohen Office of Science Center for Tobacco Products Food and Drug Administration Document Control Center Bldg. 71, Rm. G335 10903 New Hampshire Ave. Silver Spring, MD 20993–0002
- From: Alex Clark Chief Executive Officer The Consumer Advocates for Smoke-free Alternatives Association (CASAA)
- RE: USSTC MRTP Application for Copenhagen Snuff Fine Cut.

I. Introduction

The following comments are submitted on behalf of The Consumer Advocates for Smoke-free Alternatives Association (CASAA) regarding the modified risk tobacco product applications ("MRTP applications") submitted by U.S. Smokeless Tobacco Company LLC (USSTC) for Copenhagen Snuff Fine Cut. CASAA is a 501(c)(4) nonprofit public health and education NGO and is the leading representative of consumers who use or might in the future use low-risk smoke-free tobacco and nicotine products. It is a U.S. membership organization with more than 230,000 members. CASAA advocates on behalf of consumers and does not represent the interests of industry.

We are writing in full support of USSTC's application to make a single modified risk marketing claim about Copenhagen Snuff. Consumer awareness of, and access to, very low-risk alternatives to smoking is critical to improving public health. We believe that moist snuff and other smoke-free tobacco products are a vital part of the overall strategy to reduce the early death and disease attributed to smoking. Truthful marketing statements about the low risk of using smokeless tobacco are timely and crucial, and people who smoke should have been made aware of the lifesaving benefits of switching to moist smokeless tobacco decades ago.

II. Copenhagen Snuff meets the standards for a modified risk order

The Family Smoking Prevention and Tobacco Control Act ("TCA") requires the MRTP application to demonstrate that "such products, as it is actually used by consumers, will (A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (B) benefit the health of the population as a whole taking into account both the users of tobacco products and persons who do not currently use tobacco products."¹

It its MRTP application, USSTC convincingly demonstrates that Copenhagen Snuff presents lower risks to individuals and at the population level. The evidence presented goes on to demonstrate that people who completely replace their smoking habit with Copenhagen Snuff can significantly reduce their risks of developing lung cancer.

With regard to the likelihood of uptake by non-tobacco users and people who used to smoke, we note a well-known complication with using Copenhagen Snuff that is a likely deterrent to non-users. The fine cut of the tobacco (a sawdust-like grain) makes Copenhagen Snuff a difficult product to use.² Coupled with the unfortunate stigma of smokeless tobacco use and traditional tobacco control strategies, the difficulty in using the product will likely result in minimal uptake by non-users.

¹ Section 911(g)(1) of the TCA.

² Outlaw, "How to dip fine cut (Techniques & Tricks)". Youtube, January 8, 2014. Accessed from <u>https://www.youtube.com/watch?v=_r1TfeUNgOg</u>

III. The modified risk claim for which approval is sought is appropriate

USSTC seeks to make the following truthful claim:

• "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."

We note the emphasis on speaking directly to people who smoke and encouraging them to choose Copenhagen Snuff instead of continuing to smoke. Moreover, the claim makes the--what should be obvious--observation that switching completely to a smoke-free tobacco product will reduce the risk of lung cancer.

IV. Conclusion

We remain concerned that required warning labels on smokeless tobacco products continue to misinform consumers about the risks of using smokeless tobacco compared to smoking. Consumers have a fundamental right to truthful and accurate information so that they can make informed choices about decisions that affect their health and well being. It is the worst kind of public policy that insists on misleading consumers into believing that all tobacco products carry the same or similar risks. This effectively forces consumers to make decisions with bad information, leading in many cases to bad decisions that compromise their health.

While we agree that every effort should be made to discourage youth use of tobacco and nicotine products, it is imperative that FDA devote time and resources to making appropriate balancing statements about low-risk products that can help people who smoke improve their health.

For the foregoing reasons, we respectfully urge this committee to favorably recommend FDA approval of USSTC's MRTP applications for Copenhagen Snuff. Just as important, we strongly encourage TPSAC to acknowledge that people who smoke are capable of understanding risk differentials among tobacco products. Every MRTP application that this committee considers is an opportunity to begin remediating the harm of misperceptions about nicotine and smoke-free tobacco products.

Disclosure:

CASAA accepts donations from many sources and has no financial or policy agreements with industry stakeholders. CASAA's policy for allocating resources is that all contributions are used for efforts that will maximize consumer access to and awareness of low-risk, smoke-free nicotine and tobacco products. CASAA received a one-time unrestricted donation from Altria Client Services in 2018.