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January 16, 2019

Tobacco Products Scientific Advisory Committee  
c/o Caryn Cohen  
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Re: February 6-7, 2019 TPSAC meeting on the Copenhagen Snuff MRTPA

Dear TPSAC members and Ms. Cohen:

Today we submitted a comment to FDA discussing why they should not permit the U.S. Smokeless Tobacco Company (USSTC) to market Copenhagen Snuff with modified risk claims. Our comment spells out why USSTC's modified risk tobacco product application (MRTPA) fails to meet the statutory requirements specified in section 911 of the Family Smoking Prevention and Tobacco Control Act, and fails to present sufficient scientific evidence to demonstrate that Copenhagen Snuff *both* significantly reduces the risk of tobacco related diseases to individuals *and also* benefits the health of the population as a whole.

Pursuant to the December 11, 2018 notice, we are submitting this comment to the Tobacco Products Scientific Advisory Committee (TPSAC) members to review before the February 6-7, 2019 meeting. We urge you to recommend that FDA *deny* issuing to USSTC their requested modified risk order for Copenhagen Snuff because the MRTPA fails to demonstrate, as required by the statute, that the product, as actually used by consumers, will both significantly reduce harms to individuals and will benefit the public health.

In summary, our comment presents scientific evidence showing:

- Relative to using no tobacco at all, moist snuff is carcinogenic. Therefore, USSTC's claim that focuses only on lung cancer is misleading because it does not address the total carcinogenic potential of moist snuff.
- USSTC's studies did not demonstrate that consumers understand the proposed modified risk claim, that the proposed marketing will change consumers' perceptions of the product, or that it would encourage current smokers to *switch completely* to moist snuff.

- The proposed claim is especially misleading to youth, may emphasize the appeal of smokeless tobacco to youth, and may increase youth uptake of moist snuff and dual use with combustible tobacco.
- USSTC’s evidence that adult smokers “misperceive” the harm of smokeless tobacco products relative to cigarettes is insufficient to demonstrate that marketing Copenhagen Snuff with modified risk claims would improve the health of the public
- USSTC’s dynamic population impact model makes overly optimistic assumptions and uses selective, out-of-date data as inputs. Therefore, it does not support issuance of a modified risk order.

In conclusion, TPSAC should recommend that FDA *not* issue a modified risk order because USSTC has shown no evidence that the proposed marketing would encourage current smokers to *switch completely* to smokeless tobacco, that the proposed marketing would not mislead consumers, or that the proposed marketing would not have a harmful effect on youth, including users and non-users of any tobacco product.

Please see the attached detailed comment.

Best wishes,



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