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January 16, 2019

Tobacco Products Scientific Advisory Committee
c/o 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

Email: TPSAC@fda.hhs.gov and caryn.cohen@fda.hhs.gov

Re: February 6-7, 2019 TPSAC meeting on the Swedish Match General Snus MRTPA

Dear TPSAC members and Ms. Cohen:

Today we submitted a comment to FDA asking them to deny Swedish Match's request to issue a marketing order based on its amended modified risk tobacco product application (MRTPA) because Swedish Match did not provide sufficient evidence to support issuance of such an order. Doing so would not benefit public health; indeed, marketing General Snus with the proposed claims modified risk claims might in fact harm public health by promoting more use of this tobacco product, including more dual use with cigarettes.

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 Swedish Match their requested modified risk order for eight General Snus products because the MRTPA fails to demonstrate, as required by the statute, that the products, 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:

- Consumers are likely to misunderstand that the language “instead of cigarettes” in the proposed advertising and labeling means a *complete switch* to General Snus, and may instead interpret this as compatible with dual use with cigarettes or other tobacco products.
- Swedish Match presented no evidence that the proposed modified risk claim would make current smokers completely switch to General Snus.
- Swedish Match only tested a limited number of their products seeking MRTP orders, not all eight sub-brands.

- Swedish Match’s studies failed to test the effects on dual users.
- Swedish Match failed to present information on the impact of their proposed modified risk claims on youth.
- The proposed modified risk claim misleads consumers about the health risks of General Snus.
- Because the studies presented in the MRTPA use hypotheses with problematic wording and problematic testing procedures, FDA should not rely on conclusions reached in these studies.
- The results of Swedish Match’s studies suggest that their proposed modified risk claims can be misunderstood to indicate “no risk” or reduced risk of various health conditions that were not included in the claim, such as gum disease.
- The Dynamic Population Model used by Swedish Match is inappropriate to assess the population health impact of the proposed modified risk claim for a product which is already marketed in the U.S.
- Swedish Match failed to provide details about its post-market surveillance plan.

In conclusion, TPSAC should recommend that FDA *not* issue a marketing order authorizing Swedish Match to market its General Snus products with their proposed modified risk claim because they have not demonstrated public health benefits as the law requires.

Please see the attached detailed comment.

Best wishes,



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