Public Comment Regarding RJ Reynold's Camel Snus Modified Risk Tobacco Product Applications for Six Tobacco Products

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The Food and Drug and Administration (FDA) is requesting public comments on the modified risk tobacco product applications (MRTPAs), submitted by R.J. Reynolds Tobacco Company (RJRTC) for six products:

- MR0000068: Camel Snus Frost
- MR0000069: Camel Snus Frost Large
- MR0000070: Camel Snus Mellow
- MR0000071: Camel Snus Mint
- MR0000072: Camel Snus Robust
- MR0000073: Camel Snus Winterchill

As a member of the public, I am concerned that these six products when used by users will not reduce the risk of harm and risk of tobacco-related disease to the individual tobacco user and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.[1] Since RJRTC's own MRTPAs data does not support that the way the average Camel Snus users uses Camel Snus (dual-use) reduces the risk of harm and risk of tobacco-related disease for the user and non-users (because Camel snus use does not lead to significant smoking cessation and is a gateway to smoking). Thus, the FDA should reject RJRTC's modified risk tobacco product applications for RJRTC's 6 Camel snus tobacco products.[2]

Potential Public Health Effect of Camel Snus on the US Smoking Population

Since the early 2000s, tobacco companies have been aware that the FDA would eventually assert jurisdiction over them. [3] Tobacco companies prepared for at least a decade regarding tobacco product regulations that the tobacco companies assumed the FDA would impose, such as on nicotine, menthol and tar ceilings.[4] Philip Morris (PM) was aware that once the FDA asserted jurisdiction, it would be hard for PM to introduce a novel tobacco product without a harm reduction claim.[4] Although RJR knew that smokers should be migrated over to non-combustibles which are assumed to be less harmful,[5] RJR was aware prior to the Tobacco Control Act being signed that switching smokers to other tobacco products would pose a significant challenge because the smoker consider cigarettes to offer the most pleasure compared to other tobacco products- from an emotional, social and functional pleasure perspective.[5] One of the products RJR hoped to switch smokers over to included snus.[5]

In 2009, RJ Reynolds Tobacco (RJR) created 'The Smoker Cessation/Migration Study', (CSD1010) a randomized control trial, to compare Camel Snus to Nicorette nicotine replacement therapy (NRT) for smoking cessation over 1 year. This study also reported in RJRTC Camel Snus current MRTP application demonstrated that after 1 year smoking cessation rates were low at 6 and 12-months (1.4% for Camel Snus and 0.9% for nicotine lozenges).[2, 6]

Although initially in review of the tobacco industry documents demonstrated that participants of CSD1010 who continued smoking and Camel Snus reduced their cigarette consumption ($p<0.05$), although the amount was not reported in the tobacco industry documents a few years ago, in review of RJRTC executive summary for Camel snus MRTP

application, RJR decided to report the difference in cigarettes between exclusive smokers and dual-users of Camel snus and cigarettes, which was essentially the same (11.8 cigarettes per day vs 12.9 cigarettes per day).[2] Thus, RJRTC's own data demonstrates that Camel snus when used by users does not lead to smoking cessation or large decreases in the number of cigarette used by Camel snus users. Instead, RJRTC clearly states that they are aware that greater than 90% of Camel snus users will be dual/poly user of a tobacco product, where RJR states the dual use of Camel Snus and smoking confers similar mortality risk as smoking. Yet, RJR downplays that dual-users are likely to be at greater risk for cancer because the levels of many carcinogens and metals are higher in Camel snus than cigarettes.[2] Thus since, Camel snus when used by users does not decrease smoking prevalence ,[2] the most harmful form of tobacco consumption,[7] because the average smoker will not **completely** switch to Camel Snus, thus the FDA should reject RJRTC's Camel snus MRTP application.

Furthermore, in RJRTC's Camel Snus MRTP application, RJR admits that users of snus odds of progressing to smoking are higher than non-users, thus non-users (youth and adults) are harmed and lured into smoking via snus, leading to an increase in the smoking population.[2] In RJRTC's Camel Snus MRTP application, RJRTC reported regarding a study that among a youth cohort (ages 12-16 at baseline, N=2,184) who were followed for 8 years, among the youth who had tried snus, there was an increased odds of smoking at follow-up compared to youth who never tried snus at baseline (OR=1.79, 1.01-3.14).[2]

Also, RJRTC reports on a study of adult US Air Force recruits that found an increased odds of smoking initiation among current smokeless tobacco users compared to non-users (OR=2.33, 1.84-2.94).[2] Thus, RJRTC is fully aware that smokeless tobacco products are a gateway to smoking.

Lastly, RJRTC was aware the smoking sub-population that would be most likely to use Camel snus are white males,[2] the majority of smokers in the US.[8, 9] Since Camel snus leads to an increase in the largest population of individuals in the US to smoke (Whites) by increasing smoking initiation and depressing their smoking cessation, increased Camel snus use is likely not to lead to a public health benefit for the US population. [4]

Why Camel Snus Likely Leads to An Increase in the Smoking Population

As reported in RJRTC Camel Snus' MRTP application, RJRTC states that smoking cigarettes results in significantly greater and more rapid nicotine exposure than when using a pouch of Camel snus, where RJRTC reports that nicotine has a prominent role in abuse liability of tobacco products.[2] Thus, RJRTC is clearly cognizant that cigarettes abuse liability is higher than Camel snus. Thus, camel snus users are more likely to want to use cigarettes because cigarettes can deliver more nicotine to users' brains more quickly than Camel snus.

. In a study by Buzzell et al, [10] the researchers reported that measures of which demonstrated nicotine reaching Camel snus users brains (alpha suppression on EEG) is lower than some other nicotine-containing products, indicating that Camel snus compared to other tobacco products has low abuse potential because of poor nicotine delivery to users' brains.[10]

In internal EEG studies, PM knew that tobacco product users titrate their tobacco product usage to lead to the greatest P1 latency decrease (alpha suppression)[11], (ie, highest nicotine delivery to their brains),[12] and thus that is possibly why dual users of Camel Snus and cigarettes lead to similar nicotine delivery as cigarettes.[2] In review of the RJRTC's Camel Snus MRTP application both polycyclic aromatic hydrocarbon, a combustion product,[13] levels and nicotine levels are found at similar levels in dual users of Camel snus and cigarettes and exclusive cigarette users because the difference in combustible use between dual Camel snus users and

cigarettes smokers is basically statistically insignificant.[2] Furthermore, based upon the product composition Camel snus which has low nicotine absorption because, the nicotine in Camel snus is a nicotine salt.[14, 15] And since the 6 products that RJRTC are submitting all contain flavors,[2] all 6 Camel snus tobacco products are designed to be non-harsh on the users which is preferable to individuals (ie, youth) who are starting with tobacco products who have not developed a high tolerance to high levels of nicotine.[15]

Thus although, RJRTC wants the FDA to support their statement on their Camel snus products that smokers who **switch completely** from cigarettes to Camel snus greatly will reduce the risk of lung cancer, oral cancer, respiratory disease and heart disease, RJRTC's own data supports smokers will not switch and are likely to engage in dual use between Camel Snus and cigarettes, which is just as harmful, or actually carries a larger cancer risk that smoking alone.[2] RJR even conducted studies where they told smokers if they switched to Camel snus, smokers would have a health benefit, yet smokers still did not switch.[6] Furthermore, although, RJRTC concentrates on mainly on the harm of cigarettes causing, cancer, heart disease and respiratory disease, smoking causes a number of other of diseases such as pre-term labor, low birth weight,[2] setting up children to be physically disadvantaged for life,[16] and a number of other health problems.[17] Thus, the FDA creating policies that lower the smoking prevalence in the US is essential to creating a healthier America.

In the advertisement regarding Camel snus switching, RJRTC tries to convince Camel snus users they will be more free which is just code for that with Camel snus one can use Camel snus in smoke-free environments and augment cigarettes use until smokers can go outside and smoke[18] (See Image 1).[19]

Nonetheless, because camel snus use leads to increase in the smoking population and leads to dual-use that is likely to be more harmful than exclusive cigarette-use, the FDA should reject RJRTC's Camel Snus MRTP application.[2]

Recap Why Camel Snus MRTP Applications should be Rejected

1. Camel snus depresses smoking cessation.
2. Greater than 90% of Camel snus users are dual users/poly users where many dual users smoke the same number of cigarettes as exclusive smokers.
3. Since the Camel snus dual users and exclusive smokers, smokers smoke the same amount of cigarettes, and since Camel snus contains more carcinogens and metals than cigarettes, thus when dually used with cigarettes, dual users risk of diseases such as cancer are likely to be higher than exclusive smokers.
4. Camel snus is a gateway to smoking for youth and adults because it is designed to be a starter product.
5. White men, the largest smoking population in the US, are the target of Camel snus. And if white men smoking prevalence does not decrease, the smoking prevalence in the US is likely not to decrease.
6. RJRTC Camel snus MRTP application focuses only on a few diseases caused by smoking (cancer, heart disease and respiratory disease), yet smoking (and dual Camel snus use with cigarettes) will cause a host of number diseases that RJRTC failed to address.

Image 1. Advertisement by RJ Reynolds Tobacco Company to Proposing Why Smokers Should Switch to Camel Snus

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