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**September 18, 2018**

**Docket No. FDA-2017-N-4678**  
**Division of Dockets Management**  
**Food and Drug Administration**  
**5630 Fisher Lane, Room 1061**  
**Rockville, Maryland 20852**

**RE: Modified Risk Tobacco Product Applications: Applications for Six Camel Snus  
Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company**

I write to you on behalf of the R Street Institute, a Washington-based nonprofit public policy research organization dedicated to free markets and real solutions. Exploring ways that tobacco harm reduction strategies can positively impact the lives of people who use combustible cigarettes has been a major focus of R Street research since the institute opened its doors five years ago.

As an addiction researcher at The Scripps Research Institute, I led studies examining neurophysiological changes that occur in the early and late stages of drug use and addiction. The Scripps Research Institute continues to produce groundbreaking insights into potential treatments of addiction, including vaccines that target drugs to prevent entry into the brain; deep brain stimulation that mediates compulsive drug seeking; treatments that target the stress response system that perpetuates the cycle of addiction; and targeted drug delivery that prevents the initiation of addiction. Unfortunately, as is often the case, these treatments are many years away from being available and, for lack of access or efficacy, will not help everyone who may benefit from them. Real-world solutions must be available to mitigate the harms that come from risky behaviors, and they must be palatable to the intended audience.

Responsible for 480,000 deaths a year, cigarette smoking is the leading cause of preventable death in the United States. While nicotine replacement products are available for those who wish to quit, they have not been terribly effective at transitioning smokers to complete cessation; between 25 and 35 percent of smokers relapse within six months and successful quit rates at one year have been estimated at between 4 and 25 percent<sup>1</sup>. Alternative reduced risk products represent a new and likely more attractive alternative for people who are either unsuccessful in quitting using traditional nicotine replacement or who might not otherwise quit smoking.

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<sup>1</sup> R. Borland, T. R. Partos, H. H. Yong, K. M. Cummings, A. Hyland, How much unsuccessful quitting activity is going on among adult smokers? Data from the International Tobacco Control Four Country cohort survey. *Addiction* 107, 673-682 (2012).

G. M. J. Taylor *et al.*, The effectiveness of varenicline versus nicotine replacement therapy on long-term smoking cessation in primary care: a prospective cohort study of electronic medical records. *Int J Epidemiol* 46, 1948-1957 (2017).

S. H. Zhu, Y. L. Zhuang, S. Wong, S. E. Cummins, G. J. Tedeschi, E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ* 358, j3262 (2017).

It is for this reason that we urge the Food and Drug Administration to grant Camel Snus the status of Modified-Risk Tobacco Product.

**We support this application because Snus as a product category has been shown to be a less harmful alternative to combustible products and because an MRTP label will benefit public health.**

The best available research indicates that Snus compares favorably to both conventional snuff and combustible cigarettes. Compared to conventional snuff, analyses of toxicant concentrations in SNUs products uniformly demonstrate a significant reduction in concentrations of harmful chemicals. It is worth noting that in several studies, both Swedish Snus products and Camel Snus products were the comparators.

Concentrations of tobacco-specific nitrosamines, including group one carcinogens, NNN and NNK and group 3 carcinogens, NAB and NAT, are found at much lower levels in the Snus brands tested (including Camel products) than conventional moist snuff<sup>2</sup>. In a separate study, analysis of American Snus products, including RJRT's Camel Frost brand, showed a 4.5-fold decrease in NNN, a 3.0-fold decrease in NNK and a 100-fold decrease in B[a]P concentrations compared to conventional snuff<sup>3</sup>.

With the concentrations of TSNA present in Snus, the probabilistic cancer risk estimates a 3.0 to 6.0-fold decrease depending on the specific TSNA. In addition, it has been suggested that the decreased concentration of benzo[a]pyrene in Snus also translates to a 50-fold decrease in cancer risk<sup>4</sup>.

In comparing Snus products to combustible cigarettes, Snus products are far more favorable. As expected, switching from combustible cigarettes to Snus products is shown to result in lower levels of carbon monoxide – an 86 percent decrease compared to combustible cigarettes<sup>5</sup>. More importantly, Snus is associated with lower levels of the TSNA biomarker, NNAL, in those who switch from combustible cigarettes and results in comparable, if not slightly higher, abstinence rates than those who switch to NRT (43% and 41% at 4 weeks and 19.6% and 14.8% at 16 weeks)<sup>6</sup>.

We believe that product labels clearly acknowledging the reduced risk of Snus compared to combusted cigarettes will benefit public health. Product labels are a primary source of health information for consumers - and this likely extends to products beyond tobacco, such as alcohol, sugar sweetened beverages and food. Health labels and warnings are perhaps the best way to reduce disparities in access to knowledge.

With regard to tobacco products, knowledge of health risks associated with smoking is higher in countries with more comprehensive health warnings, which affects smoking behavior change and quit attempts<sup>7</sup>. It has been suggested that smokers with negative emotions towards warnings are more likely to attempt to quit<sup>8</sup>. However, as previously mention, successful one year quit rates are still rather low.

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<sup>2</sup> M. A. Song *et al.*, Chemical and toxicological characteristics of conventional and low-TSNA moist snuff tobacco products. *Toxicol Lett* 245, 68-77 (2016).

<sup>3</sup> M. F. Borgerding, J. A. Bodnar, G. M. Curtin, J. E. Swauger, The chemical composition of smokeless tobacco: a survey of products sold in the United States in 2006 and 2007. *Regul Toxicol Pharmacol* 64, 367-387 (2012).

<sup>4</sup> M. A. Song *et al.*, Chemical and toxicological characteristics of conventional and low-TSNA moist snuff tobacco products. *Toxicol Lett* 245, 68-77 (2016).

<sup>5</sup> M. D. Blank, T. Eissenberg, Evaluating oral noncombustible potential-reduced exposure products for smokers. *Nicotine Tob Res* 12, 336-343 (2010).

<sup>6</sup> M. Kotlyar *et al.*, Effect of oral snus and medicinal nicotine in smokers on toxicant exposure and withdrawal symptoms: a feasibility study. *Cancer Epidemiol Biomarkers Prev* 20, 91-100 (2011).

<sup>7</sup> D. Hammond, G. T. Fong, A. McNeill, R. Borland, K. M. Cummings, Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey. *Tob Control* 15 Suppl 3, iii19-25 (2006).

<sup>8</sup> Y. J. Cho *et al.*, Path analysis of warning label effects on negative emotions and quit attempts: A longitudinal study of smokers in Australia, Canada, Mexico, and the US. *Soc Sci Med* 197, 226-234 (2018).

Several studies have evaluated the effects of relative risk labels of Snus products with consistent results. Proposed warning labels of Snus products describing the decreased relative risk compared with combustible cigarettes increased the likelihood and motivation to buy and try Snus among current smokers with little effect on former or never smokers<sup>9</sup>. Of particular importance is the finding that if the viewer finds the warning believable, they are more likely to act accordingly. This was true for all survey participants, but had the most effect on current smokers.

Consistent with this study are findings that labels describing the reduced risk of Snus compared to combustible cigarettes better inform users of relative harm but have no effect on the perceptions of the addiction potential of Snus – study participants are aware of reduction in potential harms without compromising the knowledge of the addiction potential of nicotine<sup>10</sup>. When survey participants were provided a more thorough fact sheet explaining scientific knowledge of nicotine and the relative harms of smokeless tobacco versus combustible tobacco their knowledge of both nicotine replacement therapies and smokeless tobacco versus cigarettes greatly increased, as did the likelihood that future quit attempts would be assisted by one of these products. This is significant because assisted quit attempts have a higher rate of success. In fact, compared to nicotine patch or gum, Snus users have been shown to enjoy higher rates of success in quitting combustible cigarettes<sup>11</sup>.

Smoking is, by far, the most common way to use nicotine, as well as the most harmful way to use it. Because combustion contributes to at least 90 percent of the more than 7,000 chemicals that are inhaled in smoking traditional cigarettes, non-combustible tobacco products have an inherently reduced risk profile, which is reflected in the Camel Snus application.

To be certain, complete abstinence is the best way to reduce the burden of disease among smokers; unfortunately, it is very difficult to do successfully. The availability and use of alternative products, like Snus, are a safer way to use nicotine and can provide some smokers with the benefits they seek from combustible cigarettes.

In light of the FDA's recent proposal to begin a dialogue that will eventually lead to cigarettes with reduced nicotine content (to levels that are considered “nonaddictive”), it is necessary that the FDA approve products that can serve as acceptable alternatives to current smokers. Mandating very low nicotine cigarettes before beginning the conversation about safer alternatives will make such a strategy difficult to adopt and likely result in a proliferation of black market cigarettes and dangerous adulteration of VLNCs to increase nicotine content.

In the commissioner's statement on the future of tobacco, he called for “innovations that have the potential to make a notable public health difference.” Approving Camel Snus as a “modified-risk tobacco product” is the first step to the ultimate outcome and could yield drastic improvements in the health of smokers.

Sincerely,



Carrie Wade, PhD, MPH  
Harm Reduction Policy Director, R Street Institute

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<sup>9</sup> B. Rodu, N. Plurphanswat, J. R. Hughes, K. Fagerstrom, Associations of Proposed Relative-Risk Warning Labels for Snus With Perceptions and Behavioral Intentions Among Tobacco Users and Nonusers. *Nicotine Tob Res* 18, 809-816 (2016).

<sup>10</sup> D. Mays, M. B. Moran, D. T. Levy, R. S. Niaura, The Impact of Health Warning Labels for Swedish Snus Advertisements on Young Adults' Snus Perceptions and Behavioral Intentions. *Nicotine Tob Res* 18, 1371-1375 (2016).

<sup>11</sup> K. E. Lund, A. McNeill, J. Scheffels, The use of snus for quitting smoking compared with medicinal products. *Nicotine Tob Res* 12, 817-822 (2010).