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August 23, 2018

Tobacco Products Scientific Advisory Committee  
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RE: Modified Risk Tobacco Product Applications: Applications for Six Camel Snus Smokeless Tobacco Products Submitted by R.J. Reynolds Tobacco Company. Docket Number: FDA-2017-N-4678-0001

Dear Members of TPSAC:

R.J. Reynolds (RJR) is seeking Modified Risk Tobacco Product (MRTP) orders for six Camel Snus smokeless tobacco products: Camel Snus Frost, Camel Snus Frost Large, Camel Snus Mellow, Camel Snus Mint, Camel Snus Robust, and Camel Snus Winterchill. RJR proposed three different modified risk advertising executions for each of the six Camel Snus styles, and thus requested a total of 18 MRTP orders. FDA has asked TPSAC for its assessment of this application.

To be granted a MRTP order, Section 911(g) of the Family Smoking Prevention and Tobacco Control Act (TCA) places the burden on RJR to present sufficient scientific evidence to demonstrate that Camel Snus, *as actually used by consumers*, will *both*:

- (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and
- (2) benefit the health of the population as a whole, including users and current non-users of tobacco products.

It is important to recognize that RJR must meet *both* requirements stated in the statute; it is necessary but not sufficient, for RJR only to show that Camel Snus use is less likely to cause lung cancer, oral cancer, respiratory disease, or heart disease in individual users. Rather, RJR must demonstrate that marketing Camel Snus as an MRTP will benefit the public health, which includes considering dual use with cigarettes and other tobacco products as well as effects on tobacco initiation and cessation. In addition, RJR must demonstrate that the proposed advertising and labeling will enable the public to comprehend the information concerning modified risk in the context of total health.

UCSF has submitted five public comments (summarized in detail in the Appendix to this letter) that show that RJR has not met this burden and, indeed, that a careful reading of the material in their MRTP application suggests that the proposed marketing of Camel Snus could harm public health.

1. The premise and essential condition for all three of RJR's MRTP claims is that smokers "switch completely" from cigarettes to Camel Snus. However, the evidence RJR presents as well as the independent scientific literature shows that, *as actually used by consumers*, current smokers are

unlikely to switch completely to snus, but instead are more likely to follow a pattern of dual- or poly-use. Most Camel Snus users will continue to use cigarettes and/or other tobacco products at the same time that they use snus.

2. Camel Snus, even used alone, may increase users' exposure to some dangerous toxicants and therefore increase, rather than reduce, risks of some tobacco-induced diseases even if it lowers risks of others. Using Camel Snus in combination with cigarettes, the most likely use pattern, will increase, rather than reduce, health harms to individuals.
3. Current cigarette smokers who also use Camel Snus (the most likely use pattern) are less likely to quit smoking, and MRTP claims are likely to encourage smokers who would otherwise quit to simply add Camel Snus.
4. MRTP claims are likely to increase Camel Snus uptake among tobacco non-users, especially youth and adolescents, a point RJR does not address in its MRTP application. The flavored Camel Snus products are even more likely to attract youth and adolescents than unflavored products.
5. Youth who initiate smokeless tobacco use through Camel Snus are at increased risk of subsequently smoking cigarettes (i.e., the "gateway effect"), a reality RJR dismisses.
6. The actual evidence in RJR's MRTP application contradicts the presumption that Camel Snus assists cessation, but rather shows that snus is no better than nicotine gum as a cigarette substitute, is less appealing, is more toxic, and is associated with higher rates of prolonged use.
7. RJR did not use appropriate experimental methods that permit drawing RJR's conclusion that consumers would understand the proposed Camel Snus advertisements

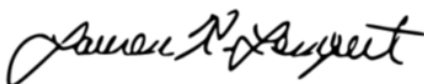
***Because RJR failed to demonstrate that marketing Camel Snus with modified risk claims will, as actually used by consumers, both significantly reduce risks and benefit the health of the population as a whole, TPSAC should recommend that FDA not issue a MRTP order to RJR for Camel Snus.***

Finally, as of August 22, 2018, FDA had still not posted the entire Camel Snus MRTP application materials. Key materials that are not yet available to the public include Module 6, Summary of All Research Findings; Module 7.2, In vivo Scientific Studies and Analyses; complete list of references; amendments. The unavailability of these key scientific materials precludes a complete scientific review and analysis of the MRTP application. As a result, TPSAC does not have the full benefit of public comment needed to aid in TPSAC's statutorily mandated review of and preparation of recommendations concerning RJR's MRTP application for Camel Snus.

Thank you for your consideration.



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## **APPENDIX: Detailed Summary of UCSF TCORS COMMENTS**

### **1. Epidemiology and Use Patterns (Benjamin Chaffee et al.)**

- a. Current combustible tobacco users are unlikely to switch completely to Camel Snus; the most probable pattern of Camel Snus use will be dual use.
- b. RJR's and independent scientific trials do not support the presumption that Camel Snus use would increase cessation, or are more effective than FDA-approved cessation products.
- c. Reynolds America Inc.'s study does not support RJR's contention that Camel Snus will assist smokers in quitting or in reducing cigarettes smoked, even with reduced risk claims.
- d. Marketing Camel Snus with reduced harm claims may depress smoking cessation.
- e. Marketing Camel Snus with MRTP claims would not confer benefit at the population level, and may increase harm.

### **2. Toxicity (Gideon St. Helen et al.)**

- a. RJR's own studies show that, rather than reducing levels of exposure, users of Camel Snus are exposed to greater levels of some dangerous toxicants, including nitrosamines (NNN and NNK) and heavy metals (cadmium, and arsenic).
- b. Contrary to RJR's claims, Camel Snus has considerably higher levels of NNN and NNK compared to at least one other major U.S. brand of snus as well as Swedish snus.
- c. Since most users of Camel Snus will likely be smoking cigarettes concurrently, their exposure to dangerous toxicants would increase their risk of several tobacco-related diseases.
- d. RJR does not present sufficient evidence in its chemistry studies to support their claim that Camel Snus users will reduce their exposure to toxicants in a way that will generally reduce their risk of harm of tobacco-related diseases, and may in fact increase their risk of other diseases.

### **3. Youth (Bonnie Halpern-Felsher et al.)**

- a. RJR does not consider the appeal to or impact of Camel Snus and its marketing claims on youth or adolescents.
- b. RJR's does not consider the likelihood that youth or adolescents will misperceive the risks of Camel Snus.
- c. RJR does not consider whether Camel Snus will result in initiation among non-users, or in dual or poly-use.
- d. RJR fails to consider the role that flavored Camel Snus will have on youth.
- e. RJR did not meet its burden to demonstrate that Camel Snus, as actually used by consumers, will benefit the health of the population as a whole, especially taking into account youth, adolescents, and other non-users.

### **4. Marketing and Communications (Lucy Popova et al.)**

- a. RJR's "Consumer Comprehension and Persuasion" studies did not use randomized experimental design and, therefore, do not demonstrate how the advertisement materials affected understanding and consumer comprehension.
- b. Contrary to RJR's claims, their proposed Camel Snus modified risk advertising materials do not "further educate smokers about the risks of cigarette smoking."
- c. RJR presents an incomplete literature to support their claim that consumers overestimate risks of smokeless tobacco compared to cigarettes and ignores relevant papers that contradict their position.
- d. The Executive Summary in RJR's MRTP application misrepresents RJR's own findings. In particular, the executive summary claims that advertisements did not increase interest among smokers who are likely to quit, but the reports for actual studies demonstrate that advertisements increased interest in both smokers who are and are not likely to quit.

- e. RJR's "likelihood of use" studies selectively asked some questions of smokers with and without quitting intentions in a way that obfuscates the effects of these advertisements on different groups. Among smokers without quitting intentions, after seeing the modified risk advertisements, only 14-22% envisioned using snus instead of smoking, while 30%-34% would replace some cigarettes with snus and 20%-23% would add snus use on top of smoking, increasing their overall tobacco use. This question was not asked of smokers with quitting intentions.
- f. RJR's MRTP application did not demonstrate that its marketing would effectively communicate scientifically accurate statements in a way that would accurately impact consumer understanding and perceptions.

## **5. Population Health Model (Wendy Max et al.)**

- a. RJR's Dynamic Population Modeler (DPM (+1)), a statistical model RJR uses to forecast the population effect of Camel Snus, is biased in favor of finding a population health benefit.
- b. Contrary to FDA's Guidance, the DPM (+1) model only considers mortality while ignoring morbidity.
- c. RJR acknowledges that they omit the possibility that snus use may delay smoking cessation, which would increase smoking-attributable mortality and decrease the public health benefit.
- d. The model does not consider the potential additive effect of dual- and poly-use.
- e. The model does not use the most recent data on smoking initiation or cessation.
- f. The model does not include the impact of Camel Snus use on non-tobacco users.
- g. The model's assumptions that switching rates (from cigarette to Camel Snus) are much greater than initiation rates (from never tobacco users to Camel Snus) bias the results.
- h. The model does not consider people who may switch from e-cigarettes to Camel Snus.
- i. Because of some unsupported assumptions, the negative impact of the gateway effect whereby youth initiate tobacco use with snus and progress to cigarettes is probably underestimated in the model.
- j. The model's estimates of the excess relative risk of smoking vs snus use are low and not based on empirical evidence and bias the findings on population health impact.
- k. The data used for validation of the DPM (+1) are problematic.
- l. The sensitivity analyses are incomplete and bias the conclusions designed to favor a positive impact on population health.
- m. RJR has not convincingly demonstrated that Camel Snus will benefit the health of the population as a whole.
- n. Because the DPM (+1) is biased in favor for finding a population health benefit for marketing Camel Snus with MRTP claims, FDA should not rely on the model results as presented by RJR.