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August 11, 2018

Mr. Mitchell Zeller, Director
Dr. Matthew R. Holman, Director, Office of Science
Members of the Tobacco Products Scientific Advisory Committee,
c/o Caryn Cohen, Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Zeller, Dr. Holman, Ms. Cohen, and Members of TPSAC,

On July 23, 2018 FDA announced that the Tobacco Products Scientific Advisory Committee (TPSAC) will meet on September 13-14, 2018 to discuss six modified risk tobacco product (MRTP) applications submitted by RJ Reynolds Tobacco Company (RJR) for six varieties of its Camel Snus products.

We believe this meeting was scheduled prematurely as the complete application materials have not yet been posted. As of August 10, 2018, many of the most crucial Camel Snus MRTP applications materials have still not been posted for public review and comment, including: Module 6 – Summary of All Research Findings, including indexes of references; sections of Module 7 – Scientific Studies and Analyses, including 7.1- Chemistry and 7.2 - In Vivo; and amendments to MRTP applications). The public cannot conduct thorough analyses of the MRTP materials before the August 29 deadline for submission of written comments to TPSAC if many of the most important materials have not been posted, and therefore TPSAC members cannot benefit from public comments by outside experts and scientists. It is not reasonable to think that TPSAC members can meet their statutory burden to adequately review and make recommendations on MRTP applications that are incomplete and that have not been systematically analyzed by outside experts and public commenters.

For this reason, ***we recommend that TPSAC postpone its September meeting on the Camel Snus MRTP applications until at least 60 days after the complete and entire MRTP applications, including all amendments, are made publicly available, thereby giving the public more time to review and submit written comments to TPSAC.***

Recommended questions for TPSAC

At the January 25, 2018 TPSAC meeting on Philip Morris's MRTP applications for IQOS, FDA asked TPSAC to vote on five specific questions (each including two subparts) that were theoretically supposed to aid FDA in determining whether to issue a MRTP order for IQOS. The specific wording of many of these questions may have inadvertently led TPSAC members to predetermined conclusions.

Questions that are more open-ended would lead to a more thorough discussion by TPSAC on the important issues, and this in turn would lead to a better report with recommendations that would provide better guidance to FDA. With this approach in mind, we suggest that FDA pose the following questions for TPSAC to discuss and/or vote on when it meets to consider the Camel Snus MRTP applications.

1. Has RJR demonstrated that Camel Snus, as actually used by consumers – including dual use with cigarettes and other tobacco products – substantially[1] reduces harm to individual tobacco users?
2. Are the estimates of actual harms associated with smokeless tobacco use presented by RJR in its MRTP application for Camel Snus unbiased? Selective? Optimistic? Pessimistic?
3. Has RJR demonstrated that Camel Snus, as actually used by consumers, substantially reduces the risk of tobacco-related diseases?
4. Has RJR demonstrated that Camel Snus, as actually used by consumers, substantially reduces the risk of lung cancer?
5. Has RJR demonstrated that Camel Snus, as actually used by consumers, substantially reduces the risk of oral cancer?
6. Has RJR demonstrated that Camel Snus, as actually used by consumers, substantially reduces the risk of respiratory disease?
7. Has RJR demonstrated that Camel Snus, as actually used by consumers, substantially reduces the risk of heart disease?
8. Does RJR's MRTP application for Camel Snus adequately address the risk of other diseases, including pancreatic cancer? Heart failure? Diabetes?
9. Has RJR demonstrated that US consumers understand what it means to "switch completely" from cigarettes to Camel Snus?
10. Has RJR demonstrated that US consumers are likely to switch completely from cigarettes to Camel Snus?
11. Has RJR adequately studied dual use of Camel Snus and cigarettes?
12. Has RJR adequately studied dual use of Camel Snus and other nicotine products, such as electronic cigarettes and heated tobacco products[2]?
13. Will use of Camel Snus by cigarette smokers encourage or depress quit attempts?
14. Will use of Camel Snus by cigarette smokers improve or worsen abstinence?
15. Has RJR demonstrated that the messages in its advertisements (e.g., "More Freedom" and "Swap the Smoke") are understood by users? By non-users? By former users? By youth, teens, and young adults?
16. Has RJR adequately studied whether the proposed marketing will appeal to non-users, including youth?
17. Has RJR adequately studied the risk of initiation, especially among youth?
18. Will the proposed advertisements for Camel Snus erode the effectiveness of existing smokefree policies?
19. Will the proposed advertisements for Camel Snus be attractive to youth?
20. Will the proposed advertisements for Camel Snus lead to initiation of tobacco use and/or nicotine use by non-users, especially youth?
21. Did RJR present adequate evidence about the impact of all of the elements contained in the proposed labeling, advertising, and other marketing materials (e.g., direct mail), including the graphic images?

[1] The statute requires that the public health benefit be "significant" and RJR makes the claim that snus will "greatly" benefit public health. We use "substantial" rather than "significantly" to avoid implying that TPSAC should make its decision only on whether the benefits are *statistically significant* (i.e., made with 95% confidence); TPSAC should also consider whether the magnitude of the change is large enough to convincingly benefit public health.

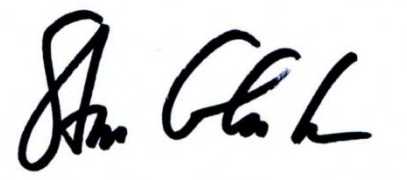
[2] FDA recently called RJR Eclipse, a heated tobacco product, a "non-combusted cigarette" when issuing a substantial equivalence marketing order.

22. Will the proposed labeling enable consumers to understand that continuing to smoke cigarettes while using Camel Snus is more dangerous than using Camel Snus alone?
23. Do RJR's perception studies demonstrate consumers' understanding of the proposed advertising?
24. Has RJR demonstrated that consumers understand that using Camel Snus is not risk-free, even if RJR can demonstrate that Camel Snus is less risky than cigarettes?
25. Does RJR's application adequately consider the differences in product composition, methods of use, and portion sizes between snus sold in the US as compared to Swedish snus (i.e., snus with lower levels of nitrosamines)?
26. Did RJR's studies control for confounding by other exposures, such as alcohol use?
27. Does RJR's MRTP application for Camel Snus rely on literature authored by unbiased scientists or on industry scientists?

Statutory framework

These questions are suggested to assist the TPSAC in meeting its statutory obligations by providing advice to FDA on whether the Camel Snus products in question, as it is actually used by consumers, will: (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 taking into account both users of tobacco products and persons who do not currently use tobacco products. (TCA section 911(g)(1)) In determining whether a MRTP benefits the health of the population as a whole, FDA must take into account: (1) the relative health risks to individuals; (2) the increased or decreased likelihood that existing users who would otherwise quit will switch to the product; (3) the increased or decreased likelihood that non-users (including youth, teens, young adults, and former users) will start using the product; (4) the risks and benefits to individuals using the product compared to using FDA-approved smoking cessation products (e.g., NRTs); and (5) comments, data, and information submitted by interested persons. (TCA section 911(g)(4))

Respectfully,



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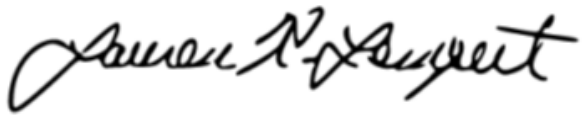

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